# Do We Need Fluid Restriction After Stapled Hemorrhoidopexy? A Pilot, Double-Blinded, Randomized Controlled Trial

**Nien-Ying Tsai**
Tri-Service General Hospital, National Defense Medical Center
**Shu-Wen Jao**
Tri-Service General Hospital, National Defense Medical Center
**Chao-Yang Chen**
Tri-Service General Hospital, National Defense Medical Center
**Chia-Cheng Wen**
Tri-Service General Hospital, National Defense Medical Center
**Chien-Chang Kao**
Tri-Service General Hospital, National Defense Medical Center
**Kuan-Ling Lin**
Tri-Service General Hospital, National Defense Medical Center
**Po-Hsien Wu**
Tri-Service General Hospital, National Defense Medical Center
**Chun-Wei Yu**
Tri-Service General Hospital, National Defense Medical Center
**Yi-Chiao Cheng** ( ndmcjoe@gmail.com )
Tri-Service General Hospital, National Defense Medical Center

**Research Article**

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# Abstract

***Background:*** Conventional hemorrhoidectomy leads to a high urinary retention rate and fluid restriction is commonly recommended to minimize complications. However, the need for postoperative fluid restriction among patients who have undergone stapled hemorrhoidopexy is unclear. We aimed to determine whether fluid restriction after stapled hemorrhoidopexy with/without partial external hemorrhoidectomy could reduce urinary retention and postoperative pain.

***Patients And Methods:*** In this prospective, double-blinded, randomized controlled trial, we enrolled patients who had grade III or IV hemorrhoids and underwent stapled hemorrhoidopexy with/without partial external hemorrhoidectomy; 250 mL/12 h of sterile 0.9% saline was administered to the fluid restriction group after the operation, and 1000 mL/12 h was given to the non-fluid-restriction group. We focused on the need for fluid restriction after stapled hemorrhoidopexy.

***Results:*** Fifty patients were studied in two groups. The surgical outcomes of the two groups were no different. The median subjective pain scores at 0, 8, 16, 24 h after the operation showed no significant difference between the two groups ($p$ = 0.55 at 0 h; $p$ = 0.38 at 8 h; $p$ = 0.98 at 16 h; and $p$ = 0.66 at 24 h). The mean times to first urination after the operation were 700.04 ± 455.03 min in the non-fluid-restriction group and 737.16 ± 426.32 min in the fluid-restriction group (no significant difference; $p$ = 0.67). No postoperative urinary retention was found in either group of patients.

***Conclusions:*** Fluid restriction after stapled hemorrhoidopexy is unnecessary.

***Trial registration:*** This study was reviewed and approved by the Tri-Service General Hospital Institutional Review Board for human subjects (No. 2-106-05-063). This study also had trial registration with clinicalTrials.gov (Identifier: NCT04459039).


# Introduction

Hemorrhoidal disease, a common anorectal disorder, is the main cause of rectal bleeding, discomfort, and pain for affected patients. The prevalence of hemorrhoid disease has been estimated at 4.4–12.8% in normal adult populations and about 40% in patients with symptoms of anal disease. However, it is difficult to estimate the exact incidence of hemorrhoid disease, because of patient embarrassment, fear, or discomfort related to the treatment.[1, 2]

There are several possible surgical treatments. Conventional hemorrhoidectomy (CH), which is currently considered the most effective treatment, involves excision of the hemorrhoidal cushions. However, it is often accompanied by postoperative pain and disability, which makes it an unpopular choice with patients. The most common complication after CH is acute urinary retention, with an incidence of about 21.9%. Urinary retention causes discomfort, and urethral injury, and urinary tract infection might occur as a result of catheterization. These also lead to delayed discharge and possibly increased medical expenses to the patient.[3, 4] Many different approaches have been tried to prevent urinary retention,

including restriction of perioperative fluid intake.[5] In 1976, a report revealed that fluid restriction could reduce the incidence of urinary retention following operations for benign anorectal diseases. According to that research, only 3.5% of patients with fluid restriction presented with postoperative urinary retention, but 14.9% of patients without fluid restriction showed it.[3, 5]

