Original Article

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Anaesthesia Section

Comparison of Intrathecal Bupivacaine with Levobupivacaine using Fentanyl as an Adjuvant for Transurethral Resection of Prostate-A Randomised Controlled Trial

INDIRA MALIK[1], SHEENAM KAMBOJ[2], HEMANT KAMAL[3], SURESH KUMAR SINGHAL[4], VINEET KUMAR[5], DEEPIKA SEELWAL[6]

ABSTRACT

Introduction: Transurethral Resection of Prostate (TURP) is a common surgical procedure performed for Benign Prostatic Hypertrophy (BPH), most commonly under Spinal Anaesthesia (SA). It is generally tolerated well by the elderly but since they suffer from several co-morbidities, therefore, it is desirable to avoid hypotension following SA, in these patients. Levobupivacaine, a pure S enantiomer of racemic bupivacaine has emerged as a safe alternative to bupivacaine with similar efficacy and better pharmacokinetic profile.

Aim: To compare the efficacy of intrathecal levobupivacaine with bupivacaine using fentanyl as adjuvant in TURP.

Materials and Methods: This randomised controlled trial was conducted at Pandit BD Sharma Postgraduate Institute of Medical Sciences, Rohtak, Haryana, India, between March 2022 to September 2022. Fifty patients, 50-80 years of age, American Society of Anaesthesiologists (ASA) I-III, posted for TURP under SA, were included in the study and divided into two groups: group B (n=25): Inj. bupivacaine (0.5%) hyperbaric 12.5 mg+25 µg fentanyl citrate, group L (n=25): Inj. levobupivacaine (0.5%) isobaric 12.5 mg+25 µg fentanyl citrate. Onset of sensory and motor block, time to onset of maximum sensory and motor block, Heart Rate (HR), Systolic Bood Pressure (SBP), Diastolic Bood Pressure (DBP) and Mean Arterial Pressures (MAP) were recorded. Data analysis was done with the help computer software using Statistical Package for the Social Sciences (SPSS), version 24.0. Means, standard deviations, Chi-square, t-values and p-values were calculated, p-value <0.05 was considered significant at 95% confidence level.

Results: Demographic data of the patients was comparable. The mean time to onset of sensory block in group B was significantly faster (3.72±0.96 min) than group L (4.47±0.73 min). The mean time to onset of motor block was faster in group B (4.74±0.91 min) than group L (7.57±1.51 min). HR was lower in group B, after SA at 5, 10, 15, 20, 30, and 45 min after SA. Group B recorded a lower SBP, DBP and MAP following SA, compared to group L (p<0.001). The duration of analgesia was significantly longer in group B (232.80±14.07 min vs 221.80±15.47 min in group L) (p<0.05). No adverse effects were reported from either of the groups.

Conclusion: Levobupivacaine provided very stable haemodynamics, good quality analgesia and muscle relaxation intraoperatively. Postoperative analgesia was clinically similar to bupivacaine, no adverse effects were reported. Thus, levobupivacaine is a safe and reliable alternative to bupivacaine for elderly patients undergoing TURP.

Keywords: Analgesia, Elderly, Hypotension, Mean arterial pressure

INTRODUCTION

The TURP is a common surgical procedure performed for the treatment of BPH. The patients are elderly (>60 years age) and many are suffering from a number of co-morbid conditions e.g., hypertension, Coronary Artery Disease (CAD), Diabetes Mellitus (DM), Chronic Obstructive Pulmonary Disease (COPD) [1,2]. SA is the most widely used anaesthetic technique for this procedure as it provides good postoperative analgesia, reduces surgical blood loss and avoids the need for airway handling, which may irritate the airway leading to postextubation coughing and straining, thus exacerbate postoperative haemorrhage. Elderly patients have been found to tolerate SA well as it helps in peripheral pooling of blood, reducing the chances of circulatory overload and complications like TURP Syndrome; signs of water intoxication, over hydration, bladder perforation, are detected early and easily under SA [3].

The major drawback of SA is risk of hypotension, due to sympathetic blockade leading to vasodilation and decreased venous return. Chemical sympathectomy extends for 2-6 dermatomes above the sensory level in SA. In elderly patients with cardiac disease systemic vascular resistance may decrease by 25%, whereas in normovolemic patients it may decrease only 15-18% [4]. Local Anaesthetics (LA) provide adequate anaesthesia for the patient and good relaxation of the pelvic floor and perineum. They can be combined with opioids or other compounds, which allows a lower dose of LA, thus better haemodynamic stability [5].

