Original Research Paper

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EVALUATION OF THE EFECT OF INTRATHECAL FENTANYL CITRATE AS AN ADJUVANT WITH HYPERBARIC BUPIVACAINE FOR CAESAREAN SECTION

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ABSTRACT

Aim : To evaluate the effect of intrathecal fentanyl in improving the quality of anesthesia with 0.5% hyperbaric bupivacaine for lower segment caesarean section.

Materials and methods: 60 female patients who underwent caesarean section were taken up for the study. The patients belonging to as ASA grade I and grade II were selected for the study. Group I patients received 1.7ml of 0.5 % hyperbaric bupivacaine with 0.5ml of normal saline (CONTROL GROUP). Group II patients received 1.7ml of 0.5 % hyperbaric bupivacaine with 0.5ml (25mcg) of fentanyl (STUDY GROUP). The following parameters were assessed, 1) The onset and duration of sensory block 2) onset of grade 3 block 3) quality of surgical anesthesia 4) period of complete analgesia 5) period of effective analgesia &6),side effects .

Observation and Results : The range of onset of grade -3 motor block does not vary in both the groups and it was statistically in significant .The maximal sensory level in Group - I was T5 while it was T4 in Group II which was statistically significant. The quality of intra operative surgical anesthesia was excellent in more than 90 % of patients in Group II compared to 63% in Group I. The mean time for regression to L1 was 118.5± 48.25 min in Group I compared to 153.96 ± 20.31 min in Group II. This was statistically significant (p less than 0.001).The period of complete analgesia was longer in fentanyl group (Group II)

,and it was 127.2± 5.46 min in Group I & 188.36± 16.32 min in group II. The mean period of effective analgesia was 152.6 38.91 min in group I as compared to 245.13± 134.44 min in group II. This value was stastically significant ($p<0.001$).

Conclusion: Addition of 25µg of fentanyl to 0.5% hyperbaric bupivacaine intrathecally provides an improved quality of surgical anaestheisa and analgesia than bupivacaine alone in caesarean section.

KEYWORDS :

INTRODUCTION

Pain following surgery is a universal phenomenon. According to American study of anesthesiologist guidelines, peri operative pain is defined as " pain that is present in a surgical patient because of preexisting disease, the surgical procedure or a combination of disease related and procedure related sources.

Failure to relieve pain is morally and ethically unacceptable. Adequate pain relief should be considered a basic human right. Uncontrolled pain has been shown to increase morbidity in many ways.

1. It causes significant postoperative respiratory dysfunction, inability to cough, splinting etc.
2. Pain promotes immobility and hence development of deep vein thrombosis.
3. Alteration in the stress response to surgery , increased catecholamine release, increased oxygen demand and cardiac work.
4. Increased catabolic response to surgical trauma and impaired immune mechanism and delayed wound healing.

The major advancement in improving the success of regional anaesthesia has come from the use of adjuvant drugs with spinal and epidural anaesthesia.. These drugs act at a secondary site. The primary drug used with local anaesthetics at the spinal cord level is opioids.

In this study, the newer opiod fentanyl is used with 0.5% hyperbaric bupivacaine for spinal anaesthesia in lower segment caesarean section and its efficacy and safety was evaluated.

AIM OF THE STUDY

1. To evaluate the effect of intrathecal fentanyl in improving the quality of anaesthesia with 0.5% hyperbaric bupivacaine for lower segment caesarean section.
2. To evaluate the efficacy of intrathecal fentanyl in providing postoperative pain relief for lower segment caesarean section
3. To assess the duration of pain relief and in the incidence of side effects.

MATERIALS AND METHODS

This study was conducted at the Government Raja Mirasudar Hospital, which is attached to Thanjavur Medical College , thanjavur.

A total of 60 female patients who underwent caesarean section were taken up for the study. The age of the patients ranged from 20-35years weighing 38-65 kg and height ranging from 145-165cms. All the patients were thoroughly examined and assessed preoperatively according to physical status, ASA Grading .only patients belonging to as ASA grade I and II were selected for the study. A informed consent was obtained from the patients .

