Follow-Up After Cardiac Surgery Should be Extended to at Least 120 Days When Benchmarking Cardiac Surgery Centers

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<u>Objective</u>: Short-term (30 days) mortality frequently is used as an outcome measure after cardiac surgery, although it has been proposed that the follow-up period should be extended to 120 days to allow for more accurate benchmarking. The authors aimed to evaluate whether mortality rates 120 days after surgery were comparable to general mortality and to compare causes of death between the cohort and the general population.

<u>Design</u>: A multicenter descriptive cohort study using prospectively entered registry data.

<u>Setting</u>: University hospital. The cohort was obtained from the Western Denmark Heart Registry and matched to the Danish National Hospital Register as well as the Danish Register of Causes of Death. A weighted, age-matched general population consisting of all Danish patients who died within the study period was identified through the central authority on Danish statistics.

<u>Participants</u>: A total of 11,988 patients (>15 years) who underwent cardiac-surgery at Aarhus, Aalborg and Odense University Hospitals from April 1, 2006 to December 31, 2012 were included.

MORTALITY IS THE MOST FREQUENTLY used out-come parameter in cardiac surgery. It commonly is divided into short-term (\leq 30 days) and long-term (> 30 days) mortality, with data readily available in various international and national databases as well as in annual statistical reports.¹⁻³ Nevertheless, a recent study⁴ evaluating mortality measures and benchmarking after cardiac surgery proved the course of mortality to differ considerably across interventions continuing up to 120 days after surgery. The study further found the quality status of the operating site to depend on time from surgery to benchmarking. This illustrated that if differences between mortality measures exists, the results of outcome evaluation might depend on which mortality measure is compared across hospitals. Thus, the study argued that the 30-day limit is inadequate when comparing postsurgical mortality and suggested that the follow-up period of short-term mortality should be extended to 120 days. Nonetheless, literature recounting course of mortality later than 30 days within the first year after cardiac surgery is sparse and further studies are needed.

The European system for cardiac operative risk evaluation $(EuroSCORE)^5$ was developed to predict the perioperative and in-hospital mortality risk (30 days), incorporating factors such as

© 2015 Elsevier Inc. All rights reserved. 1053-0770/2601-0001\$36.00/0 http://dx.doi.org/10.1053/j.jvca.2014.09.014 <u>Interventions</u>: Coronary artery bypass grafting, valve surgery and combinations.

<u>Measurements and Main Results</u>: Mortality after cardiac surgery matches with mortality in the general population after 140 days. Mortality curves run almost parallel from this point onwards, regardless of The European system for cardiac operative risk evaluation (EuroSCORE) and intervention. The causes of death in the cohort differed statistically significantly from the background population (p < 0.0001; one-sample t-test) throughout the first postoperative year. The leading cause of death in the cohort was cardiac (38%); 53% of which was categorized as heart failure. A total of 54% of these patients were assessed preoperatively as having normal or mildly impaired heart function (EuroSCORE).

<u>Conclusions</u>: This study supported an extended follow-up period after cardiac surgery when benchmarking cardiac surgery centers. Regardless of preoperative heart function, heart failure was the consistent leading cause of death. © 2015 Elsevier Inc. All rights reserved.

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age, sex, patient morbidity and surgical setting. Since its inception, it has been the subject of extensive validation as well as modifications to improve predictive ability.^{6,7}

Several studies have since proven EuroSCORE to be an independent predictor of long-term all-cause mortality.^{8,9} Hence, the course of mortality after 30 days might differ between high-risk and low-risk patients.

Cause of death after cardiac surgery is described poorly in the literature, possibly because of difficulties with obtaining valid information concerning cause of death. Although surgery does not necessarily cure the patient of cardiac disease, it aims to improve cardiac function and prevent further cardiac deterioration. As a consequence, the authors expected causes of death in the surgical cohort to approximate those of an age-matched general population with increasing time from surgery. To their knowledge, this previously has not been investigated.

The aim of this study was to evaluate 120-day mortality as an appropriate point of benchmarking after cardiac surgery, regardless of type of intervention and risk profile as expressed in the EuroSCORE. Further, to establish if mortality rate in the surgical cohort was comparable to background mortality at this point. Additionally, the authors hypothesized that cause of death was related to either underlying heart disease or surgical complication in the 30 days after surgery, after which causes of death will converge towards the distribution in the background population.

MATERIALS AND METHODS

Design and Study Population

The study was conducted as a multicenter registry-based descriptive cohort study. It was approved by the Danish Data Agency (1-16-02-17-13) and the Danish National Health Board and included all patients, age above 15 years, who underwent cardiac-surgery at Aarhus, Aalborg and Odense University Hospitals from

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April 1, 2006 to December 31, 2012. Procedures consisted of isolated coronary artery bypass grafting (CABG), isolated aortic valve replacement, isolated mitral valve repair/replacement (MVR), concomitant CABG and valve surgery (either 1 or 2 valves), and CABG or valve surgery concomitant with other procedures such as auricular clips, MAZE, and lung vein ablation. Transplants, adults with congenital heart disease, pulmonary thromboendarterectomy, thoracic aorta surgery, and single procedures other than the above mentioned, were excluded a priori because of difficulty in comparison of the different types of surgery. All double entries were examined and in case of a follow-up period of fewer than 365 days, the earliest procedure was excluded.

