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Does effective Communication of dietary Recommendations along with Prescribed Laxative in children with Functional constipation, and Therapeutic benefit

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ABSTRACT

Functional constipation is a chronic disease associated with poor quality of life. Besides drug treatment in these children, does change in lifestyle in terms of eating habits and toilet routine is beneficial remains inconclusive? Does effective communication of these instructions will be having added therapeutic benefit in such children was the research question. The present study was an open prospective cohort study in which 106 children of FC were enrolled. These were between 1-18 years of age and came to general Pediatric OPD of a tertiary level hospital in urban Ghaziabad. All were prescribed laxative PEG but the ways to communicate the desired changes in diet and toilet habits differed in two groups (0 and 1). Group 0 was attended in usual way in OPD by any doctor whose OPD was scheduled on that particular day while group 1 was explained the desired changes in diet & toilet schedule in structured, concise format & written handouts about these directions were also given. All were advised to continue laxatives for 6- 12 months, to maintain stool diary and to come for follow up at 10-15 days,1, 3 & 6 months. Primary outcome was number of stools per week & stool form on BSFS assessed beyond 3 months. Group 1 and 0 were almost same in initial months in terms of cure rates but beyond 3 months the kids in former group were better in terms of higher percentage of kids reporting softer stools, higher number of stools per week & also subjective improvement reported by many (71 % in group 1 vs 52% in group 0) and fewer relapses (17.8% in former vs 38.9% in later).The way of communication did influenced patient's adherence to the treatment as was evident by higher percentage of participants coming for follow up in group 1 even at 6 months and perusal of dietary recommendations was found in 51% children belonging to this group. The changes in diet and toilet habits are beneficial and have added therapeutic benefit in children suffering from FC. The effective communication and implementation of these changes will be helpful mainly in long term follow up by allowing lower doses of laxatives, better objective as well as subjective improvement rates, fewer relapses. It is important to communicate patiently about non pharmacological components of treatment with these families at the outset. The repeated counselling for these changes in subsequent meetings will also be equally important to ensure better compliance and higher response rates.

KEYWORDS: *Functional constipation, Diet, Fibre, fluid intake, behaviour modification, children.*

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INTRODUCTION

Functional constipation (FC) is a very common chronic disease associated with poor quality of life [1-2]. Besides drug treatment these children need change in lifestyle in terms of daily activity [3-4], eating &toileting habits [5-8]. "Whether or not these directions are helpful in improving the therapeutic benefits"- was the research question in present research work. "Whether the co-operation from patient and their parents can be influenced by the way these recommendations are communicated"-was the other component of research question? Constraints like busy OPD hours lead to short time per patient which in turn may cause incomplete or quickly conveyed nonpharmacological interventions to the care givers. It was felt that most caregivers focus solely on laxatives and ignore these important nonpharmacological interventions. This in turn is the cause of frequent relapses or poor treatment outcomes and continued misery of the child & family. Most studies address clinical profile of patients [9-12], response to laxatives [13], factors leading to treatment failure and relapses [14]. Studies focusing on additive therapeutic benefits of nonpharmacological treatment modalities like dietary and toilet habits modifications are few.

MATERIAL AND METHODS

The present study was an open cohort hospital based study in which eligible consecutive children of FC were enrolled. Study period was of 12 months from June 2021 to May 2022. These children were 1-18

years old, attended general Pediatrics OPD of a tertiary level hospital in urban Ghaziabad. Functional constipation was diagnosed using Rome IV criteria [7]. Bristol stool forming scale (BSFS) was used to know stool type. Exclusion criteria were children below 12 months of age, diagnosed case of hypothyroidism, celiac disease, Meningo-myelocele or other spinal cord anomalies. Children taking medicines like anti-cholinergic, antidepressants or patients of Autistic Spectrum Disorders/mental retardation/cerebral palsy with feeding difficulties were also excluded. All the participants were given PEG in following doses - for dis-impaction- 1.25g/kg/d for 3-6 day depending upon clinical response (whether or not child has passed stool). For maintenance the dose chosen varied from 0.4 g/kg to 0.8g/kg/d. Once child started showing sustained improvement parents were guided for the laxative dose titration. The children since enrolment were divided into two groups Group 0 & 1.

