Original Research Paper

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"COMPARISON BETWEEN INTRAVENOUS DEXMEDETOMIDINE VERSUS ESMOLOL FOR INDUCED HYPOTENSION IN FUNCTIONAL ENDOSCOPIC SINUS SURGERY: A PROSPECTIVE, CONTROLLED, RANDOMIZED DOUBLE BLINDED STUDY".

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ABSTRACT **Background:** Induced hypotension limiting the intraoperative blood loss has dramatically improved the surgical dissection during Functional Endoscopic Sinus Surgery(FESS). This study aimed to compare the efficacy of dexmedetomidine and esmolol in inducing hypotensive anesthesia in patients undergoing FESS. **Methods:** Sixty patients aging 20 to 50 years posted for FESS, belonging to ASA I or II were randomly allocated to receive a loading dose of 1 µg/kg Dexmedetomidine diluted in 10 ml 0.9% saline infused over 10 min, before induction of anesthesia, followed by continuous infusion of 0.4 – 0.8 µg/kg/h (Group D) or Esmolol as a loading dose of 1 mg/kg diluted in 10ml 0.9% saline infused over 10 min, before induction of anesthesia, followed by continuous infusion of 0.4-0.8 mg/kg/h (Group E). Hemodynamic parameters, Average Category Score for intraoperative surgical field assessment, Emergence Time, Time to attain Modified Aldrete Score ≥ 9, Sedation score at 15, 30, 60 minutes after tracheal extubation, First analgesic requirement time were recorded. **Results:** Study groups were comparable in terms of demographic data including age, gender, weight, ASA status, and duration of surgery. Hemodynamic parameters like SBP, DBP, and MAP were comparable intraoperatively. Significant higher postoperative heart rates and blood pressures were recorded with Esmolol. Emergence time, time to extubation, and the time required to attain a Modified Aldrete Score > 9 was significantly longer in the dexmedetomidine group. The first postoperative analgesic request was earlier in the Esmolol group compared to Dexmedetomidine which has a significantly prolonged postoperative sedation score. **Conclusions:** Both are effective and safe agents for hypotensive anesthesia in FESS. Compared with Esmolol, Dexmedetomidine has the advantage of providing longer postoperative pain relief due to its intrinsic analgesic, desirable sedative, and anesthetic sparing effect.

KEYWORDS : Dexmedetomidine, Esmolol, Functional Endoscopic Sinus Surgery, Hypotensive Anesthesia.

INTRODUCTION

Induced hypotension is a technique by which arterial blood pressure is decreased predictably and deliberately to reduce intraoperative bleeding, minimize blood transfusions, and enhance the visualization of the surgical field[1].

Functional Endoscopic Sinus Surgery is a minimally invasive technique, primarily a surgical treatment for chronic sinusitis, Sino-nasal polyposis, fronto ethmoidal mucocele, however, intraoperative bleeding causes poor visibility of the surgical site became a challenge for surgeons[2].

Due to enriched blood vessels in the nasal cavity and difficulty in achieving hemostasis, bleeding during FESS not only obscures the view but prolongs the duration of procedure time and increases the risk of complications[3].

Several pharmacological and non-pharmacological methods are employed to reduce intraoperative bleeding during FESS. Various agents like magnesium sulphate, sodium nitroprusside, nitroglycerine, Calcium channel blockers, opioids, propofol, high dose inhaled anesthetics have been used but associated with certain disadvantages like cyanide toxicity for nitroprusside, slow recovery from inhaled anesthetics[4].

Esmolol is an ultrashort acting β1 selective adrenergic antagonist, has a rapid onset of action following intravenous injection and infusion[5].

Dexmedetomidine is a potent centrally acting selective alpha-2 adrenergic agonist, has sedative, analgesic, anesthetic sparing effects, and sympatholytic properties[5].

The purpose of this study is to assess the efficacy and safety of dexmedetomidine versus esmolol in inducing hypotensive anesthesia in Functional Endoscopic Sinus Surgery with regard to blood loss, surgical field quality, hemodynamic parameters, and recovery profile.