Stapled hemorrhoidopexy (SH) was first described by Longo in 1998.[6] In contrast to the traditional approach, which involves removing the hemorrhoidal tissue, SH removes the submucosa above the dentate line with a circular stapler. With this position of excision, postoperative pain can be reduced, and the sensitivity of the anal canal can be maintained by preserving the transitional epithelium.[7, 8] However, the general incidence of complications after SH may be identical to conventional excisional surgery.[9] Despite the low risk, SH might also contribute to urinary retention.[5] A 1.5% urinary retention rate in the first week after being treated with SH was reported in a review of 1107 patients from 12 Italian coloproctological centers.[8]

To avoid urinary retention, we routinely arrange fluid restriction for patients undergoing SH in clinical practice. However, whether restriction of postoperative fluid intake in such cases is necessary is unknown. Therefore, we designed a prospective, randomized, double-blinded study, and aimed to investigate the influence of perioperative fluid restriction with urinary retention after SH.

## Patients And Methods

# Patients

This prospective, double-blinded, randomized controlled trial included patients with grade III or IV hemorrhoids who underwent SH with/without partial external hemorrhoidectomy at the Colorectal Division of Tri-Service General Hospital, National Defense Medical Center, Taipei, Taiwan, from February 2018 to December 2019.

Exclusion criteria were as follows: patients younger than 20 years or older than 80 years; allergy to nonsteroidal anti-inflammatory drugs; uremia or impaired renal function; pregnant or breast feeding.

Our research nurse assigned the patients to the fluid restriction (experimental group, EG) or non-fluid-restriction groups (control group, CG) at a 1:1 ratio using a computer-generated list of random numbers (Microsoft Excel). Once the patients had been assigned into either group, only the bedside nurses were informed of the allocation.

This study followed the guidelines of the 7th revision of Helsinki Declaration. All participants gave informed consent at hospital admission. This study was reviewed and approved by the Tri-Service General Hospital Institutional Review Board for human subjects (No. 2-106-05-063). This study also had trial registration with clinicalTrials.gov (Identifier: NCT04459039). The first registration was July 7$^{th}$ 2020.

# Primary endpoint:

In order to reveal if fluid restriction could avoid urine retention, the study defined the primary endpoint as the first urination after stapled hemorrhoidopexy with/without partial external.

# Preparation

All patients were admitted the day before the operation. After basic blood tests, they received uroflowmetry and bladder scans for evaluating residual urine to reduce the possible impact of selection bias related to postoperative urinary retention between the two study groups. Since most of the patients recruited in our study were middle age, the patients were given a clear liquid diet and received sodium phosphate solution or polyethylene glycol electrolyte lavage solution orally on the night before surgery for colonoscopy in order to rule out colon lesion.

# Surgery

All the patients were placed under intravenous general anesthesia using propofol and administered local anesthesia with mixed agents (15 mL 2% lidocaine, 10 mL 0.5% bupivacaine and 0.3 mL 1:200,000 epinephrine) into the intersphincteric groove. After receiving colonoscopy routinely, all patients underwent SH with/without partial hemorrhoidectomy for cosmetic concern applied by four experienced colorectal surgeons (SWJ, CYC, CCW, and YCC) after being placed in a prone jackknife position. The devices used for SH were PPH® staplers (Ethicon Inc., Cincinnati, OH, USA) or EEA® staplers (Medtronic plc, Fridley, MN, USA) according to the surgeons' preferences. The extent of internal hemorrhoids, numbers of excised external hemorrhoids, distance between the staple and dentate lines, and operation times were recorded.

After the surgical procedure, ketorolac (30 mg) was prescribed routinely immediately after the operation and every 6 h for 1 day. A rescue tramadol acetaminophen tablet (37.5 mg) was given every 6 h if needed. The patients were asked to report a 0–10 visual analogue scale (VAS) pain score at postoperative 0, 8, 16, and 24 h. No warm water sitz (hip) baths were permitted, nor any medicines other than painkillers.

