

# Comparison of Haemodynamic Effects of Clonidine and Dexmedetomidine for Intubation using Intubating Laryngeal Mask Airway in Patients undergoing Elective Surgery under General Anaesthesia: A Randomised Clinical Study

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## ABSTRACT

**Introduction:** The Intubating Laryngeal Mask Airway (LMA) is a Supraglottic Airway (SGA) device through which endotracheal intubation can be performed. Laryngoscopy and intubation are known to initiate a haemodynamic response. LMAs in general produce a lesser pressor response, but intubating LMA provokes a higher response due to the invasiveness of tracheal intubation.

**Aim:** To compare dexmedetomidine and clonidine in attenuating the haemodynamic response to intubating LMA, Ramsay sedation score, and the incidence of laryngopharyngeal injury.

**Materials and Methods:** A randomised clinical study was conducted in the Department of Anaesthesiology, Sikkim Manipal Institute of Medical Sciences, Gangtok, Sikkim, India, over a period of one year spanning from June 2020 to May 2021 to compare the two drugs in patients with American Society of Anaesthesiology (ASA)-I. The doses of clonidine and dexmedetomidine were 2.5 mcg/kg and 0.5 mcg/kg, respectively. The study parameters {Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Mean Blood Pressure (MBP), Peripheral Saturation of Oxygen (SpO<sub>2</sub>)} were recorded at baseline, pre- and post-induction, and

at various time intervals (0, 1, 3, 5 minutes) after intubation. Sedation score was also recorded before intubation and after extubation. Statistical Packages of Social Sciences (SPSS) version 23.0 was used to analyse the data ( $\chi^2$  test for categorical variables and analysis of variance for continuous data).

**Results:** There was no statistically significant difference between the two groups for the duration of surgery ( $p=0.267$ ), duration of anaesthesia ( $p=0.197$ ), and the duration between closure and extubation ( $p=0.407$ ). Dexmedetomidine better attenuated the response of HR and SBP just before induction, post-induction, and immediately post-intubation. All the haemodynamic parameters were better controlled by dexmedetomidine immediately after intubation. Sedation was better with dexmedetomidine in the pre-intubation as well as post-extubation period, except at five minutes post-drug infusion when clonidine was better.

**Conclusion:** Compared to clonidine, dexmedetomidine was more effective in attenuating the patient's haemodynamic response to intubating LMA in the immediate peri-intubation period. However, from 1 minute post-intubation onward, both drugs behaved similarly in controlling the pressor response.

**Keywords:**  $\alpha$ -2 agonist, Endotracheal intubation, Supraglottic airways, Sympathetic response

## INTRODUCTION

Although the first account of intubation dates back to the 10<sup>th</sup> century, it was not until the 18<sup>th</sup> century that life savers and obstetricians began using breathing tubes. It took almost a century for this life-saving method to be first used as elective preoperative intubation in 1880, and another 2-3 decades for it to become an established method [1,2].

There were two major issues, among many, that needed to be addressed first. First, there were haemodynamic changes which at times were life-threatening, and second, there was a large set of patients for whom Endotracheal (ET) tube intubation was not possible. The first problem was addressed by using drugs to blunt this aggressive change in vital parameters. Among many drugs, Clonidine and Dexmedetomidine are often used nowadays. Dexmedetomidine has a central sympatholytic action, providing haemodynamic stability. It has analgesic and anaesthesia-sparing properties [3]. Clonidine, which is an  $\alpha$ -2 adrenergic agonist, significantly attenuates the sympathetic response to laryngoscopy and intubation [4].

The second issue was difficult to address, as mere redesigning of the ET tube wouldn't help. This led to the development of many SGA devices like LMA, Igel, and more recently, intubating LMA (ILMA). The Difficult Airway Society has recommended the use of second-generation LMA or SGA in difficult airways [5].

