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Comparison between medical therapy and surgical approach in treatment of patients with anal fissures; a randomized clinical trial study

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ABSTRACT

Anal fissure is a common anorectal disease and the prompt optimal treatment is crucial. Regarding the importance of issue, in this study the efficacy of the medical and surgical treatment methods for the patients with anal fissure was assessed and compared. In this interventional study that was performed as a randomized clinical trial, 78 patients with anal fissure attending to Imam Reza hospital, Tehran, Iran were enrolled and randomly assigned to receive either medical or surgical treatment. Then the efficacies in two groups were determined and compared. It was seen that efficacy for reduction of pain (P=0.008) and bleeding (P=0.029) was more in patients under surgical treatment. The frequency rate of incontinence was higher in surgical group (P=0.05). There was no difference regarding the satisfaction among patients (P > 0.05). Also the recurrence rate among patients was similar in two groups. Totally, it may be concluded that surgical treatment is superior to medical treatment for patients with anal fissure and the use of this method is highly recommended.

Keywords: Anal fissure, Efficacy, Medical treatment, Surgical treatment.

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Introduction

Anorectal disorders (AD) are common issues in the field of surgery and of the main cause of patient's admissions in emergency units and surgery clinics. The most common cases of AD are including hemorrhoids, fissure and fistulas (1), which are along with symptoms such as pain, itching and rectal bleeding. This might lead to several complications in individuals and impact their quality of life (2). Therefore, diagnosis and immediate treatment is of great importance in related patients (3, 4). One of the most common anorectal disorders is anal fissure (5, 6). The cause of the disease might be the anal skin abrasions following prolonged diarrhea or constipation. This irritation causes the internal anal muscle contraction which then results in severe pain (7). This disorder, which present with unpleasant burning sensation and bleeding from the rectum during bowel movements raises many concerns for patients (5). People with the disease

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usually have severe pain during bowel movements and sometimes experience bleeding at the same time. Approximately 50% of individuals improve by sitting in a warm water tub or taking of a high-fiber diet (6, 8). Although, in some cases it appears as part of a systematic diseases such as inflammatory bowel disease (IBD) or sexually transmitted disease in which it requires deeper and more accurate investigation (9). In general, there are two types of anal ulcer, acute and chronic. In acute type, it appears as a superficial wounds and it is being improved with medication. Patients with chronic type, experience several similar pain and their wound is deeper which is along with a bumps in the anal. Dealing with this condition in this group of patients are more difficult and they do require surgery (7, 10). Treatment approaches in patients with anal fissure are classified in to medical treatments such as topical Nitroglycerin ointments and Diltiazem as well as Botulinum toxin and surgical treatments. Generally, surgical approaches are more common when medical treatment is not effective (9, 11). Indeed, each of these approaches has their peculiar effects on patients' improvement according to individuals' condition and thus comparing these methods is useful in order to carry on an appropriate treatment (12-16). In this regard, the aim of this study is to investigate and compare the efficacy of medical and surgical treatment as two different approaches in management of Iranian patients with anal fissures.

Materials and Methods

Study Population

In the present study, we investigated the efficacy of two different treatment approaches including medical and surgical treatment in 78 patients with fissure, who admitted to Imam Reza hospital, Tehran, Iran during 2013. In this randomized clinical trial study, patients were randomly distributed in to two groups. The first group received diltiazem 2% and the second group underwent lateral internal sphincterotomy as a surgical treatment approach. The effectiveness of treatment was evaluated after three month and recovery rate, treatment complications, patient satisfaction and recurrence rate was also examined between the two groups.

Data Analysis

Finally, after collecting the required data from patients, analysis of the data was performed using SPSS statistical software (version 13). For qualitative variables, frequency and rate of frequency and for continuous variables, means and standard deviations were calculated. Chi-square, Fisher exact tests and independent t-test were used and p value of 0.05 were

Ethical Considerations

Written informed consent was taken from patients and the local ethics committee of approved the study protocol. This study was in accordance with the principles of the Helsinki Declaration. Informed consent was obtained from all patients in this study.

Results

The mean age of patients (48 male, 30 female) in the present study were 38.41±10.091 in medical group and 38.54±10.057were in surgery group. Characteristics of patient participated in this study is present in table 1. There was no difference regarding the BMI between the two groups ($P > 0.05$). In this study, the pain reduction in the surgery group was significantly higher than medical group ($P = 0.008$). Accordingly, 14 (35.9) patients were in the surgical group and 3 patients were in the medical group.

Table 1. Characteristics of patients in this study according two different approaches

Groups Characteristics	Medical	Surgical	Total	
Gender				
Male	25(64.1)	23(59.0)	48(61.5)	P>0.05
Female	14(35.9)	16(41.0)	30(38.5)	
BMI				P>0.05
Thin	3 (7.7)	4 (10.3)	7(9.0)	
NL	21(53.8)	15(38.5)	36(46.2)	
Overweight	12(30.8)	16(41.0)	28(35.9)	
Obese	3 (7.7)	4 (10.3)	7 (9.0)	

Table 2. Outcome of patients in this study based on two different approaches.

