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ORIGINAL ARTICLE

# Risk factors for difficult Laryngeal Mask Airway LMA-Supreme™ (LMAS) placement in adults: a multicentric prospective observational study in an Italian population

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## ABSTRACT

BACKGROUND: Supraglottic airway devices (SADs) are precious tools for airway management in both routine and rescue situations; few studies have analyzed the risk factors for their difficult insertion.

METHODS: The aim of this study was to identify the risk factors for difficult insertion for a specific SAD, the Laryngeal Mask Airway LMA-Supreme™ (LMAS). This was a prospective multicentric observational study on a cohort of Italian adult patients receiving general anesthesia for elective surgery. The possible causes of difficulty in LMAS placement (difficulty in insertion or unsatisfactory ventilation) were identified based on literature and on the opinion of international airway management experts. A dedicated datasheet was prepared to collect patients' data, including anthropometric-parameters and parameters for the prediction of difficult airway management, as well as technical choices for the use of LMAS. Data were analyzed to discover the risk factors for difficult LMAS placement and the association between each risk factor and the proportion of incorrect positioning was evaluated through the relative risk and its confidence interval.

RESULTS: Four hundred thirty-two patients were enrolled; seventy required two or more attempts to insert the LMAS; nine required a change of strategy. At multivariate analysis, the following factors were significantly associated with difficult LMAS placement: Mallampati III-IV with either phonation or not; inter-incisor distance < 3 cm; reduced neck mobility; no administration of neuromuscular blocking agents (NMBAs).

CONCLUSIONS: The alignment of the laryngeal and pharyngeal axes seems to facilitate the procedure, together with NMBA administration; on the contrary, Mallampati grade III-IV are associated with difficult LMAS placement.

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KEY WORDS: Airway management; Laryngeal mask; Equipment failure; Risk factors.

Supraglottic airway devices (SADs) have been used successfully in many different clinical conditions,[1] and nowadays their use is common both in the operating room, and in out-of-hospital settings.[2] Nevertheless, recent literature supports the evidence of some degree of failure in

successful placement, with implications for critical airway rescue situations such as difficult or impossible mask ventilation (prevalence 1.06%)[3] and the need to resort to emergency surgical airway or similar invasive intervention.[4] Recent data from a large Danish database[5] suggest that SADs are still underused as airway "rescue" tools, such as in difficult airway or Cannot Intubate-Cannot Oxygenate scenarios, and that when used in such a perspective, they showed only a 65.1% and 62.8% success rate, respectively.

These findings strongly suggest the need for improved knowledge and experience with these devices to identify the predictive factors for difficult SAD insertion. Numerous studies have identified risk factors for the failure of direct laryngoscopy and intubation, with controversial results and a limited predictive value for different tests.[6, 7] Similar studies have been performed to predict difficult SAD insertion and ventilation, but most of these studies were carried out on non-Caucasian patients, were retrospective, and had conflicting results.[8-13]

We therefore designed the present study to identify the potential risk factors related to the difficult insertion of a specific SAD, the Laryngeal Mask Airway LMA-Supreme™ (LMAS), in a cohort of Italian adult patients undergoing general anesthesia for elective surgery.

## Materials and methods

The study was designed as a multicentric prospective observational study. After obtaining IRB approval and an identification number from the National Clinical Trials Registry (NCT02934243), two centers were identified (Naples, Florence) and led by the coordinating center (University of Florence).

Patients older than 18 years, giving informed consent, and scheduled for elective surgery with SAD airway management were consecutively enrolled for the study between September 2018 and October 2019. For the sake of data homogeneity, data were collected only from patients who received an LMAS (Teleflex Medical, Athlone, Ireland). Exclusion criteria were patients with known pathologies of the upper airways, pharyngodynia or history of voice changes; those at risk of inhalation of gastric contents (previous gastric surgery, hiatal hernia, gastroesophageal reflux, peptic ulcer, pregnancy, full stomach); BMI>35; history of difficult airway management and refusal to participate in the study.

