Volume : 2 | Issue : 12 | December 2013 • ISSN No 2277 - 8179

Research Paper

Comparison of Intrathecal Ropivacaine with Fentanyl and Bupivacaine with Fentanyl for Urological Surgery

Medical Science

KEYWORDS : Ropivacaine with fentanyl, Bupivacaine with fentanyl, urological surgery,motor block,sensory block

Dr. Bipin J. Ganvit	Senior Resident Department of Anaethesiology, GMERS Medical College & Hospiatl Valsad
Dr. Parimal H. Patel	Assistant Professor Department of Mcrobiology, GMERS Medical College & Hospiatl Valsad
Dr. Hitesh R. Ahir	Tutor Department of Microbiology, GMERS Medical College & Hospiatl Valsad

ABSTRACT

Introduction: Bupivacaine was the first long acting amino-amide local anaesthetic agent being used and ropivacaine is the pure (S-isomer) enantiomer of bupivacaine. Ropivacaine, s-enantiomer of amide local anaesthetic produces differential neural blockade with less motor blockade, cardiovascular and neurological toxicity makes it suitable for day care surgery.

Aim: To evaluate the efficacy and safety of Isobaric ropivacaine 0.75% when compared to Isobaric bupivacaine0.5% and addition of fentanyl 20mcg to provide operative anaesthesia in endoscopic urological surgeries

Material and Methods: In duration of three year (2010 to 2013) the study was randomized and double blinded, conducted in 120 adult patients scheduled for endoscopic urological surgery using spinal anaeshthesia. Anaesthtic agent uses were Inj Isobaric Ropivacaine 0.75% vial & Inj Fentanyl ampoule (group R+F) in 60 patients and Inj Isobaric Bupivacaine 0.5% vial & Inj Fentanyl ampoule (group B+F) in other 60 patients. All patients were examined for sensory and motor block was assessed at time intervals. Sensory block was assessed by using pin prick on each side of midthoracic line, and patients were asked about sensation at the site of surgery.The motor block was assessed by modified bromage score.

Result: There was no significant difference in the duration of surgery.

No. of URS surgery are more in group-R+F as compared to group-B+F & No of TURP –TURBT are more in group-B+F as compared to group-R+F. There was no statically significant difference in the onset time of sensory block in both groups. The median duration of sensory block at the T10 dermatome was significantly longer in B+F group. Onset of motor block was same in both groups. The median duration of complete motor block (modified bromage scale 3) was significantly shorter in the R+F group and after immediate post-operative period, the degree of motor block was lower in the R+F.

Conclusions: Ropivacaine with Fentanyl found to be better combination for urological surgeries as an adjuvant to general anaesthesia or sole technique with chances of less complication with high success rate.

Introduction: All urological surgeries have been performed with sole technique of either general anaesthesia or neuraxial blockade (sub-arachnoid block, epidural anaesthesia or the combination of both i.e.Combined Spinal Epidural Anaesthesia). Each of them has got their own merits and limitations. Many local anesthetics have been used for spinal and epidural anaesthesia in various strengths and volumes, which include Procaine, Cinchocaine, Mepivacaine, Tetracaine, Lidocaine, Meperidine, Bupivacaine, Levobupivacaine and the recently introduced Ropivacaine.

Bupivacaine was the first long acting amino-amide local anaesthetic agent being used and ropivacaine is the pure (S-isomer) enantiomer of bupivacaine. Both of them possess similar structure, pharmacology, mechanism of action and physiochemical properties. The property of cardiac toxicity with bupivacaine is more because of its racemic mixture[1].Both bupivacaine and ropivacaine have been used in the practice of anaesthesia for over many years. They have been used for subarachnoid block, epidural block, PCEA and peripheral nerve blocks. Ropivacaine has been recently introduced in India. Its use has since been explored by the anesthesiologist in virtue of the advantages it offers.Local anesthetic with adjuvant is more popular in recent years for better post-operative pain control with less side effects and early discharge.

