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Research Article

# A Comparative Study on Three Different Doses of Intrathecal Hyperbaric Prilocaine with Fentanyl in Elderly Patients Undergoing Day Case Lower Abdominal and Urologic Surgeries: A Randomized Clinical Trial

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**ABSTRACT**

**Background:** The objective of this work had been to identify the minimum effective and safest dosage of intrathecal hyperbaric prilocaine 2% in combination with 25 µg of fentanyl necessary for day-case lower abdominal and urologic procedures.
**Methods:** This randomized, parallel-group, double-blind clinical study included 45 individuals, aged 65 to 80 years, of both sex, planned for elective day-case lower abdomen or urologic surgeries. Patients were randomly placed in three groups. All groups were administered 25 µg of fentanyl (0.5 mL) with intrathecal prilocaine 2%, with dosages of 30 mg (1.5 mL) for group P1, 40 mg (2 mL) for group P2, and 50 mg (2.5 mL) for group P3.
**Results:** The time length of motor blockage and complete regression of sensory block were considerably prolonged in group P3 contrasted to groups P1 and P2. Intraoperative SBP and MAP were substantially elevated at 15, 30, 45, and 60 minutes in group P1 contrasted to group P3. The length of stay in the post-anaesthesia care unit (PACU) was markedly reduced in groups P1 and P2 compared to P3. Hypotension and bradycardia exhibited no significant differences across all groups
**Conclusion:** In elderly individuals having lower abdominal and urologic surgery, a low dose of prilocaine combined with fentanyl yields a reduced duration of block and a shorter PACU stay, along with improved hemodynamic stability, compared to a higher dose of prilocaine with fentanyl.

## Introduction

Over the previous four decades, the number of elderly people suffering from chronic diseases has risen. Medical services, such as outpatient and inpatient treatment, surgeries, and nursing homes, have become increasingly popular among the elderly [1].

Because of safety concerns and greater difficulties after surgery or anesthesia, it was previously debatable whether geriatric patients should accept day-case surgery. However, the smaller surgical wounds and the widespread use of short-acting anesthetics and anesthesia techniques, such as regional anesthesia, using ultrashort-acting local anesthetics with fewer side effects made it more popular [2-4]. For day-case surgery, the optimal spinal anesthetic should give immediate and effective anesthesia for an appropriate period, followed by rapid regression of sensory and motor blocking, rapid bladder voiding, and little residual effects to allow for early ambulation and discharge [5]. An optimal spinal anaesthetic for day-case surgery must offer quick and efficient anaesthesia for a suitable period, followed by a

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prompt reduction of motor and sensory blockage, instant bladder voiding, and little residual impacts to facilitate early ambulation and discharge. [5].

Short discharge periods may be achieved through the utilization of short-acting local anasthetics like chloroprocaine and lidocaine. The correlation of lidocaine and chloroprocaine with temporary neurological symptoms and neurological damage has restricted their use in spinal anesthesia. [6-7].

Despite bupivacaine's safety and little chance of transitory neurological symptoms, its extended sensory and motor blockage is a limitation for day-case spinal anesthesia [8].

Prilocaine, which is similar to lidocaine, is a local anesthetic exhibiting the same potency and lenght of effect, and it has been shown to have a reduced occurrence of transitory neurological symptoms. On the other hand, it causes a shorter motor block and less urine retention than bupivacaine, allowing for a faster recovery [9].

The work objective had been to assess the efficiency and safety of various dosages of intrathecal hyperbaric prilocaine 2% combined with fentanyl 25 µg in elderly individuals having outpatient lower abdominal and urological procedures.

## Methods

### Study design and eligibility criteria

This prospective, randomised, and double-blinded research had been conducted on 45 individuals aged between 65 and 80 years old; both sexes belonged to the American Society of Anaesthesiologists (ASA) I, II physical activity, had a body mass index (BMI) between 18.5 and 40 kg/m², and had heights between 1.60 and 1.90 cm. The individuals were selected for elective day-case lower abdomen or urologic surgeries lasted under 90 mins, performed under spinal anaesthesia in the Anesthesia Department of Cairo University Hospitals.

