February 2016: Rapid Review Evidence Summary

McGill University Health Centre: Nursing Research Division and MUHC Libraries

What is the evidence describing the effectiveness of weaning techniques for tracheostomy decannulation in adult inpatients?

This report aims to summarize the best available evidence around the effectiveness of weaning techniques for tracheostomy decannulation in adult inpatients. As a secondary question, *what is described in the literature as the length of time to safely cap a tracheostomy tube in adult inpatients prior to decannulation?* This information is to support a new protocol being introduced via the Clinical Practice Review Committee at the MUHC.

Key Messages:

- A tracheostomy is the surgical opening of the anterior wall of the trachea that allows for temporary or permanent airway management through a tube to improve airway function.
- *Decannulation* is a process whereby the tube is removed. The criteria for decannulation includes the resolution of the need for a tube, hemodynamic stability, the absence of fever or active infection, adequate mental status, absence of the need for further procedures requiring an endotracheal tube, and the ability of the patient to manage secretions and produce an effective cough.
- The literature describes several techniques for weaning patients. The effectiveness of these techniques is not clearly demonstrated and is based mainly on literature reviews or expert opinion of low to moderate quality. No systematic reviews or randomized controlled trials were found. There is little consensus in the evidence on the process of weaning:
    - Occlusion of the tube via a cap, one-way speaking valve or digit has been frequently cited a method for weaning and assessment of airway patency.
        - The length of time for occlusion ranges from 10 minutes to 72 hours in all patient populations.
    - The downgrade of tube size, with or without a cuff, and with or without fenestration has been described both as a precursor to weaning and as a weaning strategy.
    - Other weaning techniques were retrospectively studied and included the use of a tracheostomy button or retainer and single-stage decannulation.
    - Some articles focused on decannulation and the weaning process specifically for patients with neuromuscular weaknesses, prolonged mechanical ventilation or upper airway obstruction.
    - In some institutions, a standardized approach to weaning and decannulation was described and may have positive effects on the number of successful decannulations while decreasing adverse events.
- The lack of prospective clinical studies on the weaning techniques may be related to the inability to blind patients and investigators, bias on the part of the clinician, heterogeneity of the patient's condition, inability to predict the anatomical or physiological status of the patient prior to decannulation, and the multidisciplinary involvement in tracheostomy decannulation.

Who is this summary for?
This summary was requested by Natasha Dupuis, CNS, Surgical Mission, MUHC.

Information about this summary:
This report covers a broad collection of literature and evidence sources with a search emphasis on systematic reviews.

This summary includes:
Key findings from a broad collection of recently published literature (2000-2015) and evidence sources.

This summary does not include:
Recommendations, additional information, or detailed description of the interventions in the studies.

1. Background:

A tracheostomy is the surgical opening of the anterior wall of the trachea that allows for temporary or permanent airway management through a tube [1]. Several indications exist for a tracheostomy tube and can include obstruction of the upper airway, prolonged mechanical ventilation, removal of secretions and to prevent aspiration of oral/gastric secretions. This can improve vocal cord functioning and swallowing, patient comfort and self-perceived appearance.

Patients who are able to successfully wean from a tracheostomy tube have improved survival rates, increased likelihood of community-based management, and have an impact on decreasing healthcare costs [2]. There is consensus in the literature on the criteria for decannulation readiness which includes the resolution or improvement of the reason for tracheostomy, upper airway patency, adequate level of consciousness, effective cough and management of secretions, and the ability of the patient to tolerate an occlusion of the cap without respiratory distress [3]. Although the ability of the patient to tolerate a successful occlusion trial or weaning process is considered by some authors, the technique to use is unclear and the process is often vaguely described. Some weaning techniques mentioned include some or all of the following: occlusion of the tube by either a cap or one-way valve to enable speaking, the progressive downsizing of the tracheostomy tube, and the use of a tracheostomy plug or retainer. The recommendations for weaning are based on the experiences of clinicians with multiple specialities (intensivists, ENT specialists, Ward physicians, RTs, nursing etc…) and expert opinion in the literature. There are inherent challenges to studying the most effective weaning techniques, which include the inability to blind the patient or the clinician to the process and the variability in patient factors, among others. In addition, weaning techniques may vary depending on the patient's condition, reason for insertion of a tracheostomy tube and the setting for which they are being cared for (e.g.: ICU vs. ward.) This provides an argument for an individualized approach that depends on critical thinking skills; however, three articles have documented an institution-wide standardized approach to decannulation that appears to have some benefit [4-6].

