A Comparative Study between Intrathecal Dexmedetomidine and Fentanyl as Additives to Bupivacaine in Pott's Fracture Surgery

Original Article

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ABSTRACT

Background: Recently, the popularity of adjuvants in intrathecal anesthesia has grown. Reports suggest that incorporating opioids and other medications can enhance the quality of spinal anesthesia. However, to date, no single drug is completely free of side effects. This study aimed to compare the effects of adding either dexmedetomidine or fentanyl to intrathecal bupivacaine in Pott's fracture. Focusing on differences in the onset and duration of sensory and motor block, hemodynamic impacts, postoperative pain relief, and the adverse effects associated with each drug.

Materials and Methods: Using PASS 15 program for sample size calculation, setting power at 80% and alpha error at 0.05 the expected mean duration of sensory analgesia among study groups are 327, 182, 151min. sample s the study involved sixty patients categorized as ASA class I and II, who were scheduled for Pott's fracture surgery. Patients were randomly assigned to one of three groups, each consisting of 20 individuals: Group B, Group F, and Group D. In Group B, patients received 3ml (15mg) of 0.5% hyperbaric bupivacaine combined with 0.5ml of normal saline administered intrathecally. Group F patients were given 3ml (15mg) of 0.5% hyperbaric bupivacaine along with 0.5ml (25μg) of preservative-free fentanyl intrathecally. Group D patients received 3ml (15mg) of 0.5% hyperbaric bupivacaine and 0.5ml (5μg) of diluted, preservative-free dexmedetomidine administered intrathecally.

Results: Patients in the dexmedetomidine group (D) experienced quicker onset of both sensory and motor blocks compared to those in the fentanyl group (F) and the bupivacaine group (B). Patients in group D experienced notably longer sensory and motor block durations compared to those in groups F and B. Patients in the dexmedetomidine group (D) exhibited minimal hemodynamic changes, experienced extended analgesia with reduced need for additional analgesics over 24 hours and had minimal adverse effects.

Conclusion: When administered intrathecally with bupivacaine, dexmedetomidine has a quicker onset than fentanyl and bupivacaine alone. It also extends the duration of sensory and motor blocks, maintains hemodynamic stability, results in minimal side effects, and reduces the need for postoperative analgesics in the first 24 hours.

Key Words: Bupivacaine, dexmedetomidine, fentanyl, pott's Fracture, spinal anesthesia.

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INTRODUCTION

Lower abdominal and lower limb surgeries can be conducted using local, regional (spinal or epidural), or general anesthesia, but neuraxial blockade is typically the preferred method. Spinal anesthesia remains the preferred option due to its rapid onset, effective blockade, lower infection risk compared to catheter-based methods, reduced failure rates, and cost efficiency. However, it has limitations, including a shorter block duration and limited postoperative analgesia^[1].

Recently, the use of intrathecal adjuvants has become more popular, aiming to extend the duration of the block, improve success rates and patient satisfaction, reduce resource use compared to general anesthesia, and facilitate quicker recovery. Effective pain management is crucial for promoting rehabilitation and speeding up functional recovery, allowing patients to resume their normal activities more swiftly. The effectiveness of spinal anesthesia has been reported to enhance with the inclusion of opioids (like morphine, fentanyl, and sufentanil) and other agents (including dexmedetomidine, clonidine, magnesium sulfate, neostigmine, ketamine, and midazolam)^[1].

Fentanyl is a short-acting narcotic analgesic with strong morphine-like effects. It quickly produces many of its clinical effects following intrathecal administration^[2].

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Dexmedetomidine is a highly selective α_2 adrenergic agonist that is utilized for premedication and as an adjunct to general anesthesia. It reduces opioids and inhalational anesthetic requirements. Intrathecal α_2 receptor agonists have been shown to provide antinociceptive effects for both somatic and visceral pain. It works by reducing the release of C-fiber neurotransmitters and by causing hyperpolarization of postsynaptic dorsal horn neurons^[3].

