



Guidelines

An international multidisciplinary consensus statement on fasting before procedural sedation in adults and children

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Summary

The multidisciplinary International Committee for the Advancement of Procedural Sedation presents the first fasting and aspiration prevention recommendations specific to procedural sedation, based on an extensive review of the literature. These were developed using Delphi methodology and assessment of the robustness of the available evidence. The literature evidence is clear that fasting, as currently practiced, often substantially exceeds recommended time thresholds and has known adverse consequences, for example, irritability, dehydration and hypoglycaemia. Fasting does not guarantee an empty stomach, and there is no observed association between aspiration and compliance with common fasting guidelines. The probability of clinically important aspiration during procedural sedation is negligible. In the post-1984 literature there are no published reports of aspiration-associated mortality in children, no reports of death in healthy adults (ASA physical status 1 or 2) and just nine reported deaths in adults of ASA physical status 3 or above. Current concerns about aspiration are out of proportion to the actual risk. Given the lower observed frequency of aspiration and mortality than during general anaesthesia, and the theoretical basis for assuming a lesser risk, fasting strategies in procedural sedation can reasonably be less restrictive. We present a consensus-derived algorithm in which each patient is first risk-stratified during their pre-sedation assessment, using evidence-based factors relating to

patient characteristics, comorbidities, the nature of the procedure and the nature of the anticipated sedation technique. Graded fasting precautions for liquids and solids are then recommended for elective procedures based upon this categorisation of negligible, mild or moderate aspiration risk. This consensus statement can serve as a resource to practitioners and policymakers who perform and oversee procedural sedation in patients of all ages, worldwide.

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Recommendations for best clinical practice

- In these first fasting and aspiration prevention recommendations specific to procedural sedation, we present a consensus-derived algorithm (Fig. 1) to guide the management of patients of all ages undergoing procedural sedation.
- In the algorithm, each patient is first risk-stratified during their pre-sedation assessment using evidence-based factors relating to patient characteristics, comorbidities, the nature of the procedure and the nature of the anticipated sedation technique.
- Graded fasting precautions for liquids and solids are then recommended for elective procedures based on this assessment of negligible, mild or moderate aspiration risk.

What other guideline statements are available on this topic?

Several anaesthetic, paediatric and dental specialty societies have issued fasting guidelines for elective general anaesthesia and have extrapolated these recommendations to procedural sedation.

Why was this statement developed?

Procedural sedation differs from general anaesthesia in important ways and, accordingly, the committee chose to focus specifically upon procedural sedation.

How does this statement differ from existing guidelines?

This statement presents the first fasting and aspiration prevention recommendations specific to procedural sedation.

Introduction

Procedural sedation is widely performed throughout the world to attenuate pain and anxiety in patients of all ages who undergo diagnostic and therapeutic procedures. These include: fracture reduction; abscess drainage; radiographic imaging; bone marrow aspiration; dental extraction; gastro-intestinal endoscopy; and neurological diagnostic examinations. Pulmonary aspiration is a rare but potentially life-threatening complication of procedural sedation. In the hope of reducing such a risk, a period of fasting is typically recommended before these procedures, whenever possible. Fasting intervals identical to those recommended before elective anaesthesia were specified in the first procedural sedation guidelines in 1985 [1] and are still authoritatively recommended [2–9] and widely practised. With respect to pre-procedural fasting and aspiration risk, sedation and general anaesthesia have historically been viewed on equal terms. Although sedation and anaesthesia are a continuum, it is not clear that the same set of fasting intervals should necessarily be equally applicable to all sedation depths, sedation durations, procedure types and patient conditions or comorbidities. Procedural sedation intentionally targets a state in which protective airway reflexes are retained, while general anaesthesia denotes a state in which they are, by definition, absent. With sedation the procedures are often brief, there is far less active airway manipulation, and potentially emetogenic inhalational anaesthetic drugs are not routinely used. As a result, the aspiration risk for procedural sedation is almost certainly less than that of general anaesthesia (as discussed later in this article), [10–13] and, in the three decades since those original sedation guidelines were introduced, there has been important research to better clarify the relative magnitude and nature of such a risk. The

