

TREATMENT OF COLITIS THROUGH MEDICINAL PLANTS

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Abstract:

Colitis is a idiopathic inflammatory disorder in the colon, has become a clinical challenge, owing to the increasing incidence and poor prognosis inflammatory process that affects many parts of the body. Sometimes these associated extra-intestinal symptoms are the initial signs of the disease, such as painful arthritic knees in a teenager and may be seen in adults also. A widespread search has been launched to identify new anti-ulcer therapies from natural sources to replace currently used drugs of doubtful efficacy and safety. Herbs, medicinal plants, spices, vegetables and crude drug substances are considered to be a potential source to control various diseases including gastric ulcer and ulcerative colitis. In the scientific literature, a large number of medicinal plants and their secondary metabolites with anti-ulcer potential have been reported. As the gastro protective effect can be linked to different mechanisms, once demonstrated the activity, the extracts and more appropriately the active compounds should be assessed for action mechanisms to elucidate their mode of action. Medicinal plants have curative properties due to the presence of various complex chemical substance of different composition, which are found as secondary plant metabolites in one or more parts of these plants.

1. Introduction

Colitis is a chronic disease of the large intestine, also known as the colon, in which the lining of the colon becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucous. The combination of inflammation and ulceration can cause abdominal discomfort and frequent emptying of the colon. About half of all the patients with ulcerative colitis experience mild symptoms. Variability of symptoms reflects differences in the extent of disease (the amount of the colon and rectum that are inflamed) and intensity of inflammation. Generally, patients with inflammation confined to the rectum and short segment of the colon adjacent to the rectum

have milder symptoms and a better prognosis than patients with more widespread inflammation of the colon. The main symptoms are abdominal discomfort or cramps, Rectal Bleeding, Diarrhea, Other Symptoms include, anemia, fatigue, fever, nausea, weight loss, loss of appetite, Abdominal sounds, Mouth Ulcers, loss of body fluids and nutrients, skin lesions and growth failure in children. (*Thia et al 2008, Hanauer,1996, Kaur et al., 2012.*)

Ayurveda is a natural system of healing and health maintenance. According to Ayurvedic medicine, healthy digestion plays an integral part in establishing good health and well-being. When the digestive system fails to function optimally, the body becomes congested, blocking circulation and inhibiting movement of toxins out of the body. Therefore, it is imperative that people work to establish good digestion. As per Ayurveda, Ulcerative colitis can be considered as 'Pittaja Grahani'. In Ayurveda, it is known that perfect exists when the three fundamental energies (doshas: Vata, Pitta and Kapha) are in balance. Out of these three, when Pitta dosha gets imbalanced, vitiates intestines and causes Pittaja Grahani. Pitta energy fuels all the biochemical activities, including transformation, digestion, metabolism and assimilation, Pitta is responsible for all the enzymatic and endocrine activity, regulation of body temperature, pigmentation, vision, intelligence, vitality, ambition, courage and understanding. The key qualities of pitta are hot, quick, light, liquid, spreading, slightly oily and fleshy smelling. Causes of Pittaja Grahani disease are Mandagi (poor appetite and poor digestion), irregular, improper and irrelevant diet habits, heavy to digest or indigestible foods, junk food, Pitta aggravating diets like excess of spicy, pungent, acidic, sour, alkalie nature foods, food items which produces burning sensation in the body, exposure to excess hot climate, alcohol, smoking, excess anger etc. Non-following of the healthy diet habits (Pathya) in certain digestive disorders, specially the conditions of post diarrhea and irritable bowels are also one of the causes of this disease (Prabhat et al 2010).

