

A Prospective Randomized Controlled Study Comparing Cyanoacrylate Glue Injection and Conventional Fistulectomy in the Management of Fistula-in-Ano

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Abstract

Background: Fistula-in-ano is a common benign anorectal condition requiring treatment that eradicates the fistulous tract while preserving anal sphincter function. Conventional fistulectomy remains the standard treatment but is associated with postoperative pain, prolonged wound healing, and risk of continence impairment. Cyanoacrylate glue injection has emerged as a minimally invasive sphincter-preserving alternative.

Aim: To compare the clinical outcomes of cyanoacrylate glue injection and conventional fistulectomy in the management of uncomplicated fistula-in-ano.

Materials and Methods: This prospective randomized controlled study included 80 patients with uncomplicated fistula-in-ano who were randomly allocated into two equal groups. Group A (n=40) underwent cyanoacrylate glue injection, while Group B (n=40) underwent conventional fistulectomy. Operative time, blood loss, postoperative pain, wound healing, hospital stay, return to normal activities, complications, recurrence, continence preservation, and patient satisfaction were compared. Statistical analysis was performed using SPSS version 26.0, and a p-value <0.05 was considered statistically significant.

Results: Baseline characteristics were comparable between the groups. Group A demonstrated significantly shorter operative time (18.9 ± 4.3 vs. 36.8 ± 6.4 minutes), lower blood loss (8.5 ± 3.4 vs. 42.6 ± 10.8 mL), lower postoperative pain scores (VAS 2.3 ± 0.8 vs. 5.7 ± 1.2), shorter hospital stay (1.2 ± 0.5 vs. 3.4 ± 0.9 days), faster wound healing (18.4 ± 4.5 vs. 34.8 ± 6.7 days), and earlier return to normal activities (7.8 ± 2.1 vs. 18.5 ± 4.2 days) (all $p < 0.001$). Wound infection, delayed wound healing, and continence disturbances were significantly lower in Group A. Complete healing was achieved in 90% and 95% of patients, while recurrence occurred in 10% and 5% of Groups A and B, respectively, without statistically significant differences.

Conclusion: Cyanoacrylate glue injection provides superior perioperative recovery and functional outcomes with excellent continence preservation while achieving healing rates comparable to conventional fistulectomy. It represents an effective sphincter-preserving alternative for selected patients with uncomplicated fistula-in-ano.

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Introduction

Fistula-in-ano is one of the most frequently encountered benign anorectal disorders in general and colorectal surgical practice. It is characterized by an abnormal epithelialized tract connecting the anal canal or rectum to the perianal skin, most commonly resulting from cryptoglandular infection [1]. Other less common causes include inflammatory bowel disease, tuberculosis, trauma, radiation, and malignancy. The ideal treatment should achieve complete eradication of the fistula, prevent recurrence, preserve anal sphincter function, and minimize postoperative morbidity while maintaining quality of life.[2,3]The disease predominantly affects young and middle-aged

adults, with a male predominance and an annual incidence of approximately 1.2–2.8 cases per 10,000 population[4]. Persistent perianal discharge, recurrent abscess formation, pain, irritation, and hygiene difficulties significantly affect physical, psychological, and social well-being. Since fistula-in-ano commonly occurs during productive years of life, it also contributes to considerable healthcare utilization and socioeconomic burden.[5,6]The cryptoglandular theory proposed by Parks remains the most accepted explanation for fistula formation. Obstruction and infection of anal glands at the dentate line lead to abscess formation, which, after inadequate drainage or spontaneous rupture,

develops into a persistent fistulous tract. MRI and endoanal ultrasonography play important roles in defining fistula anatomy, identifying secondary extensions, and planning treatment, particularly in complex cases.[7-10] Based on its relationship with the sphincter complex, fistulas are classified according to Parks classification into intersphincteric, transsphincteric, suprasphincteric, and extrasphincteric types. The anatomical involvement of sphincter muscles significantly influences treatment selection and the risk of recurrence and postoperative continence impairment.[11,12]