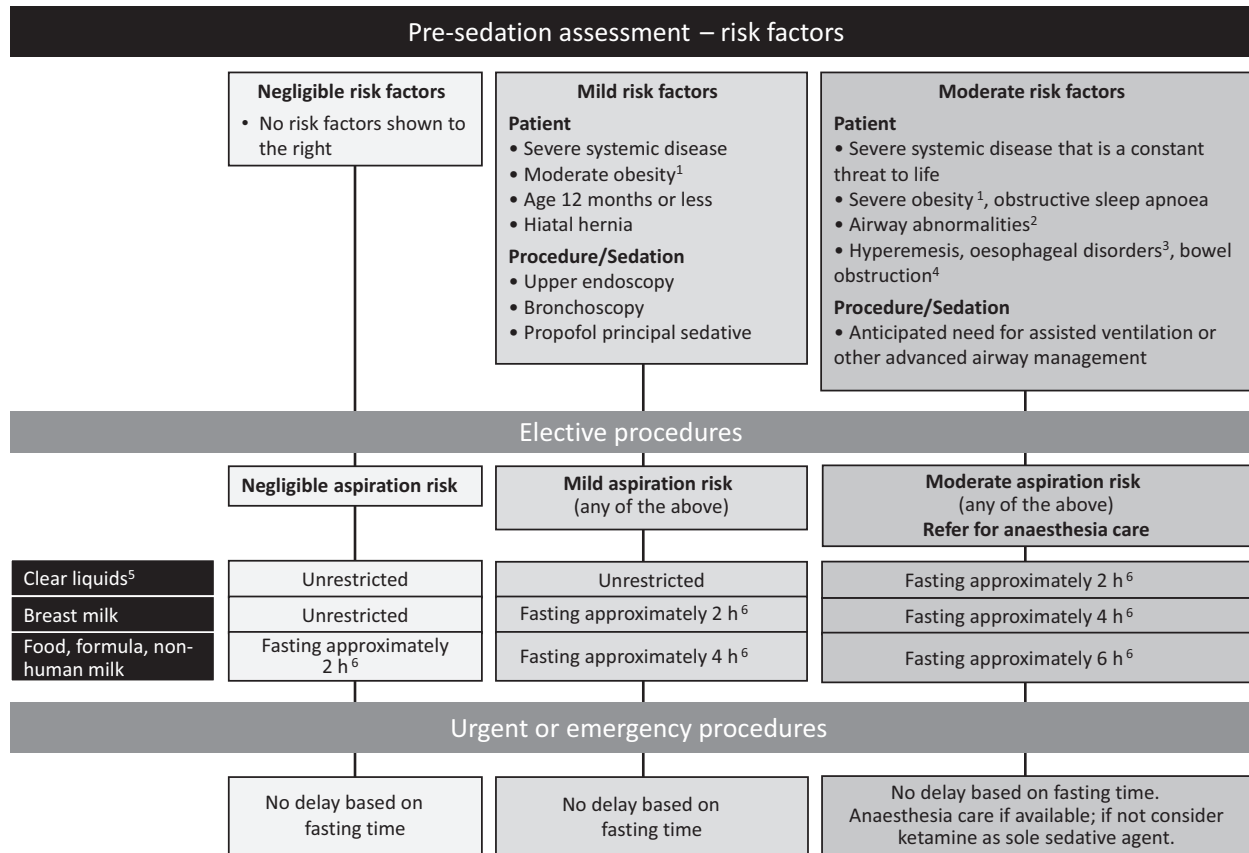


Figure 1 Algorithm linking risk stratification and fasting guidance. Notes: (1) Suggested definitions for moderate obesity are a body mass index (BMI) of 30–39 kg.m⁻² in adults or from the 85th up to the 95th BMI percentile based on age/sex in a child, and for severe obesity a BMI of 40 kg.m⁻² or higher in an adult or at the 95th percentile or greater in a child. (2) Includes micrognathia, macroglossia and laryngomalacia; (3) Includes gastroparesis, achalasia, atresia, stricture and tracheoesophageal fistula; (4) Includes ileus, pseudo-obstruction, pyloric stenosis and intussusception. (5) Clear liquids are generally considered to include water, fruit juices without pulp, clear tea, black coffee and specially prepared carbohydrate-containing fluids. (6) Fasting intervals are not absolute, with exceptions permissible when the volumes of oral intake are minor, or the fasting time reasonably close.

