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Hemodynamic Stability, Analgesic Efficacy, and Adverse Effect Profile of Intrathecal Dexmedetomidine versus Fentanyl Combined with Isobaric Levobupivacaine in Patients Undergoing Urological Surgery - A Randomized study.

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Abstract

Background: Intrathecal adjuvants are used with local anaesthetics to improve spinal block quality and prolong postoperative analgesia. Dexmedetomidine provides analgesic, sedative, and sympatholytic effects, whereas fentanyl enhances spinal analgesia with relatively limited prolongation of motor blockade. Their comparative efficacy and haemodynamic effects when combined with isobaric levobupivacaine in urological surgery require evaluation. Aim: To compare the haemodynamic stability, analgesic efficacy, block characteristics, sedation, and adverse-effect profile of intrathecal dexmedetomidine versus fentanyl combined with isobaric levobupivacaine in patients undergoing elective urological surgery. ***Materials and Methods***: This prospective, randomized, double-blinded comparative study included 70 ASA Physical Status I–II patients aged 20–70 years undergoing elective urological surgery under spinal anaesthesia. Patients were randomized into two groups of 35 each. Group LD received 12.5 mg of 0.5% isobaric levobupivacaine with dexmedetomidine 5 µg, whereas Group LF received 12.5 mg of 0.5% isobaric levobupivacaine with fentanyl 25 µg. Haemodynamic parameters, sensory and motor block characteristics, visual analogue scale scores, time to first rescue analgesic, sedation, and adverse effects were recorded. Continuous variables were compared using the independent-samples t-test, while categorical variables were analysed using the chi-square or Fisher's exact test. A p value below 0.05 was considered statistically significant. ***Results***: The onset of sensory blockade at T12 was significantly faster in Group LD than in Group LF (1.54±0.51 versus 2.51±0.51 minutes; p<0.001). Sensory block duration was significantly longer with dexmedetomidine (258.29±15.81 versus 169.71±6.41 minutes; mean difference 88.58 minutes; p<0.001). Motor block duration was also longer in Group LD (204.86±11.47 versus 132.57±5.99 minutes; mean difference 72.29 minutes; p<0.001). Time to first rescue analgesia was prolonged in Group LD (236.57±16.17 versus 147.86±5.98 minutes; mean difference 88.71 minutes; p<0.001), and the VAS score at three hours was lower (0.23±0.55 versus 0.71±0.79; p=0.005). Group LD demonstrated significantly lower heart rate and arterial blood pressures during several perioperative intervals. Hypotension and bradycardia were numerically more frequent with dexmedetomidine but did not differ significantly. Drowsiness was significantly more frequent in Group LD than Group LF (28.6% versus 2.9%; OR=13.60, 95% CI: 1.63–113.25; p=0.006). No patient developed oxygen desaturation or respiratory depression. ***Conclusion***: Intrathecal dexmedetomidine combined with isobaric levobupivacaine produced faster onset, longer sensory and motor blockade, and superior postoperative analgesia compared with fentanyl. These benefits were accompanied by greater transient haemodynamic reduction and increased sedation. Dexmedetomidine is therefore advantageous when prolonged analgesia is required, whereas fentanyl may be preferable when early motor recovery and minimal sedation are desired.

Keywords: Dexmedetomidine; Fentanyl; Isobaric levobupivacaine.

INTRODUCTION

Spinal anaesthesia is widely used for urological procedures because it provides reliable sensory and motor blockade, allows the patient to remain conscious, reduces airway manipulation, and facilitates early postoperative recovery. However, conventional long-acting local anaesthetics may cause clinically important hypotension, bradycardia, prolonged motor blockade, and systemic toxicity, particularly in elderly patients and those with associated comorbidities. Levobupivacaine, the pure S(–)-enantiomer of bupivacaine, has a lower potential for cardiovascular and central nervous system toxicity than

racemic bupivacaine while providing comparable spinal anaesthesia [1]. Its relatively favourable safety profile makes isobaric levobupivacaine an appropriate local anaesthetic for patients undergoing urological surgery. Nevertheless, when used alone, its duration of postoperative analgesia may be inadequate. Intrathecal adjuvants are therefore added to improve block quality, prolong analgesia, and reduce the dose requirement of the local anaesthetic. Fentanyl is a highly lipophilic μ-opioid receptor agonist that acts predominantly at spinal opioid receptors. When administered intrathecally with levobupivacaine, fentanyl hastens sensory block onset and improves intraoperative and postoperative analgesia without substantially prolonging motor recovery [2]. It may, however, produce adverse effects such as pruritus, nausea, vomiting, urinary retention, sedation, and respiratory depression. Dexmedetomidine is a highly selective α_2-adrenergic receptor agonist with analgesic, sedative, and sympatholytic properties. Its intrathecal action is attributed to inhibition of nociceptive neurotransmitter release in the dorsal horn and hyperpolarisation of postsynaptic neurons. Dexmedetomidine added to spinal local anaesthetics has been shown to prolong sensory and motor blockade, delay the requirement for rescue analgesia, and improve the quality of perioperative analgesia [3]. Comparative studies have demonstrated that intrathecal dexmedetomidine 5 μg generally provides longer sensory blockade, motor blockade, and postoperative analgesia than fentanyl 25 μg [4,5]. Nevertheless, its sympatholytic action may increase the likelihood of bradycardia and hypotension. Thus, selection of an intrathecal adjuvant involves a balance between prolonged analgesia and motor blockade on one hand and haemodynamic stability, early mobilisation, and adverse effects on the other. Direct comparison of these adjuvants with identical doses of isobaric levobupivacaine is particularly relevant in urological surgery, where patients are frequently older and haemodynamic stability is clinically important.

