Original Research Article

Comparison of efficacy of intrathecal nalbuphine versus fentanyl as adjuvant to subarachnoid block in cesarean section

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Abstract

Background and Aims: Spinal Anaesthesia is the common technique for lower segment cesarean delivery. This research was conducted to observe the effects of intrathecal Nalbuphine or Fentanyl when added with hyperbaric bupivacaine in lower segment cesarean section under spinal anaesthesia. **Material and Methods:** This research was conducted after obtained proper ethical committee clearance from the institution and written informed consent from all the patients in a Prospective randomized, double blinded manner. Hundred patients of ASA physical status II planned for cesarean section were randomized into group 1 and group 2; each group consisted of 50 participants. Group 1 received Nalbuphine 0.8 mg (0.5 ml prepared by addition of normal saline); Group 2 received Fentanyl 25 mcg. Both groups were given inj.Bupivacaine 0.5% 10 mg as the basic drug so that all participants received a total volume of 2.5 ml. The time taken for the onset of sensory loss at the T6 dermatome level and Grade 3 modified Bromage motor blockade, two segment regression time of sensory blockade, total duration of motor blockade, Period of effective analgesia, Pain assessment using VAS scoring system and side effects were observed in groups. **Results:** Total period of effective analgesia was 264.6±10.0 minutes in group 1 and 191±5.7 minutes in group 2 and it was significant (p=0.001). **Conclusion:** Nalbuphine 0.8 mg and Fentanyl 25 mcg are can be used as an adjuvant for central neuraxial blockade especially in spinal anaesthesia. Nalbuphine has the advantage over Fentanyl in terms of better post-operative analgesic duration.
Key Words: Bupivacaine, Cesarean delivery, Fentanyl, Nalbuphine, Subarachnoid block.

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INTRODUCTION

Opioids are used as adjuvant to local anaesthetics during subarachnoid block to improve the quality of intra operative and post-operative pain relief [1]. Fentanyl is a phenylpiperidine-derivative synthetic opioid agonist. Onset of action is rapid following intrathecal administration. Lipid solubility is more compared to morphine, which helps its passage across the blood brain barrier and the side effects were minimal.[2] Nalbuphine is an agonist and antagonist opioid and also acts on μ and kappa receptors.[3] Its agonistic effects are due to action on the kappa receptors. There is a study comparing addition of nalbuphine 0.4 mg (or) morphine along with hyperbaric Tetracaine and the side effects were comparatively less in the patients who received Nalbuphine.[4] Opioids acts as agonists on opioid receptors present in the pre synaptic and post synaptic sites mainly the brainstem and spinal cord. They also act on the peripheral tissues. There will be activation of antinociceptive system. Opioid receptors are G protein

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coupled receptor. μ type of receptors are important for spinal and supra spinal analgesia. In the spinal cord Substantia gelatinosa is the main site of action for opioids.[5] This study was done to look for the results of Intrathecal Nalbuphine or Fentanyl along with bupivacaine heavy 0.5% in cesarean delivery.

MATERIALS AND METHODS

After obtained Institutional Ethical committee clearance, patients under the inclusion criteria for this research that is physical status ASA II, aged between 20 to 35 years posted for cesarean section were randomized into group 1 which includes 50 participants and group 2 also had 50 participants by computer generated random numbers. All participants were explained about the procedure and written informed consent was obtained. Patients with contraindication for central neuraxial blockade were excluded from the study. All enrolled patients underwent routine preanaesthetic checkup and basic investigations. They were kept nil per oral as per WHO fasting guidelines and pre medicated with tablets (tablet. Metoclopramide 10 mg PO and tablet. Ranitidine 150 mg PO). Before commencement of anaesthesia in the pre-operative period all patients were educated in detail about the methods we are going to use for the assessment of sensory loss and motor blockade. The Visual Analog Scale pain scoring system was described in brief with the help of 10 cm paper strip which has 0 to 10 (0-no pain,10-worst pain.). On arrival to the operation theater all the patients were connected to standard monitoring like NIBP, ECG, and pulseoximeter and temperature probe. Base line values were noted. All patients preloaded with ringer's lactate solution (10 ml/ kg) after secured a peripheral intravenous line with 18G cannula.