International Committee for the Advancement of Procedural Sedation (ICAPS, www.proceduralsedation.org) is an international and independent consensus committee of prominent sedation researchers whose collective expertise spans patients of all ages and a diverse range of specialties and practice settings. We aimed to develop recommendations for fasting and aspiration prevention specific to procedural sedation, applicable to patients of all ages. We did not aim to produce recommendations for general anaesthesia.

Methods

In developing this statement we adhered to the principles and methodology advocated by the US Institute of Medicine (now the National Academy of Medicine) [14]. First, we identified six specific questions to address, as

presented later in this document. A medical librarian conducted a search of PubMed, Web of Science and the Cochrane Library from January 1985 to 14 August 2019, limited to human subjects and the English language. Our specific search strategy in PubMed was: (sedation [tiab] OR 'monitored anesthesia care' [tiab]) AND aspiration [All Fields] AND 'humans' [MeSH Terms], and for the other two sources was: (sedation OR 'monitored anesthesia care') AND aspiration. We searched references of pertinent articles identified by our search strategy for additional relevant papers. We selected publications with an emphasis on the past 10 years, but we did not exclude commonly referenced and influential older publications. Seventeen out of the 20 ICAPS members agreed to participate in this project, and all had full access to the search results and articles identified.

We defined procedural sedation as “*the use of anxiolytic, sedative, analgesic or dissociative drugs to attenuate pain, anxiety and motion to facilitate the performance of a necessary diagnostic or therapeutic procedure, provide an appropriate degree of amnesia or decreased awareness and ensure patient safety*” [15–17]. We considered only procedural sedation performed outside the operating room administered with the intent of maintaining the patient’s own airway (i.e. without tracheal intubation or supraglottic, oropharyngeal or nasopharyngeal airways). Pulmonary aspiration is defined as “*inhalation of oropharyngeal or gastric contents into the larynx and lower respiratory tract*” [18]. Aspiration pneumonia is defined as an “*event where emesis was noted or food material was found in the oral/pharyngeal cavity—associated with any or the following: new cough, wheeze, increase in respiratory effort, change in chest radiograph indicative of aspiration or new need for oxygen therapy after recovery from sedation*” [19].

A subcommittee drafted summaries of literature evidence for six specific questions pertinent to this topic, and tentatively expressed its confidence in the evidence available using the four-point nomenclature of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group (<http://www.gradeworkinggroup.org>): high: further research very unlikely to change confidence in result; moderate: further research likely to have important impact on confidence, may change estimate of effect; low: further research very likely to have important impact on confidence in estimate of effect, may change estimate of effect; and very low: any estimate of effect is uncertain (includes expert opinion, no direct research evidence).

Although the focus of this statement is procedural sedation specifically, the general anaesthesia context is highly relevant. Accordingly, when appropriate, we sought and appraised the general anaesthesia evidence for the topic (the findings are presented in the online Supplementary Material); in the main document, we provide the corroborating or contrasting evidence for procedural sedation. Our committee then reviewed these summaries and initiated a sequential consensus generation process using the Delphi method. Specifically, we conducted an iterative series of document reviews that took place over a period of 16 months, with a later additional cycle following peer review. After each round, the anonymised responses from all members were displayed to all. Committee members could then revise their earlier responses based upon ongoing feedback, with our co-chairs serving as moderators to guide the direction of consensus.

Participants graded each item using a 5-point Likert scale: ‘strongly disagree’, ‘disagree’, ‘no strong opinion’, ‘agree’ or ‘strongly agree’. We defined agreement a priori as at least 80% of respondents choosing ‘agree’ or ‘strongly agree’. If at least 90% of respondents chose ‘agree’ or ‘strongly agree’, this was considered ‘strong consensus’. Once we achieved consensus on the evidentiary statements, we then used these literature summaries to generate, debate and refine a list of essential facts to guide the generation of recommendations. We then drafted, debated and refined the recommendations themselves, again with sequential Delphi review. We chose to use an algorithmic format to provide optimal clarity and practicality for clinicians.

The resulting provisional statement was then submitted for external review to professional societies from multiple specialties and nationalities, and other organisations with special interest in procedural sedation (<http://proceduralsedation.org/liasons/>). Our members then reviewed the provisional document in light of this outside feedback, with additional revision and Delphi review.

