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Effect of Ondansetron for Preventing Post-dural Puncture Headaches After Spinal Anesthesia for Cesarean Section: A Randomized Controlled Trial

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Abstract

Background: Spinal anesthesia is the preferred anesthetic technique for cesarean sections due to its safety and efficacy. Post-dural puncture headaches (PDPH) are a relatively common complication. The aim of our study was to evaluate the role of ondansetron in preventing PDPH following spinal anesthesia (SA) for cesarean section.

Methods: We conducted a prospective, randomized, controlled, double-blind, bicentric study at two centers in Tunisia. The study included parturients over 18 years who were scheduled to undergo cesarean section under spinal anesthesia. The patients were randomized into two groups: Group O who received 0.10 mg/kg of ondansetron and Group C who received saline.

The primary outcome was the incidence of PDPH. Secondary outcomes were the effect of ondansetron on headache characteristics, the treatment required, the occurrence of nausea and/or vomiting, and hemodynamic status during and after surgery.

Results: In total, 281 patients were included (141 in the O group versus 140 in the C group). Demographic, anthropometric and obstetric data were comparable. Patients in group O presented less PDPH (14.2%) than those in group C (27.9%) ($p = 0.005$) with an OR = 0.396 (95% CI = 0.210 – 0.746).

The day of onset, duration and severity of headaches were similar in the two groups. The treatments used were also comparable, and no blood patch was required.

Ondansetron significantly reduced intraoperative nausea and vomiting. However, it had no impact on postoperative symptoms. Hemodynamic parameters and norepinephrine requirements were comparable between the two groups.

Conclusions: Ondansetron is effective in reducing the incidence of PDPH**.**

Trial Registration: ClinicalTrials.gov Identifier: NCT06444737. Retrospectively registered. https://clinicaltrials.gov/study/NCT06444737.

Date of registration: 13/05/2024

Introduction

Spinal anesthesia (SA) is the technique of choice for cesarean sections due to its ease of administration and high efficacy [1]. Post-dural puncture headache (PDPH) is a potential complication of SA. It results from cerebrospinal fluid (CSF) leakage at the puncture site. The incidence of PDPH following SA ranges from 1.16% to 48.8% [2]. It generally presents as an orthostatic headache and might be associated with neck stiffness, subjective hearing symptoms and photophobia [3].

Female gender and younger age are identified risk factors for PDPH. Therefore, preventing this complication in patients receiving spinal anesthesia for cesarean sections is crucial to enhance

postoperative recovery [4].

Ondansetron is a selective 5-hydroxytryptamine3 (5-HT3) receptor antagonistcommonly used for nausea and vomiting prophylaxis. Several studies have suggested that ondansetron may also reduce the incidence of PDPH following SA [5].

The aim of our study was to evaluate the efficacy of ondansetron in the prevention of PDPH following SA for cesarean sections.

Methods

We conducted a prospective, randomized, controlled, double-blind, bicentric, parallel-group study with a superiority framework at two centers in Tunisia: Mongi Slim Hospital and the Tunis Military Hospital. This study was conducted and reported in accordance with the CONSORT guidelines.

We included pregnant women aged between 18 and 45 years-old, with American Society Physical status (ASA) II or III and a gestational age greater than 37 weeks, scheduled for elective cesarean section under SA or undergoing an urgent cesarean section for non-life-threatening maternal or fetal indications — corresponding to a “green code” according to the Lucas classification [6].

We did not include patients with a personal history of cardiovascular disease, migraines, central nervous system disorder associated with headaches, coagulation disorders, renal or hepatic impairment, severe preeclampsia, known allergy to ondansetron or anesthetic agents, patients ongoing treatment with selective serotonin reuptake inhibitors (SSRIs), those having a contraindications to SA and a body mass index (BMI) greater than 40 kg/m².We excluded patients who required more than two attempts to achieve successful SA and those who had a general anesthesia conversion.

The aim of the study was explained and a verbal and written consent was obtained from all patients. The study protocol was conducted in accordance with the Declaration of Helsinki, approved by the Ethics Committee of Mongi Slim Teaching Hospital, University of Tunis El Manar (approval number 46/2023) and registered in the US Registry of Clinical Trials under the registration number ID: NCT06444737.

