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Original Research Article

A Comparative Study: Dexmedetomidine (5 micrograms) as an Adjuvant to Intrathecal Bupivacaine in Infra-Umbilical Surgical Procedures

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Abstract:

Background: To compare the safety and efficacy of a spinal anesthetic agent hyperbaric bupivacaine 0.5% combined with 5 µg dexmedetomidine and 0.5% hyperbaric bupivacaine during infra-umbilical procedures. Several variables, including variations in hemodynamic parameters, the requirement for rescue analgesia, and the onset and duration of sensory and motor blockade were carefully assessed.

Methods: The study comprised 110 ASA I & II patients (18-50 years) going through elective infra-umbilical surgery at a tertiary care hospital. Each subject was randomly assigned to one of two groups: Group I received bupivacaine alone, whereas Group II received bupivacaine plus dexmedetomidine. For spinal anesthesia, Group I was given 15 mg of 0.5% hyperbaric bupivacaine, and Group II was given the same dosage plus an additional 5 µg of dexmedetomidine. All the parameters such as the duration and commencement of the blockage, hemodynamic parameters, and the requirement for rescue analgesia.

Results: Baseline characteristics were comparable. The onset of sensory/motor blockade did not differ significantly. However, Group II exhibited significantly prolonged sensory (238.09±47.77 minutes) and motor blockade (220.35±38.07 minutes) than Group I. Rescue analgesia time was delayed in Group II (279±54.58 minutes). No significant Variations were noted in heart rate systolic/diastolic blood pressure. No postoperative nausea or vomiting occurred.

Conclusion: Spinal anesthesic 0.5% hyperbaric bupivacaine was found to be able to prolong sensory and motor blockage, delay the requirement for rescue analgesia, and sustain hemodynamic stability when combined with 5 µg dexmedetomidine, all without raising the risk of side effects. These findings imply that analgesia's quality has increased. To validate these results, more multicenter trials with bigger sample sizes are needed.

Keywords: Dexmedetomidine, Block, Spinal anesthesia, Intrathecal bupivacaine.

Introduction

On August 16, 1898, at the Royal Surgical Hospital, August Bier conducted the first spinal anesthesia, marking a significant advancement in the field of pain control. This procedure involved the administration of Cocaine directly into the spinal canal. [1,2] This pioneering procedure marked a turning point as the patient experienced no pain during the operation [3-5]. Spinal Anesthesia, characterized by its simplicity and efficacy, has become a preferred technique for lower abdomen surgeries and lower limbs. Offering rapid drug onset, reduced incision time, and enhanced postoperative care, it addresses the challenges associated with General Anesthesia (GA), such as respiratory and cardiovascular complications [6, 7]. Despite its advantages, Spinal Anesthesia has limitations, including insufficient pain relief in certain surgeries and complaints like backache and post-dural puncture headache [8-10].

To address these constraints, several adjuncts, including Fentanyl, Butyrphanol, Clonidine, and Dexmedetomidine, have been introduced. Dexmedetomidine, an Alpha 2 receptor agonist, has become notable for its ability to extend the duration of spinal blocks without causing substantial side effects [11, 12]. This study examines the safety and effectiveness of utilizing 0.5% hyperbaric bupivacaine and dexmedetomidine in conjunction with plain bupivacaine to give spinal anesthesia for procedures performed below the umbilicus. The major goals of the study are to evaluate changes in hemodynamic parameters, the onset and course of sensory and motor blockage, and the necessity of further analgesics.

Utilization of adjuvants in Spinal Anesthesia, especially Dexmedetomidine, represents a promising avenue for refining the technique and addressing its limitations. [13, 14] This study contributes to advancing our understanding of spinal anesthesia adjuvants, with potential implications for improving patient outcomes in surgical procedures.

Materials and Methods

The investigation was conducted at a Tertiary Care Centre in North Maharashtra, involving 110 patients scheduled for infraumbilical surgeries. Randomly assigned to Group I (plain 0.5% hyperbaric Bupivacaine) or Group II (0.5% hyperbaric Bupivacaine with Dexmedetomidine), participants were selected based on ASA I and II criteria. Informed consent, detailed explanations, and thorough clinical examinations were conducted. Pre-anesthesia, patients received Ringer's lactate, and vital signs were monitored using multipara monitors throughout the procedure.

