Postprint

Low incidence of pulmonary aspiration in children allowed intake of clear fluids until called to the operation suite

Original article

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a) What is already known: Today most departments apply the 6-4-2 fasting regime. Previous studies have shown incidence of pulmonary aspiration in pediatric patients to be 1-10 in 10 000.

b) What this article adds: This article investigates the safety of a 6-4-0 fasting regime. We studied 10 000 children undergoing general anesthesia for surgical procedures. The incidence of pulmonary aspiration was not increased compared to previous studies.

c) Implications for translation: Shortened fasting times may improve the perioperative experience for parents and children and reduce dehydration and hypoglycemia.

Abstract

Background: International guidelines recommend two hours of clear fluid fasting prior to general anesthesia. The pediatric anesthesia unit of Uppsala University Hospital implements a more liberal fasting regime for more than a decade; thus children scheduled for elective procedures are allowed to drink clear fluids until called to theatre. We hypothesized that this practice would not increase the risk of significant pulmonary aspiration.

Aim: To determine the incidence of perioperative pulmonary aspiration in pediatric patients allowed unlimited intake of clear fluids prior to general anesthesia.

Method: Elective pediatric procedures between January 2008 and December 2013 were examined retrospectively by reviewing anesthesia charts and discharge notes in the electronic medical record system. All notes from the care event and available chest x-rays were examined for cases showing vomiting, regurgitation and/or aspiration. Pulmonary aspiration was defined as radiological findings consistent with aspiration and/or postoperative symptoms of respiratory distress after vomiting during anesthesia.

Results: Of the 10 015 pediatric anesthetics included, aspiration occurred in three (0.03 % or 3 in 10 000) cases. No case required cancellation of the surgical procedure, intensive care or ventilation support, and no deaths attributable to aspiration were found. Pulmonary aspiration was suspected, but not confirmed by radiology or continuing symptoms, in an additional fourteen cases.

Conclusion: The incidence of perioperative pulmonary aspiration among pediatric patients allowed clear liquids prior to anesthesia was not increased compared with previous studies.

Introduction

Most current guidelines recommend fasting for six hours for solids, four hours for breast milk and two hours for clear fluids prior to anesthesia (6-4-2 regime)(1, 2). At the pediatric anesthesia unit of Uppsala University Hospital, a more liberal fasting regime has been implemented for more than a decade. Thus, children scheduled for elective procedures requiring anesthesia are allowed to drink clear fluids until they are called to the operating room (6-4-0 regime). Otherwise, the hospital follows Scandinavian guidelines with four hours fasting for breast milk and infant formula and six hours fasting for non-human milk and solids (3). The introduction of this local routine was motivated by the need for diminishing prolonged fasting when rearrangements in the surgical schedule occurred, and the lack of evidence for any benefits of clear fluid fasting. Previously, we had observed several children that were brought to the operating room with signs of dehydration in spite of the 6-4-2 regime.

Aim

The objective of this study was to determine the incidence of pulmonary aspiration associated with general anesthesia in elective procedures, in pediatric patients subjected to a 6-4-0 fasting regime.

Material and Methods

After obtaining approval from the local Ethics Committee, a list of all patients undergoing surgery at the pediatric anesthesia unit of Uppsala University Hospital between January 2008 and December 2013 was extracted from the patient data management system (PDMS). All anesthesia charts in the electronic medical record system were reviewed retrospectively. In case of vomiting, regurgitation and/or aspiration, the discharge note and any available chest x-rays were also examined. In case of suspected aspiration the anesthesia chart and discharge note were examined by two researchers to decide if an event had occurred. All chest x-rays performed to confirm or exclude pulmonary aspiration were re-examined by a radiologist. Descriptive statistics with mean values, standard deviations and ranges were used to describe incidences of events.

