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Intrathecal Dexmedetomidine Vs Intravenous Dexmedetomidine as Prophylaxis of Post-SpinalAnesthesia Shivering in Urologic Endoscopic Surgery – A Randomized Prospective Trial

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KEYWORDS
postspinal shivering prophylaxis, Intrathecal dexmedetomidine, intravenous dexmedetomidine, urologic endoscopic surgery, spinal anaesthesia

ABSTRACT:
Background: In the realm of urologic endoscopic surgery, which frequently encompasses procedures conducted under spinal anesthesia, the identification of efficacious strategies to mitigate the occurrence of post-spinal anesthesia shivering (PSAS) holds paramount significance.
The use of dexmedetomidine, a pharmaceutical drug that acts as an α2-adrenergic agonist, has become increasingly popular in the prevention of postoperative shivering and anaesthesia- induced shivering, both in intrathecal and intravenous route. The main aim of this study is to investigate the efficacy and safety of intrathecal dexmedetomidine in comparison to intravenous dexmedetomidine as a preventive measure against postoperative shivering and anaesthesia - induced shivering (PSAS) in urologic endoscopic surgery.
Methods: This randomized double blind study was carried out in patients posted for elective urologic endoscopic surgeries under spinal anaesthesia. A total of 60 patients were enrolled and arbitrarily split up into 2 groups: Group A and B. Spinal block was administered in both group under standard protocol.
Group A received Intrathecal 10mcg dexmedetomidine(0.1ml) + hyperbaric bupivacaine 0.5%(3ml) and intravenous 10ml saline immediately after block over 10min, Group B was given Intrathecal 0.1ml saline + hyperbaric 0.5% bupivacaine(3ml) and intravenous 0.75mcg/kg dexmedetomidine in 10ml saline immediately after block over 10min. Onset and duration of motor and sensory blockade, shivering incidence and scores, hemodynamic variables were recorded
Results: The present study demonstrates a notable decrease in the occurrence of post-spinal shivering at 15, 30, and 45 minutes among patients in the GROUP A as opposed to those in GROUP B (P=0.03 at 15mins, P=0.03 at 30mins, P=0.001 at 45mins). The incidence of shivering in group A was 12/30 patients(40%) compared with group B 23/30 patients(76%). The mean duration of the sensory and motor block of patients in GROUP A(208.67±14.98 mins and 180.07 ±13.06 mins) was more as compared to GROUP B(194.40±18.62 mins and 168.20±19.90 mins) and there was a significant difference between GROUP A and GROUP B(P=0.002 sensory block and P=0.008 motor block). There was no significant difference in hemodynamic variables between both groups.
Conclusion: We concluded that intrathecal dexmedetomidine has superior efficacy in controlling post-spinal shivering in immediate postoperative phase compared to intravenous route with no significant adverse effects.

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INTRODUCTION

Spinal anaesthesia, referred to as subarachnoid or intrathecal anaesthesia, is frequently utilized inurologic endoscopic surgery owing to its manifold benefits, including the provision of optimal operating settings, mitigation of systemic problems, and facilitation of expeditious postoperative recuperation. Nevertheless, the utilization of this particular methodology may lead to the occurrence of PSAS, hence causing significant suffering for both those receiving medical treatment and the healthcare professionals involved in their care. The occurrence of shivering during spinal anaesthesia not only induces discomfort but also carries the potential for unexpected sequelae, including heightened oxygen demand, instability in hemodynamics, and prolonged recovery from anaesthesia [(2)]. As a result, numerous treatments have been investigatedin order to avoid or effectively manage this illness.

The use of dexmedetomidine, a pharmaceutical drug that acts as an α2-adrenergic agonist, has become increasingly popular in the prevention of postoperative shivering and anaesthesia- induced shivering. With its sedative, analgesic, and sympatholytic effects, this substance presents itself as a compelling option for perioperative care. The two most often employed modes Spinal anaesthesia, also known as subarachnoid anaesthesia, is a medical technique commonly used in surgical procedures. It induces shivering that commonly manifests in the perioperative environment, particularly following the administration of spinal anaesthetic. The condition is distinguished by the presence of rhythmic involuntary contractions of skeletal muscles, primarily occurring in the limbs, leading to a perception of coldness and discomfort. The specific pathophysiological mechanisms that give rise to PSAS remain incompletely understood; nonetheless, multiple factors are known to contribute to its initiation [(4)]. Several crucial aspects encompass the redistribution of heat inside the body, the disturbance of typical thermoregulatory processes, and the impact of the sympathetic nervous system.

