Resuscitation 81 (2010) 817–821

Contents lists available at ScienceDirect

Resuscitation

journal homepage: www.elsevier.com/locate/resuscitation

Clinical paper

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

Omri Lubovsky[a,*,1], Meir Liebergall[a], Charles Weissman[b], Meros Yuval[b]

[a] Department of Orthopedic Surgery, Hadassah – Hebrew University Medical Center, Jerusalem, Israel
[b] Department of Anesthesiology and Critical Care Medicine, Hadassah – Hebrew University Medical Center, Jerusalem, Israel

ARTICLE INFO

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

Keywords:
Air way
External
Device
Cervical collar
Supraglottic obstruction

ABSTRACT

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.

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

☆ A Spanish translated version of the abstract of this article appears as Appendix in the final online version at doi:10.1016/j.resuscitation.2010.02.013.

☆☆ The work was funded by institutional support.

◊ Clinical Trails.gov identifier NCT00355173. Study ID Numbers LB001-HMO-CTIL.

* Corresponding author at: 660 Briar Hill Avenue, Apartment 502, M6B4B7 Toronto, ON, Canada. Tel.: +1 6473449132.
E-mail addresses: omrilu@gmail.com (O. Lubovsky), liebergall@hadassah.org.il (M. Liebergall), Charles@hadassah.org.il (C. Weissman), dmer56@walla.com (M. Yuval).

[1] During the safety phase, Omri Lubovsky was affiliated with the Department of Orthopaedic Surgery, Hadassah - Hebrew University Medical Center, Jerusalem, Israel. At the stage of the efficacy phase, Omri Lubovsky was a clinical and research fellow in the Orthopedic Surgery Department of the Sunnybrook Health and Science Center, Toronto, Canada.

0300-9572/$ – see front matter © 2010 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.resuscitation.2010.02.013

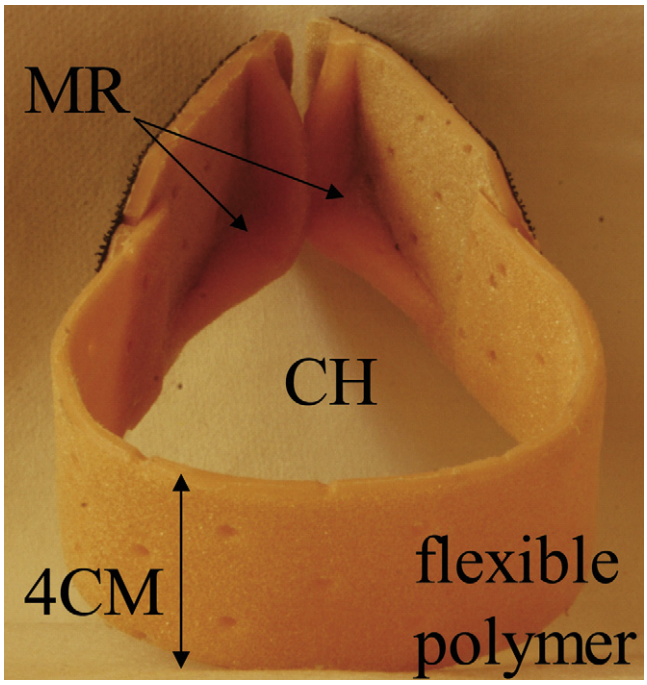

Fig. 1. Arch shaped chin holder (CH) made of flexible polymer enabling it to be adjusted to different patients. (MR) ridge that fits the posterior angle of the mandible.

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

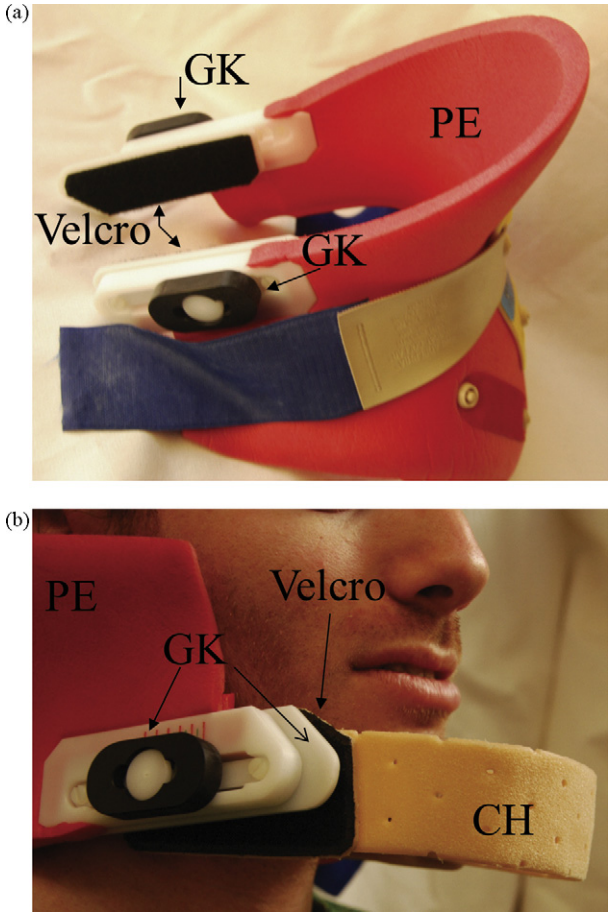

Fig. 2. (a) The posterior element (PE) with the gliding knob (GK) that can be attached to the chin holder with Velcro (black). (b) The second stage: the gliding knob (GK) of the posterior element, attached with Velcro to the chin holder (CH).