Original Article

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Effect of Two Different Doses of Dexmedetomidine on Extubation Quality Score during Tracheal Extubation in Adult Patients- A Randomised Controlled Trial

Anaesthesia Section

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ABSTRACT

Introduction: Extubation of the trachea is the process of discontinuing the artificial airway when the need for ventilation and protection of the airway are absent. Extubation most of the time is associated with haemodynamic changes like hypertension, tachycardia and dysrhythmias. Extubation during lighter planes of anaesthesia can stimulate reflexes by laryngeal and tracheal irritation which may lead to laryngospasm and bronchospasm.

Aim: To study the effect of two different doses of dexmedetomidine on extubation quality score during tracheal extubation in adult patients undergoing Ear, Nose and Throat (ENT) surgeries.

Materials and Methods: The present study was a randomised controlled trial in which 120 patients with American Society of Anesthesiologists (ASA) grade I and II, aged 18-60 years, were randomised into two groups, D1 and D2, to receive dexmedetomidine 0.3 µg/kg and 0.5 µg/kg, respectively. The drug was infused over 10 minutes before skin closure. Extubation quality score was assessed on a 5-point scale and sedation-agitation scale was recorded during tracheal extubation. Haemodynamic parameters (Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Blood Pressure (MBP), Oxygen Saturation (SpO_2), Electrocardiography (ECG) were noted at two, five and ten minutes interval during endotracheal extubation, and after that every 10 minutes till one hour. Mann-Whitney U test was used for quantitative data and Chi-square test, Fisher's-exact test were used for qualitative data.

Results: Quality of extubation was better in D2 as compared to D1. There was no severe coughing in D2 as compared to D1 {0/60 (0) vs 4/60 (6.67%), p-value 0.027}. Lesser number had minimal coughing in group D2 as compared to D1 {9/60 (15%) vs 13/60 (21.67%), p-value 0.047}, 15/60 (25%) of patients were found sedated in group D2 and 5/60 (8.33%) were found sedated in group D1 (p-value 0.039). Patients in group D2 were more haemodynamically stable than D1 during extubation.

Conclusion: Present study concluded that dexmedetomidine 0.5 µg/kg administered before tracheal extubation, had a better extubation quality score, better sedation–agitation scale and was more effective in maintaining the haemodynamic stability as compared to dexmedetomidine 0.3 µg/kg.

Keywords: Ear, nose and throat surgery, General anaesthesia with drug infusion, Sedation-agitation score

INTRODUCTION

Tracheal intubation is done to maintain patent airway during artificial ventilation. Weaning of artificial airway after surgery when there is no need is known as tracheal extubation. Reflex reactions like tracheal and laryngeal irritation can occur during extubation [1,2]. Weaning from anaesthesia is associated with rise of plasma catecholamines. The laryngopharyngeal stimulation is associated with reflex increase in sympathetic activity leading to haemodynamic changes [3]. Haemodynamic changes may be associated with tachycardia, hypertension and dysrhythmias causing elevated myocardial contractility and systemic vascular resistance. Thus, extubation should be very smooth and not associated with straining, coughing, bucking, breath holding, laryngospasm or bronchospasm during extubation [3,4]. Studies have been conducted to evaluate the effect of various drugs like opioids, inhalational agents, local anaesthetics, alpha blockers, beta blockers and calcium channel blockers on blunting of haemodynamic responses during tracheal extubation. Different concentrations of dexmedetomidine ranging from 0.25 µg/kg to 1 µg/kg have been studied for attenuation of haemodynamic responses during extubation [5,6].

Dexmedetomidine is a highly potent and selective alpha-2 adrenoceptor agonist. It causes a dose dependent decrease in BP and HR, also decreases the plasma catecholamine concentrations and reduces the sympathetic nervous activity. It induces sedation and analgesia without affecting respiratory status [7]. It confers arousable sedation with ease of orientation, anxiolysis, mild analgesia, lack of respiratory depression and haemodynamic stability at moderate dose. It provides effective baseline sedation for a broad range of surgical procedures and has better patient co-operation during extubation leading to decrease in opioid requirements and less respiratory depression [8-10].

Emergence agitation from general anaesthesia may lead to self-extubation which may cause serious complications such as hypoxia, aspiration pneumonia, bleeding. Ear, Nose and Throat (ENT) surgeries are associated with higher incidence of emergence agitation [11]. Systemic administration of dexmedetomidine decreases surgical time, intraoperative blood loss and doses of intraoperative inhaled anaesthetic gases and opioids. It also decreases postoperative pain and incidence of the emergence agitation [12,13].

