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IAPA NEWSLETTER

by Indian Association of Paediatric Anaesthesiologists
August 2017

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EDITORIAL

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The FDA warning on anesthetic and sedative agents in children and pregnant patients…. how should we react to it?

In December 2016, the Food and Drug Administration (FDA) of USA, issued a warning for the administering of general anesthetic and sedation drugs in children aged less than 3 years and in pregnant women in the third trimester.[1] It states, that 'exposure to these medicines for lengthy periods of time or over multiple surgeries may negatively affect brain development'. It also recommends that labels of general anesthetic and sedation drugs listed in the alert, should have this warning printed on them. The FDA alert, quotes studies conducted in pregnant and young animals exposed to general anesthetic and sedation drugs for more than 3 hours, which caused widespread nerve cells loss in the developing brain. Other animal studies have suggested that these changes result in long-term abnormal behaviour or learning disability.[2,3,4] The drugs listed in the FDA warning include: desflurane, etomidate, halothane, isoflurane, sevoflurane, etomidate, pentobarbitone, propofol, ketamine, methohexital, midazolam and lorazepam.

Subsequently in April 2017, the FDA amended its earlier statement by emphasizing that 'General anesthetic and sedation drugs are necessary for patients, including young children and pregnant women, who require surgery or other painful and stressful procedures. In the United States of America, surgeries during the third trimester of pregnancy requiring general anesthesia are performed only when medically necessary and rarely last longer than 3 hours. We are advising that in these situations, pregnant women should not delay or avoid surgeries or procedures during pregnancy, as doing so can negatively affect themselves and their infants. Similarly, surgeries or procedures in children younger than 3 years should not be delayed or avoided when medically necessary. Consideration should be given to delaying potentially elective surgery in young children where medically appropriate'. [4]

There are several multicentred, international trials in progress attempting to address this critical issue. The 'Pediatric Anesthesia and Neurodevelopment Assessment '(PANDA) interim study results have found no evidence for association between exposure to anaesthesia and outcomes in psychometric assessments.[5] The initial reports of 'The General Anesthesia vs. Spinal Anesthesia' (GAS) trial has shown no difference in immediate outcomes between general or awake-regional anesthesia in children. The long-term results of both these studies are awaited.[6] The Mayo Anesthesia Safety in Kids (MASK) study is in progress, to compare children exposed to a single anesthetic with children not exposed to anesthesia.[7] Neurodevelopmental outcomes of young children who are subjected to multiple anesthetic exposures will also be evaluated in the MASK study, expected to be released in 2017.[8] The Recognition Memory Study, which evaluates prolonged anesthesia in young children is expected in a few years. Unfortunately, there is no data available which can assess the association between anesthetic exposure to human foetuses in utero with postnatal neurodevelopmental delay.[9]

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Anesthesiologists have been on the alert since the publication of the animal studies in the 1990s. However, the December 2016 FDA alert to the public at large, has been received by individual anesthesiologists, obstetricians, paediatricians, physicians and professional medical societies, in the US and the rest of the world, with a sense of shock. It is true, that there needs to be an awareness amongst the public at large, but without enough clinical scientific evidence in humans, this alert is likely to create a panic reaction. The American College of Obstetrics and Gynecology (ACOG), believes the clinical significance of these findings are unknown and could inappropriately dissuade clinicians from providing women with necessary care during pregnancy.[10] Two editorials have been published more recently in the New England Journal of Medicine and in the journal Pediatric Anesthesia.[11,12]

There are several issues that these editorials raise. This topic has been a concern since the initial animal studies published in the late 1990s. The FDA statement is based on inadequate clinical evidence, the only human clinical studies available being weak and not confirmatory. The 3-year age cut off and the evidence of multiple vs single exposure is inadequate in animal studies and human studies. Parents of children, pregnant women along with the lay public are likely to only read the title of the FDA alert and not the statement that there are 'limitations of our knowledge and the weak nature of the evidence'.