Exclusion criteria were patients needing general anesthesia, ASA > III, younger than 65 or older than 80, operations requiring sensory block above T10, patients refusing to sign informed consent, and patients with known contraindications to spinal anesthesia (recognized peripheral neuropathy, neurological impairments or skeletal abnormalities, confirmed or suspected coagulopathy (international normalized ratio above 1.4), thrombocytopenia (platelet count < 100,000), and infection at the injection area).

### Ethical considerations

This research occurred after approval from the Ethics Committee of Cairo University Hospitals, Cairo, Egypt (approval code: MD-248-2022) and clinical trial registration (NCT05726968). Informed written consent was acquired from the subjects.

### Randomization and blindness

Subjects were distributed randomly to three groups according to computer-generated numbers utilising an online randomisation program (Research Randomizer). Individuals were allocated to one of three groups, each consisting of 15 individuals. Subjects were randomly assigned to the research groups via closed envelope techniques. The composition of the study groups was as follows: Group P1 was administered intrathecal 30 mg (1.5 mL) of 2% prilocaine (Takipril, prilocaine hydrochloride 20 mg/mL, hyperbar, Sintetica) combined with 25 µg of fentanyl (0.5 mL); group P2 got intrathecal 40 mg (2 mL) of 2% prilocaine alongside 25 µg of fentanyl (0.5 mL); and group P3 was given intrathecal 50 mg (2.5 mL) of 2% prilocaine along with 25 µg of fentanyl (0.5 mL). Following the application of the block, the anesthesiologist did not engage in the subsequent monitoring of the individuals, resulting in blindness. Another anesthesiologist, unknowing of the group distribution, observed blockage quality and length, PACU stay, and the incidence of side effects.

### Preoperative evaluation

On the day of operation, all subjects were admitted to the hospital after receiving the usual preoperative instructions. Every individual had surgery without prior medications. A peripheral intravenous (IV) catheter had been placed, and a crystalloid infusion of 4–8 mL/kg was started according to the individuals' general health and fasting length. During the surgery and the PACU stay, HR and SpO2 were measured constantly. Systolic, diastolic, and MAP were evaluated non-invasively at 15-minute intervals. The baseline measurements were documented. A 2 L/min nasal oxygen supply was used throughout the procedure.

### Anesthetic procedure

Three to five milliliters of 2% lidocaine were used to anesthetize the lower back's skin in an aseptic manner. Using a 25-G spinal needle, a median or paramedian approach was used to perform a spinal puncture on a seated patient at the L3–4 or L4–5 interspace. A gradual 15-second injection of room-temperature local anesthetic was administered. Subsequent to the injection, subjects were positioned supine with a small pillow below their heads. After reaching a sufficient sensory level (minimum T10), the participant was positioned supine or in the lithotomy position as indicated by surgical procedures. Supplemental oxygen was administered, and the individual was monitored using electrocardiography, pulse oximetry, and automated arterial pressure measurement.

Hypotension was characterized by a SBP of less than 90 mmHg or a reduction in MAP exceeding 20% from baseline. The patient received 5 mg of intravenous bolus ephedrine, administered every 3 minutes till the

hypotension was corrected. Bradycardia is described as a HR of below 50 beats per minute. This was treated with IV atropine 0.5 mg. A blinded anesthesiologist assessed sensory and motor blocks at 5, 10, 20, and 30 minutes post-intrathecal drug injection. The sensory blockage had been confirmed with a bilateral pinprick assessment utilising a 20G hypodermic needle. The motor blockage had been assessed utilizing a modified Bromage scale (no motor block = 0; hip block = 1; hip and knee block = 2; hip, knee, and ankle block = 3). Simultaneously. Surgical readiness was determined by the existence of sufficient motor block (Bromage's score > 2) and total loss of pinprick sensation at the T10 dermatome. A failure to attain a block level of T10 or a subsequent request for analgesia was deemed a failure and classified as a dropout. The frequency of unsuccessful instances was determined for each examined group. The inability to attain a block level of T10 or a subsequent request for analgesia had been considered.

**Postoperative follow-up**

It continued in the PACU at 15-minute intervals until the individual was released. The individuals left the PACU upon attaining an Aldrete score of no less than 9, and the duration of their stay in the PACU was documented [10].

The main result was the duration of motor blockage in minutes or a Bromage score of 0 (indicating no motor block). The secondary results were the initiation of motor and sensory block, the time to achieve peak motor and sensory blockage, complete regression of sensory block, regression to the S2 dermatome, length of PACU stay, and occurrence of side effects.

