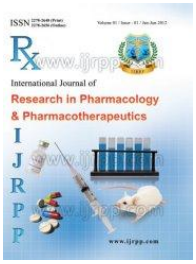
International Journal of Research in Pharmacology & Pharmacotherapeutics



ISSN Print: 2278-2648 ***IJRPP |Vol.5 | Issue 4 | Oct - Dec - 2016***
ISSN Online: 2278-2656 ***Journal Home page: www.ijrpp.com***

Research article ***Open Access***

FLORALITE Capsules: cancer supportive therapy for chemotherapy-induced diarrhea (CID)

Govind Shukla, Nagalakshmi Yaparthy, D.Sruthi Rao, C.J. Sampath Kumar

Oncowellness by Lactonova Nutripharm (P) Ltd, (Makers of Floralite capsules), 81/3, IDA Mallapur, Hyderabad, Telangana, India-500 076

***Corresponding author: Govind shukla**
Email: govindbbd@gmail.com

ABSTRACT

Diarrhea is a common side effect of chemotherapy regimens. Diarrhea can cause depletion of fluids and electrolytes, malnutrition, and dehydration. Chemotherapy-induced diarrhea (CID) can occur in as many as 50-80 percent of patients receiving chemotherapy. Probiotics have been shown effective at preventing diarrhea in inflammatory bowel disease and may prove useful in the oncology setting, Clinical research indicates that probiotics promote a healthy balance of intestinal flora and has immunomodulatory effects in cancer patients and may help minimize some of the negative gastrointestinal side effects associated with treatment. This article reviews the current available scientific literature regarding the effect of Floralite capsules in promoting immune function & As supportive therapy for chemotherapy induced diarrhea.

Keywords: Floralite capsules, ImmuneSystem, Chemotherapy induced diarrhea.

INTRODUCTION

Chemotherapy-induced diarrhea (CID) is a common problem in patients with advanced cancer resulting from the toxic repercussion of chemotherapeutic agents on the gastrointestinal mucosa [1, 2].

Prevalence and diagnosis

Chemotherapy regimen can result in up to 50–80% of patients developing CID [3,4].The severity of CID can be evaluated with the National Cancer Institute (NCI), Cancer Evaluation Program, Common toxicity criteria [5].In patients treated with certain chemotherapy regimen, the time of onset of diarrhea is usually between 5 and 14 days after dosing of the drug [6,7].Diarrhea induced by other chemotherapeutic agents typically occurs within 24 to 96 hours after infusion [1].Certain patient-related factors such as age, gender, lower performance status, bowel pathologies, and the presence of tumorous growths seem to be associated with an increased incidence of CID.

Role of Floralite capsules in Cancer Supportive Care

Changes to the intestinal milieu are often seen in cancer patients, either because of the disease (in particular cancer of the gastrointestinal tract) or because of treatment with radiotherapy or

chemotherapy. Major dysfunctions of the gastrointestinal tract are thought to be related to disturbances of the intestinal microflora.[20] Clinical research indicates that probiotics promote a healthy balance of intestinal flora and has immunomodulatory effects in cancer patients [10,11] and may help minimize some of the negative gastrointestinal side effects associated with treatment. Recent studies on lactobacillus acidophilus in floralite have shown to have anti-tumor effects [12, 13].

Lactobacillus gasseri (formerly classified as part of the L. acidophilus strain complex) [18] is among the major homofermentative Lactobacillus species that occupy the human intestinal tract. [19] In the colon, members of the Bifidobacterium family are the most predominant "friendly" bacteria. Within this family, Bifidobacterium Bifidum and Biłdobacterium longum are the well-researched strains. Floralite, contains a total of five billion live cells of a proprietary combination of L. gasseri, B. bifidum, and B. longum. These three are well-researched strains that are stable, effective, and safe for cancer patients. Bifidobacterium longum and lactobacillus bacteria's are gram positive anaerobic non-pathogenic bacteria present in human small intestine and are used in dairy industry as probiotics [8,9].

