

The intubating laryngeal mask. I: development of a new device for intubation of the trachea

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Summary

The standard laryngeal mask airway (LMA) functions both as a ventilatory device and as an aid to blind/fibrescopic-guided tracheal intubation. We describe the radiological and laboratory work used to bioengineer a new laryngeal mask prototype, the intubating laryngeal mask airway (ILMA). The aim was to create a new airway system with better intubation characteristics than the LMA. Other design goals were to eliminate the need for head–neck manipulation and insertion of fingers in the mouth during placement. Development was aided by analysis of magnetic resonance images of the human pharynx and laboratory testing with a variety of tracheal tubes. The principal features of this new system are an anatomically curved, rigid airway tube with an integral guiding handle, an epiglottic elevating bar replacing the mask bars, a guiding ramp built into the floor of the mask aperture and a modified silicone tracheal tube developed for use with the device. (*Br. J. Anaesth.* 1997; 79: 699–703).

Key words

Equipment, masks anaesthesia. Intubation tracheal. Intubation tracheal, technique.

Tracheal intubation using a laryngoscope inevitably involves distortion of the anatomy in order to bring the glottis into the line of sight. In addition, the tracheal tube (TT) is designed for ease of passage when the anatomy is thus distorted and as a result its curvature does not correspond with the contours of the relaxed anatomy of the upper airway. Because it is not always possible or desirable to distort the anatomy, the difficult airway remains an important cause of mortality and morbidity in anaesthesia¹ in spite of a plethora of intubating aids and difficult airway algorithms.² The laryngeal mask airway (LMA) has found a place in this arena³ but suffers from the disadvantages that its airway tube permits only up to a 6 mm TT and is too long to ensure the cuff of the TT does not come to lie between the vocal cords.⁴ Further, the tube is not sufficiently rigid to permit manipulation to bring the mask into alignment with the glottis and cannot be removed easily from the TT when intubation has been accomplished.⁵ In addition, the mask aperture bars

(MAB) may obstruct passage of the TT. Nevertheless, it has the advantage that ventilation can be maintained whether or not the patient's trachea can be intubated. This advantage seemed sufficiently important to justify modification of the standard device to create a more appropriate intubating tool.

The first modification incorporated a change to the LMA airway tube only and has been described elsewhere.⁶ We describe how bioengineering principles were applied to the further development of the intubating laryngeal mask airway (ILMA) using magnetic resonance imaging (MRI) and other laboratory work. The aim of the developmental process was to create a new intubating system with better insertion and intubation characteristics by making the ILMA more compatible with oropharyngeal anatomy and identifying a suitable TT for use with the device.

Methods

THE AIRWAY TUBE

Figure 1 shows how the airway tube has been modified in the new version of the ILMA. The form of the tube was derived from head and neck sagittal magnetic resonance imaging (MRI) views in 50 normal subjects whose heads were held in a neutral position (fig. 2) and differs from that described in an earlier study.⁶ Ethics Committee approval was not sought as the images had already been taken for clinical reasons unrelated to the airway; confidentiality was maintained. The convex radius of the curve of the metal tube (41.5 mm) represents a value close to the best fit curve from the concave antero-posterior curves of the palato-pharyngeal arch which were traced from the MRI images. The tube is curved around a minimum arc of 128° corresponding to the approximate alignment of the distal end with the glottic axis measured from the MRI images. The minimum internal diameter (id) of the tube was

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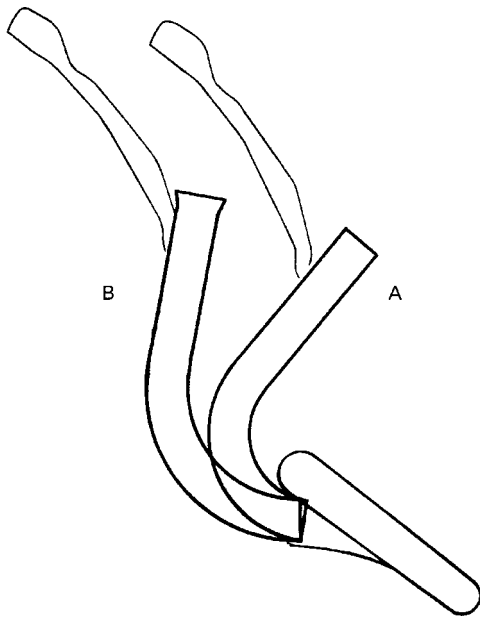


Figure 1 Airway tube: final form (A) and earlier prototype (B).

