ORIGINAL RESEARCH PAPER

Anaesthesiology

COMPARATIVE STUDY OF INTRATHECAL FENTANYL WITH HYPERBARIC BUPIVACAINE TO IMPROVE PERIOPERATIVE ANALGESIA IN PATIENT UNDERGOING ORTHOPEDIC SURGERY

KEY WORDS: motor block, fentanyl, hyperbaric bupivacaine, postoperative analgesia.

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ABSTRACT

Background: Various methods exist for treating post-operative pain which includes systemic narcotics, NSAIDS, patient-controlled analgesia, regional anaesthesia techniques, epidural local anaesthetic – narcotic mixtures, cryoanalgesia, transcutaneous electric nerve stimulation, psychological methods.

Various opioides intrathecally and epidurally have been tried for post-operative analgesia. These include - morphine, pethidine, pentazocine, methadone, tramadol, Fentanyl, sufentanyl. In present study, we tried to find out analgesic effectiveness of intrathecal Fentanyl for post-operative analgesia, combined with 0.5 % Bupivacaine and side effects if any, in patients undergoing lower limb surgeries.

Materials and Methods: After approval from the local ethics committee and with written informed consent from patient, a randomized controlled prospective study is carried out in the medical college and hospital.100 patients belonging to American Society of Anesthesiologists (ASA)classification I & II, aged between 18-60 years, posted for elective lower limb surgeries, were randomly allocated for the study.

Group-I: 50 patients received intrathecal 3 ml of 0.5 % hyperbaric Bupivacaine only.

Group-II : 50 patients received intrathecal 3 ml of 0.5% hyperbaric Bupivacaine and Fentanyl 25 mcg.The patients studied across the group did not vary much with respect to age,height, weight and sex distribution.

Results: The onset of sensory blockade was faster by 1.27 min in Group-BF. The perioperative and postoperative hemodynamic parameters were comparable in both the groups. The sensory analgesia in Group II was significantly prolonged by 159 mins, thus increasing the duration of analgesia. The time of first request of analgesics by the patients in group-II is prolonged compared to group-I thus prolonging the duration of analgesia. Analgesic requirement is also reduced in study group in early post-operative period. The onset of motor block was faster when Fentanyl was added to intrathecal Bupivacaine and it was 1.1 min earlier in study group. The duration of motor block to Bromage III was prolonged by almost 22 min in study group as compare to control group. Visual analogue scores were significantly lower in group-II compared to group-I after two hours of surgery thus reducing the frequency of supplemental postoperative analgesics.

Conclusion: With the present study we can summarize that intrathecal Fentanyl potentiates the action of Bupivacaine thereby bringing about better quality and longer duration of analgesia, intense motor block, no hemodynamic disturbance and better postoperative outcome with/ minimum side effects.

INTRODUCTION

"Failure to relieve pain is morally and ethically unacceptable." Adequate pain relief is considered as basic human right. Whether it is by drug, nerve block, surgery or any other means, every patient wants desperately to be relieved by pain.

Various methods exist for treating post-operative pain which includes systemic narcotics, NSAIDS, patient controlled analgesia, regional anaesthesia techniques, epidural local anaesthetic – narcotic mixtures, cryoanalgesia, transcutaneous electric nerve stimulation, psychological methods, and etc.[1]

Subarachnoid blockade with local anaesthetics provide intense analgesia by segmental blockade of central neural axis, but the duration is short lasting. Addition of intrathecal drug, which will prolong analgesia without causing side effects, is a logical choice. Predictably, thus a number of adjuvants have been added to spinal anaesthetics e.g. opioids like morphine, buprenorphine, pethidine, Fentanyl group. Identification of specific opiate receptor in the cord by pert and synder (1973) opened a new vista for the treatment of pain. Since then, neuraxial administration of opioids has led to new concepts for the treatment of acute and chronic pain, for example, selective spinal analgesia produced by the intrathecal injection of narcotics. This takes the advantages of these drugs acting directly on the spinal cord opiate receptor in substansia gelatinosa to interrupt pain pathway. Likewise, narcotics placed in epidural space diffuse into subarachnoid space to gain access to the spinal cord opiate receptors.[2]

Various opioides intrathecally and epidurally have been tried for post-operative analgesia. These include - morphine, pethidine, pentazocine, methadone, tramadol, Fentanyl, sufentanyl.