Pathophysiology of chemotherapy-induced diarrhea (CID)

The intestional microflora in cancer patient has been shown to undergo alteration, sometimes significantly creating a more favorable environment for pathogen overgrowth. This alteration in bowel flora may contribute to the gastrointestinal disturbance observed in cancer patients. CID appears to be a multifactorial process with acute damage to the intestinal mucosa, (including loss of intestinal epithelium, superficial necrosis and inflammation of the bowel wall) causing an imbalance between absorption and secretion in the small bowel [15].

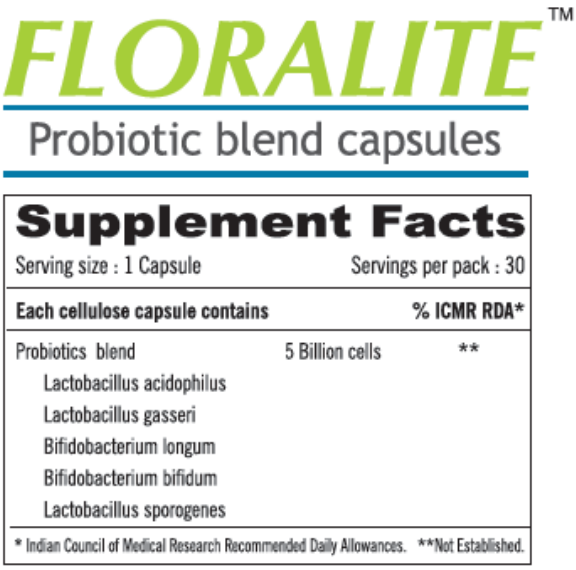
Diarrhea is a common side effect of chemotherapy regimens, particularly fluorouracil- and irinotecan-based therapies. Diarrhea can cause depletion of fluids and electrolytes, malnutrition, and dehydration, all of which can lead to serious and even lethal cardiovascular compromise. Chemotherapy-induced diarrhea (CID) can occur in as many as 50-80 percent of patients receiving chemotherapy, depending on drug combinations, dosages, and treatment schedules. [24] Clinical trials exploring the use of probiotics in patients with CID are limited, but a case study of a stage IV breast cancer patient demonstrated that treatment with a multi-species combination of probiotics successfully resolved her grade 3 chemotherapy-induced diarrhea [26].

Probiotics may prevent CID of 5-fluorouracil (5-FU), capecitabine and irinotecan [16].Probiotics have been shown effective at preventing diarrhea in inflammatory bowel disease and may prove useful in the oncology setting. Irinotecan used in metastatic colon cancer induce direct luminal environment damage, may result in growth of different geners of bacteria allowing them to proliferate. The bacterial β-glucuronidase deconjugates SN38G to the active form SN38 causing significant damage and diarrhea [17].

Role of Floralite capsules in Radiotherapy-induced Diarrhea

Radiation-induced diarrhea is frequently observed during abdominal and pelvic radiotherapy and can interfere with cancer treatment by causing dosing delays or reductions. Emerging evidence suggests probiotic therapy may be of benefit in normalizing intestinal flora and promoting a healthy immune response in the gut. In a randomized, double-blinded, placebo-controlled trial, 63 cervical cancer patients undergoing pelvic radiotherapy concurrent with weekly cisplatin were randomly assigned to a probiotic treatment containing one billion live cells of L. acidophilus and one billion live cells of B. biłdum twice daily (n=32) or placebo (n=31). Over the course of the trial, Grade 2-3 diarrhea (requiring anti-diarrheal medications) was observed in only nine percent in the probiotic group ($p=0.002$) compared to 45 percent in the placebo group. The patients in the treatment group had significantly improved stool consistency ($p<0.001$) compared to baseline.[27]Other Lactobacillus species in Floralite capsules have also been shown to significantly reduce diarrhea when given to patients during radiation to the pelvis,[28] even when given two weeks after radiation therapy [29].

