Original Article

DOI: 10.7860/JCDR/2021/49505.15815

Comparison of Two Doses of Intravenous Dexmedetomidine as Premedication for Laryngeal Mask Airway Insertion in Adults: A Randomised Clinical Trial

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ABSTRACT

Introduction: The Laryngeal Mask Airway (LMA) has gained popularity in recent years for both rescue ventilation as well as airway management device for General Anaesthesia (GA). Adequate jaw relaxation and blunting of airway reflexes prevents haemodynamic changes during LMA insertion. Several drugs have been used as adjuncts to Intravenous (IV) Propofol, of which Dexmedetomidine in a dose of 1 µ/kg is now gaining popularity. But at this dose significant bradycardia has been observed. Hence, the study aimed at comparing 1 µ/kg of Dexmedetomidine, with a lower dose of 0.8µ/kg to assess the same.

Aim: To compare two different doses of intravenous dexmedetomidine 0.8 µg/kg and 1 µg/kg as premedication with propofol 2 mg/kg for ease of insertion of LMA, attempts at LMA insertion and secondary objectives included, additional propofol requirements, adverse effects.

Materials and Methods: The present study was a randomised double blind clinical trial in which a total of 180 American Society of Anesthesiologists (ASA) grade I and II patients undergoing short procedures under GA not exceeding more than two hours were included. Those with Heart Rate (HR) <60 bpm (beats per minute), on beta blockers, restricted mouth opening were excluded. The patients were randomly divided into group 1 and 2 who received dexmedetomidine at 0.8 µg/kg and 1 µg/kg as an infusion over 10 minutes, respectively. HR, Respiratory Rate (RR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP) were noted before dexmedetomidine administration, after administration, 30 seconds after induction and 1, 3, 5 ,10, 15, 20 and 25 min after LMA insertion, conditions for LMA insertion were assessed using Muzi M et al., score which includes (Jaw mobility was graded as: 1-fully relaxed; 2-mild resistance; 3-tight but opens; 4-close. Coughing/movement were graded as: 1-none; 2-one or two coughs; 3-three or more coughs; 4-bucking/movement), number of attempts at LMA insertion, additional doses of propofol if administered, adverse effects. Statistical analysis was done using Independent t-test, Chi-square test and p-value <0.05 was considered statistically significant.

Results: The conditions for LMA insertion were adequate and comparable in both groups with 94.4% of patients in group 1 and 91.1% patients in group 2 having a Muzi M et al., score of 2 (jaw mobility graded as- fully relaxed and coughing/movement graded as- none). Five patients in group 1 and eight patients in group 2 had more than one attempt at LMA insertion (p-value of 0.303). There was statistically significant drop in HR in group 2 compared to group 1 (p-value <0.001). Also, a statistically significant drop in SBP, DBP, MAP in group 2 compared to group 1 was observed. There was no statistically significant difference in the requirement for additional propofol bolus in the two groups.

Conclusion: IV dexmedetomidine 0.8 µg/kg used as premedication, administered as an infusion over 10 min provides smooth LMA insertion conditions and can be used as a safer alternative to IV dexmedetomidine 1 µg/kg.

Keywords: Bradycardia, Double blind study, Haemodynamics, Muzi M et al score

INTRODUCTION

The LMA is now being widely accepted for both rescue ventilation as well as a primary airway management device for administration of GA and also in prehospital and emergency department environments [1]. However, for safe LMA insertion and to ensure stable haemodynamics, adequate jaw relaxation and suppression of airway reflexes is essential. Propofol has gained popularity for LMA insertion since several years particularly due to its smooth, rapid induction and more so as it is known to depress airway reflexes adequately. But propofol when used alone without any premedication is required in larger doses 3.15±3.69 mg/kg [2]. Propofol at such high induction doses is known to cause hypotension [3]. Hence, various drugs have been used as adjuvants to IV propofol to reduce its dose requirements and thus side-effects. IV lignocaine [4], IV Midazolam [5] and several opioids [6] have been used. Dexmedetomidine in a dose of 1 µg/kg has been used as an adjuvant to propofol for smooth LMA insertion conditions, but it is associated with bradycardia [7].

