Section: Anaesthesiology

Original Research Article

COMPARATIVE EVALUATION OF ORAL ATENOLOL VERSUS ORAL CLONIDINE AS PREMEDICANTS FOR HYPOTENSIVE ANAESTHESIA IN PATIENTS UNDERGOING FUNCTIONAL ENDOSCOPIC SINUS SURGERY

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Abstract

Background: Providing hypotensive anaesthesia results in good surgical outcomes, reduced transfusion rates, decreased complications and reduced time duration of surgery. The present study aimed to evaluate oral atenolol versus oral clonidine as premedicants for hypotensive anaesthesia in patients undergoing functional endoscopic sinus surgery (FESS). **Materials and Methods:** This is a Prospective randomised analytical study among 80 patients (randomly divided into two groups of 40 each, receiving oral atenolol 1 mg/kg and oral clonidine 2 microgram/kg, respectively) for hypotension anaesthesia undergoing FESS. Hemodynamic parameters (such as heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure), intraoperative complications (such as hypotension, hypertension, tachycardia, bradycardia, arrhythmias), Postoperative parameters (sedation, time of rescue analgesia), surgical parameters (such as duration of surgery, quality of operating field) were measured. **Result:** Baseline Demographic and anthropometric parameters such as age, gender, and weight were not significantly different between the groups. Hemodynamic parameters such as Systolic, Diastolic, and mean arterial blood pressure were significantly lower among the clonidine group throughout the surgery. Heart rate was significantly lower among the atenolol group. The common side effect observed was hypotension in both groups. Sevoflurane requirement and duration of surgery were lower among the clonidine group but not statistically significant. Postoperative analgesic requirement among the clonidine group was significantly lower, and there were good sedation scores for the clonidine group. **Conclusion:** Oral clonidine as premedication to the patients undergoing FESS can be effective in producing hypotensive anaesthesia, adequate sedation and lesser postoperative analgesia requirement when compared with oral atenolol.

INTRODUCTION

When conservative management fails, functional endoscopic sinus surgery (FESS) is most commonly performed for nasal polyps, nasal obstruction and chronic sinusitis. FESS is an intranasal scopic visualisation of nasal structures.[1] As the turbinates are inflamed in these conditions, the endoscopy can cause more bleeding than expected, and it is a time-consuming procedure.[2,3] FESS is challenging because it is difficult to control bleeding by surgical means as blood oozing from inflamed structures is continuously oozing. Even minimal bleeding can obstruct the view of the operating endoscope.[4] Hypotensive anaesthesia is widely practised in this type of surgery. Hypotensive anaesthesia maintains systolic BP between 80-90 mmHg and mean arterial pressure between 60-70 mmHg. MAP less than 60 mmHg for 11 to 20 minutes are associated with acute kidney injury.[5] Usually, nitro-glycerine or inhalational agents in titration doses produce controlled hypotension. But the hypotension produced by these drugs can be erratic, difficult to control and close monitoring is required.[6]

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In FESS, it is necessary to keep the surgical field clear and bloodless to identify the diseased tissue correctly. A good premedication with an antihypertensive agent helps to produce hypotension, thereby reducing the need for vasodilators intraoperatively. The ideal agent for controlled hypotension should be easy to administer, have a shorter onset time, and the effect disappears quickly when the administration is stopped, with no formation of toxic metabolites and predictable dose-dependent effects.[7] Clonidine is a Partial agonist that acts on alpha 2A receptors in the brainstem and medulla postjunctional. It reduces the sympathetic outflow and enhances the vagal tone, reducing blood pressure and heart rate.[8] Atenolol is a Beta 1 selective adrenergic antagonist, and it is cardio-selective, devoid of intrinsic sympathomimetic activity, and it has Negative chronotropic, dromotropic and inotropic effects and decreases blood pressure.[9]

Atenolol and clonidine are commonly used as oral premedications to induce hypotensive anaesthesia and to provide optimal surgical field visualisation to reduce the incidence of surgical complications. Very few studies on this topic exist, especially in the Indian context. Therefore, this study aims to assess the effectiveness in producing hypotensive anaesthesia, hemodynamic stability and surgical convenience by administering oral clonidine and oral atenolol as premedication to the patients undergoing FESS.

MATERIALS AND METHODS

This prospective randomised analytical study was performed on 80 patients (divided into two groups of 40 each, receiving oral clonidine and oral atenolol, respectively) undergoing FESS under the Department of Anaesthesiology and Critical Care, Dhanalakshmi Srinivasan Medical College and Hospital, Perambalur for 1.5 years. Written informed consent and permission from the institutional ethical committee were obtained from all the study participants before study initiation.

