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Comparison of efficacy of internal sphincterotomy versus topical 0.2 % glyceryl trinitrate ointment after hemorrhoidectomy.

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ABSTRACT… Objectives: To compare the efficacy of 0.2% glyceryl trinitrate ointment versus internal sphincterotomy after hemorrhoidectomy. **Study Design:** Randomized Controlled Trial. **Setting:** Department of Surgery Unit III, at Lahore General Hospital, Lahore. **Period:** 6 months (August 2017 to February 2018). **Material & Methods:** The OPD of the Department of Surgery included 124 patients who satisfied the inclusion criteria. There were two groups of patients, Group A and Group B. Group-A was told to use gloved finger three times daily for 0.2 percent GTN ointment topically. For Group B, lateral internal sphincterotomy was performed as day care procedure. On visit, patients were assessed for pain relief by using VAS. All data was collected using a pre-designed (attached) proforma. In SPSS v23.0 the data were input and analyzed. It was stratified for age, sex, disease duration and hemorrhoid stage. The effectiveness of both groups was compared by using a p-value of 0.05 as significant for a chi-square test. **Results:** Male predominance; in group-A, 41(66.1%) patients were male and 21(33.9%) were female, while in group-B, 52(83.9%) patients were male and 10(16.1%) were females. Efficacy was found in 11(17.7%) patients in group-A (0.2% GTN) while in 25(40.3%) patients in group-B (Internal sphincterotomy) with p-value of 0.006 which is statistically significant. **Conclusion:** Open hemorrhoidectomy internal sphincterotomy is an effective method to reduce pain after hemorrhoidectomy in contrast to Glyceryl Trinitrate (GTN) topical cream of 0.2 percent.

Key words: Glyceryl Trinitrate, Hemorrhoidectomy, Lateral Internal Anal Sphincterotomy, Post-Operative Pain.

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INTRODUCTION

Hemorrhoids are symptomatic and distal expansion of normal anal coiling and are diagnosed by proctoscoping the rectum. In the clinical practice it is common to encounter this condition on daily bases. Symptomatic hemorrhoids incidence in the general population worldwide is estimated at approximately 4.4 percent. Generally it is seen that the patients are too reluctant and embarrassed for seeking treatment of this condition. Thus the true prevalence of pathologic hemorrhoids cannot be determined accurately.[1]

The surgical treatment for hemorrhoids around the world is hemorrhoidectomy. Multiple procedures, including open (Milligan-Morgan) and closed (Ferguson) hemorrhoidectomy can be done in this method.[2] Postoperative pain due to spasm of the internal anal sphincter is taken into account.[3] During the time period, multiple methods have been incorporated to reduce this pain, including 0,2% Glyceryl Trinitrate (GTN), 0,4% GTN and 2% Lignocaine gel, as the topic of topical application.[4-5]

The ointment of glyceryl trinitrate works as an inner anal sphincter dilator whereas 0.2 GTN reduces pain in the first week following operation.[4] Numerous studies have been done on this subject. The group that used GTN experienced a significant reduction in pain for the first few weeks following the operation with the help of the Visual Analog Scale for 7 days of a study of the pain intensity.[5-6]

Postoperative pain both at rest and during defecation and healing time has been determined to decrease significantly if patients receive postoperative treatment with GTN.[7-8] Simultaneous per-operative anal sphincterotomy by one of the hemorrhoidectomy wounds is used as a way to post-operatively minimize pain.[9-11]

The studies have shown that surgical internal sphincterotomy is more advantageous to standard hemorrhoidectomy than chemical sphincterotomy and the benefit of this procedure overshadows the apparent risk of complications.[12-13] Another study concluded that there was significant rate of healing of wounds after hemorrhoidectomy without any specific complications and this was most effective due to usage of 0.2 percent glyceryl trinitrate ointment.[14]

This study aims to provide a comparison of the efficacy between 0.2% glyceryl trinitrate ointments versus internal sphincterotomy after hemorrhoidectomy.

MATERIAL & METHODS

This was a randomized trial carried out from 6 August 2017 to 6 February 2018, in Lahore, Unit III, Department of Surgery. Non-probability consecutive technique of sampling was used. Sample size of 124 cases; 62 cases were calculated in each group at 80% test power, 95% test confidence and the expected efficacy level, i.e. 43.3% internally, and 20% GTN after a hemorrhoidectomy.[15]

Inclusion Criteria

Patients of age 25-60 years of either gender with hemorrhoids (as per operational definition) undergoing hemorrhoidectomy under spinal anesthesia

Exclusion Criteria

Patients with previous anal surgery (on history and medical record)
Anal fistula, fissure, abscess perianal, and severe hemorrhoid thrombosis (on clinical assessment).
Patients with diabetes (BSR>180mg/dl), hypertension (BP≥140/90mmHg)

Data Collection and Analysis

Demographic data were collected, such as name, age, sex and disease period. The lottery method was used for dividing patients randomly into two groups. Standard post-operative measures were employed in both the groups. In group A, 0.2% GTN ointment was recommended with the use of gloved fingers on a topical basis three times a day. This scheme has been supplied with around 300 mg GTN per request.

