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Is It Time to Ask Different Questions about Aspiration?

To the Editor:

I read with interest the report by Beach *et al.*[1] on the relationship between nil per os (NPO) time and major adverse events, with special attention to pulmonary aspiration. The authors conclude that NPO status is not an independent predictor of major complications.

As reported in other studies,[2,3] the incidence of pulmonary aspiration was found to be quite low, with only 10 cases out of over 139,000 pediatric sedations collected between 2007 and 2011. It is noteworthy that NPO definitions within the Pediatric Sedation Research Consortium database (solids, 8 h; nonclear fluids, 6 h; and clears, 2 h) are out of step with the most recent American Society of Anesthesiologists guidelines from 2011,[4] which recommend 6 h for formula/milk and "light" solids, 4 h for breast milk, and 2 h for clear liquids. Many Anesthesiology departments, including ours at Vanderbilt University, Nashville, Tennessee, have moved all solids to a fasting time of 6 h. By this measure, all of the 10 cases of aspiration would have been NPO appropriate with no episodes in those not NPO.

A look at Emergency Medicine literature[5,6] shows a low incidence of aspiration even in nonfasted patients, many of whom are likely to be in pain. The American College of Emergency Physicians published a clinical policy in 2014[7] recommending that procedural sedation in the Emergency Room not be delayed solely due to NPO time. Unfortunately, the data presented in the study by Beach *et al.* are not broken down into elective *versus* emergent procedures. Additionally, the type of provider (emergency physician *vs.* other) cannot be used as a surrogate marker as emergency physicians often provide elective sedation services outside of the Emergency Room.

So where does this leave us? We are not suggesting, based on current evidence, that we reduce the NPO times for elective general anesthesia cases with planned airway instrumentation. But perhaps we should rethink the questions that we need answered regarding NPO in pediatric sedation.

What about emergent procedures without planned airway instrumentation? Many in emergency medicine would counter this question has already been answered. Can we quantify the risk of aspiration with planned airway instrumentation *versus* unplanned *versus* none at all? Does ketamine or dexmedetomidine, which preserve respiratory drive and airway tone better than propofol, offer a safer alternative in the nonfasted patient? All of these questions will be difficult to answer given the very low incidence of aspiration but we should certainly try.

Competing Interests

The author declares no competing interests.

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In Reply:

We appreciate the careful review of our article.[1] We agree with the authors that other studies also support the low incidence of aspiration in pediatric sedation. While the study by Walker[2] of 118,371 pediatric patients is also large, only information on the 24 cases of aspiration was collected. Our study collected data on all patients, allowing us to evaluate risk

factors for aspiration using major complications. We agree that our definition of *nil per os* (NPO) is not based on current American Society of Anesthesiologists guidelines from 2011 because the data were collected from 2007 to 2011.

The vast majority of our data come from elective sedations provided by sedation services, so they do not speak to the issue of emergency sedation provision. Of the 135,860 patients for whom emergency status was known, 134,539 (99%) procedures were routine and all 10 aspirations occurred in this group. One would imagine that emergency sedation could have more risk; however, the current literature does not reflect that.

Given the limitations of the study, we do not suggest that our data argue for a complete overhaul of the NPO guidelines, but rather point out that clinicians should be aware that a rigid focus on adhering to the guidelines does not offer complete protection to patients. It confirms the previous aspiration investigations that indicate aspiration in a pediatric population is more likely to track with a patient's pathology than NPO status, and issues such as underlying illness and bowel pathology are of paramount importance when considering aspiration risk.

There is a growing literature regarding enhanced recovery of surgical patients, which suggests that our current model of prolonged starvation of patients may not lead to ideal recovery outcomes. It seems appropriate for our specialty to recognize that the current guidelines, while they have likely served patients and professionals well over the course of several decades, are based on consensus and a reasoned interpretation of data from animals and gastric emptying studies. They are not, strictly speaking, evidence based. Consideration should be given to supporting studies of very large data sets with detailed intake history to further clarify risk *versus* benefit with regard to NPO status.

Competing Interests

The authors declare no competing interests.

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Fallacy…. Really?

To the Editor:

The word "fallacy" stands out in the title of the recent editorial by Avidan and Evers.[1] It is a word rarely encountered in the biomedical lexicon, because it implies a nontruth, or in this case, that the null hypothesis has been proven. Since the null hypothesis can only be disproven, the choice of the noun, "fallacy," appears unduly well settled to us, particularly when used to characterize data presented in the authors' evidentiary pyramid. It is instructive to recall that level I evidence is only achieved from a systematic review of level II evidence (randomized controlled trials [RCTs]). The systematic reviews referred to by Avidan and Evers are of level III and IV evidence. Thus, their "highest quality of evidence" is actually far from level I evidence. Moreover, many of the studies on the "not supporting an effect" edge of the pyramid report, on closer examination, reported clinically significant effect sizes of 20 to 50% in favor of persistent cognitive decline after surgery but were underpowered.[2–4] In our view, studies that cannot rule out clinically important effects cannot be used to bolster either side of the argument. Moreover, the positive study by Liu *et al.*[5] was a prospective randomized trial, and Williams-Russo *et al.'s*[6] randomized trial addressed a completely different question (regional *vs.* general anesthesia). Of note, the investigation being advocated as the nail-in-the-coffin was itself statistically positive, although the effect size was considered by its authors to be negligible.[7] Which edge of the pyramid does this go on? Would the effect size have been larger if those lost to follow-up (1.3 times more likely to have had surgery) were included? Within the discordant twin pairs wherein previous surgery was associated with persistent cognitive decline (about half), was there an unrevealed risk factor leading to a larger effect size? Recent work by Sprung *et al.*[8] is similar in that surgery was associated with persistent cognitive decline only when the additional risk factor of age was included. A study just released from Oregon Health and Science University[9] went a step further. In a longitudinal prospective cohort, surgery was associated with persistent cognitive decline in the entire group, an effect that became stronger when focusing on subgroups, women, and *ApoE*ε4 carriers. It has been argued that these "vulnerability" factors are simply comorbid surrogates for an accelerated downward cognitive trajectory as compared to others, hence the association with postoperative cognitive decline. However, there is sound clinical evidence for a superimposed inflammatory event accelerating such a trajectory,[10] so the possibility cannot be discounted with a one-model-fits-all notion. Subgroup analyses are essential.

We argue that evidence for or against "persistent cognitive decline" after surgery is insufficient to lay the matter to rest. What steps should be taken to provide the evidence? Because retrospective, case–control, or cohort