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EFFECT OF ADDING FENTANYL TO ISOBARIC 0.75% ROPIVACAINE IN SUBARACHNOID BLOCK FOR INFRAUMBLICAL SURGERIES.

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ABSTRACT

AIM: This study was aimed to evaluate the clinical efficacy and safety of intrathecal fentanyl as an adjuvant to 0.75% isobaric ropivacaine on onset, duration, intensity, and recovery time of sensory and motor blockade for infra umbilical surgeries.

METHOD: This prospective randomised double blind study involving 20 patients in each group. Group A: Inj .Isobaric 0.75%Ropivacaine 4.0 ml + 1 ml CSF, and Group B– Inj. Isobaric 0.75% Ropivacaine 4.0 ml + Fentanyl 25µg (0.25 ml) + CSF 0.75ml. Data analysis was done with unpaired t test, one way ANOVA and post hoc Tukey test.

Results: Onset of sensory block was comparable. Comparing motor block and sensory block, motor block was statistically prolonged in Group B.

Conclusion: Intrathecal fentanyl as an adjuvant to 0.75% isobaric ropivacaine demonstrated better clinical profile as compared to ropivacaine alone.

KEYWORDS : Subarachnoid Block, Fentanyl, Ropivacaine

INTRODUCTION

Subarachnoid block is well established technique, for providing anaesthesia for lower limb surgeries, pelvis, perineum, urological, gynaecological and obstetrical procedures(infraumblical surgeries).[1] Among various local anaesthetic drugs bupivacaine is most commonly used intrathecal local anaesthetic, already have undergone many researches. Ropivacaine is purely S-isomer imparting less toxicity to the cardiovascular[2] and central nervous systems[3] though producing less intense motor blockade and postoperative analgesia[4]. Therefore studies were conducted with addition of different adjuvants to isobaric ropivacaine[5,6] such as clonidine[7,8] fentanyl[9] or dexmedetomidine[10]. Fentanyl is an opioid has shown to improve analgesic potency of ropivacaine and prolong postoperative analgesia for spinal anesthesia.[11] In this study we have to evaluate Intrathecal fentanyl as an adjuvant to 0.75% isobaric ropivacaine for onset, duration of sensory and motor blockage and quality of motor block in subarachanoid block for lower abdominal and lower limb surgery.

METHOD AND MATERIAL:

After obtaining approval from ethics committee and written informed consent, this prospective double blind randomized clinical study was conducted on 60 ASA grade I and II patients, of either sex aged between 20-60yrs, undergoing elective surgery(of less than 120mins) on lower abdomen and lower limb under spinal anaesthesia. Patient`s refusal, History of sensitivity to local anaesthetic, Patient on anticoagulant therapy or with abnormal bleeding or coagulation profile, Infection at the site of injection, Spinal abnormalities, previous spine surgery, Presence of co-morbid diseases contraindicating spinal block were excluded from this study.

Detailed pre-anaesthetic examination was done and anaesthetic procedure was briefly explained to the patient. Patients were randomly allocated into 2 groups of 20 patients in each, using computer generated randomisation chart: Group A (Control group)– Inj.0.75%Isobaric Ropivacaine – 4.0 ml + 1 ml CSF and Group B– Inj. Isobaric 0.75% Ropivacaine – 4.0 ml + Fentanyl 25µg (0.25 ml) + CSF 0.75 ml.

The patients were kept nil orally for 8hrs before surgery. After shifting the patient on the OT table, routine monitors such as non-invasive blood pressure(NIBP), pulse oximeter (SpO2) and continuous electrocardiogram(ECG) were applied. Baseline Heart rate (HR),BP, respiratory rate(RR), SpO2 were recorded. A wide bore intravenous access was secured and preloading with 10ml/kg ringer lactate was done. Under strict aseptic precautions, lumbar puncture was performed by midline approach in lateral position by using 25G Quincke spinal needle at L3–L4 intervertebral space. After performing successful lumber puncture, Isobaric Ropivacaine 0.75% with or without Fentanyl was administered according to assigned study groups. Operator and investigator were blinded about the drug which was prepared by independent investigator. Table was kept in neutral position and all patients were made supine immediately following the injection.

The completion of injection was taken as time zero of induction of anaesthesia.

After spinal anaesthesia, the patient's HR, MAP, RR, and SpO2 were recorded at 0, 5, 10, 15, 20, 25, 30 minutes and then every 15mins till the end of procedure.

