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Prilocaine Fentanyl versus Bupivacaine-Fentanyl in Subarachnoid Anesthesia for Lower Abdominal Surgeries

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ABSTRACT

Introduction and aim: Spinal anesthesia is a commonly and conveniently used for lower abdominal surgeries. The research on different drugs for spinal anesthesia is still ongoing to find out the standard and ideal drug. The current work aimed to compare efficacy and safety profile between prilocaine versus bupivacaine in spinal anesthesia for lower abdominal surgeries.

Methodology: Ninety patients scheduled for elective lower abdominal surgeries were included and randomly assigned to one of two equal groups. All patients were preoperatively assessed by clinical and laboratory investigations. Hemodynamic monitoring was assessed intraoperatively every 5 minutes. Sensory and motor blockade and postoperative pain and time for first analgesic request were recorded. The primary outcomes were efficacy of block (onset of sensory block, onset and intensity of motor block and duration of action). The Secondary outcomes were hemodynamic changes, post-operative analgesia, and patient satisfaction.

Results: The time for the onset of the highest sensory block was shorter among P than B group (5.91±1.84 vs 8.26±1.98 minutes, respectively). Similarly, the time for the onset of the highest motor block level and PACU length of stay (minutes) was significantly shorter among P than B groups. The postoperative pain score was reduced in P than B group. The time for first analgesic request was shorter among P than B group (192.44±11.21 vs 235.77±29.44 minutes). Sensory regression to L1 was shorter among P than B groups. The motor regarrisons at one hour showed significant difference. The postoperative systolic blood pressure was significantly reduced in B than P group, with increased hypotension in B than P group (17.8% vs 4.4%, respectively). On the other side, no significant difference was observed for other complications or satisfaction score.

Conclusion: The combination of prilocaine and fentanyl is superior than bupivacaine and fentanyl for subarachnoid anesthesia in lower abdominal surgery.

Keywords: Prilocaine; Bupivacaine; Fentanyl; Lower Abdominal Surgery.



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INTRODUCTION

Spinal anesthesia (SA) is the most convenient anesthetic technique that offers many advantages over general anesthesia, including reduced stress response and improved post-operative pain relief. Spinal anesthesia is the most commonly used anesthetic technique for lower abdominal surgeries because it is reliable and cost effective. Also, it can provide effective analgesia, muscle relaxation, and prolonged post-operative analgesia^(1,2).

The research on different drugs for spinal anesthesia is still ongoing to find out an ideal drug which can provide adequate surgical anesthesia, pain control, and safety profile with minimal side effects⁽³⁾.

Local anesthetics are weak bases that usually carry a positive charge at the tertiary amine group at physiological pH. The nature of the intermediate chain is the basis of the classification of local anesthetics as either esters or amides. So local anesthetics may therefore be classified as aminoester or aminoamide compounds. The amino-ester local anesthetics are: procaine, chlorprocaine and tetracaine. The amino- amides consist of lidocaine, mepivacaine, prilocaine, bupivacaine, and etidocaine^(4,5).

Bupivacaine, a local anesthetic with low risk of transient neurological symptoms (TNS) with relatively long duration of action. It is a derivative of mepivacaine, and is more potent and longer acting than lidocaine. However, high doses of bupivacaine may lead to cardiovascular depression and arrhythmias, hypotension, cardiac arrest, bradycardia, CNS stimulation and/or depression, inhibition of platelet aggregation, delayed gastric emptying, hepato-toxicity, and hypersensitivity reactions⁽⁶⁾.

Prilocaine has a relatively rapid onset of action and moderate duration of action compared to other local anesthetics. It has a rapid metabolism and redistribution in comparison to other amide local anesthetics and it undergoes more rapid hepatic metabolism than other amide local anesthetics. Prilocaine prevents the generation and conduction of nerve impulses by blocking Na⁺ channels in nerve membranes^(7,8).

When the Na⁺ channel is blocked, the large transient increase in permeability to Na⁺ produced by depolarization of excitable membranes cannot occur. Methemoglobinemia may be induced or exacerbated with high doses in concentration of prilocaine of 8 mg/kg or greater. Myocardial depression, hypotension, and sometimes hypertension, bradycardia, central nervous system effects of nervousness, dizziness, blurred vision, anxiety, restlessness, and tremors may occur as the plasma level rise⁽⁹⁾. The use of fentanyl as an adjuvant with both prilocaine or bupivacaine in ambulatory surgeries has led to development of what was called "low dose spinal" technique which involves usage of low doses of local anesthetic agents with the addition of fentanyl, which has been shown to increase sensory block without increasing motor block⁽¹⁰⁾.

