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COMPARATIVE STUDY OF INTERNAL ANAL SPHINCTEROTOMY VS TOPICAL APPLICATION OF LIDOCAINE + NIFEDIPINE IN REDUCING POST OPERATIVE PAIN FOLLOWING OPEN HEMORRHOIDECTOMY – A PROSPECTIVE RANDOMIZED CONTROL TRIAL

General Surgery

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KEYWORDS

INTRODUCTION

Hemorrhoids to the surgeon, refers to abnormalities of the vascular cushions of the anus. The most common symptom is bleeding at defaecation. Commonly this is bright red and follows immediately after defaecation.

Clinically, Haemorrhoids can be Classified into Four Groups:

1. Internal haemorrhoids presenting with bleeding alone (first degree)
2. Haemorrhoids which prolapse on defaecation but reduce spontaneously (second degree)
3. Haemorrhoids which prolapse and require manual reduction (third degree)
4. Irreducibly prolapsed haemorrhoids (fourth degree).

Treatment of hemorrhoidal disease depends on the stage of the disorder and the symptoms.[1] The options for the treatment of hemorrhoids can be categorized into medical management, office-based treatments, and operative therapies.

Surgical hemorrhoidectomy is indicated for the treatment of third- and fourth-degree symptomatic hemorrhoids.[2] However, surgery is associated with severe postoperative pain which is a source of such anxiety, that some patients decide not to undergo the operation.

Post hemorrhoidectomy pain seems to be significantly associated with a spasm of the internal anal sphincter.[3,4] Nonsteroidal anti-inflammatory drugs (NSAIDs) and opiates have often been used to control pain, but their use is confined to a short period of time and is associated with frequent side effects.[5] Pain when adequately controlled, hemorrhoidectomy may be conducted in an outpatient setting, saving a lot of money.[6]

Hence, the introduction of novel methods for the control of pain after hemorrhoidectomy was required. Many invasive and non invasive methods have been developed including Surgical sphincterotomy and chemical sphincterotomy. Since IAS spasm is attributed to one of the major causes of post operative pain, advocation of IAS can abolish the spasm and has been proposed to reduce post operative pain[7]. Also recent evidence suggests that chemical sphincterotomy with the use of nifedipine, a calcium channel blocker, is effective in relaxing the anal sphincter smooth muscles and inturn reducing anal resting pressure[8]. Therefore, it seems likely that a new ointment, Anobliss containing – 0.3% nifedipine + 1.5% lidocaine may be considered as a treatment that affects one of the supposed causes for pain after hemorrhoidectomy. Lidocaine (local anesthetic) and nifedipine have complementary actions.

Hence in this study we evaluate the efficacy in postoperative pain reduction of Internal anal sphincterotomy (IAS) as compared to the topical use of Lidocaine 1.5% + Nifedipine 0.3% (Anobliss ointment) following Milligan Morgan open hemorrhoidectomy. (OH)

MATERIALS AND METHODS

Study Design

The study was a single center prospective randomized controlled trial which was conducted on patients presenting with grade 3 & 4 hemorrhoids in the department of general surgery (OPD/IPD/emergency) at SHRI ATAL BIHARI VAJPAYEE MEDICAL COLLEGE & RESEARCH INSTITUTE / BOWRING & LADY CURZON HOSPITAL, (SABVMC&RI/B&LCH)during the period of 1 year (2023 – 2024).

Patient Selection

Pateints presenting to OPD with newly diagnosed hemorrhoids were screened and those above the age group of 18 years and of grade 3 and 4 symptomatic hemorrhoids were enrolled into the study. Those patients having, strangulated/thrombosed hemorrhoids, hemorrhoids with concomittant fistula, abscess, fissure, anorectal carcinoma, inflammatory bowel disease, medical renal disease, portal hyper-tension, previous h/o anorectal surgeries, pregnant women, neurological deficit or chronic anorectal pain syndrome, hypertensives, copd/bronchial asthama, cardiac failure, those patients allergic to any of these drugs, and those unwilling for surgery and to follow up, were not consider into the study group.

