Research Publications in the Year 2019-2020

S.NO.	Title of paper	Name of the author/s	Department of the teacher	Name of journal	Year of publication
1	A Simple RP-HPLC Bio Analytical Method for Determination of Levetiracetam in Human Serum.	Sowjanya Malepu, Vijay Kumar Guduru, Vishwanath Reddy Gampala,Nagesh Adla, Goverdhan Puchchakayala	Pharmacy Practice	Journal of Chemical and Pharmaceutical Sciences	2020
2	Effect of Resveratrol pretreatment on Intestinal transport and oral Bioavailability of Carvedilol in Rats by P-gp inhibitors	Y. Shravan Kumar, Mohammed Abdul Aziz Shahid	Pharmaceutics	Research Journal of Pharmacy and Technology	2020
3	Formulation and taste masking of Metronidazole Oral Disintegrating tablets by a novel Approach	Pavani Sriram, Ashish Suttee	Pharmaceutics	International Journal of Pharmaceutical Quality Assurance	2020
4	Formulation and Evaluation of Levocetirizine Dihydrochloride and Ambroxol Hydrochloride Lozenges	T.Rajani, Sriram P,Arsam P, Suttee A	Pharmaceutics	International journal of pharmaceutical quality assurance	2020
5	Formulation and Evaluation of Dexamethasone loaded Cubosomes	T.Rajani, G.Mahesh B. Chandrashekar reddy	Pharmaceutics	Research Journal of Pharmacy and Technology	2020
6	An update on floating drug delivery system:A review	V.Rashmitha,	Pharmaceutics	International journal of advances in pharmacy and biotechnology	2020

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7	Design Synthesis and Pharmacological Evaluation of some c3 Heterocyclic - substituted Ciprofloaxcin derivatives as Chimeric Antituburcular Agents	N.Niveditha, Munnisa begum, K.Shirisha, Vanga Malla Reddy, Garlpati Achaiah	Pharmaceutical chemistry	Chemical Pharma Bulletin	2020
8	Evaluating the outcomes of surgical versus conservative treatments in head injury: A comapritive observational study using different scales	Sanisha sunny,Venkateshwarlu E, , Srinivasulu K, Sharavana Bhava B S, A, Umasankar K	Pharmacy Practice	Indian journal of Pharmacy Practise	2020
9	Formulation and evaluation of Orodispersible tablets of Chlorpheniramine Maleate	K.Ragini	Pharmaceutics	European Journal of Biomedical and Pharmaceutical Sciences	2020
10	Stability Indicating RP-HPLC Method for Estimation of Itraconazole and Terbinafine in Bulk and Tablet Dosage Forms	D.Kumara Swamy	Pharmaceutical Analysis	International Journal of Pharmacy and Biological Sciences	2020
11	Formulation and Evaluation of Dexamethasone Loaded Cubosomes	Thoutreddy Rajani, Gullapudi Mahesh , Bonepally Chandra Shekhar Reddy	Pharmaceutics	Research Journal of Pharmacy and Technology	2020
12	Evaluation of Wound healing and Antiinflammatory Activities of New Poly-herbal Formulations	D.Kumara Swamy, K.Shirisha, P.Girija, K.Srinvas Reddy	Pharmaceutical Analysis	Indian Journal Pharmaceutical Sciences	2020
13	Synthesis, Characterization and Evaluation of New Thiazole Derivatives as Anthelmintic Agents	G.sai Krishna, D.Kumara Swamy, K.Shirisha,K.Durga Prasad	Pharmaceutical Analysis	International Journal of Pharmaceutical Sciences and nanotechnology	2020

