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Original article

Effects of the Lubo cervical collar on airway patency in awake adults – A magnetic resonance imaging study

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ABSTRACT

Introduction: Intended for use by prehospital first responders, the Lubo ™ cervical collar is an adjustable, radiolucent, single-use device that incorporates a mechanical jaw thrust mechanism. The combination enables non-invasive airway management in cases of trauma where cervical motion restriction is necessary. The potential benefits include use as an airway adjuvant maintaining upper airway patency, reducing provider task loading. The limited research on the device efficacy and safety requires further investigation.

Methods: A randomized, crossover, interventional study was performed to compare mean differences in airway patency at the level of the uvula, epiglottis, tongue and soft palate with and without the Lubo collar in awake volunteers using magnetic resonance imaging (MRI). Fourteen participants each underwent two MRI scans of the upper airway: A control scan with no Lubo collar, and an intervention scan with the Lubo collar applied and jaw thrust mechanism activated. Two independent radiologists measured anterior-posterior diameter of the airway at four anatomical levels on the resulting MRI images.

Results: There was no significant difference in mean airway diameter between the control and intervention measurements at any level. Mean (SD; 95% CI: p-value) differences were 0.9 mm (-2.38; 2.3 to 0.5; p=0.17) at the epiglottis, 0.5 mm (1.6; -0.5 to 1.4; p=0.29) at the soft palate, 0.2 mm (2.86; -1.4 to 1.9; p = 0.78) at the tongue, 0.4 mm (4.04; -1.9 to 2.7; p = 0.72) at the uvula.

Conclusion: The Lubo ™ airway collar did not show a significant change in upper airway patency at four anatomical levels measured in awake adult participants. Further research is required to investigate its clinical use in patients that are unable to maintain upper airway tone. Groups of interest would include trauma, obstructive sleep apnoea, obesity and patients under general anaesthesia.

African relevance

- The Lubo ™ collar functions as a non-invasive airway device consisting of a cervical collar with jaw-thrust mechanism aimed at improving airway patency in combination with spinal motion restriction.
- This study examines the efficacy of the jaw-thrust mandibular advancement device of the Lubo collar to maintain airway patency.
- If proven, the potential benefits to African emergency practitioners may include reduced task-loading and a useful adjuvant to non-invasive airway management in trauma patients.

Introduction

The Lubo™ cervical collar was designed to provide a jaw thrust in conjunction with spinal motion restriction [1]. Many trauma patients require prehospital airway intervention [2]. A recent large prospective observational study showed that more than half of 472 patients initially treated by the prehospital team had significant airway compromise [3]. Early airway management in trauma patients is thus a critical part of basic and advanced life support and invasive airway techniques have been associated with devastating complications [3].

The jaw-thrust manoeuvre is a basic airway technique that involves forward displacement of the mandible to improve airway patency by preventing posterior displacement of the tongue against the pharyngeal wall, soft palate and epiglottis. It requires a dedicated practitioner to perform [4]. Despite the controversy surrounding cervical collars, this could potentially assist prehospital airway management by maintaining non-invasive, hands-free airway patency, however clinical studies of the device are lacking.

We aimed to assess the effects of the Lubo collar's jaw-thrust device on upper airway patency in awake volunteers using magnetic resonance imaging (MRI). The primary outcome was the comparison of

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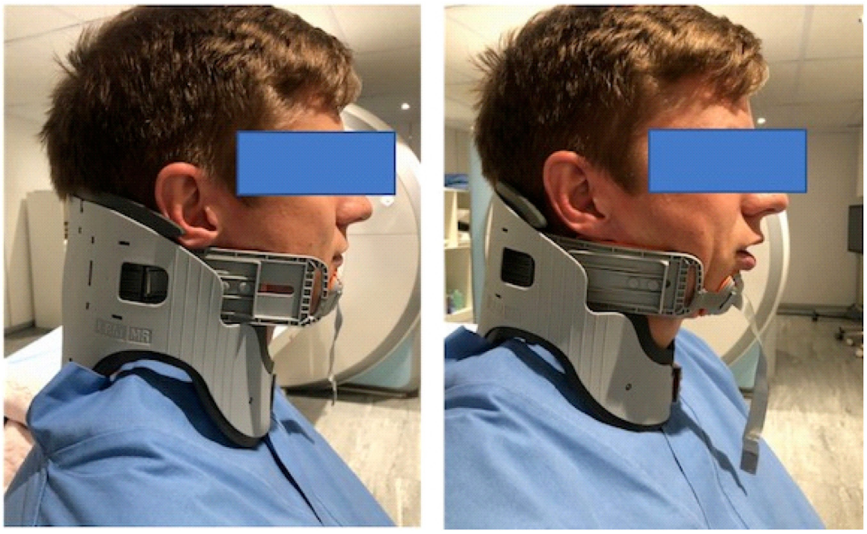


