Original Article

Intubation during spinal motion restriction using the Lubo™ cervical collar - a manikin simulation study

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ABSTRACT

Introduction: The Lubo™ collar is a cervical motion restriction device featuring a unique external jaw-thrust mechanism designed to provide non-invasive airway patency. In addition, tracheal intubation is facilitated by releasing an anterior chin strap; this allows better mouth opening than the previous generation of semi-rigid cervical collars. This study aimed to compare tracheal intubation using the Lubo™ collar combined with manual in-line stabilization (MILS) to intubation with MILS alone. The primary outcome was the time to successful intubation. Secondary outcomes compared intubation success rate, Cormack-Lehane grade, ease of intubation and dental trauma.

Methods: A randomized, cross-over, equivalence study was performed. Eighty full-time physician anaesthesia providers were recruited. Participants performed tracheal intubation using direct laryngoscopy on a manikin under two different scenarios: with the Lubo™ collar and MILS applied, and with MILS and no cervical collar. The time to successful intubation was measured and compared using two-one-sided and paired t-tests.

Results: Intubation times fell well within the *a priori* equivalence limits of 10 seconds, with a mean difference (95% CI) of 0.52 seconds (-1.30 to 2.56). There was no significant difference in intubation time with the Lubo™ collar (mean [SD] 19.2 [4.5] seconds) compared to the MILS alone group (19.7 [5.2] seconds). The overall success rate was 98.7% in the Lubo group and 100% in the MILS group. Adequate laryngoscopy views (Cormack-Lehane grades I to IIb) were equivalent between groups (Lubo 92.5% versus MILS alone 93.7%).

Conclusion: In this manikin-based study, the time to intubation with the Lubo™ collar and MILS applied was equivalent to time to intubation with MILS alone, with similar intubating conditions. Thus, the Lubo™ collar and MILS may simplify airway management by reducing the number of steps required to perform intubation in patients requiring cervical motion restriction.

African relevance

- The Lubo™ cervical collar is a novel cervical motion restriction device that may provide improved airway access in the prehospital setting.
- The collar functions as a non-invasive airway device with an external jaw-thrust mechanism to improve airway patency, which may serve as a stand-alone device or supplemental airway adjunct.
- This simplified airway management using the device may be beneficial in a resource-limited setting.
- This study examined the utility of the Lubo™ collar using standard airway equipment which is widely available on the African continent.

- This device might prove to be a useful alternative to current cervical collars, which place limitations on airway management in the injured trauma patient.

Introduction

Cervical motion restriction (previously referred to as 'immobilization') is an intervention considered essential in the management of patients with a suspected cervical spine injury.

