

COMPARATIVE STUDY OF DEXMEDITOMIDINE WITH 0.5% HYPERBARIC BUPIVACAINE AND FENTANYL WITH 0.5% HYPERBARIC BUPIVACAINE INTRATHECALLY FOR SUBARACHNOID BLOCK IN INFRAUMBILICAL SURGERIES

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ABSTRACT

Background and Aims: A subarachnoid block is a frequently used technique for infraumbilical surgeries. Fentanyl and dexmedetomidine are commonly employed as adjuvants to extend both intraoperative and postoperative pain relief. This study aims to evaluate the effectiveness of adding dexmedetomidine versus fentanyl to intrathecal bupivacaine in infraumbilical procedures.

Methods: In this double-blind, randomized clinical trial, 64 patients scheduled for elective infraumbilical surgeries were randomly assigned to two groups. Through the intrathecal route, one group received 2.5 ml of 0.5% hyperbaric bupivacaine combined with 10 micrograms of dexmedetomidine (Group D), while the other group was given 25 micrograms of fentanyl (Group F), with a total volume of 3 ml for each patient. The study compared the onset and duration of sensory and motor blocks, the maximum sensory and motor levels, time to first analgesic request, total recovery time for sensory and motor function, hemodynamic changes, and any side effects between the two groups.

Results: There were no significant differences between the groups in terms of patient demographics, ASA physical status, or hemodynamic variability. However, the onset of sensory block was quicker in Group D, averaging 1.35 ± 0.64 minutes, compared to 1.50 ± 0.53 minutes in Group F ($p = 0.006$). Group D also showed a slightly faster onset of motor block at 3.01 ± 0.74 minutes compared to 3.09 ± 0.73 minutes in Group F. The duration of motor block was significantly longer in Group D, lasting 201.28 ± 31.65 minutes, compared to 149.48 ± 38.66 minutes in Group F ($p = 0.04$). Complete sensory recovery took 325.7 ± 31.5 minutes in Group D, while it was 215.75 ± 29.4 minutes in Group F ($p < 0.000$). Additionally, the duration of complete analgesia was longer in Group D (319.43 ± 74.57 minutes) compared to Group F (209.78 ± 39.88 minutes) ($p < 0.000$). The time until the first request for rescue analgesia was significantly extended in Group D (321.43 ± 20.4 minutes) compared to Group F (213.33 ± 32.6 minutes) ($p < 0.0001$), indicating a longer-lasting sensory block in Group D.

Conclusion: The use of dexmedetomidine as an adjuvant to bupivacaine in subarachnoid blocks for infraumbilical surgeries results in a longer duration of both sensory and motor block, as well as extended postoperative analgesia.

KEYWORDS: Subarachnoid block, infraumbilical surgeries, fentanyl, dexmedetomidine, bupivacaine.

INTRODUCTION

A subarachnoid block is a commonly utilized anesthesia method for infraumbilical surgeries. However, use of

local anaesthetics alone is associated with relatively shorter duration of action. The use of adjuvants may reduce the complications and improve the duration of the anesthetic effect [1]. Fentanyl, a μ -receptor agonist, significantly reduces sympathetic blockade and postural hypotension, allowing early ambulation and avoidance of cardiovascular complications [2]. Dexmedetomidine, an α 2-adrenergic receptor agonist, prolongs the duration of both sensory and motor blockade induced by local anesthetics [3].

AIM AND OBJECTIVES

This study aimed to explore the impact of fentanyl and dexmedetomidine on postoperative analgesia and patient satisfaction when used in spinal anesthesia for infraumbilical surgeries.

METHODOLOGY

This study was carried out at Dr. Sushila Tiwari Memorial Hospital, Haldwani, after approval from Institutional Ethical Committee Letter No. 781/GMC/IEC/2023/Reg. No.736/IEC/R-19-09-2023 and CTRI Reg. No. CTRI/2024/02/062396.

