ISSN 0974-3618 (Print)
0974-360X (Online)

www.rjptonline.org

RJPT

REVIEW ARTICLE

Formulation and Evaluation of Carvedilol Sustained Release Capsules by Semisolid Matrix Filling Technique

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ABSTRACT:

The objective of the study was to prepare semisolid capsules of poorly water-soluble drug Carvedilol using a combination of technologies involving solid dispersion preparation and converting it into semisolid matrix filled in hard gelatin capsule. Different excepients like Gelucire 44/14, poloxamer 188, gelatin, PVPK30, PEG6000 were used. Fifteen capsule formulations were prepared and assessed for their release characteristics. Lipid matrix formulations prepared with increasing amount of polymer showed a substantial decrease in release rate of drug in case of poloxamer188Whereas gelucire 44/14, gelatin, PVPK30, and PEG6000 showed immediate release the mechanism of drug release from the test formulations were studied. The possible modification of carvedilol release kinetics by using poloxamer in the SSM was studied. results indicate that poloxamer188 is an appropriate carrier for the development of sustained release drug delivery systems and Gelucire 44/14 a highly hydrophilic and lipophilic balance (HLB) excipient, acts as release enhancer in the different ratios studied. Among all the formulations Carvedilol formulation with poloxamer188 in the ratio of (1:3) showed sustained release. Release kinetics studies were performed. The formulation with poloxamer in 1:3 ratio follows first order and Higuchi order release kinetics governed by Fickian diffusion mechanism with R^2 value 0.992.

KEYWORDS: Carvedilol, Gelucire44/14, Poloxamer188, Gelatin, PVPK30, PEG6000.

INTRODUCTION:

Solid dispersion can be defined as "The dispersion of one or more active ingredients in an inert carrier or matrix at solid state"[1]. Oral drug delivery is the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage form. Oral route is considered as most natural, uncomplicated, convenient and safe due to its ease of administration, patient acceptance, and cost-effective[2] manufacturing process[3].

The goal in designing sustained delivery systems[4] is to reduce the frequency of the dosing or to increase effectiveness of the drug by localization at the site of action, reducing the dose required or providing uniform drug delivery[5,6]. A single dose of a drug that is released over a sustained period of time to maintain a near constant or uniform blood level of a drug often translates into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use[7]. There are certain considerations for the preparation of sustained release formulations. If the active compound has a long half-life, it is sustained on its own[8].

Carvedilol is a non-selective beta adrenoreceptor blocker, used in the treatment of hypertension[9]. The drug was selected as a model drug for the investigation because this drug has low molecular weight (carvedilol

ISSN (Print 0974-2115) (Online 2349-8552)
www.jchps.com Journal of Chemical and Pharmaceutical Sciences

A Simple RP-HPLC Bio Analytical Method for Determination of Levetiracetam in Human Serum

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ABSTRACT

A simple, precise, accurate and linear reverse-phase high-performance liquid chromatography method using UV detection for the estimation of the novel antiepileptic, Levetiracetam was established and validated. A Simple protein precipitation method along with acetonitrile as precipitating solvent was used for the extraction of Levetiracetam from healthy human volunteers. HPLC analysis was carried out on a C18 (4.6mm*250mm, 5µm), column. The mobile phase consisted of a composition of ammonium acetate buffer (10mM, pH 5) and acetonitrile (50:50v/v) with an isocratic flow rate of 0.3mL/min over 15min runtime. Chromatograph was read at 205 nm. The retention time through this method was recorded as 7.8 min for Levetiracetam and 9.2 min for Fluconazole (internal standard). The detector response was ruled out to be linear in the concentration of 10-50 µg/mL with a mean correlation coefficient of 0.99. The limit of detection and limit of quantification were noted as 0.8µg/mL and 2.5µg/mL, respectively. The percent RSD for precision was within the acceptance criteria of not more than 2.0%. The Bio analytical Method developed above was found to be precise, accurate and linear within its therapeutic dose. This makes the method widely applicable for the regular analysis of Levetiracetam in the bio analytical matrix for toxicity or therapeutic drug monitoring.

KEY WORDS: Levetiracetam, RP-HPLC, UV detection, protein precipitation, RSD.

1. INTRODUCTION

Levetiracetam [S-enantiomer of α-ethyl-2-oxo-1-pyrrolidine acetamide; Keppra] (Fig.1) is an antiepileptic drug (AED) which is structurally and mechanistically different from other antiepileptic drugs (Hovinga, 2001). It is FDA approved drug used to treat patients with partial onset seizures, myoclonic seizures (Schachter, 2000; Nash and Sangha, 2001; Dooley and Plosker, 2000) primary generalized tonic-clonic seizures. Levetiracetam has a favorable pharmacokinetic profile; after oral intake Levetiracetam absorption was rapid and complete (Tmax< 1hour, its bioavailability is close to 100%), plasma protein binding is low (<10%), insignificant hepatic metabolism, is not metabolized by CYP-dependent pathways that produces limited drug-drug interactions, rapid attainment of steady-state concentrations, excretion is primarily renal; approximately 66% of the dose found unaffected in urine and 24% is excreted in urine as its acid metabolite form. The metabolite which excreted in urine was pharmacologically inactive. The half-life of elimination of oral Levetiracetam is between 6 to 8 hours in grown-ups (Iwasaki, 2015; Patsalos, 2004) and 5-7hrs in children (Wright, 2013). The primary adverse effects are CNS related and include a headache, asthenia, somnolence, and dizziness. Levetiracetam has better efficacy comparable to other new anti-epileptic drugs (McAuley, 2002) and it has a wide therapeutic window, where toxic doses are well differentiated from therapeutic dosages (Patsalos, 2000). The efficacy is concentration dependent (Perucca and Bialer, 1996; Pellock, 2001; Boon, 2002). For the monitoring of drug concentration serum was used as a medium.

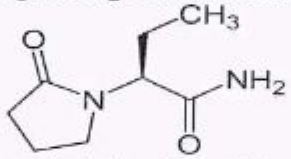

Figure.1.Chemical structure of Levetiracetam

2. MATERIALS AND METHODS

Chemicals and Apparatus: Levetiracetam was procured from Hetero Drugs Limited. Fluconazole (used as internal standard), ammonium acetate, HPLC grade water, and acetonitrile were procured from Sigma Aldrich, Mumbai. High-Performance Liquid Chromatographic system (Shimadzu's LC 20AD) typically consists of a 25µL fixed volume injector (Rheodyne). The chromatographic separation of Levetiracetam & Fluconazole (internal standard) was performed on C18 (4.6mm*250mm, 5µm), column using UV-visible detector SPD-20A.

Ethical Approval: IHEC approval was obtained after submission of protocol IHEC ECR/257/Indt/TG/2015/VCOP / MGMH /PHARM D/2017/003.

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ISSN: 2319-7064
ResearchGate Impact Factor (2018): 0.28 | SJIF (2019): 7.583

Therapeutic Drug Monitoring of Levetiracetam by High - Performance Liquid Chromatography in Paediatric Epileptic Patients

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Abstract: ***Levetiracetam is a second generation anticonvulsant drug used as adjunctive therapy or monotherapy with high efficacy and tolerability in the treatment of partial seizures, myoclonic seizures and generalized tonic-clonic seizures in children. We aimed to correlate the serum drug concentration with seizure control status, complaints and liver enzymes (Alanine aminotransferase, Aspartate aminotransferase) in pediatric epileptic population.We prospectively evaluated 36 levetiracetam monotherapy patients, the dose was administrated based on their body mass index. A rapid and specific method by high-performance liquid chromatography(HPLC) UV detection was developed to determine serum drug concentrations, observations made and analyzed. Out of 36 patients, 24 patients drug concentration was within therapeutic range (12-46µg/ml) have shown good seizure control,8 patients were in the sub-therapeutic range, of these subjects 4 had good seizure control and another 4 poor seizure control. Remaining 4 patients were in the supra-therapeutic range. This drug has no effect on liver enzymes. There is no significant correlation between serum drug concentration levels and subjective complaints.Levetiracetam can be used as a first-line broad-spectrum antiepileptic drug which is well tolerated and achieves good seizure control.***

Keywords: Levetiracetam, seizure control, therapeutic range

1. Introduction

Levetiracetam is a second generation anticonvulsant drug used as adjunctive therapy or monotherapy with high efficacy and tolerability in the treatment of partial seizures, myoclonic seizures, and generalized tonic-clonic seizures. Levetiracetam has come to clinical use since 1999 in adults and 2006 in children respectively [1-5].

Pharmacokinetic profile of Levetiracetam is quickly absorbed when taken orally (T max-< 1hour), bioavailability (>95%), protein binding (<10%) and metabolism is usually low and the volume of distribution is 0.5-0.7L/kg. Half life ranges from 6 to 8 hours as it is excreted largely unchanged by kidneys [1,3]. Therapeutic range: 12-46µg/ml [1].

Mechanism of action of Levetiracetam is unique where it binds to synaptic vesicle protein (SV2A), a transmembrane protein which involves calcium-dependent exocytosis of synaptic vesicles in the brain which delays nerve conduction and reduces the release of calcium from intraneuronal stores [1].The most common side effects of Levetiracetam include asthenia, headache, somnolence, dizziness, infection [2,3]. Behavioral symptoms like anxiety, irritability, aggression, apathy, and depression [1].

Therapeutic drug monitoring refers to a practice of measuring drug concentration in biological fluids at particular time intervals to maintain the desired concentration and optimize drug therapy. Therapeutic drug monitoring is performed for drugs with a narrow therapeutic range in clinically challenging situations, co morbidities, poor seizure control, marked inter-individual variability, failure of therapeutic drug response [1, 2].

We aimed to correlate the serum drug concentration with seizure control status, complaints and liver enzymes (ALT, AST) in pediatric epileptic population.

2. Patients and Methods

This prospective clinico-pharmacological study was designed and conducted in the Department of Pediatrics, Mahatma Gandhi Memorial Hospital /Kakatiya Medical College, Warangal. We have conducted our study for a period of one year (February to December). The study included 36 patients on Levetiracetam monotherapy for at least one month (whose parents give consent to participate in the study) considered as study subjects. 16 were male and 20 female. Age of study subjects ranged from 3 yrs -13 yrs, the youngest child was 3 years and oldest child was13 years were treated with two different dosage forms of Levetiracetam. The dose was given accordingly with their

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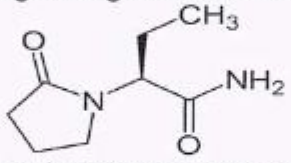

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International Journal of Science and Research (IJSR)
ISSN: 2319-7064
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Original Article

Ambispective study of adverse drug reactions in multi-drug resistant tuberculosis patients in Warangal, Telangana

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ABSTRACT

Background: Multidrug-resistant tuberculosis (MDR-TB) has become a global threat concerning to a risk of high mortality with the potential to cause adverse drug reactions (ADRs) which if not managed properly may affect patient compliance, resulting in below par treatment outcome. **Aim:** The aim of the study was to study, assess, and report the ADRs of patients diagnosed with MDR-TB. **Subjects and Methods:** An ambispective, observational study was conducted among confirmed cases of MDR-TB patients without any comorbidities during the period of January 2015–December 2018 in patients of age 15 years and above. **Statistical Analysis:** Data were analyzed descriptively using MS-Excel sheet 2013 and Chi-square test in GraphPad Prism 8.2.1. Results were expressed as either frequency, percentage, or mean ± standard deviation. ADRs were evaluated for causality, severity, and preventability attributes. **Results:** In the sample size of 400 patients, 236 (ADRs) were reported among 136 patients. The proportion of ADRs was higher in males ($P = 0.0001$) and in the age group of 36–75 years ($P = 0.0211$). Most commonly encountered ADRs include nausea and vomiting (35.31%) and arthralgia (14.04%), followed by peripheral neuropathy (8.93%) and giddiness (8.93%). Overall, 53% were of possible category and 60% of moderate level severity and 85% were unpreventable ADRs. **Conclusion:** Our study included 13 types of ADRs, of which most commonly reported were nausea and vomiting, arthralgia, and peripheral neuropathy and least common were psychosis, nephrotoxicity, and gynecomastia with a higher incidence in males. Majority of ADRs were moderate, unpreventable ADRs and had a possible relationship with the suspected drugs.

KEY WORDS: Adverse drug reaction, Causality, multidrug resistant tuberculosis, preventability assessment, severity

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Submitted: 17-Mar-2019 **Revised:** 08-Sep-2019 **Accepted:** 16-Apr-2021 **Published:** 03-Jul-2021

INTRODUCTION

Antimicrobial resistance has become a topical health and security concern for countries worldwide. In the course of previous years, it has become increasingly clear that global efforts to end tuberculosis (TB) will continue to face a major challenge with the widespread dissemination of TB strains that are resistant to the medicines used in its treatment.[1]

India (24%) is responsible for almost half of the world's cases of multidrug-resistant TB (MDR-TB).[2] Drug-resistant TB has been known from the time anti-TB drugs were first introduced for the treatment of TB. Currently, the World Health Organization estimated the incidence of MDR TB

Access this article online

Quick Response Code:

Website: www.lungindia.com

DOI: 10.4103/lungindia.lungindia_116_19

How to cite this article: Fatima S, Syeda MF, Adla N, Devi R. Ambispective study of adverse drug reactions in multi-drug resistant tuberculosis patients in Warangal, Telangana. Lung India 2021;38:330-7.

INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
www.irjponline.com
ISSN 2230 – 8407

Research Article

COMPARING THE EFFICACY OF PHENYTOIN, LEVETIRACETAM AND SODIUM VALPROATE IN PREVENTION OF POST-TRAUMATIC SEIZURES IN BRAIN INJURY

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Article Received on: 23/01/19 Approved for publication: 02/03/19

DOI: 10.7897/2230-8407.1004142

ABSTRACT

Background: Traumatic brain injury is said to be a variation of brain function or other corroboration of brain pathology, which are caused by the outward jolts, penetration or expeditious brain movements within the skull which results in mental state alteration. There is evidence that use of anti-epilepties as a prophylaxis have been found to be variable efficacy against post-traumatic seizures. In patients who are diagnosed with moderate to severe traumatic brain injury (TBI) the efficacy of Phenytoin, Levetiracetam and Sodium valproate regarding the post-traumatic seizures were compared to appraise their effectiveness's. Material and methods: Males and females of 17-80 years diagnosed with moderate to severe traumatic brain injury were included in our study. Results: There was a significant reduction in early and late post-traumatic seizures in patients treated with Phenytoin and Levetiracetam than those treated with Sodium valproate.Conclusion: From this study we concluded that the efficacy of Levetiracetam was relatively similar to Phenytoin in preventing early and late post-traumatic seizures, whereas Sodium valproate showed poor efficacy.

Key words: Post-traumatic seizures (PTS), Traumatic brain injury (TBI), early post-traumatic seizures (ePTS), Phenytoin, Levetiracetam, Sodium valproate.

INTRODUCTION

Traumatic brain injury is contemplated to be a utmost health problem, particularly in urban trauma centres with a generic difficulty in emergency properties.[1,2] Its consequential complications such as changes affecting the language, thinking , emotions or sensation, which may not be easily evident and lack of knowledge among the public, therefore it is cited as 'silent epidemic'.[3] A seizure is the' physical response to abnormal electrical activity in the brain'. [4]Post traumatic seizures have been used to describe the seizure occurrence after head trauma and they are believed to be incidentally related to the trauma itself.[5]They are arise from the traumatic brain injury and brain harm caused by physical trauma.[6] Generally post-traumatic seizures are classified into three categories based on the seizure occurrence after the brain injury as-'immediate seizures',' early seizures', and' late seizures'. Immediate seizures refers to those which occurs at or minute after the thwack; early seizures are those that occurs within a week of the brain injury whereas as those that occurs after the week of the brain injury are called as late seizures.[7,8,9] The actual therapy for TBI patients depends on the particular injuries that the patient has succoured, well timed diagnosis, imaging results and clinical data.[1,10] In a study performed for identifying the brain injury associated with development of seizures in particular species: it has shown that the enhanced risk of seizures after TBI generally depends on the injury severity and time from its occurrence.[11] An age of 65 or older, a skull fracture, brain bruise with subdural hematoma, and consciousness deficient or amnesia (more than one day) are considered to be a vital risk factors for the later seizures.[11,12,13] The time course of the risk and the risk factors are considered to be a notable factors for designing the seizure prophylaxis studies.[14] The outcomes of patients with TBI varies according to the age; in a study conducted by Aisekainen et al expressed that children are more susceptible to early seizures, whereas adolescents and adults are more prone to late seizures.[15,16] Antiepileptic's have been used for many years to prevent the development of posttraumatic seizures. The prophylactical use of the phenytoin was effective, which was proposed by early retrospective studies.[17,18,19] Nevertheless , succeeding prospective, double blind trials of treatment with phenytoin and lower doses other antiepileptic's like phenobarbital failed to show that such treatment had more benefit than placebo.[20,21,22,23] Levetiracetam has shown to have similar efficacy in preventing the seizures after the traumatic brain injury which was proposed by a study conducted by Syed Nabeel Zafar et al. However there is a limited evidence regarding this statement, further studies need to be conducted.[24] Sodium valproate has less side effects and it has been recommended to the traumatic brain injury patients. There is evidence from the clinical trials that it has no effect on reduction of late posttraumatic seizures. It has been suggested that the early posttraumatic seizures progression can be prevented by the Sodium valproate administration.[25]

MATERIAL AND METHODS

It is a prospective, comparative and observational study conducted in patients from Mahatma Gandhi Memorial hospital, Warangal. Patients were explained about the study and informed consent forms were obtained by explaining them in their local

IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 17, Issue 11 Ver. 2 (November. 2018), PP 08-11
www.iosrjournals.org

Retrospective Study on Consanguineous Marriage Birth Deffects Among Patients Attending Pediatric Ward In Tertiary Care Hospital, South India

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Abstract: *Consanguinity is the quality of being descended from the same ancestor as another person. Consanguinity is prevalent in many middle eastern and Arab cultures and societies. Genetic disorders and congenital abnormalities occur in about 2%-5% of all live births, account for up to 30% of paediatric hospital admissions and cause about 50% of childhood deaths in industrialised countries. To determine the prevalence of consanguineous marriages, type of consanguinity and to determine the role of consanguinity on congenital malformations so as to create awareness. Retrospective hospital based study with consecutive sampling of 1552 babies in Mahatma Gandhi Memorial Hospital over a period of 12 months from January to December 2015.Out of 1552 babies 61 babies were having congenital malformations. Malformed babies were noted in 8 % of consanguineous marriages versus 1 % in non-consanguineous marriages, with P value of 0.04 which is statistically significant. In conclusion, congenital malformations are more in consanguineous marriages i.e., consanguinity may play important role in high rates of malformations in children. In order to prevent, genetic counselling before marriage must be applied for all couples because they may have family history of genetic disorders and especially consanguineous couples.*

Keywords: *Consanguineous marriages, congenital anomalies, genetic counselling.*

Date of Submission: 25-10-2018 Date of acceptance: 06-11-2018

I. Introduction

The word consanguinity comes from Latin words, *con* meaning shared and *sanguis* meaning blood. In clinical genetics, consanguineous marriage is defined as a union between two individuals who are related or second cousins or closer.

However, the most common form of consanguineous marriage worldwide is between first cousins, who on average have co-inherited 1/8 of their genes from one or more common ancestors. First cousin offspring will therefore be homozygous at 1/16 of all loci, which is consanguinity expressed as a coefficient of inbreeding [f] of 0.0625[1].

The preferred types of consanguineous marriage vary according to tradition, so that in Arab society's first cousin marriage between a man and his father's brother's daughter is most common.

Population stratification may therefore be a major influence in the measurement of consanguinity associated morbidity and mortality, with straight forward comparison between the progeny of first cousins and unrelated parents genetically invalid unless both sets of parents are known to be members of same caste, tribe [2].

Consanguinity is prevalent in many Middle Eastern and Arab cultures and societies [3], some studies have shown significant differences in genetic disorders between children born to consanguineous marriage partners and those born to non-consanguineous parents [4] while others have found no significant differences [5]. Genetic disorders and congenital abnormalities occur in about 2%-5% of all live births, account for up to 30% of paediatric hospital admissions and cause about 50% of childhood deaths in industrialised countries [6].

Mental disturbances are defined as structural defects of the body and/or organs that impair viability and require intervention. Minor morphogenetic errors are small structural developmental disturbances that do not impair viability and do not need to be treated. Preventive public health measures administered through pre- and peri-conception and prenatal health care services decrease the frequency of certain congenital anomalies including those due to consanguineous marriages.

INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
www.irjponline.com
ISSN 2230 – 8407

Research Article

IMPACT OF STREPTOKINASE AND TENECTEPLASE ON ELECTROCARDIOGRAM (ST-SEGMENT) AND TWO DIMENSIONAL-ECHOCARDIOGRAPHY (REGIONAL WALL MOTION ABNORMALITIES) IN ST ELEVATED MYOCARDIAL INFARCTION

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Article Received on: 11/12/18 Approved for publication: 19/01/19

DOI: 10.7897/2230-8407.100395

ABSTRACT

Background: One of the most striving problem among coronary artery disease is ST elevated myocardial infarction. It is the infarction in which entire wall of coronary artery gets occluded and is associated with ST segment elevation (>2mm in atleast 2 chest leads or >1mm in precordial leads or limb leads) on ECG. The impact of Streptokinase and Tenecteplase on ECG and 2D-echo in patients with ST elevated myocardial infarction and the effect of timing of thrombolytic therapy were compared. Material and methods: Patients presented with chest pain within 12 hours diagnosed with st elevated myocardial infarction and received thrombolytic therapy is included in our study. Results: 40 patients were recruited for our study. 20 patients were excluded because of their advice to higher centres due to their critical condition and not available for follow up. ST elevated myocardial infarction patients who were taking streptokinase 1.5 million units and tenecteplase 40 mg completed the study. Among 20 patients 13 (65%) patients treated with streptokinase and 7 (35%) patients treated with tenecteplase. After 30 days follow up 2D echo reveals regional wall motion abnormalities in 10 patients of Streptokinase group and 2 patients of Tenecteplase group. Regional wall motion abnormalities was absent in 3 patients of Streptokinase group and 5 patients of Tenecteplase group. Conclusion: From this study we demonstrate that tenecteplase was more efficacious than streptokinase in terms of ECG readings (ST resolution), 2D-echo. Patients who were presented within 6 hours have benefited more.

Keywords: Tenecteplase, Streptokinase, ST segment, regional wall motion abnormalities, time of presentation.

INTRODUCTION

ST elevation myocardial infarction is one of the challenging problems among the acute coronary syndromes. In a year about 3 million STEMI cases are predicted to occur in India. STEMI management protocols was first done in India in the year 2011. Cardiovascular disease is one of major cause of death in India which has been projected between 1990 and 2020 and it has been accounted approximately 21% of deaths in 2010, of which almost 10% of deaths are due to coronary artery disease. More over in our study it is estimated that NSTEMI is more than STEMI[1].

STEMI is a type of acute coronary syndrome with symptoms characteristic of chest pain, shortness of breath, sweating and associated with ST segment elevation in the ECG. It is defined universal definition of myocardial infarction as new ST segment elevation at J point of at least two of >2mm of chest leads or > 1mm in any other contiguous precordial leads or limb leads[2].

12 lead ECG is important diagnostic tool because it plays an important role in decision pathway for STEMI management. Serum cardiac biomarkers are obtained to differentiate unstable angina from NSTEMI and also to assess the extent of severity of STEMI[3]. Troponin elevation is more specific and sensitive than myoglobin and creatinine kinase in myocardial infarction[4]. Typical pattern of rise and fall of CKMB are seen only in MI. Elevated levels of CKMB is also seen in other conditions but this typical pattern of rise and fall cannot be demonstrated. CKMB is first elevated in first 3-12 hours after onset of chest pain, peaks in 24 hours and returns to baseline in 48-72 hours[5].

It is class I recommended by AHA enhance of trained echocardiogram technicians to investigate regional wall motion abnormalities. The goal is to identify patients with RWMAs likely representing a significant occult coronary artery occlusion which is not evident by symptoms, ecg or initial cardiac biomarkers[6]. Apart of STEMI, ST segment elevation is also seen in other conditions like ventricular aneurysm, pericarditis, benign early repolarisation, hypothermia, hyperkalemia, hypercalcemia, LBBB and RBBB with associated repolarisation but with different patterns so carefully diagnosis should be made[7]. The treatment for STEMI includes revascularization and medical therapy.

Reperfusion strategies include pharmacologic reperfusion which is done by fibrinolytic therapy and mechanical reperfusion which is done by primary percutaneous coronary intervention. Fibrinolytic therapy remains viable option for reperfusion therapy due to limited availability of primary PCI. The most commonly used fibrinolytic agents are streptokinase, tenecteplase, reteplase, alteplase. Streptokinase is a single chain polypeptide derived from β-haemolytic streptococcus, it is antigenic in nature.

Most commonly prescribed dose of streptokinase is 1.5 million international units over 60minutes.Aspirin (325mg/day) should also be taken with streptokinase. High doses are necessary to neutralize the plasma levels of anti-streptococcal antibodies.

A REVIEW ON THE DEVELOPMENT AND EVALUATION OF PLANT BASED EMULGEL FORMULATIONS

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ABSTRACT:

Emulgels are the novel drug delivery systems meant for the enhanced and controlled delivery of drugs in general and hydrophobic drugs in specific. Being the unique combination of gels and emulsions, theses possess several merits over conventional dosage forms like creams and ointments like thixotropic, nongreasy, non-adhesive, etc. Several natural drugs from plant origin are reported in the literature for their potential to cure skin diseases but most of them are not formulated into a novel drug delivery systems due to several reasons. If formulated theses are useful to the people, government and industry in the process of eradication of such deadly diseases like Leprosy and Psoriasis. These are safe, effective and also economical in nature. The present review focussed on the recent scientific advances related to the development and evaluation of emulgel formulations with plant- based drugs and related products.

Key words: Emulgel, Natural drugs, Topical, controlled, enhanced drug delivery

1. INTRODUCTION

Emulgels cab be defined as the novel topical drug delivery systems that can be formed by incorporation of gel into the water phase of an emulsion and possess the advantages both as gels and emulsions. Therefore, these are the combination of both gels and emulsions. It is also useful in the formulation of both hydrophilic and hydrophobic drugs for their enhanced and controlled delivery through skin.

Emulgels possess several merits over conventional semisolid dosage forms as these are leading to dual and controlled and enhanced release of drugs from both the phases, thixotropic, greaseless, easily spreadable, easily removable, emollient, non-staining, transparent, pleasing in appearance, suitable in the delivery of both drugs and cosmetics, shows better stability, have grater loading capacities for drugs etc., [1-6].

At present, several drugs which belonging to the categories of non steroidal anti inflammatory drugs, anti microbial agents etc., are successfully formulated and some of which are also marketed as Emulgels[7-8]. Certain natural drugs are also successfully formulated and evaluated as emulgel formulations [9-11].

These are the dosage forms which are prepared by combination of both emulsion and gels. Possess advantages of both to deliver both hydrophilic and hydrophobic drugs in topical drug delivery systems[1-2].

These can be prepared by using aqueous materials like water and alcohol, vegetable oils like, castor oil, emulsifying agents like polyethylene glycol for improving stability, gelling agents like, carbapol 940 for consistency and thickness and skin permeation enhancing agents like oleic acid etc., [3-4].

The formulation of emulgels usually involves the following steps: Preparation of either oil in water or water in oil emulsion, preparation of gelling agent, mixing both under suitable conditions with stirring.

The emulgel obtained above can be evaluated for different parameters like, physical appearance, rheological properties, spreadability, skin irritation test using rats etc., *In-vitro* release study by using Franz diffusion cell, extrudability by tube test, swelling index, PH, stability studies, drug content etc., [5-6].

RESEARCH ARTICLE | JOURNAL OF PHARMA SCIENCE 2017(02):01 | ISSN: 2456-5520

JOURNAL OF PHARMA SCIENCE

Journal home page: http://epixpub.com/jps/index.php

Design and *In Vitro* Evaluation of Gastro Retentive Sustained Release Tablets of Ketorolac Tromethamine

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ABSTRACT

Gastro retentive sustained release tablets of ketorolac tromethamine (KT) were prepared by using hydrophilic polymers with direct compression on floating matrix technology and evaluated. KT is freely soluble in water, so it is suitable to develop it as gastro retentive sustained release tablets using hydrophilic polymers. The developed formulation is equivalent to calculated theoretical drug profile in view of its *in vitro* release. Technique has easily amenable to mass production using conventional tablet machines. KT floating tablet formulations were optimized with different polymers for floating. The effect of formulation variables like polymers, HPMC, (Hydroxy propyl Methyl Cellulose) ethyl cellulose, xanthan gum, guar-gum, with different grades of polymers, (HPMC K4M, K15M, K100M) concentration of polymer, and different excipients were studied on *in vitro* drug release. Drug release was inversely proportional to the polymer concentration and also dependent on the agitation intensity and hardness of tablet. The swelling of the polymers used in optimized formula FXV could be determined by water uptake study. The study revealed that the tablet remained in the beaker for 24hr, which indicates the increase in the gastric residence time for the effective localized action All polymer and excipients used in optimized formula were found to be compatible with the drug and it was confirmed by FT-IR and DSC studies. KT release from the developed floating formulation followed zero-order with R^2= 0.941 and Fickian diffusion where n value is < 0.5 and found to be the main mechanism of drug release. The manufacturing procedure was found to be reproducible and formulations were stable after one month of accelerated stability studies.

Keywords: Gastro retentive, ketorolac tromethamine, DSC, stability studies, zero-order, Fickian diffusion.

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Received 14 February 2016, Accepted 03 March 2016

Please cite this article as: Kshirasagar N *et al.*, Design and In Vitro Evaluation of Gastro Retentive Sustained Release Tablets of Ketorolac Tromethamine. Journal of Pharma Science 2017.

ISSN: 0975-766X
CODEN: IJPTFI
Available Online through *Research Article*
www.ijptonline.com

METHOD DEVELOPMENT, VALIDATION, AND STABILITY INDICATING STUDIES OF OLMESARTAN MEDOXOMIL AND HYDROCHLORTHIAZIDE IN BULK AND PHARMACEUTICAL DOSAGE FORM BY UV-SPECTROSCOPY

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Received on: 12-05-2021 *Accepted on: 24-06-20216*

Abstract:

Development of UV method for simultaneous estimation of Olmesartan Medoxomil development was done by Q-Absorbance ratio method and area under curve method and stability indicating studies using methanol as solvent. Most of the studies are not well validated and not cross validated by other methodology. Here we have made an attempt to develop a simple, specific, accurate, precise and reproducible method for the simultaneous estimation of hydrochlorothiazide and OLM in combined dosage form by UV spectrophotometric method, the method includes area under curve method (Method I) and Q- absorbance Ratio method (Method II). The wavelengths are 243 nm and 272 nm λ_{max} of both the drugs were selected for Method I, and for Q- absorbance Ratio method (Method II) 250 nm an isoabsorptive wavelength and 272 nm were selected for estimation of Olmesartan Medoxomil and Hydrochlorothiazide respectively and The two drugs follow Beer's law over the concentration range of 1-6 µg/ml.

The % recoveries of the both the drugs were found to be nearly 100 % representing the accuracy of the proposed methods. LOD and LOQ values of OLM was found to be 0.400,0.403,0.407,0.400,0.403,0.407 at different wavelengths 272nm, 250nm, 242nm and LOD LOQ values of HTZ were found to be 0.135, 0.133, 0.182, 0.410, 0.405, 0.550 at 272nm, 250nm, 242nm.

Validation of the proposed methods was carried out for its accuracy, precision, specificity and ruggedness according to ICH guidelines. The proposed methods successfully applied in routine work for determination of Olmesartan medoxomil and hydrochlorothiazide in combined dosage form.

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International Journal of Pharmacy and Biological Sciences-IJPBS$_{TM}$ (2020) 10 (1):212-219
Online ISSN: 2230-7605, Print ISSN: 2321-3272
Research Article | Pharmaceutical Sciences | Open Access | MCI Approved

Stability Indicating RP-HPLC Method for Estimation of Itraconazole and Terbinafine in Bulk and Tablet Dosage Forms

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Received: 19 Oct 2019 / Accepted: 06 Nov 2019 / Published online: 01 Jan 2020
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Abstract
Itraconazole is an antifungal medication used to treat number of fungal infections. On set of action within an hour and Last up to twenty-one hours. Terbinafine is an antifungal medication used to treat pityriasis versicolor, fungal nail infections and ringworm. On Set of action within an hour and Last up to 36 hours. To develop and validate simple, fast, economical and eco-friendly RP-HPLC method for the estimation of ITRA and TERB in bulk and tablet dosage form according to ICH guidelines. This method achieved by Shimadzu LC-20A instrument with isocratic elution with the mobile phase of methanol and water in the ratio of (9.5:0.5v/v) on Zodiac C 18 (250mm x 4.6mm, 5µm) with a flow rate of 1mL/min. at a wave length of 257nm with UV detector. Tablets were allowed to undergo different stress conditions like acid, base, oxidation, thermal degradation studies. Retention time of ITRA and TERB was found to be 4.288 and 2.551 respectively. The linearity of proposed method investigated in the range of 10-50µg/mL for both ITRA and TERB. The Limit of Detection of ITRA and TERB 1.25µg/mL and 8.00µg/mL respectively. The Limit of Quantification of ITRA and TERB are 3.79µg/mL and 24.00µg/mL respectively. From the above results, it can be concluded that the developed RP-HPLC method represents a good technique for determination of Itraconazole and Terbinafine contents in bulk and tablet formulation with good sensitivity, precision, and reproducibility.

Keywords
Itraconazole, Terbinafine, RP-HPLC, Forced degradation studies.

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INTRODUCTION
Both Itraconazole and Terbinafine HCl are antifungal drugs. The International Union of Pure and Applied Chemistry name of itraconazole and terbinafine HCL is 4-[4-[4-[4- [[cis-2- (2,4-dichlorophenyl)- 2-(1H-1,2,4-triazol-1-ylmethyl)-1, 3 dioxolan-4-yl] methoxy] phenyl] piperazin- 1-yl] phenyl]- 2 - [(1RS)-1methylpropyl]-2, 4-dihydro-3H-1, 2, 4-triazol-3-one] and (E)-N,6,6-trimethyl-N-(naphthalen-1-ylmethyl) hept-2-en-4-yn-1 amine hydrochloride respectively. The chemical formula of Itraconazole and Terbinafine HCl is $C_{35}H_{38}Cl_2N_8O_4$ and $C_{21}H_{25}N{\cdot}HCl$, respectively, and molecular weight is 706 g/mol and327.89084 g/mol, respectively [1, 2]. Itraconazole and terbinafine HCl both are freely soluble in acetonitrile, methanol, and dimethyl sulfoxide but insoluble in water [1,2]. The chemical structure of both drugs is given in Figs. 1 and 2. Combination of Itraconazole and Terbinafine HCl is used for the treatment of antifungal infections such as toenail onychomycosis. The literature survey reveals that there is only one reversed-phase high-performance liquid chromatography (RP-HPLC) method reported for the estimation of Itraconazole and Terbinafine HCL in tablet dosage form. Thus, the present work was carried out to develop novel,

Evaluation of Wound healing and Antiinflammatory Activities of New Poly-herbal Formulations

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Present investigation evaluated the impact of poly-herbal formulations comprising extracts of *Zingiberofficinale*, *Curcuma longa*, *Aloe barbadensis*, *Citrus aurantium*, *Emblica officinalis* and castor oil on wound healing activity using excision wound model and antiinflammatory activity using formalin-induced pawedema method. Ointments containing 2, 4 and 6 % w/w of extracts were made and used in wound healing action and all the formulations significantly ($p<0.01$) reduced the wound area. Ointment of 6 % w/w has shown better results than 2 and 4 % w/w. These results were compared to that of the standard framycetin. Poly-herbal formulation-1, poly-herbal formulation-2 and poly-herbal formulation-3 were prepared and used at doses of 100, 300 and 500 mg/kg to determine antiinflammatory activity. All poly-herbal formulations significantly ($p<0.01$) inhibited formalin-induced rat paw edema. Poly-herbal formulation-3 displayed greater inhibition than poly-herbal formulations 1 and 2. These results were comparable to that of the standard diclofenac. Present work and previous studies on poly-herbal formulations corroborates that these are safer and effective in treating inflammation and wounds.

Key words: Poly-herbal formulations (PHF's), wound healing, antiinflammatory activity, ointments, diclofenac, framycetin

Skin is the largest connective tissue in human body, which protects the body from external environment, maintains fluid homeostasis, responds to sensory stimuli and possesses self-healing ability. It is composed of highly cellular epidermis below which is the collagen rich extra cellular matrix known as dermis[1,2]. Wounds are injuries breaking the skin. Wound may cause loss of integrity as well as impair skin function to various extent ranging from severe disability to even death[3,4]. Conditions that may cause wounds include mechanical trauma, surgical procedure, decreased vascularization or aging. Wound healing is a cascade process, which involves many steps to repair the damaged tissue. It plays a vital role in preventing entry of foreign pathogen into the host and to restore the injured tissue to normal. Wound healing is classified into various phases; it begins with inflammation followed by tissue build up, granulation phase, scar remodeling and closure of the wound[5-7].

Since many decades mankind has been using plants to treat wounds, which accelerate wound healing through various mechanisms. The main advantage of the phytochemicals that are present in plants is that they are affordable. Wound healing property of phytochemicals has grabbed attention of many researchers[8]. Intense research is going on to identify the active constituents and mode of action of phytochemicals[9]. The medicinal value of plants can be attributed to the phytochemical

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January-February 2020 Indian Journal of Pharmaceutical Sciences 174

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Soujanya *et al.*: Herbal Formulations for Wounds and Inflammation

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Key words: Poly-herbal formulations (PHF's), wound healing, antiinflammatory activity, ointments, diclofenac, framycetin

Skin is the largest connective tissue in human body, which protects the body from external environment, maintains fluid homeostasis, responds to sensory stimuli and possesses self-healing ability. It is composed of highly cellular epidermis below which is the collagen rich extra cellular matrix known as dermis[1,2]. Wounds are injuries breaking the skin. Wound may cause loss of integrity as well as impair skin function to various extent ranging from severe disability to even death[3,4]. Conditions that may cause wounds include mechanical trauma, surgical procedure, decreased vascularization or aging. Wound healing is a cascade process, which involves many steps to repair the damaged tissue. It plays a vital role in preventing entry of foreign pathogen into the host and to restore the injured tissue to normal. Wound healing is classified into various phases; it begins with inflammation followed by tissue build up, granulation phase, scar remodeling and closure of the wound[5-7].

