Original Article

DOI: 10.7860/JCDR/2022/55878.16756

Efficacy of Intranasal Dexmedetomidine with Lidocaine versus Intranasal Lidocaine alone in Awake Fiberoptic Nasotracheal Intubation- A Randomised Clinical Study

Anaesthesia Section

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ABSTRACT

Introduction: Awake Fiberoptic Intubation (AFOI) is considered as the gold standard technique in patients with predicted and unpredicted difficult airway. It is best performed with the patient awake to maintain spontaneous ventilation. Dexmedetomidine has been successful in several clinical settings including AFOI due to its diverse actions like sedation, analgesia, anxiolysis, cardiovascular stabilising effect and preservation of respiratory function.

Aim: To assess the efficacy of using dexmedetomidine intranasally with lidocaine in AFOI in comparison to using lidocaine alone in terms of haemodynamic stability, sedation, ease of intubation, patient's satisfaction with the procedure and reduction in intraoperative propofol requirement.

Materials and Methods: This randomised clinical study was conducted on 100 patients of either gender aged between 18 to 60 years with American Society of Anesthesiologists (ASA) physical status I or II scheduled for elective surgeries under general anaesthesia at Government Medical College and Rajindra Hospital, Patiala, India from February 2021 to November 2021. The patients were randomly divided into two groups of 50 each namely group D (intranasal dexmedetomidine 2 mcg/kg+lidocaine 10%) and group L (intranasal lidocaine 10% alone). Maximum dose of 10% lidocaine was <5 mg/kg body weight in both groups. The various parameters were recorded in both the groups during AFOI and the data was analysed using Statistical Package for Social Sciences (SPSS) software version 22.0 and Microsoft excel. Descriptive statistics was done for all data and were reported in terms of mean, standard deviation and percentages.

Results: Among 100 patients, group D and group L comprises of 50 each. The mean heart rate during AFOI was 70.16±8.02 in group D, and 95.62±11.04 in group L. The Mean Arterial Pressure (MAP) during AFOI was 81.42±5.55 in group D and 101.78±6.22 in group L. There was statistically highly significant (p-value <0.001) decrease in mean heart rate and MAP (within normal clinical range) in group D as compared to group L. The mean Ramsay Sedation Scale (RSS) in group D was 3.66±0.48 and in group L was 2.32±0.55 (p-value <0.001). There was a significant difference (p-value <0.001) in patient tolerance, time to intubation, propofol requirement, patient satisfaction and anaesthesiologist satisfaction between the two groups. There was no significant decrease in Saturation of Peripheral Oxygen (SpO_2) or respiratory depression in both groups (p-value=0.221).

Conclusion: Intranasal dexmedetomidine with lidocaine provides better haemodynamic stability and improves the quality of intubation, reduces propofol requirement, provides good patient and anaesthesiologist satisfaction and maintains oxygen saturation during AFOI.

Keywords: Haemodynamic stability, Propofol requirement, Sedation

INTRODUCTION

Awake Fiberoptic Intubation (AFOI) is an effective technique for establishing airway access in patients having both anticipated and unanticipated difficult airway with respect to compromised airway, inadequate mouth opening as in temporomandibular joint disease, mandibular-maxillary fixation, severe facial trauma and burns, oropharyngeal mass, limited surgical field, when neck extension is to be avoided, vertebral artery insufficiency etc [1]. During awake intubation, laryngospasm and coughing in response to intubation can increase the failure rate and the number of attempts of intubation. Both optimal intubating conditions and patient comfort are necessary while preparing the patient for fiberoptic intubation [2]. Effective topical airway anaesthesia using drugs like lidocaine is essential in AFOI [1]. Conscious sedation causes a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command. It makes the procedure more tolerable for patients and helps to ensure optimal intubating conditions [3].

Dexmedetomidine is another arrow in the anaesthesiologist's quiver. It is a highly selective alpha-2 (α2) adrenergic receptor (α2-AR) agonist with sedative, analgesic properties, has anaesthetic sparing effect, sympatholytic property and also has cardiovascular stabilising property. It reduces delirium, preserves respiratory function and is useful in blunting haemodynamic responses in perioperative period [4]. It has been suggested that a smaller dose or routes other than rapid intravenous delivery may help to minimise the haemodynamic risk of dexmedetomidine [5]. Intranasal dexmedetomidine has shown to have a high rate of patient acceptance [6]. Studies showed that sedative onset time of intranasal dexmedetomidine is 45-60 min with a peak effect at 90-105 min, the absolute bioavailability is 65% (35-93%) and the pharmacological effects are similar to that of intravenous route [7,8]. Dexmedetomidine has shown better endoscopy scores, lower recall of intubation, greater patient satisfaction, provides surface analgesia, has decongestant, antisialagogue, antishivering and antiemetic effects [9,10]. Apart from these, studies also show that dexmedetomidine prolongs the duration of both sensory and motor blockade induced by local anaesthetics irrespective of the route of administration. Dexmedetomidine enhances peripheral neural blockade due to its binding to (α2-AR) [11].

