Nil Per Os Consideration for Emergency Procedures: Cornerstone of Safety or an Obstacle to Patient Care?

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Pulmonary aspiration of particulate or highly acidic gastric fluid during anesthesia is a potentially life-threatening complication. The major risk factor is the presence of gastric contents, which can be mitigated by allowing an adequate interval from the time of the last intake of food or liquid for the stomach to empty. Such considerations justifiably lead to a conservative approach toward the application of generally accepted nil per os (NPO) guidelines for patients undergoing elective procedures, or steps to rapidly secure the airway via tracheal intubation when sufficient time to empty the stomach cannot be achieved or there are risk factors for aspiration.[1] An anesthesia provider not following the American Society of Anesthesiologists (ASA) pulmonary aspiration mitigation guidelines would be subject to peer criticism if aspiration were to occur.[2]

The need for procedural sedation outside of the operating room continues to increase.[3] The emergency department (ED) is a location where such sedation commonly occurs, but this usually does not involve an anesthesiologist. Those interventions may result in deep sedation, during which patients frequently become unconscious, with reduction or loss of protective airway reflexes. Many ED patients do not meet the ASA NPO guidelines for elective procedures.[4] In the past, ED physicians would defer procedural sedation for at least 6 hours after the ingestion of solid food, consistent with the ASA guidelines.[1] However, the American College of Emergency Physicians (ACEP) has recently challenged this policy by suggesting that preprocedural fasting in adult or pediatric patients in the ED before administration of sedation of any level is unnecessary.[4] This situation has created a dichotomy of practice between the 2 specialties. As an example, for a patient who has recently eaten lunch and needs a closed reduction of a fractured humerus, many anesthesiologists, if consulted, would likely insist on rapid sequence induction and intubation, whereas many ED physicians would elect to provide deep sedation. Such scenarios bring up a disconcerting question: "Is the position of anesthesiologists regarding procedural sedation in the ED justified on the basis of scientific evidence, or are we presenting an obstacle to timely patient care?" The objective of this article was to examine the evidence behind ACEP guidelines on NPO status and sedation for emergency procedures, in contrast with current anesthesiology practice, and propose steps on how to resolve this dilemma while providing safe patient care.

Although NPO time is widely regarded as a fundamental measure to mitigate aspiration risk, evidence for a relationship between the duration of fasting and the risk of aspiration during sedation is lacking.[5,6] Support for the ACEPs policy on procedural sedation comprises only a few studies, performed on predominantly pediatric populations, and with an incidence of periprocedural vomiting ranging from 7% to 14% (Table). We were able to identify only one analogous study in adults, conducted by Bell et al,[7] which included <300 patients. In this study, 2 patients vomited during sedation, and 1 developed laryngospasm.[10] These data are insufficient to support a claim that providing sedation in patients, regardless of their NPO status, is safe. Furthermore, data do not justify a change in current anesthesiology guidelines regarding the appropriate interval of fasting before sedation. The ASA maintains the same standards for preoperative fasting for cases involving general anesthesia or sedation, mostly because, in clinical practice, it is impossible to differentiate between the 2. Much of the misunderstanding between anesthesiologists and other health care professionals when this topic is discussed relates to the failure of the latter to appreciate the continuum between deep sedation and general anesthesia. A recent systematic review of pulmonary aspiration during procedural sedation found 34 such cases, including 1 death during procedures other than upper endoscopy.[11] The authors concluded that aspiration during procedural sedation is a rare and typically benign event not related to fasting.[11] This has to be interpreted with a caution as 25 of reported cases were from pediatric literature, while the remaining 9 were extracted from a large case series of colonoscopies, single prospective ED study in Australia, and a case report.[11] Of the 34 patients who aspirated 32 had fasting time more than 6 hours. The authors interpreted this finding as demonstrating the irrelevance of fasting to aspiration. However, one can equally argue that the fasting interval had a protective effect by decreasing volume of gastric contents, thus limiting the amount aspirated and the severity of the resulting pneumonitis.

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Table. Supporting Evidence of ACEP Clinical Policy on Procedural Sedation in ED

Study	Design	Population	Outcomes
Roback et al[7]	Retrospective, single-center study	1555 pediatric patients (median age 6.7 y)	Vomiting: 7.5%, regardless of NPO duration. No clinical aspiration
Treston et al[8]	Prospective, single-center case series	257 pediatric patients (1–12 y)	Vomiting: 13.9%, increasing with NPO status >3 h, and with age. No clinical aspiration
Babl et al[9]	Prospective, single-center case series	218 pediatric patients (median age 8.3 y)	Vomiting 7%, regardless of NPO. No clinical aspiration
Bell et al[10]	Prospective observational single-center case series	400 adult and pediatric patients (286 patients older than 15 y)	Vomiting 0.5%, regardless of NPO. No clinical aspiration

Abbreviations: ACEP, American College of Emergency Physician; ED, emergency department; NPO, nil per os.

In contrast to the data for adults, there is emerging evidence of no relationship between NPO status (>8 hours for solid food, >6 hours for nonclear liquids, and >2 hours for clear liquids) and aspiration in pediatric patients. The Pediatric Sedation Research Consortium, consisting of 42 institutions in the United States, demonstrated in a sample of 139,141 patients that the incidence of aspiration was extremely low, <1 event per 10,000 patients (0.79 per 10,000 in non-NPO and 0.97 per 10,000 in NPO), and that NPO status was not an independent predictor of aspiration.[12] A total of 19,585 patients were 12–18 years of age, an age group with no significant physiological differences from adults.[12] Although the sample size was large, <1% of the 139,142 patients underwent nonelective procedures, limiting extrapolation of the findings to patients for whom emergent care is required.

