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A RANDOMIZED COMPARATIVE STUDY OF NITROGLYCERIN AND ESMOLOL FOR CONTROLLED HYPOTENSION IN FUNCTIONAL ENDOSCOPIC SINUS SURGERIES.

Anaesthesiology

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ABSTRACT

Background : Functional Endoscopic Sinus Surgery (FESS) is a minimally invasive procedure for disease of Nose and Paranasal sinuses like chronic sinusits and polyps rhinosinusitis. Intraoperative bleeding causes poor visibility of surgical field is a major concern during FESS and this may results in many complication . Controlled hypotension is a technique where in arterial blood pressure is lowered in deliberate but controlled manner to minimize blood loss and enhance operative field visibility.

Aim: To compare the hypotensive efficacies of intravenous Esmolol and intravenous Nitroglycerin in Functional Endoscopic Sinus Surgeries under general anaesthesia.In term of changes in heart rate ,systolic blood pressure, diastolic blood pressure ,mean arterial pressure, duration of surgery and operative field visibility assessment by surgeon by using Fromme scale.

Methods: This study was conducted on total 60 patients, divided into two groups.

Group Nitroglycerin (NTG) 30 patients , Group Esmolol (ESM) 30 patients.Patients between ASA grade I&II, age 18-60 years undergoing Functional Endoscopic Sinus Surgery under GA , Either injection Esmolol 100-300 mcg/kg/min and NTG groups 0.5 -10 mcg/kg/min through infusion pumps. All patient s were premedicated with Ondansetron (0.1mg/kg)IV,Midazolam(0.02mg/kg)IV,Glycopyrrolate(0.01mg/kg) and Fentanyl (2µg/kg) and then induced with Propofol 2mg/kg IV. Laryngoscopy and intubation was facilitated by Succinylcholine 2 mg/kg IV. Anaesthesia was maintained with Isoflurane vapour in balanced Nitrous oxide and Oxygen mixture and Vecuronium 1mg IV every 10-20 min for musle relaxation. Heart rate, Systolic Blood Pressure , Diastolic and Mean Arterial Blood pressure were assessed at 5min,10min,15min and so on upto 60 min.

Result: Introperative Heart rate was less in Esmolol(ESM) as compared to Nitroglycerine(NTG) group. Both drugs produced desired hypotension but ideal operating conditions were achieved at a higher MAP of 80.74±2.6 mm Hg in ESM groups ,while same operating conditions, were achieved at lower MAP of 73.49±2.07 mm Hg in NTG group.

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

KEYWORDS

Functional endoscopic sinus surgery, Controlled hypotension, Nitroglycerin, Esmolol, Fromme scale

INTRODUCTION

Nasal Polyps (Antral/Ethmoidal) are commonly detected diseases. Functional Endoscopic Sinus Surgery (FESS) are the commonly employed surgeries in the above cases but intraoperative bleeding is the major problem in these techniques. In the case of Functional Endoscopic Sinus Surgery,[1] overall, reduced visibility of the surgical field is related to an increased risk of dangerous vascular, orbital and intracranial complications, prolonged duration, and reduced quality of intervention in the FESS.

Although operative blood loss is dependant primarily upon bleeding from cut vessels, its extent may be influenced in several ways. Bleeding may be arterial, in which case it is related directly to the mean arterial pressure (MAP), capillary, Arterial bleeding can abolished by the use of a tourniquet but in FESS better controlled with decrease in the MAP[2].

Controlled hypotension is a method by which the arterial blood pressure is decreased in a deliberate but predictable manner to limit intraoperative blood loss and to provide the best possible surgical field for operating conditions[3]. Methods to achieve controlled hypotension can broadly be classified as Non-Pharmacological and Pharmacological. Pharmacological technique includes local infiltrations, non-depolarising muscle relaxants, inhalational agents, alpha/beta blockers and direct vasodilators[4].

Nitroglycerin chiefly used to treat angina, has also been used for controlled hypotension. It is a directly acting vasodilator that primarily dilates capacitance vessels reducing venous return with concomitant reductions in stroke volume and cardiac output thereby causing hypotension.

Esmolol, a short-acting cardioselective $Beta_1$ adrenergic antagonist has a rapid onset of action leading to a decrease in heart rate, cardiac output and blood pressure other than its use as a drug of choice for perioperative hypertension, It is also commonly used for controlled hypotension.[5]

In our study, an attempt will be made to compare the efficacies of Nitroglycerin and Esmolol with reference to Intraoperative bleeding and the quality of surgical field during controlled hypotensive anaesthesia[6] induced by either intravenous Nitroglycerin or intravenous Esmolol via infusion pumps during Elective **Functional Endoscopic Sinus Surgeries** under General Anaesthesia .Fromme' et al[7],define grading for blood loss in Functional Endoscopic Sinus surgeries under General Anaesthesia for better control of blood loss & good patient outcome.