Participant size- was of the total of 110 Patients, with two groups (I and II) of 55 each.

$n = (Z1-\alpha/2 + Z2-)^2 (\sigma s1\ 2 + \sigma s2^2)$

$(\text{Assumed difference})^2$

Where, α error = 1.96, β error = 0.84

$\sigma s1 = 16.6$, $\sigma s2 = 11.86$.

Assumed difference = 8.

Inclusion Criteria

- ✓ 18 -50 years.
- ✓ Patients belong to ASA I & II Physical Status.
- ✓ All patients are going through elective infra-umbilical surgery.
- ✓ Surgery Duration < 90 minutes.

Exclusion Criteria

- ✓ Pregnant women undergoing any surgery
- ✓ Patient with a History of allergy to the study drug
- ✓ Patients with coagulation problems and localized infections at the site of spinal anesthesia

Data Collection

In the data collection phase, patients meeting ASA I and II criteria for infra-umbilical surgeries were chosen based on inclusion-exclusion criteria. A Quincke spinal needle (25G) and a 24G hypodermic needle were used for spinal anesthesia, with drugs including Bupivacaine, Dexmedetomidine, ondansetron, and paracetamol. A multipara monitor, tuberculin syringe, and Visual Analog Scale (VAS) chart were employed. Spinal anesthesia was administered under aseptic conditions in the L3-L4/L2-L3 subarachnoid space. The patients were split into two groups by random assignment, with Group I receiving hyperbaric Bupivacaine alone and Group II receiving hyperbaric Bupivacaine + dexmedetomidine. It was determined how long and when sensory and motor blockages first appeared, as well as whether rescue analgesia was necessary.

Statistical Analysis

Categorical variables were portrayed as percentages and figures, while quantitative data were presented using both means±SD and median with interquartile range (25th and 75th percentiles). Non-parametric tests were employed for data not adhering to a normal distribution, with the Kolmogorov-Smirnov test determining normality. The statistical analysis utilized the Independent t-test for variables not meeting requirements and the Mann-Whitney Test for others. Qualitative variables underwent assessment through the Chi-square test. The study was conducted using SPSS version 25.0, and Microsoft Excel facilitated data entry. A significance criterion of <0.05 was employed for the p-value.

Ethical Approval

The study received approval from the Ethical Committee, and all participants provided written informed consent before participating in the study.

Results

The investigation took place at a tertiary care centre, encompassing 110 patients aged 18-50 years classified under the ASA. These patients were undergoing elective infra-umbilical surgery. Patients were divided into two groups at random: Group I (n=55) received Hyperbaric Bupivacaine (0.5%) 15mg with 0.1 ml normal saline, and Group II (n=55) received hyperbaric Bupivacaine (0.5%) 15mg with five mcg Dexmedetomidine. The distribution of age and gender was comparable between the groups (p values=0.589 and 0.303, respectively), as illustrated in Figure 1. Mean±SD of age (years) in Group I was 33.36±10.78, and in Group II was 32.49±9.29 without any discernible variations between them (p value=0.65).

