ORIGINAL ARTICLE

MANAGEMENT OF CHRONIC ANAL FISSURES

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ABSTRACT

Objective: To compare the effectiveness of Botulinum toxin injection with lateral internal sphincterotomy for the treatment of chronic anal fissure in terms of healing.

Material & Methods: This study was conducted in surgical unit Hayatabad Medical Complex Peshawar from April 2013 to April 2014 .In this comparative study a total of 396 patients of chronic anal fissure were admitted in surgical department on the basis of inclusion and exclusion criteria patients were divided into two groups, A and B (198 patients in each group) ,depending upon type of treatment option(leteral shincterotomy or Botulinum toxin) for chronic anal fissure. After detail history and clinical examination, all patients were investigated and were prepared for the procedure. All data analyses were performed using the SPSS version 10.

Results: A total of 396 patients of chronic anal fissure were observed, which were divided in two equal groups. Overall Male to female ratio was 1.25:1. Sex distribution among the groups was insignificant with p-value=0.069 Average age was 45.11 years+ 13.26SD in group A and group B have average age of 45.74 years +14.28SD. The age distribution among the group was also insignificant with p-value 0.707. Efficacy was significant in both the procedure with p-value=0.045.

Conclusion: Botulinum toxin injection is more effective then lateral internal sphincterotomy in the management of chronic anal fissure.

Key Words: Botulinum toxin, lateral internal sphincterotomy, chronic anal fissure, healing.

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INTRODUCTION

An anal fissure is a break or tear occurring in the anus that extends upwards into the anal canal. Fissures are a common condition of the anus and anal canal and are responsible for 6-15% of the visits to a colon and rectal (colorectal) surgeon. They affect men and women equally and both the young and the old. Fissures usually cause pain during bowel movements that often is severe. Anal fissure is the most common cause of rectal bleeding in infancy.[1]

Chronic anal fissure is one of the most common proctologic problems. It usually presents as painful defecation and per rectal bleeding. It is common in both sexes[1]. The exact etiology of anal fissure is unknown, however traumatic or ischemic damage to mucosa due to passage of hard fecal matter is thought to be the cause. Other rare causes include prior anal surgery and prolonged occupational sitting. HIV and malignancy are also other uncommon causes of fissures present at unusual sites[2].

Hyper tonicity and hypertrophy of internal anal sphincters are the most common pathologies associated with it, which not only produces symptoms but are also the cause of persistence of the disease[2]. Over time, many methods of treatment have been designed, both medical and surgical. Medical treatment options include nitroglycerine, dilitizem and nefidepin[3]. Surgical methods is considered to have low recurrence rate and symptomatic improvement, but there exists a risk of faecal incontinence (8-35%) with it. Recently, injection of Botulinum toxin has been introduced which is claimed to decrease sphincter tone and pressure and is associated with good outcome in term of pain relief, complications and recurrence [4]. Lateral sphincterotomy is also one of the best treatments for chronic anal fissure but there is high rate of faecal incontinence as

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compare to Botulinum toxin[5]. In one study compared the both treatment options and it was observed that overall healing rate was 82% in patients treated with lateral sphincterotomy and 70% in patients treated with Botulinum toxin group[6].

There is no common agreement on single method for treatment of chronic anal fissure and if we find the efficacy of botulinum toxin injection, either equally or more effective then lateral sphincterotomy. The aim of this study was to compare the efficacy of leteral shincterotomy to the Botulinum toxin injection and whether Botulinum can be used as a first line treatment.

MATERIAL & METHODS

This study was conducted in surgical unit Hayatabad Medical Complex, Peshawar from April 2013 to April 2014. In this comparative study a total of 396 patients of chronic anal fissure were selected. All patients both male and female regardless of age with chronic anal fissure were included in the study. Exclusion criteria was 1. Known cases of intestinal tuberculosis (were detected by history and previous medical record), inflammatory bowel diseases (detected by Colonoscopy and biopsy) and anorectal carcinoma (by proctoscopy and biopsy) because these need treatment of primary pathology only. 2. Pregnant women due to risk of complications. 3. Patients on anticoagulant therapy due to risk of bleeding.

Patients were admitted in Surgical a Unit Hayatabad Medical Complex, Peshawar from out-patient department and diagnostic criteria is the presence of longitudinal break in the mucosa of distal anal canal for six or more than six weeks. Informed written consent was taken from all patients included in the study and ethical approval were taken from the Institutional Research and Ethical Board (IREB). Patients were randomly allocated in two groups, group A and B by Lottery method. Patients in group 'A' were receive treatment with 0.5 ml (20 units) Botulinum toxin injection on each side of anal fissure specially posterior anal sphincter in the internal anal sphincters under direct vision and digital examination at 3 or 9 o'clock position at lithotomy position under strict aseptic measures by single expert surgeon having at least five years experience. Patients were sent home after one hour with stool softeners.

