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A Prospective Evaluation of Clinical Tests for Placement of Laryngeal Mask Airways

Shailendra Joshi, M.D.,* Robert R. Sciacca, Eng.Sc.D.,† Daneshvari R. Solanki, F.R.C.A.,‡
William L. Young, M.D.,§ Mali M. Mathru, M.D.‡

Background: Reliable tests of correct anatomic placement of the laryngeal mask airway (LMA) may enhance safety during use and minimize the need for fiberoptic instrumentation during airway manipulation through the device. This study assessed the correlation between the outcomes of nine clinical tests to place the LMA and the anatomic position of the device as graded on a standard fiberoptic scale.

Methods: During 150 anesthetics, the outcome of nine clinical tests of correct placement was individually scored as satisfactory (positive) or unsatisfactory (negative) for clinical use of the LMA. Anatomic placement was assessed (by fiberoptic evaluation) by an anesthesiologist, who was blinded to the placement of the device, as grade 1, vocal cords not seen; grade 2, cords plus the anterior epiglottis seen; grade 3, cords plus the posterior epiglottis seen; and grade 4, only vocal cords seen. The outcomes of clinical tests were correlated with fiberoptic grade.

Results: Tests that correlated with the fiberoptic grade were the ability to generate an airway pressure of 20 cm water, the ability to ventilate manually, a black line on the LMA in midline, anterior movement of the larynx, outward movement of the LMA on inflation of the cuff, and movements of the reservoir bag with spontaneous breathing. Two tests, ability to generate airway pressure of 20 cm water and ability to ventilate manually, correlated with fiberoptic grades 4 and 3 combined (*i.e.*, the epiglottis was supported by the LMA) and grade 2 (the epiglottis was not supported by the LMA). Tests with poor cor-

relation with fiberoptic grade were the presence of resistance at the end of insertion, inability to advance LMA after inflation of the cuff, and presence of a capnographic trace.

Conclusions: The outcome of clinical tests correlates with the anatomic placement of LMAs, as judged by fiberoptic examination. Two tests that best correlated with the fiberoptic grade were the ability to generate airway pressure of 20 cm water and the ability to ventilate manually. (Key word: Anesthetic equipment.)

THE laryngeal mask airway (LMA) was introduced into clinical anesthesia practice by Brain¹ more than a decade ago. In airway management, the LMA serves as a bridge between tracheal intubation and the facemask. Placement of the LMA is a blind procedure, without the need for laryngoscopy. When fiberoptically evaluated, a well-placed LMA should provide a direct view of the vocal cords. Because the epiglottis has been lifted anteriorly, only the base of the epiglottis should be visible.

When the placement of the LMA is assessed solely by its ability to maintain effective gas exchange, positive pressure ventilation, or both, it is successful in 94-98% of first attempts.²⁻⁴ The reported success at first attempt of a single operator with 1,500 LMA placements has been as high as 95.5%.⁵ Yet many optimally functioning LMAs may not be in an ideal anatomic position. Anatomic placement of the LMA has been assessed by various techniques, including fiberoptic,⁵⁻⁸ radiologic, computed tomography, and magnetic resonance imaging.^{9,10} Fiberoptic examinations through the LMAs may not reveal the vocal cords 14.3% of the time, even when the device is functioning optimally.⁶ Nearly 50% of the time the tip of the epiglottis may lie within the bowl of the device.⁹ A clinical test that could detect correct anatomic placement of the LMA would avoid the need for fiberoptic examination during airway instrumentation through the device.

The main objective of the current study was to establish whether departures from correct anatomic placement of the LMA occurred frequently, and, if so, whether such malplacements could be detected reliably by clinical tests.

* Assistant Professor of Anesthesiology, Department of Anesthesiology, Columbia University College of Physicians and Surgeons, New York, New York.

† Associate Research Scientist, Department of Medicine, Columbia University College of Physicians and Surgeons, New York, New York.

‡ Professor of Anesthesiology, Department of Anesthesiology, University of Texas Medical Branch at Galveston, Galveston, Texas.

§ Professor of Anesthesiology (in Neurological Surgery and in Radiology), Department of Anesthesiology, Columbia University College of Physicians and Surgeons, New York, New York.

