



Comparison of Efficacy of External Laryngeal Manipulation (ELM) from Right Versus Left Side during Modified Bimanual Laryngoscopy-A Randomised Cross Over Trial

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Abstract

Background: Glottic view differed when assistants provide external laryngeal manipulation (ELM) from right or left side. Objectives were to compare glottic view during direct laryngoscopy with ELM applied by assistant stationed on right side of scopist versus left. Primary outcome was best percentage of glottic opening (POGO) score. Secondary outcome was proportion of patients requiring switch back to initial intervention for best glottic view and intubation.

Methods: With Institutional Review Board and Ethics Committee approval and written informed consent, this randomised cross over trial enrolled participants of American Society of Anesthesiologists (ASA) grade I–II aged 20–70 years for elective surgery under General Anaesthesia (GA). Study interventions were application of ELM during modified bimanual laryngoscopy by trained assistant on right (ELM-R) and left (ELM-L) sides in each participant as per random sequence.

Results: Of the 150 participants, 68 were analysed for study interventions using Wilcoxon matched pairs test. Thirty three participants received interventions first from ELM-R and subsequently from ELM-L, while 35 had interventions vice versa. Median POGO score with ELM-R was 40 (IQR: 32.5, 50) and with ELM-L 30 (IQR: 20, 40). There was 10% difference in POGO score between interventions found to be significant ($P < .05$). Fifty six out of 68 (82.35%) participants had better POGO score when intervention was from right side. Proportion requiring switch back to initially applied intervention was 66.7% (22 out of 33) with ELM-R and 2.9% (one out of 35) with ELM-L.

Conclusion: For best glottic view, ELM applied by an assistant by right hand standing on right side of scopist is more effective.

Keywords: External laryngeal manipulation, modified bimanual laryngoscopy, difficult airway, POGO score, personal protective equipment, Macintosh laryngoscope, glottic view

Introduction

Technique and skill of direct laryngoscopy is an essential prerequisite for safe practice of anaesthesia.¹ External laryngeal manipulation (ELM) is the most important manoeuvre used to bring more of the laryngeal opening into view during direct laryngoscopy. Optimal position of assistant applying ELM during direct laryngoscopy is undefined. Few authors have commented so far on optimum position of assistant with respect to patient or intubator during laryngoscopy such that best glottic view is attained early. Therefore, this randomised open label crossover study was designed to compare efficacy of ELM performed by trained assistants standing on right versus left side of laryngoscopist during modified bimanual laryngoscopy.

The aim of the study was to compare glottic view during modified bimanual laryngoscopy with ELM applied by assistant stationed on right side of scopist versus left. Primary outcome was best percentage of glottic opening (POGO) score achieved. Secondary outcome was proportion of patients requiring switch back to initial intervention (ELM from right or left side) for best glottic view and intubation.

Methods

This randomised cross over trial was conducted in our institution. Prior approval from Institutional Ethics Committee and Institutional Review Board of MOSC Medical College, Kolenchery, Kerala, India with order number MOSC/IEC/240/2017 dated April 4, 2017 was obtained for the trial. July 12, 2017, and in accordance with the guidelines of Helsinki Declaration of 1975, as revised in 2000. Null hypothesis states that there is no difference between POGO scores obtained when ELM is applied by assistant standing on right versus left side of scopist during modified bimanual laryngoscopy. Alternate hypothesis was that POGO scores obtained are not equal when ELM is applied by assistant standing on right versus left side of scopist during modified bimanual laryngoscopy.

Anaesthetist unrelated to study did the computer generated block randomisation of sequence of study interventions. All eligible participants were allocated to study interventions ELM-R (ELM from right side) and ELM-L (ELM from left side). Position of assistant and his hand and fingers used when applying ELM determined the difference between the interventions. The ELM-R was applied by assistant standing on right side of laryngoscopist and ELM-L standing on left side. The interventions were sequenced RL (right followed by left) and LR (left followed by right) in two periods.