Since many decades mankind has been using plants to treat wounds, which accelerate wound healing through various mechanisms. The main advantage of the phytochemicals that are present in plants is that they are affordable. Wound healing property of phytochemicals has grabbed attention of many researchers[8]. Intense research is going on to identify the active constituents and mode of action of phytochemicals[9]. The medicinal value of plants can be attributed to the phytochemical

World Inventia Publishers

Journal of Scientific Research in Pharmacy

http://www.jsrponline.com/

Vol. 8, Issue 1, 2019 ISSN: 2277-9469 USA CODEN: JSRPCJ

Research Article

STABILITY INDICATING RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF ISONIAZID AND RIFAMPICIN IN BULK AND SOLID DOSAGE FORMS

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Received on: 11-12-2018; Revised and Accepted on: 23-01-2019

ABSTRACT

A simple, fast, precise, accurate, robust, economic and stability-indicating reversed phase high performance liquid chromatographic method was developed for the simultaneous estimation of Rifampicin and Isoniazid, using a Hypercil C18 column and a mobile phase composed of Acetonitrile:water 80:20 (v/v). Flow rate was 0.8 mL/min and UV detection wavelength at 303nm. The retention times of Rifampicin and Isoniazid were found to be 2.7 min and 3.3 min respectively. Linearity was established for both Rifampicin and Isoniazid in the range of 10-50 µg/ml respectively. % RSD of Rifampicin and Isoniazid were 1.18 and 1.34 respectively. The correlation co-efficient (r_2) of regression was found to be 0.998 and 0.996 for Rifampicin and Isoniazid respectively. The percentage recoveries of Rifampicin and Isoniazid were found to be in the range of 100% and 99.98-100.1% respectively. Both the drugs were subjected to acid, alkali, oxidation and thermal degradation. The degradation studies indicated, both Rifampicin and Isoniazid bulk were degraded under acid, alkali and oxidative stress in only one day. For tablet dosage form of Rifampicin and Isoniazid degraded under acid, alkali stress in only one day as bulk and degraded under oxidation stress in three days. No degradation of both individual Rifampicin and Isoniazid in bulk was observed in Thermal condition (dry heat at 60°C). So this method can be successfully employed for analysis of drug and degradation products in stability samples in industry and simultaneous quantitative analysis of Rifampicin and Isoniazid in bulk drugs and formulations.

KEYWORDS: *Rifampicin, Isoniazid, Method development, Validation, RP-HPLC, Stress Conditions, Stability Indicating Method, Simultaneous Estimation Method.*

INTRODUCTION

Tuberculosis is an infectious disease that usually affects the lungs. Compared with other diseases caused by a single infectious agent, tuberculosis is the second biggest killer, globally. TB is a chronic granulomatous disease. About $1/3_{rd}$ of the world population is infected with *Mycobacterium tuberculosis* and it is major health problem in developing countries.

Isoniazid is a mild mono amine oxidase inhibitor. Chemically Pyridine-4-carbohydrazide. It is a prodrug activated by the mycobacterial catalase-peroxidase to an active compound which inhibits the synthesis of mycolic acid, an important constituent of the mycobacterial cell wall. Isoniazid is

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DOI: https://doi.org/10.5281/zenodo.2557216

World Inventia Publishers

Journal of Scientific Research in Pharmacy

http://www.jsrponline.com/

Vol. 8, Issue 1, 2019 ISSN: 2277-9469 USA CODEN: JSRPCJ

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DOI: https://doi.org/10.5281/zenodo.2557216

Principal
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International Journal of
Dermatology and Venereology

Original Article

OPEN

Evaluation of Depression and Quality of Life in Patients With Psoriasis

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Abstract

Objective: To measure the prevalence of depression in patients with psoriasis and to evaluate the relationship between the severity of psoriasis and depression and its effect on patients' quality of life.

Methods: A total of 154 patients with a confirmed diagnosis of psoriasis were assessed to determine the severity of psoriasis based on the psoriasis area and severity index score, presence, and severity of depression using the patient health questionnaire 9, and quality of life using the dermatology life quality index 10. Pearson correlation coefficient was used to demonstrate the relationship between continuous variables with 95% confidence intervals (CIs); $P < 0.00001$ was taken to indicate statistical significance.

Results: The severity of psoriasis was mild in 36.36% of patients, moderate in 25.97%, severe in 32.47%, and very severe in 5.20%. Of the 154 patients, 139 (90.3%) had depression; the severity of depression was mild in most affected patients (46.7%) and severe in 2.6% of patients. Psoriasis had a moderate effect on the quality of life in 37.01% of patients and a very large effect in 33.77% of patients. The severity of psoriasis was positively correlated with depression (Pearson correlation coefficient, $r = 0.42$, $P < 0.00001$, 95% CI: 0.28–0.54) and quality of life ($r = 0.43$, $P < 0.00001$, 95% CI: 0.29–0.55).

Conclusion: Depression is a common comorbidity in patients with psoriasis. The severity of psoriasis is positively correlated with the severity of depression and is associated with poor quality of life.

Keywords: depression, dermatology life quality index 10, patient health questionnaire 9, psoriasis, psoriasis area and severity index score

Introduction

Psoriasis is a chronic inflammatory dermatological condition characterized by skin lesions covered with white or silver scales,[1-2] with a strong genetic susceptibility, and complex autoimmune pathogenesis.[3] Based on the lesion characteristics, psoriasis is mainly classified into two types; non-pustular psoriasis includes psoriasis vulgaris, guttate psoriasis, erythrodermic psoriasis, inverse psoriasis, and psoriatic arthritis, while pustular psoriasis includes Von Zumbusch psoriasis, impetigo herpetiformis, and acrodermatitis continua of Hallopeau.[4-6] As psoriasis is a disorder with visible skin changes, it results in physical, emotional, and social burdens on the patient. Patients with psoriasis often experience a significant decrease in their emotional wellbeing and social functioning, adversely affecting their quality of life.[8-9] As a result, patients with psoriasis have a high prevalence of psychiatric morbidities, including sleep disorders, anxiety, and most commonly depression.[10] A depressed state of mind has a negative impact on a patient's health by decreasing the adherence to self-care and medication, which consequently leads to a poor disease prognosis.[11-12] In addition, the onset and course of depression in patients with psoriasis shows a strong association with systemic inflammation,[13-14] as there is a negative bidirectional relationship between depression and inflammation in patients with psoriasis.[15-16] The ongoing inflammation causes physiologic and biochemical changes that drive an increase in the levels of inflammatory

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Author contributions: SS, SD, SBBS, and MSK performed the study conception and design; SS and SD collected data; VE, SBBS and SS performed data analysis and interpretation; SS drafted the manuscript; VE and SBBS made the critical revision; SS, SD, SBBS, VE, and MSK approved the final version of manuscript to submit.

Conflicts of interest: The authors reported no conflicts of interest.

International Journal of Dermatology and Venereology (2022) 5:1

Received: 10 February 2021, Revised: 2 June 2021, Accepted: 8 July 2021

doi: 10.1097/JDV.0000000000000150

IP_114_2021_RA

Research Article

Access this article online

Quick Response Code:

Website: www.ijponline.com

DOI: 10.4103/ijpLP_114_20

Therapeutic drug monitoring of olanzapine: Easy and reliable method for clinical correlation

Srinivas Pramod Junutula, Sai Kiran Dubasi, Sai Geethika Reddy Padide, Gireesh Kumar Miryala [1], Manasa Soumya Koppolu[1], Sharvana Bhava Bandaru Sheshagiri, Venkateshwarlu Eggadi

Abstract:

AIM: The current work establishes an easy, reliable technique for the estimation of serum Olanzapine concentration which correlates it clinically.

SUBJECTS AND METHODS: The work was agreed in 61 schizophrenic patients who were on olanzapine. Serum drug amount was estimated by normal-phase high-performance liquid chromatography and brief psychiatry rating scale was used to determine disease progression.
RESULTS: Samples provided 61 patients. 40 were under sub-therapeutic range. 18 were under therapeutic range and 3 were above the therapeutic range.

CONCLUSION: Therapeutic drug monitoring must be a part of clinical practice in psychiatric hospitals for optimizing the dose of an individual patient along with the correlation of serum concentration with the clinical assessment scales.

Keywords:

High-performance liquid chromatography and therapeutic range, olanzapine, schizophrenia, therapeutic drug monitoring

Introduction

Olanzapine is benzodiazepine derivative which is used in the management of schizophrenia and also to treat modest to severe mania allied with manic depressive psychosis. Olanzapine was widely biotransformed in the hepatocyte, mainly through direct glucuronidation and CYP1A2 mediated oxidation followed by a lesser extent with CYP2D6. Olanzapine [5–20 mg] is recommended daily dose for schizophrenic patients. [1]

Therapeutic drug monitoring (TDM) of narcoleptics choose to optimize dosage decisions to maximize effectiveness and stop unwanted effects, particularly while those are nonresponsive to management or exposed to undesirable effects through usual quantity for the reason that of demographic, illness, or treatment reciprocal action make difficult in treatment. TDM-assisted psychiatric treatment, while practice by physicians who have background of pharmacokinetics, is potentially useful and cost-effective. TDM is useful in determining drug noncompliance which is a major issue in psychiatric treatment. In many psychiatric hospitals, disease progression is assessed by using different psychiatric rating scales. This is widely used for initially diagnosed and relapse patients. [2]

Due to these reasons, there is a need to develop an easy and reliable method for determining serum Olanzapine concentration which

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How to cite this article: Junutula SP, Dubasi SK, Padide SG, Miryala GK, Koppolu VS, Sheshagiri SB, et al. Therapeutic drug monitoring of olanzapine: Easy and reliable method for clinical correlation. Ind J Pharmacol 2021;53:XX-XX.

Original Article

Drug Utilization Evaluation of Pantoprazole in Inpatients of Tertiary care Hospital

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ABSTRACT

Objectives: To review Pantoprazole drug use, prescribing patterns and promote appropriate pantoprazole use. **Methods:** The study is prospective and observational conducted in inpatients of a tertiary care teaching hospital (MGM hospital). A total of 1012 cases were enrolled according to our plan of work i.e., inpatients who were under pantoprazole therapy were enrolled in two phases, phase-I (before intervention) and phase-II(after intervention) as we assessed inappropriate use of drug, intervention was developed and implemented and therefore pertinent use of drug is increased. **Results:** Inappropriate use of drug was found in phase-I and appropriateness in terms of rational use for indication, dose, dosing interval was improved in phase-II, this may be due to implementation of intervention. **Conclusion:** Rational use of pantoprazole in accordance with appropriate drug for indication, appropriate dose, dosing interval, duration of therapy for specific indication and particular individual was found to be low in phase-I and rational use was improved after intervention in phase-II by implementing criteria and standards rational drug therapy can be achieved. Rational use of pantoprazole should be increased.

Key words: Drug Utilization Evaluation, Pantoprazole, Proton pump inhibitors, Intervention, Indication, Rational use, Criteria and Standards.

INTRODUCTION

Drug utilization evaluation (DUE) is a system of ongoing, systematic, criteria-based evaluation of drug use that will help ensure that medicines are used appropriately (at the individual patient level). It involves a comprehensive review of a patient's medication and health history before, during and after dispensing in order to attempt to achieve appropriate therapeutic decision-making and positive patient outcomes. Pharmacists participating in DUE programs can directly improve the quality of care for patients, individually and as populations, by striving to prevent the use of unnecessary or inappropriate drug therapy, prevent adverse drug reactions and improve overall drug effectiveness.[1,2] It is an ongoing empowered and organized quality improvement process, designed to

1. To amend drug use by developing criteria and standards.

2. To audit drug use.

3. To interpret prescription pattern.

Steps involved in Drug Utilization Evaluation is depicted in Figure 1

DUE cycle

Pantoprazole is a first-generation proto pump inhibitor that constrain the activity of proton pump and are used to constrain gastric acid secretions in the treatment of ulcers and gastro esophageal reflux, preventing ulcer complications related to use of NSAIDs and corticosteroids, managing gastro esophageal reflux diseases and ulcer bleeding, prophylaxis of stress ulcer and preventing gastrointestinal risks in patients receiving anticoagulants.[3] Some other conditions where this drug is used include Helicobacter Pylori eradication, Pyrosis [Heartburn], dyspepsia [OTC], Zollinger-Ellision syndrome.[4] The maximum recommended treatment duration for many

DOI: 10.5530/ijopp.14.1.x

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Case Report

Cefotaxime Induced Staphylococcal Scalded Skin Syndrome: A Case Report

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ABSTRACT

Staphylococcal scalded skin syndrome (SSSS) is as well called as Ritter von Ritterschein disease, Lyell disease, Ritter disease and staphylococcal necrolysis of the epidermis. More common in neonates and children of age less than five years and are at a greater risk of SSSS. To fight against SSSS, children should attain lifetime immunity in the form of antibodies against exotoxins of staphylococcal strains. Symptoms include fever and redness on the overall surface of skin. Within 24-48h, fluid-filled blisters appear on the body. We report a case of 2 years old male child developed SSSS after intravenous administration of Cefotaxime.

Key words: Staphylococcal scalded skin syndrome, Immunity, Exotoxins, Cefotaxime, Exfoliative, Cephalosporins.

INTRODUCTION

Staphylococcal scalded skin syndrome is one of the major exfoliating skin infections. Mainly caused by Staphylococcus and the skin looks as if it has been burnt by a hot liquid.[1] Due to the lack of immunity and underdeveloped renal clearance, there is a greater chance of SSSS in children.[2]

Two exfoliating toxins A and B which are released from *Staphylococcus aureus*, but the mechanism for exfoliation is unclear until today. Beneath the granular cell layer, separation of the epidermis and red rash occurs when these toxins act at a remote layer.[3] Two types of SSSS exist localized form superficial involvement of skin and a generalized form involvement of significant areas. Localized infection of *Staphylococcus aureus* in the skin, nose, mouth, throat, umbilicus and gastro intestinal tract (GIT). General malaise, irritability, fever, skin tenderness may be prominent. Other signs include facial edema, conjunctivitis and perioral crusting.[4]

Cephalosporin's are used as a prophylactic treatment in many patients because of their β- lactamase stability, lack of toxicity and broad-spectrum.[5] Cefotaxime is a third-generation cephalosporin antibiotic.[6] Here we discuss a case of SSSS due to Intravenous Cefotaxime administration.

CASE REPORT

A two years old male child who was hospitalized in the Pediatric Department for fever since 3 days, facial puffiness, 2 episodes of vomiting containing food for 1 day, Swelling of legs and feet for 2 days. Then the patient was given Cefotaxime 280mg IV, Paracetamol 5ml syrup, Cetirizine 5ml syrup.

After two days, the patient developed pedal edema and rashes on legs. The physician stopped the medication and the patient was referred to dermatology. On general examination child was conscious, febrile. His pulse rate was 146/min and blood pressure was 90/50mmHg. Physical examination revealed multiple fluid -filled vesicles and bullae noted on the lower limbs and hyperpigmented lesions noted on the

DOI: 10.5530/ijopp.12.1.x

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Original Article

Assessment of psychiatric variables in geriatric patients diagnosed with different types of osteoarthritis: Radiographic-based evidences

Shravani Komuravelly[1], Surishika Reddy Chevireddy[1], Ramkumar Reddy Katam[2], Sharavanabhava Bandaru[3], Vasudevamurthy Sindgi[4], Venkateshwarlu Eggadi[5]

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Abstract

Context: Osteoarthritis (OA) is the most prevalent musculoskeletal condition in the world and is the most common cause of joint disability in approximately 15% of the total world population. The severity of the disease increases with age. It can have adverse effects on mental stability and is associated with poor clinical prognosis.

Aim: The aim of the study is to assess psychiatric variables (depression, anxiety, and perceived stress) in geriatric patients diagnosed with OA based on radiographic evidence and the item(s)/question(s) from questionnaires influencing their emotional instability.

Settings and Design: The prospective observational study was conducted in a tertiary care Mahatma Gandhi Memorial Hospital, Warangal.

Subjects and Methods: The study conducted for a period of 6 months and encompasses 158 elders with different types of OA. Standardized questionnaires were used to assess psychiatric variables.

Statistical Analysis Used: Statistical analysis was conducted using Microsoft Excel 2019 and IBM SPSS Statistics for Windows, Version 22.0. (IBM Corp, Armonk, NY, USA).

Results: The results of Pillai's trace revealed the scores of depression and anxiety as severe and perceived stress as moderate. Linear logistic regression stepwise disclosed the order of included variables affecting depression, anxiety, and perceived stress based on their level of significance ($P < 0.05$).

Conclusion: The findings in our study exemplify a strong correlation between psychiatric variables and OA.

Keywords: Anxiety, depression, geriatric patients, osteoarthritis, perceived stress

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Submitted: 31-Jul-2020, **Revised:** 13-Aug-2020, **Accepted:** 30-Oct-2020, **Published:** 14-Jan-2021

Access this article online	
Quick Response Code:	Website: www.amhonline.org
	DOI: 10.4103/MH.AMH_38_20

How to cite this article: Komuravelly S, Chevireddy SR, Katam RR, Bandaru S, Sindgi V, Eggadi V. Assessment of psychiatric variables in geriatric patients diagnosed with different types of osteoarthritis: Radiographic-based evidences. Arch Ment Health 2020;21:95-100

ORIGINAL ARTICLE

INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACEUTICAL SCIENCES

Published by JK Welfare & Pharmascope Foundation Journal Home Page: www.pharmascope.org/ijrps

Hypofractionated Versus Conventional Radiotherapy with Chemotherapy in Head and Neck Cancer: A Comparative Study

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Article History:

Received on: 01 Oct 2020
Revised on: 04 Nov 2020
Accepted on: 09 Nov 2020

Keywords:

Chemotherapy, Conventional Radiotherapy, Head Cancer, Hypofractionated Radiotherapy, Neck Cancer

ABSTRACT

Head and neck cancers are a group of malignancies that arise from common anatomic sites which include the oral cavity, oropharynx, nasopharynx, hypopharynx, larynx, sinonasal cavities and from the salivary glands. Head and neck squamous cell carcinoma (HNSCC) is the sixth most common cancer in the world and has a five-year survival rate of less than 50%. It has high recurrence rates and metastasis. It is a Prospective Observational, and Comparative Study carried out in 30 patients of Loco-regionally advanced carcinoma of head and neck. The diagnosis of loco-regionally advanced cancers of head and neck was made following AJCC staging. The subjects were divided into two groups with 15 in each arm -Accelerated Hypo Fractionated Arm and Conventional Normal Fractionated Arm. All the patients were systematically interviewed, and clinical details of all the subjects were recorded. Among the 30 patients, the highest performance status of (83.3%) ECOG-1 was observed in both the groups when compared to ECOG-2, which is not statistically significant. Hypofractionated radiotherapy can achieve similar tumour response to conventionally fractionated radiotherapy in HNSCC, although with some increase in toxicity. However, to draw some reasonable conclusion, a study with a broader sample and longer follow-up needs to be performed.

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ISSN: 0975-7538

DOI: https://doi.org/10.26452/ijrps.v11i4.4372

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INTRODUCTION

Head and neck squamous cell carcinoma (HNSCC) is the sixth most common cancer in the world and has a five-year survival rate of less than 50% (Xiong *et al.*, 2019; Zhao *et al.*, 2019). HNSCC has high metastasis and recurrence rates and includes the following subgroups: oral squamous cell carcinoma (OSCC), nasopharyngeal carcinoma (NPC), and laryngeal squamous cell carcinoma (LSCC) (Zhao *et al.*, 2019; Huang *et al.*, 2019). HNSCC is associated with a variety of environmental factors as known risk factors, including smoking, alcohol abuse, and human papillomavirus (HPV) infection (Sailer *et al.*, 2019). The survival rate of patients with the disease has increased due to progress in surgical therapy, as well as radiotherapy and chemotherapy. Due to the lack of early clinical symptoms, many HNSCC patients are diagnosed with advanced cancer, the prognosis of HNSCC patients remains stagnant, with a considerable number of deaths due to recurrence and metastasis after chemotherapy and targets therapy (Lai *et al.*, 2019). Head and neck cancer is the sixth most common cancer and is responsible for almost 2,00,000 deaths around the world each year (Parkin *et al.*, 2002). The progression of HNSCC

Original Article

Safety and Efficacy of Streptokinase, Tenecteplase, and Reteplase in Patients Diagnosed with ST-Elevation Myocardial Infarction: A Comparative Study

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Abstract

Objective: Our primary objective was to compare the efficacy of streptokinase (SK), tenecteplase, and reteplase by studying patients' electrocardiogram Electrocardiogram(ECG) pre and post thrombolysis. The secondary objectives were to assess chest pain relief using Numerical Pain Rating Scale score and also to compare the side effects (bleeding, hypotension, and anaphylaxis) of three drugs. **Materials and Methods:** This study is a multicentric, prospective, randomized, comparative study. This study was conducted on 150 patients of ST-elevation myocardial infarction admitted in the wards/ICCU- Intensive Coronary Care Unit, Department of Cardiology, Mahatma Gandhi Memorial Hospital and Rohini Superspeciality Hospital. They were selectively divided into three groups. Group A consisted of patients who received SK (50), Group B who received tenecteplase (50), and Group C who received reteplase (50). The study period was 6 months. The follow-up was done in all the patients during their inhospital stay. **Results:** Post thrombolysis, reteplase, tenecteplase, and SK led to mean ST-Segment reduction of 64.9 ± 19.77, 52.43 ± 34.57, and 46.97 ± 33.09, respectively. The comparison between the three drugs revealed a significant difference ($P = 0.0103$). **Conclusion:** This study concluded that reteplase is most efficacious in the resolution of ST-elevation and also safer than other thrombolytics used.

Keywords: Reteplase, ST-elevation myocardial infarction, streptokinase, tenecteplase, thrombolytics

Introduction

ST-elevation myocardial infarction (STEMI) is one of the challenging problems among acute coronary syndromes.[1] STEMI is a clinical syndrome characterized by typical symptoms of myocardial ischemia associated with persistent electrocardiographic ST-elevation and subsequent release of myocardial necrotic biomarkers. The Universal Definition of Myocardial Infarction defined by the European Society of Cardiology/American College of Cardiology Foundation/American Heart Association (AHA)/World Heart Federation Task Force is defined as new ST-elevation at the point J in at least two contiguous leads of ≥1.5 mm (0.15 mV) in women or ≥2 mm (0.2 mV) in men in leads V2–V3 and/or of ≥1 mm (0.1 mV) in other contiguous chest leads or the limb leads, is characteristic of diagnostic ST-elevation in the absence of left ventricular (LV) hypertrophy or left bundle branch block (LBBB). Coronary artery disease (CAD) is the leading cause of mortality worldwide, and over 7.4 million people died due to CAD in 2015.[2] Nearly three million STEMI cases are estimated to occur in India per year. Cardiovascular diseases are with the highest mortality rate in India accounting for about 21% of the deaths in 2010, with 10% of overall deaths occurring due to CAD.[3]

The ACC/AHA 2013 guidelines for the management of STEMI suggest fibrinolytic therapy when there is an anticipated delay in performing primary PCI within 120 min of first medical contact and lists available fibrinolytic agents (tenecteplase [TNK-tPA], reteplase [rPA], alteplase, and streptokinase [SK]).[4]

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Access this article online

Quick Response Code:

Website:

DOI:

How to cite this article: Neela B, Gunreddy VR, Chandupatla MR, Eggadi V, Bandaru SS. Safety and efficacy of streptokinase, tenecteplase, and reteplase in patients diagnosed with ST-elevation myocardial infarction: A comparative study. J Indian coll cardiol 2020;XX:XX-XX.

Submitted: 15-Aug-2020 **Accepted:** 21-Sep-2020 **Published:** ***

Original Article

Evaluation of Corticosteroid Use Pattern and Their Adverse Effects in Patients Visiting the Dermatology Department of a Tertiary Care Teaching Hospital in Warangal, India

Gogula Archana Reddy, Samreen Ayesha, Masood Ali Sheema, Bandaru Sheshagiri Sharvana Bhava, Valupadas Chandrashekar[1], Eggadi Venkateshwarlu

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Abstract

Introduction: Corticosteroids have become a mainstay of pharmacotherapy in dermatology because of their anti-inflammatory and immunosuppressive properties. However, misuse and sudden cessation of these drugs may render a patient to develop numerous adverse effects (AEs). Adverse drug reactions (ADRs) are important causes of mortality in both hospitalized and ambulatory patients. Early detection, evaluation, and monitoring of ADRs are essential to reduce harm to patients. Therefore, to achieve optimum benefit with the least AEs, safe and effective use of these agents is very crucial.

Objective: To examine the corticosteroid use pattern, to assess the frequency of misuse and the associated AEs that are encountered in dermatological practice.

Materials and Methods: A prospective observational study was conducted in the dermatology department of a tertiary care teaching hospital, Warangal for a period of six months. All patients using at least one corticosteroid either topically or systemically were included in the study. Informed consent was taken from patients.

Results: A total of 151 participants were included in the study. Among them, 56% of females developed ADRs compared with males (44%). Among patients using topical corticosteroids (TCs), the most frequently reported ADRs include facial erythema (7.31%), acne (17.07%), and hyperpigmentation of the face (2.43%). The AEs associated with oral corticosteroids include weight gain (19.51%) and taenia corporis (19.5%).

Conclusion: Corticosteroids have extreme importance in dermatological practice. However, inappropriate and prolonged users render a patient to develop several AEs. Precise drug regimens and proper patient counseling can help in minimizing and managing the AEs associated with inappropriate use.

Keywords: Acne, corticosteroids, erythema, hyperpigmentation, taenia corporis

Key Message: To prevent or manage steroid-induced AEs.

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Received: 14-12-2020
Accepted: 06-03-2021
Published: 10-05-2021

Access this article online	
Quick Response Code:	Website: www.mgmjms.com
	DOI: 10.4103/mgmj.mgmj_91_20

How to cite this article: Reddy GA, Ayesha S, Sheema MA, Bhava BS, Chandrashekar V, Venkateshwarlu E. Evaluation of corticosteroid use pattern and their adverse effects in patients visiting the dermatology department of a tertiary care teaching hospital in Warangal, India. MGM J Med Sci 2021;8:60-6

OPEN

International Journal of Dermatology and Venereology

DOI: 10.1097/JD9.0000000000000180

Evaluation of Depression and Quality of Life In Patients With Psoriasis

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Abstract

Objective: To measure the prevalence of depression in patients with psoriasis and to evaluate the relationship between the severity of psoriasis and depression and its effect on patients' quality of life.

Methods: A total of 154 patients with a confirmed diagnosis of psoriasis were assessed to determine the severity of psoriasis based on the Psoriasis Area and Severity Index score, presence and severity of depression using the Patient Health Questionnaire 9, and quality of life using the Dermatology Life Quality Index 10. Pearson's correlation coefficient was used to demonstrate the relationship between continuous variables with 95% confidence intervals; P<0.00001 was taken to indicate statistical significance.

Results: The severity of psoriasis was mild in 36.36% of patients, moderate in 25.97%, severe in 32.47%, and very severe in 5.20%. Of the 154 patients, 139 (90.3%) had depression; the severity of depression was mild in most affected patients (46.7%) and severe in 2.6% of patients. Psoriasis had a moderate effect on the quality of life in 37.01% of patients and a very large effect in 33.77% of patients. The severity of psoriasis was positively correlated with depression (Pearson's correlation coefficient, r=0.42, P<0.00001, 95%CI: 0.28–0.54) and quality of life (r=0.43, P<0.00001, 95%CI: 0.29–0.55).

Research Article

Evaluating the Outcomes of Surgical Versus Conservative Treatments in Head Injury: A Comparative Observational Study Using Different Scales

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ABSTRACT

Background: This study is to evaluate the outcomes of surgical versus conservative treatment in head injury by using different scales to rate the quality of life in both the treatments. **Aim:** To evaluate the outcomes of surgical versus conservative treatment in Head injury. **Methods:** A prospective, comparative observational study was conducted in Neurosurgery department in a tertiary care teaching hospital for a period of 6 months. All the patients with head injury were included in the study and reviewed.Among the subjects two groups are made in which one group includes the subjects who are treated with conservative treatment and the other group who have undergone surgical treatment among these two groups GCS scale, four score scale and dementia rating scale are assessed and both the treatments are compared. **Results:** Patients with head injury between age groups of 20 to 70 years were recruited for this study. The patients recovery analysis according to GCS for conservative (93.06%) and surgical (50.40%), FSS for conservative (90%) and surgical (56.75%), DRS for conservative (100%) and surgical (50.04%). **Conclusion:** Based on the severity it is decided whether conservative or surgical treatment is given to the patient, but primary choice of treatment should be conservative treatment for patients with less severity as patients under conservative treatment had better recovery and memory compared to that of patients under surgical treatment.

Key words: Head injury, Glasgow scale, FOUR score scale, Dementia rating scale, Surgical, conservative.

INTRODUCTION

Head injury is a trauma to the scalp, skull or brain. It may be only a major or minor bump on the skull.[1] Head injury may lead to bleeding in the brain tissues and in certain layers that surrounds the brain (subarachnoid haemorrhage, subdural haemorrhage and extradural haemorrhage). Head injury is one of the most common reasons for an emergency visit to the hospital. Traumatic brain injury (TBI) accounts for over 1 in 6 injury-related admissions each year.[2] Traumatic brain injury is a leading cause of morbidity, mortality, disability, in India and other developing countries. Road traffic injuries are leading cause (60%) of traumatic brain injury followed by falls (20-25%), violence and alcohol involvement (15- 20%) in India.[3,4] The occurrence of total traumatic brain injury has reminded similar throughout history in spite of modern Kevlar helmets.[5] Head injuries are commonly caused by a blow to the head that are usually associated with vehicle accidents, falls and sports related accidents. The treatment of the condition depends on the seriousness of the injury. Mild traumatic brain injures requires over-the-counter pain relievers to treat headache and usually needs to be monitored closely at home for any persistent, exacerbating or new symptoms. Moderate to severe brain injuries concentrate on enough oxygen,

DOI: 10.5530/ijopp.12.2.21

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Research article

Rapports De Pharmacie Vol.6 (2), 2020, 637-643
ISSN: 2455-0507

EVALUATION OF INSOMNIA AND PSYCHIATRIC INFIRMITIES WITH ANTICANCER TREATMENT IN PATIENTS DIAGNOSED AT DIFFERENT STAGES OF CANCERS

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ABSTRACT

Background: Cancer is the second most leading cause of death all over the world. Cancer leads to grief and pain. The objective of the present investigation was to evaluate Insomnia and Psychiatric infirmities with anticancer treatments in cancer patients. **Methods:** The data was gathered by administration of the evaluated questionnaires [DASS-21]21 characteristics of Depression Anxiety Stress, [ISI] Insomnia Severity Index and [PHQ-15] Physical Symptoms Questionnaire.**Results:**150 patients satisfying inclusion and exclusion criteria were included in the study. The most common age group (49-58) years with female preponderance (77%).There is a significant correlation found between Insomnia and Psychiatric infirmities ($p<0.001$).Depression and Anxiety ($r=0.94$).Depression and Stress ($r=0.18$) and Anxiety and Stress ($r=0.04$). **Conclusion:** This study reveals that female cancer patients are more prone to cancer than male cancer patients and there is a significant relationship found between Insomnia, Physical symptoms and Psychiatric infirmities.

Keywords: Cancer, Insomnia, Depression, Anxiety, Stress, DASS-21, ISI, PHQ15.

INTRODUCTION

Cancer is the second most leading cause of death all over the world [1]. Incidence and mortality of cancer are rapidly growing worldwide [2]. Non – Hispanic blacks are at highest incidence and mortality rate for cancer than in Asian or pacific islanders [1]. Lung, prostate, colorectal, stomach and liver cancer are the most common types of cancer in men, while breast, colorectal, lung, cervical and thyroid cancer are the most common among women (WHO). Men are at 20% higher incidence than women for all cancers. Almost 90% of cancer related deaths are due to secondary tumor metastasis [3].Emotional disturbances are the frequent outcomes of such painful illness like cancer. In order to cure the condition systematically, it is necessary to acquire Perception into the prevalence, severity, direction of the psychological abnormality and the factors affecting them [4]. Among all cancer patients, insomnia is a common heterogeneous complaint [5]. Inspite of suggesting that sleep difficulties are one of the frequent consequences of cancer, Insomnia has received very little attention. Cancer stage, time elapsed since diagnosis, cancer recurrence, medical comorbidities and cancer treatment are the factors which has great influence on sleep. Some of the studies also suggested that women who had received radiotherapy experienced more sleep difficulties than who did not [6]. 31% and 54% of newly diagnosed and recently treated cancer patients respectively reported sleep difficulties [7-9]. Anxiety and Depression are also exaggerated due to insomnia either as a clinical feature or a psychiatric diagnosis [10]. Depression, anxiety and stress are common among patients diagnosed with cancer and these conditions may also interfere with cancer treatment [11]. It is also taken for granted that cancer patients experience psychological distress by the medical

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Research article

Rapports De Pharmacie Vol.6 (1), 2020, 622-626
ISSN: 2455-0507

CUTANEOUS MANIFESTATIONS IN PATIENTS WITH END STAGE RENAL DISEASE AND ON HEMODIALYSIS

Susmitha P[1],Shalini K[1], Rajendra Prasad P[2], Achyuth P[1], Venkatesh L[1], Venkateshwarlu E[1], KottaiMuthu A[4] and Sharavana bhava B.S[1]*

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ABSTRACT

The purpose of this study was to evaluate the prevalence of dermatologic problems among patients with End Stage Renal Disease undergoing Hemodialysis. Methods: It is a Multi-centric prospective Observational study, conducted in MGM hospital,Warangal and SVR Kidney and Dialysis centre, Hanamkonda. Results: Among the total subjects (n=243) enrolled in the study, the incidence of different skin alterations such as Hyperpigmentation, Pruritis, Xerosis etc., were recorded. Conclusion: All patients examined in study had atleast one or more Cutaneous lesions caused either by Disease or by treatment.

Keywords: End Stage Renal Disease, Hemodialysis, Hyperpigmentation, Pruritis, Xerosis.

INTRODUCTION

End Stage Renal Disease is a worldwide public health concern with an incidence rate of 17.2%. The skin is external reflector of many renal diseases. A complex array of dermatologic lesions are presented among the patients with ESRD. These manifestations are due to the electrolyte imbalance, accumulation of uremic substances and presence of co-morbid conditions[1]. Early detection of these cutaneous alterations contributes in improving Quality of life among ESRD patients.

The pigmentation on sun exposed areas has been attributed to an increase in Melanin in the basal layer of the epidermis due to an increase poorly dialyzable beta melanocyte stimulating hormone.The intensity of Melanin pigmentation increases with respect to the duration of end stage renal disease[2].High levels of urea in the blood allows accumulation of urea in the dermis , where it leeches into sweat glands and gets released onto the surface of the skin in a process described as " uridrosis"or " ruinous sweat".Drying of the aqueous portion yields the crystals of uremic frost[3].The abundance of polymorphonuclear neutrophil remnants in the early stages of these disorders has led to speculation that cellular dissolution of neutrophils with proteolytic enzyme release,including collagenase and elastase elaboration ,may initiate the pathologic process[4].Koilonychia or spoon nails, in which the nails are abnormally thin and concave, from side to side, with edges turned up[5].Patients with chronic renal failure (CRF) have impaired cellular immunity due to a decreased T lymphocyte cell count[6].Xerostomia is a condition that reduce salivary flow resulting from atrophy and fibrosis of salivary glands[7].Epidermolytic hyperkeratosis (EH) is a skin disease. The keratin filament clumping and degeneration terminally differentiating epidermal cells[8].It occurs during the early stages of regular dialysis treatment and explained on the basis refeeding after starting treatment.As a consequence of CKD and protein energy malnutrition ,pituitary gonadotropic and testicular function remain suppressed and increase in daily protein intake ,second puberty ensues ,which lead to transient gynecomastia[9].Angular cheilitis (AC) is a condition characterized by erythema ,most , ulceration and crusting at corners of the mouth[10].Cutis increases the susceptibility to infections and this is aggravated by delayed wound

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Original Article

Indian Journal of Diabetes and Endocrinology
Volume 2 Number 1, January - June 2020

Incidence of Depression in patients with Type 2 Diabetes Mellitus

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How to cite this article:
B.S. Sharavana bhava[1],Ayisha[2], Bikkireddy Sai Sharanya[3] et. al. Incidence of Depression inPatients with Type 2 Diabetes Mellitus. Indian Journal of Diabetes and Endocrinology. 2019;1(1):25-32

ABSTRACT

Introduction: Depression and diabetes are both chronic devastating conditions & their co-occurrence has been associated with poor outcomes. The link between depression and type 2 diabetes is bidirectional, significant candidate pathways include the innate inflammatory response, the hypothalamic-pituitary-adrenal (HPA) axis, and insulin resistance, which all interrelate with each other. In formerly undiagnosed diabetic patients, depression had a higher prevalence and might be due to an unfavorable or stressful lifestyle such as condensed physical activity, socioeconomic scarcity, social adversity, unhealthy diet. In this study, the emphasis was made on screening for depression in patients with T2DM.

Aim of the study: To investigate the incidence of Depression in Patients with T2DM.

Objectives of the study: To obtain demographic details, to assess the depression levels, and to establish the relation based on the severity of depression in T2DM patients.

Methodology: It is a prospective observational study design, the patient health questionnaire (PHQ-9) was used to assess depression in 387 patients aged between 30-80 years. Venous blood was collected to assess fasting blood sugar (FBS), post-lunch blood sugar (PLBS) and Glycated hemoglobin (HbA1c).

Results: The PHQ-9 revealed that 182 patients (47%) are minimal in depression severity followed by 169 patients (38.5%) are mild in depression severity. Female gender, increased age, obese patients, and longer duration of diabetes was associated with increased odds of depression. Whereas, being married was protective and was associated with decreased odds of depression.

Conclusion: In our study, we found the majority of subjects with minimal severity of depression when correlated between depression and T2DM. When HbA1c levels are compared, patients with higher levels of HbA1c are presented by subjects with moderate levels of depression.

Keywords:- Type 2 Diabetes mellitus; HbA1c; Depression; Patient health questionnaire-9; Depression severity.

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Introduction

Depression is a common and potentially debilitating mental illness characterized by a sense of inadequacy, despondency, decreased activity, pessimism, disturbed sleep or appetite, anhedonia and sadness where these symptoms severely disrupt and adversely affect the person's life [1]. It is a chronic illness that distresses around 340 million individuals at any given time worldwide [2]. The occurrence of diabetes mellitus has grasped epidemic levels worldwide ensuing massive human, economic and social costs globally. Presently, 415,000,000 public are existing with diabetes, 75% of whom live in developing nations especially India, Bangladesh, Central African Republic; this figure has been anticipated to rise to 642,000,000 by 2040 [3]. A connotation amongst depression and diabetes was recognized in the early 17th century, diabetes frequently seemed in persons who had experienced earlier life stresses or grief [4].

