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## ORIGINAL ARTICLE

# Hyperbaric prilocaine 2%-fentanyl versus hyperbaric bupivacaine 0.5%-fentanyl for Intrathecal injection in perianal surgeries

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### ABSTRACT

**Background:** prilocaine is an intermediate acting local anesthetic that can be used for spinal anesthesia in short duration surgeries. This might help reducing the traffic in postoperative care units (PACU) and reduce the duration of hospital stay. The aim of the study is to compare regression time of spinal anesthesia induced by hyperbaric prilocaine 2% with 20 $\mu$  fentanyl versus hyperbaric bupivacaine 0.5% with 20 $\mu$  fentanyl in perianal surgeries.

**Methods:** Patients were into 2 groups: Control group (Group C: n=40) were given 1.5 ml (7.5 mg) hyperbaric bupivacaine 0.5%+ 20 $\mu$  fentanyl while Group P (n=40 patients) were given 1.5 ml (30mg) hyperbaric prilocaine 2%+20 $\mu$  fentanyl. In both groups, regression of spinal anesthesia (sensory and motor), time to spontaneous micturition, postoperative analgesic behavior, duration of PACU and hospital stay were evaluated.

**Results:** maximum levels of block in both groups were comparable. Sensory and motor block regression times were statistically shorter in Group P. Time to spontaneous voiding and time to unaided walking were shorter in Group P. There were no significant differences in duration of PACU stay between the two groups. Time till home readiness was significantly shorter in Group P. There were no cases of postoperative urinary retention or transient neurologic symptoms.

**Conclusion:** Both mixtures of 30 mg hyperbaric prilocaine 2% plus 20  $\mu$ g fentanyl versus 7.5 mg hyperbaric bupivacaine 0.5% plus fentanyl 20  $\mu$ g are equipotent and safe when used intrathecally in perianal surgeries. Prilocaine is superior to bupivacaine regarding block regression and home readiness.

**Keywords:** Intrathecal, prilocaine, bupivacaine.



### INTRODUCTION

The search for a safe and licensed short-acting local anesthetic agent (with rapid onset of motor and sensory blockade, acceptable time of regression, and minimum adverse effects) to be used for spinal anesthesia has been the target of many studies [1].

Perianal surgeries are day-case surgeries that accounts for up to 10% of general surgeries and are performed under spinal anesthesia [2]. Long-time sensory and motor block with or without urinary retention can cause delayed discharge [3].

Hyperbaric Bupivacaine is used for spinal anesthesia since decades owing to the low incidence of transient neurological symptoms (TNS). However, it is a long-acting local anesthetic (of amide group) with delayed recovery of motor and sensory blockade and higher incidence of postoperative urinary retention compared to short-acting local anesthetics [4].

Prilocaine is also an amide local anesthetic which has an intermediate duration of action. It is available nowadays in the hyperbaric form that can be used for spinal anesthesia in the day case surgeries [5, 6]. It has the advantage of faster recovery than hyperbaric bupivacaine [7].

Using intrathecal fentanyl as an adjuvant to bupivacaine has been the subject of many studies in order to improve the quality of spinal block [8, 9].

The aim of the current study is to compare spinal anesthesia using hyperbaric prilocaine 2%+20 $\mu$  fentanyl to hyperbaric bupivacaine 0.5%+20 $\mu$  fentanyl for perianal surgeries in terms of sensory and motor block regression times. It was hypothesized that intrathecal injection of hyperbaric prilocaine 2%+20 $\mu$  fentanyl would improve the performance of spinal anesthesia compared to hyperbaric bupivacaine 0.5%+20 $\mu$  fentanyl for perianal surgeries.

The primary outcome is to record time to regression of spinal anesthesia (sensory and motor) in both groups.

Secondary outcomes are:

1-To record duration of surgery, time onset of motor block.

2-To assess maximum block level and the time to reach it.

