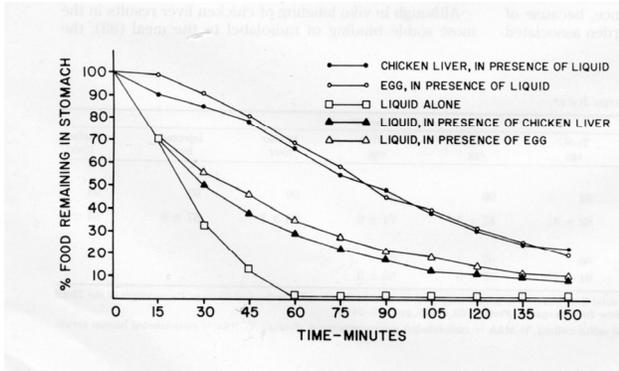


With the recent explosion of healthcare costs, feasibility, effectiveness, indications for use, and improved outcome with decreased cost have become the focus of our health care system. In turn, physicians are being asked to adjust their practice from that based on beliefs and anecdotal experiences to that based on evidence (i.e. *evidence-based medicine*). In this next lecture, we will approach some common clinical dilemmas in pediatric anesthesia using these principals.

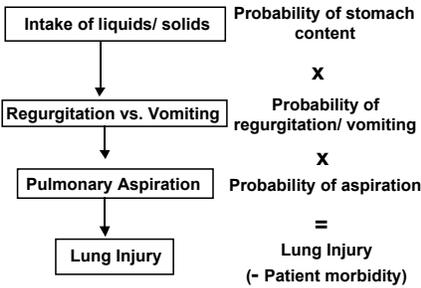
### Preoperative Fasting Guidelines

The issue of preoperative fasting is quite controversial and was the subject of practice guidelines published in 1999 by the American Society of Anesthesiology (1). The guidelines indicate that the minimal fasting period for clear liquids is 2 hours, breast milk is 4 hours, non-human milk is 6 hours, infant formula is 6 hours, light meal is 6 hours and solids is 8 hours. When one examines this issue the first question may arise is why do we need preoperative fasting guidelines? The answer seems straightforward. Appropriate fasting guidelines will decrease the gastric fluid volume, which in return will decrease the incidence of pulmonary aspiration. How much acid aspirate is needed to cause damage to the lungs? For years we have been believed that the “magic number” is 0.4 ml/kg. This



number was based on a study published by Roberts and Shirley in 1974 (2). Of particular interest is that the published study did *not* support 0.4 ml/kg and this number was only mentioned in the introduction under “our preliminary work in the rhesus monkey suggests that 0.4 ml/kg is the maximum acid aspirate that does not produce significant changes in the lungs”. In a more recent investigation that was conducted by Raidoo et al. and involved a primate model it was found that the maximal acid aspirate that will not cause damage to the lungs is 0.8 ml/kg (3). A review of NPO pediatric perioperative studies reveals that the residual gastric fluid volume (GFV) in children following two hours of

clear liquids prior to surgery ranges from 0.24±0.31 ml/kg to 0.66±0.79 ml/kg (4-5). Based on these data as well as Raidoo’s data it seems that 15-30% of patients would be at risk and thus the incidence of pulmonary aspiration would be quite high. All studies have indicated, however, that the incidence of pulmonary aspiration under general anesthesia is quite low in infants and children. A recent study by Warner et al. has reported that following 63,180



anesthetics there have been only 8 cases of pulmonary aspiration that required respiratory support or mechanical ventilation for more than 48 hours (6). Further more, Warner et al. reports that all children that needed respiratory support or mechanical ventilation had significant systemic illness such as bowel obstruction and bowel ischemia. Thus, since GFV>0.8ml/kg are common and pulmonary aspiration is not, it is likely that other factors and co-morbidities are involved in this process. Schreiner et al has addressed this issue in a recent editorial and advocated that gastric fluid volume is not really a risk factor for pulmonary aspiration but rather a surrogate marker (7). That is, GFV is easy to

measure but it has no clinical significance as an isolated indicator.