Hence, in view of significant bradycardia seen with the use of dexmedetomidine in a dose of 1 µg/kg, this study was conducted with a lower dose of dexmedetomidine to observe if it would be safer than 1 µg/kg. This study used 0.8 µg/kg of dexmedetomidine as Zhou D et al., observed that the ED50 (effective dose) and ED95 (95% confidence interval) of dexmedetomidine for suppressing cardiovascular responses to placement of LMA was 0.65 µg/kg (0.44-0.80) µg/kg and 0.94 µg/kg (0.79-2.47) µg/kg, respectively [8].

The aim of the study was to compare the efficacy of 0.8 µg/kg of dexmedetomidine with the higher dose of 1 µg/kg. The primary outcome was to compare the ease of insertion of LMA, and the number of attempts at LMA insertion in the two groups. The secondary outcome was to compare additional propofol requirements in the two groups and adverse effects.

MATERIALS AND METHODS

This randomised double blind clinical trial was conducted at Goa Medical College, Bambolim, Goa, India, from September 2017

to August 2018. Ethical committee clearance was obtained on 17th November 2017.

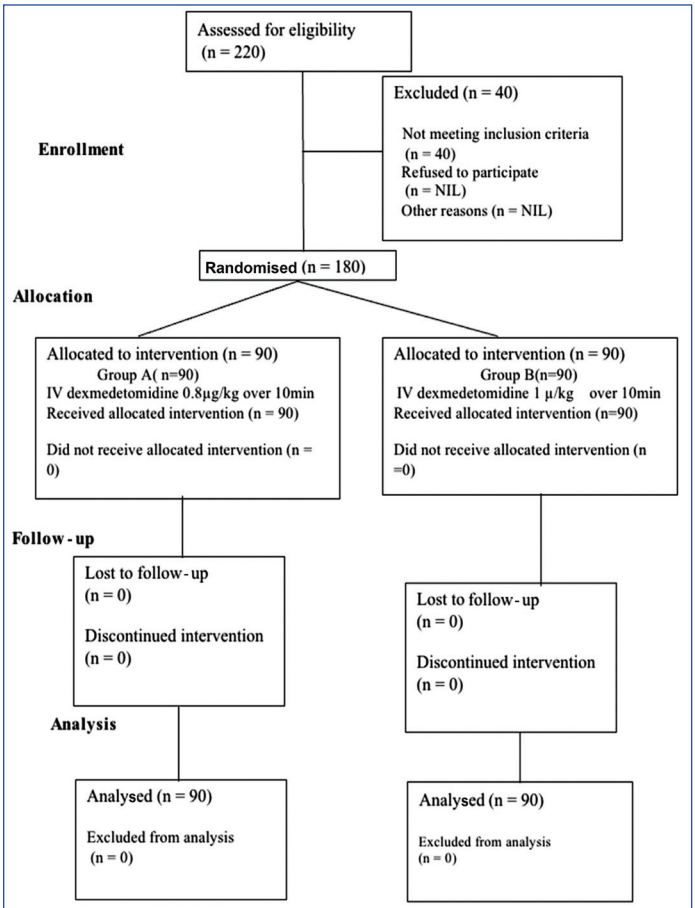
Sample size calculation: The sample size was 180, calculated using an alpha error of 0.05, confidence interval of 95% for an infinite population, calculated power of 88%. Effect size was calculated using a previous similar study [9].

Inclusion criteria: Age 18-60 years, weighing 30-70 kg, ASA grade I and II, scheduled for short surgical procedures under GA upto two hours were enrolled in the study.

Exclusion criteria: Patients with restricted mouth opening (less than 1.5 cm), those on beta blockers, calcium channel blockers, and preoperative pulse rate of less than 60 bpm were excluded from the study.

Study Procedure

Randomisation was done using a computer generated randomisation technique (research randomiser version 4), in which patients were randomly divided into one of the two groups. The ratio of randomisation was 1:1 [Table/Fig-1]. To eliminate bias, a two-operator technique was employed. After randomisation a senior resident prepared the study drug and further monitoring was done by another resident blinded to the allocated groups. Both the observer and the patient were blinded.