Sample Size

ELM is a very short procedure without any carryover effects or period effects making wash out period irrelevant. A pilot study was conducted for calculation of standard deviation of primary outcome (POGO score) and estimation of sample size. Out of 64 participants enrolled in pilot study, 30 with POGO score below 50% required ELM for the best glottic view and tracheal intubation. On comparison of POGO score obtained with study interventions, ELM-R and ELM-L resulted in standard deviation of 21. Sample size for each

intervention in full trial was 34 participants calculated using the formula viz.

$$n = \frac{\sigma^2 (z_{(1-\alpha/2)} + z_{(1-\beta)})^2}{\mu_d^2},$$

where “n” denotes minimum sample size for each intervention, $\sigma(\text{SD}) = 21$, $\alpha = 0.05$, $\beta = 0.2$ and μ_d minimum clinically important effect size of 10%.

Inclusion and Exclusion Criteria

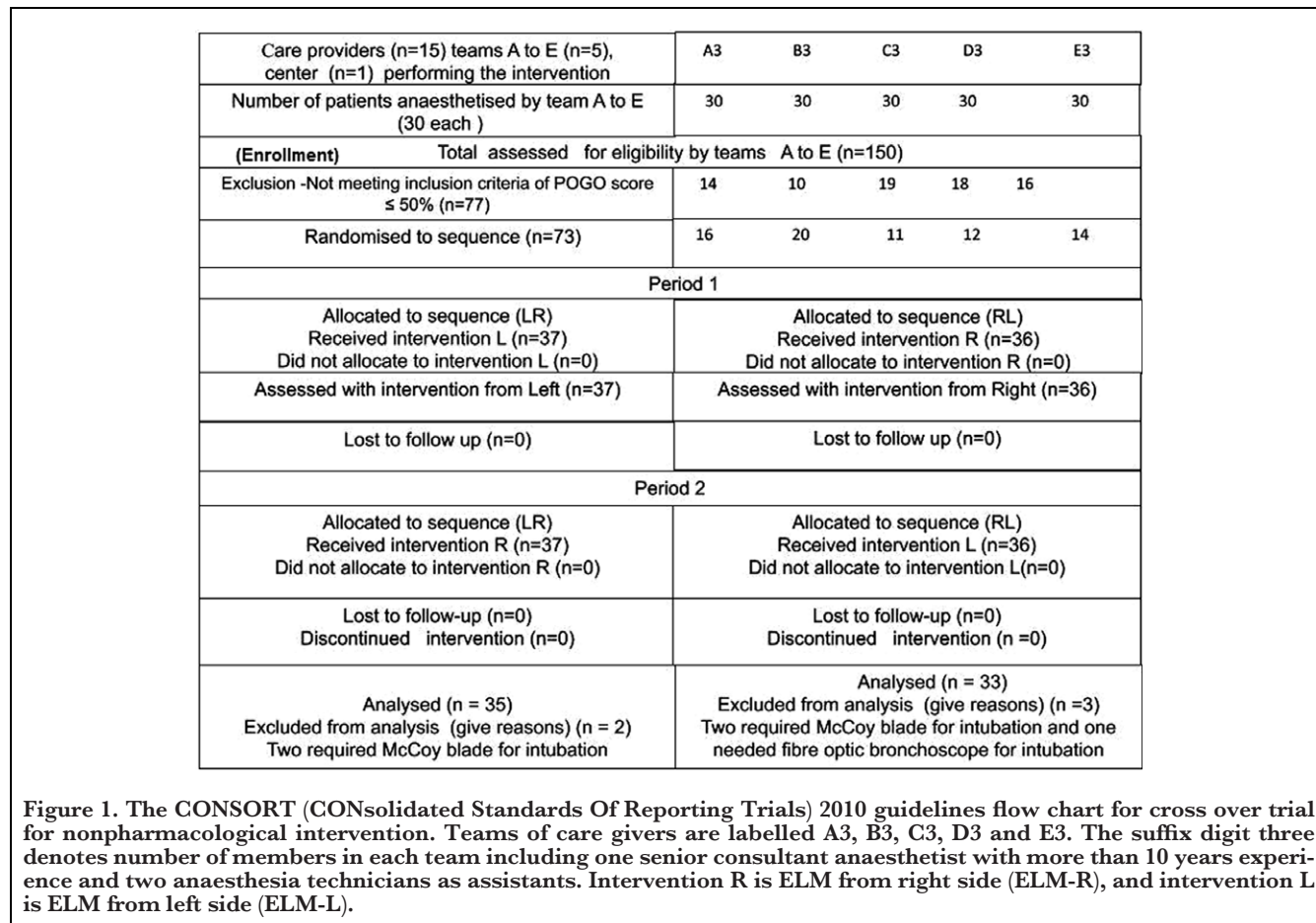
Participants with American Society of Anesthesiologists physical status I–II, aged 20–70 years scheduled for elective surgery under general anaesthesia were enrolled. Patients with a history of difficult intubation, incisor gap less than three fingers, pregnancy, POGO score more than 50% on direct laryngoscopy, participants who required a different method for glottis view or intubation were excluded from study intervention. Participants in which ventilation with a face mask became impossible were also excluded. Flow chart as per The CONSORT (CONsolidated Standards Of Reporting Trials) 2010 guidelines (CONSORT) guidelines of 150 patients enrolled after written informed consent is shown in Figure 1.