All patients were allowed to consume a soft diet at 6 h after the operation, but their oral fluid intake was restricted to <400 mL until their first urination. Within 12 h of surgery, the EG received 1000 mL 0.9% sterile saline intravenously (IV), while the CG received 250 mL similarly. The rate of fluid supply was controlled using an infusion pump. The monitor and the saline bag were masked for double-blinding. Bedside nurses recorded the time to first urination in minutes after the operation, and the time of urethral catheterization if acute urinary retention persisted. Acute urinary retention was defined as being when patients were unable to empty their bladder voluntarily and when physical examinations by doctors demonstrated bladder distention.

# Statistical Analysis

Categorical data are reported as absolute numbers and percentages while continuous variables are expressed as the mean ± standard deviation or the median and interquartile range. Quantitative data were analyzed using the Mann–Whitney nonparametric *U* test. Categorical data were compared using Chi-squared or Fisher's exact tests, as appropriate. Box-and-whisker plots were used to compare the VAS differences at 0, 8, 16, and 24 h after surgery between the EG and CG groups. Scatter plots of the time to first urination after surgery were used to demonstrate the influence of fluid restriction. A $p$ value < 0.05 was considered statistically significant. All analyses were performed using IBM SPSS Statistics for Windows (Version 25.0; IBM Corp., Armonk, NY, USA).

# Results

Fifty-three patients underwent SH. Two were excluded before the operation; one because they needed to receive a blood transfusion after the operation for severe anemia, which would increase intravenous fluid volume and make effect on the result in this study; the other patient had huge prolapsed hemorrhoids and the surgeon decided to perform a conventional hemorrhoidectomy. The remaining 51 patients were randomized to the two groups. One patient who refused intravenous fluid after the operation was excluded. Therefore, 50 cases were included finally (Fig. 1).

Table 1 shows the basic characteristics of both groups. The mean age of the patients was 54.24 ± 11.72 years in the non-fluid-restriction group and 46.40 ± 13.92 years in the fluid-restriction group ($p$ = 0.028). However, the gender distributions, body mass index, grades of hemorrhoids, uroflowmetry data, and American Society of Anesthesiology class were not significantly different between the groups.

Surgical outcomes are shown in Table 2. The two groups had no difference in terms of the use of partial external hemorrhoidectomy, operation time, the level of the stapling line, intraoperative IV fluid needs, medicine used, time to first urination, the incidence of urinary retention, complications, or postoperative length of stay.

The median VAS scores of two groups at 0, 8, 16, and 24 h after the operation are shown as box-and-whisker plots in Figure 2. The median VAS scores did not reach significant difference at any recorded hours ($p$ = 0.548 at 0 h; $p$ = 0.382 at 8 h; $p$ = 0.984 at 16 h; and $p$ = 0.657 at 24 h).

The scatter plot in Figure 3 shows individual patients' time to their first urination after the operation. The mean values were 700.04 ± 455.03 min in the non-fluid-restriction group and 737.16 ± 426.32 min in the fluid-restriction group. No significant difference was found between the groups ($p$ = 0.669).

# Discussion

Previous studies have demonstrated the contributing risk factors of postoperative urinary retention, including age, pre-existing neurologic abnormalities, bladder volume on entry to the post-anesthesia care

unit, surgical procedure, length of surgery, intraoperative aggressive fluid administration, postoperative pain, and need for postoperative analgesia, or postoperative opioid use.[4, 10] The mechanism of postsurgical urinary retention is still not clear. There are some probable causes, including anxiety, anal distention, bladder distention caused by fluid hydration during surgery, irritation or blockade of pelvic nerves, and reflex inhibition of the urinary bladder detrusor muscle arising from pain.[11, 12]

There are numerous steps reported to prevent postsurgical urinary retention, including the use of parasympathomimetic agents, alpha-adrenergic blockers and anxiolytic agents, restriction of perioperative fluid intake, avoidance of anal packing, use of sitz baths, local anesthesia, short-acting anesthesia, and outpatient surgery.[13-15]

Increased fluid intake might cause overdistension of the bladder and dysfunction of the detrusor muscle. Some studies showed that fluid restriction can prevent postoperative urinary retention effectively.[5, 15, 16] In 2006, Toyonaga et al. reported that a significant increase in postoperative urinary retention was noted in patients with IV fluids in excess of 1000 mL, and perioperative fluid restriction was recommended for prevention.[14] However, fluid restriction with preoperative patient preparation, including nothing by mouth and the use of laxatives, can cause thirst and discomfort in patients. That is why we aimed to determine whether fluid restriction after SH is necessary.

