

Original Article

Methylene Blue as an Analgesic in Stapled Hemorrhoidopexy: A Prospective Observational Trial

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Abstract

Objective: The objective of this study was to investigate the role of local infiltration of methylene blue as an analgesic in stapled hemorrhoidopexy.

Methods: This was a prospective observational trial conducted in a tertiary health care center, Peshawar from July 2021 to June 2022. Inclusion criteria was the presence of grade III hemorrhoids. The study population was divided group A being labelled as case whereas, group B was labelled as control. Group A patients were administered a perianal injection of 2mL methylene blue (1%) along with 10mL bupivacaine (25%) whereas, group B patients were administered a perianal injection of 2mL normal saline along with 10mL bupivacaine (25%). Follow-up was done prospectively for any surgical complication, pain and hospital stay.

Results: The results of our study revealed that on day 3 and day 7, study participants in group A undergone significantly lower pain scores in comparison to group B at 3rd and 7th day While insignificant at 1st and 21st day. Group B participants had consumed a significantly higher number of diclofenac on day 1 (p value = 0.006) and between days 7 and 21 with p value = 0.000. Only 2 (5.71%) patients in group B observed a prolonged hospital stay because of having pain severity.

Conclusion: Local infiltration of methylene blue may be used as an effective analgesic in PPH patients with a decreased morbidity so should be used in these patients with confidence.

Keywords: Methylene blue, Hemorrhoidopexy, Analgesics, Pain score

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Introduction

Hemorrhoids are swollen and enlarged veins that are formed inside, outside the anus and lower rectum. They are painful in nature and causes rectal bleeding. Their prevalence is between 4.4 to 36.4% and most commonly seen within 45 to 65 years of age.^{1,2} As for as their structure is concerned, they are group of connective and vascular tissues in combination with smooth muscles that are organized in three pilasters laterally with the anal canal. In a healthy person, they work as cushions that helps in maintaining continence. Though hemorrhoids are normal in their structure yet, the term hemorrhoid indicates a pathological condition.³

Stapled hemorrhoidopexy, also known as stapled hemorrhoidectomy, is a surgical procedure that uses a stapling device to remove hemorrhoidal tissue. This procedure is generally used for the patients whose hemorrhoids have prolapsed or become abnormally larger, or for those

patients who have shown little or no improvement with non-surgical management. This hemorrhoid surgical procedure requires no exterior cut. As an alternative, hemorrhoidal tissue is lifted into a ring of tissues with sutures and a stapler confiscates the hemorrhoids, effectively cutting-off blood flow to the tissue. Patients, who have undergone stapled hemorrhoidopexy, characteristically experience a lesser amount of pain in comparison to those with having traditional hemorrhoid surgery. These patients may also experience less bleeding, less swelling, and less itching around the anus and inside the rectum. Additionally, stapled hemorrhoidopexy may reduce the chance of incontinence after the procedure^{4,7}. The objective of this study was to investigate the role of local infiltration of methylene blue as an analgesic in stapled hemorrhoidopexy.

Methods

This was a single center prospective observational trial conducted in a tertiary health care center, Peshawar-KP from July 2021 to June 2022. Sample size was 70, which was calculated using WHO calculator. The Institutional Review Board of the center granted the permission to conduct this study through letter No IRB/GMC/216/2021. Presence of grade III hemorrhoids was set as an inclusion criteria. Patients with hemorrhoids with other perianal conditions including fistula-in-ano, fissure-in-ano, male candidate having prostate and allergy with methylene blue were excluded from the study. We divided the study population into two equal groups based on their OPD number. Group A was labelled as cases whereas, group B was labelled as control. Group A patients were administered a perianal injection of 2mL methylene blue (1%) along with 10mL bupivacaine (25%) whereas, group B patients were administered a perianal injection of 2mL normal saline along with 10mL bupivacaine (25%). For any surgical complication, pain and hospital stay, follow-ups were done prospectively. Procedure for prolapsed hemorrhoids (PPH) was explained to the study participants through counselling with them. The age of the study participants was between 25 and 70 years, having symptomatic grade III hemorrhoids and were willing for surgery. Methylene blue sensitivity was tested by injecting 0.1mL of the dye subcutaneously. A single team carried out all the surgical procedures. Spinal anesthesia was given to all the patients. The stapling device remained common during all the surgeries. In order to achieve the essential hemorrhoidopexy, we placed the bites at 2cm above the dentate line. We caught only mucosa and submucosa in the suture. This was because the mishandling at an inadequate level or depth may result in severe difficulties. The patients were taught about how to mark post-operative pain on visual pain scale ranging between 0 to 10 (0=no pain, 10= maximum pain). Each patient received a scorecard to take home. A high fiber diet and

