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SURGICAL MEDICAL SCIENCES / CERRAHİ TIP BİLİMLERİ

Outcomes of Secondary Fistulotomy Performed After Primary Fistulotomy or Loose Seton According to Operating Room and Outpatient Conditions

Gevşek Seton Tekniği ile Perianal Fistülün Kısmi İyileşmesinden Sonra Yapılan Fistülotomi Sonuçları

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Abstract

Objectives: Perianal fistula has a significant impact on the patient's quality of life, causing many problems ranging from pain and hygienic problems to sepsis. The primary aim of the present study is to compare the results of primary fistulotomy with fistulotomy following the loose seton technique. The secondary aim is to determine whether these surgical methods are affected by the operating room or polyclinic conditions in terms of disease course and complication rates.

Materials and Methods: A total of 382 patients who underwent surgery were retrospectively analyzed. Uncomplicated low intersphincteric and transsphincteric fistulas are included and high complex fistulas were excluded.

Results: Two hundred and twenty-eight patients underwent only fistulotomy, whereas 154 underwent fistulotomy following the partial healing process after loose seton. The recurrence significantly increases in horseshoes shaped fistulas (p=0.01). In univariate Cox proportional hazard regression analysis, length of fistula tract is proportional with the recurrence rate (p=0.005). In multivariate Cox proportional hazard regression models, transsphincteric fistula is an independent risk factor for recurrence (p=0.006). The recurrence rate was significantly higher in transsphincteric fistulas than in intersphincteric fistulas among patients who underwent fistulotomy (p<0.001). It was determined that neither the type of surgical technique nor the operation performed in the operating room or outpatient clinic conditions made a significant difference in terms of disease course and complication rates (p>0.05).

Conclusion: Transsphincteric fistula is a risk factor for recurrence independent of the surgical technique. However, after a certain period of time following loose seton, secondary fistulotomy into the fistula channel reduces the recurrence rate. In addition, no significant difference was observed in terms of the course of the disease and recurrence after secondary fistulotomy whether it is performed in operating room or outpatient clinic conditions.

Key Words: Perianal Fistula, Seton Technique, Fistulotomy

Öz

Amaç: Perianal fistül, hastanın yaşam kalitesi üzerinde önemli bir etkiye sahiptir. Ağrıdan hijyenik sorunlara ve sepsise kadar birçok soruna neden olur. Bu çalışmanın birincil amacı primer fistülotomi ile gevşek seton tekniğini takiben yapılan fistülotomi sonuçlarını karşılaştırmaktır. İkincil amaç ise bu cerrahi yöntemlerin ameliyathane veya poliklinik koşullarından hastalık seyri ve komplikasyon oranları açısından etkilenip etkilenmediğini belirlemektir.

Gereç ve Yöntem: Cerrahi uygulanan toplam 382 hasta retrospektif olarak analiz edildi. Komplike olmayan düşük intersfinkterik ve transsfinkterik fistüller dahil edildi ve yüksek kompleks fistüller hariç tutuldu.

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Öz

Bulgular: İki yüz yirmi sekiz hastaya sadece fistülotomi uygulanırken, 154 hastaya gevşek seton sonrası kısmi iyileşme sürecini takiben fistülotomi uygulandı. At nalı şeklindeki fistüllerde rekürrens anlamlı olarak artmakta olduğu saptandı (p=0,01). Tek değişkenli Cox orantılı hazard regresyon analizinde, fistül traktının uzunluğunun nüks oranını artırdığı saptandı (p=0,005). Çok değişkenli Cox orantılı tehlike regresyon modellerinde, transsfinkterik fistül nüks için bağımsız bir risk faktörüdür (p=0,006). Fistülotomi yapılan hastalarda nüks oranı transsfinkterik fistüllerde intersfinkterik fistüllere göre anlamlı olarak daha yüksektir (p<0,001). Cerrahi tekniğin tipinin ve ameliyatın ameliyathane veya poliklinik şartlarında yapılmasının hastalık seyri ve komplikasyon oranları açısından anlamlı bir fark yaratmadığı belirlendi (p>0,05).

