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**3.4.3 Research Publications
For the 2018**

Research Article

FORMULATION AND EVALUATION OF BOSENTAN FLOATING MATRIX TABLETS

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ABSTRACT:

Bosentan is a dual endothelin receptor antagonist used in the treatment of pulmonary artery hypertension (PAH). In the present study Bosentan floating matrix tablets were developed to prolong the drug release and to retain the drug delivery system above the site of absorption for the desired period of time. The preformulation parameters such as flow properties and drug-excipient compatibility studies were performed. The results shown that all the polymers used in the study are compatible with the pure drug. The floating matrix tablets of Bosentan prepared by direct compression method and the tablets were evaluated for post compression parameters like average weight, thickness, hardness, friability and swelling index, floating lag time, total floating time and in-vitro drug release studies. SEM and stability studies were carried out only for best release formulation (F2). Among the nine formulations with PEO 301(F2) showed the maximum drug release upto 98% within 12 hrs. SEM for F2 formulation revealed that surface was smooth upto 4 hrs after that swelling and porosity of tablet increased indicating the diffusion and erosion mechanism of release.

Keywords: Bosentan, direct compression, floating matrix tablets, pulmonary artery hypertension.

INTRODUCTION

Over the past three decades, oral controlled release dosage forms have been extensively developed due to their various therapeutic advantages such as flexibility in formulation of dosage form, ease of administration and patient compliance. However, this approach suffers with few physiological hurdles such as inability to retain the dosage form within the desired region of the gastrointestinal tract due to variability in gastric motility and emptying rate¹. Moreover, gastric emptying time in humans normally averages from 2 to 3 hrs² through the stomach and upper part of the intestine. Therefore brief gastric emptying time results in incomplete drug release from the drug delivery system which causes reduced efficacy of the administered dose³. However gastric emptying time is unpredictable and varies in individuals in case of any physiological problems and due to presence of food. Drugs with short half-life are quickly eliminated from the blood circulation and results in decreased bioavailability. This necessitated in controlled placement of a dosage form in a specific region of the GI tract which offers several advantages in administering drugs having narrow absorption window in the GIT or drugs having stability problem⁴. By following these considerations, oral controlled release dosage form with gastro retentive properties were developed. After oral administration, Gastro retentive dosage forms remain in the gastric region and prolong the

gastric residence time of drugs for several hours. This enables the continuous drug supply at its absorption site in the upper gastrointestinal tract⁵. Prolonged gastric retention improves solubility of drugs that are less soluble, reduces drug waste, increase bioavailability and also suitable for local drug delivery to the stomach and proximal part of small intestine⁶. Once the drug gets released completely, the system is eliminated from the stomach. This results in better control of fluctuations in plasma drug concentrations. Various attempts have been made to develop controlled drug delivery system which provides therapeutically effective plasma drug levels for longer periods and also to reduce the dosing frequency and minimize fluctuations in plasma drug concentration at steady state by delivering drug in a controlled and reproducible manner.

Gastric retention enables to achieve increased bioavailability of new products with better therapeutic activity and patient compliance. Oral route of administration is known to be the best to achieve known pharmacokinetic and pharmacodynamic advantages for controlled drug delivery.

Gastro retentive dosage forms can be designed by the currently available techniques such as floating drug delivery system⁷, bioadhesive or mucoadhesive systems^{8, 9}, expansion^{10, 11}, sedimentation^{12, 13}, low-density systems^{14, 15, 16}, high density systems¹⁷, raft systems incorporating alginate gels^{18, 19}

A REVIEW ON TRANSUNGUAL DRUG DELIVERY SYSTEM

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ABSTRACT

The nail disorders are mainly due to fungal infection. When the drug is given through oral or systemic route, the potency of drugs gets decreased at the site of action. To avoid this loss of drug potency topical route of administration is used. The absorption of the drugs into the nail unit to the nail plate is essential to produce the therapeutic effect. By the means of nail drug delivery system oral toxicity of different drugs like anti-fungal can be avoided and also drugs get longer contact time at site of application. The topical therapy is highly desirable in treating the nail disorders due to its localized effects which results in minimal adverse systemic events and possibly improved

adherence. However, the effectiveness of the topical therapies is limited by the minimal drug permeability through the nail plate. The use of chemical permeation enhancer has been a common approach for enhancing trans-nail delivery of drugs. The potential of physical permeation enhancement techniques has been found to be higher than the potential of chemical permeation enhancer in transdermal delivery of macromolecular therapeutic agent and hydrophilic drugs. However the application of physical permeation enhancement technique has not been explored for trans-nail drug delivery. This new therapy may reduce the need for hazardous systemic administration of oral anti fungal drugs for nail infections. Also the analysis of the drugs penetration is a difficult task. Here in the present article a method to analyze the drugs permeated across nail barrier is suggested.

KEYWORDS: Anti-fungal drugs, Human nail, Nail disorder, Nail barrier.

INTRODUCTION

Recent advances in topical transungual delivery have led to the development of anti fungal nail lacquers. The human nail, equivalent to claws and hooves in other mammals, evolved as our manual skill developed and protect the delicate tips of fingers and toes against trauma,

Research Article**Fabrication and characterization of pantoprazole sodium Ora-Solv tablets using different superdisintegrants**

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Abstract

Objective: In the present investigation, an attempt has been made to formulate Ora – Solv tablets of pantoprazole sodium using two different superdisintegrants like crosspovidone and primogel by direct compression method. **Materials and methods:** ORA-SOLV tablets of pantoprazole were prepared by direct compression method. In the present investigation, each superdisintegrant was used in three concentrations (2.5, 5 and 10%). Weighed quantities of Pantoprazole sodium along with appropriate concentrations of superdisintegrants i.e crosspovidone and primogel, mannitol, microcrystalline cellulose, saccharin sodium were weighed and mixed in geometric progression in a dry and clean mortar. Superdisintegrants act by decreasing the disintegration time which leads to enhanced dissolution rate. Evaluation of formulations showed that all the preparations were within the standard limits and the disintegration time for formulations ranges from 12.10 sec to 27 sec. **Results and conclusion:** It was observed that with the increase in the concentration of superdisintegrant the disintegration time decreases and among all formulation, tablets containing crosspovidone shows less disintegration time due to more hydrophilicity. From the obtained results, formulation F3 containing 10% w/w concentration of crosspovidone was considered to be the optimized formulation which releases up to 99.78% of the drug in 15 minutes. The OST's have potential advantages over conventional marketed tablets with their better patient compliance, both in geriatrics and pediatrics, ease of administration and bio-availability.

Keywords: Ora – Solv tablets, Pantoprazole, Crosspovidone, Primogel, direct compression

Introduction

Ora-Solv tablets are also known as Fast dissolving tablets, Mouth dissolving tablets, Fast disintegrating tablets, Orally disintegrating tablets, Rapid disintegrating tablets, Oro dispersible tablets and Quick dissolving tablets (Rishi, 2004). Ora-Solv tablets are those which when placed in the tongue, instantaneously disintegrates and releases the drug that dissolves or disperses rapidly in the saliva without the need of drinking water or chewing. OST's usually dissolve in the oral cavity within 15 seconds to 3 minutes. The faster the drug into solution, quicker the absorption and onset of clinical effect (Panigrahi et al., 2005). Oral drug delivery system is the most convenient and widely accepted route of administration for

various therapeutic agents. Among many oral drug delivery systems, ora-solv tablets have gained importance over past 3 decades. Ora-solv tablets are suitable for patients who have dysphasia, paediatric, geriatric and psychiatric. It is also suitable for patients with nausea, vomiting and motion sickness (Sarada et al., 2014). When formulated as OST, some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva passes down into the stomach which in turn increases the bioavailability of the drug. This is known as pre gastric absorption. Thus in OST, the amount of drug that is subjected to first pass metabolism is reduced as compared to conventional tablets. OST offers a giant leap forward in drug administration by providing a new and easy way of taking medication (Srinivas et al., 2005). Pantoprazole is a potent and selective proton pump inhibitor. It is an effective agent in the treatment of Peptic ulcers, Gastro-oesophageal reflux disease (GERD), Oesophagitis, Zollinger-Ellison syndrome and other GI hypersecretory disorders. It has poor bioavailability (~50%) and aqueous solubility, thus it is absorption and dissolution rate limited,

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DOI: <https://doi.org/10.31024/ajpp.2018.4.5.8>2455-2674/Copyright © 2018, N.S. Memorial Scientific Research and Education Society. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Review Article

COCCINIA GRANDIS: A PHARMACEUTICAL REVIEW

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ABSTRACT

The present society of diseases requires an ultimate drug which gives utmost cure, no reoccurrence, no side effects and better health. One of the requirement or some of the requirements may be reached by the present drugs. But completely achieving all the requirements is only by the traditional medicine. The ancient traditional medicines have wide range of curing any kind of ailment. One of which that ancient plant, but also using in present days is COCCINIA GRANDIS. The plant *Coccinia Grandis* having pharmacological activities like analgesic, antipyretic, anti-inflammatory, antimicrobial, antiulcer, anti-diabetic, antioxidant, hypoglycaemic, hepatoprotective, antimalarial, antidyslipidemic, anticancer, antitussive, mutagenic.

Keywords: *Coccinia Grandis*, Traditional Medicine, Ailment.

INTRODUCTION

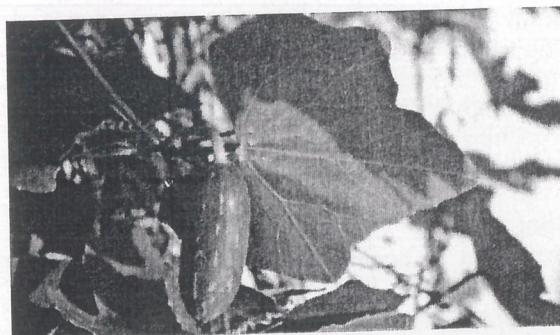
As per the present scenario of medicines, people mostly requires a kind of medicine which does not show any adverse effects. This could be possible only by the traditional plant medicines that has complete positive activity towards persons and complete pharmacological activity towards diseases. Every plant is a boon to all life kind given by god. But the problem lies in, coming to know the activity of every plant towards diseases. There are about 7,000 plant species found in India. The WHO estimates that about 80% of the population living in the developing countries depends almost on traditional medicines for their primary health care. The family of *Coccinia Grandis* is Cucurbitaceous, comprises 960 species. The family is predominantly distributed around the tropics. Most of the plants in Cucurbitaceae family are annual plants. *Coccinia Grandis* is used by humans mostly as a food crop in several countries in Australia, Asia, Caribbean, and the southern United States, Pacific Islands.

Nomenclature: The name is derived from the latin coccineus, meaning scarlet, in reference to the fruit colour¹.

kingdom	Plantae
order	Cucurbitales
family	Cucurbitaceae
genus	Coccinia
species	Coccinia grandis

Nutritional value per 100g of edible portion of *Coccinia Grandis*²

Components	Amount
Energy	21 K.Cal
Protein	1.4g
Carbohydrates	3.4g
Fat	0.2g
Calcium	25mg
Iron	0.9mg



Formulation and Optimization of Zolmitriptan Oral Fast Dissolving Films

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Abstract : The present research work deals with development and optimization of oral fast dissolving films of zolmitriptan to improve bioavailability and patient compliance. It is anti-migraine drug which has oral bioavailability of 45% due to hepatic firstpass metabolism. Oral fast dissolving films of zolmitriptan were prepared by solvent casting method using HPMC E-5 as a film forming polymer, propylene glycol as a plasticizer, sodium starch glycolate as a superdisintegrant and aspartame is added as sweetener. The prepared film characterised by FTIR showed no incompatibility between drug and polymer. A 2^3 factorial design is employed for the optimization of formulation considering concentration of polymer, plasticizer and superdisintegrant as independent variables with drug release, disintegration time, folding endurance as dependent variables. The formulations F1-F8 are made by varying the levels of independent variables and evaluated for disintegration time, dissolution rate and folding endurance. The results are treated by DesignExpert software to optimise the oral fast dissolving film. The optimised film is analysed by X-ray diffraction shows crystalline to amorphous transformation of drug and DSC thermogram shows a broad peak further confirms the amorphous nature of drug. It was found that enhancing the polymer and plasticizer concentrations shows negative effect on disintegration time and drug release. But when the concentration of superdisintegrant was increased it had a positive effect on drug release and disintegration time. From the results obtained the optimized formulation was prepared with 4% of HPMC E5, 1.5% of propylene glycol and 4% of sodium starch glycolate showed disintegration time 10 sec, drug release 93.15% and folding endurance of 260 times.

Key words : Zolmitriptan, Hydroxyl Propyl Methyl Cellulose, Propylene glycol, Sodium starch glycolate, Aspartame.

Introduction:

Fast dissolving films are most advanced form of solid oral dosage form due to its flexibility. It improves efficacy of active pharmaceutical ingredient (API) by dissolving in the short time in oral cavity after the contact with less amount of saliva as compared to mouth dissolving tablet.^[1] The oral cavity covers the cheek, lips, tongue, hard palate and soft palate. The lining of the oral cavity is referred to as the oral mucosa.^[2] The delivery

Research Article



Formulation and Evaluation of Taste Masked Oro-dispersible Tablets of an Anti-HIV Drug

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ABSTRACT

Tenofovir disoproxil fumarate is a fumaric acid salt of bis-isopropoxycarbonyloxymethyl ester derivative of tenofovir. Tenofovir exhibits activity against HIV-1 reverse transcriptase. Tenofovir disoproxil fumarate is the water soluble (BCS class – III drug) diester prodrug of the active ingredient tenofovir. The oral bioavailability in fasted patients is approximately 25%. The drug is incompletely absorbed from gastrointestinal tract. Formulation of tenofovir disoproxil fumarate into an oro-dispersible dosage form can provide fast relief with greater bioavailability. The bitter taste of drug should be masked in order to formulate it in a palatable form. In the current research work, an attempt was made to mask the bitter taste of tenofovir by complexation technique, with a formulation into oro-dispersible tablets, using superdisintegrants sodium starch glycolate (SSG), croscopolidone (CP) and croscarmellose sodium (CCS) in different concentrations. The complexes of tenofovir disoproxil fumarate with β -cyclodextrin were prepared by co-grounding method in various drug: complex ratios. The prepared solid inclusion complexes were analysed for taste masking and characterized by FT-IR. Using the optimized drug: β -cyclodextrin complex (1:1 molar ratio), oro-dispersible tablets were prepared and evaluated for thickness, weight variation, hardness, friability, drug content, wetting time, water absorption ratio, *in vitro* dispersion time, *in vitro* disintegration time and *in vitro* dissolution rate. The maximum drug release of 99.85% was obtained from the formulation F6 containing the highest concentration of CP and therefore formulation F6 was considered as the optimized formulation.

Keywords: Tenofovir disoproxil fumarate, β -cyclodextrin, Taste-masking, Co-grounding, Oro-dispersible tablets.

INTRODUCTION

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis.¹

For these reasons, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Orodispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. Fast dissolving tablets are also called as mouth-dissolving tablets, melt-in mouth tablets, Orodispersible tablets, porous tablets, quick dissolving etc.²

Cyclodextrins are cyclic oligosaccharides with a hydrophilic outer surface and a lipophilic central cavity. On account of their relatively hydrophobic interiors, CDs

have the ability to form inclusion complexes with a wide range of substrates.³ This complex-forming ability of CD have been widely exploited in the pharmaceutical field for various applications, including taste-masking of bitter drugs.⁴⁻⁶ The use of CD as a taste-masking agent has been widely reported.⁷⁻⁹

Tenofovir disoproxil fumarate (a prodrug of tenofovir) which is a fumaric acid salt of bis-isopropoxycarbonyloxymethyl ester derivative of tenofovir. *In vivo* tenofovir disoproxil fumarate is converted to tenofovir, an acyclic nucleoside phosphonate (nucleotide) analog of adenosine 5'-monophosphate. Tenofovir exhibits activity against HIV-1 reverse transcriptase. Tenofovir disoproxil fumarate is the water soluble (BCS class – III drug) diester prodrug of the active ingredient tenofovir. The oral bioavailability in fasted patients is approximately 25%.¹⁰ The drug is incompletely absorbed from gastrointestinal tract, hence there is a need to develop a suitable formulation of tenofovir disoproxil fumarate to improve its bioavailability. When a single oral dose (300 mg) is given to HIV-1 infected subjects in the fasted state, the maximum serum concentration was achieved in 1.0 ± 0.4 h (T_{max}).

Tenofovir disoproxil fumarate is a drug with bitter taste. Complexation with β -CD will mask the bitter taste of tenofovir disoproxil fumarate. It would be advantageous to formulate taste masked, orodispersible tablets of



Formulation and Evaluation of Tramadol Hydrochloride Sustained Release Matrix Tablets

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ABSTRACT

The ultimate goal of any oral drug delivery system is the successful delivery of the drug, in which almost 90% of the drugs are administered to the body for the treatment of various disorders and diseases as it is regarded as the safest, most convenient and most economical method of drug delivery having the highest patient compliance. The aim of the present study is to formulate sustained release matrix tablets of a model drug (Tramadol hydrochloride) using HPMC 100 MCR, HPC and EC 7cps as rate retarding polymers, microcrystalline cellulose as bulking agent, magnesium stearate as lubricant and aerosil as glidant. Drug and polymer interactions were evaluated by using FTIR and DSC. The FTIR spectrum and DSC thermograms stated that drug and polymer are compatible to each other. Tablets were prepared by direct compression technique. The micromeritic properties of formulation mixtures of all the formulations were carried out and they were found to be as angle of repose (31.15° - 40.10°), bulk density (0.310g/ml - 0.337g/ml), tapped density (0.355g/ml - 0.59g/ml), Carr's index (8.11% - 15.3%), Hausner's ratio (1.08 - 1.18) which are within the limits. The formulated tablets were physically acceptable and exhibited acceptable weight variation, friability. *In vitro* dissolution studies were carried out using USP type-II dissolution apparatus and of all the formulations F₆ (containing HPMC and HPC in equal proportions) exhibited prolonged drug release for about 8 hrs as per the objective of the work. The percent drug content varied between 88% to 99%. It can be concluded from the study that the sustained release tablets can be better alternative over immediate release tablets by improving patient compliance and reducing frequency.

Keywords: Sustained release, Matrix tablets, HPMC 100 MCR, HPC, EC, Osteoarthritis.

INTRODUCTION

Sustained release drug delivery systems are developed to modulate the release of drug, in order to achieve specific clinical objectives that cannot be attained with conventional dosage forms. Possible therapeutic benefits of a properly designed SR dosage form include low cost, simple processing, improved efficacy, reduced adverse events, flexibility in terms of the range of release profiles attainable, increased convenience and patient compliance. There are several reasons for attractiveness of these dosage forms: provides increased bioavailability of the drug product, reduction in the frequency of administration to prolong duration of effective blood levels, reduces the fluctuation of peak and trough concentration, side effects and possibly improves the specific distribution of the drug¹.