an oral lactulose was started to all the patients post-operatively. Seitz bath was advised to all patients thrice a day. Statistical analysis was done using GraphPad Prism 8. The statistical comparison between the two groups was done using the Chi square test and the Mann Whitney test ($P < 0.05$). Diclofenac sodium injection was given to the patients on demand in first 24hrs after surgery and were shifted on tablets later on. Postoperative pain score was measured with the help of a VAS^{55,6} at 6 h, 24 h, 72 h (through phone call), and at 1st and 3rd weeks during the outpatient visit. The pain scores were equated by the Mann Whitney test. Difficulty in passing urine or urinary retention, pain necessitating prolonged stay or spontaneous return, and reaction to methylene blue were noted and matched.

Results

The results of our study revealed that on day 3 and day 7, study participants in-group A recorded a significantly lower pain in comparison to group B. In participants of group A, the pain score on day 3 was 1.9 ± 1.04 (mean \pm SD) and that in-group B was 4.0 ± 1.22 (mean \pm SD) with p value 0.000. Similarly, the pain score on day 7 in-group A was 0.8 ± 0.42 (mean \pm SD) and that in-group B was 2.0 ± 1.4 (mean \pm SD) with p value 0.000. Pain score on day 21 in-group A post surgery was 0.34 ± 0.44 (mean \pm SD) and in group B was 0.46 ± 0.80 with p value 0.16. The results are shown in figure 1 and table I.

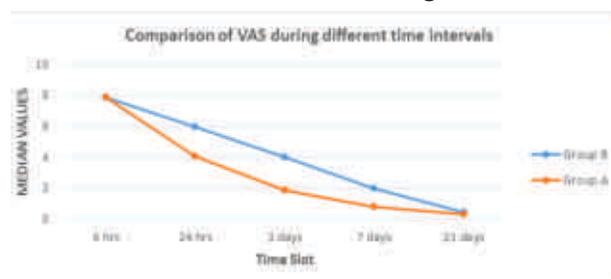


Figure 1: Comparison of VAS among groups at different time slots.

Table 1: Comparison of VAS among groups at different time slots with Mann-Whitney Test

Time Slots	Groups	Pain Score	IQR	Mann-Whitney Test	P value
6 Hrs	Group A (Cases)	7.98 \pm 2.14	2.00	1.134	0.244
	Group B Control)	8.44 \pm 2.89	2.00	No significant dfference	
24 Hrs	Group A (Cases)	4.0 \pm 1.66	2.00	1.022	0.274
	Group B Control)	5.64 \pm 2.24	2.00	No significant dfference	
3 days	Group A (Cases)	1.9 \pm 1.04	0.00	4.214	0.000*
	Group B Control)	4.0 \pm 1.22	1.20	No significant dfference	
7days	Group A (Cases)	0.8 \pm 0.42	2.00	4.664	0.000*
	Group B Control)	2.0 \pm 1.4	1.24	No significant dfference	
21 days	Group A (Cases)	0.34 \pm 0.44	0.00	1.221	0.16
	Group B Control)	0.46 \pm 0.80	2.12	No significant dfference	

*denotes significant value

Injectable and oral diclofenac taken by the stud participants

The results of our study revealed that the participant of group B required a significantly higher number of both injectable and oral diclofenac as compared to group A participants. Though there was no significant difference in pain scores between the two groups on days 1 and 21, group B participants had consumed a significantly higher number of diclofenac on day 1 (P value = 0.006) and between days 7 and 21 with p value = 0.000. The results r shown in figure 2.

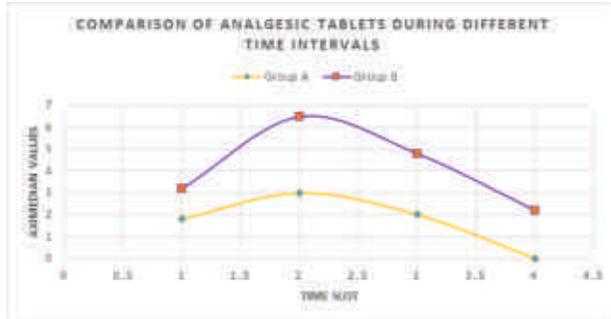


Figure 2: Comparison of inj/oral Diclofenac among the study groups.

