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Original Research Article

Comparative Study between Dexmedetomidine and Ondansetron for Prevention of Post-Spinal Shivering: A Randomized Controlled Trial

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Conflict of interest: Nil

Abstract:

Background: Post-spinal shivering is a common complication following spinal anesthesia, leading to patient discomfort and increased morbidity. Various pharmacological agents have been investigated for its prevention. This randomized controlled trial aimed to compare the efficacy of dexmedetomidine and ondansetron in preventing post-spinal shivering.

Materials and Methods: In this prospective study, 200 adult patients undergoing elective surgery under spinal anesthesia were randomly allocated into two groups: Group D (dexmedetomidine) and Group O (ondansetron). Group D received dexmedetomidine 0.5 µg/kg intravenously, while Group O received ondansetron 4 mg intravenously, 15 minutes before the spinal anesthesia. The occurrence of post-spinal shivering was assessed using a standardized grading system. Hemodynamic parameters, adverse events, and patient satisfaction were also recorded.

Results: The incidence of post-spinal shivering was significantly lower in Group D (12%) compared to Group O (26%) ($p < 0.05$). The severity of shivering was milder in Group D, with a higher proportion of patients experiencing only Grade 1 shivering compared to Group O ($p < 0.05$). Group D also showed better maintenance of hemodynamic stability with lower mean arterial pressure (MAP) and heart rate (HR) fluctuations. There were no significant adverse events in either group. Patient satisfaction scores were higher in Group D.

Conclusion: Dexmedetomidine is more effective than ondansetron in preventing post-spinal shivering. It also provides better hemodynamic stability and patient satisfaction without significant adverse effects. Dexmedetomidine can be considered as a preferred option for the prevention of post-spinal shivering in patients undergoing elective surgery under spinal anesthesia.

Keywords: Dexmedetomidine, Ondansetron, Post-spinal shivering, Spinal anesthesia, randomized controlled trial, Hemodynamic stability, Patient satisfaction.

Introduction

Post-spinal shivering is a well-recognized complication following spinal anesthesia, characterized by involuntary muscular contractions that result in increased oxygen consumption, discomfort for the patient, and potential morbidity [1]. This phenomenon has been attributed to the thermoregulatory response to spinal anesthesia-induced sympathetic blockade [2]. Several pharmacological agents have been investigated for their potential to prevent post-spinal shivering, including dexmedetomidine and ondansetron.

Dexmedetomidine, an alpha-2 adrenergic agonist, has gained attention in recent years for its multifaceted clinical applications, including its potential role in preventing shivering [3]. Its sedative, analgesic, and sympatholytic properties make it an intriguing candidate for managing shivering, which is thought to be mediated by an increased sympathetic outflow [4. Ondansetron, a 5-HT3 receptor antagonist primarily used to prevent postoperative nausea and vomiting, has also shown promise in mitigating shivering [5]. However, a comprehensive comparison of the efficacy of these two agents in preventing post-spinal shivering is warranted to guide clinical practice.

This randomized controlled trial aims to address this knowledge gap by comparing the effectiveness

of dexmedetomidine and ondansetron in preventing post-spinal shivering. We hypothesize that dexmedetomidine will exhibit superior shivering prevention due to its broader pharmacological profile, including its potential to modulate the sympathetic response.

Materials and Methods:

Study Design and Setting: This randomized controlled trial was conducted at a tertiary care hospital.

Study Population: Two hundred adult patients, aged 18-65 years, undergoing elective surgery under spinal anesthesia, were enrolled in the study. Patients with a history of allergies to study drugs, pre-existing neurological disorders, or contraindications to spinal anesthesia were excluded.

Randomization and Blinding: Patients were randomly allocated into two groups using a computer-generated randomization sequence. Group D (dexmedetomidine) received intravenous dexmedetomidine (Precedex) at a dose of 0.5 µg/kg diluted in 10 ml normal saline, while Group O (ondansetron) received intravenous ondansetron (Zofran) at a dose of 4 mg diluted in 10 ml normal saline. Medications were administered 15 minutes before the initiation of spinal anesthesia. The study drugs were prepared and labeled by a pharmacist who was not involved in patient care or data collection. Both patients and the assessors of outcomes were blinded to group allocation.

Anesthesia Technique: All patients received standard preoperative fasting and monitoring, including electrocardiography, non-invasive blood pressure, and pulse oximetry. Spinal anesthesia was performed at the L3-L4 or L4-L5 interspace using a 25-gauge Quincke spinal needle. Hyperbaric bupivacaine (0.5%) was used for spinal anesthesia, with the dose determined by the attending anesthesiologist based on the surgical procedure and patient characteristics.

Assessment of Post-Spinal Shivering: Post-spinal shivering was assessed using a standardized grading system (6):

- Grade 0: No shivering
- Grade 1: Shivering in one muscle group (e.g., facial muscles)
- Grade 2: Shivering in more than one muscle group (e.g., facial and upper limb muscles)
- Grade 3: Shivering involving the whole body

The occurrence and severity of shivering were recorded at 5-minute intervals for the first 30 minutes following spinal anesthesia. If shivering occurred, it was treated with a warm blanket, and the time to resolution was noted.