Results

We attained ‘strong consensus’ on all statement elements (see also Supporting Information, Table S1).

Question 1: Is there a difference in the incidence and outcome of pulmonary aspiration events between patients who receive general anaesthesia and those who undergo procedural sedation, and are the associated risks different between the two?

There are theoretical and practical reasons why the risk of aspiration during sedation is almost certainly lower than that during general anaesthesia. First, unconsciousness without response to painful stimuli is not a targeted endpoint in either ‘moderate’ [6, 7, 11, 16, 17] or ‘deep’ [6, 7, 11, 16, 17] sedation. Although non-responsiveness is typical with ketamine, this unique dissociative state helps maintain protective airway reflexes, and aspiration has not been previously reported with ketamine monotherapy except in compromised neonates [20, 21]. Accordingly, protective airway reflexes should be more consistently retained with moderate, deep and dissociative sedation than during general anaesthesia, in which complete or substantial loss of protective airway reflexes is implicit. Second, most elective sedations are performed on patients who are generally healthy in spite of their active procedural indication. Greater patient comorbidities have been identified as a risk factor for aspiration in both adults [22–24] and children [25, 26]. In many or most settings, ASA physical

status 3 and 4 patients often receive anaesthesia when possible. Third, aspiration during general anaesthesia most frequently occurs during airway manoeuvres such as tracheal intubation and extubation, use of muscle relaxants and following positive pressure bag/mask ventilation which can cause gas insufflation of the stomach [22–37]. Such high-risk events are less relevant to procedural sedation, where they only occur as part of rescue for significant airway or respiratory adverse events. Fourth, most procedures performed under sedation are relatively brief, which results in less time for aspiration risk. Finally, inhalational anaesthetics can be emetogenic, with nausea and vomiting common during post-anaesthesia recovery. Most procedural sedation is performed without inhalational agents and with a substantially lower frequency of emesis. The commonly used sedative, propofol, is anti-emetic [38].

Incidence and outcomes of aspiration associated with general anaesthesia and procedural sedation

The evidence relating to general anaesthesia is presented in the online Supplementary Material. The corresponding estimates of procedural sedation aspiration risk are more challenging to obtain than those for anaesthesia, as few studies have similarly large sample sizes (Table 1) [19, 39–53]. None of these studies report occurrences of aspiration-related mortality.

The best available study is a 139,142-patient, multicentre registry of paediatric sedation using primarily propofol, with an overall aspiration incidence of 1:13,914 with zero mortality (< 1:139,142) [19]. The authors studied 'high-performance sedation teams' whose outcomes might be better than those from other settings; however, contrasting factors that might reasonably promote poorer outcomes were the higher risk nature of the sample (17% were ASA physical status 3 or 4) and that, in 'many of the cases', the targeted depth of sedation was actually general anaesthesia rather than moderate or deep sedation.

A 646,080-patient meta-analysis of gastroenterologist-administered propofol sedation for upper endoscopy and colonoscopy has been reported, with about two-thirds of the data previously unpublished [46]. It did not report the frequency of overall aspiration, but stated that none of the four reported deaths were attributable to aspiration.

A recent systematic review of the literature identified 35 papers describing one or more occurrences of procedural sedation-associated aspiration between 1985 and 2016 [20]. These reports included 292 occurrences of aspiration during gastro-intestinal upper endoscopy, with eight deaths. For procedures other than upper endoscopy, there were 34 unique occurrences, with one death in a moribund patient, full recovery in 31 and unknown recovery status in two. A study of this format cannot determine an incidence of

Table 1 Literature estimates of aspiration risk during procedural sedation.