In addition, the bleeding reduction in surgical treatment group was considerably higher than the medical group (P = 0.029), (Table 2). In fact, 14 patients out of twenty patients who have experienced a sharp decline in bleeding were belonging to the surgical group. On the other hand, the frequency of incontinence in patients undergoing surgical treatment was more than medical group but this rate did not reach the statistical significance (P = 0.05). In the present study there were no significant differences between the two groups in terms of recurrence and the frequency of relapses were similar in both groups (P> 0.05). The patient satisfaction was also similar between the two groups .The disease duration in patients was also the same in both groups (P>0.05) (Figure 1).

Characteristics Group	Medical	Surgical	Total	
Disease duration (month)				
Satisfaction	4.28±2.481	4.00±2.544		P>0.05
Low	6 (15.4)	2 (5.1)	8 (10.3)	P>0.05
Medium	24 (61.5)	21 (53.8)	45(57.7)	
High	9 (23.1)	16 (41.0)	25(32.1)	
Incontinence				
Gas	3 (7.7)	9 (23.1)	12(15.4)	P=0.050
Fecal	0 (0)	2 (5.1)	2 (2.6)	
Neg	36 (92.3)	28 (71.8)	64(82.1)	
Recurrence				
Positive	4 (10.3)	3 (7.7)	7 (9)	P> 0.05
Negative	35 (89.7)	36 (92.3)	71 (91)	
Pain Decrease				
Mild	21 (53.8)	12 (30.8)	33(42.3)	P=0.008
Moderate	15 (38.5)	13 (33.3)	28(35.9)	
Severe	3 (7.7)	14 (35.9)	17(21.8)	
Bleeding decrease				
Mild	15 (38.5)	6 (15.4)	21(26.9)	P=0.029
Moderate	18 (46.2)	19 (48.7)	37(47.4)	
Severe	6 (15.4)	14 (35.9)	20(25.6)	

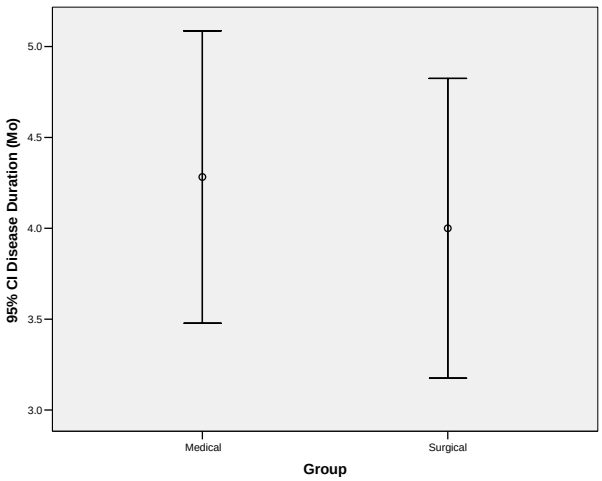

Figure 1. Disease duration in patients participated in this study.

Discussion

Treatment approaches in patients with anal fissure are classified in to medical treatments such as topical Nitroglycerin ointments and Diltiazem as well as Botulinum toxin and surgical treatments. In which surgical approaches are more common when medical treatment is not effective (9, 11). In this study the pain reduction in the surgery group was significantly higher than medical group (P = 0.008), (Figure 2). Accordingly, 14 (35.9) patients were in the surgical group and 3 patients were in the medical group.

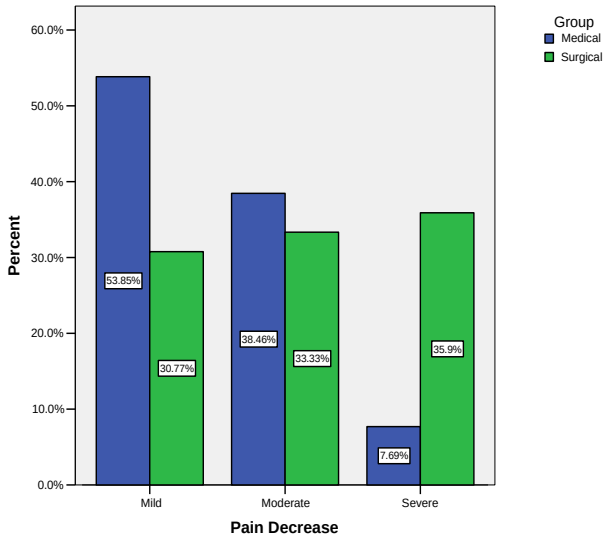

Figure 2. Pain reduction rate in patients with anal fissure.

