Role of clonidine premedication as a part of hypotensive anaesthesia during functional endoscopic sinus surgery: A placebo-controlled study

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Abstract

Objective: The present study was performed to evaluate the effectiveness of intravenous Clonidine as a part of premedication in controlled hypotensive anaesthesia during functional endoscopic sinus surgery (FESS). Material & Methods: It was a prospective study carried out in the department of Anaesthesia of a tertiary care centre of Rajasthan, India. 50 patients undergoing FESS surgery for chronic sinusitis were included in the study and were divided into two groups viz. group I, who were given normal saline and group II, who were given intravenous Clonidine 3µ/kg as a part of premedication prior to induction. The outcomes were measured by estimation of mean arterial pressure (MAP), extra requirement of isoflurane and nitrogycerine (NTG) to achieve target MAP, blood loss during the surgery, duration of surgery and post-operative complications. Results: Both the groups were matched in terms of age, sex and weight parameters. There was statistically significant difference between MAP in group I and group II before induction, average intra-operative and during immediate post-operative period. The requirement of extra isoflurane or NTG to achieve target MAP was high (in 56% patients) and moderate (in 44% patients) in group I while low requirement was needed in 60% of group II cases and rest 40% cases didn't required any extra isoflurane or NTG. The average amount of blood loss in group II was significantly less (230±66 ml) than group I (356±75 ml). Similarly, the duration was 76±16 minutes in group I surgery and 59±12 minutes in Clonidine group. Quality of surgical field as per Boezart score was significantly better in Clonidine group. The incidence of postoperative complications like bradycardia, hypotension and prolonged sedation were not significant in both the groups. Conclusion: Clonidine is cheap and safe drug to use for controlled hypotensive anaesthesia without any significant side effect in FESS.

Key Words: Clonidine, Controlled anaesthesia, Hypotension, Sinus surgery, Bradycardia

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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. 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

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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. Two main strategies being used for hypotensive anaesthesia are (a) deep anaesthesia with strong analgesia and (b) standard anaesthesia with hypotensive drugs. The first strategy may result in prolonged recovery while second strategy may result in postoperative hypotension. Hence, achieving controlled hypotensive anaesthesia in FESS is challenging and important for surgeon as well as anesthetist.Alpha2 agonists have been used in controlled hypotensive anaesthesia for decades. In addition to their antihypertensive and sympathicolytic effect, they are known to have effective sedative and analgesic effect with hemodynamic stability.² In present study, we are assessing the effect of single iv dose of Clonidine for controlled hypotensive anaesthesia in FESS surgery. The results were compared with placebo group.

MATERIAL AND METHODS

The present study was a prospective study carried out in the department of anaesthesia, Ananta Institute of Medical sciences, Rajsamand during the period of 1 year from December 2017 to December 2018.50 patients of chronic rhinosinusitis with or without nasal polyposis who were to undergo functional endoscopic sinus surgery (FESS) were included in the study. Patients were randomly allocated to two groups with 25 members in each group. Pre- anaesthesia examination of all the patients was done a day before surgery.

Group I- received 20 ml of normal saline in premedication.

Group II- received $3\mu g/kg$ body weight in 20 ml normal saline in premedication.

Exclusion criteria:

- 1. Patient with history of hypertension, cardiovascular accidents, ischaemic heart disease, hepatic and/ or renal dysfunction or poor respiratory reserve.
- 2. Pregnant or lactating female.
- 3. History of allergy to any of the drugs to be used during the study.
- 4. Patients already using the drugs that may affect the results of present study (anticoagulants, calcium channel blockers, beta-blockers, clonidine).
- 5. Obese patients weighing > 90 kg.
- 6. Patients having history of FESS done in the past.
- 7. Patients refused to give consent.

Ethical clearance: approval from institutional ethical committee was taken before starting the study and well

informed consent was also taken from all the patients involved in the study.

RESULTS

The study was conducted during the period of 1 year from December 2017 to December 2018.50 patients of chronic rhinosinusitis with or without nasal polyp who were to undergo FESS surgery and who met the inclusion criteria were included in the study. Patients were randomly divided into two groups. Group I was the placebo group in which the patients were given 20 ml of normal saline as part of premedication while in group II, patients were given Clonidine $3\mu g/kg$ in 20 ml of normal saline as part of premedication. Both the groups were matched in terms of age and sex and weight parameters. (Table 1)

Table 1: Age, sex and weight of the patients included in present

stud	study	
Parameters	Group I	Group II
Age (mean age in years)	42.62	44.91
Sex (M:F ratio)	16:9	17:8
Weight (mean weight in kg)	67.97	63.88

There was statistically significant difference between MAP in group I and group II before induction, average intra-operative and during immediate post-operative period. The MAP after induction in group I and II were 83 ± 12 mmHg and 79 ± 11 mmHg respectively but the difference was not statistically significant. (Table 2)

 Table 2: Mean Arterial Pressure of the patients of two groups in the study

1	Viean Arterial Pressure (MAP)	Group I	Group II	p-value
	Before induction	102±14	89±12	0.0009
	After induction	83±12	79±11	0.2252
	Average intra-operative	73±6	68±4	0.0011
	Immediate post-operative	101±8	84±7	0.0001

The requirement of extra isoflurane or NTG to achieve target MAP was high (in 56% patients) and moderate (in 44% patients) in group I while low requirement was needed in 60% of group II cases and rest 40% cases didn't required any extra isoflurane or NTG. (Table 3)

