



EORTC

European Organization for Research
and Treatment of Cancer

Development of an EORTC quality of life module for cholangiocarcinoma: UPDATE

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Centres:

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Dr Orhan Sezer, Dr. Claudia Fleissner

- **University Hospital, Liverpool**

Clare Byrne, Louise Broadfoot

- **National Taiwan University**

Wei-Chu Chie

Pending Sites

- University College, London

Dr S Pereira, Consultant in Gastroenterology and Hepatology, R Matull

Not recruited patients yet

- Tehran University, Iran

Dr Sotoudehmanesh

Is translating PAN26 and LMC21 into Farsi and will pilot testing these shortly.

Aims

- To test the questions and issues of the LMC21 and the PAN26 in cholangiocarcinoma patients and assess if either or both are adequate.
- If neither alone is thought to be adequate, then the EORTC protocol “guidelines for module development” will be adapted to develop a new module for cholangiocarcinoma patients.

New Methodology

Phase 1: Generation of additional issues

Database search

Use of alternative questionnaires:

- FACT-Hep (The Functional Assessment of Cancer Therapy – Hepatobiliary Questionnaire)
- WHOQOL (WHO Quality of Life Questionnaire)
- Short Form 36 (Medical Outcome Health Survey Short Form)
- GI QLI (Gastrointestinal Quality of Life Index)

Keywords

- Cholangiocarcinoma
- Bile duct cancer/neoplasm
- Hepato/biliary duct cancer/neoplasm
- Periampullary cancer/neoplasm
- Gall Bladder cancer/neoplasm
- Gastrointestinal Cancer
- Quality of life

Phase 1: References

- Cholangiocarcinoma + QOL (43)
 - 2 used psychometrically tested disease specific questionnaires
- Bile duct cancer/neoplasm + QOL (34)
 - 1 used psychometrically tested disease specific questionnaires
- Hepato/biliary duct cancer/neoplasm + QOL (0)

Phase 1: References

- Periampullary cancer/neoplasm + QOL (7)
 - 2 used psychometrically tested disease specific questionnaires
- Gastrointestinal cancer + QOL (34)
- Hepatobiliary cancer + QOL (0)
- Gall Bladder Cancer + QOL (0, incomplete)

A search for additional issues not covered by the LMC21, PAN26 and EORTC QLQ-C30 was conducted.

Phase 2: Formation of additional issues

- Did you have fevers?
- Have you had any difficulties with drainage tube/bags?
- Have you been worried by jaundice?

Combined issues

- LMC21 – 21 issues
- PAN26 – 26 issues
 - 3 replicates (dry mouth/back pain/health worries)
- 3 additional questions
- TOTAL 47 questions

Scales

- EATING (7)
- BOWELS (2)
- OTHER (9)
- JAUNDICE (4)
- TIREDNESS (3)
- PAIN (6)
- RELATIONSHIPS (6)
- BODY IMAGE (4)
- ANXIETY (4)
- HEALTHCARE SATISFACTION (2)

Phase 3 (In-progress)

- Recruited 46 patients and 10 pending
- Target 100.
- UK Sites
 - Kings = 12
 - Basingstoke = 3
 - Southampton=4
 - Liverpool=14
- Germany =10
- Taiwan =2

Phase 3 (In-progress)

- Patient group will encompass the full range of disease in terms of stage and performance status
- Gall bladder cancer now incorporated (UK MREC approval) following Freiberg Nov 04.

Study Observations:

- Interview time approx 30-40 minutes
- Home visits obtain more detailed responses
- One patient declined participation – distressed/ not wanting to confront
- A few patients not fully informed on diagnosis so unable to interview
- Difficulty with recall in frail patients

Provisional Methods

1. Delete questions where >7 patients request omission
2. Finding trends/correlations in comments
3. Mean and SD of scores
4. Range of responses
5. Prevalence ratios
6. Analyse data with clinical details

1. Preferred questions

16 out of 47 items favoured to be included
(3 from PAN 26 and 13 from LMC21)

- Eating=2
- Physical functioning=3
- Pain=1
- Disease worries=4
- Social/sexuality=2
- Jaundice/itching=2

2. Trends in comments

- Repetitive issues from the QLQ-C30 are being discarded
e.g. tiredness/bowel habit/social activity/anxiety
- Some questions are too similar
e.g. some questions in the following scales -
eating/ pain/ bowels/ body image

4. Range of responses

All 16 favoured items had a range of 1 to 4 on the Likert scale

(1 data set incomplete)

5. Prevalence ratios

(Patients who have complaint divided by total number who completed item)

All 16 items not less than 30% (range 14 to 44, out of total of 46)

(2 data sets incomplete)

Plans

- Continue to recruit until reach target of 100 so sound decisions can be made on questions.
- During interviews, continue to ask patients to comment on which questions they wish to keep or remove.
- Analysis with clinical details and additional comments (e.g. rewording suggestions) pending.