

## Valve Leaks with New Disposable Extraglottic Airway Devices

*To the Editor:*—I read with interest the letter of van Zundert *et al.*<sup>1</sup> about the valve leaks noted with the new extraglottic/supraglottic airway devices. However, there appears to be an unintentional error in their letter. In the first sentence, the authors mention that they are reporting six cases of spontaneous cuff deflation during a clinical trial with a new airway device, which sounds like these data were obtained from their ongoing study. At the end of this sentence, however, they cite a study by my colleagues and me carried out some time ago that aimed to compare airway efficacy of two supraglottic airway devices (CobraPLA *vs.* laryngeal mask airway) and showed better airway sealing pressures with the CobraPLA.<sup>2</sup> I recommend this error be corrected and that the authors cite their own study, because we did *not* observe any clinical or numerical valve leaks with any of the airway devices in our study.<sup>2</sup>

Anesthesiology 2006; 104:615

*In Reply:*—We apologize for the typographical error in our article.<sup>1</sup> The first sentence should have read: “We would like to report six cases of spontaneous cuff deflation that occurred during a clinical trial conducted by our group of a new disposable extraglottic airway device, the CobraPLA™ (Engineered Medical Systems, Inc. Indianapolis, IN).”<sup>2</sup> The intention behind citing the article by Akca *et al.*,<sup>2</sup> which we do not wish to delete, was to direct readers to previous general work on the CobraPLA™. We were fully aware that Akca *et al.*<sup>2</sup> had no problems with such leaks.

It is our practice to monitor continuously the cuff pressure of supraglottic airway devices during anesthesia, because cuff pressure can both increase (potential laryngopharyngeal trauma) or decrease (potential loss of seal). In our clinical study (unpublished data), we noted that in six cases using the CobraPLA™, the cuff pressure decreased completely to 0, although we had checked its adequacy before use as instructed by the manufacturer, which did not reveal any cuff leakage. After removal of the CobraPLA™, on checking, we were surprised to find an adequate cuff. However, further exploration by submersion in water revealed air escaping from the pilot balloon valve, showing a continuous leak at the cuff deflator valves with their surroundings. Because supraglottic airway devices are not regularly tested

Anesthesiology 2006; 104:615-6

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## Statistical Indiscretions in Papers from the American Society of Anesthesiologists Closed Claims Project

*To the Editor:*—Despite a seemingly robust mention of study limitations, Peterson *et al.*<sup>1</sup> apparently do not fully appreciate the limitations of their data, use inappropriate statistical methods, and provide misleading results.

Let's start with the results, then work backward toward a fuller understanding of the limitations. For brevity, focus on the largest odds ratio. The abstract states, “The odds of death/brain death were increased by the development of an airway emergency (odds ratio, 14.98; . . .  $P < 0.001$ ).” Because the data set is limited to patients whose care already has resulted in a closed professional liability insurance claim, a more accurate statement would qualify the reported odds

**Ozan Akça, M.D.**, University of Louisville, Louisville, Kentucky. ozan.akca@louisville.edu

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(Accepted for publication November 21, 2005.)

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for this problem before their use, these kind of leaks go unnoticed, possibly putting the patient at risk. It was our intention to urge manufacturers of supraglottic airway devices to ensure quality control on the cuff deflator valves. These valve leaks are a further support for our belief that cuff pressure monitoring should be routine practice when using supraglottic airway devices.

**André van Zundert, M.D., Ph.D., F.R.C.A.,\* Baha Al-Shaikh, F.C.A.R.C.S.I., F.R.C.A., Joseph Brimacombe, M.D., M.B., Ch.B., F.R.C.A., Eric Mortier, M.D., Ph.D.** \*Catharina Hospital-Brabant Medical School, Eindhoven, The Netherlands. zundert@iae.nl

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(Accepted for publication November 21, 2005.)

ogists Closed Claims Project is comprised of only that subset of patients whose care has resulted in a claim. Using a predictive method here is akin to predicting winners of a horse race as horses cross the finish line. Using a predictive method to attempt an explanation of the diversity of injuries among closed claims (*i.e.*, those with an array of injuries) is thus inappropriate.

