Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Laparoscopic extravesical vs transvesical repair for vesicovaginal fistula: A Randomized trial

Pranjal Chowdhury
All India Institute of Medical Sciences Bhubaneswar
Manoj Kumar Das
urol_manoj@aiimsbhubaneswar.edu.in

All India Institute of Medical Sciences Bhubaneswar
Kirti Singh
All India Institute of Medical Sciences Bhubaneswar
Gorrepati Rohith
All India Institute of Medical Sciences Bhubaneswar
Santosh Kumaraswamy
All India Institute of Medical Sciences Bhubaneswar
Mithilesh Yadav
All India Institute of Medical Sciences Bhubaneswar
Vivek Rathod
All India Institute of Medical Sciences Bhubaneswar
Prasant Nayak
All India Institute of Medical Sciences Bhubaneswar
Swarnendu Mandal
All India Institute of Medical Sciences Bhubaneswar
Kalandi Barik
All India Institute of Medical Sciences Bhubaneswar
Sambit Tripathy
All India Institute of Medical Sciences Bhubaneswar
Muhammed Huzaifa
All India Institute of Medical Sciences Bhubaneswar

Research Article

Keywords: Vesicovaginal fistula, Laparoscopic repair, Transvesical technique, extravesical technique, Mini-O'Connor, Miklos-Moore

Posted Date: September 11th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10794627/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: No competing interests reported.

Abstract

Purpose

To compare the perioperative efficiency, short-term morbidity, and repair outcomes of laparoscopic extravesical and transvesical repair for primary supratrigonal vesicovaginal fistula (VVF).

Methods

This prospective, parallel-arm randomized controlled trial was conducted at a tertiary urology centre between January 2022 and June 2024. Women with primary supratrigonal VVF were randomized to laparoscopic extravesical repair (n = 17) or transvesical repair (n = 15). The primary outcome was total operative time. Secondary outcomes included suturing time, blood loss, postoperative pain, rescue opioid requirement, duration of postoperative bladder-relaxant therapy, hospital stay, repair failure, and complications. Analyses were performed according to the intention-to-treat principle.

Results

Total operative time was significantly shorter in the extravesical group (88.06 ± 4.10 vs 94.30 ± 7.01 min mean difference − 6.24 min, 95% CI − 10.52 to − 1.96; p = 0.006). Suturing time was also shorter with the extravesical approach (15.0 ± 4.0 vs 22.0 ± 5.0 min, mean difference − 7.0 min, 95% CI − 10.31 to − 3.69; p < 0.001). Postoperative bladder-relaxant therapy was required for fewer days in the extravesical group (7.0 ± 2.0 vs 10.0 ± 3.0 days with a mean difference − 3.0 days, 95% CI − 4.89 to − 1.11; p = 0.003). Blood loss, 24-hour pain scores, rescue opioid requirement, hospital stay, complications, and repair failure were comparable between groups.

Conclusion

Laparoscopic extravesical repair was associated with shorter operative and suturing times and reduced postoperative bladder-relaxant requirement, without a demonstrated difference in short-term safety or repair success compared with transvesical repair.

Trial registration:

Clinical Trials Registry–India, CTRI/2021/09/036394.

Introduction

Vesicovaginal fistula (VVF) is a debilitating condition characterized by continuous urinary leakage, perineal irritation, and substantial psychosocial morbidity, often resulting in social isolation and impaired quality of life [1]. An estimated three million women worldwide are affected by untreated fistula [2, 15]. A simple fistula is generally characterized by a small defect (< 0.5 cm) occurring in non-irradiated tissue, whereas recurrent fistulae, larger defects, or those associated with chronic inflammatory disease or prior radiation are considered complex [3].

An abdominal approach is commonly preferred for supratrigonal fistulae, particularly in patients with a narrow vagina, a high-lying fistula, significant surrounding fibrosis, or when concomitant procedures such as ureteric reimplantation or augmentation cystoplasty are anticipated [4–6]. Minimally invasive abdominal repair has gained increasing acceptance because it retains the advantages of transabdominal access while offering improved visualization and magnification, reduced blood loss, faster recovery, and success rates comparable to open repair in experienced hands [6, 7].

Among abdominal techniques, the transvesical approach described by O'Connor has traditionally been considered a standard method. The original procedure involved sagittal bivalving of the bladder through the fistulous tract, followed by separate closure of the vaginal and bladder defects [8]. Subsequent modifications aimed at limiting the extent of cystotomy led to the development of the mini-O'Connor technique, and similar principles have subsequently been adapted to laparoscopic repair [9–11]. In contrast, the extravesical technique popularized by Miklos and Moore involves direct development of the vesicovaginal plane without formal bladder bivalving. The fistulous tract is dissected and excised, followed by further mobilization of the vesicovaginal plane to permit tension-free, separate closure of the vaginal and bladder defects, with interposition of vascularized tissue where appropriate [12].

