"We Used a Validated Questionnaire": What Does This Mean and Is It an Accurate Statement in Urologic Research?

Adam S. Dowrick, Addie C. Wootten, Declan G. Murphy, and Anthony J. Costello

OBJECTIVE To educate a clinical audience of what the specific meaning of the term "validated questionnaire" means from a research methodology perspective when used in a journal article or a conference presentation.

METHODS To emphasize what is meant by the term "validated questionnaire," we reviewed the most commonly used prostate-specific, patient-reported, outcome assessment instruments and discuss which have been appropriately validated for use in patients having surgery for localized prostate cancer.

RESULTS Not all the prostate-specific instruments used to assess outcomes after surgical treatment for localized prostate cancer have been validated for use in this population. In particular, the Sexual Health Inventory for Men and the International Prostate Symptom Score—American Urological Association-7, which are commonly used by clinicians to measure potency and urinary function, respectively, have not been validated for use in a population of patients having surgery for localized prostate cancer.

CONCLUSION Although patient-reported outcome assessment instruments are frequently used in the urologic literature, little consideration has been given to ensure that users understand why a questionnaire must be validated and what the term "validated" actually means from a research methodology perspective when used in this context. Whether an instrument displays appropriate measurement properties is not a fixed attribute but is dependent on the context and population being studied. Studies using questionnaires that have not been validated in the population of interest may be subject to measurement error, and any conclusions drawn cannot be made with total confidence. Clinicians should consider this when reading journal articles and designing study protocols. UROLOGY 85: 1304—1311, 2015. © 2015 Elsevier Inc.

The key when using patient-reported outcome assessment instruments is that whether an instrument displays appropriate measurement properties is not a fixed property but is dependent on the context and population being studied.[1] Published articles and presentations at meetings frequently state "we used a validated questionnaire" without a true understanding of what this means. Some authors remove questions to decrease study burden without acknowledging that this creates a new questionnaire that should be validated for use in the population of interest.[2] Furthermore, it has been emphasized that just because an instrument has been used previously, it does not mean that one can assume that it has been appropriately used and validated for use in a given population.[3]

Little attention has been paid in the urologic literature to explain the scientific rigor involved in selecting a questionnaire (or, more correctly termed from a research methodology perspective, a patient-reported outcome assessment instrument) for use with patients. This article will first summarize the psychometrics involved with declaring that a validated instrument was used as part of a study. It will then outline the measurement properties of a selection of the most commonly used prostate-specific instruments used when reporting patient-reported outcomes after radical prostatectomy in patients with localized prostate cancer. Finally, the article will discuss

Financial Disclosure: *Adam S. Dowrick was supported by a Neil Hamilton Fairley Overseas Clinical Fellowship from the National Health and Medical Research Council of Australia (581510). The remaining authors declare that they have no relevant financial interests.*

From the Australian Prostate Cancer Research Centre Epworth, Melbourne, Australia; the Department of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology, Trondheim, Norway; the Department of Urology, Royal Melbourne Hospital, Melbourne, Australia; and the Division of Cancer Surgery, Peter MacCallum Cancer Centre, Melbourne, Australia

Address correspondence to: Adam S. Dowrick, Ph.D., M.App.Sc., B.App.Sc., Australian Prostate Cancer Research Centre Epworth, Level 2, 185 Hoddle Street, Richmond, Victoria 3121, Australia. E-mail: drdowrick@gmail.com

Submitted: June 30, 2014, accepted (with revisions): January 2, 2015

© 2015 Elsevier Inc.
All Rights Reserved
http://dx.doi.org/10.1016/j.urology.2015.01.046
0090-4295/15

which of these commonly used instruments have been validated for use in this population. This article does not intend to present a systematic review of the tens of instruments used in this population as we feel that presenting a review of the most commonly used instruments will be of more relevance and interest to a wider clinical readership rather than presenting a discussion of every instrument used in the literature. Our objective was to inform the clinician as to the specific meaning of the term "validated questionnaire" and to ensure that this is considered when using the term in articles and conference presentations.

