

Title

EVALUATION OF THE EFFICACY OF DRIED POWDERED EXTRACT OF AEGLE MARMELOS FRUIT FOR THE MANAGEMENT OF SYMPTOMS IN PATIENTS WITH IRRITABLE BOWEL SYNDROME WITH PREDOMINANT DIARRHEA BY A PROSPECTIVE RANDOMISED CONTROLLED DOUBLE BLIND TRIAL.

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Introduction

Irritable bowel syndrome with diarrhea predominance (IBS-D) is a chronic relapsing disorder with significant impact on the patient, both in terms of treatment cost and quality of life. Further, the safety and efficacy of long term use of presently available therapies remain largely unknown. Aegle marmelos (Bael) fruit is widely available in the Asian subcontinent and has been used in traditional medicinal practice for the treatment of diarrhea since ancient times. The fruit is rich in a variety of alkaloids and pectin. There are no controlled trials to establish its efficacy in treating diarrhea. This study was carried out to evaluate the efficacy of dried powdered extract of Aegle marmelos (study medication) in patients with IBS-D.

Materials and Methods

Two hundred and twenty six patients with IBS-D and a normal colonoscopy were randomised to receive either powdered extract of Aegle Marmelos (Bael) fruit or placebo. After the colonoscopy, provided it was normal, a rest period of one week was given to the patients to allow the colon to return to normal. Patients were given symptom diary cards and told to record stool frequency, number of loose stools, incomplete evacuation, bloating and the quality of life. The Bristol Meyer stool form scale was supplied with the symptom diary card for self assessment of stool form. After a two week run in period of baseline symptom recording, a two week period of either 300 mg daily of study medication in three divided doses or matched placebo was given. Patients were then crossed over to placebo / study medication as appropriate for a further period of two weeks.

Results

For analysis of the data on treatment with extract of Aegle Marmelos (bael) fruit we adjusted the placebo treatment group and active treatment group for the baseline stool frequency and the baseline frequency of loose stools. It was seen that there was reduction in the frequency of stools and number of loose stools with dried powdered extract of Aegle marmelos. The reduction was statistically significant.

Fig. 1. Comparing number of Stools per day by treatment periods. 1 represents active treatment and 2 is placebo.12 represents the number of stools over the 14 day run in period in those who received active treatment first and 21 represents the adjusted stool frequency in those who received placebo first. It is noted that there is significant change in the number of at cross over from active drug to placebo irrespective of whether placebo was given first or second

Fig. 1.



Fig. 2 Comparing number of loose stools per day by treatment periods. 1 represents active treatment and 2 is placebo.12 represents the number of loose stools over the 14 day run in period in those who received active treatment first and 21 represents the adjusted number of loose stool frequency in those who received placebo first. It is noted that there is significant change in the number of at cross over from active drug to placebo irrespective of whether placebo was given first or second

Fig. 2.



There was no significant change in either bloating or incomplete evacuation. Significant side effects were not noted.

Conclusion

Treatment with dried powdered extract of Aegle Marmelos fruit is effective and safe in treatment of diarrhea in irritable bowel syndrome with diarrhea predominance (IBS-D). Further studies are necessary to isolate the active ingredient and subject it to clinical scrutiny.