

# A Randomized Clinical Trial Comparing the Standard McIntosh Laryngoscope and the C-Mac D blade Video laryngoscope™ for Double Lumen Tube Insertion for One Lung Ventilation in Onco surgical Patients

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## ABSTRACT

**Background and Aims:** Several devices enabling double-lumen tube (DLT) placement for thoracic surgeries are available, but there are no studies for D-blade video laryngoscope-guided DLT insertion. We compared the CMac D-blade videolaryngoscope™ and the Macintosh laryngoscope for DLT endobronchial intubation using parameters of time and attempts required for intubation, glottic view, incidence of complications and haemodynamic changes. **Methods:** Prospective, parallel group, randomised controlled clinical trial where sixty American Society of Anesthesiologists I and II patients aged 18–80 years scheduled for thoracic surgeries entailing DLT placement were randomly allocated in two groups based on the laryngoscopic device used for endobronchial intubation. Data were subjected to statistical analysis SPSS (version 17), the paired and Student's *t*-test for equality of means. Nominal categorical data between the groups were compared using Chi-squared test or Fisher's exact test as appropriate.  $P \leq 0.05$  was considered statistically significant. **Results:** Time required for intubation was comparable ( $37.41 \pm 18.80$  s in Group-M and  $32.27 \pm 11.13$  s in Group-D). Number of attempts and incidence of complications (trauma, DLT cuff rupture, oesophageal intubation) was greater in the Macintosh group, except malpositioning into the wrong bronchus (easily rectified fibre-optic bronchoscopically), which was greater with the D-blade. Greater haemodynamic changes were observed during Macintosh laryngoscopy. **Conclusion:** D-blade videolaryngoscope™ is a useful alternative to the standard Macintosh laryngoscope for routine DLT insertion.

**Key words:** CMac D-blade videolaryngoscope™, complications, double-lumen tube, haemodynamic changes, Macintosh blade

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## INTRODUCTION

Double-lumen tube (DLT) placement is the gold standard for lung isolation required in thoracic surgeries. Proper DLT placement is technically demanding and complications ranging from DLT cuff rupture to potentially life-threatening tracheobronchial disruption may occur due to the intrinsic shape and modelling, large external

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circumference and rigid stylets employed for DLT placement.<sup>[1]</sup> This risk is compounded in the difficult airway scenario. Video laryngoscopes are known to give the advantage of improvement in glottic view,<sup>[2]</sup> (Cormack and Lehane grade as well as percentage of glottic opening [POGO] scale) over the classical Macintosh blade laryngoscopes. Real-time observation of the screen allows an assistant to perform optimum external manipulation of the airway, facilitating DLT placement. Visual confirmation of DLT placement into the trachea is possible, and the anaesthesiologist can comfortably proceed to confirmation of lung isolation with the knowledge that the airway is secure.

DLT placement is technically more challenging and causes greater haemodynamic disturbance and trauma than single-lumen tube placement<sup>[3,4]</sup> even in patients with Cormack Lehane grade 1 view. This difficulty is compounded if the airway happens to be even a borderline difficult one (Cormack Lehane grade 2 onwards). Since direct laryngoscopy for single-lumen tube placement using Macintosh laryngoscope requires four times greater lifting force application to the base of tongue to expose the glottis than a video laryngoscope (translating into greater degrees of stress response and localised trauma)<sup>[4]</sup> and since the D-blade has been specially designed for difficult airway management in particular, we decided to employ the CMac D-blade video laryngoscope for DLT placement and compare the haemodynamic changes, trauma and other complications. Our subset of patients, namely oncosurgical patients, undergoing one-lung ventilation usually have diminished physiological reserve, autonomic dysfunction and cardiac co-morbidities such as hypertension, coronary atherosclerosis and left ventricular diastolic dysfunction. Haemodynamic fluctuations may precipitate dangerous complications in this scenario. Hence, in our quest for a device causing less haemodynamic stress, better glottic visualisation and fewer incidences of complications such as cuff rupture (which renders the expensive DLT useless) and trauma, we studied whether D-blade video laryngoscopy is superior to Macintosh direct laryngoscopy for DLT insertion.