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14	Incidence of Depression in patients with Type 2 Diabetes Mellitus	Bandaru Sharavana bhava, Ayisha, Bikkireddy Sai Sharanya, Eggadi Venkateshwarlu, Paithara Achyuth,	Pharmacy Practice	Indian journal of Diabetes and Endocrinology	2020
15	Therapeutic Drug Monitoring of Levetiracetam by High - Performance Liquid Chromatography in Paediatric Epileptic Patients	Nagesh Adla,Tejaswi Chillara,, Vishwanath Reddy Gampala.	Pharmacy Practice	International Journal of Science and Research	2020
16	Incidence of Depression in patients with Type 2 Diabetes Mellitus	Venkateshwarlu E, Achyuth P, Siva Subrahmanyam B	Pharmacy Practice	Indian Journal of Diabetes and Endocrinology	2020
17	Evaluation of Antiulcer Activity of Lawsonia inermis and Murraya koenigii Seed Extract in Ethanol-induced Gastric Mucosal Damage in Rats	Venkateshwarlu E, Jhansi L, Srinivasulu K, Sharavana Bhava B S, Rajasekhar Reddy A, Umasankar K	Pharmacy Practice	Asian Journal of Biological Sciences	2020
18	Effects of carvedilol in left ventricular Dysfunction in patients with heart failure	Shravya V, Chandana Ch, Siva Subrahmanyam B, Umasankar K ,Venkateshwarlu E, Sharvana Bhava B S	Pharmacy Practice	Indian Journal of Applied Research	2020
19	Efficacy of telmisartan and enalapril in patients with diabetic nephropathy	Siva Subrahmanyam B, Akhil D, Haripriya K, Suresh Venkateshwarlu E, Ashrith Reddy Ch,	Pharmacy Practice	Advances in Obesity, Weight Management and Control	2020
20	Evaluation of Insomnia and Psychiatric infirmities with anticancer treatment in patients diagnosed at different stages of cancers	S. Ashwini, Anjum Khan, B.B .Sharavana Bhava	Pharmacy Practice	Rapports De Pharmacie	2020
21	Cutaneous manifestation in patients with end stage renal disease and on Hemodialysis	Sharvana Bhava B, S.Sushmitha P, Shalini K,	Pharmacy Practice	Rapports De Pharmacie	2020

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22	Development and validation of stability indicating LC-MS/MS Technique for the quantification of tapentadol in biological matrices: Application to bioavailability study in healthy rabbits.	Adluri Phanindra, Y. Shravan Kumar	Pharmaceutics	Journal of Applied Pharmaceutical Science	2019
23	Incidence of cataracts in warangal district, telangana state: a prospective observational study	Venkatesh L, Sushma Ch, Achyuth P, Venkateshwarlu E, Kottai Muthu A, Sharavana Bhava B.S	Pharmacy Practice	Rapports De Pharmacie	2019
24	A Prospective Observational Study: Phenytoin Pharmacokinetic Pattern in Cerebrovascular Accident and Head Trauma Patients in Warangal Population	Yashwanth Kumar K, Manasa Sowmya K, Venkateshwarlu E, Sharavana Bhava B.S	Pharmacy Practice	International Journal of Advances in Pharmacy and Biotechnology	2019
25	Niosomes: Potential nanocarriers for drug delivery	Vijay mishra, Pavani Sriram, Ashish Suttee	Pharmaceutics	International Journal of Pharmaceutical Quality Assurance	2020
26	Formulation and Evaluation of Lamivudine floating tablets by sublimation method	S.Pavani, M.Sushma	Pharmaceutics	American journal of Pharmtech Research	2020
27	Evaluation of Insomnia and Psychiatric infirmities with anticancer treatment in patients diagnosed at different stages of cancers	S. Ashwini, Anjum Khan, B.B .Sharavana Bhava	Pharmacy Practice	Rapports De Pharmacie	2020
28	An update on floating drug delivery system:A review	S.Pavani,T.Rajani	Pharmaceutics	International journal of advances in pharmacy and biotechnology	2020
29	Incidence of cataracts in warangal district, telangana state: a prospective observational study	Sharavana Bhava B.S	Pharmacy Practice	Rapports De Pharmacie	2019

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30	An update on floating drug delivery system:A review	T.Rajani,	Pharmaceutics	International journal of advances in pharmacy and biotechnology	2020
31	Therapeutic Drug Monitoring of Levetiracetam by High - Performance Liquid Chromatography in Paediatric Epileptic Patients	Goverdhan Puchchakayala	Pharmacy Practice	International Journal of Science and Research	2020
32	Enhancement of solubility and solubility by Clopidogrel by Self -Nanoemulsifying Drug Delivery System	A. Aparna	Pharmaceutics	Asian Journal ofPharmaceutics	2020

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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.

