Application of dialysis and transplant registries to clinical practice: the Lombardy Registry

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Abstract

Background. Data collected from registries provide a useful source of information for clinical practice. Therefore, several regional and national registries of end-stage renal disease (ESRD) patients have been established. The Lombardy Registry of Dialysis and Transplantation (RLDT) was established in 1982, with participation of all 44 dialysis units that were present at that time within the region.

Methods. Demographic and clinical data on ESRD patients are collected yearly. We present here the results of some of the analyses that have been performed on RLDT data since it was started.

Results. Briefly, data on epidemiology of ESRD, cardiovascular disease, patterns of care and patients’ outcomes have been considered. Comparisons with international registries have also been performed.

Conclusions. This analysis shows how data collected from a homogeneous patient population receiving similar patterns of care provide precise information on that population. A clear example is provided by the similar results obtained in the comparison of high-flux vs low-flux membranes in a randomized control trial, the HEMO study, and in an analysis of RLDT data. Therefore, analysis of data collected by registries represents an important tool to improve clinical practice and possibly patients’ outcomes.

Keywords: dialysis registry; clinical practice; Lombardy Registry; transplant registry

Introduction

The Lombardy Registry of Dialysis and Transplantation (RLDT) was started in 1982 by the Lombardy Regional Section of the Italian Society of Nephrology and the Regional Health Department. The primary aim of the registry was to collect and analyse data on incidence and prevalence of end-stage renal disease (ESRD) within the region and on morbidity and mortality among these patients.

All 44 dialysis units that were present at that time in Lombardy territory enthusiastically agreed to participate in this project. Data were collected at each clinic and analysed by a central data manager center.

Since then, an annual report containing data on ESRD within Lombardy has been published. Data from the registry and annual reports are also posted on-line at the website: www.sinitalia.org/registri/lombardi/rldt/home.htm.

In order to underline the importance and utility of data collection through a registry, we briefly present here some of the aspects that have been considered in analysing data from the RLDT, as: (i) epidemiology of ESRD; (ii) international comparisons; (iii) dialysis in the elderly; (iv) cardiovascular disease (CVD) and outcomes; (v) convective treatments and patient outcomes.

Epidemiology of ESRD

As per 31 December 2001 the comprehensive Lombardy population was of 9 065 000 inhabitants. Overall, there were 9516 ESRD patients, of whom 6154 were on dialysis [either peritoneal dialysis (PD) or haemodialysis (HD)] and 3362 were kidney transplant recipients.

In the year 2000, there were 1646 incident ESRD patients. As reported by other registries, data from the RLDT demonstrated a dramatic, linear increase in the number of incident ESRD patients since the early 1990s, with an overall increase of 70% between 1990 and 2000 [1].

The growing proportion of elderly patients mainly accounts for the increase in the number of patients who started renal replacement therapy (RRT) over this time period. Analysing data from the RLDT we evidenced...
that the frequency of incident ESRD patients aged 65 years significantly and constantly increased from the early 1980s to 1997 [2]. In fact, while they represented 19.7% of incident patients in 1982, this proportion had doubled in 1992 (41.6%) and was still increasing in 1997 (almost 54%). Similarly, the prevalence of RRT in Lombardy increased over the same time frame. When considering patients on dialysis and transplant recipients together, the prevalence of RRT increased from 612 per million population (p.m.p.) in 1990 to 1018 p.m.p. in the year 2000. Despite differences in geographical distribution of ESRD within Italy, a similar pattern was observed in the Italian Registry of Dialysis and Transplantation (RIDT), with an increase in prevalence of RRT from 643 p.m.p. in 1996 to 804 p.m.p. in 2000. However, when restricting the analysis to patients from the RLDT who were on dialysis, a less striking increase in prevalence (from 491 to 661 p.m.p.) was observed (see Figure 1). These results clearly demonstrate how, possibly thanks to a sensibilization, education and organization policy within this region, the prevalence of transplant recipients importantly increased in Lombardy over the last decade.

**Dialysis in the elderly**

Using data from the RLDT, we performed an analysis of patients who started RRT in Lombardy between 1983 and 1992 at the age of 65 years or older [4]. The cumulative survival by Kaplan–Meyer analysis was 64.4% at 2 years, 39.3% at 4 years and 13.1% at 8 years. When considering treatment modality, 4 year survival was significantly higher for elderly patients on HD (54%) compared with those on PD (42.6%, P <0.05).

