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Original Research Article

Comparative Evaluation of Intrathecal Dexmedetomidine and Fentanyl as Adjuvants to Bupivacaine in Spinal Anesthesia: A Multisurgical Perspective

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Conflict of interest: Nil

Abstract:

Background: Spinal anesthesia is often used in lower abdominal, pelvic, and lower limb surgery but is limited due to its relatively short duration of action. Fentanyl and dexmedetomidine have been used as intrathecal adjuncts to prolong postoperative analysesia while improving the quality of the block.

Aim: To evaluate the efficacy and safety of intrathecal dexmedetomidine compared to fentanyl as intra-thecal adjuncts to hyperbaric bupivacaine in different surgical procedures.

Method: A prospective, randomized, double-blind controlled trial of 96 ASA I–II patients undergoing surgery below the umbilicus. The patients were randomly assigned to groups A, B or C (n=32 each): Group A - Bupivacaine + fentanyl; Group B - bupivacaine plus dexmedetomidine; Group C - buprivacaine only. Primary outcomes included the onset and duration of sensory block, onset and duration of motor block, time to first rescue analgesia and adverse effects. Statistical analysis was performed using ANOVA and Chi-square tests, with significance defined as p < 0.05.

Results: The dexmedetomidine (Group B) group showed significantly longer duration of sensory block (466.8 \pm 111.4 min) and motor block (436.7 \pm 123.1 min) than both the fentanyl (Group A) and buprivacaine (Group C) groups (p<0.001). Time to first rescue analgesia was also longest with dexmedetomidine (513.2 \pm 139.5 min). Bradycardia was documented in 12.5% of fentanyl group only, and none in the dexmedetomidine group.

Conclusion: Dexmedetomidine is superior to fentanyl in prolonging block duration and postoperative analgesia, making it ideal for longer surgeries, while fentanyl offers rapid onset and quicker recovery for shorter procedures. **Keywords:** Spinal Anesthesia, Dexmedetomidine, Fentanyl, Bupivacaine, Intrathecal Adjuvant, Postoperative Analgesia.

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Introduction

Spinal anesthesia has been a cornerstone of regional methods of anesthesia for years and remains one of the most popular and reliable methods of delivering surgical anesthesia, particularly for procedures of the lower abdomen, pelvis, and lower extremities. Spinal anesthesia can be regarded as an established, safe, and reliable anesthetic practice because of the widely established effectiveness and safety profile of the procedure [1]. Its principal benefits include being relatively straightforward to perform, rapid onset, cost effectiveness, and a lower incidence of complications compared to general anesthesia. Additionally, spinal anesthesia has the advantage of producing both sensory and motor blockade that is stable, with a low incidence of intradural failure of action, allowing for the breadth of surgical procedures found in resource constrained situations [2].

Despite these advantages, spinal anesthesia has disadvantages. The major disadvantage in spinal anesthesia is the relatively short duration of efficacy, which commonly requires the administration of adjunctive analgesia or systemic analgesics in the postoperative period. The substantial motor blockade also delays early movement, which is crucial to facilitating recovery and ensuring the same-day discharge from the outpatient surgical unit. The complication of a post-dural puncture headache (PDPH) is another widely acknowledged complication of spinal anesthesia that can negatively impact patient comfort and satisfaction [3]. These drawbacks have led to further exploration of techniques that prolong the duration of sensory analgesia while reducing motor blocks and associated morbidity.

Spinal anesthesia is defined as the injection of a local anesthetic into the subarachnoid space to produce sympathetic, sensory and motor blockade. Spread and extent of the blockade vary according to some parameters like the dose, volume, and anesthetic agent concentration used. Bupivacaine is a popular long-acting amide local anesthetic that is widely applied in the practice of spinal anesthesia due to the promising qualities that enable high motor and sensory blockade. Nonetheless, the action of bupivacaine may not be strong enough to endure long surgical operations or offer prolonged postoperative pain relief. Consequently, the administration of intrathecal adjuvants aiming to maximize the quality and the duration of spinal anesthesia has been notably enhanced [4].

