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ORIGINAL ARTICLE

# Peritoneal dialysis–first initiative in India: a cost-effectiveness analysis

Dharna Gupta[1,*], Gaurav Jyani[1,*], Raja Ramachandran[2], Pankaj Bahuguna[1], Mohammed Ameel[3], Bharat Bhushan Dahiya[3], Harbir Singh Kohli[2], Shankar Prinja[1] and Vivekanand Jha[4,5,6]

[1]Department of Community Medicine and School of Public Health, Postgraduate Institute of Medical Education and Research, Chandigarh, India, [2]Department of Nephrology, Postgraduate Institute of Medical Education and Research, Chandigarh, India, [3]National Health Systems Resource Centre, Ministry of Health and Family Welfare, New Delhi, India, [4]The George Institute of Global Health, New Delhi, India, [5]School of Public Health, Imperial College, London, UK and [6]Prasanna School of Public Health, Manipal Academy of Higher Education, Manipal, India

*These authors are joint lead authors and they contributed equally to this work.
Correspondence to: Shankar Prinja; E-mail: shankarprinja@gmail.com; Vivekanand Jha; E-mail: vjha@georgeinstitute.org.in

## ABSTRACT

**Background.** The increasing burden of kidney failure (KF) in India necessitates provision of cost-effective kidney replacement therapy (KRT). We assessed the comparative cost-effectiveness of initiating KRT with peritoneal dialysis (PD) or haemodialysis (HD) in the Indian context.

**Methods.** The cost and clinical effectiveness of starting KRT with either PD or HD were measured in terms of life years (LYs) and quality-adjusted life years (QALYs) using a mathematical Markov model. Complications such as peritonitis, vascular access–related complications and blood-borne infections were considered. Health system costs, out-of-pocket expenditures borne by patients and indirect costs were included. Two scenarios were considered: Scenario 1 (real-world scenario)—as per the current cost and utilization patterns; Scenario 2 (public programme scenario)—use in the public sector as per Pradhan Mantri National Dialysis Programme (PMNDP) guidelines. The lifetime costs and health outcomes among KF patients were assessed.

**Results.** The mean QALYs lived per KF person with PD and HD were estimated to be 3.3 and 1.6, respectively. From a societal perspective, a PD-first policy is cost-saving as compared with an HD-first policy in both Scenarios 1 and 2. If only the costs directly attributable to patient care (direct costs) are considered, the PD-first treatment policy is estimated to be cost-effective only if the price of PD consumables can be brought down to INR70/U.

**Conclusions.** PD as initial treatment is a cost-saving option for management of KF in India as compared with HD first. The government should negotiate the price of PD consumables under the PMNDP.

**Keywords:** chronic kidney disease, continuous ambulatory peritoneal dialysis, haemodialysis, peritoneal dialysis

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## INTRODUCTION

Chronic kidney disease (CKD) is a global public health problem. Approximately 17% of the global CKD population resides in India [1]. A 2006 population-based study estimated the age-adjusted incidence of kidney failure (KF) in India to be 232/million population [2]. According to a recent survey, ∼175 000 and 8500 people were receiving haemodialysis (HD) and peritoneal dialysis (PD), respectively, in India in 2018 [3]. Dialysis is expensive, and most countries spend disproportionately more for treatment of KF patients [4, 5].

Only a small proportion of KF patients get pre-emptive transplantation, while the rest are eligible for dialysis only—either HD or PD [6]. However, the delivery of treatment and costs related to the two dialysis modalities vary [7]. While HD requires sophisticated infrastructure and human resources, PD is delivered at home by patients themselves or a caregiver and does not require infrastructure.

The announcement of the Pradhan Mantri National Dialysis Programme (PMNDP) in 2016 led to a major push for universal access to kidney replacement therapy (KRT) [8]. However, given the relatively modest funding available to administer this scheme [8], developing a sustainable model of dialysis delivery is critical. Although the initial focus was on setting up HD, PD has been brought under the ambit of public funding in 2019. Globally, PD is considered to be the more cost-effective alternative [9], prompting professional societies to advocate that countries intending to provide universal coverage for dialysis should undertake PD-first or PD-preferred policies. These policies have been supported by economic evidence [10, 11]. A systematic evaluation of the available dialysis alternatives to identify the approach that would offer the maximum health benefits from the available resources has not yet been done in India in the context of budget decisions and supply constraints [12].