Postoperatively HR, NIBP and SpO2 were recorded every 2hrly until the sensory and motor functions were back to normal.

The sensory and motor blockade parameters were assessed after spinal anaesthesia at 2min intervals until the surgical anaesthesia was achieved and post-operatively every 15 minutes until the sensory and motor functions were back to normal. Time of onset of sensory and motor block, highest dermatomal level of sensory block achieved, duration of sensory and motor block were noted.

Onset time of sensory blockade was defined as the interval between intrathecal administration of drug and loss of pin prick sensation at T10 level. Level of sensory block was assessed by loss of pin prick sensation using 24G hypodermic needle bilaterally along midclavicular line at L1, T12, T10, T8, T6 and T4 level. Duration of sensory block was defined as the interval from intrathecal administration to the point of regression of sensory blockade from T10 to S1, was noted by pin prick with 24G hypodermic needle on posteromedial aspect of thigh.

Onset time of motor blockade was defined as the time interval intrathecal administration of drug and the Bromage score 3, recorded. Motor block was assessed using 3 point Modified Bromage Scale[11]. Score 0 = no motor block,1= inability to raise extended legs, 2 = inability to flex knees, and 3 = inability to flex ankle joints. Duration of motor blockade was defined as interval from intrathecal administration to the point in which the Bromage score was back to zero recorded. Duration of pain free period: The time interval from intrathecal injection of drug till demand of first rescue dose of analgesic.

Level of sedation was assessed using the sedation score described by Chernik et al. (1990)[12] Score 0= Wide awake, 1= sleeping comfortably, responding to verbal commands, 2= deep sleep, but arousable, 3=deep sleep, not arousable. It was assessed preoperative then after 15 mins, 30 mins, 45 mins, 60 mins & 120 minutes.

The occurrence of adverse events, that includes bradycardia, hypotension, pruritus, respiratory depression (RR/min and SpO2), sedation, shivering & nausea and vomiting were recorded and managed accordingly.

On patient's demand for analgesia, Inj. Diclofenac 75mg IM was given.

Stastics :
Data were compiled and analysed using software SPSS version 16. P value of < 0.05 was considered significant. The means of groups were compared using unpaired t test while the means between more than one group was compared using one way ANOVA and post hoc Tukey test. The final data was represented using tables and graphs.

Results:
Spinal anaesthesia was successful in all the patients. The mean age, sex, height, weight and duration of surgery were similar in all groups {table1} .

TABLE 1 showing demographic datas: MEAN±SD

	GROUP A	GROUP B	P value
AGE(YRS)	38±10.8	41±9.8	NS
SEX(M/F)	16/4	17/3	NS
WEIGHT (KG)	58.5±8.47	60.3±8.28	NS
HEIGHT(CM)	151±10.54	156±20	NS
DURATION OF SURGERIES(MIN)	92.50±28.72	87.25±20.23	NS

NS: Non significant p>0.05

TABLE 2: SENSORY AND MOTOR CHARACTERSTICS IN ALL GROUPS (MEAN±SD)

	GROUP A	GROUP B
Onset of sensory block(min)	4.09 ± 1.08	3.24 ± 1.05
Hightest dermatomal level	T6(T6-T12)	T4(T4-T12)
Duration of sensory block(min)	227.3 ± 62.5	383.6 ± 49.7
Onset of motor block	12.01 ± 1.57	7.88 ± 1.00
Duration of motor block	202.3 ± 64.1	318.50 ± 31.70
period of analgesia	237.8 ± 63.8	407.7 ± 52.6

The mean onset time of sensory block in Group A was 4.09 ± 1.08 min and in Group B it was 3.24 ± 1.05 min. (p>0.05). All values were comparable. Highest sensory level was recorded in Group A was T6-T12/T6 while and in group B it was T4-T12/T4. In both the groups T8-T12 level dermatomal analgesia was achieved satisfactory and distribution appeared to be uniform.

Table 2 showing Group B had lowest time of onset of motor block whereas longest duration of sensory, motor block and period of analgesia among the two groups where fentanyl 25µg was added to ropivacaine which was statistically found significant(p<0.05) using unpaired t test.