The administration of adjuvants during spinal anesthesia has various roles: extension of the relief of pain on the postoperative period, decrease of the required dose of local anesthetic (with the consequent reduction of the side effects of the anesthetic), enhancement of the efficacy of the blockade, satisfaction enhancement of the patient, and decrease of the period of postoperative monitoring and hospitalization. Several pharmacological agents were researched throughout the years as intrathecal adjuvants. These drugs include opioids such as morphine, fentanyl, and sufentanil; α2-adrenergic receptor agonists such as clonidine and dexmedetomidine; magnesium sulfate; neostigmine; ketamine; and midazolam [5]. Of these agents, opioids were the oldest and the most frequently used historically due to their strong analgesic activity and harmonious interactions with local anesthetics when administered together.

Fentanyl is a phenylpiperidine-type synthetic opioid that has been studied and used extensively as an intrathecal adjuvant. Fentanyl is a highly potent, pure μ-opioid receptor agonist, some 100 times more potent than morphine on an equianalgesic basis. Intrathecally, fentanyl evokes selective and profound analgesia with minimal motor blockade, a qualification that makes it of particular value in the surgical field where early postoperative mobilization is the purpose of surgery. However, it has not been used entirely devoid of demerits. Adverse effects that have been observed frequently with intrathecal administration of opioids include pruritus, nausea, and vomiting, and the dangerous complication of delayed respiratory depression [6]. These limitations have spurred the search for non-opioid adjuvants that will be able to provide similar or superior analgesia with minimal opioid-related side effects.

Among the non-opioid pharmacological agents, α 2-adrenergic receptor agonists have emerged as notable alternatives. Clonidine, recognized as the first agent in this category to receive extensive research attention, exhibited significant sedative, analgesic, sympathetic, and hemodynamic-modulating effects

when utilized as an intrathecal adjuvant. In more recent studies, dexmedetomidine, a novel and highly selective α2-adrenergic agonist, has attracted considerable scholarly interest. Dexmedetomidine demonstrates a substantially higher selectivity ratio of $\alpha 2$ to $\alpha 1$ receptors (1600:1) in comparison to clonidine (200:1), thus rendering it a more effective and precisely targeted agent for achieving desired outcomes such as analgesia and sedation while reducing the likelihood of adverse side effects. When administered via the intrathecal route, dexmedetomidine has been shown to extend the duration of both sensory and motor blockade, maintain stable hemodynamics during surgery, and improve the quality of postoperative pain relief, frequently with minimal negative side effects [7].

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The addition of dexmedetomidine to the practice of regional anesthesia marks an important evolution of regional anesthesia, offering an attractive alternative to opioids like fentanyl. Its multifaceted mechanisms of action include the suppression of sympathetic outflow, modulation of the nociceptive pathways both spinally and supras spinally, and enhancement of intraoperative sedation with minimal pronounced depression of respiration. However, despite the promising pharmacological profile of dexmedetomidine, the comparative efficacy and safety of the drug relative to the established opioid adjuvants like fentanyl remain the focus of several ongoing studies.

Since the surgical indications of spinal anesthesia are especially large (orthopedic, gynecological, urological, general surgery procedures, etc), it is critical to take a multisurgical approach when evaluating the efficacy of the different adjuvants. Clinical effects of the adjuvants presented may depend on the surgical type performed, characteristics of the patient, and circumstances during the surgery. Therefore, it is crucial to systematically evaluate dexmedetomidine and fentanyl as intrathecal adjuvants for different surgical settings to inform evidence-based clinical guideline development.

The current study has been performed with the primary outcome of comparing the effectiveness of intrathecal dexmedetomidine and fentanyl as adjuvants to hyperbaric bupivacaine in spinal anesthesia for lower abdominal surgery. By measuring endpoints such as the onset and duration of sensory and motor block, hemodynamic stability in surgery, postoperative analgesia, and side effects, it attempts to provide a comprehensive assessment of the two drugs. The study hopes to provide data that may assist clinicians in decision-making on the best selection of intrathecal adjuvants which may enhance the outcomes of their patients but also achieve effective, efficient surgery.