The association amongst depression and T2DM

OPEN ACCESS

Asian Journal of Biological Sciences

ISSN 1996-3351
DOI: 10.3923/ajbs.2019.884.890

Research Article

Evaluation of Antiulcer Activity of *Lawsonia inermis* and *Murraya koenigii* Seed Extract in Ethanol-induced Gastric Mucosal Damage in Rats

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Abstract

Background and Objective: Ulcer is the common gastrointestinal damage resulting from an inadequate gastric mucosal defense. Many synthetic drugs are available in the market to treat and these drugs produce side effects. The present research aims to evaluate the anti-ulcer activity of ethanolic extract of *Lawsonia inermis* and *Murraya koenigii* seeds. **Materials and Methods:** Ulcer was induced by administration of 95% ethanol (1 mL/200 g p.o.) in rats. Animals were 7 days pre-treated with *Lawsonia* (200 mg kg^{-1} p.o.) and *Murraya* (200 mg kg^{-1} p.o.) and their combination (200 mg kg^{-1} p.o.), respectively. **Results:** After treatment with extracts at 100 and 200 mg kg^{-1} significantly ($p<0.001$) shows the ulcer protective action. **Conclusion:** The selected plant extracts showed significant anti-ulcer activity.

Key words: Peptic ulcer, *Murraya koenigii*, *Lawsonia inermis*, ethanol

Citation: Venkateshwarlu Eggadi, Jhansi Lingampalli, Srinivasulu Kamma, Sharavana Bhava Sheshagiri Bandaru, Rajasekhar Reddy Alavala and Umasankar Kulandaivelu, 2019. Evaluation of antiulcer activity of *Lawsonia inermis* and *Murraya koenigii* seed extract in ethanol-induced gastric mucosal damage in rats. Asian J. Biol. Sci., 12: 884-890.

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

Original Research Paper

Volume-9 | Issue-7 | July - 2019 | PRINT ISSN No. 2249 - 555X

Pharma

EFFECTS OF CARVEDILOL IN LEFT VENTRICULAR DYSFUNCTION IN PATIENTS WITH HEART FAILURE

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ABSTRACT **Background:** we conducted single center single drug study designed to establish the efficacy and safety of Carvedilol, a beta blocker of third generation which have vasodilator properties, in chronic heart failure

Methods: 80 patients with heart failure were treated with Carvedilol, and echocardiographic evaluation was performed at the start and after 6 months.

Results: Ejection fraction, blood pressure, pulse rate were improved in patients after 6 months treatment compared to before start of treatment with carvedilol. we found significant differences in ,systolic blood pressure(p value 0.0479),diastolic blood pressure (p value 0.2455)ejection fraction(p value 0.2691); pulse rate(p value 0.2192).

Conclusion: From this study we conclude that Carvedilol have proved to have good efficacy on the ejection fraction in patients with left ventricular dysfunction despite of few limitations like small sample size. Therapy of several months is required for improvement of ejection fraction, as these changes do not occur in the short term.

KEYWORDS : Carvedilol, Ejection fraction, Left ventricular dysfunction, Heart failure, Blood Pressure, Pulse rate

INTRODUCTION

Heart failure is a progressive syndrome resulting from the heart's inability to adequately perfuse and oxygenate peripheral tissues. This syndrome is manifested by fatigue dyspnea, and congestion (1, 2). Heart failure is associated with pathologic ventricular remodeling and worsening ventricular dysfunction, resulting in adverse hemodynamic changes (3). Activation of the sympathetic nervous system is known to be associated with progressive deterioration of cardiac function and clinical condition and increased mortality in patients with heart failure (4-10). Beta adrenergic blocking agents, because of their ability to inhibit sympathoadrenergic drive, are therefore useful for the long-term treatment of this syndrome (11, 12).Carvedilol is a new beta blocker devoid of intrinsic sympathomimetic activity with associated vasodilators effects mediated by alpha-receptor antagonism (10, 13, 14).Carvedilol is a third generation β-blocker with vasodilatory and antioxidant actions, which has been established as an effective drug for mild to severe CHF (15). Heart failure is associated with an increase in adrenergic activity and in that of renin angiotensin-aldosterone system (16,17).beta blockers are one of the main stays of treatment due to their ability to reverse neuro humoral effects of sympathetic nervous system with ensuing symptomatic benefits (18,19,20). Carvedilol has significant anti oxidant properties (21, 22). It inhibits oxygen free radicals generation and prevents LDL (low density lipoprotein) oxidation, in turn LDL uptake in to coronary vasculature is reduced. This anti oxidant property contributes to Carvedilol's cardio protective effects (23).Carvedilol produce less "inverse agonism" than most other beta blockers. Thus, carvedilol produces relatively fewer negative chronotropic and inotropic effects than other beta blockers (24). In this study, we investigated the effects of Carvedilol on parameters of ejection fraction, systolic blood pressure, diastolic blood pressure and pulse rate in heart failure patients with left ventricular dysfunction. Carvedilol is a beta blocker and have more anti adrenergic activity than others because of its unselective blockade of beta1 and beta2, alpha blockade and has anti oxidant properties, which provides a greater reduction of cardiac adrenergic drive and work. (25). The aim of the study is to assess the Carvedilol efficacy on ejection fraction of heart failure patients with left ventricular dysfunction.

MATERIAL AND METHODS

It is a prospective, observational single drug study conducted in patients of "MGM hospital". Patients were explained about the study &informed consent were seeked by explaining them in their local language.

Inclusion criteria

Males and females of 25-80years diagnosed with left ventricular dysfunction will be included in our study.

Exclusion criteria

Age above 80 years , patients with bradycardia, uncontrolled diabetes mellitus, asthma, unstable angina, resting angina, severe liver impairment, grade II or III atrio ventricular block, hyperthyroidism, pregnant women, cor pulmonale, valvular heart disease, life threatening arrhythmia, cardiogenic shock, hypertrophic obstructive cardiomyopathy. Patients were also excluded if myocardial infarction or coronary artery bypass grafting had occurred within the preceeding 3 months.

Study design

It is a prospective, observational, single centered, single drug study design performed for a period of 6 months and the patients included are on beta blocker therapy with Carvedilol. The goal was to achieve improvement in ejection fraction, blood pressure, pulse rate with add-on therapy of Carvedilol.

Institutional Human Ethical Committee Endorsement was obtained after submission of protocol and IHEC number is MGM-VCOP/PHARM/DAY/05/2018.

Clinical response assessment

The efficacy of Carvedilol was assessed by measuring the change in the Ejection fraction, systolic blood pressure, diastolic blood pressure, pulse rate after 6 months of treatment. Primary end point was change in ejection fraction after 6 months treatment as compared to the baseline levels. The secondary end point was change in blood pressure, pulse rate which were measured after 6 months treatment as compared to baseline levels.

MedCrave

Advances in Obesity Weight Management & Control

Research Article

CrossMark

Efficacy of telmisartan and enalapril in patients with diabetic nephropathy

Abstract

Introduction: Diabetic nephropathy is characterised by hypertension and persistent proteinuria and is the leading cause of end stage renal disease (ESRD). [illegible] in diabetic nephropathic patients.

Material and methods: All age groups of patients diagnosed with diabetic nephropathy are included in our study.

Results: [illegible] patients were enrolled in the study. [illegible] Telmisartan and Enalapril [illegible] completed the study. There was a significant reduction in urine albumin, urine creatinine, urine albumin/creatinine ratio (UACR), serum creatinine, blood pressure, fasting blood sugar, post meals blood sugar, HbA1c, total cholesterol, low density lipoprotein, very low density lipoprotein, high density lipoprotein and triglycerides.

Conclusion: Both Telmisartan and Enalapril were efficacious in diabetic nephropathy patients, but Enalapril showed more Reno protection than Telmisartan in this study.

Keywords: diabetic nephropathy, ESRD, telmisartan, enalapril, proteinuria

Volume 9 Issue 2 - 2019

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Received: March 13, 2019 | **Published:** April 4, 2019

Background and aim

Diabetes mellitus is a metabolic complex disorder characterised by hyperglycaemia and glucose intolerance as their hallmark due to insulin deficiency or impaired effectiveness of insulin action.[1] Diabetic nephropathy is one of the potential micro vascular complications in diabetic patients. It is the leading cause of End stage renal disease (ESRD). Diabetic kidney disease refers to chronic kidney disease (CKD) presumed to be caused by diabetes.[2] Diabetic nephropathy is screened for persistent abnormal urine albumin excretion and by decreased glomerular filtration rate (GFR). Albuminuria has been divided into micro albuminuria (urine albumin creatinine ratio (UACR) 30-300 mg/dl) and macro albuminuria (UACR more than 300mg/dl). Serum creatinine derives estimates of GRF and diabetic kidney disease.[3]

Diabetic kidney disease can be detected by screening for persistent abnormal urine albumin excretion and by determining the estimated glomerular filtration rate. The main evidence based strategies for preventing or delaying loss of kidney function in diabetic patients include blood pressure control, blockade of renin-angiotensin system, and glycaemic control. Controlling these factors and reducing proteinuria are now the main focus of diabetic kidney disease management. Through a multidisciplinary approach of implementing guidelines and timely referral, care of the diabetic kidney disease patient can be improved. The key is preventing and slowing the progression of this complication, to keep the other shoe from dropping.[4]

The aim of the study is to assess and compare the efficacy of Telmisartan and Enalapril in diabetic nephropathic patients. Angiotensin converting enzyme inhibitors and angiotensin receptor blocker have reno protection effects in diabetic patients. Enalapril, Angiotensin-converting enzyme (ACE) inhibitors, which competitively block the renin–angiotensin system, decrease glomerular capillary pressure and prevent the progression of microalbuminuria to overt proteinuria.[5] The side effects of enalapril are Edema, Dry cough, Dizziness, Hypertension, Syncope. Enalapril is contraindicated in pregnancy and breast feeding. Telmisartan is a angiotensin receptor antagonist possessing selective, and insurmountable inhibitory activity specific to the angiotensin II type 1 (AT1) Receptor.[6] side effects are Tachycardia, Bradycardia, Hypotension, Edema and Allergic reactions. Telmisartan is contraindicated during pregnancy, in bilateral renal artery stenosis in which it can cause renal failure.

Literature

(Table 1).[7]

Author	Year	Study	Conclusion
Roland et al[8]	2013	Telmisartan in incipient and overt diabetic renal disease.	The Effect of telmisartan on kidney function support its use in patients with microalbuminuria or overt diabetic nephropathy
Bhansali et al[9]	2010	Antialbuminuric efficacy of ACE inhibitors and ARB'S in type 2 DM with nephropathy	Dual blockade with ramipril enhanced with antialbuminuric effect of telmisartan and reduced in blood pressure
Anthony et al[10]	2004	ARB'S versus ACE inhibitors in type 2 DM and nephropathy	Telmisartan is not inferior to enalapril in providing long term reno protection in persons with type 2 diabetes mellitus.
Jansen et al	1992	Renal protective effect of enalapril in diabetic nephropathy	Treatment with enalapril can reduce the rate of decline in kidney function in patients with diabetic nephropathy

OPEN ACCESS

Research Journal of Medicinal Plants

ISSN 1819-3455
DOI: 10.3923/rjmp.2019.155.161

Research Article

Evaluation of Nootropic Activity of *Spinacia oleracea* in Scopolamine Induced Cognitive Decline Mice

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Abstract

Background and Objective: Alzheimer disease (AD) is reflected by progressive cognitive debility usually start with impairment in the capability to form new memories, but unavoidably disturbing all knowledgeable tasks. The present study was aimed at investigating the neuroprotective effect aqueous extract of *Spinacia oleracea* (AESO) in scopolamine induced cognitive decline mice. **Materials and Methods:** Memory impairment was produced by administration of Scopolamine (1.4 mg kg^{-1} i.p.) in albino mice. Nootropic activity in mice with the treatment of AESO (200-400 mg kg^{-1}) and donepezil (5 mg kg^{-1}) were administered to different groups of mice. Effect of extract on learning and memory of mice was evaluated using elevated rectangular maze, pole climbing and morris water maze test and also estimated the brain acetylcholinesterase (AChE) concentration and the percentage of inhibition of AChE. **Results:** AESO showed significantly improved in learning and memory of mice, as indicated by the decline in transfer latency using rectangular maze test, decrease in escape latency during training, retrieval using morris water maze, pole climbing test and neuroprotective activity through reduced brain AChE concentration and increased the percentage of inhibition of AChE activity in rat brain. **Conclusion:** Thus aqueous extract of *Spinacia oleracea* showed memory enhancing and neuroprotective activity in mice probably by inhibiting brain AChE activity.

Key words: Nootropic, acetylcholinesterase, donepezil, *Spinacia oleracea*, scopolamine, neuroprotective

Citation: Lakkireddy Rachana Reddy, Kulandaivelu Umasankar, Bandaru Sheshagiri Sharavana Bhava and Eggadi Venkateshwarlu, 2019. Evaluation of nootropic activity of *Spinacia oleracea* in scopolamine induced cognitive decline mice. Res. J. Med. Plants, 13: 155-161

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

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Research article

Rapports De Pharmacie Vol.6 (3), 2020, 651-653
ISSN: 2455-0507

A CASE REPORT: BECKWITH WEIDEMENN SYNDROME

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ABSTRACT

Beckwith-Weidemenn-syndrome (BWS) is an overgrowth disorder usually present at birth, characterized by an increased risk of childhood cancer and certain congenital features. A minority (<15%) cases of BWS are familial, meaning that a close relative may also have BWS, and parents of an affected child may be at increased risk of having other children with BWS. While children with BWS are at increased risk of childhood cancer, most children with BWS do not develop cancer and the vast majority of children who do develop cancer can be treated successfully.

Keywords: Beckwith-Weidemenn-syndrome, Macroglossia

INTRODUCTION

Patients were first noted to have abdominal wall defects, macrosomia, macroglossia, and enlarged adrenal glands. Since then, clinical presentation has expanded to recognize hemihypertrophy/lateralized overgrowth, hyperinsulinism, omphalocele, and organomegaly as classic features of BWS. Additionally, it is now recognized that there is a range of clinical features seen in patients with BWS. Presentation of BWS occurs on a spectrum ranging from isolated asymmetry to classic features of BWS.It is a pediatric cancer predisposition disorder caused by changes in the imprinted gene loci on chromosome 11p15 [1]. While most autosomal genes are expressed biallelically, imprinted genes are expressed either from the maternal or paternal allele. These genes are regulated by specific regions near the genes called imprinting control regions (ICRs), which contain epigenetic marks (methylation) that coordinate gene expression. BWS is caused by genetic or epigenetic changes that disrupt theparent-of-origin specific expression of these genes [2,3]. The imprinted gene regions involved in BWS are *H19/IGF2* and *CDKN1C/KCNQ1OT1*, all genes implicated in growth during early development. *H19* encodes a long noncoding RNA that is maternally expressed; it is believed to act as a tumor suppressor. *IGF2*, or insulin-like growth factor 2, is a paternally expressed protein-coding gene. IGF2 is highly active during fetal development and acts as a growth promoter. *CDKN1C*, or cyclin-dependent kinase inhibitor 1C, is a gene that encodes a protein implicated in cell cycle regulation. *KCNQ1OT1*, or potassium voltage-gated channel subfamily Q member 1 opposite transcript 1 is the antisense transcript of the protein-coding gene *KCNQ1*. *KCNQ1OT1* is implicated in regulating other growth genes[4].Incidence is estimated to occur in 1 in 10,500 live births in the general population[5]. BWS is a congenital disorder that is commonly diagnosed in early childhood. Patients with BWS have an increased risk of developing embryonaltumors in childhood. Particularly, patients with BWS have an increased risk of developing hepatoblastoma before 4 years of age and Wilmstumor before 7 years of age [6]. Clinical features of BWS typically decrease with age. Regardless of specific presentation, all diagnosed children should be screened for tumor growth. Current screening recommendations are as follows:Ultrasound Screening. Full abdominal ultrasound every three months until age 4 years. Renal ultrasound every three months from age 4-7 years[7].

Alpha-fetoprotein (AFP) screening-AFP measurements every three months until age 4 years. Patients with Beckwith-Wiedemann syndrome (BWS) may require escalated care to manage persistent hypoglycemia. This may include treatment with diazoxide, octreotide, continuous feeds or in some cases partial panpancreatectomy. [6] Consultation with experts in managing hyperinsulinism is recommended.

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MATERIAL AND METHODS

The Patient visited MGM Hospital with fever, headache and other associated symptoms. Caretakers consent was seeked and explained about this case report publication. The Protocol and Written acceptance of them was submitted and got approved from Institutional Human Ethics Committee (IHEC).

Research article

Rapports De Pharmacie Vol.5 (3), 2019. 582-585
ISSN: 2455-0507

INCIDENCE OF CATARACTS IN WARANGAL DISTRICT, TELANGANA STATE: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Cataract is the major cause of blindness worldwide, especially in tropical belt, where the densely populated developing countries are located. Survey in different climatic zones in northern India have found cataract prevalence of 4-10%and steadily increasing after the age 30 and with prevalence 13-36%among age of 30 and above. Our aim is to study the incidence of cataracts in Warangal District, Telangana State. Materialand Methods: It is a prospective observational study in which all the patients suffering with cataracts were included as subjects. Results: Among the total 83,827 cases in outpatient department females are found to be 41,167 (0.49%) and males found to be 42,660 (0.50%) of 6816 inpatients admitted, the female population was found to be 3285 (0.48%) and male population was found to be 3531 (0.51%). The total number of cataract operations done including TOL were 5429 and females found to be 2653 (0.48%) and males 2726 (0.50%). The total corrected refractive errors were 31,427 and females were found to be17,538 (0.55%) and males were 13,889 (0.44%).Conclusion: In conclusion, we have documented the incidence of cataracts in which males more affected than females.

Keywords: Cataracts, Blindness, Incidence, Ophthalmology.

INTRODUCTION

Cataract is defined as accumulation of proteins in the lens of eye where the cloudiness can be observed and the symptoms can be seen are mainly watery eyes and blurred vision. Cataract is a major cause of blindness worldwide, especially in the tropical belt, where the most of the densely populated developing countries are located. In India 60% of all blindness may be due to cataract; Various surveys in India show that nearly 7% of the population suffers from cataracts and nearly 1.5% of the population is blind due to cataract (1,2). Accordingly, blindness control programmes in India have focused primarily on cataract. Although such programmes have improved the coverage of cataract surgerythey have not always resulted in good postoperative vision outcomes. Surveys in different climatic zones in northern India have found cataract prevalence of 4-10%, with senile cataract appearing and steadily increasing after age 30 and with prevalence 13 – 36% among persons aged 30 and older(3,4). The aim is to study the incidence of Cataracts in Regional Eye Hospital at Warangal district in Telangana state.

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MATERIAL AND METHODS

It is a prospective observational study conducted in patients from "Regional Eye Hospital" located at Warangal. Patients were explained about the study & informed consent forms were seeked by explaining them in their local language.Institutional Human Ethical Committee Endorsementwas obtained after submission of protocol and IHEC No. is MGM/VCOP/PHARMD/V/12/2017.

Inclusion criteria:

All the cataract patients of age above 40 years (Males and Females).

Exclusion criteria:

Trauma to eye and other complications, Pediatric patients, Pregnancy and Lactating mothers were excluded from this research work (5-9).

Study type: A Prospective Observational Study conducted in the Regional Eye Hospital, Warangal, Telangana State.

Statistical analysis: We had calculated the Incidence by using formula

Incidence = Number of new cases at a particular area to the total number of cases at that particular area.

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IJAPB International Journal of Advances in Pharmacy and Biotechnology

Journal homepage: http://ijapbjournal.com/

Case Study

A Prospective Observational Study: Phenytoin Pharmacokinetic Pattern in Cerebrovascular Accident and Head Trauma Patients in Warangal Population

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ARTICLE INFO

Article history:
Received 11 Jan 2019
Received in revised form 16 Jan 2019
Accepted 18 Jan 2019
doi.org/10.38111/ijapb.20190501003

Keywords:
Head injury; Pharmacokinetics; Phenytoin; Cerebrovascular accident; Head trauma.

ABSTRACT

An phenytoin is commonly administered as prophylactic or treatment of epileptic episodes in acute brain injury due to head injury. The aim of the study is to evaluate PK pattern of phenytoin in patients with traumatic and non-traumatic brain injuries. This study was carried out in 30 adult head injury patients and who were administered with phenytoin for prophylaxis of post trauma seizures or treatment. Serum Phenytoin concentrations (Cp) were determined and were compared between CVA and HT patients. The Km and Vmax were significantly higher in HT patients. The Cp and the Cp/dose ratio were higher in the CVA patients significantly ($P<0.05$). APACHE II score was significantly lower than the baseline at the end of the study in each group of patients ($P<0.05$). Due to significant differences in Cp and PK parameters between HT and CVA patients, close attention must be paid to the PK behavior of phenytoin in the efforts to improve the patient's outcome after a severe HT.

1. Introduction

Head injury is a trauma to the scalp, skull or brain which is one of the leading causes of morbidity and mortality around the globe [1]. Head injury may lead to bleeding in the brain tissues and in certain layers that surround the brain (subarachnoid haemorrhage, subdural haemorrhage and extradural haemorrhage). Head injury is one of the most common reasons for an emergency visit to the hospital. Traumatic brain injury (TBI) accounts for over 1 in 6 injury-related admissions each year [2]. Traumatic brain injury is a leading cause of morbidity, mortality, disability, in India and other developing countries. Road traffic injuries are leading cause (60%) of traumatic brain injury followed by falls (20-25%), violence and alcohol involvement (15- 20%) in India [3]. Head injuries are commonly caused by a blow to the head that are usually associated with vehicle accidents, falls, and sports related accidents.The treatment of the condition depends on the seriousness of the injury. Mild traumatic brain injures requires over-the-counter pain relievers to treat headache and usually needs to be monitored closely at home for any persistent, exacerbating or new symptoms. Moderate to severe brain injuries concentrate on enough oxygen, sufficient blood supply, blood pressure and avoid any further injury to the head. Treatment limitations for peripheral destruction of the brain immediately after an injury may contain: Diuretics, Anti-seizure drugs and Coma-inducing drugs. Urgent surgery is needed to reduce further damage to the brain. Surgery may be used for the following issues: Eliminate clotted blood (hematoma), repairing skull fractures, bleeding in the brain, and opening in the skull [4].

In the beginning stage after a mend injury, seizure may cause auxiliary cerebrum harm because of expanded metabolic requests, expanded intracranial weight, and abundance synapse discharge. It has been shown that seizures are a significant reason for dismalness.

Phenytoin has been normally utilized as an anticonvulsant specialist for the treatment of or the prophylaxis against seizures for quite a long time. Despite the fact that the confusions of early seizure are the

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CRIMSON PUBLISHERS
Wings to the Research

Research in
Medical & Engineering Sciences

ISSN: 2576-8816

Research Article

Efficacy of Epalrestat and Pregabalin in Patients with Diabetic Peripheral Neuropathy

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Submission: April 12, 2018; **Published:** May 24, 2018

Abstract

Diabetic Peripheral neuropathy (DPN) is a major long term problem allied with diabetes that can cause serious disability and also death. It is caused by damage to any nerve in the peripheral nervous system. Fifty to seventy five percent of all ulcerations and non traumatic amputations are a consequence of diabetic neuropathy. Epalrestat and Pregabalin are widely used to overcome neuronal damage. This study was designed to evaluate the efficacy of these two drug regimens.

Material and methods: Patients included in this study were experiencing pain because of diabetic neuropathy for at least 6 months to 2 years.

Results: From 256 subjects with diabetic neuropathy included in the study, 229 patients concluded final analysis. 27 patients dropped from the study (17and 10 patients from pregabalin and epalrestat respectively). Mean pain score was reduced from 5.0±0.92 [severe pain] at first visit to 3.43±0.93 [moderate pain] in the epalrestat group, from 6.42±1.03 [severe pain] at first visit to 2.57±0.99 [mild pain] in the pregabalin group.

Conclusion: We conclude that pregabalin was significantly more effective than epalrestat in controlling pain in DPN patients.

Key words: Diabetic peripheral neuropathy; Epalrestat and pregabalin

Background and Aims

Diabetic neuropathy (DPN) encompasses a wide, heterogeneous group of clinical and subclinical syndromes [1]. It is a major long term problem allied with diabetes that can cause serious disability and also death [2]. 50 to 75% of all ulceration and non traumatic amputations are a consequence of diabetic neuropathy, and cause more hospitalizations than all other diabetic complications [3]. DN affects the nervous system and causes extensive damage. Neurologic complications are not reserved for specific type of diabetes but occur equally in type 1 and type 2 [4]. Diabetic peripheral neuropathy (DPN) is often painful and debilitating condition that is caused by damage to any nerve in the peripheral nervous system.

It is a family of nerve disorders that are directly caused by diabetic complications [5]. Poor diabetic control, obesity, high blood pressure, high cholesterol and triglycerides are risk factors for developing neuropathy [6]. It affects somatic and autonomous nervous systems and is different from peripheral arterial disease which affects the blood vessels rather than the nerves and vasa nervorum [7]. Many physicians misinterpret symptoms related to neuropathy in diabetic patients. Treatment is directed towards preventing neuropathy progression, reducing symptoms and implementing measures to prevent complications of traumatic extremities [8].

The aim of this study was to analyze the effect on neuropathic pain of two widely used drugs epalrestat and Pregabalin.

Material and Methods

This was a prospective observational study carried out in Sri Bhadrikala Diabetic Clinic, Mamnoor, Hanamkonda. Institutional Human Ethics committee endorsement was received and obtained before conduct of the trial. [MC/VCOP/PHARMD/IV/007/2017]. Selection of subjects was done according to the following inclusion exclusion criteria.

Inclusion criteria

Males and females 18-75 years age. Diabetes mellitus (Type 1 or Type 2). Experiencing pain due to diabetic neuropathy for at least 6 months to 2 years. Neuropathic pain must begin in the feet with

Review Article

CrossMark

Efficacy of azilsartan and telmisartan in patients with type 2 diabetes and hypertension

Abstract

Hypertension is defined as high blood pressure or a long term medical condition in which the arterial blood pressure is continuously elevated. It is also explained as sustained diastolic BP more than 90mmHG accompanied by the elevated systolic BP more than 140mmHg. Diabetes mellitus is a disorder related with a wide variety of disorders in metabolism, the principal feature is hyperglycaemia caused by inadequate insulin action. Azilsartan and Telmisartan are widely used in control hypertension in diabetic patients. This descriptive study is designed to analyse the efficacy of Azilsartan and Telmisartan.

Material and methods: Patients included in this study were diagnosed with Type 2 diabetes mellitus and Hypertension. The age was of greater than or equal to 18yrs.

Results: From 305 subjects with diabetes hypertensive patients included in the study 152 patients received Azilsartan and 153 patients were prescribed with Telmisartan.

Conclusion: Azilsartan 40mg and Telmisartan 40mg are proved to be efficacious in the patients with hypertension and T2DM, but Azilsartan 40mg has shown more efficacy than Telmisartan 40mg.

Keywords: type 2 diabetes, azilsartan, telmisartan, T2DM, BP, RAAS

Volume 8 Issue 5 - 2018

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Received: August 20, 2018 | **Published:** October 12, 2018

Introduction

Hypertension is defined as high blood pressure or a long term medical condition in which the arterial blood pressure is continuously elevated.[1] It is also explained as sustained diastolic BP more than 90mmHG accompanied by the elevated systolic BP more than 140mmHg.[2] Diabetes mellitus is a disorder related with a wide variety of disorders in metabolism, the principal feature is hyperglycaemia caused by inadequate insulin action.[3] Most deaths(43%) fall out below 70 years of age. 422million people across the globe in 2014 had diabetes-with a 8.5% prevalence in adults.1.5million deaths in 2012 occurred due to diabetes. In 2012 among both genders it is the eighth major cause of death and fifth prime cause of death in woman. About 2,82,000 intensive care room visits for adult population aged 18 years and above encountered hypoglycaemia as an initial diagnosis and diabetes as secondary diagnosis in 2012.[4] In the past 30 years Diabetes prevalence consistently increasing and is increasing most rapidly in nations with low and middle income. Increasing concomitant risk factors like being overweight or obese are seen. Diabetes mellitus is a main reason for blindness and kidney failure, legs amputation and other chronic consequences that affect primarily on quality of life.[5]

Relationship between hypertension and diabetes

In nephropathy, ECF or extracellular fluid volume and whole body sodium (Na+) levels are increased. The action of the Renin Angiotensin Aldosterone System (RAAS) is decreased in these patients, and the high blood pressure is volume dependent, identical to other nephropathies. Other factors must play a vital role in the occurrence of high blood pressure in the non-existence of diabetic nephropathy. Both genetic and acquired factors are seen. Increased whole body sodium levels along with low or actual activity of the RAAS had been reported. People with high blood pressure have found with elevated insulin levels secondary to insulin resistance and lowered insulin clearance. Elevated insulin levels may possibly be related with increased renal sodium resorption and hyperactivity of sympathetic nervous system making way to hypertension in people with obesity and other insulin resistant conditions, such as type 2 diabetes. Insulin resistance is also linked to a decreased response of vasodilators to insulin and an elevated response for vasoconstrictors to various vasopressors. However, the action of insulin resistance in the etiology and pathogenesis related to hypertension is not clearly understood.[6]

The aim of our work is to compare Azilsartan and Telmisartan among Type 2 diabetes and hypertensive patients.

Material and methods

Our research was an observational research work carried out prospectively in Sri Bhadrakali Diabetic Clinic, located at Hanamkonda, Warangal. Before initiation of our research, endorsement was sought and received from Institutional human ethics committee (IHEC) as (VCOP/PHARM/D.V/2018/015). Study population were selected by following inclusion and exclusion criteria's.

Criteria for inclusion

All subjects diagnosed with Diabetes mellitus Type II and Hypertension with at least age greater than or equal to 18yrs.

Criteria for exclusion

Patients who were diagnosed with

i. Secondary Hypertension due to an underlying cause

ii. Stage IV chronic kidney disease (GFR <30ml/min)

iii. Type1 Diabetes mellitus

World Journal of Medical Sciences 14 (3): 57-61, 2017
ISSN 1817-3055

DOI: 10.5829/idosi.wjms.2017.57.61

Comparison of Efficacy of Telmisartan and Enalapril in Patients with Diabetic Nephropathy

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Abstract: Diabetic nephropathy is the leading cause of end – stage renal disease. It is characterised by Hypertension and persistent proteinuria. If ineffectively controlled, a progressive decline in renal function can result in end – stage renal disease. The main objective of this study was to evaluate the efficacy of Telmisartan vs Enalapril on Diabetic Nephropathy in patients with type 2 diabetes. Patients included in this study were patients who had type 2 diabetes treated by diet and/or oral hypoglycaemics; Patients treated with insulin, if they were diagnosed as being diabetic at the age of > 40 years, had been in receipt of oral hypoglycaemics for > 1 year before being treated with insulin and had a body mass index of >25kg/m^2; patients who have mild to moderate hypertension (resting systolic / diastolic blood pressures < 180/95 mmHg) while receiving an ACE Inhibitor for > 3 months before entering the study. From 344 subjects with diabetic nephropathy included in the study, 328 patients were included in the final analysis. 16 patients were dropped from the study (15, 01 patients from Telmisartan and Enalapril groups respectively). At the end of the study the reduction in urine albumin was more with Enalapril (Mean difference 43.75 ± 4.003) when compared with Telmisartan (Mean difference 36.49 ± 3.23). The p values were < 0.05 for both groups and it was found that reduction of diabetic nephropathy in Enalapril treatment group at the end of the study is statistically differs than the Telmisartan treatment group. We concluded that Enalapril confers strong renal protection in patients with type 2diabetes and nephropathy. Telmisartan is not inferior to Enalapril in providing Reno protection in subjects with Type 2 Diabetes and early nephropathy. This result is consistent with emerging data that support the clinical equivalence of angiotensin II- receptor blockers and ACE inhibitors in various conditions associated with high cardiovascular risk.

Key words: Diabetic Nephropathy · End – Stage Renal Disease · Renin – Angiotensin Aldosterone System · Telmisartan · Enalapril

INTRODUCTION

Diabetes Mellitus (DM) is the most frequent cause of chronic kidney failure in both developed and developing countries [1]. Diabetic nephropathy, also known as Kimmelstiel – Wilson syndrome or nodular diabetic glomerulosclerosis / intercapillary glomerulonephritis, is a clinical syndrome characterized by albuminuria (>300 mg/day or >200 mcg/min) confirmed on at least two occasions 3-6 months apart, permanent and irreversible decrease in glomerular filtration rate (GFR) and arterial hypertension [2]. The syndrome was first described by a British physician Clifford Wilson (1996-1997) and American physician Paul Kimmelsteil (1900-1970) in 1936 [3].

Diabetic nephropathy is a chronic condition developing over many years characterized by Gradual increasing urinary albumin excretion (UAE), High blood pressure, Declining GFR, Absence of other renal / renal tract disease, Presence of diabetic retinopathy.

The aim of this study was to analyse the effect of two widely used drugs Telmisartan and Enalapril on urinary albumin.

MATERIALS AND METHODS

This was a prospective observational study carried out in Sri Bhadrakali Diabetic Clinic, Kishanpura, Hanamkonda, Telangaana, India. Institutional Human Ethics committee endorsement was seek and obtained

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Current Research in
Diabetes & Obesity Journal
ISSN: 2476-1435

Juniper Publishers
Open to the Researchers

Research Article

Comparison of Teneligliptin and Atorvastatin on Lipid Profile in Patients with Type 2 Diabetes Mellitus

[redacted]

[redacted]

Submission: March 27, 2018; **Published:** August 02, 2018

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Abstract

Diabetes mellitus is a chronic metabolic disease characterized by hyperglycemia resulting from defects in insulin secretion, insulin actions, or both which results in long-term damage, dysfunction and failure of various organs, especially eyes, kidneys, nerves, heart and blood vessels. The efficacy of Teneligliptin and Atorvastatin on lipid profiles in patients with type 2 Diabetes mellitus were compared. The study was designed to evaluate the efficacy of these two drug regimens.

Material and methods: Males and females of 25-90 years diagnosed with type 2 Diabetes mellitus are included in the study.

Results: 275 patients were recruited for our study, 45 were excluded because of their inclusion, 30 did not participate in the study and meet exclusion criteria. 220 T2 DM patients who were taking Teneligliptin 20mg and Atorvastatin 20mg were only participated in study. There were significant decrease in the levels of TC, HDL, LDL, VLDL in Teneligliptin and Atorvastatin (p<0.1.4.1, 14.9.37, 7.5(mg/dl) and <0.1.4, 14.6.37.2, 7.6(mg/dl) respectively.

Conclusion: From the study we conclude that Teneligliptin 20mg and Atorvastatin 20mg have proved to have similar efficacy on the lipid profiles. Hence we conclude that Teneligliptin 20mg has efficacious effect in the management of glycemic control and favourable lipid profiles.

Background and Aim

Diabetes mellitus is a group of metabolic diseases which challenges the global population. Thus, there is an increasing need to conduct research in this field [1-7]. The aim of the study is to compare the efficacy of Teneligliptin and Atorvastatin on lipid profile of patients with T2 DM. Comparative evidence is required to guide appropriate therapy, to attain potent effects and prevent complications of diabetes [8-11].

Methods and Methods

It is a prospective, observational, comparative study conducted in patients from "Sri Ramdutta Diabetic Clinic" located at Nizamabad, Himachalpradesh. Patients were explained about the study & informed consent forms were provided by explaining them in their local language [e.g. Institutional Human Ethical Committee Endorsement was obtained after the approval of protocol and IHEC No. is SMM/2008/PHARMD/47/2017-2019.

Inclusion criteria

Males and females of 25-90 years diagnosed with type 2 Diabetes mellitus will be included in the study.

Exclusion criteria

Pregnant and lactating females patients are under the age 18 years of type 1 Diabetes mellitus, signs of diabetic complications (i.e. retinopathy, nephropathy and neuropathy) are to be excluded [12]. Patients with clinical signs and symptoms of acute myocardial infarction, liver failure, chronic renal failure and hypersensitive to drugs excluded.

Study design

It is a non-interventional, observational, comparative study design, and the patients who were taking Teneligliptin 20mg and Atorvastatin 20mg were selected [13].

World Inventia Publishers

Journal of Scientific Research in Pharmacy

http://www.jsrponline.com/

Vol. 8, Issue 1, 2019 ISSN: 2277-9469 USA CODEN: JSRPCJ

Research Article

STABILITY INDICATING RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF ISONIAZID AND RIFAMPICIN IN BULK AND SOLID DOSAGE FORMS

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Received on: 11-12-2018; Revised and Accepted on: 23-01-2019

ABSTRACT

A simple, fast, precise, accurate, robust, economic and stability-indicating reversed phase high performance liquid chromatographic method was developed for the simultaneous estimation of Rifampicin and Isoniazid, using a Hypercil C18 column and a mobile phase composed of Acetonitrile:water 80:20 (v/v). Flow rate was 0.8 mL/min and UV detection wavelength at 303nm. The retention times of Rifampicin and Isoniazid were found to be 2.7 min and 3.3 min respectively. Linearity was established for both Rifampicin and Isoniazid in the range of 10-50 µg/ml respectively. % RSD of Rifampicin and Isoniazid were 1.18 and 1.34 respectively. The correlation co-efficient (r_2) of regression was found to be 0.998 and 0.996 for Rifampicin and Isoniazid respectively. The percentage recoveries of Rifampicin and Isoniazid were found to be in the range of 100% and 99.98-100.1% respectively. Both the drugs were subjected to acid, alkali, oxidation and thermal degradation. The degradation studies indicated, both Rifampicin and Isoniazid bulk were degraded under acid, alkali and oxidative stress in only one day. For tablet dosage form of Rifampicin and Isoniazid degraded under acid, alkali stress in only one day as bulk and degraded under oxidation stress in three days. No degradation of both individual Rifampicin and Isoniazid in bulk was observed in Thermal condition (dry heat at 60°C). So this method can be successfully employed for analysis of drug and degradation products in stability samples in industry and simultaneous quantitative analysis of Rifampicin and Isoniazid in bulk drugs and formulations.

