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ORIGINAL ARTICLE

Comparative Study Between Intrathecal Hyperbaric Prilocaine Versus Hyperbaric Bupivacaine in Anorectal Surgery

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Abstract

Background: **The prevalence of ambulatory anorectal surgeries has been increasing, these procedures are deemed appropriate for day case surgery with the use of spinal anesthesia. This study aims to compare the anesthetic characteristics of intrathecal hyperbaric bupivacaine 0.5% and intrathecal hyperbaric prilocaine 2% in the context of elective anorectal surgery.**

Patients and methodology: **The research methodology used in this study is a prospective, double-blinded randomized approach. A total of 88 patients were divided into two similar-sized groups, and randomly allocated to the trial. Group A, got intrathecal administration of 15 mg hyperbaric bupivacaine 0.5%, whereas group B, received intrathecal administration of 60 mg hyperbaric prilocaine 2%.**

Results: **Group B demonstrated a more rapid initiation of sensory and motor block (with mean onset times of 1.86 min and 4.51, respectively), and a shorter duration time of sensory and motor block (mean of 120.8 and 105.3 min, respectively), compared with group A that had a slower initiation period of both sensory and motor block (2.6 and 5.8 min, respectively), and prolonged duration time of sensory and motor block (197.79 and 161.1 min, respectively). Group A exhibited significantly longer time to first postoperative rescue analgesia, time to first postoperative voluntary voiding, and hospital stay duration.**

Conclusion: **The utilization of hyperbaric prilocaine 2% resulted in a reduced duration of effect, with earlier recovery from sensory and motor blockade, early ambulation, voiding, and home discharge, thus reducing the overall hospital stay costs, and workload of medical staff.**

Keywords: Bupivacaine 0.5%, Hyperbaric, Intrathecal, Prilocaine 2%

1. Introduction

Once, there was a time when the preferred anesthetic techniques for ambulatory anorectal procedures was general anesthesia, owing to its fast onset and short acting drugs, allowing for early recovery, ambulance, and home discharge.[1]

General anesthesia has several drawbacks and complications such as; airway management, stress responses associated with laryngoscopy and intubation, pain not related to surgical incision (e.g. sore throat), airway trauma, difficult airway, aspiration pneumonitis, allergic reactions to anesthetic drugs, awareness, postoperative nausea/vomiting, headache, confusion, shivering, drowsiness, and increased needs for postoperative analgesics.[2]

Spinal anesthesia on the other hand is cost-effective and has a lot of advantages. It provides consistent, effective, relatively safe anesthesia, minimizes surgical bleeding and the need for transfusion, reduces postoperative pain scores and decreases the need for postoperative analgesia, less postoperative nausea/vomiting, and diminishes the necessity for postanesthesia care unit.[3]

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The widely used intrathecal drug is bupivacaine, a potent, long-acting local anesthetic. Concerns about extended motor blockade, possible postoperative urinary retention, and prolonged hospital stay, have limited its use.[4] In order to address this challenge, physician have used minimal dosage of bupivacaine for spinal anesthesia in ambulatory surgical procedures. Nevertheless, it has been observed that the administration of minimal dosages has resulted in a significant range of block density, leading to a notable rate of unsuccessful outcomes.[5]

Lidocaine, a commonly known local anesthetic characterized by moderate potency and duration, has also been administered intrathecally for ambulatory surgeries. However, concerns regarding its appropriateness for spinal anesthesia have arisen due to reports of transient neurological symptoms associated with its intrathecal application.[6]

Therefore, while spinal anesthesia is popular for inpatient surgeries, The utilization of intrathecal local anesthetic drugs in outpatient ambulatory surgeries was rather infrequent, mostly attributable to the absence of a secure and authorized short to intermediate acting medication.[7]

The best intrathecal medication for ambulatory surgery should have a quick onset of motor and sensory blocking, predictable regression within a suitable timeframe, and a low incidence of adverse effects.[8]

Prilocaine is classified as an amide local anesthetic. It is commonly administered intrathecally in a hyperbaric form with a concentration of 2%. Prilocaine has comparable characteristics to lidocaine, including rapid onset, intermediate potency, and duration of action. However, it has been observed to have a decreased occurrence of transient neurologic symptoms.[9]

Studies to determine the appropriate dosage concluded that prilocaine dosages ranging from 60 to 80 mg are suitable for lower limb and lower abdomen procedures with a duration of up to 120 min. Moreover, doses within the range of 40–60 mg have been demonstrated to be both safe and efficient for employment in ambulatory surgery.[10]

The duration of hospital discharge following the administration of intrathecal prilocaine is contingent upon the dosage administered. However, patients can generally expect to be discharged within a range of roughly 4–6 h.[11]

Regression of the blockage below the S2 level is essential to facilitate mobilization and micturition, which are often used local indicators for the discharge of patients to their homes, provided there are no additional obstacles present.[12,13]

The main aim of the study is to compare the anesthetic characteristics of intrathecal hyperbaric bupivacaine 0.5% and intrathecal hyperbaric prilocaine 2% in the context of elective anorectal surgery.