The leading factor attributed to the occurrence of PSAS is well acknowledged to be the physiological process of vasodilation that ensues subsequent to spinal Furthermore, the occurrence of PSAS can be influenced by environmental factors such as the temperature and humidity within the operating room, in addition to the aforementioned physiological considerations. In addition, many patient-related characteristics, including age, gender, and preoperative body temperature, may potentially have a role in the onset of PSAS.Hence, it is imperative to comprehend the multifaceted aspect of PSAS in order to formulate effective approaches for its prevention and treatment.

of administration for dexmedetomidine include intravenous and intrathecal methods. The process of intravenous administration entails the systemic transport of the medicine, whereas intrathecal administration involves the direct injection of the drug into the cerebrospinal fluid. Both methodologies possess their own advantages and disadvantages, and this comparative analysis has generated considerable attention among the medical fraternity [(5,13)].

The main aim of this study is to investigate the efficacy and safety of intrathecal dexmedetomidine in comparison to intravenous dexmedetomidine as a preventive measure against postoperative shivering and anaesthesia -induced shivering (PSAS) in urologic endoscopic surgery. In order to accomplish this objective, it is important to thoroughly examine the present comprehension of PSAS, the processes by which dexmedetomidine operates, and the available body of research pertaining to the various routes of administration for these substances. The thorough examination presented in this dissertation will establish a robust basis for subsequent research endeavours and the practical implementation of clinical interventions.

A comprehensive understanding of PSAS

anaesthesia. The spinal cord plays a crucial role in the thermoregulatory system, and any disruption in its regular functioning might result in the abrupt redirection of blood flow from the central regions to theperipheral tissues [(3)]. The change in blood circulation leads to a reduction in body temperature,resulting in the patient feeling cold and subsequently experiencing shivering.

The involvement of the sympathetic nervous system is of significant importance in the pathogenesis of PSAS. The surgical procedure and the administration of anaesthesia can elicit a stress reaction, leading to an increase in sympathetic outflow. The heightened sympathetic activity subsequently results in vasoconstriction and shivering. The occurrence of involuntary muscular contractions, commonly known as shivering, can lead to heightened oxygen consumption and elevated carbon dioxide levels. These physiological changes can potentially complicate the clinical management of the patient.

The Use of Dexmedetomidine as a Prophylactic Agent

Dexmedetomidine is a pharmacological agent characterized by its great selectivity as an α2- adrenergic agonist. The drug received approval from the Food and Drug Administration (FDA) in late 1999 for its application in human subjects within the intensive care unit (ICU) setting. Its designated purpose is to serve as a short-term medicine, with a duration of administration not exceeding 24 hours, primarily for the management of analgesia and sedation. The distinctive characteristics of this substance make it well-suited for the purpose of

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sedation and analgesia during the entire perioperative period [6,4]. The uses of this compound as a premedication, an anaesthetic adjunct for general and regional anaesthesia, and a postoperative sedative and analgesic are comparable to those of benzodiazepines. However, with closer examination, it becomes evident that the α2-adrenoceptor agonist exhibits a greater number of advantageous sideeffects. The introduction of dexmedetomidine at Baylor University Medical Centre occurred in August 2000. During the period spanning from that time to mid-October 2000, the aforementioned medication was administered to around 25 individuals, predominantly as an adjunct to anaesthesia in patients having cardiac interventions. Its mechanism of action involvesthe binding of dexmedetomidine to α2 receptors located in both the central and peripheral nervous systems. The distinctive pharmacological characteristics of this substance render it a compelling choice for perioperative administration. Dexmedetomidine provides sedative, analgesic, and sympatholytic effects, all of which may be advantageous in the prevention of PSAS.

The sedation caused by dexmedetomidine is frequently referred to as "cooperative sedation" dueto its ability to enable patients to sustain a specific degree of consciousness and collaboration, while concurrently Study was according to ethical principles for medicine research involving human subjects described in the Helsinki Declaration.

Thorough pre-anesthetic check-up was done one day prior to the surgery and informed written consent for participation in the study was taken. A total of 60 patients posted for urologic endoscopic surgery were enrolled. The patients were arbitrarily split up into 2 groups: Group A and B.

In the operation theatre, venous puncture was done with an 18 gauge cannula, and 500 ml of Ringer's lactate infused as preload. No premedication was given. 5 lead electrocardiogram (ECG), SPO_2, NIBP and temperature monitoring were performed. We recorded the SBP, DBP, heart rate (HR) and arterial oxygen saturation (SpO_2). The core temperature was monitored prior to the block, ensuring their comfort and relaxation. The aforementioned characteristic canoffer notable benefits in the context of urologic endoscopic surgery, wherein patients may necessitate the ability to react to precise stimuli during the course of the process.