Definitions

A perioperative pulmonary aspiration event was defined as aspiration of gastric contents occurring during induction of anesthesia, during the procedure or after extubation in the operating room. In the present study the aspiration events were subdivided into two groups:

A. Pulmonary aspiration – children vomiting during anesthesia with observations of gastric contents in the airway and/or showing radiological findings consistent with aspiration and/or symptoms of respiratory distress (i.e. reduced saturation, increased respiratory rate, coughing or wheezing) after surgery.

B. Suspected pulmonary aspiration – children vomiting during anesthesia and showing transient respiratory symptoms such as desaturation or signs as crackles, rales or obstructive breathing, but without observations of gastric contents in the airway, and without symptoms of respiratory distress (i.e. reduced saturation, increased respiratory rate, coughing or wheezing) or x-ray findings after surgery.

Anesthesia methods

The anesthesia methods have been fairly uniform at our department during the last decade. We prefer i.v. induction with propofol and fentanyl if a laryngeal mask airway with spontaneous ventilation is planned (the majority of elective cases), alternatively with thiopenthone, fentanyl and atracurium for intubation. Mask induction is used in cases of difficult i.v. access. Intubated children receive an oro-gastric tube, but the stomach is not routinely suctioned in elective cases. Maintenance of anesthesia is with sevoflurane except for oncology procedures, in which a propofol infusion is used (often together with low-dose sevoflurane). Classic deep extubation is not practiced, but LMAs are occasionally removed when the patient is still in a deep plane of anesthesia.

Study population

From January 2008 to December 2013, 11 535 elective procedures were identified in the PDMS. Children anesthetized for other procedures than surgery such as radiation therapy or radiological examinations were not included, nor were children scheduled for procedures in the operating rooms (at different locations) serving Ear Nose and Throat, Ophthalmology or Neurosurgery, since these departments still applied the 6-4-2 fasting routine and slightly different anesthesia methods. Exclusion

criteria were emergency surgery, and neonates cared for in the neonatal intensive care unit (NICU), since these patients also follow other fasting regimes.

Results

Study population

Fifteen patients were excluded since no anesthesia charts could be found, 105 had had local or regional anesthesia, 526 were NICU patients and 874 underwent emergency surgery. In all, 10 015 procedures on 9 889 patients were included. Age ranged from 0 to 16 years (mean ± SD; 6,5 ± 5,2). Anesthesia induction was usually intravenous. Inhalational induction was used only when peripheral access was difficult to obtain or when the patient requested it. Patient characteristics are shown in table 1.

Incidence of pulmonary aspiration

There were three cases of patients aspirating during procedure and showing radiological findings consistent with aspiration postoperatively. In two of these, the child also showed signs of respiratory distress. The three cases were classified as pulmonary aspiration, giving an incidence of 0.03 %. All cases of pulmonary aspiration are shown in table 2.

The first case was a 16 year old girl admitted for investigation of stomach ache, weight loss and vomiting. The patient vomited shortly after initiation of the gastroscopy. A gastrointestinal transit time exam later showed a duodenal stenosis, probably due to Crohn's disease. The second case was a six year old girl admitted for urological surgery. At induction, the child vomited and desaturated for a few minutes. The patient did not develop any postoperative symptoms and was discharged the next day. The third case was a healthy five year old boy admitted for ambulatory surgery of a hydrocele. During the procedure, the boy vomited and was intubated. He was observed in the surgical ward for one night and was discharged the next day.

Incidence of suspected pulmonary aspiration

Fourteen patients showed transient symptoms of respiratory distress such as desaturation or rales immediately after vomiting and were hence classified as suspected pulmonary aspiration, giving an

incidence of suspected pulmonary aspiration of 0.14%. In these cases, no gastric contents were observed in the trachea, endotracheal tube or laryngeal mask and the patients did not show any signs of respiratory distress postoperatively. In the two cases where chest x-ray was performed, no signs of pulmonary aspiration could be seen. In one of the cases, the event led to unanticipated hospital admission in spite of rapid attenuation of the respiratory symptoms. This patient was originally planned as an outpatient but spent one night in hospital for observation. All cases of suspected pulmonary aspiration are shown in table 3.

