

Comparison of oral pre-medication with clonidine and metoprolol on intraoperative hemodynamics and surgical conditions during functional endoscopic sinus surgery



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ABSTRACT

Background: Functional endoscopic sinus surgery (FESS) is one of the most performed surgical procedures and requires minimal bleeding during the procedure. The success of surgeries is largely dependent on the surgical field, where the presence of significant bleeding is an important factor. **Aims and Objectives:** The objectives of this study were to evaluate the clinical efficacy of oral clonidine and metoprolol following their pre-medication for induced hypotension during FESS and to assess hemodynamic stability, surgical field quality, and sedation score. **Materials and Methods:** This is an observational hospital-based study conducted on 60 patients, aged 18–60 years old for FESS assigned by randomization method in two groups including clonidine or metoprolol. Heart rate (HR) and arterial blood pressure are measured after induction, during and end of the surgery. Assessment of bleeding was done by a surgeon who was blinded. Surgical field quality, satisfaction level of the surgeon, Aldrete score, and any side effects were observed. **Results:** There was no significant difference seen in HR in patients of Group C and Group M in the pre-operative period, after loading the dose of the drug, at extubation ($P > 0.05$). A significant difference was seen in HR with lower mean values in Group C compared to Group M after induction (77.23 ± 12.23), 10 min after induction (69.47 ± 11.99), 20 min after induction (65.63 ± 8.66), 30 min after induction (64 ± 8.32), 40 min after induction (63.77 ± 7.61), and 60 min after induction (63.63 ± 7.89). A significant difference was seen in blood pressure, after loading the dose of the drug, after induction, during surgery monitored every 10 min, at extubation, after extubation monitored every hour for 6 h. Quality of surgical field and surgeon's satisfaction was better in patients who received clonidine than in those who received metoprolol. **Conclusion:** Both clonidine and metoprolol can be effectively used for induced hypotension in FESS. Clonidine is better than metoprolol with respect to intraoperative hemodynamics, quality of the surgical field, and surgeon's satisfaction with the added advantage of sedation, reduced analgesia requirement, and other anesthetic drugs.

Key words: Functional endoscopic sinus surgery; Controlled hypotension; Clonidine; Metoprolol

INTRODUCTION

Functional endoscopic sinus surgery (FESS) is a minimally invasive procedure in which the success of surgeries is largely dependent on the surgical field, where the presence

of significant bleeding is an important factor.¹ Slow oozing of blood leading to blurring of vision and recognition of anatomical landmarks becomes quite difficult.² Hypotensive anesthesia is the way out in such surgeries. Controlled hypotension is defined as a pharmacologically induced

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reduction in mean arterial blood pressure to 50–70 mm of Hg.² The main goal of hypotensive anesthesia is to lower blood pressure to a level that causes minimal bleeding, but, at the same time, maintains well perfusion to the vital organs³ thus maintaining hemodynamic stability is crucial.

Agents used to achieve controlled hypotension include: Inhalational agents (e.g., halothane), intravenous propofol infusion, vasodilators (e.g., sodium nitroprusside),³ beta-adrenergic blockers (e.g., Metoprolol),³ alpha-adrenergic agonists (e.g., clonidine),³ prostaglandin E1, remifentanyl, and magnesium sulfate.^{3,4}

Clonidine is a centrally acting alpha-adrenergic agonist that has favorable kinetics, the onset of action 30–60 min after an oral dose and an elimination half-life of 12–16 h.

Metoprolol is a cardioselective competitive beta-1 adrenergic receptor antagonist with antihypertensive properties and devoid of intrinsic sympathomimetic activity.

In this study, we try to compare oral clonidine 150 mcg and metoprolol 100 mg and establish whether these doses are sufficient to achieve a desirable oligemic surgical field.

The primary objective is to evaluate the clinical efficacy of oral clonidine and metoprolol following their pre-medication for induced hypotension during FESS surgeries and the secondary objective is to assess hemodynamic stability, surgical field quality, duration of surgery, and requirement of post-operative analgesia and sedation score.

Aims and objectives

Primary objective- to evaluate the clinical efficacy of oral clonidine and metoprolol following their pre medication for induced hypotension during FESS surgeries.