The authors (and many readers) may call attention to the explicit mention in the Limitations section that the authors are well aware of "the lack of denominator data." One hears that phrase often in relation to the authors' data set, as if it is the sole or even principal study design issue. A very recent editorial notes that rapid progress toward comprehensive clinical databases means that "[w]e may ultimately be able to have the denominator for the events that had been brought to our attention through the closed-claim studies . . . [and such data] will allow us to close the loop on how we care for patients and their outcomes."<sup>2</sup> Surely, if such denominator data were available, the authors would have used them—and their results would still be misleading.

We are ready to recognize the severe limitations of the authors' type of registry data. However well-structured and comprehensive, the data set created by the American Society of Anesthesiologists Closed Claims Project is no better than a case series, a study design whose reliability and accuracy in reflecting the universe of patients who experience injury allegedly related to anesthesia is likely to be as poor as other case series. Two landmark medical negligence studies<sup>3-7</sup> conducted in three states, 10 yr apart, offer a remarkably consistent and relevant perspective on malpractice data: (1) patient injury resulting from negligence occurs in approximately 1% of hospitalizations; (2) patients file malpractice claims in only a small proportion of hospitalizations (0.12-0.16% in these studies); and (3) only a small fraction of the patients who do file have actually experienced an injury resulting from negligence. As a result, the U.S. medical liability system has been characterized as a very biased lottery. The well-known contingency-based payment system encourages plaintiff's attorneys to accept cases that represent potentially more lucrative awards and that are judged to be more likely to be won. In addition, there are other, more subtle, biases in case selection. Particularly ingenious is the way that these lawyers are now responding to the caps on the noneconomic losses (*i.e.*, pain and suffering); they switch to an alternate theory of economic damages related to the patient's lost earned-income potential, biasing the lawyer to accept the cases of more highly compensated patients.<sup>8</sup> Thus, cases in the authors' data set reflect what is termed *biased selection*. The presence of such bias means that the injury-related claims that do progress through our legal system cannot be regarded as a random or even representative sample of the universe of such injuries. Thus, relationships that may be identified in the study sample cannot be used to infer accurately about phenomena in the universe of injuries.

Why are these issues surfacing now in an illustrious, 20-yr-old project with a substantial publication trail? The issues are not new, although grounds on which one can discuss the deficiencies have changed over time. Closed-claims studies have morphed from biased assessments of appropriateness of care—as a blinded reviewer of an early manuscript, I suggested that substantial bias would be involved in assessments when outcome severity was known to claims reviewers, which was subsequently documented in a simulation<sup>9</sup>—through in-

creasing accretion of largely inappropriate statistical analyses. Most reports arising from this data set have relied heavily on hypothesis testing (*i.e.*, statistical tests yielding a *P* value) that is suspect, particularly that involving comparisons of events across time periods and types of injuries, because of the biased selection. Logistic regression analysis seems to have been used inappropriately by the closed-claims investigators as early as 1999,<sup>10</sup> when such analysis became as easy as a few computer clicks. Statisticians responsible for logistic-regression algorithms note: "As is well-recognized in the statistical community, the inherent danger of this easy-to-use software is that investigators are using a very powerful tool about which they may have only limited understanding."<sup>11</sup> Finally, what appears in a journal is heavily influenced by reviewers who may have limited technical expertise, suggesting that clinical journals should have statisticians and/or clinical epidemiologists on retainer.

As a result of these issues, statistical tests should be used very sparingly, if at all, with the authors' data. Instead, the American Society of Anesthesiologists Closed Claims Project data should be exploited for its true value: offering rich, often unique, albeit qualitative descriptions of various complications.

**Fredrick K. Orkin, M.D., M.B.A., M.Sc.**, The Pennsylvania State University College of Medicine, Hershey, Pennsylvania. fred.orkin68@post.harvard.edu

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(Accepted for publication November 21, 2005.)

Anesthesiology 2006; 104:616-7

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*In Reply:*—We thank Dr. Orkin for pointing out the well-described limitations of the American Society of Anesthesiologists Closed Claims Project with reference to our recently published article.<sup>1</sup> We agree with him that closed claims study results may be misinterpreted by readers who fail to recognize the inherent limitations in analyzing malpractice claims and the problems with attempting to generalize beyond the closed claims population. These concerns are readily ac-

knowledged in the study limitations section and in the discussion of our manuscripts.

