Comparison of Patient-Reported Quality-of-Life and Complications in Men With Prostate Cancer, Between Two Modes of Administration

Fanny Sampurno,[1] Rasa Ruseckaite,[1] Jeremy L. Millar,[1,2] Sue M. Evans[1]

Abstract

The aim of this study was to assess the quality-of-life (QOL) of men with prostate cancer in Victoria, Australia. Results suggest that modes of administration and instruments to measure QOL outcomes in patients with potential sensitive issues need to be carefully chosen in order not to underestimate the findings. Demographic and clinical factors need to be carefully considered while interpreting the QOL outcomes and conducting follow-up studies.

Introduction: Our purpose was to: (1) assess the level of consistency between the quality-of-life (QOL) scores of men with prostate cancer for urinary/bowel/sexual bother, collected via telephone versus self-administered survey; (2) determine factors associated with variation in level of agreement; and (3) assess the efficacy of telephone interview as a mode of administration against the “gold standard” tool, EPIC-26. **Methods:** Cohen’s Kappa coefficients were calculated to investigate test-retest reliability across modes of administration. Logistic regression models explored patients’ characteristics associated with the magnitude of urinary/bowel/sexual problem. Sensitivities and specificities of the telephone mode in reference to “gold standard” were further measured. **Results:** From 221 men who agreed to participate in the study, 168 (76.0%) returned completed surveys. Kappa-linear model resulted in a moderate agreement across the urinary/bowel/sexual bother scores for both modes of administration; with greatest concordance recorded for bowel bother (90%). Patient’s age ($<$75 years), disease risk, and active treatment type determined a moderate-to-good level of agreement between administration modalities with a Kappa varying between 0.44 and 0.73; χ^2, 8.18; $P = .042$. Sensitivity tests revealed that 68% of men with a moderate/big problem during the phone interviews would respond to suffering from a moderate/big sexual problem. **Conclusion:** Results of this pilot study revealed that QOL outcomes from this registry will likely underestimate the true bother experienced by men. More research is required to determine the differences between self-administered and telephone interviews in men with prostate cancer.

Clinical Genitourinary Cancer, Vol. ■, No. ■, ■-■ © 2016 Elsevier Inc. All rights reserved.
Keywords: Bowel, Clinical registry, PROMs, Self-reported, Sexual, Urinary

Introduction

Patient-reported outcome measures (PROMs) are standardized, validated questionnaires used in a clinical setting to measure patients’ perceptions of their own physical and mental status and well-being.[1] There are thousands of PROMs questionnaires or instruments, and the quality of these instruments, in terms of their reliability and validity, varies considerably.[2,3] Many such measures were originally designed for assessing treatment effectiveness in the context of clinical trials, but are now used more widely to assess patient perspectives of care outcomes. This outcomes-based definition of PROMs distinguishes them from questionnaires used to measure patients’ experiences of the care process.[4]

Cancer is one of the most frequent condition where PROMs are used.[5] Many studies demonstrated that PROMs play an increasingly important role in clinical and palliative care[6] and also enable the assessment of health-related quality-of-life (HRQOL) of patients suffering from various forms of cancers, such as lung, colorectal, breast, or non-Hodgkin’s lymphoma.[5,7-9] Prostate cancer (PCa) is

---

[1]Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Faculty of Medicine Nursing and Health Sciences, Monash University, Melbourne, VIC, Australia
[2]William Buckland Radiation Oncology Department, The Alfred, Melbourne, VIC, Australia

Submitted: May 26, 2015; Revised: Dec 14, 2015; Accepted: Dec 16, 2015

Address for correspondence: Rasa Ruseckaite, BSc, MSc, PhD, School of Public Health and Preventive Medicine, Monash University, The Alfred Centre, Alfred Hospital, Commercial Road, Melbourne, VIC 3004, Australia
E-mail contact: rasa.ruseckaite@monash.edu

http://dx.doi.org/10.1016/j.clgc.2015.12.016

the most commonly diagnosed malignancy and second most common cause of cancer death in Australian men.[10] Men with PCa have various treatment options depending upon their stage of disease, age, and presence of comorbidity. However, these treatments typically cause side effects, which generate currently ill-defined supportive care needs.[11] Fortunately, more than 80% of men can expect to be alive 5 years after diagnosis.[11,12] With increased early detection and high survival rates, HRQOL has been playing a very important role in patients' care.[13] There are numerous tools, surveys, and instruments to measure health outcomes of PCa men.[14] One of the most frequently used tools is the Expanded Prostate Cancer Index Composite (EPIC), which is widely accepted in clinical research to monitor HRQOL of PCa survivors.[15,16]

HRQOL tools can be delivered by paper and pencil questionnaires, face-to-face or telephone interviews, or by electronic means (eg, via a computer or a handheld electronic device).[17] However, research shows that the mode of questionnaire administration can have serious effects on data quality.[18] Numerous studies compared the costs, reliability, and test-retest variability of telephone, paper, and self-administered modes of interviews.[15,17,19-21] For example, Skolarus[15] addressed the feasibility of automated telephone assessment using EPIC and showed that such mode of administration provides a cheap, sustainable, and systematic approach to measuring PROMs of PCa patients. Effects of telephone versus mail survey methods on the measurement of HRQOL of emotional and behavioral problems were addressed by Erhart et al,[19] who demonstrated small differences between scores obtained via telephone and mail surveys.

