Efficacy of the Self-inflating Bulb in Confirming Tracheal Intubation in the Morbidly Obese

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Background: This study was designed to determine the incidence of false-negative and false-positive results when the self-inflating bulb (SIB) is used to differentiate tracheal from esophageal intubation in morbidly obese patients using two techniques. In technique 1, the SIB is compressed before it is connected to the tube; in technique 2, the SIB is compressed after connection to the tube.

Methods: With institutional review board approval, 54 consenting adult morbidly obese patients (body mass index > 35) undergoing elective surgical procedures were included in the study. After anesthetic induction and muscle relaxation, both the trachea and esophagus were intubated under direct vision with identical cuffed tubes. The efficacy of the SIB in verifying the position of both tubes was tested by a second anesthesiologist. The speed of reinflation was graded as rapid (<4 s) or none (>4 s), using both techniques. In the case of tracheal intubation, the absence of reinflation was recorded as a false-negative, whereas in cases of esophageal intubation, rapid reinflation was recorded as a false-positive. Identification of tube location by the second anesthesiologist was based on SIB reinflation results from techniques 1 and 2, as well as the presence of a flatuslike sound elicited by technique 2 in esophageally placed tubes. All patients were retested by the SIB after receiving three breaths of 400–500 ml each. In all patients exhibiting false-negative results, six obese patients exhibiting true-positive results, and four nonobese patients exhibiting true-positive results, tracheal responses to the SIB maneuvers were observed directly by a flexible fiberoptic bronchoscope incorporating an airtight system, 15–20 min after mechanical ventilation was instituted.

Results: The incidence of false-negative results was initially 30% with technique 1 and 11% with technique 2, but decreased to 4% when technique 2 was used after the delivery of three breaths. The second anesthesiologist initially identified tube location in 92.5% of patients correctly. After the delivery of three breaths, tube location was correctly identified in 96.3% of patients. Fiberoptic bronchoscopic examination of the patients exhibiting false-negative results revealed exaggerated inward bulging of the posterior tracheal membrane during reinflation of the SIB when technique 1 was used.

Conclusions: Contrary to previous investigations in healthy patients, the current study demonstrates a high incidence of false-negative results when the SIB is used to confirm tracheal intubation in morbidly obese patients. If the SIB is used, the technique should include compression of the SIB after connection to the tube and should be used in conjunction with other clinical signs and technical aids. The mechanism of false-negative results in these patients seems to be related to reduction of caliber of airways secondary to a marked decrease in functional residual capacity, and collapse of large airways due to invagination of the posterior tracheal wall when subatmospheric pressure is generated by the SIB. (Key words: Airway: management; self-inflating bulb. Airway, difficult: morbid obesity. Equipment: esophageal detector device. Intubation: esophageal; tracheal.)

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OUTCOME studies have repeatedly identified unrecognized esophageal intubation as a leading cause of injury in anesthetic practice[1–5] and in prehospital[6,7] and critical care settings.[8] A vast array of clinical signs and technical aids have been introduced to verify tracheal tube placement.[9] Nevertheless, almost all of them have been documented to fail under certain circumstances.[9]

Recently, the use of the self-inflating bulb (SIB) has been popularized to differentiate tracheal from esophageal intubation.[10–13] Claimed advantages of the SIB include speed, single-handed use without a power source, and low cost. Unlike capnography or colorimetric detection, the SIB can be used before ventilation is initiated and functions equally well in patients with cardiac arrest and in those with intact circulation. Thus,

it can be used in the operating room in conjunction with capnography, but is particularly useful outside the operating room where capnography may not be available.[10-13] Two techniques for the use of the SIB have been described. In one (technique 1), the SIB is compressed before it is connected to the tube[11-13]; in the other (technique 2), the SIB is first connected to the tube and then compressed.[10,14]

Despite the documented effectiveness of the SIB in distinguishing esophageal from tracheal intubation,[10-13] recent reports[14,15] suggest that the SIB may occasionally fail to confirm proper tube placement, especially in morbidly obese patients. It has been hypothesized that the choice of technique may contribute to the incidence of false-negative results.[14] The current study was designed to determine the incidence of false-negative (tube in trachea but SIB fails to reinflate or reinflates slowly) and false-positive results (tube in esophagus, SIB reinflates) in morbidly obese patients after anesthetic induction, using the two techniques. In addition, we attempted to elucidate the mechanism(s) contributing to the occurrence of false-negative results in these patients.