Inclusion Criteria

Patients of either sex aged 18 to 60 years with ASA class I and II were included.

Exclusion Criteria

Patients who are pregnant women, ASA grade III and IV, COPD and asthma, patients having drug hypersensitivity, history of cerebrovascular accident, significant hepatic or renal disease, Ischaemic heart disease, hypertension and diabetes were excluded.

Methodology

Patients undergoing FESS under the Department of Anaesthesiology and Critical Care were explained the study's purpose and procedure. Based on the randomisation, 80 patients were divided into two groups, 40 receiving oral clonidine (Group C) and oral atenolol (Group A).

Oral premedication was given 2 hours before surgery. Oral Atenolol 1 mg/kg to group A patients. Oral clonidine 2 microgram/kg to group C patients. General Anaesthesia was given using standard protocols for all the patients. Hemodynamic parameters (such as heart rate, systolic and diastolic blood pressure and mean arterial pressure), anaesthetic parameters (such as the requirement of nitro-glycerine and inhalational agents), intraoperative complications (such as hypotension, hypertension, tachycardia, bradycardia, arrhythmias), surgical parameters (such as duration of surgery, quality of operating field), postoperative parameters (sedation, time of rescue analgesia) were measured, and throat packing done immediately after intubation.

Statistical Analysis

The collected data was entered in Microsoft Excel (windows 11) and analysed using the statistical package for social sciences (SPSS-21). Fisher's exact test/Pearson chi-square test was used to find the association between two categorical variables. The value of $P<0.05$ is considered statically significant.

RESULTS

The mean age, gender distribution, and weight were comparable between the two groups. The mean heart rate (HR) at pre-induction and after intubation was comparable between the two groups (Group C and A). However, it was statistically significant ($p<0.05$) between the two groups at other points [Table 1].

The intra-operative mean HR was comparable between the two groups at 5, 10 and 90 minutes but was statistically significant ($p<0.05$) up to 75 minutes [Table 2].

Mean SBP, at pre-induction, after induction, neostigmine, and extubation, was comparable in both Group C and A. The intra-operative mean SBP was comparable at 5, 60, 75 and 90 minutes in both groups [Table 3].

Mean DBP, at pre-induction, after induction, neostigmine, and extubation were statistically significant ($p<0.05$) after 2 minutes of neostigmine and 5 min after extubation in both Groups. The intra-operative mean DBP was comparable at 5, 10, 60 and 90 minutes in both groups [Table 4].

MAP, at pre-induction, after induction, neostigmine, and extubation, were comparable in both Group C and A. However intra-operative MAP was comparable at 5, 60, 75 and 90 minutes in both Groups C and A [Table 5].

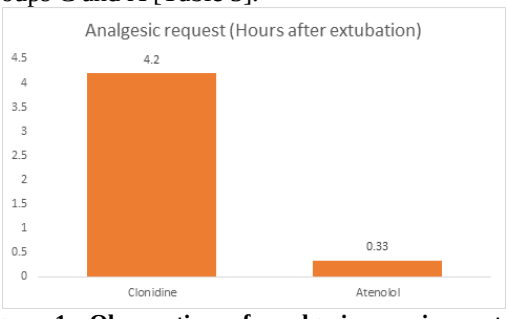

Figure 1: Observation of analgesia requirement in patients of both groups

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In Group C, the moderate requirement of Sevofluorane was reported in 3 (7.5%), whereas in Group A, it was 6 (15%). Hypotension was found 2 (5%) in Group A and 1 (2.5%) in Group C. The mean duration of surgery was reported to be slightly higher in Group A (80.25±14.19 hours) than in Group C (78.88±15.55 hours). The postoperative sedation score (determined by Ramsay sedation score) was observed to be significantly high ($p<0.05$) in group C (3.63±0.54) as compared to group A (2.45±0.60). The mean Analgesic Request among the Clonidine group was also reported significantly (4.2± 1.38) as compared to Group A (0.33± 0.76) [Table 6, Figure 1].