Eligibility Criteria: Participants posted for infraumbilical surgeries, giving voluntary written consent, with the ASA physical status of I or II, in the age range of 18-50 years of either sex were included in the study. The exclusion criteria included patients not giving informed written consent for participation in the study, belonging to ASA physical status class III or IV, having any coagulation disorder, having infection at the site of performing block, with vertebral column or spinal cord deformity, or any neurological deficit, patients with psychiatric disorders or with history of hypersensitivity to any of the drugs under study and pregnant patients. Surgeries with duration of >2 hours were also excluded from the study.

Study Selection: This study was a prospective, double-blind, randomized, interventional trial. Participants were assigned to groups using a computer-generated random number table. Both the participants and the anesthesia team were blinded to the treatment allocation, following standard blinding protocols. A total number of 64 patients were included in the study. Eligible patients were divided into two groups of 32 participants each: Group F (Fentanyl Group), which received 2.5 ml of 0.5% hyperbaric bupivacaine along with 25 mcg (0.5 ml) of fentanyl intrathecally, and Group D (Dexmedetomidine Group), which received 2.5 ml of 0.5% hyperbaric bupivacaine with 10 mcg (0.1 ml diluted with 0.4 ml normal saline) of dexmedetomidine intrathecally.

Patient information, including name, age, sex, weight, height, and ASA physical status, was recorded on a standardized form. After obtaining informed consent for the study and the procedure, all patients were prescribed oral medications the night before surgery. Tab ranitidine 150 mg, Tab metoclopramide 10 mg, and Tab alprazolam 0.25 mg. They were also instructed to fast from midnight prior to surgery.

On the day of surgery, the patients were randomly assigned to one of two groups (Group F or Group D) using a random number table. Baseline hemodynamic parameters, including NIBP, ECG, SpO₂, and heart rate, were recorded while the patient was in a supine position. A peripheral vein was cannulated with an 18 to 20 G IV cannula, and crystalloid infusion was initiated.

Spinal anesthesia was performed under aseptic conditions at the L3-L4 interspace using a 25G Quincke's needle. After confirming free flow of cerebrospinal fluid (CSF), the respective study drug (either fentanyl + bupivacaine or dexmedetomidine + bupivacaine) was administered intrathecally.

Baseline hemodynamic indices were recorded prior to incision, every 2 minutes for the first 10 minutes, and then every 5 minutes during the surgery. Sensory blockade was assessed using a pinprick test with a 24G hypodermic needle.

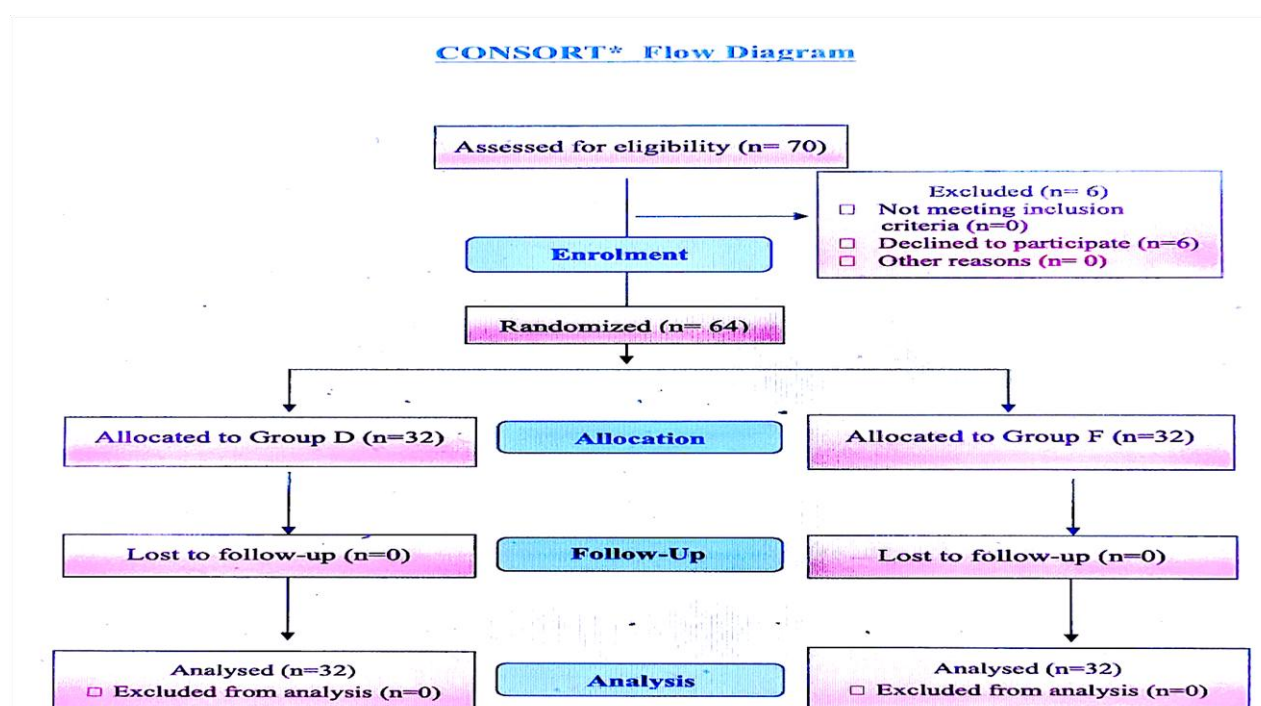
Motor blockade was evaluated using the modified Bromage scale.