The present invention relates to herbal composition for the treatment of Ulcerative and non Ulcerative colitis is refractory, chronic, and nonspecific disease occurred usually in the rectum and the entire colon. The etiopathology is probably related to dysregulation of the mucosal immune response toward the resident bacterial flora together with genetic and environmental

factors. The composition comprises extracts from medicinal or Ayurvedic plants selected from the following group:

Botanical Name	Local/ Common Name	Quantity in %
1. Curcuma longa	Haldi	10-25%
2. Glycyrrhiza glabra	Mulahathi	30-45%
3. Silybum marianum	Milk Thistle	5-10%
4. Foeniculum vulgare	Sounf	10-15%
5. Tinospora cordifolia	Giloya	5-8%
6. Boswellia serrata	Salaya guggul	10-25%
7. Brassica juncea	Rai	2-4%
8. Azadirachta indica	Neem	3-7%
9. Terminalia chebula	Harar	2-6%

The process for preparing the herbal composition of the present invention comprises procuring, cleaning, grinding of specified herbal plants as per the standard specification, disintegrating and pulverizing separately to form the coarse powder, then extracting, filtering, concentrating and spray dryings to make dry extract powder or semisolid soft extract or crude powder. Further sieving each of the extracts and powder separately and then allowing to mixing. Then adding filtered extracts and powder with suitable excipients to make granule. The herbal composition of the present invention is non alcoholic, non sedating and non freezing in nature and the process of preparation as described above does not employ pharmaceutically unacceptable organic solvents.

HERBAL ANTICOLITIS FORMULATIONS AND PROCESS FOR THE PREPARATION THEREOF TECHNICAL FIELD

The present invention relates to herbal formulation and a method for preparation thereof for providing treatment in Ulcerative non Ulcerative colitis are refractory, chronic, and non specific disease occurred usually in the rectum and the entire colon. The etiopathology is probably related to dysregulation of the mucosal immune response toward the resident bacterial flora together

with genetic and environmental factors and Which is non alcoholic, no sedating and non – freezing in nature.

BACKGROUND OF INVENTION

During the last two decades there has been an increasing interest in utilization of Indian Medicinal plants for treating chronic Ulcerative non Ulcerative colitis disorders as some of these plants are known to be used in traditional medicine for at least alleviating the symptoms associate with them.

Ayurvedic System of Medicine originated in India more than 5000 years ago, utilizes the curative properties of plants for treating diseases. Ayurveda recognizes three different humors, Vata, Pitta and Kapha, Which control the body metabolism. Vata controls all the movements of the body as it releases `energy mainly from the catabolic reactions, While Pitta is responsible for the enzymatic reactions responsible for both anabolic and catabolic pathways. However, Kapha is responsible for anabolic reactions, which are responsible for all synthetic compounds deposited in the body. A harmonious Working of the above three humors in a balanced manner is responsible for the optimum functioning of a healthy individual. Any imbalance in the harmonious working of the three humors leads to imbalance of body metabolism as well as body functions, which ultimately result, into different ailments. The primary purpose of Ayurvedic System of Medicine is to bring about a balanced state of three humors and to exert prophylactic or curative effects.

Phytochemical investigation of the herbal drugs or their extracts reveals the presence of several chemical compounds. Though all the ingredients do not possess specific therapeutic activity, it is believed that the different chemical compounds present in the plant or its extract act in harmonious manner and possibly due to synergistic effect of these compounds, some ingredients potentiate the therapeutic activity of the main active ingredient or even retard the undesirable actions of the main compound because individual compounds may not be as effective as that of the mixture of compounds present in the plant.

Multi-ingredient therapy is preferred over single drug therapy since the therapy may be effective in any one of these three humors i.e. Vata, Pitta & Kapha for the manifestation of the diseases. At the same time, most of the diseases are associated with imbalance of more than one humor

producing different symptoms involving various organs of the body. Hence a multi-ingredient therapy includes a combination of herbal drugs Which may have either a complimentary or supplementary action for each other.

Based on these principles of Ayurveda, the inventors have developed a herbal colitis remedy formulation With selected herbal ingredients that bring about a balance of three basic humors present in the body there by providing March 2008 improved treatment by administering a safe and effective amount of composition comprising of such ingredients that treats in an types of colitis. There are many patents related to innovative herbal products but employed mainly for the treatment of skin disorders, fungal infections, arthritic and joint pain, various inflammatory conditions. There are very no any patents which describe compositions for treatment of Colitis.