Pott's fracture refers to a fracture of the lower part of the fibula (the smaller bone in the lower leg), often associated with damage to the ligaments of the ankle and sometimes the tibia (the larger lower leg bone). It is a common type of ankle injury caused by twisting or impact^[4].

The objective of this study was to compare the effects of incorporating either dexmedetomidine or fentanyl with intrathecal bupivacaine. The focus was on assessing differences in the onset and duration of sensory and motor block, hemodynamic effects, postoperative pain management, and any adverse effects linked to each medication.

The primary outcome was to compare the three groups concerning sensory onset, motor onset, and duration of postoperative analgesia.

The secondary outcome was to compare the three groups in terms of side effects, including blood pressure, heart rate, and oxygen saturation, both intraoperatively and postoperatively.

PATIENTS AND METHODS

Following ethical committee approval (FMASU MS 571/2023) clinical trial number NCT06502262 and written informed consent from the patients, a prospective randomized clinical trial (nonfunded) was conducted involving 60 patients who underwent elective surgery for Pott's fracture under spinal anesthesia at Ain Shams University Hospitals and recorded at ClinicalTrials.gov.

The patients were divided into three equal groups

A control group, a fentanyl group, and a dexmedetomidine group, with 20 patients in each group.

The inclusion criteria were as follows

ASA I or ASA II patients scheduled for Potts fracture surgery, of either gender, aged between 21 and 55 years, with a height of 160 to 190cm, a BMI of 40 or less, and a procedure duration of 90 minutes or less.

The exclusion criteria included

patients with known neurological or psychiatric conditions; contraindications to spinal anesthesia such as patient refusal, bleeding or coagulation abnormalities, local infection in the lumbar region, elevated intracranial pressure, and hypovolemia; spinal abnormalities; systemic

disorders like hematological, respiratory, cardiac, renal, or hepatic insufficiencies; allergies to any of the study drugs; and women who are pregnant or breastfeeding.

Preoperative Period: Before surgery, all patients underwent a thorough assessment that included a medical history review, physical examination, and laboratory tests. They were fully briefed on the study's design, objectives, and the methods to be used. Before initiating regional anesthesia, standard monitoring was set up, which included ECG, noninvasive blood pressure measurement, and oxygen saturation. Patients were preloaded with intravenous lactated Ringer's solution at a dose of 10ml/kg. Spinal anesthesia was administered in the sitting position at the L₂-L₄ interspace, using either a midline or paramedian approach with a 25G Quincke spinal needle, following strict aseptic procedures. In this double-blinded study, patients were randomly assigned into three equal groups (20 patients each) using a closed envelope method. The injections administered were as follows: Group B (bupivacaine or control group) received 3ml (15mg) of 0.5% hyperbaric bupivacaine plus 0.5ml of normal saline intrathecally; Group F (fentanyl) received 3ml (15mg) of 0.5% hyperbaric bupivacaine plus 0.5ml (25µg) of preservative-free fentanyl intrathecally; and Group D (dexmedetomidine) received 3ml (15mg) of 0.5% hyperbaric bupivacaine plus 0.5ml (5µg) of diluted, preservative-free dexmedetomidine intrathecally. The injection was administered over 10-15 seconds, and patients were then positioned supine immediately afterward. Low-flow oxygen at 4 liters per minute was provided via an oxygen mask. Patients' ages (in years) and heights (in centimeters) were documented. Also recorded were the operation duration (in minutes) and hemodynamic parameters, including heart rate (beats per minute), mean arterial blood pressure (mmHg), and oxygen saturation (%). Monitoring and recording took place continuously at these intervals: Before spinal anesthesia. Immediately after spinal anesthesia, then every 15 minutes for 90 minutes, at the end of the surgery and again every hour for 24 hours following the operation. Hypotension was identified as a reduction in systolic blood pressure exceeding 30% from baseline or dropping below 90mmHg, and it was managed with intravenous fluids and additional doses of 3mg ephedrine. Bradycardia was defined as a heart rate below 50 beats per minute and was treated with 0.6mg of intravenous atropine. The occurrence of adverse effects, including hypotension, bradycardia, nausea, vomiting, shivering, pruritus, respiratory depression, and sedation, was documented. These effects were evaluated at the first, second, fourth, sixth, and eighth hours, and subsequently every 4 hours up to 24 hours.