Postoperative pain was evaluated using the Visual Analog Scale (VAS). Pain assessment started upon admission to the post-anesthesia care unit (PACU). Pain intensity was measured using the VAS every 15

minutes for the first 2 hours to promptly identify any need for immediate intervention. Later, during the postoperative period, VAS scores were recorded every 30 minutes for 4 hours and then every 3 hours up to 24 hours after surgery. If the VAS score exceeded 4, indicating moderate to severe pain, rescue analgesia was provided, typically in the form of an intramuscular injection of diclofenac (75 mg).

Hypotension, defined as a systolic blood pressure drop of 25% from baseline or below 90 mmHg, was managed using intravenous mephentermine. Bradycardia, characterized by a heart rate below 60 beats per minute, was treated with intravenous atropine.

Statistical Analysis: The efficiency of the interventions was assessed using t-tests for matched pairs. Correlation analysis was conducted to determine the levels of association between the various factors under consideration. For continuous variables, Pearson's correlation coefficient was used to measure the strength and direction of these associations. A multiple linear regression model was applied to analyse the duration of analgesia, incorporating variables such as age, weight, ASA class, and the type of adjuvant used. The probability of complications like hypotension and bradycardia was modelled using logistic regression.



RESULTS

Both the groups were demographically comparable with similar ASA profile of the patients and comparable duration of surgery.

Table 1 shows distribution of surgeries in both the groups. The p-value of 0.552 confirms that there is no substantial difference in the distribution of these surgeries in the two groups.

Table 1 – Infraumbilical Surgeries

Procedure	Group D	Group F	p-value
Orthopedic surgeries	15 (46.875)	14 (43.75)	0.552
Inguinal Hernia	10 (31.25)	11 (34.37)	

Urinary Bladder & Ureteric Surgery	07 (21.87)	05 (15.62)	
Total	32	32	

The onset of the sensory block was faster in Group F at 1.35 ± 0.64 minutes compared to Group D at 1.50 ± 0.53 minutes. The difference is statistically significant with p value of 0.006. In terms of motor block onset, Group D exhibits a slightly shorter initiation time of 3.01 ± 0.74 minutes compared to 3.09 ± 0.73 minutes in Group F (Figure 1).

The highest sensory level achieved in Group D was T6 while in Group F was T7 with p value 0.2420. The highest sensory level achieved in Group D was T8 while in Group F was also T8 with p value 0.9132.