MATERIAL AND METHODS

This study was carried out in Swaroop Rani Nehru Hospital associated with Moti Lal Nehru Medical College, Prayagraj(Formerly Allahabad) over a period of one year.After approval from ethical committee of Institution and obtaining written and informed consent from the patients.

PATIENTS SELECTION:

Patients of either sex selected for this study were randomly divided into two groups - Group N(NTG) and Group E(ESM). A detailed pre-anaesthetic evaluation was carried out for each patient. Appropriate and relevant laboratory and radiological investigations were asked for and evaluated accordingly. All patients were visited a day prior to the surgery and explained in detail the anaesthetic procedure and an informed and written consent obtained. All patients were kept nil per-oral for 6-8 hourly prior to the day of surgery and received Tab. Ranitidine 150 mg and Tab. Alprazolam 0.5 mg both orally as pre-medications a day before the surgery.

On the day of the surgery, in the pre-operative preparation room - Two intravenous lines were secured - one for the fluids & drugs and the others exclusively for infusion of the hypotensive agent either Nitroglycerine or Esmolol. Monitor were attached.All patients were pre-medicated with Ondansetron (0.1 mg/kg) IV, Midazolam (0.02 mg/ kg) IV,Glycopyrrolate (0.01 mg/kg) IVand Fentanyl (2µg/ kg)IV,5-10 minutes before induction.

Preoxygenation with 100% Oxygen for 3 minutes .Anaesthesia was induced using Propofol (2 -2. 5 mg/ kg)IV and Succinylcholine (1.5 mg/kg)IV .Intubation was done with appropriate sized cuffed ET tubes. After confirmation of bilateral air entry by auscultation Endotracheal tube is fixed and loading dose of Vecuronium (0.08 – 0.1 mg/ kg)was given. Anaesthesia was maintained with 0.5-1% Isoflurane in balanced(N_2O+0_2)gases and Vecuronium infusion (1-2 µg/kg/min) . Ventilation was carried out with the help of Anaesthesia work station(Dragger Fabius).

Group N was receive Nitroglycerin (0.5 - 10 µg/ kg/ min)IV and Group E was receive Esmolol (100 - 300 µg/ kg/ min)[7] through infusion pumps. Surgery was begin after a target mean arterial pressure MAP of around 60 mmHg (Range 60 - 65 mmHg) was achieved. The rate of infusion was determined by consist of heart rate, NIBP for systolic, diastolic & mean arterial pressures (MAP), Oxygen saturation and End Tidal CO_2. These parameters were monitored by the inbuilt monitor of the work station throughout the surgery.

The infusions was stopped and the residual neuromuscular paralysis was antagonized with Neostigmine (0.05 mg/ kg)IV plus Glycopyrrolate (0.01 mg/ kg)IV. The patient was extubated on the operation theatre . The surgeon's opinion was sought throughout and at the end of the surgery.

INCLUSION CRITERIA:
- Patients giving valid informed and written consents
- Patients of either sex aged between 18 and 55 years.
- Patients under ASA grades I & II.
- Patients undergoing elective ENT surgeries particularly Functional Endoscopic Sinus Surgeries.

EXCLUSION CRITERIA:
- Patient refusal
- Patients under ASA grades III and above.
- Uncontrolled Hypertensive patients.
- Cardiovascular diseases.
- Cerebrovascular diseases.
- Peripheral vascular diseases.
- Hepatic and Renal diseases
- Anaemias and Haemoglobinopathies.
- Uncontrolled Diabetes Mellitus.

PARAMETERS TO BE OBSERVED :
- Heart rate.
- Systolic and Diastolic blood pressures.
- Mean arterial pressure (MAP).
- SPO_2
- $ETCO_2$
- Blood loss.
- Quality of surgical field.
- Drug requirement to achieve targets

Observations

Table -1: Group-wise Distribution of patients

Group	Drug Administered	Number of patients
NTG	Nitroglycerin	30
ESM	Esmolol	30

Table 2: Demographic profile of patients (n=60)

	NTG[mean ±SD]	ESM[mean ±SD]	P-value
Age(year)	30±5.56	30.99±6.74	0.829
Height (cm)	168±5.88	166.33±6.30	0.2929
Weight(kg)	62.6±4.28	64.1±5.61	0.2491
Sex- ratio	62.6±4.28	20:10	

As mentioned in table 1&2 there was no Statistical difference in demographic profile between two groups. Sex ratio as shown above is almost same hence comparison is not required.