Bupivacaine was a popular drug in regional anesthesia for years until toxic reactions were reported. Ropivacaine, the S-enantiomer of the amide local anesthetic, produces differential neural blockade, with less motor blockade, cardiovascular and neurological toxicity, making it suitable for day-care surgery. Caudal analgesia is more popular because of its simple technique, predictable level of blockade and high success rate, excellent postoperative analgesia with smooth recovery.It reduces analgesic requirement and facilitates early discharge[2].

The aim of the study, which is a double-blind, retrospective, randomized study, was to determine the efficacy of ropivacaine and bupivacane with fentanyl for spinal anesthesia in urological surgery for onset, duration, sensory and motor blockade, and postoperative analgesia.

Material and Methods:

In duration of three year (2010-2-13) after obtaining institutional ethical committee approval and written informed consent, the study was conducted in 120 adult patients scheduled for endoscopic urological surgery using spinal anaeshthesia were included in this randomised, double blinded study.

Inclusion criteria ASA physical status I - II and age 20-75 yrs. 120 patients undergoing endoscopic urological surgery were randomly assigned to blindly receive either 19.5mg ropivacaine + fentanyl 20 mcg (group- R+F) or 13 mg bupivacaine + fentanyl 20 mcg (group-B+F) intrathecally.

Exclusion criteria

- ASA Grade >3
- Emergency surgeries
- Mental retardation (congenital anomaly)
- All contraindication for regional Anaesthesia
- -Those with bleeding disorders and local sepsis.
- -Those on anti-coagulants and anti-platelet agents.
- -Those allergic to amide anesthetic
- Patient refusal for the procedure.
- Technical difficuities.

Drgus and Equipments

- 25 guage spinal needle
- 5ml syringe
- Sterile towel for draping
- Sponge holding forceps
- Cotton swabs
- Inj Isobaric Ropivacaine 0.75% vial & Inj Fentanyl ampoule

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(group R+F)
- Inj Isobaric Bupivacaine 0.5% vial & Inj Fentanyl ampoule
- (group B+F)

We choose isobaric solutions because only dextrose- free ropivacaine solutions are available. All patients underwent preanaesthetic check up the day before surgery and all routine and specific investigations were noted. Patients were kept NBM for at least 6 hours. An I.V. cannula was placed. Before spinal anaesthesia, an intravenous preload of 500ml of lactated ringers solution was given over 10minutes. The baseline mean arterial blood pressure and heart rate were determined from the average of three consecutive readings taken after the administration of fluids. The baseline blood pressure, heart-rate, SpO2 measured.

The patients were placed in the right or left lateral position. Spinal anaesthesia was given with full aseptic precaution, with 25 gauge whitacre spinal needle in L1-L2, L2-L3and L3-L4 any interspace. After given spinal anaesthesia the patient was placed in supine position and the operating table was placed horizontal. The sensory and motor block was assessed at time intervals:0, 3,5,10,20,30,45,60,90,120, minutes after injection. The intra-op blood pressure, Heart rate, spo2 monitoring was recorded at 0,3,5,10,15,20,25,30,45,60,90,120,240,360,480 min intervals, throughout study and surgery.Sensory block was assessed by using pin prick on each side of midthoracic line, and patients were asked about sensation at the site of surgery.

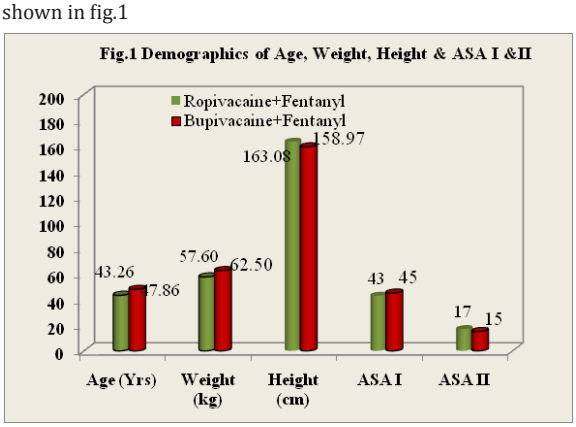
The motor block was assessed by modified bromage score[3].