Sonuç: Transsfinkterik fistül, cerrahi teknikten bağımsız olarak nüks için bağımsız bir risk faktörüdür. Ancak, gevşek seton tekniği sonrası kısmi iyileşme dönemini takiben sekonder fistülotomi yapıldığında nüks oranı azalmaktadır. Ameliyathane veya poliklinik şartlarında uygulanan fistülotomi veya seton tekniklerine bağlı olarak hastalığın seyri ve komplikasyon gelişimi açısından anlamlı bir fark gözlenmemiştir.

Anahtar Kelimeler: Perianal Fistül, Seton Tekniği, Fistülotomi

Introduction

Perianal fistula is an inflammatory pathway caused by an abscess in the intersphincteric space, most commonly between the perianal skin or perineum, due to cryptogenic infection of the anal canal. The incidence of anal fistula developing from anal abscess varies from 15 to 38% in various studies (1).

Perianal fistula has a significant impact on the patient's quality of life, causing many problems ranging from pain and hygienic problems to sepsis. The three-part external sphincter has led to the classification of fistula types explained by Parks for the first time. Simple fistulas contain uncomplicated low intersphincteric and transsphincteric fistulas. On the other hand, fistulotomy should not be attempted in complex fistulas such as suprasphincteric, extrasphincteric and high transsphincteric fistulas (2).

The management of perianal fistula remains one of the most challenging and controversial issues in colorectal surgery. Basic principles of the technique are evacuating the local infection, destroying the fistula tract, and preventing recurrence while preserving the natural sphincter function (3).

Traditionally, treatment of simple anal fistula involves opening the fistula tract by dividing all or part of the anal sphincter complex, depending on the anatomy of the fistula tract. However, although it is stated in guidelines that up to 30% of the external sphincter muscle can be cut without sacrificing fecal continence, most surgeons are reluctant to divide the external anal sphincter (4,5).

While success rates are around 90% in fistulotomy series, there is a difference between incontinence rates (0-53%). While this rate approaches nearly 0% in simple fistulas (mean 12%), it rises to 50% in high and complicated fistulas (mean 32%) (6).

Although sphincter-preserving methods have been tried to be applied in recent years, the gap between the recovery rates of the case results indicated in different articles and guide lines shows that it cannot replace fistulotomy, which has recently been accepted as the gold standard (7,8).

Due to the density of the operating rooms and the large number of cases, it seems possible that a certain part of proctological diseases can be treated on an outpatient basis (9,10).

The primary aim of this retrospective study is to compare primary fistulotomy with fistulotomy performed after the closure of the secondary canals, that is, the formation of epidermis cells in the fistula canal, in patients with loose seton application. The secondary aim is to determine whether these surgical methods are affected by the operating room or polyclinic conditions in terms of disease course and complication rates.

Materials and Methods

After approval from the Sakarya University Non-invasive Ethics Committee (protocol number: E-71522473-050.01.04-155064-207) patients who were operated for perianal fistula between August 2016 and June 2022 were retrospectively analyzed. Study patients were operated by a single surgeon. In the digital examination by using surgical instruments (e.g. stylets and forceps) performed under local anesthesia in the general surgery outpatient clinic; depending on the fibrosis status of the anal canal sphincters, it was decided to apply primary fistulotomy or loose seton. Fistulotomy was applied to those with a fistula tract under 2 cm with fibrosis. On the other hand, loose seton was preferred for patients whose fistula length extended to 4 cm without developing fibrosis.

Fistula type was determined by pelvic magnetic resonance imaging and endo-rectal ultrasound.

During the outpatient clinic examination; primary fistulotomy was performed in the outpatient clinic in patients with linear features, internal orifice, and fistula length of less than 2 cm with digital or surgical instruments. On the other hand, patients whose internal mouth could not be detected with

local anesthesia or whose external orifice and internal orifice curved towards 12 o'clock according to the jack-knife position (horseshoe-shaped fistula) were considered to have complicated anal fistula. First, imaging was performed with endoanal ultrasonography and magnetic Resonance Imaging, and then it was evaluated under general operating room conditions.

Simple intersphincteric and transsphincteric fistulas with a distance of less than 4 cm from the anus in both the outpatient clinic and the operating room were included in the study. According to the lithotomy position, anterior and especially anterior fistulas of female patients and complicated fistulas were excluded from the study.

