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Original Article

Comparative Study of 0.5% Levobupivacaine and 0.5% Levobupivacaine with Fentanyl in Transurethral Resection of Prostate

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Abstract

Background: Subarachnoid block is the most commonly used mode of anesthesia in transurethral resection of prostate. Addition of fentanyl helps in early ambulation and prolonging the duration of analgesia.

Aims and Objectives: To compare the onset and duration of motor and sensory block and duration of analgesia with levobupivacaine alone and in combination with fentanyl.

Materials and Methods: A total of 80 patients between the age group of 50-70 years of ASA Grades II and III were divided into two groups of 40 each. Subarachnoid block in Group A received 0.5% levobupivacaine 2.5 ml (12.5 mg) + 0.9% Nacl 0.5 ml. Subarachnoid block in Group B received 0.5% levobupivacaine 2.5 ml (12.5 mg) + fentanyl 0.5 ml (25 µg). Baseline vitals, onset and duration of motor and sensory block and duration of analgesia were recorded.

Results: The onset and duration of sensory block were prolonged the fentanyl group. Onset of motor block was delayed, however, duration was prolonged in fentanyl group. The duration for first rescue analgesia was prolonged in the fentanyl group.

Conclusion: Addition of fentanyl to levobupivacaine provides faster recovery from motor block and prolongs the duration for analgesic requirement, both of which help in early ambulation.

Key words: Fentanyl, Levobupivacaine, Spinal anesthesia, Transurethral resection of prostate

INTRODUCTION

Spinal and epidural administration of local anesthetics during transurethral resection of prostate (TURP) produce analgesia, anesthesia and motor block, depending on the volume, concentration and doses of drug used. For the local anesthetics selection, it is known that the agent's onset and duration of action, sensory block level to motor block level and cardiac toxicity should be considered. Levobupivacaine ([2S]-1-butyl-N- [2, 6 -dimethylphenyl] piperidine -2 -carboxamide) is an aminoamide local anesthetic which is the pure S(-) enantiomer of racemic bupivacaine has strongly emerged as a safer alternative for regional anesthesia than its racemic sibling, bupivacaine. Levobupivacaine has been found to be equally efficacious as bupivacaine, but with a superior pharmacokinetic profile[1-3] it may be preferred for spinal anesthesia in elderly also.[4,5] Fentanyl is a synthetic opioid, a tertiary amine and a phenylpiperidine derivative which is 50-100 times more potent than morphine. Fentanyl is a highly selective µ receptor agonist, which is mainly responsible for its analgesic properties. Analgesia is produced principally through interaction with µ receptors at supraspinal sites. Fentanyl also binds to K receptors causing spinal analgesia, sedation, and anesthesia.[6]

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Aims and Objectives

To compare the efficacy of levobupivacaine 0.5% and levobupivacaine 0.5% with fentanyl as an adjuvant to study:

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- Onset and duration of sensory block
- Onset and duration of motor block
- Duration of post-operative analgesia.

MATERIALS AND METHODS

After obtaining Institutional ethical clearance and written informed consent from the patients, 80 patients of ASA II and III grade posted for TURP surgery at SRMSIMS, Bhojipura, Bareilly, U.P., were included in the study. A statistician was consulted and method of randomization, adequacy of sample size, and power of test were confirmed. 80 male patients in the age group of 50-70 years undergoing elective TURP surgery of ASA status II and III were selected. Patients were divided into two groups of 40 each. Subarachnoid Block in Group A received 0.5% levobupivacaine 2.5 ml (12.5 mg) + 0.9% Nacl 0.5 ml. Subarachnoid block in Group B received 0.5% levobupivacaine 2.5 ml (12.5 mg) + fentanyl 0.5 ml (25 μg).

Exclusion Criteria

- History of drug hypersensitivity to local anesthetics
- Blood coagulation disorder
- Spinal deformities, raised intracranial tension
- Local sepsis.

