Pre-procedural fasting in emergency sedation

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ABSTRACT
Emergency physicians frequently undertake emergency procedural sedation in non-fasted patients. At present, no UK guidelines exist for pre-procedural fasting in emergency sedation, and guidelines from the North American Association of Anesthesiologists (ASA) designed for general anaesthesia (GA) are extrapolated to emergency care. A systematic review of the literature was conducted with the aim of evaluating the evidence for risk of pulmonary aspiration during emergency procedural sedation in adults. All abstracts were read and relevant articles identified. Further literature was identified by hand-searching reference sections. Papers were objectively evaluated for relevance against pre-determined criteria. The risk of aspiration in emergency procedural sedation is low, and no evidence exists to support pre-procedural fasting. In several large case series of adult and paediatric emergency procedural sedation, non-fasted patients have not been shown to be at increased risk of pulmonary aspiration. There is only one reported case of pulmonary aspiration during emergency procedural sedation, among 4657 adult cases and 17 672 paediatric cases reviewed. Furthermore, ASA guidelines for fasting prior to GA are based on questionable evidence, and there is high-level evidence that demonstrates no link between pulmonary aspiration and non-fasted patients. There is no reason to recommend routine fasting prior to procedural sedation in the majority of patients at the Emergency Department. However, selected patients believed to be significantly more prone to aspiration may benefit from risk:benefit assessment prior to sedation.

INTRODUCTION
Synopsis
Emergency physicians frequently undertake emergency procedural sedation in non-fasted patients. At present, no UK guidelines exist for pre-procedural fasting in emergency sedation, and guidelines from the American Association of Anesthesiologists (ASA) designed for general anaesthesia (GA) are extrapolated. The literature shows that the risk of aspiration in emergency procedural sedation is low, and no evidence exists to support pre-procedural fasting. Furthermore, ASA guidelines for fasting prior to GA are based on questionable evidence, and there is high-level evidence that demonstrates no link between pulmonary aspiration and non-fasted patients.

Background to procedural sedation
The administration of procedural sedation has become widespread practice in UK Emergency Departments (ED). It allows potentially painful and distressing procedures to be undertaken in a timely fashion with minimal distress to the patient. Emergency physicians now increasingly possess the necessary skills to safely manage procedural sedation and its possible complications. Potentially life-threatening complications include apnoea, hypoxia, hypotension and pulmonary aspiration. To date, there has been only one published case report of pulmonary aspiration occurring during ED procedural sedation. The aim of this study was to evaluate the evidence for risk of pulmonary aspiration during emergency sedation in adults.

Pathophysiology of pulmonary aspiration
Pulmonary aspiration can be defined as ‘the inhalation of oropharyngeal or gastric contents into the larynx and lower respiratory tract’. The consequences of pulmonary aspiration exist on a continuum from asymptomatic to fatal aspiration pneumonitis. The syndrome of aspiration pneumonitis describes a collection of features including cough, dyspnoea, hypoxia and bronchospasm, from which the majority of patients recover completely, and mortality is extremely rare.

Changing theories in risk of aspiration
Mendelson was the first to describe the pathophysiology of aspiration of gastric contents as a consequence of general anaesthesia in 1946. Mendelson described a series of 44 016 obstetric patients undergoing general anaesthesia between 1932 and 1945. He reported 45 cases of aspiration, resulting in two deaths. He went on to instil a variety of solutions into rabbit lungs and observed the consequences, and concluded that the severity of pulmonary damage in humans and animals is worse in large-volume, low-pH aspirate. He advocated the introduction of preoperative fasting to prevent aspiration of gastric acid, and subsequent studies aimed to determine the characteristic of stomach contents that were likely to produce aspiration pneumonitis. An oft-quoted study by Roberts in 1974 concluded that the risk of aspiration pneumonitis is increased if the patient has gastric volumes exceeding 25 millilitres, with a pH less than 2.5. These values were extrapolated from work done on monkeys. It has been historically taught that the degree of pulmonary injury from aspiration is directly related to volume and acidity of gastric contents, a theory that has since been disproved. Similarly, there is insufficient evidence to show that a decreased preoperative fasting time is associated with an increased risk of pulmonary aspiration.