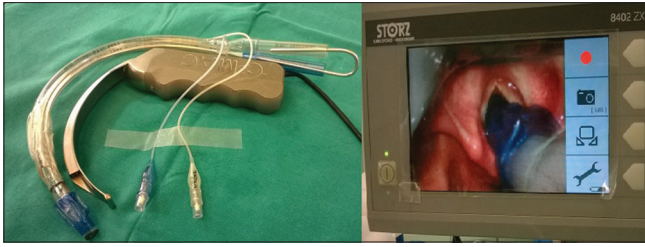
Our aim was to compare the CMac D-blade videolaryngoscope™ with the Macintosh laryngoscope for endobronchial DLT intubation. The primary outcome of our study was the time taken to intubate with DLT while the secondary outcomes of our study included comparison of glottic view, number

of intubation attempts, haemodynamic changes and incidence of complications.

## METHODS

This prospective randomised, parallel group, single-centric clinical trial was conducted after obtaining approval from the Institutional Ethics Committee. Written informed consent from all patients specified that they may or may not be given the opportunity to get intubated using the new video laryngoscope depending on whether he would fall in the Macintosh or D-blade group after randomisation. All patients were blinded to the type of laryngoscopy. Sixty adult patients of either sex fulfilling the inclusion criteria of age 18–80 years, American Society of Anesthesiologists (ASA) physical status 1–2, suffering from malignancy and requiring a DLT for elective thoracic surgery (oesophagectomy, pulmonary metastasectomy, lobectomy and pneumonectomy) were enrolled for the study. The exclusion criteria were risk of regurgitation and pulmonary aspiration, patients with tracheobronchial masses or compression, patients with <70% predicted forced expiratory volume in 1 s, <80% predicted forced vital capacity, a PaO<sub>2</sub> <9.3 kPa while breathing air and mouth opening <1.5 cm.

The airway of all patients was graded according to the El Ganzouri risk index (EGRI)<sup>[5]</sup> for difficult airway prediction based on seven parameters (body weight [kg], modified Mallampati class, mouth opening [cm], thyromental distance [cm], neck movement [degrees], prognathism and history of difficult airway) with a minimum score of 0 and a maximum possible score of 12. A difficult tracheal intubation is predicted by EGRI ≥4. All endotracheal intubations were performed by two experienced anaesthesiologists. In the D-blade group, the distal 10 cm concavity of the DLT (with the stylet *in situ*) was moulded along the D-blade convexity to facilitate intubation [Figure 1]. After premedication with midazolam 1 mg intravenous (IV) and pre-oxygenation for 3 min, fentanyl 2 µg/kg IV and propofol 1.5 mg/kg were given for induction of anaesthesia. Depending on response to verbal commands, we gave additional 10 mg boluses of propofol as and when required until anaesthesia was induced. After loss of response to verbal commands and checking for adequate mask ventilation, atracurium 0.5 mg/kg was injected. Trachea was intubated with left-sided 35 Fr/37 Fr DLT Broncho-Cath™ DLT (Mallinckrodt Medical, Athlone,



**Figure 1:** Modelling of the distal concavity of the double-lumen tube along the D-blade convexity and CMac D-blade videolaryngoscopic view of the glottic opening with a double-lumen tube negotiating it (the blue bronchial cuff is visible)

Ireland), for female patients and 37 Fr/39 Fr DLT for male patients depending on whether their height was below or above 160 cm for females and 170 cm for males, respectively. The stylet was now withdrawn up to the black ring 0.5 cm distal to the proximal border of blue cuff, and the DLT was inserted with the distal concavity facing anteriorly until the blue cuff disappeared into the glottis [Figure 1]. The stylet was then removed completely and the tube rotated 90° counter-clockwise so that the tip entered the left main bronchus. Use of the 'backwards, upwards, rightwards pressure' (BURP) manoeuvre was recorded. Whenever the POGO score for glottic view was <80% or Cormack Grade II or more on laryngoscopy, we applied the BURP technique to improve visualisation of the glottic opening.

Success at the first attempt at intubation was recorded by an independent observer. Two time durations were recorded; first, time taken for DLT insertion, and second, time taken for correct placement of DLT.

The time taken for DLT insertion was calculated from the time the laryngoscope passed between the patient's lips until three complete cycles of end-tidal carbon dioxide were displayed on the capnography using the timer incorporated in the Draeger Primus Anaesthesia Workstation. Time taken for correct positioning was defined as the time taken for fibre-optic bronchoscopy and readjustment of the DLT, if need be, for correct alignment. The primary outcome measure was time taken for successful DLT insertion. In case of multiple attempts, the time from laryngoscope insertion to withdrawal of blade in each unsuccessful attempt was added to the time taken for DLT insertion in the final attempt to calculate the time to successful DLT placement. The secondary outcome measures were time taken for correct DLT positioning, glottis visualisation (CandL and POGO score),<sup>[6]</sup> number of attempts, oropharyngeal/

dental trauma, DLT cuff rupture and haemodynamic changes.