Outcome of pulmonary aspiration

None of the cases required intensive care or respiratory support. In the two patients who developed postoperative symptoms these were limited to 24 hours with no subsequent sequelae. No procedures were cancelled due to aspirational events. No mortality was found. No patient had more than one aspirational event. In several cases when a patient with previously suspected or confirmed pulmonary aspiration was admitted for additional surgery, the anesthetist used cricoid pressure and tracheal intubation to prevent additional events.

Incidence of vomiting

Ninety-eight patients vomited or regurgitated during anesthesia, resulting in an incidence of intraoperative vomiting or regurgitation of 0.98 %.

Risk factors for pulmonary aspiration

Neither patient age nor ASA class had significant influence on the incidence of aspiration.

Discussion

There is an acute, life threatening danger linked to the aspiration of solid matter during anesthesia. Hence, patients need to be fasted long enough for the ventricle to be empty from solids. However, we are not aware of studies providing unequivocal evidence for an optimal fasting time in which the negative effects of fasting are attenuated while the risk of perioperative pulmonary aspiration is minimized. Gastric emptying of clear fluids in children occurs quickly and previous studies have not been able to detect differences in residual volume when comparing fasting times (4-7). At the pediatric

anesthesia unit of Uppsala University Hospital, the fasting regime is more lenient regarding clear fluids, while the practical rules of no solid food after midnight and four hours fasting for breast milk and formula are strictly applied (1-3). The main finding of the present study is that this practice did not result in a higher incidence of pulmonary aspiration compared with other published studies.

Incidence and outcome of pulmonary aspiration

Several studies performed the past years have reported incidences of perioperative pulmonary aspiration in pediatric patients ranging from one to ten in 10 000 (Table 4)(8-13). The reported range is likely secondary to different criteria for the diagnosis of pulmonary aspiration and different definitions for the inclusion of an event as perioperative pulmonary aspiration. In our study, we chose to also include cases where pulmonary aspiration was not proved, but could have taken place, as suspected pulmonary aspiration. In some of the earlier studies the criteria for diagnosis is not reported (8, 11, 12). In other studies, patients with only transient symptoms were not included in the analysis. Borland *et al.* defined pulmonary aspiration as visualization of non-pulmonary material in the larynx or trachea by laryngoscopy or bronchoscopy, or the patient had respiratory symptoms and radiographic signs of pulmonary aspiration (9). Warner *et al.* identified pulmonary aspiration as the presence of bilious secretions or particulate matter in the tracheobronchial tree when examined, or by postoperative chest roentgenogram with signs of aspiration (9, 10). This definition was subsequently applied in a recent multicenter survey, in which the overall incidence was 2 in 10 000 (13).Borland found an incidence of aspiration of gastric contents of 4.9 in 10 000. Of these, patients that required intubation for up to 24 hours or required bronchial lavage in order to remove solid pieces (2.9 in 10 000) were considered clinically cases of significant aspiration (9). Warner *et al.* found an overall frequency of pulmonary aspiration of gastric contents at 4 in 10 000. Of the 24 children that aspirated, 9 developed clinical symptoms, giving an incidence of clinically significant pulmonary aspiration of 1.6 in 10 000 (10). Since pulmonary aspiration is rare, the associated morbidity and mortality is hard to study. When aspiration does occur the consequences are often not as serious as expected. None of the previous studies reported any mortality in the children that aspirated (8-13). In the studies of Warner *et. al.* and Borland *et. al.,* 6 patients and 4 patients required mechanical ventilation, respectively (9, 10, 13), while Murat and coworkers found one patient that needed post-operative intensive care (8). Walker found 5 patients with severe deterioration, all of which needed postoperative ventilation or intensive care (13).

In the present study, we found two clinically significant cases in 10 000 patients, albeit neither of them needed mechanical ventilation or intensive care. Both patients were free from symptoms the day after surgery. The results of several studies thus indicate that clinically significant pulmonary aspiration is a rare event.

Notwithstanding, while differing criteria for pulmonary aspiration makes direct comparisons difficult, the lack of severe complications in the present study implies that our reported incidence is at least not underestimated.

