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ORIGINAL ARTICLE:

Comparison Between Intravenous Weight-adjusted Ondansetron Dose and Dexmedetomidine in Preventing Shivering following Spinal Anaesthesia in Transurethral Resection of Prostate: A Randomized Controlled Study

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ABSTRACT

Background: Ondansetron and Dexmedetomidine are recently used effectively to prevent shivering following spinal anesthesia.

Objectives: This study compares the effects of weight-adjusted doses of Ondansetron and Dexmedetomidine in preventing post-spinal shivering and its subsequent hazards in cases who underwent elective transurethral resection of the prostate (TURP).

Methods: In this prospective randomized double-blind controlled trial, 132 ASA (I, II) patients who were scheduled to undergo TURP were divided into 3 equal groups (44 each): Control group: received 5 ml of normal saline (0.9%) intravenously after SA; Group D: received 1 ug/kg. Dexmedetomidine was intravenously diluted in 5 mL of normal saline after SA. Group O received (0.1 mg/kg) Ondansetron intravenously diluted in 5 mL of normal saline after SA. Shivering occurrences, intensity, and duration (primary outcome), hemodynamics and core temperature changes, sedation level, total consumed rescue pethidine, and intraoperative complications were evaluated.

Results: There was a statistically non-significant difference between Ondansetron and Dexmedetomidine as regard to shivering occurrences, intensity, and duration, while it was significant when compared to the control group. Hemodynamics showed a significant decrease in heart rate in Dexmedetomidine while compared to the Ondansetron and Control groups. Additionally, sedation levels were significantly higher in the dexmedetomidine group compared to other groups. However, there was a significant increase in total consumed rescue pethidine in the control group when compared to other groups. When compared to both the Dexmedetomidine and control groups, the Ondansetron group had a significantly lower risk of hypotension.

Conclusions: The prophylactic IV weight-adjusted dose of Ondansetron is as effective as IV Dexmedetomidine in reducing the shivering occurrences, intensity, duration, and total of rescue pethidine doses in patients undergoing TURP. The IV weight-adjusted dose of Ondansetron is associated with more hemodynamic stability compared to IV Dexmedetomidine, with fewer incidences of bradycardia and hypotension.

Keywords: Ondansetron; Dexmedetomidine; Transurethral resection of Prostate; Thermoregulation; Shivering; Spinal anesthesia.

INTRODUCTION

One of the risks of anaesthesia is postoperative shivering, which can have serious consequences for the patient's health. About 50–65% of patients recovering from general anaesthesia and 60% of patients undergoing regional anaesthesia experience it [1].

Prostate tissue can be resected by urethral endoscopy, a technique known as transurethral resection of the prostate (TURP). Spinal anaesthesia is widely used for this procedure, which remains the surgical treatment standard [2]. The 0.5 °C dip caused by intrathecal block causes vasoconstriction and shivering above the block level [3]. Shivering is also more likely during TURP due to age and the increased absorption of irrigating fluids [3–5].

Shivering following a TURP is an unpleasant, extremely uncomfortable, and common complication. Clinically, it's linked to clonic or tonic skeletal muscular hyperactivity at varying frequencies and increases metabolic heat generation by up to 600% over basal metabolic level. Production of carbon dioxide causes hypoxemia, hypercarbia, and lactic acidosis, all of which are not only unpleasant but also exacerbate pain. Catecholamine release also leads to elevated heart rate, blood pressure, and cardiac output [6].

The antiemetic drug ondansetron is a selective antagonist for the 5HT-3 (5-hydroxytryptamine 3) receptor. Statistical and meta-analysis studies show that it is helpful in preventing shivering and has a favorable safety profile [7]. And studies results favor a weight-adjusted dose of Ondansetron over fixed doses in controlling shivering [8]. The exact mechanism of action is still unclear, but several studies have shown that it has a central acting mechanism as anti-serotonin at the level of the hypothalamus, increasing the shivering threshold [9].

A strong α 2 adrenergic receptor agonist, dexmedetomidine (DEX), has been utilized as a sedative and has been shown to raise the shivering threshold [10]. Mechanisms of action are still under study, but theories suggest that highly selective action on alpha2 receptors in resetting the set point of thermal regulation in both hyperthermia and hypothermia is a suspected mechanism [11].

