ORIGINAL ARTICLE

Open Hemorrhoidectomy with and without Chemical Sphincterotomy: A Randomized Control Trial

ABU RAIHAN ZABD-UR-REHMAN QURESHI[1], MUHAMMAD ARIF AZEEM[2], FOWAD KARIM[3], *UMAR FAROOQ DAR[4], MUHAMMAD WASEEM ANWAR[5], USMAN IMTIAZ[6]*

ABSTRACT

Aim: To compare mean post-operative pain score in patients undergoing open hemorrhoidectomy alone verses open hemorrhoidectomy with chemical sphincterotomy.

Methods: In this randomized control trial carried out in department of general surgery unit I, Jinnah hospital Lahore, 100 patients were randomly assigned either to open hemorrhoidectomy alone or open hemorrhoidectomy with chemical sphincterotomy with diltiazem ointment. Patients were followed for post-operative pain on day 1 and 2 by subjective assessment on visual analogue scale ranging from 0 to 10, with 10 as worst pain after procedure. Both groups were given similar pain elevating regimen. Data was collected on a structured proforma and analyzed using SPSS 17. Chi square and t test were used for categorical and continuous variables respectively.

Results: One hundred patients (57% male) with mean age 49.1±5.5 years were included. There came out a significant difference in mean post-operative pain in sphincterotomy group on day1 (p= 0.02) but non-significant difference on day 2. There was equal distribution of age, gender and degree of haemorrhoids in both treatment groups (p=0.44).

Conclusion: It is concluded that mean post-operative pain score in patients undergoing open hemorrhoidectomy with chemical sphincterotomy is significantly lesser than open hemorrhoidectomy alone on day 1, but not on day 2.

Keywords: Diltiazem ointment, hemorrhoidectomy, chemical sphincterotomy, open hemorrhoidectomy

INTRODUCTION

Many people suffer from hemorrhoids at some period during their lifetimes. Incidence is thus difficult to estimate. Different epidemiologic studies have reported prevalence ranging from 4.4 to 30%[1,2] Hemorrhoids are one of the most common diseases of mankind. Many modes of treatments have been advocated for the treatment of symptomatic hemorrhoids, including diet, local preparations, sclerotherapy, rubber band ligation, infrared photocoagulation and surgical hemorroidectomy[2].

Many authors agree that symptomatic grade I and II hemorrhoids should be treated conservatively, whereas hemorrhoids grade III and IV should be candidate for surgical extirpation.[3] Patient not responding to conservative treatment should be treated surgically as well. Milligan Morgan technique is the most frequently used surgical technique. In this technique, hemorrhoids tissues is excised from the apex and separated from the sphincter and the wound thus formed is left open to heal by secondary intention.

[1-3,5-6]Department of Surgery, Jinnah Hospital Lahore, [4]Department of Infectious Diseases, Institute of Public Health Lahore

Correspondence: Dr. Umar Farooq Dar, e-mail: umardar84@gmail.com

Pain is the frequent post hemorrhoidectomy problem[4] that is caused by the spasm of internal anal sphincter[5,6]. Different approached have been used to manage this complication which includes local anesthetic use[7], ischiorectal block[4], surgical shpincterotomy[5,6] and chemical spincterotomy[5,8,9]. Chemical sphincterotomy can be performed by using various pharmacological agents such as glyceryltrinitrate a calcium channel blocker to reduce spasm of internal sphincter and thus reduce pain[10].

In a study conducted at Surgical Unit III Civil Hospital Karachi, it was elaborated that mean pain score in study group (hemorrhoidectomy and diltiazem application) was 4.2±1.9 while in control group (hemorrhoidectomy alone) was 7.5±1.2 on second post op-day (p<0.05). Glyceryl trinitrate is mostly used as an adjunct to the hemorrhoidectomy for pain reliefs but the results are not promising. We therefore, wanted to observe the effect of diltiazem (calcium channel blocker) on post hemorrhoidectomy pain. As only three studies are available in Asia and in all previous studies sample size is small (largest sample size in one of them is 80)[10], therefore the study was conducted having large sample size to compare mean pain score on visual analogue score on 1st and 2nd post operative day in patients using diltiazem versus patients not using it with standard hemorrhoidectomy so that if found effective diltiazem

can be added to the treatment of hemorrhoid along with hemorrhoidectomy for relief of pain.

