



ORIGINAL ARTICLE

Comparison Between Atenolol, Propranolol, And Ivabradine As A Premedication For Bloodless Field Anesthesia In Lumbar Spine Surgery, A Prospective Randomized Trial

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ABSTRACT

Background: Excessive bleeding during spine surgery is a serious issue, posing a significant risk of significant blood loss and complicating the surgical approach.

Methods: This was a double-blind prospective randomized controlled investigation that was carried out on 45 participants undergoing lumbar spine surgery in the operating room at Menoufia University Hospital. Randomization was made by a computer-generated program into three equal parallel groups that were randomly assigned to either first group receiving oral atenolol (Group A n=15), second group receiving propranolol (Group P n=15) and third group receiving Ivabradine (Group I n=15) 90 min before onset of operation. The primary goal was to measure the effect of these drugs on heart rate, other secondary goals included the effect on blood pressure, surgeon satisfaction, blood loss and surgical field visibility according to Fromm and boezaart score, also the occurrence of any side effects were reported.

Results: A significant decrease in heart rate has been observed between groups at all-time points ($p < 0.05$) except at baseline, after medication, and 30 minutes post-operatively ($p > 0.05$). However, heart rate was highest in Group P and lowest in Group I. surgeon satisfaction was higher in Ivabradine group (grade 1: 66.7%) than group A (grade1: 33.3%) and group P (grade 1:20%), while there was No significant difference in blood loss, surgical field visibility or reported side effects ($p > 0.05$).

Conclusion: Our investigation revealed Ivabradine significantly lowers heart rate compared to propranolol and atenolol with better surgeon satisfaction and decreased Bleeding.

Key words: Atenolol; Propranolol; Ivabradine; Blood loss; Lumbar Spine Surgery.

INTRODUCTION

Excessive hemorrhage in the operative field throughout an intervention is one of the most serious problems in spinal operation, as it poses a risk of substantial blood loss that complicates the operative approach [1].

Various factors, such as the physical status of the case, concomitant illnesses such as

hemorrhage disorders, and the pre-existing condition of the vascular network, may affect the operative field [2].

Local measures, like the utilization of topical and injected vasoconstrictors to decrease hemorrhage, are not without side effects. Similarly, induced hypotension has its own set of disadvantages. However, the operative field

could be greatly enhanced if controlled hypotension could be achieved through a relatively effortless method without compromising the case's safety [3]. By inducing hypotension, bleeding may decrease, thereby ensuring a clear operative field [4].

Controlled hypotension must be consistent with the case's baseline pressure, which may be decreased by thirty percent below the case's baseline MAP. A minimal MAP of sixty to seventy millimeters mercury is clinically acceptable for ASA class 1 and II cases [5]. The many pharmacological interventions include: ganglion-blocking drugs, direct-acting vasodilator drugs (Na nitroprusside), alpha-blockers, beta-blockers (atenolol, metoprolol), combined alpha and beta-blockers (labetalol), calcium channel blockers, propofol, magnesium sulfate, and alpha-2 agonists (clonidine, dexmedetomidine), by specifically attaching to the beta-1 adrenergic receptors in the heart and vascular smooth muscle, atenolol and other cardio selective beta-1-adrenergic antagonists work by inhibiting the beneficial inotropic and chronotropic effects of endogenous catecholamines, such as norepinephrine, isoproterenol, and epinephrine, sympathetic activation is inhibited. Heart rate, blood pressure, and myocardial contractility all decrease as a result of this activity [6]. The objective of this investigation has been to compare propranolol, atenolol, and ivabradine as premedication for achieving bloodless field anesthesia in lumbar spine operations, with a particular emphasis on heart rate control.

METHODS

After approval of the study the institutional ethical committee [under code no. 9/2023ANET13 and Clinical trials registration number NCT06670690, this study was conducted in the department of anesthesia and Intensive care Menoufia University from 1 September 2023 to 1 September 2024 informed written consent was taken from all patients. we conducted this double-blinded prospective randomized controlled study on 45 patients undergoing lumbar spine surgery.