Figure 1. Lubo cervical collar with jaw-thrust mechanism

airway diameter at four anatomical levels (uvula, epiglottis, soft palate and tongue) using the collar compared to a control in which no collar was applied. The secondary outcomes of the study were immediate and delayed (24 and 48 hours) adverse effects, including pain in the mandible, temporomandibular region or neck, pressure sores, or skin rashes (urticarial or dermatitis) in areas where Lubo collar was in contact.

Methods

A randomized, cross-over, interventional study was performed with written informed consent. Ethical approval was granted by the University of Cape Town Human Research Ethics Committee (UCT HREC 555/2019).

The sample size calculation was based on the primary hypothesis using pilot measurements from two test scans. Calculation for a paired-samples t-test was performed using an alpha-error of 0.01 and power of 90% in MedCalc (version 19.6, MedCalc Software LTD, Ostend, Belgium; http://www.medcalc.org; 2020).This demonstrated a minimum sample of 4 paired scans, with 5 pairs required for a power of 99%. To further test this assumption, data from an earlier published study Kuna *et al* [5] were used to perform a second calculation, which demonstrated that 10 participants would be adequate for an alpha-error of 0.05 and power of 90%. We thus elected to use the larger sample estimation, but enrolled 14 participants to avoid loss of data from dropout or exclusion during imaging.

Healthy adult English-speaking prehospital providers of any gender were recruited by convenience sampling. Exclusion criteria included body mass index (BMI) greater than 30 $kg.m^{-2}$, previous head and/or neck radiation or major surgery, obstructive sleep apnoea, airway or neck masses, temporomandibular joint disorders, comorbid medical conditions, history of hypersensitivity to plastic materials, head and neck infections or wound sites, contraindication to MRI, or history of claustrophobia. A practical demonstration was performed highlighting the application and clinical relevance of the Lubo collar.

Data were collected at the University of Cape Town Cape Universities Body Imaging Centre (CUBIC) at Groote Schuur Hospital, Cape Town, South Africa over two days in January 2020 using a 3T Siemens Skyra MRI (Siemens, Erlangen, Germany). Each participant completed informed consent and an MRI safety screening checklist. Demographic information on age, sex, height and weight were collected, and BMI calculated. Six airway parameters were assessed: Mallampati score, interincisor distance, upper lip bite test, thyromental distance, cervical spine mobility and temporomandibular joint range of motion.

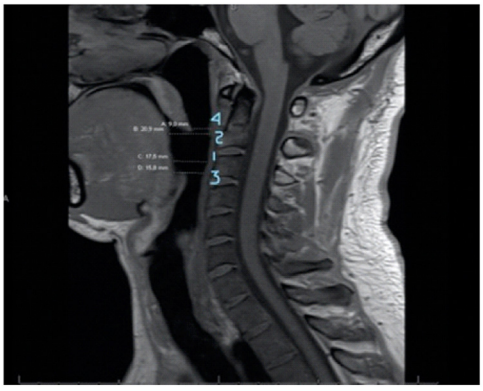


Figure 2. Magnetic Resonance Image of the four upper airway levels measured

Each participant underwent two MRI scans of approximately 15 minutes duration in a supine position performed by a trained MRI research technician. The control scan (no Lubo collar) and intervention scan (Lubo collar with jaw thrust mechanism activated) were performed in a randomized order to minimize sampling bias using a digital coin toss randomization program (https://justflipacoin.com).

A new size-appropriate Lubo collar was carefully placed for each participant by the same two researchers to ensure minimal variability. The collar was then closed, the chin strap secured, and the jaw thrust device advanced to the maximum comfortable distance (Figure 1). No sedation, anxiolytic, muscle relaxant or any other type of medication was used in the study.

All captured MRI images were securely saved as JPEG and DICOM images. Follow-up data on any adverse effects were collected at 24- and 48-hours post-intervention. MRI images measured at the level of the 1) Tongue, 2) Uvula, 3) Epiglottis and 4) Soft palate (Figure 2) were sent to two independent radiologists who were blinded to participant and control/intervention data. All quantitative data were recorded on hardcopy and then transferred into MedCalc, which was used for further statistical analysis.

