ORIGINAL ARTICLE ASIAN JOURNAL OF MEDICAL SCIENCES

Comparison of anesthetic efficacy of intrathecal 1% isobaric 2-chloroprocaine with 0.5% isobaric ropivacaine for inguinal hernia surgeries

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Submission: 28-01-2023 Revision: 02-05-2023 Publication: 01-06-2023

ABSTRACT

Background: Inguinal hernia repair is one of the most common surgical conditions. In the absence of other comorbidities, it can be performed as a day-care procedure. Spinal anesthesia is most preferred technique this surgery. Local anesthetics having rapid and smooth onset of action, good intraoperative analgesia, short recovery period, and least side effects are preferred. **Aims and Objectives:** The objective of the study was to compare the anesthetic efficacy of intrathecal 1% isobaric 2-chloroprocaine (CP) and 0.5% isobaric ropivacaine for inguinal hernia surgeries. **Materials and Methods:** Sixty patients with ASA grade I/II scheduled for elective inguinal hernia surgeries were randomly allocated into group C (n = 30), received 3 mL of 1% isobaric 2- CP and group R (n = 30), received 3 mL of 0.5% isobaric ropivacaine intrathecally. **Results:** Demographic profile, mean time for onset of sensory blockade at T10, highest level of sensory blockade, and maximum motor blockade were comparable among the groups ($P > 0.05$). The highest level of sensory blockade in group C is T7 and group R is T8. The mean time to two segment regression, complete sensory regression, complete motor recovery, recovery of parameters for achieving discharge criteria such as time to unassisted ambulation, drink water, micturition, and first rescue analgesia were significantly shorter in group C ($P < 0.0001$). Visual analog scale score at the time of first rescue analgesia was significantly higher in group C ($P < 0.0001$). Intraoperative hemodynamic changes and perioperative side effects were comparable ($P > 0.05$). **Conclusion:** CP provides faster block resolution, earlier hospital discharge, and early ambulation with minimal side effects, making it a better alternative to ropivacaine for inguinal hernia surgeries.

Key words: Chloroprocaine; Isobaric; Ropivacaine; Subarachnoid block; Visual analog scale

Access this article online

Website: http://nepjol.info/index.php/AJMS

DOI: 10.3126/ajms.v14i6.51874

E-ISSN: 2091-0576

P-ISSN: 2467-9100

INTRODUCTION

Inguinal hernia repair is one of the most common surgical conditions. Inguinal hernia affects approximately 10–12% of patients at outpatient surgery clinics.[1] Surgical procedure is completed in 60–90 min and it is associated with least intraoperative and postoperative complications.[2] Unless concurrent medical issues necessitate hospitalization for observation or specialist care, surgery can be performed as a day-care procedure.[3]

Day-care surgery has become a well-established practice with increasing rates globally.[4] In these settings, the patient is admitted on the day of the scheduled surgery and is discharged within 24 h of the procedure.[5] Advantages of day-care surgery are, early recovery, early mobilization, shorter hospital stays, minimal adverse effects, cost-effective treatment, and recovery in a comfortable environment.[1] Early ambulation and shorter hospital stay lower the risk of thromboembolism and nosocomial infections. Day care, surgery provides the same high-quality care with great patient satisfaction.[4]

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Spinal anesthesia is the most common regional anesthesia technique used in lower abdominal surgeries such as inguinal hernia repair. It has quicker onset, predictable duration of action, with the fewest side effects and reliable offsetting.[6] Spinal anesthesia was the first regional anesthesia, which was carried out and the first surgery under spinal anesthesia were made in 1898 in Germany by August Bier.[7] While certain of its characteristics, like delayed ambulation, urine retention, and pain after block regression, may limit its usage.[8]

For day-care surgery, local anesthetic agent, which have rapid and smooth onset of action, intraoperative analgesia, good surgical condition, and short recovery period with least side effects, is preferred.[2]

Although low dose of longer acting local anesthetic agents such as bupivacaine, ropivacaine, and levobupivacaine were administered intrathecally for day-care surgery, these were associated with longer hospital stay and less reliable for block efficacy, onset, and spread.[8] Furthermore, cardiotoxicity potential limits the use of bupivacaine as ideal drug for spinal anesthesia in day-care surgery.[2] Later on, local anesthetic agents with shorter duration of action as the hyperbaric prilocaine 2% and the isobaric 1% 2- chloroprocaine (CP) were used in spinal anesthesia. These short-acting local anesthetic agents can be the perfect anesthetic drug for day-care surgery.[9]

