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A COMPARISON OF THE EFFICACY OF ENEMA SOLUTIONS IN PEDIATRIC EMERGENCY DEPARTMENT PATIENTS

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Abstract

Background—Children presenting to pediatric emergency departments (EDs) are frequently given enemas for relief of constipation symptoms; very little literature guides solution selection.

Objective—To assess and compare the efficacy of the various enema solutions used in a pediatric ED, including the “pink lady,” a previously unreported compounded combination of docusate, magnesium citrate, mineral oil, and sodium phosphate.

Methods—We identified all children who received any enema over a 5-year period in an urban, quaternary care pediatric ED for inclusion in the study via electronic record review. Physician investigators retrospectively reviewed routine visit documentation to confirm the type and dosage of enema and assess co-morbidities, indications, efficacy and side effects. Subjective descriptions of output were classified as none, small, medium, or large by reviewer consensus.

Results—768 records were included; median age was 6.2 years (IQR 3.3-10.3). Solutions used were sodium phosphate (N=396), pink lady (N=198), soap suds (N=160), other (N=14). There was no significant difference in output by solution type (p=0.88). Volume delivered was highest for pink lady, with no significant association between volume delivered and output (p=0.48). Four percent of patients had side effects. Soap suds had a significantly higher rate of side effects (10.6%, p=0.0003), primarily abdominal pain.

Conclusion—There was no significant difference in reported stool output produced by sodium phosphate, soap suds, and pink lady enemas in children treated in an ED. Further study via randomized controlled trials would be beneficial in guiding selection of enema solution.

Keywords

Enema; constipation; efficacy; pink lady

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INTRODUCTION

Abdominal pain secondary to constipation is a common presenting complaint encountered in pediatric emergency departments (EDs).[1] There are a number of acute and chronic therapies available for treatment of constipation, including dietary manipulation, dietary supplements, oral medications, and rectal administration of enema solutions.[1-5] Given their potential for quick relief of symptoms, ED providers often employ enemas in their management of presentations considered to be due, at least in part, to constipation. In published reviews of pediatric ED practice, frequency of reported enema use in this population varies from 25-44%.[1,3,6] Despite the frequency with which enemas are given in the ED, there is limited literature and wide practice variability when selecting a specific enema type.[6-8] A handful of published studies have described efficacy and complications of particular enema solutions, including soap suds, milk and molasses, and sodium phosphate, but few comparison studies exist to direct selection of an enema solution.[5,9-12] In the absence of specific literature to direct practice, selection of an enema solution is determined more by physician preference and local practice patterns than by proven differences in efficacy, indications, safety, or cost.

In local clinical experience at our site, a compounded enema known as a “pink lady” (called a “pink elephant” at another local institution) is widely used, particularly by the surgical services. It consists of docusate, magnesium citrate, mineral oil and sodium phosphate. Although these ingredients, separately, are widely used for stool softening and disimpaction, to our knowledge there is no published literature specifically reporting the use or efficacy of the pink lady combination.

The objective of this study was to assess the efficacy of the various enema solutions used in our institution’s ED, including the previously unreported pink lady combination, in cases for which the treating physician has clinically selected an enema as the appropriate therapy.

METHODS

Study design and setting

This study was a five-year retrospective analysis of the use of enema solutions in the Emergency Department of an urban, tertiary- and quaternary-care University pediatric teaching hospital. The ED currently has an annual census of approximately 16,000 visits. It is primarily staffed by attending physicians board-certified in pediatric emergency medicine, supervising residents for approximately 19 hours per day and working independently during the other 5 hours. General pediatricians provide additional independent second-attending coverage approximately 8 hours per day. The majority of patients seen in this ED are under 18 years of age, but during the study period pediatric subspecialty patients were eligible to be seen until their 25th birthdays. The University’s human subjects Institutional Review Board reviewed and approved this study prior to data collection.

Enemas used

The enema solutions used in significant number in this ED during the study period included sodium phosphate enemas, the locally compounded “pink lady” enema, and soap suds enemas. The pink lady enema consists of 100 ml docusate liquid, 60 ml magnesium citrate,

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60 ml mineral oil, and 66 ml sodium phosphate enema solution. It can be ordered in a full 286 ml standard dose or a smaller dose by milliliters. It is compounded by the hospital's pharmacy at a billed cost of $28.60. The pediatric (59 ml) and adult (118 ml) sodium phosphate enemas are billed at $5 per administration; the castile soap suds enema kits are priced at $1.19 each. Pharmacy and nursing effort required for administration varies by solution, as sodium phosphate enemas come prepackaged in an applicator-tipped squeeze bottle while pink lady and soap suds are mixed by pharmacy or nursing and administered using a squeezable bag and tubing. The cost of the additional nursing time is not passed on to the patient.

