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Effectiveness of a Collaborative Treatment Program Based on the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) Guidelines for the Treatment Of Constipation.

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Effectiveness of a Collaborative Treatment Program Based on the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) Guidelines for the Treatment of Constipation

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Abstract

The North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) published clinical practice guidelines for management of childhood constipation by primary care providers; however, few pediatricians are familiar with these guidelines. Whether a constipation management program (CMP) based on simplification of these guidelines will lead to an improvement in the clinical outcome of children with constipation remains unclear. **METHODS:** A randomized controlled trial was performed to evaluate the efficacy of a CMP based on the NASPGHAN guidelines when distributed to pediatricians with an academic detailing session compared to distribution of the program with a letter explaining usage of the program. Study patients’ success of constipation therapy and parental satisfaction were compared to baseline rates from patients treated by study pediatricians prior to introduction of the CMP. **RESULTS:** Baseline clinical success of constipation therapy for patients treated by study pediatricians was 34% (n=58). Patient’s clinical success increased to 50% (p=0.31) when treated by practices which used the CMP (n=12) but did not receive an academic detailing session. Administration of an academic detailing session along with use of the CMP (n=18) led to a significantly improved clinical success rate in patients of 61% (p=0.04). Baseline satisfaction with pediatrician’s prescribed constipation therapy was 74% which increased to 83% (p=0.33) with use of the CMP. **CONCLUSIONS:** Use of a CMP (based on the NASPGHAN guidelines) by pediatricians can improve the clinical outcome of children with constipation.
especially when such a program is presented to pediatricians in the setting of an academic detailing session.
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Introduction

Parents frequently have preconceived ideas about what a “normal” stooling pattern should be and become concerned if their children have too few, large, hard, or painful bowel movements\(^1\). It is therefore not surprising that constipation accounts for 3-5% of all visits to pediatricians and approximately 25% of referrals to pediatric gastroenterologists.\(^2-3\)

A variety of medical, behavioral, and dietary therapies are available for management of children with constipation.\(^4-7\) Many evidence-based therapies were combined with expert opinion to develop clinical practice guidelines for management of childhood constipation which were published by the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN).\(^1\) These guidelines were developed to assist primary care providers in the evaluation and treatment of children with constipation; however, only 8% of pediatricians are even aware that these guidelines exist.\(^8\)

Clinical guidelines have been made available to practitioners for treatment of various clinical disorders. Studies have shown that if guidelines are too vague or nonspecific fewer than 40% of general practitioners will follow them.\(^9\) Guidelines which are too long and complicated may have important recommendations buried in so much detail that they go unnoticed by physicians. Two effective ways of implementing guidelines are to rewrite them in behaviorally specific terms and to disseminate materials during short educational meetings (i.e. lunchtime in-service).\(^9-10\)
Since publication of the NASPGHAN guidelines, many studies have shown the safety and efficacy of polyethylene glycol without electrolytes in the treatment of childhood constipation.\textsuperscript{11-13} The main purpose of this study was to develop a constipation management program (CMP) to be utilized by primary care physicians based on the NASPGHAN guidelines (with incorporation of polyethylene glycol without electrolytes) to improve the clinical outcome of children with constipation. The primary aim was to determine the efficacy of a CMP in the treatment of childhood constipation as measured by stool frequency and consistency on questionnaires administered after 3 months of therapy. A secondary aim was to determine parental satisfaction with the CMP as measured by questionnaires administered following completion of the program.

**Materials and Methods**

**Institutional oversight:** This study was approved by the Cincinnati Children’s Hospital Medical Center and University of Cincinnati institutional review boards.

**Program development:** A CMP was developed based on the NASPGHAN guidelines for management of childhood constipation. The program included evidence based recommendations that were developed after the NASPGHAN guidelines had been published; including the use of polyethylene glycol without electrolytes as the only medication for initial clean-out and maintenance therapy. The medication does not have any taste when completely dissolved in solution and has been shown to be highly effective in treating childhood constipation.\textsuperscript{14-15} The final program included educational materials, behavioral recommendations and medication dosages in a concise yet easily understandable manner that
pediatricians could incorporate into their medical practice for management of patients with constipation.

