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RESEARCH ARTICLE

COMPARATIVE STUDY OF NITROGLYCERIN AND ESMOLOL FOR CONTROLLED HYPOTENSION IN FESS

***Dr. Rahul, S. and Dr. Kusugal, R. R.**

Department of Anaesthesiology, BLDE University's Shri B.M. Patil Medical College, Hospital and Research Centre, Vijayapur, Karnataka, India

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ABSTRACT

Background: Functional Endoscopic Sinus Surgery (FESS) is a minimally invasive procedure for diseases of the nose and paranasal sinuses like chronic sinusitis and polypus rhinosinusitis. Intraoperative bleeding causing poor visibility of surgical field is a major concern during FESS and this may result in many complications. Controlled hypotension is a technique wherein arterial blood pressure is lowered in a deliberate but controlled manner to minimise blood loss and enhance operative field visibility.

Aim: To compare the hypotensive efficacies of Nitroglycerin (NTG) and Esmolol (ESM) in terms of changes in heart rate (HR), systolic blood pressure, diastolic blood pressure, mean arterial pressure (MAP), duration of surgery and operative field visibilty assessment by surgeon using Average category scale (ACS) or Fromme scale, in patients undergoing FESS under General Anesthesia (GA).

Methods: 80 ASA grade I and II patients aged between 18-60 years undergoing FESS under GA were divided into 2 groups of 40 each to receive either Inj. Esmolol 500 µg/kg over 30 seconds followed by infusion at 100-300 µg/kg/min or Inj. NTG at 5-10 µg/kg/min. All patients were premedicated with oral Alprazolam and Ranitidine on the previous night. In the operation theatre, all patients were premedicated with i.v. Glycopyrrolate, i.v. Midazolam and i.v. Fentanyl, and then induced with i.v. Propofol. Laryngoscopy and intubation was facilitated by i.v. Succinyl choline. Anaesthesia was maintained with Isoflurane vapour in balanced nitrous oxide/oxygen mixture and i.v Vecuronium for muscle relaxation. Heart rate, Systolic, Diastolic and Mean arterial blood pressure were assessed at 5, 10, 15 minutes and every 15 minutes from the start of infusion till completion of surgery. Visibility of the surgical field was rated by the surgeon using ACS with 0 being the driest and 5 making surgery impossible.

Results: Intraoperative Heart rate was less in Esmolol group compared to NTG group. Both drugs produced desired hypotension but ideal operative conditions were achieved at a higher MAP of 80.5 ± 2.5 mm Hg in ESM group, while same operating conditions were achieved at lower MAP of 70.8 ± 1.2 mm Hg in NTG group. ACS scores were significantly low in ESM group compared to NTG group ($p < 0.001$). Mean duration of surgery was less in ESM group than NTG group ($p < 0.001$).

Conclusion: Both drugs are safe and effective in providing optimal operating conditions but Esmolol is a superior agent to NTG for controlled hypotension in FESS under GA, as it minimizes surgical blood loss, enhances operative field visibility and reduces duration of surgery with minimal reduction in MAP. Absence of reflex tachycardia was the added advantage of ESM over NTG.

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INTRODUCTION

FESS is a minimally invasive procedure for diseases of the nose and paranasal sinuses like chronic sinusitis and polypus rhinosinusitis. (Stammberger, 1986) FESS has the potential for reestablishing natural mucociliary clearance mechanism, drainage and aeration of sinuses, whilst maintaining as much of the normal anatomy as possible. (Stammberger and Posawetz, 1990; Stankiewicz, 1989) Over last few years this technique has become popular worldwide due to its minimally invasive nature and preservation of mucosa. In FESS, haemostasis of the rhino-sinusoidal region poses special problems where capillary bleeding is a serious limitation because it decreases operative visibility of the surgical field. This impaired visibility prolongs the overall surgical duration and promotes haemotransfusion. Transfusion and prolongation of surgical and anaesthetic duration increase the risk of various infections and complications. (Cincikas *et al*., 2010; Simpson, 1992) Controlled hypotension is a technique wherein arterial blood

Corresponding author:* **Dr. Rahul. S.
Department of Anaesthesiology, BLDE University's Shri B.M. Patil Medical College, Hospital and Research Centre, Vijayapur, Karnataka, India.

