ROLE OF POST-OP TOPICAL DILTIAZEM CREAM IN PAIN CONTROL AFTER MILLIGAN-MORGAN HEMORRHOIDECTOMY

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ABSTRACT

Background: Spasm of internal anal sphincter is thought to be responsible for pain after hemorrhoidectomy. Topical use of a calcium channel blocker, 2% Diltiazem (DTZ), may be effective in reducing pain after hemorrhoidectomy.

Objective: To evaluate and compare pain scores on Visual Analogue Scale post-operatively after hemorrhoidectomy from day two to day five, in patients using 2% DTZ versus patients using Placebo ointment along with standard treatment for pain relief. Need for urinary catheterization was also assessed indicating severity of pain causing urinary retention.

Materials and Methods: This was a randomized control trial conducted at Hayatabad Medical Complex, Peshawar, for a period of fourteen months from 01st June 2016 to 31st August, 2017. One hundred patients, who had undergone Milligan Morgan hemorrhoidectomy, were randomly assigned to receive 2% DTZ ointment (Group A - study Group) or a placebo ointment-petroleum jelly (Group B - control group) post-operatively. Fifty patients were included in each group. Postoperative pain scores were recorded using Visual Analogue Score on second postoperative day. SPSS version 16 was used for statistical analysis.

Results: Mean age was 35.1 ±13.3years. 64(64%) patients were males whereas thirty six (36%) were females, with male to female ratio being 1.7:1. Patients using 2% DTZ ointment had significantly less pain after surgery. The best pain relief in range of 1-3 on Visual Analogue Scale was achieved in 36% patients in group-A(Study Group) while the same score was achieved by only 12% of patients in group-B(Control Group).Urinary retention because of severe pain occurred only in 2 patients(0.4%) in group-A while it occurred in 6 patients(12%) in group-B, for which catheterization was done.

Conclusion: Perianal application of 2% Diltiazem ointment after hemorrhoidectomy is effective in reducing pain post-operatively.

Key Words: Hemorrhoidectomy, Calcium Channel Blockers, Diltiazem, Milligan Morgan Hemorrhoidectomy.

INTRODUCTION

Haemorrhoids are the pathological enlargement and distal displacement of the normal anal cushions and dysregulation of the vascular tone and vascular hyperplasia seems playing important role in haemorrhoidal development and could be a potential target for medical treatment[1].

Hemorrhoidectomy is the only truly curative treatment to reduce recurrent symptoms in patients with grade 3 or 4 haemorrhoids[2]. Indications for hemorrhoidectomy include failure of non operative management, acute complicated haemorrhoids such as strangulation or thrombusis, patient preference and concomitant anorectal conditions[3].

Milligan Morgan Hemorrhoidectomy[4] is considered a relatively safe surgical treatment for the disease but complications exist. Pain at the operative site is a distressing complication after this procedure resulting in anxiety, constipation, urinary retention and increased hospital stay[5,6].

Warm sitz bath, stool softeners and systemic analgesics are standard post-operative regimen to reduce post-operative pain[7]. Spasm of internal anal sphincter is considered as one of the main factor contributing towards pain[4,8]. Internal sphincterotomy along with hemorrhoidectomy has been employed to reduce spasm but it has been found to be associated with faecal incontinence (upto 8-30%)[9,10].

Internal anal sphincter has a calcium dependent mechanism to maintain its tone. Diltiazem (DTZ) a calcium channel blocker, blocks calcium uptake by the myocytes, thus relaxing the smooth muscles of internal anal sphincter[5]. Due to fewer side effects, 2% DTZ is replacing topical glycerytrinitrate in treatment of chronic anal fissure[11]. The rationale behind this study was the conflict of data and lack of scientific consensus on selecting the best modality for post-op pain control after Milligan-Morgan hemorrhoidectomy.

MATERIAL AND METHODS

This study was a randomized controlled trial conducted at Department of General Surgery, Hayatabad

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Medical Complex, Peshawar. All patients with third and fourth degree haemorrhoids admitted to the ward from 1st June 2016 to 31st August 2017 were included after evaluation by consultant, informed consent was taken from each patient about surgery and this study. Using non-probability purposive sampling (by random allocation employing flip coin method), 100 patients with 3rd and 4th degree haemorrhoids were included in the trial and divided equally into two groups i.e. Group-A allocated to treatment by topical 2% DTZ (study group) and Group-B topical placebo (control group).

Inclusion Criteria:

i. Patients having 3rd and 4th degree haemorrhoids

ii. Aged > 16 years and < 70 years

Exclusion Criteria:

i. Previous hx of anal procedure/ pathology, anal fissure, fistula in ano, thrombosed hemorrhoids and malignancy.

ii. Patients in whom calcium channel blocker are contraindicated or any other allergy or co-morbidity.

iii. Patients with diabetes mellitus immunosupression or other spinal/ neurological abnormalities.

Standard post-operative management was employed in patients of both groups. These included IV Metronidozole 40mg TDS for three days; analgesia in the form of Ketorolac IV 30 mg TDS for three days. Stool softness syp Cremafin 2 TSF in TDS dose daily were given. Warm sitz bath for 15 minutes twice daily after immediate post-operative day was taken by all the patients.

Anal packing was removed after 24 hours. In Group-A, patients were advised to apply 2% DTZ ointment via applicator to the perianal region twice daily for four days; first dose being applied on first post-op day after removal of pack. In Group-B, placebo ointment (petroleum jelly) was advised to be applied accordingly. Both ointments looked same and were supplied in dispensers of identical appearance. All patients were examined by the consultant who was unaware of the study group of the patients on every morning of post-operative day; from day 2 to 5.

