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Original Research Paper

Intravenous Dexmedetomidine versus intranasal dexmedetomidine for attenuation of haemodynamic response to laryngoscopy and tracheal intubation: A double blinded RCT from Maharashtra

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ABSTRACT:
Introduction: Dexmedetomidine can be given by various route like intravenous, intramuscular, oral, intranasal. It is established that preoperative use of intravenous Dexmedetomidine can successfully attenuate the laryngoscopic stress response. However, adverse haemodynamic complications like hypotension, bradycardia and even cardiac arrest might have hindered the widespread use of intravenous Dexmedetomidine. **Objective**: To compare pulse rate (PR), mean arterial pressure (MAP), systolic blood pressure (SBP) and diastolic blood pressure (DBP), SpO2 between two groups in pre intubation and post intubation period**. Methodology**: The present double blinded RCT carried out in patients that were randomly allocated using computer generated randomization list into 2 groups with 30 patients in each group with allocation ratio 1:1. Group IV DEX: intravenous Dexmedetomidine. Group IN DEX: intranasal Dexmedetomidine. Results: Mean age of Group IN DEX was 42.27 ± 11.63 years. There were 12 and 14 males were included in Group IV DEX and Group IN DEX. There were 18 and 16 males were included in Group IV DEX and Group IN DEX. There was no statistically significant difference in SBP, DBP, MAP, Spo2 at all time interval in both group ($p>0.05$). There was no statistically significant difference in SBP, DBP, MAP, SPO2 at time of intubation ($p>0.05$). There was no statistically significant difference in SBP, DBP, MAP, Spo2 at all time interval in both groups ($p>0.05$). **Conclusion**: Intranasal Dexmedetomidine is as effective as intravenous Dexmedetomidine for attenuation of haemodynamic response to laryngoscopy and tracheal intubation

Keywords: Intravenous Dexmedetomidine versus intranasal dexmedetomidine, laryngoscopy and tracheal intubation

INTRODUCTION:

The safe administration of anaesthesia depends on proper airway management, which is typically straightforward. However, it has long been known that airway management issues can have serious repercussions. Airway management for general anaesthesia entails two main events, which begin with tracheal induction and intubation and end with tracheal emergence and extubation. Induction of general anaesthesia, laryngoscopy, tracheal Intubation and Extubation are associated with various haemodynamic changes. Laryngoscopy and tracheal Intubation are noxious stimuli capable of producing huge spectrum of stress response like sympathetic stimulation leading to transient, unpredictable changes like tachycardia, hypertension, laryngospasm, bronchospasm, dysarrthmia[1,2] Failure to blunt these response in susceptible individuals may manifest as myocardial insufficiency, pulmonary oedema, left ventricular failure, cerebrovascular accident, intracranial haemorrhage[3,4] So to blunt these noxious response effectively, various drug regimens and techniques such as lignocaine, opioids, nitroglycerin, calcium channel blockers like diltiazem and B blockers like esmolol have been tried [5,6] Dexmedetomidine is a highly selective short acting α2- adrenoceptor agonist with sedative, anxiolytic, and analgesic characteristics without any respiratory depressive action.[7,8] Dexmedetomidine mediates central α2A and imidazoline type 1 receptors. The activation of these central receptors results in a decrease in norepinephrine release and leads to a decrease in blood pressure and heart [9]It is ideal for relieving anxiety and nervousness before anaesthesia.[10] Dexmedetomidine can be given by various route like intravenous, intramuscular, oral, intranasal. It is established that preoperative use of intravenous Dexmedetomidine can successfully attenuate the laryngoscopic stress response. However, adverse haemodynamic complications like hypotension, bradycardia and even cardiac arrest might have hindered the widespread use of intravenous Dexmedetomidine. Delayed recovery

with intravenous Dexmedetomidine is also documented due to its sedative effect. It has been suggested that alternative routes other than rapid intravenous delivery may help to minimise the adverse effects of Dexmedetomidine[11,12] intranasal route of giving Dexmedetomidine is more convenient 16and effective than intramuscular and oral route and only few studies are available on its use. So, our present study aimed at comparing the efficacy of preoperative intravenous Dexmedetomidine with intranasal Dexmedetomidine for attenuation of haemodynamic response during laryngoscopy and intubation.