Methodology

Study Design: This was a prospective, randomized, double-blinded, controlled trial to compare the efficacy and safety of intrathecal dexmedetomidine and fentanyl as adjuvants to bupivacaine in patients undergoing elective surgeries below the level of the umbilicus using spinal anaesthesia.

Study Area: The study was carried out in the Department of Anesthesiology, Lord Buddha Koshi Medical College and Hospital, Saharsa, Bihar, India.

Study Duration: The research was carried out over a period of one year.

Sample Size: A total of 96 patients were included and randomly allocated into three groups, with 32 patients in each group.

- Group A received 12.5 mg hyperbaric bupivacaine 0.5 (2.5 ml) + 25 µg fentanyl (0.5 ml)
- Group B received 12.5 mg hyperbaric bupivacaine 0.5 (2.5 ml) + 5 μg dexmedetomidine (0.1 ml) + 0.4 ml Normal Saline
- Group C (control group) received 12.5 mg hyperbaric bupivacaine 0.5 (2.5 ml) + 0.5 ml Normal Saline

Study Population: The study population consisted of adult patients of both sexes, classified as ASA physical status I and II, with planned elective surgery on the lower abdomen, pelvis, urology, or lower extremities using spinal anesthesia.

Inclusion Criteria

- Patients aged 18–60 years
- ASA physical status I and II
- Scheduled for elective surgeries below the level of the umbilicus under spinal anesthesia
- Willing to provide written informed consent to participate in the study

Exclusion Criteria

Patients were excluded if they had any of the following conditions:

- Raised intracranial pressure
- Coagulopathy or bleeding disorders
- Local infection at the injection site
- Neurological disorders
- Fixed cardiac output states
- Previous spinal surgeries
- Current use of anticoagulant or antiplatelet therapy
- Known allergy or hypersensitivity to study drugs
- Failure of spinal anesthesia

Data Collection: Data collection began with a preanesthesia assessment for each patient, scheduled to be obtained from subjects the night prior to surgical procedures. Demographic data that were obtained included age, gender, weight, ASA classification,

and reference vital signs. All subjects received a detailed explanation of the anesthetic procedure and were trained in utilization of the Visual Analog Scale (VAS) to assess pain following the procedure. All subjects were pre-medicated with oral Lorazepam (1 mg) and Ranitidine (150 mg) the evening before surgery. All patients were NPO for a minimum of 8 hours before surgical procedures. During the intraoperative phase a second data collection period occurred when heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and oxygen saturation (SpO2) were taken at regular intervals. Subsequently during postoperative data collection, duration of sensory and motor block, VAS pain scores, thereby also documenting side effects of nausea, vomiting, or pruritus, and the time to first rescue analgesia were noted."

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Procedure: The patients were transferred to the operative room on surgery days and connected to the standard noninvasive monitoring, i.e., NIBP, SpO₂, and ECG. Intravenous access was gained by an 18G cannula, and preloading of 10 ml/kg Ringer Lactate was performed on all the patients to reduce the risk of hypotension. Participants were randomly assigned to three different groups by the computer-allocated random number table, and the group allocation remained concealed both to the patient and the observer of the outcome recorder.

Spinal anaesthesia was administered under aseptic conditions by a seasoned anaesthetist at the L3–L4 interspace whilst the patient sat, with the use of a 25G Quincke spinal needle. The study medication, made according to group allocation, was administered intrathecally, and the patient immediately laid down on the supine position, timed as time T0. Sensory level of block was assessed every 2 minutes by the pin-prick test until the dermatome T10 level was reached, and motor block by the Modified Bromage Scale. Peak sensory block level (PSBL) was the level where no further increase of block height followed on four successive checks.

The hemodynamic parameters were kept under vigilant control during the surgery, with observations every 3 minutes during the first 15 minutes and every 5 minutes thereafter till the conclusion of the procedure. Bradycardia, which is HR <50 beats per minute, was treated with the administration of Atropine 0.6 mg IV, and hypotension, which is a >30% decrease in MAP from the baseline level or MAP <60 mmHg, was treated with the administration of Ephedrine 6 mg IV. After the surgery, sensory block regression was observed every 15 minutes till the appearance of two-segment regression. Postoperative pain was observed with the VAS score, and on exceeding the score of 4, Diclofenac sodium 75 mg IV in 100 ml normal saline was given as rescue analgesia. Nausea, vomiting, and pruritus were also observed as complications. Patients who needed conversion to general anesthesia due to poor block were excluded from the final analysis.