Tramadol is a non-steroidal anti-inflammatory drug, which is used in the treatment of osteoarthritis when NSAIDs like Acetaminophen, or COX-2 inhibitors alone produce inadequate pain relief. After oral administration, Tramadol is rapidly and almost completely absorbed. Sustained-release tablets reach to peak concentrations after 4.9 hrs and have a bioavailability of 87% to 95% compared with capsules. The mean elimination half-life is ~6 hrs and requires dosing every 6 hrs in order to maintain optimal

relief of chronic pain. Consequently, once-daily extended-release tablets have been formulated. Long term treatment with sustained-release tramadol once daily is generally safe in patients with osteoarthritis or refractory low back pain and is well tolerated. It has the potential to provide patients increased control over the management of their pain, fewer interruptions in sleep, and improved compliance. Tramadol, a synthetic opioid of the aminocyclohexanol group, is a centrally acting analgesic with weak opioid agonist properties. Tramadol has been proved to be effective in both experimental and clinical pain without causing serious side effects. Tramadol and its metabolites are excreted primarily in the urine with observed plasma half-lives of 6.3 and 7.4 hours for

Table 2: Calibration Table of Tramadol hydrochloride in pH 1.2 buffer.

Conc ($\mu\text{g/ml}$)	Absorbance
0	0
20	0.111
40	0.241
60	0.365
80	0.482
100	0.671

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An Utmost Summary on Phytosomes: A Novel Drug Delivery System for Herbal Drugs

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Abstract: In the new generations of increase in solubility of the pharmaceutical formulations different problems are raised. The bioavailability and absorption of water soluble phytoconstituents is unpredictable due to poor solubility of these constituents in gastrointestinal tract. This can be overcome by a novel drug delivery system known as phytosome technology in which water soluble phytoconstituents are enabled to react with phospholipids. For better and improved bioavailability, natural phytoconstituents must have a good balance between hydrophilicity which helps in dissolution in gastrointestinal fluids and hydrophobicity which helps to cross lipid rich cell membranes can be achieved through phytosome technology. In ancient times phytomedicines are used as a health maintenance it is a complex mixture prepared from plants. Phytosomes show better pharmacokinetic and pharmacodynamic profile than conventional herbal extracts.

INTRODUCTION

Phytosome is a new patented technology developed by Indena of Italy. [1] The term Phyto means "plant" and some means "Cell like". It is also known as herbosomes. It incorporates phospholipids into standardized herb extract which improve their absorption and bioavailability. [2] Phytosomes can be employed as natural digestive aids and as carriers for both fat and water miscible nutrients. [3] Most of the phytoconstituents of herbal extracts are flavonoids viz., Anthocyanidins from bilberry, Catechin from green tea, silymarin from milk thistle. [4] The flavonoids nutrients exhibiting poor absorption due to the following two factors, such as:

1. Phytoconstituents have multiple ring molecules are too large and cannot be absorbed from the intestine into blood by simple diffusion. [5]
2. The phyto-molecules are poorly miscible with oils and other lipids are fail to pass through small intestine because of its lipid-rich outer membrane water soluble flavanoid molecule can be converted to lipid molecular complexes called phytosomes. [4,6]

According to WHO, nearly 80% of population of Asian and African countries till now depending on phytomedicines. In recent years phytomedicines has scientific evidence about the effectiveness of herbal medicines are more widely available. Phytosomes is the vesicular drug delivery systems means phytoconstituents of herbal extract surround and bound by phosphatidylcholine. [7] Phosphatidylcholine is the main component it is the outer most membrane in the cell. [6] Many phytochemicals have poor *in-vitro* and *in-vivo* correlation due to unpredictable physicochemical behaviour of active constituents resulting in poor absorption and poor bioavailability. The bioavailability can be improved by different drug delivery systems like liposomes, niosomes, phytosomes which enhance the release rate by crossing the lipid membrane. [7] Phytosomes of herbal extract are destructed by digestive secretion and gut bacteria which shows better absorption and better bioavailability and

improved pharmacological and pharmacokinetic parameters than conventional herbal extract. [6,7]

PHYTOSOMES OVERVIEW

Advantages

1. There is a marked improvement of bioavailability of herbal extracts due to their hinderance with phospholipid and better absorption in the intestinal tract. [3]
2. The formulation of phytosomes is safe and they are used in pharmaceutical and cosmetic use. [7]
3. The manufacturing process of phytosomes is simple. [9,12]
4. There is no problem in drug entrapment while formulating phytosomes. [2]
5. It assures proper delivery of the drug to the respective tissues. [8]
6. Phytosomes are superior to liposomes in skin care products. [2]
7. As the absorption of active constituents is improved, its dose requirement is also reduced. [8]

Comparison of Phytosomes with Liposomes

Like phytosomes, liposome is a mixture of hydrophilic substance and phosphatidylcholine in a definite ratio, with a water-soluble substance, is surrounded by phosphatidylcholine molecule. It is formed in the ratio of 1:1 or 2:1 molecular complex with chemical bonding between phytoconstituents and phosphatidylcholine as shown in Figure 1. Phytosomes have been proven to be efficacious in topical and skin care products than liposomes. [7,8]

Role of Phosphatidylcholine in Phytosomes Formulation

Phospholipids are belonging to the classification of lipids and serves as a major moiety in the composition of the cell membranes. They are natural digestives and act as a transporter to hydrophilic and lipophilic nutrients in homosapiens and animals. They can be extracted from egg yolk or soybean through mechanical or chemical methods with the aid of hexane. Phosphatidylcholine has two groups mainly phosphatidyl group being the lipophilic group and the choline group being the hydrophilic moiety. Choline moiety enhances the memory function and aids muscle

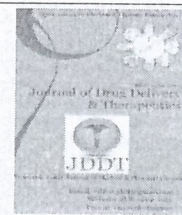
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Open Access

Review Article

An updated review on Anti-Alzheimer's herbal drugs

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ABSTRACT

Alzheimer's disease (AD) is related to cognitive impairment, dementia observed generally in aged population due to neurodegeneration in an ongoing manner. It gradually worsens memory power of the patient. The hallmark diagnosis features includes formation of senile plaques and Neurofibrillary tangles (NFT'S). Too little availability of Acetyl choline (ACh) a neurotransmitter in the cerebral region due to metabolism by an enzyme Acetyl choline esterase before showing its action and neural death are the primary reasons for AD. There are many categories of Anti-Alzheimer's drugs available for management of AD in the market but due to lack of patient compliance successful outcomes were not observed. Apart from this including Nutraceuticals in diet daily routine, Aromatherapy, modifications in the regular schedule, practicing yoga regularly relaxes mind and body from tensions, insomnia, blood circulation, detoxification of organs due to rhythmic breathings and reduce frequency of incidence of headache are proven to show best results by relieving stress according to survey. At present herbal medicine has turn out to be best choice for the management of AD because of its availability, very economic, good patient compliance, ease of formulation and lower deleterious side effects. Novel techniques can be used for the development of herbal medicine. This review totally discusses about the occurrence of AD, its Pathophysiology, different stages in the disorder, various selective therapeutic targets for AD, available Anti-AD herbal drugs such as Curcumin, Withania somnifera, Bhrami, Ginkgo biloba, guggul, ginseng, herbs with essential oils, volatile oils, source and cultivation of the herbs, mechanism of action of the Phytochemicals in the herb responsible for treating AD.

Keywords: Alzheimer's disease (AD), cognitive impairment, Dementia, Senile plaques, Nutraceuticals, Herbal medicine, Phytoconstituents.

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INTRODUCTION^{1, 12}

Alzheimer's is a neurodegenerative disorder caused due to cognitive impairment and Dementia. Alzheimer's disease International (ADI) is the international federation of Alzheimer associations around the world, in official relations with the World Health Organization believes that the key to winning the fight against dementia lies in a unique combination of Global Solutions and local knowledge. World Alzheimer's Month, celebrated each September, with World Alzheimer's Day on September 21, is an opportunity to raise global awareness about dementia and its impact on families and the important work of our members throughout the world. Alzheimer's & Related Disorders Society of India in Kerala is the Indian association that compiles all the issues related to AD. Numerous strategies, drugs, herbal medicines and various drug delivery systems exist for AD but they don't assure permanent cure for it, usage of herbal medicine along with a suitable drug delivery system as a remedy for AD is the best choice when compared to Allopathic

medicine as they overcome the unwanted side effects and improves patient compliance.

ALZHEIMER'S DISEASE^{1, 2, 13, 14}

In 1906 Dr. Alois Alzheimer upon his scrutiny identified brain of a woman who lost her life due to some unusual symptoms such as loss of memory, unpredictable behavior, cognitive impairment he then conclude the death was due the presence of neuritic plaques and neuro fibrillary tangles and named the disease as ALZHEIMERS DISEASE. It has been developed into a predominant neurodegenerative disease in the elderly population. A component of healthy nerve cells, Amyloid precursor protein derivative β -Amyloid protein deteriorates and lead to the formation of **Neuritic plaques**, they are also called as senile, dendritic or amyloid plaques. Nerve cells along with various other components it consists of twisted protein fibers positioned within nerve cells. These fibers consist of a protein, called tau, which normally occurs in neurons. When incorrectly processed, tau molecules clump together to form **Neuro fibrillary tangles**. This disease may be in some way

RESEARCH ARTICLE

Formulation and Evaluation of Pediatric Oral Soft Jellies of Salbutamol Sulphate

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ABSTRACT:

Medicated oral jelly formulations are more preferable for pediatric patients, which provide rapid dissolution and absorption of drugs thereby early onset of action. The aim of the present investigation was to formulate and evaluate oral jelly formulations of salbutamol sulphate. Salbutamol sulphate oral jellies were prepared using gelatin alone, methyl cellulose-gelatin and sodium carboxy methyl cellulose-gelatin in combination as gelling agents. The prepared jelly formulations were evaluated for pre-formulation studies, physical characteristics, drug content, pH, rheological properties, syneresis and *in vitro* dissolution testing. Fourier transform infrared analysis showed that there was no incompatibility between drug and excipients. The pH of all the formulations was found between pH 6.54 ± 0.06 and 6.74 ± 0.02 . The weight variation was found between $0.99\% \pm 1.24$ and $1.01\% \pm 0.74$ in all prepared jelly formulations. The drug content was found in the range of $98.23\% \pm 0.58$ to $99.25\% \pm 0.35$, which was in conformity with the pharmacopoeial specification of 98% - 101%. Syneresis was not observed in jellies. All formulations showed more than 50% drug release within 15 min. From the results of *in vitro* dissolution study, it was found that the rate of dissolution of salbutamol sulphate from F5 (gelatin - methyl cellulose combination) and F7 (gelatin - sodium CMC combination) was found to be higher and in conformance with the bio-pharmaceutical classification system (BCS) concept for the immediate release formulations (>85% in 30 min).

KEYWORDS: Salbutamol sulphate, paediatric patients, oral jelly, gelling agents.

INTRODUCTION:

Oral route is the most preferred route of administration by patients. Drug delivery to paediatric patients is always a challenge. Recently, more emphasis is laid down on the development of pharmaceutically elegant & patient friendly drug delivery systems for both paediatric patients^{1,2}. Many paediatric patients find it difficult to swallow tablets and capsules, which lead to high incidence of non-compliance and ineffective therapy. The jelly dosage form can be administered without water and are soft and smooth³.

The problem of dose measurement by patients is overcome as oral medicated jellies are packed in unit dose. Jellies can be versatile in nature that they can be used as such or taken with food items⁴. Jellies are formed by aggregation of polymers with at least two components; the gelling agent and the fluid component. Gellan gum, carrageenan, pectin, sodium alginate and gelatin are widely used gelling agents in pharmaceutical industries. Salbutamol sulphate is a short-acting β_2 -adrenergic receptor agonist used for the relief of bronchospasm in conditions such as asthma and chronic obstructive pulmonary disease (COPD)^{5,6}.

Salbutamol sulphate is a short acting beta-adrenergic agonist which is used for its bronchodilating properties

RESEARCH ARTICLE

Formulation and Evaluation of Fexofenadine Buccal Mucoadhesive Patches

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ABSTRACT:

Mucoadhesive buccal patches for the delivery of fexofenadine using various polyvinyl alcohol, hydroxypropyl methyl cellulose K4M and K15M and Eudragit L100 were developed using solvent casting technique. The fabricated formulations were evaluated for different physicochemical as well as mechanical parameters such as thickness, surface pH, weight uniformity, swelling index, folding endurance, drug content, percentage moisture loss, *in vitro* dispersion and *in vitro* residence time. An *in vitro* drug release study was designed and performed using freshly prepared egg membrane as semi-permeable membrane. The optimized formulation (F1) showed maximum percentage of drug release $96.18\% \pm 0.53\%$ by the end of 8 h. The sustained release of the drug was achieved up to 8 h.

KEYWORDS: Buccal delivery, mucoadhesive patches, polyvinyl alcohol, hydroxypropyl methyl cellulose, folding endurance.

INTRODUCTION:

Currently, immense research efforts have been focused on introducing a drug delivery system at a specific site of the body in order to maximize bioavailability of drug as well as minimize side effects that are dose dependent. As buccal mucosa is relatively permeable with a rich blood supply, buccal delivery of drugs can be an attractive alternative to other conventional methods of systemic delivery of drugs^{1,2}. Buccal drug delivery bypasses the first pass hepatic metabolism of drugs and avoids pre-systemic elimination in the gastro intestinal tract. Thus, the oral mucosa is considered as a feasible site for systemic drug absorption. Fexofenadine is a second generation, long lasting H₁-receptor antagonist (antihistamine) and has a selective and peripheral H₁-antagonist action used for management of seasonal allergic rhinitis.

The drug is absorbed rapidly after oral administration and 60% - 70% bound to the plasma proteins, mainly albumin and α_1 -acid glycoprotein³. The metabolism of fexofenadine is insignificant^{4,5}. About 5% of the total fexofenadine oral dose gets metabolized. The drug is un-metabolized by liver⁶. Elimination half life is 13 h - 16 h⁷. Around, 90% of fexofenadine drug is found to be unchanged in feces and urine⁸. Fexofenadine belongs to BCS class III with high solubility and low permeability. Fexofenadine oral bioavailability is only 33% due to less absorption and metabolism to some extent because of cytochrome P450 3A4 and by microflora present in the intestine. After oral administration, T_{max} of fexofenadine is 1.35 h - 1.52 h, i.e., long and variable. The effective dose of fexofenadine is approx. 30 mg. Since fexofenadine belongs to BCS Class III, having high aqueous solubility and low permeability, there is a need to improve the permeability of the drug. Taking into consideration the physicochemical properties and pharmacokinetics of the drug, it was inferred that the drug has a need to be formulated into mucoadhesive buccal patches and the drug fexofenadine was appropriate for it.



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Research Article

INSILICO ADME PROFILING OF CDK9 INHIBITORS

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ABSTRACT

Several drug targets have been identified in fighting against cancer. Inhibition of Cell cycle is one of the strategies used in anti-cancer research. CDKs [Cyclin Dependent Kinases] were found to be one of the promising drug targets. This work aims to find a potential molecule to inhibit CDKs that are involved in cell cycle progression. CDK 9 was chosen as potential drug target for cancer. Virtual screening was carried out against CDK 9 protein using Molecular Docking tools with molecules from ZINC database. Molecules were shortlisted based on their docking score, rerank score and energies. Insilico Toxicity and ADME [Absorption, Distribution, Metabolism and Excretion] analysis was carried to know the efficacy of the molecules before proceeding to invitro and invivo assays. Molecules under study were analyzed for ADME properties using Molinspiration, preAdmet and Swissadme servers. ADME profiles were evaluated and most of the molecules were found to be suitable for further studies. Insilico ADMET analysis is proved to be a good tool in drug discovery.

KEYWORDS: CDK, Cancer, Toxicity, ADME, Virtual Screening.

INTRODUCTION

Majority of deaths occurred in world is due to cancer. In search of developing strategies against cancer a huge amount of resources are being invested in various projects across the nations [1]. Drug designing is the important step in any drug discovery project. Insilico methods of drug design and development are proved to be efficient in saving lots of resources and time [2]. Cell cycle progression is one of the important steps involved in cell proliferation. Inhibition of Cell cycle progression using CDK as target is one of most suitable strategy to fight against cancer [3]. Over the last 30 years methods of computer aided drug design / discovery played a pivotal role in the development of therapeutic drugs [4]. The potential of any compound used in therapeutics depends not only on the physical and chemical properties but also on Pharmacodynamics [PD] and pharmacokinetics [PK] aspects of the compounds. Pharmacodynamics correlates health effect of drugs on an individual patient while pharmacokinetics records the course of Absorption, Distribution, Metabolism and Excretion of a given drug, both are interrelated.

Over the past 5 decades ADME played a major role in drug design process. ADME means absorption, distribution, metabolism and excretion which explain about the pharmacokinetics aspects of a drug molecule. There are several incidents reporting the attrition of drug discovery projects just because of the poor ADME profiles [5]. Therefore prior to synthesis and invivo studies, ADME profiling found to be more effective. Determination of ADME properties of compounds involves lot of experimental procedures to be followed which is time consuming and expensive. Therefore Insilico ADME models have been developed [6,7]. In

the present study an insilico approach has been utilized in determining the ADME profiles of the compounds known to be CDK 9 inhibitors.

MATERIALS AND METHODS

Insilico ADME analysis:

The Compounds used in this work were found to be inhibiting CDK 9 [8] protein as studied earlier using virtual screening studies [9]. The molecules were short listed based on their docking scores, ranking scores and rerank scores [9]. Virtual screening was carried with molecules available in ZINC database [10].

Experimental:

The test compounds to be used as potential CDK 9 inhibitors used in the study are listed in Table 1 and their structures are shown in Figure 1.

Calculation of ADME properties:

All the 2D molecular structures were drawn online at Molinspiration server [11]. ADME properties of test set compounds were calculated using Molinspiration [11], PreAdmet [12] and Swiss ADME tools [13].

1. Plasma Protein binding:

A drug is more efficient if it is free to traverse across membranes and reach the target rather binding with plasma proteins. Compounds with more than 90% PPB values are more prone to plasma protein binding thereby less effective and vice versa. %PPB value less than 90% is more effective.

2. Blood brain barrier:

Usually the drugs must not pass the blood brain barriers if the target is not related to nervous system. Blood brain barrier penetration is a parameter studied to check whether the compound crosses blood - brain barrier. PreADMET can predict *in vivo* data on rates for BBB penetration [14].

