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COMPARISON OF THREE DIFFERENT LOADING DOSES OF DEXMEDETOMIDINE FOR CONTROLLED HYPOTENSION DURING FUNCTIONAL ENDOSCOPIC SINUS SURGERY UNDER GENERAL ANAESTHESIA- A RANDOMISED CONTROLLED STUDY

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Abstract:
Background: Deliberate hypotension to provide bloodless surgical field gives better visibility of the operative field, with reduced risk of injury to adjoining structures.
This present study was conducted to compare three loading doses of dexmedetomidine for controlled hypotension in FESS surgery under GA.
Patients and Methods: Sixty patients aged between 18-60 years of either sex belonging to American Society of Anesthesiology I and II scheduled for FESS were randomly allocated to one of the three groups. Patients in group I, II and III received dexmedetomidine loading infusion at a rate of 1 µg kg-1, 0.8 µg kg-1 and 0.6 µg kg-1 respectively over 10 minutes followed by continuous infusion of 0.5 µg kg-1 h-1. The primary goal was to provide a MAP in a range of 60 - 70 mmHg before the start of surgery.
Results: It was found that Mean HR as well as MAP was significantly lower in group I as compared to group II and III at multiple points. Also, time to achieve MAP was significantly lower in group I. ($p < 0.001$). surgical field visibility and surgeon satisfaction was better in group I.
Conclusion: We concluded that using IV dexmedetomidine as an adjunct to other anesthetics is an acceptable approach to provide controlled hypotension. Administration of a loading dose of 1 µg kg-1 and 0.8 µg kg-1 compared to 0.6 µg kg-1, provides better surgical field conditions in terms of bleeding and visibility.

Keywords: Bradycardia, Controlled hypotension, Dexmedetomidine, Nasal surgical procedures, General anaesthesia

Introduction

Functional endoscopic sinus surgery (FESS) is the gold standard surgical procedure for the surgical management of chronic rhinosinusitis, nasal polyposis, and other pathology affecting paranasal sinus, such as tumoral pathology.[1] Whether local or general anaesthesia (GA) is used, intraoperative bleeding can complicate airway management .[2] To mitigate airway issues during nasal surgeries, GA is often preferred. Significant bleeding during FESS compromises the visibility within the surgical field, thereby escalating both the risks associated with the procedure and the overall duration of the surgery.[3] Moreover, other recognized complications related to FESS—such as nasal (including synechiae and anosmia) and intracranial (CSF leaks leading to meningitis), as well as orbital complications (damage to the optic nerve, nasolacrimal duct, or extraocular muscles)—can also be exacerbated by significant intraoperative bleeding .[4]

Several strategies can be employed to minimize intraoperative bleeding such as positioning the patient in a reverse Trendelenburg position, use of injected and topical local anaesthetics, and administering vasoconstrictors like phenylephrine, maintaining normothermia and employing controlled hypotension through various anaesthetic techniques.[5] Controlled hypotension involves intentionally lowering systemic blood pressure during anaesthesia, allowing for mean arterial pressure (MAP) to be decreased by up to 30% from the patient's baseline MAP, with an acceptable minimum MAP of 60 to 70 mmHg in ASA class 1 patients .[6] The intentional use of hypotensive anaesthetic techniques during FESS offers multiple benefits, including reduced blood loss, lower rates of blood transfusions, enhanced visibility in the surgical field, and shortened surgical duration. A variety of drugs are employed to intentionally induce hypotension, including vasodilators, adrenergic beta blockers, α-2 agonists such as dexmedetomidine, as well as opioids, propofol, magnesium sulphate, and inhalational anaesthetics.[6,7]

