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A COMPARATIVE STUDY ON EFFECT OF ADDITION OF CLONIDINE AND FENTANYL AS ADJUVANTS TO LOCAL ANAESTHETICS FOR SUBARACHNOID BLOCK IN PATIENTS UNDERGOING LAMINECTOMIES FOR SPINAL STENOSIS

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ABSTRACT

Background- To evaluate the clinical efficacy of clonidine 75 µg versus fentanyl 25 µg as adjuvants to bupivacaine for spinal anesthesia.

Methods- A prospective, randomized, parallel arm study was conducted on 60 continuous patients undergoing elective lumbar laminectomy were assessed for eligibility to be included in the study. Informed consent was taken from all the patients after describing the purpose of the study and explaining the anesthetic procedure in detail. Sixty patients were divided randomly into two groups, Group C and Group F. Patients in Group C received 2.5 ml of 0.5% bupivacaine heavy mixed with 0.5 ml (75 µg) clonidine intrathecally, and patients in Group F received 2.5 ml of 0.5% bupivacaine heavy mixed with 0.5 ml (25 µg) fentanyl intrathecally.

Results- The mean onset of sensory block was 3.26 and 3.12 min in Group C and Group F while complete sensory block was achieved in 10.26 and 10.46 min, respectively, which was statistically not significant. The total mean durations of sensory block were 264.68 and 242.36 min in Group C and Group F, respectively, which were again statistically not significant. The mean onset periods of motor block were 3.27 and 3.12 min in Group C and Group F and the time to complete motor block were 12.1 and 13.2 min in Group C and Group F, respectively. The differences in onset and time to complete motor block were statistically not significant. The total duration of motor block was 302.65 and 293.65 min, respectively, in Group C and Group F. The differences in total duration of motor block were statistically not significant.

Conclusion- Both clonidine 75 µg and fentanyl 25 µg when used as adjuvants to bupivacaine in the subarachnoid block have comparable beneficial results in terms of duration of analgesia, duration of motor blocks, and hemodynamic stability and also have a comparable incidence of complications.

KEYWORDS : Fentanyl, Clonidine, bupivacaine , Spinal anesthesia

INTRODUCTION

General anesthesia is the technique of choice for lumbar laminectomies; however, other alternatives include spinal or epidural anesthesia. Several studies have shown that spinal anesthesia is as safe and effective as general anesthesia for patients undergoing lumbar laminectomy[1]. The potential advantages of spinal anesthesia include decreased antiemetic and analgesic requirements and fewer complications.

Spinal anesthesia avoids many of the deleterious physiological consequences of the prone position, which are seen under general anesthesia. Spinal anesthesia may reduce blood loss as an effect of decreased peripheral venous pressure. The use of spinal anesthesia has lower incidence of pulmonary complications compared with general anesthesia. Spinal anesthesia also allows the patient to position their extremities and chest as needed to avoid brachial plexus palsy or pressure necrosis.[2]

Clonidine hydrochloride is an imidazoline derivative that acting centrally on alpha-2 adrenergic receptors as an agonist. The chemical name for clonidine is 2-((2,6-dichlorophenyl) amino)-2-imidazoline hydrochloride. Clonidine, as an alpha-adrenergic agonist in the nucleus tractus solitarii (NTS), excites a pathway that inhibits excitatory cardiovascular neurons. [3]

Fentanyl is a synthetic opioid with short-acting analgesic activity after intravenous or subcutaneous administration. The low molecular weight, high potency and lipid solubility of fentanyl make it suitable for delivery via the transdermal therapeutic system (TTS). These systems are designed to release the drug into the skin at a constant rate ranging from 25 to 100 micrograms/h , multiple systems can be applied to achieve higher delivery rates. Initially, much of the clinical experience with fentanyl TTS was obtained in patients with acute postoperative pain. [4]

MATERIAL AND METHODS

A prospective, randomized, parallel arm study was conducted on 60 continuous patients undergoing elective lumbar laminectomy were assessed for eligibility to be included in the study. Informed consent was taken from all the patients after describing the purpose of the study and explaining the anesthetic procedure in detail.