Patients were randomly assigned to two groups using a computer-generated sequence with simple randomization and an equal 1:1 allocation ratio.

- Group O (ondansetron) received 0.10 mg/kg of ondansetron diluted in 5 ml of 0.9% saline, administered intravenously over 1 minute, 5 minutes prior to SA.
- Group C (Control) received 5 ml of intravenous (IV) 0.9% saline solution over 1 minute, 5 minutes before SA.

An anaesthesiologist who was not involved in the patient’s management nor the data collection prepared the solutions in identical 5 ml syringes, labelled A (control) and B (ondansetron). Patients, clinicians, and research personnel involved in data collection were all blinded to group assignments.

Upon arrival in the operating room, each patient's identity was confirmed, and standard monitoring was initiated, including non-invasive blood pressure (BP), electrocardiogram, and heart rate (HR). An 18G intravenous catheter was inserted followed by co-loading with at 15ml/kg Ringer's solution. We administered 2 g of intravenous cefazolin as antibiotics prophylaxis (in cases of beta-lactam allergy, 900 mg of clindamycin was used as an alternative). In order to prevent intraoperative and postoperative nausea and vomiting, all patients received 8 mg of intravenous dexamethasone. Based on group allocation, we administered either ondansetron or placebo intravenously five minutes prior to SA.

Patients were placed in the sitting position, and spinal anesthesia was performed at the L4–L5 interspace using a 25-gauge Quincke spinal needle. After confirmation of CSF flow through the spinal needle, a mixture of 10 mg of 0.5% hyperbaric bupivacaine, 2.5 µg of sufentanil and 100 µg of morphine was injected and the patients placed in supine position with 30° left tilt. We used the Bromage score to assess motor blockade and the cold sensation test for the sensory block level. A bilateral sensory block up to the T4 dermatome was required to start surgery. The same surgical technique was performed on all patients, and each received oxytocin after clamping of the umbilical cord.

In case of post-spinal hypotension defined as a drop of more than 20% of the initial mean arterial pressure (MAP) we administrated 5 µg IV norepinephrine. Vomiting was managed with 10 mg IV metoclopramide.

The incidence of PDPH during the first seven postoperative days was the primary outcome.

Patients were asked to sit on the edge of their bed for five minutes before assessing the presence of headache. The latter was characterized by a throbbing pain localized to the frontal or occipital region, or occasionally holocranial, worsening in the upright position and relieved when lying down. Associated symptoms, including photophobia, blurred vision, hypoacusis, tinnitus, and neck stiffness, were also systematically assessed.

We recorded the location of the headache, day of onset, duration, aggravating and relieving factors and intensity (rated on a numerical pain scale from 0 to 10). Headache severity was classified as mild (1–3), moderate (4–6), or severe (7–10).

Mild PDPH was managed with bed rest, hydration, and caffeine. For moderate to severe cases, treatment was continued with a rescue analgesic orally, specifically paracetamol 1 g every six hours.

Postoperative analgesia was maintained for all patients with a non-steroidal anti-inflammatory drug (ketoprofen 100 mg) given as a suppository every 12 hours.

Postoperative follow-up was performed daily during hospitalization from the first postoperative day and continued at home via a telephone call on the seventh postoperative day. Hospital discharge was permitted on the second postoperative day after confirming an uncomplicated postoperative course.

For patients still experiencing symptoms on the seventh postoperative day, an additional follow-up call was conducted on day ten. Those with persistent symptoms were readmitted for further evaluation, including a detailed clinical examination and imaging if indicated. Intravenous analgesics were administered, and in cases where symptoms did not resolve, an epidural blood patch was performed. Nausea and vomiting were also assessed during the 7 days follow-up period.

Statistical analysis:

The sample size calculation was based on a previous meta-analysis [2], which reported a pooled prevalence of post-dural puncture headache of 23.47% [2]. To achieve a 10% reduction in this prevalence, with an α error of 5% and a β error of 20%, the minimum required sample size was 280 patients, corresponding to 140 patients per group. To account for potential exclusions, the total sample size was increased to 300 patients, with 150 patients allocated to each group.

