fortune Journals

Research Article

JOURNAL OF SURGERY AND RESEARCH

ISSN: 2640-1002

Efficacy and Patient Outcomes of Hybrid Rubber Seton in the Management of Complex Anal Fistulas

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Abstract

Background: Complex anal fistulas present a significant surgical challenge due to high recurrence rates and the risk of fecal incontinence. The hybrid rubber seton technique, combining features of both cutting and drainage setons, has emerged as a promising approach to improve healing while preserving sphincter function. This study evaluates the efficacy and patient outcomes of hybrid rubber seton placement in the management of complex anal fistulas.

Methods: This prospective observational study was conducted from July 2021 to June 2024 across six hospitals in Bangladesh, including 94 patients with complex anal fistulas. Operative details were documented using the St Mark's Hospital fistula operation note format. Post-operative outcomes, including seton drop time, wound healing duration, recurrence rates, and complications, were recorded. Statistical analysis was performed using SPSS version 25.

Results: The majority of patients (78.7%) had high trans-sphincteric fistulas. The median seton drop time was 6 weeks, and 59.6% of patients required more than 60 days for complete wound healing. The recurrence rate within six months was 12.8%, and no cases of permanent fecal incontinence were reported. Reactionary hemorrhage occurred in 27.7% of patients, but no infective complications were observed. Overall, 74.5% of patients reported being very satisfied with the procedure.

Conclusion: The hybrid rubber seton is an effective and safe technique for managing complex anal fistulas, offering favorable healing rates with minimal risk of incontinence. It remains a viable treatment option, balancing fistula closure and sphincter preservation. Further research should focus on long-term functional outcomes and comparative studies with newer techniques.

Keywords: Anal fistula; Hybrid rubber seton; Complex fistula; Seton technique; Fistula healing

Introduction

Complex anal fistulas pose significant challenges in colorectal surgery due to their high recurrence rates and the risk of fecal incontinence following treatment [1,2]. These fistulas often involve multiple or high tracts crossing different sphincteric planes, necessitating a delicate balance between sepsis eradication and sphincter preservation [3]. Various surgical techniques have been developed, including advancement flaps, ligation of the intersphincteric fistula tract (LIFT), fistula plug and seton placement. Among these, the use

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Citation: Tariq Akhtar Khan, Mohammad Ali, Krishna Pada Saha, Md. Nashir Uddin, Md. Lutful Kabir Khan, Nunjirul Muhsenin, Nazmun Nahar, Sawantee Joarder, Md. Kuddus Ali Khan. Efficacy and Patient Outcomes of Hybrid Rubber Seton in the Management of Complex Anal Fistulas. Journal of Surgery and Research. 8 (2025): 139-144.

Received: February 10, 2025
Accepted: February 17, 2025
Published: February 27, 2025

of setons has gained considerable attention as a method to facilitate drainage while minimizing sphincter damage [4].

Setons have been traditionally classified into cutting and drainage types. Cutting setons work by gradually transecting the sphincter, while drainage setons help in controlling infection and reducing recurrence. The hybrid rubber seton, a modification combining both principles, has emerged as a promising approach [5,6]. It allows slow cutting of the fistula tract while simultaneously providing drainage, thereby reducing post-operative pain and preserving sphincter function [7]. Despite its increasing use, there is limited high-quality evidence assessing its long-term efficacy and patient outcomes, particularly in complex cases.

Bangladesh, like many other countries, faces a high burden of complex anal fistulas, often requiring multiple interventions due to recurrence and inadequate healing. While various seton techniques are employed in clinical practice, there is a lack of standardized protocols and outcome-based research specific to the hybrid rubber seton [8,9]. Understanding the efficacy of this technique in terms of healing time, recurrence rate, and patient satisfaction is crucial for optimizing surgical strategies [10,11].

This prospective observational study aims to evaluate the efficacy and patient outcomes of the hybrid rubber seton in managing complex anal fistulas. The study focuses on key post-operative indicators, including seton drop time, wound healing duration, recurrence within six months, and overall patient satisfaction. Additionally, secondary outcomes such as pain management, complications, and return to daily activities will be assessed.