Participant characteristics and categorical data are presented with descriptive statistics. Paired t-testing was performed to compare distribution around the mean for each group at each level of the airway. *A priori* statistical significance was inferred by a p-value of less than 0.05. Interrater agreement between the blinded radiologists was assessed using the interclass correlation coefficient (ICC).

Table 1
Airway predictors of the fourteen participants.

Characteristic					Total (n=14)
Mallampati Score (1-4)	(1)	(2)	(3)	(4)	14
	8	5	1	0	
Inter-incisor Distance	>30 mm	<30 mm			14
	14 (100%)	0 (0%)			
Thyromental distance	>65mm	<65mm			14
	14 (100%)	0 (0%)			
Cervical spine mobility	Good	Limited			14
	14 (100%)	0 (0%)			
Temperomandibular joint range of motion	Good	Limited			14
	14 (100%)	0 (0%)			
Upper lip bit test	Class 1	Class 2	Class 3		14
	10 (71%)	4 (29%)	0 (0%)		

Table 2
Paired samples mean's, mean differences and t-test outcomes at each of the four anatomical levels measured.

Anatomical Level	Control		Lubo		Paired difference		P	N
	Mean	SD	Mean	SD	Mean	95% CI		
Epiglottis	13.03	3.03	13.94	2.62	0.91	-2.29 to 0.46	0.175	14
Soft palate	7.06	1.94	7.51	2.89	0.46	-0.45 to 1.37	0.297	14
Tongue	12.84	2.76	13.06	2.75	0.22	-1.43 to 1.87	0.780	14
Uvula	14.94	3.13	15.33	3.72	0.39	-1.94 to 2.73	0.722	14

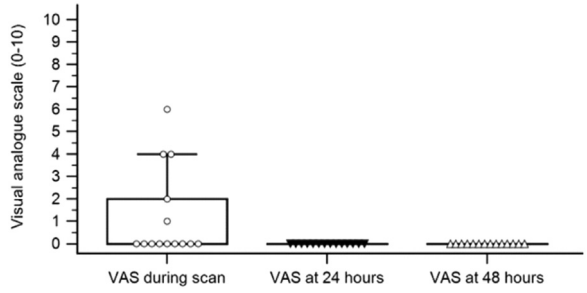


Figure 3. Visual Analogue Scale of pain during and after Lubo cervical collar application

Results

Fourteen participants were successfully included with no loss to follow-up. The mean age of the participants was 31 years; 79% (11/14) were male, and the mean BMI was 23.7 kg/m^2. All participants had normal cervical spine and temporomandibular joint range of motion. Mallampati score was Class 1 in 57%, Class 2 in 36% and Class 3 in 7%. The mean inter-incisor distance was 49.6 mm with a minimum and maximum value of 45.1 and 60 mm respectively. The mean thyromental distance was 74.8 mm. Upper lip bite test revealed 71% Class 1 and 29 % Class 2 (Table 1).

There was no significant difference in mean airway diameter between the control and intervention measurements at any level. (Table 2). Correlation between measurements performed independently by the two radiologists varied between 0.837 and 0.979 were thus considered acceptable.

In terms of the secondary outcomes, only four out of the 14 participants (36%) experienced pain during application and/or MRI scanning, with the highest and lowest VAS (Visual Analog Scale) score being 6/10 and 0/10 respectively (interquartile range 0-2). Sixty-four percent of the participants experienced no pain at all, and none of the fourteen participants experienced any pain on follow up at 24- and 48-hours' post-MRI scan (Figure 3).

The participants who experienced pain described it mainly around the mandible. No temporomandibular or neck pain was experienced. Six of the 14 participants (43%) experienced a pressure sensation around the mandibular area immediately. This resolved entirely within 10 minutes and was not experienced again. One participant continued to experience this pressure sensation at 48 hours post collar removal, which resolved soon after.

Three participants (21%) experienced mild skin flushing from the Lubo cervical collar immediately after removal. In one participant, it persisted till 48 hours after removal, with mild bruising of the skin documented. For the other two, it resolved within 5 minutes of the collar removal.

None of the participants reported any pressure sores, urticarial, contact dermatitis or hypersensitivity reactions to the Lubo cervical collar immediately after removal and at 24 and 48 hours of follow up. One participant who underwent MRI was found to have an incidental lesion in a facial sinus, which led to onward referral for surgical assessment.

