VALUE IN HEALTH ▮ (▮▮▮▮) ▮▮▮–▮▮▮

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Evaluation of Noncompletion Bias and Long-Term Adherence in a 10-Year Patient-Reported Outcome Monitoring Program in Clinical Routine

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ABSTRACT

Background: Currently there is little knowledge on real-life sustainability of routine patient-reported outcome (PRO) measurement and the representativeness of collected data. **Objectives:** The investigation of routine PRO with regard to noncompletion bias and long-term adher- ence, considering the potential impact of mode of assessment (MOA) (paper-pencil vs. electronic PRO [ePRO]) and patient characteristics. **Methods:** At our department, routine PRO measurement in oncological patients is being done since 2005 using different MOA (paper-pencil assessment until 2011 and ePRO assessment from 2011 onward). We analyzed two different patient groups: patients eligible in both periods (both-MOA group) and patients eligible in only one period (one-MOA group). The primary outcome was PRO noncompletion (100% missing questionnaires). The secondary outcome was poor PRO adherence (>20% missing questionnaires). Multivariate logistic regression models were developed, testing the impact of MOA and patient characteristics on the outcomes in the different patient groups. **Results:** Data from 1484 eligible patients were included in the analyses. Most of the patients could be included in PRO assessment at least once. PRO noncompletion rates were clearly higher during paper-pencil assessment (odds ratios between 2.72 and 4.31), as were poor PRO adherence rates (odd ratio 2.23). Analyses of potential bias by patient characteristics showed that male patients had a higher risk of poor adherence. Other factors with significant impact were age, country, and cancer diagnosis, but results were indecisive. **Conclusions:** ePRO increased the feasibility of our clinical routine PRO data for retrospective analyses by increasing completion rates. In general, potential completion bias regarding certain patient characteristics requires attention before generalizing results to the respective populations.

Keywords: clinical routine, evaluation, mode of assessment, patient-reported outcomes.

Introduction

Decision makers in health care rely on high-quality data from clinical research addressing practical issues regarding risks, benefits, and costs of medical interventions to identify the best clinical and health policy approaches for the individual patient as well as for a health care system with limited resources. Patient-reported outcome (PRO) measurement today plays an important role in the creation of such clinical evidence. PROs have become an integral part in the evaluation of therapies and health care services by providing valid and reliable information directly from the patient, including his or her quality of life (QOL) [1,2]. During the past years, there has also been an increasing interest in using PROs to inform clinical practice. Studies have evaluated routine PRO assessments showing various positive effects including timely symptom detection, improved physician-patient communication, and survival benefit of patients participating in PRO monitoring compared with standard care [3–5].

Using patients' perception of disease and treatment to inform coverage and reimbursement decisions is highly desired not only by researchers and industry but also by decision makers themselves [6,7]. Evidence suggests that, in general, there is a significant lack of data from clinical studies with sufficient quality to be used for policy decision making [1,8,9]. Addressing such quality issues concerning PRO data, recommendations and guidelines on the incorporation of PROs in comparative effectiveness research

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1098-3015$36.00 – see front matter

http://dx.doi.org/10.1016/j.jval.2017.01.009

have been developed [10,11]. Nevertheless, in addition to using evidence on pure efficacy, comparative effectiveness research draws on information from nonexperimental methods common in health service and outcome research and increasingly aims at processing so-called real-life data, such as data from disease registries [12]. On the one hand, this kind of data provides valuable information from outside the idealized setting of clinical trials; on the other hand, it is problematic because of its high susceptibility to selection bias and confounding.

Being such real-life data, this also concerns PRO data collected for use in clinical routine that may be used for secondary analyses on QOL and aspects of care as well as on the effectiveness of health interventions after their implementation in clinical practice [13–15]. Such data sets need to be carefully investigated concerning representativeness regarding sociodemographic and clinical characteristics for the population of interest.

This may start with the question on the sustainability of the integration of routine PRO measurement in practice after the end of an implementation study [16]. So far, there is little knowledge on nonresponse bias and on long-term adherence with PRO measurement in real-life settings. Although nonresponse and poor adherence with PRO measurement can be compensated in clinical practice by approaching a patient directly, we do not know how missing questionnaires impact upon representativeness of emerging data sets for the population.