Data Acquisition and Validation

The cohort was obtained from the Western Denmark Heart Registry (WDHR),¹⁰ which is a collaborative initiative covering Western Denmark's 3 major cardiac centers. It contains information on all invasive cardiac procedures since January 1, 1999. The registry underwent a major revision in March 2006 and, thus, the data were obtained from that time and forward. The registry holds extensive mandatory and prospectively registered data on patient and procedural characteristics. Because of the unique Central Personal Registry number assigned to each Danish citizen at birth and to residents upon immigration, it is possible to make accurate linkage of all registries at an individual level.¹¹ The authors matched the cohort with the Danish National Hospital Register¹² as well as the Danish Register of Causes of Death.¹³ The Danish National Hospital Register holds extensive information on every single contact between a patient and the Danish National Health Service. The Danish Register of Causes of Death holds information from individual death certificates, which is a mandatory form filled out by the doctor confirming death. The certificate states cause, place, mechanism, and manner of death, as well as the events leading up to the time of death; for example, broken thighbone leading to surgery, followed by postoperative pneumonia progressing into sepsis, and multiorgan failure. Unless an autopsy is performed, the content of the certificate is at the individual doctor's discretion.

All data concerning preoperative patient characteristics, procedural details, and length of hospitalization at the site of surgery were drawn from WDHR. Data concerning hospitalization as well as underlying diagnoses were drawn from the Danish National Hospital Register and cross-matched to data from WDHR. Information concerning cause and place of death was retrieved from the death certificate. All data from the registries were merged, followed by manual comparison to medical record entries to validate date of discharge, cause of death, and place of death. When cause of death differed between the death certificate and the medical record, the medical record was examined systematically and the most accurate cause was chosen. To validate the final dataset, the described process was repeated twice.

An age-matched general population consisting of all Danish patients who died within the 7-year period was identified through the central authority on Danish statistics,¹⁴ which collects, compiles, and publishes statistics on the Danish society. The statistics database merges all central registries and, thus, contains complete and reliable information regarding all Danish citizens, native as well as immigrants.

Data Management

The cohort was split into 2 subgroups: Survivors and nonsurvivors. The nonsurvivors were sorted into early death (0-30 days from surgery), intermediate death (31-120 days from surgery), and late death (121-365 days from surgery). Deaths then were divided into either "in-hospital" or "out-of-hospital". Furthermore, "in-hospital" was divided into "primary" composed of deaths occurring as part of the primary hospitalization, either at the site of surgery or subsequent hospitalization at the secondary care level, or "readmission" composed of deaths happening in-hospital with >1 day between discharge and readmission. See Figure 1 for flowchart.

Preoperative patient characteristics were obtained from WDHR and listed as total EuroSCORE, individual parameters, and summed subscores based on group factors as described in the additive EuroSCORE guidelines¹⁵: (1) procedure-related factors (emergency, other than CABG); (2) cardiac-related factors (left ventricular function, pulmonary hypertension, recent myocardial infarction, unstable angina); and (3) patient-related factors (age, sex, chronic pulmonary disease, extracardiac arteriopathy, neurologic dysfunction disease, previous cardiac surgery, critical preoperative state, creatinine > 200 μ mol/L, active endocarditis).

Cause of death was categorized based on organ failure into the following 6 categories: (1) cardiac; (2) infection/multiorgan failure; (3) stroke; (4) cancer; (5) other including surgical complications and accidental deaths; and (6) unknown. See Table 1 for further details.

In the general population, a weighted overall mortality rate was calculated, using 5-year intervals from 15 to 95 years of age. Further, cause of death in the general population was identified¹⁶ and categorized similar to the cohort using data from the corresponding years (2006-2012). Due to the large age span in the cohort, causes of death in the general population were pooled into 2 groups: Age 15 to 69 and age 70+.

Statistical Analysis

Numeric variables were presented as number (%), mean \pm SD, or median (interquartile range) depending on normality of data. For comparison, categoric data were evaluated using $\chi 2$ test, and for longitudinal data an independent t-test and one sample t-test (normal distribution), or Mann-Whitney U-test (not normal distribution) was used. The assumption of normality was tested with a QQ-plot. The p values less than 0.05 were considered significant. All analyses were performed using the software package SPSS vs.21 (SPSS Inc., Chicago, IL, USA).

RESULTS

Using named criteria, a cohort of 11,988 patients was identified (8,654 men, 3,334 women), age 69 (62;76) years, range (15-97). Within 1 year from surgery, 802 patients died (512 men, 290 women), age 75 (68-80) years, range (24-97). The overall mortality rate was 6.7%.

Of all events, 45% (n = 359) occurred in the early period, 28% (n = 228) in the intermediate period, and 27% (n = 215) in the late period. A total of 55% (n = 441) were never discharged to their residence, but died either at the site of surgery or during subsequent hospitalization at another hospital.

The 1-year mortality in the age-matched general population was found to be 2.65%.¹⁷ As shown in Figure 2, the Kaplan-Meier 1-year survival curve of the cohort converge with the mortality in the age-matched general population approximately 140 days after surgery, after which the 2 curves follow the same

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