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SYNTHESIS, SPECTRAL CHARACTERISATION AND PHYSIOCHEMICAL PROPERTIES DETERMINATION OF SUBSTITUTED {4-(1H-BENZIMIDAZOL-2-YL) PHENYL} DIAZENYL DERIVATIVES

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ABSTRACT

Conventional synthesis of substituted {4-(1H-benzimidazol-2-yl) phenyl} diazenyl derivatives had been synthesized at laboratory scale by diazotization followed by coupling with different phenols and amines. The compound structures were characterized by IR, ¹H and ¹³C NMR spectroscopic methods. The synthesis was followed by chemical calculations by using Chemicalize an online software providing chemical calculations and predictions like logP, PKa and solubility mg/mL. The results observed describes that values of intrinsic solubility are less than zero which indicates that the compounds were categorised with low aqueous solubility. The isoelectric points for the compounds **8s** (4.57), **7s** (5.70) and other compounds having values ranging from 6.03 to 8.70 representing the pH at which the molecule carries no net charge required to predict the solubility of a compound.

KEY WORDS

Chemicalize, spectroscopy, solubility, isoelectric point.

INTRODUCTION:

Benzimidazole is an important heterocyclic fused ring system that possesses various pharmacological actions such as antimicrobials⁽¹⁾, antivirals⁽²⁾, antiparasitic⁽³⁾, anticancer, anti-inflammatory⁽⁴⁾, antioxidants⁽⁵⁾, proton pump inhibitors⁽⁶⁾, antihypertensives⁽⁷⁾, anticoagulants⁽⁸⁾, immunomodulators⁽⁹⁾, hormone modulators⁽¹⁰⁾, CNS stimulants as well as depressants⁽¹¹⁻¹⁵⁾, lipid level modulators⁽¹⁶⁻¹⁹⁾, antidiabetic, etc. has made it an indispensable anchor for development of new therapeutic agents. Varied substituents around the benzimidazole nucleus have provided a wide spectrum of biological activities⁽¹⁹⁻²⁶⁾. However, owing to fast development of new drugs possessing benzimidazole nucleus many researchers were continuously reporting the current status of benzimidazole nucleus in medicinal

chemistry research. In the present study, various azo derivatives of substituted phenyl ring in the benzimidazole ring system were synthesised by fragment-based approach of synthesis. This fragment-based approach of synthesis is a method used for synthesising lead compounds as part of the drug designing process.

MATERIALS AND METHODS:

Reagents Used:

The following chemicals and reagents were used in the synthesis:

Ortho phenylene diamine-(LOSA-S.NO-0520700250), 4-amino benzoic acid - (KEMPHASOL-S.NO-12PU05016), Sodium Nitrite purified- (CENTRAL DRUG HOUSE PVT LTD -S.NO-14103), Hydrochloric acid- (LOSA-S.NO-



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Synthesis, characterisation and *in vitro* evaluation of antioxidant and anti-inflammatory activity of some novel 5-aryl-7-[(1e)-aryl substituted]-1h, 3h-pyrido [2, 3-d] pyrimidine-2, 4-dione derivatives

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Abstract

Novel 5-aryl -7-[(1E)-aryl substituted]-1H, 3H-pyrido [2, 3-d] pyrimidine-2, 4-dione derivatives (1p-15p) were synthesized in two steps. Step 1 by reacting various aromatic aldehydes with aliphatic ketone i.e acetone under strong basic conditions by conventional method to form 1, 5-diaryl substituted-(E, E)-1, 4-pentadien-3-one derivatives which were condensed with 6-amino uracil to form 5-Aryl -7-[(1e)-Aryl Substituted]-1H, 3H-Pyrido [2, 3-D] Pyrimidine-2, 4-Dione Derivatives. The purity and progress of reaction was assessed by TLC and melting point. Synthesised compounds were characterised by various spectroscopic methods such as IR, ¹H & ¹³C NMR. The synthesised pyridopyrimidine were evaluated for their *In vitro* antioxidant and anti-inflammatory activities by DPPH assay and heat haemolysis method respectively. The results indicate that pyridopyrimidine showed dose dependent free radical scavenging activity in DPPH method and in RBC stabilisation method. 12p and 13p compounds showed higher free radical scavenging inhibition and compounds 1p, 9p, 10p, 11p, 12p and 14p exhibited good stabilisation of RBC membrane nearer to standard drug. The study provides a good scope for further development of novel targeted molecules.

Keywords: pyridopyrimidine, DPPH method, heat haemolysis method

1. Introduction

The heterocyclic fusion of pyrimidine and pyridine rings resulted in formation of pyridopyrimidines, the structural analogs of biogenic quinazolines and pteridines. Pyridopyrimidines and related fused heterocycles are of interest as potential bioactive molecules. Also, due to the presence of pyridopyrimidine moiety in some important drugs, interest in the construction of such molecules has been aroused. In the last few years, an enormous number of papers and reviews have been reported dealing with the chemistry and applications of this class of compounds [1, 2].

Pyrido [2,3-d] pyrimidines are the most abundance isomer in the literature and hence, this scaffold is associated with a wide range of biological activities, such as molluscicidal agents against *Biomphalaria alexandrina* snails, [3] anticancer, [4-6] antimicrobial, [7-10] anti-inflammatory and analgesic, [11-13] antiviral, [14, 15] antihypertensive, potent inhibitor of dihydrofolate reductase (DHFR) [16] which is an important target site in most of the parasitic diseases, Tyrosine kinase inhibitor, [17, 18] Cyclin-Dependent Kinase 4 (CDK4) inhibitor, [19] antihistaminic, calcium channel antagonist, antileishmanial, diarrhea, and diuretic activities. [20]

2. Materials and Methods

Melting points were determined in open glass capillaries using Tempo (600) melting point apparatus and were uncorrected. IR spectra (KBr discs) Bruker analysers were confirmed by Shimadzu FT-IR Spectrophotometer using KBr pellets technique, Model No.8400S (Japan). ¹H and ¹³C NMR spectra were recorded on Bruker 400 MHz NMR spectrometer (Switzerland) using DMSO as solvent. T.L.C. was run on silica gel G plates using ethyl acetate: n-hexane (5:5) as developing solvent to assess the progress of reaction and purity of the compounds. All other chemicals used in the present study were of analytical grade.

2.1 Drugs and Chemicals

6 – Aminouracil (Alfa Aesar – L03332), Benzaldehyde (LOBA-B.NO-L107581308), Acetone (LOBA-LL17391207), P- Dimethylaminobenzaldehyde (LOBA-B.NO-G329509),

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SIMULTANEOUS ESTIMATION OF AMOXICILLIN AND DICLOXACILLIN IN BULK AND CAPSULE DOSAGE FORM BY CHEMOMETRIC ASSISTED SPECTROPHOTOMETRIC METHODS

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ABSTRACT

The objective/aim of the present study is to develop UV-Spectrophotometric method and to apply the chemometric designs to the developed method for the simultaneous estimation of Amoxicillin (AMX) and Dicloxacillin (DOX) in intact capsule dosage form without further extraction. The UV-Spectrophotometric method was developed by using 0.1N sodium hydroxide as solvent for both the drugs and the data generation from the absorption spectra was done by three chemometric designs which were based on the principles of Linear regression analysis method (LRC), Cramer's matrix (CRM) and Method of least squares (MLS). The wavelength selected for all the above methods were 246 nm (wavelength of maximum absorption; λ_{max} of AMX), and 219 nm (wavelength of maximum absorption; λ_{max} of DOX). The developed methods were simple, economical and effective. These method need a separation techniques nor derivatization procedures.

KEYWORDS: Chemometrics, UV-Visible, Simultaneous, Amoxcillin, Dicloxacillin



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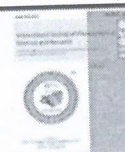
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SIMULTANEOUS ESTIMATION OF TELMISARTAN, HYDROCHLORTHIAZIDE AND AMLODIPINE IN BULK AND SOLID DOSAGE FORM BY CHEMOMETRIC ASSISTED SPECTROPHOTOMETRIC METHODS

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Keywords:

Chemometrics, UV-Visible,
Simultaneous, Telmisartan,
Hydrochlorothiazide, Amlodipine

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ABSTRACT: Chemometric designs were applied to develop a simple UV-visible spectroscopic method for the simultaneous estimation of Hydrochlorothiazide (HCT), Amlodipine (AMLO) and Telmisartan (TEL) in bulk and solid dosage form. The simultaneous spectroscopic method was developed for the three drugs and the data generated from the spectra were determined by using Chemometric methods such as trilinear regression analysis, Cramer's matrix method, Method of least squares, Multivariate calibration methods such as partial least square regression (PLS) and Principle component regression (PCR). The wavelengths selected for all the above methods were 270 nm (wavelength of maximum absorption; λ_{\max} of HCT), 342 nm (wavelength of maximum absorption; λ_{\max} of AMLO) and 292 nm (wavelength of maximum absorption; λ_{\max} of TEL). **Results:** The methods shows good linearity for TEL from 4 - 20 $\mu\text{g/ml}$, for HCT from 2-10 $\mu\text{g/ml}$ and AMLO from 2 - 10 $\mu\text{g/ml}$ with regression coefficient values of 0.970, 0.996 and 0.980 respectively. The RSD value for intraday and inter-day precision was found to be less than 2%. The percentage recovery and percentage assay was in the range of 95 - 105% for Telmisartan (TEL), Hydrochlorothiazide (HCT) and Amlodipine (AMLO) by all the methods. **Conclusion:** The developed methods neither require any oppressive separation procedure nor complex derivatization procedures for the analysis of the three drugs and moreover they are effective in minimizing the errors in analysis, simple and economical.

INTRODUCTION: Chemometrics is a branch of science which derives the data by the application of mathematical and statistical tools for the extraction of useful information from the physical and chemical phenomenon involved in a manufacturing process. Chemometrics ^{1, 2, 3, 4, 5} is used for calibration, signal correction and compression, pattern classification and recognition, multi variate data collection and analysis protocols, process modelling and statistical process control.

To overcome the significant problems in the analysis of intricate multi component formulations by conventional UV-spectroscopy ^{6, 7, 8}, HPLC ^{9, 10, 11, 12, 13, 14, 15, 16, 17} methods. Chemometric assisted analytical methods ^{18, 19, 20, 21} are designed to perform analytical investigation of such complex formulations. Telmisartan is 4' - ([4-methyl-6-(1-methyl-1H-benzimidazol-2-yl)-2-propyl-1H-benzimidazol-1-yl] methyl}-2-biphenylcarboxylic acid. It acts as antihypertensive and was used in treatment of hypertension.

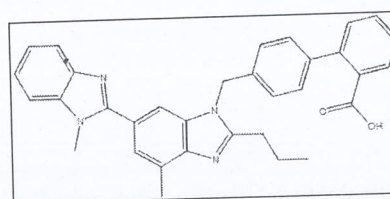



FIG. 1: STRUCTURE OF TELMISARTAN

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Simultaneous Estimation of Bacoside A3, Piperine and Crocin in Polyherbal Formulation by Chemometric Assisted RP-HPLC Method

A Elphine Prabahar^{1*}, Rama Rao Nadendla¹

Abstract: A simple RP-HPLC method was developed and chemometric designs were applied for the simultaneous estimation of bacoside A3 (BA3), piperine (PPN) and crocin (CON) in polyherbal formulation brahmi vati. The separation was carried out by using phenomenex C18 column (15 cm × 4.6 mm id, 5 µm particle size). For the optimization the ranges of independent variables used were MeCN: 33–38%, buffer conc.: 10–20 mM and flow rate: 1–2 ml/min. The data generated from the chromatograms were mined by using chemometric methods such as trilinear regression analysis and cramer's matrix method. The wavelengths selected for all the above methods were 248 nm (wavelength of maximum absorption; λ_{max} of BA3), 261 nm (wavelength of maximum absorption; λ_{max} of PPN) and 274 nm (wavelength of maximum absorption; λ_{max} of CON). The method holds good linearity for BA3 from 05–25 µg/ml, for PPN from 10–50 µg/ml and CON from 03–15 µg/ml with regression coefficient values of 0.999, 0.999 and 0.998 respectively. The intraday and inter-day precision was found to be less than 2% RSD. The percentage recovery and percentage assay was in the range of 95–105% for bacoside A3 (BA3), piperine (PPN) and Crocin (CON) by all the methods. The developed method neither requires any cumbersome separation procedure nor complex derivatization procedures for the analysis of the three herbal drugs and moreover they are effective in minimizing the errors in analysis, simple and economical.

INTRODUCTION

Chemometrics is a branch of science which derives the data by the application of mathematical and statistical tools for the extraction of useful information from the physical and chemical phenomenon involved in a manufacturing process. Chemometrics is used for calibration, signal correction and compression, pattern classification and recognition, multi variate data collection and analysis protocols, process modelling and statistical process control. To overcome the significant problems in the analysis of intricate multi component formulations by conventional UV-spectroscopy, [1–3] HPLC, [4–5] UPLC [6] methods chemometric assisted analytical methods [7] are designed to perform analytical investigation of such complex formulations.

Literature survey revealed that very few analytical methods like UV-spectroscopy and HPLC methods were reported and no chemometric methods were reported for the analysis of above combination. The present study aims to design chemometric assisted RP-HPLC methods for the intricate analysis of bacoside A3 (BA3), piperine (PPN) and crocin (CON).

MATERIALS AND METHODS

Instruments

Analytical balance.
UV-Visible spectrophotometer (Lab India -3072).
High Performance Liquid Chromatography (Agilent).

Data Handling Systems

UV-win for spectrophotometer.
EZchrom for HPLC.
The UnscrBA3ler X
Microsoft excel.

Drugs and Chemicals

Working standards of drugs were procured from Rishi Herbs, Chennai.

Commercial formulation of drugs (Brahmi, Manufactured by Herbal Daily, Batch No: BR201709102) was purchased from local market from Guntur, Andhra Pradesh. Methanol HPLC grade and Acetonitrile HPLC grade was procured from Merck (India) Ltd, Mumbai.

Preparation of Solutions

1. Preparation of Bacoside A3

10 mg of BA3 standard was weighed accurately and transferred to a 10 ml volumetric flask. The sample was dissolved by using 5 ml methanol and volume was made up to the mark with methanol. Further dilutions were made with the methanol to get required concentrations of 05, 10, 15, 20 and 25 µg/ml.

2. Preparation of Piperine Standard Solutions

10 mg of piperine standard was weighed accurately and transferred to a 10 ml volumetric flask. The sample was dissolved by using 5 ml methanol and volume was made up to the mark with methanol. Further dilutions were made with the methanol to get required concentrations of 10, 20, 30, 40 and 50 µg/ml.

3. Preparation of Crocin Standard Solutions

10 mg of crocin standard was weighed accurately and transferred to a 10 ml volumetric flask. The sample was dissolved by using 5 ml methanol and volume was made up to the mark with methanol. Further dilutions were made with the methanol to get required concentrations of 03, 06, 09, 12 and 15 µg/ml.

4. Preparation of Bacoside A3, Piperine and Crocin

Stock solution was prepared by diluting 5 ml of marketed liquid formulation to 50 ml with methanol. Required quantity of this stock solution was pipetted into

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Research article

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Phytochemical studies and anti-ulcer activity of *Limonia acidissima* linn. leaf in treating ethanol induced ulcer Albino rats

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ABSTRACT

Keywords:

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The preliminary phytochemical analysis of *Limonia acidissima* plant leaf, showed the presence of alkaloids, flavonoids, steroids, saponins, glycosides, phenols, gum and mucilage, fixed oils and fats, resins and tannins. The objective of the present investigation is to elucidate the anti-ulcer activity of ethanolic leaf extract of *Limonia acidissima* in ethanol induced GIT damage in albino rats. The lyophilized extract was given by oral gavages (200mg/kg and 400mg/kg) before administering ethanol at 1ml/kg. Pre-treatment with extract significantly decreased the ulcerated area. The volume and acidity of the gastric juice decreased in the pre-treated rats. In conclusion, *L. acidissima* was able to decrease the acidity and increase the mucosal defense in the gastric areas, thereby justifying its use as an anti-ulcerogenic agent.

1. INTRODUCTION

Ulcer is a common disorder of the gastrointestinal system, which causes much discomfort in patients, disrupting their daily routines and causes mental agony. Peptic ulcer disease can be characterized by inflamed lesions or excavations of the mucosa and tissue that protect the gastrointestinal tract. A peptic ulcer is a sore in the lining of stomach or duodenum, the first part of small intestine. If peptic ulcers are found in the stomach, they are called gastric ulcers. If they are found in the duodenum, they are called duodenum ulcers. Gastric ulcers are also associated with considerable morbidity related to chronic epigastric pain, nausea, vomiting, and anemia. Rarely, an ulcer can lead to a gastric or duodenal perforation. This is extremely painful and requires immediate surgery. Recently, *Helicobacter pylori* have been implicated in the antral gastritis, peptic ulcer, gastric malignancy and the non-ulcer dyspepsia. With the increasing use of non-steroidal anti-inflammatory drugs and alcohol consumption.

Ethanol induced gastric ulceration (EIGU) in rats is considered to be a reliable tool to study the pathogenesis of acute gastric mucosal ulceration. The gastric sub-mucosal micro vascular disturbance

resulting in local ischemia is an important early reaction following the use of ethanol. The endogenous mediators for the early vascular damage of the gastric mucosa include: nitric oxide, leukotrienes, histamine, adenosine, TNF α and endothelins. The release of endothelins plays a role not only in the pathogenesis of EIGU but also in the process of ulcer healing.

Limonia acidissima is one of the medicinally important plants belonging to Rutaceae, commonly known as wood apple. *Limonia*, confined to India, Pakistan, Sri Lanka and Southeast Asia. It is also known as wood apple, elephant-apple, monkey fruit, curd fruit, kathbel and kaitha. This plant is given as a medicine for the treatment of various disorders. *L. acidissima* is a deciduous, slow-growing, erect tree with a few upward-reaching branches bending outwards near the summit where they are subdivided into slender branchlets drooping at the tips.

Chemical Constituents: Major chemical constituents present in the ethanolic extract of leaves of *L. acidissima* are Acidissimin and Acidissiminol. Various parts of wood apple have been used against various ailments in ethnomedicine. Juice of young leaves is mixed with milk and sugar candy given as remedy for biliousness and intensive troubles of children.



**BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION
FOR SIMULTANEOUS DETERMINATION OF BICTEGRAVIR,
TENOFVIR AND EMTRICITABINE IN HUMAN PLASMA BY LC-
MS/MS**

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ABSTRACT

A simple, sensitive and fast throughput liquid chromatography tandem mass spectrometry (LC-MS/MS) method has been developed for the simultaneous estimation of bictegravir, tenofovir and emtricitabine in human plasma, using respective didanosine, stavudine and abacavir as internal standards respectively. The method involved Liquid-Liquid Extraction of the analytes and internal standards from human plasma. The chromatographic separation was achieved on a Zorbax C18 column (150×4.6mm and 5µm particle size) analytical column using isocratic mobile phase, consisting of Methanol : 0.1% formic acid in water (85:15, v/v), at a flow-rate of 1.0 mL/min with 90% flow splitting. The parent→product ion transitions were monitored at m/z 268.2 → 127.1 (BTGR), m/z 237.1→137.1 (DDI), m/z 230.2→112.1

(TNFR), m/z 248.1→130.0 (D4T), m/z 267.2→226.1 (EMTB) and m/z

SIMULTANEOUS ESTIMATION OF CARBODENAFIL AND DES-METHYL CARBODENAFIL FROM HUMAN PLASMA BY LIQUID CHROMATOGRAPHY-MASS SPECTROMETRY

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ABSTRACT

A simple, sensitive and fast throughput liquid chromatography tandem mass spectrometry (LC-MS/MS) method has been developed for the simultaneous estimation of Carbodenafil and its metabolite Des-methyl Carbodenafil in human plasma, using respective deuteriated drug as internal standards. The method involved Liquid-Liquid Extraction of the analytes and internal standards from human plasma. The chromatographic separation was achieved on a ACE, CN, (150×4.6mm and 5µm particle size) analytical column using isocratic mobile phase, consisting of 5mM Ammonium Format and Acetonitrile (25:75 v/v), at a flow-rate of 1.0 mL/min with 90% flow splitting. The parent→product ion transitions 475.40→/283.20, 461.30→ /283.20, 478.40→/283.20, 469.30→/283.20 (m/z) for Carbodenafil, Des-methyl

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LC-MS/MS METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS QUANTIFICATION OF ELBASVIR AND GRAZOPREVRIN IN HUMAN PLASMA

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ABSTRACT

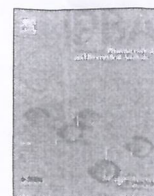
A simple, sensitive and fast throughput liquid chromatography tandem mass spectrometry (LC-MS/MS) method has been developed for the simultaneous estimation of Elbasvir and Grazoprevir, in human plasma, using respective deuteriated drug as internal standards. The method involved Solid Phase Extraction (SPE) of the analytes and internal standards from human plasma. The chromatographic separation was achieved on a Gemini, C18, (50×4.6mm and 5µm particle size) analytical column using isocratic mobile phase, consisting of 10mM Ammonium Acetate, Acetonitrile and Methanol (30:56:14 v/v), at a flow-rate of 1.0 mL/min with 75% flow splitting. The parent product ion transitions m/z 882.51 → 656.42 and m/z 888.49 → 662.43 for Elbasvir and Elbasvir-D6 respectively and the grazoprevir was detected at m/z 767.3/553.2 and Grazoprevir-D6 at m/z 773.3/559.2. The analytes and internal standards were monitored on a triple quadrupole mass spectrometer, operating in the multiple reaction monitoring (MRM) positive ion modes. The method was validated over the concentration range of 2.00-600 ng/mL and 0.5-150 µg/mL for Elbasvir and Grazoprevir respectively. The mean recovery values for both the drugs from spiked plasma samples were reproducible. The method was rugged and rapid with a total run time of 2.0 minutes.

KEYWORDS: Elbasvir; Grazoprevir; Elbasvir-D6; Grazoprevir-D6; LC-MS/MS; Liquid/liquid extraction.

1. INTRODUCTION

Elbasvir is an HCV NS5A inhibitor, and grazoprevir is an HCV NS3/4A protease inhibitor. The IUPAC name for elbasvir is Dimethyl N,N'-([[(6S)-6-phenylindolo[1,2-c][1,3] benzo xazine-3,10- diyl]bis{1H-imidazole-5,2-diyl-(2S)-pyrrolidine-2,1-diyl[(2S)-3-methyl-1-xobutane-1,2-diyl]}) dicarbamate. It has a molecular formula of C₄₉H₅₅N₉O₇ and a molecular weight of 882.02. Elbasvir is practically insoluble in water (less than 0.1 mg per mL) and very slightly soluble in ethanol (0.2 mg per mL), but is very soluble in ethyl acetate and acetone. The IUPAC name for grazoprevir is (1aR,5S,8S,10R,22aR)-N-[(1R,2S)-1-(Cyclopropylsulfonamido) carbonyl]-2-ethenylcyclopropyl]-14-methoxy-5-(2-methylpropan-2-yl)-3,6-dioxo-1,1a,3,4,5,6,9,10,18,19,20,21,22,22a-

tetradeca hydro-8H-7,10-methanocyclopropa^[18,19][1,10,3,6] dioxadiaz cyclone onadecino[11,12-b]quinoxaline-8-carboxamide. It has a molecular formula of C₃₈H₅₀N₆O₉S and a molecular weight of 766.90. Grazoprevir is practically insoluble in water (less than 0.1 mg per mL) but is freely soluble in ethanol and some organic solvents (e.g., acetone, tetrahydrofuran and N,N-dimethyl formamide). The combination product, ZEPATIER® contains two direct-acting antiviral agents with distinct mechanisms of action and non-overlapping resistance profiles to target HCV at multiple steps in the viral lifecycle. Elbasvir is an inhibitor of HCV NS5A, which is essential for viral RNA replication and virion assembly. Grazoprevir is an inhibitor of the HCV NS3/4A protease which is necessary for the proteolytic cleavage of the HCV encoded polyprotein (into mature



UPLC–MS/MS quantitative analysis and structural fragmentation study of five *Parmotrema* lichens from the Eastern Ghats

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UPLC–ToF–MS/MS

Metabolite profiling

Fragmentation studies

ABSTRACT

Comparative phytochemical analysis of five lichen species [*Parmotrema tinctorum* (Delise ex Nyl.) Hale, *P. andinum* (Mull. Arg.) Hale, *P. praesorediosum* (Nyl.) Hale, *P. grayanum* (Hue) Hale, *P. austrosinense* (Zahlbr.) Hale] of *Parmotrema* genus were performed using two complementary UPLC–MS systems. The first system consists of high resolution UPLC–QToF–MS/MS spectrometer and the second system consisted of UPLC–MS/MS in Multiple Reaction Monitoring (MRM) mode for quantitative analysis of major constituents in the selected lichen species. The individual compounds (47 compounds) were identified using Q–ToF–MS/MS, via comparison of the exact molecular masses from their MS/MS spectra, the comparison of literature data and retention times to those of standard compounds which were isolated from crude extract of abundant lichen, *P. tinctorum*. The analysis also allowed us to identify unknown peaks/compounds, which were further characterized by their mass fragmentation studies. The quantitative MRM analysis was useful to have a better discrimination of species according to their chemical profile. Moreover, the determination of antioxidant activities (ABTS⁺ inhibition) and Advance Glycation Endproducts (AGEs) inhibition carried out for the crude extracts revealed a potential antiglycaemic activity to be confirmed for *P. austrosinense*.

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1. Introduction

Lichens are nutritionally specialized fungi living in symbiotic association between fungi and algae/cyanobacteria. Several lichen species have been used in traditional medicine for centuries and are gaining considerable interest as an alternative medicine for the treatment of various ailments in different parts of the world. Symbiosis in lichens leads to production of typical secondary metabolites that includes depsides, depsidones, dibenzofurans, anthraquinones, xanthenes, pulvinic acid derivatives and naphthoquinones [1,2]. These lichen substances are responsible biomarkers for a wide range of biological activities and ecological roles [3,4].

In India, most of lichenological investigations are restricted either to Himalayan or the Western Ghats region. Nevertheless, recent studies indicate that the Deccan Plateau (DP) and the Eastern Ghats (EG) in southern part of India also present rich diversity of lichens. Around 180 lichen species are identified from this region of the country that has gained biological and economical importance [5,6]. Several *Parmotrema* species are available in the EG region and most of them became part of folklore medicine in the tribal areas of Andhra Pradesh (AP), India [7]. Although the species are medicinally important, very few species have been verified scientifically with respect to their chemical constituents [8]. Right identification of lichen species is also a challenge and out of bar-coding studies, classifications of lichens are usually carried out by morphology, anatomy along with chemical data based on color reactions obtained on thallus and medulla and metabolite characterization based on thin layer chromatography (TLC) methods. However, most of these tests have some limits to distinguish minute differences between species [9]. Alternatively, study of lichen compounds by usual LC–MS techniques [10] or direct

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Rapid identification of limonoids from *Cipadessa baccifera* and *Xylocarpus granatum* using ESI-Q-ToF-MS/MS and their structure-fragmentation study

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ABSTRACT

Limonoids found to be chemotaxonomic markers from the plants of the Meliaceae and Rutaceae families. In the present study, rapid identification of limonoids from *Cipadessa baccifera* and *Xylocarpus granatum* were achieved using fast and simple electrospray ionization quadrupole time-of-flight mass spectrometry (ESI-Q-ToF-MS/MS) in positive-ion mode. Although the structures of these compounds were found to be similar, Collision Induced Dissociation (CID) mass spectrometric analysis of these protonated/sodiated molecules indicated different fragmentation patterns by which the structures were confirmed. The fragment ions were formed due to the loss of neutral components like H₂O, CO₂, methanol, as well as McLafferty rearrangement and Retro-ene reaction. Furthermore, MS/MS spectra revealed different fragmentation pathways for different classes of limonoids which further aided dereplication.

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1. Introduction

Limonoids are a group of highly oxygenated and modified nor-triterpenoids which are characteristic components of the plants of Meliaceae and Rutaceae families [1,2]. The diversified structures and wide range of biological activities of these limonoids have attracted much attention to both phytochemists and chemical biologists [1,2]. The biological effects of limonoids include insect antifeedant and growth-regulating, antimicrobial, antimalarial activity against *Plasmodium falciparum*, anticancer, and antioxidant activities [3,4]. The chemical structures of limonoids mainly consists of polycyclic rings and structural characterization has become a major challenge. The nuclear magnetic resonance (NMR) and X-ray analysis were often employed techniques for structure elucidation of limonoids, requiring an extensive and laborious purification to perform the experiments. Mass spectrometry (MS), particularly, quadrupole time-of-flight (Q-TOF-MS) has shown its potential for analyzing the structures of secondary metabolites from the complex mixtures of botanic extracts [5]. It is widely applied method for structural elucidation of constituents

because it not only gives structural information from tandem mass (MS/MS) spectra, but also generates accurate masses both in MS and MS/MS modes, which facilitate the identification and confirmation for compounds more efficiently [6,7]. Previous studies on the analysis of limonoid compounds using various techniques such as thin layer chromatography (TLC) [8], high-performance liquid chromatography (HPLC) [9] and liquid chromatography coupled with mass spectrometry (LC-MS) using electrospray ionization (ESI) have been reported [10,11] respectively. However, to the best of our knowledge, direct identification of limonoids from crude extracts using ESI-Q-ToF-MS/MS method has not been reported till date. Therefore, as part of our continuous study on the limonoids, we developed Q-ToF-MS/MS method for the identification of minor/unknown constituents from ethyl acetate extracts of two Meliaceae plants, namely *Cipadessa baccifera* and *Xylocarpus granatum*. Our study led the rapid identification of limonoids from these extracts through the detailed fragmentation pattern with collision induced dissociation (CID-MS/MS) using electrospray quadrupole time-of-flight mass spectrometry (ESI-Q-ToF-MS/MS) in positive mode. This report describes the development of Q-ToF-MS/MS method that was adopted to investigate and understanding of CID-fragmentation patterns of specific limonoids fragmentation pattern of the constituents from the complex extracts.

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RESEARCH ARTICLE

***Terminalia chebula* Retz improve memory and learning in Alzheimer's Model: (Experimental Study in Rat)**

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ABSTRACT:

Objective: The aim of this study was to identify the potential of *Terminalia chebula* as a protective and therapeutic agent against Alzheimer's disease. **Methods:** The learning and memory enhancing activity of *Terminalia chebula* fruit extracts were investigated in rats by using the ethanol- induced cognitive impairment and diazepam induced amnesia and its effects on learning and memory were examined by using Morris water maze (MWM) test. **Results:** All the groups showed significantly (P value is <0.01 and <0.05) decrease transfer latency at all periods as compared to ethanol and diazepam inducing group. Therefore Fruit extracts of *Terminalia chebula* exhibited significant learning and memory activity in Alzheimer's disease. **Conclusion:** The present study suggests *Terminalia chebula* that modulate the oxidative stress and be involved in the protective effect against oxidative damage and neurodegenerative diseases in rat.

KEYWORDS: Ethanol, diazepam, Morris water maze, learning and memory activity, Alzheimer's disease.

INTRODUCTION:

Alois Alzheimer and Auguste D

The German psychiatrist and neuropathologist Dr. Alois Alzheimer is credited with describing for the first time a dementing condition which later became known as AD. In his landmark 1906 conference lecture and a subsequent 1907 article, Alzheimer described the case of Auguste D, a 51-year-old woman with a 'peculiar disease of the cerebral cortex,' who had presented with progressive memory and language impairment, disorientation, behavioural symptoms (hallucinations, delusions, paranoia), and psychosocial impairment. Remarkably, many of the clinical observations and pathological findings that Alzheimer described more than a century ago continue to remain central to our understanding of AD today.¹ Alzheimer's disease is a form of brain degeneration in which abnormal particles called neurofibrillary tangles and neuritic plaques form in the brain and destroy healthy neurons (brain cells).

These abnormalities tend to settle in brain areas that control the ability to learn a new fact and remember it 30 minutes, or a day later, a skill we refer to as "memory".²

Terminalia chebula Retz. (Family Combretaceae) commonly known as Haritaki and found all over the different parts of India, such as Assam, Gujarat, Mumbai, Konkan, Malbar, Chennai. The tree is great's significance to the Hindu and the dried twigs of tree are used in various vanjnas. *T. chebula* is commonly known as black myroblans in English and harad in Hindi. The *Terminalia* consists of 250 species and widely distributed in tropical areas of the world. This is one of the major components of wonder Ayurveda medicine known as Triphala Powder. Haritaki is known as "The King of Medicines". In Ayurveda, it is described t as kind of mother because "At times even mother becomes angry but Haritaki never causes a harm to a person who takes it". *T. chebula* is a medium to large deciduous tree, attaining a height of up to 30 m with wide spreading branches and a broad disk-shaped crown. The Sanskrit name 'Haritaki' is rich with meaning, referring to the yellowish dye (haritak) that it contains, as well as indicating that it grows in the abode of god siva (Hari, that is the Himalayas) and that it cures (harayet) all

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Research Article

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NEUROPROTECTIVE ACTIVITY OF *TERMINALIA CHEBULA* RETZ AGAINST ETHANOL INDUCED COGNITIVE IMPAIRMENT AND OXIDATIVE STRESS IN RATS: PROMISING FOR REGIMENTATION THE RISK OF ALZHEIMER'S DISEASE

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ABSTRACT

Terminalia chebula Retz (*T.chebula*) which is a member of the Combretaceae family is frequently used medicinal herb in Ayurvedic, Unani, Siddha & Homeopathy system of medicine. *Terminalia chebula* is called the "King of Medicine" in Tibet and is always listed at the top of the list in Ayurvedic Materia Medica due to its extraordinary power of healing. To evaluate the neuroprotective activity of *Terminalia chebula* Retz against ethanol induced cognitive impairment and oxidative stress in rats brain. The learning and memory enhancing activity of *Terminalia chebula* Retz extract were investigated in Sprague Dawley rats for 21 days and its effects on learning and memory were examined by using 8-arm radial maze (or) radial arm maze (RAM) and histopathological studies. All the groups showed significantly (P value is <0.0001) decrease in the time taken to reach paired arm (sec) & number of entries in baited arms and non-baited arms as compared to ethanol inducing group and histopathological study of *Terminalia chebula* showed significant effect when compared to the standard drug for treating Alzheimer's disease. Therefore *Terminalia chebula* was proved to be effective agent for treating Alzheimer's. The present study suggests *Terminalia chebula* that modulate the oxidative stress and be involved in the protective effect against oxidative damage and neurodegenerative diseases in rat.

Key words: Ethanol, diazepam, Radial arm maze, learning and memory activity, Alzheimer's disease.

INTRODUCTION

Alois Alzheimer and Auguste D, The German psychiatrist and neuropathologist Dr. Alois Alzheimer is credited with describing for the first time a dementing condition which later became known as AD. In his landmark 1906 conference lecture and a subsequent 1907 article, Alzheimer described the case of Auguste D, a 51-year-old woman with a 'peculiar disease of the cerebral cortex,' who had presented with progressive memory and language impairment, disorientation, behavioral symptoms (hallucinations, delusions, paranoia), and psychosocial impairment. Remarkably, many of the clinical observations and pathological findings that Alzheimer described more than a century ago continue to remain central to our understanding of AD today¹. Alzheimer's disease is a form of brain degeneration in which abnormal particles called neurofibrillary tangles and neuritic plaques form in the brain and destroy healthy neurons (brain cells). These abnormalities tend to settle in brain areas that control the ability to learn a new fact and remember it 30 minutes, or a day later, a skill we refer to as "memory"².

Terminalia chebula Retz (Family Combretaceae) commonly known as Haritaki and found all over the different parts of India, such as Assam, Gujarat, Mumbai, Konkan, Malbar, Chennai. The tree is great's significance to the Hindu and the dried twigs of tree are used in various vanjnas. *T. chebula* is commonly known as black myroblans in English and harad in Hindi. The *Terminalia* consists of 250 species and widely distributed in tropical areas of the world. This is one of the major components of wonder Ayurveda medicine known as Triphala Powder. Haritaki is known as "The King of Medicines". In Ayurveda, it is described as kind of mother because "At times even mother becomes angry but Haritaki never causes a harm to a person who takes it".

T. chebula is a medium to large deciduous tree, attaining a height of up to 30 m with wide spreading branches and a broad disk-shaped crown. The Sanskrit name "Haritaki" is rich with meaning, referring to the yellowish dye (haritak) that it contains, as well as indicating that it grows in the abode of god siva (Hari, that is the Himalayas) and that it cures (harayet) all diseases. Its other commonly used Sanskrit name, Abhaya, refer to the "fearlessness" it provides in the face of the disease³.