INCLUSION CRITERIA-

The patients undergoing lumbar laminectomy, aged more than 18 years of either sex or body weight of 50 kg and above and the American Society of Anesthesiologists (ASA) physical status of I or II, were included in the study.

EXCLUSION CRITERIA-

Patients who were unwilling for the procedure, ASA physical status III and above, patients with a history of allergy to local anesthetics, bleeding disorders, or patients on anticoagulant therapy were excluded from the study.

METHODS-

Sixty patients, who met the inclusion criteria, were divided randomly into two groups, Group C and Group F. Randomization was carried out by drawing any one of the two labeled cards (Groups C and F) from a sealed opaque envelope. Patients in Group C received 2.5 ml of 0.5% bupivacaine heavy mixed with 0.5 ml (75 µg) clonidine intrathecally, and patients in Group F received 2.5 ml of 0.5% bupivacaine heavy mixed with 0.5 ml (25 µg) fentanyl intrathecally. The total volume of solution administered in the subarachnoid space was 3 ml in both groups.

Sensory block was evaluated by Hollmen scale and recorded at an interval of every 2 min until the complete sensory block was achieved. Onset time of sensory block was taken as the time interval from the time of administration of SAB till sensory block, with a Hollmen score of 1, was achieved. Time for complete sensory block was taken as the duration of time in minutes from SAB till complete sensory block, with a Hollmen score of 4, was achieved. The total duration of sensory block was taken as the duration from onset of sensory block to the time when a Hollmen score of <4 were recorded in the postoperative period.

Motor block was evaluated using modified Bromage score for lower extremity, and the finding was recorded every 2 min from SAB till complete motor block was achieved. Onset time of motor block was taken as the time interval in minutes from SAB to the time, a modified Bromage score of 1 was achieved. Time for complete motor block was taken as the duration of time in minutes from SAB till complete motor block, with a modified Bromage score of 3, was achieved. Total duration of motor block was taken as the duration of time in minutes from onset to the time when a modified Bromage score of <3 were recorded in the postoperative period.

DATA ANALYSIS-

Data were analyzed with statistical software 'IBM SPSS Statistics for Windows, Version 20.0. (Armonk, NY: IBM Corp)' and Chi square tests were applied for categorical variables and continuous variables were compared using one-way ANOVA test. Data are expressed in terms of mean and standard deviation. *P* value was reported at the 95% confidence interval, and only $P < 0.05$ was considered statistically significant.

RESULTS

Table 1. Socio-demograpghic variable

Variable	Group C	Group F	p-value
Age in yrs	53.6±2.31	53.32±2.31	0.254
Weight in kg	63.24±8.65	63.85±9.32	0.695
Height in cm	172.36±10.23	174.24±11.32	0.695
ASA grade (I:II)	22:8	21:9	0.864
Duration of surgery (mint.)	102.36±12.65	100.25±11.98	0.98

Out of total sixty patients, majority of the patients were in the age group of 51–60 years in both groups. The mean age was 53.6 years in Group C and 53.32 years in Group F, which was statistically not significant. The mean weights of patients were 63.24 and 63.85 kg and mean heights were 172.36 and 174.24 cm in Group C and Group F, respectively, and were statistically not significant. Both groups were comparable with respect to age, sex, and ASA grade distribution.

Table 2. Comparison of sensory block

Variable	Group C	Group F	p-value
Onset sensory block (mint.)	3.26±0.98	3.12±1.12	0.254
Time for complete sensory block (mint.)	10.26±1.6	10.46±1.89	0.695
Total duration sensory block (mint.)	264.68±41.35	242.36±43.18	0.695

The mean onset of sensory block was 3.26 and 3.12 min in Group C and Group F while complete sensory block was achieved in 10.26 and 10.46 min, respectively, which was statistically not significant. The total mean durations of sensory block were 264.68 and 242.36 min in Group C and Group F, respectively, which were again statistically not significant

Table 3. Comparison of motor block

Variable	Group C	Group F	p-value
Onset motor block (mint.)	3.27±0.99	3.12±0.88	0.456
Time for complete motor block (mint.)	12.8±1.81	13.2±1.92	0.62
Total duration motor block (mint.)	302.65±38.25	293.65±41.35	0.56

The mean onset periods of motor block were 3.27 and 3.12 min in Group C and Group F and the time to complete motor block were 12.8 and 13.2 min in Group C and Group F, respectively. The differences in onset and time to complete motor block were statistically not significant. The total duration of motor block was 302.65 and 293.65 min, respectively, in Group C and Group F. The differences in total duration of motor block were statistically not significant.

