Original Research

Comparison Of Oral Clonidine vs IV Clonidine On Hemodynamic Stability Of Patients Undergoing FESS

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ABSTRACT:

Background: Establishing a near perfect surgical field during functional endoscopic sinus surgery (FESS) is essential and even a minor bleeding can severely compromise an already restricted view.

Aim: The aim of this study was to compare the hemodynamic changes and surgical conditions during FESS following premedication withoral Clonidine and IV Clonidine.

Settings and design: A total of 80 patients undergoing FESS were included in this prospective, observational study conducted at the department of Anesthesiology, critical care and painmanagement in Govt. Medical College Srinagar (J&K).

Subjects and methods: Patients were divided into two equal groups. Group A patients were premedicated with oral clonidine oral Clonidine 5 μg/kg with sips of water 90 minutes before surgeryand Group B with intravenous clonidine IV clonidine 2 μg/kg, followed by 1 μg/kg/h infusion. All patients received fentanyl 2 mcg/kg and induced with propofol 2 mg/kg. Intubation was done following Vecuronium 1 mg/kg. Anesthesia was maintained with 66% N2O, 33% O2 and 1% isoflurane. The Heart Rate and Blood Pressure were measured at 1 and 5 minutes after induction of anaesthesia and through every 5 minutes for the first 30 minutes and then every 15 minutes thereafter intraoperatively. The surgeons were asked to estimate the quality of the operative field using a pre-defined category scale with scores 1-5.

Results: In both the groups, target mean arterial pressure (MAP) of 65–70 mmHg and improved surgical field quality were achieved. MAP and heart rate (HR) were comparable among the study groups. However there was slow decrease in MAP and heart rate in the oral clonidine group with a longer duration of post-operative analgesia ($P = 0.001$). None of the groups showed any statistically significant adverse effects.

Conclusion: Both IV and oral clonidine can be used for controlled hypotension to improve surgical field quality in FESS. Oral clonidine provides more haemodynamic stability with fewer fluctuations in BP and heart rate as compared to iv clonidine.

Keywords: Hemodynamic stability, Functional endoscopic sinus surgery, oral clonidine, Intravenous clonidine, General Anaesthesia

INTRODUCTION:

Although major blood loss during FESS is rare,bleeding during functional endoscopy sinussurgery remains a main consideration because themucosa is highly rich in blood vessels [1]. Even asmall amount of blood may disturb the endoscopicview, increasing the likelihood of complicationsas well as lengthening the operative procedure andpossibly resulting in incomplete surgery[2]. Thethreat of serious complication from the poorvisibility due to excessive bleeding in the surgicalfield and the possibility of neurological damagemakes it important for anesthesiologists toproduce optimal surgical conditions[3]. Severalmethods have been designed to reduce bleedingduring surgery; none of these techniques haveconsistently provided a desirable bloodless fieldfor the surgeon. So to provide optimal field hypertensive agents given such as sodiumnitroprusside, nitroglycerine, propofol, clonidine,esmolol, metoprolol& atenolol had been usedindividually to decrease blood loss in FESS [4,5,6].But none of the single agent proved to be best aseach of them had their own advantages anddisadvantages.Hence, we aimed to comparethe hemodynamic changes and surgical conditionsduring FESS following oral premedication with clonidineor I.V clonidine in this study.

MATERIAL &METHODS:

Studyareaandduration:

The study was carried out in the Department of Anaesthesia and Critical Care at Government Medical College, Srinagar from April 2019 to September 2019. After obtainin gap proval from Hospital Ethics Committee,a written in formed consent was taken from the patients for participation in this study, who were recruited from the out-patient department at the time of pre-anesthetic check-up after meeting in clusion criteria.

STUDY POPULATION:

Inclusion Criteria:The study included patients who were:

1. AS AgradeI.
2. 20-50yearsofage.
3. Who gave in formed written consent.
4. Patients scheduled to undergo FESS under general anesthesia.

