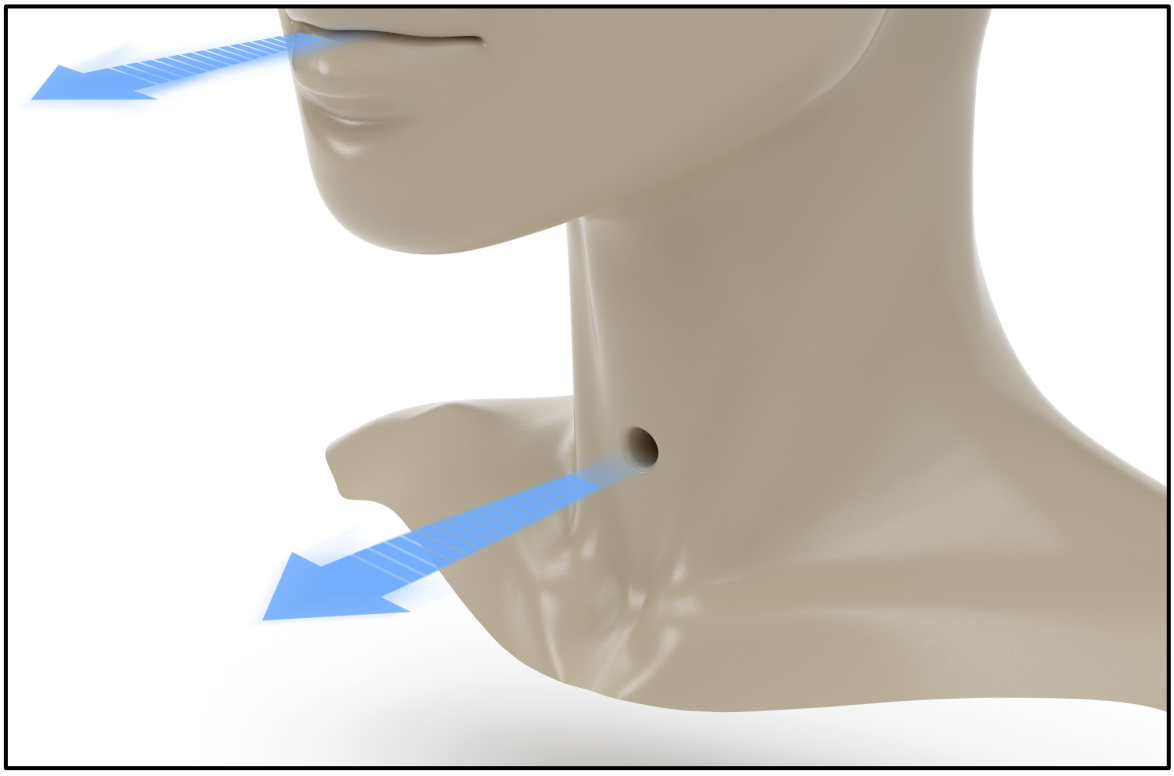
Consequence of open versus closed tracheostomy immediately after decannulation.



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Introduction

The larynx organ (voice box) is located in the upper airway. The larynx houses the vocal folds and regulates airflow, which is essential for phonation, expiratory airway pressures and cough efficacy. A tracheostomy is an artificial opening of the airway, which is performed in the tracheal frontal wall below the larynx organ. The tracheostoma is afterwards kept open by a tracheostomy tube for prolonged mechanical ventilation or for the purpose of bypassing an obstruction of the upper airway, e.g. a tumor or inflammatory swelling.

When the tracheostomy is no longer needed, the tracheostomy tube is removed; this procedure is known as decannulation. After decannulation the trachostoma will be covered by an external bandage, and the wound will be left to close spontaneously (Figure 1). Airflow will continue to bypass the larynx until the tracheostoma is closed to a level of airtightness. In the meantime, to enable speech and cough function, patients are instructed to apply pressure on the bandage with their fingers (Figure 2). The tracheostoma usually closes within a few days to weeks. However, surgical closure may become necessary [1]. The surgical approach is complex with a risk of developing subcutaneous emphysema [2]. Decannulation is an important step in the patient's rehabilitation, especially after prolonged mechanical ventilation [3].