The laryngoscope blade was inspected for blood stains and the buccal cavity, pharynx and larynx examined for any signs of trauma. Mean arterial pressure (MAP) and heart rate (HR) were recorded at baseline (before induction of anaesthesia), on laryngoscopy, on passage of DLT through the vocal cords and finally, on inflation of the bronchial cuff. Post-intubation bronchospasm was considered if increased airway pressure, expiratory rhonchi on auscultation, reduction in tidal volume during intermittent positive pressure ventilation and rise in end-tidal carbon dioxide occurred. If the arterial oxygen saturation, as measured by a pulse oximeter, dropped below 90% before successful intubation or if the intubation time exceeded 180 s, the intubation attempt was aborted. A trained assistant with a ready bag-mask device was always made available to ensure that no time was lost in assembling and applying the bag and mask as soon as SpO<sub>2</sub> dropped to 90%. Further, our patients were of ASA I and II with normal pulmonary function tests. In the event of multiple attempts at DLT insertion, both the DLT cuffs (tracheal and bronchial) were examined for any tear, and the patient adequately mask ventilated prior to the next attempt. The patient was withdrawn from the study in case of intubation failure.

Sample size calculation was done by G\*Power (Version 3.2.1, Kiel, Germany). Through the pilot study of five patients per group, the mean insertion time was calculated as 48.4 s in the Macintosh group, and 32.4 s in the D-blade group. The sample size was calculated as 29 patients per group with a power of 90%, at  $\alpha$  of 0.05 where the standard deviation (SD) of groups was 20.2 and 9.81, respectively. To allow for dropouts, we took  $n = 30$  patients per group.

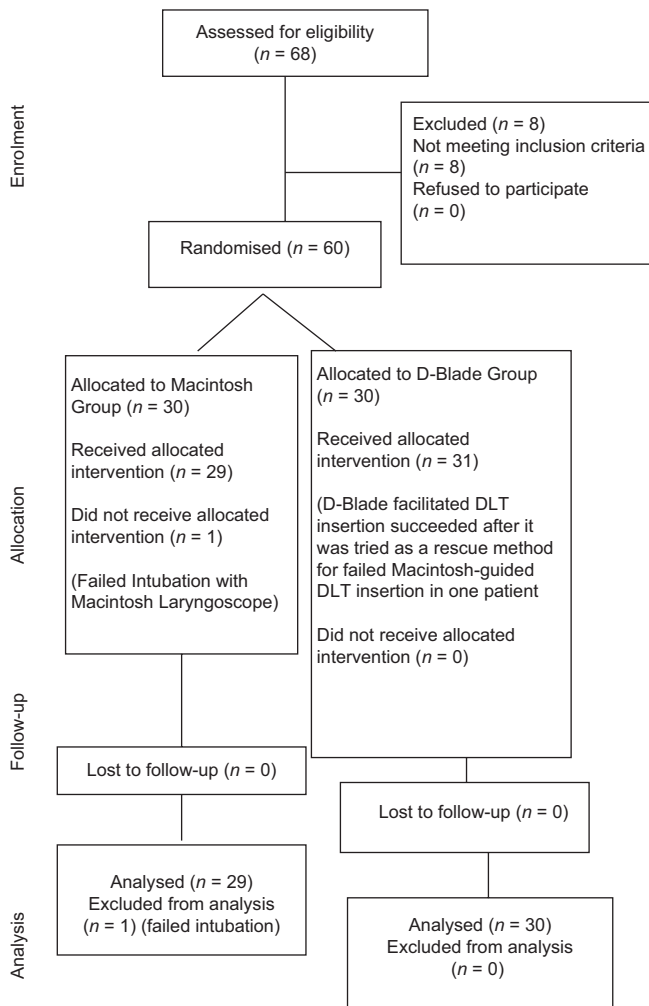
Simple computer-generated randomisation was done, and the method of concealment was sequentially numbered, sealed opaque envelopes. Statistical testing was conducted with the Statistical Package for the Social Science System version SPSS 17.0 Chicago SPSS Inc. Continuous variables were presented as mean  $\pm$  SD, and categorical variables were presented as absolute numbers and percentage. The comparison of normally distributed continuous variables between the groups was performed using Student's *t*-test. For intra-group comparisons, paired *t*-test was used. Nominal categorical data between the groups were compared using Chi-squared test or Fisher's exact test

as appropriate.  $P < 0.05$  was considered statistically significant. A single investigator was responsible for enrolling patients and assigning them to one of the two groups. In this single-blind trial, the patients were blinded to the laryngoscope group assigned to them.

