



EFFICIENCY OF LEVOBUPIVACAINE ALONE & WITH FENTANYL: A RANDOMIZED COMPARATIVE PROSPECTIVE STUDY.

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ABSTRACT

Benign hyperplasia is the cause of prostate gland enlargement in elderly males. Autopsy histology reveals that cases occur in the fourth, sixth, and ninth decades at rates of 8%, 50%, and 80%, respectively. The surgical procedure of trans-urethral prostate resection has been scheduled for an early date. The initiation of early ambulation following prostate surgery has been found to decrease the likelihood of developing deep vein thrombosis and its related complications, including pulmonary thromboembolism, while also enabling the patient's timely discharge. Van Gessel et al. reported that levobupivacaine has a comparatively lower tendency to cause hypotension than bupivacaine, which suggests that it may be more hemodynamically stable. The present investigation employed levobupivacaine and fentanyl as anesthetic agents for the purpose of urethral prostate resection. The researchers discovered that the administration of 25 mcg of intrathecal fentanyl in combination with (12.5 mg) of isobaric levobupivacaine during transurethral prostate resection results in an expedited onset and prolonged duration of both sensory and motor block. There were no statistically significant differences observed between the two groups in terms of hemodynamic variables or complications.

Keywords: Levobupivacaine, Fentanyl, Transurethral Prostate Resection, sensory and motor block, Hemodynamic Variables.

INTRODUCTION

“Benign hyperplasia is a common condition in aging males where the prostate gland undergoes enlargement. According to the findings of the autopsy histology, there is a prevalence of 8%, 50%, and 80% in the fourth, sixth, and ninth decades of life, respectively”.¹ Transurethral resection of the urethral pressure is a commonly employed technique for the management of

benign prostate hyperplasia. This is due to its ability to mitigate the potential hazards associated with general anesthesia, including but not limited to aspiration, difficult intubation, and the risks associated with positive pressure ventilation. Bupivacaine is the commonly employed medication for spinal anesthesia, administered either as a standalone agent or in combination with an adjuvant. The demographic of elderly individuals constitutes the predominant cohort of patients who are selected for transurethral prostate surgery. The geriatric population frequently presents with hypertension, diabetes, and cardiac comorbidities, as evidenced by prior research.^{2,3,4} Hazel Bardsley et al.'s research indicates that when compared to bupivacaine, levobupivacaine has less of an impact on the cardiovascular system. Based on available evidence, it can be inferred that levobupivacaine may be a comparatively safer option than bupivacaine for administration in the geriatric demographic. "According to previous research, levobupivacaine exhibited a shorter duration of motor block compared to bupivacaine, indicating its lower efficacy".⁵ Patient is so early mobilized for "trans-urethral prostate with resection surgical technique". Since "transurethral resection technique" is considered a day-surgery procedure, early mobility of the patient decreases the risk of deep vein thrombosis and related complications, such as pulmonary thromboembolism, and allows for early release.⁵ "According to Van Gessel et al., levobupivacaine induces less hypotension when compared to bupivacaine, making it look more hemodynamically stable".⁶ In order to do prostate resection via the urethra, we decided to utilize levobupivacaine alone and fentanyl in combination for our study investigation.

AIM

The current investigation evaluates hemodynamic changes following intra-theal injections of levobupivacaine alone and in combination with fentanyl during trans-urethral prostate resection, plus the onset and duration of the analgesic effect in regards to sensory and motor block.

INCLUSION CRITERIA

1. Patients falling under ASA physical status type I & II.
2. Patients with age group of 50 to 80 years .

EXCLUSION CRITERIA

1. Patients falling under ASA physical status type III or more.
2. Patients having past history of systolic type blood pressure to be less than 90 mm of hg.
3. Patients with any kind of hear diseases.
4. Those patients in which spinal anesthesia was not indicated due to some disease or disorder are excluded from our study.

MATERIAL & METHOD

This prospective, comparative, and randomized study was carried out after receiving approval from the ethics board of the Krishna Institute of Medical Sciences, deemed to be a university in Karad. This study will focus on the period of time beginning in November 2018 and ending in October 2020. It was decided to randomly divide the 80 patients into two groups of forty patients each.