Drug solution for the study was kept ready by the resident anaesthetist and the procedure was performed by another anaesthetist to ensure double blindness of the study. Data collection was done by a different person. All participants given spinal anaesthesia in the sitting posture using midline approach between L3-L4 space with the help of 25 gauge quincke babcock spinal needle .Group 1 patients received nalbuphine 0.8 mg which was 0.5 ml prepared by adding normal saline along with inj.bupivacaine 0.5% heavy 10 mg. Group 2 patients received Fentanyl 25 microgram along with inj.buphivacaine 0.5% heavy 10 mg, both the groups received a total volume of 2.5ml.After spinal anaesthesia, patients were positioned immediately in the supine posture with a wedge kept below the right hip in order to displace the uterus towards left side and avoid supine hypotension syndrome. 4L/min Oxygen was given by Hudson mask. Intra operative monitoring done continuously and recorded at five minutes interval up to 15 minutes then once in 15 minutes. If there is Hypotension (systolic blood pressure <100 mm hg or <20% from the baseline blood pressure) treated with Ringer's lactate solution and if needed vasopressor inj.ephedrine 6 mg intravenous at incremental doses was given. Bradycardia if occurs (Heart rate <60 beats /min) was treated with 0.6 mg of intravenous atropine sulphate. To assess the Sensory blockade pinprick method was used and Modified Bromage scale was used for assessment of motor blockade.[6] The time for the onset of loss of sensation to pinprick at the level of T6 dermatome level and the time taken for the grade 3 Bromage motor blockade to occur were noted. Entire motor blockade duration and time for regression of sensation 2 segment from the initial T6 dermatome level also noted. Modified Ramsay sedation score [7] was used to assess the level of sedation in the preoperative and immediate post-operative period. In the Post-operative period VAS [8] scoring system was used to assess pain at 30 minutes interval till 300 minutes. First rescue analgesic dose requirement time is noted from the intrathecal drug injection and it is considered as duration of effective analgesia. Hypotension, bradycardia, pruritus and nausea are the expected complications and patients were observed for it. When participants complained of pain they were given inj.diclofenac 75 mg intramuscularly. Statistical package for the Social Sciences (SPSS) used for statistical analysis and alpha error of probability p value< 0.05 is considered as statistically significant and it is highly significant when p value is <0.01.

RESULTS

Table 1: Demographic profile of the study population

Demographic profile	Group 1 (total no=50)	Group 2 (total no=50)	Statistical p-value
Age (in years)	25.9±3.2	27.0±3.5	0.125
Height(cm)	156.6±2.6	156.4±2.6	0.729
Weight(kg)	66.2±7.2	63.7±5.7	0.057
Duration of surgery(minutes)	57.1±4.6	57.4±4.7	0.764

Group 1 received Intrathecal Nalbuphine and group 2 received Fentanyl as adjuvant to subarachnoid block. There is no statistical significance in terms of age, weight, height and duration of surgery among the groups. None of the variables were statistically significant. That is p value >0.05.

Table 2: Sensory and motor block

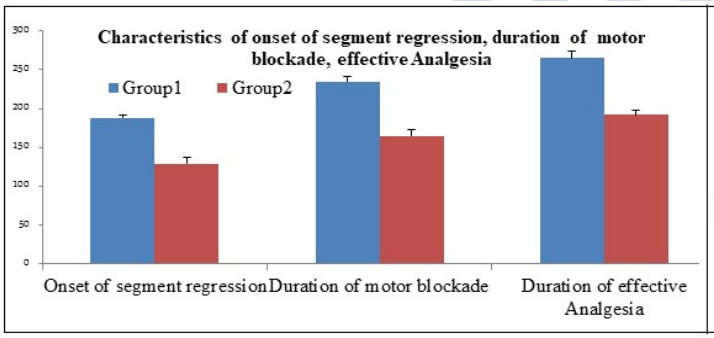
Characteristics of sensory and motor block	Group 1 (total no=50)	Group 2 (total no=50)	Statistical p-value
Time taken for Onset of sensory loss (minutes)	1.28±0.3	1.24±0.28	0.438
Time taken for Onset of motor blockade(minutes)	2.26±0.32	2.24±0.29	0.695
Onset time for two segment regression(minutes)	188.1±4.2	129.0±7.7	0.001
Duration of motor blockade(minutes)	234.7±6.3	164.7±8.6	0.001
Duration of effective Analgesia(minutes) (first analgesic dose given time)	264.6±10.0	191.1±5.7	0.001
Ramsay sedation score	2.18±0.4	2.0±0	0.002

There is no statistical significance in the onset of sensory and motor blockade between the groups. The time for the two-segment regression in group1 was 188.1±4.2 and that for group2 was 129±7.7 minutes and the difference was significant (p=0.001). The total duration of motor blockade and effective analgesia are more in nalbuphine drug received patients. Ramsay sedation score for group1 was 2.18±0.4 as compared to 2.0±0.0 for group2 (p=0.002) (Table 2).

