

# Comparison of propofol versus dexmedetomidine sedation for awake C-MAC® D-Blade video laryngoscopic nasotracheal intubation in patients with difficult airway: A randomised clinical study

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## ABSTRACT

**Background and Aims:** Awake intubation is the preferred method for securing difficult airways. We compared intravenous (IV) propofol and dexmedetomidine for C-MAC® D-blade-guided anticipated difficult nasotracheal intubation under conscious sedation. **Methods:** This randomised study included 60 patients with difficult airway (El-Ganzouri Score 4–9). After adequate airway preparation with IV midazolam 0.03 mg/kg and IV fentanyl 1 µg/kg, in Group P, propofol was infused at 250 µg/kg/min and in Group D, dexmedetomidine was infused at 1 µg/kg over 10 min, then at 0.5 µg/kg/h till a bispectral index (BIS) value 65–70 was achieved. Patients underwent C-MAC® D-blade video laryngoscope-guided nasotracheal intubation. The intubation score was the primary outcome measure. Secondary outcome measures included haemodynamic parameters, intubation time, number of attempts, the incidence of failed awake intubation, glottic view, time to achieve desired BIS, complications, study drug consumption and patient-reported satisfaction with the awake intubation technique. Quantitative variables were compared between groups using unpaired *t*-test/Welch test/Mann–Whitney Test. Qualitative variables were correlated using the Chi-square test/Fisher's exact test. A *P* value of <0.05 was considered statistically significant. **Results:** The intubation score was significantly higher in Group D versus Group P (*P* = 0.007). Patient reaction to intubation, haemodynamic parameters and percentage of glottis opening score were more favourable in Group P. Coughing and vocal cord movement were comparable between the groups (*P* > 0.05). The time to target BIS was four times longer, and the time to intubate was 6 seconds longer in Group D. **Conclusion:** Successful awake C-MAC® D-blade video laryngoscopic intubation can be performed under dexmedetomidine/propofol conscious sedation, with propofol giving a better intubation score.

**Keywords:** Conscious sedation, dexmedetomidine, El-Ganzouri score, intubation score, percentage of glottis opening scores, propofol, tracheal intubation, vocal cords

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## INTRODUCTION

The incidence of difficult airway can be split into difficult laryngoscopy 12.3%, difficult intubation 9% and failed intubation 0.47%.<sup>[1]</sup> Despite patient discomfort, an awake intubation is the preferred method for securing a difficult airway.<sup>[2]</sup> Although the few available guidelines recommend awake intubation [the gold standard being awake fiberoptic bronchoscopic intubation (AFOBI)] for anticipated

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difficult airways, it is a highly underutilised technique.<sup>[2,3]</sup>

A video laryngoscope epitomises an acceptable alternative to AFOBI.<sup>[2]</sup> A C-MAC<sup>®</sup> D-blade video laryngoscope (Karl Storz, Tuttlingen, Germany)-guided intubation under conscious sedation assures the same safety and success levels as AFOBI, besides being quicker, more user friendly and less dependent on patient cooperation or sedation. It is more amenable to suctioning of secretions, blood and slough.<sup>[3,4]</sup> Dexmedetomidine, midazolam, propofol and remifentanyl have been used for sedation and amnesia during awake tracheal intubation. Dexmedetomidine (an  $\alpha_2$  agonist), a sedative, anxiolytic and analgesic with sympatholytic properties, provides sedation with minimal respiratory impairment, haemodynamic stability and good tracheal intubating conditions.<sup>[5]</sup> Dexmedetomidine has a longer onset time (5 min) and peak effect (15 min) compared to propofol, thereby prolonging the time to tracheal intubation.<sup>[5,6]</sup> Propofol blunts the pressor response to awake tracheal intubation.<sup>[6]</sup> A literature review reveals a lack of studies utilising propofol and dexmedetomidine sedation for awake video laryngoscope-guided intubation for anticipated difficult airways.<sup>[2]</sup>

We aimed to compare propofol and dexmedetomidine conscious sedation, augmented with local anaesthesia, for C-MAC<sup>®</sup> D-blade guided anticipated difficult intubation. Our primary objective was noting the intubation score, while secondary objectives comprised heart rate (HR), mean arterial pressure (MAP), intubation time, number of intubation attempts, the incidence of failed awake intubation, glottic view, the mean time for achieving the desired bispectral index (BIS), complications, study drug consumption and patient-reported satisfaction with the awake tracheal intubation technique. We hypothesised that propofol and dexmedetomidine provide optimal sedation for awake video laryngoscopic endotracheal intubation.

