Clinical paper

A new external upper airway opening device combined with a cervical collar

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A R T I C L E   I N F O

Article history:
Received 23 October 2009
Received in revised form 9 February 2010
Accepted 10 February 2010

Keywords:
Airway
External
Device
Cervical collar
Supraglottic obstruction

A B S T R A C T

Airway problems are the main cause of mortality in otherwise survivable trauma injuries. We developed a novel external airway protector in combination with a cervical collar. The new device simultaneously opens the airway and protects the cervical spine.

Materials and methods: The device called the ‘Lubo Collar’ has a chin holder that can be attached to a gliding knob on the collar. When the knob is pushed forward, the mandible moves forward, thus imitating the jaw thrust manoeuvre and opens the airway. In order to study the safety and efficacy of this new device, a two-phase clinical trial was conducted. In the safety phase 20 patients were evaluated for adverse reactions immediately, 2 h and 24 h following application of the device. The efficacy phase evaluated the ability of the device to open and maintain an airway in anaesthetised patients. In this phase, 10 patients who had undergone orthopaedic surgery under general anaesthesia were included. Seven patients had blocked airways following anaesthesia induction. The gliding knob attached to the mandible arc was pushed 1 cm forward to open their airways.

Results: No adverse events were recorded. In the seven patients with blocked airways, the external airway/collar device opened and maintained patent airways.

Conclusion: The new external non-invasive airway device (Lubo Collar) is safe and effective in opening and maintaining an open airway in an unconscious anaesthetised patient with a blocked airway. These preliminary results may encourage assessment in the field.

⁎ A Spanish translated version of the abstract of this article appears as Appendix a.
⁎⁎ The work was funded by institutional support.
⁎ Clinical Trials.gov identifier NCT00355173. Study ID Numbers LB001-HMO-CTIL.
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An obstructed airway is the quickest killer of multiple injury patients.1 Airway problems are considered a major cause of mortality in otherwise survivable injuries.2 Supraglottic airway obstruction due to either unconsciousness or less frequently to direct trauma is very common. Endotracheal intubation is considered the gold standard for securing an open airway.3 Other less invasive methods, for example, laryngeal mask and oral or nasal airway, or more invasive procedures such as cricothyroidotomy are also in use. However all carry many risks. With pre-hospital endotracheal intubation, there are both high failure and high complication rates.4,5 Spine immobilisation is one of the most frequently performed pre-hospital procedures, despite a lack of data showing that it improves outcomes.6 Airway protection with cervical spine control is the very first action taken when treating trauma patients.1

Reducing the time from injury until hospital admission is a critical factor in patient treatment.7–9 Although not proven to change the outcome,10,11 the goal of pre-hospital emergency teams remains rapid transportation of trauma patients while maintaining a patent airway and cervical spine immobilisation.

We developed a novel, non-invasive airway protector that imitates the manual jaw-thrust manoeuvre. The jaw thrust mechanism is incorporated into a cervical collar. The device is designed to stabilise the cervical spine while pushing the mandible forward, thus relieving supraglottic airway obstruction caused by unconsciousness. As an external, easy-to-use device, it has the potential to overcome many of the obstacles faced by emergency medical service (EMS) teams and may reduce delay in safe and rapid evacuation.

A prototype was developed, following which its safety and efficacy was evaluated. The hypothesis tested was that the new device would open and maintain an open airway in unconscious patients
whose airways are blocked due to supraglottic obstruction. We also examined whether any adverse effects are caused by its application.

1. Materials and methods

The new device, called the ‘Lubo Collar’ (Patent Pending US 2007/118060), consists of three parts. The first part is an arch-shaped chin holder (CH), 4 cm wide, made of a flexible polymer, thus enabling it to be adjusted to different patients (Fig. 1). At each end of the arc there is a ridge that fits the posterior angle of the mandible (MR). These ridges are the points that push the mandible forward. The CH is the first element attached to the patient’s jaw as the patient lies supine. The second part is a semi-rigid collar, which is the posterior element (PE). It has a gliding knob (GK) that attaches to the chin holder with Velcro (Fig. 2a and b). The PE glides under the patient’s neck while the patient’s head and neck are stabilised and slightly elevated from the ground to enable the element to be positioned under the patient’s neck. After the PE is seated behind the neck, its right and left gliding knobs are attached to the CH. The third part is the anterior part (AP) of the collar, which prevents the neck from flexing towards the chest (Fig. 3a and b). After the collar is fixed and the arc is attached to both the mandibular angles, the gliding mechanism (GK attached to CH) is used to push the mandible forward, thus opening the airway (Fig. 4). The extent of the forward movement is adjustable. Once the correct position has been obtained the device is locked, fixing the position of the mandible and freeing the operator’s hands. The prototype was built using the frame of an existing Philadelphia collar because it was available and in common use in our hospital. A two-phase clinical trial was approved by the Institutional Review Board (IRB) of the Hadassah Medical Organization, registered with the National Institutes of Health (NIH) and conducted. The study was performed under the guidelines of both the NIH and the Israel Ministry of Health.