 Table 3: Extra requirement of isoflurane or NTG in two groups of

the study			
Requirem	ent (Group I	Group II
High		14	0
Moderat	е	11	10
Low		0	15

The average amount of blood loss in group I surgery was 356 ± 75 ml while in group II surgery, it was 230 ± 66 ml and the difference was statistically significant. Similarly, the duration was 76 ± 16 minutes in group I surgery and 59 ± 12 minutes in group II surgery and the difference was statistically significant. (Table 4)

Table 4: Amount of blood loss and duration of surgery in two			
groups of the study			
	Group I	Group II	p-value
Blood loss (ml) (Mean±SD)	356±75	230±66	0.0001
Duration of surgery (Mean minutes±SD)	76±16	59±12	0.0001

Quality of surgical field as measured by Boezart score was good in 8% of group I cases and 32% of group II cases, fair in 80% of group cases and 64% of group II cases, poor in 20% of group I cases and only 4% of group II cases. (Table 5)

Table 5: Quality of surgical field in two groups of the study

Grade	Group I	Group I
Good (0-1)	2	8
Fair (2-3)	20	16
Poor (4-5)	5	1

20% of group I patients had complications (hypotension 8%, Bradycardia 8% and prolonged sedation 4%) and 28% of group II patients developed complications (hypotension 12%, bradycardia 8% and prolonged sedation 8%). (Table 6)

 Table 6: Incidence of post-operative complications in present

 study

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Complications	Group I	Group II
Hypotension (< 50mmhg)	2	3
Transient Bradycardia	2	2
Prolonged sedation	1	2
Total	5	7

DISCUSSION

FESS is the preferred surgical method to treat chronic sinusitis which are refractory to medical treatment. Bloodless field is often required in FESS for better visibility of surgical field and to avoid complications and failure. Many pre-operative and intra-operative strategies have been explored till now to minimize the risk of bleeding in patients undergoing FESS. The success of these strategies is determined based on their impact on amount of blood loss during surgery, duration of surgery, quality of surgical field explained by surgeon and postoperative complications. Various methods are preoperative antibiotics and steroids, position of the patient (reverse Trendelenburg position), intra-operative use of local decongestant, local vasoconstrictor injections, warm saline irrigation, controlled hypotensive anaesthesia and use of tranexemic acid.⁴ The present study is a placebocontrolled study performed to assess the hypotensive effect of intravenous Clonidine in FESS surgery. In present study, we successfully achieved the target MAP between 50-70 mmHg in all the patients. The average MAP during intra-operative period in group I and group B were 73±6 mmHg and 68±4 mmHg respectively. Thus,

it was observed that average MAP was significantly lower in Clonidine group than placebo group. Further, to achieve the target MAP, there was high to moderate requirement of extra isoflurane or NTG in placebo group while very less requirement was there in Clonidine group. (Table 3)Similar results were observed in a study done by V. A. Praveen and R. Krishna Prabu in 2016. They studied the effect of Clonidine as a part of hypotensive anaesthesia for FESS and found that 60% patients of placebo group required high amount of extra isoflurane and NTG while in clonidine group, there was very less requirement of extra isoflurane and NTG to achieve target MAP. ⁵ Similar results were obtained in other studies by Jabalameli et al, Hackmann et al, Howie et al. and Engelman E et al. ^{6, 7, 8, 9} The average amount of blood loss in Clonidine group (230±66 ml) was significantly less than placebo group (356±75 ml) in present study. The results were similar to another study done by Okuyama et al in 2005. They studied the effects of clonidine and prostaglandin E1 on blood loss during FESS and concluded that Clonidine constricts peripheral blood vessels and reduces nasal mucous blood flow which accounts for the reduction of blood flow. 10 Jabalameli et al also had the similar results with their studies on effect of Clonidine on reducing bleeding in FESS. 6The average duration of surgery was also very less in Clonidine group (59±12 min) as compared to placebo group (76±16 min). The results were similar to studies done by Nair S et al and Wawrzyniak et al. 11, 12 In present study, the surgical field grading showed that Clonidine group had better grading than the placebo group. The results were highly correlated with results of past studies done by Jabalameli M et al and Anvari et al^{6,13} 28% cases from clonidine group developed complications like hypotension (in 12% cases), bradycardia (in 8% cases) and prolonged sedation (in 8% cases) but the complications were not severe and relieved without any treatment. 20% cases from placebo group developed similar complications. The incidence of complications was similar in both the groups. Similar results were obtained by Meghna Jiwanmall et al in their study to assess the effect of intravenous Clonidine in FESS. They also used 3µg/kg Clonidine in premedication and compared the results with placebo group. The incidence of complication between two groups was statistically insignificant. Out of 30 patients in Clonidine group, 3 patients had prolonged sedation, 10 patients had hypotension and 1 patient had bradycardia. The results were hoghly correlated with the results of present study. ¹⁴Similar results were obtained by Sahajananda and Rao et al and Samantaray et al. They also used 3µg/kg Clonidine as a part of premedication and observed no significant incidence of complications like hypotension,

bradycardia which required treatment and thus correlates better with the results of present study.^{15,16}

CONCLUSION

A single intravenous dose of Clonidine $(3\mu/kg)$ as a part of premedication is effective to achieve controlled hypotensive anaesthesia in FESS. It maintains the mean arterial pressure within limits without additional requirement of isoflurane or NTG. It significantly reduces the amount of blood loss and provides a better field of visibility for surgery and thus shortens the duration of surgery. Clonidine is cheap and safe drug to use for controlled hypotensive anaesthesia without any significant side effect.

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