Dexmedetomidine, which is a highly selective α2-agonist, serves as a sedative, anxiolytic, and hypotensive agent in anaesthesia. The recommended loading dose is 1 μg kg^{-1} administered over ten minutes, followed by a maintenance dose of 0.3-0.7 μg kg^{-1} h^{-1}.[8] The hypotensive effects and ability to lower heart rate make this agent a logical

option for procedures that require "controlled hypotension" and studies have shown it to be more effective compared to other alternatives in this context.[9,10] It is also associated with a decrease in the incidence of postoperative shivering, nausea, vomiting, delirium, and postoperative cognitive dysfunction. Aside from all the benefits, dexmedetomidine also has its side effects, the most important of which is severe bradycardia and in rare cases even, cardiac arrest can occur. Since hemodynamic changes mostly occur during loading infusion, we hypothesized that decreasing the loading dose of dexmedetomidine, the incidence and severity of bradycardia is reduced while maintaining the hypotensive effect. So, we planned the present study to compare three distinct loading doses of dexmedetomidine (1 μg kg^{-1}, 0.8 μg kg^{-1}, and 0.6 μg kg^{-1}) for controlled hypotension. To achieve and maintain target MAP 60 – 70 mmHg during surgery was taken as a primary objective. Changes in hemodynamic parameters, surgical field assessment, surgeon's satisfaction, minimum alveolar concentration of inhaled anaesthetics (MAC) and adverse effects, if any were taken as secondary objectives.

Materials and Methods

The current prospective, randomized, and double-blind clinical trial was carried out in the tertiary care teaching hospital from April 2023 to Jan 2024, following the approval of the institutional ethical committee The study was registered in the Clinical Trials Registry-India (vide registration number *CTRI/2023/04/051531)*. Sixty patients of age18 to 60 years with American Society of Anesthesiologists (ASA) physical status I and II, scheduled to undergo FESS were included in the study. Individuals with a history of uncontrolled hypertension, hypotension (mean arterial pressure < 70), a heart rate of < 60 beats per minute, beta-blocker treatment, diabetes, cardiovascular or cerebrovascular diseases, renal and liver dysfunction, coagulation disorders, morbid obesity, those scheduled for revision FESS, allergies to alpha-2 adrenergic agonists and anemia (hemoglobin < 10 g/dL) were excluded from the study.

The purpose and the protocol of study was explained to all the patients and an informed and written consent was taken from them for participation in the study. Standard fasting guidelines were followed and premedication was given in the form of tablet alprazolam 0.25 mg and pantoprazole 40 mg the night

before and two hours prior to surgery. *In the operation theatre, standard monitors like electrocardiography (ECG), noninvasive blood pressure (NIBP), capnography (EtCO2), pulse oximetry (SpO2), depth of anaesthesia (BIS) were attached. Intravenous access was established with two appropriate size cannulas and fluids were administered at a rate of 4 to 6 ml kg-1 before the induction.* Patients were randomly assigned to one of three study groups I, II and III using computer-generated numbers. Patients received a loading infusion of dexmedetomidine at rates of 1 μg $kg^{-1,}$ 0.8 μg kg^{-1}, and 0.6 μg kg^{-1}, respectively, over a duration of 10 minutes, followed by a continuous infusion at a rate of 0.5 μg kg-1 h^{-1}. A Junior resident initially prepared and established the infusion rate for the loading dose, while a second junior resident, who was blinded to the group assignments, managed anaesthesia according to the study protocol and gathered the data. Standard anaesthesia induction was carried out with fentanyl 2 μg kg-1 and propofol 2 mg/kg atracurium 0.5 mg kg-1 after the completion of the dexmedetomidine loading infusion. Airway was secured with oral endotracheal tube of appropriate size and lungs were mechanically ventilated to maintain the EtCO2 30 to 35 mmHg. Anaesthesia was maintained with sevoflurane, nitrous and oxygen and adjusted to bispectral (BIS) index of 40-60. Oropharynx was packed with saline soaked oropharyngeal pack. All patients were positioned in 25°reverse trendelenberg position. 3-4 ml of a solution containing lidocaine 2% and epinephrine 1:200,000 was locally administered by the surgeon before starting the operation. Continuous intravenous infusion of dexmedetomidine was maintained throughout the procedure and was terminated 10 min before the end of surgery and discontinuation of inhalation anaesthetics. After termination of surgery, the oropharyngeal pack was removed and the oropharynx was suctioned under direct vision using the rigid laryngoscope. The residual neuromuscular blockade was reversed with IV neostigmine 0.05 mg kg -1 and glycopyrrolate 0.01 mg kg -1 and trachea was extubated. Sedation was assessed using Ramsay sedation score on arrival to PACU.

