

A Randomized Open Label Study to Evaluate the Efficacy and Tolerability of Synbiotic in the Treatment of Ulcerative Colitis

Malathi K1, Nandini R1, Dhanasekar KR2 and Shilpa BN2* 1Institute of Pharmacology, Madras Medical College and Hospital, Chennai, Tamil Nadu, India; 2Department of Medical and Scientific Affairs, Tablets India Limited, Chennai, Tamil Nadu, India

ABSTRACT

Introduction: Ulcerative Colitis (UC) is a chronic inflammatory condition of the colon affecting 5 million patients globally. Despite the recent clinical advances in drug therapies, patients continue to have exacerbations of UC. Alterations in gut microbiota, more specifically reduced intestinal microbial diversity, have been found to be associated with relapse of UC. Therefore therapeutic strategy targeting the gut microbiota has the potential to induce remission in UC. This study was done to evaluate the efficacy and tolerability of synbiotic as an adjuvant to standard therapy in patients with UC and to evaluate the ability of synbiotic in preventing relapse and prolonging the remission of UC. **Methods:** An interventional open label, randomized, comparative clinical trial was done with 32 patients. Patients were randomized into two groups, Study group (n=16) received synbiotic one capsule b.d along with standard therapy. Group B (n=16) received standard therapy only. Statistical analyses of the efficacy and safety parameters were done using chi square test paired t test and ANOVA. **Results:** In our study, at the end of 6th month, statistically significant number of patients had remission in study group when compared to control group, with $p < 0.05$. Significantly higher number of patients in control group had relapse compared to study group and also there was a statistically significant reduction in steroid intake in study group. **Conclusion:** From this study we can conclude that synbiotic therapy along with standard treatment is effective in inducing and maintaining remission with a reduction in steroid dosage in UC and tolerable. **Keywords:** Ulcerative colitis; Synbiotic therapy; Probiotics; Steroids; Remission; Relapse; Gut microbiota

INTRODUCTION Ulcerative colitis (UC) is characterized by relapsing and remitting episodes of inflammation limited to the mucosal layer of the colon. The incidence of UC is rising with time, with prevalence 44.3 per 100,000 in India. In UC 15% of the patients have a life time risk to develop severe exacerbations requiring hospitalization 67% of patients have at least one relapse within 10 years 48.1% of the patients who had taken standard therapy experience relapse in 12 months.

Twenty to thirty percent of patients with ulcerative colitis will require colectomy for acute complications or for medically intractable

disease. Incidence of Colorectal cancer is 2.5 percent after 20 years and 7.6 percent after 30 years of disease. The aim of treatment of UC is induction of remission, prevention of relapses, mucosal healing, the avoidance of colectomy, and decreasing the likelihood of the development of cancer. Preparations such as 5 aminosalicylates (5-ASA) preparations are effective in inducing and maintaining remission in approximately 75% of the patients. In patients who fail to respond to 5-ASA therapy, oral corticosteroids like prednisone are used to induce remission and are not used for maintenance due to lack of efficacy and adverse effects. Only 60% of the

*Correspondence to: Shilpa BN, Department of Medical and Scientific Affairs, Tablets India Limited, Chennai, Tamil Nadu, India, Tel: +91-9384800396; E-mail: bns@tabletsindia.com Received: December 13, 2018, Accepted: February 13, 2019, Published: February 18, 2019 Citation: Malathi K, Nandini R, Dhanasekar KR and Shilpa BN (2019) A Randomized Open Label Study to Evaluate the Efficacy and Tolerability of Synbiotic in the Treatment of Ulcerative Colitis. *J Hepatol Gastroint Dis* 10:398. doi: 10.35248/2475-3181.5.165 Copyright: © 2019 Malathi K, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.,000 live births if