We disagree with Dr. Orkin's statements concerning statistical "in-discretions" resulting from use of logistic regression analysis in our recent papers. Logistic regression analysis is fully justified in the analysis of closed malpractice claims, because it can be used to test an association between two variables. There is no assumption in the

logistic regression methodology about the time order of the dependent and independent variables, and there is no requirement that there be a population at risk.<sup>2</sup> Logistic regression analysis is applied legitimately without an identified population at risk and where the outcome is identified after the potential risk factors. The analysis of case-control studies is such an example in which the entire sample is identified at the time of occurrence of an outcome. The analysis of the closed claims is analogous, where cases are those claims with death and brain damage and controls are those claims with other outcomes. The interpretation of the results in the closed claims studies is limited to the closed claims population and not the general anesthesiology population at large. Hence, the challenge arises with the interpretation of what a positive association means, and inferring from the closed claims population to the anesthesia population at large.

We agree with Dr. Orkin that the American Society of Anesthesiologists Closed Claims Project does offer rich and unique qualitative descriptions of various complications. However, we also believe that

more sophisticated statistical analysis can provide useful additional information concerning associations of independent variables and outcomes among the closed claims population.

**Karen B. Domino, M.D., M.P.H.,\* Gene N. Peterson, M.D., Ph.D., Robert A. Caplan, M.D., Karen L. Posner, Ph.D., Lorri A. Lee, M.D., Frederick W. Cheney, M.D., Nayak L. Polissar, Ph.D.**  
\*University of Washington, Seattle, Washington.  
kdomino@u.washington.edu

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(Accepted November 21, 2005.)

Anesthesiology 2006; 104:617

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## Obesity and Difficult Intubation: Where Is the Evidence?

*To the Editor:*—We read Shiga *et al.*'s meta-analysis of predictors of difficult tracheal intubation.<sup>1</sup> They analyzed four studies involving obese patients<sup>2-5</sup> and concluded that intubation problems are three times more likely to occur in this patient population compared with normal-weight patients.

Although the standard sniffing position for tracheal intubation is achieved in nonobese patients by raising the occiput 8 to 10 cm with a pillow or head rest, obese patients require much greater elevation of their head, neck, and shoulders to produce the same alignment of axes for intubation. We demonstrated that elevating the upper body and head of morbidly obese patients to align their sternum and ear in a horizontal line (head-elevated laryngoscopy position) results in significant improvement in laryngoscopic view.<sup>6</sup> In two of Shiga *et al.*'s four references, head position was described only as sniffing and may therefore have been suboptimal. Suboptimal positioning would result in a higher incidence of grade 3 and 4 Cormack-Lehane laryngoscopy views, making direct laryngoscopy and hence tracheal intubation more challenging. Until a standard intubating position for obese patients is adopted for research purposes, comparing studies using different positions will continue to confound the issue.

Shiga *et al.* defined difficult intubation as a Cormack-Lehane grade 3 or 4 view during direct laryngoscopy using a standard laryngoscopy blade. However, they used a different definition for two of the four studies, although each of the original references included standard grading of laryngoscopy. For example, they incorrectly cited a 12% incidence of problematic intubations in our study rather than the actual 9% incidence of grade 3 views we encountered.<sup>4</sup> Similarly, in another study the actual incidence of grade 3 or 4 views was 10%, but they listed difficult intubation as 15% based on their own intubation difficulty scale.<sup>3</sup> Such inconsistencies contributed to their conclusions.

We would like to emphasize that difficult laryngoscopy is not synonymous with difficult intubation. The American Society of Anesthesiologists Task Force on the management of the difficult airway defines a difficult airway as the "clinical situation in which a conventionally trained anesthesiologist experiences problems with (a) face mask ventilation of the upper airway or (b) tracheal intubation, or both."<sup>7</sup> The airways of morbidly obese patients are more difficult to ventilate by mask, but whether they are more difficult to laryngoscope is not substantiated by Shiga *et al.*'s study. There were a total of 378 obese

patients in the studies they reviewed, and every patient except one was intubated successfully by direct laryngoscopy. All four of the studies they analyzed specifically stated that the magnitude of obesity does not influence laryngoscopy difficulty.<sup>2-5</sup>