As a seton, a perforated section of the 2.67 mm (0.8) CH minivac drain was used. Minivac drain was preferred to better close the secondary channels and to ensure easy placement of the laser tip if laser closure is required in patients at risk of developing incontinence due to secondary fistulotomy. In order to understand how long the loose seton should be kept for a minimum in fistula healing, patients who underwent secondary fistulotomy at 1, 2 and 3 months were examined in 3 different groups. Depending on the fibrotic healing process of the fistula canal, secondary fistulotomy was performed in the 1st, 2nd and 3rd months and the data were recorded. In patients who underwent both primary and secondary fistulotomy, those who passed the third month were called for 6-month follow-ups. At the same time, those who spent the third month without complications were considered to have fully recovered.

Statistical Analysis

Data analysis was performed using IBM SPSS Statistics version 25.0 software (IBM Corporation, Armonk, NY, US). Kolmogorov-Smirnov test was used to investigate whether the normal distribution assumption was met. Categorical data were expressed as numbers (n) and percentage (%) while quantitative data were given as mean ± standard deviation and median (minimum-maximum). While the mean differences between groups were compared by Student's t-test, otherwise, Mann-Whitney U test was applied for comparisons of the not normally distributed data. Qualitative data were analyzed by $\chi 2$ or Fisher's exact test, where appropriate. Recurrence-free survival (RFS) was computed by the method of Kaplan-Meier survival analyses and categorical variables were compared by the log-rank test. Crude survival (success) ratios and mean expected duration of life with 95% confidence intervals (CIs) for each sub-group were also calculated. Whether the associations between patients' demographic and clinical characteristics with RFS were statistically significant or not was examined by Univariate Cox's Proportional Hazard Regression models. Multiple Cox's proportional hazard regression models were generated in order to determine the best independent predictors which mostly affected on RFS after adjustment for clinically important factors. Hazard ratios (HR), 95% CIs and Wald statistics were also calculated for each independent variable. A p-value less than 0.05 was considered statistically significant.

Results

There was no significant difference between the groups in terms of age, gender, duration of disease, fistula shape, position, fecal contamination, location of fistula according to Goodsall's rule, compliance with Goodsall's rule, recurrence and follow-up time (p>0.05). However, the mean fistula length was significantly higher in the loose seton technique group (p=0.004). In addition, loose seton technique was significantly much more performed in transsphincteric fistulas than the intersphincteric fistulas (p=0.002), (Table 1).

Table 1: Demographic and clinical characteristics of the cases according to the groups with and without loose seton

Age (year)	**42.6±12.6**	**42.5±12.7**	**42.9±12.5**	**0.729**
Gender				0.553
Male	279 (73.0%)	164 (71.9%)	115 (74.7%)	
Female	103 (27.0%)	64 (28.1%)	39 (25.3%)	
Disease duration (months)	12 (1-360)	12 (2-360)	24 (1-360)	0.192
Length of fistula	3.1±1.2	2.9±1.1	3.4±1.4	**0.004**
Type of fistula				**0.002**
Intersphincteric	183 (47.9%)	124 (54.4%)	59 (38.3%)	
Transsphincteric	199 (52.1%)	104 (45.6%)	95 (61.7%)	
Shape of fistula				0.362
Horseshoe	11 (2.9%)	5 (2.2%)	6 (3.9%)	
Linear	371 (97.1%)	223 (97.8%)	148 (96.1%)	
Position				0.786
Jack knife	305 (79.8%)	181 (79.4%)	124 (80.5%)	
Litotomy	77 (20.2%)	47 (20.6%)	30 (19.5%)	

