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Original Research Article

Comparison between PEG 3350 and PEG 4000 for treatment of functional constipation in children aged 4 to 18 years

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ABSTRACT

Background: Two molecular weight variants of PEG, viz. PEG 3350 and PEG 4000 are available commercially for treatment of functional constipation in children, however, relative efficacy of these two formulations has not yet been established. Hence, we compared the efficacy of PEG 3350 and PEG 4000 for treatment of functional constipation in children aged 4 to 18 years.
Methods: A total of 90 children were enrolled in the study. The patients were randomized either to receive PEG 3350 (Group A) or PEG 4000 (Group B). Stool frequency and other associated outcomes were noted at baseline and at 4-, 12- and 24-weeks follow-up.
Results: At baseline there was no significant difference between the two groups for patient and disease characteristics. Mean stool frequency was 2.98±0.50 and 2.96±0.47 respectively in Groups A and B at baseline; 5.04±0.56 and 5.18±0.75 at 4 weeks, 6.53±0.81 and 7.00±0.00 at 12 weeks and 7.00±0.00 and 7.00±0.00 respectively at 8 weeks in the corresponding groups. Statistically, there was no significant difference between the two groups at any time interval. For other outcomes too, there was no significant difference between the two groups at any follow-up interval except for stool consistency which attained significantly higher score in Group B as compared to Group A at week 4 follow-up (p=0.006). Incidence of diarrhea was also comparable between the two groups.
Conclusions: Both PEG3350 and PEG4000 were equally safe and effective measures for treatment of functional constipation in children aged 4-18 years.

Keywords: Functional constipation, Polyethylene glycols, PEG3350, PEG4000, Stool frequency

INTRODUCTION

Functional constipation (FC) is a common functional gastrointestinal problem in the childhood. The exact prevalence of functional constipation in children remains unknown in view of the absence of a universal diagnostic criteria and changes in definition. Hence there is wide variation in its prevalence that is reported to range from 0.7% to 29.6% across the world.[1] As per rough estimates, it is responsible for nearly 3 to 5% of pediatric primary care visits and comprises nearly 25% of pediatric gastroenterology consultations.[2,3] It remains to be independent of age and sex and is a global problem not confined to a particular geographical region. However, Asian children as compared to American and European children are less commonly affected by FC. The possible reason for this could be difference in dietary and lifestyle factors apart from social factors like toilet habits.[1,4] Whether it is a socioeconomic problem remains to be explored. A number of reports have found it to be unrelated with the sociodemographic factors.[5,6] However, few studies report it to be a problem of lower socioeconomic class.[7] Epidemiological studies, however, show that familial history of constipation and health issues in family members may have a role to play.[5,6] With the adaptation of ROME IV criteria, age related differences in prevalence of childhood constipation have

become more peculiar resulting in emergence of younger children and infants to be more affected by it.[8]

Management of functional constipation in children is done primarily with the help of dietary interventions, education and behavioural therapy.[9] Among pharmacological interventions, faecaldisimpaction followed by maintenance therapy is the most common approach. For this purpose, high-dose oral polyethylene glycols (PEGs) remain to be the most common therapeutic pharmacological interventions.[8,9]

Conventionally PEG 3350 containing PEG with a molecular weight of 3350 g/mol is widely used for this purpose, however, in the recent year a higher molecular weight alternative PEG 4000 that contains PEG with a molecular weight of 4000 g/mol has become available. Despite safety and efficacy of this new alternative been established, there are lack of comparative studies comparing these two alternatives for their relative efficacy in management of functional constipation in children.[10-12] Hence, the present study was planned to compare the efficacy of PEG 3350 with PEG 4000 in management of functional constipation in children aged 4 to 18 years.

METHODS

The present study was carried out as an open label randomized controlled trial after getting approval from institutional ethics committee and getting informed assent/consent from patients and their parents.

