TRACHEOSTOMY: Some Unresolved Questions and Pragmatic Approaches

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Disclosures

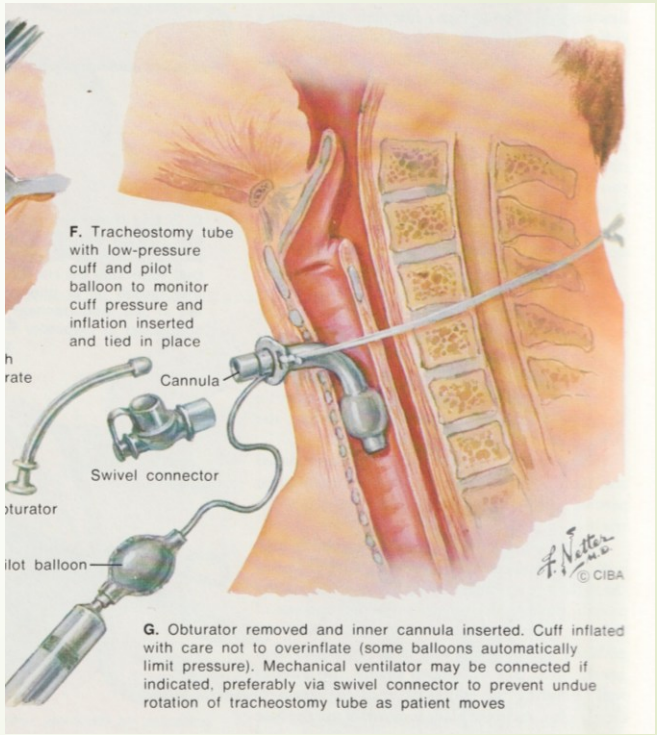
- Octet Medical Inc
- InVent Respiratory
- Connected Rock Ventures
- Innoviva Specialty Therapeutics

Tracheostomy: Some Unresolved Questions

- Is early tracheostomy (vs later) beneficial
- How best to wean tracheostomy to decannulation
- Is percutaneous or open tracheostomy a superior approach
- Endoscopy prior to decannulation
- When to change trach tubes

Question: Is early tracheostomy superior to late tracheostomy

- Tracheostomy Indications (ELECTIVE)
  - Prolonged ventilator dependence
  - To control airway prior to head & neck cancer therapy
  - Refractory obstructive sleep apnea
  - Chronic aspiration
  - Advanced neuromuscular disease
  - Severe subglottic stenosis or laryngeal paralysis refractory to other therapies



Potential Benefits of Tracheostomy vs Continued Intubation

- Increased comfort, reduction in sedation need
- Improved oral care and hygiene
- Possible reduction in laryngeal and upper airway injury
- Facilitates speech and swallowing in some
- May improve mobilization
- Reduced dead-space ventilation
- Easy on-off the ventilator
- Permits leaving ICU with airway
- ? May facilitate weaning
- ? Less pneumonia

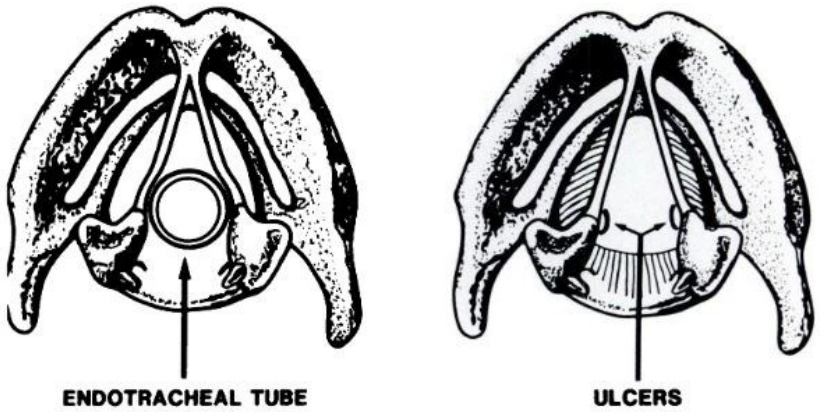


FIGURE 1. *Left*: A schematic view looking into the larynx with an endotracheal tube positioned between the vocal cords is shown. *Right*: At laryngoscopy, following extubation or tracheostomy, ulcers along the posterior aspects of both vocal cords were commonly seen as shown in this schematic. The site of these ulcers corresponds to the area where the translaryngeal endotracheal tube pressed against the vocal cords.