The practical and difficult issue at hand is, how do we deal with this alert in our daily practice? Given the global impact of information technology, we have to be prepared for the repercussions of this FDA in India as well. How should anesthesiologists and surgeons respond especially since millions of children are involved? When questioned, and when surgery cannot be postponed, how do we discuss with the families of a child younger than 3 years of age, or if the child is likely to require multiple or prolonged surgeries and anesthetic exposures?

Physicians, surgeons and hospital administrations need to discuss this matter and prepare a coordinated response, with the aim of putting this warning in perspective. That these studies demonstrate no developmental problems in children exposed to a single, short anesthetic or sedation is documented. There is no alternative to providing anesthesia. Most surgical procedures performed in small children are clearly indicated and cannot be delayed. What is worrisome is that the fear of neurological complications of anesthesia, may result in postponement or delay in necessary procedures, resulting in a marked increase in morbidity and mortality. Our main role as anesthesiologists is to continue to help parents, pregnant women and families make their decision and consent for anesthesia by discussing the benefits and risks involved if surgery is to be postponed.

Until results of studies in progress are published, we will have to try and quell untoward anxiety. Concerted efforts need to be made by our professionals across the globe to study and follow up effects of anesthetics on foetuses and small children. Our response to the FDA warning depends on how we interpret it.

QUIZ ANSWERS from Pg 3

Q1 **Ans. C** - The use of nitrous oxide for minimal sedation is defined as the administration of nitrous oxide 50% or less with the balance as oxygen without any other sedative, narcotic or other depressant drug.

Q2 **Ans. C** - There is no difference in the tidal volume, but neonates have increased oxygen consumption, to compensate for this, the alveolar ventilation is increased and there is an increase in respiratory rate to balance it.

Q3 **Ans. D** - Even during CPB, hypoglycemia is common in children, due to low glycogen reserves while hyperglycemia is frequent in adults.

Q4 **Ans. B** - Wilm's tumor is common malignancy in children, presenting with abdominal mass. The treatment includes surgery, chemotherapy and radiotherapy. The chemotherapeutic agents commonly used – cyclophosphamide and Adriamycin. Both can cause thrombocytopenia, cardiac toxicity and cyclophosphamide can cause inhibition of plasma cholinesterase. However, pulmonary fibrosis is not seen.

Q5 **Ans. D** - According to AHA updated guidelines in 2015, the maximum dose for defibrillation should not exceed 10 J/Kg or adult maximum dose.

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QUIZ SECTION

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1. According to AAP Guidelines on monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures introduced in 2016, the use of nitrous oxide for minimal sedation is defined as administration of

a) Nitrous oxide > 20% but < 50% with oxygen and narcotic
b) Nitrous oxide > 20% but < 50% without oxygen and narcotic
c) Nitrous Oxide < 50% with oxygen
d) Nitrous oxide > 50% with oxygen

2. Which of the following respiratory indices in increased in newborn in comparison to adults?

a) TV (mL/kg)
b) pH
c) Alveolar ventilation (mL/kg/min)
d) None of the above

3. During CPB, about the, glucose regulation among adults and pediatrics, the correct statement is

a) Hyperglycemia is common in children, hypoglycemia in adults
b) Hyperglycemia is common in both
c) Hypoglycemia is common in both
d) Hypoglycemia is common in children, hyperglycemia in adults

4. A 3yr old child of Wilm's tumor post surgery, post chemotherapy consisting of adriamycin and cyclophosphamide is scheduled for non – oncologic surgery under general anesthesia, anaesthetic concerns include all except -

a) Cardiac depression
b) Pulmonary fibrosis
c) Inhibition of plasma cholinesterase
d) Thrombocytopenia

5. According to AHA 2015 updated guidelines on pediatric ACLS, maximum dose of energy that can be used during defibrillation is

a) 2 J/Kg
b) 6 J/Kg
c) 8 J/Kg
d) 10 J/Kg

(Answers on page 2)

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CASE REPORT

Inadvertent massive overdose of lignocaine in an infant with arthrogryposis multiplex congenita successfully treated with lipid emulsion

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Introduction: Intravenous lipid emulsion (IVLE) has remarkable success and safety record in local anaesthetic systemic toxicity (LAST).1 However, there is paucity in the literature of its application and safety in infants. Moreover, use of 10% IVLE in LAST has not been documented.