By analyzing data from six hospitals in Bangladesh, this study seeks to provide robust clinical insights into the hybrid rubber seton's role in complex anal fistula management. The findings will contribute to the growing body of evidence on sphincter-preserving techniques and help refine surgical approaches for better patient outcomes.

Methodology and Materials

This prospective observational study was conducted over three years, from July 2021 to June 2024, involving 94 patients diagnosed with complex anal fistula who underwent hybrid rubber seton placement. The study was carried out in six hospitals across Bangladesh, including five in Dhaka (Shaheed Suhrawardy Medical College Hospital, Mugda Medical College Hospital, Super Specialized Hospital, Impulse Hospital, and Labaid Cancer & Super Specialty Hospital) and one in Jhenaidah (Rabeya Hospital).

Initially, 445 patients were diagnosed with anal fistula. Of these, 351 patients were excluded as they did not meet the criteria for hybrid rubber seton placement. This included 35 patients with superficial fistulas, 213 patients with inter-sphincteric fistulas, 1 patient with Extra-sphincteric and 102 patients with low trans-sphincteric fistulas, as these cases were more suitable for fistulotomy or other treatment approaches. Patients with superficial, inter-sphincteric, low trans-sphincteric (in males), and extra-sphincteric fistulas were excluded from our study. After these exclusions, 94 patients with complex anal fistulas were enrolled in the study.

Patients were selected based on clinical and radiological confirmation of complex anal fistula. Exclusion criteria included simple fistulas, inflammatory bowel disease-associated fistulas, and patients with significant comorbidities affecting wound healing. All surgical procedures were performed by experienced colorectal surgeons following a standardized technique. Wrist band of surgical gloves were used as the seton material in all cases. It was just snugly fitted around the external sphincter at the time of surgery. All other tissues involved in the tract were divided. Seton was usually first tightened at second post operative follow up at 3rd week using a silk suture material proximal to the knot of the seton.

Operative data were documented using St Mark's Hospital fistula operation note format, detailing fistula classification, seton placement technique, and intraoperative findings. Demographic data and post-operative outcomes were recorded using a structured data sheet. Patients were followed up at one week post-surgery, then every two to four weeks until complete healing was achieved. Data collected included seton drop time, wound healing duration, recurrence within six months, complications, and patient satisfaction.

Post-operative pain management included multimodal analgesics. Patients were monitored for reactionary hemorrhage, infective complications, and relief from perianal symptoms. The primary outcome measures were time to seton drop, complete wound healing, recurrence rate, and overall patient satisfaction. Secondary outcomes included hospital stay duration, return to daily activities, and the number of follow-ups required.

Ethical approval was obtained from the respective institutional review boards of all participating hospitals, and informed consent was taken from all patients. Data were analyzed using SPSS version 25, with results presented in descriptive and comparative formats. Statistical significance was determined where applicable.

Results

Figure 1 presents the age distribution of 94 patients undergoing hybrid rubber seton treatment for anal fistula. The majority of patients (41.5%) were in the 31–40 years age group, followed by 21–30 years (22.3%) and 41–50 years (17.0%). The mean age was 39.3 ± 11.9 years, with only a small proportion of patients aged ≤20 years (1.1%) and >60 years (6.4%).

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Khan TA, et al., J Surg Res 2025
DOI:10.26502/jsr.10020430

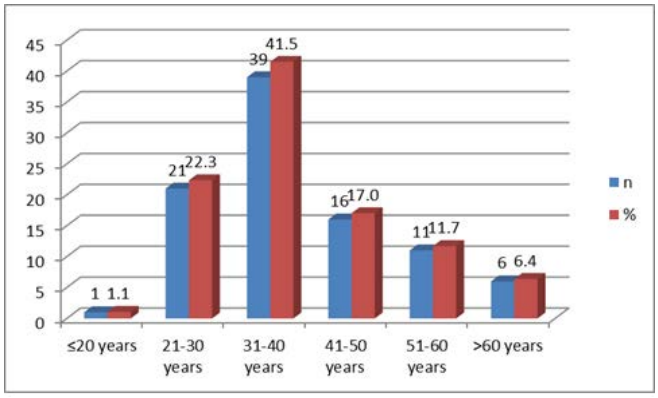

Figure 1: Age distribution (N = 94).