**Sample size calculation**

The sample size had been established with PASS 15 Power Analysis and Sample Size Software (2017). NCSS, LLC, located in Kaysville, Utah, USA, may be found at ncss.com/software/pass. The period of motor block in elderly subjects administered intrathecal 50 mg prilocaine 2% combined with 25 µg fentanyl was 158 ± 12 minutes [11]. Consequently, in a single-factor ANOVA analysis, sample sizes of 12, 12, and 12 are collected from the three groups whose means are to be compared. The sample of 36 patients attains 93% power to identify a minimum difference of 30 minutes (20% difference) utilising the Tukey-Kramer (pairwise) multiple comparison test at a significance level of 0.05. The SD within the group is considered to be 12 minutes. The quantity of envelopes was raised to 45 to account for any dropouts, with 15 envelopes allocated to each group.

**Statistical analysis**

Statistical analysis had been performed using SPSS version 27 (IBM©, Chicago, IL, USA). Shapiro-Wilk's test and histograms had been utilised to evaluate the data distribution normality. Quantitative parametric data had been expressed as mean and standard deviation (SD) and analyzed using the ANOVA (F) test with the Tukey post hoc test. Qualitative parameters had been expressed as frequency and percentage and examined utilising the chi-square test. A two-tailed P-value of below 0.05 is deemed statistically significant.

## Results

58 individuals had been assessed for eligibility; 7 patients didn't satisfy the requirements, and 6 individuals rejected to take part in the study. The remaining 45 participants had been allocated at random to three equal groups of fifteen people for each. All assigned subjects were observed and subjected to statistical analysis (Figure 1).

Age, sex, weight, BMI, height, ASA physical activity, DM, hypertension, chronic renal disease, kind of surgery, and length of operation showed no significant variations among the three groups. Ischemic heart disease shown no significant variation among group P2 and the combined groups P1 and P3, whereas group P1 had a considerably greater incidence than group P3 (P= 0.013) (Table 1). The start of sensory block, beginning of motor block, duration to attain the peak sensory block, motor block at peak sensory block, sensory blockage at 5 and 10 minutes, and motor block at 5, 10, 20, and 30 minutes revealed no significant variations across the three groups. The length of motor blockage and complete regression of sensory block showed no significant difference across groups P1 and P2, but group P3 exhibited considerably longer durations compared to both groups P1 and P2 ($P < 0.05$). Groups P2 and P3 had a superior thoracic dermatomal degree of sensory block at 20 and 30 minutes compared to group P1, with a statistically significant difference ($P<0.05$). Conversely, no significant variation was seen among group P2 and group P3 (Table 2).

Intraoperative HR, diastolic blood pressure (DBP), and SpO2 at baseline, 15 min, 30 min, 45 min, 60 min, and 75 min and postoperative HR, SBP, DBP, MAP, and SpO2 throughout the PACU period were insignificantly variable between the three groups. Intraoperative SBP and MAP were insignificantly different at baseline and 75 min among the three groups. Intraoperative SBP and MAP were significantly higher at 15 min, 30 min, 45 min, and 60 min in group P1 than in group P3 ($P < 0.05$) and were insignificantly varied among group P2 and (group P1 and group P3) (Figure 2). The duration of PACU had been insignificantly varied among group P1 and group P2 and had been significantly reduced in group P1 and group P2 than in group P3 ($P<0.05$). Hypotension and bradycardia were insignificantly different among the three groups. Apnea, nausea, shivering, pruritus, and pain didn't occur in any subject of the three groups (Table 3)