Study	Population	Principal Agent	Endoscopy?	Total Subjects	Aspiration overall	Aspiration during non-fasted procedures	Aspiration mortality
Bhatt[39]	Children	Ketamine	No	6295	None	None	None
Beach[19]	Children	Propofol	Some	139,142	1:13,914	1:12,701	None
Chiaretti [40]	Children	Propofol	Some	36,516	None	None	None
Friedrich [41]	Adults	Propofol	All	15,690	1:541	Not stated	None
Rajasekaran [42]	Children	Propofol	All	12,447	None	None	None
Agostoni [43]	Mixed	Propofol	All	17,999	1:1,000	Not stated	None
Dean [44]	Mostly adults	Propofol	None	62,125	None	Not stated	None
Green [45]	Children	Ketamine	None	8282	None	None	None
Rex [46]	Adults	Propofol	All	646,080	Not stated	Not stated	None
Horiuchi [47]	Adults	Propofol	All	10,662	None	None	None
Vespasiano [48]	Children	Propofol	None	7304	1:7,304	Not stated	None
Onody [49]	Mostly Children	Nitrous oxide	Some	35,828	None	None	None
Tohda [50]	Adults	Propofol	All	27,500	1:6,875	Not stated	None
Sanborn [51]	Children	Pentobarbital	None	16,467	1:8,234	None stated	None
Walker [52]	Adults	Propofol	All	9152	1:9,152	Not stated	None
Gall [53]	Children	Nitrous oxide	Some	7511	None	None	None

^aTo include just the largest studies, we display those with 5000 or more patients. We also exclude studies which report duplicate subsets of patients.

aspiration, although it would be assumed that many millions of patients received procedural sedation worldwide during this three-decade period. It is possible that these literature reports underestimate aspiration frequency due to under-reporting. However, a compilation of anecdotal 'sedation disasters' and subsequent critical incident analysis failed to identify a single instance of sedation-associated aspiration during a 27-year study period [54, 55].

Contrast between data for general anaesthesia and procedural sedation

As noted above, reasonable point estimates for the incidence of aspiration associated with general anaesthesia (1:7103 for adults and 1:4800 for children) are higher than the best available procedural sedation point estimate (1:13,914 in children), which may itself be an overestimate given the frequent targeting of a depth similar to general anaesthesia rather than deep sedation [19]. The limitations of contrasting such estimates must again be recognised, as they include aggregate patients without factoring in the presence or absence of specific aspiration risk factors (discussed in Question 2). Only 34 occurrences of non-endoscopic sedation-associated aspiration have been reported in the medical literature from 1985 to 2016, [20] affirming the rarity of this event. As noted earlier, reasonable point estimates for aspiration mortality associated with general anaesthesia are 1:78,732 for adults and immeasurably small for children. No corresponding estimate for procedural sedation is available; however, there were only nine sedation-associated aspiration deaths reported in the medical literature from 1985 to 2016, only one of which was for a non-endoscopic procedure [20]. None of these nine deaths were in children or in low-risk adult patients.

Question 2: What are the known risk factors for pulmonary aspiration with general anaesthesia and with procedural sedation?

The evidence relating to general anaesthesia is presented in the online Supplementary Material. The evidence regarding sedation-associated aspiration risk factors comes mainly from case series in which aspiration occurrences, when present, were contrasted with patients who did not suffer aspiration [19, 41–48, 50–52]. The most reliable of these is the 139,142-subject, multicentre registry of paediatric sedation using primarily propofol referred to earlier [19]. Additional information comes from a systematic review of the 326 occurrences of sedation-associated aspiration reported from 1985 to 2016, in which the authors describe

patient characteristics and procedural features that seem to be over-represented in the aspiration events, which may thus be thought of as possible risk factors [20].

Compared with the general anaesthesia studies (see also Supporting Information, Table S3), most sedation studies have smaller sample sizes and a lower incidence of aspiration. Despite this, the two main contributing studies [19, 20] are of higher methodological quality than many of the anaesthesia studies and systematically assessed multiple clinical variables. We summarise findings from these reports in Table 2 and discuss specific items in the context of both the general anaesthesia and sedation literature below.

Greater patient comorbidities

When a medical illness that could pose a risk to life was reported (i.e. ASA physical status of 3 or greater), there were consistent observations of increased aspiration risk for both general anaesthesia [22–24, 56] and procedural sedation [19, 20, 50].

Tracheal intubation/extubation/airway manipulation

Numerous general anaesthesia studies have observed occurrences of aspiration temporally associated with tracheal intubation/extubation, insertion of supraglottic airway devices, or other airway manipulation [22–36, 56, 57].

Table 2 Risk factors for pulmonary aspiration associated with procedural sedation.