Table 1: Continued				
Fecal soiling	2 (0.5%)	1 (0.4%)	1 (0.6%)	>0.999
Operation site				0.601
Operating room	82 (21.5%)	51 (22.4%)	31 (20.1%)	
Policlinic	300 (78.5%)	177 (77.6%)	123 (79.9%)	
Location of fistula according to Goodsall				0.777
1	34 (8.9%)	20 (8.8%)	14 (9.1%)	
2	27 (7.1%)	18 (7.9%)	9 (5.8%)	
3	25 (6.5%)	13 (5.7%)	12 (7.8%)	
4	21 (5.5%)	16 (7.0%)	5 (3.2%)	
5	27 (7.1%)	18 (7.9%)	9 (5.8%)	
6	81 (21.2%)	47 (20.6%)	34 (22.1%)	
7	28 (7.3%)	14 (6.1%)	14 (9.1%)	
8	37 (9.7%)	22 (9.6%)	15 (9.7%)	
9	34 (8.9%)	23 (10.1%)	11 (7.1%)	
10	20 (5.2%)	10 (4.4%)	10 (6.5%)	
11	31 (8.1%)	17 (7.5%)	14 (9.1%)	
12	17 (4.5%)	10 (4.4%)	7 (4.5%)	
Goodsall eligibility				0.649
Yes	198 (51.8%)	116 (50.9%)	82 (53.2%)	
No	184 (48.2%)	112 (49.1%)	72 (46.8%)	
Recurrence	29 (7.6%)	18 (7.9%)	11 (7.1%)	0.940
Follow-up time (months)	32 (2-82)	32.5 (2-82)	30.5 (2-75)	0.111

In Table 2, the effects of demographic and clinical characteristics of the cases on RFS were analyzed by Kaplan-Meier survival analysis. Among all cases, 29 relapses developed, and the disease free survival (clinical success) rate was 92.4%. The mean RFS time of the cases was 75.8 (95% Cl= 73.6-78.0) months. The Figure 1 shows the Kaplan-Meier curve for RFS in all cases. On the other hand, there was no statistically significant difference in RFS according to gender, position, operation site, fistula according to Goodsall's rule, and compliance with Goodsall's rule (p>0.05). There was a significant difference in the rate of recurrence according to fistula type (p<0.001), and the rate of recurrence was higher in transsphincteric fistulas than in intersphincteric fistulas.

Table 2: Effects of demographic and clinical characteristics of cases on recurrence-free survival - Kaplan-Meier survival analysis results

	N	Recurrence (n)	Overal survival (%)	Recurrence free survival (month)*	Log-Rank	p-value
Gender					0.547	0.460
Male	279	23	91.8	75.2 (72.6-77.9)		
Female	103	6	94.2	73.6 (70.1-77.0)		
Type of fistula					14.163	**<0.001**
Intersphincteric	183	4	97.8	80.2 (78.5-81.9)		
Transsphincteric	199	25	87.4	69.2 (65.6-72.8)		
Shape of fistula					6.636	**0.010**
Horseshoe	11	3	72.7	52.6 (32.1-73.1)		
Linear	371	26	93.0	76.3 (74.1-78.4)		
Position					0.006	0.940
Jack knife	305	23	92.5	69.4 (67.2-71.6)		
Lithotomy	77	6	92.2	75.4 (70.4-80.5)		
Operation site					0.134	0.714
Operating room	82	7	91.5	74.9 (69.8-79.9)		
Policlinic	300	22	92.7	69.6 (67.4-71.8)		

Table 2: Continued

	N	Recurrence (n)	Overal survival (%)	Recurrence free survival (month)*	Log-Rank	p-value
Location of fistula according to Goodsall					16.221	0.133
1	34	2	94.1	34.0 (31.4-36.7)		
2	27	0	100.0	N/A		
3	25	1	96.0	60.6 (56.1-65.2)		
4	21	0	100.0	N/A		
5	27	2	92.6	63.2 (56.9-69.6)		
6	81	5	93.8	72.8 (68.3-77.2)		
7	28	3	89.3	68.8 (60.1-77.5)		
8	37	3	91.9	72.5 (65.4-79.5)		
9	34	2	94.1	70.7 (64.9-76.5)		
10	20	4	80.0	46.9 (37.1-56.6)		
11	31	6	80.6	52.2 (43.8-60.8)		
12	17	1	94.1	61.5 (54.9-68.1)		
Goodsall eligibility					2.264	0.132
Yes	198	19	90.4	74.3 (71.0-77.6)		
No	184	10	94.6	74.6 (72.0-77.3)		
Type of operation					0.071	0.790
Fistulotomy	228	18	92.1	75.6 (72.7-78.4)		
Loose seton	154	11	92.9	69.6 (66.6-72.7)		
Duration of seton					1.405	0.704
One month	102	9	91.2	67.9 (64.1-71.7)		
Two months	30	1	96.7	40.7 (38.4-43.1)		
Three months	27	1	96.3	32.5 (26.1-38.9)		
More than 3 months	7	0	100.0	N/A		
Total	382	29	92.4	75.8 (73.6-78.0)	-	-

