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Spinal Anaesthesia for Infraumbilical Surgeries: Hyperbaric Bupivacaine with Dexmedetomidine and Fentanyl

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Abstract: ***Background: To assess and compare total dose of rescue analgesic required in first 24 hr with dexmedetomidine and fentanyl as intrathecal adjuvants to 0.5% hyperbaric bupivacaine in infraumbilical surgeries under spinal anaesthesia. Method: With institutional ethical committee clearance prospective, randomized, double blind study was conducted. After obtaining informed written consent total of 50 patients scheduled for infraumbilical surgeries were randomly allocated into two groups of 25 patients each. Following a spinal tap, patient received 2.0 ml of 0.5% hyperbaric bupivacaine with 25μg fentanyl (0.5ml) in group A and 5μg dexmedetomidine (0.5ml) in group B intrathecally by adding 0.5ml of normal saline in both the groups and the total volume in the both groups will be 3.0ml. The haracteristics of sensory and motor block, hemodynamic data, side effects were recorded. Results: There were no significant differences among these two groups for patient demographic, intraoperative hemodynamic parameters and side effects. The two segment regression time was significantly different (p<0.05) between group F (82.24 ± 15.36) and group D (127.44 ± 22.79). The mean time of total duration of motor block in group F was 142.76 ± 24.654 minutes and in group D was 420.64 ± 45.51 minutes respectively. The difference in mean time of total duration of complete motor block was highly significant among these two groups (p value <0.001). The mean time to first rescue analgesia was significantly different (p<0.05) between group F (162.56 ± 25.09) and group D (262.76 ± 48.042). Conclusion: Both the regimes are effective, but the duration of sensory block and postoperative analgesia was prolonged in dexmedetomidine as compare to fentanyl group***

Keywords: Anaesthetic technique; spinal anaesthesia; hyperbaric bupivacaine, analgesics, opiod; fentanly, dexmedetomidine

1. Introduction

Subarachnoid Block is the preferred means of anaesthesia for lower limb surgeries being simple to perform, economical and produces rapid onset of anaesthesia and complete muscle relaxation. It carries high efficiency, involves less drug dosage. Spinal anaesthesia pioneered by August bier (1898), who is recognized as father of spinal anaesthesia, volunteered himself for administering spinal anaesthesia[1]. Studies have shown that resumption of the different physiologic functions were more rapid, reduced hospital stay and greater compliance when abdominal gynaecologic surgeries were performed under spinal anaesthesia than with general anaesthesia[2]. However, it also produces a fixed duration of anaesthesia, postdural puncture headache, hypotension and lesser control of block height. Still the limitations and complications of spinal anaesthesia are preventable, if technique is employed meticulously under all aseptic precautions skillfully, in properly selected cases[3].

Spinal anaesthesia was described over 100 years ago. Since then, neuraxial drug administration has advanced exponentially and nowadays includes a large variety of medication that provides not only anaesthesia, but analgesia as well. Spinal adjuvant drugs have been used since the beginning of subarachnoid anaesthesia. Adrenaline, an α2 agonist, was the first drug used to enhance duration of spinal anaesthesia, and morphine was the first opioid injected with eucaine in the lumbar spinal space to relieve vertebral pain[4]. After the first article on spinal analgesia using opioids was written by Yaksh and Rudy in 1976[5], the neuraxial route to inject opioids as adjuvants drugs grew logarithmically. In the context of augmentation strategies, a number of adjuvants had been added to spinal local anaesthetic agents. E.g. α2-adrenergic agonist (clonidine)[6], anticholinesterases (neostigmine)[7], benzodiazepines (midazolam)[8], steroids (dexamethasone)[9], N-methyl-d-aspartate (NMDA) antagonists (Ketamine)[10], opiod receptor agonist (nalbuphine)[11], fentanyl and others (octreotide[12], calcitonin[13], adenosine[14]). There are many receptors which modulate spinal pain response; however, there are only few FDA approved drugs to be used via subarachnoid as adjuvants or sole medications.

Literature is available were spinal block characteristics of bupivacaine with fentanyl compared to bupivacaine with dexmedetomidine[15-23].