2. Patients and methods

This is a prospective, double-blinded randomized study, performed under the supervision of Department of Anesthesiology and Intensive Care Medicine, Al-Azhar University.

2.1. Sample size, study population, and inclusion criteria

A total of 88 patients of both sexes-undergoing elective anorectal procedures, that are expected to last no more than 45 min, were enrolled and randomly divided into two equal groups, group A 44 patients, received intrathecal 3 ml (15 mg) hyperbaric bupivacaine 0.5% (Sunnypivacaine 20MG/4 ml), and group B 44 patients, received intrathecal 3 ml (60 mg) hyperbaric prilocaine 2% (Takipril 100MG/5 Ml).

2.2. Exclusion criteria

Age below 18 or over 75 years, ASA greater than or equal to III, BMI greater than 40, pregnant, or lactating females, patients who had absolute or relative contraindications to spinal anesthesia.

2.3. Ethical consideration

The study protocol received approval from the Ethical Committee of the Faculty of Medicine at Al-Azhar University. Informed written consent was obtained from all individuals. Sufficient measures were in place to ensure the preservation of participant privacy and the confidentiality of the collected data.

2.4. Pre-operative management (Study preparations)

At ward, all patients were visited, full history was obtained, patients were clinically examined, investigations were checked, anesthetic procedure was fully explained, informed written consent was obtained, and patients were asked to void just before surgery.

In the preanesthetic room, an intravenous access was established and secured, baseline monitoring included heart rate, respiratory rate (RR), electrocardiogram (ECG), noninvasive blood

pressure (NIBP), peripheral oxygen saturation (SpO_2%), and temperature, all were measured and recorded.

2.5. Intra-operative management (Study procedure and methodology)

While maintaining asepsis, patient's back was disinfected with antiseptic, and an intradermal wheal, using 2 ml lidocaine 2. While ensuring double-blindedness, single shot spinal anesthesia technique using a disposable 25-gauge Quincke tip spinal needle, through paramedian approach was carried out for all patients, patient was then placed flat in supine position immediately, continued to be monitored (Pulse Oximetry, NIBP, and ECG), and supported (IV fluids, vasopressors, and/or oxygen face mask if needed). Crystalloid infusion (7 ml/kg) was initiated as a co-load.

Sensory block evaluation was carried out by pinprick test, using a hypodermic needle tested at the mid clavicular line. The assessment of the onset time of sensory block was considered when a total absence of sensations within the designated dermatome of T10 (specifically at the level of the umbilicus). In contrast, the duration of the sensory block was determined by measuring the time elapsed from the initiation of the sensory block until its complete regression.

The assessment of motor block was conducted using the Modified Bromage Scale. The determination of the start time of motor block was based on the attainment of grade 3 on the Modified Bromage Scale. Meanwhile, the duration of motor block was estimated as the period from the onset of motor block (Bromage 3) to complete regression (Bromage 0).

The achievement of successful spinal anesthesia and preparedness for a surgical treatment is determined by the establishment of an ideal block (complete sensory block at the T10 level and a Bromage Score of 3).

Mean arterial pressure and Heart rate were monitored throughout the operation, and recorded at specific intervals.

Hypotension, (which is considered whenever a reduction in mean arterial pressure of at least 20% relative to the basal measurement), was managed by either 250 ml of crystalloid fluid boluses or a 5 mg intravenous bolus of ephedrine. Bradycardia, (which is considered whenever a reduction in heart rate of at least 20% relative to the basal measurement), was managed with the administration of intravenous bolus atropine at a dosage of 0.5 mg.

The assessment of postoperative pain levels was conducted with the numerical rating scale, as depicted in Fig. 1.

As per the established local hospital practice for postoperative pain management, it is customary for all patients to be administered a 1 g dose of intravenous paracetamol immediately upon their transfer to the ward following surgery.

Whenever numerical rating scale was greater than or equal to 4; an intravenous infusion of 30 mg ketorolac was initiated as rescue analgesia, and time of need for first postoperative analgesia was recorded.

Patients were encouraged to void frequently, and time to first voluntary voiding, as well as time to home discharge were recorded.

