THE LARYNGEAL MASK—A NEW CONCEPT IN AIRWAY MANAGEMENT

A. I. J. Brain

SUMMARY
A new type of airway is described, which may be used as an alternative to either the endotracheal tube or the face-mask with either spontaneous or positive pressure ventilation. The results of a pilot study involving 23 patients are presented and the possible merits and disadvantages of the device are discussed, bearing in mind that the study is of a preliminary nature.

Viewed mechanically, tracheal intubation is a procedure in which two tubes, one man-made and the other anatomical, are connected together by inserting one into the other, a cuff being inflated on the inner tube to effect a gas-tight seal. In engineering terms, this solution to the problem of forming a gas-tight junction between two tubes is rather unsatisfactory, since it necessarily involves a degree of constriction at the point of junction unless the outer tube is itself expanded to compensate. Ideally, it is desirable that both tubes are of the same internal diameter at their point of junction, since this has clear advantages in terms of gas flow. This involves connecting them end to end, since the option of expanding the anatomical tube is not practicable.

An examination of postmortem specimens of the adult male and female larynx was made to assess how such a joint might be achieved. It was noted that an airtight seal could be effected against the perimeter of the larynx posteriorly by an elliptical cuff inflated in the hypopharynx. This observation led to the concept of the Laryngeal Mask.

MATERIALS AND METHODS
A prototype was constructed (fig. 1) by forming a shallow mask with an inflatable rubber cuff, joined to a tube communicating with the lumen of the mask at right angles. The rubber cuff of a Goldman paediatric dental mask was stretched onto the diagonally-cut endotracheal end of a Portex 10-mm clear plastic tube and fixed in position using acrylic glue. The resulting apparatus resembles a spoon. A means of inflating the elliptical cuff was provided by re-routing the pilot tube used to inflate the endotracheal cuff. The pilot tube was provided with a non-return valve.

Further reference to anatomical specimens served to confirm that the device could be inserted easily into the hypopharynx via the mouth, provided that it was inserted facing backwards and then rotated through 180 degrees as it was passed downwards into position behind the larynx (fig. 2).

Twenty-three patients who gave informed consent were studied. Sixteen were female patients undergoing laparoscopic investigation or sterilization, or both. These were studied first to assess the feasibility of positive pressure ventilation using the laryngeal mask. Premedication was with either

FIG. 1. Prototype of the laryngeal mask.
lorazepam or papaveretum and hyoscine. Anaesthesia was induced with thiopentone, and alcuronium 0.2 mg kg\(^{-1}\) was used to provide neuromuscular blockade. This relatively small dose was chosen because it was not considered likely that relaxation was essential to insertion of the device. During the procedure a form was completed which gave the following information:

1. Ease of insertion, graded as: easy/difficult/impossible.
2. Time taken to insert device: measured from moment mouth was opened to moment when mask was in position (excluding time taken to inflate cuff).
3. Whether or not a laryngoscope was used.
4. Whether leaks were detected at 2.0 kPa inflation pressure using a stethoscope held to the side of the neck overlying the larynx. The pressure was measured with reference to the Manley ventilator anaeroid pressure guage.
5. Total air in cuff (ml).
6. Greatest peak airway pressure on IPPV (kPa).
7. Inspired and expired minute volumes, the latter using Wright's mechanical spirometer.
8. Action taken to decrease any leak developing.
9. Whether blind suction, using a soft catheter to effect pharyngeal toilet after reversal of neuromuscular blockade, was associated with problems attributable to the presence of the laryngeal mask.
10. Whether removal of the mask was easy, difficult, required a laryngoscope or was associated with coughing, retching, vomiting, or laryngospasm.
11. Whether removal of the mask was preceded by any of the above.

Patients were questioned on recovering consciousness and again on the following day, concerning the development of sore throat, difficulty in swallowing or difficulty in phonation, or any other symptoms that might be attributable to use of the laryngeal mask.

