BJS Open, 2025, zraf023
https://doi.org/10.1093/bjsopen/zraf023
Randomized Clinical Trial

Preoperative enema for anal surgery: randomized clinical trial

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Abstract

Background: Haemorrhoidal surgery and anal fistula surgery are two of the most common procedures in proctology. Currently, there is no definitive consensus on the need to administer a preoperative enema. The objective of this study was to evaluate the efficacy and benefits of preoperative enemas in anal surgical procedures.

Methods: Patients diagnosed with grade III or IV haemorrhoids and anal fistulas at the Taipei Medical University Shuang-Ho Hospital, Taiwan, between 2022 and 2023, were enrolled in a randomized clinical study comparing the use of preoperative enema (intervention) *versus* no preoperative enema (control). The primary outcome measures included postoperative visual analogue scale scores and analgesic usage from postoperative day 0 to day 7. Secondary outcomes of interest were postoperative complications, including surgical site infection, postoperative bleeding and urinary retention. Subgroup analyses were performed according to the type of procedure for the same outcomes.

Results: A total of 266 patients were enrolled in this study, with 133 allocated to the enema group and 133 to the control group. No significant differences were observed in postoperative visual analogue scale scores, analgesic consumption and postoperative complications between the two groups. Subgroup analysis revealed that patients undergoing stapled haemorrhoidopexy and anal fistula surgery also showed no significant differences in postoperative visual analogue scale scores, analgesic consumption, and postoperative complications between the enema and control groups. However, in the subgroup of patients undergoing Milligan–Morgan haemorrhoidectomy, the mean(s.d.) visual analogue scale score was significantly higher in the control group than in the enema group on day 2 (5.69(2.14) *versus* 3.77(2.45), $P = 0.021$), day 3 (5.85(2.61) *versus* 3.92(2.73), $P = 0.042$) and day 4 (5.23(2.55) *versus* 3.42(2.18), $P = 0.027$).

Conclusion: Preoperative enema in anal surgery did not yield additional benefits or reduce complications when compared with patients who did not undergo enema before anal surgery. Based on the study findings, its use can be omitted in anal surgery, especially for patients undergoing stapled haemorrhoidopexy and anal fistula surgery.

Introduction

Anal surgery is commonly performed to treat conditions such as haemorrhoids and anal fistulas. In the case of high-grade haemorrhoids, a haemorrhoidectomy is typically recommended[1]. On the other hand, for individuals with anal fistulas, current management predominantly revolves around two conventional surgical options: fistulotomy and fistulectomy[2]. While these surgeries are relatively short, patients often require some time to fully recover and return to their normal activities. Additionally, there can be complications following anal surgeries, including pain, urinary retention, postoperative haemorrhage and infections[3].

As an opening of the faecal passage that connects between the rectum and the skin, the anus is considered to contain numerous bacteria. A previous study suggested that chronic anal fistulas may become colonized by various bowel organisms[4]. If appropriate preoperative bowel preparation to evacuate stool is not performed, complications such as infection and pain may arise following anal surgeries. Therefore, it has been conventionally believed that preoperative enema can reduce the risk of infective and anastomotic complications by decreasing faecal mass and bacterial count in the bowel lumen[5].

However, there is limited research on the subject of preoperative enema before anal surgery. One study conducted a small

Received: December 01, 2024. **Revised:** January 21, 2025. **Accepted:** January 23, 2025

sample-sized randomized clinical study in 2013, involving 40 participants, which revealed that mechanical bowel preparation before Milligan–Morgan haemorrhoidectomy (MMH) did not yield intraoperative or postoperative benefits[6]. In a previous comparative retrospective study from our group, the administration of a preoperative enema before haemorrhoidal surgery did not offer added benefits when compared with not using a preoperative enema before haemorrhoidal surgery but led to increased postoperative pain from the day of the operation to 2 days afterward[7]. Consequently, the decision to administer enemas before anal surgeries is often influenced by surgeons' personal preferences and experiences due to the lack of substantial evidence in the existing research.

Overall, the majority of existing literature predominantly focused on preoperative enemas before colorectal surgeries and lacks data on the use of preoperative enemas before anal surgeries, thus this randomized clinical trial (RCT) aimed to compare the outcomes of anal surgeries with and without preoperative enemas.

Methods

Study design and setting

This study was a RCT comparing preoperative enema and without preoperative enema for postoperative analgesic effects and complications in anal surgery. The study was conducted in accordance with the guidelines outlined in the Declaration of Helsinki[8]. All procedures involving participants received approval from the Taipei Medical University Joint Institutional Review Board and Ethics Committee (Approval Number: N202209016). Every eligible patient was provided with comprehensive information about the study and signed the informed consent. This study was also registered at clinicaltrials.gov (NCT05602987). All patients in the study underwent surgery between November 2022 and August 2023 at the proctology department of Taipei Medical University Shuang-Ho Hospital, a referral centre performing approximately 1200 anal surgeries annually.

Patient selection

Adults aged 20–85 years who underwent haemorrhoidal surgery and anal fistula surgery at a single institute were potential candidates. The inclusion criteria were: patients who underwent conventional haemorrhoidectomy or circular stapled haemorrhoidopexy (SH); patients who underwent fistulotomy or fistulectomy for anal fistula. The exclusion criteria were: emergency surgery; patients who underwent haemorrhoidal treatments except for conventional haemorrhoidectomy or SH, such as rubber band ligation or laser treatment, etc.; patients who underwent anal fistula surgery except fistulotomy and fistulectomy, such as fistula tract ligation, mucosal flap, fistuloscopy surgery, etc.; patients who had colorectal cancer; patients who had liver cirrhosis; patients who had coagulopathy; patients who had human immunodeficiency virus (HIV) infection.

