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Prilocaine compared with bupivacaine in spinal anesthesia for lower abdominal day case surgeries: A prospective randomized double-blind controlled study

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Abstract

Background: Day-case spinal anaesthesia using hyperbaric prilocaine, a short-acting local anaesthesia, has a short duration of action and a low incidence of transient neurological symptoms (TNS).

Purpose: The current study aim to evaluate and compare hyperbaric prilocaine 2% and hyperbaric bupivacaine 0.5% for spinal anaesthesia in lower abdominal day case surgeries.

Methods: This work was conducted as a prospective randomized controlled double-blind study on a total of 70 individuals, both male and female, who were planned for day case surgeries using spinal anaesthesia. The participants were allocated into two groups: group I, who received a dose of 15 mg HB 0.5%, and group II, who received a dose of 60mg HP 2%

Results: The group that received prilocaine had a rapid onset of sensory (3.9 ± 0.36 min) and motor block (6 ± 0.7 min) compared to the other group ($p < 0.001$). The Prilocaine group exhibits a shorter duration of sensory (92.4 ± 2.5 min) and motor blockage (113.7 ± 8.8 min) compared to the bupivacaine group (193.6 ± 10.9 min for sensory blockage and 261.9 ± 19.8 min for motor block). The Prilocaine group demonstrated a significantly less time to walk without assistance (120.7 ± 7.8 min) and void spontaneously (256.4 ± 21.5 min) compared to the corresponding times in group I, where the duration to walk without assistance and void spontaneously were (301.8 ± 13.9 min) and (345.4 ± 24.5 min) correspondingly.

Conclusion: Group II offers rapid onset, less duration of action, and rapid recovery in ambulatory surgeries contrasted to Group I in lower abdominal day-case surgeries.

Keywords: Spinal Anesthesia, Prilocaine 2%, Hyperbaric, Bupivacaine 0.5%

Introduction

The majority of operations are carried out under spinal anaesthesia in an outpatient setting. Regrettably, there is now no local anaesthesia available that may provide immediate relief, predictable duration, high efficacy and rapid recovery, and absence of adverse effects. (Korhonen, A.M. 2006) Spinal lidocaine has been the preferred local anaesthesia for outpatient procedures due to its rapid onset and short duration. Nevertheless, there have been reports of transient neurological symptoms (TNS), characterized by back discomfort that radiates to the lower limbs. (Zaric D, 2005) As a result of this knowledge, several practitioners have chosen to discontinue the administration of lidocaine for spinal anaesthesia. In an effort to make hyperbaric bupivacaine, a local anaesthesia with long-lasting effects, suitable for outpatient use, lower amounts have been tested. Nevertheless, administering lesser dosages of anaesthetic may result in a longer duration of the blocks, and they might potentially lead to inadequate anaesthesia (Kaufmann M, *et al.*, 1993). Moreover, bupivacaine often causes urine retention, resulting in longer intervals before ambulatory patients may be discharged due to delayed initial voiding.

Spinal anaesthesia in ambulatory surgeries utilized small quantities of long-acting local anaesthetics, which include bupivacaine, levobupivacaine, and ropivacaine. The administration of high quantities of extended-release local anaesthesia resulted in an increasing issue of delayed discharge, whereas smaller dosages exhibited significant variation in the duration of the anaesthetic effect and the rate of treatment failure. (Zaric and Pace 2009) [15].

Prilocaine has been suggested as a beneficial substitute for lidocaine and modest dosages of long-acting local anesthesia for brief operations conducted under spinal anaesthesia. This is because prilocaine has a moderate duration of action and a decreased occurrence of TNS.

