Research Article
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Comparative study of a biofeedback-driven strategy with a standard deep breathing coaching technique used during preoxygenation of patients before induction of general anesthesia

Abstract

Purpose: Preoxygenation is considered an important patient safety practice prior to induction of general anesthesia and establishment of a secure airway by most anesthesia providers. Studies show that four deep breaths over thirty seconds (four-breath technique) or eight deep breaths over sixty seconds (eight-breath technique) are superior to three to five minutes of passive spontaneous mask ventilation. However, there are no published randomized studies that evaluate maneuvers to improve the quality of deep breathing during preoxygenation in a routine clinical setting. The goal of this study is to determine if the use of a biofeedback strategy effectively improves deep breathing volumes during preoxygenation as compared to a standard coaching technique.

Methods: This prospective randomized study was conducted in two groups: Investigational (N=11) and Control (N=11). Both groups were initially preoxygenated with four standardized deep breaths (DBs). For Control subjects, four additional DBs were performed using the traditional coaching technique. However, for the Investigational group, the first four DBs were followed by four breaths utilizing a biofeedback approach where increasing DB targets were provided to the patients in real time.

Results: There was a statistically significant increase in volume of DBs 5 to 8 ($p=0.005$) in the Investigational group compared to controls. When the volume of each DB was compared to participants' predicted VC, DB 5 to 8 in Investigational subjects more closely approximated predicted VC ($p=0.002$).

Conclusion: DB volumes are significantly greater using a breath-to-breath biofeedback technique compared to a standardized DB coaching technique.

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Introduction

Preoxygenation is commonly utilized in preparation for establishing a secure airway before the induction of general anesthesia in elective surgeries, hospital setting emergencies, and out of hospital care.[1-5] Increasing oxygen stores by pre-oxygenation maneuvers provides critical time to manage the unexpected difficult airway, a circumstance that is not always predictable. Since the middle of the twentieth century, researchers and physicians dedicated to improving patient safety, debated how best to accomplish pre-oxygenation.[1] Studies comparing pre-oxygenation techniques focused on various end-points for analyzing efficacy and efficiency of those methods.[2,6] One goal of preoxygenation is to minimize oxygen desaturation that might occur during the induction of anesthesia until the re-establishment of ventilation in a secured airway. Effective preoxygenation should increase the time until desaturation occurs in the event of significant hypoventilation or apnea. The Duration of Apnea without Desaturation (DAWD) measure begins with apnea and extends until the patient's oxygen saturation drops to less than 90%, the point at which oxygen precipitously desaturates from the hemoglobin molecule and hypoxemia begins. In some settings DAWD is a very useful measure of the effectiveness of a preoxygenation technique;[7] however, given its risks of hypoxemia, measuring desaturation time poses ethical concerns if intentionally induced. In lieu of DAWD, other measurements have been used as effective surrogates such as maximum deep breath volumes that approach vital capacity, end-tidal oxygen concentration, end-tidal nitrogen concentration, and arterial oxygen tension.[2,6,8] Deep breath volumes approaching a vital capacity breath results in a physiologic increased wash-in of oxygen and wash-out of nitrogen in patients breathing 100% oxygen using a breathing system with minimal leak. An increased reserve of oxygen in the lungs provides a longer time to desaturation in the event of prolonged apnea or hypoventilation and was considered important to the safety of four- and eight- breath preoxygenation techniques. The effectiveness of deep breath techniques is predicated on patients achieving volumes of deep breaths that approximate vital capacity to maximally replace nitrogen with oxygen. In patients who may be receiving preoperative sedatives, or otherwise distracted, cooperation with routine deep breath coaching may be compromised. This study seeks to evaluate the effectiveness of a real-time biofeedback motivational technique compared to a standard technique to achieve deep breaths that more closely approximate predicted vital capacity in the clinical operative setting.