Over the years, many theories have been proposed, and much research has focused on identification of risk factors for aspiration during general anaesthesia. The first studies on animals showed that lungs exposed to stomach acid demonstrated histological changes of chemical
pneumonitis. Consequently, the use of antacid therapies began, in order to reduce the likelihood of pneumonitis occurring should pulmonary aspiration of gastric contents occur. However, although antacid medications have been shown to lower gastric pH, there is no evidence that therapeutic prophylaxis lowers aspiration risk or improves outcomes and it is not recommended by the ASA in healthy patients. In obstetric anaesthesia, ASA guidelines advise anaesthetists to consider prophylaxis before caesarean delivery.

Another relevant theory is that a minimum volume of fluid needs to be aspirated into the lungs before a pneumonitis occurs, and that the gastric volume at the time of anaesthesia impacts on the volume aspirated. This has been superseded by more recent evidence, demonstrating that clear liquids ingested up to 2 h prior to surgery do not increase gastric volume or decrease gastric pH. Significantly, aspiration of clear fluids is associated with a low risk of pneumonitis, and it is now recognised that asymptomatic aspiration of gastric contents occurs physiologically during normal sleep. Research on intubated patients has also been reported in patients with no risk factors, and it is, therefore, the risk of particulate matter aspiration that should be the priority in the development of a guideline for procedural sedation.

Other factors have been implicated in the past such as pregnancy, obesity and opioid use, but these do not seem to be independent risk factors. Confirmed risk factors for pulmonary aspiration include airway difficulties (eg, laryngospasm, technically difficult intubation), old age and conditions predisposing to gastro-oesophageal reflux (eg, hiatus hernia, bowel obstruction, raised intracranial pressure). Significantly, pulmonary aspiration has also been reported in patients with no risk factors, and may still occur when the precaution of rapid sequence of induction has been employed. One theory of particular interest to emergency physicians, is that acutely stressful experiences can cause a delay in gastric emptying. However, this theory remains controversial, and although distress is often quoted as a risk factor for pulmonary aspiration secondary to delayed gastric emptying, several studies have failed to show an association.

Regarding general anaesthesia, a Cochrane review in 2003 concluded that ‘there is no evidence to suggest a shortened fluid fast results in an increased risk of aspiration, regurgitation or related morbidity compared with the standard’. However, despite the myriad literature there are relatively few trials that specifically investigate the relationship between preoperative fasting and the risk of pulmonary aspiration. Several randomised controlled trials (RCTs) indicate that despite deviation from ASA fasting guidelines there is no increased risk of pulmonary aspiration. It is difficult to apply this evidence to sedation in the emergency department for a number of reasons:

1. During general anaesthesia protective airway reflexes are lost, and airway manipulations are common. This is very different to sedated patients who do not usually undergo airway manipulations, and are presumed to maintain their airway reflexes in most cases.

2. The anaesthetic literature relates to elective procedures. Patients being sedated in emergency departments are, by definition, unplanned.

3. The alternative oral intake regimens trialled by these studies included small volumes of clear fluids (maximum of 400 millilitres), which is very different to patients undergoing sedation in the ED, who have usually had unlimited fluid and solid intake prior to attendance.

However, it is clear from up to date evidence, that the ASA guidelines for fasting are not based on recent clinical trials, and that the evidence that historically led to the development of fasting guidelines, which remain in place today, has minimal scientific support.

### Pulmonary aspiration in emergency procedural sedation

Preoperative fasting guidelines have been extrapolated to procedural sedation. The ASA guidelines require at least 2 h of fasting for clear liquids and 6 h for solids, and indicate that this should also apply to ‘light pre-procedural sedation’. These guidelines are now in widespread use in the UK, and have been incorporated into ED sedation protocols.

