

EORTC

European Organization for Research
and Treatment of Cancer

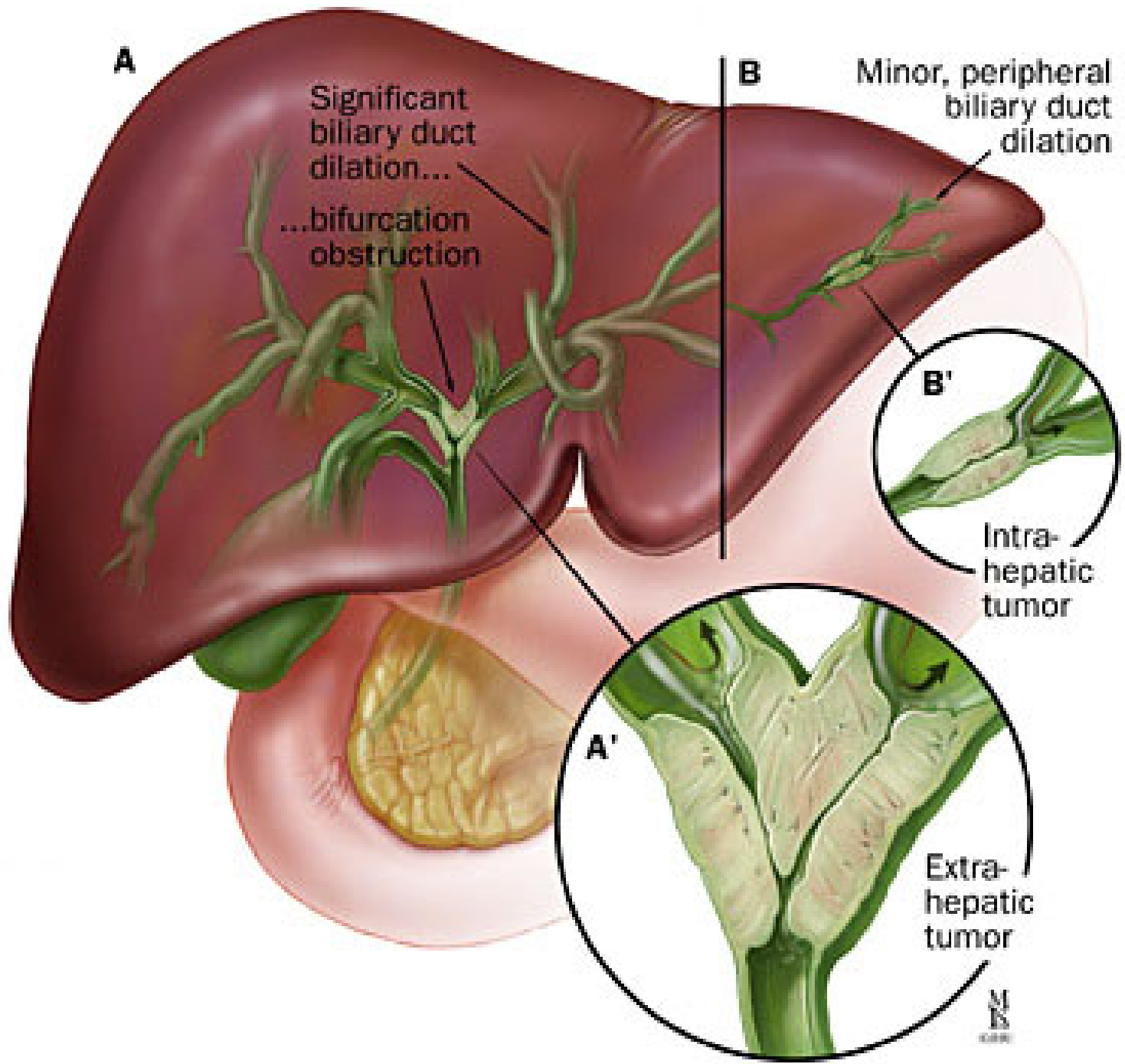
Development of an EORTC quality of life module for cholangiocarcinoma: UPDATE

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Cholangiocarcinoma (CCC)

- Malignancy of the biliary duct system
- Uncertain aetiology
- Slow growing, many patients present with unresectable and metastatic disease
- Encountered in 3 geographical regions
Intrahepatic/Extrahepatic (perihilar)/distal extrahepatic



Why is a module needed?

- Mortality rates from intrahepatic CCC have risen steeply over the last 30 years
- In 1997 and 1998 there were almost 1000 deaths/year in England and Wales
- More significant rises have been noted in Asia and worldwide it is a significant burden of disease

Centres involved in the study:

- **North Hampshire Hospital, Basingstoke**
Dr J Ramage, Consultant Physician in Gastroenterology and Hepatology
Mr M Rees, Consultant Surgeon
- **Kings College Hospital, London**
Mr N Heaton, Consultant Hepatobiliary and Transplant surgeon and honorary Senior Lecturer
- **University of Bristol (BRI)**
Ms J Blazeby, Consultant Surgeon and Senior Lecturer

- University College London

Dr S Pereira, Consultant in Gastroenterology and Hepatology

- Southampton University

Mr C Johnson, Consultant Surgeon and Reader in Surgery

- Universitätsklinikum Charité Berlin, Campus Mitte

Dr. med. Claudia Fleissner

- Royal Liverpool Hospital

- University Hospitals Nottingham?

- Taiwan?

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

Databases searched

Medline

Cinhal

Embase

AMED

Psychinfo

Cancer

Keywords

- Cholangiocarcinoma
- Bile duct
cancer/neoplasm
- Hepato/biliary duct
cancer/neoplasm
- Periapillary
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

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

Phase 1: Health Care Providers Interviews

- Aim to conduct 15-20 interviews
- Individual and priority ratings of questions
- With respect to deletion of questions:
At this stage, one should feel reluctant to delete questions.
- With respect to adding issues:
In principle, if one or more health care providers mention an additional issue, it should be included.

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
 - 5 replicates (taste/dry mouth/
jaundice/back pain/health worries)
- 3 additional questions
- TOTAL 45 questions

Scales

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

Phase 3

Inclusion criteria:

- a) Age 18-80
- b) Able to give informed consent
- c) More than 1 week post diagnosis
- d) Biopsy proven diagnosis is preferable. If a biopsy is not obtained then patients that are considered to have a diagnosis of cholangiocarcinoma by a multidisciplinary team (after review of CT/MRI/ERCP) can be included. It is also essential that the patient has been informed of the most likely diagnosis of cancer by their clinician.

Phase 3

Exclusion criteria:

- a) History of other significant malignant disease.
- b) Those patients who are confused or unable to understand the questions.

Phase 3 (In-progress)

- 100 patients
- Patient group will encompass the full range of disease in terms of stage and performance status.