OBJECTIVE:

To compare pulse rate (PR), mean arterial pressure (MAP), systolic blood pressure (SBP) and diastolic blood pressure (DBP), SpO2 between two groups in pre intubation and post intubation period.

MATERIAL AND METHODS:

After obtaining Institutional Ethical committee approval the present clinical, prospective, randomised, double blind study about comparison between intravenous Dexmedetomidine and intranasal Dexmedetomidine for attenuation of haemodynamic response to laryngoscopy and tracheal intubation was carried out in Department of Anaesthesiology of our institute, during period of July 2020- 2023.

Sample Size of 23 subjects in each group were required to be enrolled with Confidence limits as % of 100(absolute ± %) (d): 5% with Confidence Level (%) of 95% using following Equation

– Sample size n = [DEFF*Np (1-p)]/ [(d2 /Z21-α/2*(N-1) +p*(1-p)]. (OpenEpi, Version 3, opensource calculator—SSPropor) (www.openepi.com) though we selected a larger group of 30 patients in each group. Sample size included a total of 60 subjects who were recruited & divided into two group's i.e. 30 subjects in each group.

INCLUSION CRITERIA:

1. Patient with written valid and informed consent.
2. Age between 18- 60 yr.
3. ASA grade 1 and 2 of either sex.
4. Scheduled for elective surgery under general anaesthesia with endotracheal intubation.

EXCLUSION CRITERIA:

1. Patient with baseline heart rate <60/min
2. Patient with any type of atrioventricular block or heart failure. 3 History of hepatic, renal or respiratory disease.
3. Patient with any nasal pathology like nasal ulcer, nasal polyp, nasal septum deviation.
4. Predicated difficult airway.
5. Known allergy or hypersensitivity to Dexmedetomidine.
6. Patient refusal for study.

Total of 60 patients who satisfied inclusion and exclusion criteria were enrolled for the study. Informed written consent was taken from the patient for participation in the study in local languages spoken in Maharashtra. Study was carried out according to guidelines laid down by the Declaration of Helsinki. The participants were free to withdraw anytime during the conduct of study. Patients were randomly allocated using computer generated randomization list into 2 groups with 30 patients in each group with allocation ratio 1:1. The allocation sequence was sealed in an envelope to be reopened after collection of data & statistical analysis. (https://www.graphpad.com/quickcalcs)

Group IV DEX: intravenous Dexmedetomidine
Group IN DEX: intranasal Dexmedetomidine

Group IV DEX: Inj. Dexmedetomidine iv 0.5 µg/kg diluted up to 50 ml with normal saline infused over 40 min with infusion pump. Intranasal normal saline instilled into both nostril in equal volume using 1 ml syringe with patient in supine and head down position. Patient instructed, not to sneeze after intranasal drug administration.

Group IN DEX: Intranasal Dexmedetomidine 1 µg/ kg instilled into both nostril in equal volume using 1 ml syringe with patient in supine and head down position, 40 min before induction of general anaesthesia. Patient instructed, not to sneeze after intranasal drug administration. Intravenous normal saline 50 ml infused over 40 min with infusion pump

RESULTS:

Table 1: Age wise distribution

Age of the patients included in the present study ranged from 18- 65 years. Mean age of Group IV DEX was 44.47 ± 10.19 years. Mean age of Group IN DEX was 42.27 ± 11.63 years.

Age (years)	Group IV DEX	Group IN DEX	Total	p value
	Number	Number		
<20	4	6	10	0.063
	5	6	11	

21-30				
	8	9	17	
31-40				
41-50	9	6	15	
51-60	3	2	5	
>60				
	1	1	2	
Total	30	30	60	

Table 2: Gender wise distribution

SEX	Group IV DEX	Group IN DEX	Total	p value
	Number (%)	Number (%)		
Male	12 (40.0)	14 (46.7)	23	0.18
Female	18 (60.0)	16(53.3)	37	
Total	30 (100.0)	30(100.0)	60	

There were 12 and 14 males were included in Group IV DEX and Group IN DEX.
There were 18 and 16 males were included in Group IV DEX and Group IN DEX.

Table 3: Pre-intubation vital parameters:
After drug administration PR, SBP, DBP, MAP, Spo2 were noted every 10minute up to 40 minutes (before the time of intubation) in both the group. Statistically significant difference was observed in PR at 30minute and 40minute after the drug administration, in both the group ($p<0.05$). There was no statistically significant difference in SBP, DBP, MAP, Spo2 at all time interval in both group ($p>0.05$).