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Address reprint requests to Dr. Mathru: Department of Anesthesiology, John Sealy Hospital, University of Texas Medical Branch at Galveston, 301 University Boulevard, Galveston, Texas 77555-0591. Address electronic mail to: cbarker@utmb.edu

Table 1. Stratification of Fiberoptic Results

Clinical Test Result	Fiberoptic Grades (6,17)/Findings	
	II/Vocal Cords + Anterior Epiglottis III/Vocal Cords + Posterior Epiglottis IV/Only Vocal Cords Seen	I/Cords Not Seen
Satisfactory (positive)	True-positive	False-positive
Unsatisfactory (negative)	False-negative	True-negative

Materials and Methods

The institutional review board for human subjects at the University of Texas Medical Branch, Galveston, approved the study. Informed consent was waived for inclusion into the study. This prospective double blinded observational study was conducted during 150 LMA insertions in adult day-surgery patients classified as American Society of Anesthesiologists physical status I and II. Persons with upper airway disease and those at risk for aspiration were excluded. Patients were anesthetized with 1 μ g/kg fentanyl and 1.5–2.5 mg/kg propofol. Anesthesia was supplemented with oxygen (33%), nitrous oxide (67%), and isoflurane. Fresh gas flow was set at 6 l/min based on the anticipated flow requirements across a range of patient body weights. Muscle relaxants were not used. A size 3 LMA was used in women weighing <70 kg, and size 4 was used in men and in women who weighed > 70 kg. The LMAs were inserted after the loss of eyelash reflex and the relaxation of the jaw muscles with the head extended and the neck flexed.^{11–13} The anesthesiologists (with experience of > 200 insertions) used the technique described by Brain *et al.*¹⁴ Once placed, size 3 and 4 LMAs were inflated with 20 and 30 ml air, respectively.^{14,15} The anesthesiologist placing the LMA determined whether the placement was satisfactory. The attempt was to achieve a clinically satisfactory LMA placement as judged by the nine clinical tests evaluated in the study. Although effective gas exchange (ability to ventilate and presence of a capnographic trace) were usually achieved without difficulty, additional attempts were required to achieve satisfactory placement when judged by other tests. The number of attempts required before satisfactory placement of the LMA was noted. The outcome of clinical tests was recorded only for the final attempt. The anesthesiologist who inserted the LMA assessed all except two of the nine clinical tests of LMA placement. Two signs of LMA placement were observed by a second anesthesiologist. The second anesthesiologist, who was positioned by the side of the patient, observed the outward movement of

the LMA and the anterior movement of the larynx. Each test was scored as positive (*i.e.*, satisfactory) or negative (*i.e.*, unsatisfactory), for clinical use of the LMA. The results were recorded on a standard form before fiberoptic evaluation. Once placed, the LMA was taped to the upper jaw to avoid displacement before and during fiberoptic examination. The head position, which influences leak pressure,¹⁶ was not allowed to change after the device was inserted.

The following tests were used to evaluate placement of the LMA.

1. Sign at placement: Presence of resistance at the end of insertion
2. Signs on inflating of the cuff: Outward movement of the LMA, anterior displacement of the larynx, inability to advance the LMA further once inflated
3. Signs after placement of the LMA: Black line on the LMA in the midline at the incisors; ability to generate airway pressure of 20 cm water during manual inspiration; ability to ventilate manually as judged by movement of the chest, condensation of expired gases, adequacy of expired gas volume, and the feel of the bag; carbon dioxide evident on capnography, with a minimal alveolar plateau phase during exhalation during manual ventilation; and movement of the anesthesia bag with return of spontaneous breathing.