Risk factor repeatedly reported without conflicting data (Quality of evidence: High):
Oesophageal endoscopy in adults [20, 41, 43, 50, 52]
Risk factors reported more than once and not specifically refuted elsewhere (Quality of evidence – Moderate)
Greater comorbidities in children [19] and adults [20, 50]
Propofol as the sedative choice [19, 20]
Risk factors reported in a single study and not specifically corroborated or refuted elsewhere (Quality of evidence – Moderate)
Infant 12 months of age or less [19]
Obstructive sleep apnoea in children [19]
Oesophageal endoscopy in children [19]
Bronchoscopy in children [19]
Clinical features found to not be risk factors, with no conflicting data (Quality of evidence – Moderate)
Emergency procedure in children [19, 20] and in adults [20]
Absence of fasting in children [19, 20] and in adults [20]
Upper respiratory infection in children [94]
Pregnancy in teenagers and adults [44]

Emergency surgery or procedure

Most studies observed that aspiration was more common during emergency surgery in adults [22–24, 28, 30, 31, 35], with mixed results in children [25, 26, 36, 56].

In contrast, emergency procedures were not identified as risk factors for procedural sedation (Table 2). This probably reflects the fact that emergency sedation is usually of short duration, performed with an intact airway, and without rapid sequence tracheal intubation or other airway manipulation.

Oesophageal endoscopy/surgery

Multiple studies have identified oesophageal endoscopy/surgery as presenting greater aspiration risk in both general anaesthesia (adults [23, 24, 35, 57] and children [26]) and procedural sedation (adults [20, 41, 43, 50, 52] and children [19]).

Oesophageal disorders and bowel obstruction

There are repeated reports of aspiration in anaesthetised patients with oesophageal disorders (both structural and motility-related) in adults [24, 27, 57] and children, [26] and with bowel obstruction in adults [22] and children [36].

Obesity

Contrary evidence regarding obesity was observed in studies of general anaesthesia (for [23, 25, 28, 57] with against [22]), with no specific data for procedural sedation.

Co-administered opioids

Contrary evidence regarding co-administered opioids was observed in studies of general anaesthesia (for [27, 28] and against [22]), with no specific data for procedural sedation.

Age

No consistent age-based profiles for risk were apparent for either anaesthesia or procedural sedation. Any observed over-representation of children or older adults may simply reflect the higher baseline prevalence of surgery or procedures in these populations.

Specific sedative drugs

Propofol is the most common sedative associated with aspiration during procedural sedation [19, 20] despite its anti-emetic effects. It is unclear whether this is a result of the more widespread application of this agent, the use of concomitant opioids or the targeting of deep sedation and the potential for rapid overshoot in sedation depth. Ketamine, unlike other sedatives, helps preserve protective airway reflexes, [21] and

there were no reports of aspiration (despite its association with vomiting and, particularly with gastro-intestinal endoscopy, laryngospasm) in patients receiving this agent alone except in compromised neonates [20, 21].

Sedation duration

The risk of overall complications is known to increase with the duration of anaesthesia [58, 59]. However, any such association with aspiration remains to be established. Morbidity and mortality resulting from aspiration occur more frequently when endoscopy includes extended procedures, for example, percutaneous gastrostomy tube placement, submucosal dissection, endoscopic retrograde cholangiopancreatography, active gastro-intestinal bleeding. [20] There are no corresponding data for other procedural sedation indications, although most such procedures are brief.

Physician specialty

Intensive care specialists as the sedation provider have been identified in a disproportionate number of aspiration occurrences [19, 20], although this is probably confounded by the higher proportion of critically ill patients undergoing sedation, and by their disproportionate contribution of sedation data to the literature. No other appreciable differences are evidence-based upon the specialty of the sedation provider. [60].

Pharmacological pre-treatment

The anaesthetic literature provides no persuasive evidence that therapeutic prophylaxis (e.g. antacids, histamine antagonists, prokinetics, anticholinergics) lowers aspiration risk or improves outcomes [6]. There are no corresponding data for procedural sedation.

Fasting

Non-compliance with fasting guidelines was not identified as a risk factor in either the anaesthesia [22, 26] or procedural sedation literature [19, 20], and this area is discussed in detail in Question 3 below.