Ropivacaine is a long-acting enantiomerically almost pure (>99% S-enantiomer), amino amide local anesthetic agent. It is less lipid soluble, so blockage of myelinated motor nerve fibers such as A beta is slower in onset, less in intensity, and shorter in duration of action. However, nerve fibers involved in pain transmission (A delta and C fibers) are not affected. It has a greater sensory motor differentiation. Ropivacaine produces similar sensory block at equipotent dose and a shorter duration of motor block (50–67% that of bupivacaine) and thus it might be a very useful agent for day-care surgeries.[8]

CP is an amino ester local anesthetic agent with a very short half-life, and it was introduced and has been successfully used for spinal anesthesia since 1952, and sodium bisulfate was then added as a preservative after 1956. In 1980, several cases of neurological deficits in patients receiving accidentally high doses of intrathecal CP during epidural labor analgesia were reported, which limits its use in regional anesthesia. Recently, newer preservative-free formulation has been extensively evaluated in clinical practice. It has favorable profile in terms of safety and efficacy.[8]

Compared with hyperbaric forms of local anesthetic agent, in isobaric form, the intrathecal spread of the local anesthetic agent is not affected by the patient's position during and after the injection.[10] In contrast to hyperbaric solutions, isobaric solutions are associated with a lower thoracic dermatomal sensory blockade.[11] Because of the less extensive intrathecal spread, isobaric spinal anesthesia is more hemodynamically stable.[12] Therefore, it is helpful in lower abdominal surgeries such as inguinal hernia surgery.

Aims and objectives

Primary objective

1. To compare and evaluate the anesthetic efficacy of intrathecal 1% isobaric 2-CP and 0.5% isobaric ropivacaine.

Secondary objectives

1. To study the hemodynamic parameters during intraoperative period
2. To study any untoward side effects and complications associated with the study drugs and technique.

MATERIALS AND METHODS

After obtaining approval from the ethics committee of the institute, 60 patients were chosen, who were scheduled for elective inguinal hernia repair surgeries in JA Group of Hospitals.

Sample size was calculated using formula:

$$n = \frac{2\left(S_1^2 - S_2^2\right) \times \left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2}{\left(\bar{x}_2 - \bar{x}_1\right)^2}$$

n = (34.82 -30.562)2 × (1.96+1.64)2/= 27875.87/=18

(105.62-145.9) 2 1'622.478

At 5% level of significance and 95% power of test, the required minimum sample size is 18 in each group. To increase the efficacy of study, sample size increases from 18 to 30 in each group.

Evaluation of study data in electronic form required performing additional statistical analyses. Data were composed in suitable spreadsheet, i.e., EXCEL and SPSS. After compilation of data, it was analyzed statistically by SPSS software version 22.0. Statistical tests used were student t-test (paired and unpaired) and Chi-square test. Significance level will be 95% confidence level ($P<0.05$). Data were described as a frequency (percentage) distribution as well as in mean±SD. $P<0.05$ was considered significant and $P<0.001$ was considered highly significant.

Patients of either sex, aged 18–60 years, belonging to ASA grade I/II, weighing between 50 and 75 kg with height ranging from 150 to 180 cm, giving consent to participate in the study and scheduled to undergo inguinal hernia surgery under spinal anesthesia, were included. Patients having a history of allergy or sensitivity or any other reaction to local anesthetic or para-aminobenzoic acid, neurological disease (multiple sclerosis, symptomatic lumbar herniated disc, and spinal stenosis), cardiac or renal insufficiency, having atypical plasma cholinesterase, bleeding diathesis, platelets <75,000/cu.mm, use of anticoagulant drugs, international normalized ratio >1.3, drug abuse, and giving negative consent or uncooperative or unable to understand the procedure were excluded.

Pre-operative complete blood count, random blood sugar, liver function test, renal function test, chest X-ray, and a 12-lead electrocardiogram (ECG) were done. A thorough pre-anesthetic checkup was done before surgery. Informed and written consent was taken. All patients kept nil orally for at least 6 h before the procedure. Upon arrival of the patient in the operation theater, intravenous access with 18 G cannula was inserted into the patient's forearm, and preloading done with lactated ringer solution (10 mL/kg). Pulse oximeter, non-invasive blood pressure, and ECG were recorded by multipara monitor (Mindray Bene view T5 CM 23123727) and all the baseline (B0) vital parameters were noted preoperatively.