Sample size estimation: Based on review of past literature [6] who found that mean \pm SD of

heart rate at 30 minutes was 66.20 ± 5.43 and 76.85 ± 11.50 in group M and group P respectively. The least sample size calculated using statistics and sample size pro is 12 participants per each group and increase up to 15 participants per each group to avoid 20% dropout rate, so the total sample size is 45 participants. The power of the study is 80% and the confidence interval is 95%

Inclusion criteria: 45 adult patients, ASA physical status I and II, aged from twenty to fifty years old and scheduled for elective lumbar spine operations.

Exclusion criteria: uncontrolled hypertension, uncontrolled diabetes mellitus, heart block, coagulation disorders, anemia (Hb < 10 g/dL), alcohol or drug abuse, allergy to any of atenolol, propranolol, and ivabradine, and history of beta-blockers, calcium channel blockers, tricyclic antidepressants, anticoagulant, or clonidine intake.

Randomization: The randomization was performed using sealed envelopes indicating the group of the assignment at the time of preoperative assessment. A blinded anesthesiologist who did not participate in the study or data collection, read the number contained in the envelope and made group assignments, patients were randomized into three groups:

Group A: 15 cases have been premedicated with atenolol (50 mg); **Group P:** 15 patients were premedicated with propranolol (10 mg); and **Group I:** 15 patients were premedicated with Ivabradine (5 mg). Oral premedications will be given with a sip of water ninety minutes before the induction of anesthesia.

All patients were subjected to the following:

Complete history taking: Anesthesia history, including relevant family history, review of other systems, including major system abnormalities and major operations, drug or food allergies, current medications and potential drug interactions, and current vital signs.

Anesthetic technique:

Noninvasive blood pressure, an ECG, capnography, pulse oximetry, and temperature monitoring were performed upon arrival in the

surgery room. An infusion of lactated ringer (6 to 8 ml/kg/hr) was initiated after an 18-gauge catheter was placed in a peripheral vein. After that, fentanyl (one microgram per kilogram) and propofol (2 mg per kilogram) were used to induce anesthesia till unconsciousness. Orotracheal intubation and mechanical ventilation have been facilitated by the use of atracurium (half a milligram per kilogram). Following induction, 1.5 MAC isoflurane in a 1:1 air-to-oxygen combination has been used to maintain anesthesia. In the meantime, isoflurane MAC was modified to maintain BIS 40–50 and the cases were mechanically ventilated with an ETCO₂ goal of 35–40 millimeters mercury. **Recovery:** At the end of the surgery, the fresh gas flow was changed to 4 L/min, the residual neuromuscular block has been reversed with Neostigmine (0.02–0.05 milligrams per kilogram) and atropine (0.01–0.02 milligrams per kilogram) IV, and then the endotracheal tube will be removed after attaining the accepted global and respiratory criteria for extubation. Then the patient was transferred to PACU. The patient was ready to discharge from PACU when the modified Aldrete score > 9 [7], then the patient was discharged to the ward.

The primary goal was to measure the effect of these drugs on heart rate other secondary goals included the effect on blood pressure, surgent satisfaction, blood loss and surgical field visibility according to Fromm and boezaart score also the occurrence of any side effects were reported.

The items that were measured in this study: the hemodynamic variables heart rate (HR), mean arterial blood pressure (MAP) have been checked prior to (T_b) and following (T_i) induction, immediately following intubation (T₀), then every fifteen minutes till the end of operation, then every fifteen minutes for an hour in the recovery room, with interference if HR decreased by more than 20% of baseline recorded by atropine 0.01 mg/kg to maintain HR and if MAP decreased by 20% of baseline recorded by ephedrine 5–10 mg iv bolus not to exceed a cumulative dose of 50 milligrams to maintain BP. Blood loss & surgical field

visibility score: To evaluate the quality of the operative field throughout the operation, intra-operative bleeding was measured by collecting blood in a marked Container of 2L capacity, the blood soaked by towels were measured by weighing the towel pieces before autoclaving and after the surgical procedure. Packed RBCs were transfused if Hct was less than 25% at any time during surgery and the target was to achieve Hct=25%. In addition, the quality scale suggested by Fromm and Boezaart has also been utilized [8]. The surgeon's evaluation of surgical field condition (surgeon's satisfaction) was reported and graded from 1 very satisfied 2 moderately satisfied 3 not satisfied. incidence of complication: The patients were examined for bradycardia, or tachycardia hypo or hypertension; post-operative shivering; respiratory depression; dizziness; visual disturbance; nausea; vomiting.