The study group was explained about the procedure and postoperative follow up pattern. The visual analog scoring was explained as 0-10cm scale reading and patient was asked to fill the number. The patients were specifically instructed to inform immediately as they perceive pain in the postoperative period.

No medication was given to the patient. The patients were randomly divided into 2 groups of 30 each.

Group I: (n=30)
These patients received 1.7ml of 0.5%hyperbaric bupivacaine with 0.5ml of normal saline- CONTROL GROUP

Group II : (n=30)
These patients received 1.7ml of 0.5% hyperbaric bupivacaine with 0.5ml(25µg) of fentanyl-STUDY GROUP.

All the study agents were injected intrathecally and the total volume administered was 2.2ml.

PROCEDURE

Patients were shifted into the theatre. Anaesthesia machine was checked and emergency drugs and equipments were kept ready. The patients were cannulated with 18G IV cannula and preloaded with lactated ringer solution. The patients were randomly divided into 2 groups of 30 each. Patient was positioned in the right lateral position and under aseptic precautions , subarachnoid block was given using 23G spinal needle in the L3-L4 inter space. This is to minimize the postoperative headache. After subarachnoid injection, patient was put in supine position and with left lateral tilt provided by a wedge under right buttock. Uppermost level of analgesia was tested by pinprick. Motor block was assessed by bromage scale. All pateints received supplementation of oxygen (4lit/min) via polymask. Foetal heart rate was noted for bradycardia.

The systolic blood pressure and pulse rate were recorded every minute for the first 10 min and then every 5 min until the surgery was over. Respiratory rate , pain score, discomfort and occurrence of side effects such as pruritus, nausea, vomiting and shivering were recorded. SPO2 was monitored continuously.

A fall in systolic BP of 30 mmHg from the baseline was taken as hypotension and promptly treated with rapid IV infusion of crystalloids and inj. Ephedrine 6mg IV increments. Bradycardia was said to be present if the pulse rate falls below 60/min and treated with inj atropine 0.6mg IV. Respiratory depression was said to be present if respiratory rate < 9 breaths/min and desaturation if SPO2<90%.

The onset and duration of sensory block were assessed by pin prick method and time taken from the intra thecal injection to the highest level of sensory block and sensory regression to L1 dermatome were recorded.

To assess the quality of surgical anaesthesia a scale proposed by belzarena et al (1992) was used

I, Excellent	There were no complaints from the patient at any time of surgery.
II, Good	Mild discomfort
III, Regular	Minimal pain
IV, Poor	Severe discomfort or pain where the patient needed large doses of analgesics or GA had to be administered.

Pain was evaluated using a standard 10cm linear visual analaog scale with 0 corresponding to no pain and 10 to the worst possible pain.

The duration of complete analagesia-time from subarachnoid block to first report of pain with a pain score greater than 0 and 'EFFECTIVE ANALGESIA' was taken as the time taken from subarachnoid block to first dose of rescue analgesia. The APGAR score was recorded 1 minute and 5 minute after delivery of the baby.

POST OPERATIVE FOLLOW UP

Post operatively vital signs were monitored for 12hrs. No narcotics or analgesia were given. The duration and the quality of postoperative analgesia was assessed by subjective feeling of the patients. The end point of postoperative analgesia was taken as the time when patients requested for rescue analgesia.

TABLE 1 : Maximum level of sensory block

SENSORY LEVEL	GROUP – I	GROUP - II
T_4	-	14
T_5	7	10
T_6	13	6
T_7	10	-

The maximal sensory level in Group – I was T5 while it was T4 in Group – II which is statistically significant.

