

Methodological Challenges to collecting Clinical and Economic Outcome Data: Lessons from the Pilot Dialysis Outcomes India Study

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Abstract

Introduction: Contemporary data on clinical and economic outcomes and quality of care amongst dialysis patients in India are not available. This pilot prospective study evaluated the feasibility of data collection and follow up within routine dialysis practice to inform setting up a dialysis registry.

Methods: An electronic instrument was developed to collect information on clinical and socio-demographic characteristics, outcome and out-of-pocket expenditure on incident patients commencing haemodialysis (HD) at two centres. Dialysis unit staff were trained in collecting and entering information on an electronic case record form. Patients were followed up at 1, 3, 6, 9 and 12 months to ascertain outcomes and treatment related costs.

Results: A total of 119 patients (37 females, age 47.5 ± 17.2 years) were enrolled. After 1 year, 38 (32%) patients were continuing on HD; 35 (29%) had died, 30 (25%) underwent a kidney transplant, and 16 (13%) had stopped dialysis. We noted a high prevalence of catastrophic health expenditure. Data collection was facilitated by appointing a designated staff member who received an incentive. Collection of financial information, clinical course for patients transferring out of the primary unit and the cause of death, when it occurred out of hospital was challenging.

Conclusions: Prospective data collection of incident dialysis patients was feasible but is resource-intensive. High out-of-pocket costs force some patients to stop dialysis and can generate a sense of despair. Poor patient experiences and suspicion over the use of such data adversely affects collection of important clinical and health economic data.

Introduction

Managing the ever-growing burden of end stage kidney disease (ESKD) is a challenge for healthcare systems around the world. In developed countries, universal access to renal replacement therapy (RRT) is an accepted standard of care. It is estimated, however, that globally, about 2.3-5.2 million people die annually because of lack of access to dialysis, mostly in low and low-middle income countries.(1) In India alone, this number is estimated at 150,000-200,000, with a 50% increase in kidney failure deaths over the last decade.(2)

In recent years, many developing countries, including India, have started offering access to dialysis as part of universal health coverage programs.(3) This opening up of access has seen an increase in the number of patients on dialysis.(4) However, data on the outcomes and on the sustainability of such treatment in a country with low personal incomes and a limited social safety net is scarce. Earlier studies suggested high and early dropout from RRT and high mortality. (5,6) Understanding the interplay of clinical and economic factors, especially the out-of-pocket expenditure, and their impact on patient outcomes is essential to develop interventions to improve outcomes, which requires systematic collection of data.

RRT registries allow a deeper analysis of the scale and nature of the problem, as well as aid in guiding investment targets. There remain numerous challenges in collecting robust outcome data in resource-poor settings where dialysis delivery mechanisms are not structured and out-of-pocket expenditure is high. It is important, therefore, to develop instruments that can be administered easily to uniformly collect data on dialysis practices, quality, outcomes and cost of care.

We undertook a pilot prospective observational study to determine the feasibility of data collection in routine practice to understand factors influencing clinical and socioeconomic outcomes of dialysis in India.

Methods

The study protocol has been published.⁽⁷⁾ In brief, this prospective pilot followed 100 incident haemodialysis patients for 12 months at two Indian dialysis centres; Postgraduate Institute for Medical Education and Research in Chandigarh (a public facility) and Medanta the Medicity Hospital in National Capital Region of Delhi (a private facility). Patients starting dialysis in the Intensive Care Unit (ICU) or for acute kidney injury were not included. Data collection was modelled on existing dialysis registries with additional fields exploring the economic impact of treatment, using an open source clinical research platform (OpenClinica™) hosted on the secure servers of The George Institute for Global Health, India. Staff representatives at the study sites were trained to record clinical and outcome data.

Data collection took place between November 2014 and July 2016. All patients were followed up at 1, 3, 6 and 12 months. Medical records were utilized to extract demographic and clinical information, with patient interviews to collect socio-economic status and costs of care. For patients transferring out of the primary centres after dialysis initiation, data were collected by telephone from the treating nephrologists at the new centre or directly from the patients/caregivers. Cause of death was recorded from the death certificate. Where death occurred out of hospital, attempts were made to ascertain the cause through a remotely administered verbal autopsy.⁽⁸⁾

Ethics approval was obtained. The study was registered with the national clinical trials registry (CTRI/2014/12/005283). A patient information sheet and informed consent form, developed in Hindi and English were given to the patients to explain the procedure of the study. Patients could withdraw consent any time during the study.