Parameters observed during 24 hrs postoperatively were:
- Vitals- heart rate, mean blood pressure, SpO2
- Duration of complete motor and sensory block
- Time to mobilisation observed.
- Post op complication observed (headache, backache)

Result:
This prospective study was carried out in 120 ASA I & II adult patients undergoing endoscopic urological surgeries during the period of 2010- 2013 yrs.

Fisher Exact test & Chi-squre analysis was used for comparing Categorical data.P-values <0.05 were considered to be statistically significant.

The characteristics of the two groups were comparable in terms of age, weight, height and ASA classifications. There was no significant difference in the duration of surgery. Demographic data shown in fig.1



ASA=American Society for Anesthesiology

The type of surgeries done in both the groups are shown in the table 1.URS surgery are more in group-R+F as compared to group-B+F & No of TURP –TURBT are more in group-B+F as compared to group-R+F.

Table 1 type of surgeries done in both the groups

Name of Surgery	Group-B+F	Group-R+F
URS	26	43
D.J.Stenting	3	4
Cystolithotripsy	9	6
PCCL	1	2
Cystoscopy	2	2
TURP	9	2
TURBT	8	1
D.J.Removal	2	0

Development and regression of sensory block shown in Table 2

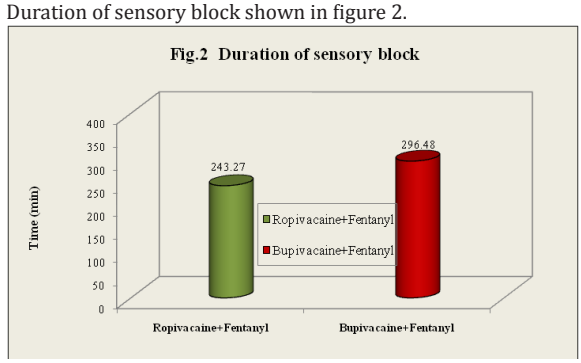
Table 2 Development and regression of Sensory block:

	Group-B+F	Group-R+F	P-value
Onset of sensory block T10 (min)	1.6 (±0.87)	1.58 (±0.82)	0.977
Cephalad spread of sensory block	T4(T4-T8)	T6(T6-T10)	0.05
2 Segement regression time (min)	127.8 (± 29.08)	102.8 (± 22.8)	<0.0001
Duration of Sensory block T10(min)	279.5 (± 54.9)	240.4 (± 52.1)	0.045

P< 0.05 is Significant

There was no stastically significant difference in the onset time of sensory block in both groups. Which was 1.6 min (1-3 min) in the B+F group & 1.58 min (1.4-3 min) in R+F group? Cephalad spread of sensory block was higher with B+F group than R+F group. Sensory block to the T10 dermatome or above was achieved and was sufficient for surgery in all patients.

Duration of sensory block shown in figure 2.



The median duration of sensory block at the T10 dermatome was significantly longer in B+F group.(296.48 min) compared with (243.27 min) in the R+F group.(p<0.045) Segment regression time was significantly shorter in Group-R+F (102.8 min) as compared to Group-B+F(127.8 min) p<0.0001.

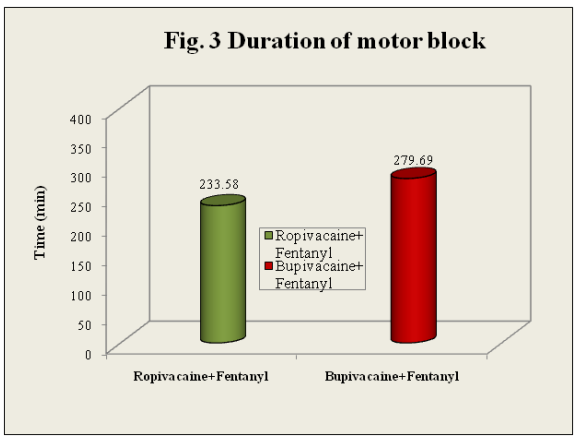
Onset of motor block shown in table 3 was same in both groups. The time to achieve a bromage score of 3 was 10 min in the R+F group and 8 min in the B+F group. This difference was not significant.