Risk factors for pulmonary aspiration

The physiology of fasting and risk factors for perioperative pulmonary aspiration have recently been reviewed by Kelly and Walker (14). Several conditions are associated with a higher risk of pulmonary aspiration, the majority due to delayed gastric emptying. Only a few studies of risk factors for perioperative pulmonary aspiration have been performed in the pediatric population. A recent prospective multicenter survey reported the presence of at least one risk factor for pulmonary aspiration in 16 of the 24 patients that aspirated (13). Borland *et al.* found no association between fasting duration and risk for pulmonary aspiration (9). Some earlier studies have shown a statistically significant relationship between ASA physical status and aspiration (9, 11). Previous studies have also reported a range in the incidence of pulmonary aspiration in different pediatric age groups, although the results are not conclusive (8, 9, 11). The current study was not powered to detect differences due to age or ASA physical status, and thus no statistically significant differences could be identified. Of the three cases in the present study, the first did have known risk factors for pulmonary aspiration such as ASA II and gastrointestinal motility disorder. Regardless of fasting regime, it is important to identify patients with risk factors, and adapt the procedure to minimize the risk of pulmonary aspiration.

Incidence of intraoperative vomiting

There is a paucity of studies on the incidence of vomiting *during* general anesthesia (as opposed to postoperative nausea and vomiting) and there is a risk of underestimating the risk due to omitted reporting in retrospective studies. An earlier study reported an incidence of 28-136 in 10 000 (15), which however is in accordance with our results.

Adverse effects of fasting in pediatric patients

Fasting induces catabolism that may increase the harmful effects of surgery. Maekawa *et al.* found higher plasma levels of ketone bodies in children fasting for 4 hours compared to the 2-hour fasting regime (16). This indicates that a more lenient fasting regime may lead to a reduced catabolic response. Fasting increases the risk of preoperative dehydration and hypoglycemia and increases postoperative insulin resistance which may result in hyperglycemia (17). Shortened fasting time for clear liquids is likely to preserve intravascular volume and thus improve hemodynamic conditions and facilitate vascular access. Several studies have shown that children allowed to drink closer to surgery experience less thirst, hunger and anxiety, show better behavior and are more comfortable (4, 5, 18-22). Further research is needed concerning the effect of a free fluid regime on gastric volume and pH. Schmidt et al have recently reported no difference in gastric volume or pH when comparing one to two hours of fasting for clear fluids (23).

Benefits from allowing children to drink clear fluids before anesthesia

The risk for prolonged fasting due to rearrangement of the surgical schedule is probably reduced with a 6-4-0 fasting regime, although this remains to be shown in future studies. For practical purposes, the 6-4-2 regime is in reality only possible to apply to the first patients of the morning lists, as subsequent cases can only be given an approximate time point for when to stop drinking clear fluids. In contrast, when the child is allowed to drink right up until he or she is called to the operating room, the estimated time for induction does not have to be set in advance to communicate to ward staff and parents when the absolute fasting period must begin. When changes in the surgical schedule do occur, it is even more important to allow the child to drink clear liquids. Furthermore, when children are permitted to drink clear fluids freely, we feel that it is easier to be rigid in enforcing strict rules for other food and drink, especially solid food (the aspiration of which may lead to serious morbidity and mortality). In our current practice, we actually enforce strict fasting from solid foods from midnight. For instance, we have cancelled the odd teenager who happily admitted staying up until two in the morning to prepare for fasting by consuming a teenage-sized hamburger with fries. In spite of the latter case, we believe that compliance to these rules may increase when children and their parents are given something in return, *i.e.* to be able to drink clear fluids while fasting for food.