KEYWORDS: *Rifampicin, Isoniazid, Method development, Validation, RP-HPLC, Stress Conditions, Stability Indicating Method, Simultaneous Estimation Method.*

INTRODUCTION

Tuberculosis is an infectious disease that usually affects the lungs. Compared with other diseases caused by a single infectious agent, tuberculosis is the second biggest killer, globally. TB is a chronic granulomatous disease. About $1/3_{rd}$ of the world population is infected with *Mycobacterium tuberculosis* and it is major health problem in developing countries.

Isoniazid is a mild mono amine oxidase inhibitor. Chemically Pyridine-4-carbohydrazide. It is a prodrug activated by the mycobacterial catalase-peroxidase to an active compound which inhibits the synthesis of mycolic acid, an important constituent of the mycobacterial cell wall. Isoniazid is

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DOI: https://doi.org/10.5281/zenodo.2557216

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International Journal of Pharmaceutical Sciences and Nanotechnology
Volume 14 • Issue 4 • July – August 2021
Research Paper https://doi.org/10.37285/ijpsn.2021.14.4.8 MS ID: IJPSN-2-22-21-HARIKA

Formulation and Evaluation of Salbutamol Sulphate Taste Masked Oral Disintegrating Tablets

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Received February 22, 2021; accepted May 29, 2021

ABSTRACT

Salbutamol is a short acting, selective beta2-adrenergic receptor agonist used in the treatment of astama and COPD. The aim of this study is to formulate oral disintegrating tablets of salbutamol sulphate to achieve rapid dissolution, absorption and further improving the bioavailability of the drug. Oral disintegrating tablets of salbutamol sulphate were designed with a view to enhance the patient compliance and provide a quick onset of action. The oral disintegrating tablets were prepared by using different synthetic polymers by direct compression method. Development of the formulation in the present study was mainly based on the concentration of superdisintegrants and the properties of the drug. Nine batches of tablets were formulated and evaluated for various parameters: drug content, weight variation, water absorption ratio, wetting time, *in vitro* disintegration, hardness, friability, thickness uniformity, and *in vitro* dissolution. A fourier-transform infrared spectroscopy (FTIR) study showed that there were no significant interactions between the drug and the excipients. The prepared tablets were good in appearance and showed acceptable results for hardness and friability. The *in vitro* disintegrating time of the formulated tablet batches was found to be 14.39-32.41 sec and the drug content of tablets in all formulations was found to be between 87.48-99.96 %, which complied within the limits established in the Indian pharmacopeia. The study concluded that taste of the drug was masked with the help of sodium saccarhin and flavor and the concentration of super disintegrating agent increases the disintegration time of tablets get decreases. The formulation (F9) had a minimum disintegration time of 14.39 sec and 99.96 % of the drug was released within 20 min.

KEYWORDS: Direct compression; Salbutamol sulfate; Crosspovidone; Crosscaramellose sodium; Sodium starch glycolate; Super disintegrant.

Introduction

Salbutamol is a short acting, selective Beta2-adrenergic receptor agonist used in the treatment of astama and COPD (Amperiadou et al., 1995). More than 50% of pharmaceutical products are orally administered for several reasons. Undesirable taste is one of the important major problem when the formulations prepared for oral purpose. Taste of a pharmaceutical product is an important parameter governing compliance (Sohi et al., 2004). Hence taste masking of oral pharmaceutical has become important tool to improve patient compliance and the quality of treatment especially in pediatrics. Hence formulation of taste masked products is a challenge to the pharmacist (Thoke et al., 2012).

Oral administration is the most popular route about 50-60 % of dosage forms (Talevi et al., 2018) are administered due to ease of ingestion, pain avoidance, versatility (to accommodate various types of drug candidates), and most importantly patient compliance (Venkateswarlu et al., 2016, Pollothu et al., 2018). Solid oral delivery systems do not require sterile conditions and are therefore less expensive to manufacture (Mohalkar et al., 2014, Pande et al., 2016). One important drawback of solid dosage forms is the difficulty in swallowing (dysphasia) or chewing in some patient's particularly pediatric and geriatric patients (Zakia et al., 2020). oral disintegrating drug delivery systems (oddds) offer several benefits such as easy administration to children and elderly patients having difficulties in swallowing (dysphagia) and in the case of tremors or mental retardation condition (Samvedna et al., 2018). Oral administration of oral disintegrating tablets (odt) donot require water, yet dissolve/disperse/ disintegrate in mouth in a matter of seconds, it have a pleasing mouth feel with an acceptable taste masking property and also leave minimal or no residue in mouth after administration (Heer et al., 2013, Bandari et al., 2014). The drug is released immediately when the tablet is placed on the tongue (Samvedna et al., 2018). They are also called as mouth-dissolving tablets, fast disintergrating tablets, fast dissolving tablets, orodispersible tablets, rapimelts, porous tablets, quick dissolving tablet (Yadav et al., 2012, Hannan et al., 2016). The ODTS are in ever-increasing demand compared to liquid dosage forms due to the ease of handling, accurate dose and good stability during storage (Parkash et al., 2011). They improve the oral bioavailability of drugs as compared to

International Journal of Pharmaceutical Sciences and Nanotechnology
Volume 14 • Issue 4 • July – August 2021
Research Paper https://doi.org/10.37285/ijpsn.2021.14.4.8 **MS ID: IJPSN-2-22-21-HARIKA**

Formulation and Evaluation of Salbutamol Sulphate Taste Masked Oral Disintegrating Tablets

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IJPSR (2020), Volume 11, Issue 4 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 07 June 2019; received in revised form, 07 November 2019; accepted, 06 February 2020; published 01 April 2020

METHOD DEVELOPMENT AND VALIDATION OF LC-ESI-MS/MS TECHNIQUE FOR THE ESTIMATION OF MODAFINIL IN HUMAN PLASMA; APPLICATION TO PHARMACOKINETICS IN HEALTHY RABBITS

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Keywords:

Modafinil, Narcolepsy, LC-ESI-MS/MS, FDA guidelines, Precision and Accuracy

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ABSTRACT: A new simple and sensitive liquid chromatography-electrospray ionization-tandem-mass spectrometric (LC-ESI-MS/MS) technique was developed and validated for the estimation of modafinil in human plasma and the method was applied to study pharmacokinetics in healthy rabbits. Chromatography was attained on Phenomenex- C_{18} (50mm × 4mm) 5µ column and acetonitrile, methanol and 0.1% formic acid (25:60:15 v/v) mixture as the movable phase at 0.7 ml/min flowrate. Modafinil and modafinil-D5 internal standards were detected at m/z 274.2/229.0, m/z 279.1/234.0 respectively. Modafinil and modafinil-D5 (internal standard) were separated with liquid-liquid extraction. The technique was linear over the 2.0-600.0 ng/ml concentration range. This technique established with intrabatch and inter batch precision within 1.54-7.18% and 1.82-6.25%. This technique established with intrabatch and inter batch accuracy within 98.56-102.80% and 97.62-102.76 %.The drug was shown mean T_{max} of 3.833; average C_{max}, AUC0_t and AUC0_α, for test formulation is 677.667; 6306 and 6471 respectively in the pharmacokinetic study on healthy rabbits.

INTRODUCTION: Modafinil acts as a eugeroic for the treatment of narcolepsy (sleepiness), sleep disorder due to different shift work and more day-time sleepiness which was associated with OPA (obstructive sleep apnea) [1-4]. It was administered by the oral route. It acts by inhibiting selectively and weakly the dopamine reuptake process and indirectly promotes the releasing of histamines and orexin neurological peptides from the tuberomammillary nucleus and lateral hypothalamus, respectively and leads to contribution to heightened-arousal.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.11(4).1837-44

This article can be accessed online on www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.11(4).1837-44

Chemically Modafinil designated as 2-[(diphenylmethyl) sulfinul] acetamide **Fig. 1** having a molecular mass of 273.35 g/mol [5, 6].

Modafinil activates the cytochrome-P450 enzymes CYP-1A2, CYP-3A4, and CYP-2B6, as well as inhibition of CYP-2C9 and CYP-2C19 *in-vitro*. Modafinil also produces P-glycoprotein (Pgp) material which affects drug transportation by this glycoprotein (as digoxin). The bioavailability of modafinil is greater than 80% of the administered dose. An *in-vitro* study of the medicament indicates that 60% of the drug is bound only to plasma proteins in the clinical concentration level. The percentage sometimes changes with change in the concentration. C_{max} occurs nearly at 2-3 h after drug administration. In the presence of food, the drug will show slow absorption, but it will not affect total AUC. The half-life of the drug was approximately between 10–12 h range, which was

A REVIEW ON THE DEVELOPMENT AND EVALUATION OF PLANT BASED EMULGEL FORMULATIONS

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ABSTRACT:
Emulgels are the novel drug delivery systems meant for the enhanced and controlled delivery of drugs in general and hydrophobic drugs in specific. Being the unique combination of gels and emulsions, theses possess several merits over conventional dosage forms like creams and ointments like thixotropic, nongreasy, non-adhesive, etc. Several natural drugs from plant origin are reported in the literature for their potential to cure skin diseases but most of them are not formulated into a novel drug delivery systems due to several reasons. If formulated theses are useful to the people, government and industry in the process of eradication of such deadly diseases like Leprosy and Psoriasis. These are safe, effective and also economical in nature. The present review focussed on the recent scientific advances related to the development and evaluation of emulgel formulations with plant- based drugs and related products.

Key words: Emulgel, Natural drugs, Topical, controlled, enhanced drug delivery

1. INTRODUCTION

Emulgels cab be defined as the novel topical drug delivery systems that can be formed by incorporation of gel into the water phase of an emulsion and possess the advantages both as gels and emulsions. Therefore, these are the combination of both gels and emulsions. It is also useful in the formulation of both hydrophilic and hydrophobic drugs for their enhanced and controlled delivery through skin.

Emulgels possess several merits over conventional semisolid dosage forms as these are leading to dual and controlled and enhanced release of drugs from both the phases, thixotropic, greaseless, easily spreadable, easily removable, emollient, non-staining, transparent, pleasing in appearance, suitable in the delivery of both drugs and cosmetics, shows better stability, have grater loading capacities for drugs etc., [1-6].

At present, several drugs which belonging to the categories of non steroidal anti inflammatory drugs, anti microbial agents etc., are successfully formulated and some of which are also marketed as Emulgels[7-8]. Certain natural drugs are also successfully formulated and evaluated as emulgel formulations [9-11].

These are the dosage forms which are prepared by combination of both emulsion and gels. Possess advantages of both to deliver both hydrophilic and hydrophobic drugs in topical drug delivery systems[1-2].

These can be prepared by using aqueous materials like water and alcohol, vegetable oils like, castor oil, emulsifying agents like polyethylene glycol for improving stability, gelling agents like, carbapol 940 for consistency and thickness and skin permeation enhancing agents like oleic acid etc., [3-4].

The formulation of emulgels usually involves the following steps: Preparation of either oil in water or water in oil emulsion, preparation of gelling agent, mixing both under suitable conditions with stirring.

The emulgel obtained above can be evaluated for different parameters like, physical appearance, rheological properties, spreadability, skin irritation test using rats etc., *In-vitro* release study by using Franz diffusion cell, extrudability by tube test, swelling index, PH, stability studies, drug content etc., [5-6].

Formulation and Evaluation of Acyclovir Microspheres

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Abstract

The present study is to formulate and evaluate Acyclovir (ACV) microspheres using natural polymers like chitosan and sodium alginate. ACV is a DNA polymerase inhibitor used in treating herpes simplex virus infection and zoster varicella infections. Acyclovir is a suitable candidate for sustained-release (SR) administration as a result of its dosage regimen twice or thrice a day and relatively short plasma half-life (approximately 2 to 4 hours). Microspheres of ACV were prepared by an ionic dilution method using chitosan and sodium alginate as polymers.

The prepared ACV microspheres were then subjected to FTIR, SEM, particle size, % yield, entrapment efficiency, *in vitro* dissolution studies and release kinetics mechanism. The FTIR spectra's revealed that, there was no interaction between polymer and ACV. ACV microspheres were spherical in nature, which was confirmed by SEM. The particle size of microspheres was in the range of 23.8µm to 39.4µm. 72.9% drug entrapment efficiency was obtained in the formulation F3 (1:3 ratio) with a high concentration of calcium chloride (4% w/v).

The *in vitro* performance of ACV microspheres showed sustained release depending on the polymer concentration and concentration of calcium chloride. The release data was best fitted with zero order kinetics and Korsemeyer-Peppas release mechanism and diffusion exponent 'n' value of was found to be Non-Fickian.

Keywords: Acyclovir, Microspheres, Chitosan, Sodium alginate.

Introduction

Acyclovir is a guanosine analog that acts as an antimetabolite. Acyclovir is converted by viral thymidine kinase to acyclovir mono phosphate, which is then converted by host cell kinases to acyclovir tri phosphate (ACV-TP).ACV-TP, in turn, competitively inhibits and inactivates HSV-specified DNA polymerases preventing further viral DNA synthesis without affecting the normal cellular processes. Acyclovir, BCS class III drug is widely used in the treatment of herpes simplex virus infection as well as varicella zoster infection. ACV is a guanosine analogue antiviral drug. It is the one of the most commonly used antiviral drug [(1)]. It has short biological half-life (2-4 hours) and is usually administered orally3-4 times a day. In this work, the ionic gelation technique [(2)] was used due to its simplicity, reproducibility, avoidance of organic solvents and heat. Sodium alginate and Chitosan were employed as biodegradable polymers [(3, 4)].

Materials and Methods

Materials

Acyclovir as a gift sample was procured from Maithri Laboratories Pvt. Ltd. Chitosan was obtained from Panvo organic Pvt. Ltd, sodium alginate was Loba Chemi, Mumbai, Glacial acetic acid from TriveniInterchem Pvt. Ltd. and Calcium chloride from TKM PharmaIndia, Secunderabad.

Methods

Preformulation studies

Preformulation testing is the first step in the rationale development of dosage forms of a drug substance. It can be defined as an investigation of physical and chemical properties of a drug substance alone and when combined with excipient. The main objective of preformulation testing is to generate useful information to the formulator in developing stable and bioavailable dosage forms.

Calibration curve for Acyclovir in 0.1 N HCl

100 mg of Acyclovir was dissolved in small amount of 0.1 N HCl and shaken vigorously, then volume was made up to 100 ml with 0.1 N HCl to obtain the primary stock solution. The necessary dilutions were made by using 0.1 N HCl to obtain the different concentrations of Acyclovir (10 to 100µg/ml).As the first step the solution is scanned on a UV scanner between 200 to 400 nm and the maxima peak obtained was considered as λ_{max}. The diluted solutions prepared for calibration curve were checked for their absorbance using UV-VIS spectrophotometer at 252 nm against buffer as blank. Standard graph was plotted between the concentration on X- axis and absorbance on Y-axis.

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Received: 30/9/2017
Accepted: 8/12/2017

RESEARCH ARTICLE

Formulation and Taste Masking of Metronidazole Oral Disintegrating Tablets by a Novel Approach

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Received: 13th June, 2020; Revised: 12th July, 2020; Accepted: 20th August, 2020; Available Online: 25th September, 2020

ABSTRACT

The anti-protozoal drug, metronidazole, is developed as an oral disintegrating tablet (ODT) to treat amoebiasis and to bypass hepatic metabolism. The work aimed to prepare, taste-masking oral disintegrating tablets of metronidazole using different proportions of the drug and disintegrants in various ratios by an effervescent method. The ODT was developed by direct compression with various concentrations of super disintegrating agents (1-7%). In this technique, sodium bicarbonate and tartaric acid were used to generate effervescence. The formulated tablets were assessed for physicochemical characteristics. The results of FTIR spectroscopy indicated the stable character of metronidazole. *In vitro* studies revealed that batch F6 was having a 97.65% cumulative amount of drug release at 20th minute compared to other formulations. Due to the effervescent method, there was a significant increase in drug release, seen at the 1:1.5 ratio. Taste evaluation studies were conducted on healthy human volunteers.

Keywords: Effervescent method, Metronidazole, Oral disintegrating tablets, Super disintegrants, Taste masking.

International Journal of Pharmaceutical Quality Assurance (2020); DOI: 10.25258/ijpqa.11.3.15

How to cite this article: Sriram P, Suttee A, Marasakatla Z. Formulation and Taste Masking of Metronidazole Oral Disintegrating Tablets by a Novel Approach. International Journal of Pharmaceutical Quality Assurance. 2020;11(3):399-403.

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

Because of the easiness of administration and formulation, oral delivery is the foremost widely accepted route.[1,2] But commonly used oral dosage forms are difficult in accepting or chewing, leading to patient's incompatibility.[3,4] An ODT is a compact dosage form that comprises medical substance and disintegrates speedily in seconds without water when positioned on the tongue. This is very suitable for patients traveling or who do not have instant access to water and thus provide better patient compliance. The availability of drugs is also improved due to absorption from mouth, pharynx, and esophagus.[5,6] Good mouthfeel, specifically for pediatrics, a taste-masking method, is employed to avoid the bitter taste of medicaments. Metronidazole is an anti-protozoal drug formulated as an orally disintegrating tablet to treat amoebiasis and to bypass liver metabolism.

MATERIALS AND METHODOLOGY

Metronidazole received as a gift sample from DRL, Hyderabad. Sodium bicarbonate and tartaric acid were procured from Hetero Drugs, Hyderabad. Remaining other chemicals obtained for this work were of analytical grade.

Drug-Excipient Compatibility Studies

The Compatibility studies of the pure drug along with excipients were studied employing a Fourier Transform – Infra-Red (FTIR) spectrophotometer and the spectrum of every sample was noted over 450–4000 cm^{-1}.

Method of Preparation

The pure drug, sodium bicarbonate, tartaric acid, Avicel pH 102, was accurately weighed and blended in a glass mortar for 15 minutes. All the formulations were prepared as per the composition given in Table 1, and finally, tablets were compressed using 9 mm round flat-faced punches.

Evaluation of Oral Disintegrating Tablet (ODT) Formulations

The developed tablets were evaluated for weight uniformity using an electronic balance, thickness using a digital screw gauge, hardness with Monsanto hardness tester, and friability was determined by Roche friabilator, and drug content was determined by dissolving the powder equivalent to one dose in a suitable solvent, and the obtained solution was filtered, and absorbance was measured by means of UV Visible spectrophotometer at 270 nm against blank.[7]

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Curr Drug Metab. 2021 Feb 22. doi: 10.2174/1389200222666210222152940. Online ahead of print.

Design and Evaluation of Ornidazole Sustained release Dental Inserts

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Affiliations

PMID: 33618642 DOI: 10.2174/1389200222666210222152940

Abstract

Aim & Background: Ornidazole an antimicrobial drug used to treat certain types of vaginal, urinary tract, and interstitial infections. The objective of this study is to formulate and evaluate the dental inserts by using drug candidate to sustained release of drug to improve patient compliance, reduce dosing frequency, better therapeutic efficacy and fewer side effects, reduce the risk of dose dumping as well as also to avoid the first-pass metabolism.

Materials & method: The dental inserts were prepared using various polymers and in combination with the different ratios of polymers. The evaluation parameters like thickness, drug content, content uniformity, moisture reuptake, weight variation, swelling studies, and erosion studies of the optimized inserts were studied. The in-vivo studies were conducted for determining the reduction of pocket depth in human volunteers.

Results: The system containing ethylcellulose and hydroxyl methyl propyl cellulose K100M (4:1) formulation F6 was optimized because drug release was sustained up to 120 hrs with respect to other formulations. Optimized formulation follows first-order kinetics and Peppas release kinetics via fickian diffusion. There was no swelling, itching, irritation and the reduction of pocket depth was absorbed in in-vivo studies.

Conclusion: The study concluded that dental inserts can extend the release of Ornidazole for many hours also enhanced bioavailability, further it also helps in avoiding the first-pass effect. The observations of in vivo studies were, there was no itching, irritation, swelling, and reduction in pocket depth was observed.

Keywords: Anaerobic bacteria; Enhanced bioavailability; Ethylcellulose; Intra pocket drug delivery; Minimum inhibitory concentration; Periodontal Disease; Pocket depth; Sustained-release.

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RESEARCH ARTICLE

Potential Approaches of Nanotechnology for Cancer Therapy: An Insight

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Received: 18th December 2020; Revised: 30th June, 2021; Accepted: 8th August, 2021; Available Online: 25th September, 2021

ABSTRACT

Cancer is one of the most severe threats to people all over the world. Cancer incidence and mortality are also on the rise. Chemotherapy, surgery, and radiation therapy are examples of traditional cancer treatment methods. Chemotherapy has been widely used in clinics due to its simple and effective process; however, the therapeutic potential of cancer chemotherapy is severely unsatisfactory due to side effects and drug resistance, non-specific distribution of medicines, multidrug resistance (MDR), and cancer heterogeneity. A drug delivery system (DDS) that combines chemotherapy with supplementary cancer management is required to overcome these limitations and improve cancer therapeutic efficiency. Because of nanomaterials' distinct physicochemical and biological properties, nanotechnologies have presented high potential in cancer therapeutics in recent years. Nanocarriers such as nanodiamonds, quantum dots, high-density lipoprotein nanostructures, liposomes, polymer nanoparticles, dendrimers, nanoconjugates, and gold nanoparticles are used in drug delivery of their physicochemical and optical properties, adaptability, sub-cell size, and biocompatibility. They provide an efficient means of transporting small molecules and biomacromolecules to diseased cells/tissues. In context to cancer, it provides a unique approach and comprehensive technology for early diagnosis, prediction, prevention, personalized therapy, and medicine. As a result, combinational therapy based on chemotherapy facilitated by nanotechnology is the current trend in clinical research, resulting in significantly improved therapeutic efficiency with minimal side effects to normal tissues. The review focuses on recent developments and approaches in nanotechnology for cancer treatment.

Keywords: Cancer, Drug delivery, Nanocarriers, Nanoparticles, Nanotechnology.

International Journal of Drug Delivery Technology (2021); DOI: 10.25258/ijddt.11.3.24

How to cite this article: Mishra V, Sriram P, Suttee A. Potential Approaches of Nanotechnology for Cancer Therapy: An Insight. International Journal of Drug Delivery Technology. 2021;11(3):797-155.

Source of support: MHZ supervised and designed the whole project: ATS performed the experiments, analyzed the data, and drafted the manuscript.

Conflict of interest: None

INTRODUCTION

Cancer is one of the leading causes of mortality worldwide. The pace of cancer is increasing with time because of factors like higher pollution, radiation, lack of exercise, and a balanced diet, including genetics.[1] Cancer control has been quite complex due to the distinctive pathophysiology of the cancer cells, which show therapeutic resistance and clinical diversity on the phenotypical and genetic levels. Any of these factors can lead to a mutation in cell DNA, including oncogenes, and causes cancer.[2]

The immortalization and longevity of discrete and amazingly replicated cells exceed all healthy functional cells and causes death ultimately. Initially, cancers start to spread to remote places throughout the body but are likely limited to a small area,[3] making cancer incurable. While our understanding of cancer biology has improved dramatically in the last 20 years, cancer is still the second leading cause of death in the world. More than 10 million new cases and more than 5 million illness-related deaths are reported every year.[4] A cancer analysis was considered earlier terminal, although the prognosis is favorable at an early stage. A considerable number of cancer patients are asymptomatic until the final stages of the disease are reached. Chemotherapy, radiotherapy, and surgery are among the most common cancer treatments.[5]

Chemotherapy is widely used to inhibit the growth of fast-growing cancer cells by the systemic administration of cancer medicines to patients.[6] A high volume of distribution for low-molecular active ingredients leads to cytotoxicity from chemotherapy. The primary clearance from systemic circulation is another major limitation of chemotherapy. Small molecular chemicals are promptly excreted. They are washed away by macrophages from the body. They, therefore, persist for a short period in systemic circulation and cannot be interconnected with cancer cells, resulting in lower therapeutic

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Biochemistry and Biophysics Reports 26 (2021) 100962

Contents lists available at ScienceDirect

Biochemistry and Biophysics Reports

journal homepage: www.elsevier.com/locate/bbrep

Fluorescent quantum dots: An insight on synthesis and potential biological application as drug carrier in cancer

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ARTICLE INFO

Keywords:
Quantum dot
Nanomedicine
Theranostic agent

ABSTRACT

Quantum dots (QDs) are nanocrystals of semiconducting material possessing quantum mechanical characteristics with capability to get conjugated with drug moieties. The particle size of QDs varies from 2 to 10 nm and can radiate a wide range of colours depending upon their size. Their wide and diverse usage of QDs across the world is due to their adaptable properties like large quantum yield, photostability, and adjustable emission spectrum. QDs are nanomaterials with inherent electrical characteristics that can be used as drug carrier vehicle and as a diagnostic in the field of nanomedicine. Scientists from various fields are aggressively working for the development of single platform that can sense, can produce a microscopic image and even be used to deliver a therapeutic agent. QDs are the fluorescent nano dots with which the possibilities of the drug delivery to a targeted site and its biomedical imaging can be explored. This review is mainly focused on the different process of synthesis of QDs, their application especially in the areas of malignancies and as a theranostic tool. The attempt is to consolidate the data available for the use of QDs in the biomedical applications.

1. Introduction

Quantum dots are semiconducting nanocrystals with intermolecular distance of approximately 2–10 nm. The use of QDs extends from the commonly seen items like lights, reflectors, photovoltaic devices and sign boards to the more sophisticated, delicate and precise medicines to be administered to humans. In case of medicines, QDs are useful as drug carriers and are also used as tools for diagnosis of diseases when seen under light of particular wavelength [1]. QDs can be synthesized by many well established documented procedures and uniqueness lies in the fact that different QDs emit different emission spectra when excited under same wavelength. This is based on the composition of materials used for their synthesis and resultant particle size obtained for fluorescent dot [2]. The ease of conjugating QDs with drug delivery vehicles viz; a polymer, solid lipid nanoparticles, micelles, liposomes and carbon based nanomaterials allows the use of such fluorescent nano dots in the field of nano medicine [3]. Very recently the application of nanomaterials is seen in the areas of diagnosis as well as treatment for even complicated conditions like diabetes, cardiovascular ailments, neuro-muscular diseases and cancer. Due to the property of photo

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https://doi.org/10.1016/j.bbrep.2021.100962
Received 25 September 2020; Received in revised form 11 February 2021; Accepted 22 February 2021

RESEARCH ARTICLE

Niosomes: Potential Nanocarriers for Drug Delivery

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Received: 25th June, 2020; Revised: 29th July, 2020; Accepted: 16th August, 2020; Available Online: 25th September, 2020

ABSTRACT

Niosomes are novel vesicular drug delivery systems, where the solution is surrounded by non-ionic surfactant vesicles. The niosomes offer different benefits over the traditional drug delivery system. Niosomes are structurally similar to liposomes, as they also consist of a bilayer. In the case of niosomes, the bilayer consists of non-ionic surface-active agents instead of phospholipids, as seen in liposomes. Niosomes are much more stable during the process of formulation and storage, as compared to liposomes. Niosomes may resolve the issues of insolubility, volatility, poor bioavailability, and rapid drug degradation. It has been discovered in recent years that, these vesicles can enhance drug bioavailability and can act as a new strategy to deliver many conventional therapeutic agents, such as, protein drugs, and gene materials. It is also easy to prepare and scale up this novel delivery system with low production costs. The delivery of drugs via niosomal formulations may be relevant to several pharmacological agents for their activity against different diseases. The present review provides an overview about the advantages and disadvantages, fabrication techniques, types, characterization technique, and different applications of niosomes.

Keywords: Application of niosomes, Drug delivery, Fabrication techniques, Niosomes.

International Journal of Pharmaceutical Quality Assurance (2020); DOI: 10.25258/ijpqa.11.3.13

How to cite this article: Mishra V, Nayak P, Singh M, Sriram P, Suttee A. Niosomes: potential nanocarriers for drug delivery. International Journal of Pharmaceutical Quality Assurance. 2020;11(3):389-394.

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

The current research and development approach relies on developing drug delivery systems that make clinically proven drugs perform their best in treatment instead of searching for new drugs. The goal of any drug delivery system should always be to achieve the highest therapeutic action with minimal side effects. Non-ionic surfactants can form vesicular delivery, like phospholipids, and when dispersed in water, called niosomes.[1]

Non-ionic surfactant based vesicles that are uni/multilamellar in structures enclosing lipophilic components and an aqueous solution of solutes are called niosomes. These vesicles are produced by the self-assembly of hydrated surfactant monomers. Compared to liposomes, niosomes overcomes the stability associated problems, which includes oxidation, high economy, a purity that influences on size and shape. Both hydrophilic and lipophilic drugs can be entrapped in niosomes (Figure 1). The bilayers of niosomes have sandwiched lipophilic areas in between the hydrophilic inner and outer surfaces of the bilayers. Hence, drugs can be delivered extensively along with other required materials using niosomes.

In recent years, these were extensively studied for their modified potential of the biodistribution and activity profile of the drug. It acts as a carrier in the release of medicaments, hormones, antigens, and bioactive molecules. Moreover, niosome also acts as an alternate version to unravel the problem of insolubility, unsteadiness, and rapid deprivation of drugs.[2,3]

COMPOSITION OF NIOSOMES

A normal niosomal vesicle consists of an amphiphilic-forming vesicle, i.e., a non-ionic surfactant such as Span-60, which is normally balanced by the introduction of cholesterol and a small amount of anionic surfactant such as dicetyl phosphate, which also tends to stabilize the vesicle.[4] The two key

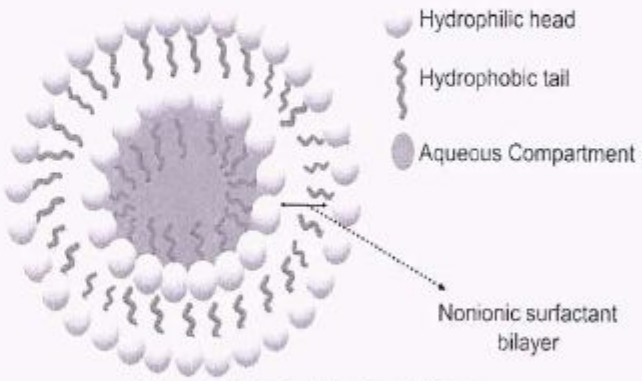

Figure 1: A typical structure of niosome

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IJAPB International Journal of Advances in Pharmacy and Biotechnology

Journal homepage: http://ijapbjournal.com/

Review Article

An Update on Floating Drug Delivery System: A Review

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ARTICLE INFO

Article history:
Received 27 Nov 2020
Received in revised form 08 Dec 2020
Accepted 10 Dec 2020
doi.org/10.38111/ijapb.20200604003

Keywords:
Controlled drug delivery system, Floating drug delivery systems, Gastric residence time, polymers, evaluation, Gastro retentive drug delivery systems.

ABSTRACT

The oral route is the most appropriate and widely used for the delivery of drugs to the systemic circulation. This route has high acceptability for patients, particularly due to the ease of administration. Over the years, oral dosage forms have become increasingly world-wise in the pharmaceutical field, with controlled release drug delivery systems that release the drug at a predetermined rate playing a major role. Various approaches have been designed and utilized to achieve efficient drug delivery for those drugs that have poor bioavailability and shorter gastric residence time. On the other hand floating drug delivery system, one of the most extensively used approaches of the Gastro retentive drug delivery system has an advantage for the drugs that are absorbed primarily in the upper segments of the Gastrointestinal tract i.e., stomach, duodenum, and jejunum. The main purpose of writing this review article is to emphasize the types of floating drug delivery systems, the principle, and mechanism of floating action to achieve gastric retention. This review also outlines the In-vitro and In-vivo studies used to evaluate the potential, performance, and application of floating systems in to overcome various problems encountered during the development of a dosage form.

1. Introduction

Despite enormous advancements in the drug delivery, the oral route remains the most favorable, desirable route for the therapeutic agent which has high patient acceptability, particularly due to the ease of administration. Over the years, oral dosage forms have become increasingly world-wise in the pharmaceutical field, with controlled release drug delivery (CRDDS) systems that release the drug at a predetermined rate playing a major role. CRDDS provides drug release at a predictable, predetermined, and controlled rate, which is an important pre-requisite for the successful performance of an oral CRDDS. The gastro retentive drug delivery system (GRDDS) is an approach to prolonging the duration of gastrointestinal residence, thereby targeting the site-specific release of drugs in the upper gastrointestinal tract (GIT) to generate local or systemic effects. Gastro retentive systems can remain in the gastric region for several hours which helps in enhancing the bioavailability of the drug, reducing the drug waste, also aids in improving the solubility of poorly soluble drugs in a higher pH environment. Drug absorption in GIT is a highly variable process, which depends on various factors like gastric emptying process, gastro intestinal transit time of dosage forms, drug release from the dosage form, and site of drug absorption [1].

The following two parameters are optimized to develop sustainable orally controlled releasing drug delivery systems that deliver a drug for the required duration for optimal treatment at a therapeutically efficient range to a desirable place.

1) Gastrointestinal transit modulation time: Modulate the transit time for GIT so that dosage form can be taken to or around the target absorption site and thus extend the time limit for maximizing the delivery of drugs.

2) Minimizing the elimination of the first hepatic pass: If the drug to be given undergoes extensive first-pass hepatic removal, preventive measures should be developed to either bypass **or** minimize the extent of hepatic metabolism.

Gastrointestinal tract Anatomy and Physiology

For successful modulation of GI transit time of a dosage form via GRDDS for drug absorption in GIT and site-specific delivery, a complete understanding of the human GIT is required. Today, the design of the Oral drug delivery system (ODDS) was based on an empirical understanding of GIT anatomy and physiology.

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IJAPB International Journal of Advances in Pharmacy and Biotechnology

Journal homepage: http://ijapbjournal.com/

Review Article

Formulation and Evaluation of Valacyclovir Hydrochloride Effervescent Floating Tablets

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ARTICLE INFO

Article history:
Received 16 Feb 2021
Received in revised form 27 Feb 2021
Accepted 15 March 2021
doi.org/10.38111/ijapb.20210701007

Keywords:
Valacyclovir hydrochloride, Effervescent, Floating, Tablets, HPMC K100 M, HPMC K 15 M, Sodium alginate, Xanthan gum

ABSTRACT

The purpose of this research was to develop gastro-retentive drug delivery system of Valacyclovir hydrochloride to prolong gastric residence time with desired in vitro release profile. Valacyclovir hydrochloride is an Anti-viral drug with high solubility in gastric pH. In the present study, Valacyclovir hydrochloride floating tablets were prepared by effervescence method using sodium bicarbonate and citric acid as a gas generating agent. The tablets were formulated using direct compression method using polymers like HPMC K15M, HPMC K100M, Xanthan gum and Sodium alginate. Pre-compression parameters such as for angle of repose, bulk density, tapped density and hausner's ratio whereas the prepared tablets were evaluated for weight variation, thickness, hardness, friability, drug content, floating lag time, total floating time, in vitro dissolution study and in vivo radiographic studies. FT-IR and DSC studies elucidated the compatibility of the drug with the polymers and other excipients used in the study. In Vitro release studies of the prepared tablets depicted to follow Zero order kinetics with R2 value of 0.941 and Fickian diffusion where n value is < 0.5 and found to be the main mechanism of drug release. The manufacturing procedure was found to be reproducible and formulations were stable after one month of accelerated stability studies.

1. Introduction

Oral route is considered as the most common route of administration for drug delivery [1]. Effective oral drug delivery may depend upon the factors such as gastric emptying process, gastrointestinal transit time of dosage form, drug release from the dosage form and site of absorption of drugs [2]. Most of the oral dosage forms suffer from several physiological limitations such as variable gastrointestinal transit, variable gastric emptying time, non-uniform absorption profiles, incomplete drug release and shorter residence time of dosage form in stomach [3].

As a result, drugs with absorption window in the upper part of the small intestine undergo incomplete absorption [4]. Hence a beneficial delivery system would be one which possesses the ability to control and prolong the gastric emptying time and can deliver drugs in higher concentrations to the absorption site i.e. upper part of the small intestine [5]. Gastric retention of drugs is one of the approaches used in the prolongation of gastric retention time with suitable therapeutic activity [6].

Valacyclovir Hydrochloride is an anti- viral drug used commonly in the treatment of infections caused by Herpes virus [7]. Valacyclovir HCl converts to acyclovir with L-valine by first-pass metabolism [8]. Plasma concentrations of unconverted valacyclovir are low with transient, generally becoming non-quantifiable by 3 hours after administration. Peak plasma valacyclovir centrations are generally less than 0.5 mcg/mL at all doses [9].

Valacyclovir hydroconchloride is suitable for floating drug delivery system as it undergoes hepatic metabolism which hinders with the oral bioavailability of the drug. It also has multiple dosage activity for a day that maintains stable drug plasma concentration [10].

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ISSN 0974-3618 (Print)
0974-360X (Online)

www.rjptonline.org

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RESEARCH ARTICLE

Fabrication and Evaluation of Lidocaine Hydrochloride loaded Cubosomes

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ABSTRACT:

Topical delivery of local anaesthetic drugs such as Lidocaine HCl using carriers and novel nanotechnology can enhance effective drug permeation through the skin into deeper layers and exhibit desirable duration of action. The present study was aimed to formulate and evaluate Lidocaine HCl loaded cubosomes (LHLCs) for sustained therapeutic topical action. Cubosomes emanated as favourable means for the delivery of the drug. LHLCs were prepared by top-down technique using lipid and polymer. Eight formulations of LHLCs were prepared using different concentrations of glyceryl monooleate (GMO) and Poloxamer 407 (P-407). Local anaesthetics create loss of sensation in particular region of the body by inhibiting impulse generation and propagation. Lidocaine HCl is most commonly used amino amide local anaesthetic. It is used as local, topical, intravenous, epidural, peripheral and spinal anaesthesia. The prepared cubosomal dispersions were evaluated to determine surface morphology, particle size, poly dispersibility index (PDI), zeta potential, entrapment ability, tissue distribution studies, and *in vitro* drug release studies. Scanning Electron Microscopic analysis confirmed that drug was encapsulated in bicontinuous structure. The maximum entrapment efficiency was found to be 89.85±1.1% with vesicle size as 228±2.1nm, charge as -5.68±2.7, PDI as 0.295 and 98.83%± 0.12 *in vitro* drug release at the end of 12 hr for F7 formulation, which was confirmed as optimized cubosomal dispersion.

KEYWORDS: Cubosomes, Lidocaine HCl, local anaesthetic, sustained drug delivery.

1. INTRODUCTION:

Skin is a tough barrier and allows only small quantities of drug molecules to penetrate inside. The outer most layer, Stratum corneum is highly lipophilic in nature and hence acts as rate limiting step in topical drug delivery[1]. Enormous innovations have been developed pertaining to novel transdermal drug delivery with prime aim of extended and targeted delivery of drugs[2]. There are different colloidal carriers such as micro particles, nano particles, micro and nano spheres, liposomes, sphinogosomes, cubosomes, transferosomes etc[3]. These carriers are used for transportation of various drug molecules which have difficulty in penetrating through skin and for poorly bio available drugs[4]. They enable to sustain the effect of drug at constant rate following zero order kinetics with minimized undesirable side effects[5].

