Establishing normative values for swallow strength and timing in hospitalized patients

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This study aims to provide normative values for sEMG swallow function. Clinicians using sEMG for clinical and research purposes may use this data for a more complete understanding and interpretation of their results. Individual results and changes...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46394

Source
ToetsingOnline

Brief title
ENVSH

Condition

- Other condition

Synonym
difficulty swallowing

Health condition

Dysfagie, onafhankelijk van de oorzaak, betreft verschillende klassen

Research involving
Human

Sponsors and support

Primary sponsor: Zuyd Hogeschool, Heerlen
Source(s) of monetary or material Support: SilverFit apparatuur en stickers voor sEMG

Intervention

Keyword: hospitalized patients, normative values, swallowing strength, swallowing timing

Outcome measures

Primary outcome

Quantitative parameters will be described by mean ±SD. Comparisons will be analyzed using The Statistical Package for Social Sciences (SPSS, Inc., Chigaco, IL, USA) version 23. Qualitative parameters will be described by relative and absolute frequencies. Statistical significance was accepted if p-values were < 0.05.

Accuracy of identification of OD is assessed by comparing the results from the EAT 10 and V VST.

The difference between the average peak sEMG from the first and the last 3 swallowing events during the test period at the patients* maximal level will be calculated for swallow strength and timing. All sEMG data will be stored in an anonymzed way for later off-line analysis. Group analysis based on hospital wards will be shown through descriptive statistics and group differences will be tested through ANOVA with Tukey posthoc tests (significance when p< 0.05).

All data will be used to establish normative values for hospitalized patients.

Secondary outcome

Demographic data (gender, age, reason for hospital admission, length of hospital stay, medical history data related to potential dysphagia, any

treatment limitations) will be recorded. Also, drugs (and dosages) that could impair swallowing function, e.g. anticholinergic drugs like antipsychotics will be recorded (appendix 4).

This information will be derived from the patient*s medical record prior to recruiting the patient. In addition we will record the time of day of the test, because this may be an important factor due to patients* fatigue and concentration capacity. Also oxygen saturation by means of finger pulse oximeter will be obtained.

Study description

Background summary

Oropharyngeal dysphagia (OD) is defined as difficult and/or disordered swallowing of food (semisolid or solid), liquid or both and is a risk factor for developing malnutrition, dehydration and community acquired pneumonia1. In hospitalized patients OD has been associated with prolonged length of hospital stay and increased risk of pneumonia, reintubation or death, imposing a significant burden on patient well-being and healthcare costs.
Despite growing awareness of OD, a lot remains unknown regarding its prevalence, incidence, pathophysiology, diagnostic testing and treatment options.
Few studies have reported the prevalence of OD in hospitalized patients with an overall prevalence of OD ranging from 5% to even 75% in elderly patients admitted with a community acquired pneumonia.
There is a significant variability in the instrumentation used to objectively establish and measure dysphagia, ranging from bedside screening methods, like the Eating Assessment Tool (EAT-10) and the Volume-Viscosity Swallow test (V-VST) to the highly sensitive and specific but invasive videofluoroscopy (VFS) and the Fiberoptic Endoscopic Evaluation of Swallowing (FEES). Recently the non-invasive method of surface electromyography (sEMG) is used to characterize swallowing function concerning muscle activity in people with OD. During swallowing more than 25 muscle pairs are used. sEMG is a non-invasive method to measure muscle activity patterns of muscles used during swallowing. Thereby the occurrence of swallowing and its physiology can be described. These signals may be used in individual patients to evaluate changes in swallowing function. sEMG has shown to be a promising tool to improve swallowing function

in patients with OD. sEMG is an intuitive, interactive way that uses biofeedback and assists people with OD to perform swallowing exercises more elaborately. sEMG is a fairly new early-intervention method, used in hospital settings by speech and language therapists (SLT).
The effects of swallow exercises with sEMG can improve swallow function and therefore quality of life.
In order to optimally use a sEMG program in dysphagia rehabilitation in hospitals it is essential to understand sEMG scores on an individual as well as a group level. Therefore sEMG programs should provide normative values of swallow characteristics (e.g swallow strength and timing).
Characteristics of sEMG values of people with and without OD should be known to be able to compare swallow strength and swallow timing of both groups with each other. Thereby clinicians can evaluate 1) how deviant the swallow pattern of the person with OD is in comparison with peers and 2) at which point the swallow is accurate enough and treatment can be stopped. In existing screening tools (e.g EAT-10, V-VST) the risk of OD can be detected, but no objective information of swallow strength and timing can be derived. The provision of these objective swallow characteristics enables clinicians to set adequate goals for treatment.

