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EQUIPMENT

# The LMA 'ProSeal'—a laryngeal mask with an oesophageal vent

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We describe a new laryngeal mask airway (LMA) that incorporates a second tube placed lateral to the airway tube and ending at the tip of the mask. The second tube is intended to separate the alimentary and respiratory tracts. It should permit access to or escape of fluids from the stomach and reduce the risks of gastric insufflation and pulmonary aspiration. It can also determine the correct positioning of the mask. A second posterior cuff is fitted to improve the seal. A preliminary crossover comparison with the standard mask in 30 adult female patients showed no differences in insertion, trauma or quality of airway. At 60 cm $H_2O$ intracuff pressure, the new LMA gave twice the seal pressure of the standard device ($P<0.0001$) and permitted blind insertion of a gastric tube in all cases. It is concluded that the new device merits further study.

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This paper describes a new type of laryngeal mask airway (LMA) incorporating a drainage tube (LMADT). The main aim of the drainage tube is to enhance the safety and the scope of the device, particularly when used with positive pressure ventilation.

## Evolution of the concept

The standard LMA has been successful because it usually requires little skill to achieve a patent airway.[1] Suboptimal insertion or fixation of the LMA may allow its distal end to lie anywhere from the nasopharynx[2] to the rima glottidis,[3 4] yet often the airway remains clinically clear. However, the mask was designed to lie with its distal end wedged against the upper oesophageal sphincter (UOS). Any other position is intrinsically unstable for anatomical reasons, as the shape of the mask is an imitation of the pocket-like hypopharynx in which it is intended to lie.

This instability may allow movement during anaesthesia or recovery. A recent report[5] described 82 out of 283 female patients in whom the LMA had rotated onto its side. In addition, mismatch between the mask and pharyngeal contours may result in an inadequate seal,[6] causing the anaesthetist to increase intracuff pressure, which can damage superficial nerves. Evidence from cadavers suggests the mask may protect against regurgitation if its tip is correctly wedged against the UOS.[7] However, this position is not always achieved because the UOS is visible in up to 10–15% of patients when a fibrescope is passed down the airway tube.[8 9] Clearly an LMA which allows the user to detect malposition would be advantageous.

In 1983, the inventor noted that if a second tube was placed in the long axis of the mask, with a distal opening at the mask tip and open proximally to the atmosphere, an effective seal could not be achieved against the larynx unless the distal end of the mask, with its open second tube, was sealed against the UOS. An effective seal around the larynx indicated an effective seal of the second tube at the UOS, as otherwise gases would escape through the second tube. As such leakage was easily detected, this double-tube design seemed desirable because it indicated poor mask position (Fig. 1).

The second tube in the device allows a second sealed junction against the UOS, giving continuity with the alimentary tract and isolating it from the airway. Theoretically this should give (i) some channelling of regurgitated gastric contents; (ii) in consequence, less need for effective occlusion of the UOS by the mask tip in the event of regurgitation; (iii) the opportunity to pass a gastric tube through the

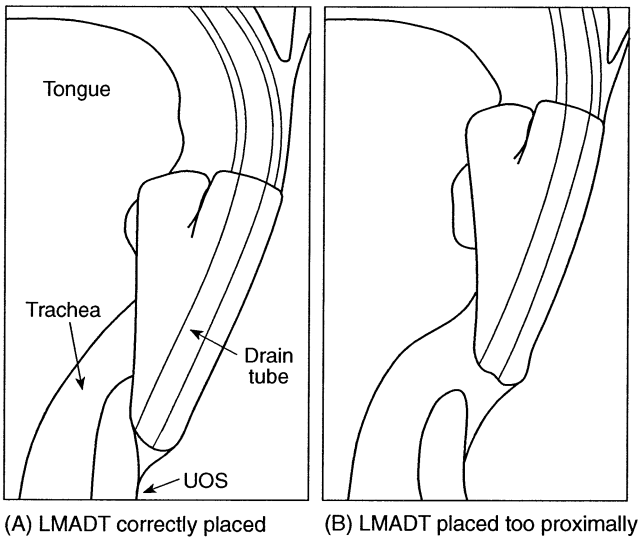


**Fig 1** (A) The LMADT correctly placed. The distal opening of the drainage tube is wedged against the upper oesophageal sphincter, preventing escape of inspired gas through the drainage tube. (B) The LMADT is lying too proximally. The distal end of the drainage tube may communicate with the airway, resulting in gas leaks from the proximal end of the drainage tube.