Time Interval	Pre-Intubation vital parameters (mean ± SD)													
	PR (/min)		p value	SBP (mmHg)		p value	DBP (mmHg)		p value	MAP (mmHg)		p value	Spo_2 (%)		p value
	IV DEX	IN DEX		IV DEX	IN DEX		IV DEX	IN DEX		IV DEX	IN DEX		IV DEX	IN DEX	
0 min	86.97 ±13.25	90.93 ±9.33	0.185	125.87 ±10.30	129.63 ±14.09	0.247	79.70 ±8.57	82.60 ±9.07	0.208	95.07 ±8.41	98 ±10.03	0.225	97.90 ±0.71	97.90 ±0.76	1.000
10 min	85.17 ±12.48	90.03 ±8.49	0.083	123.97 ±10.52	126.53 ±13.30	0.410	78.03 ±8.57	80.30 ±9.13	0.325	93.47 ±8.44	95.50 ±10.25	0.405	97.90 ±0.71	97.90 ±0.76	1.000
20 min	82.80 ±12.19	87.53 ±8.58	0.087	120.83 ±10.40	124.67 ±13.72	0.228	75.43 ±8.37	78.43 ±9.52	0.195	90.67 ±8.10	93.87 ±10.53	0.192	97.90 ±0.71	97.90 ±0.76	1.000
30 min	80.73 ±12.17	86.70 ±7.95	0.028*	119.27 ±10.20	123.37 ±12.89	0.177	74.03 ±7.91	76.03 ±9.87	0.389	89.28 ±7.74	91.63 ±10.59	0.330	97.90 ±0.71	97.90 ±0.76	1.000
40 min	78.87 ±11.65	85.07 ±7.51	0.017*	117.20 ±9.85	120.27 ±13.56	0.320	72.67 ±8.02	74.03 ±8.91	0.535	87.63 ±7.56	89.83 ±9.72	0.334	97.90 ±0.71	97.90 ±0.76	1.000

Table 4: Vital parameters at time of intubation.

At time of intubation PR, SBP, DBP, MAP, Spo2 were recorded. Statistically significant difference was observed in PR at time of intubation between two group ($p<0.05$). There was no statistically significant difference in SBP, DBP, MAP, SPO2 at time of intubation ($p>0.05$).

Vital parameters	Group IV DEX (mean ±SD)	Group IN DEX (mean ±SD)	p value
PR (/min)	94.73±8.81	98.90±6.96	0.047*
SBP (mmHg)	132.27±9.70	134.47±10.35	0.15
DBP (mmHg)	85.07±7.31	84.13±6.87	0.7
MAP (mmHg)	99.46±8.31	110.2±9.87	0.89
Spo2 (%)	100.00±0.00	100.00±0.00	1.00

Table 5: Post intubation vital parameters

After intubation PR, SBP, DBP, MAP, Spo2 were noted at 1min, 3 min, 5min, 7min and 10min. There was no statistically significant difference in SBP, DBP, MAP, Spo2 at all time interval in both groups ($p>0.05$).

Time Interval	Post-Intubation vital parameters (mean ± SD)													
	PR (/min)		p value	SBP (mmHg)		p value	DBP (mmHg)		p value	MAP (mmHg)		p value	Spo_2 (%)		p value
	IV DEX	IN DEX		IV DEX	IN DEX		IV DEX	IN DEX		IV DEX	IN DEX		IV DEX	IN DEX	
1 min	90.20 ±8.02	92.10 ±5.12	0.11	128.27 ±9.03	131.73 ±12.71	0.270	82.10 ±7.23	84.73 ±8.54	0.203	97.58 ±6.85	101.30 ±9.01	0.077	100 ±0.00	100 ±0.00	0
3 min	86.00 ±7.37	89.60 ±6.29	0.15	124.77 ±9.31	129.67 ±12.64	0.093	79.73 ±7.96	80.60 ±9.20	0.698	94.47 ±7.38	97.13 ±9.24	0.277	100 ±0.00	100 ±0.00	0
5 min	82.30 ±7.30	84.17 ±5.82	0.56	121.77 ±9.69	126.00 ±11.77	0.134	77.80 ±8.38	78.33 ±8.76	0.810	92.50 ±7.92	94.13 ±9.00	0.457	100 ±0.00	100 ±0.00	0
7 min	80.47 ±8.08	83.67 ±6.45	0.22	118.93 ±8.92	122.87 ±11.82	0.151	75.33 ±7.87	76.07 ±9.33	0.743	89.87 ±7.09	91.40 ±9.43	0.479	100 ±0.00	100 ±0.00	0
10 min	82.80 ±7.93	83.63 ±6.88	0.14	117.40 ±8.81	120.20 ±11.74	0.300	73.90 ±7.45	72.73 ±9.65	0.602	88.23 ±6.83	88.60 ±9.56	0.865	100 ±0.00	100 ±0.00	0

