

Ambulatory seton placement followed by fistulotomy: efficacy and safety for perianal fistula treatment

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Purpose To evaluate the efficacy and safety of ambulatory seton placement followed by superficial fistulotomy as treatment of perianal fistula.

Methods Retrospective observational analysis of patients with cryptogenic perianal fistula aged 18–90 years, followed in a central hospital proctology consultation between 2006 and 2017. Data were obtained through clinical record's analysis. Fistula was characterized, using Parks Classification. A probe was passed through the fistula tract, followed by a seton, which remained in situ until superficial fistulotomy was possible.

Results Ninety-six patients were included (66.67% males, mean age 56 ± 15 years old). Nineteen patients (19.89%) had previous history of perianal fistula and 14 (14.58%) previous anorectal surgery. Seventy-four patients (78.72%) were submitted to fistulotomy, three (3.19%) had seton fistulotomy and one had no seton progression. Intention-to-treat and per-protocol efficacy analyses were 80.2 and 98.7%, respectively. Among the 74 patients who completed the procedure, type of fistula and time with seton were distributed as followed: 47 (63.51%) intersphincteric fistula (15 ± 31 weeks), 26 (35.14%) transsphincteric fistula (32 ± 47 weeks), one (1.35%) suprasphincteric fistula (11 weeks). Previous fistula was associated with a longer time with seton ($P = 0.018$). Incontinence was reported in two (2.7%) patients, who had previous perianal fistula or anorectal surgery. Two patients (2.7%) had recurrence after fistulotomy.

Conclusion Placement of seton followed by superficial fistulotomy in an ambulatory setting is a safe and effective method for simple low perianal fistula treatment. Incontinence rate may be higher in patients with previous perianal fistula or anorectal surgery. *Eur J Gastroenterol Hepatol* 33: 956–960

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Introduction

Anal abscess and fistula are the acute and chronic phase of the same infectious process, which significantly decreases quality of life of those who suffer from it. An infection of an anal gland, in the crypt of Morgagni, is the etiologic factor in most of the cases, with a minor percentage related to Crohn's disease, anal fissure, infections or anorectal trauma [1]. Fistula tract anatomy is characterized by an internal opening, usually at the anal gland, and an external opening, often seen at perianal inspection. Depending on its relation with anal sphincters, anal fistulas are classified as intersphincteric, transsphincteric, suprasphincteric, and extrasphincteric, according to Parks classification [2].

Symptoms such as pain, swelling or drainage should raise the suspicion of anal fistula, which can be easily confirmed by a thorough proctological examination. Imaging techniques such as MRI or anorectal endosonography

may confirm the diagnosis and help to characterize fistula tract anatomy [3].

Anal fistula treatment is challenging for it should be effective but continence sparing. Treatment traditionally included fistulotomy or fistulectomy, which seem to be very effective. However, they are associated with anal incontinence, specially for high fistulas, since a considerable amount of muscle is cut [4,5]. Sphincter sparing techniques (SST) are emerging, although most of them have insufficient supportive data to be recommended, as well as a lower efficacy [3].

Setons have long been used for fistula drainage or definite treatment [6]. They are placed into the fistula tract, where they promote both drainage and a gradual muscle cut, allowing fibrosis to occur and minimizing fecal incontinence. As the fistula tract becomes superficial, a fistulotomy can be performed [7].

The aim of our study was to evaluate the efficacy and safety of ambulatory seton placement followed by superficial fistulotomy as treatment of perianal fistula.

Patients and methods

Patients and variables

This is a retrospective observational study which took place in a central hospital of Lisbon, Portugal, between January 2006 and December 2017.

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Patients who underwent perianal fistula treatment were identified by an informatic code ('crypt opening'), which was associated to their informatic process at the time of treatment. Patients over 18 and under 90 years old were included.

Clinical records of patients who met inclusion criteria were analyzed. They were searched for information on sex, age and comorbid conditions. Perianal fistulas were characterized based on proctological examination and frequently treated without previous image evaluation. Whenever clinical evaluation was dubious or there was some limitation to the procedure, an anorectal endosonography or MRI was performed in order to better define fistula anatomy. Parks classification [2] was used to address these fistulas. There is no consensus on the definition of simple and complex fistula [8]. In our study, we considered complex fistula those with multiple external fistula openings, fluctuation to suggest abscess or evidence of rectovaginal fistulas.

Time of seton permanence in the fistula tract, adverse events and relapse after fistulotomy were also evaluated. Relapse was defined as a new suppuration, abscess or fistula tract documentation.