Randomization and blinding

Once patients agreed to participate in this clinical trial and signed the informed consent, they were randomly assigned to either the enema group or the group without enema in a 1:1 ratio. A random group list was generated by a computer, and the group assignments were stored in sequentially sealed envelopes. After completing the informed consent, each patient was randomized to one of the two groups by opening the next envelope in sequence. This study utilized a partially blinded design. While patients could not be blinded due to the nature of the intervention, both surgeons and data analysts were blinded to group allocations to minimize potential bias.

Intervention and comparison

All patients were admitted the day before surgery. In the enema group, patients underwent an enema procedure administered by a ward nurse using a solution of monosodium phosphate and disodium phosphate (EVAC enema, 118 ml/bottle, Purzer Pharmaceutical Co., Ltd), the evening (from 21.00 to 23.00 hours) before the surgery. All patients were instructed to hold for 15 min after the enema before proceeding to defaecate. In the control group, patients did not undergo the enema procedure, and there were no other instructions such as to attempt bowel movements before surgery.

All patients underwent surgery in the jackknife position. The preferred anaesthesia method was spinal anaesthesia. General anaesthesia was used only in special circumstances, such as in patients with a bleeding tendency or those unable to cooperate with regional anaesthesia. Four different surgeons conducted each surgery using the same established procedures. These procedures encompassed circular SH, MMH, fistulotomy and fistulectomy. Upon completion of the anal surgery, the surgeon inserted an absorbable gelatin sponge into the patient's anal canal once complete haemostasis was achieved. Variables collected and analysed included age, sex, body mass index (BMI), preoperative symptoms and their duration, haemorrhoid grade, fistula type, surgical method, anaesthesia type, American Society of Anesthesiologists (ASA) score, postoperative hospital stay, time to first defaecation, type and dosage of postoperative analgesics, complications and hospital costs.

Postoperative analgesics

All patients adhered to the prescribed analgesic protocol following surgery. Patients were provided with diclofenac (25 mg) orally four times a day as their analgesic medication. In cases where patients had allergies to non-steroidal anti-inflammatory drugs (NSAIDs) or insufficient kidney function, their analgesics were switched to acetaminophen (500 mg) orally four times a day. The administration of these medications was discontinued if the patient became pain-free upon discharge from the hospital. If a patient reported experiencing severe pain (visual analogue scale (VAS) score $\geqq$ 4) and requested additional analgesics, 40 mg of parecoxib could be administered intravenously during their hospitalization.

Outcomes of interest

The primary study outcomes were the assessment of pain intensity from postoperative 8 h to postoperative day 7 and postoperative analgesic consumption from postoperative day 0 to day 7. Secondary outcomes included the examination of postoperative bleeding and surgical site infections, within the first 30 days after surgery, and the analysis of urinary retention incidence from postoperative day 0 to day 7. Additionally, costs and the time to the first defaecation after surgery were also recorded.

Postoperative pain levels were assessed using the VAS, a scale ranging from 0 to 10, where 0 indicates no pain and 10 represents the worst pain ever experienced. Patients were provided with a questionnaire by the surgeon and were asked to record their daily pain scores, oral analgesic consumption, defaecation frequency from postoperative day to day 7, as well as the time of their first