The Sensory assessment was performed using iced cubes to evaluate the following onset of sensory analgesia, defined as the time taken to achieve the highest sensory level, which will be evaluated every minute following the intrathecal injection until the peak level is reached.

Sensory assessment will be conducted using pinprick and cold application, rated on a 3-point scale: 0= normal sensation, 1= loss of pinprick sensation, and 2= loss of touch sensation. The duration of the sensory block is defined as the time required for the sensory level to return to the S1 dermatome. This was recorded every 15 minutes from the highest sensory level obtained. All durations were calculated with the spinal injection time set as time zero.

Motor blockade was assessed as follows

Onset of Motor Block: Measured as the time taken to achieve a Modified Bromage Score (MBS) of 1, with evaluations conducted every minute after the intrathecal injection. Duration of Motor Block: Recorded from the onset of the block until the patient could lift their legs against gravity while in bed. Evaluations were performed every 15 minutes until the MBS reached 6. This assessment used the Modified Bromage Scale^[5]. 1-Complete block (unable to move feet or knees). 2-Almost complete block (able to move feet only). 3-Partial block (just able to move knees). 4-Detectable weakness of hip flexion while supine (full flexion of knees). 5-No detectable weakness of hip flexion while supine. 6-Able to perform partial knee bend.

Postoperatively, pain intensity was assessed using a visual analog scale (VAS), where 0 indicated no pain and 10 represented the worst pain imaginable. Pain intensity will be assessed every 2 hours for up to 24 hours postoperatively^[6]. If the pain score exceeds 4, 0.5mg/kg of IV pethidine will be administered, and pain levels will be re-evaluated after five minutes. If pain persists, an additional dose of 0.25mg/kg of IV pethidine will be given. The total amount of analgesic administered within the first 24 hours will be recorded, ensuring that the daily pethidine dose does not exceed 400mg.

Statistical Analysis

The collected data were reviewed, coded, and entered a PC using SPSS version 23. Data presentation included mean and standard deviation (\pm SD) for quantitative parametric data, median and range for quantitative non-parametric data, and counts and percentages for qualitative data. The type of analysis applied depended on the data characteristics. A *p*-value of <0.05 was deemed statistically significant.

The following statistical tests were employed

- *One-way Analysis of Variance (ANOVA):* Used to compare the means of multiple subgroups. A post-hoc test was performed for pairwise comparisons if ANOVA indicated significant differences.
- Chi-square (χ^2) Test: Utilized to compare proportions between categorical variables. The Bonferroni method was applied to adjust p-values for multiple comparisons of proportions.

- Confidence Interval and Margin of Error: The confidence interval was set at 95%, with an accepted margin of error of 5%. Significance levels were defined as follows:
 - *p*-value <0.05: Significant.
 - *p*-value <0.001: Highly significant.
 - *p*-value >0.05: Not significant.

RESULTS

The research involved 60 participants, who were categorized into three distinct groups: a Control group consisting of 20 individuals, a Fentanyl group with 20 participants, and a Dexmedetomidine group also comprising 20 individuals. All groups adhered to identical inclusion and exclusion criteria.

There were no significant differences observed in the demographic data, including gender, age, weight, height, BMI, and operative time (Tables 1, 2).

The data on the onset and duration of sensory and motor block, presented in Table (3), revealed significant differences among the groups. The Control group showed a mean onset time of 5.35 ± 0.69 minutes, while the Fentanyl group had a mean of 4.85 ± 0.73 minutes, and the Dexmedetomidine group recorded the shortest mean onset time of 4.40 ± 0.59 minutes, with a p-value of less than 0.001, indicating high significance.

Regarding the duration of the sensory block, the Dexmedetomidine group had the longest mean duration at 324.75 ± 30.91 minutes, followed by the Fentanyl group at 180.70 ± 15.86 minutes, and the Control group at 150.80 ± 14.13 minutes, all with a *p*-value of less than 0.001.

