SodiumPhosphate (NaP) versus polyethylene glycol-electrolyte lavage solution (PEG-ELS) tolerability: a prospective randomized study in patients with gynecological malignancy

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Summary

Purpose: The aim of the study was to evaluate patient tolerability and compliance to two bowel cleansing agents (PEG-ELS and NaP) as well as to compare the cost effectiveness. *Methods:* Three hundred and forty-three consecutive patients were randomized to receive either the standard 4 l of polyethylene glycol and electrolyte lavage solution (PEG-ELS) or 90 ml of sodium phosphate (NaP). All patients were advised to be on a clear liquid diet one day before starting the bowel cleansing regimen and to take ornidazole orally (3 x 2 tablets) 24 hours before surgery. Patient tolerabilty and compliance to the regimens were assessed based on complaints of nausea, vomiting and the need of antiemetics. In addition completion of the regimens was evaluated in both groups. *Results:* The need for antiemetics because of nausea and vomiting was statistically higher in the PEG-ELS group than the NaP group ($p = 0.000$). Regimen completion rate was statistically higher in the NaP group than in the PEG-ELS group ($p = 0.000$). NaP is more cost effective than PEG-ELS. *Conclusion:* NaP was rated superior to PEG-ELS in terms of patient tolerability, compliance, completion of the regimen and cost effectiveness and should be the first-choice treatment.

Key words: PEG-ELS; NaP; Tolerability; Regimen completion; Cost effectiveness.

Introduction

Bowel cleansing before gynecological malignancy surgery is important because of the risk of bowel injury. Recently polyethylene glycol-electrolyte lavage solution (PEG-ELS) and oral sodiumphosphate (NaP) are the preferred agents in bowel preparation regimens. The bowel cleansing efficacy of PEG-ELS and NaP have been studied widely in patients who underwent colonoscopic evaluation, and a similar efficacy of the two agents has been suggested. The main disadvantage of PEG is that large volumes have to be ingested, and this is not well tolerated by some patients. The advantage of NaP preparations is that smaller volumes are administered which are more tolerable for the patient [1].

The aim of this study was to evaluate patient tolerability and compliance to two bowel cleansing agents (PEG-ELS and NaP) as well as to compare the cost effectiveness. This is the first study on the tolerance of bowel cleansing regimens in abdominal gynecological malignancy rather than an evaluation of the efficacy of the two regimens.

Materials and Methods

A prospective randomized study at the Obstetrics and Gynecology Department of Gaziantep University Faculty of Medicine was carried out between 2000 and 2006 on 343 consecutive patients with gynecological malignancies with normal clinical histories and biochemical parameters.

The patients were randomized to receive either 4 l of standard PEG-ELS or 90 ml of NaP.

Exclusion criteria for the study included electrolyte and fluid disturbances, heart disease, and impaired kidney function. Moreover patients experiencing nausea and vomiting secondary to malignancy and other gastric problems were excluded from the study.

One hundred and sixty-one patients were diagnosed with ovarian carcinoma; 135 had endometrial carcinoma and 47 had cervix carcinoma. Patient ages ranged between 25 and 72 (Table 1).

One hundred and seventy-three patients in the PEG-ELS group were instructed to drink 4 l of the solution (PEG-ELS) 24 hours before surgery.

In the NaP group 170 patients received 90 ml of the solution (a 2.4 g monobasic and 0.9 dibasic solution) in a split regimen of two 45-ml doses separated by 12 hours prior to surgery.

All patients were advised to be on a clear liquid diet one day before starting the bowel cleansing regimen and to take ornidazole (3 x 2) tablets orally 24 hours before surgery.

The primary endpoints included the tolerance and acceptability assessed by complaints of nausea, vomiting, and the need for antiemetics (parenteral metachlopramide). The secondary endpoint was completion of the regimen.

Statistical analysis

Data were analyzed with SPSS software (version 10.0, SPSS Inc., Il, USA) using the chi-square test. Differences were considered as statistically significant for p values < 0.05.

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Table 1. — *Patient characteristics*.

Tumor types	PEG-ELS	NaP	Age
Ovarian carcinoma	82	79	25-72
Endometrial carcinoma	73	62	53-68
Cervix carcinoma	18	29	38-70
Total	173	170	

Results

In the PEG-ELS group, 163 patients vomited more than three times during the regimen. All of the 173 PEG-ELS group patients needed antiemetic therapy because of severe nausea. Only 113 patients in this group were able to completed the procedure, whereas in the NaP group 90 patients needed antiemetics during the regimen and 30 of these patients vomited more than three times. All the 170 patients completed the intake of the NaP solution. Regimen completion rates were statistically different between the two groups (Table 2, p = 0.000).

The need for antiemetics was higher in the PEG-ELS group than the NaP group (Table 2, p = 0.000).