LMAS was placed in all patients according to the manufacturer's instructions,[14] sizing criteria were based on weight (LMAS size 3 if patient was less than 50 kg, LMAS size 5 if patient was more than 90 kg) and gender (smaller sizes were preferred for female patients). The attending anesthesiologist was, however, given the opportunity to decide on a different size or to change the device during the procedure. A dedicated datasheet was prepared to collect patients' data, including anthropometric parameters, registration of difficult SAD insertion and the anesthesiologist's experience with the insertion of LMAS.

The following factors, based on literature data[7, 9-13] and on the opinion of internationally known Italian experts in airway management from the Airway Management Study Group of SIAARTI (Italian Society of Anesthesia, Analgesia, Resuscitation and Intensive Care) (Supplementary Digital Material 1: Supplementary Text File 1) were chosen as data to evaluate LMAS difficult placement:

• anthropometric data: gender, age (years), weight (kg), height (cm), BMI (kg/cm2); difficult airway predictive factors:[15, 16] presence of maxillary prognathism (>1 cm); thyromental distance (<6 cm); sternomental distance (<12 cm); neck circumference (>40cm); dentition (other than fully represented); upper lip bite test (grade 3); STOP BANG (score>4); Mallampati (III-IV in phonation and not); inter-incisor distance (<3 cm); reduced neck mobility (neck mobility: extension from neutral position: normal, at least 35 degrees; reduced, less than 35 degree); evidence of difficult mask ventilation (need to use an oropharyngeal airway); size of tonsils (grade 3 or more), neck scars or history of neck radiation.

• technical factors for LMAS placement: head hyperextension; use of incorrect pillow (higher or lower than a standard-3cm pillow); LMAS tip manipulation (angling the LMAS tip upwards for a few seconds before insertion; this is a suggestion proposed by Dr Archie Brain; personal

communication of Dr Micaglio), inflated/deflated cuff, use of drugs for premedication; use of NMBAs (used when indicated for surgical needs); attending anesthesiologist's experience (cut-off: 70 LMAS placements to be defined as "expert").[2, 17]

Difficult LMAS placement was defined as: difficulty in insertion (requiring more than one attempt or requiring use of a different strategy, impossible insertion, evidence of airway trauma) and/or in achieving satisfactory ventilation (desaturation, unacceptable/absent capnography, clinical judgement) after its placement. The following data were collected at the time of the device insertion: successful placement on the first attempt; need for two or more placement attempts; need for change to a different LMAS size/SAD; need for change of airway management strategy (intubation, awakening). Furthermore, the following endpoints were identified:

- calculation of the number and proportion of difficult LMAS placements by anesthesiologists with experience associated to lower success rate (in our opinion: less than 70 LMAS placements);
- calculation of the number and proportion of difficult LMAS placements if at least one of the identified risk factors (Supplementary Digital Material 2: Supplementary Figure 1) was recorded.

### Ethical approval

Ethical approval for this study (Ethical Committee number CEAVC OSS 16.268) was provided by the "Comitato Etico Area Vasta" Careggi University Hospital of Firenze, Italy, on October 12, 2016.

### Statistical methods

The statistical analysis is described in Table I.[8]

## Results

Data were analyzed for 432 consecutive LMAS insertions from four Clinical Units of the two enrolling centers (Naples and Florence). Demographic data were: 118 males and 314 females; mean age 50±14.7 years; mean weight 67.9±13.2 kg; mean height 166.2±8,1 cm, mean BMI 24.5±4.2 Kg/m$^2$. The LMAS used had the following proportions: size 3=138 cases, size 4=266 cases and size 5=28 cases.

A first-attempt successful placement was obtained in 353 patients (easy, "E" group; 81.7%). In the remaining 79 patients, placement was more difficult (difficult "D" group; 18.3%): in nine cases (2.1%) airway strategy was changed in favor of orotracheal intubation due to impossible LMAS placement, whereas 70 patients required two or more attempts and/or change of the LMAS size.

Gender distribution was as follows: 98 male (27.8%) and 255 females (72.2%) in the E group and 20 male (25.3%) and 59 female (74.7%) patients in the D group (NS). About the remaining anthropometric parameters, there were no significant differences between the two groups (Table II). Comorbidities were found in 146/353 and in 37/79 cases in groups E and D respectively (NS); neither the frequency of asthma (group E = 19/353, group D=7/79; P=NS) nor of smoking (group E=92/353, group D=20/79; P=NS) were identified as significant causes of possible difficulty.

