Randomized Controlled Trial Assessing the Feasibility of Shortened Fasts in Intubated ICU Patients Undergoing Tracheotomy

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Abstract

Objective. American Society of Anesthesiology guidelines recommend preoperative fasts of 6 hours after light snacks and 8 hours after large meals. These guidelines were designed for healthy patients undergoing elective procedures but are often applied to intubated intensive care unit (ICU) patients. ICU patients undergoing routine procedures may be subjected to unnecessary prolonged fasts. This study tests whether shorter fasts allow for better nutrition delivery and patient outcomes without increasing the risk.

Study Design. Randomized blinded controlled trial.

Setting. Tertiary academic medical center.

Subjects. ICU patients undergoing bedside tracheotomy.

Methods. Intubated ICU patients who were receiving enteral feeding and for whom bedside tracheotomy was indicated were enrolled prospectively and randomly allocated to 2 parallel preoperative fasting regimens: a 6-hour fast (control) and a 45-minute fast (intervention). Patients were assessed for aspiration, caloric delivery, metabolic markers, and infectious and noninfectious complications.

Results. Twenty-four patients were enrolled and randomized. There were no complications related to the procedure. There were no cases of intraoperative aspiration identified. There was a single postoperative pneumonia in the control group. Median (interquartile range) length of fast and caloric delivery were significantly different between the control group and the shortened fast group: 22 hours (18, 34) vs 14 hours (5, 25; P < .001) and 429 kcal (57, 1125) vs 1050 kcal (825, 1410; P = .01), respectively.

Conclusions. Shortening preoperative fasts in intubated ICU patients allowed for better caloric delivery in the preoperative period.

Keywords

preoperative, fast, tracheotomy, ICU, nutrition, enteral

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In 1999, in response to a groundswell of research and advocacy efforts, the American Society of Anesthesiologists published new guidelines describing appropriate preoperative fasts.1 The guidelines imposed a 2-hour fast for clear liquids, 4 hours for breast milk, 6 hours for other milks and light meals, and 8 hours for large fatty meals. This was a dramatic shift from dogmatic overnight fasts aimed at limiting patient discomfort while mitigating the risk of perioperative aspiration. By design, the guidelines were applicable only to healthy adults undergoing elective surgery, yet they are often applied to other clinical scenarios.

Intubated intensive care unit (ICU) patients may deserve special consideration and unique guidelines. Their metabolic demand is higher, and they are at much higher risk of malnutrition.2,3 Inadequate enteral nutrition also increases the risk for septic complications and insulin resistance syndrome. Additionally, pulmonary aspiration of gastric secretions during anesthesia is a very rare event.4-6 When it occurs, it is most likely related to a complication during induction of anesthesia, laryngoscopy, or upon extubation.7 Intuitively, one could advocate for shortened preoperative fasting.
schedules for patients who are already endotracheally intubated and have easy access to the stomach via nasogastric or orogastric tubes.

It has been our practice for several years to reduce the fasting times on our bedside tracheotomy patients. Bedside tracheotomies are often performed on a more flexible schedule and carried out per the availability of the patient, surgeon, respiratory therapist, and ICU team. Patients under consideration for tracheotomy are typically among the most critically ill in the hospital, with multiple comorbid conditions. Without a shortened fast, cases are often delayed, and patients may be left fasting for more than a single day. Furthermore, when tracheotomy is postponed for inadequate nil per os status, floor transfers are often delayed, lengthening ICU stays and increasing costs of care.

The barriers to employing shortened fast times prior to tracheotomy are largely the fear of sacrificing safety for the benefits highlighted above. We performed a randomized controlled trial to assess the feasibility of shortened preoperative fasts on intubated ICU patients undergoing bedside tracheotomy. Our primary objective was to assess for changes in caloric delivery via enteral nutrition in patients with a shortened fasting regimen. Secondarily, we aimed to determine the safety of shortened fasts by assessing for aspiration, metabolic derangements, and infectious complications. We hypothesized that shortening fasts before tracheotomy would facilitate better caloric delivery without compromising safety.