There has been no consensus on the optimum dosage of dexmedetomidine infusion used for smooth extubation in patients undergoing ENT surgeries. The ideal concentration would be, which leads to minimal haemodynamic response and emergence agitation and also leaves the patients awake, oriented and arousable.

Dexmedetomidine in a dose of 0.25-1 µg/kg for tracheal extubation has been studied commonly [14]. In order to search for a safe dose of dexmedetomidine in ENT surgeries for tracheal extubation which would not cause enough sedation, authors had used 0.3 and 0.5 µg/kg doses. This study was planned using 0.3 µg/kg and 0.5 µg/kg dose of dexmedetomidine as an infusion to be given

during 10 minutes before skin closure. The aim of the study was to determine the effect of two different doses of dexmedetomidine on extubation quality score during tracheal extubation in adult patients undergoing elective ENT surgeries, this was primary objective.

The secondary objective was to determine sedation-agitation score and haemodynamic parameter between two different doses of dexmedetomidine 0.3 µg/kg and 0.5 µg/kg during tracheal extubation in adult patients undergoing elective ENT surgeries.

MATERIALS AND METHODS

The randomised controlled trial study was conducted in the Department of Anaesthesia and Intensive Care, after taking approval from hospital Ethics Committee (IEC/VMMC/SJH/Thesis/October/2018-94), and taking written informed consent from all the patients. Study period was of 18 months from June 2019 to December 2020.

Inclusion criteria: Adult patients, 18-60 years of age of either sex of ASA grade I and II undergoing elective ENT surgery requiring oral tracheal intubation were included in the study.

Exclusion criteria: Patients with heart disease, reactive airway disease and pregnant females were excluded from the study.

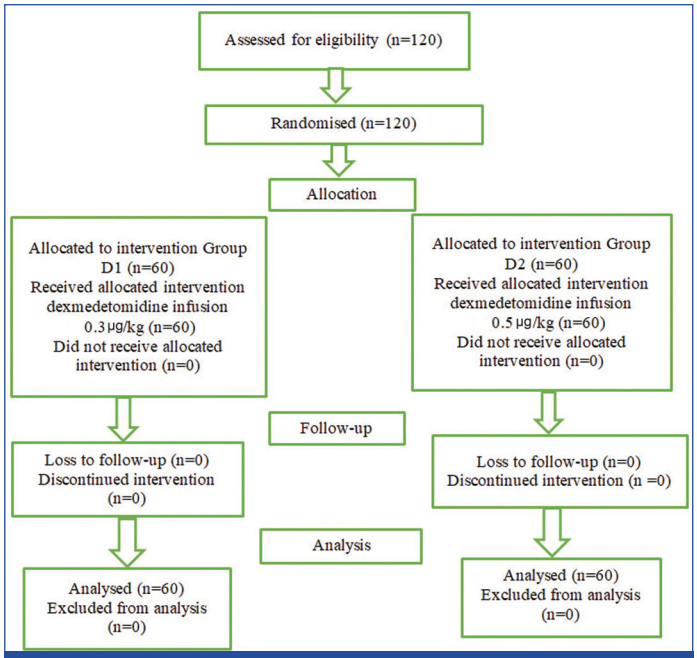
Sample size calculation: Sample size was calculated using study conducted by Vankayalapati SD et al., [15]. Extubation quality score compared with two different doses of dexmedetomidine was studied during endotracheal extubation. The minimum required sample size with 80% power of study and 5% level of significance was 60 patients in each study group. So, total sample size taken was 120 (60 patients per group), n=60 group D1, n=60 group D2, total n=120.

Procedure

After pre-anaesthetic check-up and overnight fasting, patients were shifted to the operation theatre. Standard ASA monitoring was attached and 18G IV (Intravenous) was secured. All the patients were pre-oxygenated with 100% oxygen for three minutes and anaesthesia was induced with injection (inj.) fentanyl citrate 2 µg/kg and propofol 2 mg/kg intravenously. After check ventilation, inj. vecuronium bromide 0.1 mg/kg was administered intravenously. Patients were ventilated with mixture of O_2/N_2O (50:50) with isoflurane (0.8%) for three minutes and then trachea was intubated with cuffed endotracheal tube of size 8.0 mm Internal diameter (ID) for males, 7.0 mm Internal diameter (ID) for females. Anaesthesia was maintained with closed circuit on O_2/N_2O (33%:67%) with isoflurane (0.4-0.8) on controlled ventilation. Throat packing was done and haemodynamic parameters including HR, SBP, DBP, MBP, SpO_2 and ECG, Train of Four (TOF) were recorded.

