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Prospective Clinical and Fiberoptic Evaluation of the Supreme Laryngeal Mask Airway™

Arnd Timmermann, M.D., Ph.D., D.E.A.A., M.M.E., Stefan Cremer, M.D.,† Christoph Eich, M.D., D.E.A.A.,* Stephan Kazmaier, M.D., Ph.D., * Anselm Bräuer, M.D., Ph.D., D.E.A.A.,* Bernhard M. Graf, M.D., M.Sc.,‡ Sebastian G. Russo, M.D., D.E.A.A.**

Background: **In March 2007, a new disposable laryngeal mask airway (LMA) became available. The *LMA Supreme*™ (The Laryngeal Mask Company Limited, St. Helier, Jersey, Channel Islands) aims to combine the *LMA Fastrach*™ feature of easy insertion with the gastric access and high oropharyngeal leak pressures of the *LMA ProSeal*™.**

Methods: **The authors performed an evaluative study with the *LMA Supreme*™, size 4, on 100 women to measure the ease of insertion, determinate the laryngeal fit by fiberoptic classification, evaluate the oropharyngeal leak pressure, and report adverse events.**

Results: **Insertion of the *LMA Supreme*™ was possible in 94 patients (94%) during the first attempt, and in 5 patients (5%) during the second attempt. In one small patient, the *LMA Supreme*™ could not be inserted because of limited pharyngeal space. This patient was excluded from further analysis. Insertion of a gastric tube was possible in all patients at the first attempt. The median time for *LMA Supreme*™ insertion was 10.0 s (±4.7 s; range, 8–30 s). Laryngeal fit, evaluated by fiberscopic view, was rated as optimal in all patients, both immediately after insertion of the *LMA Supreme*™ and at the end of surgery. After equalization to room pressure, the mean cuff volume needed to achieve 60 cm H_2O cuff pressure was 18.4 ml (±3.8 ml; range, 8–31 ml). The mean oropharyngeal leak pressure at the level of 60 cm H_2O cuff pressure was 28.1 cm H_2O (±3.8 cm H_2O, range, 21–35 cm H_2O). Eight patients (8.1%) complained of a mild sore throat. No patient reported dysphagia or dysphonia.**

Conclusions: **Clinical evaluation of the *LMA Supreme*™ showed easy insertion, optimal laryngeal fit, and low airway morbidity. Oropharyngeal leak pressure results were comparable to earlier data from the *LMA ProSeal*™.**

THE *Laryngeal Mask Airway Supreme*™ (LMA; The Laryngeal Mask Company Limited, St. Helier, Jersey, Channel Islands) is a new disposable airway device that combines features of the *LMA Fastrach*™ (curved shaft to ease insertion), the *LMA ProSeal*™ (The Laryngeal Mask Company Limited) with gastric access tube to separate the respiratory and gastric tract to minimize the risk of aspiration and high oropharyngeal leak pressure (OLP), and the *LMA Unique*™ (The Laryngeal Mask Company Limited).[1,2] The idea of the *LMA Supreme*™ was to fulfill several requirements (verbal personal communication with Archie Brain, M.D., F.F.A.R.C.S.I., Honorary Consultant Anesthesiologist and Honorary Research Fellow, Institute of Laryngology, London, United Kingdom, November 2007): A larger, precurved cuff contributes to optimal laryngeal positioning and improved seal; a kink-proof, flattened airway design imitates the upper airway passageway; a less transverse diameter at the upper end of the mask reduces the minimally required mouth opening; an increased cuff volume eliminates the need for a second (posterior) cuff used with the *LMA ProSeal*™; a reinforced tip over the molded distal cuff was designed to prevent foldover; an elliptical airway tube allows easy placement with a stable airway *in situ* and prevents kinking; the dual cuff and internal webbing of the tip was developed to keep the drain tube open; the epiglottic fins may prevent the epiglottis from entering and obstructing the airway; a fixation tab ensures tip engagement with the upper esophageal sphincter and easy fixation to keep the *LMA Supreme*™ in position throughout the entire surgical procedure; and finally, an integral bite block protects the device against patient bite.

We conducted a prospective evaluation of the *LMA Supreme*™ to assess the ease of insertion, verify the laryngeal position by fiberoptic assessment immediately after insertion, and, at the end of surgery, measure the OLP to determinate early postoperative airway morbidity and report adverse events.

