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A COMPARISON OF INTRATHECAL DEXMEDETOMIDINE AND FENTANYL AS ADJUVANT TO HYPERBARIC BUPIVACAINE FOR LOWER ABDOMINAL AND LOWER LIMB PROCEDURES

Anaesthesiology

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ABSTRACT

BACKGROUND: Various adjuvants have been used with local anesthetics in spinal anesthesia to avoid intraoperative visceral and somatic pain and to provide prolonged postoperative analgesia. Dexmedetomidine, the new highly selective α2-agonist drug, is now being used as a neuraxial adjuvant. This study aimed to evaluate the onset and duration of sensory and motor block, hemodynamic effect, postoperative analgesia, and adverse effects of dexmedetomidine or fentanyl was given intrathecally with hyperbaric 0.5% bupivacaine.

MATERIALS AND METHODS: Sixty patients classified in the American Society of Anesthesiologists Classes I and II scheduled for lower abdominal and lower limb surgeries were studied. 30 patients in each group were randomly allocated to receive Inj. Bupivacaine 0.5% Hyperbaric 3ml (15mg) + Inj. dexmedetomidine 0.5ml (Inj. Dexmedetomidine 100mcg diluted with preservative-free normal saline with a concentration of 10mcg/ml) (group D, n=30) and Inj. Bupivacaine 0.5% Hyperbaric 3ml (15mg) + Inj. Fentanyl 25mcg (group F, n=30).

RESULTS: Sensory and motor block in group D patients were longer than group F patients.

CONCLUSION: Intrathecal dexmedetomidine when added to bupivacaine heavy (0.5%) provide better and prolonged analgesia in comparison to fentanyl.

KEYWORDS

Fentanyl, Bupivacaine, Intrathecal, Dexmedetomidine

INTRODUCTION

Neural anesthesia is becoming popular because of its ease of practice, fast onset, deep block, and cost-effectiveness. However, the high failure rate, limited duration of analgesia, and lack of knowledge limit its acceptance. Various improvements have been done in the technique and drugs to curtail the undesirable events and increase the efficiency in a precise direction. The addition of adjuvants such as fentanyl, dexmedetomidine to bupivacaine is one of the alterations, which can improve the outcome [1].

Postoperative pain, however, is an important concern, as the medications used have a limited duration of action compelling postoperative analgesia administration. To extend the duration and minimize side effects, combinations of other types of analgesics with local anesthetics have been used [2].

In modern anesthesia, small doses of adjuvants are added to local anesthetics to fasten the time of onset, improve the quality of intraoperative anesthesia, prolong analgesia, and reduce the complications associated with high-dose intrathecal administration of hyperbaric bupivacaine alone [3].

The subarachnoid block is the most commonly used technique for orthopedic lower limb and lower abdominal surgeries [4]. In perioperative and critical care settings, dexmedetomidine, a highly selective alpha2 adrenergic agonist, has evolved as a panacea for different applications and procedures. It is also a valuable addition to regional anesthesia and analgesia, where progressive studies have proved that central neuraxial blocks can be safe to use[5].

Based on earlier human studies, it is hypothesized that an intrathecal 5 mcg the dexmedetomidine would produce prolonged postoperative analgesia with hyperbaric bupivacaine in spinal anesthesia with minimal side effects [6].

The most frequently used opioids adjuvant fentanyl also provides prolonged perioperative analgesia and stable hemodynamics [7].

Fentanyl is a strong μ-receptor agonist. It is a lipophilic opioid with rapid onset following intrathecal injection. It improves the quality of postoperative anesthesia with few side effects.

Hence a study is designed to compare the effects of dexmedetomidine vs fentanyl to hyperbaric bupivacaine for lower abdominal and lower limb surgeries.

The objective of this study was to compare the onset and duration of the sensory and motor block, the duration of postoperative analgesia, and the hemodynamic parameters, while the secondary objective was to observe any complications or side effects of dexmedetomidine and to note the need for postoperative rescue analgesia [9].

MATERIAL & METHODS

After obtaining approval from the Institutional ethical committee and written informed consent from patients 60 patients belonging to ASA Grade I & II between age 20 to 60 years of both sexes, height >150cm, BMI <35kg/m^2 undergoing elective surgeries under spinal anesthesia for lower abdominal and lower limb surgery were included in the study. Whereas patients' refusal to participate in the study, allergy to study drugs, patients with uncontrolled cardiovascular disease, bronchospastic disease, hepatic or renal disease (ASA grade III or more) emergency surgeries, taking any adrenergic or psychotropic drugs, with difficult intubation, with Myasthenia Gravis or musculoskeletal disorder were excluded. Patients were divided into two groups of 30 each. Group D (*n*= 30) received 3ml 0.5% Bupivacaine with Dexmedetomidine 5mcg; total volume 3.5ml. Group F (*n*= 30) received 3ml 0.5% Bupivacaine with 25 μg Fentanyl to make a total volume of 3.5ml. Thorough preoperative evaluation was done. Investigations such as complete hemogram, blood grouping, urine microscopy, blood urea, creatinine, electrocardiogram (ECG), and chest X-ray were done.

