

**A COMPARATIVE RANDOMIZED STUDY OF ATENOLOL AND CLONIDINE AS
PREMEDICATION FOR HYPOTENSIVE ANAESTHESIA IN PATIENTS
UNDERGOING FUNCTIONAL ENDOSCOPIC SINUS SURGERY UNDER GENERAL
ANAESTHESIA**

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Abstract

Introduction: Functional endoscopic sinus surgery (FESS) has been emerged as treatment of choice for chronic rhinosinusitis with or without nasal polyp refractory to medical treatment. During the surgery, even a small amount of bleeding can decrease visibility of the surgical field and is directly related to increased risk of complications and surgery failure. Hence it is important to minimize bleeding during the surgery. Preoperative preparation using antibiotic and steroid medications, intra-operative use of local decongestant and hypotensive anaesthesia by an expert anaesthetist are the methods which are being used to control bleeding during FESS and better visualization of surgical field. Many drug combinations and protocols for controlled hypotensive anaesthesia have been used and compared in past years.

Materials and Methods: A prospective, randomised, double blind study was conducted at tertiary care hospital on 120 patients of ASA grade I & II of either sex with the age and weight between 15-50 years and 45 to 70 kg respectively, undergoing functional endoscopic sinus surgery. After taking informed written consent, patients were randomly divided into two groups, of 60 patients each using a computer generated randomization schedule. In group A, patients received single dose oral clonidine 5mcg/kg and in group B patients received oral atenolol 1mg/kg, 90 minutes before induction of anaesthesia.

Results: A total of 120 patients who underwent functional endoscopic sinus surgery were enrolled for the study and were randomly allocated to 2 groups of 60 patients each. In Group A, 50% patients were males and 50% patients were females, while in Group B, 54% patients were males and 46% patients were females. Mean age of patients in Group A and Group B was 36.10 ± 7.30 yrs and 37.12 ± 6.20 yrs respectively, mean weight in Group A was 58.10 ± 6.10 kg while mean weight in Group B was 59.12 ± 6.50 kg, the mean duration of surgery in group A was 76.12 ± 7.50 min and group B was 77.12 ± 7.06 min. Both the groups were comparable with respect to age, weight and duration of surgery, ($P > 0.05$).

Conclusion: Present study concluded that premedication with oral clonidine 5mcg/kg 90 min before the induction is better than oral atenolol 1mg/kg in terms of hemodynamic stability, lesser blood loss and quality of surgical field without any significant side effects. Though hypotension and bradycardia are known side effects of both clonidine and atenolol, but in our study there were no any obvious side effects observed in either group. Tablet clonidine is a cheaper drug so when used as preanaesthetic medication in FESS is cost-effective, also it has anxiolytic property, analgesic property, reduces the anaesthetic agent requirement without significant side effects.

Key Words: Functional endoscopic sinus surgery, chronic rhinosinusitis, hemodynamic stability.

INTRODUCTION

Functional endoscopic sinus surgery (FESS) has been emerged as treatment of choice for chronic rhinosinusitis with or without nasal polyp refractory to medical treatment. During the surgery, even a small amount of bleeding can decrease visibility of the surgical field and is directly related to increased risk of complications and surgery failure.¹

Hence it is important to minimize bleeding during the surgery.² Preoperative preparation using antibiotic and steroid medications, intra-operative use of local decongestant and hypotensive anaesthesia by an expert anaesthetist are the methods which are being used to control bleeding during FESS and better visualization of surgical field.³ Many drug combinations and protocols for controlled hypotensive anaesthesia have been used and compared in past years.⁴

This study proposes to analyze the anaesthetic challenge of keeping the operating field free of blood through pharmacological therapy. It compares how premedicating with either atenolol or clonidine affects the conduct of the fixed anaesthesia protocol evolved in our institute on patients undergoing FESS procedure under GA, and requiring a hypotensive technique to improve operating conditions.⁵

So we designed the present study to compare the effects of oral premedication with tablet clonidine and tablet atenolol by as both of them possess nearly similar pharmacokinetic and pharmacodynamic profile. Oral route is considered as safe option, because hypotension and bradycardia are major adverse effects with intravenous administration of clonidine and beta

blockers. So, we decided to compare clonidine and atenolol as oral premedication for functional endoscopic sinus surgery and study their merits and demerits.

