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COMPARISON OF 0.5% LEVOBUPIVACAINE AND 0.5% BUPIVACAINE WITH FENTANYL FOR SPINAL ANAESTHESIA FOR TRANSURETHRAL RESECTION OF PROSTATE / BLADDER TUMOUR: A PROSPECTIVE RANDOMIZED AND CONTROLLED CLINICAL STUDY

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Keywords *TURP/TURBT, Bupivacaine, Levobupivacaine, Fentanyl, Bromage score..*

Abstract

Background – The aim of this study is to compare safety and efficacy of bupivacaine 0.5% of 2ml (10mg) with 25mcg fentanyl and levobupivacaine 0.5% of 2ml with 25mcg fentanyl when given intrathecally in patients of Transurethral Resection of Prostate/Bladder Tumor Surgeries

Methods–After local ethics committee approval,60 patients were selected according to eligibility criteria and a written informed consent was obtained from each patient after explaining the technique prior to inclusion in this study in their own vernacular language and randomly allocated in two groups of 30 each. GROUP I: patients received 2 ml(10 mg) 0.5% bupivacaine with 25 mcg fentanyl intrathecally to achieve an adequate level of anaesthesia.GROUP II: patients received 2 ml(10 mg) 0.5% bupivacaine with 25 mcg fentanyl inrathecally to achieve adequate level of anaesthesia.Spinal block was performed by an anaesthesiologist consultant. Patients were monitored for sensory blockade,motor blockade,Ramsay sedation score,VAS score and complications. Hemodynamics were compared in both the groups.

Observations –In this study we evaluated and compared 0.5% bupivacaine and fentanyl with 0.5% levobupivacaine and fentanyl in terms of intraoperative hemodynamic changes, onset & duration of sensory block, onset of motor block, level of sedation and occurance of complications when given intrathecally for transurethral resection of prostate/bladder tumors.It was observed that sensory blockade qualities were comparable in both the groups. However, motor blockade was significantly reduced in group-II(Levobupivacaine) as compared to group-I(Bupivacaine). Patients in Group II had better hemodynamic stability,good patient and surgeon satisfaction and fewer side effects as compared to Group I.

Conclusion –0.5% Levobupivacaine plus fentanyl provides less motor blockade,better hemodynamic stability and fewer side effects in patients undergoing TURP/TURBT compared to 0.5% bupivacaine plus fentanyl.

Introduction

Central neuraxial blockade is an important tool in the armamentarium of the anaesthesiologists as the alterations in physiology and biochemistry and there by morbidity and mortality brought about by central neuraxial blockade are minimal as compared to general anaesthesia. Subarachnoid block is the most popular and widely practiced technique all over the world.

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Local anaesthetics (LA) based intrathecalanaesthesia has been widely used for transurethral surgery since it allows early recognition of symptoms caused by bladder perforation, over-hydration and transurethral resection of prostate (TURP) syndrome.[1] A large proportion of the patients undergoing urological surgery, such as TURP and (transurethral resection of bladder tumor (TURBT) are elderly people who have coexisting cardiac, pulmonary or other comorbid disease.[2] Although LA based intrathecalanaesthesia has advantages in lower postoperative pain score, less demand for analgesics during recovery and shorter recovery time compared with general anesthesia.[3,4] It is also associated with prolonged motor block and several side effects, such as disturbed proprioception, hypotension and urinary retention that are dose dependent.[5] These limitations may increase management complexity of the comorbid diseases, interfere with early mobilization and prolong hospital stay of the patients. Therefore, reducing the side effects associated with intrathecalanaesthesia is quite helpful to support better postoperative management.

As practice of medicine focuses increasingly on outpatient care, spinal anaesthetics should provide short acting and adequate anaesthesia without compromising early ambulation and discharge from day care surgery unit.
A higher level of sensory block is required but increasing the dose of long acting local anaesthetics may produce extensive sensory and motor block.

At the same time,short acting spinal anaesthesia with minimum motor block can be useful and assumed that recovery and mobilization of the patient could be faster, if the motor block is less intense. For this purpose, short acting or low doses of local anaesthetics can be used.[6,7]

LA drugs can be divided into ones that are short, intermediate or long acting.The shortest acting local anaesthetic is chloroprocaine.Lidocaine is an intermediate acting often used for slightly longer procedures.While Bupivacaine is longer acting.