Materials and methods

This study was approved by the Thomas Jefferson University Institutional Review Board and patients gave written informed consent to participate on the morning of surgery prior to entering the operating room. ASA physical status 1 - 3 patients undergoing elective surgery were eligible to participate in the study. All studies were performed using a Dräger Apollo® anesthesia machine (Lübeck, Germany), a

Medline Anesthesia Circuit (Medline Industries Inc., Northfield, Illinois, USA), and a Medline Adult Regular face mask (Northfield, Illinois, USA) inflated to optimize the interface between the mask and the patient's face. The adjustable pressure-limiting (APL) valve was set to the fully open position and the oxygen flow was set to 8 Liters per minute for all measurements. Block randomization was used to separate patients into 2 groups: Investigational and Control coaching techniques prior to the start of the study. Patients agreeing to participate were eligible for participation if the following criteria were met: a good mask fit determined by the investigators, normal capnographs, and a Ramsay Sedation Score of less than 3 during the passive preoxygenation phase. Patients who met the mask fit and sedation criteria within 3 minutes of the start of passive preoxygenation had their randomization status, either Control or Investingational, unblinded to the anesthesia care team. There were two phases to the study. In the first phase, all patients were provided scripted coaching by one of the investigators to "take 4 deep breaths in as deep as you can." Each breath was then counted loudly enough that the patient was aware. The investigator had the prerogative to repeat the request one time if the first deep breath was lower than expected tidal volume. In the second phase, after completion of the first 4 deep breaths, Control patients were given the same initial request to "take 4 more deep breaths in as deep as you can", and count repeated. However, the Investigational patients were provided actual measured volumes (without units) starting with the volume of the 4th breath and asked to increase the volume to a specific target number 200 mL more than the previous breath for 4 more breaths. Induction of anesthesia was initiated after the 8th breath. Volume and end tidal oxygen were both manually recorded for each breath and end tidal carbon dioxide and pulse oximeter readings also noted. Video recordings of capnographic information was used to facilitate verification of constant measurement conditions for each patient. All studies were performed with patients in the supine position with the OR bed at 0 degrees. This clinical study was registered with clinicaltrials.gov under the title Goal Directed Numeric Coaching as a Means of Preoxygenation (code NCT05978635).

For each patient, predicted vital capacity was calculated using the following formulas:

for females = (21.78 - 0.101 x (age (yrs)) x height (cm) and for males = (27.63 - 0.112 x (age (yrs)) x height (cm). Demographics and clinical variables between groups were compared using the student t-test, Chi square, and Fisher's exact tests. Respiratory and gas exchange measurements were analyzed using ANOVA with repeated measures. Post hoc analysis was performed with Bonferroni correction applied for multiple pairwise comparisons. Statistical analyses were performed using IBM SPSS version 28 (Chicago, Illinois, USA) and GraphPad Prism version 9 (San Diego, California, USA) software. A $p < 0.05$ was considered statistically significant.

Results

Twenty-five patients gave written informed consent to participate in the study. There were 3 patients who failed criteria due to over sedation (N = 1) or poor mask fit verified by abnormal capnographs suggesting a leak (N = 2) and were not randomized or otherwise included in the study. Data analysis was therefore conducted for two groups of 11 patients (N = 22). Baseline patient demographics were evenly matched between the Investigational and Control groups for age, gender, BMI, ASA status (Table 1). Regarding intravenous premedication with fentanyl, one patient in the Control group received 50 mcg of fentanyl, while 50 mcg and 100 mcg of fentanyl were given to a total of two patients in the Investigational group prior to preoxygenation. In addition, 8 Control and 7 Investigational patients were administered 2mg of midazolam and an additional 2 Investigational patients were given 1 mg of midazolam. Comparison showed that these premedication doses did not differ between groups and Ramsey score for all study patient (N = 22) was 2 (Table 1).