TABLE 3: Comparison of Sedation Score between the Groups

Groups	After 15 min	After 30 min	After 45 min	After 60 min
Group A	0.15 ± 0.37	0.25 ± 0.44	0.10 ± 0.31	0.05 ± 0.22
Group B	0.20 ± 0.41	0.30 ± 0.66	0.05 ± 0.22	0.05 ± 0.22
P value	0.687, NS	0.862, NS	0.679, NS	0.609, NS

One-way ANOVA test

Post-hoc Tukey Test:

Group Pairs	After 15 min ('t', P value)	After 30 min ('t', P value)	After 45 min ('t', P value)	After 60 min ('t', P value)
Group A-B	0.43, P=0.901	0.27, P=0.960	0.44, P=0.898*	0.00, P=1.000

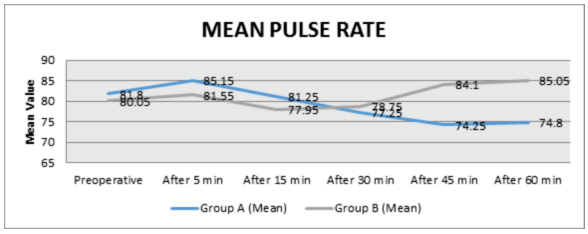
One-way ANOVA was applied to find out the statistical significance among the groups. Non-significant P values were obtained for all time intervals. Post-hoc Tukey shows the significance between different pairs of groups for different time intervals.

TABLE 4:Complications seen in all the three groups

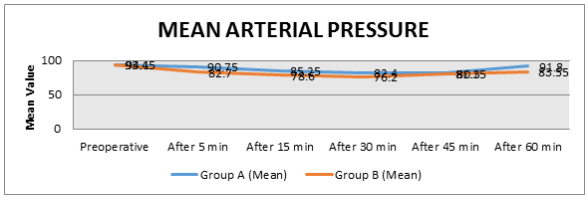
Complications	Group A	Group B
Uneventful	14	8
Nausea & vomiting	1	1
Hypotension	2	4
Mild pruritus	0	3
Bradycardia	2	4
Pain	1	0

As shown in table 4, incidence of complications were less in group A as compared to group B.

Graph 1: The mean pulse rate has been shown in line graph below



Graph 2:The mean arterial pressure has been shown in line graph below.



Discussion:
Subarachnoid block has been used in both elective and emergency procedures[13]. Recently ropivacaine is being getting used commonly as local anaesthetic of choice[14]. Fentanyl as adjuvant to ropivacaine enhances analgesic effect of local anaesthetic drug without intensifying motor and sympathetic block in spinal anaesthesia, thus leading to lower incidences of hypotension, early recovery and mobilization, with additional benefit of decreasing total dose of local anaesthetic drug needed[1]. Khaw KS et al.[14] concluded that during spinal anaesthesia in lateral position hyperbaric solution tends to spread more in cephalic direction while isobaric solution tends to concentrate at lumbar segments which was similar to our study showing comparatively lower segmental analgesic distribution with isobaric ropivacaine. Isobaric ropivacaine produces less intense, unpredictable and variable height of block when given intrathecally for spinal anaesthesia[6] but in our study not a single patient felt any discomfort during surgery did not require any analgesic supplementation.

In our study we found that following subarachnoid block; changes in HR, MAP and RR were not clinically significant similar to study done by Nuray and Berrin with intrathecal ropivacaine with fentanyl. They did not find any significant difference with respect to hemodynamic parameters.[15] The mean onset time of sensory block in Group A was 4.09 ± 1.08 min and in Group B it was 3.65 ± 1.05 min and comparable with each other. Our results were similar to study conducted by Boztug et al[16] who studied the effects of intrathecal isobaric ropivacaine 10mg and intrathecal ropivacaine 8mg with fentanyl 25µg for out-patient arthroscopic knee surgery. The onset for T10 level of blockade was faster in Group R compared to Group RF (3.60±1.84 min vs. 5.25±2.04 min), but the results were not statistically significant. Chaudhary A et al17 observed the same results of onset of sensory block when compared isobaric ropivacaine 15mg(0.75%) and isobaric ropivacaine 13mg (0.75%) with fentanyl 10µg given intrathecally.

Highest sensory level was recorded in Group A was T6-T12/T6 while in group B it was T4-T12/T4. Parlow et al[18] established the fact that hypobaricity influenced the extent of subarachnoid block and explained high cephalic levels of sensory block when fentanyl was added to isobaric local anaesthetic solution. In the present study, sensory level of T4 was observed in group B but in group A the extent of sensory block reached only up to T6 dermatome, which is similar to Gupta K, Singh Set al[1] where they showed maximum dermatomal involvement was T6 (T6-T10) in group RC and T4 (T4-T10) level in group RF. Kaushik rao et al[19] also reported T6 level (T4-T9)with 19.5 mg ropivacaine plus 20µg of fentanyl was used.