## RESULTS

The flow of participants is depicted by the CONSORT flow diagram [Figure 2]. The first patient was enrolled in April 2014. The trial ended in May 2015 after the requisite number of cases was successfully completed.

Both groups were comparable with respect to age, height, weight, gender distribution, ASA status and EGRI [Table 1]. Five patients in the Macintosh group and 6 patients in the D-blade group were predicted to have a difficult airway as per EGRI.



**Figure 2:** The CONSORT diagram showing the flow of participants through each stage of MACD double-lumen tube randomised controlled trial

The time required for endobronchial intubation and time required for correct DLT positioning was comparable, and the difference was not statistically significant [Table 2]. The percentage of patients with Cormack and Lehane Grade 1 was much higher in the D-blade group as compared to the Macintosh group [Figure 3]. The Cormack and Lehane grades were CL 1: 21/30 versus 8/30 ( $P = 0.0008$ ); CL 2a 5/30 versus 10/30 ( $P = 0.136$ ); CL 2b 3/30 versus 11/30; CL 3, 0/30 versus 1/30, for D-blade group as compared to Macintosh group respectively. The mean POGO score ( $68.10 \pm 24.29$  in Macintosh group and  $88.0 \pm 19.90$  in D-blade group;  $P = 0.001$ ) was significantly higher with the D-blade facilitated endobronchial intubations as compared to the Macintosh blade group even though the EGRI for predicting difficult airway predicted similar levels of difficulty in both the groups.

Fifty-three per cent of the patients could be intubated in the first attempt utilising the Macintosh blade whereas 87% of the intubations were successful in the first attempt using the D-blade [Figure 3]. In majority of the patients where intubation attempt needed to be aborted, the cause of abortion of intubation attempt was time duration exceeding 180 s. In only two patients, both belonging to the Macintosh group, the pulse oximeter reading dipping to 90% was the cause of termination of intubation attempt.

Bleeding or trauma was almost 4 times more frequent in the Macintosh group as compared to the D-blade group (10/30 vs. 3/30;  $P = 0.006$ ). The incidence of DLT cuff rupture (10/30 vs. 2/30;  $P = 0.012$ ) was 5 times higher in the Macintosh group. The incidence of entering the wrong bronchus was 4 times greater in the D-blade group (4/30 vs. 1/30;  $P = 0.112$ ), and this was easily rectified using the fibre-optic bronchoscope. In 10% cases belonging to the Macintosh group, the DLT slipped into the oesophagus whereas no oesophageal intubation was witnessed in the D-blade group (3/30 vs. 0/30;  $P = 0.239$ ) [Figure 3].

The HR and MAP values were recorded in both the groups at four identical time-points namely, before induction of anaesthesia (T-1), at the beginning of laryngoscopy (T-2), just when the DLT crossed the vocal cords (T-3) and on bronchial cuff inflation (T-4). The HR in both the groups was comparable at all-time points, and the change in HR from baseline was not statistically significant. The MAP in both the groups was comparable before induction of

**Table 1: Demographic parameters**

Demographic parameters	Macintosh group		D-Blade group		P
	Mean±SD	Minimum-maximum	Mean±SD	Minimum-maximum	
Age (y)	52.13±12.69	20-69	54.57±11.06	25-69	0.124
Weight (kg)	71.73±14.30	37-105	67.90±7.44	50-84	0.198
Height (cm)	166.86±7.86	150-179	167.60±7.18	151-177	0.727
Sex (female/male)	10/20	NA	8/22	NA	0.390
EI Ganzouri risk index (0, 1, 2, 3, 4, 5)	5, 8, 8, 4, 3, 2	NA	2, 7, 9, 6, 5, 1	NA	0.395
ASA grade (I/II)	16/14	NA	14/16	NA	0.596

SD – Standard deviation; NA – Not available; ASA – American Society of Anesthesiologists