The application of rigid or semi-rigid cervical collars has been shown to place limitations on airway management by prolonging attempts at intubation and worsening the Cormack-Lehane grade of view at laryngoscopy [1–3]. They are associated with reductions in mouth opening, cervical flexion and atlanto-occipital extension [3–5], making it difficult to align the airway to attain the same view that could be achieved in the optimal "sniffing" position. Due to suboptimal intubating conditions, added force is often needed to perform laryngoscopy with the rigid cervical collar in place. These additional forces have been shown to be transferred to the cervical spine, resulting in the motion of unstable cervical segments [1,4,6].
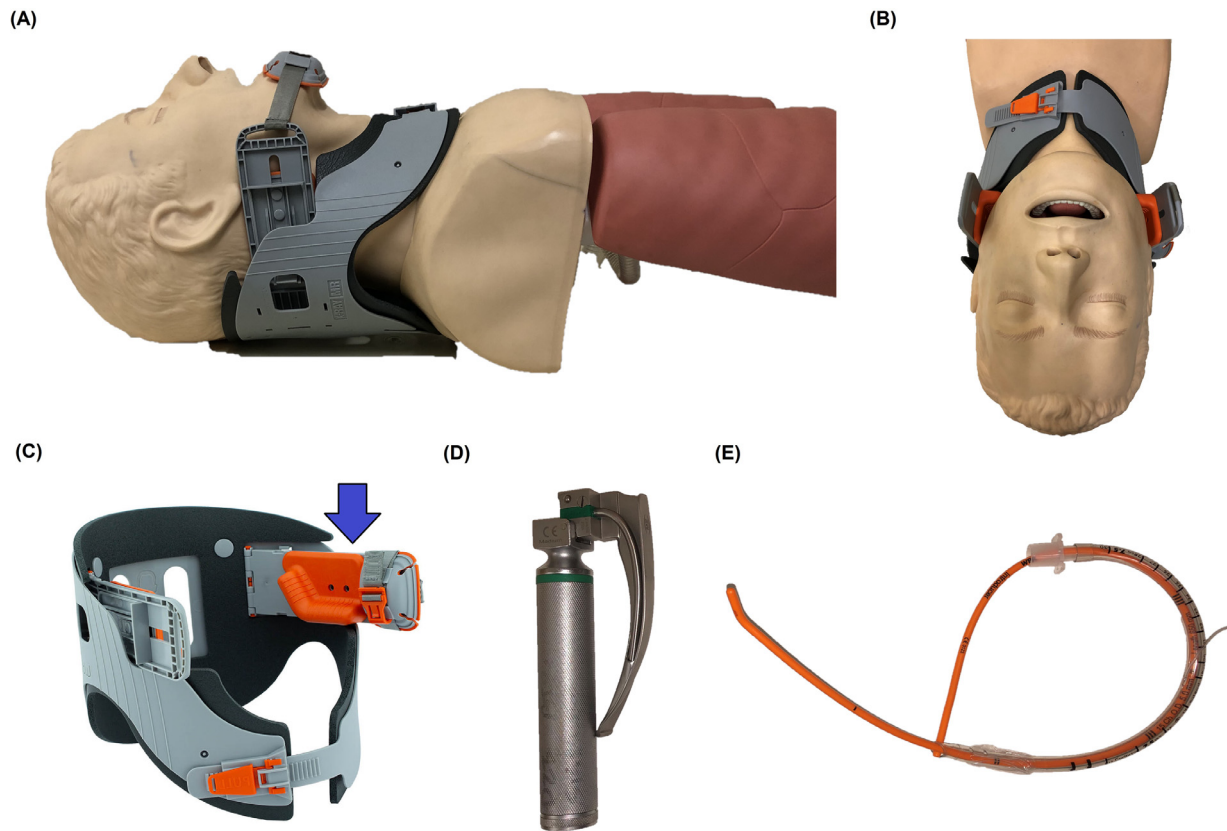
Fig. 1. (A) Manikin with Lubo^TM applied, (B) Lubo^TM with chin strap released, (C) Jaw-thrust mechanism, bilateral ridges facilitate anterior displacement of the mandible, (D) Macintosh laryngoscope, (E) Endotracheal tube pre-loaded with a gum-elastic bougie utilizing the DuCanto 'D-grip' [19].

Current recommendations are to maintain cervical motion restriction with manual in-line stabilization (MILS) during tracheal intubation [7–9]. If already in place, standard practice is to remove the cervical collar (or anterior portion thereof) while an assistant provides MILS and replace the collar on completion. However, the application and removal of cervical collars has been associated with motion of cervical segments [10,11]. Due to many disadvantages with the current generation of rigid cervical collars, many practitioners now recommend against their routine use [12–16].

A novel device, the Lubo^TM (Inovytec Medical Solutions LTD., Raanana 4366507, Israel), is a semi-rigid cervical collar with a few salient features. In addition to providing cervical motion restriction [17], it consists of an external jaw-thrust mechanism (Figure 1. C) aimed at improving airway patency. (This property is the subject of a separate study.) Furthermore, it allows intubation with the collar in place by release of the anterior chin strap [18] This may reduce the number of steps required to perform intubation and reduce the risk of applying additional forces to the injured cervical spine. Although it is theorized that the Lubo^TM allows intubation without removal, it is unknown whether the collar provides similar intubating conditions to MILS alone.

This study compared intubation when using the Lubo^TM collar with MILS to intubation with MILS alone. The primary outcome was equivalence in the time to successful tracheal intubation. As traditional cervical collars have been shown to hinder intubation attempts [1–5], our null hypothesis was that the time to intubation with the Lubo^TM would be delayed when keeping the collar in place. The secondary outcomes of the study were to: (1) compare the success of tracheal intubation, (2) assess the ease of intubation, (3) compare the Cormack-Lehane view of the larynx during laryngoscopy, and (4) assess the degree of dental trauma during laryngoscopy.

