

**EPIDEMIOLOGICAL STUDY OF THE PERITONEAL DIALYSIS
PROGRAM IN NEPAL, COMPARISON TO OTHER REGIONS,
CHALLENGES AND OPPORTUNITIES TO STRENGTHEN
PERITONEAL DIALYSIS ACTIVITY IN THE SOUTH ASIAN
REGION**

PhD thesis

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List of Abbreviations

AKI: Acute Kidney Injury

AVF: Arterio-Venous Fistula

BCM: Body Composition Monitor

BNP: Brain Natriuretic Peptide

BP: Blood Pressure

CAPD: Continous Ambulatory Peritoneal Dialysis

CKD: Chronic Kidney Disease

COVID-19: Corona Virus Disease -2019

CVD: Cardio-Vascular Disease

eOH: Estimated Over-Hydration

ESKD: End-Stage Kidney Disease

ESRD: End Stage Renal Disease

GNI: Gross National Income

HD: Hemodialysis

IDWG: Inter-Dialytic Weight Gain

IQR: Inter-Quartile Range

NRs: Nepali Rupees

OPD: Outpatient Department

PD: Peritoneal Dialysis

QoL: Quality of life

RRT: Renal Replacement Therapy

SD: Standard Deviation

SF-36: 36-item Short Form Health Survey questionnaire

SHS: Social Health Security

UF: Ultrafiltration

UN: United Nations

USD: United States Dollars

USRDS: United States Renal Data System

1. Introduction

1.1 PD in the world

Renal replacement therapy (RRT) has placed significant burden on all types of health care systems in the world (Li et al. 2017). This is especially true since the treatment requires lifelong commitment with high cost and multiple co-morbidities complicate the care of these patients. PD offers cost-saving not only in medical equipment and manpower, but due to being a home-based therapy and offering higher quality of life, there is benefit in all aspects for the patient (Zent et al. 1994).

Continuous ambulatory peritoneal dialysis (CAPD) was established initially in the 1970's (Popovich et al. 1976). However, there were plenty of technical issues and it was not widely utilized (Oreopoulos et al. 2010). Later, the use of plastic bags instead of glass bottles, the Y-shaped connecting system and the flush before fill technique by Oreopoulos has made CAPD viable alternative to hemodialysis (HD) (Oreopoulos et al. 1978, Nolph et al. 1988). From the 1990's peritoneal dialysis (PD) has become even more widely utilized in many parts of the world, including the developing countries (Zent et al. 1994, Krediet RT. 2007).

Building up a national PD program can be challenging (Gokal R. 2002). Financial support from the government as well as support from the industry are important in the development of PD programs (Gadallah et al. 2001). Examples of countries where PD was made cost-effective include Mexico, Hong Kong and Thailand with the latter two adopting a PD-first strategy with rapid growth of PD (Kwong et al. 2015, Treviño-Becerra et al. 2002, Wilkie M. 2018).

In countries, where healthcare costs are mainly out-of-pocket, lack of health insurance limits the ability of patients to afford costly dialysis services (Briggs et al. 2019, Jha V. 2009). In these countries, dialysis practice is dictated less by medical and more by nonmedical factors eg. capacity, availability, and financial factors (Nayak et al. 2009).

1.2 History of PD in Nepal

In 1971, the first case of successful acute intermittent PD treatment was reported from Bir Hospital in Kathmandu. The patient was a 28 years old male, who developed acute kidney injury (AKI) after mastoidectomy (Shrestha et al. 1971). The first Nephrology Outpatient Department (OPD) was established in 1984 by Prof. Puskar Raj Satyal, who is the first nephrologist in Nepal and is also called the father of nephrology. Few years later, in 1989, the first Nephrology Unit was also started at Bir Hospital, which is the first and oldest hospital in Kathmandu. HD was started in Nepal from 1988 at Bir Hospital (Hada et al. 2009).

The first CAPD patients were managed at Bir Hospital from 1992 (Sharma et al. 2009). The modern, Y-system, 2-liter, double-bag, fluids used for CAPD were initially imported from Thailand (Baxter Asia Co.). Later on from 1996, the newly established Baxter manufacturing plant in Gurgaon, near New-Delhi, India was able to supply, making the availability easier and bringing down the costs.

In the 1990`s HD capacity was very limited in Nepal. Thus those patients, who could afford it, went to India for renal transplant. For those, who were not able to get transplanted, CAPD was a viable option. Prof. Georgi Abraham, who started CAPD in India from 1990 after training under Dr Oreopolus in Toronto, was most influential on starting the first CAPD program in Nepal. Two CAPD nurses from Bir Hospital were trained in Chennai, India at Prof. Georgi`s institution in 1995-1996. However, this CAPD program was not sustained. The major challenges faced were high rate of peritonitis, cost and nonavailability of consumables. From 1996 hemodialysis services started to expand in Nepal, especially after opening of a nonprofit organization, the National Kidney Center in Kathmandu.

The first sustained CAPD program was established in 2002, by Prof. Dr. Sanjib Kumar Sharma, in Dharan, the eastern part of Nepal (Sharma et al. 2003). During the period of 2002 to 2007 he had enrolled 50 patients (Sharma et al. 2010). Later on, from 2008 two other hospitals in the capital also started CAPD (Tribhuvan University Teaching Hospital and Nepal Medical College). From 2012, Dr Kalpana Shrestha has initiated a CAPD program in a government owned facility, a kidney specialist hospital, Human Organ Transplant Center (today known as Shahid Dharma Bhakta National

Transplant Center) in Bhaktapur, located at the capital. Her program became the largest in Nepal with nearly 100 patients. From 2014 CAPD was also started in the western region of Nepal, with over 50 patients (Paudel et al. 2016).

1.3 Advantages and disadvantages of PD

The major advantages of PD compared to HD are: superior rehabilitation and quality of life, avoidance of frequent hospital visits and travel, home-based therapy even in rural settings, freedom from blood-borne infections eg. hepatitis B and C, less need for erythropoietin or blood transfusions, and cost savings (Abraham et al. 2015). Cost is saved especially if PD fluid is manufactured locally or in a nearby country and also by not needing expensive HD machines (Holley et al. 1998). Currently, as the COVID-19 pandemic is affecting the world, the other important benefit of PD is that patients can stay at home and do not need frequent hospital visits. Despite the clear advantages, PD utilization is limited in most developing countries, while HD is growing (Li et al. 2017).

Among the disadvantages of PD, we need to mention the following factors: difficulty in delivering the fluid supply to the patient's home, risk of peritonitis, catheter related complications eg. flow problems, need for carer if patient is unable to do exchanges themselves, ultrafiltration (UF) is membrane dependent and in some cases UF failure can occur. In some countries PD is more expensive than HD, especially in places where HD consumables and health care workers' wages are low (Karopadi et al. 2013).

1.4 Examples of PD programs in developing countries

In Table 1. countries from Asia and Africa are listed with the available data about their PD programs, along with the challenges they faced.

Table 1. Examples of CAPD programs from a few developing countries

Country	Start of CAPD	Number of PD patients (year of data collection)	Cost coverage	Challenges
Iran (Najafi et al. 2010, Najafi et al. 2014)	1995	2239 (2010)	Free	Lack of knowledge on PD among doctors and patients, lack of incentives to doctors, fast access to transplantation (no waiting list)
Thailand (Tungsanga et al. 2008, Chuengsaman et al. 2017, Thammatacharee et al. 2020)	From 2008 PD first policy and steady growth	20 000 (2017)	Universal coverage from 2008	Cost, lack of incentives, lack of education and PD nurses, fear of peritonitis, lack of government policy – of which all were changed after introduction of PD first policy
India (Jha V. 2004, Abraham et al. 2002, Jha V. 2008)	1990 – slow growth; from 1994 local manufacture of fluid resulted in favorable program growth	5000 (2015)	Depends on states and various insurances, mostly not covered by government programs	Economic factors, inadequate government policies, nephrologist bias, and lack of adequate pre-dialysis care; financial support

Indonesia (Suhardjono 2008, Hustrini et al. 2019)	1985 (slow) from 1998 increasing numbers	1737 (2017)	Government support from 1998	High drop out rates due to death, infection, catheter failure
Vietnam (Van Bui P. 2008)	1998 (stopped after the first 10 cases) restarted in 2001	700 (2008)	Insurance coverage for EPO and dialysis from 2005	Skepticism and concern of both patients and physicians about effectiveness and infection risk
Egypt (Mahmoud et al. 2010, Elzorkany KMA 2017)	1997 (most patients unable to use HD due to lack of vascular access)	33 (2010)	None	Problems with availability of PD fluid, patient factors (education and motivation), lack of national program
Sudan (Elhassan et al. 2007)	2007		Free CAPD from 2007	Cost of medications and laboratory tests
Tanzania (Abu-Aisha et al. 2010, Callegari et al. 2012)	2009 – only for AKI		PD for AKI reimbursed by national health insurance	Sustainability of fluid supply and staff, lack of timely referral and awareness

1.5 Introduction to Nepal, its health care system and dialysis system

Nepal is located in the South Asian region with 29.1 Million population (United Nations (UN) estimate, mid year 2020). According to the World Bank classification, Nepal was a low-income country until July 2020, when it was upgraded to lower-middle-income country, with a Gross National Income (GNI) per capita 1090 USD in 2019. Also,

World Bank data estimates, that 79.85% of the population live in rural areas (World Bank, 2019).

As of 2019, in Nepal there were 23146 doctors registered at Nepal Medical Council, with a doctor to population ratio of 1:1257 (Nepal Medical Council, 2019). However, there is a geographical maldistribution: while in the capital there is a 1:850 ratio, in the rural areas it can be 1:150 000 (Shankar PR 2017, Ailuogwemhe et al. 2005).

According to the records of the Nepal Society of Nephrology, in 2012 there were only 13 nephrologists in the country, whereas in 2021 the number has reached 60, serving a population of 29 million. Among the 60 nephrologists, 48 (80%) are in the capital, while 12 are serving the population in other parts of the country. Renal transplantation is only available in the capital.

The health system in Nepal is characterized by a wide network of government and private health facilities and community workers. Nepal's Interim Constitution of 2007 addresses health as a fundamental right, stating that every citizen has the right to basic health services free of cost, but it is not the reality. Even in government owned facilities, the out-of-pocket expenditures are significant. In 2013 a National Health Insurance Policy and later in 2015 a social health security scheme (SHS) was proposed, which aims to increase the access of health services to the poor and the marginalized, though challenges remain with financing (Mishra et al. 2015).

