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Limited Outward Migration of the Internal Opening Occurs in Most Anal Fistula Patients in Response to Long Term Loose Seton Use and May Limit the Later Utilization of the Lift and Advancement Flap Treatment Options

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Abstract

Introduction: Loose setons are used in anal fistula patients prior to LIFT, advancement flap or other definitive surgery. At times, they are used for extended periods in recurrent fistula patients and in those who are phobic about surgery. Internal Opening Migration (IOM) outwards has been reported previously in some loose seton patients. This study's purpose was to assess IOM and the long term ramifications of loose setons.

Methods: Transphincteric anal fistula patients who had a loose seton 6 months or longer were studied retrospectively. Office, hospital, and operative records were reviewed. IOM was assessed at each visit and recorded as was continence and seton tolerance.

Results: Thirty two patients met study criteria (mean age 41; M 23, F 9; cryptogenic 25, IBD 7). The mean seton duration was 18.8 months [range 7-48]; the mean IOM for the group was 1.2 cm (range 0-2.5 cm). When patients were divided into groups based on seton duration (≤ 10 mos, 11-20, 21-30, >30) there was no difference in the median IOM between groups (1.26, cm 1.05, 1.13, 1.2, respectively; $p=ns$). Also, when patients were grouped according to IOM distance (<0.5 cm, $0.5- <1$, $1- <1.5$, $1.5- <2$, ≥ 2 cm) there was no difference noted in the mean seton duration of each group. L.I.F.T. procedures were done post seton in 3 patients. Nine patients (28%) with robust IOM were offered cutting setons and 5 underwent this treatment successfully. In 50% IOM extended to or beyond the Intersphincteric groove which eliminated L.I.F.T. as an option. Further, IOM resulted in either a healed fissure-like scar along the migration path or an enlarged IO which made endorectal advancement flap more difficult. Loose setons remain in 17 patients. At last follow up, continence was maintained in all but 1 patient who reported flatal incontinence.

Conclusion: In most, long duration loose setons do migrate ("cut") partway through the encompassed muscle. In a few, robust migration allows safe use of a cutting seton to complete the treatment, but, in most, substantial external sphincter remains within the fistula. Continence is preserved despite IOM. Post IOM, subsequent LIFT or advancement flaps may not be feasible; if these methods are to be used they should be carried out several months after loose seton placement.

Keywords: Anorectal Fistula; Seton; Loose Seton; Marking Seton

Introduction

Fistula surgeons must balance the desire to eradicate the fistula with the need to preserve sphincter function and continence. The most effective treatments (fistulotomy and cutting seton) divide, entirely, the sphincter muscle encompassed by the fistula tract. However, as regards continence, even for low transphincteric fistulas, this muscle division may result in incontinence [1,2]. Sphincter sparing methods such as endorectal advancement flap, Ligation of Intersphincteric Fistula Tract (LIFT), fistula plug, and fibrin glue are

selectively employed for middle and high transphincteric fistulas. The most often used sphincter saving procedures are the endorectal advancement flap and the LIFT procedure. Of note, although the rate of complete healing following these procedures has been reported to be above 80% by some investigators [3-9], other surgeons report success rates in the 50-65% range [10-16].

Another treatment option is the "loose" seton also known as a "non cutting" or "marking" seton. The loose seton, most often a silk suture or vessel loop, is passed through the fistula tract and the two

ends overlapped and tied together forming a lax and redundant loop. The seton keeps the fistula tract open allowing for daily drainage and, in so doing, prevents the transient fistula tract obstructions that lead to swelling, pain, and, finally, drainage that most fistula patients experience on a regular basis. There are numerous situations in which loose setons are utilized [17].

