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A COMPARATIVE STUDY OF DEXMEDETOMIDINE AND NITROGLYCERIN IN INDUCED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC SINUS SURGERY

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ABSTRACT

Background: Functional Endoscopic Sinus Surgery (FESS) requires a clear surgical field, often achieved through induced hypotension by lowering MAP to 50–65 mmHg. Various agents are used for this, including nitroglycerin, sodium nitroprusside, volatile anesthetics, magnesium sulfate, propofol, ganglion blockers, alpha and beta blockers, and α2 agonists like dexmedetomidine. **Aim:** The general objective of this study is to improve surgical field visibility and reduce complications during FESS. Specifically, it compares the efficacy of dexmedetomidine and nitroglycerin in achieving induced hypotension and evaluates their impact on surgical conditions and patient outcomes. **Materials and Method:** This prospective, double-blind study was conducted at North Bengal Medical College from May 2019 to April 2020 with ethical clearance. 96 ASA I/II patients aged 18–60 years, scheduled for elective FESS, were randomly assigned to two groups: Group D received dexmedetomidine (0.5–1 µg/kg/hr) and Group N received nitroglycerin (5–10 µg/kg/min). **Result:** Both groups achieved an optimal ACS Score of 2-3 with a target MAP of 55-65 mmHg. There were no significant differences in surgical field visibility or blood loss between the groups. However, Group N exhibited a statistically significant higher heart rate throughout the surgery compared to Group D. **Conclusion:** Dexmedetomidine and nitroglycerin are both effective for induced hypotension in FESS, with comparable outcomes in surgical field quality and blood loss.

INTRODUCTION

Chronic rhinosinusitis is an important cause of morbidity and discomfort in patients. Functional endoscopic sinus surgery is a minimally invasive procedure with the added advantage of preservation of nasal mucosa.[1] As nasal mucosa is highly vascular, bleeding is the major problem. It is necessary to keep the surgical field bloodless to improve the visibility of surgical field and reduce the associated complications like optic nerve injury, orbital cellulitis, meningitis in addition to multiple blood and blood products transfusion, transfusion related acute lung injury, spreading of acquired immune deficiency syndrome, hepatitis b infection etc.[2,3] Induced hypotension has been used to reduce blood loss and thereby address both these issues.[4] By constricting the capillaries of the area involved with the help of the topical vasoconstrictor, patient's positioning or induced hypotension technique along with general anaesthesia can reduce blood loss.

General anaesthesia along with induced hypotension is preferable than local anaesthesia as patients remain pain free during surgery. Additionally, many drugs used in general anaesthesia help to attain induced hypotension technique too.

Induced hypotension is defined as a reduction of the systolic blood pressure (BP) to 80 - 90 mmHg, a reduction of mean arterial pressure (MAP) to 50 - 65 mmHg or a 30% reduction of baseline MAP which in turn decreases the hydrostatic pressure within the capillaries consequently reducing oozing from capillaries. Thus, this procedure can be applicable in suturing and clipping in aortic surgery, aneurysmal surgery, and AV malformation. However, induced hypotension is not complications free. Permanent cerebral damage, delayed awakening, cerebral thrombosis, brain ischemia can happen.

A variety of medications can be used to induce hypotension including vasodilators like sodium nitroprusside, nitroglycerin, volatile anesthetics like isoflurane and sevoflurane, magnesium sulphate, intravenous anesthetics like propofol, combined alpha and beta blockers, beta adrenergic antagonists like esmolol, prostaglandins, calcium channel blockers, adenosine and α2 agonists like Dexmedetomidine.[5,6,7,8] By releasing nitric oxide (NO), nitroglycerin (NTG) converts guanosine triphosphate (GTP) to guanosine 3', 5'-monophosphate (cGMP) in vascular smooth muscle and other tissues. cGMP ultimately helps in the dephosphorylation of myosin light chains within smooth muscle fibers. This activity causes the relaxation of smooth muscle within blood vessels, resulting in the desired vasodilatory effect.[9] By activating postsynaptic α2 adrenoceptors in the central nervous system (CNS), Dexmedetomidine inhibits sympathetic activity and thus can decrease blood pressure and heart rate. Combined effects on presynaptic and postsynaptic α2 receptors can produce analgesia, sedation, and anxiolysis. Moreover, it does not cause reflex tachycardia, rebound hypertension.[10] Dexmedetomidine combines all these effects, thereby avoiding some of the side effects of multiagent therapies, and it is gaining wide acceptance.