The fiberoptic examination with a flexible bronchoscope was done within approximately 5 min of final placement by an anesthesiologist who was not present during placement of the LMA. The fiberoptic observations were made with the tip of the bronchoscope located at the inner aperture of the LMA. Anatomic placement was graded on a four-point scale (1 to 4), which is similar to one described by Brimacombe and Berry^{6,17} (table 1): grade 4, only vocal cords seen; grade 3, vocal cords and posterior epiglottis seen; grade 2, vocal cords and anterior epiglottis seen; and grade 1, vocal cords not seen. Brimacombe and Berry assigned a grade of 0 to mask failure; *i.e.*, failure to insert in 10 s or failure of the

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Table 2. Definitions

Clinical Test Result	Anatomical (Fiberoptic) Placement	
	Correct	Incorrect
Positive	a (true positive)	b (false positive)
Negative	c (false negative)	d (true negative)

Sensitivity = $a/(a+c)$: true positive clinical tests/all correct anatomical placements. Specificity = $d/(b+d)$: true negative clinical tests/all incorrect anatomical results. Overall accuracy = $(a+d)/(a+b+c+d)$: true positive + negative clinical tests/all clinical tests.

mask to function with cords not seen fiberoptically. We did not assign a 0 grade during our fiberoptic evaluation because we believed it had little to contribute to the final anatomic placement of the mask. We also recorded the occurrence of laryngospasm at placement of LMA, visibility of the esophagus or transient glottis closure (< 30 s) during fiberoptic evaluation, and presence of blood on removal of the LMA. Blinding in this study was achieved by independently observing the clinical and fiberoptic assessments.

Fiberoptic evaluation determined if the clinical test result was true- or false-positive or negative. Fiberoptic grades 2, 3, and 4 were considered anatomically acceptable placements, whereas grade 1 was considered a malplacement. Thus a true-positive clinical test result implied a positive clinical test result that coincided with fiberoptic grades 2, 3, or 4, and false-positive coincided with fiberoptic grade 1. Conversely, a true-negative result coincided with fiberoptic grade 1, whereas a false-negative coincided with fiberoptic grades 2, 3, or 4 (table 1). The specificity, sensitivity, and overall accuracy of nine tests to detect malplacement were determined (table 2). To determine if any clinical tests could detect the failure of LMA to support the epiglottis, the clinical results with fiberoptic grades 3 and 4 placements were combined and compared with grade 2 placements.

Statistical evaluation of the association of the outcome of clinical tests and fiberoptic grade was performed using Cochran Mantel-Haenszel statistics. The association between clinical tests and fiberoptic grade was assessed by chi-squared analysis with a continuity correction. Logistic regression analysis was used to assess a correlation between the outcome of clinical tests for combined fiberoptic grades 3 and 4 (*i.e.*, the epiglottis is supported by the LMA) placements *versus* grade 2 placements (the epiglottis is not supported by the LMA). Statistical significance was accepted at $P < 0.05$.

Results

One patient developed laryngospasm during induction, which required intubation before fiberoptic assessment and thus was excluded from the study. Data were available from the remaining 149 patients, 72 men and 77 women whose ages ranged from 19 to 79 yr. The LMA was placed during the first, second, and third attempts in 75.8%, 20.1%, and 4% of the patients, respectively. The chance of better anatomic placement was higher on the first than on the subsequent attempts ($P = 0.0015$). There were 14 fiberoptic grade 1 placements, but clinical tests did not detect malplacement in four of these (tables 3 and 4).

Six clinical tests correlated best with fiberoptic grade: anterior movement of the larynx, LMA moves out on cuff inflation, black line midline on the LMA, ability to ventilate manually, ability to generate an airway pressure of 20 cm of water, and movements of the reservoir bag on return of spontaneous breathing ($P < 0.02$ to 0.001; table 5). Three clinical tests were poorly correlated with the fiberoptic grade: presence of resistance at the end of insertion, inability to advance after inflation of the cuff, and presence of a capnographic trace (table 5). All nine clinical tests for LMA placement had a higher sensitivity (91%–100%) than specificity (0%–71%) rate. The overall accuracy ranged from 86–94%.

When data from fiberoptic grades 3 and 4 (the epiglottis was supported by the LMA) were combined and compared with grade 2 fiberoptic placement (the epiglottis was not supported by the LMA), two tests showed a correlation with fiberoptic grade. These tests were the ability to ventilate manually ($P = 0.0019$) and the ability to generate an airway pressure of 20 cm water ($P = 0.001$).

