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Formulation Development and Evaluation of Duloxetine Hydrochloride Multi-Particulate Delayed-Release Capsules

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ABSTRACT

Background: Multi-particulate drug delivery systems are mainly oral dosage forms consisting of a multiplicity of small discrete units, each exhibiting some desired characteristics. Duloxetine hydrochloride is acid-labile thus it is formulated as gastro-resistant pellets. **Objective:** The work aims to develop Delayed-release oral capsules comprising Duloxetine Hcl pellets which is similar in dissolution profile and bioavailability, there by establishing bio equivalence to that of the reference product-Cymbalta®. **Methods:** The pellets are formulated in a fluidised bed processor, by Wurster process. The finished pellet consists of four different layers, coated over the sugar spheres. The first layer is the drug layer, followed by a barrier layer to separate enteric layer and drug, finally a top layer that acts as a moisture barrier. The pharmaceutical equivalence and stability of finished product to that of the standard was the primary objective during the development of each layer. Thus, in all stages of development, the dissolution and stability were closely monitored and the excipients were optimized based on it. **Results:** Poor process efficiency, multi-pellet formation and low dissolution of the drug layer are resolved by the addition of HPMC,

talc and corn starch respectively. The moisture permeability across the barrier layer was arrested by Opadry® AMB white. 25-30%. 25% coating thickness with Eudragit L30-D55 provides acid resistance and timely drug release. Finally, a 5% coating with Opadry® AMB again provides complete moisture protection. **Conclusion:** Developed pharmaceutically equivalent and stable dosage form of Duloxetine Hydrochloride

Key words: Duloxetine Hcl, Multi-particulate, Delayed release, Eudragit, Pellets, Wurster coating,

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INTRODUCTION

Major depressive disorder (MDD) is a common psychiatric disease. It is one of the leading causes of disability,¹ significant morbidity, mortality and suffering for patients and their families.² MDD is characterized by a persistent feeling of sadness low self-esteem, loss of interest in normally enjoyable activities, low energy and pain without a clear cause. The mood can sometimes appear as irritability. The etiology of MDD is multi factorial.³ Fortunately, MDD is well symptomatic and easily understood in the medical community. Among the various methods to treat MDD, Duloxetine of Serotonin and noradrenaline reuptake inhibitors (SNRIs) class is a newer molecule. It is neither sedative, nor anticholinergic, antihistaminic and an α blocker.⁴ US FDA approved Duloxetine for the treatment of MDD, diabetic peripheral neuropathic pain and generalized anxiety disorder. The European Medicinal Agency (EMA) approved it for the treatment of moderate to severe stress urinary incontinence.⁵

Duloxetine exists in its salt form as duloxetine hydrochloride (DXL) with Molecular Formula: $C_{18}H_{19}NOS \cdot HCl$. It is well absorbed and has a bioavailability of 80%. However, the DXL is least stable with acidic pH of gastric fluid. 60% of DXL gets degraded in 30min of contact with acid. Some degradation product of duloxetine includes “ α - naphthol”, “4 - naphthol Duloxetine”, “3 -acetyl Duloxetine” Figure 1. Thus, to prevent acid degradation it must be developed as delayed-release formulation.

Current work aims to develop the DXL as a multi particulate delayed-release capsule. Multi-particulate drug delivery systems (MPDDS) are oral dosage forms consisting of a multiplicity of small discrete units,

each exhibiting some desired characteristics. In these systems, the dosage of the drug substances is divided into the number of subunits, typically consisting of thousands of spherical particles with a diameter of 0.05-2.00mm.⁶ The purpose of designing MPDDS is to develop a reliable formulation that has all the advantages of a single unit formulations and yet devoid of the danger of alteration in drug release profile and formulation behavior due to unit to unit variation, change in gastrointestinal pH and enzyme population. Pellets are a type of MPDDS where drug profiles are created by layering an active drug onto a neutral core such as sugar spheres, crystals or granules Figure 2, followed by the application of a rate-controlling or a functional membrane.⁷

MATERIALS AND METHODS

Materials

Sugar spheres (Suglets® from Colorcon 250-255 μ m) HPMC E 5 methocel™ LV Povidone K29/32 (Plasdone™) EUDRAGIT L-100-55, EUDRAGIT L-30-D-55 (Evonik) Opadry AMB white (colorcon®) received as gift sample from Orchid Health Care, Chennai. All other chemicals and reagents used were of analytical grade.