Table 1 Demographic data. Number of patients based on birth-assigned sex, mean and standard deviation of age and BMI, median ASA status, midazolam dose, fentanyl dose, and Ramsay Sedation Scores with representative p-values

		Control (N=11)	Investigational (N=11)	p-value
	Sex	**4M/7F**	**4M/7F**	**0.67**
Mean ± SD				
	Age (yrs)	48.7 ± 12.6	44.4 ± 11.7	0.523
	BMI (kg/m2)	25.8 ± 5.2	25.5 ± 3.0	0.899
Median				
	ASA status	2	2	1
	Midazolam dose (mg)	2	2	0.898
	Fentanyl dose (mcg)	0	0	0.699
	Ramsay Sedation Score	2	2	1

SD, Standard deviation; BMI, Body Mass Index; M, Male; F, Female; NS, not statistically significant.

As outlined in the Methods section, the first 4 deep breaths (DB) were elicited using the same traditional coaching technique in both the Control and Investigational groups. Comparison of the tidal volumes observed during this phase of preoxygenation showed no statistically significant difference between corresponding DBs in the Control or Investigational subjects (p=0.831, Figure 1). For example, the mean volume for DB 4 was approximately 1286 ± 477 mL for the Control group and approximately 1399 ± 943 mL for the Investigational group (Table 2). For the second 4 deep breaths, biofeedback motivated techniques were implemented for only the Investigational group. Results show that there was a significant increase in observed volumes for DB 5 to 8 in the Investigational group in comparison to the Control group who were coached using traditional methods (p=0.005, Figure 1). Moreover, Bonferroni corrected post hoc analysis showed that the Investigational DB 8 (mean volume of 2410 ± 859 mL) were larger than tidal volumes achieved by control patients using conventional instructional technique (mean volume of 1267 ± 553 mL) to a p=0.001 (Figure 1, Table 2).

Table 2 Predicted vital capacity (mL) and analysis of tidal volumes (mL) for deep breaths 1 through 8 for Control and Investigational groups

	pVC (mL)	Deep breaths (mL)							
		DB 1	DB 2	DB 3	DB 4	DB 5	DB 6	DB 7	DB 8
Control (N=11)									
Mean	3154.72	1163	1286.63	1436.63	1285.72	1451.72	1235.18	1343.36	1266.54
Median	---	1103	1412	1411	1465	1477	1223	1295	1350
SD	586.96	621.4	525.91	686.24	476.71	543.19	453.36	541.66	552.65

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Table 2 Continued...

	pVC (mL)	Deep breaths (mL)							
		DB 1	DB 2	DB 3	DB 4	DB 5	DB 6	DB 7	DB 8
Investigational (N=11)									
Mean	3384.36	885.09	1226.45	1428	1399	2025.63	2120.45	2250.63	2410.18
Median	---	995	1090	1110	1110	1791	1910	2106	2160
SD	646.59	528.58	736.9	861.68	943.2	817.74	811.78	753.64	859.84

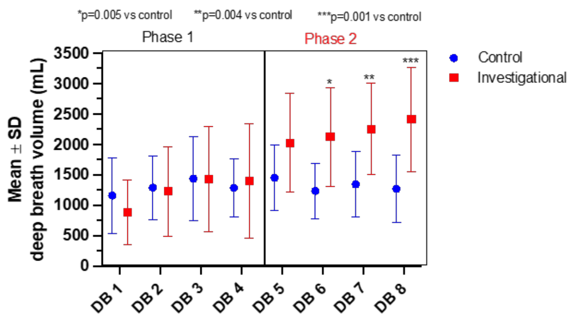

Figure 1 Mean and standard deviation of deep breath volumes (mL) for Control and Investigational groups. The two-phase protocol is illustrated for both groups. The first 4 deep breaths elicited by traditional method are shown in the left panel and the subsequent 4 deep breaths observed after experimental biofeedback technique in the right panel. There was a statistically significant increase in deep breath volumes during phase two in the Investigational subjects (red square) coached compared to the Control subjects (blue circle). P-values indicate significant differences between coached DB 6 to 8 compared to the 4 standard DB.