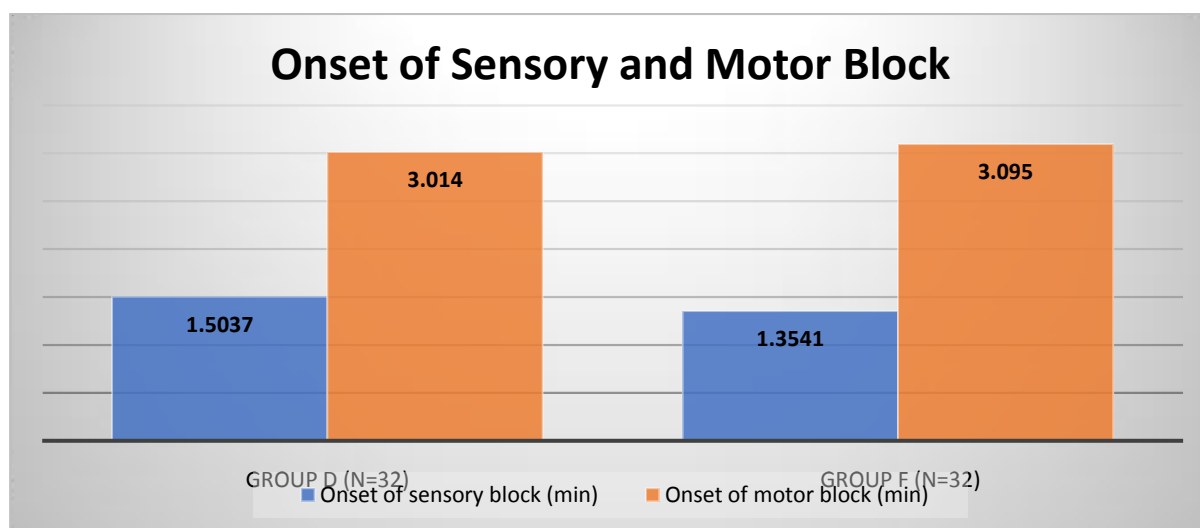


Figure 1- Onset of Sensory and Motor Block

Table 2- Characteristics of Block

Characteristics	Group D (n=32)	Group F (n=32)	p-value
Time to complete sensory recovery(min)	325.7 ± 31.5	215.75 ± 29.4	<0.0001
Time for first analgesic medication (min)	321.43 ± 20.4	213.33 ± 32.6	<0.0001
Duration of complete analgesia (min)	319.43 ± 74.57	209.78 ± 39.88	<0.0001
Duration of motor block (min)	201.28 ± 31.65	149.48 ± 38.66	0.0400

Table 2 shows the time to complete sensory recovery was 325.7 ± 31.5 min in Group D and 215.75 ± 29.4 min in Group F ($p < 0.0001$). The time to the first request for rescue analgesia, which was much higher in Group D (321.43 ± 20.4 minutes) compared to Group F (213.33 ± 32.6 minutes). Duration of complete analgesia (min) was 319.43 ± 74.57 min in Group D and 209.78 ± 39.88 min in Group F ($p < 0.0001$). Total time of motor block is significantly longer in Group D, lasting 201.28 ± 31.65 minutes, compared to 149.48 ± 38.66 minutes in Group F. This indicates that dexmedetomidine, in combination with 0.5% bupivacaine, produces a significantly longer time of motor blockade ($p 0.04$).

Table 3: Intraoperative Hemodynamic Parameters

Parameter	Group D (Dexmedetomidine)	Group F (Fentanyl)	p-value
Systolic BP (mmHg)	110 ± 10	108 ± 12	0.6523
Diastolic BP (mmHg)	65 ± 8	70 ± 9	0.8234
Mean Arterial Pressure (MAP) (mmHg)	70 ± 10	80 ± 11	0.7825
Heart Rate (beats/min)	65 ± 7	67 ± 8	0.3764
Oxygen Saturation (SpO2) (%)	98 ± 1	98 ± 1	1.0

Group D (Dexmedetomidine) and Group F (Fentanyl) show similar hemodynamic parameters for Systolic BP (110 ± 10 vs. 108 ± 12 mmHg) and for Diastolic BP (65 ± 8 vs. 70 ± 9 mmHg), MAP (70 ± 10 vs. 80 ± 11 mmHg), Heart Rate (65 ± 7 vs. 67 ± 8 beats/min), and SpO2 ($98 \pm 1\%$ for both).

