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Comparative Evaluation of The Effects of Addition of Intrathecal Fentanyl and Clonidine Added to 0.5% Hyperbaric Bupivacaine for Lower Segment Caesarean Section.

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ABSTRACT

Background: Additive effects of intrathecal fentanyl and clonidine added to 0.5% hyperbaric bupivacaine for lower segment caesarean section is a simple, safe technique for patients undergoing elective (or) emergency LSCS under ASA I and II category, thus providing improved intra operative analgesia, prolonged post operative analgesia and stable Hemodynamics. Aim: To evaluate the effects of fentanyl and clonidine added to Bupivacaine, for caesarean section in spinal Anaesthesia. **Methods:** The three groups were namely A (Bupivacaine only), B (Bupivacaine + intrathecal clonidine) and C (Bupivacaine + intrathecal fentanyl + Clonidine). Each group 40 Caesarean Sections were selected and data were collected before during and after surgery. **Results:** The sensory level T4 was obtained by Group C was significantly greater than the other A & B groups (P<0.0001). The two-segment regression time for Group C was significantly more than Group B. The sedation level of A (57.5%) and B (70%) groups was associated with level 1 and C (72.5%) was associated with level 2. The improvement was very highly significant (P<0.001). The Apgar score between the three groups was not significant at 1 Minute, But at 5 minutes, Group A was significantly improved than Group B (9.1±0.5 > 8.8 ±0.5 and P<0.05). **Conclusion:** Clonidine when added to a bupivacaine-fentanyl mixture increased the duration of effective analgesia and the duration of sensory and motor block in lower segment caesarean section.

Keywords: Intrathecal 0.5% Bupivacaine (Heavy) Fentanyl, Clonidine, LSCS, Post-operative analgesia.

INTRODUCTION

Spinal anesthesia with bupivacaine is administered routinely for lower abdominal and lower limb surgeries. The resulting nerve block is sufficient to ensure patient's wellbeing, while motor block facilitates the surgeon's work. It also provides effective pain relief in the initial post-operative period. When a patient is going to receive spinal anesthesia, with local anesthesia agents like bupivacaine, addition of an adjuvant drug intrathecally that will increase the efficacy of neuraxial block is a logical choice. Predictably, thus, a number of adjuvants have been added to spinal local anesthetics e.g., opioids like morphine, buprenorphine, pethidine, hydromorphone, fentanyl, sufentanil, and tramadol.[1] Various additives have been evaluated in the quest for an ideal adjuvant, which can enhance the quality of analgesia and prolong the duration of spinal anesthesia with minimal adverse effects. However, success with many additives has been variable, especially with regards to side-effects such as hypotension, bradycardia, pruritus, respiratory depression, nausea, vomiting, and urinary retention.[2] Fentanyl has been used as a spinal additive to lower the dose of bupivacaine and prolong postoperative analgesia though at the expense of side effects such as pruritus and respiratory depression. In recent times, clonidine has been attempted as a spinal additive. However, the most common adverse effects reported with the use of intrathecal clonidine are sedation and hypotension.[3,4] Clonidine has been used as a sole agent as well as admixed with opioids and local anaesthetics in labor analgesia and gynecological surgeries.[5,6]

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Aim

To evaluate the effects of fentanyl and clonidine added to Bupivacaine, for caesarean section in spinal Anaesthesia

MATERIALS AND METHODS

This Randomized control clinical trial was done in Department of Obstetrics and Gynecology at Tirunelveli Medical College Hospital, in 120 patients undergoing elective or emergency caesarean section after getting informed consent from each patient and explaining the procedure. Inclusion and

Exclusion Criteria:

Term, parturient, ASA 1 an ASA 1E who were fit to undergo spinal anaesthesia for caesarean section, age between 18 - 35 years are selected. Patients with medical and obstetrical complications and impaired placental function were excluded; patients who were converted to general Anaesthesia were also excluded from the study. Preoperatively all patients were seen by the anesthetist. The procedure was explained in detail and informed consent was obtained. No premedication was given. Patients were randomly allocated into 3 groups of 40 each.

Table 1: Study Group.

Group		Drug
A	Control	Injection (0.5%) Bupivacaine 1.8 ml +0.4 ml NS
B	Study group 1	Injection (0.5%) Bupivacaine 1.8 ml + Clonidine 30 µg) + 0.2 ml NS
C	Study group 2	Injection (0.5%) Bupivacaine 1.8 ml + Clonidine (30 µg) + fentanyl (10µg)

RESULTS

The three groups were namely A (Bupivacaine only), B (Bupivacaine + intrathecal clonidine) and C (Bupivacaine + intrathecal fentanyl + Clonidine). Each group 40 Caesarean Sections were selected and data were collected before during and after surgery. For Randomization the three groups were matched according to their selected and related demographic characteristics and base level Physiological characteristics. They were not significantly differed between them (P>0.05).

The Physiological characteristics of three groups were matched. There was no significant differences were observed between groups in respect of their base Physiological characteristics (P>0.05).

The maximum sensory level and maximum time taken to reach the level were compared between three groups. The 2 segment regression time was also compared between the three groups. The group A was associated with T7, B was associated with T6 and C was associated with T5. The above associations were statistically very highly significant (P<0.0001). [Table 2]

Table 2: Distribution of Sensory level.