Exclusion Criteria: The study excluded patients with:

1. AS A physicalstatusIIorgreater.
2. Agemorethan50years, less than20years.
3. Pregnant,lactatingand menstruatingfemales.
4. History of Drug/alcoholabuse.
5. Patientswithchronicpain,psychiatricdisease,peripheralvasculardisease.
6. Anticipated difficultintubation.
7. Patientsallergic to study medications.

Study design:

The study was designed as a hospital-based prospective observational clinical trial involving 80 patients of ASA physical status I of either sexs cheduled toundergo FESS procedureun dergeneralana esthesia.

Methodology:
Patients selected for surgery were admitted 24 hours prior to surgery. Pre-anaesthetic evaluation was done at this stage. Age, gender, weight, type of surgery,ASA physical status was noted down in all patients. A thorough history includinghi storyofanyco-morbid disease,previousana esthetic exposure,smoking,medications, allergy to any drugs and personal habits was elicited. Any history of palpitations and previous heart conditions was duly noted.

General physical examination as well as systemic examination of cardiovascular system,respiratorysyste mand centralnervous system was performed.Air way assessment was also donetopredi ctany difficultintubation.All routinein vestigation slikehaemoglobin,platelet count,BT/CT,bloodurea and serum Creatinine,blood glucose,chest X-ray (P/Aview), ECG were checked.The patients were advised to remain fasting overnight.

Anesthesiaprotocol:
After patient identification, a short preoperative historywas taken; clinical examination and routine investigationswere rechecked in all patients. Study objective and procedurewere explained to the participants and written informedconsent was obtained from each participant. Intravenousaccess was secured, and an infusion of Ringer's lactatesolution was started. Patients were randomly assigned toreceive either 5µg kg-1 orally clonidine 90 minutes before surgery or IV clonidine 2 µg/kg in 10 ml of saline over 10 min followed by 1 µg/kg/h infusionbefore induction ofanaesthesia respectively. The degree of sedation was gradedusing the Ramsay sedation scale and patients were shifted tothe operating room after which routine non-invasive monitorwas applied and vital signs monitored.All the patients received a nasal packing 2% xylocaine and 1:200000 of adrenaline in order to shrink the nasal mucosal vessels. Injection Glycopyrolate 0.2 mg i.m was given as an anti-sialogogue 45 minutes prior to Induction. Preoxygenation with four to five breaths of 100% oxygen. Allpatients received Injection fentanyl 2µg kg-1 then patientswere induced with IV propofol 2.5 mg kg-1 in incrementaldoses until loss of eyelash reflex occurred, then patient'sairway assessed for ventilation and IV Vecuronium bromide 0.1 mg kg-1 was given over 20 sec. Patients were ventilatedwith oxygen and 1% isoflurane using IPPV with a fresh gasflow of 6 liters min-1 by Bain circuit until intubation. After intubation, anaesthesiawas then maintained with O2 and isoflurane. Thereafter the Heart Rate and Blood Pressure were measured at 1 and 5 minutes after induction of anaesthesia and through every 5 minutes for the first 30 minutes and then every 15 minutes thereafter intraoperatively. To maintain hypotension for producing a bloodless surgical field, mean arterial pressure was proposed to be 60-70 mm Hg. If unsuccessful, Intravenous Injection Nitroglycerin diluted to a concentration of 100µg/ml and given as bolus doses.

Parameters and Statistical Analy
sisSummary statistics of patient gender, age, and weight forboth the groups were reported as means, standard deviation.Ramsay sedation scale was used to assess the level ofsedation in all patients before induction.