A detailed preanesthetic evaluation was carried out for each patient with relevant laboratory and radiological investigations. All patients were visited a day before the surgery and explained in detail the anesthetic procedures and an informed written consent was obtained. All patients were kept nil orally before the day of surgery and received tablet ranitidine 150 mg and tablet alprazolam 0.5 mg both orally as premedication on the night before surgery. On the day of surgery, in the pre-operative preparation room IV line was secured with 18G cannula. Vital parameters such as heart rate, noninvasive arterial blood pressure, SPO2 were monitored. Continuous electrocardiogram (lead II) monitoring was done with the chest leads connected to patients. Baseline readings were recorded. Under aseptic precautions subarachnoid block was given at L3-L4 interspace using 25 G spinal needle in sitting position. The drug was injected into the subarachnoid space according to group assigned after noting the clear free flow of cerebrospinal fluid and given over 10-15 s with the operation table kept flat. Patients were made supine immediately. Oxygen was administered through mask. Vital parameters such as BP, HR, SpO_2, and RR were monitored every 5 min for 45 min. Postoperatively, the time for rescue analgesia was when patient complained of pain at surgical site, which was recorded and treated with suitable analgesics.

Statistics

Data were entered using Microsoft Excel 2010 and statistical analysis was done using IBM SPSS v 20.0.0. Categorical variables were analyzed using proportions and percentages. Continuous variables were summarized by mean and standard deviation. Association between continuous variables was established by parametric tests with 95% confidence intervals where applicable.

RESULTS

The characteristics of the three groups were comparable in terms of age, weight, weight of prostate, and duration of surgery. The onset of sensory block was delayed in Group B (3.15±0.362) as compared to Group A (2.05±0.2207). This was statistically significant. The duration of sensory block was delayed in Group B (361.3±3.22) as compared to Group A (334.1±10.65), which was statistically significant. The onset of motor block was delayed in Group B (4.3±0.464 min) as compared to Group A (3.2±0.4051 min). This was statistically significant but clinically not significant because the difference was of only 66 s, i.e., 1.1 min. The duration of motor block was prolonged in Group A (167.3±3.345) min as compared to Group B (145.2±3.35 min). Analysis was done using "independent *t*-test" which showed a statistically and clinically significant difference between the two groups. *Z*-test of proportion showed that the effective duration of analgesia assessed by duration between the time of establishment of spinal anesthesia to time of first request of rescue analgesia was significantly prolonged in Group B (214.65±8.511) when compared to Group A (121.6±3.82).

Mean age of both groups was compared applying "*Z*-test of proportion" and showed no statistically significant difference (Table 1 and Figure 1).

Mean weight of both groups was compared using "*Z*-test of proportion" and showed no statistically significant difference (Table 2 and Figure 2).

Mean weight of prostate of both groups was compared using "*Z*-test of proportion" and showed no statistically significant difference (Table 3 and Figure 3).

Mean duration of surgery of both groups was compared using "*Z*-test of proportion" and showed no statistically significant difference (Table 4 and Figure 4).

The onset of sensory block was delayed in Group B (3.15±0.362) as compared to Group A (2.05±0.2207). On comparison, using t-test of proportion, a statistically

significant difference was found between the two groups (Table 5 and Figure 5).

The duration of sensory block was delayed in Group B (361.3±3.22) as compared to Group A (334.1±10.65). On comparison, using *t*-test of proportion, a statistically significant difference was found between the two groups (Table 6 and Figure 6).

The onset of motor block was delayed in Group B (4.3±0.464 min) as compared to Group A (3.2±0.4051 min). On comparison, using *t*-test of proportion, a statistically significant difference was found between the two groups. This was clinically not significant because the difference was of only 66 s, i.e., 1.1 min (Table 7 and Figure 7).

Table 1: Comparison of mean age

Parameters	Mean±SD		Z	P
	Group A (*n*=40)	Group B (*n*=40)		
Age (years)	63.23±8.43	63.93±8.24	−0.3756	0.7072

SD: Standard deviation

Table 2: Comparison of mean weight

Parameters	Mean±SD		Z	P
	Group A (*n*=40)	Group B (*n*=40)		
Weight (Kg)	62.84±4.60	63.88±4.48	−1.0244	0.3057

SD: Standard deviation

Table 3: Comparison of mean weight of prostate (g)

Parameters	Mean±SD		Z	P
	Group A (*n*=40)	Group B (*n*=40)		
Weight of prostate (g)	40.28±6.02	39.48±7.15	0.5413	0.5883

SD: Standard deviation

Table 4: Comparison of duration of surgery (min)

Parameters	Mean±SD		Z	P
	Group A (*n*=40)	Group B (*n*=40)		
Duration of surgery (min)	46.82±5.93	46.60±7.32	0.1477	0.8826

SD: Standard deviation

Table 5: Comparison of onset of sensory block (min)

Parameters	Mean±SD		Z	P
	Group A (*n*=40)	Group B (*n*=40)		
Sensory block	3.15±0.362	2.05±0.2207	16.4091	<0.0001(S)

SD: Standard deviation

The duration of motor block was prolonged in Group A (167.3±3.345 min) as compared to Group B (145.2±3.35 min). Analysis was done using "independent *t*-test" which showed a statistically and clinically significant difference between the two groups (Table 8 and Figure 8).