Anaesthesia Protocol

The design, inclusion and exclusion criteria, random allocation and anaesthesia protocol were same for pilot study and final trial. Five consultant anaesthetists with more than 10 years of experience who were familiar with POGO score conducted the laryngoscopy and intubation. The study was planned to be completed in a period of 6 months so that each consultant will be conducting only five cases per month with at least 1 week interval between two adjacent cases. Consultants were randomly assigned 30 participants each by draw of lots for the conduct of anaesthesia and study interventions. After attaching pre-induction monitors pulse oximeter, ECG and noninvasive blood pressure, a 20 gauge cannula was inserted on dorsum of right hand and Ringer lactate commenced at 75 mL h⁻¹. All patients were premedicated with intravenous midazolam 1 mg and fentanyl citrate 50 µg. The patient's head was placed in the sniffing position, elevated with a pillow under occiput and table tilted 25° backup so that external auditory meatus and sternal angle were in same horizontal line. Height of operation table was adjusted so that xiphisternum of intubator was corresponding to forehead of participant. Patients were preoxygenated for 3 minutes with fresh gas flow 8 L min⁻¹ using circle system with APL valve fully open. Anaesthetic induction was with propofol 2.5 mg kg⁻¹ and complete muscle paralysis attained with vecuronium 0.1 mg kg⁻¹. Depth of anaesthesia was maintained with volatile anaesthetic sevoflurane, and laryngoscopy was performed using Macintosh laryngoscope blades, preferably with sizes three and four in females and males, respectively. Pulse rate, blood

Main Points

- Optimal laryngeal view is a prerequisite for safe first pass success during laryngoscopy and tracheal intubation.
- External laryngeal manipulation (ELM) improves glottic view during tracheal intubation, when percentage of glottic opening (POGO) score is suboptimal.
- Previous studies have not compared the effect of ELM done by assistant standing on the right versus left side of the scopist and its impact on laryngeal view.
- ELM applied by the assistant by right hand, standing on the right side of the scopist will improve the glottic view significantly during modified bimanual laryngoscopy, while application from the left side may distort the glottic view.
- Correct technique and time are critical factors for patient safety, during airway management in an emergency.



pressure and oxygen saturation were being continuously monitored during laryngoscopy and intubation. Tracheal tube position was confirmed with a sustained reading of end tidal carbon dioxide tension. During laryngoscopy, POGO score was evaluated first without ELM. Participant was included in study if POGO score was 50% or lower. Soon the serially numbered sealed opaque cover was opened by an anaesthetist not involved in the study. He revealed the randomly allocated sequence by which ELM was to be applied from right side followed by left or vice versa in each participant. Laryngoscopist with his right hand guiding the hand of assistant for ELM continued the scopy for attaining the best glottic view during modified bimanual laryngoscopy. In RL intervention sequence, ELM-R was applied first and subsequently ELM-L. In LR intervention sequence, ELM was applied first from ELM-L followed by from ELM-R. In both sequential interventions, subsequent ELM was applied only after POGO score during initial ELM was noted and hand of assistant withdrawn from that side of neck. POGO score was thus evaluated thrice in all participants allocated in both interventions. The score was first assessed without ELM and then with ELM-R and ELM-L as per the randomly allocated sequence. Assistants pre-positioned one on either side of laryngoscopist were