So, we aimed at this randomized clinical study for evaluation of the efficacy of an IV weight-adjusted dose of Ondansetron and IV DEX for reducing post-spinal shivering among cases who were undergoing TURP.

METHODS

After institutional review board approval of the IRB (9330-2-3-2022), written informed consent was obtained from all participants. The study was done according to the Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

This prospective randomized double-blind controlled study was carried out at Zagazig University Hospitals from May 2022 to March 2023.

The sample size was calculated by assuming that the incidence of post-spinal shivering was reduced by 88.1% in the Ondansetron group versus 95% in the Dexmedetomidine group. So, the sample size was 132 cases (44 cases in each group), the confidence interval was 95%, and the power of the test was 80%. The study included 132 male patients aged 41–86 years old, BMI ≤ 30 kg/m2, ASA I and II, who were scheduled for transurethral resection of the prostate under spinal anesthesia. Patients with a history of allergy to the studied drugs, chronic use of analgesics, receiving antiemetic 48 hours before surgery, contraindication of spinal anaesthesia, neuromuscular disease, or neurologic disturbance, receiving fluid more than 2 liters, and needing blood transfusion during surgery were excluded from this study.

All patients were scheduled for a visit to inform them about the entire process and outcome of the study, to discuss the pros and cons of the procedure, and to obtain informed written consent from each of the participating patients. Baseline vital signs were recorded, and a physical examination involved examining heart and lung symptoms and excluding contraindications. Investigations include a complete blood count (CBC), coagulation profile, liver function tests (LFTs), and kidney function tests (KFTs). Patients were kept

fasting for 6 hours for solid food and 2 hours for clear fluid before the surgery.

Intraoperative:

The operating room temperature was maintained at about 24–26 °C during the perioperative period. On arrival at the operative theatre, a 20G intravenous cannula was inserted in a peripheral vein, and all patients were preloaded with a 10 ml/kg warm lactated ringer's solution infused over 20 minutes prior to the spinal anaesthesia. Nurses who were not involved in patient care or data collection prepared all-warmed solutions. Routine monitors were applied to record heart rate (HR), electrocardiogram (ECG), mean arterial blood pressure (MABP), oxygen saturation value (SPO2), and basal readings.

Sedation level was assessed and recorded. Sedation was scored according to the Richmond Agitation Sedation Scale (RASS) from 0 to 5 [12].

The block was administered in the seated position using an aseptic approach, with 2.5 ml of 0.5 percent hyperbaric bupivacaine (12.5mg) and 25 ug of fentanyl injected into the L3/4 or L4/5 interspace. All patients were placed in the supine position and given 2 liters of oxygen per minute through a face mask as soon as the spinal anaesthesia was complete. After the T10 block was achieved, the patient was placed in the prone position for surgery.

Using computer-generated randomization tables, patients were randomly assigned to one of three groups (44 patients in each group):

Group C: patients (control group) received 5 mL of normal saline (0.9%) intravenously slowly by IV route over 5 minutes.

Group D: patients received (1 ug/kg) dexmedetomidine diluted in 5 mL of normal saline (0.9%) slowly by IV route over 5 minutes.

Group O: patients received (0.1 mg/kg) Ondansetron diluted in 5 mL of normal saline (0.9%) slowly by IV route over 5 minutes.

All the study drugs were given after the completion of the intrathecal block. Immediately after SA at 5 minutes and every 10 minutes during the surgical procedure, the data of mean arterial blood pressure (MABP), heart rate (HR), oxygen saturation (SPO2), and core body temperature were recorded till the end of surgery.

Hypotension (a decrease in MABP of more than 20% from the baseline) was managed by increments of 6 mg ephedrine IV; bradycardia (HR $\leq$ 50 bpm) was treated with 0.4 mg atropine sulphate IV; and intraoperative nausea and vomiting (IONV) was treated by metoclopramide 10 mg IV.

Bedside shivering was assessed using the Bedside Shivering Assessment Scale (BSAS) before SA and then every 10 minutes after SA until the operation ended [13, 14].

The intensity and duration of shivering were recorded. If shivering reached a score of 3 according to the shivering score for at least 3 minutes, prophylaxis was regarded as ineffective, and a therapeutic dose of 0.5 mg/kg IV pethidine was given as a rescue drug. Also, sedation level was recorded in the first 20 minutes after the studied drugs were introduced.