In anticipation of an advancement flap, L.I.F.T., or other procedure many surgeons use loose setons and leave them in place for 2-3 months prior to the definitive operation. During this time the residual para-fistula induration and secondary tracts/sinuses resolve and the principal tract usually becomes more fibrotic which facilitates the next operation. Loose setons are also used in patients with recurrent fistulas after one or more prior "definitive" fistula repair attempts. They are also commonly used in patients with Crohn's disease in whom muscle cutting procedures are generally avoided and in whom multiple and complex fistulas may be present [18]. Setons are also utilized in sphincter conscious patients with newly diagnosed fistulas reluctant to undergo a definitive operation due to fear of incontinence. Since these setons are loose, the authors assumed that the amount of muscle encompassed by the fistula tract would not change regardless of how long the seton was in place.

The authors' interest in setons was piqued by a case in which a LIFT procedure was planned in a transsphincteric fistula patient who had had a loose seton for 10 months. At surgery it was noted that the Internal Opening (IO) had migrated from its original position at the dentate line to a point external to the intersphincteric groove. Having been taught that loose setons did not "cut" this finding came as a surprise. A literature search led to 2 publications concerning long dwelling "non cutting" loose setons in whom fistula migration had been noted.

Lentner et al in a retrospective review of 108 patients with low transsphincteric or intersphincteric fistulas in whom long term loose setons were employed reported seton migration in all patients [19]. A non-absorbable braided suture, the ends of which were tied together, served as the loose seton. The mean seton duration was 54 weeks. In 19 patients the seton eventually fell out, having fully traversed the fistula. In 80 patients the fistula migrated distally and became more superficial; in these cases the residual tract was divided at a second operation; 4 patients chose to keep the seton. One patient developed intermittent incontinence of flatus; none reported incontinence to stool.

Subhas et al reported on a series of 24 complex anal fistula patients in whom a loose silk suture seton was inserted and left in place an average of 14 months [18]. Patients were instructed to fully rotate the seton 360 degrees each day. Six patients did not tolerate the setons and underwent other fistula procedures. In the remaining 18 patients the seton was well tolerated. In 9 patients the seton fully migrated to the surface which obviated the need for further surgery. In the remaining 9 patients, the seton migrated outwards such that only a skin bridge remained. In this group, the remaining tract was laid open surgically. None of the long standing seton patients developed recurrences or incontinence to stool, however, 2 patients reported incontinence of gas.

Several years ago, in response to the above mentioned case and

articles, the senior author began to include in his fistula treatment discussion with patients who had high or mid-level transsphincteric fistulas the option of leaving a loose seton in place for an extended period with the hope that it would migrate outwards. Whereas a good number of patients had no interest in this approach, another group who were concerned about their sphincter function and phobic about doing a definitive procedure chose the long duration loose seton method. This is a retrospective review of the results with this approach. This study's purpose was to evaluate the effectiveness of the non-cutting seton as a long-term therapy as well as to determine the consequences, if any, of this practice.

Methods

Starting in January 2011 the senior author offered long duration loose setons as an option to patients with transsphincteric fistulas, both cryptogenic and Crohn's related, when it was believed that that fistulotomy might impact function. Patients were told that although there was no definitive data regarding the use of loose setons as definitive treatment that there were preliminary reports of notable fistula migration in some patients. Patients who agreed to loose seton placement were asked to return to the office every 4 to 6 months for exam. The interval between office visits varied. The option of performing a definitive fistula operation (LIFT, advancement flap, fistula plug, cutting seton, etc) was reviewed with all patients at each visit.

Transsphincteric fistula patients who had a "loose" seton for 6 months or more for whom adequate follow up was available were eligible for this study. The time period reviewed was from January 2011 to March 2017. The following data was obtained from office and hospital charts as well as operative records: etiology of fistula (cryptoglandular, Crohns disease), type of fistula (radial, curved ½ horse shoe type), number of fistulas, number of external and internal openings, level of the internal opening(s) (rectal mucosa, dentate line, or anodermal level), date of seton placement, seton type and subsequent operations or procedures relating to the fistula.