Data collection & statistical analysis

The acquired information has been tabulated and analyzed using SPSS (Statistical Package for the Social Sciences) statistical package version 26 on an IBM-compatible computer. Two categories of statistics have been conducted: descriptive statistics were expressed number and percentage (No & %) for qualitative data, mean (\bar{x}) & standard deviation (SD) for normally distributed quantitative data and median, interquartile range (IQR) & range for not normally distributed quantitative data. and analytical statistics, included the Chi-squared test and Monte Carlo test for qualitative variables, One-Way ANOVA for comparing normally distributed quantitative data, Kruskal-Wallis for non-normal data, with a P-value < 0.05 considered significant.

RESULTS

At the study's enrolment, 50 patients were assessed for eligibility 5 patients were excluded due to refusing to participate. 45 patients met the eligibility criteria and were randomized in an equal manner to receive study's interventions; there was no loss of follow-up in any of study's groups (Figure 1).44.4% of examined participants were males, and the remaining 56.6% of examined participants were females, with a mean body mass index and age

of 33.93 ±8.97 years and 28.89 ±2.43 kg/m², respectively. All examined participants underwent lumbar spine surgery (Table 1). No significant difference has been observed among groups in regard to heart rate at baseline, after medication, and 30 minutes post-operatively (p-value more than 0.05), while a statistically significant difference has been observed among groups regarding heart rate at other intervals, as it was highest in Group P and lowest in Group I (p-value less than 0.05). (figure 2). Regarding mean arterial blood pressure there was no statistically significant difference between studied groups at base line, after medication, at induction, after intubation, 15 minutes, 45 minutes, 60 minutes intra-operative and 30 minutes, 60 minutes post-operative (p-value >0.05). There was a statistically significant

difference between studied groups regarding their mean arterial blood pressure at 30 minutes, 75 minutes, 90 minutes, 105 minutes and 120 minutes intra-operative (p-value <0.05) (figure 3). No significant difference has been observed among examined groups regarding blood transfusion and blood loss (p-value more than 0.05) (Table 2). A statistically significant difference has been observed among groups with regards to surgeon satisfaction as surgeons were more satisfied in group I than the other two groups (p-value less than 0.05) (Table 3). As for post operative complication there was no statistically significant difference between studied groups regarding 1st 24 hrs (p-value >0.05) (table 4).

Table 1: Demographic characteristics among examined groups (number=45)

Variable	Group A (number =15)		Group P (number =15)		Group I (number =15)		Total (number= 45)		Test of significance	p-value
	No.	%	No.	%	No.	%	No.	%		
Sex									χ ² =2.88	0.237 (NS)
Male	4	26.7	8	53.3	8	53.3	20	44.4		
Female	11	73.3	7	46.7	7	46.7	25	56.6		
Age (Years)	33.67 ±9.39 20-50		34.60 ±8.97 21-48		33.53 ±9.15 20-49		33.93 ±8.97 20-50		F=0.06	0.942 (NS)
Mean ±SD										
Range										
BMI (Kg/m ²)	29.13 ±2.80		28.73 ±2.22		28.80 ±2.40		28.89 ±2.43		F=0.11	0.895 (NS)
Mean ±SD	25-33		25-33		25-32		25-33			
Range										
Operation Lumbar spine surgery	15	100	15	100	15	100	45	100	-----	-----

NS: non-significant, SD: standard deviation, χ²: Chi-squared test, F: one-way ANOVA test, BMI: body mass index, Group A: Patients pre-medicated with atenolol (50 mg); Group P: Patients pre-medicated with propranolol (10 mg); Group I: Patients pre-medicated with ivabradine (5 mg).