Methods

Wurster fluid bed coating

FBP (Fluidized bed processor) from Glatt GPCG-1, Germany. Bottom spray, ‘C’ plate, ASTM #40 mesh was used for fluid bed coating. The core material (sugar spheres) of 710-850 μ m size after sieving through

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Novel Method to Synthesis Indazole and Hydrazone Derivatives with Significant Antibacterial Property

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ABSTRACT

Indazole derivatives exhibit a versatile biological activity and have attained position in the field of medicinal chemistry. To synthesise indazole derivatives by a novel method and analyse the structure by IR, NMR and MASS spectra and evaluate its antibacterial action. The substituted groups of aldehyde and ketone are reacted with hydrazine in presence of DMF to give an indazole derivative and that upon the action of methyl iodide, KOH and acetone gives the methylated indazole & hydrazine derivatives. The structure was evaluated by spectral studies and its antibacterial action through agar well diffusion method. Indazole containing derivatives were synthesized from aldehydes and ketones gives hydrazones through this novel method and it possess significant antimicrobial action against *E.coli*, compare with the standard drug streptomycin.

Keywords: Indazole, Hydrazones, Synthesis, Antibacterial, Novel method, IR, NMR, LCMS

INTRODUCTION

Indazole, is a heterocyclic aromatic compound, also called isoindazole which is rare in nature and have a wide range of biological and pharmaceutical applications. Heterocyclic compounds are cyclic organic compound containing at least one atom other than carbon in a ring formation such as N, O and S. In case of Indazole, it belongs toazole family containing two nitrogen as hetero atoms in 1, 2 positions. Indazole was first defined by scientist Emil Fishes as a "Pyrazole ring formed with Benzene ring". Due to its interesting chemical and biological properties, these compounds are extensively studied [1]. Indazole nucleus is present in naturally occurring alkaloids and biologically





Literature-Based Research on Antidiabetic Potential of Okra

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ABSTRACT

Diabetes mellitus is an endocrine disorder that affects about 10% of the world population. Management of diabetes without any side effects have been a significant challenge to the medical field since almost all the available allopathic medications have been reported toxic and having side effects. So it is prudent to look for options in herbal medicines which considered to be less toxic and free from side effects than the synthetic ones. Traditional antidiabetic plants can overcome the high cost, side effects of currently available drugs like organ toxicity. This project aims to identify the potential antidiabetic effect of different extracts of okra. *Abelmoschus esculentus* (okra) is a flowering plant belonging to the Mallow family with sufficient hypoglycaemic effect. Several research and review articles discussing the hypoglycaemic effect (both in vivo and in vitro) of okra has collected, and its antidiabetic potential is compared. The results show that the okra can have a glucose reduction in the range of 20 – 70% and the green methanolic okra extract 5mg/kg shows the highest reduction of about 73%.

Keywords: Diabetes mellitus, *Abelmoschus esculentus*, Streptozotocin, Alloxan, Phytochemical analysis..

INTRODUCTION

Diabetes mellitus is a chronic endocrine disorder characterized by impaired insulin secretion or action, which may result in hyperglycemia [1]. Physical inactivity and unhealthy dietary habits result in overweight and insulin resistance which forms the major risk factors for diabetes mellitus [2]. At present, the chronic use of synthetic medicine for the management of diabetes causes severe side effects. Researchers have been looking for alternative therapies that include herbal or natural remedies [3]. Several traditional medicines of herbaceous plants proved to be highly useful in reducing blood glucose levels. Experimental evaluation and isolation of active constituents from





Formulation and Evaluation of Topical Gel Incorporated with Nimesulide Loaded Magnetite Nanoparticles

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ABSTRACT

Nimesulide is a COX-2 selective, non-steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties. It is used for the treatment of acute pain, inflammation and for the symptomatic treatment of osteoarthritis. But nimesulide is banned in many countries due to chances of liver failure. Thus the present study was aimed to develop a suitable dosage form to apply topically at inflammatory conditions, without affecting internal organs. This study converts nimesulide into magnetically modulated topical gel for topical application. The magnetic field over the applied area helps to retard the movement of drugs into the deeper tissues. This results in accumulation of dosage form and delivery of drug at controlled rate in the target site. The nimesulide drug has been loaded over the magnetite particles using HPMC E5 rate controlling polymer by powder coating method. Seal coating was given to the drug loaded magnetite nanoparticles to prevent the solubility of nimesulide in the gel. The prepared drug loaded magnetite particles were converted into topical gel preparation.