Spinal lidocaine has been a popular choice for ambulatory spinal anaesthesia since its introduction in 1945. After that, more than 100 million patients have been operated under lidocaine spinal anaesthesia.[8]Lidocaine has been popular because of the rapid repression of the sensory and motor blockade. Though lidocaine has enjoyed a long history of safety and popularity, it has recently come under scrutiny because of transient neurologic symptoms (TNS), which were first described by Schneider *et al*.1993. They reported four patients who, after uneventful spinal anaesthesia with hyperbaric 5% lidocaine, developed a triad of symptoms including low back pain and dysaesthesia with radiation to the buttocks, thighs and lower limbs 1–20 hours after recovery from spinal anaesthesia. The pain was described as dull and aching, and it occasionally decreased when the patient stood up and walked around. It responded well to NSAIDs and resolved spontaneously within two to five days. There were no sensory, motor or reflex disturbances, nor bladder or bowel dysfunctions.[9]

Bupivacaine is long acting local anaesthetic and is available in 0.25%,0.5% or 0.75% preservative free solutions. The onset of time is around 20 minutes with duration of upto 225 minutes. More dilute concentrations such as 0.125% to 0.25% can be used for analgesia.However, disadvantages include cardiac and central nervous system toxicity and the potential for motor block from large doses. Solutions 0.5% and 0.75% are used to provide surgical anaesthesia.

Levobupivacaine is the S(-) enantiomer of racemic bupivacaine. Levobupivacaine has similar efficacy but an enhanced safety profile when compared to bupivacaine, a major advantage in regional anaesthesia. Intrathecal opioids added to local anaesthetics enhance analgesia without intensifying motor and sympathetic block, and make it possible to achieve successfulanaesthesia in spite of the use of a low dose local anaesthetic.

Fentanyl is an opioid, it can be used to enhance analgesia and successful anaesthesia. Fentanyl has been widely used as an adjunct to local anaesthetics for enhancement of analgesia without intensifying motor and sympathetic block in spinal anaesthesia.

Methods and materials

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The study was conducted in 60 patients of age group 40 to 70 yrs of ASA grade I and II undergoing TURP and bladder Tumours surgery under spinal anaesthesia at Rajindra Hospital attached to Government Medical College Patiala. The patients were randomly divided into 2 groups of 30 each:-

Patients were selected using following exclusion criteria for spinal anaesthesia:-

- Patient's refusal
- Having abnormality of spine
- Any skin infection or local cellulitis.
- Any coagulation defect.
- Recent myocardial infarction.
- Patients with neurological disorders
- Unstable angina.
- Significant aortic stenosis.

A written informed consent was obtained from each patient after explaining the technique prior to inclusion in this study in their own vernacular language. Patients were randomly divided into 2 groups of 30 each.

During pre-anaestheticcheck up a detailed history was taken. A thorough physical and systemic examination was done for all patients to detect any evidence of systemic disease and determine the suitability of patient for spinal anaesthesia. Patient with any abnormality of spine, previous spinal surgery, and neurological or gross cardiovascular disease, any local lesion of skin, bleeding diasthesis or use of anticoagulants was excluded from the study.

Patient's age, weight and height was noted.

Investigations

a) Routine: Hb, BT, CT, urine complete examination,Triple H.
b) Special: FBS, blood urea, serum creatinine.
c) Others: L.F.T, any other required.
d) ECG,X-Ray Chest.

All patients were given inj midazolam 1mg and injphenergan 25 mg intramuscularly 30 mins before the operation.In the operation theatre, the baseline blood pressure and pulse rate was recorded in every patient. I/V line was secured before the spinal anaesthesia. Pre loading was done with 500ml Ringer lactate solution.