Lidocaine HCl is a well known Local anaesthetic[6]. Topical anaesthetic agents are used in the treatment of pain associated with minor procedures and symptomatic relief in burns, joints, muscles, haemorrhoids, neuralgia and used in post-operative pains[7]. The half life of highly water soluble Lidocaine HCl is 1.5 to 2hr[8]. Most of the anaesthetics have tendency to bind back to plasma proteins in blood. This affects the duration of action of drug[9]. Nano structured lipid carriers such as Tocopheryl derivative induced systems were also proved to be effective in topical delivery of Lidocaine HCl[10]. Lidocaine HCl can be incorporated in vesicular carriers such as cubosomes, liposomes etc for extended release[11]. Due to greater stability of the cubosomes compared to liposomes which are prepared by phospholipids, the former is gaining prominence in topical drug delivery[12].

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ISSN 0974-3618 (Print)
0974-360X (Online)

www.rjptonline.org

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RESEARCH ARTICLE

Formulation and Evaluation of Dexamethasone Loaded Cubosomes

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ABSTRACT:
Cubosomes are altered cubic phase systems, which are emerging as promising drug delivery system for the delivery of both hydrophilic and lipophilc drugs. Dexamethasone is a lipophilic steroidal drug with poor hydrophilicity. Lipophilic drugs like Dexamethasone can be successfully administered by use of novel transdermal systems like cubosomes, nanoparticles, liposomes, implants etc. Controlled drug delivery, increased time scale of action, preventing the necessity of frequent parenteral and ophthalmic admisitration is enhanced by loading Dexamethasone in the form of cubosomes. The main aim of present research was to encapsulate Dexamethasone in cubosomes for sustained drug release. Dexamethasone loaded cubosomes were prepared by top-down technique using Glyceryl Mono Oleate and Poloxamer 407 in different ratios. The prepared formulations were subjected to evaluation studies for excipient compatability, particle size, zeta potential, drug content, entrapment efficiency and *In vitro* drug release. The maximum entrapment efficiency was found as 96% with vesicle size as 119.4 nm, charge as -22.1±5.66 mV, Poly Dispersity Index as 0.153 and *In vitro* drug release as 92.12% by dialysis bag method over 24hrs. Stability studies were also conducted for the formulations as per protocol mentioned in ICH guidelines. These results suggest that the cubosomal formulation F6 is suitable for the delivery of Dexamethasone.

KEYWORDS: Dexamethasone, Cubosomes, Glyceryl Mono Oleate, Poloxamer 407, Top down approach, Sustained release.

1. INTRODUCTION:
Dexamethasone ($C_{22}H_{29}FO_5$) is a strong synthetic glucocorticoid steroidal drug used to treat various inflammatory and autoimmune conditions like Rheumatoid arthritis, edema, nasal and opthalmic allergies. It is poorly water soluble and is lipophilic in nature. Parenteral and Ophthalmic routes are commonly used to administer Dexamethasone. It has half-life of about 30-52 hours and 70% of protein binding[1].

Oral usage of glucocorticoids causes numerous adverse and toxic effects like stomach upset, disturbances in electrolytic balance, muscle atrophy, negative protein balance (catabolism), enhanced appetite causing significant weight gain etc[2]. Use of transdermal routes eliminates the above side effects, increases patient compliance and maintains the plasma drug level for a longer period of time[3].

Lipophilic drugs like Dexamethasone can be successfully administered by use of novel transdermal systems like cubosomes, gels, nanoparticles, liposomes, implants etc. Controlled drug delivery, increased time scale of action, preventing the necessity of frequent parenteral and ophthalmic admisitration is enhanced by loading Dexamethasone in the form of cubosomes[1].

Cubosomes are discrete, sub-micron, nanostructured particles of cubic liquid crystalline phase. These are microstructure particles containing surfactants with

Received on 10.07.2019 Modified on 07.08.2019
Accepted on 11.09.2019
Research J. Pharm. and Tech 2020; 13(2):709-714.
DOI: 10.5958/0974-360X.2020.00135.3

RESEARCH ARTICLE

Formulation and Evaluation of Levocetirizine Dihydrochloride and Ambroxol Hydrochloride Lozenges

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Received: 22nd March, 2020; Revised: 12th April, 2020; Accepted: 21st May, 2020; Available Online: 25th June, 2020

ABSTRACT

The present work aims to formulate and evaluate levocetirizine dihydrochloride and ambroxol hydrochloride hard candy lozenges to produce a slow-release of drugs for the management of cold and cough. The lozenges were prepared using sucrose, liquid glucose, hydroxyethylcellulose, and hydroxypropyl methylcellulose K4M by heating and congealing method. Sweetener with flavors was utilized to facade the bitter taste of the drug. The developed lozenges were exposed to various physical and chemical characters, and *in vitro* disintegration and dissolution. The developed formulations include hardness of 8 to 11 kg/cm^2, non-gritty, and agreeable mouthfeel. The optimized formula was examined for drug excipient interactions subjecting to Fourier transform infrared (FTIR) spectral analysis. Drug release for lozenges was highest in formulation FL8. The hard candy lozenges can present an attractive substitute formulation in allergic conditions.

Keywords: Ambroxol hydrochloride, Hard candy, Levocetirizine dihydrochloride, Lozenges, Polymers.

International Journal of Pharmaceutical Quality Assurance (2020); DOI: 10.25258/ijpqa.11.3.18

How to cite this article: Sriram P, Arsham P, Thout Reddy R, Suttee A. Formulation and evaluation of levocetirizine dihydrochloride and ambroxol hydrochloride lozenges. International Journal of Pharmaceutical Quality Assurance. 2020;11(3):417-423.

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

Lozenges are solid preparations that comprise one or more drugs, generally in a flavored, sweetened base, and are meant to be sucked and held in the mouth to lubricate, and pacify irritated tissues of the throat. They are planned to be dissolved in the posterior surface of the tongue to deliver drugs locally to the mouth, tongue, and throat, and to relieve oropharyngeal symptoms. The dosage form can be implemented for local as well as systemic treatment.[1] They can deliver medicine multi-directionally into the oral cavity or mucosal surface through the buccal linings.[2,3] Since sublingual lozenges may be unfeasible due to their size, buccal lozenges are developed and have been widely used and are placed between the cheek and the gums. Sucking and the consequent production of saliva might also lead to improved dilution of the drug and accidental swallowing.[4]

Levocetirizine dihydrochloride is an antihistamine to get rid of allergy signs such as watery eyes, runny nose, sneezing, and itching. Ambroxol hydrochloride is a mucolytic agent used in the management of respiratory diseases accompanying with viscid or excessive mucus. The work has been designed to formulate flavored slow dissolving lozenges.

MATERIALS AND METHODS

Materials

Levocetirizine dihydrochloride obtained as a gift sample from Sai Mirrainnopharm Pvt. Ltd., Chennai. Ambroxol hydrochloride was from Hetero Pharmaceuticals, Hyderabad. Hydroxypropyl methylcellulose (HPMC) K4M, and hydroxyethylcellulose (HEC), and aspartame were from SD Fine Chemicals Limited, Mumbai. Liquid glucose from Deccan Bottle Traders, Hyderabad. Color and flavor from Manju Chemicals, Chennai, and all other reagents used were of pharmaceutical grade.

Preformulation Studies

Preformulation studies are principally done to examine the physicochemical properties of drugs and to know its compatibility with excipients. Levocetirizine dihydrochloride and ambroxol hydrochloride were mixed in equal proportions, and subjected to physical observation and FTIR studies. The spectra of active pharmaceutical ingredient, excipient, and optimized formulation obtained by means of FTIR spectrophotometer (BRUKER).

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International Journal of Pharmaceutical Sciences and Nanotechnology
Volume 12 • Issue 5 • September – October 2019
MS ID: IJPSN-8-10-19-SUNCHU

Research Paper

Formulation and Evaluation of Metoprolol Tartrate Sustained Release Matrix Tablets

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Received August 10, 2019; accepted September 5, 2019

ABSTRACT

The objective of the present work was to develop sustained release matrix tablets of Metoprolol tartrate using different polymers viz. Guar gum, Xanthan gum, Kondagogu gum and HPMC K100M. The release rates were modulated by combination of two different rates controlling material and triple mixture of two different rate controlling materials. After evaluation of physical properties of tablet, the *in-vitro* release study was performed in phosphate buffer pH 6.8 up to 12 hrs. Dissolution data was analyzed for release kinetics. It was observed that matrix tablets contained polymer Xanthan gum was successfully sustained the release of drug up to 12 hrs. Among all the formulations, F6 which contains 45 % of Xanthan gum, release of drug which follows zero order kinetics via, swelling, diffusion and the release profile of formulation F6 was compared with marketed product. The FTIR study revealed that there was no chemical interaction between drug and excipient.

KEYWORDS: Metoprolol; Guar gum; Xanthan gum; Kondagogu gum; Direct compression; Matrix.

Introduction

A controlled release drug delivery system delivers the drug locally or systemically at a predetermined rate for a specific period of time. The goal of such systems is to provide desirable delivery profiles that can achieve therapeutic plasma level. Drug release is dependent on polymer properties, thus the application of these properties can produce well characterized and reproducible dosage forms (Thakur and Thakur, 2015). Controlled release system can be influenced by physiological conditions such as motility, ions, pH and enzymes (Shargel and Yu, 1993). It is the type of tablet that is designed to it releases its contents in first order kinetics or zero order kinetics due to special arrangement and combination of hydrophobic and hydrophilic polymers as an excipient to form a matrix (Gibson, 2009). The primary mechanism of drug release from hydrophilic matrices occurs when the polymer swells on contact with the aqueous medium to form a gel layer on the surface of the system. The drug then releases by dissolution, diffusion, and/or erosion (Thakur and Thakur, 2015).

In the present study, we sought to prepare sustained release matrix tablets of metoprolol tartrate, a β-adrenoceptor blocking agent. Metoprolol tartrate was chosen as a model drug due to its low oral bioavailability, short half-life, water solubility and multiple daily dosing, which makes it an appropriate candidate for a formulation in a sustained release, twice-a-day dosage form. The sustained release dosage form is prepared by using different concentrations of guar gum, Kondagogu gum and xanthan gum in combination with HPMC K100M by using direct compression method and the evaluation was done for prepared tablets.

Materials and Methodology

Drugs and Chemicals

Metoprolol tartrate was gift sample from Merlin Pharma, Guar gum from Lucid Colloids, Mumbai, India. Xanthan gum from Lucid Colloids, Mumbai, India. Kondagogu gum from Nice Chemicals, HPMC from Finar Chemicals Pvt Ltd., Ahmedabad. MCC from Nice Chemicals, Magenesium stearate from Finar Chemicals Pvt Ltd., Ahmedabad. Aerosil from Nice Chemicals, Lactose monohydrate from Lucid Colloids, Mumbai, India. Potassium dihydrogen ortho phosphate from Finar Chemicals Pvt Ltd. Ahmedabad. Sodium hydroxide from Finar Chemicals Pvt Ltd., Ahmedabad, India.

Methodology

Preparation of Metoprolol tartrate matrix tablets

Metaprolol tartrate matrix tablets prepared by direct compression method: Accurately weighed amount of drug, polymer, and diluents were mixed geometrically in a mortar. This mixture was passed through 40 number sieve and thoroughly mixed in a polythene bag for 15 minutes. The powder blend was then lubricated with magnesium stearate and Aerosil for 2 minutes and compressed into tablets on a 16-station rotary tableting machine using 10 mm round, flat-faced punches.

WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES

SJIF Impact Factor 7.632

Volume 10, Issue 3, XXX-XXX Review Article ISSN 2278 – 4357

FORMULATION AND EVALUATION OF CLOTRIMAZOLE LOZENGES

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Article Received on
12 Jan. 2021,

Revised on 02 Feb. 2021,
Accepted on 22 Feb. 2021

DOI: 10.20959/wjpps20213-18567

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ABSTRACT

Clotrimazole is formulated as lozenges to provide slow release medicament for the management of oral thrush. Clotrimazole is an azole antifungal that works by preventing the growth of fungus. Many dosage forms like syrups, tablets available in market but still there is a need for new dosage form which acts effectively and locally for paediatrics and people with difficulty in swallowing. So the present investigation has been taken up design prepare and evaluate hard candy lozenges to meet the need of improved bioavailability. The benefits of these prepared lozenges showed increase in bioavailability, reduction in gastric irritation, bypassing of first metabolism and increase in onset of action. The lozenges are prepared using sucrose as base; liquid glucose is used for transparency and smoothness; Hydroxy propyl methyl cellulose K15M (HPMC $K_{15}M$) are used as polymers. Sodium saccharine are used as artificial sweeteners. Sweeteners along with flavours are used to mask the bitter taste of drug. All the formulations prepared are subjected to various physicochemical parameters like weight variation, hardness, thickness, friability, content uniformity, and moisture content etc. the prepared formulations have a hardness of 8-11 kg/cm2, non-gritty and pleasant mouth feel. Some selected formulations are also tested for drug excipient interactions subjecting to Infrared Spectral analysis, *in vitro* release rate studies showed that the drug release for lozenges was maximum in formulation F6 (99.52±1.23%) after 25 minutes. The moulded lozenges can provide an attractive alternative formulation in allergic condition.

KEYWORDS: Clotrimazole, antifungal, lozenges, saccharine, $K_{15}M$, liquid glucose.

ISSN 0974-3618 (Print)
0974-360X (Online)

www.rjptonline.org

RJPT

RESEARCH ARTICLE

Formulation and Evaluation of Theophylline Lozenges

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ABSTRACT:
Theophylline hard candies lozenges were prepared to provide slow release of medicament for the treatment of wheezing, shortness of breath, and breathing problems caused by asthma. It makes breathing easier by relaxing and opening air passage in the lungs. There are several dose forms like syrups, tablets, ODT`s offered within the market however still there's would like for brand new dose forms that acts effectively and domestically for paediatric and people with difficulty in swallowing. The local acting mechanism of theophylline makes it more suitable to formulate as lozenges. The hard candy lozenges were formulated using sugar as a base Locust Bean gum, Kondagogu gum and Neem gum are used as natural polymers. The usage of corn syrup in the formulation made the lozenges smooth which helped in improving the elegance of the formulation. Stevia was used as sweetener. Sweeteners along with flavours are used to mask bitter taste of drug. The formulation of hard Candy lozenges was subjected to physico-chemical as well as in vitro drug release. Among all the formulations of hard candy lozenges F10 had shown in vitro drug release of 98.9% at the end of 30 minutes.

KEYWORDS: Theophylline, Stevia, Kondagogu gum, Locust Bean gum, Neem gum.

INTRODUCTION:
Lozenges are solid preparations that contain one or more medicaments, usually in a flavoured, sweetened base, and are intended to dissolve slowly in the mouth.

Theophylline is used to treat wheezing, shortness of breath, and breathing problems caused by asthma, and other lung diseases. It is an anti-asthmatic and bronchodilator agent. It is readily absorbed through oral mucosa as oral bioavailability of Theophylline is more. Also, Theophylline is a heat stable drug which is ideal property for preparing lozenges.[1,7]

MATERIALS:
Sugar, Liquid glucose, Theophylline (drug), Stevia, Neem gum, Locust Bean gum, Kondagogu gum, Citric acid, Colouring and Flavouring agents.

METHODOLOGY:
Preformulations Studies:
Preformulation studies area unit primarily done to research the chemistry properties of drug and to determine its compatibility with different excipients.

Received on 15.12.2019 Modified on 10.04.2020
Accepted on 22.06.2020
Research J. Pharm. and Tech 2021; 14(3):1601-1606.
DOI: 10.5958/0974-360X.2021.00284.5

Drug-Excipient Compatibility study:
Theophylline (DRUG) was mixed with all excipients, used in the formulation in different ratios and subjected to FTIR.

FT-IR:
A Fourier Transform - Infra Red Spectrophotometer (FTIR Spectrum BX series 2.19 version) equipped with spectrum v2.19 software was used to study the non-thermal analysis of drug-excipient (binary mixture of drug: excipient 1:1 ratio) compatibility. The spectrum for each sample was recorded over the 450-4000 cm^{-1} spectral region with a resolution of 4 cm^{-1}.[3-6]

Determination of λ-max using UV Visible Spectrophotometer:
Determination of λ-max using UV Visible Spectrophotometer: Standard stock solution of Theophylline (1mg/mL) was prepared in methanol. For the selection of analytical wavelength solutions of drug Theophylline 100µg/ml was prepared by appropriate dilution of standard stock solution with distilled water and scanned in the spectrum mode from 200-300nm. The wavelength with maximum absorption was chosen for further analysis.

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INTERNATIONAL RESEARCH JOURNAL OF PHARMACY

www.irjponline.com
ISSN 2230 – 8407

Research Article

NEW RP-HPLC METHOD FOR THE SIMULTANEOUS ESTIMATION OF PARACETAMOL AND TRAMADOL HYDROCHLORIDE IN BULK AND TABLET DOSAGE FORM

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Article Received on: 16/03/18 Approved for publication: 29/05/18

DOI: 10.7897/2230-8407.09694

ABSTRACT

The present work was focused on developing a new RP-HPLC method for the simultaneous estimation of paracetamol and tramadol hydrochloride in bulk and tablet dosage form and to validate it as per ICH and USP guidelines. The method involves use of water and acetonitrile in 9:1 ratio as mobile phase pumped at a rate of 1ml/min. The optimum wavelength selected for monitoring was 268nm. C_{18} column (4.6mm ×250mm) of 5µ particle size was used as stationary phase. The method was finally validated, and parameters were reported. The system suitability parameters passed in which the asymmetric factors for Paracetamol and Tramadol were 1.54 and 1.09 respectively. Linearity ranges were found to be 20 to 100µg/ml with a correlation coefficient of 0.998. Accuracy studies reported a mean recovery of 98.7% for both the drugs. Faster retention times (1.1min and 4.1min) make the method simple and economic. Thus a validated and sensitive RP-HPLC method was developed for simultaneous estimation of Paracetamol and tramadol in bulk and tablet dosage form.

KEY WORDS: HPLC, Method, Paracetamol, Tramadol hydrochloride, Validation.

INTRODUCTION

Pain is an unpleasant sensation which can lead to distress and discomfort[1]. Pain can be acute or chronic. Drugs used to treat pain are called pain killers or analgesics. Paracetamol and Tramadol are commonly used analgesics. Paracetamol (Figure 1) is

chemically N-(4-Hydroxyphenyl)ethanamide or N-(4-Hydroxyphenyl)acetamide. It is a cyclooxygenase-2 (Cox-2) inhibitor and it is used to treat fever and pain. Tramadol (Figure

2) is chemically trans-2-(Dimethylaminomethyl)-1-(m-methoxyphenyl)cyclohexanol. It is an Opioid receptor agonist, 5-HT inhibitor and it is used to treat mild to severe pain, depression. Both paracetamol and tramadol are practically freely soluble in water and methanol[2,3].

Literature survey reveals that much work is documented on the chromatographic (HPLC & HPTLC) estimation of these two drugs in combined pharmaceutical dosage forms[4-17]. However, they are tedious, time consuming and costly. Hence there is a need for the development of a relatively simple, precise, accurate, reproducible and cost effective HPLC method for the estimation of paracetamol and tramadol in tablets and to validate the developed method as per ICH and USP guidelines.

MATERIALS AND METHODS

Instrumentation

The analysis was carried out on a HPLC system (SPINCO BIOTECH) equipped with UV detector. Other apparatus and instruments used were electronic balance (Keroy). Digital pH meter (Systronics). Magnetic stirrer (Remi). Millipore (Direct Q UV3). Ultra sonicator (Pci). Micro pipette (Physio care).

INTERNATIONAL RESEARCH JOURNAL OF PHARMACY

www.irjponline.com
ISSN 2230 – 8407

Research Article

NEW RP-HPLC METHOD FOR THE SIMULTANEOUS ESTIMATION OF PARACETAMOL AND TRAMADOL HYDROCHLORIDE IN BULK AND TABLET DOSAGE FORM

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ABSTRACT

The present work was focused on developing a new RP-HPLC method for the simultaneous estimation of paracetamol and tramadol hydrochloride in bulk and tablet dosage form and to validate it as per ICH and USP guidelines. The method involves use of water and acetonitrile in 9:1 ratio as mobile phase pumped at a rate of 1ml/min. The optimum wavelength selected for monitoring was 268nm. C_{18} column (4.6mm ×250mm) of 5µ particle size was used as stationary phase. The method was finally validated, and parameters were reported. The system suitability parameters passed in which the asymmetric factors for Paracetamol and Tramadol were 1.54 and 1.09 respectively. Linearity ranges were found to be 20 to 100µg/ml with a correlation coefficient of 0.998. Accuracy studies reported a mean recovery of 98.7% for both the drugs. Faster retention times (1.1min and 4.1min) make the method simple and economic. Thus a validated and sensitive RP-HPLC method was developed for simultaneous estimation of Paracetamol and tramadol in bulk and tablet dosage form.

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INTRODUCTION

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Current Research in
Diabetes & Obesity Journal
ISSN: 2476-1435

Juniper Publishers
Key to the Researchers

Research Article
Volume 5 Issue 2 - August 2018
DOI: 10.19080/CRDOJ.2018.05.555755

Comparison of Teneligliptin and Atorvastatin on Lipid Profile in Patients with Type 2 Diabetes Mellitus

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Submission: March 27, 2018; **Published:** August 08, 2018

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Abstract

Diabetes mellitus is a chronic metabolic disease characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both which results in long term damage, dysfunction and failure of various organs especially eyes, kidneys, nerves, heart and blood vessels. The efficacy of Teneligliptin and Atorvastatin on lipid profiles in patients with type 2 Diabetes mellitus were compared. The study was designed to evaluate the efficacy of these two drug regimens.

Material and methods: Males and females of 25-90 years diagnosed with type 2 Diabetes mellitus are included in our study.

Results: 275 patients were recruited for our study. 47 were excluded because of their inability to attend or participate and did not meet inclusion criteria. 229 T2 DM patients who were taking Teneligliptin 20mg once daily or Atorvastatin 20mg once daily completed the study. There were significant decrease in the levels of TC, HDL, LDL, TG, VLDL in Teneligliptin and Atorvastatin are 35.1, 4.1, 14.0, 37, 7.5(mg/dl) and 35.1, 4, 14.6, 37.1, 7.6(mg/dl) respectively.

Conclusion: From this study we conclude that Teneligliptin 20mg and Atorvastatin 20mg have proved to have similar efficacy on the lipid profiles. Hence we conclude that Teneligliptin is an efficacious drug for T2 DM patients in management of glycemic control and lowering lipid profiles.

Background and Aim

Diabetes mellitus is a group of metabolic diseases which challenges the global population. Thus, there is an increasing need to conduct researchs in this field [1,2]. The aim of the study is to compare the efficacy of Teneligliptin and Atorvastatin on lipid profile of patients with T2 DM. Comparative evidence is required to guide appropriate therapy to attain lipid control and prevent complications of diabetes [3,4].

Material and Methods

It is a prospective, observational, comparative study conducted in patients from "Sri Bhadrakali Diabetic Clinic" located at Gatemaguri, Hanamkonda. Patients were explained about the study & informed consent forms were sought by explaining them in their local language [5,6]. Institutional Human Ethical Committee Endorsement was obtained after submission of protocol and IHEC No. is MGM/VCOP/PHARMD/V/017/2017.

Inclusion criteria

Males and females of 25-90 years diagnosed with type 2 Diabetes mellitus will be included in our study.

Exclusion criteria

Pregnant and lactating females, patients on insulin therapy, history of type1 Diabetes mellitus, signs of diabetic complications (neuropathy, nephropathy and retinopathy) are to be excluded [7]. Patients with clinical signs and symptoms of acute myocardial infarction, liver failure, chronic heart failure, and hypertension are to be excluded.

Study design

It is a prospective, observational, comparative study design, and the patients who were taking Teneligliptin 20mg and Atorvastatin 20mg were included [8].

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World Journal of Medical Sciences 14 (3): 57-61, 2017
ISSN 1817-3055

DOI: 10.5829/idosi.wjms.2017.57.61

Comparison of Efficacy of Telmisartan and Enalapril in Patients with Diabetic Nephropathy

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Abstract: Diabetic nephropathy is the leading cause of end – stage renal disease. It is characterised by Hypertension and persistent proteinuria. If ineffectively controlled, a progressive decline in renal function can result in end – stage renal disease. The main objective of this study was to evaluate the efficacy of Telmisartan vs Enalapril on Diabetic Nephropathy in patients with type 2 diabetes. Patients included in this study were patients who had type 2 diabetes treated by diet and/or oral hypoglycaemics; Patients treated with insulin, if they were diagnosed as being diabetic at the age of > 40 years, had been in receipt of oral hypoglycaemics for > 1 year before being treated with insulin and had a body mass index of >25kg/m^2; patients who have mild to moderate hypertension (resting systolic / diastolic blood pressures < 180/95 mmHg) while receiving an ACE Inhibitor for > 3 months before entering the study. From 344 subjects with diabetic nephropathy included in the study, 328 patients were included in the final analysis. 16 patients were dropped from the study (15, 01 patients from Telmisartan and Enalapril groups respectively). At the end of the study the reduction in urine albumin was more with Enalapril (Mean difference 43.75 ± 4.003) when compared with Telmisartan (Mean difference 36.49 ± 3.23). The p values were < 0.05 for both groups and it was found that reduction of diabetic nephropathy in Enalapril treatment group at the end of the study is statistically differs than the Telmisartan treatment group. We concluded that Enalapril confers strong renal protection in patients with type 2diabetes and nephropathy. Telmisartan is not inferior to Enalapril in providing Reno protection in subjects with Type 2 Diabetes and early nephropathy. This result is consistent with emerging data that support the clinical equivalence of angiotensin II- receptor blockers and ACE inhibitors in various conditions associated with high cardiovascular risk.

Key words: Diabetic Nephropathy · End – Stage Renal Disease · Renin – Angiotensin Aldosterone System · Telmisartan · Enalapril

INTRODUCTION

Diabetes Mellitus (DM) is the most frequent cause of chronic kidney failure in both developed and developing countries [1]. Diabetic nephropathy, also known as kimmelstiel – Wilson syndrome or nodular diabetic glomerulosclerosis / intercapillary glomerulonephritis, is a clinical syndrome characterized by albuminuria (>300 mg/day or >200 mcg/min) confirmed on at least two occasions 3-6 months apart, permanent and irreversible decrease in glomerular filtration rate (GFR) and arterial hypertension [2]. The syndrome was first described by a British physician Clifford Wilson (1996-1997) and American physician Paul Kimmelsteil (1900-1970) in 1936 [3].

Diabetic nephropathy is a chronic condition developing over many years characterized by Gradual increasing urinary albumin excretion (UAE), High blood pressure, Declining GFR, Absence of other renal / renal tract disease, Presence of diabetic retinopathy.

The aim of this study was to analyse the effect of two widely used drugs Telmisartan and Enalapril on urinary albumin.

MATERIALS AND METHODS

This was a prospective observational study carried out in Sri Bhadrakali Diabetic Clinic, Kishanpura, Hanamkonda, Telangaana, India. Institutional Human Ethics committee endorsement was seek and obtained

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Original Article

International Journal of
Dermatology and Venereology

OPEN

Evaluation of Depression and Quality of Life in Patients With Psoriasis

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Abstract

Objective: To measure the prevalence of depression in patients with psoriasis and to evaluate the relationship between the severity of psoriasis and depression and its effect on patients' quality of life.

Methods: A total of 154 patients with a confirmed diagnosis of psoriasis were assessed to determine the severity of psoriasis based on the psoriasis area and severity index score, presence, and severity of depression using the patient health questionnaire 9, and quality of life using the dermatology life quality index 10. Pearson correlation coefficient was used to demonstrate the relationship between continuous variables with 95% confidence intervals (CIs); $P < 0.00001$ was taken to indicate statistical significance.

Results: The severity of psoriasis was mild in 36.36% of patients, moderate in 25.97%, severe in 32.47%, and very severe in 5.20%. Of the 154 patients, 139 (90.3%) had depression; the severity of depression was mild in most affected patients (46.7%) and severe in 2.6% of patients. Psoriasis had a moderate effect on the quality of life in 37.01% of patients and a very large effect in 33.77% of patients. The severity of psoriasis was positively correlated with depression (Pearson correlation coefficient, $r = 0.42$, $P < 0.00001$, 95% CI: 0.28–0.54) and quality of life ($r = 0.43$, $P < 0.00001$, 95% CI: 0.29–0.55).

Conclusion: Depression is a common comorbidity in patients with psoriasis. The severity of psoriasis is positively correlated with the severity of depression and is associated with poor quality of life.

Keywords: depression, dermatology life quality index 10, patient health questionnaire 9, psoriasis, psoriasis area and severity index score

Introduction

Psoriasis is a chronic inflammatory dermatological condition characterized by skin lesions covered with white or silver scales,[1-2] with a strong genetic susceptibility, and complex autoimmune pathogenesis.[3] Based on the lesion characteristics, psoriasis is mainly classified into two types; non-pustular psoriasis includes psoriasis vulgaris, guttate psoriasis, erythrodermic psoriasis, inverse psoriasis, and psoriatic arthritis, while pustular psoriasis includes Von Zumbusch psoriasis, impetigo herpetiformis, and acrodermatitis continua of Hallopeau.[4-6] As psoriasis is a disorder with visible skin changes, it results in physical, emotional, and social burdens on the patient.[7] Patients with psoriasis often experience a significant decrease in their emotional wellbeing and social functioning, adversely affecting their quality of life.[8-9] As a result, patients with psoriasis have a high prevalence of psychiatric morbidities, including sleep disorders, anxiety, and most commonly depression.[10] A depressed state of mind has a negative impact on a patient's health by decreasing the adherence to self-care and medication, which consequently leads to a poor disease prognosis.[11-12] In addition, the onset and course of depression in patients with psoriasis shows a strong association with systemic inflammation,[13-14] as there is a negative bidirectional relationship between depression and inflammation in patients with psoriasis.[15-16] The ongoing inflammation causes physiologic and biochemical changes that drive an increase in the levels of inflammatory

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Author contributions: SS, SD, SBBS, and MSK performed the study conception and design; SS, and SD collected data; VE, SBBS and SS performed data analysis and interpretation; SS drafted the manuscript; VE, and SBBS made the critical revision; SS, SD, SBBS, VE, and MSK approved the final version of manuscript to submit.

Conflicts of interest: The authors reported no conflicts of interest.

International Journal of Dermatology and Venereology (2022) 5:1

Received: 10 February 2021, Revised: 2 June 2021, Accepted: 6 July 2021

doi: 10.1097/JDV.0000000000000150

Research Article

Access this article online

Quick Response Code:

Website: www.ijp-online.com

DOI: 10.4103/ijp.IJP_114_20

Therapeutic drug monitoring of olanzapine: Easy and reliable method for clinical correlation

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Abstract:

AIM: The current work establishes an easy, reliable technique for the estimation of serum Olanzapine concentration which correlates it clinically.

SUBJECTS AND METHODS: The work was agreed in 61 schizophrenic patients who were on olanzapine. Serum drug amount was estimated by normal-phase high-performance liquid chromatography and brief psychiatry rating scale was used to determine disease progression.

RESULTS: Samples provided 61 patients, 40 were under sub-therapeutic range, 18 were under therapeutic range and 3 were above the therapeutic range.

CONCLUSION: Therapeutic drug monitoring must be a part of clinical practice in psychiatric hospitals for optimizing the dose of an individual patient along with the correlation of serum concentration with the clinical assessment scales.

Keywords:

High-performance liquid chromatography and therapeutic range, olanzapine, schizophrenia, therapeutic drug monitoring

Introduction

Olanzapine is benzodiazepine derivative which is used in the management of schizophrenia and also to treat modest to severe mania allied with manic depressive psychosis. Olanzapine was widely biotransformed in the hepatocyte, mainly through direct glucuronidation and CYP1A2 mediated oxidation followed by a lesser extent with CYP2D6. Olanzapine (5–20 mg) is recommended daily dose for schizophrenic patients.[1]

Therapeutic drug monitoring (TDM) of narcoleptics choose to optimize dosage decisions to maximize effectiveness and stop unwanted effects, particularly while those are nonresponsive to management or exposed to undesirable effects through usual quantity for the reason that of demographic, illness, or treatment reciprocal action make difficult in treatment. TDM-assisted psychiatric treatment, while practice by physicians who have background of pharmacokinetics, is potentially useful and cost-effective. TDM is useful in determining drug noncompliance which is a major issue in psychiatric treatment. In many psychiatric hospitals, disease progression is assessed by using different psychiatric rating scales. This is widely used for initially diagnosed and relapse patients.[2]

Due to these reasons, there is a need to develop an easy and reliable method for determining serum Olanzapine concentration which

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Submitted: 23-Aug-2023
Revised: 01-Dec-2023
Accepted: 14-Mar-2024
Published: ...

How to cite this article: Junutula SP, Dubasi SK, Padide SG, Miryala GK, Koppolu MS, Sheshagiri SB, et al. Therapeutic drug monitoring of olanzapine: Easy and reliable method for clinical correlation. Ind Jn J pharmacol 2021;53:XX-XX.

Original Article

Drug Utilization Evaluation of Pantoprazole in Inpatients of Tertiary care Hospital

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ABSTRACT

Objectives: To review Pantoprazole drug use, prescribing patterns and promote appropriate pantoprazole use. **Methods:** The study is prospective and observational conducted in inpatients of a tertiary care teaching hospital (MGM hospital). A total of 1012 cases were enrolled according to our plan of work i.e., inpatients who were under pantoprazole therapy were enrolled in two phases, phase-I (before intervention) and phase-II(after intervention) as we assessed inappropriate use of drug, intervention was developed and implemented and therefore pertinent use of drug is increased. **Results:** Inappropriate use of drug was found in phase-I and appropriateness in terms of rational use for indication, dose, dosing interval was improved in phase-II, this may be due to implementation of intervention. **Conclusion:** Rational use of pantoprazole in accordance with appropriate drug for indication, appropriate dose, dosing interval, duration of therapy for specific indication and particular individual was found to be low in phase-I and rational use was improved after intervention in phase-II by implementing criteria and standards rational drug therapy can be achieved. Rational use of pantoprazole should be increased.

Key words: Drug Utilization Evaluation, Pantoprazole, Proton pump inhibitors, Intervention, Indication, Rational use, Criteria and Standards.

INTRODUCTION

Drug utilization evaluation (DUE) is a system of ongoing, systematic, criteria-based evaluation of drug use that will help ensure that medicines are used appropriately (at the individual patient level). It involves a comprehensive review of a patient's medication and health history before, during and after dispensing in order to attempt to achieve appropriate therapeutic decision-making and positive patient outcomes. Pharmacists participating in DUE programs can directly improve the quality of care for patients, individually and as populations, by striving to prevent the use of unnecessary or inappropriate drug therapy, prevent adverse drug reactions and improve overall drug effectiveness.[1,2] It is an ongoing empowered and organized quality improvement process, designed to

1. To amend drug use by developing criteria and standards.

2. To audit drug use.

3. To interpret prescription pattern.

Steps involved in Drug Utilization Evaluation is depicted in Figure 1

DUE cycle

Pantoprazole is a first-generation proto pump inhibitor that constrain the activity of proton pump and are used to constrain gastric acid secretions in the treatment of ulcers and gastro esophageal reflux, preventing ulcer complications related to use of NSAIDs and corticosteroids, managing gastro esophageal reflux diseases and ulcer bleeding, prophylaxis of stress ulcer and preventing gastrointestinal risks in patients receiving anticoagulants.[3] Some other conditions where this drug is used include Helicobacter Pyloric eradication, Pyrosis [Heartburn], dyspepsia [OTC], Zollinger-Ellision syndrome.[4] The maximum recommended treatment duration for many

DOI: 10.5530/ijopp.14.1.x

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Case Report

Cefotaxime Induced Staphylococcal Scalded Skin Syndrome: A Case Report

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ABSTRACT

Staphylococcal scalded skin syndrome (SSSS) is as well called as Ritter von Ritterschein disease, Lyell disease, Ritter disease and staphylococcal necrolysis of the epidermis. More common in neonates and children of age less than five years and are at a greater risk of SSSS. To fight against SSSS, children should attain lifetime immunity in the form of antibodies against exotoxins of staphylococcal strains. Symptoms include fever and redness on the overall surface of skin. Within 24-48h, fluid-filled blisters appear on the body. We report a case of 2 years old male child developed SSSS after intravenous administration of Cefotaxime.

Key words: Staphylococcal scalded skin syndrome, Immunity, Exotoxins, Cefotaxime, Exfoliative, Cephalosporins.

INTRODUCTION

Staphylococcal scalded skin syndrome is one of the major exfoliating skin infections. Mainly caused by Staphylococcus and the skin looks as if it has been burnt by a hot liquid.[1] Due to the lack of immunity and underdeveloped renal clearance, there is a greater chance of SSSS in children.[2]

Two exfoliating toxins A and B which are released from *Staphylococcus aureus*, but the mechanism for exfoliation is unclear until today. Beneath the granular cell layer, separation of the epidermis and red rash occurs when these toxins act at a remote layer.[3] Two types of SSSS exist localized form superficial involvement of skin and a generalized form involvement of significant areas. Localized infection of *Staphylococcus aureus* in the skin, nose, mouth, throat, umbilicus and gastro intestinal tract (GIT). General malaise, irritability, fever, skin tenderness may be prominent. Other signs include facial edema, conjunctivitis and perioral crusting.[4]

Cephalosporin's are used as a prophylactic treatment in many patients because of their β- lactamase stability, lack of toxicity and broad-spectrum.[5] Cefotaxime is a third-generation cephalosporin antibiotic.[6] Here we discuss a case of SSSS due to Intravenous Cefotaxime administration.

CASE REPORT

A two years old male child who was hospitalized in the Pediatric Department for fever since 3 days, facial puffiness, 2 episodes of vomiting containing food for 1 day, Swelling of legs and feet for 2 days. Then the patient was given Cefotaxime 280mg IV, Paracetamol 5ml syrup, Cetirizine 5ml syrup.

