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ORIGINAL RESEARCH

Comparison of 0.5% levobupivacaine with fentanyl versus 0.5% levobupivacaine for spinal anaesthesia for transurethral resection of prostate/ bladder tumour

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Abstract

Introduction: Spinal anaesthesia for transurethral resection of prostate (TURP) and transurethral resection of bladder tumor (TURBT) has been frequently used. Levobupivacaine 0.5% has been found to be equally effective as bupivacaine 0.5% in spinal anaesthesia.

Aims & Objectives: To compare safety and efficacy of levobupivacaine 0.5% 2 ml (10 mg) with 25 µg fentanyl and levobupivacaine 0.5% 2 ml (10 mg) when given intrathecally in patients of transurethral resection of prostate/bladder tumor surgery.

Methodology: Sixty patients in the age group of 45 to 70 years, ASA grade I and II undergoing TURP and TURBT under spinal anesthesia at Govt. Medical college, Rajindra Hospital Patiala were randomized into groups of 30 patients each. Group A received subarachnoid block with drug containing 2ml (10 mg) of 0.5% levobupivacaine and 25 mcgs of injection fentanyl and Group B received block with drug containing 2ml (10 mg) of 0.5% levobupivacaine plain. The changes in intra- operative haemodynamics (SBP, DBP, MBP, HR, SPO2, RR and PR), onset of sensory and motor block, level of sedation, duration of analgesia and occurrence of complications was recorded for both the groups. Data was tabulated and subjected to statistical analysis.

Results: The results showed statistically non-significant difference in haemodynamics, occurence of complications, postoperative vitals, level of sedation and postoperative pain which were comparable in both the groups ($p>0.05$). The mean onset of sensory blockade was earlier and action was prolonged in group with 0.5% levobupivacaine with fentanyl. Onset of motor blockage was slightly delayed in levobupivacaine with fentanyl as compared to levobupivacaine plain, however it was statistically non-significant.

Conclusion: Levobupivacaine with fentanyl showed better haemodynamic stability, prolonged duration of action, good patient and surgeon satisfaction as compared to levobupivacaine plain in the elderly patients undergoing a urological intervention under spinal anaesthesia.

Key words: levobupivacaine, transurethral resection, prostrate, bladder tumor

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Introduction

Spinal anaesthesia is popular and commonly used worldwide. Spinal anaesthesia for transurethral resection of prostate (TURP) and transurethral resection of bladder tumor (TURBT) has been frequently used, because symptoms of over hydration, TURP syndrome and bladder perforation can be recognized earlier. The advantages of an awake patient, minimal drug costs has made this the method of choice for many surgical procedures.[1] It produce analgesia, anaesthesia and motor block depending on the volume and concentration of the drug used. Adequate anaesthesia and good relaxation of pelvic floor and the perineum, early recognition of signs and symptoms of water intoxication, fluid overload and accidental bladder perforation make spinal anaesthesia the procedure of choice for TURP surgeries.[2]

A large proportion of the patients undergoing urological surgery, such as TURP and transurethral resection of bladder tumour (TURBT) are elderly people who have coexisting cardiac, pulmonary or other comorbid disease. Spinal anaesthesia in contrast to general anaesthesia is usually preferred for elderly patients for TURP due to its relatively limited effect on myocardial performance, blood pressure and cardiac output.[3]

Lidocaine was a popular local anaesthetic for SA in day care surgical patients, but is known to cause transient neurological symptoms (TNS) which is highly reported for patients having surgery in the lithotomy position. Prilocaine has the similar potency and duration of action of lidocaine and also have been reported to have a lower incidence of TNS. Also, bupivacaine carries a low risk of TNS, but its long duration of action makes it unsuitable for day care surgery. However, by using low doses of bupivacaine and intrathecal opioids together, successful anaesthesia and analgesia were reported to be obtained for TURP procedures.[4]

Levobupivacaine, an S (-) enantiomer of bupivacaine is a long acting amide type local anaesthetic agent. It has less cardiovascular and central nervous system toxicity. Levobupivacaine ([2S]-1-butyl-N- [2, 6-dimethylphenyl] piperidine-2-carboxamide) is an amino-amide local anaesthetic drug belonging to the family of n-alkyl substitute pipecoloxylidide. Its chemical formula is $C_{18}H_{28}N_2O$. Levobupivacaine reversibly blocks neuronal sodium channels and thereby blocks nerve conduction. Myelinated and small diameter nerve fibres are blocked rapidly than others.[5]