THE AIM OF THE WORK

The aim of this study was to compare efficacy and safety profile between intrathecal prilocaine plus fentanyl versus bupivacaine plus fentanyl in spinal anesthesia for patients undergoing lower abdominal surgeries.

PATIENTS AND METHODS

The current work was designed as a prospective randomized double-blind comparative clinical study. It had been completed at the department of Anesthesiology and Intensive Care (Al-Azhar University hospital (Al-Hussien hospital), Cairo, Egypt, between the first of April to the end of September 2021. Ninety patients scheduled for elective lower abdominal surgeries, of both sexes, with ASA physical status I and II, aged 21-45 years, signed an informed consent and included in the study. The study protocol was accepted by the Research Ethics Committee, Faculty of Medicine (Al-Azhar University in Cairo).

Patient was excluded from the current work if he/she refused to participate or refused regional anesthesia, had vertebral column deformities, had previous cesarean delivery, had skin infection at the site of block area, had history of hypersensitivity to amides local anaesthetics, his/her laboratory investigations revealed abnormal coagulation profile or he/she was an obese (BMI >30 kg/m²).

Pre-operative assessment was performed at the anesthesia clinic by history taking, clinical examination, and laboratory investigations (e.g., complete blood count, coagulation profile, liver and kidney function tests). Then, patient was counseled and reassured, the procedure was explained and an informed consent had been signed. Patients were instructed to fast eight hours fasting from solids and two hours from bulb free fluids before surgery. The Ninety patients were randomly categorized into two equal groups using computer generated randomization in closed sealed envelopes (45 patients in each group). The first group was Group (P) (prilocaine group), where patients in this group received intrathecal injection of 4 ml prilocaine (Takipril 20mg/ml ampoule, Sintetica, London, UK) plus 30 µg fentanyl (Fentanyl 0.1mg/ml, Sunny Medical, Cairo, Egypt). The second group was the B group (bupivacaine group), where patients received intrathecal injection of 4 mL bupivacaine (Sunnypivacaine 20mg/4ml ampoule, Sunny Medical, Cairo, Egypt) 0.5% plus 30 µg fentanyl. The same volume of injection was used for each group.

Intraoperative management:

After arrival of the patient to operating room without premedication, an intravenous line (IV) was secured through insertion of IV cannula with fluid preload of 10ml/kg of lactated ringer solution over (10 – 20) minutes. Patients were monitored by five leads electrocardiogram (ECG) tracing, non-invasive arterial blood pressure, and pulse oximetry.

Anesthesia technique: After placement of patient in the sitting position, area was sterilized with povidone iodine solution and sterile drapes was applied. The selected intervertebral space (L₂₋₃) was punctured using spinal 25-gauge needle (Cutting TIP, B BRUNE). After proper placement of spinal needle, and obtaining free, pure cerebrospinal fluid (CSF), the anesthetic solution was injected into subarachnoid space. All study drugs were given within 60 seconds by the same anesthesiologist. Another anesthesiologist blinded to studied drugs document the results of the studied patients

The patient blood pressure (systolic, diastolic and mean arterial blood pressure), heart rate and oxygen saturation were closely monitored pre- and post-spinal injection of anesthetic drug every 5 minutes for 20 minutes then every 15 minutes, in cases with hypotension (decrease in Bp more than 20% from base monitoring) Ephedrine (0.25 mg/kg) iv was given and Atropine (0.01 mg/kg) iv was given in patients with bradycardia (pulse <60 b/m). Sensation was checked by ice cube test and sensory block level was recorded every three minutes to detect onset time and level of stabilization (T10) for three consecutive tests. Onset of motor block were assessed and intensity of block using the Bromage scoring system along with the

sensory block assessment and regression time ⁽¹¹⁾.

Post-operative follow-up was continued in the post anesthesia care unit (PACU) every ten minutes until the patient was discharged. For Patients to be discharged from PACU, they be hemodynamically stable, they should respond to verbal stimulation, be able to answer questions appropriately and to be oriented to their surroundings. They should be able to move all four limbs. Post-operative pain assessment was completed by visual analog scale (VAS). Time for first analgesic request was recorded and if VAS \geq 4, 30 mg Ketorolac was administered as a rescue analgesic. Complications as post-operative nausea, vomiting and pruritis were recorded. Both patient and anesthetist were asked about their satisfaction. The satisfaction was of five grades (very dissatisfied, slightly dissatisfied, neutral, satisfied and highly satisfied).