Methodology

Institutional ethical committee clearence was obtained (IEC/RP/166/23-24) following which the study was initiated after taking consent from the patients. As per the statistical analysis a total sample size of 30 was allocated, where 15 in each arm were considered. The study was designed to assess the difference in mean visual analogue pain score among the groups. The eligible consented subjects were randomized (computer generated randomization) into 2 groups - Group A (Open miligan morgan hemorrhoidectomy + IAS) and Group B (Open miligan morgan hemorrhoidectomy + Anobliss – Lidocaine 1.5% + Nifidepine ointment 0.3%). They were blinded to respective treatment arms. The operating surgeon surgery was blinded to the group allocation and was not involved in the post operative assessement.

Procedure

A Detailed clinical history was taken and patients were examined thoroughly. The consented patients with a pre operative clearence were subjected to open miligan morgan hemmo-rhoidectomy under SA. The patients were then randomized to 2 groups where – Group A, underwent an additional procedure of IAS (Internal Anal Sphincter was divided through one of the hemmorhoidectomy wounds and hemostasis was achieved) and Group B had an application of ANOBLISS ointment (LIDOCAINE 1.5% + NIFEDIPINE 0.3%) post open miligan morgan hemmorhoidectomy. The first topical dose of ANOBLISS ointment was applied on table at the end of surgery, and the subsequent doses were administrated by the patient in an identical manner as follows: once in the evening of the surgery day, followed by thrice daily (morning, afternoon, evening) from POD 1 - POD 6. Post operatively – All patients were given the medical and nursing care as per protocol. Patients were allowed full oral feed six hours after surgery. They were advised for High fiber diet, Plenty of oral fluids (min 2lts), Antibiotics, PPI, Tab Paracetamol 500mg as per rescue analgesic protocol, laxatives, Anobliss application (TID till POD 6), Sitz bath (TID), Medications for co morbid conditions, Good toiletary habits and perianal hygiene. As an oral sedative, and from the ethical point of view for the management of post operative Pain, all patients in the study of both the groups were prescribed tab paracetamol 500 mg on a BD dose (as a RESCUE ANALGESIC), till POD 3 and

when discharged, Tab paracetamol 500 mg was prescribed again as a RESCUE ANALGESIC, on SOS basis. Patients who were fit were planned for discharge (tentatively on POD3) with the appropriate advise on discharge and were called to visit for a follow up on POD 7. The patients were asked to maintain a record of the number (in a book) of RESCUE ANALGESIC consumed at home post discharge and were calculated and assessed for pain on the follow up period at POD 7. Post-hemorrhoidectomy pain was assessed by a blinded assessor using the VISUAL ANALOUGE SCORE at POD 1 , POD 2 , POD3 and POD 7. The cumulative number of RESCUE ANALGESIC consumed in the first 3 days and post discharge till POD 6 was calculated on POD 7.

Data Collection

Postoperative assessment, follow-up and data collection was done by an surgical assistant who was blinded to group allocation and procedure performed.