Besides the anatomic location of the LMA, fiberoptic examination revealed the esophagus in five cases. Laryngospasm occurred in one case that required intubation

Table 3. Table Showing the Fiberoptic Grades and Number of Attempts at Placing the LMA*

Fiberoptic Grade	Number of Attempts			
	First	Second	Third	Total
IV	63	7	1	71
III	23	9	1	33
II	19	10	2	31
I	8	4	2	14
Totals	113	30	6	149

* Fiberoptic evaluation was done only after last placement.

Table 4. Outcome of Clinical Tests and Fiberoptic Grades during 149 Placements

Clinical Test			Fiberoptic Grade			
			IV	III	II	I
Test at placement						
Resistance to advance after insertion	+		71	33	31	14
	-		0	0	0	0
Tests at inflation of LMA cuff						
Anterior movement of the larynx	+		68	31	24	
	-		3	2	7	
LMA moves out on cuff inflation	+		69	31	25	
	-		2	2	6	
Inability to advance after inflation	+		71	33	31	1
	-		0	0	0	
Tests after inflation of cuff						
Black line in midline	+		70	31	28	
	-		1	2	3	
Ability to ventilate manually	+		71	33	30	
	-		0	0	1	
Satisfactory capnographic trace	+		71	33	31	1
	-		0	0	0	
Movements of reservoir bag	+		71	33	31	1
	-		0	0	0	
Airway pressure of ≥ 20 cm H ₂ O	+		70	32	26	
	-		1	1	5	1

LMA = laryngeal mask airway.

and was excluded from the study. Transient glottis closure was not observed. Blood was seen during removal of the LMA in eight cases. There was a correlation between the number of attempts and the presence of blood on the LMA ($P = 0.046$).

Discussion

Various tests of the placement of the LMA have been recommended, yet their accuracy in predicting the correct anatomic placement of the device has not been evaluated. Our results suggest that clinical tests of LMA placement correlate with anatomic placement of the

device as assessed by fiberoptic evaluation. It can be debated if correct anatomic placement of the LMA is the valid end point for assessing the satisfactory placement of the device. Studies using fiberoptic examination, computed tomography, or magnetic resonance imaging show that the airway can be functionally patent and clinically acceptable even though anatomic placement is less than perfect.^{6,9,10} Although there is a paucity of hard data, we suspect that a malplaced LMA is more likely to be associated with complications, such as airway trauma and obstruction, gastric distention with mechanical ventilation, postoperative paralysis of vocal cords, and probably regurgitation.¹⁸⁻²⁰

Table 5. Characteristics of Clinical Tests of LMA Placement as Judged by Fiberoptic Evaluation I

Test	Sensitivity (%)	Specificity (%)	Overall Accuracy (%)	P Value
Resistance to advance after insertion	100	0	91	NA
Anterior movement of the larynx	91	36	86	0.01
LMA moves out on cuff inflation	93	36	87	0.004
Inability to advance after inflation	100	0	91	NA
Black line in midline	96	57	92	<0.001
Ability to ventilate manually	99	43	94	<0.001
Satisfactory capnographic trace	100	7	91	0.16
Movements of reservoir bag	100	14	92	0.001
Airway pressure of 20 cmH ₂ O	95	71	92	<0.001

LMA = laryngeal mask airway; NA = not applicable.

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The most convenient method to assess anatomic placement available for large clinical studies is fiberoptic examination through the LMA. When fiberoptically evaluated, a well-placed LMA should reveal a direct view of the cords. Because the epiglottis has been lifted anteriorly, only the base of the epiglottis should be visible at best. The fiberoptic scale described by Brimacombe and Berry¹⁷ provides a convenient tool to assess the placement of the LMA and has been used by other investigators.²¹ However, limitations of such a scale must be recognized. For example, Asai²² commented that differences in fiberoptic assessment could be due to differences in the relative size of the larynx and the LMA. A relatively large LMA may not support the epiglottis,⁷ which thus affects the fiberoptic grade.²² This may be particularly true in pediatric case series, which have reported a high incidence of down-folded epiglottis. In adult patients, in whom there is less variation in the size of the larynx, the concerns raised by Asai may be less applicable.