Methods

A prospective, randomized, cross-over equivalence study was performed with ethical approval by the University of Cape Town Human Research Ethics Committee (UCT HREC 394/2020).

Physician anaesthesia providers in an academic department were considered eligible for participation if they had more than one year of full-time anaesthesia experience and had performed more than 200 tracheal intubations during their careers. After written informed consent, participants were shown a presentation highlighting the application and clinical relevance of the Lubo^TM collar, and a practical demonstration was performed. Participants then each performed two manikin intubations. In one, the Lubo^TM collar remained in place with MILS applied (Lubo group), and in the other, MILS was maintained with no collar in place (MILS group; standard care). To minimize sampling bias or learning effect, participants undertook each simulation in a computer-generated random order (https://justflipacoin.com). To minimize variability, MILS was provided using a standardized technique by the same trained provider for both attempts.

Equivalence testing was used to compare the mean intubation times between the two groups. Sample size estimation was based on a review of data obtained from a previous study by *Smereka* [2], with the mean time to intubation for the two respective groups estimated at 27 ($\pm$7) and 23 ($\pm$5) seconds. An equivalence limit of 10 seconds was deemed to be clinically relevant. To achieve 90% power with an equivalence limit of 10 seconds and an alpha error of 0.025 using a two-one-sided test (TOST), we calculated that 59 subjects in a cross-over design would be required. However, a sample size of 80 participants was chosen to account for inaccuracy in sample size estimation, and loss of data pairs due to any failed intubations.

Table 1
Qualification level of participants.

Qualification	Number (n=80)	(%)
Consultant	35	43.7
Senior registrar	26	32.5
Junior registrar	12	15.0
Medical officer	7	8.8

Data were collected over one month at training hospitals associated with the University of Cape Town Department of Anaesthesia and Perioperative Medicine (Groote Schuur, New Somerset, and Red Cross War Memorial Hospitals), Cape Town, South Africa. Participants were afforded two practice attempts with no cervical immobilization before randomization. Participants then performed one attempt at intubation under both scenarios. Intubation times were measured in seconds from the participants' first contact with the laryngoscope until visual confirmation of successful lung inflation, using a digital stopwatch (Volkano Track Series, Volkano, New York, NY, USA). An attempt was deemed a failure if successful lung inflation could not be demonstrated, if oesophageal intubation occurred, or if the intubation attempt exceeded 60 seconds. All intubation attempts were performed on a Laerdal® Airway Management Trainer manikin (Laerdal Medical, Stavanger, Norway). Direct laryngoscopy was performed using a standard size 4 Macintosh laryngoscope. A size 7.5 cuffed endotracheal tube (Curity®, Tyco Healthcare, Mansfield, MA, USA), pre-loaded with a coude-tip introducer utilizing the DuCanto 'D-grip' [19] was used for all attempts at intubation.

Dental trauma was assessed by the surrogate measure of evaluating the number of manikin "teeth clicks" audible during laryngoscopy (induced by excessive force being applied to the teeth of the manikin). A modified Cormack-Lehane (Yentis and Lee) [20] grading system was used to evaluate the laryngoscopy view reported by participants in both scenarios . Subjective ease of intubation was ranked by each participant using a visual analogue scale (virtual slider), ranked from '0 to 100', with '0' being very easy and '100' being very difficult.

Study data were collected and managed using REDCap (Research Electronic Data Capture) [21, 22] electronic data capture tools. Data were then exported into MedCalc, Statistical Software, version 19.6 (MedCalc Software LTD, Ostrend, Belgium; http://www.medcalc.org; 2020) for further statistical analysis. Data were summarized using descriptive statistics, and the D'Agostino-Pearson test for normality was applied. The primary outcome was assessed using the two-one-sided and paired t-tests.

Results

Eighty participants completed the study, 42 of whom (52.5%) were female. The mean experience as a full-time anaesthesia provider was 8.9 years (95% CI 7.5 to 10.3). Participant level of qualification is shown in Table 1; more than 75% were highly experienced intubators of a senior registrar or consultant level.