Based on both our clinical experience at an active bariatric surgical center and on the few prospective studies that have addressed this issue, we question the validity of the general statement that obese patients are three times more difficult to intubate than their slimmer counterparts. The tracheas of a smaller subgroup of morbidly obese patients, that is, those with obstructive sleep apnea, high Mallampati class (III and IV), and large neck circumferences, are more difficult to intubate.<sup>2,4</sup>

The incidence of obesity in the adult population is growing. More obese and morbidly obese patients are undergoing surgery. As with any patient, the anesthesiologist must always be prepared to manage airway problems. However, there is no evidence that obesity *per se* is a risk factor for difficult laryngoscopy and tracheal intubation.

**Jeremy S. Collins, M.B., Ch.B., F.R.C.A.,\* Harry J. M. Lemmens, M.D., Ph.D., Jay B. Brodsky, M.D.** \*Stanford University Medical Center, Stanford, California. jeremycollins@stanford.edu

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(Accepted for publication November 29, 2005.)

David C. Wartier, M.D., Ph.D., acted as Handling Editor for this exchange.

Anesthesiology 2006; 104:618

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## Predicting Difficult Intubation

*To the Editor:*—In their meta-analysis, Shiga *et al.*<sup>1</sup> review the diagnostic accuracy of bedside tests for predicting difficult intubation in patients with no airway pathological features. This analysis did not take into account tests proposed by other authors, such as the upper lip bite test<sup>2</sup> or indirect laryngoscopy,<sup>3</sup> probably because of the exclusion criteria that were applied. The authors carried out an analysis with a Bayesian focus based on sensitivity, specificity, and likelihood ratios in which they suggest that “combinations of individual test or risk factors add some incremental diagnostic value in comparison to the value of each test alone.” This would lead us to think that the addition of likelihood ratios from various tests is useful in predicting difficult laryngoscopy. However, this focus makes two big assumptions. The first is that sensitivity, specificity, and likelihood ratios are not modified with the incidence, and the second is that the tests used to modify the probability are completely independent. Although the first assumption is not true, that is not a limitation for clinical application of this tool. However, the second assumption does not permit application of this approach to the prediction of difficult laryngoscopy, in that the tests are based on physical examination of the head and neck, which makes it impossible to suppose that they are independent. Also, the authors do not directly take into account the agreement between observers, which is another factor that interferes with the operational performance of a diagnostic test.

In addition, the evaluated outcome is only useful for predicting difficult laryngoscopy. Other studies have shown the poor correlation between the Cormack classification and difficulty in intubation.<sup>4</sup> Given the above, it is clear that clinical research on the prediction of a

difficult airway should focus on multivariable analysis to predict difficult intubation<sup>5</sup> and difficult mask ventilation,<sup>6</sup> which both permits the combination of interdependent tests and also evaluates outcomes with greater clinical interest.

**David A. Rincón M.D.**, Universidad Nacional de Colombia, Bogotá, Colombia. darinconv@unal.edu.co

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(Accepted for publication November 29, 2005.)

Anesthesiology 2006; 104:618–9

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*In Reply:*—We thank Drs. Collins and Rincón for their interest in our study.<sup>1</sup> Both doctors emphasized that difficult intubation is synonymous with difficult laryngoscopy. We used the term *difficult intubation* because most studies use a Cormack-Lehane grade of 3 or more to define difficult intubation. The American Society of Anesthesiologists Task Force on Difficult Airway Management<sup>2</sup> defines difficult tracheal intubation as that requiring multiple attempts, in the presence or absence of tracheal pathological features, whereas difficult laryngoscopy is defined as being impossible “to visualize any portion of the vocal cords after multiple attempts at conventional laryngoscopy.” We could have altered the title to a more appropriate one such as “Predicting Difficult Laryngoscopy in Apparently Normal Patients,” rather than “Predicting Difficult Intubation in Apparently Normal Patients.” We agree with both doctors in that, strictly speaking, our findings are validated only in cases of difficult laryngoscopy, not in cases of difficult intubation or difficult airway. Nevertheless, both words were often confused in many of the studies and reviews we cited.

