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Effectiveness of Pre-Emptive Perianal Methylene Blue and Ropivacaine Infiltration in Alleviating Pain After Hemorrhoidectomy: A Comparative Study

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ABSTRACT

The postoperative course of hemorrhoidal surgery is extremely painful, justifying the administration of substantial amounts of analgesics such as opioids, which may in turn produce nausea and vomiting, increase urinary retention decrease bowel motility. Present study was aimed to compare effectiveness of pre-emptive perianal methylene blue and ropivacaine infiltration in alleviating pain after hemorrhoidectomy. Present study was single-center, prospective, comparative study, conducted patients posted for Milligan-Morgan hemorrhoidectomy. Patients were randomly allocate patients into two groups, group under trial received methylene blue and Ropivacaine and the control group was tramadol oral tablet. 34 patients were taken into each group. Majority of the patients (34.37%) were in the 31-50 years of age group, 55 were males. In both case as well as control pain associated with hemorrhoidal disease and bleeding per rectum has been a constant factor for patient seeking remedial surgeries. The patients who participated in this trial were mainly those who had grade 3 and grade 4 symptomatic haemorrhoids. There is significant difference of vas score at 7th hours,12th hours and at 1 week between two means at 95%. The VAS scores observed clearly indicates the efficacy of infiltration of Methylene blue and Ropivacaine in preventing post operative pain in haemorrhoidectomies. It has been observed that post operative complication like nausea, vomiting, urinary retention has been observed more number in control group as compared to cases. Perianal infiltration of Methylene blue with Ropivacaine is not only effective but is also a safe procedure can be a better alternative strategy for reducing the pain of patients who are undergoing haemorrhoidectomy.

INTRODUCTION

Haemorrhoids are normal vascular cushions of submucosal tissue containing venules, arterioles smooth muscle fibers that are suspended longitudinal in the anal canal. The pathogenesis of symptomatic haemorrhoids is most likely due to weakening of the connective tissue within vascular cushion that produces bleeding with or without prolapse of hemorrhoidal tissue[1,2]. These symptoms occur as a result of low fiber diet intake, excessive straining, chronic constipation, prolong sitting, pregnancy, anticoagulant therapy and deterioration of anchoring connective tissue that occurs with advanced age[2,3]. Because haemorrhoids are a normal part of anorectal anatomy, treatment is only indicated if they become symptomatic. Today there are a variety of treatments available for symptomatic haemorrhoids. Patients can be treated conservatively with sitz bath, anaesthetics, corticosteroids, analgesics, soothing agents. Office procedures for treatment include: rubber band ligation, injection therapy, cryotherapy photocoagulation. Surgical methods like Open/closed Haemorrhoidectomy, Whitehead's Haemorrhoidectomy[2,4] Procedure for Prolapse and Haemorrhoids/Stapled Haemorrhoidectomy[5] and Doppler-Guided Hemorrhoidal Artery Ligation[6] have evolved over the period of years.

The postoperative course of hemorrhoidal surgery is extremely painful, justifying the administration of substantial amounts of analgesics such as opioids, which may in turn produce nausea and vomiting, increase urinary retention decrease bowel motility[7]. Incisional infiltration with local anaesthetics has been documented to improve postoperative pain control after inguinal hernia repair or laparoscopic cholecystectomy[8]. Infiltration with local anaesthetics may also participate in providing adequate pain control after hemorrhoidal surgery. Present study was aimed to compare effectiveness of pre-emptive perianal methylene blue and ropivacaine infiltration in alleviating pain after hemorrhoidectomy.

MATERIAL AND METHODS

Present study was single-center, prospective, comparative study, conducted in department of Surgery, Medical College and SSG Hospital, Baroda, India. Study period was from November 2019 to November 2021. Study approval was obtained from institutional ethical committee.

Inclusion Criteria:

- All patients posted for Milligan-Morgan haemorrhoidectomy, willing to participate in present study

Exclusion Criteria:

- Patients taking nonsteroidal anti-inflammatory drugs, opioids, or other analgesics agents one week before surgery
- Chronic alcoholic
- Allergic to proposed drug

Study was explained to patients in local language and written consent was taken for participation and study. Patients underwent history taking, clinically examination and routine laboratory investigations preoperatively. Preoperatively patients were kept nil per oral overnight and received phosphate enema in the morning of the day of surgery. All surgeries were performed under General Anesthesia in in this study. Sealed envelopes containing a number indicative of the group assignment were used to randomly allocate patients into two groups in the operating room. The group under trial received methylene blue and Ropivacaine and the control group was tramadol oral tablet.

