

The potential of patient-reported outcomes in urothelial cancer patients receiving immuno- or chemotherapy – a feasibility study of electronic reporting in an aging and comorbid population.

REGION

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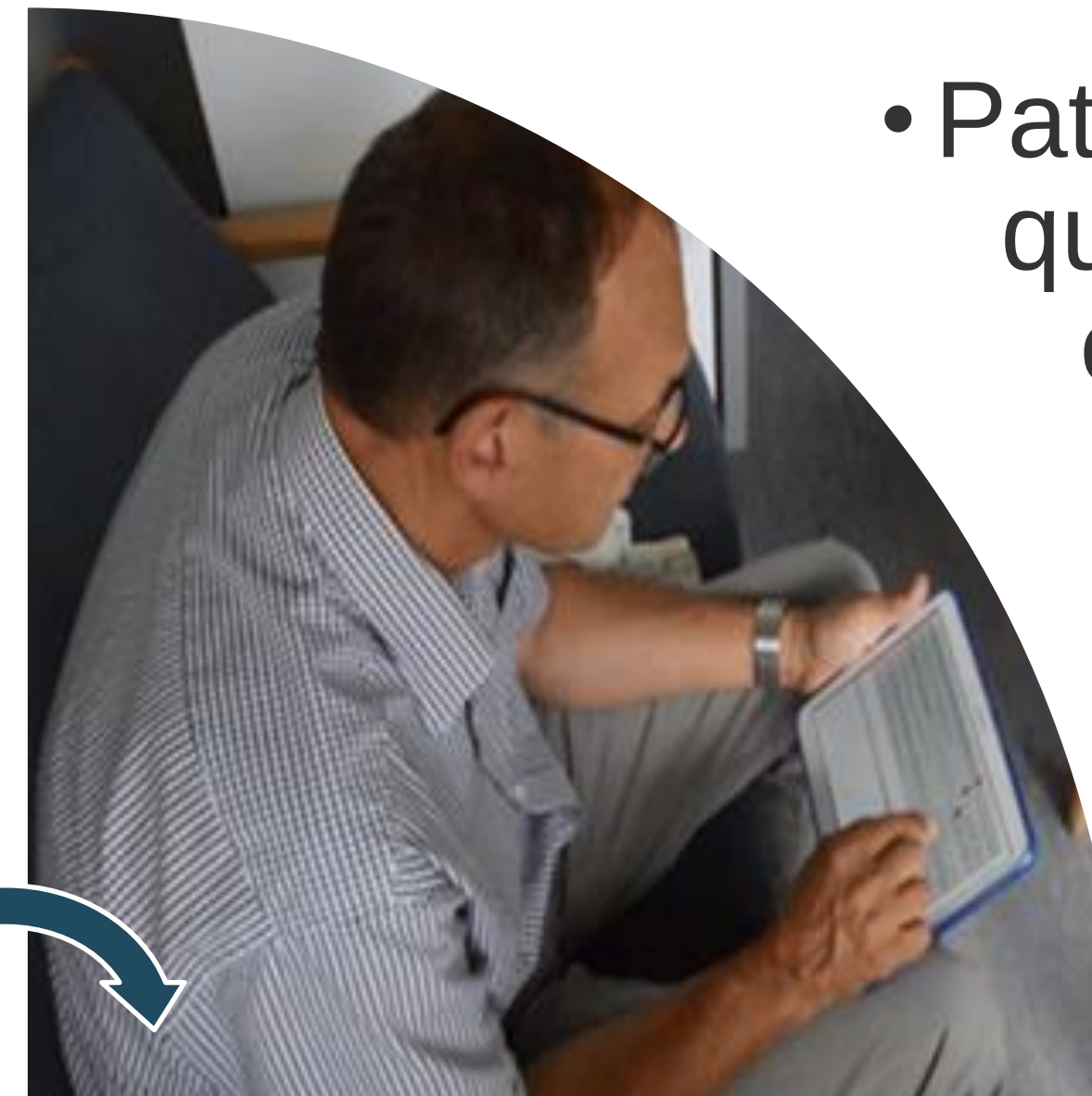
BACKGROUND

Worldwide urothelial cancer (UC) is one of the most common malignant diseases and causes of death. Patients with UC often have comorbidities, troubling completion of treatment, thus enhancing the need for better supportive instruments during treatment. Patient-reported outcomes (PROs) have been suggested as such, although the use of these has not yet been demonstrated feasible in this aging and comorbid population. Furthermore the literature is sparse on toxicities and quality of life (QoL) during treatment for UC patients outside of clinical trials. This study shall demonstrate the feasibility of electronic reporting of PROs and describe toxicities and QoL in the UC population.