Mean difference (95% CI) in intubation time between the two groups was 0.52 seconds (-1.3 to 2.6), falling within the *a priori* equivalence limit of 10 seconds (Fig. 2). Further assessment showed no significant difference in intubation time with the Lubo™ collar (mean [SD] 19.2 [4.5] seconds) compared to the MILS alone group (19.7 [5.2] seconds). One failure (oesophageal intubation) occurred in the Lubo group. As there was no time to tracheal intubation for this participant, they were excluded from analysis of the primary outcome.

Secondary outcomes are depicted in Table 2. The overall success rate was 98.8% in the Lubo group and 100% in the MILS group. As noted above, the failure in the Lubo group involved an oesophageal intubation.

Adequate laryngoscopy views (Cormack-Lehane grades I to IIb) were equivalent between groups (Lubo 92.5% versus MILS alone 93.7%). However, there were more Cormack-Lehane grade I views in the Lubo group (30% compared to 17.5%). No grade IV views were reported in either scenario (Fig. 3).

The ease of intubation is depicted in Fig. 4. In the MILS alone scenario, participants reported ease of intubation with a median of 40.5/100 (IQR 20-53). In the Lubo scenario, ease of intubation with a median of 32/100 (IQR 18-55) was reported. There was no observable trend in ease of intubation with either device at any level of provider experience.

Discussion

This study suggests that the time to successful manikin intubation with the Lubo™ cervical collar with MILS is equivalent to intubation with MILS alone. Therefore, it can be extrapolated that the Lubo™ collar provides similar intubating conditions to manual in-line stabilization in a manikin. Further study will be required to identify whether this translates to clinical practice.

The secondary outcomes suggest further equivalence. The combined number of Cormack-Lehane grade I and IIa views are comparable in both scenarios, with no grade IV views produced in either scenario. It is interesting to note that there was a larger proportion of grade I views in the Lubo group, which may be related to the jaw-thrust mechanism or the anterior portion of the collar applying external force on the larynx of the manikin, akin to external laryngeal manipulation often used to improve view during intubation. Whether this would translate to clinical practice is purely speculative.

A limitation of this study is that tracheal intubations were not performed on live patients. The Lubo™ collar is a novel device, and studies examining its effects in clinical practice are limited. Therefore, its application on a patient-based sample group with limited prior evidence of its effect on the invasive procedure of endotracheal intubation was not ethically feasible. The positive attributes to performing a manikin-based study are that the conditions surrounding each intubation attempt are easily reproducible in a safe and controlled environment.

Indirect laryngoscopy may have favorable advantages over direct laryngoscopy in the context of cervical motion restriction. Video laryngoscopy has been shown to produce better views of the glottic opening and faster intubation times than direct laryngoscopy, with no significant difference in intubation success rates or incidence of aspiration, hypoxia and mortality [2,23–27] Intubation using a lighted intubating stylet, video laryngoscopy and fibre optic intubation have been shown to cause less cervical motion and create better views of the larynx [28–31]. However, these devices are often costly, require additional expertise and training and are seldom available in the often resource-limited and prehospital setting. Direct laryngoscopy is widely available and remains common practice and was thus chosen as the most appropriate modality to test the intubation with the Lubo™ collar.

The authors had concerns about the potential for cervical motion upon release of the Lubo™ chin strap, as this component contributes to the collar's ability to provide motion restriction. It is for this reason manual in-line stabilization was applied for all intubations involving the Lubo™ collar. The time taken to release the chin strap was not included in the measured time to intubation. This additional step would not have had any likely effect on the overall success of intubating but may have lengthened the time to intubation in this group.

It was difficult to draw any conclusions about the significance of any forces transferred to the cervical spine when removing a semi-rigid cervical collar due to the paucity of evidence, with only small studies in cadaveric models [10,17]. Subsequent to the performance of our study, Jung et al. compared the Lubo™ to two traditional rigid collars, measuring cervical motion restriction. In this setting, although all collars showed some movement, the Lubo™ performed the poorest in limiting flexion [17].