They were found 263 patients associated with the informatic code within the period of the study, of whom 246 met inclusion criteria (one patient was aged over 90 years old and 16 corresponded to coding errors, having no perianal fistula). Among these, 111 patients (45.1%) had no sufficient recorded data on clinical process for analysis. From the 135 patients left, the following were excluded: seven for human immunodeficiency virus (HIV) infection, four for inflammatory bowel disease (IBD), seven for complex fistula, 19 for submucosal fistula, and two for seton in-situ at the time of data collection.

Procedure

Patients were treated in proctology consultation, in an ambulatory regimen. Procedure was performed by different proctology doctors, who were assisted by an experienced nurse. An initial proctological examination was performed to the patient on knee-elbow position. Internal and external fistula openings were identified. Fistula was then cannulated by passing a probe with lidocaine through the tract from the external to the internal opening. A nylon 0 seton was subsequently tied to the probe extremity and pulled through the fistula tract as the probe was taken off. Seton was left in situ to promote drainage and cut. Patients were assessed on consultation every 3 weeks or in shorter intervals if clinically justified. When fistula tract was superficial to the skin, a fistulotomy was performed with an electric cautery, under local anesthesia. After fistulotomy, patients were monitored for adverse events or relapse.

Statistical analysis

Statistical analysis was performed using Microsoft Excel 2013 and IBM SPSS Statistics 20. Variables with normal distribution were expressed as mean \pm SD and nonnormal variables were expressed as median \pm interquartile range. The procedure efficacy was determined by a per-protocol (PP) and intention-to-treat (ITT) analysis. A chi-square test was used to determine association between two categorical variables and a Mann–Whitney test was performed

to verify if there was statistical difference of a continuous variable between two groups.

Results

Ninety six patients with perianal fistula intended to treat by seton placement followed by superficial fistulotomy were analyzed. Sixty-four of them (66.7%) were male and the mean age was 56 ± 15 (23–86) years old. Nineteen patients (19.89%) had a previous perianal fistula and 14 (14.58%) had a previous anorectal surgery.

Among the 96 patients, fistula cannulation was not possible in two (2.08%), for a partially closed fistula tract. Of the 94 patients submitted to fistula cannulation, three (3.19%) had spontaneous seton fistulotomy and 74 (78.72%) were submitted to electric fistulotomy. Among the others, fistulotomy was not possible due to loss of follow up in 16 patients (17.02%) and therapeutic failure due to nonprogression of seton in one patient (1.06%), who was referred for surgery. Figure 1 represents patients distribution based on the possibility of fistula cannulation and fistulotomy.

We evaluated 74 patients effectively submitted to seton cannulation and fistulotomy for perianal fistula treatment. The mean follow-up time was 59 ± 45 [6–144] months. Of these patients, according to Parks classification, 47 (63.51%) had intersphincteric fistula (time with seton 15 ± 31 weeks), 26 (35.14%) had transsphincteric fistula (time with seton 32 ± 47 weeks) and one (1.35%) had a suprasphincteric fistula (time with seton 11 weeks). Table 1 and Fig. 2 represent this distribution, according to the type of fistula.

The efficacy of the procedure for perianal fistula treatment was 80.2% in an ITT analysis and 98.7% in a PP analysis.

Adverse events were reported in four (5.4%) patients: two (2.7%) had transient pain after the procedure and two (2.7%) reported new-onset incontinence: one case of gas incontinence and one case of fecal incontinence (Wexner score [9] 3 and 12, respectively).

Two patients (2.7%) had recurrence after fistulotomy, in less than 8 weeks (new fistula tract).

Subgroup analysis

We performed a subgroup analysis of patients with previous perianal fistula or previous anorectal surgery (Table 2).

We found time with seton to be longer in patients with previous perianal fistula compared with those without fistula history (median time 51 vs. 20 weeks, $P = 0.018$).

Moreover, efficacy was slightly lower in those patients (ITT 63.2%, PP 92.3%), comparing to the global efficacy. Indeed, the only case of therapeutic failure (need for surgery) occurred in one patient with previous perianal fistula, although a statistically significant association was not found between previous perianal fistula and therapeutic failure ($P = 0.221$).

Both cases of incontinence occurred in patients with previous perianal fistula or anorectal surgery, although no significant association was found between its occurrence and those personal factors ($P = 0.277$ and $P = 0.282$, respectively).

