

Assessing the health-related quality of life in patients hospitalised for acute heart failure

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Acute heart failure (AHF) is a common cause of hospitalisation, presenting substantial economic and humanistic burden for healthcare systems and patients. This study was designed to capture proxy UK health-related quality of life (HRQoL) data for hospitalised patients with AHF.

Proxy assessments of HRQoL for patients were obtained from 50 experienced UK cardiac nurses (formal caregivers) and from 50 UK individuals who acted as caregivers for patients who had experienced an AHF event leading to hospitalisation (informal caregivers). Data were collected retrospectively for four time points (days 1, 3, 5 and 7 post-hospital admission for AHF event) using the EQ-5D. Results show a disparity in reported HRQoL at day 1 values between caregiver types (mean single utility index 0.20 vs. 0.68, respectively, $p < 0.001$). By day 7, formal caregivers rated typical patients' HRQoL as being comparable to informal caregivers' assessments (0.82 vs. 0.73, respectively, $p = 0.145$).

In conclusion, collection of utility data in severe acute conditions is challenging. This study captures values through the use of proxy assessment. Data suggest that AHF hospitalisation is associated with a significant HRQoL burden and that there exists a need for development of new treatments aimed at improving hospitalisation outcomes.

Introduction

Acute heart failure (AHF) has been defined by the European Society of Cardiology (ESC) as the rapid onset of, or change in, symptoms and signs of heart failure, and is a life-threatening condition that requires immediate medical attention.¹ These symptoms and signs include shortness of breath



at rest or during exertion, fatigue, pulmonary or peripheral fluid retention, a cough, and evidence of an abnormality of the structure or function of the heart at rest.²⁻⁴ This change in cardiac function results in an urgent need for therapy, and AHF is among the most common causes of hospitalisation.⁵ AHF can, therefore, be seen to represent a huge burden on healthcare resources,⁶ with the need for hospitalisation in order to stabilise the condition of patients being the single largest contributor to the costs of managing AHF.⁷ The situation is further worsened in that readmission rates are high following discharge; approaching 50% within six months.⁸

As well as the substantial economic burden on healthcare services, a diagnosis of AHF is associated with a significant health-related quality of life (HRQoL) burden for patients. When making decisions about allocation of healthcare resources, many decision makers consider the impact of the intervention on both costs and health outcomes.⁹ Health outcomes are commonly aggregated into quality-adjusted life years (QALYs), which is a metric that combines both survival and quality of life. AHF represents a significant challenge to quality of life for patients, due to a combination of the debilitating effects of the condition and the necessity for hospitalisation. Despite the incidence of the condition and the extent of burden experienced there is a paucity of utility data available for AHF, which could be used in economic analyses.

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Table 1. Participant characteristics for the two caregiver groups

Characteristics	Formal caregivers (cardiac specialist nurses)	Informal caregivers (patient's relatives)
	n=50	n=50
Gender		
Females (%)	74	56
Age, years (n)		
18–21	–	9
22–29	6	24
30–39	19	11
40–49	15	2
50–59	10	2
60+	–	2
Ethnicity (n)		
White	46	38
Black/Black British	–	5
Asian/Asian British	2	6
Chinese	1	–
Mixed	1	1
Employment		
Full or part time (%)	100	58

Table 2. EuroQol five dimension (EQ-5D) utility values for the four time points following acute heart failure event, mean (standard deviation)

	Day 1	Day 3	Day 5	Day 7
Caregivers				
Formal	0.199 (0.43)	0.563 (0.25)	0.701 (0.24)	0.817 (0.20)
Informal	0.675 (0.42)	0.662 (0.40)	0.713 (0.37)	0.726 (0.39)

AHF patients were surveyed. In an attempt to address potential sources of bias, proxy assessments were made both by relatives of patients that had experienced recent AHF and by healthcare professionals who regularly manage patients with the condition.

Materials and methods

Participants and methods

Fifty nurses with a minimum of two years' experience, who regularly treat cardiac patients (formal caregivers), and 50 close relatives of different patients who had been hospitalised as a result of AHF within the last six months (informal caregivers), were recruited in the UK via a specialist agency. Prior to any data collection taking place, ethical approval was sought for the study protocol from an institutional review board. Potential participants were forwarded a URL for the study website where they were presented with additional information pertaining to the study. Basic sociodemographic data were obtained before proceeding with the assessment exercise.