pressure is lowered in a deliberate but controllable manner to minimize surgical blood loss and enhance the operative field visibility. (Simpson, 1992) Synonyms for controlled hypotension are elective hypotension, deliberate hypotension, induced hypotension and controlled circulation. The advantages of controlled hypotension to the anaesthesiologist are reduced intraoperative bleeding and hence a minimization of the need for blood transfusion and a reduced duration of anaesthesia. The surgeon enjoys a dry (bloodless) operative field with minimal use of diathermy and suturing and an overall reduction in the surgical duration. There are several pharmacological and non-pharmacological techniques of inducing hypotension the mechanical ones being; tourniquets, table positioning and Intermittent positive pressure ventilation (IPPV). (Simpson, 1992) α receptor agonists like Dexmedetomidine and antagonists like Phentolamine, β receptor antagonists like Esmolol, nitrovasodilators like Sodium nitroprusside and Nitroglycerin are the most commonly used drugs for controlled hypotension. (Testa and Tobias, 1995) Nitroglycerin which is chiefly used to treat angina, has also been tried for hypotensive anaesthesia. It is a directly acting nitrovasodilator that dilates capacitance vessels, causing reduced venous return with concomitant reductions in stroke volume and cardiac output and thereby causing hypotension. Esmolol, a cardio selective β_1 adrenergic antagonist, has a main advantage of ultra short action, (Simpson, 1992; Testa and Tobias, 1995) rapid onset of action leading to a decrease in heart rate, cardiac output and blood pressure. Other than its use in tachyarrhythmias and perioperative hypertension, it has been used for hypotensive anesthesia. This study attempted to compare the hypotensive efficacies of the NTG and Esmolol in patients undergoing FESS under general anesthesia in terms of Reduction in blood pressure, surgeon's assessment of the quality of operative field, surgical duration and complications if any.

MATERIALS AND METHODS

This randomised study was carried out in the Department of Anaesthesiology, B.L.D.E.U's Shri B.M Patil Medical College, Hospital and Research centre, Vijayapur from December 2015 to June 2017 in patients undergoing FESS under General anaesthesia. Study was approved by the institutional medical ethics committee and written informed consent was obtained from all patients participating in the study. 80 patients were selected based on inclusion criteria and were randomly divided into two groups-

NTG Group – Nitroglycerin group (n=40): i.v. infusion of NTG at 5-10 µg/kg/min after intubation.

ESM Group – Esmolol group (n=40): Initial bolus of i.v. Esmolol at 500 µg//kg over 30 seconds followed by an infusion at 100-300 µg//kg/min after intubation.

Inclusion criteria

- Elective FESS under general anaesthesia.
- Patients aged 18-60 yrs.
- Patients of ASA grade I and II
- Mallampati grade I and II
- Patients consenting for study.

Exclusion criteria

- Patients of ASA grade III and above.
- Anaemic, diabetic and hypertensive patients.
- Cardiovascular and cerebrovascular diseases.
- Renal, hepatic and peripheral vascular diseases.
- Known or suspected allergy or intolerance to study drugs.
- Anticipated difficult airway.