Patients were kept nil by mouth for 6 hours before the procedure. All patients were premedicated by Tab. Pantoprazole 40mg orally the night before surgery. In the operating room, preloading was done with ringer lactate solution at 10 ml /kg. All patients were monitored with pulse oximetry, non-invasive blood pressure, and electrocardiogram.

Under all aseptic precautions, a subarachnoid block was given with 23-gauge Quincke's spinal needle in a sitting position. The drug was given over 10 to 15 sec. Immediately after completion of the block patient was given a supine position with a wedge under the right hip and Oxygen was administered at 4 L/min using a face mask. Hemodynamic monitoring such as heart rate (HR), systolic blood pressure (SBP) diastolic blood pressure, mean arterial pressure (MAP), ECG and SpO2 were done throughout the procedure.

The Following Parameters Were Studied

1.Sensory block - tested by pinprick method every 2 minutes. Following observations were noted

a) Time to reach sensory block at T10 dermatome
b) Maximum level of upward spread
c) Time to reach peak block hight
d) Time for two-segment regression
e) Time for a requirement for rescue analgesia (VAS pain score >3)

2. Motor block level was assessed by modified Bromage scale.[7]
3. Quantification of pain score was assessed by VAS pain score 0 – 10, where 0 is no pain & 10 being worst possible pain.
4. Haemodynamic variables were studied at 5 minutes intervals during the intra-operative period & 30-minute intervals in the postoperative period for 8 hours in the ward. Hypotension (i.e., SBP < 90 mm of Hg or MAP < 20 % from baseline) was treated with IV fluids, IV injection mephenteramine as needed. Bradycardia (HR <60 beats/min) was treated with inj. Atropine 0.6mg I.V. O2 supplementation was given through face mask @ 5L/min if Spo2 falls <90%.
5. Perioperative side effects like nausea, vomiting, tremor, headache, or any transient neurological symptoms were noted.
6. Level of sedation was assessed by Modified Ramsay Sedation Score.[4]

STATISTICAL ANALYSIS: Data was collected & analyzed using a one-tailed Students t-test (paired or unpaired as appropriate) for continuous variables & Chi-Square test for categorical data. Data analysis was done by an appropriate statistical method with statistical software SPSS Ver.20. (Statistical Package for the Social Sciences).

RESULTS

The groups were comparable for age, height, and ASA physical status. The characteristics of the sensory block are summarized in Table 1. There was no difference between groups D and F in the highest level of block achieved in the two groups (T4 dermatome). The time to reach peak level and block regression were significantly slower with the addition of intrathecal dexmedetomidine as compared with fentanyl, as both time to two-segment regressions and time to S2 regression were significantly more with intrathecal dexmedetomidine. There was a significant difference in the onset time to Bromage 3 motor block (296.67±39.42sec in group D and 353.67±45.37sec in group F) but the regression of motor block to Bromage 0 was significantly slower with the addition of dexmedetomidine [Table 1]. The time to rescue analgesia was significantly longer in group D as compared to group F. Although the patients in both groups remained hemodynamically stable intraoperatively, the mean sedation scores were found to be comparable & statistically not significant (p>0.05) preoperatively & intraoperatively. 24 hours VAS score in the postoperative period was less in the dexmedetomidine group as compared to the Fentanyl group. This difference was statistically significant (p<0.05).

There were no complications, such as respiratory depression (RR <10 breaths/min) & retention of urine, headache, back pain, residual neurologic deficit, or transient neurological symptoms in patients of either group [Table 2].

Table 1: Summary Of Results

	GROUP D (n=30) %	GROUP F (n=30) %	P value (Significance)
Maximum level of sensory block	T_4 dermatome	T_4 dermatome	0.925(NS)
Time from injection to highest sensory level (min)	7.93± 1.05	7.37 ± 0.83	0.023(S)
Time of two segment regression from the highest sensory level (min)	108.17± 10.33	101.40 ± 6.17	0.003(S)
Time for sensory block (min)	192.83± 13.56	172.17 ± 10.06	<0.0001 (HS)
Onset to Bromage 3 (sec)	296.67 ± 39.42	353.67± 45.37	<0.0001 (HS)
Regression to Bromage 0 (min)	171.03 ± 6.70	160.67± 10.31	<0.0001 (HS)
Duration of Surgery(min)	101.37± 10.42	101.97 ± 11.51	0.833(NS)
Postoperative Analgesia(min)	288.33± 22.06	234.00 ± 20.32	<0.0001 (HS)

***(NS): Not Significant, (S): Significant, (HS): Highly Significant**

Table 2: Side Effects In Two Groups

	GROUP D (n=30) %	GROUP F (n=30) %	P value (Significance)
Bradycardia	4	1	0.178(NS)
Hypotension	5	1	0.102(NS)
Nausea	0	1	0.317(NS)
Pruritis	0	2	0.157(NS)
Shivering	0	1	0.317(NS)

(NS): Not Significant

DISCUSSION

Uncontrolled pain in the postoperative period can have detrimental physiological and psychological effects. Pain can greatly impede the return of normal pulmonary functions such as inability to cough, bronchospasm which leads to atelectasis & hypoxemia especially in upper abdominal & thoracic surgeries. Pain promotes immobility & hence increases the risk of deep vein thrombosis. It also leads to the stress response, increased catecholamine release, increased oxygen demand & increased cardiac work. Increased catabolic response to surgical trauma impairs immune mechanisms & delays wound healing. Hence, adequate pain relief undoubtedly decreases morbidity & mortality.