This rapid review summarizes best available evidence with regards to the effectiveness of weaning techniques to decannulation in adult inpatients. Also, it provides a description from the literature of the length of capping time. A detailed search strategy was developed by an experienced librarian (specific search terms are available upon request). Sources included Medline via OvidSP, Pubmed via Medline, Embase via OvidSP and CINAHL Complete via EbscoHost. Search concepts included Subject Headings and text words. The search date was January 19, 2016. In addition, the EIDM-Advisor reviewed the cited references of the included articles, and searched in the Uptodate and Joanna Briggs libraries. Duplicates and out of scope articles were discarded by the librarian. The analysis of studies, including appraisal and summary, and the final report were prepared by the EIDM-A and reviewed by the librarian and Chair of the Clinical Practice Review Committee of the MUHC.

The studies included in this rapid review were those that specifically studied a weaning technique and/or described the decannulation process for adult inpatients. When a length of occlusion trial was mentioned, it was included in the review in table format (See Table 1). Neither systematic reviews, nor randomized clinical trials were found. Most of the studies reviewed were literature reviews or expert opinion. The studies are of low to moderate quality and the overall level of evidence is low (mainly literature reviews). A list of all the articles found and reviewed is available upon request (sonia.castiglione@muhc.mcgill.ca).

Levels of Evidence (adapted from OHRI KTA Evidence Summary document)

Each piece of evidence presented in this summary is assigned a level.

This assignment is based on the evidence being presented and not on the claim made by the authors.

- **Platinum:** Systematic reviews and meta-analysis
- **Gold:** Randomized controlled trials
- **Silver:** Observational studies (non-randomized trials, case-control, time-series, cohort studies, case series, literature reviews, qualitative studies.
- **Bronze:** Expert committee guidelines, reports or opinions, commentary or editorials.
- **Level of evidence** cannot be determined.

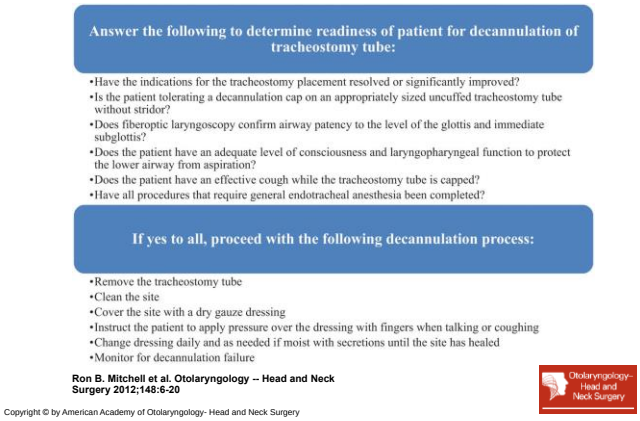
2. Summary of Findings:

a. Articles describing an overview of the weaning process

i. Unspecified patient population

In 2014, a standardized protocol for tracheostomy capping and decannulation was implemented at the John Hopkins Hospital to improve patients' safety. The protocol proposed criteria of eligibility for a capping trial and subsequent decannulation. The criteria included: a tracheostomy tube of 4.0 and cuffless was present, the patient must be able to tolerate a speaking valve during the waking hours (no time expectancy given), the patient must be able to mobilize secretion and maintain stable oxygen saturation and must demonstrate ability to remove the cap in less than 30 seconds and to use the call bell during an emergency. In addition, suctioning for secretions should be less than every 4 hours, and there is no anticipated need for sedation or anesthesia for the patient. If the patient fully met fully these criteria, they proceeded to a capping trial for 24 hours. If successful, which was defined as absence of O_2 desaturation, increased O_2 requirements to above 40% FiO_2 or removal of the cap for any reason, and then the patient was decannulated. In 57 patients enrolled during a 12 month period, 45 patients met the criteria all were successfully decannulated. If the patient did not meet the criteria, modifications were made such as downsizing the tube size, examination with bronchoscopy to determine areas of obstruction, continuous monitoring etc… In these patients, an altered capping trial was attempted where patients underwent capping for 12 hours, followed by a 12 hour uncapped period before proceeding to the 24 hour capping. 5 patients required modifications which then led to successful decannulation in the 12-month period. Further to this, the authors described a decrease in reported events from 7 to 1 in the 6-months pre-implementation to 6-months post implementation. Despite the small sample size, and significant presence of bias due to retrospective data collection, the authors claimed that the protocol developed and implemented by a multidisciplinary team can significantly decrease adverse events associated with decannulation. [6]

