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POST OPERATIVE ANALGESIA AFTER SPINAL ANAESTHESIA WITH MORPHINE AND BUPIVACAINE VERSUS FENTANYL AND BUPIVACAINE FOR UNILATERAL INGUINAL HERNIA REPAIR IN ADULT MALE : A COMPARATIVE STUDY

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ABSTRACT **Background:** The study is aimed to compare the effects of intrathecal fentanyl and intrathecal morphine combined with 0.5% hyperbaric bupivacaine on the quality of postoperative pain control for unilateral inguinal hernia repair in adult male population. **Materials and Methods:** Fifty –five patients aged 18-60 years with American Society of Anesthesiologists physical status I-II scheduled for elective inguinal hernia repair surgery were enrolled in this prospective randomized double blinded study. Patients received spinal anesthesia with either 25 mcg fentanyl plus 15 mg heavy bupivacaine intrathecally (group F, n=55) or 0.2 mg morphine plus 15 mg heavy bupivacaine intrathecally (group M, n=55).Hemodynamic parameters, time to first analgesic requirement, postoperative pain scores, the number of analgesic requirements and side effects over postoperative 24 h were recorded **Results:** Pain scores were significantly lower in group M compared with group F in the postoperative 24 h. The time to first analgesic requirement was higher in group M than group F. Analgesic requirement was higher in group F than group M for the first 24 hours, postoperative **Conclusion:** We concluded that the addition of 0.2 mg morphine intrathecally to 15 mg heavy bupivacaine provides improved postoperative analgesia than 25 mcg fentanyl for inguinal hernia repair under spinal anesthesia.

KEYWORDS : Spinal anesthesia; morphine; fentanyl; postoperative

INTRODUCTION:

Spinal anaesthesia or sub arachnoid block, is a form of regional anaesthesia, involving injection of a local anaesthetic drug into the sub arachnoid space which is a safe and effective alternative to general anaesthesia when the surgical site is located on the lower extremities, perineum, lower abdomen or lower body wall.

It has been observed in different lower abdominal surgeries like inguinal hernia repair, peritoneum is pulled causing visceral pain. [1] A subarachnoid block with only hyperbaric bupivacaine, a high sensory blockade reaching T4-T6 level may be insufficient and additional intraoperative analgesia is often required. Higher dose of bupivacaine to increase the level of blockage enhance hypotension and also increase the risk of respiratory complications. [1, 2] In order to limit these adverse effects local anaesthetic agents are combined with low dose of opioid which allow decreasing the dose of bupivacaine and thus its adverse effects. This combination also improves the quality of intraoperative analgesia. Their analgesic effect lasts longer in the postoperative period too, thus side effect associated with intravenous analgesic opiods e.g. nausea, vomiting, pruritus, respiratory depression are also decreased. [3,4]

It has become a popular practice to add opioids to spinal solution. Intrathecal opioids are synergistic with local anesthetics and intensify the sensory block without increasing the sympathetic block. Morphine and Fentanyl are the two commonly used opioids for this purpose.

Intrathecal morphine which is less hydrophobic than other opioids has a longer residence time in the CSF and provides excellent postoperative analgesia. Different studies show the clear differences between morphine and mu-opioid receptor agonist fentanyl in time course and dermatomal extent of analgesia. According to experimental studies intrathecally administered fentanyl is cleared from CSF within a relatively short duration of time in comparison to morphine and also travel shorter distance causing lesser dermatomal distribution.

This prospective randomised controlled study was proposed to compare the post operative analgesic effect and also the adverse effect of intrathecal morphine and fentanyl when used along with hyperbaric bupivacaine (0.5%) to induce spinal anaesthesia in unilateral inguinal hernia repair in adult male population.

MATERIALAND METHODS:

Randomised controlled prospective double blinded study was done on patients undergoing unilateral inguinal hernia at the department of surgery , R.G Kar Medical College and Hospital.