Study outcomes:

Primary outcomes were efficacy of block (onset of sensory block, onset and intensity of motor block and duration of action).

Secondary outcomes were hemodynamic changes, post-operative analgesia, global patient satisfaction score and incidence of complications (nausea, vomiting and pruritis).

Statistical Analysis: Data entry and statistical analyses was performed using SPSS (statistical package of social sciences) version 21 (SPSS Inc., Chicago, IL, USA). Continuous normally distributed data was expressed in mean and standard deviation. The quantitative data was examined by Kolmogorov Smirnov test for normality of data. Independent sample t test (student t test) will be used for continuous normally distributed data. Analysis of variance (ANOVA) test was used for multivariate continuous normally distributed data. Statistical significance was considered when probability (P) value is less than or equal to 0.05.

Sample size calculation: The number of patients enrolled in the study was determined after an initial power analysis, with anticipated block behavior based upon prior clinical experience. Using a log rank test, it was determined that 23 subjects in each arm of the group would provide 80% power at a two-tailed type-1 error of 0.05 to detect a

difference in median time to sensory block regression of 1.0 h in one group, vs 2.5 h in the other ⁽⁹⁾. To allow more powerful analysis and prevention of possible drop-outs or other problems, the numbers were rounded up to 45 in each group.

RESULTS

This study completed with participation of 90 patients who underwent elective lower abdominal surgeries at Al-Azhar University hospital (Al-Hussien hospital), Cairo, Egypt. They were divided randomly into two equal groups, one for prilocaine-fentanyl (P) and the second for bupivacaine- fentanyl (B). Both groups were comparable as regard patient age, gender distribution, body mass index, and ASA classification (Table 1).

Regarding the highest block levels, one patient (2.2%) in P group reached T10 levels, while none in the B group reached these levels. The highest level in B group was T9, reported in two patients (4.4%). There was no significant difference between P and B groups regarding the highest level obtained. On the other side, the time for the onset of the highest sensory block was significantly shorter among P than B group (5.91 \pm 1.84 vs 8.26 \pm 1.98 minutes, respectively). Similarly, the time for the onset of the highest motor block level and PACU length of stay (minutes) was significantly shorter among P than B groups (Table 2).

Regarding postoperative data, pain score was reduced in P than B group (1.62 \pm 1.03 vs 2.07 \pm 1.60, respectively). However, the difference did not reach the statistical significance. On the other side, the time for first analgesic request was significantly shorter among P than B group (192.44 \pm 11.21 vs 235.77 \pm 29.44 minutes, respectively). Sensory regression to L1 also was significantly shorter among P than B groups. The motor regarrisons at one hour showed significant difference; while at 2 hours, the difference become non-significant (Table 3). The postoperative systolic blood pressure was significantly reduced in B than P group, with increased hypotension in B than P group (17.8% vs 4.4%, respectively). On the other side, no significant difference was observed for other complications or satisfaction score (Table 4).

Table (1): Demographic characteristics of study population

		Group (P) (n=45)	Group (B) (n=45)	Total	Test	P value
Age		33.48 \pm 7.61; 21-45	33.37 \pm 7.52; 23-45	33.43 \pm 7.52; 21-45	0.07	0.94
Gender	Male	27(60.0%)	32 (71.1%)	59(65.6%)	1.32	0.26
	Female	18(40.0%)	13(28.9%)	31(34.4%)		
BMI Kg/m ²		22.88 \pm 2.28	23.08 \pm 2.40	22.98 \pm 2.33	0.40	0.68
ASA class	I	27(60.0%)	25 (55.6%)	52(57.8%)	0.18	0.67
	II	18(40.0%)	20 (44.4%)	38(42.2%)		

Table (2): Highest block level obtained

		Group (P) (n=45)	Group (B) (n=45)	TOTAL	Test	P value
Highest level obtained	T3	6 (13.3%)	19(42.2%)	25(27.8%)	12.05	0.10
	T4	10(22.2%)	10 (22.2%)	20(22.2%)		
	T5	9(20.0%)	6(13.3%)	15(16.7%)		
	T6	8(17.8%)	5(11.1%)	13(14.4%)		
	T7	2(4.4%)	2(4.4%)	4(4.4%)		
	T8	3(6.7%)	1(2.2%)	4(4.4%)		
	T9	6(13.3%)	2(4.4%)	8(8.9%)		
	T10	1(2.2%)	0(0.0%)	1(1.1%)		
Onset of blockade	Onset of highest sensory level (min)	5.91 \pm 1.84	8.26 \pm 1.98	7.08 \pm 2.24	5.83	<0.001*
	Onset of highest motor level (min)	10.0 \pm 1.61	12.24 \pm 1.76	11.12 \pm 2.02	6.31	0.001*
	PACU length of stay (min)	58.22 \pm 12.43	91.55 \pm 13.04	74.89 \pm 21.01	12.40	<0.001*