Keywords: Magnetite nanoparticles, nimesulide gel, powder coating, seal coating.

INTRODUCTION

Nimesulide is a preferential COX-2 inhibitor that has been effectively used for the treatment of a variety of inflammatory and painful conditions, including osteoarthritis. Nimesulide is almost completely absorbed orally, 99%

27082





Screening of *In vitro* Antidiabetic Activity of Coconut Shell and Pericarp by Alpha Amylase Inhibitory Assay

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ABSTRACT

Diabetes mellitus is a group of metabolic disease that affects half of the world population. It is characterized by hypoglycemia resulting from defects in insulin secretion, insulin action, or both. In India 40 million people with diabetes and by 2025 this number will raise up to 70 million. The current work aims to develop a drug from *Cocos nucifera*, which has the ability to control diabetes up to a level. For that, the collected *Cocos nucifera* samples were extracted with different solvents like petroleum ether, methanol, and water using a different method of extraction. Then the extracts are evaluated for anti-diabetic activity using the *In-vitro* alpha-amylase inhibitory method. The results conclude that the water extract of the pericarp and the decoction of the shell shows a percentage inhibition of 69.5% and 69.7% respectively. The extracts are then subjected to phytochemical analysis which reveals the presence of phenolic compounds. This work attempts to summarize and evaluate *Cocos nucifera* as an anti-diabetic agent.

Keywords: *Cocos nucifera*, Diabetes mellitus, Anti-diabetic activity, Alpha-amylase, Phenolic compounds

INTRODUCTION

Diabetes mellitus is a disease in which the body's ability to produce or respond to the hormone insulin is impaired, resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood. The root and causes of diabetes are complex. Most cases begin with mainly two processes metabolic and autoimmune. Metabolic factors include lifestyle factors such as overeating, physical inactivity, and obesity leads to inefficiency of the body to use insulin (insulin resistance) [1]. Metabolic forms of diabetes include type 2 and gestational diabetes. Type 2 diabetes accounts for 90-95% of diabetic cases. Autoimmune diabetes includes type 1 diabetes and latent

27057



TELMISARTAN AND ROSUVASTATIN:A REVIEW ON THE ANALYTICAL METHODS FOR THE INDIVIDUAL AND COMBINED DOSAGE FORMS.

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Abstract:

Rosuvastatin calcium belongs to the class “statins”, which is indicated for dyslipidemias and decreases the level of bad cholesterol .Telmisartan is an oral antihypertensive agent that acts by blocking angiotensin receptors.Rosuvastatin calcium and telmisartan , is a fixed drug combination given to treat hypertension and dyslipidemia. The article gives glimpses of published analytical methods reported so far in the literature for the determination of Rosuvastatin calcium and telmisartan, individually and/or in combinations present in pharmaceutical formulations and biological fluids by various methods like Spectrophotometry, High Performance Liquid Chromatography using Ultra Violet and Flourimetric detection, Liquid chromatography coupled with Tandem mass spectrometry, Immunoassays, and Electrochemical methods such as Cathodic absorptive stripping voltammetric method.

Index terms:Rosuvastatin calcium, Telmisartan,Analytical methods

1.TELMISARTAN: A REVIEW OF ANALYTICAL METHODS

Introduction^[2]:

Telmisartan is an angiotensin II receptor antagonist (AT₁) used in the management of hypertension. It selectively antagonizes angiotensin II binding to the AT₁ subtype receptors. Inhibition of AT₁ receptors leads to vasodilation and inhibits the angiotensin II mediated aldosterone production which in turn leads to decrease in sodium and water excretion and also increases potassium excretion and thereby causes a reduction in blood pressure. Chemically 2-(4-{{4-methyl-6-(1-methyl-1H-1,3-benzodiazol-2-propyl-1H-1,3benzodiazol-1-yl] methyl}phenyl)benzoic acid.