Conventional fistulectomy remains a widely practiced surgical treatment and involves complete excision of the fistulous tract with the advantage of direct visualization and high healing rates in appropriately selected patients.[13-15] However, it is associated with limitations such as prolonged wound healing, postoperative pain, need for repeated dressings, delayed return to daily activities, and potential continence disturbances, particularly in high or recurrent fistulas involving significant sphincter muscle.[16-18] These limitations have encouraged the development of sphincter-preserving procedures, including fibrin glue, fistula plugs, LIFT, VAAFT, laser ablation, and advancement flaps.

Cyanoacrylate glue injection has emerged as a promising minimally invasive option due to its simple technique, rapid polymerization, tissue adhesion, bacteriostatic effect, and ability to promote fibrosis without sphincter division.[19,20] It offers potential advantages including reduced postoperative pain, shorter hospital stay, faster wound healing, preservation of continence, and earlier return to normal activities. Although previous studies have reported encouraging healing rates with cyanoacrylate glue, variations exist due to differences in patient selection, fistula characteristics, and follow-up duration. Most available studies are limited by small sample sizes and observational designs, with insufficient comparative evidence against conventional fistulectomy, particularly in the Indian population.[20]

Therefore, the present prospective randomized controlled study was conducted to compare cyanoacrylate glue injection with conventional fistulectomy in patients with fistula-in-ano, evaluating operative time, postoperative pain, wound healing, hospital stay, return to routine activities, complications, recurrence, continence outcomes, and overall treatment success to determine the optimal surgical approach.

Materials and Methods

This prospective randomized controlled study was conducted in the Department of General Surgery at a tertiary care teaching hospital. The study was conducted at ESIC Medical College and research institute, Kalaburgi over a period of two year, from January 2023 to January 2025.

Study Population: Patients presenting with fistula-in-ano to the General Surgery outpatient department or admitted for elective surgical treatment during the study period were screened for eligibility. A total of 80 patients satisfying the inclusion and exclusion criteria were enrolled in the study and were randomly allocated into two equal groups.

- **Group A (n = 40):** Patients underwent cyanoacrylate glue injection.
- **Group B (n = 40):** Patients underwent conventional fistulectomy.

Eligibility Criteria

Inclusion Criteria

Patients were included if they:

- Were aged between 18 and 65 years.
- Had a clinically diagnosed low fistula-in-ano (intersphincteric or low transsphincteric fistula).
- Had a single external opening.
- Were fit for surgery under spinal anaesthesia.
- Were willing to participate and provided written informed consent.

Exclusion Criteria

Patients were excluded if they:

- Had recurrent fistula-in-ano.
- Had high, complex, horseshoe, suprasphincteric, or extrasphincteric fistulas.
- Had fistulas associated with Crohn's disease, tuberculosis, malignancy, radiation, or trauma.
- Presented with acute anorectal abscess requiring emergency drainage.
- Had uncontrolled diabetes mellitus, immunocompromised status, or severe systemic illness.
- Had previous anorectal surgery affecting sphincter function.
- Were pregnant or lactating.
- Declined participation in the study.

Preoperative Evaluation: All enrolled patients underwent a detailed clinical evaluation that included history taking and physical examination. Demographic variables such as age, sex, body mass index (BMI), duration of symptoms, presenting complaints, history of previous perianal abscess, and associated comorbidities were recorded. Routine laboratory investigations included complete blood count, fasting blood sugar, renal and liver function tests, coagulation profile, viral

serology, urine examination, and electrocardiography whenever indicated. The diagnosis was established by clinical examination, and MRI fistulography was performed in selected patients whenever the fistula anatomy was unclear or complex anatomy was suspected. Patients underwent routine bowel preparation according to institutional protocol and received prophylactic intravenous antibiotics approximately 30 minutes before surgery.