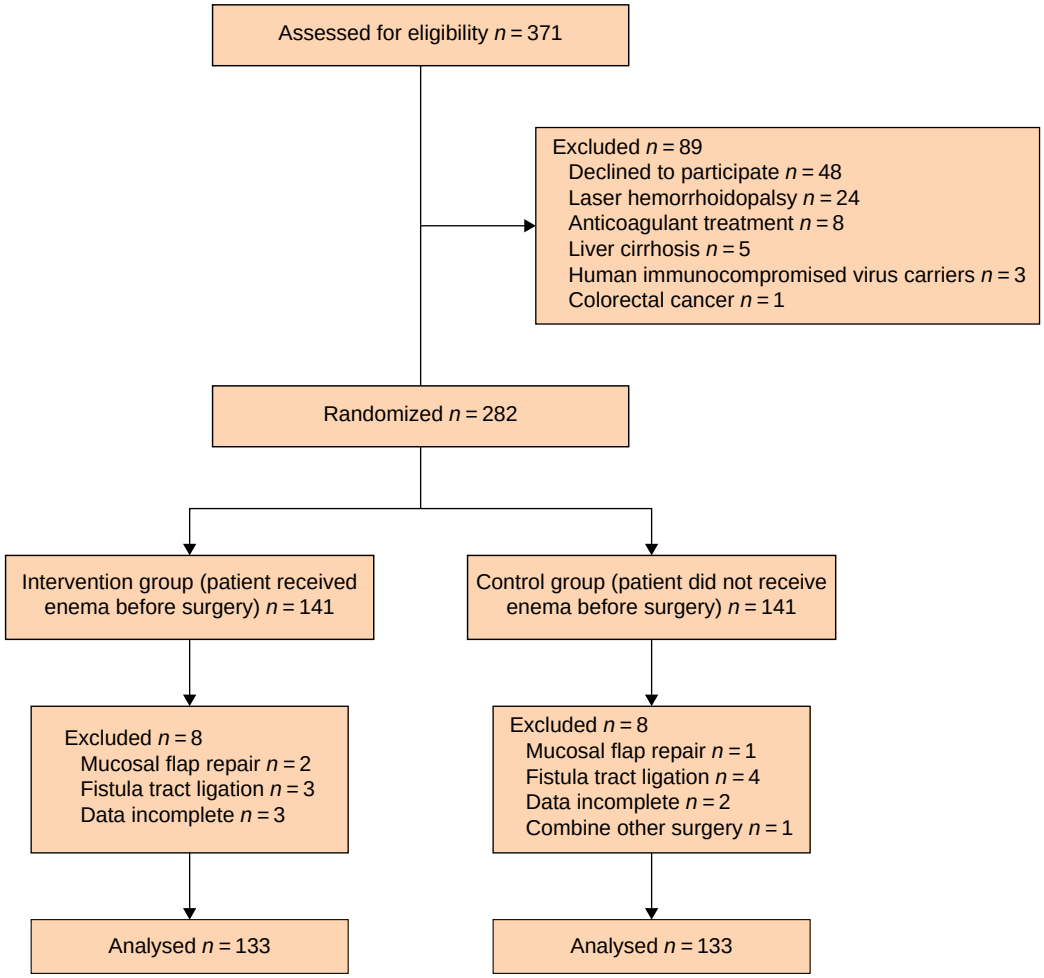

Fig. 1 Diagram of the flow of participants

defaecation. Outpatient department follow-ups were scheduled for 1 week and 1 month after hospital discharge. During these follow-ups, the surgeon reviewed the completed questionnaires to evaluate postoperative pain levels, analgesic usage, and the time elapsed between surgery and the first defaecation.

Postoperative bleeding was defined as the need for surgical intervention or hospital readmission within 30 days following anal surgery. Urinary retention was defined as a patient requiring urinary catheterization from postoperative day to day 7 after anal surgery. Surgical site infection was defined as either hospital admission for infection management or the need for surgical intervention to address wound-related issues within 30 days. All complications were classified using the Clavien–Dindo classification system.

Sample size and statistical analysis

Based on prior research findings, the mean VAS score from postoperative day 0 to day 2 was 4.6 for patients who received preoperative enema and 5.7 for patients who did not receive preoperative enema[7]. Therefore, a power analysis for a two-tailed independent group *t* test indicated that the minimum sample size to yield a statistical power of at least 0.9 with an α of 0.05 and a medium effect size (d = 0.4) is 266. Allowing for 6% loss of patients because of unusable or missing data, we aimed to recruit 282 patients in total.

Continuous data were summarized as mean and standard deviation (mean(s.d.)). Categorical data were expressed as counts and percentage. A two-sample *t* test was used to compare continuous data, and a chi-squared test or Fisher's exact test was used to compare categorical data. All statistical tests were two-tailed, and a *P* value less than 0.05 indicated statistical significance. If baseline factors were inconsistent between the two groups, subgroup analysis and multivariable analysis were considered. A generalized estimating equation was used to analyse other possible factors associated with differences in patients' postoperative course. Subgroup analyses were performed according to the type of operation methods for the same outcomes.

Results

Study population

Between November 2022 and August 2023, 371 patients were screened, and 282 with anal fistulas and grade III or IV haemorrhoids were enrolled and underwent randomization. After randomization, 141 patients were assigned to receive an enema before surgery, and 141 patients were assigned to receive no enema before surgery. In the enema group, eight patients were excluded—five had undergone mucosal flap repair or fistula tract ligation, and the remaining three did not complete

Table 1 Baseline characteristic, perioperative outcome and complications of all patients

Baseline characteristic	Enema group ($n = 133$)	Control group ($n = 133$)	P
Age (years), mean(s.d.)	48.71(12.83)	48.43(12.95)	0.860*
Sex			0.625†
Male	65 (49)	61 (46)	
Female	68 (51)	72 (54)	
BMI, mean(s.d.)	24.71(4.69)	24.44(5.33)	0.659*
Diabetes mellitus	7 (5.3)	12 (9)	0.235†
Haemorrhoid/fistula	107/26	102/31	0.457†
Surgical method			0.827‡
Haemorroid	107 (80.4)	102 (76.7)	
Stapled haemorrhoidopexy	81	89	
Milligan–Morgan haemorrhoidectomy	26	13	
Fistula	26 (19.6)	31 (23.3)	
Fistulectomy	25	30	
Fistulotomy	1	1	
Anaesthesia			0.653†
General anaesthesia	2	3	
Spinal anaesthesia	131	130	
Operation time (mins), mean(s.d.)	13.76(7.09)	13.32(6.7)	0.600*
Postoperative hospital stay (days), mean(s.d.)	1.09(0.38)	1.06(0.34)	0.498*
Hours until first defaecation, mean(s.d.)	41.48(31.50)	38.95(31.21)	0.511*
Postoperative i.v. Parecoxib usage	86 (64.7)	74 (55.6)	0.173†
Postoperative i.v. Parecoxib (times), mean(s.d.)	0.90(0.94)	0.81(0.99)	0.448*
Postoperative oral analgesics			0.421†
Diclofenac	97 (72.9)	91 (68.4)	
Acetaminophen	36 (27.1)	42 (31.6)	
Usage of oral analgesic after 7 days	86 (64.7)	75 (56.4)	0.169*
Complications			
Urinary retention	10 (7.5)	16 (12)	0.217†
Local infection	0 (0)	0 (0)	0.999†
Bleeding	0 (0)	0 (0)	0.999†
Clavien–Dindo classification			
Grade I	10 (7.5)	16 (12)	
Total hospital cost (euros), mean(s.d.)	1266(414)	1285(392)	0.709*

Values are *n* (%) or *n* unless otherwise indicated. BMI, body mass index; i.v., intravenous. *t test. †Chi-square test. ‡Fisher's exact test.

the questionnaire. In the control group, eight patients were excluded—five had undergone mucosal flap repair or fistula tract ligation, two did not complete the questionnaire and another patient who underwent haemorrhoidectomy also had abdominal wall tumour excision. Finally, 266 patients were included in the analysis for this study, with 133 patients in the enema group and 133 patients in the control group, *Fig. 1*.