Direct comparative evidence between these approaches remains limited, with most published data derived from case series and non-randomized studies [2, 7]. This evidence gap is clinically relevant because the choice of surgical approach may influence operative efficiency, perioperative morbidity, postoperative recovery, and functional outcomes. We hypothesized that avoidance of a deliberate cystotomy in the extravesical approach could reduce operative and suturing times and potentially lessen postoperative bladder irritation and morbidity. We therefore conducted a randomized controlled trial comparing laparoscopic extravesical and transvesical repair of primary supratrigonal VVF, with the aim of evaluating operative efficiency, perioperative morbidity, and short-term repair outcomes.

Patients and Methods

Study Design

This was a prospective, parallel-arm randomized controlled trial.

Study setting

The study was conducted in the Department of Urology at All India Institute of Medical Sciences, Bhubaneswar, between 2022 and 2024.

Study Participants.

From January 2022 to June 2024, all patients presenting with supratrigonal vesicovaginal fistula (VVF), confirmed by cystoscopy, were screened for eligibility. Women aged 18–85 years undergoing elective laparoscopic repair of a primary supratrigonal VVF were eligible for inclusion. Patients with recurrent VVF, a history of pelvic irradiation or genitourinary tuberculosis, multiple or complex fistulas, or those requiring concomitant procedures that could influence operative time or blood loss were excluded. Participant enrolment and allocation are summarized in the **CONSORT flow diagram (**Fig. 3**).**

Ethics approval and trial registration

Ethics approval

was provided by institutional ethics committee. Trial registration was done under Clinical trials registration of india CTRI/2021/09/036394 registered on 09/09/2021.

Randomization & Blinding

A computer-generated randomization sequence was used to allocate participants in a 1:1 ratio to either laparoscopic extravesical or laparoscopic transvesical vesicovaginal fistula repair. The sequence was generated by an independent statistician who was not involved in participant enrolment, surgery, or outcome assessment. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes (SNOSE) with tamper-evident sealing. The envelope was opened by the circulating nurse after induction of anaesthesia and immediately before surgery.

Blinding- Participants, outcome assessors, and data analysts were blinded to treatment allocation. The operating surgeons could not be blinded because of the nature of the surgical intervention.

Intervention

All procedures were performed under general anaesthesia using a transperitoneal laparoscopic approach. Following induction, cystoscopy was performed, both ureteric orifices were identified and stented, and the fistulous tract was cannulated with a ureteric stent or infant feeding tube to aid intraoperative localization.

Extravesical repair

The peritoneum overlying the vesicovaginal plane was incised and the plane between the bladder and vagina was developed. The fistulous tract was identified, excised along with surrounding fibrotic tissue,

and the vesicovaginal plane was further mobilized. The bladder and vaginal defects were closed separately with 2 – 0 Vicryl sutures, followed by a bladder leak test. An omental flap was interposed and a pelvic drain was placed.

Transvesical repair

The bladder dome was opened vertically and the cystotomy was extended posteriorly towards the fistulous opening. The bladder was separated from the vagina, and the fistulous tract with adjacent fibrotic margins was excised. The vaginal and bladder defects were closed separately with 2 – 0 Vicryl sutures, followed by a leak test, omental interposition, and drain placement.

A Foley catheter was maintained for 3 weeks in both groups.

Representative operative images of the extravesical and transvesical approaches are shown in Figs. 1 and 2.

Outcomes

Primary outcome:

To compare the total operating time of the laparoscopic transvesical technique and laparoscopic extravesical technique of supratrigonal vesicovaginal fistula repair.
Secondary:
Secondary outcomes included suturing time, intraoperative blood loss, repair success at 3 months, postoperative pain at 24 hours, rescue analgesic requirement, duration of bladder relaxant use, hospital stay, and postoperative complications.

Sample Size Calculation

The sample size was calculated based on **total operative time as the primary outcome**. Laparoscopic transvesical VVF repair was considered the control group and laparoscopic extravesical VVF repair the intervention group. The study was designed to detect a clinically meaningful difference of 30 minutes in mean operative time between the two groups.

The following assumptions were used:

- Anticipated mean operative time in the transvesical group: **170 minutes**
- Anticipated mean operative time in the extravesical group: **140 minutes**
- Pooled standard deviation: **30 minutes**
- Two-sided significance level (α): **5%**
- Statistical power: **80%**
- Allocation ratio: **1:1**

Using these assumptions, **32 participants (16 per group)** were required to detect a mean difference of 30 minutes with 80% power at a two-sided α of 0.05.

Using these assumptions, **32 participants (16 per group)** were required to detect a mean difference of 30 minutes with 80% power at a two-sided α of 0.05.

$$n = \frac{2\sigma^2(Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

The sample size was calculated using **EZR statistical software** according to the formula:

$Z_{\alpha/2}$ is the critical value corresponding to the two-sided significance level, Z_{β} corresponds to the desired statistical power, σ^2 is the assumed population variance, and d is the minimum clinically important difference to be detected.