**Table 1** Differences between early (1995) and current models of LMA with drainage tube (DT). ILMA = intubating laryngeal mask airway

| Prototype LMA with drainage tube (1995) | New LMA with drainage tube (1999) |
|---|---|
| DT behind airway tube and mask bowl | DT arranged lateral to airway tube |
| DT runs posterior to mask bowl | DT runs anterior to mask bowl |
| Mask aperture bars | No mask aperture bars |
| Distal orifice of DT cut square | Distal orifice of DT cut obliquely |
| DT not designed to collapse on deflation | DT orifice designed to collapse on deflation |
| Bowl of mask in same position as standard LMA | Bowl of mask moved posteriorly |
| Mask is same shape as standard LMA | Mask has posterior extension proximally |
| Mask has large posterior cuff to increase seal | Mask seal increase achieved partly by deeper bowl, partly by smaller posterior cuff |
| Not fitted with finger/introducer locating strap | Fitted with finger/introducer locating strap |
| Not fitted with bite-block | Fitted with integral bite-block |
| No introducer tool | Introducer tool available |
| Insertion requires rotation, like Guedel airway | Insertion same as standard LMA (using finger) or same as ILMA (using introducer tool) |
| Airway tube identical to standard LMA, but stiffened by presence of posteriorly placed DT | Airway tube is wire-reinforced, more flexible than standard LMA |

drainage tube; and (iv) avoidance of gastric insufflation during positive pressure ventilation.

A crude prototype incorporating a drainage tube was described in 1995.[10] Important differences from the previous (1995) prototype are summarized in Table 1.

This paper describes a more developed form of the LMADT (LMA ProSeal, LMA Company) and preliminary data obtained from a feasibility study.

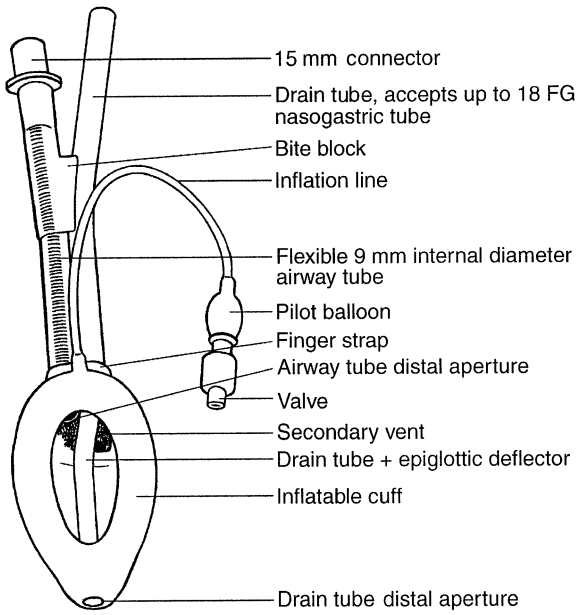


**Fig 2** The size 4 LMADT seen from the front.

## Device description

Figure 2 shows the LMADT from the front.