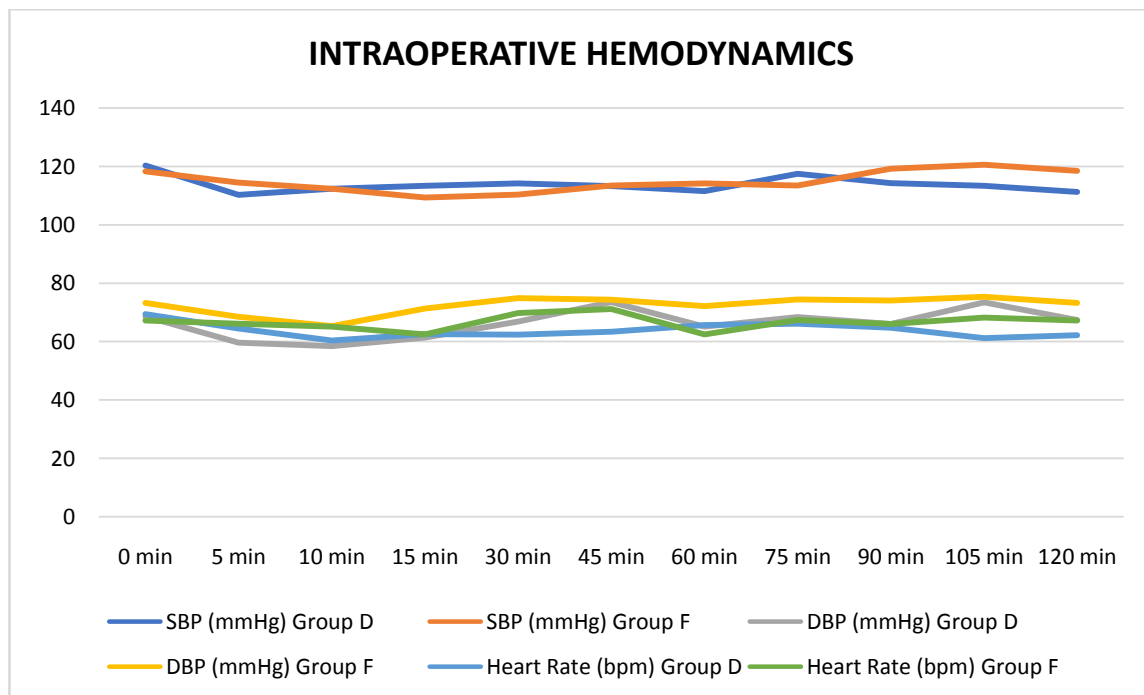


Figure 2: Intraoperative Hemodynamic Parameters

VAS score was 0 in both the groups till 3 hours but patients in Group F demanded rescue analgesia near around 4 hours post spinal block. While Group D demanded at around 5.5 hours and rescue analgesia was given. The results were highly significant as Group D demanded rescue analgesia much later than Group F.