Randomization: Patients were randomized into two equal groups using a computer-generated randomization sequence. Allocation concealment was achieved using serially numbered, sealed opaque envelopes, which were opened immediately before surgery.

Surgical Procedure

Group A: Cyanoacrylate Glue Injection: Patients assigned to Group A underwent cyanoacrylate glue injection under spinal anaesthesia in the lithotomy position. The external and internal openings of the fistula were identified using a malleable probe. The fistulous tract was gently curetted to remove granulation tissue and irrigated thoroughly with normal saline.

After complete drying of the tract, sterile cyanoacrylate tissue adhesive was injected through the external opening until the entire tract was adequately filled. Excess adhesive was removed, and no sphincter division or tissue excision was performed.

Group B: Conventional Fistulectomy: Patients in Group B underwent conventional fistulectomy under spinal anaesthesia in the lithotomy position. After identification of the fistulous tract using a probe, the entire tract was excised along its course while preserving as much sphincter muscle as possible. Adequate haemostasis was achieved, and the wound was left open to heal by secondary intention. Sterile dressing was applied at the end of the procedure.

Postoperative Management: Postoperative care was standardized for both groups. Intravenous antibiotics and analgesics were administered according to institutional protocol and were subsequently converted to oral medications. Patients were advised warm sitz baths beginning on the first postoperative day. Regular wound dressing was performed in patients undergoing fistulectomy until satisfactory wound healing was achieved.

Patients were encouraged to resume oral intake and ambulation as early as possible. Discharge was planned once pain was adequately controlled and the patient's general condition was satisfactory.

Outcome Measures

Primary Outcome: The primary outcome was complete healing of the fistula without recurrence during the follow-up period.

Secondary Outcomes

The secondary outcome measures included:

- Operative time (minutes)
- Postoperative pain assessed using the Visual Analogue Scale (VAS)
- Duration of hospital stay (days)
- Time required for complete wound healing (days)
- Time to return to normal daily activities (days)
- Postoperative complications (bleeding, wound infection, urinary retention, and anal incontinence)
- Recurrence rate
- Overall patient satisfaction

Follow-up: Patients were followed up at 1 week, 2 weeks, 1 month, 3 months, and 6 months after surgery. At each follow-up visit, wound healing, pain score, continence status, postoperative complications, and evidence of recurrence were assessed and documented.

Data Collection: Clinical and operative data were recorded using a predesigned case record form. Information regarding demographic characteristics, clinical presentation, operative findings, postoperative recovery, wound healing, complications, recurrence, and follow-up outcomes was systematically collected for all participants.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean $\pm$ standard deviation (SD), while categorical variables were presented as frequency and percentage. Data normality was assessed using the Shapiro-Wilk test. Continuous variables were compared using the independent Student's t-test for normally distributed data or the Mann-Whitney U test for non-parametric data. Categorical variables were analyzed using the Chi-square test or Fisher's exact test, as appropriate. A p-value <0.05 was considered statistically significant.

Results

A total of 80 patients with fistula-in-ano were enrolled and randomly allocated into two equal groups. Group A (n=40) underwent cyanoacrylate glue injection, whereas Group B (n=40) underwent conventional fistulectomy. All patients completed the study protocol and were included in the final analysis. The baseline demographic and clinical characteristics were comparable between the two groups. The mean age was 39.8 ± 10.2 years in Group A and 41.1 ± 9.8 years in Group B.

($p=0.562$). There was a male predominance in both groups (77.5% vs 75.0%; $p=0.791$).

Similarly, BMI, duration of symptoms, and fistula type distribution (intersphincteric and low transsphincteric fistula) showed no statistically significant differences between the groups, confirming adequate baseline comparability (Table 1). Comparison of operative parameters demonstrated significant advantages of cyanoacrylate glue injection over conventional fistulectomy.