The patient was taken to the post-operative care unit (PACU) once surgery was finished, and the sedation level was documented there. Then the patient was transferred later to the ward, and the other parameters, such as MABP, HR, SPO2, core body temperature, and shivering (occurrence, intensity, and duration), were recorded at 30 minutes and 1 hour postoperatively.

Data collection:

For each patient, the following parameters were collected:

1. Age, body mass index (BMI), ASA status, duration of surgery, and amount of irrigating fluid throughout the surgery
2. Hemodynamics such as HR, MABP, and SPO2
3. Core body temperature, using a tympanic membrane temperature probe.
4. Shivering Assessment (primary outcome), using BSAS.
5. Sedation level, using RASS.

6. Intraoperative complications, such as complications related to surgery (TURP syndrome) (tachypnea, hypoxia, cyanosis, pulmonary oedema, headache, nausea, vomiting, confusion, and convulsion or coma), Complications related to anaesthesia include hemodynamic instability such as hypotension, bradycardia, and IONV.

Statistical analysis:

IBM's statistical analysis software, SPSS, version 20.0, was used to process the data [15]. Qualitative data was represented with numerical and percentage-based language. The Kolmogorov-Smirnov test was used to examine the data for its normal distribution. Quantitative information was summarized as the mean and standard deviation. ANOVA was used to see if there was a significant difference in means between more than two study groups. The means of any two groups can be compared using the post-hoc test. A Student t test was used to find out if there was a statistically significant difference between the groups. Chi-square and Fisher's exact tests were used to examine the relationship between two qualitative variables.

RESULTS

There were 155 individuals scheduled to undergo TURP with spinal anaesthesia. Twenty-three individuals were excluded because they either did not match study requirements (13 of them) or declined participation (10 of them). There was a total of 132 patients, and they were split evenly among three groups of 44. No statistically important differences were found between the three groups with respect to age, body mass index, analytic scoring system, operating room temperature, length of surgery, or irrigating fluid volume (Table 1).

There was statistically significant decrease in HR in the DEX group at 5 and 10 minutes after SA compared to the control and Ondansetron groups, with no significant difference between the two groups (Figure 1).

There was statistically significant decrease in MABP in the control group and DEX group at 5 and 10 min intraoperatively compared to the Ondansetron group, with no difference between the control and DEX groups. Also, at 20, 30, 40, and 50, there was a significant decrease in the control group after SA intraoperatively compared to the Ondansetron group (Figure 2).

No significant differences were observed in core temperature after induction of SA and all throughout the intraoperative measurement and postoperative periods, where p values were all > 0.05 between all three groups (Figure 3).

There was statistically significant increase in shivering occurrence at 40, 50, 60, and 70 minutes intraoperatively in the control group compared to the DEX and Ondansetron groups, with no significant difference between the latest groups. (Figure 4). Regarding the shivering score observed intraoperatively and postoperatively, there was a significant increase in the incidence of scores 2 and 3 in the control group compared to the DEX group and Ondansetron groups, with no significant difference between the latest groups (Figure 5).

There was a significant increase in the use of ephedrine boluses in the control group compared to the DEX group and the Ondansetron group. There was a highly significant increase in the use of atropine boluses in the DEX group compared to the control and Ondansetron groups. Furthermore, the most recent groups showed no statistically significant differences. Pethidine bolus administration was significantly higher in the control group than in the DEX and Ondansetron groups (Figure 6).

Table 1: Patient's characteristics and operative data among three studied groups.

Parameters		Groups			Test of significance p-Value
		Group C (N= 44)	Group D (N= 44)	Group O (N= 44)	
Age (years)		60.14 ± 9	62.7 ± 9.02	61.95 ± 4.28	0.514 [(a)]
BMI (Kg/m^2)		30.09 ± 3.09	29.82 ± 3.06	30.48 ± 3.28	0.615 [(a)]
ASA	**I**	28 (63.6%)	29(66.0%)	31(70.45%)	0.261 [(b)]
	II	16(36.36%)	15(34.0%)	13(29.55%)	
Duration of surgery (Minutes)		60.11 ± 11.99	59.75 ± 10.32	58.95 ± 13.05	0.896 [(a)]
Operating room temperature(°C)		24.91 ± 0.86	25.05 ± 0.83	25.07 ± 0.87	0.642 [(a)]
Volume of irrigating fluids (mL)		1642.12 ± 401.65	1453.02 ± 520.27	1536.96 ± 320.32	0.367 [(a)]

C: Control group; D: Dexmedetomidine; O: Ondansetron; BMI: Body mass index; ASA: American Society of Anesthesia; a: One-way Anova test; b: Chi-squre test (b)
Data were expressed as Mean ± SD and ASA was expressed as Number with percentage (%)
P>0.05: Non-significant.

