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COMPARISON OF HYPOTENSIVE PROPERTIES OF DEXMEDETOMIDINE AND ESMOLOL AND THEIR EFFICACY TO PROVIDE OLIGEMIC SURGICAL FIELD DURING FUNCTIONAL ENDOSCOPIC SINUS SURGERY

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ABSTRACT

INTRODUCTION: Induced hypotension to minimize bleeding during FESS is of vital importance to decrease risk of complications.

METHODS: Sixty patients of ASA-I/II were equally randomly assigned into two groups. Group D received loading dose of Dexmedetomidine 1µg/kg over 10min followed by infusion of 1µg/kg/hr and Group E received esmolol in loading and maintenance dose of 1mg/kg over 1min and 1mg/kg/hr respectively. Visibility of surgical field was assessed using Average Category Scale. Hemodynamic variables, emergence time and postoperative sedation score were recorded.

RESULTS: Both Dexmedetomidine and Esmolol were effective in maintaining intraoperative mean arterial pressure within the target range. Heart rate, systolic blood pressure, diastolic blood pressure and MAP were comparable between the two groups during intraoperative period till the stoppage of study drug. Average Category Scale was comparable between two groups.

CONCLUSION: Both Dexmedetomidine and Esmolol are effective in providing ideal surgical conditions during FESS.

KEYWORDS : Induced Hypotension, FESS, Dexmedetomidine, Esmolol

INTRODUCTION:

Functional endoscopic sinus surgery (FESS) is highly sophisticated type of surgery, which has revolutionized the surgical management of acute and chronic sinus pathologies when conservative management has failed.[1] During FESS under general anesthesia , bleeding impairs the visibility of surgical field and increases the operation risk and time.[2] Intraoperative bleeding may be reduced most effectively by induced systemic hypotension. In hypotensive anesthesia, the patient's baseline MAP is reduced by 30% .[3,4] For achieving controlled hypotension, several agents such as nitroglycerine, higher dose of inhaled anesthetics, vasodilator such as sodium nitroprusside, β-blocker have been used either alone or in combination with each other.The ideal agent used for controlled hypotension must have certain characteristics such as a short onset time, rapid elimination without toxic metabolites, easy to administer, an effect that disappears quickly when administration is discontinued and dose dependent predictable effects.

Esmolol is an ultrashort acting selective β1 adrenergic antagonist that reduces heart rate and blood pressure. It has rapid onset of action of bolus i.v. injection and infusion. Dexmedetomidine is a potent highly selective α_2 adrenergic receptor agonist. It has sedative, analgesic and anesthetic sparing effect, and sympatholytic properties.[5] It reduces the prevalence of emergence agitation.

With this background, this study was designed to compare the efficacy and safety of dexmedetomidine and esmolol as a hypotensive agent in functional endoscopic sinus surgery with attention on the quality of surgical field, emergence time, sedation score, recovery profile and to evaluate the side effects, if any.

MATERIAL AND METHODS:

This hospital based randomized comparative interventional study was conducted with the permission of institutional ethics committee on the patients of either sex, 18-55 years of age, ASA grade I-II, with body weight of 45-65 kgs, undergoing elective resection of nasal polyps of 60-90 minutes under general anaesthesia.

Sample size was calculated to be 24 subjects for each of two groups at an alpha error 0.05 and power 80% expecting minimum detectable difference in mean blood pressure in both groups from baseline to be 6.4±7.6 mmHg after induction based on the study done by Bajwa et al.[6] So, for study purpose, 30 patients were taken in each group. Routine pre-anaesthetic check-up was done a day before the surgery and patients with recurrent sinus surgery, hypertension, coronary artery diseases and renal, hepatic or cerebral insufficiency and patients with coagulopathies were excluded from the study. Patients in group D received inj. dexmedetomidine i.v.

bolus 1mcg/kg in 10ml of saline, over 10minutes followed by an infusion of 1mcg/kg/hr through infusion pump. Patients in group E received inj. esmolol i.v.

bolus 1mg/kg over 1minute followed by an infusion of 1mg/kg/hr through infusion pump.

After checking fasting status, informed written consent and PAC, the patients were randomly divided into 2 groups, each of 30 patients by sealed envelope method.