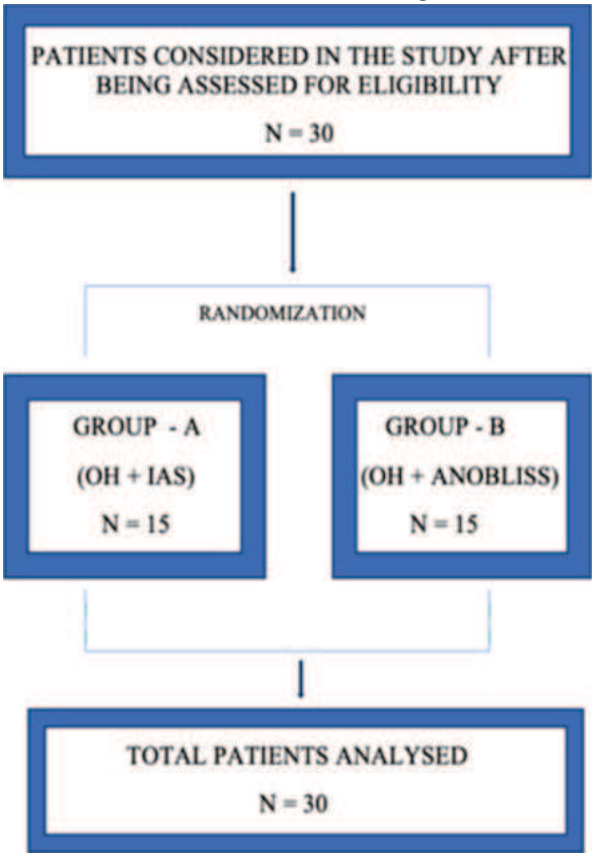
Statistical Analysis

Data was entered in Microsoft Excel format 2000 and was analyzed by using SPSS Version 10. Comparison and analysis between VAS, in two groups, on various days were done by using Student T test. Statistical techniques applied were Chi-square and Fisher's Exact Test. To see the change over a period of time, two-way analysis of variance (Repeated Measure Analysis) followed by Port-Hoch (Multiple range test) was done. P value less than 0.05 was considered as significant.

RESULTS

A total of 30 eligible patients were incorporated in the study and they were randomized into two groups of 15 cases each. Group A were designated for internal anal sphincterotomy while Group B for topical LIDOCAINE 1.5% + NIFEDIPINE 0.3%. (ANOBLISS ointment) The data collected was analyzed.

The Flowchart of the Trial is Summarized in Figure 1.



Of the total 30 patients incorporated in the study 15 patients were classified into group A (OH + IAS) and the other 15 were classified into group B (OH + ANOBLISS ointment - lidocaine 1.5% + nifedipine 0.3%.). The mean age was 42.35 in group A and 48.46 in group B respectively. The study had predominantly male patients in both the groups. Grade 3 haemmorhoids were predominantly found in group B and grade 4 haemmorhoids were dominant in group A of the study. Demographic details summarised in Table 2.

Table 2 – Demographic Details.

DEMOGRAPHICS	GROUP A (N=15) OH + IAS	GROUP B (N=15) OH + ANOBLISS (LIDOCAINE 1.5% + NIFEDIPINE)
MEAN AGE	42.35	48.46
MALE	12	9
FEMALE	3	6
GRADE 3	6	10
GRADE 4	9	5

The mean VAS scores were compared between the 2 groups for POD1, 2, 3 & 7 and the consumption of rescue analgesic noted. It was noted that till POD 3 there was no statistically significant difference in the VAS between 2 groups, but a statistically significant difference was noted on POD 7. VAS score was significantly lower in group A (table 3).

Table 3 - Comparison of VAS Score Among Both the Groups.

DAY	GROUP - A (N=15) OH + IAS (MEAN + SD)	GROUP - B (N=15) OH + ANOBLISS ((LIDOCAINE 1.5% + NIFEDIPINE) (MEAN + SD)	P VALUE 0.05
POD 1	7.59 + .60	8.96 + 0.68	0.61
POD 2	6.13 + 1.07	7.89 + 0.62	0.59
POD 3	4.71 + 1.13	5.37 + 0.86	0.52
POD 7	0.34 +0.27	1.25 + 0.09	0.02

The mean number of analgesic tablets required by Group A was 11.36 + 1.13 ; while that in Group B was 17.31 + 1.24. The difference of analgesic consumption was statistically significant among the groups was less in group A (table 4).

Table – 4. Comparison of RESCUE ANALGESIC consumption among Both the Groups.