A further six patients were studied to assess the performance of the laryngeal mask in patients breathing spontaneously. The mask was also used in one dental patient to assess its value in this situation.

RESULTS

In all 16 patients undergoing laparoscopy, ventilation of the lungs was achieved successfully using one of the prototype laryngeal masks (which varied slightly from one another in size and shape), with a Manley Blease ventilator. Adequacy of ventilation was measured by comparing expired with inspired minute volumes and by auscultation of the neck laterally at a point overlying the larynx.

In all patients the device was inserted without the aid of a laryngoscope, by placing the head and neck in the usual intubating position and inserting the deflated mask with its lumen facing backwards to facilitate negotiation of the angle behind the tongue. The dorsum of the mask was liberally coated with "KY" jelly to facilitate this manoeuvre. No analgesic throat spray was used. Downward descent of the mask could be discerned by observation of the front of the neck, where a slight but unmistakeable bulging of the tissues overlying the larynx served to indicate that the mask was in position. The mask was designed in such a way that when its distal tip reached the triangular base of the hypopharynx, further downward progress could not occur unless excessive force were used. A definite end-point was felt at this level, which also coincided with correct placement of the mask against the laryngeal inlet. In practice, it was found that by observing the front of the neck and feeling for resistance to further down-
ward progress, the mask could be reliably positioned.

The results, as tabulated on the questionnaire, were as follows: Insertion was graded as easy in all patients, although experience led to more frequent correct placement at the first attempt. The average time taken to insert the device was 7.3 s (range 2–15 s). Leaks were present initially in six patients, but were successfully abolished in all (table I). Of the leaks which developed, all occurred after insertion but before surgery was started and all were overcome with little difficulty. No case of obstruction occurred, either partial or complete. The average volume of air required to inflate the cuff sufficiently to form a gas-tight seal at 2.0 kPa was 17.5 ml (range 7–25 ml).

During IPPV the average peak airway pressure was 1.8 kPa (range 1.5–2.3 kPa). The readings obtained from the Wright respirometer were all greater than the inspiratory minute volume as measured by rotameter readings, presumably reflecting the known inertial characteristics of this respirometer, which in fact gave readings which were on average 14.68% greater than the measured inspired minute volumes (range 10.6–25%).

Following reversal of neuromuscular blockade, suction was performed and judged to be easy in all patients and no laryngospasm was provoked by pharyngeal toilet. The mask was removed after complete deflation of the cuff using a 20-ml syringe, and was judged easy in all patients. There were no instances of coughing, laryngospasm, retching, vomiting or apnoea before, during or after removal of the mask. On all occasions, spontaneous respiration, which had been established before removal was attempted, continued without change in respiratory pattern. Following operation, three patients complained of sore throat, all graded as mild (< 20%). No other symptoms were reported.

Of the six patients who were allowed to breathe spontaneously, three received suxamethonium electively to facilitate insertion and, by way of comparison, three received no neuromuscular blocking drug. All six patients maintained an unobstructed airway throughout the operation. Those patients in whom the device was inserted without the help of neuromuscular blockade required a level of anaesthesia sufficient to abolish the gag reflex and relax the jaw before it became possible to insert the mask. Once this level was reached, insertion was not judged to be more difficult than under conditions of neuromuscular blockade.

One patient undergoing a difficult dental extraction was studied. The fact that the mask took up most of the space in the hypopharynx reduced the volume of packing required and it was found that the mask afforded more protection to the larynx from fragments of teeth, blood and debris than an endotracheal tube. Insertion and removal of the mask were easy and without incident, and a good airway was maintained throughout the procedure.

**DISCUSSION**

Although endotracheal intubation has a long history as one of the most widely accepted techniques in anaesthetic practice (Keys, 1945; Armstrong Davidson, 1965) it is not without complications, most of which arise from the need to visualize and penetrate the laryngeal opening (Kambic and Radsel, 1978). The laryngeal mask was designed primarily as a means of offering some of the advantages of endotracheal intubation while avoiding this fundamental disadvantage, since the vocal cords need be neither visualized nor forced apart.