RESEARCH ARTICLE

A Validated RP-HPLC Method for the Simultaneous Estimation of Atorvastatin calcium and Clopidogrel Bisulphate in Combined Dosage Forms

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ABSTRACT:

The present work describes an isocratic, simple, accurate and precise RP-HPLC method for the simultaneous estimation of Atorvastatin calcium and Clopidogrel Bisulphate in combined capsule dosage forms. Waters HPLC System with 515-HPLC Pump, Spherisorb 5 μ silica (4 \times 250mm i.d.) column and PDA-2998 detector was used for the analysis. The mobile phase consisting of Acetonitrile and 0.1% ortho-phosphoric acid in the ratio of 65:35% v/v was used for the separation of drugs. The mobile phase flow rate was 1ml/min and the eluents were detected at 245nm. Using the optimized chromatographic conditions, resolved sharp peaks corresponding to Atorvastatin Calcium and Clopidogrel Bisulphate could be obtained at retention time of 2.007 and 5.977min respectively. The method was validated in terms of linearity, precision and accuracy.

KEYWORDS: Copper nanoparticles, *Mimosa pudica*, UV-Visible, FTIR, XRD, TEM, bacterial, fungal and *in-vitro* cytotoxicity.

INTRODUCTION:

Atorvastatin calcium is a synthetic pentasubstituted pyrrole heptanoic acid derivative antilipemic agent. It limits cholesterol formation by competitively inhibiting the conversion of HMG – CoA to mevalonate by HMG – CoA reductase. Chemically, atorvastatin calcium is the calcium salt of (β R, 8R) – 2 – (4 – fluorophenyl) – α , δ , – dihydroxy – 5 – (1 – methyl ethyl) – 3 – phenyl – 4 – [(phenyl amino) carbonyl] – 1 H – pyrrole – 1 – heptanoic acid trihydrate.

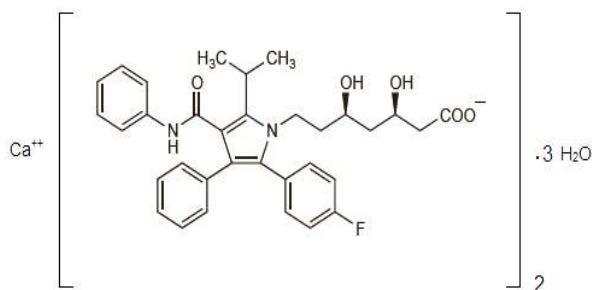


Fig 1. Structure of Atorvastatin Calcium

Clopidogrel bisulphate is a thieno pyridine drug that target P2Y₁₂, a key ADP receptor on platelets. Activity of clopidogrel dependent on hepatic transformation to an active metabolite. The principle metabolite found in human plasma (SR 26334) is inactive. Clopidogrel selectively inhibit ADH – induced platelet aggregation by irreversibly blocking P2Y₁₂. Chemically, Clopidogrel bisulphate is methyl (S) – α – (o – chlorophenyl) – 6,7 – dihydrothieno [3,2 C] pyridine – 5 – (4H) – acetate sulphate.^{5,6,7}



RESEARCH ARTICLE

Formulation and Evaluation of Preungual Delivery System Containing Eugenol for the Treatment of Onychomycosis

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ABSTRACT

The purpose of the present study was to formulate a preungual delivery system of Eugenol containing two different penetration enhancers for the treatment of Onychomycosis and to find out at which concentration of penetration enhancers gave better release as well as to carry out the antifungal testing on the best formulation obtained. Nail lacquer was prepared by simple mixing method using two polymers; ethyl cellulose and eudragit RL100. Preliminary evaluation tests were performed. In-vitro diffusion studies were carried out in Franz diffusion cell using phosphate buffer pH 7.4 and methanol as a medium, whereas the permeation studies were carried out using hooves membrane. The percentage cumulative drug release was determined by UV-Spectrophotometer. The formulation containing 10%w/v of Ethyl cellulose along with 2.5%v/v of Dimethyl sulfoxide showed a good release. From the preliminary evaluations, it was found that the Ethyl cellulose was best for formulating as a lacquer. The formulation showed a zero-order release pattern and Higuchi model for the mechanism of release. The present study reveals that, the Eugenol nail lacquers are a safe topical delivery system for Onychomycosis treatment. The topical therapy is the preferred route, as it avoids the hepatotoxicity related to antifungal drugs when taken orally. Hence this work could be a promising factor for the patients in future, since it is more convincing than the conventional dosage forms.

Keywords: Nail lacquer, Onychomycosis, Preungual drug delivery, Eugenol, Penetration enhancers.