instructed to use their corresponding hands for applying ELM. Assistant on right side of scopist used his right hand and that on left side used his left hand. The assistant's hand as if it is an instrument, with thumb on one side and index and middle fingers on other side of thyroid cartilage, was physically guided by scopist to apply ELM. POGO score during each ELM was noted and trachea intubated in the best possible glottic view. Number of attempts for intubation was also recorded. Number of participants who required a switch back to first applied ELM-R or ELM-L for intubation in the best laryngeal view was also noted.

Data

Collected data was analysed using software (EZRversion 1.41). POGO scores were compared using Wilcoxon matched pairs test for any significance as data do not follow normal distribution based on Kolmogorov–Smirnov test. A $P \leq .05$ was considered to assume statistical significance.

Results

This study was carried out over a period of 6 months from January 2018. As given in Tables 1 and 2, the average age,

Table 1. Particulars of Participants in Allocated Sequence of (ELM) Intervention

Particulars	Sequence of the intervention (ELM)	Median (IQR)	U test	P
Age	RL	43 (32, 50)	460	.149
	LR	49 (31, 57)		
Weight (kg)	RL	61 (58, 68)	575	.975
	LR	62 (55, 70)		
Height (m)	RL	1.58 (1.52, 1.63)	564	.868
	LR	1.56 (1.52, 1.67)		
BMI	RL	25.28 (22.65, 27.06)	521	.448
	LR	24.61 (22.89, 25.97)		
Modified Mallampati score	RL	1 (0, 1)	509	.334
	LR	1 (0, 1)		
Thyromental distance (cm)	RL	5 (5, 6)	473	.163
	LR	5 (5, 6)		

P < .05 is statistically significant.
 ELM, external laryngeal manipulation; RL, ELM from right followed by ELM from left side; LR, ELM from left side followed by ELM from right side; IQR, interquartile range.

Table 2. Chi-square Tabse Showing Male and Female, Distribution of Participants for the Interventions ELM-R and ELM-L in Sequences of RL and LR of RL and LR

Sex	Intervention sequence of ELM		x ²	P
	RL	LR		
Male	18	18	0.06	.79
Female	15	17		

P < .05 is statistically significant.
 ELM-R, external laryngeal manipulation from right side; ELM-L, external laryngeal manipulation from left side; RL, right followed by left side; LR, left followed by right side.

sex, BMI, modified Mallampati scores and thyromental distances were similar in all participants in both sequences of interventions. All patients were easy to ventilate, and there was no failed intubation. None of the participants required a second attempt for intubation. Two participants each in both sequences of interventions, RL and LR, required McCoy blade and one in intervention sequenced RL needed fibre optic bronchoscope for intubation and were excluded from analysis. Among 150 participants, 77 were excluded as their initial POGO score on direct laryngoscopy without ELM was more than 50%. Of the 73 enrolled, five were excluded from analysis as they required a different method for intubation as detailed. Sixty-eight participants enrolled were analysed for study interventions using Wilcoxon matched pairs test. Thirty-three participants received inter-