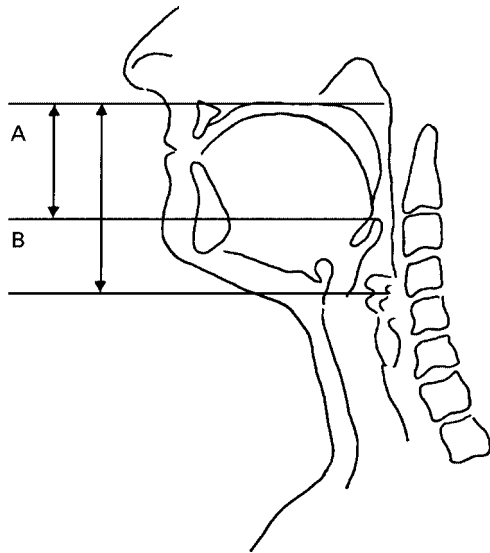


Figure 2 Typical sagittal section MRI from which the following measurements were made: A = distance from the dome of the hard palate to the epiglottic tip (PE distance); B = distance from the dome of the hard palate to the arytenoid cartilage (PA distance).

chosen to be 13 mm, with a wall thickness of <1 mm. This accepted up to an 8.0 mm id cuffed TT. Wider tube diameters were found to be impossible to curve sufficiently tightly to meet the anatomical requirement using stainless steel and moreover could not be drawn down into the correct dimensions for a standard 15 mm outside diameter (od) connector. Stainless steel was chosen because of its compatibility with silicone, high strength (permitting a good id:od ratio), malleability (low risk of fracturing), ease of sterilization and cleaning, and absence of toxicity. To minimize trauma risk and facilitate secure bonding with the mask portion, the tube was covered with a silicone sheath giving an od of 17.6 mm, apart from its distal or outer end which was accurately pressed into a standard 15 mm

connector shape. The maximum od (20 mm) occurs in the plane of the curvature of the tube at the point where it is overlapped by the proximal part of the cuff. Unlike the standard LMA tube, which had to protrude sufficiently from the mouth to be gripped easily and to permit stabilization by bending down over the chin, the rigid metal tube with its gripping handle could be made shorter, terminating close to the mouth. Thus the relative shortness and increased id of the tube allowed passage of an adult sized TT to its correct depth, overcoming the main disadvantage of the standard LMA as an intubating guide.

The stainless steel handle welded to the outer end of the tube proximal to the 15 mm connector facilitated device manipulation and made it possible to perform insertion without placing the fingers in the mouth. The handle was stiff but malleable, permitting some adjustment of the angle it made with the tube.

The distal end of the tube was not cut squarely but had a 30° bevel anteriorly, in order to permit compression of the device at its widest point for patients with reduced inter-dental distance.

EPIGLOTTIC ELEVATING BAR

As both the epiglottis and the bars across the LMA aperture may impede passage of a TT through the LMA,⁷ the bars were replaced with a single central bar, or epiglottic elevating bar (EEB), attached only at the upper rim of the mask so that its free end could be swung out by the advancing TT, pushing the epiglottis out of the way as it did so. Critical to performing this function was the level of the EEB tip in the pharynx, as it has to lie deeply enough to engage with the epiglottis but not so deep that it became wedged posterior to the caudal rim of the glottic aperture. In order to arrive at the correct position and size of the EEB, the pharyngeal level of the epiglottis in each of the MRI views was measured. Epiglottic depth was expressed as the distance between the free end of the epiglottis and the dome of the hard palate (PE distance), measured along a line drawn parallel to the first five cervical vertebrae and a line at right angles to this line passing