Levobupivacaine 0.5% and bupivacaine 0.5% were shown to be equally effective in spinal anaesthesia. However, there is paucity of data on usage levobupivacaine in low doses intrathecally for TURP surgery. The present study was conducted compare safety and efficacy of levobupivacaine 0.5% 2 ml (10 mg) with 25 µg fentanyl and levobupivacaine 0.5% 2 ml (10 mg) when given intrathecally in patients of transurethral resection of prostate/bladder tumor surgery.

Sample size

Based on the result of onset of sensory block in key article Belgin et al, the effect size was calculated to be 1.777, taking alpha error 0.05 and power required 95% minimum sample size required was 20 i.e. 10 in each group.

Power analysis was done in GPower software ver 3.1.2

Confidence interval was set at 95%

t tests - Means: Difference between two independent means (two groups)

Analysis: A priori: Compute required sample size

Input: Tail(s) = Two

Effect size d = 1.7779491

α err prob = 0.05

Power (1-β err prob) = 0.95

Allocation ratio N2/N1 = 1

Output: Noncentrality parameter δ = 3.9756150

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Critical t = 2.1009220
Df = 18
Sample size group 1 = 10
Sample size group 2 = 10
Total sample size = 20
Actual power = 0.9637394

Methodology

The study consisted of 60 patients, randomly divided into 2 groups of 30 each:
Group I: Spinal administration of 2 ml (10 mg) 0.5% levobupivacaine with 25 µg fentanyl.
Group II: Spinal administration of 2 ml (10 mg) 0.5% levobupivacaine plain.
All patients fulfilling below mentioned criteria were included in the study after obtaining written informed consent.

Inclusion Criteria

- Patients who give consent for the surgery.
- Normal coagulation profile.
- ASA grade I and II.
- Age group 45 to 70 years.
- Body mass index (calculates as weight in kilograms divided by square height in meters) of less than 30.

Exclusion Criteria

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

A detailed history was obtained during pre- anaesthetic check up. All necessary investigations (Hb, BT, CT, urine examination, FBS, blood urea, serum creatinine, LFT,ECG) were done. Patients were advised overnight fasting and Tab Rantidine 150 mg and tab lorazepam 1mg orally were given as pre- medications at 6 am in the morning on the day of surgery with a sip of water. In the operation theatre, the baselnie blood pressure and pulse rate was recorded in every patient. All patients were pre- loaded with 15 ml/kg Ringer's lactate solution.

Spinal Block

Patients were placed in sitting position or lateral spinal position. Under complete aseptic precautions, lumber puncture was performed in L2- L3 or L3- L4, intervertebral space using midline approach with a 23 gauge quinke spinal needle. After ensuring free and clear flow of CSF, patients in group I were given 2 ml (10 mg) 0.5% levobupivacaine with 25 µg fentanyl and in group II 2 ml (10 mg) 0.5% levobupivacaine plain. Immediately after spinal injection, the patient was turned supine and oxygen was administered via venturi mask. Level of analgesia was assessed and then surgery allowed to start.
Clinically patients were monitored and heart rate, respiratory rate, SPO2 and blood pressure were recorded intra-operatively.

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Level of sensory neural blockage was assessed by pin prick method using visual analog scale for the level of analgesia. Level of sensory block was checked every 5 minutes after giving the block. Motor neural blockage was assessed by modified Bromage scale. Grades of sedation during surgery was assessed by the modified Ramsay sedation scale every 5 minutes till 30 minutes and then every 15 minutes till end of surgery.

Post- operative assessment of pain was done with the help of VAS score, every hour till 10 hours and vitals were recorded at the same time intervals. Duration of analgesia was taken as the time from onset of analgesia upto time when VAS reached 5. Intramuscular Diclofenac (75 mg) was administered to the patient as rescue analgesia when required. Complications like nausea, vomiting, urinary retention, headache, pruritis, respiratory depression were recorded.

All recorded data was tabulated and subjected to appropriate statistical analysis.

