PRC

EPCCS
The European Palliative Care Cancer Symptom study

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Outline

- Palliative care research on the agenda
- The EPCRC study – **one of our previous studies**
- The EPCCS study – **one of our ongoing studies**
- Current standing of the EPCCS

Palliative care research on the agenda

- EAPC report-2006 documented significant progress with respect to research, academic activity, recognition of PC as a medical specialty etc.
  - BUT: emphasized the need for international collaboration to improve the quality and quantity of research

EPCRC – European Palliative Care Research Collaborative

- First palliative project financed by the EC!
- 6th framework programme for research, LifeSciHealth
  - “Combatting cancer”
  - ”Palliative care, symptom relief; Pain, depression, fatigue/cachexia”
- Several objectives
  - Genetics, symptom assessment / classification, guidelines and a continuous palliative research collaboration

The EPCRC-CSA study, 1

- Work package 2.1, aim:
  - To develop a computer based tool for symptom assessment and classification
    - pain, cachexia, depression
- An international multi-centre study
  - Started 2008, closed Dec 2009
  - Entirely computer-based
  - Provider part
    - Minimum dataset, medical/socio-demographic variables
    - Pain classification system, ECS-CP, from Canada
  - Patient part
    - Self-report of symptoms, pain - primary focus

EPCRC-CSA, 2

- Cross-sectional
- 1071 patients, 17 centres, 8 countries
  - 4 language groups; Italian, English, Norwegian, German
- A huge data collection
  - 74 items to be answered by all
  - maximum 167 – skip sessions!
- All registrations by computers
  - Data entry by tapping directly on the screen with a stylus

Hjermstad MJ et al, JPSM 2012, e-pub

What did we learn from the CSA, 1?

- It was feasible to do the study
- The entire assessment was completed by 95%,n=965
  - mean age 62 years (SD 12.4)
  - mean Karnofsky score 71 (SD 16.3)
  - > 50% preferred computers for assessment
- Predictive factors for non-completion were
  - higher age, lower KPS and more pain (p-values <0.012)

What did we learn, 2?

- Healthy bias?
- Convenience sample?
- We know much about the included patients
  - We know much about those who aborted the study
  - We know nothing about those who were not included!

- Relevant questions
  - Was the sample representative of a pall care population?
  - Who said “no”?
  - Who were not approached?

So, then we moved on…….

European Palliative Care Research Centre / The EAPC Research Network

The European Palliative Care Cancer Symptom study (EPCCS)

A prospective data collection

Main responsibility

- Marianne Jensen Hjermstad, PI
  - Stein Kaasa, PI
- Trude Camilla S. Frøseth in the trial office

Objectives

- **Objective A1**
  - to extend the knowledge about the palliative care cancer population at the participating sites
  - to gain new insight in the prevalence and development of the most frequent symptoms over time

- **Objective A2**
  - continue the work towards a standardized assessment system to improve symptom management
  - to evaluate the clinical usefulness of the newly agreed-upon classification and assessment system

– **BMJ Supportive & Palliative Care, 2011**

Objectives, cont'd

- **Objective B**
  - to collect data on the organization and delivery of PC, economic and academic resources at the participating sites

- **Objective C**
  - to further develop and consolidate the international collaboration in PC cancer research

Design

- A prospective data collection
  - International
  - Multi-centre
  - Descriptive

A basic study in two parts, 1

- Objectives A1 and A2 - the assessment part
  - Health care providers
    - CRF on medical and treatment data
      - basic set: height, current weight, current medication and treatment, diagnosis (ICD-10), time of diagnosis, stage of disease, current anti-cancer treatment, site of treatment
      - MMSE, 4 item version
      - KPS - performance status
      - ECS-CP - pain classification

Fayers, Hjermstad JPSM 2006

A basic study in two parts, 2

- Objectives A1 and A2 - the assessment part
  - Patients
    - EORTC-PAL15, symptoms, QoL
    - ESAS-r – the revised version

      Watanabe, JPSM 2011
      Carvajal, EJC 2011

      - ESAS (trad); probably the most widely used general symptom assessment tool
      - Difficulties in relation to terminology and numerical ratings
      - Too many, un-validated, adapted versions exist
    - Screening items
      - Pain intensity, neuropathic pain, breakthrough pain depression, cachexia/appetite

Why screening questions?