Dexmedetomidine possesses an additional crucial characteristic, namely analgesic properties. Byexerting its effects on α2 receptors located in the dorsal horn of the spinal cord, it effectively suppresses the release of norepinephrine, thereby attenuating the transmission of pain signals.

This phenomenon is especially advantageous in the mitigation of PSAS, since the sensation of pain and discomfort represents one of the primary stimuli for the initiation of shivering.

METHODS

This was a randomized double blind study carried out in patients posted for elective urologic endoscopic surgeries using intrathecal and intravenous dexmedetomidine for post-spinal shivering. Following approval by the Institutional Ethics Committee, Rohilkhand Medical College and Hospital, Bareilly, 60 patients were randomly divided in two groups in 1:1 allocation ratio, each comprising 30 patients. Consent and approval of patients for participation in study was taken.

promptly following the block and every 15min for 4hr after the block. Under all aseptic techniques, Spinal block was administered at the L2-L3 intervertebral space with a 26- gauge spinal needle in sitting position.

Group A: Intrathecal 10mcg dexmedetomidine(0.1ml) + hyperbaric bupivacaine 0.5%(3ml) and 10ml saline immediately after block over 10min

Group B: Intrathecal 0.1ml saline + hyperbaric 0.5% bupivacaine(3ml) and 0.75mcg/kg dexmedetomidine in 10ml saline immediately after block over 10min

The onset and duration of the motor & sensory blockade was assessed by the Modified Bromage scale and pinprick test (24-gauge hypodermic needle), respectively, observation was continued until the sensory block had regressed to S1 dermatome level and complete motor blockregression. The block level was evaluated to make sure that it is between T10-T8.

The motor block was assessed using the Modified Bromage Scale [4]. (Table 1)

Grade	Criteria	Degree of block
0	Able to lift legs against gravity	Nil (0%)
I	Knee flexion decrease but full flexion of feet and ankle	Partial (33%)
II	Unable to flex knees, but flexion at ankle and feet present	Almost complete (66%)
III	Unable to flex knee or ankle or move toes	Complete (100%)

Patient was draped, and all the irrigation and IV fluids were maintained at room temperature (kept at 24 °C). A blinded observer recorded the frequency and intensity of shivering after the block is administered, every five minutes for the first 15 minutes, and then every 15 minutes for the next four hours using the Crossley and Mahajan scale [2](Table 2)

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Grade	Description
0	No shivering.
1	Despite the absence of any discernible muscular action, there may be peripheralcyanosis, piloerection, or peripheral vasoconstriction (other causes excluded).
2	Muscle activity confined to only one muscle group.
3	Moderate movement of several muscle groups, but no generalized shaking
4	violent muscle contractions that affect the entire body.

The sedation level was observed and recorded every 30 min for 4hr using the Ramsaysedation scale [(4)].(Table 3)

Sedation Score	Response
1	The patient is agitated and nervous, or both
2	Patient is obedient, oriented, and at ease
3	Patient responding to the commands only
4	Patient responding quickly to a loud auditorystimulation or a mild glabellar tap
5	Patient responding slowly to a loud auditorystimulation or a gentle glabellar tap
6	Patient exhibiting no response

The patients were monitored for complications.50mg of Tramadol was kept ready for patients with shivering of grade 2 or more. Bradycardia (HR <50) was planned to be treated with a bolus of 0.4mg of atropine, and hypotension (20% reduction in SBP from baseline) with gradualinjection of 6 mg of Mephentermine and 200 ml of Ringer's lactate solution. 10 mg of metoclopramide to relieve nausea and vomiting. Following surgery, patients were moved to the post-anesthesia care unit (PACU), where they were watched over and given a cotton sheet to cover themselves.

STATISTICALANALYSIS

In our study a total of 60 patients were included which were statistically calculated by using thesoftware, power and sample size program G power version 3.1. The sample size calculated in each group is 30. Descriptive statistics was performed by calculating mean and standard deviation for the continuous variables. Nominal categorical data between the groups were compared using chi-square goodness-to-fit test.

The software used for the statistical analysis was SPSS (statistical package for social sciences)version 23.0. The **p-value** was taken significant when less than 0.05 **(p<0.05)** and Confidenceinterval of 95% was taken.