Table 1: Observation of Demographic and Hemodynamic parameters of patients in both groups

Parameters		Observation N (%)		P-value
		Group C (Clonidine) (N=40)	Group A (Atenolol) (N=40)	
Age (Years)		24.28 ±5.44	26.35 ±4.77	0.074
Gender	Male	22 (55%)	20 (50%)	0.655
	Female	18 (45%)	20 (50%)	
Weight (kg)		51.25 ±9.32	53.98± 5.70	0.120

Table 2: Mean heart rate between groups

Mean heart rate (HR) (Beats/min)	Group C (Clonidine)	Group A (Atenolol)	P-value
HR at pre-induction	68.95± 7.35	67.25± 8.13	0.33
HR after Induction	72.08± 7.35	66.75 ±9.31	0.006
HR after Intubation	71.13± 7.76	75.00 ±11.76	0.086
HR after neostigmine	70.15 ±6.42	63.60 ±9.43	0.001
HR at 2 min after neostigmine	69.80± 6.01	61.85 ±10.07	0.001
HR after extubation	77.80± 8.64	73.05 ±8.35	0.015
HR at 2 min after extubation	77.35 ±6.08	63.05 ±10.89	0.001
HR at 5 min after extubation	78.55 ±7.11	70.10 ±9.49	0.001
Heart rate Intra-operative			
5 min	73.15± 7.59	71.93 ±10.80	0.559
10 min	70.90± 8.23	69.13± 9.05	0.362
15 min	71.05 ±7.77	66.38 ±8.39	0.012
20 min	72.80 ±7.95	65.95 ±8.02	0.001
30 min	71.80± 6.68	66.03 ±7.92	0.001
40 min	73.08 ±8.19	68.18 ±7.81	0.008
50 min	73.10 ±7.91	65.74 ±7.68	0.001
60 min	70.34 ±6.84	65.57 ±6.15	0.003
75 min	70.59 ±7.93	63.32± 6.72	0.001
90 min	72.17± 8.00	67.65 ±9.93	0.192

Table 3: Systolic blood pressure between groups

SBP (mmHg) (mean± SD)	Group C (Clonidine)	Group A (Atenolol)	P-value
SBP at pre-induction	111.75± 8.98	112.20 ±8.95	0.823
SBP after Induction	95.10± 7.13	97.00± 4.89	0.169
SBP after Intubation	99.60± 3.47	98.03 ±4.77	0.096
SBP after neostigmine	106.05 ±10.40	108.38 ±7.88	0.263
SBP at 2 min after neostigmine	111.80± 11.15	109.08± 7.24	0.199
SBP after extubation	112.70 ±7.87	108.03 ±8.24	0.011
SBP at 2 min after extubation	111.05 ±10.87	107.58 ±7.25	0.097
SBP at 5 min after extubation	109.85± 10.23	108.75± 6.79	0.573
SBP Intra-operative			
5 min	83.13 7.17	81.30 4.35	0.171
10 min	82.25 5.66	87.38 4.45	0.001
15 min	82.83 6.89	86.63 4.25	0.004
20 min	83.35 4.61	87.28 4.39	0.001
30 min	84.93 5.00	87.45 4.25	0.017
40 min	83.45 6.10	86.53 4.60	0.013
50 min	84.51 6.14	87.30 4.87	0.028
60 min	85.05 6.39	86.31 3.87	0.313
75 min	85.08 14.52	86.44 4.41	0.656
90 min	93.10 8.50	94.00 3.28	0.675

Table 4: Diastolic blood pressure between groups

DBP (mmHg) (mean± SD)	Group C (Clonidine)	Group A (Atenolol)	P-value
DBP at pre-induction	79.10± 7.48	79.55 ±7.41	0.788
DBP after Induction	64.35 ±7.42	64.60± 4.53	0.856
DBP after Intubation	73.45 ±9.31	74.63± 5.13	0.484
DBP after neostigmine	73.75 ±7.84	76.83 ±5.97	0.052
DBP at 2 min after neostigmine	76.00± 5.84	80.05 ±6.08	0.003
DBP after extubation	77.55± 8.23	79.63± 6.90	0.224
DBP at 2 min after extubation	76.85 ±10.56	78.13± 6.58	0.517
DBP at 5 min after extubation	73.70 ±8.23	78.03 ±6.41	0.01

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DBP Intra-operative			
5 min	66.75 ±5.95	65.23 ±3.82	0.177
10 min	63.45 ±5.71	64.15± 4.64	0.549
15 min	57.80 ±4.93	63.05 ±4.49	0.001
20 min	60.08± 5.48	64.13 ±3.82	0.001
30 min	61.28± 7.16	65.28 ±4.06	0.003
40 min	59.20 ±6.13	64.98 ±4.11	0.001
50 min	59.38 ±5.43	64.78± 3.79	0.001
60 min	62.54± 6.49	64.43 ±4.28	0.152
75 min	60.16± 9.60	65.48± 5.47	0.017
90 min	66.80±8.42	64.25 ±4.99	0.350