Consecutively enrolled children with odd number were placed in were placed in group 1 & even number children were placed in group 0. Group 0 Children were attended in usual way in OPD by any doctor whose OPD was scheduled on that particular day while group 1 children were attended by the primary investigator who interactively explained the need of symptom charting using BSFS Chart, desired changes in diet & toilet schedule. Printed handouts of all these nonpharmacological intervention were given to group 1.The need to continue laxative for long duration was stressed in both groups. By Effective communication it was meant-1. Diet related- were based on current recommendations of ICMR. Parents had to ensure that child consume diet following all these guidelines-Daily 3 major meals (breakfast, lunch, dinner) and 2 snacks. Two or more serves* of GYOR vegetables and fruits per day. (*1 serve of vegetable =50gms,1 serve of fruit= 1medium size fruit). Two serves of cereals per day (as per age recommendations),encourage use of multigrain flour with husk.(1 serve= 1 medium size roti approx. 25 gram or equivalent),Daily consumption of at least 1-2 serve of whole pulses or split pulses with skin. Milk equal to or less than 500 ml (2 glass) per day. Avoidance of dietary items made of Maida to less than 2 times per month.

Toilet habits related- Parents were asked to make child sit on toilet seat with his/her feet supported on ground/hard surface after all major meals for at least 5 minutes daily. They were explained and given handouts of Bristol stool form scales (BSFS) and were asked to mark the type of stool daily in stool diary till completion of follow up. Successful outcome /cure was considered when all of the diagnostic criteria had subsided for at least 1 month, Partial response was when child showing some improvement in number of stools per week or softer stools (on BSFS) but few other symptoms were persisting. Follow-up was advised at 10 days, 1, 3 & 6 -12 month. Parents were reminded telephonically for 3rd FU, if they did not turn up on their own. Cured or partial response was assessed only after this visit. The institutional ethical committee approval was obtained. The data collected from two groups was compared and analysed for significance using SPSS version 22.0. Mean no of stools/week, stool type on BSFS in same group (either group 0 or 1) at different time period was compared. This comparison was also done in between the 2 different treatment groups at different time period using General linear model. Frequency of different symptoms were calculated at enrollment, and also at follow up beyond 3 months to decide cure or response. Frequency of pre-treatment duration of symptoms, time to get response, and duration of follow-up in study subjects was also calculated and expressed as percentage. Primary outcome variable was improvement in constipation for=/>1 month.

RESULT AND DISCUSSION

A total of 106 children with functional constipation were enrolled with 53 children each in groups0 and group 1. Prior to enrolment children were symptomatic for a minimum of 3 months to a maximum of 34 months duration (Table 1). Almost all children, irrespective of treatment group responded to prescribed treatment by 4-6 weeks. Follow Up of participants was 100% in both groups till 3 months but beyond that Loss in follow up was higher at 32% (17/53) in group 0 than 15% (8/53) in group 1. Compliance to laxative beyond 3 months was poorer in group 0 (21,39.6%) in comparison to group 1 (39,73.6%).Compliance to dietary recommendations was better in Group 1 from the very beginning ,23(51 %) children in this group were following the prescribed diet even beyond 3 months in contrast to none in group 0 . Relapses beyond 3 months were commoner in group 0 (28, 39.6%) than in group 1 (8,17.8%) (Table 2). Is it prescribing nonpharmacological interventions alone in children with FC, who are already taking laxatives or is it the effective communication of these recommendations which augments the therapeutic benefits -was the research question. PEG with or without dietary modification proved to be an effective laxative an observation in concordance with other researchers [17]. The cure rate was 100% in both groups beyond 6 weeks. Response usually became apparent by 2-3 weeks and increased drastically beyond 3 weeks of continued consumption of PEG.