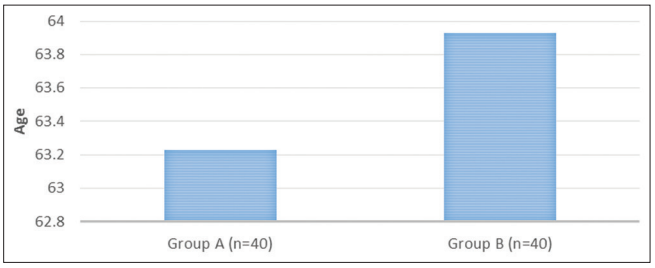

Figure 1: Multiple bar diagrams showing comparison of age in study groups

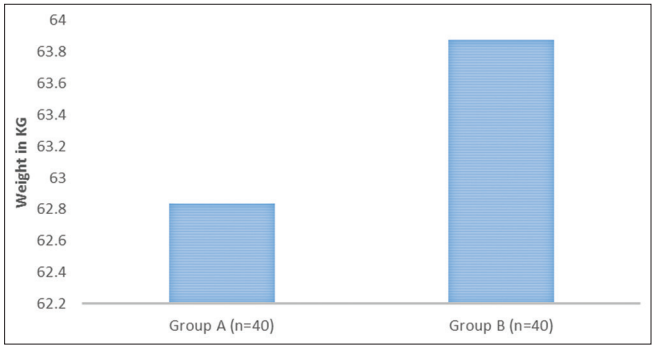

Figure 2: Weight (kg)

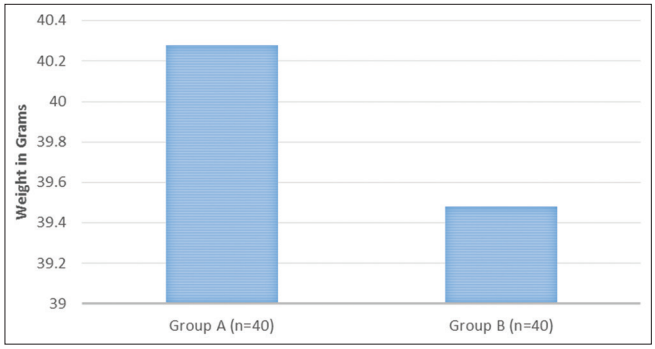

Figure 3: Weight of prostate (g)

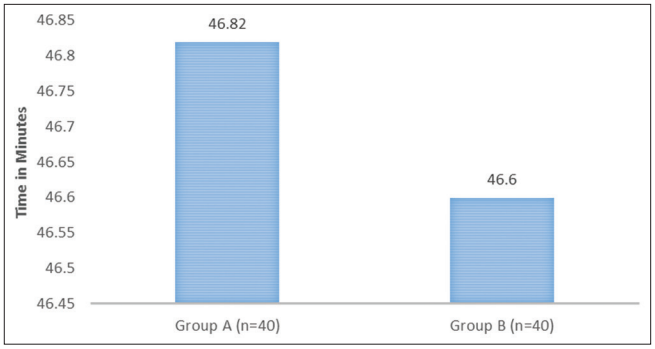

Figure 4: Duration of surgery (min)

Post-operative analgesia was assessed by time for rescue analgesia. *Z*-test of proportion showed that the effective duration of analgesia assessed by duration between the time of establishment of spinal anesthesia to time of first request of rescue analgesia was significantly prolonged in Group B (214.65±8.511) when compared to Group A (121.6±3.82) (Table 9 and Figure 9).

Thus, it is statistically proved that Group B patients had better and long lasting post-operative analgesia than Group A patients.

DISSCUSSION

Adequate anesthesia and good relaxation of the pelvic floor and the perineum, early recognition of signs and symptoms of water intoxication and fluid overload and accidental bladder perforation make subarachnoid block the procedure of choice for TURP surgeries.