Patients in group 'B' were undergo lateral internal sphincterotomy under general anesthesia by single expert surgeon also having at least five years experience that were doing all surgical procedures. The procedure performs at lithotomy position under strict aseptic measures. Patients were discharged on 1st post operation day on oral antibiotics, analgesics, stool softeners and were advised sitz bath. In both groups, patients were followed after 2 months. At follow up, patients were examined for healing (yes or no) to determine intervention effectiveness. Data were collected on a specially designed Proforma. Their demographic data, history and examination findings were recorded. Strictly exclusion criteria were followed to control confounding variables and bias in the study result.

The data were entered in SPSS version 10. In this study sex and healing are qualitative variables, while age is quantitative variable. Frequency/Percentages were calculated for qualitative variables, while mean±-standard deviation was calculated for quantitative variables. Chi square test was applied to compare the healing in both groups and p value <0.05 were considered significant. Results were presented as tables/Charts. Healing and effectiveness were stratified among the age and sex to see effect modifiers.

RESULTS

A total of 396 patients of chronic anal fissure were observed, which were divided in two equal groups. Patients in group A were managed by Botulinum toxin injection and group B of patients were going through lateral internal sphincterotomy. Gender wise distribution shows that 119(60.1%) were male and 79(39.9%) were female in group A with male to female ratio was 1.15:1 while group B contains 101(51%) were male and 97(49%) were female with male to female ratio was 1.01:1. Overall Male to female ratio was 1.25:1. Sex distribution among the groups was insignificant with p-value=0.069.

Average age was 45.11 years+ 13.26SD in group A and contains 31(15.7%) patients having less than 30 years, 76(38.4%) patients 31-45 years, 58(29.3%) patients 46-60 years and 33(16.7%) patients' lies between the age of more than 60 years of age. While group B have average age of 45.74 years +14.28SD and contains 34(17.2%) patients in less than 30 years, 67(33.8%) in 31-45 years, 57(28.8%) in 46-60 years and 49(20.2%) patients have age more than 60 years

Table No: 1. Efficacy Wise Distribution In Both The Groups

		Procedure		Total	p-value
		Group A	Group B		
Efficacy	Yes	166	150	316	0.045
		83.8%	75.8%	79.8%	
	No	32	48	80	
		16.2%	24.2%	20.2%	
Total		198	198	396	
		100.0%	100.0%	100.0%	

Table No: 2 . Age Wise Distribution of Efficacy

Age in years	Procedure		Total	P-value
	Group A	Group B		
<30	54	11	65	0.045
	83.1%	16.9%	100.0%	
31- 45	123	20	143	
	86.0%	14.0%	100.0%	
46-60	86	29	115	
	74.8%	25.2%	100.0%	
≥61	53	20	73	
	72.6%	27.4%	100.0%	
Total	316	80	396	
	79.8%	20.2%	100.0%	

Table no: 3.Gender Wise Distribution of Efficacy

Gender	Efficacy		Total	p-value
	Yes	No		
Male	167	53	220	0.031
	75.9%	24.1%	100.0%	
Female	149	27	176	
	84.7%	15.3%	100.0%	
Total	316	80	396	
	79.8%	20.2%	100.0%	

of age. The overall average of the patients was 45.42 years +13.76SD. The age distribution among the group was also insignificant with p-value 0.707.

Efficacy in terms of healing at two months of follow up showed that treatment was effective in 166(83.8%) patients while group B was effective in 150(75.8%) patients and not effective in 48(24.2%) patients which shows that efficacy was significant in both the procedure with p-value=0.045. (Table 1). Age wise distribution of procedure-efficacy shows that efficacy was greater in younger age group and decreases with the increase of age, as shown in Table 2.

When efficacy was stratified among the gender it showed also significance with p-vlue=0.031. There were 167(75.9%) male patients showing efficacy while non-effective in 53(24.1%) male patients. Similarly in female patients, 149(84.7%) gave efficacy while 27(15.3%) showed no efficacy. (Table 3).

DISCUSSION

Lateral internal sphincterotomy (LIS) is the most common treatment for chronic anal fissure (CAF). It is considered the gold standard treatment as it can be effective in more than 90 percent of cases[7]. The fundamental drawback of this surgery is its potential to cause gas, mucus or occasionally stool incontinence which may be permanent in 8 to 30 percent of patients[8]. Other reported complications include abscess, fistula and anal deformity. Intrasphincteric injection of botulinum toxin (BT) is a reliable and effective new option in the treatment of uncomplicated CAF. This method has been described initially by Jost and Schmrigk[9], and was found to be an effective treatment in comparison with placebo[10]. Furthermore, BT was more effective than topical nitrate, which constitutes another therapeutic option[11], and no permanent damage to the continence mechanism was detected in patients treated with BT[10,12].