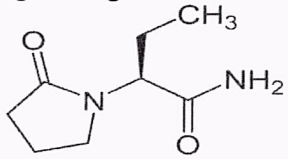
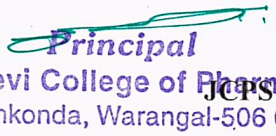


Figure.1.Chemical structure of Levetiracetam

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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RESEARCH ARTICLE

Effect of Resveratrol Pretreatment on Intestinal Transport and Oral Bioavailability of Carvedilol in Rats by P-gp Inhibition

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ABSTRACT:

Carvedilol is effluxly transported back by p-glycoprotein in to the intestine. Bioavailability of carvedilol, will get effected when drugs like resveratrol used concomitantly which is an inhibitor of P-glycoprotein. Present study evaluates the effect of herbal drug resveratrol on the intestinal transport of carvedilol across rat intestine by invitrononeverted intestinal sac method. The rats were pretreated with resveratrol for 7 days. The rats were sacrificed by using anesthetic ether. The intestinal segments were isolated and used for the studies. The probe drug (carvedilol) solution was placed in the isolated intestinal sac. Samples were collected at preset time points and replaced with fresh buffer. The drug content in the samples was estimated using high performance liquid chromatography method. Control experiments were also performed. The results reveal that there was a significant ($p<0.05$) difference compared to control, in the transport of carvedilol from the intestinal sacs which were pretreated with resveratrol. It suggests that resveratrol might be acting by inhibiting the transporters and enzymes which are responsible for transport/metabolism of carvedilol. From the results it can be concluded that resveratrol be acting by inhibiting p-glycoprotein as carvedilol is transported by p-glycoprotein. Further studies are recommended to prove their effects in human beings.

KEYWORDS: Carvedilol, P-gp, Resveratrol, Bioavailability, Pharmacokinetics.

INTRODUCTION:

Carvedilol (a β-receptor blocker) is used in the treatment of cardiovascular diseases like hypertension, ischemic heart disease, and congestive heart failure [1, 2] .Carvedilol is an arylethanolamine that is used clinically as a racemic mixture of 2 enantiomers. The S-(–)-enantiomer has the β-adrenoceptor-blocking activity, while the racemate also has the α1-receptor-blocking activity due to the activity of the R-(+)-enantiomer [3, 4]. The drug is highly lipophilic and is also highly protein bound; it is rapidly absorbed and it undergoes extensive first-pass metabolism in the liver [3].

Lipophilic β-blockers, such as carvedilol, are metabolized via cytochrome P450 (CYP) enzymes. The drug is subject to an oxidative biotransformation and conjugation, being metabolized by CYP2D6 to 4'-hydroxyphenyl carvedilol and5'-hydroxyphenyl carvedilol, by CYP2C9 to O-desmethylcarvedilol, by CYP1A2 to 8-hydroxy carbazolylcarvedilol[5, 6].

Resveratrol (RSV) (3,4′,5-trihydroxystilbene) is a naturally occurring phytoalexin present in grape skins, fruits, vegetables, and especially in red wine. RSV is known to have diverse biochemical and physiological properties including anti-inflammatory, immune modulatory activities as well as wide range of health benefits ranging from chemoprevention to cardio protection[7,8]. It is produced by the plants in response to stress, injury, ultraviolet irradiation, and fungal infection as part of their defense mechanism, and it is synthesized by grapes in response to fungal infections

RESEARCH ARTICLE

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

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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.

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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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RESEARCH ARTICLE

Formulation and Evaluation of Levocetirizine Dihydrochloride and Ambroxol Hydrochloride Lozenges

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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.

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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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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

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Review Article

An Update on Floating Drug Delivery System: A Review

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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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Regular Article

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

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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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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,

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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

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

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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.

*****

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,

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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

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

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

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

Original Article

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Incidence of Depression in patients with Type 2 Diabetes Mellitus

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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

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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

Original Article

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Incidence of Depression in patients with Type 2 Diabetes Mellitus

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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

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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

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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

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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 pathololgic 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 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/V/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

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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 nephropathy 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

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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).[8-11]

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	Antialbuminemic efficacy of ACE inhibitors and ARB'S in type 1 DM with nephropathy	Dual blockade with ramipril enhanced with antualbuminemic 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.
Johnsen et al.[11]	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.