Secondary objective- to assess hemodynamic stability, surgical field quality, duration of surgery and requirement of post operative analgesia and sedation score.

MATERIALS AND METHODS

The present study is an observational hospital-based study conducted in the Department of Anesthesiology, Gandhi Medical College and associated Hamidia Hospital from January 2021 to July 2022. After approval from the Institutional Ethics Committee under letter number (26823/MC/IEC/2021), the study was conducted on 60 patients of ASA grade 1 and 2, aged between 18 and 60 years undergoing elective endoscopic ear, nose, and throat (ENT) surgery under general anesthesia. Of 60 patients, 30 were given either clonidine (Group C) and

the other 30 were given metoprolol (Group M) masking the surgeon who performed the surgery. The surgeon was asked to provide a score at the end of surgery for the quality of the surgical field using a predefined category scale while being unaware of which drug the patient was receiving.

Inclusion criteria

The following criteria were included in the study:

- Age group between 18 and 60 years
- Patients of either gender male or female
- ASA grades 1, 2, and 3
- Patient posted for elective FESS.

Exclusion criteria

The following criteria were excluded from the study:

- Patient refusal
- Patients with a history of allergy to either clonidine or metoprolol
- Patients with uncontrolled hypertension, diabetes mellitus, bronchial asthma, or cardiovascular disease
- Patients with hepatic and renal and neurological dysfunction
- Patients having coagulation or bleeding disorder
- Chronic or acute intake of sedatives or analgesic drugs
- Patients on adrenergic blocking drugs.

Methods

All the patients were kept nil per orally for 6 h before the surgery.

On the day of surgery, patients of either sex were given either tablet clonidine 150 µg (Group C) or tablet metoprolol 100 mg (Group M) 2 h before surgery with sips of water after recording basal vital parameters such as heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure, and SPO₂ in pre-anesthetic room. The patient's vitals were monitored.

Pre-medication

All patients were given IV glycopyrrolate 0.01 mg/kg body weight, IV midazolam 0.01 mg/kg body weight, IV fentanyl 1.0 µg/kg body weight, and IV ondansetron 0.1 mg/kg body weight, and pre-loading was done with Ringer lactate solution 5 mL/kg body weight.

- Anesthesia was induced with an injection of propofol (2 mg/kg IV), waiting up to 30 s and mask ventilation was confirmed. Injection of succinylcholine 2 mg/kg was given to facilitate laryngoscopy and intubation. Oxygenation continued by intermittent positive pressure ventilation. At the onset of apnea, intubation was done with a well-lubricated appropriate size cuffed endotracheal tube after gentle laryngoscopy. Anesthesia was maintained with oxygen, nitrous oxide, and isoflurane with intermittent use of injection atracurium

and controlled ventilation. An oropharyngeal packing was done after intubation. All patients were placed in a 15° reverse Trendelenburg position and their nasal cavities were packed with a cotton pack soaked with epinephrine in a concentration of 1:10,000. All the surgeries were performed by the same surgeon, who was blinded to the study drug used, so as to ensure consistency in estimating the quality of the surgical field. The residual neuromuscular blockade was reversed with IV neostigmine (0.05 mg/kg) and IV glycopyrrolate (0.01 mg/kg), throat pack was removed. After observing and confirming adequate motor recovery and spontaneous breathing efforts, patients were extubated. Parameters monitored: Blood pressure, HR, and quality of surgical field. The patient was transferred to post-anesthesia care unit, and vitals were monitored. Sedation was assessed by Ramsay sedation score, surgeon satisfaction by Likert scale scored from 1 to 5 (very bad, bad, average, good, and excellent), and quality of surgical field by Fromme–Boezaart scale.^{5,6}

Statistical analysis

The categorical variables were presented in the form of number and percentage (%). On the other hand, the quantitative data were presented as the means ± standard deviation and as median with 25th and 75th percentiles (interquartile range).