Hemodialysis centers are two types, private or government owned. Among private units there are three types:

1. Units in teaching hospitals - they belong to a medical college, which provide health care services at lower fees and have larger number of patients, (they are able to reduce prices since their main income is from student fees and their main interest is to have more patients);
2. Not-for-profit organisations eg. Non-government organizations, charity or community units;
3. For-profit private hospitals, with higher fees but provide higher quality of care.

Currently there are 65 HD centers in Nepal: 22 government owned, 8 non-profit organization, 10 in teaching hospitals and 25 private units. Among these 25 are located in the capital and 40 are outside the capital.

Government hospitals are few in numbers, mostly one in each location. There are only two in the capital, and one in each district headquarter (Nepal has 77 districts). Most of the largest cities have hemodialysis unit in the government hospital, but at the smaller cities, the district hospitals may not have, or if they have, there will be 2-3 machines only, with trained nurses, but no nephrologist.

All of the PD centers belong to a hemodialysis center which is led by a nephrologist who is willing to promote PD. They are only available at larger cities. In Nepal currently there are 10 PD centers and they are found in 4 major cities: Kathmandu, Pokhara, Dharan and Biratnagar only.

From 2011, the Government of Nepal initially started to support hemodialysis with 50 000 Nepali Rupees (NRs) per year (Approx. 425 USD), that patients were able to avail from government hospitals. In 2013 they announced that hemodialysis will be free for one year for poor people with maximum twice weekly schedule. This meant the patients were eligible for 104 hemodialysis session in total. The method of allocation is that every government hospital was automatically involved, and other private units could apply for this scheme and if accepted, they will provide the hemodialysis for free, and get reimbursed by the government later. The hemodialysis reimbursement fee was set at 2500 NRs (approx. 21 USD). However, this fee has not been increased in the past 8 years. It was meant for poor patients only, but since it is not regulated, all nepali citizens are able to avail it. In 2014 the initial one-year period was extended to two-years, and the following year it was extended for life-long dialysis reimbursement.

As for PD, starting from 2014, the reimbursement fee initially was made equal with the HD amount, meaning if for HD they give 20 000 NRs per month (approx. 8 HD sessions), then for PD they also give 20 000 NRs per month, which was covering about 2 bags per day, the cost of one PD bag being about 300 NRs at that time. From 2015 it was extended upto 3-4 bags per day, as per need and for lifelong. (The prime minister of Nepal in 2015, K.P Sharma Oli, himself a patient of end-stage kidney disease (ESKD) and received two kidney transplants played major role in establishing free dialysis in Nepal).

During the years from 2014 till today, the price of the PD bags has increased steadily from 300 to 350 to 380 to 408 to 430 and now to 492 NRs. However, the government has freezed the bag reimbursement price at 408 NRs. Thus, the cost of PD has gradually became approx. twice as costly for the government as HD.

2. Objectives

In our research we try to answer the following questions, by examining the PD practice in Nepal and in South Asia:

1. What are the PD practices in Nepal?
 - a. Demographics and educational background of Nepalese PD patients
 - b. PD Catheter types and methods of implantation in Nepal
 - c. Transport status and number of exchanges in PD in Nepal
 - d. Complications and outcomes of PD in Nepal
 - e. Indications and motivating factors to choose PD
2. What are the differences between PD and HD patients in Nepal, in terms of basic characteristics, quality of life and fluid balance?
3. Are the PD practices in Nepal different than in other countries or regions? We compare available data about RRT and PD practices from other countries and regions with data from Nepal.
4. What are the main challenges and opportunities to strengthen PD programs in low-resource settings, such as Nepal and other South Asian countries?
 - a. What are the main challenges in developing a PD program?
 - b. What are the key points that need to be addressed while establishing a PD program?
 - c. How to overcome the obstacles and what are the models for success?

3. Methods

3.1. Methods of data collection

The study was approved by the local ethics committee, and conducted in agreement with the Declaration of Helsinki. All study subjects have given informed consent before collecting their data.

In Nepal there is no renal registry and in most hospitals, electronic medical records and proper medical documentations are lacking. To get a clear view on the PD practices of Nepal, we have used the following available means of information:

1. Nepal Government, Health Services Department, Free Dialysis Scheme reimbursement records

Since 2013 the Government of Nepal has started supporting dialysis for the disadvantaged population.

For reimbursement purposes, hospitals need to report the amount of dialysis each patient received. Data need to be uploaded on a daily basis at the government site. There is limited access to this database, however we were able to access for prevalent data on June 2018. The number of HD patients and PD patients from each center were provided.

2. PD clinical coordinator`s records of patients from the Kathmandu valley

In the Kathmandu Valley the main distributor (Baxter) has clinical coordinators, who support patient care in all major PD centers and have network and contact with all PD patients within the Valley. They collected data about patients prospectively including complications and outcomes. During the period of 2012 to 2016, a total of 236 PD patient`s data were collected. Demographic data - age and gender, geographic data - address (district), treatment data – exchanges per day, complications – peritonitis episodes, outcomes – death or drop out cause and time. For few patients, peritoneal equilibrium test (PET) data were also available.

3. Interviewing PD patients from multiple centers

Interviewing PD patients was done personally in two centers in Pokhara, Nepal. This was a cross-sectional overview, with total number of 56 PD patients. All patients from two centers were included, who were willing to participate. The interview was done either personally or by phone. A questionnaire was administered, in which we asked about the motivating factors of choosing PD. There were 6 prestructured answers from which they could choose and it was multiple choice option.

4. Peritoneal dialysis patients registry between 2014-2021 at Pokhara

Between 2014 to 2021 total 88 patients were initiated on peritoneal dialysis by the author. Details of their catheter insertion, early and late complications, survival and technique survival data, as well as basic characteristics such as demographic, geographic, etiological and occupational data were collected.

5. Interviewing HD patients in the Pokhara region

This is a cross-sectional study from 6 centers in the Pokhara region, that was conducted in 2019. Total 219 hemodialysis patients were included. All patients were interviewed with the help of a questionnaire, either personally or by phone. Patients, who were reachable and gave consent for the interview were included. Demographic, geographic, etiological and occupational data were collected, along with a survey on the details of foreign employment, medical history and family history. The purpose of this cross-sectional study was to compare PD and HD patients' characteristics.

6. Interview of HD and PD patients from two centers in Pokhara about quality of life and fluid balance

It was a cross-sectional study. Regular HD patients from two centers in Pokhara were approached, and 50 out of 85 HD patients gave consent and were reachable. Also, 20 prevalent PD patients were included. We interviewed patients about quality of life with the help of SF-36 questionnaire. Also collected data about urine output, dialysis

parameters such as interdialytic weight gain, estimated dry weight, pre- and postdialysis weight, ultrafiltration of each dialysis in the past one month and for PD patients the daily ultrafiltration rate.

3.2. Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 26.0 software package. For the Kathmandu valley PD cohort the PD.excel software was also used for data collection and analysis, developed by Baxter Healthcare Asia Pacific.

Continuous variables were reported as mean \pm standard deviation (SD) if normally distributed, and as median and interquartile range (IQR) if skewed. Differences between patient groups were analyzed by independent samples t-test and Mann-Whitney U test, for normally distributed and for non-parametric data, as appropriate. Technique survival and patient survival data was assessed by Kaplan-Meier analysis and log rank test. Categorical variables were expressed as percentage and groups were compared by Chi-square tests. All tests were two-tailed and p-values of < 0.05 were considered significant.

4. Results

4.1. PD practice in Nepal

4.1.1. Demographics and educational background of Nepalese PD patients

According to the database of the Government of Nepal, Health Services Department, by June 2018, there were 4398 prevalent dialysis patients under the government's free-dialysis scheme. Among them, 177 patients were on CAPD (4.0%).

Demographic data of 236 PD patients from multiple centers are shown below. As per age distribution, the majority of patients are in the 40-65 years range (see Figure 1.). According to gender distribution, male patient number is more than double than that of female (68% vs 32%) (see Figure 2.). Among PD patients more than half of them had diabetes mellitus (53%), thus it is proposed that they had diabetes as primary kidney disease. Other main causes of renal failure were hypertension (14%) and chronic glomerulonephritis (13%) (see Figure 3.). Educational background of patients is variable, but remarkably, 21% of patients although illiterate, had no problem in learning and doing CAPD (see Figure 4.) (Paudel K et al. 2018). During PD training the nurses taught the patient basic writing skills, eg. numbers to be able to record their treatment.