Group B conducted lateral inner sphincterotomy as day care procedure. Park's anal retractor was inserted and internal sphincter was stretched and made easily palpable. A small incision was then made on the lateral aspect of anal canal just below the internal sphincter. An inter sphincteric plane was developed between anal skin and internal sphincter by using scissors and internal sphincter was then divided by scissors.

Bleeding was controlled by firm finger pressure. Patients in both groups were prescribed to take stool softeners and isphagul husk. Patients were followed in OPD after 1 week. Pain had been evaluated postoperatively on the 7th day by using a visual analog scale. No Pain = 0, Mild Pain = 1-3, Moderate Pain = 4-6, and Severe Pain = 7-10.

Efficacy was labeled if there was complete absence of pain i.e. '0' on visual analogue scale after 7 days of hemorrhoidectomy. On visit, patients were assessed for pain relief by using VAS. Efficacy was labeled if patient was complaint any pain (as per operational definition). All surgeries were done by the same surgical team to minimize bias.

In SPSS v23.0 the data were input and analyzed. Average and standard deviation were calculated as quantitative variables such as age, pain and duration of a disease. As frequency and percentage quality variables, such as gender, hemorrhoid degree and effects were calculated. The effectiveness of the p-value value p-0.05 was equivalent to both classes by using chi-square tests. Data for age, class, disease's duration and hemorrhoid level have been stratified. The Chi-

square test was opted for post-stratification, while p-value was used for the value of 0.05.

ETHICAL CONSIDERATIONS

After taking permission from Hospital Ethical Committee, 124 patients fulfilling the inclusion criteria were selected from OPD of Department of Surgery, Lahore General Hospital, Lahore. Informed consent was taken from all participants before interviewing by the investigators themselves.

RESULTS

Total of 124 patients with hemorrhoids (as per operational definition) undergoing hemorrhoidectomy under spinal anesthesia were enrolled in this study. Patients were divided in two groups i.e. Group-A (0.2% GTN) and Group-B (Internal sphincterotomy).

The age range was between 25 and 60 years for this analysis and the mean age was 42.2±10.5 years. Group-A patients had a mean age of 40.1±9.9, and Group-B had a mean age of 44.4±10.7. The mean pain score was 2.2±1.6 for group A and 1.0±1.1 for group B.

In group-A, 41(66.1%) patients were male and 21(33.9%) were females, while in group-B, 52(83.9%) patients were male and 10(16.1%) were females.

In group-A, majority of the patients 23(37.1%) were of 25-35 years age group, while in group-B, majority of the patients 29(46.8%) were of ≥46 years age group.

In group-A, majority of the patients 39(62.9%) had fourth degree of hemorrhoids, while in group-B, majority of the patients 45(72.6%) had fourth degree of hemorrhoids.

In group-A, majority of the patients 47(75.8%) had ≤12 months duration of disease, while in group-B, majority of the patients 36(58.1%) had >12 months duration of disease.

Efficacy was found in 11(17.7%) patients in group-A (0.2% GTN) while in 25(40.3%) patients in group-B (Internal sphincterotomy) with p-value of 0.006 which is statistically significant.

DISCUSSION

Pain and discomfort after hemorrhoidectomy has been the major concern for the surgeons and patients.[15] This is the sole reason for the development a painless hemorrhoidectomy and several modalities are used.[16] Our study focused on the comparison of efficacy of the of 0.2% glyceryl trinitrate ointment versus internal sphincterotomy after hemorrhoidectomy and it depicted interesting finding .This would help in knowing how effective the method was for the

Gender	Efficacy	Groups		Total	P-Value
		0.2% GTN	Internal Sphincterotomy		
Male	Yes	8	22	30	0.020
		19.5%	42.3%	32.3%	
	No	33	30	63	
		80.5%	57.7%	67.7%	
	Total	41	52	93	
		100.0%	100.0%	100.0%	
Female	Yes	3	3	6	0.301
		14.3%	30.0%	19.4%	
	No	18	7	25	
		85.7%	70.0%	80.6%	
	Total	21	10	31	
		100.0%	100.0%	100.0%	

Table-I. Comparison of efficacy in both groups with respect to gender

Age Groups	Efficacy	Groups		Total	P-Value
		0.2% GTN	Internal Sphincterotomy		
25-35 years	Yes	4	4	8	0.493
		17.4%	26.7%	21.1%	
	No	19	11	30	
		82.6%	73.3%	78.9%	
	Total	23	15	38	
		100.0%	100.0%	100.0%	
36-45 years	Yes	2	9	11	0.009
		10.5%	50.0%	29.7%	
	No	17	9	26	
		89.5%	50.0%	70.3%	
	Total	19	18	37	
		100.0%	100.0%	100.0%	
≥46 years	Yes	5	12	17	0.236
		25.0%	41.4%	34.7%	
	No	15	17	32	
		75.0%	58.6%	65.3%	
	Total	20	29	49	
		100.0%	100.0%	100.0%	

