



## Clinical paper

# Comparison of health-related quality of life and functional recovery measurement tools in out-of-hospital cardiac arrest survivors<sup>☆</sup>



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## ABSTRACT

**Introduction:** Although a number of validated health-related quality of life (HR-QOL) instruments exist for critical care populations, a standardised approach to assessing the HR-QOL of out-of-hospital cardiac arrest (OHCA) survivors has not been developed. We sought to compare the responses of 12-month OHCA survivors to three HR-QOL and functional recovery instruments, and assess instrument validity.

**Methods:** The Victorian Ambulance Cardiac Arrest Registry invited 12-month OHCA survivors to participate in telephone follow-up between January 2011 and December 2015. Responders provided answers to the 12 Item Short Form Health Survey (SF-12), Three-Level EuroQol-5D (EQ-5D-3L) and the Glasgow Outcome Scale-Extended (GOSE). The SF-12 was also used to derive the SF-6D. Responses were used to assess the interpretability and construct validity of the instruments.

**Results:** A total of 1188 patients and proxies responded. Large ceiling effects were observed for the EQ-5D-3L (patients = 46%, proxies = 23%). Substantial variability was also observed in SF-6D responses for patients who reported full health according to the EQ-5D-3L. For patient responders, the strongest correlations were observed between the EQ-5D-3L index score and SF-6D ( $\rho = 0.65$ ,  $p < 0.001$ ), and between the SF-6D and SF-12 physical component ( $\rho = 0.69$ ,  $p < 0.001$ ). The distribution of the SF-6D and EQ-5D-3L differed significantly for patients reporting a lower or upper moderate GOSE outcome and lower or upper good recovery ( $p < 0.001$  for all comparisons).

**Conclusions:** The EQ-5D-3L demonstrated limited interpretability due to the presence of ceiling effects. However, the measurement properties of the SF-12, SF-6D and GOSE suggest that these may be useful measures of HR-QOL and functional recovery in OHCA survivors.

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## Introduction

Out-of-hospital cardiac arrest (OHCA) is a leading cause of mortality worldwide.<sup>1</sup> From a patient perspective, the ultimate outcome following OHCA is not only survival, but survival with little neurological impairment.<sup>2</sup> Realisation of the significance of patient-centred outcomes in recent years has increased the importance of assessing the long-term outcomes of OHCA survivors.<sup>3,4</sup>

The 2015 update to the Utstein resuscitation registry template includes a recommendation for the use of validated measurement tools to assess health-related quality of life (HR-QOL) post-arrest.<sup>5</sup> Additionally, a consensus statement from the American Heart Association has recommended that future cardiac arrest clinical trials focus on assessing neurocognitive impairment and the quality of life of survivors.<sup>6</sup>

Although a number of validated HR-QOL instruments exist for critical care populations, a standardised approach to assessing and reporting HR-QOL has not been developed for OHCA populations.<sup>7</sup> A systematic review of 70 HR-QOL cardiac arrest studies reported substantial variation between the assessment tools in use, including many undefined questionnaires and unstructured interviews.<sup>4</sup> In addition, a recent systematic review examining the endpoints used in cardiac arrest clinical trials concluded that there exists a lack of consistency and transparency in outcome reporting, and that guidance is required to reduce heterogeneity.<sup>7</sup>

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In order to standardise assessment and reporting, HR-QOL tools must be validated within the OHCA population. However, very few studies have validated HR-QOL tools within OHCA populations, and as such the most appropriate assessment tools are yet to be elucidated.<sup>8,9</sup> Since 2011, the Victorian Ambulance Cardiac Arrest Registry (VACAR) has conducted HR-QOL interviews with adult OHCA survivors 12 months post-arrest.<sup>3</sup> Three common instruments are used to assess HR-QOL and functional recovery, including the 12-item Short-Form Health Survey (SF-12), Three-Level EuroQol-5D (EQ-5D-3L) and the Glasgow Outcome Scale-Extended (GOSE). However, all three of these tools are yet to be validated in the OHCA population. We sought to compare participant responses across these three tools, and assess their validity in survivors of OHCA.

## Methods

### Study design

A registry-based retrospective study of all adult ( $\geq 18$  years) OHCA survivors to hospital discharge identified within the VACAR, whose arrest occurred between January 1, 2010 and December 31, 2014. This study, and the VACAR, were approved by the Victorian Government Department of Health Human Research Ethics Committee as quality assurance projects.