[Table/Fig-1]: CONSORT flow chart.

After obtaining informed consent, patient was wheeled inside the Operation Theatre (OT), an 18/20 gauge IV cannula was inserted and IV fluids were administered. The patients were connected to a multichannel monitor which displayed HR, SBP, DBP, MAP, end tidal carbon dioxide concentration ($EtCO_2$), SpO_2, continuous ECG monitoring via leads 2, lead V5. A baseline SBP, DBP, HR, RR, SpO_2 was noted. This was followed by the administration of the study drug according to the respective group allocation: group 1 received 0.8 µg/kg dexmedetomidine (n=90), group 2 received 1 µg/kg dexmedetomidine (n=90).

In both the groups, dexmedetomidine was administered as a slow infusion over 10 minutes to avoid any potential initial hypertension associated with rapid infusion, i.e., a typical biphasic response [10]. At the end of infusion SBP, DBP, HR, RR was noted. Patients were preoxygenated with 100% Oxygen at 12/L minute followed by administration of IV propofol in a dose of 2.0 mg/kg [11] standardised for both the groups. Ninety seconds after administering propofol bolus, first attempt at insertion of classical LMA was made. No muscle relaxant was used.

Conditions for LMA insertion were assessed using Modified Muzi M et al., score [12] (Jaw mobility is graded as: 1-fully relaxed; 2-mild resistance; 3-tight but, opens; 4-close. Coughing/movement is graded as: 1-none; 2-one or two coughs; 3-three or more coughs; 4-bucking/movement. Other events such as spontaneous ventilation, breath holding, expiratory stridor and lacrimation were noted. In each category, scores ≤2 were considered optimum for LMA insertion). Optimal depth of anaesthesia for insertion of LMA was assessed by performing Jaw Thrust [13], and jaw mobility, coughing or movement, and other events like breath holding, lacrimation, expiratory stridor were noted. A score of 2 was considered adequate and LMA was then inserted with the cuff partially inflated. Proper placement was confirmed by capnography and ability to ventilate. If the initial attempt at LMA insertion was a failure, a second attempt was made after administering an additional 0.5 mg/kg of IV propofol, which was also noted. SBP, DBP, HR, RR were monitored. Attempts at LMA insertion were also noted. Maintenance of anaesthesia was achieved with nitrous oxide 66%, oxygen 33% and sevoflurane 2%. Adverse effects mainly hypotension and bradycardia were noted.

STATISTICAL ANALYSIS

Statistical analysis was done using Statistical Package for the Social Sciences (SPSS) software version 25.0. Independent t-test and Chi-square test was used to compare the observations and a p-value <0.05 was considered statistically significant.

RESULTS

Both the groups were comparable demographically using Independent t- test and Chi-square test and there was no statistically significant difference as shown in [Table/Fig-2].

Age	Mean±SD (years)	p-value
Group 1	38.13±14.613	0.545
Group 2	36.82±14.401	
Gender	**N (%)**	**p-value**
Male	Group 1-44 (48.9)	0.455
	Group 2-39 (43.3)	
Female	Group 1-46 (51.1)	
	Group 2-51 (56.7)	

[Table/Fig-2]: Demographic comparison between the two groups.

As shown in [Table/Fig-3], only five patients in group 1 and eight patients in group 2 had a Muzi M et al., score above 2. The score was better in group 1 as compared to group 2 with a Chi-square

Muzi M et al., score	Group 1	Group 2	p-value (Chi-square)
Score 2	85 (94.4%)	82 (91.1%)	0.549
Score 3	3 (3.3%)	6 (6.7%)	
Score 4	0	0	
Score 5	1 (1.1%)	1 (1.1%)	
Score 6	0	1 (1.1%)	
Score 7	1 (1.1%)	0	

[Table/Fig-3]: Comparison of Muzi M et al., score in the two groups.

value of 3.054, but this was not statistically significant with p-value of 0.549. Whilst observing coughing/movement in present study, it was noted that 96.7% of patients in group 1 had a coughing/movement score of 1, whilst 94.40% patients in group 2 had a coughing/movement score of 1. Only three patients (3.33%) in group 1 and five patients (5.6%) in group 2 had scores above 1. Bucking and movement was seen only in two patients in either of the 2 groups (i.e., a 1.1%). Thus, the score was better in group 1 as compared to group 2 with a Chi-square value of 1.023 and p-value of 0.60, but this is not statistically significant.

