Validation of a visual analogue symptom score - the LRTI (lower respiratory tract infections)-VAS- in non-CF bronchiectasis

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To assess the validity, reliability and responsiveness of the LRTI-VAS in non-cystic fibrosis bronchiectasis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON34926

Source
ToetsingOnline

Brief title
VAS-validation

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Irriversible dilatation of the large en medium-size airways.

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Foreest Instituut Medisch Centrum Alkmaar

Intervention

Keyword: Bronchiectasis, VAS

Outcome measures

Primary outcome

The results of the 4 questionnaires, correlated to lung function and arterial

ogygen saturation.

Validity, responsiveness en stability of the VAS-score.

Secondary outcome

nvt

Study description

Background summary

Bronchiectasis means irreversible, pathologic dilatation of the small and medium-sized bronchi, resulting from a vicious cycle of inflammation and bacterial colonization [1-3]. Although the etiology remains unclear in a large percentage of patients (53-60%), common causes include immune defects, early childhood infections, and aspiration [4-6]. Typically, the course of the disease is highly variable, including nearly symptom free periods interspersed with infective exacerbations.
A fairly large percentage of patients with bronchiectasis suffers from chronic complaints, such as productive cough, dyspneu and fatigue [7,8]. Infective exacerbations are characterized by worsening of symptoms and signs of pneumonia [9].
Although the disease was considered offensive and untreatable in the pre-antibiotic era, infections and symptoms are nowadays mostly well controlled with antibiotics and supportive therapy [10]. However, many patients with bronchiectasis today still experience feelings of embarrassment about their coughing or bronchorrhoea, sometimes leading towards social isolation.

Clinical measures, such as FEV1 or oxygen saturation often correlate only moderately with functional capacity and well-being of a patient with bronchiectasis [11-13]. The main determinants of a patients health-related quality of life (HRQL) appear to be the degree of dyspnoea and daily sputum production together with the number of infective exacerbations [14,15].

Measurement of symptoms and HRQL is therefore very useful in monitoring disease activity and assessing the impact of the disease on the patient*s daily life.
Clinical trials designed to evaluate the effect of treatment in pulmonary diseases also frequently use HRQL or patient-reported symptoms as outcome measures.
Nevertheless, only one specific HRQL-measure has been developed and validated for bronchiectasis, the St George*s Respiratory Questionnaire (SGRQ) [16].

We developed a symptom scale that can be used to quantify the degree of dyspnoea, fatigue, cough, pain and sputum colour in bronchiectatic patients.
The LRTI-VAS consists of a set of horizontal lines with two anchor points, one at each extreme, each line representing a different symptom. The VAS (visual analogue scale) is scored from 1 to 10, the subjects being unaware of the numbers. Higher scores indicate more severe symptoms. Other authors showed that a VAS-score allows reproducible measurement of breathlessness and fatigue in both normal subjects and patients [17-19]. Furthermore it has been shown to be sensitive to changes when measuring breathlessness [20].
The LRTI-VAS is significantly less time consuming than the SGRQ and has a low administrative burden. Because of its simple design, it is equally suitable for use in patients with reading difficulties or educationally subnormal patients.

Study objective

To assess the validity, reliability and responsiveness of the LRTI-VAS in non-cystic fibrosis bronchiectasis.

Study design

Part 1:
20 participants are studied on two separate days, 3 weeks apart, in a clinically stable situation (no infective exacerbations one month before study entry). At day 1 and day 21 each patient is asked to complete the VAS-score and a number of other HRQL- measurements; the SF-36 Health Survey Questionnaire, the St George Respiratory Questionnaire (SGRQ) and the Hospital Anxiety and Depression (HAD) scale. The questionnaires are presented to the patients in a randomized order.
On both occasions flow-volume spirometry is performed, by means of a hand-held spirometer, operated by the researcher. Arterial oxygen saturation is measured, using a fingertip pulse oximeter.
For each patient results of recent (< 6 months ago) lung function testing and a HRCT-scan are obtained. Furthermore, at day 1 each patient is asked to report the number of infective exacerbations they have experienced over the year before study entry and the date of the last exacerbation.

Part 2:
30 patients with bronchiectasis who present with an acute infectious

exacerbation are asked to complete the SGRQ, VAS, HADS and SF-36. The questionnaires are completed immediately prior to commencing antibiotic treatment and 1 week following completion of treatment. The questionnaires are adapted to ask about symptoms in the preceding week.
On both occasions flow-volume spirometry is performed, by means of a hand-held spirometer, operated by the researcher. Arterial oxygen saturation is measured, using a fingertip pulse oximeter.

Study burden and risks

nvt

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

Part 1:
- Bronchiectasis confirmed by HRCT
- Spirometry (FEV1, FVC) < 6 months ago
- No infective exacerbation < 1 month before study entry
- Ability to read and write
- Informed consent. ;Part 2:
Bronchiectasis confirmed by HRCT
Spirometry (FEV1, FVC) < 6 months ago
Infective exacerbation of bronchiectasis (PDE or NPDE (see below) for which a course of oral or iv-antibiotics is prescribed.
Ability to read and write
Informed consent.

Exclusion criteria

- Illiteracy or psychological incapacity to complete a standard questionnaire.
- No informed consent
- Cystic fibrosis

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2010
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL31093.094.09