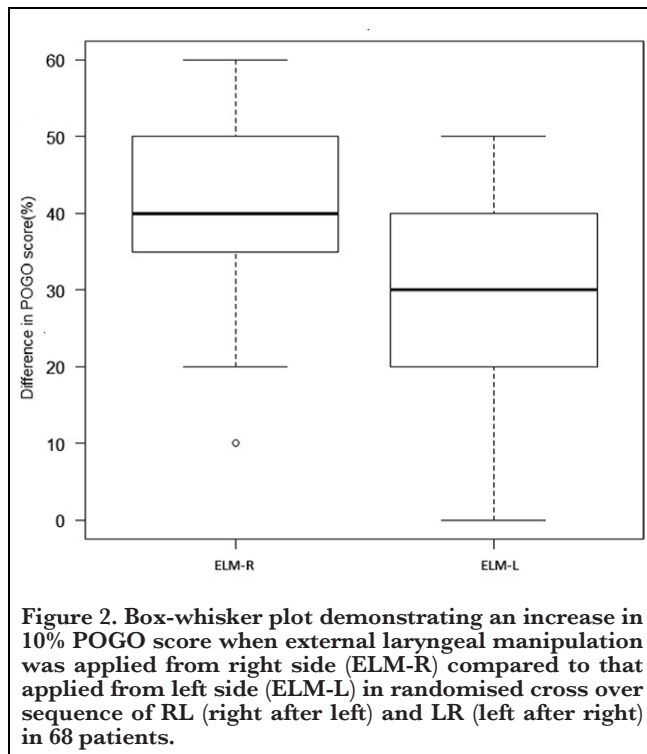
ventions first from ELM-R and subsequently from ELM-L. Remaining 35 participants received interventions first from ELM-L followed by from ELM-R. As given in Table 3, median POGO score with ELM-R and ELM-L was 40 (IQR: 32.5, 50) and 30 (IQR: 20, 40), respectively. There was a 10% difference in POGO score obtained between the two interventions with *P* < .001 (sig *P* ≤ .05) as explained by the Box-Whisker plot given in Figure 2. Fifty-six out of 68 (82.35%) participants had a better POGO score when the intervention was from ELM-R. Proportion of patients who required a switch back to initially applied ELM was 22 out of 33 (66.7%) with intervention ELM-R and one out of 35 (2.9%) with intervention ELM-L.

Discussion

To our knowledge, this is the first randomised trial comparing glottic views when ELM is applied from right versus left side of scopist during modified bimanual laryngoscopy. Present study shows that during direct laryngoscopy for obtaining best glottic view, in patients with POGO score below 50%, modified bimanual laryngoscopy with ELM applied from right side is significantly more effective compared with that applied from left side. The very high proportion of switch back to the intervention from right side in the RL sequence of intervention demonstrates the efficacy, reliability and consistency of the intervention when performed from right side. Very low number of reapplication of the intervention from left side in the LR intervention sequence denotes the very high risk involved if care is not taken regarding position of

Table 3. Showing Test Statistic of Comparison of Intervention				
Study intervention	Median	IQR (Q1, Q3)	Wilcoxon matched pairs test statistic (Z)	P
ELM-R	40	(32.5, 50)	-6.44	<.001
ELM-L	30	(20, 40)		

P < .05 is statistically significant.
IQR, interquartile range; ELM-R, external laryngeal manipulation from right side; ELM-L, external laryngeal manipulation from left side; Q1, first quartile; Q3, third quartile.



assistant designated for ELM during modified bimanual laryngoscopy for management of a difficult airway.

Need for ELM and number of attempts are indicators of difficulty encountered during laryngoscopy and intubation.² First line use of Macintosh laryngoscope for securing airway is a common practice. During direct laryngoscopy, laryngeal view is easier while using straight blades but intubation is easier when curved blades are used.^{3,4} ELM helps in reducing the incidence of Cormack and Lehane grade IV from 9% to 1.3% of cases.⁵ Glottic view during laryngoscopy can be assessed using validated POGO score.⁶ In a systematic review and meta-analysis of randomised control trials, Ludwin et al.⁷ have concluded that wearing of personal protection equipment reduces the effectiveness of endotracheal intubation. This meta-analysis without reference to ELM found that on comparison, direct laryngoscopy is associated