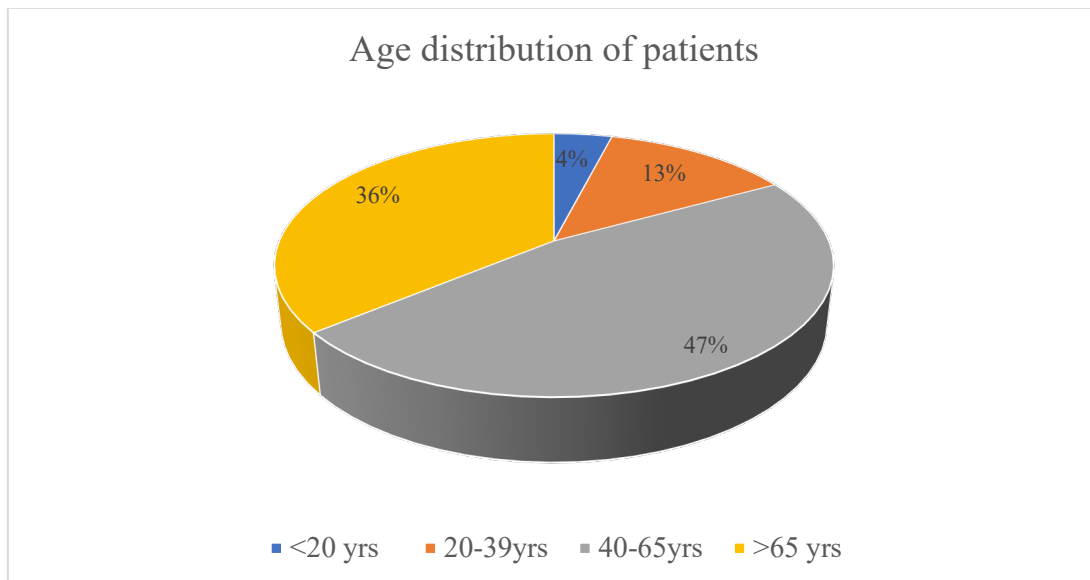


Figure 1. Age distribution of PD patients

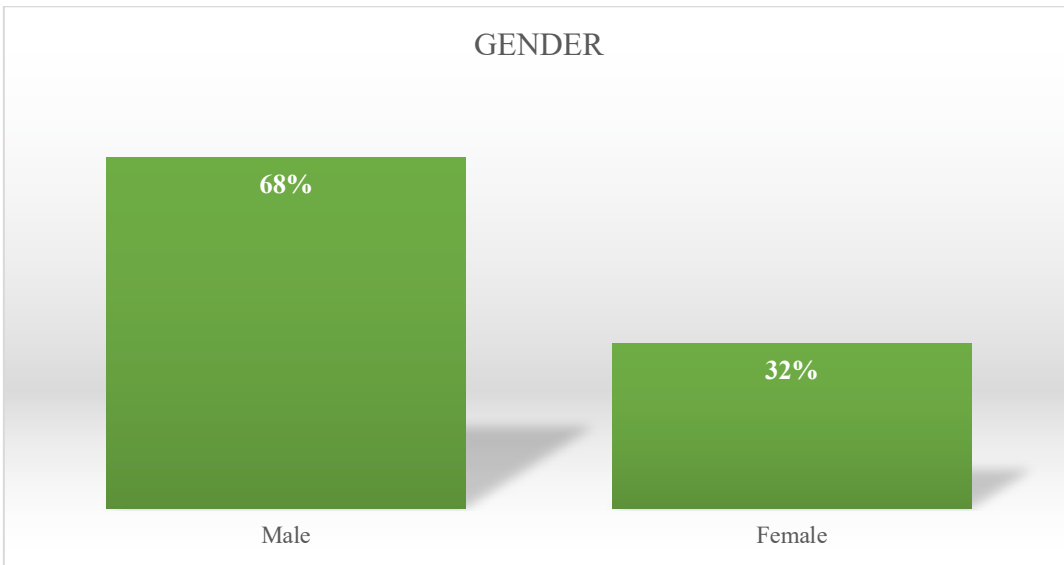


Figure 2. Gender distribution of PD patients

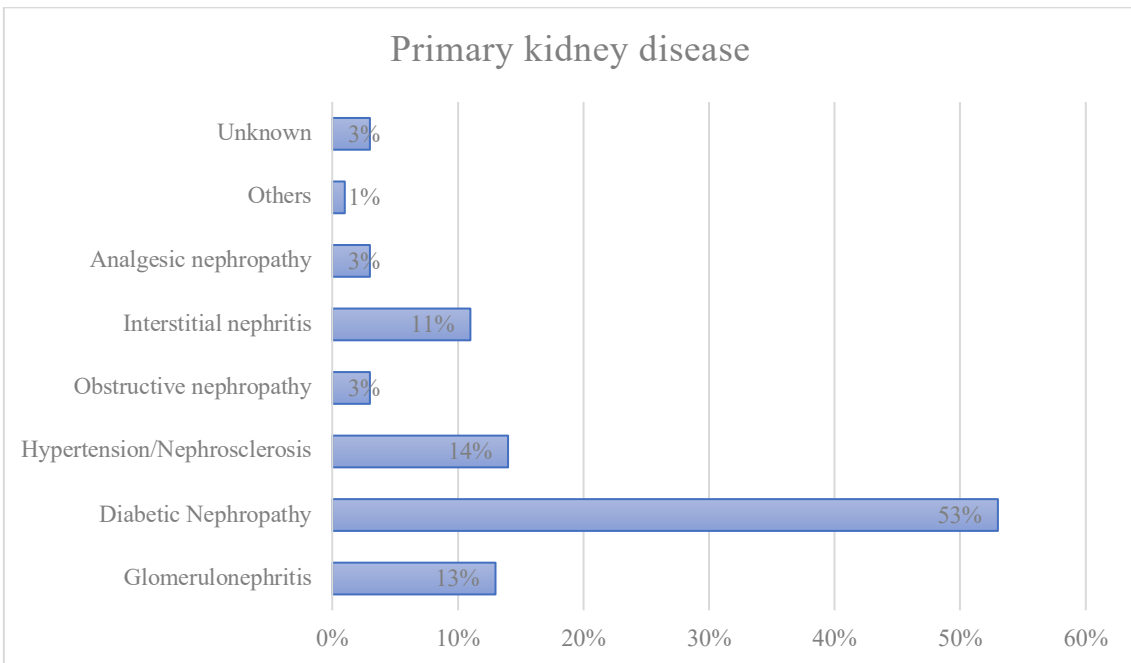


Figure 3. Primary kidney disease distribution among the PD patient population

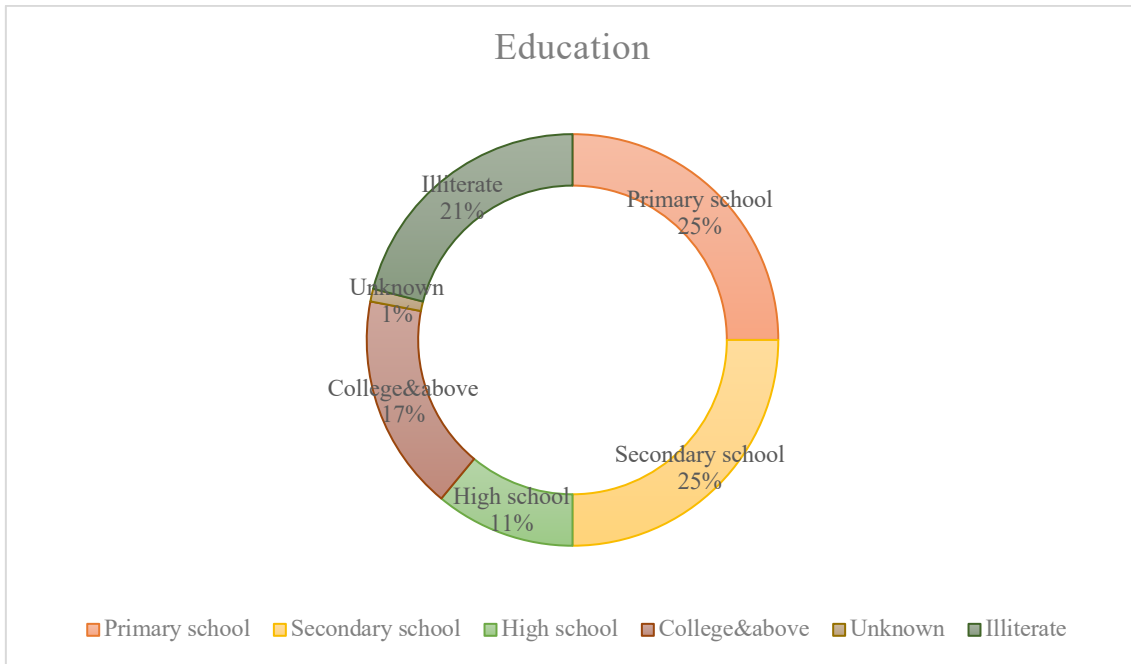


Figure 4. Educational background of PD patients

4.1.2. Catheter types and methods of implantation in Nepal

For successful PD, catheter is essential, the lifeline of the patient. Worldwide and in Nepal as well, the Tenckhoff, double cuffed, silicon catheters are used. These catheters have various types, eg. straight or swan-neck external part, straight or curled internal part. As for insertion, percutaneous blind method, open surgical insertion or laparoscopic insertion are the three main methods used (Paudel K. 2020). For percutaneous insertion the straight catheter and for surgical insertion the swan-neck catheter is used. The internal part can be straight or curled, depending on availability. There are 10 CAPD centers in Nepal and only 3 centers practice percutaneous insertion by nephrologist. The other 7 centers use open method by surgeon or urologist.

In Nepal, majority of patients presenting to nephrologists are in the late stages of ESKD with uremic symptoms, thus most patients will start HD via a double lumen catheter. After few sessions of HD a Tenckhoff catheter is placed and HD is continued until complete heal of catheter (2 weeks). Only very minimal number of patients will be suitable for early start CAPD or preemptive catheter insertion. Besides, for early start CAPD there is a need for 24 hours nurse backup, which is often missing at the sites.

The method for percutaneous insertion is done by the Seldinger method, with local anaesthesia. It is done in operation theater for sterile conditions. The patient will have prior bowel preparation with laxatives to reduce the chances of bowel injury, since this is a blind method. After proper cleaning and draping, local anaesthesia applied, incision below umbilicus in midline is done, blunt dissection done upto the rectus muscle and linea alba. A needle inserted upto the peritoneum and normal saline instilled. If saline has free flow, we know we are inside the peritoneum. A guidewire is inserted through the needle and the needle is withdrawn. Through the guidewire a dilator and peel-away sheath inserted and introduced towards the pelvis. Then the dilator is withdrawn, the PD catheter is inserted via the peel-away sheath and the sheath is removed. The catheter function is then tested with normal saline or PD solution. If good flow obtained, then the subcutaneous tunnel and exit site is created.

For the surgical method, there are two options. Simple open method, in which a mini laparotomy is done and through a small incision the PD catheter is introduced to the pelvis via a forcep. This is a blind method too, but with the surgeon's finger adhesions can be detected and location secured. The other method is with laparoscopy in which proper visualization possible and the catheter can be tied with a stitch to the pelvis.

Advantages of percutaneous method is that patient does not need general anesthesia, can be scheduled early and easily as the nephrologist's time allows. It is noted worldwide, that centers where the nephrologist is able to perform insertion (usually via the percutaneous method), have higher uptake in PD patients, but there are wide variations between centers (Asif et al. 2005, Li et al. 2009). Disadvantage is that there is chance for catheter flow problems, omental wrapping or catheter migration, when still help from surgeon is needed.

Advantages of laparoscopic insertion are: less complications in means of leaks and flow problems, higher success rate in catheter function. Disadvantages are: requires general anesthesia and scheduling, more costly compared to the other methods (Ozener et al. 2001, Asif A. 2004, Sampathkumar et al. 2008).