The baseline characteristics of all patients are presented in *Table 1*. There were no significant differences observed between the groups in terms of age, sex, BMI, presence of diabetes, diagnosis of anal disease and the method of anaesthesia. In the enema group, 110 (78.0%) patients had haemorrhoids and 31 (22.0%) had anal fistulas. In the control group, 105 (74.4%) patients had haemorrhoids and 36 (25.6%) had anal fistulas. There were no significant differences in the prevalence of anal disease between the two groups ($P = 0.49$). Among all the patients, only five received general anaesthesia (five in the enema group and four in the control group), while the remaining 273 patients received spinal anaesthesia.

Perioperative outcomes and complications

The perioperative outcomes and complications of all patients are presented in *Table 1*. There were no significant differences in terms of operation time, hospital stay, and the usage of intravenous and oral analgesics between the two groups. The time to the first defaecation after surgery was slightly longer in the enema group (41.5 h) compared with the control group (38.9 h) ($P = 0.511$), although this difference did not reach statistical significance. Regarding postoperative complications, none of the patients experienced infections or postoperative haemorrhages after surgery. However, 26 patients had urinary retention, with 10 in the enema group and 16 in the control group respectively.

Subgroup analysis of haemorrhoidal surgery

The subgroup analysis of haemorrhoidal surgery is shown in *Table 2*. In haemorrhoidal surgery, 170 patients underwent SH and 39 patients underwent MMH. In SH, 81 patients were in the enema group, 89 patients were in the control group and there were no significant differences in terms of age ($P = 0.874$), sex ($P = 0.436$), haemorrhoid grade ($P = 0.230$), symptoms duration ($P = 0.054$), anaesthetic method (0.925) or complications (0.259). In MMH, there were 26 patients in the enema group and 13 patients in the control group. Among the preoperative symptoms, the enema group exhibited a higher proportion of patients with preoperative bleeding symptoms compared to the control group (61.5% *versus* 92.3%, $P = 0.045$), while no significant differences were observed in other symptoms between the two groups. The time to first defaecation in the enema group was more than 12 h longer than that in the control group (46.9(34.0) h *versus* 33.9(17.3) h, $P = 0.124$).

Subgroup analysis of anal fistula surgery

In *Table 3*, a total of 57 patients underwent anal fistula surgery, with 26 of them in the enema group and 31 in the control group. There were no statistically significant differences among the groups with respect to age ($P = 0.179$), sex ($P = 0.493$), fistula

Table 2 Baseline characteristic of patients with haemorrhoidal surgery

Baseline characteristic	Stapled haemorrhoidopexy			Milligan–Morgan haemorrhoidectomy		
	Enema group (*n* = 81)	Control group (*n* = 89)	*P*	Enema group (*n* = 26)	Control group (*n* = 13)	*P*
Age (years), mean(s.d.)	48.80(12.65)	49.11(12.77)	0.874*	47.81(14.58)	52.08(15.14)	0.400*
Sex			0.436†			0.825†
Male	32 (39.5)	30 (33.7)		15 (57.7)	7 (53.8)	
Female	49 (60.5)	59 (66.3)		11 (42.3)	6 (46.2)	
BMI, mean(s.d.)	24.10(4.72)	23.78(4.45)	0.678*	24.69(4.53)	24.19(3.99)	0.740*
DM	4 (4.9)	7 (7.9)	0.441†	1 (3.8)	2 (15.4)	0.213†
Haemorrhoid grade						
III	7 (5.7)	13 (14.6)	0.230†	4 (15.4)	1 (7.7)	0.511†
IV	74 (94.3)	76 (85.4)		22 (84.6)	12 (92.3)	
Symptom						
Bleeding	61 (75.3)	65 (73)	0.737†	16 (61.5)	12 (92.3)	0.045†
Protruding	64 (79)	63 (70.8)	0.220†	18 (69.2)	9 (69.2)	0.999†
Pain	43 (53.1)	48 (53.9)	0.913†	13 (50)	8 (61.5)	0.508†
Itching	1 (1.2)	4 (4.5)	0.211†	0 (0)	1 (7.7)	0.160†
Discharge	0 (0)	1 (1.1)	0.342†	0 (0)	1 (7.7)	0.160†
Duration			0.054‡			0.862‡
<1 month	9 (11.1)	17 (19.1)		6 (23)	3 (23.1)	
1–3 months	5 (6.2)	8 (9)		1 (3.8)	2 (15.4)	
3–12 months	5 (6.2)	9 (10.1)		4 (15.4)	0 (0)	
>12 months	62 (76.5)	55 (61.8)		15 (57.7)	8 (61.5)	
Prior treatment	1 (1.2)	1 (1.1)	0.947†	1 (3.8)	2 (15.3)	0.213†
ASA score			0.196 ‡			0.658‡
I	35 (43.2)	47 (52.8)		12 (46.2)	5 (38.5)	
II	43 (53.1)	40 (44.9)		14 (53.8)	8 (61.5)	
III	3 (3.7)	2 (2.2)		0 (0)	0 (0)	
Anaesthesia			0.925†			0.999†
General anaesthesia	2 (2.5)	3 (3.4)		0 (0)	0 (0)	
Spinal anaesthesia	79 (97.5)	86 (96.6)		26 (100)	13 (100)	
Operation time (mins), mean(s.d.)	14.41(6.36)	14.84(6.32)	0.655*	14.15(7.06)	13.15(5.8)	0.662*
Postoperative hospital stay (days), mean(s.d.)	1.1(0.41)	1.09(0.33)	0.875*	1.15(0.37)	1.08(0.28)	0.511*
Hours until first defaecation, mean(s.d.)	42.91(32.08)	44.94(34.65)	0.693*	46.96(34.04)	33.93(17.28)	0.124*
Postoperative i.v. parecoxib	62 (76.5)	63 (70.8)	0.244*	18 (69.2)	8 (61.5)	0.642*
Postoperative i.v. parecoxib (times), mean(s.d.)	1.09(0.96)	0.97(0.96)	0.417*	0.88(0.82)	1.23(1.17)	0.287*
Postoperative oral analgesics			0.906†			0.360†
Diclofenac	67 (82.7)	73 (82)		21 (80.8)	12 (92.3)	
Acetaminophen	14 (17.3)	16 (18)		5 (19.2)	1 (7.7)	
Complications						
Urinary retention	8 (9.9)	14 (15.7)	0.259†	1 (3.8)	2 (15.4)	0.213†
Clavien–Dindo classification						
Grade I	8 (9.9)	14 (15.7)	0.259†	1 (3.8)	2 (15.4)	0.213†
Total hospital cost (euros), mean(s.d.)	1579(141)	1549(109)	0.127*	806(113)	764(40)	0.211*