Missing data were minimal (< 5%) and assumed to be missing completely at random. Therefore, complete-case analysis was performed without imputation.

For the descriptive analysis, absolute and relative frequencies were calculated for qualitative variables, and means ± standard deviations with ranges, when appropriate, for quantitative variables following a normal distribution. For quantitative variables not normally distributed, medians with interquartile ranges were reported.

For the analytical study, the Chi-square test or Fisher's exact test was used to compare proportions. Student's *t*-test or the Mann–Whitney *U* test was applied to compare means, depending on the distribution of the variables, which was verified using the Shapiro–Wilk test. The strength of the association between two qualitative variables was estimated using Odds Ratios (ORs) along with their 95% confidence intervals (CIs).

Factors associated with the occurrence of post-dural puncture headache were analyzed using bivariate and subsequently multivariate analyses through binary logistic regression. The level of statistical significance was set at $p < 0.05$.

Results

From November 2023 to June 2024, 855 patients underwent cesarean delivery under SA, 555 were not included due to a cardiac disease (n=2), established diagnosis of migraine (n=49), contraindication to SA (n=8), red or orange code emergency caesarean (n=393), a BMI greater than 40 kg/m² (n=45), severe preeclampsia (n=48) and refusal to participate to the study (n=10).

A total of 300 patients were enrolled and randomly assigned to either the control or intervention group. After excluding 19 patients, 281 patients remained for analysis, with 141 in Group O and 140 in Group C (Fig.1).

The results revealed no significant difference between the two groups regarding demographic, anthropometric and anesthetic data (p > 0.05) (Table 1).

Table 1: Demographic characteristics in the control (C) and the intervention (O) groups

	Group O*	Group C**	P value
Age (years)	31.7±5.3	31.3±4,1	0.451
Height (m)	1.63 ± 0,05	1.64 ± 0.06	0.09
Weight (kg)	80.1 ± 13.4	80.4 ± 13.3	0.854
Body mass index (Kg/m²)	30.1 ± 4.6	29.8 ± 4.3	0.692
Previous spinal anesthesia	78 (55.3%)	77 (54.6%)	0.957
History of previous PDPH* **	10 (7%)	9 (6%)	0.825
Attempts of spinal anesthesia			
1 attempt	112 (79.4 %)	106 (75.7%)	0.455
2 attempts	29 (20.6 %)	34 (24.3 %)	

Note : Quantitative data are expressed as mean ± standard deviation; qualitative variables are expressed as number (percentages); O*: Ondansetron ; C**: Control ; PDPH***: Post-dural puncture headaches.

PDPH was less frequently observed in Group O (14.2%) compared to Group C (27.9%). This difference was statistically significant in both bivariate analysis (p=0.005) and multivariate analysis (p = 0.004), with an adjusted Odds Ratio (aOR) of 0.396 (95% CI: 0.210–0.746).

There was no difference between the two groups regarding the day of onset, duration of symptomatology, severity and location of headaches, associated signs and symptomatic treatments needed (Table 2).

None of the patients required cerebral imaging.

Table 2: Comparison between PDPH characteristics, associated symptoms and needed treatments in Group C and Group O.

	Group O*	Group C**	P value
Onset of PDPH* (days)**	3 [1; 6]	3 [1; 7]	0.475
Duration of PDPH (days)	3 [1; 8]	2 [1; 10]	0.947
	location		
Frontal	12 (60%)	22 (56%)	0.4
Occipital	7 (35%)	9 (23%)	
Occipito-frontal	1 (5%)	6 (15%)	
holocranial	0	2 (5%)	
Severity of PDPH			
Mild	12 (60%)	17 (43.6%)	0.233
Moderate	8 (40%)	22 (56.4%)	
Severe	0	0	
Associated symptoms			
Visual blurring	3 (15%)	8 (21%)	0.734
Photophobia	4 (20%)	12 (31%)	0.378
Tinnitus	6 (30%)	12 (31%)	0.952
Neck stiffness	7 (35%)	17 (46.3%)	0.585
Treatments			
Hyperhydration	17 (85%)	37 (94.9%)	0.325
Bed rest	15 (75%)	32 (82.1%)	0.518
Caffeine	8 (40%)	19 (48.7%)	0.525
First-line analgesics	9 (45%)	22 (56.4%)	0.406
Blood patch	0	0	-

O*: Ondansetron ; C**: Control ; PDPH***: Post-dural puncture headaches.