Data from Pokhara, Nepal on PD catheter insertions and complications

According to the experience of the author: during the period of 2014-2021 the number of inserted peritoneal catheters and their outcomes are summarized as follows:

Number of catheters inserted: 88

Percutaneous: 83 (94.3%) (all inserted by the author)

Primary surgical: 5 (5.7%)(indications for surgical: obesity, previous surgery)

Started as percutaneous and converted to surgical: 6 (7.2%) (indications: unable to reach peritoneum with percutaneous needle, outflow failure immediately after insertion)

Percutaneously inserted, but later on required surgical procedure due to catheter malfunction: 2 (2.4%) (indications: omental wrap, catheter migration)

As the experience grew, the method of patient selection also changed. Recently, the following method is adopted: before procedure, an ultrasound screen is done to look for adhesions and the size of the omentum. If omentum is upto umbilicus, we expect a very uneventful insertion. If omentum is upto pelvis, we expect omental wrap problems and we rather plan for laparoscopic insertion with omentopexy.

Directly started PD 5 (5.7%) patients (preemptive catheter insertion or non-urgent start), 4 (4.5%) patients switched from chronic HD (upto 5 years on HD, reasons for switching: loss of vascular access, convenience of staying at home), the other 79 (89.8%) patients had a short bridge period of HD before starting PD, usually 2-4 weeks.

Catheter related complications:

1. Catheter malfunction within 1 month of insertion: outflow failure in 9 (10.2%) patients, probable due to omental wrap or catheter migration. In 5 (5.7%) patients the outflow problem resolved on its own with regular heparin flushes and laxatives. The maximum duration of flow problem was 3-4 weeks after insertion. Another 2 (2.3%) patients underwent surgical revision with laparoscopy and catheter repositioning/ omentopexy for the outflow failure. However, 2 (2.3%) patients were not able to continue PD as the outflow failure did not resolve on its own and there was no timely surgical backup available and later patient refused/ was not able to afford further surgeries.

2. Leaks. Pericatheter leak was observed in 5 (5.6%) patients. PD was discontinued for 2 weeks and the leak healed. However, in 2 patients the leak recurred and then PD was on hold for longer period (1-2 months), after which it healed again.
3. External cuff extrusion: in 2 (2.3%) patients the external cuff extruded and caused exit site infection. The cuff was shaved and exit site infection resolved in both patients and were able to continue PD without further complications.
4. One patient developed granulosis over both the internal and external cuff causing tissue growth and purulent discharge. The patient continued PD for another 2-3 month until AV fistula was ready, during which time had ongoing exit site infection, but did not have peritonitis. Once AV fistula was matured, the PD catheter was removed which solved the problem.

4.1.3. Transport status and number of exchanges in Nepal

PET test data were collected from 53 patients and were analysed. Their transport status was as follows: low transporter 3.7%, low average 35.8%, high average 49.0%, high transporter 11.3%. The distribution is also shown in Figure 5.

Based on the data from 236 PD patients between 2012-16, majority of patients (89.8%) could be managed with three bags per day. Some patients, especially those who are starting CAPD with significant residual renal function, can still be managed with once daily exchanges (2.1%) or twice daily exchanges (5.1%). A small number of patients required four exchanges per day (3.0%). The distribution of number of exchanges are shown in Table 2. All patients use CAPD, there are no patients on APD in Nepal. All patients use 2 liter bags for exchange.

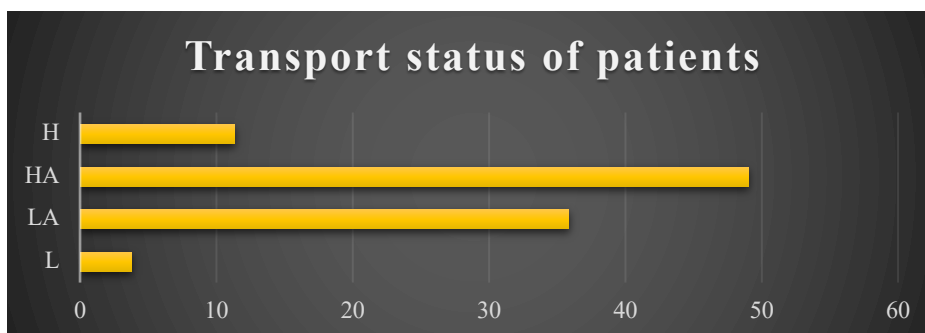


Figure 5. Transport status of patients (based on available PET test results from 53 patients)

Table 2. Number of exchanges used by the PD patients (based on 236 PD patients' data from 2012-2016 in Nepal)

Number of exchanges	% of patients
One bag/day	2.1%
Two bags/day	5.1%
Three bags/day	89.8%
Four bags/day	3.0%

4.1.4. Infectious complications of PD in Nepal

Based on available data, the peritonitis rate was 1:41 patient-months in 2015 in the Kathmandu valley area. In Pokhara, the peritonitis rate was 1:19 in the first year of starting the CAPD program, later on it dropped to 1:29. Microbiological data on peritonitis is not available.

Exit site infection is rare. There are no proper documentations and thus we cannot calculate the rate, but the clinical coordinator was able to recall about 6-8 exit site infections in the Kathmandu valley during the five-year period in 2012-2016.

4.1.5. Outcomes of PD in Nepal

The one-year survival rate was 87% and the one-year technique survival rate was 81% between January 2012 to December 2015. Major reason for dropout was death in 50%, 13% of patients had renal transplants and 25% were transferred to hemodialysis, the rest were lost to follow up or missing data. Cause of death was cardiovascular disease

(CVD) in 15%, other medical reason 35%, peritonitis 12%, other infection 12%, dialysis withdrawal 4% and unknown cause 22%.

4.1.6. Indications and motivating factors to choose PD in Nepal

We have evaluated our Nepalese PD patient population to find answer to the question as what are the main indications and motivating factors for choosing PD.

In two centers in Pokhara, a total of 56 PD patients were interviewed about how and why they did start on PD. They were able to select multiple answers from the questionnaire. The main indications and motivating factors revealed were as follows:

1. Better quality of life (50/56) – 89.3%
2. Long distance from home (30/56) – 53.5 %
3. Unavailability of HD seats (16/56) – 28.5%
4. Intolerance to HD (heart disease, low blood pressure, weakness) (10/56) –17.8%
5. Lack of vascular access to HD (failed arteriovenous fistula (AVF) or unable to create AVF) (5/56) – 8.9%
6. Frequent shortness of breath and fluid overload on HD (3/56) – 5.3%

4.2. Comparison of PD vs HD patient characteristics in Pokhara, Nepal

In 2019, we have conducted a cross-sectional study on hemodialysis patients in Pokhara. From the six hemodialysis centers all prevalent patients` data was collected after informed consent. Peritoneal dialysis patients` data was collected from the personal register of the author between 2015 and 2021, at Pokhara.

Total 219 hemodialysis patients` data were collected. Among them, 129 patients were located in Pokhara city, while 90 patients were from the surrounding districts. Diabetes was present in 46 (21.0%) patients and 21 (9.5%) patients had family history of kidney disease. Working abroad: among the 219 patients, 57 gave history of working abroad. Among this subgroup, the ratio of diabetic patients is similar (11 patients, 19.2%) $p > 0.5$, no significant difference. Among them 47 worked in Middle-East countries (Saudi

Arabia, Qatar, Dubai, Kuwait, etc.) and 10 worked in other countries (India, Malaysia, Japan, etc.).

In Table 3. listed are demographic, geographic and etiological data of this hemodialysis cohort and it is compared with data from the PD cohort of Pokhara of 88 patients. Mean age, male/female ratio, family history of kidney disease and working abroad were not significantly different in the HD and PD populations. Diabetic patients and patients from rural area were significantly more among the PD patients.

Table 3. Comparison of characteristics of PD and HD patients in Pokhara (demographic, geographic and etiological aspects)

	Peritoneal dialysis	Hemodialysis	P value
Total Patient number	88	219	
Mean age in years	45.1 ± 16.5 (incident)	48.4 ± 15.7 (prevalent)	NS
Male:female ratio	61M:37F 1.65:1	142M:77F 1.84:1	NS
Urban vs rural	37 urban vs 51 rural	129 urban vs 90 rural	P=0.00368
Diabetes	29 patients (32.9%)	46 patients (21.0%)	P=0.0139
Family history of kidney disease	5 (5.7%)	12 (9.5%)	NS
History of working abroad	22 (25.0%)	57 (26.0%)	NS

4.3. Quality of life of dialysis patients in Nepal and its relation to fluid balance

In this part of our study, we compared quality of life and fluid balance among PD patients and HD patients in Nepal. For this comparison we have interviewed 20 prevalent PD patients and 50 HD patients in one center in Pokhara. Table 4. shows the basic characteristics of the two cohorts. For evaluating Health Related Quality of Life (QoL), we used the 36-Item Short Form Health Survey questionnaire (SF-36), and analysed the results based on domains. Table 5. shows the comparison of QoL between PD and HD patients. Physical functioning, physical role, bodily pain and social functioning domains showed significantly higher scores in the PD patient cohort. None of the SF-36 QoL domain performed worse in the PD group compared to the HD group.

Table 4. Characteristics of PD and HD patient cohorts in Pokhara, Nepal

	Peritoneal Dialysis	Hemodialysis	p-value
Number of patients	20	50	
Age (years)	49.1 ± 14.6	44.3 ± 12.3	NS
Male %	12 (60%)	34 (68%)	NS
Religion (% hindu)	12 (60%)	37 (74%)	NS
Marital status (% married)	19 (95%)	48 (96%)	NS
Percentage of anuric patients	5 (25%)	17 (34%)	NS
Daily UF (ml)	880 ± 432	834 ± 664	NS
Duration of dialysis (months)	15.8 ± 13.0	25.9 ± 21.3	0.0525

Note: daily UF calculated in HD patient as weekly UF divided by 7 days

Table 5. QoL results based on domains and comparison between hemodialysis and peritoneal dialysis cohorts

Domains	Peritoneal Dialysis		Hemodialysis		p-value
	mean	SD	mean	SD	
Physical functioning (PF)	68.25	36.21	49.62	14.51	0.0029
Role – Physical (RP)	76.25	42.82	53.82	10.77	0.0009
Bodily Pain (BP)	89.50	19.47	72.18	9.18	<0.0001
General Health (GH)	61.50	26.45	63.26	13.05	NS
Vitality (VT)	65.00	27.65	65.84	9.14	NS

Social Functioning (SF)	76.88	26.18	64.41	13.61	0.0011
Role – Emotional (RE)	80.00	40.34	74.37	8.95	NS
Mental Health (MH)	68.40	22.60	73.33	12.32	NS

In Nepal, majority of patients undergo only twice weekly HD (instead of the generally accepted thrice weekly HD in developed countries), which can give rise to fluid overload especially in patients with anuria. In order to determine the effect of fluid overload on QoL, we have conducted a study in HD patients in Pokhara. Total 50 HD patients were interviewed after informed consent, from two centers in Pokhara. In these two centers there were total 85 patients and we interviewed all who were reachable and gave consent. Among them 35 patients either refused to answer the questionnaire or was not reachable during the study period. Health related QoL was assessed by the SF-36 questionnaire. Also, additional data was collected from patient records: average interdialytic weight gain (IDWG) in past one month, 24-hour urine output, and estimated overhydration (eOH), calculated as the difference of predialysis weight and estimated dry weight, in average of the past one month.