Case report: A 3 month old male weighing 3.9 kg, diagnosed as Arthrogryposis multiplex congenita was posted for femoral shortening and soft tissue alignment surgery. Child had upper respiratory tract infection which had been treated 2 weeks ago. Preoperative investigations were within normal limits. After preoxygenation, induction was done using sevoflurane (5-8%) in 100% oxygen. The child had anticipated difficult airway due to retrognathia and high arched palate, so his trachea was intubated with a Truview EVO2® video laryngoscope. At the end of uneventful surgery, following reversal of neuromuscular blockade with neostigmine and glycopyrrolate, the child developed inspiratory stridor and paradoxical movement of chest and abdomen. Positive pressure ventilation, jaw thrust and inj. propofol 4 mg administered for possible laryngospasm, partially relieved the symptoms. At the same time, 6 mg preservative free lignocaine (Xylocard TM) was administered intravenously by a trainee. Suddenly the baby became unresponsive and hemodynamically unstable. Heart rate decreased from 180 bpm to 124 bpm and blood pressure decreased from 67/44 mmHg to 41/18 mmHg respectively, with a wide complex rhythm and the baby had focal seizures. Bag-mask ventilation was continued; Ringer's lactate bolus of 50 ml and intravenous midazolam 0.2 mg were also administered. The child transiently improved but soon started having generalized tonic clonic seizure. Retrospectively, it was revealed that 6 ml of Lignocaine (120 mg) had been injected instead of 6 mg. 10% IVLE (Fresenius Kabi AB, Uppsala, Sweden) was administered in the dose of 3 ml/kg (12 ml) slowly over 2 - 3 minutes. Within seconds of completion of its injection, seizures subsided and patient became hemodynamically stable. Considering the baby was still lethargic and had low muscular tone, a second bolus of 10 ml of 10% IVLE was repeated, followed by infusion at 1 ml/min for 2 hours. He was intubated and shifted to ICU for overnight ventilation with midazolam sedation. There was no recurrence of seizure in ICU, his vitals remained stable and was extubated next morning. He was discharged 3 days later after confirming normal biochemistry profile (including serum amylase and triglyceride).

Discussion: The present report describes use of 10% IVLE to treat life threatening lignocaine over dosage in an infant. IVLE has been reported for resuscitating patients with amide local anaesthetic (LA) toxicities.[1] The LAs being lipid soluble, are taken up into IVLE (lipid sink), reducing their concentration in aqueous phase, decreasing their unbound fraction and reducing toxicity.[2] Most case reports of LA toxicity are reported in regional blocks and 20% IVLE has been used as antidote. Infants have increased vulnerability to toxicity with lignocaine due to prolonged elimination half-life, increased volume of distribution and reduced serum binding proteins. IVLE has been shown to reduce serum lidocaine levels from toxic levels of 7.6 mcg/ml to therapeutic levels of 3 mcg/ml and treat its systemic toxicity.[3,4] IVLE may not be effective when hypoxia, acidosis and electrolyte abnormalities set in, after ongoing resuscitative measures have failed. So there has been a recent trend of early use of IVLE during suspected LAST.[5] In the patient with suspected LA toxicity, the initial step is stabilization of potential threats to life. If the signs and symptoms develop during administration of the LA, stop the injection immediately and prepare to treat the reaction. Ensure adequate oxygenation, whether by face mask or by intubation. Attention to impending airway compromise, significant hypotension, dysrhythmias, and seizures takes precedence.