Intrathecal bupivacaine 0.5% (heavy), an amide LA is the most commonly used drug for SA and has stood the test of time [2]. However, caution has been advised in elderly or debilitated patients to use the least possible dose that provides adequate anaesthesia, in order to avoid high plasma levels of the drug and systemic side-effects. Levobupivacaine {(2S)-1-butyl N-(2,6 dimethylphenyl) piperidine-2-carboxamide} is a pure S enantiomer of racemic bupivacaine which has strongly emerged as a safe alternative to bupivacaine with similar efficacy and better pharmacokinetic profile [6]. It produces less motor block than bupivacaine when administered intrathecally at low doses. It has been considered a safe drug for SA in elderly patients too, considering its safer Cardiovascular (CVS) and Central Nervous System (CNS) profile [7].

Various adjuvants, especially opioid analgesics, like fentanyl have become popular to prolong duration of action, ensure patient comfort and prevent adverse effects of SA such as haemodynamic alterations, shivering, nausea, vomiting etc [6]. Other adjuvants that

have been used are sufentanil, pethidine, clonidine, ketamine to name a few.

Fentanyl in combination with bupivacaine has been used widely for various general surgical, orthopaedic, gynaecological and urological procedures to increase the duration of sensory block without increasing duration of motor block or time to micturition [8]. Previous studies comparing levobupivacaine with bupivacaine have reported a slower onset of sensory and motor block with levobupivacaine, a shorter duration of block and lesser period of postoperative analgesia [9-11].

The aim of the present study was to observe the efficacy of levobupivacaine with fentanyl as compared with bupivacaine and fentanyl, in TURP. This study compared the onset and quality of sensory and motor blockade using the two drugs, intraoperative haemodynamic stability, postoperative recovery from sensory and motor blockade and duration of analgesia.

MATERIALS AND METHODS

This randomised controlled trial was conducted at Pandit BD Sharma Postgraduate Institute of Medical Sciences, Rohtak, Haryana, India, between March 2022 and September 2022. Approval from Biomedical Research Ethics Committee was obtained, letter no. BREC/Th/20/Anaesth/25 and trial was registered with Clinical Trial Registry India, CTRI/2022/03/040873.

Sample size calculation: Based on a similar study by Devi R, the estimated sample size was calculated, taking into consideration time to onset, duration of sensory and motor blockade, with 95% confidence interval, 80% power and alpha level of 0.05 [9].

N=size per group;

SD=Standard Deviation=1.9

δ=mean difference=4.54-2.92=1.62

$Z_{\alpha/2}=Z_{0.05/2}=Z_{0.025}=1.96$- From Z table at type I error of $5Z_{\beta}=Z_{0.20}=0.842$- at 80% power

$$N=2\times\frac{(Z_{\alpha/2}+Z_{\beta})^2}{(\delta_0)^2}\times SD^2$$

$=2\ (1.96+0.84)^2(1.9)^2/(1.62)^2$

$=15.68*3.61/2.62$

$=56.6/2.62$

$=21.6$

$=25$

Inclusion criteria: Fifty patients aged 50-80 years, ASA I-III, posted for TURP under SA, were included in the study.

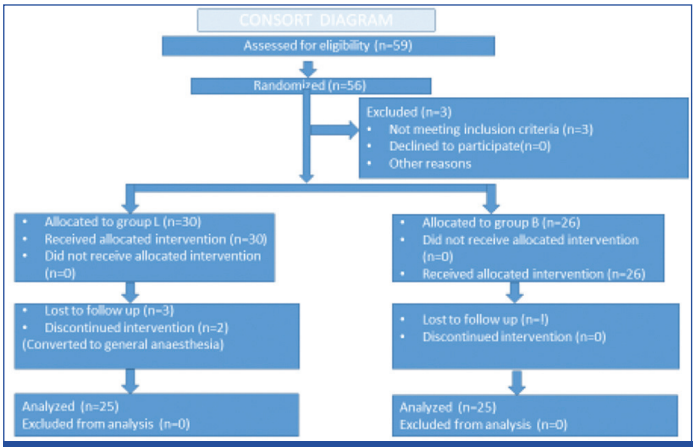
Exclusion criteria: Patient refusal, local site infection, bleeding diathesis, anticoagulant therapy, diseases of the CNS or spinal cord, raised intracranial pressure, allergy to any of the study drugs, were considered as exclusion criteria.