Pre anesthetic evaluation was done on the day before surgery and required investigations were advised. All patients received Tab. Ranitidine 150 mg before and Tab. Alprazolam 0.5 mg after their evening meals after which they were advised to be nil by mouth for a minimum of 8 hours from midnight. On the day of surgery, patient was shifted to the operating room. Two i.v. accesses were secured on both hands – one meant for the i.v fluids and the other for the hypotensive drug. Ringer Lactate at 4 ml/kg/hr was started through one i.v line. All patients were catheterized for monitoring urine output. Monitors were attached for continuous recording of heart rates and rhythm, non-invasive blood pressure (SBP, DBP and MAP) and oxygen saturation and basal readings were noted. All patients were premedicated with i.v. Glycopyrrolate at 0.01 mg/kg, i.v. Midazolam at 0.02 mg/kg and i.v. Fentanyl at 2 µg//kg. and preoxygenated with 100% oxygen for 5 minutes. Anaesthesia was induced with i.v Propofol 2 mg/kg. Direct laryngoscopy and endotracheal intubation were facilitated with a 1 mg/kg bolus of i.v. Succinyl Choline. Care was taken to ensure a smooth, dextrous and gentle laryngoscopy so as to avoid any haemodynamic variations from the basal values. After intubation, normocapnoeic ventilation (30-35 mmHg) was carried out. Anaesthesia was maintained with 0.4% Isoflurane in balanced N_2O/O_2 mixture and Vecuronium boluses at appropriate intervals. The dial concentration of isoflurane was kept constant (0.4%) throughout the anaesthetic duration. NTG group (n=40) received i.v. Nitroglycerin (5 - 10 µg/ /kg/min) and ESM group (n=40) received i.v. Esmolol 100-300 mcg/kg/min (after a bolus of 500 µg/kg over 30-60 seconds) through syringe pumps. NTG solution was prepared by adding 50 mg (10 ml) of injectable NTG to 40 ml of 0.9% saline to make a 50 ml NTG solution (1 mg/ml). Esmolol solution was prepared by loading 500 mg (50 ml) of injectable Esmolol hydrochloride solution in a 50 ml syringe (10 mg/ml). MAP was gradually reduced in decrements of 5 mmHg. The infusions were adjusted and steadied when the MAP reached 60-65 mmHg or when the surgeon gave 2 points for the operative visibility on the average category scale (ACS) of Fromme *et al*. (1986) whichever was earlier. Surgery was allowed to commence at the 5^{th} minute of infusion. Local infiltration of Lignocaine with adrenaline was given by the surgeon. Patients who developed severe hypotension (MAP<60 mmHg) were first observed for 5 minutes after discontinuation of the hypotensive agent and if the low MAP persisted or did not improve, they were promptly treated with a 6 mg bolus of Inj. Ephedrine. These patients were excluded from the study. Similarly any patients in the Esmolol group, who developed bradycardia (HR <50/min) received Inj. Atropine 0.6 mg and were excluded from this study. Heart rate, ECG, SBP, DBP, MAP, SpO_2, capnography and urine output were monitored throughout the surgery. Infusion of the hypotensive agent was stopped 10 minutes before the anticipated end of surgery. Isoflurane was stopped 5 minutes before the end of the surgery. The balanced N_2O/O_2 mixture was gradually converted to 100% O_2 to avoid diffusion hypoxia. At the end of the surgery, the residual neuromuscular paralysis of all patients was reversed with i.v. Neostigmine 0.05 mg/kg and i.v. Glycopyrrolate 0.01 mg/kg. All patients

were extubated on the table and shifted to PACU for further monitoring. The surgeon's opinion was sought throughout the surgery and at the end of the procedure. Baseline Heart rate, SBP, DBP and MAP were noted, followed by readings every 5 minutes for the first 15 minutes (following treatment with the hypotensive agent) followed by every 15 minutes until the infusions were stopped. The average category scale (ACS) was assessed by the surgeon first at the 10th min of infusion and then every 15 minutes till closure. This ACS was based on the 6 points (0-5) assessment tool proposed and popularized by Fromme *et al*. (1986).

This average category scale is as follows:

- 5–Massive uncontrollable bleeding. Surgery impossible. Constant suctioning required.
- 4–Heavy but controllable bleeding that interferes with dissection. Prompt suctioning required.
- 3–Moderate bleeding that moderately compromises surgical dissection. Frequent suctioning required.
- 2–Moderate bleeding but without interference with accurate dissection. Surgical field not threatened. Occasional suctioning required.
- 1 – Bleeding, so mild it is not even a surgical nuisance. No suctioning.
- 0 – No bleeding, virtually bloodless field.

Statistical analysis

All characteristics were summarized descriptively. For continuous variables, the summary statistics of N, mean, standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries. Chi-square ($\chi 2$)/Fisher exact test was employed to determine the significance of differences between groups for categorical data. The difference of the means of analysis variables was tested with the unpaired t-test. If the p-value was < 0.05, the results were considered to be significant. Data was analyzed using SPSS software v.23.0.