Let us than review the data that exists in the literature and explains the findings to date. As can be seen from the figure above, in order for lung injury to occur there has to be intake of liquids or solids. Next there has to be an act of active vomiting or passive regurgitation followed by aspiration and lung injury. In order to calculate the incidence of lung injury we need to multiply the probability of stomach content X the probability of vomiting or regurgitation X the probability of aspiration X the probability that lung injury will indeed occur and lead to patient morbidity. Lets examine this path. First, what is the likelihood of a patient having clear liquids or solids in their stomach? The answer obviously depends on the time the patient ate last. Please refer to the below graph that illustrates GFV as a function of time. As can be seen, water are being absorbed very quickly with minimal water remaining in the stomach at 60 minutes. This illustration, which is based on radionucleotide studies, is supported by the perioperative clinical studies that indicate minimal GFV at 2 hours following water intake. The data of the perioperative studies is less clear when formula, breast milk or rice cereal is discussed. This issue will be addressed

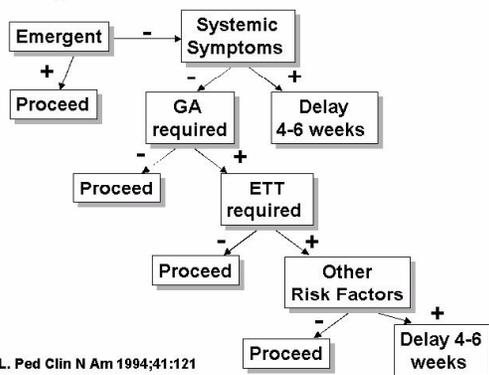
during the lecture. Also, Sethi et al. has recently reported the results of an ultrasonographic study that demonstrated that the traditional NPO times might be unnecessary long; this study will also be addressed during the lecture (8). Unlike Clear liquids, the illustration demonstrates that gastric emptying of solids is more involved and is dependent on a number of factors. Overall, one can conclude based on available data that it takes at least 8 hours to evacuate a full heavy dinner (1692 Kcal) and about 4-6 hours for light meal. Next, we need to address the likelihood of active vomiting or passive regurgitation to occur. There is paucity of data in the literature with regard to this issue. Plourde and Hardy have addressed the issue of passive regurgitation in a cat model (9) The investigators found that gastric volume required to produce regurgitation in cats under general anesthesia is  $20.8 \pm 7.8$  ml/kg and the range is 8-41 ml/kg. These volumes are obviously quite higher than the 0.8 ml/kg of gastric aspirate that is needed to cause lung damage. Next, a patient needs to actually aspirate the stomach content that was vomited or regurgitated. There are no data in the literature with regard to the likelihood of this event to occur. Finally, even if the patient aspirated that does not mean that significant morbidity will develop. Please refer to the study by Warner et al that we reviewed earlier (6). Based, on all the data above it seems that some of the ASA recommendations can be questioned. Specifically, clear liquids (1 hour?), breast milk (3 hours?), non-human milk (3 hours?) and infant formula (4 hours ?). There are no data to indicate that the NPO period for light meal or full meal should be challenged. More data are required before final determination can be made.

### Upper Respiratory Infections:

Currently, the most common reason for cancellation of surgery in children, which is not preventable, is upper respiratory illness (URI). Cohen et al., in a prospective, case-controlled study involving over 20,000 anesthetics, found that the incidence of respiratory complications increased two to seven-fold, and increased eleven-fold if endotracheal intubation was performed in children with URI (10). The investigators also found that the incidence of respiratory complications was correlated with patient age; children 1 to 5 years had an intermediate risk, while those older than 5 had significantly less risk. In fact, if one reviews all the available literature, one concludes that there are good data to suggest that the incidence of minor complications, such as mild oxygen desaturation as well as more potentially serious complications such as bronchospasm, laryngospasm, and respiratory failure, may increase in children who either have URI's or who have recently recovered from one (11-15). One should note, however, that a significant number of studies had methodological limitations, including small sample size, no good definition of a URI and retrospective data. A recent study by Tait et al. aimed to overcome many of these problems (16). Tait et al studied over 1000 children who were scheduled to undergo general anesthesia and elective surgery (16). The investigators found that children with active or recent URI had significantly more episodes of breath holding, desaturation episodes (<90%), and a greater incidence of overall adverse respiratory episodes. The investigators reported that risk factors for development of respiratory complications include endotracheal intubation, history of prematurity, surgical procedure involving the airway, reactive airway disease and nasal congestion. As in previous studies, none of the complications was associated with any long-term adverse sequel.