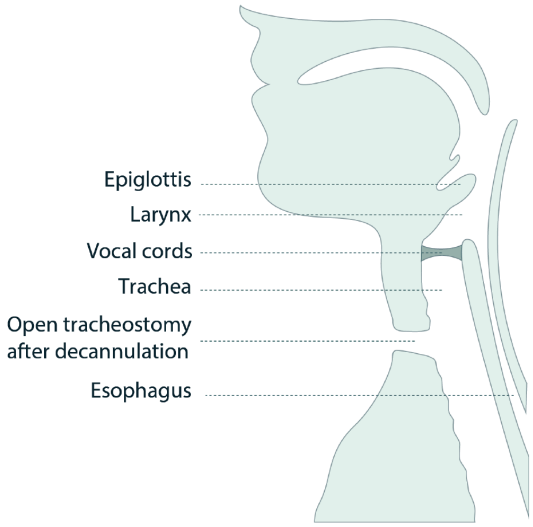

Figure 1: Open tracheostomy after decannulation.

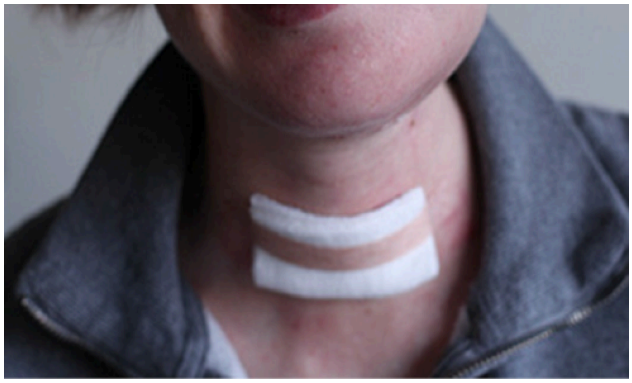

Figure 2: Neck bandage after decannulation.

Hypothesis

- It is possible to restore/increase airflow in the upper airway with a temporary silicone closure disc immediately after decannulation.
- Cough strength and speech function is significantly improved with the temporary silicone closure disc

Aims

We aim to measure expiration of airflow through mouth and evaluate cough strength and speech on patients with an open versus closed tracheostoma. Closure of the tracheostoma is achieved by insertion of a temporary seal immediately after decannulation.

Method

Population

20 patients from Intensive Care Unit or the Department of Otorhinolaryngology, Head and Neck Surgery at Aarhus University Hospital subjected to tracheostomy decannulation will be included.

Inclusion criteria

- Tracheostomy for minimum 7 days.
- Age > 18 years.
- Capped uncuffed tube size 7 or 8 for at least 24 hours.

Exclusion criteria:

Cognitive dysfunction (patients who are not able to cooperate with investigation)

Day 1.

1. Patients receive oral and written information.

Day 2.

1. Informed consent is obtained.
2. Decannulation will follow standard procedure described in the hospital guideline.

3. Patients will be asked to speak and cough. Spirometry will be performed.
4. Insertion of temporary closure seal “type 1”.
5. Patients will be asked to cough and speak. Spirometry will be performed again.

There will be an option for 2 different degrees of softness: Type 1 “shore 50” and Type 2 “shore 60” (Figure 3).

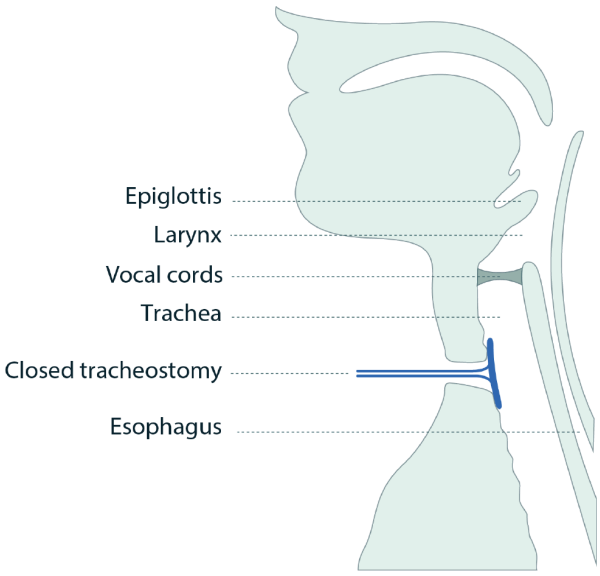

Figure 3: Tracheostomy closed by silicone disc.