3-To record time to first analgesic demand, time to first spontaneous urination, times for the patient to be able to ambulate independently, and to record occurrence of TNS if occurred.

4-To assess patient satisfaction using patients' satisfaction score.

## METHODS

This is a double-blind, prospective, comparative, randomized controlled clinical trial that was conducted in Zagazig University Hospitals from June to September 2022. Approval was obtained from the ethics committee of faculty of medicine, Institutional Research Board approval (IRB No: 10041/9-5-2022) and the Department of Anesthesia, Pain management and Intensive Care, Zagazig University, Egypt.

Informed written consent was obtained from each patient. Eighty patients (ASA status I-II) of both

sexes were included. Exclusion criteria included allergy to the studied drugs, patients with contraindications to spinal anesthesia, patients with advanced cardiac, renal, or hepatic diseases. Patients were randomized using closed envelopes in two groups: Control group (Group C) given bupivacaine (Marcaine, heavy hyperbaric bupivacaine 5mg/ mL 0.5%, glucose 8%, Astra Zeneca, Sweden) and the comparative group (Group P) given prilocaine (Takipril, hyperbaric Prilocaine 2% 20mg/ml, glucose 6%, Sintetica SA, Switzerland). (Group C: n=40 patients) were given 1.5 ml (7.5 mg) hyperbaric bupivacaine+ 20 $\mu$  fentanyl while Group P (n=40 patients) were given 1.5 ml (30mg) hyperbaric prilocaine+20 $\mu$  fentanyl.

Baseline mean arterial blood pressure (MAP), heart rate (HR) and oxygen saturation (SpO<sub>2</sub>) were measured and recorded. All patients were asked to void before surgery. After inserting an 18 G intravenous cannula, patients were preloaded with 7 ml/kg Ringer's solution.

Intrathecal anesthesia was performed under complete sterile conditions in the sitting position between lumbar vertebrae L3-L4 using a 25 G Quincke needle and midline approach (needle bevel directed laterally). Free flow of cerebrospinal fluid was assured before injecting the study drug. Duration of injection was around 10 seconds. Patients were kept in sitting position for 3 minutes before being placed in lithotomy position and were kept in this position during surgery. Nasal cannula for supplemental oxygen was provided. Midazolam (1-5mg) was planned to be used for sedation if needed and would be recorded.

Neurological assessment of intrathecal block:

The sensory and motor blockades were evaluated by an anesthesiologist who blinded to the study protocol.

A.Sensory block has been assessed using pinprick test (via a 25 gauge hypodermic needle) at the described anatomical sites every 2 minute after intrathecal injection of local anesthetic mixture until the maximum block is achieved and time and level were recorded. Testing for sensory block regression was performed every 10 minutes from intrathecal injection. The sensory block regression time was defined as the time from intrathecal injection until sensation will be regained at S1 dermatome and time was recorded.

The described anatomical sites for sensory examination when patient is in supine position are [10]:

Thoracic spinal nerves

T4: upper chest (area of nipples)

T5-T7: mid-chest

T8, T9: upper abdomen

T10: abdomen (area of belly button)

T11-T12: lower abdomen

Lumbar spinal nerves

L1: lower back, hips, groin

L2-L3: lower back, front and inside of thigh

L4: lower back, front of thigh and calf, area of knee, inside of ankle

L5: lower back, front and outside of calf, top and bottom of foot, first four toes

Sacral spinal nerves

S1: lower back, back of thigh, back and inside of calf, last toe

S2: buttocks, genitals, back of thigh and calf

S3: buttocks, genitals

S4-S5: buttocks

B. Motor block was assessed using Bromage score [11] every 3 minutes after intrathecal injection of local anesthetic mixture until the block reaches its maximum level. Bromage score is graded as follows: (0=no motor block and can freely moves legs and feet, 1=can flex the knee with free feet movement, but can't raise the leg, 2= can move feet only, 3= unable to move feet or knee). The onset of motor blockade was defined as the time from intrathecal injection of local anesthetic until a grade 3 Bromage score was achieved. After 30 minutes patients were evaluated for motor regression every 5 minutes. Time of regression of motor block was defined as the time from intrathecal injection until Bromage score is 0 and it was recorded.