A Review on the Antidiabetic Potential of *Murraya koenigii*

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ABSTRACT

Diabetes Mellitus is a group of metabolic disorders characterized by hyperglycemia. *Murraya Koenigii* (M.K) belongs to the family Rutaceae (citrus family) commonly called "curry patta" in Hindi. The anti-diabetic activity is proved due to the presence of active constituents present in the plant. Certain active constituents present in the plant have the ability to treat many diseases like diabetes mellitus, inflammation, and vomiting and body pain. This review article mainly deals with the anti-diabetic activity of curry leaves. Phytoconstituents like flavonoids, terpenes, alkaloids, carbohydrates, niacin, alanine, cadinine, etc. are responsible for the hypoglycaemic effect in aqueous, methanolic and petroleum ether extracts. This study identified the plant part, the dose of the extract, standard drug and the best inducing chemical for diabetes by comparing the in-vivo and in-vitro studies. By comparing standard drugs like metformin, glibenclamide, and glimepiride, metformin was found to be highly effective. The standard drug metformin produced 63.05% glucose reduction at a dose of 200mg/kg. Among aqueous, ethanolic and petroleum ether extracts, an aqueous extract shows good activity compared to the other two extracts. Hypoglycemic activity Different plant parts with different doses are used to identify which one has highly active. Aqueous leaf extract of *Murraya Koenigii* at a dose of 200mg/kg shows 85% glucose reduction occurs. It has more percentage of glucose reduction occurs compared with other plant parts and doses. Inducing chemical is STZ and alloxan; STZ is more potent than alloxan. STZ at a dose of 50mg/kg has the ability to induce diabetes.

Keywords: Diabetes Mellitus, *Murraya Koenigii*, Streptozotocin (STZ), Phytoconstituents





AMELIORATIVE EFFECT OF *Psidium guajava* LEAVES ON ULCERATIVE COLITIS

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Inflammatory Bowel Disease, Ulcerative colitis, Acetic acid, *Psidium guajava*, haematological parameters,

ABSTRACT

Inflammatory bowel disease (IBD) is a common chronic inflammatory disease of the gastrointestinal tract. There are two main subtypes of IBD; Crohn's disease (CD) and ulcerative colitis (UC). The leaves of *Psidium guajava*, belonging to the family *Myrtaceae* were evaluated for its efficacy in ameliorating the acetic acid induced Ulcerative colitis. Male *albino Wistar* rats were randomly divided into five groups. Group I was given the vehicle tween 80, group II received 2 ml of 4% acetic acid solution on 8th day intrarectally, group III was given 2 ml of 4% acetic acid solution once intrarectally on 8th day and 2mg/kg of prednisolone orally for 3 days starting from the day of acetic acid treatment. Group IV and V received 7 days pretreatment with 250 mg/kg and 500 mg/kg of ethanolic leaf extract of *Psidium guajava* (PGEL) respectively and 2 ml of 4% acetic acid solution once intrarectally on 8th day. Drug treatment was continued till 10th day. The rats were sacrificed on 11th day and the haematological, macroscopical and biochemical parameters were assessed. Pre-treatment with the extract improved the haematological parameters, body weight and the stool consistency score as compared to positive control.

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INTRODUCTION

Medicinal and aromatic plants have a significant role in the life of people with great importance in treating diseases. As mentioned in Ashtanga Hridaya all the plants in this earth are considered as medicinal in Indian tradition. In modern drug development, herbal plants and their derivatives have a very important role. Ulcerative colitis is a subtype of Inflammatory bowel disease (IBD), which is a common chronic inflammatory disease of the gastrointestinal tract. It commonly involves the rectum and may extend to involve other parts of the colon (Ordas I *et al*, 2012). The major symptom of UC is inflammation of the mucosal lining of the colon which results from the interaction between different molecular constituents of the cells (Al-Rejaie *et al.*, 2013; Vinay Kumar *et al.*, 2013) Ulcerative colitis affects individuals in the second or third decade of life with symptoms of abdominal pain and diarrhoea mixed with blood along with weight loss, fever and anaemia (Danese S and Fiocchi C., 2011). Etiological factors such as genetic, immunological and environmental are associated with the pathophysiology of the disease. Inflammation of the mucosal lining of the colon results from the interaction between different molecular constituents of the cells. UC increases the possibility for colon cancer caused by the repeated cycle of inflammation that leads to spontaneous mutation in the DNA repair mechanism, oncogenes and tumor suppressor genes like P 53 (Al-Rejaie *et al.*, 2013 ;