Table 2: Comparison between studied groups regarding blood loss & surgical field visibility according to Fromm and boezaart score

Score	Group A (n=15)	Group P (n=15)	Group I (n=15)	Test of significance	p-value
15 min intra-operative Median (IQR) Range	1 (1-2) 1-2	1 (1-2) 1-2	1 (1-2) 0-2	K=2.47	0.291 (NS)
30 min intra-operative Median (IQR) Range	2 (2-2) 1-3	2 (1-2) 1-3	1 (1-2) 0-3	K=2.54	0.281 (NS)
60 min intra-operative Median (IQR) Range	2 (2-2) 1-3	2 (1-3) 1-3	2 (1-2) 1-3	K=2.96	0.227 (NS)
90 min intra-operative Median (IQR) Range	2 (2-3) 1-3	2 (1-3) 1-3	2 (1-2) 1-3	K=2.44	0.295 (NS)
120 min intra-operative Median (IQR) Range	2 (2-3) 1-3	2 (2-2) 1-3	2 (1-2) 1-3	K=2.08	0.353 (NS)

*: Statistically significant, χ^2 : Chi-squared test, MC: Monte Carlo test, NS: Non-significant, Group A: Patients pre-medicated with atenolol (50mg), Group P: Patients pre-medicated with propranolol (10mg), Group I: Patients pre-medicated with Ivabradine (5mg)

Table 3: Comparison between studied groups regarding surgeon satisfaction (n=45)

Surgeon satisfaction	Group A (n=15)		Group P (n=15)		Group I (n=15)		χ^2	p-value ^{MC}
	No.	%	No.	%	No.	%		
Grade 1	5	33.3	3	20	10	66.7	20.50	<0.001*
Grade 2	2	13.3	10	66.7	5	33.3		
Grade 3	8	53.3	2	13.3	0	0		

*: Statistically significant, χ^2 : Chi-squared test, MC: Monte Carlo test, NS: Non-significant, Group A: Patients pre-medicated with atenolol (50mg), Group P: Patients pre-medicated with propranolol (10mg), Group I: Patients pre-medicated with Ivabradine (5mg)

Table 4: Comparison between studied groups regarding post-operative complications (n=45)

Variable	Group A (n=15)		Group P (n=15)		Group I (n=15)		χ^2	p-value ^{MC}
	No.	%	No.	%	No.	%		
Nausea Present Absent	3 12	20 80	3 12	20 80	2 13	13.3 86.7	0.30	1.000 (NS)
Vomiting Present Absent	3 12	20 80	3 12	20 80	2 13	13.3 86.7	0.30	1.000 (NS)
Bradycardia Present Absent	3 12	20 80	3 12	20 80	4 11	26.7 73.3	0.26	1.000 (NS)
Tachycardia Present	0	0	0	0	0	0	-----	-----

Absent	15	100	15	100	15	100		
Hypotension Present	2	13.3	4	26.7	1	6.7	2.37	0.468 (NS)
Absent	13	86.7	11	73.3	14	93.3		
Hypertension Present	0	0	0	0	1	6.7	2.05	1.000 (NS)
Absent	15	100	15	100	14	93.3		
Respiratory depression Present	0	0	0	0	1	6.7	2.05	1.000 (NS)
Absent	15	100	15	100	14	93.3		
Dizziness Present	3	20	2	13.3	3	20	0.30	1.000 (NS)
Absent	12	80	13	86.7	12	80		
Visual disturbance Present	2	13.3	1	6.7	1	6.7	0.55	1.000 (NS)
Absent	13	86.7	14	93.3	14	93.3		
Shivering Present	3	20	3	20	2	13.3	0.30	1.000 (NS)
Absent	12	80	12	80	13	86.7		

χ^2 : Chi-squared test, MC: Monte Carlo test, NS: Non-significant, Group A: Patients pre-medicated with atenolol (50mg), Group P: Patients pre-medicated with propranolol (10mg), Group I: Patients pre-medicated with Ivabradine (5mg)