### Setting

Ambulance Victoria is the provider of emergency medical services (EMS) in the state of Victoria, Australia, servicing a population of approximately 5.9 million people. Advanced life support and intensive care paramedics respond to OHCA events, while fire fighters and volunteer first responders also co-respond in select areas of the state. Resuscitation clinical practice guidelines are aligned with recommendations of the Australian Resuscitation Council (<http://www.resus.org.au>).

### Data sources

The VACAR is a clinical quality registry which captures all OHCA events attended by EMS in the state and has been described in detail previously.<sup>10</sup> Data is recorded in accordance with the Utstein template for resuscitation registries.<sup>5</sup> Hospital follow-up data, including discharge direction, is obtained from medical records for the vast majority of transported patients. Survival status is also validated with data from the Victorian Registry of Births, Deaths and Marriages.

For adult ( $\geq 18$  years) survivors to hospital discharge arresting on or after January 1st 2010, the VACAR has conducted 12-month follow-up interviews. The 12-month outcomes, including the follow-up process, of patients arresting between 2010 and 2012 have been described in detail previously.<sup>3</sup> Briefly, before being invited to participate in a telephone interview, patients are cross-validated against the Victorian Registry of Births, Deaths and Marriages. For patients identified as alive at 12 months post-arrest, a dedicated researcher, who is experienced in the administration of HR-QOL instruments, makes multiple attempts to contact the patient. A next of kin or a proxy may respond on the patient's behalf where the patient is unable to participate (e.g. severe disability or work commitments preclude reaching an agreeable time). The interview takes 20 min on average, and includes responses to introductory questions related to work and residential status, as well as the SF-12, EQ-5D-3L and the GOSE.

### HR-QOL instruments

#### SF-12

The SF-12 includes 12 items derived from the SF-36. Proxy responses to this tool are not considered reliable<sup>11</sup> and thus only patient responders may participate in this questionnaire. Norm-based standardised scoring algorithms are applied to obtain Mental Component Summary (MCS) and Physical Component Summary (PCS) scores. Both scores range from zero to 100, with higher scores representing greater health.<sup>12</sup> Questions within the SF-12 can also be used to derive the SF-6D, a single health state value which ranges from 0.345 to 1.00.<sup>13,14</sup> The SF-6D applies preference based weights, obtained from a sample of the general population, to seven items of the SF-12 which cover six health dimensions. The six health dimensions include: physical functioning, role limitations, bodily pain, social functioning, mental state and vitality.

#### EQ-5D-3L

The EQ-5D-3L is a generic measure of health status, as defined by five health dimensions including mobility, self-care, usual activities, pain/discomfort and anxiety/depression, each with three levels of response.<sup>15</sup> Responses to the five dimensions can be converted into a single utility index (EQ-5D Index) which ranges from  $-0.594$  to 1.00. Negative values represent a health state worse than death, while a value of one represents full health.

#### GOSE

The GOSE provides a measure of functional status after non-traumatic brain insult on an 8-level scale ranging from one (death) to eight (upper good recovery). Health domains include consciousness, independence, work, social activities, family/friendships and return to normal life.<sup>16</sup>

### Definitions

We defined measurement instrument properties in accordance with the COSMIN definitions.<sup>17</sup> The only measures applicable to our study were interpretability and construct validity. Interpretability refers to the degree to which one can assign qualitative meaning to an instrument's quantitative scores.<sup>17</sup> This can be measured through assessment of the distribution of scores within a population and relevant subgroups, including through floor and ceiling effects. Floor and ceiling effects describe the proportion of responders who achieve the lowest or highest possible scores on a questionnaire, respectively.<sup>18</sup> Construct validity assesses the degree to which scores of a tool are consistent with hypotheses, based on the assumption that the tool measures the construct that it was designed to measure. Such hypotheses may include the relationship of scores between instruments, or differences in scores between relevant subgroups.<sup>17</sup>

### Statistical analyses

All analyses were conducted using Stata Statistical Software Release 14 (College Station, TX: StataCorp LP). A  $p$ -value of  $<0.05$  was considered statistically significant. Respondents were categorised as either patients or proxies and analysed separately for a number of reasons. First, proxy responders have a tendency to report poorer health states than patients. Second, proxy response is a valuable method for understanding the HR-QOL outcomes of OHCA survivors who may otherwise remain undescribed. As such, it is important to understand the validity of proxy response to measurement tools. Finally, the SF-12 is not suitable for proxy response.<sup>3</sup> Descriptive statistics are presented as frequencies and proportions for categorical data, and mean (standard deviation (SD)) or median (interquartile range (IQR)) as appropriate for

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