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Effect of Ondansetron in Preventing Spinal Anesthesia-Induced Hypotension in Pregnant Women Undergoing Elective Cesarean Section

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ABSTRACT

Aims Spinal anesthesia-induced hypotension is a major challenge during cesarean sections under spinal anesthesia. Ondansetron may be a good option for solving this complication. This study aimed to evaluate the effect of ondansetron in preventing spinal anesthesia-induced hypotension in pregnant women undergoing elective cesarean section.

Materials & Methods This prospective clinical trial was conducted in 2023 with 120 pregnant women classified as ASA I or II. The women were divided into two groups: One group received 4mg of ondansetron diluted in 10ml saline, and the second group received 10ml of normal saline. Different parameters, including systolic and diastolic blood pressure, heart rate, and SpO2, were recorded at multiple time intervals. The incidence of nausea, vomiting, and shivering was also assessed.

Findings The ondansetron group showed a significant reduction in systolic and diastolic blood pressure compared to the saline group at several intervals immediately following the block. The results did not show differences in heart rate between the two groups, except during recovery, when the normal saline group had a higher heart rate. The incidence of nausea and shivering was similar between groups, while vomiting was slightly less frequent in the ondansetron group; the difference was not statistically significant.

Conclusion Ondansetron may temporarily reduce blood pressure following spinal anesthesia in pregnant women undergoing cesarean section. Further studies are needed to determine its role in preventing hypotension during spinal anesthesia and to explore its potential effects on other perioperative parameters.

Keywords Ondansetron; Hypotension; Blood Pressure; Pregnant Women; Anesthesia

CITATION LINKS

[1] Cesarean section is associated with increased risk of postpartum depressive symptoms in Japan ... [2] Anesthesia for cesarean delivery: General or regional anesthesia ... [3] Association of general anesthesia and neuraxial anesthesia in caesarean section with maternal postpartum ... [4] Cesarean section and risk of postpartum ... [5] General anesthesia for cesarean section: Are we ... [6] Prediction of spinal anesthesia-induced hypotension during elective cesarean section: A ... [7] Definitions of hypotension after spinal anaesthesia for caesarean section: Literature search ... [8] International consensus statement on the management of hypotension with vasopressors ... [9] A review of the impact of obstetric anesthesia on maternal and ... [10] Can point-of-care ultrasound predict spinal hypotension during ... [11] Norepinephrine versus phenylephrine infusion for prophylaxis against post-spinal anaesthesia ... [12] Dose-response study of 4 weight-based phenylephrine infusion regimens ... [13] Fluid and vasopressor management for cesarean delivery under spinal ... [14] Prevention of spinal anesthesia-induced hypotension during cesarean ... [15] The Bezold-Jarisch reflex revisited: Clinical implications of inhibitory ... [16] The effect of ondansetron administration 20 minutes prior ... [17] Effect of ondansetron in prevention of spinal anesthesia-induced hypotension in pregnant ... [18] The effects of different doses of intravenous ondansetron ... [19] Effects of ondansetron on attenuating spinal anesthesia-induced hypotension ... [20] Effects of prophylactic ondansetron on spinal anesthesia-induced ... [21] Reduction in spinal-induced hypotension with ondansetron in parturients ... [22] Efficacy of prophylactic intravenous ondansetron on the prevention of hypotension ... [23] Comparing two different doses of intravenous ondansetron with placebo on attenuation of spinal-induced ...

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Introduction

Cesarean sections (CS) rank among the most common surgical operations, with a global rate of 18.6% [1]. CS is a common method of childbirth that is often performed under spinal anesthesia [2]. The primary goal of CS is to save lives by increasing the likelihood that both the mother and the child will survive. It has progressively become a popular delivery method due to developments in medical technology and shifts in societal perspective [3]. However, there are drawbacks to CS, including a higher chance of maternal problems such as infection, postpartum hemorrhage, bladder and ureter damage, uterine rupture, persistent pelvic pain, gastrointestinal issues, and hospitalization [4]. On the other hand, managing parturient anesthesia can be difficult since both the mother and the infant must be cared for at the same time [2]. Using suitable and efficient anesthetic during CS lowers the risk of intraoperative mother awareness and maternal and fetal morbidities [5]. All over the world, spinal anesthesia is the most common anesthetic technique used for elective CS [6]. One up to 70% of instances result in spinal anesthesia-induced hypotension, which is still a prevalent and significant clinical issue [7, 8]. In addition to fetal impairment, hypotension can cause maternal nausea, vomiting, dizziness, and, in rare cases, loss of consciousness, cardiac arrest, and death [8, 9].