A study by Mirkheshti A et al., (2017) showed decrease in sudden changes in haemodynamic values and improved patient tolerance and intubation scores on use of intranasal Dexmedetomidine

during fiberoptic bronchoscopy [12]. Niyogi S et al., (2017) showed that intranasal dexmedetomidine was effective as intravenous dexmedetomidine in attenuating the haemodynamic stress response of laryngoscopy and endotracheal intubation [13]. However, after extensive review of literature, author could find very limited number of studies on use of dexmedetomidine by intranasal route in AFOI, thus an endeavour has been made to further enhance our knowledge regarding the same.

The present study was conducted to compare the efficacy of using dexmedetomidine 2 mcg/kg intranasally with lidocaine 10% in comparison to intranasal lidocaine 10% alone during AFOI in terms of haemodynamic stability and degree of sedation as primary outcome variables. Patient's tolerance, time to intubation, patient and anaesthesiologist satisfaction with the procedure and reduction in intraoperative propofol requirement were the secondary outcome variables.

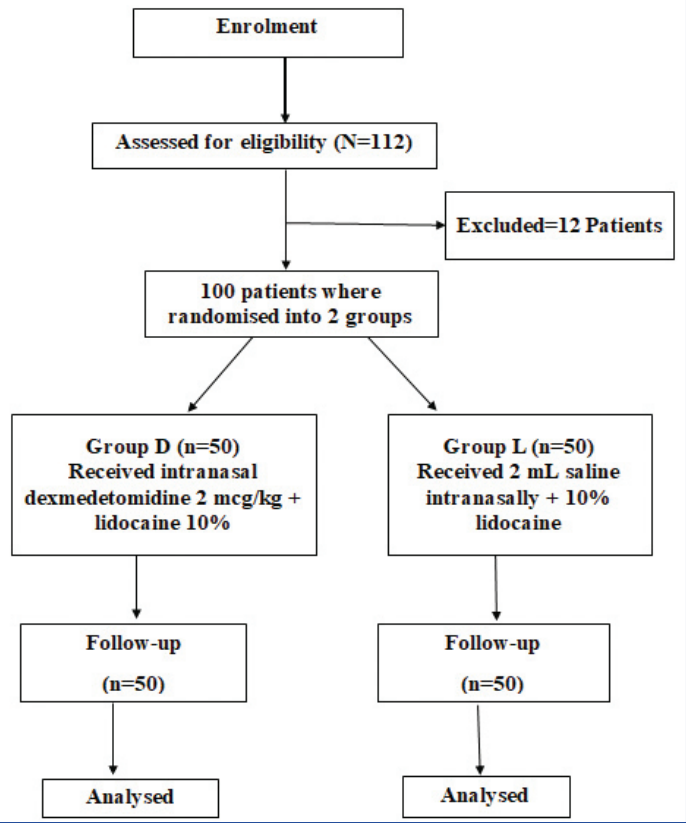
MATERIALS AND METHODS

This randomised clinical study was conducted on 100 patients at Government Medical College and Rajindra Hospital, Patiala, Punjab, India from February 2021 to November 2021. Institutional Ethics Committee approval (No.BFUHS/2K21p-TH/54B dated 22/1/2021) was taken prior to starting the study. Written informed consent was also obtained from all the patients in their own vernacular language.

Inclusion criteria: Patients of either gender, aged between 18 to 60 years, belonging to ASA physical status I or II, and scheduled for various elective general surgeries (which included laparoscopic and open cholecystectomy, laparotomy, hemithyroidectomy etc.,) under general anaesthesia were included in the study.

Exclusion criteria: Patients with ASA physical status more than II, non fasting patient, thrombocytopenia or coagulopathy, nasal polyps, history of previous nasal surgery/nasal trauma, mentally ill patients, pregnant females, allergic to the drugs involved in the study were excluded from the study.