Saxena *et al.*, 2014). The disease is classified by the extent of involvement as distal colitis, extensive colitis and pancolitis (Sninsky, 2010). As the specific pathogenesis underlying inflammatory bowel disease is complex animal models are essential to understand the mechanistic details that will facilitate better preclinical drug/therapy design to target specific components involved in the disease pathogenesis. A UC-like phenotype can be induced in animals easily using either chemical administration or bacterial infection (Daren low *et al.*, 2013).

Psidium guajava L. known as Guava is a medicinal plant belonging to the family *Myrtaceae*. *Psidium guajava* is a well known traditional medicinal plant used in various indigenous systems of medicine. It is widely distributed throughout India. The leaves and bark of *Psidium guajava* tree have a long history of medicinal uses and is used in this era also. It is a small tree of about 10 meter height with spreading branches that grows on all kinds of soils (Shirur Dakappa Shruthi, 2013 ; Joseph and Mini Priya, 2011). Fruits, leaves, bark and roots of Guava have been used for treating stomach ache and diarrhoea in many countries. Leaves and seeds are used to treat respiratory and gastrointestinal disorders and they are also used as antispasmodic, antiinflammatory, antihypertensive and antidiabetic. The seeds are used as antimicrobial, antiallergic and anticarcinogenic (Barbalho & Machado, 2012 ; Kamath *et al.*, 2008).

This objective of the study was to evaluate the efficacy of *Psidium guajava* leaves to ameliorate Ulcerative colitis.

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EVALUATION OF AMELIORATIVE EFFECT OF *SYZYGIUM CUMINI* LEAVES ON ULCERATIVE COLITIS

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Keywords:

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Ulcerative colitis, Acetic acid,
Syzygium cumini

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ABSTRACT: Ulcerative colitis is a subtype of Inflammatory Bowel Disease. The leaves of *Syzygium cumini* belonging to the family Myrtaceae were selected to evaluate its efficacy in ameliorating the acetic acid-induced Ulcerative colitis. Male albino Wistar rats were randomly divided into five groups. Group 1 was given the vehicle tween 80, group II received 2 ml of 4% acetic acid solution on 8th day intrarectally, group III was given 2 ml of 4% acetic acid solution once intrarectally on 8th day and 2mg/kg of prednisolone orally for 3 days starting from the day of acetic acid treatment. Group IV and V received 7 days pretreatment with 250 mg/kg and 500 mg/kg of ethanolic leaf extract of *Syzygium cumini* (SCEL), respectively, and 2 ml of 4% acetic acid solution once intrarectally on 8th day. Drug treatment was continued till 10th day. The rats were sacrificed on the 11th day, and the hematological, macroscopical and biochemical parameters were assessed. Pre-treatment with the extract improved the hematological parameters, body weight, and the stool consistency score as compared to the positive control.

INTRODUCTION: Medicinal plants provide medicine to maintain health, prevent disease, and cure ailments. Throughout the world, medicinal plants are used in traditional systems of medicines. In modern drug development, herbal plants and their derivatives have a very important role. Medicinal plants are natural resources in developing new drugs. Inflammatory bowel disease (IBD) is a common chronic inflammatory disease of the gastrointestinal tract. There are two main subtypes of IBD; Crohn's disease (CD) and Ulcerative colitis (UC). The major symptom of UC is inflammation of the mucosal lining of the colon, which results from the interaction between different molecular constituents of the cells.

This disease is characterized by abdominal pain and diarrhea mixed with blood along with weight loss, fever, and anemia^{1, 2}. UC is associated with ulceration, bleeding, and morphological changes in the intestinal mucosa, involving infiltration of polymorphonuclear cells, abscess formation in mucosal crypts and glands distortion. These changes are concentrated in the mucosa and restricted to the colon and rectum³.

UC increases the possibility for colon cancer caused by the repeated cycle of inflammation that leads to spontaneous mutation in the DNA repair mechanism, oncogenes, and tumor suppressor genes like P 53. Change in the constituent, number, and activity of the colon microflora also contributes to the development of UC^{1, 4}. The specific pathogenesis underlying inflammatory bowel disease is complex. Animal models are essential to intrude into mechanistic details that will facilitate better preclinical drug/therapy design to target specific components involved in the disease pathogenesis.

