Study Protocol

Barriers and facilitators to palliative care of patients with chronic heart failure in Germany: a study protocol

Stefan Köberich,[1,2] Jeantte Ziehm,[1] Erik Farin,[1] Gerhild Becker[3]

[1]Institute for Quality Management and Social Medicine, Medical Centre - University of Freiburg, [2]Heart Centre, University of Freiburg; [3]Department of Palliative Care, Medical Centre, University of Freiburg, Germany

Significance for public health

Patients with chronic heart failure suffer from similar symptoms and symptom burden than patients with malignant diseases. However, palliative care differs between these groups in a quantitative and qualitative way. This study will help to understand why patients with chronic heart failure receive less palliative care than patients with malignant disease. In addition, measures to overcome barriers and to promote facilitators of palliative care in patients with chronic heart failure will be developed. These recommendations could provide a basis for quality improvement projects or studies aiming at improving symptoms and symptom burden of heart failure patients. The recommended measures could also be used to reduce caregiver burden.

Abstract

Background. Despite its high prevalence, similar symptoms and symptom burden, people suffering from chronic heart failure receive less palliative care than patients with malignant diseases. Internationally, numerous barriers to palliative care of patients with chronic heart failure are known, however, there are no credible data regarding barriers and facilitators to palliative care of people suffering from chronic heart failure available for Germany.

Design and Methods. Tripartite study. First part of this study evaluates health care providers' (physicians and nurses) perceived barriers and facilitators to palliative care of patients with chronic heart failure using a qualitative approach. At least 18 persons will be interviewed. In the second part, based on the results of part one, a questionnaire about barriers and facilitators to palliative care of patients with chronic heart failure will be designed and applied to at least 150 physicians and nurses. In the last part a classic Delphi method will be used to develop specific measures to improve the palliative care for chronic heart failure patients.

Expected Impact for Public Health. The results of this study will help to understand why patients with heart failure are seldom referred to palliative care and will provide solutions to overcome these barriers. Developed solutions will be the first step to improve palliative care in patients with heart failure in Germany. In addition, the results will help health care providers in other countries to take action to improve palliative care situations for heart failure patients.

Background

Chronic heart failure (CHF) is one of the most common diseases of the cardiovascular system in Germany. Due to our aging population and the high survival rate after myocardial infarction, an increase in its prevalence in the coming years and decades has been predicted. In Germany it is expected that the number of CHF patients older than 80 years will double from a population of 141,000 in 2009 to 353,000 in 2050.[1] CHF is the third leading cause of death after chronic ischaemic heart diseases and myocardial infarctions and is ahead of diseases like malignant lung, bronchial, breast, and colon cancers.[2] The course of CHF is characterised by worsening symptoms such as dyspnoea, pain, and fatigue leading to a reduction in daily activities and decreased quality of life.[3] CHF is also a burden to family and friends, especially when patients' symptoms and everyday limitations become worse. Family members can suffer from social isolation, anxiety, insomnia, depression, and physical exhaustion as well as worries about their financial situation.[4-5]

In addition to optimised medical standard of care, palliative care is known to contribute to improving the situation for CHF patients and their relatives and its importance has therefore been acknowledged in national and international guidelines for the management of people suffering from CHF.[6]

The WHO defines palliative care as an approach to improve quality of life, further it is addressed to patients and their families struggling with problems resulting from a life-threatening disease.[7] Through early detection, accurate diagnoses, the treatment of pain and other physical, psychological, and psycho-social afflictions, palliative care concentrates on the prevention and alleviation of suffering and if required, can be initiated at the time of diagnosis. Studies with small sample sizes suggest that the palliative care of CHF patients is associated with decreasing symptom burden and depression and a higher quality of life,[8] as well as greater satisfaction with the treatment, less need for additional opioids thanks to more effective pain management,[9] and fewer rehospitalisations.[10] Moreover, patients and their relatives consider palliative care as a facilitator to a holistic and continuous treatment approach which focuses on therapy goals while offering valuable support in coping with the course and consequences of the disease. A retrospective analysis of 40,000 patients at a German university hospital found that heart failure was a significant risk factor for requiring palliative care (Becker *et al*., personal communication). Some CHF patients suffer from severe pain and dyspnoea and can thus experience symptoms and a symptom burden similar to those of cancer patients.[11] The palliative care of CHF and that of cancer patients differs in Germany with only up to 6.7% of patients diagnosed with a cardiovascular disease receiving palliative care in 2013.[12]