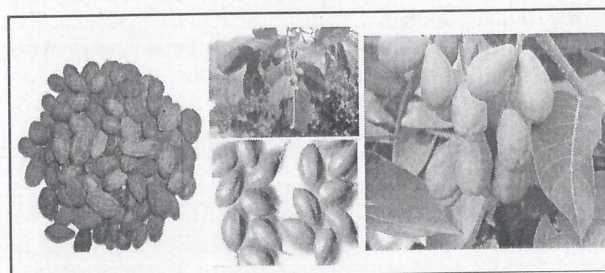


Figure 1: *Terminalia chebula* fruit leaf and tree⁴

MATERIALS AND METHODS

Collection & Authentication of Plant Material

The fruits of *Terminalia chebula* was identified and purchased from local market of Guntur and authenticated by P.Satyanarayana Raju (Plant taxonomist) of Department of Botany and Microbiology in Acharya Nagarjuna University, Guntur, India.

Research Article

Investigation of antiparkinsonian effect of *Terminalia chebula* Retz. on haloperidol-induced experimental animal model

Lakshmi Kakunuri*, Karishma Shaik, Amreen Sultana S, Narendra Babu A, Naga Lakshmi J, Bhargav Kumar N

ABSTRACT

Aim: The present study aimed to evaluate the antiparkinsonian activity of *Terminalia chebula* (*T. chebula*) fruit extracts by haloperidol-induced catatonia model in Sprague Dawley (SD) rats. **Methodology:** Parkinson's disease was induced by administering haloperidol (4 mg/kg p.o) daily for a week. The SD rats were divided into four groups with five animals in each group. Group I - inducing group - haloperidol (4 mg/kg P.O), Group II - standard group - Syndopa Plus (10 mg/kg P.O), Group III - Test-1 (aqueous fruit extract of *T. chebula* [TCAE] - 100 mg/kg P.O), and Group-IV - Test-2 (Ethanollic fruit extract of *T. chebula* [TCEE] - 100 mg/kg P.O). All the treatment group animals received respective inducing, standard, and test treatment 30 min before the haloperidol administration. Antiparkinsonian effect was evaluated using block method and locomotor activity. **Results:** Haloperidol induced a time-dependent increase in cataleptic score in rats, as compared to other groups. All the groups showed significantly ($P < 0.05$) lower scores of catalepsy at all time periods as compared to haloperidol-inducing group. **Discussion:** Fruit extracts of *T. chebula* exhibited a significant antiparkinson's activity.

KEY WORDS: Antiparkinsonian activity, Block method, Catatonia, Haloperidol, Locomotor activity

INTRODUCTION

Parkinson's disease (PD) is a slowly progressive neurodegenerative disease caused when a small group of brain cells that control body movements die. This disease was first described by James Parkinson in 1817. It is characterized clinically by bradykinesia, resulting tremor, rigidity, and postural instability. Pathological features of PD include loss of dopamine neurons in substantia nigra and presence of intracytoplasmic inclusions known as Lewy bodies in surviving dopamine neuron. It is not clear why Lewy body formation causes neuronal cell death. Among the available antiparkinson drugs, levodopa remains the most efficacious and still the mainstay of therapy. However, long-term use of levodopa leads to wearing off phenomenon, on-off phenomenon, motor fluctuations, and dyskinesia, which limit its further usage. Even though antiparkinson drugs are highly effective in alleviating the symptoms of Parkinsonism,

they do not give complete cure. Moreover, these drugs are often associated with frequent side effects such as nausea, vomiting, depression, hallucinations, dizziness, dry mouth, sore throat, postural hypotension, diarrhea, mydriasis, and anxiety. The significance of many indigenous medicinal plants and their phytoconstituents in the management of Parkinsonism with minimal side effect profile arises in this context. There has been an enormous demand for the further scientific development of animal models that can mimic the progressive motor impairment as in PD. One such model is haloperidol-induced catalepsy, i.e., a state of akinesia with muscular rigidity in animals. It is an established model for screening the drugs for antiparkinson effect.^[1]

Terminalia chebula Retz. (family Combretaceae) is commonly known as Haritaki and found all over the different parts of India, such as Assam, Gujarat, Mumbai, Konkan, Malabar, and Chennai. The tree is of great significance to the Hindu, and the dried twigs of the tree are used in various vanjnas. *T. chebula* is commonly known as black myrobalans in English and harad in Hindi. The terminalia

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Pharmacological evaluation of leaf extracts of *Crataeva religiosa* for its anxiolytic activity in Albino mice

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Abstract

Objective: To study the anxiolytic activity of ethanolic extract and aqueous extract of *Crataeva religiosa* in mice.

Methods: the anxiolytic activity of ethanolic extract and aqueous extract of leaves of *Crataeva religiosa* (20 mg/kg) in mice assessed by using open field test and light and dark test (behavioural test) Diazepam standard drug.

Results: Aqueous leaf extract showed significant anxiolytic activity when compared with methanolic leaf extract, standard and control treatment groups using open field test and light and dark test.

Conclusion: The ethanolic extract and aqueous extract of *Crataeva religiosa* possess antianxiolytic activity since it reduced the duration of anxiety produced by open field test and light and dark test.

Keywords: *Crataeva religiosa*, Open field test, light and dark box test.

INTRODUCTION

The name *Crataeva* is given in the honor of Crataevus, a Greek botanist, who was living in the time of Hippocrates and the name *religiosa* indicates its growth near the places of worship (1). *Crataeva religiosa* is much branched deciduous tree belonging to the family capparidaceae commonly called as Varuna (2). The trade name given for this tree is three leaved capper [3]. The leaves are trifoliate, glabrous, and ovate.

2. Distribution

Crataeva religiosa is globally distributed in India, Myanmar, Sri Lanka, Malaysia, Indonesia and China. In India, it is found in Peninsular India, Western India, Gangetic Plains, and Eastern India, up to Tripura and Manipur [2]. It is also found in Sikkim and Andaman and Nicobar Island [3]. It is found mostly along the bank of the river and streams and near to temple side [5], [6].

3. Ethnobotany

The plant part used for the medicinal purpose includes Leaves, stem bark and Root bark [7], [8], [9]. These parts of *C. nurvala* are commonly applied to regulate equilibrium among Vata, Pitta and Kapha in Ayurvedic system while the stem bark is used to promote the appetite and to decrease the secretion of the bile in unani medicines [10]. Recently Bopana and Saxena [11] critically reviewed *C. nurvala* for its ethno botanical and pharmacological properties. Plant is used ethno pharmacologically as diuretic, laxative, lithonotriptic, antirheumatic, antiperiodic, bitter tonic, rubifacient and counterirritant [7], [8]. The bark is used in the urinary disorders including kidney and bladder stones, antiemetic, and calculous affections and as an antidote in snakebite [7]. *C. religiosa* is valuable in treating vata (blood flow, waste elimination and breathing), Pitta- (fever and metabolic disorder) and Kapha (joint lubrication, skin moisture, wound healing, strength and vigour, memory loss, heart and lung weakness and weak immune system [9]. A preparation called 'Varunal' contains *Crataeva* in combination with *Eclipta*, *Picrorrhiza*, *Achillea*, *Cichorium*, *Solanum*, *Arjuna*, and *Cassia* seeds are used against hepatitis, edema, ascites, urinary stones and arthritis [12]. The bark is contraceptive and cytotoxic and useful in kidney bladder stones, fever vomiting and gastric irritation [13]. Roots and bark are laxative and lithonotriptic and increase appetite and biliary secretion [14]. Leaves are used as externally rubifacient and used in rheumatism. Leaves are given internally febrifuge and tonic [15], [16]. According to Gurrero [http://www.mbpi.da.gov.ph. 2009], In Philippines, leaves are useful in irregular menstruation and also in stomachic, whereas the bark is used to cure convulsions and tympanites. Sanyal and Ghose

[http://www.bpi.da.gov.ph. 2009] speculated that the crushed leaves are applied in the form of paste for swelling of feet and also for a burning -sensation in the soles of feet. The bark and the leaves are pounded and applied in the form of a poultice in rheumatism. The fresh leaves bruised with little vinegar, applied to skin. Bark and roots are rubifacient and vesicant. Decoction of bark is used in the disorders of urinary organs and urinary calculi. Roots and bark in the form of decoction are used as calculus affections [http://www.bpi.da.gov.ph. 2009]. Traditionally, the plant is used as oxicotic, in rheumatic fever in kidney stones, bladder stone and as tonic [17]. It is useful as antipyretic, antilithitic, antihelminthic, demulcent in blood and chest diseases [18]. NR-AG-I is a polyherbal formulation containing *Crataeva religiosa*, *Dolichos biflorus*, *Tribulus terrestris* and *Shilajit*. NRAG-II is another herbal formulation containing *Crataeva religiosa*, *Boerhavia diffusa*, and *Saccharum officinarum*. and *Butea frondosa*. Between these two, NR-AG-II is having good diuretic potential than NR-AG-I [19]. A mixture containing- *Tribulus terrestris* fruits (25%); *Zinziber officinalis* roots(10%); *Solanum xanthocarpum* whole plant (10%); *Asparagus racemosus* roots (10%); *Tephrosia purpurea* leaves (10%) and *Crataeva religiosa* bark (25%) was prepared and 4gm of mixture given to patient twice daily with water in urinary disorder [20].

Drugs obtained from natural sources are perceived to have fewer side effects while having same ability to cure disorders in much the same way as their synthetic counterparts. Therefore, present study was undertaken to evaluate anxiolytic activity of ethanolic extract and aqueous extracts of *Crataeva religiosa* leaves.

MATERIALS AND METHODS:

Plant collection:

The leaves of *Crataeva religiosa* were collected from medicinal plant garden of Chalapathi institute of pharmaceutical sciences, Guntur. The plant was authenticated by Dr.P.Raghu Ram, Department of botany, Acharya Nagarjuna University, Guntur and voucher specimen was deposited in herbarium for further reference.

Extraction procedure:

The leaves of *Crataeva religiosa* were washed thoroughly and dried under shade and then made into a coarse powder using dry grinder. The powder leaves was passed through sieve no. 40 and stored in an air tight container at 25°C, used for further study. Powdered plant material (1.2 kg) were successively extracted using Soxhlet apparatus using the solvents in order of increasing polarity viz. methanol and water

Research Article

Formulation and evaluation of novel organic toothpaste using cow dung coal powder

Thalathoti Vandana Raj^{1*}, P. Hema Soundarya², A. Narendra Babu³, K. Prakash⁴

ABSTRACT

Aim: The aim of the present research is to formulate and evaluate organic toothpaste using cow dung powder. **Materials and Methods:** Cow dung coal powder, sorbitol (humectant), gum tragacanth, gum acacia, sodium CMC (binders), sodium benzoate (preservative), sodium saccharine (sweetener), cinnamon oil (flavoring agent), sodium lauryl sulfate (surfactant), and polyethylene glycol were used for formulating the toothpaste. The cow dung was collected and dried, after that it was burnt to produce cow dung coal powder which was used as a main ingredient in toothpaste formulation. Toothpastes were prepared using different binders such as gum tragacanth, gum acacia, and sodium CMC. Later, different evaluation tests were performed on these formulations. **Results and Discussion:** The formulated cow dung coal powder toothpaste had shown good results as like the commercial products in the market. **Conclusion:** As we prepared different formulations using different concentrations of binders, the formulation prepared using sodium CMC 1% was found effective compared with other formulations prepared with different binders.

KEY WORDS: Antibacterial activity, Binders, Cow dung coal powder, Evaluation tests

INTRODUCTION

Cow dung is the waste excreted by cows which consists of undigested residues of consumed matter which has passed through the gastrointestinal system of the animal. The fecal matter ranges in color from greenish to black and it darkens on exposure to air. The dung has been used as organic fertilizer and in the production of biogas to generate electricity and heat.^[1] The cow dung has been also used as insecticides and has been reported to contain antibiotic agents.^[2] The use of cow dung in the bioremediation of toxicants in the environment has been reported.^[3] The cow dung is utilized for fields and plants as fertilizer. The cow dung is used for gas plants. The cow dung is an efficacious disinfectant and often used as fuel in lieu of firewood in India, and cow dung is also an antiseptic. Not only it is free from bacteria but also it does a good job of killing it. In addition, smoke from a dung fire keeps flies away and acts as a mosquito repellent. If packed on the outside walls of a house, cow dung acts as an insulator, keeping heat out in the summer and holding it inside in winter.^[4]

Not only has the cow dung but also cow urine had also disinfectant properties. The usage of cow dung and urine in cosmetic products was also increased. A company in Mumbai known as "Cowpathy" was manufacturing soaps, shampoos, hair oil, and toothpastes using cow dung, urine, and cow ghee. The dung is generally dried for over a week and then blended at a very high temperature to kill all harmful bacteria and germs. The final product, a dung powder, is mixed with variety of ingredients to make the medicines and toiletries.^[5]

MATERIALS AND METHODS

Materials

Cow dung coal powder, sorbitol (humectant), gum tragacanth, gum acacia, sodium CMC (binders), sodium benzoate (preservative), sodium saccharine (sweetener), cinnamon oil (flavoring agent), sodium lauryl sulfate (surfactant), and polyethylene glycol were used.

Equipment

Ball mill, Brookfield viscometer, beakers, glass rod, measuring cylinders, glass plates, egg shells, and dry vessel were used as equipment.

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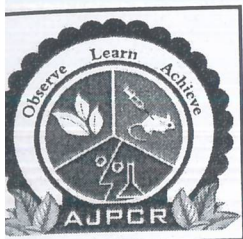
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BIOLOGICAL EVALUATION OF *CUCUMIS SATIVUS* LEAF EXTRACT USING ALBINO MICE

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ABSTRACT

Cucumis sativus (Cucumber) is a widely cultivated plant (Family: Cucurbitaceae). It is a creeping vine that bears cucumiform, fruits that are used as vegetables. Traditionally, *Cucumis sativus* possesses anti-diarrhoeal, anti-urolithiatic, anti-inflammatory, anti-hypertensive, proteolytic, anti-fungal, antioxidant and anti panic activities. The leaves of this plant is used for headache, seeds as diuretic, the fruit juice of this plant is used as nutritive and as a demulcent in anti-acne lotions. In the present study the ethanolic leaf extract of *Cucumis sativus* is screened for its phytochemical and biological activity (anti-panic activity) as per the traditional value by scientific manner. The results concluded that the ethanolic leaf extract of *Cucumis sativus* possessed significant anti-panic activity when compared with the standard diazepam.

KEYWORDS

Cucumis sativus, Urolithiatic, panic, Phytoconstituents and Diazepam.

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INTRODUCTION

Depressive anxiety is one of the most common emotional disorders and treatment of phobias or panic attacks is still not trivial. Pharmacological therapies play an important role in the therapeutic concept¹. Benzodiazepines have been the most widely used anxiolytics in various practices for many year and are relatively safe drugs for a shorten treatment of anxiety disorder despite their drug dependence potential and side effects. Diazepam and Buspirone are standard anxiolytic and also employed in behavioral pharmacology as the reference compound for an anxiolytic like effect

Pharmacological Evaluation of Leaf Extract of *Terminalia bellerica* with *Moringa oleifera* for its Synergistic action on Anti-Anxiety Activity in Rats

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Original Research Article

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Abstract: To evaluate the pharmacological action of leaf extract of *Terminalia bellerica* with *Moringa oleifera* for its synergistic action on anti-anxiety activity in rats. The pharmacological evaluation of standardized aqueous extract of the leaves of *Terminalia bellerica* with *Moringa oleifera* was carried by using the following Stimuli model: Anti-anxiety activity by Elevated plus Maze. The parameters of various activities to assess anti-anxiety were evaluated and found That, The combination of extracts possess a better response then alone. The aqueous leaf extract of the combination of *Terminalia Bellerica* with *Moringa oleifera* has shown significant anti-anxiety activity when compared with standard and extract alone.

Keywords: *Moringa oleifera*, *Terminalia bellerica*, Elevated plus maze, Anti-anxiety activity.

INTRODUCTION

Anxiety disorders are among the most common psychiatric disorders that affect all age groups of the general population[1]. It characterized as concern or fear about some defined or undefined future threat and emotional behavior, unpleasant mood, uneasiness and discomfort associated with disability in both educational and professional life. Anxiety exhibited negative impact on quality of life and increases suicidal behavior in individuals[2] Major drug classes for the treatment of anxiety disorders are benzodiazepines and selective serotonin-reuptake inhibitors (SSRIs). However, these compounds have a number of undesirable effects such as insomnia, muscle relaxation and hepatotoxicity.

These considerations implicate the search for new anxiolytic compounds that have a fast onset of action present with less side effects and a wider safety margin. Medicinal plants are a good source to find new remedies for these disorders.

Terminalia bellerica also referred to as, Beleric Myrobalan belonging to family Combretaceae. *Terminalia bellerica* is used in traditional medicine due to the wide spectrum of pharmacological activities associated with the biologically active chemicals present in this plant. The phytoconstituents isolated from various parts of the plant include alkaloid, coumarin, flavones, steroids (β - Sitosterol), lignans (termilignan, thannilignan), tannins (gallic acid, ellagic acid), glycosides (fructose, sucrose, galactose), terpenoid (belleric acid and chebulagic acid), saponin (bellericoside and bellericanin). *Terminalia bellerica* is one such plant showing multifarious medicinal properties viz. analgesic activity, antibiofilm activity, anticancer activity, antidepressant activity, antidiabetic activity, antidiarrhoeal activity, antiulcer activity, immunomodulatory activity, antispasmodic and bronchodialatory activity, antifertility activity,

antihypertensive activity, antifungal, antimicrobial activity, anti-inflammatory activity, antioxidant activity[3].

Moringa oleifera Lam, popularly called "the miracle tree", is a monogeneric plant of the family Moringaceae. *Moringa oleifera* is rich in minerals, carbohydrates, proteins, fats, moisture, crude fiber, and ash contents *M. oleifera* leaves have been used by local traditional healer in treatment of various ailments such as diabetes, gastric discomfort, stomach ulcer, diarrhea, and dysentery and skin infections. The leaves have also been found to possess antitumor, antipyretic, antiepileptic, anti-inflammatory, anti-ulcer, anti-hypertensive and anti-oxidant properties. Phytochemical analysis of *Moringa oleifera* showed the presence of flavonoid, anthraquinone, alkaloids, saponins, steroids, terpenoids, cardiac glycoside, anthocyanintannins and carotenoid in aqueous extract[4].



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PHARMACOLOGICAL EVALUATION OF CITHAREXYLUM SERRATUM FOR ITS ANXIOLYTIC AND MUSCLE RELAXANT ACTIVITIES ON MICE

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ARTICLE INFO

ABSTRACT

Key Words

Citharexylum Serratum, anxiolytic, muscle relaxation, Photoactometer, Open field test, Elevated Plus Maze, Chimney test, IR Actimeter, Hole board apparatus, Circular tangle.