*Period of time without relapse

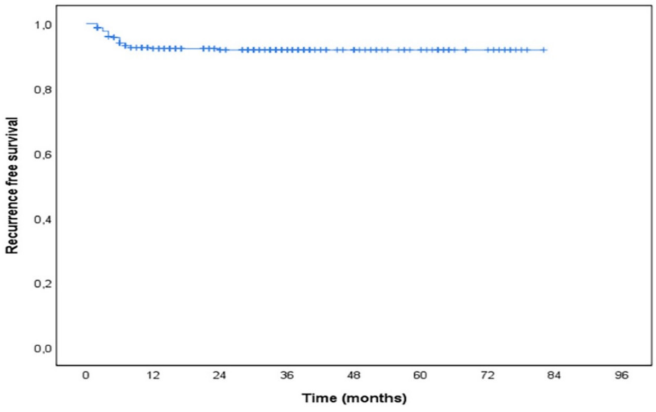

Figure 1: Kaplan-Meier curve for overall recurrence-free survival

Biopsies were taken from the base of the fistula of the patients who underwent secondary fistulotomy in the first, second and third months, and as a result of pathological examinations where the cuboid epithelium transformed into stratified squamous epithelium (Figure 2). It was observed that the epidermis was formed in the groups at the first month,

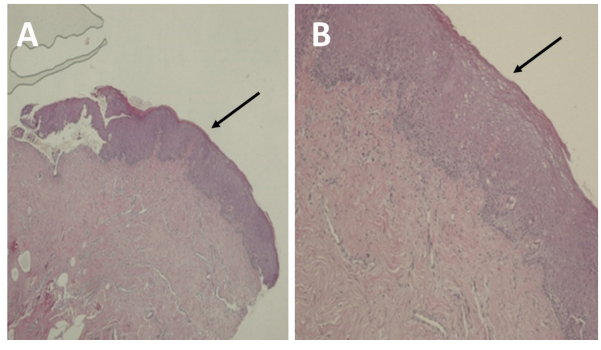

Figure 2: A) In the staining of the specimen sent in the first month with hematoxylin-eosin, inflammatory cell infiltration was observed, with a large amount of epithelialization on the surface of the tissue at 1/40 magnification, mononuclear cells predominantly observed in the tissue stroma. **B)** In the play sent in the third month; Staining with hematoxylin-eosin at 1/400 magnification showed stratified squamous epithelium on the surface, and mild mononuclear cells and inflammatory infiltration in the stroma

and the stromal infiltration was more. On the other hand, pathological examination of the canal biopsy of the patients who underwent fistulotomy in the third month showed a thicker epithelial layer with reduced stromal infiltration (Figure 3).

There was no significant difference between the fistulotomy group and the loose seton technique group in terms of RFS (p=0.790), (Figure 4). Similarly, while no significant change was observed in the recurrence rate depending on the seton time (p=0.704). It can be said that the clinical success rate increases in patients whose seton duration is more than 3 months, that is, the longer the seton is left in the patient (Table 2).

In Table 3; the effects of age, disease duration, and fistula size on RFS were analyzed by univariate Cox's proportional hazard regression analysis. While no statistically significant change was observed in the recurrence rate according to age and disease duration (p>0.05), the recurrence rate increased statistically as the fistula length increased (HR=1.316, 95% CI= 1.088-1.592, p=0.005).