Methods

Enrollment and Eligibility

With approval of our institutional review board, we prospectively enrolled patients over an 18-month period between 2012 and 2014. Eligible patients were ≥18 years; were admitted to the medical, surgical, cardiac, or cardiothoracic ICU; and were currently intubated without plans for extubation. Patients had to be candidates medically and physically for a bedside procedure. Exclusion criteria were limited to severe cardiac disease necessitating cardiac anesthesia support and inability to fit on a standard ICU bed due to body habitus. It was also a requirement that the patient be receiving enteral nutrition via nasogastric, orogastric, or percutaneous gastric feeding. Written informed consent was obtained from a designated health care proxy, in person, by the study coordinators.

Randomization and Intervention

Enrolled patients were randomized into 1 of 2 arms via a 1:1 allocation ratio and a variable block-size, computer-generated randomization list. Those in arm A were given standard fasts lasting at least 6 hours prior to the procedure. In arm B, feeds were continuously administered until preparations began for the tracheotomy procedure, approximately 45 minutes prior to incision. The attending surgeon, consenting adult, and data recorder were blinded to the feeding status. Families were blinded to the feeding status, although no placebo was administered. Enrollment is described in the CONSORT flowchart (Figure 1).

Surgical Procedure

Prior to positioning the patient, the stomach was suctioned via enteral feeding access. Ten milliliters of a concentrated blue food-coloring solution were then pushed through the enteral tube into the stomach. A standard open surgical tracheotomy was performed by 1 of the 3 senior authors (B.A.S., T.J.O., A.T.). Upon incising the trachea, a white cotton applicator was used to assess tracheal secretions for the presence of blue dye and gastric contents.

Outcomes

Postoperatively, patients were followed for 30 days or until discharge. Postoperative pneumonias were assessed according to the published guidelines of the American Thoracic Society for the diagnosis and management of hospital-acquired and ventilator-associated pneumonia. They list several criteria for identifying ventilator-associated pneumonia, including clinical symptoms 48 hours after intubation and new evidence of consolidation on chest films. To capture all intervention-related pneumonias, we broadened our criteria to include any new consolidation in a 5-day period after the intervention. For the purposes of our study, blue dye in the trachea during surgery or a new pulmonary consolidation was considered an aspiration-related event. Given the vulnerable nature of the ICU patient population and the rarity of perioperative aspiration events, the study was to be discontinued if we identified 2 cases of aspiration in either arm. Data regarding the patient’s medical status, feeding, and nutritional markers were then extracted from the chart.

The primary goal of this study was to demonstrate improved delivery of nutrition by decreasing fast time. Length of fast (LOF) was calculated as the entire length of time between the last preoperative meal until feeding was restarted postoperatively. This total LOF thus included the preoperative fasting time that was randomly allocated plus the time of the operation and the postoperative time prior to the first postoperative meal. The amount of kilocalories delivered was determined by multiplying the volume of feeds delivered by

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![Figure 1. CONSORT enrollment flowchart: demonstration of patients enrolled and excluded from randomization and analysis.](image)
the caloric density of the supplement. We measured caloric delivery during the 24-hour period before and after surgery. Additionally, we calculated the caloric delivery 72 hours before and after surgery to determine if fasting length also influenced nutritional delivery in the extended perioperative period.

The study was powered to identify a 25% difference (as expected with a 6-hour fast) in kilocalories delivered per day with a sample size of 30 in each arm.

Our secondary goals were to assess the safety of the shortened fast by comparing perioperative aspiration and other complications between the 2 arms. Infectious and non-infectious postoperative events were recorded for each patient during his or her ensuing hospital stay. Metabolic markers were assessed retrospectively and compared for both arms, and they included albumin, insulin administration, and morning glucose measurements, as well as length of stay.

