

Effectiveness of Bupivacaine after Rubber Band Ligation of Hemorrhoids for Post Procedure Pain

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ABSTRACT

Introduction: Pain is the most common complication of rubber band ligation (RBL) of hemorrhoids when compared to other non-operative techniques to treat hemorrhoids. Local anesthetic injection has been used in a few studies to reduce pain after RBL but its routine use is still not established. We evaluated the effectiveness of local injection of bupivacaine after RBL of hemorrhoids to reduce pain after the procedure.

Objective: To compare the mean pain scores by visual analogue scale with and without local injection of bupivacaine after RBL of 1st and 2nd degree hemorrhoids.

Design: Randomized controlled trial.

Material and Methods: Study was conducted in Surgical unit 1, Civil Hospital, Karachi, for a period of 2 months, from Aug 17, 2016 to Oct 17, 2016. 60 patients having first and second degree hemorrhoids were included in the study from OPD by non-probability consecutive sampling. They were randomized to either to receive local injection of bupivacaine or no injection after RBL of hemorrhoids by closed envelop method. Pain score at 2 hours after the procedure was the main outcome measured.

Results: Our study showed that there was a significant reduction in the pain at 2 hours after RBL of hemorrhoids with the use of local bupivacaine injection, mean pain scores 3.30 ± 1.055 when compared to 3.93 ± 0.944 in patients without administration of bupivacaine with p -value = 0.017.

Conclusion: Our study concluded that local bupivacaine injection may be used routinely after RBL of hemorrhoids to reduce pain after the procedure.

Key words: Hemorrhoids, bupivacaine, local anesthetic, rubber band ligation, visual analogue scale.

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INTRODUCTION

Hemorrhoidectomy is the gold standard treatment of hemorrhoids. But it is a very painful procedure with potential for complications including damage to the anal sphincters^{1,2}.

Non-operative techniques are used for 1st, 2nd and early 3rd degree hemorrhoids and are associated with fewer complication, which are observed with hemorrhoidectomy. Rubber band ligation (RBL) is the most frequently used non-operative procedure with a high rate of symptom control^{3,4,5,6}. However when compared to other non operative techniques, pain can occur in up to 84% of patients after RBL, which

is worst after 4 hours of the procedure and makes it troublesome for the patient if used as a day care or OPD procedure^{6,7,8}. The pain is especially worse if multiple bandings are performed in a single session^{9,10}.

Different pharmacological agents have been used in an attempt to reduce pain after RBL. In a recent study, mean pain score after RBL reduced with the use of local injection of bupivacaine¹¹. In other similar studies, there was a significant reduction in pain at 30 minutes and 6 hours post banding with local bupivacaine injection^{12,13,14}. Bupivacaine has a long duration of action of 2-9 hours. Law and Chu used local lignocaine injection after RBL but failed to show significant reduction in pain after RBL¹⁰. There is a controversy regarding the best method to reduce pain after RBL. The available literature is limited and the routine use of local anesthetic after RBL is still a matter of debate. Also, local studies have not been conducted to address this issue specifically. The purpose of our randomized controlled trial was to compare the mean pain scores

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using visual analogue scale with and without local injection of bupivacaine after RBL of 1st and 2nd degree hemorrhoids.

MATERIAL & METHODS

The study was conducted in Surgical unit 1, Civil Hospital Karachi. Rubber band ligation was performed in the minor operation theater of Surgical unit 1. Patients stayed in the ward for a period of 2 hours after the procedure. The duration of the study was from Aug 17, 2016 to Oct 17, 2016.

The sample size of 60 patients was calculated by WHO sample size calculator by taking mean pain score in group A i.e., 2.6 ± 0.65 and in group B i.e., 4.1 ± 1.025 , power of study 80%, confidence interval 95%. Sampling technique was non-probability consecutive sampling.