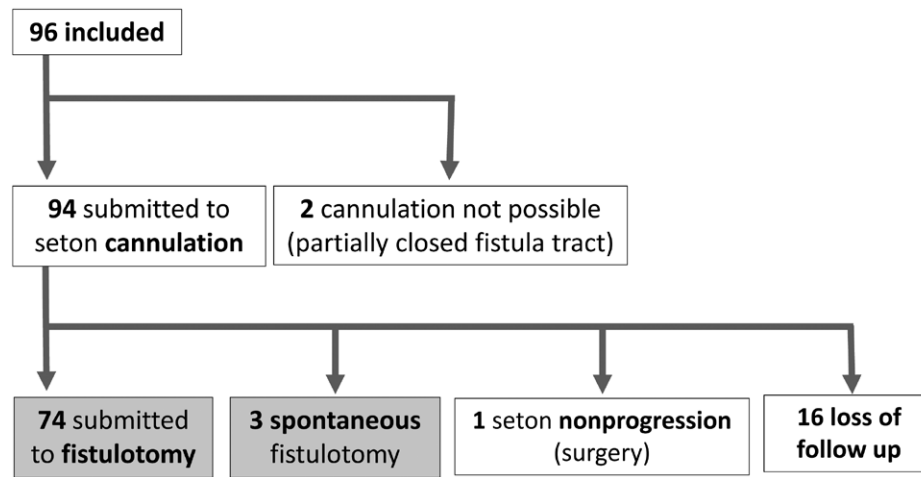


Fig. 1. Patients diagram according to fistula cannulation and fistulotomy status. Gray boxes signal cases of successful therapy.

Table 1. Time with seton for different types of fistula

Fistula classification (Parks)	n (%)	Time with seton (median ± IQR weeks)
Intersphincteric	47 (63.51)	15 ± 31
Transsphincteric	26 (35.14)	32 ± 47
Suprasphincteric	1 (1.35)	11
Total	74 (100)	25 ± 35

Discussion

Perianal fistula has been traditionally treated by fistulotomy or fistulectomy, with an overall success rate of over 90% [4,10,11]. However, anal incontinence is a real concern. Indeed, a multicentric study which included 537 patients who underwent fistulotomy for low perianal fistulas, reported a major incontinence rate of 28%, with only 26.3% of patients having a perfect continence status [4]. Incontinence after fistulotomy seem to be even higher for high fistulas [5].

This led to the development of SST, such as flap advancement, intrafistular injection of glue, insertion of collagen plug, ligation of the intersphincteric fistula tract or fistula tract laser closure. Some of these techniques may be combined in video-assisted anal fistula treatment (VAAFT). VAAFT uses a fistuloscope to better define fistula tract and to promote its diathermic destruction, while closing the internal fistula opening, after its correct identification. These SST are rarely associated to anal incontinence, although efficacy is lower than that with fistulotomy and recurrence is high [12,13]. Endoanal clip or injection of autologous cells are also promising treatments. However, many of these techniques need further documentation so they could be formally recommended [14].

The use of a cutting seton promotes a gradual erosion through sphincter muscle, allowing fibrosis to hold the ends of the muscle relatively close together while still allowing the fistula to heal [7]. Furthermore, by promoting appropriate drainage, setons have also an important role in preventing abscess formation and sepsis, as well as in improving symptoms. We aimed to evaluate efficacy and safety seton cannulation followed by superficial fistulotomy for treatment of perianal fistulas.

In our study, we excluded HIV infected or IBD patients, as well as those with complex fistula, even without any

other established diagnosis. Indeed, complex fistula may be associated to neoplasia, radiation exposure, Crohn's disease or infectious diseases, by different pathophysiological mechanisms other than cryptoglandular inflammation alone. Therefore, their treatment is more complex itself and may include targeted therapy, such as local or systemic immunosuppressants or specific antibiotics. Submucosal fistulas were also excluded, for many of them were originated in chronic fissures and did not involve the sphincteric complex. We opt to include one patient with a suprasphincteric fistula, since it was an uncomplex cryptoglandular fistula. However, high fistulas are inadequately represented in our study. Therefore, the results of this study should be applied to simple cryptoglandular inter or transsphincteric perianal fistulas.

We consider 96 patients to be a representative sample for the procedure efficacy and safety.

We found seton cannulation and fistulotomy to be very effective for treatment of perianal fistula: 98.7% in PP analysis and 80.2% in ITT, with this last result mainly influenced by dropouts. These high efficacy levels are consonant with other similar studies. In their study, Kelly *et al.* [15] reported a 100% efficacy of the procedure (7% with seton placement alone with no need of fistulotomy), which was applied also for high and complex fistulas. Efficacy rates of near 100% were also documented by other studies [16,17].

As efficacy appears to be maximized with this technique, so does the adverse events were minimized. In fact, significant pain after procedure was reported in only 2 patients. More important, in our study, incontinence rate and recurrence was 2.7%, which is also comparable to other studies' findings [16,18,19]. Curiously, an increased continence after cutting seton treatment for transsphincteric fistula has been reported in a 121 patients study [17].

