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EVIDENCE SYNTHESIS

Review of studies and guidelines on fasting and procedural sedation at the emergency department

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Abstract

Aim Procedural sedation and analgesia allows urgent procedures to be performed safely by preserving patients' airway reflexes. Fasting, which is required before deeper levels of sedation, and where the airway reflexes are not preserved, is difficult to impose in emergencies. This paper aims to synthesise evidence on the need for pre-procedure fasting to minimise aspiration among adults undergoing procedural sedation and analgesia for emergency procedures.

Methods Overviews, guidelines with graded recommendations and primary studies on aspiration and pre-procedure fasting in procedural sedation and analgesia were retrieved from Medline, Cochrane, and Center for Reviews and Dissemination Databases. Terms searched were *procedural sedation*, *fasting*, *emergency* and *sedation*.

Results One primary study and one guideline were included. The American College of Emergency Physicians Clinical Policies Subcommittee on Procedural Sedation and Analgesia issued a recommendation based on 'preliminary, inconclusive or conflicting evidence, or on panel consensus'. The recommendation states: 'recent food intake is not a contraindication for administering procedural sedation and analgesia . . .'. The primary study conducted by Bell in an emergency department in Australia compared patients who last ate or drank more than 6 and 2 h from induction, respectively, with those who last ate or drank within 6 and 2 h. There were no cases of aspiration in both groups. Out of 118 patients who fasted, 1 (0.8%) vomited, as did one of 282 patients (0.4%) who did not fast.

Conclusions Aspiration risk is expected to be lower in procedural sedation and analgesia than in general anaesthesia. Current guidelines rely on expert consensus due to the lack of primary studies. Contextualisation of existing guidelines are quick and efficient strategies for developing locally relevant tools.

Key words: aspiration, complication, emergency, fasting, procedural sedation.

Introduction

Procedural sedation and analgesia (PSA) is a valuable tool that allows emergency physicians to safely and effectively conduct urgent diagnostic or therapeutic procedures on patients with acute problems. Examples of procedures performed in the emergency department for which PSA is useful include reduction of fractures with vascular compromise, management of severe burns, debridement of large surface areas with significant pain and cardioversion for unstable arrhythmias.[1,2] Medications used in PSA are inherently known to cause serious adverse effects, which include vomiting, respiratory depression, hypoxia, hypotension and cardiac arrest.[1] A potentially fatal complication associated with the administration of inhalational and intravenous anaesthetics in general is aspiration pneumonia, which results from breathing in contents of the upper gastrointestinal tract due to drug impairment in airway-protective reflexes. While PSA supposedly preserves these protective reflexes, the very agents used in PSA are the same ones responsible for complications associated with deeper levels of sedation. Attempts to prevent such complications include the imposition of predetermined fasting periods before initiation of the procedure. This allows time for gastric contents to empty into the intestines, thus reducing the risk of regurgitation of stomach contents into the respiratory tract.

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Table 1 Continuum of depth of sedation[4]

First level	Second level	Third level	Fourth level
Minimum sedation = Anxiolysis	Moderate sedation and analgesia = Conscious sedation = Procedural sedation and analgesia	Deep sedation and analgesia	General anaesthesia

This paper aims to synthesise available evidence on the ideal fasting time as a measure to prevent aspiration, among adult patients undergoing procedural sedation with or without analgesia before emergency procedures.

Formerly referred to as 'conscious sedation', PSA brings about minimally depressed level of consciousness, enabling the patient to maintain airway patency.[3] While under PSA, the patient responds appropriately to physical stimulation and verbal commands.[3] PSA is the second of four levels in the continuum of sedation and analgesia (Table 1).

Unlike deep sedation and general anaesthesia, PSA works by minimising the patient's awareness and discomfort, while allowing the patient to maintain spontaneous respiration and airway-protective reflexes. A variety of pharmacological agents are available for the delivery of PSA. The ones most commonly used include etomidate, ketamine, fentanyl, midazolam and propofol.[1]

A clinical dilemma frequently encountered in the emergency setting is deciding between immediately performing a critical procedure under PSA and delaying the procedure until the patient has been adequately fasted. Unfortunately, time is a luxury that patients brought to the emergency department often cannot afford. The challenge to the emergency physician is to effectively address the patient's acute condition in a timely manner while avoiding a complication that could well be as life-threatening as the patient's presenting problem. Although preservation of airway-protective reflexes is an advantage of PSA over greater depths of sedation, there is a need to assess the actual risk of aspiration among patients subjected to this procedure, given various fasting protocols.