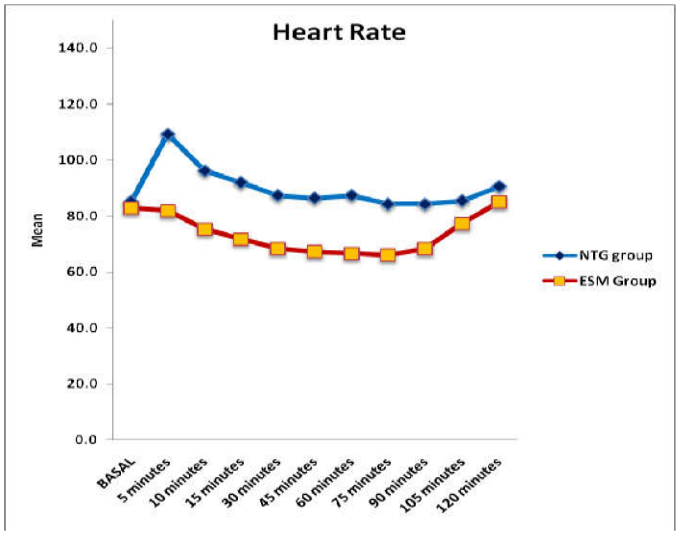
RESULTS

This comparative clinical study was conducted on 80 patients of ASA Grade I & II, aged between 18 - 60 yrs, undergoing FESS under General anesthesia to evaluate and compare the hypotensive effects of intravenous infusion of Inj. Nitroglycerin and Inj. Esmolol. The patient characteristics and demographic data are shown in Table 1. There was no statistically significant difference in the demographic characteristics of the patients between the two groups.

Table 1. Demographic Parameters

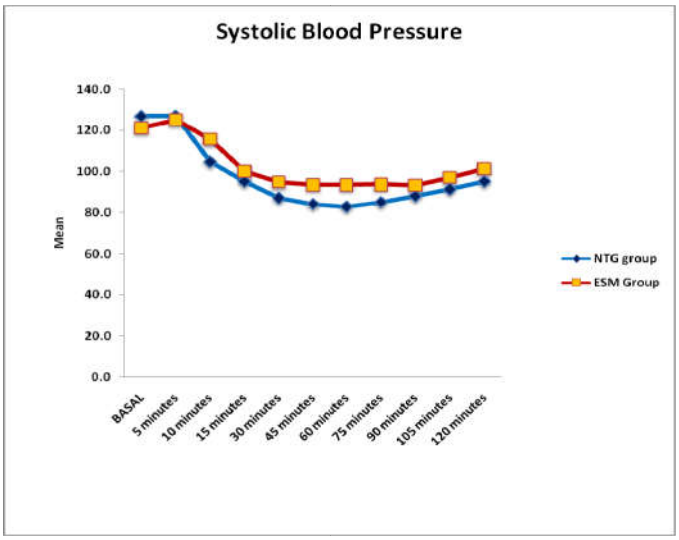
Parameter	Group NTG	Group ESM
Age (years) (mean± sd)	33.9±11.9	32.2±14.9
Sex : males	20	22
Females	20	18
Weight (kg)	60.7±8.8	59.8±9.0

In the NTG group, the basal heart rate was 85.2 ± 9.9 beats per minute and in the ESM group, it was 82.9 ± 10.5 beats per minute. At the 10th min of infusion, the heart rate in group ESM was much lower (75.3 ± 5.1 bpm) compared to the NTG group (96.3 ± 7.9 bpm). This difference is highly significant ($P < 0.001$). The ESM group displayed a lower mean heart rate and NTG group had a slight rise in the mean heart rate from the baseline value during the hypotensive period as shown in Graph 1.



Graph 1.