Therefore, the objective of the present study was to evaluate the completeness of the PRO data we collected over a period of 10 years in clinical routine at a clinical department where routine PRO monitoring has been in place since 2005 and computer-based monitoring since 2011. To our knowledge, this is the first such study being able to draw on a decade of collected data.

We analyzed logistic and patient-related factors potentially affecting noncompletion of PRO questionnaires as well as poor long-term adherence with routine PRO measurement. On the basis of the literature [17,18], we hypothesized that one such risk factor would be the mode of assessment (MOA).

Methods

Patient Cohort and Routine PRO Assessment

The study was conducted at the Department of Nuclear Medicine at the Medical University of Innsbruck. The department is a reference center for nuclear therapy and diagnostics in Austria, performing about 600 treatments using radiopharmaceuticals every year. PRO data are routinely collected at the inpatient ward where patients are treated mainly for thyroid carcinoma (ThyCa) or neuroendocrine tumors (NETs). Patients are admitted for inpatient stay to receive therapy or to undergo examinations involving radiopharmaceuticals. According to Austrian regulations for radiation protection, therapeutic dosages as well as dosages for follow-up examinations require isolation of the patient. Hence, all patients have to be admitted for inpatient stay several times.

Since 2005, we have been inviting all patients at the department to participate in routine PRO assessment. At each inpatient visit, patients are asked to complete a PRO questionnaire on health-related quality of life (HRQOL), that is, the European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire—Core 30 [19]. Eligibility criteria for PRO monitoring are as follows:

1) cancer diagnosis;
2) 18 years or older;
3) no brain metastases;
4) no diagnosis of dementia or other cognitive impairment; and
5) using the QLQ-C30 at the time of inpatient visit.

Patients may refuse to participate in routine PRO monitoring without having to anticipate negative consequences in care. Also, they are allowed to skip questions without giving reasons, both in paper-pencil and in electronic assessment.

The completion of the questionnaire is embedded in the admission procedures performed by the nursing staff; that is, the patients are approached by the nurse and asked to complete the questionnaire along with the other information material the patient has to provide before admission. This is usually done before the patient is seen by the physician and takes about 10 minutes of a patient's time. The information provided by the nurse involves a short explanation of HRQOL assessment and the rationale for collecting the data in clinical routine as well as that individual questionnaire results will be accessible only by the clinical staff of the ward.

PRO assessment was done in paper-pencil between 2005 and June 2011. Since June 2011, electronic PRO (ePRO) assessment has been implemented. Both in paper-pencil and in ePRO assessment, questionnaires were completed by the patients themselves. ePRO was done using a tablet PC and a software designed for the purpose of PRO assessment (Computer-based Health Evaluation System) [20]. The software allows the electronic collection of questionnaire and clinical data and provides immediate graphical representation of assessment results. ePRO assessment does not require specific computer skills on part of the patient because he or she is presented only the tablet PC with the screen already exhibiting the first question. The survey shuts down automatically after the last question without requiring any action by the patient or the nurse.

Paper-pencil data were fed into the ePRO software by research assistants from 2009 onward making old paper-pencil data available electronically for carers.

Patient Groups for Analyses

Because of different MOA, there were two distinct groups of patients to be considered in the analyses. The first was the both-MOA group. It comprised patients who were eligible for PRO monitoring in both assessment periods, that is, those who were asked to complete at least once a paper-pencil questionnaire and at least once an electronic version of the questionnaire. Data from this group allowed to control for subject effects and therefore were used for the main analyses on the impact of MOA and patient characteristics on missing assessments.

The second group was the one-MOA group. It comprised patients who were eligible for PRO monitoring in the paper-pencil period or the ePRO period only. Data from this group were used for sensitivity analyses.

Patients could belong to only one group; that is, there was no overlap of patients between the both-MOA group and the one-MOA group.

Factors and Covariates with Potential Impact on Outcomes

We hypothesized that the following sociodemographic and clinical characteristics potentially influence missing data: country (Austria vs. other), cancer diagnosis (ThyCa vs. NET vs. other), age, sex, education (A level vs. below A level), and children (yes vs. no). The country variable was tested because the department is a reference center for nuclear therapy in Austria and for surrounding non-Austrian regions. We hypothesized that the commitment to the department's procedures might be different for patients receiving treatment outside their own country. Also, there may be different attitudes toward questionnaire administration. Furthermore, it could be that the hospital staff approaches these patients differently.

Cancer diagnosis was considered because the groups were different concerning prognosis and symptom burden. Patients