This study was undertaken to assess the comparative cost-effectiveness of initiating KRT with either of the two options: PD or HD. The analysis was conducted from two different points of views: first, as per the current care-seeking pattern and costs (Scenario 1: real-world scenario); and second, comparing universal use of HD or PD under the PMNDP (Scenario 2: public programme scenario). We also determined the value-based price of the consumables used in PD.

## MATERIALS AND METHODS

### Overview of the analysis

We conducted a cost–utility analysis of costs and health outcomes in two different scenarios (Table 1) from a societal perspective [13]. Outcomes are valued in terms of the number of KF deaths, life years (LYs) and quality-adjusted life years (QALYs). These methodological principles are consistent with the Indian reference case for conducting economic evaluations used by the agency for Health Technology Assessment in India (HTAIn) [14]. The International Society for Pharmacoeconomics and Outcomes Research Task Force Consolidated Health Economic Evaluation Reporting Standards were used to report the findings [15].

### Model overview

The cost and health outcomes of the two dialysis alternatives were measured in a hypothetical cohort of 1000 KF patients. A mathematical Markov model was parameterized in Excel (Microsoft, Redmond, WA, USA) to assess the clinical course of eligible patients. The progression was divided into distinct 'health states' and the movement of patients among these health states over a 1-year cycle was modelled (Figure 1). The lifetime costs and outcomes for both the alternatives were estimated by attaching estimates of resource use to these health states and running the model over many cycles. The modelling only considers in-centre HD and non-cycler-assisted continuous ambulatory peritoneal dialysis (CAPD) reflective of prevailing standards and costs.

Patients could continue with the initial dialysis modality indefinitely or switch to the other modality only upon development of complications. In case of HD, two access-related complications—fistula failure and catheter-related bloodstream infections (CRBSIs)—and three blood-borne infections [BBIs; hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV)] have been taken into account [16]. For PD patients, we considered the risk of developing peritonitis [17]. Each of these complications has been modelled as a separate health state. The mean age of the start of dialysis was 47 years [2]. To obtain the present value of costs and outcomes occurring in the future, all future costs and outcomes were discounted at 3%.

The model makes the following assumptions: a patient infected with any BBI (HBV, HCV and HIV) will not be infected with another BBI, patients may recover from access-related complications to their previous health state, patients who develop HBV and HIV infections move to another health state, patients with HCV infection will continue to be on the same cycle after treatment, ∼5% of patients with HCV will need more than one 3-month treatment cycle to develop a sustained virologic response [18, 19] and a patient who has recovered from HCV has the same chances of reinfection with any of the BBIs as a patient who has never been infected in the past. Finally, the patients are assumed not to opt for kidney transplant in both arms.

### Cost of dialysis care

Health system costs and out-of-pocket expenditures (OOPEs) were estimated separately for both initiation (one-time) and recurrent costs for both HD and PD. The health system cost of initiating HD comprised the cost of arteriovenous (AV) fistula creation or dialysis catheter insertion. As per the Indian Society of Nephrology, only 10% of patients start dialysis with a functioning AV fistula [16]. For the rest, the cost of both the vascular catheter and fistula surgery was applied. The recurrent health system cost of providing one session of HD at public health facilities was estimated by analysing the PMNDP data, a nationally representative dataset of 22 809 patients maintained by the National Health Systems Resource Centre, New Delhi. Using the state-wise provider payment rate (paid to private provider per HD session) and the number of HD sessions in each state, we computed a national weighted average cost per HD session paid to private providers for 2019.