**Table 2: Comparison of time to intubate and time for double-lumen tube placement**

Groups	Mean±SD (minimum-maximum)	
	Time taken for insertion of DLT	Time taken for correct placement of DLT
Macintosh group (n=29)	37.41±18.80 (15-90)	81.41±19.70 (35-180)
D-blade group (n=30)	32.27±11.13 (20-62)	88.75±14.33 (40-198)
P	0.438	0.357

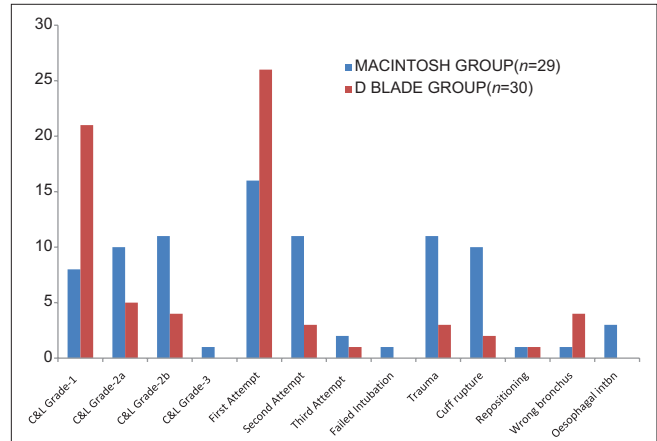
SD – Standard deviation; DLT – Double-lumen tube

anaesthesia (baseline). On initiation of laryngoscopy, the rise in MAP was significantly greater ( $P = 0.001$ ) in the Macintosh group ( $86.83 \pm 10.74$  mmHg) as compared to the D-blade group ( $78.93 \pm 7.19$  mmHg). When DLT crossed the vocal cords, the MAP was  $101.73 \pm 16.75$  mmHg and  $94.13 \pm 9.27$  mmHg in the Macintosh and D-blade groups, respectively ( $P = 0.035$ ). On bronchial cuff inflation, the MAP was significantly higher ( $P = 0.001$ ) in the Macintosh group ( $115.83 \pm 13.47$  mmHg) as compared to the D-blade group ( $86.37 \pm 6.48$  mmHg) [Figure 4].

### DISCUSSION

The CMac D-blade videolaryngoscope™ (Karl Storz GmbH and Co.KG, Tuttlingen, Germany) shows a pronounced angulation of 40°. Unlike other blades in the CMac assortment, the latest D-blade’s camera chip, optical lens (aperture 80°) and light socket are located closer at just 40 mm from the steel blade’s distal tip. The light source comprises a high-power LED connected to a portable 7inch display monitor.<sup>[7,8]</sup> Hence, the three airway axes need not be aligned to make intubation possible.<sup>[7-9]</sup>

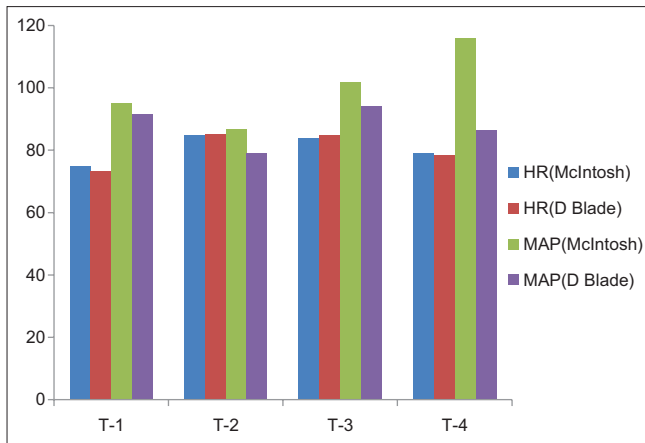
DLTs have a greater external diameter and are relatively more rigid than regular single-lumen tubes; therefore, insertion is technically more difficult and stressful.<sup>[1,10-12]</sup> Laryngoscopy alone is the major trigger of stress response depending upon two independent variables: Duration of intubation and force exerted



**Figure 3:** Comparison of 1. Glottic view (Cormack and Lehane grade); 2. Number of intubation attempts required for successful double-lumen tube placement and 3. Complications resulting from double-lumen tube insertion; Values on the Y-axis depict the number of patients related to the parameters compared

on the tongue. The former is comparable for both the groups as per the primary outcome of our study while the force exerted on the tongue is lesser when the D-blade is used which may be the reason behind the greater haemodynamic stability exhibited by the D-blade group. This makes it an attractive alternative to the standard Macintosh blade for DLT insertion in patients with poor cardiac reserve where intraoperative tachycardia and hypertension increases the risk of myocardial ischaemia and infarction.