The number of attempts at LMA insertion was similar in both groups and was not statistically significant as shown in [Table/Fig-4]. Five patients in group 1 and eight patients in group 2 had more than one attempt in LMA insertion which was not statistically significant. 18.90% patients had hypotension in group 1 and 44.5% in group 2. Thus, adverse effects were more pronounced in group 2 with a Chi-square value of 22.569, which is found to be statistically significant with a p-value of <0.001. Only 7.8% of patients in group 2 and 3.3% of patients in group 1 required an additional 0.5 mg/kg of propofol for successful LMA insertion. Only 1.1% of patients in group 1 required an additional 1 and 1.5 mg/kg of propofol. This was statistically not significant with a Chi-square value of 3.6 and p-value of 0.305.

Variables		Group 1	Group 2	p-value (Chi-square)
Number of attempts	1	85 (94.5%)	82 (91.1%)	0.303
	2	4 (4.4%)	8 (8.9%)	
	3	1 (1.1%)	0	
Adverse effects	Nil	71 (78.9%)	42 (46.6%)	<0.001
	Bradycardia	2 (2.2%)	8 (8.9%)	
	Bradycardia/Hypotension	3 (3.3%)	16 (17.8%)	
	Hypotension	14 (15.6%)	24 (26.7%)	
Additional propofol (0.5 mg/kg)	Nil	85 (94.5%)	83 (92.2%)	0.305
	Once	3 (3.3%)	7 (7.8%)	
	Twice	1 (1.1%)	0	
	Thrice	1 (1.1%)	0	

[Table/Fig-4]: Shows attempts at LMA insertion in the 2 groups, comparison of adverse effects, additional propofol requirements in the two groups.

The SBP, DBP and MAP were compared using Independent t-test. The baseline SBP, DBP and MAP were comparable but showed a significant drop in group 2 beyond 5 minutes of LMA insertion with a p-value of 0.005 and <0.001 at 5 and 10 minutes, respectively. Also, there was a significant drop in HR in group 2 following administration of dexmedetomidine 1 µg/kg which persisted throughout the surgery with a p-value of <0.001, which persisted throughout the surgery [Table/Fig-5]. None of the patients needed IV atropine or mephentermine.

DISCUSSION

The aim of the study was to assess and compare the ease of insertion of LMA in both the groups. Studies have been conducted using dexmedetomidine in doses of 1 µg/kg , and many of these studies including Kulkarni AG et al., and Choudhary J et al., observed suitable conditions for LMA insertion but was associated with significant bradycardia, which is a known side-effect of all α-2 receptor agonists [14,15]. Khan AA et al., in their comparative study of 1.0 µg/kg, 0.8 µg/kg and 0.5 µg/kg doses of dexmedetomidine for attenuation of haemodynamic responses to intubation reported a higher incidence of hypotension and bradycardia with the use of higher dose of the drug [16]. Jang YE et al., in their study comparing dexmedetomidine 1.0 µg/kg with a placebo for I-gel insertion, observed significant bradycardia in the patients receiving dexmedetomidine [17].

Zhou D et al., determined that the ED50 and ED95 (95% confidence interval) of dexmedetomidine for suppressing cardiovascular responses to placement of LMA was 0.65 µg/kg and 0.94 µg/kg [8]. Thus, the present study conducted, aimed at comparing a lower dose of dexmedetomidine i.e., 0.8 µg/kg versus 1 µg/kg dexmedetomidine with a standard dose of IV propofol for LMA insertion, to assess if the lower dose of dexmedetomidine can provide suitable conditions for LMA insertion whilst reducing the adverse effects. Thus, in this study a dose of 0.8 µg/kg of dexmedetomidine was used.

