

Original article

Quality of life and symptom assessment in randomized clinical trials of bladder cancer: A systematic review

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Abstract

Objectives: Patient-reported outcomes (PRO) help patients, caretakers, clinicians, and policy makers make informed decisions regarding treatment effectiveness. Our objective was to assess the quality of PRO reporting and methodological strengths and weaknesses in randomized controlled trials (RCT) in bladder cancer.

Methods: A systematic literature search of bladder cancer RCT published between January 2004 and March 2014 was performed. Relevant studies were evaluated using a predetermined extraction form that included trial demographics, clinical and PRO characteristics, and standards of PRO reporting based on recommendations of the International Society for Quality of Life Research.

Results: In total, 9 RCTs enrolling 1,237 patients were evaluated. All studies were in patients with nonmetastatic disease. In 5 RCTs, a PRO was the primary end point. Most RCTs did not report the mode of administration of the PRO instrument or the methods of collecting data. No RCT addressed the statistical approaches for missing data.

Conclusions: We found that few RCTs in bladder cancer report PRO as an outcome. Efforts to expand PRO reporting to more RCTs and improve the quality of PRO reporting according to recognized standards are necessary for facilitating clinical decision making. © 2015 Elsevier Inc. All rights reserved.

Keywords: Bladder cancer; Patient-reported outcomes; Clinical trials; Quality of life; Clinical decision making

1. Introduction

Bladder cancer is the seventh most common cancer in men worldwide, with estimated 429,793 new cases and 165,068 deaths in 2012 [1]. Bladder cancer is more

common in the Western world and is the sixth most common cancer in the United States, accounting for an estimated 74,690 new cases and 15,580 deaths in 2014 [2].

Approximately 30% of newly diagnosed patients will have muscle-invasive bladder cancer (MIBC), for which neoadjuvant chemotherapy and radical cystectomy with urinary diversion are considered the standard of care [3]. A subset of patients with non-muscle-invasive bladder cancer (NMIBC) will progress to invasive disease whereas many others will have a protracted disease course that may include invasive monitoring and intravesical treatments [4].

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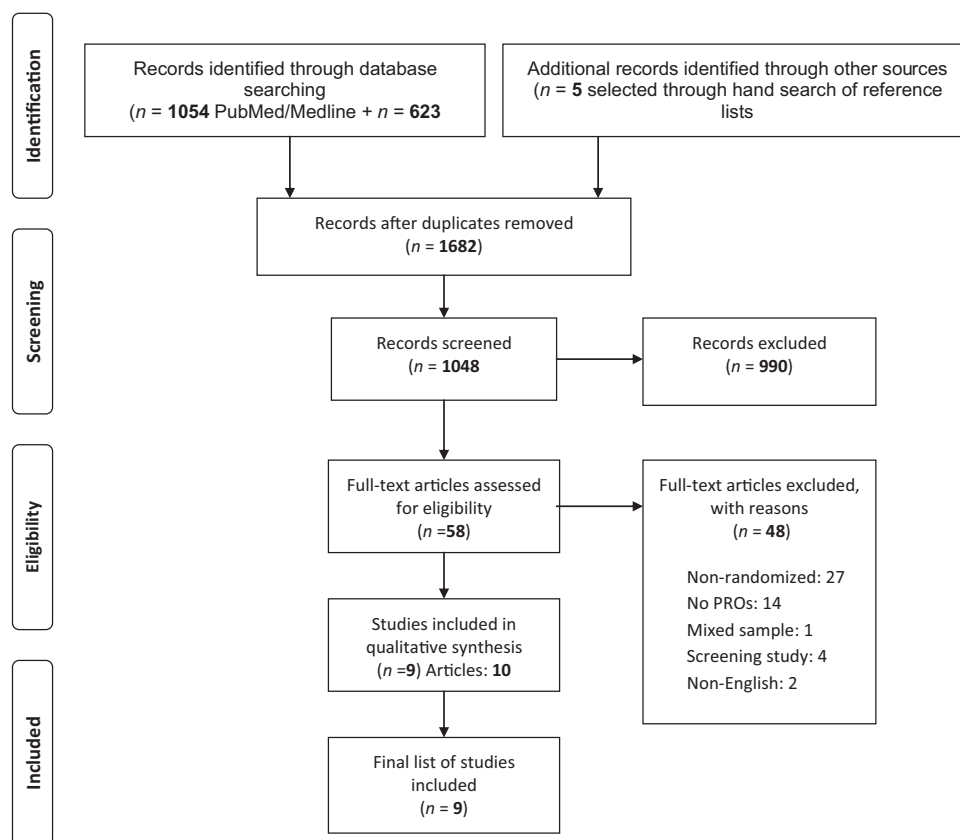


Fig. Schematic breakdown of literature search results of bladder randomized controlled trials.

For any stage of bladder cancer, informed decision making needs to consider objective outcome measures with a high level of evidence as well as the patient's values and experience [5]. It is increasingly recognized that patient-reported outcomes (PRO) help patients, caretakers, clinicians, and policy makers make decisions regarding treatment effectiveness [6,7]. However, previous systematic reviews have noted several weaknesses in PRO studies in bladder cancer, including retrospective study design and use of nonvalidated questionnaires [8,9]. Furthermore, reviews in other cancers have shown poor PRO reporting in randomized controlled trials (RCT) [10,11]. Therefore, standards for reporting PRO in RCTs have recently been established [12,13]. The objective of this review was to identify the number of RCTs in bladder cancer that have included PRO as an end point and to assess the quality of PRO reporting from these studies.

2. Materials and methods

2.1. Search strategy and identification of studies

An electronic, systematic literature search using Pubmed/Medline, the Cochrane Library, PsycINFO, and PsychARTICLES was used to identify RCTs in bladder cancer with a PRO component from January 2004 to March 2014. Details of our search strategy used in other cancers have been

previously described [10,11,14]. We limited our search to the past 10 years because a previous MEDLINE search of the literature from 1966 to January 2004 found no RCT evaluating PRO after radical cystectomy [9]. Relevant studies listed as references were also considered.

2.2. Selection criteria

English-language RCTs involving adult patients with bladder cancer were included regardless of disease stage. Studies had to enroll at least 50 patients to be included. Studies of patients undergoing screening or involving patients with benign disease were excluded. Conference abstracts were not included. Interventions included any RCT comparing conventional treatments. Studies considering psychological intervention or complementary or alternative medicine were excluded. Any studies evaluating a PRO either as a primary or secondary outcome were included. This included both multidimensional health-related quality of life outcomes and any other type of PRO measuring the effect of an intervention. Studies evaluating only treatment adherence or satisfaction were not included.

2.3. Data extraction and type of information analyzed

Data were gathered through the Patient-Reported Outcome Measurements Over Time IN Oncology (PROMOTION) Registry (<http://promotion.gimema.it>) [14]. For the

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