DISCUSSION:

Laryngoscopy and tracheal intubation are noxious stimuli capable of producing huge spectrum of stress response like sympathetic stimulation leading to transient, unpredictable changes like tachycardia, hypertension, laryngospasm, bronchospasm, dysarrthmia.[1,2] This sympathetic activation begins after 5 seconds of laryngoscopy, peaks in 1-2 minutes, and

then returns to normal levels within 5-10 minutes. In our study, group IV DEX patients received Inj. Dexmedetomidine intravenous 0.5 µg/kg diluted up to 50 ml with normal saline infused over 40 min with infusion pump. Group IN DEX patients received Intranasal Dexmedetomidine 1 µg/ kg instilled into both nostril in equal volume using 1 ml syringe. Ravi kumar keshri et al[13] Compared different doses (0.5 µg/kg iv and 1µg/kg iv) of Dexmedetomidine. According to them, a lower dose (i.e0.5 µg/kg iv) is cost effective as well as free of side effects which are associated with the higher dose of Dexmedetomidine (1µg/kg iv). S. Niyogi et al[1] compared efficacy of 1µg/kg intranasal Dexmedetomidine with 0.5 µg/kg intravenous Dexmedetomidine for attenuation of stress response to laryngoscopy and endotracheal intubation. Multiple studies have been carried out to identify adequate dose of Dexmedetomidine infusion. Higher doses usually > 0.5 µg/kg are associated with adverse effects like hypotension, bradycardia, and sedation. To avoid this unwanted side- effects we used lower effective dose 0.5 µg/kg of IV Dexmedetomidine. Similar dose of 0.5 µg/ kg was used by S. Niyogi et al[1], Sebastian et al[14], Sulaiman et al[15] and Sarkar A et al[16] In our study baseline pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure, Spo2 were comparable between both IV DEX group and IN DEX group($p>0.05$). After giving study drug we observed pulse rate, systolic blood pressure, and diastolic blood pressure and mean arterial pressure, Spo2 every 10 min up to 40 minutes, at the time of intubation, 1, 3, 5, 7 and 10 minutes after intubation. There was statistically significant difference in PR from baseline value in IV DEX group than IN DEX group at 30 min and 40 min after drug administration ($p<0.05$). At the time of intubation pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure increased from baseline value but maintained within 20% from baseline in both the group. Bon Sebastian et al[14] in their comparative study between normal saline and intravenous Dexmedetomidine, found statistically significant decrease in HR and MAP in Dexmedetomidine group than normal saline group. Boksh SZ et al[17] also found that intravenous Dexmedetomidine in dose 0.5-1 µg/kg did not obtund laryngeal and tracheal intubation response completely but maintain within 20% from baseline. In our study we did not find incidence of significant bradycardia, tachycardia, hypotension or hypertension requiring intervention in both IV DEX and IN DEX group (table number 10) only two patient of IV DEX experienced nausea. None of the patient in both group experienced vomiting, respiratory depression, nasal irritation, sneezing. S. Niyogi et al[1] Boksh SZ et al[17] Sulaiman et al[15] Li et al[18] also observed that both intranasal and intravenous Dexmedetomidine were well tolerated without any significant side effects like bradycardia, tachycardia, hypotension or hypertension with no irritation or pain associated with administration of drug. A Kocher et al[19] noted that intranasal Dexmedetomidine 2 µg/kg associated with significant bradycardia when compared to intranasal Dexmedetomidine 1 µg/kg.

CONCLUSION:

Thus, we conclude from present study that intranasal Dexmedetomidine is as effective as intravenous Dexmedetomidine for attenuation of haemodynamic response to laryngoscopy and tracheal intubation.

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