The main outcomes on which data were collected included survival and withdrawal from treatment. Out-of-pocket costs for dialysis was collected to understand the economic impact on patients and families. Continuous data were recorded as mean (standard deviation) or median (interquartile range) and categorical data as frequencies. Differences between means were tested using Student's t-test and the chi-square was used to test for associations using SPSS version 20. The designated centre staff maintained qualitative notes reflecting the feasibility and challenges of data collection. The secondary source for this information was the documentation maintained during the periodic project reviews.

Results

Patient Characteristics

A total of 119 incident ESKD patients commencing chronic haemodialysis were enrolled. The participants were predominantly male, with a mean age of 47.5 years (Table 1). The public hospital enrolled 70 participants (59%) and 49 (41%) were enrolled at the private hospital. Diabetes and hypertension were the leading causes of ESKD amongst the study participants (Table 1).

The patients at the public hospital were generally younger and had lower income. Overall health insurance coverage was low, with public hospital patients having a lower proportion

of insured patients. Only 19% of the females had health insurance as compared to 30% of the male patients. A difference in the family structure of the participants was observed, with patients from the public hospitals having higher numbers of dependent family members compared to patients from private hospitals. Participants from the private hospital were more likely to be on thrice a week dialysis whereas the frequency was lower in the public sector patients. The majority of patients at both sites received their first dialysis through a temporary internal jugular catheter.

Feasibility of Data Collection

Recruitment of the required number of participants was completed on schedule in the first three months. Electronic capture of the clinical data was an introduced practice at both sites. Staff representatives at each of the study sites had no previous training on collection of socioeconomic, economic or clinical outcome data. In a clinical environment where the main aim is patient treatment, collecting research data was not considered to be part of patient-care and outside of the job description. Motivation and data quality improved after a staff member was designated at each site and provided a token financial incentive on top of their existing salaries.

Participants were particularly sensitive about revealing information on socioeconomic status and medical expenses. As the study progressed, we encountered increasing missing data for patient recall of out-of-pocket costs and health service use. Challenges were also introduced because of patients moving away from the primary dialysis centre because of geography or cost of care. Patients or their caregivers were less likely to be responsive to follow up by phone once they had moved away. The outcome could not be determined in 16 (13%) because the

patients were lost to follow up (stopped reporting to the dialysis centres and no response was forthcoming on phone calls). The local nephrologists speculated that the patients had either died at home or withdrew from dialysis because of financial reasons. We attempted to identify cause of death by a modified verbal autopsy over phone, but found that family members were often unwilling to provide this information, either because of distress over the loss or the perceived shortcomings of the healthcare system that failed to provide appropriate care.

Outcomes

At the end of one year, 35 (29%) of the patients had died, 30 (25%) underwent a kidney transplant, 16 (13%) had stopped reporting to dialysis centres and were uncontactable, leaving 38 (32%) still on haemodialysis (Table 2 and Fig 1). Females were less likely to receive a kidney transplant (14% versus 30%; $p=0.04$). Patients who died were older compared to those who underwent kidney transplantation and those who continued haemodialysis.

Death in 9 (25%) patients was attributable to cardiovascular causes. A total of 26 (75%) deaths occurred at home and the cause of death could not be ascertained for any of these patients, despite attempts at verbal autopsies.

The average out-of-pocket expenditure was 165% of family income (Table 3). The absolute out-of-pocket expenditure on dialysis for the private hospital patients was 4.8 times higher than the public hospital patients. However, the proportion of income being spent on dialysis by public hospital patients was 184% compared to 155% for private hospital patients, reflecting the lower income levels of patients presenting to public hospitals. Nearly 85% of

the patients on dialysis reported spending more than 100% of their income on dialysis during the first year of treatment.

Analysing the combined outcome of death or withdrawal from dialysis, there were no differences between patients with income above median compared to those with incomes equal to or below the median (27% versus 48%, $p = 0.21$).