In present study, we tried to find out analgesic effectiveness of intrathecal Fentanyl for post-operative analgesia, combined with 0.5 % Bupivacaine and side effects if any, in patients undergoing lower limb surgeries.

MATERIALS AND METHODS

After approval from the local ethics committee and with written informed consent from patient, a randomized controlled prospective study is carried out in the medical college and hospital from November 2009 to October 2010.

During this one-year study, total 100 ASA Grade I/II patients aged 18-60 years were studied who were scheduled for the lower limb surgeries up to two hrs duration. The patients were randomly allocated in-

Group I: who received 3ml (15mg) hyperbaric 0.5% bupivacaine hydrochloride.

Group II:who received 3ml (15mg) hyperbaric 0.5% bupivacaine hydrochloride + 25 mcg of Fentanyl.

Following were the inclusion and exclusion criteria for this

study.

INCLUSION CRITERIA: 1. ASA Grade I/II physical status.2. Weight 30-80 kg.3. Age 18 - 60 yrs.

EXCLUSION CRITERIA: 1. ASA Grade III and IV patients 2. Patients with history of known allergy to the drugs to be used. 3. Patients on chronic analgesic therapy.4. Gross spinal deformity .5. Patients in whom regional anaesthesia is contraindicated. 6. Patients with peripheral neuropathy. 7. Surgeries lasting for more than 2 hours.

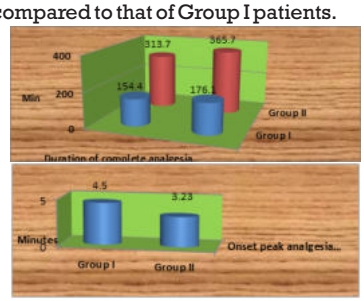
Detailed preoperative evaluation was carried out in all patients with detailed history, physical examination including height, weight, evidence of spinal deformity or presence of any neurological disease and mental status of the patient. Vital parameters were noted and systemic examination was performed along with general and spine examination. Preoperatively adequate starvation was confirmed and baseline vital parameters were noted. Monitoring was done with pulse oximeter, non-invasive blood pressure and ECG.

A peripheral venous access with 18/20G cannula was secured on the dorsum of the hand and preloading with lactated ringer 10ml/kg done 15 minutes prior to subarachnoid block. No sedative premedication was given to any of these patients.

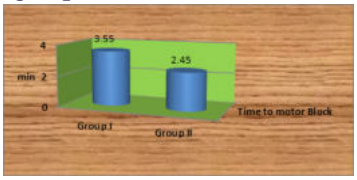
After explaining the patient about the procedure, subarachnoid block was given in sitting position with midline approach with strict aseptic precautions using 25G Quincke's spinal needle. The study drugs i.e. either Bupivacaine alone (Group- B) or combination of Bupivacaine and Fentanyl (Group-BF) was injected intrathecally.

RESULTS

Graph No 1: Comparison of onset of analgesia in between the groups- Onset of peak analgesia in Group I was at 4.5 min with 0.5 S.D and that in Group II was 3.23 with 0.24 S.D. The duration of onset in Group I had mean difference of 1.27 min. The onset of peak analgesia in Group I was longer than group II and this difference was found to be statistically highly significant. ($p<0.01$). Duration of complete analgesia in Group I was 154.5 min and that in Group II was 313.7 min with the difference of 159.2 min in them. Group II had statistically significant ($p<0.01$) longer duration of complete analgesia compared to Group I patients. Effective analgesia duration in Group I was 176.1 min and in Group II was 365.7 min with the mean difference of 189.6 min. Patients in Group II has statistically significantly ($p<0.01$) longer duration of effective analgesia compared to that of Group I patients.