Based on these specific patient data, we divided the patients into two groups, low IDWG (<1 kg/day) and high IDWG (\geq 1 kg/day). We have compared the SF-36 domain results between the two groups. Also, based on urine output we identified two groups: anuric and non-anuric (anuric definition: urine output is <100 ml/day) ; based on estimated overhydration we identified two groups: eOH <5 liters and \geq 5 liters. We compared SF-36 data between these groups. Paired t-tests were used to calculate differences between groups. Results are shown in Tables 6., 7., 8. and 9. Patients with low IDWG had higher scores, especially in the physical functioning, physical role and emotional role domains.

Table 6. Characteristics of study population

	<1 kg/day IDWG	≥1 kg/day IDWG
Number of patients	30	20
Age	45.0±15.42	44.95±11.21
Male %	66.7	70
Religion (% hindu)	80	65
Marital status(% married)	96.67	95
Urine output (% anuric)	16.7	60
IDd (mean±SD)	4.68± 2.16	3.13±0.54
Duration of HD (months)	22.7±21.3	30.0±21.2
Estimated OH (mean±SD)	4.75±2.09	8.46±3.39
IDWG/d (kg)	0.68±0.23	1.23±0.19

Table 7. QoL results based on domains and comparison between low and high IDWG groups

Domains	IDWG < 1kg/day		IDWG ≥1kg/day		p-value
	mean	SD	mean	SD	
Physical functioning (PF)	54.38	14.57	42.48	14.46	0.044
Role – Physical (RP)	74.25	6.75	23.18	14.8	0.0002
Bodily Pain (BP)	72.16	8.83	72.22	9.54	NS
General Health (GH)	64.70	12.4	61.11	13.7	NS
Vitality (VT)	66.48	9.88	64.9	8.4	NS
Social Functioning (SF)	64.77	12.56	63.89	14.67	NS
Role – Emotional (RE)	78.89	8.45	67.59	9.45	0.006
Mental Health (MH)	72.73	13.89	74.25	10.75	NS

Table 8. QoL results based on domains and comparison between anuric and non-anuric groups

Domains	Anuric		Non-anuric		p-value
	mean	SD	mean	SD	
Physical functioning (PF)	44.19	16.65	53.38	13.03	0.038
Role – Physical (RP)	26.79	14.39	21.19	9.90	NS
Bodily Pain (BP)	72.06	0	72.28	3.84	NS
General Health (GH)	58.23	8.55	66.69	14.29	0.015
Vitality (VT)	58.45	12.73	71.19	11.3	0.0004
Social Functioning (SF)	56.62	15.59	70.11	0.76	0.0002
Role – Emotional (RE)	71.57	4.72	75.36	2.25	NS
Mental Health (MH)	72.64	13.69	73.96	8.74	NS

Table 9. QoL results based on domains and comparison between low eOH and high eOH groups

Domains	eOH < 5 L		eOH ≥ 5 L		p-value
	mean	SD	mean	SD	
Physical functioning (PF)	53.90	16.18	46.32	14.94	0.044
Role – Physical (RP)	23.75	8.75	24.67	14.15	NS
Bodily Pain (BP)	72.50	3.53	71.00	2.83	NS
General Health (GH)	62.33	11.76	64.10	13.60	NS
Vitality (VT)	63.33	12.24	68.00	10.55	NS
Social Functioning (SF)	65.00	9.43	64.00	5.65	NS
Role – Emotional (RE)	75.00	6.67	73.33	2.52	NS
Mental Health (MH)	71.00	12.75	74.08	9.55	NS

4.4. Comparison of data from Nepal and other countries and regions in the world

4.4.1. Comparing data from Nepal with other developed countries and regions

Characteristics of RRT population in Nepal, Hungary, Europe and USA

We aim to compare basic data about RRT population from Nepal with data from Hungary, Europe and USA. For data source we used the ERA-EDTA registry report from 2019, USRDS Annual Data from 2020 and for Hungarian data we used a publication by Kulcsar Imre et al. from 2019. (ERA-EDTA 2019, USRDS 2020, Kulcsar et al. 2019.) Data are shown in Table 10. In a study from Nepal which retrospectively analysed data of 10 years of HD patients in Kathmandu, Nepal, found, that 70% of patients were between the age of 20-60 years with mean age of 46.7 ± 16.7 years (Hada et al. 2009). In Hungary, among the dialysed patients, 50.7% are above the age of 65 years (in 2017) (Kulcsar et al. 2019). Using the student's t-test and taking into account the mean age of RRT population as 46.7 ± 16.7 years in Nepal and 63.4 ± 14.2 years in Hungary, having an RRT population of 4398 patients in Nepal and 6539 patient in Hungary, the p value is <0.0001 , meaning that the RRT population mean age is statistically different in Nepal compared to Hungary. We can say, that the RRT patients in Nepal are younger than those in Hungary.

The male: female ratio of our study group was 68 vs 32 % (2.1:1). Similarly, in the above study it was 1.8:1 (Hada et al. 2009). This male predominance is seen in the United States Renal Data System (USRDS) Annual Data Report as well, in 2017, the incidence of reported end stage renal disease (ESRD) was 450,8 per million population for male and 314,2 per million population for female (1.4:1) (USRDS, 2019). In the ERA-EDTA registry, among the prevalent patients on RRT in 2017, the gender distribution was 60% men and 40% women (1.5:1) (ERA-EDTA, 2018). Although in all countries male predominance is seen among RRT population, in Nepal, the proportion of male among the RRT patients is significantly higher, than in the other developed countries ($p < 0.007$).

Table 10. Comparison of the population on RRT - Europe, Hungary and USA versus Nepal

	Nepal	Europe	Hungary	USA
Mean age (±SD) in years (incident data)	N/A	65.4 (male) 64.9 (female)	62.8 (2017)	55.0 ± 16
Mean age (±SD) in years (prevalent data)	46.7 ± 16.7	N/A	61.8 (2017) 63.4 ± 14.2	N/A
Male:Female ratio	2.1:1 (68%) 1.8:1 (64.3%)	1.5:1 (60%)	N/A	1.4:1 (58.3%)
Primary kidney disease	DM 53% HTN 14% GN 13% Ukn 3%	DM 16% HTN 10% GN 21% Ukn 18%	DM 26% HTN 23% GN 12% Ukn 7%	N/A
HD:PD ratio	96% v. 4%	92% v. 8%	87% v. 13%	89% v. 11%
Number of exchanges per day used by majority of CAPD patients	3	4	4	4

Note: DM=diabetes mellitus and diabetic kidney disease, HTN=hypertensive nephropathy, GN=glomerulonephritis, Ukn=Unknown

References: ERA-EDTA registry report 2019, USRDS Annual Data 2020, Kulcsar et al. 2019, Hada et al. 2009.

PD outcome data in Nepal versus in South Korea and Sweden

For comparison we used data from South Korea and Sweden (Chung et al. 2005). The one-year survival rates and causes of death are shown in Table 11. In Nepal, in the “other causes of death” category we included other medical reasons and dialysis withdrawal.

Table 11. Survival and causes of death in Nepal, South Korea and Sweden

	Nepal	Korea	Sweden
Survival rate (one-year)	87%	91.9%	94.9%
Cause of death	CVD 15% Infection 24% Other 39% Unknown 22%	CVD 29% Infection 38% Other 4% Unknown 29%	CVD 41% Infection 23% Other 13% Unknown 23%

Note: CVD = cardiovascular disease

Comparing motivating factors for choosing PD

While in the developed world, patient comfort and right to choose, survival benefit and other ethical issues play a part and the financial aspects are less important; in the low-resource setting capacity, availability and affordability play the major role (Shrestha BM. 2018, Nanayakkara et al. 2017).

If we compare this to other high-income countries, we find, that in Taiwan the main factors influencing RRT choice were age, education level and activities of daily living, however not the nephrologist recommendation or travel time to clinics (Chiang et al. 2016). While in Switzerland, it was found, that public vs private center made a difference, private centers preferring less PD, individual opinions of the staff (nephrologist and nurses) – bias, influenced the choice (Wauters et al. 2004). Also, travel distance to the unit, socio-familial factors such as presence of housing facilities or a spouse, and more individual factors such as education, profession, age, and co-morbidities played role (Wuerth et al. 2002).

4.4.2. Comparing data from Nepal with the South Asian region

In our comparison we include the following 5 countries: Nepal, Sri Lanka, Pakistan, India and Bangladesh. In Table 12. the latest population data from 2020 is shown, along with country geographic area. India is the most populous country, followed by Pakistan and Bangladesh. These three countries make up of 22% of the whole world's population (2020). All countries belong to the lower middle-income category by the

World Bank, however based on GNI and % of population living below the poverty line, among these countries, Sri Lanka is the economically strongerst country.

The CKD and dialysis data of these countries are shown in Table 13. The prevalence rate for CKD is highest in Nepal, according to the data given by V. Jha in a summary about the state of nephrology in South Asia (Jha V et al. 2019). However, this data includes all stages of CKD, not only ESRD. Pakistan and Bangladesh have the lowest number of nephrologists per million population (0.7/million) and Nepal has the highest number among these countries (2.1/million) (Iqbal S et al. 2018). In contrast, in Hungary in 2017 there were 189 nephrologists involved in dialysis services, which is 18.9/million and it does not count the number of nephrologists who do not work in dialysis (Kulcsar et al. 2019). In the USA in 2013 there were 9007 nephrologists, making it 28.5/million population (Center for Disease Control and Prevention. Chronic Kidney Disease Surveillance System – United States. Website: <https://nccd.cdc.gov/ckd> assessed on 14th June 2021.)

