Official Title of Study: CPAP to Improve Swallow Function Post Total Laryngectomy

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Attached is the UC Davis IRB approved Protocol and there have been no protocol changes since 2016.

Sincerely,

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PROTOCOL TITLE: Utilization of Continuous Positive Airway Pressure to Improve Swallow Function in Patients Post Total Laryngectomy

1) Protocol Title

Utilization of Continuous Positive Airway Pressure to Improve Swallow Function in Patients Post Total Laryngectomy
Version date: 5.3.16

2) Objectives

To determine whether use of Continuous Positive Airway Pressure (CPAP) can improve the swallow function in patients who underwent total laryngectomy and are experiencing difficulty swallowing.

3) Background

Total laryngectomy is a procedure that involves surgical removal of the larynx and separation of the digestive and airway tracts. The procedure is typically conducted for cases of laryngeal cancer and intractable aspiration. Following this procedure, patients are no longer at risk for aspiration; however some patients continue to experience difficulties in propulsion of food or drink throughout the pharynx. These difficulties can result from pharyngeal neuromuscular damage caused by surgery and radiation (1). Previous research has demonstrated a reduction in pharyngeal contractile pressure and increased pharyngeal transit time in patients post laryngectomy (2,3). Continuous Positive Airway Pressure (CPAP) may assist bolus propulsion in these patients by increasing pressure in the direction of bolus flow. This study aims to evaluate the utility of a CPAP mask to improve pharyngeal swallow outcomes in patients with dysphagia following total laryngectomy. This specific population could be well-suited for this application, since the digestive tract and airway are completely separate and there is no risk of the aspiration into the airway.

4) Inclusion and Exclusion Criteria

Inclusion criteria:

- Age ≥18 years.
- Patients at least 2 months after total laryngectomy undergoing a dynamic swallow study (DSS).

Exclusion criteria:

- Patients with 100% neopharyngeal stenosis
- Patients with active cancer within 2 months of the study
- Patients with pharyngocutaneous fistula
- Vulnerable population:
  - Adults unable to consent
  - Individuals who are not yet adults (infants, children, teenagers)
  - Pregnant women
  - Prisoners

5) Study Timelines

The subjects will be in study from the time they sign the consent form to completion of the videofluoroscopy study. Approximately 5 additional minutes will be added to each subject's clinical DSS study, with no more than 1-2 seconds of additional fluoroscopic exposure The estimated date of complete of the study will be 12 months after IRB approval.

6) Study Endpoints

Primary endpoint of the study is complete videofluoroscopic data for all 10 patients.

7) Procedures Involved

Each subject will undergo a standard DSS for the purpose of medical diagnosis. The research study portion will be incorporated into the procedure for patients who consent to participation in the study. The dynamic swallow study is a radiologic examination of swallowing function using fluoroscopy. Standard examinations consist of multiple radio-opaque boluses of different consistencies. During a standard videofluoroscopic study, subject are asked to

swallow barium-coated foods of the following volumes and consistencies in side and front view. Swallows can be added to the protocol in order to assess clinical questions relevant to each specific patient.

Lateral Plane

- 1 ml liquid barium (X2)
- 20 ml liquid barium (X2)
- 60 ml thin liquid barium consecutive sips via straw
- 3 ml pudding

Anterior-to-Posterior Plane

- 20 ml liquid barium
- 13 mm barium tablet

In order to minimize exposing participants to additional radiation during this this study, the patients will be asked to wear the CPAP mask during standard swallows test for one of the two swallows of the following consistencies in side view:

- 1 ml thin liquid barium
- 20 ml thin liquid barium

One additional 3ml pudding bolus swallow with the CPAP mask will be added in order to compare swallow function of a pudding consistency with and without the CPAP. This additional swallow will add no more than 1-2 seconds of videofluoroscopic exposure time.

8) Data and/or Specimen Management and Confidentiality

The measures explained in the online application will be taken to protect the confidentiality of subjects.

Videofluoroscopic data collected from the above protocol will be analyzed by paired sample T test and repeated measures of analysis of variance. Data will be stored anonymously and securely, accessible with a password available only to participating researchers.

9) Data and/or Specimen Banking

N/A

10) Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A. This study does not pose more than a minimal risk to subjects.

11) Withdrawal of Subjects

Subjects unable to complete the entire protocol may be withdrawn from the study and not included in data analysis.

12) Risks to Subjects

Patients are undergoing the videofluoroscopic procedure as standard of care. One additional swallow will be added to the standard protocol, adding a minimal 1-2 seconds of fluoroscopic exposure time.

The risks of the CPAP device include skin irritation, dry mouth, nasal congestion. These risks are unlikely to occur during this study in which patients will be wearing the mask for only several minutes. Subjects may experience stomach bloating. Subjects may experience discomfort from wearing the mask.

13) Potential Benefits to Subjects

No direct benefit to participating subjects is anticipated.

14) Multi-Site Research

N/A

15) Sharing of Results with Subjects

Results will not be shared with subjects.

16) Prior Approvals

Radiation Use Committee approval was obtained before IRB submission

17) Provisions to Protect the Privacy Interests of Subjects

Subjects will undergo the protocol privately with a limited number of qualified personnel present. Beyond determining eligibility as described above, no personal or medical information will be sought from participants. The procedure will be limited to only what is described in the above protocol. Only qualified research personnel working on the project will access subjects' secure data, which will be password-protected.

18) Compensation for Research-Related Injury

N/A. The study procedure does not pose more than minimal risk to subjects.

19) Economic Burden to Subjects

N/A

20) Drugs or Devices

N/A

References

1. Zhang T, Szczesniak M, Maclean J, Bertrand P, Wu PI, Omari T, et al. Biomechanics of Pharyngeal Deglutitive Function Following Total Laryngectomy. Otolaryngol--Head Neck Surg Off J Am Acad Otolaryngol-Head Neck Surg. 2016 Apr 26;

2. McConnel FM, Mendelsohn MS, Logemann JA. Manofluorography of deglutition after supraglottic laryngectomy. Head Neck Surg. 1987 Feb;9(3):142–50.

3. McConnel FM, Cerenko D, Mendelsohn MS. Dysphagia after total laryngectomy. Otolaryngol Clin North Am. 1988 Nov;21(4):721–6.