The baseline values of HR, systolic blood pressure, diastolic blood pressure,MAP, SPO_2 and respiratory rate were recorded. All measurements were made with the patient supine and with no tilt on the operating table. An intravenous access was secured using 20G cannula. Inj. Ringer lactate infusion was started.

Administration of bolus doses of dexmedetomidine and esmolol was done before induction of anaesthesia. Maintenance doses of study drugs were given by infusion after induction of anaesthesia. All the infusions were titrated to maintain a mean arterial blood pressure between 65-70 mmHg. . If mean arterial blood pressure fell below 65 mmHg, then initially fluids were given. If there was no improvement, then the rate of infusion of study drug was decreased. Still, if there was no improvement, inj. Mephentermine 6mg i.v. bolus was given. Patient was premedicated with Inj. Ranitidine 1mg/kg , Inj. Metoclopramide 0.1 mg/kg , Inj.

Glycopyrrolate 0.004mg/kg, Inj. Midazolam 0.02mg/kg and Inj. Fentanyl 2mcg/kg.

After preoxygenation with 100% O_2, anaesthesia was induced with inj. thiopentone sodium 5mg/kg intravenously slowly and intubation was facilitated with inj.

succinylcholine 2mg/kg, then laryngoscopy and tracheal intubation were performed. Loading dose of inj. atracurium 0.5mg/kg was given. Anaesthesia was maintained with 40% O2+60% N2O and inj. atracurium 0.1 mg/kg and isoflurane 0.4 MAC. Intraoperative monitoring and vital parameters (HR, SBP, DBP, MAP, SPO_2) were recorded after every 10minutes. Surgical site for bleeding and need of suctioning were checked after every 10minutes using a predefined category scale adopted from that of Fromme *et al*.[7]

0 - No bleeding
1 - Slight bleeding – no suctioning of blood required
2 - Slight bleeding – occasional suctioning required. Surgical field not threatened
3 - Slight-bleeding – frequent suctioning required. Bleeding threatens surgical field a few seconds after suction is removed
4 - Moderate bleeding – frequent suctioning required. Bleeding threatens surgical field directly after suction is removed.
5 - Severe bleeding – constant suctioning required Bleeding appears faster than can be removed by suction. Surgical field severely threatened and surgery not possible.

The ideal category scale values for surgical conditions were predetermined to be two and three. The infusion of study drug was stopped 5minutes before completion of surgery. At end of surgery, patient was reversed with inj.

neostigmine 0.05mg/kg i.v. and inj. glycopyrrolate 0.01mg/kg. Extubation was done when patient was fully awake. Hemodynamic parameters were recorded.

Emergence time after surgery and the time to first analgesic request was noted.

The post-operative sedation was assessed every 30minutes upto 2hours after surgery by using Ramsay Sedation Score. This was the end point of our study. In both the groups, patients were supplemented with additional dose of inj. Fentanyl 1 µg/kg if more than 20% increase in HR and MAP from baseline were recorded.

Incidence of adverse effects like nausea, vomiting, shivering, dry mouth, bradycardia was also recorded.

Emergence Time was defined as interval between discontinuation of anesthetic drugs to response of eye opening to verbal commands.

STATISTICALANALYSIS:

Data were compiled in Microsoft Excel™ and analysed using EP INFO version 7.2.1.0 software. The quantitative data (Mean HR, SBP, DBP, and MAP) were expressed as Mean±SD and their significance was analysed by unpaired student t- est. Mann-Whitney test applied for median sedation score and qualitative data were analysed using chi-square test. The 'p'value<0.05 was considered significant.

RESULTS:

Demographic profile of both the groups was analysed. The mean age in group D and E (33.70±3.28 years versus 33.63 ±4.10 years), mean weight (58.32±2.26 kgs versus 57.62 ±2.54 kgs), sex distribution, ASA physical status, mean duration of surgery (73.23±9.96 minutes versus 74.50 ±9.70 minutes) were statistically comparable (p>0.05).