RESULTS

The two groups were comparable regarding age, weight, gender and hemodynamic variables(HR, SBP, DBP, MAP). Mean time of onset of motor and sensory block between two groups were not significant. T6 was the most common peak height for the sensory block in 21 patients in Group Aand 23 patients in Group B. The mean duration of the sensory block of patients in Group B was 194.40±18.62 minutes and in Group A, it was 208.67±14.98 minutes. the mean duration of the Motor block of patients in Group B was 168.20±19.90 minutes, and in Group A, it was 180.07±13.06 minutes. The mean duration of the motor and sensory block of patients in Group Bwas less as compared to Group A and there was a significant difference between Group A and B. Incidence of post spinal shivering in group A and B at 15, 30 and 45mins are 7, 5, 0 and 11, 9, 3 patients respectively. There was significant difference in post spinal shivering after 15,30 and 45mins between group A and B(P value 0.03, 0.03, 0.001).There was no post-spinal shivering in both groups after 60mins. Sedation scores at different time intervals between two groups were notsignificant

DISCUSSION

The study aimed to assess the preventive effectiveness of intravenous (IV) and intrathecal (IT) administration of dexmedetomidine in managing post-spinal anaesthetic complications. The effectiveness of current preventive treatments varies, leading to the investigation of new interventions such dexmedetomidine, which is a specific α2-adrenergic agonist recognized for its calming and analgesic effects.

The average age, distribution of gender, and weight were similar between the IV and IT groups, suggesting that any disparities in results are more likely to be caused by the method of dexmedetomidine administration rather than by differences in demographics.

The characteristics of sensory and motor block offer useful insights into the pharmacodynamic profile of dexmedetomidine. Although the two groups shown comparable onset times for sensoryand motor block, the IV group demonstrated a noteworthy decrease in the duration of sensory and motor block. This finding implies that intravenous administration may offer a

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possible benefit in terms of creating a more precise and reversible blockade.

Table 1. Comparison of mean duration of sensory block in groups.

Duration of Sensory Block	N	Mean	Std. Deviation	P-Value
GROUP A	30	208.67	14.98	0.002*
GROUP B	30	194.40	18.62	(significant)

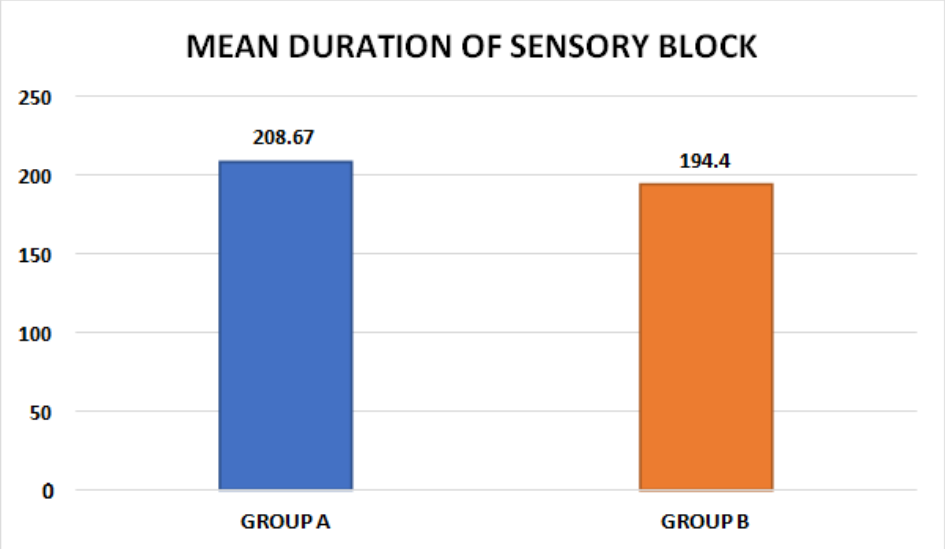
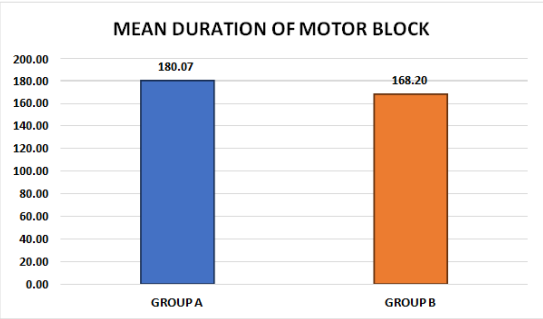


Table 2. Comparison of mean duration of motor block in groups.

