A Randomized Double-Blind Controlled Trial Comparing Two Forms of Enema for Flexible Sigmoidoscopy

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Objective: *To compare bowel preparation quality and patient tolerance of two common enema solutions for flexible sigmoidoscopy.*
Material and Method: *Three hundred adults were randomized to receive a hypertonic sodium chloride or hypertonic sodium phosphate enema regime, each consisting of two enemas administered 60 and 30 min before the procedure. Patients completed surveys on preparation comfort. Patients and endoscopist were blinded to the preparation used. During the procedure, the endoscopist took pictures of the mucosa and intraluminal content. All pictures were later evaluated by a single doctor who graded the quality of the preparation.*
Results: *There were no serious complications during or following the procedures. The preparation quality was rated as excellent or good by 76.9% of the hypertonic sodium chloride group and 72.9% of the hypertonic sodium phosphate group (p = 0.423). The hypertonic sodium chloride enema was associated with more abdominal discomfort (p = 0.018).*
Conclusion: *Both enemas were safe for all patients with no statistical difference between the qualities of the two bowel preparations. Both preparations performed their bowel-cleaning function well and were suitable for the preparation of patients before flexible sigmoidoscopy. The less expensive hypertonic sodium chloride solution may be an option for hospitals where budgetary considerations are important.*

Keywords: *Flexible sigmoidoscopy, Phosphate enema, Sodium chloride enema, Bowel preparation*

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Flexible sigmoidoscopy is a commonly performed procedure with numerous indications, and it is recommended as part of a regular checkup by the American Cancer Society for healthy asymptomatic average-risk individuals over age 50[1]. It is a useful and simple procedure for evaluation of the left side colon. Good visualization of the colonic mucosa is essential for a successful procedure. Numerous preparations have been used over the years to cleanse the bowel prior to the procedure. To date, the best and most cost effective bowel cleansing regimen for patients undergoing flexible sigmoidoscopy has not been generally agreed. An ideal colonic preparation for flexible sigmoidoscopy should be inexpensive, safe, easy to administer, well tolerated, and provide adequate cleansing. This is usually achieved with one or two hypertonic sodium phosphate enemas taken 1-2 hours before the procedure. Previous studies have found no difference between one- or two-enema routines, with no significant difference in patient comfort rating between tested groups[2]. In Thailand and Southeast Asia, the most common enema used is a hypertonic sodium chloride solution. It has not been reported in European countries. This solution has a considerably lower price than the hypertonic sodium phosphate enema. Both enemas function as an osmotic agent and cathartic laxatives. The aim of this randomized study was to compare patient tolerance and quality of bowel cleansing between the sodium chloride enema used in Thailand and the common sodium phosphate enema solution for flexible sigmoidoscopy.

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Material and Method

All patients undergoing flexible sigmoidoscopy in Songklanagarind Hospital, the major tertiary referral hospital in southern Thailand, between April 1, 2005 and March 31, 2006 formed the study sample. Exclusion criteria included undergoing the procedure without preparation, a history of renal insufficiency or serum creatinine > 2.0 mg/dL, congestive heart failure, a history of hyperphosphatemia or hypermagnesemia, or age < 18 years. The authors' institution's Human Use Investigation Committee approved this trial and all patients provided informed consent.

Patients were randomized by simple randomization without replacement to receive either a hypertonic sodium phosphate enema (Unema enema, 133 ml) or a hypertonic sodium chloride enema (Unison enema, 15%NaCl 100 mL). Two enemas were given to each patient, 60 and 30 min before the procedure. Immediately before undergoing the sigmoidoscopy, each patient completed a survey by a nurse giving information on the procedure indication, duration time that the patient could retain the enema in the large bowel before evacuation, and level of discomfort felt during the routine. The flexible sigmoidoscopy was performed by general surgery trainees and staff. Both subjects and endoscopists were blinded with regard to the type of preparation used. All procedures were performed using a 60 cm videoendoscope (CF-Q 160S, Evis Exera, Olympus). During the procedure, the endoscopist took pictures of the interior of the colon at the rectum, sigmoid colon, descending colon, and any areas of stool appearance. All pictures thus taken during the course of the present study were later used to grade the quality of the preparation as poor (solid stool), fair (semi-solid stool), good (liquid stool), or excellent (no stool) by a single principal investigator according to the following standards derived after a review of the literature and by consensus among endoscopists from the Department of Surgery. The diagnostic findings, depth of insertion and duration of procedure were recorded. The patients were observed in the recovery room for 30 min after the procedure to watch for any early complications.