Graph No 2: Comparison of Time to motor Block in between the groups

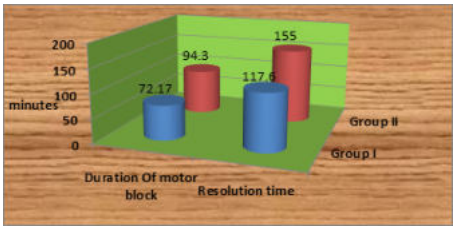


Mean Time to motor block to Bromage I in Group I was 3.55 min and in Group II was 2.45 with mean difference of 1.1 min. Patients in Group I had statistical significantly ($p<0.01$) longer time to motor block compared to that in Group II.

Mean duration of motor block to Bromage III in Group I patients was 72.17 min and in Group II was 94.33 min with the difference of 22.17 min. Patients in Group II had statistically Significant ($p<0.01$) longer duration of motor block compared to that in Group I patients.

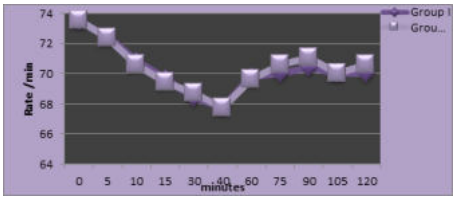
Mean resolution time to Bromage 0 in Group I was 117.67 min and in Group II was 155 min with the mean difference of 37.33 min. Patients in Group II has statistically significant ($p<0.01$) longer duration of resolution time compared to that of Group I patients.

Graph No 3: Comparison of duration and resolution time of motor Block



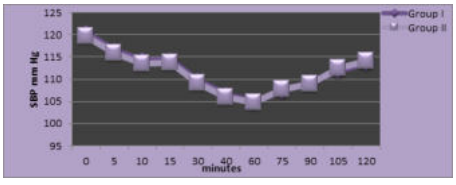
Intra operative comparison of pulse rate in between patients in Group I and Group II had no statistical significant ($p>0.05$) difference after 0, 5,10, 15, 30, 40, 60, 75, 90, 105 and 120 minutes of the surgical procedure.

Graph No 4: Comparison of intra operative pulse rate in between the groups.



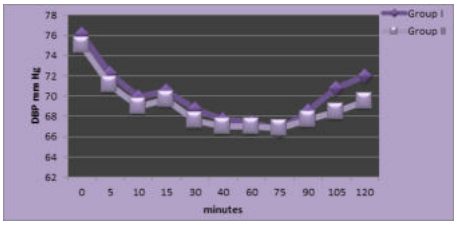
Systolic blood pressure in between Group I and Group II patients was not statistically ($p>0.05$) different at 0, 5, 10, 15, 30, 40, 60, 75, 90, 105 and 120 minutes during the operative procedure.

Graph No 5: Comparison of intra operative Systolic Blood Pressure (SBP) in between the groups.



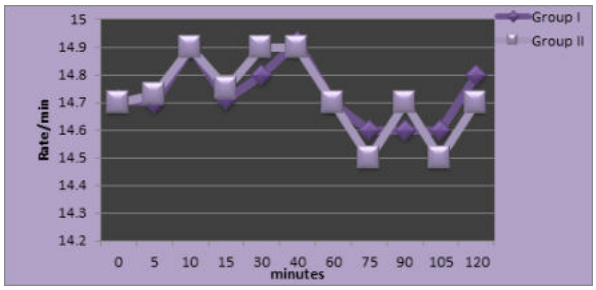
Intra operative comparison of diastolic blood pressure in between patients in Group I and Group II had no statistical significant ($p>0.05$) difference after 0, 5, 10, 15, 30, 40, 60, 75, 90, 105 and 120 minutes of the surgical procedure.

Graph No 6: Comparison of intra operative Diastolic Blood Pressure.