Further , randomization in the 2 groups were done with the help of microsoft (MS) word into following 2 groups as follows:-

- Group1 includes levobupivacaine (L) received 0.5% 2.5 ml isobaric levobupivacaine + 0.5cc normal saline. Group 2 includes

- Group 2 includes levobupivacaine with fentanyl (LF) received 0.5% 2.5 ml levobupivacaine isobaric + fentanyl 25 mcg (0.5ml).

The anesthesiologist performed the role of the research's observer, whereas the person receiving treatment was kept in the dark about the medicine that would be administered. given to them. All patients scheduled for transurethral prostate removal had a pre-operative anesthetic assessment and a routine investigation. A large 18-gauge cannula is placed on the day of the surgery, and intravenous ranitidine (50 mg) and metoclopramide (10 mg) are given by IV. Before shifting the patient to the operation theater, 500 ml of normal saline were preloaded. After transferring the patient to the operating room, baseline measurements, as well as the saturation probe, ECG leads, and shifting blood pressure cuff, were noted. With a 25-gauge, 89-mm Quincke's needle placed in the left lateral decubitus position, a subarachnoid block was given while all aseptic procedures were being performed. 0.5% isobaric, 2.5 ml of levobupivacaine and (0.5 cc) of normal saline, were administered to the levobupivacaine (L) group. 0.5% isobaric, 2.5 ml of levobupivacaine plus 25 mcg of fentanyl (0.5 ml), was administered to the levobupivacaine with fentanyl (LF) group. The inability to respond to a small hypodermic needle pinprick was used to determine bilateral sensory block. An adapted Bromage stairway provides access to the motor block. Face masks capable of delivering 4-6 liters of oxygen per minute After the subarachnoid block, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure at 0 minutes, 2 minutes, 5 minutes, 10 minutes, and 15 minutes, and then every 15 minutes until the patient achieved 90 minutes of blood pressure in our study.

Bromage scale 0	No paralysis able to flex hip, knees and ankle
Bromage scale 1	Able to flex knees but unable to raise extended legs
Bromage scale 2	Able to flex ankles but not knees
Bromage scale 3	Unable to move any part of lower limb

TABLE 1 : MODIFIED BROMAGE SCALE.

In the study, hypotension was operationally defined as a reduction of 20% in systolic blood pressure from the baseline measurement. The intervention for this condition consisted of administering an intravenous injection of mephenteramine at a dosage of 6 mg. The medical condition known as bradycardia was characterized by a decrease in pulse rate that did not exceed 20% from the individual's baseline. The recommended treatment for this condition involved administering an intravenous injection of (0.3–0.6 mg) of atropine. Adverse effects, namely nausea and pruritus, were observed intraoperatively and postoperatively.

STASTICAL ANALYSIS

The application of descriptive statistics involves the utilization of measures of central tendency. The Generalized Linear Model (GLM) can be utilized for analyzing repeated measures of parametric values. The non-parametric properties were assessed utilizing the Fisher exact test, while the association between two variables was evaluated using the Chi-square test. A p-value that was deemed statistically significant was one that was less than 0.05. The statistical analysis was performed utilizing SPSS 20 for Windows, a software package developed by SPSS Inc., located in Chicago, Illinois.

RESULT

1. COMPARISON OF ONSET AND DURATION OF SENSORY AND MOTOR BLOCK

A. SENSORY BLOCK

I) ONSET OF SENSORY BLOCK

GROUP	Mean(SD) (in minutes)	Mean Difference	Statistical Inference
L	7.42 (1.65)	2.78	P = 0.00
LF	4.64 (1.36)		Not significant

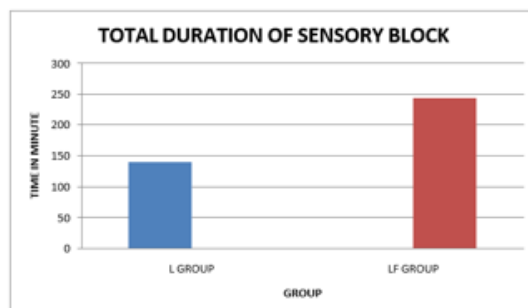
TABLE 2 : ONSET OF SENSORY BLOCK TO T10 DERMATOM.