Patient selection

We selected subjects for inclusion in the study if electronic pharmacy or nursing order records indicated that they received any type of liquid enema in the pediatric emergency department between January 2011 and January 2016; patients receiving air enemas for intussusception were not sampled. Treating physicians determined that enema therapy was indicated according to usual clinical practice; detailed assessment of the evaluation and thought processes that led to that decision is beyond the scope of this study. We identified but did not exclude patients with significant comorbidities such as recent surgery, inborn errors of metabolism, short bowel syndrome, or history of organ transplantation. Repeat ED visits by the same patient were evaluated separately.

Data collection

Initial data obtained through the institution's electronic health record (EHR) database included patient name, date of birth, medical record number, date of service, weight, gender, race, ethnicity, age, chief complaint, enema medications given during ED visit, ordering physician, discharge diagnosis and date of the ED encounter. For each patient encounter thus identified, physician investigators directly reviewed physician and nursing notes and orders from the ED visit encounter to abstract the following findings: the use and dosage of enema products, the order of use for patients who received multiple enemas, relevant past medical and surgical history, the use of radiographs and their results, disposition, reported stool output following administration of each enema, and documented side effects after each enema. Investigators confirmed data points that were missing or unclear in the electronic dataset during manual chart review.

Outcomes

The primary study outcome was stool output after enema administration. Although recording of this outcome in standard charting is necessarily subjective, we selected it because it is commonly used by clinicians to determine therapeutic success or failure after enema delivery. Physician investigators reviewed all physician and nursing notes to establish reported stool output following enema administration. In cases where there was a disagreement between nursing and physician notes, we prioritized nursing reports as we felt that in our setting nurses were more likely to have directly visualized the stool output. We categorized stool output as large, medium, small, or none. In cases where the wording used did not straightforwardly map to one of these categories, reviewers designated the output as "other" and recorded the specific wording used. Principal investigators (JA and MAH)

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reviewed these “other” cases together and allocated them to the more general categories by consensus. Due to the unavoidable subjectivity of our primary outcome, we also performed a subgroup analysis of those patients for whom recorded stool output met our *a priori* categories of none, small, medium, and large. For this analysis, we collapsed small, medium, and large outputs into a single “yes” variable indicating any passage of stool and compared them to those patients for whom no stool output was reported.

Other findings that we assessed or confirmed by direct EHR review included enema dose, chief complaint, comorbidities, side effects documented as having occurred in the ED after enema administration, attending physician identity, the use of additional enemas, patient disposition, and the use and findings of radiographs.

We randomly selected ten percent of cases for repeat abstraction by principal investigators JA or MAH to assess inter-rater agreement; in cases where JA or MAH had conducted the initial abstraction, the other conducted the repeat.

Statistical analysis

We used descriptive statistics (count, percentage, mean, standard deviation and median) to summarize the data collected. In comparing age, sex, weight, and comorbidity between enema types, we used analysis of variance (ANOVA) for continuous variables and Fisher’s exact tests for categorical variables. Mean dose (ml/kg) was compared between stool output groups using ANOVA. If the overall ANOVA was significant, we made pairwise comparisons with a Tukey-Kramer adjustment for multiple comparisons. We used Fisher’s exact tests to compare stool output, side effects, admission rate and attending physician between enema types. To assess inter-rater agreement on the key qualitative variable of stool output, we used kappa statistics. We considered p-values less than 0.05 to be statistically significant, and used SAS V9.4 (SAS Institute Inc., Cary, NC) for the analysis.

RESULTS

We identified a total of 768 patients who had received at least one enema in the ED during the five-year study period to be included in the study. Table 1 outlines patient presenting information and initial enema usage. The largest subgroup of patients identified as White, followed by African American. Clinicians obtained abdominal radiographs in 65% of cases, with the majority read as showing “moderate” stool.

Table 2 outlines patient age, sex, weight, and comorbidity status. There were some significant differences in these factors by enema type. Median age and weight varied by enema type, with sodium phosphate patients being younger and smaller than those receiving soap suds or pink lady enemas ($p<0.001$). Gender also varied by enema type, with an overall female predominance ($p=0.026$) as well as fewer listed comorbiditites ($p<0.0001$) in soap suds recipients. “Other” comorbidities were numerous and included a wide variety of conditions, including 26 patients reported as having autism, 35 with various forms of developmental delay, and 39 with complex gastrointestinal or surgical histories such as inflammatory bowel disease or repaired gastroschisis.