Table 5: Mean arterial pressure between groups

MAP (mmHg) (mean± SD)	Group C (Clonidine)	Group A (Atenolol)	P-value
MAP at pre-induction	89.80 ±7.86	90.25 ±7.80	0.798
MAP after Induction	74.40± 6.83	75.40± 3.44	0.411
MAP after Intubation	74.60± 10.60	75.76 ±3.38	0.511
MAP after neostigmine	84.40± 8.59	87.34± 5.06	0.067
MAP at 2 min after neostigmine	87.90± 7.10	89.73 ±4.18	0.166
MAP after extubation	88.55±7.80	89.09± 4.68	0.708
MAP at 2 min after extubation	86.20 ±10.25	87.94 ±5.55	0.348
MAP at 5 min after extubation	86.05± 8.42	88.27 ±4.94	0.156
MAP Intra-operative			
5 min	72.54± 5.78	70.58 ±2.92	0.059
10 min	69.72± 5.25	71.89 ±3.75	0.036
15 min	66.14± 4.75	70.91 ±3.36	0.001
20 min	67.83± 3.94	71.84 ±2.74	0.001
30 min	69.16± 5.69	72.67± 3.24	0.001
40 min	67.28 ±5.57	72.16± 3.33	0.001
50 min	66.07± 11.59	72.28± 3.23	0.002
60 min	70.05± 5.67	71.72 ±3.19	0.129
75 min	68.47 ±11.01	72.47 ±4.35	0.087
90 min	74.90± 7.50	74.17± 3.52	0.754

Table 6: Observation of different evaluation parameters of patients in both group

Parameters	Observation N (%)		P-value
	Group C (Clonidine) (N=40)	Group A (Atenolol) (N=40)	
Sevoflurane requirement			
Low requirement	37 (92.5%)	34 (85%)	0.164
Moderate requirement	3 (7.5%)	6 (15%)	
Complication			
Hypotension	1 (2.5%)	2 (5.0%)	0.38
Hypertension	0 (0.0%)	1 (2.5%)	0.5
Duration of Surgery (hours)	78.88± 15.55	80.25± 14.19	0.681
Post Operation Sedation Score	3.63± 0.54	2.45± 0.60	0.001
Analgesic Request (Hours After Extubation)	4.20 ±1.38	0.33± 0.76	0.001

DISCUSSION

By providing hypotensive anaesthesia, the surgical outcome is good, with reduced transfusion rates, decreased complications and reduced surgery duration.[1,2] Atenolol and clonidine are commonly used as oral premedications to induce hypotensive anaesthesia and to provide optimal surgical field visualisation to reduce the incidence of surgical complications. The main objective of the study is to study the effectiveness in terms of hypotensive anaesthesia, Intraoperative requirement of other hypotensive agents, surgical convenience, postoperative sedation assessment and rescue analgesia postoperatively by administering oral clonidine and oral atenolol as premedication to the patients undergoing FESS. Baseline Demographic and anthropometric parameters such as age, gender and weight were not significantly different between the groups. Hence the role of confounding in the study results can be ruled out. The study groups were assigned based on randomisation; therefore, the study groups will be comparable. These findings in the present study follow earlier reported studies.

In this study, the heart rate after induction, after administration of neostigmine, at 2 min after neostigmine administration, after extubation, at 2 min after extubation, and 5 min after extubation were significantly lesser among the atenolol group. The heart rate between the groups pre-induction and after intubation was not significantly different. Intra-operatively, the heart rates at 5, 10 and 90 min were not significantly different between the groups. Intraoperatively, the heart rate at 15, 20, 30, 40, 50, 60 and 75 min was significantly lesser among the atenolol group. The systolic blood pressure after intubation, after extubation, and at 2 min after extubation were not significantly different. Intraoperatively, the systolic blood pressure at 10, 15, 20, 30, 40, and 50 min was significantly lesser among

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the clonidine group. Diastolic blood pressure after intubation, 2 min after neostigmine administration, after extubation, and at 2 min after extubation were not significantly different. Intraoperatively, the diastolic blood pressure at 10, 15, 20, 30, 40, 50 and 75 min was significantly lesser among the clonidine group. The mean arterial blood pressure after intubation, after extubation, and at 2 min after extubation were not significantly different. Intraoperatively, the mean arterial blood pressure at 5, 10, 15, 20, 30, 40, and 50 min was significantly lesser among the clonidine group.