SUBJECTS AND METHODS

To achieve the above said objective, a randomized control trial was carried out in surgical unit I of Jinnah Hospital Lahore. Using Non probability consecutive sampling, 100 clinically diagnosed male and female patients with age ranging from 16 to 60 years presenting with 3rd and 4th degree haemorrhoids were enrolled. It was hypothesized that there is difference in mean postoperative pain score among patients undergoing open hemorrhoidectomy with chemical sphincterotomy as compared to open hemorrhoidectomy alone. Patient having associated perianal pathologies like fistula, anal cancer, history of recurrent haemorrhoids and history of hypersensitivity to topical calcium channel blockers were excluded.

After taking informed consent, on arrival of a patient detailed history, general physical examination and perianal examination was done, along with systemic examination. The patients were randomly allocated into two groups by using random number table. In group A: open hemorrhoidectomy alone, in group B: open hemorrhoidectomy with chemical sphincterotomy with diltiazem ointment. The patients were counselled regarding the objective and importance of open hemorrhoidectomy and chemical sphincterotomy. The demographic information was recorded (name, age, sex). All the information was collected on a predesigned proforma. In all patients hemorrhoidectomy was performed by the senior surgical trainee or a consultant under caudal / spinal / general / local anaesthesia. In group B 1st doze of diltiazem was applied at the time of hemorrhoidectomy and later on three times a day for 7 days. 1st doze of analgesia was provided in the form of injectable morphine derivative and later on Tab Dicloran 50mg was given three times a day orally. The patient's pain was assessed on 1st and 2nd post-op-day using visual analogue scale to record the pain score.Pain was categorized as No pain (0 score on VAS), Mild Pain (1-3), Moderate Pain (4-6), Severe Pain (7-10).

Data collected was entered and analyzed in the SPSS version 17. Mean with standard deviation was calculated for quantitative variables like age and pain score on visual analogue scale. Frequency and percentages in case of categorical variables like gender and degree of haemorrhoids. Mean pain score in both groups was compared using independent sample t test. Data was analyzed to control the effect of age and sex and pain categories by classifying both groups in to appropriate age and gender and pain categories and chi square test was applied. A p value $\leq$ .05 was taken as significant.

RESULTS

One hundred patients with mean age 40.27±9.8 years were randomly distributed into two categories i.e. open hemorrhoidectomy alone and hemorrhoidectomy with chemical sphincterotomy. Pain score on day one was compared in both treatment groups using independent sample t-test the result was significant (p value= 0.002). While on day 2 there was non-significant difference in mean pain score (p=0.44).Mean age was equally distributed in both treatment groups (p=0.129). 37% of included patients were female and gender distribution was similar in treatment groups (p=0.534). 44% patients belong to 3rd degree of haemorrhoids. Degree of haemorrhoid was equal in both treatment groups (p=0.227). 65% of the patients were having moderate pain when we categorized pain in to 3 categories i.e. sever, mild and moderate. These categories showed non significance association with either treatment group (Tables 1-4).