A total of 90 children aged 4-18 years attending the tertiary care teaching hospital in Lucknow fulfilling the definition of constipation recommended for application in Indian children were included in the study conducted from the period of May 2022 to December 2023. Children with functional constipation, i.e., presence of≥2 of the following after 4 weeks observance period: (a) Defecation frequency≤2 times per week, (b) Fecal incontinence≥1 times per week after acquisition of toileting skills, (c) History of excessive stool retention (retentive posture, stool withholding behaviour), (d) History of painful or hard bowel movements and (e) Presence of large diameter stools that may obstruct the toilet, were enrolled in the study.[13]

Exclusion criteria was patients with motility related disorders: Hirschprung disease, congenital anomalies: anal stenosis, anteriorly displaced anus, spinal cord anomalies (tethered cord, spina bifida), developmental defect: Mental retardation, autism or Cerebral palsy, using PEG within 2 months before inclusion or concurrent use of other drugs influencing gastrointestinal motility–opiates, anticholinergic agents, phenobarbitone vincristine.

Sample size for the study was estimated on the basis of a previous study 14 at 95% confidence and 90% power after making provisions of 10% data loss. The calculated sample size was 44 in each group, however, we included 45 cases in each group.

Following enrolment, all the children were clinically examined and detailed history was obtained from the parents/child. Children were randomly allocated to two groups; randomization was done using SNOSE (Sequentially numbered opaque sealed envelope) technique. A total of 45 children were recruited to Group A who were managed by PEG3350 while rest 45 children were recruited to Group B who were managed by PEG4000.

Drug constituents

PEG3350 (Dose: 0.4-0.8 gm/kg/day in 1-2 divided doses) 1 sachet of 17 gm granules. Cost of drug Rs 41/- per sachet. PEG4000 (Dose 0.4-0.8 gm/kg/day in 1-2 divided doses) 1 sachet of 17 gm granules. Cost of drug Rs 45/- per sachet. Each dose of the preparation to be dissolved in 150 ml normal water and taken once daily. Cost of the drug was borne by the patient. Before start of treatment, parents were given dietary advice and behavioural (Toilet training, if required) therapy. Parents were advised to maintain a bowel dairy: variables to be diarized were stool frequency, consistency (as per Bristol stool chart) 15, difficulty/pain in passing stool, soiling, toilet training need, abdominal pain, bloating/flatulence and/or rectal bleeding. Adverse events during the treatment like nausea, vomiting and diarrhea were also recorded in the diary. All the patients in both the groups were given behaviour training with respect to establishment of a positive routine of sitting in toilet for passing stools after meals regularly, comfortable sitting, avoidance of embarrassment or punishment, positive reinforcement by offering rewards to children avoiding soiling and regularly sitting in the toilet.

Follow up

After initiation of treatment follow up was done at 4 weeks, 12 weeks and 24 weeks. Children were also followed up telephonically on 2, 8, 16 and 20 weeks for any inconvenience or problem as well as positive reinforcement. Children missing any scheduled follow-up (4, 12 and 24 weeks) were considered as loss to follow-up.

Statistical analysis

The statistical analysis of data was done using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical Analysis Software. The values were represented in Number (%), Mean±SD and Median (IQR). Chi-square test was used to test the significance of categorical data while to test the significance of two mean values student ‘t’ test was used. Scalar data was compared using Mann-Whitney U test. Level of significance was $p<0.05$.