After two days, the patient developed pedal edema and rashes on legs. The physician stopped the medication and the patient was referred to dermatology. On general examination child was conscious, febrile. His pulse rate was 146/min and blood pressure was 90/50mmHg. Physical examination revealed multiple fluid -filled vesicles and bullae noted on the lower limbs and hyperpigmented lesions noted on the

DOI: 10.5530/ijopp.12.1.x

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Original Article

Assessment of psychiatric variables in geriatric patients diagnosed with different types of osteoarthritis: Radiographic-based evidences

Shravani Komuravelly[1], Surishika Reddy Chevireddy[1], Ramkumar Reddy Katam[2], Sharavanabhava Bandaru[3], Vasudevamurthy Sindgi[4], Venkateshwarlu Eggadi[5]

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Abstract

Context: Osteoarthritis (OA) is the most prevalent musculoskeletal condition in the world and is the most common cause of joint disability in approximately 15% of the total world population. The severity of the disease increases with age. It can have adverse effects on mental stability and is associated with poor clinical prognosis.

Aim: The aim of the study is to assess psychiatric variables (depression, anxiety, and perceived stress) in geriatric patients diagnosed with OA based on radiographic evidence and the item(s)/question(s) from questionnaires influencing their emotional instability.

Settings and Design: The prospective observational study was conducted in a tertiary care Mahatma Gandhi Memorial Hospital, Warangal.

Subjects and Methods: The study conducted for a period of 6 months and encompasses 158 elders with different types of OA. Standardized questionnaires were used to assess psychiatric variables.

Statistical Analysis Used: Statistical analysis was conducted using Microsoft Excel 2019 and IBM SPSS Statistics for Windows, Version 22.0. (IBM Corp, Armonk, NY, USA).

Results: The results of Pillai's trace revealed the scores of depression and anxiety as severe and perceived stress as moderate. Linear logistic regression stepwise disclosed the order of included variables affecting depression, anxiety, and perceived stress based on their level of significance ($P < 0.05$).

Conclusion: The findings in our study exemplify a strong correlation between psychiatric variables and OA.

Keywords: Anxiety, depression, geriatric patients, osteoarthritis, perceived stress

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Submitted: 31-Jul-2020, **Revised:** 13-Aug-2020, **Accepted:** 30-Oct-2020, **Published:** 14-Jan-2021

Access this article online	
Quick Response Code:	Website: www.amhonline.org
	DOI: 10.4103/AMH.AMH_35_20

How to cite this article: Komuravelly S, Chevireddy SR, Katam RR, Bandaru S, Sindgi V, Eggadi V. Assessment of psychiatric variables in geriatric patients diagnosed with different types of osteoarthritis: Radiographic-based evidences. Arch Ment Health 2020;21:95-100.

ORIGINAL ARTICLE

INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACEUTICAL SCIENCES

Published by JK Welfare & Pharmascope Foundation Journal Home Page: www.pharmascope.org/ijrps

Hypofractionated Versus Conventional Radiotherapy with Chemotherapy in Head and Neck Cancer: A Comparative Study

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Article History:

Received on: 01 Oct 2020
Revised on: 04 Nov 2020
Accepted on: 09 Nov 2020

Keywords:

Chemotherapy, Conventional Radiotherapy, Head Cancer, Hypofractionated Radiotherapy, Neck Cancer

ABSTRACT

Head and neck cancers are a group of malignancies that arise from common anatomic sites which include the oral cavity, oropharynx, nasopharynx, hypopharynx, larynx, sinonasal cavities and from the salivary glands. Head and neck squamous cell carcinoma (HNSCC) is the sixth most common cancer in the world and has a five-year survival rate of less than 50%. It has high recurrence rates and metastasis. It is a Prospective Observational, and Comparative Study carried out in 30 patients of Loco-regionally advanced carcinoma of head and neck. The diagnosis of loco-regionally advanced cancers of head and neck was made following AJCC staging. The subjects were divided into two groups with 15 in each arm -Accelerated Hypo Fractionated Arm and Conventional Normal Fractionated Arm. All the patients were systematically interviewed, and clinical details of all the subjects were recorded. Among the 30 patients, the highest performance status of (83.3%) ECOG-1 was observed in both the groups when compared to ECOG-2, which is not statistically significant. Hypofractionated radiotherapy can achieve similar tumour response to conventionally fractionated radiotherapy in HNSCC, although with some increase in toxicity. However, to draw some reasonable conclusion, a study with a broader sample and longer follow-up needs to be performed.

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ISSN: 0975-7538

DOI: https://doi.org/10.26452/ijrps.v11i4.4372

Production and Hosted by

Pharmascope.org

INTRODUCTION

Head and neck squamous cell carcinoma (HNSCC) is the sixth most common cancer in the world and has a five-year survival rate of less than 50% (Xiong *et al.*, 2019; Zhao *et al.*, 2019). HNSCC has high metastasis and recurrence rates and includes the following subgroups: oral squamous cell carcinoma (OSCC), nasopharyngeal carcinoma (NPC), and laryngeal squamous cell carcinoma (LSCC) (Zhao *et al.*, 2019; Huang *et al.*, 2019). HNSCC is associated with a variety of environmental factors as known risk factors, including smoking, alcohol abuse, and human papillomavirus (HPV) infection (Sailer *et al.*, 2019). The survival rate of patients with the disease has increased due to progress in surgical therapy, as well as radiotherapy and chemotherapy. Due to the lack of early clinical symptoms, many HNSCC patients are diagnosed with advanced cancer, the prognosis of HNSCC patients remains stagnant, with a considerable number of deaths due to recurrence and metastasis after chemotherapy and targets therapy (Lai *et al.*, 2019). Head and neck cancer is the sixth most common cancer and is responsible for almost 2,00,000 deaths around the world each year (Parkin *et al.*, 2002). The progression of HNSCC

Original Article

Safety and Efficacy of Streptokinase, Tenecteplase, and Reteplase in Patients Diagnosed with ST-Elevation Myocardial Infarction: A Comparative Study

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Abstract

Objective: Our primary objective was to compare the efficacy of streptokinase (SK), tenecteplase, and reteplase by studying patients' electrocardiogram Electrocardiogram(ECG) pre and post thrombolysis. The secondary objectives were to assess chest pain relief using Numerical Pain Rating Scale score and also to compare the side effects (bleeding, hypotension, and anaphylaxis) of three drugs. **Materials and Methods:** This study is a multicentric, prospective, randomized, comparative study. This study was conducted on 150 patients of ST-elevation myocardial infarction admitted in the wards/ICCU- Intensive Coronary Care Unit, Department of Cardiology, Mahatma Gandhi Memorial Hospital and Rohini Superspeciality Hospital. They were selectively divided into three groups. Group A consisted of patients who received SK (50), Group B who received tenecteplase (50), and Group C who received reteplase (50). The study period was 6 months. The follow-up was done in all the patients during their inhospital stay. **Results:** Post thrombolysis, reteplase, tenecteplase, and SK led to mean ST-Segment reduction of 64.9 ± 19.77, 52.43 ± 34.57, and 46.97 ± 33.09, respectively. The comparison between the three drugs revealed a significant difference ($P = 0.0103$). **Conclusion:** This study concluded that reteplase is most efficacious in the resolution of ST-elevation and also safer than other thrombolytics used.

Keywords: Reteplase, ST-elevation myocardial infarction, streptokinase, tenecteplase, thrombolytics

Introduction

ST-elevation myocardial infarction (STEMI) is one of the challenging problems among acute coronary syndromes.[1] STEMI is a clinical syndrome characterized by typical symptoms of myocardial ischemia associated with persistent electrocardiographic ST-elevation and subsequent release of myocardial necrotic biomarkers. The Universal Definition of Myocardial Infarction defined by the European Society of Cardiology/American College of Cardiology Foundation/American Heart Association (AHA)/World Heart Federation Task Force is defined as new ST-elevation at the point J in at least two contiguous leads of ≥1.5 mm (0.15 mV) in women or ≥2 mm (0.2 mV) in men in leads V2–V3 and/or of ≥1 mm (0.1 mV) in other contiguous chest leads or the limb leads, is characteristic of diagnostic ST-elevation in the absence of left ventricular (LV) hypertrophy or left bundle branch block (LBBB). Coronary artery disease (CAD) is the leading cause of mortality worldwide, and over 7.4 million people died due to CAD in 2015.[2] Nearly three million STEMI cases are estimated to occur in India per year. Cardiovascular diseases are with the highest mortality rate in India accounting for about 21% of the deaths in 2010, with 10% of overall deaths occurring due to CAD.[3]

The ACC/AHA 2013 guidelines for the management of STEMI suggest fibrinolytic therapy when there is an anticipated delay in performing primary PCI within 120 min of first medical contact and lists available fibrinolytic agents (tenecteplase [TNK-tPA], reteplase [rPA], alteplase, and streptokinase [SK]).[4]

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Access this article online

Quick Response Code:

Website: www.joicc.org

DOI: 10.4103/JICC.JICC_62_20

How to cite this article: Neela B, Gunreddy VR, Chandupatla MR, Eggadi V, Bandaru SS. Safety and efficacy of streptokinase, tenecteplase, and reteplase in patients diagnosed with ST-elevation myocardial infarction: A comparative study. J Indian coll cardiol 2020:XX:XX-XX.

Submitted: 16-Aug-2020 **Accepted:** 21-Sep-2020 **Published:** ***

Original Article

Evaluation of Corticosteroid Use Pattern and Their Adverse Effects in Patients Visiting the Dermatology Department of a Tertiary Care Teaching Hospital in Warangal, India

Gogula Archana Reddy, Samreen Ayesha, Masood Ali Sheema, Bandaru Sheshagiri Sharvana Bhava, Valupadas Chandrashekar[1], Eggadi Venkateshwarlu

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Abstract

Introduction: Corticosteroids have become a mainstay of pharmacotherapy in dermatology because of their anti-inflammatory and immunosuppressive properties. However, misuse and sudden cessation of these drugs may render a patient to develop numerous adverse effects (AEs). Adverse drug reactions (ADRs) are important causes of mortality in both hospitalized and ambulatory patients. Early detection, evaluation, and monitoring of ADRs are essential to reduce harm to patients. Therefore, to achieve optimum benefit with the least AEs, safe and effective use of these agents is very crucial.

Objective: To examine the corticosteroid use pattern, to assess the frequency of misuse and the associated AEs that are encountered in dermatological practice.

Materials and Methods: A prospective observational study was conducted in the dermatology department of a tertiary care teaching hospital, Warangal for a period of six months. All patients using at least one corticosteroid either topically or systemically were included in the study. Informed consent was taken from patients.

Results: A total of 151 participants were included in the study. Among them, 56% of females developed ADRs compared with males (44%). Among patients using topical corticosteroids (TCs), the most frequently reported ADRs include facial erythema (7.31%), acne (17.07%), and hyperpigmentation of the face (2.43%). The AEs associated with oral corticosteroids include weight gain (19.51%) and taenia corporis (19.5%).

Conclusion: Corticosteroids have extreme importance in dermatological practice. However, inappropriate and prolonged users render a patient to develop several AEs. Precise drug regimens and proper patient counseling can help in minimizing and managing the AEs associated with inappropriate use.

Keywords: Acne, corticosteroids, erythema, hyperpigmentation, taenia corporis

Key Message: To prevent or manage steroid-induced AEs.

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Received: 14-12-2020
Accepted: 03-02-2021
Published: 16-04-2021

Access this article online	
Quick Response Code:	Website: www.mgmjms.com
	DOI: 10.4103/mgmj.mgmj_91_20

How to cite this article: Reddy GA, Ayesha S, Sheema MA, Bhava BS, Chandrashekar V, Venkateshwarlu E. Evaluation of corticosteroid use pattern and their adverse effects in patients visiting the dermatology department of a tertiary care teaching hospital in Warangal, India. MGM J Med Sci 2021;8:60-5

OPEN

International Journal of Dermatology and Venereology

DOI: 10.1097/JD9.0000000000000180

Evaluation of Depression and Quality of Life In Patients With Psoriasis

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Abstract

Objective: To measure the prevalence of depression in patients with psoriasis and to evaluate the relationship between the severity of psoriasis and depression and its effect on patients' quality of life.

Methods: A total of 154 patients with a confirmed diagnosis of psoriasis were assessed to determine the severity of psoriasis based on the Psoriasis Area and Severity Index score, presence and severity of depression using the Patient Health Questionnaire 9, and quality of life using the Dermatology Life Quality Index 10. Pearson's correlation coefficient was used to demonstrate the relationship between continuous variables with 95% confidence intervals; P<0.00001 was taken to indicate statistical significance.

Results: The severity of psoriasis was mild in 36.36% of patients, moderate in 25.97%, severe in 32.47%, and very severe in 5.20%. Of the 154 patients, 139 (90.3%) had depression; the severity of depression was mild in most affected patients (46.7%) and severe in 2.6% of patients. Psoriasis had a moderate effect on the quality of life in 37.01% of patients and a very large effect in 33.77% of patients. The severity of psoriasis was positively correlated with depression (Pearson's correlation coefficient, r=0.42, P<0.00001, 95%CI: 0.28–0.54) and quality of life (r=0.43, P<0.00001, 95%CI: 0.29–0.55).

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Research Article

Evaluating the Outcomes of Surgical Versus Conservative Treatments in Head Injury: A Comparative Observational Study Using Different Scales

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ABSTRACT

Background: This study is to evaluate the outcomes of surgical versus conservative treatment in head injury by using different scales to rate the quality of life in both the treatments. **Aim:** To evaluate the outcomes of surgical versus conservative treatment in Head injury. **Methods:** A prospective, comparative observational study was conducted in Neurosurgery department in a tertiary care teaching hospital for a period of 6 months. All the patients with head injury were included in the study and reviewed.Among the subjects two groups are made in which one group includes the subjects who are treated with conservative treatment and the other group who have undergone surgical treatment among these two groups GCS scale, four score scale and dementia rating scale are assessed and both the treatments are compared. **Results:** Patients with head injury between age groups of 20 to 70 years were recruited for this study. The patients recovery analysis according to GCS for conservative (93.06%) and surgical (50.40%), FSS for conservative (90%) and surgical (56.75%), DRS for conservative (100%) and surgical (50.04%). **Conclusion:** Based on the severity it is decided whether conservative or surgical treatment is given to the patient, but primary choice of treatment should be conservative treatment for patients with less severity as patients under conservative treatment had better recovery and memory compared to that of patients under surgical treatment.

Key words: Head injury, Glasgow scale, FOUR score scale, Dementia rating scale, Surgical, conservative.

INTRODUCTION

Head injury is a trauma to the scalp, skull or brain. It may be only a major or minor bump on the skull.[1] Head injury may lead to bleeding in the brain tissues and in certain layers that surrounds the brain (subarachnoid haemorrhage, subdural haemorrhage and extradural haemorrhage). Head injury is one of the most common reasons for an emergency visit to the hospital. Traumatic brain injury (TBI) accounts for over 1 in 6 injury-related admissions each year.[2] Traumatic brain injury is a leading cause of morbidity, mortality, disability, in India and other developing countries. Road traffic injuries are leading cause (60%) of traumatic brain injury followed by falls (20-25%), violence and alcohol involvement (15- 20%) in India.[3,4] The occurrence of total traumatic brain injury has reminded similar throughout history in spite of modern Kevlar helmets.[5] Head injuries are commonly caused by a blow to the head that are usually associated with vehicle accidents, falls and sports related accidents. The treatment of the condition depends on the seriousness of the injury. Mild traumatic brain injures requires over-the-counter pain relievers to treat headache and usually needs to be monitored closely at home for any persistent, exacerbating or new symptoms. Moderate to severe brain injuries concentrate on enough oxygen,

DOI: 10.5530/ijopp.12.2.21

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www.ijopp.org

Research article

Rapports De Pharmacie Vol.6 (2), 2020, 637-643
ISSN: 2455-0507

EVALUATION OF INSOMNIA AND PSYCHIATRIC INFIRMITIES WITH ANTICANCER TREATMENT IN PATIENTS DIAGNOSED AT DIFFERENT STAGES OF CANCERS

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ABSTRACT

Background: Cancer is the second most leading cause of death all over the world. Cancer leads to grief and pain. The objective of the present investigation was to evaluate Insomnia and Psychiatric infirmities with anticancer treatments in cancer patients. **Methods:** The data was gathered by administration of the evaluated questionnaires [DASS-21]21 characteristics of Depression Anxiety Stress, [ISI] Insomnia Severity Index and [PHQ-15] Physical Symptoms Questionnaire. **Results:** 150 patients satisfying inclusion and exclusion criteria were included in the study. The most common age group (49-58) years with female preponderance (77%).There is a significant correlation found between Insomnia and Psychiatric infirmities ($p<0.001$).Depression and Anxiety ($r=0.94$),Depression and Stress ($r=0.18$) and Anxiety and Stress ($r=0.04$). **Conclusion:** This study reveals that female cancer patients are more prone to cancer than male cancer patients and there is a significant relationship found between Insomnia, Physical symptoms and Psychiatric infirmities.

Keywords: Cancer, Insomnia, Depression, Anxiety, Stress, DASS-21, ISI, PHQ15.

INTRODUCTION

Cancer is the second most leading cause of death all over the world [1]. Incidence and mortality of cancer are rapidly growing worldwide [2]. Non – Hispanic blacks are at highest incidence and mortality rate for cancer than in Asian or pacific islanders [1]. Lung, prostate, colorectal, stomach and liver cancer are the most common types of cancer in men, while breast, colorectal, lung, cervical and thyroid cancer are the most common among women (WHO). Men are at 20% higher incidence than women for all cancers. Almost 90% of cancer related deaths are due to secondary tumor metastasis [3].Emotional disturbances are the frequent outcomes of such painful illness like cancer. In order to cure the condition systematically, it is necessary to acquire Perception into the prevalence, severity, direction of the psychological abnormality and the factors affecting them [4]. Among all cancer patients, insomnia is a common heterogeneous complaint [5]. Inspite of suggesting that sleep difficulties are one of the frequent consequences of cancer, Insomnia has received very little attention. Cancer stage, time elapsed since diagnosis, cancer recurrence, medical comorbidities and cancer treatment are the factors which has great influence on sleep. Some of the studies also suggested that women who had received radiotherapy experienced more sleep difficulties than who did not [6]. 31% and 54% of newly diagnosed and recently treated cancer patients respectively reported sleep difficulties [7-9]. Anxiety and Depression are also exaggerated due to insomnia either as a clinical feature or a psychiatric diagnosis [10]. Depression, anxiety and stress are common among patients diagnosed with cancer and these conditions may also interfere with cancer treatment [11]. It is also taken for granted that cancer patients experience psychological distress by the medical

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Research article

Rapports De Pharmacie Vol.6 (1), 2020, 622-626
ISSN: 2455-0507

CUTANEOUS MANIFESTATIONS IN PATIENTS WITH END STAGE RENAL DISEASE AND ON HEMODIALYSIS

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ABSTRACT

The purpose of this study was to evaluate the prevalence of dermatologic problems among patients with End Stage Renal Disease undergoing Hemodialysis. Methods: It is a Multi-centric prospective Observational study, conducted in MGM hospital,Warangal and SVR Kidney and Dialysis centre, Hanamkonda. Results: Among the total subjects (n=243) enrolled in the study, the incidence of different skin alterations such as Hyperpigmentation, Pruritis, Xerosis etc., were recorded. Conclusion: All patients examined in study had atleast one or more Cutaneous lesions caused either by Disease or by treatment.

Keywords: End Stage Renal Disease, Hemodialysis, Hyperpigmentation, Pruritis, Xerosis.

INTRODUCTION

End Stage Renal Disease is a worldwide public health concern with an incidence rate of 17.2%. The skin is external reflector of many renal diseases. A complex array of dermatologic lesions are presented among the patients with ESRD. These manifestations are due to the electrolyte imbalance, accumulation of uremic substances and presence of co-morbid conditions[1]. Early detection of these cutaneous alterations contributes in improving Quality of life among ESRD patients.

The pigmentation on sun exposed areas has been attributed to an increase in Melanin in the basal layer of the epidermis due to an increase poorly dialyzable beta melanocyte stimulating hormone.The intensity of Melanin pigmentation increases with respect to the duration of end stage renal disease[2].High levels of urea in the blood allows accumulation of urea in the dermis , where it leeches into sweat glands and gets released onto the surface of the skin in a process described as " uridrosis"or " ruinous sweat".Drying of the aqueous portion yields the crystals of uremic frost[3].The abundance of polymorphonuclear neutrophil remnants in the early stages of these disorders has led to speculation that cellular dissolution of neutrophils with proteolytic enzyme release,including collagenase and elastase elaboration ,may initiate the pathologic process[4].Koilonychia or spoon nails, in which the nails are abnormally thin and concave, from side to side, with edges turned up[5].Patients with chronic renal failure (CRF) have impaired cellular immunity due to a decreased T lymphocyte cell count[6].Xerostomia is a condition that reduce salivary flow resulting from atrophy and fibrosis of salivary glands[7].Epidermolytic hyperkeratosis (EH) is a skin disease. The keratin filament clumping and degeneration terminally differentiating epidermal cells[8].It occurs during the early stages of regular dialysis treatment and explained on the basis refeeding after starting treatment.As a consequence of CKD and protein energy malnutrition ,pituitary gonadotropic and testicular function remain suppressed and increase in daily protein intake ,second puberty ensues ,which lead to transient gynecomastia[9].Angular cheilitis (AC) is a condition characterized by erythema ,most , ulceration and crusting at corners of the mouth[10].Cutis increases the susceptibility to infections and this is aggravated by delayed wound

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Original Article

Indian Journal of Diabetes and Endocrinology
Volume 2 Number 1, January - June 2020

Incidence of Depression in patients with Type 2 Diabetes Mellitus

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How to cite this article:
B.S. Sharavana bhava[1],Ayisha[2], Bikkireddy Sai Sharanya[3] et. al· Incidence of Depression inPatients with Type 2 Diabetes Mellitus. Indian Journal of Diabetes and Endocrinology. 2019;1(1):25-32

ABSTRACT

Introduction: Depression and diabetes are both chronic devastating conditions & their co-occurrence has been associated with poor outcomes. The link between depression and type 2 diabetes is bidirectional, significant candidate pathways include the innate inflammatory response, the hypothalamic-pituitary-adrenal (HPA) axis, and insulin resistance, which all interrelate with each other. In formerly undiagnosed diabetic patients, depression had a higher prevalence and might be due to an unfavorable or stressful lifestyle such as condensed physical activity, socioeconomic scarcity, social adversity, unhealthy diet. In this study, the emphasis was made on screening for depression in patients with T2DM.

Aim of the study: To investigate the incidence of Depression in Patients with T2DM.

Objectives of the study: To obtain demographic details, to assess the depression levels, and to establish the relation based on the severity of depression in T2DM patients.

Methodology: It is a prospective observational study design, the patient health questionnaire (PHQ-9) was used to assess depression in 387 patients aged between 30-80 years. Venous blood was collected to assess fasting blood sugar (FBS), post-lunch blood sugar (PLBS) and Glycated hemoglobin (HbA1c).

Results: The PHQ-9 revealed that 182 patients (47%) are minimal in depression severity followed by 169 patients (38.5%) are mild in depression severity. Female gender, increased age, obese patients, and longer duration of diabetes was associated with increased odds of depression. Whereas, being married was protective and was associated with decreased odds of depression.

Conclusion: In our study, we found the majority of subjects with minimal severity of depression when correlated between depression and T2DM. When HbA1c levels are compared, patients with higher levels of HbA1c are presented by subjects with moderate levels of depression.

Keywords:- Type 2 Diabetes mellitus; HbA1c; Depression; Patient health questionnaire-9; Depression severity.

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Introduction

Depression is a common and potentially debilitating mental illness characterized by a sense of inadequacy, despondency, decreased activity, pessimism, disturbed sleep or appetite, anhedonia and sadness where these symptoms severely disrupt and adversely affect the person's life [1]. It is a chronic illness that distresses around 340 million individuals at any given time worldwide [2]. The occurrence of diabetes mellitus has grasped epidemic levels worldwide ensuing massive human, economic and social costs globally. Presently, 415,000,000 public are existing with diabetes, 75% of whom live in developing nations especially India, Bangladesh, Central African Republic; this figure has been anticipated to rise to 642,000,000 by 2040 [3]. A connotation amongst depression and diabetes was recognized in the early 17th century, diabetes frequently seemed in persons who had experienced earlier life stresses or grief [4].

The association amongst depression and T2DM

OPEN ACCESS

Asian Journal of Biological Sciences

ISSN 1996-3351
DOI: 10.3923/ajbs.2019.884.890

Research Article

Evaluation of Antiulcer Activity of *Lawsonia inermis* and *Murraya koenigii* Seed Extract in Ethanol-induced Gastric Mucosal Damage in Rats

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Abstract

Background and Objective: Ulcer is the common gastrointestinal damage resulting from an inadequate gastric mucosal defense. Many synthetic drugs are available in the market to treat and these drugs produce side effects. The present research aims to evaluate the anti-ulcer activity of ethanolic extract of *Lawsonia inermis* and *Murraya koenigii* seeds. **Materials and Methods:** Ulcer was induced by administration of 95% ethanol (1 mL/200 g p.o.) in rats. Animals were 7 days pre-treated with *Lawsonia* (200 mg kg^{-1} p.o.) and *Murraya* (200 mg kg^{-1} p.o.) and their combination (200 mg kg^{-1} p.o.), respectively. **Results:** After treatment with extracts at 100 and 200 mg kg^{-1} significantly ($p<0.001$) shows the ulcer protective action. **Conclusion:** The selected plant extracts showed significant anti-ulcer activity.

Key words: Peptic ulcer, *Murraya koenigii*, *Lawsonia inermis*, ethanol

Citation: Venkateshwarlu Eggadi, Jhansi Lingampalli, Srinivasulu Kamma, Sharavana Bhava Sheshagiri Bandaru, Rajasekhar Reddy Alavala and Umasankar Kulandaivelu, 2019. Evaluation of antiulcer activity of *Lawsonia inermis* and *Murraya koenigii* seed extract in ethanol-induced gastric mucosal damage in rats. Asian J. Biol. Sci., 12: 884-890.

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

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Original Research Paper

Volume-9 | Issue-7 | July - 2019 | PRINT ISSN No. 2249 - 555X

Pharma

EFFECTS OF CARVEDILOL IN LEFT VENTRICULAR DYSFUNCTION IN PATIENTS WITH HEART FAILURE

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ABSTRACT **Background:** we conducted single center single drug study designed to establish the efficacy and safety of Carvedilol, a beta blocker of third generation which have vasodilator properties, in chronic heart failure.

Methods: 50 patients with heart failure were treated with Carvedilol, and echocardiographic evaluation was performed at the start and after 6 months.

Results: Ejection fraction, blood pressure, pulse rate were improved in patients after 6 months treatment compared to before start of treatment with carvedilol, we found significant differences in :systolic blood pressure(p value 0.0479);diastolic blood pressure (p value 0.2455);ejection fraction(p value 0.2691); pulse rate(p value 0.2192).

Conclusion: From this study we conclude that Carvedilol have proved to have good efficacy on the ejection fraction in patients with left ventricular dysfunction despite of few limitations like small sample size. Therapy of several months is required for improvement of ejection fraction, as these changes do not occur in the short term.

KEYWORDS : Carvedilol, Ejection fraction, Left ventricular dysfunction, Heart failure, Blood Pressure, Pulse rate.

INTRODUCTION

Heart failure is a progressive syndrome resulting from the heart's inability to adequately perfuse and oxygenase peripheral tissues. This syndrome is manifested by fatigue dyspnea, and congestion (1, 2). Heart failure is associated with patholoIgic ventricular remodeling and worsening ventricular dysfunction, resulting in adverse hemodynamic changes (3). Activation of the sympathetic nervous system is known to be associated with progressive deterioration of cardiac function and clinical condition and increased mortality in patients with heart failure (4-10). Beta adrenergic blocking agents, because of their ability to inhibit sympathoadrenergic drive, are therefore useful for the long-term treatment of this syndrome (11, 12).Carvedilol is a new beta blocker devoid of intrinsic sympathommetic activity with associated vasodilators effects mediated by alpha,-receptor antagonism (10, 13, 14).Carvedilol is a third generation β-blocker with vasodilatory and antioxidant actions, which has been established as an effective drug for mild to severe CHF (15). Heart failure is associated with an increase in adrenergic activity and in that of rennin angiotensin-aldosterone system (16,17).beta blockers are one of the main stays of treatment due to their ability to reverse neuro humoral effects of sympathetic nervous system with ensuing symptomatic benefits (18,19,20). Carvedilol has significant anti oxidant properties (21, 22). It inhibits oxygen free radicals generation and prevents LDL (low density lipoprotein) oxidation, in turn LDL uptake in to coronary vasculature is reduced. This anti oxidant property contributes to Carvedilol's cardio protective effects (23).Carvedilol produce less "inverse agonism" than most other beta blockers. Thus, carvedilol produces relatively fewer negative chronotropic and ionotropic effects than other beta blockers (24). In this study, we investigated the effects of Carvedilol on parameters of ejection fraction, systolic blood pressure, diastolic blood pressure and pulse rate in heart failure patients with left ventricular dysfunction. Carvedilol is a beta blocker and have more anti adrenergic activity than others because of its unselective blockade of beta1 and beta2, alpha blockade and has anti oxidant properties, which provides a greater reduction of cardiac adrenergic drive and work (25). The aim of the study is to assess the Carvedilol efficacy on ejection fraction of heart failure patients with left ventricular dysfunction.

MATERIAL AND METHODS

It is a prospective, observational single drug study conducted in patients of "MGM hospital". Patients were explained about the study &informed consent were seeked by explaining them in their local language.

Inclusion criteria

Males and females of 25-80years diagnosed with left ventricular dysfunction will be included in our study

Exclusion criteria

Age above 80 years , patients with bradycardia, uncontrolled diabetes mellitus, asthma, unstable angina, resting angina, severe liver impairment, grade II or III atrio ventricular block, hyperthyroidism, pregnant women, corpulmonale, valvular heart disease, life threatening arrhythmia, cardiogenic shock, hypertrophic obstructive cardio myopathy. Patients were also excluded if myocardial infarction or coronary artery bypass grafting had occurred within the preceeding 3 months .

Study design

It is a prospective, observational, single centered, single drug study design performed for a period of 6 months and the patients included are on beta blocker therapy with Carvedilol. The goal was to achieve improvement in ejection fraction, blood pressure, pulse rate with adds on therapy of Carvedilol.

Institutional Human Ethical Committee Endorsement was obtained after submission of protocol and IHEC number is MGM/ VCOP/ PHARM/ D/Y/05/2018.

Clinical response assessment

The efficacy of Carvedilol was assessed by measuring the change in the Ejection fraction, systolic blood pressure, diastolic blood pressure, pulse rate after 6 months of treatment. Primary end point was change in ejection fraction after 6 months treatment as compared to the baseline levels. The secondary end point was change in blood pressure, pulse rate which were measured after 6 months treatment as compared to baseline levels.

MedCrave

Advances in Obesity Weight Management & Control

Research Article

Open Access CrossMark

Efficacy of telmisartan and enalapril in patients with diabetic nephropathy

Abstract

Introduction: Diabetic nephropathy is characterized by hypertension and persistent proteinuria and is the leading cause of end stage renal disease (ESRD). The comparison of Telmisartan and Enalapril was designed to assess and compare the efficacies of both drugs in diabetic nephropathic patients.

Material and methods: All age groups of patients diagnosed with diabetic nephropathy are included in our study.

Results: 112 patients were recruited in the study. Patients taking Telmisartan and Enalapril once daily completed the study. There was a significant reduction in urine albumin, urine creatinine, urine albumin/creatinine ratio (UACR), serum creatinine, Blood pressure, Fasting blood sugar, Post lunch blood sugar, HbA1C, Total cholesterol, low density lipoprotein, very low density lipoprotein, high density lipoprotein and triglycerides.

Conclusion: Both Telmisartan and Enalapril were efficacious in diabetic nephropathy patients, but Enalapril showed more Reno protection than Telmisartan in this study.

Keywords: diabetic nephropathy, ESRD, telmisartan, enalapril, proteinuria

Volume 9 Issue 2 - 2019

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Received: March 13, 2019 | **Published:** April 16, 2019

Background and aim

Diabetes mellitus is a metabolic complex disorder characterised by hyperglycaemia and glucose intolerance as their hallmark due to insulin deficiency or impaired effectiveness of insulin action.[1] Diabetic nephropathy is one of the potential micro vascular complications in diabetic patients. It is the leading cause of End stage renal disease (ESRD). Diabetic kidney disease refers to chronic kidney disease (CKD) presumed to be caused by diabetes.[2] Diabetic nephropathy is screened for persistent abnormal urine albumin excretion and by decreased glomerular filtration rate (GFR). Albuminuria has been divided into micro albuminuria (urine albumin creatinine ratio (UACR) 30-300 mg/dl) and macro albuminuria (UACR more than 300mg/dl). Serum creatinine derives estimates of GRF and diabetic kidney disease.[3]

Diabetic kidney disease can be detected by screening for persistent abnormal urine albumin excretion and by determining the estimated glomerular filtration rate. The main evidence based strategies for preventing or delaying loss of kidney function in diabetic patients include blood pressure control, blockade of renin-angiotensin system, and glycaemic control. Controlling these factors and reducing proteinuria are now the main focus of diabetic kidney disease management. Through a multidisciplinary approach of implementing guidelines and timely referral, care of the diabetic kidney disease patient can be improved. The key is preventing and slowing the progression of this complication, to keep the other shoe from dropping.[4,5]

The aim of the study is to assess and compare the efficacy of Telmisartan and Enalapril in diabetic nephropathic patients. Angiotensin converting enzyme inhibitors and angiotensin receptor blocker have reno protection effects in diabetic patients. Enalapril; Angiotensin-converting enzyme (ACE) inhibitors, which competitively block the renin–angiotensin system, decrease glomerular capillary pressure and prevent the progression of microalbuminuria to overt proteinuria.[6]

The side effects of enalapril are Edema, Dry cough, Dizziness, Hypertension, Syncope. Enalapril is contraindicated in pregnancy and breast feeding. Telmisartan is a angiotensin receptor antagonist possessing selective, and insurmountable inhibitory activity specific to the angiotensin II type 1 (AT1) Receptor.[7] side effects are Tachycardia, Bradycardia, Hypotension, Edema and Allergic reactions. Telmisartan is contraindicated during pregnancy, in bilateral renal artery stenosis in which it can cause renal failure.

Literature

(Table 1).[2-11]

Author	Year	Study	Conclusion
Roland et al[4]	2013	Telmisartan in incipient and overt diabetic renal disease.	The Effect of telmisartan on kidney function support its use in patients with microalbuminuria or overt diabetic nephropathy.
Bhansali et al[7]	2010	Antialbuminuric efficacy of ACE inhibitors and ARB'S in type 1 DM with nephropathy	Dual blockade with ramipril enhanced with antialbuminuric effect of telmisartan and reduced in blood pressure
Anthony et al[8]	2004	ARB'S versus ACE inhibitors in type 2 DM and nephropathy	Telmisartan is not inferior to enalapril in providing long term reno protection in persons with type 2 diabetes mellitus.
Johnsen et al	1992	Renal protective effect of enalapril in diabetic nephropathy	Treatment with enalapril can reduce the rate of decline in kidney function in patients with diabetic nephropathy.

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OPEN ACCESS

Research Journal of Medicinal Plants

ISSN 1819-3455
DOI: 10.3923/rjmp.2019.155.161

Research Article

Evaluation of Nootropic Activity of *Spinacia oleracea* in Scopolamine Induced Cognitive Decline Mice

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Abstract

Background and Objective: Alzheimer disease (AD) is reflected by progressive cognitive debility usually start with impairment in the capability to form new memories, but unavoidably disturbing all knowledgeable tasks. The present study was aimed at investigating the neuroprotective effect aqueous extract of *Spinacia oleracea* (AESO) in scopolamine induced cognitive decline mice. **Materials and Methods:** Memory impairment was produced by administration of Scopolamine (1.4 mg kg^{-1} i.p.) in albino mice. Nootropic activity in mice with the treatment of AESO (200-400 mg kg^{-1}) and donepezil (5 mg kg^{-1}) were administered to different groups of mice. Effect of extract on learning and memory of mice was evaluated using elevated rectangular maze, pole climbing and morris water maze test and also estimated the brain acetylcholinesterase (AChE) concentration and the percentage of inhibition of AChE. **Results:** AESO showed significantly improved in learning and memory of mice, as indicated by the decline in transfer latency using rectangular maze test, decrease in escape latency during training, retrieval using morris water maze, pole climbing test and neuroprotective activity through reduced brain AChE concentration and increased the percentage of inhibition of AChE activity in rat brain. **Conclusion:** Thus, aqueous extract of *Spinacia oleracea* showed memory enhancing and neuroprotective activity in mice probably by inhibiting brain AChE activity.

Key words: Nootropic, acetylcholinesterase, donepezil, *Spinacia oleracea*, scopolamine, neuroprotective

Citation: Lakkireddy Rachana Reddy, Kulandaivelu Umasankar, Bandaru Sheshagiri Sharavana Bhava and Eggadi Venkateshwarlu, 2019. Evaluation of nootropic activity of *Spinacia oleracea* in scopolamine induced cognitive decline mice. Res. J. Med. Plants, 13: 155-161

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

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Research article

Rapports De Pharmacie Vol.5 (3), 2019, 582-585
ISSN: 2455-0507

INCIDENCE OF CATARACTS IN WARANGAL DISTRICT, TELANGANA STATE: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Cataract is the major cause of blindness worldwide, especially in tropical belt, where the densely populated developing countries are located. Survey in different climatic zones in northern India have found cataract prevalence of 4-10%and steadily increasing after the age 30 and with prevalence 13-36%among age of 30 and above. Our aim is to study the incidence of cataracts in Warangal District, Telangana State. Materialand Methods: It is a prospective observational study in which all the patients suffering with cataracts were included as subjects. Results: Among the total 83,827 cases in outpatient department females are found to be 41,167 (0.49%) and males found to be 42,660 (0.50%) of 6816 inpatients admitted, the female population was found to be 3285 (0.48%) and male population was found to be 3531 (0.51%). The total number of cataract operations done including TOL were 5429 and females found to be 2653 (0.48%) and males 2726 (0.50%). The total corrected refractive errors were 31,427 and females were found to be17,538 (0.55%) and males were 13,889 (0.44%).Conclusion: In conclusion, we have documented the incidence of cataracts in which males more affected than females.

Keywords: Cataracts, Blindness, Incidence, Ophthalmology.