Even though several strategies are employed to reduce hypotension, including intravenous fluid administration, prophylactic vasopressor therapy, and patient posture, the incidence can still reach 30% [10, 11]. Up to 30% of women develop reactive hypertension when taking vasopressors as a preventative measure [12]. Although uncommon, side effects such as volume overload, anaphylaxis, and coagulopathy must be considered, as hypotension occurs in at least 40% of patients following fluid loading [13]. It is believed that bradycardia is caused by the Bezold-Jarisch reflex. This inhibitory parasympathetic response originates in cardiac sensory receptors brought on by the right atrium's diminished filling, which activates serotonin-mediated peripheral 5-hydroxytryptamine receptors (5-HT3 type) [14, 15]. Recent studies on obstetric, non-obstetric, and animal populations suggest that 5-HT3 antagonists may eliminate the Bezold-Jarisch reaction [16].

Ondansetron, an antagonist of the serotonin receptor (5-HT3), is a common medication used to treat and prevent nausea and vomiting nowadays. It is primarily used as an antiemetic and is believed to cause bradycardia with spinal block-induced hypotension [17, 18]. Studies have linked this medication to a lower risk of bradycardia and hypotension when used for spinal anesthesia [19, 20].

Hypotension and bradycardia are among the most significant complications of spinal anesthesia and require careful attention. The incidence of hypotension and bradycardia increases in patients undergoing CS under spinal anesthesia. Addressing these complications can have a profound impact on the clinical outcomes for pregnant women. Therefore, this study aims to evaluate the effect of ondansetron in preventing spinal anesthesia-induced hypotension in pregnant women undergoing elective CS.

Materials and Methods

Participants

This study was a prospective clinical trial conducted in 2023 at Dr. Shariati Women's Hospital in Bandar Abbas. The research protocol was approved by the Medical Ethics Committee of the Bandar Abbas University of Medical Sciences before the commencement of the study. 120 pregnant women with ASA I and II classifications who were referred to Shariati Hospital in Bandar Abbas in 2023 and were eligible for elective cesarean section procedures participated in this trial. The day before surgery, an anesthesiologist examined and assessed each patient. All patients provided written informed consent, and the thesis committee reviewed and approved the topic. Participants were excluded from the study if they had a history of ondansetron or local anesthetic hypersensitivity, had cardiovascular failure or hypertensive disorders related to pregnancy, were taking serotonin reuptake inhibitors or migraine medications, or had coagulation issues or hemodynamic instability.

Data collection

Before surgery, each patient received 500ml of lactated Ringer's solution. Upon entering the operating room, required monitoring equipment, including pulse oximeters and ECF NIBP cuffs, was connected, and baseline vital signs were measured and documented. Patients were then randomly assigned in an alternating manner to one of two groups:

Group 1: Received 4mg of ondansetron diluted in 10ml saline over one minute.

Group 2: Received 10ml of normal saline over one minute.

Five minutes later, spinal anesthesia was administered by an anesthesiology specialist using a 25-gauge needle, with the patient seated at the L3-L4 or L4-L5 interspace. Upon confirmation of the subarachnoid space and cerebrospinal fluid (CSF) aspiration, 2ml of 0.5% bupivacaine was injected. Patients were then immediately placed supine, with the surgical table tilted 15 degrees to the left. Peripheral oxygen saturation, heart rate, mean arterial pressure and systolic and diastolic blood pressure were recorded at the following intervals: Immediately after the block, every two minutes for the first ten minutes, and then every five minutes until the end of the procedure. Additionally, the

incidence of nausea, the frequency of vomiting episodes, and the use of antiemetic medications were documented using a specific form. Surgery proceeded once the sensory block reached the T4-T6 level, as confirmed by sensory level assessment. Hypotension, defined as systolic blood pressure below 90mmHg or a reduction of more than 20% from baseline, was treated with intravenous ephedrine. Symptomatic bradycardia (heart rate<60bpm) or a heart rate below 50bpm was managed with intravenous atropine. The incidence of shivering, the need for its treatment, episodes of bradycardia and hypotension, and the dosages of atropine and ephedrine were also recorded.