Table 3.Onset and duration of motor block:

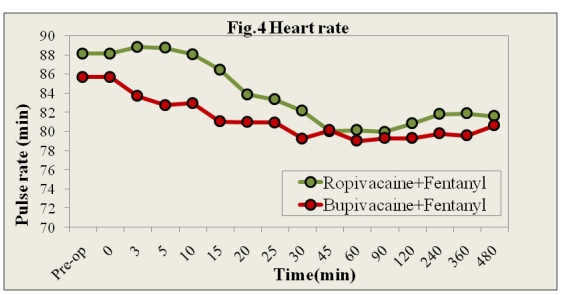
	Group-B+F	Group-R+F	P-value
Onset of motor block (min)	2.4 (±1.44)	2.46 (±2.1)	0.855
No of patients with Bromage 3	58 (96.6%)	55 (91.6%)	0.243
Duration of Motor block (min)	279.6 (±46.5)	233.5 (±48.06)	<0.0001

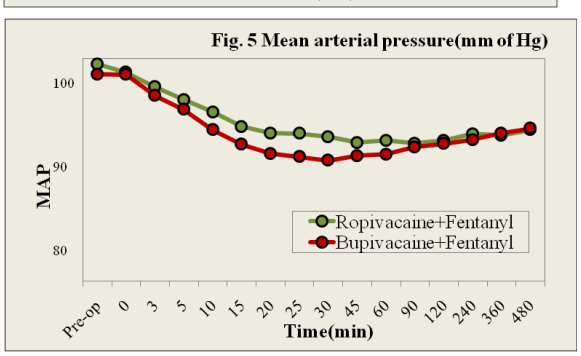
P< 0.05 is Significant.

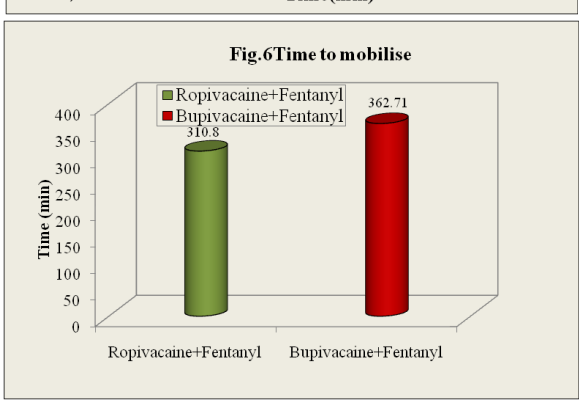
The median duration of complete motor block (modified bromage scale 3) was significantly shorter in the R+F group compared with the B+F group(233.58 vs 279.69 min, p<0.0001) . After immediate post-operative period, the degree of motor block was lower in the R+F patients compared with patients receiving B+F group. Shown in Figure 3.



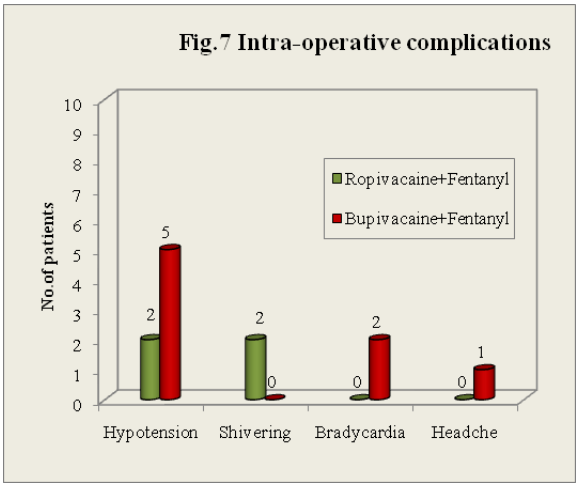
Heart rate, Mean arterial Pressure, Time to mobilise, intraoperative complication and postoperative complication shown in figure 4,5,6,7and 8 respectively.