Heart rate (bpm)	Group	Mean±SD	p-value*	MAP (mm of Hg)	Group	Mean±SD	p-value*
HR baseline	Group 1	84.38±11.735	0.418	MAP baseline	Group 1	96.04±8.98	0.161
	Group 2	82.71±15.567			Group 2	98.18±11.29	
HR after dexmedetomidine	Group 1	74.2±11.41	<0.001	MAP after dexmedetomidine	Group 1	88.82±10.21	0.319
	Group 2	66.24±12.648			Group 2	87.26±10.70	
HR 30 secs after induction	Group 1	75.72 ±11.779	<0.001	MAP 30 secs after induction	Group 1	86.44±10.62	0.11
	Group 2	68.89 ±12.607			Group 2	83.74±11.88	
HR at 1 min after LMA insertion Min	Group 1	76.29±10.937	<0.001	MAP at 1 min after LMA insertion	Group 1	80.68±9.20	0.754
	Group 2	68.36±3.083			Group 2	81.22±13.50	
HR at 3 mins after LMA insertion	Group 1	77±11.493	<0.001	MAP at 3 mins after LMA insertion	Group 1	79.70±9.27	0.108
	Group 2	70.44 ±12.106			Group 2	77.03±12.65	
HR at 5 mins after LMA insertion	Group 1	76.7±10.902	0.003	MAP at 5 mins after LMA insertion	Group 1	79.14±10.03	0.005
	Group 2	71.54 ±11.968			Group 2	74.52±11.80	
HR at 10 mins after LMA insertion	Group 1	75.97±10.665	0.002	MAP at 10 mins after LMA insertion	Group 1	79.62±9.36	<0.001
	Group 2	70.68±11.369			Group 2	73.54±10.95	
HR at 15 mins after LMA insertion	Group 1	75.42±10.731	0.001	MAP at 15 mins after LMA insertion	Group 1	79.46±9.91	<0.001
	Group 2	69.79±11.589			Group 2	72.92±10.55	
HR at 20 mins after LMA insertion	Group 1	75.21 ±10.308	<0.001	MAP at 20 mins after LMA insertion	Group 1	79.72±9.67	<0.001
	Group 2	69.16±11.726			Group 2	74.72±9.03	
HR at 25 mins after LMA insertion	Group 1	75.14±9.884	0.001	MAP at 25 mins after LMA insertion	Group 1	80.95±7.76	<0.001
	Group 2	70.16±10.596			Group 2	76.93±7.43	

[Table/Fig-5]: Haemodynamic parameters in the two groups.
*A p-value <0.05 was considered to be statistically significant

In the present study, the conditions for LMA insertion were satisfactory with both the doses of dexmedetomidine as measured using Modified Muzi M et al., score. There was comparable jaw relaxation in both the groups. However, three patients (3.33%) in group 1 and five patients (5.55%) in group 2 had coughing and bucking and movement was seen only in two patients in either of the two groups (i.e., a 1.1%), which was not statistically significant. The number of attempts at LMA insertion was comparable. Kulkarni AG et al., showed 96% of patients receiving nalbuphine (0.2 mg/kg) had satisfactory LMA inserti on conditions, whereas 93% patients in dexmedetomidine (1 µ/kg) group had satisfactory conditions but this difference was not found to have any statistical significance [14]. Repalle SK and Kalyan R observed that jaw relaxation was significantly better in the dexmedetomidine (1 µ/kg) group as compared to the clonidine (1 µ/kg) [18]. In comparison to the present study, Repalle SK and Kalyan R found no coughing in patients receiving dexmedetomidine (1 µ/kg) whilst in those receiving clonidine (1 µ/kg), 20% patients had grade 2 coughing and 1 patient had grade 4 coughing. Only 3.33% patients required two attempts at LMA insertion in the dexmedetomidine (1 µ/kg) group and 16.67% patients in clonidine group required two attempts at LMA insertion [18]. This difference was however not statistically significant. (p-value=0.08). Thus, based on the observations in the present study, it can be stated that dexmedetomidine in a dose of 0.8 µ/kg provides suitable conditions for LMA insertion.