Tools

All patients in both groups had their arterial oxygen saturation (SpO_2), heart rate, systolic and diastolic blood pressure, frequency of shivering, and episodes of nausea and vomiting measured and assessed. These measurements were taken at baseline and predetermined intervals: Every two minutes for the first ten minutes after the block, every five minutes until the end of surgery, and during recovery room monitoring. ECF NIBP cuffs, pulse oximeters, and other appropriate monitoring equipment were used to perform these measurements.

Data analysis

After collecting the required samples and data, the information was entered into a computer and analyzed using SPSS 19 statistical software. Statistical methods were employed for data analysis, including Chi-square (χ^2) tests and t-tests. A p-value of less than 0.05 was considered statistically significant.

Findings

The groups had no significant differences in height (p=0.15) and/or age (p=0.13). However, there was a significant difference in weight, with Group B having a higher mean weight (74.24±13.42kg) than Group A (69.53±11.87kg; p=0.02). Regarding baseline vital signs, the two groups observed no significant differences in arterial oxygen saturation (SpO_2), heart rate, systolic blood pressure, diastolic blood pressure, or mean arterial pressure (MAP). The women were classified into two levels based on the American Society of Anesthesiologists (ASA) physical status classification. Of 151 participants, 130 (85.4%) were ASA I, and 21 (14.6%) were ASA II. In Group A, 70 patients (85.4%) were ASA I, and 12 (14.6%) were ASA II. Similarly, in Group B, 60 patients (87%) were ASA I, and 9 (13%) were ASA II (p=0.06; Table 1).

Table 1. The mean demographic variables and baseline vital signs for the ondansetron group (Group A) and the normal saline group (Group B)

Parameter	Group A (ondansetron)	Group B (normal saline)	p-Value
Height (cm)	158.18±9.37	159.91±3.50	0.15
Weight (kg)	69.53±11.87	74.24±13.42	0.02
Age (years)	37.13±2.45	37.66±1.17	0.13
SpO_2 (%)	99.46±1.43	99.75±0.58	0.12
Heart rate (beats/min)	93.20±14.11	92.89±17.51	0.90
Systolic BP (mmHg)	121.75±19.19	124.85±16.67	0.06
Diastolic BP (mmHg)	75.35±16.23	75.02±12.95	0.10
Arterial pressure (mmHg)	82.56±13.50	81.88±13.56	0.13

Table 2. The effect of ondansetron on blood pressure in times after block

Time	SBP (ondansetron)	SBP (saline)	p-Value	DBP (ondansetron)	DBP (saline)	p-Value	MAP (ondansetron)	MAP (saline)	p-Value
Baseline	121.75±19.19	124.85±16.67	0.06	75.35±16.23	75.02±12.95	0.10	89.88±16.41	87.11±15.56	0.29
2 min	110.32±21.71	118.31±19.81	0.02	67.62±18.71	71.17±15.50	0.25	79.32±17.96	84.16±18.07	0.11
4 min	110.86±21.44	113.55±19.30	0.50	65.92±15.89	65.39±16.94	0.72	79.15±17.38	78.52±16.94	0.82
6 min	116.18±24.79	109.85±18.86	0.08	68.12±16.70	61.98±13.51	0.01	82.19±19.73	74.55±14.95	0.01
8 min	120.45±15.12	115.33±18.23	0.05	71.46±14.43	66.66±15.90	0.04	85.23±15.60	80.26±13.83	0.04
10 min	117.49±16.68	120.73±18.29	0.29	68.96±14.13	68.68±14.13	0.87	83.22±14.71	82.49±15.53	0.77
15 min	116.35±16.06	118.46±13.55	0.50	66.91±14.06	67.37±12.91	0.98	81.21±15.49	81.34±11.04	0.95
20 min	112.50±12.89	116.70±14.47	0.38	64.10±14.46	64.07±11.81	0.81	77.49±17.52	78.96±1.98	0.55
25 min	110.45±16.72	111.52±16.43	0.92	63.89±14.08	60.47±11.83	0.14	78.59±15.34	74.97±12.15	0.19
30 min	113.92±14.23	110.71±16.09	0.22	64.01±15.10	59.05±9.65	0.04	78.77±14.69	73.10±10.49	0.04
35 min	114.07±12.81	112.07±13.89	0.44	65.45±11.85	60.30±10.24	0.04	80.10±11.30	74.73±10.13	0.04
40 min	111.91±12.62	114.44±13.87	0.67	65.91±12.40	63.61±12.40	0.25	76.73±10.51	76.00±7.49	0.84
50 min	114.36±14.28	118.25±10.13	0.80	67.52±18.57	61.87±8.42	0.28	83.85±12.19	82.12±10.38	0.72
Recovery	115.65±15.37	119.14±10.93	0.14	70.76±15.39	70.24±9.19	0.68	84.10±14.75	82.71±9.26	0.50