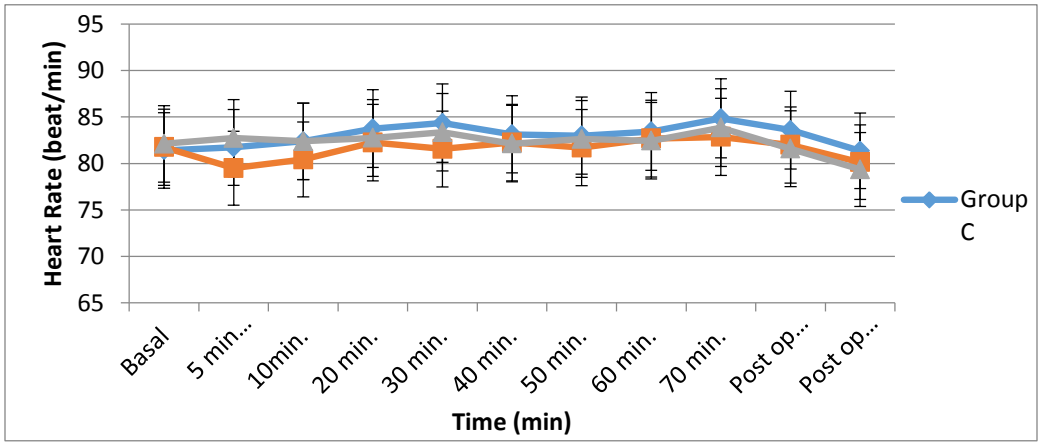

Figure 1: Heart rate (beats/min.) at different times

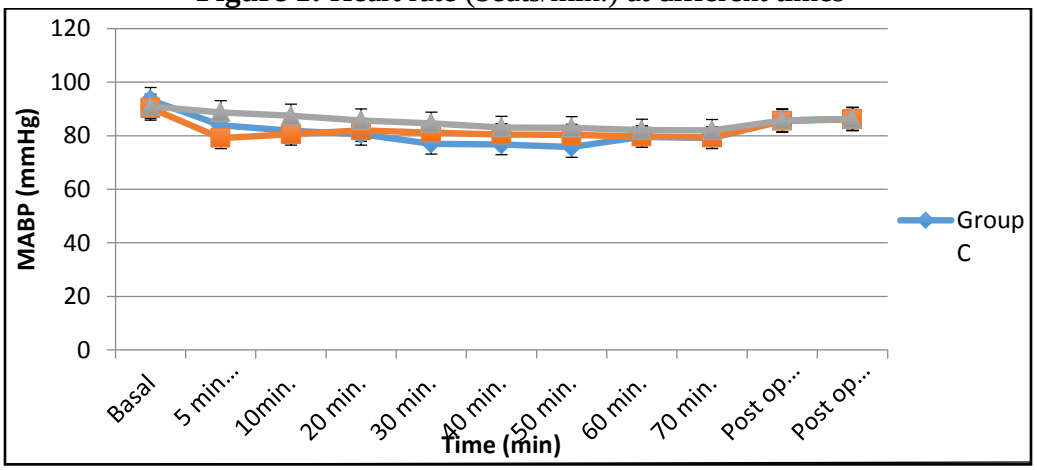

Figure 2: MABP (mmHg) at different times.

