

A16 Comparing one sample's observed survival with the expected in the general population or in specific high-risk subgroups

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Introduction

There are doubts if a certain therapy is safe in some diseases. End-stage renal disease (ESRD) is an example for which patient's life expectancy is reduced. The high rate of comorbidities and therapy adjustments has been a major concern. Whether these patients would benefit from an invasive procedure needs to be evaluated since their fragile clinical status may result in reduced survival, regardless of the intervention. The knowledge about which/when would the outcomes of high-risk patients be observed is of utmost relevance, using previous studies or registries.

The most frequently reported method to compare the observed patient's survival with the expected in the general population uses life tables and a one-sample log-rank test (1, 2). However, life tables available in each country limit the analysis to comparisons with the general population. It is difficult to extrapolate about the impact of an intervention in specific patients, e.g. ESRD, to a population with the same disease but with no intervention, since there are no adequate registries in those subgroups. To surpass this caveat, we considered the paper from Guyot et al. who depicted the process of digitising Kaplan-Meier (KM) curves to extract survival statistics (3).

The aim of this study was to explore two methods of comparing the observed survival of our ESRD patients submitted to coronary artery bypass grafting (CABG) with (i) the expected survival in the general population, age and sex-matched; and (ii) the expected survival in a haemodialysis (HD) population not submitted to CABG.

Methods

Single-centre retrospective study including consecutive HD patients submitted to CABG. To compare the observed survival of the sample with the expected in general population we used the one-sample log-rank test, available at <http://biostatistics.mgh.harvard.edu/biostatistics/resources.html> as an excel spreadsheet with a supplement (4). Data from the observed sample, (age at operation, gender, race and follow-up (FUP) time) were introduced. To determine the time-to-event in the general population, the annual death rate for each age during the FUP time, adjusted for age, gender and race, obtained through <https://www.ine.pt/> was inserted. The survival rate in the sample at each year after diagnosis ($S_0(s)$) results from dividing the sum of N survival rates at each time by the number of patients (N): $S_0(s) = \frac{1}{N} \sum_{i=1}^N e^{-H_i(a_i+s)}$. The expected number of deaths is calculated by cumulative death rates at last FUP for all patients and for each year after diagnosis: $H_i(t) = \sum_{u=a_i}^{t-1} h_i(u)$. This expected number of deaths (E) results from adding the cumulative death rate at the last age of FUP (t_i) over the sample size (N): $E = \sum_{i=1}^N H_i(t_i)$. The software calculates the expected survival for a similar subject in the population and a standardized mortality ratio (SMR).

Using GetData Graph Digitizer 2.26 (<http://getdata-graph-digitizer.com/>), we imported and digitised the curve from Almeida et al. (5) reporting the survival of Portuguese HD patients; and the KM curve from our sample. A delineation of each curve was done and two ASCII (text) files, were exported. An event table was built considering the number of patients at risk provided for each year. These files were imported by an R script to read the number at risk at each time point and calculate approximations of number of censored on each interval, i ; adjusting the total number at risk and number of events within each i according to KM estimates from curves. It obtains individual patient data (time, event and group). Finally, the *coxph* formula to estimate hazard ratio (HR) and confidence intervals through Cox proportional hazard regression was applied.

Keywords:

Expected Survival;
Epidemiologic Methods; Follow-up Studies; Life Tables; One-sample log-rank test; Standardized Mortality Ratio; Survival Analysis

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Conflict of interest:

The authors declare no conflict of interests.

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Results

In our preliminary analysis of 35 chronic HD patients who underwent CABG the observed survival was 89%, 69%, 51% and 27%, at 1, 3, 5 and 10-years, respectively. These survival rates were significantly lower than the expected in the general population (99%, 96%, 94% and 86%, at 1, 3, 5 and 10-years, SMR (95%CI): 10.6 (6.8-16.5), $p < 0.001$). Comparing with the survival expected in HD patients (84%, 68% and 55% at 1, 3 and 5-years), the estimated survival rates, by the Guyot et al. algorithm, were 89%, 69% and 51% at 1, 3 and 5-years and the estimated HR (95% CI) was 1.11 (0.72-1.70), $p = 0.649$.

Discussion and Conclusion

Our results show a significantly decreased long-term survival of a sample of haemodialysis patients undergoing CABG, compared with the general Portuguese population. However, compared with a sub-sample under haemodialysis of the general population the survival rates were similar. Hence, it seems that a major cardiac intervention in haemodialysis patients does not present an additional mortality risk for this specific high-risk population. Further studies should be conducted to validate these results.

Ethics committee

The current research was approved by an independent ethics committee.

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