Values are *n* (%) unless otherwise indicated. BMI, body mass index; DM, diabetes mellitus; ASA, American Society of Anesthesiologists; i.v., intravenous. *t test. †Chi-square test. ‡Fisher's exact test.

type ($P = 0.506$), the number of fistula tracts ($P = 0.228$), anaesthetic methods ($P = 0.364$), symptom duration ($P = 0.534$) or complications ($P = 0.279$). However, a statistically significant difference was observed in terms of preoperative pain symptoms, with the control group experiencing a higher prevalence compared with the enema group (90.3% *versus* 65.4%, $P = 0.021$).

Postoperative pain score

The continuous progression of daily VAS scores for all patients is represented in *Fig. 2*. The VAS scores in the enema group were lower than those in the control group from 8 h after surgery to day 6; however, this difference did not reach statistical significance. In subgroup analysis, there was no significant difference in VAS scores between the two groups for patients who underwent SH and anal fistula surgery from 8 h after surgery to day 7. However, patients who underwent MMH had lower VAS scores in the enema group compared with the control group from postoperative day 2 to day 4. The mean(s.d.) pain scores in both groups were 3.77(2.46) and 5.69(2.14) ($P = 0.021$) on day 2, 3.92(2.73) and 5.85(2.61) ($P = 0.042$) on day 3, and 3.42(2.18) and 5.23(2.56) ($P = 0.027$) on day 4 respectively.

Postoperative oral analgesic consumption

Daily analgesic consumption was higher in the control group than in the enema group for all patients (*Fig. 3*) from the postoperative day to day 7; however, this difference did not reach statistical significance. In subgroup analysis, patients who underwent SH and MMH also had higher analgesic consumption in the enema group compared with the control group from the postoperative day to day 7. However, patients who underwent fistula surgery had higher analgesic consumption in the enema group than the control group from the postoperative day to day 7. Despite these observations, none of these differences reached statistical significance.

Cost analysis

The mean(s.d.) total hospital cost for the enema group was 1266(414) euros, while it was 1285(392 euros) for the control group. There was no significant difference observed between the two groups ($P = 0.709$), as indicated in *Table 1*. Subgroup analysis further revealed

Table 3 Baseline characteristic and postoperative outcomes of all patients with fistula surgery

	Fistula ($n = 57$)		P
Baseline characteristic	**Enema group ($n = 26$)**	**Control group ($n = 31$)**	
Age (years), mean(s.d.)	49.31(11.97)	44.94(12.18)	0.179*
Sex			0.493†
Male	18 (69.2)	24 (77.4)	
Female	8 (30.8)	7 (22.6)	
BMI, mean(s.d.)	26.75(4.32)	26.46(7.42)	0.861*
Diabetes mellitus	2 (7.7)	3 (9.7)	0.796†
Type			0.506†
Superficial type	7 (26.9)	6 (19.4)	
Intersphincteric type	19 (73.1)	25 (80.6)	
Number of fistula tract			0.228†
I	23 (88.5)	30 (96.8)	
II	3 (11.5)	1 (3.2)	
Surgical type			0.901†
Fistulectomy	25 (96.2)	30 (96.8)	
Fistuloctomy	1 (3.8)	1 (3.2)	
Symptom			
Bleeding	12 (46.2)	11 (35.5)	0.423†
Protruding	11 (42.3)	11 (35.5)	0.606†
Pain	17 (65.4)	28 (90.3)	0.021†
Itching	0 (0)	2 (6.5)	0.194†
Discharge	8 (30.8)	8 (25.8)	0.684†
Duration			0.534‡
<1 month	11 (42.3)	15 (48.3)	
1–3 months	4 (15.4)	4 (12.9)	
3–12 months	3 (11.5)	6 (19.4)	
>12 months	8 (30.8)	6 (19.4)	
Prior treatment	2 (7.7)	2 (6.5)	0.858†
ASA score			0.137†
I	6 (23.1)	13 (41.9)	
II	20 (76.9)	18 (58.1)	
Anaesthetic method			0.364†
General anaesthesia	0 (0)	1 (3.2)	
Spinal anaesthesia	26 (100)	30 (96.8)	
Operation time (mins), mean(s.d.)	11.35(8.86)	9.00(6.35)	0.251*
Postoperative hospital stay (days), mean(s.d.)	1(0.28)	0.97(0.41)	0.735*
Hours until first defecation, mean(s.d.)	31.55(25.41)	23.85(17.05)	0.179*
Postoperative i.v. Parecoxib	6 (23)	3 (9.7)	0.173*
Postoperative i.v. parecoxib (times), mean(s.d.)	0.35(0.8)	0.19(0.75)	0.460*
Postoperative oral analgesics			0.199†
Diclofenac	9 (34.6)	6 (19.4)	
Acetaminophen	17 (65.4)	25 (80.6)	
Complications			
Urinary retention	1 (3.8)	0 (0)	0.279†
Clavien–Dindo Classification			
Grade I	1 (3.8)	0 (0)	0.279†
Total hospital cost (euros), mean(s.d.)	753(135)	744(106)	0.768*

Values are *n* (%) unless otherwise indicated. BMI, body mass index; ASA, American Society of Anesthesiologists; i.v., intravenous. *t test. †Chi-square test. ‡Fisher's exact test.

that the total hospital cost remained non-significantly different between the enema group and the control group for SH, MMH and anal fistula surgery, as presented in *Tables* 2 and 3.