MATERIALS AND METHODS

Study Design: A Comparative Randomized Study.

Study location: Department of Anaesthesiology, ESIC Medical College and Hospital, Kalaburagi, Karnataka.

Sample Size: 120 patients, 60 in each of clonidine, atenolol groups.

Study duration: January 2022 to December 2022.

A prospective, randomised, double blind study was conducted at tertiary care hospital on 120 patients of ASA grade I & II of either sex with the age and weight between 15-50 years and 45 to 70 kg respectively, undergoing functional endoscopic sinus surgery. After taking informed written consent, patients were randomly divided into two groups, of 60 patients each using a computer generated randomization schedule. In group A, patients received single dose oral clonidine 5mcg/kg and in group B patients received oral atenolol 1mg/kg, 90 minutes before induction of anaesthesia. Patients with age less than 15 years and more than 50 years, patients preferring local anaesthesia, patients with major systemic diseases like rheumatic heart disease, ischaemic heart disease, hypertension, heart blocks, diabetes mellitus, anaemia, sick sinus syndrome, sinus bradycardia, respiratory diseases like chronic obstructive pulmonary disease, bronchial asthma, renal and hepatic derangements, disease of central nervous system, allergic fungal sinusitis, patients on clonidine or beta blockers, agents influencing autonomic nervous system and blood coagulation were excluded from the study.

A detailed case history, clinical examination and all relevant investigations were done for all the patients. Baseline parameters like pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial blood pressure were noted.

The detailed data was entered into the Microsoft excel sheet and subsequently analyzed by using appropriate statistical tests. Graphical display was done for better visual inspection.

RESULTS

A total of 120 patients who underwent functional endoscopic sinus surgery were enrolled for the study and were randomly allocated to 2 groups of 60 patients each. In Group A, 50% patients were males and 50% patients were females, while in Group B, 54% patients were males and 46% patients were females. Mean age of patients in Group A and Group B was 36.10 ± 7.30 yrs and 37.12 ± 6.20 yrs respectively, mean weight in Group A was 58.10 ± 6.10 kg while mean weight in Group B was 59.12 ± 6.50 kg, the mean duration of surgery in group A was 76.12 ± 7.50 min

and group B was 77.12 ± 7.06 min. Both the groups were comparable with respect to age, weight and duration of surgery, ($P > 0.05$).

Variables	Group A	Group B	P-Value
Age (years)	36.10 ± 7.30	37.12 ± 6.20	0.650
Weight (Kg)	58.10 ± 6.10	59.12 ± 6.50	0.656
duration of surgery (min)	76.12 ± 7.50	77.12 ± 7.06	0.592

Table 1: Patient Demographics

Variables	Group A	Group B
Preoperative		
0 min	113	108
10 min	112	106
20 min	112	98
30 min	112	98
40 min	112	98
50 min	112	98
60 min	112	98
70 min	110	98
80 min	110	98
90 min	108	98
Postoperative		
15 min	110	98
30 min	111	99
45 min	111	100
60 min	112	104
75 min	113	105
90 min	113	106
105 min	113	107
Postoperative hour		
2 h	118	108
3 h	119	108
4 h	120	109
5 h	120	110
6 h	120	120
7 h	120	120
8 h	120	120

Table 2: comparison of systolic BP in group A and group B

Variables	Group A	Group B
Preoperative		
0 min	70	75
10 min	70	74
20 min	71	60

30 min	60	73
40 min	60	73
50 min	61	73
60 min	62	74
70 min	61	74
80 min	62	75
90 min	62	76
Postoperative		
15 min	63	77
30 min	63	77
45 min	65	77
60 min	70	77
75 min	72	78
90 min	73	78
105 min	73	78
Postoperative hour		
2 h	75	78
3 h	75	78
4 h	76	79
5 h	77	79
6 h	78	80
7 h	80	80
8 h	80	80

Table 3: comparison of DBP in group A and group B

Variables	Group A	Group B
Preoperative		
0 min	82	85
10 min	82	84
20 min	78	83
30 min	76	83
40 min	75	83
50 min	75	85
60 min	75	82
70 min	75	83
80 min	77	82
90 min	78	82
Postoperative		
15 min	78	82
30 min	78	83
45 min	78	83
60 min	80	83
75 min	80	83
90 min	80	82
105 min	81	83