Accidental high dose of intravenous LA, lead to recurrent seizure and imminent danger of cardiovascular collapse. Increasing evidence suggests that the IVLE can reverse the cardiac and neurologic effects of LA toxicity. Case reports support the early use of lipid emulsion at the first sign of arrhythmia, prolonged seizure activity, or rapid progression of toxic manifestations in patients with suspected local anaesthetic toxicity.[1] Since 20% IVLE was not

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available, we used 3 ml/kg of 10% IVLE (instead of 1.5 ml/kg of 20%) within 5-7 minutes of the injection of lignocaine. Infusion was continued to maintain LA levels below critical levels so as to avoid recurrence of toxicity. We presume that IVLE injection brought the plasma levels of lignocaine below the toxic range and led to immediate improvement in the clinical picture. We did not have the facility to objectively demonstrate any fall in lignocaine levels after IVLE but drawing analogy from a previous case report, the favourable outcome in case of our patient was presumably due to IVLE.4 In our case we had used 142 ml of 10% IVLE which is well below the maximum recommended dose (40 ml/kg over 24 hours, 160 ml for our patient) as mentioned in its package insert. Laboratory testing and one-week follow-up of the child did not reveal any adverse effects.

Conclusion: Immediate recognition of the toxicity, continuity of care and early use of IVLE possibly led to favourable outcome in our patient.

Ethics: NA
Funding: None
Disclosures/conflict of interest: None

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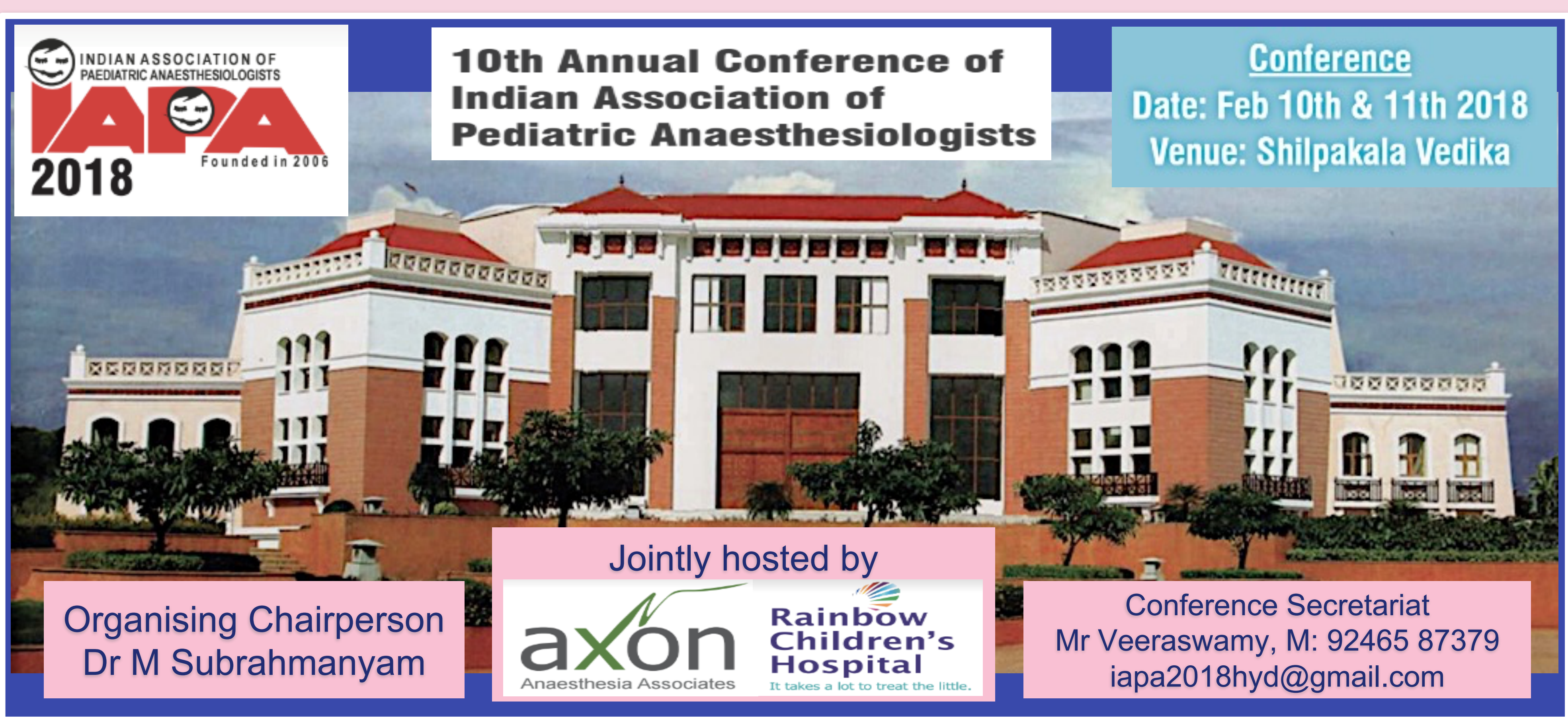