## METHODS

This randomised, two-arm, single-centric, double-blind study was conducted in a tertiary care oncology setup from March 2020 to September 2020. Adherence to the Helsinki Protocol, 2013, and good clinical practice was ensured. Written informed consent was obtained from all patients for participation in the study and using the

patient data for research and educational purposes. Institutional Ethics Committee clearance (vide approval number RGCIRC/IRB/355/2019; dated 9 October 2019) and Clinical Trials Registry-India (vide registration number CTRI/2020/03/023678; www.ctri.nic.in) registration were obtained. Sixty American Society of Anesthesiologists physical status I–III patients of either gender, aged 18–70 years, with an anticipated difficult airway (El-Ganzouri Score 4–9),<sup>[7]</sup> mouth opening/inter-incisor gap >1.5 cm/1 finger, requiring nasotracheal intubation for head–neck oncosurgery were included. Exclusion criteria comprised refusal to consent, liver cirrhosis, severe bradycardia, atrioventricular block, heart failure and thrombocytopaenia/coagulopathy.

Randomisation, blinding, concealment and intervention involved different investigators. A computerised table generated the sequences for block randomisation (15 blocks of four patients each) and allocation into Group D (dexmedetomidine infusion) and Group P (propofol infusion), each comprising 30 patients (allocation ratio 1:1). Group allocation was concealed in sequentially numbered, sealed, opaque envelopes. All tracheal intubations were performed by an investigator proficient in C-MAC<sup>®</sup> video laryngoscopy; this investigator was not the same as the one responsible for randomisation and allocation concealment. This was a participant- and outcome assessor-blinded study. The patients were blinded to the drug (dexmedetomidine/propofol) used for sedation, and so were independent observers who noted the vocal cord movement from the monitor screen of the C-MAC<sup>®</sup> video laryngoscope and closely observed the patient reaction to intubation and any associated cough (intubation score). A third investigator prepared and controlled the study drug infusions and concealed the syringe pumps behind a screen, out of sight from the patient and the independent observer. A fourth investigator noted the secondary outcome measures and managed the patient intraoperatively.

Premedication with intravenous (IV) glycopyrrolate 4  $\mu$ g/kg was instituted after securing a wide-bore IV cannula in the operation theatre. After nebulisation with 3 ml of 4% lignocaine, a transtracheal block with 2 ml of 4% lignocaine was instituted. Nasal preparation comprised xylometazoline drops, instructing patients to inhale 2 ml of 2% lignocaine jelly through the more patent nostril and packing the nostril with 0.5 ml of 4% lignocaine-soaked ribbon gauze. After premedication with IV midazolam 0.03 mg/kg, IV fentanyl 1  $\mu$ g/kg

was administered to all patients. After preoxygenation with 100% oxygen for 3 min using a face mask, Group P patients received propofol infusion (250 µg/kg/min). Group D patients received dexmedetomidine 1 µg/kg infusion over 10 min, followed by 0.5 µg/kg/h. Both were continued till adequate sedation (BIS 65–70). Oxygenation via face mask at 6 l/min was continued during this period. C-MAC® D-blade video laryngoscope-guided nasotracheal intubation with a 7-mm internal diameter flexometallic cuffed endotracheal tube (ETT) was performed in sedated patients who were breathing spontaneously. Intubation score, intubation time, number of attempts at intubation, incidence of failed awake intubation and glottic view [percentage of glottis opening (POGO) score] were recorded immediately after intubation. HR and MAP were measured at baseline, pre-laryngoscopy, during laryngoscopy, at intubation, and 1, 3, and 5 min post-intubation. Complications, amount of study drug consumed and patient-reported satisfaction were noted postoperatively.