METHODS

Study Design: A prospective, randomized double blinded study.
Study Location: The study was carried out in the ENT Department, Rangaraya Medical College Kakinada, Andhra Pradesh.
Study Duration: January 2021 to August 2021.
Sample Size: 60 patients.
Subjects & Selection Method: 60 patients in the age group of 20-50 years of age undergoing FESS under general anesthesia belonging to ASA grade I or II were selected. Patients were allocated into 2 groups:
1)GROUP D(n=30): Patients receiving Dexmedetomidine
2)GROUP E(n=30): Patients receiving Esmolol.

Patients were randomly allocated into two groups, including 30 patients each. Simple randomized sampling is done by computer random numbers. A master list of the drugs corresponding to each patient was kept in a secure place by a third party not directly connected with the study. This was revealed only to the person administering the drug outside the operation theatre at the time of the study. Only at the end of the study, the list was released to the investigator for the analysis of the results of the study.

Inclusion Criteria:
Patient belonging to the age group of 20-50yrs, ASA grade I and II, scheduled for elective Functional endoscopic sinus surgery under general anesthesia were included.

Exclusion Criteria: Patient refusal, ASA grade III and IV, Patients with recurrent sinus surgery, Hypertensive disorders, associated renal hepatic insufficiency, Coronary artery disease, Cerebral insufficiency, Patients with coagulopathies, were excluded from the study.

Procedure And Methodology:
Preoperative Preparation:
All patients were thoroughly evaluated in pre-anesthetic checkups and all relevant investigations were done.

On the day of surgery, after the patient shifted to the operating room, standard ASA monitors – Pulse oximeter, Non-Invasive Blood Pressure, ECG were connected and baseline values were recorded. Two cannulae were secured, one for infusion of the drug included in the study and the other for the administration of fluids and other drugs.

Premedication:
All patients were premedicated with Inj. Midazolam (0.05-0.1mg/kg), Inj. Glycopyrrolate (0.01mg/kg), Inj. Ondansetron (0.1mg/kg), Inj. Fentanyl (1-2mcg/kg). Preoxygenation was done for 3mins with 100%oxygen before induction.

In GROUP D, patients received a loading dose of 1 µg/kg Dexmedetomidine diluted in 10 ml 0.9% saline infused over 10 min, before induction of anesthesia, followed by continuous infusion of

0.4 – 0.8 µg/kg/h.

In GROUP E, patients received Esmolol as a loading dose of 1 mg/kg diluted in 10ml 0.9% saline infused over 10 min, before induction of anesthesia, followed by continuous infusion of 0.4-0.8 mg/kg/h.

Induction of general anesthesia was achieved with intravenous Thiopentone sodium (3-5mg/kg), and Endotracheal intubation was facilitated with vecuronium 0.1mg/kg with a suitable-sized cuffed tube and anesthesia was maintained with 2– 2.5% sevoflurane and 50% oxygen in 50% nitrous oxide. Additional fentanyl was given to achieve hemodynamic stability. These hypotensive agents infusion was administered using a syringe pump and were adjusted and steadied when target MAP was reached.15-degree reverse Trendelenburg position was kept to enhance venous drainage. Epinephrine in a concentration of 1:80000 soaked cottonoids was inserted into the nasal cavity and in between the polyps to reduce blood loss.

Intraoperative Monitored Parameters:
Hemodynamic parameters such as PR, SBP, DBP & MAP were recorded every minute for the first 5 minutes and every 5 minutes during the first hour, and every 15 minutes thereafter, until the end of surgery. For statistical purposes, they were documented at 0, 1, 2, 3, 4, 5, 10, 15, 30, 45, and 60minutes, depending on the duration of surgery, and at 5minutes and 10 minutes after stoppage of the study drug. The Spo2 and ECG were monitored continuously intraoperatively and postoperatively.

The average category scale was assessed by the surgeon who was blinded to the hypotensive agent used, at 10minutes of infusion and then every 15minutes till closure. It was based on the 5 points assessment proposed by Fromme et al– Predetermined category scale values two and three were considered ideal for surgery.

