

Prospective Randomized Trial of Simple Drainage vs. Drainage and Initial Fistula Management for Perianal Abscesses

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Abstract

Background and Aims: Perianal abscess is one of the most frequent proctological disorders and needs urgent treatment. Incision and drainage consists the gold standard therapy of this disorder. However, due to high rates of abscess recurrence, few surgeons favor primary fistula treatment at the time of abscess drainage to decrease the risk of recurrence. This clinical study was designed to compare incision and drainage of perianal abscess with or without fistula treatment.

Patients and Methods: Two hundred consecutive patients suffering from acute perianal abscess were prospectively randomized into two groups: group A; treatment of abscess with incision and drainage, group B; incision and drainage plus primary fistula treatment. All patients were followed-up for at least 12 months. Primary endpoints of the study were the rates of abscess recurrence and anal incontinence. Secondary end point was abscess recurrence rate during the overall follow-up period.

Results: The 12-month recurrence rate was higher in group A than group B and this difference was statistically significant (44% in group A vs. 6% in group B, $p < 0.001$). Four patients of group B suffered from postoperative incontinence (two with flatus and two with liquid incontinence), while no patient of group A experienced anal incontinence. However the difference between the two groups was not statistically significant ($p = 0.121$). With a median follow-up of 31 months, the overall recurrence rate almost reached 70% in group A, while in group B it was only 10% ($p < 0.001$).

Conclusion: The results of our study show that management of perianal abscesses with drainage and synchronous fistula treatment can be effectively and safely performed by experienced surgeons, giving excellent results as far as recurrence and incontinence rates are concerned.

Keywords: Perianal abscess; Fistula-in-ano; drainage, Fistulotomy; Recurrence; Incontinence; initial fistula management; Primary fistula management

Introduction

Perianal abscess is a very common proctological disorder that is characterized by purulent collection in the perianal tissues. Taking the Parks and Eisenhamer's theory for granted, that in most cases perianal abscesses originate from infected intersphincter glands and that they often coexist with the presence of a fistulous track [1], the most appropriate treatment in terms of effectiveness and safety is still in controversy. More specifically, the conflict between surgeons is whether a primary fistulotomy should be included in the first-line treatment of anorectal abscesses [2].

The most popular method is incision and drainage of the abscess, mostly due to its simplicity [3]. However this method is associated with high rates of recurrence, probably due to the existence of a remnant fistulous tract.

On this basis, there is a group of surgeons who believe that both abscess and fistula should be managed by a simple-stage procedure

(drainage combined with fistulotomy), in order to eradicate the source of recurrence.

The aim of the present prospective randomized clinical study was to compare simple drainage vs. drainage plus primary fistula treatment in patients with perianal abscess, in terms of recurrence and incontinence rates.

Patients and Methods

From January 2008 to December 2011, a total of 200 patients [144 (72%) male, 56 (28%) female, median age 45 years, range: 17-76] treated for perianal abscesses in our Surgical Department were enrolled in this prospective randomized clinical trial.

Exclusion criteria included history of inflammatory bowel disease, malignancy, immunosuppression and anal incontinence. Of 200 patients, 49 (24.5%) had a history of at least one surgical procedure involving perianal area before study entry (Table 1).

Patients were randomly divided into two groups of 100 patients (group A and group B) using the sealed envelope technique. Patients of group A were treated by simple abscess drainage, while in patients of group B drainage and primary fistula treatment (fistulotomy, fistulectomy or seton placement) were attempted.

	Group A	Group B	p
No of patients	100	100	
Gender (male/female)	71/29	64/32	NS
Age (median)(range)(years)	42 (17-68)	47 (20-76)	NS
Follow-up (median)(range)(months)	27 (13-57)	23 (12-60)	NS
Type of Abscess			
ischianal	45		
perianal	28		
intersphincteric	13		
supralevator	3		
unspecified	11		
Type of Fistula			
intersphincteric(low/high)		26/21	
transphincteric(low/high)		20/17	
suprasphincteric		1	
extrasphincteric		2	
horseshoe		3	
unspecified		10	
Previous anal surgery	22	27	NS

Table 1: Patients' characteristics. Group A: Drainage alone, Group B: Drainage and fistula treatment, NS: Non-statistically significant difference.

All patients were operated by the same team of surgeons, characterized by tantamount experience in the field of anorectal surgery. Written informed consent was taken from each patient prior to operation and the study was accredited by the scientific committee of the hospital.