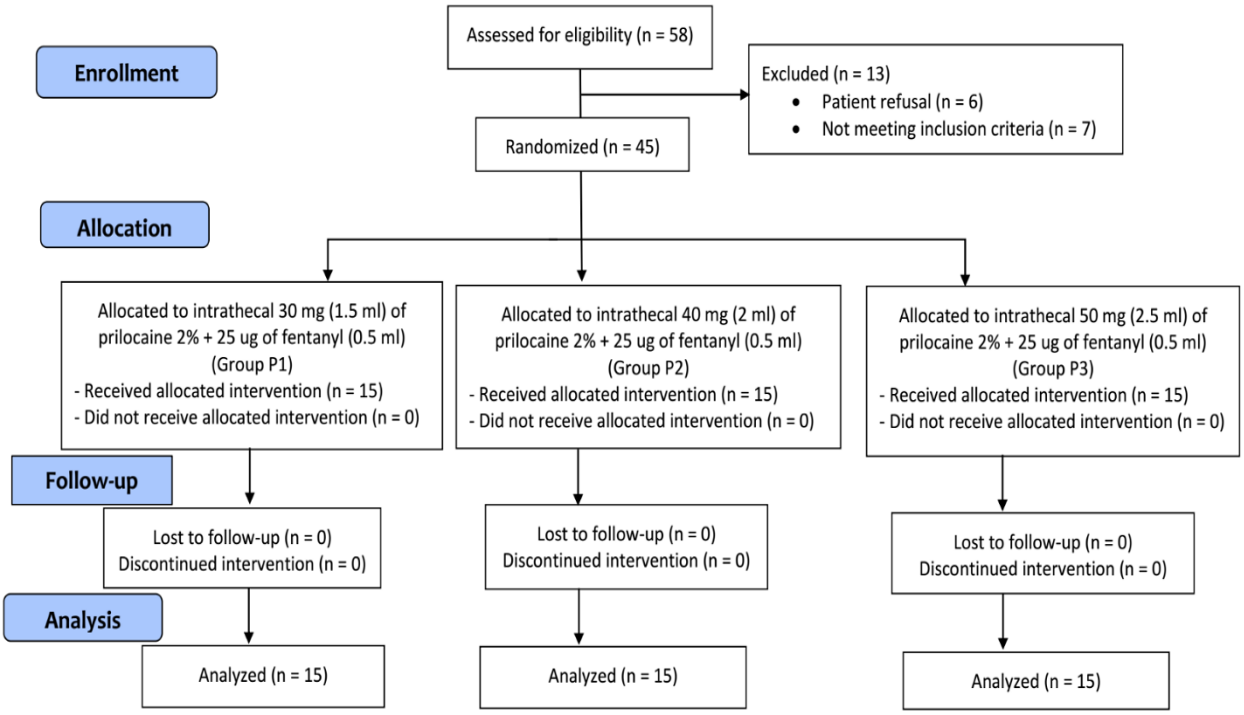



**Figure 1- CONSORT flowchart of the enrolled patients.**

**Table 1- Baseline and demographic data.**

| | | Group P1 (n=15) | Group P2 (n=15) | Group P3 (n=15) | P |
|---|---|---|---|---|---|
| Age (years) | | 72.7±4.3 | 72.7±3.29 | 72.4±4.07 | 0.970 |
| Sex | Male | 6 (40%) | 9 (60%) | 3 (20%) | 0.082 |
| | Female | 9 (60%) | 6 (40%) | 12 (80%) | |
| Weight (kg) | | 75.4±11.22 | 80.3±13.78 | 73.6±13.52 | 0.343 |
| Height (cm) | | 160.3±6.24 | 161.1±5.84 | 161±5.33 | 0.916 |
| BMI (kg/m$^2$) | | 29.5±4.83 | 30.9±4.24 | 28.4±4.71 | 0.329 |
| ASA physical status | I | 4 (26.67%) | 2 (13.33%) | 7 (46.67%) | 0.226 |
| | II | 6 (37.5%) | 5 (31.25%) | 2 (12.5%) | |
| | III | 5 (33.33%) | 8 (53.33%) | 6 (40%) | |
| Comorbidities | DM | 8 (53.33%) | 8 (53.33%) | 3 (20%) | 0.103 |
| | HTN | 8 (53.33%) | 6 (40%) | 4 (26.67%) | 0.329 |
| | IHD | 7 (46.67%) | 4 (26.67%) | 1 (6.67%) | 0.047* |
| | | P1=0.256, P2=0.013*, P3=0.142 | | | |
| | CKD | 1 (6.67%) | 1 (6.67%) | 2 (13.33%) | 0.760 |
| Type of operation | Cystoscopy | 5 (33.33%) | 5 (33.33%) | 8 (53.33%) | 0.819 |
| | Transurethral resection of prostate | 1 (6.67%) | 2 (13.33%) | 2 (13.33%) | |
| | Inguinal hernioplasty | 3 (20%) | 3 (20%) | 2 (13.33%) | |
| | Inguinal lymph node biopsy | 3 (20%) | 1 (6.67%) | 2 (13.33%) | |
| | Penile prothesis implantation | 3 (20%) | 4 (26.67%) | 1 (6.67%) | |
| Duration of operation (min) | | 67.7±5.56 | 67.5±5.88 | 69.3±5.97 | 0.664 |