Access to dialysis is limited in all of the five countries, making it average less than 20-25% of the population. Pakistan has the lowest number of patients on dialysis compared to population (90 patients/million population) and Sri Lanka has the highest number (256 patients/million population). PD utilization is highest in Sri Lanka with 7% of the total dialysis population and lowest in Pakistan with 0.4%.

Table 12. Demographic, geographic, economic and health indicators of South Asian countries (Nepal, Sri Lanka, Pakistan, India and Bangladesh)

	Nepal	Sri Lanka	Pakistan	India	Bangladesh
Population (2020)	29.1 million	21.4 million	220.9 million	1380 million	164.7 million
Total area	147,180 km ²	65,610 km ²	796,100 km ²	3,287,000 km ²	148,460 km ²
Income category (World Bank, 2020)	Lower middle income	Lower middle income	Lower middle income	Lower middle income	Lower middle income
GNI per capita (2019)	1090 USD	4020 USD	1410 USD	2120 USD	1940 USD

% population living below national poverty line (2018)	25.2%	4.1%	29.5%	22.0 %	20.5 %
Life expectancy (2018)	66.2 years	75.7 years	66.0 years	69.4 years	72.3 years
Literacy (2018-2019)	64.7%	92.6%	58.7%	73.2 %	73.9 %

Table 13. Indicators of CKD and dialysis in the South Asian countries

	Nepal	Sri Lanka	Pakistan	India	Bangladesh
Incidence number of CKD	106,355	40,996	331,921	3,349,963	418,831
Prevalence rate of CKD (per 100,000 population)	4843	2821	2409	3351	3609
Number of nephrologists	60	30	151	1639	123
Nephrologist/million population	2.1	1.4	0.7	1.2	0.75
Proportion ESKD of patients who have access to dialysis	20%	2-12%	5-15%	5-100%	25%
Number of dialysis patients (chronic)	4398	5482	20 000	175,000	18000
Number of chronic dialysis patients/million population	151	256	90	127	109
Number of PD patients	177 (4%)	365 (7%)	76 (0.4%)	5000 (3%)	500 (3%)

4.5. Challenges and opportunities to strengthen PD programs in the South Asian region

In this chapter the author would like to share personal experiences on establishing a new PD program in Nepal and describe about overcoming obstacles (Paudel et al. 2021).

4.5.1. Possible challenges for a CAPD program

The major issues limiting the development and growth of PD programs include problems with staff training and retention, patient concerns and issues, maintenance of a reliable supply of fluids, and adequate financial support (Abraham et al. 2008, Mehrotra et al. 2018, Liu et al. 2015, Lameire et al. 2010, Correa-Rotter et al. 2001) (Table 14.). Also see Table 1. for examples of the same. Source: personal experience and opinion.

Table 14. The most frequently encountered challenges while starting or strengthening a PD program in a developing country

Patient factors	lack of education/illiteracy home environment fears/myths
Cost	high out-of-pocket expenses lack of national health insurance government supports HD but not PD
Fluid supply	lack of accessible and sustained supply transportation, taxes, delays
Doctor/nephrologist/physician	lack of trust lack of PD education myths and skepticism lack of time lack of incentives
Nurse/technician/coordinator	Lack of access to PD education high staff turnover

Despite the need to have a guideline or recommendation on setting up a new PD program, there is scarce literature on how to do it (Abraham et al. 1999, Finkelstein et al. 2009, Finkelstein et al. 2011).

4.5.2. Key points that need to be addressed while establishing a PD program

While trying to establish a PD program, there are certain key points that need to be addressed and none should be missed out (see Table 15.). The first crucial point is the manpower, which includes three main areas, first is the nephrologist or physician, second is the nurses or clinical coordinators and third is the surgeon. All three should be available to have a sustained PD program. All three should have adequate education on PD.

The second key point is the institutional and health care system factors. A stable fluid supply has to be established, for which an importer company or manufacturing company is necessary. The second is the financial support, since many developing countries have no stable health insurance system and patients have large out-of-pocket expenses. There should be either reimbursement system from the government or other health insurance policies.

Table 15. Key points in establishing a PD program

Skilled manpower	Institutional and health care system factors
A. Nephrologist/physician	D. Fluid supply
B. Nurse/Clinical coordinator	E. Financial support (Insurance or reimbursement from government)
C. Surgeon	

A. Nephrologist/physician

The nephrologist is the first most important key factor. When we try to start up or expand a CAPD program, we face the following challenge: since there are less CAPD

patients, doctors have minimal experience in managing CAPD patients, if they have ever seen any. Thus they will not feel comfortable with this modality.

Patients trust the doctor first and opting for PD there is a huge need to trust in the doctor, especially when the treatment is new and not much known to people. Only the doctor will be able to convince patients to start on PD. Thus, there is no start to PD program unless the doctor believes and trusts in this modality.

In Nepal PD programs were started by nephrologists who have spent some time abroad in a large PD center. In 2013 the author had a fellowship focusing on PD, sponsored by the International Society of Nephrology and spent one year at the Royal London Hospital in UK, at one of the largest PD units of Europe. This experience enabled her to be confident in starting PD and managing PD patients on her own.

B. Nurse/Clinical coordinator

Doctors can convince patients, insert catheters, manage prescriptions and monitor clinical status, however doctors will never have the time to train the patients, manage supply and deal with all small details. Thus, a doctor alone will never be able to sustain a PD program and nurses are very important (Tan et al. 2003, Blake PG 2006).

Baxter Healthcare and Fresenius Medical Care (providers of PD fluid) in many developed countries provide training and support for nurses or have their own employed clinical coordinators that work closely with institutions. However these companies are not represented in many developing countries. In some countries local manufacturers are present (eg. China, India, Malaysia, Mexico, etc.), with limited resources. In most developing countries PD fluids are supplied by local importers who may not have financial capacity to provide manpower and education (Fang et al. 2014).

In Nepal, when the author started her PD program, there were no trained PD nurses in her area (there were only 2 PD nurses in the whole country). She had to train the PD nurses. She organized a 5 days workshop and involved all the 12 nurses that were working in the hemodialysis unit. Just before the workshop, the first patient got her PD catheter inserted by the percutaneous method and during the workshop there was live presentation of the technique. Right after the workshop, the nurses were able to continue practicing

what they have learned and continued training the patient. Soon more patients were enrolled in the program, about 10 patients in the first month, which helped them to deepen their knowledge. Later on, when a nurse resigned, it did not affect the program, since all were involved and any new comers learnt PD soon as well.

C. Surgeon

Surgeon is essential for any PD program for the management of catheters. Nephrologists, who are able to perform percutaneous insertions, have advantage and can handle most patient`s catheters, however sometimes these procedures can fail, and some patients will require surgically inserted catheters due to previous abdominal surgery. Catheter related complications will also require surgical backup e.g. omental wrap, repositioning, etc. (Brook et al. 2004, Ratajczak et al. 2017, Crabtree et al. 2019). Usually surgeons do not require extensive training on PD catheter insertion techniques due to the straightforward nature. There are also good online resources available for learning (Haggerty et al. 2014, Crabtree et al. 2016).

In Nepal, the author did not have a surgeon in her area who would have PD experience. She taught the surgeon personally about the catheter concept and initially they also learnt by doing it together. Luckily, only basic surgical skills are required.

D. Fluid supply

Continuous and reliable supply of PD fluid is essential for developing a sustainable PD program (Jensen et al. 2015). When a new PD program is developed in a country or region, this key point poses particular challenges. Since the import of PD fluid will be through local agents, there is a chance that they cannot invest large amounts unless a certain patient number is guaranteed, which is unlikely in a new program. Another issue with local agents is the significant mark-up in prices, especially if tax and transport need to be added (Reddy et al. 2011).

An example for the importance of stable fluid supply can be the situation that happened in Nepal in 2017. A large manufacturer, who was the sole supplier in Nepal,

closed their plant in India, without prior notice, and there was an acute shortage of PD fluid in Nepal and Sri Lanka for 3-4 months. The import had to be arranged from the Philippines, which took several months to arrive. Moreover, for a year, intermittent supply difficulties continued. Few patients coped during the acute shortage by reducing their dialysis exchanges but many were forced to convert to HD. Unfortunately, this instability of PD supply led patients and doctors to lack of confidence in this modality. It also led to difficulties restarting PD programs that were decimated by the fluid shortage.

E. Financial support

Most developing countries do not have a strong health insurance system. Most of the health care facilities are private and even in government hospitals, there are significant out-of-pocket expenses (Li et al. 2001). Dialysis is one of the most expensive medical treatments, where the expenses are life-long. Thus, only a small proportion of the population is able to afford it (Li et al. 2011). The only difference is when there is a national scheme from the government level, which reimburses or provides free dialysis. Some people might be enrolled in health insurance systems too, eg. exarmy, police, corporate associations, etc.

In Nepal, government initially provided free HD since 2013, but not CAPD. However, equality between HD and PD was achieved after successful lobbying of Health Ministries in 2014.

In some developing countries and most South-Asian countries HD is generally not expensive due to low wages for nurses and technicians and cheap consumables (Tang et al. 2020). Thus, the government has to spend more on PD, and thus the motivation to support PD is also less. In Nepal, one session of HD is reimbursed by the government with 2500 Nepali rupees (21 USD) and most patients are maintained on twice weekly HD due to cost savings and capacity deficit (Chugh et al 1995, Chugh et al 1999). Thus on average, the government need to spend 168-189 USD per month for an HD patient. For PD one bag costs 408 Nepali rupees (3.42 USD) and most patients use three bags per day amounting to 308 USD per month, which is almost the double of the cost of HD. However, this HD cost only covers for consumables and salaries (Mcgee et al. 2018). The

true costs of HD include the construction of an HD unit, the purchase of machines and water treatment, rent, the purchase of water and electricity, maintenance of the facility, and other accessory costs; if this is done, then the cost of HD is more expensive than PD (Abraham G, 2004, Tang et al. 2020). Without government support, PD is likely to remain a niche due to the high cost of fluids. Even with government support, there remains substantial financial barriers (Abraham G, 2009).