Materials and Methods

With institutional review board approval, 54 consenting adult morbidly obese patients (body mass index ≥ 35 kg/m^2 body surface area) undergoing elective surgical procedures requiring tracheal intubation were included in the study. They gave no history suggestive of drug allergy, and none had clinical evidence of active cardiovascular, pulmonary, or gastroesophageal disease. Patients who were suspected of potential airway problems during intubation were excluded from the study. All anesthesiologists involved in the care of these patients cooperated in this prospective study. A number of sterilized SIBs (capacity = 75 ml; Premium Plastic, Chicago, IL) fitted with standard 15-mm adapters were prepared beforehand. The SIBs were tested for airtightness before use by connecting the compressed bulb to a clamped tracheal tube; the absence of reinflation indicated airtightness.[9]

The experimental protocol was designed so that patient safety would not be compromised. Had intubation become prolonged or hemoglobin oxygen saturation decreased to 92%, the experiment would be suspended and manual ventilation instituted. In addition, initial testing was limited to a maximum of 25 s. In the operating room, routine monitoring including pulse ox-

imetry and capnography was used. Fentanyl (50–100 μg) and 1–2 mg midazolam were given intravenously. After denitrogenation of the patient's lungs with an inspired oxygen fraction greater than 0.9, 3–4.5 mg d-tubocurarine was given. After 2 to 3 minutes, anesthesia was induced with a thiopental, etomidate, or propofol/succinylcholine sequence. Cricoid pressure was applied from the time the patient lost consciousness until tracheal intubation and cuff inflation were accomplished. Under direct-vision rigid laryngoscopy performed by an experienced anesthesiologist, two identical, lubricated, disposable, Murphy-eye, tracheal tubes (Mallinckrodt Anesthesiology, St. Louis, MO, or Sheridan Catheter, Argyle, NY; 7.0 mm ID for women and 7.5 mm ID for men) were placed, one in the trachea and one in the esophagus. The tubes were inserted the same distance (21–22 cm for women, 22–23 cm for men) measured from the maxillary incisors or alveolar ridge so that they appeared externally identical. The tube cuffs were inflated with 10 ml air and cricoid pressure was discontinued. Before initiation of controlled ventilation, the efficacy of the SIB in differentiating esophageal from tracheal intubation was tested by a second, independent anesthesiologist who had no knowledge of the location of the tubes. The speed of reinflation of the SIB was graded as rapid (<4 s), or none (>4 s) using both techniques. In addition, during the use of technique 2, the second anesthesiologist attempted to elicit a flatuslike sound from both tubes during compression of the SIB. The order in which the tubes were tested and the order in which the SIB maneuvers were performed were chosen randomly by the second anesthesiologist. The SIB was disconnected from the tubes between tests. Manual ventilation of the lungs was avoided until initial SIB testing of tube placement was completed. Identification of tube location by the second anesthesiologist was based on SIB reinflation results from techniques 1 and 2 as well as the presence of a flatuslike sound elicited by technique 2. Definitions included: true-positive—tube in trachea, SIB reinflates in <4 s; true-negative—tube in esophagus, SIB does not reinflate or reinflates in >4 s; false-positive—tube in esophagus, SIB reinflates; and false-negative—tube in trachea, SIB does not reinflate or requires >4 s.