Results

The mean age of group I patients was 59.49± 5.24 years and of group II patients was 60.20± 7.46 years. Group I comprised of 24 (80.0%) males and 6 (20%) females and group II comprised of 23 (76.7%) males and 7 (23.3%) females. The difference was statistically non-significant (P> 0.05), hence the two groups were age and gender matched.

There were 7 (23.3%) in group I and 13 (43.3%) in group II who underwent TURP. 23 (76.7%) in group I and 17 (56.7%) patients in group II who underwent TURBT. The difference was non- significant (P> 0.05).

The baseline vitals were comparable in Group I and Group II (p>0.05). The intraoperative and postoperative HR, SBP, DBP, MAP, SPO2 and RR were comparable in Group I and Group II (p>0.05).

The onset of sensory block in group I was 2.80 minutes and in group II was 4.0 minutes. The difference between both the groups was statistically significant (P< 0.05). However, the onset of motor block in group I was 4.37 minutes and in group II was 3.53 minutes. The difference between both the groups was statistically non- significant (P> 0.05).

the mean modified Bromage score at 5 minutes in group I was 1.67, in group II was 1.53, at 10 minutes in group I was 1.72 and in group II was 1.43, at 15 minutes in group I was 1.87 and in group II was 1.70, at 20 minutes in group I was 1.50 and in group II was 1.40, at 25 minutes was 1.07 in group I and 1.00 in group II and at 30 minutes in group I was 1.00 and in group II was 1.00. The difference between both the groups was statistically non- significant (P> 0.05). No patient required additional sedation during surgery and the mean MRSS was statistically non-significant between both the groups (p>0.05).

Table 1: Post- operative VAS

Post- operative VAS (hours)	Groups	Mean	SD	P value
1	Group I	.87	.629	.492
	Group II	.90	.712	
2	Group I	1.40	.675	.274
	Group II	1.60	.770	
3	Group I	1.50	.777	.668
	Group II	1.67	.758	
4	Group I	1.68	.695	.954
	Group II	1.47	.690	
5	Group I	1.90	.607	.816
	Group II	1.73	.785	
6	Group I	1.67	.661	.978
	Group II	1.43	.626	

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7	Group I	2.00	.910	1.000
	Group II	2.00	.910	
8	Group I	1.67	.844	1.000
	Group II	1.73	.868	
9	Group I	1.60	.770	.430
	Group II	1.83	.699	
10	Group I	1.80	.664	.352
	Group II	1.97	.850	

The above table shows that there was non- significant difference in post- operative VAS score in both groups (P> 0.05) and intramuscular Diclofenac (75mg) was used as rescue analgesia when required.

Table 2: Duration of Sensory Block (minutes)

Duration of sensory block (mins)	Mean	SD	P value
Group I	130.47	5.725	0.04
Group II	116.0	3.184	

The above table shows that the duration of sensory block in group I was 130.47 minutes and in group II was 116 minutes. The difference between both the groups was statistically significant (P< 0.05).

Table 3: Complications

Complications		Group I	Group II	P value
Nausea/Vomiting	NO	27	25	0.265
		90%	83.3%	
	YES	3	5	
		10%	16.7%	
Hypotension	NO	27	25	0.706
		90.0%	83.3%	
	YES	3	5	
		10.0%	16.7%	
Bradycardia	NO	27	28	0.640
		90.0%	93.3%	
	YES	3	2	
		10.0%	6.7%	
Pruritis	NO	27	30	0.076
		90.0%	100.0%	
	YES	3	0	
		10.0%	.0%	

The above table shows that there was non- significant difference between two groups in terms of complications (p>0.05).

Discussion

We observed no significant decline in heart rate intra-operatively and difference was found to be non-significant in both the groups.This is in accordance with findings of the study by **Kulkarni et al** where no significant alterations were found in heart rate both before and during the surgery in both the groups (levobupivacaine with fentanyl and levobupivacaine plain). [6]

Attri et al also found the results similar to our study where there was no significant change in heart rate from baseline throughout the procedure in both the groups LF (levobupivacaine

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plus fentanyl) and group L (levobupivacaine).[7] The heart rates were also comparable in the study by **Akan et al** where fentanyl and sufentanyl were used as adjuvants with levobupivacaine as compared to levobupivacaine alone.[8]

In our present study there was fall in SBP,DBP and MBP at 5,10,15,20 minutes in both the groups however the difference between them was non significant and both the groups were comparable in all these parameters and SBP, DBP and MBP were found to be non significant in our study and haemodynamics were stable throughout the surgery.

