

Comparison of Botulinum Toxin Injection and Botulinum Toxin Injection with Glyceryl Trinitrate for Treatment of Chronic Anal Fissure

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ABSTRACT

Anal fissure (AF) is an illness of anal canal and is characterized by cracks appearing in stratified squamous epithelium of distal anal canal. The tear, being present in the squamous part of the epithelium, causes considerable pain, fresh bleeding while defecation. The current study is planned to compare the Botulinum toxin Injection and botulinum toxin Injection with Glyceryl trinitrate for the treatment of chronic anal fissure in terms of healing.

Materials and Methods: Patients will be sent home after one hour with stool softener .while patients in group B will be will receive treatment with 0.2 ml (20 units) Botulinum toxin injection plus 1 gram 0.2% topical glyceryl trinitrate cream 8 hourly with dose of 1 gram on middle fingers tip and apply it 1 cm² in anal canal circumferentially. In both groups, patients will be assessed at follow up after 2 , 4 and 8 weeks post treatment. At follow up, patients will be examined for healing (yes or no) and any other side effect will be documented.

Results: In Botulinum toxin injection group, 26(78.8%) had wound healing after 2 months and 30(90.9%) in Botulinum toxin injection with glyceryl trinitrate group with a p-value = 0.170.

Conclusion: Botulinum toxin injection with glyceryl trinitrate is a better technique for treatment of chronic anal fissure healing in comparison with Botulinum toxin injection alone.

Keywords: Chronic Anal Fissure, Treatment, Botulinum Injection, Botulinum Injection with Glyceryl Trinitrate, Comparison

INTRODUCTION

Anal fissure (AF) is an illness of anal canal and is characterized by cracks appearing in stratified squamous epithelium of distal anal canal. The tear, being present in the squamous part of the epithelium, causes considerable pain, fresh bleeding while defecation.¹ Anal fissures are a common problem and have a amassed lifetime incidence of 11%.³ Anal fissure causes significant discomfort, loss of working days and reduction in quality of lifestyles.² Anal fissure occurs in particular in young wholesome adults with none different clinical problems¹. The inner anal sphincter contraction is related with ache comfort and remission and might be done by way of both surgical and chemical sphincterotomy. Lateral inner shinctotomy , the standard remedy for anal fissure, is a easy and actual technique causing in restoration and remove symptoms in more than ninety % of the sufferers. but however its foremost difficulty stays its side outcomes and headaches especially incontinence upto 40 %..⁵⁻⁷⁻⁹

A local study was done to conclude the outcome of Botulinum toxin Injection and glyceryl trinitrate for the management of Chronic Anal fissure which results in healing results in healing of Anal fissure upto 94% Vs GTN cream 60 to 71 %.⁹ They reported that Pain (68%), bleeding from wound site (25%) and wound sepsis (16%) were the common complications followed by transient urinary retention (9%), incontinence (8%) and recurrence (7%).² They reported efficacy of 0.2 ml (20 units) Botulinum toxin Injection as 61.5 % and Botulinum toxin Injection with glyceryl trinitrate was 94%, p-value <0.05 with significantly higher efficacy of Botulinum toxin Injection with Glyceryl trinitrate.⁸⁻⁹

The current study is planned to compare the Botulinum toxin Injection and botulinum toxin Injection with Glyceryl trinitrate for the treatment of chronic anal fissure in terms of healing. Though data exists on local population separately on Botulinum toxin injection¹ and Glyceryl Trinitrate² and also only one study is available on their comparison⁹. If we consider separate studies they favored their respective treatment while Botulinum toxin Injection was preferred by Iqbal Z et al.⁸

MATERIAL AND METHODS

Patients fulfilling inclusion criteria in outdoor were examined after taking prior informed consent and permission of ethical committee. All cases meeting inclusion criteria were enrolled through

department of Surgery Services Hospital Lahore. Their demographic data, history and examination findings were recorded. Patients will be randomly allocated in two groups by lottery method, group A and B. Patients in group 'A' will receive treatment with 0.2 ml (20 units) Botulinum toxin injection at each site into intersphincteric plane away from anal fissure at 3 and 9 o'clock at lithotomy position under strict aseptic measures by single expert surgeon having at least five years' experience. Patients will be sent home after one hour with stool softener .while patients in group B will be will receive treatment with 0.2 ml (20 units) Botulinum toxin injection plus 1 gram 0.2% topical glyceryl trinitrate cream 8 hourly with dose of 1 gram on middle fingers tip and apply it 1 cm² in anal canal circumferentially. In both groups, patients will be assessed at follow up after 2 , 4 and 8 weeks post treatment. At follow up, patients will be examined for healing (yes or no) and any other side effect will be documented .The patients were subsequently followed up in the outpatient department for up to one year contacted by phone every months Subsequently, while they are fortified to return back if symptoms recurred¹¹. All data will be collected by researcher himself. Collected data was move in to SPSS version 23 and was analyzed. Quantitative data like age and pain score was described with mean ± SD. Qualitative variables like gender, pre procedure and post procedure anal fissure healing described as frequencies, percentages and proportions. Comparison of two groups Botulinum toxin Injection and Botulinum toxin Injection with Glyceryl Trinitrate was done with the help of Chi-Square test and Quantitative variable like Post-operative Pain was analyzed with the help of t-test. P-value ≤ 0.05 was considered significant.