The block was considered successful block if both sensory block reached dermatome of L1, and a Bromage score of 3 was achieved within 20 min following the injection.

If no sensory or motor block after 20 min from the spinal injection of local anesthetic, this was considered as failed block, patients were planned to be excluded from the study and general anesthesia would be started.

Intraoperative monitoring:

Patients were monitored using electrocardiography, pulse oximetry and non-invasive blood pressure measurement. MAP, HR, and SpO<sub>2</sub> were monitored throughout the operation and were recorded every 5min in the 1st 15 min, then every 10 min till the end of surgery. Hypotension (MAP decreased  $\geq$  20% compared to the baseline values) was planned to be treated with 250 mL crystalloid fluid boluses or 5 mg

IV ephedrine. Bradycardia (HR decreased  $\geq$  20% compared to baseline values) and was planned to be treated with 0.5 mg IV atropine.

The duration of surgery was considered as the time between the surgical incision and wound closure.

Postoperative management

At the end of surgery, patients were transferred to postoperative care unit (PACU) and MAP, HR, and SpO<sub>2</sub> were recorded every 15 min intervals.

Pain degree was assessed using a 10 point visual analogue scale [12] (VAS) (where 0= no pain, 10= worst pain ever). Time of first analgesic demand was recorded. Postoperative analgesia was given as paracetamol infusion 1g/8hours (PERFALGAN 10 mg/ml) with the first dose started on admission to PACU. If VAS score become  $\geq$ 3, 30 mg ketorolac was given as complementary analgesia and recorded. Postoperatively, patients were asked to urinate on admission to PACU and every 15 minutes after. Time to first urination was recorded. Patients, who were not capable of spontaneous urination for more than 30 min of admission to PACU, were assessed with ultrasonography to evaluate bladder volume. Urinary catheter was applied if bladder volume was  $\geq$ 400 ml.

Patients were assessed and encouraged to sit, stand, and/or walk unassisted and the time to first unassisted walking was recorded.

Patient readiness to discharge from PACU was evaluated using Post Anesthesia Recovery (PAR) score [13] and the time of PACU stay was recorded. The assessment was performed on admission and every 15 minutes for the first 90 minutes, then, every hour until a score of 8 is reached. Evaluation includes:

1) Activity:

Able to move 4 limbs = 2

Able to move 2 limbs = 1

Able to move 0 limbs = 0

2) Respiration:

Able to take deep breath and cough = 2

Dyspnea, shallow or limited breathing = 1

Apnea, obstructed airway = 0

3) Circulation:

Blood pressure  $\pm$  20mm Hg of pre-anesthesia value = 2

Blood pressure  $\pm$  20 - 49mm Hg of pre-anesthesia value = 1

Blood pressure  $\pm$  50mm Hg of pre-anesthesia level = 0

4) Consciousness:

Fully awake =2

Arousable on calling = 1  
 Non-responsive = 0  
 5) Oxygen saturation:  
 More than 92% on room air = 2  
 Requires supplemental oxygen to maintain O2 saturation > 90% = 1  
 Less than 90% even with O2 supplement = 0  
 Since the complaints of transient neurologic symptoms (TNS) (in the form of pain in the buttocks and/or legs) might occur within 24 hours of spinal anesthesia, lasts 2–5 days, and expected to completely resolve without sequelae [14]; thereby, patients were evaluated with daily telephone calls for the first three postoperative days and symptoms were recorded if occurred.  
 Patient satisfaction was evaluated using a satisfaction scale as follows: (1= bad, 2=not satisfied, 3=have no idea, 4=satisfied, 5=very satisfied)  
 Sample size:  
 The power of the current study will be prospectively performed using G\*POWER program [version 3.1.9.2, (Heinrich Heine; Universitat Dusseldorf; Germany)]. Before calculating sample size, a pilot study including 10 patients in each group was conducted to detect time of regression of block to S1 (TS1) dermatome which is considered the primary

