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The Burden of Diabetes Mellitus in Patients with Coronary Heart Disease: A Methodological Approach to Assess Quality-Adjusted Life-Years Based on Individual-Level Longitudinal Survey Data

Michael Laxy, MPH^{1,2,*}, Matthias Hunger, PhD¹, Renée Stark, MD, MPH¹, Christa Meisinger, MD, MPH^{3,4}, Inge Kirchberger, PhD, MPH^{3,4}, Margit Heier, MD^{3,4}, Wolfgang von Scheidt, MD⁴, Rolf Holle, PhD^{1,2}

¹Institute of Health Economics and Health Care Management, Helmholtz Zentrum München, German Research Center for Environmental Health, Neuherberg, Germany; ²German Center for Diabetes Research, Neuherberg, Germany; ³Institute of Epidemiology II, Helmholtz Zentrum München, German Research Center for Environmental Health, Neuherberg, Germany; ⁴KORA Myocardial Infarction Registry, Augsburg Hospital, Augsburg, Germany

ABSTRACT

Background: Reliable burden of disease (BOD) estimates are needed to support decision making in health care. **Objectives:** The objective of this study was to introduce an analysis approach based on individual-level longitudinal survey data that estimates the burden of diabetes in patients with coronary heart disease in terms of quality-adjusted life-years (QALYs) lost. **Methods:** Data from two postal surveys (2006, N = 1022; 2010–2011, N = 716) of survivors from the KORA Myocardial Infarction Registry in Southern Germany were analyzed. Accumulated QALYs were calculated for each participant over a mean observation time of 4.1 years, considering the non-informative censoring structure of the follow-up study. Linear regression models were used to estimate the loss in (quality-unadjusted) life-years and QALYs between patients with and without diabetes, and generalized additive models were used to analyze the nonlinear association with age. The cross-sectional and longitudinal association with quality of life (QOL) and QOL change and the impact on mortality

were analyzed to enhance the understanding of the observed results. **Results:** Diabetes was associated with a reduced QOL at baseline (cross-sectional: $\beta = -0.069$; $P < 0.001$), but not with a significant longitudinal QOL change. Mortality in patients with diabetes was increased (hazard ratio = 1.68; $P < 0.005$). This resulted in a loss of 0.14 life-years ($P = 0.003$) and 0.37 QALYs ($P < 0.001$). Results from generalized additive models indicated that the burden of diabetes is less pronounced in older subjects. **Conclusions:** The application of the proposed approach provides confounder-adjusted BOD estimates for the studied time horizon and can be used to compare the BOD across different chronic conditions. Curative efforts are needed to diminish the substantial diabetes-related QALY gap. **Keywords:** burden of disease, coronary heart disease, diabetes, population-based, QALYs.

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Introduction

Diabetes and cardiovascular diseases, such as coronary heart disease (CHD), are major public health problems [1,2]. Particularly, the coexistence of metabolic and cardiovascular conditions is frequent and known to have an overproportional impact on health outcomes [3–5]. Currently, around 10% of the German adult population has a diagnosis of CHD and around one-third of them suffer from diabetes mellitus [6,7]. Although the influence of diabetes and CHD on quality of life (QOL) or survival is well studied, there are few studies investigating the impact of these conditions

on combined measures of morbidity and mortality [3,4,8]. To comprehensively quantify the burden of diseases (BODs), measures such as quality-adjusted (QA) life-years (QALYs) that account for both the length and the quality of life are needed. The QALY concept is based on utility theory and welfare economics and was established to evaluate the cost-effectiveness of health care interventions over a certain time horizon [8]. It relies on the idea that each health state has a preference-based utility value attached to it and that health can be understood as “value-weighted time,” or more concretely, as the accumulated product of QOL and life years (LY), the QALYs [9].

Conflict of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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* Address correspondence to: Michael Laxy, Helmholtz Zentrum München, German Center for Environmental Health, Institute of Health Economics and Health Care Management, Ingolstädter Landstraße 1, 85764 Neuherberg, Germany.

E-mail: michael.laxy@helmholtz-muenchen.de.

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Representative and reliable BOD estimates are important, first, to quantify the relative impact of a disease on the society's health; and, second, to feed decision analytic models to assess the cost-effectiveness of large-scale interventions outside of controlled trials. To date, different methodological approaches have been used to estimate the burden of specific conditions quantitatively. Jia et al. [10–12] proposed to combine aggregated cross-sectional QOL data sources with abridged life table statistics to estimate the reduction in quality-adjusted life expectancy (QALE) due to a specific condition nationwide. Other researchers estimated the QALYs lost over a certain time horizon by using the method of quality-adjusted survival, either by matching longitudinal primary mortality data with aggregated cross-sectional QOL data [13,14] or by using longitudinal primary data [15,16].

