

Comparative Evaluation of Pudendal Nerve Block with Local Anesthetics And Methylene Blue versus Saddle Block in Benign Perianal Surgery – A Prospective, Randomized Study

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Received: 25-08-2024 / Revised: 23-09-2024 / Accepted: 26-10-2024

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Conflict of interest: Nil

Abstract:

Objective: The present study was conducted to compare SEPTA block technique with SADDLE anesthesia in benign Anorectal diseases.

Methods: A prospective randomized comparative study was performed with 30 patients in each of two groups. Patients in Group A received SEPTA block and in Group B received Saddle anesthesia. Comparison was done between two groups in terms of total amount of drug given, average time of starting surgery after anesthesia, average duration of operation, average time of giving first rescue analgesia, average time of ambulation and post operative VAS score after 4 and 12 hours of benign perianal surgery.

Results: In this study average amount of the drug given was 30 mL in Group A and 2 mL in Group B. Average time of starting surgery after giving anesthesia was 3.5 minutes in Group A and 8.5 minutes in Group B. First rescue analgesia was required average 220 minutes after surgery in Group A and 125 minutes after surgery in Group B. Average time of ambulance after surgery was 45 minutes in Group A and 240 minutes in Group B. Comparison of post operative VAS score after 04 hours and 12 hours was not statistically significant between two groups. In Group A 01 patients developed urinary retention while in Group B 03 patients were developed urinary retention. In Group B 03 patients developed headache while in Group A none of the patients had headache.

Conclusions: The SEPTA technique offers the benefits of quick onset, long lasting analgesic effect, early mobilization, and less complications as compared to SADDLE block Anesthesia. As a result, it can serve as an alternative to Saddle Block anesthesia for benign anorectal surgeries.

Keywords: Anorectal surgeries, Hemorrhoids, Local anesthesia, Pudendal, SEPTA Block, Saddle block.

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Introduction

Saddle block anesthesia is commonly used for anorectal surgeries such as hemorrhoidectomy and fistula repair, which despite being shorter procedures are associated with significant postoperative pain due to the dense sensory supply of the perineal region [1]. Saddle block provided better outcome including sensory block levels without motor blockade and also requirement of Post-operative analgesia is low. Recently it was conclude that spinal anesthesia did not reduced the catecholamine response therefore the hemodynamic changes was there and also blocked the increases in cardiac index [2]. Lower complication rates and earlier mobilization revealed that caudal block can be used as a safe method in patients undergoing anorectal surgeries.

Studies suggest that patients undergoing hemorrhoidectomy experience higher levels of pain compared to those undergoing cholecystectomy and appendectomy [3,4]. Recently, it was revealed that spinal anesthesia did not reduce the catecholamine response despite mid-thoracic analgesia levels. Therefore, the hemodynamic variables did not change [5].

However, patients are required to remain seated for an extended period post-administration, which can lead to complications such as postoperative urinary retention [6]. The simplified easily reproducible pudendal nerve block technique for anorectal surgery (SEPTA), introduced by Ladha et al., and presents a more straightforward method of local

anesthesia (LA). In this technique, the LA solution is injected into the center of the ischioanal fossa, allowing it to spread to the pudendal neurovascular bundle without the need for rectal finger insertion, thereby minimizing patient discomfort and the risk of nerve injury. SEPTA has several benefits, such as a faster onset of action, no risk of urinary retention, early mobilization of the patient, and reduced postoperative pain, which can lead to shorter hospital stays[7].

Injecting methylene blue around the perianal area has been found to ablate nerve endings, providing pain relief following hemorrhoidectomy. In recent years, this local injection technique has been studied for various pain-related conditions, demonstrating a notable long-lasting analgesic effect [8].

Material and Methods

This prospective, randomized, comparative, single blinded study was conducted in the department of surgery and anesthesia of GCS Medical college and research centre from August 2024 to November 2024. After the approval from the institutional

ethical committee and informed written consent, 60 patients of the American Society of Anesthesiologist (ASA) Grade I, II, and III scheduled for anorectal surgeries were included in our study.

The study will involve two groups of patients: the case group, consisting of those scheduled to undergo a pudendal nerve block, and the control group, made up of patients set to receive a saddle nerve block. Participants will include those diagnosed with hemorrhoids (of any type or grade), anal fissures, or low-lying perianal fistulas, and classified as ASA grade I, II, or III. Exclusion criteria include patients younger than 18, individuals with complex perianal fistulas or malignant perianal diseases, those with G6PD deficiency, pregnant women, and anyone who refuses to provide consent. Using a convenient sampling technique, a total of 60 patients were involved with benign perianal diseases admitted to the Surgery Department of GCS Medical College and grouping was done according to the CONSORT Statement 2010. Each group consisted of 30 patients, as shown.