Maximum sensory level	Groups			Significance
	A	B	C	
T4	1	2	10	P<0.0001
T5	3	13	21	
T6	14	25	9	
T7	19	0	0	
T8	3	0	0	

Table 3: Duration of time (minutes) to attain Sensory blockade or level between groups.

Groups	Mean	SD	Significance
A	3.8	0.8	P<0.05
B	3.6	0.7	
C	4.3	0.8	

The mean time of A was 3.8±0.8 minutes with mean time of B (3.6±0.7) and C (4.3±0.8) not differed significantly (P>0.05). But the means of B (3.6±0.7) and C (4.3±0.8) were differed significantly (P<0.05). [Table 3]

Table 4: Two-segment regression time (minutes) to attain Sensory level between groups

Groups	Mean	SD	Significance
A	69.4	8.6	P<0.05
B	89.5	5.7	
C	101.1	8.1	

The two segment regression time between the groups were compared in [Table 4]. The means of three groups were differed significantly between them (P<0.0001). Pulse rate at different intervals like at 5 minutes 15 minutes and 30 minutes. The group A was significantly differed with group B (P<0.05) and C was not significantly differed with groups A and C (P>0.05) at 5 minutes. At 15 minutes no significant difference was observed between the three groups (P>0.05). At 30 minutes B significantly differed with C (P<0.01) and at the same time A&B and A&C were not significantly differed (P>0.05). The SBP at different interval between the groups were shown in [Table 8]. At 5 minutes, three groups were not significantly differed between them (P>0.05). At 15 minutes A significantly differed with the groups B and C (P<0.001). But B&C was not significantly differed between them (P>0.05). At 30 minutes A&B differed significantly (P<0.05). But A vs C and B vs. C were not significantly differed (P>0.05). The pain free, the duration of time without pain was analyzed between the three groups to identify in which group thepain was lasting.[Table 5]

Table 5: Comparison of pain free time (minutes) between the groups.

Groups	Mean	SD	Significance
A	125.8	23.1	
B	178.2	14.4	P<0.0001
C	221.6	28.4	

The pain free time between the groups were compared in [Table 9]. The means of three groups were 125.8+23.1, 178.2+14.4 and 221.6+28.4 respectively. They were significantly differed between them (P<0.0001).

Table 6: Comparison of sedation between three groups.

Sedation level	Groups			Significance
	A	B	C	
0	17	2	0	P<0.0001
1	23	28	3	
2	0	10	8	
3	0	0	8	
Total	40	40	40	

The sedation levels of three groups were associated in table 10. The sedation level 1 was associated with groups A and B. The sedation level 2 was associated with group C. The above associations were statistically very highly significant (P<0.0001). [Table 6]

Table 7: Comparison of Apgar scores at 1 minute and 5 minutes.

Interval	Group	Mean	SD	Significance
1 Min	A	7.6	0.5	P>0.05
	B	7.5	0.6	
	C	7.5	0.7	
5 Min	A	9.1	0.5	P>0.05
	B	8.8	0.5	
	C	9.0	0.3	

The Apgar score at 1 minute and 5 minutes were compared between the three groups in [Table 7]. At 1 minute the Apgar were not significant between groups (P>0.05). At the Apgar scores of groups A&B was significantly differed (P<0.05). The others A&C and B&C were not statistically significant (P>0.05).

Inter-operative Complications: Nausea and vomiting occurred in 7.5% of all three groups. Pruritus developed in only one patient i.e. 2.5% of group A. In group B, 7.5% of patients developed pruritus. In group C, 12.5% of patients developed pruritus.

Post-Operative Complications : Nausea and vomiting occurred in 5% of patients in group A and group B and 2.5% in group C. Pruritus occurred in 2.5% of patients in group B and 7.5% of patients in group C.

DISCUSSION

Clonidine is an alpha 2 agonist, which potentiates both sensory and motor blockade of local anaesthetics. The analgesic effect following intrathecal administration is mediated via the activation of postsynaptic alpha 2 receptors in the substantia gelatinosa of the spinal cord. It works by blocking conduction of the Ad and C fibers, and also intensifies the conduction block of local anesthetics.[7] Evidence to conclude, improved quality of analgesia in the post-operative period.[8] Also there is not of much difference in the onset of analgesia, similar to the other studies.[9] The time to two segment regression also was longer with C>B>A, similar to the studies.[10] In view of prolonged duration of analgesia, it was increased in the order C>B>A consistent with the studies.[11]

The other parameters were hemodynamically stable. There were fewer incidences of hypotension and Bradycardia, which were consistent with the studies.[12]

Complications like respiratory depressions, did not occur in any of these patients, which were also consistent with the studies.[13] Pruritus developed in 12.5% in Group C, consistent with the studies.[14]

The fetal outcome was not affected due to any these drugs, even the low dose opioids had no adverse effects in fetus and neonates.[15]

CONCLUSION

Intrathecal clonidine and the clonidine fentanyl combination, both improved quality of Intra Operative analgesia. Combination of clonidine with fentanyl increased the intra operative analgesic efficacy and significantly prolonged post-operative analgesia compared with clonidine alone. Stable Intra Operative hemodynamics was obtained. Duration of analgesia was prolonged. The incidence of side effects due to additive effects of the drugs was minimal. Fetal outcome was not altered.

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