For the onset of motor block, the Control group had a mean of 4.15 ± 0.61 minutes, the Fentanyl group had 3.90 ± 0.51 minutes, and the Dexmedetomidine group demonstrated the shortest onset at 3.40 ± 0.50 minutes, again with a p-value of less than 0.001. Additionally, the duration of motor block was significantly longer in the Dexmedetomidine group at 252.55 ± 26.31 minutes, followed by the Fentanyl group at 147.70 ± 14.68 minutes, and the Control group at 107.20 ± 14.01 minutes, with a *p*-value of less than 0.001.

Table (4) showed a statistically significant difference in VAS scores among the three groups, with a *p*-value of less than 0.05. Over time, VAS scores increased, with the Control group experiencing the highest pain levels, followed by the Fentanyl group. In contrast, the Dexmedetomidine group reported the lowest pain scores.

Table (5) displayed results regarding the time to request analgesia. The findings revealed that the Control group had a significantly shorter time to the first request

for rescue analgesia, averaging 6.18 ± 1.42 hours. This was followed by the Fentanyl group at 8.24 ± 1.90 hours, while the Dexmedetomidine group had the longest duration at 17.51 ± 4.03 hours, with a *p*-value of less than 0.001.

In terms of the number of patients requiring analgesia and the total dose of pethidine administered, the Control group had the highest frequency, followed by the Fentanyl group, and then the Dexmedetomidine group, with a *p*-value

of less than 0.05. Additionally, the total dose of pethidine was greatest in the Control group, followed by the Fentanyl group and the Dexmedetomidine group, with a p-value of less than 0.05 as well (Tables 6, 7).

(Figures 1-4) illustrate that there were no notable complications or side effects reported among the three groups.

Table 1: Comparison between groups according to Demographic data:

Demographic data	Control group (n= 20)	Fentanyl group (n= 20)	Dexmedetomidine group (n=20)	Test value	P-value	Sig
Age (years)						
Mean±SD	41.45 ± 9.39	39.60 ± 11.59	40.35±9.22	0.169	0.845	Ns
Range	25-55	24-54	23-54	0.109		INS
Height						
Mean±SD	174.80 ± 9.32	172.65 ± 9.08	174.15±7.62	0.221	0.727	N-
Range	160-190	161-190	161-185	0.321		Ns
BMI						
Mean±SD	30.55 ± 3.76	31.30±3.59	29.90 ± 4.00	0.695	0.508	N
Range	25-35	24-36	24-36	0.685		Ns

Table 2: Comparison between groups according to duration of operation "min":

Duration of operation (min)	Control group (n= 20)	Fentanyl group (n=20)	Dexmedetomidine group $(n=20)$	Test value	<i>P</i> -value	Sig
Mean±SD	74.05±9.04	73.95±7.37	76.85 ± 8.82	0.761	0.472	Ns
Range	60-90	61-85	60-89	0.761	0.472	INS

Table 3: Comparison between groups according to Onset and duration of sensory and motor blocks:

	Control group (n=20)	Fentanyl group (n= 20)	Dexmedetomidine group (n=20)	Test value	<i>P</i> -value	Sig
Onset of sensory block (min)	5.35±0.69A	4.85±0.73B	4.40±0.59C	6.478	0.000	HS
Duration of sensory block (min)	$150.80\pm14.13C$	$180.70 \pm 15.86 B$	324.75±30.91A	68.972	0.000	HS
Onset of motor block (min)	4.15±0.61A	3.90±0.51B	3.40±0.50C	7.476	0.000	HS
Duration of motor block (min)	107.20±14.01C	$147.70 \pm 14.68B$	252.55±26.31A	35.854	0.000	HS

Table 4: Comparison between groups according to VAS score:

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VAS score	Control group (n= 20)	Fentanyl group (n=20)	Dexmedetomidine group (n=20)	Test value	P-value	Sig
Immediate Post. Op.	0(0-1)	0(0-1)	0(0-0)	0.704	0.307	Ns
After 2hrs.	0(0-1)	0(0-2)	0(0-0)	1.940	0.105	Ns
After 4hrs.	3(2-4) A	1(0-2) B	0(0-0) C	7.480	0.000	HS
After 6hrs.	3(0-5) A	1(1-3) B	0(0-0) C	10.531	0.000	HS
After 8hrs.	0(0-1) B	2(1-3) A	0(0-0) C	8.836	0.000	HS
After 10hrs.	1(1-2) A	1(0-2) A	0(0-0) B	5.283	0.008	S
After 12hrs.	1(1-1)	1(1-2)	0(0-1)	1.998	0.145	Ns
After 14hrs.	1(1-1)	1(1-2)	1(1-2)	0.938	0.397	Ns
After 16hrs.	1(1-2)	1(1-2)	1(1-1)	1.056	0.355	Ns
After 18hrs.	2(1-2) A	2(1-2) A	1(1-2) B	4.233	0.019	S
After 20hrs.	3(2-3) A	2(2-2) B	2(1-2) B	5.582	0.006	S
After 22hrs.	3(2-3) A	3(2-3) A	2(2-2) B	7.344	0.001	S
After 24hrs.	3(2-3) A	3(2-3) A	2(2-2) B	6.611	0.003	S

Table 5: Comparison between groups according to Time to request for analgesia:

Time to request for analgesia "hrs."	Control group (n= 20)	Fentanyl group (n= 20)	Dexmedetomidine group (n= 20)	Test value	<i>P</i> -value	Sig
Mean±SD	6.18±1.42C	$8.24{\pm}1.90B$	17.51±4.03A	10.592	0.001	HS
Range	4-8hrs	6-10hrs	14-20hrs	10.583	0.001	пъ

Table 6: Comparison between groups according to number of patients request analgesia:

	Control group (n= 20)	Fentanyl group (n=20)	Dexmedetomidine group (n= 20)	Test value	<i>P</i> -value	Sig.
Needed of request analgesia	8(40%)A	5(25%)B	3(15%)C	5.682	0.027	S

Table 7: Comparison between groups according to total dose of pethidine:

Total pethidine	Control group (n=20)	Fentanyl group (n=20)	Dexmedetomidine group (n=20)	Test value	<i>P</i> -value	Sig
Mean±SD	29.68±2.68A	24.39±3.19B	19.19±1.75C	3.572	0.021	S

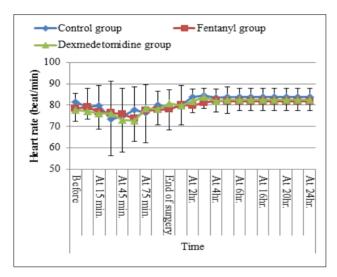


Fig 1: Comparison between groups according to Heart rate (beat/min).

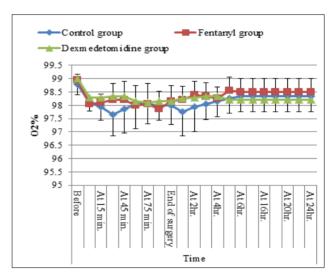


Fig 3: Comparison between groups according to spo 2%.

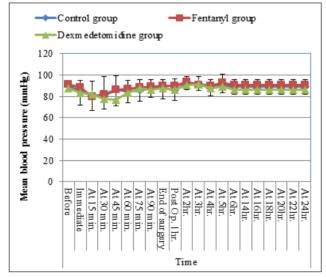


Fig 2: Comparison between groups according to Mean blood pressure (mmHg).

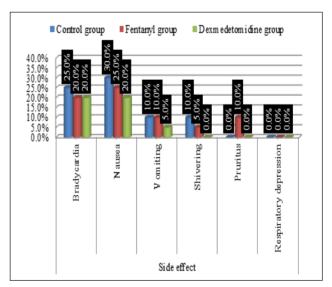


Fig 4: Comparison between groups according to Side effect.