Statistical analysis

Previous studies have shown approximately 67.5% (range 50% to 85%) of patients who used a hypertonic sodium phosphate enema as part of a bowel cleansing regimen have had good to excellent quality colonic preparation[1,3-5]. Thus, the authors calculated that 135 patients would be required in each arm of the present study to detect a 17.5% difference as statistically significant at a power of 80% and a two-sided α of 0.05. The total number of patients in each arm was then rounded up to 150 for a safety allowance.

Continuous variables were compared using the Student t test. Categorical variables and the quality of the preparations were compared by using Chi-squared analysis and rank test (Kruskal-Wallis). A two-tailed p-value of less than 0.05 was considered statistically significant. Statistical analysis was performed by using STATA version 8 (Stata Corporation, Texas USA).

Results

Three hundred consecutive patients undergoing flexible sigmoidoscopy were randomized to receive either a hypertonic sodium phosphate enema (n = 144) or a hypertonic sodium chloride enema (n = 156). There were no differences in demographic data between the two groups of patients (Table 1). All patients tolerated the preparations and examination well. During the present study, no adverse events were observed with either form of preparation.

The most common indication for flexible sigmoidoscopy in the present study was complete staging for malignant neoplasm of the cervix (60.33%) and the most frequent procedural finding was normal mucosa (70.33%). The mean procedure time was 9.67 min, and the mean depth of insertion of the sigmoidoscope was 51 cm. There was no difference in mean depth of insertion between the two groups.

The hypertonic sodium phosphate enema preparation resulted in good to excellent ratings in 73% (105/144) of cases, compared with 77% (120/156) in the hypertonic sodium chloride enema preparation group (p = 0.423). Patients with poor bowel preparation were 3.85% (6 of 156) in the sodium chloride group compared to 8.33% (12 of 144) in the sodium phosphate group (p = 0.102). Patients in the hypertonic sodium phosphate group retained the enema in the large bowel for a longer time before evacuation than the sodium chloride group (p = 0.000), but this time was not associated with the quality of the bowel preparation as later assessed by the doctor. The proportion of patients with abdominal discomfort in the phosphate enema group was significantly lower than in the sodium chloride group (54% vs. 82%, p = 0.018). The level of abdominal pain was also significantly different between the groups, with patients in the sodium chloride group indicating a mean abdominal pain score of 3.24, SD 3.61, while the sodium phosphate group registered a

Table 1. Demographic details and outcomes by preparation type

Data	Hypertonic sodium chloride (n = 156)	Hypertonic sodium phosphate (n = 144)	p-value
Patient characteristics			
Average age (yrs) mean ± SD	53.0 ± 13.9	51.8 ± 14.4	
Female (%)	87.8	86.8	
Procedure indication (%)			
Staging cervix cancer	62.8	57.6	
LGIB	6.4	8.3	
Screening colorectal cancer	7.0	6.3	
Surveillance colorectal cancer	7.0	6.3	
Other	16.8	21.5	
Procedural findings (%)			
Normal	68.6	72.2	
Colorectal cancer	11.5	8.3	
Polyps	9.6	6.3	
Hemorrhoid	1.2	4.8	
Other	9.1	8.4	
Retention time (min) mean ± SD			
First administration	1.7 ± 1.5	4.0 ± 4.2	0.000*
Second administration	1.6 ± 1.60	93.8 ± 3.7	0.000*
Depth of insertion (cm) mean ± SD	52.1 ± 16.9	49.7 ± 18.7	
Duration of procedure (min) mean ± SD	10.9 ± 7.9	8.4 ± 5.0	
Quality of bowel preparations (%)			
Good to excellent	76.9	72.9	0.224
Poor to fair	23.1	27.1	0.423
Patient symptoms after enema (%)			
Abdominal pain	52.6	37.5	0.018*
Bloating	1.9	2.8	0.213
Mean abdominal pain score ± SD	3.24 ± 3.61	1.81 ± 2.71	0.006*

* statistical significant $p < 0.05$

mean abdominal pain score of 1.81, SD 2.71 ($p = 0.006$, Kruskal-Wallis rank test).

Discussion

The present study found no differences in procedure-preparation quality between the traditional fleet-type hypertonic sodium phosphate enema and the hypertonic sodium chloride enema. The phosphate enema group retained the solution in the large bowel before evacuation longer than the sodium chloride group and indicated significantly lower abdominal discomfort. The costs of the sodium chloride and sodium phosphate enemas were USD 0.5 and 1.00, respectively, a considerable difference for a developing country over the long run. The procedure was successful in all 300 patients and there were no complications with either solution.