	GROUP A OH + IAS	GROUP – B OH + ANOBLISS (LIDOCAINE 1.5% + NIFEDIPINE)	P value (0.05)
Number of Tab Paracetomol 500mg consumed since the time of surgery till POD 7	11.36 + 1.13	17.31 + 1.24	0.01

Post operative complication incidence was more in Group A (20%) compared to that in Group B (10%), however, this difference was not significant (P= 0.748; Table 5).

Table – 5. Post Operative Complications.

	GROUP - A	GROUP – B
Bleeding	1	0
Faecal soiling	1	0
Mucus discharge	2	0
Incontinence to flatus	1	0
Headache	0	2
Anal stenosis	0	0
Recurrence	0	0

DISCUSSION

Hemorrhoids are one of the most common surgical pathologies encountered by the surgeon. Hemorrhoids treatment depends upon the stage of disease and that the current treatment for third- and fourth-degree symptomatic hemorrhoids is hemmorhoidectomy.[2,9] But since, surgery is associated with severe postoperative pain which is a source of such anxiety, that some patients decide not to undergo the operation. The exact cause of postoperative pain after hemorrhoidectomy has not been defined yet, but hypertonia of internal sphincter is widely believed to be the cause of postoperative pain after hemorrhoidectomy has not been defined yet, but hypertonia of internal sphincter is widely believed to be the cause of postoperative pain after hemorrhoidectomy.

Eisenhammer[10] was the first to propagate the idea that post-hemorrhoidectomy pain is due to spasm of the internal sphincter and described that its division through one of the hemorrhoid wounds is certainly an effective way to lessen postoperative pain. Hence Pain when adequately controlled, hemorrhoidectomy may be conducted in an outpatient setting, saving a lot of money.[4] Several novel methods (invasive and non invasive) were developed including Surgical sphincterotomy and chemical sphincterotomy, for the control of pain after hemorrhoidectomy.

Several investigators[11,12] have concluded that sphincterotomy significantly improves the postoperative course after hemorrhoidectomy and that the procedure is safe. Since IAS is known to lead to permanent minor impairment of continence leading to incontinence of flatus, mucus, or occasionally stool, some of them have advocated the concept of chemical sphincterotomy with topical nitrates and calcium channel blockers. Tho much of the learnings of chemical sphincterotomy have come from the experience of treating chronic fissure in ano.[13-16]

Amongst the agents employed for "chemical sphincterotomy" calcium channel blockers have been opted over topical nitrates citing the much lower incidence of complications in the former. [17,18]Topical nifedipine blocks the calcium uptake in the myocytes thereby decreasing contraction and tone of internal anal sphincter, aiding in reducing post operative pain.[11] such type of chemical sphincterotomy has also demonstrated to have significant healing rates for chronic anal fissures by reducing the anal sphincter pressure. [19-21]

Hence in this study we tried to evaluate the efficacy in postoperative pain reduction of Internal anal sphincterotomy as compared to topical use of Anobliss ointment (Lidocaine 1.5% + Nifedipine 0.3%) following Milligan Morgan hemorrhoidectomy. Our study had 2 group where mean age in group A was 42.35 and in group B was 48.46. the study had a male preponderance among the groups.

Our study demonstrated that pain relief was statistically significant in patients subjected to IAS than topical anobliss ointment group, which was noted on post operative day seven. The VAS scores were assessed and recorded on post operative day 1,2,3 and 7, by a surgical assistant who was blinded to the study. We also measured the pain perception indirectly by recording the number of rescue analgesics (Tab paracetamol 500mg) consumed.

The overall incidence of complications was higher in the IAS group (A) as mentioned in table – 5. The concern of faecal soiling was noted in 1 patient and Incontinence to flatus was found in 2 patients. Although the mentioned complications were not as big a concern as mentioned in the literature, especially incontinence.[22] Calcium channel blockers when taken systemically might result in some of the cardiovascular event like headache, dizziness, flushing, palpitations. In our study, the complication noted in group (B) where there was topical application of Nifidepine 0.3% + lignocaine 1.5% following OH had only 2 cases of headache. This less incidence of complication could be most likely due to the topical application of calcium channel blocker, which appears to be safe, when compared to that taken systemically. At the end of the study group A had a better outcome in terms of pain relief when compared to group B. Although the complication rates were more in group A, there were not statistically significant nor alarming.