A microcosting exercise was undertaken to assess the one-time health system cost of PD initiation, which comprised catheter insertion surgery and patient training. This included collection of data on capital resources such as the infrastructure, equipment, furniture etc. and recurrent resources such as consumables, human resources etc. to provide the training. The cost of human resources and capital resources used were then apportioned based on the time taken to perform each of these activities. The cost of these services was estimated as a product of the volume of services and the respective per-unit cost of

**Table 1. Description of the scenarios**

| Scenario | Scenario name | Description | Cost assumptions | Effects |
|---|---|---|---|---|
| 1 | Real-world scenario | Current utilization patterns of dialysis modality HD—both private and public-sector facilities PD—public-sector tertiary care hospitals | Proportion of people utilizing HD: Public secondary: 0.28 Public tertiary: 0.02 Private tertiary: 0.1 Private dialysis centres: 0.53 Charitable facilities: 0.07 | LYs QALYs |
| 2 | Public programme scenario | Assumes 100% coverage by the PMNDP Eligible patients are being provided HD and PD at a secondary level | HD—secondary-level costs as per the PMNDP PD—according to the prices predicted in the PD guidelines as per the PMNDP | LYs QALYs |

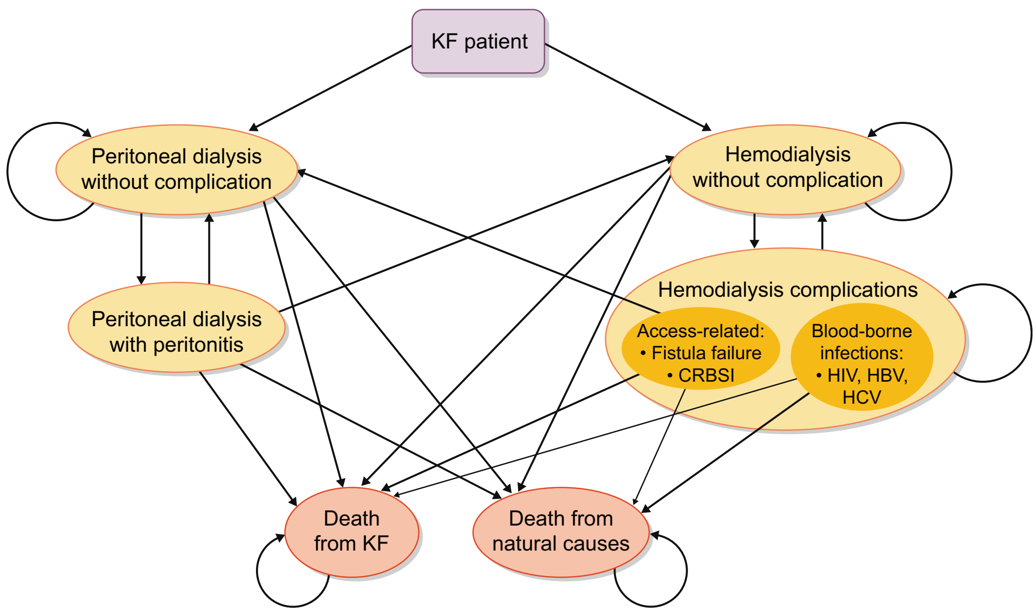


**FIGURE 1:** Markov model depicting progression of the kidney failure patients.

these services as per the published literature [20, 21]. The volume of services used by PD patients was determined on the basis of a standard pattern of clinical care developed by the subject experts. The recurrent health system cost of PD only comprised the cost of outpatient department (OPD) consultations {Indian National Rupee [INR] 546[International Dollar (I$26)]}, as derived from a previous study [20]. The data pertaining to the number of OPD contacts required, proportion of patients that require hospitalization, number of hospitalizations per patient per year and frequency and type of laboratory investigations required were based on expert opinion.

OOPEs were estimated as direct medical and non-medical expenditures by interviewing 115 HD and 77 PD patients recruited from one secondary-level public facility and one tertiary care public facility using structured questionnaires [21]. The direct medical OOPEs associated with HD comprised procedure fees, medications and laboratory investigations. For the private sector, it was assumed that the cost incurred by a patient for HD treatment covered both the OOPEs and health system costs. The direct medical OOPEs for PD included expenditures incurred for PD solutions and accessories, medicines, laboratory investigations and consumables (dressings etc.). The direct non-medical OOPEs measured for both HD and PD included travel, food, lodging etc.