In present study duration of sensory block was maximum in group B. Statistically when group A when compared with group B, difference was highly significant (P<0.05). Higher dose (25 µg) of fentanyl appears to be more promising to increase duration of sensory block. Seetharam KR et al[19]reported in their study that duration of sensory block is prolonged by addition of fentanyl 25µg to isobaric ropivacaine 18.5mg in subarachnoid block as compared to isobaric ropivacaine alone. They observed the duration of sensory analgesia of 341.6+/-15.03 minutes in fentanyl group and 240.4+/-13.08 minutes in control

group**.** Gupta A et al[20] and Yegin A et al[21] reported in a study that duration of sensory block was prolonged significant(P<0.05) in group RF(ropivacaine with fentanyl) as compared to group R(control) in different surgeries.

Jagtap et al[22]showed that adding fentanyl improved the quality and duration of analgesia when they compared fentanyl plus ropivacaine with fentanyl plus bupivacaine alone for spinal anaesthesia in minor urological procedures. Similarly**,** Kaushik rao et al[19], Boztug et al[16] Sanli et al[23] and Layek et al[24] found that time for analgesic requirement prolonged in fentanyl group compared to control group.

This study had shown statistical significant difference in both the groups. isobaric ropivacaine plus 25µg fentanyl offered rapid onset than ropivacaine alone. Our results were similar with studies conducted by Gupta K et al[1] and Chaudhary A et al[17].

Boztug N et al[16] and Seetharam R K et al[19] reported that onset of motor block was faster in group RF than group R but results were statistically insignificant.

In the present study duration of motor block was prolonged significantly (p<0.05) by addition of fentanyl in group B(p<0.05).Results of present study is comparable to results of Seetharam et al[19] and Gupta K et al[1].

Mean duration of postoperative analgesia was 237.8±63.6 min in group A and 407.7±52.6 in group B. Statistically the changes in duration of postoperative analgesia were highly significant (P<0.05). Yegin A et al[21]reported in the study that duration of pain relief from intrathecal fentanyl administration until the first request for supplemental analgesia was significant prolonged: 213.0+/-29.3 minutes (Group F- hyperbaric ropivacaine 15mg with fentanyl 10mcg) as compared to other group (Group S- hyperbaric ropivacaine 15mg) it was 161.2+/-32.6 minutes. Similarly study done by SeetharamK R et al[22] observed same thing. Kaushik rao et al[19]reported S2 regression time (Group R vs. Group RF, 240.4±13.087 min vs. 341.6±15.032 min) and Sanli et al[11] reported time to regression to L5 (Group S vs. Group F, 150.3±13.4 min vs. 168.3±17.3 min) were prolonged significantly in fentanyl group. These finding were similar to our results showing prolongation of analgesia duration in group B.

Degree of muscle relaxation**:** In the present study all patients achieved Bromage score 3 except in 2 patients of group A, it was score 2.

Group A- Bromage score of 3/3 in (90%) of cases.
Group B- Bromage score of 3/3 in (100%) of cases.

In Group B, all the 20 (100%) patients were having Bromage scale of 3. The sedation score as per Chernick`s score in the present study was 0 to 2, But it is not statistically significant (P>0.05). Sedative effect of fentanyl is due to systemic absorption of lipid-soluble opioid, although cephalad migration of opioid in the CSF and subsequent interaction with opioid receptors located in the ventral medulla may also be responsible.

Hypotension was recorded in 4 cases of group B and 2 cases of group A. Bradycardia was seen 2 cases in group A and 4 cases in group B. The incidence of vomiting was in one case each in group A (5%) and group B (5%). So it is very obvious that higher doses of fentanyl not only enhances the beneficial effects of isobaric ropivacaine but also increase number of side effects. Complications were not clinically significant and could be managed easily. Although ropivacaine is safe and well-tolerated during subarachnoid block, a few adverse effects were observed in the present study. Besides hypotension and bradycardia, pruritus, shivering, and nausea were also encountered.

Limitation of this study: Differences in injection technique, amount of dilution with CSF, speed of injection, brand of drug used and differences in drug concentration.

CONCLUSION:

Intrathecal fentanyl as an adjuvant to 0.75% ropivacaine was safe and well-tolerated for infra umbilical surgeries under subarachnoid blockade with reduced systemic toxicity. Early mobilization and voiding accelerate post-operative recovery and earlier discharge. Its clinical profile gives reasonable choice due to rapid recovery of motor function.

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