The intubating LMA goes a step further, allowing endotracheal intubation through an LMA, which makes it unique and different from other LMAs. The unique feature of endotracheal intubation through the LMA initiates a higher pressor response due to the invasiveness of the process. Endotracheal intubation with the help of ILMA involves three steps: insertion of the ILMA, intubation via the ILMA, and removal of the ILMA. Removal of the ILMA produces a larger reflex response than ILMA insertion or intubation via the ILMA [6-8]. Literature is available comparing various drugs or their combinations in ET tube intubation, but these new devices still require some research.

Therefore, the present study aimed to compare clonidine and dexmedetomidine in blunting the haemodynamic changes of intubating LMA.

The aim of the study was to compare the change in the following parameters while using clonidine and dexmedetomidine during intubation using intubating LMA. a. Heart Rate (HR), b. Systolic, diastolic, and mean blood pressure, c. SpO<sub>2</sub> and to compare the Ramsay Sedation Score between the two groups and to find out the incidence of pharyngolaryngeal morbidity after 24 hours in the two groups.

## MATERIALS AND METHODS

The study was designed as a randomised clinical study and was conducted in the Department of Anaesthesiology, Sikkim Manipal Institute of Medical Sciences, Gangtok Sikkim, India, over a period of one year spanning from June 2020 to May 2021. The study was approved by the Institutional Research Protocol Evaluation Committee and Institutional Ethics Committee (letter number SMIMS/IEC/2019-131).

**Inclusion and Exclusion criteria:** Patients aged between 18 to 65 years undergoing laparoscopic cholecystectomy for symptomatic, uncomplicated gallbladder stone disease with American Society of Anaesthesiology (ASA) Grade-I were included in the study. Exclusion criteria included complicated gallbladder stone disease (history of obstructive jaundice and pancreatitis or pre or intraoperative finding of empyema or mucocele), any systemic co-morbidity including diabetes and hypertension, patients on any drug, pregnant and lactating mothers, patients with bradycardia (HR<55/min), and surgery duration exceeding 90 minutes.

**Sample size calculation:** The sample size was calculated for the randomised comparison of two groups, with an  $\alpha$ -error of 5% (Significance 0.05) and a study power (1- $\beta$ ) of 90%, and an attrition rate of 10%. The final sample size was calculated to be 132 patients, with 66 patients in each group.

## Study Procedure

The procedure of randomisation and blinding was explained to patients and their relatives by a team of anaesthesiologists and surgeons. Randomisation was done using a computer-generated random number table. Blinding was ensured at three levels: 1) patients; 2) the team involved in the administration of study drugs as they were provided with coded, identical looking drug solutions in 100 mL normal saline bottles; and 3) the anaesthesiologist.

The drugs were prepared as follows:

- Group C: Clonidine 2.5 mcg/kg [9] in 100 mL normal saline.
- Group D: Dexmedetomidine 0.5 mcg/kg [10] in 100 mL normal saline.

The drugs were infused over a period of 10 minutes in the preoperative area by an Operation Theatre (OT) technician not involved in the process of anaesthesia and surgical procedure.

The study parameters (HR, SBP, DBP, MBP, SpO<sub>2</sub>) were recorded at the following intervals after discussion among the faculty of the anaesthesia department:

- Before infusion of drugs in the preoperative area-baseline.
- Before induction, in the operative room-pre-induction (10 minutes after drug infusion).
- After induction-post-induction.
- After intubation with intubating LMA-immediately (post-intubation 0), at 1 minute (post-intubation 1), at 3 minutes (post-intubation 3), and at 5 minutes (post-intubation 5).

The Ramsay Sedation Score [11] was noted at the following intervals:

- After the infusion of the study drug, in the preoperative area-at 5 minutes (post-drug 5), at 10 minutes (post-drug 10), and at 15 minutes (post-drug 15).
- After extubation-immediately (post-extubation 0) and at 15 minutes (post-extubation 15).