The aim of this study was to: (1) assess the level of consistency between PCa HRQOL scores for urinary, bowel, and sexual bother collected via telephone versus self-administered surveys; (2) determine factors associated with variation in level of agreement including stage of disease at diagnosis, age at diagnosis, type of treatment, and time lapse between the last treatment to survey completion; and (3) assess the efficacy of telephone interview as a mode of administration against the "gold standard" HRQOL tool, the self-administered EPIC-26.[16]

Materials and Methods

Victorian Prostate Cancer Registry

The Victorian Prostate Cancer Registry in Australia (PCR) was established in 2009 involving a number of Victorian hospitals.[10] Ethics approvals were obtained from each participating institution prior to the commencement of PCR in each participating site. In Victoria, there is a statutory obligation to report all patients diagnosed with a malignancy to the Victorian Cancer Registry. Upon ethics approval at a site, hospitals authorize the release of mandatorily reported PCa notifications sent to the Victorian Cancer Registry. A key goal of the PCR is to assess the quality of care and to report clinical credible data to clinicians and health services.[10,22,23]

Data Collection and Surveys

As part of the clinical and research data collected by the PCR, patient-reported HRQOL and complication data were routinely collected from participating men by trained registry staff via a structured telephone interview. At 12 and 24 months post-diagnosis, participants were contacted by telephone to verify management details and to measure general health and disease-specific QOL. The general HRQOL tool selected for use by PCR was the SF12v2.[10] For the disease-specific QOL, men were asked the following 3 questions extracted from the EPIC-26 relating to bowel, urinary, and sexual bother: (1) "How big a problem has your urinary function been for you during the last 4 weeks?" (2) "How big a problem have your bowel habits been for you during the last 4 weeks?" (3) "How big a problem has your sexual function or lack of sexual function been for you during the last 4 weeks?" These questions were scored as discrete items within the EPIC-26 tool.[16] For each of the questions above, men were given an option from a 5-point ordinal response scale: 'no problem,' 'very small problem,' 'small problem,' 'moderate problem,' and 'big problem.'

We stratified our recruitment to private and public, and regional and metropolitan hospitals. Consecutive patients were selected across the groups. In this way, we over-sampled from regional Victoria relative to the overall PCa incidence in Victoria. At the end of the phone interview, participants were asked to complete the EPIC-26 questionnaire either via web-based or mail-out paper questionnaire. A web-based data collection tool (http://www.surveymonkey.com/s/PCR_ValidationStudy) was utilized to conduct the online questionnaire.

To protect participant confidentiality, a registry-specific identification number (ID) was created for a unique participant identification. A code, consisting of the first three surname letters and the first two letters of participants' first name was also added to verify the participants' identification. An explanatory statement along with a brief instruction of how to complete the questionnaire was sent to the agreed participants via email. An explanatory statement and EPIC-26 questionnaires with pre-filled Participant ID and code along with a self-addressed envelope were also mailed to participants who chose to complete the questionnaires on paper. Participants were asked to fill in the date of completion on the mail-out questionnaires to enable us to measure the number of days taken for each participant to complete the questionnaire. All returned questionnaires, both completed online and on paper, were collated, and responses were recorded into an excel spreadsheet.

Data Analysis and Institutional Review Board Approval

Descriptive analysis was conducted to describe demographic and treatment characteristics of the study participants, grouped according to the National Comprehensive Cancer Network risk of disease progression categories.[22,24] After numerous consultations with urologists and radiologists, PCa treatment categories were grouped into: (1) radical prostatectomy (RP); (2) radiation therapy (RT), which included external beam radiation therapy (EBRT), high−dose-rate brachytherapy, and unknown rate brachytherapy treatment modalities; (3) EBRT and RP; (4) low−dose-rate (LDR) brachytherapy; (5) androgen deprivation therapy (ADT); (6) active surveillance (AS)/watchful waiting (WW); and (7) other.

Due to a small number of study participants who returned their surveys online, online and paper-based responses were collated into one group, further referred to as "self-administered." The time lapse between the telephone and self-administered tool was calculated in days. Differences between the scores were calculated using the responses from EPIC-26 versus "bother" questions asked during telephone interviews. Negative numbers of −100, −75, −50,