## Methods

### *Preliminary clinical data*

*Study aims*

We had only one size of prototype device. We planned a limited comparison of the new LMA with the standard device to assess the following: (i) ease of insertion with or without a special introducer tool; (ii) airway seal pressure at standard intracuff pressure of 60 cm $H_2O$; (iii) an appropriate patient weight for the single size of trial device available (equivalent to a size 4 LMA); (iv) ease and reliability of insertion of nasogastric tubes up to 18 French gauge

We obtained local ethical committee approval to compare the new device (LMADT) with the standard LMA within the same patient. We studied 30 fasted ASA 1 or 2 adult female patients who had given written informed consent and were undergoing procedures requiring general anaesthesia where a standard size 4 LMA would normally have been chosen. Before starting the study, three investigators, who were of consultant grade, were taught how to use the device by the inventor (AIJB). Each then performed 10 insertions with the index finger and then 10 insertions with the introducer tool, before collecting data from a further 10 patients, in five of whom the insertion tool was used. The device to be used first was selected randomly by opening a sealed envelope. A standard size 4 LMA and the test

device were inserted into each patient and inflated to 60 cm $H_2O$ intracuff pressure, using a calibrated aneroid manometer. Insertion using the index finger was identical to the standard insertion technique described in the LMA instruction manual,[11] but insertion using the tool provided was identical to that for the intubating laryngeal mask airway.[12]

Anaesthetic technique and premedication were not standardized, but in all cases patients were paralysed and ventilated and standard monitoring was applied before anaesthesia. Using the anaesthetist's choice of non-depolarizing agent at a dose appropriate for tracheal intubation, neuromuscular block was achieved before insertion of the device. Immediately after insertion and cuff inflation, manual ventilation of the lungs was carried out with the circuit closed to determine (i) whether an expired volume of more than 8 ml $kg^{-1}$ could be achieved, using a Datex Monitor AS/3 (Datex Engstrom, Helsinki, Finland) and, in the case of the test device, (ii) whether leaks occurred up the drainage tube at less than 20 cm $H_2O$ airway pressure. A minimum $V_T$ of 8 ml $kg^{-1}$ was chosen in an attempt to avoid gastric insufflation. Leak detection was sought below a peak airway pressure of 20 cm $H_2O$ as significant leaks up the drainage tube below this level would suggest malposition of the device. For the latter measurement, an in-line manometer was placed immediately proximal to the airway device and a bolus of 0.5–1 ml of lubricant jelly was placed in the proximal orifice of the drainage tube to seal it. The airway pressure at which this bolus was ejected was noted. If such leaks were detected, malposition was diagnosed and a further insertion attempt was made after the device had been deflated carefully. If partial or complete airway obstruction was noted or the minimum expired tidal volume was not achieved despite adequate neuromuscular block, entry of the distal end of the device into the laryngeal vestibule was presumed and the device was removed and reinserted. A maximum of three attempts was permitted with each device, after which the alternative device was used. If neither device could achieve a satisfactory airway, as defined above, the patient's trachea was intubated conventionally.

If a satisfactory airway had been achieved, the selected device was fixed in place with its cuff inflated to 60 cm $H_2O$. A single within-patient comparative test was carried out under steady-state conditions (before surgical manipulation) to determine the relative seal pressure for each device at which leaks occurred, as follows: the ventilator was switched off, the spill valve closed and pressure allowed to rise in the breathing circuit at 3 litre $min^{-1}$ fresh gas flow, until no further increase in pressure was seen. Circuit pressure was not allowed to increase above 40 cm $H_2O$ and oxygen saturation, measured with finger transmission oximetry (Datex AS/3), was not permitted to fall below 95%. Except when one of the devices had previously failed to provide an airway within three attempts, the device currently in place was then deflated, removed and immediately replaced with the alternative device, after which the measurement was repeated. In the case of the test device, a lubricated nasogastric tube (12–18 French gauge) was inserted blindly down the drainage tube after demonstration of correct device position and after pressure measurements had been made. Suction was applied, the volume of any gastric fluid noted and the catheter removed. Ease or difficulty of placement was noted. Investigators were warned that in no circumstances should force be used in attempting to pass the nasogastric tube.