AIM

To compare the haemodynamic stability, analgesic efficacy, block characteristics, and adverse-effect profile of intrathecal dexmedetomidine versus fentanyl combined with isobaric levobupivacaine in patients undergoing elective urological surgery.

OBJECTIVES

1. To compare perioperative haemodynamic parameters—heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure—between the LD and LF groups.
2. To compare the onset, maximum level and duration of sensory blockade, onset and duration of motor blockade, two-segment sensory regression time, postoperative pain scores, and time to first rescue analgesic.
3. To compare sedation and the incidence of adverse effects, including hypotension, bradycardia, nausea, vomiting, pruritus, shivering, oxygen desaturation, and respiratory depression.

MATERIALS AND METHODS

Source of Data

The study data were obtained from adult patients admitted for elective urological surgery under spinal anaesthesia at Vivekananda Polyclinic and Institute of Medical Sciences, Lucknow, Uttar Pradesh. Patients were enrolled after pre-anaesthetic evaluation, confirmation of eligibility, and receipt of written informed consent. Information was collected from patient interviews, clinical examinations, anaesthesia records, monitoring charts, investigation reports, and postoperative follow-up assessments.

Study Design

This was a hospital-based, prospective, randomized, parallel-group, double-blinded comparative study. The enrolled patients were allocated in a 1:1 ratio to receive either intrathecal isobaric levobupivacaine with dexmedetomidine or isobaric levobupivacaine with fentanyl.

The study medication was prepared by an anaesthesiologist who did not participate in patient management or outcome assessment. The anaesthesiologist administering spinal anaesthesia and assessing the block remained unaware of group allocation.

Study Location

The study was conducted in the operation theatre complex and postoperative recovery area of Vivekananda Polyclinic and Institute of Medical Sciences, Lucknow, Uttar Pradesh, after approval from the Institutional Ethics Committee.

Study Duration

The study was conducted over 12 months, from 1 June 2015 to 31 May 2016.

Sample Size

A total of 70 patients were enrolled and randomized into two equal groups:

- **Group LD (n=35):** Patients received 12.5 mg of 0.5% isobaric levobupivacaine (2.5 mL) with dexmedetomidine 5 µg diluted with preservative-free normal saline to 0.5 mL. The total intrathecal volume was 3.0 mL.
- **Group LF (n=35):** Patients received 12.5 mg of 0.5% isobaric levobupivacaine (2.5 mL) with fentanyl 25 µg (0.5 mL). The total intrathecal volume was 3.0 mL.

The sample size was based on an anticipated difference in the duration of sensory blockade between dexmedetomidine and fentanyl groups, with 80% statistical power and a two-sided significance level of 5%. The sample size was calculated using the formula for comparing two independent means:
After allowing for possible exclusions or incomplete observations, the final sample was fixed at 35 patients per group.

Sampling and Randomization
Eligible patients were recruited consecutively until the required sample size was achieved. They were allocated to either Group LD or Group LF using a computer-generated random-number sequence. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes that were opened by the anaesthesiologist responsible for preparing the study solution.

Inclusion Criteria
- Patients aged 20–70 years.
- Patients of either sex.
- American Society of Anesthesiologists Physical Status grade I or II.
- Patients scheduled for elective urological surgery under spinal anaesthesia.
- Patients weighing between 30 and 80 kg.
- Patients who provided written informed consent.

Exclusion Criteria
- Age below 20 years or above 70 years.
- ASA Physical Status grade III or IV.
- Body weight below 30 kg or above 80 kg.
- Body mass index greater than 35 kg/m².
- Height below 150 cm or above 185 cm.
- Severe cardiovascular or cerebrovascular disease.
- Uncontrolled diabetes mellitus or chronic renal failure.
- Coagulopathy, local infection at the injection site, severe hypovolaemia, raised intracranial pressure, or another contraindication to spinal anaesthesia.
- Known allergy to amide-type local anaesthetics, dexmedetomidine, fentanyl, or other study medications.
- Pre-existing neurological or spinal disorders likely to interfere with block assessment.
- Long-term opioid or analgesic treatment.
- Inability to understand the visual analogue scale.
- Uncooperative patients or patients who refused participation.

Pre-anaesthetic Assessment
A detailed history and complete physical examination were performed. Routine investigations included haemoglobin, blood grouping, blood glucose, blood urea, serum creatinine, and coagulation profile. Electrocardiography and other investigations were performed when clinically indicated.
Baseline heart rate, respiratory rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation were recorded. The spinal anaesthesia procedure and visual analogue scale were explained to each patient. Patients were kept fasting for at least eight hours before surgery.

Procedure and Methodology
On arrival in the operation theatre, standard monitoring—including continuous electrocardiography, pulse oximetry, and non-invasive blood pressure monitoring—was initiated. Three readings were recorded, and their average was considered the baseline value. An intravenous line was secured using an appropriately sized cannula. Patients were preloaded with an appropriate crystalloid solution at 10 mL/kg over approximately 20 minutes.
With the patient in the sitting position and under strict aseptic precautions, lumbar puncture was performed at the L3–L4 intervertebral space using a 25-gauge Quincke spinal needle. After confirmation of free flow of clear cerebrospinal fluid, the assigned 3-mL study solution was administered intrathecally at approximately 1 mL every three seconds. The operating table was kept horizontal, and the patient was immediately positioned supine.

Haemodynamic and Respiratory Monitoring

Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, respiratory rate, and oxygen saturation were recorded at baseline and at 2, 5, 10, 15, 20, 25, 30, 40, 50, 60, 90, 120, 150, 180, 240, 300, and 360 minutes after intrathecal injection.