Table 1: Average Category Scale

0	NO BLEEDING VIRTUAL BLOODLESS FIELD
1	BLEEDING – SO MILD IT IS NOT EVEN A SURGICAL NUISANCE.NO SUCTIONING OF BLOOD REQUIRED
2	MODERATE BLEEDING –BUT WITHOUT INTERFERENCE WITH ACCURATE DISSECTION. OCCASIONAL SUCTIONING IS REQUIRED. SURGICAL FIELD NOT THREATENED
3	MODERATE BLEEDING – FREQUENT SUCTIONING REQUIRED. BLEEDING MODERATELY COMPROMISES SURGICAL DISSECTION.
4	HEAVY BLEEDING – PROMPT SUCTIONING REQUIRED. BLEEDING CONTROLLABLE THAT INTERFERES WITH DISSECTION.
5	MASSIVE BLEEDING – CONSTANT SUCTIONING REQUIRED. UNCONTROLLABLE BLEEDING

Five minutes before the end of the surgery, the Infusion of the study drugs was stopped and Emergence time was recorded. Inj. Neostigmine (0.05 mg/kg) and Inj. glycopyrrolate (0.01 mg/kg) was used to reverse the neuromuscular blockade and after extubation, patients were shifted to PACU and the time required for the first analgesic dose was recorded.

The time required to obtain A MODIFIED ALDERET SCORE (0-10), of ≥9 was recorded.

Table 2: Modified Alderete Score

VARIABLES	SCORE	INTERPRETATION
RESPIRATION	2	ABLE TO KEEP DEEP BREATH AND COUGH
	1	DYSPNEA/SHALLOW BREATHING
	0	APNEA
O_2 SATURATION	2	MAINTAINS>92% ON ROOM AIR
	1	NEEDS OXYGEN INHALATION TO MAINTAIN O_2 SATURATION >90%
	0	SATURATION <90% EVEN WITH SUPPLEMENTAL O_2
CONSCIOUSNESS	2	FULLY AWAKE
	1	AROUSABLE ON CALLING
	0	NOT RESPONDING
CIRCULATION	2	BP± 20mmHg PREOPERATIVELY
	1	BP± (20-50)mmHg PREOPERATIVELY
	0	BP± 50 mmHg PREOPERATIVELY
ACTIVITY	2	ABLE TO MOVE 4 EXTREMITIES VOLUNTARY OR ON COMMAND
	1	ABLE TO MOVE 2 EXTREMITIES VOLUNTARY OR ON COMMAND
	0	ABLE TO MOVE 0 EXTREMITIES VOLUNTARY OR ON COMMAND

THE MODIFIED RAMSAY SEDATION Scale used to assess the Sedation score, employed at 15, 30, and 60 minutes after tracheal extubation.

Table 3: Modified Ramsay Sedation Scale

Modified Ramsay Scale

Score	Response	State
1	Anxious, agitated or restless	Awake
2	Cooperative, oriented, tranquil	Awake
3	Asleep, brisk response to loud auditory stimulus	Awake
4	Asleep, sluggish response to loud auditory stimulus	Sleep
5	No response to loud auditory stimulus, but response to painful stimulus	Sleep
6	No response to painful stimulus	Sleep

Statistical Analysis
The statistical analysis was done using MS-EXCEL and SPSS 16.0 software.

Pearson's Chi-square test was used to know the statistical significance between qualitative variables represented as frequencies or percentages. One way ANOVA was used to know the statistical significance between quantitative variables represented as means and standard deviation. For all the analyses, a p-value <0.05 is considered significant.

RESULTS
Study groups were comparable in terms of demographic data including age, gender, weight, ASA status, and duration of surgery. Hemodynamic parameters were comparable intraoperatively. The Average Category Score was comparable at 10 min, 20 min, and 30 min during the surgery.

Significant higher postoperative heart rates, blood pressures were recorded with Esmolol.

Emergence time is defined as the period between ceasing anesthetics administration at the end of surgery and the response of eye-opening to a vocal command and the time to extubation was significantly longer in group D.

The time required to attain a Modified Aldrete Score > 9 was longer in the dexmedetomidine group. The first postoperative analgesic request was earlier in the Esmolol group compared to Dexmedetomidine which has a significantly prolonged postoperative sedation score.