INTRODUCTION

Cataract is defined as accumulation of proteins in the lens of eye where the cloudiness can be observed and the symptoms can be seen are mainly watery eyes and blurred vision. Cataract is a major cause of blindness worldwide, especially in the tropical belt, where the most of the densely populated developing countries are located. In India 60% of all blindness may be due to cataract; Various surveys in India show that nearly 7% of the population suffers from cataracts and nearly 1.5% of the population is blind due to cataract (1,2). Accordingly, blindness control programmes in India have focused primarily on cataract. Although such programmes have improved the coverage of cataract surgerythey have not always resulted in good postoperative vision outcomes. Surveys in different climatic zones in northern India have found cataract prevalence of 4-10%, with senile cataract appearing and steadily increasing after age 30 and with prevalence 13 – 36% among persons aged 30 and older(3,4). The aim is to study the incidence of Cataracts in Regional Eye Hospital at Warangal district in Telangana state.

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MATERIAL AND METHODS

It is a prospective observational study conducted in patients from "Regional Eye Hospital" located at Warangal. Patients were explained about the study & informed consent forms were seeked by explaining them in their local language.Institutional Human Ethical Committee Endorsementwas obtained after submission of protocol and IHEC No. is MGM/VCOP/PHARMD/V/12/2017.

Inclusion criteria:

All the cataract patients of age above 40 years (Males and Females).

Exclusion criteria:

Trauma to eye and other complications, Pediatric patients, Pregnancy and Lactating mothers were excluded from this research work (5-9).

Study type: A Prospective Observational Study conducted in the Regional Eye Hospital, Warangal, Telangana State.

Statistical analysis: We had calculated the Incidence by using formula

Incidence = Number of new cases at a particular area to the total number of cases at that particular area.

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IJAPB International Journal of Advances in Pharmacy and Biotechnology

Journal homepage: http://ijapbjournal.com/

Case Study

A Prospective Observational Study: Phenytoin Pharmacokinetic Pattern in Cerebrovascular Accident and Head Trauma Patients in Warangal Population

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ARTICLE INFO

Article history:
Received 11 Jan 2019
Received in revised form 16 Jan 2019
Accepted 18 Jan 2019
doi.org/10.38111/ijapb.20190501003

Keywords:
Head injury; Pharmacokinetics; Phenytoin; Cerebrovascular accident; Head trauma.

ABSTRACT

An phenytoin is commonly administered as prophylactic or treatment of epileptic episodes in acute brain injury due to head injury. The aim of the study is to evaluate PK pattern of phenytoin in patients with traumatic and non-traumatic brain injuries. This study was carried out in 30 adult head injury patients and who were administered with phenytoin for prophylaxis of post trauma seizures or treatment. Serum Phenytoin concentrations (Cp) were determined and were compared between CVA and HT patients. The Km and Vmax were significantly higher in HT patients. The Cp and the Cp/dose ratio were higher in the CVA patients significantly ($P<0.05$). APACHE II score was significantly lower than the baseline at the end of the study in each group of patients ($P<0.05$). Due to significant differences in Cp and PK parameters between HT and CVA patients, close attention must be paid to the PK behavior of phenytoin in the efforts to improve the patient's outcome after a severe HT.

1. Introduction

Head injury is a trauma to the scalp, skull or brain which is one of the leading causes of morbidity and mortality around the globe [1]. Head injury may lead to bleeding in the brain tissues and in certain layers that surround the brain (subarachnoid haemorrhage, subdural haemorrhage and extradural haemorrhage). Head injury is one of the most common reasons for an emergency visit to the hospital. Traumatic brain injury (TBI) accounts for over 1 in 6 injury-related admissions each year [2]. Traumatic brain injury is a leading cause of morbidity, mortality, disability, in India and other developing countries. Road traffic injuries are leading cause (60%) of traumatic brain injury followed by falls (20-25%), violence and alcohol involvement (15- 20%) in India [3]. Head injuries are commonly caused by a blow to the head that are usually associated with vehicle accidents, falls, and sports related accidents.The treatment of the condition depends on the seriousness of the injury. Mild traumatic brain injures requires over-the-counter pain relievers to treat headache and usually needs to be monitored closely at home for any persistent, exacerbating or new symptoms. Moderate to severe brain injuries concentrate on enough oxygen, sufficient blood supply, blood pressure and avoid any further injury to the head. Treatment limitations for peripheral destruction of the brain immediately after an injury may contain: Diuretics, Anti-seizure drugs and Coma-inducing drugs. Urgent surgery is needed to reduce further damage to the brain. Surgery may be used for the following issues: Eliminate clotted blood (hematoma), repairing skull fractures, bleeding in the brain, and opening in the skull [4].

In the beginning stage after a mind injury, seizure may cause auxiliary cerebrum harm because of expanded metabolic requests, expanded intracranial weight, and abundance synapse discharge. It has been shown that seizures are a significant reason for dismalness.

Phenytoin has been normally utilized as an anticonvulsant specialist for the treatment of or the prophylaxis against seizures for quite a long time. Despite the fact that the confusions of early seizure are the

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Iranian Journal of Pharmaceutical Sciences
2018: 14 (3): 107-116
www.ijps.ir

Original Article

Neuroprotective and Nootropic Activity of *Carica Papaya* Seeds on Diabetes induced Cognitive Decline in Rats

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Abstract

The aim of present study is to investigate neuroprotective and nootropic activity of Petroleum Ether Extract of *Carica papaya* seeds (PEECPS) on diabetic induced cognitive decline rats. Rectangular maze and morris water maze models were used to evaluate nootropic activity and neuroprotective effects were studied by estimating acetyl cholinesterase (AchE), malondialdehyde (MDA), superoxide dismutase (SOD), nitric oxide (NO), catalase (CAT) and glutathione (GSH) levels in the brains of diabetic rats. In rectangular maze and morris water maze models, 400 mg/kg of PECPS were shown the significant effect compared with diabetic control on day 75. Significant decrease in AchE ($P<0.001$), MDA ($P<0.01$), NO ($P<0.05$) and significantly ($P<0.01$) increased levels of SOD, CAT and GSH with PECPS (200 and 400 mg/kg) compared with diabetic control. There is a need of further studies on *Carica papaya* seeds as it showed protection against diabetes induced cognitive decline to reveal its mode of action.

Key words: *Carica papaya* seeds, morris water maze, neuroprotective, nootropic, radial arm maze, cognitive, diabetes

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Cite this article as: Venkateshwarlu E, Srilatha K, Sheshagiri Sharvana Bhava B, Umasankar K, Neuroprotective and Nootropic Activity of Carica Papaya Seeds on Diabetes induced Cognitive Decline in Rats. 2018; 14 (3): 107-116

1. Introduction

Diabetes mellitus (DM) is a worldwide health problem afflicting millions in both developed and developing countries. DM is a chronic metabolic disorder characterized by hyperglycemia resulting from either low level or resistance to insulin. DM causes chronic kidney failure, blindness, high blood pressure, and premature coronary artery diseases. The complications of DM such as cognitive

CRIMSON PUBLISHERS
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ISSN: 2576-8816

Research in
Medical & Engineering Sciences

Research Article

Efficacy of Epalrestat and Pregabalin in Patients with Diabetic Peripheral Neuropathy

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Submission: April 12, 2018; **Published:** May 04, 2018

Abstract

Diabetic Peripheral neuropathy [DPN] is a major long term problem allied with diabetes that can cause serious disability and also death. It is caused by damage to any nerve in the peripheral nervous system. Fifty to seventy five percent of all ulcerations and non trauma amputations are a consequence of diabetic neuropathy. Epalrestat and Pregabalin are widely used to overcome neuronal damage. This study was designed to evaluate the efficacy of these two drug regimens.

Material and methods: Patients included in this study were experiencing pain because of diabetic neuropathy for at least 6months to 2 years.

Results: From 256 subjects with diabetic neuropathy included in the study, 229 patients concluded final analysis. 27 patients dropped from the study (17and 10 patients from pregabalin and epalrestat respectively). Mean pain score was reduced from 5.08±0.82 (severe pain) at first visit to 3.43±0.93 (moderate pain) in the epalrestat group, from 6.42±1.03 (severe pain) at first visit to 2.57±0.99 (mild pain) in the pregabalin group.

Conclusion: We conclude that pregabalin was significantly more effective than epalrestat in controlling pain in DPN patients.

Keywords: Diabetic peripheral neuropathy; Epalrestat and pregabalin

Background and Aims

Diabetic neuropathy (DPN) encompasses a wide, heterogeneous group of clinical and subclinical syndromes [1]. It is a major long term problem allied with diabetes that can cause serious disability and also death [2]. 50 to 75% of all ulceration and non-traumatic amputations are a consequence of diabetic neuropathy, and cause more hospitalizations than all other diabetic complications [3]. DN affects the nervous system and causes extensive damage. Neurologic complications are not reserved for specific type of diabetes but occur equally in type 1 and type 2 [4]. Diabetic peripheral neuropathy (DPN) is often painful and debilitating condition that is caused by damage to any nerve in the peripheral nervous system.

It is a family of nerve disorders that are directly caused by diabetic complications [5]. Poor diabetic control, obesity, high blood pressure, high cholesterol and triglycerides are risk factors for developing neuropathy [6]. It affects somatic and autonomous nervous systems and is different from peripheral arterial disease which affects the blood vessels rather than the nerves and vasa nervorum [7]. Many physicians misinterpret symptoms related to neuropathy in diabetic patients. Treatment is directed towards preventing neuropathy progression, reducing symptoms and implementing measures to prevent complications of insensate extremities [8].

The aim of this study was to analyze the effect on neuropathic pain of two widely used drugs: epalrestat and Pregabalin.

Material and Methods

This was a prospective observational study carried out in Sri Bhadrakali Diabetic Clinic, Naimnagar, Hanamkonda. Institutional Human Ethics committee endorsement was sought and obtained before conduct of the trial (MGM/VCOP/PHARMD/V/067/2017). Selection of subjects was done according to the following inclusion exclusion criteria:

Inclusion criteria

Males and females 18-75 years age; Diabetes mellitus (Type1 or Type2); Experiencing pain due to diabetic neuropathy for at least 6 months to 2 years; Neuropathic pain must begin in the feet with

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Review Article

Efficacy of azilsartan and telmisartan in patients with type 2 diabetes and hypertension

Abstract

Hypertension is defined as high blood pressure or a long term medical condition in which the arterial blood pressure is continuously elevated. It is also explained as sustained diastolic BP more than 90mmHG accompanied by the elevated systolic BP more than 140mmHg. Diabetes mellitus is a disorder related with a wide variety of disorders in metabolism, the principal feature is hyperglycaemia caused by inadequate insulin action. Azilsartan and Telmisartan are widely used to control hypertension in diabetes patients. This dissertation was designed to assess the efficacy of Azilsartan and Telmisartan.

Material and methods: Patients included in this study were diagnosed with Type 2 diabetes mellitus and Hypertension of least age of greater than or equal to 18yrs.

Results: From 305 subjects with diabetes hypertensive patients included in the study 152 patients received Azilsartan and 153 patients were prescribed with Telmisartan.

Conclusion: Azilsartan 80mg and Telmisartan 80mg are proved to be efficacious in the patients with hypertension and T2DM, but Azilsartan 40mg has shown more efficacy than Telmisartan 40mg.

Keywords: Type 2 diabetes, azilsartan, telmisartan, T2DM, BP, RAAS

Volume 8 Issue 5 - 2018

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Received: August 20, 2018 | **Published:** October 12, 2018

Introduction

Hypertension is defined as high blood pressure or a long term medical condition in which the arterial blood pressure is continuously elevated.[1] It is also explained as sustained diastolic BP more than 90mmHG accompanied by the elevated systolic BP more than 140mmHg.[2] Diabetes mellitus is a disorder related with a wide variety of disorders in metabolism, the principal feature is hyperglycaemia caused by inadequate insulin action.[3] Most deaths(43%) fall out below 70years of age. 422million people across the globe in 2014 had diabetes-with a 8.5% prevalence in adults.1.5million deaths in 2012 occurred due to diabetes. In 2012 among both genders it is the eighth major cause of death and fifth prime cause of death in woman. About 2,82,000 intensive care room visits for adult population aged 18 years and above encountered hypoglycaemia as an initial diagnosis and diabetes as secondary diagnosis in 2012.[4] In the past 30 years Diabetes prevalence consistently increasing and is increasing most rapidly in nations with low and middle income. Increasing concomitant risk factors like being overweight or obese are seen. Diabetes mellitus is a main reason for blindness and kidney failure, legs amputation and other chronic consequences that affect primarily on quality of life.[5]

Relationship between hypertension and diabetes

In nephropathy, ECF or extra cellular fluid volume and whole body sodium (Na^+) levels are increased. The action of the Renin Angiotensin Aldosterone System (RAAS) is decreased in these patients, and the high blood pressure is volume dependent, identical to other nephropathies. Other factors must play a vital role in the occurrence of high blood pressure in the non-existence of diabetic nephropathy. Both genetic and acquired factors are seen. Increased whole body sodium levels along with low or actual activity of the RAAS had been reported. People with high blood pressure have found with elevated insulin levels secondary to insulin resistance and lowered insulin clearance. Elevated insulin levels may possibly be related with inclined renal sodium resorption and hyperactivity of sympathetic nervous system making way to hypertension in people with obesity and other insulin resistant conditions, such as type 2 diabetes. Insulin resistance is also linked to a decreased response of vasodilators to insulin and an elevated response for vasoconstrictors to various vasopressors. However, the action of insulin resistance in the etiology and pathogenesis related to hypertension is not clearly understood.[6]

The aim of our work is to compare Azilsartan and Telmisartan among Type 2 diabetes and hypertensive patients.

Material and methods

Our citation was an observational research work carried out prospectively in Sri Bhadrakali Diabetic Clinic, located at Hanamkonda, Warangal. Before initiation of our research, endorsement was seeked and received from Institutional human ethics committee (IHEC) as (VCOP/PHARM D/V/2018/013). Study population were selected by following inclusion and exclusion criteria's:

Criteria for inclusion

All subjects diagnosed with Diabetes mellitus Type II and Hypertension with at least age greater than or equal to 18yrs.

Criteria for exclusion

Patient who were diagnosed with

i. Secondary Hypertension due to an underlying cause
ii. Stage IV chronic kidney disease (GFR<30ml/min)
iii. Type1 Diabetes mellitus

Current Research in Diabetes & Obesity Journal
ISSN: 2476-1435

Juniper Publishers
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Research Article
Volume 8 Issue 2 - August 2018
DOI: 10.19080/CRDOJ.2018.08.555735

Curr Res Diabetes & Obes J

Comparison of Teneligliptin and Atorvastatin on Lipid Profile in Patients with Type 2 Diabetes Mellitus

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Abstract

Diabetes mellitus is a chronic metabolic disease characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both which results in long term damage, dysfunction and failure of various organs especially eyes, kidneys, nerves, heart and blood vessels. The efficacy of Teneligliptin and Atorvastatin on lipid profiles in patients with type 2 Diabetes mellitus were compared. This study was designed to evaluate the efficacy of these two drug regimens.

Material and methods: Males and females of 25-90 years diagnosed with type 2 Diabetes mellitus are included in our study.

Results: 275 patients were recruited for our study. 47 were excluded because of their inability to attend or participate and did not meet inclusion criteria. 229 T2 DM patients who were taking Teneligliptin 20mg once daily or Atorvastatin 20mg once daily completed the study. There were significant decrease in the levels of TC, HDL, LDL, TG, VLDL in Teneligliptin and Atorvastatin are 35.1, 4.1, 14.8, 37, 7.5(mg/dl) and 35.1, 4, 14.6, 37.1, 7.6(mg/dl) respectively.

Conclusion: From this study we conclude that Teneligliptin 20mg and Atorvastatin 20mg have proved to have similar efficacy on the lipid profiles. Hence we conclude that Teneligliptin is an efficacious drug for T2 DM patients in management of glycemic control and lowering lipid profiles.

Background and Aim

Diabetes mellitus is a group of metabolic diseases which challenges the global population. Thus, there is an increasing need to conduct research in this field [1,2]. The aim of the study is to compare the efficacy of Teneligliptin and Atorvastatin on lipid profile of patients with T2 DM. Comparative evidence is required to guide appropriate therapy to attain lipid control and prevent complications of diabetes [3,4].

Material and Methods

It is a prospective, observational, comparative study conducted in patients from "Sri Bhadrakali Diabetic Clinic" located at Naimnagar, Hanamkonda. Patients were explained about the study & informed consent forms were seeked by explaining them in their local language [5,6]. Institutional Human Ethical Committee Endorsement was obtained after submission of protocol and IHEC No. is MGM/VCOP/PHARMD/V/017/2017.

Inclusion criteria

Males and females of 25-90 years diagnosed with type 2 Diabetes mellitus will be included in our study.

Exclusion criteria

Pregnant and lactating females, patients on insulin therapy, history of type1 Diabetes mellitus, signs of diabetic complications (neuropathy, nephropathy and retinopathy) are to be excluded [7]. Patients with clinical signs and symptoms of acute myocardial infarction, liver failure, chronic heart failure, and hypertension are to be excluded.

Study design

It is a prospective, observational, comparative study design, and the patients who were taking Teneligliptin 20mg and Atorvastatin 20mg were included [8].

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World Journal of Medical Sciences 14 (3): 57-61, 2017
ISSN 1817-3055

DOI: 10.5829/idosi.wjms.2017.57.61

Comparison of Efficacy of Telmisartan and Enalapril in Patients with Diabetic Nephropathy

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Abstract: Diabetic nephropathy is the leading cause of end – stage renal disease. It is characterised by Hypertension and persistent proteinuria. If ineffectively controlled, a progressive decline in renal function can result in end – stage renal disease. The main objective of this study was to evaluate the efficacy of Telmisartan vs Enalapril on Diabetic Nephropathy in patients with type 2 diabetes. Patients included in this study were patients who had type 2 diabetes treated by diet and/or oral hypoglycaemics; Patients treated with insulin, if they were diagnosed as being diabetic at the age of > 40 years, had been in receipt of oral hypoglycaemics for > 1 year before being treated with insulin and had a body mass index of >25kg/m^2; patients who have mild to moderate hypertension (resting systolic / diastolic blood pressures < 180/95 mmHg) while receiving an ACE Inhibitor for > 3 months before entering the study. From 344 subjects with diabetic nephropathy included in the study, 328 patients were included in the final analysis. 16 patients were dropped from the study (15, 01 patients from Telmisartan and Enalapril groups respectively). At the end of the study the reduction in urine albumin was more with Enalapril (Mean difference 43.75 ± 4.003) when compared with Telmisartan (Mean difference 36.49 ± 3.23). The p values were < 0.05 for both groups and it was found that reduction of diabetic nephropathy in Enalapril treatment group at the end of the study is statistically differs than the Telmisartan treatment group. We concluded that Enalapril confers strong renal protection in patients with type 2diabetes and nephropathy. Telmisartan is not inferior to Enalapril in providing Reno protection in subjects with Type 2 Diabetes and early nephropathy. This result is consistent with emerging data that support the clinical equivalence of angiotensin II- receptor blockers and ACE inhibitors in various conditions associated with high cardiovascular risk.

Key words: Diabetic Nephropathy · End – Stage Renal Disease · Renin – Angiotensin Aldosterone System · Telmisartan · Enalapril

INTRODUCTION

Diabetes Mellitus (DM) is the most frequent cause of chronic kidney failure in both developed and developing countries [1]. Diabetic nephropathy, also known as kimmelstiel – Wilson syndrome or nodular diabetic glomerulosclerosis / intercapillary glomerulonephritis, is a clinical syndrome characterized by albuminuria (>300 mg/day or >200 mcg/min) confirmed on at least two occasions 3-6 months apart, permanent and irreversible decrease in glomerular filtration rate (GFR) and arterial hypertension [2]. The syndrome was first described by a British physician Clifford Wilson (1996-1997) and American physician Paul Kimmelsteil (1900-1970) in 1936 [3].

Diabetic nephropathy is a chronic condition developing over many years characterized by Gradual increasing urinary albumin excretion (UAE), High blood pressure, Declining GFR, Absence of other renal / renal tract disease, Presence of diabetic retinopathy.

The aim of this study was to analyse the effect of two widely used drugs Telmisartan and Enalapril on urinary albumin.

MATERIALS AND METHODS

This was a prospective observational study carried out in Sri Bhadrakali Diabetic Clinic, Kishanpura, Hanamkonda, Telangaana, India. Institutional Human Ethics committee endorsement was seek and obtained

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Shastrala et al. Future Journal of Pharmaceutical Sciences (2021) 7:99
https://doi.org/10.1186/s43094-021-00252-0

Future Journal of Pharmaceutical Sciences

RESEARCH Open Access

Synthesis, characterization, and pharmacological evaluation of some metal complexes of quercetin as P-gp inhibitors

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Abstract

Background: Six different metal complexes of quercetin (Cu, Zn, Co, Vd, Mo, Ni) were synthesized, purified, and characterized by their physical and spectral (UV, IR) data. They were evaluated for their P-gp (permeability glycoprotein) inhibitory activity by in vitro everted sac method in rats. The apparent permeability of atorvastatin (P-gp substrate) from everted sac of the rat intestine was determined in control, standard (verapamil), and groups treated with quercetin-metal complexes. The drug contents were analyzed by validated RP-HPLC method using a mixture of acetonitrile and water (60:40 v/v) adjusted to pH 2.8 with phosphate buffer as mobile phase.

Results: In vitro studies revealed that the apparent permeability of atorvastatin (P-gp substrate) across the small intestine is much affected by the treatment with Cu/Co/Ni complexes of quercetin. The mean ± SD and apparent permeability of atorvastatin decreased after pre-treatment with these metal complexes.

Conclusions: The quercetin Cu/Co/Ni complexes could inhibit P-gp and increase the atorvastatin absorption. Hence, they could be considered P-gp inhibitors.

Keywords: Quercetin, Metal complexes, Atorvastatin, P-gp, Inhibitors, P-glycoprotein

Background

Cancer is a dreadful disease, killing a large number of the population worldwide. More than 100 different types of cancer are reported to affect humans [1, 2]. Chemotherapy is widely used for cancer treatment but it is hindered mostly due to the resistance of tumor cells to anticancer drugs [3, 4]. Several mechanisms underlying drug resistance were identified. Increased efflux of drugs by cancerous cells, due to over expression of membrane transporter proteins (efflux pumps) is one of the major mechanisms documented. P-glycoprotein (P-gp) is the first discovered multidrug transporter that pumps drugs out of tumor cells, resulting in decreased intracellular drug concentrations and thus reducing the efficacy of drugs [5]. It is present in several normal tissues like intestinal lining epithelium, endothelial cells, and bone marrow.

Quercetin (Q) is a major naturally occurring flavonoid, belonging to the class of flavonols. It is ubiquitously found in a wide variety of plant products like coffee, tea, dyes, vegetables, and fruits [6]. The beneficial effects of quercetin are mostly due to its free radical scavenging or antioxidant property and its ability to chelate metal ions (Fe^{2+} and Fe^{3+}, Cu^{2+}, Ni^{2+}) [7–12]. Quercetin and some of its metal complexes displayed various biological actions such as antimicrobial, antiulcer, antiallergic, anti-Alzheimer's, and anticancer [13–18]. It was reported that quercetin could competitively inhibit the members of MDR family, P-gp, MRP1, and BCRP [19–23]. But, hitherto, there are no reports on the P-gp inhibitory activity of quercetin-metal complexes. In this regard, the present

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Regular Article

Design, Synthesis and Pharmacological Evaluation of Some C_3 Heterocyclic-Substituted Ciprofloxacin Derivatives as Chimeric Antitubercular Agents[1)]

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Received June 27, 2020; accepted August 24, 2020

A series of new C_3 heterocyclic-substituted ciprofloxacin derivatives were prepared from ciprofloxacin acid hydrazide as possible chimeric molecules. They were evaluated for their possible *in vitro* antibacterial (agar cup/bore diffusion method) and antitubercular (Lowenstein–Jensen (LJ) slant method) activities. The results indicated that all the test compounds are highly effective against all the bacterial strains and have shown excellent anti-tubercular activity against normal, multidrug resistant and extensively drug resistant strains of *Mycobacterium tuberculosis*. They were found to be more potent antibacterial and antitubercular agents than the standard, ciprofloxacin. The minimum inhibitory concentration (MIC)'s of all the compounds against *M. tuberculosis* were found to be 0.0625 μg/mL as compared to ciprofloxacin (MIC = 2 to > 8 μg/mL). Molecular docking studies were performed by using AUTODOCK 4.2 on the new ciprofloxacin derivatives at the active site of crystal structure of fluoroquinolones target enzyme Mtb DNA gyrase GyrA N-terminal domain (PDB ID: 3ILW) and also on the active site of crystal structure of chosen heterocyclics target enzyme enoyl-acyl carrier protein (ACP) reductase enzyme (PDB ID: 4TZK). Interestingly, almost all the compounds have shown relatively greater binding affinity at both the active sites than ciprofloxacin. Compound 6 exhibited the highest affinity for 3ILW and 4TZK.

Key words chimeric; ciprofloxacin; fluoroquinolone; antitubercular activity; antibacterial activity

Introduction

Bacteria represent an outsized domain or kingdom of prokaryotic microorganisms. Pathogenic bacteria cause severe infectious diseases, widely prevalent throughout the world. One of the bacterial diseases with highest disease burden is tuberculosis (TB), caused by the bacterium *Mycobacterium tuberculosis* (Mtb), which kills about 2 million people a year. TB is a chronic infection and its condition is worsened by the existence of multidrug resistant tuberculosis (MDR-TB) and extensively drug resistant tuberculosis (XDR-TB) strains. In view of such a devastating nature of the disease, WHO had declared Tuberculosis (TB) as a "Global Health Emergency." This particular disease is also known to be one of the most severe health problems as it causes not only 'morbidity' leading to loss of human work hours which is detrimental to National Economy, but also culminates in 'mortality.'[2)]

Fluoroquinolones are the major class of antibiotics useful for the treatment of tuberculosis. They act mainly by DNA gyrase and topoisomerase IV inhibition.[3)] Isatin is an endogenous indole found in mammalian brain, peripheral tissues, and body fluids. Heterocyclic moieties like isatin, phthalimide and 1,3,4-oxadiazole are also reported to possess antibacterial and antitubercular activities.[4–6)] They act by inhibiting the enzyme enoyl-ACP reductase.[7–9)]

Ciprofloxacin is one of the widely used fluoroquinolones that exhibits potent *in vitro* and *in vivo* antimycobacterial activity. Fluoroquinolones are also found to be active against diverse types of bacteria, including *Staphylococcus (S.) aureus, S. epidermis, Bacillus (B.) subtilis, Escherichia (E.) coli* and Mtb, at concentrations less than 1 μg/mL. Fluoroquinolones are therapeutically advantageous because of their extended antimicrobial activity, lack of plasmid-mediated resistance, large volume of distribution (or greater amount of tissue distribution) and minimal adverse effects.[10)]

In view of this, the area of fluoroquinolones has experienced an exponential growth over the last few decades and is still being pursued with more vigor to make available better drugs having multifunctional action.[11)] Chimeric drugs, a broad class of 'Multi-functional compounds' are the single entity molecules that constitute two or more pharmacophoric groups representing different mechanisms of action. They possess advantages such as reduced molecularity, improved pharmacokinetics and pharmacodynamics, devoid of drug–drug interactions *etc.*[12–14)] They are known to produce response by interacting with respective receptors of constituent pharmacophores, thus restoring the efficacy of individual drugs they represent. In this context, chemotherapy is the prime area of attention, hence the emergence of chimeric antibiotics to provide most effective multimechanistic, multimodal, multipotential molecules to treat more effectively the diseases like tuberculosis. Till date there are not many reports on chimeric fluoroquinolones.[15,16)] Hence in continuation of our works on developing anti-tuberculosis agents,[17–19)] now it is felt worthwhile to make an attempt to bring some potential

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Indian Journal of Chemistry
Vol. 60B, March 2021, pp. 433-438

Synthesis and anticonvulsant activity of some 1,4-dihydropyridine derivatives

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Received 25 February 2020; accepted (revised) 11 January 2021

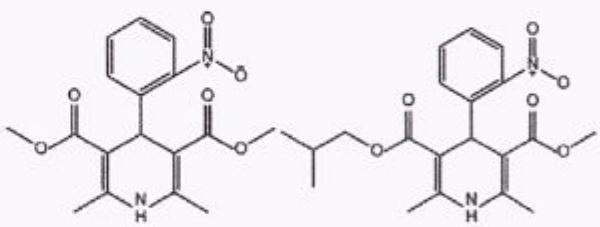
A series of asymmetrical 4-alkyl/aryl-2,6-dimethyl-3-N-(aryl/heteroaryl)-carbamoyl-5-ethoxycarbonyl-1, 4-dihydropyridines **3a-d** and symmetrical 4-alkyl/aryl-2,6-dimethyl-3,5-bis-(ethoxycarbonyl)-1,4-dihydropyridines **4a** and **4b** have been prepared by the condensation of various benzaldehydes, ethylacetoacetate, 2-aminopyridine or *p*-toludine in ethanol (Hantzch method). The structures of all the synthesized 1,4-dihydropyridine derivatives have been confirmed by spectral data (IR, ^{1}H NMR) and elemental analysis. Compounds **3a-c**, **4a** and **4b** (10 mg/kg) have been evaluated for their anticonvulsant effect against pentylenetetrazole- induced convulsions with phenytoin (4 mg/kg) as the standard. The anticonvulsant potential of the newly synthesized compounds have been assessed on the basis of increase in latency (onset time) to induce convulsions; decrease in number of convulsions and increase in latency of death compared to control and standard.

Keywords: 1,4-Dihydropyridine, Hantzsch method, pentylenetetrazole, anticonvulsant, synthesis

Convulsion is where the body muscles contract and unwind quickly and over and again, bringing about a wild shaking of the body[1]. In 1950's Bromide was introduced as first true antiepileptic drug (AED). The usage of Bromide has decreased in twentieth century when Phenobarbitone was accidentally discovered to be effective in suppressing seizures. Due to the side effects, toxicity and teratogenic effects of current antiepileptic drugs in the treatment of epilepsy, calcium channel blockers as antiepileptic agents have recently been considered[2]. There are considerable evidences that calcium is an important factor for the induction of epilepsy. Specifically, interesting seizure-instigating administrators or frameworks cause a quick intraneuronal union of calcium particles[3]. In particular, unique seizure-inciting operators or systems cause a fast intraneuronal convergence of calcium particles, which is easily identified with the ensuing epileptiform movement[4]. Conversely, calcium channel inhibitors (1,4-dihydopyridines) are effective against the whole range of convulsive procedures including electro, pentylene tetrazole, sound and pressure-induced seizures. Nifedipine and other dihydropyridine derivatives such as nimodipine, nitradipine, and nisoldipine (Figure 1) are potent blockers of the calcium channels of smooth muscles and also bind with high affinity to the brain membranes, hence can be employed as antiepileptic agents[5-8]. Considering the anticonvulsant potential of 1,4-dihydropyridines and in continuation to our work[9-14] on this scaffold herein we report the synthesis and anticonvulsant activity of 4-alky/aryl-2,6-dimethyl-3-N-(aryl/heteroaryl)-carbomo yl-5-ethoxycarbonyl-1,4-dihydropyridines **3a-d** and 4-alkyl/aryl-2,6-dimethyl-3,5-bis-(ethoxycarbonyl)-1,4-dihydropyridines **4a** and **4b** (Scheme I).

Results and Discussion

N-(aryl/heteroaryl)acetoacetamide **2** was synthesized from the reaction of *p*-toludine/2- aminopyridine and ethylacetoacetate **1** using conventional and microwave irradiation methods. In both the methods there was an increase in yield with increase in concentration of ethylacetoacetate up to 1:1.8 (*p*-toludine/ 2-aminopyridine: ethylacetoacetate), beyond which it decreased. Hence this ratio where highest yield was



Nifedipine Nisoldipine

Figure 1 — Potent calcium channel blockers

Indian Journal of Chemistry
Vol. 60B, April 2021, pp. 616-623

Synthesis, characterization and evaluation of new thiazole derivatives as anthelmintic agents

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Received 25 October 2019; accepted (revised) 3 March 2021

A series of 2-amino substituted 4-phenyl thiazole derivatives has been synthesized by the conventional method. The thiazole derivatives have been synthesized by three steps. The obtained five derivatives have been purified by recrystallization process by using methanol as solvent and column chromatography [IVd Compound] and have been characterized by melting point, TLC, FTIR, ^{1}H NMR and mass spectral data. All the five derivatives have been evaluated using *in silico* studies by using different softwares (Lipinski's Rule of 5, OSIRIS molecular property explorer, Molsoft molecular property explorer, PASS and docking studies). These compounds have then been evaluated for anthelmintic activity against Indian adult earth worms (*Pheretima postuma*). All the compounds show significant anthelmintic activity. The compound IVc and IVe are shown to be potent compounds when compared with the standard drug (Mebendazole). Molecular docking studies have guided and prove the biological activity of the sythesised compounds against beta tubulin protein (1OJ0).

Keywords: Anthelmintic activity, *Pheretima postuma*, molecular docking, thiazole derivatives, β-tubulin protein

Helminthic infections are one of the World's long standing health problems in humans and domestic animals. We can recognize many of the characteristic clinical features of helminthes infections from the ancient writings of Hippocrates, Egyptian medical papyri, and the Bible. In recent past, several reports of failures in the treatment of human helminthes have been published and suspected for anthelmintic resistance (AR). AR is the most important disease problem faced by sheep-farming industry in Australia, South Africa. Even multiple-drug resistance is not uncommon in helminthes of veterinary importance. Helminthes are resistant to all available broad spectrum anthelmintics[1-5]. Considering the fact of AR, its potential threat and potential anthelmintic activity of thiazole derivatives, it was planned to synthesize new thiazole derivatives as anthelmintic drugs.

Thiazole is a five-membered heterocyclic ring with nitrogen and sulfur atom. Thiazole and related compounds are called 1,3-azoles (nitrogen and one other heteroatom in a five- membered ring). They are isomeric with the 1,2-azoles, containing nitrogen and sulfur atoms called isothiazole. Thiazole itself is a clear to pale yellow liquid with a boiling point of 116-118°C. Its specific gravity is 1.2 and it is sparingly soluble in water. It is soluble in alcohol and ether[6]. Thiazole is an aromatic ring on the basis of delocalization of a lone pair of electrons from the sulfur atom. The resonance forms of thiazole are shown in Scheme I. The thiazoles synthesized by using different techniques are from haloketones using halogen and thiourea[7], using NBS and thiourea[8], using oxidizing agent[9], using formamide disulfide dihydrobromide[10], from α-haloketones[11] (Scheme I).

Experimental Section

Chemicals used for the synthetic work were 4-methyl acetophenone, Bromine (Br_2), hydrobromic acid (HBr), glacial acetic acid, thiourea, thionyl chloride ($SOCl_2$), acetonitrile, acetyl chloride, chloro acetic acid, ethyl chloro formate, 4-chloro aniline, benzoyl chloride.

All the reactions were performed in the dried Borosil glass beakers, round bottomed flasks, conical flasks. Precoated silica gel plates (Merck) were used for TLC to monitor progress of the reaction. Compounds melting points were determined by capillary method and are uncorrected. JASCO UV chamber was used for detection of spots in TLC. IR spectra were recorded on Bruker FTIR spectrometer. ^{1}H NMR spectra were recorded on Bruker-400MHz spectrometer using DMSO-d_6 as solvent. The chemical shift data were expressed as values relative to TMS in δ (ppm).

Indian Journal of Chemistry
Vol. 61, March 2022, pp. 293-297

Synthesis, characterization and evaluation of thiopyrimidine derivatives as possible antimicrobial agents

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Received 7 June 2020; accepted (revised) 8 November 2021

A series of new thiopyrimidine derivatives have been synthesized *via* the reaction of Chalcones **3a-c** with thiourea to give the corresponding pyrimidine thiones **4a-c**. S-alkylation of pyrimidine thiones have resulted in novel 4,6-diaryl-2-alkyl thiopyrimidine **5a-i** derivatives. Molecular properties like number of hydrogen bond acceptors, number of hydrogen bond donors, volume, polar surface area, molar refractivity, number of rotatable bonds and drug likeness for synthesized compounds have been predicted by using different softwares such as Molinspiration, Molsoft and Chemsketch. The newly synthesized 4,6-diaryl-2-alkyl thiopyrimidine derivatives **5a-i** have been evaluated for their possible anti-microbial activity. Compounds **5b**, **5d** and **5e** have revealed significant activity against *E. coli*, *P. aerugenosa* (Gram +ve) and *B. subtilis*, *S. aureus* (Gram −ve) species while compounds **5a**, **5c**, **5f-i** are moderately active as compared to the standard drug Ciprofloxacin. Compounds **5c** and **5g** show potent anti-fungal activity against *Penicillium* species amongst the series in comparison to the standard Fluconazole.

Keywords: Chalcone, thiopyrimidine, S-alkylation, molecular properties, anti-microbial

Pyrimidine is one of the most important heterocycles exhibiting remarkable pharmacological activities. It contains two nitrogen atoms at positions 1 and 3 of the six-membered ring exhibiting a wide range of biological activities. Numerous methods for the synthesis of pyrimidine offer enormous scope in the field of medicinal chemistry[1,2]. Condensed pyrimidine derivatives have been reported as anti-microbial, analgesic, anti-viral, anti -inflammatory, anti- HIV, anti-tubercular, anti-tumor, anti-neoplastic, anti-malarial, diuretic, cardiovascular agents and hypnotic drugs for the nervous system, calcium-sensing receptor antagonists, adenosine receptor antagonists, *etc*.[3] Thiopyrimidines (Figure 1) are broadly found in bioorganic and medicinal chemistry with applications in drug discovery and developments[4]. They are reported to possess broad spectrum of biological activities such as antibacterial, fungicidal, insecticidal, antihypertensive, tranquilizing, analgesic, antidiabetic, anticancer, *etc*.[5,6] Recent reports revealed thiopyrimidine derivatives as platelet aggregation inhibitors and as selective inhibitors of CDK2 transferase[7].

Thus, in view of their biological potential and to produce new molecules to combat the problem of drug resistance in microbial infections, some new thiopyrimidine derivatives have been designed in the present work based on our earlier studies on thiopyrimidines[8]. Herein, we report the synthesis and antimicrobial activity of some 4,6-diaryl-2-alkyl thiopyrimidines **5a-i**.

Results and Discussion

Chemistry

α,β-Unsaturated ketones (chalcones) **3a-c** have been prepared according to crossed aldol condensation by condensing aromatic/heteroaromatic methyl ketone **1** with different aromatic/heteroaromatic aldehydes **2** in dilute ethanolic sodium hydroxide solution at RT. Reaction of appropriate chalcones **3a-c** with thiourea and sodium hydroxide in ethanol produced thiopyrimidines **4a-c**. S-alkylation of thiopyrimidines **4a-c** using appropriate alkyl halides in presence of ethanolic sodium hydroxide solution *via* nucleophilic substitution reaction afforded 4,6-diaryl-2-alkyl thiopyrimidines **5a-i** (Scheme I).