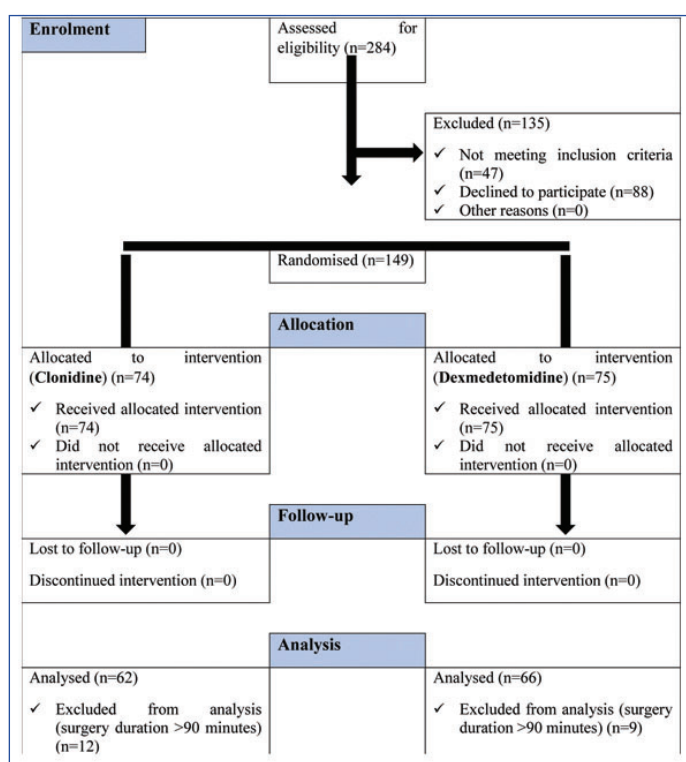
**Laryngopharyngeal morbidity:** Patients were asked about any sore throat, cough, or hoarseness of voice after 24 hours.

## STATISTICAL ANALYSIS

The data was tabulated and analysed using IBM® SPSS® version 23. Categorical variables were compared using  $\chi^2$  analysis, and continuous variables were compared using Analysis of Variance (ANOVA).

## RESULTS

The Consolidated Standards of Reporting Trails (CONSORT) flowchart shows the number of patients who participated (n=284), were excluded (n=135), and were analysed (n=128) in the study [Table/Fig-1]. Group C (clonidine) and Group D (dexmedetomidine) were compared and found to be identical in their demographic structure (male/female ratio, age, and Body Mass Index (BMI) and surgical parameters (duration of surgery, duration of anaesthesia, and duration between closure and extubation) with p>0.05 [Table/Fig-2].



**[Table/Fig-1]:** CONSORT flow diagram showing the progress of participants through the study.

Variables	Clonidine	Dexmed	Total	Sig (p)
M:F ratio	1:2.3	1:2.5	1:2.4	0.485*
Age (years)	35.2±8.8	37.3±12.1	36.3±10.6	0.278*
BMI (kg/m <sup>2</sup> )	23.2±2.5	24.1±2.6	23.7±2.6	0.057*
Surgery duration (min)	53.7±19.3	57.4±17.6	55.6±18.5	0.267*
Anaesthesia duration (min)	68.8±20.9	73.1±16.8	71.0±18.9	0.197*
Duration between closure and extubation (min)	9.3±3.2	9.7±1.7	9.5±2.5	0.407*

**[Table/Fig-2]:** Demographic composition and surgical parameters of the two groups. Statistically insignificant difference means the two groups were matched for these parameters. Significance of difference has been calculated using  $\chi^2$  analysis and #one-way ANOVA. All durations are in minutes. Continuous data is in mean±SD.