Table 4: Shows Demographic And Various Variables

	GROUP D	GROUP E	P value
Age (years)	29.27±5.97	29.97±5.14	0.628
Weight (Kg)	58.80±7.78	57.73±9.18	0.629
Gender(male:female)	17:13	16:14	0.795
ASA (I:II)	17:13	15:15	0.605
Duration of surgery (min)	45.69±4.66	45.97±5.40	0.779

Group D= Dexmedetomidine; Group E =Esmolol; Mean±SD

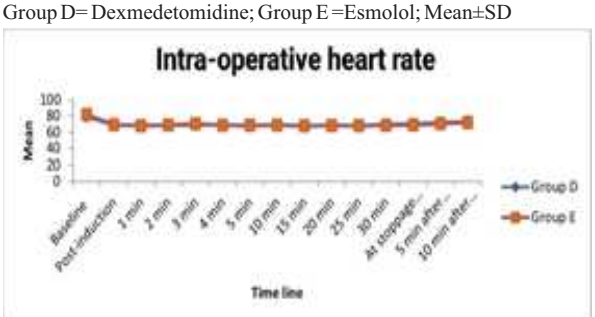

Figure-1: Line Diagram Showing Comparison Of Heart Rate(bmp) Of Study Groups In The Intraoperative Period

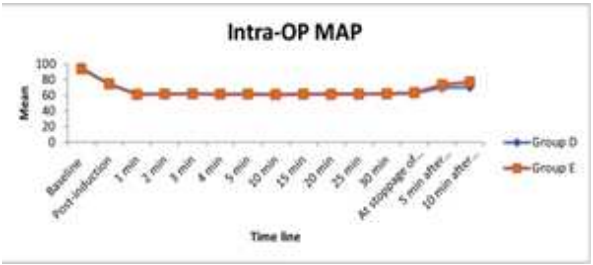

Figure-2: Line Diagram Showing Comparison Of Intraoperative Mean Arterial Pressure(mmhg) Of Study Groups

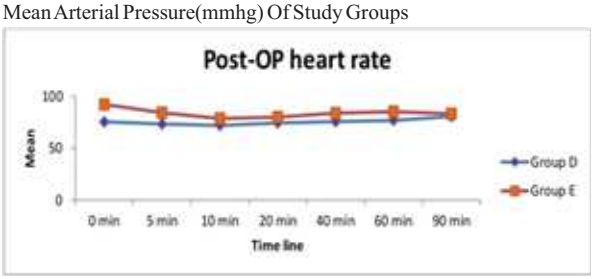

Figure-3: Line Diagram Showing Comparison Of Postoperative Heart Rate(bpm) In The Study Groups

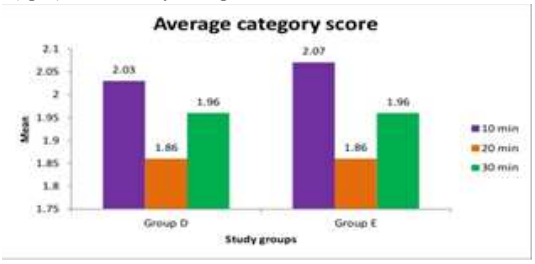

Figure-4: Comparison Of Average Category Score In Study Groups

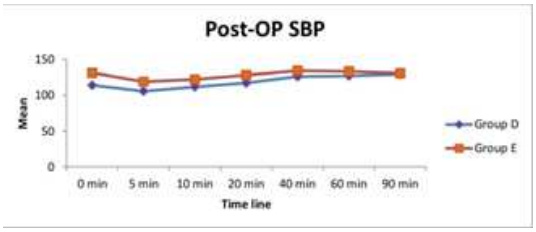

Figure-5: Line Diagram Showing Comparision Of Post-operative SBP(mmhg) In The Study Groups

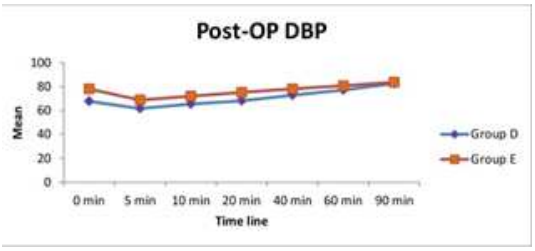

Figure-6: Line Diagram Showing Comparision Of Post-operative DBP(mmhg) In The Study Groups