The results showed that the MAP and HR were comparable between the two groups during surgery ($p > 0,05$) (Fig.2 and 3). There was no difference in the median cumulative dose of norepinephrine administered to patients who experienced episodes of hypotension (15 [10; 25] µg vs 20 [10; 25] µg; $p = 0.937$).

The incidence of intraoperative nausea and vomiting (IONV) was significantly lower in the Group O (24.8%) compared to control group (46.8%) (p< 0.001). However, there was no significant difference in the incidence of postoperative nausea and vomiting (PONV) between Group O and the control group, both immediately after surgery (5.7% vs. 10.8%, p = 0.119) and during the first seven postoperative days (1.4% vs. 4.3%, p = 0.173).

Binary logistic regression, including variables with a p-value ≤ 0.2, showed that a family history of migraine and a personal history of PDPH were predictive factors for the occurrence of headaches. Ondansetron intake was found to be a protective factor (Table 3).
Patients had a 2.5-fold lower likelihood of developing these headaches.

Table 3: The risk factors for post-dural puncture headache

Parameter	Odds Ratio	95% Confidence Interval	p-value
Age	0.961	0.899 – 1.027	0.239
Family history of migraine	4.24	1.816 – 10.577	<0.001
Personal history of PDPH	3.455	1.255 – 9.514	0.016
Number of puncture attempts	1.584	0.806 – 3.116	0.182
Ondansetron use	0.396	0.210 – 0.746	0.004

95% CI: 95% confidence interval; PDPH: post-dural puncture headache.

DISCUSSION

This double-blinded controlled randomized trial aimed to evaluate the effect of intravenous 0.10mg/kg ondansetron on preventing PDPH in patients who underwent cesarean section under SA. Ondansetron significantly reduced the incidence of PDPH during the seven first post-operative days in the intervention group (14.2%) comparatively to the control group (27.9%; p = 0.005). This difference remained significant after multivariate analysis using multiple logistic regression (p = 0.004; OR = 0.396, 95% CI = 0.210–0.746). Ondansetron administration was associated with a 2.5-fold reduction in the risk of developing PDPH. However, we did not find a difference between the two groups concerning the onset, duration, location, severity, associated symptoms and needed treatments.

Moreover, ondansetron significantly reduced the incidence of IONV (p < 0.001).

5-HT3 receptors are involved in various physiological processes, including central and peripheral nervous system function and vasomotor regulation [7, 8].

The mechanism of PDPH remains uncertain. It seems to involve loss of CSF, which may lead to traction on pain-sensitive intracranial structures—particularly when the patient is in an upright position—due to

decreased CSF pressure [9]. Another theory suggests that the headache may be associated to a intracerebral vasodilatation as a compensatory mechanism of reduced CSF pressure [10].

Various pharmacological agents have been investigated for PDPH prevention. Zhao et al. (2023) [5] conducted a network meta-analysis including 22 randomized controlled trials with 4 921 parturients, evaluating seven different drugs. While ondansetron was associated with a significantly lower incidence of PDPH compared with placebo (OR = 0.37, 95% CI 0.16–0.87), only a limited number of trials specifically assessed ondansetron, and the total number of patients remains modest.

Fattahi conducted the first clinical trial in 2015 aiming to evaluate the efficacy of ondansetron in the prophylactic management of PDPH [11]. This study showed that ondansetron (0.15 mg/kg) significantly reduced the incidence of PDPH in the intervention group (4.71%) compared to the control group (20.75%; p = 0.001). It also significantly reduced the severity of headaches and the incidence of PONV and the MAP during surgery.