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In many cases, the wording used to describe the stool output did not directly correspond to our *a priori* categories of small, medium, large, and none. The assignment of alternative wordings we selected after review of these cases is reported in Table 3.

Table 4 describes results by enema type. There was no statistically significant association between reported stool output (small, medium, or large) and enema solution for the three most frequent enema types, sodium phosphate, pink lady, and soap suds (p=0.88). When we collapsed our stool output results into a simple yes/no variable for stool passage for the subgroup of patients whose outcomes met our *a priori* categories of none, small, medium, and large (N=433), there remained no significant association between stool output and enema type (p=0.14). Although there was a statistically significant association between side effects and enema type (p=0.0003 for any side effect, p<0.0001 for abdominal pain, others not significant), the rate of reported side effects was low. Hospital admission rate was 9.0%, with no significant association between enema type and admission (p=0.076); no patients were admitted to the intensive care unit. Thirty-two percent of admissions had admitting diagnoses related to constipation. In the assessment of inter-rater agreement, simple kappa for output from the first enema was 0.74 (ASE 0.065, 95% CI 0.61-0.88); weighted kappa was 0.70 (ASE 0.091, 95% CI 0.53-0.88), indicating substantial agreement.

The dose of solution delivered differed by solution type. For sodium phosphate enemas, the median dose was 59 ml (3.1 ml/kg), with a maximum dose of 118 ml. For pink lady, median dose was markedly higher, with both the median and maximum doses at 286 ml (9.6 ml/kg). Median dose of soap suds was 240 ml (7.5 ml/kg), with a maximum of 300 ml. We found no statistically significant association between ml/kg dose used and stool output overall (p=0.48) or within enema type (sodium phosphate p=0.38; pink lady p=0.27; soap suds p=0.14). In addition, there was substantial variation in enema selection depending on the identity of the attending physician (p<0.0001), with one attending selecting soap suds in 97% of cases and another selecting sodium phosphate in 95%.

DISCUSSION

Although enemas are widely used as one tool in the management of acute pediatric constipation, there is little literature to guide solution selection. In the only study we located directly comparing two solutions, a retrospective comparison of 96 patients, Hansen *et al* reported no difference between sodium phosphate and milk and molasses enemas.[9] We located two additional studies directly comparing different approaches to the use of enemas for management of constipation in the pediatric emergency department. In the first, Miller *et al* describe 79 patients randomized to milk and molasses enema alone vs. three days of polyethylene glycol 3350, showing some improvements in the enema group.[5] In the second, Bekkali *et al* found no significant difference in a similar comparison on an outpatient basis.[12] To our knowledge, our report is the first large case series to compare the efficacy of multiple enema types for pediatric constipation treated in the ED, as well as the first report of the pink lady compounded enema.

After direct review of the medical records of 768 patients, we report no significant differences in stool output or admission rate between pediatric ED patients who were given

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sodium phosphate, pink lady, or soap suds enemas. Our clinical observation in undertaking this assessment was that in the absence of helpful literature, the selection of an enema solution is more a function of the preference of the ordering physician than of clinical factors, providing a measure of natural randomization depending on the treating physician. This is supported by our finding of strong association between ordering physician and enema selection.

Another consideration is the possibility that variation in efficacy could be attributed to differences in volume administered rather than the specific solution selected. This would favor the pink lady combination, as its frequently-used standard dose of 286 ml led to a higher mean ml/kg dose. However, no we found no significant correlation between ml/kg dose and stool output either within enema type or across the three major solutions. One area in which we did find variability is cost, with the pink lady being significantly more expensive than soap suds or sodium phosphate. In addition, the nursing effort required to administer the pink lady and soap suds solutions is greater than that for sodium phosphate.

Our study did not identify any significant complications during the time that patients were in the ED, but there have been reports of severe complications with the use of enemas for constipation, particularly in patients with significant comorbidities. There are a number of reports of sodium phosphate enemas being associated with fluid and electrolyte disturbances, including some deaths.[13-17] Milk and molasses enemas have been associated with hemodynamic compromise, including one death.[18] There have been reports of colitis[19,20] and anaphylaxis[21] after soap suds enemas. As the pink lady combination is heretofore unreported, no specific complications have been described from it. However, given that sodium phosphate enema solution is a key ingredient of the solution, it is presumably subject to the same risks, plus any additional risks introduced by its other ingredients. Sodium phosphate and soap suds enemas have been reported in the literature as far back as the 1950s,[22,23] and are likely widely used both at home without prescription and in hospitals; it is thus difficult to determine the denominator for consideration of side effect prevalence.