Inclusion criteria: All patients presenting with 1st and 2nd degree hemorrhoids in the OPD, aged 18-65 years, including both male and female patients and consenting to participate in the study were included in the sample. A total of 60 patients were identified who met the inclusion criteria.

Exclusion criteria: Patients with anal fissures, external skin tags, perianal hematoma, thrombosed hemorrhoids, bleeding tendency, rectal cancer and other painful anal conditions were not included. Also, cardiac patients, patients with chronic liver disease and those having pain as the only or the predominant symptom of hemorrhoids were excluded from the study.

Ethics approval for research was taken from institutional review board. It was a double blinded randomized controlled trial. Patients and residents collecting the data were unaware of the treatment offered. Informed consent was obtained from all the patients participating in the study. Patients were randomly allocated in two groups by closed envelop method. 30 patients were included in each group. RBL of hemorrhoids was performed by consultant general surgeons. Group A patients received local injection of 2 ml of 0.5% Bupivacaine into the banded hemorrhoidal tissue after RBL. While group B did not receive any injection after the procedure. All the data was collected on a proforma by the general surgery resident on duty including pain scores at 2 hours after banding, without analgesia. Double blinding was done to control bias.

Data was analyzed using IBM SPSS statistics software version 20. Frequency and percentage was calculated for degree of hemorrhoids and gender. T-test was

applied to compare the mean pain score in both groups. Stratification with respect to age, gender, degree of hemorrhoids and number of bands was done. Post stratification t-test was applied. P values = 0.05 were taken as significant. Mean +/- SD was calculated for age and pain score.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all patients for being included in the study.

RESULTS

Age Distribution: Age of the patients was between 18 and 60 years. Mean age was 38.78 ± 11.86 years. Mean age in group A was 37.33 ± 11.50 years while that in group B was 40.23 ± 12.22 years. There was no significant difference in the mean age of the patients between the two groups (p-value = 0.348).

Gender Distribution: The study consisted of 39 (65%) male and 21 (35%) female patients. There were 23 male and 7 female patients in group A while there were 16 male and 14 female patients in group B.

Degree of Hemorrhoids: Only the patients having first and second degree hemorrhoids were included in the study. Overall 27 (45%) patients had first degree and 33 (55%) patients had second degree hemorrhoids. There were 15 patients in group A and 12 patients in group B with first degree hemorrhoids. There were 15 patients in group A and 18 patients in group B with second degree hemorrhoids.

Number of Band Applied: Overall single band was applied to 17 (28.3%) patients and multiple (2-3) bands were applied to 43 (71.7%) patients. In group A, single and multiple bands were applied to 9 and 21 patients respectively while in group B these figures were 8 and 22 respectively.

Pain Score at 2 Hours after Band Ligation (Main Outcome): There was significant difference between the mean pain scores of the two groups (p-value = 0.017).

The stratification of mean pain score with respect to age groups, gender, degree of hemorrhoids and number of bands applied was done. There was no significant difference in the mean pain score between the two

groups when it was stratified with respect to these variables except after multiple band ligations where a significant difference in pain was observed after bupivacaine injection (3.38 ± 1.024 vs 4.14 ± 0.941 , p -value=0.016).

Complications (Other Than Pain): 7 patients experienced mild bleeding per rectum which stopped spontaneously in all cases and occurred after day 5 of the procedure. It was reported on the follow up in the OPD.

Table 1: Mean pain score at 2 hours after band ligation

Group	n	Mean pain score at 2 hours	Std. Deviation	Min	Max	p-value
Group A (with inj. bupivacaine)	30	3.30	1.055	1	5	
Group B (without inj. bupivacaine)	30	3.93	0.944	3	6	0.017
Total	60	3.62	1.043	1	6	

Table 2: Stratification of Mean pain score between the two groups at 2 hours after banding w.r.t. single band applied (n=17)