In Table 4, there are proportional hazard regression models of the multivariate Cox, in which the combined effects of all possible factors that are thought to be effective on RFS are examined. According to model 1, transsphincteric fistula type was an independent risk factor for the development of recurrence independent of other factors (HR=5.298, 95%

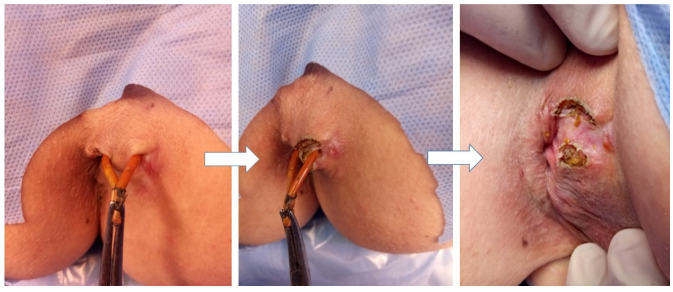

Figure 3: Fistulotomy was performed 3 months after the loose seton was applied. A stratified squamous epithelium is observed at the end of the base of healed fistula

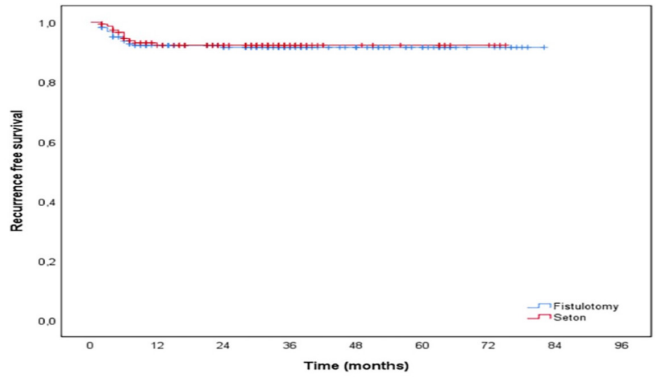

Figure 4: Comparison of the fistulotomy and fistulotomy after loose seton groups according to recurrence free survival

Table 3: Effects of age, disease duration, and fistula size on recurrence-free survival - results of univariate Cox proportional hazard regression analysis

	Hazard ratio	95% Confidence interval	Wald	p-value
Age	0.997	0.969-1.026	0.037	0.847
Disease duration	0.995	0.984-1.005	0.993	0.319
Length of fistula	1.316	1.088-1.592	7.969	**0.005**

Table 4: Examination of the combined effects of all possible factors thought to have an impact on recurrence-free survival - multivariate Cox proportional hazard regression models

	Hazard ratio	95% Confidence interval	Wald	p-value
Model 1				
Age	0.994	0.965-1.024	0.151	0.697
Male	1.246	0.504-3.083	0.226	0.634
Transsphincteric	5.298	1.607-17.463	7.506	**0.006**
Length of fistula	1.060	0.753-1.493	0.112	0.738
Horseshoe fistula	2.522	0.719-8.850	2.086	0.149
Goodsall eligibility	1.160	0.521-2.585	0.132	0.716
Loose seton application	0.679	0.317-1.455	0.991	0.319
Model 2				
Transsphincteric	5.166	1.591-16.776	7.466	**0.006**
Length of fistula	1.075	0.773-1.496	0.186	0.666
Horseshoe fistula	2.605	0.750-9.048	2.273	0.132
Goodsall eligibility	1.166	0.523-2.601	0.141	0.707
Loose seton application	0.668	0.313-1.427	1.084	0.298

CI= 1.607-17.463, p=0.006). Although loose seton technique had a protective effect on the development of recurrence when adjusted for other factors, this finding was not statistically significant (HR=0.679, 95% CI=0.317-1.455, p=0.319).

Compared to model 2 (unlike model 1, age and gender were excluded from the model), it was seen that the fistula type being transsphincteric was an independent risk factor for the development of recurrence independent of other factors (HR=5.166, 95% CI=1.591-16.776, p=0.006). Although loose seton technique had a protective effect on the development of recurrence when adjusted for other factors, this finding was not statistically significant (HR=0.668, 95% CI=0.313-1.427, p=0.298).

In Table 5, the effect of loose seton application in each fistula type and the fistula type in each surgical approach on RFS were examined. Among the cases with intersphincteric fistula, there was no significant difference in terms of RFS between the fistulotomy group and the loose seton group (p=0.781). Likewise, among the patients with transsphincteric fistula, there was no statistically significant difference in RFS between the fistulotomy group and the loose seton group (p=0.345). The recurrence rate was significantly higher in transsphincteric fistulas than in intersphincteric fistulas among patients who underwent fistulotomy (p<0.001). On the other hand, there was no significant difference in RFS among the cases in which loose seton was applied according to the fistula type (p=0.054).