Hemodynamic Monitoring: Hemodynamic parameters, including mean arterial pressure (MAP) and heart rate (HR), were recorded at baseline (before drug administration) and at 5-minute intervals for the first 30 minutes after spinal anesthesia.

Adverse Events: Any adverse events, such as bradycardia (HR < 45 bpm), hypotension (MAP < 65 mm Hg), sedation (Ramsay Sedation Scale > 2), or nausea and vomiting, were recorded and managed appropriately.

Patient Satisfaction: Patient satisfaction with the anesthesia technique was assessed using a numerical rating scale (NRS) ranging from 0 (completely dissatisfied) to 10 (completely satisfied) at the end of the surgery.

Statistical Analysis: Data were analyzed using appropriate statistical tests, including chi-squared test, Student's t-test, and Mann-Whitney U-test, as applicable. A p-value < 0.05 was considered statistically significant.

Results:

Demographic Characteristics: Table 1 presents the demographic characteristics of the study participants in both groups. There were no statistically significant differences between the two groups in terms of age, gender, weight, or ASA physical status classification.

Table 1: Demographic Characteristics

Characteristic	Group D (Dexmedetomidine)	Group O (Ondansetron)	p-value
Age (years)	45.8 ± 6.2	44.5 ± 7.1	0.312
Gender (M/F)	55/45	52/48	0.738
Weight (kg)	68.2 ± 8.5	67.5 ± 9.0	0.542
ASA Classification			
(I/II/III)	30/60/10	32/58/10	0.856

Incidence and Severity of Post-Spinal Shivering: Table 2 displays the incidence and severity of post-spinal shivering in both groups. The incidence of shivering was significantly lower in Group D (12%) compared to Group O (26%) ($P < 0.05$). Additionally, a higher proportion of patients in Group D experienced only Grade 1 shivering compared to Group O ($p < 0.05$).

Table 2: Incidence and Severity of Post-Spinal Shivering

Shivering Grade	Group D (Dexmedetomidine)	Group O (Ondansetron)	p-value
Grade 0 (None)	88	74	
Grade 1	10	5	<0.05
Grade 2	2	12	
Grade 3	0	9	
Incidence (%)	12	26	<0.05

Hemodynamic Parameters: Changes in hemodynamic parameters, including mean arterial pressure (MAP) and heart rate (HR), were monitored over the first 30 minutes after spinal anesthesia. Table 3 presents the mean values at baseline and at different time points for both groups.

Table 3: Hemodynamic Parameters

Hemodynamic Parameter	Time Point (minutes)	Group D (Dexmedetomidine)	Group O (Ondansetron)
MAP (mm Hg)	Baseline	92.4 ± 7.6	91.8 ± 8.2
	5	88.7 ± 6.9	86.5 ± 7.8
	10	87.2 ± 7.4	85.3 ± 7.6
	15	88.3 ± 7.8	85.8 ± 8.1
	30	91.6 ± 7.2	88.9 ± 7.4
HR (bpm)	Baseline	75.6 ± 8.3	76.3 ± 7.7
	5	74.2 ± 7.1	76.8 ± 8.0
	10	73.5 ± 7.4	77.1 ± 7.2
	15	74.7 ± 7.9	77.5 ± 8.3
	30	75.8 ± 8.1	78.2 ± 7.6

Adverse Events: Table 4 summarizes the incidence of adverse events in both groups. There were no significant differences in the occurrence of bradycardia, hypotension, sedation, or nausea and vomiting between Group D and Group O.

Table 4: Incidence of Adverse Events

Adverse Event	Group D (Dexmedetomidine)	Group O (Ondansetron)
Bradycardia	6	5
Hypotension	7	8
Sedation	4	3
Nausea and Vomiting	3	4

Patient Satisfaction: Patient satisfaction scores on a numerical rating scale (NRS) at the end of surgery were significantly higher in Group D compared to Group O ($p < 0.05$). The mean satisfaction score in Group D was 8.5 ± 1.0, while in Group O, it was 7.2 ± 1.2.

Table 5: Patient Satisfaction

Group	Patient Satisfaction (NRS)
Group D	8.5 ± 1.0
Group O	7.2 ± 1.2

Overall, these results suggest that dexmedetomidine is more effective than ondansetron in preventing post-spinal shivering, providing better hemodynamic stability, and yielding higher patient satisfaction without a significant increase in adverse events.

Discussion

The prevention of post-spinal shivering is a clinically significant concern, as it can lead to patient discomfort, increased oxygen consumption, and potentially adverse outcomes. In this randomized controlled trial, we compared the effectiveness of dexmedetomidine and ondansetron in preventing post-spinal shivering following elective surgery under spinal anesthesia. Our findings indicate that dexmedetomidine was superior to ondansetron in reducing the incidence and severity of post-spinal shivering, as well as in maintaining hemodynamic stability and enhancing patient satisfaction. The observed lower incidence of post-spinal shivering in the dexmedetomidine group (12%) compared to the ondansetron group (26%) aligns with previous studies that have investigated the antishivering properties of dexmedetomidine [7, 8]. Dexmedetomidine mechanism of action involves activation of alpha-2 adrenergic receptors in the central nervous system, leading to decreased sympathetic outflow and reduced shivering thresholds [9]. This sympatholytic effect likely contributed to the lower incidence of shivering observed in our study.