RESULTS

A total of 90 patients aged between 4 and 17 years were enrolled in the study. Mean age of patients was 9.04±3.40 and 10.27±4.18 years respectively in Groups A and B. Majority of children in Group A were males (51.1%) whereas majority of children in Group B were females (51.1%). Mean weight and height of patients in Group A was 25.28±8.30 kg and 125.69±16.66 cm as compared to 25.48±11.24 kg and 132.21±20.39 cm respectively. Mean stool frequency in Groups A and B was 2.98±0.50 and 2.96±0.47 respectively. In both the groups, median Bristol stool consistency score was 1. Difficulty/pain in passing stool, soiling, toilet training need, bloating/flatulence and rectal bleeding were reported by 45 (100%), 17 (37.8%), 8 (17.8%), 45 (100%), 30 (66.7%) and 3 (6.7%) patients respectively in Group A and 45 (100%), 14 (31.1%), 9 (20%), 45 (100%), 26 (57.8%) and 2 (4.4%) patients respectively in Group B. Statistically, there was no significant difference between two groups for age, sex, height, weight, stool frequency and other constipation characteristics (p>0.05) (Table 1). At week 4 follow-up mean stool frequency was 5.04±0.56 and 5.18±0.75 respectively in Groups A and B. Although median stool consistency was 4 in both the groups, however, upper quartile of Group B had higher value as compared to that in Group A (p=0.006). Frequencies of difficulty/pain in passing stool, soiling, toilet training need, bloating/flatulence and rectal bleeding were 27 (60%), 7 (15.6%), 5 (11.1%), 19 (42.2%), 20 (55.5%) and 0 (0%) respectively in Group A and 27 (60%), 6 (13.3%), 4 (8.9%), 25 (55.6%), 19 (42.2%) and 0 (0%) respectively in Group B. Statistically, there was no significant difference between two groups for these outcomes at week 4 follow up (p>0.05) (Table 2). At week 12 follow-up mean stool frequency was 6.53±0.81 and 7.00±0.00 respectively in Groups A and B. Median stool consistency was 5 in both the groups. None of the patients experienced difficulty/pain in passing stool, soiling, toilet training need, abdominal pain and rectal bleeding. There were 11 (24.4%) patients in Group A and 10 (22.2%) patients in Group B. Statistically, there was no significant difference between two groups for any of the outcomes at week 12 follow up (p>0.05) (Table 3). At week 24 follow-up, two patients in Group A and one patient in Group B was lost to follow-up. Mean stool frequency was 7.00±0.00 and Median stool consistency was 5 in both the groups. None of the patients experienced difficulty/pain in passing stool, soiling, toilet training need, abdominal pain, bloating/flatulence and rectal bleeding. Statistically, there was no significant difference between two groups for any of the outcomes at week 24 follow up (p>0.05) (Table 4). During the entire course of study, none of the patients experienced nausea and vomiting. There were 7 (15.6%) patients in Group A and 8 (17.8%) patients in Group B who experienced diarrhea as the associated adverse effects. Statistically, there was no significant difference between the two groups for any of the adverse drug effects (p>0.05) (Table 5).

Table 1: Demographic and clinical profile of patients at enrolment.

S. no.	Variable	Group A (n=45)	Group B (n=45)	Statistical significance
1	**Mean Age±SD (Range) years**	9.04±3.40 (4-16)	10.27±4.18 (4-17)	t=1.522; p=0.132
2.	**Male: Female**	23:22	22:23	χ^2=0.044; p=0.844
3.	**Mean weight±SD (kg)**	25.28±8.30	25.48±11.24	t=0.092; p=0.927
4.	**Mean height±SD (cm)**	125.69±16.66	132.21±20.39	t=1.662; p=0.100
5.	**Mean stool frequency±SD**	2.98±0.50	2.96±0.47	t=0.216; p=0.829
6.	**Median stool consistency**	1 (1-1)	1 (1-1)	z=0; p=1.000
7.	**Difficulty/Pain in passing stool**	45 (100%)	45 (100%)	χ^2=0; p=1.000
8.	**Soiling**	17 (37.8%)	14 (31.1%)	χ^2=0; p=1.000
9.	**Toilet training need**	8 (17.8%)	9 (20.0%)	χ^2=0.073; p=0.788
10.	**Abdominal pain**	45 (100%)	45 (100%)	χ^2=0; p=1.000
11.	**Bloating/Flatulence**	30 (66.7%)	26 (57.8%)	χ^2=0.756; p=0.384
12.	**Rectal bleeding**	3 (6.7%)	2 (4.4%)	χ^2=0.212; p=0.645

Table 2: Week 4 follow-up outcome.