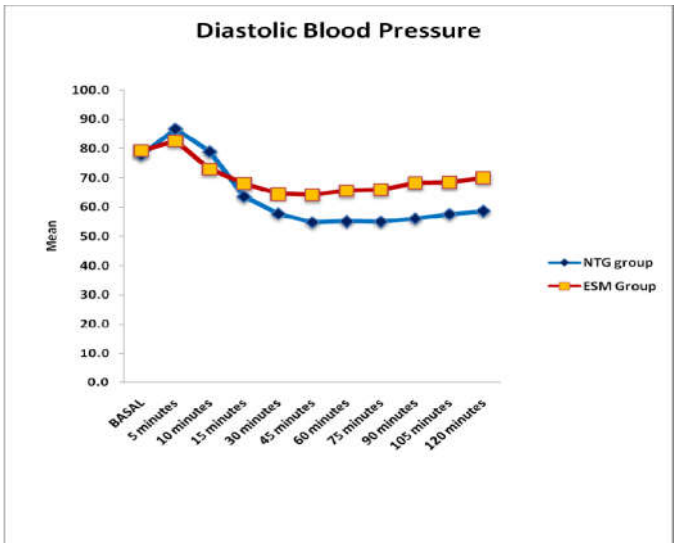
The mean baseline values of Systolic BP (SBP) in the NTG group were 127.1 ± 5.3 mm Hg whereas that of ESM were 121.2 ± 7.6 mm Hg. Fall in SBP was seen much earlier in NTG group than in the ESM group (at 10th min, NTG = 104.8 ± 3.4 and ESM = 115.7 ± 5.4). This difference is highly significant ($P < 0.001$) (Graph 2).



Graph 2

The mean basal Diastolic BP (DBP) values of NTG and ESM group were 77.8 ± 6.2 mm Hg and 79.3 ± 5.4 mm Hg respectively. DBP decreased significantly in NTG group compared to baseline values and in comparison to Esmolol grop. Throughout the hypotensive period, the difference in DBP between the two groups was highly significant ($p<0.001$) (Graph 3).

The basal mean arterial pressure (MAP) values of NTG and ESM group were 93.8 ± 5.5 mmHg and 93.2 ± 4.3 mmHg, respectively. Fall in MAP was more in NTG group compared to Esmolol group. Basal and intraoperative mean arterial pressures during the procedure is shown in Table 3 and Graph 4.