The Cases Group: After the procedure local infiltration was performed by surgeon approximately 1 cm away from incision edge. Careful aspirations are repeated to avoid accidental intravascular introduction of solution. Solution of infiltration was 0.16 percent methylene blue prepared by mixing 2 ml (20 mg) of Methylene blue injection with 10 ml (75 mg) of Ropivacaine hydrochloride injection solution.

The Control Group: 100mg of tramadol hydrochloride sustained release tablet were given orally twice for 5 days after surgery.

Patients were extubated after the surgery following fulfilment of extubation criteria. Pain intensity was be measured on a visual analog scale (VAS) graded from 0 (no pain) to 10 (the maximum pain imaginable). Pain assessment was performed 1st, 2nd, 4th, 7th, 12th hours, 7th day and 14 days after the end of the surgical procedure. Rescue medication as 100 mg of Tramadol hydrochloride sustain release tablet was given when visual analogue scale score = 6. Patients were also be evaluated for side effects such as nausea, vomiting and urinary retention, bleeding. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi- square test or Fisher exact test as applicable. $p<0.5$ was considered as statistically significant.

RESULTS AND DISCUSSIONS

Total of 68 patients were taken into the study and were then divided into cases and controls. 34 patients were taken into each group. Patients were allocated to their group in a randomized manner. It was observed that majority of the patients (34.37%) were in the

Table 1: Age and gender distribution

	Cases			Controls		
Age	**Male**	**Female**	**Total**	**Male**	**Female**	**Total**
1-10	0	0	0	0	0	0
11-20	2	0	2	2	0	2
21-30	7	1	8	5	1	6
31-40	4	0	4	5	3	8
41-50	6	0	6	10	0	10
51-60	5	0	5	4	1	5
61-70	3	3	6	1	1	2
71-80	0	0	0	0	1	1
81-90	0	3	3	0	0	0
	27	7	34	27	7	34

Table 2A: Presentation of symptoms in CASE

Age in years	No: of patients	Mass protrusion per anus	Bleeding PR	Pain	Grade		
					2	3	4
1-10	-	-	-	-			
11-20	2	yes	yes	yes	-	2	-
21-30	8	yes	yes	yes	2	6	-
31-40	4	yes	yes	yes	0	4	0
41-50	6	yes	yes	yes	0	6	0
51-60	5	yes	yes	yes	2	2	1
61-70	6	yes	yes	no	0	6	1
71-80	0	-	-	-	-	-	-
80-90	3	yes	-	no	0	1	2
Total	34				4	27	4

Table 2B: Presentation of symptoms in Control

Age in years	No: of patients	Mass protrusion per anus	Bleeding PR	Pain	Grade		
					2	**3**	**4**
1-10	-	-	-	-			
11-20	2	yes	yes	yes	-	2	-
21-30	6	yes	yes	yes	-	5	1
31-40	8	yes	yes	yes	1	7	0
41-50	10	yes	yes	yes	0	9	1
51-60	5	yes	yes	yes	0	4	1
61-70	2	yes	yes	no	0	1	1
71-80	1	yes	no	yes	0	1	0
80-90	-	-	-	-	-	-	-
Total	34				1	29	4

Table 3: Relation of VAS score >6 in cases

Age	Number	VAS @ 1 HOUR	VAS@ 2 HOUR	VAS @ 4 HOUR	VAS @ 7 HOUR	VAS @ 12 HOUR	VAS @ 1 WEEK	VAS @ 2 WEEKS
1-10	0	-	-	-	-	-	-	-
11-20	2	-	-	-	-	-	-	-
21-30	8	-	-	-	-	-	-	-
31-40	4	-	-	-	-	-	-	-
41-50	6	-	-	-	-	-	-	-
51-60	5	-	-	-	-	-	-	-
61-70	1/6	-	-	-	-	-	yes	-
71-80	0	-	-	-	-	-	-	-
81-90	1/2	-	-	-	yes	yes	yes	-

Table 4: Relation of VAS score >6 in control

Age	Number	VAS @ 1HOUR	VAS@ 2HOUR	VAS @ 4HOUR	VAS @ 7HOUR	VAS @ 12 HOUR	VAS @ 1 WEEK	VAS @ 2 WEEKS
1-10	0	-	-	-	-	-	-	-
11-20	1/2	-	yes	-	-	-	-	-
21-30	3/6	-	-	yes	yes	yes	-	-
31-40	8	-	-	-	-	-	-	-
41-50	2/10	-	-	yes	-	-	-	-
51-60	5	-	-	-	-	-	-	-
61-70	1/2	-	-	-	yes	-	-	-
71-80	1	-	-	-	yes	-	-	-
81-90		-	-	-	-	-	-	-