Furthermore, the bleeding reduction in surgical treatment group was considerably higher than the medical group (P = 0.029), (Figure 3). In fact, 14 patients out of twenty patients who have experienced a sharp decline in bleeding were belonging to the surgical group. On the other hand the frequency of incontinence in patients undergoing surgical treatment was more than medical group but this rate did not reach the statistical significance (P = 0.05), (Figure 4). In the present study there were no significant differences between the two groups in terms of recurrence and the frequency of relapses were similar in both groups (P> 0.05). The patient satisfaction was also similar between the two groups . Similar to our study, in a clinical trial study by Liratzopoulos and colleagues in 2006 on 246 patients with anal fissures, reported that in 97.5 % of the patients underwent lateral internal sphincterotomy were improved and complications from the surgery was observed only in 2.1% of patients (13). In a review article by Altomare and colleagues in Italy in 2011 showed that the effectiveness of medical treatments, including topical ointments nitroglycerin, Nifedipine and Diltiazem have been significantly high and promoted the healing of anal fissure in 50 to 90 percent of patients (12), which is in consistent to our findings on diltiazem therapeutic efficacy range in our patients. Similar to our results, Bhardwaj etal. on 2007, revealed that medications such as Diltiazem were effective and had little side effects in patients with anal fissure on England's population (17).

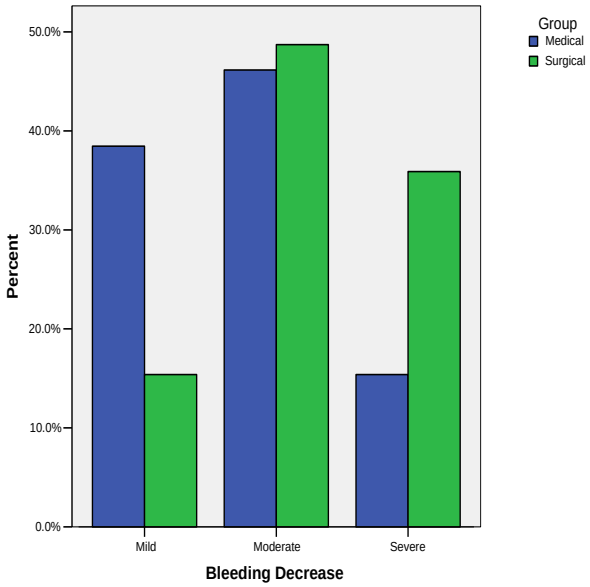

Figure 3. Reduction of bleeding in two groups.

Although, according to our findings, in comparison to medical approach the surgical treatment has more efficacies. In another study by Jawaid et al. on 80 Pakistani patients with anal fissure, demonstrated that, 77.5 % of patients in Diltiazem group and 82.5 % of patients in Nitroglycerin group showed a significant improvement although there was no statistical differences between the two groups in this regard (18).

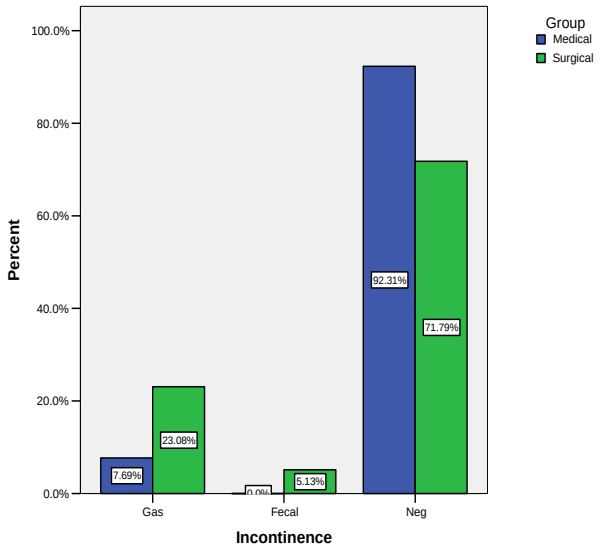

Figure 4. Frequency of incontinence in patients participated in this study.

The study of Tsunoda et al. on 30 Japanese patients revealed that Diltiazem improved the patient's status on 70% of cases. They also observed a significant increase in quality of life in related patients which is similar to our finding in this study (19). Jonas et al. study on 39 patients with anal fissure with negative respond to nitroglycerin ointment, indicated that tropical Diltiazem results in improvement in 49% of individuals which is less than our findings in this study (20). In another study Jonas and colleagues in 2001 demonstrated that tropical Diltiazem led to clinical improvement in 65% of cases and oral Diltiazem improved 38 % of patients (21).

Conclusion

In conclusion, according to our findings, the efficacy of surgery in treatment of patients with anal fissure seems to be higher than the medical group. Therefore application of surgery approach is highly recommended in this group of patients. Further multicenter studies with larger sample size in this area are required to confirm our findings. In addition, it is suggested that all other risk factors also should take in to consideration for their possible effect on patient's outcome. Regarding the effectiveness of surgical treatment, comparison of other surgical approaches is also highly recommended.

Conflict of Interest

Not Declared

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