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A comparative study between clonidine, fentanyl, and buprenorphine as adjuvants to intrathecal 0.5% hyperbaric bupivacaine in lower abdominal and lower limb surgeries

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Abstract

Background and Objectives: Spinal anesthesia is the most convenient anesthetic technique that offers many advantages over general anesthesia, including reduced stress response and improved post-operative pain relief. Hyperbaric Bupivacaine is routinely used for this purpose because of its high potency and minimal neurological symptoms. The administration of local anesthetics in combination with opioids intrathecally is an excellent technique for managing postoperative pain following abdominal, pelvic, and orthopedic procedures on the lower extremities. This study is designed to compare the clinical effects of the addition of adjuvants fentanyl, clonidine, and buprenorphine to intrathecal hyperbaric bupivacaine for major lower limb and lower abdominal surgeries.

Methods: 90 patients belonging to ASA physical status I & II scheduled for lower abdominal and lower limb surgeries were randomly selected for the study. They were divided into three groups of 30 each. Patients received intrathecal injections as follows: Group BF: Bupivacaine (15 mg) + Fentanyl (25 mcg), Group BC: Bupivacaine (15 mg) + Clonidine (50 mcg), Group BB: Bupivacaine (15 mg) + Buprenorphine (75 mcg). Parameters - onset, and duration of sensory block, onset and duration of motor block, the height of sensory block, hemodynamic parameters, and adverse effects if any were studied.

Results: The three groups had no significant difference in the mean time to onset of peak motor block (p-value 0.314). Still, the onset of the sensory block within group BF was 1.80±0.74 minutes, 1.94±0.49 minutes in group BC, and 2.28±0.46 minutes in the BB group(P value 0.006) indicating the faster onset of action in fentanyl group. The maximum sensory height attained ranged between T6 and T8 in both groups, which was clinically and statistically not significant (p-value 0.390). The mean duration of the sensory block was 306.2±29.21 minutes in Group BF, 358.27±44.68 in Group BC, and 347.08±46.62 minutes in Group BB with p value<0.001 which is statistically significant. The mean duration of the motor block in Group BF was 168.9±13.54, Group BC was 191.7±24.82 and that of Group BB was 177.27±22.53 with p-value <0.001. The quality of intraoperative analgesia, hemodynamic parameters, and side effects were comparable in all three groups.

Conclusion: The addition of Fentanyl (25 µg) was found to have a faster onset and a shorter duration of action which is advantageous where early ambulation is appreciated. Clonidine (50 µg) and Buprenorphine (75 µg) increase the duration of both sensory and motor block with less hemodynamic instability therefore can be a good choice in prolonged lower abdominal and lower limb surgeries.

Keywords: Bupivacaine, fentanyl, clonidine, buprenorphine, intrathecal

Introduction

The greatest gift that God has given to mankind is not happiness but relief from pain. Since time immemorial, many attempts have been made to relieve pain, particularly pain during and after surgery. Spinal anesthesia was introduced into clinical practice by Karl August Bier in 1898 [1]. More than a century has passed; even today, it is one of the most popular elective and emergency surgical techniques. It is simple to perform, offers rapid onset of action, has relatively fewer side effects, allows the patient to remain awake and minimizes or completely avoids problems with airway management, economical and rapid turnover has made this anesthetic technique the choice of many surgical procedures [2]. Lower abdominal and lower limb surgeries may be performed under local, regional (spinal or epidural), or general anesthesia. Spinal block is still the first choice because of its rapid onset, superior blockade, low risk of infection as from catheter in situ, lower failure rates, and cost-effectiveness.

Still, it possesses the limitations of brief block duration and inadequate postoperative analgesia. The versatility of spinal anesthesia is afforded by a wide range of local anesthetics and additives that allow control over the level, time of onset, and duration of spinal anesthesia [3].