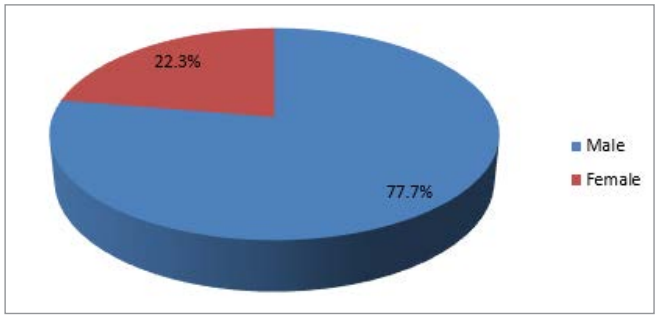

Figure 2: Sex distribution (N = 94)

Figure 2 illustrates the sex distribution of 94 patients undergoing hybrid rubber seton treatment for anal fistula. Males constituted the majority (77.7%, n=73), while females accounted for 22.3% (n=21). The male-to-female ratio was 3.5:1, indicating a higher prevalence of anal fistula cases among males.

Table 1: Parks Classification in all the anal fistula diagnosed patients (N = 445).

Tract Type	N	%
Superficial	35	7.9
Intersphicteric	219	49.2
Transsphincteric (Low)	102	22.9
Transsphincteric (High)	74	16.6
Suprasphincteric	14	3.1
Extrasphincteric	1	0.2
Total	445	100

Table 1 presents the Parks classification of all 445 diagnosed anal fistula patients. The most common type was intersphincteric fistula (49.2%), followed by low transsphincteric (22.9%) and high transsphincteric (16.6%) fistulas. Superficial fistulas accounted for 7.9%, while suprasphincteric (3.1%) and extrasphincteric (0.2%) fistulas were less frequent. This classification highlights the distribution of fistula types in the study population.

Table 2 presents the Parks classification of the 94 patients who underwent hybrid rubber seton placement. The majority had high trans-sphincteric fistulas (78.7%), followed by supra-sphincteric fistulas (14.9%). A small subset of female patients with low trans-sphincteric fistulas (6.4%) was also included.

Table 2: Rubber Seton Parks Classification (N = 94)

Tract Type	n	%
low trans-sphincteric (female)	6	6.4
Trans-sphincteric (High)	74	78.7
Supra-sphincteric	14	14.9
Total	94	100

Table 3: Fistula AGA Classification (N = 445).

Type	n	%
Simple	286	64.3
Complex	159	35.7
Total	445	100

Table 3 presents the AGA classification of 445 fistula cases. The majority were simple fistulas (64.3%), while complex fistulas accounted for 35.7%, indicating a significant proportion of challenging cases requiring specialized management.

Table 4: Rubber Seton AGA Classification (N = 94)

Type	n	%
Simple	0	0.0
Complex	94	100.0
Total	94	100

Table 4 shows the AGA classification of fistulas treated with a rubber seton in 94 patients. All cases (100%) were classified as complex, highlighting the use of rubber seton primarily for managing complicated fistulas.

Table 5 presents the seton drop time after surgery in 94 patients. Most patients (38.3%) had seton drop after more than 6 weeks, while 27.7% experienced it within 4–6 weeks. Additionally, 22.3% had seton drop within 2–4 weeks, and 11.7% within 2 weeks, indicating variability in healing time.

Table 5: Seton Drop Time from Surgery (N = 94).

Time (weeks)	n	%
<2 weeks	11	11.7
<4 weeks	21	22.3
<6 weeks	26	27.7
>6 weeks	36	38.3
Total	94	100

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Table 6 shows the wound healing time after surgery in 94 patients. The majority (59.6%) took more than 60 days to heal, while cumulative 40.4% healed within 30–60 days. Only 5.3% achieved wound healing in less than 30 days, indicating a prolonged recovery period in most cases.

