Original Article

Effect Of Dexmedetomidine Added To Intrathecal Hyperbaric Bupivacaine Versus Bupivacaine Alone On Mean Postoperative Analgesia After Spinal Saddle Block

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Abstract

Objective: Spinal saddle anaesthesia is the most prevalent method for perineal surgeries. Dexmedetomidine, a unique medication that acts on α2-adrenergic receptors in the spinal cord, relieves pain. The goal is to assess the efficacy of intrathecal dexmedetomidine in combination with bupivacaine.

Methods: A total of 60 patients undergoing elective uncomplicated peri anal surgeries were included in the study. 30 patients were in the 0.75% hyperbaric Bupivacaine group (Group A) and 30 patients were in the 0.75% hyperbaric Bupivacaine with Dexmedetomidine 5 mcg group (Group B). Intensity of pain was analysed through the Visual analogue pain score VAS which was described to the patients on a scale from 0-10 (No pain to severe pain). Mean analgesia duration was measured from time 0 of SSB until the patient asked for additional pain killers (VAS score >4).

Results: The mean duration of surgery was 29.866±1.87 minutes in group A and 28.866±2.06 minutes in group B. Motor block was of lesser duration in group A (152.90±9.09 minutes) as compared to group B (203.00±18.95 minutes) with $p<0.05$. Mean analgesia duration was significantly prolonged in group B (630.66±78.50 minutes) versus group A (325.33±36.67 minutes) with a statistically significant p-value. ($p<0.05$) Postoperatively, a lower frequency of painkiller demands was made by group B patients in 24 hours. ($p<0.05$)

Conclusion: In SSB, Dexmedetomidine added to Bupivacaine intrathecally increases the duration of analgesia postoperatively.

Keywords: Dexmedetomidine, Bupivacaine, Spinal saddle block.

Contributions:
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SF, MK - Acquisition, Analysis, Interpretation
MSBF, SF, MK - Drafting
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Introduction

The most popular anaesthetic method for adult peri-anal operations is saddle spinal block (SSB). When seated patients get moderate intrathecal injections of hyperbaric local anaesthetic, sympathetic block is relieved, enabling earlier ambulation.[1] Nevertheless, it does not result in long-term analgesia, particularly when a local anaesthetic is the only medication utilised. To enhance the effectiveness and duration of pain treatment, a variety of intrathecal adjuvants, such as opioids and benzodiazepines, etc. are employed. Although intrathecal opioids prolong analgesia, they are not suitable for general use due to their negative effects, such as pruritus and respiratory depression.[2-7] Selective alpha-2 adrenoceptor agonist Dexmedetomidine has been administered intravenously to treat pain, however, its intrathecal use is more effective.[8] When injected intravenously with a local anaesthetic, Dexmedetomidine is thought to prolong analgesia via binding to pre-synaptic C-fibres and post-synaptic dorsal horn nuclei in the spinal cord. Lipophilicity may explain why these drugs have additive or synergistic effects on the effects of local anaesthetics.[9,10] Saddle spinal block is the most widely utilised anaesthetic technique for adult peri-anal procedures (SSB). However, no local clinical trials regarding intrathecal administration of Dexmedetomidine in saddle block have been done.

Materials And Methods

This is a cross-sectional prospective study conducted from 1st July 2024 to 31st December 2024, which employs a non-probability consecutive sampling technique after taking approval from the Ethical Review Committee. The study included 60 patients (30 in each group) from the department of Surgery at PAF Hospital Mushaf Sargodha who were on the elective list for perianal operations and met the inclusion criteria. Each patient provided a detailed history as well as a written informed consent. Using the lottery approach, the patients were then randomly separated into two groups. Thirty patients were given 0.75% hyperbaric Bupivacaine (Group A), and thirty patients were given 0.75% hyperbaric Bupivacaine and Dexmedetomidine (Group B).