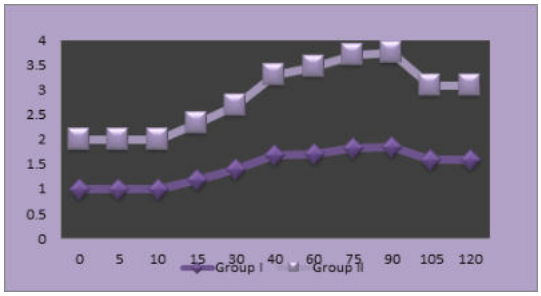
Respiratory rate in between Group I and Group II patients was not statistically ($p>0.05$) different at 0, 5, 10, 15, 30, 40, 60, 75, 90, 105 and 120 minutes during intra operative procedure.

Graph No 7: Comparison of intra operative respiratory rate.



Intra operative comparison of sedation score in between patients in Group I and Group II had no statistical significant ($p>0.05$) difference after 0, 5, 10, 15, 30, 40, 60, 75, 90, 105 and 120 minutes of the surgical procedure.

Graph No 8: Comparison of intra operative Sedation score.



Mean difference of VAS for pain between Group I and Group II patients was not statistically significant ($p>0.05$) at 0, 30min & 1hr of operative procedure. However, after 2 hrs, 4 hrs, 6 hrs, 8 hrs, 10 hrs, 12 hrs and 24 hrs of the procedure there was reduction in VAS score in both groups with Group II patients having lower mean VAS score than Group II patients. The group II patients had statistically highly significant ($p<0.001$) lower VAS compared to the Group I. Mean number of analgesic supplementations required in Group I was 3.63 and in Group II 2.43 was needed.

There was a mean difference of 1.19 with Group I needing statistically highly significant ($p<0.001$) more number of analgesic supplementations. In 6.8% (4) patients, adverse effect of nausea/ vomiting or hypotension was noted in Group I while 5.1% had complained of urinary retention. In Group II 5 % (3) had complained of nausea/vomiting or hypotension and 3.3% either had urinary retention or pruritus complaint .None of the patient had developed bradycardia.

DISCUSSION

The drugs commonly used for spinal subarachnoid block are Lignocaine and Bupivacaine. One disadvantage with spinal anaesthesia using local anaesthetic alone is that analgesia ends with the regression of the block, which means that there is an early post-operative need of analgesia, apart from causing discomfort which has other deleterious effects involving mainly the cardio-respiratory system.

In recent years, the use of intrathecal narcotics has become widespread, albeit at the cost of an increased risk for respiratory depression.

Fentanyl has a rapid onset and shorter duration of action following intrathecal administrations. It prolongs the duration of Bupivacaine induced sensory blockade. This suggests a potential synergism between Fentanyl and Bupivacaine as reported in an animal study by Wang et al reported that Fentanyl is one of the safest opioids. Orthopaedic patients were chosen as most orthopaedic procedures can be done under spinal anaesthesia.[3]

Onset of peak analgesia in Group I was at 4.5 min with 0.5 S.D and that in Group II was 3.23 with 0.24 S.D. The onset of peak analgesia in Group II was faster than group I by almost 1.27 min and this difference was found to be statistically highly significant ($p<0.01$).

Lee yy et al found that adding Fentanyl 10 mcg to intrathecal Bupivacaine provide fast onset and good analgesia for longer duration compare to plain Bupivacaine.[4]

Seewal R et a found that addition of 10 mcg of Fentanyl to 0.5 % hyperbaric Bupivacaine significantly improve the quality and duration of analgesia. No other advantage occurs if the dose of Fentanyl is increased up to 40 mcg.[5]

Duration of complete analgesia in Group I was 154.5 min and that in Group II was 313.7 min with the difference of 159.2 min in them as in table no.4. Group II had statistically significant ($p<0.01$) longer duration of complete analgesia compared to Group I patients. Effective analgesia duration in Group I was 176.1 min and in Group II was 365.7 min with the mean difference of 189.6 min. Patients in Group II has statistically significantly ($p<0.01$) longer duration of effective analgesia compared to that of Group I patients.