The primary outcome measure comprised the intubation score<sup>[8]</sup> (cough, vocal cord movement, patient reaction to laryngoscopic endotracheal intubation). Secondary outcome measures included HR, MAP, intubation time (from nasotracheal tube insertion to end of intubation), number of attempts (introduction of the nasotracheal tube with an intent to pass into the trachea) at intubation, incidence of failed awake intubation, POGO score, mean time for achieving desired BIS, complications (desaturation episodes, soft tissue/dental trauma, local anaesthetic toxicity), amount of study drug (propofol/dexmedetomidine) consumed and patient-reported satisfaction (Likert scale) with the awake intubation technique. The intubation score<sup>[8]</sup> comprised a summation of three parameters: coughing, vocal cord movement and the patient's reaction to the introduction of the C-MAC® video laryngoscope and placement of the nasotracheal tube. An intubation score of 3 was considered clinically excellent, and a score of 12 was clinically poor.

Sample size calculation taking the level of significance ( $\alpha$ ) as 5%, power (1-  $\beta$ ) as 90% and proportion of patients with absence of coughing on awake nasotracheal intubation as 60% in the dexmedetomidine group and 16.7% in the propofol group as per a study by Goel *et al.*<sup>[9]</sup> yielded a sample size of 24 per group. Allowing for 20% dropouts due to logistic issues, we enrolled 30 patients per group.

Data analysis utilised Statistical Package for the Social Sciences statistics software version 21.0 (IBM Corp, Armonk, NY, USA). Categorical variables (intubation score, gender, intubation attempts, patient report) were presented as numbers and percentages, and continuous variables (age, weight, HR, MAP, intubation time, amount of study drug used, POGO, time to achieve desired BIS) were presented as mean and standard deviation (SD). The normality of data was established by the Kolmogorov–Smirnov test. Quantitative variables with normal data distribution were compared (intergroup analysis) using an unpaired *t*-test (age, weight, HR, MAP, POGO). Welsch test (assuming unequal variances) was used for intubation time and time to achieve the desired BIS, and the Mann–Whitney test was used for non-parametric data (ASA physical state, El-Ganzouri score, patient experience). Qualitative variables (cough, vocal cord movement, patient reaction, gender, intubation attempts) were assessed using the Chi-square test/Fisher's exact test. A *P* value <0.05 was considered statistically significant.

## RESULTS

Figure 1 (Consolidated Standards of Reporting Trials flowchart) depicts the flow of participants. The demographic parameters (age, gender, weight) were comparable in both groups [Table 1].

The mean intubation score was 4.4 (SD: 1.3) (95% CI: 3.9–4.9) in Group D and 3.6 (SD: 1) (95% CI: 3.2–4) in Group P (*P* = 0.007) [Figure 2].

Statistically significant changes in HR and MAP were observed at laryngoscopy (*P* < 0.001 and *P* < 0.001, respectively, in Group D; *P* < 0.001 and *P* < 0.001, respectively, in Group P) and intubation (*P* < 0.001 and *P* = 0.001, respectively, in Group D; *P* < 0.001 and *P* < 0.001, respectively, in Group P) compared to pre-laryngoscopy values in both groups [Figure 3]. In addition, in Group D, the mean difference in HR at 1 and 3 min post-laryngoscopy compared to pre-laryngoscopy values (*P* = 0.007, *P* = 0.041) and the mean difference in MAP at 5 min post-intubation

Table 1: Demographic parameters

Variable	Group D (n=30)	Group P (n=30)
Age (years), mean (SD)	53.9 (10.8)	50.8 (11.4)
Weight (kg), mean (SD)	69.8 (11.0)	68.4 (10.82)
Gender (male/female), n	27/3	25/5

Data expressed as mean (SD) or number. n=number of patients, SD=standard deviation