4.5.3. How to overcome the challenges and what are the models for success?

According to our experience, for training, a nephrologist specializing in PD will benefit from a period of 'fellowship' in an established PD unit. Duration may vary according to availability and experience of local expertise. At a minimum, it shall provide the nephrologist confidence to work alone and troubleshoot unexpected issues that fall outside of published guidelines. Also, resource limitations mean that creative solutions to unusual problems need to be developed locally to establish needed skills, confidence and experience.

Options for nephrologist training include International Society of Nephrology (ISN) fellowship, International Society of Peritoneal Dialysis (ISPD) fellowship, which is possible to avail for a minimum of 1-3 months upto 12 months durations. Besides local connections can also be used.

For nurse training, similar visit to a large center can be useful if feasible. If that is not possible, in-house nurse training can be organised. In Nepal when the program was started in the Western Region of Nepal, there were no other large centers in the country and sending a nurse abroad was not possible. Thus, a 5-days workshop was arranged and all HD nurses were trained on PD. In Table 16. the key topics for in-house nurse training are summarized, which were developed by the author at the nurse training workshop. Later these HD nurses rotated in training new patients and all learnt PD very well, however it is necessary to have a single lead PD nurse (Tan et al 2003, Blake PG 2006, Luongo et al. 2003). In case, if only one or two trained PD nurses are available, there is a high risk of affecting the program once that nurse leaves the job. Stanford University,

working along with the team in Sri Lanka, has developed an online platform for training PD nurses, which is available at ISN education website (Stanford, 2017).

When starting up a PD center, it is also important to have written protocols for the center. In Table 17. the list of necessary protocols are shown. This list is based on the experience of the author. These protocols also act as continued education and in case of staff turnover it provides stable quality to the program.

Table 16. Key topics for in-house nurse training (curriculum developed by the author)

Key topics for in-house nurse training
1. Predialysis education, Indications and contraindications to PD, patient counselling on PD, patient selection, advantages of PD
2. Theory basics of peritoneal membrane and difference in types of fluids
3. Exit site selection and care
4. Catheter insertion and pre-/postoperative management
5. Fluid overload signs and symptoms, its management, and prescription guide based on urine output and weight
6. Inadequate dialysis signs and symptoms, modifications in prescription
7. Signs and symptoms of peritonitis, diagnosis and management, IP medications, recording and reporting peritonitis episodes
8. Management of exit site infections
9. Management of flow problems
10. Diet in PD
11. Emergency procedures and troubleshooting
12. Other noninfectious complications
13. Recording, monitoring and patient follow-up

Table 17. List of protocols necessary while starting a PD center (based on the author`s experience)

Necessary protocols for a new PD center
<ol style="list-style-type: none"> 1. Pre- and postoperative care protocol for PD catheter insertion 2. Checklist and protocol for patient training 3. Protocol for the management of PD peritonitis 4. Protocol for the exit site care 5. Protocol for flow problem troubleshooting 6. Protocol for initial prescription and modification of it 7. Protocol for fluid overload management

This second key factor is far more difficult to establish, than the first one. For fluid supply there need to be a reliable manufacturing company and a local agent that imports. Unless the manufacturing happens inside the country. Having more than one supplier provides higher chance for stable fluid supply. If there is only one supplier, it can mean monopoly and manipulate prices and availability. With two or more suppliers there is competition and if one has shortage, the other might still be able to provide.

In Nepal, in the 1980`s the first nephrologist of the country, Dr Puskar Raj Satyal, upon his return from the UK where he learned about intermittent peritoneal dialysis, he speedily arranged with the government the manufacturing of peritoneal dialysis fluids in the government owned pharma factory, thus enabling the Nepalese people to have access to dialysis for AKI even before a single hemodialysis machine entered the country.

Besides fluid supply it is even more important to have financial support. In Table 18. the advocacy process that can help gain government support for PD costs is summarized (Qayyum A. 2020). The treatment benefits and cost-effectiveness are well documented (Teerawattananon et al. 2016, Jeloka et al. 2012).

Table 18. Advocacy process to gain government support for PD costs

Gaining government support for PD costs – advocacy process
<ol style="list-style-type: none">1. With the help of senior nephrologists, build relations with high ranked political officials2. For any local nephrology conference or CME program, the invited senior international faculties can have a special meeting with Health Ministry officials to advocate for PD3. Prepare an information booklet or brochure on PD with focus on the benefits for patients, for health care services and cost savings for the government; provide scientific data to support your statements and hand it over to Health Ministry officials4. It will need frequent follow-up, the process might take some time, but never give up on it

5. Discussion

For the first time an epidemiological study was conducted with scientific purpose to characterize PD practices in Nepal.

In Nepal majority of patients who require RRT will be on HD, and only 4% are on CAPD. This could be explained by the small number of nephrologists in the country and also the lack of PD education among nephrologists. A large number of HD units run without nephrologist. Only a few centers run sustained PD programs, and we found, that these centers are the ones, where the nephrologist have been abroad via a fellowship program (ISPD or ISN) and had an immersive experience in a large PD center (Rope et al. 2018). Capacity deficit in HD is present all over the country, which could be a potential drive to expand PD. Nepal has the highest mountains in the world, including Mt. Everest and due to the hilly nature, lack of roads and infrastructure, a large number of patients live in remote areas, making PD the ideal choice (Hirachan et al. 2010). Comparing with the international data, in developed countries there is higher PD penetrance, based on ERA-EDTA, USRDS and the Hungarian data, among dialysed patients, 8-13% are on PD (ERA-EDTA 2018, USRDS 2019, Kulcsar et al. 2019). In some countries in the world, eg. Mexico, Hongkong, Thailand there is even higher PD penetrance with PD first policy (Kwong et al. 2015, Treviño-Becerra et al. 2002, Wilkie M. 2018). Based on these findings, there is a need to develop and further disseminate PD in Nepal.

In our study, the three main causes for ESRD were identified as diabetes mellitus, hypertension and glomerulonephritis, which is very similar to the data from other developed countries. However, in the PD data set we found much higher prevalence of diabetes mellitus among the PD patients (53%). This does not represent the RRT population, rather it is a selection bias, since vascular access may be more difficult to create in diabetic patients, and are forced to choose PD due to lack of vascular access.

In our dataset, the percutaneous insertions had a high success rate with 90% functioning on first attempt. Based on own results, there was a low rate of complications. Primary surgical insertion was indicated in very few patients, and only 2.4% of cases required surgical intervention after percutaneous insertion. Catheter related complications lead to drop out from PD in only 3.4% of patients. These results are excellent even in the

view of international data (Wright et al. 1999). In contrast to the high number of percutaneous insertions done by the author, in Nepal only 3 out of 10 PD centers use this method. Since in Nepal the number of nephrologists is very low, no doubt, that their workload is high. Since performing the percutaneous insertion personally requires time and high commitment to the technique, it is not a surprise, that only very few centers use this technique.

Most patients in our PD cohort in Pokhara had a short period of bridging with HD, since they had late presentation and only 5 patients (5.7%) were suitable for non-urgent start. In Nepal, there is no general practitioner system, and doctors are found only in bigger cities. Most people go to health care facilities once they are very unwell, and minority of people will do regular health checkups (especially when nothing is for free and health checkup is costly). Thus, especially for ESRD, late presentation or `crash-landing` is very common. Even in countries, where there is a strong health care system with national insurance, late presentations are high – about 20-50%, depending on the definition of late presentation (Baer et al. 2010, Roderick et al. 2002). To avoid late presentation, predialysis care would provide solution, however in Nepal due to the insufficient basic health care and low number of nephrologists, it has significant difficulties. This is also an obstacle for the internationally recognized “PD first” initiative, meaning that the ESRD patients should be advised to choose PD as first modality in order to preserve residual renal function (Chaudhary et al. 2011, Xiaoqing et al 2014).

In Nepal most PD patients have a prescription containing three 2 liter exchanges per day. This is in contrast to the recommendation of four exchanges per day in developed countries (Abraham et al. 2003). This prescription has two main reasons. First is cost saving. Second is, people in the Asian regions are usually smaller eg. lower height and weight compared to Caucasian populations and they can still achieve very good clearance and quality of life with three exchanges (Jeloka et al. 2012).

According to PET test results, the transport status distribution in our study population showed the highest number of low average and high average transporters. Since the description of peritoneal equilibrium test by Twardowski et al. in 1987, this test is widely used to determine about exchange times and numbers for PD patients (Twardowski et al. 1987). High transporters usually need more frequent exchanges, while

average and low transporters will have adequate ultrafiltrate with 3-4 times exchanges per day.

Peritonitis rate data is lacking from most centers in Nepal, we have only data from Kathmandu and Pokhara from two time points. Due to lack of manpower and lack of electronic patients records, these data are not adequately collected and calculated in most centers. According to the ISPD recommendation, the peritonitis rate should be monitored by every PD center at least once yearly. The peritonitis rate should be not more than 0.5 episode per year at risk (Li et al. 2016). This is one of our future goals in Nepal, to establish a PD register and store patient data electronically in each PD center.

In our Nepalese PD patient population, the one-year survival rate was comparable to the Swedish and South-Korean data. This is surprising, given the economical, social and infrastructure differences of these countries. Overall, comparing the Nepalese data to other countries in the world, we find that our data stands in comparable state. These data support our experience, that although illiteracy is high among PD patients in Nepal, but with adequate training they are still able to sustain and safely perform PD in their home on the long run. This is also supported by the data from the Kathmandu region.

Comparing HD and PD patients in Pokhara, PD patients are slightly younger. This could be explained by the fact, that young patients are best candidates for PD as they will be able to do their treatment themselves and they are fast learners, so it is a selection bias. It was shown that in the PD group there was higher ratio of rural population. We see from our experience, that a high percentage of patients are forced to move from their rural home to the city and rent a room to be able to undergo regular HD. Especially because in Nepal the road infrastructure is very poor in rural areas, most roads outside the highway are not paved, in rainy season there are landslides and road blocks, which makes it fairly difficult to travel. In these roads only certain buses or jeeps are able to move, making it also a costly and often long journey. Even for PD patients it is often challenging to make it to the hospital once in a month for the monthly supply of PD fluids. These facts support our study's results on the motivating factors for choosing PD, being slightly different from other developed countries' PD choice motivators. One of the most important points being the insufficient HD capacity and distance of home to HD center. Nepal having poor road infrastructure also supports the advantages of PD choice. All these facts emphasize

the importance of disseminating PD practice in Nepal.