The primary objective was to provide a MAP in a range of 60 - 70 mmHg before the start of surgery. If MAP exceeded this limit, provided that depth of anaesthesia is adequate, further management was done according to the patient's HR changes. If the

HR increased simultaneously to more than 20% of the preoperative value, 1 μg kg^{-1} of fentanyl was administered, but if MAP increased without significant changes in HR, a 0.5 ml bolus of dexmedetomidine (4mcg^{-}) was infused twice. If still MAP was high, IV NTG 25 μg was given and recorded. In case of hypotension, defined as a MAP < 60 mmHg, a bolus of 100 mL of crystalloid solution was given, and the infusion of the drug was temporarily discontinued until the return of MAP to the desired value. If the drop in MAP did not improve, a bolus of IV ephedrine 3 mg was administered. If bradycardia (HR less than 60 beats/min and decreased by more than 20% compared to the baseline value) occured, the infusion of dexmedetomidine was reduced; and if bradycardia was accompanied by hypotension, a bolus of intravenous atropine 0.3 mg and 200 ml of IV crystalloid solution was administered.

Hemodynamic parameters like heart rate, mean arterial pressure were recorded upon arrival of the patient to the operating room, 10 minutes after start of dexmedetomidine loading dose infusion, before induction of anaesthesia, 1, 5 and 15 minutes after tracheal intubation, 2 minutes after local infiltration of epinephrine and every 15 minutes after tracheal intubation and after tracheal extubation. The condition of the surgical field was assessed by the surgeon in terms of bleeding and visibility, using a 6-point scale adapted from Fromme et al [**11]** named as bleeding score.

0 = no bleeding

1 = minor bleeding, but no aspiration required

2 = minor bleeding, aspiration required

3 = minor bleeding, frequent aspiration required

4 = moderate bleeding, often aspiration is required as operative field is visible only after aspiration

5 = severe bleeding, continuous aspiration required

Surgeon was blinded to the group and first assessment was done 15 min after the start of surgery and then every 30 min. Surgeon's satisfaction: surgeon's satisfaction was also assessed based on a Likert scale: Excellent (5) Good (4) Satisfactory (3) Poor (2) Very poor (1). The inhaled concentration of sevoflurane was recorded every 15 minutes. The duration of surgery (the time from start of surgical intervention till its end), the extubation time (the time from discontinuation of isoflurane till removal of the endotracheal tube), the duration of anaesthesia (time span from induction of general anaesthesia till the extubation) and

time for interaction (the time from discontinuation of isoflurane till verbal contact or response to commands) was also recorded. Adverse effects like episodes of hypotension & bradycardia, desaturation was recorded during surgery, after tracheal extubation and during patients' stay in the post-anaesthesia care unit (PACU). Any effects like nausea & vomiting, shivering, delirium, bleeding from surgical site were also noted.

Our sample size calculation was based on **MAP** among the groups in the study by Motilagh et al. [15] We considered 95% confidence interval, 80% power and alpha level of 0.05, with defined mean difference of 0.6 from previous study and sample size came out to be 20 in each group. Hence, we recruited 60 patients for the study.

Data was analyzed by using Statistical Package for Social Sciences(SPSS) software, Version 20. For Quantitative parameters ,the mean values were compared between study groups using ANOVA. For Quantitative parameters, medians and Interquartile range (IQR) were compared across the study groups using Kruskal Wallis test. Categorical outcomes were compared between study groups using Chi square test /Fisher's Exact test.

Results

Total of 60 patients were assessed for eligibility and they were divided into three groups of 20 patients each. All participants completed the study. The study groups were comparable in terms of age, gender, and ASA physical status. The duration of surgery and anaesthesia was also similar in all groups (Table 1).

Table 1: Demographic profile and duration of anaesthesia of patients in the study groups

Parameter	Study groups			p value
	Group I (n=20)	Group II (n=20)	Group III (n=20)	
Age(years, mean±SD)	38.5 ± 9.99	38.75 ± 12.58	33.4 ± 12.44	0.274
Weight(kg, mean±SD)	64.75 ± 9.17	73.65 ± 15.29	71.25 ± 10.28	0.058
Gender-Female(%)/Male(%)	8(40%)/12(60%)	11(55%)/9(45%)	11(55%)/9(45%)	0.549
ASA physical status	I-10(50%) II-10(50%)	I-6(30%) II-14(70%)	I-10(50%) II-10(50%)	0.338
Duration of anaesthesia (minutes, **mean±SD**)	117.0 ± 13.71	133.15 ±35.69	136.05 ±27.81	0.200