METHODS

A hand search was conducted of 3 peer-reviewed urologic journals, 2 peer-reviewed general oncology journals, and 1 peer-reviewed health care administration journal from January 2000 to August 2012. The selected journals were as follows: *European Urology*, *Journal of Urology*, *British Journal of Urology International*, *The Lancet Oncology*, *Journal of Clinical Oncology*, and *Medical Care*. These journals were selected on the basis of their affiliation with the leading urological societies and their standing as clinical research journals in oncology. *Medical Care* was specifically chosen as it has historically published patient-reported outcome assessment instrument validation articles in other medical fields. In addition to the hand search, a search of the MEDLINE database was performed using the PubMed interface for each journal.

These criteria led to the selection of the following instruments:

(1) University of California Los Angeles—Prostate Cancer Index (UCLA-PCI)
(2) Expanded Prostate Cancer Index Composite (EPIC)
(3) International Index of Erectile Function-5 (IIEF-5)—Sexual Health Inventory for Men (SHIM)
(4) International Prostate Symptom Score (IPSS)—American Urological Association-7

Psychometrics: Assessing the Measurement Properties of an Instrument

The underlying assumption of using a patient-reported outcome assessment instrument is that it has been evaluated for the relevant measurement properties in the population to be studied. The key measurement properties are reliability and validity. Reliability assesses whether random error is minimal and that an instrument produces stable results.[4] The evaluation of reliability is generally undertaken in terms of internal consistency and reproducibility. Internal consistency is an assessment of whether the items in a scale are measuring the same construct and is most often measured using Cronbach alpha.[5] Although there has been debate in the literature regarding the interpretation of this statistic,[6] it is generally accepted that values of >0.70 are desirable when comparing groups[7,8] and that values >0.90 may indicate redundancy of items.[1,9] Reproducibility is measured using test-retest reliability where a test is instituted at 2 time points far enough apart that the patients ca not remember their previous answers but close enough together that there is stability in the functional ability or the disease-state of the patient.[1,10] This test provides information regarding how repeatable the results of an instrument are when instituted at 2 time points when no change is expected.[11] Correlation values of >0.60[12] should be observed. Validity assesses whether an instrument truly measures what it intends to measure.[4] Face, content, and construct validity are the most relevant measures of validity when evaluating patient-reported outcome assessment instruments.[4] Face validity examines whether an instrument appears to be measuring what it is intended to measure.[13] Content validity is a qualitative assessment of whether an instrument examines all the important domains[1,13] and consists of a judgment performed by relevant stakeholders. Construct validity is a type of empirical evidence that shows if an instrument is measuring an abstract variable of interest that is not able to be directly observed (eg, things such as pain or anxiety).[1] Construct validity is assessed by investigating logical relationships between an instrument and theoretical concepts (constructs).[4] For example, a patients' score on a questionnaire should change presurgical and postsurgical treatment. Table 1 summarizes how reliability and validity are assessed psychometrically. Furthermore, instruments should have minimal floor and ceiling effects (ie, few patients scoring the maximum and minimum values) so that patients at the extreme ends of the scale can be discriminated and so that changes in health in these patients can be measured.[14] In addition, to minimize burden on the patient and study resources, an instrument should be brief, easy to administer, score, and interpret.[15]

RESULTS

University of California Los Angeles—Prostate Cancer Index

Initial development of the UCLA-PCI was based on structured qualitative input from prostate cancer patients (diagnosed at a mean of 5.6 years before questionnaire administration) and their spouses who indicated that they were most concerned with function and bother related to urinary, sexual, and bowel outcomes.[16] After a series of pretesting of items,[17] validation of the UCLA-PCI was undertaken in 255 respondents being treated for prostate cancer between 1961 and 1991 from the tumor registry and enrollment list of a large health maintenance organization in southern California.[16,17] Two hundred fourteen of these respondents had localized prostate cancer (84% of respondents).[17] Test-retest reliability was exhibited over a period of 1 month in all bar the urinary bother scale[18] (Table 2). Internal consistency was observed in all 3 multi-item scales[16] (Table 2). The expected associations between the UCLA-PCI scales and other variables supported the construct validity of the instrument[16] (Table 2). The involvement of patients and their spouses in the initial design of the UCLA-PCI is likely to mean that it measures outcomes that are highly relevant to patients when deciding their treatment. The validation in a sample of predominantly localized prostate cancer patients means that conclusions drawn when using this instrument can be made with some confidence. Further development of the UCLA-PCI has resulted in the production of a new instrument known as the EPIC.

Download English Version:

https://daneshyari.com/en/article/3897999

Download Persian Version:

https://daneshyari.com/article/3897999

Daneshyari.com