2. Material and Methods

After obtaining the approval of our Institutional Ethics Committee and patient's informed consent, 25 patients, aged 20-65 years, weight 40-60kg, height >145cm, ASA grade I and II patients scheduled for infraumbilical surgeries were included in a prospective, randomized, double blind study. Patients with unwillingness for the procedure, anaemia (Hb<10gm%) coagulation or neurological disorders, chronic history of headache and backache, spinal deformity or infection at the local site, head injury, allergy to the study drug and any other contraindication for spinal anesthesia were excluded from the study. Patients were randomly divided into two groups of 25 each using **sealed enveloped** method.

A day before surgery detailed pre-anaesthetic check-up was done. General physical examination along with proper systemic examination, assessment of airway and local examination of lumbar spine was done. Relevant investigations were reviewed. Visual analogue scale (VAS) was explained to the patients to determine the level of analgesia in the postoperative period. Patients were asked to restrict solids and fluids by mouth at least 6 h before surgery.

None of the patients received any premedication. Patients were monitored non-invasively for systolic and diastolic blood pressure, peripheral oxygen saturation, respiratory rate, heart rate (HR), and electrocardiography evaluations. Patients were preloaded with 10 ml/kg ringer's lactate solution. Under all aseptic precautions, spinal anaesthesia was given in L_3 and L_4 space with 25 gauge Quincke spinal needle via midline approach in sitting position. On free flow of cerebrospinal fluid, study drugs were injected intrathecally. Group F will receive intrathecal 0.5% hyperbaric bupivacaine 2.0 ml + 5µg dexmedetomidine (total volume will be 3 ml, by adding 0.9% normal saline) [50µg (0.5ml) dexmedetomidine diluted to 5 ml by adding 0.9% normal saline so the concentration would be 10µg /ml and 0.5 ml of total solution taken and 0.5 ml 0.9% normal saline added to make total volume of 3.0 ml] and group D will receive intrathecal 0.5% hyperbaric bupivacaine 2.0 ml ±fentanyl 25µg(0.5 ml) [total volume will be 3.0 ml by adding 0.5 ml of 0.9% normal saline] Patient was placed in supine position with a 15° head down tilt immediately after spinal injection. An indewelling urinary catheter was inserted before the start of the operation. Intra-operative fluid management was done according to the blood loss and hemodynamic parameters. Intraoperative, vitals will be recorded at 2 mins interval for first 20 mins from the time of injection of spinal solution and there after every 10 mins for the complete period of surgery.

Hypotension, defined as a decrease of systolic blood pressure by more than 20% from baseline or a fall below 90 mmHg, was treated with incremental IV doses of IV mephentermine 5 mg and IV fluid titrated according to blood pressure. Bradycardia, defined as heart rate < 55 bpm, was treated with IV atropine 0.3-0.6 mg.

The level of sensory block was tested by pin prick bilaterally at mid-clavicular line which was done every 2 minutes till the maximum sensory level is achieved for four consecutive tests. Further sensory testing will be performed at 20 min intervals till 2 segment regression. Onset of sensory block (when patient does not feel pin prick at T_{10} level), highest level of sensory block achieved, time to maximum sensory block, Time to two segment regression of sensory block and total duration of sensory block was noted. Motor block was assessed by using the modified Bromage scale. Onset of motor block (time taken to achieve Modified Bromage score 1 from the time of subarachnoid injection) and total duration of motor block (motor recovery to modified Bromage 6) was noted. All parameters were noted by taking the time of giving the study drug intrathecally as time 0.

In the postoperative period, patients were monitored for haemodynamic parameters and postoperative analgesia using VAS score, at regular interval of 15 min for first one hour, 30 minutes for second hour, once every two hours until the eight hour and once every four hours for the next sixteen hours in all two groups. Rescue analgesia in the form of injection diclofenac sodium intramuscularly was given when VAS >3 in all two groups. Time at which patient demanded first dose of rescue analgesia was taken as total duration of analgesia. Number of doses of rescue analgesia required in the postoperative period was also noted. Patients were monitored for any side effects or complications like hypotension, bradycardia, nausea, vomiting, sedation, urinary retention, pruritis, headache, backache and neurological changes for 24 hours. Nausea and vomiting were treated with Inj. Ondensetron 4 mg iv. Post-operative sedation level was measured by using **Four Point Sedation Scale**

The patients were discharged from the recovery room after the motor block was completely resolved, had stable vital signs, minimal nausea or vomiting and no severe pain or bleeding.

3. Statistical analysis

All the statistical analysis of data was done with statistical programming software – SPSS (Statistical Package for the Social Science) version 20.0.0 (SPSS Inc., Chicago, Illinois, USA).