No statistically significant differences were found between groups E and D regarding the

TABLE I.—*Statistical analysis.*

| Power analysis | |
|---|---|
| We performed the POWER analysis | *A priori* |
| On the primary outcome | Two or more maneuvers for the insertion of LMAS, or the change of strategy |
| Based on the one-tailed statistical test | Relative risk |
| And accepting the cut-off for significance (α) | 0.05 |
| And a power (1-β) of | 0.90 |
| The variability of the primary outcome (standard deviation) was | Not present for proportion outcome |
| Based on data taken from | Cook *et al.*[8] |
| We considered as clinically relevant a difference of | 10% of failure *vs.* 20% of failure |
| Consequently, the effect size was | RR=2 |
| The total sample size needed was | 432 |

TABLE II.—*Mean±SD of anthropometric parameters.*

| | Group D (N.=79) | Group E (N.=353) | P |
|---|---|---|---|
| Age (years) | 53.3±16.4 | 49.6±14.3 | 0.39 |
| Weight (kg) | 69.6±16.1 | 68.5±13.1 | 0.79 |
| Height (cm) | 167.3±9.2 | 166.7±8.4 | 0.94 |
| BMI (KG/m²) | 24.8±4.9 | 24.5±3.9 | 0.75 |

Student's *t*-test (P>0.05=NS).
Group D: patients with difficult LMAS insertion; group E: patients with easy LMAS insertion.

following factors: presence of maxillary prognathism (>1 cm), thyromental distance (<6 cm), sternomental distance (<12 cm), neck circumference (>40 cm), dentition (other than fully represented), upper lip bite test grade 3, STOP BANG score >4, use of drugs for premedication, inexperienced anesthesiologist (<70 LMA positions), hyperextension of head, no LMAS tip manipulation, deflated cuff (Table III).

On the contrary, the following factors with the chosen cut-off values were significantly different between the groups (Table IV): Mallampati III - IV in phonation and not; inter-incisor distance <3 cm; reduced neck mobility; difficulty in face mask ventilation; size of the tonsils (grade 3 or more), use of incorrect pillow (higher or lower than standard 3 cm-pillow); absence of NMBAs administration.

At a multivariate analysis, the following factors resulted significantly related to difficult insertion of LMAS: Mallampati III-IV, inter-incisive distance <3 cm, hypomobile or stiff neck, no NMBAs (Table V).

## Discussion

Pre-emptive identification of factors addressing suspicion or certainty of a difficult SAD placement is of paramount importance in the context of a strategy for airway management.[18] SADs are

TABLE III.—*Relative risk (RR) and 95% Confidence Interval (CI) of the analyzed risk factor not significantly related to difficult LMAS insertion.*

| Risk Factor | Group D (N.=79) | Group E (N.=353) | RR | CI | P |
|---|---|---|---|---|---|
| Maxillary prognathism >1 cm | 28 | 93 | 1.40 | 0.9-2.15 | 0.1 |
| Upper lip bite test =3 | 8 | 16 | 1.91 | 0.9-3.35 | 0.51 |
| Thyromental distance <6 cm | 10 | 36 | 1.21 | 0.61-2.17 | 0.52 |
| Sterno-mental distance <12 cm | 6 | 37 | 0.74 | 0.29-1.59 | 0.43 |
| Neck circumference >40 cm | 15 | 63 | 1.06 | 0.60 - 1.78 | 0.46 |
| Dentition other than fully represented | 42 | 174 | 0.91 | 0.45-2.13 | 0.61 |
| STOP BANG score >4 | 22 | 81 | 1.21 | 0.77-1.82 | 0.35 |
| Inexperienced anaesthetist | 24 | 119 | 0.87 | 0.54-1.38 | 0.55 |
| No premedication | 47 | 237 | 0.76 | 0.49-1.17 | 0.18 |
| Head hyperextension | 24 | 120 | 0.87 | 0.54-1.36 | 0.52 |
| No manipulation of LMAS tip | 33 | 188 | 1.46 | 0.95-2.25 | 0.06 |
| Cuff mask deflation | 64 | 282 | 1.04 | 0.62-1.85 | 0.85 |

$\chi^2$ test (P>0.05=NS).
Group D: patients with difficult LMAS insertion; group E: patients with easy insertion of LMAS.