While model-based long-term predictions might be limited in precision and validity, the method of quality-adjusted survival analyses was not specifically designed to handle varying follow-up times resulting from varying study start and termination dates, as is often the case in population-based follow-up studies. Although methodological extensions to handle censoring for quality-adjusted survival have been published and a lot of data from prospective cohort studies are available, population-based longitudinal data have rarely been used for comprehensive BOD studies [17]. A method based on individual-level longitudinal QOL and respective survival times that considers the censoring structure in population-based studies and provides reliable BOD estimates can therefore be expected to be a valuable extension of current methodological approaches.

The primary objective of this study was to present an analysis approach that estimates the burden of diabetes in patients with CHD in terms of QALYs lost on the basis of individual-level data from a population-based follow-up study. The study further analyzes the cross-sectional and longitudinal association with QOL and QOL change and the impact on mortality to enhance the understanding of the observed results and suggests an approach regarding how to consider the potentially nonlinear relationship between age and BOD.

Methods

Data Sources

Data for this analysis originated from the KORA (Cooperative Health Research in the Region of Augsburg) Myocardial Infarction (MI) registry. This population-based registry has been collecting information on all cases of coronary deaths and acute nonfatal MI in inhabitants aged 25 to 74 years in the city of Augsburg and the two surrounding counties in Southern Germany [18,19]. A total of 2950 patients who were registered with an acute MI between 1985 and 2004 and were known to be alive ($n = 4394$) answered an initial postal survey between August and December 2006 (67% participated). Because of feasibility issues and prioritization of research questions to be answered, only a subset ($n = 1022$) of statutorily insured patients (~88% of the German population is statutorily insured) of the baseline sample was followed and patients known to be alive by the end of 2010 were contacted again in a postal “follow-up” survey in 2011. During the mean observation time of 4.1 years (mean follow-up time until censoring), 141 participants died and 716 replied to this follow-up survey (85% participated). A brief overview of the design of this follow-up study is provided in the upper part of Figure 1. Both the 2006 and 2011 surveys included standardized questions, assessing socioeconomic characteristics, medical history, current medication, lifestyle habits, quality of medical care, and QOL. Medical and sociodemographic information recorded at the time of the last MI were available from the MI registry. The study was granted full ethical approval by the ethics commission of the Bavarian Medical Association (registration no. 12057).

Measures

Outcomes

QOL was assessed by using the EuroQol five-dimensional questionnaire (EQ-5D). The EQ-5D is a multiattribute descriptive system comprising five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), each of which has three response levels (no problems/some or moderate problems/extreme problems). The 243 resulting health states can

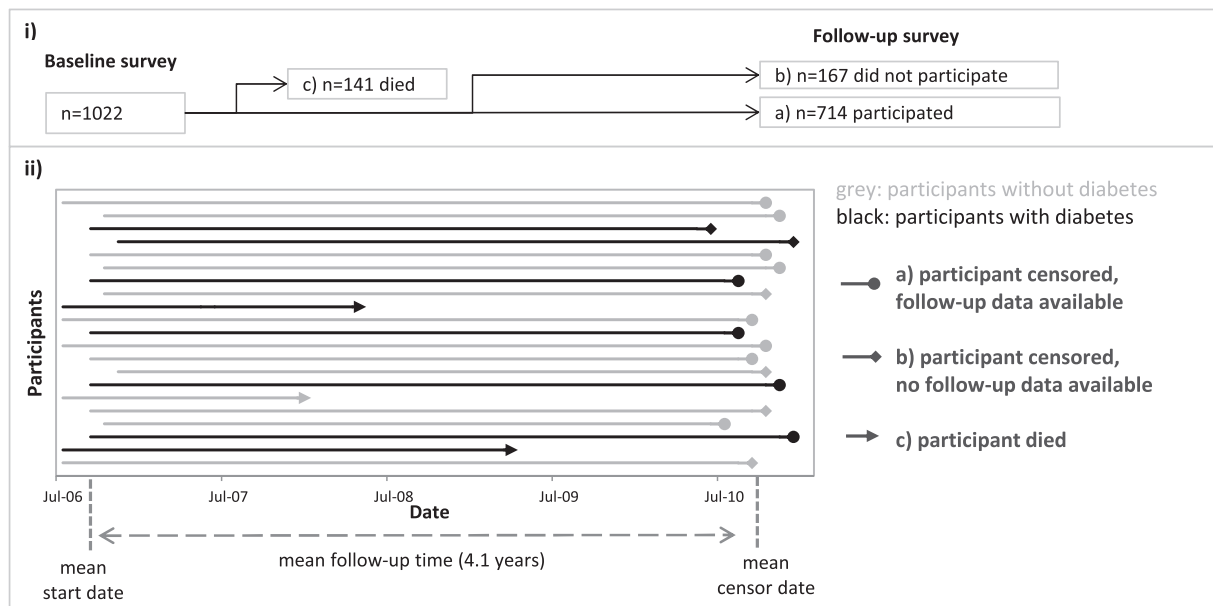


Fig. 1 – Qualitative description of the data and censoring structure of the follow-up study.

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