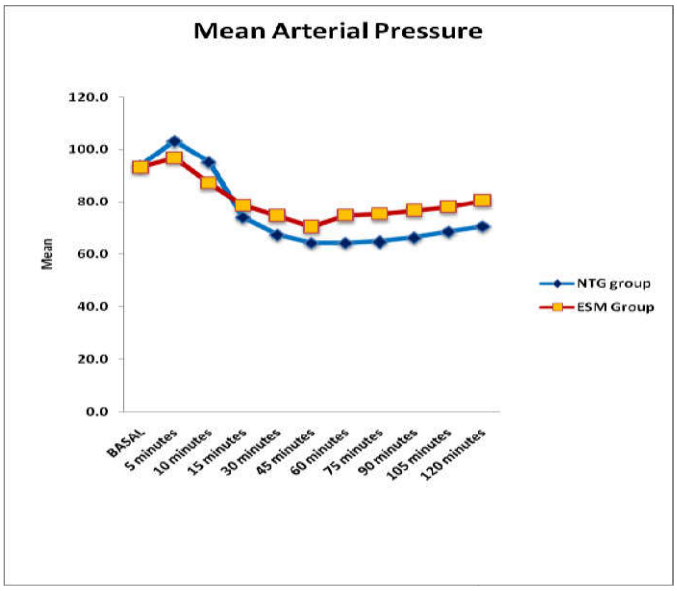


Graph 3

Table 3. Change in Mean arterial pressure (MAP) between study groups

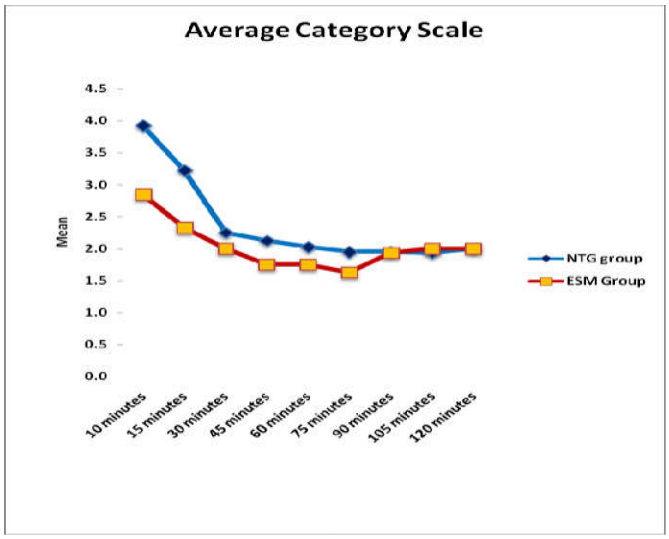
MABP	NTG group		ESM Group		p value
	Mean	SD	Mean	SD	
BASAL	93.8	5.5	93.2	4.3	0.558
5 minutes	103.2	6.2	96.8	3.9	<0.001*
10 minutes	95.2	5.7	87.2	3.1	<0.001*
15 minutes	74.1	3.1	78.7	3.6	<0.001*
30 minutes	67.6	3.2	74.8	1.2	<0.001*
45 minutes	64.4	2.0	70.6	15.8	0.016*
60 minutes	64.4	1.7	74.9	1.3	<0.001*
75 minutes	65.1	1.9	75.4	1.3	<0.001*
90 minutes	66.5	1.6	76.7	1.2	<0.001*
105 minutes	68.7	1.6	78.1	1.0	<0.001*
120 minutes	70.8	1.2	80.5	2.5	<0.001*

*Significant p value is shown in Bold



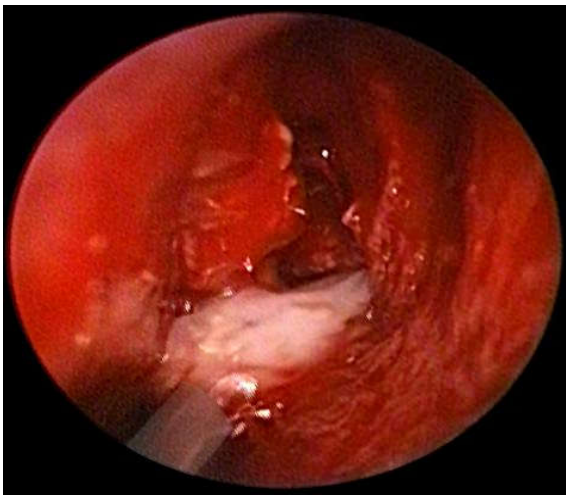
Graph 4

The patients of the ESM group achieved the target Fromme's score of 2 earlier than the NTG group.($p<0.05$) While most patients in the NTG group were given a surgical score of 4, an almost equal number of patients of the ESM group had 3, which is superior in terms of surgical dryness. At 30 minutes, all patients of the ESM group had a score of 2 while most patients in the NTG group had a score of 3 (Graph 5).



Graph 5

The optimal surgical field dryness was achieved at higher MAP in the ESM group than in the NTG group (Figure 1). In the figure, the surgical field of the ESM group seems much superior to NTG group.

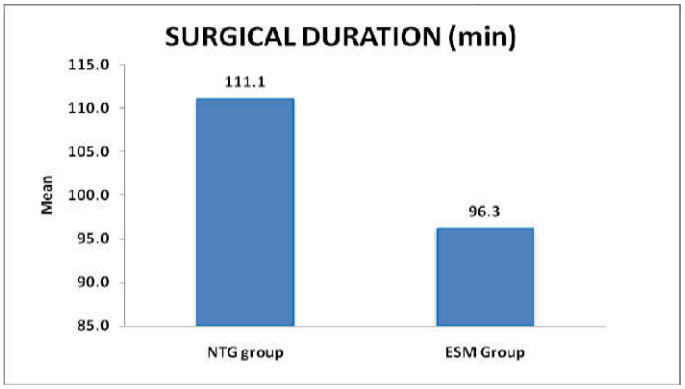


NTG Group

ESM Group

Figure 1. Quality of surgical dryness in majority of cases

Mean duration of surgery was 111.1 ± 9.3 minutes in NTG group and 96.3 ± 8.8 minutes in ESM group. p value was statistically significant (< 0.001) (Graph 6)