Unlike previous research, our study demonstrated that patients in the non-fluid-restriction group did not have higher urinary retention rates than the fluid-restriction group, although 22 of the 50 patients had external hemorrhoids excised (Table 2). Moreover, the patients in the non-fluid-restriction group patients were significantly older and more likely to exhibit postoperative urinary retention.[17] This might be explained by the lower pain produced by the SH procedure and adequate pain relief after the surgery. In addition, postoperative pain can lead to urinary retention through inhibition of the micturition reflex via increased sympathetic nervous system activity.[14] We found here that fluid restriction itself did not cause pain in patients who underwent hemorrhoidopexy at any time after the operation (Fig. 2), or increase the use of analgesic drugs (three patients in the non-fluid-restriction group and five in the fluid-restriction group; $p = 0.702$; Table 2). Although overdistension of the bladder is a known risk factor for urinary retention, it did not appear to cause this in our study.[18]

Unexpectedly—as shown in Figure 3—there was no statistically significant difference in the average time to first urination between the two groups (700.04 ± 455.03 min in the non-fluid-restriction group and 737.16 ± 426.32 min in the fluid-restriction group; $p = 0.669$). This probably arose because all of our patients received intravenous anesthesia so the use of perioperative intravenous fluid was inevitable. Although the perioperative intravenous fluid volumes (218 ± 87.66 mL in EG and 212 ± 89.30 mL in CG), with some oral intake, when combined with irritation from the anal wound, were enough to trigger urination. Therefore, fluid restriction had no effect on delaying urination in these patients.

Although spinal anesthesia with the patient in a prone jackknife position with detailed history taking by the anesthesiologist is thought to enable airway patency, all of our patients were subjected to intravenous anesthesia plus local anesthesia safely. Spinal anesthesia can dull bladder sensations and inhibit the

voiding reflex.[18] This could also explain why our patients had lower urinary retention rates after the operation.

In terms of postoperative complications, there were two cases of delayed bleeding, and both of them were in the non-fluid-restriction group. According to previous studies, such bleeding occurs either immediately or 4–10 days after surgery.[19, 20] Delayed bleeding in our two cases occurred at 10 and 14 days after surgery, but we consider that it had no link with fluid restriction. Nisar et al. published a meta-analysis on 15 prospective randomized trials, and reported that the hemorrhoidopexy: hemorrhoidectomy ratio of postoperative rectal bleeding was 2.3 to 1.[21] In addition, in both of our cases with this complication we used a PPH stapler, which has been reported to lead to more postoperative bleeding than the EEA device.[22]

# Limitations

Although this was a prospective, double-blinded, randomized controlled trial, the strength of this study was limited by the small sample size and because it was a single-center experience. The low numbers of recruited patients might lead to low power analysis in this study. Further multiple-center trials are needed to test the validity of our findings.

# Conclusions

Fluid restriction after SH with or without partial external hemorrhoidectomy did not reduce postoperative pain, postpone the time to first urination, or decrease the risk of postoperative urinary retention. Therefore, fluid restriction after SH is unnecessary.

# Declarations

**Consent to publish:**

Not applicable

**Availability of data and materials:**

All the data regarding the findings are available within the manuscript.

