Study Protocol and Statistical Analysis Plan

Official Title

Effect of Vulvar Re-Antisepsis Before CO_2 Cystoscopy Performed After Laparoscopic Hysterectomy on Postoperative Urinary Infections

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NCT07232446

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1. Study Title

Effect of Vulvar Re-Antisepsis Before CO_2 Cystoscopy Performed After Laparoscopic Hysterectomy on Postoperative Urinary Infections

2. Background and Rationale

Urinary tract injury is an important complication of gynecologic surgery, particularly during hysterectomy. Although the absolute incidence of bladder and ureteral injuries is relatively low, delayed recognition may lead to substantial morbidity, prolonged hospitalization, reintervention, readmission, and medicolegal consequences. Intraoperative cystoscopy is therefore frequently used after laparoscopic hysterectomy to evaluate bladder integrity and ureteral patency.

Carbon dioxide cystoscopy has emerged as a practical alternative to liquid-based cystoscopy techniques. CO_2 cystoscopy provides a clear visual field, avoids the need for intravenous dyes or liquid distension media, and may facilitate rapid visualization of ureteral efflux during laparoscopic gynecologic surgery.

Postoperative urinary tract infection is a clinically relevant outcome after hysterectomy and intraoperative urinary tract instrumentation. Although preoperative vulvovaginal antisepsis is routinely performed before gynecologic surgery, contamination or recolonization of the vulvar and periurethral field may occur during the operation. Since cystoscopy is usually performed after completion of hysterectomy, an additional vulvar antiseptic preparation immediately before cystoscopy may theoretically reduce contamination during urethral instrumentation and decrease postoperative urinary symptoms or urinary tract infection.

However, there is limited evidence regarding whether vulvar re-antisepsis immediately before intraoperative CO_2 cystoscopy reduces postoperative urinary tract infection after laparoscopic hysterectomy. This study was designed to evaluate the effect of additional vulvar re-antisepsis before CO_2 cystoscopy on postoperative urinary infections.

3. Study Objective

The primary objective of this study was to evaluate whether vulvar re-antisepsis performed immediately before CO_2 cystoscopy after laparoscopic hysterectomy reduces the incidence of postoperative urinary tract infection.

The secondary objectives were to compare postoperative urinary symptoms, cystoscopy duration, delayed catheter removal, operative characteristics, and postoperative outcomes between patients managed with standard antisepsis alone and those receiving additional vulvar re-antisepsis before cystoscopy.

4. Study Design

This was a prospective observational cohort study.

Patients undergoing laparoscopic hysterectomy for benign gynecologic indications were enrolled consecutively during the study period. Patients were grouped according to the antiseptic approach used before intraoperative CO_2 cystoscopy.

This was not a randomized interventional trial. The study compared outcomes between patients who underwent standard antisepsis alone and patients who underwent additional vulvar re-antisepsis immediately before cystoscopy.

5. Study Setting

The study was conducted at a high-volume tertiary referral center.

6. Study Period

Patients who underwent laparoscopic hysterectomy between November 25, 2025 and March 1, 2026 were included.

All patients were followed postoperatively for 6 weeks. The study was completed on April 15, 2026.

7. Study Population

Women undergoing laparoscopic hysterectomy for benign gynecologic indications were eligible for inclusion.

A total of 98 patients were included in the final analysis. Of these, 53 patients were managed with standard antisepsis alone and 45 patients underwent additional vulvar re-antisepsis before cystoscopy.

8. Inclusion Criteria

Patients were eligible for inclusion if they met all of the following criteria:

Female patients undergoing laparoscopic hysterectomy;

Surgery performed for benign gynecologic indications;

Intraoperative CO_2 cystoscopy performed after laparoscopic hysterectomy;

Age 18 years or older;

Provision of informed consent;

Availability of postoperative follow-up data.

9. Exclusion Criteria

Patients were excluded if any of the following criteria were present:

Preoperative urinary symptoms;

Positive preoperative urine culture;

Known urinary tract anomaly;

Conversion to laparotomy;

Continuation of surgery through a vaginal route;

Postoperative pathologic diagnosis of malignancy;

Incomplete postoperative follow-up data.

No immunosuppressed patients were present in either study group.

10. Study Groups

Patients were classified according to the antiseptic approach used before intraoperative cystoscopy.

10.1 Standard Antisepsis Group

Patients in this group underwent routine preoperative surgical antisepsis only. No additional vulvar antiseptic preparation was performed immediately before cystoscopy.

10.2 Vulvar Re-Antisepsis Group

Patients in this group underwent routine preoperative surgical antisepsis followed by additional vulvar antiseptic preparation immediately before intraoperative CO_2 cystoscopy.