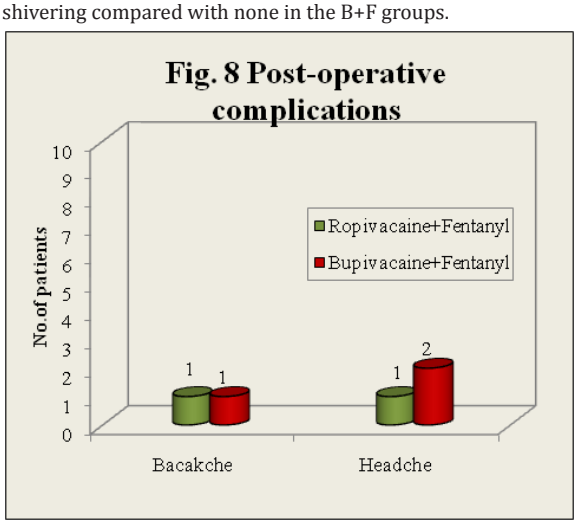




The patients mobilised earlier in R+F group.(310.8 min) compared to B+F group.(362.71 min) p<0.0001.



Intra-op hypotension requiring treatment with i.v. mephentermine 10 mg occurred in two patients in R+F groups and in 5 patients in the B+F groups. Two patients in the B+F group also required i.v. atropine 0.6 mg for the treatment of bradycardia compared with none in the R+F group. Two patients in the R+F group also required i.v. Tramadol 25 mg for the treatment of shivering compared with none in the B+F groups.



The most commonly reported adverse events during the first 24 h were backache and headache. The events were equally distributed between groups.

Discussion:

Introduction of spinal anaesthesia into clinical practice by August Bier and his assistant August Hilderbrandt in the year 1898[4] . The first drug used intrathecally was cocaine. There were several side effects noted with the use of cocaine like nausea, vomiting, dizziness, headache, restlessness and excitability to mention a few. Rapid recovery after spinal anaesthesia is useful for the facilitation of early mobilisation after endoscopic urological and other surgery of short duration. However, the best drug and combinations to achive these are controversial. Previously, *Gaiser RR et al*[5] had used hyperbaric lignocaine 50mg/ml as a common local anaesthetic for short surgical procedures. However, its use has declined because of concerns about cauda equina syndrome and transient neurological symptoms. This has aroused interest in alternative local anaesthetics and combinations which can produce spinal anaesthesia of relatively short duration. With the introduction of bupivacaine, the first long acting amino amide into clinical practice in 1963, its use has been widespread. However, its cardio-toxic and central nervous system effects has made researchers to come up with a new drug, ropivacaine which is a pure S-enantiomer of bupivacaine with similarities in structure, pharmacokinetics, pharmacodynamics and mechanism of action but with relatively less

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cardio-toxic and central nervous system effects[6]. It was introduced in 1997 in U.S and in 2009 in India.

Reducing the duration of hospital stay is becoming more important, especially for in-patients. Therefore in operation performed under spinal anaesthesia, early ambulation as a consequence of a shorter duration of motor block is considered desirable. Ropivacaine has been advocated as a drug with similar characteristics of block but with a shorter duration of motor block than bupivacaine. The use of intrathecal ropivacaine was suggested because it does not affect the spinal cord blood flow and does not induce neurotoxic effect after intrathecal administration in patients with different doses of ropivacaine. It was initially considered to have similar potency to bupivacaine. However, equivalent doses of ropivacaine and bupivacaine have now been identified for operations, with bupivacaine appearing 1.4 to 1.68 times more potent than ropivacaine.