Statistical Analysis

All analyses were performed according to the intention-to-treat principle using **IBM SPSS Statistics, version 27.0** (IBM Corp., Armonk, NY, USA). Continuous variables were assessed for normality using the Shapiro–Wilk test. Normally distributed continuous variables were expressed as mean ± standard deviation (SD) and compared using the independent-samples Student's t-test, whereas non-normally distributed variables were expressed as median (interquartile range [IQR]) and compared using the Mann–Whitney U test.

Categorical variables were presented as frequency and percentage and compared using the chi-square test or Fisher's exact test, as appropriate. Between-group differences for continuous outcomes were reported as mean differences or median differences with 95% confidence intervals (CIs), while binary outcomes were reported as risk ratios (RRs) with 95% CIs, where applicable.

All statistical tests were two-sided, and a p-value < 0.05 was considered statistically significant. There were no missing outcome data.

Results

The CONSORT flow diagram is shown in Fig. 3. A total of 32 participants were randomized, with 17 allocated to the extravesical group and 15 to the transvesical group. Baseline demographic and clinical characteristics are summarized in Table 1.

Table 1
Baseline demographic and clinical characteristics

Variable	Extravesical group (n = 17)	Transvesical group (n = 15)
Age, years	44.8 ± 6.1	42.8 ± 8.2
BMI, kg/m²	24.4 ± 2.0	26.0 ± 3.0
Menopausal, n (%)	9 (52.9)	7 (46.7)
Etiology of VVF, n (%)		
Total abdominal hysterectomy	13 (76.5)	9 (60.0)
Vaginal hysterectomy	1 (5.9)	4 (26.7)
Laparoscopic hysterectomy	3 (17.6)	1 (6.7)
Obstructed labour	0	1 (6.7)
Interval from index surgery to presentation (Weeks)	14.7 ± 13.2	17.4 ± 13.8
Fistula size, cm	0.98 ± 0.71	1.03 ± 0.75
Duration of VVF symptoms, weeks	12 ± 2	13 ± 4
Comorbidities, n (%)		
Anemia	2 (11.8)	1 (6.7)
Diabetes mellitus	0	2 (13.3)
Hypertension	1 (5.9)	2 (13.3)
Smoking/tobacco use	1 (5.9)	2 (13.3)

Operative times.

Total operative time, the primary outcome, was significantly shorter in the extravesical group than in the transvesical group (88.06 ± 4.10 vs 94.30 ± 7.01 min, mean difference − 6.24 min, 95% CI − 10.52 to − 1.96, p = 0.006).

Mean suturing time was also significantly shorter with the extravesical approach (15.0 ± 4.0 vs 22.0 ± 5.0 min; mean difference − 7.0 min, 95% CI − 10.31 to − 3.69; p < 0.001). These findings demonstrate shorter operative and suturing times with the extravesical technique (Table 2; Fig. 4).

Table 2
-Operative times

Outcome	Extravesical	Transvesical	Effect estimate (95% CI)	p-value
Operative time, min	88.06 ± 4.10	94.30 ± 7.01	−6.24 (− 10.52 to − 1.96)	0.006
Suturing time, min	15.0 ± 4.0 min	22.0 ± 5.0 min	-7.0 (-10.31 to -3.69)	< 0.001

Other operative outcomes.

Other secondary outcomes are summarized in Table 3. Mean blood loss was comparable between the extravesical and transvesical groups (134.1 ± 21.6 vs 125.3 ± 19.2 mL) with a mean difference 8.8 mL, 95% CI − 5.34 to 22.94; p = 0.236). There was also no significant difference in 24-hour postoperative VAS pain scores (4.5 ± 1.3 vs 4.8 ± 1.5) mean difference (− 0.30, 95% CI − 1.28 to 0.68; p = 0.599). Following catheter removal, the duration of postoperative bladder relaxant therapy was significantly shorter in the extravesical group (7.0 ± 2.0 vs 10.0 ± 3.0 days; mean difference − 3.0 days, 95% CI − 4.89 to − 1.11; p = 0.003). Length of hospital stay was comparable between the groups (4.00 ± 1.46 vs 4.27 ± 1.28 days) with a mean difference (− 0.27 days, 95% CI − 1.22 to 0.68; p = 0.586). Rescue opioid requirement was lower in the extravesical group, although the difference was not statistically significant (2/17 [11.8%] vs 5/15 [33.3%]; RR 0.35, 95% CI 0.08–1.56; p = 0.21). Repair failure occurred in 2/17 (11.8%) patients in the extravesical group and 1/15 (6.7%) in the transvesical group, with no significant between-group difference (RR 1.75, 95% CI 0.18–16.67; p = 1.00).