For practicing anesthesiologists, the question can be phrased simply: "In patients undergoing brief urgent procedures who do not meet NPO status defined for elective surgery, is sedation a safe and reasonable option, or should rapid sequence induction and tracheal intubation remain as the best choice to mitigate the risk of periprocedural aspiration?" Current evidence can neither support nor refute either. The situation is further complicated by the lack of large observational studies among anesthesiologists regarding their practical application of NPO guidelines in the context of emergent or urgent procedures outside the operating room requiring deep sedation. There may be a dichotomy from what anesthesiologists say they would do based on the presentation of scenarios and what they actually do. The previously cited Pediatric Consortium study, being observational by design, illustrated the existence of variability of care. Resolving this dilemma demands several steps.

First, there is need a for high-quality multicenter study on adults to establish the actual incidence of aspiration and pulmonary complications during sedation, with attention to the depth and duration of sedation, agent choice, and incidence of apnea requiring positive bag-mask ventilation. The Pediatric Sedation Consortium demonstrates how such a challenging study can be accomplished. Mild to moderate sedation with benzodiazepines and opioids alone is different than with propofol, which more frequently results in intervals of general anesthesia, and may lead to apnea requiring rescue bag-mask ventilation. Synergism of sedatives and opioids causing loss of consciousness is well understood by anesthesiologists, but frequently underappreciated by other practitioners administering sedation. Physicians, whether they are ED doctors or anesthesiologists, who think they are so skilled in the administration of propofol that they can avoid inducing general anesthesia or apnea are mistaken.

Second, the tendency to make simplistic guidelines should be avoided. Injury and pain, especially in conjunction with opioid administration, delay gastric emptying, the degree of which is unpredictable and cannot be extrapolated from healthy patients. Logically, the NPO time before the injury should be considered as opposed to the duration of NPO to the time of the procedure. Use of point-of-care ultrasonographic measurement of antral cross-sectional area represents a promising modality to determine which patients have stomach contents that place them "at risk" (high volume or particulate matter). Such testing would allow individualized periprocedural decision making regarding the appropriateness of deep sedation.[13,14] Although ultrasound assessment of gastric volume has been shown to be highly reproducible, the study included only 3 anesthesiologists with extensive experience in abdominal ultrasound.[15] ED physicians have integrated diagnostic point-of-care ultrasonography in many aspects of their practice, and expanding its application to identify patients whose gastric contents put them at increased risk would be valuable. Defining the minimum training requirements to ensure accurate assessments has been suggested as the area that requires further investigation before this modality can be recommended for a broad adoption.[16]

Third, there is a need for a multidisciplinary task force that would include experts from anesthesiology and emergency medicine to produce universal NPO clinical guidelines that would resolve the present dichotomy. The best approach should be dictated by safety considerations based on scientific evidence, not the competing interests of 2 specialties.

In 1946, Mendelson[17] presented his sentinel work on aspiration of stomach contents during a meeting of the New York Obstetrical Society. At that time, it was customary to deliver a general anesthetic via mask rather than tracheal tube, and fasting was not required before surgery. He analyzed 44,016 cases of anesthetic administration for labor and cesarean delivery, and found 66 (0.15%) cases of aspiration. Among those cases, 21 (32%) had a delayed presentation of symptoms, and 2 patients died due to airway obstruction from solid aspirated material. The risk of Mendelson syndrome during routine childbirth eventually led to the abandonment of general anesthesia delivered by mask in favor of tracheal intubation if general anesthesia was needed, and contributed to subsequent expansion of neuraxial techniques for labor analgesia and cesarean delivery. This study also laid the foundation of a focus by anesthesiologists on

risk reduction during procedures, resulting in the highest patient safety standards among all medical specialties.[18] To put professional safety standards into perspective, a study done in an ED setting would need to exceed 585 patients to observe 1 episode of aspiration (estimated risk of 0.17%, 95% upper confidence interval) to make it comparable to operating room practice in 1946, before wide adoption of tracheal intubation and aspiration precautions. Moreover, current estimates of perioperative aspiration in the setting of emergency surgery in the range of 1 per 895 cases should be considered for power analysis in study design.[19] Finally, the majority of patients who aspirate, up to 63%, do not have any clinical symptoms. These episodes of silent aspiration manifest as arterial desaturation, with subsequent radiographic findings consistent with aspiration pneumonitis.[19]

The disparity in practice between ED physicians and anesthesiologists regarding sedation practices will likely continue for the foreseeable future. Although the ASA is currently working on deep sedation guidelines (Apfelbaum J, personal communication, November 15, 2017), this will likely take years before approval. In the meantime, anesthesiologists may continue to be called by the ED at times to consult or to assist with some cases of sedation. While developing or recommending a sedation plan, they should consider that if aspiration were to occur, they would be held to the guidelines and standards of care of the ASA, not the ACEP. Anesthesiologists should be able to explain and educate colleagues from other specialties that high safety standards and sufficient evidence are the drivers of our practice and the reason for the dramatic reduction in anesthetic mortality that has taken place over the past several decades.[20] Until adequately powered, high-quality studies contradict anesthesiologists' current approach to NPO considerations for mitigation of the risk of aspiration, our current practices related to sedation in patients with potentially full stomachs should remain intact.

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