The patients were categorised into two different groups D1 and D2 (n=60 in each), using the sealed envelope method. Group D1 received dexmedetomidine infusion of 0.3 µg/kg in 50 mL of normal saline and group D2 received dexmedetomidine infusion of 0.5 µg/kg in 50 mL of normal saline, over a period of 10 minutes using infusion pump before the anticipated time of extubation. After skin closure dexmedetomidine was stopped and patients were put on 100% oxygen [Table/Fig-1].

After completion of surgery, throat pack was removed after suction of oral secretions and neuromuscular blockade was reversed with inj. neostigmine 50 µg/kg and after inj. glycopyrrolate 10 µg/kg trachea was extubated when TOF was 80-90%., the trachea was extubated [10]. Quality of extubation was evaluated based on cough immediately after extubation using a 5 point rating scale known as Extubation Quality Score: Score 1=No coughing, Score 2=Smooth extubation, minimal coughing (1 or 2 times), Score 3=Moderate coughing (3-4 times), Score 4=Severe coughing (5-10 times) and straining, Score 5=Poor extubation, very uncomfortable (laryngospasm and coughing >10 times) [6]. Riker Sedation-agitation scale (Score 7=Dangerous agitation, Score 6=Very agitated, Score 5=Agitated, Score 4=Calm, co-operative, Score 3=Sedated, Score 2=Very sedated, Score 1=Unarousable) was also recorded during tracheal extubation [14].



[Table/Fig-1]: Consort flowchart.

Haemodynamic parameters (HR, SBP, DBP, mean BP) were noted at two, five and 10 minutes during endotracheal extubation and then every 10 minutes for one hour [11]. Awakening time (spontaneous eye opening) and orientation time (able to obey commands) were noted before shifting the patients to recovery room [16].

STATISTICAL ANALYSIS

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean±Standard Deviation (SD) and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used. Quantitative variables were compared using Mann-whitney test. Qualitative variables were compared using Chi-square test/Fisher's-exact test. A p-value of <0.05 was considered statistically significant. The data was entered in MS excel spread sheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

RESULTS

The patients in the two groups were comparable for demographic variables like age, weight, height, sex [Table/Fig-2-4].

Age (years)	D1 (n=60)	D2 (n=60)	Total	p-value (Mann-whitney U test)
18-20	11 (18.33%)	8 (13.33%)	19 (15.83%)	0.402
21-30	22 (36.67%)	15 (25%)	37 (30.83%)	
31-40	15 (25%)	20 (33.33%)	35 (29.17%)	
41-50	7 (11.67%)	14 (23.33%)	21 (17.50%)	
51-60	5 (8.33%)	3 (5%)	8 (6.67%)	
Mean±SD	32.12±11.75	33.87±10.87	32.99±11.31	

[Table/Fig-2]: Age distribution between two groups.

Gender	D1 (n=60)	D2 (n=60)	Total	p-value (Chi-square test)
Female	29 (48.33%)	24 (40%)	53 (44.17%)	0.358
Male	31 (51.67%)	36 (60%)	67 (55.83%)	
Total	60 (100%)	60 (100%)	120 (100%)	

[Table/Fig-3]: Gender distribution between two groups.

Anthropometric parameters	D1 (n=60)	D2 (n=60)	Total	p-value (Mann-whitney U test)
Height (cm)				
Mean±SD	166±9.44	167.62±7.51	167.29±8.5	0.504
Median(IQR)	165 (160-173.5)	170 (160-171)	170 (160-173.25)	
Weight (kg)				
Mean±SD	60.17±9	62.03±8.06	61.1±8.56	0.306
Median (IQR)	60 (63.75-68)	60 (60-70)	60 (60-70)	

[Table/Fig-4]: Height and weight distribution between two groups.

Nasal surgeries were done in both the groups and the duration of surgery was approximately two hours [Table/Fig-5].

The patients in group D2 tolerated the endotracheal tube very well and had smooth extubation, as more number of patients had no coughing in group D2. 'Minimal coughing' and 'severe coughing' was seen more in D1 group as compared to D2 which was statistically significant (p<0.05) [Table/Fig-6].

Nature of surgeries	D1	D2
Functional endoscopic sinus surgery (FESS)	45% (27)	40% (24)
Rhinoplasty	55% (33)	60% (36)

[Table/Fig-5]: Distribution of surgeries between two groups.