Participants were asked to provide assessments of the HRQoL of either a 'typical' AHF patient (formal caregivers) or the affected relative who was under their care (informal caregivers) at each of four time points (time elapsed since hospital admission = one day, three days, five days, seven days). All assessments were made using the EuroQol five dimension (EQ-5D) instrument.

EQ-5D

The EQ-5D is a widely used generic HRQoL instrument and is the preferred measure of health status for bodies such as the National Institute for Health and Clinical Excellence (NICE).⁹ It comprises of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) each with three levels detailing the extent of problems experienced. Subsequent to these evaluations, the EQ-5D contains a 100 mm visual analogue scale (VAS) addressing the individual's reported current overall health. The EQ-5D has been used previously to assess critically ill individuals in intensive care settings with a variety of different conditions.^{13,14} Additionally, it has previously demonstrated sensitivity to the HRQoL impact

Most HRQoL assessment relies on self-report from patients, but for individuals who are severely or acutely ill this is often not possible for a variety of practical and ethical reasons. Capturing HRQoL information accurately from individuals who are unable or unwilling to complete appropriate instruments, therefore, poses a challenge. One potential approach to overcoming this issue is through the use of proxy assessment. Proxy measures have been successfully used previously in a number of different patient populations including rehabilitation patients¹⁰ and individuals with

developmental disabilities.¹¹ These studies have demonstrated agreement between self-reported assessments and those of proxies, but other findings suggest that proxy assessment may be subject to bias and measurement error.¹²

The purpose of the current study was to capture quality of life data for patients in the days immediately following AHF hospitalisation. Given the practical and ethical challenges posed by collecting data directly from acutely ill patients, a proxy assessment approach was employed in which the caregivers of

of a number of different heart conditions (including coronary artery bypass and aortic valve surgery, coronary heart disease, and acute coronary syndrome).¹⁵⁻¹⁸ Although the instrument was originally designed to be self-completed, many studies have used proxy administration where patient completion may be inappropriate or even impossible.¹⁹⁻²¹ Calculation of the EQ-5D single index utility value involves the application of preference weights collected from large scale data collection efforts with the general public. Application of the UK weights typically leads to a range of scores from 0 (representing states of health equivalent to being dead), up to a maximum of 1 (representing a state with no health problems). Negative values are possible for states of extremely poor health and represent states rated worse than being dead. The VAS component of the EQ-5D produces scores from 0 (worst imaginable health) to 100 (best imaginable health).

Statistical analysis

Demographic data were summarised using frequency counts and percentages, and independent *t*-tests were performed to assess differences between caregiver groups at each time point.

Results

Study participants

The characteristics of the two caregiver groups are presented in **table 1**.

Proxy EQ-5D assessments

The mean EQ-5D single index utility values calculated for the four time points post-AHF event are reported in **table 2**. Formal caregiver assessments of HRQoL are significantly lower than those of informal caregivers at day 1 (*t*[98]=−5.570, *p*<0.001). Later assessments do not differ significantly between groups and demonstrate a steady improvement in perceived HRQoL over the course of the seven-day period post-AHF event. **Figure 1** presents the utility values plotted over time.

The EQ-5D VAS scores for the four time points post-AHF event are presented in **table 3**. The disparity in HRQoL assessment at day 1 between the two groups is less marked than seen with the utility values. Formal caregivers assessments of HRQoL based on their experience do, however, remain lower