Limitations

Although the existing recommendations in our hospital have been available for over a decade one cannot assume that they are strictly adhered to by patients and ward staff. Compliance to the applied fasting routines could not be measured in our study. Some children will inevitably have fasted for two hours or more for various reasons as indicated by a preliminary survey in our own recovery room showing that many of the children still starve longer times than recommended. In this small subgroup of 52 patients, we found that children allowed free clear fluids fasted 1.7 hours in average, compared to 6.2 hours in a few children incorrectly instructed to fast for at least two hours. These results are not significant, but in concordance with previous studies (24).There is a need for repeated educational programs for ward staff on current fasting routines and it is important that ward staff and anesthesia services convey the same information to patients and parents, in order to avoid prolonged fasting, regardless of which fasting regime is implemented.

Another limitation of the present study is the difficulty to accurately diagnose aspiration retrospectively. Most aspirations occurring during general anesthesia are silent aspirations with neither symptoms nor sequelae (25). This makes the incidence of perioperative pulmonary aspiration difficult to measure even in prospective studies. Furthermore, it may occasionally be difficult to distinguish symptoms due to aspiration from *e.g.* coughing and bucking that have other causes.

Pulmonary aspiration is fortunately a rare event in modern anesthesia practice. We performed a power analysis that yielded at least 60 000 subjects to prove equal risks between different fasting routines, although we had sufficient power to be able to detect increased risk in the present study. To detect an increase in incidence from 0.04 % to 0.09 %, with a 5 % significance level and 80 % power, a sample size of 9 100 patients was required. Moreover, comparing our findings to others has inherent difficulties. Although we used the similar definitions of pulmonary aspiration as Walker (13) and Warner (10), we could still identify three cases from Walker's study that we may have classified as suspected pulmonary aspiration, *i.e.* case 4, 15 and 19 (13). Not only do we use slightly different definitions of pulmonary aspiration, but except for the recent study by Walker (13), the former studies were published from ten up to almost 30 years ago (8-12), with the risk of changing practice influencing the results. For instance, in the last decades the laryngeal mask airway is commonly used

instead of either mask ventilation or endotracheal intubation for a majority of procedures. There are other factors than fasting time that are likely to have an impact on the risk of pulmonary aspiration, such as induction method, airway management technique and level of experience of the providing anesthetist. The influence of these factors could not be ascertained in the present study due to lack of power.

Finally, the present study was performed in a single institution, in an operating room (OR) setting with trained pediatric anesthesiologists and nurse anesthetists always present. Patients that regurgitated or vomited gastric fluid were immediately suctioned, usually after being turned to the lateral position to minimize the risk of aspiration. The results cannot be extrapolated to a non-OR setting, i.e. for sedation in the radiology suite or in the emergency room. In addition, the term 6-4-0 fasting regime may be slightly misleading, since anesthesia induction in our department usually occurs at least 30 minutes after the child is called to the operating room. With this practice, only a negligible amount of fluid is actually ingested during the last half-hour before induction. Furthermore the children are allowed to drink clear fluids freely, but not encouraged to drink excessive amounts without being thirsty. Other departments that would like to consider implementing a 6-4-0 fasting regime must take this into account when interpreting our results, and in how the regime is implemented and communicated to patients, parents and ward staff.

Future perspectives

The lack of observed clinically significant morbidity in the present study and the many advantages associated with avoiding dehydration prior to anesthesia suggests a need for further studies to corroborate our findings in a large prospective trial, and to investigate the distribution of real fasting times and gastric fluid content with very short fasting regimes and the association of dehydration and metabolic derangements with long vs short fasting times.

Conclusion

Allowing children to drink fluids freely until called to the operating room did not result in an increased risk of pulmonary aspiration in this single-center retrospective analysis. We found no mortality, and the

morbidity was even less than in earlier studies, which suggests that there may be reasons to question the commonly adopted rule of at least two hours of fasting for clear fluids prior to anesthesia.

Disclosures

1. ETHICS – Ethical approval was obtained by the local ethics committee in Uppsala 2013-12-04, registration number 2013/450.

2. FUNDINGS – The study was funded by departmental resources.

3. DISCLOSURES – There are no conflicts of interests known to the authors.

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Table 1. Characteristics of patients included in the study.