Patients were subsequently randomly (done using slips-in the box technique) allocated into group C and group R of 30 each. Patients of group C received 3 mL of 1% isobaric 2- CP and group R received 3 mL of 0.5% isobaric ropivacaine intrathecally.

Under all aseptic precautions, lumbar puncture was done in lateral position at the L2-L3 inter vertebral space through midline approach using 23 G Quincke spinal needle. Subarachnoid block was performed after ensuring free flow of CSF, the study drug was injected and then patient was positioned in supine position. After noting the time of induction, the sensory and motor effects were checked every 3 min for the first 15 min, then every 5 min up to 30 min. Hemodynamic parameters including pulse rate (PR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) were recorded at B0, S3, S6, S9, S15, S25, S30, S40, S50, and S60 min after giving study drug intrathecally. During surgery, any fall in MAP below 20% of baseline value was treated with bolus dose of injection. mephentermine 6 mg i.v. and PR<60 beats/min was treated with I/V injection atropine sulfate 0.3–0.6 mg. Total dosage of bolus drugs were recorded.

Time from intrathecal injection of drug to attain sensory blockade at T10, highest level of sensory blockade, time to achieve highest sensory blockade, two segment regression, complete sensory regression (returning pinprick sensation down to the level of S1), onset of complete motor blockade, and time to complete motor block resolution were noted. Sensory blockade was assessed by the loss of pinprick sensation with 23-gauge hypodermic needle. Evaluation of motor blockade was assessed by the Modified Bromage scale. 0=No motor block; 1=Able to bend the knee (hip blocked); 2=Able to dorsiflex the foot (hip and knee blocked); and 3 = Complete motor block (hip, knee, and ankle blocked).[2]

To assess the quality of anesthesia, patients were assessed for feeling of sensation during operation and were graded as excellent: no sensation throughout the operation; good: sensation of manipulation of sac but no pain; fair: mild pain during operation, but no need of analgesia; and poor: pain and need for analgesia.[2]

Visual analog scale (VAS) score at the time of first rescue analgesia (TRA1) was assessed by a 10 cm horizontal scale with gradations marked as 0 means no pain at all and 10 means worst pain. VAS score rating: 0=No pain, 1–3=Mild pain, 4–6=moderate pain, and 7–10 = Severe pain.[2] VAS score >3 was managed with rescue analgesia with injection tramadol 2 mg/kg i.v.in 100 mL normal saline to relieve postoperative pain. TRA1 was also noted.

Any side effect or complication due to the drug or technique was noted including hypotension, hypertension, bradycardia, tachycardia, postoperative nausea vomiting, sedation, shivering, and transient neurological symptoms (TNS).

Postoperatively, patients were monitored every 15 min for the regression of motor and sensory effects. The times to reach different discharge parameters were noted. Discharge parameters were following: no breathing difficulties, stability of hemodynamic parameters, ability to walk, complete orientation to time and place, ability to drink without nausea and vomiting, voluntary micturition, and no more than slight pain.

RESULTS

The sixty patients included in the study were comparable between the groups with respect to demographic variables (age, sex, ASA grade, height, and weight). Onset of sensory block characteristics, onset time of highest motor blockade, intraoperative hemodynamic variables, quality of analgesia, and intra/post-operative side effects were comparable, and the association was found to be statistically insignificant among groups.

In our study, the mean standard deviation of age, weight, and height was calculated as (45.83±5.76 years vs. 45.6±8.25 years) and (56.66±4.06 kg vs. 57.33±6.24 kg) and (161.06±4.44 cm vs. 159.66±5.74 cm), respectively, in group C and group R (Table 1). The above association found to be statistically not significant (P>0.05), which shows that age, weight, and height were comparable among both groups. In addition, the gender status in both the groups, all patients were males (100% vs. 100%), whereas ASA classification status described as all of the patients in the both groups (100%) belonged to ASA II status.