TABLE IV.—*Relative risk (RR) and 95% Interval Confidence (CI) of the analyzed risk factor significantly related to difficult insertion of LMAS.*

| Risk factor | Group D (N.=79) | Group E (N=353) | RR | CI | P |
|---|---|---|---|---|---|
| Mallampati III-IV | 21 | 37 | 2.34 | 1.46-3.53 | 0.001 |
| Mallampati III-IV in phonation | 10 | 14 | 2.46 | 1.29-3.96 | 0.002 |
| Inter-incisive distance <3 cm | 11 | 15 | 2.52 | 1.36-3.98 | 0.001 |
| Neck mobility (yes/no) | 11 | 19 | 2.16 | 1.15-3.52 | 0.007 |
| difficult mask ventilation | 10 | 14 | 2.46 | 1.29-3.96 | 0.002 |
| pharyngeal tonsils ≥ grade 3 | 7 | 3 | 10.43 | 2.49-50.36 | 0.001 |
| head position other than on a 3 cm-pillow | 35 | 91 | 1.72 | 1.23-2.32 | 0.001 |
| No NMBAs | 30 | 83 | 1.72 | 1.11-2.61 | 0.009 |

$\chi^2$ test (P>0.05=NS).
Group D: patients with difficult LMAS; group E: patients with easy LMAS insertion.

TABLE V.—*Multivariate analysis of the risk factors significantly related to difficult insertion of LMAS.*

| Risk factor | RR | CI | |
|---|---|---|---|
| Mallampati ©III-IV yes *vs.* no | 2.438 | 1.256 | 4.730 |
| Inter-incisive distance <3 cm yes *vs.* no | 3.527 | 1.475 | 8.434 |
| Hypomobile or stiff neck yes *vs.* no | 2.835 | 1.291 | 6.229 |
| No NMBAs yes *vs.* no | 1.948 | 1.131 | 3.354 |

routine airway devices, but they have been shown to be lifesaving during difficult airway management scenarios[19] and they are recommended in many international guidelines,[20] though recent evidence highlights their underuse in clinical practice.[5] Our study indicates that there are risk factors for difficult LMAS placement as well as useful suggestions to facilitate its insertion. Reduced inter-incisor distance, advanced Mallampati grade (III-IV), and limited/impossible neck movements represent significant risk factors for difficult LMAS placement, whereas optimal head positioning and administration of NMBAs may help successful "insertion," defined in our study as both first attempt correct positioning and effective possibility of ventilation after induction.

Different studies have been performed[6, 7] and new techniques[20] have been proposed, to improve reliability and performance of predictive tests for both face mask ventilation,[3] laryngoscopy and intubation. Similar studies for SADs are limited, often retrospective in nature, mostly performed on Asiatic populations and propose controversial results,[8-13] not forgetting the great differences in design (and consequentially in learning curves) between different devices.[21]

Cook *et al.*,[8] in a study evaluating the placement of the LMAS in 100 patients, reported a 90% first pass success rate with nine patients requiring two attempts and one three attempts, without any use of NMBAs. Our result is poorer, possibly because there is an average greater experience of the anesthesiologists with this device in the UK.[4, 19]

Ramachandran *et al*.[9] carried out a 3-year observational study enrolling 15,795 adult patients undergoing general anesthesia with the Unique LMA (uLMA™, Oñati, Spain). Only 170 (1.1%) patients experienced uLMA™ placement failure, with 4 independent risk factors identified: rotation of the operating table, male sex, edentulous patients and increased BMI. In our dataset, obese (>35 BMI) patients were excluded from the study, while female patients were more numerous in the D group. The gender difference may suggest we should reconsider sizing criteria, as the anatomical space where the SAD cuff should be positioned could be related more to height than to weight.[2]

Katsiampoura *et al*.[10] conducted a retrospective study on 69 adult surgical patients excluding obstetric patients; the physicians in charge of airway management were training in anesthesia. The LMA insertion was successful in 67 patients and in only two (2.9% of the sample) failed. The study succeeded in identifying two independent risk factors relating to difficult LMA placement: female sex and neck circumference ≥44cm.