At each follow up visit patients were questioned about their tolerance of the seton, the presence of seton related symptoms (irritation, pain, swelling, etc), and their continence (soiling or flatal/fecal incontinence). The perianal area was visually examined and the seton(s) inspected at each visit; a digital exam and anoscopy was also performed for the vast majority of patients (starting 6 weeks after seton placement). The following data was routinely recorded at each follow up visit: External Opening (EO) location and migration distance (if present) and, with an anoscope in place, IO location and migration distance from the original position. The migration distance from the original location was measured using a flexible plastic ruler (operating room disposable ruler cut in half lengthwise). The rare finding of an abscess or sinus related to the fistula was noted. Also, in patients with vessel loop setons, the silk ties securing the overlapped ends were replaced, when necessary.

In a proportion of loose seton patients, after a period of time, additional fistula operation(s) were performed. The findings at surgery as well as the operation performed were noted. The outcome of subsequent operations was noted as regards fistula resolution or persistence and sphincter function. The status of each patient at last

Table 1: Internal Opening Migration Distance (p=ns for comparisons of the IOM subgroups as regards median seton duration).

| Internal Opening Migration Distance (cm) | Number of patients (percent of overall group) | Mean Int. Opening migration distance (cm) | Median seton duration, months (range) |
|--|---|---|---------------------------------------|
| 0 cm | 2 (6.3) | 0 | 24.5 (mean) (17,32 mos) |
| >0 - 0.5 cm | 3 (9.4) | 0.43 | 17 (6-19) |
| 0.5-1.0 cm | 10 (31.3) | 0.93 | 18 (8-30) |
| 1.1- 1.5 cm | 8 (25) | 1.28 | 15 (8-48) |
| 1.51-2.0 cm | 5 (15.6) | 1.76 | 12 (7-26) |
| > 2 cm | 4 (12.5) | 2.2 | 15 (10-42) |

follow up was also noted.

Statistical analysis

All data analysis was performed using SPSS version 15.0 (SPSS, Inc., Chicago IL). Results were presented as percentage (%), mean (standard deviation) for parametric data and median (interquartile range) for non-parametric data. Continuous variables were compared by Wilcoxon rank sum test Results with a p value of <0.05 were considered statistically significant.

Results

This retrospective review identified 32 fistula patients with setons who met the study criteria. The mean was age 41 (range 22-73) and the male:female ratio was 23:9. Seven patients (22%) had IBD (Crohns, 6; indeterminate CUC/Crohns, 1). All patients were treated by the senior author. As regards prior fistula surgery, 5 percent had undergone elective fistula operations prior to loose seton placement (LIFT, fistula plug, prior setons).

As regards the findings at the time of seton placement; in the great majority (28, 87.5%) the IO was located at the dentate line, however, in 4 patients it was either more superficial or proximal to the dentate line. There were 8 (25%) curved fistula tracts and 24 (75%) radial fistulas. Seven patients (22%) had multiple fistulas (more than 1 fistula with separate internal openings). The remainder (25 patients) had fistulas with a single IO although 3 had two or more EO's. In the latter cases separate setons were placed via each EO. In 31/32 cases vessel loops were the seton material utilized while a silk suture was used in 1 patient. In all patients 2 separate vessel loops were placed in each fistula tract (the second was a backup in case the first fell out).

The mean duration of seton use was 18.8 months [range 6-48]. The mean IOM for the entire group was 1.2 cm (range 0-2.5 cm). The data was first analyzed according to the IOM distance. No IOM was noted in 2 patients (6% of overall group, mean duration 24.5 mos). IOM was between 0 and less than or equal to 0.5 cm in 3 patients (9%, mean IOM 0.43 cm, median duration 17 months). IOM between 0.51 and 1.0 cm was noted in 10 patients (31%, mean IOM 0.93 cm, median duration 18 mos.). IOM between 1.1 cm and 1.5 cm was noted in 8 patients (25%, mean IOM 1.28 cm, median duration 15 mos). In 5 patients the IOM was between 1.51 and 2.0 cm (15.6%, mean IOM 1.76 cm, mean duration 12 mos.). Finally, in 4 patients the IOM was more than 2 cm (12.5%, mean IOM 2.2 cm, median duration 15 mos.) (Table 1). There was no significant differences noted in the median seton durations when the subgroups were compared (p=ns).