RESULTS

Total 66 patients with clinical diagnosis of chronic anal fissure were enrolled in this study. Patients were divided in 2 groups i.e. Group-A (Botulinum toxin injection) and Group-B (Botulinum toxin injection with glyceryl trinitrate). In group-A, 14(42.4%) patients were Males and 19(57.6%) were Females; while in group-B, 12(36.4%) patients were males and 21(63.6%) were females. Age series in this study was from 18 to 60 years with mean age of 39.5±10.5 years. The mean age of patients in group-A was 38.1±9.9 years and in group-B was a 39.4±10.7 year. In group-A, 18(54.5%) were in 18-30 years, while 4(12.1%) and 11(33.3%) in 31-45 years and 46-Sixty years age group respectively, while in

group-B, 16(48.5%) were in 18-30 years, while 5(15.2%) and 12(36.4%) in 31-45 years and 46-60 years age group respectively.

In group-A, 20(60.6%) had anal fissure for <12 weeks and 13(39.4%) had for >12 weeks. In group-B, 21(63.6%) had anal fissure for <12 weeks and 12(36.4%) had for >12 weeks. In Botulinum toxin injection group, 26(78.8%) had wound healing after 2 months and 30(90.9%) in Botulinum toxin injection with glyceryl trinitrate group with a p-value = 0.170.

Table-1: Comparison of duration of disease distribution between groups

Duration of disease	Groups		Total
	Botulinum toxin injection	Botulinum toxin injection with glyceryl trinitrate	
<12 weeks	20	21	41
	60.6%	63.6%	62.1%
≥12 weeks	13	12	25
	39.4%	36.4%	37.9%
Total	33	33	66
	100.0%	100.0%	100.0%

Table-2: Comparison of wound healing between groups

Wound Healing	Groups		Total	p-value
	Botulinum toxin injection	Botulinum toxin injection with glyceryl trinitrate		
Yes	26	30	56	0.170
	78.8%	90.9%	84.8%	
No	7	3	10	
	21.2%	9.1%	15.2%	
Total	33	33	66	
	100.0%	100.0%	100.0%	

DISCUSSION

In recent days no affected person UK is treated by means of directly going for sphincterotomy for anal fissure until as a minimum first line, and in some instances, 2d-line remedy is used because of bowel incontinence with sphincterotomy¹⁰.

The most widely used first-line is with nitric oxide donors, commonly glyceryl trinitrate cream, however different formulations of topical nitrates supply equal results. The cream is applied, where viable, over fissure after defecation and at night time first of all, increasing packages to four times a day if signs don't improve. The most important problem is headache, taking place in 30% to forty%, but if treatment can be tolerated, tachyphylaxis in such that headaches do no longer persist for greater than five to six days¹¹. Nitric oxide donors are not tolerated in 20% to 30% due to persistent headache. If sufferers are capable of keep on with for four weeks, entire remedy of anal ache in 60% to 70%, however in 10% to twenty% are may be a relapse of anal fissure at some point of three months for that reason, restoration is accomplished in 45% to 60% of patients in three months¹³. For those who relapse a repeat treatment course achieves healing in a 20% to 30%, overall recovery is 60% to eighty%¹⁴.

If the patients have a persistent anal fissure and symptoms or cannot tolerate nitric oxide donors alternative first-line over the counter is diltiazem, a calcium channel blocker¹⁵. Diltiazem cream is used topically over fissure twice day by day to begin with however up to 4 applications a day if needed. The preparation is more costly, re are definitely no aspect results. The outcome in phrases of resolution of ache is comparable to accomplished with topical nitrates; ache free at 4 weeks 60% to 70%, with healing at 3 months of forty% to 60%¹⁶. For those who relapse a repeat course achieves recovery in 20% to 30%, basic healing is 60% to eighty%¹⁷. While 1st-Line fails, injection of Botulinum toxin into intersphincteric plane away from fissure, commonly at three and 9 o'clock, with a dose varying from 2.5 to twenty devices at each site

achieves restoration in forty% to 60%¹⁸. Complications consist of brief incontinence, hematoma, or sepsis, however those are unusual. For refractory instances, repeat injection can be used. On account that transient incontinence is now diagnosed, patients should be clearly informed about this.

CONCLUSION

Based on the results of this study it can be concluded that Botulinum toxin injection with glyceryl trinitrate is a better technique for treatment of chronic anal fissure healing in comparison with Botulinum toxin injection alone.

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