Evaluation of mechanical bowel preparation methods in urinary diversion surgery

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Objectives: We performed the first prospective, randomized, multi-center comparison of overall quality and patient tolerability of polyethylene glycol (PEG) and sodium phosphate (NaP) solution for mechanical bowel preparation prior to urinary diversion surgery.

Methods: Between 2001 and 2003, 36 patients at six institutions underwent major urological reconstructive surgery incorporating small intestine (35 radical cystectomy with urinary diversion and 1 bladder augmentation). Patients were prospectively randomized to receive either oral polyethylene glycol (group 1, n = 16) or sodium phosphate (group 2, n = 20) for mechanical bowel preparation prior to surgery, according to our multi-institutional IRB-approved protocol. All patients completed a questionnaire the morning of surgery to assess the tolerability and side effects of each agent. Quality of the bowel preparation was recorded based

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Intro

on intraoperative findings of the attending surgeon, who was blinded to the preparation method.

Results: Both bowel cleansing regimens were safe and well tolerated. Patient-reported ease of use and subjective incidence of side effects were statistically similar in the two groups, and a statistically non-significant trend to more bloating in the PEG group was also noted (p = 0.085). Surgeon-scored overall quality of preparation adequacy revealed no significant differences between oral sodium phosphate and polyethylene glycol solutions (p = 0.555). Postoperative complications were rare for each bowel preparation agent.

Conclusions: Performance characteristics of oral sodium phosphate and polyethylene glycol bowel preparations appear to be similar. Each method is safe, efficacious, and well-tolerated when used prior to urinary diversion surgery. The cost for the NaP preparation was \$1.40 versus \$19.70 for the PEG bowel preparation. Sodium phosphate may have a slight advantage because of its convenience and economic advantage.

Key Words: mechanical bowel preparation, urinary diversion, phosphosoda, polyethylene glycol

Introduction

Traditional mechanical bowel preparation for intestinal surgery consists of the oral administration of 4 liters of a polyethylene glycol (PEG) electrolyte solution (GoLYTELY, Braintree Laboratories, Braintree Massachusetts) the evening before surgery.¹ Since the introduction of oral sodium phosphate (NaP, Fleet Phospho Soda, C. B. Fleet Co., Lynchburg, Virginia) in 1990, the solution has proven to be an attractive alternative to polyethylene glycol for mechanical bowel preparation in colonoscopy² and colorectal surgery³

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because of its reduced cost, improved patient tolerance, smaller volume, and simplified dosing schedule. These two methods of mechanical bowel preparation have yet to be formally evaluated in urological surgery. We conducted the first prospective, randomized, surgeon-blinded trial of polyethylene glycol versus sodium phosphate solution as mechanical bowel preparation for urinary diversion surgery to evaluate patient tolerance, efficacy, and surgical outcome. Because they were both of considerable importance in this study, both physician and patient outcomes were evaluated. The importance of patients' opinions on bowel preparation methods and their compliance with the preparation was addressed, as was the importance of having adequate bowel preparation intraoperatively.

Material and methods

A statistical power analysis predicted that 32 total patients enrolled would be sufficient to detect a 25% difference in physician and patient scores within a 95% confidence level and a power of 80%. During the statistical design of the study, we arbitrarily chose a 25% difference because clinical significance would be likely at this level. Accordingly, after IRB approval, 36 patients undergoing urinary diversion surgery (radical cystectomy with small bowel urinary diversion or bladder augmentation) from 2001 to 2003 were prospectively randomized to receive either oral polyethylene glycol (group 1, n = 16) or sodium phosphate (group 2, n = 20) for mechanical bowel preparation the day prior to surgery. Patients in group 1 were instructed to drink 0.24L of polyethylene glycol every 10 minutes until stool returned clear effluent, requiring between 3 and 4 liters of total fluid intake. Those in group 2 were given two 45 ml doses of sodium phosphate solution taken 4 hours apart the night before surgery, each dose diluted equally into three 0.24L glasses of cold soft drink taken 20 minutes apart. The six participating institutions were (in order of patient accrual) Brooke Army Medical Center, Wilford Hall Medical Center, Madigan Army Medical Center, University of Texas Health Science Center at San Antonio, Wayne State University, and Naval Medical Center San Diego.

Nearly all patients underwent standard pelvic lymph node dissection and cystoprostatectomy or anterior exenteration followed by urinary diversion with a segment of small bowel or construction of an orthotopic neobladder. One patient underwent ileocystoplasty for neurogenic bladder dysfunction. Preoperatively, all patients received erythromycin and neomycin base (1 gm) at 1 pm, 2 pm, and 11 pm on the day prior to surgery, and 2 gm IV cefoxitin 1 hour prior to surgery.