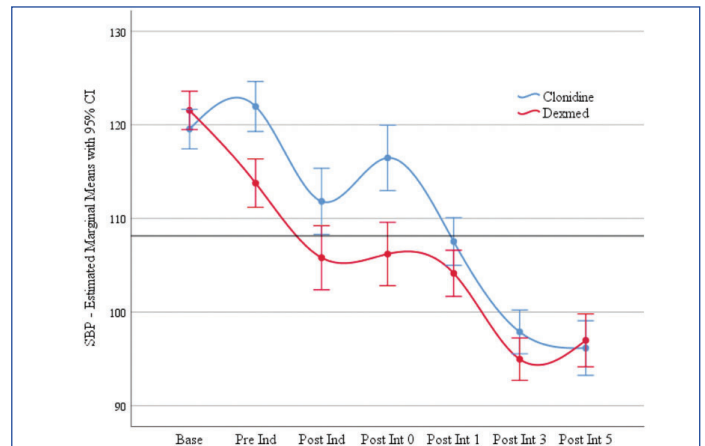
**Haemodynamic parameters:** The effect of clonidine and dexmedetomidine on pressor response to intubating LMA (HR, blood pressure, and SpO<sub>2</sub>) was compared by repeated measure ANOVA at various time intervals as mentioned in the methodology and has been presented in [Table/Fig-3]. Both groups had similar

Timing		Haemodynamic parameters							
		HR		SBP		DBP		MBP	
		C	D	C	D	C	D	C	D
Baseline	Mean	74	74	119	121	78	81	92	95
	95% CI	71-77	71-77	117-122	122-126	75-81	79-84	89-94	93-98
	p-value	0.968		0.182		0.101		0.117	
Pre Ind	Mean	76	65	122	114	73	73	89	86
	95% CI	73-79	62-68	119-125	115-121	71-75	71-75	87-91	85-90
	p-value	<0.001		<0.001		0.971		0.088	
Post Ind	Mean	85	68	112	106	62	68	79	81
	95% CI	81-89	64-72	108-115	103-110	59-66	65-71	75-82	77-84
	p-value	<0.001		0.017		0.022		0.468	
Post Int 0	Mean	89	69	116	106	74	69	88	81
	95% CI	86-92	66-72	113-120	103-110	70-77	65-72	85-91	78-85
	p-value	<0.001		<0.001		0.048		0.006	
Post Int 1	Mean	80	70	107	104	67	67	80	79
	95% CI	77-83	67-73	105-110	102-107	64-70	64-69	78-83	77-82
	p-value	<0.001		0.060		0.897		0.466	
Post Int 3	Mean	72	69	98	95	59	59	72	71
	95% CI	70-75	67-72	95-100	93-97	56-62	56-61	69-74	69-73
	p-value	0.154		0.079		0.970		0.654	
Post Int 5	Mean	69	68	96	97	60	60	72	72
	95% CI	66-72	65-70	93-99	94-100	58-63	58-63	70-75	70-74
	p-value	0.579		0.689		0.919		0.905	

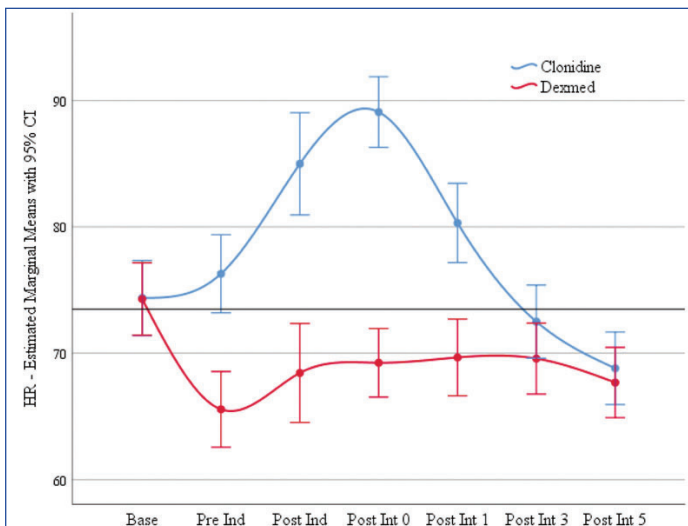
**[Table/Fig-3]: Comparison of Clonidine and Dexmedetomidine for controlling the haemodynamic response to intubation using intubating LMA.**