The mean time for the regression of sensory effects, such as time to two segment regression (52.16±5.96 min vs. 76.9±7.66 min) and time to complete sensory regression (75.03±3.95 min vs. 215.06±7.75 min) were shorter in group C than group R (Table 2). The above association is found to be statistically highly significant (P<0.001).

In this study, the mean time to complete motor recovery was faster in group C (70.46±5.03 min) than group R (226.76±9.49 min) (Table 3). The above association is found to be statistically highly significant among the study groups (P<0.001).

Table 4 shows VAS score at the TRA1, which was observed as 4.68±0.60 versus 3.75±0.75, respectively, in group C and group R, and the association found to be statistically highly significant among study groups (P<0.001).

Table 5 shows mean time to achieve different discharge parameters such as patient able to walk without support (127.36±3.20 min vs. 409.2±19.20 min), time to drink water (188.2±10.92 min vs. 381.4±21.49 min), time to micturition (159.93±7.18 min vs. 453.03±6.16 min), and time to first rescue analgesia (78.56±2.96 min vs. 169.1±9.25 min) were shorter in duration in group C as compare to group R, and the association was found to be statistically highly significant (P<0.001).

Graph showing intraoperative hemodynamic parameters

The results obtained from the analysis showed that there was no statistically significant difference observed between two study groups (P>0.05).

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In this study, bradycardia was observed in one patient (3.33%) in group C, whereas in group R, bradycardia was observed in two patients (6.66%). Hypotension and shivering were found in one patient (3.33%), respectively, in each group, which were statistically insignificant (P>0.05).

Table 1: Demographic profile of study participants

Demographic parameter	Group C (n=30)	Group R (n=30)	P-value
Age (years)	45.83±5.76	45.6±8.25	0.900
Height (cm)	161.06±4.44	159.66±5.74	0.295
Weight (kgs)	56.66±4.06	57.33±6.24	0.623
ASA Grade			
Grade I	0	0	1.0000
Grade II	30	30	
Gender			
Male	30	30	1.0000
Female	0	0	

Table 2: Intergroup statistical analysis of regression of sensory blockade

Time (minutes)	Group C (Mean±SD)	Group R (Mean±SD)	P-value
Time to two segment regression	52.16±5.96	76.9±7.66	<0.001**
Time to complete sensory regression (return of pinprick at S1 level)	75.03±3.95	215.06±7.75	<0.001**

**= highly significant

Table 3: Intergroup statistical analysis of regression of motor blockade

Time (Minutes)	Group C (Mean±SD)	Group R (Mean±SD)	P-value
Time to complete motor recovery (modified Bromage grade 0)	70.46±5.03	226.76±9.49	<0.001**

Table 4: VAS score at time for first rescue analgesics (TRA1)

At TRA1	Group C (n=30)	Group R (n=30)	t value	P-value
	Mean±SD	Mean±SD		
VAS score	4.68±0.60	3.75±0.75	−5.303	<0.001**

DISCUSSION

In this prospective randomized study, sixty patients scheduled for elective inguinal hernia surgeries were studied after being given spinal anesthesia with either 3 mL of 1%

Table 5: Mean time to achieve discharge parameters

Time (Min)	Group C (n=30)	Group R (n=30)	t value	P-value
	Mean±SD	Mean±SD		
Patient able to walk without support	127.36±3.20	409.2±19.20	79.307	<0.001**
Time to drink water	188.2±10.92	381.4±21.49	43.899	<0.001**
Time to micturition	159.93±7.18	453.03±6.16	169.695	<0.001**
Time to first rescue analgesia	78.56±2.96	169.1±9.25	51.061	<0.001**

isobaric 2 - CP and 3 mL of 0.5% isobaric ropivacaine, with respect to anesthetic efficacy, intraoperative hemodynamic changes, and any perioperative side effects.

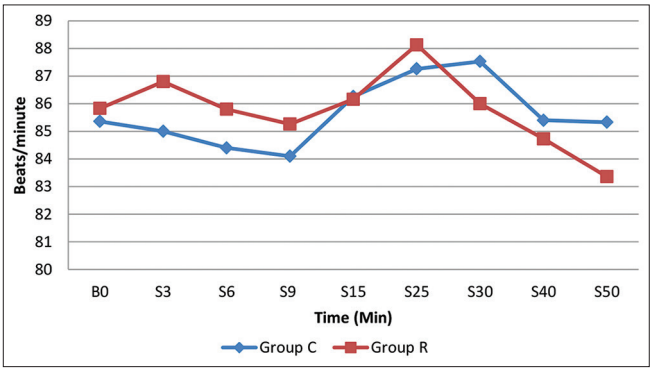
In this study, the demographic parameters (age, weight, and height distribution) were comparable among the study groups (P>0.05). In addition, the gender status in both the groups, all patients were males (100% vs. 100%) and all patients in both the groups (100%) belong to ASA II status (Table 1).