S. no.	Variable	Group A (n=45)	Group B (n=45)	Statistical significance
1.	**Mean stool frequency±SD**	5.04±0.56	5.18±0.75	t=0.956; p=0.342
2.	**Median stool consistency (IQR)**	4 (4.4)	4 (4.5)	z=2.741; p=0.006
3.	**Difficulty/Pain in passing stool**	27 (60%)	27 (60%)	χ^2=0; p=1.000
4.	**Soiling**	7 (15.6%)	6 (13.3%)	χ^2=0.090; p=0.764
5.	**Toilet training need**	5 (11.1%)	4 (8.9%)	χ^2=0.123; p=0.725
6.	**Abdominal pain**	19 (42.2%)	25 (55.6%)	χ^2=1.601; p=0.206
7.	**Bloating/Flatulence**	20 (44.4%)	19 (42.2%)	χ^2=0.045; p=0.832
8.	**Rectal bleeding**	0	0	χ^2=0; p=1.000

Table 3: Week 12 Follow-up outcome.

S. no.	Variable	Group A (n=45)	Group B (n=45)	Statistical significance
1.	Mean stool frequency±SD	6.53±0.81	7.00±0.00	t=2.769; p=0.007
2.	Median stool consistency (IQR)	5 (5.5)	5 (5.5)	z=1.000; p=0.317
3.	Difficulty/Pain in passing stool	0	0	χ^2=0; p=1.000
4.	Soiling	0	0	χ^2=0; p=1.000
5.	Toilet training need	0	0	χ^2=0; p=1.000
6.	Abdominal pain	0	0	χ^2=0; p=1.000
7.	Bloating/Flatulence	11 (24.4%)	10 (22.2%)	χ^2=0.062; p=0.803
8.	Rectal bleeding	0	0	χ^2=0; p=1.000

Table 4: Week 24 Follow-up outcome (n=87).

S. no.	Variable	Group A (n=43)	Group B (n=44)	Statistical significance
1.	Mean stool frequency±SD	7.00±0.00	7.00±0.00	t=0; p=1.000
2.	Median stool consistency (IQR)	5 (5.5)	5 (5.5)	z=1.000; p=0.317
3.	Difficulty/Pain in passing stool	0	0	χ^2=0; p=1.000
4.	Soiling	0	0	χ^2=0; p=1.000
5.	Toilet training need	0	0	χ^2=0; p=1.000
6.	Abdominal pain	0	0	χ^2=0; p=1.000
7.	Bloating/Flatulence	0	0	χ^2=0; p=1.000
8.	Rectal bleeding	0	0	χ^2=0; p=1.000

Table 5: Comparison of Adverse Drug Reactions between two groups.

S. no.	Effect	Group A (n=45)		Group B (n=45)		Statistical significance	
		No.	%	No.	%	χ^2	'P'
1.	Nausea	0	0	0	0	-	-
2.	Vomiting	0	0	0	0	-	-
3.	Diarrhoea	7	15.6	8	17.8	0.080	0.777

DISCUSSION

In the present study, excellent improvements in functional constipation were seen in both the study groups from the first follow-up interval itself when mean stool frequencies reached to more than five as compared to less than 3 at the baseline assessment. Similar improvement in stool consistency and other patient complaints were also seen. By the end of 24 weeks follow-up all the patients had achieved mean stool frequency of 7 and normalcy of stool consistency and there was complete resolution of all the patient complaints.

Both the groups were similar in terms of efficacy throughout the entire study period, excepting stool consistency scores showing a better outcome for PEG 4000 as compared to PEG 3350 at 4 weeks follow-up. As far as safety of the drugs is concerned, the drugs were entirely safe in terms of gastrointestinal side effects like nausea and vomiting. However, almost one sixth (16.7%) patients experienced at least one episode of diarrhea during the study period, though this effect also did not differ significantly between the two groups. As such, the performance of two formulations could be termed to be similar.