The most common serious side effects from spinal anesthesia are hypotension and bradycardia.[7] Hence, if a drug which itself produces intense analgesia without any sympathetic blockade, is available and is added to levobupivacaine, then it will reduce the hemodynamic

Table 6: Comparison of duration of sensory block (min)

Parameters	Mean±SD		*Z*	*P*
	Group A (*n*=40)	Group B (*n*=40)		
Duration of sensory block	334.1±10.65	361.3±3.22	−15.4616	<0.0001

SD: Standard deviation

Table 7: Comparison of onset of motor block (min)

Parameters	Mean±SD		*Z*	*P*
	Group A (*n*=30)	Group B (*n*=28)		
Motor block	3.2±0.4051	4.3±0.464	−11.2947	<0.0001

SD: Standard deviation

Table 8: Comparison of duration of motor block (min)

Parameters	Mean±SD		*Z*	*P*
	Group A (*n*=40)	Group B (*n*=40)		
Duration of motor block	167.3±3.345	145.2±3.35	29.5248	<0.0001

SD: Standard deviation

Table 9: Comparison of time for rescue analgesia (duration of effective analgesia)

Parameters	Mean±SD		*Z*	*P*
	Group A (*n*=40)	Group B (*n*=40)		
Time (h)	121.6±3.82	214.65±8.511	−63.0831	<0.0001