Our study also demonstrated that Fentanyl, 25 mcg intrathecally reduced the analgesics requirement of the patients postoperatively. This suggests a potential synergism between Fentanyl and Bupivacaine as reported in an animal study by Wang ET al.[6]

Duration of motor block Bromage 3 was prolonged in Group II (94.33±14.89) as compare to Group I (72.17±13.35). Moreover, this difference was statistically significant in our study.

Resolution time of motor block to Bromage grade 0 was significantly prolonged in Group II (155±21.75) than Group I (117.67±16.09).

Though most of the studies have shown that there is no prolongation of motor block with the use of Fentanyl. Our study results are comparable with Kuusniemi KS et al who conducted a study on 80 men undergoing urologic surgery and randomized then into four groups: Group I- Bupivacaine 10 mg, Group-II Bupivacaine 10 mg with Fentanyl 25 mcg, Group III Bupivacaine 7.5 mg with Fentanyl 25 mcg and Group IV-Bupivacaine 5 mg with Fentanyl 25 mcg. They concluded that the addition of 25 mcg of Fentanyl to intrathecal Bupivacaine increases the intensity of motor block.[7,8]

In our study Intra operative comparison of sedation score in between patients in Group I and Group II had no statistical significant ($p>0.05$) difference after 0, 5, 10, 15, 30, 40, 60, 75, 90, 105 and 120 minutes of the surgical procedure. Thus with intrathecal Fentanyl in the dose of 25 mcg achieves adequate analgesia but no sedation intraoperatively. Also, in the postoperative period none of the patient of both the groups found statistically significant sedation score.

However, according to Singh H et al Fentanyl addition does not cause any sedation and our study results are comparable with the same.[9]

Heart rate, blood pressure (systolic and diastolic), respiratory rate and saturation preoperatively in both the groups did not vary significantly. In addition, the difference was not statistically significant.

After giving spinal anesthesia all the vital parameters were monitored carefully and results were noted. In our study, no instances of bradycardia in any patient of both the groups were found intraoperatively.

Also, only 4 patients developed hypotension in group I and 3 patients in group II, this was nothing but the extension of the pharmacological action, and they were treated with iv fluids and boluses of inj. Mefentermine 6 mg iv. All those results had p value > 0.05 and statistically not significant in both the groups. It has been reported that neuraxial administration of Fentanyl with local anesthetic can lead to an increased incidence of hypotension following co-administration of Fentanyl and local anesthetic, increased incidence of hypotension may be related to higher sensory level achieved, as reported by Adkinsson et al In our study, the highest sensory level achieved were T8 to T10 in both the groups. Animal studies have shown that Fentanyl does not potentiate the effect of Bupivacaine on efferent sympathetic pathways.[10,11]

Nausea and vomiting were found in 6.8% of the Group I and 5% of the Group II patients.

None of the patient in our study of both the Group had a episode of bradycardia and almost equal no. of patients (5-6%) of both the Group had developed hypotension Intraoperatively.

5.1 % patient of Group I and 3.3% patients of Group II had urinary retention.

So our study demonstrated that Fentanyl, 25 mcg reduced the analgesic requirement without increasing the incidence of episodes of Desaturation, nausea, respiratory depression or pruritus during the early postoperative period. Belzarena found that Fentanyl, 0.5 mcg/kg and 0.75 mcg/kg it, increased the duration of post-operative analgesia in parturient following caesarean delivery; however this increased duration was associated with a decrease in the respiratory rate during the intraoperative period, and an increased incidence of sedation and pruritus related to higher doses of Fentanyl.[12]

CONCLUSION-

With the present study we can summarize that intrathecal Fentanyl potentiates the action of Bupivacaine thereby bringing about better quality and longer duration of analgesia, intense motor block, no hemodynamic disturbance and better postoperative outcome with minimum side effects.

Conflict of Interest

The authors declare that there is no conflict of interest.

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