

Post hemorrhoidectomy pain. Does Diltiazem really work?

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Abstract:

Objectives: To compare the mean pain scores on visual analogue scale on second postoperative day after hemorrhoidectomy in patients using 2% diltiazem versus placebo.

Study design: Clinical Trial.

Setting: Surgical unit III, Civil Hospital, Karachi.

Duration with dates: Nine-month period from 01st July 2009 to 31st March 2010.

Subjects and methods: After open hemorrhoidectomy, eighty patients were randomly assigned to receive 2% diltiazem ointment (group A - study group) or a placebo ointment (group B - control group). Forty patients were included in each group. Mean postoperative pain scores were recorded using Visual Analogue Score on second postoperative day. The SPSS version 10 was applied to the data.

Results: Mean age was 38.79+14.86 years. Sixty five (81.3%) patients were male whereas fifteen (18.7%) were female, with male to female ratio being 4:1. Patients using diltiazem ointment had significantly less pain. Mean pain scores in 2% diltiazem group was 4.2+1.09 while in placebo group was 7.5+1.2 on second postoperative day ($p<0.05$).

Conclusion: Peri anal application of 2% diltiazem ointment is effective in reducing pain after hemorrhoidectomy.

Keywords: Milligan Morgan Hemorrhoidectomy, Pain, Diltiazem.

Introduction:

Hemorrhoid is one of the commonest problem among the perianal pathological conditions. It results from pathological enlargement and displacement of upper hemorrhoidal plexus.^{1,2} Milligan Morgan hemorrhoidectomy is considered as a relatively safe procedure but complications exist. Pain at the operative site is a distressing complication after hemorrhoidectomy.^{3,4}

Spasm of internal sphincter is considered as one of the component of this pain.^{3,5} To relieve spasm, measures like internal sphincterotomy along with hemorrhoidectomy has been employed but it was found to be associated with fecal incontinence (up to 8-30%).^{6,7} Medical alternatives using pharmacological agents like glyceryl trinitrate, and calcium channel blockers have shown to relieve the spasm of internal

sphincter thus relieving pain.³⁻⁵

Diltiazem, a calcium channel blocker, blocks calcium uptake by the myocytes, thus relaxing the smooth muscles of internal anal sphincter.³ Due to fewer side effects, diltiazem is replacing glyceryl trinitrate for the relieve of the sphincteric spasm.⁸

Therefore, the rationale of this study is to compare the mean pain scores on visual analogue scale on second post-operative day after hemorrhoidectomy in patients using 2% diltiazem versus patients using placebo ointment along with standard treatment so that if found effective diltiazem can be added to standard treatment including warm sitz bath, stool softener and systemic analgesics for the relieve of pain after hemorrhoidectomy.

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Patient and method:

This clinical trial was carried out in surgical unit III, Civil Hospital, Karachi from 01st July 2009 to 31st March 2010. Eighty patients with third degree hemorrhoids admitted to surgical wards of the hospital were included in the study. Patients who had concomitant other anal pathology like anal fissure, fistula in Ano, thrombosed hemorrhoids and malignancy were excluded from study.

Informed consent was taken from each patient. Patients were then randomly allocated into group A (study group) and group B (control group) by using random allocation software version 1.0.0. Patients in both groups were underwent elective hemorrhoidectomy using Milligan Morgan technique. Postoperative pain was measured by visual analogue scale. Patient was asked to mark on the line where they think their pain was which was then matched with a standard 10 centimeter scale to determine the value in centimeters. Zero end of the line represented “no pain” while ten end indicated “worst pain”. All patients were examined on second postoperative day in the ward. Proforma was used to document all findings. It included demographic information (age and gender), hospital registration number, study group of patient (group A and B), pain scores on visual analogue scale on second postoperative day.

Results:

Between July 2009 to March 2010, 80 patients with third degree hemorrhoids undergoing Milligan Morgan hemorrhoidectomy were randomly assigned in Group A and Group B. Post-

operatively, topical 2% diltiazem ointment was applied in patients of group A whereas placebo ointment application was carried out in patients of group B.