RESULTS

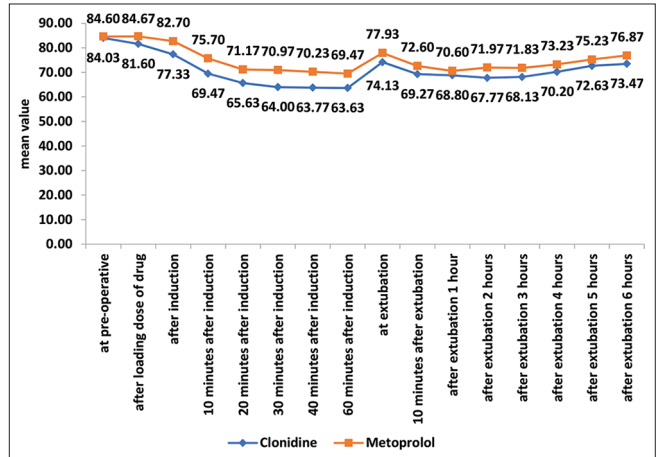
In our study, patients were given either of the two drugs: Group C: Clonidine in the dose of 150 mcg (n=30) and Group M: Metoprolol in the dose of 100 mg (n=30).

Patients in both groups were comparable in terms of age, sex, and weight, no statistical significance was seen in age, sex, and weight (Table 1). No significant difference was seen in HR in pre-operative period, at extubation, and thereafter. Significant difference was seen after induction, and till 60 min of induction monitored every 10 min in both the groups (Graph 1). On comparing for blood pressure, a significant difference was seen after loading the dose of the drug, after induction, during surgery monitored every 10 min, at extubation, and after extubation monitored every hour for 6 h (Graph 2).

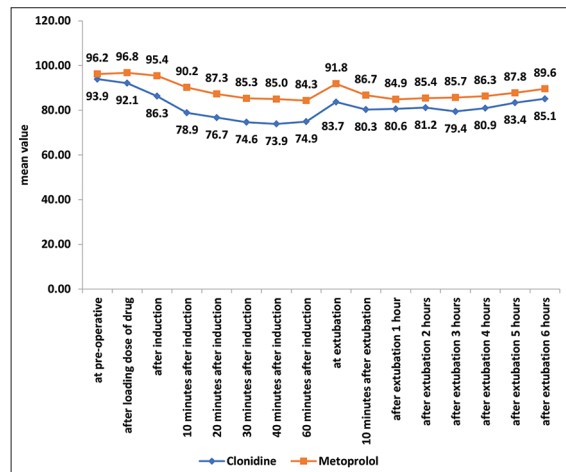
The quality of the surgical field was assessed according to Fromme–Boezaart surgical field grading. Median (25th–75th percentile) of average category score at 15 min, 30 min, and 60 min in metoprolol was 2 (2–2), 3 (2–3), and 3 (2–3) which was significantly higher as compared to clonidine (2 [1–2] [P=0.0005], 2 [2–2] [P<0.0001], and 2 [2–2] [P<0.0001]) (Graph 3). A significant difference was seen in sedation score at 15 min and 30 min between

Table 1: Demographic data

Parameters	Clonidine (n=30)	Metoprolol (n=30)	P-value
Age (years)	44.97±10.5	44.9±11.15	0.981
Weight (kg)	52.43±7.05	54.77±11.29	0.341
sex (M/F)	18/12	17/13	0.963



Graph 1: Comparison of heart rate (per minute) between clonidine and metoprolol



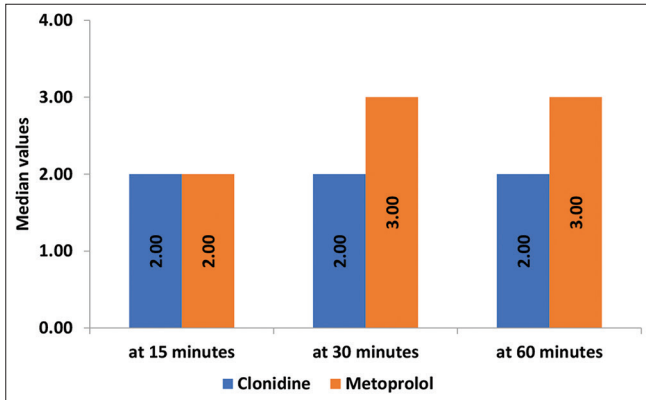
Graph 2: Comparison of mean blood pressure (mmHg) between clonidine and metoprolol

clonidine and metoprolol (P<0.05) (Graph 4). The median (25th–75th percentile) of the Likert scale in clonidine was 3.5 (3–4) which was significantly higher as compared to metoprolol (2 [2–3]) (P<0.0001) (Graph 5).