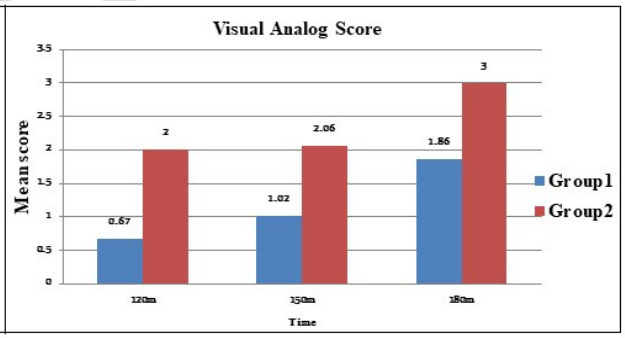
Table3: VAS score measured at 120, 150 and 180 minutes

VAS score (Time in minutes)	Group 1 (Total no=50)	Group 2 (Total no=50)	Statistical p-value
120 minutes	0.68±0.47	2.0±0.0	0.001
150 minutes	1.02±0.14	2.06±0.24	0.001
180 minutes	1.86±0.35	3.0±0.0	0.001

VAS score at 120 minutes for group1 was 0.68±0.47 and it was 2.0±0.0 for group2 and the difference was seeming to be significant (p=0.001). VAS score at 150 minutes for group1 was 1.02±0.14 and it was 2.06±0.24 for group2 and it was significant (p=0.001). VAS score was 1.86±0.35 at 180 minutes in group1 and it was 3.0±0.0 in group2 and the p value is 0. 001.Since the VAS score was zero at 30, 60 and 90 min, it was not comparable. Graph: Comparison of VAS score at 120, 150 and 180th minute



Graph 1



Graph 2

Complications

Two patients in group 1 and one patient in group 2 developed bradycardia. Hypotension incidence was one in group2 whereas it was 2 in group1. Pruritus was noted one in each group. First analgesic dose requirement: The first analgesic dose requirement for group1 was very late at 300th minute for all 50 cases while it was occurred at 210th minute for 94% (47) of the patients in group 2.

DISCUSSION

We have decided to use Nalbuphine at a dose of 0.8 mg because jyothi *et al*[9] done a study and found that this is the dose at which Nalbuphine provides better analgesia without any adverse effects compared to 1.6 mg and 2.5 mg for lower abdominal and orthopedic surgeries. Bogra J *et al* [10] used Fentanyl along with bupivacaine for lower segment cesarean delivery under subarachnoid block and found that bupivacaine dosage can be reduced and so it's expected complications.

The time for the onset of sensory loss was not statistically significant in our groups, similar results were observed in Naaz *et al*[11], Umesh N Prabhakaraiah *et al*[12] and Gomaa *et al*[13]. In a study by Bhavana B Gurunath *et al* [14] the time taken for the two-segment regression in nalbuphine group was significantly prolonged as comparable to fentanyl group. The same results were noted in our research also. The time taken for regression of two segment from T6 level was found more in Nalbuphine group. As like in Tiwari *et al*[15] and Muhammad *et al*[16] the time for regression of two segment and duration of motor blockade were prolonged in nalbuphine group in our

study also. The duration of Bromage grade 3 motor blockade and duration of effective analgesia were more in nalbuphine group in our research and the same observation is noted in tripat *et al* [2]and Ahmed *et al* [17].Sapate *et al* [18] done a study to see the quality of intrathecal Nalbuphine in patients underwent lower abdominal surgeries under subarachnoid block and it showed better results. Borah *et al* [19] conducted a comparative study to compare the Effects of spinal Nalbuphine along with Ropivacaine in lower limb procedures and found that Nalbuphine can be intrathecally used as a good alternative to other opioids as an adjuvant to produce a prolonged postoperative analgesic effect with reduced risk of side effects. Shraddha *et al* [20] done a research to see the effect of nalbuphine when used with Bupivacaine for spinal anaesthesia and proved that nalbuphine is an effective intrathecal adjuvant for postoperative analgesia. Kumaresan *et al* [21] conduted a study to find out what is the appropriate dose required for intrathecal nalbuphine in patients underwent lower limb orthopedic surgeries and concluded that intrathecal nalbuphine of 0.6 mg provides prolonged duration of post-operative analgesia without any increased outcome in the adverse effects. Ramsay sedation score was found to be significant in the post-operative period. However, at the end of procedure all the patients were arousable. The VAS score in our research was significant between the groups at 120, 150 and 180 minutes, it is more in fentanyl group which means nalbuphine group showed better post-operative analgesia. Requirement of first analgesic dose in the post-operative period was delayed in nalbuphine group compared to fentanyl group. The complications were not significant. Neelam singh *et al* [22] concluded that Nalbuphine used as adjuvant to intrathecal bupivacaine caused good quality of post procedure analgesia and there is less requirement for the analgesic dose in the post-operative period without any increased side effects or complications. Verma *et al* [23] studied the effects of intrathecal tramadol (50 mg) or nalbuphine (2 mg) when added to hyperbaric bupivacaine (12.5 mg) in patients underwent lower limb orthopedic procedure. There was a reduced requirement for post-operative analgesia. Shahedha Parveen *et al* [24] also showed similar results and reduced risk of side effects. The main aim of postoperative pain management is to reduce or eliminate the pain with minimal risk for side effects. Intrathecal opioids are preferably used to prolong and improve the quality of post-operative analgesia.

CONCLUSION

Intrathecally administered Nalbuphine as an adjuvant to hyperbaric Bupivacaine in central neuraxial blockade provides good quality of post-operative analgesia, without any significant increase in the side effects when compared to intrathecal Fentanyl.

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