with overall intubation time reduction and intubation success rate than videolaryngoscopy. Hahn et al.⁸ found that ELM when applied during indirect laryngoscopy with C-MAC and Glidescope video laryngoscopes significantly improve POGO score. Best way to apply optimal ELM on the larynx is by laryngoscopist's thumb, index and middle fingers of right hand.⁹ Knill named external laryngeal pressure as backwards upwards and rightwards pressure (BURP) where two fingers of assistant are used to achieve directional movement of thyroid cartilage.¹⁰ Levitan et al.¹¹ termed application of ELM during laryngoscopy as bimanual laryngoscopy. In conventional bimanual laryngoscopy, the scopist applies pressure over lower part of thyroid cartilage to obtain best glottic view. When scopist takes away his right hand for intubation assistant takes over to continue the same pressure and push on the cartilage as told by scopist. During modified bimanual laryngoscopy, scopist physically guides right hand of assistant already placed over thyroid cartilage for applying ELM, thereby ensuring dynamic continuity of best glottic view during intubation.¹² As the number of attempts at intubation increases, incidence of adverse events increases substantially. Knopp in an editorial has opined that ELM is a simple but effective and essential technical skill to be practiced by emergency physicians for tracheal intubation.¹³ Soltani et al.¹⁴ found that cricoid pressure in combination with BURP manoeuvre improves glottis view, while cricoid pressure alone worsens it in paediatric patients under general anesthesia. Glottis view is the main determinant of successful tracheal intubation during direct laryngoscopy. When difficulties arise, ELM is usually the first and simplest technique to facilitate glottis view at the first intubation attempt. ELM is a directional push on thyroid cartilage by intubator's or assistant's right hand so that best glottic view is obtained during laryngoscopy. Stein et al.¹⁵ in a standard mannequin study by novice intubators found that head elevation is the most effective manoeuvre for improving laryngoscopic view in a normal airway and ELM as most effective in difficult airway. Ochroch et al.¹⁶ found that both modified version of Cormack and Lehane grading classification and POGO score have good inter-physician and intra-physician reliabilities. Because POGO score can distinguish patients with large and small degrees of partial glottic visibility, it might provide a better outcome for assessing difference between

various intubation techniques. Levitan noted that in cadaver models laryngoscopic view improved with bimanual laryngoscopy by 25% when compared with no manipulation, cricoid pressure and BURP on larynx. Levitan also found that pressing on neck during curved blade laryngoscopy greatly affects laryngeal view. Swann et al.¹⁷ have referred to the need for anterior laryngeal pressure for obtaining best laryngeal view measured by Fremantel score during videolaryngoscopy. Harioka et al.¹⁸ in their comparative study found that McCoy blade along with ELM had a better laryngeal view than without during direct laryngoscopy. Akhtar et al.¹⁹ and Prakash et al.²⁰ in two separate trials comparing simple head extension with sniffing position during laryngoscopy found that patients in simple head extension group required ELM more than those in sniffing position. Kim et al.²¹ in their study found that sniffing position and elevated sniffing position provide better laryngeal views when compared to simple extension of head during direct laryngoscopy in edentulous patients. Reddy et al.²² on comparing glottic views in supine and 25° head up positions found that the latter group required less ELM for better glottic view. Thus, during direct laryngoscopy sniffing position, head end elevation of 25° along with ELM has an important role for improvement of glottic view and early, less traumatic tracheal intubation. As the POGO scoring system allows for the detection of minor changes in laryngeal views, in our study a minimally effective clinical difference in POGO score was taken as 10%.²³ In emergency unanticipated difficult airway scenarios, even a 10% difference may allow early and safe passage of a bougie or tracheal tube into trachea in first attempt. Out of hospital settings, being more challenging for securing airway, optimal ELM will reduce laryngeal trauma and mortality. This requires ideal or optimal positioning of assistant in relation to patient and/or the intubator along with head elevation with sniffing position and 25° propped up position. Improper application of cricoid pressure and BURP on thyroid cartilage may obscure laryngeal view.¹¹ The statement of Davies J, that assistant be directed to stand on right side of patient to apply pressure on larynx, is clinically appropriate but lacks evidence.²⁴ Till date no study has compared glottic view when ELM is applied from right or left side of scopist or patient. In this study conducted in operating room, anesthesia technicians trained in ELM as part of job were selected as assistants. They were assigned to stand on either side of laryngoscopist. Standing on either side of the laryngoscopist will provide for the ease of assistance and maximum mechanical advantage for applying ELM. Assistants standing on right and left sides were instructed to offer their right and left hands respectively, as if it was an instrument or as an extension of fingers of the laryngoscopist, for applying ELM as manually guided by scopist.²⁵ Difference in POGO score between the interventions ELM-R and ELM-L may be explained by the position of hands and fingers leading to difference in the forces applied from either side. In this study when scopist after guiding ELM takes away his hand for