**Authors' contributions:**

Nien-Ying Tsai: wrote the manuscript

Shu-Wen Jao: recruited the patients and did the operations

Chao-Yang Chen: recruited the patients and did the operations

Chia-Cheng Wen: recruited the patients and did the operations

Chien-Chang Kao: analyzed the reports of uroflowmetry and residual urine

Kuan-Ling Lin: data analysis and randomize the patients

Po-Hsien Wu: data collection

Chun-Wei Yu: manuscript editing

Yi-Chiao Cheng: designed the study and wrote the manuscript

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**Compliance with Ethical Standards:**

**Funding:** This study was supported by the study project of Tri-Service General Hospital (ATSGH-C107-201). The funder had no role in study design and data analyze.

**Conflict of Interest:**

Nien-Ying Tsai declares that she has no conflict of interest.

Shu-Wen Jao declares that he has no conflict of interest.

Chao-Yang Chen declares that he has no conflict of interest.

Chia-Cheng Wen declares that he has no conflict of interest.

Chien-Chang Kao declares that he has no conflict of interest.

Kuan-Ling Lin declares that she has no conflict of interest.

Po-Hsien Wu declares that he has no conflict of interest.

Chun-Wei Yu declares that he has no conflict of interest.

Yi-Chiao Cheng declares that he has no conflict of interest.

**Ethical approval:**

This study was reviewed and approved by the Tri-Service General Hospital Institutional Review Board for human subjects (No. 2-106-05-063). This study also had trial registration with clinicalTrials.gov (Identifier:

NCT04459039). The first registration was July 7th 2020.

**Informed consent:**

Informed consent was obtained from all individual participants included in the study.

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# Tables

**Table 1. Characteristics**

| | Non-fluid restriction, n=25 | Fluid restriction, n=25 | *P* value |
|---|---|---|---|
| Age (years) | 54.24±11.72 | 46.40±13.92 | 0.028 |
| Male (%) | 16(64) | 13(52) | 0.390 |
| BMI (kg/m$^2$) | 23.06±3.02 | 23.19±2.96 | 0.969 |
| Hemorrhoids, Grade | | | |
| III | 22 | 19 | 0.289 |
| IV | 3 | 6 | |
| Pre-operative uroflowmetry | | | |
| Peak flow | 16.60±8.05 | 19.29±9.25 | 0.284 |
| Mean flow | 9.16±4.72 | 11.13±5.96 | 0.233 |
| Residual urine | 23.72±48.70 | 39.36±50.97 | 0.092 |
| ASA* | | | |
| I | 4 | 8 | 0.478 |
| II | 19 | 16 | |
| III | 2 | 1 | |