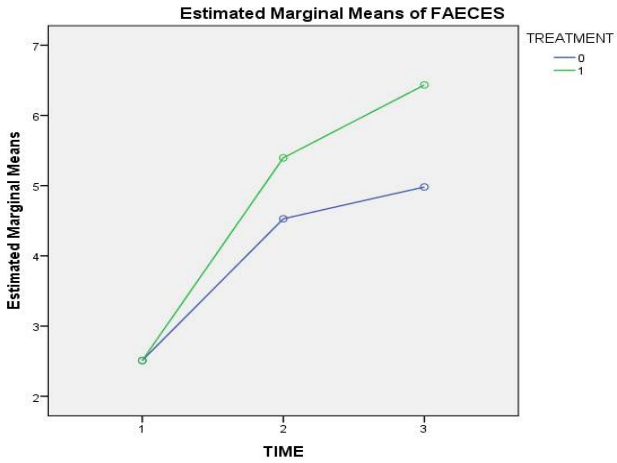
It was found that in follow up the more children belonging to group 1 were following dietary modifications and were passing softer stools as per BSFS & also the number of stools per week was higher. The subjective improvement in other associated symptoms of FC in this group children was higher than the other group. In a study from Chennai the researcher concluded that there is significant negative association between FC and consumption of fresh fruits and vegetables [18]. It was observed in present research that most difficult part in treatment of FC was, to convince care givers to continue the drug for prescribed period as approximately 60% children in present study were constipated & distressed for more than 6 months prior to enrolment, yet many of these caregivers stopped giving laxative as soon as they noticed improvement in symptoms on their own. The drug treatment beyond 3 months was discontinued by all participants. Intermittent use beyond 3 months was reported by some parents whenever the symptoms recurred. Similar were the findings of Khanna *et al* [6] who in their retrospective case control study stated that noncompliance to prescribed dose and duration of laxative was the first important reason of treatment failure & the second reason being not following advice about diet and change in toilet habits.

Table 1: Participants characteristics, Total children (106)

Age (years)	**number n**	**(%)**
1-4	**45**	**42.4**
5-10	**33**	**31.1**
11-18	**28**	**26.4**
Duration of constipation prior to enrolment (months)		
3-6	**43**	**40.6**
6-12	**38**	**35.8**
>12	**25**	**23.6**
Participants in Regular FU after enrolment at		
<3 months	**53 100**	**53 100**
3-6 months	**36 67.9**	**45 84.9**
Compliance to Laxative at		
1-2 months	**46 86.8**	**47 88.7**
>2-3 months	**39 73.6**	**42 79.2**
>3-6 months	**21 39.6**	**39 73.6**
>6 months	**0**	**0**
Compliance to dietary & defecation instructions at		
1 month		
3 months	**42 79.2**	**53 100**
6 months	**16 30.1**	**42 79.2**
	0	**23 51.1**
Recurrence of constipation at		
3 months	**0**	**0**
>3-6 months	**21 39.6**	**8 17.8**
Number of stools/week		
Mean(SD)		
At enrolment	**2.51(.541)**	**2.51(.693)**
At 15-30 days	**4.53(.868)**	**5.40(.862)**
At 3-6 months	**4.98 (.796)**	**6.43(.572)**
Stool type on BSFS		
Mean(SD)		
At enrolment	**1.87(.680)**	**1.75(677)**
At 15-30 days	**2.74(.560)**	**3.17(.643)**
At 3-6 months	**3.25(.434)**	**3.81(.395)**

