A Prospective Study on Efficacy of Probiotics in Diabetic Functional Gastrointestinal Disorders

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Abstract: Functional gastrointestinal disorders contributes to severe morbidity in diabetic patients. Recent studies have proved an association between FGID and TYPE 2 DIABETES MELLITUS risk especially with regard to intestinal dysbiosis(1) . Diabetic individuals have proven esophageal,gastric,intestinal,gall bladder and ano rectal dysmotility(2). So we planned to conduct a prospective study to assess the efficacy of probiotics in Diabetic FGID. Our study has shown a dramatic improvement in FGID symptoms through probiotics treatment in diabetic individuals which certainly support the ideology of intestinal dysbiosis as causative factor in FGID in type 2 diabetes mellitus

I. Introduction
Functional gastrointestinal disorders contributes to severe morbidity in diabetic patients. Functional gastrointestinal disorders in diabetes include dyspepsia,nausea, vomiting,diarhoea or constipation and abdominal fullness(3) and these symptoms are seen to be associated with intestinal dysbiosis(4). So we planned a prospective study to see the efficacy of probiotics in FGID in diabetes mellitus in OPD of our tertiary care centre.

II. Aims And Objectives
To Assess The Efficacy Of Probiotics In Fgid In Type 2 Diabetes Mellitus

III. Materials And Methods
Study Type: Interventional
Study Design: Non Randomised Prospective Study
Study Group: 100 patients with type 2 diabetes mellitus presenting with FGID symptoms in out patient department of general surgery in GMKMCH,Salem were considered as data source. Individuals who fulfilled the inclusive and exclusive criteria were enrolled in the study.

Inclusion criteria:
1.AGE: 30 to 55 years
2.sex: male & female
3.Type2 diabetes mellitus with FGID symptoms such as heart burn,dyspepsia,vomiting,nausea,abdominalfullness, constipation or diarrhea.

Exclusion criteria:
1.Not willing to give consent
2.Organic causes for gastro intestinal symptoms such as malignancy
3.Other immunocompromised individuals
Type 2 diabetic individuals presenting to general surgery opd with FGID complaints such as heart burn,dyspepsia,vomiting,nausea,abdominalfullness, constipation or diarrhea were included in this study. Malignancy was excluded first by GI endoscopy,ultra sound abdomen, CECT abdomen and colonoscopy in selective cases to exclude the organic causes.
Non randomized selection of consecutive 100 eligible persons were included in this study. Probiotics (saccharomycesboulardic 282.5 mgs and lacto bacillus 120 spores) were given as twice daily dose for 8 weeks. Proton pump inhibitors were deliberately avoided and glycaemic control was strictly maintained by our physician team. Symptom profile were documented every 15days using a VAS ruler. Its is a linear anologue 10 point scale with markings from 0 to 10, in which 0 denotes absence of symptoms and 10 denotes most severity. Intake of tablet and self reporting were documented as compliance. Results were documented as per clinical examination, visual analog scale for FGID symptoms and upper GI scopy at the initial session and at the end of session.

Followup:
Bimonthly follow up was done in all patients for a period of 8 weeks and then monthly follow up for next three months for all cases.

IV. Results
Out of 100 patients included in this study 65% patients had dyspepsia, 42% patients had heart burn, 35% had constipation, 6% had frequent episodes of diarrhea, 12% had frequent episodes of nausea or vomiting, 70% patients had post prandial abdominal fullness or discomfort. VAS score of 10 was recorded by 62% patients and others recorded a VAS score of 5 to 9. After probiotics treatment for 8 weeks, a significant decrease in VAS scoring from 10 to 4 in 8 weeks and complete remission of symptoms occurred in 60% patients. Severity of symptoms and complete remission was directly proportional to the duration of diabetes disease.

FGID SCORE

Assessment Of Fgid symptoms in VAS scale: So, our study supports the ideology of intestinal dysbiosis as a responsible cause for FGID In type 2 diabetes mellitus and also probiotics therapy significantly reduces the severity of symptoms. Also there were no complications in our study.

V. Discussion
Diabetes mellitus is the leading cause for prolonged morbidity in both developing and developed countries. Recent studies have proved that FGID is more commonly associated with the type 2 diabetes mellitus, especially with regard to intestinal dysbiosis(13,14). Also increased incidence of FGID symptoms are documented with dysmotility disorders in diabetic individuals(15). Dysbiosis of gut has been the central dogma of causation of many intestinal and extra intestinal diseases(16). Hence, we focused on maintaining the gut ecosystem for FGID in diabetes mellitus. Delayed gastric emptying in diabetes not only aggravates the patients morbidity, but also it retards the absorption of oral hypoglycaemic drugs. So dysmotility of gut not only renders the patient symptomatic, but also retards the drug absorption, thereby hindering the glycaemic management. So maintainence of gut microbial eco system needs to be primarily addressed. Our study is the first documented study of this kind. So, drugs to maintain the gut ecosystem is the need for the hour in relieving the symptoms.

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and to aid in the absorption of drugs. A metaanalysis of randomized controlled trials have proved that probiotic consumption significantly decreased hemostasis model assessment of insulin resistance (HOMA-IR)\(^5\). Persistent low grade inflammation due to gut dysbiosis is supposed to be the reason for FGID. Obviously in diabetes mellitus as it is highly associated with the gut dysbiosis, probiotics combats the leaky gut through promotion of growth of commensals. In our study, the mixed probiotics were given for period of 8 weeks, and significant improvement have been documented. We planned both fungal and bacterial commensals to combat both pathogenic fungi and bacteria in gut.

VI. Conclusion

Our study proves that probiotics therapy for a prolonged period significantly reduces the severity of symptoms of FGID, and henceforth our study supports the ideology of intestinal dysbiosis as a causative factor for FGID in type 2 diabetes mellitus. This study has to be further expanded to a major population for further assessment of outcome.

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