The standard treatment workflows for managing the complications of HD and PD treatments were ascertained with the help of expert opinion. The health system cost for management of complications was calculated on the basis of guidelines where available or treatment workflows developed by experts [16–18]. The cost of treatment of BBIs (HBV, HCV and HIV) was obtained from the published Indian data [19]. The HD frequency was estimated at 10 sessions per month; for CAPD, we considered three exchanges per day as per prevailing practice.

For Scenario II, the health system cost was determined as per the published PMNDP guidelines [8]. In case of PD, the cost incurred on PD consumables is obtained from the guideline while the rest of OOPE (such as medicines, dressings, cost of OPD visits, etc.) is determined from primary data. The cost parameters used in Scenario II are presented in Supplementary Appendix S1.

All costs are reported in INR and I$ using the average conversion of I$1 = INR21.2 in 2019 [22] and were adjusted for inflation to 2019 prices using the World Bank Group gross domestic product (GDP) deflator [23].

### Indirect costs

The indirect cost due to productivity loss was estimated using the human capital approach [24]. We used the average national wage rate (INR247/day) as a proxy of daily productivity in economic terms [25, 26]. The productivity of a patient with KF was considered at 80% compared with a healthy individual [25]. In case of PD, the patient is assumed to be 80% productive on all the days of the year, except on the OPD days or in case of any hospitalization (due to peritonitis), wherein the patient would incur complete wage loss for those days [25]. Similarly, in the case of HD, the patient is assumed to incur complete wage loss on the days of HD procedure and hospitalization (if any) and 80% on the rest of the days. These productivity losses were measured for the duration between the development of disease and the average age of retirement in India (60 years) or death, whichever occurs earlier [27]. Besides productivity losses due to illness, lost productivity due to premature mortality was also estimated.

### Valuation of consequences

The outcomes were assessed in terms of LYs and QALYs. The rates of transition of a patient with KF to the subsequent health states were obtained from the published literature and converted into annual transition probabilities using standard methods (S1) [28]. It was assumed that one-third of the patients on PD develop peritonitis within 1 year [29], ∼70% of whom recover, while the rest may switch to HD or die [30]. In case of HD, it was assumed that no patient will die just due to AV fistula failure. The fistula would be revised or repaired or the patient will switch to PD. Age-specific all-cause mortality rates from each health state were obtained from the sample registration system life tables [31].

To measure health-related quality of life, the European Quality of Life 5-Dimensions questionnaire (EQ-5D), comprising the five-level EQ-5D descriptive system and the EuroQol visual analogue scale (EQ-VAS), was administered to 115 HD and 77 PD patients. As the tariff values are not available for India, the profiles were converted to their corresponding utility scores using the tariff values from Thailand [32]. The choice of the Thailand value set to calculate index utility scores was based on the recommendations of the draft Indian reference case for undertaking HTAs [33]. The quality of life (QoL) scores were adjusted as per the various sociodemographic characteristics such as age, gender, Rrligion, education status, caste and locality of the patient with respect to the type of treatment (HD or PD) using multilinear regression analysis. The factor (B-value) obtained was then used to calculate the utility score of PD with respect to HD.

The comparative cost-effectiveness was assessed in terms of incremental cost per QALY gained. The incremental cost-effectiveness ratio (ICER) was estimated as the ratio of the difference in costs and the difference in effectiveness between the PD and HD treatment arms.

$$\mathrm{ICER(QALY)} = \frac{\text{Total lifetime cost of PD} - \text{Total lifetime cost of HD}}{\text{Total lifetime QALY for PD} - \text{Total lifetime QALY for HD}}$$

### Sensitivity, threshold and scenario analyses

The impact of changing the parameter values on the results was analysed by applying a probabilistic sensitivity analysis (PSA). The probability of the PD-first programme to remain cost-effective at a willingness-to-pay threshold equal to per capita GDP was estimated using the societal perspective. The per capita GDP of India in 2019 was INR148 171 (I$6986) [34].