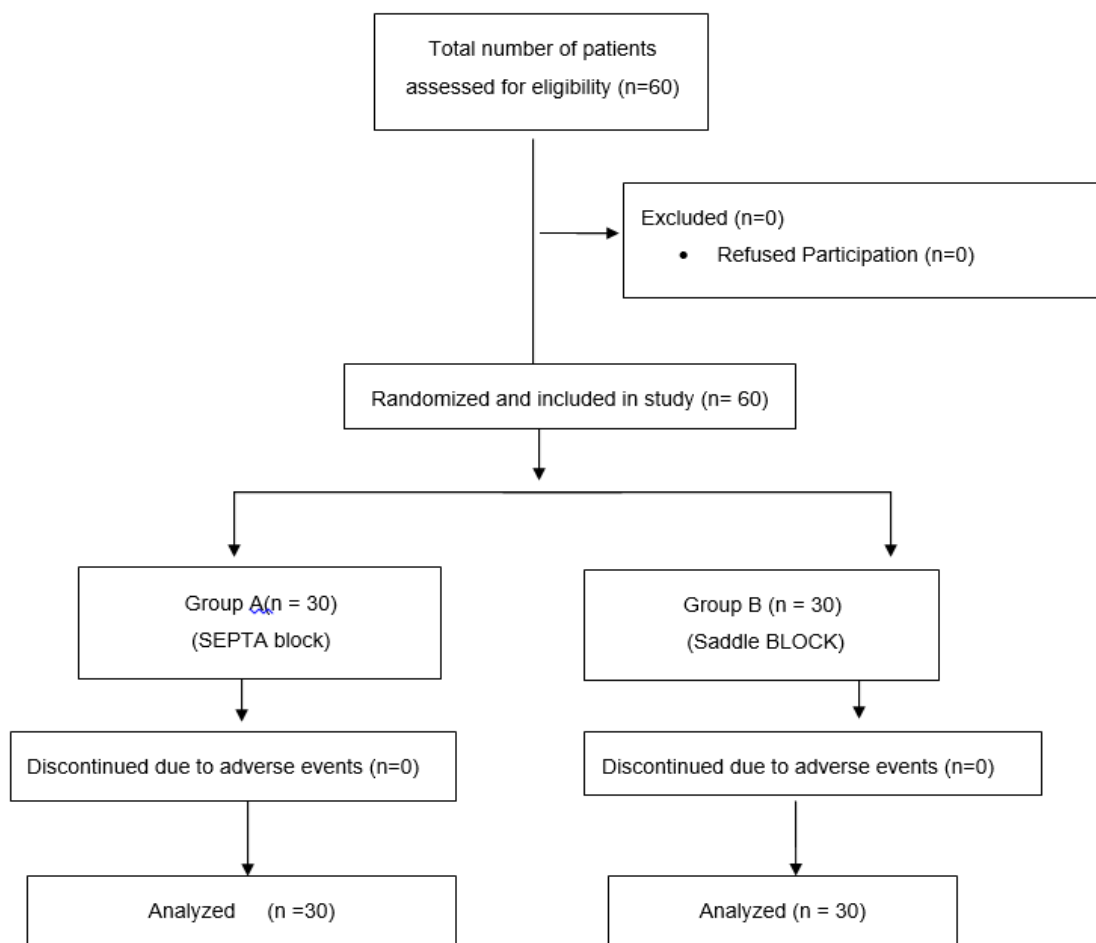


Figure 1: Consort Diagram

Study Producer: All patients underwent a routine pre-anesthetic evaluation, and written informed

consent was obtained. They were instructed to fast for 6 hours for solid food and 2 hours for clear liq-

uids before the block procedure. Using computer-generated randomization, the patients were randomly assigned into two groups of 30 each. Upon arrival in the operating room, heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SpO₂), and electrocardiogram monitors were applied to record baseline measurements. An intravenous (IV) line was secured, and IV fluids were initiated.