GRAPH 1: MAXIMUM LEVEL OF SENSORY BLOCK

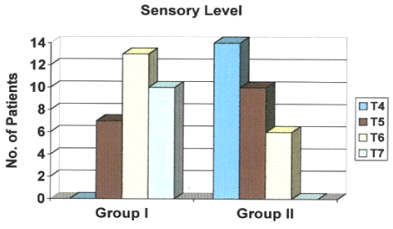


TABLE 2: Quality of surgical Anaesthesia

GRADES	GROUP – I	GROUP - II
1. EXCELLENT	**19 (63.3 %)**	**28 (93.3%)**
2. GOOD	**11 (36.7 %)**	**2 (6.6%)**
3. REGULAR	-	-
4. POOR	-	-

The quality of intraoperative surgical anaesthesia was excellent in >90 % of patients in Group – II compared to 63 % in Group – I.

GRAPH 2: QUALITY OF SUGICAL ANAESTHESIA

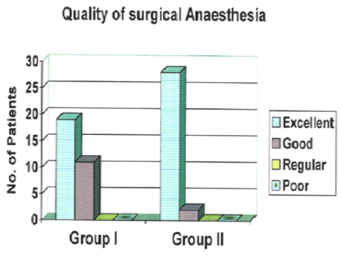


TABLE 3 : Time for sensory regression to L_1

Reg. To L_1 (in min)	Group – I	Group - II
MINIMUM	107	144
MAXIMUM	130	159
MEAN	118.5	153.96
S.D. σ	48.25	20.31

mean time for regression to L1 was 118.5 ± 48.25 min. in Group – I compared to 153.96 ± 20.31 min. in Group – II.

This was statistically significant as detected by one tailed two sample student's t-test ($p<0.001$)

TABLE 4 : Period of complete analgesia

COMPLETE ANALGESIA (in min)	Group – I	Group - II
MINIMUM	124	182
MAXIMUM	130	194
MEAN	127.2	188.36
S.D. σ	5.46	16.32

Fentanyl group (Group - II) had a longer duration of complete analgesia.

The mean period of complete analgesia was 127.2 ± 5.46 min. in Group – I and 188.36 ± 16.32 min. in Group – II.

This value was statistically significant as calculated by student's t-test. (P<0.001)

TABLE 5 : Period of effective analgesia

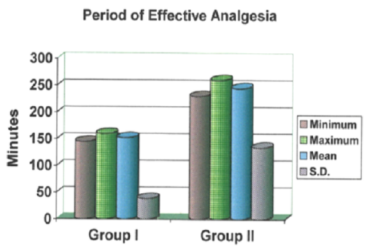
EFFECTIVE ANALGESIA (in min)	Group – I	Group - II
MINIMUM	145	230
MAXIMUM	160	260
MEAN	152.6	245.13
S.D. σ	38.91	134.44

Fentanyl group (Group - II) had a longer duration of effective analgesia.

The mean period of effective analgesia was 152.6 ± 38.91 min . in Group – I as compared to 245.13 ± 134.44 min. Group – II.

This value was statistically significant as calculated by student's t-test. ($p<0.001$)

GRAPH 5: PERIOD OF EFECTIVE ANALGESIA



Side effects

Side effects in both the groups are tabulated below.

SIDE EFFECTS	Group – I	Group - II
Hypotension	4	5
Nausea and Vomiting	3	-
Respiratory depression	-	-
Pruritus	-	2
Shivering	2	-
Headache	-	-
Bradycardia	-	-
Urinary retention	2	4

All the side effects were easily managed. The patients who had urinary retention even after 12hrs were treated conservatively and responded well. Only 2 patients in group – II needed catheterization due to failure of conventional methods.

DISCUSSION

60 patients undergoing caesarean section with physical status of ASA –I were taken up for the study. They were randomly allocated into two groups , 30 patients in each group. Variables like age, weight and height were standardized in both groups.

Group-I (control group) received 1.7ml of 0.5% hyperbaric bupivacaine with 0.5ml of normal saline intrathecally.

Group-II (study group) received 1.7ml of 0.5%hyperbaric bupivacaine with 0.5ml (25µg) of fentanyl citrate intrathecally.