Buprenorphine, a μ receptor partial agonist with low intrinsic activity can be safely used in subarachnoid blocks. It prolongs the duration of sensory block and thus decreases the need for postoperative analgesia [4]. It also has high lipid solubility and the highest affinity for opiate receptors [4]. It is compatible with CSF and produces no or minimal adverse reactions like pruritis and nausea. It has high molecular weight and is lipophilic which may prevent its rostral spread and thus respiratory depression. Fentanyl, which belongs to an opioid family, with μ receptor agonist opioid. Intrathecally It exerts its effect by combining with opioid receptors in the dorsal horn of the spinal cord and may have a supraspinal spread and action. The effectiveness of Intrathecal opioids depends on their bioavailability [5]. The addition of intrathecal Fentanyl as an adjuvant to spinal anesthesia produces a faster onset time and excellent quality peri-operative analgesia. Clonidine is a selective partial agonist for α2 adrenergic receptors and it is the most studied drug used for neuraxial anesthesia. It is more potent after neuraxial than systemic administration, known to prolong both sensory and motor block of local anesthetics, indicating the spinal site of action and favoring neuraxial administration [6]. Clonidine being moderately lipid soluble, provides effective and long-lasting post-operative analgesia due to its ability to penetrate the blood-brain barrier and activate cholinergic pathways, and thus provides effective and long-lasting post-operative analgesia. Recently, Clonidine has also been shown to increase acetylcholine (Ach) levels in lumbar cerebrospinal fluid, as cholinergic activation imparts analgesia. It may also cause local vasoconstriction [6]. Intrathecal α2 agonistic action of clonidine results in antinociceptive action for both somatic and visceral pain.

This study was designed as an attempt to evaluate the effectiveness of adding 75 mcg buprenorphine 50 mcg clonidine and 25 mcg fentanyl to 0.5% hyperbaric bupivacaine for spinal anesthesia and also to study the various effects and side effects and duration of post-op analgesia with these three drugs as adjuvants.

Methodology

This clinical study was conducted on a hundred adult patients of ASA physical status I & II in the age group of 18 to 65 years, of either sex, posted for elective major lower limb &lower abdominal surgeries under spinal anesthesia after taking informed consent at Chigateri General Hospital, Woman and Children Hospital, and Bapuji Hospital attached to J.J.M. Medical College, Davangere, during the academic year from December 2015 to August 2017. After institutional committee approval and written informed consent, a comparative study was carried out on ninety adult patients. Patients were randomly divided on an alternative basis into three groups of thirty each and received intrathecal injection with the following drug- Group BB: 3cc of 0.5% hyperbaric bupivacaine (15 mg) + 0.5cc Buprenorphine (75 μg), Group BC: 3cc of 0.5% hyperbaric bupivacaine (15 mg) + 0.5cc Clonidine (50 μg), Group BF**:** 3cc of 0.5% hyperbaric bupivacaine (15 mg) + 0.5cc Fentanyl (25 μg)]. Patients giving valid informed consent, ability to comprehend the full nature and purpose of the study, including possible risks and side effects, and ability to co-operate and comply with the requirements of the entire study. The exclusion criteria were patient refusal, pregnancy, contraindications to spinal anesthesia, history of neuromuscular diseases to the lower extremities, ASA physical status III-V, allergy: ascertained or presumptive hypersensitivity to the active principle and/or formulations ingredients, diseases: ascertained psychiatric and neurological diseases, drug: history of drug abuse, therapeutic use of opioids, bleeding coagulopathy. Pre-anesthetic checkup was carried out with a detailed history, general physical examination, and systemic examination including airway and spinal column assessment. The following laboratory examinations were done - hemoglobin, urine analysis, blood sugar, blood urea, serum creatinine, coagulation profile, blood grouping and Rh typing, electrocardiogram, and chest x-ray. The patient's weight and height were also recorded. All patients were kept nil orally for 8-10 hours.

Preoperatively, the patient's informed written consent was taken. Nil per oral status was confirmed. The procedure of subarachnoid block was explained and the patient was informed to communicate with the anesthesiologist about the perception of pain or discomfort during surgery. Following arrival into the operation theatre, intravenous access is established with an 18G or 20G IV cannula on the forearm and Lactated Ringer's Solution 10 ml/kg was infused before the block. Multipara monitors (ECG, noninvasive blood pressure, pulse oximeter) are attached and baseline parameters are recorded. Patient in sitting or left lateral position, under aseptic precautions subarachnoid block is performed with a 25 G spinal needle (Quinckes needle), and the patient receives one of the three study drugs.