Discussion

We have illustrated the feasibility and identified the challenges of prospective collection of clinical, demographic, economic and outcome data in incident dialysis patients in India. In addition, we have documented the financial burden that dialysis treatment imposes upon patients and the high rates of death and withdrawal from dialysis treatment in the first 12 months in a largely uninsured population.

This study provides important lessons for the feasibility of collecting clinical and economic data in the setting of routine dialysis care provision, and will inform efforts to create a dialysis registry in the context of the recently announced National Dialysis Service. Currently, clinical data collection within dialysis units is not standard practice and thus is seen as a burden. Ensuring that responsible staff are incentivised for collecting this information was integral to improving the quality of data. The additional (small) cost of data collection is likely to be more than offset by opportunities to improve the service quality and closer monitoring of outcomes. Based on the experience from this pilot study, we have scaled up the prospective collection of follow-up data for ESKD patients on dialysis to ten new sites across India.

Financial issues emerged as the primary matter of concern in this study. The absolute out-of-pocket-expenditure was higher in the private hospital as compared to public hospital. However, the public hospital patients were spending a higher proportion of their income on medical care, despite being on less frequent dialysis and less likely to receive additional (costlier) supportive therapies such as erythropoiesis stimulating agents. This pilot found a low use of health insurance, especially among the participants from public hospitals and females which was consistent with the latest estimates of the Insurance Information Bureau of India.(9)

The high rates of kidney transplant recorded here reflect the fact that both study sites are active referral kidney transplant centres. Subjects who are either not eligible for a transplant or do not have a suitable living donor at these centres are urged to continue maintenance dialysis closer to home, as these centres prioritize dialysis for patients who are transplant candidates and continuing dialysis closer to home is more affordable for patients. Continuing dialysis closer to home also reduces health-related out-of-pocket costs such as transport, accommodation and carer expenses, which can be substantial. In the absence of a standardised referral network, follow-up and ascertainment of outcomes for patients who had discontinued dialysis at the recruiting centres is challenging. Incorporating the recently introduced national unique identification number in the database might help in tracking, but concerns related to data privacy and security need to be addressed.

Absence of reliable estimates of patient out-of-pocket expenses related to dialysis treatment has confounded accurate costing of HD treatment, leading to a general belief that HD is cheap in India. (10) We attempted to remedy this by collecting information from patients directly

about their income and expenses related to dialysis. Collection of such data was challenging, possibly because of patients' uncertainty about how this information would be used, or anxiety that revealing this might affect the cost of care or eligibility for certain income-related subsidies provided by the Government. We envisage that encouraging patients to keep records of clinical or other important events with patient engagement tools (such as patient diaries, mobile apps) might reduce the likelihood of missing data. We also found ascertainment of out-of-hospital cause of death to be difficult. The verbal autopsy interviewer was perceived by the family member as a representative of the healthcare delivery system that had somehow failed to provide the expected level of care, either because they did not receive enough information from their care providers or were upset about the high cost of care.

Despite being a small pilot, this study found gender inequities in care, females were less likely to have received a transplant and more likely to have died. This trend, also noted elsewhere (11), needs confirmation in larger sample. Our data adds strength to existing evidence showing high health expenditure amongst dialysis patients.(12,13) The recently announced National Dialysis Scheme is likely to materially reduce some of these costs for patient and their families, particularly as challenges are likely to remain for paying the costs of time lost from work, ancillary treatment costs (such as medicines) and travel. Robust mechanisms, therefore, are important to systematically collect accurate information on the out-of-pocket expenditure in order to understand the residual barriers to care.

Conclusions

This pilot study highlights the individual as well as system level challenges in the feasibility of collecting comprehensive data on clinical and economic outcomes of patients starting dialysis in India. Prospective data collection of incident dialysis patients was feasible but is resource-intensive. High out-of-pocket costs force some patients to stop dialysis and can generate a sense of despair. Poor patient experiences and suspicion over the use of such data adversely affects collection of important clinical and health economic data. A nationally representative registry that records clinical and socioeconomic outcomes would add significant value in evaluating the impact of the recently introduced National Dialysis Service in India and potentially serve as a model for other countries who are also contemplating rolling strategies to improve access to dialysis care.

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