outcome. TS1 in the control group (Group C) was 110±4 min while TS1 in Group P was 72±7min as expressed by mean ±SD. Thereafter, sample size was calculated and showed that 38 patients are needed in each group in order to achieve an alpha error level of 0.05, with 80% power and 95% confidence interval. Allowing a 5% drop out rate, the final sample size needed in each group is 40 patients. Significant differences will be considered when P value < 0.5.

**Statistical analysis:**

Statistical analysis was done using SPSS software version 15.0. Nominal and qualitative data were represented as number of total. Parametric data were represented as mean ± standard deviation (SD). Repeated measure ANOVA, independent t-test, and chi-square test were use when appropriate. A p-value < 0.05 was considered as statistically significant and p-value < 0.001 as statistically highly significant.

**RESULTS**

Data in Table 1 showed that there were no significant differences in demographic data of the patients, duration and type of perianal surgeries between the two groups of the study. Both drugs achieved a quality of sensory and motor blocks that allowed adequate time for the surgical procedures.

**Table 1: Demographic data of the patients, duration and type of perianal surgeries:**

Variable	Group C (n=40)	Group P (n=40)	P value
Age (yr.)	35.7±3.3	34.2±3.9	0.061
BMI (kg/m <sup>2</sup> )	37.3±1.4	36.1±2.1	0.618
Sex (Male/Female) (n)	27/13	29/11	0.625
ASA classification I/II (n)	31/9	26/14	0.217
• Duration of surgery (min):	29 ± 7	28 ±10	0.606
• Type of perianal surgery:			
Fistula (n)	7 (17.5%)	5 (12.5%)	0.752
Haemorrhoids (n)	23 (57.5%)	26 (65%)	
Fissure	10 (25%)	9 (22.5%)	

p value was considered statistically significant when <0.05.  
 Data were represented as mean ±SD or number (percent).  
 Chi-square was used to compare paired data  
 BMI: body mass index.  
 ASA: American Society of Anesthesiologists.

As shown in Table 2, the maximum levels of block in both groups were comparable. The duration needed for maximum sensory and motor block and the time until sensory and motor block regression occurred were statistically shorter in prilocaine-fentanyl group (Group P) as compared to

bupivacaine-fentanyl group (Group C). The time needed until the patient can be able to walk without assistance was highly significantly shorter in Group P than Group C. patients were also more rapidly capable of spontaneous voiding in Group p than in Group C. The number of patients who needed

intraoperative midazolam, and those who needed postoperative ketorolac, as well as the time for need of ketorolac were comparable between both groups. There were no significant differences in duration of PACU stay between the two groups, however, time till home readiness was significantly shorter with prilocaine (Group P) as compared to bupivacaine (Group C).

As shown in Table 3, the changes in heart rate and mean arterial blood pressure showed no statistical significant differences between the two groups. However, when compared to basal data, there were significant decrease in heart rate and blood pressure in both groups between minute 10 to minute 35 following intrathecal injection. Those patients did not hit the margin of bradycardia or hypotension that

necessitates medical interference. Beyond and after these times, there were neither significant changes in heart rate nor blood pressure in both groups as compared to basal readings.

Oxygen saturation showed no significant differences between groups and also when compared to basal data of the patients. None of the patients in the current study developed postoperative transient neurologic symptoms TNS in the next three days after surgery during which phone calls follow up was performed. Failed spinal did not also occur in this study. Urinary retention was not recorded in any case in the study.

Patient satisfaction showed no significant differences between both groups (Table 4).