The addition of fentanyl to local anaesthetics has several advantages including a synergistic analgesic effect. This combination may be useful for lower abdominal and lower limb surgery of limited duration when early mobilisation is required, for example in ambulatory surgery.

In our study we have found that patients in R + F group had shorter duration of motor block as well as a faster resolution of sensory block compared to B + F group.

This is consistent with the study of M Mantouvalou et al in 2008. They have found that ropivacaine without opioid presented a slower onset and a shorter duration of motor block, as well as a faster resolution of sensory block compared with bupivacaine7.

*Mc Namee et al*8 compared 17.5 mg of plain ropivacaine with 17.5 mg of plain bupivacaine in patients undergoing total hip arthroplasty under spinal anesthesia. A more rapid postoperative recovery of sensory and motor function was seen in the ropivacaine group compared with the bupivacaine group. This was consistent with our study where in patients in R + F group had a faster recovery of sensory and motor function (240.4 ± 52.1 min and 233.5 ± 48.05 min) when compared to B + F group. (279.5± 54.9 min and 279.6 ± 46.5 min)

In our study cephalad spread of sensory blocks was higher in B + F group as compare to R + F fentanyl group. Jean-Marc Malinovsky et al.17 showed that the cephalad spread of sensory blocks was higher & faster with bupivacaine group than with ropivacaine group

The duration of motor block was longer in B + F group which was 279.6± 46.5 minutes whereas that in R + F group was 233.5± 48.06 minutes.

The duration of sensory block was longer in B + F group was 279.5 ± 54.9 minutes whereas that in R+F group was 240.4± 52.1minutes.

K.Koltaka et al[9] used equipotent doses of bupivacaine 13mg + fentanyl 20mcg and ropivacaine 19.5mg + fentanyl 20mcg for lower abdominal surgery. They observed a shorter duration of motor & sensory block and time to mobilisation was shorter in ropivacaine+ fentanyl group (139± 39 & 160± 40 min. and 255 ± 55 min.) compared to bupivacaine+ fentanyl group. (182± 46 & 185 ± 40 min and 300 ± 65 min). In our study, result was shown a shorter duration of motor & sensory block and time to mobilisation was also shorter in R+ F groups.(233.5 ± 48.06 & 240.4 ± 25.1 min and 310.8 ± 50.12 min) compared to B + F group. (279.6 ± 46.5 & 279.5 ± 54.9 min and 362.71 ± 53.34 min)

Study conducted by *Lee YY et al*[10] noted, plain ropivacaine 10mg + fentanyl 15mcg when used for spinal anaesthesia in urological surgery, provided similar sensory anaesthesia but with a shorter duration of motor block and early mobilisation (126 [93-162] min) compared with plain bupivacaine 10mg plus fentanyl 15mcg. (189 [157-234] min) this is similar to our study, showing shorter duration of motor block and time to early mobilisation in plain ropivacaine+ fentanyl group (233.5 ± 48.06 min & 310.8 ± 50.12 min) compared to bupivacaine + fentanyl group. (279.6 ± 46.5 min & 362.71 ± 53.34 min)

The potential suitability of ropivacaine in this respect was initially suggested in vitro and animal studies by *Feldman hs et al*[11]. Subsequently, a clinical study also showed that spinal ropivacaine was associated with motor block of shorter duration when compared with bupivacaine in *Ogun co et al*[12]. study. Our clinical results was also shown that motor block was shorter in R+F group compared to B+F group.

Gautier PE et al13 and Casati A et al14 reported that intrathecal ropivacaine 12mg produced similar sensory and motor block compared to 8mg bupivacaine. With respect to possible differences in motor block, despite use of apparent equipotent doses (ratio of 1:1.5) including the same doses of fentanyl with each drug, we found that ropivacaine is associated with a shorter duration of block. This difference in potency may be because ropivacaine is an L-isomer, whereas bupivacaine is a racemic mixture.