Post-operative pain was measured by Visual Analogne Score and need of catheterization because of severe pain. Self-designed questionnaire was used to document all findings. It included demographic data of the patients and average of pain scores on Visual Analogne Scale and the need of catheterization. The software program SPSS was utilized for all statistical analysis. The p-value of 0.05 was considered significant statistically.

RESULTS

The age range of patients was between 16 to 17 years with overall mean (± SD) age of patients 35.1 (± 13.3) years. Out of 100 patients in this study, 64 (64%) were male and 36 (36%) were female; and male to female ratio was 1.7:1in figure 1. Mean pain scores (percentage) as assessed on Visual Analogne Score and the need of catheterization because of urinary retention called caused by severe pain.

As evident from results, best pain relief (1-3 on Visual Analogne Scale) was achieved in 18 (36%) of patients in study Group-A while only in 6 (12%) patients in control Group-B. The same is the case with urinary catheterization which was required by only 2 (0.04%) patients in study Group-A while needed by 6 (12%) patients in control Group-B because of urinary retention caused by severe pain.

DISCUSSION

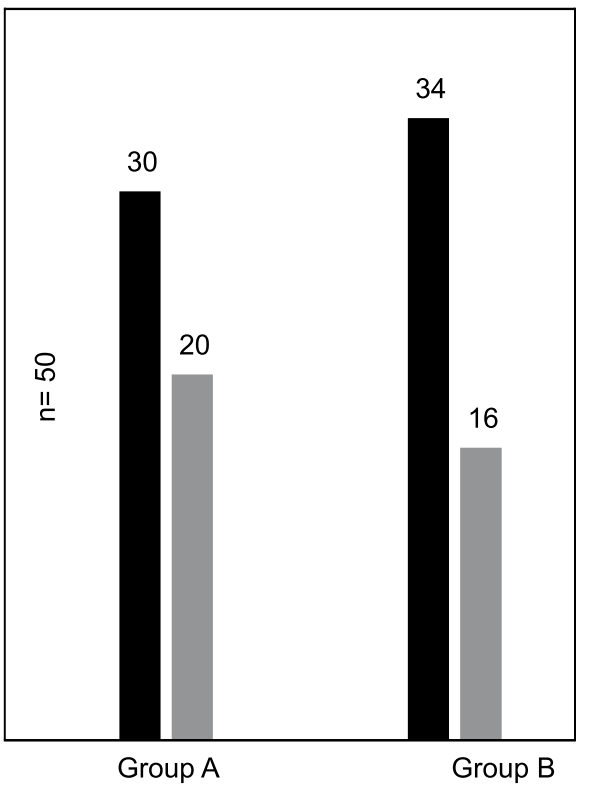

Figure 1:

Table 1:

Pain Score	Group-A n(%)	Group-B n(%)
1-3	18 (0.36)	6 (0.12)
4-5	20 (0.40)	26 (0.52)
6-8	9 (0.18)	12 (0.24)
9-10	3 (0.06)	6 (0.12)
Catheterization	2 (0.04)	6 (0.12)

Post-hemorrhoidectomy pain has always been a major concern both for the surgeons and patients[12]. It is associated with hypertonia of internal sphincter[13] and the lateral sphincterotomy has been found effective in muscle relaxation, pain relief and quick healing[14]. Galzia et al[15] prospectively randomized 42 consecutive patients with prolapsed haemorrhoids concluded that lateral sphincterotomy with hemorrhoidectomy significantly improves pain as compared to hemorrhoidectomy alone. Kanellos and associates9 evaluated the effect of lateral sphincterotomy on pain after Milligan-Morgen hemorrhoidectomy and concluded that the addition of lateral sphincterotomy to open hemorrhoidectomy have a positive effect as it relaxes muscles but may be associated with significant risk of incontinence[10].

Topical application of nitroglycerine has also been employed by various surgeons[16] after disappointment of long term result of lateral sphincterotomy[10,6]. The pain post-operatively was reduced6,16 but frequency of headache was high and required additional analgesics, With understanding of intestinal and sphincter physiology, alternative treatment with fewer side effects is necessitated.

Diltiazem is a CCB with few side effects and similar benefits as compared to nitroglycerine[17-19]. Amoli et al conducted a prospective study to evaluate the role of topical 2% Diltiazem after Hemorrhoidectomy and came to the conclusion that topical Diltiazem cream is of significant importance in reducing post-operative pain[20].

Similar study was conducted by Silvermen et al[5] using DTZ post-Hemorrhoidectomy for pain relief and they concluded that topical DTZ reduces pain and other co-morbidity. Chauhan et al prospectively randomized 108 patients of Grade 3 & 4 haemorrhoids and compared the efficacy of internal sphincterotomy with topical application of 2% DTZ ointment after Hemorrhoidectomy for the relief of pain. No significant difference was found in mean pain scores as both procedures involved relieving the spasm of anal sphincter while the former one is more radical.

In our study, pain perception was significantly reduced in the Diltiazem group as compared to Placebo group. Best pain relief (1-3 on Visual Analogue Scale) was achieved in 18 (36%) of patients in study Group-A while the same level of pain relief was achieved in Placebo Group-B in only 6 patients (12%).

The urinary catheterization was only needed in two patients out of fifty patients in study Group-A while six patients out of fifty patients needed urinary catheterization in Plaecbo Group-B (control group) which showed the severity of pain causing urinary retention.

CONCLUSION

It is concluded that application of 2% Diltiazem ointment along with standard treatment significantly reduces the pain after Hemorrhoidectomy (Morgan-Milligen Hemorrhoidectomy) as compared to other radical procedures. On the basis of above study, topical DTZ 2% ointment can be used along with standard post-op regimen after Hemorrhoidectomy; but it still needs a more robust study and comparison with other modalities.

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