Pregnancy

Pregnancy might present greater aspiration risk due to the associated physiological changes, including prolonged gastric emptying and increased gastro-esophageal reflux. [44] General anaesthesia data are mixed (for [23] and against [22]). A study of 62,125 fasted women receiving deep sedation with propofol for elective termination of pregnancy (including 11,039 s trimester) observed no occurrences of aspiration [44].

Patient position

There is inadequate evidence to support or refute the contention that placing the patient on their left side or in a head-down position might decrease aspiration risk [61].

Absent risk factors

Multiple authors have noted occurrences of aspiration in healthy patients without apparent risk factors, suggesting that aspiration may be either idiosyncratic or due to unknown, unrecognised factors [23, 25, 29, 31, 36, 57]. It should also be noted that, whilst risk factors can predict problems, the absence of risk factors neither logically nor clinically implies that any particular hazard cannot occur.

Question 3: What is the evidence that fasting before general anaesthesia or procedural sedation improves outcomes?

The longstanding tradition of fasting before elective surgery and procedural sedation has minimal scientific support and was instead prompted by early reports of aspiration [62] and the logical presumption that regurgitation of gastric contents cannot physically occur if the stomach is empty [7, 12, 13, 63]. There are no prospective, controlled trials to guide decision making concerning the impact of fasting intervals on aspiration; therefore, conclusions regarding association or causal relationships rely on observational series and indirect evidence as outlined below. There is no conclusive evidence to support assertions about safe fasting intervals and thus current fasting recommendations from prominent specialty societies [2–9] (see also Supporting Information, Table S4) are largely consensus driven.

As noted in Question 2, large general anaesthesia studies have not identified an association between aspiration and non-compliance with typical fasting recommendations in either adults [22] or children [26]. The best available corresponding evidence for procedural sedation similarly notes no apparent association between aspiration and non-compliance with fasting recommendations in adults [20] or children. [19, 20]. A limitation of studies contrasting patients with and without fasting compliance is that few in the latter sub-group are non-compliant to the point of having a 'full stomach'; most are non-compliant due to lesser intake of fluids or solids [19, 64].

Further evidence pertinent to fasting and general anaesthesia is presented in the online Supplementary Material, with evidence relating to procedural sedation below.

Acutely ill or injured patients presenting to Emergency Departments often require procedures that are extremely painful (e.g. abscess incision and drainage, fracture and

dislocation reduction) or that are unduly frightening (e.g. facial laceration repair or neuroimaging in a child). General anaesthesia is often impractical, unwarranted and unavailable for these typically brief and simple procedures. Procedural sedation is required to compassionately and expeditiously perform these procedures, even when patients do not comply with existing fasting guidelines intended for elective interventions. Despite this regular ongoing performance of non-fasted sedation over past decades, Emergency Department patients have not been identified as at undue risk for aspiration [19, 20]. Although under-reporting may occur in any setting, emergency procedures appear to have no higher risk than elective ones in either children [19, 20] or adults [20]. Indeed, there have been only two cases of aspiration reported in the emergency department setting; both patients had been fasted (2 hours liquids, 6 hours solids) before sedation, and both made a full recovery [20]. Multiple Emergency Department observational series have not identified any association between non-compliance with elective fasting guidelines and complications or adverse outcomes [11, 64–71].

Although it is suggested, despite contrary evidence [72–74], that gastric emptying is delayed by acute stress or anxiety, the rarity of Emergency Department aspiration suggests that, even if this is true, it is not clinically important. Similarly, fasting time before adult colonoscopy is being widely reduced due to the popularity of superior split- and large-volume bowel preparations in which the last dose is typically completed 3 hours before the procedure. Such shorter fasting does not increase gastric volume or acidity [75–78], and does not appear to increase aspiration risk during the associated propofol deep sedation or anaesthesia [75–79].

Procedural sedation is regularly performed in other settings in which fasting is frequently incomplete: cardiac catheterisation [80]; therapeutic abortions [81]; eye surgery [82–85]; and abdominal imaging in children who have first received oral contrast [86–88]. None of these settings have been identified as showing an increased aspiration risk.

Question 4: Does compliance with pre-anaesthesia and pre-sedation fasting guidelines negatively impact patient comfort, patient health, the anaesthesia or sedation experience or workflow?