Table 6 shows multiple comparisons of RFS within various subgroups. There was no significant difference in terms of RFS between the group that underwent fistulotomy in the operating room and the group that underwent loose seton (p=0.830).

Table 5: The effect of seton application within each fistula type and fistula type on recurrence-free survival within each surgical approach

	N	Number of relapsed cases	Overal survival (%)	Disease free survival (month)*	Log-Rank	p-value
Intersphincteric					0.077	0.781
Fistulotomy	124	3	97.6	80.0 (77.9-82.2)		
Loose seton	59	1	98.3	70.8 (68.5-73.1)		
Transsphincteric					0.893	0.345
Fistulotomy	104	15	85.6	67.6 (62.3-72.9)		
Loose seton	95	10	89.5	67.3 (62.9-71.8)		
Fistulotomy					11.448	**<0.001**
Intersphincteric	124	3	97.6	80.0 (77.9-82.2)		
Transsphincteric	104	15	85.6	67.6 (62.3-72.9)		
Loose seton					3.726	0.054
Intersphincteric	59	1	98.3	70.8 (68.5-73.1)		
Transsphincteric	95	10	89.5	67.3 (62.9-71.8)		

*Disease-free survival time

Table 6: Multiple comparisons of recurrence-free survival across various subgroups

	N	Number of relapsed cases	Overall survival (%)	Disease free survival (month)*	Log-Rank	p-value
Operating room					0.046	0.830
Fistulotomy	51	4	92.2	75.4 (69.3-81.6)		
Loose seton	31	3	90.3	67.9 (60.4-75.5)		
Policlinic					0.179	0.673
Fistulotomy	177	14	92.1	69.2 (66.3-72.1)		
Loose seton	123	8	93.5	59.0 (56.2-61.7)		
Fistulotomy					0.001	0.972
Operating room	51	4	92.2	75.4 (69.3-81.6)		
Policlinic	177	14	92.1	69.2 (66.3-72.1)		
Loose seton					0.274	0.601
Operating room	31	3	90.3	67.9 (60.4-75.5)		
Policlinic	123	8	93.5	59.0 (56.2-61.7)		

*Disease-free survival time

There was no statistically significant difference in terms of RFS between the fistulotomy group and the loose seton group in the outpatient clinic (p=0.673). Among the patients who underwent fistulotomy, there was no statistically significant difference in terms of RFS between the group treated in the operating room and the group treated in the outpatient clinic (p=0.972). Among the cases in which loose seton was applied, there was no statistically significant difference in terms of RFS between the group treated in the operating room and the group treated in the outpatient clinic (p=0.601).

Discussion

Fistulotomy is the most common applied procedure for simple anal fistulas. It is easy to perform and has a high success rate, but the risk of incontinence is increased in high complex fistulas (11). The main goal in the treatment of fistula is based on the complete destruction of the fistula canal and its mucosal structure with connective tissue (12).

In complicated fistulas, resection of the fistula canal and simplification of the fistula are usually required, whereas in simple fistulas, canal resection is often not required. Secondary fistulotomy may be required sometimes after primary fistulotomy or seton application within a certain period of time. After loose seton application, cuboidal mucosal cells in the primary canal are replaced by stratified squamous epithelium, healing is achieved and anal continence is preserved (13). In the study by Jimenez and Mandava (13) and several other articles, it was stated that fistulas maturated after seton application. It is understood that the existing channel is cut only in the cutting seton technique, and in the loose seton techniques, the seton is removed and followed after a certain period of time. However, Zheng et al. (14) mentioned that seton may cause persistence of the fistula by continuously stimulating fibrosis and may lead to low cure rates. In addition, fistulotomy was not applied to the fibrous canal.

In the present study; simple fistulas involving the internal and 1/3 part of the proximal external sphincter, the principle of elimination of the canal after the epidermis cells cover the entire canal fistulotomy was performed.