Group A: 4mg Intrathecal 0.75% hyperbaric Bupivacaine.
Group B: 4mg Intrathecal 0.75% hyperbaric Bupivacaine, followed by 5 mcg Dexmedetomidine.
Patients with age 18-65 years of either gender, with ASA grade I and II, without any known comorbid such as liver or kidney disease, scheduled for outpatient elective perianal surgery including hemorrhoids, anal fistula, anal polyps etc, were included in the study. Patients with contraindications to spinal anaesthesia [patient's refusal, local infection, coagulopathy (D-dimer, TAT and PPIC 12.0 µg/ml, 11.0 ng/ml and 1.8 µg/ml, respectively, on lab test), severe hypovolemia (1500 to 2000 ml, blood loss during procedure), aortic or mitral stenosis], morbid obesity, bleeding disorders, mental health problems, language barrier, taking psychotropic or analgesic medication, history of allergic/ hypersensitivity reactions to amide local anaesthetics or dexmedetomidine, patients on alpha or beta blockers, anti-arrhythmic or calcium channel blocker, patients on anti-coagulants were excluded from the study.
Consenting patients were randomly allocated into Group A (intrathecal Bupivacaine) or Group B (intrathecal Bupivacaine + Dexmedetomidine) using a computer-generated randomisation list. The entire randomisation sequence was generated before enrollment of the first participant. Allocation was blinded by sequentially numbered sealed opaque envelopes that were opened at the time of randomisation. A staff member who did not participate in the study organised and kept the randomisation code until study completion. Patients, anesthesiologists, obstetricians and researchers were blinded to the group assignments.
Following thorough aseptic procedures, all patients received saddle spinal anaesthetic by midline route in sitting posture. The intervertebral gap between L3 and L4 vertebrae was identified, and a lumbar puncture with a 25-gauge spinal needle was done. The free flow of CSF was evaluated before administering the medication according to group allocation. After the injection, the patient was instructed to stay seated for the next ten minutes with the assistance of a nurse, while blood pressure, heart rate, and oxygen saturation were measured using a non-invasive blood pressure monitor and a pulse oximeter, respectively. A single anesthesiologist conducted all lumbar punctures. The time of induction of spinal saddle block SSB was recorded as the time of SSB and was set to zero. The Pinprick technique was used to test the onset of sensory block, while the Bromage scale was used to assess motor block onset. The pinprick technique is graded as 0 for no feeling, 1 for mild pain, and 2 for extreme pain. To evaluate the onset of motor block, the modified Bromage scale was used, where 2= total hip flexion, 1= partial hip flexion and 0= no flexion at the hip region. Surgery was permitted after it was determined that the sensory and motor block of the perianal region was adequate. The Visual analogue scale was used to measure patients' perceptions of pain, ranging from 0 to 10 for pain severity (0= no pain, and 10= worst pain conceivable). The mean duration of analgesia was recorded from the start of the spinal saddle block until the visual analogue pain score reached 4 or above and the first painkiller was requested (Rescue Analgesic Demand).
Hemodynamic parameters such as blood pressure, heart rate, oxygen saturation, and respiratory rate were measured, and any adverse symptoms such as hypotension (a systolic blood pressure drop of more than 20% from baseline), bradycardia (a heart rate of less than 50 beats per minute), hypoxemia (an oxygen saturation of less than 90%), and nausea and vomiting were treated accordingly. The patients got discharged immediately after surgery in cases of daycare surgery, and they were then followed up for 24 hours post-operatively by phone call for the amount of analgesics taken after the operation. In case of ICU admission, the surgical ICU staff recorded the frequency of painkillers demanded over 24 hours post-operatively.
Sample size was calculated with the help of the WHO sample size calculator, taking a confidence level of 95%, a power of the test of 80%. Mean ±S.D of analgesia duration is 284.24 +58.38 minutes for group A and 501.35 +306.46 minutes for group B.[1] The number of patients to be included was 60 (30 patients in each group). 30 patients were in the 0.75% hyperbaric Bupivacaine group (Group A) while 30 patients were in the 0.75% hyperbaric Bupivacaine with Dexmedetomidine 5 mcg group (Group B). Data was analysed using a statistical analysis tool (IBM-SPSS V-23). For quantitative variables such as age, BMI, and ASA classification grade, the Mean +sd was calculated. Frequency was computed for qualitative variables such as gender. An independent sample T test was applied to compare sensory and motor block duration in both groups and the VAS score of both groups at initial analgesic demand and at 24 hours after surgery. $P< 0.05$ was considered statistically significant.