Study Procedure

All patients were kept Nil By Mouth (NBM) for six hours prior to surgery. Written informed consent was obtained from all patients, tablet Alprazolam 0.25 mg administered at bedtime and two hours prior to surgery with a sip of water. Using computer generated randomisation number table, the patients were divided into two groups [Table/Fig-1]:

- Group B (n=25): Inj. bupivacaine (0.5%) hyperbaric 12.5 mg+25 µg fentanyl citrate
- Group L (n=25): Inj. levobupivacaine (0.5%) isobaric 12.5 mg+25 µg fentanyl citrate

In the operating room, routine ASA monitors were attached. An 18 G i.v. line was secured on the dorsum of the non dominant hand and 500 mL Ringer lactate started. Subarachnoid Block (SAB) was performed in the sitting position, in the L2/L3 or L3/L4 intervertebral spaces, with 23/25 G Quincke's needle, after skin



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) diagram.

infiltration with 2% lignocaine. After confirmation of free flow of Cerebrospinal Fluid (CSF), patients in group B received bupivacaine 0.5% hyperbaric 12.5 mg (2.5 mL) with 25 µg fentanyl, while patients in group L received levobupivacaine 0.5% isobaric 12.5 mg (2.5 mL) with 25 µg fentanyl mixed together. Patient was placed in supine position and oxygen given by face mask.

Onset of sensory block was assessed using cold alcohol swab in the midclavicular line bilaterally till T8 level was achieved. Onset of motor block was assessed by the modified Bromage scale and time to onset of maximum sensory and motor block was noted. HR, SBP, DBP and MAP were recorded every five minutes intraoperatively, till the end of surgery.

Hypotension was defined as decrease in SBP >20% from baseline and was managed with intravenous crystalloid infusion and 3 mg boluses of mephentermine. Bradycardia was defined as HR <50/min and was treated with Inj. atropine 6 mg i.v. Need for postoperative analgesia and intraoperative complications like nausea, vomiting, shivering, pruritus were also noted. Any patient having VAS >4 was considered as having postoperative pain; managed by paracetamol 1 g/inj. tramadol i.v. 50-100 mg as rescue analgesia.

STATISTICAL ANALYSIS

Data analysis was done with the help of computer software using SPSS version 24.0. Means, standard deviations, Chi-square, t-values and p-values were calculated, p-value <0.05 was considered significant at 95% confidence level. Unpaired t-test was used to compare mean±standard deviation between the two groups for numerical values such as age, height, weight, onset of sensory and motor block, duration of stable sensory and motor block and haemodynamic variables. Pearson's Chi-square test was applied to see the difference between the two groups for categorical variables.

RESULTS

Demographic characteristics and ASA grade were comparable between the two groups [Table/Fig-2].

There was significant difference in peak sensory block level; Group L had significantly higher number of cases with T10 sensory block, while Group B had significantly higher number of cases with T8 level. Group B also had significantly larger number of cases with grade IV block [Table/Fig-3].

The mean time to onset of sensory and motor block in Group B was significantly faster than in Group L. The total duration of sensory block was significantly greater in Group B, while the total duration of motor block was similar in both the groups [Table/Fig-4]. Patients in Group B experienced a longer duration of analgesia, than patients of Group L [Table/Fig-5].

There was significant difference in HR after administration of SA, between the groups with Group L recording a higher value of HR at

Code of group		Group B	Group L	Total	Pearson's Chi-square	p-value
ASA	Grade I	1	3	4	1.374	0.503
	Grade II	21	18	39		
	Grade III	3	4	7		
Total		25	25	50		
Varibles	**Group**	**Mean±SD**			**t-value**	**p-value**
Age (in years)	B	68.32±9.65			0.030	0.976
	L	68.40±8.92				
Height (in cms)	B	169.44±2.55			0.273	0.786
	L	169.24±2.63				
Weight (kg)	B	66.56±7.02			0.086	0.931
	L	66.72±6.02				

[Table/Fig-2]: Demographic data.

Code of group		Group B	Group L	Total	Pearson's Chi-square	p-value
Peak sensory block	T6	1	0	1	14.743	0.001
	T8	23	12	35		
	T10	1	13	14		
Peak motor block (Bromage scale)	III	0	7	7	8.14	0.004
	IV	25	18	43		
Total		25	25	50		

[Table/Fig-3]: Peak sensory and motor block level.