Statistical Analysis: The Collected data were statistically evaluated by the Statistical Package for the Social Sciences (SPSS) version 20.0 (SPSS Inc., Chicago, USA). Continuous parameters, such as onset and duration of sensory and motor block, presented as mean \pm standard deviation (SD) and were compared between the three groups by Analysis of Variance (ANOVA). Categorical parameters, such as the incidence of side effects, were presented as number and percentage and were evaluated by the Chi-square test or by Fisher's exact test, as appropriate. A p-value of <0.05 was evaluated to be statistically significant.

Result

"Table 1 presents the demographic profile of the study participants across the three groups (n = 32

each). The mean age was comparable among the groups, with Group A having 40.6 ± 13.3 years, Group B 42.4 ± 11.5 years, and Group C 44.4 ± 14.9 years. Males constituted the majority of participants in all groups, accounting for 81.2% in both Groups A and B and 93.8% in Group C, while females were fewer, with 18.8% in Groups A and B and 6.2% in Group C. The mean body weight was slightly higher in Group C (65.8 \pm 7.6 kg) compared to Group B $(63.4 \pm 7.9 \text{ kg})$ and Group A $(62.5 \pm 9.1 \text{ kg})$. Regarding ASA (American Society of Anesthesiologists) physical status classification, most patients were ASA I, representing 68.8% in Group A, 43.8% in Group B, and 56.2% in Group C. ASA II classification was more frequent in Group B (46.9%), followed by Group C (37.5%) and Group A (21.9%). A small proportion of patients were ASA III, with 9.4% in Groups A and B and 6.2% in Group C. Overall, the three groups were comparable in terms of baseline demographic characteristics.

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Table 1: Demographic profile of the study population			
Variables	Group A (n = 32)	Group B (n = 32)	Group $C (n = 32)$
Age (years), mean ± SD	40.6 ± 13.3	42.4 ± 11.5	44.4 ± 14.9
Sex, n (%)			
Female	6 (18.8%)	6 (18.8%)	2 (6.2%)
Male	26 (81.2%)	26 (81.2%)	30 (93.8%)
Weight (kg), mean ± SD	62.5 ± 9.1	63.4 ± 7.9	65.8 ± 7.6
ASA, n (%)			
III	3 (9.4%)	3 (9.4%)	2 (6.2%
II	7 (21.9%)	15 (46.9%)	12 (37.5%)
I	22 (68.8%)	14 (43.8%)	18 (56.2%)

Table 2 presents the block characteristics of the study population. The mean duration of motor block (DOMB) was significantly different among the groups (p < 0.001), with Group B having the longest duration (436.7 \pm 123.1 min), followed by Group A $(316.6 \pm 100.5 \text{ min})$, and Group C showing the shortest duration (213.7 \pm 82.4 min). Similarly, the duration of sensory block (DOSB) was highest in Group B (466.8 \pm 111.4 min), moderate in Group A $(378.8 \pm 127.6 \text{ min})$, and lowest in Group C (245.9 \pm 90.5 min) with a highly significant difference (p < 0.001). The time to maximum motor block (TTMI) and time to sensory regression (TTSR) also differed significantly (p < 0.001); Group C had the longest TTMI (5.5 \pm 0.9 min) and the shortest TTSR (42.2 \pm 16.8 min), while Group B demonstrated the fastest TTMI (3.0 \pm 1.6 min) and the longest TTSR (92.2 \pm 20.4 min). The time to achieve the T10 sensory level was shortest in Group B (5.2 \pm 1.9 min) and longest in Group C ($7.7 \pm 1.4 \text{ min}$), with Group A in between $(6.2 \pm 2.0 \text{ min})$ (p < 0.001). The duration of surgery (DOS) did not differ significantly between groups (p = 0.596). Regarding peak sensory block level (PSBL), T7 was the most frequently achieved level in Groups A (65.6%) and C (71.9%), whereas Group B showed higher proportions at T5 (34.4%) and T7 (31.2%), with a significant overall difference (p = 0.016). The total time for regression of anesthesia (TFRA) was longest in Group B (513.2 ± 139.5 min), followed by Group A (396.2 \pm 77.3 min), and shortest in Group C (268.6 \pm 76.7 min) (p < 0.001). Bradycardia occurred only in Group A (12.5%), showing a significant difference among the groups (p = 0.015). Hypotension was reported in 6.2% of Group A and 3.1% of Group C, but no cases were seen in Group B, with no significant difference (p = 0.356). These findings indicate that Group B consistently demonstrated longer block durations and higher block levels compared to Groups A and C.