HR: Heart rate; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; and MBP: Mean blood pressure; in mmHg; C: Clonidine group; D: Dexmedetomidine group. Baseline, before giving the drug; pre Ind. 10 minutes after the drug infusion; post-Ind. after induction and before giving muscle relaxant; post Int. after intubation (at 0, 1, 3 and 5 minutes)

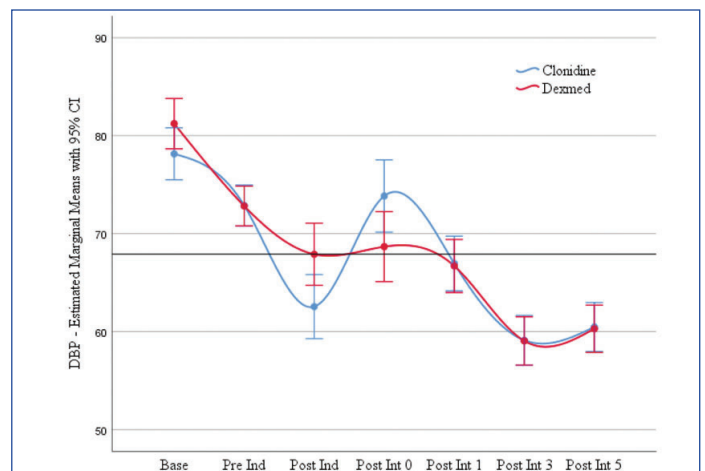
baseline values. Pre-induction HR ( $F=24.329$ ;  $df=1$ ;  $p<0.001$ ) and SBP ( $F=18.998$ ;  $df=1$ ;  $p<0.001$ ) significantly declined in the dexmedetomidine group. Immediately after induction, the fall in HR ( $F=33.851$ ;  $df=1$ ;  $p<0.001$ ) and SBP ( $F=5.854$ ;  $df=1$ ;  $p=0.017$ ) was greater in the dexmedetomidine group, but DBP ( $F=5.398$ ;  $df=1$ ;  $p=0.022$ ) declined more in the clonidine group. After intubation, a significant fall in HR ( $F=101.732$ ;  $df=1$ ;  $p<0.001$ ) and SBP ( $F=17.440$ ;  $df=1$ ;  $p<0.001$ ) persisted in the dexmedetomidine group, but the fall in DBP ( $F=3.976$ ;  $df=1$ ;  $p=0.048$ ) in the clonidine group reversed to reach its pre-induction level. One minute after induction, the difference in parameters was insignificant except in HR ( $F=23.303$ ;  $df=1$ ;  $p<0.001$ ). The fall in haemodynamic parameters was gradual, smoother, and more predictable in the dexmedetomidine group as compared to the clonidine group [Table/Fig-4-7]. No difference was found in mean SpO<sub>2</sub> at any point in time as almost all patients maintained the value at 98-100%.



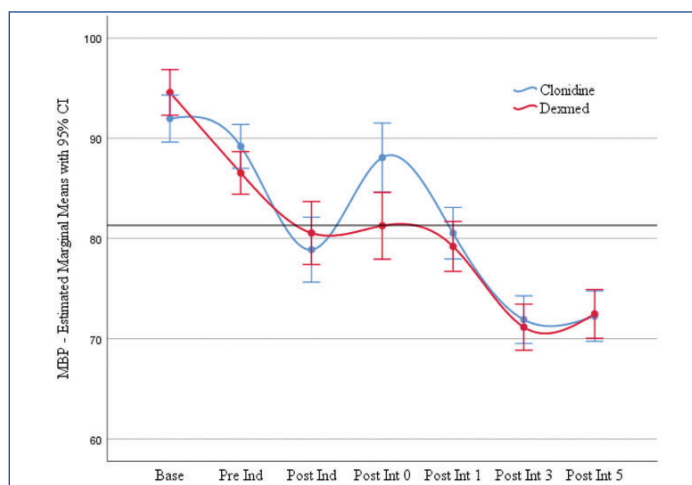
**[Table/Fig-5]: Systolic Blood Pressure (SBP).** Dexmedetomidine and clonidine both had almost similar effect on SBP. Dexmedetomidine better attenuated the response.