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SPECIAL ARTICLE

Ultrasound – A Key Gadget for Paediatric Anaesthesiologists'

Dr. Ekta Rai, Dr. Vibhavari Naik

Introduction

The use of ultrasound has recently gained popularity amongst intensivists and anaesthesiologists as it enables rapid, by-the-bed, and relatively inexpensive diagnostic evaluation of unstable patients. It has not only changed the outlook of intensivists in management of critically ill patients, but also helped anaesthesiologists by making different regional techniques safer and accurate. The structures of interest in children are superficial and need high frequency probes which can give a better resolution images. In infants, the cranial sutures are not fused and hence ultrasound can provide crucial information about the brain. The most common use of ultrasound among paediatric anaesthesiologists is for gaining vascular access and for performing various regional blocks. Other 'point of care' ultrasound applications are in hemodynamic monitoring, lung scanning, airway assessment, detection of esophageal intubation, identification of cricothyroid membrane prior to intubating a difficult airway child, and optic nerve sheath scanning to reflect on intracranial pressure.

We intend to cover the role of ultrasound as a gadget for anaesthesiologists for our newsletter readers in a module based manner over the next few newsletters.

Ultrasound Principle and Knobology

Ultrasound imaging is based on the principle of generation of sound waves beyond the audible range (20 kHz). Frequencies used for ultrasound are higher than those in the audible range, and typically vary from 2 to 15 MHz for diagnostic procedures. These waves have power to penetrate different tissues of the body at different speed and are reflected back from the tissue interface. The amplitude of reflected energy is used to generate ultrasound images. The knowledge of knobology is an essential first step of using ultrasound for various applications. A hands-on course or workshop in knobology is desirable to acquaint one-self with the available ultrasound machine and its function.

MODULE 1 : Ultrasound for Airway

Ultrasound does not penetrate air and hence was never traditionally used for evaluating the airway. The recent interest in using this modality at the 'point of care' has opened a whole new arena of its applications in the airway which will be covered in this module.

1.What is the need of using ultrasound in airway management?

Safe airway management has always been the anaesthesiologists' primary concern. Airway management in infants and neonates is challenging due to higher incidence of airway related complications, as compared to older children. Ultrasound has been shown to add safety and accuracy in airway management. It is easier to learn, teach and reproduce. Also, most hospitals are equipped with ultrasound machines, that can be availed by the anaesthesiologists. Hence it is essential for all of us to learn ultrasound and its applications relevant to us.

2. What is the ideal position for performing airway ultrasound?

Position – centered, sniffing position
Ideal USG Probe - 7.5-Mhz high-frequency linear transducer.
Hydrogel – to eliminate the air interface
Ideal Settings - Depth-3-4 cm and Focus 1 cm posterior to the target structure
Approaches - Longitudinal (long axis) and Transverse (short axis) at various levels

3. What should I look for?

A) Learn to identify normal structures

Hyoid (Transverse Axis) - is the main bone present in airway anatomy and is hyperechoic.

Epiglottis (Transverse Axis) - Hypoechoic U-shaped structure present at thyroid–hyoid space. The space anterior to epiglottis is pre-epiglottic space, which has hyperechoic air–mucosa interface.

Thyroid cartilage (Transverse Axis) - Hypoechoic structure with respect to the vocal cords, followed by an acoustic shadow corresponding to the airway. Thyroid–hyoid space and the acoustic shadow in the hyoid bone can be evaluated.

Cricoid cartilage (Transverse Axis) - Hypoechoic, inverted U structure inferior to the thyroid cartilage is the cricoid cartilage.