Extubation quality score	D1 (n=60)	D2 (n=60)	Total	p-value (Chi-square test)
No coughing	43 (71.67%)	51 (85%)	94 (78.33%)	0.121
Minimal coughing	13 (21.67%)	9 (15%)	22 (18.33%)	0.047
Moderate coughing	0	0	0	-
Severe coughing	4 (6.67%)	0	4 (3.33%)	0.027
Laryngospasm	0	0	0	-

[Table/Fig-6]: Comparison of extubation quality score between groups D1 and D2. p-value <0.05 was considered to be statistically significant

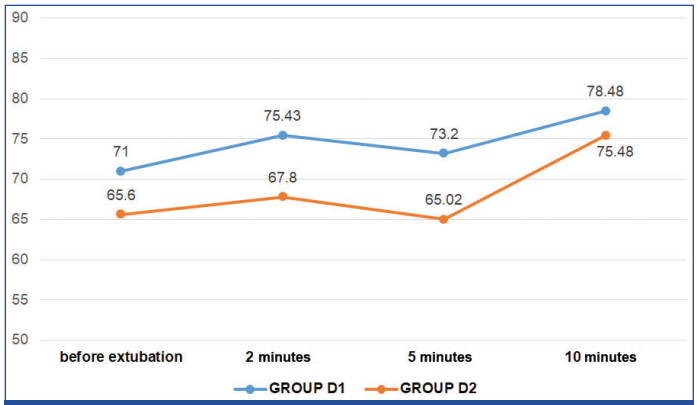
Group D2 had more sedated patients than group D1, which was statistically significant (p<0.05). Group D1 had more agitated patients than group D2 but was statistically insignificant [Table/Fig-7].

Sedation agitation scale	D1 (n=60)	D2 (n=60)	Total	p-value (Chi-square test)
Unarousable	0	0	0	-
Very sedated	0	0	0	-
Sedated	5 (8.33%)	15 (25%)	20 (16.67%)	0.039
Calm and co-operative	52 (86.67%)	44 (73.33%)	96 (80%)	0.268
Agitated	3 (5%)	1 (1.67%)	4 (3.33%)	0.240
Very agitated	0	0	0	-
Dangerous agitation	0	0	0	-

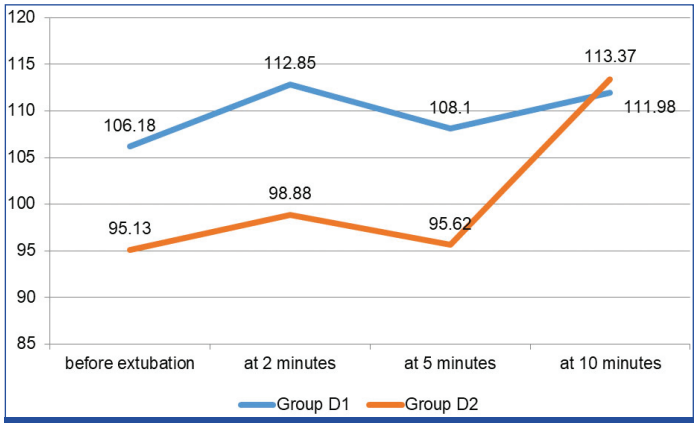
[Table/Fig-7]: Comparison of sedation agitation scale between groups D1 and D2. p-value <0.05 was considered to be statistically significant

HR was significantly less in group D2 in comparison to D1 at 2 and 5 minutes postextubation (67.8±4.92 vs 75.4±8.96) (65.02±5.18 vs 73.2±10.23), respectively with a p-value=0.001. SBP was significantly less in group D2 at 2 and 5 minutes as compared to D1 (98.88±10.44 Vs 112.85±10.56) (95.62±9.52 vs 108.1±12.33) with a p-value=0.001 in both groups. DBP was significantly less in group D2 at 2 and 5 minutes as compared to D1 (65.15±5.47 vs 71.98±8.09) (62.25±5.56 vs 69.62±7.84) with a p-value=0.001. MBP was significantly less in group D2 at 2 and 5 minutes as compared to D1 (76.5±6.45 Vs 86.03±8.13) (73.37±6.76 vs 82.78±8.81) with a p-value=0.001. None of the patients had any episodes of hypotension and bradycardia.