All patients were given three manual breaths of 400–500 ml each (Ohmeda model 5400 volume monitor) *via* the tracheal tube, by the intubating anesthesiologist and were retested by the second anesthesiologist. The tracheal tube was then connected to the anesthesia circuit, and controlled ventilation was commenced as the
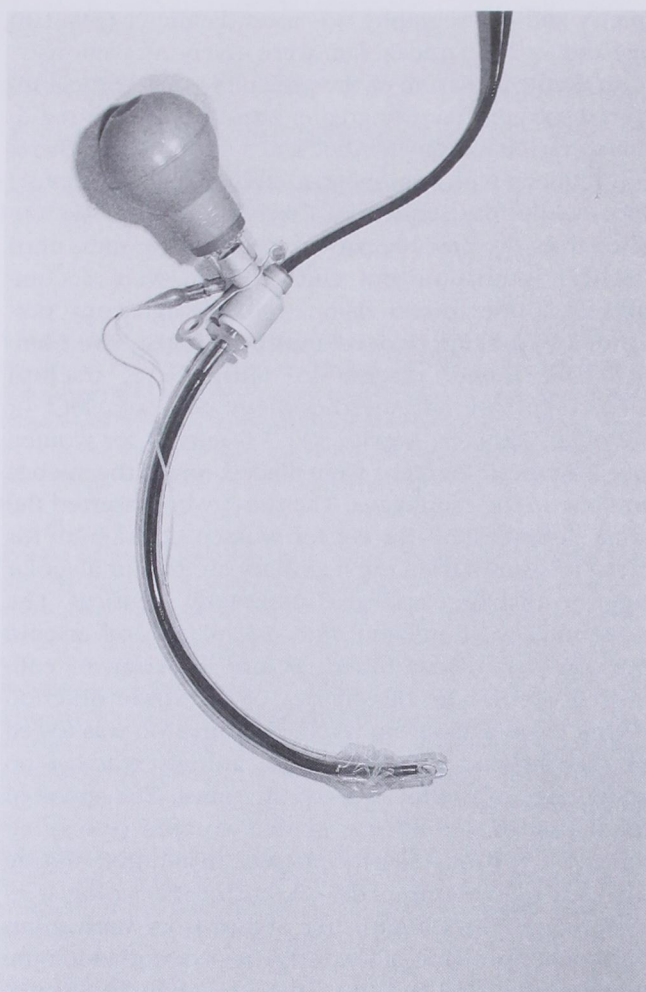
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Fig. 1. Airtight system incorporating self-inflating bulb, flexible fiberoptic bronchoscope, and adapter.

exhaled carbon dioxide waveform was monitored using mass spectrometry. The esophageal tube was removed after cuff deflation, and the volume of air in the cuff of the tracheal tube was adjusted to the minimum necessary to prevent a leak around the cuff.

In patients exhibiting false-negative results, the tracheal responses to the SIB maneuvers with techniques 1 and 2 were directly observed by fiberoptic bronchoscopy 15–20 min after mechanical ventilation was instituted. These responses were compared with tracheal responses to the SIB maneuvers in six morbidly obese and four normal patients exhibiting true-positive results. An airtight system (fig. 1) comprising a 4.9-mm OD flexible fiberoptic bronchoscope (Olympus BF TYPE P30; Olympus America, Lake Success, NY) and an adapter (Portex, Keene, NH, or Sontek Medical,

Hingham, MA) connected to the proximal end of the tracheal tube, with the SIB connected to the side-arm of the adapter was designed. The flexible fiberoptic bronchoscope was passed through the adapter's self-sealing cap to the distal end of the tube. The carina and the segment of the trachea distal to the tube were visualized on a video monitor (Endoscopic Video Monitor, Olympus OEV 201, Matsushita Electric Industrial, Kanagawa, Japan) using a Digital 3CCD video camera (Olympus OTV-SX, Olympus America, Lake Success, NY). The two maneuvers (techniques 1 and 2) were repeated, and the tracheal responses recorded using an S-VHS videocassette recorder (Toshiba, model SV-970, Tokyo, Japan). Color still photographs were printed from the videotape using a Sony Color Video Printer (model UP-5200, Sony, Tokyo, Japan). Esophageal responses to the SIB inflation maneuvers (techniques 1 and 2) also were visualized and recorded using a system similar to that used to visualize the tracheal responses in four patients.

Demographic data are displayed as mean ± standard deviation (SD). Statistically significant differences in age, weight, and body mass index in patients with and without false results were analyzed with the two-tailed Student's t test. Chi-square analysis or Fisher's exact test were employed to determine statistically different incidences of false-negative results with respect to technique used or gender. Statistical significance was accepted when $P < 0.05$. Also calculated were sensitivity (true-negative/[true-negative + false-positive] × 100), specificity (true-positive/[true-positive + false-negative] × 100), and predictive value (true-negative/[true-negative + false-negative] × 100) of the SIB employing techniques 1 and 2.