Equipments used for spinal Anaesthesia

- An autoclaved set containing sterile bowl, sterile towels, swabs and sponge holding forceps.
- Sterile gloves.
- 0.5 % hyperbaric bupivacaine
- Inj fentanyl
- 0.5% levoupivacaine
- Spinal sheet
- Ampoule cutter
- Normal Saline
- 23 G spinal needle

Spinal block was performed by placing the patient in sitting position. Under complete aseptic precautions lumbar puncture was performed in L2- L3 or L3 –L4, intervertebral space using midline approach with a 23 gauge quincke's spinal needle. After ensuring free and clear flow of CSF, patients in group I was given 2 ml (10mg) 0.5% hyperbaric bupivacaine +25 mcg fentanyl; patients in group II was given 2 ml (10mg) 0.5% levobupivacaine + 25 mcg fentanyl. Immediately after spinal injection the patient was turned supine and oxygen was administered via venturi mask. Clinically patients were monitored and following observations were recorded during the course of anaesthesia.

Monitoring

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Blood pressure will be recorded every 5 minutes for 30 minutes after intrathecal injection and then every 15 minutes. Fall in systolic blood pressure < 90mmHg or >25 % of fall from baseline value will be taken as hypotension. It will be treated with intravenous bolus dose of ephedrine 5 mg.Heart Rate and rhythm will be recorded after every 5 minutes for 30 minutes after injection and then every 15 minutes till competion of surgery. Pulse rate <60/ minutes will taken as bradycardia and will be treated with intravenous injection of 0.6mg atropine.Respiratory Rate will be recorded through out the operation. SpO_2 will be recorded through out the operation.

A careful watch will be kept on all the patients for any signs of toxic manifestations of local anaesthetic drug such as respiratory and cardiac depression.

Observations

In our study, analysis was conducted using IBMM SPSS statistics (version22.0). Numerical data was expressed as mean and standard deviation and statistically analysis was done using the independent t-test to compare the two groups. For skewed data/scores Mann -Whitney U-test was used. Gender was compared using Chi square test.

1 The demographic parameters – age, weight and gender in both the groups were statistically not significant.Onset and duration of sensory block was comparable in both the groups while the hemodynamic parameters – heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure were statistically significant inlevobupivacaine group showing that levobupivacaine is hemodynamically more stable and having fewer side effects .Maximum motor blockade was alsosignificantally reduced in levobupivacaine group.However postoperative vitals, level of sedation and postoperative pain were comparable in both groups.

Heart Rate:

