

A PROSPECTIVE STUDY TO ASSESS THE EFFICACY OF BOWEL PREPARATION IN PEDIATRIC PATIENTS WITH THE USE OF A BOWEL CLEANSING PREPARATION AND A NUTRITIONAL FOOD PACKAGE COMPARED WITH ORAL SODIUM PHOSPHATE

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BACKGROUND

A clean colon is essential for adequate visualization during colonoscopy. The inability of children to comply with preparation regimens requiring liquid diet and the intake of cleansing medications can result in a poorly cleansed colon and suboptimal visualization of the colon. Allowing the patients to continue to eat will improve their compliance with the cleansing regimen. It has been suggested that the use of a prepackaged, low-residue solid and liquid diet/bowel prep kit may serve as a dependable and effective way of preparing the colon by leaving a minimal amount of retained stool while providing complete nutritional balance for patients.

OBJECTIVES

To evaluate the adequacy and acceptance of the bowel cleansing prep and nutritional food package for colonoscopies in children. The prepackaged, low-residue solid and liquid foods (E-Z-EM NutraPrep®) in combination with magnesium citrate, Bisacodyl tablets and suppository (E-Z-EM LoSo Prep™), was compared with oral sodium phosphate (Fleet® Phospho-Soda).

METHODS

After obtaining informed consent, patients were randomly assigned to one of three study preparations:

Group 1:

- **Diet:** Prepackaged, low-residue solid and liquid foods (E-Z-EM NutraPrep) on the day prior to procedure
- **Laxation:** (E-Z-EM LoSo Prep)
 - Mg citrate (one powdered sachet) given at 6 pm the day before the procedure.
 - Oral bisacodyl tablets at 8 pm on the day before the procedure. Dose: >12 yr: 20 mg; 8-12 yr: 15 mg; 4-8 yr: 10 mg.
 - Bisacodyl suppository administered on the day of procedure at least 1 hour prior to departure. Dose: >12 yr: 10 mg; <12 yr: 5 mg

Group 2:

- **Diet:** Clear liquids on the day prior to colonoscopy.
- **Laxation:**
 - 45 mL/1.7 m² of Fleet Phospho-Soda mixed with equal amount of water given at 3 pm the day before the procedure, repeated at 6 pm followed by continual hydration with clear liquids 1.5-2.0 L/1.7 m² until retiring for the evening

Patient demographics are shown in Table 1.

Reference: El-Baba M, Padilla M, et. al. *Journal of Pediatric Gastroenterology and Nutrition* 2003; 37(3):329.

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DEMOGRAPHICS

Table 1. Demographic Data

| | Group 1 | Group 2 |
|---|-------------|---------------|
| Number of Patients | 36 | 29 |
| Gender - Male: Female | 16:20 | 13:16 |
| Race - Caucasian: Afro-American: Others | 13:20:3 | 15:11:3 |
| Mean Age (years) | 12.7 (6-20) | 11.3 (4.5-18) |

The adequacy of bowel preparation was graded by the blinded endoscopist performing the procedure. The preparations were rated by patients for tolerance, compliance, side effects and desire for food.

RESULTS

Cleansing Efficacy:

The quality of colon cleansing for the two preparations is presented in Figure 1 and Table 2.

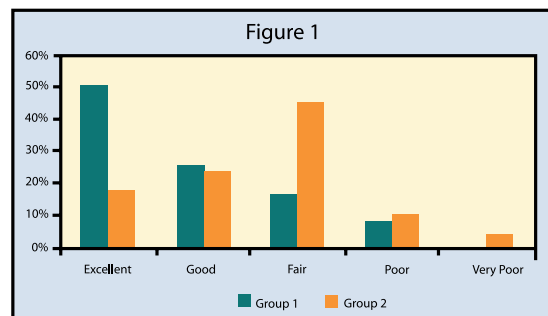


Table 2. Quality of Preparation

| | Group 1 | Group 2 | p-Value |
|--|----------|----------|---------|
| Preparation Rated Excellent | 18 (50%) | 5 (17%) | < 0.017 |
| Adequate Visualization of the Colon | 33 (92%) | 24 (83%) | 0.44 |
| Moderate to Large Amount of Retained Stool | 9 (25%) | 17 (59%) | < 0.02 |

Cleansing Efficacy:

33 patients (92%) in Group 1 reported excellent compliance with the preparation compared to 23 patients (79%) in Group 2. However, the difference was not statistically significant ($p = 0.26$).

Tolerance:

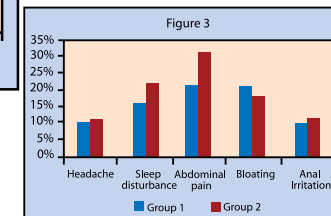
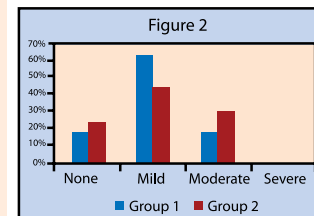
There was no difference in the tolerance of the preparation between the two groups. Twenty-eight patients (78%) in Group 1 rated the preparation to be tolerable to very tolerable compared to 21 patients (72%) in Group 2 ($p = 0.77$).

Desire for food:

- Moderate to severe desire for food during the preparation was reported in 56% of patients in Group 1 compared to 90% in Group 2. The difference was statistically significant ($p < 0.005$).
- The taste of food in the meal kit given to patients in Group 1 was rated very good by 24%, good 56%, bad 14%, and very bad 6%. Fifty percent of the patients ate 5-7 of the 7 items in the kit, 33% ate 3-4 items, while 17% ate less than 3 items.

Side effects: Figures 2 and 3

The reported side effects were not different between the two groups.



CONCLUSIONS

- E-Z-EM bowel cleansing preparation and nutritional food package resulted in a superior colon cleansing and decreased amount of retained stool as compared to oral sodium phosphate and clear liquid diet.
- Patients who took oral sodium phosphate and clear liquid diet were much more likely to experience hunger and desire for food during the preparation compared to those who took the E-Z-EM bowel cleansing preparation and nutritional food package.
- Both regimens did not significantly differ in adequacy of colon visualization, preparation tolerance, side effects or compliance.
- E-Z-EM bowel cleansing preparation (LoSo Prep) and nutritional food package (NutraPrep) has been demonstrated to be an effective, safe and well tolerated bowel regimen.