Code of group		Mean±SD	p-value
Onset of sensory block (min)	Group B	3.72±0.96	0.003
	Group L	4.47±0.73	
Onset of motor block (min)	Group B	4.74±0.91	<0.001
	Group L	7.57±1.51	
Duration of stable sensory block (min)	Group B	209.20±8.90	0.007
	Group L	200.76±12.16	
Duration of motor block (min)	Group B	183.32±9.52	0.861
	Group L	183.76±8.05	

[Table/Fig-4]: Onset and duration of sensory and motor block.

Code of group		N	Mean±SD	p-value
Duration of surgery (min)	Group B	25	49.20±12.64	0.704
	Group L	25	50.40±9.35	
Duration of analgesia (min)	Group B	25	232.80±14.07	0.011
	Group L	25	221.80±15.47	

[Table/Fig-5]: Duration of surgery and analgesia.

10 min, 15 min, 20 min, 30 min and 45 min (p<0.001) except HR at 60 min [Table/Fig-6a].

Patients of Group L also recorded a significantly higher SBP, following SA, compared to the patients of Group B at all time intervals except at 60 min [Table/Fig-6b]. When compared with the baseline values of SBP, none of the patients in either group experienced a fall in SBP >20%. Patients in group L, depicted a fall in SBP <10% of baseline values.

Patients of group L also had a higher DBP following SA, [Table/Fig-6c] compared to the patients of group B. MAP in group L was also significantly higher compared to group B (p<0.001) [Table/Fig-6d]. Thus, the patients in the levobupivacaine group showed minimal variation of haemodynamic parameters from the baseline values, which is desirable in elderly patients. None of the patients from either group experienced any adverse events.

DISCUSSION

Central neuraxial blockade, especially SA, has been the mainstay for performing TURP. It provides adequate anaesthesia, surgical relaxation and allows early detection of fluid overload since the patient is awake. However, these patients are elderly with a number

Code of group		Mean±SD	p-value
Baseline HR (beats/min)	Group B	76.76±9.67	0.324
	Group L	79.56±10.19	
HR (5 min)	Group B	71.36±10.70	0.044
	Group L	77.20±9.19	
HR (10 min)	Group B	63.12±10.29	<0.001
	Group L	74.92±10.08	
HR (15min)	Group B	67.48±8.76	0.003
	Group L	75.20±8.95	
HR (20 min)	Group B	70.52±7.33	0.001
	Group L	78.40±8.22	
HR (30 min)	Group B	71.40±8.11	<0.001
	Group L	80.72±6.90	
HR (45 min)	Group B	76.12±7.50	0.004
	Group L	82.32±7.18	
HR (60 min)	Group B	77.33±3.06	0.320
	Group L	81.67±6.50	

[Table/Fig-6a]: Heart Rate (HR) (baseline and postspinal).

Code of group		N	Mean±SD	p-value
Baseline SBP (mmHg)	Group B	25	130.12±16.38	0.527
	Group L	25	132.72±12.16	
SBP (5min)	Group B	25	112.32±12.11	<0.001
	Group L	25	128.64±11.86	
SBP (10min)	Group B	25	107.00±11.58	<0.001
	Group L	25	125.84±10.22	
SBP (15 min)	Group B	25	107.12±10.28	<0.001
	Group L	25	125.20±11.87	
SBP (20 min)	Group B	25	111.72±10.87	<0.001
	Group L	25	127.60±9.82	
SBP (30 min)	Group B	25	113.00±11.29	<0.001
	Group L	25	127.88±10.42	
SBP (45 min)	Group B	25	116.04±8.71	<0.001
	Group L	25	128.84±9.62	
SBP (60 min)	Group B	3	118.67±11.72	0.135
	Group L	5	131.60±9.42	

[Table/Fig-6b]: SBP (baseline and postspinal).

Code of group		Mean±SD	p-value
Baseline DBP (mmHg)	Group B	78.60±9.40	0.054
	Group L	83.52±8.15	
DBP (5min)	Group B	69.12±7.37	<0.001
	Group L	80.96±7.07	
DBP (10 min)	Group B	66.64±6.94	<0.001
	Group L	78.32±6.56	
DBP (15 min)	Group B	68.96±7.46	<0.001
	Group L	78.28±5.93	
DBP (20 min)	Group B	72.68±7.43	<0.001
	Group L	81.56±5.64	
DBP (30 min)	Group B	72.16±5.67	<0.001
	Group L	80.80±6.75	
DBP (45 min)	Group B	73.76±5.38	<0.001
	Group L	81.72±5.65	
DBP (60 min)	Group B	73.33±3.06	0.014
	Group L	82.60±3.97	

[Table/Fig-6c]: DBP (baseline and postspinal).