Discussion

This study revealed that there was no obvious advantage in the postoperative outcomes of the enema group compared with the control group. No significant difference in the complication rate was observed between the groups, except significantly higher VAS scores in the control group than in the enema group 2–4 days after MMH.

As a region teeming with bacteria, the passage connecting the rectum and anus has heightened susceptibility to postoperative infections. Consequently, preoperative enema has become a routine practice aimed at diminishing the faecal volume and lowering bacterial counts in the intestinal lumen to reduce the risk of wound infection[5]. Nevertheless, conflicting findings in previous studies related to colorectal surgery suggest that mechanical bowel preparation may be unnecessary and could even pose harm in preventing wound infections[9]. Conversely, opting not to undergo mechanical bowel preparation appears to be a safe approach that may decrease the incidence of postoperative risks[10]. A Cochrane review in 2011, encompassing a total of 5805 participants, failed to provide statistically significant evidence supporting the benefits of mechanical bowel preparation or the utilization of rectal enemas[11]. In the context of anal surgeries, there is only one prior randomized clinical study, involving 40 patients each in the enema and non-enema groups, which aimed to assess the impact of enema administration before MMH[6]. The results of this study indicated that enemas did not confer any advantages in terms of intraoperative visualization, postoperative VAS scores or infection. The present study, encompassing a larger sample size

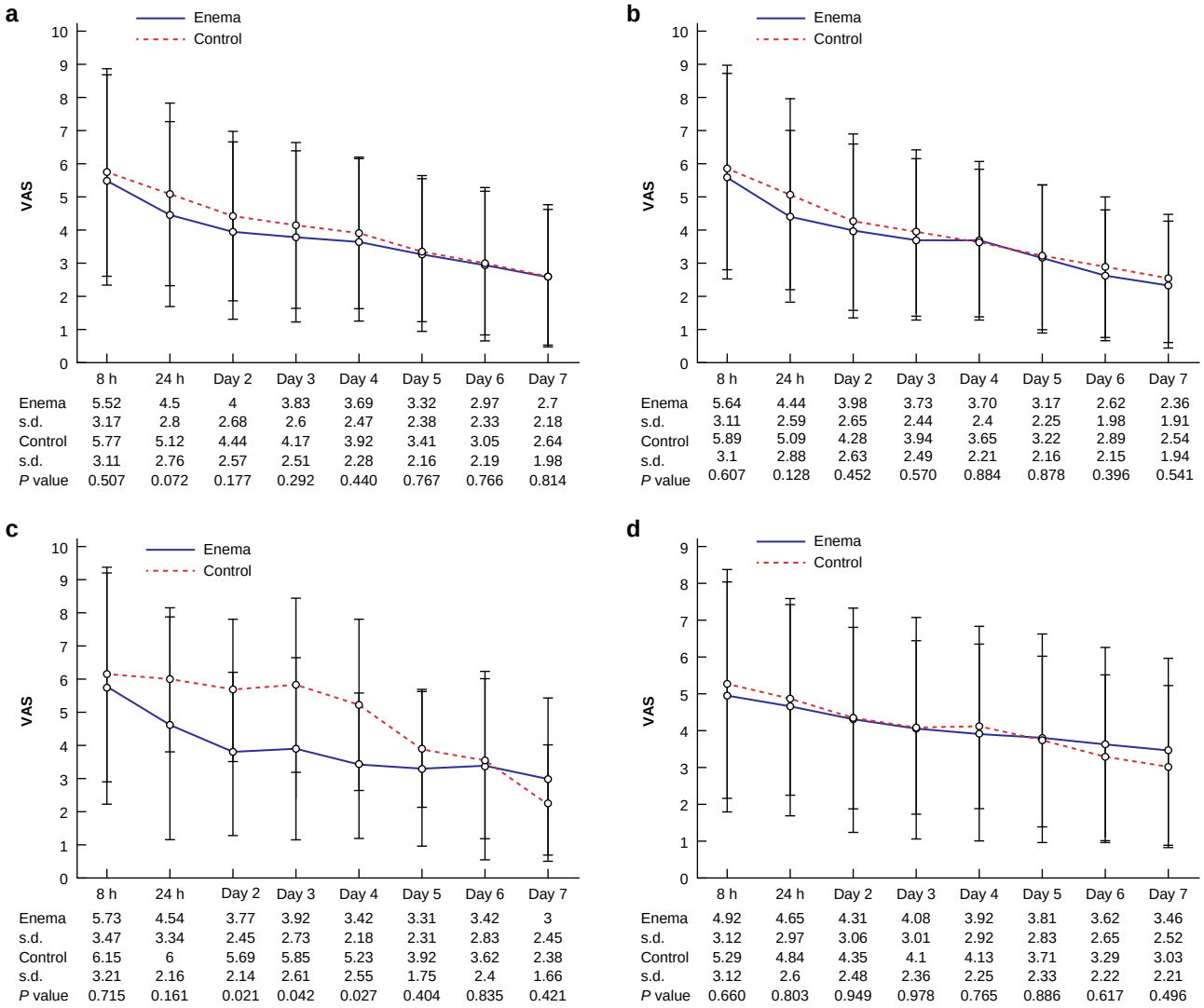

Fig. 2 Postoperative visual analogue scale of patients after anal surgery with mean(s.d.)