Table 1: Distribution of pain score on day 1 in treatment groups

Group	No.	Mean±SD
Hemorrhoidectomy	50	6.12±1.31
Hemorrhoidectomy with sphincterotomy	50	5.32±1.25
P value	0.002 (Significant)	

Table 2: Distribution of pain score on day 2 in treatment groups

Group	No.	Mean±SD
Hemorrhoidectomy	50	6.36±1.24
Hemorrhoidectomy with sphincterotomy	50	5.56±1.38
P value	0.44 (Not significant)	

Table 3: Crosstab between gender and treatment group

Gender	Hemorrhoi-dectomy	Hemorrhoidectomy + sphincterotomy	Total
Male	17	20	37
Female	33	30	63
Total	20	50	100
P value	0.534		

Table 4: Distribution of age in both groups

Group	No.	Mean±SD
Hemorrhoidectomy	50	38.78±9.94
Hemorrhoidectomy with sphincterotomy	50	41.76±9.51
P value	0.129 (Not significant)	

DISCUSSION

Post-operative pain is one of the major outcomes in a surgical treatment of 3rd degree and 4th degree hemorrhoids.[10-12] Different treatment strategies are so far used to reduce usage of non-steroidal anti-inflammatory agents and opiate pain killers[13,14]. Diltiazem is a calcium channel blocker used orally for cardiovascular diseases as vascular dilation[15].

Different studies have demonstrated that there was a more marked improvement of symptoms and relief of anal pain, and a significantly lower administration of oral analgesics with fewer side-effects using diltiazem compared with placebo as described earlier[12,15-18]. Hyper tonicity of the internal anal sphincter is thought to play a role in post-operative pain. A reduction in the mean resting anal pressure after using topical perianal diltiazem has been demonstrated in chronic anal fissures[18].

Chemical sphincterotomy with diltiazem (2%) ointment is an effective first-line treatment for spasm of the internal anal sphincter that is thought to be the source of pain after anal surgery and may contribute to postoperative hemorrhoidectomy pain[12]. We therefore followed that strategies aimed at reducing internal sphincter tone might be beneficial in reducing pain following hemorrhoidectomy. Diltiazem acts by inhibiting the flow of extracellular calcium ions into the sarcoplasm of the human internal anal sphincter, with a consequent saving of oxygen, resulting in muscle relaxation and pain relief[15].

Current study showed that open hemorrhoidectomy with chemical sphincterotomy is better than without it. But the significant difference lies only on day 1 showing that it reduced the pain associated with spasm secondary to surgical procedure only. On second day although the trend of lesser pain was on sphincterotomy group but there was not a significant difference.

Hemorrhoids do reflect a social disease process also as more male personnel presented for surgical treatment. There may be taboos associated with it and lack of female surgeons in our tertiary care. Age group is also showing that it is the dietary changes and life style which made it a disease of younger age groups.

When we categorized the pain score into three categories based on operational definitions we found non-significant difference in both treatment groups. The reason is probably that our categories are broad enough to cater the difference produced. Secondly it shows that difference in post-operative score is not as big as reported by previous studies[12,16,17]. We also additionally analyzed the gender distribution regarding degree of hemorrhoids in our study population. It was equally distributed in both treatment groups[17]. The study was designed to reduced many of biases because of randomization. We have shown the age was equally distributed in both hemorrhoidectomy groups with or without sphincterotomy.

Limitation of our study includes not taking into account the side effects of diltiazem ointment as some studies have reported in treatment of chronic anal fissure. Different side effects like headache and hypotension[15] was encountered during study but had not recorded as it was out of scope of current study. The second important limitation is time taken for the procedure. Although sphincterotomy does not consume much time but difference may be significant when weighted across reduction in pain achieved. Our population does not know much about drug sensitivity. Same was the case regarding diltiazem, as most of patient did not responded whether they were allergic to any drug or not.

CONCLUSION

It is concluded that mean post-operative pain score on day 1 in patients undergoing open hemorrhoidectomy with chemical sphincterotomy versus is significantly lower than open hemorrhoidectomy alone. While on day 2 there is non-significant difference in mean pain score in both treatment groups. Further studies should be encouraged in this regard.