The IOM distance was also assessed in relation to seton duration

(Table 2). Interestingly the mean migration distance for the 4 different duration groups (≤ 10 mos., 10.1-20 mos., 20.1-30 mos., >30 mos.) did not significantly increase with increasing duration (median IOM values 1.26 cm, 1.05 cm, 1.13 cm, 1.2 cm, respectively). Subgroup comparison revealed no significant differences in the median IOM values. Regardless of seton duration category the mean IOM was less than 1.5 cm. IOM was judged to have proceeded to or beyond the intersphincteric groove in 16 patients (50%).

In 9 patients fistulas migrated to a point where the amount of external sphincter involved was judged amenable to division without endangering continence; all were offered a cutting seton. Five agreed to seton placement which was successful in all without functional loss. The remaining 4 patients refused the cutting seton, most were fearful of incontinence. These patients chose to keep their setons and have reported no control problems.

Three patients underwent L.I.F.T. procedures; 1 was successful. One LIFT patient developed a recurrent fistula after which a loose seton was placed; after 6 months excellent migration was noted and a cutting seton was placed that eradicated the superficial fistula without functional loss. The third patient's fistula recurred and a loose seton again placed.

As regards the IBD patients (n=7), the mean IOM was 1.28 cm (range 0.4-2.1 cm) and the mean seton duration was 19.7 months; in contrast, the non IBD patients (n=25) mean IOM was 1.18 cm (range 0-2.5 cm) and mean seton duration was 18.5 months (IBD vs non-IBD, p=ns). Five of 7 IBD patients with setons received monoclonal antibody treatment and steroids were given to 1 patient. Of note, in 3 of the 7 Crohn's patients excellent IOM was noted such that little external sphincter remained in the fistula. Had these not been Crohn's patients cutting setons would have been offered. At last follow up, the setons remain in 6 of these patients. Of note, EO migration toward the anus was noted in 6 patients (0.8-2.25 cm). In 3 of these patients, small abscesses or symptomatic sinuses developed between the original and new EO; all were drained, unroofed, and/or curreted which led to healing of these perianal wounds.

At last follow up, loose setons remained in place in 17 of the 24 patients who did not undergo subsequent definitive fistula operations. The anal fistula, itself, remains in 23/24 patients; in 1 patient with indeterminate IBD the fistula spontaneously resolved on monoclonal antibody treatment.

Importantly, in most patients in whom substantial Internal Opening Migration (IOM) occurred, a very thin epithelial layer was noted to cover the radial furrow that was the migration path.

Table 2: Relationship between seton duration and internal opening migration distance ($p=ns$ for comparison the seton duration subgroups as regards IOM).

| Duration of Seton Use | Number of Patients (%) | Internal opening migration (median) | Mean duration (months) |
|-----------------------|------------------------|-------------------------------------|------------------------|
| ≤ 10 months | 7 (21.9) | 1.26 cm | 7.9 |
| 10.1 - 20 months | 14 (43.8) | 1.05 cm | 15.5 |
| 20.1 - 30 months | 8 (25.0) | 1.13 cm | 25.8 |
| > 30 months | 3 (9.4) | 1.20 cm | 40.7 |

In these patients there was a clear step off from the intact, normal, full thickness anorectal lining adjacent to the migration path. In a minority of patients, in whom migration occurred, the migration path did not heal; instead the IO simply became larger.

At last follow up 1 patient reported intermittent flatal incontinence. None of the 31 other patients reported fecal or flatal incontinence.