Graph 6

DISCUSSION

FESS is routinely employed for common conditions like rhino-sinusitis and polypus sinusitis. Bleeding is an impediment to quality intervention because it impairs operative field visibility and prolongs the duration of surgery and anaesthesia. (Cincikas *et al*., 2010; Simpson, 1992) Deliberate controlled hypotension is a tried and tested anaesthetic technique wherein the arterial blood pressure is lowered in a predictable manner to reduce the operative blood loss and improve the surgeon's field. (Simpson, 1992) This is particularly required in endoscopic surgeries of nose and paranasal sinuses, tympanoplasties and spine surgeries. Several hypotensive techniques have been tried. The earlier ones included mechanical methods like tourniquets and positioning. High spinal and epidural anaesthesia have also been used. Later, various pharmacological agents including ganglion blockers, sympatholytic and adrenolytic drugs have been employed successfully. (Simpson, 1992) Nitrovasodilators like NTG dilate the capacitance vessels and reduce the venous return with concomitant reductions in stroke volume and cardiac output thereby causing hypotension. NTG has been tried by various authors for inducing hypotension (Kadam *et al*., 1993; Cincikas and Ivaskevicius, 2003; Kamal and Abd El-Rahman, 2008; Guney *et al*., 2012; Srivastava *et al*., 2013; Dongre *et al*., 2012) Esmolol produces hypotension by reducing the heart rate, cardiac output and blood pressure. Other than its use as an anti-arrhythmic agent, it has also been found useful by several authors for the induction of controlled hypotension. (Guney *et al*., 2012; Srivastava *et al*., 2013; Dongre *et al*., 2012; Menkhaus *et al*., 1985; Boezaart *et al*., 1995; Ornstein *et al*., 1990; Shams *et al*., 2013) In the NTG group, the basal heart rate was 85.2 ±9.9 beats per minute and 82.9 ±10.5 beats per minute in Esmolol group. At the 10th minute of infusion, the heart rates in group ESM were much lower (75.3 ±5.1) compared to the NTG group (96.3 ± 7.5). This difference was highly significant (p<0.001). This fall in heart rates in the ESM group is attributed to the beta-adrenergic blocking effects of Esmolol. Throughout the surgery, the mean heart rates in the ESM group were much lower than in the NTG group. The mean heart rates in the NTG group are consistent with the fact that NTG causes either no change or a slight increase in heart rates during a continuous infusion as a reflexive phenomenon which is the baroreceptor mediated response secondary to the hypotension. One patient in group NTG had a consistent tachycardia throughout the surgery. This is probably the reflex tachycardia that is seen with NTG. Guney *et al*. (2012) conducted a study comparing Esmolol and NTG in 40 patients undergoing nasal surgeries and found a drop in heart rate by 18% in Esmolol group compared to NTG group. Srivastava *et al*. (2013) conductd a study comparing hypotensive effects of Esmolol and NTG in 50 patients undergoing FESS and found that the mean heart rates in Esmolol group were 83.87±7.58 compared to 90.88±8.54 beats per minute in the NTG group. Our results with regards to the trend and drop in heart rates in the Esmolol group are similar to the study results obtained by the aforesaid authors.