Materials and Methods

With approval of the Human Research Committee of the University of Göttingen Medical School and informed consent, we studied 100 women undergoing elective surgery. During the study period, only *LMA Supreme*™ size 4 was available. Exclusion criteria included increased risk of difficult airway management, history of gastroesophageal reflux, American Society of Anesthesiologists physical status of P4 or P5, and age <18 yr. The evaluation was performed from April 1 to October 31, 2007.

The *LMA Supreme*™ was prepared as shown in figure 1. Anesthesia was induced with fentanyl 2 μg/kg and propofol 2 mg/kg. Anesthesia was maintained with

* Staff Anesthesiologist, † Resident in Anesthesiology, ‡ Professor of Anesthesiology, Department of Anesthesiology, Emergency and Intensive Care Medicine, University Medical Center, Göttingen, Germany.

Received from the Department of Anesthesiology, Emergency and Intensive Care Medicine, University Medical Centre, Göttingen, Germany. Submitted for publication March 17, 2008. Accepted for publication September 29, 2008. A total of 110 *LMA Supreme*™ devices for use in this study were provided by The Laryngeal Mask Company Limited, St. Helier, Jersey, Channel Islands. The LMA Deutschland GmbH, in addition to several other companies, supports the Georg-August University of Göttingen in educational issues, including medical simulation and airway management courses. However, none of the above companies had any influence on data collection and analysis, interpretation of results, or drafting of the manuscript.

Address correspondence to Dr. Timmermann: Department of Anesthesiology, Emergency and Intensive Care and Medicine, University Medical Centre Göttingen, Robert-Koch-Strasse 40, 37075 Göttingen, Germany. atimmer@med.uni-goettingen.de. Information on purchasing reprints may be found at www.anesthesiology.org or on the masthead page at the beginning of this issue.

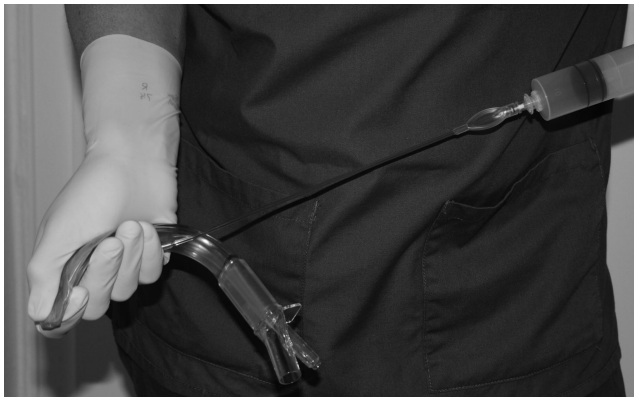

Fig. 1. Preparing the *LMA Supreme*™. While deflating the *LMA Supreme*™ (The Laryngeal Mask Company Limited, St. Helier, Jersey, Channel Islands) completely, the tip is slightly compressed between the thumb and the index finger to provide a flattened and slightly curved forefront. Simultaneously, the inflation line is pulled backwards to flatten the cuff.

sevoflurane 2% in oxygen during the study period. The *LMA Supreme*™ was inserted using the one-handed rotational technique, with the patient's head in the neutral position.[3] The cuff was equalized to ambient pressure and then inflated with air to a maximum pressure of 60 cm H_2O. The required inflation volume was recorded. A breathing circuit was connected and ventilation was graded as described before.[4] When an air leak through the drain tube was detected, the position was optimized by gently pushing the *LMA Supreme*™ further down the pharynx and/or to the lateral side using the fixation tab until the air leak ceased. When ventilation *via* the *LMA Supreme*™ proved impossible, one further insertion attempt was allowed. Air leak through the drain tube was detected by adding lubricant into the drain tube and detecting upcoming bubbles during ventilation ("lube tube or bubble test"). The time to achieve successful insertion was defined as the time from removing the face mask from the patient to the first valid capnography reading.

A 14-French size gastric tube was inserted *via* the drain tube; the success and the number of attempts were recorded. After stable ventilation with sevoflurane in oxygen, OLP was measured according to the method described by Keller *et al.*[5] Once the OLP was noted, a 3.5-mm fiberscope (Karl Storz GmbH & Co. KG, Tuttlingen, Germany) was introduced just proximal to the end of the ventilatory conduit, and the laryngeal view was recorded and categorized. This procedure was repeated at the end of surgery.

We defined an optimal fiberoptic position of the *LMA Supreme*™ with three criteria: The tip is placed behind the arytenoids; the epiglottis is visible, not folded down or entering the airway; and the vocal cords are visible during inspiration or when the fiberscope is placed under the epiglottis (fig. 2). Any deviation from these criteria was judged as a suboptimal position.