Data presented as mean ± SD or frequency (%), *: significant P value <0.05; P1: P value between group P1 and group P2; P2: P value between group P1 and group P3; P3: P value between group P2 and group P3; BMI: body mass index; ASA: American Society of Anesthesiologists; DM: diabetes mellitus; HTN: hypertension; IHD: ischemic heart disease; CKD: chronic kidney disease

**Table 2- Sensory and motor outcomes and levels.**

| | | Group P1 (n=15) | Group P2 (n=15) | Group P3 (n=15) | P |
|---|---|---|---|---|---|
| Onset of sensory block (min) | | 4.5±2.03 | 3.9±1.28 | 4±1.25 | 0.599 |
| Onset of motor block (min) | | 2.8±1.26 | 2.3±1.11 | 2.7±0.98 | 0.509 |
| Full regression of sensory block (min) | | 129.3±16.29 | 141.6±22.75 | 167.8±31.82 | <0.001* |
| | | P1=0.364, P2<0.001*, P3=0.015* | | | |
| Duration of motor block (min) | | 116.4±17.41 | 124.9±21.53 | 151.4±31.07 | 0.001* |
| | | P1=0.598, P2<0.001*, P3=0.012* | | | |
| Highest dermatomal level of sensory block (thoracic) | | 7.9±1.41 | 6.4±1.35 | 6.4±1.35 | 0.006* |
| | | P1=0.015*, P2=0.015*, P3=1 | | | |
| Time to reach highest sensory block (min) | | 11.7±1.44 | 12±1.69 | 11.8±3.91 | 0.958 |
| Motor block at time of reaching highest sensory block | | 2.3±0.49 | 2.4±0.51 | 2.3±0.49 | 0.913 |
| Sensory block | 5 min | 10.27±1.03 | 9.33±1.23 | 9.73±1.83 | 0.202 |
| | 10 min | 8.67±1.23 | 7.6±1.35 | 7.6±1.72 | 0.079 |
| | 20 min | 7.87±1.41 | 6.4±1.35 | 6.27±1.28 | 0.003* |
| | | P1=0.013*, P2=0.006*, P3=0.960 | | | |
| | 30 min | 7.87±1.41 | 6.4±1.35 | 6.27±1.28 | 0.003* |
| | | P1=0.013*, P2=0.006*, P3=0.960 | | | |
| Motor block | 5 min | 2±0 | 2±0 | 2.07±0.26 | 0.376 |
| | 10 min | 2.13±0.35 | 2.13±0.35 | 2.07±0.26 | 0.810 |
| | 20 min | 2.4±0.51 | 2.4±0.51 | 2.27±0.46 | 0.694 |
| | 30 min | 2.4±0.51 | 2.4±0.51 | 2.27±0.46 | 0.694 |

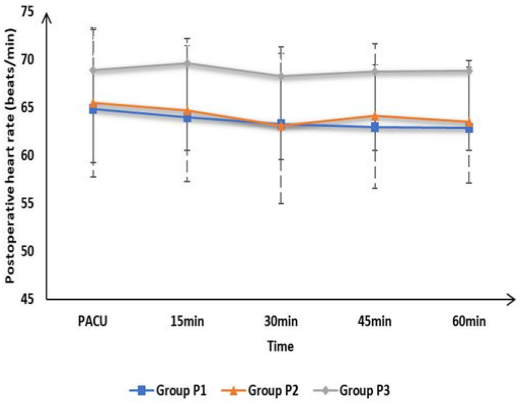
Data presented as mean ± SD, *: significant P value <0.05; P1: P value between group P1 and group P2; P2: P value between group P1 and group P3; P3: P value between group P2 and group P3