- [Group BB: 3cc of 0.5% hyperbaric bupivacaine(15 mg) + 0.5cc Buprenorphine(75 mcg)]
- [Group BC: 3cc of 0.5% hyperbaric bupivacaine(15 mg) + 0.5cc Clonidine(50 mcg)]
- [Group BF: 3cc of 0.5% hyperbaric bupivacaine(15 mg) + 0.5cc Fentanyl(25 mcg)]

Heart rate, blood pressure, and oxygen saturation are to be monitored throughout the study. Hypotension was defined as a 20% decrease in blood pressure from baseline values, and was treated with intermittent IV boluses of ephedrine 6 mg Bradycardia was defined as a heart rate less than 60 bpm and treated with IV atropine 0.6 mg. After administration of spinal anesthesia, oxygen (5 L/min) by facemask was given. Fluid therapy was maintained with lactated Ringer's solution (10 ml/kg/hour). The level of sensory (pin prick method) and motor block (Modified Bromage Scale) is to be evaluated at 2, 4, 6, 8, and 15 minutes and thereafter at 15-minute intervals for 6 hours. The pain was assessed by a visual analog scale (VAS) score. All the patients were instructed about the VAS and to point out the intensity of pain on a scale of 0-no pain, and 10-worst pain. Duration of effective analgesia was defined as the time from the intrathecal injection to VAS <5 and duration of rescue analgesia as the time from the intrathecal injection to VAS >5 with the time taken for the first pain medication. Analgesics were avoided until demanded by the patients. Complications such as bradycardia, hypotension, nausea & vomiting, pruritus, and shivering, if any are noted

intraoperatively. Postoperatively duration of analgesia as per time to requirement of first analgesic rescue, duration of the motor blockade is calculated from the onset of loss of any voluntary motor movement to appearance of first voluntary movement postoperatively, complications if any.

Data Analysis and Interpretation

Data was entered into Microsoft Excel (Windows 7; Version 2007) and analyses were done using the Statistical Package for Social Sciences (SPSS) for Windows software (version 20.0; SPSS Inc, Chicago). Descriptive statistics such as mean and standard deviation (SD) for continuous variables, frequencies, and percentages were calculated for categorical Variables. Association between the anesthesia Group and other categorical Variables like Gender were analyzed using the chi-square test of independence. Comparison of the mean of various quantitative variables like Heart rate were analyzed using ANOVA (Analysis of Variance). Bar charts and Pie charts were used for visual representation of the analyzed data. Line diagrams were used to show trends of Heart Rate, SBP & DBP Over time. The level of significance was set at 0.05.

Results

The mean age in Group BF is 40.50±12.99 years the mean age in Group BC is 37.30±9.31 years and the mean age group in Group BB is 36.37±9.45 years with a p value of 0.298 is comparable among the three groups. There were equal number of males (18) and females (12) in all three groups. 24 participants were belonging to ASA I in group BF, 26 in group BC, and 24 in group BB. ASA II patients were 6 in Group BF, 4 in Group BC, and 6 in Group BB. This was statistically not significant with a p-value of 0.738. ASA III & IV were not taken as per the exclusion criteria. The mean height in group BF is 166.30±6.19 cms, 167.0±4.59 cms in group BC, and 167.8±4.24 in group BB with a p-value of 0.204. The mean weight is 60.2±10.24 kg in group BF and is 60.2±6.31 kg in group BC and 60.93±5.88 in group BB with a p-value of 0.914. There is no statistically significant difference between the two groups with regards to height and weight, the samples are height and weight-matched. The mean onset of time for the sensory block was 1.80±0.74 in group BF, 1.94±0.49 in group BC, and 2.28±0.46 in group BB which is statistically comparable with a significant p-value (0.006), suggesting that BF group has a faster onset of sensory block compared to group BC and BB. The onset of the motor blockade in Group BF was 2.68±0.56 minutes and was 2.93±0.69 minutes in Group BC and 2.86±0.66 in Group BB with a p-value of 0.314 No statistical significance for the type of surgery between the three groups. The highest level of block achieved in Group BF was T6 with 22(73.3%) of patients achieving it. The highest level of block achieved in Group BC was T6 with 25(83.3%) of patients achieving it and that with Group BB was T6 with 26(86.7%) patients achieving it. These findings were clinically and statistically not significant in the current study. Complete motor blockade was observed in all patients in Group BF and BC and 93.3% of patients in Group BB with a p-value of 0.129, which is statistically insignificant. The mean value for the duration of the Sensory block was 306.2±29.21 minutes in Group BF, 358.27±44.68 in Group BC, and 347.08±46.62 minutes in Group BB with p value<0.001 which is statistically significant. The mean duration of the Motor block in Group BF was 168.9±13.54, Group BC was 191.7±24.82 and that of Group BB was 177.27±22.53 with p-value <0.001.Major findings are summarized in Table 1.