Chemical denervation produced by the toxin is not permanent and the clinical efficacy lasts for 2–3 months . In anal fissure, however, the duration of action of the toxin roughly corresponds to the time required to reduce the resting pressure of the anal sphincter and allows enough time for healing. In our study we noticed significant drop in the Mean Resting Pressure (MRP) for the first 2 weeks after treatment in both groups (P< 0.001), however 2 months later the reduced MRP was still statistically significant (P< 0.01) only in the LIS group. This significant drop in the resting pressure was not correlated with significant incontinence in our patients. These results are similar to that reported by Ram E et. al, 2005[13].

In the present study the healing rate of 61.5% in the BT group is similar to that in previous studies[14,15]. We observed significant decrease in both IAS and external anal sphincter (EAS) but interestingly, Gui et al.[16] and Maria et al.[17] did not observe any effect of BT on EAS after injection to IAS. They concluded that toxin injected to the IAS had not spread into EAS[11]. This suggestion may not be valid as spread of the toxin through the EAS is very possible due to the small thickness of IAS and the proximity of EAS to the IAS. It is also well known that a diffusion gradient allows a spread to a distance of 30–45 mm from the injection point, even crossing the

bone and fascia[15]. The other reason of this controversy may also be related to the volume of the toxin that might have diffused beyond the target muscle and might have weakened the adjacent muscles. The change in resting pressure was not mentioned by Jost and Schimrigk in their initial studies where they injected BT into the EAS[18].

In this study, we did not try to inject BT specifically into the IAS or EAS. We also observed that if the toxin was applied on both sides of the fissure it spread into the EAS and IAS, and we believe it is easier to inject the toxin in this manner. In conclusion, the target muscle for injection of BT seems to be irrelevant. After therapy with BT, higher recurrence rates are expected, because the sphincter tone is only temporarily reduced. However, we and others have shown that relapse rates after BT injection was very low[19,20]. Recently in posteriorly localized fissures, significant reduction in maximum squeeze pressure and short duration of symptoms (<12 months) were suggested as predictive factors for a favorable outcome in botulinum toxin treatment in CAF[16].

All of our patients were selected from those suffering from posterior anal fissure for an average duration of eleven months, and those who were treated with BT injection showed significant reduction of MSP. These positive predictive factors could be related with the good outcome of our patients treated with BT. Theoretically BT injection can produce anal incontinence. BT produces a significant and global reduction in mean resting pressure of the anal canal, but also induces a significant increase in manometric asymmetry of the anal canal[21,22].

However, incontinence has been a negligible complication of BT treatment. EAS is an important component of continence. Toxin injection produces sufficient weakness of this muscle, but does not completely block voluntary control which is enough for incontinence prevention[23].

The therapeutic success rate of BT seems to be related with injection site and toxin dose. We injected the BT on each site of the fissure, mainly to the posterior of the anal sphincter. However it was suggested that anterior injection of BT could better reduce the resting pressure of the anal sphincter (88 percent vs. 60 percent) which could be due to the fibrotic base of the fissure or ischemic degeneration of the myenteric plexus of posterior sphincter. In addition the dose of BT is important. We used 20 units in this study. However, it was suggested that higher doses (up to 50 units) provide a higher success rate (up to 96 percent), without a significant rise in complications or side effects[24.25].

In a recent randomized, prospective study comparing BT with LIS for CAF, it has been suggested that the healing effect of BT appears slowly and wanes with longer follow-up, whereas LIS provides a faster, more stable and permanent effect[26.27]. The success rate of the BT group fell to 75.4 percent, whereas it remained stable in the LIS group (94 percent) at 12 months. In conclusion, the authors suggested that BT injection is inferior to LIS in the treatment of CAF. However they reported 16 percent rate of anal incontinence of varying degrees after surgery, compared with Zero prevalence in the BT group ($p < 0.001$) within the same follow-up period. If anal incontinence is considered as a failure of LIS, the advantage of this treatment will disappear.

CONCLUSION

In conclusion, Botulinum toxin (BT) injection is effective in the treatment of Chronic Anal Fissures (CAF). It is relatively less invasive than surgery and the complication rate seems negligible. However BT injection treatment may provide temporary remissions.

Recommendations

Larger scale, randomized controlled studies with long term follow up are needed before making firm conclusions about the advantages of this treatment modality over the conventional methods.

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AUTHOR'S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

Iqbal Z: Idea and operating surgeon.

Khan K: Data collection.

Khan S: Bibliography.

Shareef G: Statistics.

Saboor Z: Follow up.

Amin A: Operating surgeon and data analyser.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.