Figure 1. Prerequisites for decannulation in adult patients.Note: The decannulation protocol does not apply to pediatric patients.



In 2013, a clinical consensus statement regarding the management and care of patients with a tracheostomy was published based on the opinions of healthcare professionals convened by the American Academy of Otolaryngology-Head-and-Neck Surgery Foundation. Following a systematic review of the literature, experts were asked to rate their consensus on statements related to tracheostomy care and removal using a Delphi approach. 77 statements reached consensus and were retained on adult and pediatric practices. For decannulation in adults, suggestions for practice included that tracheostomy tube cuffs should be deflated when the patient no longer requires mechanical ventilation. In addition, prior to decannulation, patients should tolerate capping of the tube, with no presence of stridor and the presence of effective cough and a fiberoptic laryngoscopy should confirm airway patency. Finally, the tube should be uncuffed and may need to be downsized prior to decannulation. There were no suggestions of the length of time a capping trial should be tolerated. A figure to outline prerequisites for decannulation was included (see Figure 1). The authors cautioned that these are not to be considered as recommendations for practice, but as suggestions. [3]

A 2011 literature review described the considerations for tracheostomy decannulation and the procedure that could be followed. Patients should first be assessed as candidates for decannulation and then must pass a trial. Once patients are considered candidates for decannulation, a trial may include allowing patients to ventilate under observation with a deflated cuff and occluded tube. The authors state that if the patient does not present with dyspnea, difficulty with secretions, hypoxia or stridor for ≥ 30 min, and is alert and able to generate a forceful cough, experts suggest that decannulation is recommended. They acknowledged that experts have also advocated for a longer trial of 24-72 hrs. They also identified that for patients with prolonged mechanical ventilation or underlying chronic illness, this longer observation is also applicable. In the case where the patient does not tolerate the initial capping, the authors suggest that a reduction in tube size may be warranted to decrease airway resistance, followed by another capping trial. They did not describe in which setting the weaning trials should be taking place [7].

A 2009 review of tracheostomy literature described general strategies for weaning. When the need for airway protection or mechanical ventilation is satisfied, decannulation can be considered. With regards to reduction in tube size, they state that over time, patients may have their tubes downsized or changed to fenestrated or cuffless tubes. They describe introducing a cap or 1 way speaking valve (specifically the Passy-Muir valve) that can facilitate speaking and motivation to speed recover, once air passage (cuff leak) is confirmed around the tube. They describe that the weaning strategy is often institutional dependent and can vary, from once the speaking valve is tolerated to 48 hrs. They did not provide details regarding tolerance to the cap or valve [8].

In 2008, a survey was developed and sent to physicians and respiratory therapists to determine what factors clinicians consider to be important in determining whether to decanulate a tracheotomised patient. 225 clinicians responded to questions regarding specific factors and 2 clinical scenarios, which included the ability of the patient to tolerate a capping trial for 24 or 72 hours. Clinicians rated the ability to tolerate capping as a highly important factor to consider, in addition to level of consciousness, cough effectiveness, and secretion. However, when presented with a clinical scenario, tolerance to capping (for 24 or 72 hours) did not influence the clinicians' decision to decannulate. The authors "propose that a patient's level of consciousness, couch effectiveness, secretions and oxygenation be tested in a clinical trial as four simple bedside factors… when determining whether to decannulate." The study reflects the opinions of practitioners from over 100 medical centre, however, it remains there opinion and does not reflect practice informed by evidence [9, 10].