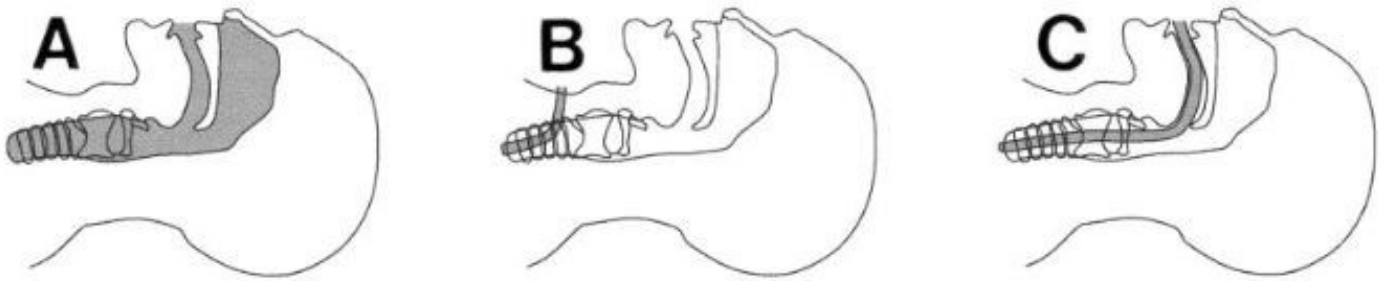


Fig. 1. Diagrams of the dead-space volume of the upper airway (A), a tracheostomy tube (B), and an oral endotracheal tube (C).

Complications of Tracheostomy

- Operative
  - Bleeding
  - Airway fire
  - Pneumothorax/mediastinum
  - Subcutaneous emphysema
  - Esophageal damage
  - Recurrent laryngeal n. damage
- Early Postoperative Phase
  - Tube obstruction
  - Dislodgement/false passage
  - Accidental decannulation
  - Infection
- Later / Longterm
  - Tracheomalacia
  - Tracheo-innominate fistula
  - Tracheo-esophageal fistula
  - Granulation tissue
  - Tracheal or subglottic stenosis
  - Infection
  - Persistent stoma after removal

Complications of Tracheostomy

- Retrospective cohort study, 2006 (Nationwide Inpatient Sample)
- 113,653 tracheostomies done in adults
- 3.2% incidence of tracheostomy complications (in-hospital)
- 19.2% in-hospital mortality
- Mortality did not vary with or without tracheostomy complication
- Higher mortality in > 50 yo, cardiac conditions, CHF

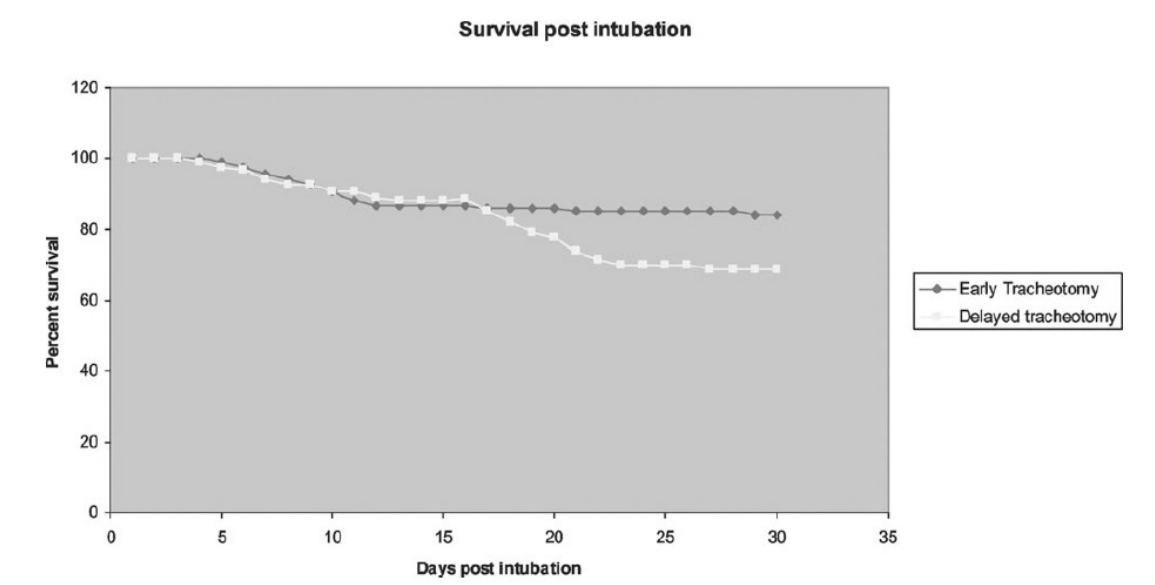
Shah ***Laryngoscope*** 2012; 122:25

Defining ‘Early’ vs ‘Late’ Tracheostomy

- Range in literature from 2 days to 4 weeks
  - Wide variation in timing among studies: early – 2-10 d, late 6-29 d
  - Makes direct comparisons difficult to assess
- General acceptance of 7 – 10 days as a reasonable cut point
- Up to 1/3 ventilated ICU patients will undergo tracheostomy

PETAL Network ***N Engl J Med*** 2019; 380:21
Cox ***Crit Care Med*** 2004; 32:2219