This proof-of-concept study was designed to evaluate the mechanical ability of the novel device to maintain a patent airway in an unconscious patient by non-invasive means. In order to eliminate factors that can influence these metrics, for example, an inexperienced operator; patient resistance to treatment; patient medical conditions that necessitate well-accepted airway protection methods; and to achieve proper monitoring, the study was preformed under controlled conditions. The ability of the device to compensate for the reduction in muscle tone and control of the supraglottic airway obstruction under anaesthesia was evaluated.

The study was carried out at the Hadassah-Hebrew University Medical Center. During the safety phase of the study, we wanted to ensure that no adverse effects were caused by continuous pressure applied to the posterior angle of the mandible. Local pressure directed from back to front on the posterior angle of the mandible might cause local pain or tenderness or the material might cause a hypersensitivity reaction. Theoretically, pressure on this area could dislocate the mandible, causing masseter muscle, lower jaw or tooth pain. The aim of the efficacy phase was to examine whether the mechanical jaw thrust manoeuvre actually opens and effectively maintains a patent airway.

Twenty patients were enrolled in the safety phase and 10 were enrolled in the efficacy phase. Since the 10 participants in the efficacy phase were also evaluated for adverse reactions, a total of 30 patients were evaluated.

The first phase of the study was designed to assess the safety of the device. This phase had two stages. During the first stage, following receipt of informed consent, the device was fitted to 10 healthy volunteers for 30 min. The protocol included 5 min without activation and 25 min with 1 cm forward mandibular displacement. After the collar was removed, the volunteers were immediately evaluated. (a) The posterior element (PE) with the gliding knob (GK) that can be attached to the chin holder with Velcro (black). (b) The second stage: the gliding knob (GK) of the posterior element, attached with Velcro to the chin holder (CH).
Fig. 3. (a) The anterior part (AP) protects the cervical spin from flexion. (b) The third stage: the anterior part (AP) attached to the posterior element (PE) with Velcro (blue). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.)

examined for adverse reactions and again following 2 and 24 h. Suspect adverse events included: hypersensitivity; skin reaction or urticaria; dislocation of the temporomandibular joint and/or pressure sores.

A visual analogue pain scale (VAS) was used to measure pain, following the use of the device, on a scale of 0 (no pain) to 10 (severe pain).

The second stage of the safety trial was performed on 10 patients scheduled for distal limb orthopaedic surgery under general anaesthesia. The patients were 18–60 years of age with a body mass index (BMI) of less than 32, without any known airway, cervical spine or temporomandibular joint problems and without any serious systemic disease (ASA I & II). After obtaining informed consent, the patients underwent general anaesthesia and the airway was secured with either an endotracheal tube or a laryngeal mask airway (LMA). After induction of general anaesthesia and successful airway instrumentation, the device was fitted for 30 min (5 min without activation and 25 min with 1 cm forward mandibular displacement). The patients were examined for adverse reactions immediately and after 2 and 24 h.

The second phase evaluated the efficacy of the device, in particular, its ability both to open and to maintain (for 5 min) an open airway in an unconscious patient. The inclusion criteria were similar to the previous phase and included 10 patients scheduled for minor elective orthopaedic surgery under general anaesthesia. After receiving informed consent, the patients were connected to standard monitoring including ECG, non-invasive blood pressure, pulse oximeter and capnograph. At this stage the collar was placed around the patient’s neck but was not engaged. General anaesthesia was induced using propofol and morphine after which the airway was evaluated. If the airway was open despite unconsciousness, the patient was excluded from the efficacy trial and was only evaluated for safety. If the airway was obstructed (no tracing on the capnograph during spontaneous inhalation/exhalation chest movement attempts, no tracing of air flow as evident by listening to the chest with a stethoscope), the device was engaged to push the mandible forward. No other manipulation was performed, for example, oral airway. Capnograph monitoring of CO₂ and restoration of spontaneous air flow as evident by listening to the chest with a stethoscope were used to monitor the presence of ventilation through the patient’s airway. The ability to maintain adequate blood oxygen saturation levels (above 95%) was measured with an SpO₂ monitor. After this investigation, the airways were secured with either an endotracheal tube or a laryngeal LMA. The device was in place for a total of 30 min. All patients were assessed for adverse effects immediately and after 2 and 24 h.