We did this study to compare Nitroglycerin and Dexmedetomidine infusion in FESS under general anesthesia with the general objective of providing better visibility of the surgical field and reduce the incidence of major complications during functional endoscopic sinus surgery and specific objective being monitoring heart rate, mean arterial pressure, emergence time, sedation score and adverse effects.

MATERIALS AND METHODS

Study Design: The study was a prospective double blinded comparative study.

Study Settings and Timeline: This study was carried out in patients posted for FESS surgery in North Bengal Medical College and Hospital (NBMCH) during the period of 1 year from May 2019 to April 2020 after getting permission from the Institutional Ethics committee and approval of West Bengal University of Health Sciences (WBUHS).

Place of study: North Bengal Medical College and Hospital at Main Ot Complex.

Study population: Patients between 18 to 60 years of age, American Society of Anesthesiologist (ASA physical status 1 and 2 scheduled for elective FESS surgery in our hospital).

Sample size: 96 FESS patients

Study groups: Patients will be divided into two groups, named Group D (n = 48) and Group N (n = 48). Group D will obtain infusion of dexmedetomidine (0.5-1 μg/kg/hour) and group N will obtain infusion of nitroglycerin (5-10 μg/kg/min).

Inclusion Criteria

- Age group: 18-60
- Sex: Male and female
- ASA grade: 1 and 2

Exclusion Criteria

- Patients with the following diseases will be excluded from the study -
- Diagnosed Coronary artery disease
- Diabetes mellitus
- Hypertension
- Renal dysfunction
- Hepatic dysfunction
- Bleeding diathesis
- Cerebrovascular disease
- Recurrent sinus surgery

Study Variables

- Duration of surgery
- Total anaesthesia time
- Emergence time: defined as the ending stage of anesthesia featuring the transition from unconsciousness to complete wakefulness and recovery of consciousness (RoC).
- Time of reversibility of the hypotensive state at the end of surgery
- Amount of blood loss during surgery– was calculated by the amount of blood collected in the suction apparatus and by weighing the total number of soaked gauze pieces in the gravimetric method.
- Visibility of the surgical field assessed by the surgeon according to the ACS score adopted from Fromme et al.[13] It was categorized as 0 = absence of bleeding; 1 = slight bleeding, suctioning of blood not necessary; 2 = slight bleeding, sometime blood has to be suctioned out; 3 = slight bleeding, sometime blood has to be evacuated, visible operative field for some seconds after evacuation; 4 = average bleeding, blood has to be often evacuated, operating field is only visible right after evacuation and 5 = high bleeding, constant blood evacuation is needed, sometimes bleeding exceeds evacuation.
- Any side effects like nausea and vomiting, shivering and dry mouth
- Duration of the sedation during post operative period (by Ramsay sedation score):1. Patient is anxious and agitated or restless or both 2. Patient is cooperative, oriented and tranquil 3. Patient responds to command only 4.A brisk response to light glabellar tap or loud auditory stimulus 5.A sluggish response to light glabellar tap or loud auditory stimulus 6. No response to light glabellar tap or loud auditory stimulus.

- Intraoperative HR and MAP were recorded every 5mins and then average values of intraop HR and MAP were taken.
- Time for rescue analgesia

After getting approval from the Institutional Ethics Committee, patients were selected during pre-anaesthetic check-up considering both the inclusion and exclusion criteria. Written informed consents were then obtained from all the patients. Pre-anaesthetic evaluation was performed in each patient including detailed history-taking, thorough physical examination routine and specific examinations. Then patients were randomly allocated into group D and group N having 48 patients in each using a sealed envelope system.

Patients remained in a fasting state for 8 hrs according to ASA fasting guideline after a light meal. All patients received a tablet Diazepam 10mg orally on the night before surgery. The patient's consent form and all PAC reports were checked. 2 ml of injectable inj. Dexmedetomidine (100 microgram per ml) in a 50 ml syringe and diluted with 48 ml of normal saline (4µg/ml). An infusion of NTG was made by adding 25mg (5ml) of NTG to 45ml of normal saline (500µg/ml).