**Table 2: Performance of intrathecal block, duration of PACU stay, and time to home readiness:**

Variable		Group C (n=40)	Group P (n=40)	t-test	P value
<b>Sensory</b>	Maximum level of block	L1 (T11-L1)	L1 (T12-L1)	-	-
	Time to reach maximum level (min)	5.5 ± 0.38	3.9 ± 0.11**	30.376	<0.0001
	Time to block regression (min)	167.3 ± 9.1	89.8 ± 2.6**	51.791	<0.0001
<b>Motor</b>	Time of onset of motor block (min)	5.63 ± 2.4	3.75 ± 1.8*	3.963	P=0.002
	Time to block regression (min)	197.9 ± 4.1	103.6 ± 7.6**	69.065	<0.0001
	Time to independent ambulation (min)	241 ± 5.2	125 ± 3.1**	122.02	<0.0001
<b>Autonomic</b>	Time to spontaneous voiding (min)	253.4 ± 11.6	174.5±16.8**	24.442	<0.0001
<b>Need for intraoperative midazolam (n)</b>		7	9	-	0.5766
<b>Need for postoperative ketorolac (n)</b>		14	19	-	0.2561
<b>Time to need ketorolac in ward (min)</b>		350.6 ± 17.9	343.8 ± 19.8	1.611	0.111
<b>Duration of PACU stay</b>		25.2 ± 1.2	24.8±1.1	1.166	0.247
<b>Time till home readiness</b>		325.7 ± 5.9	226.1 ± 7.6**	65.472	<0.0001

Data were represented as mean ±SD, median (range), or number p value was considered statistically significant when <0.05 and highly significant when P<.0001.

\* Statistically significant as compared to other group.

\*\* Statistically highly significant as compared to other group.

PACU: postanesthesia care unit

**Table 3: Heart rate (HR), and mean arterial blood pressure (MAP) in the two groups during different times of the study:**

	HR (beat/min)			MAP (mmHg)		
	Group C (n=40)	Group P (n=40)	P value	Group C (n=40)	Group P (n=40)	P value
<b>Baseline</b>	82.9±4.6	83.2±3.9	0.754	92.3±1.4	92.8±2.8	0.288
<b>Following intrathecal injection:</b>						

<b>5 min</b>	82.2±4.8	82.9±4.4	0.499	92.1±1.8	91.8±2.6	0.550
<b>10 min</b>	82.2±3.9	82.4±4.1	0.824	90.8±0.9**	90.3±1.1**	0.029
<b>15 min</b>	81.4±3.1	81.2±3.6*	0.791	91.1±1.3**	90.9±1.5**	0.526
<b>25 min</b>	81.2±2.6*	81.1±3.1*	0.876	91.2±1.1**	91.3±1.3**	0.711
<b>35 min</b>	80.8±3.2*	81.9±2.6	0.096	91.3±1.1**	91.5±1.5*	0.499
<b>45 min</b>	81.8±2.9	81.7±3.1	0.882	91.8±1.3	91.9±1.1	0.711
<b>55 min</b>	82.0±2.7	82.8±3.6	0.289	92.6±0.8	92.7±1.1	0.167
<b>65 min</b>	82.6±3.7	83.1±3.4	0.531	92.2±1.3	92.2±1.1	0.067

Data were represented as mean ±SD

*p* value was considered statistically significant when <0.05 and highly significant when *P*<.0001.

\* Statistically significant and \*\* statistically highly significant as compared to basal data.

*p* value shown in the table shows the statistical analysis of significance between the two groups.

**Table 4: Patients' satisfaction in both groups of the study:**

Degree of satisfaction	Bad	Not satisfied	Have no idea	Satisfied	Very satisfied	P value
<b>Group C</b>	none	none	3	34	3	0.515
<b>Group P</b>	none	none	1	37	2	

Data were represented as numbers.

*p* value was considered statistically significant when <0.05.

### DISCUSSION

Prilocaine isn't a new drug since the first publications reporting its intrathecal use appeared in 1965 [15]. Few years later, it has been withdrawn from the market because of problems in its stability related to the manufacturing process [16, 17]. In 2005, 2% prilocaine hydrochloride reappeared as both plain and hyperbaric preparation.

