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Original Research Article

Effect of Intravenous versus Nebulised Dexmedetomidine on Intubating Conditions during Awake Fiberoptic Intubation: A Prospective Randomised Double Blind Comparative Study

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Conflict of interest: Nil

Abstract:

Background and Aims: Awake fibreoptic intubation (AFOI) tend to be safer than conventional laryngoscopy for difficult airway conditions. Dexmedetomidine can be used for sedation as it ensures spontaneous breathing with airway patency. We aim to assess the effect of intravenous versus nebulized dexmedetomidine on intubating conditions during AFOI.

Methods: In this prospective randomized double blind comparative study, after IEC approval, CTRI registration and informed written consent, ASA grade I, II patients of either gender aged 18-60 year with Mallampati grade I, II undergoing elective surgery under general anaesthesia were allocated into two groups –Group N and I to receive dexmedetomidine 1mcg/kg via nebulization and intravenous route respectively. Patients were intubated with fibreoptic bronchoscope. The primary outcome assessed was cough score. Secondary outcomes were- time taken for AFOI, intubating conditions, vocal cord position, post intubation score, Ramsay sedation scale, haemodynamic parameters, patient comfort, cooperativeness and satisfaction. Data were analysed using SPSS version 25. Continuous, ordinal and categorical data were presented as mean±SD, median±IQR and proportion respectively. Student-t test, Mann Whitney U test and Chi-square test were applied where deemed appropriate. $p<0.05$ was considered statistically significant.

Results: Greater proportion of patients in Group I (56.66%) showed lesser severity of cough as compared to Group N (10%, p=0.0001). Group I also reported a faster intubation time (176±58.54 v/s 245±84.14, p=0.0001), better vocal cord position(p=0.00003), better sedation [2(2-2) v/s 1(1-1), p=0.000] and more stable haemodynamic parameters.

Conclusion: Compared to nebulized route, dexmedetomidine administered through intravenous route provides better intubating conditions for AFOI with reduced cough severity.

Keywords: Dexmedetomidine, Endotracheal Intubation, Sedation, Vocal Cord.

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Introduction

Endotracheal intubation with conventional laryngoscopy can be challenging in difficult airway conditions. Poor airway management can lead to hypoventilation, hypoxemia, aspiration, brain injury or even death.[1]

Awake Fibreoptic Intubation (AFOI) has become the procedure of first choice in difficult airway patients, particularly since the publication of American Society of Anesthesiologists (ASA) guidelines on Difficult Airway Management.[2] AFOI is safe with a higher success rate as it preserves muscle tone, avoids airway collapse and keeps the airway patent. It allows spontaneous breathing on command which opens the obstructed airway passages and hence chances of desaturation are minimal during AFOI.[3]

AFOI, if performed without proper sedation or airway blocks can lead to severe patient discomfort and sympathetic stimulation leading to deleterious haemodynamic responses like tachycardia, hypertension, arrhythmias and even myocardial ischaemia.[4] Airway blocks have been used for

anaesthetizing the airway for AFOI but performance of block is an invasive and painful procedure which invariably causes patient discomfort along with inadvertent risk of haematoma and infection.[5]

Many medications, including benzodiazepines, opioids, ketamine, propofol and sevoflurane have been used to induce sedation. These medications can be administered singly or in combination, but these drugs may cause excessive sedation with respiratory depression with resultant hypoxaemia.[6] Dexmedetomidine, a highly selective centrally acting α_2 agonist, can be an optimal drug for conscious sedation as it ensures spontaneous breathing with acceptable airway patency, patient cooperation and favourable intubating conditions with minimal risk of respiratory depression. Dexmedetomidine in dose of 1mcg/kg bolus has been found to be effective even without airway blocks, nerve blocks or topical anaesthesia.[7] Dexmedetomidine can be administered via intravenous, intramuscular, oral, intranasal or nebulization route and each route of administration has its unique advantages and disadvantages.[8]

Dexmedetomidine has been used intravenously (IV) for providing optimal intubating condition during AFOI. There is paucity of literature evaluating the effect of dexmedetomidine on AFOI when administered via nebulization route. The present study was planned to compare the effectiveness of intravenous dexmedetomidine and nebulized dexmedetomidine in facilitating AFOI by assessing cough score (severity of cough) as primary objective and time taken for AFOI, intubating condition, vocal cord position, patient sedation, patient comfort, patient satisfaction and haemodynamic parameters as the secondary objectives.