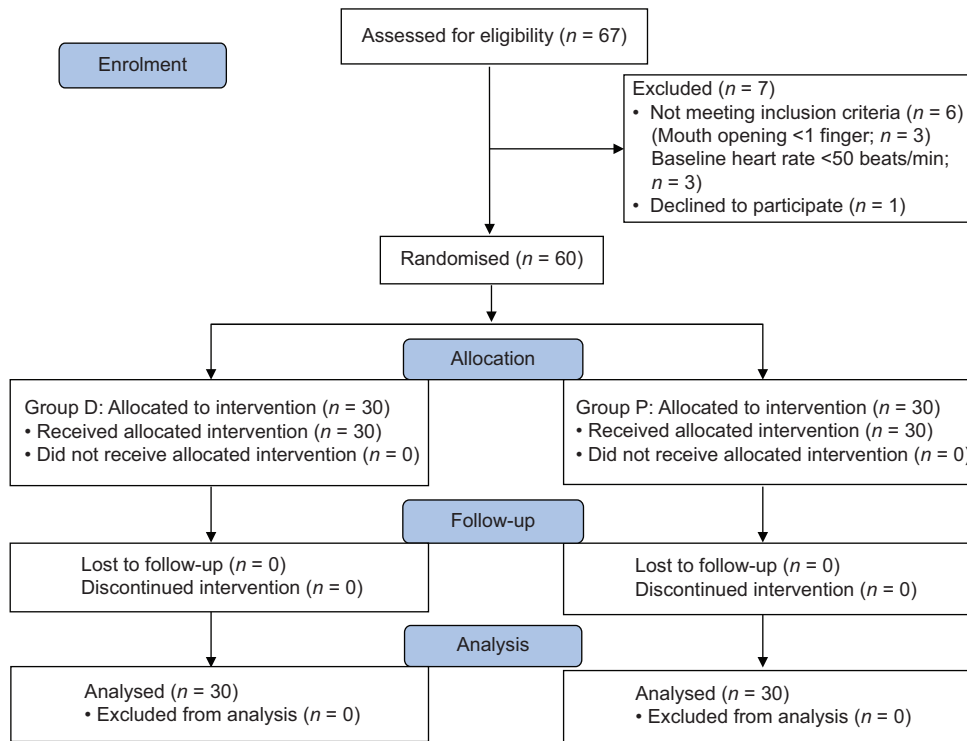


Figure 1: CONSORT flowchart depicting the flow of participants across both groups. CONSORT = Consolidated System of Reporting Trials

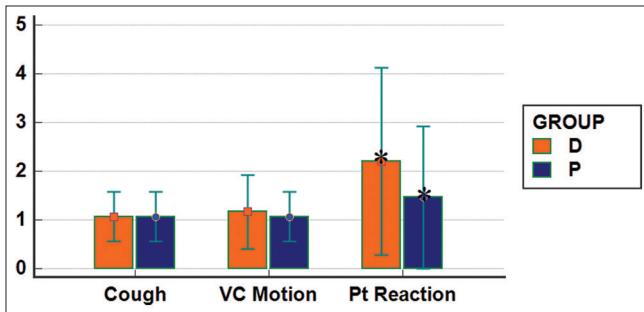


Figure 2: Intergroup comparison of intubation score parameters (\* = significant *P* values). Group D = dexmedetomidine group, Group P = propofol group, Pt = patient, VC = vocal cords

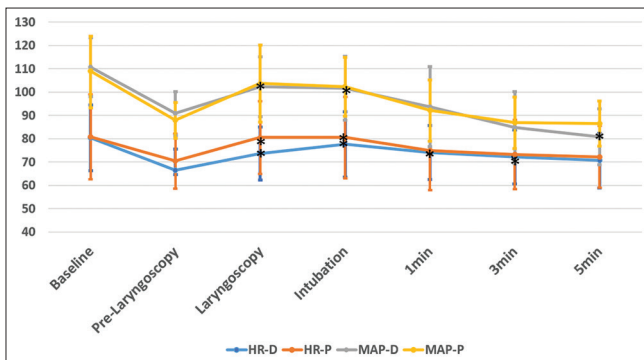


Figure 3: Trendline with error bars depicting trends in haemodynamic parameters over time [y axis represents beats/min for heart rate and mmHg for mean arterial pressures] [black\* = significant *P* value compared to pre-laryngoscopy values (paired *t*-test)]. Note: On intergroup comparison, all *P* values were statistically insignificant for both HR and MAP. HR = heart rate, MAP = mean arterial pressure

compared to pre-laryngoscopy values ( $P = 0.001$ ) were statistically significant.

