



## Original Article

# Clinical outcome of elastic seton in comparison to non elastic seton in the management of adult patients with complex anal fistula -a randomized controlled trial.

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### Abstract

**Background:** Complex fistula-in-ano is a therapeutic challenge for both the surgeon and the patient. Surgery is associated with significant morbidity despite of recent advances in treatment modalities. The aim of this study was to evaluate the outcome of elastic seton for the management of complex anal fistula.

**Methods:** This prospective randomized controlled trial was done in clinically diagnosed patients of complex anal fistula who underwent operation by cutting seton placement in the colorectal surgery unit, department of surgery, Bangabandhu Sheikh Mujib Medical University, Dhaka from May, 2015 to April, 2016.

Total 36(50%) patients treated by application of elastic seton (Experimental group) were included in group I and 36 (50%) patients treated by non elastic seton (control group) were included in group II after randomization by lottery. Post operative outcome variables within 6 months follow up after surgery were evaluated.

**Results:** In this study, majority of the patients were found in between 30 to 50 years of age and in the both groups, number of male were higher. Mean healing time was  $42.91 \pm 13.71$  days in elastic seton group and  $77.36 \pm 17.29$  days in non elastic seton group. Staged fistulotomy was required in 35(97.2%) cases of group-II whereas no cases of group-I required staged fistulotomy. Mean duration of seton in place was  $17.02 \pm 7.07$  days in group-I and  $52.38 \pm 7.28$  days in group-II. No significant difference of post operative pain, incontinence and recurrence in both groups.

**Conclusion:** This study showed that the elastic cutting seton may be a valid alternative for the treatment of complex anal fistula, eliminating the need for postoperative adjustment or staged procedure.

**Key words:** Complex anal fistula, Elastic seton, Outcome.

### Introduction

The term complex fistula is modification of Parks classification, which fall in any one of these conditions that is the tract crosses >30% of the external sphincter, anterior fistula in females, multiple tracts, recurrent, or the patients has preexisting incontinence,

Crohn's diseases. The treatment of complex fistula poses a high risk of impairment of continence due to involvement of large portion of anal sphincter.<sup>1</sup>

The objective of fistula surgery is to cure the fistula with the lowest possible recurrence rate, with minimal if any, alteration in continence and do so in the shortest period of time.<sup>2</sup>

In contrast to fistulotomy for low, uncomplicated anal fistulas, a well accepted simple safe and efficient method is still lacking for complex anal fistulas.<sup>3</sup> Several alternative treatment strategies have been practiced in order to preserve the sphincter mechanism including various setons, anorectal

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advancement flap, ligation of intersphincteric fistula tract, glues, anal fistula plug, fistulotomy with reconstruction of the sphincter mechanism, fistula laser closure, VAAFT but none has proven to be ideal.<sup>4</sup>

The oldest and theoretically the simplest seton techniques still occupy an important position in the treatment of complex anal fistula. A seton can be any type of string like foreign material inserted through a fistulous tract, causing an inflammatory reaction which stimulates fibrosis that fixes and prevent retraction of the sphincter continuity when it is divided. It also slowly drains and divides the fistulous tract resulting in eradication of fistula and healing of the wound.<sup>5</sup>

Different types of elastic and non-elastic materials like non-absorbable suture (Silk, Nylon, Polypropylene), Penrose drains, rubber bands, vessel loops, silastic catheters elastic band of surgical gloves, chemical thread and so forth are used for this purpose.<sup>6,7,9</sup> Many variations in seton materials and techniques are described in the literature but there are still insufficient studies comparing surgical and functional results in seton division using different materials till now.<sup>8</sup>

The purpose of this study was to compare the outcome of elastic seton and conventional non- elastic seton in terms of requirement of staged fistulotomy, healing time, disturbance of continence and recurrence of symptoms.

### Materials and Methods:

**Methods:** This prospective randomized controlled trial was done in clinically diagnosed patients of complex anal fistula who under went operation by cutting seton placement in the colorectal unit, department of surgery, Bangabandhu Sheikh Mujib Medical University, Dhaka from May, 2015 to April, 2016 after getting the approval from Institutional Review Board. Total 36(50%) patients were treated by application of elastic seton (Experimental group) included in group I and 36 (50%) patients were treated by non elastic seton (control group) included in group II after randomization by lottery. This trial was registered in Clinical trial.gov.

Complex anal fistula associated with inflammatory bowel disease, malignancy, tuberculosis, patient with pre-operative fecal incontinence, supra levator extension, Patient with diabetes mellitus were excluded from the study.

Outcome variables were post operative pain, postoperative complications, time of complete wound healing, any form of fecal incontinence, requirement of staged procedure, duration of seton in place & recurrence of symptoms.

Patients, who were considered for operation by cutting seton placement due to complex fistula- in-ano at BSMMU were included according to inclusion criteria. Patients were selected from the potential participants after taking consents by random sampling.