**[Table/Fig-4]: Heart Rate.** Dexmedetomidine had a better control on HR compared to clonidine. In the peri-intubation period, HR spiked in clonidine group.



**[Table/Fig-6]: Diastolic Blood Pressure (DBP):** Response of dexmedetomidine was smoother compared to clonidine. There was a sharp decline in DBP immediately after induction.



**[Table/Fig-7]: Mean blood pressure (MBP).** The control of MBP was almost similar but the response of dexmedetomidine was smoother. Patients had a sharp uprise in MBP immediately after intubation in clonidine group.

**Ramsay sedation score:** A significantly higher proportion of patients had a sedation score of 3 from post-drug 5-15 minutes in the dexmedetomidine group ( $p < 0.001$ ). At 15 minutes after extubation, more patients 24 (36.4%) in the dexmedetomidine group had a score of 3 compared to Group C (09, 14.5%) ( $p = 0.004$ ) [Table/Fig-8].

Time interval	Score	Clonidine (n=62)	Dexmed (n=66)	Sig (p1) <sup>1</sup>
Post-drug 5	2	37 (59.7)	51 (77.3)	0.025
	3	25 (40.3)	15 (22.7)	
Post-drug 10	2	31 (50)	28 (42.4)	0.248
	3	31 (50)	38 (57.6)	
Post-drug 15	2	27 (43.5)	13 (19.7)	0.003
	3	35 (56.5)	53 (80.3)	
Sig (p2) <sup>2</sup>		0.192	<0.001	-
Post-extubation 0	2	30 (48.4)	33 (50)	0.498
	3	32 (51.6)	33 (50)	
Post-extubation 15	2	53 (85.5)	42 (63.6)	0.004
	3	09 (14.5)	24 (36.4)	
Sig (p2) <sup>2</sup>		<0.001	0.128	

**[Table/Fig-8]: Ramsay sedation score.** No patient had a score of 1, 4, 5 or 6. Score of 3 has been shaded for easy follow-up of patients with a higher score over time. <sup>1</sup>p1 shows the between-group comparison of number of patients in both groups using *Pearson's  $\chi^2$  test* and <sup>2</sup>p2 denotes the within-group comparison of proportions of patients having either score over time using *Cochran Q test*. Figures in parentheses are percentage.

**Laryngopharyngeal injury:** No patient suffered any injury due to intubating LMA.

## DISCUSSION

The present study compared the effect of clonidine and dexmedetomidine on haemodynamic changes arising due to intubation using intubating LMA. Although both clonidine and dexmedetomidine suppressed the pressor response of intubating LMA, dexmedetomidine did so more effectively. Abundant literature [12-18] is available comparing clonidine and dexmedetomidine in attenuating the response to laryngoscopy and endotracheal intubation. However, no studies have compared the two drugs as to how they affect the response to intubating LMA. The present study found that dexmedetomidine is better and more predictable compared to clonidine in controlling the pressor response of intubating LMA.

Adhav MS and Kumar A, studied the effect of clonidine (1 mcg/kg) and dexmedetomidine (1 mcg/kg) for attenuating the haemodynamic response to Proseal LMA. They found better control of HR and blood pressure with dexmedetomidine compared to clonidine. The

present study also revealed similar findings for clonidine (2.5 mcg/kg) and dexmedetomidine (0.5 mcg/kg). However, Proseal LMA is different from intubating LMA as in the former intubation was not done, so the haemodynamic response was not as prominent as with the intubating LMA [12].

In 2017, Kholi AV et al., compared the efficacy of clonidine (1 mcg/kg) and dexmedetomidine (1 mcg/kg) for endotracheal tube intubation and found that dexmedetomidine caused better attenuation of the pressor response and provided better analgesia and sedation than clonidine [13]. The findings were similar to the findings of the present study.