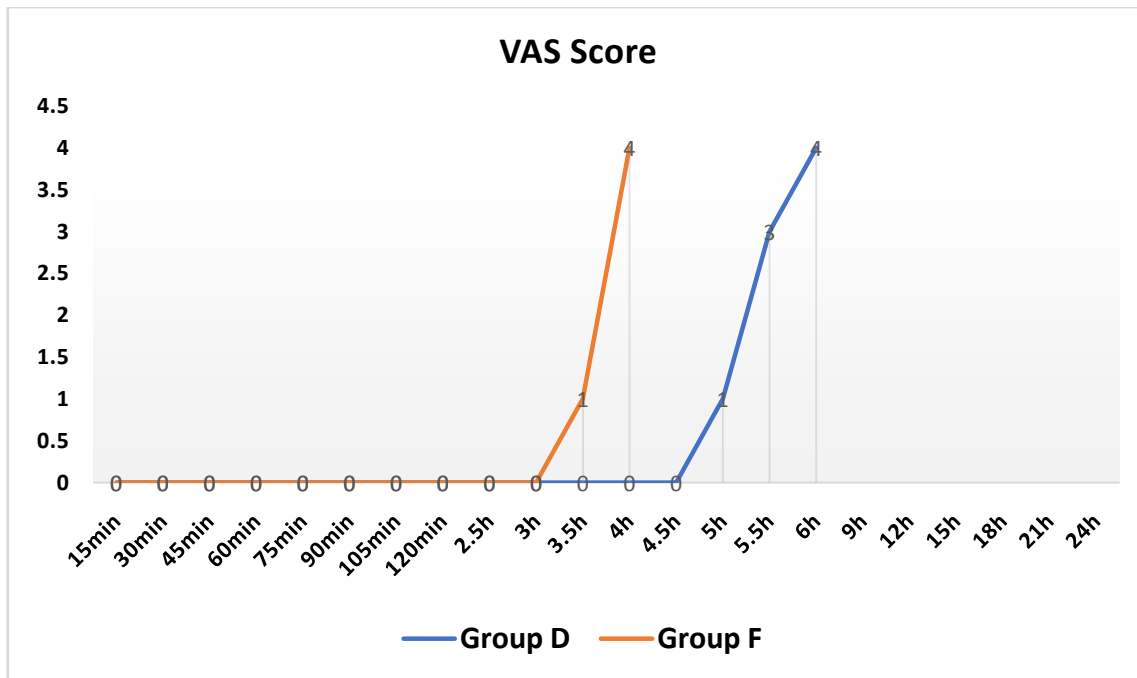


Figure 3: VAS Score

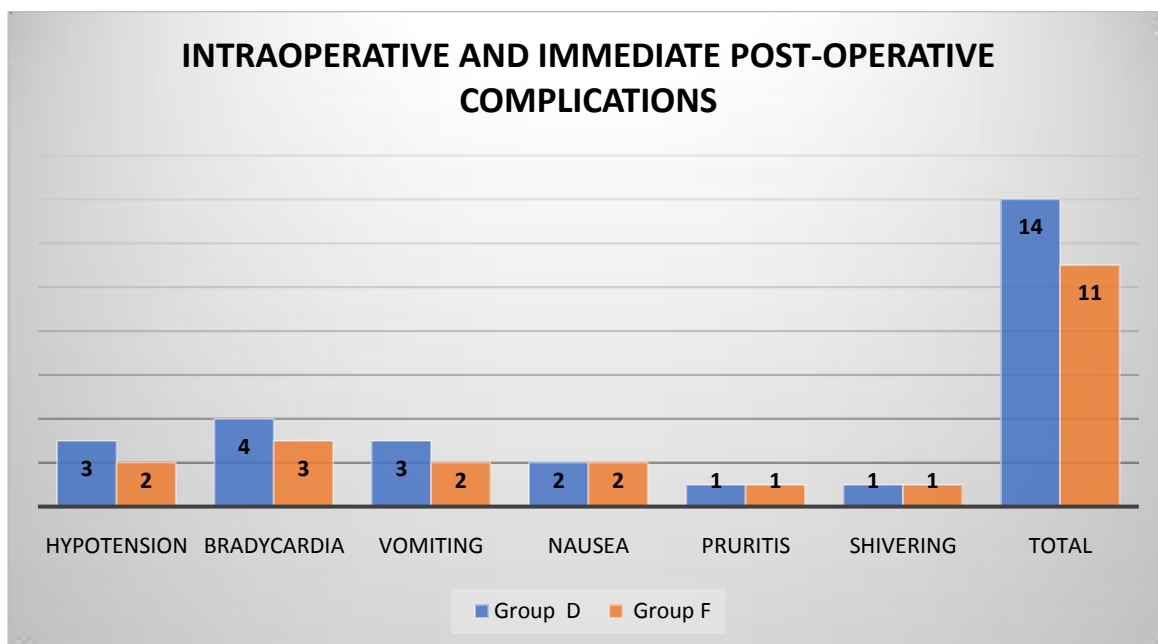


Figure 4: Intraoperative and Immediate Post-operative Complications

In comparing the rate of complications such as hypotension, bradycardia, nausea, vomiting, pruritis and shivering, both dexmedetomidine and fentanyl are comparable with no statistically significant difference in the incidence of complications between the two groups.