Table 3
Secondary Outcomes: Continuous variables and binary variables

Outcome	Extravesical	Transvesical	Effect size	p-value
Blood loss, mL	134.1 ± 21.6	125.3 ± 19.2	8.8 (95% CI − 5.34 to 22.94)	0.236
VAS pain at 24 h (0–10)	4.5 ± 1.3	4.8 ± 1.5	-0.30 (95% CI − 1.28 to 0.68)	0.599
Bladder relaxant	7.0 ± 2.0	10.0 ± 3.0	−3.0 (95% CI − 4.89 to − 1.11)	< 0.05
Hospital stay, days	4.00 ± 1.46	4.27 ± 1.28	−0.27 (95% CI − 1.22 to 0.68)	0.586
Outcome	Extravesical	Transvesical	RR	p-value
Rescue opiods	11.8%	33.3%	RR 0.35 (95% CI 0.08–1.56)	0.21
Repair failure	2/17	1/15	1.75 (95% CI 0.18–16.67)	1.00

Complications

Postoperative complications were comparable between the transvesical and extravesical groups. UTI occurred in 20.0% versus 11.8% (p = 0.645), urinary retention in 6.7% versus 5.9% (p = 1.00), and hematuria in 6.7% versus 11.8% (p = 1.00), respectively. No ureteric injury was observed in either group.

Discussion

Whether laparoscopic extravesical repair offers meaningful advantages over the traditional transvesical approach for vesicovaginal fistula (VVF) remains uncertain [7]. To our knowledge, this is the first randomized controlled trial directly comparing these two laparoscopic approaches. The principal finding was that the extravesical approach was associated with shorter total operative and suturing times, while short-term safety and repair outcomes were comparable between the two groups.

Our findings are broadly consistent with the available comparative literature. Zhou et al. reported comparable repair success, blood loss, and postoperative outcomes between laparoscopic transvesical and extravesical techniques [13]. Similarly, Tilala et al. observed comparable success rates with both approaches, while the extravesical technique was associated with shorter operative time, lower blood loss, reduced analgesic requirement, fewer postoperative complications, and shorter hospital stay [14]. Although these studies were non-randomized, their findings support the potential perioperative advantages of avoiding extensive bladder opening.

The observed difference in operative efficiency may be related to the inherent technical differences between the two procedures. The extravesical approach relies on targeted development of the vesicovaginal plane and direct dissection of the fistulous tract without formal bladder bivalving. In contrast, the transvesical approach requires intentional cystotomy, intravesical identification and dissection of the fistula, followed by additional bladder closure. In the present study, both total operative time and suturing time were shorter with the extravesical approach. However, the relationship between these components should be interpreted as an association rather than assuming that the reduction in suturing time alone accounted for the shorter overall operative time.

Another notable finding was the shorter duration of postoperative bladder-relaxant therapy following extravesical repair. One possible explanation is that avoidance of a larger cystotomy and subsequent bladder closure may reduce postoperative bladder irritation and spasm [6]. Nevertheless, bladder spasm was not independently quantified using a validated symptom measure, and this finding should therefore be interpreted cautiously.

The two approaches otherwise demonstrated similar short-term perioperative outcomes. Blood loss, postoperative pain, hospital stay, rescue opioid requirement, postoperative complications, and repair failure did not differ significantly between groups. These findings are consistent with previous reports demonstrating acceptable morbidity and high repair success with both laparoscopic techniques [13, 14]. Comparable repair outcomes may reflect adherence to the fundamental principles of fistula surgery, including adequate exposure, meticulous dissection, excision of unhealthy tissue where required, tension-free layered closure, non-overlapping suture lines, watertight bladder closure, tissue interposition, and adequate postoperative urinary drainage [7].

Although the extravesical technique required less suturing in the present series, technical difficulty and surgeon workload were not formally assessed. Therefore, conclusions regarding ease of performance,

learning curve, or suitability for trainees cannot be drawn from these data. Future studies incorporating objective measures of surgical complexity and surgeon experience may help clarify these potential advantages.

Limitations

This study has several limitations. First, the relatively small sample size limited the statistical power for secondary outcomes, particularly rescue opioid requirement, postoperative complications, and repair failure. Second, this was a single-centre study performed by surgeons experienced in minimally invasive reconstructive surgery, which may limit the generalizability of the findings to other centres and surgeons with different levels of expertise. Third, follow up was focused on early repair outcomes and longer term assessment is required to evaluate durability of repair, late recurrence, lower urinary tract symptoms, sexual function, and patient-reported quality of life.

Conclusion

Our results indicate that, while maintaining blood loss, hospital stay, complication rates, and repair success comparable to those of transvesical repair, laparoscopic extravesical repair offers shorter operating and suturing times and lessens the need for extended postoperative bladder relaxant therapy. When combined with the existing research, this suggests a customized approach: transvesical repair is still a viable choice for more complicated fistulas or situations where intravesical exposure is beneficial, whereas extravesical repair may be favored for simple supratrigonal VVF.

Declaration of Generative AI in Scientific Writing- No AI tool was used for study conception, data collection, data analysis, interpretation of results, generation of scientific content, or formulation of conclusions. Generative artificial intelligence tools were used solely for grammar correction, language refinement, and improving the readability and legibility of the manuscript. The authors reviewed and approved the final manuscript and take full responsibility for its content.

Declarations

Funding-

No source of funds.