All the patients had an i.v line with an 18G cannula for infusion of Ringer lactate at 5 mL/kg. Another 18G i.v cannula was inserted in the opposite limb for infusion of study drug. Foley's catheterisation was done to monitor urine output. All patients had radial arterial catheters to measure MAP. All patients were premedicated with inj. Ranitidine 50mg i.v, inj. Ondansetron 4mg i.v, inj. Glycopyrrolate 200µg i.v, inj. Midazolam 0.05mg/kg i.v and inj. Pentazocine i.v 0.3 mg/kg body weight. Patients of group D received inj. Dexmedetomidine loading dose 1 µg/kg over a period of 10 min before induction followed by maintenance infusion of 0.5-1 µg/kg/hour after intubation via syringe infusion pump. Group N received inj. Nitroglycerin 5-10µg/kg/min after intubation via syringe infusion pump. The infusion dose was titrated to obtain mean arterial pressure between 55-65 mmHg. When the MAP had fallen below 55 mm of Hg, then corrective measures were taken by giving inj. Mephentermine i.v bolus 6mg (1ml). Induction agent i.v Propofol was administered at a dose of 2 mg/kg until the loss of verbal response of the patients. After giving short acting depolarizing muscle relaxant i.e. inj. Suxamethonium 1mg/kg i.v and pressor response attenuating agent i.e. inj. Lignocaine 1.5mg/kg i.v, patients were intubated with appropriate size cuffed oral endotracheal tube. In group D maintenance infusion dose of Dexmedetomidine 0.5-1µg/kg/hour was started immediately after intubation and in group N Nitroglycerin infusion 5-10µg/kg/min was given after intubation. Anaesthesia was maintained with 60% N_2O/O_2 mixture along with sevoflurane and inj. Atracurium 0.3 mg/kg i.v bolus dose, followed by intermittent dose of 0.1mg/kg i.v. Patients were ventilated maintaining $ETCO_2$ 35 to 45 mmHg and SPO_2 > 95% in 30°reverse trendelenburg position. An oropharyngeal pack was given to every patient along with that their nasal mucosa were infiltrated by Epinephrine in a concentration of 1:1,00,000 by the surgeon. Maximum infusion rate in group D will be 1 µg/kg/hour and in group N - 10µg/kg/min. Once the target MAP was reached the surgeon was allowed to proceed with the surgery and then patients were monitored continuously for pulse rate MAP, SPO_2 and $ETCO_2$ and datas were collected at 15 mins intervals during surgery.

Dexmedetomidine/Nitroglycerin infusion was stopped approximately 15 mins before the expected end of surgery. After the stoppage of the infusion, the patients were monitored at a 2min interval for vital parameters like MAP and HR. Time was noted for MAP to return to its base level. Patients were reversed and extubated after the criteria for extubation were satisfied. Patients were monitored for intraoperative complications like reflex tachycardia and bradycardia. Reflex tachycardia (increased in HR> 20% than baseline) was treated with inj. Esmolol 0.5 mg/kg i.v. Patients developed bradycardia were treated with inj Atropine 0.02 mg/kg body weight i.v. Patients were monitored for postoperative complications like nausea and vomiting, hypotension, shivering for a period of upto to 2 hours.

Statistical Analysis

For statistical analysis, data were initially entered into a Microsoft Excel spreadsheet and then analyzed using SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism (version 5). Numerical variables were summarized using means and standard deviations. Categorical variables were expressed as Number of patients and percentage of patients and compared across the 2 groups using Pearson's Chi Square test for Independence of Attributes/Fisher's Exact Test as appropriate. Continuous variables were expressed as Mean plus minus Standard Deviation and compared across the 2 groups using unpaired t test if the data did follow normal distribution and Mann-Whitney U test if the data those did not follow normal distribution.