Discussion

The current study also tried to compare the effectiveness of dexmedetomidine and fentanyl as intrathecal adjuvants to bupivacaine in spinal anaesthesia during various surgical procedures. Demographic features, such as age, sex, weight, and ASA status, were similar between the three groups and therefore ruled out demographic bias when the block characteristics and outcomes were assessed. These results parallel past research where the demographics between study groups were comparable across study groups so that the differences encountered were more due to the type of adjuvants utilised [7,8] (Gupta et al., 2011; Al-Ghanem et al., 2009)."

In our trial, the onset of sensory block to T10 level was significantly faster with the dexmedetomidine group (Group B) at 5.2 ± 1.9 minutes than the fentanyl group (Group A, 6.2 ± 2.0 minutes) and the control group (Group C, 7.7 ± 1.4 minutes) (p < 0.001). This is evidence of faster onset of spinal block conferred by dexmedetomidine, which is advantageous if needing fast surgical readiness. Rahimzadeh et al. (2018) [9] similarly presented data demonstrating that dexmedetomidine as an adjuvant to bupivacaine significantly decreased onset time of sensory block when compared to bupivacaine alone and compared to the fentanyl group. Likewise, El-Attar et al. (2015) [10] also described similar faster onset of sensory block with dexmedetomidine which corroborated the improved efficacy of this drug as a spinal adjuvant. However, Nayagam et al. (2014) [11] reported that the sensory block onset time with dexmedetomidine did not differ significantly from the group with fentanyl suggesting that the type of surgery and/or the dose of bupivacaine may affect the qualities of the block.

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The peak sensory block level (PSBL) of our study revealed greater cephalad spread in the dexmedetomidine group with 34.4% of patients reaching T5 compared with 12.5% in the fentanyl group and in 3.1% of control group (p = 0.016). Gupta et al. (2011) also observed similar outcomes, where dexmedetomidine reached a higher block level (T5) than did fentanyl (T6). The reason a higher block can be reached by dexmedetomidine is that the bupivacaine-dexmedetomidine synergy enhances the spread and the efficacy of the local anesthetic (Kanazi et al., 2006) [12].

The time of sensory and motor block was significantly extended in the dexmedetomidine group, where the mean sensory block time was 466.8 \pm 111.4 minutes and the motor block time was 436.7 \pm 123.1 minutes. On the contrary, the fentanyl group showed modest extension (sensory: 378.8 ± 127.6 ; motor: 316.6 ± 100.5) of the sensory and motor block duration, respectively, and the control group experienced the shortest duration of the sensory and motor block (sensory: 245.9 ± 90.5 ; motor: $213.7 \pm$ 82.4) (p < 0.001). These observations were similar to those of Al-Ghanem et al. (2009) [8], which revealed that 5 µg of dexmedetomidine significantly extended the sensory and motor block duration significantly more than 25 µg of fentanyl did. In a similar vein, Leelavathy et al. (2016) [13] established the result that the duration of both sensory and motor block by dexmedetomidine significantly exceeded that of fentanyl, supporting our result. However, Mahendru et al. (2013) [14] reported a long sensory block by dexmedetomidine but insignificant extension of motor block duration, differing from our result. This difference may have been due to different doses of drugs and diverse patients' populations.