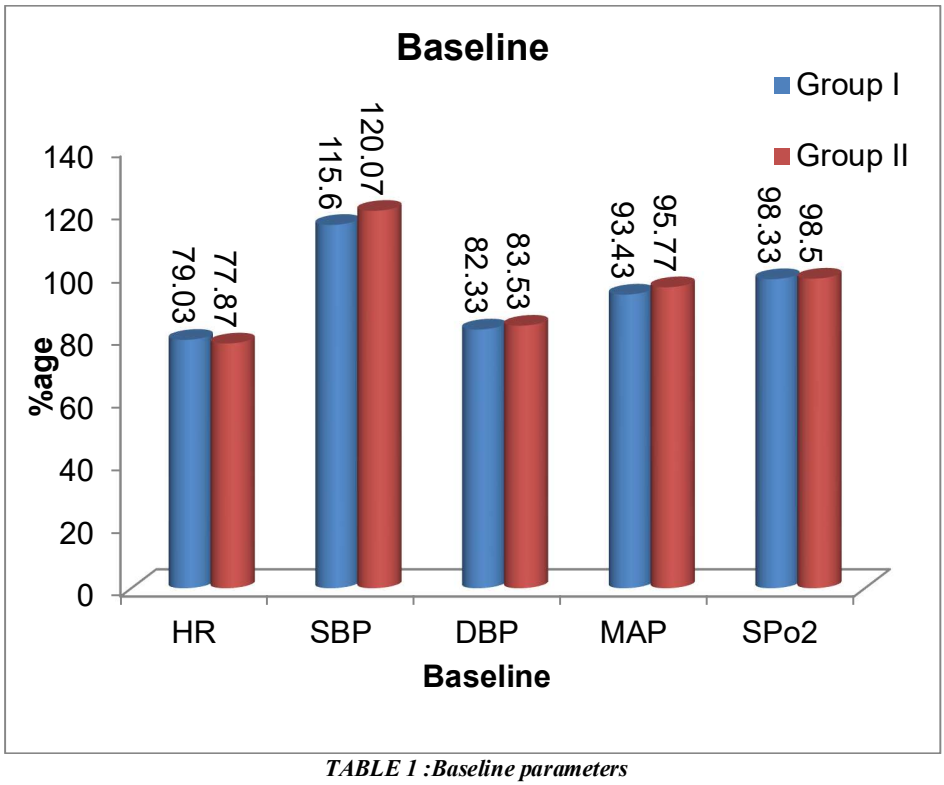

TABLE 1 :Baseline parameters

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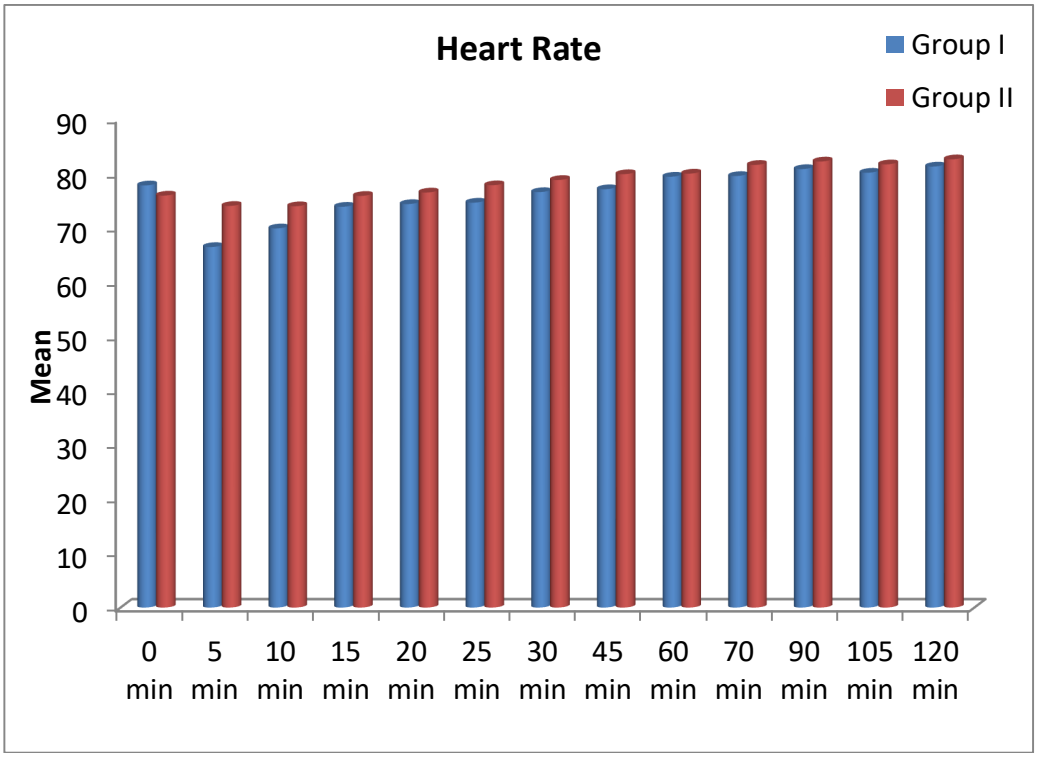

Table 2: Mean Heart Rate (Per Minute) At Different Time Intervals During Intraoperative Period