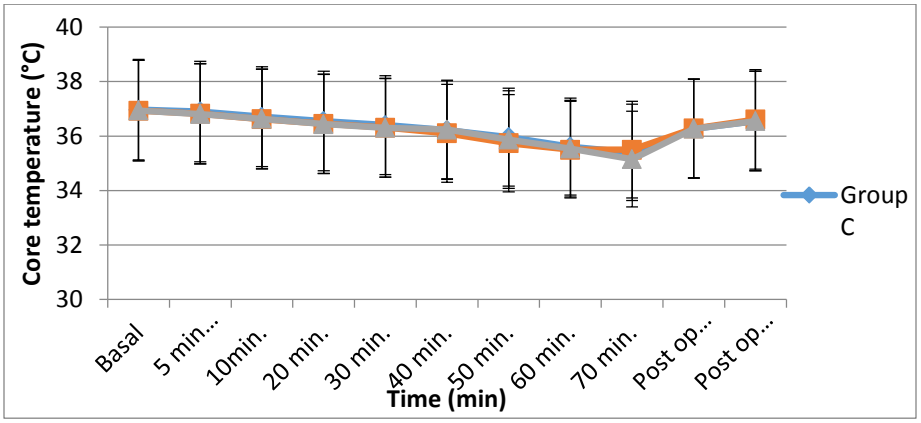

Figure 3: Body core temperature (°C) at different times.

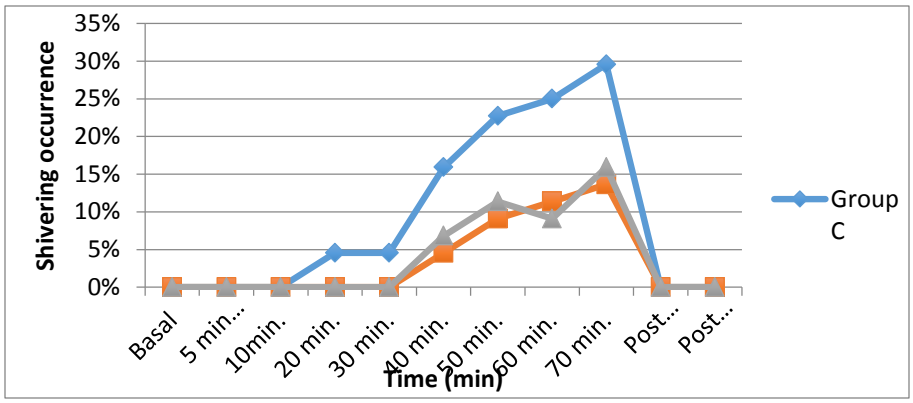

Figure 4: Comparison between the three studied groups regarding shivering occurrence.

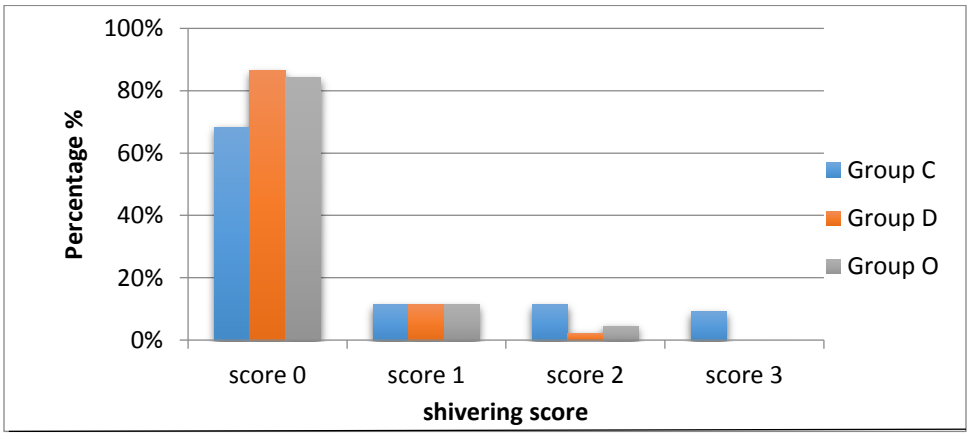

Figure 5: Comparison between the three studied groups according to shivering score