11. Perioperative Management

All procedures were performed laparoscopically. In patients without contraindications, perioperative antibiotic prophylaxis was administered with intravenous cefazolin.

Surgical field preparation was performed with 10% povidone-iodine and included both the abdominal and vulvovaginal operative fields. After sterile draping, laparoscopic hysterectomy was performed using a standard intraperitoneal approach.

12. CO_2 Cystoscopy Technique

After completion of laparoscopic hysterectomy, intraoperative cystoscopy was performed using CO_2 as the bladder distension medium.

Before cystoscopy, the bladder was emptied and the Foley catheter balloon was deflated. Bladder insufflation was achieved using a trocar and Foley catheter setup. A 30-degree 5-mm optic was used to evaluate the bladder mucosa and bilateral ureteral jet efflux. After cystoscopic evaluation, the Foley catheter was reinserted and the balloon was reinflated.

13. Postoperative Management and Follow-up

All patients were followed for 6 weeks postoperatively.

Patients were routinely scheduled for outpatient follow-up visits on postoperative days 10 and 30. At these visits, patients were assessed for urinary symptoms. When clinically indicated, urinalysis and urine culture were obtained, and treatment was initiated as appropriate.

14. Data Collection

Clinical data were recorded prospectively using a structured case report form.

Baseline variables included:

Age;

Body mass index;

Gravidity;

Parity;

Menopausal status;

Smoking status;

Diabetes mellitus;

Previous abdominal surgery;

Hormone replacement therapy use.

Operative and postoperative variables included:

Surgical indication;

Operation time;

Cystoscopy time;

Delayed catheter removal(>6 hours);

Postoperative urinary symptoms;

Postoperative urinary tract infection.

15. Outcome Measures

15.1 Primary Outcome

The primary outcome was the incidence of postoperative urinary tract infection.

Postoperative urinary tract infection was defined according to the Centers for Disease Control and Prevention/National Healthcare Safety Network criteria. Diagnosis required compatible postoperative urinary symptoms together with microbiological confirmation by urine culture.

The primary outcome was assessed during the postoperative follow-up period.

15.2 Secondary Outcomes

Secondary outcomes included:

Incidence of postoperative urinary symptoms;

Urine culture positivity when clinically indicated;

Cystoscopy time;

Delayed catheter removal;

Operation time;

Postoperative complications.

Postoperative urinary symptoms included symptoms suggestive of urinary tract infection, such as dysuria, urinary frequency, urgency, suprapubic discomfort, or fever when clinically relevant.

Delayed catheter removal was defined as Foley catheter removal later than 6 hours after surgery.

16. Sample Size

This was a prospective observational study including all eligible consecutive patients during the predefined study period. No formal sample size calculation was performed before study initiation.

A total of 98 patients were included in the final analysis.

17. Statistical Analysis Plan

Statistical analyses were planned to compare baseline, operative, and postoperative outcomes between the standard antisepsis group and the vulvar re-antisepsis group.

Continuous variables were presented as mean ± standard deviation or median with interquartile range, depending on data distribution. Categorical variables were presented as number and percentage.

Normality of continuous variables was assessed using appropriate statistical methods. Between-group comparisons for continuous variables were performed using parametric or nonparametric tests, as appropriate. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate.

Logistic regression analysis was used to identify predictors of postoperative urinary tract infection. Univariable logistic regression analyses were first performed. A multivariable logistic regression model was then constructed to evaluate independent predictors of postoperative urinary tract infection.

The regression model included the following variables:

Vulvar re-antisepsis;

Age;

Body mass index;

Diabetes mellitus;

Operation time;

Delayed catheter removal greater than 6 hours;

Cystoscopy time.

Crude and adjusted odds ratios with 95% confidence intervals were calculated.

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 24.0.

A two-sided p value of <0.05 was considered statistically significant.

18. Ethical Considerations

The study was approved by the local ethics committee and was conducted in accordance with the principles of the Declaration of Helsinki.

Written and verbal informed consent was obtained from all participants before enrollment.

The study was registered at ClinicalTrials.gov with the identifier NCT07232446.

19. Data Confidentiality

All study data were collected using a structured case report form. Patient data were handled confidentially. No document uploaded to ClinicalTrials.gov contains the names of research participants or personally identifying information.

20. Summary of Final Study Status

The study was completed after the planned postoperative follow-up period. A total of 98 patients were included in the final analysis. The study compared 53 patients in the standard antisepsis group with 45 patients in the vulvar re-antisepsis group.

The primary outcome was postoperative urinary tract infection according to CDC/NHSN criteria. Secondary outcomes included postoperative urinary symptoms, cystoscopy time, delayed catheter removal, operative characteristics, and postoperative outcomes.