DISCUSSION

This study provides methodological control by performing detailed statistical analysis and comparison between Group D (dexmedetomidine with 0.5% hyperbaricbupivacaine) and Group F (fentanyl with 0.5% hyperbaric bupivacaine) with regards to subarachnoid block in lower abdominal surgeries. [4]. This prospective, double blinded, interventional, randomised, comparative study was carried out in Dr. STM

Hospital, Haldwani. It included 64 patients in total in 2 groups of 32 patients each:

- Group F- 0.5% Hyperbaric bupivacaine with fentanyl
- Group D- 0.5% Hyperbaric bupivacaine with dexmedetomidine

Both the groups were similar in age distribution, gender distribution, ASA classification, types of surgeries to be performed, and the duration of the anesthesia required for surgery to eliminate confounding factors. These results were similar to previous studies conducted by **Akhondzadeh et al. (2023)**[5], **Mir et al. (2023)**[6], **Khosravi et al. (2020)**[7], **Taher-Baneh et al. (2019)**[8] and **Gupta et al. (2011)**[9].

Characteristics of Block

The onset of the sensory block is faster in Group D at 1.35 ± 0.64 minutes compared to Group F at 1.50 ± 0.53 minutes. This difference is statistically significant ($p = 0.006$). **Akhondzadeh et al. (2023)** and **Taher-Baneh et al. (2019)** also found faster onset of sensory block with Group D.

In terms of motor block onset, Group D exhibits a slightly shorter initiation time of 3.01 ± 0.74 minutes compared to 3.09 ± 0.73 minutes in Group F. These results were also supported in studies by **Taher-Baneh et al. (2019)** and **Mir et al. (2023)**.

The highest sensory level achieved in Group D was T5 while in Group F was T6, with p value 0.2120. The highest sensory level achieved in Group D was T6 while in Group F was T7 with p value 0.5732, both the results were statistically insignificant. More importantly, total time of motor block is significantly longer in Group D, lasting 201.28 ± 31.65 minutes, compared to 149.48 ± 38.66 minutes in Group F. This indicates that dexmedetomidine, in combination with 0.5% hyperbaric bupivacaine, produces a significantly longer time of motor blockade ($p = 0.04$). **Taher-Baneh et al. (2019)** and **Mir et al. (2023)** came up with similar results in their respective studies.

The time to complete sensory recovery (min) was 325.7 ± 31.5 min in Group D and 215.75 ± 29.4 min in Group F. The results were highly significant with p value of <0.0001 . These results were supported in studies by **Taher-Baneh et al. (2019)** and **Mir et al. (2023)** who also had higher recovery time for dexmedetomidine-bupivacaine group.

Duration of complete analgesia (min) was 321.43 ± 20.4 min in Group D and 213.33 ± 32.6 min in Group F. The results were thus statistically significant with p value of <0.0001 . **Taher-Baneh et al. (2019)** and **Mir et al. (2023)** came up with similar results in their respective studies.

The time to the first request for rescue analgesia, which was much higher in Group D (319.43 ± 74.57 minutes) compared to Group F (209.78 ± 39.88 minutes) ($p = 0.0001$). **Taher-Baneh et al. (2019)** and **Khosravi et al. (2020)** support these results in their studies.

Postoperative Pain

VAS score was 0 in both the groups till 3 hours but patients in Group F demanded rescue analgesia near around 4 hours post spinal block. While Group D demanded at around 5.5 hours and rescue analgesia was given. The results were highly significant as Group D demanded rescue analgesia much later than Group F. This denotes longer sensory block in Group D. Similar results were observed by **Taher-Baneh et al. (2019)** and **Khosravi et al. (2020)**.