There is a need to provide a herbal composition having an improved therapeutic efficacy for the treatment of various types of colitis. There is need to provide a herbal composition having an improved therapeutic efficacy for the treatment of various types of colitis. In view of the foregoing shortcomings inherent in the known types of herbal compositions as mentioned in the prior (1st page), the present invention provides a novel herbal composition Where in the same can be utilized for relieving colitis related symptoms. It is still further object of the present to provide herbal composition, Which does not freeze, at zero temperatures thus preserving the medicinal properties of the herbs and thereby making it more efficacious and better patient compliant.

To attain this, the composition of present invention is developed which comprises of herbal mixture of following plants for the preparation of the composition of the present invention.

***Curcuma longa* (Haldi):** *Curcuma longa*) have anti-inflammatory activity. It has been found to induce the flow of bile, which helps break down fats. Additionally, it could reduce the secretion of acid from the stomach and protect against injuries such as inflammation along the stomach (gastritis) or intestinal walls and ulcers from certain medications, stress, or alcohol. In a preliminary trial, 5 of 5 people with chronic ulcerative proctitis had an improvement in their disease after supplementing with Chemical compound. Chemical compound inhibits the activation of NF-kB. NF-kB promotes the synthesis of many antioxidants enzymes. Chemical compound directly binds to thioredoxin reductase and irreversibly changes its activity from an antioxidant to a strong pro-oxidant (Holt et al 2005).

***Glycyrrhiza glabra* (Mulahathi):** Therapeutically used parts are peeled roots. It is extensively used extensively as a demulcent, mild expectorant and anti-inflammatory agent. Anti-inflammatory action is attributed to glycyrrhizic acid and glycyrrhizin . It relieves vata and kapha inflammations, it is also used in eye diseases, throat infections, symptomatic relief in peptic ulcer and as an antiarthritic agent. Glycyrrhizin could improve intestinal mucosal inflammation in rats and, importantly, reduce expression of NF-kb, TNF- α , and ICAM –I in inflamed mucosa. Clinical studies on *Glycyrrhiza glabra* have also been performed in combination with other herbs and demonstrated to be effective in the management of UC (Yuan et al 2006 and Prabhat et al, 2010)

***Silybum marianum* (Milk Thistle):** *Silybum marianum* is composed mainly of silymarin with small amounts of other silibinin stereoisomers, namely isosilybin, 7-8 dihydrosilybin, silydianin and silychristin. It has been used for the treatment of liver diseases of different etiology due to its hepatoprotective activity. The action of Silymarin is due to its antioxidant, inhibition of lipid peroxidation and the membrane stabilizing effects (Vahid et al 2012).

***Foeniculum vulgare* (Sounf):** *Foeniculum vulgare* contain essential oil limonene, alfa pinene, myrcene, cisocimene, alfa phellandrene and methyle chavicol which are useful in constipation and stomach pain (Nadkarni 1976).

***Tinospora cordifolia* (Giloya) :** The plant contains columbin, chasmanthin, palmarin, berberine, T. acids Beta sitosterol, and giloin, giloinisin, which are effective in inflammatory, digestive, constipating. It is also useful in vitiated condition of vata, burning sensation hyperpiesia (Nadkarni 1976).

***Boswellia serrata* (Salaya guggul):** Boswellic . acid, the major constituent of *Boswellia serrata*, is through to contribute to most of the herbal pharmacologic activities. In vitro studies and animal models have shown that B. acid could inhibit 5-lipoxygenase selectively with anti-inflammatory and antiarthritic effects. Since the inflammatory process in IBD is associated with increased function of leukotrienes, the benefits of *Boswellia serrata* in the treatment of UC have

proved a positive result. Moreover, it has also been found to directly inhibit intestinal motility with a mechanism involving L-type Ca^{2+} channels. *Boswellia serrata* has been found to reduce chemically induced edema and inflammation in the intestine in rodents (Dos Reis, et al 2009).

***Brassica juncea* (Rai):** *Brassica juncea* are rich in indol-3-carbinol a chemical which boosts DNA repair in cells and appears to block the growth of cancer cells. They are also a good source of carotenoids, with broccoli having especially high levels. 3,3'- diindolylmethane in JB SSSS a potent modulator of the innate immune response system with potent antiviral, antibacterial and anticancer activity (Manohar et al 2009).