Hypotension was defined as a reduction in systolic blood pressure of more than 20% from baseline or an absolute systolic blood pressure below 90 mmHg. It was treated by increasing intravenous fluid administration and, when required, intravenous mephentermine in 6-mg incremental doses.

Bradycardia was defined as a heart rate below 50 beats/minute and was treated with intravenous atropine 0.6 mg.
Respiratory depression was defined as a respiratory rate below 10 breaths/minute or oxygen saturation below 94% and was managed with airway support, supplemental oxygen, and other appropriate treatment.

Assessment of Sensory Blockade

Sensory blockade was evaluated bilaterally using the pinprick method with a 22-gauge hypodermic needle. Assessment was performed every two minutes until the sensory level stabilised across four consecutive examinations.

- **Onset of sensory blockade:** Time from completion of intrathecal injection to attainment of a T12 sensory level or the dermatomal level required for surgery.
- **Maximum sensory level:** Highest dermatome at which loss of pinprick sensation was observed.
- **Time to maximum sensory level:** Time from completion of injection to attainment of the highest sensory level.
- **Two-segment regression time:** Time from maximum sensory level to regression by two dermatomal segments.
- **Duration of sensory blockade:** Time from intrathecal injection until regression of sensory block to the S1 dermatome.

Assessment of Motor Blockade

Motor blockade was assessed using the Modified Bromage Scale:

- Grade 0: No motor paralysis.
- Grade 1: Unable to raise the extended leg.
- Grade 2: Unable to flex the knee.
- Grade 3: Unable to flex the ankle.

The onset of motor blockade was defined as the interval between completion of intrathecal injection and attainment of Bromage grade 1. Time to maximum motor block and the highest Bromage grade attained were recorded. Duration of motor blockade was measured from intrathecal injection until complete motor recovery to Bromage grade 0.

Assessment of Postoperative Analgesia

Postoperative pain was assessed using a 10-cm visual analogue scale, where 0 represented “no pain” and 10 represented “worst imaginable pain.” Pain was assessed at predetermined intervals for six hours following spinal injection.
Duration of analgesia was defined as the period from completion of intrathecal injection to the first request for rescue analgesia. Intramuscular diclofenac 75 mg was administered when the VAS score exceeded 5 or when the patient requested analgesia. The time of administration was recorded.

Sedation Assessment

Sedation was evaluated using the Modified Wilson Sedation Scale:

1. Oriented and responsive to verbal questioning.
2. Drowsy but arousable to verbal command.
3. Arousable only to mild physical stimulation.
4. Unarousable to mild physical stimulation.

Adverse-Effect Assessment

Patients were observed for hypotension, bradycardia, nausea, vomiting, pruritus, shivering, excessive sedation, oxygen desaturation, respiratory depression, post-dural puncture headache, and other complications. All adverse events, their timing, severity, and treatment were documented. Patients were followed for 24 hours after surgery.

Sample Processing

No blood, urine, tissue, or other biological specimen was collected specifically for the study; therefore, laboratory sample processing was not applicable. Routine preoperative investigations were performed and processed by the institutional laboratory according to standard hospital procedures. The principal study measurements were clinical observations and monitor-derived haemodynamic data.

Data Collection

A predesigned case-record form was used to record demographic characteristics, ASA grade, anthropometric measurements, type and duration of surgery, baseline clinical variables, study-group allocation, sensory and motor block characteristics, haemodynamic measurements, respiratory parameters, VAS scores, sedation scores, time to rescue analgesia, adverse events, interventions, and postoperative complications.

Data were recorded prospectively by an observer blinded to group allocation. Completed forms were checked for completeness and internal consistency. Each participant was assigned a unique identification number, and personally identifying information was kept confidential.

Statistical Methods

Data were entered into a spreadsheet, validated, coded, and analysed using SPSS for Windows. Continuous variables were summarised as mean and standard deviation when normally distributed and as median and interquartile range when distributions were skewed. Categorical variables were presented as frequencies and percentages.

Baseline continuous variables and block-duration outcomes were compared using the independent-samples Student's t-test or Mann–Whitney U test, as appropriate. Categorical variables, including adverse events, were compared using the chi-square test or Fisher's exact test when expected cell frequencies were small. Ordinal outcomes such as sedation and Bromage scores were analysed using appropriate non-parametric tests.

Serial haemodynamic measurements were compared using repeated-measures analysis of variance or a linear mixed-effects model, with study group, time, and group-by-time interaction included in the analysis. Within-group changes from baseline were assessed using paired comparisons with correction for multiple testing where applicable.

Effect estimates were reported with 95% confidence intervals. All statistical tests were two-sided, and a p value below 0.05 was considered statistically significant.

RESULTS

Table 1: Overall comparison of haemodynamic stability, analgesic efficacy, block characteristics, and adverse-effect profile