1. To assess the prevalence and fluctuation over time
2. To reduce respondent burden
3. To facilitate conduction of in-depth companion studies using subgroups of the patient sample
   - biomarkers etc., e.g. cachexia
   - pain domains, clinical characteristics
   - qualitative and quantitative studies in those who screen positive for NP or BTP
     - Subject to specific protocol amendments
     - Designated PIs for each protocol amendment/side study

Proposed side - studies

- EPCCS facilitates screening in a large no. of patients
- Initially many ideas, esp. in relation to pain
  - But haven't really seen that many!?

- The Italian group
  - The MGIO study Malignant Gastro-Intestinal Obstruction
    - to describe the clinical management of gastro-intestinal obstruction (diagnosis, treatment and symptomatology) in PC patients with advanced malignant abdominal disease

A basic study in two parts, 3

- Objective B, the centre survey
  - To be answered only once
  - To be completed on the internet, only
  - English language only
  - To assess provision and delivery of palliative care
    - Patient mix
    - Staff mix
    - Organization
    - Resources, economy and manpower
    - Academic affiliation, chairs, research etc.

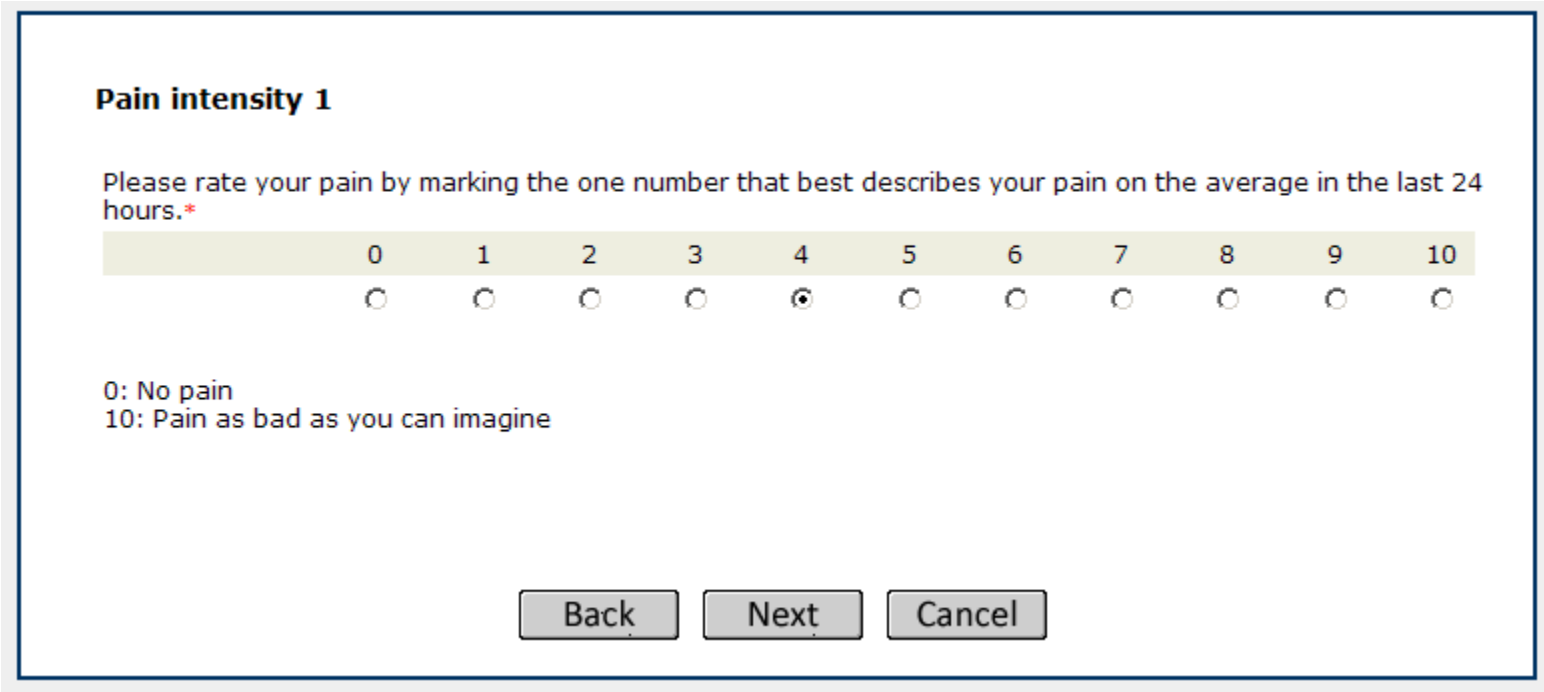
Methods; data collection

- Intended as a web-based study (primarily)

- The center survey – no options
  - Internet and English only

- CRFs and patient data – optional
  - Computer (= web) vs. paper forms
  - Local language (of course!)

Example of the web presentation



Interesting!

- Pre-study survey
  - An overwhelming interest for computers (>80%)
- BUT
  - only 9 centers use computers only!
  - the vast majority of centers have chosen paper forms, some use both paper and web

Methods; inclusion criteria

- a verified cancer diagnosis
- local, loco-regional or metastatic disease
- defined as a palliative care patient; enrolled in a palliative care programme
- 18 years or above
- written informed consent
- ability to complete the study, preferably without help
- available for follow-up registration, at least once

vs.

Patients receiving curative treatment

Methods; follow-up

- Included when coming to the participating center