Discussion

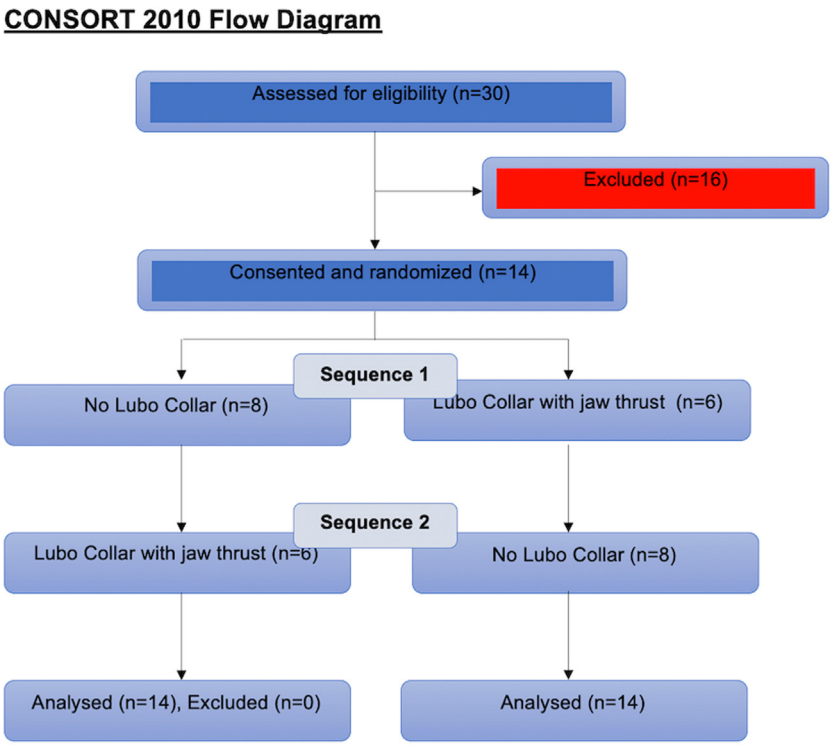
This study showed no significant change in airway diameter at four anatomical levels measured in awake adult participants with application of the Lubo cervical collar.

Fevang *et al* conducted a large meta-analysis looking at mortality in pre-hospital intubation compared to patients intubated in the emergency department. The mean mortality rate showed a 48% versus 29%, respectively [6] Early intubation and airway management is crucial in the trauma patient. However, it is associated with complications and highlights the requirement for application of non-invasive airway techniques such as the head-tilt/chin-lift and jaw thrust.

During wakefulness, airway patency is maintained by pharyngeal tone. Airway tone is affected by pathologies such as a depressed level of consciousness, alcohol, and direct trauma. With deep sedation, general anaesthesia and the use of neuromuscular blockade, there is also a significant decrease in airway tone due to decreased cortical, mechanoreceptor and chemoreceptor influences, which may lead to upper airway obstruction [7]. The importance of the jaw-thrust is that it produces sufficient mandibular advancement, preventing pharyngeal collapse and maintaining upper airway patency and airflow.

The jaw thrust manoeuvre is part of basic adult life support, which is taught to first responders, medical students, doctors and anaesthetists

Figure 4.



[8], was described as "pulling the mandible upward and forward with the head slightly extended to retract the tongue from the posterior pharyngeal wall." [4] In a study by Greene *et al*, the use of the jaw thrust manoeuvre relieved upper airway obstruction at the level of the soft palate and base of the tongue [9]. This improves oxygenation and ventilation, and can buy critical time for healthcare providers to prepare for later invasive measures such as endotracheal intubation or other means of securing a definitive airway.

Angular motion, axial displacement and anteroposterior translation were greater with the head-tilt/chin-lift than a jaw-thrust manoeuvre [10]. This demonstrates the importance of the jaw-thrust in basic adult life support associated with cervical spine injury [16].

The cervical collar is a traditional device that plays an important role in immobilising the cervical spine during suspected injury during trauma. However, when co-existing airway management is required, the collar has shown to increase difficulty [11]. Reduced mouth opening is a major concern when classic semi-rigid collars are used [12,13]. During tracheal intubation with a suspected cervical spine injury, removal of the hard collar with manual in-line stabilization has been advocated. However, MILS has been shown to worsen views during laryngoscopy [14]. It is thus recommended that the anterior part of hard collars be removed before attempting tracheal intubation [12,15].With the Lubo^{TM} airway collar, the anterior chin strap can be removed while still immobilizing the cervical spine with its posterior support, facilitating laryngoscopy [1].