Patients and Methods

This work was conducted as a prospective randomised controlled double-blind clinical study on 70 individuals of both genders who had been planned for day case surgeries using spinal anaesthesia. The purpose of the work was to compare the impact of intrathecal hyperbaric prilocaine 2% and hyperbaric bupivacaine 0.5% in terms of enhancing the safety and effectiveness of anaesthesia, as well as being ready for discharge following ambulatory surgeries. The participants were admitted to Tanta University Hospitals. The documented patient characteristics include individuals of both genders, aged between 21 and 65 years, who are scheduled for day case surgeries using spinal anaesthesia. The American Society of Anesthesiologists (ASA) classifications: ASA class I and ASA class II. The duration of the procedure doesn't exceed 75 minutes. The criteria for exclusion included anyone with a known allergy to the medications being examined. Individuals who have medical conditions or circumstances that make them unsuitable candidates for spinal anaesthesia. Individuals suffering from advanced cardiac, renal, and hepatic diseases.

Participants were assigned to two equal groups using a computer randomization procedure based on the study medicines. The control group, referred to as Group I (hyperbaric bupivacaine group), consisted of 35 individuals who received 3mL (15 mg) of 0.5% hyperbaric bupivacaine intrathecally. (Marcaine, which contains heavy HB at a concentration of 5mg/mL in a solution of 0.5% glucose from Astra Zeneca, Sweden). The Group II, consisting of 35 individuals, received intrathecal administration of 3 mL (60 mg) of 2% HP (Prilotelal, prilocaine 20mg/mL 2%, glucose 6%, Mercury Pharma, UK).

Participants were provided with a detailed explanation of the anaesthetic process and obtained signed informed permission from them. Each patient was instructed to empty their bladder just before to the surgical procedure. A cannula with a diameter of 18-gauge was placed intravenously, and the participants were administered a premedication of 0.03 mg / kg of IV midazolam. Preparation before surgery: Upon entering the operation room, all patients had routine monitoring, which included electrocardiography (ECG), pulse oximetry, and non-invasive blood pressure (NIBP). The first measurements of heart rate (HR), mean arterial blood pressure (MAP), and oxygen saturation (SpO₂) were documented. A preload of crystalloid infusion at a rate of 10 mL / kg was started. A fully equipped anesthetic machine, including an oxygen supply, laryngoscope, airway devices, and resuscitation medicines, was present in the operating theater. The study medicines were prepared by a separate anesthetist who was not engaged in the research or data gathering of the study. The patients placed in sitting position while their skin was prepped with 10% betadine. The skin and subcutaneous tissues were subsequently anesthetized with a 2% lidocaine injection administered in a sterile manner. A spinal anesthetic procedure was conducted in the L3-4

intervertebral area utilizing a 25 G Quincke spinal needle. The needle was introduced in a midline approach, with the bevel oriented laterally. The local anesthesia had been administered into the intrathecal region within 15 seconds following confirming the unobstructed flow of clear cerebrospinal fluid. The needle was removed and the skin was wrapped. Subsequently, subjects were promptly repositioned into a supine posture while wearing an oxygen face mask.

During surgery, the evaluation and interventions performed. The assessment of sensory blockade was conducted using a pinprick test, performed with a 25-gauge hypodermic needle, at the mid-clavicular line. This evaluation was carried out for the first 20 minutes, during which the highest degree of block and the corresponding duration were documented. The motor blockage was evaluated using the modified Bromage score at five-minute intervals during the first 20-minute period following the administration of a local anesthetic by spinal injection. The scoring system for this assessment is as follows: (0 indicates no motor block, 1 indicates the ability to bend the knee and move the foot, but not raise the leg, 2 indicates the ability to move the foot alone, and 3 indicates the inability to move the knee or the foot). The initiation of the motor blockage can be explained as the period starting with the administration of local anesthesia by spinal injection until a Bromage score of grade 3 is attained. Spinal anaesthesia was considered successful when the desired level of numbness (dermatome of T10) was reached and a Bromage score of 3 was acquired 20 minutes after the administration. If there is no sensory or motor blockage within 20 minutes following the spinal injection of a local anesthesia, this is deemed a failed spinal anaesthesia. In such cases, general anaesthesia is initiated and subjects are excluded from the research. An anesthesiologist, who was unaware of the group assignment, assessed the sensory and motor blockages. Intraoperative sedation, if required, was administered with Midazolam at a dosage of 1-5 mg. The time required for the patient to be prepared for surgery after the administration of a local anesthesia by intrathecal injection, up to the point when the sensory block reaches its maximum level. MAP, HR and SpO₂ were continually monitored and recorded at 5-minute intervals throughout the whole surgery. In the first 15 minutes, the recordings were taken every 5 minutes, and thereafter every 10 minutes till the end of the intervention. Hypotension is characterized by a reduction of at least 20% in the MAP when contrasted to the initial readings. It's treated by administering 250 mL of crystalloid fluid boluses or five mg of iv ephedrine in case it happened. Bradycardia, which is characterized by a reduction in HR of at least 20% relative to the initial readings, was managed by administering 0.5 mg of IV atropine, if it happened. The length of surgeries was determined as the interval from the initiation of the surgical incision to the completion of closure of the wound.