Statistics

Statistical analysis was performed with SPSS 20 for Windows (IBM Corp, Armonk, New York). Statistical comparisons between the treatment arms were assessed with Fisher’s exact tests for categorical variables and Mann-Whitney U tests for continuous variables. Pearson correlations between each continuous variable and LOF (also as a continuous variable) were calculated for both groups combined; continuous variables included metabolic markers (insulin dose, fasting glucose, albumin concentration), postoperative infections, and length of stay in the ICU. P values <.05 were considered statistically significant.

Results

Table 1 describes the characteristics of participants enrolled in each study arm. A total of 24 participants were recruited, and 12 patients were randomized to each arm. There were no statistically significant or clinically meaningful differences between the 2 groups among the variables assessed. APACHE II (Acute Physiology and Chronic Health Evaluation II) scores estimate disease severity and mortality and were similar between the 2 groups.

Half the patients enrolled in our study were treated for pneumonia prior to enrollment, corresponding to other reports of the prevalence of pneumonia in ICU settings. Admission diagnoses and comorbidities were determined by documentation in admission records.

The details of nutritional delivery for patients in the 2 arms of the study are presented in Table 2. The difference in median LOF was statistically significant between groups (22.5 hours for controls and 14.5 hours for the short fast [intervention] group; P < .001). The amount of kilocalories delivered were higher in all periods for the intervention group, but this difference was statistically significant (P = .01) in only the preoperative 24 hours.

Observed outcomes are described in Table 3. There were no important adverse events related to the tracheotomy procedures. One control patient did have an episode of postoperative bleeding that was managed nonsurgically at the bedside with pressure. No cases of blue dye or gastrointestinal aspiration were noted upon visualization of the subglottis and trachea. A new pulmonary consolidation was noted in the postoperative period in 1 control patient, and no patients developed a pulmonary consolidation in the cohort.
with the shortened fast. Finger stick glucose measurements and the quantity of insulin delivered before and after surgery were compared as surrogates for insulin sensitivity as described in other papers. There were no meaningful differences in these variables between groups. Additionally, when the groups were pooled and these variables were correlated with LOF, there were no statistically significant correlations. Postoperative infectious complications were similar between groups. Four patients died during the observation period: 3 in the control arm and 1 receiving the shortened fast. These were all determined to be events independent of the tracheotomy procedures and our study protocol.

Discussion

Nil per os from the night before surgery was the standard practice for more than a century. The American Society of Anesthesiology (ASA), in the 1999 guidelines, acknowledged and addressed a striking anachronism rooted in a time before evidence-based medicine and modern anesthetic techniques. While prolonged preoperative fasts were designed to avoid perioperative aspiration, aspiration is actually remarkably rare

### Table 2. Enteral Nutrition Delivery Comparison.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Control (n = 12)</th>
<th>Shortened Fast (n = 12)</th>
<th>P Value</th>
<th>Length of Fast, r (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days receiving enteral nutrition preoperatively</td>
<td>4.5 (2.5, 9.5)</td>
<td>2.5 (1, 5.5)</td>
<td>.24</td>
<td></td>
</tr>
<tr>
<td>Time to feeding goal rate, h</td>
<td>0 (0, 6)</td>
<td>0 (0, 0)</td>
<td>.44</td>
<td></td>
</tr>
<tr>
<td>Calories delivered preoperative day, kcal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (24 h)</td>
<td>429.0 (57, 1125)</td>
<td>1050.0 (825, 1410)</td>
<td>.01</td>
<td></td>
</tr>
<tr>
<td>1-3 (72 h)</td>
<td>2700 (842, 4297)</td>
<td>2782 (1481, 4667)</td>
<td>.387</td>
<td></td>
</tr>
<tr>
<td>Calories delivered postoperative day, kcal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (24 h)</td>
<td>1045 (721, 1230)</td>
<td>1295 (825, 1905)</td>
<td>.16</td>
<td></td>
</tr>
<tr>
<td>1-3 (72 h)</td>
<td>3693 (2358, 4882.50)</td>
<td>4440 (3202.50, 5635)</td>
<td>.22</td>
<td></td>
</tr>
<tr>
<td>Length of fast, h</td>
<td>22 (18, 34)</td>
<td>14 (5, 25)</td>
<td>&lt;.001</td>
<td></td>
</tr>
</tbody>
</table>

*Values presented as median (interquartile range). P values assessed with Mann-Whitney U tests.