Lubovsky *et al* developed the Lubo^{TM} airway collar with a jaw-thrust mechanism intended to open the upper airway while protecting the cervical spine . The original study assessed device efficacy and safety. A 1 cm mandibular advancement using the jaw-thrust device in participants under general anaesthesia after induction showed the reappearance of the capnography waveform, indicating relief of upper airway obstruction [1]

An MRI study similar in principle to ours was conducted by Kuna *et al.*[16]. An intraoral device was used to assess the effects of mandibular advancement on the pharyngeal airway, which is similar to the jaw-thrust device on the Lubo^{TM} airway collar. As in our study, four airway levels at the uvula, soft palate, tip, and base of the epiglottis were examined for airway patency and diameter change. As already stated, general anaesthesia and sedation are associated with upper airway pharyngeal collapsibility impeding airflow and oxygenation. Kuna *et al.* showed a decrease in airway diameter at all four levels during anaesthesia, with no mandibular advancement compared to a wakeful state [16]

Vaithialingam *et al.* used the Lubo collar with its jaw-thrust to improve airflow using Transnasal Humidified Rapid Insufflation Ventilatory exchange (THRIVE) in 150 patients for electroconvulsive therapy under thiopental anaesthesia. None of the patients desaturated during this study [17]. The Lubo collar thus facilitated hands free apnoeic oxygenation efficiently. Sundaram *et al.* used the collar in a patient with oromandibular dystonia during dexmetomidine sedation to prevent upper airway collapse to facilitate MRI for diagnostic purposes [18].

Jung *et al.* compared the remaining motion of an immobilized cervical spine using the Lubo cervical collar to two traditional cervical collars on in a cadaveric model [19]. Traditional collars proved to be superior for spinal motion restriction. However, all of the collars assessed allowed spinal motion. Further investigation of this function is therefore required.

Our study has several limitations. Although calculated to provide a statistically robust result, sample size was limited by available funding for the use of the UCT CUBIC MRI, which increases the margin for error. Variation in standardized MRI measurement software and interobserver variability between the two radiologists could also influence the results, although intraclass correlation was considered good.

The Lubo Collar is a new device which has had minimal clinical application to date, and thus the researchers had little prior experience with the device. Application to participants was performed by two different clinicians, which could have influenced placement variability.

Participants received no sedation, anxiolysis, general anaesthesia or neuromuscular blockade during the process, which allowed for self-manipulation of airway tone and mandibular advancement. Loss of airway tone and reflexes in the obtunded or unconscious trauma patient, or those under sedation or general anaesthesia, may be a considerably different situation, where mandibular advancement may result in increase in upper airway diameter. However, decreased level of consciousness may also allow for greater mandibular advancement and increase in

airway patency from a jaw thrust, as it negates the influences of pain and discomfort during application. In our study, maximal mandibular advancement using the Lubo Cervical Collar of each participant was limited to each individual's comfort and pain threshold.

As participants were awake, they could swallow and make voluntary movements. During MRI this can lead to motion artefacts, degrading image quality. In these instances, the MRI sequence had to be repeated.

All participants included in this study had a BMI of less than 30 kg/m^2 and no history of obstructive sleep apnoea (OSA). We know that important anatomical variations in these subsets of patients affect airway patency, muscle tone, and diameter. Sleep induced relaxation of the airway muscles (oropharyngeal dilator and abductor) attached to the soft tissue structures that make up the lumen of the oropharynx is the underlying concern in patients with OSA. The upper airway can collapse when sub-atmospheric intraluminal pressure during inspiration overwhelms the stabilizing forces produced by these muscles. Considering this anatomical and pathological variation, further investigation of the device in patients with obesity and OSA may be useful.

Most participants in our study were male. Anatomical and anthropometric variations in mandibular structure and variations in overlying soft tissues may influence the fitting and placement of the Lubo collar.

In conclusion, application of the Lubo collar with jaw-thrust mechanism did not significantly alter the airway diameter at multiple levels in awake participants. This may be due to the significant limitation of maintenance of normal airway tone and airway musculature in awake participants, rather than a failure of the device. Further research is required with the Lubo collar in patients who have factors that directly affect airway tone such as decreased level of consciousness, muscle relaxants, ethanol, sedation, anxiolytics or a threatened airway. Although more challenging to study, these are all real-life emergency scenarios in the trauma patient which require investigation with the device before recommendations can be made for clinical practice.

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: RJ contributed 40%; RH contributed 30%; DB and SC contributed 10%; and PD and KB contributed 5% each. All authors approved the version to be published and agreed to be accountable for all aspects of the work.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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