Patients in group A received Pudendal Nerve Block by SEPTA technique after proper premedication (injectable pentazocine 30 mg and promethazine 12.5 mg), the patient was positioned in the lithotomy position, using 15 mL of 0.25% bupivacaine with 15 mL of 2% lignocaine with 2 mL of methylene blue with 8 mL distilled water. 8 mL of this mixture was given at 12, 3, 6 and 9 clock position subdermally 2 mL each. 5 mL was given post anal space and 5 mL was given in intersphincteric plane and 11 mL in centre of each ischioanal fossa at midpoint between outer margin of external sphincter and ipsilateral ischial tuberosity. Wait for 1 to 2 minutes and start procedure. After waiting for 1–2 min, a well-lubricated finger was inserted in rectum and slight traction was given posterior to relax sphincter complex. The surgeon was allowed to start surgery after assessing sphincter relaxation.

Patients in Group B received a saddle block while in a sitting position. The patient's back was cleaned and draped, and the L3/L4 space was identified using anatomical landmarks. A dose of 1.5 mL to 2 mL of 0.5% hyperbaric bupivacaine was administered, after which the patient remained seated for 10 minutes before being placed in a supine position with a pillow under the head. The level of sensory block was then evaluated using cotton wool soaked in ethyl alcohol to assess temperature sensation.

Statistical Analysis: Data was analysed with the help of SPSS software. Unpaired t test and chi-square test was used and p-value was taken less than or equal to 0.05 ($p \leq 0.05$) for significant differences.

Observations: In this study, 60 patients were evaluated, with 30 patients in each group. Age, gender, comorbidities, diagnosis, and type of surgery were compared between the two groups (Table/Figure 2). Outcome parameters such as the total amount of drugs administered, the average time to start surgery after anesthesia, the average duration of surgery, the time to first additional analgesia, and the average time to ambulation were compared between the two groups. The total amount of drugs administered was significantly higher in Group A (30 ± 5 mL) compared to Group B (2 ± 1.5 mL), with a statistically significant *p*-value of <0.0001 (Table/Figure 3). The average time to start surgery after anesthesia was shorter in Group A (3.5 ± 1.5 minutes) compared to Group B (8.5 ± 3.5 minutes), with a *p*-value of <0.0001 (Table/Figure 3).

The average duration of surgery was 40.5 ± 10 minutes in Group A, compared to 60.5 ± 15 minutes in Group B. The first additional analgesia was required earlier in Group A (220 ± 60 minutes after surgery) compared to Group B (125 ± 30 minutes), with a statistically significant *p*-value of <0.0001 (Table/Figure 3). The average time to ambulation was significantly shorter in Group A (45 ± 20 minutes) compared to Group B (240 ± 60 minutes), with a *p*-value of <0.0001 (Table/Figure 3). Four hours after surgery, 22 patients in Group A had a VAS score between 0-3, compared to 21 patients in Group B. Only one patient in Group A had a VAS score between 7-10, compared to three patients in Group B. These results were not statistically significant, with a *p*-value of 0.5769 (Table/Figure 4). Twelve hours after surgery, 22 patients in Group A had a VAS score between 0-3, compared to 18 patients in Group B. One patient in Group A had a VAS score between 7-10, compared to four patients in Group B, with a *p*-value of 0.3220, indicating no statistical significance (Table/Figure 4).

In Group A, only one patient experienced urinary retention, while three patients in Group B reported this complaint. Headache occurred in two patients in Group B, but none in Group A (Table/Figure 5).

Table 1: Demographic data of study patients in two groups.

Variable		Group A (SEPTA) (n=30)	Group B (SADDLE) (n=30)
Age Group (years)	<20	00	01
	21-30	08	06
	31-40	04	05
	41-50	09	08
	51-60	07	08
	>61	02	02
Gender	Male	25	24
	Female	05	6
Comorbidity	Hypertension	15	17
	Diabetes	12	12
	IHD	05	07

	Thyroid	02	04
	None	05	03
Diagnosis	Hemorrhoids	18	15
	Anal Fissure	08	05
	Perianal fistula	02	08
	Others	02	02
Operations	Laser Hemorrhoidoplasty	10	12
	Hemorrhoidectomy	08	03
	Lateral anal sphincterotomy	08	05
	Fistulotomy	02	08
	Other	02	02

Table 2: Outcome parameters in two groups.

Variable	Group A (SEPTA) (n=30)	Group B (SADDLE) (n=30)	P value
Total amount of Drug given (average in mL)	30 +/- 5	2 +/- 1.5	<0.0001
Average time of starting surgery after giving anesthesia (min)	3.5 +/- 1.5	8.5 +/- 3.5	<0.0001
Average duration of operations (min)	40.5 +/- 10	60 .5 +/- 15	<0.0001
First Additional analgesia required time (min)	220+/- 60	125+/-30	<0.0001
Average Time of ambulation (in minute)	45+/-20	240+/- 60	<0.0001

*p<0.05 significant result, unpaired t-test

Table 3: postoperative VAS score comparison between two groups.