Previous studies have likewise found that dexmedetomidine gives benefits like earlier onset of sensory block, longer duration of analgesia, and improved postoperative pain control to fentanyl [10]. Similar findings were published in their systematic review that analysed several RCTs and noted that, because of its ability to act as a selective α_2 -adrenoceptor agonist, dexmedetomidine results in a quicker onset of sensory blockage as it influences the release of spinal cord neurotransmitters.

More particularly, our investigation confirms previous hypotheses which have proposed that because of its longer half-life and possible opioid-saving effect, dexmedetomidine might be helpful in surgeries that need

long-lasting anesthesia and improved postoperative analgesia.

Hemodynamic Variability:

There were no significant differences in intraoperative and immediate postoperative hemodynamic parameters as Tables 7 indicated. Group D (Dexmedetomidine) and Group F (Fentanyl) show similar parameters. For Systolic BP (120 ± 10 vs. 118 ± 12 mmHg) and for Diastolic BP (75 ± 8 vs. 74 ± 9 mmHg), MAP (90 ± 10 vs. 89 ± 11 mmHg), Heart Rate (65 ± 7 vs. 67 ± 8 beats/min), and SpO₂ ($98 \pm 1\%$ for both). **Taher-Baneh et al. (2019)** and **Khosravi et al. (2020)** support these results in their studies.

Intraoperative and Immediate postoperative Complications:

Both groups have statistically similar complication rates and, therefore, are safe in clinical practice. While in Group D, the occurrence of complications encompasses hypotension (9.37%), bradycardia (12.5%), vomiting (12.5%), nausea (6.25%), pruritis (3.12%), and shivering (3.12%). On the other hand, Group F shows rates of hypotension (12.5%), bradycardia (9.7%), vomiting (6.25%), nausea (6.25%), pruritis (6.25%), and shivering (3.12%). The p-value for the intraoperative and immediate post-operative complications, is 1.0. This was similar to previous studies done by **Taher-Baneh et al. (2019)** and **Gupta et al.**

Strengths and Limitations:

Randomization of patients in the study was rigorously conducted to ensure that patients were randomly allocated either to the Dexmedetomidine group (Group D) or the Fentanyl group (Group F). The focus on diverse statistical parameters, such as descriptive analyses, t-tests, and regression analysis, strengthened the approach to data analysis. The large amount of obtainable data helped in achieving a multifaceted understanding of the impact of dexmedetomidine and fentanyl on anesthesia outcomes of lower abdominal surgeries [96]. The study has notable clinical implications for anesthesia practice in lower abdominal surgeries. Clinicians can consider dexmedetomidine as a preferred adjuvant because it has the advantage of yielding longer sensory or motor block durations as compared to fentanyl.

This study is conducted at one center which can pose a limitation for generalization and the sample size of this study is somewhat small. A major strength is the randomization of participants which could however be prone to inherent selection biases inherent from the single-centre study. Furthermore, patient variance regarding age, co-morbidity, and procedure indication may have impacted outcomes, which affects the credibility of dexmedetomidine and fentanyl comparisons of efficacy and safety. The making of this study implicates short-term effects like the extent of sensory and motor block times, the number of analgesics used, and the first-stay postoperative complications therefore eliciting more details on acute perioperative period. The pharmacogenomic characteristics of drug metabolites and their response to the agents used in anesthesia could vary across different populations of patients, and could thus possibly alter the effectiveness and safety ratio of the fentanyl and dexmedetomidine examined in the current study.

CONCLUSION

To conclude, the findings indicate that dexmedetomidine leads to a quicker onset of sensory block and a longer duration of motor block compared to fentanyl. Additionally, patients who received dexmedetomidine experienced extended pain relief and took longer to require rescue analgesia after surgery. Both groups had similar risk factors, with no significant differences in intraoperative or early postoperative complications. These results underscore the importance of tailoring anesthesia plans to individual patient needs and the specifics of the surgery. Dexmedetomidine might offer benefits, particularly for surgeries that require extended anesthesia or enhanced postoperative pain management.

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