The duration of two-segment regression (TTSR) took appreciably longer in the dexmedetomidine group (92.2 \pm 20.4 minutes) than with fentanyl (70.4 \pm 11.4 minutes) and control (42.2 \pm 16.8 minutes) (p < 0.001). Kurhekar et al. (2016) [15] also reported long TTSR with dexmedetomidine when compared to morphine and bupivacaine alone during gynecological surgery, showing the efficacy of the agent to prolong neural blockade duration significantly. Long TTSR has clinical advantage of providing long postoperative analgesia making it unnecessary to administer early rescue analgesics.

Regarding analgesic requirements, the time for first rescue analgesia (TFRA) was significantly delayed in the dexmedetomidine group (513.2 \pm 139.5 minutes) compared to the fentanyl (396.2 \pm 77.3 minutes) and control groups (268.6 \pm 76.7 minutes) (p < 0.001). This indicates superior postoperative analgesia with dexmedetomidine. Rahimzadeh et al. (2018) [9] and Routray et al. (2015) [15] also reported delayed analgesic requirements with dexmedetomidine, consistent with our findings. The mechanism involves dexmedetomidine's α 2-adrenergic agonist activity, which suppresses nociceptive transmission in the dorsal horn and enhances analgesic effects (Kanazi et al., 2006) [12].

The adverse event profile in our trial was benign, with few complications observed. Bradycardia was observed in 12.5% of patients in the fentanyl group, while no cases were seen in the dexmedetomidine group and control group (p = 0.015). Hypotension occurred in 6.2% of patients in the fentanyl group and 3.1% of the control group patients, with no instances observed in the dexmedetomidine group (p = 0.356). Routray et al. (2015) [16] also reported no remarkable difference between the incidence of bradycardia, hypotension, nausea, vomiting, and pruritus between the dexmedetomidine and the fentanyl groups. However, few studies, like Nayagam et al. (2014) [11], indicated marginally increased rates of hypotension and bradycardia with the use of dexmedetomidine, which necessitates careful monitoring of patients.

Our study strongly verifies the greater efficacy of dexmedetomidine relative to fentanyl and bupivacaine by themselves to produce more rapid onset, deeper block level, longer duration of block, and superior postoperative pain relief. However, differences between studies in adverse event occurrence illustrate the role of patient-specific factors and dosing protocols. It is a study limitation that ASA III and ASA IV patients, the more highly risk-popula-

tions, could not be studied because of our study design of making contact with practicing anesthesiologists, and that sedation scores were not collected and would be valuable information concerning the action of the dexmedetomidine as a sedative.

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In summary, dexmedetomidine is superior to fentanyl as an intrathecal adjuvant when bupivacaine is used for spinal anesthesia by virtue of faster onset, longer sensory and motor blockade, and better postoperative pain relief with few side effects. These observations are parallel with some of the foregoing studies and validate the increasing popularity of the usage of dexmedetomidine in a multisurgical scenario.

Conclusion

The study showed that both dexmedetomidine and fentanyl were effective intrathecal adjuvants to bupivacaine in spinal anesthesia, enhancing the quality of the block, although both agents had important differences in their respective properties and clinical profiles. Specifically, dexmedetomidine resulted in. overall, a longer duration of motor and sensory block, a delayed time to first rescue analgesia, and prolongation of postoperative analgesia compared with fentanyl and plain bupivacaine, demonstrating a beneficial effect on prolonged analgesia and reduced additional analgesic requirements. Fentanyl also objectively improved block quality compared with plain bupivacaine but was associated with faster block onset and earlier recovery, making it suitable for surgical procedures of short duration where early postoperative mobility was the aim. Hemodynamic parameters were generally stable in all groups, although dexmedetomidine was associated with bradycardia. Clinicians must use caution and monitor patients when using dexmedetomidine due to the recognition of bradycardia. Overall, dexmedetomidine demonstrated more of an advantage as an adjuvant for prolonged analgesia and characterized enhancement of spinal anesthesia, whereas fentanyl was an advantage for quick recovery from spinal anesthesia for surgical procedures with shorter duration. In summary, since the importance of the adjuvant should relate to its use being appropriate to the duration of the surgery and tailored to the experience of the individual patient, it is taken to illustrate the value of recognizing important differences and tailoring the adjuvant selected to the method of surgery and individual patient.

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