Composition of floralite capsule



Mechanism of action of Floralite capsules

Alteration of intestinal metabolism by modulating activity of β-glucuronidase, nitroreductase and other bacterial enzymes may reduce the risk of CID in colon cancer [14]. Probiotic-based therapies have been shown to exert beneficial effects, including modulation of the microflora, increase of the immune response, protection of the host against viral infection and inhibition of carcinogenesis. [25]

Potential mechanisms to consider include

1. modulation of GI immunity by altering inflammatory cytokine profiles and downregulating proinflammatory cascades or inducing regulatory mechanisms in a strain-specific manner;
2. displacement of gas-producing, bile salt-deconjugating bacterial species and thus possibly inhibiting pathogenic bacterial adherence;
3. alteration of bacterial flora by acidification of the colon by nutrient fermentation;
4. enhancement of epithelial barrier function;
5. induction of μ-opioid and cannabinoid receptors in intestinal epithelial cells;
6. reduction of visceral hypersensitivity, spinal afferent traffic, and stress response [33,34,20]

Clinical Study Reports on Probiotics in Florolite capsules.

Probiotics in florolite might reduce the risk of colon cancer by inhibiting carcinogen-induced DNA damage in intestinal tract. The genotoxicity of fecal water, after dietary intervention into yogurt containing probiotic strains L. acidophilusand B. longum, was examined in 9 healthy volunteers. Fecal water from the patients receiving probiotic yogurt incubated with human colon tumor cells HT29 clone 19A demonstrated significantly lower genotoxicity compared to standard yougurt. There was reduction of stand break-induced in human fecal water after dietary intervention with these probiotic bacteria. Fecal water from the probiotic group reduced overall genetic damage in the cell line [21].

Emerging evidence indicate probiotic administration is of particular benefit in patients with colorectal cancer. Analysis of stool and blood samples fom10 colon rectal cancer patients given L.gasseri once daily for 12 weeks yielded an increased detection rate of L.gasseri, decreased total count of pathogen clostridum perfringens , decreased fecal pH indicates acidosis, decreased synthesis of fecal putrefaction products, and increased levels of the beneficial short-chain fatty acid, isobutyric acid. Interleukin- 1beta (IL-1β) and natural killer (NK) cells activity values were significantly higher from the fourth week of treatment onward compared to the base line. These results indicate L.gasseri in florolite administration improves the intestinal environment in colon rectal cancer patients, suggesting it may have a role in normalizing the intestinal milieu in patients with established cancers [22].

Floralite capsules in Acute Diarrhea

Numerous studies shows administration of probiotic bacteria in Floralite capsules is beneficial in patients experiencing acute diarrhea of various etiologies. In a multi-center, randomized, double-blinded, placebo-controlled clinical trial of 169 adult subjects with acute diarrhea, a fixed combination of L. gasseri and B. longum given three times daily for six days resulted in complete recovery from diarrhea in 93 percent of patients taking the combination formula. The number of loose stools and duration of diarrhea was also significantly reduced in the subjects receiving the combination strain.[10] A smaller, uncontrolled preliminary clinical study of 13 adults with diarrhea noted a significant reduction in diarrhea in 11 of the patients after administration of a probiotic formula containing L. gasseri, B. bifidum, and B. longum. The probiotic was administered for six months at dosages between 1.7-6.8 billion live cells daily (depending on stage of study) [23].

Stability, Colonization, and Efficacy of Floralite capsules

Counts of from 108 to 109 lactic acid-producing bacteria have been shown to be clinically effective. Thus, a minimum of one billion live cells of bacteria should be consumed to assure efficacy. The strains in Floralite have been shown to provide at least five times this amount of live cells after being held at room temperature (77°F / 25°C) for three years. B. longum, B. bifidum, and L. gasseri have shown a strong ability to adhere to the intestinal mucosa, distribute throughout the intestinal tract, and be recovered from the feces [30-32].

Summary & Conclusion

Radiation-induced diarrhea is frequently observed during abdominal and pelvic radiotherapy. Emerging evidence suggests probiotic therapy of Floralite capsules may be of benefit in normalizing intestinal flora and promoting a healthy immune response in the gut. . Probiotics in Floralite capsules have been shown effective at preventing diarrhea in inflammatory bowel disease and may prove useful in the oncology setting, Clinical research indicates that probiotics in Floralite capsules promote a healthy balance of intestinal flora and has immunomodulatory effects in cancer patients.

Recommended Usage

1-2 Floralite capsules per day or As Directed by Health care Practioner

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