Unlike the study by Fattahi [11], which used a weight-based dose of ondansetron (0.15 mg/kg), Pazoki [12] investigated the effect of two fixed doses: 4 mg and 8 mg. While the incidence of headache was slightly higher in the 4 mg group compared to the 8 mg group (35.94% vs 34.92%), the difference was not statistically significant ($p > 0.05$). Both doses were associated with a significantly lower incidence of headache compared to the control group($p < 0.01$).

Baharavand [13] used a different ondansetron administration protocol. It consisted in administrating a total of 8 mg of ondansetron in two separate 4 mg injections—one given intraoperatively immediately after foetal delivery, and the other on postoperative day one. This approach proved effective, as patients in the control group had a 4.11-fold increased risk of developing post-dural puncture headache, regardless of when the assessment was conducted. In our study, the administered dose was 0.10 mg/kg. Although ondansetron has demonstrated a significant effect in reducing the incidence of PDPH in parturients undergoing SA for cesarean delivery, the available literature remains insufficient to determine the minimal effective dose.

According to our findings, none of the patients developed a severe form of headache. Moderate forms were more frequently observed in the control group, while mild forms were more common in the ondansetron group. However, this difference was not statistically significant ($p = 0.233$). A similar result was reported by Baharvand [13], where the difference in mean pain scores was also not statistically significant between the ondansetron and control groups ($p = 0.25$). In that same study, pain intensity decreased significantly over time, regardless of group allocation. No specific difference between the ondansetron and control groups was observed concerning the changes in pain intensity over time.

Although some studies have suggested that ondansetron may reduce headache severity [11, 12, 14, 15], these results remain uncertain. Most relied on simple unidimensional pain scales, which are subjective and prone to bias, and their methodological heterogeneity limits the strength of the evidence [16].

Baharvand also reported that the highest incidence of PDPH occurred on 3rd and 4th days postoperative. Moreover, the analysis showed that with each passing day, the risk of developing PDPH increased by approximately 23% during the early postoperative period and then declining over the first 7 days, regardless of the group allocation. [13].

This may help explain the findings of the study conducted by Dehghanpisheh [15], which compared the effects of ondansetron, aminophylline, and placebo, and found no significant difference in PDPH incidence between the different groups. These results could be attributed to the limited duration of patient follow-up, restricted to 24, 48, and 72 hours postoperatively, whereas in other studies, including ours, follow-up was extended to postoperative day seven.

Ondansetron is a pharmacological agent with potent antiemetic properties. It works centrally by blocking 5-HT3 receptors in the chemoreceptor trigger zone of the area postrema, which plays a key role in initiating nausea and vomiting. It also has peripheral effects, acting on the vagus nerve to further help reduce these symptoms [8].

According to the literature, ondansetron is efficient in preventing PONV, with fewer adverse effects compared to other antiemetic agents [17, 18]. This effect appears to be enhanced when ondansetron is combined with another agent, such as dexamethasone [19, 20].

However, the effect of ondansetron on the prevention of SA-induced hemodynamic disturbances remains debated. In the meta-analysis by Tubog [21], ondansetron significantly reduced the risk of SA-induced hypotension across various surgical procedures, including cesarean sections, with relative risks of 0.64 and 0.63, respectively. A similar reduction was observed for bradycardia (RR = 0.31). These findings contrast with those of an earlier meta-analysis [22], which found no significant hemodynamic benefit of ondansetron in non-obstetric populations when subgroup analysis was performed by type of surgery.

This clinical trial had a few limitations. Daily monitoring after hospital discharge was not possible and telephone follow-up may have affected the accuracy of tracking symptom progression. Additionally, relying on phone follow-up made it difficult to ensure a fully standardized approach to managing PDPH.

It also has notable strengths. Its bicentric design ensured uniform protocol implementation across two university hospitals. Moreover, with 281 patients analyzed and follow-up extended to seven days postoperatively, the study included a larger sample and longer observation period than most comparable studies.

A larger, multicenteric, randomized trial using a standardized protocol appears warranted to better define the optimal use of ondansetron in preventing PDPH and to reduce the variability observed in previous studies.

CONCLUSIONS

Based on our findings, 0.10mg/kg intravenous ondansetron prior to SA can decrease the incidence of post-dural puncture headache, as well as IONV, in patients undergoing cesarean section.