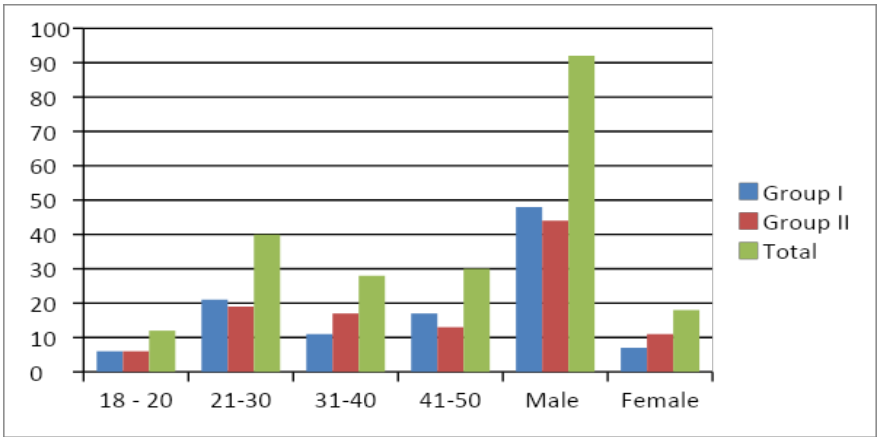

Figure 1: Comparing of Age/ Gender in group I and II

The distribution of ASA grade was comparable between Group I and II, with 65.45% and 60%, respectively, for Grade I and 34.55% and 40%, for Grade II (p value=0.554), as illustrated in Table 1.

Table 1: Comparison of group I and II's ASA grades.

ASA grade	I	II	Total	P value
I	36 (65.45%)	33 (60%)	69 (62.73%)	
II	19 (34.55%)	22 (40%)	41 (37.27%)	
Total	55	55	110	0.554

No statistically significant difference in heart rate (per minute) was noticed between Group I and Group II at baseline (p value=0.642), as demonstrated in Figure 2. Furthermore, there was not a noticeable distinction in systolic blood pressure (mmHg) at baseline (p value=0.167), as indicated in Table 2.

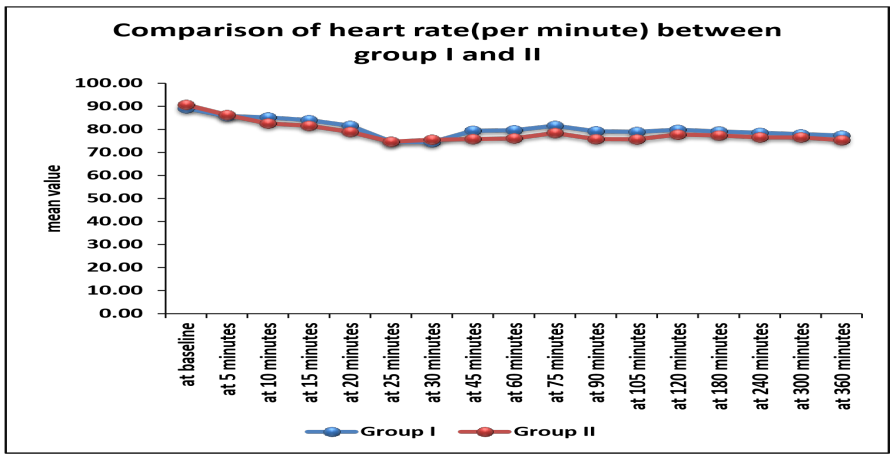

Figure 2: Comparison of trend of heart rate

Table 2: Systolic blood pressure comparison (mmHg) between groups I and II.

Systolic blood pressure (mmHg)	Group I (n=55)	Group II (n=55)	Total	P value
At baseline				
Mean±SD	136.02±12.6	133.02±9.85	134.52±11.36	
Median (25th-75th percentile)	138(132-142)	132(128-140.5)	136(128-142)	0.167†
Range	111-158	109-154	109-158	

Discussion

There was not a noticeable distinction between Group I and II in the study's measure of the beginning of a sensory block, which was measured from the intrathecal injection to the loss of pinprick feeling at the T10 dermatome (5.27+/-1.76 minutes) and Group II (5.04+/-1.94 minutes) (p=0.524). This finding contrasts with the study by S Patro, H Deshmukh et al. (2016), where Dexmedetomidine significantly accelerated sensory block onset compared to plain hyperbaric Bupivacaine [15]. Gupta M et al. (2014) found no discernible change in sensory block onset between Dexmedetomidine and Buprenorphine groups [16]. Furthermore, in our study, the onset of motor block was identified by measuring the interval between the injection and

attainment of complete motor block regression. (Brommage Score of 3) showed no statistically significant difference between Group I (4.28+/-2.11 minutes) and Group II (4.48+/-3.06 minutes) (p=0.682). This finding deviates from the observations of Patro (2016), who noted a significantly faster onset with Dexmedetomidine compared to plain Bupivacaine [15]. However, consistent with our study, Gupta and Shailaja (2014) found no discernible change in motor block onset between Dexmedetomidine and Buprenorphine groups [16].