Table (3): Postoperative data among studied groups

			Group (P)	Group (B)	Total	Test	P value
VAS Score			1.62±1.03	2.07±1.60	1.84±1.35	1.57	0.12
Time for first analgesic request (min)			192.44±11.21	235.77±29.44	214.11±31.07; 180-290	9.22	<0.001*
Sensory regressing to L1 (min)			43.33±11.48	48.57±12.94	45.95±12.44; 25-70	2.03	0.045*
Motor regression	Bromage score at 1 hour	Zero	34(75.6%)	0(0.0%)	34(37.8%)	54.90	<0.001*
		1	6(13.3%)	26(57.8%)	32 (35.6%)		
		2	3(6.7%)	14(31.1%)	17(18.9%)		
		3	2(4.4%)	5(11.1%)	7(7.8%)		
	Bromage score at 2 hours	Zero	37(82.2%)	35(77.8%)	72(80.0%)	1.81	0.61
		1	5(11.1%)	6(13.3%)	11(12.2%)		
		2	2(4.4%)	4(8.9%)	6(6.7%)		
		3	1(2.2%)	0(0.0%)	1(1.1%)		

Table (4): Postoperative complications and satisfaction score among studied groups

		Group (P)	Group (B)	Total	Test	P value
PO complications	Baseline systolic BP (mmHg)	117.78±8.43	120.44±8.64	119.11±8.59	1.48	0.14
	Postoperative systolic BP (mmHg)	94.33±7.51#	90.22±6.65#	92.28±7.35#	2.75	0.007*
	Hypotension	2(4.4%)	8(17.8%)	10(11.1%)	4.05	0.044*
	Bradycardia	2(4.4%)	3(6.7%)	5(5.6%)	0.21	0.64
	Nausea and vomiting	5(11.1%)	6(13.3%)	11(12.2%)	0.10	0.74
	Pruritis	6 (13.3%)	8(17.8%)	14 (15.6%)	0.33	0.56
Satisfaction Score	Scale (1)	0(0.0%)	0(0.0%)	0(0.0%)	0.30	0.58
	Scale (2)	0(0.0%)	0(0.0%)	0(0.0%)		
	Scale (3)	0(0.0%)	0(0.0%)	0(0.0%)		
	Scale (4)	38(84.4%)	36 (80.0%)	74(82.2%)		
	Scale (5)	7(15.6%)	9 (20.0%)	16(17.8%)		

#=Significant reduction of postoperative systolic blood pressure when compared to baseline values

DISCUSSION

The research on different drugs for spinal anesthesia is still ongoing to find out an ideal drug which can provide adequate surgical anesthesia, pain control, and safety profile with minimal side effects (3). In our study, we compared intrathecal prilocaine and bupivacaine with addition of fentanyl to them regarding their safety and efficacy profile for patients undergoing lower abdominal surgeries. Ninety (90) patients were randomly classified into two equal groups (45 patients in each group). Group (P) (prilocaine group) patients in this group received intrathecal injection of 4 ml prilocaine plus 30 µg fentanyl 3.5 ml was injected. Group (B) (bupivacaine group) in which patients received intrathecal injection of 4 mL bupivacaine 0.5% plus 30 µg fentanyl 3.5 ml was injected.