The age range of patients was between 17 to 78 years. Majority of the patients were between 31 to 40 years of age. Mean age±SD were 38.79±14.86 years (Table 1). Sixty five (81.3%) patients in this study were male, fifteen (18.7%) were female (Figure 1). On second postoperative day, mean pain scores+SD assessed by Visual Analogue Scale was 4.2±1.09 in group A patients whereas 7.5±1.2 pain scores were observed in group B patients (p<0.05) (Table 2).

Discussion:

The pain after hemorrhoidectomy has always been a major concern for both surgeons and the patients.⁹ It is associated with hypertonia of internal sphincter,¹⁰ and the traditional therapy of lateral sphincterotomy has been effective in muscle relaxation and thus pain relief.¹¹ Galizia et al¹² prospectively randomized 42 consecutive patients with prolapsed hemorrhoids concluded that lateral sphincterotomy with hemorrhoidectomy significantly improves postoperative outcomes. Kanellos and associates⁶ also evaluated the effect of lateral sphincterotomy on pain after open hemorrhoidectomy. They concluded that although addition of lateral sphincterotomy to open hemorrhoidectomy seems to reduce postoperative pain, but may be associated with significant risk of incontinence.⁷

Topical application of nitroglycerine to reduce pain after open hemorrhoidectomy has also been employed by various authors^{4,13}. They observed

Table 1: Age distribution

Age of patients (years)	Group A (Study group)		Group B (Control group)		Total	
	(n = 40)	%	(n = 40)	%	(n = 80)	%
15-20	02	2.4	01	1.3	03	3.7
21-30	10	12.5	12	15	22	27.5
31-40	14	17.5	10	12.5	24	30
41-50	08	10	07	8.8	15	18.8
51-60	02	2.5	05	6.2	07	8.7
61-70	02	2.5	03	3.8	05	6.3
>70	02	2.5	02	2.5	04	5

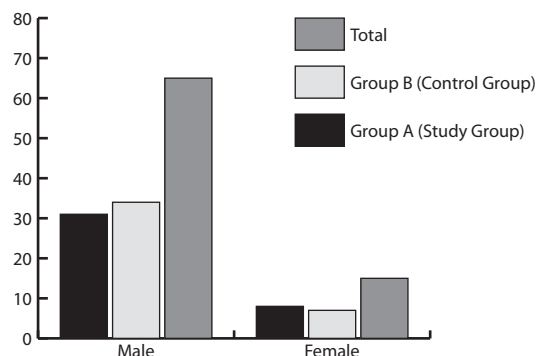


Figure 1: Gender distribution

Table 2: Postoperative pain scores on second postoperative day

	Group A (Study group) (n=40)	Group B (Control group) (n=40)
Mean pain scores+SD	4.2+1.09	7.5+1.2

reduction in amount of postoperative pain in patients using topical nitroglycerine ointment but unfortunately associated with significant headache. Hence, an alternative treatment with fewer side effects is necessitated. Diltiazem is a calcium channel blockers with few side effects and similar benefits compared to nitroglycerine¹⁴⁻¹⁶. Amoli and associates prospectively evaluated a role of topical 2% diltiazem application after hemorrhoidectomy and concluded that perianal application of diltiazem cream after hemorrhoidectomy significantly reduces postoperative pain and is perceived as beneficial with no increase in associated morbidity¹⁷.

Chauhan et al¹⁸ prospectively randomized 108 patients of third and fourth degree hemorrhoids and assessed the efficacy of internal sphincterotomy compared with topical application of 2% diltiazem ointment after hemorrhoidectomy for pain relief. They encountered no significant difference in mean pain scores on second postoperative day.

Silverman et al³ evaluated the effects of topical diltiazem in reducing pain after hemorrhoidectomy. They randomly assigned 18 patients of hemorrhoidectomy to receive 2% diltiazem and placebo ointment; and noticed mean pain scores of 5.2 in diltiazem group as compared to 8.8 in placebo group on second postoperative day. Hence, concluded that application of 2% diltiazem ointment after hemorrhoidectomy significantly reduces postoperative pain and is perceived as beneficial, with no increase in associated morbidity.

In this study, pain perception was significantly reduced in the diltiazem group as compared to placebo group. Average pain scores after using topical diltiazem ointment on second postoperative day was 4.2 as compared placebo ointment (7.5), which is nearly comparable to above

mentioned studies. Hence, there was significant reduction of hemorrhoidectomy pain on second postoperative day in patients who applied topical diltiazem ointment.

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