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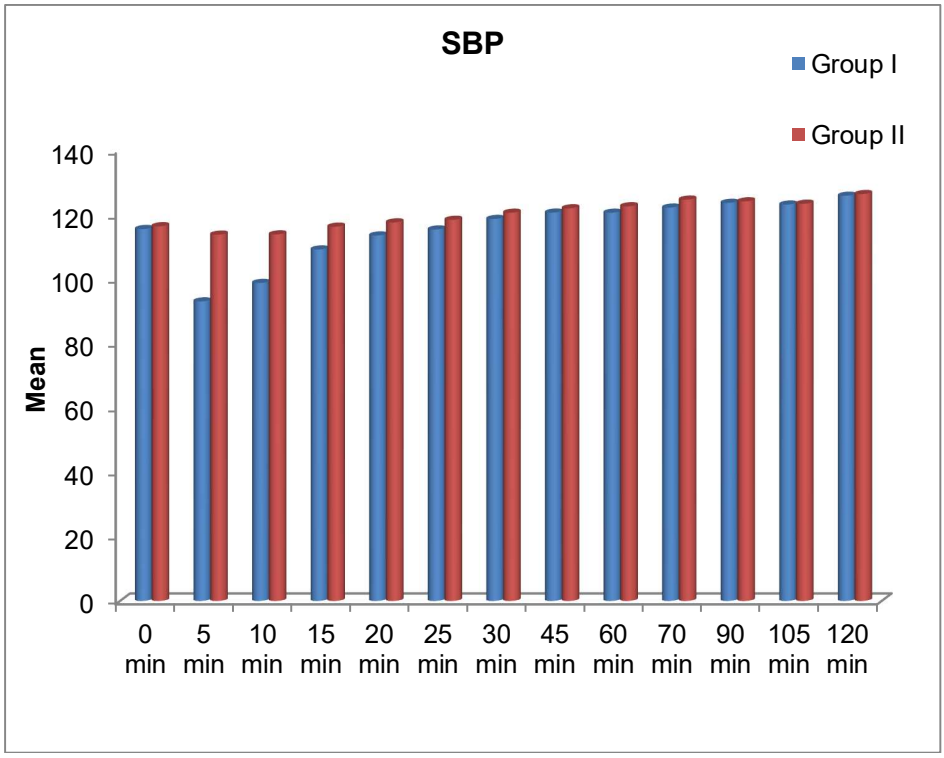

Table 3: Mean Systolic Blood Pressure (mmHg) At Different Time Intervals During Intraoperative Period

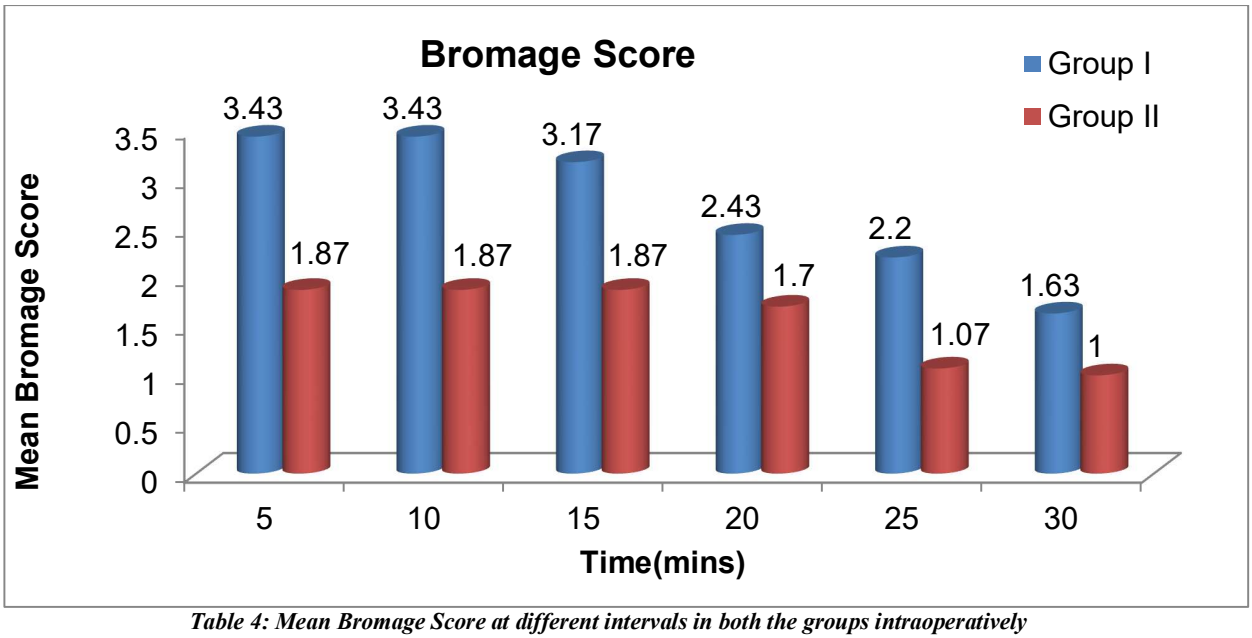

Table 4: Mean Bromage Score at different intervals in both the groups intraoperatively