Since data validates that biofeedback motivated breaths performed during phase two increase mean DB volumes compared to traditional technique, subsequent calculations focused on how closely these DBs approximate each patient's predicted vital capacity (VC). For each patient, a predicted VC (pVC) was calculated based on their age, height, and gender. Mean pVC volumes did not significantly differ between the two groups ($p=0.393$, Table 2). The ratio between the volume achieved at each deep breath and patient-specific predicted VC was calculated for each patient to obtain the percent of pVC. Means and standard deviations of these results were plotted in Figure 2. Results showed that there was no significant difference in the percent change from pVC for standard DB 1 through 4 between Control and Investigational subjects ($p=0.477$). In addition, there was no difference in percent of pVC volumes for all of the DBs performed by the Control group. In contrast, biofeedback coached DB 5 to 8 more closely approached pVC when compared to standard DBs ($p=0.002$). For example, on average, DB 8 was approximately 70.45 ± 16.48% of pVC for the Investigational group, but only 39.37 ± 15.54% of pVC for the Control group ($p<0.001$).

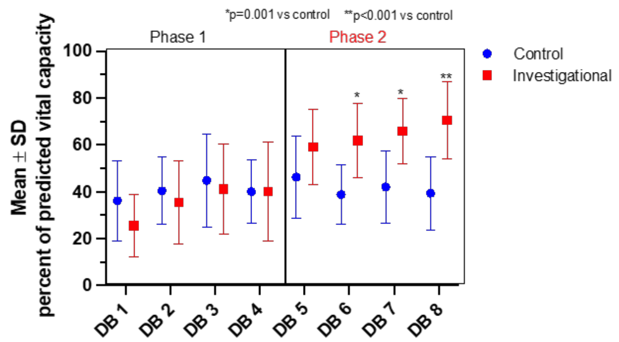

Figure 2 Mean and standard deviation of percent change from predicted vital capacity for Control and Investigational groups. Percent change from pVC represents the volume at each DB and each patient's calculated VC as described in Methods section. Percentages obtained from volumes measured from phase 1 of the protocol, where traditional techniques were used for both groups was plotted in the left panel, and data from phase 2, where the biofeedback motivated technique was used only for the Investigational group, was plotted in the right panel. The p values reflect the statistically significant increase in percent change from predicted vital capacity in the Investigational subjects coached using biofeedback (red square) to perform deep breaths (DB 5 to 8) compared to the Control subjects (blue circle).

Next, average oxygen saturation, end-tidal oxygen (EtO_2), and end-tidal carbon dioxide ($ETCO_2$) recorded at the end of each DB were analyzed. There was no difference in $ETCO_2$ or oxygen saturation as measured by pulse oximeter between Control and Investigational groups. In addition, no desaturations, defined as an oxygen saturation less than 95%, were observed at any time during preoxygenation, induction, or intubation. There was no statistical difference in measured EtO_2 between Control and Investigational subjects for DB 1 to 4 ($p=0.905$); however, this is not unexpected as the oxygen saturation prior to mask ventilation remained greater than or equal to 96%. However, during the latter part of phase 2, mean EtO_2 did significantly increase for DB 7 and 8 (Table 3).

Post hoc analysis identified a significant within-group increase in EtO_2 from DB 5 to 8 in both groups (Figure 3). For the Investigational group, EtO_2 at DBs 7 and 8 were significantly elevated when compared to EtO_2 at DB 5 ($p=0.029$, $p=0.014$). In addition, mean at EtO_2 DB 8 (84.4 ± 3.6 mmHg) was also significantly higher than those at DB 6 (80.2 ± 6.5 mmHg, $p=0.027$).

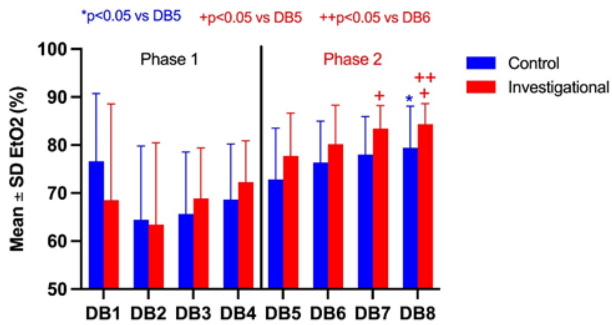

Figure 3 Mean and standard deviation of EtO2 measured during the two-phase protocol for the Control and Investigational subjects. Bar graphs are used to represent mean EtO_2 in mmHg for Controls (in blue) and Investigational participants (in red). The listed p-values represented the significance between the DB 5 and 8 for Controls, DB 5 and 8 for the Investigational group, and DB 6 and 8 for the Investigational group.