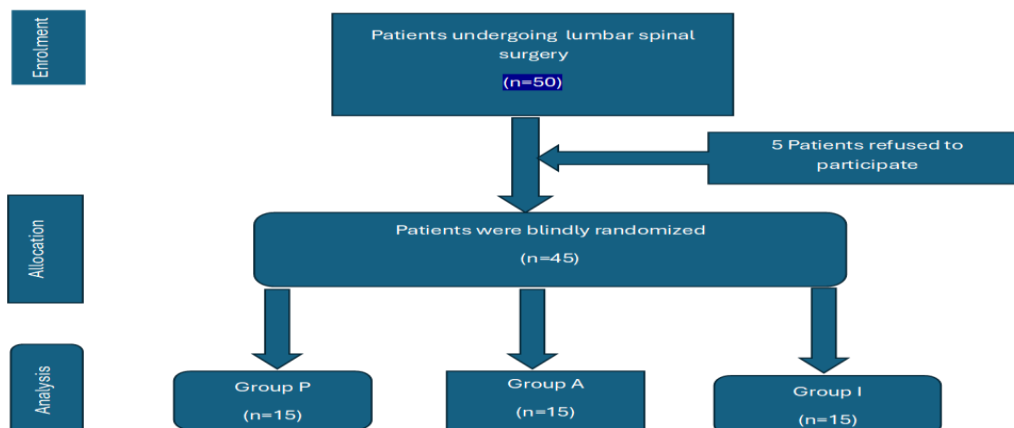


Figure 1: flow chart of the studied groups

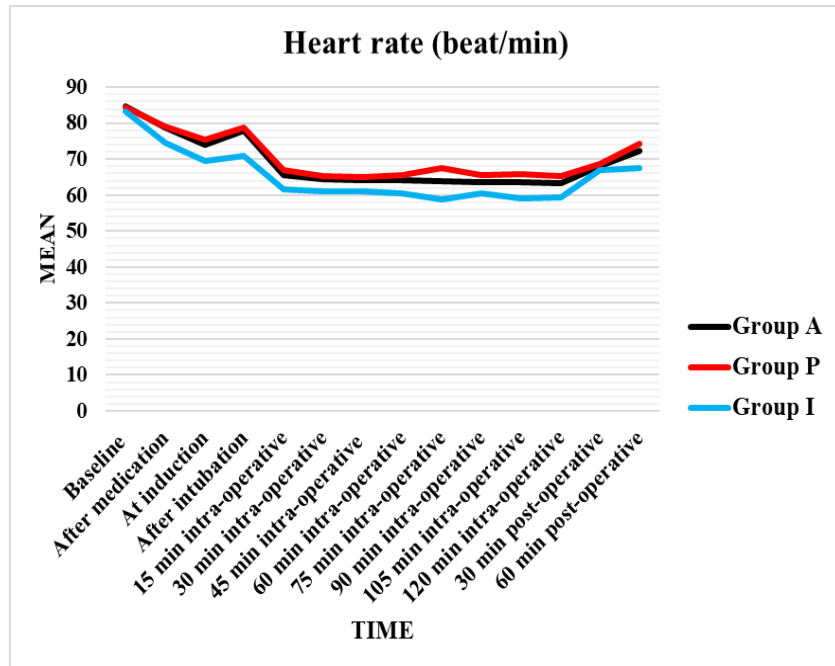


Figure 2: Heart rate variations in between the studied groups

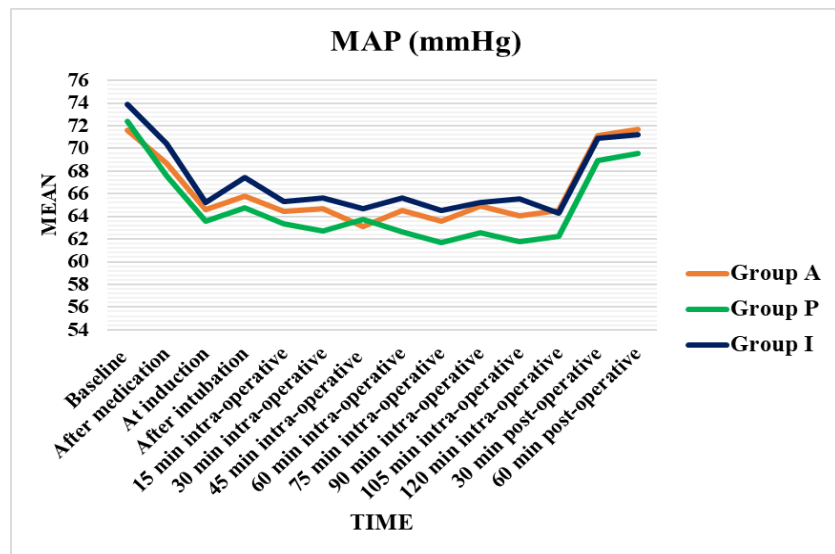


Figure 2: Mean Arterial Blood Pressure variations in between the studied groups

DISCUSSION

In spine surgery, achieving optimal surgical field visibility is particularly important due to the presence of critical and delicate neurological structures that are highly susceptible to injury

Avoidance of hemodynamic fluctuations decreases blood loss, reduces blood transfusion requirements, and allows better visualization of the surgical field thus increasing the quality of the surgery. This study primary aim was to compare atenolol, propranolol, and ivabradine as a premedication to achieve bloodless field anesthesia primarily controlling heart rate in lumbar spine surgery, Our outcomes revealed that no significant difference has been observed among examined groups with regards to heart rate at baseline, after medication, and 30 minutes post-operatively (p-value more than 0.05), while a statistically significant difference has been observed among examined groups with regards to heart rate at other intervals, as it was highest in Group P and lowest in Group I (p-value <0.05) Our study supported by *Lotfy et al.* compared the impact of oral ivabradine against oral propranolol as a premedication prior to nitroglycerin-induced hypotensive anesthesia on the reduction of reflex tachycardia in FESS. The study has been conducted on forty cases divided into two equal groups (twenty each); group P had oral propranolol, and group I had oral ivabradine and reported that regarding heart rate, it was high with a significant difference in group P compared to group I at all-time points [9], Additionally, *Parakh et al.