Heart rate, SBP, DBP, and mean arterial blood pressure (Graphs 1-5) were noted down as baseline, 3, 6, 9, 15, 25, 30, 40, and 50 min after giving spinal anesthesia. The results were found statistically insignificant among two groups (P>0.05). In contrast to our study, Dadhich et al.,[13] found that SBP and DBP were significantly lower at 25 min and 30 min after giving spinal anesthesia with P<0.05 in the group ropivacaine. The mean values for MAP were also significantly low at 4, 25, 30, and 40 min postspinal anesthesia, with P<0.05 in group ropivacaine. However, the intraoperative variations in heart rate at various time points - 1, 2, 3, 4, 5, 10, 15, 20, 25, 30, 40, 50, 60, and 70 min after giving spinal anesthesia were comparable in group C and group R.

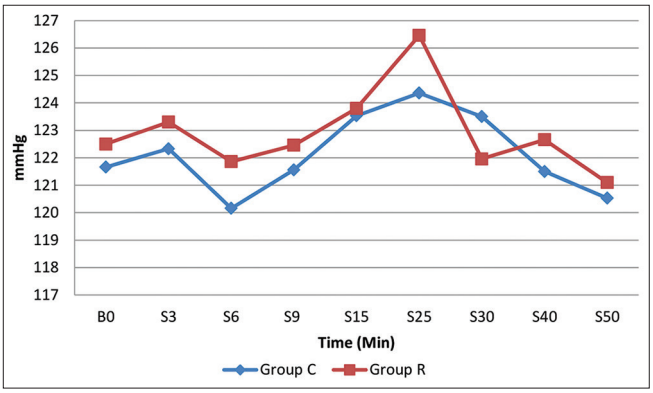
There was no statistically significant difference between two groups regarding block characteristics such as mean time to onset of sensory analgesia at T10, mean time of highest level of sensory blockade and mean time to achieve maximum motor block (P>0.05). Time to two segment regression (52.16±5.96 min vs. 76.9±7.66 min), time of complete sensory regression (75.03±3.95 min vs. 215.06±7.75 min), and time to complete motor recovery (70.46±5.03 min vs. 226.76±9.49 min) were significantly shorter in group C, compared to group R (P<0.001) (Tables 2 and 3). These findings were consistent with the findings of Patel et al.,[14] and Kumari et al.[15]

In our study, VAS score at the time of the first rescue analgesic was significantly higher (4.68±0.60) in group C than group R (3.75±0.75), (P<0.001) (Table 4), which was similar to findings of Kumari et al.[15]

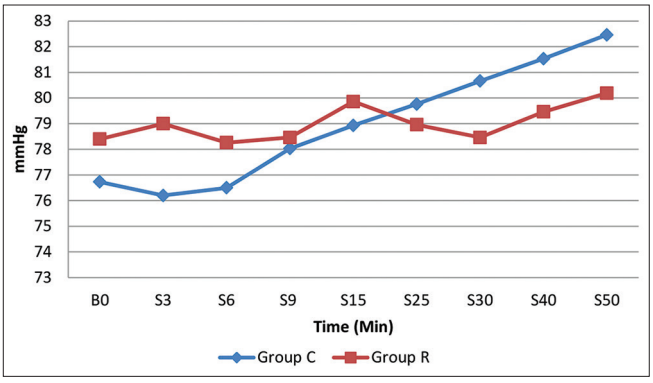
In our study, recovery of discharge parameters, including time to unassisted ambulation (127.36±3.20 min vs. 409.2±19.20 min), time to drink water (188.2±10.92 min vs. 381.4±21.49 min), time to micturition (159.93±7.18 min vs. 453.03±6.16 min), and time to first rescue analgesia (78.56±2.96 min vs. 169.1±9.25 min) were significantly shorter in group C than group R (P<0.001) (Table 5). Similar conclusion was derived by Lacasse et al.[16]