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RESULTS

Table 1: Comparison of heart rate between the two study groups. SD: Standard Deviation, NS: Not significant, S: Significant. Data were expressed as mean ± standard deviation and tested with Mann Whitney U test

Parameter	Group						P-Value	Significance
	Group D			Group N				
	Mean	Median	SD	Mean	Median	SD		
Baseline HR	78.71	78	3.75	79.98	79.5	5.23	0.399	Not Significant
HR after starting infusion of study drug	64.75	65	2.69	81.33	80	4.94	<0.001	Significant
HR after induction	66.21	66.5	2.48	79.15	78	4.66	<0.001	Significant
HR after intubation	71.15	72	2.75	92.79	92.5	7.13	<0.001	Significant
HR 5min after intubation	67.56	68	2.66	95.25	95	7.84	<0.001	Significant
Intra-op avg HR	67.08	67	2.71	94.5	94.5	6.73	<0.001	Significant
HR after reversal	70.96	70.5	2.67	95.69	95	6.93	<0.001	Significant
HR 20min after extubation	68.44	68	3.29	91.21	90.5	6.42	<0.001	Significant

Table 2: Comparison of MAP (in mm of Hg) between the two study groups. SD: Standard Deviation, NS: Not significant, S: Significant. Data were expressed as mean ± standard deviation and tested with Mann Whitney U test.

Parameter	**Group**						**P-Value**	**Significance**
	Group D			**Group N**				
	Mean	**Median**	**SD**	**Mean**	**Median**	**SD**		
Baseline MAP	96.9	97	2.45	97.54	97	3.21	0.415	Not Significant
MAP after starting infusion of study drug	88.04	88	1.89	90.52	90	3.09	<0.001	Significant
MAP after induction	78.69	78	1.59	82.58	82	3.45	<0.001	Significant
MAP after intubation	81.44	82	1.79	89.5	90	2.72	<0.001	Significant
MAP 5 min after intubation	74.27	74	2.05	77.04	76	3.8	<0.001	Significant
Intra-op avg MAP	61.81	63	2.76	61.83	63	2.64	0.997	Not Significant
MAP after reversal	77.75	79	3.55	89.27	89	2.46	<0.001	Significant
MAP 20 min after extubation	91.79	92	2.59	91.81	92	2.3	0.85	Not Significant

Table 3: Comparison of time for rescue analgesia (in minutes) in Group D and Group N

Rescue analgesia	**Group**						**P-Value**	**Significance**
	Group D			**Group N**				
	Mean	**Median**	**SD**	**Mean**	**Median**	**SD**		
	64.44	64.5	6.97	41.46	40	4.35	<0.001	Significant

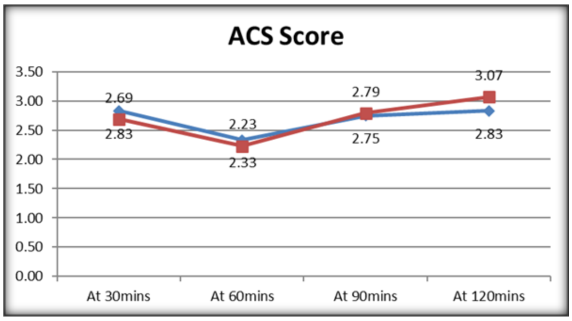

Figure: 1: Quality of surgical field assessed by ACS score between the study Group N (red), and study Group D (blue)

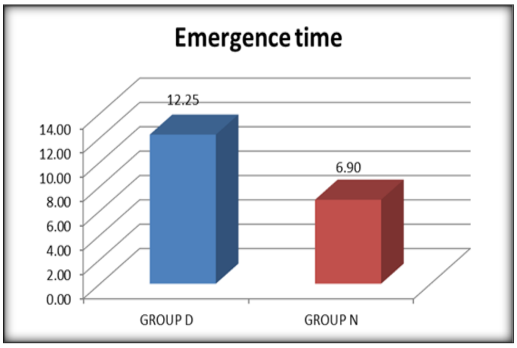

Figure: 3. Bar diagram showing comparison of emergence time between the study groups

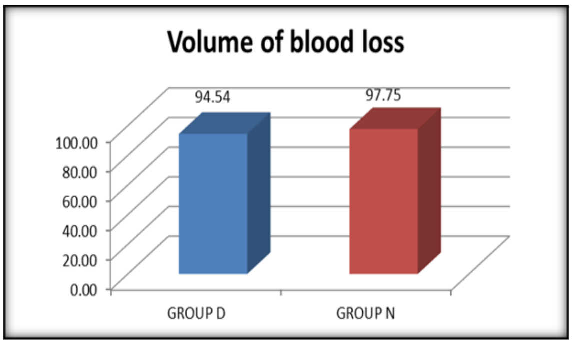

Figure 2: Bar diagram showing volume of intraoperative blood loss (in mL) between the study groups