Figure 1. EQ-5D utility values by caregiver group across time points

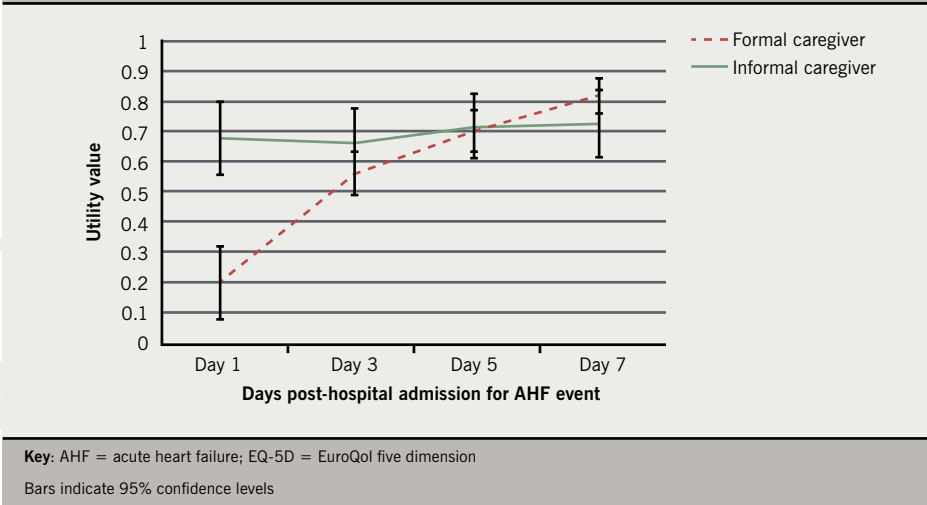


Table 3. EQ-5D visual analogue scale (VAS) values for the four time points following AHF event, mean (standard deviation)

	Day 1	Day 3	Day 5	Day 7
Caregivers				
Formal	42.00 (20.26)	52.42 (15.72)	61.20 (18.28)	66.38 (19.31)
Informal	62.44 (23.79)	69.42 (23.34)	73.24 (23.57)	74.82 (25.98)

than informal caregivers across all time points and differ significantly at day 1 (*t*[98]=−4.63, *p*<0.01), day 3 (*t*[98]=−4.27, *p*<0.01) and day 5 (*t*[98]=−2.85, *p*<0.01). Visual analogue scale scores for day 7 approximate those for an existing survey of the UK general population (mean 82.5, standard deviation [SD] 17).²² Unlike the trend witnessed with the utility values, the rate of improvement in HRQoL for the two groups is broadly similar (albeit with the formal caregivers suggesting greater overall improvement due to lower baseline values). **Figure 2** presents VAS scores plotted over time.

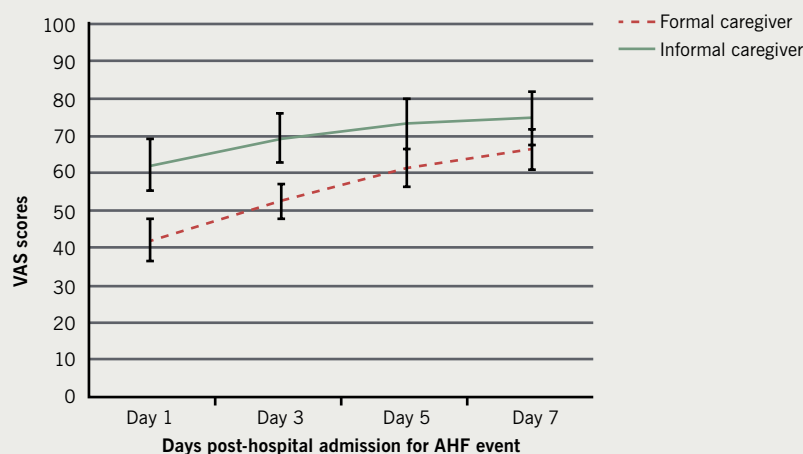
Discussion

This study aimed to assess HRQoL for patients who have been hospitalised as a result of AHF. Health utilities were captured via proxy administration of the EQ-5D instrument with both formal and informal caregivers. The findings suggest that AHF hospitalisation is associated with very poor quality of life, at least in the short term. Over the course of the seven days following hospitalisation, significant improvement occurs as evidenced by the

increase in reported utility values. The results also demonstrate some disparity exists as to the average extent of problems experienced by patients as judged by the different caregiver groups. The utility values for the formal and informal caregivers deviate greatly at day 1 after the AHF event but, as expected, both suggest that patients experience substantial problems related to ill health and hospitalisation. Previous studies have found the EQ-5D instrument can be valid when administered by proxy.²³⁻²⁴ The decision to use two different sources of proxy values in the study was an attempt to avoid introducing systematic bias into the results. It is likely that both the formal and informal caregiver group assessments are influenced by a number of factors unique to their relationship with patients. Formal caregiver assessments of a ‘typical’ AHF patient suggest that HRQoL is more detrimentally affected by event-related hospitalisation. This may be a product of a more ‘functional capacity’ based approach to evaluating health. Given the extremely