For undertaking PSA, we used a gamma distribution for parameters related to cost and a beta distribution for parameters related to risk of complications and overall survival. For the rest of the parameters we used uniform distribution to simulate random values. Upper and lower bounds were computed from the standard error estimated in the primary data or estimates provided in the literature sources. Wherever the upper and lower bounds were not provided in the literature, we assumed a variation of 20% on either side of the base estimate for clinical parameters and 30% variation for risk of mortality, treatment patterns and cost parameters. The Monte Carlo method was used for simulating the results and the number of iterations was restricted to 1000 times. The median was computed along with the 2.5th and 97.5th percentiles to estimate the 95% confidence interval.

Since PD hass not yet been introduced under the PMNDP programme (Scenario 2), we undertook multiple PSAs at different prices for consumables (PD solution and mini-caps) in order to assess the probability of PD to be cost-effective at different prices for PD consumables. This analysis was undertaken from a health system perspective. The cost-effectiveness threshold (the maximum amount a decision maker is willing to pay for 1 U of health outcome) was considered to be equal to per capita GDP, as advocated by the HTAIn [14, 35].

## ETHICAL CONSIDERATIONS

The study protocol was approved by the Institute Ethics Committee of the Post Graduate Institute of Medical Education and Research, Chandigarh, India (NK/5376/Study/052).

## RESULTS

### Costs

The health system bears a cost of INR1595 (I$75) per dialysis session for providing HD under the PMNDP. The OOPEs incurred by the patient were calculated at INR1173 (I$55) per session. Therefore the total annual direct cost for HD treatment at a secondary level was estimated to be INR332 196 (I$15 662). The total costs for management of AV fistula failure and one episode of CRBSI were INR6120 (I$288) and INR11 347 (I$535), respectively. The annual indirect cost incurred on an HD patient without complications for 1 year was estimated at INR41 743 (I$1968).

The one-time health system cost and OOPEs of PD initiation were INR17 054 (I$804) and INR34 978 (I$1649), respectively, and the recurrent average daily OOPE was INR1329 (I$63). The annual health system cost and OOPEs incurred on PD were estimated as INR6550 (I$309) and INR478 303 (I$22 551), respectively.

The total cost of treating one episode of peritonitis was estimated to be INR7219 (I$340). The indirect cost for PD treatment initiation was estimated to be INR2470 (I$116) and the total recurrent annual indirect cost for a patient receiving PD without complications was estimated to be INR23 366 (I$1102).

## Cost-effectiveness

We estimated that the KF patients treated with PD and HD have an overall mean survival of 5.05 and 2.6 LYs, respectively. After factoring in the quality of life, this would translate into 3.3 and 1.6 QALYs, respectively. From a societal perspective, the policy of PD first is a cost-saving strategy, as it yields an increase in QALYs and is less costly as compared with the policy of HD first in both the scenarios. If KRT is initiated with PD instead of HD, a KF patient will be living an additional 1.7 QALYs, and in the real-world scenario, the patient will save INR92 105 (I$4342) during his/her lifetime. If KF patients seek treatment as per the public programme scenario (Scenario 2: PMNDP scenario), then the average lifetime cost savings was found to be INR697 000 (I$32 862).

The detailed results for the study cohort are presented in Table 2.

## Sensitivity analyses

If the consumables used in the PD exchange are purchased at a price of INR70/U, which is 65% less than the NHSRC recommended price (INR200/U), the OOPEs of a KF patient will decrease to INR195 999 (I$9241) per year. At this price, even if only direct costs of treatment are considered, there is a 75% probabil-