Antiemetic usage in the ovarian carcinoma group was significantly higher than for the cervical and ovarian carcinoma groups (Table 3, p = 0.046).

The cost of PEG-ELS for one patient is $10.00 (US) versus $3.00 (US) for NaP.

Table 2. — *Patient tolerability*.

	PEG-ELS	NaP	p
Vomiting more than 3 times	163	30	0.000
Need for antiemetics (3 ampuls of metochlopramide)	173	80	0.000
Regimen completion	113	170	0.000

Table 3. — *Metoclopramide use in PEG-ELS and NaP regimens*.

	Over	Endometrium	Cervix	p
Metoclopramide 253 (3 ampuls)	125	100	28	0.046
Met+PEG-ELS 173	82	73	18	0.17
Met+NaP 80	43	27	10	0.37
PEG-ELS only 0	0	0	0	
NaP only 90	36	35	19	0.046

Discussion

Bowel preparation before a surgical procedure for abdominal gynecological malignancy is crucial. Large-volume polyethylene glycol-electrolyte lavage solution (PEG-ELS) and oral sodium phosphate (NaP) preparations are the most popular regimens for colon cleansing worldwide [2].

PEG, a non-absorbable and osmotically balanced lavage solution, has proven to be safe as there is virtually no net absorption or excretion of water and electrolytes because of its electrical neutrality and iso-osmolality with plasma. However the unpleasant taste and large volume of PEG-ELS frequently lead to poor compliance with recommended dosing regimens, often causing patients significant dissatisfaction with the procedure.

NaP acts via an osmotic effect, drawing plasma water into the gastrointestinal tract. It has been shown to be effective as a cleansing preparation in many randomized trials [1].

The primary aim of our study was not to compare the efficacy of NaP vs PEG-ELS but rather the tolerability and cost effectiveness in patients with gynecological malignancies. The similar effect of these two agents has already been reported by numerous studies in the literature [1-4]. Nonetheless there has been no trial in the literature about the efficacy and tolerability of the two regimens in gynecological malignancies.

The bowel cleansing efficacy of PEG-ELS and NaP has been studied widely in patients who underwent colonoscopic evaluation. Comparison of these two regimens has yielded conflicting results, although a recent meta-analysis favored NaP [3]. The meta-analysis was based on the data of 1,286 subjects in eight trials. NaP and PEG-ELS were equivalent for the quality of preparation, but excellent quality of preparation and ability to complete the cleansing were more likely with NaP [4].

In a meta-analysis of the 16 trials in the PEG vs NaP group, nine concluded that NaP was superior in terms of bowel cleansing ability. Six trials reported that both PEG and NaP were comparable in efficacy, and one trial was in favor of PEG [5].

In this study two groups were evaluated on complaints of nausea, vomiting and need of antiemetics. It has been suggested that the PEG-ELS regimen is highly correlated with more than three times the vomiting and antiemetic use compared with NaP (p = 0.000). The emesis rates (> 3) for PEG-ELS and NaP were 94% and 17%, respectively. Antiemetic usage in the ovarian carcinoma group was significantly higher than in the cervical and endometrial carcinoma groups.

In the study the PEG-ELS group cessation rate of the regimen was 34%, whereas in the NaP group it was 0% (p = 0.000).

In many studies physical complaints have mainly been reported by patients taking PEG-ELS, and significantly more patients reported moderate to severe complaints of nausea, abdominal distension and anal irritation than patients taking NaP [4]. All the patients on NaP completed the intake of the solution and significantly fewer patients did so in the PEG-ELS group.

In a recent meta-analysis, it was shown that significantly more patients were able to complete the NaP preparation when compared with PEG (94.4% vs 70.9%). Therefore it has been noted that this would have an impact on the quality of bowel cleansing, and the superior cleansing ability of NaP may be partly due to a greater rate of completion of bowel preparation by patients [1].

In a study by Vanner *et al*. [6] the use of oral sodium phosphate preparation was found to be more effective than a PEG lavage solution and also better tolerated. In addition it has been shown that sodium phosphate makes no clinically significant changes in intravascular volume and is more cost-effective than other solutions [7].

On the other hand when cost effectiveness was compared, NaP was more favorable than PEG-ELS as the cost of PEG-ELS for one patient is $10.00 vs $3.00 for NaP. Moreover more metachlopramide use in the PEG-ELS group than the NaP group is important to cost effectiveness.

Conclusion

Bowel cleansing before surgery for gynecological malignancies with NaP was found to be superior to PEG-ELS in terms of patient tolerability, compliance, completion of the regimen and cost effectiveness. As NaP is more effective in bowel cleansing than PEG and is comparable in terms of number of adverse events like severe nausea and vomiting, it should be considered as the first-choice treatment.

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