For clarity, the following definitions for sedation level will be used throughout this review:

| Table 1 Categories of sedation |
|--------------------------------|
| **Minimal sedation** | **Moderate sedation** | **Deep sedation** | **General anaesthesia** |
| Responsiveness | Normal response to verbal stimulation | Purposeful* response to verbal or tactile stimulation | Purposeful* response following repeated or painful stimulus | Unrousable, even with painful stimulus |
| Airway reflexes | Unaffected | No intervention required | Intervention may be required | Intervention often required |
| Breathing | Unaffected | Adequate | May be inadequate | Frequently inadequate |
| Cardiovascular | Unaffected | Usually maintained | Usually maintained | May be impaired |

*Reflex withdrawal from painful stimulus is NOT considered a purposeful response.
2. Airway manipulation: During procedural sedation, airway manipulation does not routinely take place, unless there has been a complication. It is reported that two-thirds of aspirations during general anaesthesia occur during intubation. However, improving the sedation techniques could provide evidence regarding fasting in adults undergoing emergency sedation. However, it was expected that there would be little evidence available. If this was the case, the literature search would be expanded to identify relevant topics such as paediatric emergency sedation.

In the preliminary literature search, an electronic search was carried out, using the terms: [exp EMERGENCY] or [exp EMERGENCY TREATMENT] or [emergency.mp] AND [exp CONSCIOUS SEDATION/OR exp DEEP SEDATION/] or [sedation.mp] AND [procedur$.mp]. Limit to Humans and (Age Groups All Adult 19 plus years) and English Language. Searches were made of the following databases via Athens: MEDLINE (1950 to 2008 187 titles), EMBASE (1974 to 2008, 415 titles). All abstracts were read and relevant articles identified. Further literature was identified by hand-searching reference sections. Papers were assessed for relevance by applying the following inclusion criteria: (1) Design: case series, trials, cohorts. (2) Population: studies recruiting adult patients undergoing sedation for emergency procedures. (3) Interventions: Sedation for urgent procedures carried out in ED. (4) Outcome measures: adverse effects reported. Exclusion criteria: studies that did not document fasting status, and whose authors, when contacted, could not provide information on fasting status in the study population.

Due to the lack of conclusive evidence in the published literature regarding fasting in adult procedural sedation, a search was also conducted for evidence in paediatric emergency medicine. An electronic search was carried out, using the same terms as above, but also limited to ‘paediatric’. Searches were made of the following databases using the NHS library via Athens: MEDLINE (1950-2008, 226 titles), EMBASE (1974-2008, 425 titles). All abstracts were read and relevant articles identified. Further literature was identified by hand-searching reference sections. The same inclusion and exclusion criteria were applied. The results of the two literature searches will be discussed in two separate parts.

ADULT PROCEDURAL SEDATION

Results

One case report of pulmonary aspiration associated with sedation has been published to date, summarised in table 2.

Several large series were identified in the literature search. None of these papers specifically addressed the risk of pulmonary aspiration in procedural sedation. However, all the papers listed in table 3 specifically reported any adverse events occurring procedural sedation, of which vomiting and pulmonary aspiration were specifically included.

Comment

With the exception of one case report, there are no reports of pulmonary aspiration associated with emergency procedural sedation in the literature. However, cases of vomiting during sedation are described. In total 4657 cases of emergency sedation appear in table 3, all of which describe adults requiring emergency procedures, using a variety of sedative drugs, who had not been fasted according to ASA guidelines. In total, 17 cases of vomiting were reported during sedation, but none of the patients who vomited showed evidence of pulmonary aspiration. Of the cases that vomited during procedural sedation, one was being intubated for decreased level of consciousness, and was later found to have had a hypertensive intracranial haemorrhage prior to sedation. Another patient vomited after a period of apnoea for which they received bag-valve-mask ventilation (but no airway manipulation). The other cases had no specific additional cause for vomiting reported.

### Table 2 Case report

| Reference | Subjects | Study design | Findings | Comments |
|-----------|----------|--------------|----------|----------|
| Cheung 2007 | Single patient, fasted for 5 h undergoing manipulation of a fractured ankle | Case report | Pulmonary aspiration occurred | Alcohol consumed. Sedated on two occasions. Sedation administered by orthopaedic team |
In summary, there is no high-level evidence that specifically addresses the risk of pulmonary aspiration associated with sedation for emergency procedures. However, large numbers of patients are described in these studies, and there remains only one case report of pulmonary aspiration in the literature to date.