✸ *In 2007, a review of the literature and a description of the authors' own experience with tracheostomy care and specifically decannulation on a weaning unit were presented. A downsizing of the tube followed by a capping trial for 24 to 72 hours preceded decannulation when criteria for weaning for met. This included cessation of mechanical ventilation, evaluation of the upper airways, swallowing and secretions. The authors did not evaluate the process they described [11].*

✸ *A 2005 review article discusses the benefits, physiological effects and options for decannulation. They presented options for preparing and weaning a patient for decannulation. These included deflating the cuff with digital occlusion to evaluate the upper airway, reduction in tube size with an inner diameter of 6mm or less. After 4 days, the patient was decannulated if blood gases showed a Ph of greater than 7.35 with less than 5% increase in P_{aCo2}. They also described intermediate steps of capping, tracheostomy button and one-way speaking valve for patients with long-term tracheostomy. They did not provide any clear guidelines for decannulation [12].*

✸ *A 2002 review provided an approach to decannulation. There were no citations supporting the method though the authors presented their preference for weaning. They describe 3 weaning approaches that can be once conditions for decannulation have been met. Some pros and cons were also described for each process. The authors preferred method was to immediately remove the tube, especially if the patient appears to be doing well and has no significant risk of deterioration. The second approach described progressive downsizing of the tracheostomy tube before removal. They state that this approach is used best in patients with secretion clearance difficulties. They state that this approach reduces comfort, facilitates swallowing and allows for continued suctioning if needed. It can present a problem if the patient deteriorates and requires ventilation. The third approach is to replace the tube with a tracheostomy button to temporarily maintain the stoma and tract. They claim that it best used in patients with a high risk of respiratory failure because it allows for recannulation should the patient deteriorate. The reduction of airway resistance, improvements in swallowing and elimination of secretions being stuck in the tube were stated as beneficial. The authors acknowledge that there is inadequate data to support one particular approach over the others, but report that the "best approach varies from patient to patient." [13]*

⦿ *A 2001 continuing education article for nurses described the process for weaning and tracheostomy tube removal. The authors designed a weaning chart that describes the checklist for weaning criteria, the process as well as indications for causes of distress. This chart was apparently evaluated by healthcare professionals but the data was not described. Candidates for weaning must satisfy among others, the ability to tolerate a deflated cuff for at least 12 hours. They recommended that a fenestrated uncuffed tube be used while weaning. If tolerable to the patient, a digital occlusion of the tube or the insertion of a one way valve is applied for at least 10 minutes and to assess for signs of respiratory distress, decrease in oxygen saturation, stridor and to allow the patient to adapt to breathing through the mouth and nose. The authors suggest in proceeding for longer occlusion times if the patient is able to thus far. This includes further occlusion for 12 hours, followed by a rest overnight. Then an occlusion trial for 24 hours is followed by a collaborative assessment to determine whether the patient can have their tube fully removed. The authors concede that there is a lack of research to demonstrate the benefit of occasional capping over three days before 24hr occlusion and recommend that "the weaning procedure is carried out at a pace that fits with the patient's ability to maintain occlusion." [14]*

ii. Patients in the ICU

✸ *A review article described a systematic method for tracheostomy progression for patients in the ICU in 2014. The purpose was to support critical care nurses as facilitators to "execute a planned and systematic approach to downsizing and decannulation." 10 steps were identified for decannulation in the ICU following resolution of the need for a tracheostomy tube. Steps 1-4 involve the patient is ready for weaning trial (such as hemodynamic stability, effective coughing etc...) Further steps involve deflating the cuff for 24 hours with replacement to a cuffless tube or tight to shaft tube if tolerated. If the patient continues to respond positively, a capping trial of 24 to 48 hours can be initiated. A second 24 hour trial is then recommend if the patient does not show any further signs of respiratory distress. If the first capping trial is not tolerated, they recommend removal of the cap and vigorous suctioning and a return to the tracheostomy collar. The process is reviewed and attempted again. Once a*

second 24 hour trial is completed, they recommend re-evaluating the cough strength prior to full decannulation and covering of the stoma. The process described was systematic and rationales were provided, though no levels of evidence were used to support each step. It is unknown whether this particular stepwise approach was evaluated [15].