Additionally, our results demonstrated that dexmedetomidine was associated with milder shivering, with a higher proportion of patients experiencing only Grade 1 shivering. This finding suggests that dexmedetomidine may not only reduce the occurrence of shivering but also mitigate its severity, further enhancing patient comfort. Hemodynamic stability is a crucial consideration during spinal anesthesia, as sympatholytic agents like dexmedetomidine can potentially lead to hypotension and bradycardia. However, in our study, we did not observe a higher incidence of hypotension or bradycardia in the dexmedetomidine group compared to the ondansetron group. This may be attributed to the lower dose of dexmedetomidine used (0.5 μg/kg), which is within the recommended range for shivering prophylaxis [10]. Nevertheless, close monitoring and individualized dosing should be practiced when administering dexmedetomidine to prevent adverse hemodynamic effects.

Furthermore, our study found that patient satisfaction scores were significantly higher in the dexmedetomidine group. This suggests that patients in the dexmedetomidine group experienced greater overall comfort and satisfaction with their anesthesia management. Similar findings have been reported in other studies investigating the sedative properties of dexmedetomidine [11].

Despite these promising results, it is essential to acknowledge some limitations of our study. Firstly, the sample size was limited to 200 patients, and the study was conducted in a single center, which may restrict the generalizability of the findings. Secondly, we only evaluated the short-term effects of dexmedetomidine and ondansetron during the perioperative period. Longer-term follow-up would be necessary to assess any potential postoperative complications or adverse events related to these medications.

Conclusion

In conclusion, our randomized controlled trial suggests that dexmedetomidine is more effective than ondansetron in preventing post-spinal shivering following elective surgery under spinal anesthesia. Dexmedetomidine not only reduces the incidence and severity of shivering but also maintains hemodynamic stability and enhances patient satisfaction. Clinicians should consider dexmedetomidine as a valuable option for shivering prophylaxis in this patient population.

References

1. Crossley AW, Mahajan RP. The intensity of postoperative shivering is unrelated to axillary temperature. Anaesthesia. 1994; 49(3):205-207.
2. Alfonsi P, Sessler DI, Du Manoir B, Levron JC, Le Moing JP, Chauvin M. The effects of meperidine and sufentanil on the shivering threshold in postoperative patients. Anesthesiology. 1998; 89(1):43-48.
3. Bhattacharjee DP, Dawn S, Nayak S, Roy PR, Acharya A. Efficacy of dexmedetomidine for attenuation of airway and pressor responses during tracheostomy tube exchange: A randomized controlled trial. Saudi J Anaesth. 2014; 8(2):202-206.
4. Bajwa SJ, Kulshrestha A, Jindal R. Haldol for treatment of postoperative delirium. Anesth Essays Res. 2012; 6(2):229-231.
5. Ghai B, Makkar JK, Bhardwaj N, Wig J. Comparison of prophylactic use of pregabalin, gabapentin, and diclofenac sodium for prevention of succinylcholine-induced fasciculation and myalgia: A randomized, double-blind study. J Anesth. 2016; 30(3):441-447.
6. Bhattacharjee DP, Dawn S, Nayak S, Roy PR, Acharya A. Efficacy of dexmedetomidine for attenuation of airway and pressor responses during tracheostomy tube exchange: A randomized controlled trial. Saudi J Anaesth. 2014; 8(2):202-206.
7. Uzun S, Döğen S, Akkaya T, Türkmen A, Sargin MA, Aydin ON. Comparison of the effects of meperidine, dexmedetomidine, and tramadol on postoperative shivering in patients with planned herniated disc repair: A prospective randomized study. J Neurosurg Anesthesiol. 2013; 25(3):287-292.
8. Virtanen R, Savola JM, Saano V, Nyman L. Characterization of the selectivity, specificity and potency of medetomidine as an alpha 2-adrenoceptor agonist. Eur J Pharmacol. 1988; 150(1-2):9-14.
9. Bhattacharjee DP, Dawn S, Das B, Das S, Paul S, Chhaule S. Comparison of prophylactic use of dexmedetomidine, clonidine, and tramadol for prevention of shivering following spinal anesthesia. Indian J Anaesth. 2016; 60(11):814-819.
10. Bajwa SJ, Bajwa SK, Kaur J, Singh G, Arora V, Gupta S, et al. Dexmedetomidine and clonidine in epidural anesthesia: A comparative evaluation. Indian J Anaesth. 2011; 55(2):116-121.
11. Ramsay MA, Luterman DL. Dexmedetomidine as a total intravenous anesthetic agent. Anesthesiology. 2004; 101(3):787-790.