Time after operation	VAS score	Group A (SEPTA) (n=30)	Group B (SADDLE) (n=30)	P value
After 4 hours	0-3	22	21	0.5769
	4-6	07	06	
	7-10	01	03	
After 12 hours	0-3	22	18	0.3220
	4-6	07	08	
	7-10	01	04	

*p<0.05 significant result, chi-square test

Table 4: Postoperative Complications.

Complications	Group A (SEPTA) (n=30) (%)	Group B (SADDLE) (n=30) (%)
Bleeding	00	00
Urinary retention	01 (3.3 %)	03(10%)
Perianal abscess	00	00
Headache	00	02(6.6 %)

Discussion

Saddle block anesthesia is an effective technique for anesthesia in obstetric, urological, and perianal procedures. It involves low spinal anesthesia that specifically targets the sacral segments, preserving sympathetic function and resulting in minimal hemodynamic disturbances [5,11]. It provides several benefits, including rapid onset, a dense block, early patient mobilization, and shorter hospital stays, making it an ideal choice for perianal surgeries (12). However, a drawback of saddle block anesthesia is the need for extended bed rest, which can lead to urinary retention in some patients, with others also reporting nausea, vomiting, and headaches [5,13].

Multiple studies have demonstrated the feasibility of using SEPTA block as the sole anesthetic technique for anorectal surgeries. Various local

anesthesia (LA) techniques offer advantages such as reduced side effects (e.g., nausea, vomiting, and headaches), shorter hospital stays, lower costs, and quicker case turnover [14,15]. Recently, methylene blue injections have been evaluated for the treatment of various pain conditions and have shown a significant long-lasting analgesic effect [16].

In our study, an average of 30 mL of a mixture containing 2% bupivacaine, 2% lignocaine, methylene blue, and distilled water was used. In contrast, a study by Bharati et al. used 40 mL of 0.2% ropivacaine with dexmedetomidine [9]. The average time of anesthesia onset in Group A was 8.5 minutes, compared to 3.5 minutes in Group B, which was statistically significant. Similarly, in a study by Saini et al., the average onset time was 7.5 minutes in Group A and 3.72 minutes in Group B,

which was also statistically significant (10). In our study, the average duration of surgery was 40.5 minutes in Group A and 60.5 minutes in Group B. In the study by Saini et al., the average surgery duration was 67.4 minutes in Group A and 65.7 minutes in Group B [10]. The average time to rescue analgesia in our study was 220 minutes for Group A and 125 minutes for Group B. In studies by Jinjil et al. and Bharati et al., the average time to first rescue analgesia was 287 minutes and 5 hours, respectively, for local anesthesia in the perianal region [9,10]. The average ambulation time in our study was 45 minutes for Group A and 240 minutes for Group B. In the study by Saini et al., ambulation times were 32.7 minutes for Group A and 297 minutes for Group B. Results were statistically significant in both studies.

In our study, 73% of patients in Group A had a VAS score between 0 and 3 after 4 hours, with only 3.3% reporting a VAS score between 7 and 10. After 12 hours, VAS scores remained unchanged. In Group B, 70% of patients had a VAS score between 0 and 3 after 4 hours, with 10% reporting scores between 7 and 10. After 12 hours, 60% of patients had VAS scores between 0 and 3, while 13% had scores between 7 and 10. These results were not statistically significant. Similar outcomes were observed in the study by Saini et al. [9]. In this study, 3.3% of patients in Group A experienced urinary retention, compared to 10% in Group B. No patients in Group A experienced headaches, while 6.6% of patients in Group B reported postoperative headaches. In the study by Saini et al., 13.3% of patients in the saddle anesthesia group experienced urinary retention, while 3.3% reported postoperative headaches. In the SEPTA block group, no patients reported urinary retention or headaches [9].

Limitations: Small sample size is the limitation of this study. This can be performed with larger sample size.

Conclusions

The SEPTA technique offers the benefits of quick onset, no risk of urinary retention, early initiation of oral feeding, early mobilization, and timely patient discharge. As a result, it can serve as an alternative to Saddle Block anesthesia for anorectal surgeries, provided that patients give informed consent and are adequately counselled about the procedure.

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