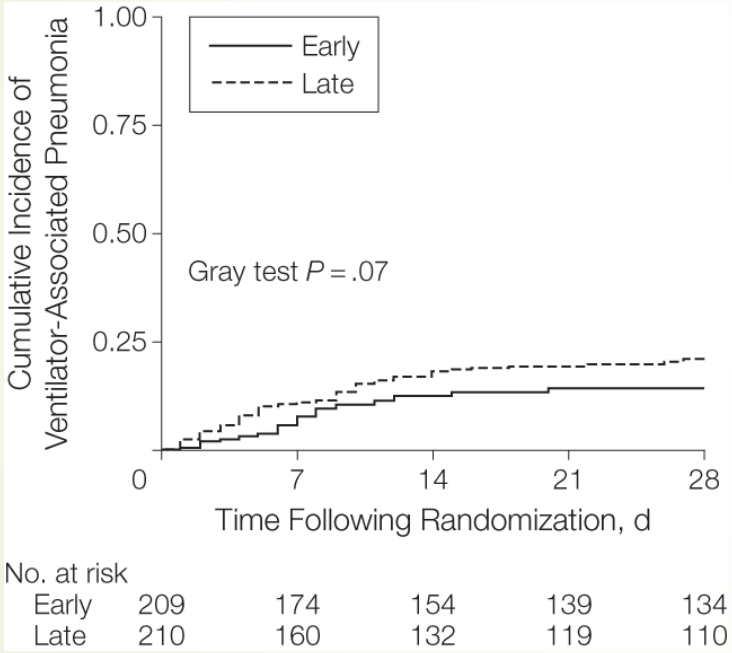
Early Randomized Trial of Early vs Late Percutaneous Tracheostomy



- **Design**
  - RCT single center, general MICUs
  - *n* = 120, judged likely to need 14 d ventilation
  - Early (≤ 2 d) v Late (14-16 d)
- **Key Findings**
  - Less mortality (31.7% vs 61.7%)
  - Less VAP
  - Less time on vent, ICU LOS
  - Questions about selection: very high mortality in late group

Rumbak ***Crit Care Med*** 2004; 32:1689

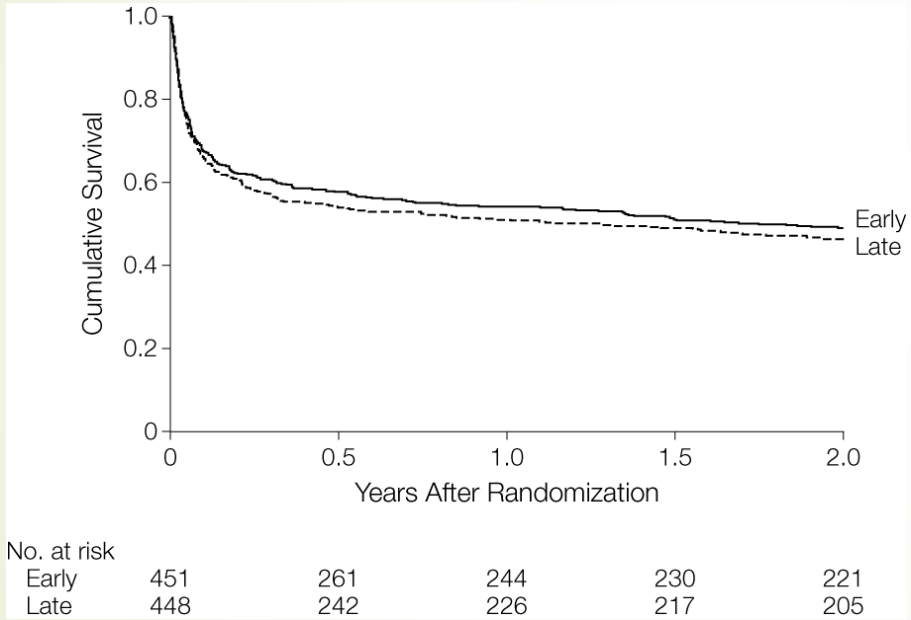
2010 RCT for Prevention of VAP



- **Design**
  - 12 Italian ICUs
  - Early (6-8 d) vs Late (13-15 d)
  - *n* = 600 (419 got trach)
- **Key Findings**
  - No SS reduction in VAP
  - No SS change in mortality
  - More vent-free, ICU-free days
  - More successful weaning

Terragni ***JAMA*** 2010; 303:1483

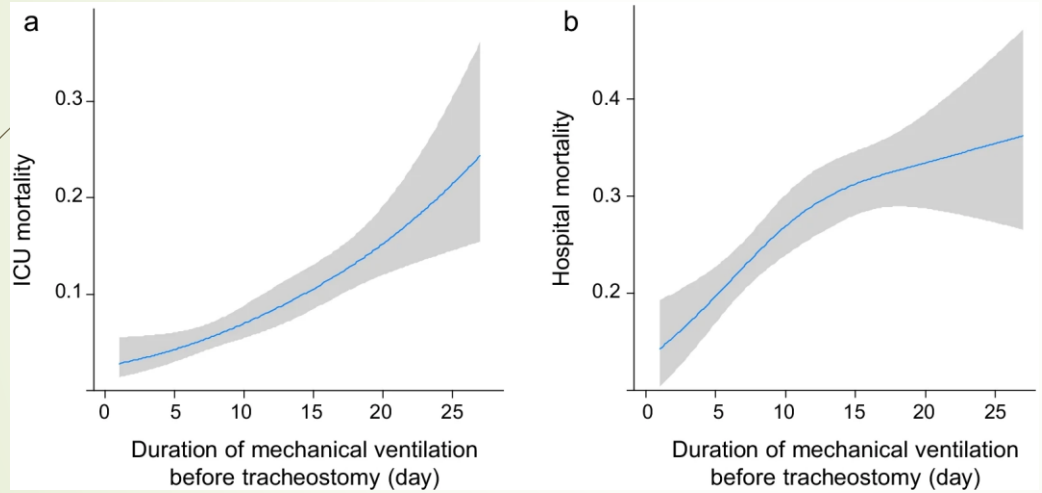
TracMan Trial



- **Design**
  - UK multicenter RCT, 72 ICUs
  - Early (≤ 4 d) vs Late (> 10 d)
  - *n* = 909
- **Key Findings**
  - No Δ mortality (~ 47% 1 year)
  - No Δ secondary endpoints
  - 2/3 in 'late' group did not need trach (recovery, d/c vent/ICU)