Characteristic	n	%
Age		
< 1 yr	822	8
1-5 yr	4314	43
6-12 yr	2932	29
13-16 yr	1947	19
ASA physical status score		
I	5851	58
II	3016	30
III	734	7
IV	23	0
Unknown	392	4
Induction method		
Intravenous	8707	87
Inhalation	1288	13
Unknown	20	0
Airway management		
Laryngeal mask	5449	54
Intubation	3823	38
Other*	723	7
Unknown	20	0

*Other methods of airway management are *e.g.* spontaneous breathing *via* mask, nasal canula or tracheostoma.

Table 2. Description of aspiration events showing patients characteristics, airway management technique, postoperative symptoms and radiological findings. All three patients were intubated for the procedure and subsequently treated with antibiotics but no one needed postoperative ventilatory support or intensive care. All symptoms had diminished the day after surgery without sequelae.

Event	Age	ASA class	Time of event	Airway management	Symptoms at event	Postoperative symptoms	Radiological examination	Prolonged stay in hospital (y/n)	Type of surgery
2	16	2	Maintenance	laryngeal mask	none	Chest pain, subdued breathing, desaturation to 91-92 %	Findings consistent with aspiration	n	Gastroscopy & colonoscopy
6	6	2	Induction		Desaturates to 85 %, rales and rhonchi	none	Findings consistent with aspiration	y	Urological
14	5	1	Induction	laryngeal mask	none	Fever and rales	Findings consistent with aspiration	y	Urological

Table 3. Description of suspected aspirational events showing patients characteristics, airway management technique and symptoms at event. None of these patients showed postoperative symptoms from the respiratory system or radiological findings. All events occurring during induction resulted in subsequent intubation.

Event	Age	ASA class	Time of event	Airway management	Symptoms at event	Prolonged stay in hospital (y/n)	Type of surgery
1	8	2	Maintenance	laryngeal mask	Desaturates to 80 %, crackles	n	Gastroskopi
3	2	3	Induction			n	hematological
4	3	2	Maintenance	laryngeal mask	Desaturates to 80 %, obstructive	n	Hematological
5	3	2	Induction		Rales	n	Orthopedic
7	9	1	Maintenance	intubated	Red fluid in the tube, rales.	n	Urological
8	1	1	Induction		Desaturates to 71 %, rales	n	Urological
9	2	2	Maintenance	intubated	Rales	n	Urological
10	3	2	Extubation	intubated	Rales	n	Gastroscopy
11	4	2	Induction	laryngeal mask	Desaturation and bilateral rales	n	Hematological
12	1	2	Maintenance	intubated	Rales	n	Gastroscopy &colonoscopy
13	3	3	Induction	laryngeal mask	Somerales, Sat 92-99 %	n	Hematological
15	12	1	Maintenance	laryngeal mask	Desaturates, rales	y	Urological
16	1	1	Induction		Desaturates to 60 %, rales dx	n	Urological
17	11	1	Maintenance	laryngeal mask	Desaturates to 75 %.	n	gastroscopy

Table 4. Incidence of pediatric pulmonary aspiration and complications after aspiration. Summary of five studies of pediatric pulmonary aspiration associated with general anesthesia performed the past decades. NR = not reported.

Authors	Time period	Study design	Study size	Aspirational events(incidence)	Need for ventilation support
Olsson 1986(11)	1967-1970, 1975-1983	Retrospective	NR	34 (0.06-0.09 %)	NR
Tiret 1988(12)	1978-1982	Prospective	40 240	4 (0.01 %)	NR
Borland 1998(9)	1988-1993	Retrospective	50 880	52 (0.10 %)	4 (7.7 %)
Warner 1999(10)	1985-1997	Prospective	56 138	24 (0.04 %)	6 (25 %)
Murat 2004(8)	2000-2002	Prospective	24 165	10 (0.04 %)	NR
Walker (2013)(13)	2010-2011	Prospective	118 371	24 (0,02 %)	5 (20.8 %)
Present study	2008-2013	Retrospective	10 015	3 (0.03 %)	0 (0 %)