### Table 3. Outcome Assessment.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Control (n = 12)</th>
<th>Short Fast (n = 12)</th>
<th>P Value</th>
<th>Length of Fast, r (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intraoperative aspiration</td>
<td>0</td>
<td>0</td>
<td>&gt;.99</td>
<td></td>
</tr>
<tr>
<td>New pneumonia POD 1-5</td>
<td>1 (8.3)</td>
<td>0</td>
<td>&gt;.99</td>
<td></td>
</tr>
<tr>
<td>Metabolic outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total insulin POD 1-3, U</td>
<td>5 (0, 100)</td>
<td>39 (0, 130)</td>
<td>.44</td>
<td>−0.14 (.52)</td>
</tr>
<tr>
<td>Change in insulin after surgery, %</td>
<td>−16.3 (−18.8, 4.5)</td>
<td>10.8 (−4.5, 47.3)</td>
<td>.38</td>
<td>−0.22 (.30)</td>
</tr>
<tr>
<td>Average morning FSG POD 1-3, mg/dL</td>
<td>134 (109, 211)</td>
<td>143 (114, 202)</td>
<td>.84</td>
<td>0.01 (.99)</td>
</tr>
<tr>
<td>Change in morning FSG after surgery, %</td>
<td>−14.0 (−17.2, 28.2)</td>
<td>0.5 (−19.3, 32.6)</td>
<td>.44</td>
<td>0.01 (.98)</td>
</tr>
<tr>
<td>Change in albumin after surgery, %</td>
<td>−4.1 (−6.1, 30.6)</td>
<td>4.7 (−14.4, 17.4)</td>
<td>.79</td>
<td>−.31 (.36)</td>
</tr>
<tr>
<td>Observations during hospital stay</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infections POD 5-30</td>
<td>0 (0, 3)</td>
<td>1 (0, 3)</td>
<td>&gt;.99</td>
<td>−.19 (.37)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>1 (8.3)</td>
<td>2 (16.7)</td>
<td>&gt;.99</td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>1 (8.3)</td>
<td>4 (33.3)</td>
<td>.32</td>
<td></td>
</tr>
<tr>
<td>Wound</td>
<td>4 (33.3)</td>
<td>4 (33.3)</td>
<td>&gt;.99</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>2 (16.7)</td>
<td>4 (33.3)</td>
<td>.64</td>
<td></td>
</tr>
<tr>
<td>Decubitus ulcer</td>
<td>2 (16.7)</td>
<td>2 (16.7)</td>
<td>&gt;.99</td>
<td></td>
</tr>
<tr>
<td>Death during observation</td>
<td>3 (25)</td>
<td>1 (8.3)</td>
<td>.59</td>
<td></td>
</tr>
<tr>
<td>Days remaining in intensive care unit</td>
<td>4 (3, 11)</td>
<td>7 (2, 10)</td>
<td>.83</td>
<td>0.20 (.35)</td>
</tr>
</tbody>
</table>

Abbreviations: FSG, fingerstick glucose measurement; POD, postoperative day.

*Values presented in median (interquartile range) or n (%).

Outcomes are grouped into operative (suggestive of aspiration or pneumonia), metabolic (to determine nutritional deficiencies and insulin insensitivity), and observational (complications after the immediate postoperative period that are unrelated to the surgery itself).