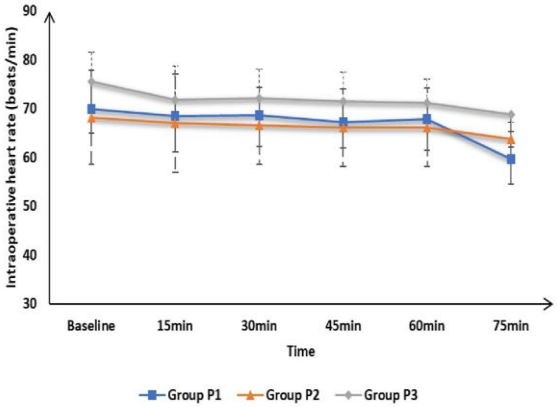
**Table 3- Duration of post anesthesia care unit and complications.**

| | Group P1 (n=15) | Group P2 (n=15) | Group P3 (n=15) | P |
|---|---|---|---|---|
| Duration of PACU (min) | 61.7±16.72 | 74.1±22.41 | 98.5±33.01 | 0.001* |
| | P1=0.371, P2<0.001*, P3=0.028* | | | |
| Complications | | | | |
| Hypotension | 0 (0%) | 1 (6.67%) | 2 (13.33%) | 0.343 |
| Bradycardia | 1 (6.67%) | 1 (6.67%) | 0 (0%) | 0.593 |
| Apnea | 0 (0%) | 0 (0%) | 0 (0%) | --- |
| Nausea | 0 (0%) | 0 (0%) | 0 (0%) | --- |
| Shivering | 0 (0%) | 0 (0%) | 0 (0%) | --- |
| Pruritis | 0 (0%) | 0 (0%) | 0 (0%) | --- |
| Pain | 0 (0%) | 0 (0%) | 0 (0%) | --- |

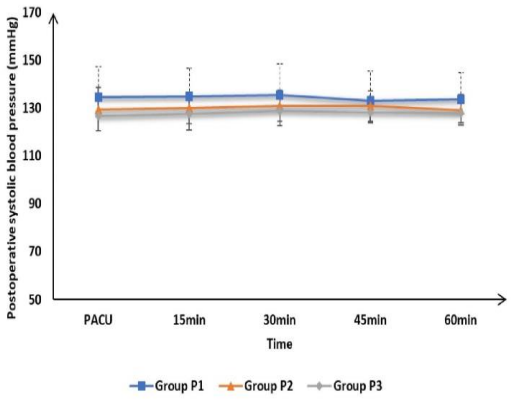
Data presented as mean ± SD or frequency (%), *: significant P value <0.05; P1: P value between group P1 and group P2; P2: P value between group P1 and group P3; P3: P value between group P2 and group P3; PACU: post anesthesia care unit

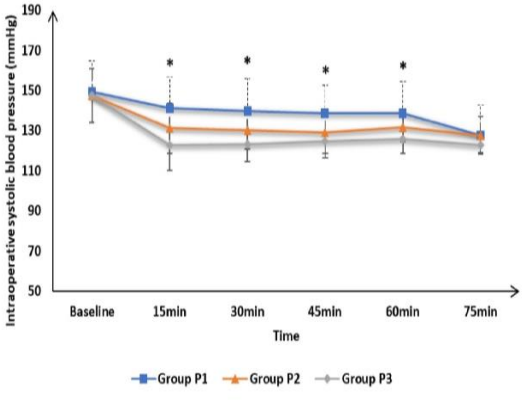
(A)


Postoperative heart rate (beats/min)
75
70
65
60
55
50
45
PACU
15min
30min
45min
60min
Time
Group P1
Group P2
Group P3

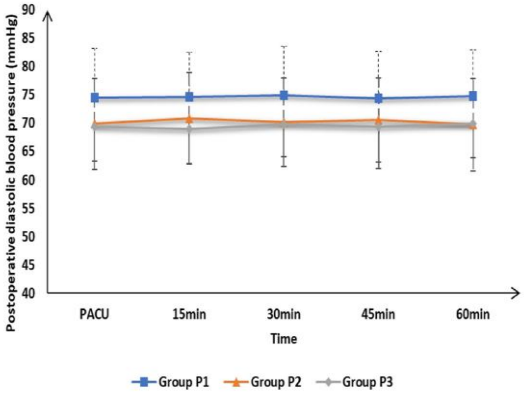

Intraoperative heart rate (beats/min)
90
80
70
60
50
40
30
Baseline
15min
30min
45min
60min
75min
Time
Group P1
Group P2
Group P3