So now it may be questioned that if hemorrhoidectomy has to be complimented with IAS or just hemorrhoidectomy for a better post operative pain relief. Authors like mathias etal.,[24] and khubchandani[25] reported in their studies that there was no statistically different pain score among those who underwent hemorrhoidectomy with IAS and just hemorrhoidectomy. But in our study statistically significant scores were noted in group A which was comparable to the study conducted by Amorotti et al.,[26] and Ashutosh Chauhan et al.[27]

There were few limitations of the study too and that it was a Small Sample size. With regards to inadequate pain relief in group B, Local absorption of nifedipine + lignocaine is not only proportional to the amount applied, but also to factors such as skin thickness and the degree of tissue inflammation. Due to this, perianal wounds following hemorrhoidectomy may significantly affect the dynamics of Nifidepine + lignocaine absorption and that its efficacy in controlling pain by relaxing the IAS may be reduced which could be a bias factor.[23] Also the pain relief documented in the study could have been correlated to the pre and post op anal manometric studies to more effectively highlight the pain reducing techniques among the 2 groups. But still this wouldn't be an important limitation as our primary objective was to assess the pain using a clinical assessement tool and that was valid. And lastly a Short follow up period.

CONCLUSION

From our study we conclude that the pain scores were less in the group who underwent IAS when compared to the chemical sphincterotomy group as an adjunt procedure to standard hemmorhoidectomy.