Author Contribution

P.C., M.K.D., and P.N. conceived and designed the study. P.C., K.S., G.R., S.K., S.M., K.B., and S.T. contributed to patient recruitment, clinical management, and data acquisition. P.C., M.Y., V.R., M.H., A.K., S.R., and S.D. contributed to data collection and maintenance of the study database. P.C. and M.K.D. performed the statistical analysis and interpreted the results.P.C. prepared the initial draft of the

manuscript. M.K.D., P.N., S.M., and S.T. critically revised the manuscript for important intellectual content. P.C., K.S., and G.R. prepared the tables and figures.

Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request, subject to institutional and ethical restrictions.

References

1. Alio AP, Merrell L, Roxburgh K, Clayton HB, Marty PJ, Bomboka L, Traoré S, Salihu HM. The psychosocial impact of vesico-vaginal fistula in Niger. Archives of gynecology and obstetrics. 2011;284(2):371–8.
2. Hillary CJ, Osman NI, Hilton P, Chapple CR. The aetiology, treatment, and outcome of urogenital fistulae managed in well-and low-resourced countries: a systematic review. European urology. 2016;70(3):478–92.
3. Angioli R, Penalver M, Muzii L, Mendez L, Mirhashemi R, Bellati F, Crocè C, Panici PB. Guidelines of how to manage vesicovaginal fistula. Critical reviews in oncology/hematology. 2003;48(3):295–304.
4. Rajaian S, Pragatheeswarane M, Panda A. Vesicovaginal fistula: review and recent trends. Indian Journal of Urology. 2019;35(4):250–8.
5. Woo HH, Rosario DJ, Chapple CR. The treatment of vesicovaginal fistulae. European urology. 1996;29(1):1–9.
6. McKay E, Watts K, Abraham N. Abdominal approach to vesicovaginal fistula. Urologic Clinics. 2019;46(1):135–46.
7. Ramphal SR. Laparoscopic approach to vesicovaginal fistulae. Best Practice & Research Clinical Obstetrics & Gynaecology. 2019;54:49–60.
8. O'Conor VJ, Sokol JK. Vesicovaginal fistula from the standpoint of the urologist. The Journal of urology. 1951;66(4):579–85.
9. Mallikarjuna C, Nayak P, Reddy KP, Ghouse SM, Ragoori D, Bendigeri MT, Reddy S. The AINU technique for laparoscopic vesico-vaginal fistula repair: a preliminary report. Urologia Internationalis. 2015;95(3):357–60.
10. Dalela D, Ranjan P, Sankhwar PL, Sankhwar SN, Naja V, Goel A. Supratrigonal VVF repair by modified O'Connor's technique: an experience of 26 cases. European urology. 2006;49(3):551–6.
11. Llueca A, Herraiz JL, Rodrigo M, Mazzouzi Y, Piquer D, Guijarro M, Cañete A, Escrig J. Intravesical mini-laparoscopic repair of vesicovaginal fistulas. Gynecological Surgery. 2015;12(4):323–6.
12. Miklos JR, Moore RD. Laparoscopic transperitoneal extravesical approach to vesicovaginal fistula repair without omental flap: a novel technique. International urogynecology journal. 2015;26(3):447–8.

13. Zhou P, Deng W, Li J, Pan H, Wang Y, Song C, Liu W, Fu B. Transvesical versus extravesical approach to laparoscopic posthysterectomy vesicovaginal fistula repair: A retrospective study from two medical centers. Neurourology and Urodynamics. 2021;40(6):1593–9.
14. Tilala YM, Panda S, Paul AS, Mohanty PK, Choudhuri S, Swain S. Comparative Analysis Between Laparoscopic Extravesical Repair and Laparoscopic O'Connor Repair for Supratrigonal Vesicovaginal Fistula. Urology Research and Practice. 2024;50(1):58.
15. Wall LL. Obstetric vesicovaginal fistula as an international public-health problem. The Lancet. 2006;368(9542):1201–9.