Given the complications that may develop, why not to cancel all cases involving URI? The average child gets 6-7 URI's per year and each URI lasts about 7 to 10 days. Further, there is evidence to suggest that airway reactivity is

#### URI Algorithm



Martin L. *Ped Clin N Am* 1994;41:121

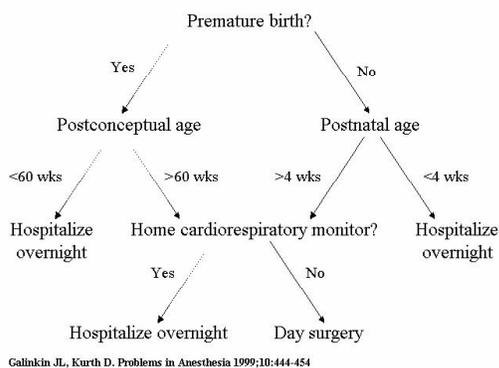
has suggested the above algorithm to help in the decision process (18). Clearly, some groups of patients are clearly at increased risk. These include children with asthma, especially those who symptoms are exacerbated by upper respiratory infections, children with bronchopulmonary dysphasia, Children with a history of prematurity, children

increased for at least 7 weeks after a URI. That is, of the 52 weeks per year only about 9 weeks may be left in which the average does not have a URI episode or after a URI episode. This does not leave a lot of room for cancellation and rescheduling. Moreover, a child is quite likely to be developing another URI by the time that waiting period is over! If we do not cancel all cases involving URI, should we cancel all cases of a 'serious URI'? But how do define a serious URI? One should realize that there are no good laboratory tests that can be used to decide whether to postpone surgery or not. Baker has suggested that if a child has 2 of the following criteria the case should be delayed: sore throat; sneezing; rhinorrhea and congestion; nonproductive cough; temp > 101<sup>0</sup>F; laryngitis & malaise (17). Martin et al.

under one year of age, children with sickle cell disease, and children who are to undergo surgery involving the airway. Patients in these categories should be carefully assessed and strong consideration should be given to postponing elective surgery. We may need to be less conservative, however, with children who are about to undergo procedures such as PE tube placement or T&A. These procedures are therapeutics and may have a direct impact on the patient's respiratory well being.

### The Former Premature Infant: Postoperative Apnea

General anesthetics and sedative hypnotics all can depress ventilatory drive and cause central apnea in infants less than 56 weeks postconceptual age (19-21). With improved medical technology, the gestational age at which premature infants are saved has lowered significantly, and while in the past only tertiary care centers were providing services for these patients, today these children may present to community hospitals. The former premature infant has an increased risk for complications, including anemia, bronchopulmonary dysplasia and postoperative apnea. The issue of postoperative apnea after general anesthesia is of particular importance as a significant number of patients are today being treated as outpatients. The incidence of this phenomenon in the PACU is unclear, but is thought to range between 0 and 32% (32-34). The reason for this variation is related to a lack of a uniform definition of "apnea". While some studies define apnea as a lack of turbulent airflow under the nostrils, other studies define it as no breathing movements for a period of over 30 seconds (19-21). This raises the very interesting issue of "surrogate outcomes". A surrogate outcome is defined as an outcome that is easily



measured but is *not* relevant to clinical practice and the overall well being of the patient. In this case, is the air flow under the patient's nostrils relevant to our clinical practice? Perhaps not. What may be relevant is a period of apnea that results in a significant morbidity ('real outcome'). The challenge is, of course, to conduct clinical trials that will measure real outcomes without scarifying patient safety. At what postconceptual age is the child no longer at risk to develop this phenomenon? The answer varies based on the data examined and it ranges from 48 to 60 weeks postconceptual age. Children who are at risk to develop postoperative apnea *must* be admitted to the hospital for a period of 24 hours after anesthesia for cardiorespiratory monitoring. Please refer to the algorithm below as an