Our study differs from others because the LMA were inserted by anesthesiologists with experience of > 200 insertions, although at first glance the number of attempts required for satisfactory placement seems to be unacceptably high. There was only one failure to place the LMA in 150 placements, which compares with large series in which successful placement was achieved in >99% of the patients.^{5,23} The incidence of grade 1 placement in the current study was 9.4%, which is well within range of other studies.^{20,24} The apparent high failure rate in the first attempt is explained by the fact that the anesthesiologists evaluated placement by several tests, not merely by the ability of the device to permit gas exchange. It is possible that the reported improvement in fiberoptic grades with increasing experience (> 750 placements)⁵ is due in part to a similar increase in sophistication in evaluating LMA placement.

There are no uniform guidelines to evaluate satisfactory placement of LMAs. The 1996 LMA instruction manual for the United States recommends three tests to check for correct placement of the device¹: slight outward movement of the LMA on inflation of the cuff,² smooth oval swelling extending behind the thyroid and the cricoid cartilage,³ and no cuff visible in the oral cavity.¹⁵ However, other clinical tests are frequently used to assess LMA placement. These include the presence of resistance to further downward movement,² an anterior bulge of the larynx on inflation of the cuff,² chest wall movement with manual ventilation,⁷ the ability to ventilate effectively²⁵ or to generate a specified

airway pressure,²⁶ or a specified end-tidal carbon dioxide level.²⁷

The clinical test of LMA placement we used may differ from those of other investigators. For example, Pennant and Walker²⁷ considered an expired carbon dioxide level of 25 mmHg an indicator of correct placement. In our study, we considered the presence of capnographic trace with minimal alveolar plateau to be the end point of satisfactory placement because it was less likely to be affected by hemodynamic changes at induction or by changes in minute ventilation volume. Similarly, there are several different methods to assess an effective seal around the larynx by the LMA, such as listening to the escape of gas from the mouth, measuring expired gas volume, or measuring nitrous oxide concentrations at a specified distance from the LMA.²⁶⁻²⁸ We assessed the seal around the larynx by determining if we could generate an airway pressure of 20 cm water while squeezing the reservoir bag at a fresh gas flow of 6 l/min. It can be argued that such a test could have overlooked significant leak because fresh gas flow was sufficiently high. We selected the fresh gas flow because it was clinically appropriate and an initial high flow is required to prime the disconnected breathing system. To make the test clinically relevant, we did not specify the ventilatory parameters because ventilators are rarely used during LMA placement. The anesthesiologist could vary the ventilatory parameters to achieve the peak airway pressure.

To avoid any controversy, we defined anatomic malplacement as the inability to see the vocal cords. Using this definition could determine the sensitivity, specificity, and overall accuracy of each test (tables 2 and 5). The most specific test to detect malplacement was the ability to generate airway pressure of 20 cm water (71%), whereas the ability to ventilate manually had the highest overall accuracy (94%). When grade 2 placements (*i.e.*, the epiglottis was not supported by the LMA) were compared with 3 and 4 placements combined (*i.e.*, epiglottis supported by the LMA) to determine if clinical tests could show whether the device was supporting the epiglottis, the outcome of only two clinical tests correlated with the fiberoptic grade. These tests were the ability to generate airway pressure of 20 cm water and the ability to ventilate manually, suggesting that only these two tests are likely to detect that the epiglottis is supported by the LMA. Therefore we consider the ability to generate 20 cm water pressure and the ability to ventilate manually to be the best clinical tests of correct anatomic placement of the LMA.

This question arises: should a fiberoptic bronchoscope be used routinely to confirm correct placement of the LMA? The strong statistical correlation in our study between the outcome of some clinical tests with the fiberoptic grade suggests that fiberoptic evaluation is unnecessary for routine use of the LMA. However, in four of the 14 grade 1 placements, the tests failed to demonstrate malplacement, suggesting that the tests evaluated are not sufficiently reliable to permit blind airway manipulation. The success rate with blind placement of an endotracheal tube through a blindly placed LMA ranges from 30% to 90%.^{29,30} Even when a battery of clinical tests suggests satisfactory placement of the device, our results do not recommend blind placements through the LMA.

We conclude that clinical tests of LMA placement, particularly the ability to generate an airway pressure of 20 cm water and the ability to ventilate manually, correlate with the correct anatomic placement of the device as judged by fiberoptic examination.

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