Base line MAP was comparable among the three groups (p = 0.114). Intragroup comparison showed that there was a significant decrease in MAP in all the groups. However MAP was significantly lower in group I as compared to group II and III at multiple time points (immediately after loading dose of dexmedetomidine, after induction and one and five minutes, at T15, T30, T60 after intubation). But it was significantly higher than group III at Tr15 and Tr30 min in the recovery room(p value= 0.005). MAP also showed significant fall (p value= 0.012) in group I & II as compared to group III at T30, T60 minutes after intubation (Figure 1).

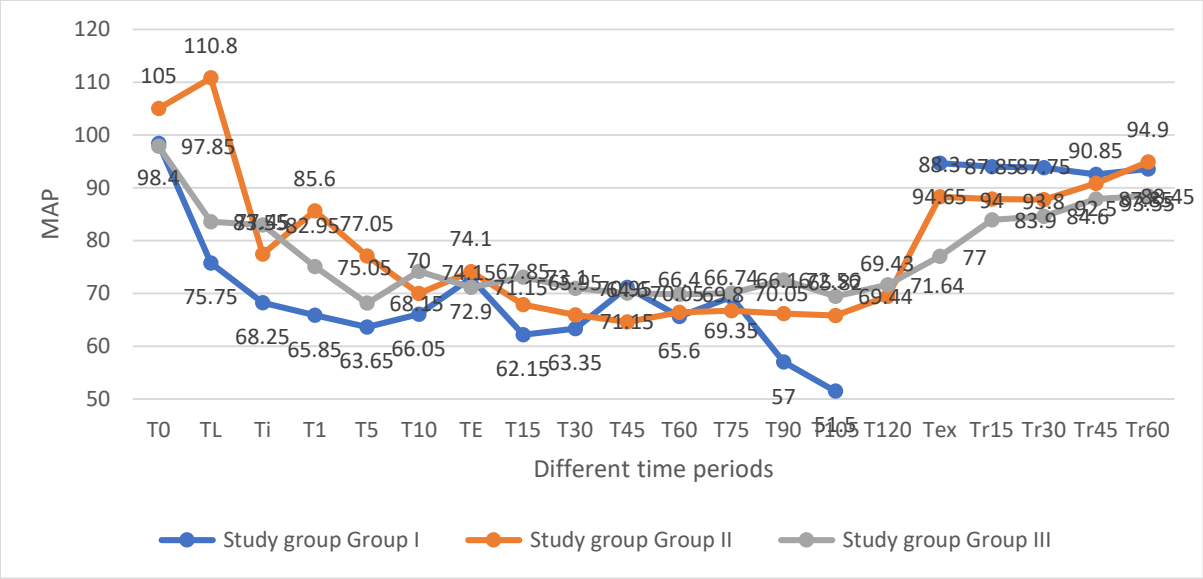

Figure 1: Trend line diagram of mean MAP (mmHg) across the study group at different time periods

Baseline mean HR was comparable among the groups. It was also statistically similar after loading dose of dexmedetomidine amongst the groups with HR values (beats/min, mean±SD) of 61.5±6.24, 69.55±12.53 and 74.05±28.45 in group I,II and III respectively (p value = 0.50, 1.00). Intragroup comparison showed that there was a significant decrease in HR in all the groups. Mean HR was significantly lower in group I as compared to group II and III at multiple time points (after induction and one and five minutes after intubation). It was significantly lower when compared to group II at Tr 15, Tr45 and also significantly lesser as compared to group III at Tr 60. (p = 0.018) (Figure 2).