Onset of sensory block was significantly early in levobupivacaine with fentanyl group (LF) as compared to levobupivacaine group (L)

II) .DURATION OF SENSORY

GROUP	Mean(SD) (in minutes)	Mean difference	P value
L	140.53(7.36)	103.05	P = 0.00
LF	243.58(30.75)		Significant

TABLE 3: TOTAL DURATION OF SENSORY BLOCK



GRAPH 1: TOTAL DURATION OF SENSORY BLOCK.

Total duration of sensory block was statistically prolonged in levobupivacaine with fentanyl group as compared to levobupivacaine group.

B. MOTOR BLOCK

I) ONSET OF MOTOR BLOCK

GROUP	N	Mean(SD) (in minutes)	Mean difference	P value
L	40	12.05(2.12)	3.84	P = 0.00
LF	40	8.21(1.88)		Significant

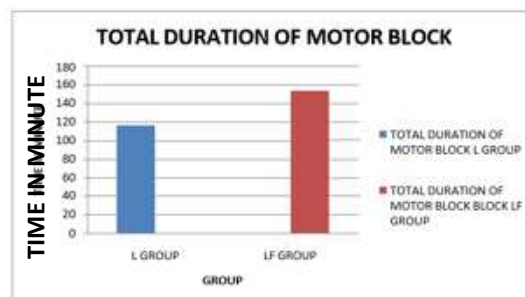
TABLE 4: ONSET OF MAXIMUM MOTOR BLOCK.

Onset of motor block was significantly early in levobupivacaine with fentanyl group(LF) as compared to plain levobupivacaine group(L).

II) DURATION OF MOTOR

GROUP	Mean(SD) (in minutes)	Mean difference	P value
L	115.9(4.17)	38.03	P = 0.00 Significant
LF	153.93(11.13)		

TABLE 5:DURATION OF MOTOR BLOCK.



GRAPH 2 : TOTAL DURATION OF MOTOR BLOCK.

Duration of motor block was significantly prolonged in levobupivacaine with fentanyl group(LF) as compared to plain levobupivacaine group(L).

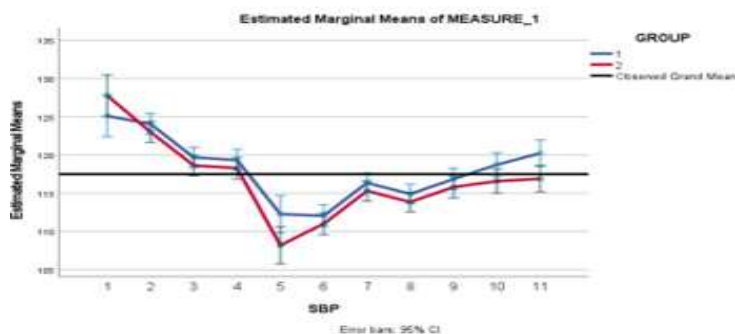
2. HAEMODYNAMIC CHANGES

A. SYSTOLIC PRESSURE

Descriptive Statistic of both group				
	GROUP	Mean	Std. Deviation	N
PRE OP S BP	1	125.1	8.62	40
	2	127.78	8.529	40
	Total	126.44	8.626	80
SBP AT 0	1	124.05	4.212	40
MINUTE	2	123	4.529	40
	Total	123.52	4.378	80
SBP AT 2	1	119.68	3.996	40
	2	118.62	4.522	40
	Total	119.15	4.273	80
SBP AT 5	1	119.33	4.358	40
MINUTE	2	118.28	4.707	40
	Total	118.8	4.538	80
SBP AT 10	1	112.27	5.818	40
MINUTE	2	108.2	9.282	40
	Total	110.24	7.966	80
SBP AT 15	1	112.05	4.284	40
MINUTE	2	111	4.75	40
	Total	111.52	4.526	80