Outcome	Group LD (n=35), Mean (SD) or n (%)	Group LF (n=35), Mean (SD) or n (%)	Effect estimate (95% CI)	Test of significance	P value
Heart rate at 60 min, beats/min	65.11 (5.08)	70.74 (4.60)	MD −5.63 (−7.94 to −3.32)	t=−4.86	<0.001*
Systolic BP at 60 min, mmHg	113.89 (4.52)	125.37 (9.63)	MD −11.48 (−15.09 to −7.87)	t=−6.38	<0.001*
Diastolic BP at 60 min, mmHg	66.69 (6.06)	72.74 (7.99)	MD −6.05 (−9.44 to −2.66)	t=−3.57	0.001*
Mean arterial pressure at 60 min, mmHg	82.42 (5.19)	90.29 (8.22)	MD −7.87 (−11.16 to −4.58)	t=−4.79	<0.001*
Onset of sensory block to T12, min	1.54 (0.51)	2.51 (0.51)	MD −0.97 (−1.21 to −0.73)	t=−7.96	<0.001*
Duration of sensory block, min	258.29 (15.81)	169.71 (6.41)	MD 88.58 (82.77 to 94.39)	t=30.72	<0.001*
Duration of motor block, min	204.86 (11.47)	132.57 (5.99)	MD 72.29 (67.90 to 76.68)	t=33.05	<0.001*
Time to first rescue analgesic, min	236.57 (16.17)	147.86 (5.98)	MD 88.71 (82.83 to 94.59)	t=30.44	<0.001*
VAS score at 3 hours	0.23 (0.55)	0.71 (0.79)	MD −0.48 (−0.81 to −0.15)	t=−2.95	0.005*
Hypotension	4 (11.4%)	2 (5.7%)	OR 2.13 (0.36–12.46)	Fisher's exact test	0.673
Bradycardia	2 (5.7%)	1 (2.9%)	OR 2.06 (0.18–23.83)	Fisher's exact test	1.000
Drowsiness/sedation	10 (28.6%)	1 (2.9%)	OR 13.60 (1.63–113.25)	Fisher's exact test	0.006*

Table 1 presents the overall comparison of haemodynamic stability, block characteristics, analgesic efficacy, and adverse effects between the LD and LF groups. At 60 minutes, Group LD had significantly lower mean heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure than Group LF. The corresponding mean differences were

−5.63 beats/min, −11.48 mmHg, −6.05 mmHg, and −7.87 mmHg, respectively, and all differences were statistically significant (p≤0.001). Sensory blockade developed significantly faster in Group LD, with the T12 level attained approximately 0.97 minutes earlier than in Group LF (p<0.001). Group LD also demonstrated markedly longer sensory and motor blockade, with mean differences of 88.58 and 72.29 minutes, respectively (both p<0.001). The mean time to first rescue analgesia was prolonged by 88.71 minutes in Group LD (p<0.001), while the mean VAS score at three hours was 0.48 points lower (p=0.005), indicating superior postoperative analgesia. Hypotension and bradycardia were numerically more frequent in Group LD, but the differences were not statistically significant. Drowsiness or sedation occurred in 28.6% of Group LD compared with 2.9% of Group LF; patients receiving dexmedetomidine had 13.60 times higher odds of sedation (95% CI: 1.63–113.25; p=0.006).

Table 2: Comparison of perioperative haemodynamic parameters

Parameter/time	Group LD Mean (SD)	Group LF Mean (SD)	MD: LD−LF (95% CI)	t value	P value
Heart rate, beats/min					
Baseline	75.20 (5.14)	73.09 (4.48)	2.11 (−0.19 to 4.41)	1.83	0.072
30 min	66.23 (5.02)	66.74 (5.78)	−0.51 (−3.09 to 2.07)	−0.39	0.695
60 min	65.11 (5.08)	70.74 (4.60)	−5.63 (−7.94 to −3.32)	−4.86	<0.001*
90 min	66.37 (4.92)	71.77 (3.96)	−5.40 (−7.53 to −3.27)	−5.06	<0.001*
120 min	68.83 (5.12)	73.49 (4.07)	−4.66 (−6.87 to −2.45)	−4.22	<0.001*
180 min	71.69 (5.17)	77.94 (3.90)	−6.25 (−8.44 to −4.06)	−5.71	<0.001*
240 min	74.09 (5.35)	76.00 (4.20)	−1.91 (−4.21 to 0.39)	−1.66	0.102
360 min	75.60 (5.08)	79.89 (4.17)	−4.29 (−6.51 to −2.07)	−3.86	<0.001*
Systolic blood pressure, mmHg					
Baseline	129.89 (7.90)	132.46 (11.29)	−2.57 (−7.23 to 2.09)	−1.10	0.274
30 min	110.06 (5.14)	119.66 (10.45)	−9.60 (−13.55 to −5.65)	−4.88	<0.001*
60 min	113.89 (4.52)	125.37 (9.63)	−11.48 (−15.09 to −7.87)	−6.38	<0.001*
90 min	115.89 (5.57)	127.89 (9.50)	−12.00 (−15.73 to −8.27)	−6.45	<0.001*
120 min	119.09 (6.27)	130.34 (9.49)	−11.25 (−15.10 to −7.40)	−5.85	<0.001*
180 min	125.26 (6.65)	133.66 (9.09)	−8.40 (−12.21 to −4.59)	−4.41	<0.001*
240 min	130.69 (8.26)	134.00 (8.80)	−3.31 (−7.38 to 0.76)	−1.62	0.109
360 min	129.14 (6.67)	133.03 (9.89)	−3.89 (−7.92 to 0.14)	−1.93	0.058
Diastolic blood pressure, mmHg					
Baseline	76.86 (7.96)	77.54 (9.38)	−0.68 (−4.83 to 3.47)	−0.33	0.745
30 min	64.97 (4.76)	68.86 (7.72)	−3.89 (−6.96 to −0.82)	−2.54	0.014*
60 min	66.69 (6.06)	72.74 (7.99)	−6.05 (−9.44 to −2.66)	−3.57	0.001*
90 min	68.74 (4.50)	74.17 (8.32)	−5.43 (−8.64 to −2.22)	−3.40	0.001*
120 min	71.31 (5.27)	75.94 (8.37)	−4.63 (−7.98 to −1.28)	−2.77	0.008*
180 min	74.74 (6.46)	79.31 (7.55)	−4.57 (−7.92 to −1.22)	−2.72	0.008*
240 min	77.31 (7.18)	79.31 (7.82)	−2.00 (−5.58 to 1.58)	−1.11	0.269
360 min	78.51 (7.33)	77.71 (7.91)	0.80 (−2.84 to 4.44)	0.44	0.662