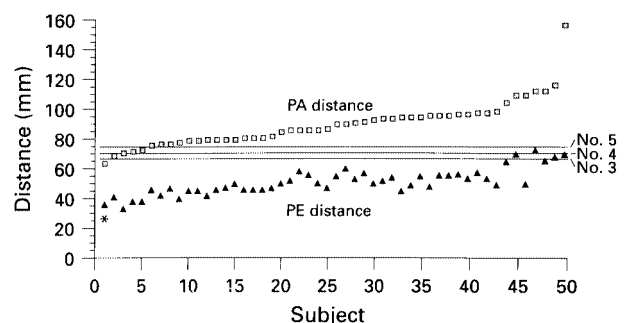


Figure 3 Palato-arytenoid distance (PA) and palato-epiglottic distance (PE) in each of the 50 MRI subjects. The gap between PA and PE represents the size of the glottic aperture in the cephalo-caudal axis. The horizontal lines represent distances of the tip of the epiglottic elevator bar (EEB) from the dome of the hard palate for the three sizes of the ILMA, measured along the same axis. In only one subject (*) was the glottic aperture too high for all three sizes of the LMA.

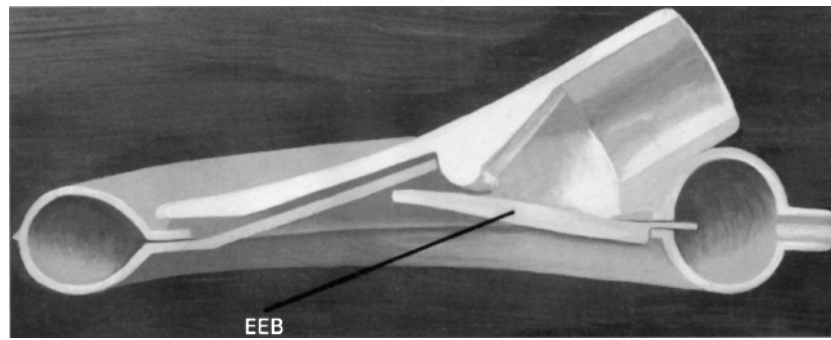


Figure 4 A prototype ILMA sectioned longitudinally in the mid-line to show the arrangement of the guiding ramp. EEB = Epiglottic elevator bar.

tangential to the dome of the hard palate. The distance between the hard palate and the arytenoid cartilages was also measured along the same axis (PA distance) (fig. 2). The length of the glottic aperture was then calculated (PA-PE). The length of EEB which would bring the EEB tip most reliably into a position behind the epiglottis where it could act as an epiglottic lever could then be determined. Keeping the size of the tube constant, three sizes of mask were used, into each of which an EEB was fixed proportional to the size of the mask. The mask sizes corresponded to sizes 3, 4 and 5 of the standard LMA. After tracing the predicted position of each mask size onto tracings of the MRI pictures, a suitable length of EEB was arrived at, such that the EEB tip rested at the approximate mid-point in the bowl of each size of mask. Assuming the airway tube lay in contact with the palatal dome, the relative distances from the tip of the EEB to the highest point or apex of the palatal dome for the three sizes of the ILMA were measured along the same axis as PE distance. These distances were 67, 71 and 75 mm for sizes 3, 4 and 5 ILMA, respectively. A plot of PE and PA measurements in the 50 subjects showed that for all except one subject the position of the EEB tip came to lie within the glottic aperture for at least one of the three sizes of ILMA (fig. 3).

TRACHEAL TUBE GUIDING RAMP

In order to direct the TT anteriorly as it emerged from the mask aperture, the passage immediately behind the EEB was provided with a 20° ramp in its floor (fig. 4). This gave a 47° angle with the plane of the mask cuff. The posterior floor of the ramp was contoured in a "V" instead of a "U" shape in order to centralize tubes passed through it irrespective of diameter; this avoided the problem of TT being deviated to the left or right when they impinged on the EEB.