operational guide. It should be noted, however, that the 60 weeks mark is somewhat conservative and that some anesthesiologists would replace it with 48 or 52 weeks. The question of when to perform semi-elective surgery, such as inguinal herniorrhaphy, in premature infants is controversial. Although inguinal herniorrhaphy may be considered an elective procedure, there is an increased risk of incarceration in these patients, making this not a purely elective procedure. One therefore must frequently proceed in these cases and accept the risk of postoperative apnea. Purely elective surgery, however, is best postponed until the child reaches at least 52-60 weeks postconceptual age. We have to realize that this entire topic is quite controversial and is under much debate. More with regard to this will be presented in the lecture.

### Parental Presence During Induction of Anesthesia

Potential benefits from parental presence during induction of anesthesia include reducing the need for preoperative sedatives such as midazolam and avoiding the anxiety that occurs upon separation to the OR. Other benefits may include increasing child's compliance and increased parental satisfaction. Objections to parental presence during induction of anesthesia include concern about disruption of the operating room routine, crowded operating rooms, and possible adverse reactions of parents. Other objections include prolonged anesthetic induction, and additional stress on the anesthesiologist especially should a complication develop.

Although early studies suggested reduced anxiety if parents were present during induction (22), *all* recent randomized controlled trials indicate that routine parental presence is *not* beneficial (23-25). When data of survey studies are reviewed, it is noticed that most anesthesiologists use *either* parental presence or sedative premedication to treat preoperative anxiety. When sedative premedication were directly compared to parental presence, however, it was found that children receiving oral midazolam are significantly less anxious and more compliant during the induction process. A recent study examined whether a combination of parental presence *and* oral midazolam is more effective than oral midazolam alone parental presence. The investigators found that parental presence has *no*

additive anxiolytic effects for children who received oral midazolam preoperatively. Parents who accompany their sedated children into the operating rooms, however, are significantly less anxious and more satisfied both with the separation process and with the *overall* anesthetic, nursing and surgical care provided.

When interpreting the results of these studies, however, it should be noted that the design of a randomized controlled study, does *not* reflect the practice of *all* anesthesiologists. That is, we hypothesize that while a RCT is applicable to centers that offer parental presence for *all* parents, it may not be applicable to centers that consider each request for parental presence based on personality characteristics of each child and parent. Such centers may have different results with parental presence during induction of anesthesia than were demonstrated in RCT's. Research interests should shift towards an emphasis on *what parents actually do* during induction of anesthesia, rather than simply on their presence. Some parental behaviors, such as criticism and commands, reassurance with empathic statements, apologizing, and bargaining are associated with greater distress. In contrast, parental behaviors such as distraction methods (humor, toys, party blowers etc.) and commands to engage in active coping are associated with decreased child's anxiety in the psychological and pain literature (26). Recently, we have developed such an instructional program at our institution and we are currently looking into the effectiveness of the program. In conclusion, allowing a parent into an operating room without significant preparation may be counterproductive and some process control has to be implemented.

Finally, parental presence during induction of anesthesia is also associated with important legal implications. Lewyn described a case in which a mother was invited to accompany her son into an emergency treatment room (27). According to the court, the mother fainted and suffered an injury to the head. In its verdict the Illinois Supreme court stated that a hospital which *allows* a non-patient to accompany a patient during treatment does not have a duty to protect the non-patient from fainting. However, if medical personnel *invite* the non-patient to participate in the treatment than the hospital has a legal responsibility toward the non-patient. Interestingly, some hospitals in the United States now require the parents to sign a written informed consent acknowledging the risk of being present during induction of anesthesia.