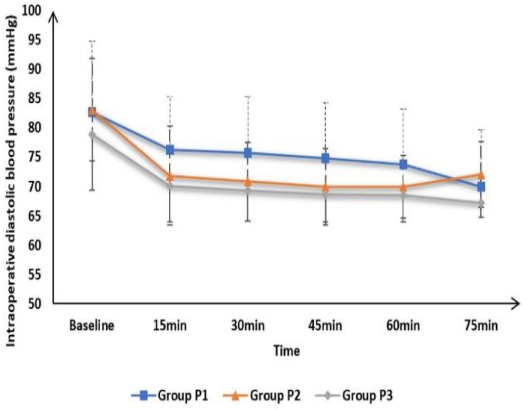
(B)


Postoperative systolic blood pressure (mmHg)
170
150
130
110
90
70
50
PACU
15min
30min
45min
60min
Time
Group P1
Group P2
Group P3

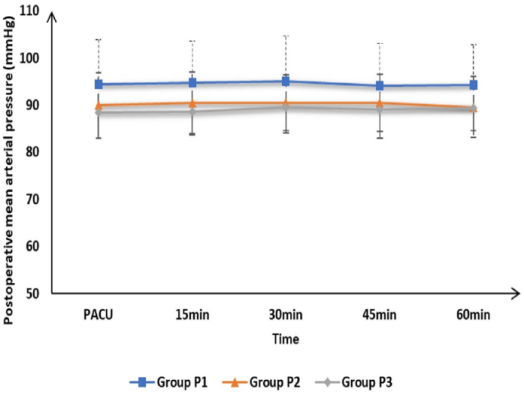

Intraoperative systolic blood pressure (mmHg)
190
170
150
130
110
90
70
50
*
*
*
*
Baseline
15min
30min
45min
60min
75min
Time
Group P1
Group P2
Group P3

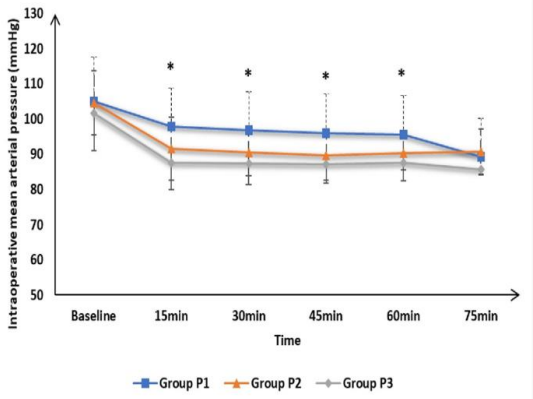
(C)


Postoperative diastolic blood pressure (mmHg)
90
85
80
75
70
65
60
55
50
45
40
PACU
15min
30min
45min
60min
Time
Group P1
Group P2
Group P3


Intraoperative diastolic blood pressure (mmHg)
100
95
90
85
80
75
70
65
60
55
50
Baseline
15min
30min
45min
60min
75min
Time
Group P1
Group P2
Group P3

(D)


Postoperative mean arterial pressure (mmHg)
110
100
90
80
70
60
50
PACU
15min
30min
45min
60min
Time
Group P1
Group P2
Group P3


Intraoperative mean arterial pressure (mmHg)
130
120
110
100
90
80
70
60
50
*
*
*
*
Baseline
15min
30min
45min
60min
75min
Time
Group P1
Group P2
Group P3

(E)