Figures

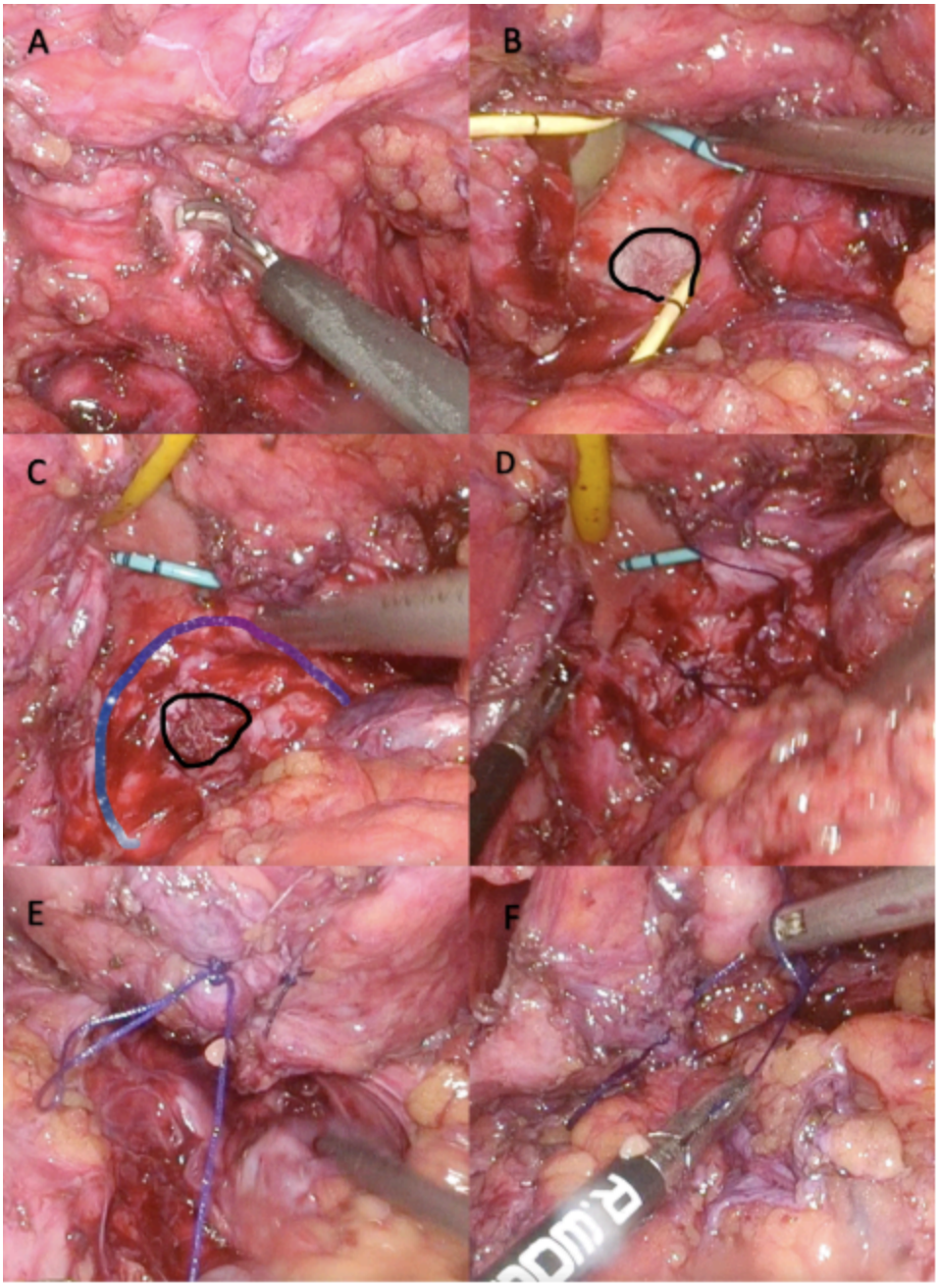


Figure 1

Transvesical approach

(a) Laparoscopic cystotomy and opening of the bladder.

(b) Identification of the fistulous opening within the bladder, aided by catheterization of the tract.

(c) Extension of the cystotomy towards the fistula with delineation of the vesicovaginal plane and fistulous tract.

(d) Closure of the vaginal defect following dissection/excision of the fistulous tract.

(e) Closure of the bladder defect/cystotomy.

(f) Completion of bladder closure prior to omental interposition.