Glottic abnormalities and insertion of the first seal will be evaluated by endoscopic visualization. The endoscopy will be removed before spirometry test with the seal in place. In case of audible signs of insufficient sealing (weak voice and sound from the tracheostoma) seal type 2 will be tested. The rod will be anchored by 2 separate medical clamps outside the neck. See figure 4 and 5. Furthermore, a handheld newton meter will be attached to ensure and measure a constant force on the seal

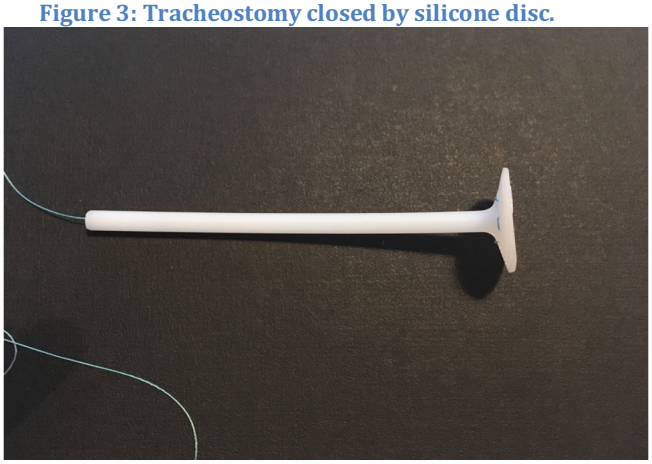

Figure 4: Photo of sealing disc with safety thread.

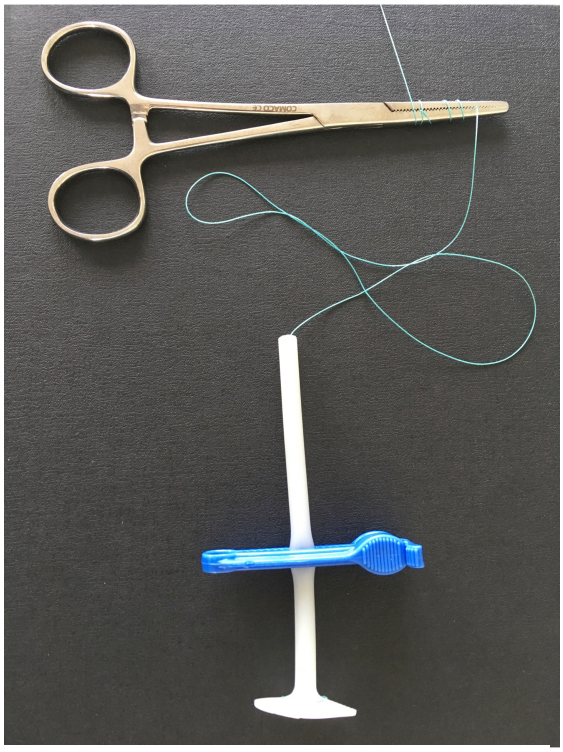

Figure 5: Sealing device with 2 safety clamps.

Number of Patients

To our knowledge, no other study has investigated the consequence of air leakage from a tracheostoma. Therefore, our sample size is based on few other studies on airway physiology related to tracheostomy decannulation. A study from 2002 investigated physiological effects of decannulation in tracheostomized patients with a taped dressing outside the neck; 9 patients were included in that study [4]. Two studies in peak cough flow parametres included 16 and 26 patients, respectively [5, 6]. With reference to these 3 studies, we have chosen to apply for inclusion of 20 patients. When we have conducted tests in 10 patients, we wish to perform an interim analysis to evaluate the significance of differences in airway physiology with open tracheostoma versus closed tracheostoma.