Results of the current work are in line with the study of **Demir et al.** (6) who reported that, bupivacaine, a local anesthetic with low risk of transient neurological symptoms (TNS) with relatively long duration of action. It is a derivative of mepivacaine and is more potent and longer acting than lidocaine. However, high doses of bupivacaine may lead to cardiovascular depression and arrhythmias, hypotension, cardiac arrest, bradycardia, CNS stimulation and/or depression, inhibition of platelet aggregation, delayed gastric emptying, hepatotoxicity, and hypersensitivity reactions. In addition, **Sharan et al.** (7) reported that, prilocaine has a relatively rapid onset of action and moderate duration of action compared to other local anesthetics. It has a rapid metabolism and redistribution in comparison to other amide local anesthetics and it undergoes more rapid hepatic metabolism than other amide local anesthetics. Prilocaine prevents the generation and conduction of nerve impulses by blocking Na+ channels in nerve membranes. These results are in line with the current work. **Akdeniz et al.** (9) reported that, methemoglobinemia may be induced or exacerbated with high doses in concentration of prilocaine of 8 mg/kg or greater. Myocardial depression, hypotension, and sometimes

hypertension, bradycardia, central nervous system effects of nervousness, dizziness, blurred vision, anxiety, restlessness, and tremors may occur as the plasma level rise.

The use of fentanyl as an adjuvant with both prilocaine or bupivacaine in ambulatory surgeries has led to development of what was called "low dose spinal" technique which involves usage of low doses of local anesthetic agents with the addition of fentanyl, which has been shown to increase sensory block without increasing motor block (10). The median peak of sensory block highest was T4 in group P compared to T3 in group B. A prior study by **Hendriks et al.** (13), using intrathecal 'plain' prilocaine (50 mg), found a median peak sensory block height of T10. This could be explained by addition of fentanyl, which could be responsible for this difference.

Our study demonstrated that time to block onset was faster, and onset time for obtain of the highest motor block was significantly shorter in the prilocaine-fentanyl combination than bupivacaine -fentanyl combination. These results are in line with **Black et al.** (12) study that reported a significant difference between the prilocaine -fentanyl combination and bupivacaine -fentanyl combination in ambulatory arthroscopic surgery.

The length of stay in the PACU was shorter in group (P) than group (B). This agreed with the study of **Kaban et al.** (14) that reported shorter PACU stay in group (P) in perianal surgery with mean time of (63) minutes.

Along with prolonged sensory and motor block, pain was an important cause for discharge delay. Despite the shorter block duration in Group P, the postoperative VAS pain scores, and the time to first analgesic intake were the same between the groups in our study. These results like **Kaban et al.** (14) study results who reported no difference in VAS score between two groups and reported 190 minutes as the first time to ask analgesia in group P.

We measured the time to sensory regression to L1. The mean time of sensory regression was significantly shorter in prilocaine group than bupivacaine group. **Lacasse et al.** (15) used 0.75% 7.5mg bupivacaine in anorectal surgery and reported the time to S2 regression as 329 min. In another study comparing different bupivacaine doses, the time to the resolution of the spinal block to the S2 dermatome with 15mg bupivacaine was 343 minutes (16). The long recovery times reported in these studies may be explained by the high concentration of bupivacaine used in the first study and the high dose bupivacaine in the second study.

In the present study, the Bromage scores were measured after one and two hours. The differences between the prilocaine and bupivacaine only at the first hour was statistically significant. However, no significant difference was reported at the second hour. In **Black et al.** (12) study, Motor block regression was much faster in the prilocaine group. five of 22 patients in Group P never at any stage attained a Bromage score of greater than zero, compared with Group B where this did not occur in any patient. Such early regression of motor block allowed for earlier fitness for discharge.

Overall, the results of the current work are in line with a recent study of **Goffard et al.** (17) who reported that, median motor block was significantly shorter in the prilocaine group (110 [104 to 150] versus 175 [135 to 189] min, in bupivacaine group, $P = 0.001$). First unassisted ambulation was achieved faster after prilocaine (204.5 [177 to 46.5] minutes than bupivacaine 314 [209.25 to 400] minutes), and the incidence of maternal hypotension was significantly higher with bupivacaine. No supplementary epidural analgesia was required. Most recently, **Chapron et al.** (18) reported that, the median motor block duration was significantly shorter in the prilocaine group, than bupivacaine group. In addition, the median length of stay in the post-anesthetic care unit was significantly shorter in the prilocaine group, 135 vs. 180 minutes, $p = 0.009$. There was no difference between groups for intra-operative hypotension, postoperative pain and patients' satisfaction. These results are in partial agreement with the current study. However, they concluded that hyperbaric prilocaine induces a shorter and more reliable motor block than hyperbaric bupivacaine for elective abdominal surgery.

Limitation of the study: TNS were not observed in our study.

Conclusion: This study demonstrated the superiority of the combination of prilocaine and fentanyl over that of bupivacaine and fentanyl for subarachnoid anesthesia in lower abdominal surgery.

Declaration of Financial and Non-Financial Relationships and Activities of Interest: None

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