Objective: To carry out the preclinical evaluation of methanolic extract of the leaves of *Citharexylum Serratum* for anxiolytic and muscle relaxation activity. **Methodology:** The preclinical evaluation of standardized diazepam and methanolic extract of the leaves of *Citharexylum serratum* for anxiolytic and muscle relaxation activity was carried out by using the following experimental models: a) Elevated Plus Maze b) Chimney test c) IR Actimeter d) Hole board apparatus e) Photo actometer f) Open field test g) Circular tangle. **Results:** The models for studying drugs or conditions that affect muscle relaxation and anxiolytic activity was standardized and evaluated by using leaf extracts of *Citharexylum serratum*. The methanolic leaf extract of *Citharexylum serratum* has shown significant muscle relaxation and anxiolytic activity by all the employed experimental models. **Conclusion:** Screening models for studying drugs or conditions that affect anti anxiety and muscle relaxation was standardized and evaluated by using methanolic extract of *Citharexylum Serratum*. The leaf extract has shown significant activity of anxiolytic and muscle relaxant when compared with standard treatment group.

INTRODUCTION:

Herbal medicine is the oldest form of healthcare known to mankind. Herbs had been used by all cultures throughout history. It was an integral part of the development of

modern civilization. Primitive man observed and appreciated the great diversity of plants available to him. The plants provided food, clothing, shelter, and medicine. Much of the

What Has Come out from Phytomedicines and Herbal Edibles for the Treatment of Cancer?

Srinivasa Reddy Bonam,^[a, b, c] Yuan Seng Wu,^[d] Lakshmi Tunki,^[b] Ranjithkumar Chellian,^[d] Mahabalarao Sampath Kumar Halmuthur,^{*,[b, c]} Sylviane Muller,^{*,[a, e]} and Vijayapandi Pandey^{*,[d, f]}

Several modern treatment strategies have been adopted to combat cancer with the aim of minimizing toxicity. Medicinal plant-based compounds with the potential to treat cancer have been widely studied in preclinical research and have elicited many innovations in cutting-edge clinical research. In parallel, researchers have eagerly tried to decrease the toxicity of current chemotherapeutic agents either by combining them with herbals or in using herbals alone. The aim of this article is to present an update of medicinal plants and their bioactive compounds, or mere changes in the bioactive compounds, along with herbal edibles, which display efficacy against diverse cancer cells and in anticancer therapy. It describes the

basic mechanism(s) of action of phytochemicals used either alone or in combination therapy with other phytochemicals or herbal edibles. This review also highlights the remarkable synergistic effects that arise between certain herbals and chemotherapeutic agents used in oncology. The anticancer phytochemicals used in clinical research are also described; furthermore, we discuss our own experience related to semisynthetic derivatives, which are developed based on phytochemicals. Overall, this compilation is intended to facilitate research and development projects on phytopharmaceuticals for successful anticancer drug discovery.

1. Introduction

Cancer is one of the leading causes of death, and reports by the World Health Organization revealed that cancer accounted for 8.2 million deaths in 2012; the same year saw approximately 14 million new cancer cases.^[1] Although there are several types of cancer treatment options in practice, their success depends on the type and stage of cancer. Among the various

treatment options, surgical removal of cancerous tissues/tumors, radiation therapy, chemotherapy, and immunotherapy are commonly adopted.^[2] These therapeutic options are effective in treating various types of cancers, but they have limitations such as disease recurrence and noncompliance owing to severe adverse effects like pain, fatigue, anemia, nausea, emesis, and hair loss, to name only a few less tolerable side effects.^[3] It is important to emphasize that most synthetic chemotherapeutic agents that have been developed in the past, failed to fulfill expectations during clinical trials, despite the high expenditure incurred for their development.^[4] Therefore, new, effective and affordable anticancer drugs are in high demand.

Researchers in academia and industry have recently focused more on herbal medicines for the treatment and prevention of cancer.^[5] Evidence of toxicity associated with chemotherapeutic agents, even at therapeutic doses, has been growing over the years, as has the percentage incidence of commonly observed toxic effects during chemotherapy.^[6] These limitations have urged researchers to investigate natural remedies against chemotherapy-induced toxicity.^[7] Diverse medicinal plant extracts or phytochemicals have been reported to have anticancer activity at various stages of tumor progression.^[8] Approximately 60% of chemotherapeutic agents used for cancer treatment are obtained from natural products, with medicinal plants being the main source.^[9] The earliest plant-based compounds that were approved and used in clinical practice include vinblastine and vincristine (vinca alkaloids isolated from the plant *Catharanthus roseus*, Apocynaceae), paclitaxel and docetaxel (i.e., taxanes, a class of diterpenes initially identified

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Methanolic extract of *Morinda citrifolia* Linn. unripe fruit attenuates methamphetamine-induced conditioned place preferences in mice

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Mice
Noni fruit

ABSTRACT

The first objective of the present study was to determine the appropriate dose of methamphetamine (Meth) to induce a successful conditioned place preference (CPP) in mice. The next objective was to examine the effect of a methanolic extract of *M. citrifolia* unripe fruit (MMC) against Meth-induced CPP in mice. In answering to the first objective, following the preconditioning test, an intraperitoneal injection of a fixed dose of Meth (0.5 or 1 or 2 mg/kg, i.p.) or saline (10 ml/kg, i.p.) was given on alternate days during the 10 days conditioning period followed by a postconditioning test conducted in Meth-free state. The first experiment revealed that 0.5 mg/kg of Meth could be an appropriate fixed low dose to induce CPP in mice. Meanwhile, in other experiments, the effect of MMC and bupropion (BUPR) against the expression, extinction, and reinstatement of Meth (0.5 mg/kg)-induced CPP in mice, respectively, was investigated. In a separate set of studies on each phase, an oral administration of MMC (1, 3 and 5 g/kg, p.o.) or BUPR (20 mg/kg, p.o.) was given 60 min prior to CPP post-conditioning testing or extinction testing or reinstatement testing in mice. Extinction trials were conducted in Meth-free state to weaken CPP over the next 5 days. Reinstatement test was conducted by a single low dose priming injection of Meth (0.1 mg/kg, i.p.). The present study, however, failed to establish a successful extinction and reinstatement of Meth-CPP in mice. Further studies using other doses of Meth are warranted for a successful establishment of all phases of Meth CPP in mice. This study also demonstrates that MMC (3 and 5 g/kg, p.o.) and BUPR (20 mg/kg, p.o.) could attenuate the expression of Meth-induced CPP in mice.

1. Introduction

Compulsive drug use of methamphetamine (Meth), a psychostimulant with high dependence liability resembling those of heroin and nicotine, currently poses a significant detrimental health issue, globally [1]. Meth is widely abused in many countries, including Malaysia, causing major medical, psychiatric and legal consequences [2]. The effects of Meth abuse on an individual are quite serious and grave. Initially, Meth increases alertness, physical activity, and respiration and reduces fatigue and body weight. However, in long term abuse, it can cause psychosis, violent behaviour, mood disturbance, memory loss and brain dysfunctions [3]. Chronic use of Meth is neurotoxic to dopaminergic and serotonergic neurons in the central nervous system. There are chemical and molecular changes in the brain associated with changes in the activity of dopaminergic system involved in reduced motor skills and impaired learning [3], and increased likelihood

development of Parkinson's disease [4]. Despite the dangerous documentation of Meth use, there is a report which revealed that the hospital emergency room visits associated with Meth use increased from about 68,000 in 2007 to 103,000 in 2011 in United States [5]. Other than that, a report from National Anti-Drug Agency (AADK) revealed a drastic increase in the use of Meth from 4026 in 2011 to 8133 in 2015 in Malaysia [6]. Nevertheless, currently there is no medication approved by the Food and Drug Administration (FDA) for treating Meth dependence. Globally, many research attempts have been made on pharmacotherapy to alleviate craving to Meth and the probability of relapse [7]. Relapse, or return to drug use following a period of drug cessation by months or years, was preceded by drug craving associated with an intense urge or desire to use the drug, commonly caused by drug re-exposure and/or the environmental cue stimuli that has been formerly brought with the recent drug use [8].

Morinda citrifolia Linn, commonly known as Noni, is a small tree or

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journal homepage: www.elsevier.com/locate/biopharmProtective effect of α -asarone against nicotine-induced seizures in mice, but not by its interaction with nicotinic acetylcholine receptorsRanjithkumar Chellian*, Vijayapandi Pandey¹

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ABSTRACT

Alpha-asarone is one of the bioactive phytochemicals present in the rhizomes of *Acorus* species and demonstrated its anticonvulsant activity in rodents. Alpha-asarone protected mice from the gamma-aminobutyric acid (GABA) type A receptor antagonist or N-methyl-D-aspartate (NMDA) receptor agonist-induced seizures. In our recent study, α -asarone attenuated the nicotine withdrawal-induced depression-like behavior in mice. The seizures induced by nicotine is mediated through the activation of nicotinic acetylcholine receptors (nAChRs) and stimulation of NMDA receptors. Therefore, we hypothesized that α -asarone might be effective against nicotine-induced seizures. Also, the interaction of α -asarone with nAChRs is unknown. In this study, we investigated the effect of α -asarone on the locomotor activity and body temperature in mice. In addition, we studied the effect of α -asarone on nicotine-induced seizures in mice. Finally, we assessed *in vivo* pharmacodynamic interaction of α -asarone with nAChRs using nicotine-induced hypomotility and hypothermia tests in mice. The results of this study showed that the α -asarone (50–200 mg/kg, i.p.) and diazepam (5 mg/kg, i.p.) treatment significantly decreased the locomotor activity and body temperature in mice. Furthermore, α -asarone (50–200 mg/kg, i.p.) and diazepam (5 mg/kg, i.p.) pretreatment significantly prolonged the onset time of nicotine-induced seizures in mice. However, α -asarone (30 and 50 mg/kg, i.p.) pretreatment did not inhibit the nicotine-induced hypomotility or hypothermia in mice. Conversely, mecamylamine (1 mg/kg, s.c.) pretreatment completely blocked the nicotine-induced seizures and significantly prevents the nicotine-induced hypomotility and hypothermia in mice. Overall, these results suggest that the protective effect of α -asarone against nicotine-induced seizures did not mediate through the antagonism of nAChRs. We also postulated that the GABAergic and glutamatergic activities of α -asarone could be involved in its protective effect against nicotine-induced seizures and based on this aspect further studies are required.

1. Introduction

Alpha-asarone (Fig. 1) is one of the main psychoactive phytochemical presents in the rhizomes of *Acorus* species (Acoraceae) such as *Acorus calamus* Linn, *Acorus tatarinowii* Schott, and *Acorus gramineus* Solander [1,2]. Epilepsy is a neurological disorder characterized by recurrent spontaneous seizures. The seizures occur mainly due to the disrupted balance between glutamatergic signaling (excitatory) and gamma-aminobutyric acid (GABA) ergic signaling (inhibitory) [3]. In rodents, α -asarone demonstrated its antiepileptic activity in the lithium-pilocarpine induced status epilepticus and maximal electroshock-induced seizure models (refer review article authored by Chellian et al.) [4–9]. Moreover, α -asarone protected mice against the N-methyl-D-aspartate (NMDA, a specific NMDA receptor agonist), kainate (a

kainate receptor agonist), or pentylenetetrazol and picrotoxin (GABA type A (GABA_A) receptor antagonists)-induced seizures [4,6,7,9,10].

Nicotine is an agonist at the nicotinic acetylcholine receptors (nAChRs). The activation of nAChRs by nicotine stimulates the glutamate release mediated through calcium-calmodulin cascades. The released glutamate activates NMDA receptors and leads to seizures [11]. In recent studies, a nonselective and noncompetitive antagonist of the nAChRs (mecamylamine), a selective α_7 -nAChRs antagonist (methyllycaconitine) [12–14], a positive allosteric modulator of GABA_A receptors (diazepam, ethanol, and midazolam) [15,16] and NMDA receptor antagonists (dizocilpine or MK-801, memantine, and amantadine) [12] were effective in suppressing the nicotine-induced seizures in rodents. Nicotine also is known to cause a decrease in locomotor activity (hypomotility) and hypothermia in rodents [17,18]

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Original Article

ASSESSMENT OF THE NUTRITIONAL BEHAVIOUR AMONG COLLEGE STUDENTS-A SURVEY

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ABSTRACT

Objective: To assess the nutritional behaviour among college students.

Methods: A prospective observational survey was conducted randomly among college students in Guntur. A self-administered data collection form was designed to understand the nutritional behaviour of the subjects.

Results: A total of 300 subjects were included in the study, among them 225(75%) were females and 75(25%) were males. The survey revealed that most of them skipped their meals. A majority of 184(61.33%) students opted for high-fat diet and 268(89.33%) opted for starch-rich foods. A total of 222(74%) students usually eat four different varieties of vegetables but only 71(23.66%) of them eat fruits in each week.

Conclusion: From this study, it was evident that majority of students have poor dietary habits. Lack of awareness on balanced diet and due to their busy schedules, teenagers were not maintaining a proper diet. This could be reduced by bringing minimum awareness on dietary habits to them. Taking proper diet is very essential to reduce the risk of diseases in future and to improve nourishment.

Keywords: Balanced diet, Nutritional status, Improper diet, Skipping meals, Poor nutritional effects

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INTRODUCTION

A balanced diet is a way of eating all of the right nutrients that your body needs in order to be healthy. Healthy eating contributes to overall healthy growth and development, including healthy bones, skin, and energy levels; and a lowered risk of dental caries, eating disorders, constipation, malnutrition, and iron deficiency anemia [1]. It is also important because your organs and tissues need proper nutrition to work effectively. Without good nutrition, the body is more prone to disease, infection, fatigue, and poor performance [2]. In recent decades, important socio-economic changes in most developed countries have undeniably affected the eating habits and level of physical activity of citizens. This trend was clearly illustrated by the current increase in illnesses directly or indirectly related to the increase in overweight and obesity [3]. It has been established that a poor nutrition and insufficient physical activity are the main risk factors for various diseases. Some research studies suggest that any type of physical activity reduces the risk of developing coronary heart disease, stroke as well as various metabolic disorders like hypertension, diabetes and improves the patient quality of life [4].

Nutrition is an intake of food, considered in relation to the body's dietary needs. Good nutrition is an adequate, well-balanced diet combined with regular physical activity. It is a cornerstone of good health. Poor nutrition can lead to reduced immunity, increased susceptibility to disease, impaired physical and mental development, and reduced productivity. Many of us are in the habit of eating too many carbohydrate-rich foods and not quite enough protein-rich foods, so our intake is out of balance. In addition to this, often the high carbohydrate foods that we choose have been so processed that they contain very few vitamins and minerals. Eating too much carbohydrate leads to diabetes. Leading cause of bad nutrition in college students is eating fast food which affects them to become obese and malnourished. Consumption of junk food has increased manifold, which has led to a number of diseases related to nutritional deficiencies [5]. Another biggest mistake that students make in their dieting habit is to skip meals. Skipping meals on a regular basis particularly breakfast disturbs body metabolism.

According to the Food and Agriculture Organization of the United Nations, poverty and lack of resources are the two main causes that contribute to the estimated 925 million people worldwide suffering the effects of malnutrition and its companion diseases [6]. Getting regular exercise, adequate sleep and balancing the demands of work with relaxation help to provide a balanced, healthy lifestyle. More emphasis in one area while neglecting the, due to stress, poor health and the inability to cope up with the demands of daily life. Stress and nutrition have always been linked to each other and someone with a healthy and balanced diet is likely to be far less stressed than someone with poor diet [7]. Nutrition education is one of the important practical aspects. It plays an important role in raising public awareness and ultimately the health of society [8]. Awareness camps on nutrition and balanced diet will help the public to maintain a proper diet. On the other hand, some researchers have shown that most students are not familiar with healthy foods needed for their body in different conditions [9, 10] and need to have nutrition education programs. The present study was conducted to understand the nutritional behaviour of the college students.

MATERIALS AND METHODS

The survey was conducted to assess the nutrition status in college students by using a self-administered questionnaire. This was designed to allow the subjects to assess the nutritional value of their diet. The survey was carried among 300 subjects in different places of Guntur city in the state of Andhra Pradesh. The survey was conducted among people aged between 17 to 23 y and estimated the results. The consent form was given to subjects. The survey to the maximum targeted the subjects in relation to their dieting habit like how often they skip meals, how often they include a portion of vegetables and fruits in their diet, how often and how much of fats, sugars, starchy foods, salt, drinks and alcohol they consume.

RESULTS AND DISCUSSION

A total number of subjects was 300. Out of which female participants were dominated 225 (75%) and male participants were 75(25%). This is depicted in fig. 1.

ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE IN HYPERTENSIVE PATIENTS IN RURAL POPULATION OF GUNTUR DISTRICT IN SOUTH INDIA

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ABSTRACT

Background: Hypertension is considered as one of the leading causes of death and disability, and its prevalence is rapidly increasing in developing countries. Adequate treatment of high blood pressure lowers the cardiovascular risk and other complications like vascular disease, and chronic kidney disease. However, the major problem for controlling hypertension is compliance with treatment

Aim and Objectives: To study and assess the quality of life in patients suffering from hypertension.

Methodology: A prospective observational cohort study was conducted for a period of 6 months in a rural area of Guntur. A total of 300 hypertensive patients who are newly diagnosed or suffering from hypertension since 3 years were recruited. Blood pressure was measured by using a sphygmomanometer and other demographics were collected. Health related quality of life was assessed by using 36-item short form (SF-36) and respective scores were calculated.

Results: By using SF-36 questionnaire Physical health (49.4) was the component mostly effected in hypertensive patients followed by Vitality (61.75), emotional aspects (69.06), pain (67.3), social functioning (78.54), appear to be least effected.

Conclusion: Proper treatment and awareness about hypertension is necessary to improve patient's quality of life. Good compliance not only improves the clinical outcomes, it is also having a great impact on improving quality of life and reducing health care costs which are due to complication and co-morbidities of hypertension.

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INTRODUCTION

Hypertension is one of the most common chronic disease affecting humans and is a major risk factor for stroke, myocardial infarction, vascular disease, and chronic kidney disease. Due to the associated morbidity and mortality and cost of disease to society, preventing and treating hypertension is an important public health challenge now-a-days. Modern life is full of hassles, deadlines, frustrations and demands. Mental stress or psychosocial stress is one of the major risk factor for hypertension, which it is the risk factor for various other cardiovascular diseases.

The Constitution of the World Health Organization (WHO) defines health as "A state of complete physical, mental, and social well-being not merely the absence of disease". It follows that the measurement of health and the effects of health care must include not only an indication of changes in the frequency and severity of diseases but also an estimation of

well-being and this can be assessed by measuring the improvement in the quality of life related to health care. WHO defines Quality of Life as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.^[1]

Quality of life (QOL) is a broad multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life.