SD: Standard deviation

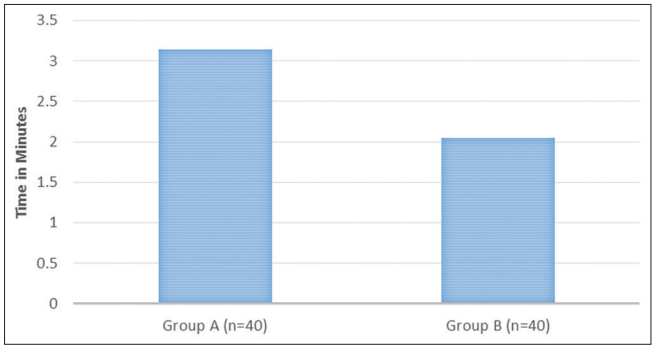

Figure 5: Onset of sensory block

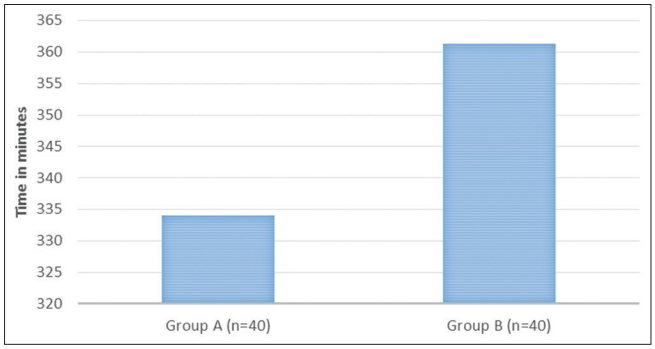

Figure 6: Duration of sensory block

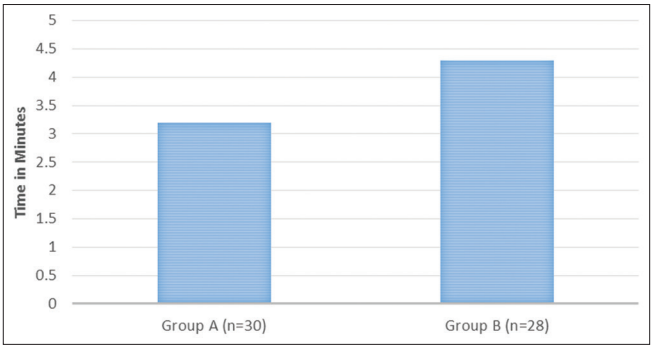

Figure 7: Onset of motor block

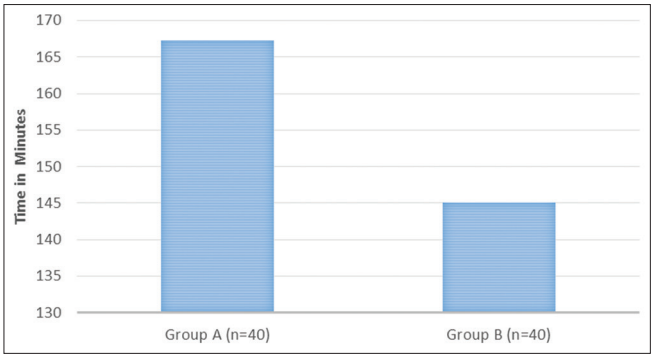

Figure 8: Duration of motor block

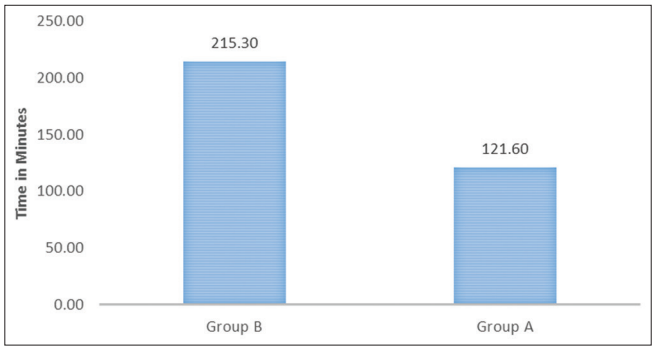

Figure 9: Post-operative analgesia

instability. In this context, spinal opiates have been of much interest in recent times because of their local anesthetic sparing effect. Fentanyl, a synthetic opioid which is 100 times more potent than morphine, having greater lipid solubility, has the quickest onset of action and is, therefore, suitable as an additive to isobaric levobupivacaine when used intrathecally.

Spinal opiates thus administered not only potentiate and reduce the dose local anesthetic agents but also act as post-operative analgesics, because their duration of action is generally longer than that of levobupivacaine.

In our study, the onset of sensory block was delayed in Group B (3.15±0.362) as compared to Group A (2.05±0.2207). The duration of sensory block was delayed in Group B (361.3±3.22) as compared to Group A (334.1±10.65). The onset of motor block was delayed in Group B (4.3±0.464 min) as compared to Group A (3.2±.4051 min). The duration of motor block was prolonged in Group A (167.3±3.345 min) as compared to Group B (145.2±3.35 min).

This shows that addition of fentanyl to levobupivacaine delays onset of sensory and motor block which is clinically insignificant and practically acceptable.

It prolongs the duration of sensory block but reduces the duration of motor block which is favorable for TURP surgeries as it helps in early mobilization.

Cuvas *et al.*[5] conducted a study on spinal anesthesia for transurethral resection operations: Levobupivacaine with or without fentanyl in 2010. It concluded that both regimes were effective and the addition of fentanyl to levobupivacaine offers the advantage of shorter duration of motor block and maybe used as an alternative to pure levobupivacaine for TURP.

Akan *et al.*[8] conducted a study on comparison of levobupivacaine alone and in combination with fentanyl and sufentanil in patients undergoing transurethral resection of the prostate in 2013. It concluded that combining lower dose levobupivacaine with fentanyl and sufentanil provided faster onset of sensorial block, lower frequency and shorter duration of motor block, and longer analgesia time in TURP under spinal anesthesia.

Brahmbhatt *et al.*[9] conducted a study on combination of low dose isobaric levobupivacaine 0.5% and fentanyl compared with isobaric levobupivacaine 0.5% in spinal anesthesia for lower abdominal and perineal surgeries in 2015. It concluded that combination of intrathecal fentanyl with low dose levobupivacaine provides good surgical anesthesia but early motor recovery which is well suited for outpatient anesthesia.

In this study, the mean duration of analgesia in fentanyl group was 214 min which was significantly prolonged compared to levobupivacaine group where patients had effective analgesia only up to about 121 min.

These findings are very well complimented by following previous studies.

Akan *et al.*[8] conducted a study on comparison of levobupivacaine alone and in combination with fentanyl and sufentanil in patients undergoing transurethral resection of the prostate in 2013. It concluded that addition of fentanyl to levobupivacaine in spinal anesthesia prolonged the duration of analgesia in TURP surgeries.

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CONCLUSION

We have concluded that it is safe to use levobupivacaine alone or with fentanyl as an adjuvant in ASA III patients. The addition of 25 mcg of fentanyl to levobupivacaine 15 mg in contrast to levobupivacaine 15 mg does not clinically significantly compromise with onset of sensory and motor block. It delays the onset and prolongs the duration of sensory block and shortens the duration of motor block. This is beneficial for early ambulation of patients. Duration of post-operative analgesic requirement was better in the levobupivacaine with fentanyl group as compared to levobupivacaine which was also statistically significant.

Hence, fentanyl added to levobupivacaine provides good prolonged post-operative analgesia and provides early ambulation in TURP surgeries.

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