Abbreviations

5-HT3: 5-hydroxytryptamine3

aOR: Adjusted Odds Ratio

ASA: American Society Physical status

BMI: Body mass index

BP: Blood pressure

Cis: Confidence intervals

CSF: Cerebrospinal fluid

HR: Heart rate

IONV: Intraoperative nausea and vomiting

IV: Intravenous

MAP: Mean arterial pressure

Ors: Odds Ratios

PDPH: Post-dural puncture headaches

PONV : Postoperative nausea and vomiting

SA: Spinal anesthesia

SSRIs: Selective serotonin reuptake inhibitors

Declarations

Ethics approval and consent to participate

Written informed consent was obtained from all participants. The study protocol was conducted in accordance with the Declaration of Helsinki, approved by the Ethics Committee of Mongi Slim Teaching Hospital, University of Tunis El Manar (approval number 46/2023) and registered in the US Registry of Clinical Trials under the registration number ID: NCT06444737.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analysed during this study are included in this published article

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

A.B. and M.K.O conceived and designed the clinical study; A.B., M.K.O., and H.A. performed the clinical study; F.H. and Y.T. analyzed the data and drew graphs and tables; A.B. and F.H drafted this manuscript; and all authors approved the final manuscript.

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Figures

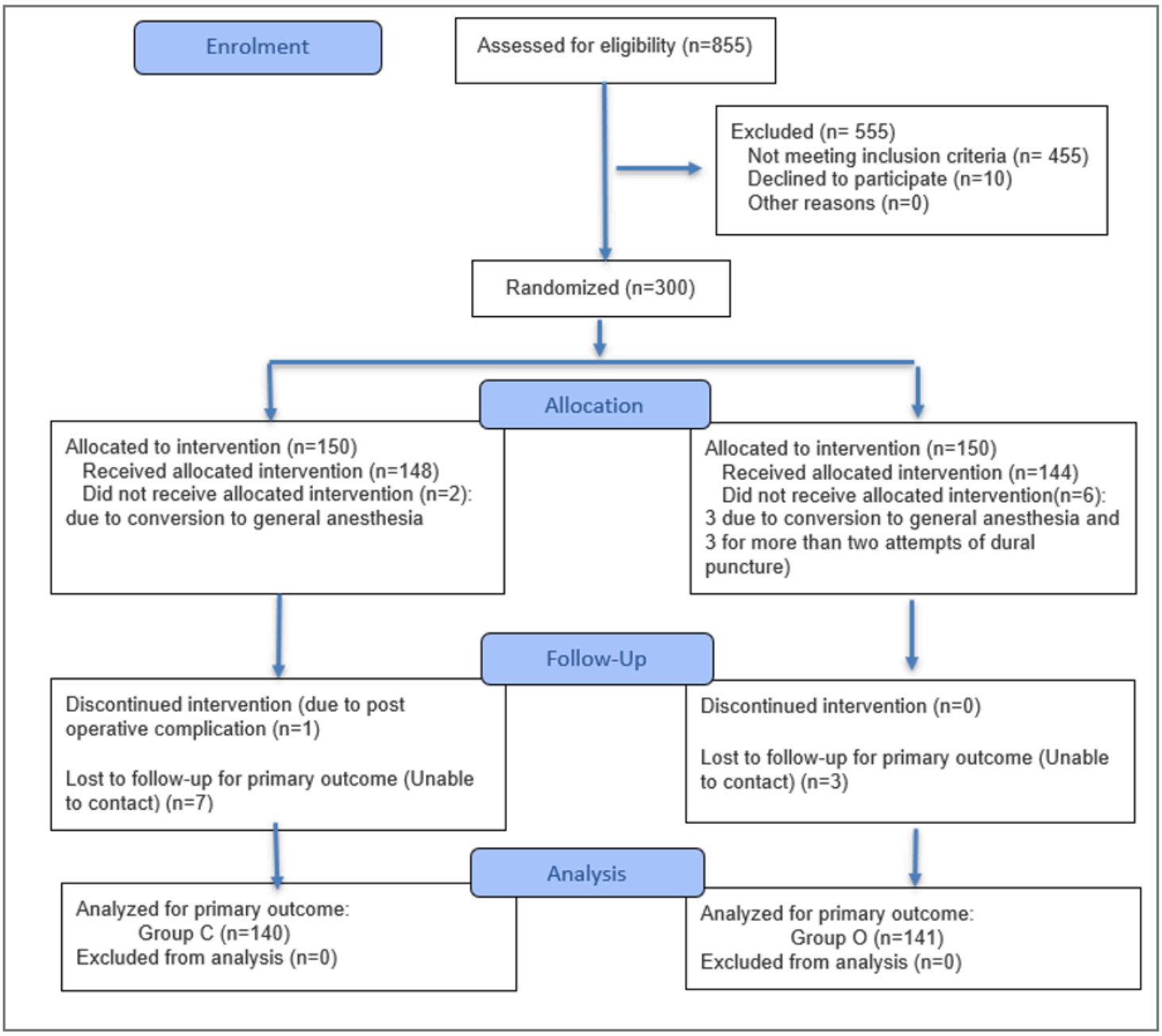


Figure 1

Consort Flowchart of patients

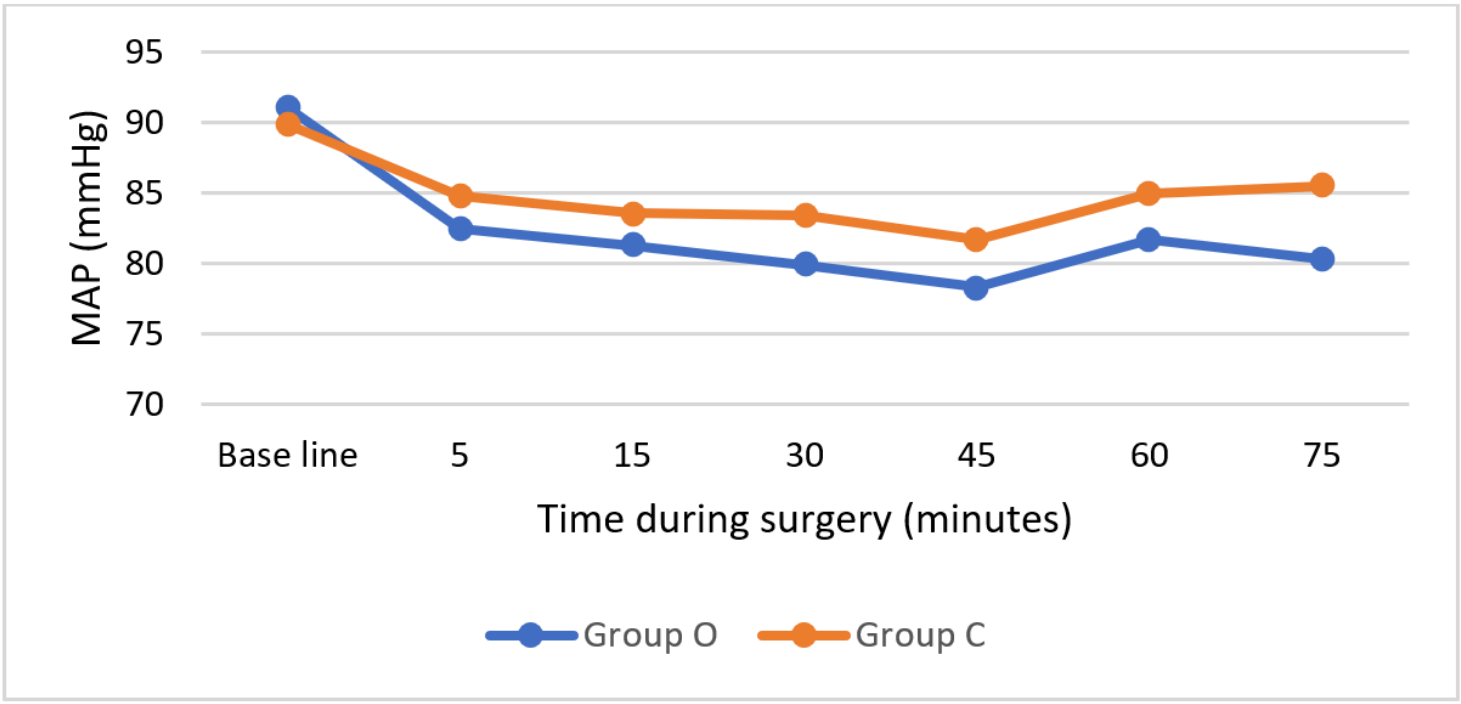


Figure 2

Variation of mean arterial pressure (MAP) in both groups during surgery.