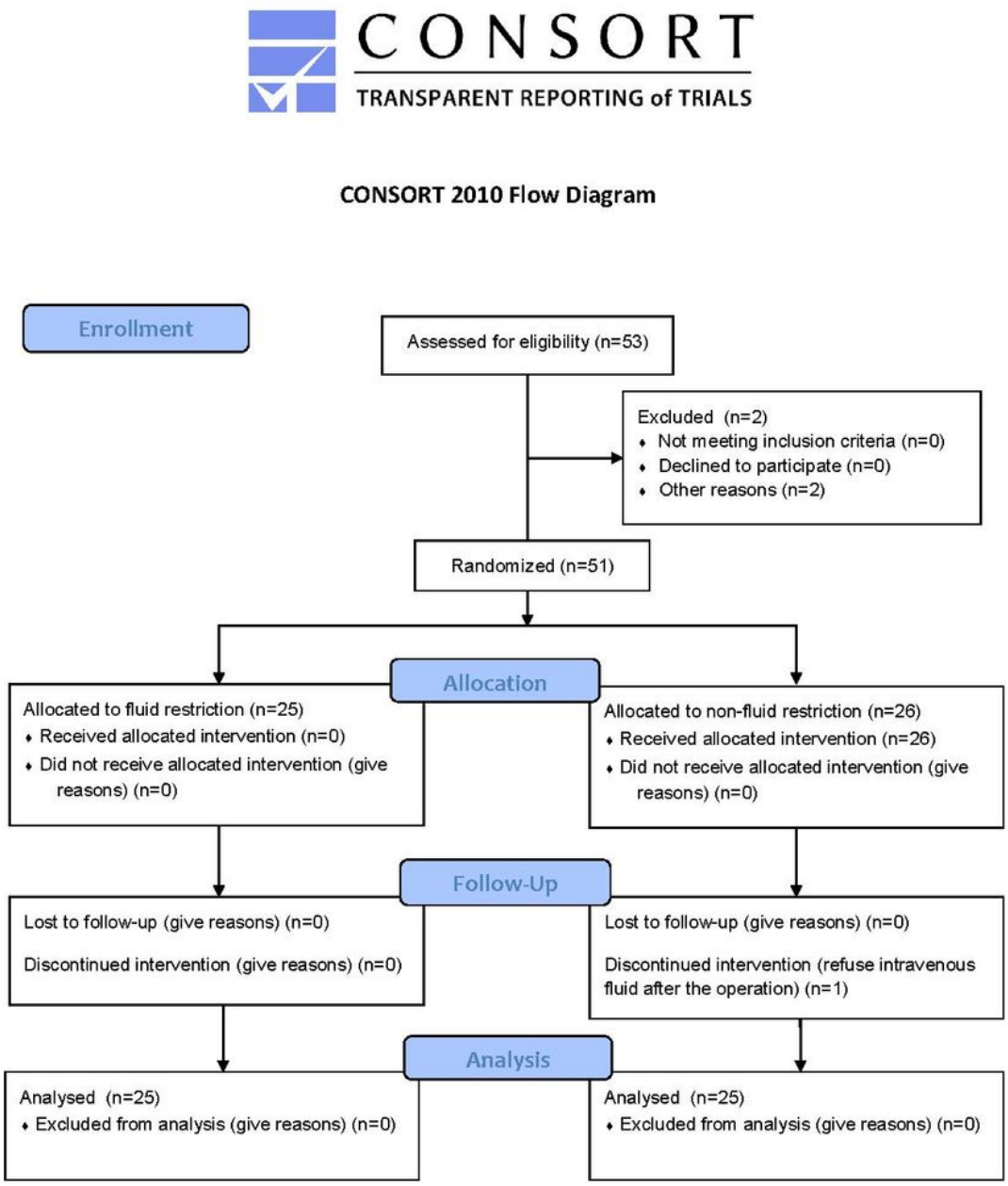
*ASA class=American Society of Anesthesiologists Classification

**Table 2. Outcomes**

| | Non-fluid restriction, n=25 | Fluid restriction, n=25 | *P* value |
|---|---|---|---|
| With partial external hemorrhoidectomy | 12 (19 lumps) | 10 (13 lumps) | 0.569 |
| Operation time (min) | 32.08±8.47 | 32.88±10.85 | 0.954 |
| Staple line (mm above the dentate line) | 19.0±4.8 | 19.8±8.2 | 1.000 |
| Intraoperative IV fluid (mL) | 218±87.66 | 212±89.30 | 0.712 |
| Use of rescued medicine | 3 | 5 | 0.702 |
| Time to 1$^{st}$ urination (min) | 700.04±455.03 | 737.16±426.32 | 0.669 |
| Urinary retention | 0 | 0 | N/A |
| Complications | 2 (PPH, delayed bleeding) | 0 | 0.490 |
| Post-operative LOS* | 2.64±0.49 | 2.60±0.65 | 0.634 |