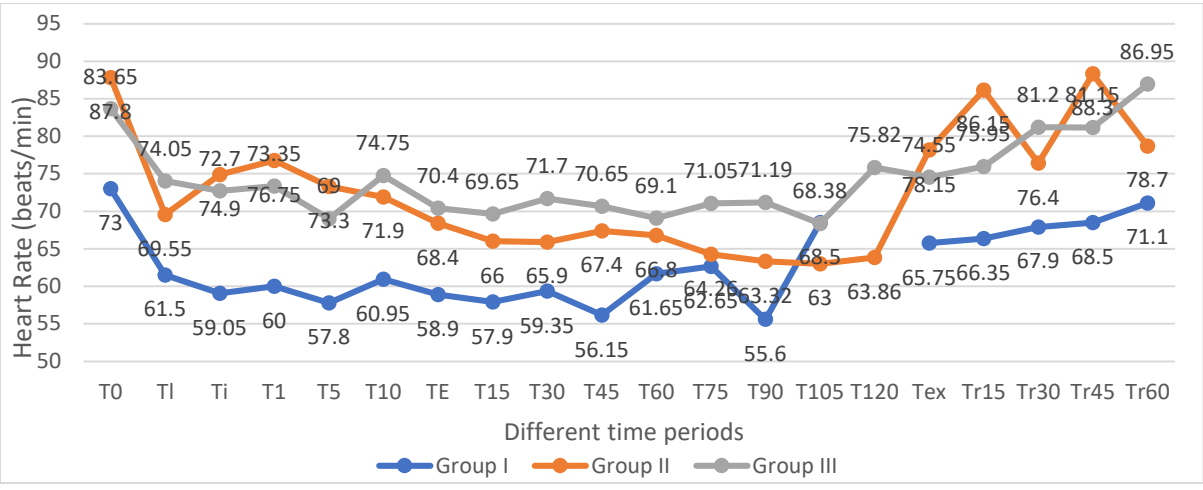

Figure 2: Trend line diagram of mean heart rate across the study group at different time periods

Time to achieve target MAP was significantly lower in group in I, followed by almost similar time in group II and III ($p < 0.001$) (table 2).

The condition of the surgical field as assessed by the surgeon in terms of bleeding and visibility, using a Fromme Boezzart scale was found to be worst in group IIIand almost similar in group1& II. But at 120 minutes, both groups II and III had similar surgical field condition ($p = 0.053$)(Fig.3).

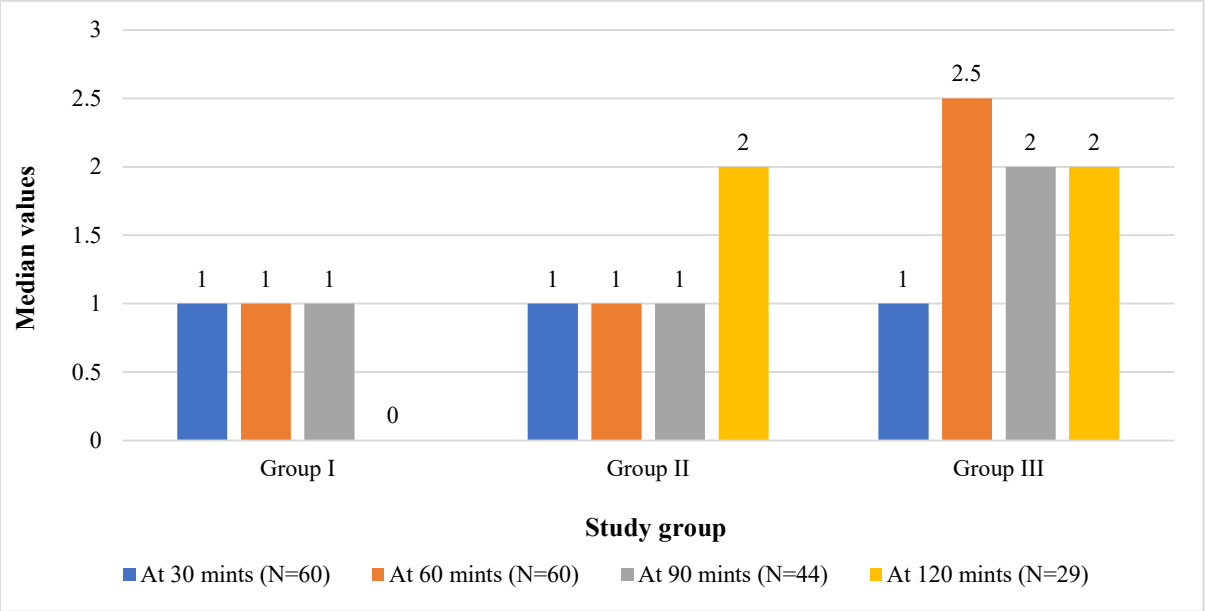

Figure 3: Comparative bar chart of median of surgical field assessment (as per fromme et al bleeding score) across study group at different time periods

Overall, inhaled concentration of sevoflurane was significantlylower in group I and II as compared to group III. BIS values were overall on higher side in group III as compared to group I and II.