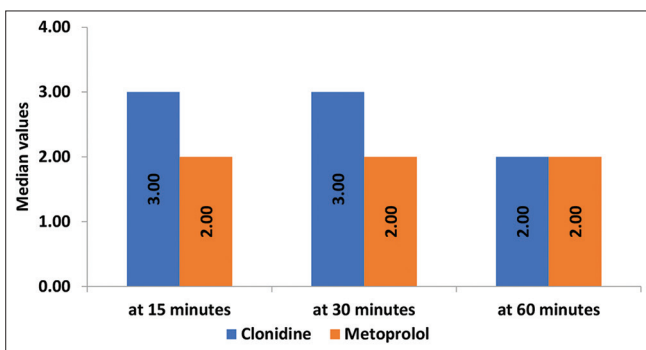
The most frequent side effect seen was hypotension with clonidine, although statistically insignificant (Table 2).

DISCUSSION

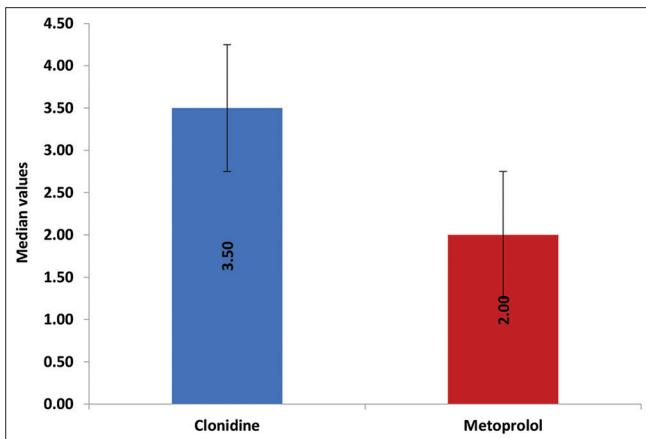
Functional endoscopic surgeries are one of the most frequently performed surgeries in ENT. Establishing



Graph 3: Comparison of average category score between clonidine and metoprolol



Graph 4: Comparison of the trend of sedation score at different time intervals between clonidine and metoprolol



Graph 5: Comparison of the Likert scale between clonidine and metoprolol

Side effects	Clonidine	Metoprolol	Total (%)
Hypotension	3	0	3 (10)
Bradycardia	0	1	1 (3.3)
Nausea and vomiting	0	0	0 (0.0)
Rashes	0	1	1 (3.3)
Dryness of mouth	0	1	1 (3.3)

a clear field is essential as minor bleeding can severely compromise an already restricted view obtained through a rigid intranasal bronchoscope increasing the likelihood of complications as well as lengthening the duration of the operative procedure and possibly resulting in incomplete surgery.⁷ Hypotensive anesthesia or controlled anesthesia during FESS surgeries has significantly helped in reducing bleeding and thereby resulting in improved surgeon’s visibility, satisfaction, and quality of the surgical field.

In the present study, we have observed and compared the effects of oral tablet clonidine 1500 mcg given as pre-medication 2 h before surgery for induced hypotension in FESS surgery with oral tablet metoprolol 100 mg.

In our study, the demographic profile was compared between patients of both Groups C and M, results found were not significant ($P>0.05$). We observed that the mean age of patients in Group C was 44.97 ± 10.5 whereas in Group M was 44.57 ± 10.5 . The majority of patients included in the study are male, that is, 60% in Group C and 56.67% in Group M. There is no statistically significant difference in age, gender, and weight in Groups C and M. Similar results were also found in other studies, as done by Menezes et al.,⁸ in their study, age (Group C 49 ± 12 ; and Group M 52 ± 11 ; $P=0.48$), gender (male-to-female ratio 10:13 and 11:9 for Group C and M, respectively; $P=0.65$), and weight (Group C 72 ± 14 and Group M 72 ± 13 ; $P=0.93$).