A large retrospective 3-year study published by Saito *et al.*[11] conducted on adult patients, included several well-known risk factors for difficult airways. The primary outcome set by the investigator was difficult ventilation through the SAD, defined as the inability to ventilate during induction. A complete failure, observed in 29 patients (0.2% of the patients' sample), was instead defined as any event, from the insertion of the mask until the end of the surgery, requiring LMA removal and subsequent intubation. Multivariate logistic regression analysis identified four risk factors for difficult SAD ventilation: male sex; age >45 years, thyromental distance <6 cm, limited neck mobility (the last resulted as similar risk factor in our analysis too). The same authors, based on these results, in a subsequent study,[12] proposed a new scoring system to predict difficult SAD ventilation. The previously identified risk factors were assigned a weighted score on the parametric estimates: male=1, age >45 yrs=1, short thyromental distance=3, limited neck movements=2. The resulting score, ranging from 0 to 7, allowed the author to set up a cut-off for significant higher risk of difficult SAD ventilation whenever the score was ≥4.

A recent study by Vannucci *et al*.[13] retrospectively analyzed 19,693 cases involving the positioning of an extraglottic airway device; failure occurred in 383 (1.9%) of the cases, at three different stages of the procedure (during insertion, before surgery, during surgery). The use of Des-

flurane (odds ratio [OR], 1.67; 95% confidence interval [CI], 1.23-2.25) and the size of laryngeal mask, size 4 or 5 *vs.* 2 or 3 (OR, 0.07; 95% CI, 0.05-0.10) were identified as the main causes of the failed placement.

Each of the above-mentioned studies has added important information regarding the possible causes of SAD malposition. However, each study has some limits: being retrospective or derived from databases in the case of larger studies, in some cases without rigorous statistical criteria (both prospective and observational), and often including non-Caucasian patients. Unsurprisingly, the results reported in literature are controversial, because "SAD failure" – defined as impossible placement of SAD – which was chosen as the aim of most studies, is an extremely rare condition in non-predicted difficult airway situations. For this reason, we have included in the definition of LMAS failure not only "complete" failure, but also the need to make further attempts, or successful insertion but unsatisfactory ventilation soon after induction; our prospective observational study is therefore based and powered on more frequent events.

The experience of the anesthesiologist should represent a critical factor for SAD placement success; nevertheless, in our study, it did not determine a difference in the probability of success. Our cut-off was arbitrary but supported by data from Lopez-Gil *et al.*[17] who found that less than 75 LMA placement was associated with less success rate. Different explanations could be hypothesized: this finding could depend on the ease of the SAD placement itself; different SADs may have different learning curves, and precise data on SAD use skill are missing.[2] Such a finding may also reflect an average greater experience of the anesthesiologists (regardless of the role played by the executor of the maneuver) in the enrolled centers, which participated because SAD use is routine procedure in these centers.

Many of the parameters that appear to be significant for predicting a difficult laryngoscopy do not appear to be significant for difficult SAD placement in our analysis. Up to now sternomental distance and neck circumference have not correlated with difficult SAD placement; this information underlines how this procedure is different from laryngoscopy and intubation and that the difficulties are based on different principles. This observation is important and reinforces the suitability of SDA use indicated in the different flow charts for the management of difficult airways.[16] Inter-incisor distance is a common difficulty risk factor, which in some cases, depending on the type of SAD, might be more significant when compared to laryngoscopy, given that certain SADs are relatively bulky. On the other hand, limited inter-incisor distance interferes with the line-of-sight achievement during laryngoscopy, so it is an important difficulty risk factor for both procedures, and critical values should suggest spontaneous breathing techniques for airway management.[21] On the other hand, the presence of a limited inter-incisor distance may be associated with a smaller space in the oral cavity which may have been the cause of difficulty in LMAS positioning in our study.