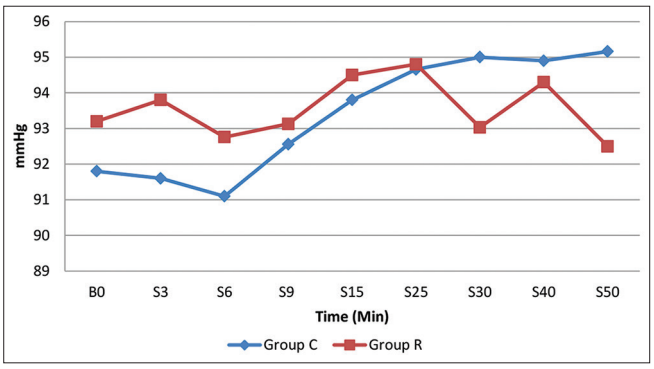
Graph 1: Heart rate



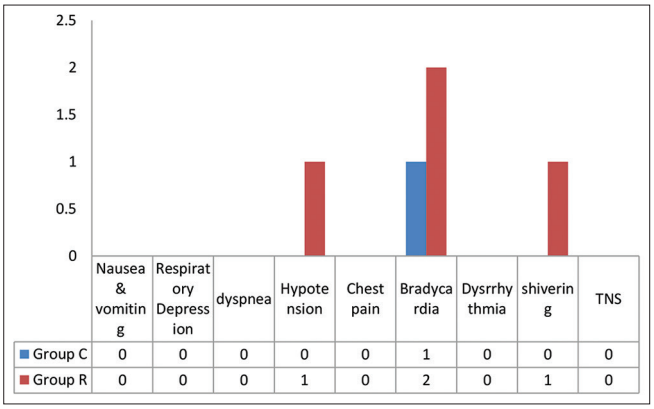
Graph 2: Systolic blood pressure



Graph 3: Diastolic blood pressure



Graph 4: Mean arterial blood pressure



	Nausea & vomiting	Respiratory Depression	dyspnea	Hypotension	Chest pain	Bradycardia	Dysrrhythmia	shivering	TNS
Group C	0	0	0	0	0	1	0	0	0
Group R	0	0	0	1	0	2	0	1	0

Graph 5: Perioperative side effects

Patel et al.,[14] found that CP had a substantially shorter average discharge time (278±12.03 min) than ropivacaine (304±10.64 min). Ropivacaine considerably increased the length of analgesia (170±12.61 min) and decreases the overall analgesic requirement. Average discharge time was significantly lower with CP. Ropivacaine dramatically improved patient satisfaction scores. They concluded that ropivacaine was linked to improved analgesia, lower analgesic needs, and higher patient satisfaction, which may make it a more attractive alternative even if CP use led to quicker discharge times.

It was observed that bradycardia found in one patient in group C (3.33%) and two patients (6.66%) in group R. Shivering and hypotension in one (3.33%) in each group, which were statistically insignificant (P>0.05). There were no episodes of respiratory depression, dyspnea, chest pain, dysrhythmia, or TNS in either study group.

Limitations of the study

The block in the Chloroprocaine group regressed earlier and faster, and the blinded observer was able to determine the group to which the subject had been assigned. This was reduced by using a single blindfolded observer to collect all the data throughout the whole investigation.

CONCLUSION

We concluded that intrathecal CP is associated with faster block resolution, earlier hospital discharge, and early ambulation with minimal side effects. Hence, intrathecal CP can be used as better alternative to ropivacaine for day-care surgeries such as inguinal hernia surgery. However, time to achieve sensory and motor blockade, intraoperative hemodynamic parameters, and side effects were comparable and both provides an excellent quality of analgesia.

ACKNOWLEDGMENT

We are thankful to our colleagues, guide, teachers, and head of the department of anesthesiology, for their guidance and support during study period.

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Authors' Contributions:
SPT- Literature survey, prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, manuscript preparation and submission of article; **SG-** Concept, design, clinical protocol, manuscript preparation, editing, manuscript revision and supervision; **AG -**Design of study, statistical analysis and interpretation; **KA-** Concept, coordination and preparation of manuscript; **PG-** Proofreading and revision of manuscript.

Work attributed to:
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Source of Support: Nil, **Conflicts of Interest:** None declared.