Results

Demographic data of the patients studied are shown in table 1. All of the patients were ASA physical status 2.

The incidence of false-negative and false-positive results employing both techniques is presented in table

Table 1. Demographic Data

Gender	11 males/43 females
Age (yr)	41.5 ± 14.5 (15–74)
Weight (kg)	116.2 ± 17.6 (89.1–152.3)
BMI (kg/m²)	43.9 ± 12.3 (35.3–100)

Values are mean ± SD (range).

2. Of 54 patients studied, 16 had false-negative results when technique 1 was employed, whereas only 6 had false-negative results when technique 2 was used. All 6 patients with false-negative results using technique 2 also had false-negative results with technique 1. After the delivery of three breaths of 400–500 ml each to all patients, false-negative results were again obtained in 13 of 16 patients when technique 1 was employed and in 2 of 6 patients when technique 2 was used. Those patients who had true-positive results before receiving the three breaths, continued to have true-positive results after receiving the three manual breaths. There were no false-positive results when technique 1 was used. There was 1 false-positive result when technique 2 was used. This same patient also had a false-negative result with technique 1, but not technique 2.

Patients with false results did not differ significantly from those with true-positive or true-negative SIB results in terms of mean age, weight, or body mass index. Chi-square analysis revealed that the results obtained with technique 2 were statistically different from those obtained with technique 1 ($P = 0.0315$). No association between gender and the incidence of false-negative results was established. A comparison of sensitivity, specificity and predictive values between techniques 1 and 2 is shown in table 2.

In 50 of 54 patients a flatuslike sound was generated when technique 2 was used to distinguish esophageal and tracheal tubes; this sound always came from the tube that was ultimately demonstrated to be in the esophagus and never from the tracheal tube. The flatuslike sound associated with technique 2 had a sensitivity of 92.6%, a specificity of 100%, and a predictive value of 100%. Before initiating controlled ventilation, the second anesthesiologist was able to correctly differentiate the esophageal from the tracheal tube in 50 of 54 patients (92.5%). After the delivery of three breaths, the second anesthesiologist correctly identified the location of the tube in 52 of 54 (96%) of patients.

Flexible fiberoptic bronchoscopic examination in the six morbidly obese and four normal patients exhibiting true-positive results revealed minimal or no changes in tracheal caliber regardless of the SIB maneuver used. In morbidly obese patients exhibiting false-negative results, different responses were seen (figs. 2 and 3). When technique 1 was used, there was an exaggerated inward bulging of the posterior tracheal membrane during reinflation of the SIB (fig. 2B). Thereafter, it returned to its resting position. When technique 2 was employed, there was a brief outward bulging of the

Table 2. Incidence of False Positives and False Negatives When Using the Self-inflating Bulb to Differentiate Tracheal from Esophageal Intubation

	T1	T2
False positives	0/54 (0%)	1/54 (2%)
False negatives		
(before 3 breaths)	16/54 (30%)	6/54 (11%)
Sensitivity	100	91
Specificity	77	90
Predictive value	70	89
False negatives		
(after 3 breaths)	13/54 (24%)	2/54 (4%)
Sensitivity	100	98
Specificity	81	96
Predictive value	76	96

posterior tracheal membrane during compression of the SIB (fig. 3A) followed by an inward bulging of this membrane as the SIB reinflated (fig. 3B). After reinflation of the SIB, the posterior tracheal membrane returned to its resting position. Direct fiberoptic examination through the esophageal tube after the application of techniques 1 and 2 showed the esophageal mucosa being sucked into and occluding the distal opening and Murphy eye of the tube.

Tracheal intubation was confirmed by direct laryngoscopy and mass spectrometry, which showed the classical rectangular carbon dioxide waveform in all patients. The pulse oximetry reading was $\geq 90\%$ in all patients during the study period. There were no complications reported in connection with this study.