A Consolidated Standards for the Reporting of Trials (CONSORT) flowchart flow chart for this randomised clinical study is presented in [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram.
mcg: Microgram; kg: Kilogram

Sample size calculation: It was estimated based on pilot study, where mean difference in Ramsay Sedation Scale [14] in two groups was 1.34 with standard deviation (SD) of 0.07. The sample size was calculated with 95% confidence interval, 80% power and alpha level of 0.05, using the formula:

$$n=2\sigma^2(Z_{1-\alpha/2}+Z_{1-\beta})^2/\Delta^2$$

Where n was calculated to be 46, sample size was taken as 50 for each group to increase the power of the study. The patients were randomly divided using sealed envelope method, into two groups of 50 each - group D and group L.

Procedure

Preanaesthetic check-up and routine investigations were done. Intravenous (i.v.) line was secured with 18 gauge i.v. cannula in the preoperative room. Patient's baseline vitals i.e., Heart Rate, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), MAP, SpO_2 were documented and nasal patency was assessed before administration of drug in both the groups. Intranasal drug administration was performed 45 to 60 minutes prior to shifting patient to operation theatre.

Group D: Patients here received dexmedetomidine 2 mcg/kg (diluted with Normal Saline (NS) to make a total volume of 2 mL) intranasally as drops using a syringe without needle +10% lidocaine spray was administered 30 minutes later (each depression of release button delivered 0.1 mL=10 mg).

Group L: Patients here received 2 mL saline intranasally as drops using a syringe without needle+10% lidocaine spray was administered 30 minutes later.

In both groups 10% lidocaine was sprayed two times each into the more patent nostril, tonsillar pillars, posterior part of tongue and posterior pharyngeal wall. In this study high dose of dexmedetomidine (2 mcg/kg) was used in order to provide better sedation and improve the quality of intubation. Once patient was shifted to operation theatre, further preparation of airway was accomplished with local anaesthetic. All patients received inj. glycopyrrolate 0.2 mg intravenously to reduce secretions and inj. nalbuphine 0.2 mg/kg intravenously for analgesia, sedation and anxiolysis before AFOI. When sufficient level of sedation (Ramsay Sedation Scale of 4) was achieved, nasotracheal fiberoptic intubation was done. Once tracheal intubation was completed and the tube was secured, General Anaesthesia (GA) was induced using inj. propofol in titrated doses (with dose requirement monitoring) and anaesthesia was maintained. If RSS <3 or if the patient tolerance score during any part of AFOI procedure was ≥4 or if the anaesthesiologist was uncomfortable, rescue inj. propofol was given intravenously in incremental doses and the dose requirement was recorded. Occurrence of bradycardia during any part of the study was managed using inj. atropine 0.6 mg intravenously.

Parameters measured: HR, SBP, DBP, MAP, SpO_2 were monitored as follows- at baseline, then after every 15 minutes interval on administration of intranasal drug. During AFOI procedure, vitals were taken every minute for first 5 minutes followed by every 5 minutes after AFOI for first 20 minutes. Sedation, patient tolerance, patient satisfaction and anaesthesiologist satisfaction score were measured as mentioned in [Table/Fig-2]. Time to intubation and perioperative propofol requirement was also monitored.

STATISTICAL ANALYSIS

The data was analysed using Statistical Package for Social Sciences software (SPSS) version 22.0 and Microsoft excel. Descriptive statistics was done for all data and were reported in terms of mean, standard deviation and percentages. Appropriate statistical tests of comparison were applied. Categorical variables like age, gender were analysed with the help of Chi-square test and type of surgery with Fisher's exact test. Continuous variables like HR, MAP, SpO_2, patient tolerance score, patient and anaesthesiologist satisfaction

Parameters	Assessment	Score
Patient tolerance score during AFOI	No reflex from the patient	1
	Mild grimace	2
	Significant grimace	3
	Verbal complaining	4
	Defensive posture with head or hands	5
Patient tolerance score after AFOI	Calm and co-operative	1
	Restless	2
	Complete resistance and in need of rapid general anaesthesia	3
Patient's satisfaction score 24 hours post-operation	Very satisfied	1
	Satisfied	2
	Dissatisfied	3
	Very dissatisfied	4
Anaesthesiologist's satisfaction score	Excellent	1
	Good	2
	Fair	3
	Poor	4

[Table/Fig-2]: Scoring criteria [12].
AFOI: Awake fiberoptic intubation

score were analysed with Student's t-test and Mann Whitney U test, where applicable. The p-value of <0.05 was taken as statistically significant and <0.001 was taken as highly significant.