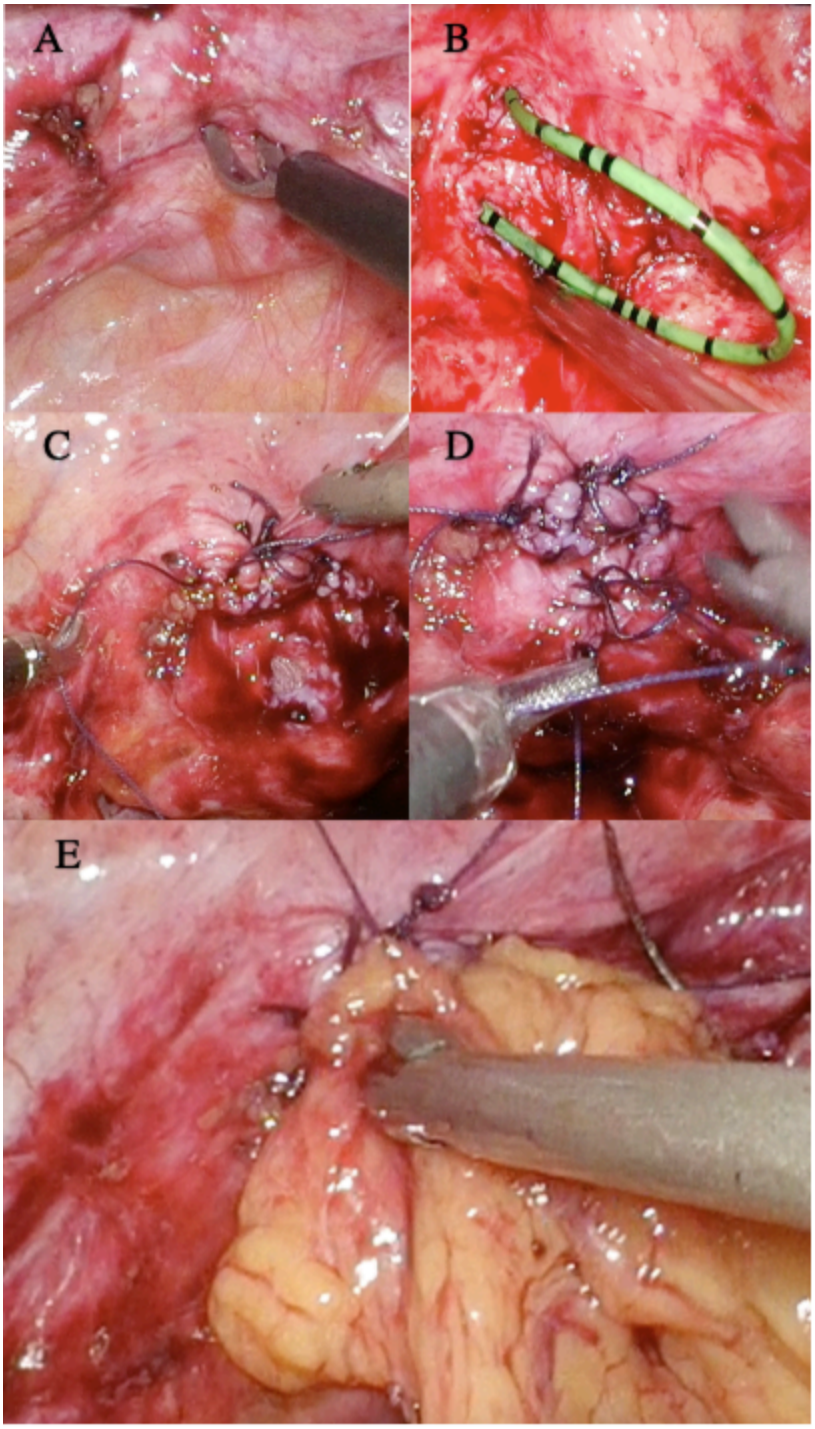


Figure 2

Extravesical approach

(A) Identification of the fistulous site and development of the vesicovaginal plane.

(B) Delineation of the fistulous tract using a catheter/stent passed across the fistula.

(C) Closure of the vaginal defect after dissection/excision of the fistulous tract.

(D) Closure of the bladder defect.

(E) Interposition of an omental flap between the bladder and vaginal suture lines.