Results

Saddle spinal block was possible for all patients, and no rescue analgesic or general anaesthesia was necessary intraoperatively. No patient had leakage of the original administered dose while changing syringes for injecting the study drug. The study included 30 patients in each of Groups A and B. Regarding age, BMI and ASA classification grade, the groups were similar. See Table 1. The duration of surgery did not differ significantly. See Table 2. The mean duration of surgery was 29.533±1.79 minutes in group A and 29.200±2.23 minutes in group B. Motor and sensory block were of lesser duration in group A (151.533±9.24 and 338.866±34.48 minutes) as compared to group B (189.466±5.90 and 559.533±18.81 minutes) with $p<0.05$. When Dexmedetomidine was added to bupivacaine, the duration of analgesia was greatly extended vs bupivacaine alone (662.266±12.41 minutes in group B vs 403.533±15.82 minutes in group A) with $p<0.05$.

Table 1: Demographics of patients in both groups n=60

Demographics	Mean±SD Group A n=30	Mean±SD Group B n=30	P value
Age (years)	38.933±10.94	42.166±10.71	0.252
Gender (male: female)	17:13	16:14	1.000
ASA status (I: II)	18:12	17:13	1.000
BMI (Kg/m2)	25.293±1.82	25.026±1.81	0.572

Table 2: Comparison of characteristics of anaesthesia in both groups

Anesthesia characteristics	Mean±SD Group A n=30	Mean±SD Group B n=30	P Value
Duration of surgery (minutes)	29.533±1.79	29.200±2.23	0.527
Sensory block duration (minutes)	338.866± 34.48	559.533± 18.81	<0.001
Motor block duration (minutes)	151.533±9.24	189.466±5.90	<0.001
Mean analgesia duration (minutes)	403.533±15.82	662.266±12.41	<0.001

Table 3: Comparison of post-operative pain and analgesia characteristics in both groups n=60

Post-operative pain and analgesia characteristics	Mean±SD Group A n=30	Mean±SD Group B n=30	P value
VAS pain score at Rescue Analgesic Demand	4.466± 0.50	3.366± 0.49	<0.001
Frequency of pain killers demanded in 24 hours	2.466± 0.62	1.900± 0.48	<0.001

Table 4: Complications occurring after giving a block n=60

Complications	Group A n=30 (%)	Group B n=30 (%)	P Value
Nausea and vomiting	1 (3.3%)	1 (3.3%)	
Bradycardia	0	2 (6.6%)	
Hypotension	1 (3.3%)	2 (6.6%)	0.624
Shivering	3 (10%)	2 (6.6%)	
No complications	25	23	

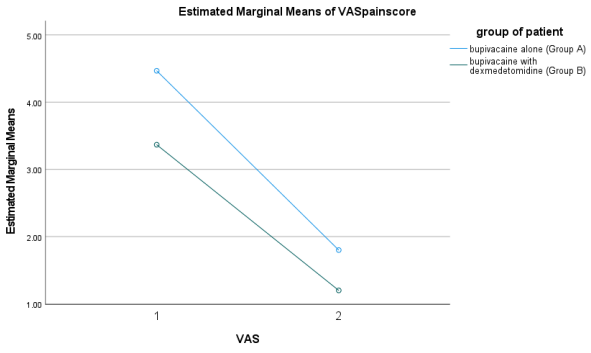

Figure 1: Plotting of VAS pain scores at the time of Rescue analgesic demand and 24 hours postoperatively in both groups of patients

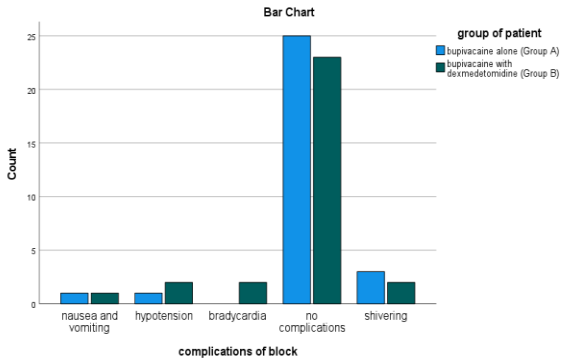

Figure 2: Complications of block

Up to 24 hours postoperatively, group B's maximum VAS score was lower than group A's. Group B experienced far longer periods of analgesia and used significantly less analgesics. See Table 3 and Figure 1. The 60 patients experienced no significant side effects, such as drowsiness, itching, or pruritus. Atropine 1 mg IV was effective in treating bradycardia (HR <50/min) in two of group B's patients. Phenylephrine was given to overcome hypotension in patients of both groups. Antiemetics were given due

to nausea and vomiting intraoperatively in one patient of both groups A and B, respectively (p=0.624). At the postoperative follow-up, no patient reported any temporary neurological symptoms, post-dural puncture headache, or lasting neurological deficits. See Table 4 and Figure 2.