DISCUSSION

Regarding the sensory onset, it was significantly quicker in Group D compared to Groups B and F (P= 0.000). This result is consistent with the findings of Shukla et al.,[1]. Which showed that the sensory onset with intrathecal dexmedetomidine (10µg) as an adjunct to (15mg) hyperbaric bupivacaine for lower limb and lower abdominal procedures was quicker than that achieved with magnesium sulfate and hyperbaric bupivacaine. In this study, the mean onset time for the dexmedetomidine group was 4.40 ± 0.59 minutes, whereas Shukla and colleagues reported an onset time of 2.27±1.09 minutes. Both studies noted significantly faster onset times compared to the other groups, although the variation in onset times may be attributed to different definitions of sensory onset used. The current study defined onset as the time until the highest sensory level was achieved, while Shukla et al., measured it until T₁₀ was reached. Another study by Sunil et al., [7] found that the onset with 10µg of dexmedetomidine was quicker compared to 10mg the hyper baric bupivacaine group for infra umbilical procedures, with mean onset times of 3.1±0.5, 3.5±0.8, and 4.7±1.1 minutes, respectively. In contrast, Al-Ghanem et al.. [8] did not observe a significant difference in onset times among the groups when comparing 5µg dexmedetomidine and fentanyl as adjuvants to 12.5mg hyperbaric bupivacaine in gynecological surgeries. Possible explanations for this discrepancy include the use of isobaric bupivacaine instead of hyperbaric bupivacaine in their study, as well as differing definitions for onset time—reaching T₁₀ in their study versus the highest sensory level in the current research. Additionally, patient positioning may have influenced the results; the previous study positioned patients in lithotomy, whereas the current study used a supine position.

In terms of motor onset, it was significantly quicker in Group D compared to Groups B and F, with a p-value of less than 0.001. This finding is consistent with the results of Shukla et al.,[1] and Sunil et al.,[7] Additionally, Ogan et al., [9] reported a faster motor onset in the dexmedetomidine group compared to fentanyl when used as an adjuvant to intrathecal bupivacaine in labor outcomes. However, this contrasts with the findings of Al-Ghanem et al., [8], which can be explained by similar factors that influenced the sensory onset. Furthermore, Mahendru et al.,[10] observed no significant difference in motor onset times between the dexmedetomidine group and the other groups when comparing intrathecal dexmedetomidine, clonidine, and fentanyl as adjuvants to hyperbaric bupivacaine. This discrepancy may be attributed to the lower total volume injected intrathecally in their study (3ml compared to 3.5ml in the current study).

Regarding the duration of motor and sensory blocks, Group D exhibited significantly longer sensory and motor durations compared to Groups B and C. Specifically, Group D showed a notably extended duration when compared to Group F, which aligns with the findings of Mahendru *et al.*,^[10], who reported significantly prolonged sensory and motor block durations. This conclusion is further supported by studies conducted by Al-Ghanem *et al.*,^[8], Kanazi *et al.*,^[11], and Al-Mustafa *et al.*,^[12] for urological surgery 5µg of dexmedetomidine and 12.5 hyper baric bupivacaine. These studies examined the impact of dexmedetomidine on spinal bupivacaine in urological procedures and noted a dose-dependent increase in both motor and sensory durations when the dexmedetomidine dosage was raised from 5 to 10µg.

Concerning the VAS scores, there was a significant difference among the three groups, with the highest scores recorded in Group C, followed by Group F, and the lowest scores in Group D. This finding aligns with the observations of Gupta *et al.*,^[3] who use 5µg dexmedetomidine in 0.5ml of normal saline and 3ml of 0.75% isobaric ropivacaine. And Mahendru *et al.*,^[10], who noted lower VAS scores in the 5µg dexmedetomidine group compared to 12.5mg the bupivacaine group in lower limb surgery.