**Patient enrollment:** Six pediatric practices were selected to enroll patients for the study. Each practice was selected because of its interest and prior experience in performing clinical research. Randomization occurred at the level of the pediatric practices with all six practices receiving the CMP and a detailed letter regarding its use; however, only three of the practices were randomly selected to also receive a 20 minute academic detailing session on childhood constipation and use of the CMP. This academic detailing session was given by the same pediatric gastroenterology fellow (Dean R. Focht, M.D.) and attending (M. Susan Moyer, M.D.). One pediatric practice scheduled to receive the academic detailing session was eventually dropped from the study after multiple attempts were made to schedule the academic detailing session to no avail. This practice was replaced by another pediatric practice before enrollment of any patients had occurred.

Patient enrollment occurred over a 6 month period (August 2004-January 2005). Inclusion criteria for participation in the study included all patients between the ages of 3-10 years who were newly diagnosed with constipation and had no plans of relocation during the 3 months following study entry. Exclusion criteria included any structural, endocrine or metabolic cause of constipation; mental retardation; or treatment with drugs that slow gastrointestinal motility.

**Data acquisition:** Parental questionnaires were developed to assess a child’s clinical response to constipation therapy as well as parental satisfaction with that
therapy. A positive clinical response to constipation therapy was based on the Rome II criteria\textsuperscript{16} for diagnosis of functional constipation and defined as the absence of “firm” or “hard” stools and stooling 3 or more times per week. In addition, the absence of painful bowel movements was included as evidence of a positive clinical response.

Parental questionnaires were distributed to all new patients treated for constipation from the study practices in the 6 months prior to study initiation. These initial surveys provided a baseline clinical success rate and parental satisfaction with the pediatric practices’ constipation therapy. Since these patients were unable to give informed consent, participating practices distributed anonymous questionnaires to the formerly treated patients but follow up of non-responders was not feasible because of issues of patient confidentiality. Similar questionnaires were distributed to study patients 3 months after therapy with the constipation management program to determine the clinical success rate and satisfaction with the constipation program. Non-responders were sent a second questionnaire and if no response was again obtained then telephone follow up was attempted.

**Statistical analysis:** Data analysis was performed using the chi-square test to determine rates of clinical success in constipation management.

**Results**

The 6 participating pediatric practices serve a diverse patient population, including urban, suburban, and rural areas. Baseline clinical success rates for constipation management were obtained for these 6 practices. A total of 192
surveys were distributed to the parents of children who were treated for constipation in the 6 months prior to introduction of the CMP. Eighteen of 77 returned surveys were children outside of the study participants’ age range and therefore not included in the final analysis. One additional survey respondent did not complete the questionnaire adequately to allow analysis of clinical success. A total of 58 surveys were therefore included in the final analysis. Seventy-four percent of parents were satisfied with their child’s clinical response to the pediatrician’s prescribed constipation therapy (Figure 1) despite only 20 patients (34%) being successfully “cured” of their constipation based on previously defined clinical criteria (Figure 2).

The three pediatric practices which received the academic detailing session enrolled a total of 26 patients. Follow up was obtained on 19 of these patients; however, one respondent did not complete the questionnaire adequately to allow analysis of clinical success. Eighty-three percent of parents were satisfied with their child’s clinical response to the CMP (Figure 1). Sixty-one percent of patients were successfully “cured” of their constipation (Figure 2) which was significantly improved from baseline (p = 0.04).

The other three pediatric practices which simultaneously received the CMP but did not receive the academic detailing session enrolled a total of 18 patients. Follow up was obtained on 12 of these patients. Eighty-three percent of parents were satisfied with their child’s clinical response to the CMP (Figure 1). Although 50% of patients were “cured” of their constipation compared to 34%
at baseline (Figure 2), this increased percentage did not reach statistical significance (p = 0.31).