In the present study, there was a significant decrease in HR, SBP, DBP, MAP in group 2 in comparison to group 1 after administration of the study drug. The HR showed a significant drop (p-value <0.005) in group 2 soon after administration of dexmedetomidine 1 µg/kg which persisted for up till 25 minutes thereafter. This was in accordance to its alpha-2 agonism and the resulting decrease in central sympathetic outflow. However, none of these patients required either IV atropine or IV mephentermine. Thus, from the observations made in this study, dexmedetomdine at 0.8 µ/kg is associated with stable haemodynamics in comparison with 1 µ/kg. Kulkarni AG et al., in their study whilst comparing nalbuphine 0.2 mg/kg to dexmedetomidine 1 µg/kg noted that bradycardia (HR <60 bpm) was statistically significant in the dexmedetomidine group especially at 1 and 3 minutes after LMA insertion with a p-value of 0.001 [14]. The SBP, DBP, MAP showed a statistically significant drop (p-value <0.001) beginning at 10 minutes post LMA insertion to 25 minutes. Repalle SK and Kalyan R, conducted a study similar to present, comparing clonidine 1 µg/kg with dexmedetomidine 1 µg/kg and noted a significant drop in BP in the dexmedetomidine group at 1 to 3 minutes after LMA insertion [18]. Choudhary J et al., also conducted a study comparing fentanyl 1 µg/kg with dexmedetomidine 1 µg/kg and noted a significant reduction in HR, BP in the dexmedetomidine group which remained statistically significant at each time period of the study interval [15].

In this study, 94.4% of patients in group 1 and 92.2% of patients in group 2 did not require additional propofol. Total 7.8% patients in group 2 and 3.3% in group 1 required an additional 0.5 mg/kg of propofol for successful LMA insertion. Only 1.1% patients in group 1 required an additional 1 and 1.5 mg/kg of propofol. This was statistically not significant. Ramaswamy AH et al., also used 2 mg/kg standard dose for induction and they observed that 12.5% patients in the fentanyl group (1 µ/kg) and only 7.5% patients in the dexmedetomidine (1 µ/kg) group required additional 0.5 mg/kg IV propofol [19]. From these observations it can be said that dexmedetomidine, when used in a lower dose of 0.8 µ/kg as premedication, safely reduces the dose of IV propofol for smooth LMA insertion, similar to the higher dose of 1 µ/kg.

Limitation(s)

Although the study shows that the lower dose of dexmedetomidine is safer, present study was limited to patients less than 65 years of age, and authors could have extended it to those above 65 years, a population least studied upon and a population with larger co-morbidities. The cost effectiveness of dexmedetomidine is questionable, as an ampoule of Xamdex 200 micrograms costs nearly Rs 600 and cheaper alternatives are available.

CONCLUSION(S)

Intravenous dexmedetomidine 0.8 µg/kg used as premedication, administered as an infusion over 10 minutes provides smooth LMA insertion conditions and can be used as a safer alternative to IV dexmedetomidine 1 µg/kg. Hence, from the present study it can be concluded that Dexmedetomidine 0.8 µg/kg can be used as an adjunct to IV propofol for LMA insertion.

Dexmedetomidine is gaining popularity in recent years and has an ever expanding scope in modern day anaesthesia. From the present study, authors can conclude the safety profile and suitability of dexmedetomidine 0.8 µg/kg for LMA insertion in adults. Authors can extend this study to the geriatric population and also observe the efficacy of this lower dose of dexmedetomidine in prevention of postoperative delirium, especially in those elderly patients who are more prone.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jun 28, 2021
- Manual Googling: Oct 25, 2021
- iThenticate Software: Nov 29, 2021 (14%)

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: **Jun 26, 2021**
Date of Peer Review: **Aug 05, 2021**
Date of Acceptance: **Nov 27, 2021**
Date of Publishing: **Dec 01, 2021**