Dr. Collins pointed out that we incorrectly cited his results regarding the incidence of difficult laryngoscopy in an obese population. Misinterpretation of the data in the process of data extraction for a meta-analysis is possible unless additional information is requested from every author cited, which is unduly challenging. We recalculated the incidence of difficult intubation (more precisely, difficult laryngoscopy) in obese patients according to corrected data provided by Dr. Collins. Our revised analysis showed the incidence of difficult laryngoscopy in obese patients to be 12.7% (95% confidence interval, 11.5–14.0%), which was 15.8% (95% confidence interval, 14.3–17.5%) in our original data and is still more than twice as high as that in nonobese patients. This suggests that difficult laryngoscopy is more likely to occur in obese patients than in nonobese patients. More than

a decade ago, Wilson showed obesity to be a risk factor for difficult intubation or difficult laryngoscopy,<sup>3</sup> but whether it is indeed a risk factor remains controversial. Further discussion on this topic is needed.

We think the average anesthesiologist is not as skilled in dealing with airways of obese patients as are those who experience a high volume of these cases, such as those at Dr. Collins' bariatric surgical center. We believe that the head-elevated laryngoscopy position is very useful in working with obese patients, but further randomized controlled trials are required.

Dr. Rincón noted that our analysis excluded both the upper lip bite test and indirect laryngoscopy. In searching MEDLINE and the Cochrane Central Register (1980 through May 2004), we could find only one or two reports on these methods; furthermore, these tests are not as popular or generally used as are the Mallampati classification or Wilson risk score. Therefore, we did not include these tests. Dr. Rincón also said that our conclusions are based on the big assumptions that sensitivity, specificity, and likelihood ratios are not modified by incidence. However, the general understanding is that positive and negative predictive values depend on the prevalence of abnormality in the study sample, but sensitivity, specificity and likelihood ratios are independent of prevalence.<sup>4</sup> We may not be able to answer adequately the latter question from Dr. Rincón because we are not statistical experts, but we believe that generalization of the test results to other sample populations is possible whether the tests are based on physical examination or laboratory testing. We think that it is not the characteristic of the test, but prevalence of abnormality, that matters.

We did not take into account the interobserver agreement because it was not specified in most of the studies included in our meta-analysis. Yet, we agree on that this is an important factor influencing the diagnostic accuracy of bedside screening tests.

Toshiya Shiga, M.D., Ph.D.,\* Zen'ichiro Wajima, M.D., Ph.D., Tetsuo Inoue, M.D., Ph.D. \*Nippon Medical School, Chiba Hokusoh Hospital, Chiba, Japan. qzx02115@nifty.com

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(Accepted for publication November 29, 2005.)

Anesthesiology 2006; 104:619

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## An Unusual Event with the Bispectral Index® Monitoring System

*To the Editor:*—We have had concerns with the new Bispectral Index® Monitoring System (BIS®) Quatro sensor electrode from Aspect Medical Systems (Newton, MA) with respect to the possibility of causing frequent “paper cuts,” or pressure groove injuries, to the foreheads of patients because of its design, in particular, its sharp proximal edge.

During one recent cardiac case, a BIS® Quatro sensor was placed properly on a patient's forehead at induction with specific attention given to avoid injury to the patient's forehead by the proximal edge. However, at the onset of cardiopulmonary bypass, the pulmonary



**Fig. 1.** The electrode's position during cardiopulmonary bypass.



**Fig. 2.** The pressure groove on the patient's forehead.

artery catheter was withdrawn 2 cm, which caused the electrode's position to shift, as demonstrated in figure 1. It was not until later that a pressure groove was noted on the patient's forehead, as shown in figure 2, and the electrode was repositioned.

We suggest that Aspect Medical should reconsider the design of its electrodes. Practitioners should also consider placing a small piece of gauze under the proximal edge of the electrode to reduce any harm.

**Bachar Hachwa, M.D.,\* Andrew Brewer, M.D., Glenn Gravlee, M.D.** \*The Ohio State University, Columbus, Ohio. hachwa.1@osu.edu

Support was provided solely from institutional and/or departmental sources.

(Accepted October 24, 2005.)