Postoperative Assessment and Treatments: Following the completion of the surgical procedure, the participants were sent to the post-anaesthesia care unit (PACU). The HR, MAP, and SpO₂ percentage were measured at 15-minute intervals during the patient's stay in the PACU. The length of the sensory block was evaluated by measuring the duration from the beginning of the sensory block to the regression to S3. The duration of motor block resolution

was evaluated as the time interval from the initiation of motor block and the determination of Bromage score 0. The patients were evaluated for their capacity to independently perform tasks such as sitting, standing, walking, and urinating at 15-minute intervals. The occurrence of postoperative urinary retention (POUR) was assessed in the PACU using ultrasonic bladder scanning. Urinary catheterization was scheduled if the bladder capacity above 500 mL and the patient hadn't urinated spontaneously. The patients' transition from the PACU to the ward was evaluated utilizing the Modified-Aldrete-Postanesthesia-Score, often referred to as the Post Anesthesia Recovery (PAR) score. The patients departed from the PACU whenever they attained a modified Aldrete score of 9 or above. The duration of their stay in the PACU was documented. The duration of home readiness was evaluated by measuring the time elapsed from the intrathecal injections of local anesthesia until the subjects met the criteria for discharge. All unfavorable incidents were documented and handled prior discharge, particularly postoperative nausea and vomiting (PONV) and problems with urination. The following day, all participants were contacted by telephone and asked about pain experienced at the site of the puncture, occurrence of headache, usage of analgesics, and any complaints of TNS, that is characterized as discomfort, dyesthesia, or both in the buttocks and/or lower limbs. TNS usually manifests within 24 hours after

spinal anaesthesia, persists for a duration of 2-5 days, and disappears entirely without any long-term consequences.

Statistical Analysis

The data gathered throughout history, together with the results of clinical examinations, laboratory tests, and outcome assessments, were organized, inputted, and evaluated by utilizing Microsoft Excel software. The data had been subsequently imported into the (SPSS version 20.0) program for analysis.

Qualitative data is expressed as numbers and percentages, whereas quantitative variables is expressed as mean \pm standard deviation (SD). The following tests were utilised to determine the significance of discrepancies. The Chi-square test (χ^2) is utilised to measure the variation and relationship between qualitative parameters. Comparisons between independent groups utilising a t-test to analyze quantitative data. P value was set at <0.05 for significant results and <0.001 for high significant result.

Results

The participants' features and surgical data in both groups under study had been similar, with no statistically substantial variations seen in terms of gender, age, BMI, ASA classification, type, and length of operation (P-value > 0.05), (Table 1).

Table 1: Patient's characteristics and surgical data of both groups under the study.