Materials and Methods

After taking approval from institutional ethical committee (RNT/ACAD/IEC/2023/621) along with registration in Clinical Trials Registry India (CTRI/2023/08/056201) and following the declaration of Helsinki, the present study was carried out in a tertiary care institute. After obtaining informed written consent, 60 patients aged 18-60 years of either gender with ASA physical status I, II and Mallampati Class I, II undergoing elective surgery under general endotracheal anaesthesia were included in this prospective randomized double blind comparative study. Patients who had history of drug allergy, baseline heart rate <50 bpm, blood pressure <100/50 mmHg, history of hypertension, cardiac disease, coagulopathy, refusal for study participation, history of long-term opioids or sedative medications, contraindication to nasal intubation were excluded from the study.

Sample size was calculated on the basis of a previous study by Gu W et al [9] where proportion of patients experiencing severe cough was 15% when dexmedetomidine was administered by nebulization route as compared to 50% when dexmedetomidine was administered IV. For present study, considering two tailed α error of 5% and power of 90%, sample size calculated was 27 in each group. To compensate for possible dropouts and to remain in compliance with central limit theorem, we enrolled 30 patients in each group.

Patients were randomly allocated into two groups of 30 patients each using computer generated randomisation tables and allocation concealment was done using opaque sealed envelope technique as depicted in figure- I. Group N (n =30) patients received nebulization with dexmedetomidine 1 µg/kg (diluted upto 1ml with NS) added to 4ml of 4% lignocaine for 20 min along with IV infusion of 100 ml NS over 15 min. Group I (n =30) patients received dexmedetomidine IV (1 µg/kg) diluted in 100 ml NS over 15 min along with nebulization with 4ml of 4% lignocaine + 1 ml NS for 20 min.

For ensuring double blinding, this trial was managed by two experienced anaesthesiologists who had experience of performing more than 50 AFOI. One anaesthesiologist managed the drug administration while the second anaesthesiologist performed fiberoptic intubation, graded the endoscopy and intubating conditions and recorded the data. The intubating anaesthesiologist and patients were kept unaware of the group allocation.

All patients were subjected to routine preanaesthetic checkup which included present and past medical/surgical/drug history, physical examination, airway examination by Modified Mallampatti grading,[10] routine and specific investigations as deemed necessary.

All patients were premedicated with alprazolam 0.5mg tablet on the night before surgery. On arrival in operating room, standard monitoring including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and peripheral oxygen saturation (SpO_2) were applied and recorded. An IV line with 20G IV cannula was secured and infusion of Ringer Lactate started. Injection glycopyrrolate 0.01mg/kg IV and injection fentanyl 2 µg/kg IV were administered to all patients. 2-3 drops of xylometazoline 0.1% were instilled in each nostril for decongestion of the nasal mucosa. Then study drugs were administered to the patients as per the group allocation. Depth of sedation was assessed at end of study drug infusion by Ramsay sedation scale (RSS). [11]

The patients were then intubated with fiberoptic bronchoscope (HugeMed Flexible Fiberoscope VL3S M52, Shenzhen HugeMed Medical Technical Development Co. Ltd.) Assessment of fiberoptic

intubation condition was done by a 6 point grading system as enumerated in Table- I [12]

Table 1: Grading System to assess Intubating Conditions, Vocal Cords Position, Patient comfort and Satisfaction