Median time of seton permanence was 25 weeks (close to 6 months), greater for transsphincteric than for intersphincteric fistulas, which seems intuitive.

Our results suggest that seton placement followed by fistulotomy is also an effective procedure for patients with previous fistula or anorectal surgery fistulotomy, although a previous perianal fistula may lead to a longer time with seton and a slightly lower efficacy rate. However, these group of patients may be in special risk for incontinence,

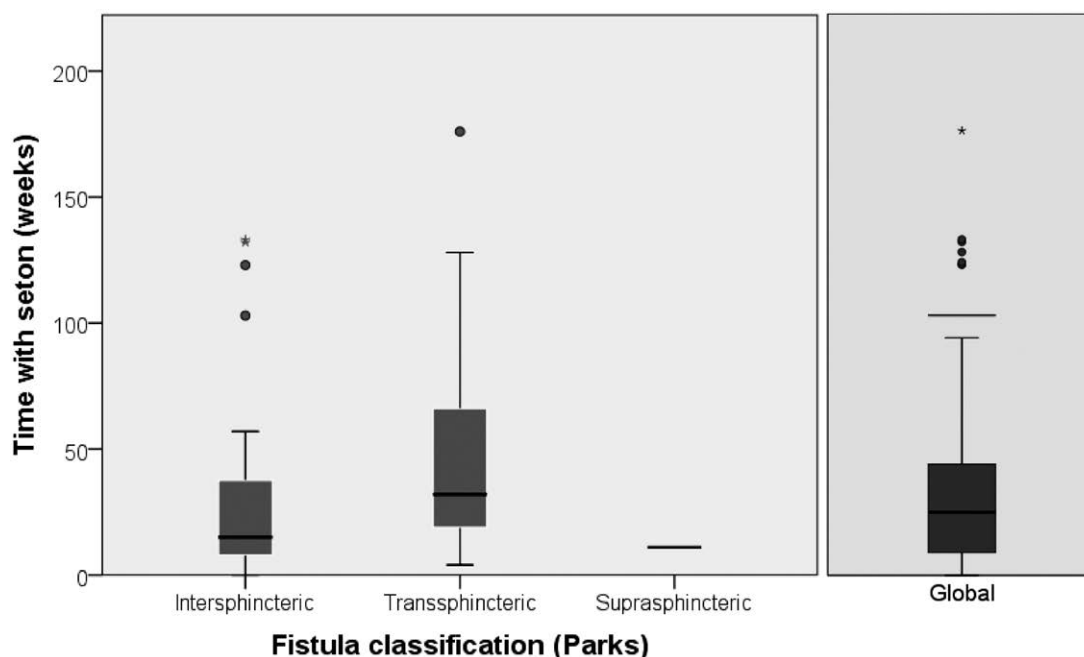


Fig. 2. Boxplot graphic on time with seton depending on type of fistula.

Table 2. Subgroup analysis of patients with Previous perianal fistula or Previous anorectal surgery

	Previous perianal fistula (n = 19)	Previous anorectal surgery (n = 14)
Male sex, n(%)	15 (78.9)	9 (64.3)
Age, median ± IQR weeks	48 ± 24.7	50 ± 35
Cannulation not possible, n (%)	1 (5.3)*	1 (6.7)*
Spontaneous seton fistulotomy, n (%)	1 (5.3)**	1 (6.7)**
Therapeutic failure, n (%)	1 (5.3)	0
Electric fistulotomy, n (%)	11 (57.9)	10 (71.4)
Time with seton (median ± IQR weeks)	51 ± 97	23 ± 35
Incontinence, n (%)	1 (9.1)	1 (10)
Relapse, n (%)	1 (9.1)	0
Intention-to-treat efficacy analysis	63.2%	78.6%
Per-protocol efficacy analysis	92.3%	100%

*/**both numbers represent the same patient, who had previous history of both perianal fistula and anorectal surgery.

which can be as high as 10% among those who are submitted to electric fistulotomy.

It may have been a selection bias, due to a retrospective inclusion of patients based on an informatic code, which may not have been attributed in all occasions. Moreover, a huge percentage of those identified patients (45.1%) had no sufficient data for inclusion.

Unlike previous studies, most of them performed by a surgeon in an operating room, ours took place in a proctology consultation, in an ambulatory setting. This made the procedure much cheaper and more convenient for the patient, provided that all the equipment and expertise were available.

In conclusion, our results place seton treatment among the most favorable risk-benefit ratios, as it seems to be as effective as classical fistulotomy, more effective than SST, with incontinence rates that approach those of SST.

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All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and

with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Written informed consent from the participants was waived because this was a retrospective nonintervention study.

Conflicts of interest

There are no conflicts of interest.

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