All patients were placed in the lithotomy position and the main applied anesthetic technique was sedation, followed by orotracheal intubation and local anesthesia, according to anesthesiologists' preference. In patients of group A, simple drainage was performed by means of a wide incision at the point of maximum fluctuation and the abscess cavity was washed out thoroughly with H₂O₂ and povidone iodine solution. In patients of group B the applied technique (drainage plus fistulotomy or fistulectomy or seton application) was based on surgeon's decision, according to the type of the abscess. In all patients pus was collected and sent for culture. Both abscesses and fistulas were classified according to Park's classification [4].

After hospital discharge, each patient was instructed to take sitz baths twice daily and was followed-up for at least 12 months. The scheduled follow-up examinations were at 1, 3, 6 and 12 months after the operation and thereafter each patient was under telephone observation (once per year), except recurrence or any other symptoms presented.

Study End Points

Primary end points were the rate of abscess recurrence at 12 months and the rate of anal incontinence. Secondary end point of the study was abscess recurrence rate during the overall follow-up period.

Statistical Analysis

The statistical analysis was performed using the statistical program SPSS, v.15.0 (Statistical Package for Social Sciences, Chicago, IL, USA). The comparisons between the two groups regarding recurrence and incontinence rates were performed by chi-square and Fischer's exact tests, as appropriate, while regression methods were used to examine the effect of chosen method on recurrence and incontinence rate. Analysis was done on an intention-to treat basis.

Statistical significance was established at the level of $p=0.05$. As a consequence, any p -value of less than 0.05 showed the presence of statistically significant difference.

Results

According to the study protocol, all patients of group A were treated with simple abscess drainage. Based on Park's classification, these abscesses were classified as ischioanal, perianal, intersphincteric and supralevator in 45, 28, 13 and three cases, respectively. In 11 cases, classification was not possible. The drainage of all supralevator abscesses was performed through the rectal lumen and not through the ischioanal fossa.

Regarding surgical techniques that were applied in group B, in 46 patients fistulotomy or fistulectomy took place for low intersphincteric ($n=26$) and uncomplicated transphincteric fistulas ($n=20$). In 41 cases with complex fistulas (21 with high intersphincteric, 17 with transphincteric, one with suprasphincteric and two with extrasphincteric fistulas), seton was inserted into the fistula for progressive fistulotomy. In three abscesses that were located through the probing process, more than two openings were found, that were connected with each other. These abscesses were classified as horseshoe fistulas and were treated by fistulotomy of the tracts along the arms of horseshoe fistula and drainage of the post-anal space abscess with posterior midline incision. Finally, in 10 patients only simple drainage was performed as the internal opening of the fistulous tract could not be determined.

In patients of group A, the 12-month postoperative recurrence rate was 44%, comparing to 6% of patients of group B and this difference was statistically significant ($p<0.001$). Moreover, by the end of the study and with a median follow-up of 31 months (range: 12-60 months), the overall recurrence rate in group A almost reached 70%, while in group B it was only 10% ($p<0.001$) (Table 2).

Among the 44 patients of group A that relapsed during the first postoperative year, five (11.3%) presented abscess recurrence during the first month, 10 and 20 till the third month and sixth month, respectively, and the remaining nine patients experienced recurrence between the sixth and twelfth month. After the first year, 23 more patients of group A relapsed during the overall follow-up period, raising the total recurrence rate to 69%.

Group	12-month recurrence		Overall recurrence		Incontinence			
	n	%	n	%	Overall	flatus	liquid	solid
Group A (n=100)	44	44	69	69	0	0	0	0
Group B (n=100)	6a	6	10b	10	4c	2	2	0
D+S (n=41)	1	2,4	2	4,8	2	1	1	0
D+F (n=49)	3	6,1	4	8,1	2	1	1	0
Drainage (n=10)	2	20	4	40	0	0	0	0

Table 2: Recurrence and incontinence rates. D+S: Drainage and seton placement, D+F: Drainage and fistulotomy/fistulectomy, a: $p < 0.001$ in relation to group A, b: $p < 0.001$ in relation to group A, c: $p = 0.121$ in relation to group A, $p < 0.05$: presence of statistically significant difference.

Among the six patients of group B that experienced recurrence during the first postoperative year, one relapsed during the first month, two till the third month, two till the sixth month, while one patient presented recurrence between the sixth and twelfth month.

There was no statistically significant difference, regarding recurrence rate and incontinence, between male and female patients, in both groups.

Regression analysis showed that patients who were treated with simple abscess drainage were 12.3 times as likely to have recurrence as patients in whom fistula was identified and treated primarily, during the first postoperative year (95% CI=4.9-30.7; $p < 0.001$). This risk was even higher for the overall recurrence rate since patients of group A were found to have 20 times as likely increased risk of recurrence as patients of group B (95% CI=9.19-43.64; $p < 0.001$).