Table 1: Findings of the study variables in different group

		GROUP			P Value
		BF	BC	BB	
Onset of Blockade (MIN)	SENSORY	1.80 (0.74)	1.94 (0.49)	2.28 (0.46)	0.006
	MOTOR	2.68 (0.56)	2.93 (0.69)	2.86 (0.66)	0.314
Highest Level of Sensory Block	T6	22 (73.3)	25 (83.3)	26 (86.7)	0.390
	T8	8 (26.7)	5 (16.7)	4 (13.3)	
Degree of Motor Blockade	2	0 (0.0)	0 (0.0)	2 (6.7)	0.129
	3	30 (100.0)	30 (100.0)	28 (93.3)	
Duration of Blockade (MIN)	SENSORY	306.2 (29.21)	358.27 (44.68)	347.0 (46.62)	<0.001
	MOTOR	168.9 (13.54)	191.7 (24.82)	177.27 (22.53)	<0.001

In our study, all the groups had variation in heart rate which is significant except at the early period of the surgery which is clinically insignificant ($p \geq 0.05$) without significant side effects. There was no significant change in heart rate following subarachnoid block between the three groups. The heart rates were comparable in all three groups without any clinical or statistical significance. In our study, there was a significant fall in diastolic blood pressure in the BB and BC groups following subarachnoid block compared to the BF group. However, there were no significant differences in DBP towards the end of the surgery. Hypotension was seen in 13.3% of the patients in Group BC, and Group BF and BB showed 6.7%. Bradycardia was seen in 3.3% of all the three groups. Nausea and Vomiting were seen in 3.3% of the participants in Group BB. 3.3% of patients in the BF group and none in the BC and BB group experienced pruritus in our study. It was found that there were no significant comparable side effects between the three Groups.

Discussion

Spinal anesthesia involves injecting a local anesthetic solution into the cerebrospinal fluid, temporarily blocking nerve transmission within the subarachnoid space and is being used widely, safely, and successfully, for almost 100 years. It is an inexpensive and easy-to-administer technique that also offers a high level of post-anesthesia satisfaction for patients. Spinal anesthesia has many potential advantages over general anesthesia especially for operations involving the lower abdomen, perineum, and lower extremities. Opioids added to local anesthetic for spinal anesthesia were first introduced into clinical practice in 1979 with morphine as a forerunner [7]. Opioids administered together with local anesthetics intrathecally,

reduce the requirement of local anesthetic, resulting in a shorter duration of motor block as well as significantly extended postoperative analgesia without prolonging the recovery and producing minimal side effects. Clonidine being a selective partial agonist for α_2-adrenoreceptors, is known to increase both sensory and motor block of local anesthetics. The analgesic effect following intrathecal administration is mediated spinally through the activation of postsynaptic α_2-adrenoreceptors in the substantia gelatinosa of the spinal cord and it works by blocking the conduction of C and Aδ fibers[8]. This study aimed to evaluate and compare the efficacy of analgesia, hemodynamic parameters, and also the side effect profile of three very commonly used adjuvants to hyperbaric bupivacaine in routine practice, ie Clonidine Fentanyl and Buprenorphine, in patients undergoing elective lower abdominal and lower limb surgeries.