Mean dexmedetomidine consumption in Group D was 101.2 (SD: 25.3) (95% CI: 91.8,110.7)  $\mu\text{g}$ , whereas 106.9 (SD: 42.7) (95% CI: 90.9,122.8) mg propofol was consumed in Group P. Tables 2 and 3 show the secondary outcome measures. In Group D, the majority (29/30) of patients developed no complications and only one patient experienced desaturation ( $\text{SpO}_2 < 95\%$ ) during laryngoscopy/intubation, whereas no Group P patient had any complications ( $P = 0.313$ ).

Nil/30 versus 1/30 patients reported excellent, 9/30 versus 21/30 patients reported good and 15/30 versus 7/30 patients reported fair experience in Group D versus Group P, respectively. Six/30 versus 7/30 patients reported poor and none experienced very poor experience in Group D versus Group P, respectively ( $P = 0.006$ ).

## DISCUSSION

Although both the drugs provide good intubating conditions, better suppression of airway reflexes by propofol and the resultant higher mean intubation score in Group D versus Group P make propofol better suited for awake video laryngoscopic intubation as per our study.



Table 2: Study parameters

Parameter	Group D (n=30)	Group P (n=30)	Effect size, r (95% CI)	P
Intubation time, s	35.5 (24.4)	32 (44.2)	-3.53 (-22.07, 15.01)	0.703
POGO (%)	40.2 (8.8)	50.3 (9.2)	10.16 (-1.17, 21.51)	0.078
Time to BIS- 65 (min)	11.22 (1.9)	2.97 (1.3)	-8.25 (-9.10, -7.39)	<0.001
Intubation attempt- first/second	27/3	29/1	-	0.739
Patient report- excellent/good/fair/poor/very poor	0/9/15/6/0	1/21/7/7/0	-	0.006

Data expressed as mean (standard deviation) or number. BIS=bispectral index, CI=confidence interval, NA=not applicable, POGO=percentage of glottis opening, n=number of patients

Table 3: Intergroup comparison of ASA physical status, El-Ganzouri's score and patient experience

Variables	Group D (n=30)	Group P (n=30)	P
ASA physical status	3 (2-3) (2, 3)	3 (2-3) (2, 3)	0.440
El-Ganzouri score	5 (5-6) (5, 6)	6 (5-8) (5, 7)	0.168
Patient experience	3 (2-3) (2, 3)	2 (2-3) (1, 2)	0.001

Data expressed as median (interquartile range) (95% confidence interval). ASA=American Society of Anesthesiologists, n=number of patients

The low and comparable incidence of cough on intubation in both groups was chiefly attributable to an effective transtracheal block and topicalisation. While both propofol and dexmedetomidine have been individually used as sedatives for awake video laryngoscopic intubation, no published literature compares their efficacy for this purpose. Mariyappa *et al.*<sup>[10]</sup> compared propofol-fentanyl versus dexmedetomidine sedation in 60 patients undergoing AFOBI and reported a better cough score in the propofol-fentanyl group (76.7%), which is attributable to the added effect of fentanyl. In our study, all patients received IV fentanyl 1 µg/kg in addition to either propofol or dexmedetomidine to nullify any confounding effect of fentanyl.

None of our patients had closing/closed vocal cords, as corroborated by Mariyappa *et al.*,<sup>[10]</sup> where both groups had comparable vocal cord movement. Dey *et al.*<sup>[11]</sup> compared dexmedetomidine and propofol sedation for AFOBI in oral cancer patients and reported a better intubation score for dexmedetomidine, although this difference was statistically insignificant. The better intubation scores for both the groups in our study are attributable to nebulisation and lignocaine jelly instillation, thereby augmenting suppression of vocal cord movement. Two-thirds of our Group P patients showed no reaction to laryngoscopic intubation, while more than two-thirds of Group D patients displayed grimacing. Corroboratively, Mariyappa *et al.*<sup>[10]</sup> reported defensive limb movement in four patients in the dexmedetomidine group versus none in the propofol-fentanyl group. Although all the patients could be successfully intubated using the C-MAC® D-Blade in both groups, the intubation scores differed significantly.