Table 5: Recovery Characteristics, Sedation Scores And Time To First Analgesic Request

	GROUP D(n=30)	GROUP E(n=30)	P value
Emergence time (min)	7.17±1.09**	4.90±1.21	<0.0001
Time to modified Alderet score>9 (min)	10.17±2.73**	7.30±2.01	0.000
Sedation score 0 min after surgery	2.87±0.57	2.60±0.49	0.059
Sedation score 20 min after surgery	2.87±0.57**	2.20±0.41	<0.0001
Sedation score 40 min after surgery	2.47±0.51**	2.07±0.25	0.000
Sedation score 60 min after surgery	2.00±0.00	0.31±0.078	0.078
Time to first analgesic request (min)	53.33±5.98**	30.33±6.53	<0.0001

**Highly significant when group D compared to group E (P<0.001)

DISCUSSION

Induced hypotension limiting the intraoperative blood loss has dramatically improved the surgical dissection during Functional Endoscopic Sinus Surgery(FESS). A relatively bloodless surgical field provides better visualization of the operating field, with reduced risk of injury to adjoining structures[6]. Induced hypotensive anesthesia is a technique advocated to reduce bleeding, transfusion requirement, to improve the better visualization of the surgical field.

Neethirajan SGR et[7] al demonstrated Dexmedetomidine as an optimal effective agent in decreasing blood loss by controlled hypotension during FESS providing an ideal surgical field with better sedative and analgesic properties. Dexmedetomidine is a potent selective α2 adrenergic agonist (1,620:1 α2 to α1), has sedative, analgesic, anesthetic sparing effects, and sympatholytic properties.

Ayla Guney et al[8] compared esmolol to nitroglycerine in terms of effectiveness in controlling hypotension during nasal surgery and concluded that Esmolol provides good hemodynamic stability and good surgical field visibility.

Esmolol is a short-acting β1 adrenoceptor antagonist that causes increased sympathetic tone in mucous membrane arterioles, which causes unopposed adrenergic effects on the mucous membrane vasculature, resulting in capillary vasoconstriction and reduced bleeding. Esmolol Hydrochloride preferentially inhibits β1 receptors located in the cardiac muscle, associated with slowing of sinus rate, slowing of conduction of cardiac impulses, and a decrease in inotropy which ultimately causes a reduction in cardiac output and thence hypotension, but this effect is not absolute and it begins to inhibit β2 receptors located in the bronchial and vascular musculature at higher doses.

In this study, Dexmedetomidine and Esmolol were compared in terms of hemodynamic stability, quality of the surgical field, postoperative recovery and pain relief, and sedation score.

A similar study conducted by Erbesler et al[9] concluded that both Esmolol and Dexmedetomidine are effective in inducing hypotensive anesthesia in fifty patients posted for tympanomastoidectomy and observed that there was no significant difference in hemodynamic variables between the two groups.

In this study the hemodynamic parameters were comparable between the two groups during the intraoperative period till the stoppage of the study drug which was similar to the study conducted by Erbesler et al.

A study conducted by Aya A. Bayoumy et al[10] compared dexmedetomidine and magnesium sulphate in FESS reported that both surgeon satisfaction and visualization of the surgical field were better with the dexmedetomidine group, where in this study The Average Category Score was comparable at 10 min, 20 min, and 30 min during the surgery.

A similar study conducted by shams, et al[11] concluded that the emergence time and time to achieve modified Aldrete score >9 were significantly shorter in the esmolol group similar to this study.

A study conducted by Bladev P Sahu et al[12] and Mostafa I.A. Sharaf, et al concluded that the time of first analgesic request and postoperative sedation score at 15 minutes and 30 minutes was found to be longer with dexmedetomidine than Esmolol and these differences were found to be statistically significant, which were similar to the findings of the present study.

This study demonstrated that dexmedetomidine or esmolol are effective and safe agents for hypotensive anesthesia in Functional Endoscopic Sinus Surgery providing an ideal surgical field. Compared with Esmolol, Dexmedetomidine has the advantage of providing longer postoperative pain relief due to its intrinsic analgesic, desirable sedative, and anesthetic sparing effect.

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