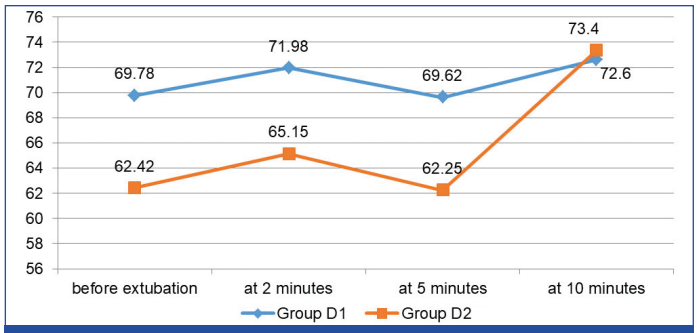
This showed that patients remained more haemodynamically stable in group D2 as compared to group D1 till 5 minutes during extubation. HR, SBP, DBP, MBP were comparable at 10 minutes of extubation [Table/Fig-8-11].



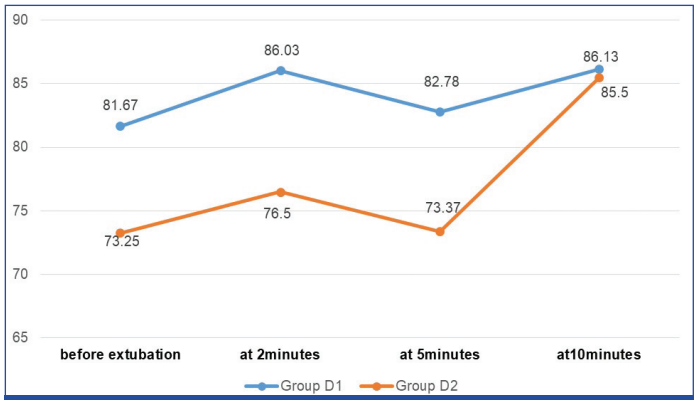
[Table/Fig-8]: Comparison between heart rate (bpm) during extubation between group D1 and D2.



[Table/Fig-9]: Comparison between systolic blood pressure (mmHg) during extubation between group D1 and D2.



[Table/Fig-10]: Comparison between diastolic blood pressure (mmHg) during extubation between group D1 and D2.



[Table/Fig-11]: Comparison between mean blood pressure (mmHg) during extubation between group D1 and D2.

Difference was observed in awakening time (spontaneous eye opening) and orientation time (time taken to obey command) between 2 groups and it was found to be statistically significant.

Median value for awakening time in group D1 was 9 minutes and 11 minutes in group D2. Median value for orientation time in group D1 was 10 minutes and 12.5 minutes in group D2 (p-value <0.001). This showed that patients were more sedated in postextubation phase in group D2 and took little longer to become fully awake with spontaneous eye movements and follow verbal commands [Table/Fig-12].

	D1 (n=60)	D2 (n=60)	Total	p-value (Mann-whitney U test)
Awakening time (in minutes)				
Mean±SD	8.77±1.37	10.98±1.35	9.88±1.75	<0.001
Median (IQR)	9 (8-10)	11 (10-12)	10 (9-11)	
Range	6-12	9-15	6-15	
Orientation time				
Mean±SD	10.52±1.56	12.78±1.58	11.65±1.93	<0.001
Median (IQR)	10 (9-12)	12.5 (12-14)	12 (10-13)	
Range	8-14	10-17	8-17	

[Table/Fig-12]: Comparison of awakening time and orientation time (in minutes) between groups D1 and D2.
p-value <0.05 considered significant

DISCUSSION

Emergence from general anaesthesia and extubation of trachea is related to extensive fluctuations in the haemodynamics that can cause tachycardia, hypertension and arrhythmias and is of equal concern as intubation response [16]. Dexmedetomidine is associated with control of these haemodynamic changes and worrying airway responses. In the present study, 0.3 µg/kg and 0.5 µg/kg of dexmedetomidine was used to study the extubation quality score in adult patients undergoing ENT surgeries.

Group D2 was associated with no coughing in 51/60 (85%) vs 43/60 (71.67%) of patients as compared to group D1 with a p-value of 0.121. Results were clinically significant but statistically insignificant. A 4/60 (6.67%) patients in group D1 had severe coughing as compared to group D2 where none of the patients had severe coughing. Minimum coughing was more in group D1 as compared to group D2. These results were statistically and clinically significant (p=0.027). Quality of extubation was found superior in group D2 as compared with group D1 as more patients had no coughing in group D2. On the contrary minimal coughing and severe coughing was found to be more in group D1. Patients tolerated the endotracheal tube better in group D2 leading to smooth extubation as compared to group D1. Similar results were shown by Antony D et al., in their study, where 27/30 (90%) of patients in group dexmedetomidine 0.5 µg/kg could be extubated smoothly with no or minimal cough whereas only 3/30 (10.0%) had moderate cough as compared to group dexmedetomidine 1 µg/kg where 28/30 (93.3%) of patients were extubated smoothly with no or minimal coughing whereas only 2/30 (6.7%) had moderate cough [6]. This also indicated that higher doses of dexmedetomidine lead to better tolerances of tracheal tube and smooth extubation.