Discussion

This retrospective study of patients in whom loose setons were employed for 6 months or longer demonstrates that for most (94%) the fistula's IO migrated some distance outwards. In 46% IOM was less than 1 cm and in 25% was between 1.1-1.5 cm. In 28 % the IOM was greater than 1.5 cm and in 4 patients (12%) the IOM was greater than 2 cm. In 50% of patients the IO migrated to or beyond the intersphincteric groove which has consequences regarding future surgical treatment options. Of note, the IOM distance did not correlate with the length of time the seton was in place. The mean migration distance of patients who had loose setons for more than 30 months was less than the average IOM for the subgroup that had the seton for 6-10 months. Thus, this data suggests that a loose seton results in the movement of the IO within the first 10 months after placement, following which, in most patients, the IO location remains stable.

It is important to note that sphincter length varies notably from patient to patient and is related to body habitus and sex, thus, the impact of a 1 cm IOM will vary. In a tall man with a dentate line IO, a 1 cm migration will not reach the intersphincteric groove; however, in a petite woman it might reach that point.

Why does this movement occur? Does the loose seton apply traction to the fistula tract? Does the presence of a foreign body spur the body to expel it like it does a subcutaneous splinter or titanium staple in a bowel anastomosis? Equally puzzling is why migration stops at 1-1.5 cm in most patients. The choice of seton material may impact the bodies response and the migration distance. Silk suture, although less aesthetic and harder to clean, may be a better material. Subhas and Lentner reported more dramatic IOM and better results with silk sutures [18,19]. It is the authors' unproven opinion that the vessel loop is not the ideal long term seton material as regards IOM. A braided suture may result in more local inflammation and irritation and may lead to greater migration.

The authors hoped that long term loose seton use would result in dramatic IOM such that only subcutaneous tissue or a slip of muscle remained within the tract. Such migration did occur in 9 patients; in 5 the fistula was safely eradicated using cutting setons. However, in most patients (72%) substantial migration through the external sphincter portion of the fistula did not occur. Importantly, partial

migration may actually limit the number of definitive treatment options open to patient and surgeon.

If the IO has migrated to the intersphincteric groove or beyond then a L.I.F.T. is not an option because the IO is immediately adjacent to external sphincter). Also, because the epithelial covering of the migration path is quite thin, there is a distinct step off from the intact mucosal edge on either side of the migration path that results in a depressed furrow similar to a healed fissure. The IOM distance determines the length of this epithelialized depression. This altered anatomy does not lend itself to an anorectal advancement flap. Despite the inclusion of internal sphincter muscle in the flap, the flap integrity may be poor and the mucosa may split along the IOM path. Also, the greater the IOM distance the further the flap must be advanced outwards to sew it to intact anoderm. This can be quite challenging and is likely to be associated with a higher failure rate. Also, if successful, an ectropion may result.

It is important for the patient and surgeon to understand that long term loose seton use may make it impossible to do a L.I.F.T. and may notably decrease the chances for success of an advancement flap. If a patient is interested in these sphincter sparing options then the operation should be done 2-4 months after seton placement. Thus, patients should be seen in office no more than 3 months after placement at which time a decision will be made regarding a L.I.F.T. or flap. Patients who choose to keep their loose seton for extended periods must understand that the LIFT and advancement flap options may be "off the table" as future options.

The success of the loose seton approach as a definitive or near definitive treatment may be a function of the amount of muscle involved. Lenter's series concerned low fistulas and he reported complete or near complete migration [19]. Perhaps the variation in IOM is a function of the amount of encircled external sphincter. The categorization of transsphincteric fistulas into low, middle, or high types is a subjective determination in the absence of an MRI. Perhaps the completed cases (cutting seton after excellent migration) were in patients that had the least muscle involved.