The study was designed to test the ability of the new external airway device to change the state of the airway from obstructed to open. Each patient was his/her own control since once the airway was blocked while anaesthesia continued, the airway could not reopen without intervention. After efficacy was tested, the external airway device was exchanged for an established invasive airway device (an endotracheal tube or LMA) for the remainder of the procedure, because without an airway device the patient’s airway would remain obstructed.

2. Results

The study group included 25 males and five females with a mean age of 33.6 years.
Patient demographics and body habitus are described in Table 1. We were able to adjust the collar in all 30 patients and push the mandible into a ‘jaw-thrust manoeuvre’, that is, 1 cm forward.

2.1. Safety

The hypothesis that application of the new device would cause adverse effects was ruled out. No adverse events were recorded in the safety phase (20 patients) or in the efficacy phase (10 patients). No hypersensitivity, skin reaction or urticaria, dislocation of the temporomandibular joint or pressure sores were noted. No other adverse events were observed. Local pain was minimal with a VAS not greater than 1 on a scale of 0 (no pain) to 10 (severe pain).

2.2. Anaesthesia

All anaesthetised patients (10 safety and 10 efficacy) achieved 100% oxygen saturation prior to anaesthesia induction by breathing oxygen through a mask for 5 min. All patients were anaesthetised using propofol, morphine and isoflurane. Satisfactory level of anaesthesia was indicated once there was absence of the eye-lid reflex.

2.3. Efficacy

Of the 10 patients participating in the efficacy phase, seven had obstructed airways, as evidenced by no tracing on the capnograph with continued chest movements (inhalation/exhalation attempts) and no tracing of air flow as evident by listening to the chest with a stethoscope. In the three patients with open airways after induction of anaesthesia, the device was only tested for safety. The efficacy of the device was therefore only tested in the seven patients who had airway obstruction immediately following induction of general anaesthesia. Due to pre-oxygenation and good physical condition, patient saturation dropped to no less than 95% after their airway was blocked. The application of the device by pushing the knob 1 cm forward opened the patients’ airways as was proven by the reappearance of the capnography waveform, restoration of breath sounds and by the elevation of saturation levels above 97%.

3. Discussion

The Lubo Collar was found to be safe and effective in maintaining an open airway in unconscious patients with supraglottic airway obstruction caused by general anaesthesia. This device might thus introduce a new concept in airway management and provide another modality to assist in maintaining a patent airway during spontaneous breathing or while performing bag–mask ventilation.

Manual anterior displacement of the mandible during anaesthesia dilates and stiffens the pharyngeal airway and is commonly performed to restore pharyngeal airway patency in anaesthetised or deeply sedated, non-intubated patients. In our study, we were able to restore airway patency by advancing the mandible 10 mm forward. These results agree with a recently reported study by Kuna et al. who reported that maximal advancement of the mandible by an average of 16.8 mm during propofol anaesthesia returned antero-posterior and lateral airway diameters to dimensions observed during wakefulness.

Airway obstruction is a major cause of preventable death in trauma patients and since cervical spinal immobilisation can contribute to airway compromise, the possibility that such immobilisation increases mortality and morbidity cannot be excluded. The modified cervical collar examined in this study provides a possible solution for this problem since it does not block the airway, and in fact opens it, avoiding the dilemma of cervical spine stabilisation versus airway compromise.

4. Limitations

This study aimed to be a proof-of-concept investigation and was thus performed on a small group of young healthy adults. The efficacy of the device was proven on only seven elective patients in a controlled environment. Different results might have been obtained in real trauma patients. The Lubo Collar is intended to be a non-invasive airway adjunct used as a ‘bridge’ to definitive airway care. It does not protect the patient from aspiration and cannot be connected to a ventilator. Instead, it serves as a mechanical ‘second hand’ permitting the operator to have a free hand while also preventing hand fatigue. The intended use of this device is during the pre-hospital phase of treatment. Our experiment was conducted in a very controlled hospital environment. Further studies are needed to validate its efficacy in the field.

5. Conclusions

The novel Lubo Collar device which combines an external airway protector with a cervical collar appears to be safe and effective in opening and maintaining patent airways of anaesthetised, supine patients. Further clinical studies are indicated to determine the safety and utility of this device under pre-hospital conditions.

Conflict of interest statement

The corresponding author (OL) is one of the inventors of the ‘Lubo Collar’ (Patent Pending US2007/118060). None of the other authors have rights or any kind of benefits from this patent.

References

8. Sampalis JS, Lavoie A, Williams JL, Mulder DS, Kalina M. Standardized mortality ratio analysis on a sample of severely injured patients from a large Canadian