Postoperative hour		
2 h	82	89
3 h	82	89
4 h	82	89
5 h	84	90
6 h	85	90
7 h	90	90
8 h	90	90

Table 4: comparison of MAP in group A and group B

Variable	Group A	Group B	P Value
Blood loss (ml)	101.7±6.05	130.1±8.13	<0.001

Table 5: Comparison of blood loss in both groups

Quality of surgical field (grades)	1	2	3	4	Total
Group A	15	45	0	0	60
Group B	5	15	25	15	60

Table 6: Comparison of quality of surgical field in Group A and Group B

Comparison of quality of surgical field in group A and group B, the median grade in group A was 2 and group B was 3. There was significant difference between median grades for quality of surgical field in both the groups, quality of surgical field was better in clonidine group compared to atenolol group.

We did not observe the significant sedation which require any additional interventions in preoperative period and postoperative period in patients of both groups. There were no any serious side effects (like nausea, vomiting, hypotension, bradycardia, or shivering) observed after giving clonidine and atenolol as premedication in either groups.

DISCUSSION

Although major blood loss during FESS is rare, bleeding during functional endoscopy sinus surgery remains a main consideration because the mucosa is highly rich in blood vessels. Even a small amount of blood may disturb the endoscopic view, increasing the likelihood of complications as well as lengthening the operative procedure and possibly resulting in incomplete surgery.⁶

The threat of serious complication from the poor visibility due to excessive bleeding in the surgical field and the possibility of neurological damage makes it important for anesthesiologists to produce optimal surgical conditions.⁷ Several methods have been designed to reduce bleeding during surgery, none of these techniques have consistently provided a desirable bloodless field

for the surgeon. So to provide optimal field hypotensive agents given such as sodium nitroprusside, nitroglycerine, propofol, clonidine, esmolol, metoprolol & atenolol had been used individually to decrease blood loss in FESS.⁸

But none of the single agent proved to be best as each of them had their own advantages and disadvantages. So we decided to compare oral clonidine and oral atenolol as premedication, as both of them possess nearly similar pharmacokinetic and pharmacodynamic profile. We compare these two drugs as oral premedication, because hypotension and bradycardia are major adverse effects of intravenous administration of clonidine and beta blockers as compared with oral premedication, so oral premedication is considered as safe option.⁹

Matot et al, Singh and Arora and Gupta et al studied the hemodynamic stability after oral clonidine and oral atenolol premedication and reported decrease in pulse rate and blood pressure. In present study, there was a significant decrease in PR, SBP, DBP and MAP in both the groups in spite of surgical stimulus. On comparison the reduction in PR, SBP, DBP, MAP was greater in clonidine group than atenolol group, which shows that hemodynamic stability was better in spite of intraoperative instrumentation in clonidine group.

The amount of blood loss was less in both clonidine and atenolol groups but clonidine group had less amount of bleeding intraoperatively compared to atenolol group which proves that clonidine is better as premedication in FESS. Therefore, severity of bleeding was lesser in clonidine group compare to atenolol group. There was significant difference between median grade for quality of surgical field in group A and group B. Our findings were similar to the studies done by Jabalamelli in which patients undergoing endoscopic sinus surgery for chronic sinusitis were randomly allocated to receive either oral clonidine 0.2 mg or identical-looking placebo tablets 90 min before arrival at the operating room. Blood loss was less in clonidine group (214 ± 67 ml) compared to placebo group (276 ± 78 ml). The median (range) bleeding score in the clonidine group was significantly lower than that in the placebo group. Accordingly, the surgeon was more satisfied with the surgical field in the clonidine group than with that in the placebo group. Also Jabalamelli and Masood Mohseni et al reported that bleeding severity was significantly lesser in clonidine group. Similar to our study, they concluded that premedication with oral clonidine 0.2 mg can effectively reduce bleeding during FESS.¹⁰

CONCLUSION

Present study concluded that premedication with oral clonidine 5mcg/kg 90 min before the induction is better than oral atenolol 1mg/kg in terms of hemodynamic stability, lesser blood loss and quality of surgical field without any significant side effects. Though hypotension and bradycardia are known side effects of both clonidine and atenolol, but in our study there were no any obvious side effects observed in either group. Tablet clonidine is a cheaper drug so when used as preanaesthetic medication in FESS is cost-effective, also it has anxiolytic property, analgesic property, reduces the anaesthetic agent requirement without significant side effects.

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