REFERENCES

1. Holzheimer RG. Hemorrhoidectomy: indications and risks. Eur J Med Res. 2004;9:18–36.
2. Nisar PJ, Scholefield JH. Managing haemorrhoids. BMJ. 2003;327:847–51.
3. Wasvary HJ, Hain J, Mosed-Vogel M, et al. A randomized, prospective, double-blind, placebo-controlled trial of effect of nitroglycerin ointment on pain after hemorrhoidectomy. Dis Colon Rectum. 2001;44:1069–73.
4. Roe AM, Bartolo DC, Vellacott KD, et al. Submucosal versus ligation excision haemorrhoidectomy: a comparison of anal sensation, anal sphincter manometry and postoperative pain and function. Br J Surg. 1987;74:948–51
5. Goldstein ET, Williamson PR, Larach SW. Subcutaneous morphine pump for postoperative hemorrhoidectomy pain management. Dis Colon Rectum. 1993;36:439–46.
6. Carapeti EA, Kamm MA, McDonald PJ, et al. Double-blind randomised controlled trial of effect of metronidazole on pain after day-case haemorrhoidectomy. Lancet. 1998;351:169–72.
7. Kanellos I, Zacharakis E, Christoforidis E, et al. Usefulness of lateral internal sphincterotomy in reducing postoperative pain after open hemorrhoidectomy. World J Surg. 2005;29:464–8.
8. Chrysos E, Xynos E, Tzovaras G, et al. Effect of nifedipine on rectoanal motility. Dis Colon Rectum. 1996;39:212–6
9. Deutsch AA, Moshkovitz M, Nudelman I, et al. Anal pressure measurements in the study of hemorrhoid etiology and their relation to treatment. Dis Colon Rectum. 1987;30:855–7
10. Eisehammer S. Internal anal sphincterotomy plus free dilatation versus anal stretch with special criticism of the anal stretch procedure for hemorrhoids: The recommended modern approach to hemorrhoids treatment. Dis Colon Rectum 1974;17:493-522.
11. Galizia G, Lieto E, Castellano P, Pelosio L, Imperatore V, Pignatelli C. Lateral internal sphincterotomy together with Hemorrhoidectomy for treatment of Hemorrhoids: A randomized prospective study. Eur J Surg 2000;166:223-8.
12. Kanellos I, Zacharakis E, Christoforidis E, Angelopoulos S, Kanellos D, Pramateftakis MG, et al. Usefulness of lateral internal sphicterotomy in reducing post operative pain after open hemorrhoidectomy. World J Surg 2005;29:464-8.
13. Altomare DF, Rinaldi M, Milito G, Arcanà F, Spinelli F, Nardelli N, et Chauhan, et al.: Internal sphicterotomy vs topical Diltiazem in post hemorrhoidectomy pain relief al. Glyceryl trinitrate for chronic anal fissure- healing or headache? Results of a multicenter, randomized, placebo-controlled, double- blind trial. Dis Colon Rectum 2000;43:174-9
14. Schouten WR, Briel JW, Boerma MO, Auwerda JJ, Wilms EB, Graatsma BH. Pathophysiological outcome of intra-anal application of isosorbide dinitrate in patients of chronic anal fissure. Gut 1996;397:465-9.
15. Parellada C. Randomized prospective trial comparing 0.2 percent isosor bide dinitrate ointment with sphincterotomy in treatment of chronic anal fissure: A two- year follow-up. Dis Colon Rectum 2004;47:437-43.
16. KatsinelosP,KountourasJ,ParoutoglouG,BeltsisA,Chatzimavroudis G, Zavos C, et al. Aggressive treatment of acute anal fissure with 0.5% nifedipine ointment prevents its evolution to chronicity. World J Gastroenterol 2006;12:6203-6.
17. Ezri T, Susmallian S. Topical nifedipine vs topical glyceryl trinitrate for treatment of chronic anal fissure. Dis Colon Rectum 2003;46:805-8
18. Bielecki K, Kolodziejczak M. A prospective randomised trial of diltiazem and glyceryltrinitrate ointment in the treatment of chronic anal fissure. Colorectal Dis 2003;5:256-7.
19. Carapeti EA, Kamm M, Phillips R. Topical diltiazem and bethanechol decrease anal sphincter pressure and heal anal fissure without side effects. Dis Colon Rectum 2000;43:1359-62.
20. Jonas M, Neal KR, Abercrombie JF, Scholefield JH. A randomized trial of oral vs. topical diltiazem for chronic anal fissures. Dis Colon Rectum 2001;44:1074-8.
21. Silverman R, Bendick PJ, Wasvary HJ. A randomized, prospective double-blind, placebo - controlled trial of the effect of a calcium channel blocker ointment on pain after haemorrhoidectomy. 2005;48:1913-6.
22. Brown CJ, Dubreuil D, Santoro L, Liu M, O'Connor BI, McLeod RS. Lateral internal sphincterotomy is superior to topical nitroglycerin for healing chronic anal fissure and does not compromise long-term fecal continence: Six-year follow-up of a multicenter, randomized, controlled trial. Dis Colon Rectum 2007;13:134-8
23. Steele SR. Madoff RD. Systematic review: The treatment of anal fissure. Aliment Pharmacol Ther 2006;24:247-57.
24. Mathai V, Ong BC, Ho YH. Randomised controlled trial of lateral internal sphicterotomy with haemorrhoidectomy. Br J Surg 1996;83:380-2.
25. Khubchandani IT. Internal sphincterotomy with hemorrhoidectomy does not relieve pain: A prospective, randomized study. Dis Colon Rectum 2002;45:1452-7.
26. Amorotti C, Mosca D, Trenti C, Pintaudi U. Usefulness of lateral internal sphincterotomy combined with hemorrhoidectomy by the Milligan-Morgan's technique: Results of a prospective randomized trial. Chir Ital 2003;55:879-86.
27. Ashutosh Chauhan, S Tiwari, V k Mishra. Comparison of internal sphincterotomy with topical diltiazem for post-hemorrhoidectomy pain relief: A prospective randomized trial. January 2009: Journal of Postgraduate Medicine 55(1):22-6.