Before starting the study, we measured the volume of each device at atmospheric pressure and then its static compliance when inflated with up to 30 ml additional air. In patients, we recorded body weight, height ($n$=20), subjective ease of insertion (1=very easy, 2=easy, 3=difficult, 4=very difficult), volume added to the cuff to achieve an intracuff pressure of 60 cm $H_2O$, duration of anaesthesia, anaesthetic agents used, whether regurgitation was observed at any time with either device and how this was detected, and any comments by recovery staff regarding the quality of recovery. Removal of the device in all cases was timed to coincide with the return of consciousness, indicated by response to command.

In a subgroup of 20 patients (group 2), further data were recorded: (i) fibre-optic assessment (fibreoptic bronchoscope, FOB) was made to compare views through the LMA and LMADT using a scoring system (1=full view of cords, 2=view of cords partially blocked by epiglottis, 3=only arytenoids visible, 4=no laryngeal structures visible); (ii) the body mass index was also calculated in this group to see whether this was related to seal pressure.

### *Statistical analysis*

To detect a minimum difference of 5 cm $H_2O$ between the two devices, we took interpatient variability as SD=4, based on experience and an empirical finding of a coefficient of variation (CV) of 0.2. Instrumental accuracy was taken as being within a CV of 0.1, giving SD=2. Together, this gives a power of 0.915 when taking 18 readings with each device. Allowing for possible exclusions, we chose to examine a minimum of 20 patients. Data were analysed using the chi-squared test, and $P<0.05$ was taken as statistically significant. Data are reported as mean (range) unless stated otherwise.

## Results

Cuff volumes for the LMADT and LMA at atmospheric intracuff pressure were 30 and 25 ml respectively. Progressive inflation with a further 30 ml air gave a mean compliance for each device of 0.36 (0.04–0.02) and 0.13 (0.02–0.01) ml cm $H_2O^{-1}$ respectively.

Twenty patients were recruited from our institution and a further 10 from a second institution. Propofol and Atracurium were used in all patients. The patients had a body weight of 67.5 (50–95) kg, height of 161 (152 –172) cm

**Table 2** Fibre-optic scores and ease of insertion for the standard LMA and the LMA with drainage tube (LMADT). Fibre-optic scores: 1 = cords fully visible; 2 = cords partly occluded by epiglottis; 3 = only arytenoids visible; 4 = no laryngeal structures visible. Ease of insertion scores: very easy, easy, difficult, very difficult/impossible. Data were analysed with the chi-squared test. There were no significant differences between the scores for either feature ($P$=0.49 for fibre-optic score, $P$=0.13 for ease of insertion)

| Device | Fibre-optic score | | Ease of insertion | |
|---|---|---|---|---|
| | 1 | 2, 3 | Very easy | Easy |
| LMA | 13 | 7 | 28 | 2 |
| LMADT | 15 | 5 | 24 | 6 |
| Totals | 28 | 12 | 52 | 8 |

and duration of anaesthesia of 48 (20–120) min. No patients were judged difficult for insertion of either device. Two LMA insertions and six LMADT insertions were scored 'easy' as opposed to 'very easy' ($P$=0.13) (Table 2). The insertion tool did not affect ease of insertion. At an intracuff pressure of 60 cm $H_2O$, mean seal pressures were twice as high with the LMADT as with the standard LMA: 30 (15–40) compared with 15.8 (10–32) cm $H_2O$ respectively ($P$<0.0001). There was no relation to body weight ($P$= 0.7). Mean volume of air injected into the cuff to achieve an intracuff pressure of 60 cm $H_2O$ was 25.9 (16–34) ml for the LMADT and 15.3 (10–25) ml for the LMA. Leaks from the LMADT drainage tube were detected at lung inflation pressures less than 20 cm $H_2O$ in five of 30 patients, but were abolished in all but one of these either by pressing the device more firmly into place ($n$=2) or by reinsertion ($n$=2). Obstruction immediately after insertion was diagnosed in one case with the LMA and in two cases with the LMADT, only one of which required reinsertion to correct it. A tidal volume of 8 ml $kg^{-1}$ was achieved in 29 of 30 cases with the LMA and in all cases with the LMADT. No patient required tracheal intubation. A nasogastric tube was inserted through the LMADT drainage tube easily in 28 patients, with difficulty in two. Gastric fluid was aspirated from the stomach in 25 of 30 cases, the volume being 15 ml (0–80). After device removal in the recovery area, a trace of blood was seen on the LMA mask in one and on the LMADT mask in two cases (difference not significant). There were no cases of regurgitation or aspiration.