***Terminalia chebula* (Harar):** Therapeutically used part is fruit, Fruits contain about 30% astringent substances such as tannic acid, gallic acid etc. Resin and a purgative principles of the nature of anthraquinone and sennoside are also present. The extracts of the powdered fruits exhibit a Wide anti-bacterial and antifungal spectrum. The fruit pulp also exhibits laxative activity. It is used extensively in the preparations of many Ayurvedic formulations for infectious diseases Which impart immunity and body resistance against diseases and also have beneficial effects on all the tissues (Prabhat et al, 2010).

***Azadirachta indica* (Neem):** Antiulcer effect *Azadirachta indica* leaf aqueous extract produces effect in rats exposed to restraint cold stress or ethanol orally by preventing mucus depletion and mast cell degranulation. An aqueous extract of neem bark has been show our laboratory to possess highly potent antacid secretary and atulcer activity and the bioactive compounds has been attributed to a glycoside *Azadirachta indica* leaves and Bark aqueous extract effectively suppresses oral squamous cell carcinoma induced dimethylbenz anthracene (DMBA), as revealed by reduced incidence of neoplasm (Nadkarni 1976).

SUMMARY OF THE INVENTION

The present invention is based on the discovery that an herbal composition comprising of specific herbs properly extracted and blended in correct proportions will safely and significantly treat Colitis from different etiology.

Allopathic Colitis Drugs are commercially marketed from a long time and contain ingredients 5-aminosalicylic acid (5-ASA). These include *sulfasalazine* (trade name *Azulfadine*), a compound that has been used for more than half a century. The sulfapyridine in *sulfasalazine* causes a number of side effects, which include mild to severe headaches, nausea, and vomiting. These are usually dose-related, although some people cannot tolerate the medication at all. *Azulfadine* can be purchased in an enteric-coated tablet, which helps many people reduce the nausea caused by uncoated tablets.

The present herbal formulation is developed so as to provide relief in all types of chronic Ulcerative and non Ulcerative Colitis are refractory, chronic, and nonspecific disease occurred usually in the rectum and the entire colon. First time such a formulation developed comprising of such ingredients, Which helps in balancing of all types of Colitis.

The present herbal formulation is developed in such a manner that the precise blend of specified herbal extracts and selected excipients, non-freezing at subzero temperature thus preserves therapeutic efficacy of the herbal constituents at freezing temperatures Without changing the state of formulation and hence provides better efficacy. This ensures delivering the composition with maximum efficacy for treatment of all Ulcerative and non Ulcerative Colitis are refractory, chronic, and non specific disease occurred usually in the rectum and the entire colon. The non freezing nature of the composition of the present invention leads to improve patient compliance as it can be readily self administered by patient as and when required.

Also the presence of *Tinospora cordifolia* stem extract and *Foeniculum vulgare* seeds powder as one of the active ingredients in the present composition imparts an inherent mild desirable laxative activity.

The basis of preparation of novel herbal formulation comprises of various therapeutically active Ayurvedic medicinal plants having the following therapeutic properties as given below—to be selected from the following medicinal plants

Curcuma longa rhizome extract has an analgesic, anti-inflammatory, healing and antibacterial action.

Glycyrrhiza glabra root extract has an anti-inflammatory, demulcent and expectorant action

Silybum marianum has been used liver and biliary tract, gastroenterologists antioxidants, increase hepatocyte protein synthesis.

Foeniculum vulgare has carminative action anti-inflammatory, antispasmodic, antimicrobial properties.

Tinospora cordifolia has immunomodulatory activity.

Boswellia serrata has used for treating chronic laryngitis, furethorrhea, jaundice, diaphoresis, convulsions and ringworm. It is possesses diuretic, expectorant, anti-inflammatory and antiseptic.

Brassica juncea has anodyne, aperitif, diuretic, emetic, rubefacient, and stimulant,

Azadirachta indica has Anti-bacterial, Anti-viral, Pain relief – anaglesic. Calmative. Anti-inflammatory, antipyre *Terminalia chebula* has an antiseptic and expectorant, laxative action, antibacterial and antifungal spectrum.

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