**PAEDIATRIC PROCEDURAL SEDATION**

Paediatric emergency physicians, like their counterparts in the adult ED, are increasingly undertaking sedation for painful and unpleasant procedures such as suturing and joint/fracture manipulations. Similar to adult emergency sedation, there are no guidelines that specifically relate to sedation for paediatric emergency procedures. Again, the ASA guidelines are frequently applied to this group of patients, despite general acceptance that most procedural sedation is not likely to result in loss of protective airway reflexes. For emergency procedures, the ASA believes that the same fasting rules should apply as for elective procedures, that is, 2 h for clear liquids, 4 h after breast milk and 6 h after food or formula milk. The ASA states that if the patient is not starved and requires an emergency procedure, sedation should be modified to be lighter.
| Reference          | Subject                                      | Study Design            | Findings                                                                 | Comments                                      |
|--------------------|----------------------------------------------|-------------------------|---------------------------------------------------------------------------|-----------------------------------------------|
| Bassett KE32       | 393 children sedated using propofol          | Prospective observational study | No vomits during procedure, no cases of aspiration reported               | Patients fasted for 3 h                       |
| Newman DH32        | 1351 children sedated using various agents   | Prospective observational study | Three cases of vomiting during sedation, no cases of aspiration reported  | Patients fasted for 3 h                       |
| Agrawal D38        | 1014 children sedated using various agents   | Prospective observational study | 15 cases of vomiting during procedure. No cases of aspiration reported    | 56% subjects not fasted according to ASA guidelines |
| Roback MG30        | 2085 sedated using various agents            | Cohort study            | 156 children vomited, no cases of pulmonary aspiration reported. No difference in vomiting between fasted and non-fasted groups | 1/3 of 2085 patients not fasted according to ASA guidelines |
| Pena BMG35         | 1180 children sedated using various agents   | Prospective observational study | Two cases of vomiting during procedure. No cases of aspiration reported  | Patients not fasted                           |
| Sachetti A33       | 341 children sedated with various agents     | Prospective multicentre observational study | No cases of vomiting or aspiration reported                               | Patients not fasted                           |
| Pitetti RB34       | 1244 children sedated using midazolam and/or ketamine | Prospective observational study | Vomiting occurred in 13 patients, no cases of aspiration reported        | Patients fasted for >3 h                      |
| Dickinson R35      | 53 children sedated using etomidate          | Retrospective chart review | No cases of vomiting or aspiration reported                               | Patients kept nil by mouth from arrival at ED |
| Bell A31           | 400 children sedated for using propofol      | Prospective observational study | One patient vomited during sedation, no cases of aspiration reported     | 70% cases not fasted according to ASA guidelines |
| Skokan EG36        | 40 children sedated using propofol           | Prospective observational study | No cases of vomiting or aspiration reported                               | Patients fasted for >4 h                      |
| Woolard D37        | 759 children sedated using various agents    | Retrospective chart review | 18 cases of vomiting, no cases of aspiration reported                     | Patients not fasted                           |
| Kennedy RM38       | 260 children sedated using midazolam or ketamine | Prospective partially blinded trial | 18 cases of vomiting, no cases of aspiration reported                     | Patients not fasted                           |
| Godambe SA39       | 113 children sedated using various agents    | Prospective partially blinded trial | Two cases of vomiting, no cases of aspiration reported                   | Patients fasted for >4 h                      |
| Pohlgheers AP40    | 133 children sedated using fentanyl and diazepam | Retrospective chart review | One case of vomiting, no cases of aspiration reported                     | Patients kept nil by mouth from time of arrival to ED |
| Holloway VJ41      | 100 children sedated using ketamine          | Retrospective chart review | No cases of vomiting or aspiration reported                               | Patients fasted for 3 h                       |
| Younge PA42        | 59 children sedated for using oral ketamine and midazolam | Prospective randomised double blind trial | Five cases vomited, no cases of aspiration reported                      | Patients not fasted                           |
| Treston G43        | 272 children sedated using ketamine          | Prospective observational study | No vomits during procedure, no cases of aspiration reported               | Patients not fasted                           |
| Luhmann JD44       | 55 children sedated using ketamine           | Randomised comparison     | Two children vomited, no cases of aspiration reported                     | Patients fasted for 2 h                       |
| Kim G45            | 20 children sedated using ketamine           | Prospective observational study | No cases of vomiting or aspiration reported                               | No full meal within 3 h                       |
| Ng KC46            | 500 children sedated using ketamine          | Retrospective observational study | No reports of aspiration. Vomiting not reported                           | Patients fasted for 3 h                       |
| Heinz P47          | 83 children sedated using ketamine           | Prospective randomised double blind study | No reports of aspiration. No vomits during procedure reported            | Patients fasted for minimum of 3 h            |
| McGlone R48        | 87 children sedated using ketamine and midazolam | Prospective comparative study | One report of vomiting, no cases of aspiration reported                  | Patients fasted for 3 h                       |
| McGlone RG49       | 501 children sedated using ketamine          | Prospective observational study | No vomits during sedation, no cases of aspiration reported               | Patients fasted for 3 h                       |
| Ellis D40          | 89 children sedated using ketamine           | Prospective observational study | One case of vomiting during procedure. No cases of aspiration reported   | Patients fasted for 4 h                       |
| Roback MG51        | 2500 children sedated using various agents   | Prospective observational study | No cases of aspiration.                                                  | Patients fasted for 3 h                       |
| Green SM52         | 181 patients vomited, not clear if during procedure or recovery | Retrospective chart review | No cases of aspiration. One case of vomiting reported                    | No full meals within 3 h                      |
| Langston WJ53      | 268 children sedated using ketamine          | Double blind RCT          | No cases of aspiration. 22 cases of vomiting in the ED or after discharge | >-50% of patients not fasted to ASA guidelines |
Table 4 Continued