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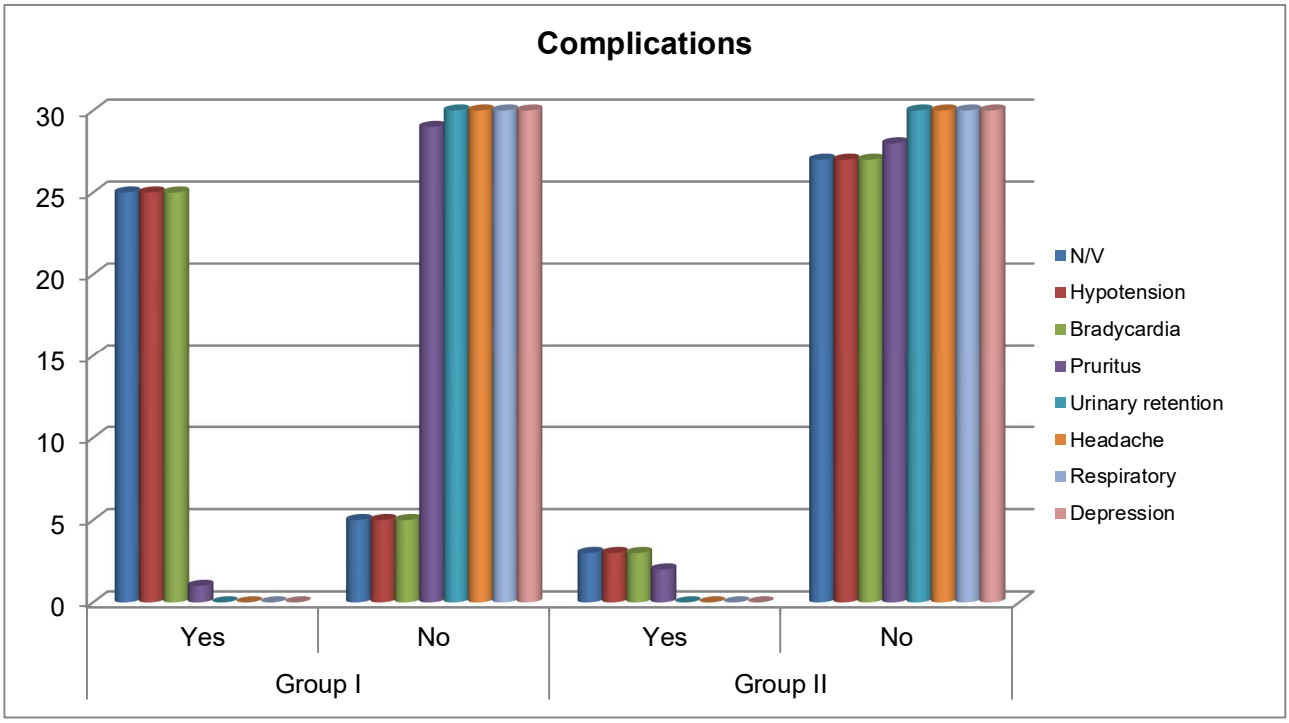

TABLE 5 : Complications

Discussion

For TURP/TURBT surgery a sensory block extending to T10 dermatome is necessary to provide adequate analgesia. This study suggests that 10 mg 0.5% levobupivacaine with 25 mcg fentanyl usage in spinal anaesthesia can provide adequate sensorial blockade,less motor block, stable hemodynamic profile and good patient and surgeon satisfaction for TURP surgery.

Levobupivacaine, the S-(-)-enantiomer of bupivacaine was shown to be equally effective,in spinal and epidural anaesthesia.In present studyIncidence of bradycardiain groupI is 33.3% and in group II 10% while incidence of hypotension in group I is 43.3% and in group II it is 10%.Thus levobupivacaine is hemdynamically more stable.