When the 2 study arms were compared, P values were assessed with Mann-Whitney U tests for continuous variables and Fisher’s exact tests for categorical variables. For analysis with length of fast as a continuous variable, the 2 study arms were combined, and a correlation coefficient (r) was calculated for length of fast with each continuous variable.
(incidence, 0.007%-0.04%), and longer fasts are rarely protective.4,7,12-14 Similarly, the application of the ASA guidelines to endotracheally intubated ICU patients demonstrates a disregard for patient comfort and safety, as well as the physiology of aspiration-related events.

In our study, shortening the preoperative fast allowed for 244% more kilocalories to be delivered during preoperative day 1 and 123% during postoperative day 1, as compared with controls. This translated to an additional 685 kcal preoperatively and 400 kcal postoperatively. In our protocol, patients were assigned either a 6-hour or a 45-minute fast. The median LOF, or time between the last preoperative and first postoperative meals, typically extended well beyond these assignments (22 and 14 hours, respectively). While we were able to control the nil per os start time in the intervention group, the control group fasts generally exceeded our protocol. Fast times in excess of guidelines is a common occurrence. Shime et al found that 90% of Japanese anesthesia departments use longer fasts than recommended.15 Breuer et al found a 45% compliance rate to German fasting guidelines.16 Others have noted that fasts for solids actually ranged from 12 to 14 hours rather than 6 to 8 hours and can be as long as 37 hours.17,18 Falconer et al pointed out that surgeons and anesthesiologists are not always the source of prolonged fasting.19 Worries about delaying a surgery may push a patient or a consulting service to take extra precautions and start fasting sooner than necessary. For bedside procedures, other factors, including surgeon availability and secondary procedures, may further delay enteral nutrition. Shortening the fast to the immediate preoperative period removes this ambiguity and allows the surgeon to control the actual LOF. In fact, LOF in both groups often extended several hours after the procedure. Had we restarted feeds immediately after surgery, LOF would likely have been further reduced. The degree of variability in the postoperative management of feeding was not anticipated in the design of this study and is worthy of further investigation. It is also important to note that in the 72 hours before surgery, the 82-kcal difference between arms is not clinically significant. We did not control or assess for variations in patient care in that period, and this likely reflects the difficulties in delivering nutrition to this patient population.

A preoperative fast in isolation may not seem like a significant interruption in nutritional delivery, and for some patients, it may be a benign occurrence. Many ICU patients are subjected to multiple procedures that necessitate frequent feeding stoppages.20 Consequently, up to 59% of ventilated patients are never able to attain adequate nutrition.2 Parenteral nutrition, as an alternative, is known to cause more infectious complications and should be avoided in patients that can be sustained enterally.21 Fasting results in depletion of liver glycogen, increased whole-body protein catabolism, elevation of plasma nonesterified fatty acids, and increased resting energy expenditure due to gluconeogenesis and ketogenesis.22,23 Most of these effects are reversible, but overcoming these hurdles may prove impossible in a convalescent patient. Insulin and glucose homeostasis is a critical factor in mitigating morbidity in ICU patients.10,23 This balance is compromised when enteral nutrition is withheld. LOF is shown in other studies to correlate with insulin resistance, an independent risk factor for increased length of stay and morbidity in the ICU.22,23 We did not find statistically significant differences in morning glucose measurements and insulin requirements before and after surgery between the 2 arms of the study. While there was a negative correlation between changes in insulin requirements and LOF, this was not statistically significant.

Few studies have addressed shortening preoperative fasts in ICU patients directly. A survey of medical critical care, surgical critical care, and anesthesia departments found considerable variability in their internal protocols.13 Surgical ICUs had shorter fasts for procedures than medical ICUs and anesthesia departments (median, 4 vs 6 hours), but each specialty had similarly wide ranges of fasts for tracheotomies (0-8 hours). Pousman et al described shortened fasts for patients receiving jejunal feeding.24 Using a 45-minute fast before bedside procedures, they noted no change in ventilator-associated pneumonias as compared with controls and a tendency toward increased caloric delivery.