Compared to the present study that had a 100% success rate for both the drugs over a period of 24 weeks, Bekkali et al, in their study reported treatment success after 52 weeks of treatment in 50% of PEG3350 and 45% of PEG4000 group of patients respectively.[14] The reasons for this difference could be many. First of all, in the present study patients were much older (mean age 9.04 and 10.27 years in two study groups) as compared to their study that had mean age of patients much below (5.5 and 5.9 years in the two study groups).

Moreover, their study had a high follow-up loss rate (32%). Moreover, differences in environment could also be held responsible for difference in success rate. Moreover, the patients in their study had a much severe constipation with mean bowel frequency<2/week at the time of enrolment as compared to nearly three/week in the present study. Difference in inclusion criteria of two studies could also be a reason for this difference. In the

present study we adopted the constipation criteria applicable to Indian children, that allowed enrolment of even those cases who had defecation frequency>2 per week.[13]

As far as other studies in children are concerned, a success rate of 98% and 95% respectively have been reported for PEG 3350 in the studies by Jarzebicka et al, and Mansour et al, following a treatment period of 12 weeks.[16,17] In the present study, we also found this success rate to be 93.3% at 12 weeks based on the mean stool frequency in PEG 3350 group. In the present study, we had achieved 100% success rate for patients in PEG 4000 group even at 12 weeks and were able to maintain the same till 24 weeks follow-up.

In an earlier study, Lee and Bae found drop in hard consistency of stool from 82.35% to 0% following treatment with PEG 4000, thus showing a success rate of 100%.[18] In the present study, we also found that not only the stool frequency but stool consistency also showed a change from harder to normal consistency reaching to Bristol score 5 at 12 weeks follow-up itself. In another study, the success rates for two different doses of PEG 4000 were reported as 89% and 97% respectively.[19] As such for both the drugs, the success rates in the present study were similar to those reported in earlier studies.

As far as safety, acceptability and impact of PEG 3350 and PEG 4000 on constipation related symptoms is concerned, almost all the earlier studies have found these to be safe, well-tolerable and effective in resolution of constipation related symptoms. Worona-Dibner et al, in their study reported complete resolution of fecal incontinence, fecal impaction and abdominal pain in 97.6% of their patients receiving PEG3350.[20]

In the present study, none of the patients needed any rescue therapy experienced adverse effects like nausea and vomiting. A total of eight (17.8%) of PEG3350 and seven (15.6%) of PEG4000 group patients experienced diarrhea. There was no statistically significant difference between the two groups for adverse drug reactions. These findings are in agreement with the observations of Bekkali et al, who also found the two groups were similar with respect to incidence of adverse events.[14] No drug-related serious adverse events were reported for either of two drugs.

None of the earlier studies similar to the present study reported any serious adverse effect or adverse reactions like nausea and vomiting. Esmaeilidooki et al, in their study did not find diarrhea as an adverse effect in any of the patients receiving PEG4000 as compared to 15.6% in the present study which may be attributable to a relatively shorter intervention period in their study (4 weeks).[21] In another study Gondo et al, reported mild adverse drug reactions like decreased appetite, abdominal pain and diarrhea in 2.6% patients receiving PEG3350.[22] Roy et al, reported diarrhea and vomiting as the side effects in 3% and 4.1% of the patients receiving PEG3350.[23] As such most of the studies, similar to the present study have found these two formulations to be safe and free of serious adverse effects. One of the limitations of the study was the fact that we did not take into account children's experience in terms of taste and other hedonic properties with respect to acceptability of the two formulations.

CONCLUSION

The findings of the present study were interesting and showed that the newer molecule of PEG 4000 is similar in efficacy as the PEG3350 and thus suitable alternative for treatment of functional constipation in children>4 years of age . Further studies on a larger sample size targeting comparative efficacy of these two formulations using a randomized block design with inclusion of younger children<4 years and inclusion of hedonic assessment are recommended.

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