All patients completed a previously validated questionnaire modified from a similar report⁴ to assess the tolerance and possible side effects of the bowel preparation agent, Table 1, and they returned it on the morning of surgery. Postoperatively, the surgeon blinded to the agent used scored the adequacy of the mechanical bowel preparation based on intraoperative findings, Table 2. All questions on both forms were scored from 1 to 5, with higher responses being more favorable. The student's paired t-test was used to compare the mean values of each response. Surgeons were also asked to rate the overall quality of the bowel preparation by giving a score of 10 possible points. Surgical outcomes were reviewed in all patients for the occurrence of both major and minor complications.

TABLE 1. Preoperative patient questionnaire. Responses graded 1 (strongly disagree) to 5 (strongly agree).

- 1. The bowel cleansing medication was easy to drink.
- 2. If another bowel cleansing were necessary, I would prefer the same method.
- 3. The timing and instructions for taking the bowel cleansing medication were simple to follow.
- 4. The cleansing process was easy to complete.
- 5. The bowel cleansing process did not cause me to feel dehydrated.
- 6. I had no problem with nausea during the bowel preparation.
- 7. I had no problem with vomiting during the bowel preparation.
- 8. I had no problem with bloating during the bowel preparation.
- 9. I had no problem with abdominal cramping during the bowel preparation.
- 10. I had no problem with chills during the bowel preparation.

TABLE 2. Physician questionnaire. Responses graded 1 (strongly disagree) to 5 (strongly agree).

- 1. Only scant amounts of bowel contents were noted upon entering the lumen of the small bowel.
- 2. No electrolyte abnormalities occurred in the perioperative and/or immediate postoperative period related to the bowel preparation.
- 3. Bowel decompression at the time of surgery was excellent.
- 4. The patient did not appear to be clinically dehydrated after the bowel preparation.

Although statistical analysis implied that our study was adequately powered, we did note that the patient and physician questionnaires were of a very subjective nature. Because of this, the expected variance potentially could be quite large, at least +/-1 on the five point scale. Because of the potentially large expected variance, the resulting confidence intervals could increase as well. In this event, a larger sample size would be more favorable in the setting of our negative outcome.

Results

All patients successfully completed the prescribed bowel preparation. Based on surgeon score of overall quality of preparation adequacy, no significant differences were identified between oral sodium phosphate and polyethylene glycol solution (p =0.555). Differences in the surgeon-scored parameters did not reach statistical significance, Table 3. Patientreported ease of use and the subjective incidence of side effects were also similar in the two groups, Table 4. A statistically non-significant trend to more

TABLE 3. Results of patient questionnaire. Responses graded 1 (strongly disagree) to 5 (strongly agree).

Patient Question No.	Phosphosoda Avg (range)	PEG Avg (range)	p value
1	3.44 (1 – 5)	3.00 (1 – 5)	0.394
2	3.66 (1 – 5)	3.64 (1 – 5)	0.956
3	4.27 (3 – 5)	4.28 (2 – 5)	0.975
4	3.72 (1 – 5)	3.92 (1 – 5)	0.622
5	3.94 (2 – 5)	3.85 (1 – 5)	0.826
6	3.61 (2 – 5)	4.00 (1 – 5)	0.406
7	4.44 (2 – 5)	4.00 (1 – 5)	0.254
8	3.61 (1 – 5)	4.35 (2 – 5)	0.085
9	3.72 (1 – 5)	4.07 (2 – 5)	0.417
10	4.16 (2 – 5)	3.78 (1 – 5)	0.399

bloating in patients taking the polyethylene glycol solution was noted (p = 0.085). The rate of postoperative complications (wound dehiscence, ileus, anastomotic leak) in each bowel preparation patient group were equivalent with a mean patient follow-up of 12 months (range 6 to 24 months). Overall, there were three complications with polyethylene glycol and four complications with sodium phosphate. Cost for the sodium phosphate preparation was \$1.40 versus \$19.70 for the polyethylene glycol bowel preparation.⁵

Comment

Mechanical bowel preparation remains the worldwide standard of care in intestinal surgery, and polyethylene glycol has been the customary bowel preparation prior to urinary diversion surgery. Recent trends in colorectal surgery, however, have demonstrated a shift to using oral sodium phosphate solution due to improved patient tolerance, smaller volume, simplified dosing schedule and lower cost. A 2003 survey of North American colorectal surgeons demonstrated that sodium phosphate has now surpassed polyethylene glycol as the mechanical bowel preparation of choice with 61% of surgeons using phosphosoda as either the preferred cleansing modality (47%) or selectively alternating between sodium phosphate and polyethylene glycol (14%).³

TABLE 4. Results of physician questionnaire. Responses graded 1 (strongly disagree) to 5 (strongly agree)

Physician Question No.	Phosphosoda Avg (range)	PEG Avg (range)	P value
1	3.56 (1 – 5)	4.07 (1 – 5)	0.258
2	4.44 (3 – 5)	4.57 (3 – 5)	0.628
3	4.11 (2 – 5)	3.92 (2 – 5)	0.783
4	3.83 (2 – 5)	4.00 (3 – 5)	0.556