RESULTS

Demographic parameters: The distribution of patients according to age, gender and weight was similar in both groups. Both the groups were comparable and statistically non significant (p-value >0.05) [Table/Fig-3].

Demographic parameters	Group D n (%)	Group L n (%)	p-value (Chi-square)
Age (years)			
≤20	1 (2)	1 (2)	0.925
21-30	14 (28)	10 (20)	
31-40	13 (26)	15 (30)	
41-50	11 (22)	12 (24)	
51-60	11 (22)	12 (24)	
Gender			
Male	16 (32)	15 (30)	0.829
Female	34 (68)	35 (70)	
Weight	**Mean±SD**		
Group D	60.70±8.75		0.259
Group L	62.62±8.14		

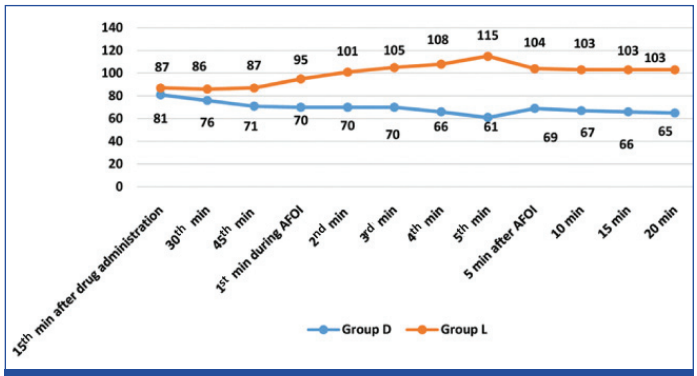
[Table/Fig-3]: Demographic comparison between the two groups.
N: Number; %: Percentage; SD: Standard deviation

Haemodynamic parameters: The baseline HR, MAP and SpO_2 were comparable and statistically non significant in both the groups (p-value >0.05) [Table/Fig-4].

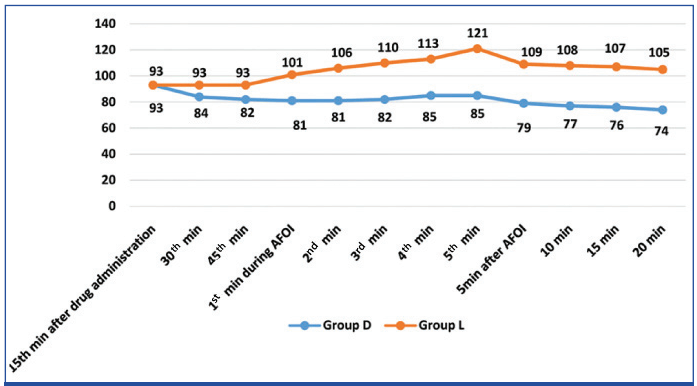
Haemodynamic parameters	Group D	Group L	p-value
Heart rate (beats per minute)	85.44±9.00	87.76±10.55	0.240
MAP (mmHg)	94.08±7.54	94.04±6.85	0.978
SpO_2 (%)	99.68±0.77	99.58±0.73	0.221

[Table/Fig-4]: Comparison of baseline heart rate, MAP and SpO_2 between the two groups.
MAP: Mean arterial pressure; SpO_2: Saturation of peripheral oxygen (Student's t test)

Comparison of mean HR showed highly significant (p-value <0.001) decrease in heart rate (within normal clinical range) after administration of intranasal drug, during and after AFOI in group D as compared to group L [Table/Fig-5]. Four patients experienced bradycardia (HR 50-59 bpm). Comparison of mean MAP showed statistically highly significant (p-value <0.001) decrease in MAP (within normal clinical range) after administration of intranasal drug, during and after AFOI in group D as compared to group L The mean heart rate during AFOI was 70.16±8.02 in group D, and 95.62±11.04, in group L. The Mean Arterial Pressure (MAP) during AFOI was 81.42±5.55 in group D and 101.78±6.22, in group L [Table/Fig-6].