Patients were also assessed for the side effects. HR, SBP,DBP, and MAP were recorded during monitoring. From thedata, RPP was calculated by multiplying heart rate withsystolic blood pressure. Patients were also observed forcomplications like over sedation, hypotension, nausea,hypertension, arrhythmias, and hypoxemia. Haemodynamicvariables were represented by mean, SD. ANOVA withrepeated measures was used to compare the changes in HR,SBP, DBP and MAP. Analyzed data were presented in theform of mean, where the level of significance was given as pvaluein a separate column. A p-value of less than 0.05 wastaken as significant. Man-Whitney U

test was used to analyzethe data since the data were not following a normaldistribution. Nominal data were compared using the Chi-Square test. The statistical package SPSS 14.0 was used.

CONFLICT OF INTEREST: Nil

FUNDING: NIL

RESULTS:
The demographic profile of the study population was comparable as shown in (Table 1). No significant difference was found with regard to demographic profile among the study population.

Table1: Demographic Profileofthe Patients

Variable	Group A (n=40)	GroupB(n=40)	P-value
Age(years)	37.8±6.70	39.7±8.41	0.208
Weight(kg)	58.2±6.21	57.5±6.16	0.686
Height(cm)	160.3±6.49	169.2±6.07	0.562
Gender(M/F)	22/18	18/22	0.586
ASA status I	40	40	0.761

Values in the table are mean ± SD or absolute numbers (percentage). SD = Standard deviation, ASA = American Society of Anesthesiologists.

While comparing HRs among groups, there was a significant difference between groups at pre-induction, 15, 30, 45, 60, 75 and 90 min ($P < 0.05$) with Group B patients showing a statistically lower HR. There was no significant difference between groups at 105 and 120 min ($P > 0.05$) [Table 2].

Table 2: Comparison of mean HR

Time	Group oral clonidine (Group A)	Group IV clonidine (Group B)	P value
Pre	82.1	69.2	<0.001
15	75.2	73.3	<0.001
30	71.1	63.4	<0.001
45	73.5	61.1	<0.001
60	68.8	62.8	<0.001
75	67.9	65.4	<0.001
90	66.8	63.7	<0.001
105	69.1	68.8	>0.001
120	68.4	69.1	>0.001

When SBP was compared between groups, there was a significant difference between groups at pre-induction and at 120 min ($P = 0.01$) with Group B patients showing a statistically higher SBP. There was no significant difference between groups at 15, 30, 45, 60, 75, 90 and 105 min ($P > 0.05$) [Table 3]

Table 3: Comparison of mean systolic BP

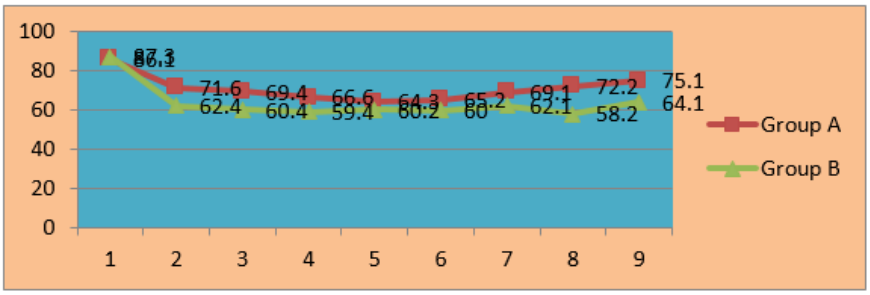
Time	Group oral clonidine (Group A)	Group IV clonidine (Group B)	P value
Pre	**107.3**	**115.1**	**<0.001**
15	**95.4**	**99.6**	**>0.001**
30	**95.1**	**95.5**	**>0.001**
45	**93.1**	**96.1**	**>0.001**
60	**92.2**	**97.0**	**>0.001**
75	**98.5**	**94.2**	**>0.001**
90	**96.3**	**94.1**	**>0.001**
105	**98.2**	**97.9**	**>0.001**
120	**92.2**	**99.5**	**<0.001**

When DBP was compared between groups, there was a significant difference between groups at 30 and at 60 min (*P* value 0.00 and 0.01 respectively) with Group B patients showing a statistically lower DBP. There was no significant difference between groups at pre-induction, 15, 45, 75, 90, 105 and 120 min (*P* values more than 0.05) [Table 4].