Of note, in a minority, the external opening may migrate towards the anus. Interestingly, in 2 patients a small abscess and partly drained sinus developed between the original and the new external opening; this was easily treated in office by unroofing and curetting this outer area. It is important to note that these patients had no abscess or problem associated with the shortened fistula tract.

Interestingly, loose seton related fistula migration as per the present study and 2 published reports is associated with a 0 rate of major fecal incontinence and a very low rate of flatal incontinence [18,19]. It is the authors unsubstantiated opinion that if comparable amounts of sphincter muscle were abruptly cut in patients with mid

or high level fistulas more incontinence would result. Why isn't this case in patients in whom lengthy IOM occurs? Regardless of the time period, the seton, "cuts" through muscle. Perhaps, because the seton traverses the muscle over a much longer time period, there is less separation of the divided muscle which allows a scar to form between the muscle edges, thus limiting the weakening effects. Of note, the same argument is used for cutting setons (*vs* fistulotomy) although the time period during which the muscle is divided is much shorter (weeks to a month) than for a loose seton (greater than 6 months).

Crohn's patients, in whom most surgeons are loathing to cut any muscle, deserve special discussion. In the present study, the mean IOM distance in the IBD subgroup, 1.29 cm, was slightly greater than the non-IBD patient result of 1.17 cm, however, the difference was not significant. In several patients the IOM was very impressive. It is important to note that Crohn's fistulas, unlike cryptogenic fistulas, can spontaneously resolve, most often in response to medical treatment. Whereas loose setons are commonly employed in Crohn's patients with complex and highly symptomatic fistulas to allow for resolution of associated abscess, side tracks, and perianal induration, it is not clear that long term use is justified. In the present series there is a Crohn's patient on a monoclonal Ab in whom several loose setons greatly decreased her symptoms. After a year, the GI MD requested seton removal so as to allow full resolution of the fistulas in response to medical treatment. This is a reasonable argument, however, in regards to the case in question; the patient is reluctant to remove the setons.

As mentioned, some patients in whom considerable IOM had occurred were reluctant to undergo a "completion" fistulotomy even though only a thin band of muscle remains in the tract. Also, most other patients in this series, in whom less IOM had occurred, chose to keep their seton(s) and did not pursue a definitive procedure (LIFT, advancement flap, or other). These patients have adjusted to the seton and don't want to "rock the boat". In general, the main goal of these patients is preservation of continence. Many are fearful of a definitive operation that would require the cutting of some muscle or be associated with a fairly high failure rate.

Finally, a proportion of patients does not tolerate the loose seton and will insist on early removal; common complaints are discomfort, difficulty cleaning the area, an offensive smell, or heavy drainage. These patients, most often, go on to a definitive fistula operation. Of note, the majority of patients tolerate the loose setons well.

Summary

This series of 32 fistula patients suggests that loose setons, after 6 months or longer, are associated with migration of the IO outwards in the majority. In 16 % the extent of migration was great enough that a cutting seton could be safely used to "complete" the fistulotomy without loss of continence (another 12 % with impressive migration declined a cutting seton). In 40% the migration distance was ≤ 1 cm. There was no relationship between seton duration and extent of migration after 6-10 months. Fistula migration was not associated with fecal incontinence or soiling; flatal incontinence was noted in 1 patient (3%). Importantly, in 50% the IOM migrated to the intersphincteric groove or beyond which eliminated a L.I.F.T. as a treatment option. Also, after IOM, either a depressed epithelialized "trough" resulted or the IO simply got bigger (diameter equal to IOM

distance). If an advancement flap is subsequently made it must be advanced further outside and may split (if furrow present). Thus, long term loose seton use limits the definitive operative treatment options in most patients. Both patient and surgeon should understand that if a L.I.F.T. or advancement flap is planned it probably best done within 3 months after seton placement. Finally, these results demonstrate that loose setons (also known as "non-cutting" setons) when left in place for 6-10 months, do in fact, "cut" to a limited extent.

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