The role of several potential risk factors on survival was tested using a Cox proportional hazard model. Risk factors that were significantly associated with decreased survival included age, systemic atherosclerosis, severe cardiopathy and nephropathy due to systemic diseases (P <0.001). Surprisingly, in this cohort of elderly patients neither gender, severe hypertension, cirrhosis nor malignancies were associated with increased mortality. After adjusting for these risk factors, hazard ratio was still significantly higher for PD patients (1.36; 95% CI: 1.48, 1.16) vs HD patients. It should be noticed, however, that the worse survival reported for PD patients could at least partly be explained by a hidden negative selection effect that was not fully taken into account in the Cox analysis.

**Cardiovascular disease and outcomes**

**CVD as cause of death**

Data from the RLDT allowed us to make a survey of causes of death among prevalent ESRD patients in Lombardy in 1997. The main cause of death was CVDs, responsible for more than 40% of the observed mortality. Other important causes of death were vascular accidents, infections and malignancies [1].
We analysed the presence of CVD at the start of RRT among incident patients in Lombardy between 1994 and 1997 [5]. At the start of RRT, coronary artery disease (CAD) and myocardial infarction (MI) were present in 10 and 8.3% of patients, respectively, while 8.9% of patients presented signs and/or symptoms of congestive heart failure (CHF).

Over the observation period, the proportion of incident ESRD patients with CAD or MI at the start of RRT remained stable (from 9.5 to 9.9% and from 8.4 to 8.6%, respectively). However, an increase in prevalence of CHF (from 5.4 to 10.6%) was observed. The presence of CHF at the start of RRT was strongly associated with reduced overall 4 year survival: patients with CHF had 20% 4 year survival vs 60% of those without CHF (P < 0.05). After adjustment for age, diabetes and other CV factors, the RR was significantly higher for patients with CHF (RR 1.64; 95% CI: 1.36, 1.98). The presence of ischaemic heart disease at the start of RRT also largely affected mortality from any cause. Patients with either CAD or MI at the start of RRT had significantly lower survival at 48 months (38 and 40%, respectively) compared with patients without ischaemic heart disease (65%). After adjusting for age, gender, diabetes and other cardiovascular comorbidities, the presence of MI at the start of RRT (RR 1.32; 95% CI: 1.07, 1.61), age and diabetes but not CAD (RR 1.15; 95% CI: 0.95, 1.38) were significantly associated with increased mortality [5].

**CVD, dialysis modality and outcomes**

To evaluate the effect of kind of RRT (PD vs HD) on survival and development of CVD, we performed a historical prospective analysis of 4064 patients who started RRT in Lombardy between 1994 and 1997 [6]; 2772 patients on HD and 1292 on PD were analysed. 3210 patients did not present signs of CVD at the start of RRT and were considered for analysis of the risk of developing de novo CVD. HD was compared with PD by use of a Cox regression proportional hazard model, stratified by diabetes. After adjustment for age, gender, presence of established CV and diabetes, no significant difference in 4 year survival was observed between HD and PD patients (RR 0.91: 95% CI 0.79, 1.06). Similarly, the risk of developing de novo CVD did not differ for PD vs HD patients (RR 1.06: 95% CI: 0.79, 1.06). RR of death was significantly higher for older age, and in the presence of MI and CHF. Only age was significantly associated with risk of developing de novo CVD.

In summary, the risk of mortality and of developing de novo CVD for incident ESRD patients in Lombardy between 1994 and 1997 was similar for HD and PD patients [6].

**Conclusions**

While the hierarchy of evidence that derives from different kind of studies (namely, from experimental vs observational studies) should be kept in mind, the results we have presented clearly show the valuable information that a registry (namely, the RLDT) can provide for clinical practice in nephrology.

Specifically, data collected from a large number of patients can provide useful information on dialysis practice (e.g. type of membrane, duration of dialysis treatment, dose of dialysis delivered) and on effects on different outcomes (mortality, morbidity, β2-microglobulin plasma levels).

The experience from the RLDT has already provided several useful benefits. First, it has provided the administrative and planning structure that can be used for further studies and collaborative trials, as we have here presented. From this point of view, the RLDT has been and continues to be an excellent stimulus to increase and improve the quality of clinical research, not only within the region but also in comparison with other geographic areas. Furthermore, data collected by the RLDT can be used by health care providers to better prevent and plan health care for patients within our region.

Finally, and most importantly, the integration of results from clinical trials and from observational studies will possibly lead to an improvement in the quality of care of ESRD patients.

**References**