Mean arterial pressure, mmHg					
Baseline	94.53 (7.82)	95.85 (9.87)	−1.32 (−5.57 to 2.93)	−0.62	0.537
30 min	80.00 (4.55)	85.79 (8.37)	−5.79 (−9.02 to −2.56)	−3.60	0.001*
60 min	82.42 (5.19)	90.29 (8.22)	−7.87 (−11.16 to −4.58)	−4.79	<0.001*
90 min	84.46 (4.42)	92.08 (8.38)	−7.62 (−10.83 to −4.41)	−4.76	<0.001*
120 min	87.24 (5.30)	94.08 (8.44)	−6.84 (−10.21 to −3.47)	−4.06	<0.001*
180 min	91.58 (6.14)	97.43 (7.68)	−5.85 (−9.17 to −2.53)	−3.52	0.001*
240 min	95.10 (7.08)	97.54 (7.76)	−2.44 (−5.98 to 1.10)	−1.37	0.174
360 min	95.39 (6.69)	96.15 (8.17)	−0.76 (−4.32 to 2.80)	−0.43	0.672

Table 2 compares serial perioperative haemodynamic parameters between the two groups. Baseline heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were comparable, indicating haemodynamic similarity before spinal anaesthesia. Heart rate did not differ significantly at 30 minutes, but it was significantly lower in Group LD at 60, 90, 120, and 180 minutes, with mean differences ranging from −4.66 to −6.25 beats/min (all $p<0.001$). The difference became non-significant at 240 minutes but was again significant at 360 minutes. Systolic blood pressure was significantly lower in Group LD from 30 to 180 minutes, with the largest difference observed at 90 minutes (MD −12.00 mmHg; 95% CI: −15.73 to −8.27; $p<0.001$). By 240 and 360 minutes, systolic blood pressure had recovered, and the between-group differences were no longer significant. Diastolic blood pressure was similarly lower in Group LD from 30 to 180 minutes, with mean differences ranging from −3.89 to −6.05 mmHg ($p=0.014$ to 0.001). No significant difference was detected at 240 or 360 minutes. Mean arterial pressure was significantly lower in Group LD between 30 and 180 minutes, with the greatest reduction at 60 minutes (MD −7.87 mmHg; $p<0.001$); thereafter, the values became comparable.

Table 3: Comparison of sensory block, motor block and postoperative analgesic efficacy

Block/analgesic parameter	**Group LD Mean (SD) or n (%)**	**Group LF Mean (SD) or n (%)**	**Effect estimate (95% CI)**	**Test of significance**	**P value**
Onset of sensory block to T12, min	1.54 (0.51)	2.51 (0.51)	MD −0.97 (−1.21 to −0.73)	t=−7.96	<0.001*
Time to sensory block at T10, min	5.51 (0.95)	6.80 (0.87)	MD −1.29 (−1.72 to −0.86)	t=−5.92	<0.001*
Maximum sensory level T6	15 (42.9%)	24 (68.6%)	—	χ^2=4.69	0.030*
Maximum sensory level T8	20 (57.1%)	11 (31.4%)	OR 2.91 (1.09–7.74)	χ^2=4.69	0.030*
Time to highest sensory level, min	11.17 (1.40)	13.09 (1.25)	MD −1.92 (−2.55 to −1.29)	t=−6.05	<0.001*
Two-segment sensory regression, min	116.14 (9.08)	72.86 (3.89)	MD 43.28 (39.92 to 46.64)	t=25.92	<0.001*
Regression of sensory block to S1, min	258.29 (15.81)	169.71 (6.41)	MD 88.58 (82.77 to 94.39)	t=30.72	<0.001*
Onset of motor block, min	2.91 (0.89)	4.11 (0.68)	MD −1.20 (−1.58 to −0.82)	t=−6.34	<0.001*
Time to maximum motor block, min	12.83 (1.77)	10.91 (0.82)	MD 1.92 (1.26 to 2.58)	t=5.82	<0.001*
Maximum Modified Bromage score	2.43 (0.50)	2.69 (0.47)	MD −0.26 (−0.49 to −0.03)	t=−2.24	0.028*
Regression of motor block to Bromage 0, min	204.86 (11.47)	132.57 (5.99)	MD 72.29 (67.90 to 76.68)	t=33.05	<0.001*
Time to first rescue analgesic, min	236.57 (16.17)	147.86 (5.98)	MD 88.71 (82.83 to 94.59)	t=30.44	<0.001*
VAS at 1 hour	0.00 (0.00)	0.00 (0.00)	MD 0.00	Not applicable	—
VAS at 2 hours	0.00 (0.00)	0.09 (0.28)	MD −0.09 (−0.19 to 0.01)	t=−1.90	0.066

VAS at 3 hours	0.23 (0.55)	0.71 (0.79)	MD −0.48 (−0.81 to −0.15)	t=−2.95	0.005*
VAS at 4 hours	2.97 (0.66)	3.37 (0.55)	MD −0.40 (−0.69 to −0.11)	t=−2.75	0.008*
VAS at 5 hours	3.89 (0.47)	4.17 (0.71)	MD −0.28 (−0.57 to 0.01)	t=−1.95	0.056
VAS at 6 hours	4.11 (0.63)	4.37 (0.55)	MD −0.26 (−0.54 to 0.02)	t=−1.84	0.070

Table 3 demonstrates significant differences in sensory block, motor block, and postoperative analgesic characteristics. Group LD achieved sensory blockade at T12 and T10 significantly faster than Group LF, with mean differences of −0.97 and −1.29 minutes, respectively (both p<0.001). The distribution of the maximum sensory level also differed significantly: T8 blockade was more common in Group LD, whereas T6 blockade was more frequent in Group LF (p=0.030). The odds of attaining T8 rather than T6 were 2.91 times higher in Group LD. The maximum sensory level was attained 1.92 minutes earlier with dexmedetomidine (p<0.001). However, two-segment regression and complete sensory regression to S1 were prolonged by 43.28 and 88.58 minutes, respectively, in Group LD (both p<0.001).