The age at onset of constipation varied among study participants but was greatest between 3-6 years (Figure 3). No significant difference in response to treatment was noted when constipation onset was < 3 years compared to ≥ 3 years among patients not treated with the CMP (p = 0.21) or those treated with the program (p = 0.07). While 47% of children surveyed had been constipated for <6 months before treatment was sought from their pediatrician, 30% were constipated for over 1 year (Figure 4). Although not statistically significant, it was interesting to note that more children treated with the CMP tended to be constipated for ≥ 6 months compared to those children not treated with the program (p = 0.08).

Prior to treatment with the CMP, 50% of study participants were having fewer than 3 bowel movements per week (Figure 5) and 80% were having painful bowel movements (Figure 6). After treatment with the CMP, 97% of study patients were having at least 3 bowel movements per week (p = 0.36 when compared to baseline) and 90% were not having painful bowel movements (p = 0.30 when compared to baseline). While only 30% of study patients were having at least 1 soiling episode per week prior to therapy (Figure 7), this percentage decreased to 7% after treatment with the CMP (p = 0.02); however, the number of soiling episodes after therapy was not statistically different between patients treated with and without the CMP (p=0.76).
Figures and Tables

Figure 1. Parental satisfaction with prescribed constipation therapy.

* ‘Controls’ represents patients treated with practices’ baseline constipation therapy (n=58). ‘No Detailing’ represents patients treated with the CMP from practices which did not receive the academic detailing (n=12). ‘Academic Detailing’ represents patients treated with the CMP from practices which received a 20 minute academic detailing session (n=18).
Figure 2. Clinical response to pediatrician’s prescribed constipation therapy.

* ‘Controls’ represents patients treated with practices’ baseline constipation therapy (n=58). ‘No Detailing’ represents patients treated with the CMP from practices which did not receive the academic detailing (n=12). ‘Academic Detailing’ represents patients treated with the CMP from practices which received a 20 minute academic detailing session (n=18).
Figure 3. Patient’s age at onset of constipation.

* ‘Controls’ represents patients treated with practices’ baseline constipation therapy (n=57). ‘Study patients’ represents patients treated with the CMP (n=30).
Figure 4. Duration of constipation before treatment by the pediatrician.

* ‘Controls’ represents patients treated with practices’ baseline constipation therapy (n=58). ‘Study patients’ represents patients treated with the CMP (n=30).
Figure 5. Patient’s average number of bowel movements per week.

* ‘Controls’ represents patients treated with practices’ baseline constipation therapy (n=59). ‘Study patients’ represents patients treated with the CMP (n=30).
Figure 6. Percent of patients having painful bowel movements.

* 'Controls' represents patients treated with practices' baseline constipation therapy (n=58). ‘Study patients’ represents patients treated with the CMP (n=30).
Figure 7. Number of soiling episodes per week in study patients.

* ‘Controls’ represents patients treated with practices’ baseline constipation therapy (n=56). ‘Study patients’ represents patients treated with the CMP (n=30).
**Discussion**

Childhood constipation is a common problem with a prevalence reported to be as high as 10-28%.\(^{15,17}\) If young children are not treated appropriately, constipation may potentially lead to stool toileting refusal and delayed or ineffective toilet training.\(^{18-19}\) Despite development and publication of clinical practice guidelines for management of childhood constipation, most primary care providers are not familiar with these guidelines.\(^8\) This may represent one reason why primary care physicians have been reported to under-treat childhood constipation.\(^{20}\)

Guidelines exist for management of various clinical disorders; however, their existence and dissemination does not necessarily mean that the guidelines are being utilized by physicians.\(^{21-22}\) Barriers which may prevent physicians from using guidelines include lack of familiarity or awareness of guidelines, attitudes about guidelines, and other external barriers.\(^{23}\) One method which may improve guideline utilization amongst primary care providers is distribution of guideline educational materials to practitioners at academic detailing sessions.\(^{24-26}\)

In this prospective study, 26 children were enrolled from pediatric practices which received academic detailing sessions and 18 children were enrolled from practices which did not receive the educational sessions. Our results found a significant increase in children “cured” of their constipation when treated with the CMP from physicians who received the academic detailing session when compared to baseline success rate. We also found a non-
significant increase in cure-rate among children treated with the program from practices which did not receive the academic detailing session.