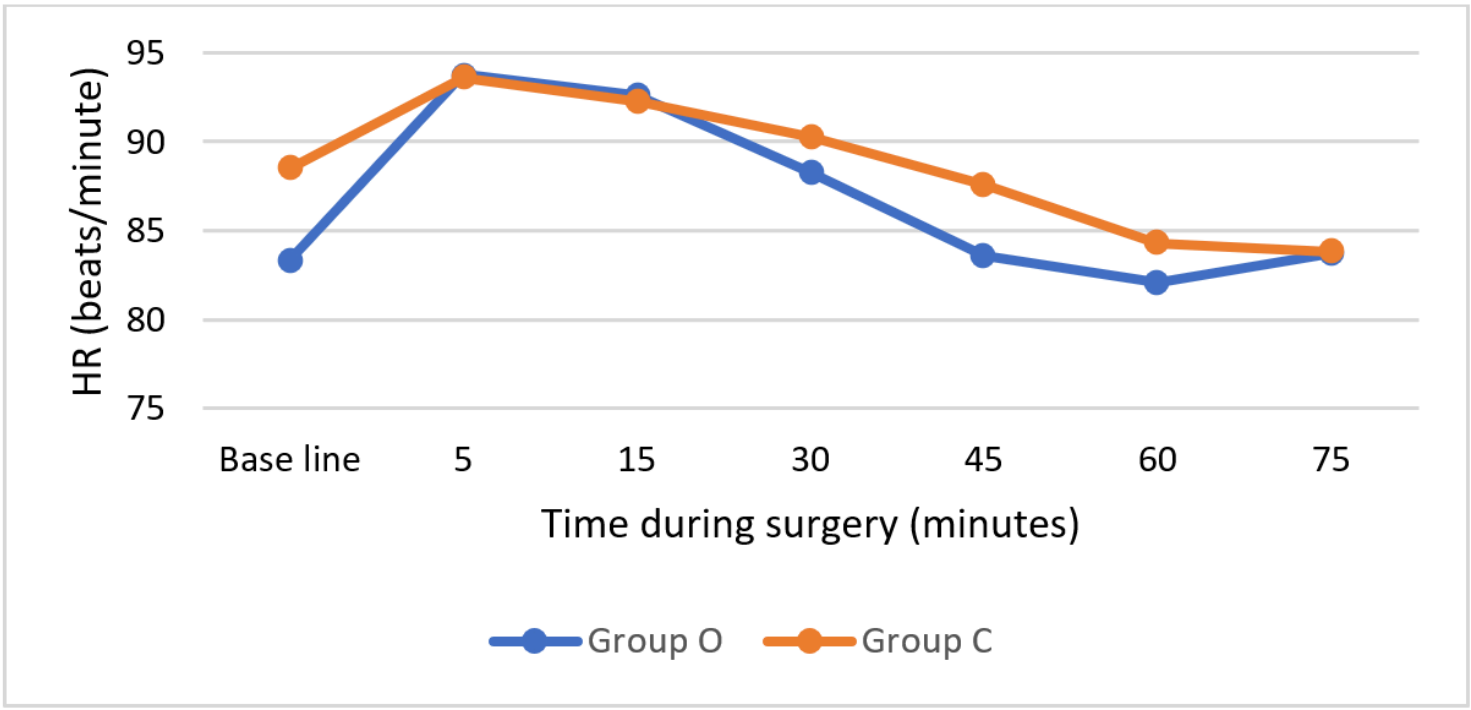


Figure 3

Variation of mean heart rate (HR) in both groups during surgery.