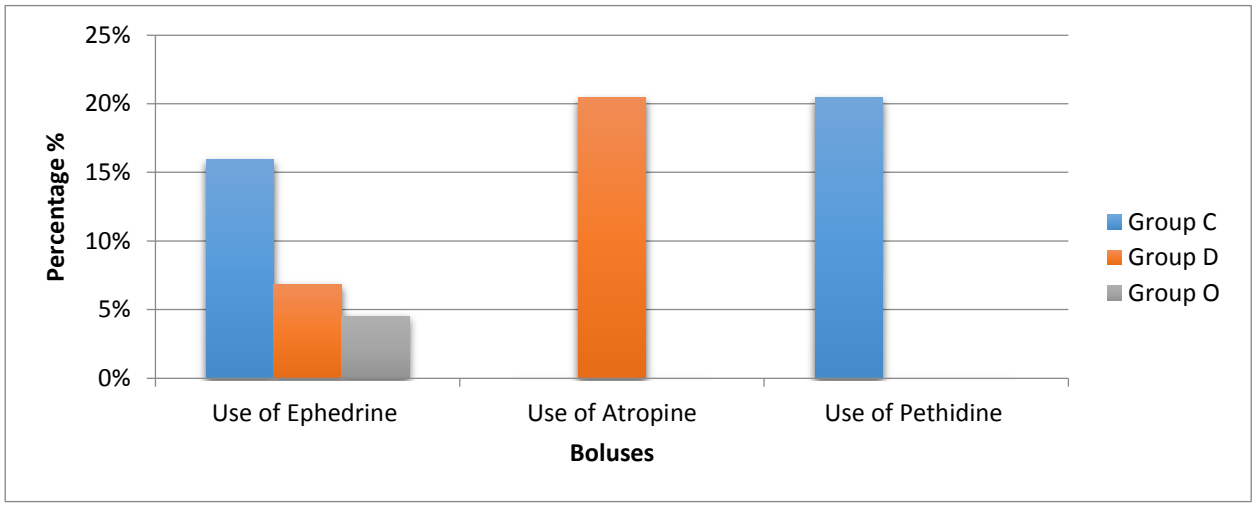

Figure 6: Comparison between the three studied groups regarding boluses of Ephedrine, Atropine and Pethidine used.

DISCUSSION

We aimed at this work to compare the efficacy of the IV weight-adjusted dose of Ondansetron versus IV DEX in prophylaxis of post-spinal shivering occurrences, intensity, duration, and total consumption of rescue pethidine in patients undergoing TURP.

The rationale for using the weight-adjusted dose of Ondansetron (0.1 mg/kg) was according to the volume of distribution according to the relation between the binding volume to albumin and the free one. The more the volume free of drug, the more drug excretion, which means, according to pharmacokinetics, that Ondansetron is a dose-dependent drug. Therefore, using dose-dependent Ondansetron is more efficient to avoid low dosing, decreasing its effectiveness, or overdosing, increasing its side effects. Also, several studies revealed the efficacy of weight-adjusted Ondansetron over fixed doses in preventing shivering compared to fixed doses [8, 14, 15].

Our study found no statistically significant difference between Ondansetron and DEX in terms of the frequency or severity of shivering; however, this difference was present when compared to the control group. Subsequently, there was a significant increase in total doses consumed of pethidine in the control group when compared to the Ondansetron and DEX groups.

In accordance with the present study, Botros et al. [16] reported in a comparative study between IV DEX (1 ug/kg) and Ondansetron fixed doses (8mg) for prevention of PSS undergoing orthopedic, general, or gynaecological surgeries. They obtained similar results regarding overall shivering occurrence and scores between DEX and Ondansetron at all-time points, which were significantly less than placebo at time points 10 to 35 minutes after intrathecal blocks.

Nallam et al. [17] and Badawy et al. [18] conducted two studies each comparing Ondansetron 8 mg and placebo to assess its ability to prevent post-spinal shivering in elective CS, and they both had similar results confirming that Ondansetron was very effective in reducing PSS. The grade 3 shivering incidence was 10% and 7.8% in the Ondansetron groups in both studies, respectively, while it was 22% and 31%, respectively, in the placebo groups.

In contrast to our results, Browning et al. [19] conducted a RCT of two groups: one received 8 mg of Ondansetron and the other received normal saline at 0.9% undergoing CS. They found that Ondansetron did not prevent shivering or decrease its severity. This could be

justified by the fact that their cases were under continuous spinal epidural anaesthesia, which may have increased the level of block, therefore increased the risk of hypotension and blocked the mechanism of thermal regulation.