Young ***JAMA*** 2013; 309:2121

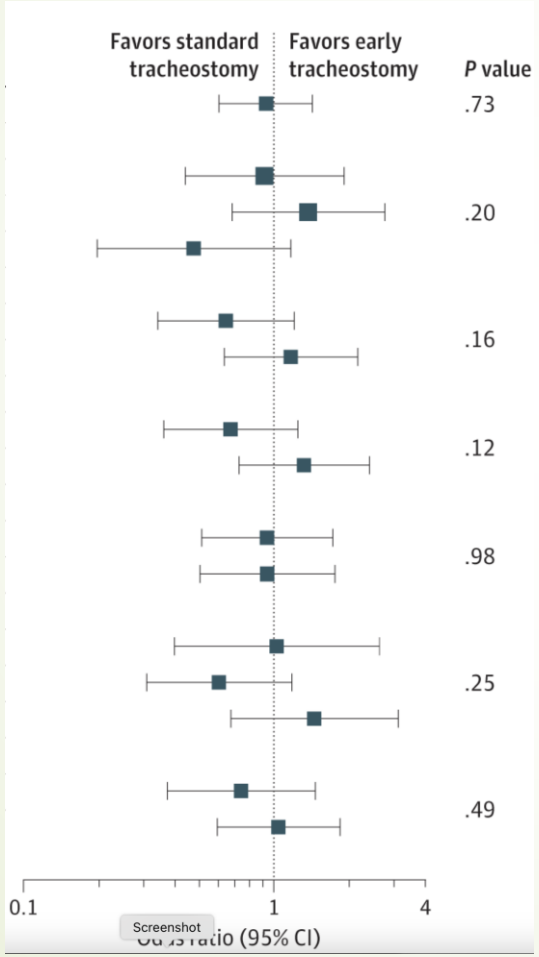
Retrospective Cohort Analysis - Japan



- **Design**
  - Retrospective cohort 2015-19
  - All trach patients up to 29 d ICU
  - *n* = 153
  - Quartiles analyzed:
    - ≤ 6 d; 7-10 d; 11-14 d; > 14 d
- **Key Findings**
  - SS Δ mortality in groups 2, 3, 4 vs 1
  - Stepwise increase in mortality
  - Limited by retrospective design

Tanaka ***J Intensive Care*** 2022; 10:19

SETPOINT-2 Trial – Severe Stroke



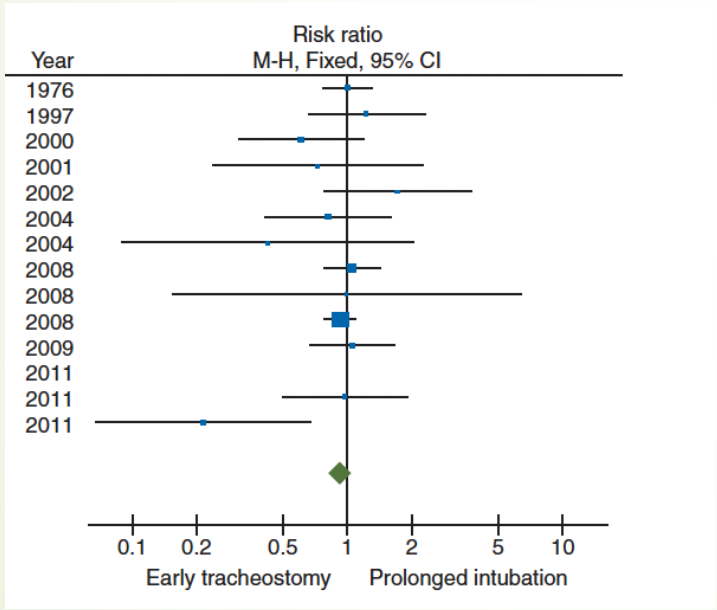
- **Design**
  - RCT, severe stroke on ventilator
  - Early (≤ 5d) vs std (≥ 10 d)
  - Germany + U.S.
  - *n* = 366
  - Endpoint: 6 mo function outcome
- **Key Findings**
  - No Δ 6 mo functional outcome