*'s study, which examined the effectiveness of ivabradine versus atenolol in terms of mean arterial blood pressure in 50 patients with mild to moderate mitral stenosis and normal sinus rhythm, revealed that using ivabradine and atenolol significantly decreased mean heart rate from baseline, with ivabradine causing a statistically significant greater heart rate decrease than atenolol [10]. According to mean arterial blood pressure This study showed that there was no statistically significant difference between the studied groups at base line, after medication, at induction, after intubation, 15 minutes, 45 minutes, 60 minutes intra-operative and 30 minutes, 60 minutes post-operative (p-value >0.05), but there was a statistically significant difference between studied groups regarding their mean arterial blood pressure in some cases at 30 minutes, 75 minutes, 90 minutes, 105 minutes and 120 minutes intra-operative (p-value <0.05). These results goes in the same line *Ibrahim and Atallah* who evaluated the effect of oral ivabradine (5 mg

tablet) on both blood glucose level and hemodynamics level in micro laryngoscopic surgeries compared with propranolol (10 mg tablet) given orally, the study was conducted on 50 patients divided to 25 patients in each group and found no significant difference between the studied groups in mean arterial blood pressure at base line and before induction (p-value >0.05), but there was a statistical difference between studied groups after induction and other intervals (p-value <0.05)[11].