Motor blockade began 1.20 minutes earlier in Group LD (p<0.001), although the time to maximum motor blockade was 1.92 minutes longer (p<0.001). Group LF had a marginally higher mean maximum Bromage score (2.69 versus 2.43; p=0.028). Despite this, complete motor recovery was substantially delayed in Group LD, with motor blockade lasting approximately 72.29 minutes longer (p<0.001). The time to first rescue analgesia was also prolonged by 88.71 minutes in Group LD (p<0.001). VAS scores were identical at one hour and did not differ significantly at two hours. Group LD reported significantly lower pain scores at three and four hours, with mean differences of −0.48 and −0.40 points, respectively. Although VAS scores remained numerically lower in Group LD at five and six hours, these differences were not statistically significant.

Table 4: Comparison of sedation and adverse-effect profile

Adverse effect	**Group LD (n=35), n (%)**	**Group LF (n=35), n (%)**	**Odds ratio: LD vs LF (95% CI)**	**Test of significance**	**P value**
Hypotension	4 (11.4%)	2 (5.7%)	2.13 (0.36–12.46)	Fisher's exact test	0.673
Bradycardia	2 (5.7%)	1 (2.9%)	2.06 (0.18–23.83)	Fisher's exact test	1.000
Nausea	1 (2.9%)	0 (0.0%)	3.09 (0.12–78.41)†	Fisher's exact test	1.000
Vomiting	1 (2.9%)	0 (0.0%)	3.09 (0.12–78.41)†	Fisher's exact test	1.000
Pruritus	0 (0.0%)	1 (2.9%)	0.32 (0.01–8.23)†	Fisher's exact test	1.000
Shivering	2 (5.7%)	1 (2.9%)	2.06 (0.18–23.83)	Fisher's exact test	1.000
Oxygen desaturation	0 (0.0%)	0 (0.0%)	Not estimable	Not applicable	—
Respiratory depression	0 (0.0%)	0 (0.0%)	Not estimable	Not applicable	—
Post-dural puncture headache	0 (0.0%)	0 (0.0%)	Not estimable	Not applicable	—
Oriented/no sedation	25 (71.4%)	34 (97.1%)	Reference category	—	—
Drowsiness/sedation	10 (28.6%)	1 (2.9%)	13.60 (1.63–113.25)	Fisher's exact test	0.006*

Abbreviations: LD, levobupivacaine–dexmedetomidine; LF, levobupivacaine–fentanyl; MD, mean difference; OR, odds ratio; BP, blood pressure; MAP, mean arterial pressure; VAS, visual analogue scale; SD, standard deviation; CI, confidence interval.

*Statistically significant at p<0.05.

Table 4 compares sedation and the incidence of adverse effects. Hypotension occurred in 11.4% of patients in Group LD and 5.7% in Group LF, while bradycardia occurred in 5.7% and 2.9%, respectively. Although both events were numerically more frequent with dexmedetomidine, neither difference was statistically significant. Nausea and vomiting were each reported in one patient in Group LD and none in Group LF, whereas pruritus occurred in one patient in Group LF and none in Group LD. Shivering occurred in two patients in Group LD and one patient in Group LF. None of these differences reached statistical significance, and the wide confidence intervals reflected the small number of events. No patient in either group developed oxygen desaturation, respiratory depression, or post-dural puncture headache. Most patients remained

oriented, although this proportion was lower in Group LD than in Group LF (71.4% versus 97.1%). Drowsiness or sedation was significantly more frequent in Group LD, occurring in 28.6% compared with 2.9% in Group LF. The odds of sedation were 13.60 times higher with dexmedetomidine (95% CI: 1.63–113.25; p=0.006).

DISCUSSION

The present randomized study compared intrathecal dexmedetomidine 5 µg and fentanyl 25 µg as adjuvants to 12.5 mg isobaric levobupivacaine in patients undergoing urological surgery. The principal findings were that dexmedetomidine produced an earlier onset and substantially longer duration of sensory and motor blockade, prolonged postoperative analgesia, and lower early postoperative VAS scores. These benefits were accompanied by a greater reduction in heart rate and blood pressure and a significantly higher incidence of drowsiness, although clinically defined hypotension, bradycardia, respiratory depression, and other adverse effects were not significantly increased.

Haemodynamic stability

Baseline haemodynamic parameters were comparable between the groups, suggesting that subsequent differences were primarily attributable to the intrathecal adjuvant. From 60 to 180 minutes, heart rate was significantly lower in Group LD. Systolic, diastolic, and mean arterial pressures were also significantly lower, particularly between 30 and 180 minutes. At 60 minutes, the mean differences in heart rate, systolic pressure, diastolic pressure, and MAP were −5.63 beats/min, −11.48 mmHg, −6.05 mmHg, and −7.87 mmHg, respectively. These findings are pharmacologically plausible because dexmedetomidine activates central and spinal α_2-adrenergic receptors, suppresses sympathetic outflow, and reduces the release of norepinephrine.