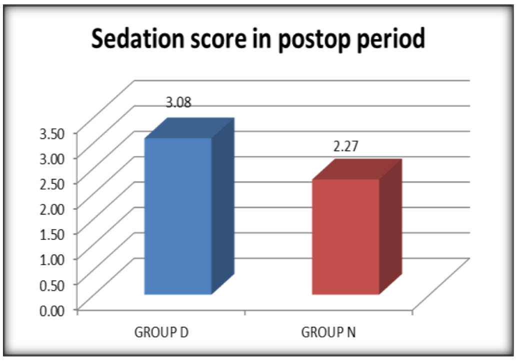

Figure 4: Bar diagram showing post operative sedation score in the study groups

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Initially, we assessed the optimum quality of the surgical field based on the satisfaction of the same surgeon who performed all FESS procedures. Fig 1 showed that Average category scale (ACS) of 2-3 was attained in both groups. There was no significant difference in group scores during surgery with no significant difference in intraoperative blood loss; Group D total blood loss was 94.54±18.91 mL, while in Group N it was 97.75±21.50 mL ($p= 0.501$), Fig 2.

Additionally, Group D exhibited significantly lower mean heart rates throughout the procedure ($p < 0.001$), with only two cases of reflex tachycardia in Group N requiring intravenous esmolol. Mean arterial pressure (MAP) was consistently lower in Group D post-induction and post-intubation ($p < 0.001$), although both groups maintained desired hypotensive levels although time taken for MAP to return to normal after reversal was significantly less in Group N (2.42±0.54) compared to Group D (8.88±2.72).

Emergence time was longer in Group D ($p < 0.001$), but patients required rescue analgesia later (64.44 ± 6.97 min vs. Group N), indicating prolonged postoperative analgesia. Postoperative sedation scores were higher in Group D (3.08 ± 0.68) than in Group N (2.27 ± 0.45), with $p < 0.001$. No serious side effects were noted; dry mouth occurred in 10.42% of Group D, and shivering was reported in 14.58% of Group D and 16.67% of Group N.

DISCUSSION

FESS is a surgical procedure, during which all necessary manipulations are performed while using a fiber optic camera. During the surgery, capillary bleeding which influences the operative field must be reduced to increase the visibility of surgical field as well as to reduce complications by inducing hypotension and using local vasoconstrictors. Under general anaesthesia, the induced hypotension technique is a well-accepted technique, which deliberately decreases the patient's Mean Arterial Pressure (MAP) to below normal. Use of various pharmacological agents has been showed in literature to produce induced hypotension in various surgeries.[11]

Vital organ perfusion as well as tissue perfusion is decided by MAP. Therefore, MAP was chosen as a parameter to quantify hypotension. We kept the target MAP between 55-65 mm of Hg in our study.[12] Hormonal and metabolic responses were investigated by various researchers and found to have no risk of tissue ischemia. Alpha-2 receptors are located on blood vessels and mediate vasoconstriction. But on sympathetic terminals, they inhibit norepinephrine release. At lower doses, dexmedetomidine is predominantly sympatholytic. Upon binding to α2 receptors, it reduces the sympathetic outflow and an augmented cardiac vagal activity result in decreased HR and cardiac output. On the other hand, NTG acts by liberating nitrite ions which get converted to nitric oxide. This activates guanylyl cyclase to eventually cause vascular smooth muscle relaxation. This reduction in smooth muscle tone is more pronounced in the venous system, causing a decreased venous return to the heart and thereby reducing the stroke volume which reduces the cardiac output. NTG infusion causes activation of the renin-angiotensin system. This may have been the cause of tachycardia observed in the two patients from the NTG group.