Table 7 shows the recurrence rate of anal fistula within six months post-surgery in 94 patients. Recurrence occurred in 12.8% of cases, while 87.2% remained recurrence-free, suggesting a favorable outcome with the hybrid rubber seton technique.

Table 8 summarizes post-operative outcomes and patient satisfaction in 94 patients. Reactionary hemorrhage occurred in 27.7% of cases, but no patients required pethidine injection or experienced infective complications within one month. Most (91.5%) had relief from perianal itching within 30 days. The majority (86.2%) required only 2–3 follow-ups. The mean operative time was 45.3 ± 9.5 minutes, with a median hospital stay of 1.4 days and a return to daily activities in 3.7 days. Overall, 74.5% were very satisfied, while dissatisfaction was minimal (1.1%).

Table 6: Wound Healing Time from Surgery (N = 94).

Time (days)		n	%
Cumulative 40.4% within 60 days	<30	5	5.3
	30-60	33	35.1
More than 60 days	60-90	56	59.6
Total		94	100

Table 7: Recurrence of Anal Fistula within 6 Months (N = 94)

Recurrence	n	%
Yes	12	12.8
No	82	87.2
Total	94	100.0

Table 8: Summary of Post-Operative Outcomes and Patient Satisfaction (N = 94).

Variable		n	%
Reactionary hemorrhage	Yes	26	27.7
	No	68	72.3
Need for Pethidine injection	Yes	0	0.0
	No	94	100.0
Infective complications (within 1 month)	Yes	0	0.0
	No	94	100.0
Relief of perianal itching (days)	<30	86	91.5
	30-60	6	6.4
	>60	2	2.1
Number of post-operative follow-ups	2-3	81	86.2
	>4	13	13.8
Operative time (minutes)	Mean ± SD	45.3 ± 9.5	
Hospital stay (days)	Median	1.4	
Return to daily activity (days)	Median	3.7	
Patient satisfaction	Very satisfied	70	74.5
	Satisfied	14	14.9
	Not sure	9	9.6
	Dissatisfied	1	1.1
	Very dissatisfied	0	0.0

Discussion

The management of complex anal fistulas remains a surgical challenge due to the risk of recurrence and sphincter dysfunction. The hybrid rubber seton technique, which combines features of both cutting and drainage setons, has been proposed as an effective approach to balance healing and continence preservation. This study evaluates its efficacy and patient outcomes in a cohort of 94 patients, focusing on seton drop time, healing duration, recurrence rates, and post-operative complications.

Our findings align with previous studies supporting the hybrid seton's role in complex anal fistula treatment. Ege et al. examined 128 patients treated with hybrid setons and reported favorable healing rates with minimal impact on continence [12]. Similarly, Schrader et al., demonstrated that a slowly cutting seton combined with staged fistulotomy resulted in improved healing outcomes with preserved sphincter function [13]. In our study, 87.2% of patients experienced successful healing without recurrence within six months, reinforcing the efficacy of this technique.

One of the key advantages of the hybrid rubber seton is its ability to facilitate gradual tissue division while allowing adequate drainage. Fibrosis associated with secondary healing prevented the two cut ends of the sphincter to retract. The majority of patients in our study experienced seton drop within six weeks, with 38.3% requiring more than six weeks. This is consistent with previous reports from Velchuru et al. indicating an average seton drop time of 4–8 weeks, depending on fistula complexity and patient factors [14].

In terms of healing, 59.6% of patients required more than 60 days, while 35.1% healed within 30–60 days. These results mirror findings from Mukherjee et al. who observed a prolonged healing period in high trans-sphincteric and supra-sphincteric fistulas treated with setons [15]. The delayed healing can be attributed to the slow cutting of sphincter followed by fibrosis and gradual closure of the fistula tract, which reduces the risk of incontinence but necessitates prolonged post-operative care.

Fecal incontinence is a major concern in anal fistula

surgery. Vial et al. conducted a systematic review comparing seton treatments with and without sphincter division, concluding that incontinence rates were significantly lower when the internal anal sphincter was preserved [16]. In our study, no cases of permanent incontinence were reported, and there were no instances of post-operative infective complications, contradictory with the results from Ye et al. which highlighted the importance of sphincter-preserving approaches in complex fistulas [17].