P values represent the comparisons between the two groups at each time point. The *y*-axis represents the pain score, with 0 indicating no pain and 10 representing the worst pain ever experienced. **a** All patients, **b** patients who underwent stapled haemorrhoidopexy, **c** patients who underwent Milligan–Morgan haemorrhoidectomy, **d** patients who underwent anal fistula surgery. VAS, visual analogue scale.

and more types of anal surgeries, reaffirms these findings, establishing that preoperative enema preparation does not yield significant benefits in reducing complication and surgical site infection rates. Therefore, based on the present findings, the routine use of preoperative enema preparation may not be warranted for all patients undergoing anal surgery.

Postoperative pain management remains a significant challenge in anal surgeries. The primary source of pain stems from the necessity to excise tissue to eliminate prominent haemorrhoidal cushions, resulting in two to three wounds in an area densely innervated with sensory fibres[12]. These fibres are subsequently subjected to repeat stretching during postoperative defaecation. The prevailing belief is that administering laxatives or enemas before anal surgery can soften stool and postpone defaecation postsurgery, potentially mitigating postoperative pain induced by irritation of the anal wounds. One previous study indicated that the effect of 4 days of preoperative lactulose reduces pain after haemorrhoidectomy[13]. To date, there has been a lack of studies exploring the relationship between preoperative enema and the timing of the first bowel movement after surgery. This experience indicates that preoperative enema marginally delays the onset of the first postoperative bowel movement (41.5 h in the enema group *versus* 38.9 h in the control group), although this difference did not reach statistical significance. This observation may have contributed to the absence of significant differences in daily pain between the two groups 1 week after surgery.

However, in the subgroup analysis, an approximate half-day delay in the first defaecation time after MMH in the enema group compared with the control group was observed. We suggest that administering an enema in conventional surgery could contribute to a delayed time of the first bowel movement or make the stool softer, thereby mitigating wound irritation and reducing postoperative pain. This could explain why patients who received enemas reported less pain on the second to fourth days after surgery. Given the limited number of patients who underwent MMH (39 patients), these findings should be interpreted with caution. Additional studies with larger sample sizes are required to further validate the effect of preoperative enema on postoperative pain. In contrast, SH achieves anal lifting and avoids