Group	n	Mean pain score at 2 hours	Std. Deviation	p-value
Group A (with inj. bupivacaine)	9	3.11	1.167	
Group B (without inj. bupivacaine)	8	3.38	0.744	0.592
Total	17	3.24	0.970	

Table 3: Stratification of Mean pain score between the two groups at 2 hours after banding w.r.t. multiple bands applied (n=43)

Group	n	Mean pain score at 2 hours	Std. Deviation	p-value
Group A (with inj. bupivacaine)	21	3.38	1.024	
Group B (without inj. bupivacaine)	22	3.38	0.941	0.016
Total	43	3.77	1.043	

DISCUSSION

Our results showed that the local injection of bupivacaine resulted in significant reduction of pain at 2 hours after rubber band ligation of hemorrhoids.

Hemorrhoids is a common anorectal disease and involve one in twenty adults and almost one half of all older than 50 years of age. Rubber band ligation is a simple and effective treatment for 1st and 2nd degree hemorrhoids⁵.

Ideally, there should be no pain if the rubber band is applied above the dentate line. But the most common side effect reported in the literature is pain which is especially severe in the early post procedure period^{6,7,8}. Our results were consistent with the findings of these studies. The mean pain score was $3.93 (\pm 0.944)$ at 2 hours after band ligation when no local anesthetic was used. This is a high mean pain score for a procedure which is supposed to be painless and usually being promoted as an OPD/day care procedure. Therefore, some studies have concluded that this procedure should not be carried out on outpatient basis as it may cause significant pain to the patient^{7,8}. Subsequently, there are a few studies in the literature which have aimed to reduce the early post procedure pain by different ways. William JA et al. tried anesthetic steroid suppositories while Kayhan B et al. tried 5-aminosalicylic acid suppositories. Both of these did not observe significant improvement in post procedure pain^{15,16}. On the other hand some authors used local injection of bupivacaine after rubber band ligation of hemorrhoids and found significant reduction in pain especially in the early post procedure period^{11,12,13}. Our results were similar to these findings with a significant difference in pain with and without local bupivacaine injection after band ligation (p -value=0.017). Pain is most severe in the early post procedure period which can be reduced with local bupivacaine injection. It has a long duration of action of 2-9 hours which provides analgesia to the patients so that they can reach home easily without pain. Both of these effects allow rubber band ligation to be used safely as a day care or OPD procedure.

According to a study conducted by Lee HH et al., multiple bandings in a single session resulted in greater post procedure pain when compared to single band (29% versus 4.5%). On the other hand, some authors¹⁷⁻²² recommended the use of triple band ligation in the same session as a safe option. We stratified our data with respect to single and multiple band ligations. There was significant difference in pain with and without local bupivacaine injection given after multiple band ligations in a single session (p -value=0.016). These results point to the efficacy of local bupivacaine injection after multiple band ligations in a single session to reduce the post procedure pain. Multiple bandings help to reduce the need for undergoing RBL repeatedly, which is uncomfortable for the patients, however, further studies are required to validate the findings of our study.

In addition to pain, bleeding was the other complication which was observed in our study. It was mild and occurred in 2 patients (3.33%) after day 5 of the

procedure. It stopped spontaneously in all cases. Mild bleeding is reported in 2.4 % of the patients by Forlini A et al.²¹ and in 2 % by Lu LY et al.²² after RBL and is due to the sloughing off of the banded hemorrhoids.

Our study was a single center trial as the study was conducted in Surgical unit 1, Civil Hospital Karachi. Therefore, the results cannot be applied to general population. This study only addressed the issue of early pain after the procedure but prolonged follow up was not carried out. Other limitations in this study was small sample size.

CONCLUSION

Our findings suggest that local bupivacaine injection may be used routinely after RBL of hemorrhoids especially when done in an OPD/day care setting when the patient does not have access to medical services immediately after the procedure. It will also allow the patient a pain free journey back to the home. Moreover, local bupivacaine injection may be useful especially after multiple band ligations to reduce the post procedure pain.

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