Table 3:Comparison of Heart Rate in Two groups(per minute)

	NTG [mean]	NTG [SD]	ESM [mean]	ESM (SD)	p-value
Pre op	88.076	10.26	85.076	5.08	<.158
5min	99.99	10.33	81.33	8.47	<.001
10min	79.86	6.02	71.33	5.09	<.001
15min	78	2.56	68.43	4.53	<.001
20min	78	2.56	68.43	4.53	<.001
25min	87.76	4.26	65.34	2.66	<.001
30min	87.76	4.26	65.34	2.66	<.001
35min	87.66	3.91	65.09	3.06	<.001
40min	87.66	3.91	65.09	3.06	<.001
45min	85.2	2.65	72.43	3.38	<.001
50min	85.2	2.65	72.43	3.38	<.001
55min	84.66	2.08	72.8	2.66	<.001
60min	84.66	2.08	72.8	2.66	<.001
65 min	83.73	2.03	72.8	2.66	<.001
70 min	83.73	2.03	72.8	2.66	<.001
75min	81.33	2.11	65.22	2.67	<.001
80 min	81.33	2.11	65.22	2.67	<.001
85min	77.86	3.76	64.33	2.44	<.001
90min	77.86	3.76	64.33	2.44	<.001

Srivastava[8] et al(2013) conducted a study comparing hypotensive effect of Esmolol & NTG in 50 patients undergoing FESS and mean Heart rate in Esmolol group were 83.87±7.5beats/min as compared to 90.88±8.54 beats/min in NTG group.

Table 4: Comparison between Systolic Blood Pressure in two groups

	NTG(mean)	Std	ESM(mean)	Std	P-value
Pre op	127.366	3.34	124	6.08	.01
5min	106.23	3.29	110.33	6.2	.001
10min	103.33	3.38	107.86	8.48	.01
15min	93.06	4.06	96.467	2.64	.0052
20 min	93.06	4.06	96.467	2.64	.0052
25min	92.33	5.59	95.67	3.95	.02
30 min	92.33	5.59	95.67	3.95	.02
35min	91.02	5.02	95.06	2.64	.0098
40min	91.02	5.02	95.06	2.64	.0098
45min	88.7	3.31	94 .6	2.64	.0003
50min	88.7	3.31	94 .6	2.64	.0003
55min	87.86	2.20	94.2	3.05	<.0001
60min	87.86	2.20	94.2	3.05	<.0001
65min	86.73	3.58	94	5.6	<.0001
70min	86.73	3.58	94	5.6	<.0001
75min	85.33	1.76	93.77	2.26	<.0001
80 min	85.33	1.76	93.77	2.26	<.0001
85min	84.66	2.08	92.6	6.66	<.0001
90min	84.66	2.08	92.6	6.66	<.0001

Guney A,Kaya FN[9] et al (2012) compare Esmolol to Nitroglycerine in controlling hypotension during nasal surgery.

Table No 5: Comparison of Diastolic Blood Pressure between two groups

Time	NTG[mean]	NTG[SD]	ESM[SD]	ESM[SD]	p-value
Pre op	78.83	5.68	75	6.09	.0022
5min	86.13	3.24	90.43	4.32	<.0001
10min	80.60	7.46	84.66	2.78	<.0001
15min	67.4	2.74	72.13	2.64	<.0001
20min	67.4	2.74	72.13	2.64	<.0001
25min	62.53	2.61	72.32	3.64	<.0001
30min	62.53	2.61	72.32	3.64	<.0001
35min	61.2	1.24	70.06	3.42	<.0001
40min	61.2	1.24	70.06	3.42	<.0001
45min	60.73	1.27	65.56	2.76	<.0001
50min	60.73	1.27	65.56	2.76	<.0001
55min	61.29	1.13	65	2.46	<.0001
60min	61.29	1.13	65	2.46	<.0001
65min	61.26	1.35	65.92	3.05	<.0001
70min	61.26	1.35	65.92	3.05	<.0001
75min	60.86	1.47	64.72	2.72	<.0001

80min	60.86	1.47	64.72	2.72	<.0001
85min	60.77	1.35	73.43	2.69	<.0001
90min	60.77	1.35	73.43	2.69	<.0001

Dongre H, Sharma V[10] et al 2012 compared the efficacy of Esmolol & Nitroglycerine by creating dry operative field by producing controlled hypotension in spinal surgeries.