Table 4: Comparison of mean diastolic BP

Time	Group oral clonidine (Group A)	Group IV clonidine (Group B)	P value
Pre	75.1	73.7	>0.001
15	69.2	63.3	>0.001
30	68.6	58.1	<0.001
45	67.0	65.5	>0.001
60	70.2	61.1	<0.001
75	69.5	62.3	>0.001
90	66.2	61.2	>0.001
105	69.2	62.4	>0.001
120	66.3	64.8	>0.001

When MAP was compared between the groups, there was a significant difference between groups at 30 min (*P* = 0.01) and at 75 min (*P* = 0.04) with Group B patients showing a statistically lower MAP [Fig 1].



The range of the Ramsay sedation score was 2-5 in the oral andIV clonidine groups. The highest Ramsay sedation score of 2 was seen 65% and 67.5% with no significant difference in the oral andIV clonidine groups (P>0.05) [Table 5].

Table 5. Shows the clinical assessment in the IV and oral clonidine groups

Variables	Group A	Group B	P Value
Ramsay Sedation Score 2	26 (65)	27(67.5)	0.654
Ramsay Sedation Score 3	9(22.5)	10(25)	0.034
Ramsay Sedation Score 4	3(7.5)	2(5)	0.351
Ramsay Sedation Score 5	4(10)	3(7.5)	0.752

DISCUSSION:

There were many previous studies comparing effects of various hypotensive agents on the surgical field during endoscopic sinus surgery,[7-9] but there is no direct comparison between the effects of oral clonidine and IV clonidine as hypotensive agents in FESS. So in this study, we compared the effects of these two drugs. The effect of clonidine given as an oral pre-anesthetic medication in producing a bloodless surgical field in patients undergoing middle ear surgery was examined by Marchal *et al*.[10] and the patients received clonidine (300 mcg/oral) 90 minprior to surgery. So, in the present study we decided to give either 5µg kg-1 orally clonidine 90 minutes before surgery or IV clonidine 2 µg/kg in 10 ml of saline over 10 min followed by 1 µg/kg/h infusion before induction of anaesthesia respectively.

It has been postulated that reduction of MAP during general anesthesia (GA) can minimize Intraoperative bleeding.[11,12] But regarding hemodynamic variables, not only MAP, but also venous pressure and capillary blood flow account for the extent of surgical bleeding. Of these variables, only arterial pressure is easily and readily measured. However studies [13] have demonstrated that MAP and total blood loss are not necessarily correlated. Improved surgical field during FESS with a beta blocker has been attributed to vasoconstriction of the mucous membrane arterioles and pre-capillary sphincters resulting from unopposed alpha adrenergic effects of endogenous catecholamines [14] and solely on the effect of MAP.

Controlled hypotension has a definitive role in FESS as it reduces bleeding during surgery which will decrease blood loss and improves visibility of the surgical field.It will further decrease the duration of surgery and anaesthesia time.In the present study, we compared oral clonidine to IV infusion of clonidine in terms of haemodynamic stability and side effects.We found that though induced hypotension was achieved with both the drugs, oral clonidine produced more consistent haemodynamics in terms of MAP and HR as compared to iv clonidine.Use of Nitroglycerine for any increase in MAP was comparable in both groups.Sudden bradycardia and hypotension was more common in Iv clonidine group as compared to oral clonidine group with comparable hymodynamic parameters.

CONCLUSION:

Oral Clonidine premedication 90 minutes prior to surgery reduces bleeding during FESS by providing hypotensive anesthesia comparable to Iv clonidine with less side effects.This will not only reduce blood loss but also decrease surgical time with clearer surgical field.It also reduces (almost negligible) the need for other hypotensive drugs to provide a clear field for surgery. Therefore Oral Clonidine can be used as premedicant as well as a hypotensive agent for FESS surgery.

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