Bösel ***JAMA*** 2022; 327:1899

Systematic Studies

Szakmany - 2015

- Short term mortality

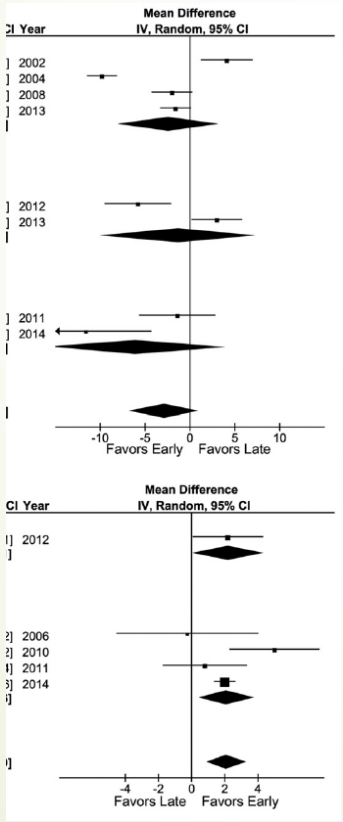


- **Design**
  - Meta-analysis, 14 trials
  - n = 2406
  - Early = within 10 d intubation
- **Key Findings**
  - No Δ mortality
  - No Δ ICU or ventilator days
  - No Δ VAP
  - Decrease in sedation
  - Increase in trachs

Szakmany ***Br J Anaesth*** 2015; 114:396

Hosokawa - 2015

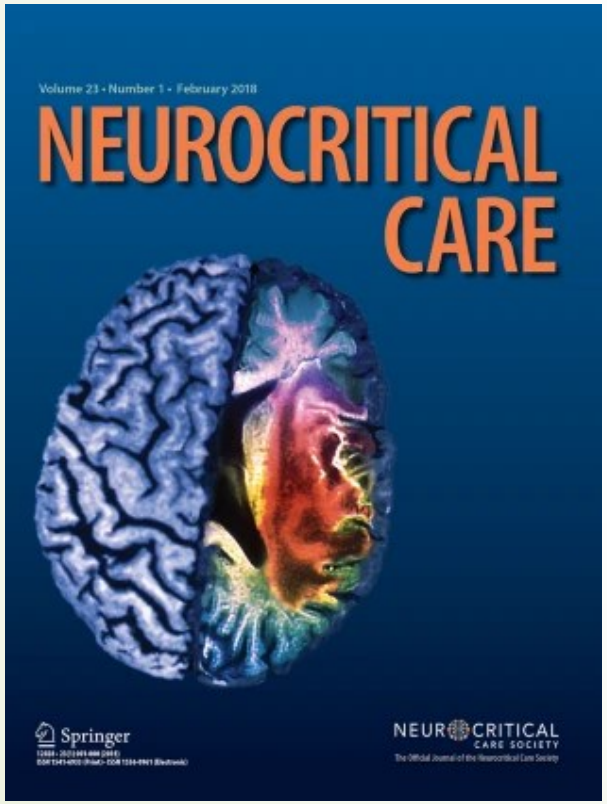
- Days Vent (up)/Vent-free (down)



- **Design**
  - Meta-analysis, 12 studies
  - 3 a priori categories of timing
    - < 4 d vs > 10d
    - ≤ 4 d vs ≥ 5 d
    - ≤ 10 d vs > 10 d
- **Key Findings**
  - More vent-free days
  - Decrease ICU LOS
  - Decrease sedation usage
  - Decreased long-term mortality

Hosokawa ***Crit Care*** 2015; 19:424

Acute Brain Injury Patients - 2016

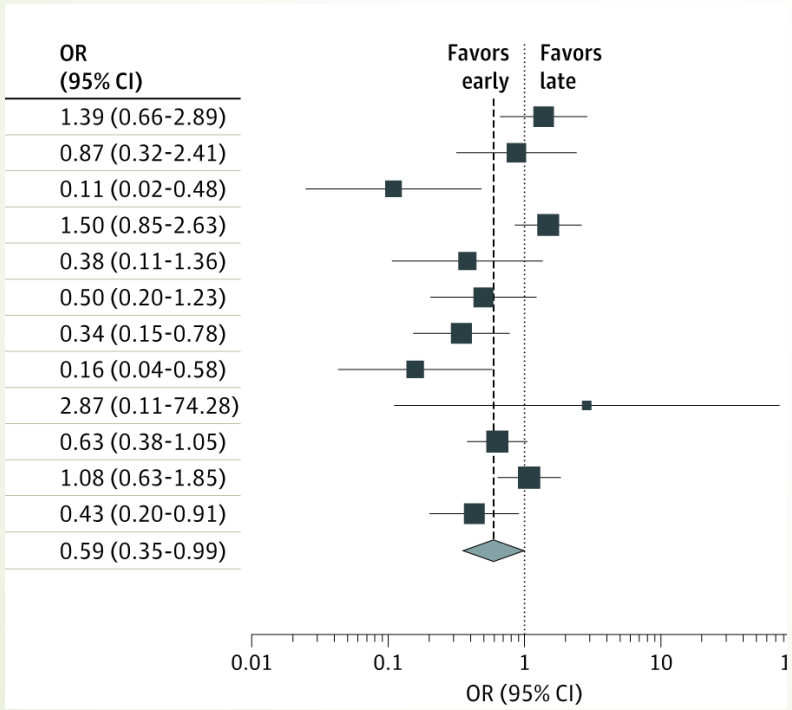


- **Design**
  - Meta-analysis, 10 trials
  - ≤ 10 d vs > 10 d
  - *n* = 503
- **Key Findings**
  - Reduced long (but not short-term) mortality (p = 0.02)
  - Decrease duration ventilation
  - Decrease ICU LOS