SBP AT 30	1	116.35	4.029	40
MINUTE	2	115.3	4.345	40
	Total	115.82	4.197	80
SBP AT 45	1	114.9	3.875	40
MINUTE	2	113.85	4.197	40
	Total	114.38	4.048	80
SBP AT 60	1	116.85	4.21	40
MINUTE	2	115.8	4.614	40
	Total	116.33	4.42	80
SBP AT 75	1	118.73	5.134	40
MINUTE	2	116.58	4.771	40
	Total	117.65	5.042	80
SBP AT 90	1	120.23	5.659	40
MINUTE	2	116.9	5.344	40
	Total	118.56	5.719	80

Measure: MEASURE_1						
Transformed Variable: Average						
Source	Type III Sum of Squares	Df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	12147855.1	1	12147855.1	51159.063	0	0.998
GROUP	367.91	1	367.91	1.549	0.217	0.019
Error	18521.307	78	237.453			



GRAPH 3: GLM SYSTOLIC BLOOD PRESSURE

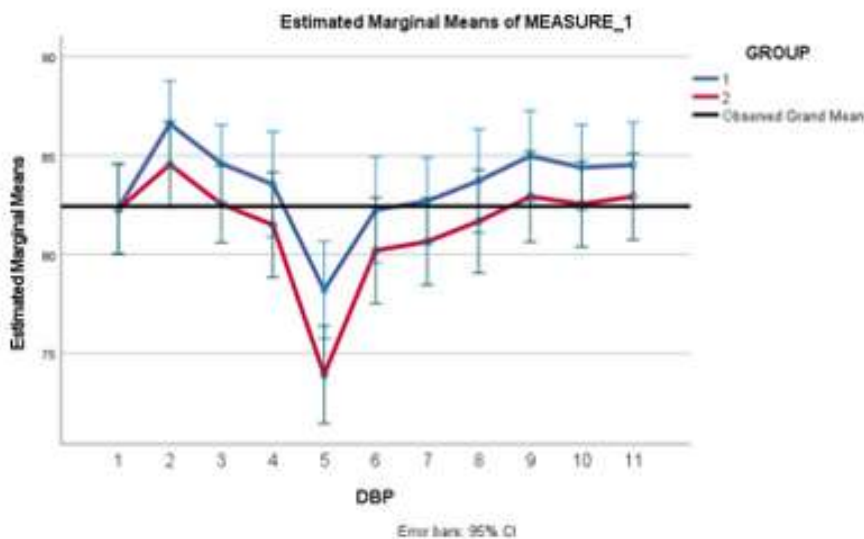
Comparison of Systolic blood pressure between the two groups. The study utilized the General Linear Model for repeated assessments and found no statistically significant differences in systolic blood pressure between the two groups.

DYSTOLIC PRESSURE

Descriptive Statistics of Dystolic blood pressure				
	GROUP	Mean	Std. Deviation	N
PRE OP D BP	1	82.33	2.965	40
	2	82.28	9.772	40
		82.3	7.175	80
DBP AT 0	1	86. Total 60	6.736	40
MINUTES	2		7.02	40
	Total	85.57	6.913	80
DBP AT 2	1	84.6	6.13	40
MINUTES	2	82.55	6.218	40
	Total	83.58	6.221	80
DBP AT 5	1	83.55	8.314	40
MINUTES	2	81.5	8.611	40
	Total	82.53	8.473	80
DBP AT10	1	78.2	6.944	40
MINUTES	2	73.93	8.621	40
	Total	76.06	8.07	80
DBP AT 15	1	82.25	8.384	40
MINUTES	2	80.2	8.662	40
	Total	81.22	8.533	80
DBP AT 30	1	82.7	6.745	40
MINUTES	2	80.65	7.188	40
	Total	81.68	7.002	80
DBP AT 45	1	83.73	8.149	40
MINUTES	2	81.68	8.435	40
	Total	82.7	8.305	80
DBP AT 60	1	84.97	7.163	40
MINUTES	2	82.93	7.385	40
	Total	83.95	7.302	80
DBP AT 75	1	84.4	6.834	40
MINUTES	2	82.55	6.887	40
	Total	83.48	6.88	80