- *A prospective study in 2009 described the decannulation practice and failure in a tertiary hospital between 2002 and 2006. Of 823 decannulation decisions in critically ill patients who required support with mechanical ventilation or airway secretion clearance, 40 were unsuccessful, with a failure rate of 4.8%. This did not include patients followed by ENT. The group of failed decannulation did not differ from the group that was successfully decannulated in age, gender, tracheostomy procedure, tube type or size. They different significantly only in the median duration of tracheostomy insertion which was longer in the failed group (29 days) compared to 15 days in the failed group. Most patients who failed decannulation were recannulated within 18 hours (median time). In addition, the most common reason for failed decannulation was sputum retention (in 21 patients). No mortality was associated with decannulation in the 4 years of study. The authors did not describe in detail their weaning strategy. They indicated that if patients met the criteria for decannulation, the cuff was deflated, and the airflow was checked. They did not provide criteria for decannulation, nor how the airflow was assessed. If airflow was satisfactory, the tube was removed very soon after. If there was poor airflow around the tube, they mentioned that a consultation to ENT could have been made, though they did not describe how many consultations were actually made. They concluded that based on their low decannulation failure rate, "an assessment by experienced clinicians is an appropriate approach for making decannulation decision in patients with tracheostomy post-critical illness." They also did not provide the experience level of the clinicians involved [5].*

- *A 2000 article reviewed the different options for weaning and decannulation of patients in the ICU, with disclosure that guidelines are unclear. The authors presented multiple options for weaning and decannulation, but provided few details. For example, they describe that once a patient has been weaned from mechanical ventilation, deflation of the tracheostomy balloon should occur. Following this, inspection of the upper airway and trachea for edema can follow, although they mentioned that this can be skipped should the patient be able to tolerate an occlusion (with a cap or one way valve) for 24 hours with continuous monitoring. If this is tolerated by the patient, the authors report that decannulation can occur. Decreasing tube size was presented as an option to decrease irritation of the upper airway tract, or the use of stomal stents or a fenestrated tube can be used an as alterative. Given the multiple approaches with unclear supporting evidence, the authors conclude that "despite the method employed in decannulation, a standardized, institution-wide method appears to be more effective than a random one that varies from patient to patient." [16]*

iii. Patients with prolonged mechanical ventilation and/or neurological muscular weakness and/or upper airway obstruction

- *A 2015 review article presented factors to be considered before making the decision to decannulate patients with upper airway obstruction, prolonged mechanical ventilation and patients with neuromuscular insufficiency. In all patients, stable vital signs, effective cough, absence of infections, no significant abnormality on chest x ray, presence of at least partial swallowing and the absence of respiratory tract obstruction needed to be satisfied before decannulation. They recommended that to determine the patency of the airway, a fully deflated cuff followed by digital occlusion of the tube can be performed. A patient that is able to tolerate this can be safely decannulated or proceed to a capping or one way valve occlusion trial. They did not specifically define a time for the trial, though a period of 12 hours was presented in an algorithm included in the article. If the patient is unable to tolerate digital occlusion, they recommended the use of endoscopy to assess the airway. Decreasing the tube size with a deflated cuff can then be preceded by another capping trial. In patients who have endured prolonged weaning they suggested a multidisciplinary approach to weaning where the criteria for weaning remains the same but may require more time, such as an addition 24 hour capping trial and in cases of neuromuscular insufficiencies peak cough flow may also need to be considered as well. The authors stated that not all patients are suitable for weaning and an individualized approach may be warranted given the complexity of the patients' condition [17].*

✸ *The authors of a 2012 prospective cohort study wanted to determine the relationship between cough peak flow (CPF) values before and after decannulation. 26 patients with diagnoses of muscular weaknesses had Passy-Muir valves or caps applied to the tube and were asked to cough forcibly unassisted, with lung volume recruitment and a manually assisted cough 24hrs prior and when possible within 24 hours of decannulation. All the patients had tracheostomy tubes that were cuffed, and had a median inner diameter of 7mm, and outer diameter of 10mm. 21 used non-fenestrated tubes while 5 had fenestrated tubes. The authors demonstrated an increase in CPF after tracheostomy decannulation. The authors did not explicitly state the decision-making related to the application of a cap vs. Passy Muir valve, and for how long the patients were capped [2].*