It should be stated that this study was of a very preliminary nature and that the number of patients studied was too small for firm conclusions to be drawn. Nonetheless, ease and simplicity of use and the fact that the device was well tolerated without serious side-effects, were positive features. In two patients the anatomy was such as to suggest that endotracheal intubation might have presented at least moderate difficulty. Neither presented difficulty with regard to insertion of the laryngeal mask. In carrying out pharyngeal toilet, it was noted that the catheter tip could not irritate the larynx since the mask effectively shielded it. It was also apparent that the secretions were easily accessible since the bulk of the mask when inflated caused secretions to pool above it rather than behind it. In the one dental patient studied, the shielding action of the mask was appreciated since it prevented blood or tooth frag-

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**TABLE I. Instances in which leaks developed at the laryngeal mask – larynx interface**

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>Action required to eliminate leak</th>
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<tbody>
<tr>
<td>1</td>
<td>Change mask position</td>
</tr>
<tr>
<td>1</td>
<td>Reduce cuff volume</td>
</tr>
<tr>
<td>1</td>
<td>Increase cuff volume</td>
</tr>
<tr>
<td>1</td>
<td>Change to wider mask prototype</td>
</tr>
<tr>
<td>1</td>
<td>Change to larger mask prototype</td>
</tr>
<tr>
<td>1</td>
<td>Leak stopped spontaneously</td>
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</tbody>
</table>
FIG. 3. The site and extent of this malignant growth made visualization of the larynx difficult. The airway could not be adequately maintained with a face-mask in spite of insertion of a Guedel airway. A laryngeal mask, shown in position, was inserted without difficulty, requiring neither laryngoscope nor neuromuscular blocking agent.

ments dropping into inaccessible positions. Since no neuromuscular blocker was used, time spent performing a venepuncture was saved and the patient spared the side-effects of suxamethonium.

The disadvantage which became of importance during the study was the initial failure to obtain a good seal in six of the patients when an inflation pressure of 2 kPa was applied to the airway, although the problem was overcome without difficulty in all of these (table I). Clearly, improvements can be made in the construction of the prototypes which need to be available in a range of sizes. While this study is too small for firm conclusions to be drawn, the concept would appear sufficiently promising to justify more extensive trials, which are under way. A further 108 patients have been studied to date and the results have so far confirmed the safety and efficacy of the device when used as an alternative to the face-mask in the spontaneously breathing patient. Once experience has been gained, difficulty in insertion can be expected in less than 1\% of patients. In only one patient has it been found that apparently correct insertion failed to provide an adequate airway. However, sufficient depth of anaesthesia is essential to successful insertion, unless a neuromuscular blocking agent is used. It is sometimes necessary, in patients with a large epiglottis, to pull this structure forward, using a laryngoscope in the usual way. This problem has not occurred in females and it is felt likely that it could be eliminated by improved design of the device, which is still in the form of a relatively crude prototype.

The laryngeal mask would appear to be of particular value where difficulty is experienced in maintaining the airway, or when operating on the face or eyes, where it offers a less invasive alternative to tracheal intubation. It may be of similar value where the patient is a professional singer and it has been found useful in cases of difficult intubation (fig. 3).

ACKNOWLEDGEMENTS
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REFERENCES
Die laryngeale maske—Ein neuer begriff in der Beatmungstechnik

Zusammenfassung

Mascara laringea – un nuevo concepto en la gestión de conductos de aire

Sumario
Se describe un nuevo tipo de conducto de aire que puede usarse como alternativa al tubo endotraqueal o a la máscara facial, tanto para la ventilación espontánea como para la de presión efectiva. Se presentan los resultados de un estudio de orientación en el que incluyeron 23 pacientes, al tiempo que se discuten las posibles ventajas y desventajas de tal dispositivo, teniendo en cuenta que el estudio es de naturaleza preliminar.