Our study design consisted of 90 patients aged between 18-65 years of either sex, ASA physical status I and II undergoing elective major lower limb and lower abdominal surgery under spinal anesthesia were randomly divided into three groups of 30 each Group BB: 3cc of 0.5% hyperbaric bupivacaine (15 mg) + 0.5cc Buprenorphine (75 mcg), Group BC: 3cc of 0.5% hyperbaric bupivacaine (15 mg) + 0.5cc Clonidine (50 mcg) and Group BF: 3cc of 0.5% hyperbaric bupivacaine (15 mg) + 0.5cc Fentanyl (25 mcg)

DEMOGRAPHIC PROFILE ACROSS THE GROUP: In our study, the majority of patients were middle-aged in both groups. In group BF there were 12 females and 18 males, in group BC there were 12 females and 18 males and in group BB there were 12 females and 18 males. The mean height and the mean weight in either group were also comparable. The types of surgeries performed were also identical in both groups. These parameters were kept identical in both groups to avoid variations in intraoperative and postoperative outcomes of patients.

Onset Of Sensory And Motor Blockade: In our study, the mean time of onset of sensory block in group BF was 1.80±0.74 minutes, 1.94±0.49 minutes in group BC, and 2.28±0.46 minutes in the BB group. The mean time for the onset of motor block in group BF was 2.68±0.56 minutes, in group BC was 2.93±0.69, and in group BB was 2.86±0.66 minutes. There was a statistically significant difference in the onset of sensory between the groups with faster onset in group BF as compared to group BC and group BB. In a study conducted by Pritam Jadhav *et al.*, it was observed that the onset of sensory and motor block was comparable with clonidine and fentanyl. Fentanyl is faster in onset, which correlates to our current study. Our findings were comparable to the study done by F A Khan *et al.* [9], who compared low-dose Fentanyl and Buprenorphine as adjuvants to spinal anesthesia on sixty patients scheduled for elective transurethral resection of the prostate (TURP). They concluded that the use of Bupivacaine with Fentanyl spinal anesthesia resulted in the earlier onset of both sensory and motor block compared to Bupivacaine and Buprenorphine. A similar study conducted by Krishnakumar Srinivasagam *et al.* [10] compared the same drugs as our present study as adjuvants to hyperbaric bupivacaine for lower abdominal surgeries and the study found that all three drugs resulted in a faster onset of sensory block, with no significant difference in onset time between the groups. Another study conducted by Deepak V. Dhummansure, S. G. Patil *et al.* [11], compared clonidine and fentanyl as adjuvants to hyperbaric bupivacaine. They concluded that the onset time for sensory and motor block is comparable between the two groups.

Degree of motor block: In our study, we observed that 100% of the patients attained complete motor block in group BF and BC and 93.3% attained complete motor block in group BF, which is statistically not significant. These findings correlate with the studies done by Deepak V. Dhummansure *et al.* [11], and F A Khan *et al.* [9].

DURATION OF SENSORY BLOCKADE: A study done by Krishnakumar Srinivasagam *et al.* [10], stated that the difference in duration of analgesia was also significant in all three 3 groups being the longest in group BC and lowest in group BF (195.83±7.30 min). The duration of the sensory block with group BC was (353.19±7.69 min) which is comparable to our study of 358.27±44.68. The duration of analgesia with buprenorphine was 294±17.93 minutes. In another study conducted by Deepak V. Dhummansure *et al.* [11], which compared fentanyl and clonidine as adjuvants found that the mean duration of sensory block in group C was 343.67 min, and in group F, the mean duration of sensory block was 250.83 min. Both of these values are correlating to our present study. Negi A S, Gupta M *et al.* [12], found that there was significant prolongation of sensory block (355.8±63.85 vs 283.20±53.80) in patients who received intrathecal clonidine compared to intrathecal buprenorphine. These findings are correlating with our present study. In a study conducted by Pritam Jadhav *et al.* [27], although time of onset sensory and motor blockade was faster in Fentanyl compared to clonidine. The duration of sensory and motor block was significantly higher with Clonidine than Fentanyl. These findings correlate with the current study. Shailaja S [13] conducted a comparative study on intrathecal clonidine 60 µg versus intrathecal buprenorphine 60 µg. Intrathecal Buprenorphine 60µg gives adequate analgesia up to 818.9±135 min mins to significantly longer than that of intrathecal clonidine i.e. 686.5±41.9 min which does not correlate with our study findings. In another study done by Marzieh Beigom Khezri *et al.* [14], the duration of anesthesia, and the mean time to first analgesic request was also significantly longer in group Clonidine (519.44±86.25) than in group Fentanyl (277.88±97.25). The duration of group Fentanyl in this study is comparable to the current study. The mean value for the duration of the Sensory block was 306.2±29.21 minutes in Group BF, 358.27±44.68 in Group BC, and 347.08±46.62 minutes in Group BB with p value<0.001 which is statistically significant.