The relationship between body mass index and seal pressure is shown for the 20 patients in group 2 in Figure 3. There was no significant difference in fibre-optic score (Table 2).

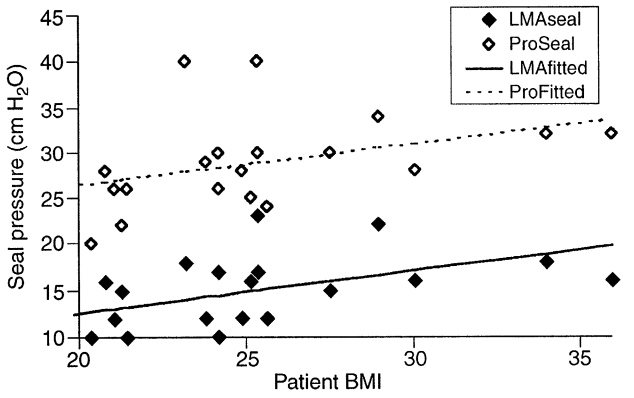


**Fig 3** LMA and LMADT seal pressures at 60 cm $H_2O$ intracuff pressure in relation to body mass index (BMI). Slope of line shows the increase in seal pressure for each unit increase in BMI (0.44 cm $H_2O$). Seal pressure achieved with the LMADT is on average 14 cm $H_2O$ higher than with the LMA ($P$<0.0001).

## Discussion

We compared a new laryngeal mask incorporating a drainage tube (LMADT) with the standard LMA in a preliminary crossover study in 30 female patients. The following conclusions were drawn.

(i) The LMADT and the standard device are equally easy to insert.

(ii) The device can indicate correct or incorrect insertion, but further study will be required to confirm whether this is a reliable diagnostic feature.

(iii) On average, the seal pressure obtained was 10.8 cm $H_2O$ higher than with the LMA. ($P$<0.0001). It is tempting to relate this finding to the greater compliance of the new device (0.36 compared with 0.13 ml cm $H_2O^{-1}$). However, at 60 cm $H_2O$ cuff pressure *in vivo*, cuff volumes were less in both devices than measured volumes at atmospheric intracuff pressure *in vitro* (25.9 compared with 30 ml for the LMADT and 15.3 compared with 25 ml for the LMA). Therefore, at 60 cm $H_2O$ intracuff pressure, seals were achieved at inflation volumes lower than those required to expand the silicone walls of the cuff in both cases. We hypothesize that the larger capacity of the new device may give increased seal pressure by allowing the cuff walls to match the contours of the pharyngeal and laryngeal surfaces more effectively.

(iv) Seal pressures are not influenced by body weight over the range studied ($P$=0.7); however, in 20 patients in whom the body mass index was calculated, an upward trend of seal pressure was noted in both devices (0.44 cm $H_2O$ per body mass index unit, $P$=0.007), an interesting finding which warrants further investigation.

(v) Nasogastric tube insertion was usually easy, and this appears to be one of the most potentially useful aspects of the new device. However, it was difficult to insert a size larger than 16 French gauge in these preproduction samples.

In summary, the LMADT may offer some advantages over the existing LMA. The ease of nasogastric tube insertion through the new device was interesting. There is no technical reason why the tube could not be guided into place irrespective of the patient's position, once the mask itself is correctly positioned. Positive pressure was easily achieved over a wide weight range in female adults. The

value of the drainage tube, to reduce gastric inflation and reduce regurgitation and possible aspiration, needs further assessment.

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