- HRQOL is related to both self-reported chronic diseases (diabetes, breast cancer, arthritis, and hypertension) and their risk factors (body mass index, physical inactivity, and smoking status).
- Measuring HRQOL can help determine the burden of preventable disease, injuries, and disabilities, and can provide valuable new insights into the relationships between HRQOL and risk factors.
- Measuring HRQOL will help monitor progress in achieving the nation's health objectives.^[2]

The QOL construct, implemented presently, includes a framework for assessing personal outcomes, a social construct

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AWARENESS ON CERVICAL CANCER-RISK ASSESSMENT

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ABSTRACT

Objective: To create awareness on cervical cancer, a level of knowledge about cervical cancer, to be advised of effective screening procedures based on their risk assessment, to educate about preventive measures after screening.

Methods: This is a prospective questionnaire-based survey conducted by providing materials such as patient information leaflets, video clips and posters and educating the public regarding the disease from 1st January 2016–30th June 2016 i.e. for a period of 6 mo.

Results: Knowledge was provided by using pictures, presentations, and patient information leaflets. Out of 1000 population, the respondents 762 (76.2%) females and 200 (20%) males were aware of cervical cancer. Among the 48 women who attended the screening, 23(47.9%) were identified with various symptoms and are on treatment. Out of these, 3 members were diagnosed positively and level of knowledge has increased significantly after creating awareness.

Conclusion: Primarily health care professionals such as nurses and pharmacists should also be educated in various aspects to upgrade their knowledge as it was observed that their level of knowledge was relatively low. Clinical pharmacist in this regard has a major role to play in up lifting and improving the quality of life of the patient.

Keywords: Cervical cancer, Knowledge, Screening, Awareness

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INTRODUCTION

Cervical cancer is the second most common cancer in women worldwide, with over 90% of cases occurring in developing countries. Most of the cases and deaths are seen in developing countries and India attributes to about 15% of the cancer deaths in the world mostly in rural areas. A persistent infection with a high-risk oncogenic human papillomavirus (HR-HPV) is involved in almost all cases [1]. HPV infection is very common in young women with early sexual activity, with a peak before 25 y, usually without clinical consequence. In nearly 10% of cases, this infection persists and is associated after 5 to 10 y with lesions that may regress, remain stable or progress to a higher grade and invasive cancer. Evolution of cervical intraepithelial neoplasia (CIN) to invasive cancer is slow, about 10 to 20 y for an immunocompetent woman. This slow progression allows an effective secondary prevention based on screening and treatment of precancerous lesions, using cervical cytological testing according to Papanicolaou (Pap smear or Pap test), visual inspection of the cervix with 3–5% acetic acid (VIA), or more recently HPV DNA testing. Immuno-suppression, especially due to human immunodeficiency virus (HIV) infection, is a predisposing factor for persistent infection with HR-HPV and the development of squamous intraepithelial lesions (SIL). High HIV viral loads and low CD4 counts are associated with a higher risk of HR-HPV infection and cervical abnormalities. The risk of recurrence or progression of cervical lesions is 4–5 times higher in women living with HIV. Infection with one of the 15 HR-HPV genotypes is significantly more common in HIV-infected women, while the distribution of low-risk oncogenic HPV is not affected by HIV status [2, 3]. This reflects a higher propensity of HR-HPV in determining persistent infections. A vaccine called Gardasil has been developed that protects against the two high-risk HPV types (types 16 and 18), which cause 70% of cervical cancers in women and 90% of all HPV-related cancers in men five. It also protects against two low-risk HPV types (types 6 and 11), which cause 90% of genital warts. Gardasil is used in the school-based national HPV vaccination program. Another vaccine called Cervarix is available, which protects against the same two high-risk HPV types (types 16 and 18). It does not protect

against low-risk HPV types which cause genital warts. Over 187 million doses of Gardasil have been given safely, in over 130 countries around the world [4].

MATERIALS AND METHODS

A community-based Prospective self-questionnaire survey to create awareness among the public about cervical cancer and, advice for effective screening, lifestyle modifications, prevention among the public was conducted for a period of 6 mo from January to June in Guntur.

Materials

Consent form, Data collection form-I, Data collection form-II, Awareness aids-Patient information leaflets, Posters, Multimedia, Questionnaire forms-I and II, Risk assessment questionnaire, Feedback form.

Inclusion criteria

All men and women aged above 14yrs for awareness.

Exclusion criteria

Women with total hysterectomy.

Women with a positive history of cervical cancer.

Plan of work

The work was planned to carry out accordingly as follows.

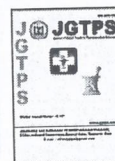
To include people satisfying the criteria, we had designed a patient data collection form and a questionnaire form to collect all the data required for the study which helps to create awareness on cervical cancer about its screening procedures, risk factors, lifestyle modifications and prevention by circulating leaflets, visual presentation, oral and poster presentation to motivate the women for the effective participation in the screening program. We had also collected feedback about the awareness after creating awareness had enlightened the study.



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A SURVEY ON RISK ASSESSMENT AMONG DIABETIC POPULATIONS IN GUNTUR REGION OF ANDHRA PRADESH

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Key Words

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ABSTRACT

Diabetes mellitus (DM) has evolved as a major public health concern worldwide, as its prevalence is increasing exponentially. Therefore, finding an effective way to identify individuals at risk of developing diabetes is necessary. The objective of this study is to review the problems and risk limitations facing by the existing diabetic population to assess the need for further development in their drug therapy and life style. Obesity and diabetes are major causes of morbidity and mortality as evidences from several studies indicates that these obesity and weight gain are associated with an increased risk of diabetes. There is however considerable new knowledge regarding the etiology of different forms of diabetes as well as more information on different blood glucose values for the complications of diabetes. Along with these, many other factors like age, sex, life style, physical exercise, family history, diabetic education, drug therapy and follow up etc., plays a major role in the risks and other limitations in diabetic patients. Predictions, risk assessment and risk profiling are among the various decision support techniques that this survey increasingly rely on to provide early diagnose in patients with elevated risks and to slow down the rapid increase in prevalence of chronic diseases.



INTRODUCTION:

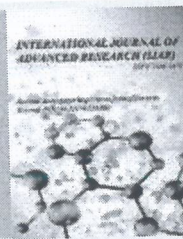
The recent studies estimates by the International Diabetes Federation (IDF) showed that the number of adults affected by the disease in 2011 was 366 million which was projected to increase to 552 million by 2030. Nearly 80% of the affected people live in middle- and low-income countries. Type 2 diabetes mellitus, which constitutes more than 95% of all the diabetic populations, has an insidious onset with a long, latent, asymptomatic phase. Among the top 10

Countries/territories with the largest number of diabetic adults, five are in Asia. China tops the list with 90.0 million followed by India which has 61.3 million persons affected by diabetes. The numbers are estimated to rise to 129.7 million and 101.2 million, respectively by 2030. Predictions, risk assessment and risk profiling are among the various decision support techniques that this survey increasingly rely on to provide early diagnose in patients with elevated risks and to slow down the rapid increase in prevalence of chronic diseases.



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RESEARCH ARTICLE

DIETARY BEHAVIOUR IN SCHOOL GOING ADOLESCENTS IN GUNTUR.

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Abstract

Background: Awareness of health and nutrition is not just significant in rural masses but also among school children i.e the antecedent adults or the so called adolescents where improper nutrition either over nutrition or under nutrition affects their civic education, physical as well as mental development in addition to a future risk of major health consequences.

Aims:

1. To study and Monitor the spectrum of the nutritional status in adolescent population.
2. Provide periodical updates on underweight, overweight/obesity among adult populations.
3. To report the regional estimated number of underweight, overweight and obese adults.
4. To Identify vulnerable population groups (i.e. age, sex, geographical area).
5. To Assess the trends in nutrition transition (i.e. relationship between BMI and dietary patterns).
6. To Raise political awareness and commitment for action.

Method: A Cross-sectional Prospective Questionnaire based Survey was conducted in the schools of Guntur. The study period is from January to June 2017. Nutritional and health status was assessed using a questionnaire.

Results: A total no of 1515 adolescents of age 11-17years met our inclusion criteria, boys were 839(55.5%) and girls were 676(44.6%). From our data underweight were 87.81% , normal were 93.9% and obese were 11.46%.

Conclusion: The present findings add to other results in the literature in suggesting that nutrition knowledge is an important target for health education. In order to promote healthy nutritional behaviours and prevent underweight, overweight and obesity, it is important to target this population with interventions concerning their eating habits and lifestyles. So it was concluded that there should be an immediate action to reduce the incidence through appropriate nutrition intervention programmes involving school children, their parents and school

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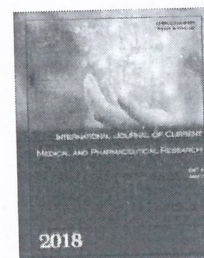
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Research Article

IMPACT OF MEDICATION ADHERENCE IN HYPERTENSIVE PATIENTS IN RURAL POPULATION OF GUNTUR DISTRICT IN SOUTH INDIA

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ABSTRACT

Aim and Objectives: To study and assess the impact of medication adherence in patients suffering from hypertension.

Methodology: A prospective observational cohort study was conducted for a period of 6 months in a rural area of Guntur. A total of 300 hypertensive patients who were newly diagnosed or suffering from hypertension since 3 years were recruited. Blood pressure was measured by using a sphygmomanometer and other demographics were collected. Medication adherence was assessed using the HILL-BONE compliance to high blood pressure therapy scale (HILL-BONE CHBPTS).

Results: Hill-Bone scores were analyzed in the aspects of medication compliance, salt usage, appointment keeping and observed a modest improvement in all aspects with an average of 8.49.

Conclusion: Proper treatment and awareness about medication and their usage will improve medication adherence. Good medication adherence not only improves the clinical outcomes, it is also having a great impact on improving the quality of life and reducing health care costs which are due to complications and co-morbidities of hypertension. Clinical pharmacists play a vital role in improving the adherence by providing periodic counselling, which in turn helps to reduce the burden of illness.

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INTRODUCTION

Hypertension is one of the most common chronic diseases affecting humans and is a major risk factor for stroke, myocardial infarction, vascular disease, and chronic kidney disease. Due to the associated morbidity a mortality and cost of disease to society, preventing and treating hypertension is an important public health challenge now-a-days. Modern life is full of hassles, deadlines, frustrations and demands. Mental stress or psychosocial stress is one of the major risk factor for hypertension, which in turn is the risk factor for various other cardiovascular diseases.^[1] Adherence is referred as "active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behavior to produce a therapeutic result. Adherence and compliance are often interchangeable synonymous terms. In patients with hypertension, adherence to medication is critically important for controlling blood pressure and reducing associated risk of cardiovascular complications.^[2] Compliance consists of three components, namely, acceptance of medication prescribed, adhering to it and continuing with it. Thus compliance is a complex and dynamic health enhancing behavior that involves

acts of appointment keeping, obtaining and ingesting medications and persisting with a health provider. Compliance with treatment at the individual level improves the quality of life by preventing complications and thereby premature death.^[3] There is a positive relationship between levels of adherence and knowledge regarding treatment. When patients have positive beliefs regarding the efficacy of their treatment and also trust that their medication is working well to control their illness, their adherence often improves.^{[6][12]}

In the rural areas most of the people are illiterate and lack awareness on condition and medications. Some of the barriers include poor provider-patient communication, inadequate knowledge about a drug and its use, not being convinced of the need for treatment, fear of adverse effects of the drug, long term drug regimens, complex regimens that require numerous medications with varying dose schedules, cost and access barriers. Adherence to therapies is a primary determinant of treatment success. Failure to adhere is a serious problem which not only affects the patient, but also the health care system.^[4] Patient counseling was provided verbally either to patients or to their representatives regarding directions of medication

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IMPACT OF CLINICAL PHARMACIST INTERVENTIONS IN USE OF ORAL ANTI-CLOTTING AGENTS

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Anticlotting agents, clinical pharmacist, acenocoumarol, Stroke, thromboembolism

ABSTRACT

Anticoagulants and antiplatelet agents are medicines that reduce blood clotting in an artery, a vein or the heart. Blood clots can block the blood flow to your heart muscle and cause a heart attack. They can also block blood flow to your brain, causing a stroke. Pharmacist's unique knowledge of pharmacology, pharmacokinetics and interactions makes them well-suited to assist patients in maintaining safe and effective therapy. Successful therapy improves patient adherence, implies fewer incidences of therapeutic failures and bleeding complications. A total of 187 patients with anti-clotting therapy was randomised and analysed. Knowledge was assessed to both groups before and after education, in control group has no significant difference in score from 2.39 ± 2.18 to 2.50 ± 2.30 ($P=0.078$), in intervention group score was improved from 2.15 ± 1.67 to 3.98 ± 2.05 ($p=0.001$) and adherence score by Mo risky scale in intervention group improved from 4.01 ± 1.84 to 2.07 ± 1.32 ($p=0.001$) and in control group no difference 3.80 ± 1.84 to 3.72 ± 1.81 ($p=0.2387$) and 24 interactions and 16 adverse effects reported in control group due to lack of knowledge and in intervention group 8 interactions and 8 adverse effects were reported. This concludes that pharmacist intervention play an role in improving adherence, and quality of life.

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INTRODUCTION

Over the past 40 years, major changes have occurred in the area of anticoagulation management. New strategies have been developed for older anticoagulants, older beliefs have been challenged, new anticoagulants have been introduced, and new indications have been identified for existing anticoagulants. The role of the pharmacist in managing anticoagulant therapy has been established, and clinicians have learned more about the critical importance of medication safety. Advances have spanned from the outpatient setting to the critical care setting¹. Anticoagulants and antiplatelet agents are medicines that reduce blood clotting in an artery, a vein or the heart. Blood clots can block the blood flow to your heart muscle and cause a heart attack. They can also block blood flow to your brain, causing a stroke. Pharmacist's unique knowledge of pharmacology, pharmacokinetics and interactions makes them well-suited to assist patients in maintaining safe and effective therapy. Successful therapy improves patient adherence, implies fewer incidences of therapeutic failures and bleeding complications.

Pharmacists can play an important role in keeping patients with atrial fibrillation adherent to anticoagulants.

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Adherence to anticoagulant therapy is important when considering that a missed dose could mean a lack of protection. Pharmacists can monitor adherence during transitions of care from the hospital to outpatient treatment by tracking whether the patient tolerates the prescribed anticoagulant. Some others ways in which pharmacists can help atrial fibrillation patients stay adherent are refill reminders and patient education.

Anti clotting agents

Anticoagulants and antiplatelet agents are medicines that reduce blood clotting in an artery, a vein or the heart. Blood clots can block the blood flow to your heart muscle and cause a heart attack. They can also block blood flow to your brain, causing a stroke¹.

Anti-clotting medication is used to prevent blood clots from forming, and therefore lower the risk of certain cardiovascular diseases like heart attacks and strokes. As the name suggests, they make sure that the blood does not clot as quickly. The colloquial term "blood thinner" is not strictly correct, because the medication does not actually thin the blood, but rather make sure that certain components of the blood do not stick together so easily. Anti-clotting medications can be divided into two groups: Anticoagulants stop clotting factors from forming or working. Antiplatelets stop the blood platelets (thrombocytes) from clotting so easily^{8,9}.



Research Article

ASSESSING THE NEED OF DOSAGE ADJUSTMENTS OF THYROXINE AMONG PREGNANT WOMEN WITH HYPOTHYROIDISM

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ARTICLE INFO	ABSTRACT
<p>Article History:</p> <p>Received 7th April, 2018 Received in revised form 16th May, 2018 Accepted 3rd June, 2018 Published online 28th July, 2018</p> <p>Key words:</p> <p>Hypothyroidism, dosage adjustment, levothyroxine</p>	<p>Aim & objective: The aim of the study is to assess the need of dosage adjustments of thyroxine among pregnant women with hypothyroidism.</p> <p>Methodology: To evaluate the effects of pregnancy on thyroxine requirements, we prospectively reviewed the thyroid function of 86 women receiving treatment for hypothyroidism in pregnancy. Study design: Prospective observational study</p> <p>Results and findings: Out of 86 subjects, 44 subjects are having pre pregnancy hypothyroidism and 42 subjects are having gestational hypothyroidism. Age at presentation (yrs) was 23.78+ 4.17; Weight (kgs) was 61.11+13.27. Among 44(51.16%) subjects in pre pregnancy hypothyroidism, 9(20.45%) subjects required increase in levothyroxine dose; 10(22.7%) required decrease in levothyroxine dose. Among 42(48.83%) subjects in gestational hypothyroidism, 5(11.9%) subjects required increase in levothyroxine dose; 2(4.76%) subjects required decrease in dose; (P=0.032). Remaining 60 subjects in both pre pregnancy and gestational hypothyroidism required no change due to sufficient dose.</p> <p>Conclusion: Based on our prospective observational study we finally conclude that Levothyroxine requirements was more in all trimesters but mostly in first trimester followed by third trimester. Levothyroxine requirement was more in Gestational hypothyroidism (19.76%) compared to Pre pregnancy hypothyroidism (16.27%).</p>

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INTRODUCTION

Background

Women with hypothyroidism have been thought not to require an increase in thyroxine replacement during pregnancy. In our clinical practice, we observed an apparent increase in the thyroxine requirement in a number of pregnant women with hypothyroidism.

Need of the Study

- Hypothyroidism is most common in pregnant women. As thyroid hormone requirements increase during pregnancy often leading to the need to increase the levothyroxine dose.
- It is necessary to assess TSH levels and adjust the dose of levothyroxine.
- Women who don't receive enough thyroid hormone during pregnancy are at greater risk of complications like miscarriage, low birth weight, neuro- psychological problems, respiratory problems, premature birth, post partum hemorrhage, abruptio placentae, pre-eclampsia, anemia.

Aim

To study the need of dosage adjustments of thyroxine among pregnant women with hypothyroidism.

Objective

To monitor the thyroxine requirements in pregnancy with hypothyroidism based on TSH levels.

METHODOLOGY

Study design: Prospective observational study.

Study site: Department of Obstetrics and Gynaecology, Government general hospital, Guntur.

Study period: October 2017 to March 2018 (6 months).

Sample size: Out of 137 subjects, 86 subjects were included in our study based on study criteria.

Materials: Lab reports, data collection form, prescriptions, case records.

Inclusion criteria: Pregnant women with hypothyroidism of age group more than 18 years.

Exclusion criteria: Pregnant women with hypothyroidism who are chronically ill.