DBP AT 90	1	84.53	7.165	40
MINUTES	2	82.93	6.662	40
	Total	83.73	6.921	80

Tests of Between-Subjects Effects Diastolic blood pressure						
Measure: MEASURE_1						
Transformed Variable: Average						
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	5980098.7	1	5980098.7	11246.625	0	0.993
GROUP	890.028	1	890.028	1.674	0.2	0.021
Error	41474.461	78	531.724			



GRAPH 4: GLM DIASTOLIC BLOOD PRESSURE

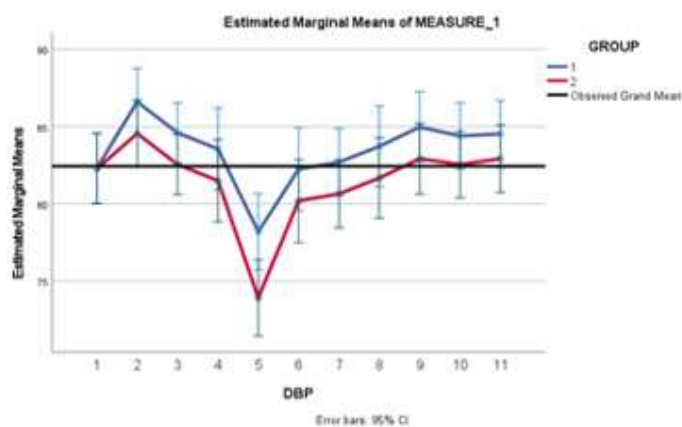
Comparison of Diastolic blood pressure between the two groups. In our study, when we applied the general linear model to repeated data, there were no significant variations in diastolic BP between the two groups.

B. MEAN ARTERIAL PRESSURE

Descriptive Statistics Mean Arterial Pressure				
	GROUP	Mean	Std. Deviation	N
MEAN P O	1	96.5258	4.7303	40

BP	2	96.8083	9.32948	40
	Total	96.6671	7.35086	80
MEAN BP 0 MINUTES	1	99.0383	5.80162	40
	2	97.2333	6.16109	40
	Total	98.1358	6.01502	80
Mean BP 2 MINUTE	1	96.2467	5.26945	40
	2	94.4417	5.54956	40
	Total	95.3442	5.45312	80
M BP 5 MINUTE	1	95.43	6.84263	40
	2	93.625	7.27443	40
	Total	94.5275	7.07552	80
MEAN BP 10 MINUTE	1	89.5133	6.38162	40
	2	85.2167	8.60628	40
	Total	87.365	7.83223	80
MEAN BP 15 MINUTE	1	92.1383	6.90899	40
	2	90.3333	7.32431	40
	Total	91.2358	7.13253	80
MEAN BP 30 MINUTE	1	93.8717	5.66974	40
	2	92.0667	6.20119	40
	Total	92.9692	5.97313	80
MEAN BP 45 MINUTE	1	94.0717	6.61797	40
	2	92.2667	7.00395	40
	Total	93.1692	6.83107	80
MEAN BP 60 MINUTE	1	95.555	6.07209	40
	2	93.75	6.41737	40
	Total	94.6525	6.27354	80
MEAN BP 75 MINUTES	1	95.7967	6.0787	40
	2	93.7583	6.07193	40
	Total	94.7775	6.12324	80
MEAN BP 90 MINUTES	1	96.38	6.43073	40
	2	94.1167	6.02263	40
	Total	95.2483	6.29435	80

Tests of Between-Subjects Effects Diastolic blood pressure						
Measure: MEASURE_1						
Transformed Variable: Average						
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	5980098.7	1	5980098.7	11246.625	0	0.993
GROUP	890.028	1	890.028	1.674	0.2	0.021
Error	41474.461	78	531.724			



GRAPH 5: GLM DIASTOLIC BLOOD PRESSURE

Comparison of Diastolic blood pressure between the two groups After applying General Linear Model for repeated measures, there was no significant variations in diastolic BP between both the groups.

