Prospective study on cost-effectiveness of the Provox®2 and the Groningen Ultra Low Resistance tracheoesophageal shunt prostheses in voice rehabilitation of post-laryngectomy patients.

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The objective of the study is a prospective study to evaluate which type of TE shunt prosthesis is the most cost-effective.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON29968

Source
ToetsingOnline

Brief title
Cost-effectiveness study on Provox®2 and Groningen ULR prostheses

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
Larynx carcinoma, laryngeal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cost-effectiveness, lifetime, prosthesis, quality of life., tracheo esophageal shunt

Outcome measures

Primary outcome

Lifetime of both types of TE shunt prosthesis

Secondary outcome

1. Total costs for the use of both the Provox®2 and Groningen ULR TE shunt

prostheses. An incremental cost analysis.

2. Quality of life

3. Evaluation of both types of prostheses

4. Preference of patients for one of both types of prostheses.

5. Experience with replacement and -technique.

6. Diet. Food products that influence lifetime of the TE shunt prosthesis

7. Expenses made by patient.

Study description

Background summary

Some of the patients with laryngeal cancer have to be treated with a total laryngectomy. During this procedure the whole larynx is taken out of the patient which means that after surgery speech rehabilitation will be necessary. In this rehabilitation a tracheo-esophageal shunt prosthesis (TESP) is used which is placed in a shunt between the trachea and the esophagus that is formed during the total laryngectomy. This TESP is made of silicone rubber and has a valve mechanism that can only be opened in the direction of the esophagus. This

opening happens when air is pushed from the trachea through the prosthesis into the esophagus while closing the tracheostoma with a thumb or finger. With this air sound is produced. In the Netherlands and the rest of Europe the Provox®2 and the Groningen Ultra Low Resistance (ULR) TESPs are most frequently used. Both have a limited lifetime and have to be replaced on a regular basis. The lifetime of the TESP varies between patients, per worn prosthesis and between types of TESPs. This was studied in a pilot (n=22) in our clinic: the mean lifetime of the Groningen ULR was 1,5 times longer than the mean lifetime of the Provox®2.
The burden on the patient of the replacement procedure is substantial. To replace the TESP a patient needs to visit an ENT outpatient clinic that has authorized personnel to perform the replacement. This means that numerous expenses have to be made for travelling and time. This influences the quality of life of the patient. Additionally the procedure itself can be very uncomfortable and can induce pain, minor bleeding, cough and gag reflexes.
Many patients prefer the Provox®2 TESP. First this is because of the replacement technique. The Provox®2 is anterogradely replaced through the tracheostoma, a relatively easy procedure. The Groningen ULR was previously replaced retrogradely through the mouth which was very uncomfortable for the patient. Nowadays the Groningen ULR is also replaced anterogradely with the *frontloading system*. A second reason why the Provox®2 was preferable is the higher resistance during phonation with the older Groningen type TESP. However the newer Groningen ULR has a speech resistance that is comparable to that of the Provox®2.
The price of the Provox®2 is between 250-300 euros and that of the Groningen ULR about 90-100 euros. The Provox®2 is also more expensive in use due to the more frequent need for replacement.
Hypothesis 1: the Groningen ULR and the Provox®2 are the same in terms of the replacement method, the burden on the patient and the convenience of the replacement and of the resistance during phonation.
Hypothesis 2: the Groningen ULR has a longer lifetime than the Provox®2 and is thus less expensive in use.
Hypothesis 3: the quality of life of the patient is higher while using the Groningen ULR than when using the Provox®2.

Study objective

The objective of the study is a prospective study to evaluate which type of TE shunt prosthesis is the most cost-effective.

Study design

A prospective randomized cross-over design with a group of 80 patients aged 45-70 out of our population of over 134 post laryngectomy patients that have been using a TESP for their phonation for at least six months. The patients are randomly divided into four groups according to the following schedule:

Group N Baseline Interval 0 Interval 1 Interval 2
1 20 G/P G G G
2 20 G/P G G P
3 20 G/P P P G
4 20 G/P P P P

G= groningen ultra low resistance
P= Provox®2

In this way, individual differences and preferences can be found.

Study burden and risks

The burden on the patient exists from filling in the questionnaires on set times during the two years of research. These questions are very non-invasive. There is no higher risk for the patient because in the techniques used this study are already standard techniques in our clinic and the rest of Europe. The patient can quit the study at any time, for example if a patient is very unhappy with the type of prosthesis used at one moment in the study, the patient can change to the prosthesis of his or her choice at any time.

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

Patients from our outpatient clinic (ENT, UMCG): post-laryngectomees that use a TE shunt prosthesis for their phonation. Patients have to have at least 6 months of experience with the use of the TE shunt prosthesis. Patient should be 45-70 years of age.

Exclusion criteria

Patients that have a metastasis or recurrence of their previous larynx carcinoma.
Patients with less than 6 months of experience with the TE shunt prosthesis.
Patients younger than 45 or older than 70.
Patients that currently smoke tobacco.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-02-2007
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	1: Groningen Ultra Low Resistance voice prosthesis;2: 2:Provox®2 voice prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-10-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL12933.042.06