	Intubating condition	Vocal cord position	Patient comfort indices			Postoperative patient satisfaction
			Cough severity	Comfort during intubation	Post intubation assessment	
Grade1	Optimal (no hold-up or collision of tracheal tube with vocal cords)	Relaxed/glottis open	No cough	No reaction	Cooperative	Excellent
Grade 2	Suboptimal (hold-up relieved by one rotation of the tube)	Moving/glottis partially open	Slight (<2 coughs)	Grimacing	Restless/ minimal resistance	Good
Grade 3	Difficult (hold-up requiring more than one rotation of the tube)	Adducted/ glottis closed	Moderate (3-5 coughs)	Verbal objection	severe resistance/ requirement for immediate general anaesthesia	Fair
Grade 4	Failure (failed attempt at awake intubation)		Severe (>5 coughs)	Defensive movements		Poor

All patients were kept undisturbed for a period of 10 min after intubation for noting the vital parameters like HR, SBP, DBP, MAP and SpO_2 at the following time points: baseline (T_B), after nebulisation (T_N), post-intubation at 1, 3, 5 and 10 min (T_1, T_3, T_5 and T_{10}). Time taken for AFOI was considered as time interval from the passage of tip of the bronchoscope through the nostril to the appearance of capnography waveform. Complications such as laryngospasm, arrythmia, local injury, bleeding and cyanosis were recorded.

After intubation, general anaesthesia was administered to all the patients by injection propofol (2mg/kg IV) and muscle relaxation was achieved by administering injection atracurium (0.5 mg/kg IV), and surgery was then allowed to proceed. Anaesthesia was maintained with oxygen and air (50:50), Sevoflurane up to 2% v/v and intermittent doses of atracurium 0.1 mg/kg IV. All the patients also received injection paracetamol (10-15 mg/kg IV). Residual neuromuscular blockade was reversed with injection neostigmine (0.05 mg/kg IV) and injection glycopyrrolate (0.2 mg for each mg of neostigmine IV) at the end of surgery. The patients were extubated after meeting extubation criteria and were shifted to post anaesthesia care unit (PACU).

The primary outcome measured was cough score (severity of cough) whereas intubating conditions, vocal cord position, patient comfort indices, ramsay sedation score, haemodynamic parameters and postoperative patient satisfaction were evaluated as the secondary outcomes. Results obtained in the study were entered into Microsoft Excel and analysed using SPSS 25 software. Continuous variables were presented as mean±SD and compared using student's t test. Ordinal data were presented as median±IQR and analysed using Mann Whitney U test. Categorical data were presented as number (proportion) and compared with chi-square test. $p<0.05$ was regarded as statistically significant.