Table-II. Comparison of efficacy in both groups with respect to age

Degree of Hemorrhoids	Efficacy	Groups		Total	P-Value
		0.2% GTN	Internal Sphincterotomy		
Third	Yes	3	17	20	0.034
		13.0%	37.8%	29.4%	
	No	20	28	48	
		87.0%	62.2%	70.6%	
	Total	23	45	68	
		100.0%	100.0%	100.0%	
Fourth	Yes	8	8	16	0.043
		20.5%	47.1%	28.6%	
	No	31	9	40	
		79.5%	52.9%	71.4%	
	Total	39	17	56	
		100.0%	100.0%	100.0%	

Table-III. Degree of hemorrhoids and comparison of efficacy in both groups

Duration of Disease	Efficacy	Groups		Total	P-Value
		0.2% GTN	Internal Sphincterotomy		
≤12 months	Yes	7	15	22	0.006
		14.9%	41.7%	26.5%	
	No	40	21	61	
		85.1%	58.3%	73.5%	
	Total	47	36	83	
		100.0%	100.0%	100.0%	
>12 months	Yes	4	10	14	0.443
		26.7%	38.5%	34.1%	
	No	11	16	27	
		73.3%	61.5%	65.9%	
	Total	15	26	41	
		100.0%	100.0%	100.0%	

Table-IV. Duration of disease for comparison of efficacy in both groups

patients comfort and satisfaction and further exploration of the subject.

Operational hemorrhoidectomy is the most popular treatment method for hemorrhoids of the third and fourth degrees currently used. The system can be open or closed. The exact causes of postoperative pain have not yet been identified after hemorrhoidectomy but the cause is often thought to be increased tone of the inner sphincter.[17]

Recent manometric studies in hemorrhoid patients show the presence of the spasm even before surgery. The awareness about the treatment of anal fissures consists in all the details about the process for controlling pain. The first to be identified was Eisenhammer in the post-hemorrhoidectomy painting for internal sphincter spasm.[18] This is evident in our research and several parallel studies that the direction of the postoperative procedure after haemorrhoidectomy improves sphincterotomy dramatically and this procedure is very effective.[1] External sphincterotomy was found to lead to mild continent damage, leading to flatus, mucus or occasionally stool incontinence and for this reason it was contrasted with chemical sphincterotomy with topical nitrates and diltiazim.[19]

A 0,2% Topical glyceryl trinitrate lowers internal anal sphincter contraction. The healing rates for chronic anal cracks were notable by decreasing the anal sphincter pressure. A study has found that pain relief in internal sphincterotomy patients is better than topical, comparable 0.2 percent glyceryl trinitrate. We must also understand that internal sphincterotomy was a consistent technique among patients; this is not the case with 0.2% trinitrate.[17-18]

In a study, it was concluded that, Mean post-operative pain score was significantly low in group B (Internal Sphincterotomy) 2.07±0.9 as compared to group A (GTN) 3.17±1.1 (p=0.0005).[20] This is concurrent to the results of our study. In another study, it was reported that, post-operative pain was comparatively less in group A (Internal Sphincterotomy) 20% as compared to group B (GTN) 43.3% (p = 0.014).[21] In our study, efficacy was found in 11(17.7%) patients in group-A (0.2% GTN) while in 25(40.3%) patients in group-B (Internal sphincterotomy) with p-value of 0.006 which is statistically significant and concomitant to previous studies.

0.2 percent local GTN absorption is proportional, not only to the amount applied but also to factors like skin thickness and tissue inflammation quantity. This is why perianal wounds will significantly impact 0.2 percent GTN kinetics and decrease their activity by tachyphylaxis after hemorrhoidectomy. This may be one major reason why lower pain relief in this group has been obtained. The average pain of post-hemorrhoidectomy in Das et al was 3.26 ± 2.258 in comparison with 1.6 ± 0.599 in the study with lateral anal sphincterotomy using 0.2 percent of topical Glyceryl Trinitrate (GTN).[22]

In this regard it is worthy of note that anal inner sphincterotomy is important and mainly prevents postoperative pain, as several multi-center clinical studies have already highlighted.[23-24] Instead, several writers said the internal sphincterotomy does not affect the after surgical pain.[25-26] Sometimes after healing, pain may persist over time. In most cases, the cause of the pain was due to an anal fissure on the groove of one of the excised peduncles. It was also found.

A similar work was carried out by Galicia et al, randomised prospective analysis, an anorectal manometric results and then assessed postoperative trajectories in 42 patients with and without lateral internal sphincterotomy, after hemorrhoidectomy had been performed. These results show that pain levels and analgesic conditions between the two groups differ significantly. In comparison to studies on chemical methods, it has come to the attention of the beneficial effects of hemorrhoidectomy by the addition of lateral internal sphincterotomy.

CONCLUSION

Open hemorrhoidectomy internal sphincterotomy is an effective method for reducing pain after hemorrhoidectomy compared to a topical

Glyceryl Trinitrate (glyceryl) cream of 0.2 per cent. But a robust study and comparison with other modalities is still needed.

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