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Knowledge pertaining to COVID19 among medical population of Indian state of Kerala: An online cross-sectional survey

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Abstract The coronavirus disease 2019, the first case of India surfaced in Kerala. Hence, an exploration of knowledge of medical professionals regarding transmission and steps adopted for prevention and spread of disease was assessed via a cross-sectional study, designed and disseminated through media. The study revealed no significant difference in knowledge score based on district, age and medical discipline. However, majority of the participants lacked basic knowledge and opted social media to update knowledge, which pinpoints towards the need for online training courses in newer diseases.

Keywords: Coronavirus, coronavirus disease 2019, Kerala model of COVID, SARS Cov-2

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INTRODUCTION

SARS Cov-2, a new strain of coronaviruses, resulted in a viral respiratory disease called coronavirus disease 2019 (COVID-19) with symptoms similar to pneumonia. This strain was first isolated in the Republic of China on January 7, 2019.^[1] Subsequently, the viral disease spread took off and has been reported in various countries. On March 11, the World Health Organization (WHO) declared COVID-19 as a pandemic as the disease spread to more than 200 countries with 90,000 deaths as of April 9, 2020.^[2]

The first 10 cases of COVID-19 in India were reported from Kerala state among travellers from the Republic of China and Italy and their primary contacts.^[3] The incidence of the disease was 0.0002 per 1,000,000 people in India.^[4]

The state of Kerala thus initiated procedures to prevent the secondary transmission of infections and thus quarantined travellers from COVID-19 reported countries with the isolation of symptomatic people, followed by testing for COVID-19.^[5] Educational institutions and other public gathering areas were closed and work from home policy was enforced. The government provided relevant information regarding COVID-19, along with its mode of transmission, ensuring personal hygiene, hand-washing techniques and preventive measures through media.

However, the spread of fake information's via social media and the internet led to inaccurate information, resulting in rumours and false practices among the public. Even though the health-care team, along with medical students,

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RESEARCH

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Guideline-directed medical therapy in heart failure patients: impact of focused care provided by a heart failure clinic in comparison to general cardiology outpatient department

Jeeva Joseph^{1*} , Stephy P S¹, Jude James¹, Suja Abraham¹ and Jabir Abdullakutty²

Abstract

Background: The usage of guideline-directed medical therapy (GDMT) in the treatment of heart failure (HF) has shown to reduce morbidity and mortality. However, majority of the HF patients do not receive GDMT or do not achieve the target dose. Literature has shown that the patients who are managed in HF clinics receive GDMT and target doses of disease-modifying drugs (DMD) when compared to those treated in other general cardiology outpatient departments (OPD's). It was a retrospective hospital-based study in which patients treated in HF clinic and other cardiology OPD in the year of 2017 were included (200 patients in each arm). The aim of this study was to assess the impact of heart failure clinics in medication therapy management including usage of guideline-directed medical therapy, if target dose specified by the guideline is achieved and time to reach target dose in comparison to other general cardiology OPD's. IRB and IEC approval were obtained before the commencement of the study. Data relevant to the study were obtained from the electronic medical record (EMR) and were compared between the study groups to see for the adherence to guideline and achievement of target doses. Data storage and analysis were performed using SPSS Version 24. A significance level of 5% was used.

Results: The usage of GDMT was higher in HF clinic when compared to other cardiology OPD (81% vs 55%, $P = 0.001$). A significantly higher number of patients in HF clinic achieved target dose when compared to other cardiology OPD (58% vs 29% -betablockers, 45% vs 9% -ACEI/ARB/ARNI, $P = 0.000$). Moreover, the number of eligible patients receiving DMD was found to be higher in HF clinic (98% vs 85% -betablockers, 69% vs 44% -ACEI/ARB/ARNI, 76% vs 44% -MRA). Also, the patients in HF clinic attained the target doses faster when compared to other cardiology OPD. In addition, there was better improvement in ejection fraction, as well as decreased rate of rehospitalisation and mortality in patients managed in HF clinic.

Conclusion: HF clinics were compared with other cardiology OPD for various parameters and it was observed that HF clinics were better than other cardiology OPD in maintaining the medication therapy management.