The mean operative time was significantly shorter in Group A compared with Group B (18.9 ± 4.3 vs 36.8 ± 6.4 minutes; $p<0.001$). Intraoperative blood loss was also markedly lower in the cyanoacrylate group (8.5 ± 3.4 vs 42.6 ± 10.8 mL; $p<0.001$). Furthermore, a significantly greater proportion of patients undergoing cyanoacrylate glue injection were suitable for day-care discharge (80.0% vs 10.0%; $p<0.001$), with a shorter mean hospital stay (1.2 ± 0.5 vs 3.4 ± 0.9 days; $p<0.001$) (Table 2).

Postoperative recovery parameters showed significant benefits with cyanoacrylate glue injection. Patients in Group A experienced significantly lower postoperative pain scores at 24 hours compared with Group B (VAS score: 2.3 ± 0.8 vs 5.7 ± 1.2 ; $p<0.001$) and required fewer analgesic doses during the first 48 hours (2.1 ± 0.7 vs 4.2 ± 1.1 ; $p<0.001$).

Wound healing occurred significantly earlier in the cyanoacrylate group (18.4 ± 4.5 vs 34.8 ± 6.7 days; $p<0.001$), and patients returned to normal activities much earlier (7.8 ± 2.1 vs 18.5 ± 4.2 days; $p<0.001$) (Table 3). The comparative trend of postoperative pain reduction and accelerated recovery is illustrated in Figure 1. The incidence of postoperative complications was significantly lower among patients treated with cyanoacrylate glue injection. Wound infection occurred in 5.0% of patients in Group A compared with 20.0% in Group B ($p=0.043$). Delayed wound healing was

also significantly less frequent in the cyanoacrylate group (5.0% vs 25.0%; $p=0.012$). Temporary flatus incontinence occurred only in the fistulectomy group (0% vs 10.0%; $p=0.040$). Although bleeding and urinary retention were numerically lower in Group A, these differences were not statistically significant (Table 4).

The distribution of postoperative complications between the two groups is presented graphically in Figure 2. At six months follow-up, complete healing was achieved in 90.0% of patients in the cyanoacrylate group and 95.0% in the fistulectomy group; however, the difference was not statistically significant ($p=0.394$). Similarly, recurrence rates (10.0% vs 5.0%; $p=0.394$) and requirement for re-intervention (7.5% vs 5.0%; $p=0.643$) were comparable between the groups. However, preservation of continence was significantly higher following cyanoacrylate glue injection (100.0% vs 87.5%; $p=0.021$) (Table 5). The overall follow-up outcomes are depicted in Figure 3. Patient satisfaction was significantly superior in the cyanoacrylate group. A greater proportion of patients reported excellent satisfaction after cyanoacrylate injection compared with fistulectomy (60.0% vs 35.0%; $p=0.031$). The mean overall satisfaction score was also significantly higher in Group A (9.1 ± 0.8 vs 7.6 ± 1.2 ; $p<0.001$) (Table 6).

Overall clinical outcome analysis demonstrated that although conventional fistulectomy had a slightly higher procedure success rate (95.0% vs 90.0%; $p=0.394$) and lower recurrence rate (5.0% vs 10.0%; $p=0.394$), cyanoacrylate glue injection provided significant advantages in terms of reduced hospital stay, faster wound healing, earlier return to work, and lower overall complication rates. The overall complication rate was significantly lower in Group A compared with Group B (15.0% vs 47.5%; $p=0.002$) (Table 7).