Given our central finding that the composition of the enema solution has no relation to the output achieved, transition to the use of a neutral solution such as normal saline to decrease both cost and the risk of rare but serious side effects may be an area for further study. Although the rectal or colonic use of normal saline has been described in some settings,[24-28] there is no literature of which we are aware that describes its use for constipation in the pediatric ED, nor comparing it to other enema solutions. High-quality randomized controlled trials would be an important next step in clarifying the optimal approach toward the selection and use of enema solutions in the pediatric ED; it may be beneficial if such trials included normal saline as a low-adverse-event-risk option.

Limitations

There are a few issues that may complicate the interpretation of these results. First, because we were unable to assess the reasoning behind the selection of a solution for a given patient, it is possible that enema types were matched to patient factors in an unaccounted way. However, our assessment of physician-level data shows strong preferences for particular

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solutions by specific physicians, making it less likely that they were matching the solution to the patient in an unreported way.

Second, as is common in the existing literature on this topic,[1-3,6,7,10,11,25,27] we report data collected retrospectively. This introduces an unavoidable degree of variability based upon the highly subjective nature of clinicians' identification of enema indications, assessment of stool output, need for an additional enema, whether a side effect warranted notation in the chart, and need for hospital admission. We have worked to mitigate this by having two investigators classify descriptions that did not directly fit into the predetermined output categories and by conducting a separate, simplified analysis of only those patients who did fit into the predetermined categories. Likewise, as documentation varies and radiographic findings have not been shown to correlate well with clinical symptoms in constipation,[29,30] we lacked an accurate way to assess pre-enema stool burden in study patients. It is possible that initial stool burden would affect the degree of symptom relief available through stool passage, which would not be well captured in our primary outcome of stool output. As Table 2 shows, we included comments about symptom relief when they were available, and there is no reason to believe that this effect would bias the results in a particular direction. In addition, the fact that the assessment of success was often made by the same physician who was ordering the solutions could have led to an association between solution choice and tendency to over- or under-state results. The preferential inclusion of nursing reports of output partially alleviates this, as nurses were deemed more likely to view the stool directly and had no role in the selection of an enema solution.

Finally, as with any negative study, there is the possibility that a larger sample size would have identified variability that was not noted in this sample. However, with 768 patients this study is by far the largest such comparison to date.

CONCLUSION

In this large, retrospective case series, we found no difference in stool output produced by sodium phosphate, soap suds, and pink lady enemas when given to children cared for in our institution's pediatric ED. The previously unreported pink lady enema combination was as well tolerated as other, better-known enema solutions, but was more expensive without being more effective.

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ARTICLE SUMMARY

Why is this topic important?

Enemas are a commonly used therapy for children presenting to emergency departments with constipation or abdominal pain, but very little literature exists to guide selection of a solution.

What does this study attempt to show?

This study sought to assess the relative efficacy of several commonly used enema solutions, including a previously unreported combination of docusate, magnesium citrate, mineral oil, and sodium phosphate known as a “pink lady.”

What are the key findings?

In this large, retrospective study we found no significant difference in stool output by solution type between sodium phosphate, soap suds, and pink lady enemas. Abdominal pain was the most frequent side effect, and was significantly more common in patients receiving soap suds. The pink lady enema was more expensive without being more effective.

How is patient care impacted?

The negative findings of this large comparison study indicate that there is little reason to believe that the choice of an enema solution has a significant effect on resulting stool output. In the absence of further evidence from randomized controlled trials, solution selection should likely be based on cost, ease of administration, and potential for adverse events rather than perceived differences in efficacy.

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Table 1.

Patient demographics, presenting complaints, imaging, and treatment information, N=768

	N(%)
Race/Ethnicity	
White (non-Hispanic or Latino)	312 (40.6%)
White (Hispanic or Latino)	14 (1.8%)
African American	257 (33.5%)
Race not specified (Hispanic or Latino)	43 (5.6%)
Asian	27 (3.5%)
American Indian or Alaska Native	18 (2.3%)
American Indian or Alaska Native (Hispanic)	3 (0.4%)
African American and White	16 (2.1%)
Other Mixed Race or Other	13 (1.7%)
Declined, Unknown, Missing	65 (8.5%)
Chief Complaint[a]	
Abdominal pain	484 (63.0%)
Constipation	229 (29.8%)
Vomiting	177 (23.0%)
Fussiness	37 (4.8%)
Other	35 (4.5%)
Missing	36 (4.7%)
Abdominal X-ray obtained	501 (65.4%)
X-ray results	
Small stool	24 (4.8%)
Moderate stool	289 (57.7%)
Large stool	155 (30.9%)
Other	33 (6.6%)
First enema given	
Sodium phosphate	396 (51.6%)
Pink lady	198 (25.8%)
Soap suds	160 (20.8%)
Other	14 (1.8%)

[a]Some patients had more than one chief complaint.