Discussion

The principle underlying the use of esophageal detector devices is based on anatomic differences between the trachea and the esophagus. The trachea remains constantly patent because of C-shaped rigid cartilaginous rings, whereas the esophagus, being a fibromuscular tube, readily collapses when negative pressure is applied to its lumen.[16,17] Thus, when a 60-ml syringe is connected to a tube correctly placed in the trachea, withdrawal of the plunger of the syringe will aspirate gas from the patient's lungs without any resistance.[16,17] In contrast, if the tube is in the esophagus, withdrawal of the plunger will cause further apposition of the walls of the esophagus, thus occluding its lumen, and resistance will be felt when the plunger is pulled back.[16,17] This technique has been modified by replacing the sy-
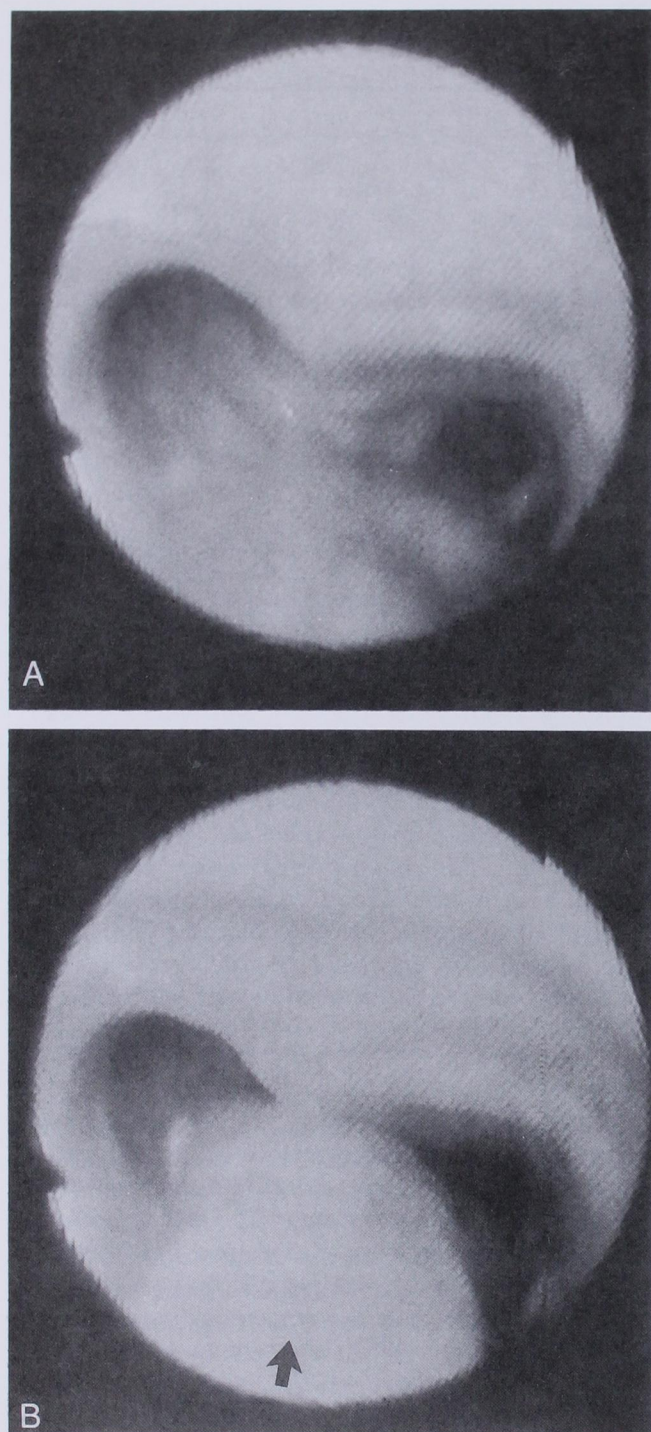
Fig. 2. Tracheal responses in an obese patient exhibiting a false-negative result to technique 1. (*A*) Trachea and carina in resting state. (*B*) Compressed self-inflating bulb connected to the tube generates subatmospheric pressure causing invagination of the posterior tracheal membrane (arrow).
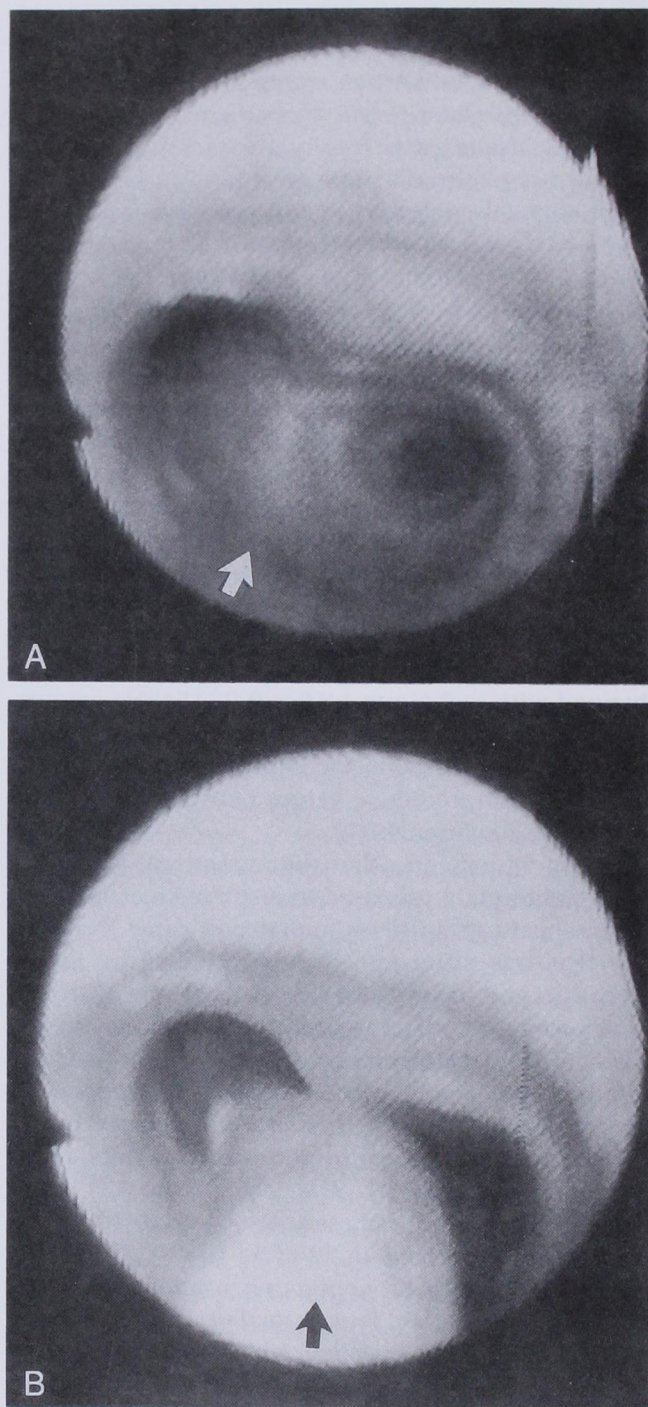
Fig. 3. Tracheal responses to technique 2 in the same patient. (*A*) Compression of the self-inflating bulb results in outward bulging of posterior tracheal membrane (arrow). (*B*) With release of the self-inflating bulb, subatmospheric pressure is generated and posterior tracheal membrane (arrow) invaginates into the tracheal lumen.