Table 1: Baseline Demographic and Clinical Characteristics

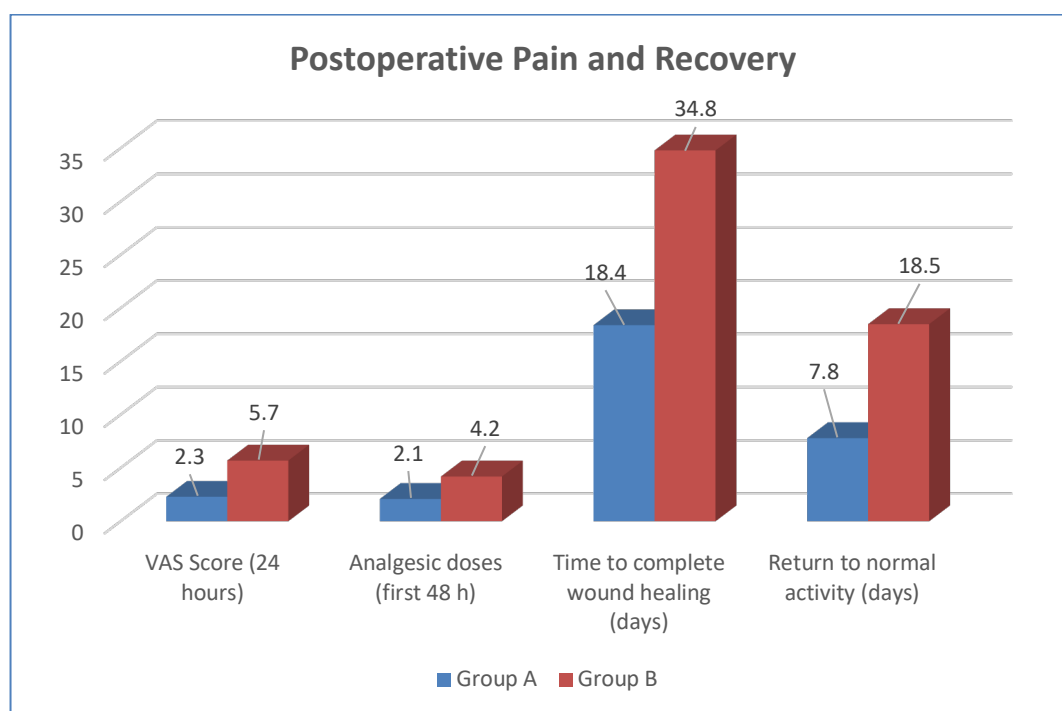
Variable	Group A (Cyanoacrylate) (n=40)	Group B (Fistulectomy) (n=40)	p-value
Age (years), Mean $\pm$ SD	39.8 ± 10.2	41.1 ± 9.8	0.562
Male, n (%)	31 (77.5)	30 (75.0)	0.791
Female, n (%)	9 (22.5)	10 (25.0)	
BMI (kg/m ²), Mean $\pm$ SD	24.7 ± 3.2	25.1 ± 3.5	0.611
Duration of symptoms (months), Mean $\pm$ SD	8.6 ± 3.9	9.1 ± 4.2	0.584
Intersphincteric fistula, n (%)	24 (60.0)	23 (57.5)	0.820
Low transsphincteric fistula, n (%)	16 (40.0)	17 (42.5)	

Table 2: Operative Characteristics

Parameter	Group A (Cyanoacrylate)	Group B (Fistulectomy)	p-value
Operative time (minutes), Mean $\pm$ SD	18.9 $\pm$ 4.3	36.8 $\pm$ 6.4	<0.001
Blood loss (mL), Mean $\pm$ SD	8.5 $\pm$ 3.4	42.6 $\pm$ 10.8	<0.001
Day-care discharge, n (%)	32 (80.0)	4 (10.0)	<0.001
Hospital stay (days), Mean $\pm$ SD	1.2 $\pm$ 0.5	3.4 $\pm$ 0.9	<0.001

Table 3: Postoperative Pain and Recovery

Parameter	Group A	Group B	p-value
VAS Score (24 hours)	2.3 $\pm$ 0.8	5.7 $\pm$ 1.2	<0.001
Analgesic doses (first 48 h), Mean $\pm$ SD	2.1 $\pm$ 0.7	4.2 $\pm$ 1.1	<0.001
Time to complete wound healing (days), Mean $\pm$ SD	18.4 $\pm$ 4.5	34.8 $\pm$ 6.7	<0.001
Return to normal activity (days), Mean $\pm$ SD	7.8 $\pm$ 2.1	18.5 $\pm$ 4.2	<0.001