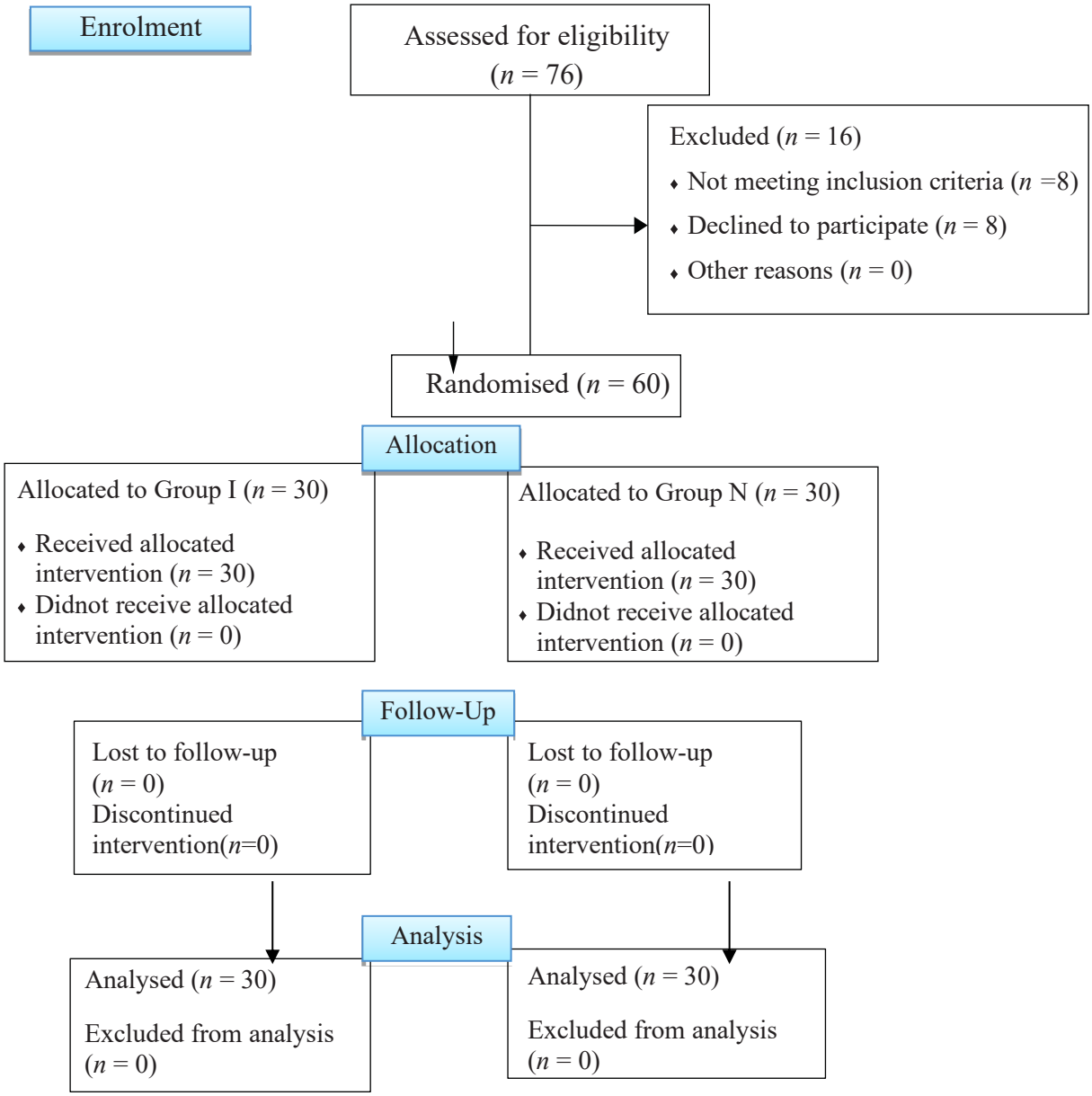

Figure 1: Consort diagram

Table 2: Demographic profile of study population

Characteristics	Group N (n=30)	Group I (n=30)	p-value
Age (years)	43±11	39±12	0.642
Gender (M/F)	15(50.00%)/15(50.00%)	18(60.00%)/12(40.00%)	0.430
ASA Grade I/II	21(70.00%)/9(30.00%)	22(73.34%)/8(26.66%)	0.774
MPG I/II	9(10.00%)/ 21(70.00%)	10(33.34%)/20(66.66%)	0.781

Table 3: Comparison of Intubation time and Sedation score between both the groups.

Outcome	Group N (n=30)	Group I (n=30)	p-value
Time for intubation (sec)	245.3±84.14	176.9±58.54	0.000
RSS (Median ±IQR)	1 (1-1)	2 (2-2)	0.000

Table 4: Comparison of Grading of intubating conditions between both the groups.

Outcome	Group N (n=30)	Group I (n=30)	p-value
Intubating conditions (I/II/ III/ IV)	18(60.00%)/12(40.00%)/ 0(0.00%)/0(0.00%)	27(90.00%)/2(6.67%)/ 1(3.33%)/0(0.00%)	0.006
Vocal cord position (I/II/ III)	2(6.67%)/28(93.33%)/ 0(0.00%)	17(56.67%)/13(43.33%)/ 0(0.00%)	0.00003
Cough severity (I/II/III/IV)	3(10.00%)/14(46.67%)/ 11(36.67%)/2(6.66%)	17(56.67%)/12(40.00%)/ 1(3.33%)/0(0.00%)	0.0001
Patient comfort (I/II/III/ IV)	4(13.34%)/21(70.00%)/ 4(13.33%)/1(3.33%)	16(53.34%)/13(43.33%)/ 1(3.33%)/0(0.00%)	0.007
Post intubation assessment (I/II/ III)	9(30.00%)/18(60.00%)/ 3(10.00%)	19(63.34%)/10(33.33%)/ 1(3.33%)	0.032
Patient satisfaction (I/II/ III/ IV)	0(0.00%)/16(53.33%)/ 12(40.00%)/2(6.67%)	1(3.33%)/26(86.67%)/ 3(10.00%)/0(0.00%)	0.01