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Figure 2. EQ-5D VAS scores by caregiver group across time points



Key: AHF = acute heart failure; EQ-5D = EuroQol five dimension; VAS = visual analogue scale
Bars indicate 95% confidence levels

is difficult to avoid when employing such a methodology. We have attempted to limit the potential for this to occur by including an inclusion criteria that the patients under the informal caregivers care had to have experienced the AHF event a maximum of six months previously (with the majority doing so within a three-month period). Although this shorter period of time should facilitate more accurate recall, the relatively small window of time between each study time point (day 1, 3, 5 and 7 post-AHF event) may serve to blur distinctions in the patient's quality of life at these intervals. This may be reflected in the fact that the range of utility values for the informal carer group is narrower than that of the formal caregivers. All of these potential sources of bias were recognised when the study was designed, which led us to make the decision to include data collection from two independent groups. Despite these limitations we believe that the study has provided some insight into the HRQoL effects of AHF hospitalisation as viewed by different caregiver groups. Interestingly, a recent draft of the NICE guidelines for health technology assessment has proposed the use of caregiver derived utility values in preference to those provided by healthcare professionals when collecting HRQoL data.²⁵

The study supports previous research suggesting that there is a marked decline in HRQoL associated with hospitalisation as a result of experiencing an AHF event. Recent research has suggested that there is significant variation in prescribing practices, which may have led to suboptimal outcomes for many patients.²⁶⁻²⁷ Improved pharmacological management of AHF to reduce the incidence of hospitalisation and length of stay, could confer substantial benefits for patients and healthcare systems ●

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Conflict of interest

SHO and PL are employed by Novartis Pharma AG. Oxford Outcomes were paid a fixed fee to design and conduct this study by Novartis Pharma AG.

debilitating immediate impact of an AHF event this could lead to reports of greatly diminished HRQoL. In contrast, informal caregiver assessments of relatives HRQoL suggest that the deterioration is somewhat less pronounced. It is likely that these particular assessments are informed by a more intimate knowledge of the pre-event baseline health status of patients and reflect a 'relative change' based evaluation approach. Although the assessment exercises conducted by the raters are essentially different in terms of their focus, it is difficult to argue that either assessment is objectively superior when looking solely at data collected using the EQ-5D. As the instrument was designed specifically for use by members of the general public with no formal medical training this should not disadvantage informal caregivers in making valid assessments. Future work looking at the level of agreement between retrospective patient assessments of HRQoL and those made by proxies may give a clearer indication of which values correspond more closely. Of course, such retrospective assessments are themselves subject to confounds in the form of recall biases.

The study has some important limitations that should be considered when interpreting the results. No assessment was captured

directly from any patient, which introduces concerns over the validity of the values obtained. However, there are clearly a number of logistical and ethical issues, such as the difficulty in obtaining informed consent from severely ill patients, which make prospective data collection challenging. Retrospective data collection presents one possible alternative method for obtaining suitable HRQoL data. Such an approach could be nonetheless affected by a selection bias with only those who survived (and perhaps, therefore, those with the least severe events or best outcomes) being capable of providing data. It is possible that this selection bias may have influenced the current study, with the caregivers who participated being relatives of patients who are recovering or have recovered from the AHF event (although we do not have sufficient data to verify this assumption). Informal caregivers may have been assessing a less severely affected group of patients than formal caregivers, and this could, therefore, at least partly explain differences in the HRQoL ratings from the two groups. The retrospective assessment approach taken in this study may also have led to recall bias. Given the nature of their occupation, formal caregivers are more likely to have had recent and frequent experience of patients in the immediate post-AHF state. In practical terms, this problem

Key messages

- Acute heart failure (AHF) is a common cause of hospitalisation, presenting a substantial burden for healthcare systems, as well as patients. This study was designed to capture proxy UK health-related quality of life (HRQoL) data for hospitalised patients with AHF
- This study demonstrates the feasibility of capturing HRQoL data for acutely unwell patients, perhaps unable or unwilling to self-report such issues
- Results show a disparity in reported HRQoL at day 1 values between caregiver types; however, by day 7, formal caregivers rated typical patients' HRQoL as being comparable to informal caregivers ratings
- Findings suggest AHF hospitalisation is associated with notable HRQoL burden and that improved pharmacological management could lead to significant benefits for both patients and healthcare systems

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