## References

1. Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures: A Report by the American Society of Anesthesiologists Task Force on Preoperative Fasting . *Anesthesiology* 1999;90:896-905.
2. Roberts R, Shirley M. Reducing the risk of acid aspiration during cesarean section. *Anesth Analg* 1979;53:859-868.
3. Raidoo DM, Marszalek A, Brock-Utne JG. Acid aspiration in primates. *Anaesth Intensive Care* 1988;16:375-76.
4. Schreiner MS. Preoperative and postoperative fasting in children. *Peds Clinic of North America* 1994;41:110-121.
5. Schwartz DA, Connelly NR et al. Gastric Contents in Children presenting for upper endoscopy. *Anesth Analg* 1998;757-60.
6. Warner M, Warner M, Warner D et al. Preoperative pulmonary aspiration in infants and children. *Anesthesiology* 1999;90:66-71.
7. Schreiner M. Gastric fluid volume: Is it really a risk factor for pulmonary aspiration? *Anesth Analg* 1998;87:754-6.
8. Sethi AK, Chatterji C, Bhargava SK, Narang P. Safe pre-operative fasting times after milk or clear fluid in children. *Anaesthesia* 1999; 54: 51-59.
9. Plourde G, Hardy JF. Aspiration pneumonia: assessing the risk of regurgitation in the cat. *Can Anaesth Soc J*. 1986;33:345-8.
10. Cohen MM, Cameron CB. Should you cancel the operation when a child has an upper respiratory tract infection? *Anesth Analg* 1991;72:282-288.
11. Rolf N, Cote CJ. Frequency and severity of desaturation events during general anesthesia in children with and without upper respiratory infections. *J Clin Anesth* 1992;4:200-203.

12. Schreiner MS, O'Hara I, Markakis DA, Politis GD. Do children who experience laryngospasm have an increased risk of upper respiratory infections? *J Clin Anesth* 1996;85:475-480.
13. Tait AR, Knight PR. Intraoperative respiratory complications in patients with upper respiratory tract infections. *Can J Anesth* 1987;34:300-303.
14. Tait AR, Reynolds PI, Gustein HB. Factors that influence an anesthesiologist's decision to cancel elective surgery for the child with an upper respiratory tract infection. *J Clin Anesth* 1995;7:491-499.
15. Levy L, Pandit UA, Randel GI, Lewis IH, Tait AR. Upper respiratory tract infections and general anaesthesia in children. Peri-operative complications and oxygen saturation. *Anaesthesia* 1992;47:678-682.
16. Tait AR, Malviya S, Voepel-Lewis T et al. Risk Factors for perioperative adverse respiratory events in children with upper respiratory infections. *Anesthesiology* 2001;95:299-306.
17. Baker SB. Upper Respiratory Infection in Children. *Semin Anesth* 1992;41:121-123.
18. Martin LD. Anesthetic implications of an upper respiratory infection in children. *Pediatr Clin No Am* 1994;41:121-30.
19. Cote CJ, Zaslavsky A, Downes JJ, Kurth CD, Welborn LG, Warner LO, Malviya SV. Postoperative apnea in former preterm infants after inguinal herniorrhaphy. A combined analysis. *Anesthesiology* 1995;82:809-822.
20. Kurth CD, Spitzer AR, Broennle AM, Downes JJ. Postoperative apnea in preterm infants. *Anesthesiology* 1987;66:483-488.
21. Welborn LG, Ramirez N, Oh TH, Ruttimann UE, Fink R, Guzzetta P, Epstein BS. Postanesthetic apnea and periodic breathing in infants. *Anesthesiology* 1986;65:658-661.
22. Hannallah RS, Rosales JK. Experience with parents' presence during anaesthesia induction in children. *Can Anaesth Soc J* 1983;30:286-9.
23. Kain ZN, Mayes LC, Caramico LA, Silver D, Spieker M, Nygren MM, et al. Parental presence during induction of anesthesia. A randomized controlled trial. *Anesthesiology* 1996;84:1060-7.
24. Kain Z, Mayes L, Wang S, Krivutza D, Hofstadter M. Parental Presence and a Sedative Premedicant for Children Undergoing Surgery: A Hierarchical Study. *Anesthesiology* 2000;92:939-946.
25. McCann M, ZN. K. Management of Preoperative Anxiety in Children: An Update. *Anes Analg* 2001;93:98-105.
26. Blount R, Bachanas P, Powers S. Training children to cope and parents to coach them during routine immunizations: Effects on child, parent, and staff behaviors. *Behav Ther* 1992;23:689-705.
27. Lewyn MJ. Should parents be present while their children receive anesthesia? *Anesth Malpract Protect* 1993;May:56-57.