Duration of motor blockade: In a study done by Krishnakumar Srinivasagam *et al.* [15], the duration of motor block in group BF (151.27±12.02 min) shows that fentanyl does not prolong it as supported by the current study. However, they found that Clonidine significantly prolongs the duration of motor block up to 254.67±72.05 minutes as supported by the studies of Elia *et al.* [14] and also our current study. However, this was in contrast to the study of kabbachi *et al.* [10], who concluded that the addition of 2µg/kg Clonidine (= 100µg) to hyperbaric 0.5% bupivacaine does not prolong the duration of motor block. Jahnabee Sarma *et al.* [16], also stated that bupivacaine with clonidine

50 µg has a comparable duration of motor block as our current study. In the study done by Negi A S, Gupta M, *et al.* [12], it was found that there was significant prolongation of motor block (277.9±37.56 vs 198.8±42.21) with clonidine 37.5 µg compared to patients who received buprenorphine 75µg. These findings are in contrast with the study done by Sapkal Pravin S *et al.* [2], which concluded that intrathecal Buprenorphine 60µg gives adequate analgesia up to 818.9±135 min mins which is significantly longer than that of intrathecal clonidine i.e. 686.5±41.9 min. In our study, the mean duration of the Motor block in Group BF was 168.9±13.54, which is lower than Group BB was 177.27±22.53. Group BC was found to have a maximum duration of motor block of 191.7±24.82. These findings are in affirmation of the above studies.

Hemodynamic parameters and side effects: Hypotension was seen in 13.3% of patients in Group BC compared to 6.7% in Group BF and BB. This was supported by the study done by Krishnakumar Srinivasagam *et al.* [15] and also Elia N *et al.* [17]. Bradycardia was seen in 3.3% of the patients in all three groups with no significant fall in either of the groups. The most significant side effects reported about the use of intrathecal α2 adrenoreceptor agonists are bradycardia and hypotension. In the present study, these side effects were not significant probably because we used small doses of intrathecal clonidine, buprenorphine, and fentanyl with high doses of local anesthetics. Pruritis is a well-known adverse effect of neuraxial narcotics was observed in a few patients but was not significant in 3.3% of patients in the BF group and none in the BB and BC group experienced pruritis. Nausea and vomiting were seen in 3.3% of patients in the BB group and none in the BF and BC group. Shivering was seen in 3.3% of patients in all three groups. However, according to Negi A S *et al.* [12], shivering was significantly lower in patients receiving intrathecal clonidine. The hemodynamic parameters heart rate, systolic blood pressure, and diastolic blood pressure were comparable between the groups, and no significant hemodynamic alteration was seen in the three groups in our study. Group BF and Group BB were more hemodynamically stable compared to Group BC but this was not significant as none of the groups led to a significant fall in hemodynamic parameters which required pharmacological intervention. The incidence of other side effects was also minimal.These findings were consistent with the studies done by Negi A S, Gupta M, *et al.* [12], and Mahendru V *et al.* [18]

Conclusion

Our study revealed that the addition of adjuvants like Fentanyl (25 µg), Clonidine (50 µg), or Buprenorphine (75 µg) intrathecally to 15 mg of hyperbaric bupivacaine for subarachnoid block gives adequate anesthesia for lower abdominal and lower limb surgeries. The Fentanyl group was found to have a faster onset of sensory block compared to the other two adjuvants in the study. The Fentanyl group also had better hemodynamic stability than the clonidine group and a lesser duration of motor and sensory block. Therefore it can be used successfully for surgeries of the lower abdomen and lower limb where early ambulation is appreciated. However, there was a significant prolongation of sensory and motor block with the Clonidine group than the Buprenorphine and Fentanyl group with minimal hemodynamic instability and side effects; hence can be used as an ideal adjuvant with hyperbaric bupivacaine in the subarachnoid block for long-duration surgical procedures.

Limitations

Single centered study with modest sample size

Conflict of Interest

Not available

Financial Support

Not available

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