Though endorectal USG and MRI has some role in delineating the fistulus tract, these investigations were not performed in all cases due to unavailability and financial constrains. Initial diagnosis was done by clinical examination and confirmed by examination under anaesthesia. Final examination and operation was performed under spinal anaesthesia in lithotomy position. Seton was inserted through the fistula tract. The portion of the tract outside the external sphincter including any secondary tract were laid open and curetted. The internal sphincter below the internal opening was divided.

A thin circular strip with the thicker sleeve from the latex surgical glove (comfit) was used as elastic seton and non absorbable suture material no.1 polypropylene was used as non elastic seton. In case of non elastic cutting seton second stage fistulotomy was done under spinal anaesthesia usually after six weeks.

Preoperative and postoperative continence status were evaluated by Jorge/Wexner Continence Grading Scale. Postoperative pain was evaluated with a visual analog score on the first and seventh postoperative days.

Postoperative follow up was done after 2 weeks, 1 month, 3 months and 6 months in the colorectal unit of department of surgery.

All results were analyzed by using the SPSS version -21. The qualitative data were analyzed by chi square test and quantitative data were analyzed by students t- test. P value <0.05 was accepted as significant.

of group I and 3(9%) patients of group II had history of previous surgery for fistula in ano.

Serous discharge was present in four cases in group I & there was statistically significant difference between two groups (p<0.05).



**Fig 1 a-d :** Elastic seton was made by rounded thicker sleeve of latex surgical glove. **b-c :** Application of elastic seton. **d :** Application of polypropylene-1 around the external sphincter after probing.

## Results

Patients with complex anal fistula who underwent operation by cutting seton placement in the Colorectal Surgery Unit, Department of Surgery, BSMMU, Dhaka were analyzed and presented here. A total of 72 patients were recruited into the trial.

Study revealed maximum patients were in between 30 to 50 years of age & male patients were more in both groups. There were no significant difference in the age and sex distribution between the two groups.

In group-I, 34 (94.4%) patients had high transsphincteric fistula and 2 (5.6%) patients had suprasphincteric fistula. In group-II, 31 (86.1%) patients had high transsphincteric fistula and 5 (13.9%) patients had suprasphincteric fistula. No cases had extrasphincteric fistula.

Maximum cases external openings were posterior in position and were single in number in both groups. Multiple external openings were found in 8(22.2%) and 9(25.0%) patients of group I and II respectively. Six (17%) patients.

Reactionary Hemorrhage was found in one & three cases in group I & group II respectively.

Mean post operative pain at 24 hours, was  $4.19 \pm 1.28$  in group-I and  $4.22 \pm 1.24$  in group-II and at 7 days, the score was  $1.38 \pm 0.68$  in group-I and  $1.52 \pm 0.94$  in group-II respectively. There was no statistically significant difference in mean post operative pain score at 24 hours and 7 days in both groups.

No cases required staged fistulotomy in group-I whereas 35 (97.2%) cases of group-II required staged

fistulotomy. There was significant difference between these two groups ( $p < 0.05$ ). Mean duration of seton in place in group-I was  $17.02 \pm 7.07$  days and in group-II was  $52.38 \pm 7.28$  days. There was statistically significant difference between these two groups ( $p < 0.001$ ). Among the patients developing incontinence, all had transient incontinence and no patient of both groups had any form of incontinence at one month. There was no statistically significant difference between these two groups ( $p > 0.05$ ).

There were recurrence of symptoms within 6 months in two (5.6%) and one (2.8%) cases of elastic seton and non-elastic seton groups respectively. There was no statistically significant difference between these two groups ( $p > 0.05$ ).

Mean duration of healing in group-I was  $42.91 \pm 13.71$  days and group-II was  $77.36 \pm 17.29$  days. Healing time was significantly rapid in elastic seton group.  $p < 0.001$ .

**Table I**

*Distribution of study subjects according to postoperative pain in groups*

Post operative pain	Group		p value
	Group-I	Group-II	
At 24 hours			
• Moderate	33 (91.7)	34 (94.4)	0.643
• Severe	3 (8.3)	2 (5.6)	
At 7 days			
Mild	32 (88.9)	31 (86.1)	0.772
Moderate	4 (11.1)	5 (13.9)	

**Table II**

*Distribution of study subjects according to staged fistulotomy in groups*

Staged fistulotomy	Group		p value
	Group-I	Group-II	
Required	0 (0.0)	35 (97.2)	<0.001
Not required	36(100.0)	1 (3.0)	

**Table III**

*Distribution of study subjects according to fecal incontinence in groups*

Fecal incontinence (at 14 days)	Group		p value
	Group-I	Group-II	
Flatus	4 (11.1)	3 (8.3)	0.547
Liquid stool	1 (2.8)	0 (0.0)	

### Discussion:

Seton division is an old surgical process which is still widely applied for the management of complex anal fistula. Non-elastic seton used as cutting seton and two stage fistulotomy technique has higher risk of continence disturbance and needs post-operative adjustment or staged procedure. Cutting seton causes intermittent sharp cut which is a painful procedure and needs repeated hospital visit.<sup>9,12</sup> Two staged fistulotomy, done under spinal anaesthesia, needs hospital readmission which lengthens total times of hospital stay, prolong healing time, delayed return to work and cutting seton technique was therefore conceived.