The mean basal values of SBP of the NTG group were 127.1 ± 5.3 mm Hg while that of Esmolol were 121.2 ± 7.6 mm Hg. These values were statistically significant (p<0.001). It is noteworthy that on an average, fall in Systolic BP was achieved much earlier in NTG group than in the Esmolol group (at 10th min, NTG = 104.8 ± 3.4 and ESM = 115.7 ± 5.4 mm Hg). The difference was highly significant (p<0.001). This is attributed to the mechanism of hypotension caused by each drug. NTG has a venodilatory action while Esmolol reduces the cardiac output by negative chronotropism. The latter mechanism takes some time. Even though the SBP fall is higher in the NTG group, the surgical dryness was superior in the Esmolol group. The mean basal DBP values of NTG and ESM group were 77.8 ±6.2 mm Hg and 79.3 ± 5.4 mm Hg respectively. Throughout the hypotensive period, the difference in DBP between the two groups was highly significant. The basal MAP values of NTG and ESM group were 93.8 ± 5.5 mm Hg and 93.2 ± 4.3 mm Hg respectively. On examining the mean MAPs of both groups, we found that the ESM group achieved the target ACS score of 2 or below at higher MAP values and hence, the MAPs were not further lowered in this group. To achieve similar operative dryness, the MAP had to be reduced much lower in the NTG group. On an average, the mean MAPs of ESM group in the hypotensive period was 80.5 ± 2.5 while for NTG, it was 70.8 ± 1.2 mm Hg. Boezaart *et al*. (1995) compared Esmolol and Sodium nitroprusside (SNP) in 20 patients undergoing FESS and found that optimal surgical field visibility was achieved at higher MAP in Esmolol group compared to SNP group. Dongre *et al*. (2012) compared Esmolol and NTG for hypotensive anesthesia in spine surgeries and reported better operative field visibility with Esmolol at higher MAP compared to NTG. A close relationship between reduced MAP values surgical field quality has been shown by Sieskiewicz *et al*. (2010) Cincikas and Ivaskevicius (2003) observed improved surgical field quality with a low MAP of 50-60 mmHg with NTG in nasal surgeries. Blau *et al*. (1992) in their study comparing the effects of Esmolol and SNP, with a target MAP of 55-65 mmHg during orthognathic surgery reported an average MAP of 58.7±0.7 mm Hg with Esmolol and said that the reduction of blood loss with Esmolol was more effective. On an average, we found that similar operative visibility was obtained in the Esmolol group with much higher MAPs than in the NTG group. Our findings pertaining to the trends in heart rate, systolic blood pressure, diastolic blood pressure and mean arterial blood pressure are similar to the results obtained by the above mentioned authors and Guney *et al*. (2012) and Srivastava *et al*. (2013).

Several authors have opined that the quality of operative field is improved with controlled hypotension but all have suggested that it is difficult to accurately measure and compare the

minute blood losses. Hence the Fromme *et al*. (1986) scoring system was accepted to enable the surgeon to make his own assessment of the operative field. This scoring system has been used by almost all authors who have attempted to study hypotensive anaesthesia. The mean average category scale score for NTG group at 10^{th} min was 3.9 ± 0.6 while in the Esmolol group was 2.9 ± 0.6. At 30^{th} min, patients in Esmolol group had a mean score of 2 compared to NTG group that had mean score of 2.3 ± 0.4. It is also worthwhile to note that at 30^{th} min, the MAPs in the ESM group was 74.8 ± 1.2 versus a 67.6 ± 3.2 mm Hg in the NTG group. The average surgical duration in the NTG group was 111.1 ± 9.3 minutes while it was 96.3 ± 8.8 minutes in the ESM group. This difference is significant. The shorter duration in the ESM group is probably owing to the superior operative field. Our findings on surgical duration are comparable to the findings of Srivastava *et al*. (2013) Capillary bleeding is the major impediment in FESS. Esmolol blocks the adrenergic effect of vasoactive amines released during hypotension. Esmolol causes unopposed alpha-adrenergic effects which causes vasoconstriction of arterioles and pre-capillary sphincters leading to contraction of nasal mucosal blood vessles leading to less oozing and thus a superior operative field. In contrast, the endogenous catecholamines have minimal effect on vascular smooth muscles when NTG is used. This might result in vasodilatation (1982) with the consequence of more oozing and surgical blood loss. In addition, reflex tachycardia will further contribute to this. These factors contribute to a longer duration of surgery. None of the patients of either group presented with the need for intraoperative haemotransfusion or suffered any post operative complications. To summarize, Both Esmolol and NTG produce hypotension required for FESS. Optimum operative conditions with better surgical field visibility were achieved at higher MAPs with Esmolol whereas similar operative conditions were achieved only with more reduction in MAP with NTG. Absence of reflex tachycardia is an added advantage of Esmolol over NTG. Better surgical field dryness with reduced intraoperative bleeding was seen in the Esmolol group compared to NTG group with a statistical significant difference between both groups. The average duration of surgery was significantly lower in the Esmolol group.

Conclusion

Controlled hypotension is a vital tool during FESS for improving operating conditions. It is safe, simple and easy to administer. Esmolol is a safe and superior agent to NTG for controlled hypotension in FESS as it minimizes surgical blood loss, enhances the operative field visibility and reduces overall duration of surgery at higher MAPs compared to NTG.

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