Methods

Articles that dealt with the relationship between aspiration pneumonia and duration of fasting among adult patients undergoing procedural sedation in the emergency setting were reviewed. Studies conducted after 1965 involving adult patients and that were considered as meta-analysis, systematic reviews, guidelines directly linked to systematic reviews, randomised clinical trials, cohort or case–control studies were searched. Search terms included *procedural sedation*, *fasting*, *emergency* and *sedation*. Medline, Cochrane Database of Systematic Reviews, and Center for Reviews and Dissemination Databases were searched for relevant literature. The search for primary studies was conducted by two independent reviewers. References in reviews and guidelines were individually assessed for possible inclusion of other relevant studies not previously identified.

Results

There were no relevant studies retrieved from the Center for Reviews and Dissemination Databases. Only one study on the relationship between fasting and perioperative complications was retrieved from the Cochrane database. However, the Cochrane review was excluded as it focused specifically on patients who underwent general anaesthesia rather than procedural sedation.[5]

Twenty-nine articles were retrieved from the Medline search. Editorials, studies on children, non-relevant articles and consensus articles were excluded from the review. Guidelines were excluded if there was insufficient proof of having been informed by a systematic review or if it did not provide graded recommendations. In addition, guidelines and reviews were excluded if their reference lists did not allow sufficient identification and assessment of primary studies purported to have contributed to their results and recommendations. No clinical trials and case–control studies on the association between pre-procedural fasting for PSA and aspiration in adults were identified. Out of the 29 articles, only one met the inclusion criteria. The included article was a prospective cohort study on the effect of fasting on adverse respiratory events in patients who underwent PSA. The excluded articles consisted of four consensus-based articles, 17 paediatric studies, two that were not relevant to the emergency department setting, three narrative reviews and two that did not focus on the effect of fasting. The reference lists of identified guidelines and reviews were screened for other relevant articles. From the lists of references, one guideline was found that met the inclusion criteria. There were thus two articles included in this review.

The included guideline was authored by the American College of Emergency Physicians Clinical Policies Subcommittee on Procedural Sedation and Analgesia.[6] Recommendations were based on a systematic review conducted through a Medline search of English-language articles from January 1992 to January 2004. However, in the absence of literature, consensus of emergency physicians was taken instead. The paper provides guidance to seven clinical questions including 'Is pre-procedural fasting necessary before initiating procedural sedation?' Ultimately, the policy recommendation was that 'recent food intake is not a contraindication for administering procedural sedation and analgesia, but should be considered in choosing the timing and target level of sedation'. As this was based on preliminary, inconclusive, conflicting evidence or on panel consensus, the recommendation was graded 'Level C'.

The included primary study conducted by Bell *et al.* utilised a prospective cohort design.[7] The study was conducted among patients who underwent procedural sedation with propofol for brief procedures at the Redcliffe emergency

department in Queenstown, Australia. One hundred and eighteen patients who last ate more than 6 h from induction of anaesthesia or last drank more than 2 h from induction were compared with 282 patients who last ate within 6 h or last drank within 2 h of induction. Two patients vomited, one from the fasted and the other from the non-fasted group. The patient who fasted vomited during the procedure, while the non-fasted patient vomited while awake after completing the procedure. There were no observed aspirations in either group. Although there did not appear to be any excess of adverse events in either group, the authors recommended additional research that is adequately powered to examine these events.[7]

Discussion: PSA-related adverse events

A variety of adverse events have been documented to occur in PSA. Transient hypoxaemia and subclinical respiratory depression with the use of propofol, hypertension and hypertonicity encountered with ketamine, and myoclonus with etomidate are a few of the reported adverse events of specific medications used in PSA.[8–10] In another study involving 979 patients, hypotension and desaturation occurred in 1.3% and 1.4% of the patients, respectively.[11] No cases of aspiration, endotracheal intubation or death were recorded. Unlike adverse events that are generally transient and reversible when addressed in a timely manner, aspiration of gastrointestinal contents into the respiratory tract causes serious, long-standing debilitation, and is sometimes fatal. As PSA is one of the levels in the continuum of sedation and analgesia, medications used for PSA are the same as those for deeper levels of sedation. Thus, reports of aspiration in deep sedation and general anaesthesia have triggered concern about the risk of similar adverse events occurring in PSA.

The incidence and mortality rate from aspiration pneumonia in patients undergoing general anaesthesia vary according to setting. In one review, the risk of aspiration reported from large studies in Canada, the USA, France, Sweden, Finland, the UK and South Africa range from 1 case in 14 150 to 1 in 1116 procedures, while mortality ranges from 1 death in 240 483 to 1 in 45 454 procedures.[12] Another review reveals very similar incidence rates among adults undergoing general anaesthesia of 1 per 14 139 to 1 per 1566. Mortality from aspiration ranged from 1 per 84 835 to 1 per 46 340.[13] The 4-year incidence of aspiration in a university hospital in the USA was 1 event in 7300 general anaesthesia procedures,[14] while a nationwide survey in Japan revealed an incidence of 0.8 per 10 000 procedures.[15] There were no reported deaths in both studies. A PubMed search by the authors using the terms 'procedural sedation' and 'aspiration' in adult populations yielded nine articles, one of which discusses the first reported case of aspiration pneumonitis following PSA in the medical literature.[16] There have previously been no such cases reported.[13,17] There is thus insufficient good quality research to provide the answer to the hypothesis that pre-procedure fasting results in a decreased incidence of adverse outcomes in patients undergoing moderate sedation.[18,19]