At baseline, SBP was comparable between the two groups (p=0.06). However, two minutes after the block, the ondansetron group showed significantly lower SBP than the saline group (p=0.02). At the same time, SBP fluctuations occurred throughout the monitoring period. It shows that ondansetron may temporarily decrease SBP immediately after the block but does not maintain a consistent impact throughout the surgery. For diastolic blood pressure (DBP), significant reductions were observed in the ondansetron group at six minutes (p=0.01), eight minutes (p=0.04), 30 minutes (p=0.04), and 35 minutes (p=0.04) compared to the saline group. This indicates that ondansetron has a more prolonged

effect on DBP compared to SBP, with several intervals showing reduced values compared to the normal saline group. Significant differences were noted for mean arterial pressure (MAP) at six minutes (p=0.01), eight minutes (p=0.04), 30 minutes (p=0.04), and 35 minutes (p=0.04), where the ondansetron group consistently showed lower MAP values. These findings align with DBP trends and suggest that ondansetron may influence the stability of vascular tone and blood pressure in the perioperative period (Table 2).

Table 3. Heart rate (HR) measurements for the ondansetron and normal saline groups at various time points

Time point	Group A (ondansetron)	Group B (normal saline)	p-Value
Baseline	93.20±14.11	92.89±17.51	0.90
2 minutes after block	114.64±13.23	98.72±22.91	0.25
4 minutes after block	97.47±23.07	125.34±15.91	0.11
6 minutes after block	99.95±20.78	105.69±46.32	0.31
8 minutes after block	101.43±23.67	98.45±23.04	0.43
10 minutes after block	101.50±20.22	98.11±19.98	0.31
15 minutes after block	96.75±19.02	98.13±17.21	0.64
20 minutes after block	98.08±15.30	97.90±14.67	0.94
25 minutes after block	97.21±13.38	98.38±17.35	0.68
30 minutes after block	93.77±15.45	96.89±14.05	0.30
35 minutes after block	94.83±13.38	96.11±15.49	0.70
40 minutes after block	90.28±13.03	97.66±14.74	0.06
45 minutes after block	88.20±13.51	92.10±14.51	0.44
50 minutes after block	89.14±12.80	84.12±8.95	0.32
Recovery	85.60±11.39	92.85±12.27	0.001

At baseline, HR was similar between the groups (p=0.9). No statistically significant differences in HR were observed at most time points during the surgical procedure. At recovery, HR in the normal saline group was significantly higher than in the ondansetron group (p=0.001), Suggesting a possible stabilization effect of ondansetron on heart rate during recovery (Table 3).

At the 1-minute mark, the Apgar score for newborns in the ondansetron group was significantly lower than that of the normal saline group (p=0.01). At other marks, no statistically significant differences were observed between the groups (Table 4).

Table 4. Apgar scores of newborns delivered in the ondansetron and normal saline groups at different time points

Time point	Group A (ondansetron)	Group B (normal saline)	p-Value
1 minute	8.57±1.05	8.92±0.46	0.01
5 minutes	9.79±1.26	9.92±0.31	0.38
10 minutes	9.73±0.66	9.96±0.17	0.08

There was no significant difference in the incidence of nausea between the both groups. Although the ondansetron group showed a lower percentage of vomiting (14.6%) compared to the normal saline group (20%), the difference was not statistically significant (p=0.07). The occurrence of shivering was slightly higher in the ondansetron group (32%) than in the normal saline group (25%), but this difference was also not statistically significant (p=0.55; Table 5).