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Table 3 Mean and standard deviation of end-tidal oxygen for Control and Investigational groups during Phase 2. EtO_2, measured in mmHg, was recorded at the end of each deep breath. Means were compared using one sided student's paired t-test

	Control (N=11)	Investigational (N=11)	p-value			
End-tidal oxygen (mm Hg, Mean ± SD)				48.7 ± 12.6	44.4 ± 11.7	0.523
DB 5	73 ± 11	78 ± 9	0.13			
DB 6	76 ± 9	80 ± 8	0.15			
DB 7	78 ± 8	83 ± 5	0.03			
DB 8	79 ± 9	84 ± 4	0.05			

Discussion

In this study, the authors hypothesized that maximal deep breaths during preoxygenation could be improved by implementation of real-time, goal-directed coaching to promote larger volume deep breaths than traditional coaching techniques. This study clearly demonstrated a statistically significant increase in deep breath volume that more closely approximated predicted vital capacity in the Investigational subjects coached to perform four biofeedback deep breaths when compared to the Control subjects. These results are not surprising since the investigational coaching protocol was based on well-established motivational strategies that emphasize the value of providing specific feedback and achievable goals as promulgated by behavioral psychologist David McClelland in the 1960's.[9]

The motivational theory described by Dr. McClelland is composed of three components: (1) well-defined achievable goal, (2) timely feedback, and (3) a suitable reward. In this study, the goal is for the patient to achieve a deep breath larger than the previous and the breath's volume provided at the end of each breath serves as immediate feedback. The patient's reward is that their overall care will benefit from their efforts. In traditional studies, implementation of these techniques requires weeks or years; however, in this study, biofeedback deep breath coaching was successfully utilized over minutes prior to induction.

To permit data comparison, a standardized script was provided to each patient. Prior to induction, all study participants were informed that preoxygenation with a face mask improves anesthetic safety. Interestingly, this "reward" was not sufficient to independently motivate patients to take their maximal deep breath during the first phase nor during the second phase in Control patients. During the first phase of mask ventilation, all practitioners instructed the patient to "take 4 deep breaths in as deep as you can." During the second phase, either (1) the prior instructions were repeated or (2) the patient was instructed to increase each breath volume by 200 and each breath volume was recited to the patient. The investigators chose this specific phrasing since it emphasizes maximal inspiratory effort more than expiratory effort. A deep breath volume achieved by expansion of the inspiratory reserve volume (IRV) is more likely to preserve small airway integrity than a deep breath achieved by increasing the expiratory reserve volume (ERV) and potentially exceeding closing capacity (CC) in higher risk patients. Unfortunately, there was no way to determine if patients were motivated toward increasing IRV more than ERV in their effort to achieve a higher number.

Investigational group patients were verbally presented with a simple numeric exactly as displayed on the anesthesia machine monitor and provided a new target volume slightly greater than the size of the prior breath in order to provide real time breath to breath information on how they were doing. The limited time frame of the preoxygenation sequence coupled with the necessity to provide breath by breath feedback precluded providing anything other than a simple number. Although the simple numeric lacked some clarity without providing units and provided no other context such as the best value they might attain, it was sufficient to independently encourage an increase in deep breath volume in the Investigational group of patients.