Anesthesiology 2006; 104:620

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*In Reply:*—We thank Dr. Hachwa *et al.* for providing this illustrative Letter to the Editor concerning a pressure groove caused by unusual twisting of the BIS® Sensor (Aspect Medical Systems, Newton, MA). The length of the tab portion of the sensor was designed specifically to minimize the possibility of pressure reactions to the larger cable connector, but as shown in this case, twisting of a sensor that is placed low across the forehead can result in a mechanical pressure reaction. Aspect recommends that clinicians apply the BIS® Sensor so that it lies flat on the surface of skin in the correct placement position. Dr. Hachwa's suggestion to use gauze padding may be appropriate in some situations; however, we do not believe it is routinely required. Other practitioners have stabilized this portion of the BIS® Sensor with tape to prevent inadvertent twisting. Although Dr. Hachwa speculates that

the design characteristics of the BIS® Sensor are responsible for this observation, it is important to bear in mind that excessive pressure on any monitoring element (*e.g.*, electrocardiogram cables, pulmonary artery catheter) also could produce similar observed grooves. Nevertheless, we believe that clinicians should remain vigilant to intraoperative conditions that may cause a change in BIS® Sensor positioning resulting in sustained pressure on one skin location. This may be especially relevant in patients in a prone position.

**Paul J. Manberg, Ph.D.**, Aspect Medical Systems, Inc., Newton, Massachusetts. pmanberg@aspectms.com

(Accepted for publication October 24, 2005.)

Anesthesiology 2006; 104:620

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## Solutions to the Nasogastric Tube–ProSeal LMA™ Conundrum

*To the Editor:*—Surgeons sometimes request, either before or after induction, that a nasogastric tube be inserted for the postoperative period. This can be problematic when using the ProSeal™ laryngeal mask airway (PLMA; Laryngeal Mask Company, San Diego, CA), because the drain tube only facilitates orogastric tube placement. A potential solution to the preinduction request is to insert the nasogastric tube before PLMA placement; however, in principle this might (1) impede placement of the PLMA, (2) reduce the efficacy of seal with both the respiratory and gastrointestinal tracts by altering the shape of the pharynx, (3) increase the frequency of mechanical airway obstruction by reducing the hypopharyngeal space, and (4) render the nasogastric tube nonfunctional by compression of its lumen between the cuff and pharynx. We report our retrospective experience of this technique in 48 adults undergoing elective intraabdominal surgery. Ethical committee approval was obtained to publish these data.

Patients were induced with alfentanil, midazolam, and propofol. No muscle relaxants were given. The size 4 was used for women, and the size 5 was used for men. The mean (range) age, height, and weight were 58 (19–85) yr, 68 (45–125) kg, and 170 (144–198) cm, respectively. The male:female ratio was 29:19. The nasogastric tube, either a 12 or 14 French gauge, was successfully placed using a laryngoscope and Magill forceps in all patients, although three required more than one attempt. PLMA placement was successful at the first attempt in all patients with use of the laryngoscope-guided, gum elastic bougie-guided technique.<sup>1</sup> Oropharyngeal leak pressure, fiberoptic position of the airway tube, and ventilatory capability were similar to those in

previous studies with no nasogastric tube.<sup>2</sup> There were no airway management problems, and gastric insufflation was not detected during positive-pressure ventilation. The nasogastric tube was patent in all patients. There were no problems with displacement of the nasogastric tube during removal of the PLMA.

We conclude that this technique is feasible and does not interfere with the function of the PLMA or nasogastric tube. If there are doubts about the patency of the nasogastric tube, an orogastric tube can always be inserted down the drain tube. In situations where the surgeon's request comes after induction, perhaps the best solution is to slide the nasogastric tube behind the cuff of the PLMA, as described for the LMA-Classic™ (Laryngeal Mask Company).<sup>3</sup> Alternatively, the nasogastric tube can be inserted when the patient is awake.

**Joseph Brimacombe, F.R.C.A., M.D.,\* Christian Keller, M.D.**  
\*James Cook University, Cairns Base Hospital, Cairns, Australia.  
jbrimaco@bigpond.net.au

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(Accepted for publication October 4, 2005.)

Support was provided solely from institutional and/or departmental sources. Drs. Brimacombe and Keller have worked as consultants for the Laryngeal Mask Company, San Diego, California.