Cricothyroid membrane (Longitudinal Axis) - A hypoechoic structure between the thyroid and the cricoid cartilages can be observed through a longitudinal section along the larynx.

Tracheal rings (Longitudinal Axis) - Tracheal cartilage in longitudinal plane is seen as a "string of beads" and inverted U in the transverse section.

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Vocal Cord (Transverse Axis) - Vocal cord is best seen using transverse plane through the thyroid cartilage as a window. The hyperechoic appearance of the vocal ligaments delineates the vocal cord.

B) Learn to identify abnormal structures

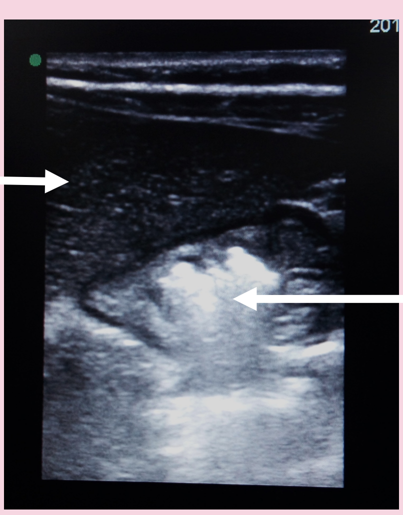
Epiglottitis - With the transducer placed in longitudinal plane of thyrohyoid membrane, a hyperechoic thickened epiglottis seen in relation to the acoustic shadowing of the hyoid bone as an "alphabet P sign" signifies acute epiglottitis.

3. <u>What are the clinical indications of use of ultrasound for airway</u>?

<u>I. Anticipating difficult airway</u> - Ultrasound has been used by many to identify the difficult airway predictors. Various distances like pre-epiglottic space, anterior space to thyroid, distance between the hyoid and mentum, depth of tongue, are being studied to help predict difficult airway. Since the studies are mainly in adults, their role in children is unclear.

<u>II. Predicting perioperative gastric aspiration risk</u> – Studies have suggested that it is possible to quantify the amount of gastric contents in children with ultrasound, thus predicting the gastric aspiration risk. The gastric antrum is visualized in right parasagittal plane between the left lobe of liver and pancreas; and the cross-sectional area is measured.

Fig 1 Subcostal view of gastric antrum to evaluate the aspiration risk



<u>III. Identifying position of endotracheal tube</u> - The confirmation of the endotracheal intubation can be done directly or indirectly. Direct verification is identifying the ETT in trachea or esophagus. The indirect evidence would be identifying pulmonary ventilation and the movement of diaphragm. The successful endotracheal intubation may be confirmed in real time with the artifacts generated when the tube is introduced inside the trachea. And if tracheal intubation fails, a new circular structure can be seen with artifacts generated by the presence of the tube inside the esophagus. The sensitivity of this technique is high and there is no need to ventilate. This technique is superior to clinical auscultation of breath sounds as well as capnography, both of which need ventilation with a few breaths to identify correct placement of the ETT. But the time taken by ultrasound may be longer as compared to capnography.

Fig 2 Transverse view of the neck to identify type of intubation

The indirect tracheal intubation verification includes the use of the linear transducer for checking ventilation throughout the pulmonary fields.

The 'sliding lung sign' between two ribs, is highly sensitive to confirm the tracheal intubation. Unilateral lung sliding is an indication of endobronchial intubation in the absence of other lung pathology. Diaphragmatic movements seen from the substernal view are also indicative of tracheal intubation, but need more expertise and training.

<u>IV. ETT sizing and depth of insertion</u>- There has been extensive research in the ability of ultrasound to determine airway size and estimate appropriate size of ETT, tracheostomy and double lumen tube. The ultrasound measured subglottic diameter correlates well with the outer diameter of the optimal ETT in older children. It is found that this technique underestimates the ETT size in children less than 1 year. The ultrasound based ETT size selection is found superior to the traditional age based formula. The direct ETT tip visualization is possible in neonates and infants but not in older children. The optimal depth of ETT is when the tip lies about 1 cm above the aortic arch in infants, which corresponds to about 0.5cm above the carina. Ultrasound determination of the depth of insertion of ETT is faster than the gold standard chest X ray. Filling the ETT cuff with saline improves its visualization at the suprasternal notch and is a good technique for verifying