Table 5: Independent samples t-test

	Controls	Cases
VAS Score @7 Hr	2.3824±1.6146	0.3529±1.0977
VAS Score @12 Hr	2.0588±1.5559	0.7647±1.1822
VAS Score @1 wk	2.4118±1.0764	0.2647±1.8473
VAS Score @2 wk	0.6176±0.7392	0.2941±0.6291
Test statistic t	-3.862	
Two-tailed probability	P = 0.0003	

Table 6: post operative complication

incontinence	Nausea and vomiting	Urinary retention	Wound infection	Bowel
Case	-	-	1	-
Control	1	2	2	2

31-50 years of age group. Of total 68 patients, 55 were males and 13 were females.

In both case as well as control pain associated with hemorrhoidal disease and bleeding per rectum has been a constant factor for patient seeking remedial surgeries. Almost all age group similarly had complained of hemorrhoidal mass protruding out of anus. Out of 68 patients both cases and control had slight variation to grade of hemorrhoids. Of 34 patients in cases 5 had grade 2, total of 25 patients had grade 3 and 4 patients had grade 4 hemorrhoids. Of 34 patients in control 1 patient had grade 2, total of 31 had grade 3 and 2 patient had grade[4]. Taking into account the VAS score of patients, in cases it was apparent that out of 34 patients taken into study there was significant analgesia and pain free period where rescue drug had to be given if VAS score was 6 or more.

Taking the value of VAS score of 6 or more to be significant or intolerable pain in this study, it was observed that patient had pain free post hemorrhoidal surgery. Where two subject developed VAS score of 6 in monitoring hour at 7th hours, 12th hours and at 1 week post-operatively. In most case patient receiving the study drug had prolong analgesic effect most of which not requiring additional analgesic as rescue drug in long 2 weeks of follow up. The painful period post hemorrhoidal surgery from 12-48 hours patient tend to be restless due pain, followed by multiple complications such as urinary retention, vomiting etc. can be avoided with good analgesic as demonstrated in this study.

The VAS score of "control" arm of study with conventional analgesic treatment revealed that significant number of patients had VAS score 6 or more requiring extra analgesic as rescue drug. Of 34 patients taken under control group, 7 patient developed VAS score of 6 or more requirin g extra analgesic. Peculiar time interval after operation was noticed in control group with patient experiencing pain between 2nd-7th hours post -surgery. There are no cases with pain or vas score more than 0 at [1,2,3] hours and 2 weeks so we cannot use any significant test as controls are present with pain. Here we can present the data with proportion of controls have pain respectively where cases had not developed any pain. There is significant difference of vas score at 7th hours,12th hours and at 1 week between two means at 95% It has been observed that post operative complication like nausea, vomiting, urinary retention has been observed more number in control group as compared to cases. In control group 1 patient complain of nausea,[2] patient developed urinary retention which one patient required Foley's catheterization as was not relieved on analgesic supplement for concomitant post operation pain. However, foleys was removed the following day with normal return of bladder habit subsequently. On weeks follow-up in control group 2 patient complained of bowel incontinence associated with wound infection which was managed with antibiotic, local hygienic, sitz bath with stool softener. One patient with Grade 4 hemorrhoid complained of perianal excoriation which was managed with interdepartmental Dermatologist consultation

No significant post operative complication was noted in in case group as compared to control arm of the study. One patient with grade 4 hemorrhoid and perianal excoriation developed post hemorrhoidectomy wound and perianal excoriation which was managed with antibiotic, local hygiene, sitz bath and Dermatologist consultation with full recovery following weeks of treatment. No patient in both arms of the study developed any post hemorrhoidectomy bleeding, any life-threatening complication such as local sepsis or septicemia. Hemorrhoidectomy is usually associated with considerable pain during the postoperative period, which may delay discharge, recovery and return to work. In recent years many new surgical methods have been developed such as circular stapled hemorrhoidopexy and partial stapled hemorrhoidopexy with advantage of less trauma, minor post operative pain and fewer complications. A variety of methods for reducing pain after hemorrhoidectomy have been investigated including pudendal nerve block, perianal infiltration of local anesthetics or botulinum toxin application of topical preparation such as metronidazole, glyceryl nitrate calcium channel blocker[9].