**Figure 1: Postoperative Pain and Recovery****Table 4: Postoperative Complications**

Complication	Group A n (%)	Group B n (%)	p-value
Wound infection	2 (5.0)	8 (20.0)	0.043
Bleeding	1 (2.5)	5 (12.5)	0.089
Urinary retention	1 (2.5)	3 (7.5)	0.306
Delayed wound healing	2 (5.0)	10 (25.0)	0.012
Temporary flatus incontinence	0 (0.0)	4 (10.0)	0.040
Persistent fecal incontinence	0 (0.0)	1 (2.5)	0.314

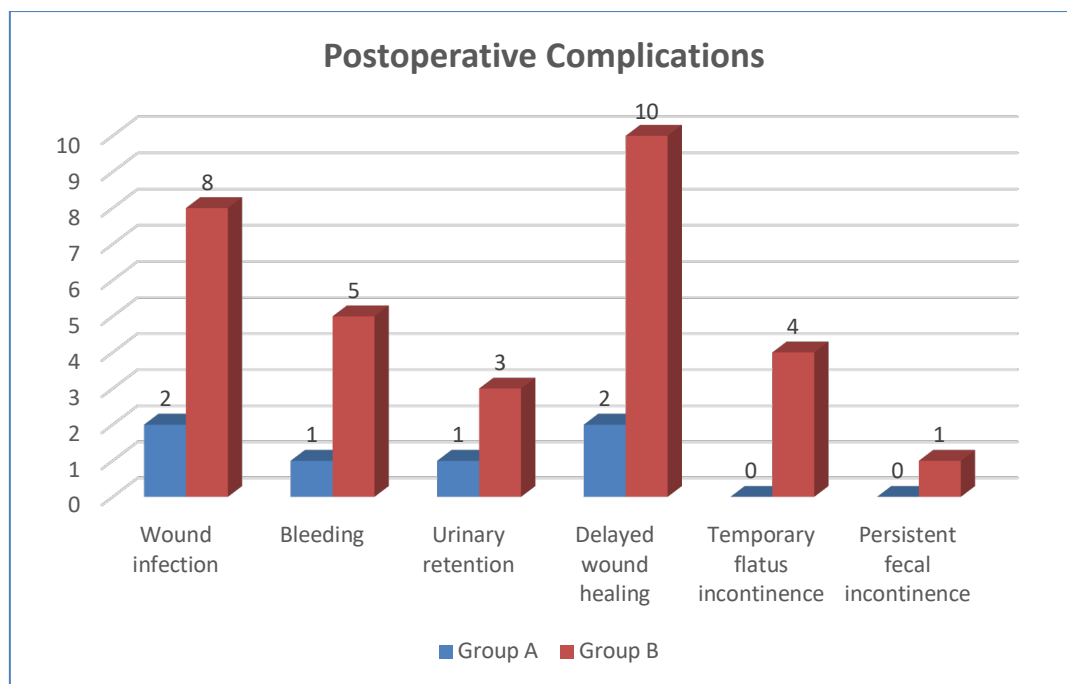


Figure 2: Postoperative Complications

Table 5: Follow-up Outcomes

Outcome	Group A	Group B	p-value
Complete healing, n (%)	36 (90.0)	38 (95.0)	0.394
Recurrence within 6 months, n (%)	4 (10.0)	2 (5.0)	0.394
Re-intervention required, n (%)	3 (7.5)	2 (5.0)	0.643
Continence preserved, n (%)	40 (100.0)	35 (87.5)	0.021