The continuous variables (quantitative data) like age,weight, height, blood pressure, heart rate, time were presented as mean and standard deviation and analyzed by applying one way –ANOVA test .

The categorical variables (qualitative data) like ASA grade, sedation score were presented in frequency and percentage and were analyzed with Chi-Square test (for nominal data).A p value of less than 0.05 was considered statistically significant in all the analysis.

4. Results

In the present study, all two groups were comparable with respect to demographic characteristics, baseline haemodynamic parameters and duration of surgery as shown in Table 1 and fig.1. After administering the study drugs intrathecally, the mean time taken for onset of sensory block to T_{10} dermatome in group F(3.24±0.663) was significantly less ($p<0.05$) as compared to group D(3.72±0.9798). Difference of mean time of onset of motor block among two groups was statistically significant ($p<0.05$).mean time of onset of motor block was higher in dexmedetomidine group (11.2±1.84) as compared to fentanyl group (9.96 ±1.743) The mean time to two segment regression taken in group F was 82.24 ± 15.36 minutes and in group D 127.44 ± 22.79 minutes respectively. The difference in mean time to two segment regression was highly significant among these two groups (p value< 0.001). The mean time of total duration of motor block in group F was 142.76 ± 24.654 minutes and in group D was 420.64 ± 45.51 minutes respectively. The difference in mean time of total duration of complete motor

block was highly significant among these two groups (p value <0.001). The mean time to first rescue analgesia in group F was 162.56 ± 25.09 minutes and in group D was 262.76 ± 48.042 minutes respectively.

Table 1: Demographic profile of patients in group F and D

Parameters	Group F (n=25)	Group D (n=25)	P Value
Age (Year)	35.1 ± 9.2	33.28 ± 9.56	>0.05
Weight (Kg.)	68.1 ± 9.22	62.6 ± 11.254	>0.05
Height (cms.)	155.6 ± 22.05	152.76 ± 20.648	>0.05
ASA Grade (I / II)	23/2	24/2	>0.05

Table 2: Characteristics of Spinal Anesthesia in three Groups

	Group F (n = 25)	Group D (n = 25)	P
Sensory block			
Time to T_{10} (min)	3.24 ± 0.663	3.72 ± 0.9798	<0.05
Mean Time to maximum sensory level (min)	8.24 ± 2.402	10.16 ± 1.178	<0.001
Time to two segment regression (min)	82.24 ± 15.3630	127.44 ± 22.796	<0.001
Time for First rescue analgesia	162.56 ± 25.09	262.76 ± 48.042	<0.001
Motor block			
Time of onset of motor block (min)	9.96 ± 1.743	11.2 ± 1.8484	<0.05
Duration of motor block (min)	142.76 ± 24.654	420.64 ± 45.51	<0.001

Data are means ± standard deviation, median (range) or number of patients* p<0.05: A significant differences among two groups.

Visual analog scale score was used to monitor the patients for postoperative pain. VAS was 0 at 90 min of the study period then it started increasing in both the groups. VAS was on higher side in group D as compared to group F. The total number of doses of rescue analgesia required in 24 h was also significantly less in group D as compared to group F (*P* <0.001).

Patients were monitored for hemodynamic parameters at various time intervals starting from baseline till 24 h. There was no significant change in HR, SBP, DBP and mean arterial pressure from baseline among these the groups throughout the study period.