In this study a lower dose of bupivacaine with 0.5ml (25µg of fentanyl) making a total volume of 2.2ml to assess the quality of anaesthesia. The quality of intra operative surgical anaesthesia was excellent in 93% of patients in fentanyl group as compared to 63% in bupivacaine group. All the patients who recived 1.7ml of hyperbaric bupivacaine with fentanyl were comfortable during the intraoperative period.

SERGIO D.BELAZARENA studied the quality of intra operative surgical anaesthesia and the level of consciousness in patients undergoing caesarean section. The quality of surgical anaesthesia was excellent in100% of fentanyl (25µg) group as compared to <80% in bupivacaine group, who received 0.5% heavy bupivacaine alone. Nearly 75% of patients were sleepy but in a state of easy arousal in fentanyl group.

Time of regression to L1 dermatome level

Regression of anaesthesia to L1 dermatome took longer (153.96± 20.1min) in fentanyl group as compared with (118.5±48.2 min) in bupivacaine group. This was proved statistically significant.

The results of our study goes in consistent with the study conducted by D.SHENDE, G.M COOPER and M.I BOWDEN. In their study the mean time for regression to L1 was 184 minutes in study group who received 15µg of fentanyl along with 2.5ml of 0.5% hyperbaric bupivacaine compared to 156 minute in control group who received 2.5ml of 0.5% hyperbaric bupivacaine alone.

Duration of complete analgesia

The duration of complete analgesia evaluated was significantly prolonged in fentanyl group 188.36±16.62 min as compared to 127.2±5.46 in bupivacaine group. This was statistically significant.

Duration of effective analgesia

The duration of effective analgesia evaluated was significantly prolonged in fentanyl group 245.13±134.44 min compared to 152.6±38.91 in bupivacaine group. The requirement for the first dose of analgesia is significantly prolonged in fentanyl group.

The incidence of hypotension was similar in both groups. It is clear that hypotension in this study was due to inherent property of the local anaesthetics used rather than the fentanyl. Minimal amount of intrathecal fentnayl (25µg) produce negligible hemodynamic changes with prior fluid administration.

Fentanyl causes little histamine release, intra thecal administration of fentanyl is associated with pruritis, the mechanism of which is not clear. It is self limiting ,can also be antagonized by antihistamines. No patients required treatment in our study.6.6% of patients in our study had pruritus as compared to 27.8% in a study conducted by, N Giam SK, Chong JL and 15% in a study conducted D.Shende , C.M Cooper and M.I Bowden.

Opioids produce nausea and vomiting by direct stimulation of chemoreceptor trigger zone. This effect is dose related and can be treated with anti- cholinergics or phenothiazine those are antagonistic at dopamine receptor.

The incidence of vomiting in our study is 10% , but it was 25% in the study by knneth H, Gwirtz M.D Jerry v .The higher incidence in their study might be due to combined administration of fentanyl and morphine intrathecally.

Retention of urine is a frequent finding with intrathecal opioids. It is caused by an increase in the urinary sphincter tone and a decrease in central inhibition of detrusor tone. The incidence of urinary retention in our study is 13.3% .those who had difficulty in passing urine were managed conservatively except one who required catheterization. Respiratory depression did not occur in any of the cases in our study probably due to minimal dose of intrathecal fentanyl.

It has been found out by this study that 25µg of intrathecal fentanyl with 1.7ml of 0.5% hyperbaric bupivacaine provides

1. An improved quality of intra operative surgical anaesthesia.
2. Increase in the duration of regression to L1 dermatome (153.96±20.31)
3. Increase in the duration of complete analgesia (188.36±16.32) and an effective postoperative analgesia (245.13±133.44)

The occurrence and intensity of side effects were so minimal and not significant. The benefit associated with administration of intrathecal fentanyl citrate in a dose of 25µg out weighs the disadvantages of it.

CONCLUSION

It has been concluded from this study that addition of 25µg of fentanyl to 0.5% hyperbaric bupivacaine intrathecally provides an improved quality of surgical anaestheisa and analgesia than bupivacaine alone in caesarean section without increasing significant maternal and foetal side effects.

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