ringe with an SIB (originally an Ellick's evacuator).[18] The advantages of the SIB over the syringe include simplicity, speed, and uniformity in testing.[18,19] Various studies, mostly performed in essentially healthy patients, have demonstrated the efficacy of both the syringe and the SIB in confirming tracheal tube placement.[10–13,16,17] However, it has been noted that both the syringe and the SIB occasionally fail to confirm tracheal tube placement in the following situations: in infants, in whom the tracheal wall is not held open by rigid cartilaginous rings[20]; if the tube is obstructed[21,22]; in patients with high airway resistance[21]; when the tube is at the carina or in a mainstem bronchus[22]; in morbidly obese patients[14,15,19]; and in other patients who have marked reduction of their functional residual capacity (FRC).[14,15,19]

Earlier studies[11–13] have showed that the sensitivity, selectivity, and positive predictive values of the SIB in differentiating esophageal from tracheal intubation were each 100%. These studies, however, were performed on ASA physical status 1 patients.[11–13] Contrary to the results of these studies, the current report shows a high incidence of false-negative results, before the initiation of mechanical ventilation, in anesthetized morbidly obese patients. Although the technique of compressing the SIB after, rather than before, connection to the tracheal tube significantly decreased the incidence of false-negative results (11% *vs.* 30%), it did not completely eliminate them. Only after the delivery of three breaths did the incidence of false-negative results dramatically decrease (to 4%) when the SIB was compressed after connection to the tube. In this population of patients, the specificity ranged from 77.1% to 96.4%, and the predictive value from 70.4 to 96.3 depending on whether the SIB was compressed before or after attachment to the tracheal tube, and on whether the test was performed before or after the administration of several manual breaths (table 2).

Despite the 11% incidence of false-negative results when both techniques were initially used, the second anesthesiologist correctly identified tube locations in 92.5% of patients. This can be attributed to two factors. First, detection of the flatuslike sound in the vast majority of patients might have provided an additional clue to the location of esophageally placed tubes. Second, the current study involved the placement of two tubes, one in the trachea and the other in the esophagus. This scenario might have made the observer's decision as to the location of each tube easier in some cases.[9]

In a recent study conducted on 2,140 consecutive anesthetized patients, Wafai *et al.*[14] reported a 4.6% incidence of false-negative results when the SIB was compressed before it was connected to the tube; whereas when the SIB was compressed after connection, the incidence decreased to 2.4%. They found that 85.5% of patients in whom false-negative results were encountered had a body mass index >35 kg/m^2, thus identifying morbid obesity as the most common factor associated with delayed or absent reinflation of the SIB in anesthetized patients. The current study confirms these findings and further suggests that one cannot rely solely on the SIB to differentiate esophageal from tracheal intubation in morbidly obese patients before mechanical ventilation has been initiated.

To clarify the mechanisms of false-negative results in morbidly obese patients, it would have been ideal to perform fiberoptic bronchoscopic examination of the distal trachea and carina in these patients during the initial applications of the various SIB maneuvers. However, this could not be done because of concern for patient safety. Although the fiberoptic bronchoscopic examination was performed some time after controlled ventilation was initiated, and presumably after restoration of the FRC, the findings are still helpful in proposing a hypothesis to explain the false-negative results seen in some of these patients. We surmise that this phenomenon is the culmination of a chain of events as a consequence of the decreased FRC in morbid obesity. The supine position, anesthetic induction, and muscular paralysis all compound the decrease in FRC, which is well below the closing capacity leading to premature small airway closure and reduced caliber of intrathoracic airways.[23–26] It has been shown that a compressed SIB can generate a negative pressure of 55–58 mmHg. Application of such a negative pressure to the trachea may be enough to overcome the structural integrity of the large airways, reverse the transmural pressure gradient, and result in partial collapse of the large airways by causing invagination of their posterior wall. This, in turn, will either prevent or retard reinflation of the SIB (fig. 4). Although this phenomenon may occur in normal patients, the response is much more exaggerated in the morbidly obese. It also is possible that other factors including mediastinal compression contribute to the occurrence of false-negative results, but such mechanisms need to be elucidated.

The restoration of normal function of the SIB in some patients after the delivery of three small breaths is indicative of the contribution of the markedly decreased

FRC in initiating the false-negative results in morbidly obese patients. When the SIB is compressed after connection to the tracheal tube, a volume of gas is first introduced into the airway before subatmospheric pressure is generated by the SIB. This insufflation of about 70 ml would have little effect on the FRC of a healthy patient. However, in the anesthetized, intubated morbidly obese patient, this volume may represent a proportionally large addition to the FRC. Baraka *et al.*[15] found that the preoperative expiratory reserve volume in a morbidly obese patient with a false-negative response to the SIB was 220 ml. Furthermore, we have documented an outward bulging of the posterior tracheal wall after compression of the SIB during technique 2. It is conceivable that the volume of gas that is introduced by compression of the SIB during technique 2 maintains the patency of the tracheobronchial tree allowing the SIB to refill. Such a modification of the technique markedly reduces the incidence of false-negative results without causing a concomitant increase in the incidence of false-positive results.