As per table-1, Intra group comparison was done using Repeated measure ANOVA with bonferroni post hoc analysis. In Group D, the mean HR was significantly lower than the baseline values after induction, at 10min, 20min, 80 min, 90 min and lowest after loading (66.2±2.8, p<0.05). In Group E, the mean HR was significantly lower than the baseline values after induction, at 10min, 20min, 70min, 80min, 90 min and lowest after loading(67.6 ±4,p<0.05).

Intergroup comparison as depicted shows that mean HR at baseline was comparable between the two groups. The mean HR decreased in both the groups after loading of study drugs and was comparable. There was no statistically significant difference in mean HR between the two groups at most of the times during intraoperative period except after stoppage of infusion of study drugs and at the end of surgery that is at 70, 80 and 90 min. when the mean HR was statistically significantly higher in group E.

Table 1- TREND OF MEAN HR

Time point	Group D	Intra group p value	Group E	Intra group p value	Inter group P value
Baseline	75.8 ± 6.6	-	76.3 ± 6.6	-	0.786
After loading	66.2 ± 2.8	0.00003*	67.6 ± 4	0.00048*	0.112
After induction	67.2 ± 3.6	0.00005*	68.8 ± 3.6	0.00036*	0.097
After intubation	71.7 ± 5.4	0.664	73.7 ± 4.4	1.000	0.117
10 minutes	68.9 ± 4.8	0.012*	69.3 ± 4.6	0.001*	0.786
20 minutes	68.4 ± 6.4	0.015*	69.5 ± 6.4	0.028*	0.536
30 minutes	70.8 ± 7	0.329	73.7 ± 6.5	1.000	0.083
40 minutes	69.9 ± 4.8	0.068	71.9 ± 4.1	0.238	0.094
50 minutes	70.2 ± 4.9	0.089	72.5 ± 5	1.000	0.080
60 minutes	71.8 ± 7	1.000	73.9 ± 5.6	1.000	0.202
70 minutes	69.1 ± 5.7	0.0189	73.1 ± 5.7	1.000	0.008*
80 minutes	68.3 ± 5.6	0.003*	72.8 ± 5.7	1.000	0.003*
90 minutes	69.3 ± 5.6	0.021*	73.7 ± 5.8	1.000	0.004*

*p value is significant

The mean of MAP at baseline was not significantly different between the two groups as depicted in table 2. There was no statistically significant difference in mean of MAP between the two groups after loading of study drug, after induction, after intubation and upto 70 minutes of intraoperative period. It was statistically significantly higher (p value <0.05) in group E as compared to group D after stoppage of study drug and at the end of surgery that is at 80 and 90 minutes. Intra group comparison was done using Repeated measure ANOVA with bonferroni post hoc analysis.

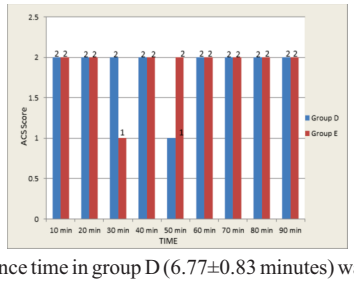
Table 2- TREND OF MAP

Time point	Group D	Intra group p value	Group E	Intra group p value	Inter group P value
Baseline	94.7 ± 6.6	-	94.7 ± 5.5	-	0.983
After loading	66.9 ± 6.7	0.000098*	69.5 ± 5.5	0.000064*	0.098
After induction	67.8 ± 6.5	0.00011*	70.5 ± 5.6	0.000077*	0.103
After intubation	66.8 ± 6.4	0.000081*	69.5 ± 5.5	0.00064*	0.082
10 minutes	65.2 ± 6.3	0.000033*	66.3 ± 5.6	0.000026*	0.489
20 minutes	66.1 ± 6.4	0.000064*	67.1 ± 6.2	0.000044*	0.533
30 minutes	69.8 ± 6.5	0.00018*	71.5 ± 6.3	0.00011*	0.306
40 minutes	71.1 ± 6.4	0.00089*	71.9 ± 6.7	0.00016*	0.642
50 minutes	70.1 ± 6.6	0.00028*	71.9± 6.6	0.00013*	0.292
60 minutes	69.9 ± 6.2	0.00021*	72.4 ± 7.4	0.00021*	0.158
70 minutes	70.8 ± 6.1	0.00067*	73.8 ± 7.9	0.00032*	0.099
80 minutes	71.9 ± 6	0.00094*	76.1 ± 8.1	0.00088*	0.017
90 minutes	70.4 ± 4.7	0.00048*	75.2 ± 8.5	0.00067*	0.003

*p value is significant

The average category scale as depicted in fig1 demonstrated no statistically significant difference between the two groups at most of the times during ntraoperative period with values ranging from 1-3. Statistically significant
difference in average category scale was seen at a few time intervals that is at 30, 40 and 50minutes with p value < 0.05.