[Table/Fig-5]: Comparison of mean heart rate between the two groups.
(p-value is 0.05 at 15 minute after drug administration and <0.001 thereafter)
AFOI: Awake fiberoptic intubation; (Student-t test)



[Table/Fig-6]: Comparison of mean MAP between the two groups.
(p-value is 0.901 at 15 minute after drug administration and <0.001 thereafter)
AFOI: Awake fiberoptic intubation; MAP: Mean arterial pressure; (Student's t test)

There was no respiratory depression in both groups. Both groups maintained SpO_2 above 93% throughout the study.

Sedation: Mean Ramsay Sedation Scale in group D was 3.66±0.48 and in group L was 2.32±0.55. There was statistically highly significant difference between the two groups (p<0.001). Group D patients experienced better sedation.

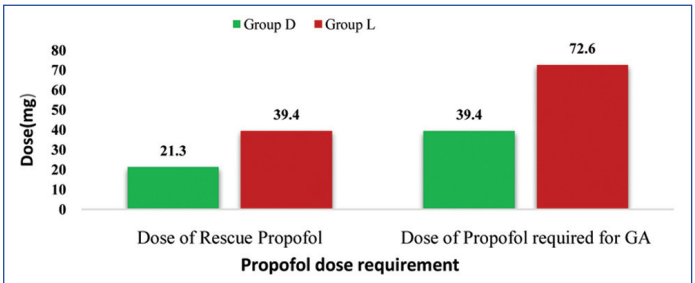
Patient tolerance and time to intubation: The mean patient tolerance score during and after AFOI showed statistically highly significant difference between the two groups (p-value <0.001). Group D patients showed higher tolerance compared to group L [Table/Fig-7]. The mean time to intubation was 3.18±0.48 minutes in group D and 3.56±0.70 minutes in group L (p-value <0.001).

Patient and anaesthesiologist score	Group D	Group L	p-value (Student-t test)
Tolerance during AFOI	1.42±0.50	2.44±0.58	<0.001
Tolerance after AFOI	1.20±0.40	1.94±0.51	<0.001
Patient's satisfaction	1.54±0.50	2.12±0.33	<0.001
Anaesthesiologist satisfaction	1.32±0.47	2.12±0.33	<0.001

[Table/Fig-7]: Comparison of the mean patient tolerance score, patient satisfaction and anaesthesiologist satisfaction between the two groups.
AFOI: Awake fiberoptic intubation; p-value <0.001 was taken as statistically highly significant

Propofol dose reduction: The number of patients who required rescue propofol were 45 (90%) in group D and 50 (100%) in group L respectively (p<0.05).The mean rescue propofol dose required in group D was 21.30±8.19 mg and in group L was 39.40±5.12 mg. The mean propofol required for induction of General Anaesthesia (GA)

in group D was 39.40±9.07 mg and in group L was 72.60±9.22 mg (p-value <0.001) [Table/Fig-8].



[Table/Fig-8]: Comparison of perioperative propofol requirement between the two groups.
p-value <0.001; mg: Milligram; GA: General anaesthesia

Patient and anaesthesiologist satisfaction: The patient satisfaction 24 hours postoperatively and anaesthesiologist satisfaction was better in group D compared to group L (p-value <0.001) [Table/Fig-7].

DISCUSSION

Dexmedetomidine is found to be useful to overcome the major challenges associated with AFOI in providing adequate sedation without respiratory depression and has cardiovascular stabilising properties. Intranasal dexmedetomidine being colourless, odourless, painless and tasteless is more acceptable to the patient than intravenous route [15]. Moreover, it is well-known fact that dexmedetomidine enhances the peripheral neural blockade due to its binding to (α2-AR), thereby producing surface analgesia [10,11]. Above all dexmedetomidine given through intranasal route results in minimal haemodynamic perturbations.

The present study showed that intranasal dexmedetomidine 2 mcg/kg with 10% lidocaine was effective in attenuating haemodynamic response to AFOI. There was statistically significant decrease in mean heart rate (within the normal clinical range) after administration of intranasal drug, during and after AFOI in group D as compared to group L. A randomised controlled study by Wang SS et al., (2014) showed results similar to the current study, where the HR and MAP measured after administering intranasal drug, before laryngoscopy and after intubation was significantly lower in intranasal dexmedetomidine 2 mcg/kg group [16]. Similarly findings were reported by Jambure NP et al., (2021), reported intranasal dexmedetomidine 2 mcg/kg caused statistically significant decrease in HR and MAP, after premedication and 15 min after intubation heart rate and MAP returned back to the baseline values, thus it reduced the haemodynamic stress response to tracheal intubation [17]. The study by Jayaraman L et al., (2013) reported contrary findings, where there was no statistically significant attenuation of pressor response to tracheal intubation and there was no statistical difference in MAP by intranasal dexmedetomidine [18]. The reason for not achieving obtunded pressor response could be due to a lower dose of intranasal dexmedetomidine (1 mcg/kg).