Table 5: Comparison of haemodynamic parameters between both the groups

HR			
Time interval	**Group N (beats per min)**	**Group I (beats per min)**	**p-value**
TB	80.10±14.87	83.03±14.05	0.436
TN	80.03±14.96	77.40±11.66	0.450
T1	92.53±11.50	85.46±11.30	**0.019**
T3	91.26±11.49	82.90±9.90	**0.003**
T5	86.00±12.07	78.10±11.11	**0.010**
T10	83.56±13.23	76.10±13.10	**0.032**
SBP			
TB	118.20±13.64	121.96±11.84	0.258
TN	114.03±12.95	114.10±15.31	0.984
T1	130.30±9.13	129.10±12.29	0.669
T3	125.16±6.80	120.23±9.29	**0.024**
T5	120.26±9.17	113.73±14.56	**0.042**
T10	116.90±11.97	109.43±11.14	**0.015**
DBP			
TB	75.96±10.21	78.30±7.76	0.320
TN	72.26.±10.08	71.40±9.82	0.739
T1	80.33±7.93	83.96±11.19	0.152
T3	79.83±7.09	75.1±9.75	**0.035**
T5	77.73±6.46	71.06±11.71	**0.008**
T10	76.56±9.17	70.8±11.63	**0.037**
MAP			
TB	89.93±11.16	92.86±8.75	0.260
TN	86.16±10.82	85.73±11.32	0.880
T1	97.03±7.84	99.13±11.18	0.400
T3	94.96±6.56	90.20±8.79	**0.020**
T5	91.90±6.60	85.20±12.27	**0.010**
T10	89.96±9.51	83.26±11.35	**0.010**

TB: Baseline; TN: After nebulization; T1, T3, T5, T10: Post intubation at 1min, 3min, 5min and 10min respectively.

Results

Both the groups were statistically comparable with regard to distribution of patients according to age, gender, ASA grading, and modified mallampatti grading (Table II).

The time taken for intubation was statistically significantly lesser in group I (176.9±58.54 sec) as compared to group N (245.3±84.14 sec, p=0.00) (Table III). RSS measured at the end of administration of study drug was statistically significantly higher in group I [2 (2-2)] as compared to group N [1(1-1), p=0.00].

In present study greater proportion (90%) of patients in group I had grade I intubating condition compared to group N (60%) and this difference was found statistically significant. Similar observations were noted for vocal cord position, cough score, patient comfort, post intubation assessment and patient satisfaction grading (Table IV).

On comparison of HR at different time intervals, we observed that at baseline and after nebulization, HR among both groups was statistically comparable but post intubation at 1min, 3 min, 5 min and 10 min, HR was found higher in group N compared to Group I and this was found statistically significant. On comparing SBP, DBP and MAP at different time intervals, we observed that at baseline, after nebulization and post intubation (1minute), these parameters were statistically comparable among both groups but post intubation at 3 min, 5 min and 10 min, higher values were noted in group N as compared to Group I ($p<0.05$) (Table V). On comparison of SpO_2 between both groups at different time intervals, no significant difference was found in mean SpO_2 values.

None of the patients in both the groups experienced any episodes of laryngospasm, cyanosis, and arrythmias. 6 patients in group I and 5 patients in group N had local injury with slight bleeding in nasal cavity which did not require any intervention.

Discussion

This study was undertaken to evaluate and compare the effect of dexmedetomidine administered by two different routes viz. intravenous and nebulization during AFOI. We noted that intravenous route has shorter time for AFOI and less cough severity, better vocal cord positioning, better intubating conditions, better patient comfort, better patient tolerance and satisfaction with a more stable haemodynamics and better sedation score.