DISCUSSION

Benign hyperplasia of prostate is normal physiological senile change in prostate gland of male genital system. Autopsy studies have observed a histological prevalence of 8%, 50% and 80% in the 4th, 6th and 9th decades of life, respectively.¹ For the treatment of benign hyperplasia of prostate, trans-urethral resection of prostate surgery is done under spinal anaesthesia because it reduces the risk of general anaesthesia such as aspiration, difficult intubation, risk associated with positive pressure ventilation and early detection of TURP syndrome is possible. Most commonly used drug for spinal anaesthesia is bupivacaine alone or bupivacaine with some adjuvant.^{2,3}

All the patient posted for trans-urethral resection of prostate surgery belong to geriatric age group. Prevalence of hypertension, diabetes and cardiac co morbidities are common in geriatric age group.^{2,3,4} Levobupivacaine have less effects on cardio vascular system as compared to bupivacaine according to Hazel bardsley et al. So again use of levobupivacaine in geriatric population is safer than use of bupivacaine. Levobupivacaine found to be shorter acting as compared to bupivacaine in terms of duration of motor block so patients get early mobilized.⁵ Early mobilization of patient reduces the chances of deep vein thrombosis and its consequences such as pulmonary thrombo-embolism. Levobupivacaine causes less hypotension as compared to bupivacaine according to Van Gessel et al., so levobupivacaine appear more hemodynamically stable than bupivacaine. So I decided to use levobupivacaine alone and levobupivacaine with fentanyl in trans-urethral resection of prostate surgery.⁶ In my comparative randomized clinical study we compared isobaric levobupivacaine with and without fentanyl in trans-urethral resection of prostate surgery. Total 80 patient ASA I and II 50 to 80 years of age were selected and randomly allocated in two group L, LF (40 patient in each) groups. Demographic data collected and noted.

Group L received [12.5 mg(2.5cc)] isobaric levobupivacaine + 0.5 cc normal saline total 3 cc volume. Group LF received [12.5 mg (2.5cc)] isobaric levobupivaine + 0.5 cc undiluted fentanyl 25 mcg total 3 cc volume. Base line and after spinal (0, 2, 5, 10,15 minute) and every 15 minutes till 90 minute heart rate, blood pressure and mean arterial pressure were recorded. Onset and duration of sensory and motor block were recorded with pin prick test and bromage scale respectively. Incidence of vomiting, pruritus and hypotension noted.

SENSORY ONSET TIME

A combination of opioids and local anesthetics delivered intrathecally has been shown to have a synergistic analgesic effect. When Attri et al. (25) compared the effects of 0.5% 2-cc levobupivacaine alone and in combination with 25-mcg fentanyl, they discovered that the levobupivacaine with fentanyl group had sensory block to the t10 level earlier than the levobupivacaine alone group (7.61.46; 4.81.50) whereas, Bidikar et al. (27) compared the maximal sensory cephalad spread of 10mg levobupivacaine alone to that of 7.5mg

levobupivacaine plus 25 mcg fentanyl in patients receiving LSCS [a1], they found no statistically significant difference between the two groups (9.52.3 minutes vs. 8.91.6 minutes). In patients undergoing LSCS, Ozyilkan et al. (35) found that the onset of sensory block was earlier in the fentanyl or su combination group as compared to the plain levobupivacaine group.

Furthermore, in our study, we found that the onset of sensory block was earlier in the group with levobupivacaine as compared to the group with fentanyl alone, but I found contradictory results to Bidikar et al. (27), and this may be due to the low dose of fentanyl used in his study.

DURATION OF SENSORY BLOCK

According to Cuvas et al., the focus of this research was on patients undergoing prostate surgery through the urinary system. The LF group was given 2.2 cc of levobupivacaine with 15 mcg of fentanyl, whereas the L group got 2.5 cc.⁷ In terms of total sensory block duration, no statistically significant difference was found. Lee et al., conducted research on patients scheduled for outpatient urological treatments. One group was given 0.5% levobupivacaine in a 2.6-cc plain solution, whereas the other got 0.5% levobupivacaine in a 2.3-cc solution containing 15 mcg fentanyl.⁸ In terms of total sensory block duration, there was no statistically significant difference between the two groups. Attri et al., studied levobupivacaine 2 cc alone and 2 cc levobupivacaine with 25 mcg fentanyl and found a statistically significant difference in total sensory block duration between the two groups (197.5811.20 vs. 270.9828.60 seconds).⁹ Further, our study findings indicates that the levobupivacaine group exhibited a longer duration of sensory block compared to the fentanyl group. This outcome is consistent with the findings of Attri et al.,⁹ but differs from those of Cuvas et al.,⁷ and Lee et al.,⁸ which may be attributed to the administration of lower doses of fentanyl in both groups.