Similar to our study, clonidine was compared with the placebo by, Tugrul et al. They observed that the parameters of hemodynamic stability were better (with significantly lower SBP, DBP, MAP), good quality of surgical field with surgeon's satisfaction score and lesser amount of loss of blood among the clonidine group (compared to the placebo), with no serious adverse effects.[10]

Contrary to our study results, the following studies observed no difference in hemodynamic stability. Puthenveetti et al. compared the effect of oral clonidine (300mcg) and oral metoprolol (50 mg) and observed a good quality of surgical field among the clonidine group with no difference in hemodynamic parameters such as SBP, DBP and MAP. The category scale score used for intraoperative surgical field assessment revealed the clonidine group had significantly lower scores.[11] Singh et al. compared the effect of oral clonidine (100mcg) and oral atenolol (50mg) and observed that the hemodynamic stability was similar between the groups, with good quality of the surgical field and lesser amount of loss of blood among the clonidine group.[12]

At clinical concentrations, inhalation drugs (Isoflurane and Sevoflurane) have the advantage of being a hypotensive agents.[13] In this study, 92.5% of the clonidine group had a low requirement, and 7.5% had a moderate requirement compared to the atenolol group. Of these, 85% had a low requirement, and 15% had a moderate requirement, and the difference was not having statistical significance ($p>0.05$). Similar to our study results for side effects, Mydhili et al. observed that the hemodynamic stability was better, good quality of the surgical field, reduced requirement of hypotensive agents and lesser amount of loss of blood among both the atenolol and clonidine group, with lesser incidence of complications and adverse effects among the atenolol group.[14]

Important organs and tissues, primarily the brain, heart, and kidneys, run the danger of hypoperfusion when under the effects of hypotensive anaesthesia.[15] In this study, 2.5% of the Clonidine group had hypotension, which is lower but not statistically significant ($p>0.05$) compared to the atenolol group of whom 5% had hypotension. None in the Clonidine group had hypertension, which is lower but not statistically significant ($p > 0.05$) compared to the atenolol group, of whom 2.5% had hypertension. No subjects in both groups had arrhythmia, tachycardia, bradycardia and ischemia. Kumar et al. compared the effect of oral clonidine and oral atenolol as premedication and observed that the demographics, hemodynamic stability, and side effect profile were similar among both groups. Good quality of the surgical field and a lesser amount of loss of blood were observed among the clonidine group.[16]

Hypotensive anaesthesia provides optimal surgical field visualisation to reduce blood loss and the incidence of blood transfusions. It also increases the surgeon's satisfaction and decreases the surgery's duration.[17] In this study, the mean duration of surgery among the clonidine group was 78.88 (± 15.55) hours, which is lower by 1.38 hours but not statistically significant compared to 80.25 (± 14.19) hours in the atenolol group. Patil et al. compared the effect of oral clonidine (5mcg/kg) and oral atenolol (1mg/kg) and observed that the hemodynamic stability was better, good quality of the surgical field and lesser amount of loss of blood among the clonidine group, with no serious adverse effects among both the groups.[18]

Clonidine produces sedation with suppression of delirium, maintenance of respiratory drive, decreased O2 consumption, renal function maintenance, and protein metabolism. The primary action of clonidine is analgesia, followed by sedation. (60– 63)In this study, the mean Post Op Sedation Score among the clonidine group was 3.63 (± 0.54), greater by 1.18 and statistically significant compared to 2.45 (± 0.6) in the atenolol group. Ali et al. also reported similar findings in their investigation.[19]

In this study, the mean analgesic requirement (Hours after Extubation) among the clonidine group was 4.2 (± 1.38), which is greater by 3.88 and statistically significant compared to 0.33 (± 0.76) in the atenolol group. Amarnath et al. compared the effect of oral clonidine and oral atenolol and observed that the hemodynamic stability was better, good quality of the surgical field and lesser amount of loss of blood among both the atenolol and clonidine group, with higher adverse effects among the atenolol group and reduced requirement of postoperative analgesia among clonidine group.[20]

Limitations

The sample size was smaller for studying the different side effects and the associations. The standards of this hospital-based study in a tertiary care setting are different from the lower health care settings. Hence, the study results are subjected to Berkesonian bias and cannot be generalised.

CONCLUSION

Oral clonidine as premedication to the patients undergoing FESS can be effective in producing hypotensive anaesthesia, adequate sedation and lesser postoperative analgesia requirement when compared with oral atenolol.

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