| Reference | Subject | Study Design | Findings | Comments |
|-----------|---------|--------------|----------|----------|
| Pruitt JW26 | 37 children sedated using ketamine and midazolam | Prospective observational series | No cases of aspiration reported, one case of vomiting during recovery phase | No full meals within 3 h of procedure |
| Green SM25 | 108 children sedated using ketamine | Prospective uncontrolled trial | No cases of aspiration. One case of vomiting during sedation | No full meal within 3 h of procedure |
| McCarty EC16 | 114 children sedated using ketamine | Prospective case series | No cases of aspiration reported. No cases of vomiting during procedure | No full meal within 3 h of procedure |
| Dachs RJ57 | 30 children sedated using ketamine | Prospective observational study | No cases of aspiration or vomiting during procedure. Two cases of post procedural vomiting | Patients fasted for 3 h for solids. |
| Green SM26 | 1022 children sedated using ketamine | Prospective consecutive case series | No cases of aspiration reported. 6.7% of cases vomited | No full meal within 3 h of procedure |
| Sherwin TS29 | 104 children sedated using ketamine and midazolam | RCT | No cases of aspiration reported. No cases of vomiting during procedure | No full meal within 3 h of procedure |
| Waterman GD46 | 266 children sedated using ketamine and midazolam | RCT | No cases of aspiration reported. No cases of vomiting during procedure | Length of fast varied between 3.6 and 8.1 h of procedure |
| Priestley SJ61 | 28 children sedated using ketamine and midazolam | Prospective observational study | No cases of aspiration reported. No cases of vomiting during procedure | Patients fasted for 4 h for solids |
| Luhmann JD62 | 42 children sedated using various agents | Consecutive prospective case series | No cases of aspiration reported. One patient vomited. | Fasting times between 1.6 and 8.8 h of procedure |
| Losek JD63 | 116 children sedated using ketamine and midazolam | Retrospective chart review | No cases of aspiration or vomiting reported. | Patients not fasted |
| Waterman GD46 | 858 children sedated using ketamine | Retrospective chart review | No cases of aspiration reported. 10 cases of vomiting | Patients fasted for 4 h of procedure |
| Sharieff GD35 | 20 children sedated with ketamine and propofol | Prospective observational study | No cases of aspiration or vomiting reported during procedure | Patients fasted for 6 h for solids and 4 h for liquids |
| McKee MR46 | 471 children sedated with ketamine | Retrospective chart review | No cases of aspiration reported. 17 patients vomited | Patients fasted for 4 h for solids and 2 h for liquids |
| Langston WT53 | 255 children sedated with ketamine | Double blind RCT | No cases of aspiration reported. 25 patients vomited. | >50% of patients not fasted according to ASA guidelines |
| Acworth JP67 | 53 children sedated with ketamine and/or midazolam | Randomised trial | No cases of aspiration reported. One case of vomiting during procedure | Patients not fasted |
| Connors K68 | 58 children sedated with midazolam | Double blind, randomised trial | No cases of aspiration or vomiting reported | Patients not fasted |
| Shane SA69 | 34 children sedated with midazolam or placebo | Double blind randomised trial | No cases of aspiration or vomiting reported | Patients fasted for 2 h of procedure |