Molecular Properties Prediction

Various molecular properties for synthesized compounds were predicted by using different softwares such as Molinspiration, Molsoft and Chemsketch[9].

International Journal of Pharmacy and Pharmaceutical Sciences

ISSN- 0975-1491

Vol 10, Issue 11, 2018

Original Article

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Methods: Diabetes is induced by intraperitoneal injection of alloxan at a dose of 120 mg/kg b. w in rats. Rats were divided into 5 groups (normal control, disease control, metformin, test 1 and test 2). In test groups 1 and 2, SASESC (standardized aqueous seed extract of *syzygium cumini*) and SAFEMC (standardized aqueous fruit extract of *momordica charantia*) were respectively administered orally to alloxan induced diabetic rats, and their serum electrolyte levels were observed at 1st, 4th, 7th and 14th days.

Results: By the 14thday, the Na^+ and K^+ levels in groups 4 and 5 were almost normal. However, in group 3 (standard), Na^+ levels were relatively lower and K^+ levels were relatively higher than groups 4 and 5 (test). In group 2 (disease control) as compared to group 1 (normal control), a decrease in Na^+ and increase in K^+ levels was observed even on day 14.

Conclusion: Treatment with anti diabetic drugs like metformin, *syzygium cumini* (test-1), *momordica charantia* (test-2) restored the electrolyte levels almost back to normal over a period of study (14 d). There was significant (**P<0.01, *P<0.05) normalization of electrolyte levels in diabetic rats. It was concluded that *syzygium cumini* and *momordica charantia* showed better efficiency in restoring the electrolyte imbalance as compared to metformin during our study.

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INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic diseases characterized by high blood glucose level (hyperglycemia) resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs like the eyes, kidneys, nerves, heart, and blood vessels [1, 2]. Electrolytes are salts in the body that conduct electricity and are found in fluid, tissue and blood. A proper balance of electrolytes such as sodium (Na^+), potassium (K^+), calcium (Ca^{2+}), magnesium (Mg^{2+}) and others are essential for overall health. They have a pivotal role in the maintenance of homeostasis inside the body, regulation of heart and brain function, body fluid balance, ventilation, pH etc [3]. Deficiency or imbalance of electrolytes can lead to serious conditions. DM is amongst those diseases which show frequent disturbances of electrolytes and acid-base relations, especially in patients with deranged renal function and other end-organ injury, mal-absorption syndromes, acid-base imbalances and multiple drug regimens and medications for DM management. The knowledge and insight of the disease process and its management would create the way for 'pathophysiology-directed therapy', leading to prevention of the several adverse effects associated with acid-base and electrolyte disorders and their management [4-8].

Alterations of ionized Na^+, K^+, and Mg^+ in the serum have been reported in DM subjects, both as causes and consequences. There is also increasing evidence that electrolyte imbalances are early biochemical events responsible for long-term diabetic complications. Considerable variations in the electrolyte metabolism may exist in populations depending on the genetic constitution, nutritional status, and environmental situation. It has been suggested that alterations in Na^+, K^+, Ca^{2+} and other biologically relevant elements might occur due to malfunction of Na^+-K^+ pumps. There is increasing evidence that these alterations of electrolytes across the cell may play a vital role in the mechanism of cellular injury leading to retinopathy, nephropathy, and neuropathy in DM subjects [9]. The present study was chosen to investigate the serum levels of Na^+ and K^+ in alloxan-induced diabetic rats without any complications.

Drugs used to treat DM like metformin and sulfonylureas along with tricyclic antidepressants (used to treat neuropathy) can also cause electrolyte and acid-base disturbances. In modern medicine, no satisfactory effective therapy is available to control DM along with electrolyte imbalance. The literature survey reveals that anti-diabetic herbs have the capacity to cure electrolyte imbalance along with DM [10-13]. In this regard, an herbal anti-diabetic drug used traditionally viz., *momordica charantia* and *syzygium cumini* were chosen for the present study to investigate a possible effect of the standardized aqueous fruit extract of *momordica charantia (*SAFEMC*)* and standardized aqueous seed extract of *syzygium cumini* (SASESC) on the serum electrolytes in alloxan-induced diabetic rats.

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International Journal of Pharmacy and Pharmaceutical Sciences

ISSN- 0975-1491 Vol 10, Issue 12, 2018

Original Article

NEW VALIDATED METHOD DEVELOPMENT FOR THE ESTIMATION OF SULFAMETHOXAZOLE AND TRIMETHOPRIM IN BULK FORM BY VISIBLE SPECTROSCOPY

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Received: 11 Apr 2018 Revised and Accepted: 13 Nov 2018

ABSTRACT

Objective: To develop three novel, sensitive, simple validated visible spectrophotometric methods for the quantitative estimation of sulfamethoxazole (SMZ) and trimethoprim (TMP) in bulk form.

Methods: Methods were based on coupling the diazotized aromatic primary amino group of the studied drugs with *o*-phenylenediamine (OPD) in an acidic medium. The first two methods have been proposed for estimation of SMZ and rest for TMP. The resulting products were measured by spectrophotometric (method I, II and III) tools. The methods were validated as per ICH guidelines.

Results: In method I, the absorbance was measured at 482 and 457 nm with linearity ranges of 4.0-40.0 and 5.0-45.0 µg/ml for SMZ. On the other hand, method III was devoted to estimate TMP spectrophotometrically at 457 nm with linearity range of 5-30 µg/ml. The r^2 value for all methods were found to be 0.99. The percentage recoveries of SMZ and TMP were found to be 97.98%, 97.56% and 97.55% respectively. The developed methods were subjected to detailed validation procedure in their pure forms.

Conclusion: The study concludes that visible spectrophotometric validation methods can be very efficient and economically promising technique for the quantitative analysis of SMZ and TMP in bulk form. The statistical analysis of data indicates that the developed methods were reproducible and specific. It was found that there is a good agreement between the obtained results and those obtained by the reported methods; moreover they can be used for the routine estimations of SMZ and TMP in bulk form.

Keywords: Sulfamethoxazole, Trimethoprim, Diazotization, Visible spectrophotometry, Validation

DOI: http://dx.doi.org/10.22159/ijpps.2018v10i12.26650

INTRODUCTION

Sulfonamides are extensively used for the treatment of different bacterial infections in human and veterinary practice [1]. Sulfonamides of pharmaceutical products usually consist, of one sulfonamide mixed with another drug that increases the power of the sulfonamide, e.g. the SMZ and TMP binary mixture. The synergistic antibacterial effect of TMP in combination with sulfonamide is well known both in the *in vitro* and *in vivo* situations [2].

SMZ is chemically 4-amino-N-(5-methylisoxazol-3-yl)-benzene sulfonamide (fig. 1) is a structural analog of para-aminobenzoic acid. Inhibiting the production of dihydrofolate intermediate binding through dihydropteroate synthetase interferes with the normal bacterial synthesis of folic acid, which inhibits the folate-dependent metabolic process for bacterial growth [3].

TMP is designated chemically as 5-(3,4,5-trimethoxy benzyl) pyrimidine-2,4-diamine (fig. 2) which binds dihydrofolate reductase and decrease the levels of tetrahydrofolic acid which an essential precursor in the thymidine synthesis pathway, inhibits bacterial DNA synthesis. TMP affinity for bacterial dihydrofolate reductase is several thousand times greater than its affinity for human dihydrofolate reductase [4].

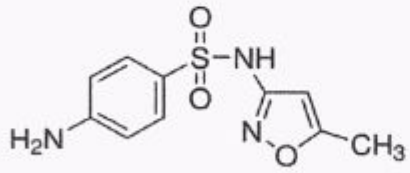

Fig. 1: Structure of SMZ

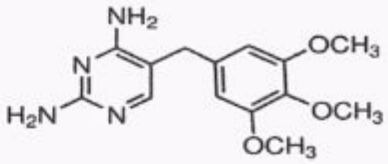

Fig. 2: Structure of TMP

Among the various methods available for the estimation of these drugs in literature survey, such as charge transfer complexation [5], uv-visible spectrophotometry [6-16], square wave voltametry [17], rapid UPLC [18], HPLC [19], chemical evaluation [20], spectroflourimetry [21] and flow injection system/HPLC with potentiometry [22], colorimetric sensors have attracted increasing considerations for their convenience of visual observation and simple operations in recent years [23-25]. OPD and its derivatives have been widely used in the estimation of enzymes and drugs [26, 27].

From literature, hitherto there are no visible spectrophotometric methods reported for the estimation of SMZ and TMP using OPD through diazotization followed by coupling reaction which encouraged us to develop these methods. Hence, for the first time, we describe few simple, sensitive, cost-effective, novel methods using OPD to assay these drugs in bulk samples.

MATERIALS AND METHODS

Apparatus

The visible spectra of drug solutions were recorded on a Shimadzu 1800 UV/Vis spectrophotometer at room temperature in 1 cm quartz cell. The wavelength range was from 200 to 800 nm. For spectral data acquisition and processing UV probe software was used.

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Objective: To develop three novel, sensitive, simple validated visible spectrophotometric methods for the quantitative estimation of sulfamethoxazole (SMZ) and trimethoprim (TMP) in bulk form.

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Results: In method I, the absorbance was measured at 482 and 457 nm with linearity ranges of 4.0-40.0 and 5.0-45.0 µg/ml for SMZ. On the other hand, method III was devoted to estimate TMP spectrophotometrically at 457 nm with linearity range of 5-30 µg/ml. The r^2 value for all methods were found to be 0.99. The percentage recoveries of SMZ and TMP were found to be 97.98%, 97.56% and 97.55% respectively. The developed methods were subjected to detailed validation procedure in their pure forms.

Conclusion: The study concludes that visible spectrophotometric validation methods can be very efficient and economically promising technique for the quantitative analysis of SMZ and TMP in bulk form. The statistical analysis of data indicates that the developed methods were reproducible and specific. It was found that there is a good agreement between the obtained results and those obtained by the reported methods; moreover they can be used for the routine estimations of SMZ and TMP in bulk form.

Keywords: Sulfamethoxazole, Trimethoprim, Diazotization, Visible spectrophotometry, Validation

DOI: http://dx.doi.org/10.22159/ijpps.2018v10i12.26650

INTRODUCTION

Sulfonamides are extensively used for the treatment of different bacterial infections in human and veterinary practice [1]. Sulfonamides of pharmaceutical products usually consist, of one sulfonamide mixed with another drug that increases the power of the sulfonamide, e.g. the SMZ and TMP binary mixture. The synergistic antibacterial effect of TMP in combination with sulfonamide is well known both in the *in vitro* and *in vivo* situations [2].

SMZ is chemically 4-amino-N-(5-methylisoxazol-3-yl)-benzene sulfonamide (fig. 1) is a structural analog of para-aminobenzoic acid. Inhibiting the production of dihydrofolate intermediate binding through dihydropteroate synthetase interferes with the normal bacterial synthesis of folic acid, which inhibits the folate-dependent metabolic process for bacterial growth [3].

TMP is designated chemically as 5-(3,4,5-trimethoxy benzyl) pyrimidine-2,4-diamine (fig. 2) which binds dihydrofolate reductase and decrease the levels of tetrahydrofolic acid which an essential precursor in the thymidine synthesis pathway, inhibits bacterial DNA synthesis. TMP affinity for bacterial dihydrofolate reductase is several thousand times greater than its affinity for human dihydrofolate reductase [4].

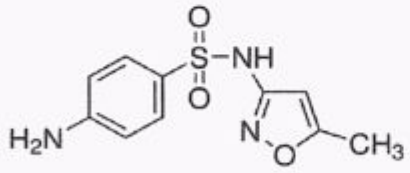

Fig. 1: Structure of SMZ

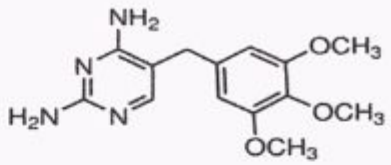

Fig. 2: Structure of TMP

Among the various methods available for the estimation of these drugs in literature survey, such as charge transfer complexation [5], uv-visible spectrophotometry [6-16], square wave voltametry [17], rapid UPLC [18], HPLC [19], chemical evaluation [20], spectroflourimetry [21] and flow injection system/HPLC with potentiometry [22], colorimetric sensors have attracted increasing considerations for their convenience of visual observation and simple operations in recent years [23-25]. OPD and its derivatives have been widely used in the estimation of enzymes and drugs [26, 27].

From literature, hitherto there are no visible spectrophotometric methods reported for the estimation of SMZ and TMP using OPD through diazotization followed by coupling reaction which encouraged us to develop these methods. Hence, for the first time, we describe few simple, sensitive, cost-effective, novel methods using OPD to assay these drugs in bulk samples.

MATERIALS AND METHODS

Apparatus

The visible spectra of drug solutions were recorded on a Shimadzu 1800 UV/Vis spectrophotometer at room temperature in 1 cm quartz cell. The wavelength range was from 200 to 800 nm. For spectral data acquisition and processing UV probe software was used.

International Journal of Pharmaceutical Sciences and Nanotechnology
Volume 13 • Issue 5 • September – October 2020
Research Paper https://doi.org/10.37285/ijpsn.2020.13.5.4 MS ID: IJPSN-5-12-20-SIRISHA

Design, Synthesis and Pharmacological Evaluation of New Thiazole Derivatives as Anthelmintic Agents

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Received May 12, 2020; accepted June 21, 2020

ABSTRACT

Pharmacological agents that kills parasites are essential drugs in some tropical countries. In this study, a series of 2-amino substituted 4-phenyl thiazole derivatives (4a-e) have been synthesized by the conventional method. The thiazole derivatives were synthesized by three steps. The obtained five derivatives were purified by recrystallization using methanol as a solvent or column chromatography. They were characterized by melting point, TLC, FTIR, ^{1}H NMR and MASS spectral data. Compounds 4a-e were evaluated *in silico* by using different software's (Lipinski's Rule of 5, OSIRIS molecular property explorer, Molsoft molecular property explorer, and PASS & docking studies). These compounds were then evaluated for their possible anthelmintic activity against Indian adult earth worms (*Pheritima postuma*). All the compounds displayed significant anthelmintic activity. Compound 4c and 4e were more potent compounds when compared with the standard drug (mebendazole). Molecular docking studies guided and proved the biological activity against beta tubulin protein (1OJ0). In conclusions, these new molecules have promising potential as anthelmintic for treatment of parasites.

KEYWORDS: Anthelmintic ativity; *Pheritima postuma*; Molecular docking; Thiazole derivatives; β-tubulin protein.

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Thiazole is a five-membered heterocyclic ring with nitrogen and sulfur atoms. It is a 1, 3-azole which is found to have various pharmacological activities like Anticancer (Gomha *et al.*, 2017), Antibacterial (Seema and Satya 2017), Antifungal & Anti-convulsant (Krizysztof *et al.*, 2018), Anti-inflammatory, Analgesic (Bhosale *et al.*, 2012) and Anthelmintic (Himaja *et al.*, 2012) activities. Considering the fact of AR, its severe threat and potential anthelmintic activity of thiazole derivatives, here in an attempt was made to design, synthesize, and evaluate some new thiazole derivatives as anthelmintic drugs.

Materials and Methods

Chemicals used for the synthetic work were 4-methyl acetophenone, bromine, hydrobromic acid, glacial acetic acid, thiourea, thionyl chloride, acetonitrile, acetyl chloride, chloro acetic acid, ethyl chloro formate, 4-chloro aniline, benzoyl chloride.

All the reactions were performed in dried borosil glass beakers, round bottomed flasks, conical flasks. Precoated silica gel plates (MERCK) were used for TLC to monitor progress of the reaction. Compounds melting points were determined by capillary method and are uncorrected. JASCO UV chamber was used for detection of spots in TLC. IR spectra were recorded on BRUKER FTIR spectrometer. ^{1}H NMR spectra were recorded on BRUKER-400MHZ spectrometer using DMSO as solvent. The chemical shift data were expressed as values relative to TMS in ppm. Mass spectra were recorded on a 70eV GC-MS Shimadzu instrument. Elemental analyses (C, H, and N) of the compounds were obtained from Perkin-Elmer 240B analyzer and were within ± 0.4%of the theoretical values.

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In Silico Screening

Lipinski's rule of 5 filtration

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IJPSR (2021), Volume 12, Issue 4 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 03 April 2020; received in revised form, 19 August 2020; accepted, 05 September 2020; published 01 April 2021

SIMULTANEOUS ESTIMATION OF CIPROFLOXACIN AND METRONIDAZOLE IN BULK AND TABLET FORMULATION BY UV SPECTROPHOTOMETRY

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Keywords:

UV, Simultaneous equation method, Q-absorbance ratio method, Ciprofloxacin, Metronidazole

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ABSTRACT: Three simple and economical UV-spectrophotometric methods have been developed and validated for simultaneous estimation of ciprofloxacin (CIP) and metronidazole (MET) in a tablet dosage form using distilled water as a green solvent. The proposed methods were; simultaneous equation method (method A), Q-absorbance ratio method (method B), and area under curve method (method C). λ_{max} of CIP & MET in distilled water were found to be 271 nm and 320 nm, respectively. The isoabsorptive point was observed at 290 nm. The linearity was obtained in the concentration range of 1-9 µg/ml, and 2-18 µg/ml for CIP and MET respectively by methods A, B & C. Validation parameters were carried out. All three methods were found to be linear, accurate, precise, and specific. Good results were achieved using distilled water as solvent due to its greater solubility, reproducible readings with maximum absorbance. Among the three methods, method C was found to be the most sensitive. Hence, this method can be recommended for the routine analysis of this drug combination.

INTRODUCTION: Ciprofloxacin (CIP) is chemically 1-cyclopropyl-6-fluoro-1, 4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinoline carboxylic acid **Fig. 1**. It is a fluoroquinolone antibiotic useful for the treatment of various infections caused by Gram-positive, Gram-negative organisms and against *Mycobacterium tuberculosis*. The bactericidal action of CIP results from inhibition of the enzymes topisomerase 2 (DNA gyrase) and topisomerase 4, which are required for bacterial DNA replication, transcription repair, and recombination [1, 2]. Metronidazole (MET) is designated chemically as 2-(2-methyl-5-nitro-1*H*-imidazole-1-yl) ethan-1-ol **Fig. 2**.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.12(4).2247-56

This article can be accessed online on www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.12(4).2247-56

It is a prodrug unionized and the most useful antiprotozoal nitroimidazole derivative. It has been found to possess efficacy against obligate anaerobic bacteria due to their ability to intracellularly reduce MET to its active form, which then covalently binds to DNA, disrupts its helical structure, inhibiting the bacterial nucleic acid synthesis and results in bacterial cell death [3, 4].

A survey of literature has revealed several analytical methods for the determination of CIP in pharmaceutical dosage form and biological fluids, including spectrophotometry [5-9], spectrofluorimetry [10], HPLC [11-13], potentiometry [14], electrical micro-titration [15], and HPTLC [16]. CIP in admixtures with MET [17] and ampicillin has been determined by NMR [18]. HPLC methods either with fluorescence detection or coupled with mass spectrometry (LC/MS) for determination of CIP in human plasma [19, 20], and by SPE-UHPLC-PDA [21] have also been published. MET has been determined by several methods involving spectrophotometry [22]

IJPSR (2021), Volume 12, Issue 4 **(Research Article)**

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INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
www.irjponline.com
ISSN 2230 – 8407

Research Article

NEW RP-HPLC METHOD FOR THE SIMULTANEOUS ESTIMATION OF PARACETAMOL AND TRAMADOL HYDROCHLORIDE IN BULK AND TABLET DOSAGE FORM

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Article Received on: 16/03/18 Approved for publication: 29/05/18

DOI: 10.7897/2230-8407.09694

ABSTRACT

The present work was focused on developing a new RP-HPLC method for the simultaneous estimation of paracetamol and tramadol hydrochloride in bulk and tablet dosage form and to validate it as per ICH and USP guidelines. The method involves use of water and acetonitrile in 9:1 ratio as mobile phase pumped at a rate of 1 ml/min. The optimum wavelength selected for monitoring was 268nm. C_{18} column (4.6mm×250mm) of 5µ particle size was used as stationary phase. The method was finally validated, and parameters were reported. The system suitability parameters passed in which the asymmetric factors for Paracetamol and Tramadol were 1.54 and 1.09 respectively. Linearity ranges were found to be 20 to 100µg/ml with a correlation coefficient of 0.998. Accuracy studies reported a mean recovery of 98.7% for both the drugs. Faster retention times (1.1min and 4.1min) make the method simple and economic. Thus a validated and sensitive RP-HPLC method was developed for simultaneous estimation of Paracetamol and tramadol in bulk and tablet dosage form.

KEY WORDS: HPLC, Method, Paracetamol, Tramadol hydrochloride, Validation.

INTRODUCTION

Pain is an unpleasant sensation which can lead to distress and discomfort[1]. Pain can be acute or chronic. Drugs used to treat pain are called pain killers or analgesics. Paracetamol and Tramadol are commonly used analgesics. Paracetamol (Figure 1) is chemically N-(4-Hydroxyphenyl)ethanamide or N-(4-Hydroxyphenyl)acetamide. It is a cyclooxygenase-2 (Cox-2) inhibitor and it is used to treat fever and pain. Tramadol (Figure 2) is chemically trans-2-(Dimethylaminomethyl)-1-(m-methoxyphenyl)cyclohexanol. It is an Opioid receptor agonist, 5-HT inhibitor and it is used to treat mild to severe pain, depression. Both paracetamol and tramadol are practically freely soluble in water and methanol[2-3].

Literature survey reveals that much work is documented on the chromatographic (HPLC & HPTLC) estimation of these two drugs in combined pharmaceutical dosage forms[4-17]. However, they are tedious, time consuming and costly. Hence there is a need for the development of a relatively simple, precise, accurate, reproducible and cost effective HPLC method for the estimation of paracetamol and tramadol in tablets and to validate the developed method as per ICH and USP guidelines.

MATERIALS AND METHODS

Instrumentation

The analysis was carried out on a HPLC system (SPINCO BIOTECH) equipped with UV detector. Other apparatus and instruments used were electronic balance (Keroy). Digital pH meter (Systronics). Magnetic stirrer (Remi). Millipore (Direct Q UV3). Ultra sonicator (Pci). Micro pipette (Physio care). Membrane filters (Sartorins). UV- Spectro photometer (Shimadzu UV 1800) (Toshvin). Pipettes and volumetric flasks (Borosil). All instruments and glass-wares were calibrated

Materials

API of Paracetamol was obtained from MSN labs and Tramadol hydrochloride was obtained from NEQ Pvt. Ltd. Tablets (ULTRACET) were purchased from Local market. All chemicals and reagents used were of AR grade.

Chromatographic Conditions

The mobile phase consisted of water and acetonitrile. The chromatograph was operated in the isocratic mode starting at a mobile phase of water: acetonitrile (90:10 v/v). Eluent was delivered at a flow rate of 1 mL/min. Absorbance was monitored at 268 nm.

Preparation of Mobile Phase

Mix 90ml water and 10ml acetonitrile and degas in ultrasonic water bath for 15 minutes. Filter through 0.2 µ filter under vacuum filtration before injection.

Standard Solution preparation

Accurately weigh and transfer 20 mg each of paracetamol and tramadol hydrochloride standard drugs into a 10ml clean dry volumetric flask, add about 7ml of methanol and sonicate to dissolve it completely and make up the volume to the mark with methanol. From this stock solution, aliquots were transferred in

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DOI: 10.7897/2230-8407.09694

ABSTRACT

The present work was focused on developing a new RP-HPLC method for the simultaneous estimation of paracetamol and tramadol hydrochloride in bulk and tablet dosage form and to validate it as per ICH and USP guidelines. The method involves use of water and acetonitrile in 9:1 ratio as mobile phase pumped at a rate of 1ml/min. The optimum wavelength selected for monitoring was 268nm. C_{18} column (4.6mm×250mm) of 5µ particle size was used as stationary phase. The method was finally validated, and parameters were reported. The system suitability parameters passed in which the asymmetric factors for Paracetamol and Tramadol were 1.54 and 1.09 respectively. Linearity ranges were found to be 20 to 100µg/ml with a correlation coefficient of 0.998. Accuracy studies reported a mean recovery of 98.7% for both the drugs. Faster retention times (1.1min and 4.1min) make the method simple and economic. Thus a validated and sensitive RP-HPLC method was developed for simultaneous estimation of Paracetamol and tramadol in bulk and tablet dosage form.

KEY WORDS: HPLC, Method, Paracetamol, Tramadol hydrochloride, Validation.

INTRODUCTION

Pain is an unpleasant sensation which can lead to distress and discomfort[1]. Pain can be acute or chronic. Drugs used to treat pain are called pain killers or analgesics. Paracetamol and Tramadol are commonly used analgesics. Paracetamol (Figure 1) is chemically N-(4-Hydroxyphenyl)ethanamide or N-(4-Hydroxyphenyl)acetamide. It is a cyclooxygenase-2 (Cox-2) inhibitor and it is used to treat fever and pain. Tramadol (Figure 2) is chemically trans-2-(Dimethylaminomethyl)-1-(m-methoxyphenyl)cyclohexanol. It is an Opioid receptor agonist, 5-HT inhibitor and it is used to treat mild to severe pain, depression. Both paracetamol and tramadol are practically freely soluble in water and methanol[2-3].

Literature survey reveals that much work is documented on the chromatographic (HPLC & HPTLC) estimation of these two drugs in combined pharmaceutical dosage forms[4-17]. However, they are tedious, time consuming and costly. Hence there is a need for the development of a relatively simple, precise, accurate, reproducible and cost effective HPLC method for the estimation of paracetamol and tramadol in tablets and to validate the developed method as per ICH and USP guidelines.

MATERIALS AND METHODS

Instrumentation

The analysis was carried out on a HPLC system (SPINCO BIOTECH) equipped with UV detector. Other apparatus and instruments used were electronic balance (Keroy). Digital pH meter (Systronics). Magnetic stirrer (Remi). Millipore (Direct Q UV3). Ultra sonicator (Pci). Micro pipette (Physio grip). Membrane filters (Sartorins). UV- Spectro photometer (Shimadzu UV 1800) (Toshvin). Pipettes and volumetric flasks (Borosil). All instruments and glass-wares were calibrated

Materials

API of Paracetamol was obtained from MSN labs and Tramadol hydrochloride was obtained from NEQ Pvt. Ltd. Tablets (ULTRACET) were purchased from Local market. All chemicals and reagents used were of AR grade.

Chromatographic Conditions

The mobile phase consisted of water and acetonitrile. The chromatograph was operated in the isocratic mode starting at a mobile phase of water: acetonitrile (90:10 v/v). Eluent was delivered at a flow rate of 1 mL/min. Absorbance was monitored at 268 nm.

Preparation of Mobile Phase

Mix 90ml water and 10ml acetonitrile and degas in ultrasonic water bath for 15 minutes. Filter through 0.2 µ filter under vacuum filtration before injection.

Standard Solution preparation

Accurately weigh and transfer 20 mg each of paracetamol and tramadol hydrochloride standard drugs into a 10ml clean dry volumetric flask, add about 7ml of methanol and sonicate to dissolve it completely and make up the volume to the mark with methanol. From this stock solution, aliquots were transferred in

ISSN (Print 0974-2115) (Online 2349-8552)
www.jchps.com Journal of Chemical and Pharmaceutical Sciences

Development and Validation of a new UFLC method for the estimation of Chlorhexidine in bulk drug

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ABSTRACT

A simple, sensitive and specific UFLC method was developed to estimate Chlorhexidine in bulk drug. Acetonitrile and Water were used in 60:40 v/v ratio as mobile phase. The flow rate of eluent was fixed at 0.8 mL/min. Absorbance was monitored at λmax of 235 nm. A reverse phase column C18, (250mm x 4.6mm i.d., 5µm) was used as stationary phase. The retention time was found to be 2.99 minutes. The linearity range of Chlorhexidine was found to be 1-6 µg/ml at 235nm wavelength.

KEY WORDS: UFLC, Chlorhexidine, Retention time, Linearity.

1. INTRODUCTION

Chlorhexidine is a biguanide antiseptic. Its chemical name is N, N^1-1, 6-Hexanediylbis [N^1-(4-chlorophenyl) imidodicarbonimidic diamide] and its molecular formula is $C_{22}H_{30}Cl_2N_{10}$ (Figure.1.) (Jeffery, 1989). It has a broad spectrum of activity against different microorganisms. Hence it is widely used in dentistry, human and veterinary medicine (Fiorentino, 2010). Antimicrobial effects of Chlorhexidine are associated with the attraction between the drugs and bacterial cells bearing negative charge, thus disrupting the cell membrane integrity.

Literature survey reveals that several reports have been published on the spectroscopic (UV) (Gurdeep, 1991; Paresh, 2014; Rushikesh, 2016; Tarig, 2017) or chromatographic (HPLC) (Bagdanovska, 2014; Liljana, 2014; Zhesu, 2013; Dave, 2012; Zhang, 2012; Soyseven, 2012; Marco, 2011; Beckett, 2002; Snyder, 1997; Skoog, 1980) estimation of chlorhexidine. However, majority of the reports on HPLC revealed the usage of mobile phase containing buffers and longer retention times. Hence, it is felt worthwhile to develop and validate a new, simple, faster UFLC method to estimate chlorhexidine.

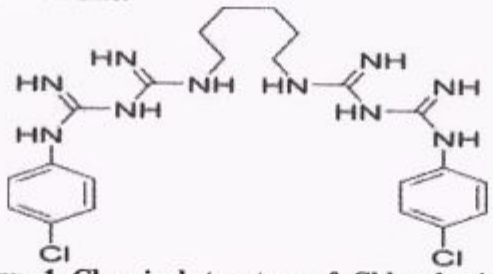

Figure.1. Chemical structure of Chlorohexidine

2. MATERIALS AND METHODS

Instrumentation: UFLC SPD-20A (SHIMADZU), UV-VIS spectrophotometer, UV-1800 (SHIMADZU), Analytical balance AY220 (SHIMADZU), pH meter MK V1 (DIGITAL), Ultra SonicatorPCi (BIOTECHNICS).

Chemicals and reagents: Analytically pure Chlorohexidine was gifted by MSN laboratories. HPLC grade Methanol (HIMEDIA), Acetonitrile (SIGMA ALDRICH), Triethylamine, Ortho phosphoric acid (FINAR) were purchased. Millipore water of HPLC grade was used.

Chromatographic conditions: Glassware used were thoroughly washed using chromic acid cleansing mixture, rinsed with water and dried. Acetonitrile and Water were used in ratio of 60:40 v/v as mobile phase. 0.8 mL/min was fixed as flow rate to deliver the eluent, the run time was 10 minutes and the injection volume was 20µL. Absorbance was monitored at λmax of 235 nm.

Preparation of mobile phase: A mixture of about 400 mL water and 600 mL Acetonitrile (HPLC grade) were mixed and degassed in an ultrasonicator for 5 min. 0.45 µ filter was used to filter the final solution under vacuum. The mobile phase thus prepared was also used as diluent.

Standard Solution Preparation: Standard stock solution of Chlorhexidine was obtained by dissolving 10mg of Chlorhexidine bulk drug in 10ml of methanol to give 1mg/ml of solution (Stock solution). Further dilutions were prepared from the standard stock solution to obtain 1, 2, 3, 4, 5, 6 µg/ml of the solutions.

3. RESULTS AND DISCUSSION

Determination of absorption maxima (λ_{max}): 10µg/ml standard solution of Chlorhexidine was prepared using methanol and scanned in UV Spectrophotometer from 200-400 nm.

Pharmaceutical Chemistry Journal, Vol. 52, No. 1, April, 2018 (Russian Original Vol. 52, No. 1, January, 2018)

SEARCH FOR NEW DRUGS

MULTIDRUG RESISTANCE REVERSAL ACTIVITY OF SOME NEW DIHYDROPYRIDINES STUDIED BY *IN SITU* SINGLE-PASS INTESTINAL PERFUSION (SPIP) METHOD IN RAT

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Original article submitted March 20, 2017.

P-glycoprotein (P-gp) mediated efflux affects the pharmacokinetics of several drugs. By analogy to verapamil, 1,4-dihydropyridines (DHPs) have been widely studied as P-gp inhibitors. Previously, we have reported on two new DHPs: IA_1(A) and IIA_5(B) as inhibitors of human MRP1, an efflux protein closely related to P-gp. The aim of the present study was to investigate the inhibitory effects of these two compounds on intestinal P-gp using the method of *in situ* single-pass intestinal perfusion (SPIP) in rat. According to this, the intestinal absorption of zidovudine (a P-gp substrate) was studied in anaesthetized rat jejunum in the absence and presence of DHPs IA_1(A) and IIA_5(B) (2 mg/kg). Verapamil (0.8 mg/kg), a well-known P-gp inhibitor, was employed as a standard. Zidovudine solution (200 ig/mL) in phosphate buffer (pH 7.4) was perfused through the jejunal segment, the perfusate concentrations were quantified by HPLC, and the permeability coefficient (P_{eff}) and fraction absorbed (F_{abs}) were calculated. Phenol red was used as a non-absorbable marker to correct water flux through the segment. In rats pretreated with compounds IA_1 and IIA_5, P_{eff} and F_{abs} of zidovudine were found to be 0.1669 ± 0.12 cm/sec, 0.2035 ± 0.18 and 0.2798 ± 0.12 cm/sec, 0.3015 ± 0.14, respectively, and were comparable to those of the standard ($P_{eff} = 0.462713 \pm 0.3$ cm/sec, $F_{abs} = 0.511835 \pm 0.14$). The differences between IA_1, IIA_5 and the standard were evaluated using ANOVA and found to be statistically significant ($P < 0.05$). Compounds IA_1 and IIA_5 have a modulating effect on intestinal P-gp. Compound IIA_5 was relatively more potent P-gp inhibitor and, quite interestingly, the results were in agreement with our earlier *in silico* and *in vitro* studies.

Keywords: P-glycoprotein; multidrug resistance, 1,4-dihydropyridines; *in situ* SPIP.

1. INTRODUCTION

Multiple drug (multidrug) resistance (MDR) phenomenon is one of the main therapeutic obstacles in the chemotherapy of cancer and microbial infections [1]. MDR can be defined as the intrinsic or acquired resistance of microorganisms and cancer cells to multiple classes of structurally and mechanistically unrelated drugs [2]. Initially responsive diseases often develop a drug-resistant phenotype after repeated cycles of chemotherapy. The acquisition of MDR is a serious impediment to improved healthcare. MDR occurs at the cellular level and is multi-factor in nature [3, 4]. This is a condition enabling a disease-causing organism to resist distinct drugs or chemicals of a wide variety of structures and functions targeted at eradicating it. Circumvention of MDR is a new field of investigation in chemotherapy, and safe and potent MDR inhibitors are needed for clinical use.

The 1,4-dihydropyridine derivatives (DHPs) are among the chemical classes widely studied as MDR inhibitors for their analogy to verapamil [5, 6]. Some members of this group of calcium channel blockers, such as nifedipine and nimodipine, were identified as potent MDR antagonists

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ISSN 1068-1620, Russian Journal of Bioorganic Chemistry, 2022, Vol. 48, No. 3, pp. 636–642. © Pleiades Publishing, Ltd., 2022.

Anchoring and Hydrophobic Nature of Coumarin in Newer Coumarin Based Chalcones: Synthesis, In Silico, and In Vitro Cell Viability Studies

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Received June 29, 2021; revised November 1, 2021; accepted November 16, 2021

Abstract—Coumarin is active pharmacophore; to enhance the activity of chalcone we inserted coumarin along with other cyclic groups. Fewer pyrazolone aldehydes produced using Wills Maeyer Haack reaction by grinding method. In alcoholic sodium hydroxide, cyclic ketones react with aldehydes to produce title compounds. To treat the ill cell a drug must be with a linker, anchoring group, and hydrophobic group. Herein, the enone group acts as a linker, the rings on both sides are connected, one side ring acts as the anchoring group, and the other side ring acts as the hydrophobic group; anchoring, hydrophobic dual roles played by coumarin ring. In this series, In silico studies results have shown that many compounds of this series potent for anti-cancer activity along with other biological activities, the In vitro cell viability studies of the series shows that, chalcone (I), (VIII), and (IV) are having IC_{50} values 2.96, 2.97, and 2.82 μM against call 27 (or) oral cancer cell line.

Keywords: aldehydes, ketones, chalcone, coumarins, MTT assay

DOI: 10.1134/S1068162022030153

INTRODUCTION

Chalcones serves as the starting material for number of key biological molecules. The biogenetic antecedents of flavonoids and isoflavonoids, which are plentiful in plants, are called chalcones [1]. Polyfunctionalized 3-benzylidenechromone-4 chalcone contained a novel series prepared, among them the majority of compounds have shown a good immune modulatory effect against various cancer cells and compared with the standard drug etoposide [2]. One molecule showed the highest (Tumor specificity) TS and (Potency–Selectivity Expression) PSE values among 15 chalcone derivatives, comparable to doxorubicin and methotrexate, respectively. Chemical modifications to the main molecule could be a viable option for developing novel anticancer medicines [3].

Malaria is a leading cause of death in endemic areas and the rise of drug-resistant parasites is concerning, powerful plant products have been identified. The synthesis of 10 chalcones with different substitutions, and evaluation of their antimalarial activity using chloroquine as a standard, reveals that cytotoxicity, and influence on hemozoin production [4]. Many of tocopherol-based compounds used for gene delivery since they were designed and synthesized by differing in the head group region. Four distinct cell lines were tested for cytotoxity. The data is based on an average of three tests and indicates percentage of viability. The tocopherol-based heterocyclic formulations performed better in all four cell lines evaluated when compared to (Lipofectamine-2000) L2K [5]. A one-pot synthesis of newer 1,4-benzoxazine, 2,4-oxadiazole hybrids prepared from propanenitrile, and different aromatic carboxylic acids. In vitro anti-cancer activity of these compounds tested against four cancer cellines compared with etoposide [6].

Fourteen coumarin-derived compounds prepared and docking, molecular dynamics, and MM/GBSA studies shows that the molecule binds to the active rMAO-B site [7]. For global cancer control, efforts to develop a sustainable infrastructure for the spread of cancer prevention measures and the provision of cancer care in transitioning nations are crucial [8]. On the human hepatoma HepG2 cell line, the cytotoxicity of the decoction and individual plant extracts were assessed. The decoction has a substantial dose-dependent cytotoxic action, according to the results of MTT and SRB experiments [9]. Novel coumarin-pyridazine hybrid compounds with different polarizability and lipophilicity features were produced and evaluated against the two MAO isoforms, MAO-A and MAO-B,

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