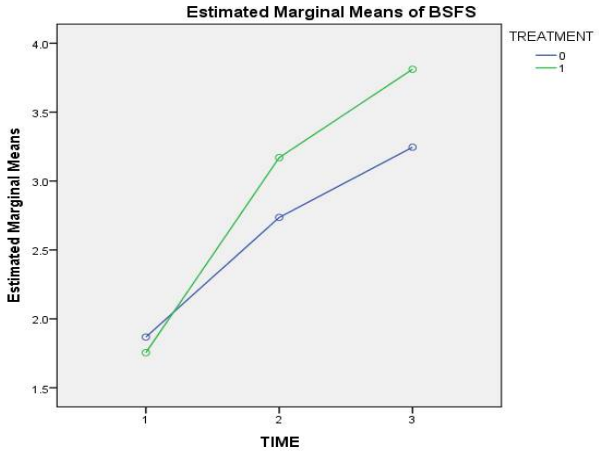
Successful outcome was measured objectively and compared in two study groups by using stool number per week (Fig 1) and stool type on BSFS (Fig 2) in follow-up. Change in number of faces/week (mean, SD) from enrolment till last follow-up were compared in two study groups and are shown in figure 1. It is evident that children in group 1 showed increase in number of stools earlier than group 0. Moreover, this increase was well sustained and was at higher level in group 1 at all-time.

Figure 1.Comparison of Stools frequency (number/wk) between 2 study groups at different time period



Second variable to compare outcome of two study group was- stool type based on BSFS during follow up (Figure 2. It is apparent that initially there was no difference between two study groups but beyond 3 months stool were softer in group 1 children than group 0.

Figure 2. Comparison of stool type on BSFS in 2 study groups at different time interval.



Compliance to dietary modification was better than that for laxative & 79% of total participants were still following these modifications at 3 months. Regular laxative intake was stopped beyond 3 months by all in both the groups but around 51% children of group 1 were still following dietary and toileting modifications & were definitely better than the other group. The plausible explanation could be the intention of parents to avoid the use of drug for long time and they prefer use of non-pharmacological measures to sustain response. The other plausible explanation we can think of, for this behavior is that as all had improved by 3 months, so they became carefree and chose to ignore the advice given to them at enrolment and resumed to their previous life style completely or partially. Khanna et al[6] in their research stated that fear of side effects, or addiction and reluctance of child were few reasons for this behavior. The second component of research question that to make patients stick to the recommendations can be influenced by the way it is communicated to them, proved correct. We conclude this because, we found that loss to follow up was lesser when doctor patient rapport was better, specific & structured instructions were given. The percentage of cases with longer follow up were higher in group 1 than in group 0 (67.9% vs 84.9%) which highlights the importance of better rapport between doctor and patient as it can lead to better treatment compliance. More over the compliance to dietary recommendations was good in these children even at 6 months as compared to the other group who was attended in usual way in OPD. We would like to interpret this as better explanation of instructions led to better understanding of treatment plan and led to longer compliance and so led to higher successful outcome rate.

The added therapeutic benefits availed by this group were clearly fewer relapses .The relapse rate were significantly low in this group 1 and relapses beyond 3 months of drug treatment in group 0 were complained in 38.9% children as compared 17.8% subjects in group 1 .The importance and impact of

balanced diet (providing adequate fiber) is more on long-term outcome ie longer remission with or without laxative and fewer relapses. Similar were the results of Quintadomo *et al* & many other researchers [19-20]. The limitations of present study are sampling technique which was a sample of convenience and children were placed in two groups for comparison without randomization so the results could be skewed in favour of group 1.Besides the loss in follow up was high at around 24% when to start with the sample size was only 106.
Scope for future studies are need of large sample size randomized trials with longer follow up.

CONCLUSION

The changes in diet and toilet habits are beneficial and have added therapeutic benefit in children suffering from FC. The effective communication and implementation of these changes will be helpful mainly in long term follow up by allowing lower doses of laxatives, better objective as well as subjective improvement rates, fewer relapses. So it's extremely important to communicate patiently about non pharmacological components of treatment with these families at the outset. The repeated counselling for these changes in subsequent meetings will also be equally important to ensure better compliance and higher response rate.

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