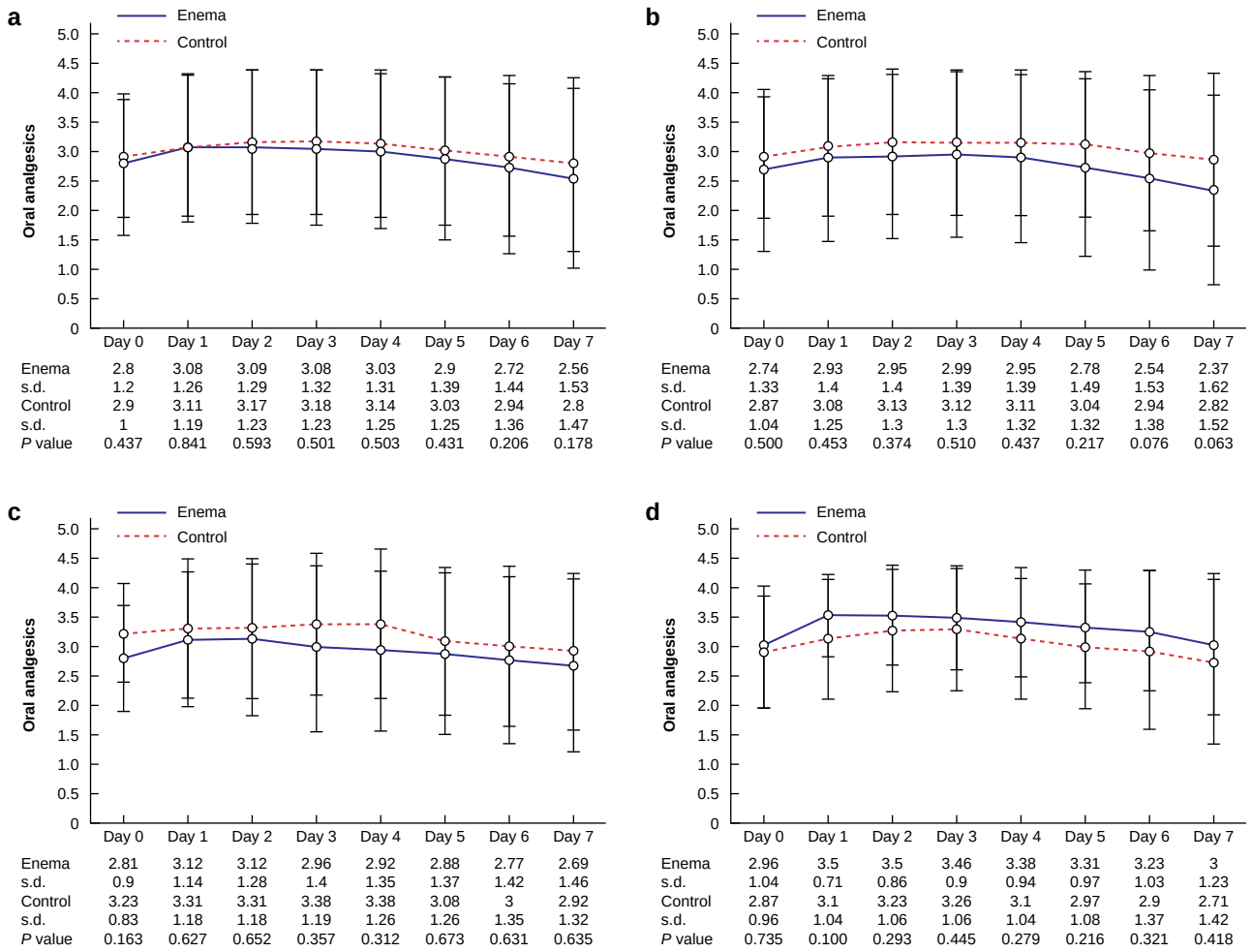

Fig. 3 Daily consumption of oral analgesics over time for all patients, with mean and standard deviation
P values represent the comparisons between the two groups at each time point. The *y*-axis represents the daily quantity of acetaminophen or diclofenac tablets consumed by patients each day. **a** All patients, **b** patients who underwent stapled haemorrhoidopexy, **c** patients who underwent Milligan–Morgan haemorrhoidectomy, **d** patients who underwent anal fistula surgery

anoderm wound irritation by performing circular mucosectomy, thereby reducing postoperative pain[14]. Consequently, the presence or absence of an enema may not significantly impact the postoperative pain experienced by such patients.

Postoperative bleeding is a common complication following haemorrhoidal surgery. Bleeding typically occurs within 24 h after the procedure, and severe cases can lead to hypovolaemic shock, posing a life-threatening risk. The incidence of posthaemorrhoidectomy bleeding ranges from 1.5% to 15.6%[15–19]. In our cohort, no instances of postoperative bleeding occurred. This suggests that the administration or omission of an enema before surgery may not impact the surgical field, potentially leading to incomplete haemostasis during the procedure and subsequent postoperative haemorrhage.

Urinary retention was another notable complication, with an overall rate of 9.8% among all patients in our study. A meta-analysis, comprising six RCTs comparing excisional haemorrhoidectomy under local anaesthesia and spinal anaesthesia, reported a urinary retention incidence of 27.4% in the spinal anaesthesia group, compared with only 3.2% in the local anaesthesia group[20]. In contrast, another RCT comparing conventional haemorrhoidectomy and SH reported that less than 2% of patients experienced urinary retention after surgery, as over 95% of the patients underwent general anaesthesia[21]. The primary cause of urinary retention under spinal anaesthesia is detrusor muscle dysfunction due to impaired bladder sensation and inhibition of the bladder reflex[22]. In the present trial, nearly all patients underwent spinal anaesthesia, explaining the high rate of urinary retention observed.

While this study demonstrated that preoperative enemas do not significantly impact the overall hospitalization cost, their administration does pose an inconvenience for patients[23–25]. Moreover, it exposes patients to the risk of fluid and electrolyte imbalance. In a retrospective study, the use of sodium phosphate enemas in older adults was associated with complications such as hypotension, volume depletion, hyperphosphataemia, hypo- or hyperkalaemia, metabolic acidosis, severe hypocalcaemia, renal failure and prolonged QT interval in electrocardiogram[26]. Additionally, the administration of enemas places a burden on nursing staff.

This study has several limitations, with the primary constraint being its design as a single-centre clinical trial. The findings may lack generalizability due to the limited scope of patient diversity inherent in a single-centre study. Conducting multicentre RCTs with a larger and more diverse patient population would enhance the accuracy and applicability of the results. A significant limitation of our study is the absence of a double-blind design. Given that the administration of an enema is a procedure that

patients are consciously aware of, they may be able to discern whether they have received the treatment or not. This lack of blinding introduces the potential for bias, as patients' expectations and perceptions could influence the reported outcomes. Additionally, the surgeries were performed by different surgeons, introducing variability in experience and surgical practices that could impact the recovery outcomes. This surgeon-related variability is another potential source of bias that may affect the consistency of the results. Moreover, it is crucial to note that the majority of procedures in this study involved SH, which is considered less invasive than conventional haemorrhoidectomy. This inherent bias could impact the generalizability of our study results. However, it is essential to emphasize that our study primarily focuses on evaluating the influence of enema administration on overall outcomes in anal surgery. In addition, regardless of whether it is haemorrhoid surgery or anal fistula surgery, the preoperative preparation and postoperative care protocols are typically the same in the same hospital. Therefore, investigating the impact of enema administration on both haemorrhoid surgery and anal fistula surgery simultaneously is indeed necessary. To address potential biases, subgroup analyses were conducted to assess the impact of enema in SH, MMH and anal fistula surgery separately.

In conclusion, this RCT indicates that preoperative enema does not reduce postoperative complications or hospital costs, nor does it provide significant benefits for patients undergoing SH and anal fistula surgery. This study only demonstrates a reduction in postoperative pain on the second to fourth days after surgery for patients undergoing MMH, but this finding requires validation in a larger patient population. Based on this research, we suggest that preoperative enemas can be omitted in anal surgery, particularly for patients undergoing SH and anal fistula surgery.

Funding

The authors have no funding to declare and this study also received no funding.

Disclosure

The authors declare no conflict of interest.

Author contributions

Meng-Che Tsai (Data curation, Formal analysis, Investigation, Project administration, Software, Writing—original draft), Ting-Yu Su (Data curation, Formal analysis, Investigation, Project administration, Software, Writing—original draft), Kee-Thai Kiu (Data curation), Min-Hsuan Yen (Data curation), Ying-Wei Chen (Data curation), Ka-Wai Tam (Methodology, Software, Validation), Tuan Ly Huu (Supervision) and Tung-Cheng Chang (Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Validation, Visualization, Writing—original draft, Writing—review & editing).

Data availability

The datasets used for this study are available from the corresponding author on reasonable request.

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