More patients were sedated in group D2 with a p-value of 0.039 but all patients were arousable and maintained pulse oximetry. Patients were more agitated in group D1 as compared to D2. Similar results were found by Vankayalapati SD et al., in which 76.66% of the patients were drowsy but responded to commands in dexmedetomidine group whereas in the placebo group 93.33% of the patients were oriented, co-operative and tranquil. They gave dexmedetomidine 0.5 µg/kg in one group and placebo in other group [15]. Bindu B et al., also observed in their study that 84% of the patients were drowsy but responded to commands in dexmedetomidine group (0.75 µg/kg) whereas in placebo group 80% of the patients were cooperative, oriented and tranquil [1].

The HR, SBP, DBP, MAP variation between groups D1 and D2 were statistically significant at 2 and 5 minutes (p-value=0.001) during extubation whereas at 10 minutes (p-value=0.062) was statistically comparable. Group D2 had significant control over HR, SBP, DBP and MAP as compared to group D1. Similar results were found by Luthra A et al., which compared the effects of two infusion doses of dexmedetomidine i.e., 0.2 µg/kg/hr and 0.4 µg/kg/hr with placebo in 90 patients of 30 patients in each group. There was a significant reduction in HR and MAP just before extubation and upto 10 minutes postextubation in the both group of dexmedetomidine as compared to saline (p-value=0.001) but difference between the dexmedetomidine groups was not significant, this could be because of use of lower concentration of dexmedetomidine in both the groups as compared to our study [17]. Similar study was conducted by Fan Q et al., which compared dexmedetomidine for tracheal extubation in deeply anaesthetised adult patients for otological surgery. A comparison was done amongst group remifentanil (n=25), group dexmedetomidine 0.5 µg/kg (n=25), group dexmedetomidine 0.7 µg/kg (n=25) were administered for 10 minutes at the end of surgery. HR and MAP was higher in remifentanil than in dexmedetomidine groups at 5, 10, 15 minutes after extubation. The haemodynamic effects were clinically insignificant in both groups which received dexmedetomidine [18].

Median awakening time was 11 (10-12) minutes in group D2 which was higher as compared to group D1 9 (8-10) minutes and was statistically significant (p-value <0.001). Median orientation time was 12.5 (12-14) minutes in group D2 which was higher as compared to group D1 with 10 (9-12) minutes and was statistically significant (p-value <0.001). Aksu R et al., observed that awakening time was 10.86 minutes in dexmedetomidine group in comparison with fentanyl group was 10.75 minutes. Orientation time was 14.66 minutes in dexmedetomidine group in comparison with fentanyl group was 15.09 minutes. Both results were comparable (p-value >0.05). In their study they used 0.5 µg/kg dexmedetomidine and 1 µg/kg fentanyl [16].

There was no incidence of bradycardia, hypotension, respiratory depression, laryngospasm and bronchospasm during administration of drug infusion or during extubation in both groups.

Limitation(s)

Authors did not collect the data during the first hour of the postoperative period. There was no placebo group in the study. Mean awakening and orientation time could be better analysed with postextubation haemodynamic and pulse oximetry.

CONCLUSION(S)

Both the doses of dexmedetomidine (0.3 µg/kg and 0.5 µg/kg) were able to maintain extubation quality score and haemodynamic stability during tracheal extubation in ENT surgeries. Quality of extubation was better in group D2 as majority of patients had no severe coughing and lesser patients had minimal and severe coughing as compared to group D1. Group D1 had more number of agitated patients as compared to group D2. Group D2 had more sedated patients but they were arousable and haemodynamically stable. Awakening and orientation time were more in group D2 but patients were arousable and following verbal commands.

So, it can be concluded that dexmedetomidine 0.5 µg/kg administered before tracheal extubation, had a better extubation quality score, better quality sedation-agitation scale and was more effective in maintaining the haemodynamic stability as compared to dexmedetomidine 0.3 µg/kg.

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- 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

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