ONSET OF MOTOR BLOCK

“In a study conducted by Attri et al., a comparison was made between the administration of 2 cc of levobupivacaine alone and 2 cc of levobupivacaine with 25 mcg of fentanyl. The results indicated that the onset of motor block was significantly earlier in the group that received levobupivacaine with fentanyl (8.38 1.78 minutes) compared to the group that received levobupivacaine alone (12.26 1.85 minutes)”.⁹ Bidikar and colleagues conducted a study to compare the onset of motor block in two groups: one receiving 7.5mg levobupivacaine with 25 mcg fentanyl and the other receiving 10mg levobupivacaine. The results indicated no significant statistical difference between the two groups in terms of onset of motor block (2.51 minutes vs. 3.11.2 minutes).¹⁰ The study conducted by Ozyilkan et al., revealed that the initiation of motor block was observed to occur earlier in the group administered with 2.2 mcg of 0.5% fentanyl as compared to the levobupivacaine group. The difference was found to be statistically significant (3.0 (1.5-20.0) CC vs. 10.0 (7-15) CC).¹¹ In contrast to the findings of the groups led by Attri et al.,⁹ and Ozyilkan et al.,¹¹ .Furthermore, our study revealed that the initiation of motor block was prompt in the fentanyl group as compared to the

levobupivacaine group. The potential cause of this phenomenon could be attributed to the comparatively reduced quantity of fentanyl administered in the Bidikar cohort.

DURATION OF MOTOR BLOCK

According to Kuunsiemi et al., the incorporation of 25 micrograms of fentanyl into 5 mg of bupivacaine produced satisfactory anesthesia and a short-lived motor block during spinal anesthesia.¹² According to the research conducted by Ben-David and colleagues, the administration of 10 micrograms of fentanyl to a 3 milliliter solution of 0.17% bupivacaine during knee arthroscopies for ambulatory patients resulted in an enhanced sensory block while having no impact on the motor block or prolonging the recovery period. Erkan Yavuz and colleagues conducted a study that found that the inclusion of fentanyl in levobupivacaine did not produce any motor block.¹³ The study conducted by Attri et al., revealed that the administration of levobupivacaine with fentanyl resulted in a significant increase in the duration of motor block when compared to the administration of levobupivacaine alone.⁹ Specifically, the duration of motor block was observed to be 152.769.79 minutes in the group receiving levobupivacaine alone, while it was 188.529.81 minutes in the group receiving levobupivacaine with fentanyl. Henceforth, In contrast to the findings of Kuunsiemi et al.,¹ and Erkan Yavuz et al.,¹³ the present study reveals that the duration of fentanyl-induced motor block is significantly prolonged in the levobupivacaine-treated group.

HEMODYNAMIC CHANGES

In a study conducted by Attri et al., a comparison was made between the administration of 2 cc of levobupivacaine alone and 2 cc of levobupivacaine with 25 mcg of fentanyl.⁹ The results indicated that there was no statistically significant difference in hemodynamics between the two groups. I. Akan et al. found no statistically significant difference between the levobupivacaine and fentanyl groups with respect to mean heart rate or blood pressure. Cuvas et al.,⁷ and Lee et al.,⁸ both reported results that were equivalent. Likewise, The study revealed that the hemodynamic alterations observed in both groups were similar.

CONCLUSION

The study found that the inclusion of 25 mcg of intrathecal fentanyl in 12.5 mg of isobaric levobupivacaine during transurethral prostate resection leads to an accelerated onset and extended duration of both sensory and motor block. There were no statistically significant differences observed between the two groups in relation to hemodynamic variables or complications.

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*EFFICIENCY OF LEVOBUPIVACAINE ALONE & WITH FENTANYL: A RANDOMIZED
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Section A -Research paper