TRACHEAL TUBE

Direct laryngoscopy requires distortion of the anatomy to obtain a line of sight from the mouth to the vocal cords. The TT has traditionally been shaped to facilitate its placement when the head, neck and anterior pharyngeal structures have been distorted. On encountering the laryngeal inlet, a TT is required to reverse its curvature by approximately

30° from the plane of the inlet to pass into the trachea. In view of this it was clearly undesirable to use a TT the natural curvature of which was in the reverse direction. Moreover, polyvinylchloride (PVC) TT were found to retain the additional curvature imposed on them by the ILMA tube. Bench testing using standard PVC TT showed that PVC significantly retained the curvature imposed by passage through the metal tube and that this effect was retained even when the tubes were warmed to 37 °C (fig. 5). This effect was not seen with silicone tubes. Therefore, it appeared logical to use straight, soft, cuffed silicone TT when intubating through the ILMA device. Accordingly, prototype 8 mm id cuffed silicone TT were prepared (Accusil Inc, IN, USA). These were marked transversely with a depth marker to show the user the point at which the tip of the TT was about to lift away the EEB. In addition, a longitudinal line similar to the black line on an LMA tube was provided to serve as a guide to the

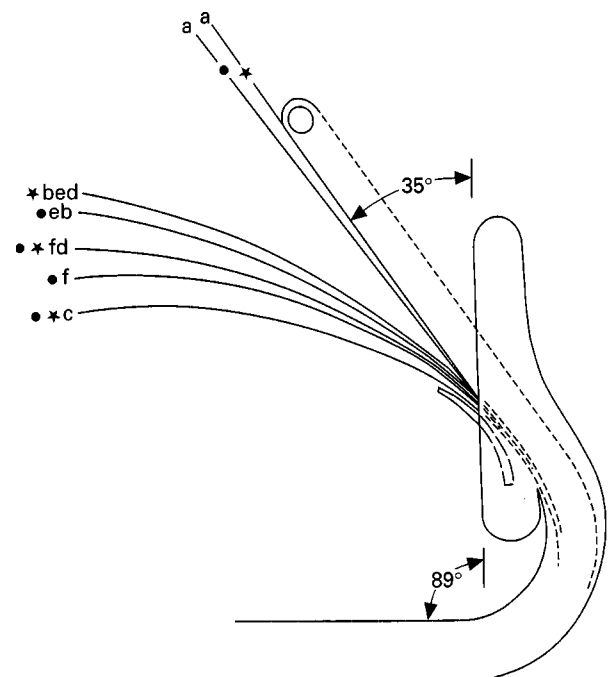


Figure 5 Effect on tracheal tube curvature for different tubes at 25 °C (●) and 37 °C (★) when passed through the ILMA tube: a = straight silicone 8 mm; b = curved Euromedical PVC 8 mm; c = Rusch red rubber 8 mm; d = Portex PVC 8 mm; e = Mallinkrodt PVC 8 mm; and f = Mallinkrodt PVC reinforced 7 mm.