AFOI is the gold standard technique for management of patients with anticipated difficult airway but this procedure may give a very unpleasant experience to the patient and can have a deleterious effect on haemodynamic parameters of the patient.[4] Hence, a pharmacological agent or intervention is required for making the procedure more tolerable to the patient and ensuring stable haemodynamics along with providing optimal intubating conditions.

Dexmedetomidine is a highly selective α-2 adrenoceptor agonist with sympatholytic, anxiolytic, analgesic, and sedative properties with added advantage of no significant respiratory depression. In addition, it also attenuates the sympathoadrenal response to intubation.8 Intravenous route is the most common route of administration of dexmedetomidine but rapid IV administration can lead to bradycardia and hypotension. Alternate route of administration (oral, intramuscular, intranasal, nebulisation) may offer a better alternative with fewer side effects.[8] Dexmedetomidine administered via nebulization route offer advantages of easier route of administration, not causing mucosal stimulation and ensures homogenous deposition of drug in nasal and laryngopharyngeal tract. The effects of dexmedetomidine administered via nebulization route can be explained by the absorption of dexmedetomidine through the nasal route, which may cross the blood–brain barrier and produce the effects on the central nervous system directly. Furthermore, through the high vascularity of the subepithelial surface of the nasal cavity, it may access systemic circulation directly, thus avoiding first pass metabolism in the liver. Nebulized dexmedetomidine has a bioavailability of 65% through the nasal mucosa and 82% through the buccal mucosa.[13]

In the present study, the authors noted that the time to intubation was significantly shorter when dexmedetomidine was administered via intravenous route. This may be explained by the higher plasma level achieved by IV route resulting in a better sedation score.[14] Similarly cough severity, vocal cord positioning, intubating conditions, patient comfort, patient tolerance and patient satisfaction were better on administering dexmedetomidine through intravenous route as compared to nebulization route. Our findings find support of the study conducted by Srinivas C et al [14] who also reported a shorter intubation time, lesser cough severity, better intubating conditions and better patient satisfaction in patients who were administered dexmedetomidine by intravenous route as compared to nebulisation route. Although the study findings of Sancheti AG et al [13] contradicts our findings, this may be due to use of additional transtracheal route along with nebulization for administering dexmedetomidine in their study.

In the present study, we also observed that patients who received dexmedetomidine intravenously had a better attenuation of sympathoadrenal response to intubation and were more sedated as compared to patients who received dexmedetomidine by nebulisation. Our findings are similar to study conducted by Vishwadeep S et al [8] who also reported a better sedation score (RSS) and lower HR and MAP in patients receiving dexmedetomidine intravenously as compared to dexmedetomidine administered by nebulisation for attenuation of laryngoscopy and intubation induced sympathoadrenal stress response. Srinivas C et al [14] has also reported a better sedation score as assessed by Observer Assessment Sedation/Alertness Score (OAAS) when dexmedetomidine was administered intravenously as compared to nebulisation route.

The sedative and analgesic effects of dexmedetomidine are mediated by stimulation of central α_2 adrenergic receptors, primarily at locus coeruleus. The stimulation of central α_2 adrenergic receptors results in decreased systemic nor-epinephrine levels. This blunts the adrenergic

sympathetic response to airway manipulation and prevents the rise in blood pressure and HR during the procedure.[8]

Our study has few limitations. This study is a single centre trial. Moreover, different doses of dexmedetomidine were not compared so as to find the optimal dose. Further plasma levels of dexmedetomidine were not measured. Lastly, feasibility of this trial in emergency cases was not assessed. Further study should consider these limitations.

Conclusion

Intravenous dexmedetomidine as compared to nebulized route provides better intubating conditions for AFOI with reduced cough severity and incidence of glottic closure, faster intubation time, better conscious sedation, patient comfort, tolerance and satisfaction along with a better haemodynamic stability.

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