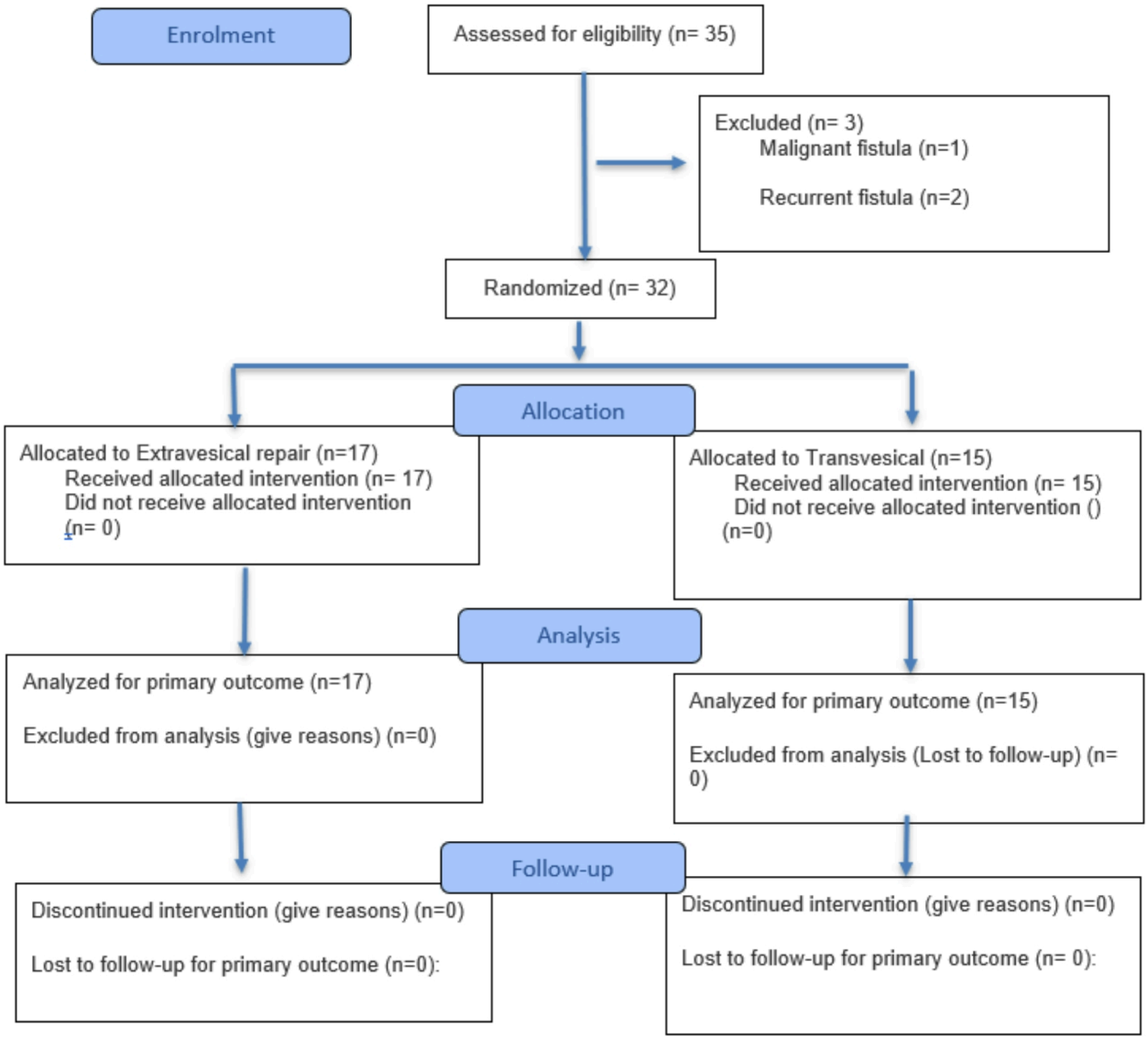


Figure 3

CONSORT Flow diagram.

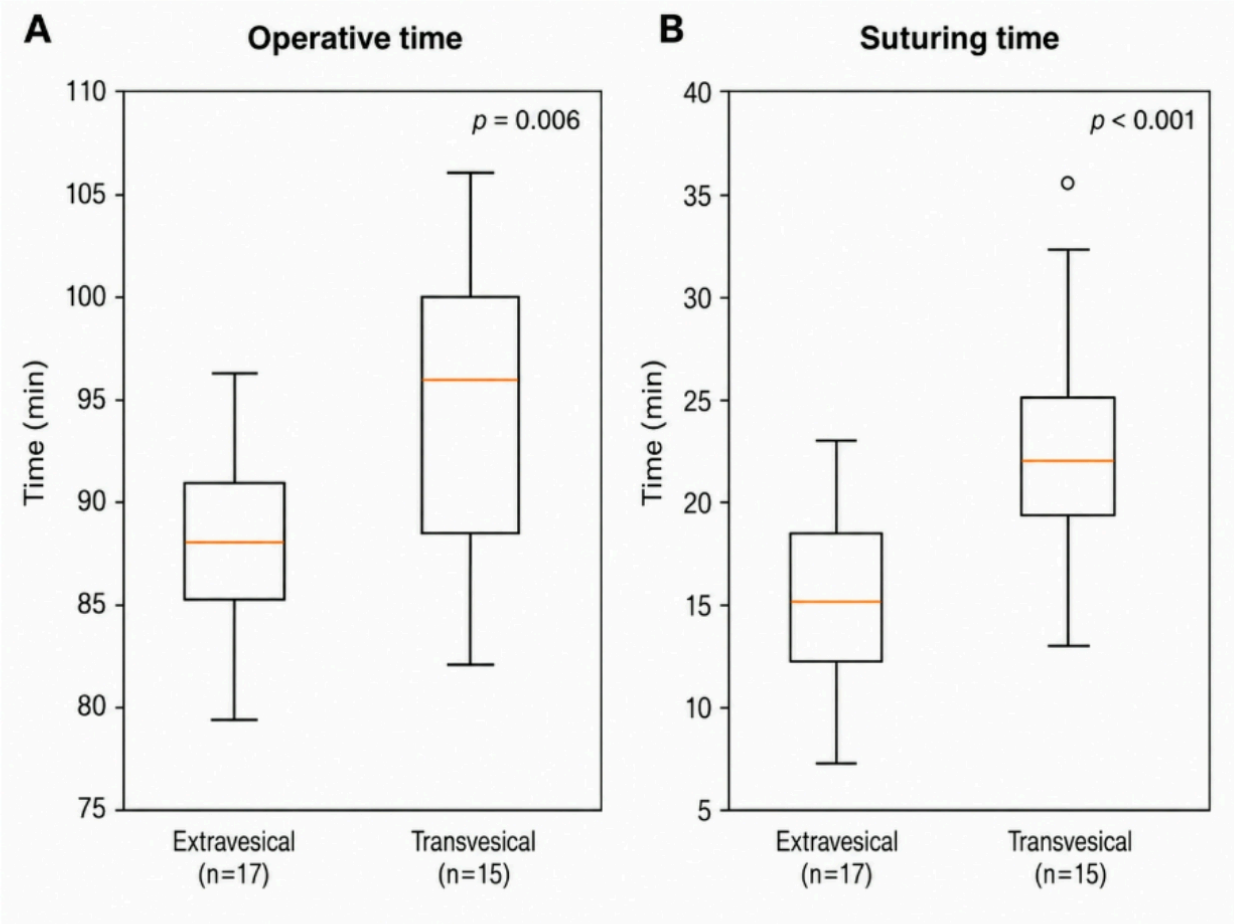


Figure 4

Box-and-whisker plots comparing operative and suturing times between the laparoscopic extravesical and transvesical groups.