Calder *et al.*[27] reported a case in which the SIB failed to refill when connected to a 6-mm Portex nylon reinforced tube correctly placed in the trachea. They hypothesized that rotation of the tube, which lacked a Murphy eye, during insertion, positioned the bevel against the posterior tracheal wall, which is unsupported by cartilage. In this position, the mucosa of the posterior tracheal wall can be sucked into the bevel during testing, thus preventing reinflation of the SIB.[23] When they rotated the tube 90°, so that the bevel pointed toward the side wall of the trachea, the SIB refilled rapidly.[27] It is unlikely that the same scenario existed in our patients because we used tracheal tubes with Murphy eyes and rotation of the tube, in our experience, did not result in rapid refill of the SIB in these morbidly obese patients. However, it is possible that at low lung volumes, with reduced caliber of airways, the tracheal mucosa is more likely to be in close proximity to the distal end of the tracheal tube and the Murphy eye and is therefore more likely to occlude them when subatmospheric pressure is generated by the SIB with technique 1. Conversely, with the use of technique 2, the tracheal mucosa is "pushed" away from the openings during compression of the SIB, thus allowing refill on release.

Earlier studies conducted in essentially normal patients reported a 0% incidence of false-positive results when the SIB was used to differentiate esophageal from tracheal intubation.[10–13] Even after the intentional de-
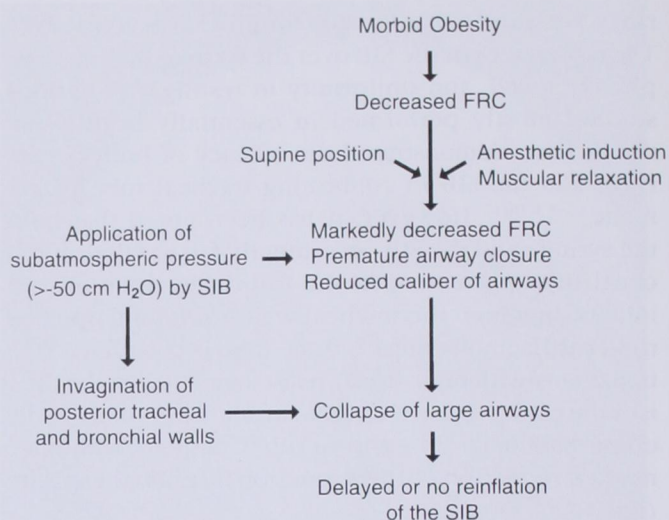

Fig. 4. Proposed sequence of events resulting in false-negative results when using the self-inflating bulb (SIB) to confirm tracheal intubation in morbidly obese patients. FRC = functional residual capacity.

livery of three small breaths (300–350 ml) through esophageally placed tubes in 72 patients, the SIB was effective in detecting esophageal intubation in all patients.[12] In the current study, we encountered one false-positive result when the SIB was compressed after it was connected to an esophageally placed tube. This may be related to increased abdominal pressure collapsing the esophagus, a compliant tube, as it enters the thorax from the abdomen. This phenomenon has been documented with respect to the inferior vena cava.[28] After compression of the SIB, the insufflated air would be trapped in the esophagus, and refill the SIB when the compression is released. It also is possible that as a result of the increased intragastric pressure and decreased tone of the lower esophageal sphincter in the morbidly obese,[29] gastric gases may leak through an incompetent lower esophageal sphincter into the esophageal lumen, decreasing the negative pressure created by the SIB and possibly leading to reinflation of the SIB.

In conclusion, the current study demonstrates a high incidence of false-negative results when the SIB is used to verify tracheal tube placement in morbidly obese patients. These false-negative results were more frequent when the SIB was compressed before, rather than after its connection to the tracheal tube. It is evident that the mechanism is predominantly related to the reduction of caliber of airways secondary to the marked decrease in FRC, and the collapse of large airways ow-

ing to invagination of the posterior tracheal wall when subatmospheric pressure is generated by the SIB.

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