Keywords: Heart failure clinic, Guideline-directed medical therapy, Target dose, Personalized care

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Impact of Focussed Care in Heart Failure Patients on Hospital Readmission and Mortality

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ABSTRACT

Objectives: To compare patient health outcomes like mortality and rehospitalisation among heart failure patients receiving focussed care under HF clinics and those receiving usual care under regular cardiac outpatient department. **Methods:** A total of 200 heart failure patients who consulted in Heart Failure clinic and general cardiology outpatient department during the year of 2017 who satisfied the inclusion and exclusion criteria were selected for the study. The study was carried out in a tertiary care Interventional Cardiology and Cardiac Surgery hospital with a dedicated well established heart failure clinic in Kerala, for a period of 1 year. Patients were followed retrospectively for a period of one year and relevant patient data were obtained from the electronic medical record. The data collected were then evaluated for health outcomes like rehospitalisation and mortality among the two groups. **Results:** Among the total number of rehospitalisation's reported, only 32.8% of them were from Heart Failure clinic while 67.2% of reported rehospitalisation's were from general cardiology outpatient department. Chi square test was applied

and statistically significant difference was obtained when mortality rate was compared between the two study groups. 80% of reported cases of death was among patients who consulted in general cardiology outpatient department while only 20% was from Heart Failure clinic. **Conclusion:** Management of heart failure patients in heart failure clinic was associated with significant reduction in one year mortality and rehospitalisation.

Key words: Heart Failure, Heart failure clinics, Rehospitalisation, Mortality, Cardiology, Cardiac care.

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INTRODUCTION

Heart Failure (HF) is a clinical syndrome characterized by typical symptoms (e.g. Breathlessness, ankle swelling and fatigue) that may be accompanied by signs (e.g. elevated jugular venous pressure, pulmonary crackles and peripheral edema) caused by a structural and/or functional cardiac abnormality, resulting in a reduced cardiac output and or elevated intracardiac pressures at rest or during stress.¹ Approximately 1–2% of the adult population in developed countries has Heart Failure (HF), with the prevalence rising to $\geq 10\%$ among persons 70 years of age or older.^{2,3} Heart failure is a condition characterized by high rate of hospital readmissions, increased rate of mortality and reduced quality of life. Data from the Nova Scotia (ICONS) registry was used to compare rehospitalisation and mortality among heart failure patients managed under heart failure clinic group and those managed under non clinic group. This comparative study brought out that management of HF patients in Heart failure clinics were associated with significant reduction in one year rehospitalisation and mortality (35% versus 58%, $P < 0.001$).⁴ Data analysis of the Trivandrum heart failure registry showed 12.5% and 18.1% of mortality rates after 30 and 90 days of follow up.⁵ An estimated increase in the prevalence of heart failure and its risk factors in the country represent an enormous burden on our health care system.^{6,7} As the prevalence, rehospitalisation and mortality associated with heart failure is rising at an alarming rate, it is conceivable to practice multidisciplinary patient focused approaches like heart failure clinics. Heart failure clinics are a powerful intervention made for the treatment of heart failure patients. HF clinics are patient centered clinics that have

proved to reduce heart failure associated rehospitalisation and mortality.⁴ Multiple randomized and non-randomized clinical studies have proved that treatment in specialized heart failure clinics proved to significantly reduce the mortality rate and also to improve the quality of life of heart failure patients.⁸ Provision of education and interventions through heart failure clinics had projected to improve the outcomes of heart failure patients.⁹ Multidisciplinary care provided to congestive heart failure patients has shown to improve the patient's quality of life and reduce heart failure associated hospital readmissions.¹⁰

Majority of studies have evaluated the effectiveness of heart failure clinics in improving patient outcomes. But none of the studies from India had shown to compare heart failure clinics with the usual cardiac care given in outpatient department. Only limited number of health care providers in India practice the provision of patient focused care to heart failure patients through heart failure clinics. And also only a few hospitals in India have a dedicated well established heart failure clinic. This study was carried out in specialized cardiac care and Surgery hospital in Kerala. This study is the first of its kind to compare the occurrence of rehospitalisation and mortality in heart failure patients receiving personalized care in heart failure clinics and those receiving usual care in other cardiology outpatient department (OPD). The objective of the study was to assess patient health outcomes like mortality and rehospitalisation among heart failure patients receiving focussed care under HF clinics and those receiving usual care under regular cardiac outpatient department.

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