At the end of anesthesia, the *LMA Supreme™* was removed and traumatic alterations of the upper airway

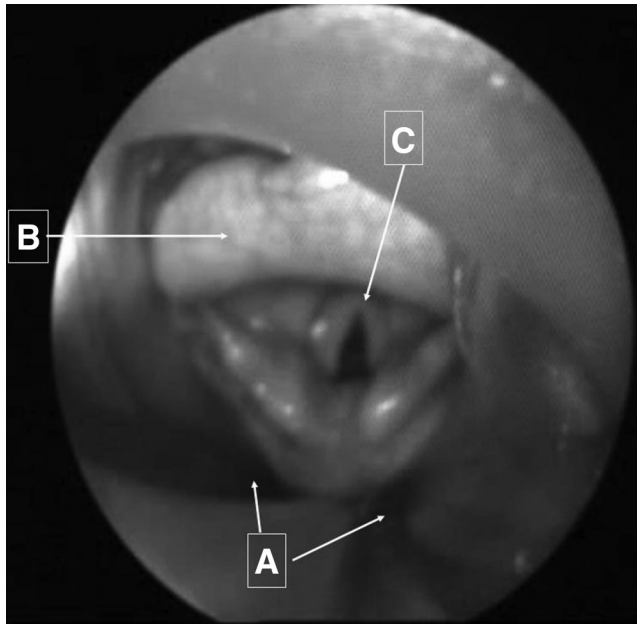

Fig. 2. Fiberoptic criteria for an optimal position of the *LMA Supreme*™ (The Laryngeal Mask Company Limited, St. Helier, Jersey, Channel Islands). (*A*) The tip of the *LMA Supreme*™ placed behind the arytenoids at the entrance to the upper esophageal sphincter. (*B*) The epiglottis visible, not folded down and not entering the airway. (*C*) The vocal cords completely visible during inspiration or after passing the fiberscope under the epiglottis.

were assumed based on any visible blood inside or outside the *LMA Supreme™* and a questionnaire. The questionnaire, which evaluated any sore throat, dysphagia, or dysphonia 2 h postoperatively (0–10 visual analog scale), was obtained by recovery nurses and recorded in a checklist.

Statistical Analyses

The data from each *LMA Supreme™* insertion were collected and analyzed using a spreadsheet program (Microsoft Office Excel 2003; Microsoft Corp., Redmond, WA) and a statistics program (SPSS 12.0.1; SPSS Inc., Chicago, IL). If not stated differently, all values are reported as mean, SD, and range.

Results

A total of 100 applications of the *LMA Supreme™* were assessed. The mean age was 52.4 yr (±18.4 yr; range, 19–88 yr), mean height 166.3 cm (±6.5 cm; range, 150–180 cm), mean body weight 71.5 kg (±14.9 kg; range, 48–120 kg), and mean body mass index 25.9 kg/m^{-2} (±5.2 kg/m^2; range, 17.0–41.5 kg/m^2). Ten patients had a body mass index in excess of 35 kg m^{-2}. Thirty-three patients were categorized as American Society of Anesthesiologists classification status P1, 61 as P2, and 6 as P3. Mean surgical procedure time was 64 min (±41 min; range, 11–180 min).

Insertion of the *LMA Supreme™* was possible in 94 patients (94%) on the first attempt, and in 5 patients (5%) on the second attempt. In 1 patient, a 53-yr-old woman with a body height of 1.50 m and a body weight of 48 kg, a size 4 *LMA Supreme™* could not be inserted within two attempts because of limited pharyngeal space. This patient was therefore excluded from further analysis. Of the remaining 99 patients, initial ventilation quality was classified as adequate in all patients. The median time for *LMA Supreme™* insertion was 10.0 s (±4.7 s; range, 8–30 s). Air leak of the drain tube was detected in 13 patients. In all of these patients, the *LMA Supreme™* position was adjusted without complete reinsertion.

Insertion of a drain tube was possible in all patients during the first attempt. Based on three criteria (fig. 2), laryngeal positioning was assessed by fiberoptic view and rated as "optimal" in all patients, both immediately after insertion of the *LMA Supreme™* and after the surgery.

After equalization to room pressure, the mean cuff volume necessary to achieve 60 cm H_2O cuff pressure was 18.4 ml (±3.8 ml; range, 8–31 ml). Mean OLP at the level of 60 cm H_2O cuff pressure was 28.1 cm H_2O (±3.8 cm H_2O; range, 21–35 cm H_2O). OLPs were 21–25 cm H_2O in 32 patients, 26–30 cm H_2O in 36 patients, and 31–35 cm H_2O in 31 patients.