Regarding hemodynamics, there was a statistically significant decrease in HR in the DEX group compared to the control and Ondansetron groups, with no significant difference between the two groups. As a result, there was a highly significant increase in the incidence of bradycardia in the DEX group when compared to the other two groups, and so on. There was also a highly significant increase in the use of atropine boluses. On the other hand, there was a statistically significant decrease in MAPB in the DEX and control groups compared to the Ondansetron group. Therefore, hypotension was a highly statistically significant incidence increase in the DEX and control groups when compared to Ondansetron, indicating an increase in the use of ephedrine boluses.

The higher incidence of hypotension and bradycardia in the DEX group addressed in previous studies [20–22] showed that adding IV DEX greater than 0.5 ug/kg was associated more with hemodynamic instability like bradycardia and hypotension. They also conducted the most effective dose in the prevention of shivering and sedation (0.86 ug/kg), which explains our results in the current study as we used 1 ug/kg.

Javahertalab et al. [23] compared intravenous DEX and clonidine in lower limb orthopaedic surgeries undergoing spinal anaesthesia with ropivacaine in terms of hemodynamic changes and block, and doses were in DEX group IV (0.2 ug/kg) and clonidine group IV (0.4 ug/kg). Although doses were lower than in our study, there was a significant decrease in MABP in the DEX and clonidine groups compared to the control saline group.

Bhiwal et al. [24] assessed patients undergoing CS under spinal anaesthesia for evaluation of the effect of two different doses of Ondansetron (4mg and 8 mg) as prophylactics to prevent hypotension during spinal anesthesia. They concluded that prophylactic intravenous Ondansetron 8mg reduced the incidence of decreasing MABP.

These results could be explained by the fact that the neurotransmitter 5-HT3 is crucial in activating the BJR via its receptors, which are located in the intracardiac vagal nerve endings and ventricular wall. The reflex acts in response to decreased venous return, which produces noxious ventricular stimuli received by 5-HT3 chemoreceptors and mechanical receptors within the ventricular wall [25]. Ondansetron is a serotonin receptor blocker that antagonizes 5-HT3 receptors, therefore blunting the BJR and therefore reducing further vasodilatation and hypotension.

Abotaleb et al. [26] conducted a study comparing DEX (1 ug/kg) and Granisetrone (4mg) on patients undergoing elective lower limb and lower abdominal surgeries and found that there was a significant difference in the incidence of hypotension (23.3%) in the DEX group and (8.3%) in the Granisetrone group. Also, there is a significant difference in the number of cases that need atropine in DEX compared to the granisetrone group.

Hou et al. [27] conducted a meta-analysis to study if Ondansetron reduces the hypotension incidence after spinal anaesthesia in studies that were done from 2013 to 2022. There was a moderate reduction in the risk of hypotension, a substantial reduction in the risk of bradycardia, and a significant reduction in the need for vasopressor medication rescue when using Ondansetron (high-quality evidence).

In contradiction with the current study, Oofuvong et al. [28] did a triple-blinded controlled trial of Two hundred and twenty-eight pregnant women were randomly assigned to receive either normal saline (group NS), 0.05 mg/kg of Ondansetron, or 0.1 mg/kg of Ondansetron intravenously 5 minutes prior to the administration of spinal anaesthesia with 2 ml of Marcaine and 0.2 mg of morphine. They concluded that neither Ondansetron 0.5 mg/kg nor 0.1 mg/kg reduced the incidence of hypotension during caesarean delivery. Although CS deliveries are associated with high

blood loss, there was no statistically significant increase in cases recorded of shivering, which agreed with the primary goal of our study.

Limitations:

The impact of anxiety on shivering and the symptoms it can cause have not been evaluated. Generalizability concerns could be raised by the study's limited sample size of people from similar socioeconomic backgrounds. Only elderly patients undergoing a variety of procedures were eligible for this treatment.

CONCLUSIONS

Prophylactic IV weight-adjusted doses of Ondansetron are as effective as IV Dexmedetomidine in reducing the incidence of shivering occurrences, intensity, duration, and total rescue pethidine doses in patients undergoing TURP under spinal anaesthesia without major adverse events. The IV weight-adjusted dose of Ondansetron is associated with more hemodynamic stability compared to IV Dexmedetomidine, with fewer incidences of bradycardia and hypotension.

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