A further limitation is that this study did not examine the motion of cervical segments during laryngoscopy. This is beyond the scope of this study, and thus we do not make any inferences regarding the de-
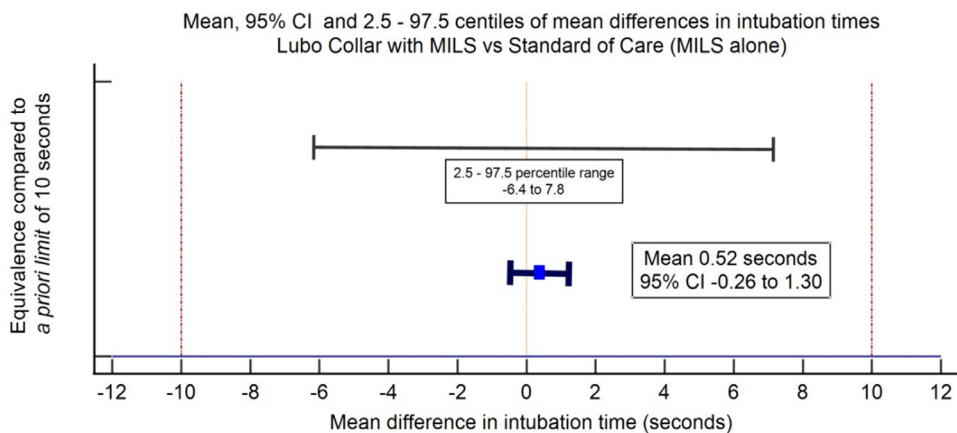
Fig. 2. Mean difference in intubation times of both scenarios.

Table 2
Frequency table.

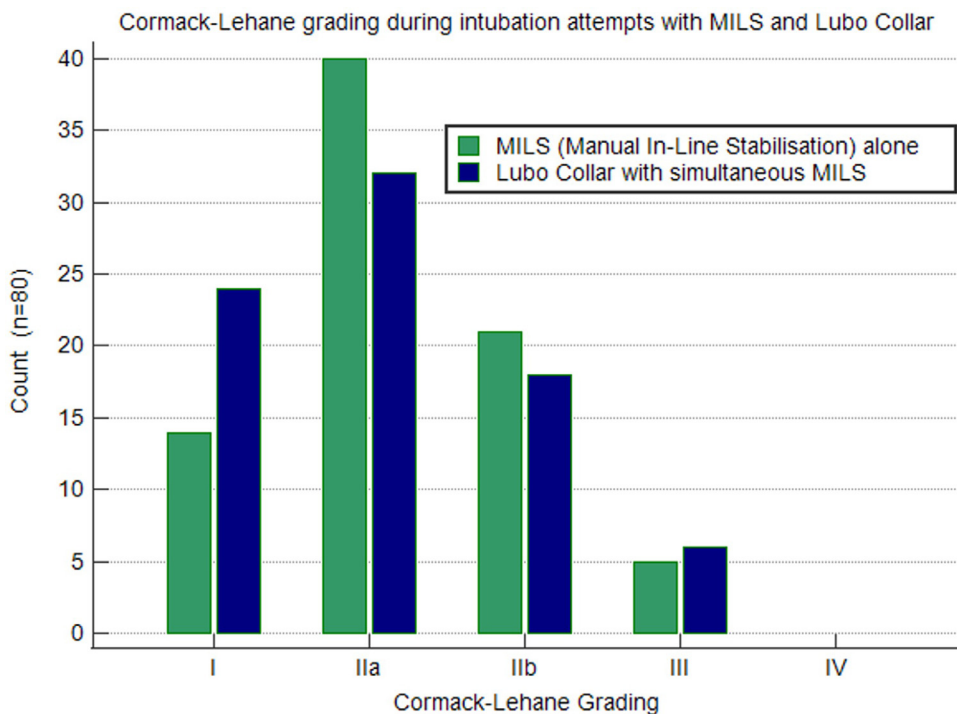|	MILS Alone	Lubo + MILS	Mean difference (95% CI)	p-value
Intubation success, n (%)	80 (100)	79 (98.8)	1.2 (-3.59 to 6.67)	0.33
Intubation time in seconds, mean (SD)	19.74 (5.12)	19.20 (4.51)	0.52 (-1.30 to 0.26)	0.19
Ease of intubation [0-100], median (IQR)	40.5 (20-53)	32 (18-55)	1.2 (-3.45 to 5.78) [Mean 38.1 vs 36.9]	0.62
Number of teeth clicks (%)				
0	65 (81.2)	69 (86.2)		
1	7 (8.8)	9 (11.3)		
2	8 (10)	0 (0)		
3	0 (0)	1 (1.3)		
4	0 (0)	1 (1.3)		
Cormack-Lehane Grade (%)				
1	14 (17.5)	24 (30)		
2a	40 (50)	32 (40)		
2b	21 (26.2)	18 (22.5)		
3	5 (6.2)	6 (7.5)		
4	0 (0)	0 (0)		