McCredie ***Neurocrit Care*** 2016; 26:14

Chorath - 2021

VAP



- **Design**
  - Meta-analysis, 17 trials
  - ≤ 7 d vs > 7 d
  - *n* = 3145
- **Key Findings**
  - No Δ mortality
  - Decrease VAP, ICU LOS
  - Increase vent-free days

Chorath ***JAMA Otolaryngol Head Neck Surg*** 2021; 147:450

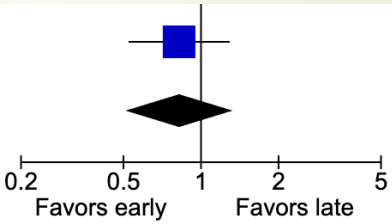
Cochrane Review Szafran - 2023

- **Design**
  - Meta-analysis, 1 RCT, 24 nonRCT
  - All Covid-19 patients
- **Key Findings**
  - No Δ mortality
  - No Δ ICU or vent duration
  - No Δ VAP rates

Mortality

Eeg-Olofsson 2022	22	72	29	78	100.0%	0.82 [0.52 , 1.29]
Total (95% CI)		**72**		**78**	**100.0%**	**0.82 [0.52 , 1.29]**
Total events:	22		29			

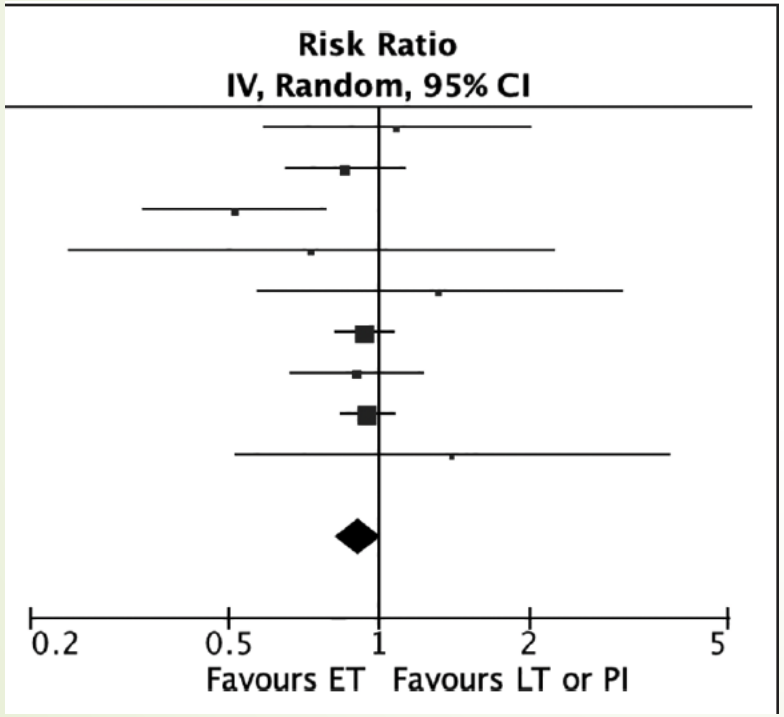
Heterogeneity: Not applicable
Test for overall effect: Z = 0.85 (P = 0.40)
Test for subgroup differences: Not applicable



Szafran ***Cochrane Reviews*** 20 Nov 2023

Villemure-Poliquin - 2023

- Mortality



- **Design**
  - Meta-analysis, 9 trials
  - *n* = 2457
  - < 10 d vs 10 day or prolonged
  - Non-neurologically injured adults
- **Key Findings**
  - No Δ mortality
  - No Δ hospital or ICU LOS
  - No Δ duration ventilation
  - No Δ VAP

Villemure-Poliquin ***Crit Care Med*** 2023; 51:310

NAMDRC Consensus Conference Guidelines - 1989

1. For anticipated need of the artificial airway up to 10 days, the translaryngeal route is preferred
2. For anticipated need of the artificial airway for greater than 21 days, tracheotomy is preferred
3. When the time anticipated for maintenance of an artificial airway is not clear, daily assessment is required to determine whether conversion to tracheotomy is indicated
4. The decision to convert to tracheotomy should be made as early as possible in the course of management to minimize the duration of translaryngeal intubation. Once the decision is made, the procedure should be done without delay…(except mitigating circumstances)

Chest 1989; 96:178

Guidelines

Tracheotomy in the intensive care unit: Guidelines from a French expert panel☆

Jean-Louis Trouillet [a], Olivier Collange [b,c], Fouad Belafia [d], François Blot [e], Gilles Capellier [f,g], Eric Cesareo [h,i], Jean-Michel Constantin [j,k], Alexandre Demoule [l,m], Jean-Luc Diehl [n,o], Pierre-Grégoire Guinot [p,q], Franck Jegoux [r], Erwan L'Her [s,t], Charles-Edouard Luyt [a,u], Yazine Mahjoub [v], Julien Mayaux [l,m], Hervé Quintard [w,x], François Ravat [y], Sébastien Vergez [z], Julien Amour [aa], Max Quillot [c,ab,*], For the French Intensive Care Society, Max Quillot For the French Society of Anaesthesia and Intensive Care, Olivier Collange

R1.1–The experts suggest that tracheotomy be proposed in cases of prolonged weaning from mechanical ventilation and of acquired and potentially reversible neuromuscular disorder.