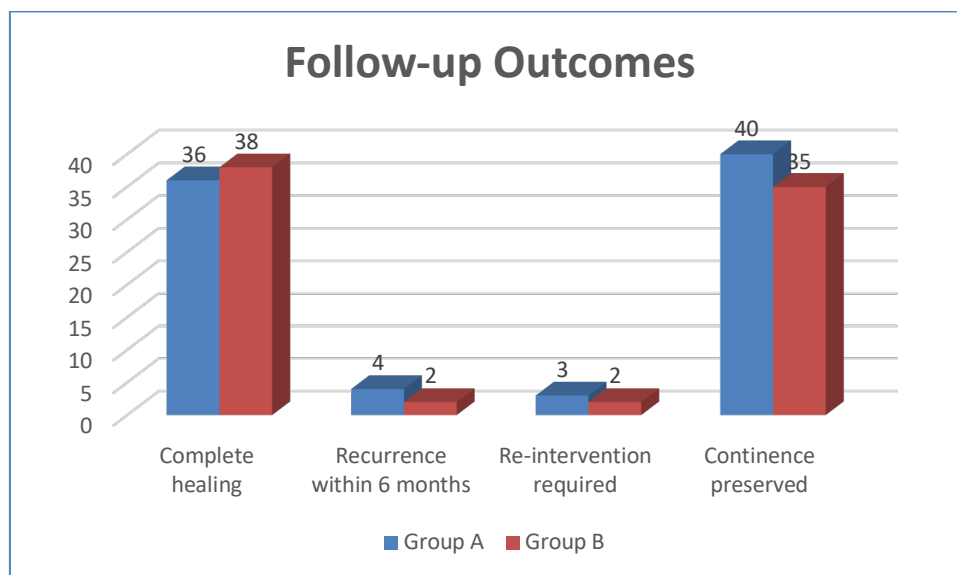


Figure 3: Follow-up Outcomes

Table 6: Patient Satisfaction

Parameter	Group A	Group B	p-value
Excellent	24 (60.0)	14 (35.0)	0.031
Good	12 (30.0)	16 (40.0)	
Fair	3 (7.5)	8 (20.0)	
Poor	1 (2.5)	2 (5.0)	
Overall satisfaction score (0–10), Mean $\pm$ SD	9.1 $\pm$ 0.8	7.6 $\pm$ 1.2	<0.001

Table 7: Comparison of Overall Clinical Outcomes

Clinical Outcome	Group A	Group B	p-value
Procedure success (%)	90.0	95.0	0.394
Mean hospital stay (days)	1.2 ± 0.5	3.4 ± 0.9	<0.001
Mean wound healing time (days)	18.4 ± 4.5	34.8 ± 6.7	<0.001
Return to work (days)	8.9 ± 2.4	20.2 ± 4.5	<0.001
Overall complication rate, n (%)	6 (15.0)	19 (47.5)	0.002
Overall recurrence rate, n (%)	4 (10.0)	2 (5.0)	0.394

Discussion

The present prospective randomized controlled study compared cyanoacrylate glue injection with conventional fistulectomy for uncomplicated fistula-in-ano. Cyanoacrylate glue demonstrated significant perioperative and postoperative advantages, including shorter operative time, reduced blood loss, lower postoperative pain, shorter hospital stay, faster wound healing, and earlier return to daily activities, fewer wound-related complications, better continence preservation, and higher patient satisfaction. Although conventional fistulectomy achieved slightly higher healing (95% vs. 90%) and lower recurrence rates (5% vs. 10%), the differences were not statistically significant, indicating that cyanoacrylate glue provides comparable disease control with superior functional outcomes. The operative time was significantly shorter in the cyanoacrylate glue group (18.9 ± 4.3 vs. 36.8 ± 6.4 minutes; $p < 0.001$), with significantly lower intraoperative blood loss (8.5 ± 3.4 vs. 42.6 ± 10.8 mL; $p < 0.001$). This advantage is attributed to the minimally invasive nature of glue therapy, which avoids extensive dissection, tissue excision, and open wound management. Previous studies have also demonstrated reduced operative duration and feasibility of day-care management following cyanoacrylate glue injection in simple fistula-in-ano.[19,20] These findings highlight its potential benefits in improving operative efficiency and reducing anaesthetic exposure.