Age(year)						
	Group I			Group II		
Range	21-65			23-62		
Mean \pm SD	33.57 \pm 10.91			33.83 \pm 10.91		
T-Test				0.099		
P-Value				0.922		
Weight (Kg)						
	Group I			Group II		
Range	68-95			69-92		
Mean \pm SD	80.74 \pm 6.73			80.37 \pm 6.72		
T-Test				0.231		
P Value				0.818		
Height (cm)						
	Group I			Group II		
Range	152-179			155-176		
Mean \pm SD	169.54 \pm 4.96			167.63 \pm 6.27		
T-Test				1.416		
P Value				0.161		
Duration of surgery (min)						
	Group I			Group II		
Range	40-59			40-56		
Mean \pm SD	49.89 \pm 6.17			48.29 \pm 4.77		
T-Test				1.214		
P Value				0.229		
Type of surgery						
Hernia	10	30.3	11	33.3	0.07	0.7
Piles	6	18.2	5	15.2	0.11	0.74
Voricoceles	6	12.1	6	12.1	0.0	1.0
Ueretroscope	7	21.2	8	24.2	0.09	0.76
Hysteroscopy	6	18.2	5	15.2	0.11	0.74

Table 2: There is a substantial disparity in the block features between groups

Sex		Group I	Group II	Total
Male	N	25	21	46
	%	71.4%	60.0%	65.7%
Female	N	10	14	24
	%	28.6%	40.0%	34.3%
Total	N	35	35	70
	%	100.0%	100.0%	100.0%
Chi-square	X ²	1.014		
	P-Value	0.314		
ASA		Group I	Group II	Total
I	N	21	19	40
	%	60.0%	54.3%	57.1%
II	N	14	16	30
	%	40.0%	45.7%	42.9%
Total	N	35	35	70
	%	100.0%	100.0%	100.0%
Chi-square	X ²	0.233		
	P-Value	0.629		

There is a substantial disparity in the block features between group (II) and group (I), with group (II) exhibiting a shorter start time, as well as less time of sensory and motor blockage.

Group (II) has a notably shorter duration for regaining the ability to walk and void spontaneously after the sensory and motor blocks, contrasted to group (I), (p<0.001).

Group II had a substantially reduced hospital discharge time contrasted with Group I, (P=0.0013 and P=0.03) respectively (Table 2).

Table 3: There is no statistically substantial variation among the groups under the study at various time intervals

	Group (II), N=35	Group (I), N=35	T	P
Onset time of sensory block (min)				
Mean± SD	2.95±0.08	3.9±0.4	8.8	< 0.001**
Range	2-4	2-5		
Onset time of motor block (min)				
Mean ± SD	4.87±0.7	6.1±1.0	5.4	< 0.001**
Range	4-6	3-8		
Duration of Sensory block (min)				
Mean ± SD	92.4±2.5	193.6±10.9	59.1	<0.001**
Range	83-93	180-210		
Duration of Motor block (min)				
Mean ± SD	113.7±8.8	261.9±29.8	37.8	< 0.001**
Range	90-130	210-310		
Time to walk unassisted				
Mean ± SD	120.7 ± 7.8	301.8 ± 13.9	61.5	<0.001**
Range	120-170	290-340		
Time to void spontaneously				
Mean ± SD	256.4±21.5	345.4±24.5	15.7	<0.001**
Range	225-300	310-390		
Time of readiness to discharge to home				
Mean ± SD	304±20	412±29.5	18.5	0.001**
Range	270-330	390-430		

There is no statistically substantial variation among the groups under the study at various time intervals. No substantial alterations intraoperatively in MAP among both groups

Discussion

Many different local anesthetics have been used in SA. The most popular local anesthetic in day case surgical

patients is lidocaine but high incidence of TNS after intrathecal lidocaine led to the search for an alternative to lidocaine. The present study shows that prilocaine is an alternative to bupivacaine as a short-acting spinal anaesthetic

The solution of 2% hyperbaric prilocaine, contains 6% glucose and has a density ranging from 1.024 to 1.027 g/cm³ at 20°C, corresponding to a mean density value of 1.021 at 37°C, higher than the cerebrospinal fluid density at 37°C. It is well known that baricity of the injected drugs mainly affects their spinal spread. These solutions lead to a faster spread to a higher median dermatomal level with less variation in maximum sensory and motor block in comparison with isobaric solutions.