It is interesting to point out that the mobility of the neck and the position of the head represent two mutually related risk factors, probably because both concur to the impossibility of providing a correct alignment between the pharyngeal and laryngeal axes which limit the correct positioning of the tip of the laryngeal mask in the laryngopharynx. Furthermore, it should be emphasized that advanced Mallampati grades (in both phonation and not), and the presence of large tonsils were both significantly greater in the D group, indicating that physical limitation to mouth opening and lack of space in the oropharynx cavity strongly interfere with LMAS positioning, representing at the same time a risk factor for difficult mask ventilation.[3, 15] Therefore, despite the fact that the use of SAD is indicated in case of difficult airways, it should be remembered that, since the anatomical characteristics are the same, difficult face mask ventilation may represent a risk factor for SAD placement as well: for example, when the uLMA failed, there was a 3-fold increased difficulty in mask ventilation.[9] Unfortunately, as stated by Cook and MacDougall-Davis[22] when one aspect of airway management is difficult, others are also more likely to be – so that when intubation is difficult, the likelihood of difficult mask ventilation, SAD placement and emergency surgical airways

or similar invasive interventions are all individually more likely.

The administration of NMBAs represents a facilitating factor for SAD placement in our dataset, which could be explained by different mechanisms: NMBAs facilitate mouth opening and correct head positioning, reduce upper airway tone, thus increasing the dislocation of different structures, and finally improve controlled lung ventilation.

Given their role in airway management, we believe there is a strong need to identify risk factors in order to predict difficult supraglottic airway management, both in elective and emergency situations. Such a need was also perceived by the Italian anesthesiologists who responded to the SIAARTI survey accompanying this study, who highlighted the perception that conventional predictive tests for laryngoscopy and intubation should not be applied tout-court for SAD placement and its effective performance.

### Limitations of the study

Some limitations of our study should be listed: we analyzed only LMAS placement in elective surgery, therefore our results cannot be applied to emergency conditions and pertain only to a specific type of SAD; the cut-off definition of "expert" we chose may be arbitrary, although similar to what proposed by Lopez-Gil *et al.*;[17] also, the definition of difficult mask ventilation was arbitrary. One of the four enrolling units was dedicated to gynecological surgery, therefore more women were enrolled in the study. Patients with a prior history of difficult intubation were excluded from the study because, according to Italian guidelines, awake fiberscopic intubation is more suitable; patients with high BMI (>35) or undergoing certain types of surgery were also excluded since the positioning of the laryngeal mask may be contraindicated. These criteria may have ruled out some of the causes of laryngeal mask malposition and therefore limit the generalizability of our data. These limitations could not allow to demonstrate in a clear way a useful role of LMAS in many difficult scenarios. So, further studies with a larger patient sample and different types of SDAs are needed to improve our ability to predict difficulties with SAD placement and improve their use in both basic and rescue airway management strategies.

## Conclusions

Based on our results on a sample of 432 Italian patients, we have identified four risk factors for difficult LMAS placement, and we give two suggestions for optimization maneuvers.

Reduced inter-incisor distance, advanced Mallampati grade (III-IV), and limited/impossible neck movements represent significant risk factors for difficult LMAS placement, whereas optimal head positioning and administration of NMBAs may help successful "insertion", defined in our study as both first attempt correct positioning and effective possibility of ventilation after induction. Experience with the LMAS (and perhaps with SADs) does not seem to have a determinant value, but the cut-off definition of "expert" we chose may be arbitrary, since an unequivocal learning curve for SAD placement has yet to be defined, therefore our results need to be confirmed by larger studies.

### What is known

• Placement of a SAD can be difficult or even impossible, even though this occurs less frequently than carrying out orotracheal intubation. The tests used to predict difficult intubation are not adequate for predicting the difficulty of inserting SADs. Specific tests predicting the difficulty of positioning of SADs- which can be specific for the single type of device - are needed.

### What is new

• In this prospective, randomized study, we identified four factors (reduced inter-incisor distance, advanced Mallampati grade (III-IV, limited/impossible neck movements and no use of NMBAs) predictive of difficulty in positioning a specific SAD, the LMA-Supreme™.

• Correct head positioning and administration of NMBAs are, on the contrary, two suggestions to facilitate positioning of this specific SAD.

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