The criteria for home discharge included: complete resolution of motor and sensory blocks, tolerance of oral fluids, and successful voluntary voiding. Patients with modified post-anesthetic discharge score system (MPADSS) greater than or equal to 9 were eligible for home discharge (Table 1).[13]

2.6. Post-operative management (Further details)

Following the completion of the surgical procedure, patients were then transferred to the Post-anesthesia care unit (PACU). In this unit, patients had continuous monitoring, ensuring the maintenance of hemodynamic stability, while also

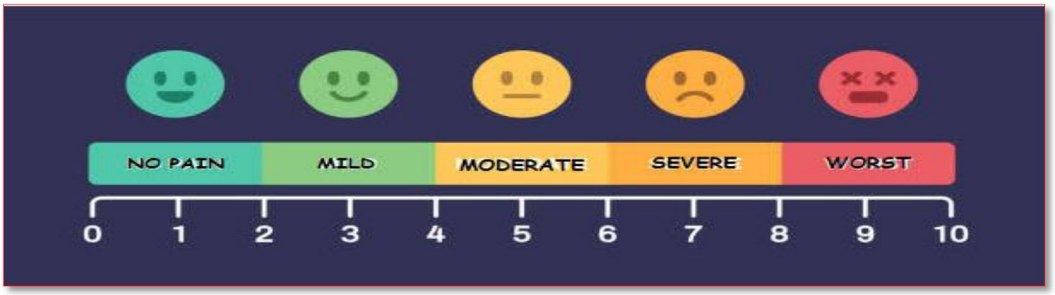

Fig. 1. Numerical Rating Scale for pain assessment.

Table 1. Modified post-anesthetic discharge scoring system (MPADSS).

Vital signs	Score	Postintervention bleeding	Score
Within 20% of baseline	(2)	Minimal (No dressing changes needed)	(2)
Within 20–40% of baseline	(1)	Moderate (up to 2 dressing changes)	(1)
Beyond 40% change from baseline	(0)	Sever (3 or more dressing changes)	(0)
Nausea and vomiting	Score	Activity level	Score
No to Mild (improves with oral medications)	(2)	Wander unassisted	(2)
Moderated (improves with parenteral medications)	(1)	Wander with assistance	(1)
Sever (does not improve despite treatment)	(0)	Unable to ambulate	(0)
Pain	Score		
Minimal to Mild (improves with oral analgesics)	(2)	Patients who achieved a MPADSS Score of 9 or higher were home discharged.	
Moderate (improves with parenteral analgesics)	(1)		
Sever (does not improve despite treatment)	(0)		

Table 1: Revised postanesthetic discharge scoring system.

assessing for the absence side effects, or control the existing ones.

In the ward setting, patients were consistently subjected to ongoing monitoring and assessment procedures. The patients were advised to commence activities such as sitting, standing, walking, and voiding trials. The time at which the first postoperative rescue analgesia was required, the time at which the first voluntary voiding occurred, and the time at which the patient was discharged to go home were all recorded.

2.7. Statistical analysis

The data was collected, organized into tables, and subjected to statistical analysis. A *P* value less than or equal to 0.05 is indicative of a statistically significant difference, a *P* value less than 0.001 suggests a highly significant difference, and a *P* value more than 0.05 suggests a lack of statistical significance.

3. Results

Group A: bupivacaine group. Group B: prilocaine group. n: number. SD: standard deviation. BMI: body mass index. ASA: American Society of Anesthesiologist. χ^2: Chi square test. T: Independent *T* test. P: probability value.

Table 2: No significant difference between the two studied groups regarding age, gender, BMI, ASA, surgical procedure, surgery duration, and total volume of intraoperative fluid given to patients.

Table 2. Patients' characteristics and surgical data of the two studied groups.

	Group (A) ($N = 44$) [n (%)]	Group (B) ($N = 44$) [n (%)]	Test of significance	*P* value
Age (y)				
Mean ± SD	32.82 ± 9.3	30.5 ± 7.11	t˜1.31	0.192
Sex (n %)				
Male	32 (72.7)	34 (77.3)	$\chi^2 \approx 0.242$	0.622
Female	12 (27.3)	10 (22.7)		
BMI				
Mean ± SD	25.36 ± 2.47	24.27 ± 2.85	t˜1.92	0.059
ASA (n %)				
I	41 (93.1)	40 (90.9)	$\chi^2 \approx 0.52$	0.47
II	3 (6.9)	4 (9.1)		
Surgical Procedure				
Anal fissure	10 (22.7)	12 (27.3)	2.47	0.650
Hemorrhoids	20 (45.5)	18 (40.9)		
Anal fissure and Hemorrhoids	10 (22.7)	12 (27.3)		
Anal fistula	2 (4.5)	2 (4.5)		
Anorectal abscess	2 (4.5)	0		
Duration of Surgery (min)				
Mean ± SD	18.8 ± 4.1	17.5 ± 5.3	t≈1.7	0.45
Total volume of intraoperative fluid given to the patient (ml)				
Mean ± SD	640 ± 210	556 ± 180	t≈1.519-	0.07
Range	500–1000	500–1000		

Table 3. Anesthetic characteristics (onset time and duration of LAs) for the two studied groups.