R1.2–The experts suggest that the indication for tracheotomy in patients with chronic respiratory failure should be the subject of multidisciplinary discussion.

R1.3–Tracheotomy in intensive care should not be performed before the fourth day of mechanical ventilation.

GRADE 1+, Strong agreement
Rationale:

Trouillet ***Anaesth Crit Care Pain Med*** 2018; 37:281

Predicting Need for Long-Term Ventilation

- Severe brain injury: stroke, TBI, anoxic injury
- Neuromuscular disease, advanced: e.g. Guillain Barre
- Polytrauma
- High cervical cord injury
- Severe chronic lung disease
- Unresolving ARDS

Early vs Late Tracheostomy - Summary

- Invasive procedure with real complications
- "Early" usually defined as within 5-10 days of intubation
- Research is not supportive of ***universal*** early tracheostomy in ICU ventilated patients
- Timing should be tailored to each patient's clinical context:
  - Risks
  - Specific pathology pattern
  - Organ system dysfunction
  - Overall clinical trajectory

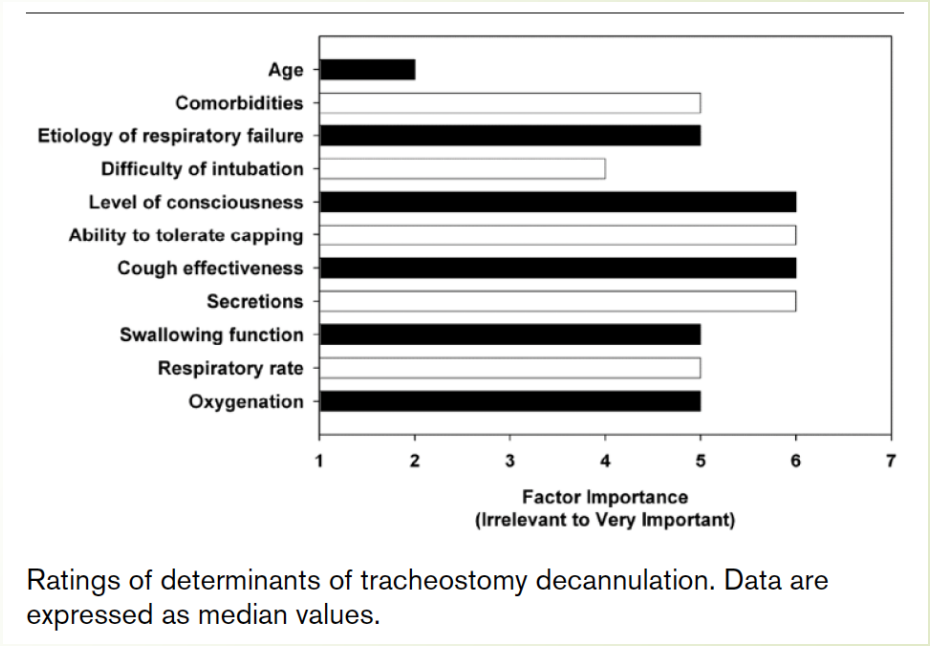
Question: What is the Protocol or Best Process to Wean to Decannulation?

- Criteria and approach vary center-to-center
- Some do CT neck or endoscopic evaluation beforehand
- No scientifically proven optimal approach, though many recommended techniques are described
- Some data that a multidisciplinary approach involving nursing, speech, clinicians and perhaps a protocol may improve safety of decannulation

Pandian ***Laryngoscope*** 2014; 124:1794
Mirski ***Crit Care Med*** 2012; 40:1827

Prerequisites for Decannulation

- Mechanical ventilation no longer required
- Absence of significant upper airway obstruction
  - Laryngeal edema, subglottic stenosis, tracheal stenosis et al
- Satisfactory cough
  - Typically associated with acceptable neurologic status
- Minimal secretions
- ? Neurologic or swallow function



Ratings of determinants of tracheostomy decannulation. Data are expressed as median values.