Code of group		Mean±SD	p-value
Baseline mean blood pressure (mmHg)	Group B	90.20±14.77	0.328
	Group L	93.96±12,02	
MAP (5 min)	Group B	83.04±7.89	<0.001
	Group L	96.64±8.17	
MAP (10 min)	Group B	79.96±8.16	<0.001
	Group L	94.52±7.25	
MAP (15 min)	Group B	81.64±7.86	<0.001
	Group L	93.60±7.76	
MAP (20 min)	Group B	86.12±9.13	<0.001
	Group L	96.88±6.58	
MAP (30 min)	Group B	85.88±6.97	<0.001
	Group L	96.56±7.45	
MAP (45 min)	Group B	87.84±6.22	<0.001
	Group L	97.28±6.64	
MAP (60 min)	Group B	88.33±6.11	0.037
	Group L	99.00±5.15	

[Table/Fig-6d]: MAP (baseline and postspinal).

of co-existing medical conditions involving the cardiopulmonary system and their reserves are compromised.

Age-related changes in the spinal anatomy and CVS reflexes may lead to adverse haemodynamic and pulmonary effects, following greater distribution of LA agents. Efforts have been made to reduce the dose of bupivacaine, by using adjuvants, to achieve good quality sensory and motor block with the least possible dose, to minimise its adverse CVS effects. Levobupivacaine which is the L-isomer of bupivacaine has a faster protein binding rate, therefore, less cardiotoxic and provides good sensory and motor blockade. The present study tried to observe its efficacy in cases of TURP, as an effective and safer alternative to bupivacaine.

Since, isobaric levobupivacaine was used in the study, head down tilt was avoided for all the cases and the doses of LA, as well as fentanyl, were same in both the groups to avoid any bias. Level of sensory block achieved was significantly higher in the bupivacaine group, compared to the levobupivacaine group ($p<0.05$). Level of motor block achieved was significantly denser in the bupivacaine group as compared to the levobupivacaine group ($p<0.004$). However, clinically there was no difference in patient comfort or surgical ease during the procedure. In addition, accidental bladder perforation is easily detected if the sensory block is limited to T10 level, as the patient will complain of abdominal and referred shoulder pain [12].

Time to onset of maximum sensory block and motor block was significantly shorter in the bupivacaine group as compared to the levobupivacaine group ($p<0.001$). These observations were similar to those of Devi R who compared the efficacy of levobupivacaine and bupivacaine in SA in 100 cases of endourology. They observed that time to onset of sensory blockade upto T10 level was significantly longer in levobupivacaine group as compared to bupivacaine group as was the mean time to reach maximal motor blockade [9]. In another study, isobaric levobupivacaine was compared with hyperbaric bupivacaine in 60 patients undergoing lower abdominal surgeries under SA. Onset of sensory block was significantly faster in bupivacaine group (6.00±1.05 min) compared to levobupivacaine group (9.17±1.01 min). Onset of motor block also was earlier in bupivacaine group (6.73±1.23 min versus 8.8±1.45 min). These findings were similar to the observations in the present study [10]. Singh A et al., who compared SA with levobupivacaine and hyperbaric bupivacaine combined with fentanyl in 60 full term parturients, posted for elective caesarean section also reported a delayed onset of motor block with levobupivacaine. However, a faster onset of sensory block with levobupivacaine and fentanyl combination was observed [11]. Thakore S et al., found that time taken to attain highest level of sensory block and onset of motor block was significantly delayed with levobupivacaine, as compared to bupivacaine [13].

In the present study, HR, SBP, DBP and MAP, in the bupivacaine group was significantly lower than levobupivacaine group, at five-minute intervals, upto 45 minutes after SA. Though the values of SBP, DBP and MAP were significantly lower with bupivacaine, none of the patients experienced hypotension. In fact, haemodynamic parameters in Group L varied by <10% from baseline after SA. Thus, levobupivacaine demonstrated a better haemodynamic profile compared to bupivacaine. Earlier studies observed significant incidence of hypotension and bradycardia with bupivacaine [5,9,11].