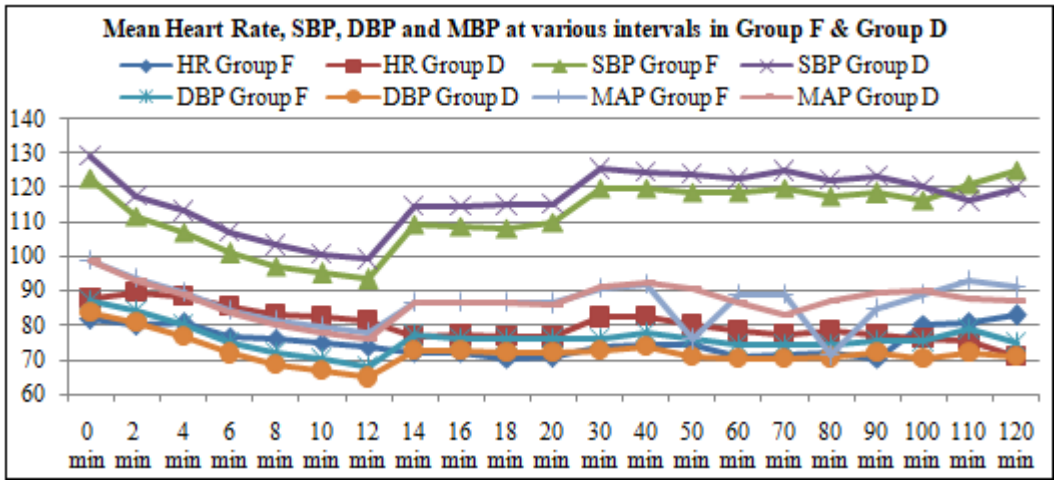

Figure 1: Mean heart rate, Systolic blood pressure and diastolic blood pressure at various intervals in group F and group D

Patients were monitored for side effect and complications for 24 h. Hypotension was seen in 4 patients in Group F, 4 patients in Group D which was statistically non significant (p>0.05). The incidence of bradycardia was 2 in Group F, 2 in Group D which was statistically non significant among these groups. Respiratory depression was not observed in any of the patient among the 2 groups. While 2 patients of butorphanol group reported with pruritis. Nausea and vomiting was seen in 2 in group F, 2 in group D which was statistically non-significant.

Degree of sedation produced in 2 groups was comparable. 22 out of 25, 23 out of 25 were fully awake and alert (grade 1) in fentanyl and dexmedetomidine group respectively. While 3 out of 25, 2 out of 25 showed mild sedation of Grade 2.

5. Discussion

Regional anaesthesia for Infraumbilical surgeries is associated with a short duration of analgesia post operatively which can be extended by i.m. and i.v. analgesics once patient experiences pain and demands for its relief. Also excessive high regional blocks and local anaesthetics toxicity are the commonest causes of mortality associated with regional blocks. So, reduction in the doses of local anaesthetics, the use of new techniques to avoid higher blocks and better management of local anaesthetic toxicity are the new goals for decreasing mortality associated with regional anaesthesia. Circumvention of this concern by pre-emptive mixing of analgesic with local anaesthetics for regional anaesthesia provides a better alternative.

Intrathecal opioids as an adjuvant to low dose local anesthetics, produces a synergistic effect by acting directly on the opioid receptors in the spinal cord.

Fentanylstimulates both μ1 and μ2 receptors and potentiates the afferent sensory blockade. However, side effects due to μ-receptor stimulation like respiratory depression, pruritus, urinary retention and abuse liability remain a concern. This makes it necessary for the search of an opioid which can prolong the duration of analgesia but without μ-receptor related side effects like nausea and pruritiseg.

Though various studies in the past have established the role of Fentanyl and Dexmedetomidine as an adjuvant to local anaesthetic, only one study as far as we know have compared the efficacy between them.

The results of the present study demonstrated that addition of Fentanyl and Dexmedetomidine to 0.5% hyperbaric bupivacaine improves the sensory and motor block characteristics, prolongs postoperative analgesia with decreased requirement of rescue analgesics in the postoperative period, without increasing the incidence of side effect and complications.

Rajni Gupta et al (2011)[15] conducted study of intrathecal dexmedetomidine and fentanyl as adjuvant to bupivacaine, they found that the patients in dexmedetomidine group (D) had a significantly longer sensory and motor block time than patients in fentanyl group (F). They also conclude that intrathecal dexmedetomidine is associated with better hemodynamic stability and reduced demand for rescue analgesic in 24hr as compared to fentanyl.

Vidhi Mahendru & her colleagues (2013)[16] allocated 120 patients into 4 groups. Group BS received 12.5mg hyperbaric bupivacaine with NS, Group BF received 12.5mg hyperbaric bupivacaine with 25microgram Fentanyl, Group BC received 12.5mg hyperbaric bupivacaine with 30 microgram clonidine, Group BD received 12. 5mg hyperbaric bupivacaine with 5 microgram dexmedetomidine. They found that intrathecal dexmedetomidine is associated with prolonged motor and sensory block, better hemodynamic stability, and reduced demand of rescue analgesia in 24 hr as compared to clonidine, fentanyl or bupivacaine alone.

6. Conclusion

Intrathecal dexmedetomidine is associated with prolonged motor and sensory block, hemodynamic stability and reduced demand for rescue analgesics in 24 hours compared to fentanyl.

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