Ceriana ***Intensive Care Med*** 2003; 29:845
Stelfox ***Crit Care*** 2008; 12(01):R26
Trouillet ***Anaesth Crit Care Pain Med*** 2018; 37:281
O'Connor ***Respir Care*** 2010; 55:1076

Chronic Tracheostomy Needs in Long-Term Facilities (total *n* = 162)

Chronic disorder of consciousness – TBI	29
Chronic disorder of consciousness – ischemic injury	34
Chronic lung disease, vent-dependent, long wean	14
Restrictive thoracic disorder	12
Neuromuscular disease (MS,ALS, SCI, etc)	27
Stroke, ICH, airway protection	32
Misc encephalopathy	7
Subglottic or tracheal stenosis, VC paralysis	5
Laryngeal Ca or tumor	2

Willms, Unpublished data

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Techniques for Decannulation

1. Progressive Capping Trials
   - 12, 24, 48, 72 hrs
   - Sometimes patient needs time to acclimate to capping
   - 30 min success with capping predicts successful decannulation, uncontrolled trial
     - Rumbak: 63/75 passed initial trial
     - Bronchoscopy done in all subjects
     - Only those that failed initial cap trial had clinically significant findings at endoscopy

Rumbak ***Crit Care Med*** 1997; 25:413

2. Progressive Decrease in Size Trach Tube
   - Until breathing with smallest size tube (e.g. #4)
   - Allows stoma to decrease around the tube
   - 80% success in an observational study

Ceriana ***Intensive Care Med*** 2003; 29:845

Techniques for Decannulation

3. Immediate Decannulation
   - Usually after endoscopic inspection of upper airway
   - Brief capping trial, followed by decannulation
   - Only for highly selected patients

Cohen ***Laryngoscope*** 2016; 126:2057

4. Heated Humidified High Flow Oxygen + Low Freq Suction
   - RCT 24 hr cap vs HFTO and minimal suction
   - 7 days less time to decannulation (and less pneumonia/bronchitis)
   - Similar rate of decannulation

Hernandez Martinez ***NEJM*** 2020; 383:1009

Heated Humidified Trach Oxygen vs Capping Trials

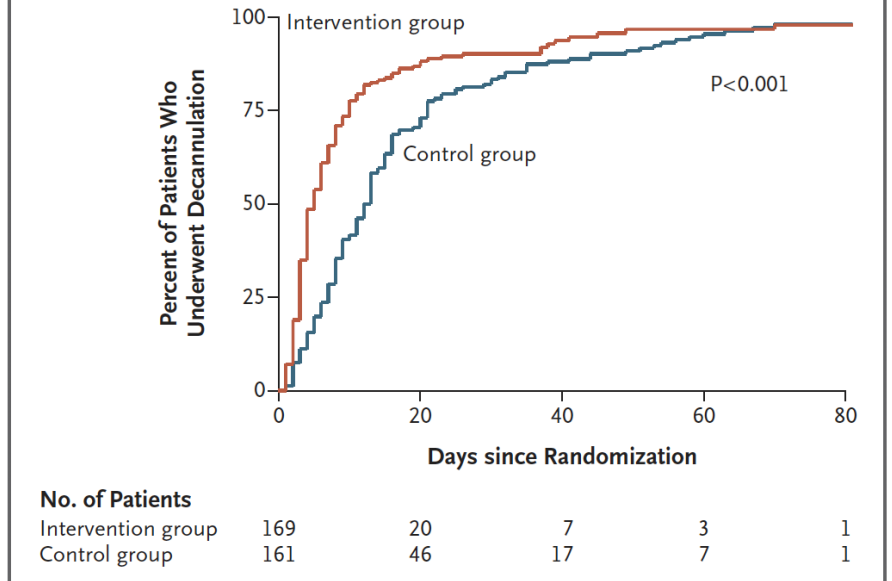

Figure 2. Kaplan–Meier Analysis of the Time to Decannulation (Intention-to-Treat Population).

The analysis was truncated at 80 days. Patients who underwent decannulation after this time had their data censored. In the control group, one patient underwent decannulation at 83 days and one at 319 days; in the intervention group, one patient underwent decannulation at 142 days.

Hernandez Martinez ***NEJM*** 2020; 383:1009

Should Endoscopic Exam Precede Decannulation?

- Study from Brazil – 51 trach patients potentially ready for decannulation
- Mean # days with trach in place 46 ± 28
- Capped (metal cuffless trach) x24 h – if pass, considered 'clinically fit'
- Then endoscopy in all
- 40 patients 'clinically fit' (passed cap trial 24 h)
  - 8 (20%) found to have lesions *contraindicating* decannulation

Clinical conditions that prompted orotracheal intubation or tracheostomy	Plastic Orthosis Period (days)	Bronchoscopyic laryngotracheal changes contraindicating decannulation
Convulsive crisis	74	Bilateral paresis of vocals cords in adduction
Trauma	105	Grade II tracheomalacia
Airway obstruction	24	Grade II tracheomalacia
STROKE	26	Grade II tracheomalacia
Sepsis	41	Grade II tracheomalacia
Pneumonia	49	Grade II tracheomalacia
STROKE	30	Grade II tracheomalacia
Decompensated CHF	25	Bilateral paresis of vocal cords in adduction

Rodrigues ***Rev Col Bras Cir*** 2015; 42:75

Another Approach

- Start cuff deflation, and when tolerates, change to cuffless trach
- Speaking valve placement – stepwise increase in time with valve
- If secretions manageable, begin capping
- Stepwise increase in capping
- Once 24 hrs per day capped - ? Number of days -> decannulate
- Endoscopic exam at any point if difficulty with progressing due to airway issue

Decannulation – Other Issues

- Delayed tracheostomy stomal closure
- Failed decannulation
  - Early – insert smaller tube, or dilate and recannulate
  - Late – oral intubation and elective tracheostomy
- Use of tracheal stoma plug or button