  - Patients will be at different stages in the disease trajectory
- Initially planned
  - Patients followed every 4 weeks for at least 6 months
- Modified
  - Due to high attrition and different case mix
  - Patients followed every 4 weeks for up to 3 months

Is attrition a problem?

- No, not necessarily, because
  - This is an inherent part of research in palliative care
  - All (eligible) patients are asked to participate
  - All patients who decline, drop out etc. are registered
  - The patient mix at each site is very different
  - This is reflected in
    - A. the center survey
    - B. the final study sample

- Yes, if patients are included as a convenience sample

Timeline

- Study closed for new centers to enter
- No exact deadline for closure has been set
  - 50 pts. with 3 mos. follow-up is demanding
  - Requires that a large no. of pts. are included
- Exact no. of pts. is difficult to ascertain, as
  - Few centers are expedite in returning forms!!

Inspiring!

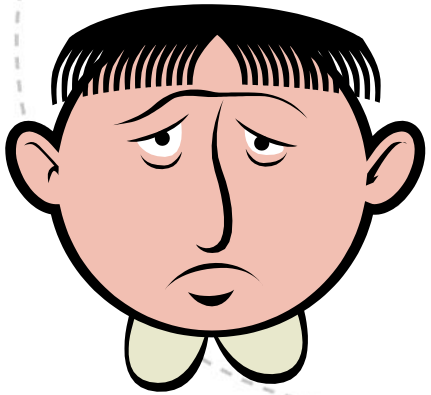
- The EPCCS has gained huge attention
- By Oct, 2012;
  - 49 centers agreed to participate
    - 9 have not responded at all, after initial contact
    - 5 have not completed the center survey
  - 34 have started patient inclusion
  - 13 countries
    - 8 Italian and 6 Spanish centers have started
  - 12 languages, some are really challenging!
    - Helpful assistance from local study coordinators
    - Georgian and Bulgarian are challenging!

Surprises always occur

- Change of practice, 1
  - Extended pall service
    - more patients receive attention
    - more patients followed longer
  - problematic?

- Change of practice, 2
    - “we have written an ancillary/companion protocol with new inclusion criteria of only NEWLY diagnosed cancer patients (no longer palliative medicine pts)”
    - one assessment only
  - problematic?

Disappointed?



- I hope not,
  - the EPCCS captures some of the features of doing research in palliative care
  - attrition
  - things take time!

The EPCCS gives

- good insight in the prevalence and development of symptoms
- good overview of PC delivery across Europe
- ample opportunities for international collaboration

And is feasible!