	Group A (n = 44)	Group B (n = 44)	t	P
Onset time of sensory block (min)				
Mean ± SD	2.6 ± 0.5	1.86 ± 0.34	8.12	**<0.001**
Range	2–3	1.5–2.2		
Onset time of motor block (min)				
Mean ± SD	5.8 ± 1.4	4.51 ± 0.58	5.66	**<0.001**
Range	5–7	4–5		
Duration of Sensory block (min)				
Mean ± SD	197.79 ± 7.9	120.8 ± 4.7	55.15	**<0.001**
Range	200–240	115–125		
Duration of Motor block (min)				
Mean ± SD	161.1 ± 10.7	105.3 ± 5.8	30.38	**<0.001**
Range	160–210	90–115		

Table 3: There was a notable disparity observed in terms of the onset and duration of sensory and motor blockage between the two groups under investigation. It was observed that the beginning of blockade was more rapid in group B, while duration of the block was seen to be longer in group A.

Table 4: Significant difference regarding Modified Bromage Scale (MBS), between the two studied groups after 5 min from injection, MBS was higher in the prilocaine group, i.e. faster motor block. Another significant difference at 90 min, 2, 2.5, and 3 h after injection, MBS was lower in the prilocaine group, i.e. early recovery and ambulance.

Table 5: Time to 1st postoperative analgesia need, time to 1st postoperative voluntary voiding, and hospital stay time, was significantly higher among bupivacaine group compared with prilocaine group.

4. Discussion

The present investigation revealed a statistically significant distinction between the two groups (P value < 0.001) in terms of both onset time and duration. The group administered with prilocaine exhibited a more rapid onset time and a shorter duration of sensory and motor block compared with the group administered with bupivacaine. The prilocaine group's mean sensory block onset time was 1.86 min, while for motor block it was 4.51 min. The mean duration of sensory block in the prilocaine group was 120.8 min, and for motor block it was 105.3 min. In contrast, the bupivacaine group's mean onset times for sensory and motor blocks were 2.6 and 5.8 min, respectively. The mean duration of sensory block in the bupivacaine group was 197.79 min, and for motor block it was 161.1 min.

Based on the findings of a study conducted by Rabei Gheth *et al.* in 2022, another prospective randomized double-blinded trial was conducted on 66 patients who were scheduled for day case surgery. The patients were divided into two independent groups: group P received a dosage of 60 mg of hyperbaric prilocaine 2%, whereas group C received a dosage of 15 mg of hyperbaric bupivacaine 0.5%. The

Table 4. Modified Bromage Scale (MBS) distribution between the two studied groups.

	Group A (n = 44)	Group B (n = 44)	t	P
2 min after injection Mean ± SD	1.1 ± 0.371	1.3 ± 0.451	1.93	0.011
5 min after injection Mean ± SD	1.6 ± 0.481	2.6 ± 0.121	13.39	**<0.001**
10 min after injection Mean ± SD	3	3	–	–
15 min after injection Mean ± SD	3	3	–	–
20 min after injection Mean ± SD	3	3	–	–
25 min after injection Mean ± SD	3	3	–	–
30 min after injection Mean ± SD	3	3	–	–
60 min after injection Mean ± SD	3	3	–	–
90 min after injection Mean ± SD	3	2.1 ± 0.291	21	**<0.001**
2 h after injection Mean ± SD	2.91 ± 0.291	1.1 ± 0.291	29.17	**<0.001**
2.5 h after injection Mean ± SD	2.18 ± 0.390	0	37.01	**<0.001**
3 h after injection Mean ± SD	1.18 ± 0.390	0	20.03	**<0.001**
3.5 h after injection Mean ± SD	0.180 ± 0.390	0	3.067	056–
4–6 h after injection Mean ± SD	0	0	–	–

Table 5. Post-operative clinical characteristics between the two studied groups.