Study objective

This study aims to provide normative values for sEMG swallow function. Clinicians using sEMG for clinical and research purposes may use this data for a more complete understanding and interpretation of their results. Individual results and changes in swallow function of hospitalized patients with OD may hereby be placed within the broader context of normative values which contributes to the quality of dysphagia care in hospitals. Prior to this study similar data was collected in Gelre hospital in Apeldoorn in 2017. We plan to combine this data with our data in a database to establish a representative sample of normative values of swallowing.

Objective
1) To establish normative values for swallow strength and timing in hospitalized patients.

Study design

Prospective, observational, mono-center study.

Study burden and risks

The sEMG measurement with Rephagia takes between 10 and 15 minutes altogether, depending on the capabilities of the patient. This non-invasive measurement takes about 20 minutes with a maximum of 30 minutes for the patient to complete the full protocol (EAT 10, V VST and sEMG).

At any time a break can be taken or the measurement can be stopped completely if this is the desire of the patient. Even though this measurement is scheduled on a convenient time for the patient and other hospital staff, this measurement will be stopped in case of acute care or family visits. If the patients like to continue at another time a new appointment will be scheduled. If the measurement is stopped during a specific part, it will be picked up from that part (e.g. Rephagia swallow strength). Already collected data will not be repeated.
There are no expected risks to participation in this study. Very vulnerable or at risk patient for OD are excluded beforehand. Any illness affecting swallow ability like extreme cold or influenza, are also part of the exclusion criteria. When swallowing water, choking can occur and the residue will be coughed up. Choking on water is not pleasant, but in itself not dangerous and can happen spontaneously with any swallow.19,20 Choking on other foods or liquid than water is more harmful, therefore strict use of water is chosen for this protocol and only a small bolus (max 20 ml) is offered to the patient.19,20 Researchers are trained in handling choking incidents of choking in water and medical staff is nearby.
The placement of the sensor on the throat can feel a bit strange, but is safe and so far in previous studies like in Gelre hospital there has been no record of complains of the material.
In case of oversensitive skin or wounds in that area, patients will be excluded. Since patients are expected to swallow frequently throughout the measurement, fatigue can occur. In case of fatigue a break can be taken or the measurement can be stopped completely. In the study in Gelre hospital fatigue was not reported as a common side-effect of the study.

The Gelre study showed that patients overall thought the measurement was quite pleasant and enjoyed the kangaroo game in particular. We have no reason to expect that the Zuyderland population will report different experiences.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 18 years
- Admission duration >24 hours. Patients need to be admitted at least 24 hours before they will be asked to participate. This way people are already settled in and their own treatment plan will already be discussed with them. By respecting a minimum of 24 hours hospital stay, participation to this study will not interfere or distract them from their acute care
- Normal diet
- Stay at the following hospital wards: General Internal Medicine; Cardiology; Pulmonology; General Surgery; Geriatric; Neurology

Exclusion criteria

- No informed consent
- Severe dysphagia (score >2 EAT 10; score >1 V VST)
- No oral intake permitted or severe impairment of oral intake which prohibits participation to this study
- Severe illness which prohibits assessment of swallowing
- Permanent cognitive impairment or language barriers that prevents participation in testing and following instructions
- Patients admitted to general ward after ICU stay
- Presence of a beard (and unwillingness to shave off part of the beard in suprahyoid area) extreme hair growth in this region prohibits the sensor from accurately measuring swallow function
- Oversensitive skin and/or wounds in throat area
- Severe vision impairment which prevents seeing the swallowing cues in Rephagia

- Patients in isolation

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-02-2018
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL64658.096.18
Other	nog niet bekend