50% of surgeons graded satisfaction as excellent in group I, where as it was 15 % in group II and none of the surgeons graded excellent in group III. **The mean difference among the three groups was statistically significant (p = 0.001)**(Fig.4).

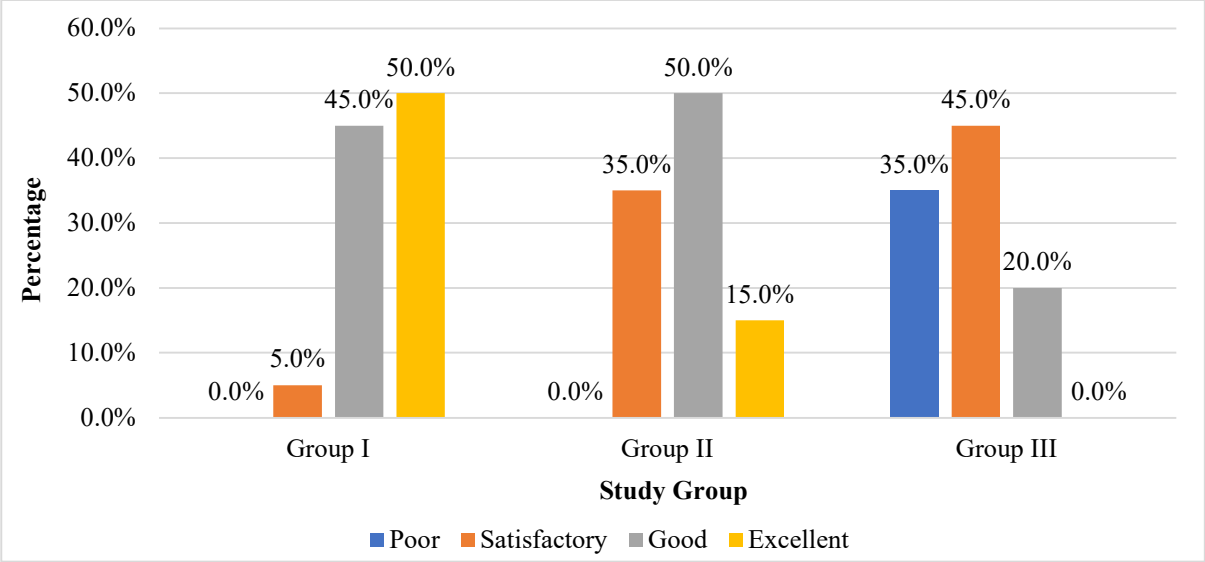

Figure 4: Cluster bar chart of comparison of surgeon satisfaction score across study group (N=60)

The extubation time and time for interaction was found to be longest in group I followed by group II and then group IIIas shown in the table 2. Sedation score was also significantly higher in group I and II than group III at all measured times points (p = 0.002). Although more number of patients experienced hypotension and bradycardia in group I when compared to group II & III, but it was statistically insignificant(Table II).

Table II: Time to achieve MAP, Extubation time, interaction time, Sedation score, inhaled conc of sevoflurane, Complications(sedation score shows an ordinal number as per Ramsay sedation score)

Parameter	Study groups			p value
	Group I (n=20)	Group II (n=20)	Group III (n=20)	
Time to achieve MAP(in min) mean±SD	15.15 ± 3.63	23.55 ± 5.62	22.7 ± 3.63	<0.001
Extubation time(in min)	20.15 ± 2.66	17.75 ± 3.35	9.15 ± 1.81	<0.001 (I & II vs III)
Timefor interaction(in min)	21.45 ± 3.90	20.8 ± 4.56	17.15 ± 3.84	0.021
Sedation score in PACU (at 15 min)	3	4	3	<0.001
Inhaled concentration of sevoflurane(at 30 min)	1.17 ± 0.16	1.29 ±0.4	1.51 ±0.31	0.003 (I vs III)
Complications Hypotension No. of patients(%)	3(15%)	4(20%)	1(5%)	0.364
Bradycardia No. of patients(%)	5(25%)	3(15%)	0(0%)	0.065

