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## The Expanding Role of "Stand-Alone" Hemodialysis Units in Chronic Renal Replacement Therapy: A Descriptive Study from North Kerala

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#### Summary

Renal replacement therapy in India is predominantly a private health-care-driven initiative making it an expensive treatment option due to high out-of-pocket expenditures. Moreover, with the rapid increase in the number of chronic kidney disease patients requiring dialysis, hemodialysis units (HDUs) are getting saturated. Community "stand-alone" dialysis centers could be an important alternative to HDUs in meeting the growing demand in an affordable model. The aim of this study was to find hemodialysis (HD) delivery in "stand-alone" dialysis units (SAUs) with respect to expanding coverage, patient costs, and patient safety safeguards. The total number of HD sessions was collected at three points. The information regarding patient safety safeguards at SAUs and impact of SAUs on patient costs were collected by interviews and from hospital records. There was 11.5 times increase in HD sessions from 2008 to 2017, out of which 75.3% was provided at SAUs. Following objective clinical and safety measures, high-quality dialysis was delivered at SAUs and it significantly reduced the mean patient cost of treatment per session.

Key words: Economics, feasibility, renal replacement therapy, renal replacement therapy gap, safety, stand-alone hemodialysis unit

Chronic kidney disease (CKD) is a major public health concern worldwide. There is a paucity of data on the prevalence of CKD in India, but the reported prevalence ranges from <1% to 17%.<sup>[1,2]</sup> Furthermore, with the increasing incidence of diabetes among younger Indians, the prevalence of CKD is expected to rise further as diabetes accounts for 40%–60% of cases of end-stage renal disease (ESRD).<sup>[3]</sup>

In the developed countries, hemodialysis (HD) is the mainstay of renal replacement therapy (RRT) accounting to 80% of patients.<sup>[4]</sup> In India, there are over 130,000 patients receiving dialysis, and the number is increasing by about 232 per million population, a reflection of increasing longevity in general.<sup>[2]</sup>

RRT in India is predominantly a private health-care-driven initiative making it an expensive treatment option due to high out-of-pocket expenditures (OOPEs).<sup>[5]</sup> Because of the high OOPEs, only a minority of patients in India are able to continue long-term HD. Taking into account the financial pressures on the affected households, the Government of

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India recently announced a National Dialysis Services Programme (now referred as the Pradhan Mantri National Dialysis Programme) to provide free dialysis services to the poor in public sector hospitals in its Union Budget 2016–2017.<sup>[6]</sup>

In many countries around the world, RRT is gradually shifting from HD units (HDUs) to community stand-alone HDUs, thereby increasing the quality of life and productivity of caregivers. In the USA, there are only 4% of patients in hospital-based dialysis centers.<sup>[4]</sup> In Beijing, China, almost 25% of HD patients were treated in community dialysis centers and the average costs for dialysis sessions at the end of May 2016 reduced by 17.3%.<sup>[7]</sup>

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With the rapid increase in the number of CKD patients requiring dialysis in India, HDUs are getting saturated. Community stand-alone dialysis centers could be an important alternative to HDUs in meeting the growing demand in an affordable model. Considering this fact, the Indian Government, in its Healthcare Union Budget 2016, announced the plan for stand-alone HD centers for patients with ESRD.<sup>[2]</sup>

In 2009, the first "stand-alone HD unit" was established in North Kerala with active participation of private hospitals and nongovernmental organizations (NGOs). At present in North Kerala, hospital-based dialysis, both in government and private run hospitals, is fully occupied and also encountering limitations of space along with cost constraints, while the number of stand-alone dialysis units (SAUs) is growing and SAUs have assumed prominence in chronic RRT in the region. Our aim was to describe HD delivery in SAUs with respect to expanding coverage, patient costs, and patient safety safeguards.

This research is a descriptive, retrospective cross-sectional study in which its data were collected after obtaining ethical committee approval from the Institutional Review Board of the hospital. The data regarding total number of dialysis sessions were collected at three points. The total number of HD session at two HDUs during December 2008 at two tertiary care hospitals was retrospectively collected to determine the baseline numbers of dialysis sessions held before SAUs were established. The total number of HD sessions from January 1 to December 31, 2016, at 2 HDUs and 15 SAUs was retrospectively collected to compare the growth of HD sessions between HDUs and SAUs. Finally, the total number of HD sessions during July 2017 at 2 HDUs and 15 SAUs was collected to ascertain the overall expansion of RRT services in the two tertiary care hospitals and associated SAUs. We also compared the sociodemographic and clinical details of 74 patients at HDUs and 67 patients at SAUs, who were undergoing dialysis during the study period. The data were extracted from the hospital digital documents, and a purposive sampling technique was used while collecting data.

The standard operating procedure to address patient safety at SAUs was collected by interviewing two nephrologists associated with running the service, both at HDUs and SAUs, using a semi-structured questionnaire.

The direct dialysis procedure-related cost was collected from HDUs and SAUs from hospital records and compared. The indirect costs such as cost of drugs and travel were not considered. Descriptive statistics was used for quantitative analysis of data.

The community-based dialysis facility as SAUs was started in 2008 initially with a single unit of 10 dialysis stations and subsequently expanded to 176 dialysis stations in 14 centers spanning three districts over 9 years. In the meantime, there was only a 32% increase in hospital-based stations.

In December 2008, the two tertiary hospital HDUs provided 1400 sessions of HD catering to 180 patients. In 2017, the

total number of dialysis sessions in both HDUs and SAUs was 16,182 dialysis sessions (11.5 times increase compared to 2008), of this 75.3% was provided at SAUs.