intubation, the assistant from left side continues the push and pressure as physically guided, with left thumb while the other two fingers remain passive. On his turn, assistant from right side continues the pull and pressure as guided, with the two fingers of his right hand, the thumb being held passive. Use of two fingers (index and middle fingers) will result in a uniform force over the whole area and results in a translation of thyroid cartilage leading to best laryngeal view by shifting larynx in the direction of line of sight during laryngoscopy. In contrast, the localised forces created due to use of left thumb alone from left side may create a couple that can cause a rotation of thyroid cartilage rather than a translation leading to poor view of glottis. Handedness has not affected the result of the study as ELM was guided by laryngoscopist to attain maximum glottic view. Left handed assistants applying ELM from left side may not improve glottic view as the area covered by thumb will be less than that covered by index and middle fingers, thereby applying more force from left side distorting the glottic view. In our study, when ELM was applied from right side, median POGO score improved by 10% more than when applied from left.

Strengths and Limitations

Primary outcome was laryngeal view and not success of first attempt intubation. None of the cases had failure of first attempt or traumatic intubation except five cases which were excluded requiring other methods of laryngoscopy. Thus, the incidence of unanticipated difficult airway was comparable. Intubation time was not recorded, as only ASA I and II patients without anticipated difficult airway were included and anesthesia was induced as per protocol. POGO score described with video laryngoscopy was used in direct laryngoscopy. The study could not be done involving left handed assistants. This is a small, single centre study. Reducing the effect of learning and bias in airway studies could be achieved by multicentre double blind studies of two separate groups with large power and sample size involving only one participant for one consultant. In this study, critical position of the assistants only in relation to the scopist was studied. Position of assistants on either side of the shoulder of patient was not made part of trial. Cormack and Lehane grading was not checked which is a standard method of assessing glottic view on laryngoscopy. The pressure or force exerted on thyroid cartilage was not measured.

The study was partially blinded, but conducted according to protocol, thereby reducing chance of bias. Being a crossover study requires only small sample size and random error is less since the participant himself forms his or her own comparison. Smallest effect size of ten percent may appear theoretically ineffective but is clinically significant in unanticipated difficult airway. Uniform lifting force during laryngoscopy was assumed as the laryngoscopists were experienced anaesthesiologists. Due to ethical reasons and preference to safety in airway study avoidance of factors like 25° back up position of patient, neck flexion with pillow, adjusting table height so that forehead of patient corresponds to

xiphisternum of the scopist in all cases was not attempted. Avoidance of these factors might have provided conditions for the effectiveness of the study interventions producing higher percentages of difference than the minimum clinically effective difference measured. Based on this study, caregivers will be sensitised to select their position in relation to the scopist while securing airway. Approach to difficult airway remains modified to this extent.

Conclusion

ELM applied by assistant with right hand stationed on right side of scopist results in a consistently better glottic view when compared to that obtained with the assistant applying ELM with left hand positioned on left side of scopist. Application of ELM from the left side of the patient may distort the glottic view. During modified bimanual laryngoscopy, assistant should keep his hand on thyroid cartilage as if it is an instrument for the scopist to handle.

Clinical Significance

ELM is a definite skill to be acquired by caregivers for management of the airway by laryngoscopy and tracheal intubation. For best laryngeal view, ELM should be applied correctly on thyroid cartilage with the right hand of assistant standing on right side of the scopist.

Ethics Committee Approval: Ethical committee approval was received from the M.O.S.C. Medical College (MOSC/IEC/240/2017 dated April 21, 2017).

Informed Consent: Informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

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Conflicts of Interest: The authors have no conflicts of interest to declare.

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