Khan et al. (2015)[1] similarly observed lower heart rate and blood pressure following intrathecal dexmedetomidine compared with fentanyl, although the reductions generally remained within clinically manageable limits. Safari et al. (2016)[2] also reported that dexmedetomidine prolonged spinal blockade without producing major haemodynamic instability. Rahimzadeh et al. (2018)[3] found no clinically important difference in hypotension or bradycardia between dexmedetomidine and fentanyl groups despite the longer blockade produced by dexmedetomidine. In contrast, Modir et al. (2024)[4] reported significantly lower MAP with intrathecal dexmedetomidine than with fentanyl or magnesium sulphate, which closely supports the serial MAP findings of the present study.

Khosravi et al. (2020)[5] found no significant between-group differences in serial heart rate, SBP, DBP, or MAP after administering dexmedetomidine 5 µg or fentanyl 25 µg with bupivacaine for caesarean section. Differences from the present findings may be related to the younger obstetric population, different local anaesthetic baricity, intravenous fluid management, vasopressor use, and shorter surgery. Kalbande et al. (2022)[6] likewise found acceptable haemodynamic stability with both adjuvants. Thus, dexmedetomidine may cause a greater numerical reduction in haemodynamic measurements, but this does not necessarily translate into a significantly higher incidence of clinically treated hypotension or bradycardia.

The haemodynamic differences in the present study became non-significant for most blood-pressure measurements by 240–360 minutes, indicating that the sympatholytic effect was predominantly transient. This recovery pattern is clinically important in urological patients, many of whom are elderly and may have reduced cardiovascular reserve. Continuous monitoring and readiness to administer intravenous fluids, vasopressors, or atropine therefore remain necessary.

Sensory block characteristics

Sensory blockade developed significantly faster with dexmedetomidine. The mean time to reach T12 was 1.54 minutes in Group LD compared with 2.51 minutes in Group LF, while the time to reach T10 was 5.51 versus 6.80 minutes. The maximum sensory level was also attained approximately 1.92 minutes earlier in Group LD. Dexmedetomidine may accelerate sensory blockade through presynaptic inhibition of C-fibre neurotransmitter release and postsynaptic hyperpolarisation of dorsal-horn neurons.

Sun et al. (2015)[7] found that adding dexmedetomidine to intrathecal bupivacaine accelerated block onset and enhanced spinal anaesthesia compared with fentanyl or bupivacaine alone. Safari et al. (2016)[2] similarly observed a significantly shorter sensory onset with dexmedetomidine than with fentanyl. Ravipati et al. (2017)[8], using isobaric ropivacaine, reported earlier sensory onset with dexmedetomidine 5 µg than fentanyl, indicating that the effect is not restricted to levobupivacaine. Gautam et al. (2018)[9] also found that dexmedetomidine produced better-quality intrathecal anaesthesia and reduced visceral discomfort during abdominal hysterectomy.

In the present study, two-segment sensory regression was prolonged from 72.86 minutes with fentanyl to 116.14 minutes with dexmedetomidine, a mean difference of 43.28 minutes. Complete sensory regression to S1 was prolonged by 88.58 minutes. Bhure and Jagtap (2019)[10], who directly compared dexmedetomidine and fentanyl with isobaric levobupivacaine, similarly reported prolonged sensory regression with dexmedetomidine. The close correspondence is important because their local anaesthetic and route were similar to those used in the present study.

Gupta et al. (2024)[11] compared both adjuvants with 0.5% hyperbaric levobupivacaine and demonstrated longer sensory and motor blockade with dexmedetomidine. Liu et al. (2020)[12], in a meta-analysis focusing on intrathecal

dexmedetomidine 5 µg, concluded that this dose significantly prolonged sensory and motor blockade when combined with bupivacaine. Kumar et al. (2022)[13] analysed 21 randomized trials involving 1,382 participants and also found substantial prolongation of sensory blockade with intrathecal dexmedetomidine. These pooled findings support the magnitude and direction of the sensory-block effects observed in the present study.

Motor block characteristics

Motor block began significantly earlier in Group LD, with a mean onset of 2.91 minutes compared with 4.11 minutes in Group LF. Complete motor recovery was delayed from 132.57 minutes with fentanyl to 204.86 minutes with dexmedetomidine, corresponding to a mean prolongation of 72.29 minutes. Dexmedetomidine may intensify the action of local anaesthetics on motor neurons in the dorsal and ventral horns and may produce local vasoconstriction, slowing the vascular uptake of levobupivacaine.

Khan et al. (2015)[1] reported significantly prolonged motor blockade with dexmedetomidine compared with fentanyl. Ravipati et al. (2017)[8] and Rahimzadeh et al. (2018)[3] documented comparable findings with ropivacaine and bupivacaine, respectively. Kalbande et al. (2022)[6] also found earlier onset and delayed regression of motor blockade with dexmedetomidine 5 µg. The systematic review by Liu et al. (2020)[12] confirmed that even a 5-µg dose significantly prolonged motor recovery.

Naaz et al. (2016)[14] demonstrated a dose–response relationship between intrathecal dexmedetomidine and the duration of spinal anaesthesia. Higher doses provided longer block duration but were associated with more haemodynamic adverse effects. Although they considered 10 µg an optimal dose in their population, the current results show that 5 µg produced substantial prolongation while limiting clinically significant hypotension and bradycardia. Prolonged motor block may be useful during lengthy procedures but may delay mobilisation and discharge after short-stay urological surgery. Fentanyl may therefore remain preferable when rapid motor recovery is a priority.