Chronic heart failure patients receiving palliative care suffer more dyspnoea, are given fewer medications than prescribed, and die alone more often than cancer patients in palliative care.[13] The reasons for the qualitative and quantitative differences between palliative care of CHF *vs*. cancer patients have therefore far received little research attention. One main reason for the differences might be the course of heart failure, which is characterised by stages of exacerbation and relief which makes predicting the right time to initiate palliative care difficult.[14] Furthermore, palliative care is regarded as end-of-life care even though the WHO recommends its initiation at the time of diagnosis. Other likely barriers to the palliative care of CHF patients are the lack of knowledge about its features and structures, communication problems between primary care physicians, cardiologists, and other healthcare system participants regarding the initiation and management of palliative care, difficulty identifying which patients should receive palliative care, and diverse attitudes on the part of different professions.[15] To the best of our knowledge, there is no credible data available for Germany regarding physicians' and nurses' attitudes towards palliative care or its barriers and facilitators for CHF patients.

This is the first study to identify barriers and facilitators to palliative care of CHF patients as perceived by key participants within the healthcare system (physicians and nurses caring for CHF patients) in Germany, and thereby to develop action plans to improve the situation. This study's findings may facilitate future interventions to develop and expand palliative care for people suffering from CHF and could reduce their symptom burden as well as the strain on their relatives.

This project will focus on the following research questions: I) Which attitudes do healthcare system participants (primary care physicians, resident cardiologists, hospital physicians in the cardiology area, nurses in acute and ambulant areas) hold regarding the palliative care of people suffering from CHF? II) Which barriers and facilitators do healthcare system participants perceive regarding the palliative care of patients with CHF? III) What action plans can be derived from the barriers and facilitators thus identified?

Study design and methodology

Our project is organised in three phases. I) Qualitative study to identify barriers and facilitators regarding the palliative care of CHF patients as perceived by physicians and nurses. II) Development of a questionnaire and survey to assess the perceived barriers and facilitators to palliative care of people suffering from CHF more broadly. III) Generation of action plans to promote palliative care for CHF patients.

Phase 1 (qualitative study – problem-focused interviews)

In the first phase we will assess the barriers, facilitators, personal theories, and decision-making rules regarding palliative care for CHF patients as perceived by physicians (hospital physicians, resident cardiologists, primary care physicians) and nurses (hospital, ambulant care, heart failure nurses) using qualitative methods of data collection. We plan to conduct nine guided, problem-centred interviews with each professional group (overall N=18). The interview guideline will be developed by applying current knowledge of the topic and will be tested in one to two interviews and adapted accordingly if required. Once we have the interviewees' approval, the interviews will be taped. Their professional and biographical background and socio-demographic data will also be documented. Interviews will be analysed according to Mayring's qualitative content analysis.[16] Additional interviews will be conducted if we do not reach data saturation after the first 18 interviews. Data analysis will be performed within an established qualitative analysis group to ensure quality criteria like inter-subjective reconstruction. Those results will be discursively and inductively transferred to an explanatory model, which will clarify the activities of healthcare system participants in their dealings with people suffering from CHF. Interviewees will be recruited by our contacts in each regional office of the *Competence Centre Palliative Care Baden-Wuerttemberg*. This competence centre is a network of the four university hospitals in Baden-Wuerttemberg (Freiburg, Heidelberg, Tubingen, Ulm). The project members' professional networks should also be used. Interviews will be conducted face-to-face or by telephone. Face-to-face interviews are preferred, as interviewees are usually more open in such a setup. Telephone interviews will serve to enhance data saturation. Interviewees for the face-to-face interviews will be recruited from Freiburg and its environs, which possess a good palliative care infrastructure. Nevertheless, CHF patients receive too little palliative care there too, as the investigators can attest. The data analysis should enable us to identify specific barriers and facilitators to the palliative care of CHF patients. To guarantee data saturation, physicians and nurses from other regions will be interviewed as well.

Phase 2 (questionnaire development and survey)

A questionnaire derived from the interview results will be developed and tested in phase 2. This will focus on the following attributes: i) barriers and facilitators to the palliative care of CHF patients; ii) attitudes toward the palliative care of CHF patients.

Barriers and facilitators are defined as influencing factors that support or hinder palliative care of CHF patients as perceived or experienced by participants in the healthcare system. The term *attitudes* refers to the individual judgements and opinions about the palliative care of CHF patients held by medical practitioners that can result in genuine behavioural changes (*e.g.*, setting up palliative care programs). Statements extracted from the interviews will be grouped and operationalized. To determine content validity the Content Validity Index (CVI) will be assessed by consulting specialists in palliative care. This entails rating the relevance of a central item assessing the construct of interest on a 4-point Likert scale (1 = irrelevant; 4 = very relevant). An item is approved if y of x raters estimates the item as relevant (value 3 to 4 on the Likert scale; Table 1).

To psychometrically test the instrument, a minimum of N=150 physicians and/or nurses will be surveyed online. The following instrument properties will be checked.