As supported by numerous studies that identified end-tidal oxygen greater than 85% having fewer desaturation events in a variety of clinical settings,[10] end-tidal oxygen served as a surrogate marker for adequate arterial preoxygenation. The study was not designed for detecting between group differences in end tidal oxygen concentration since the Investigational group started out with four deep breaths using traditional coaching in the same manner as the Control group. Nevertheless, there was evidence of a statistically significant difference between the expired oxygen concentration for deep breaths 7 and 8 between the Control and Investigational groups that might be construed as a clinical benefit. There may have been a greater clinical and statistical significance in a larger cohort of patients treated exclusively with biofeedback coaching versus exclusively standardized coaching.

Efficiently increasing the functional residual capacity (FRC) oxygen stores using the demonstrated biofeedback-driven strategy could benefit patient care, especially for critically ill-patients or during emergencies. It is known that increasing lung volumes increases minute ventilation. Greater ventilation drives a more alkalotic blood milieu and more tightly binds oxygen to hemoglobin shifting the hemoglobin saturation to the left resulting in a slower hemoglobin desaturation.[1,3,4] This protective mechanism was proposed as an explanation why Baraka et al. found eight deep breaths a superior technique to the 3-minute TV technique despite finding similar arterial partial pressure of oxygen (PaO_2) between study groups.[3,4] Total body oxygen uptake increases exponentially and plateaus at one minute, and is primarily determined by the volume of oxygen stores in the FRC.[3,4,11] To the contrary, blood oxygen plateaus almost immediately and contributes much less to overall body uptake. Lastly, tissue oxygen stores increase slowly in a linear fashion and continue to increase over several minutes which explains the benefit of 3-5 minutes of preoxygenation.[5,11] As expected, we found no significant differences in $ETCO_2$ between the Investigational and Control groups which is likely due to the offsetting effects of increased minute ventilation (decreased ETCO2) and improved alveolar sampling of $ETCO_2$ (increased $ETCO_2$) in the Investigational group.

Another limitation in the study methodology is that the short lag time between the patient's actual deep breath and the volume as displayed on the anesthesia machine makes it more difficult to provide timely information in patients breathing rapidly. This was not an issue in this study but would likely be encountered at some point in clinical practice so the technique used in this study may not be usable in those patients. Ideally, measuring DAWD or other measurement of oxygen tension with a set apneic time, seen in observational studies in emergency settings, would best highlight differences between pre-oxygenation techniques.[12] In our study of elective patients, measuring time to reach hypoxemic states, might have added unnecessary risk to study participants which could potentially pose ethical dilemmas. Lastly, unblinded investigators may expose bias to the volume assessments through coaching; however, this concern was partially mitigated initially treating the Control and Investigational groups similarly for the first 4 breaths of the study. It would be more difficult to instigate investigator bias in phase 2 without any evidence in phase 1.

Conclusion

In summary, this study demonstrated that a biofeedback-driven protocol used during preoxygenation is superior to a traditional coaching technique with respect to increasing the volume of deep breaths. Future research using this motivational tool might be directed at demonstrating greater efficacy in preoxygenation but the magnitude of effect on increasing patient's deep breath volume suggests a different direction for study. It may be of more value to focus on patients who do not respond to this motivational tool to identify patients at higher risk for perioperative pulmonary complications not identified preoperatively and may benefit from an alternate strategy such as non-invasive ventilation.[13] Artificial intelligence-driven processing software might potentially be built to rapidly process patients' respiratory performance data and facilitate more timely feedback for achievable goals in a wider range of patients.

Data availability

The pre-processed data used to support the findings of this study may be released upon request to the corresponding author (Dr. David Wyler at david.wyler@jefferson.edu).

Conflict of interest statement

The authors declare that there is no conflict of interest regarding the publication of this article.

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Contributions

Conceptualization: all authors; Methodology: Stephen E. McNulty, David A. Wyler, Marc C. Torjman; Data gathering: Stephen E. McNulty, Alexander E. Grant; Formal analysis and investigation: Marc C. Torjman, David A. Wyler, Stephen E. McNulty; Manuscript writing: David A. Wyler, Courtney D. Singleton, Stephen E. McNulty, Marc C. Torjman; Final approval of manuscript: all authors.

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