Discussion

According to our study, administering five mcg of intrathecal adjuvant Dexmedetomidine in addition to four mg of hyperbaric Bupivacaine in SSB significantly sustained analgesia while decreasing analgesic demand. This finding is consistent with previous research, however, they used higher doses of local anesthetic.[11] Our study has shown that adding Dexmedetomidine to a modest dosage of Bupivacaine greatly prolonged analgesia. Our Dexmedetomidine group's data dispersion, which has a higher standard deviation, is in line with another research that discovered notable participant heterogeneity.[12] The reason seems to be our finding that two of the group's patients did not need analgesics for a full day.

Spinal anesthesia is often suitable for short term lower abdominal procedures such as perineal surgeries, transurethral resection of prostate TURP and cesarean section etc. A typical dosage of bupivacaine combined with an adjuvant may result in moderate hypotension during TURP procedure, but in older patients, the same quantity may reach the mid-thoracic level and block the sympathetic ganglia, resulting in severe and irreversible hypotension.[13,14] Dexmedetomidine has been added to intrathecal bupivacaine (10–15 mg) in several clinical trials, which has resulted in hemodynamic instability. Consequently, a lower dosage of bupivacaine can overcome that problem and so, according to research by Kim JE et al., combining three mcg of Dexmedetomidine with six mg of Bupivacaine caused a faster onset of maximal sensory block—eight minutes as opposed to ten. After surgery, three patients in group A were given antiemetic medication to treat their nausea (p=0.443). However, there was no statistically significant difference in the mean time until the first self-void (group B, 366.60 ± 77.27 min; group A, 331.33 ± 62.13 min) (p=0.101).[15] Devanad et al. also discovered that analgesia lasted 321 and 459 minutes, respectively, when they administered 0.5% hyperbaric bupivacaine 6 mg to both groups and 5 micrograms of dexmedetomidine to the study group. Difference in the concentration of Bupivacaine is probably the reason for substantial departure of the study's results from the results of our study.[16]

In our study, the frequency of postoperative analgesic usage was dramatically decreased by Dexmedetomidine. This finding aligns with the findings of Gupta et al., who found that Dexmedetomidine decreased the use of analgesics by 64% over the course of a day.[17] In our study, VAS at the time of the initial analgesic request and after 24-hours showed similarities, suggesting consistent pain treatment; nevertheless, it was based on the judgment of surgeons, which is typical clinical practice.

During our study, spinal saddle block SSB was very effective in preventing bradycardia and hypotension. The main goal of SSB is to target the sacral nerve roots with a small intrathecal drug solution, the spread of which is mainly governed by gravity and baricity.[17] Low-dose spinal anesthesia from spreading is prevented by good posture and cautious injection technique. The protocol stated that each person in our study received a two-minute injection while they sat for ten minutes.

The lowest effective dose of bupivacaine for SSB is 4- 7.5 mg; therefore, we used 4 mg.[18] The lipophilic nature of Dexmedetomidine, its low dosage, and its administration technique may have contributed to the lack of an increase in the degree of motor block, the number of blocked dermatomes, and peak sensory block. This contributes to the explanation of why the groups' urine retention and time to void are the same. These findings, however untested, would suggest intrathecal Dexmedetomidine has no detrimental effects on ambulation or discharge time.

This anesthetic technique does not require complicated technology or skill, nor does it require close supervision due to the low chance of serious adverse consequences. It may, therefore, be advantageous for this surgical population, who has the worst pain during the first few days following surgery. Furthermore, the dose-dependent effects of intrathecal Dexmedetomidine remain stable between 3 and 10 micrograms.[19,20]

Conclusions

Intrathecal Dexmedetomidine given as an adjuvant to hyperbaric bupivacaine in saddle spinal block during elective peri-anal surgery in adults prolongs analgesia and reduces postoperative analgesic demand without producing any appreciable side effects. Limitations of our study was that many patients were left out because of their age, the usage of anti-hypertensive medications, and the preference of surgeons for prone placement. With the growing number of elderly and hypertensive people, this is a serious disadvantage, and further study including geriatric population is required.

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