Table 4. Duration of post-operative analegesia

Duration of post-operative analegesia	Group C	Group F	p-value
(mint.)	634.23±123.21	611.54±99.23	0.087

There was no statistically significant difference between the two groups when the mean duration of postoperative analgesia was compared.

DISCUSSION

Decompressive laminectomies of the lumbar spine have been practiced extensively both under general or central neuraxial blockade. The advantages of using general anesthesia for lumbar laminectomies include the ability to carry out prolonged operations in the prone position, with adequate airway control.

Alternatively, the advantages of spinal anesthesia are, decrease in intraoperative blood loss and consequently improved operative conditions, decreased postoperative hypoxemic episodes, decreased arterial and venous thrombosis, lesser incidence of brachial plexus injury and pressure necrosis, and better postoperative pain control[5]

Opioids and α_2 agonists are used as adjuncts to SAB to improve the quality of block, quality of anesthesia, and prolongation of analgesia in the postoperative period. Efficacy of intrathecal opioid to relieve visceral pain and somatic pain is well established.[6,7] Antinociceptive action of clonidine also exists for both somatic and visceral pain. Clonidine being a lipophilic drug, it is possible to achieve analgesia, with its systemic, epidural, or intrathecal administration. However, clonidine is more potent after neuraxial than systemic administration, indicating a spinal site of action[8]

Fentanyl, a highly lipophilic opioid, has been combined with bupivacaine for SAB. The synergism between intrathecal local anesthetic agents and opioids such as fentanyl is well established. Various doses from 10 to 30 µg have been used intrathecally for labor and postoperative pain relief for lower abdominal surgeries[9,10] Lower doses do not enhance postoperative analgesia and doses higher than 30 µg cause mild to moderate side effects such as pruritus. Hence, a dose of 25 µg fentanyl for intrathecal administration was chosen for this study.

Singh *et al*. studied the effect of oral clonidine 200 µg and intrathecal fentanyl 10 µg on the onset and duration of hyperbaric tetracaine-induced spinal block.[11] In their study, intrathecal fentanyl 10 µg did not change the onset or duration of tetracaine-induced spinal block. However, oral clonidine 200 µg shortened the onset time of tetracaine's sensory block and prolonged the duration of sensory and motor block.

However, clonidine premedication increased the risk of hypotension and bradycardia. However, in our study 75 µg clonidine and 25 µg fentanyl were administered intrathecally, and no difference was observed in complication rate in intra-operative and post-operative period between the two groups.

Islam *et al*. compared the complications, quality of anesthesia, and duration of postoperative analgesia with the use of adjuvant clonidine 75 µg or fentanyl 25 µg with hyperbaric bupivacaine in SAB for cesarean section[12] The study revealed that subarachnoid clonidine and fentanyl, as adjuvant with low-dose hyperbaric bupivacaine, provides better quality of block, better quality of anesthesia, more hemodynamic stability, and longer duration of postoperative analgesia, compared to bupivacaine alone.

It is also revealed that clonidine is a better alternative to fentanyl as an adjuvant with bupivacaine in SAB. However, in this study, we found that both clonidine 75 µg and fentanyl 25 µg as adjuvants to bupivacaine in SAB have comparable results in terms of duration of motor and sensory blocks and duration of analgesia.

CONCLUSION

Both clonidine 75 µg and fentanyl 25 µg when used as adjuvants to bupivacaine in SAB have comparable results in terms of duration of motor and sensory blocks and duration of analgesia. This study was conducted on patients undergoing lumbar laminectomies; however, both clonidine and fentanyl at these doses, when used as adjuvants to bupivacaine in SAB, will be beneficial to patients undergoing any infraumbilical surgery.

Conflict of interest:- There is no conflict of interest between authors.

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