Sample size for the study was calculated with time to first rescue analgesic as the primary outcome variable. It is calculated that 55 subjects should be required per group in order to detect clinical difference of 180 minutes in this time parameter between the two groups with 95% confidence level and assuming 80% power of the test.

The study was initiated after obtaining approval of institutional ethics committee and written consent from all patients. Patients between 18-60 years of age of ASA I and II were counselled to take part in the study and also that it is a part of the anaesthesia technique in the planned surgical intervention. Patients were made to familiarize the subjective test parameters that were evaluated and required the patients cooperation. Following a detailed preoperative check up of all the patients along with relevant investigations, the patients were divided randomly into two equal groups using computer generated random numbers with each group containing 55 patients.

Group F: Patients who has received intrathecal injection of 3 ml (15mg) of 0.5% hyperbaric bupivacaine plus 0.5 ml of Fentanyl (25 micrograms) for spinal anaesthesia.

Group M : patients who has received 0.2 mg of intrathecal Morphine as additive with 3 ml (15mg) of 0.5% hyperbaric bupivacaine for spinal anaesthesia.

10 mg/ml morphine is diluted in 5%, 25 ml dextrose [i.e 0.4mg morphine/ml solution] and 0.5 ml of this solution [i.e. 0.2 mg morphine] is taken to add with 3 ml (15mg) of 0.5% hyperbaric bupivacaine for group M.

A peripheral 18 G intravenous canula was inserted to a peripheral vein of all patients before operation. Basic hemodynamic monitoring

which consists recording of five leads ECG, non invasive BP, SpO2 which were applied on patient after entering the operation theatre.

All patients were put in sitting position with leaning forward. Maintaining proper asepsis, subarachnoid block was given to all patients at the level of L4-L5 or L3-L4 interspaces with 25G Quincke's spinal needle. The M and F group received 0.2 mg morphine and 25 micrograms of fentanyl respectively as additive with 3 ml (15 mg) of

heavy bupivacaine (0.5%). Spinal injections were given by anaesthetists who were not participating in recording patient's data. Both patient and observer were blind to the drug given. After injecting spinal solution, patient were immediately placed in supine position. Continuous monitoring of conscious level and SpO2 was done. Sensory block (assessed by pin prick) and motor block (assessed by Bromage scale) level was continuously recorded until skin incision. Surgical incision was allowed when the block reach T6 dermatome. Oxygen supplementation was given by face mask @ 4litre/minute. Heart rate and blood pressure were measured noninvasively at every 2 minute interval for first 15 minutes and then measured at every 5 minute interval.. Atropine and vasopressor phenylephrine were kept to deal with bradycardia (bradycardia to be defined as heart rate below 50/minute with hemodynamic instability) and hypotension (hypotension to be defined by 20 % fall of SBP or DBP in respect to baseline resting value) respectively.

VAS was recorded intraoperatively. Complications related to spinal block and drug allergy and itching was recorded and managed accordingly

In postoperative period, respiration, sensory level, motor block were recorded in every 15 minute interval along with continuous monitoring of conscious level and SpO2 till complete recovery. Heart rate and blood pressure were recorded in every two hours.

The duration of analgesia (from intrathecal injection to VAS> 0) and the time of first analgesic dose (i.e. effective analgesic time measured by time interval between intrathecal injection and VAS >/= 4) were noted in every patient. NSAIDS was given for analgesia to all patients scoring VAS >/=4).

Any complication, if occurred, was recorded and managed accordingly. For vomiting, injection Ondansetron 4mg intravenously, for pruritus 10 mg propofol intravenously, for shivering 20 mg pethidine intravenously was given.

Statistical Analysis

The data collected was charted in "Microsoft Excel 2007TM" software by a blinded observer and then analysis was done using "IBM® SPSS® Statistics 20", Armonk, New York.