In the present study, intrathecal injection of 30mg hyperbaric prilocaine or 7.5mg hyperbaric bupivacaine to perform saddle block (with 20µfentanyl as an adjuvant), were enough to provide equivalent quality of sensory and motor blocks that lasted through out the whole time of surgery. Prilocaine showed more rapid onset, faster regression time, faster time to first spontaneous voiding, earlier independent mobilization of the patients, and earlier home readiness to discharge. These results came in accordance with the results obtained by Ratsch et al. [18] which was the first study to compare between the two drugs in lower limb surgeries. Black et al. [19] added intrathecal 20 µg fentanyl and also agreed to those results. Moreover, Kaban et al. [20] in their study in which patients were scheduled for perianal surgeries, compared 30 mg hyperbaric prilocaine 2% plus 20 µg fentanyl versus 7.5 mg hyperbaric bupivacaine 0.5% plus fentanyl 20 µg (which are the same doses used in the current study). Their results were concomitant to those obtained in the present study regarding block regression, unassisted ambulation and home readiness.

In their study, Black et al. [19] defined the recovery of intrathecal block as the time to sensory block regression to the L4 dermatome. They thought that it is unreasonable to use S3 as a defining dermatome to sensory block regression because some patients were ambulating well, with a sensory block level higher than S2. On the other hand, Kaban et al. [20] used dermatome S3 for the same definition as they thought that perianal surgeries are associated with high risk of urinary retention, thereby, S3 might be a better choice than L4. In the current study, S1 dermatome was used to define regression of sensory block being easy approach and less annoying to the patients than other sacral dermatomes and urinary bladder retention was monitored using ultrasound.

To achieve successful saddle block, patients should be kept sitting 3-10 min after intrathecal injection [21]. The level of block in the present study was L1 in both groups of the study after keeping the patients in sitting position for 3 minutes before being placed in lithotomy position. Gebhardt et al. [22] reached L4 and their patients sat for 10 minutes after intrathecal injection of 30mg prilocaine. The study by Kaban et al. [20] reached the T9 after keeping their patients sitting for only 2 minutes which is not needed in our opinion during perianal surgery.

It is well known that, the capability for spontaneous micturition is the last function to recover after resolution of spinal anesthesia (not before S3 dermatome regression) [23]. In the current study, no cases of urinary retention were encountered in both groups of the study, while in the study by Kaban et al. [20] one case occurred in each group. However,

other studies also showed no cases of urinary retention as well [24, 25]. The study by Kaban et al. [20] had the shortest duration for urinary voiding with prilocaine compared to the current study and the study by Gebhardt et al. [22] ( $152 \pm 104$  vs  $174.5 \pm 16.8$  and  $211 \pm 33$  respectively). This might be explained by that the duration of spinal anesthesia is inversely related to intrathecal spread of the same anesthetic dose [26] which is again related to the duration of sitting after intrathecal injection.

None of the patients in the current study had TNS in the first three postoperative days which come in accordance with a survey that included 5,000 cases of intrathecal anesthesia using 1mg/kg prilocaine 2% where no case of TNS were reported [27]. Hampl et al. [28] compared prilocaine to lidocaine and bupivacaine for the incidence of TNS (30 patients in each group). Nine patients in lidocaine group developed TNS compared to 1 patient in prilocaine group and none in bupivacaine. Other studies also recommended prilocaine due to its low incidence of TNS [1, 29].

## CONCLUSION

Both mixtures of 30 mg hyperbaric prilocaine 2% plus 20 µg fentanyl versus 7.5 mg hyperbaric bupivacaine 0.5% plus fentanyl 20 µg are equipotent and safe when used intrathecally in perianal surgeries. Prilocaine is superior to bupivacaine regarding block regression and home readiness.

**Conflict of interest:** None.

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