Also, these findings are in line with those of *Talaat and El Gendy*, who sought to determine if oral propranolol premedication prior to hypotensive anesthesia during shoulder arthroscopic surgery may reduce reflex tachycardia after nitroglycerine (NTG) infusion and endotracheal intubation. 60 participants participated in the trial, 30 of whom received propranolol and 30 of whom received a placebo. During the pre-induction phase and the final two minutes following endotracheal intubation, there were no appreciable differences between the two groups ($P > 0.05$). However, the first two minutes and three minutes following endotracheal intubation saw a significantly substantial drop in the MABP. According to our findings, there was no statistically significant difference between the groups under investigation in terms of blood loss and transfusion (p-value greater than 0.05) [12]. To assess the impact of premedication with oral atenolol or enalapril in combination with remifentanyl under sevoflurane anesthesia on intraoperative blood loss by attaining appropriate intentional hypotension (DH) during orthognathic surgery, *Kim et al.* provided support for our findings. Twenty-three enalapril patients, twenty-four atenolol patients, and twenty-five placebo patients were involved in the study. According to the study, the enalapril group's overall blood loss throughout the procedure was much lower than that of the placebo group. However, there was no discernible difference between the three groups in the quantity of autologous blood transfusions received during the procedure [13]. Moreover, *Amr and Amin* sought to ascertain whether oral β -blocker premedication prior to sodium nitroprusside hypotensive anesthesia could enhance the surgical field, reduce blood loss, and shorten the duration of surgery and the need for homologous blood transfusions. Eighty patients participated in the trial; forty in group I received atenolol, while forty in group II received a placebo. According to the study, Group I had a higher-quality surgical field than Group II at every

measurement point, with less blood loss and a lower requirement for blood transfusions. [14]. Moreover, with *Iyengar et al.*, who sought to ascertain whether an oral ivabradine dose administered before to surgery decreased intraoperative hemorrhage during functional endoscopic sinus surgery (FESS) and enhanced operational field visibility. Thirty patients participated in the trial, with fifteen in each of the two groups (placebo and ivabradine). According to the study, the mean final blood loss for Group I was 165.73 ± 43.48 mL, while the mean final blood loss for Group P was 246.25 ± 30.76 mL. The mean ultimate blood loss (mL) between the two groups differed significantly ($P < 0.001$). Group I had FBS 1 with 13.33% and FBS 2 with 86.67%, while Group P had FBS 2 with 6.67%, FBS 3 with 86.67%, and FBS 4 with 6.67%. Consequently, Group I was statistically significant and had a lower FBS than Group P [15]. In line with *Apipan and Rummasak*, who sought to ascertain whether premedication with oral propranolol prior to hypotensive anesthesia with sodium nitroprusside could reduce reflex tachycardia, the amount of sodium nitroprusside used, and blood loss during hypotensive anesthesia for orthognathic surgery, this study demonstrated that there was no statistically significant difference between the studied groups regarding the incidence of nausea, vomiting, bradycardia, tachycardia, hypotension, hypertension, and respiratory depression post-operatively (p -value > 0.05). There were 60 patients in the trial, with 30 patients in each group [16]. In terms of surgeon satisfaction, this study revealed a statistically significant difference between the groups under investigation (p -value < 0.05); group I had the highest level, group P had the lowest, and group A had the lowest. This study goes along with *Nagwa and Mahmoud*, who aimed to evaluate the effect of preoperative clonidine vs. Atenolol on providing optimum surgical field in patients undergoing spine fusion surgery, and to minimize intraoperative blood loss and lastly for assessment of intraoperative surgeon satisfaction. There were 60 patients in the research. The study reported that regarding surgical satisfaction the field was much better in Atenolol Group. The study reported that there was no statistically significant difference in complications observed in either group [17]. This study showed that there was a statistically significant difference between studied groups regarding surgeon satisfaction (p -value < 0.05), it was best in group I, less in group P and lowest in group A. This is also in line with the findings of *Amr and Amin* [14], who

stated that neither group experienced any statistically significant difficulties. Furthermore, according to *Iyengar et al.* [15], ivabradine has been associated with a small number of side effects, including lightheadedness, dizziness, and blurred vision, but these are uncommon and rare

Conclusions

Our study revealed that preoperative oral Ivabradine significantly lowers heart rate compared to propranolol and atenolol without much variation of blood pressure, and thus significant distinction regarding surgeon without any significant reported side effects.

Limitations of study

Some of the limitations of this study are that it is a single-center study, we did not compare different doses of the used drugs and small sample size.

Recommendations

Premedication with oral beta blocker is an easy, safe and cheap method to achieve bloodless field anesthesia in spine surgery with much better results in the case of Ivabradine.

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Conflict of interest:

The authors declare that they have no conflicts of interest with respect to authorship or publication of this article.

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