The total number of HD sessions performed in HDU from January 1 to December 31, 2016, was 45,585 (including HD for acute kidney injury). For the same period, 44,193 sessions were performed in one SAU catering to the largest number of patients. All SAUs put together 121,493 sessions of HD were performed in the year 2016 [Figure 1]. The comparison of patient characteristics at HDUs and SAUs is shown in Table 1.

All patients were screened by the nephrology team for medical fitness for transfer to SAU. Patients with significant cardiovascular comorbidities, especially those with ongoing symptoms suggestive of coronary artery disease or left ventricular systolic dysfunction, were required to continue treatment from HDUs. All patients mandatorily required a recent 2D echo study before transfer to SAUs. Patients with temporary access for dialysis, uncuffed femoral or jugular dialysis catheters, were not allowed transfer of care to a SAU. All patients in the SAU were prescribed 4 h per session three times per week HD. Compliance to dialysis prescription was near universal. Patients with high interdialytic weight gain and frequent hypotension and patients defaulting dialysis sessions at SAUs were transferred to HDUs. Patients with acute illnesses requiring hospitalization were screened by the nephrology team again for fitness for transfer back to SAUs. Dialysis data were communicated electronically to the nephrology team daily from 20% SAUs. The mean number of visits by nephrologists to SAUs during the year 2017 was seven per month. Monthly laboratory tests including hemoglobin, serum calcium, serum phosphorus, and serum potassium were performed for all patients including those from not for profit SAUs. Transferrin saturation was performed once in 3 months and intact parathyroid hormone measurements at least once a year. Each patient's laboratory work was reviewed and medications and dietary plans modified as required by nephrology consultant.

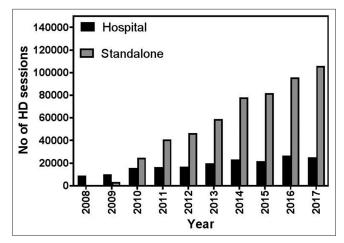


Figure 1: Number of hemodialysis sessions in the hospital and stand-alone centers.

Variables	Hospital-based units (n=74)	Stand-alone centers (n=67)
Age in years (mean±SD)	60.3±10.3	53.9±12.8
Gender (female:male)	30:44	21:46
Diabetic kidney	59.4	44.8
Type of dialysis initiation (elective: emergency)	21:53	37:30
Arteriovenous fistula as first access No. (%)	16 (22)	29 (43)
Echo-proven ventricular dysfunction or regional wall motion abnormality No. (%)	12 (16)	5 (7.5)

SD: Standard deviation

The mean patient cost of treatment per session in 2017 was Rs. 1900 in HDU1 and Rs. 900 in HDU2 compared to Rs. 520 in SAUs. Costs were further subsidized in SAUs through community-generated resources, the involvement of philanthropists, and local self-government schemes.

The growth of SAUs over a period of 9 years from a single unit with 10 dialysis stations to 176 dialysis stations in 14 centers expanded the accessibility to RRT and presumably reduced the RRT gap in the region. SAUs also reduced many barriers associated with HDUs such as transport and reducing caregiver burden. The community SAUs have been discussed as an important step for increasing the outreach of dialysis all over India. Community dialysis center or satellite dialysis units offer dialysis facility at a reasonable price by cutting down the overheads associated with hosepitals.

Most of the SAUs in North Kerala were built by NGOs. The entire space and machinery belongs to the local NGOs, and they provide dialysis on a no profit no loss basis. HD machines were donated to such units by philanthropic support. Other supports included setting up a laboratory to check monthly biochemical parameters at lower cost, transport facility, and lower cost of erythropoietin (EPO). In addition, local self-government schemes including the Snehasparsham programme of the Kozhikode District Panchayat are made available for all patients residing in the district.<sup>[8]</sup> INR 3000 per month is provided as dialysis subsidy by way of this scheme to all enrolled patients. The option of availing the Government of Kerala 's Karunya Benevolent Fund Scheme was available in HDU2 as well as one SAU (which has been serving the largest number of patients).<sup>[9]</sup> Under this scheme, the participating centers are paid a total lifetime amount of INR 200,000 toward meeting the dialysis costs of individual patients.

The HD at SAUs is not free from safety and quality concerns. Literature regarding charitable dialysis has raised concerns on safety of dialyzer reuse, lower EPO dosing, and higher incidence of hepatitis C resulting in higher morbidity and mortality.<sup>[10]</sup> However, by following objective clinical and safety measures, a high quality of dialysis was delivered at SAUs. The selection of patients to be transferred to SAUs was performed following standard operating procedure regarding patient safety in a significant number of cases. Those who are undergoing dialysis at SAUs were younger in age with lesser diabetic nephropathy, and in majority of the patients, dialysis

was initiated on elective basis with an arteriovenous fistula created upfront. Elective initiation usually indicates better pre-HD care and initiation through permanent access while clinically stable. Timely transfer out of sick patients could be ensured by imparting good training to nursing staff. In SAUs of North Kerala, high quality of nursing services could be provided due to the dominant nursing community spread across the state.

In conclusion, our study shows that stand-alone HD centers have improved access to dialysis reducing the RRT gap, and safe and adequate dialysis as prescribed is feasible at SAUs for vast majority of patients at a much lower cost. These centers in the future may serve as a bridge to home HD.

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#### **Conflicts of interest**

There are no conflicts of interest.

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