Valve Leaks with New Disposable Extraglottic Airway Devices

To the Editor:—I read with interest the letter of van Zundert et al.1 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.2 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.2

In Reply:—We apologize for the typographical error in our article.1 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).”2 The intention behind citing the article by Akca et al.2 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.2 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 In our clinical study (unpublished data), we noted that in six cases using the CobraPLA™, the cuff pressure decreased completely to 0, although we had checked its adequacy before use as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 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 believe that cuff pressure monitoring should be routine practice when using supraglottic airway devices.


References

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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.1 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 an 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 ratio as relating to patients whose care has resulted in a closed claim. Because anesthesia practitioners cannot know prospectively which of their patients will result in a closed claim, the odds ratio is bizarre, if not nonsense. (That an airway emergency in the context of a difficult airway is associated with death/brain death makes clinical sense but does not validate generating a nonsensical odds ratio.)

Accounting for this bizarre situation is the use of an inappropriate statistical method: logistic regression is a predictive modeling technique that has meaning only when applied to a population at risk—in this case, patients who are about to have anesthesia care—before adverse events occur. However, the American Society of Anesthesiol-
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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.¹ 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 acknowledged in the study limitations section and in the discussion of our manuscripts.

We disagree with Dr. Orkin’s statements concerning statistical “indiscretions” 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 increasing 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 1999,¹⁰ 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.”¹¹ 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.

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To the Editor—We read Shiga et al.’s meta-analysis of predictors of difficult tracheal intubation.1 They analyzed four studies involving obese patients2–4 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.5 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 laryngoscope 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.6 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.7 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.” 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.2–5

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 leaner 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.2–4

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.

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

Obesity and Difficult Intubation: Where Is the Evidence?

Obesity and Difficult Intubation: Where Is the Evidence?
To the Editor:—In their meta-analysis, Shiga et al.1 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 test2 or indirect laryngoscopy,3 probably because of the exclusion criteria that were applied. The authors carried out an analysis with a Bayesian focus 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.4 Given the above, it is clear that clinical research on the prediction of a difficult airway should focus on multivariable analysis to predict difficult intubation5 and difficult mask ventilation,6 which both permits the combination of interdependent tests and also evaluates outcomes with greater clinical interest.

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In Reply:—We thank Drs. Collins and Rincón for their interest in our study.1 Both doctors emphasized that difficult intubation is not 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 Management2 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 not directly take into account the agreement between observers, which is another factor that interferes with the operational performance of a diagnostic test.

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,3 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.4 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.
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 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.

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Fig. 1. The electrode’s position during cardiopulmonary bypass.

Fig. 2. The pressure groove on the patient’s forehead.


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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.

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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. ANESTHESIOLOGY 2002; 96:289–95

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