A second, but much less likely explanation is that in the study of *Camorcia et al*15 0.5% bupivacaine was compared with 0.5% ropivacaine using different volumes of the same concentration and also saline (which could cause a difference in baricity) whereas in our study we compared the same volume of different concentration but without the addition of saline. The study was not designed to investigate this matter. This can be explained either by differences in differential sensory and motor block or a difference in actual potency using this dose ratio.

Wide range of doses of ropivacaine i.e. 17.5mg to 25 mg. have reported to be effective for spinal anaesthesia in lower limb surgery.

There are conflicting results as to appropriate doses of intrathecal ropivacaine for various settings. Successful blocks after ropivacaine 12mg have been described by *Gautier PE et al*[13]in arthroscopy procedures and by *Wahedi W et al*[16] in unilateral spinal anaesthesia. On the other hand, for operations in which it is necessary to achive a higher block, even much higher doses have proved insufficient. *Wahedi et al*[16] had a failure rate of 20% with intrathecal plain ropivacaine 15mg (3ml of 5mg/ml solution) in abdominal surgery and *Malinovsky et al*[17] found that anaesthesia from plain ropivacaine 15 mg (5ml of 3mg/ml solution) was associated with inadequate spinal anaesthesia in 16% of patient in urological surgery. In our study, patients were for endoscopic urological surgery, where in 4 patients of Plain ropivacaine 19.5mg plus fentanyl 20mcg groups. while in 1 patients of plain bupivacaine 13mg plus fentanyl 20mcg groups was having inadequate motor block. In previous, studies with plain ropivacaine for spinal anaesthesia have a high failure rate. The addition of glucose and fentanyl or both should increase the efficacy and decrease the failure rate. But hyperbaric ropivacaine is not available so that we have used isobaric ropivacaine with fentanyl.

Mc Namee et al8 found plain ropivacaine 18.75mg (2.5ml of 7.5mg/ml solution) or 17.5 mg (3.5 ml of 5mg/ml solution) provided adequate spinal anaesthesia for 98 and 100% of patients respectively for major orthopaedic surgery. It appears that for sensory blocks to T10 or higher, a doses of at least 15mg of plain ropivacaine is required. Endoscopic urosurgery requires sensory block upto a level of T8-T10, so we have taken more than 15mg (i.e.19.5mg) of ropivacaine plus fentanyl 20mcg in our study. It was sufficient for endoscopic urologic surgery, despite a lower maximum sensory spread than from bupivacaine 13mg plus fentanyl 20mcg.

Experience with intrathecal bupivacaine has shown that the addition of fentanyl increases the level and duration of sensory block, without altering motor block characteristics33.

In our study, number of patients with modified bromage score 3

are 55 out of 60 (91.6%) in R+F group and 58 out of 60 (96.6%) in B+F group, these are similar in *K.Kotalka et al* 14study, time to mobilise is also same in this study. Two segment regression time was shorter in plain ropivacaine + fentanyl group (102.8 ± 22.8 min.) compared to plain bupivacaine + fentanyl group. (127.8 ± 29.08 min.)

In our study, both regimens using plain solutions provided good cardiovascular stability and a lower incidence of bradycardia, as previously reported in *Mc Namee et al*8for major orthopaedic surgery, *Kallio H et al 18* for lower limb surgery and a lower incidence of hypotension in previously noted *Martyr JW et al*19 study. Because the addition of fentanyl, allows the use of smaller doses of local anaesthetic agents and a lower incidence of excessively high block previously noted in *Ben devid b et al*-20study.

Previous studies had shown intrathecal ropivacaine with an increased incidence of post-dural puncture headache and low back pain. But in this present study, the incidence of headache and backache are less in both groups. It may be due to small guage (no 25 quincke) needle we have used.

To conclude now a days of day care anaesthesia, shorter hospital stay is preferred in minor surgical procedures. Plain ropivacaine + fentanyl group had shorter time of motor and sensory block and so early mobilisation is possible, which is beneficial in this respect.

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