Over years, there is the advent of various sophisticated techniques in anesthesia. The most widely used procedure for lower limb surgery is spinal anesthesia. Regional anesthesia has various advantages over general anesthesia such as reduced incidence of deep vein thrombosis, pulmonary embolism, reduced cardiac complications in high-risk patients, reduced bleeding & transfusion requirement. Regional anesthesia allows an earlier return of gastrointestinal functions, decreased stress response resulting in less perioperative ischemia & reduced morbidity & mortality in patient with coronary artery disease. Regional anesthesia does not affect immunity perioperatively & allows earlier wound healing. Thus, postoperative pain treatment should be started even before it occurs.

However, a relatively short duration of action is associated with spinal anesthesia using only local anesthetics, and early analgesic intervention is therefore required in the postoperative period [12].

Numerous trials have confirmed the effectiveness of intrathecally administered opioids for postoperative pain management after the first clinical use of intrathecal Morphine in 1979. However, opioids do not remain localized to the site of an intrathecal injection after spinal block, as they undergo redistribution by rostral spread, which explains the occurrence of nausea, vomiting, pruritus & respiratory depression [11].

Dexmedetomidine is a selective adrenergic alpha-2 receptor agonist inhibiting the release of norepinephrine from synaptic vesicles. This leads to the inhibition of postsynaptic activation of adrenoreceptors that inhibit sympathetic activity, leading to sedation and anxiolysis. The sedative, anxiolytic, and analgesic properties of dexmedetomidine may contribute to patients' comfort and tolerance.

The most frequently used opioid adjuvant fentanyl is a strong μ-receptor agonist. It is a lipophilic opioid with rapid onset following intrathecal injection. It improves the quality of postoperative anesthesia with few side effects.

This study is designed to compare the effects of dexmedetomidine vs fentanyl to hyperbaric 0.5% bupivacaine for lower abdominal and lower limb surgeries.

In this study, it is hypothesized that the intrathecal bupivacaine and dexmedetomidine mixture prolonged sensory blockade and better analgesia than the intrathecal bupivacaine and fentanyl.

About sensory and motor block onset it was significantly earlier in group D than in group F. The mean (±SD) time of onset of sensory& motor block in group D was 267.0± 36.68 sec& 353.67±45.37 sec and in group F were 212.00 ± 30.89 seconds & 296.67±39.42 (P<0.0001). SidharthSrabamRoutray[4] *et al* observed that 24 hours VAS score in the postoperative period was less in the dexmedetomidine group as compared to the Fentanyl group.

In the present study, basal mean arterial blood pressure (MAP) between Group D (91.73±6.78mmHg) & Group F (91.16±6.86mmHg) was found to be statistically comparable after applying the T-test (p=0.750).

Mean arterial blood pressure (MAP) changes at all time intervals were found to be statistically not significant & comparable (p>0.05) between the two groups. In a study piloted by Sidharth SrabamRoutray[4] *et al* authors witnessed no significant difference between the two groups, which coincides with our study.

In the study, the mean baseline pulse rate in Group D (80.93±7.71 beats/min), & in Group F (79.20±7.78 beats/min) was found to be statistically comparable (p>0.05). Although patients in both groups remained hemodynamically stable perioperatively maximum fall in pulse was noted between 10-40 minutes with the dexmedetomidine and between 10-20 minutes with fentanyl. Mean pulse rate changes at all time intervals were found to be statistically not significant & comparable (p>0.05) in between the two groups. Our study results also concur with the results of studies by Mishra[3] *et al* and Mahendru[5] *et al.*
In our study 4 patients in the dexmedetomidine group and 1 patient in the fentanyl group had bradycardia. Bradycardia was managed with IV atropine 0.6mg. 5 patients in group D and 1 patient in group F had hypotension and was managed with inj. Mephenteramine 6mg IV and intravenous fluids. 1 patient in the fentanyl group had nausea and 1 patient had shivered. 2 patients in the Fentanyl group had pruritis. No patients in Group D had nausea, shivering, and pruritis. None of the patients developed respiratory depression or dry mouth in both groups. Khilji *et al*[7]. also reported maximum hypotension and bradycardia with dexmedetomidine and pruritis with fentanyl.

CONCLUSION

It can be concluded that dexmedetomidine has a faster sensory and motor level onset than fentanyl. A prolonged sensory and motor block was seen with the dexmedetomidine than in fentanyl so also the prolonged duration of two-segment regression time & duration of the sensory block with excellent quality of anesthesia. The dexmedetomidine as an adjuvant significantly prolongs the duration of postoperative analgesia as compared to Fentanyl without any significant complications perioperatively.

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