

Adaption of the EORTC QLQ-Breast Cancer Module BR 45 for male BC Phase I

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BACKGROUND

Approximately 1% of all new cases of breast cancer (BC) occur in men. Care of male BC is largely based on extrapolation from treatment strategies and management of symptoms in women. The impact of BC diagnosis and therapy on Quality of Life (QoL) in women with BC is well documented. Comprehensive, prospective data about QoL in men treated for BC are sparse.

Due to the lack of a validated male BC QoL questionnaire, we previously evaluated the QoL of the male BC using the original EORTC QLQ-C30 and breast module QLQ BR23 with "female" items replaced by male-specific items from the EORTC QoL prostate module (EORTC QLQ-PR25).

The development of a validated worldwide questionnaire for male BC is sponsored by EORTC QoL Group and will be completed in cooperation with EORTC Breast Group and the International Male BC Program (a cooperation between EORTC-BCG, TBCRC, within the BIG and NABCG networks).

AIMS

1. To carry out an evaluation of the EORTC QLQ-BR 45 (adapting for male BC) for suitability of use in male BC patients
2. To carry out an evaluation of the EORTC QLQ-PR25 (adapting for male BC) for suitability of use in male BC patients
3. To provide recommendations of the EC on a suitable assessment approach to assess HRQoL in male BC

METHODS

1. Literature review

A systematic literature review to assess what factors are unique to male BC in influencing their QoL and what QoL measures exist for male BC was done by reviewing all studies with male BC participants, investigator brochures describing side effects in male BC patients, as well as by evaluating issues captured by other EORTC modules (Figure 1).

86 potential quality of life issues relevant for male breast cancer patients were identified. These can be categorized into the following domains:

1. Systematic Therapy Side Effects (10)	7. Skin Mucosis Symptoms (4)	14. Coping (1)
2. Body Image (7)	8. Role functioning (1)	15. Cancer Care System (4)
3. Sexual functioning (8)	9. Social functioning (3)	16. Heart Problems (2)
4. Arm Symptoms (3)	10. Pain (3)	17. Others (2)
5. Breast Symptoms (3)	11. Compliance (1)	
6. Endocrine Therapy Symptoms (11)	12. Emotional functioning (20)	
	13. Global Health Status / QoL (2)	

Table 1. Domains of the issue list. Number of issues per domain in brackets

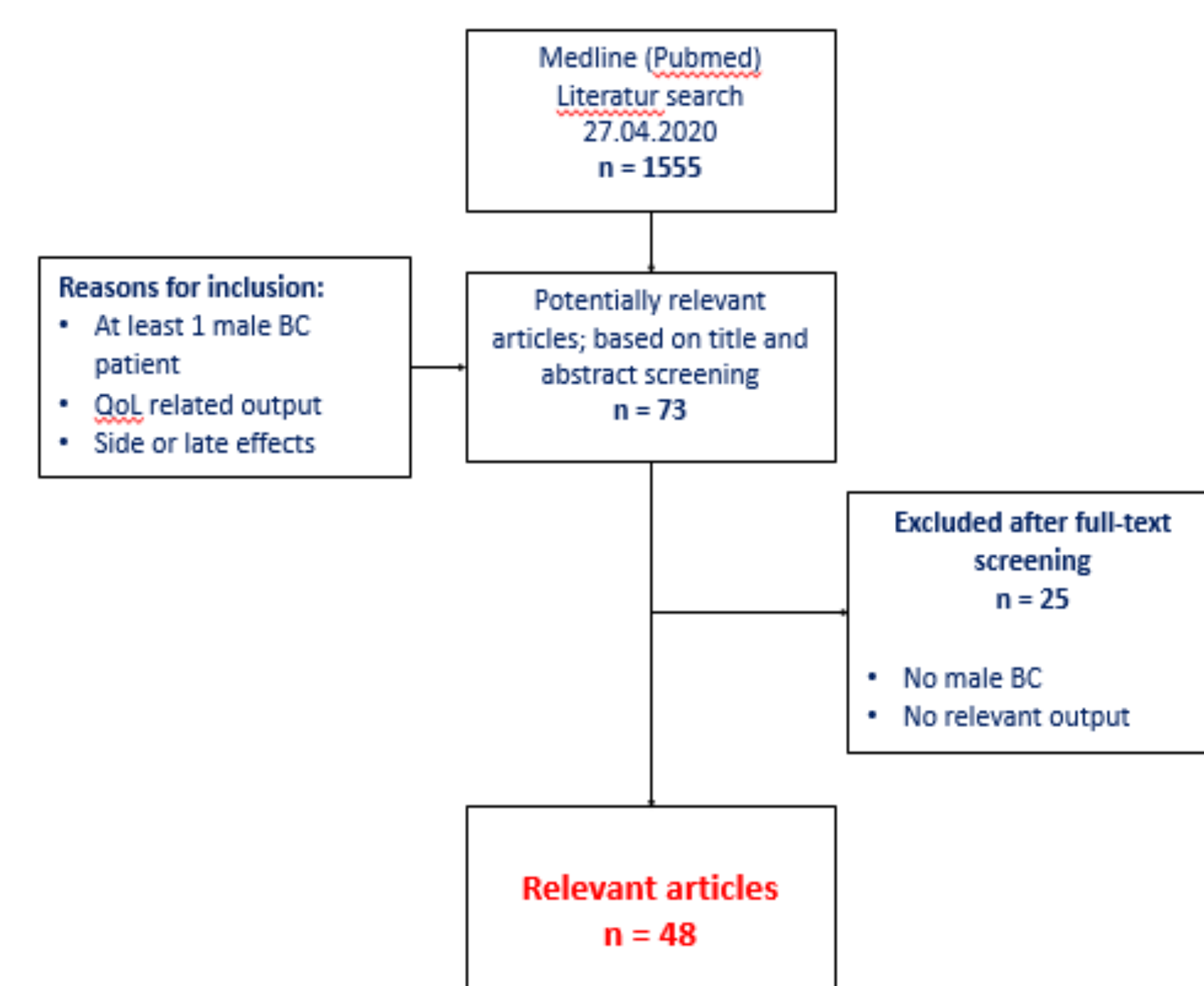


Figure 1. Flow chart of the literature search

2. Interviews with patients

A total of 2-5 patients/year recruited from collaborating centres (ideally 40 overall) will be interviewed before, during or after treatment. Purposive sampling will aim to achieve good representation according the treatment

3. Interviews with health care professionals (HCP)

At least at 2 experts/unit from the all collaborating centres will be included in the interview to discuss and consider the potential issues.

4. Consultation of experts in oncology and QoL

Experts will be asked to comment on our findings and will also be asked specific questions around the necessity of the development of a new module, based on those findings and their expert views.

CURRENT STATUS

- Study started: October 2019
- 17 centres worldwide are participating in the study to date
- New centres may still join
- 5 patients an 3 HCP could be recruited so far (date: 05.01.2021)

→ **Recruitment until end of 2021**

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