The total duration of analgesia was longer in the bupivacaine group compared to the levobupivacaine group, in the present study. Though fentanyl was used as an adjuvant in both the groups, it did not create a significant difference clinically, in the duration of analgesia between them. However, addition of fentanyl to levobupivacaine would have increased the duration of analgesia, since the pain free period in the levobupivacaine group was clinically only 10 minutes shorter than the bupivacaine group. Kalepalli K reported that the time for first rescue analgesic requirement was earlier in the levobupivacaine group [5] and Metta R et al., also found that the duration of analgesia was significantly longer in bupivacaine group [10]. Singh A et al., observed that the duration of anaesthesia was significantly shorter with levobupivacaine [11]. In another study by Thakore S et al., 90 patients, scheduled to undergo elective medical termination of pregnancy and sterilisation, under SA, were divided into two groups. Group L received 1.5 mL (7.5 mg) isobaric levobupivacaine 0.5% with 1 mL of 5% dextrose and fentanyl 25 µg. Group B received 1.5 mL (7.5 mg) hyperbaric bupivacaine 0.5% with 1 mL of normal saline and fentanyl 25 µg. Total duration of analgesia was prolonged in Group L compared with Group B [13]. This was in contrast to the observations of the present study, possibly attributable to the fact that isobaric levobupivacaine was converted to hyperbaric by adding 1 mL 5% dextrose, thus, increasing its potency.

In the present study, the total duration of motor block was similar in both the groups. Thus, a combination of intrathecal levobupivacaine and fentanyl created similar intraoperative conditions and postoperative pain relief, as compared to intrathecal bupivacaine and fentanyl but without significant haemodynamic alterations intraoperatively. Previous studies have reported a shorter two segment regression time and recovery of sensory blockade with levobupivacaine [9] and a longer duration of motor blockade with bupivacaine [10]. Kalepalli K observed that two segment regression time and complete regression of motor block was significantly faster with levobupivacaine, similar to the present study [5]. Thakore S et al., observed that the total duration of sensory block was prolonged with levobupivacaine compared to bupivacaine. Time to two-segment regression of block was delayed with levobupivacaine. These observations were in contrast to the present study. However, duration of motor block was prolonged in bupivacaine group, as reported by Thakore S et al., [13].

Incidence of complications like hypotension did not show any difference between the groups. This was an important observation and probably resulted from the avoidance of head-down tilt in all the patients. Earlier studies reported a high incidence of hypotension and bradycardia in the bupivacaine group [5]. Singh A et al., found the incidence of hypotension to be 32% [11].

Limitation(s)

The present study was conducted on 50 patients, a larger sample size may be more representative of the general population. A power analysis was conducted by the authors and sample size was found to be adequate. All the patients underwent TURP surgery, so the quality of postoperative analgesia with levobupivacaine, in other types of surgery, may be quite different.

CONCLUSION(S)

From the present study, it can be concluded that levobupivacaine provides good intraoperative analgesia and relaxation and a reasonably good duration of postoperative analgesia in combination with intrathecal fentanyl. Haemodynamic parameters varied less than 10% from baseline values and no complications or adverse effects were reported. Thus, levobupivacaine is a safe and efficacious alternative to racemic bupivacaine for elderly patients undergoing TURP under SA. Further studies including other types of surgical procedures and larger sample size can be conducted in elderly patients using this combination, to assess its efficacy.

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PARTICULARS OF CONTRIBUTORS:
1. Assistant Professor, Department of Cardiac Anaesthesia, Pt. BD Sharma, PGIMS, Rohtak, Haryana, India.
2. Postgraduate Student, Department of Anaesthesiology and Critical Care, Pt. BD Sharma, PGIMS, Rohtak, Haryana, India.
3. Professor, Department of Urology, Pt. BD Sharma, PGIMS, Rohtak, Haryana, India.
4. Senior Professor and Head, Department of Anaesthesiology and Critical Care, Pt. BD Sharma, PGIMS, Rohtak, Haryana, India.
5. Assistant Professor, Department of Anaesthesiology and Critical Care, Pt. BD Sharma, PGIMS, Rohtak, Haryana, India.
6. Assistant Professor, Department of Anaesthesiology and Critical Care, Pt. BD Sharma, PGIMS, Rohtak, Haryana, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Indira Malik,
608, First Floor, Omaxe City, Rohtak, Haryana, India.
E-mail: mdr.indira@yahoo.in

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