Duration of Motor Block	N	Mean	Std. Deviation	P-Value
GROUP A	30	180.07	13.06	0.008*
GROUP B	30	168.20	19.90	(significant)



The evaluation of the safety and stability of the perioperative period is contingent upon the monitoring of hemodynamic indicators. Hemodynamic instability following spinal anaesthesia is a frequent occurrence during surgery. The observed heart rate, systolic and diastolic blood pressure, and mean arterial pressure values in both the intravenous (IV) and intrathecal (IT) groups at different time intervals demonstrate that both methods of administering dexmedetomidine efficiently maintained hemodynamic stability.

Postoperative shivering is a common and distressing complication that can occur after surgery under spinal anaesthesia. It can range in severity from piloerection to severe and continuous spasms of the skeletal muscles, affecting up to 50-80% of patients. In our study occurrence of post-spinal shivering, exhibited a notable disparity between the intrathecal (IT) and intravenous (IV) groups at 15, 30, and 45 minutes following the administration of the spinal block. Incidenceof shivering was (23/30) 76% in group B whereas only (12/30) 40% had shivering in group A. This discovery provides evidence in favour of the concept that the administration of dexmedetomidine by intrathecal means may be more efficacious in reducing shivering in the initial postoperative phase when compared to the intravenous route.

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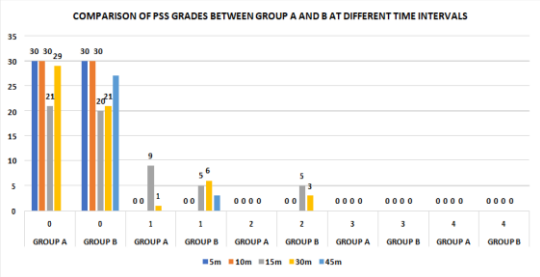
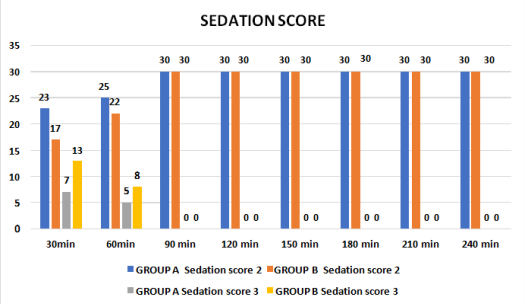
PSS	CROSSLEY AND MAHAJAN GRADE IN GROUP A				
Time (in min)	0	1	2	3	4
5m	30	0	0	0	0
10m	30	0	0	0	0
15m	21	9	0	0	0
30m	29	1	0	0	0
45m	0	0	0	0	0

PSS	CROSSLEY AND MAHAJAN GRADE IN GROUP B				
Time (in min)	0	1	2	3	4
5m	30	0	0	0	0
10m	30	0	0	0	0
15m	20	5	5	0	0
30m	21	6	3	0	0
45m	27	3	0	0	0





In group A 10 patients experienced grade 1 shivering. In group B 11 patients experienced grade 1and 8 patients grade 2 shivering. Shivering was of lower grades in both groups and no treatment was given .None of the patients experienced any adverse events like bradycardia, hypotension, nausea and vomiting.

In their investigation, **Mittal G et al**. observed Grade 3 shivering in all 50 participants who underwent different surgical procedures under spinal anaesthesia. The patients were divided into two groups, each consisting of 25 patients, and were assigned to receive either dexmedetomidine 0.5µg/kg or tramadol 0.5 mg/kg using a gradual intravenous bolus. There was no statistically significant disparity in the time it took for shivering to begin between the two groups. Nevertheless, the dexmedetomidine group exhibited a considerably shorter time delay between administering themedicine after the start of shivering and the end of shivering, in comparison to the tramadol group.

The sedation scores observed in the present study in IV and IT groups at various time intervals demonstrate that both administration methods achieved equivalent levels of sedation. This finding indicates that the sedative properties of dexmedetomidine were consistent regardless of the method of administration, underscoring its adaptability in attaining the intended amount of sedation without inducing undue drowsiness.

Notwithstanding the encouraging outcomes, it is imperative to realize the limitations inherent in this investigation. The limited sample size of the study may pose constraints on the extent to whichthe findings can be generalized. Additionally, the study's narrow focus on elective urologic endoscopic operations may restrict the relevance of the results to broader surgical scenarios.

CONCLUSION

The present study demonstrates a notable decrease in the occurrence of post-spinal shivering at 15, 30, and 45 minutes among patients in the intrathecal (IT) group as opposed to those in the intravenous (IV) group. This finding underscores the significance of route-specific differences in the administration of dexmedetomidine from a clinical standpoint. It implies that the use of intrathecal dexmedetomidine may offer superior efficacy as a preventive intervention in the immediate postoperative phase.

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