	Group A (N = 44)	Group B (N = 44)	t	P
Time to need of 1st postoperative analgesia (hrs.) Mean ± SD	4.81 ± 0.332	3.14 ± 0.321	**24**	**<0.001**
Time to 1st postoperative voluntary voiding (hrs.) Mean ± SD	5.39 ± 0.637	3.69 ± 0.499	**14**	**<0.001**
Hospital stay (hrs.) Mean ± SD	7.64 ± 1.79	6.73 ± 1.56	**2.54**	**0.013**

findings of the study demonstrated that the prilocaine group exhibited a significantly faster mean onset time (sensory: 1.95 min, motor: 4.87 min) and a shorter mean duration time (sensory: 92.4 min, motor: 110.7 min) in comparison to the bupivacaine group (mean onset time: sensory: 2.8 min, motor: 6.1 min; mean duration: sensory: 207.6 min, motor: 253.9 min).[14]

Conversely, in a study conducted by Wesselink *et al.* (2019), 150 patients were randomly assigned to receive either 40 mg of 2-chloroprocaine or 40 mg of prilocaine intrathecally for ambulatory knee arthroscopy. The findings of the study demonstrated that the administration of 2-chloroprocaine offered distinct advantages compared with prilocaine. Specifically, 2-chloroprocaine exhibited a more rapid onset and regression of sensory block.[15]

A notable disparity was observed in relation to the Modified Bromage Scale, between the two studied groups after 5 min from injection, where Bromage score was greater in the prilocaine group-i.e. faster motor block, and another significant difference at 90 min, 2 h, 2.5 h, and 3 h after injection, where Bromage score was lower in the prilocaine group, i.e. early recovery and ambulance.

Our results was supported by study performed by Zeinab A *et al.*, 2022, on 66 patients divided randomly into three groups receiving either 2% prilocaine, 0.5% bupivacaine, and lidocaine 2% for spinal anesthesia. The study demonstrated that there was statistically significant difference between study groups regarding MBS at 1st and 2nd hours, where there was delayed recovery from motor blockade in bupivacaine group compared with both lidocaine and prilocaine groups.[16]

In contrast to the present study, Mohta-*et al.* (2015); 50 patients who had spinal anesthesia were included in a study that was done for elective caesarean section. Intrathecal hyperbaric 55 mg Ropivacaine was administered to the first group, while the second group received 12.5 mg bupivacaine. In both groups, the anesthetic was mixed with 3 μg sufentanil and 0.1 mg morphine. The study findings indicated that there was no statistically significant distinction observed between the two groups in relation to MBS.[17]

Our study demonstrated a significant statistical difference between the two studied groups (P value < 0.001) regarding; Time of need for 1st postoperative rescue analgesia was 4.81 ± 0.332 h. For bupivacaine group, and 3.14 ± 0.321 h. For prilocaine group. Time to 1st voluntary voiding was 5.39 ± 0.637 h. For bupivacaine group, and 3.69 ± 0.499 h. For prilocaine group. Mean hospital stay time and home readiness was 7.64 ± 1.79 h to 6.73 ± 1.56 h for bupivacaine and prilocaine groups, respectively.

In accordance with the findings presented in the study conducted by Manassero A. *et al.* (2017), a research investigation was carried out involving a total of 88 patients who were scheduled to undergo lower-limb surgery with a maximum duration of 45 min under spinal anesthesia. These patients were randomly assigned into two groups, with one group receiving a dosage of 15 mg of 0.5% hyperbaric bupivacaine and the other group receiving a dosage of 60 mg of 2% hyperbaric prilocaine. The average duration before spontaneous micturition was found to be 306 min for the prilocaine group and 405 min for the bupivacaine group. This discrepancy indicates a statistically significant distinction between the two groups, with those in the prilocaine group exhibiting earlier voluntary voiding.[7]

In a study conducted by Rabei Gheth *et al.* in 2022, the researchers observed that the mean time to home release was 275 min (±standard deviation) for prilocaine and 390 min (±standard deviation) for bupivacaine group. In comparison, our study found a mean time of 360 min (±standard deviation) for the prilocaine group and 420 min (±standard deviation) for the bupivacaine group, indicating that the duration of hospital stay in our study was longer.[14] This differences between our and their study, regarding home readiness, may be attributed to differences in local hospital discharging protocols.

4.1. Conclusion

Spinal anesthesia using both hyperbaric bupivacaine 0.5% and hyperbaric prilocaine 2% provided reliable and competent anesthesia. However, in contrast to bupivacaine, the use of hyperbaric prilocaine 2% yielded shorter duration of action, This leads to a more prompt resolution of sensory and motor blocks, facilitating early mobilization, urination, and discharge to home, hence decreasing hospitalization expenses, alleviating the burden on healthcare personnel, and providing a more safe and improved patient outcome, in the context of day-case anorectal surgery.

Conflicts of interest

There are no conflicts of interest.

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