Our primary outcome parameters were to assess the visibility of the surgical field with the use of Average Category Scale (ACS) Score and to measure the amount of blood loss. We took the ACS score as per reference from Fromme et al,[13] and our result was consistent with the result produced by Farah Nasreen et al. who studied the effects of Dexmedetomidine for patients undergoing middle ear surgery with induced hypotension technique and found that the patients receiving Dexmedetomidine infusion had bloodless surgical field and better visibility,[14] and Ghodraty M et al. (2017) compared Labetalol and Nitroglycerin on inducing induced hypotension and intraoperative blood loss in Rhinoplasty the surgeons were more satisfied with nitroglycerin than labetalol.[15]

In terms of amount of intraoperative blood loss, the result was comparable in both the groups in our study which was consistent with the results of Das A et al. (2016) who also observed that patients receiving Dexmedetomidine suffered from significantly less nasal bleeding, and surgeon's satisfaction score was also high in this group.[16] Also, in a randomized clinical trial Hadavi MR et al (2015) showed that the bleeding amount was slightly higher in the labetalol group than Nitroglycerin group.[17]

Our results were, however, in contrast with the results of Jamaliya et al. They observed that the amount of blood loss and blood transfusion requirements were significantly higher in Nitroglycerin group than in Dexmedetomidine group. They carried out this study in spine surgeries and blood loss in spine surgery is mainly dependent on congestion of veins around the vertebral bodies. NTG is a peripheral vasodilator agent with its predominant effect on veins. Dilatation of the venous plexus around the vertebral bodies may have contributed to increased blood loss when NTG was used for induced hypotension.[18]

Though desired MAP was achieved in both study groups, patients who received Dexmedetomidine infusion showed cardiovascular stability whereas there was significant tachycardia in Group N which persisted throughout the surgical duration. This was consistent with the results obtained by Malhotra et al (2013) who studied the effects of Dexmedetomidine on hypotensive anaesthesia in patients undergoing FESS and found that heart rate was significantly lower with the use of Dexmedetomidine.[19] Jamaliya et al. who also observed that the NTG group showed a mean rise in heart rate of 28.46% from baseline values as compared to the DEX group which showed a mean fall in heart rate of 21.7%. The underlying mechanism for tachycardia with nitroglycerin

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infusion is activation of the renin angiotensin system.[18]

In our study Emergence time showed a statistically significant difference between two groups and our result was consistent with the results of Richa F et al who showed that recovery from anaesthesia was slower in a group of patients receiving Dexmedetomidine for induced hypotension.[20]

Time taken for MAP to return to normal was significantly lower in Group N compared to Group D. Result of our study was consistent with Dharmendra Patel D et al,[21] The cause of this finding may be as Nitroglycerin has a half-life of one and a half minutes only, but Dexmedetomidine acts by binding to α2 receptors with higher affinity. So, the hypotension in group D can be reverted only when the drug diffuses out of its receptors.

In our study the time for rescue analgesia was significantly higher in group D, which was 64.44±6.97 mins than group N. This result was consistent with Bielka K et al.[22] There are several possible mechanisms underlying the long-term analgesic effect: Dexmedetomidine uses a different α2AR-dependent downstream mechanism to act as an analgesic. Another reason might be that Dexmedetomidine prolongs the analgesic time and analgesic effect of other analgesics.[23]

Our study showed that sedation score in postop period in group D (3.08±0.68) was significantly higher than group N (2.27±0.45). This result is consistent with the result of Chattopadhyay U et al study which showed that patients receiving Dexmedetomidine were more sedated during the postoperative period (P value <0.0001), but without any impairment of ventilation.[24]

Our study has few limitations like We did not monitor Bispectral index for assessing the depth of anaesthesia, cardiac output due to limited resources. Furthermore, we did not take any control group as it would be unethical not to control bleeding during surgery, did not assess the effect of dexmedetomidine on the dose of the induction agent and the effect of dexmedetomidine on serum cortisol level in post-op period could not be assessed. We could not include the effect of induced hypotension on serum urea, creatinine, LFT etc and did not assess uncommon adverse reaction in post operative period. These can be studied in future.

CONCLUSION

The observation of this study was that both Dexmedetomidine and Nitroglycerin can be effectively used in induced hypotension for FESS. Both groups were comparable regarding quality of surgical field, intraoperative blood loss. Dexmedetomidine achieved a markedly smoother hemodynamic profile than nitroglycerin during functional endoscopic sinus surgery, maintaining significantly lower heart rate and mean arterial pressure values at nearly every peri operative milestone while still achieving the target hypotensive range. Along with that Sedation score in the post operative period was significantly higher, and time required for rescue analgesia was again prolonged with Dexmedetomidine than Nitroglycerin. Thus, this study shows that dexmedetomidine has added advantages like sedation and analgesia.

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