Haemodynamic changes were similar in a study by **Kulkarni et al** in both the groups II (levobupivacaine plus fentanyl) and I (levobupivacaine plain) and remained stable throughout the surgery. [6] However, **Akan et al** found that the incidence of side effects like hypotension was more in 10mg levobupivacaine group as compared to other groups where fentanyl and sufentanyl were used as adjuvants along with levobupivacaine.[8]

The present study demonstrated an early onset and increased duration of sensory blockade in Group I (Levobupivacaine with fentanyl) in comparison to the group II (Levobupivacaine). Our study was similar to **Kulkarni et al** who found out that onset of sensory block was earlier in group II (levobupivacaine with fentanyl) (4.74±0.723) than in group I (levobupivacaine plain) (5.7±0.953) which was statistically significant (p<001). [6] Similar results were found in the study by **Attri et al** who found out that onset of sensory block was rapid in group LF (levobupivacaine plus fentanyl) (4.8±1.50) as compared to group L (levobupivacaine) (7.6±1.46).[7]

Akan B et al also found that there was rapid onset of sensory block in group 2 and group 3 (levobupivacaine in combination with fentanyl and sufentanyl respectively) as compared to group 1(levobupivacaine plain).[8] On the contarary a study by **Mohan et al** in which the authors compared (levobupivacaine plain) group A and (levobupivacaine with fentanyl) group B in TURP which showed delayed onset of sensory block in group B (3.15±0.362) as compared to group A (2.05±0.2207).[9]

The duration of sensory block in group I was 130.47 minutes and in group II was 116 minutes. Our results were also similar to the study done by **Mohan et al** who found that the duration of sensory block was delayed in Group B (levobupivacaine with fentanyl) (361.3±3.22) as compared to Group A (levobupivacaine plain) (334.1±10.65), which was statistically significant. [9] On the contrary a randomised study by **Kulkarni et al** the duration of sensory block was longer in group which contained levobupivacaine plain only (292.2±8.154) as compared to group in which adjuvant fentanyl was added to levobupivacaine (260±11.066). [6]

Our study found out that onset of motor block was slightly delayed in group I as compared to group II but it was clinically insignificant (p>0.05). These results were similar to studies by **Mohan et al** where onset of motor block was slightly delayed in group B which consisted of levobupivacaine with fentanyl (4.3±0.464) as compared to group A (3.2±4.051).[9] On the contrary **Attri et al** found out that time to achieve maximum motor block was reduced in group LF (8.38±1.78) as compared to group L (12.26±1.85).[7]

The mean modified Bromage score was calculated at 5, 10, 15, 20, 25, 30 minutes. The difference between both the groups was statistically non- significant (P> 0.05). Our results were also similar to the study done by **Kulkarni et al** who observed that the time to achieve Bromage 3 was (6.92±1.066) slightly more in group II which contained levobupivacaine with fentanyl as compared to group I which had plain levobupivacaine alone (6.5±1.403) but the result was non-significant in this case. [6]

In our study grades of sedation during surgery was assessed by Ramsay sedation score. No patient required additional sedation during surgery. **Erdil et al** found that none of the patients required additional sedation during surgery which was similar to our study.[10] On the

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contrary, **Akcaboy EY et al** concluded that only small doses of IV midazolam were used in a few patients for sedation.[11]
Postoperatively, assessment of pain was done with the help of VAS score. Our results were in accordance to those found by **Kulkarni et al** where 2 hour postoperative VAS was similar in both the groups. [6]

Conclusion

The study highlighted that in transurethral resection of prostate/bladder tumor surgeries, that required a sensory block till at least T10 dermatome was attained using low dose 2ml (10mg) 0.5% levobupivacaine with 0.5ml (25mcg) fentanyl which provided rapid onset and prolonged duration of sensory blockade along with the haemodynamic stability, good patient and surgeon satisfaction as compared to 2ml (10mg) 0.5% levobupivacaine plain. So we suggest that levobupivacaine with fentanyl may be preferred over levobupivacaine plain in the elderly patients undergoing a urological intervention under spinal anaesthesia.

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