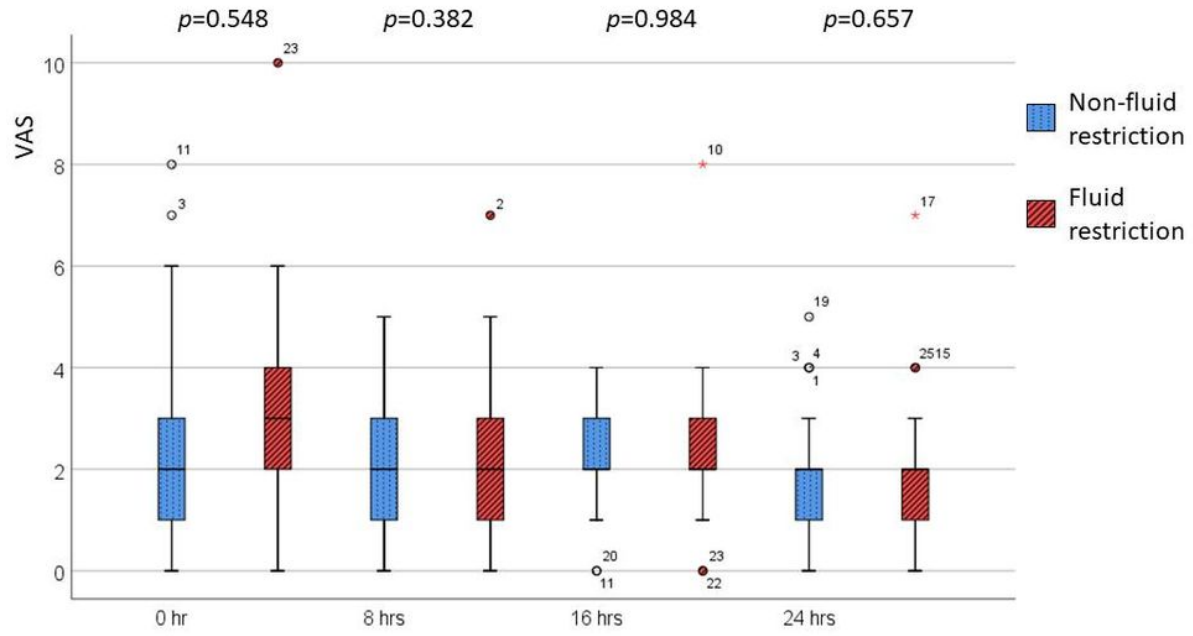
*LOS=Length of stay

# Figures




## Figure 1

CONSORT 2010 Flow Diagram




## Figure 2

The median VAS scores of two groups at 0, 8, 16, and 24 h after the operation.

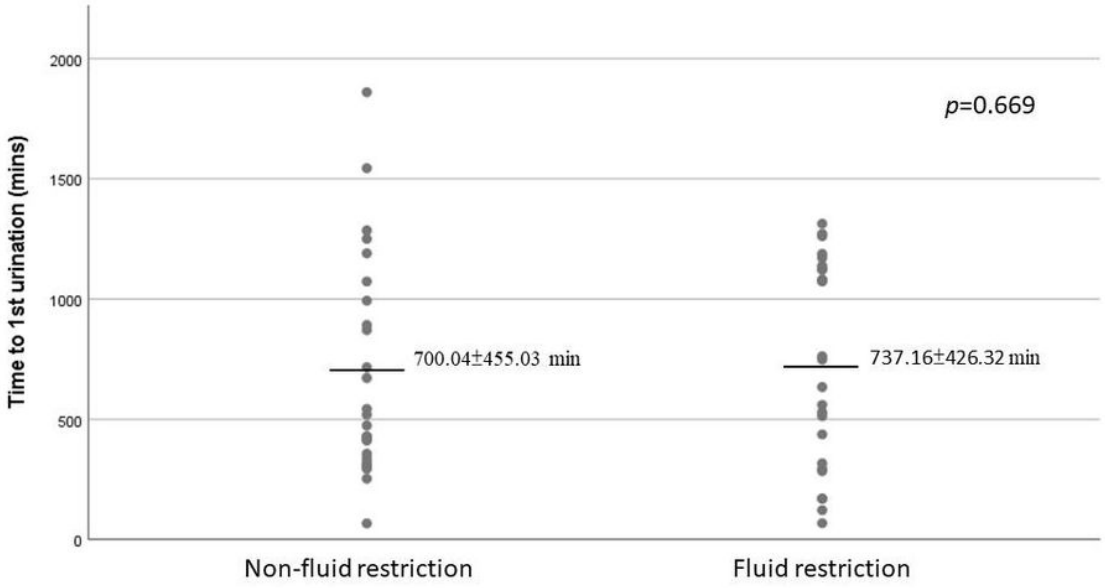


**Figure 3**

Individual patients' time to their first urination after the operation.

# Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORT2010Checklist2021.doc