ASA, American Society of Anesthesiologists; ED, emergency department; RCT, randomised controlled trial.

Results

Three studies were found that specifically investigated the relationship between pre-procedural fasting and adverse effects. All three studies show no association between the two. Agrawal et al28 report a consecutive series of 1014 children undergoing procedural sedation, of whom 56% were not fasted in accordance with ASA guidelines. There were no reported cases of pulmonary aspiration, and 15 reported cases of vomiting. There were no differences in airway complications, vomiting or any other adverse events between fasted and non-fasted groups. Roback et al29 in a study of 2085 children undergoing emergency procedural sedation, found no association between pre-procedural fasting and incidence of adverse events. Although 156 (7.5%) patients vomited there were no cases of pulmonary aspiration, and when the fasting time was divided into 2-h groups (0-2, 2-4, 4-6, 6-8 and >8 h) no association was found. The higher rates of vomiting in this study compared to others may be explained by a higher percentage of cases sedated using ketamine. An observational study by Bell et al31 reports 400 cases of paediatric sedation using propofol for emergency procedures. Seventy per cent of cases had eaten between 2 and 6 h prior to the procedure. No adverse outcomes were reported. In this study two patients vomited, the first during sedation and the other after recovering to the extent of being able to talk. Neither case showed evidence of aspiration.

A number of other paediatric sedation papers are listed in table 4, describing 17672 cases of paediatric procedural sedation. There are no reports of pulmonary aspiration among them.

Comment

There are several important considerations when applying the evidence from paediatric emergency sedation to adults. Ketamine is generally used more commonly in children, although its use has been widely reported in all ages. Ketamine is known to produce a dissociative state, rather than true sedation or anaesthesia,55 and is therefore believed to be less likely to suppress protective airway reflexes. It is also thought to be more emetic than other drugs.70 The paediatric population as a whole
are also believed to have a higher incidence of vomiting than adults. Nevertheless, there are no reports of pulmonary aspiration in children undergoing emergency procedural sedation, the majority of whom were not fasted in line with ASA guidelines.

CONCLUSION

The risk of aspiration during emergency procedural sedation is very low, and no evidence exists to support pre-procedural fasting. In several large case series of adult and paediatric emergency procedural sedation, there have been no published reports of pulmonary aspiration. Evidence to support ASA guidelines for fasting prior to general anaesthesia, which have been extrapolated for use in emergency sedation, has minimal scientific support. Indeed, several randomised trials have failed to show any link between non-fasted patients and pulmonary aspiration. Therefore, there is no reason to recommend fasting patients prior to procedural sedation in the ED.

However, selected patients believed to be significantly more prone to aspiration may benefit from a risk:benefit assessment prior to sedation. This assessment should consider the relative risks and benefits of the proposed procedure and sedation technique, including factors that may increase the risk of aspiration such as old age and conditions predisposing to gastro-oesophageal reflux.

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