The present study showed that HR was comparable in patients receiving either clonidine or metoprolol. There was no significant difference seen in HR (per minute) in patients of Group C and Group M in pre-operative period, after loading the dose of the drug, at extubation ($P>0.05$). Significant difference was seen in HR (per minute) with lower mean values in Group C compared to Group M after induction (77.23 ± 12.23), 10 min after induction (69.47 ± 11.99), 20 min after induction (65.63 ± 8.66), 30 min after induction (64 ± 8.32), 40 min after induction (63.77 ± 7.61), and 60 min after induction (63.63 ± 7.89). The results obtained were similar to the ones obtained in other studies; Patil and Kulakarni 2017⁹, the reduction in PR in the clonidine group was more than that in the atenolol group but without any significant bradycardia. In contrast to the results obtained, in the study done by Puthenveetil et al., done on 40 patients, a significant difference was obtained in terms of HR in both the groups at pre-induction, 15, 30, 45, 60, 75, and 90 min ($P<0.05$) with Group B patients showing a statistically lower HR.

We observed that mean arterial pressure (MAP) in both the groups was non-significant in pre-operative period ($P>0.05$) as a study done by Patil and Kulakarni 2017⁹

who compared oral clonidine and oral metoprolol in FESS surgery and found that reduction in PR, SBP, DBP, and MAP in clonidine group was more than that with atenolol group but without any significant bradycardia or hypotension.

A study by Mydhili et al., in 2021¹⁰, found no statistically significant difference in SBP, DBP, and MAP between both clonidine and metoprolol groups.

In our study, results support the finding that the quality of the surgical field is better in patients who received clonidine than in those who received metoprolol at 15, 30, and 60 min ($P=0.0005$, 0.0001 , and 0.0001 , respectively) as found in a study done by Puthenveetil et al., at 15, 30, 45, and 60 min; there was a significant difference between groups. In a study by Bajpai and Pyati,¹¹ surgical conditions assessed by blood loss, Fromm's score and duration of surgery were best in Group II (NTG) compared to Group I (oral pre-medication with clonidine and metoprolol).

On comparing for sedation score, in our study, significant difference was found between those who received clonidine and others who received metoprolol at 15 min (2.7 ± 4.7 vs. 2.4 ± 0.5), $P=0.021$ and at 30 min (2.67 ± 0.48 vs. 2.23 ± 0.43), $P=0.0008$ after surgery. While comparing the sedation score at 60 min, no significant difference was obtained ($P=0.557$). On the contrary side, results obtained in a study done by Praveen and Prabu¹² found no significant difference in post-operative sedation score in clonidine and placebo group given intravenously 20 min before surgery to those posted for FESS.

The surgeon's satisfaction as observed in our study was found statistically significant in patients who received clonidine than in those who received metoprolol ($P<0.0001$). The results are comparable to Patil and Kulakarni that they also found that surgeons were more satisfied with the surgical field in the clonidine group than with that in the placebo group. A study by Motazedian et al.¹³ found that there was no significant difference between the two groups in terms of surgeon satisfaction.

In this study, hypotension was found more commonly in the clonidine group while bradycardia, rashes, and dryness of mouth were more common in the metoprolol group but these were not statistically significant. The results obtained were comparable to Chakole et al.,¹⁴ they found that during the study, one patient in Group C (clonidine) had bradycardia and hypotension which was managed using injection of atropine 0.6 mg IV

and IV fluids and injection mephentermine 6 mg IV, respectively.

Limitations of the study

The limitation of this study is that a quantitative assessment of blood loss could not be done and the anesthesiologist providing anesthesia was blinded to the study drug.

CONCLUSION

Both study drugs clonidine and metoprolol can be effectively used for induced hypotension in FESS. The results concluded that clonidine is better than metoprolol with respect to intraoperative hemodynamics, quality of the surgical field, and surgeon's satisfaction with the added advantage of sedation, reduced analgesia requirement, and other anesthetic drug.

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