The evidence relating to general anaesthesia is presented in the online Supplementary Material. There is substantially less evidence available specific to procedural sedation; however, fasting has been associated with decreased sedation efficacy [89] and an increased incidence of

sedation failure [90, 91]. Hypoglycaemia has been reported after pre-procedural fasting in an adult diabetic patient [92].

Question 5: What is the impact of published guidelines and clinical strategies for pre-operative or pre-procedural care (including fasting) on the prevention of pulmonary aspiration?

The incidence of aspiration associated with general anaesthesia has been declining over recent decades (see also Supporting Information, Table S2); however, it is not clear whether this is due to pre-operative fasting or simply improved airway management and other anaesthetic techniques [24, 25, 31]. Given this rarity of aspiration, in 1990, Cote argued that the amount of resources directed at preventing it seemed unjustified, asking: "Is aspiration pneumonia in routine healthy patients a nonissue?" [93]. As noted in question 3, there is no confirmation that specific strategies (including pre-procedural fasting) have a clinically important impact in preventing pulmonary aspiration. Although it is possible that pre-procedural restrictions on solid food (rather than liquids) may be protective, current evidence suggests that there may be trivial or no impact from either food or liquid restriction, with the greater contributing factor being the prior identification of patients with risk factors (Table 2 and see also Supporting Information, Table S3) and increased precautions with their airway management. We suggest that the current overriding focus on fasting may be largely misguided.

Question 6: Are there barriers to the development of fasting recommendations for procedural sedation that differ from existing guidelines designed for general anaesthesia?

The evidence relating to general anaesthesia is presented in the online Supplementary Material. Similar barriers exist to procedural sedation practitioners who desire, based on evidence previously discussed, to deviate from fasting guidelines stipulated for anaesthesia. Despite the differences between sedation and anaesthesia and the compelling evidence and basis for differential aspiration risk, in the past it has been near-universal to specify identical fasting precautions for both [1, 4, 6, 7, 16, 17]. Given these many decades of precedent and an unwillingness for institutions to appear to be 'breaking the rules', individual clinicians are likely to be challenged and could face censure if applying the evidence contrary to existing guidelines.

The algorithm we designed to support our recommendations (Fig. 1) summarises the approach we advocate. In this flow chart, each patient is risk stratified

during their pre-sedation assessment using evidence-based factors relating to patient characteristics, comorbidities, the nature of the procedure and the nature of the anticipated sedation technique. For elective procedures, graded fasting precautions for liquids and solids are then recommended based upon this assessment of negligible, mild or moderate aspiration risk. We did not include a high-risk category, because even with the most notable risk factors, the evidence suggests that aspiration remains uncommon.

Discussion

We present the first recommendations for fasting and aspiration prevention specific to procedural sedation, based upon rigorous literature review and consensus generation. These were designed to apply to patients of all ages and settings and are not intended for general anaesthesia.

Our recommendations are not a substitute for physician judgement or clinical assessment, and we expect that there will be situations in which clinicians will appropriately deviate from them due to unique clinical circumstances. This statement is not intended to assert a legal standard of practice or absolute requirement and cannot be expected to guarantee any specific outcome. No single document can rigidly categorise appropriate practice in this setting and, therefore, we offer this as a clinical guide combined with practical suggestions.

We recognised in advance when planning this project that our literature search would be unlikely to identify randomised, controlled trials of preventative interventions, given the rarity of aspiration in both procedural sedation and general anaesthesia, and the prohibitive sample sizes thus required for any such effort. Accordingly, as has been necessary for earlier fasting guidelines for general anaesthesia (see also Supporting Information, Table S4), we were required to rely upon evidence less rigorous than would ordinarily be preferred. Large observational studies and indirect evidence make up the literature supporting this statement, with such evidence then framed using an international, multidisciplinary panel and a rigorous Delphi consensus process. We were unable to use guideline methodologies designed to evaluate and grade randomised, controlled trials and, given the diversity of articles and content areas required to frame this multiple questions addressing this topic, it was not practical or appropriate to attempt to grade the methodological quality of each study. Accordingly, we selected the GRADE approach, which permitted us to express our confidence in the evidence supporting specific statements. We are unaware of another methodological technique likely to be

more valid for this topic area. We believe that the process was fair and transparent and demonstrated a measurable degree of final consensus.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Data S1. Context summary for general anaesthesia.