Ayesha goyal et al,[10] evaluated isobaric levobupivacaine with fentanyl and hyperbaric bupivacaine with fentanyl in elective cesarean sections and found the incidence of bradycardia is 13.33% in LF group and 33.33% in BF group whileincidence of hypotension was 26.67% in group LF and 66.67% in group BF and the difference is statistically significant.In the study of **GulenGuler et al**[11] on Comparison of Spinal Anaesthesia with Levobupivacaine and Hyperbaric Bupivacaine for Caesarean Sections and found the incidence of bradycardia is 30% in bupivacaine group and 4% in levobupivacaine group while incidence of hypotension was 16.67% In Levobupivacaine And 36.67% In Bupivacaine group andthe difference is statistically significant.However in the study of**Herrera R et al**[12] on Hemodynamic impact of isobaric levobupivacaine versus hyperbaric bupivacaine for subarachnoid anaesthesia in patients aged 65 and older undergoing hip surgery found that incidence of bradycardia is 5% in group B versus 9% in group L and the difference is statistically non significant.While theincidence of hypotension is 38% in BUPI group and 13% in LEVO group and the difference is statistically significant.

By using small doses of local anaesthetics, one can limit the distribution of spinal block. But low doses of local anaesthetics could not provide an adequate level of sensory block. Adjuvant agents like opioids can be used to enhance analgesia and successful spinal anesthesia. Fentanyl has been widely used as an adjunct to local anesthetics for enhancement of analgesia without intensifying motor and sympathetic block in spinal anaesthesia.

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By combination of bupivacaine and fentanyl, dose reduction of bupivacaine can be provided and this will cause less sympathetic blockade, also resulting in lower incidence of hypotension, early recovery and mobilization. Since the usage of low dose levobupivacaine in spinal anaesthesia for urological surgery has not been reported yet, we tried to compare the effectiveness of the low doses of levobupivacaine and bupivacaine when they are combined with fentanyl, which were showed to be effective in spinal anaesthesia for TURP surgery when used in higher doses. By using 10 mg levobupivacaine + 25 µg fentanyl, an effective sensorial blockade was provided with less motor blockade than usage of 10 mg bupivacaine + 25 µg fentanyl.

Akcaboy et al[13] reported less motor block in levobupivacaine group . Vercauteren et al[14] also reported that, slight motor impairment seems to occur more often with the use of racemic bupivacaine than levobupivacaine . Also in the study of Camorcia et al,[15] the potencies for motor block of intrathecalropivacaine, levobupivacaine and bupivacaine were compared and bupivacaine was found to have more potency for motor block when compared with bupivacaine and ropivacaine.The present study is also consistent with these studies.

In present study incidence of nausea in GroupI is 23.3% and in group II is 10% while incidence of vomiting is 10% in both the groups which is consistent with studies of Guler et al,[12]Ayesha et al.[10]Erdil et al.[16]

Pruritis is the common adverse effect of intrathecal fentanyl.In present study 10% patients had pruritis in group I while 6% patients had pruritis in group II.However none of them required treatment.These findings are also consistent with the studies of Akcaboy et al,[13]Erdil et al.[16]

As spinal opioids carry the risk of respiratory depression especially in elderly patients. No respiratory depression or transient hypoxia was observed in either group. It can be sug-gested that, 25 µgintrathecal fentanyl can be safely administered when O_2supplementation was continued during the procedure.

Conclusion

So we conclude that in Transurethral Resection of Prostate/Bladder tumor surgeries, that were requiring a sensory block to at least T10 dermatome was attained using low dose 2ml(10mg) 0.5% levobupivacaine with 0.5ml(25mcg) fentanyl which provides better haemodynamic stability, good patient and surgeon satisfaction, fewer side-effects and at the same time the less motor blockade compared to 2ml(10mg) 0.5% bupivacaine with 0.5ml(25mcg) fentanyl. So we suggest that levobupivacaine may be preferred over bupivacine in the elderly patients undergoing a urological intervention under spinal anaesthesia.

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