• Patient receives questionnaires electronically



• Patient answers questionnaires electronically



• Clinician view of patient's answers



Symptom	Frequency
Abdominal pain	0
Back pain	0
Bleeding	0
Breast pain	0
Breast swelling	0
Breast tenderness	0
Breast lumps	0
Breast changes in shape or size	0
Breast changes in color	0
Breast changes in texture	0
Breast changes in smell	0
Breast changes in taste	0
Breast changes in touch	0
Breast changes in sight	0
Breast changes in sound	0
Breast changes in smell	0
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• Patient view of questionnaire

AIM

This study will evaluate the feasibility of electronic reporting and describe toxicities, QoL, rate of completion and hospital admissions. The results of this study will contribute to the content of a randomized patient-reported outcomes study in the UC population initiated this autumn (2018).

CHALLENGES

- Can this population handle electronic reporting?
- Is ePRO ready for implementation in clinical practice?
- Will the doctors use this e-tool in their conversation with the patient?
- What do we know about patients with urothelial cancer outside clinical trials?

TRIAL DESIGN

Patients

- Inclusion criteria:
 - Urothelial cancer stages T2-T4NxMx
 - No serious cognitive impairment
 - If dyslectic, have relative to read questions aloud
 - Have electronic communication with authorities (>90% of all Danes)

Treatment

- Chemo- or immunotherapy outside a clinical trial
 - Chemotherapy: cisplatin/gemcitabine, carboplatin/gemcitabine or vinflunine
 - Immunotherapy: pembrolizumab

Sites

- Rigshospitalet and Herlev Hospital, University Hospitals of Copenhagen, Denmark

Period

- February 2018 until 40 patients are enrolled.

Intervention

- Baseline and weekly during treatment complete four e-questionnaires: EORTC QLQ-C30 & QLQ-BLM30, HADS, selected PRO-CTCAE™ questions and finally three general health questions.
- The selected PRO-CTCAE questions were the result of a process of
1. journal audit of patients in chemotherapy for urothelial cancer
 2. patient interviews
 3. EMA and FDA product resumes for cisplatin, carboplatin, gemcitabine and vinflunine(only EMA) including symptoms with ≥ 10% in frequency. All PRO-CTCAE questions corresponding to the found symptoms were included resulting in 45 symptoms being explored by a total of 84 PRO-CTCAE questions

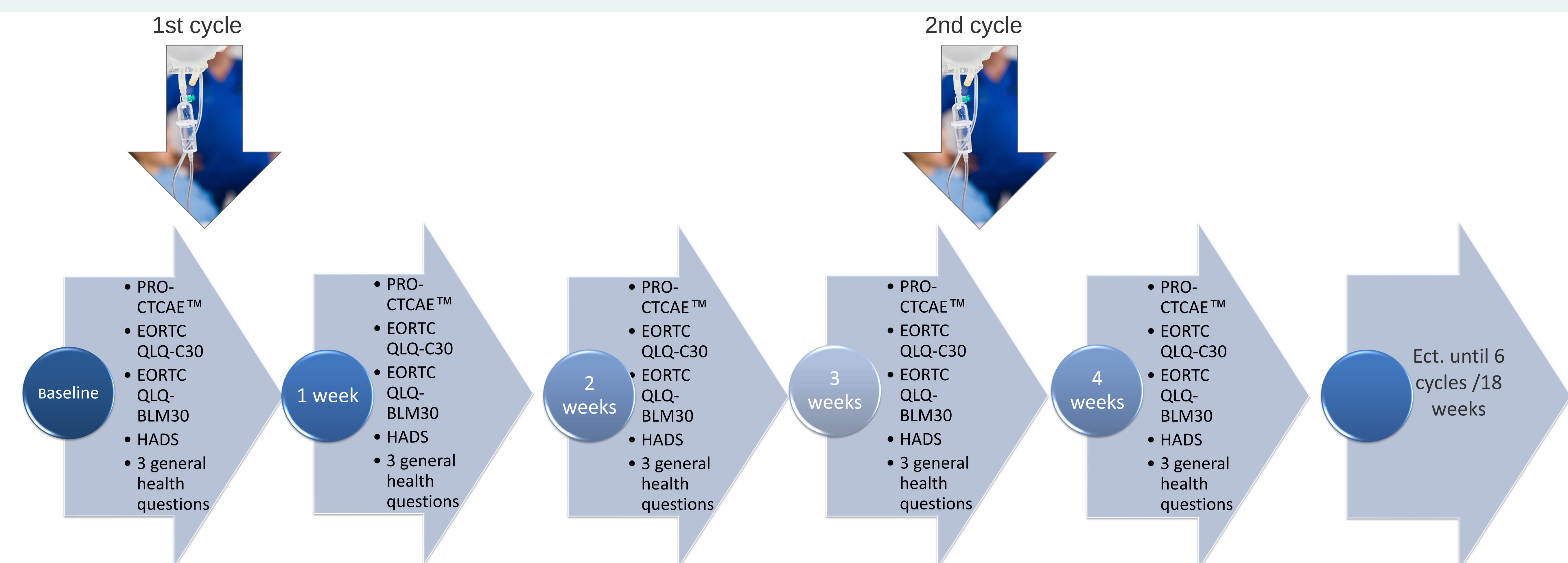


Figure 1. Study design. Interval of questionnaires answered by 30 patients receiving chemotherapy. Data collection by paper or internet.