For purposes of our study, we defined a patient’s constipation as being “cured” if there was absence of “firm” or “hard” stools, stooling 3 or more times per week, and the absence of painful bowel movements. Although not included in the Rome II criteria for functional constipation, we included painful bowel movements in our definition of constipation because of their association with functional fecal retention. Parental follow-up questionnaires to evaluate clinical success and satisfaction were administered 3 months after starting treatment with the CMP. Although both groups of children treated with the CMP showed an improved cure rate percentage compared to baseline, it was the children treated from practices which received the academic detailing whose improved success rate was statistically significant. It was interesting to note that while parental satisfaction was highest among those patients who used the CMP, almost 75% of parents whose children were treated without the CMP were satisfied with the prescribed constipation therapy despite a relatively low clinical success rate. This may suggest that our definition of constipation was too strict or parents may simply be pleased that their pediatrician is attempting to address their child’s constipation problem.

This study did not address whether academic detailing sessions would be the best way to increase utilization of a CMP or how frequently academic detailing sessions would need to be repeated to maintain such a high clinical success rate of constipation therapy. It is possible that pediatricians’ use of the
CMP may decrease over time leading to a reduced effectiveness of constipation therapy. Efforts are currently underway to standardize constipation therapy between pediatric gastroenterologists and primary care providers by incorporating the same CMP into a large pediatric GI practice.

One limitation of our study was the substantial variability in baseline constipation therapies by pediatricians. Study pediatricians reported several different medications they use as first-line therapy for their patients with constipation as well as a variety of dietary and behavioral recommendations. Standardization of practice management with evidence-based guidelines may lead to an improved clinical outcome for children with constipation. Another limitation of our study was follow-up on survey non-respondents. One hundred-fifteen of the 192 surveys mailed to parents previously treated from the study practices were not returned and may therefore represent a biased sample. Follow-up was not able to be performed on these survey non-responders to insure compliance with the Health Insurance Portability and Accountability Act (HIPAA). These patients had not given informed consent and therefore could only receive an anonymous survey mailed from the pediatric practices at which they were seen. One possibility would be that those individuals who returned the surveys were more likely to have complied with the physicians recommendations and therefore had a more successful clinical outcome of their child’s constipation. There were also 13 patients who initially agreed to participate in our study but were unable to be contacted for follow-up despite multiple mailings and telephone call attempts.
The sample size selected allowed a significant improvement to be detected in patients treated with the CMP from practices which received an academic detailing session; however, lack of significance among pediatricians who used the CMP but did not receive the detailing may be secondary to a Type II error. There was a trend towards an improved clinical outcome with use of the CMP without an academic detailing session but a larger sample size would be needed to show statistical significance. One final limitation may have been a selection bias which occurred with the practices that agreed to participate in the study. Several pediatric practices were initially contacted but declined to participate in the study. A majority of physicians in the practices who agreed to participate are currently involved or have been involved in prior clinical studies. It is possible that study physicians may represent a biased group with different rates of familiarization with the constipation guidelines or with higher rates of motivation and success with their baseline constipation therapy. It is unclear the degree to which such bias may limit the generalizability of study results to other physician practices.

In summary, this study shows that pediatricians successfully treat ~35% of constipated children when painful bowel movements are included in the definition of constipation. Results also suggest that use of a CMP based on the NASPGHAN guidelines can lead to an increased rate of clinical success in treating childhood constipation especially when combined with an academic detailing session. Despite a majority of parents being satisfied with the baseline constipation therapies recommended by their pediatrician, a higher percentage of
parents were satisfied with the CMP. Expanded use of the CMP by primary care providers would likely result in improved clinical outcomes for children with constipation.
References


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