Urinary retention among study groups

We used Chi square test in order to compare urinary retention or any difficulty while passing urine in both the study groups. 8 out of 35 patients (22.85%) in group A experienced difficulty while passing urine while in group B, 5 patients (14.28%) possessed urinary retention. The difference was not significant. The results can be visualized in table II.

Table 2: Comparison of Urinary Retention

Urinary retention	Study groups		Total
	Group A	Group B	
Yes			
Count	8	5	13
%	22.85	14.28	18.57
No			
Count	27	30	57
%	77.14	85.71	81.42
Total	35	35	70
%	100	100	100
Pearson Chi-square: 0.514		p-value: 0.446	

Prolonged hospital stay due to pain severity

Hospital discharge was given to all the study participants after 24hrs of surgical procedure. Only 2 patients (5.71%) in group B observed a prolonged hospital stay for a period of 48hrs because of pain severity.

Discussion

PPH involves the confiscation of uncharacteristically distended mucosal tissue, followed by a relocation of the remaining hemorrhoidal tissue back to its typical anatomical position. In order to achieve optimal results, patient’s selection plays a vital role. PPH is done in patients having second and third degree hemorrhoids as well as rectal mucosal prolapse. Fourth degree hemorrhoids having larger external components should not be treated with this technique⁸. A precise selective approach is needed for patients suffering from IBS (inflammatory bowel syndrome). PPH causes substantial postoperative pain in 10–30% of patients and in some patients; pain severity is more severe⁹. Pain after hemorrhoidectomy has always been the main reason for patients to refuse surgery, whereas surgeons have a major apprehension for controlling postoperative pain. Numerous harmonizing treatments have been suggested to lessen postoperative pain, including the use of diverse surgical tools (scalpel, diathermy, scissors, bipolar etc.), local or systemic injection of analgesic, antibiotics, or associated measures such as lateral internal sphincterotomy to reduce postoperative sphincter spasm. No treatments address the fact that the sensitive anal mucosa is devastated severely during the removal of hemorrhoids.¹²

The results of our study revealed that that on day 3 and day 7, study participants in-group A (cases group) reported significantly lower pain in comparison to group B (control group). In participants of group A, the pain score on day 3 was 1.9 ± 1.04 and that in-group B was 4.0 ± 1.22 with p value 0.000. Similarly, the pain score on day 7 in-group A was 0.8 ± 0.42 and that in-group B was 2.0 ± 1.4 with p value 0.000. Pain score on day 21 in-group A after surgery was 0.34 ± 0.44 and in group B was 0.46 ± 0.80 with p value 0.16. The lower intensity of pain following earlier PPH surgical procedure is due to lower staple line in the sensitive lower and upper anal canal rectum. This might be due to squeeze thread suture taken in closer proximity to the dentate line¹¹. The results of our study are consistent with the findings of other some researchers.^{13,14}

It is evident from numerous studies that the use of methylene blue is caudal and long term relief is possible with the use of epidural anesthesia.^{15,17} Some researchers displayed its results in the treatment of intractable and severe pruritus ani.^{3,4} Methylene blue alters an acid base balance and membrane potential through acting on glucose metabolism and thus, entangling injected local anesthetic by extending its effects.¹⁸⁻²⁰

Our study assess the efficacy of methylene blue on post PPH pain intensity. The results revealed a reduction in postoperative pain between days 1 and 7 in study participants who undergone an injectable therapy of methylene blue. None of the study participants experienced severe

pain and were required a reduced quantity of oral analgesics as well. Sim et al²¹ observed the same findings following open hemorrhoidectomy by perianal intradermal injection of methylene blue. A discoloration of skin was observed during the earlier 7-10 days, which vanished at day 21. Methylene blue is found to be a good agent in augmenting the beneficial effects of PPH by eliminating the severe pain. This procedure is more acceptable to both the patients and the surgeons. Further studies with a larger subject size are required for the validation of our results.

Conclusion

Local infiltration of methylene blue may be used as an effective analgesic in PPH patients with a decreased morbidity so should be used in these patients with confidence.

Conflict of Interest: *None*

Funding Source: *None*

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