Risks, side effects and disadvantages

The procedure will take place at the specialized treatment room in the Intensive Care Unit, Aarhus University Hospital, where all safety equipment for airway intervention is available and ~~under supervision of~~ specialists in anaestesiology will supervise. Local anesthesia (xylocain spray) is applied through nose and into the tracheostoma, if the patient requests so. The seal will be sprayed with sterile saline water to minimize friction prior to insertion. Louise Devantier (MD, Department of Otorhinolaryngology, Head and Neck Surgery) and Thomas Pasgaard (MD, Department of Anaesthesiology and Intensive Care at Aarhus University Hospital) will perform the technical procedure in cooperation. Both physicians have thorough experience with tracheostomy. The patient may experience tickling cough during procedure. The insertion of the temporary closure seal is estimated to last 2 minutes.
Risks for obstruction of the airway is mitigated by clamps and holding string.
The seal and rod are made of medical grade silicone. A thread for safety precaution is attached to the seal. The thread will be anchored to a medical clamp before insertion. Total procedure is performed without removal of the clamp. In addition, the rod will be kept in place by a second clamp and manual hold during procedure.

Additionally, design of the seal has taken the risk of airway obstruction into account. The seal dimension takes up max one third of the tracheal lumen. Average cross sectional area of the male adult trachea is approximately 2,8 cm^2. The seal is 1 mm thick and a diameter of 26 mm.

With this dimension the seal will take up maximum 1/3 of the cross section area of the airway. The cross sectional area of a trachestomy tube size 7 and 8 is 0,865 cm^2 - 1,11 cm^2, respectively. While the material is flexible, the material and design ensures that the seal will stay in upright position despite some degree of tensioning from outside the neck. The device has been manufactured by Prolink Sourcing and Trading; a company experienced in manufacturing medical silicone devices.
The seal and tube for insertion will be packed and sterilized locally at Aarhus University Hospital and the procedure will be performed according to standard clinical hygiene precautions and standard handling of tracheostomy.

Spirometry

Having the patient in a relaxed sitting position with both feet flat on the floor, the procedure consist of breathing through a mouthpiece with a nose clamp. Before performing the forced expiration, tidal (normal) breaths can be taken first, then a deep breath taken while still using the mouthpiece, followed by a further quick, full inspiration. Data collected by ~~a~~spirometry. 1) Forced expiratory volume in 1 s (FEV1). 2)Forced vital capacity (FVC), the maximum amount of air that can be exhaled when blowing out as fast as possible. 3) Vital capacity (VC), the maximum amount of air that can be exhaled when blowing out as fast as possible. 4) FEV1/FVC ratio. 5) Peak expiratory flow (PEF), the maximal flow that can be exhaled when blowing out at a steady rate. 6) Forced expiratory flow, also known as mid-expiratory flow; the rates at 25%, 50% and 75% FVC are given. 7) Spirometry is generally a safe test. Some patients may feel a brief shortness of breath or dizziness after performance of the test.

Upper-airway endoscopy

Endoscopy (nasolaryngoscopy) uses a small flexible telescope. The scope is passed through the nose and into the throat. This is the most common method for examination of the voice box. The patient is awake during the procedure. Numbing medicine will be sprayed into nose and throat on request. This procedure typically takes less than 1 minute.
Endoscopy visualization of the upper airway is standard procedure at decannulation in our Ear Nose and Throat department.

Evaluation of cough and speech

In the newly decannulated patients, cough and speech is challenged (impaired) due to the artificial opening below the glottis. In order to evaluate cough strength, the cough strength scoring tool adopted from Duan et al [7] will be used . The scoring cough pattern ranges from 0 – 5:

- 0= no cough on command
- 1= audible movement of air, but no audible cough
- 2= weakly (barely) audible cough
- 3= clearly audible cough
- 4= stronger cough
- 5= multible sequential strong coughs.

A similar tool (Likert scale) will be used to evaluate speech function.

Data collection from the patients' medical journal

In order to assess any unforeseen risks for the patients, we will assess the patient medical journal for an overall assessment of inclusion into the study. Furthermore, we will record age, sex, cannulation time, verification of tube capping time, tube size and tube product supplier, neurologic, height and weight.