Despite a comparable baseline HR, the mean HR at all other time points was lower in the dexmedetomidine group due to α<sub>2</sub>-agonist action. Although a statistically significant rise in HR from pre-laryngoscopy values was seen at laryngoscopy and intubation in both groups, this rise was statistically significant for up to 3 min post-intubation only in Group D, signifying lower haemodynamic stress response under propofol. Corroborating our findings, Mariyappa *et al.*<sup>[10]</sup> reported a fall in HR in both groups towards the end of the study drug infusions. In Group D, the greater rise in MAP at laryngoscopy and intubation versus pre-laryngoscopy values, compared to Group P, indicates better suppression of intubation stress response by propofol.

The four times longer time to achieve desired BIS values in Group D versus Group P is attributable to the longer onset time (5 min) and the peak effect (15 min) of dexmedetomidine, which makes propofol a better option in time-sensitive situations. The short and comparable intubation time in both groups implies that both drugs facilitate intubation similarly.

A smaller number of second intubation attempts in Group P emphasises better intubating conditions with propofol. This corroborates with the findings of Selvam *et al.*<sup>[12]</sup> in 30 laryngeal tumour patients, intubated using C-MAC® video laryngoscope, under dexmedetomidine sedation and topicalisation, where 86.7% of the patients were intubated in the first attempt. All three patients could be intubated in the first attempt in another case series (awake C-MAC® video intubation under propofol sedation).<sup>[13]</sup> Besides ours, these are the only two studies using either dexmedetomidine or propofol sedation for awake C-MAC® video laryngoscopy.

The absence of dental/soft tissue trauma can be attributed to the near absence of patient resistance/struggle in both groups. Video laryngoscopy ensures ETT placement under direct observation throughout the intubation process, mitigating the potential for

airway trauma.<sup>[14]</sup> None of our patients developed local anaesthetic toxicity since we remained within the prescribed toxic limit of lignocaine (5 mg/kg body weight; for topicalisation, 9 mg/kg body weight).<sup>[3,15]</sup> Bilateral superior laryngeal nerve blocks were avoided to circumvent patient discomfort from two unnecessary cervical pricks, to refrain from bringing the total lignocaine dose closer to the toxic limit and because of the high failure rate.

The propofol we utilised was comparable with Shah *et al.*<sup>[13]</sup> for awake C-MAC<sup>®</sup>-guided intubation. The propofol and dexmedetomidine we utilised were lower in amount than Dey *et al.*'s,<sup>[11]</sup> probably because AFOBI takes longer than awake video laryngoscopy.

In Group D, three-fourths of patients reported a good/fair response to intubation when enquired after tracheal extubation the following day versus all except one patient reporting an excellent/good/fair response in Group P, which makes propofol better suited from the patient comfort perspective.

Limitations include utilising the C-MAC<sup>®</sup> D-Blade video laryngoscope in all patients; hence, our results may not be generalisable to other video laryngoscopes. Secondly, training in C-MAC<sup>®</sup> D-Blade video laryngoscopy is a mandatory prerequisite, with the results being skill-dependent.<sup>[15]</sup> Thirdly, although target-controlled infusion (TCI) of study drugs would have been ideal, propofol TCI was not utilised to assure uniformity in methodology. Future multicentric, randomised controlled trials using different video laryngoscopes can be undertaken to compare the efficacy of various sedatives (dexmedetomidine, propofol, remifentanyl, ketamine) for awake nasotracheal intubation in anticipated difficult airways.

## CONCLUSION

Propofol infusion (250 µg/kg/min till BIS 65–70 is reached) gives a better intubation score than dexmedetomidine infusion (1 µg/kg infused over 10 min followed by 0.5 µg/kg/h until BIS 65–70 is reached) for awake C-MAC<sup>®</sup> D-blade-guided nasotracheal intubation in anticipated difficult airway patients.

### Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the

corresponding author) and shall be shared after approval as per the authors' institution policy.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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