- *Distribution of items*: i) analysis of response distribution by determining number and percentage distribution of responses per item; ii) analysis of floor- and ceiling effects (given if over 50% of subjects choose extreme response categories on a Likert scale).
- *Scale structure and factorial validity* (exploratory factor analysis): i) to assess which data suit an exploratory factor analysis, the following values are computed: Kaiser-Meyer-Olkin coefficient should be >0.60; ii) Bartlett's sphericity test: this test should be significant; iii) factor analysis [a) principle component analysis with varimax rotation; b) factors' eigenvalues should be >1].
- *Unidimensionality of the resulting scales* (confirmatory factor analysis). The following fit indices and critical values will be evaluated: i) Comparative Fit Index: >0.9: acceptable model fit; >0.95: good model fit; ii) Tucker-Lewis Index: >0.9: acceptable model fit; >0.95: good model fit; iii) Root mean square error of approximation: <0.10: mod-

Table 1. Content Validity Index item approval criteria.

Overall number of raters (x)	Minimum number (y) of raters to estimate the item as relevant
2-5	y=x
6-8	y=x−1
9-10	y=x−2

erate model fit; <0.05: good model fit; iv) Standardised root mean square residual: <0.08.
- *Criterion validity* (to confirm theoretically-expected relations between the assessed constructs and external criteria).
- *Internal consistency:* computation of Cronbach's Alpha (target value >0.70) and its 95% confidence interval for scales and subscales.

The results from this project phase will be used to describe participants' attitudes and perceived barriers and facilitators. Subgroup analyses serve to distinguish between occupation and professional experience. Relevant specialised organisations will be asked whether they can contact their members by mail to inform them about potential participation in this study.

Phase 3 (development of action plans)

In phase 3, we will design specific measures to improve the palliative care for CHF patients in accordance with the results we obtain (thus evidence-based). These measures will be developed using a classic Delphi method in three rounds. Ten to 15 heart-failure specialists from cardiology and palliative care will be invited to participate for this purpose. The Delphi method will be conducted online. In the first round of the Delphi method, the experts will be presented with the findings from our project's phase 2. In reference to those, the experts will propose measures to support palliative care for people suffering from CHF. Their proposals will be categorised using content analysis. In round 2 the proposals will be presented to the experts together with recommendations by the project group for agreement. Proposals from the phase-1 interviewees will also be integrated. Proposals will be evaluated according to *relevance* and *practicability* on an 11-point numeric rating scale (relevance: 0 = no relevance; 10 = highest relevance; practicability: 0 = not practicable; 10 = highly practicable). Means and standard deviations of experts' responses will be computed. In round three of the Delphi method, the experts will be asked to re-evaluate the proposals while being informed about the means and standard deviations from the second round as additional evaluation criteria. In so doing, the experts should reach a consensus on the proposals' appropriateness and feasibility. The expert group should ideally consist of physicians (primary care physicians, resident cardiologist, hospital physicians), nurses (ambulant care, hospital), and representatives of self-help groups, health insurers, and palliative care organisations (theory and practice). The implementation of the activity proposals will not constitute part of this project.

Discussion

Despite the current knowledge from foreign countries about barriers and facilitators to the palliative care of CHF patients, there are no data from German-speaking regions (Germany in particular) available. This study has been designed to contribute to the description of the reality of palliative care for CHF patients and hence to the development of recommendations for improving therapy structures for CHF patients. The strength of this study lies especially in the variety of methods we will apply, as they will enable us to assess individual opinions and experiences of health professionals and also to gather a large pool of quantitative data by conducting a survey. To the best of our knowledge, no Delphi method has ever been used in this respect. The advantage of this method is that it will enable palliative care experts to come to a consensus regarding strategies and recommendations in order to improve the care situation without being influenced by opinion leaders.

This study's main challenge will be to find enough interviewees willing to talk openly about their attitudes about the palliative care of CHF patients. Furthermore, we are wary of the various *philosophies*, attitudes and interests described in other studies concerning palliative care – that they will be defended by participants in the healthcare system and thus hinder the development of recommendations for improving the situation for CHF patients. We are well aware that choosing the experts for the Delphi method will be difficult. It would be worthwhile considering whether experts from communication research and healthcare-system research outside the fields of cardiology and palliative care should eventually be included to ensure an interdisciplinary approach.

Correspondence: Stefan Köberich, Institute for Quality Management and Social Medicine Medical Centre - University of Freiburg, Engelbergerstrasse 21, 79106 Freiburg, Germany.
Tel.: +49.761.270.73590 - Fax: +49.761.270.73310.
E-mail: stefan.koeberich@uniklinik-freiburg.de

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