One of the main factors we keep in mind while choosing PD is the better quality of life, both in Nepal and in other parts of the world. Our study confirmed the superior health related QoL in PD patients compared to HD patients, especially in physical domains. Fluid balance is an important factor in the care of our dialysis patients, that can affect quality of life (Sapkota et al. 2013, Shrestha et al. 2008). PD patients usually have much less fluid overload. The reason behind is most probably the fact, that PD removes fluid every day continuously, thus it is easier to achieve dry weight with a proper prescription, then with the twice weekly hemodialysis. Due to non-compliance and capacity deficit in HD system, many HD patients never achieve dry weight. In the study evaluating QoL of HD patients based on fluid balance, our hypothesis was, that fluid overload can affect quality of life in a negative way. We have found some evidence for it, in certain domains of the QoL. Interestingly, those patients who were more overhydrated and with higher interdialytic weight gains were actually the ones who were more frequently dialysed. So, it may be that not the less frequent dialysis, but the non-compliance with diet along with anuria, that predisposes to fluid overload.

As mentioned above, monitoring fluid balance in dialysis is crucial for patient management. Advanced technical methods can help these, especially bioimpedance - such as Body Composition Monitor (BCM), lung ultrasound, serum highly sensitive troponin and brain natriuretic peptide (BNP) measurements, as shown by earlier studies of the author (Paudel et al. 2015(1), Oei et al. 2016, Paudel et al. 2015(2)). Introducing these methods in Nepal is one of the author's future challenges.

In the second part of our study, we compared data from Nepal to other countries and regions in the world. In our demographic data, comparing it to other developed countries - Hungary, Europe and USA, we found that Nepalese dialysis patients are significantly younger. This can have socio-economical and cultural reasons, as well as higher prevalence of glomerulonephritis in the younger population. Since treatment is mainly out-of-pocket expense, many families are less likely to spend large amounts on elderly patients who are not expected to live long.

The male: female ratio of the Nepalese population in our datasets are higher than in any other developed countries or regions we compared. This suggests, that in Nepal the

male predominance in RRT use is stronger than that of other developed countries. This phenomenon may have several reasons in the background, especially social and cultural factors. A study conducted in the south area of Nepal found, that especially women and less-educated had larger barriers to accessing healthcare (Ashworth et al. 2019). Male are the main breadwinners of a family and we see in the Nepalese society it is more likely that a man gets treatment, then a woman, if the family has poor financial situation.

Comparing PD outcomes in Nepal to other developed countries such as South Korea and Sweden, there is a fairly good outcome reported from Kathmandu. Among the cause of death, cardiovascular disease (CVD) is less than in the other two countries, however, in Nepal CV disease might be underestimated for high chance of undiagnosed conditions.

There is a substantial difference when choosing RRT modality in a developed country compared to a low-resource setting (Wearne et al. 2017). It is because in developing countries, health care is not universally free and often self-payd. Also, because priorities are more on providing basic needs, while in developed countries, convenience and comfort are priorities, since basic needs are already fulfilled.

In the South Asian region we compared our data from Nepal to India, Pakistan, Bangladesh and Sri Lanka. Comparatively Sri Lanka might be the most advanced among these countries, based on GNI per capita in 2019, and lowest poverty rate, the number of nephrologists and access to RRT among ESKD patients is still low, in the South Asian region there is average 10-20 times less nephrologists for a given population, than in Hungary or USA. The low number of doctors have several reasons in Nepal. Medical schools only started in the late 1900`s, until 1996 there was only one medical school in whole Nepal, most medical graduates studied abroad with very limited numbers. After the millennium, more private and government medical colleges opened. Compared to Europe and USA, where most medical universities have over 200 years of history. (USA - Harvard medical school founded in 1782, England St. George medical school in 1733, Semmelweis University in Hungary 1769.)

The third part of our study was focusing on how to establish strong PD programs in low-resource settings. This section describes the experience of the author along with other South Asian authors (Paudel et al. 2021). The main focus is manpower and fluid

supply. One needs dedication to be able to develop a program on their own, for which we have seen many examples from various countries (see Table 1. about PD history and state in various developing countries). Still many nephrologists, especially young and energetic nephrologists, who undertake a fellowship in any center of excellence, wish to go to their homeland and start up PD programs, yet they do not know how to start at all. This article was written especially for them to provide encouragement and a roadmap to start (Paudel et al. 2021).

PD is beneficial for the patients and sadly there is a low intake rate in PD all over the world. It is our mission to change this.

6. Conclusion

This thesis has demonstrated an example on a PD program in Nepal, a low-resource setting area among the developing countries. We found, that demographics of the PD population are different to other developed countries especially in terms of age, gender distribution and primary renal diseases. Catheter types are same as in other places, especially the Tenckhoff catheters used, but insertion technique varies between centers based on the experience and skills of the nephrologists. In Nepal, most patients use less exchanges compared to other developed countries, namely 3 exchanges per day, which is feasible as patients have lower body mass and can achieve a fairly adequate clearance. The one-year patient survival rate is comparable to other developed countries. Peritonitis rate was higher than the recommended ISPD target, and the monitoring of peritonitis rate is also lacking. We have shown, that the indications and motivating factors to choose PD can be different from other developed countries, especially because capacity, affordability and availability plays major roles in the selection of RRT options. In Nepal the nephrologist to population ratio is very low and they are overwhelmed by the workload, thus proper documentation and monitoring might be lacking in most centers.

In this thesis we also explored the possible challenges while trying to establish a PD program in a low-resource setting. It is demonstrated, that two main areas need to be addressed, first, the manpower which needs to be trained and skilled, namely – doctors/nephrologists, nurses/technicians/coordinators, and surgeon. Another two key factors are the fluid supply that needs to be stable and reliable with good quality products and the financial support from government or insurance. The thesis provides practical advices on how to overcome these challenges, especially with tables that demonstrate these step by step.

PD is an important part of RRT programs in the world but sadly it is represented in very low numbers in most places. We need to explore all possibilities to promote this modality.

7. Summary

7.1. Summary in English

For the first time an epidemiological study was conducted with scientific purpose to characterize PD practices in Nepal. For data collection we used cohorts of PD patients from Kathmandu and Pokhara. Basic characteristics, complications, survival and outcome indicators, information on PD fluid prescription and PET test results were collected. In cohorts from Pokhara, catheter insertion outcomes, quality of life (SF-36 in both HD and PD patients) and motivating factors were evaluated with the help of questionnaires.

Second, we collected data from existing literature about the RRT and PD situation in other developed countries and regions - Hungary, Europe and USA; and in South Asian countries - India, Pakistan, Bangladesh, Sri Lanka and compared them to our data in Nepal.

In the third part of the thesis, based on experience of ourselves and other colleagues in the South Asian region, we describe the challenges that can be faced while trying to establish and expand PD programs in Nepal and other similar low-resource countries. These include manpower training and retaining (doctor, nurse, surgeon), stable fluid supply and financial support from government (reimbursement).

The most important findings were: Nepalese PD patients are younger and have larger proportion of males compared to other developed countries. Among PD patients there are more diabetic patients. Only three exchanges are the standard prescription compared to four in developed countries, still with a comparable survival rate.

Building up a PD program in a low-resource setting is challenging however, these are the populations that benefit the most out of a PD program. Dedication, confidence and competence from the leading nephrologist is most essential and overcoming these challenges is possible and desirable.

7.2. Summary in Hungarian

Először készült ilyen epidemiológiai felmérés tudományos céllal, a nepáli és a dél-ázsiai PD viszonyok jellemzésére. Adatgyűjtés és elemzés céljára a Kathmandu és Pokhara térség PD-betegeinek adatait használtuk fel. Alapvető adatokat, demográfiai adatokat, szövődményeket, kimeneteli eredményeket, katéter típusokat, az oldatsere előírásokat és a PET vizsgálat eredményeit összegeztük. Pokharában, a katéter beültetések eredményeit és szövődményeit, az egészséggel kapcsolatos életminőséget (SF-36 kérdőívvel, PD és HD betegek között is) és a PD választás indikációit mértük fel kérdőívek segítségével.

Másodsorban a nemzetközi irodalom alapján összehasonlítottuk a nepáli adatokat a PD és a veseelégtelenség kezelésének helyzetéről más régiók, Magyarország, Európa és USA, valamint a nagyobb Dél-Ázsiai országok - India, Pakisztán, Bangladesh és Sri Lanka adataival.

A dolgozat harmadik részében személyes és dél-ázsiai kollégáink tapasztalatait összegeztük azzal kapcsolatban, hogy milyen kihívások merülnek fel egy PD program létrehozásakor és kibővítésékor Nepálban és más hasonló, alacsony erőforrásokkal rendelkező országokban. Ebbe beletartozik a munkaerő képzése és megtartása, beleértve az orvosokat, az ápolókat és a sebészeket, a stabil folyadékellátás biztosítása és állami pénzügyi támogatás elnyerése.

A legfontosabb eredmények: a PD betegek fiatalabbak és nagyobb arányban vannak köztük férfiak, mint más fejlettebb országokban. A PD betegek között több a cukorbeteg, mint a HD betegek között. Napi háromszori oldatsere az alap oldatelőírás, szemben a fejlett országokban alkalmazott napi négyszeri oldatcserével, mely azonban összehasonlítható túlélési adatokat eredményez.

Alacsony erőforrásokkal rendelkező országokban PD-program elindítása meglehetősen nagy kihívást jelent, azonban ezek a populációk nyerhetnének a legtöbbet a PD-programból. Elengedhetetlen a vezető nephrológus odaadása, magabiztossága és hozzáértése, aki nélkül a PD program nem lesz sikeres. Ezeknek a kihívásoknak a leküzdése azonban lehetséges és kívánatos.

8. References

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9. Bibliography of own publications

Related to the theme of the PhD thesis

1. **Paudel K**, Qayyum A, Wazil AWM, Sharma SK, Shrestha K, Fan S, Haris A, Finkelstein FO, Nanayakkara N. (2021) Overcoming barriers and building up a strong CAPD program – experience from three South-Asian countries. *Perit Dial Int*, 41: 480-483. **Impact factor: 1.768**
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