Several factors are purportedly responsible for the difference in risk between those undergoing general anaesthesia and PSA. Given that airway-protective reflexes are lost with the use of general anaesthesia, and that the depth of sedation in PSA is restricted to a point where the patient maintains these reflexes, intuitively the risk of aspiration in patients undergoing PSA is expected to be lower. Second, it has been observed that most cases of aspiration occur during manipulations of the airway.[17] Although these manipulations are part and parcel of general anaesthesia, they are unusual in PSA. In one study, 59% of cases of aspiration occurred during induction of anaesthesia and the intubation period.[20] Third, many inhalational agents used in general anaesthesia are known to induce vomiting. Lastly, patients undergoing PSA particularly at the emergency department are typically younger, healthier and, in general, have no or mild systemic disease (American Society of Anesthesiologists clinical classification I or II), in contrast to patients undergoing general anaesthesia.[7,17]

Some authors have resorted to surrogate markers, particularly gastric volume and pH, to represent the risk of aspiration. Gastric fluid volumes ranging from 0.4 to 0.8 mL/kg have been used as cut points to indicate increased aspiration risk.[21,22] Unfortunately, the recommendation to adhere to the 6-h pre-procedure fasting limit for solid foods is based largely on critical values of gastric volume and pH, which have not been proven in humans.[12] The lack of evidence has left professional organisations no choice but to rely on these arbitrary thresholds.[23] Søreide *et al.* mention that gastric emptying of clear fluids from a full stomach follows an exponential curve, with less than 10% of gastric content volume remaining after 1 h.[18] On the other hand, gastric emptying of solids exhibits a linear pattern with half the volume of a full stomach passed on to the duodenum within 2 h. By the fourth hour, less than 10% of solid food would remain.[18] In addition, there is no evidence from randomised clinical trials, cohort or case–control studies on humans that shows a link between gastric fluid volume and an increase in risk of pulmonary aspiration. It is unlikely that such evidence will be available anytime soon as existing technology relies on invasive techniques for measuring gastric fluid volume.[21]

The absence of strong primary evidence to support fasting recommendations in PSA does not diminish the need for guidance on the proper conduct of this relatively common procedure. As has been pointed out in the results of this review, most of the guidelines on pre-procedural fasting for PSA are informed by consensus opinion.[13,17,18,24] The American Society of Anesthesiologists Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists contains the consensus-based statement: 'In emergency situations, when preprocedure fasting is not practical, the consultants agree that the target level of sedation should be modified (i.e. less sedation should be administered) for moderate sedation.'[19] This recommendation is consistent with the American College of Emergency Physicians recommendation cited in the results of this review.

Despite there being only one reported case of PSA-related aspiration thus far, it is possible that such events are under-

reported in light of society's increasing awareness of patients' rights and the prevailing medicolegal climate.[13] As these incidents are difficult to uncover, physicians must always be wary of potential complications of the procedure.

Conclusion and recommendations

Although most of the attention has focused on the adverse effect of conducting urgent procedures within the critical non-fasted period, attempts should be made to investigate the detrimental effects of delays in treatment. Regardless of the time of last oral intake, measuring the risk of adverse events following delayed procedures should provide a glimpse of the 'other side of the fence'. This allows healthcare providers to make better decisions based on anticipated consequences of trade-offs between timeliness and extra caution.

The best evidence for this research question involving harm as the outcome is likely to come from observational studies. Unfortunately, the outcome of interest appears so rare that cohort and case–control studies would require very large sample sizes for results to reach significance. The lack of primary research suggesting a difference in the risk of aspiration between fasted and non-fasted patients undergoing PSA is a reflection of the rarity of the event. Out of necessity, professional organisations are left to rely on expert consensus for the development of guidance.

'Right decisions right now' fittingly describes patients' expectations of services at the emergency department. Faced with the challenge of administering PSA on a non-fasted patient, the question emergency physicians ask is 'Is right now the right decision?' As there is currently no solid basis for a definitive answer, emergency physicians must continuously undergo structured training and self-study[13] particularly in PSA to constantly upgrade their skills in anticipating and addressing adverse events including aspiration.

Acknowledging the value of high-quality evidence to support decisions, researchers should continue gathering data from patients undergoing PSA until the sample is sufficiently large to detect a significant effect size. Until such time, healthcare providers are encouraged to make good use of the best available evidence consisting of consensus-based guidelines by comparing their merits, examining their individual applicability to the local context, and possibly converting these into a form that is locally useful and relevant.

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