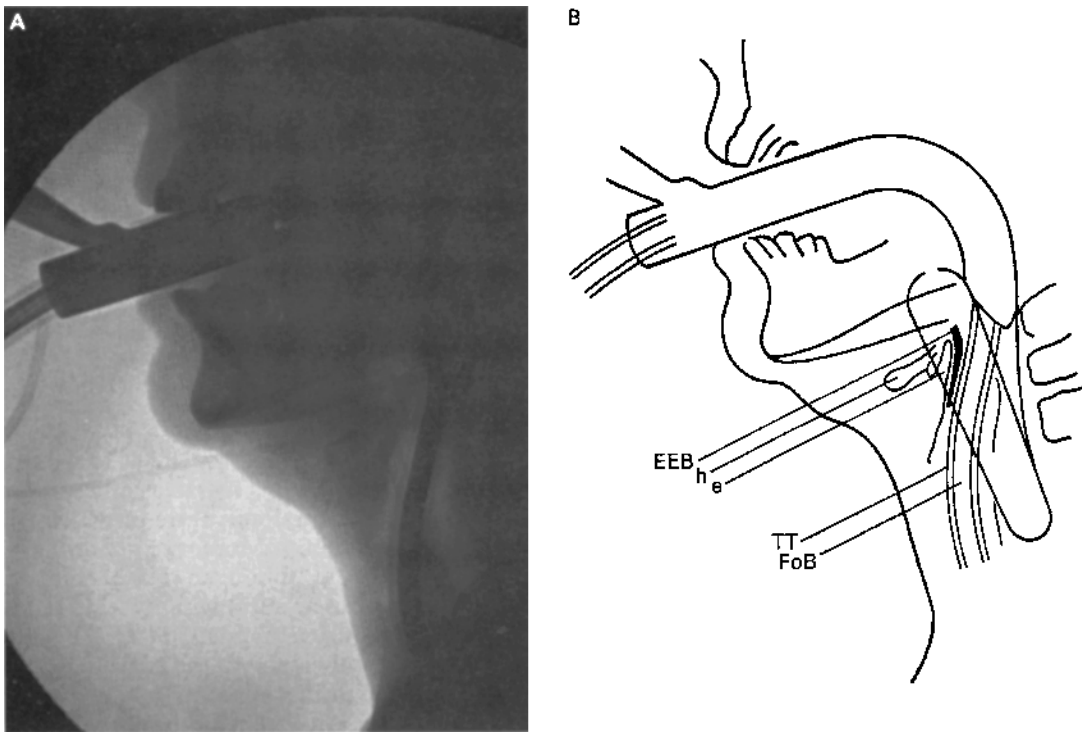


Figure 6 Soft tissue radiograph with explanatory drawing of a patient's trachea intubated through the ILMA. A fibreoptic scope had been passed through the straight silicone tube subsequently. EEB = Epiglottic elevator bar; h = hyoid; e = epiglottis; TT = straight silicone tracheal tube; and FoB = fibreoptic bronchoscope.

orientation of the TT bevel. The pilot balloon and valve were small enough to pass easily through the metal tube of the ILMA, and the TT connector was removable (standard connectors are too large to pass through the ILMA tube) in order that the ILMA could be removed from the patient when intubation has been achieved.

Figure 6 is a soft tissue radiograph with explanatory drawing showing a patient's trachea intubated through the device using a silicone tube, through which a fibrescope has been passed. The EEB can be seen displacing the epiglottis anteriorly.

Discussion

We have described the further development of an ILMA prototype to aid tracheal intubation.

Our initial studies with a modified LMA⁶ indicated that with manipulation of the head and neck it was possible to place a TT blindly while maintaining ventilation by connecting the TT to the anaesthesia system. With the further development of the ILMA, several potential advantages compared with conventional laryngoscopy and intubation are apparent. The standard tracheal tube is subject to distortion stresses when in place which, as Lindholm pointed out, are transmitted to the anatomy.⁸ This factor combined with the distortion stresses inherent in laryngoscopic manipulation make it unsurprising that the conventional practice of tracheal intubation is associated with significant morbidity.⁹ The ILMA design allows a soft, flexible, silicone tube to be directed towards the plane of the glottis without distortion of the anatomy. Further, the ILMA is inserted without manipulation of the head and neck.

Circulatory responses to direct laryngoscopy and tracheal intubation were first described in 1951¹⁰ and since then much work has focused on ways to attenuate these responses. It has been shown that placement of the LMA is associated with a reduced stress response compared with the TT^{11,12} and this may be advantageous in those patients likely to be adversely affected, such as those suffering from hypertension or ischaemic heart disease, or both. It is possible that tracheal intubation through the ILMA may be less stimulating than conventional laryngoscopy, but this remains unsubstantiated. Ease of placement without head and neck manipulation and without the need for the rescuer to be positioned behind the head or to insert fingers into the mouth, together with its ability to serve as a sole airway suggest a role in emergency medicine. This role is made more attractive by the possibility of subsequently being able to insert an appropriate sized TT through the device without first having to remove it. Finally, inability to ventilate a patient's lungs during attempts at TT placement remains an unsolved problem in anaesthesia. We believe this ILMA prototype has the potential to help alleviate this problem, not only by permitting continued ventilation during intubation attempts, but because avoidance of the need to obtain a line of sight should in theory eliminate the major cause of such difficulties. Our preliminary clinical experience with this device in 150 patients with routine and abnormal airways is reported subsequently.¹³

Acknowledgement

We thank the Department of Radiology at the Royal Berkshire Hospital for their assistance in making available the MRI and Dr J. Brimacombe for advice.

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