Numerous previous studies have shown that sodium phosphate is better tolerated by patients with equal or superior cleansing quality when compared with polyethylene glycol. Cohen et al reported 80% of patients questioned after colonoscopy would take the same preparation again versus only 19% for polyethylene glycol.⁶ A meta-analysis of eight colonoscopist-blinded trials found that patients taking sodium phosphate were more likely to complete the preparation and that sodium phosphate resulted in a higher quality preparation during colonoscopy. In addition, using sodium phosphate led to an overall cost savings of \$40 per patient based on the lower cost of the agent and decreased procedure time.⁷ Oliveira and colleagues from the Cleveland Clinic demonstrated sodium phosphate and polyethylene glycol to be equally effective and safe for colorectal surgery in a prospective, randomized, surgeonblinded trial but noted that patients were much more likely to tolerate the smaller volume of sodium phosphate, thereby offering a distinct advantage.⁴ The frequency and intensity of clinical side effects tended to be the same with both agents.

Introduced in 1980, polyethylene glycol is an isosmotic solution with minimal net fluid absorption and electrolyte changes compared to historical whole gut irrigation methods using isotonic solutions or mannitol.^{4,8} It remained the method of choice in the mid 1990s prior to introduction of oral sodium phosphate. The primary disadvantage of polyethylene glycol is the oral intake requirement of 4 liters of a salty solution over a short period of time which can lead to bloating, nausea, vomiting and discomfort, causing at least 5% to 15% of patients to be unable to complete the entire preparation.^{7,9}

Sodium phosphate is a potent osmotic purgative requiring only two divided doses of 45 ml a few hours apart the evening prior to surgery. Recognized contraindications include renal insufficiency, symptomatic congestive heart failure, ascites, hyperphosphatemia, hypocalcemia, history of seizures, or myocardial infarction or stroke in the past 6 months.^{7,10,11} Both agents have been associated with similar rates of asymptomatic electrolyte imbalances^{5,12} and ambulatory cardiac monitoring of patients while receiving either sodium phosphate or polyethylene glycol has demonstrated no cardiac arrhythmias.¹³ For urologists, polyethylene glycol should be used preferentially in the presence of renal insufficiency, chronic bowel motility disorders, and significant heart or liver disease, as well as in patients taking bisphosphonates.^{11,12} Recent studies in the colorectal surgery literature have recently questioned

the requirement for mechanical bowel preparation prior to colorectal surgery.¹⁴ Small prospective trials have reported no statistically significant differences in complication rates (infection, anastomotic leak, abscess) when bowel preparation is omitted.¹⁵⁻¹⁸ Nonetheless, more than 99% of American colorectal surgeons routinely utilize mechanical bowel preparation.³

Although Ferguson and associates recently reviewed contemporary mechanical and antibiotic bowel preparation for urinary diversion surgery,¹⁹ mechanical bowel preparation methods have not been previously prospectively evaluated in urology. Although we anticipated the quality of the bowel preparation would be roughly equivalent in the two patient groups (surgeon scores), we were surprised to find that neither bowel preparation technique was clearly preferable to the patients. Although this series was relatively small, we believe that it was adequately powered to affirm that no difference was present in the quality of the bowel preparation, as was determined intraoperatively. Bladder cancer patients undergoing radical cystectomy with urinary diversion may have different attitudes about their disease and their care than the above colonoscopy or colorectal surgery patients, who tended to clearly prefer sodium phosphate in similarly designed prospective studies.

One recent study from Ireland evaluated 22 patients who received cystectomy and ileal conduit urinary diversion without bowel preparation compared to 64 patients receiving a 4-day preparation involving castor oil, clear fluids, tap-water enema, and rectal washouts.²⁰ The authors reported a lower rate of postoperative ileus, a reduced hospital stay (22.8 days versus 31.6 days) and no significant differences in wound complications in the group without bowel preparation. However, an overall mortality rate of 9%, wound dehiscence in 10%, and a prolonged hospital stay in both groups make the results of this study difficult to incorporate into contemporary urological practice in the United States, where mortality rates and length of stay are much lower.²¹

The importance of a thorough mechanical bowel preparation prior to urinary diversion surgery has clear theoretical advantages. "Clean" bowel has a reduced bacterial count, protects the fresh bowel anastomosis, and reduces the risk of fecal spillage and contamination of the wound during surgery.²² Moreover, failure to adequately remove particular matter in the chosen intestinal segment could lead to urinary infection, stone formation, or obstruction.

Conclusions

This prospective, randomized, multi-center investigation provides good evidence that both sodium phosphate and polyethylene glycol are similarly efficacious, safe, and well-tolerated in urological surgical patients. Because sodium phosphate is a less expensive and more convenient option, it appears reasonable to consider it a viable first-line bowel preparation agent for use in urinary diversion surgery, although its use should be cautioned in patients with certain existing comorbidities.

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