Discussion

The current study indicated that all three loading doses of dexmedetomidine (1 µg kg^{-1}, 0.8 µg $kg^{-1}$and 0.6 µg kg^{-1}) were effective to provide controlled hypotension. MAP of 60-70 mmHg could be achieved in

all the patients, but time to achieve required MAP was significantly longer in group III and II. Furthermore, a loading dose of 1 μg kg^{-1} and 0.8 μg kg^{-1} yielded improved conditions in the surgical field regarding bleeding and visibility. More number of surgeons were found to be satisfied in group I than II & III. MAP and HR decreased significantly in group I than II & III. The extubation time and time for interaction was also significantly prolonged in group I. Sedation score was also significantly higher in group I and II than group III at all measured times points.

Similar results were reported by many authors.[10,12] Although they compared dexmedetomidine dose (1 μg kg^{-1} bolus followed by 0.3-0.7 1 μg kg^{-1} h^{-1}) with some other drug or placebo but reported similar findings as in the present study. Bharathwaj et al [10] found that MAP at induction and at multiple time points intraoperatively was significantly lower in dexmedetomidine. They also reported similar time to reach the target MAP as in the present study. On the contrary, Chhabra et al,[16] in his study achieved the desired MAP much earlier in group Dexmedetomidine. Neethirajan et al[12] also reported significant fall in MAP with dexmedetomidinewithin 5 minutes of the start of study drug infusion till the end of surgery. Similar fall in MAP was observed by Parvizi et al [13]and Mahendran et al [14]in the group D after induction and during intraoperative period ($p = 0.001$). However, Motlagh et al[15] reported conflicting findings; they observed no differences in MAP across the three groups at any of the recorded times, except for one instance post-intervention. This discrepancy may be attributed to the varying loading doses administered and the specific type of surgery conducted in the present study, which involved doses of 1, 0.8, and 0.6 μg kg-1 for functional endoscopic sinus surgery (FESS).

In general, the visibility of the surgical field was poorer in group III compared to groups I and II. Collateral findings were reported by Motlagh et al[15] and Chhabra et all.[16] The concentration of inhaled sevoflurane was lesser in in group I & II than III. Group III exhibited higher BIS values when compared to groups I and II. Similar observations were made by Motlagh et al[15] who noted that the

average intraoperative requirement for isoflurane was lower in group Dexmedetomidine. While previous studies did not report BIS values, some adjusted the concentrations of isoflurane or sevoflurane to maintain BIS within the 40-60 range.Extubation time and interaction time was found to be longest in group I. These findings are consistent with those reported by Neethirajan et all,[12] who noted that emergence time was greater in the dexmedetomidine group**.** Consistent with our findings, a study by Abel Rahman et all[17] revealed that the Ramsay sedation score was significantly elevated in the group receiving a higher infusion dose of dexmedetomidine (Dex 0.8 > Dex 0.4).

There are some limitations of the present study. We studied only ASA I or II patients so results of the study cannot be generalized to the other subgroups. Secondly, invasive blood pressure monitoring was not done for controlled hypotension. Third, hypotensive anaesthesia in relation to the patient's preoperative blood pressure was not followed but a standard target MAP of 60-70 mmHg was used.

Conclusion We conclude that all three studied loading doses of IV dexmedetomidine an acceptable approach to provide controlled hypotension. Administration of a loading dose of 1 µg kg^{-1} and 0.8 µg kg^{-1} compared to 0.6 µg kg^{-1}, provide better surgical field conditions in terms of bleeding and visibility and better surgical satisfaction but the recovery time was prolonged. These higher loading doses were associated with more episodes of hypotension and bradycardia but it was statistically insignificant.

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Work concept and design 1,3
Data collection and analysis 1,4,5
Responsibility for statistical analysis 1,2,3
Writing the article 1,2,3
Critical review, 2,5,6
Final approval of the article 1,2,3,4,5,6

Each author believes that the manuscript represents honest work and certifies that the article is original, is not under consideration by any other journal, and has not been previously published.
Availability of Data and Material: The corresponding author is prompt to supply datasets generated during and/or analyzed during the current study on wise request.

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