Categorical data were presented as numbers (n) and percentage (%), numerical data were presented as the mean and standard deviation (as median and minimum maximum where necessary). Nonparametric MannWhitney U test was used for the time to the first analgesic requirement, the number of analgesic requirements and a cumulative number of analgesic requirements. Chi-Square test and T-test were used in demographic data analysis. A p value <0.05 was considered statistically significant.

RESULTS

One hundred and sixteen patients were eligible for this study. One hundred and ten patients have completed the study. There was no statistical significance in demographic and hemodynamic (SBP, DBP, and HR) data between the two groups.

Table 1. shows the analysis of the demographic parameters which included age, height and weight revealed that both the Group M and Group F were statistically comparable.

Table 1. Demographic data of the groups

PARAMETERS	Group M (n =55)	Group F (n = 55)	p value	Significance
Age (years)	41.09 ± 11.029	40.13 ±10.538	0.640	Not significant
Weight (Kg)	65.11± 8.877	64.24± 7.829	0.586	Not significant
Height (cm)	168.13± 7.386	169.44± 6.297	0.319	Not significant

Comparison of ASA status, perioperative vitals / hemodynamic parameters which included non-invasive mean arterial blood pressure, heart rate, peripheral oxygen saturation, spinal anaesthesia parameters like onset of the block and time to reach highest dermatomal level and regression of sensory block to T10 level, time of onset and time to resolution of motor block by t-test revealed no statistically significant difference among the two groups.

In our study the onset of sensory block , time taken to reach the highest dermatomal level(which included either T6 or T8) and duration of sensory block was similar in both groups . Regarding motor block parameter, onset of complete motor blockage and

complete resolution of it as measured by Bromage scale 3 and 0 respectively was found to be statistically insignificant between the two group when analysed by t test .

The data of the visual analogue scale for postoperative pain assessment was analysed by the t-test to calculate the mean, standard deviation and the two-tailed P value as shown in Table 2.

Table 2. Data of Visual Analogue Score for Post operative Pain Assessment

Parameters	GroupM (Mean±SD) (Hrs)	GroupF (Mean±SD) (Hrs)	P value	Significance
VAS 2	15.95 ± 2.889	2.82 ± 0.772	0.000	significant
VAS >/= 4	21.84± 3.190	4.20±.951	0.000	significant

Time taken to achieve the VAS Score (for assessment of postoperative pain) 2 and 4 in the postoperative period is significantly high in the Group M compared to Group F as demonstrated by the P value (two-tailed) less than 0.001 in both situation.

Analgesic Requirement:

Analysis of time of requirement of first rescue analgesic in the postoperative period by t test yields following data as shown in the table 3.

Table 3. showing the time of requirement of first rescue analgesic in the postoperative period

	Group M (Mean±SD)	Group F (Mean±SD)	P Value	Significance
Time of first rescue analgesic (hours)	21.84±3.190	4.20±0.951	<0.001	Significant

Our study found that the time to giving the first rescue analgesic was significant in the morphine group which was 21.84±3.190 hrs in comparison to the fentanyl group which was 4.20±0.951hrs.

Side Effect Profile:

There is no significant difference found in respect of adverse effect profile of two groups except a higher incidence pruritus which was experienced by people of group M. Though most of this episode of pruritus were mild in nature and managed by simple assurance.

DISCUSSION :

Spinal anaesthesia or sub-arachnoid block has been evident as one of the common techniques in the daily practice of anaesthesia and it is aimed mainly for lower abdominal or lower limb surgeries. Along with this, postoperative analgesia is a constant concern for better patient comfort and outcome. Bupivacaine is a local anaesthetic agent that is much in vogue for its use in regional techniques and in central neuraxial blocks. But often addition of adjuvants is essential to improve the duration or quality of the block. [5,6]

Intrathecal opioids cause segmental analgesia by binding to opioid receptors in the dorsal horn of the spinal cord. They prolong the duration of analgesia without affecting motor or autonomic nervous function. Their combination with intrathecal local anesthetics limits the regression of the sensory block seen with local anesthetics alone. Respiratory depression is the most serious side effect of intrathecal opioids while pruritus is the commonest. Others include nausea, vomiting, urine retention and sedation. [7,8]

In this prospective randomized double blind study, the post-operative analgesic requirements and the spinally mediated analgesic effects of bupivacaine (hyperbaric) 0.5% in combination with fentanyl (25 mcg) or morphine (200 mcg) in male patients undergoing unilateral inguinal hernia were observed and recorded.