In the current study, four patients experienced bradycardia (HR 50-59 bpm) after administration of dexmedetomidine and were easily managed with inj. atropine. There was no significant decrease in SpO_2 or respiratory depression in both groups (p-value=0.221).

In the present study, patients belonging to group D experienced good sedation compared to group L. The findings are similar to the study by Kumari P et al., (2021) who observed that the mean Ramsay Sedation Score was higher in dexmedetomidine + lidocaine group when compared to the other two groups (Fentanyl+Lidocaine and Saline+ Lidocaine) [14].

Dexmedetomidine binds to (α2-AR) of locus ceruleus and spinal cord which causes sedation and analgesia respectively [14]. Thus in the present study, patients of group D showed better tolerance and overall patient satisfaction compared to group L. Similar findings were reported by Mirkheshti A et al., (2017), where local dexmedetomidine group showed better patient tolerance compared to local lidocaine alone (control) group [12]. Similar to the present study, Kumari P et al., (2021) also reported that patients in dexmedetomidine group was more satisfied and comfortable with better cough scores during awake flexible fiberoptic broncoscopy procedure when compared to fentanyl or lidocaine alone [14].

In the present study, time to intubation was significantly less in group D compared to group L. In another study, the time taken to intubate the trachea was less in case of dexmedetomidine as compared to that of propofol. It was found that dexmedetomidine facilitated better vocal cord opening in 71% patients as compared to 58% patients in propofol group which could have contributed to the ease of intubation and lesser time to intubation in dexmedetomidine group [19].

The present study showed decrease in perioperative propofol requirement in intranasal dexmedetomidine with lidocaine group [Table/Fig-8]. The induction dose of propofol required for GA in the present study was reduced by 33% in group D. The findings of the present study were similar to the study conducted by Bi Y et al., (2019) where it was observed that premedication with intranasal dexmedetomidine reduced the number of patients in need of rescue propofol and dose of rescue propofol required during the flexible fiberoptic broncoscopy [20]. The findings of the current study also coincide with few other studies [21-23]. A study conducted by Sen S et al., (2013) showed that dexmedetomidine reduced the mean requirement of propofol for induction and maintenance of anaesthesia by 48.08% and 61.87% respectively [21]. LeGuen M et al., (2014) conducted a placebo controlled trial in which dexmedetomidine reduced the propofol requirement for induction and maintenance of anaesthesia by 23% and 29% respectively [22]. Dutta A et al., (2019) concluded that dexmedetomidine causes a 15% reduction in propofol induction dose and 29% reduction in propofol maintenance dose while providing a consistent depth of anaesthesia state [23].

In this study, the anaesthesiologist satisfaction was significantly better in group D than group L. This could be because of the antisialagogue property of dexmedetomidine which causes decrease in secretions and hence provided a better field of vision during AFOI [11]. Moreover, patients of group D experienced good sedation and were more co-operative which added to the comfort of the anaesthesiologist. This finding coincides with study by Candiotti KA et al., (2010) showed that anaesthesiologist satisfaction and comfort was better with dexmedetomidine. Anaesthesiologist indicated that the ease of achieving and maintaining target sedation level was significantly better with dexmedetomidine [24].

Limitation(s)

To achieve desired results intranasal dexmedetomidine needs to be administered 45 to 60 minutes prior to starting the procedure. This longer time to onset of action can sometimes be undesirable when there is long list of surgeries or when procedure needs to be started earlier.

CONCLUSION(S)

Intranasal dexmedetomidine 2 mcg/kg with 10% lidocaine provides better haemodynamic stability and improves the quality of intubation during AFOI by decreasing time to intubation and improving patient tolerance. It also reduces propofol requirement, provides good patient satisfaction, anaesthesiologist satisfaction and maintains oxygen saturation during AFOI.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Mar 12, 2022
- Manual Googling: Apr 22, 2022
- iThenticate Software: Jul 04, 2022 (17%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Mar 06, 2022**
Date of Peer Review: **Apr 05, 2022**
Date of Acceptance: **May 12, 2022**
Date of Publishing: **Aug 01, 2022**