Spinal anesthesia has become accepted for use in day surgery with the introduction of low-dose local anesthetic techniques and newer shorter acting local anesthetics such as hyperbaric prilocaine 2%,

The purpose of the work was to compare the impact of intrathecal hyperbaric prilocaine 2% and hyperbaric bupivacaine 0.5% in terms of enhancing the safety and effectiveness of anaesthesia, as well as being ready for discharge following ambulatory surgeries

The present work revealed that patient's features and surgical data among both groups under the study are comparable, as regard sex, age, ASA classification, BMI, duration and type of surgeries (P value > 0.05).

The present study revealed that group (II) exhibits a more rapid initiation of motor and sensory blocks, as well as a shorter duration of motor and sensory blockage.

The research conducted by Cannata *et al.* (2016) included a prospective controlled randomised study on individuals who were having endoscopic urological surgeries. The participants were randomized in a random manner to receive either 20 mg of prilocaine (P) or 0.4 ml of fentanyl (equivalent to 20 micro g) by intrathecal administration, with a total volume of 2.4 ml. The second group (B) obtained an equal dose of 2 ml (7.5 mg) of bupivacaine and 0.4 ml (20 micro g) of fentanyl. They showed that the time it took for the sensory block to begin was quicker in the P contrasted to the B group, with an average of 6-7 minutes against 13 minutes, correspondingly. The prilocaine group had a considerably shorter sensory blockage duration, with a mean of 154 minutes (range 97-211), contrasted to the bupivacaine group, which had a mean of 280 minutes (range 233-328). The average period for sensory blockage resolution was less in Group P compared to Group B (133.8 ± 41.4 and 200.4 ± 64.8 min, correspondingly). Despite using lesser dosages in their trial, they administered an additional 20 µg fentanyl to each group, which explains the prolonged length seen in their study.

In addition, the study conducted by Chapron *et al.* (2021), which examined a cohort of 50 individuals who had elective cesarean deliveries with spinal anesthesia. Subjects were administered either 60 mg of intrathecal HP or 12.5 mg of intrathecal HB in a randomized manner. Their results revealed that the prilocaine group had a motor block length of 158 minutes, while the bupivacaine group had a duration of 220 minutes.

In a work conducted by Kaban *et al.* (2014), fifty patients who were having perianal surgeries were randomly allocated to two different groups. In the study, the group that obtained bupivacaine-fentanyl (Group B) was given a total of 1.9 mL containing 7.5 mg of 0.5% HB and 20 µg of

fentanyl. The prilocaine-fentanyl group (Group P) obtained the same volume but with 30 mg of 0.5% HP and 20 µg of fentanyl. The results showed that the duration of sensory and motor blockage was less in Group P contrasted to Group B. Specifically, Group P had an average time of 4.6 ± 1.3 minutes for sensory and motor blocks, while Group B had an average time of 5.9 ± 0.9 minutes ($P = 0.017$). Additionally, Group P had an average time of 13.2 ± 7.5 minutes for sensory and motor blocks, while Group B had an average time of 15.3 ± 6.6 minutes ($P = 0.04$). The length of the motor and sensory blockage was substantially reduced in Group P compared to Group B. Specifically, the duration was 45.7 ± 21.9 min in Group P and 59.7 ± 20.9 min in Group B ($P = 0.024$). Additionally, the duration was 133.8 ± 41.4 min in Group P and 200.4 ± 64.8 min in Group B. The reduced recovery periods seen in these investigations may be attributed to the administration of lower dosages of bupivacaine and prilocaine.

According to the outcomes of the current work by Manassero *et al.* (2017), using 35 mg of prilocaine and 25 µg of fentanyl for day-case intrathecal anaesthesia during anorectal surgeries leads to a fast onset of blockage and declaration of the block. This is in comparison to using 10mg of bupivacaine and 25 µg of fentanyl. The literature suggests that for the lower limbs and lower abdominal procedures that lasts up to 90 minutes, a dosage between 40 and 60 mg of prilocaine is recommended. For minor perianal surgeries, a dosage of 10 mg of 2% hyperbaric prilocaine is suggested.