**Table 2. Discounted costs, consequences and cost–effectiveness of the study cohort of PD-first treatment policy as compared with HD-first treatment policy**

| Health outcomes | Scenario 1 PD-first, median (95% CI) | Scenario 1 HD-first, median (95% CI) | Scenario 2 PD-first, median (95% CI) | Scenario 2 HD-first, median (95% CI) |
|---|---|---|---|---|
| LYs | 5053 (5017–5095) | 2635 (2325–2974) | 5053 (5018–5096) | 2635 (2338–2944) |
| QALYs | 3296 (2750–3754) | 1591 (1404–1796) | 3296 (2777–3736) | 1591 (1410–1777) |
| Health systems cost (million INR) | 68.7 (65.5–72.5) | 165 (133–204) | 69.9 (64.1–76.5) | 488 (433–544) |
| OOPEs (million INR) | 2416 (2398–2434) | 829 (692–979) | 1692 (1683–1701) | 390 (432–348) |
| Indirect cost (million INR) | 3092 (3077–3107) | 4674 (4407–4915) | 3092 (3078–3106) | 4674 (4435–4906) |
| Total cost (million INR) | 5577 (5563–5591) | 5669 (5482–5832) | 4854 (4848–4861) | 5551 (5412–5687) |
| Incremental values | | | | |
| LYs | 2418 (2121–2691) | – | 2418 (2152–2677) | – |
| QALYs | 1705 (1346–1960) | – | 1705 (1366–1958) | – |
| Total cost (million INR) | −92.1 (−241–75.5) | – | −697 (−826 to −564) | – |
| Incremental cost per LY gained (INR) | −38 091 (−94 555–40 641) | – | −288 315 (−310 441 to −260 279) | – |
| Incremental cost per QALY gained (INR) | −54 025 (−137 819–57 303) | – | −408 918 (−582 966 to −309 737) | – |

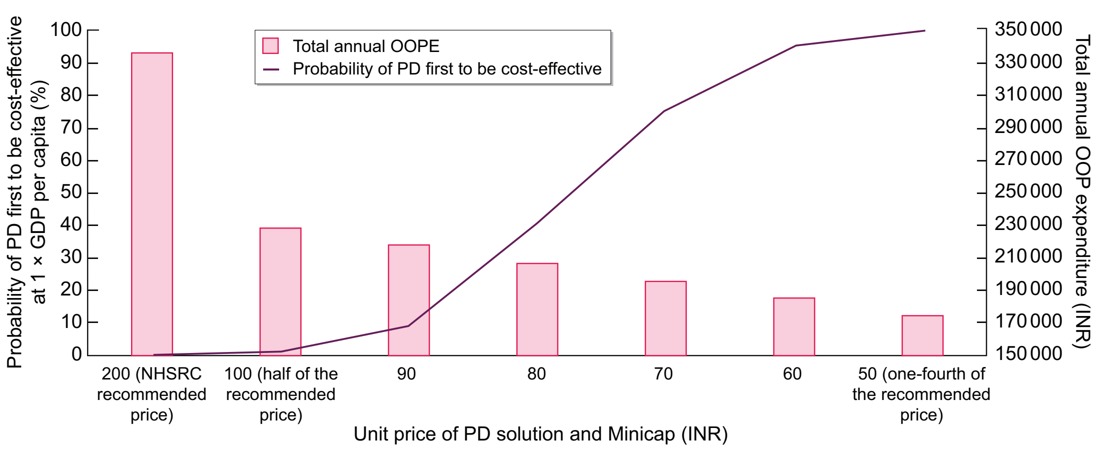


**FIGURE 2:** Threshold price analysis for PD consumables prices in Scenario 2 (PMNDP scenario).

ity for PD to be cost-effective (at a threshold of per-capita GDP) (Figure 2).

## DISCUSSION

Our analysis indicates that the proposed intervention of PD-first treatment is cost saving as compared with the HD-first approach in India from a societal perspective. If the prices of PD consumables can be reduced by 65%, the use of a PD-first policy has a 75% probability to be cost-effective from a health system perspective. This is likely to happen if there is bulk procurement through a public system. In view of this, our study findings recommend the adoption of a PD-first policy in the national PMNDP.

### Model validation

The findings of our model are in concurrence with existing epidemiological studies. Our model estimates show the overall survival for CKD patients with PD at 5 and 7 years to be 39.5 and 26.3%, respectively, similar to studies by Prasad et al. [36] and Lasfar et al. [37] that reported similar long-term survival of 39% at 5 years and 30% at 7 years. In the case of HD, the annual disease-related mortality of 23.2% as per our model correlates well with a population-based study that reports that 22.4% of patients die in 12 months [38].