Fig. 3. Modified Cormack-Lehane grade view for Lubo with MILS scenario versus MILS alone scenarios.
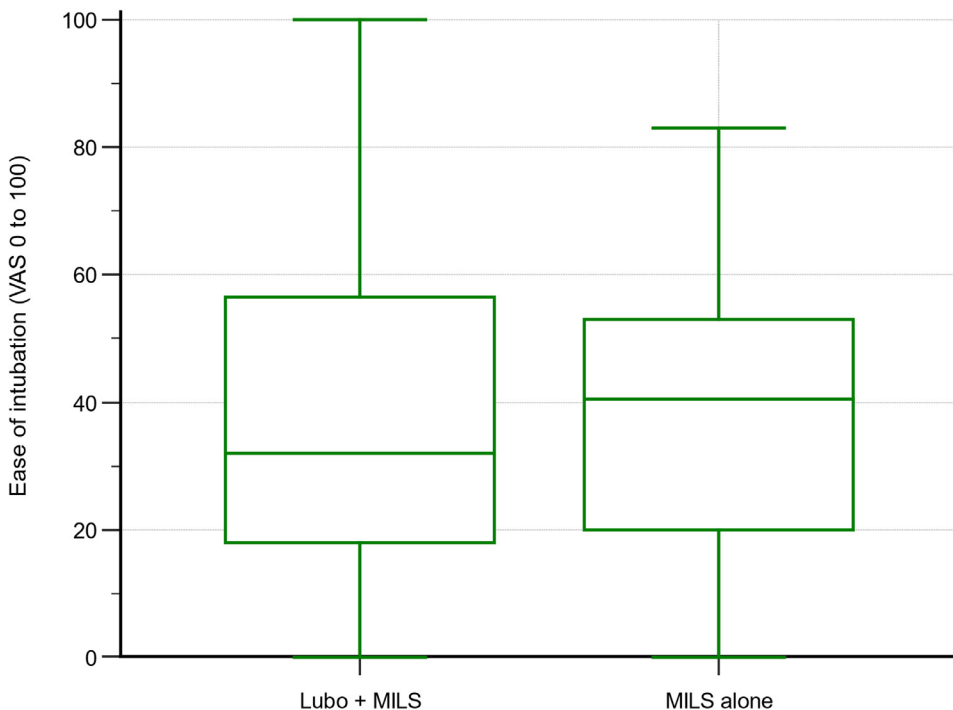
Fig. 4. Box and whisker plot showing ease of intubation. Subjective ease of intubation was ranked by each participant using a visual analogue scale (virtual slider), ranked from '0 to 100', with '0' being very easy and '100' being very difficult.

gree of cervical motion restriction provided by the Lubo™ collar during intubation.

In conclusion, in a manikin simulation model, intubation using the Lubo™ cervical collar and manual in-line stabilisation during tracheal intubation was equivalent to MILS alone. Further studies of the clinical efficacy of the device are required.

Dissemination of results

The results of this study were shared with staff members at the Department of Anaesthesia and Perioperative Medicine at the University of Cape Town, South Africa.

Authors' contribution

Authors contributed as follow to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content: DB contributed 40%, RJ contributed 10%, KB contributed 10%, RH contributed 40%. All authors approved the version to be published and agreed to be accountable for all aspects of the work.

Declaration of Competing Interest

The manuscript will be submitted for a Master of Medicine (MMed) dissertation at the University of Cape Town, South Africa. Lubo™ collars were provided at no cost by Supra Healthcare (Pty) Ltd (Suprahealthcare, Avacare Health, Gauteng, South Africa). No external funding was received, and the authors received no remuneration for this study. The authors have no conflicts of interest.

Acknowledgments

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.afjem.2022.06.009.

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