Theerapol et al. (15) reported recurrence rates ranging from 8-22%, depending on the type of seton used. In a study in which the loose and cutting seton technique were applied together in the same patients, 78% reported that the fistula was completely healed, the average healing time was nine weeks, and none of the patients developed fecal incontinence.

To understand the duration of epithelial lining of the fistula canal, loose seton was kept for 4-12 weeks. A biopsy was taken from the fistula canal to confirm whether the canal was healed or not. According to the biopsy results; Although the epidermis was formed after 4-5 weeks, it was confirmed that the epidermis thickening began to fully mature after the 12 weeks. Therefore, it was noticed that patients with loose seton could recover after the 3rd month at the earliest and if fistulotomy was to be applied, these times should be followed. Cariati (16) reported that recovery times ranged from 1 to 6 months in 97% of patients treated with setons. At the same time, Gamelas et al. (17) reported 2.7% recurrence and 2.7% incontinence in patients who underwent fistulotomy and fistulotomy after loose seton. Moreover; Vogel et al. (5), in a multicenter, retrospective study of 537 patients with "low perineal fistula" (including less than one-third of the sphincter complex) undergoing fistulotomy, 28% of patients developed fecal incontinence.

In the present study; none of the patients mentioned gas and fecal contamination at the sixth month follow-up both in patient's groups with primary fistulotomy and secondary fistulotomy after the loose seton application. Therefore, they were not sent for anal manometry. In the literature short-term recovery rates after loose seton applied without secondary fistulotomy varies between 44% and 83% (17). In contrast, cutting setons have been used to slowly divide sphincters, allow fibrosis to occur, and limit muscle ring disruption, with recurrence rates ranging from 22 to 39% (18).

In the present study; when the effect of seton application in each fistula type and fistula type in each surgical approach on healing and recurrence was examined, no statistically significant difference was found (p=781).

In the present study, the recurrence rate was significantly higher in transsphincteric fistulas than in intersphincteric fistulas in patients who underwent fistulotomy (p<0.001). It has been observed that transsphincteric fistula type is an independent risk factor for the development of recurrence (HR=5.166, 95% CI=1.591-16.776, p=0.006). As the fistula length increased, the rate of recurrence increased significantly (HR=1.316, 95% CI=1.088-1.592, p=0.005).

In the study by Litta et al. (19), they applied a sphincter cut procedure, predominantly fistulotomy, to a total of 4883 patients with simple anal fistula, and reported an average recovery rate of 93.7% and a postoperative incontinence in 12.7% of the patients. In our study, 29 patients developed recurrence among all cases, and disease-free survival success rate was 92.4%. The mean RFS time of the cases was 75.8 (95% CI=73.6-78.0) months.

We could not find a multicenter study comparing general operating room and outpatient clinic conditions in the literature. The fact that there was no difference in terms of recurrence and recovery time after seton or fistulotomy application in both the operating room and the outpatient clinic increased our tendency to perform these procedures on an outpatient basis.

Study Limitations

Anal sphincter pressures were not measured with an anal manometer during follow-up visits after secondary fistulotomy. Also gas and fecal incontinence were evaluated subjectively.

Conclusion

When we interpreted our study in the light of the literature, the recurrence rate of low transsphincteric fistulas was higher than that of intersphincteric fistulas. In low transsphincteric fistulas, less recurrence is seen in those who underwent secondary fistulotomy after loose seton application instead of primary fistulotomy. There was no significant difference between the operations performed in the operating room and the outpatient clinic, regardless of the type of surgery. This showed that patients with simple fistulas can be operated in outpatient clinic. Although the seton time was not significant, it was observed that the recurrence rate decreased as the time increased. It was determined that the use of secondary fistulotomy after seton in low transsphincteric fistulas had positive effects on healing and with reduced recurrence.

Ethics

Ethics Committee Approval: The study was approved by the Sakarya University Non-invasive Ethics Committee (protocol number: E-71522473-050.01.04-155064-207).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: H.D., K.K., Design: H.D., K.K., Data Collection and Processing: E.G., M.Y., G.Ç.Ç., Analysis or Interpretation: E.G., K.K., Literature Search: H.D., R.Ç., Writing: H.D., E.G., M.Y., G.Ç.Ç., R.Ç., K.K.

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