



Improving synthesis of patient-reported outcomes (PROs) with core outcome sets

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Background

- Comparison and amalgamation of patient-reported outcome (PRO) data from trials is hindered partly because of the wide range of scales and items measured by generic and disease-specific questionnaires.
- The identification of a core set of PRO domains for particular treatments or conditions would facilitate this process, because mandatory predetermined domains would be measured and reported in all trials.
- We aim to develop a core outcome set for RCTs of curative treatment for oesophageal cancer.

Objective

- This study examined existing patient-reported outcomes for curative treatments for oesophageal cancer, and grouped PROs into domains to inform the development of a core outcome set.

Methods

- Systematic literature searches identified studies measuring PROs.

Search strategy:

- MEDLINE, Embase, PsycINFO and CINAHL databases
- Oesophageal cancer studies with curative intent
- Surgical / chemotherapy / radiotherapy interventions
- At least 1 multi-dimensional PRO measure
- Jan 2006 – May 2011

- All validated questionnaires used in the studies were examined, including additional oesophageal-specific questionnaires known to authors.

- A complete list of PROs was compiled from verbatim names of questionnaire scales, single items and ad-hoc questions measured in each study.

- Terminology was examined, and scales with identical and similar names were compared.

- Components of questionnaires (individual items) were categorised into generic or symptom specific health domains.



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Results

Search results:

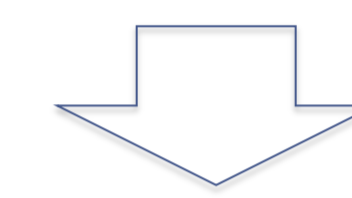
1351 identified records

111 full-text articles assessed for eligibility

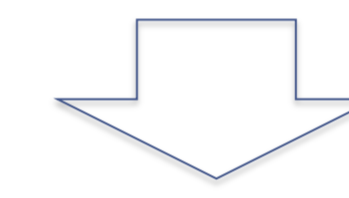
55 papers included (reporting 4 RCTs & 52 non-randomised studies)

19 questionnaires
identified from studies

2 questionnaires
from authors' knowledge



116 scales
32 single items
74 ad-hoc questions



132
verbatim terms
for PROs

- Inconsistent / unclear terminology
- Identically named scales but heterogeneity in content

- Categorized into 32 health domains:

Appetite/Eating/Taste	Sexual function
Belching/ Bloating/Gas	Weight
Body Image	Cognition
Breathing	Emotional function
Choking	Fatigue
Communication /Speech difficulties	Financial issues
Constipation	Generic health
Cough	Global QOL
Diarrhoea /Frequent bowel movements	Hair loss
Dizziness/Dumping	Nausea
Dry mouth	Physical function
Dysphagia /swallowing saliva	Role emotional
Eating - social impact	Role physical/ADLs
Pain /Odynophagia	Sleep
Reflux/Heartburn	Social function
Regurgitation /Vomiting	Spiritual issues

- Emotional function, pain/odynophagia, physical activity/activities of daily life and appetite/eating/taste were most commonly assessed across questionnaires.
- Ad-hoc questions most typically related to appetite/eating/taste.

Conclusions

- A myriad of tools are available to assess PROs after treatment for oesophageal cancer. Heterogeneity between instruments prevents comparison across studies and meta-analysis of results.
- A Delphi consensus study is underway to prioritise which PRO domains are important for a core outcome set.