In a review of aspiration, Warner et al identified only 68 cases of aspiration in >215,000 general anesthetic procedures.7 All the aspirations occurred before, after, or during airway manipulations and during induction of or emergence from anesthesia. At these points, the airway is most susceptible to gastric content aspiration, as the patient is recumbent with muted protective reflexes and esophageal tone. Even in high-risk emergency intubations, the factor predisposing patients to the highest risk of aspiration is multiple intubation attempts and the need for bag mask ventilation that can inflate the stomach.14 Among patients who are already intubated, these factors should be mitigated so that the only event that would lead to such risky maneuvers would be loss of airway access during the airway exchange. Known risk factors for perioperative aspiration include higher ASA physical status, gastric emptying impairment, pregnancy, and difficult airway status.1 Inherently, ICU patients have higher ASA status, and gastrointestinal motility is a constant concern. Plourde et al demonstrated in a cat model that esophageal regurgitation required 21 mL/kg of free fluid in the stomach.25 Taylor et al also demonstrated that blind suctioning of gastric contents removed all but 14 mL of fluid on average (range, 4-23 mL).26 All of our patients were suctioned with multiorifice devices preoperatively and during the procedure to achieve a more complete gastric evacuation. Utilizing this protocol, we felt confident that despite the current ASA guidelines, our patients would be safe for surgery with a shortened fast.

It is notable that in our series, there were no overt aspirations identified in either group at the time of surgery. In each case, we were able to view the trachea and had injected the stomach with dye so that any aspiration would have been evident. The single case of a new consolidation was a critical factor in mitigating morbidity in ICU patients.10,23
in our control group. Given the rarity of aspiration events in the setting of surgery, a noninferiority study would require enrollment of at least 7500 patients to demonstrate a statistical difference in safety. While we cannot fully support this assertion with the present feasibility study, in our practice, we have found shortened fasts to be safe and effective in this group of patients. Our results reinforce the benefits of this practice and are generalizable to most enterally fed, intubated patients undergoing tracheotomy.

Limitations

Intubated ICU patients represent a vulnerable population and necessitate extra precautions for enrollment into prospective studies. We rigidly adhered to an in-person consent process with a designated health care proxy, and the majority of eligible patients did not have health care proxies available in-house. When a health care proxy was available on site, enrollment was declined >50% of the time. While we performed >250 bedside tracheotomies during the enrollment period and attempted to enroll all eligible patients, we were able to enroll only 24 patients over an 18-month period (see Figure 1). Our initial power assessment required enrollment of 60 patients to assess the differences in kilocalories and fasting times (α = 0.05, β = 0.2), but this became impossible due to the constraints discussed above. The small sample size meant lower-than-adequate power for our primary and secondary measures. Nonetheless, the LOF and the 1-day preoperative caloric consumption showed sufficiently large differences such that they were statistically significant. These results describe our clinically meaningful observations but may be skewed by bias and small sample size.

Conclusions

Shortening preoperative fasts in intubated ICU patients allowed for better preoperative caloric delivery. Although we did not identify any metabolic benefits related to our intervention, we did not identify any complications, thereby suggesting that shortening preoperative fasts in intubated ICU patients may be a safe practice. Given the safety observed in this and other studies and our positive experience with shortened fasts, we hope to standardize this regimen within our institution for continued observation. Furthermore, we feel that these results pave the way for larger prospective studies to confirm the safety of this practice in select patients.

Author Contributions

Nathan Gonik, design, drafting, acquisition of data, analysis of data, revising, accountability for all aspects of the work; Andrew Tassler, acquisition of data, revising, final approval; Thomas J. Ow, acquisition of data, revising, final approval; Richard V. Smith, acquisition of data, revising, final approval; Stefan Shuaib, acquisition of data, revising, final approval; Hillel W. Cohen, data analysis, revising, final approval; Catherine Sarta, design of study, acquisition of data, analysis of data, review of manuscript and final approval; Bradley A. Schiff, research design, acquisition of data, drafting, final approval, accountability for all aspects of the work.

Disclosures

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