Research article

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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

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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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Development and validation of stability indicating LC-MS/MS Technique for the quantification of tapentadol in biological matrices: Application to bioavailability study in healthy rabbits

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Tapentadol, LC-MS/MS, validation, matrix effect, healthy rabbits and bioavailability study.

ABSTRACT

An Liquid chromatography tandem mass spectrometry (LC-MS/MS) technique is one of the best analytical methods for the quantification of drugs in biological samples. A stability-indicating analytical technique was developed for the quantitation of tapentadol in biological matrices as tapentadol with short runtime. Developed technique also suitable for bioavailability studies in healthy rabbits. Separation of tapentadol and tapentadol-d3 were achieved from plasma sample with solid-phase extraction and elution was processed with Luna-C_{18} (5 µ, 100 mm × 4.6 mm) stationary column with movable phase ratio comprising 2-mM ammonium acetate buffer (pH-3.6) and acetonitrile in the proportion of 10:90 % V/V. Quantitation was processed by processing the transitions of tapentadol and tapentadol-d3 at *m/z* 222.2 → 177.1 and 228.2 → 183.1, respectively, in positive ionization mode. Linearity was performed over the concentration range of 0.121 to 35.637 mg/ml ($R^2 > 0.99$) without matrix effect (2.74%). The inter- and intra-day precision findings were within 8.62% and 11.38%, respectively. Stability data showed that the tapentadol was stable when it exposed to different stability conditions. This technique was effectively applied to bioavailability studies of tapentadol in healthy rabbits.

INTRODUCTION

Tapentadol (TPD) is a synthetic analgesic drug which acts centrally. Analgesic activity of drug is due to µ-opioid agonist action and it prevents nor-epinephrine reuptake. Morphine is 18 times more potent than tapentadol to bind µ-opioid receptors and tapentadol is less effective in animals to induce analgesia. TPD increases noradrenaline concentrations by obstructing the nor-adrenaline reuptake at brain of the tats (Fidman and Nogid, 2010; Mahaparale and Samuel, 2015; Singh *et al.*, 2013). TPD produce its analgesic effect without an active metabolite. It is chemically designated as 3-[(1R, 2*R*)-3-(dimethyl amino)-1- ethyl-2-methyl propyl] phenol hydrochloride.

An average absolute bioavailability is 32% approximately due to first-pass metabolism after single-dose administration. Maximum TPD serum concentration was observed after 1.25 hours (after dosing). A multiple dose (every 6 hours) study with vary in dose from 75 to 175 mg TPD showed an average of 1.6 accumulation factor to parent drug and 1.8 is for main metabolite (TPD-O-glucuronide), which were estimated primarily by medicating interval and half-life of TPD and drug metabolite (Leonhart, 2009; Raffa, 2012; Tzschentke *et al.*, 2006; WHO, 2014).

In humans, TPD HCl metabolism is extensive, because 97% of parent drug is metabolized. Most of the drug is metabolized through Phase-2 path, and few amount metabolized through Phase-1 pathway (oxidative). The major metabolism pathway of TPD is glucuronic acid conjugation to yield glucuronide. After administration of drug by oral route, 70% (O-glucuronide—55.0%, sulfate of TPD—15%) of the drug dose is eliminated as conjugated form in the urine (Nossaman *et al.*, 2010; WHO, 2014).

Literature review unveils that one Liquid chromatography tandem mass spectrometry (LC-MS/MS) (Coulter *et al.*, 2010)

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Research article

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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.

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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

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

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Statistical analysis: We had calculated the Incidence by using formula

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Case Study

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

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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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RESEARCH ARTICLE

Niosomes: Potential Nanocarriers for Drug Delivery

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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.