Information to trial participants

Trial participant will orally and in writing receive detailed information of the study in which they will participate. Written information includes the "Information to trial Participant" and "Your Rights as a trial participant in a biomedical research trial" from the Central Scientific Ethical Committee. A doctor gives the detailed oral information. This is done in closed room and the presence of an observer will be optional. The doctor must ensure that the participant has read and understood the above-mentioned material before the participant signs the trial consent form. Patients will have at least 24 hours of time for reflection before decision. The participants are informed that the consent form may be withdrawn at any time without justification.

Data storage and notification of authorities

All data will be stored and handled in accordance with the legislation on data storage and data security. The participant's data are logged under a participant number, and a participant list is created where consistency between the participant number, participant name, and social security number is documented. The participant list and participant data are archived separately. Data and documents related to the study will be stored for 5 years after completion of the project. The project will be registered in Region Midt internal records of research projects. Within 90 days after the end of the study, the Research Ethics Committee will be notified. The above mentioned authorities will be informed within 15 days if the study for some reason ends sooner than planned.

Ethics

Before the inclusion of project participants the Region Midt Research Ethics Committee must approve the project. The act regarding handling of general data protection regulation and the data protection act will be respected. Participants will receive both written and oral information prior to study entry and it will be highlighted that participation is voluntary.
If trial staff during the trial become aware of the health concerning information that is relevant to the participants, e.g. results from the test, it will not be possible for the participant to refuse this information, as we will not be able to vouch for the consequence of withholding such information. We will inform of this at the information interview, and the participant must agree to these terms to participate in the project.
Potential benefit for the individual patient and future patients overweight the potential small risk for the participating patients. Participating patients will receive enhanced observation, caution and ventilation assess compared to those undergoing normal procedure.

Information to project participants

Potential project participants will orally and in writing receive detailed information of the study the day prior to decannulation. Written information includes the "Information to trial Participant" and "Your Rights as a trial participant in a biomedical research trial" from the Central Scientific Ethical Committee. A doctor gives the detailed oral information. This is done in

closed room and the presence of an observer will be optional. The doctor must ensure that the participant has read and understood the above-mentioned material before the participant signs the trial consent form. The participants are informed that a given consent may be withdrawn at any time without justification and without any consequences for the patient.

Exclusion of participants from the trial / stopping of the trial

Trials Participant may at any time during the study withdraw their consent form. A doctor will address unforeseen side effects or events. Trial participants that do not meet the inclusion criteria will not be included in the trial.

Procedures if a participant leaves the trial

If a trial participant for one reason or another leaves the study is completed a new volunteer will be recruited to replace the discontinued participant. This will be done by the same procedure as the other inclusions. There will be no further follow-up for discontinued participants.

Financing and responsibilities

Reinhold Helbo Jensen, consultant, is the main supervisor and initiator of the project. Louise Devantier and Karen Juelsgaard Christiansen are in charge of the daily management of the project. Reinhold Helbo Jensen and Thomas Pasggard will be in charge of the enrolment of participants. Louise Devantier, Thomas Pasgaard and Michael Pedersen will be in charge of data analyses and dissemination of the results.

An Exploratory pre-seed grant from the Novo Nordisk Foundation has supported (350.000 DKK) the production of a seal suitable for temporary closure test of a tracheostomy immediately after decanulation. The Danish Medicine Agency has been contacted in order to clarify our obligation to notify the tracheostoma sealing disc, which is not a commercial product. The sealing disc has been developed for the purpose of the present study. Generation of data may be useful in a development of a new device for sealing a tracheostomy, however without direct economic benefit from our study. Karen Juelsgaard is beside her job as critical care nurse in ICU and project nurse at Comparative Medicine Lab engaged with the development of a new device for tracheostomy.

The patients will be covered by Aarhus University Hospital's patient insurance fund in case of any unforeseen event or side effects originated from the study.

Time-frame

The main time frame of the project will be:

- Inclusion of study participants is intended to begin in June 2019.
- Data collection is expected to be completed no later than June 2022.

Publication

Any reference to or publication of the results from the study can only take place with mutual agreement of the project participants. Project participants will cooperate to have the results published with respect to the Vancouver criteria. Regardless if the results are negative, positive or inconclusive it will be published. We aim to publish in international journals preferably with open access.

References

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