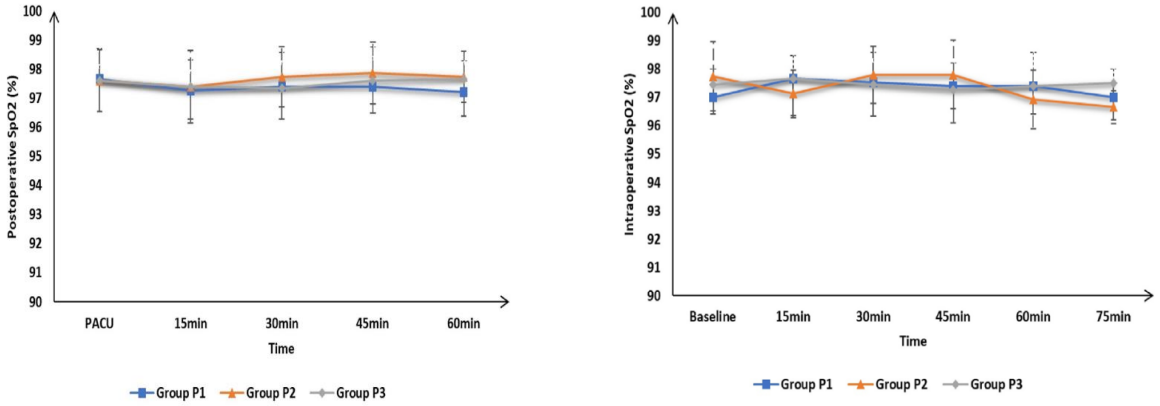



**Figure 2- (A) Heart rate, (B) systolic blood pressure, (C) diastolic blood pressure, (D) mean arterial blood pressure, and (E) oxygen saturation of the studied groups**

## Discussion

Day-case operations need an anesthetic approach that allows for rapid turnover, ensures high-quality treatment, and maintains affordable prices. Spinal anesthesia is a straightforward and cost-effective treatment, characterized by rapid onset and few adverse effects. [12]. The current investigation revealed that the length of motor blockage and complete regression of sensory blockage showed no significant differences across groups P1 and P2, whereas group P3 exhibited considerably longer durations compared to both groups P1 and P2. The peak dermatomal degree of sensory block (thoracic) was much lower in group P1 compared to groups P2 and P3, with no significant difference seen among groups P2 and P3. Our data indicate that sensory block exhibited no significant differences at 5 minutes and 10 minutes across the three groups. The sensory block was markedly reduced after 20 and 30 minutes in group P1 compared to groups P2 and P3, with no significant difference seen among groups P2 and P3. The motor block exhibited negligible differences at 5, 10, 20, and 30 minutes across the three groups. El-Sayed et al. [13] noted that sensory block occurs at different times at the early time of operation; there is no statistically significant difference among low, medium, and higher doses of prilocaine as regards sensory level, while after 60 min, low prilocaine doses were sufficient to obtain sensory level. There is a significantly higher motor block with high doses of prilocaine compared to low and medium doses with $p < .001$ at different times. As regards the time for complete motor block and the onset time to obtain the highest motor block level, it was shorter in higher doses of prilocaine compared to low and medium doses. Palumbo et al. [14] revealed a statistically significant difference in sensory and motor blockage, with high-dose prilocaine exhibiting better efficacy than low-dose prilocaine.

Our outcomes indicate that intraoperative SBP was not substantially different at baseline and 75 minutes between the three groups. Intraoperative SBP was markedly elevated at 15, 30, 45, and 60 minutes in group P1 contrasted to group P3, but the variation among group P2 and both group P1 and group P3 was statistically insignificant. The intraoperative DBP was not substantially different at baseline, 15 minutes, 30 min, 45 min, 60 min, and 75 min among the three groups. The intraoperative MAP was not substantially variable at baseline and 75 minutes between the three groups. Intraoperative MAP was markedly elevated at 15, 30, 45, and 60 minutes in group P1 contrasted to group P3, but the difference among group P2 and both group P1 and group P3 was statistically insignificant. Postoperative heart rate exhibited no significant differences at PACU, 15 min, 30 min, 45 min, and 60 min between the three groups. Consistent with our results, El-Sayed et al. [13] demonstrated that SBP was markedly elevated in the low-dose prilocaine group compared to the high-dose prilocaine group. Nevertheless, HR and DBP were markedly elevated in the low-dose prilocaine group contrasted to the high-dose prilocaine group.

The length of the PACU was not substantially variable among groups P1 and P2 but was considerably shorter in both groups P1 and P2 compared to group P3. The present investigation found no significant differences in hypotension and bradycardia between the three groups. Camponovo et al. [15] shown that lower doses resulted in earlier voiding and discharge, comparing 40 mg and 60 mg of hyperbaric prilocaine at 20 mg/mL (voiding: 195 vs. 218 min; discharge: 208 vs. 256 min).

The study's limitations were a very small sample size, potentially yielding inconsequential outcomes. The work had been performed at a single center, which might provide various outcomes compared to other sites.

## Conclusion

In conclusion, in the geriatric patient undergoing lower abdominal and urologic surgery, low-dose prilocaine (30

mg) in combination with fentanyl (25 µg) would result in a shorter length of block and a shorter stay in the PACU with better hemodynamic stability than utilizing a higher dosage of prilocaine (50 mg) combined with fentanyl (25 µg).

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