As per current practice, almost all of the cost for PD is borne by patients as OOPEs. This is in concurrence with the findings of previous studies reporting that in low- and middle-income countries, the cost of PD is higher due to the higher price of PD supplies and the lack of government aid [39, 40]. Given the way HD and PD are currently financed in India, it is not appropriate to report the ICERs from the health systems' perspective. This is mainly because the price of HD is already highly controlled in India. So, from the perspective of the PMNDP, the scenario analyses help us to estimate the probable reduction in the prices of PD consumables that will make the PD-first policy a cost-effective option with uniform public funding for both dialysis modalities. There is existing evidence showing that government procurement of medical devices and pharmaceuticals results in a substantial reduction in prices. This will be aided by the promotion of domestic production of PD consumables as compared with importing them at higher prices [41, 42].

### Findings in context of the existing evidence

Analyses in countries like Thailand, Singapore and Indonesia have shown that the PD-first policy is important for achieving universal coverage of dialysis care. In most of these studies, PD and HD were compared with modalities such as transplant, palliative care etc. [43, 44]. While we reported 3.26 QALYs in the PD-first scenario, Yang et al. [25] reported 3.27 QALYs in the CAPD arm. However, the QALYs gained with HD are not similar, as the relative QoL for HD and PD move in opposite directions as compared with our study. There is, however, a comparable difference between the QoL scores reported by our study and other published analyses [5, 44].

Our study is the first to report the cost-effectiveness of dialysis modalities in the Indian context. We used a Markov model that is based on the current understanding of the disease and its outcomes. As far as possible, we used Indian evidence on epidemiology, clinical effectiveness in terms of survival, complication rates and cost of care. Primary data were collected to estimate OOPEs and quality of life; national programme data from the PMNDP were used to assess the health system costs of HD. We also incorporated in our analyses private-sector utilization and costs. Hence our findings are generalizable and should be used for policymaking.

However, there are certain limitations of this analysis. First, we only considered the two common dialysis modalities and did not include the costs and complications associated with kidney transplant. Because of the lack of donors and legal machinery, the number of transplants being performed in India is low compared with the demand. Second, due to the lack of robust registry and clinical data, the parameters were obtained from cross-sectional studies rather than systematic reviews. There is limited population-based survival evidence with regard to HD and PD in the Indian context. The study takes into consideration only CAPD, and not automated cycler-assisted PD, because CAPD in patients is cheaper, more popular and likely to be the preferred policy option. The study also does not incorporate indirect costs incurred by the caregivers or patients' families due to the illness.

## CONCLUSIONS AND POLICY IMPLICATIONS

There are a few important implications of our findings. First, the PD-first policy is a cost-saving policy. Second, if the PD-first policy is utilized in the PMNDP, it should result in lower prices for PD consumables, which will make PD even more efficient. Third, since the cost of providing PD is largely currently being borne by patients, subsidized treatment under the PMNDP will result in reduced financial hardships. Finally, since most of the HD facilities are located in urban and well-connected cities [4], introduction of the PD-first policy linked to primary healthcare services is likely to improve access to treatment for patients in rural and remote areas, thereby making outcomes more equitable. Moreover, with augmentation of the primary healthcare capacity in India through creation of the Health and Wellness centres [45], a functional linkage of community-level primary healthcare services with PD services for CKD patients should also be considered.

## SUPPLEMENTARY DATA

Supplementary data are available at ckj online.

## FUNDING

No specific funding was obtained to carry out this research.

## CONFLICT OF INTEREST STATEMENT

The results presented in this article have not been published previously in whole or part, except in abstract format. V.J. reports grants from BSK, Baxter Healthcare and Biocon and personal fees from AstraZeneca, Baxter Healthcare and NephroPlus, outside the submitted work. All funds go to his institution. All other authors declare no conflicts of interest.

## DATA AVAILABILITY STATEMENT

All data relevant to the study are included in the article or uploaded as supplementary information.

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