Also, the research conducted by Camponovo *et al.* (2018) assessed the efficacy of 40 mg and 60 mg HP doses compared to 60 mg regular P in ambulatory surgeries. They found that HP is superior to regular P in ambulatory surgeries, as it leads to quicker recovery of motor blockage and shorter surgical blockage lengths. The average time for sensory blockage onset was 7 ± 4 minutes in the hyperbaric 60 group, 9 ± 5 minutes in the HP 40 group, and 14 ± 7 minutes in the plain 60 group ($P = 0.0004$ and $P = 0.0124$, correspondingly). Additionally, the 40-mg dosage resulted in a shortest period to end of anaesthesia of 25 minutes, compared to 60 and 72 minutes in the hyperbaric 60 mg and plain 60 mg groups. Consequently, the total time required for motor function to fully return after administering 40 mg of 2% HP was 92 minutes, which was faster than the recovery times of 118 and 157 minutes seen in the hyperbaric 60 mg and plain 60 mg groups, respectively, for the decline of motor blockage.

The present research showed that Group II exhibited a substantially reduced duration for ambulation (unassisted walking) and spontaneous voiding compared to Group I. Additionally, the hyperbaric prilocaine group demonstrated a shorter time for home discharge in comparison to the bupivacaine group.

In their study, Camponovo *et al.* (2010) conducted a comparison between the administration of 40 mg and 60 mg dosages of hyperbaric prilocaine and a 60 mg dosage of ordinary prilocaine in the context of ambulatory surgeries. Their findings indicate that HP is more effective than plain P in the ambulatory surgeries. The average time for spontaneous voiding was 277 minutes, which is similar to our own findings of 265 minutes. The reported time for home discharge with 60mg hyperbaric prilocaine was 256 minutes, that is comparable to our own finding of 304 minutes.

In addition, Aguirre *et al.* (2015) discovered that the group treated with 2% prilocaine had an average time for spontaneous voiding of 220 minutes (135-290 minutes) and a discharge time of 334 minutes (± 55 minutes). Similarly, Manassero *et al.* (2017) observed that the time for spontaneous voiding was 306 minutes for P and 405 minutes for B, with a discharge time of 308 minutes after administering 2% HP at a dosage of 60 mg. It is important to note that our recorded discharge time of 304 minutes (\pm SD) is slightly shorter than theirs.

The variations in duration seen in these studies may be attributed to the utilization of distinct methodologies for spinal anaesthesia, varying doses, and discharge criteria.

The present study showed that no statistically substantial disparity was existed among both examined groups as regard the average HR and MAP throughout both the intraoperative and postoperative periods, at various time intervals.

Unlike our investigation, the work conducted by Cannata *et al.* (2016) was a prospective controlled randomised work on individuals who were having endoscopic urological surgeries. The participants were allocated at random to receive either 20 mg of P and 0.4 ml of fentanyl (20 micro g) administered intrathecally in a total volume of 2.4 ml. The second group (B) received an equivalent dosage of 2 ml (7.5 mg) of B and 0.4 ml (20 micro g) of fentanyl. A clinically meaningful drop in systolic arterial pressure of more than 20% occurred in 32% and 73% of the prilocaine and bupivacaine groups, respectively. The inconsistent findings might be attributed to the diverse populations suitable for intrathecal anaesthesia, since Black and colleagues included ASA I, II and III patients of varying ages (18-65 years).

Conclusions

Hyperbaric prilocaine offers several advantages over bupivacaine in ambulatory surgeries. It showed rapid onset, shorter duration of spinal block, and earlier recovery for patients. Considering the potential benefits of more rapid rehabilitation, prilocaine may be a good substitute to bupivacaine in day-case surgeries. We advocate doing broader comparison investigations with a substantial number of participants and a prolonged follow-up period in many research centers to validate our results.

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Conflict of Interest: Nil

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