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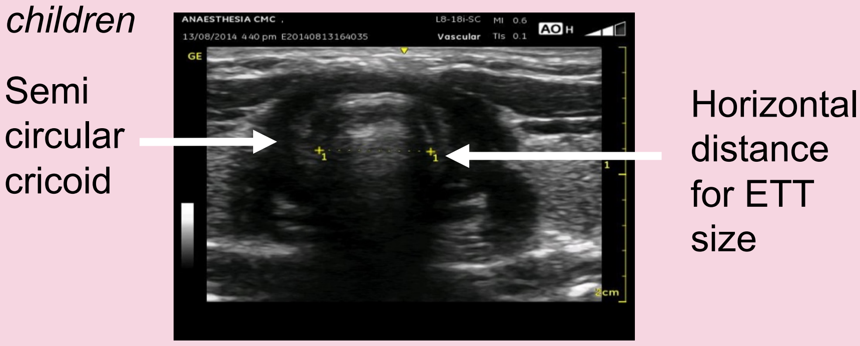
ETT position in older children.

Fig 3 Cricoid Cartilage in Transverse view for ETT sizing in children



V. LMA position – The use of ultrasound to verify the correct placement of LMA in children is still preliminary. The use of fluid to fill the LMA or the use of sono-enhancing material for LMA may be the future direction.

VI. Prepare for Plan D in difficult airway – Ultrasound is a fast and reliable technique to mark cricothyroid membrane for emergency cricothyroidotomy as a plan D in difficult airway scenarios. Marking cricothyroid membrane prior to difficult intubation will not only save the time in the crisis scenario but also avoiding the vessels can make it safer.

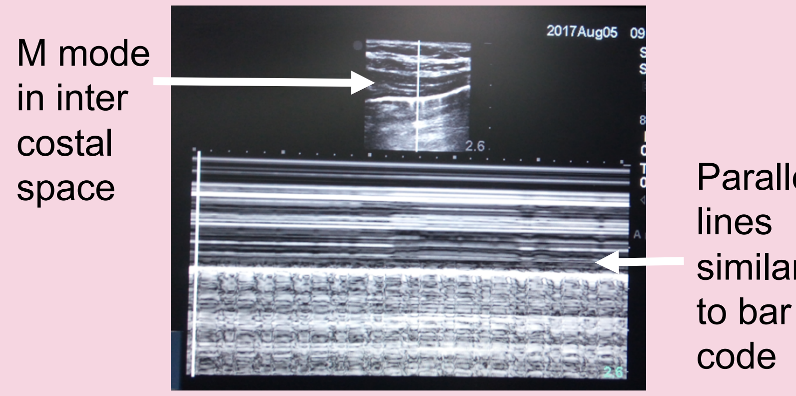
Fig 4 Longitudinal midline view to plan surgical airway

VI. Post extubation stridor - Ultrasound measurement of the laryngeal air column width, before and after cuff deflation can predict post extubation stridor in adults, but parallel studies in children are awaited. Ultrasound can be used to evaluate post extubation vocal cord movements.

Fig 5 Transverse view at the level of vocal cords

VII. Identifying intraoperative pneumothorax – The use of ultrasound is the fastest way to identify pneumothrorax intraoperatively. The absence of lung sliding on one side supports, while the presence of lung point confirms the presence of pneumothorax. A 'Bar code sign' on the M mode is characteristic of pneumothorax instead of the 'Sea shore sign'.

Fig 6 'Bar code sign' on M-mode in pneumothorax



4. Is it really difficult to learn?

Scanning to identify the esophageal or tracheal intubation needs a brief period of training and hands-on practice, but at the same time it is a very useful technique to exclude esophageal intubation, thus improving oxygenation of the child and hence the overall outcome. Other skills like quantifying the gastric contents and identifying difficult airway are more complex and need extensive research and training. Portability, non-invasiveness, cost effectiveness, easy trainability and reproducibility are the reasons why ultrasound is here to stay in the future.

Reading Material

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