Postoperative analgesic efficacy

The time to first rescue analgesia was 236.57 minutes in Group LD compared with 147.86 minutes in Group LF, representing an additional pain-free period of approximately 88.71 minutes. VAS scores were significantly lower with dexmedetomidine at three and four hours. Although scores remained numerically lower at five and six hours, the differences were no longer statistically significant, possibly because rescue analgesia had already been administered to some patients.

Attri et al. (2015)[15] demonstrated that fentanyl improved the onset and duration of spinal anaesthesia when added to levobupivacaine; however, the present findings indicate that dexmedetomidine prolongs analgesia considerably more than fentanyl. Khosravi et al. (2020)[5] reported a mean analgesic duration of 428.64 minutes with dexmedetomidine compared with 273.18 minutes with fentanyl and lower early postoperative pain scores. The absolute durations were longer than in the present study, probably because of differences in surgical population, bupivacaine dose, definition of rescue analgesia, and pain threshold used for treatment.

Paramasivan et al. (2020)[16] concluded from randomized trials that intrathecal dexmedetomidine significantly increased the duration of postoperative analgesia and reduced postoperative pain scores. Shen et al. (2020)[17] similarly reported that intrathecal dexmedetomidine enhanced spinal block and postoperative analgesia during caesarean delivery. The meta-analysis by Kumar et al. (2022)[13] demonstrated a large pooled effect on analgesic duration, while Gupta et al. (2024)[11] confirmed the benefit specifically with levobupivacaine. Collectively, these results suggest that prolonged postoperative analgesia is the most consistent advantage of dexmedetomidine over fentanyl.

Sedation and adverse effects

Clinically defined hypotension occurred in 11.4% of Group LD and 5.7% of Group LF, while bradycardia occurred in 5.7% and 2.9%, respectively. Although the odds ratios were greater than 2, the differences were not statistically significant, and their wide confidence intervals reflected the small number of events. Kumar et al. (2022)[13] similarly found no significant pooled increase in hypotension or bradycardia with intrathecal dexmedetomidine. Khosravi et al. (2020)[5] and Rahimzadeh et al. (2018)[3] also reported comparable incidences between dexmedetomidine and fentanyl groups.

Drowsiness occurred in 28.6% of patients receiving dexmedetomidine compared with 2.9% receiving fentanyl. The odds of sedation were 13.60 times higher in Group LD. This finding reflects the central α_2-agonist effect of dexmedetomidine and agrees with Safari et al. (2016)[2], who observed more appropriate, arousable sedation with dexmedetomidine. Unlike opioid-induced sedation, dexmedetomidine generally causes cooperative sedation with minimal respiratory suppression. Nevertheless, the wide confidence interval for the odds ratio indicates uncertainty regarding the exact magnitude of the association.

Nausea, vomiting, pruritus, and shivering were infrequent and comparable between groups. Pruritus occurred only in the fentanyl group, which is consistent with its neuraxial opioid action, although the number of events was insufficient to establish a significant difference. No oxygen desaturation or respiratory depression occurred. Sun et al. (2020)[18] reported that intrathecal dexmedetomidine prolonged postoperative pain-free duration and reduced shivering without significantly increasing spinal anaesthesia-related adverse effects. Kalbande et al. (2022)[6] also observed no serious respiratory complications with either adjuvant.

CONCLUSION

Intrathecal dexmedetomidine 5 µg combined with 12.5 mg isobaric levobupivacaine provided a faster onset and significantly longer duration of sensory and motor blockade than intrathecal fentanyl 25 µg. Dexmedetomidine also prolonged the time to first rescue analgesia by approximately 89 minutes and produced lower early postoperative pain scores. However, it caused greater transient reductions in heart rate and blood pressure and a significantly higher incidence of drowsiness or sedation. The incidences of clinically significant hypotension, bradycardia, nausea, vomiting, pruritus, shivering, oxygen desaturation, and respiratory depression were otherwise comparable between the groups. Thus, dexmedetomidine may be preferred when prolonged anaesthesia and postoperative analgesia are required, whereas fentanyl may be more suitable for shorter or day-care urological procedures where better haemodynamic stability, less sedation, and earlier motor recovery are priorities. Careful haemodynamic monitoring remains essential when intrathecal dexmedetomidine is used.

Limitations

1. The study was conducted at a single centre with a relatively small sample of 70 patients, limiting the precision and generalizability of the results.
2. Only ASA Physical Status I and II patients aged 20–70 years were included; therefore, the findings may not apply to higher-risk patients, very elderly individuals, or those with major cardiovascular, neurological, renal, or metabolic disorders.
3. Only one dose of dexmedetomidine and one dose of fentanyl were evaluated, preventing assessment of dose–response relationships and determination of the minimum effective dose.
4. The study included different elective urological operations whose duration, surgical stimulation, positioning, and postoperative pain intensity may have varied.
5. Postoperative pain was assessed for only six hours, and adverse events were monitored for 24 hours. Consequently, delayed complications and longer-term analgesic requirements were not evaluated.
6. The study was not sufficiently powered to detect uncommon adverse events such as severe bradycardia, profound hypotension, respiratory depression, neurological injury, or post-dural puncture headache.
7. Sedation and pain scores were subjective observer- and patient-reported outcomes and may have been affected by assessment variability.
8. Serial haemodynamic comparisons were performed at multiple time points, increasing the possibility of type I error unless adjustment for repeated comparisons was applied.
9. Outcomes such as total 24-hour analgesic consumption, time to ambulation, urinary retention, patient satisfaction, discharge readiness, and cost-effectiveness were not assessed.
10. The findings were specific to isobaric levobupivacaine and cannot be directly extrapolated to hyperbaric levobupivacaine, bupivacaine, ropivacaine, or other intrathecal local anaesthetics.

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