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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

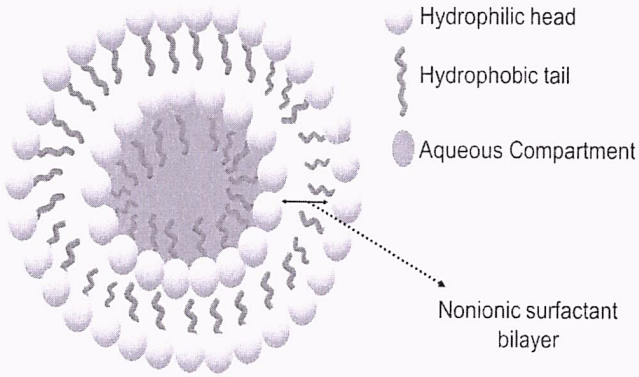

Figure 1:. A typical structure of niosome

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Formulation and Evaluation of Lamivudine Floating Tablets by Sublimation Method

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ABSTRACT

The objective of the study was to develop an oral controlled release drug delivery system of Lamivudine using the sublimation method. Camphor was used as the sublimation material to prepare gastro retentive tablets that are low-density and easily floatable. Camphor was changed to pores in the tablet during the sublimation process. Floating properties of tablets and tablet density were affected by the sublimation of camphor. Release profiles of the drug from the gastro retentive tablets were affected by tablet density/porosity. The effects of different formulation variables HPMC and the effects of different concentrations were studied. The *in vitro* evaluation was carried out and it was found that the drug release was affected by different concentrations of polymers used. The highest percentage of drug release (96.89±0.83) was observed with xanthan polymer and followed diffusion with erosion mechanism (Non-Fickian transport).

Keywords: Lamivudine, floating, HPMC K4M, Xanthan, Camphor, Non-Fickian transport.

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Review Article

An Update on Floating Drug Delivery System: A Review

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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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Research article

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

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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

ORIGINAL ARTICLE

Enhancement of Solubility and Dissolution Rate of Clopidogrel by Self-nanoemulsifying Drug Delivery System

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Abstract

Introduction: A self-nanoemulsifying drug delivery system (SNEDDS) has been explored to improve the solubility and dissolution rate of poorly water-soluble drug clopidogrel. **Materials and Methods:** Different formulations were prepared using an oil, surfactant, and cosurfactant in varying ratios. A pseudo-ternary phase diagram was constructed to identify the self-nanoemulsification region. Further, the resultant formulations were investigated for clarity, phase separation, drug content, % transmittance, globule size, freeze-thaw method, *in vitro* dissolution studies, particle size analysis, and zeta potential. **Results:** On the basis of particle size, zeta potential and dissolution profile and other studies, F6 was found to be the best formulation of clopidogrel SNEDDS. The particle size of the emulsion is a crucial factor in self-emulsification performance because it determines the rate and extent of drug release as well as absorption. The particle size of the optimized SNEDDS formulation was found to be 5.2 nm and zeta potential was found to be −29 mV which comply with the requirement of the zeta potential for stability. The % release from optimized SNEDDS formulation F6 was highest (98.93%) and faster than other SNEDDS formulations and pure drug substance (32%) indicating influence of droplet size on the rate of drug dissolution. The faster dissolution from SNEDDS may be attributed to the fact that in this formulation, the drug is a solubilized form and on exposure to dissolution medium results in small droplet that can dissolve rapidly. Fourier transform infrared data revealed no physicochemical interaction between drug and excipients. **Conclusion:** Thus, clopidogrel with SNEDDS formulation may be used for the improvement of solubility and dissolution rate for the effective management of heart disease.

Key words: Acrysol K150, clopidogrel, myocardial infarction, self-nano emulsifying drug delivery system, solubility

INTRODUCTION

Drugs with poor solubility are difficult to formulate by applying conventional approaches as they pose problems such as slow onset of action, poor oral bioavailability, lack of dose proportionality, failure to achieve steady state plasma concentration, and undesirable side effects, thus resulting in over or under medication and poor patient compliance.[1] These challenges can be overcome by applying self-nanoemulsifying systems that offer benefits such as reduction in dose frequency, lowering of dose size, site-specific targeting, enhanced permeability, and improvement in oral bioavailability. Nanotechnology is a promising strategy in the development of drug delivery systems especially for those potent drugs whose clinical development failed due to their poor solubility, low permeability, inadequate bioavailability, and other poor biopharmaceutical properties.[2] Self-nanoemulsifying drug delivery system (SNEDDS) formulations for poorly water-soluble drugs have shown considerable increase in solubility and bioavailability.[3] Clopidogrel, sold as the brand name Plavix among other is a medication that is used to reduce the risk of heart disease and stroke in those at high risk. The main aim of the study is to formulate and evaluate the SNEDDS clopidogrel formulation to improve its solubility and dissolution rate.

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