In the entire intraoperative and postoperative [for 24 hrs] period the patients were monitored for noninvasive mean arterial pressure, heart rate and the peripheral oxygen saturation at regular intervals. Both the

Group M and the Group F had similar intra and postoperative haemodynamic profiles and the statistical analysis by t-tests proved the same. The findings of our study corroborated with the finding of previous studies of Hala Mostafa Gomaa et al in 2013,Jorgen B. Dahl, et al in 1999. In all these studies the haemodynamic and respiratory parameters were stable and with no incidences of side effects under these parameters. [9,10]

Our main aim in our study was to assess the postoperative pain free period The postoperative assessment of pain was done by Visual analogue scale (VAS) in regular interval. Appearance of postoperative pain and requirement of first analgesic were significantly earlier in Group F compared to Group M. Our results are comparable to a study done by Refika Kılıçkaya et al (2018) which concluded that the addition of 0.1 mg morphine intrathecally to 12.5 mg heavy bupivacaine provides improved postoperative analgesia, especially after postoperative 12 h than 25 mcg fentanyl for inguinal hernia repair under spinal anesthesia.[11]

This finding is similar to previous study of Semra Karaman and others (2010) who studied the effect of morphine and fentanyl alone or in combination added to intrathecal bupivacaine in spinal anaesthesia for cesarean section and found that 0.2mg intrathecal morphine is as effective as 25 micrograms fentanyl for intraoperative analgesia and produces better and prolong postoperative analgesic quality than fentanyl. [12]

Woiciech Weigl , Andrej Bierylo (2016) in a similar study in elective cesarean section found intrathecal morphine significantly prolonged the time to first PCA use when compared to fentanyl. The mean VAS score was also lower in patient who received intrathecal morphine. In this study, The mean use of pethidine during the first 24 h was significantly higher in group F than in group M ($p<0.001$); the mean time to the first start of the PCA pump was markedly longer after morphine. [13]

Efficacy of intrathecal morphine for prolong postoperative analgesia is also documented in the study by Abouleish E, Rawal N, Rashad MN . [14]

Regarding side effect profile, there is no significant difference found in respect of adverse effect profile of two groups except significantly higher incidence pruritus had experienced by people of group M. Though most of this episode of pruritus were not bothersome in nature and managed by simple assurance.

There is neither any event of major arrhythmia nor anyone of both group experienced respiratory depression. 25 mcg fentanyl and 200 mcg seems safe considering the induction of sedation or late respiratory depression although the findings of the present study are not explicit.

In conclusion ,the principal findings of this study are that intrathecal morphine-bupivacaine mixture provides longer duration and superior analgesia (with lesser requirement for rescue analgesia) as compared to intrathecal fentanyl-bupivacaine mixture.

The obvious limitation of our study includes the absence of a control group (in which patients would have received 3 ml of hyperbaric bupivacaine along with 0.5 ml of saline intrathecally). The inclusion of a control group would have further supported our findings. We also recognize the fact that the wide variability in the age of the patients included in the study is a confounding factor in relation to perception of pain as pain perception varies for various age groups.

Limited sample size and not including other type of lower abdominal surgery are other limitation of this study.

Further investigation can be aimed at finding the minimal possible doses of intrathecal fentanyl and morphine in conjunction with hyperbaric bupivacaine that will provide adequate anesthesia and analgesia for lower abdominal surgeries like inguinal hernioplasty.

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