Gupta SK and Singhal A, compared the two drugs (clonidine 3 mcg/kg; dexmedetomidine 0.5 mcg/kg) for laryngoscopy and intubation and found both drugs to be equally effective in attenuating the haemodynamic response to endotracheal intubation [14]. However, the present study found dexmedetomidine to be better than clonidine.

Katakwar M et al., studied both drugs and found that both drugs significantly attenuate the haemodynamic changes during laryngoscopy and intubation, but similar to the present study, dexmedetomidine (1 mcg/kg) was more effective than clonidine (2 mcg/kg) and therefore a better drug to attenuate the haemodynamic response [15].

Botelho R et al., published the findings of a randomised clinical trial where he compared two doses of dexmedetomidine (1 mcg/kg vs 0.8 mcg/kg) and found that dexmedetomidine at 0.8 mcg/kg can be used as a safer alternative to the 1 mcg/kg dose in achieving the same attenuation of the pressor response [16]. The present study showed that even 0.5 mcg/kg dexmedetomidine effectively suppressed the pressor response of intubating LMA.

Meena R et al., conducted a randomised clinical trial which finished in 2020. They compared dexmedetomidine and clonidine to placebo and found that both drugs attenuate the pressor response to laryngoscopy and intubation better than the placebo. But in contrast to the present study, they did not find the difference between dexmedetomidine and clonidine to be statistically significant [17].

Muthayala VK and Vallabha R, conducted a similar study for laryngoscopy and intubation and found that even though dexmedetomidine better attenuated the HR response compared to clonidine, there was no statistically significant difference for SBP, DBP, and Mean Blood Pressure [18]. The present study showed that dexmedetomidine better attenuated the parameters during the induction and immediately after intubation. The difference in HR persisted for the maximum duration compared to other parameters.

Kumbhar SM et al., found that the Ramsay sedation score was significantly better in the dexmedetomidine group three minutes after the test dose. They did not compare the sedation after the extubation [19]. Srivastava U et al., compared the two drugs for sedation in critical care unit patients and found that dexmedetomidine was better for short-term sedation compared to clonidine [20]. However, Reena and Kumar A did not find any difference between the two drugs in providing sedation in the pediatric age group patient [21]. The present study showed that five minutes after the test dose, more patients in the clonidine group had a higher sedation score, but after that, dexmedetomidine provided better sedation, and that persisted after extubation.

Sener EB et al., and Sharma MU et al., reported a low incidence of mild hoarseness of voice and sore throat in their studies. However, the present study did not find any incidence of laryngopharyngeal morbidity [22,23].

Most of the literature [12-16] concluded that both clonidine and dexmedetomidine attenuated the pressor response arising due to endotracheal intubation, but dexmedetomidine did it better. Only a few studies showed that there was either no difference [17] or only a few parameters were significantly different [18]. The present study too inferred that dexmedetomidine better attenuated the response, and this included all haemodynamic parameters, especially in the

peri-intubation period. However, an important point to note was that the authors did not find any study where the two drugs were compared for intubating LMA.

### Limitation(s)

Authors did not measure the blood catecholamine levels, which tend to increase during airway manipulation.

## CONCLUSION(S)

The present study concluded that both clonidine and dexmedetomidine attenuate the haemodynamic response (changes in HR, blood pressure, and SpO<sub>2</sub>) to intubation using an intubating LMA. The effect of dexmedetomidine in controlling the response was better, smoother, and statistically significant. All the parameters were effectively controlled by dexmedetomidine in the peri-intubation period when it was most required. In the post-surgery, post-extubation period, more patients remained sedated in the dexmedetomidine group. No patient suffered any injury in the laryngopharynx due to intubating LMA. The authors conclude that dexmedetomidine is better than clonidine in the suppression of the haemodynamic response to intubating LMA.

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