Regarding incontinence rates, patients of group A did not mention postoperatively any incontinence disturbances. On the contrary, four patients of group B developed anal incontinence, two with flatus incontinence and two with incontinence of liquid stool. However, this difference between the two groups was not statistically significant ($p = 0.121$). Of interest, in three out of four patients of group B with incontinence, the problem was restored gradually, while in only one patient incontinence to liquid stool still remains. In addition, regression analysis did not reveal any increased risk of incontinence development when primary treatment of the fistula was attempted (95% CI=0.68-10.42, $p = 0.89$).

Discussion

Fistulas-in-ano are believed to emerge mostly as a consequence of a previous cryptoglandular perirectal abscess that was either drained surgically or spontaneously discharged [2,5]. For that reason the term "fistulous abscess" was introduced in 1954 [5] to point out that anal abscess and fistulas are virtually the two different sides of the same coin. For surgeons who deal with the acute perianal sepsis, the main goal is to efficiently eradicate it, without disturbing the anatomy of the sphincter muscles, in order to preserve the ano-rectal function and avoid, if possible, the recurrence of sepsis in the future [6]. In that direction, many different surgical techniques have been developed, with controversial results. Till now the concurrent fistulotomy and drainage of an anorectal abscess remains one of the most controversial

topics in anorectal surgery and recommendations for this therapeutic strategy are weak (2B) [7]. A recent European review study [8] suggests that concomitant primary fistulotomy and drainage should be performed only for superficial abscesses and by expert surgeons.

The results of our randomized clinical study show that simultaneous management of abscess and fistula during the acute perianal sepsis leads to reduction in recurrence risk that exceeds 90% compared with drainage alone. These results are comparable to the results of a recent meta-analysis by Quah et al. [5], which showed that primary fistula tract treatment reduces the recurrence risk by 83%. A few randomized clinical trials have concluded to contradictory conclusions, either because of small sample size or because of a narrow time lag of follow up [9-12].

Another remarkable finding of our study was the successful detection of the internal opening in 90% of cases. This percentage is extremely high compared to other studies in which the internal openings were identified in 5-34.7% [5,13-15]. A possible explanation could be the increased experience of the surgeons who participated in this study, a fact that indicates that in the hands of a well trained surgeon and with persistent and careful attempts, the fistula could be detected in most cases.

Those who tend to treat the anorectal abscess by simple drainage claim that this technique is simple, fast and safe, as it can be performed by less experienced surgeons in rectal surgery [3,5]. Since the identification of a fistulous tract is more difficult in the presence of acute inflammation, the risk of developing false passages is high, thus putting patient at great risk of recurrence [3,5,11]. Moreover, they argue that less than 50% of patients will develop fistula after drainage of an anorectal abscess [2,3,11,16]. However, our results are in contrast with these reports, since the rate of identified internal opening was high (90%). Additionally, the low recurrence rate in patients of group B (10%) does not support the worries of iatrogenic injury and increased risk of recurrence.

In relation to the risk of incontinence, our study showed that the comparing surgical approaches did not affect the incontinence rate at a statistically significant level. In the group that underwent primary treatment of the fistula, only four cases of incontinence occurred ($p > 0,05$) and therefore the theory of increased risk of fecal incontinence after a single-stage treatment [4] does not seem to be

confirmed by our study. In previous randomized trials [9-11], information about the height of fistula was not provided and the evaluation of fecal incontinence regarding the amount of sphincters that had been divided could not be done.

A theoretical limitation of our study is that patients of group B underwent various types of operations (fistulotomy, fistulectomy and seton placement) depending on the type of abscess, which were characterized by different recurrence rates. More specifically, in 49 patients that underwent lay open technique, the recurrence rate was 8.1% (4 out of 49 patients) and in those that seton was placed, 4.8% (2 out of 41 patients), being comparable with international literature (0-18% for fistulotomy and 0-29% for seton) [17]. Nonetheless, the number of cases in the two subgroups (lay open technique and seton) is quite small to perform statistical analysis without avoiding the risk of making a Type II statistical error. Moreover, our study's aim was identification of any difference between the initial treatment of a fistula in acute perianal sepsis and the standard method of simple incision and drainage.

In conclusion, our study shows that in case of perianal abscess, one-stage abscess and fistula treatment by identification of fistula's tract minimizes the risk of recurrence, thus leading to safe and definite treatment. However, this approach should be attempted only by surgeons with huge experience in anorectal surgery.

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