Table 6:Comparison between Mean arterial blood pressure in two groups

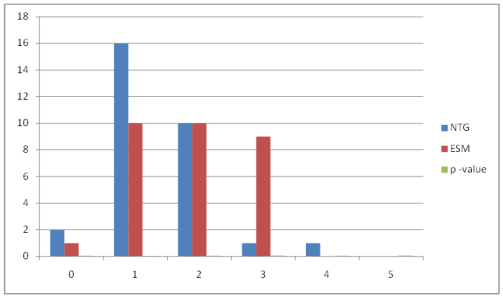
	NTG (mean)	NTG (SD)	ESM (mean)	ESM (SD)	P-value
Pre op	92.33	5.59	92.6	10.33	.91
5min	90.53	3.67	96.43	2.61	<.0001
10min	87.86	3.46	93	1.95	<.0001
15min	75.33	2.37	90.76	1.75	<.0001
20 min	75.33	2.37	90.76	1.75	<.0001
25min	72.2	2.57	79.34	2.27	<.0001
30min	72.2	2.57	79.34	2.27	<.0001
35min	71.0	1.98	76.34	2.06	<.0001
40min	71.0	1.98	76.34	2.06	<.0001
45min	69.30	1.44	71.56	3.59	.0022
50min	69.30	1.44	71.56	3.59	.0022
55min	69.33	±1.2	71.4	3.49	.0043
60min	69.33	±1.2	71.4	3.49	.0043
65min	68.76	1.03	76.53	1.02	<.0001
70min	68.76	1.03	76.53	1.02	<.0001
75min	68.46	1.37	80.03	1.52	<.0001
80min	68.46	1.37	80.03	1.52	<.0001
85min	68.46	1.37	80.03	1.52	<.0001
90min	68.46	1.37	80.03	1.52	<.0001

S hams T,Abu-Samra[11] et al 2013 –Induced hypotension for FESS by comparing Dexmedetomidine and Esmolol and saw MAP was better maintained in NTG group as compared with ESM group. **Table 7: Comparison between bleeding score in two groups[Fromme et al- and Boezaart et ..al]**

Table 7: Comparison between bleeding score in two groups [Fromme et al- and Boezaart et ..al]

Variable	NTG	ESM
Score 0= no bleeding	2	1
Score1=minor bleeding	16	10
Score2=minor bleeding aspiration required	10	10
Score3=minor bleeding frequent aspiration required	1	0
Score4=moderate bleeding	1	0
Score5=severe bleeding	0	0

Graph-1: Comparison of bleeding score in two groups (NTG vs ESM).



RESULTS

1) Mean heart rate is more decrease in ESM group 70.03±3.50 than NTG 84.23±3.86 in NTG group increase heart rate due to reflex tachycardia. In ESM group has advantage there is no reflex tachycardia.(Table -3)
2) Mean systolic Blood pressure is less in NTG group (92.44±3.43) than ESM group (97.63±4.19) NTG group more reduction SBP is due to its vasodilatory effect.(Table-4)
3) Mean Diastolic Blood pressure is reduced in NTG group(64.14±2.25) than ESM group(70.97±3.16).(Table-5)
4) Mean Arterial Blood Pressure is reduced in NTG group 73.49±2.07 than Esmolol group 80.74±2.6 (Table-6)
5) Controlling hypotension is vital tool during FESS for better operative condition.better surgical field dryness with reduced intraoperative bleeding is seen in ESM group than NTG Group. (Table -7)
6) Duration of surgery is less in ESM group due to less bleeding and better visibliity in operative field.(Table-7)
7) Both Hypotensive durgs in FESS provided good result, but ESM groups gives better result than NTG group with having added advantage of no relex tachycardia.(graph-1)

We conclude that the Esmolol is better durg ,it is safe , simple and easy to adminster. It is superior and safe agent than NTG for controlled hypotension in FESS as it reduced surgerical blood loss ,enhances the operative field visibility and reduces overall duration of surgery .

CONCLUSION-

The present study the title As "A RANDOMIZED COMPARATIVE STUDY OF NITROGLYCERIN AND ESMOLOL FOR CONTROLED HYPOTENSION IN FUNCTIONAL ENDOSCOPIC SINUS SURGERIES" was conducted in SWAROOP RANI NEHRU HOSPITAL assiociated to MOTI LAL NEHRU MEDICAL COLLEGE , PRAYAGRAJ, over a period of one year .This prospective study was conducted in 60 patients of ASA physical status 1-2, aged 18 -60 year scheduled for Functional endoscopic sinus surgeries. Patients were randomly assigned in to two groups consisting 30 patients in each group.

1. Group N-Nitroglycerin group
2. Group E- Esmolol group

We conclude that the Esmolol is better durg , it is safe , simple and easy to adminster. It is superior and safe agent than NTG for controlled hypotension in FESS as it reduced surgerical blood loss ,enhances the operative field visibility and reduces overall duration of surgery .

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