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Table 2.

Key patient characteristics by enema type

	All (N=768)	**Sodium Phosphate (N=396)**	**Pink Lady (N=198)**	**Soap Suds (N=160)**	**Other (N=14)**
Age in years					
Median (IQR)	6.2 (3.3-10.3)	4.7 (2.6-8.5)	7.3 (4.6-12.0)	7.9 (4.7-11.9)	4.7 (3.8-16.3)
Range	0.0-24.6	0.2-18.5	1.1-23.0	0.0-24.6	0.3-17.6)
Female N(%)	418 (54.6)	200 (50.6)	109 (55.1)	103 (64.8)	6 (42.9)
Weight (kg)					
N missing	8	3	2	2	2
Median (IQR)	22.1 (14.8-35.8)	18.5 (12.9-29.8)	26.4 (18.0-44.2)	30.1 (18.4-47.0)	21.0 (10.1-41.6)
Range	5.5-120.5	5.5-107.5	9.1-91.8	7.8-120.5	6.1-103.4
Comorbidities (N (%))					
None	590 (76.8)	296 (74.8)	146 (73.7)	143 (89.4)	5 (35.7)
Surgery <1 month	15 (2.0)	6 (1.5)	8 (4.0)	1 (0.6)	0
Cystic Fibrosis	17 (2.2)	7 (1.8)	7 (3.5)	1 (0.6)	2 (14.3)
Organ transplant	11 (1.4)	1 (0.3)	9 (4.6)	1 (0.6)	0
Metabolic disease	8 (1.0)	4 (1.0)	3 (1.5)	1 (0.6)	0
Other	127 (16.5)	82 (20.7)	25 (12.6)	13 (8.1)	7 (50.0)

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Table 3.

Assignment of free-text wordings to categories of stool output after enema administration

Small	Medium	Large
Bowel movement	Felt better	Excellent
Diarrhea	Good	Several
Enema solution	Hard stool	Significant
Hard pebble stools	Helpful	Stool x 3
Incomplete/poor	Improvement	Very good
Liquid	Medium-large	
Little	Productive	
Minimal	Responded well	
Positive	Some relief of abdominal pain	
Responsive	Stool x 2	
Resulting	Successful	
Some	Symptoms improved	
Stool output	Symptoms resolved	
Two small rock hard		

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Table 4.

Enema dosing, stool output, side effects, and disposition

	All (N=768)	Sodium Phosphate (N=396)	Pink Lady (N=198)	Soap Suds (N=160)	Other (N=14)
Stool output (N(% of non-missing values))					
None	52 (7.5)	20 (5.5)	11 (6.3)	17 (11.3)	4 (36.4)
Small	144 (20.6)	81 (22.38)	31 (17.7)	29 (19.3)	3 (27.3)
Medium	243 (34.8)	128 (35.4)	63 (36.0)	49 (32.7)	3 (27.3)
Large	253 (36.3)	133 (36.7)	66 (37.7)	53 (35.3)	1 (9.0)
Other	6 (0.9)	0	4 (2.3)	2 (1.3)	0
Not listed	70	34	23	10	3
Additional enema(s) given	48 (6.3)	21 (5.3)	10 (5.1)	15 (9.4)	2 (14.3)
Enema side effects					
Any	31 (4.0)	5 (1.3)	9 (4.6)	17 (10.6)	0
Abdominal pain	23 (3.0)	2 (0.5)	6 (3.0)	15 (9.4)	0
Vomiting	10 (1.3)	2 (0.5)	4 (2.0)	4 (2.5)	0
Fussiness	0	0	0	0	0
Other	2 (0.3)	1 (0.3)	0	1 (0.6)	0
Admitted to inpatient floor (N(%))					
	69 (9.0)	28 (7.0)	17 (8.6)	22 (13.8)	2 (14.3)
Primary admitting diagnosis associated with constipation (N(%))					
	22 (31.9)	8 (28.6)	9 (52.9)	4 (18.1)	1 (50.0)

[a]Doses were not available for these enemas