Table 5. The frequency of nausea, vomiting, and shivering in the ondansetron (A) and normal saline (B) groups (the numbers in parentheses are percentages)

Condition	Category	Group A (ondansetron)	Group B (normal saline)	p-Value
Nausea	Yes	18 (22)	16 (23)	0.35
	No	64 (78)	53 (77)	
Vomiting	Yes	12 (14.6)	14 (20)	0.07
	No	70 (85.4)	55 (80)	
Shivering	Yes	26 (32)	17 (25)	0.55
	No	56 (68)	52 (75)	

The baseline SpO_2 levels were comparable between the two groups with no significant difference (p=0.12), and they remained similar in both groups with no statistically significant differences (p>0.05). At recovery, the normal saline group exhibited significantly higher SpO_2 levels than the ondansetron group (p=0.048; Table 6).

Table 6. Arterial oxygen saturation (SpO2) in the ondansetron (A) and normal saline (B) groups

Time point	Group A (ondansetron)	Group B (normal saline)	p-value
Baseline	99.46±1.43	99.75±0.58	0.12
2 minutes after block	99.69±0.62	99.52±0.67	0.30
4 minutes after block	99.51±1.25	99.59±0.57	0.20
6 minutes after block	99.49±1.43	99.56±0.58	0.69
8 minutes after block	99.64±0.65	99.33±1.70	0.25
10 minutes after block	99.46±1.21	99.46±1.19	0.97
15 minutes after block	99.59±0.70	99.53±0.68	0.59
20 minutes after block	98.12±7.45	99.71±1.18	0.09
25 minutes after block	98.41±6.04	99.78±1.31	0.15
30 minutes after block	98.94±3.54	99.70±0.46	0.19
35 minutes after block	99.32±0.91	99.50±0.58	0.36
40 minutes after block	99.30±0.86	99.55±0.51	0.26
45 minutes after block	99.17±1.10	99.80±0.42	0.09
50 minutes after block	99.14±1.45	99.85±0.35	0.17
Recovery	98.42±4.70	99.56±0.69	0.048

Discussion

This study was conducted to investigate the effects of ondansetron in preventing spinal anesthesia-induced hypotension in pregnant women undergoing elective CS. The results showed that the ondansetron group demonstrated significantly lower SBP two minutes after the block than the saline group. It suggests that ondansetron may lead to a transient reduction in SBP immediately following the block. However, the fluctuations observed throughout the monitoring period indicate that this effect is not sustained during the surgery. The results for DBP showed that the ondansetron group had significant reductions at multiple intervals, including six minutes, eight minutes, 30 minutes, and 35 minutes, compared to the saline group. These findings suggest that ondansetron has a more prolonged effect on DBP than on SBP, with multiple time points showing lower values in the ondansetron group. Additionally, significant

differences in MAP were observed at six minutes (p=0.01), eight minutes, 30 minutes, and 35 minutes, where the ondansetron group had consistently lower MAP values than the saline group. These results are consistent with the trends observed for DBP and indicate that ondansetron may affect vascular tone, contributing to a more sustained reduction in blood pressure during the perioperative period. In the study by Sahoo *et al.* [21], a decrease in DBP was noted in the ondansetron group compared to the saline group, which is consistent with our findings. Wang *et al.* [22] showed that the SBP and MAP were lower in the ondansetron group compared to the saline group, a finding that is particularly consistent with our study concerning MAP. Further support was provided by the study by Marashi *et al.* [23], which found that patients in the saline group were more likely than those in the ondansetron group to have arterial pressure below 80 mmHg during operation.

All of these trials support the idea that ondansetron might have a greater positive impact on blood pressure stability throughout the perioperative phase. At most stages during the surgical process, there were no statistically significant variations in heart rate (HR) between the ondansetron and normal saline groups. In the study by Marashi *et al.* [23], the heart rate during the surgery was lower in the ondansetron group compared to the normal saline group, and the difference between the two groups was significant, supporting our findings. In the study by Sahoo *et al.* [21], the heart rate after surgery was higher in the ondansetron group than in the normal saline group, which did not align with our study. The results show that ondansetron may not significantly impact heart rate during the perioperative period. This supports the idea that ondansetron does not directly affect heart rate; Rather, its main effects are nausea, vomiting, and potentially blood pressure modulation. HR was considerably higher in the normal saline group during the recovery period than in the ondansetron group, despite no significant differences for most of the surgical process. This result might suggest that the ondansetron group had a more stable cardiovascular profile after surgery, which could result from a better reaction to the procedure or less stimulation of the sympathetic nervous system. A higher stress reaction or a difference in the two groups' recovery patterns could cause the normal saline group's elevated HR during recovery. More research would be necessary to completely comprehend the mechanisms underlying these variations and their possible therapeutic importance.

