Key outcome and reporting measures in pediatric airway reconstruction: international expert consensus

Objective: Develop multidisciplinary and international consensus on patient, disease, procedural, and perioperative factors, as well as key outcome measures and complications, to be reported for pediatric airway reconstruction studies.

Methods: Standard Delphi methods were applied. Participants proposed items in three categories: 1. Patient/disease characteristics, 2. Procedural/intraoperative/perioperative factors, and 3. Outcome measures and complications. Both general and anatomic site-specific measures were elicited. Participants also suggested specific operations to be encompassed by this project. We then used iterative ranking and review to develop consensus lists via a priori Delphi consensus criteria.

Rationale
Background: A lack of uniform outcome measures has limited progress in the arena of open airway reconstruction for stenosis. While multicenter data collection or pooling of data are essential, these efforts cannot move forward without agreement on key outcome measures and covariates to include in data collection.

Objectives:
1. Develop multidisciplinary and international consensus on patient, disease, procedural, and perioperative factors, as well as key outcome measures and complications, to be reported for pediatric airway reconstruction studies.
2. Move forward with International Consensus on Anatomic site
3. Develop a list of anatomic site-specific outcome measures.
4. Develop an expanded list of patient- and surgery-related measures.

Study Design

Objective: Develop multidisciplinary and international consensus on patient, disease, procedural, and perioperative factors, as well as key outcome measures and complications, to be reported for pediatric airway reconstruction studies.

Methods: Standard Delphi methods were applied. Participants proposed items in three categories: 1. Patient/disease characteristics, 2. Procedural/intraoperative/perioperative factors, and 3. Outcome measures and complications. Both general and anatomic site-specific measures were elicited. Participants also suggested specific operations to be encompassed by this project. We then used iterative ranking and review to develop consensus lists via a priori Delphi consensus criteria.

Consensus: outcomes included in this consensus statement

Expansion procedures (single or double-stage)
- Laryngotraceoplasty
- Tracheal resection
- Cervical slide laryngotraceoplasty
- Vocal cord lateralization

Resection procedures (single or double-stage)
- Open cricoid split
- Partial cricoidtracheal resection
- Thoracic slide laryngotraceoplasty
- Laryngeal web repair

Slide procedures
- Extended partial cricotracheal resection
- Sliding tracheoplasty
- Open arytenoidectomy

Glossectomy/supraglottic procedures

Endoscopic procedures
- Other procedures
- Balloon dilation
- Open tracheal stent placement
- Endoscopic cricoid split
- Tracheal tube placement
- Endoscopic posterior graft laryngotraceoplasty
- Tracheal homograft

Consensus: operational details

Consensus: airflow disease, patient-related factors

Airway details
- Airway factors
- Patient factors
- Outcomes

Airway anatomy
- Central airway and bronchi
- Airway compression
- Pulmonary/thoracic/cardiac
- Aspiration status

Distance from vocal cords to stenosis
- Tracheomalacia presence and severity
- Need for mechanical ventilation leading up to surgery

Length of stenosis
- Bronchomalacia presence and severity
- GERO

Anatomic
- Vocal fold mobility: neurologic
- Prior airway history
- Secondary airway lesions
- Syndrome/sequence-related
- CHARGE

Functional
- Voice fold mobility
- Vocal fold mobility: neurologic
- Prior airway history
- Secondary airway lesions
- Syndrome/sequence-related
- CHARGE

Mortality
- Need for adjunctive procedures

Relevance of study
1. This study forms the basis for standardization of outcome assessment for open pediatric airway reconstruction for laryngeal and tracheal stenosis.
2. We have developed a consensus list of general and site-specific outcome measures, as well as patient- and surgery-related measures.
3. Each consensus and near-consensus measure has also been defined in terms of studies or tools, validated where possible, that should be used to measure it.

Limitations
1. Expert consensus is low-level evidence; much further study is needed to develop evidence on optimal outcome measures.
2. Majority of participants were otolaryngologists.
3. Only a single cardiothoracic surgeon participated.
4. No participants from Africa or Asia.

Questions?

Please contact Karthik Balakrishnan at balakrishnan.karthik@mayo.edu

Key Findings

Results: 38 pediatric airway experts from 8 countries represented otolaryngology, pulmonology, general surgery, and cardiothoracic surgery.

240 items proposed. Delphi process led to:

- Consensus on new consensus
- Anatomic
- Airway factors
- Patient factors
- Outcomes

- Anatomic site
- Complications/adverse events
- Surgical site outcomes
- Respiratory outcome
- Swallow/feeding outcome
- Voice outcomes

Site-specific outcome measures

- Anatomic site
- Complications/adverse events
- Surgical site outcomes
- Respiratory outcome
- Swallow/feeding outcome
- Voice outcomes

Note: insufficient space to list each item, so number of consensus/near consensus/eliminated items listed below

- Anatomic site
- Complications/adverse events
- Surgical site outcomes
- Respiratory outcome
- Swallow/feeding outcome
- Voice outcomes

Study Design

Objective: Develop multidisciplinary and international consensus on patient, disease, procedural, and perioperative factors, as well as key outcome measures and complications, to be reported for pediatric airway reconstruction studies.

Methods: Standard Delphi methods were applied. Participants proposed items in three categories: 1. Patient/disease characteristics, 2. Procedural/intraoperative/perioperative factors, and 3. Outcome measures and complications. Both general and anatomic site-specific measures were elicited. Participants also suggested specific operations to be encompassed by this project. We then used iterative ranking and review to develop consensus lists via a priori Delphi consensus criteria.

Questions?

Please contact Karthik Balakrishnan at balakrishnan.karthik@mayo.edu