



*FDA Safety Communication: General Anesthetic and Sedation Drugs: Drug Safety Communication - New Warnings for Young Children and Pregnant Women (posted 12/14/2016)*¹

What are the long-term risks of anesthesia to children?

Most surgical procedures performed in the operating room are under general anesthesia, in which the patient is not conscious during the operation and is not feeling any pain.

Tens of millions of surgical procedures are carried out each year with an excellent record of safety, but concern has been raised about the safety of medicines used during general anesthesia and sedation in young children, specifically from the time in the womb until age three. Some animal studies have identified a possibility that exposure to anesthetic medications can lead to long-term injury to the developing brain of infants and toddlers, which could potentially result in abnormalities in behavior, learning and memory.

Based on the most current studies, single, short exposures to anesthetic medicine in young children are unlikely to have a significant impact on behavior or learning, but further research is necessary to understand the real impact of these exposures.

<http://smarttots.org/about/consensus-statement/>

While patients and their families need to be clear of the risks of surgical procedures and of anesthesia, they should understand that surgery is typically recommended to benefit the patient's health and quality of life. In many cases, postponing or refusing recommended surgeries on children could mean that real health issues are not being addressed.

What does the US Food and Drug Administration (FDA) say about anesthesia in fetuses and children?

"Health care professionals should balance the benefits of appropriate anesthesia in young children and pregnant women against the potential risks, especially for procedures that may last longer than 3 hours or if multiple procedures are required in children under 3 years. Discuss with parents, caregivers, and pregnant women the benefits, risks, and appropriate timing of surgery or procedures requiring anesthetic and sedation drugs."

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm533195.htm>



What are some surgeries performed by otolaryngologist-head and neck surgeons on children and how much anesthesia time is needed*?

(* times are approximate)

TYMPANOSTOMY TUBE (EAR TUBE) INSERTION

- 2nd most common surgery after circumcision and most common outpatient surgery on children, with 667,000 annual procedures on children
- By age 3, almost 1 in 15 children have tympanostomy tubes
- Done for chronic ear fluid and/or recurrent ear infection that can result in hearing loss, speech issues, academic decline, balance issues, or recurrent use of antibiotics
- Outpatient procedure usually under general anesthesia in children lasting less than 30 minutes, though some teenagers and adults can often undergo this awake in clinic

TONSILLECTOMY AND/OR ADENOIDECTOMY

- 3rd most common surgery after circumcision and tympanostomy tubes, with over 530,000 annual procedures on children
- Done mostly for obstructive sleep apnea (which can cause significant issues with concentration and academic performance, and long-term issues of the cardiovascular and metabolic systems), breathing issues and for recurrent or chronic infection
- Generally an outpatient procedure lasting less than 60 minutes under general anesthesia

LARYNGOSCOPY AND/OR BRONCHOSCOPY

- Using scopes to assess the region of the voicebox or windpipe to assess for scarring or blockages or to remove life-threatening foreign bodies
- Procedure/s performed under general anesthesia, lasting less than 60 minutes

FRENULOPLASTY

- Clipping of tongue tie can improve speech and feeding and dental issues in children
- In young babies and older children can be done in clinic but in older babies and younger children is done under general anesthesia, lasting less than 30 minutes

TYMPANOPLASTY

- Repair of eardrum perforation to improve hearing and allow the child to get water in the ear
- Outpatient procedure lasting less than 120 minutes under general anesthesia

TURBINATE REDUCTION

- Decrease amount of swollen tissue in the nose to improve nasal congestion and mouth breathing
- Outpatient procedure lasting less than 30 minutes under general anesthesia

CERVICAL NODE BIOPSY

- Excision of a lymph node in the neck to check for tumor
- Outpatient procedure lasting less than 60 minutes under general anesthesia

1 <https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm533195.htm>