A notable post-operative complication observed in our study was reactionary hemorrhage, occurring in 27.7% of patients. However, none required additional surgical intervention, or blood transfusion because hemorrhage were very little amount and self-limiting. No patients reported severe pain requiring opioid analgesia. These findings support the hybrid seton's safety profile, consistent with Collins et al. who emphasized the importance of effective local anesthesia in anorectal procedures to minimize post-operative pain [18].

Hwang et al. emphasized that treatment selection should be individualized, considering patient factors and fistula characteristics [19]. In our study, patient satisfaction was high, with 74.5% of patients reporting being "very satisfied," indicating that the hybrid rubber seton is well-accepted and effective in real-world clinical practice.

Several alternative techniques have been explored for complex anal fistulas, including fistula plugs, advancement flaps and LIFT procedures. Muhlmann et al. compared complex fistula management strategies and found that seton placement had a comparable success rate to flap-based procedures while reducing the risk of sphincter dysfunction [20]. Williams et al. further noted that hybrid setons offer a balance between cutting efficiency and drainage, making them a preferred option in high trans-sphincteric cases [21].

Recent advancements in minimally invasive techniques, such as laser ablation and video-assisted anal fistula treatment (VAAFT), have also been explored. However, these methods are often limited by high recurrence rate, cost and availability, particularly in resource-limited settings [22]. The hybrid rubber seton remains a cost-effective and widely accessible option, particularly in regions like Bangladesh, where affordability and feasibility play crucial roles in treatment selection also offers a very low recurrence rate compared to other technique.

In our study, the hybrid rubber seton demonstrated a recurrence rate of 12.8%, which is comparatively lower than the recurrence rates reported for other techniques in managing complex anal fistulas. For instance, Andreou et al. reported a recurrence rate of approximately 23% over a mean follow-up of 80 months for mucosal advancement flap procedures [23]. Similarly, Zahra et al. documented a recurrence rate of around 24% for the ligation of the intersphincteric fistula tract (LIFT) technique [24]. Fistula plug treatments, as studied by Hansen et al., have shown recurrence rates ranging from 26.3% to 44.4% [25]. Laser treatments, such as fistula laser closure, reported by Al-Turaihi et al. demonstrated a success rate of approximately 69%, implying a recurrence rate of about 31% [26]. Furthermore, La Torre et al. found that video-assisted anal fistula treatment (VAAFT) had a recurrence rate ranging from 29% at one year to as high as 63% at five years postoperatively [27]. These comparisons highlight that the hybrid rubber seton may offer a more favorable outcome in terms of recurrence rates, making it a promising option for managing complex anal fistulas.

Limitations of the study

This study is limited by its single-country setting and moderate sample size (N=94), which may affect generalizability. The follow-up period of six months may not fully capture long-term recurrence and functional outcomes. Additionally, lack of a control group prevents direct comparison with other treatment methods. Further randomized controlled trials with extended follow-up are needed to validate these findings.

Conclusion

In conclusion, our study demonstrates that the hybrid rubber seton is a highly effective and safe technique for managing complex anal fistulas. It offers favorable healing rates, preserves sphincter function, and maintains high patient satisfaction. While recurrence remains a concern, its rate is comparable to other surgical approaches. Future studies should focus on long-term functional outcomes and comparative trials with newer minimally invasive techniques to further optimize treatment strategies.

Financial support and sponsorship

No funding sources.

Conflicts of interest

There are no conflicts of interest.

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Citation: Tariq Akhtar Khan, Mohammad Ali, Krishna Pada Saha, Md. Nashir Uddin, Md. Lutful Kabir Khan, Nunjirul Muhsenin, Nazmun Nahar, Sawantee Joarder, Md. Kuddus Ali Khan. Efficacy and Patient Outcomes of Hybrid Rubber Seton in the Management of Complex Anal Fistulas. Journal of Surgery and Research. 8 (2025): 139-144.