Previous studies have shown excellent/good evaluations for enema or oral preparation for flexible sigmoidoscopy in the range of 50-80%[2-5]. In the present hospital that uses a routine enema for bowel cleansing before flexible sigmoidoscopy, the present study found excellent and good preparations at a rate of 75%, similar to the upper range of the previous studies. Oral phosphate solutions have been used in some hospitals for bowel preparation in flexible sigmoidoscopy, but these oral preparations have not proven superior to enema preparation and have been associated with serious side effects such as hyperphosphatemia, hypocalcemia, hypernatremia, hypokalemia, and changes in intravascular volume, dehydration, metabolic acidosis, pancytopania, renal failure, respiratory and circulatory failure, and abnormalities of the colonic mucosa changes similar to the aphthous ulceration[4,6,7]. Also, oral phosphate preparations usually contain a large sodium load and must be used with caution in patients with congestive heart failure, ascites, renal insufficiency, cardiovascular disease, bowel

obstruction, or poor gut motility[8], and thus normal solution enemas are usually a preferable method for normal bowel cleansing.

Conclusion

An inexpensive hypertonic sodium chloride enema provided adequate bowel preparation for flexible sigmoidoscopy, with both patients and doctors finding it comparable in quality to the more traditional, and expensive, hypertonic sodium phosphate enema. Both substances were safe, easy to administer, tolerated, and provided adequate cleansing. Both are also relatively inexpensive, but the hypertonic sodium chloride solution is 1/2 the cost of the hypertonic sodium phosphate, a consideration in developing countries where budgets are small and every item must be carefully considered. The hypertonic sodium phosphate enema induced significantly less abdominal discomfort.

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การศึกษาแบบสุ่มโดยวิธีปิดเปรียบเทียบผลของสารสวน 2 ชนิด สำหรับเตรียมผู้ป่วยก่อนรับการตรวจส่องกล้องลำไส้ใหญ่ส่วนปลาย

ศักดิ์ชาย เรืองสิน, วรพงศ์ เชาวน์ชูเวชช

วัตถุประสงค์: *เพื่อศึกษาเปรียบเทียบผลของสารสวน 2 ชนิดที่ใช้โดยทั่วไปในการเตรียมผู้ป่วยก่อนการส่องกล้องลำไส้ใหญ่ส่วนปลาย*

วัสดุและวิธีการ: *ผู้ป่วยจำนวน 300 รายที่ได้รับการจับฉลากแบบสุ่มเพื่อรับการเตรียมลำไส้ใหญ่ด้วยสารสวนโซเดียมฟอสเฟตความเข้มข้นสูง หรือ โซเดียมคลอไรด์ความเข้มข้นสูงอย่างใดอย่างหนึ่ง เป็นเวลา 60 และ 30 นาทีก่อนเริ่มทำการส่องกล้องลำไส้ใหญ่ส่วนปลาย หลังการถ่ายอุจจาระเสร็จสิ้นผู้ป่วยจะได้รับการซักถามอาการและผลข้างเคียงจากสารสวนทันที หลังจากนั้นผู้ป่วยจะได้รับการส่องกล้องลำไส้ใหญ่ส่วนปลายตามปกติ ทั้งแพทย์ผู้ทำการส่องกล้องและผู้ป่วยจะไม่ทราบชนิดของสารสวนที่ได้รับ ในระหว่างการส่องกล้องแพทย์จะทำการถ่ายรูปเยื่อบุผิวของลำไส้และสิ่งตกค้างที่เหลืออยู่เพื่อนำมาให้ผู้ทำการวิจัยเพียงหนึ่งท่านทำการประเมินคุณภาพของการเตรียมลำไส้*

ผลการศึกษา: *จากการศึกษาไม่พบภาวะแทรกซ้อนที่เป็นอันตรายเกิดขึ้นกับผู้ป่วย คุณภาพของการเตรียมลำไส้ที่อยู่ในเกณฑ์ดี และดีมาก ในกลุ่มที่ได้รับสารสวนโซเดียมคลอไรด์ความเข้มข้นสูง พบร้อยละ 76.9 และในกลุ่มที่ได้รับสารสวนโซเดียมฟอสเฟตความเข้มข้นสูง พบร้อยละ 72.9 ($p = 0.423$) ผู้ป่วยที่ได้รับสารสวนโซเดียมคลอไรด์จะพบอาการปวดมวนท้องมากกว่าอย่างมีนัยสำคัญทางสถิติ ($p = 0.018$)*

สรุป: *สารสวนทั้งสองชนิดสามารถใช้ได้อย่างปลอดภัยโดยไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติในด้านคุณภาพของการเตรียมลำไส้ สารสวนทั้งสองชนิดสามารถเตรียมลำไส้ได้อย่างมีประสิทธิผล จึงเหมาะในการใช้เตรียมลำไส้ใหญ่ส่วนปลาย สารสวนโซเดียมคลอไรด์มีราคาถูกกว่าอาจเป็นทางเลือกอีกตัวหนึ่งสำหรับโรงพยาบาลที่ต้องคำนึงถึงเรื่องราคาลงทุนเป็นสำคัญ*