Newborns in the ondansetron group had a substantially lower Apgar score at one minute than those in the normal saline group. The results align with Sahoo *et al.* [21]. This first discrepancy might be explained by ondansetron's transient impact on newborn outcomes in the immediate postpartum period, which might be brought on by its pharmacological effects on the mother during labor and delivery. It is noteworthy that no statistically significant differences between the two groups were seen at subsequent time intervals (5 and 10 minutes), indicating that the initial difference in Apgar ratings was temporary and did not last. Ondansetron's short-term effect on the newborn's Apgar score appears to have no lasting effects, as evidenced by the lack of significant variations at the 5- and 10-minute marks. The Apgar score is a brief and broad evaluation of a newborn's health right after birth. However, it is impacted by several variables, such as the mother's drugs, the circumstances of labor, and the newborn's early physiological adjustment to life outside of the mother's body. It may be concluded that any effect of ondansetron on the baby was transient and did not lead to long-lasting changes in neonatal health, as shown by the Apgar score, because no changes were seen beyond the first one-minute mark. Ondansetron does not appear to have a meaningful effect on neonatal well-being when measured by Apgar scores after the first minute, based on the general lack of significant differences at later times. This implies that the long-term health of newborns is not substantially impacted by the clinical use of ondansetron during birth.

The incidence of nausea did not differ significantly between the ondansetron and normal saline groups, indicating that ondansetron may not be very effective at preventing nausea after surgery. Although there was a marginally reduced rate of vomiting in the ondansetron group than in the normal saline group, the difference was not statistically significant, suggesting that ondansetron might not be significantly more effective than saline in this situation. Shivering also occurred a little more frequently in the ondansetron group. This implies that ondansetron does not considerably impact the incidence of shivering during or after the surgery. In this situation, ondansetron might not benefit significantly over regular saline for treating nausea, vomiting, or shivering.

There were no statistically significant differences in SpO_2 across the groups over the observed period. In contrast to the ondansetron group, the normal saline group showed higher SpO_2 values during recovery. The results are similar to those reported by Sahoo *et al.* [21] and Marashi *et al.* [23]. This result implies that ondansetron may have a minor influence on oxygen saturation after recovery, with the normal saline group showing a better oxygenation status at that time, even if there was no discernible effect on SpO_2 during the surgical process.

This study has strength points, such as a controlled study design that provides a clear insight into the effects of ondansetron during the perioperative period. The study assessed a range of clinical

parameters, such as blood pressure, heart rate, oxygen saturation, and postoperative complications, strengthening the findings' validity and comprehensiveness. However, it has limitations, such as a small sample size that limits the generalizability of the findings and a lack of long-term follow-up to assess the prolonged effects of ondansetron. The current study was conducted at a single center, which may limit the external validity and applicability of the results.

Conclusion

Ondansetron may temporarily affect blood pressure, with a notable reduction in systolic and diastolic blood pressure shortly after the block. However, its impact on heart rate was minimal, with no significant differences between the groups at most time points. Ondansetron did not significantly reduce the incidence of nausea or shivering; It did show a slightly lower incidence of vomiting. Regarding oxygen saturation, the normal saline group had higher levels at recovery. In conclusion, ondansetron may influence certain perioperative parameters, but the clinical significance of these effects remains unclear.

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Authors' Contribution: Hoseinikhah SA (First Author), Introduction Writer/Methodologist/Original Researcher/Statistical Analyst (30%); Pazooki S (Second Author), Introduction Writer/Methodologist/Original Researcher/Statistical Analyst (30%); Jarineshin H (Third Author), Methodologist/Discussion Writer (15%); Fekrat F (Fourth Author), Introduction Writer/Methodologist/Original Researcher/Discussion Writer (25%)

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