b. Articles with a focus on a single weaning technique

i. Single-stage decannulation

✸ *A 2015 retrospective study reviewed the medical records of adult patients who underwent traditional decannulation versus single stage decannulation in one hospital. Percutaneous dilatation tracheostomy was performed, with a Portex cuffed tracheostomy tube inserted without fenestration, with an inner diameter of 7.5-8mm for a majority of all patients. Both groups met indications for decannulation which included a mature tracheostomy (over 7 days), normal vital signs, effective cough, normal swallowing and a positive leak test (air passage around the deflated cuff). The single stage decannulation group then underwent 3 endoscopies, including nasolaryngeal, then with removal of the tube, 2 views through the stoma. If all measures were within normal limits, the tube was not returned and a dressing applied to the stoma. Patients were observed overnight in the ICU and discharged if stable. For the control group, a reduction in tube size and/or capping trial for breathing and speech production was initiated. The length of trial time was not discussed in the article. Endoscopy was not routinely done, and was left at the discretion of the clinician. The single stage decannulation group had lower rates of complication (respiratory distress, pneumonia, and reinsertion of tube) 24 hours post decannulation and shorter hospital stays (1 day vs. 20 days) compared to the traditional decannulation group. Despite a small sample size, lack of procedure related details from the medical records, and sampling from one centre, the authors concluded that "immediate decannulation is safe and feasible" with higher complication rates in the traditional weaning group [18].*

ii. Tracheostomy retainer/button

✸ *In 2012, the use of a tracheostomy retainer (TR) was assessed for practicability and clinical value in patients with prolonged weaning and persistent respiratory failure. In a retrospective analysis of 384 patients with prolonged weaning and insertion with percutaneous tracheostomy, 166 had successful insertion of a TR. These patients were intubated for a median of 7 days prior, and had a tracheostomy tube in place for 31 days. The reasons for intubation were varied and mostly due to cardiopulmonary failure (including COPD) and pneumonia. In 80.6% of patients with TR, the first or second decannulation was successful; however, the weaning process was not described. Non-invasive ventilation (NIV) was used after decannulation in 81% of these patients. Patients who required recannulation had lower P_{aO2}, were older, had higher creatinine levels and had higher severity and mortality scores (SAPS II). They also had a shorter time period of spontaneous breathing, and shorter percent time periods of spontaneous breathing within the last 24-48 hours prior to decannulation. The authors were able to demonstrate that a TR may facilitate a high success rate of decannulation while retaining an option for effective NIV for patients with persisting respiratory failure. However, they concluded that "these results are only observational; they should be validated in prospective clinical trials." [4]*

c. Capping trial length

Table 1: Length of capping trial prior to decannulation described in the literature			
Patient population	*Technique*	*Time*	*Reference*
Not specified	Digital occlusion	≥ 30 minutes	[7]
	One way valve or cap	24-72 hours or unknown	[3, 6, 8, 10, 11, 19]
	Digital occlusion + Cap	≥ 10 minutes or unknown + 12 hours, overnight rest + 24 hours	[6, 12, 14]
ICU patients	Cap	24 hours	[13]
	Deflated cuff + cap	12-24 hours, + 24-48 hours + 24 hours	[15, 20]
Neuromuscular weakness, prolonged ventilation, upper airway obstruction	One way valve or cap	Unknown	[2]
	Digital occlusion + one-way valve/cap	Unknown +12 hours + 24 hours if warranted.	[17]

3. Additional sources:

- *The Joanna Briggs Institute provides a summary for decannulation in 2013. It recommends a deflated cuff for 24 hours during which O_2 Saturation is maintained. Patients are to be continuously monitored for a further trial of capping for 24 hours prior to tube removal. This was supported with Level 5 evidence, which are clinical practice guidelines [20].*

- *An Uptodate article provided an overview of clinical issues related to tracheostomy decannulation. The literature was updated as of November 2015. The authors recommended that once a patient has successfully weaned from mechanical ventilation and has adequate cough, controlled secretions and absence of upper airway obstruction, readiness for decannulation can take place. This may involve decreasing the tube size or by capping a fenestrated tube for periods of 12 to 72 hours. A tracheostomy plug was mentioned as an option for patients with borderline clearance of secretions, those that require maintenance of the stoma for a prolonged observation period, or those that have undergone Percutaneous Dilatational Tracheostomy [19].*

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