REFERENCES

1. Kaidar-Person O, Person B, Wexner SD. Hemorrhoidal disease: a comprehensive review. J Am Coll Surg 2007;204(1):102-17.
2. Chong PS, Bartolo DC. Hemorrhoids and fissure in ano. Gastroenterol Clin North Am 2008;37:627-44.
3. Haveran LA, Sturrock PR, Sun MY, McDade J, Singla S, Paterson CA, et al. Simple harmonic scalpel hemorrhoidectomy utilizing local anesthesia combined with intravenous sedation: a safe & rapid alternative to conventional hemorrhoidectomy. Inter J Colorectal Dis 2007; 22(7):801-6.
4. Rajabi M, Hosseinpour M, Jalalvand F, Afshar M, Moosavi G, Behdad S. Ischiorectal block with bupivacaine for post hemorrhoidectomy pain. Kor J Pain 2012;25(2):89-93.
5. Chauhan A, Tiwari S, Mishra V, Bhatia P. Comparison of internal sphincterotomy with topical diltiazem for post-hemorrhoidectomy pain relief: a prospective randomized trial. J Postgrad Med 2009;55(1):39-43.
6. Abedidost S, Poya M, Shakouri MS. The effect of internal sphincterotomy on post hemorrhoidectomy pain. Arak Med Univ J 2011;14(2): 59-61.
7. Haas E, Onel E, Miller H, Ragupathi M, White PF. A double-blind, randomized, active-controlled study for post-hemorrhoidectomy pain management with liposome bupivacaine, a novel local analgesic formulation. Am Surg 2012;78(5):574-81.
8. Siddiqui MRS, Abraham-Igwe C, Shangumanandan A, Grassi V, Swift I, Abulafi AM. A literature review on the role of chemical sphincterotomy after Milligan–Morgan hemorrhoidectomy. Inter J Colorectal Dis 2011;26(6):685-92.
9. Hashmi F, Siddiqui FG. Diltiazem (2%) versus glyceryltrinitrate cream (0.2%) in the management of chronic anal fissure. J Coll Physicians Surg Pak 2009;19(12):750-3.

10. Joshi GP, Neugebauer EA, PROSPECT Collaboration. Evidence-based management of pain after haemorrhoidectomy surgery. Br J Surg 2010; 97:1155-64.
11. Ozer MT, Yigit T, Uzar AI, Mentes O, Harlak A, Kilic S, Cosar A, Arslan I, Tufan T. A comparison of different hemorrhoidectomy procedures. Saudi Med J 2008;29(9):1264-90.
12. Sugimoto T, Tsunoda A, Kano N, Kashiwagura Y, Hirose K, Sasaki T. A randomized, prospective, double-blind, placebo-controlled trial of the effect of diltiazem gel on pain after hemorrhoidectomy. World J Surg 2013; 37(10): 2454-7
13. Thaha MA, Irvine LA, Steele RJ, Campbell KL. Postdefaecation pain syndrome after circular stapled anopexy is abolished by oral nifedipine. Br J Surg 2005; 92:208-19.
14. Eshghi F, Hosseinimehr SJ, Rahmani N, Khademloo M, Norozi MS, Hojati O. Effects of aloe vera cream on posthemorrhoidectomy pain and wound healing: results of a randomized, blind, placebo-control study. J Alter Comple Med 2010, 16(6): 647-59.
15. Perrotti P, Dominici P, Grossi E, Cerutti R, Antropoli C. Topical nifedipine with lidocaine ointment versus active control for pain after hemorrhoidectomy: results of a multicentre, prospective, randomized, double-blind study. Can J Surg 2010 Feb;53(1):17-24.
16. Jayaraman S, Colquhoun PH, Malthaner RA. Stapled versus conventional surgery for hemorrhoids. Cochrane Database Syst Rev 2006; :CD005393.
17. Arabi Y, Alexander-Williams J, Keighley MR. Anal pressures in hemorrhoids and anal fissure. Am J Surg 1977; 134:608-17.
18. Bleday R, Pena JP, Rothenberger DA, et al. Symptomatic hemorrhoids: current incidence and complications of operative therapy. Dis Colon Rectum 1992; 35:477-88.