Ropivacaine is a long-acting local anaesthetic which is commonly used to produce long-lasting anaesthesia and analgesia[10]. Because a high vascular absorption is supposed to occur after perineal infiltration with local anaesthetics, ropivacaine may thus guarantee a good safety margin between effective and toxic doses[11]. 11 In recent years Methylene blue has wide use in clinical medicine such as Methemoglobinemia, septic shock, Intro-op mapping of micro-bleeds12 and sentinel lymph node biopsy[13]. This study documents that perianal infiltration of 0.16 percent of Methylene blue and Ropivacaine improves pain control after post operative hemorrhoidal surgeries. Samrath *et al.,*[14] documented that perianal infiltration of 0.75 percent Ropivacaine in hemorrhoidal surgery had significant pain free period with demand for analgesic at 8 hours following surgery in comparison to placebo. Feng *et al.,*[15] documented significant low VAS score than control at 5th post

hemorrhoidectomy with no significance difference between in VAS score over 6th-14 days after surgery with combination of local infiltration of Methylene blue and Ropivacaine. Chester *et al.,*[16] used 0.5 percent bupivacaine, did not report any difference in pain scores, but the delay before analgesic administration was four times that in the infiltration group. In the present study, the combined use of 0.16 percent prepared by mixing 2ml (20mg) of Methylene blue and 10ml of (75mg) of Ropivacaine hydrochloride did not produce any local or systemic toxicity. The analgesic effect of perianal infiltration profoundly decreased demand for analgesic as seen in this study for week long period but limited number of patients included in this study hindered any significant number where demand for analgesic could be ascertained in particular period post operatively.

In the current study it is clearly seen that VAS scores are lower in the group which was given ropivacaine. Patients in the control group felt post operative pain in 7th-12th hour of post operative period. This also led to the increased incidence of use of Tramadol in the control group. In the study conducted by Beom Gyu Kim *et al.,*[17] the VAS pain score in control group was above 30 mm until 8 hours. Pain scores were significantly reduced in group ropivacaine group compared with those of control group. Fentanyl use for analgesia was the highest in control group and the low in ropivacaine group.

In the study conducted by Beatrice Vinson-Bonnet *et al.,*[18] the delay before first analgesic demand was longer in the ropivacaine group (90 (60-190) vs. 176 (90 720) minutes. P 0.02). Pain scores were significantly lower in the ropivacaine group at 1, 3 6 hours (P 0.05). Cumulative PCA morphine doses were lower in the ropivacaine group at 3, 6 12 hours (P 0.05). Therefore, in line with the previous study, this study also had results which confirms the efficacy of methylene blue and ropivacaine in reducing the VAS scores, In this study one patient had complaint of bowel incontinence. On the other hand, control group had 2 patients with urinary retention post operatively. Bleeding was not seen in any of both control group and case group. Post operative nausea and vomiting was seen in 1 patients of control group and none in the case group. Wound infection and bowel incontinence was seen in 1 patient in case and 2 in the control group

In the study conducted by Beom Gyu Kim *et al.,*[17] 9.5% of the patients had complaint of urinary retention in both cases and control group. Post operative nausea and vomiting was seen in 14% of patients of control group and 19% of the patients in the case group.

In the study conducted by Be'atrice Vinson-Bonnet *et al.,*[18] no patient complained of nausea or vomiting, but 3 patients in the saline group and 5 in the ropivacaine group had micturition difficulties. This shows that there was a higher rate of complications possibly pertaining to pain in the control group as compared to those in the case group. In this study incidence of urinary retention and Beatrice bowel incontinence cannot be attributed to pain alone as post operative wound infection and perianal excoriation could have been a compounding factor in development of symptoms whereas similar presentation was seen in the control group with healthy wound.

Some advantages of the current study are worth mentioning. Such as we studied only elective open MILLIGAN MORGAN Hemorrhoidectomy in our study to avoid type, nature and durations of pain associated with different types of surgery. More-over, all observation were carried out by single observer to eliminate any inter observer variability. Thus, we can assume that the difference in pain relief only the efficacy of the anti-nociceptive measures. The conjunctive use of Methylene blue with Ropivacaine has cumulative long lasting analgesic effect post hemorrhoid surgery decreasing considerably patient requiring analgesic. The lasting effect of Ropivacaine is compounded by reversible damage of cut nerve ending by Methylene blue producing prolong pain free period.

CONCLUSION

The analgesic effect of local infiltration of Methylene blue with Ropivacaine contributes to improvement in pain control after haemorrhoidectomy. It is a safe and simple technique that significantly improves the patient's comfort on awakening from anaesthesia and in the following hours. The technique is simple and easy to learn. Further it can be performed in a few minutes. We conclude by recommending that perianal infiltration of Methylene blue with Ropivacaine is not only effective but is also a safe procedure can be a better alternative strategy for reducing the pain of patients who are undergoing haemorrhoidecto

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