These variations in onset times could be attributed to differences in study populations, drug doses, and specific methodologies across studies. It's important to consider these factors when interpreting and comparing study results. Mohamed Taznim et al. (2017) conducted a study on Dexmedetomidine, contrasting various hyperbaric Bupivacaine dosages for spinal anesthesia. They used 5mcg of Dexmedetomidine with doses of 7mg, 8mg, and 9mg hyperbaric Bupivacaine. The duration required for analgesia to begin (to reach the T10 sensory level) was slower. In Group A (9.7±1.088 min) compared to Group B (9.59±1.583 min) and C (8.90±1.709 min), notwithstanding the fact that No statistically significant variation was found (P=0.0831) [17].

The duration of sensory occlusion during the current trial varied statistically significantly among the two groups, as discovered. The length of the sensory block was measured from the moment the sensory level dropped to S1 until the T10 dermatome level was attained. Group I experienced a sensory obstruction lasting 187.2±36.88 minutes, while Group II experienced it for 238.09±47.77 minutes (P<0.0001). According to Patro, H. Deshmukh et al. (2016), Group II had a sensory block for a total of 317.70±16.16 minutes, while Group I had a block for a total of 188±11.86 minutes [15]. Milad Minagar et al. examined the effectiveness of intrathecal bupivacaine and dexmedetomidine for lower abdominal surgery in a 2018 publication. The Bupivacaine group's average length of the sensory block was 230±86 minutes, which was considerably less than the Dexmedetomidine + Bupivacaine group's average of 495±138 minutes ($p < 0.000$) [18].

Gupta Mahima, S Shailaja, et al. (2014) compared intra-thecal Dexmedetomidine with Buprenorphine as adjuvants to Bupivacaine in spinal anesthesia. In the Buprenorphine group, the length of sensory blockade was 225±64.94 minutes, but in the Dexmedetomidine group, it was 451.4±270.19 minutes (P=0.002). This suggests that Dexmedetomidine considerably extended the duration of sensory block in comparison to Buprenorphine. [16]. In our investigation, the length of the motor block was ascertained by timing the injection and the completion of the full motor block regression. (Brommage Score of 3). Group I had motor blockade for 179.45±43.79 minutes, while Group II experienced it for 220.35±38.07 minutes (P<0.0001). This aligns with the findings of Patro, H Deshmukh et al. (2016), where the total duration of motor block was 286.33±15.15 minutes in Group II (Dexmedetomidine + Bupivacaine) and 166.5±12.11 minutes in Group I (Bupivacaine) [15]. Gupta, S Shailaja (2014) further demonstrated that there were substantial differences in the length of motor blockage in the groups receiving buprenorphine and dexmedetomidine. [16].

In terms of postoperative pain, the NRS score was recorded 90 minutes after achieving the T10 sensory level, and rescue analgesia administration time was notably prolonged in Group II (279±54.58 minutes) compared to Group I (226.35±46.14 minutes, P<0.001) [19-21]. Similar findings were reported by Patro S, H Deshmukh et al. (2016), where the duration of analgesia was 333.6±20.67 minutes with Dexmedetomidine compared to 193±7.06 minutes in the Bupivacaine group [22]

Conclusions

The current clinical comparison study conclusion indicates that there are a number of advantages to combining 5 µg (0.1 ml) of dexmedetomidine with 0.5% hyperbaric bupivacaine (15 mg or 3 ml) for spinal anesthesia. These consist of extending the duration of the motor and sensory blockades. Additionally, there was an observed increase in the duration of analgesia and an improvement in its quality. Furthermore, the inclusion of Dexmedetomidine contributes to better hemodynamic stability during the procedure.

However, it's crucial to note that the study acknowledges the need for further research validation. The recommendation is for a multicenter, more extensive sample size investigation. This would help to confirm and strengthen the reliability of the current findings.

Summary

The study suggests that Dexmedetomidine is a potent adjuvant to Intrathecal Bupivacaine for spinal anesthesia, but further investigation is required for comprehensive confirmation.

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