Recently, some centre used elastic seton which was created by cutting a thin circular strip from a surgical glove including its thicker sleeve. The positive contribution of elastic seton is to reduce continence disturbance effected by a slower gradual severance of tissue. There was no requirement of replacement or re-tightening or staged procedure due to the elastic nature of this seton which ensure its slow migration caudally. The elastic seton also causes minimal patient discomfort due to its soft nature.<sup>9,12,14</sup>

This study has shown that elastic seton is an effective tools for the treatment of complex anal fistula. In this study, maximum patients belong to 4th, 5th decades and male predominate in both groups which were in accordance with the literatures<sup>2,21</sup>.

Serous discharge was present in 4(11.1%) cases of group I until the elastic seton dropped out, may be due to tissue reaction of latex material, which was managed conservatively. Similar result was also found in other studies where latex material (surgical gloves) was used as elastic seton<sup>9,12</sup>. With regard to postoperative pain, there was no significant difference of pain score between two groups.

In elastic seton group, no cases required staged fistulotomy whereas about all cases (97.2%) of non elastic seton group required staged fistulotomy. In one (2.8%) patient treated by non elastic seton, tract became more superficial and the seton lies just beneath the surface which was removed and the wound was healed without any recurrence.

This study result was similar to the studies of Turkey where no cases of elastic seton required staged fistulotomy or any post operative adjustment<sup>9,12,14</sup>. On the other hand, second stage fistulotomy was required in almost all cases of non elastic seton<sup>10,11</sup>. Munir and Falah used polypropylene-1 as cutting seton where post operative retightening was required until the seton completely cut through the sphincter but it was a painful procedure and may cause uncontrolled division of sphincter<sup>4</sup>. Total length of hospital stay was more in group II due to second surgical intervention.

Mean duration of elastic seton in place (cut through the sphincter and drop) was  $17.02 \pm 7.07$  (range 7-42) days which was about similar to the result of other studies<sup>8,9,13</sup>. Leventoglu et al reports the application of elastic seton for horseshoe fistula where mean time of elastic seton in place was  $40.33 \pm 19.98$  days<sup>14</sup>. The relatively longer duration was due to application of less tension. This result differs from present study.

Mean duration of seton in place was  $52.38 \pm 7.28$  days for group 11, similar result also found in others studies where mean duration of seton in place was 50, 53, 40 and 59 days respectively<sup>11,15-17</sup>.

Healing time was rapid after fistulotomy by elastic cutting seton which was also found in a study of Ege et al. where complete healing was achieved in 52.3% cases at 1 month and 100% at 3 months.<sup>12</sup> In fistulotomy by non-elastic cutting seton, healing time was more prolong due to re-adjustment or repeat surgical intervention and formation of a second wound.

Study by Munir and Falah, Theerapol et al. shows similar result for cases treated by non elastic seton



where median healing time was about two and half months.<sup>4,18</sup>

Minor fecal incontinence was found in both groups in some cases during first follow up at 2 weeks. There were wide variation in the description of incontinence between the studies, the average rate of incontinence was 12%, ranging from 0% to 67%. Montes et al. , Chuang-Wei et al. , Mohite et al. and others showed nearly similar result in their studies where their were no or minor postoperative fecal incontinence.<sup>4,8,9,14,17-19</sup>

The range of reported incontinence after cutting seton treatment was wide and there was no relationship between it and the frequency of tightening, type of seton material or classification of fistula. Other studies showed that incontinence was associated with female sex, high anal fistula, type of surgery and previous fistula surgery.<sup>10,19</sup>

Recurrence rate varies from (0-22%) in different types and techniques of seton placement <sup>3</sup>. Factors associated with recurrence included complex type of fistula, horseshoe extension, lack of identification or lateral location of internal opening, previous fistula surgery and surgeon performing the procedure <sup>10</sup>.

Recent reports with regard to cutting seton are all of limited case number and maximum are retrospective study. There was no standardized procedure about the seton material, the tension of seton tightening and time interval of second procedure to remove the seton along with fistulotomy

The slow and stable cutting of the sphincter by elastic seton eventually accomplishes a primary fistulotomy. The total duration of seton in place and healing time is earlier as there is no second wound but there were no differences in recurrence and incontinence rate.

### Conclusion:

With our limited experience in a relatively small number of patients and shorter follow up period, there were reasonably good evidences in favour of elastic seton for single stage procedure, shorter healing time and less duration of seton in place. The outcome of this study suggest that the elastic seton may be a valid and better alternative for the treatment of complex anal fistula to reduce the need for repeated hospital visit or readmission, anaesthetic hazards, financial burden as well as early return to work.

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