The time to first rescue analgesia was significantly shorter in the control group, averaging 6.18±1.42 hours, followed by the fentanyl group at 8.24±1.90 hours, and the dexmedetomidine group at 17.5±4.03 hours, with a p-value of less than 0.001. Additionally, 75% of patients in Group D did not require rescue analgesia, compared to 50% in Group F and only 10% in Group B. There was also a significant reduction in the total analgesic requirements (pethidine) over 24 hours in Group D compared to Groups B and F. This is consistent with findings from Mahendru et al.,[10], who compared 5µg of dexmedetomidine with 30µg of clonidine and 25µg of fentanyl, further supporting the analgesic efficacy of dexmedetomidine as an intrathecal adjuvant. Moreover, Al-Mustafa et al.,[12] reported a reduced need for analgesics in a dose-dependent manner when comparing 5μg and 10μg of dexmedetomidine.

Regarding heart rate and blood pressure, no significant differences were observed among the three groups, consistent with the findings of Kanazi *et al.*,^[11], who also reported no significant decrease in heart rate or mean arterial blood pressure when investigating the effects of 3µg dexmedetomidine and 30µg clonidine added to intrathecal hyperbaric bupivacaine in lower limb surgery.

Concerning SpO₂ levels, there were no significant differences between the groups throughout the measurement intervals. This lack of variation may be attributed to two main factors: first, the local anesthetic dosage used in this study was minimized to avoid affecting the intercostal muscles and/or diaphragm during motor blockade. Second, supplemental oxygen was administered via a face mask throughout the procedure. These findings are supported by similar conclusions drawn by Sunil *et al.*,^[7] and Hala

et al.,^[13] when investigating the effects of 10μg dexmedetomidine and 15mg hyperbaric bupivacaine for anterior cruciate ligament reconstruction.

As for side effects such as nausea, vomiting, shivering, pruritus, respiratory depression, and sedation, their occurrence was not significantly different across the groups in this study, which aligns with the findings of Sunil $et\ al.$, [7]. In contrast, Abdelhamid and El-Lakany^[14] reported significant shivering in the 15mg hyperbaric bupivacaine group (12 patients) compared to the 5µg dexmedetomidine group (two patients) in lower abdominal surgery. This suggests that α_2 adrenergic agonists may possess anti-shivering properties, as noted by Talke $et\ al.$, [15] administered by computer-controlled infusion, targeting plasma dexmedetomidine concentrations of 0.0, 0.3, and 0.6ng/ml.

CONCLUSION

The use of dexmedetomidine as an adjuvant to intrathecal bupivacaine, in comparison to fentanyl, resulted in a quicker onset of action and extended durations of both sensory and motor blockade. Furthermore, it was associated with longer-lasting postoperative analgesia and reduced analgesic consumption. Importantly, it did not lead to significant sedation or serious side effects.

LIMITATION OF THE STUDY

Sample Size

While the study included 60 patients divided equally into three groups, the relatively small sample size may limit the generalizability of the findings to larger populations or different clinical settings.

Single-Center Design

The study was conducted exclusively at Ain Shams University Hospitals, which may restrict the applicability of results to other institutions with varying patient demographics or clinical practices.

Short-Term Outcomes

The study primarily focused on intraoperative and immediate postoperative outcomes. Long-term follow-up was not included, which limits the ability to evaluate prolonged effects, such as chronic pain or functional recovery.

Nonfunded Nature

Being a nonfunded study, resource constraints may have influenced the extent of data collection, monitoring, or the inclusion of additional parameters for analysis.

Specific Patient Population

The study was limited to patients undergoing elective surgery for Pott's fracture under spinal anesthesia. Results may not be generalizable to other types of fractures, surgeries, or anesthetic techniques.

Potential for Observer Bias

Although the study aimed to be randomized, the potential for observer bias during data collection cannot be completely excluded, especially in subjective measures like pain scores.

No Assessment of Long-Term Side Effects

The study did not evaluate the long-term side effects or complications related to the use of fentanyl or dexmedetomidine.

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Randomization Challenges

Despite randomization, inherent variability among patients, such as differences in baseline health or pain thresholds, might have influenced the results.

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CONFLICT OF INTERESTS

There are no conflicts of interest.

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