Fig 1 AVERAGE CATEGORY SCALE(Median, Range)



Mean emergence time in group D (6.77±0.83 minutes) was statistically significant longer than in group E (4.05±0.63 minutes). Mean time to

first analgesia request was statistically significant longer in group D (59.9±7.34 minutes) than in group E (30.7±3.54 minutes). Postoperative sedation scores as depicted in table3 showed statistically significant difference between the two groups at all the time intervals upto 120 minutes with p value of <0.001.

Table 3 POSTOPERATIVE SEDATION SCORES

Time Interval		Sedation Score								
	Group	1	2	3	4	5	6	N	Mean	p value
0 min	D	0	0	13	17	0	0	30	3.5	<0.001(S)
	E	0	15	14	1	0	0	30	2.5	
30 min	D	0	0	18	12	0	0	30	3.4	<0.001(S)
	E	8	21	1	0	0	0	30	1.76	
60 min	D	0	6	21	3	0	0	30	2.9	<0.001(S)
	E	16	14	0	0	0	0	30	1.4	
90 min	D	0	18	12	0	0	0	30	2.4	<0.001(S)
	E	21	9	0	0	0	0	30	1.3	
120 min	D	4	23	3	0	0	0	30	1.96	<0.001(S)
	E	24	6	0	0	0	0	30	1.2	

DISCUSSION:

Bleeding is undesirable during any surgical procedure since it is disturbing to the surgeon as well as more of it can be dangerous for the patient. An important technique to reduce bleeding during the surgery is controlled reduction in blood pressure to such levels so that bleeding is minimal, but at the same time perfusion to the vital organs is well-maintained. This is the underlying concept for controlled hypotensive anesthesia.[8] Dexmedetomidine causes reduction in blood pressure, slowing of HR, sedation and analgesia. The fall in blood pressure is mainly due to inhibition of central sympathetic outflow and also due to stimulation of presynaptic α_2 adrenoceptors decreasing norepinephrine release.[9] Shen *et al*. in a placebo-controlled trial found that esmolol not only produces relative hypotension and bradycardia but also significantly improves the surgical field and reduces the average blood loss.[10] In our study, there was no statistically significant difference in mean HR between the two groups at most of the times during intraoperative period except after stoppage of infusion of study drugs and at the end of surgery that is at 70, 80 and 90min. when the mean HR was statistically significantly higher in group E. This observation was similar to those observed by Arokyamuthu et al.[11] between i.v. dexmedetomidine and i.v. esmolol.

In our study, there was no statistically significant difference in SBP, DBP and MAP between the two groups after loading of study drug, after induction, after intubation and upto 70 minutes of intraoperative period. It was statistically significantly higher (p value <0.05) in group E as compared to group D after stoppage of study drug and at the end of surgery that is at 80 and 90minutes. This trend in blood pressure is because of shorter context sensitive half-life of esmolol as compared to dexmedetomidine. This finding was similar to the study done by Shams et al[12] and Arokyamuthu et al.[11] he ACS for quality of surgical field was comparable in both groups in the range of MAP (65-70 mmHg). This finding is also similar to the findings in the study conducted by Erbselar et al.[13] in which there was no statistically significant difference between the groups regarding the bleeding scores and surgeon satisfaction (p>0.05). We found that sedation scores were significantly higher in dexmedetomidine group than esmolol group at 30, 60, 90 and 120minutes after surgery. This was consistent with the results obtained by C.R. Patel et al.[14]

CONCLUSION:

Both dexmedetomidine and esmolol are safe agents for controlled hypotension and are effective in providing ideal surgical field during FESS. Dexmedetomidine provides an additional benefit of reducing the analgesic requirements and providing postoperative sedation.

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