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ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH METASTATIC BONE DISEASE BEING TREATED WITH BISPHOSPHONATES AND EXTERNAL BEAM RADIATION THERAPY

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Cancer, Bone metastasis, Bisphosphonates, EBRT, QOL, EORTC-QLQ-BM22.

ABSTRACT

Background: Bone is the most common site of metastasis in cancer. Bone metastasis is a devastating condition that can have a negative impact on the lives of patients with advanced cancer in many ways. Although the overall incidence of bone metastasis (BM) is unknown, BMs are a frequent complication in patients with advanced cancer. Patients may experience limitations in the activities of daily living (ADL), decreases in quality of life (QOL) and threat of survival due to bone metastases. Thus in our study we focused to assess the QOL of patients suffering with metastatic bone disease. **Aim:** To study the QOL in patients with metastatic bone disease receiving Bisphosphonates and External Beam Radiation Therapy. **Methodology:** A Prospective observational study was carried out in Government General Hospital, Guntur for duration of 6 months i.e., October 2017 to March 2018 after obtaining approval from Institutional Ethics Committee. The Patients were screened based on inclusion and exclusion criteria. Patients who satisfy inclusion criteria were included in the study after obtaining informed consent. The data was collected in the specifically designed data collection form. Assessment of quality of life was performed using EORTC QLQ BM 22 questionnaire which consists of 22 questions categorized into 4 groups, representing painful sites (Q1 to Q5), pain characteristics (Q6 to Q8), functional interference (Q9 to Q16) and psychosocial aspects (Q17 to Q22) respectively. The obtained results were tabulated and interpreted using suitable statistical software (SPSS version 22.00, Paired t-test). **Results:** 36 patients who met the inclusion criteria were included in the study. On reviewing the demographic data it was found that bone metastasis was found to be more predominant in females within the age group of 51-70 years. Our study also revealed that there was no significant family history noted in patients who developed metastasis. In our current study it was found that patients suffering with breast cancer, lung cancer and prostate cancer are more likely to develop bone metastasis. We also assessed quality of life of patients suffering with bone metastasis being treated with Bisphosphonates and EBRT (upto 10#, 30Gy) and noted that, painful site, painful characteristic and psycho social status was significantly improved ($p < 0.0001^{***}$) from baseline after receiving zoledronate and EBRT therapy. **Conclusion:** Based on the results obtained our study *strongly concludes* that use of Bisphosphonates and EBRT is effective in improving QOL of patients with bone metastasis.

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INTRODUCTION

Bone is a common site for metastasis owing to high blood flow in the bone marrow. Bone metastasis or "bone mets" occurs when cancer cells from the primary tumor relocate to the bone. Bone metastasis is a devastating condition that can have a negative impact on the lives of patients with advanced cancer in many ways.

survival due to bone metastases. Although the overall incidence of bone metastasis (BM) is unknown, BMs are a frequent complication in patients with advanced cancer. The most common human cancers such as breast, prostate, kidney, thyroid and lung have a great avidity for bone, leading to painful skeletal symptoms. The distress associated with this symptom adds significantly to the overall burden for patients and their families. Pain is among the most prevalent symptoms and poses a challenge for the cancer health-care system. BMs can be associated with skeletal-related events (SREs), which include pathologic fracture, the need for surgery or radiation to bone, spinal cord compression, and hypercalcemia of malignancy (HCM)^[1]. Palliative radiotherapy and

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RESEARCH ARTICLE

PROMINENCE OF CLINICAL PHARMACIST IN ENHANCING THERAPEUTIC OUTCOMES OF DIABETES WITH HYPERTENSION IN LOW SOCIO-ECONOMIC POPULATION

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Key Words:

Therapeutic Outcomes,
KAP Questionnaire,
Drug Related Problems,
Medication Adherence.

Abbreviations:

DBP : Diastolic Blood Pressure
FBS : Fasting Blood Glucose
KAP : Knowledge, Assessment, Practise
RBS : Random Blood Sugar
SBP : Systolic Blood Pressure

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ABSTRACT

Background: Clinical pharmacy is a health science discipline whereby pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention. The practice of clinical pharmacy embraces the philosophy of pharmaceutical care; it blends a caring orientation with specialized therapeutic knowledge, experience, and judgment for the purpose of ensuring optimal patient outcomes. This field of pharmacy practice focuses on patient-oriented rather than drug product-oriented service.

Objectives:

- To identify drug interactions.
- To identify adverse drug reactions.
- To monitor impact of counselling.
- To improve medication adherence.
- To improve therapeutic outcome for chronic disease patients (Diabetes with hypertension.)

Method: The study was conducted from October 2017 to March 2018 in Government General Hospital, Guntur. Patients were recruited in the study based on inclusion criteria. Data was collected by using data collection forms. Questionnaires were given to the patients. Regular follow-ups had been conducted and their laboratory data was recorded. During follow-ups patients were monitored for dispensing errors, prescription errors, dose errors, adverse drug reactions, drug interactions. Counselling had been provided to the patients regarding their medications, diseases, life style modifications. After continuous follow-ups for 3 months (20 days interval), we observed for improvement in knowledge regarding disease and drugs, medication adherence, therapeutic outcomes.

Results: 60 patients are included (Diabetes with Hypertension). The mean therapeutic outcome value in Diabetes with Hypertension initially and after follow-ups is 175.88±39.15(FBS), 284.61±73.31(RBS), 152.16±15.95(SBP), 94.16±7.65(DBP) and 161.83±23.95(FBS), 226.15±44.86(RBS), 147.5±12.57(SBP), 92.16±6.13(DBP) respectively. KAP before counselling and after counselling was 55.45±6.41 and 42.51±2.44.

Conclusion: By counselling the patients there is an increase in KAP, medication adherence, decrease in DRP's thereby increase in therapeutic outcomes. So, clinical pharmacists are important in enhancing patient care.

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INTRODUCTION

Pharmacists have extensive clinical knowledge and expertise in the use of medications, and are one of the most approachable of all health care professionals. This makes them uniquely positioned in the health care system to help patients optimize appropriate use of medication, reduce medication

delivery of pharmacist-provided patient care services, including medication therapy management (MTM), health promotion and education, and disease prevention and mitigation (American pharmacist association, 2008).

MATERIALS AND METHODS

A Prospective Observational cohort study conducted in Outpatient department, government general hospital, Guntur,

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Research Article

**IMPORTANCE OF CLINICAL PHARMACIST IN ENHANCING THERAPEUTIC OUTCOMES
IN SEIZURE PATIENTS IN OUT PATIENT DEPARTMENT OF A TERTIARY
CARE TEACHING HOSPITAL**

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Key words:
Therapeutic Outcomes, KAP Questionnaire,
Drug Related Problems

ABSTRACT

Aim: To assess the importance of clinical pharmacist in enhancing therapeutic outcomes in seizure patients in outpatient department of a tertiary care teaching hospital.
Method: The study was conducted from October 2017 to March 2018 in Government General Hospital, Guntur. Patients were recruited in the study based on inclusion criteria. Data was collected by using data collection forms. Questionnaires were given to the patients. Regular follow-ups had been conducted. During follow-ups patients were monitored for dispensing errors, prescription errors, dose errors, adverse drug reactions, drug interactions. Counseling had been provided to the patients regarding their medications, diseases, life style modifications. After continuous follow-ups for 3 months (20 days interval), we observed for improvement in knowledge regarding disease and drugs, medication adherence, therapeutic outcomes.
Results: 100 seizure patients were included. The knowledge of patients during initial and after follow-ups was 30.45 ± 1.96 and 22.84 ± 1.59 respectively. The medication adherence during initial and after follow-ups was 20.05 ± 2.60 and 41.73 ± 3.16 respectively.
Conclusion: By counseling the patients there was an increase in Knowledge Assessment practise, medication adherence, decrease in Drug Related Problem's thereby increase in therapeutic outcomes. So, clinical pharmacists are important in enhancing patient care.

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INTRODUCTION

Pharmacists have extensive clinical knowledge and expertise in the use of medications, and are one of the most accessible of all health care professionals. This makes them uniquely positioned in the health care system to help patients optimize appropriate medication use, reduce medication related problems and improve health outcomes through the delivery of pharmacist-provided patient care services, including medication therapy management (MTM), health promotion and education, and disease prevention and mitigation.^[1]

MATERIALS AND METHODS

A Prospective Observational cohort study conducted in Outpatient department, government general hospital, Guntur, Andhra Pradesh. It was conducted in a period of 6 months i.e., between Octobers 2017 to March 2018. Our study population is about 100 patients. Before the commencement of the study the Ethical Committee Permit has been taken.

Annexure that were used in our study includes Data collection forms, Alert cards, Patient information leaflets, KAP questionnaires. Patients receiving medications from Neurology department diagnosed with seizures were included. Patients from Pediatrics, Gynecology, Psychiatry, Orthopedics, Cardiology and age below 12 years and age above 70 years were excluded.

Patients were recruited in the study based on inclusion criteria. Data was collected regarding their demographics, personal history, social history, past medical and medication history, laboratory investigations and current medications during the initial follow-up. Questionnaires were also given to the patients. Regular follow-ups had been conducted. During follow-ups patients were monitored for dispensing errors, prescription errors, dose errors, adverse drug reactions, drug interactions. Counseling had been provided to the patients regarding their medications, diseases, life style modifications. After continuous follow-ups for 3 months with an interval of 20 days between each follow-up we observed for improvement in knowledge regarding disease and drugs, improvement in medication adherence, improvement in their therapeutic outcomes

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RESEARCH ARTICLE

DEVELOPMENTAL FACTORS CONTRIBUTING TO ALCOHOLISM AND ASSESSING THE IMPACT OF SELF MOTIVATION TOWARDS ALCOHOL WITHDRAWAL TREATMENT

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URICA scale,
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Motivation to change,
Alcohol withdrawal.

Abbreviations:

AUDIT - Alcohol Use Disorder Identification Test
CIWA-R - Clinical Institute for Withdrawal
Assessment - Revised
SAD-Q - Severity of Alcohol Dependence
Questionnaire
URICA - University of Rhode Island Change
Assessment Scale

ABSTRACT

Background: Alcohol consumption and heavy episodic drinking tends to be higher during young adulthood than at any other period across the lifespan. This may be the effect of developmental factors before adolescence which include external factors like family, house hold structure, impact of relatives, peers, childhood, significant events with siblings, society etc., and internal factors like personality, coping skills, attitude to school, workforce aspiration, misbehavior, interaction and involvement etc. Motivation appears to be a critical dimension in influencing patients to seek, comply with, and complete treatment as well as to make successful long-term changes in their drinking. Although many patients attend treatment, they may not be ready to change their drinking pattern and may not actively participate in treatment hence motivation is important for predicting treatment participation and recovery.

Objectives:

- To identify various childhood and adolescent developmental factors which had led to alcohol consumption in later stages of life.
- To assess the severity of alcohol abuse and the impact of motivation for change in alcohol withdrawal treatment and recovery.
- To evaluate progress in meeting therapeutic goals by estimating CIWA.

Method: A prospective case controlled observational study was conducted in the government general hospital, Guntur, for a period of 6 months i.e, from Oct 2017- March 2018. Factors predicting youth alcohol consumption (1997) Donovan model was used to determine developmental factors contributing to alcoholism. Severity of Alcohol Dependence Questionnaire (SADQ) and CIWA was used to determine severity of alcohol dependence. University of Rhode Island Change Assessment Scale (URICA) was used to assess readiness for change and differentiate them in stages.

Results: A total number of 154 patients were assessed using Donovan model which contains facilitators and inhibitors of external and internal factors. From our data, majority of subjects were observed with facilitators which contribute to alcoholism and their significant improvement in motivation was assessed by using URICA scale. Self motivation plays an important role in alcohol treatment and recovery.

Conclusion: There are many facilitators in both internal and external factors contributing to alcoholism in test group. The significant understanding of these factors could help in reducing the incidence of adolescent alcohol abuse in the society by reducing the facilitators from childhood onwards.

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INTRODUCTION

Alcoholism is on the rise all over the world. Early adolescence is the key developmental period for the initiation of alcohol use that progresses onto regular use and problem drinking in mid and later adolescence and young adulthood. Over the past century, researchers have increasingly explored family's role in the development, course, treatment and prevention of alcohol abuse and dependence.

The likelihood of starting to drink was also found to relate to adolescent perceptions of mother's and father's permissiveness.

Developmental factors affecting alcohol abuse

These include external factors like family, household structure, impact of relatives, peers, childhood, significant events with siblings, society, etc., and internal factors like personality, coping skills, attitude to school, workforce aspiration, misbehaviour, interaction and involvement (Brook et al., 1986). Among adolescents, alcohol is the most commonly used psychoactive drug. Alcohol consumption and heavy episodic

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Pharmacoepidemiological Study of Gynecological Disorders Among Women in Community Setup

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ABSTRACT

Background: Gynecological problems are universal in occurrence. Lack of awareness about various gynecological problems, economic and social barriers, delay the early diagnosis of the gynecological problems. In order to understand and to create awareness about gynecological problems this study was undertaken.

Materials and Methods: Observational cross sectional study was conducted in the community settings (In and around Guntur) by taking samples randomly for a period of 6 months i.e., from October 2017- March 2018. Subjects were selected based on inclusion and exclusion criteria and Patients were informed about study and obtained Informed Consent Form (ICF). The data was collected by using a self administered questionnaire. Subjects were educated on their disease by verbal and also by providing patient information leaflets.

Results: Out of 5000 subjects, only 826 subjects met the inclusion criteria. Incidence (3.44%) and prevalence (4.6%) of abnormal uterine bleeding was high among all gynecological related problems followed by urinary tract infections in the age group between 26-35 years.

Conclusion: There was a high prevalence (4.6%) and incidence (3.44%) of abnormal uterine bleeding among other gynecological problems. Generally urinary tract infection is self limiting, so by educating about medication usage, lifestyle modification, medication adherence and by providing patient information leaflets we observed there was a reduction in symptoms. Finally from the study we concluded that awareness plays a significant role in decreasing disease progression, complications and thereby reducing the economic burden

Key Words: Abnormal uterine bleeding, Awareness, Gynecological problems, Incidence and prevalence

INTRODUCTION

Epidemiology is the "study of the distribution and determinants of health-related states or events in a specified population and the application of this study is to control diseases and other health problems".^[1]

Aim of epidemiological studies was to control or eliminate diseases in the community.

Need of epidemiological studies

- In a typical Indian society, the health problems of women are often neglected more so the gynecological

problems because women in their reproductive years prioritize the health of children, husband and other family members over their own.

- Lack of awareness about various gynaecological problems, economic and social barriers, delay the early diagnosis of the gynecological problems.
- In recent years it has been observed that improper awareness on a disease or a condition is leading to more number of surgeries or complications.
- Infertility is also being reported in a very high rate which always has any other gynecological disorder as an underlying problem.

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Research article

Medical research

Factors leading to failure of firstline anti retroviral therapy (ART); a retrospective study in indian tertiary care government settings

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ABSTRACT

Background

HIV is a lenti virus that causes HIV infection in humans in which progressive failure of immune system allows life threatening opportunistic infections and cancers to thrive. So it is important to study the factors that lead to failure of first line ART.

Aims and Objectives

To find out the factors leading to failure of first line ART like socio-demographic factors, clinical factors, immunological factors, virological factors etc. To assess the CD4 count in subjects using first line and second line ART. To assess the viral load in subjects who failed first line ART.

Methodology

Retrospective cohort observational study was conducted to assess the factors leading to the failure of first line ART. HIV patients who met inclusion criteria were informed consented and included in the study and relevant data was collected in a prior designed data collection form.

Results

In our study we found that controls were more among 30-40 yrs age. Males and females were equally distributed in cases and controls. Widowed females were found more among cases. Illiterates were found more among cases than controls. Cases children were more HIV seropositives than controls. Cases were more in WHO stage-4 clinical staging than controls. Cases had more number of drug substitutions, drug related adverse effects, low medication adherence, more number of LFUS and hospitalisations than controls. Cases were more in number who travels more than 60 minutes and more time gap between diagnosis and time of ART initiation and cases had raised RFTS, LFTS, and lipid profile at time of treatment failure. Cases had more serious opportunistic infections than controls.

Conclusion

From our study we found that marital status, illiteracy, labour work, low income status, loss of follow up's, wrong diagnosis of type of HIV virus initially that lead to the wrong treatment, positive family history of HIV,

STATUTORY GUIDELINES AND SYSTEMATIC ASSESSMENT OF BIOSIMILARS APPROVAL PROCESS IN INDIA, USA AND JAPAN

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Biosimilar is a bio-therapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product. This article summarizes the regulatory guidelines for approval of biosimilars in India, USA and Japan. These countries require comparability exercise of a biosimilar with reference biological product for generating comparative analytical non-clinical and clinical data. These guidelines address the regulatory pathway regarding manufacturing process, safety, efficacy & quality aspects for biosimilars; and also the pre-market regulatory requirements including comparability exercise for quality, preclinical studies & post-market regulatory requirements for biosimilars.

The purpose of this article is that an uncertainty over the terminology "bio-similar" has led to concerns about patient safety due to misleading published reports on its apparent ills. Therefore, a comparison is made among the different regulatory approvals globally with intend of achieving harmony in regulations and escalating entry to safe medicines globally.

A. Introduction:

Biosimilars are defined as "biological product highly similar to the reference product notwithstanding minor differences in clinically inactive components" and there are no meaningful differences between the biological product and the reference product in terms of safety, purity and potency. They undergo rigorous evaluation as defined in FDA or WHO biosimilar guidelines before regulatory approval. Their approval is based upon similarity of the compound with original with respect to quality, safety and efficacy. They should not be mistaken as generic drugs which have simple structures and are produced to be exact copies of an already approved drug. The significant differences between biosimilars and generics are given in Table 1.

B. Regulatory Requirements for Biosimilars in India:

In India, biosimilars are designated as "similar biologics". Developing biosimilars regulatory policy is

a challenge to the Indian authorities because it is utmost important to create balance between serving quality and safety of drug, which is affordable and has easy access to people. The regulatory requirements for marketing authorization of similar biologics in India were released in 2012 and require extensive quality / analytical comparative data in addition to abridged clinical / non-clinical studies are required for biosimilars approval.^[1]

Various applicable guidelines^[2,3] are as follows:

- Recombinant DNA Safety Guidelines, 1990.
- Guidelines for generating preclinical and clinical data for rDNA vaccines, diagnostics and other biologicals, 1999.
- **CDSCO guidance for industry, 2008:** Submission of clinical trial applications for evaluation of safety & efficacy; Requirements for permission of new drug approval; Preparation of quality information for drug submission for new drug approval: biotechnological / biological products; and Post approval changes in biological products: quality, safety & efficacy documents.

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