Improvement in glottic view, especially in patients with reduced mouth opening and limited neck extension, is an added advantage of the D-blade (26.7% vs. 70% CL grade 1 and 68% vs. 88% mean POGO score). There was one noteworthy instance (Cormack Lehane grade 3 with Macintosh laryngoscope which improved to CL 2b with the video laryngoscope) when the D-blade came to our rescue where conventional laryngoscopy with the Macintosh blade failed, and we could successfully intubate the trachea using the video laryngoscope.



**Figure 4:** Comparison of haemodynamic changes (heart rate in beats/minute and mean arterial pressure in mmHg)

The number of attempts at intubation has a direct co-relation with airway difficulty and the fact that 86.7% of the patients could be intubated in the first attempt with the D-blade as against only 53.3% in the Macintosh group despite similar predicted difficult airway risk (EGRI), proves that the D-blade reduces airway difficulty and shifts the CL grade 1 notch upwards.<sup>[13]</sup>

As reported by Maassen *et al.*, the maximum force on the maxillary teeth using Macintosh direct laryngoscopy (61N) was 8 times larger than that attained during indirect video laryngoscopy (7.6N).<sup>[14]</sup> This diminishes the risk of dental trauma, especially in patients with a difficult airway.

A sequential lookup, look-down technique described by Karalapillai *et al.*<sup>[15]</sup> can further minimise the risk of trauma while using the D-blade. Both, insertion of the D-blade into the oral cavity and DLT into the oral cavity must be done under direct vision (look down) This is alternated with visualisation of the larynx and directing the DLT through the vocal cords which are both done by 'looking up' at the display monitor. This may have reduced the incidence of trauma to one-fourth that in the Macintosh group in our study. During standard Macintosh laryngoscopy, the DLT stylet is 4 cm from the distal end of the tube whereas in our study, we placed the stylet 4.5 cm above the distal end of the tube as an added precaution so as not to damage the tracheal mucosa due to the increased curvature of the DLT in the C Mac D-blade group.

There were three instances when the DLT slipped into the oesophagus in the Macintosh group while there was no such event in the video laryngoscope

group since the endotracheal intubation was done under vision until the last moment when the DLT successfully entered the trachea. Hence, with the airway secure, there was ample time to thoroughly check lung isolation by conventional auscultatory method as well as fibre-optic confirmation of DLT placement without worrying about a possible oesophageal intubation, especially in CL 2b and above difficult airway scenarios. Probing blindly under the epiglottic fold in CL grade 3 patients results in longer time and rising number of futile attempts at intubation while causing complications such as mucosal trauma, arytenoid dislocation and even tracheal rupture.

Increased incidence of DLT entry into the wrong bronchus is attributable to the fact that the original preformed shape of the anterior concavity of the DLT was slightly altered to conform to the greater angulation of the D-blade before intubation with the D-blade. This can be easily rectified using the fibre-optic bronchoscope and in our view is a small price to pay for the significantly lesser incidence of trauma, cuff rupture and haemodynamic changes noted when utilising the D-blade.

A limitation of our study is that with the stylet *in situ* in the DLT, a lot of concavity is obtained in performing the DLT as per the D-blade and on withdrawal of stylet, it is difficult to blindly rotate the DLT into the respective bronchus causing a higher incidence of misplacement into the wrong bronchus. Tracheal injury may also result from this increase in concavity even though we were fortunate enough not to have encountered it. This warrants further evaluation. Another limitation of our study is that the predictive value of EGRI has been evaluated for conventional Macintosh laryngoscope and for glide scope video laryngoscope but not for CMac D-blade video laryngoscope. Our results co-relate with previous studies<sup>[13,16-19]</sup> using video laryngoscopes for DLT insertion<sup>[2,10,11]</sup> and may be extrapolated for other oncosurgical patients with similar demographic characteristics requiring DLT insertion

## CONCLUSION

D-blade videolaryngoscope™ is a useful alternative to the standard Macintosh laryngoscope for routine DLT insertion.

## Financial support and sponsorship

Nil.

## Conflicts of interest

There are no conflicts of interest.

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## Announcement

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