Postoperative recovery was significantly better with cyanoacrylate glue. Patients had lower pain scores at 24 hours (2.3 ± 0.8 vs. 5.7 ± 1.2 ; $p < 0.001$), required fewer analgesic doses during the first 48 hours (2.1 ± 0.7 vs. 4.2 ± 1.1 ; $p < 0.001$), and returned to routine activities earlier (7.8 ± 2.1 vs. 18.5 ± 4.2 days; $p < 0.001$). Complete wound healing occurred earlier in the glue group (18.4 ± 4.5 vs. 34.8 ± 6.7 days). The absence of an open surgical wound following glue application reduces postoperative discomfort, need for repeated dressings, and prolonged wound care. Similar improvements in pain control, recovery time, and hospital stay have been reported with cyanoacrylate glue and other sphincter-preserving procedures.[19,20] Preservation of continence is a major consideration in fistula surgery. In the present study, all patients in the cyanoacrylate glue

group maintained normal continence, whereas temporary flatus incontinence occurred in 10% and persistent fecal incontinence in 2.5% of patients undergoing fistulectomy (overall continence preservation: 100% vs. 87.5%; $p = 0.021$). Since glue injection does not involve sphincter division or extensive dissection, the risk of functional impairment is minimized. Previous studies have similarly demonstrated excellent continence outcomes with sphincter-preserving techniques, supporting their role in reducing postoperative morbidity.[19,20] Wound-related complications were significantly lower after cyanoacrylate glue injection. Wound infection occurred in 5% of patients compared with 20% after fistulectomy ($p = 0.043$), and delayed wound healing was reduced (5% vs. 25%; $p = 0.012$). The overall complication rate was significantly lower in the glue group (15% vs. 47.5%; $p = 0.002$). These findings are explained by reduced tissue trauma, absence of an open wound, and decreased inflammatory response associated with glue-based closure.[19,20] Healing outcomes remained comparable between the two techniques. Complete healing was achieved in 90% of glue-treated patients and 95% after fistulectomy, with no significant difference in recurrence (10% vs. 5%; $p = 0.394$). Although glue therapy does not excise the tract, meticulous curettage and complete filling of the fistulous pathway can achieve satisfactory closure. Previous studies have reported variable healing rates (40–85%) with cyanoacrylate glue, depending on fistula complexity, patient selection, and procedural technique.[19,20] The favourable healing rate observed in the present study may be attributed to inclusion of uncomplicated fistulas and standardized treatment methodology. Patient satisfaction was significantly higher in the cyanoacrylate glue group, with more patients reporting excellent outcomes (60% vs. 35%) and higher satisfaction scores (9.1 ± 0.8 vs. 7.6 ± 1.2 ; $p < 0.001$). Reduced pain, rapid recovery, shorter hospitalization, avoidance of wound dressing, and preservation of continence contributed to improved patient experience.

Conclusion

Cyanoacrylate glue injection is a safe, effective, and minimally invasive sphincter-preserving treatment for uncomplicated fistula-in-ano. Compared with conventional fistulectomy, it significantly reduced operative time, postoperative

pain, hospital stay, wound-related complications, and time to return to normal activities while providing excellent continence preservation and higher patient satisfaction. Although conventional fistulectomy demonstrated a marginally lower recurrence rate, the difference was not statistically significant. Cyanoacrylate glue injection may therefore be considered a valuable alternative to conventional fistulectomy in appropriately selected patients with simple fistula-in-ano.

Limitations

The present study was conducted at a single tertiary care center with a relatively small sample size and a follow-up period of only six months. Longer-term multicentric studies with larger patient populations are required to evaluate the long-term recurrence rates, durability of healing, continence outcomes, and cost-effectiveness of cyanoacrylate glue injection.

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