As an unexpected adverse event, we observed a narrowing of the vocal cords in 11 patients (11.1%). An increased inspiratory airway pressure was observed in three of these patients, and an inspiratory stridor in another two patients. None of these patients required stopping the surgery or reinsertion or removal of the *LMA Supreme™*.

Possible traumatization of the upper airway was identified in 9 patients (9.1%) with visible blood on the outside of the *LMA Supreme™* cuff, and in 1 patient (1.0%) with visible blood inside the cuff. No patient had signs of lip, tongue, or mouth trauma. Eight patients (8.1%) complained of a mild sore throat (3 or less on a visual analog scale of 10) 2 h postoperatively, which was not associated with blood on the device. No patient reported dysphagia or dysphonia.

Discussion

The two major goals for the development of the new *LMA Supreme™* were easier insertion and better protection against unexpected gastric reflux. Our results are similar to a preliminary study published by Ferson *et al.*,[1] who reported 96% and 98% success rates for the first and second attempts, respectively. As compared with other LMA devices, *LMA Supreme™* first-attempt insertions were more successful than *LMA ProSeal™* insertions, which were reported as 87% in a meta-analysis by Brimacombe.[6] The *LMA Supreme™* has a curved shaft like the *LMA Fastrach™* to ease insertion. In a meta-analysis of the *LMA Fastrach™*, successful first insertions were reported as 91% and successful insertions as 99% overall, which is similar to our findings.[7]

LMA-Supreme™ insertion failed in one patient. This patient was small (48 kg, 150 cm) and might have benefitted from a *LMA Supreme™* size 3, which was not available during the study period. Nonetheless, size 4 was suitable for women ranging from 150 cm to 180 cm in body height, and from 50 to 120 kg in body mass. Insertion, ventilation, and fiberoptically evaluated laryngeal position were also optimal in obese patients with a BMI >35 kg/m^2. Therefore, the goal of developing an LMA that fit a large variety of adult female patients has been met, as confirmed by our study.

It is important to realize that the drainage tube might detect a misplacement of the *LMA Supreme™*, which can be corrected by using the air outflow of the drain tube as a guide until the air outflow stops.[8,9] This safety feature cannot be used in the *LMA Classic™*, as it does not have a drain tube. The *LMA Supreme™* is made of plastic, which offers greater rigidity as compared with the *LMA ProSeal™*. Therefore, the device is easier to insert without placing the index finger in the patient's mouth, and repositioning is possible without the need for complete reinsertion. In addition, our fiberoptic findings indicate that the *LMA Supreme™* does remain in the initial position with the help of its distinct fixation system, as intended, given that the laryngeal view did not change during surgery.

The mean OLP in our study was 28 cm H_2O, and hence is similar to studies that reported a mean OLP between 27 and 32 cm H_2O with *LMA ProSeal™* sizes 4 and 5.[10–13] This supports the designer's assumption that, because of its newly designed large-volume cuff, the *LMA Supreme™* achieved similar OLPs without the need for the *LMA ProSeal™*'s second cuff on the back of the device. However, our data did not confirm high OLPs of 35 cm H_2O (initially) and 39 cm H_2O (after 30 min), as were reported recently in a preliminary study including 22 patients with *LMA Supreme™*.[2] This may be explained by the fact that our OLP limit was set to a maximum of 35 cm H_2O by vote of our local ethics committee. A limitation of the OLP was not noted in the other study. In addition, many factors such as body weight, use of muscle relaxants, position of the head, or cuff pressure influence the OLP and might not be comparable between the two studies.

This study has several limitations. Only the *LMA Supreme™* size 4 was used, exclusively in women. Therefore our results only reflect this study population. According to the decision of our ethic committee, maximum OLP was set to 35 cm H_2O. In other studies, maximum OLP was set to 40 cm H_2O or above; therefore our reported mean OLP might be underestimated. Postoperative airway morbidity was assessed only 2 h post-

operatively, when the effects of anesthesia and opioids may still have been present, and sore throat may have developed later.

In summary, this evaluation study showed that the *LMA Supreme™* is easy to insert. The tip of the *LMA Supreme™* was always placed in the hypopharynx. No folding down of the epiglottis was observed. OLP was comparable to data from *LMA ProSeal™* studies. Airway morbidity 2 h postoperatively was low. Comparative studies with other supraglottic devices are required to estimate the value and effect of the *LMA Supreme™*.

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