

TECHNOLOGY ASSESSMENT OF NOCTURNAL HOME HEMODIALYSIS AND QUALITY OF LIFE IN END STAGE RENAL DISEASE PATIENTS IN GREECE

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Abstract: Home nocturnal hemodialysis is an intensive form of hemodialysis, where patients perform their treatments at home for about 7 hours approximately 6 nights a week. Home nocturnal hemodialysis is associated with a higher quality of life and a superior cost utility when compared to conventional hemodialysis. This review measured the quality of life of 146 end stage renal disease patients undergoing hemodialysis all over Greece, studied the factors that affect their choice to adopt a specific treatment and evaluated and compared the costs and outcomes of home nocturnal versus conventional hemodialysis.

Introduction

Despite advances in the field of hemodialysis (HD) over the last decade, the therapy remains a difficult and restricted life for many patients. Multiple medications, severe fluid and dietary restrictions, and adherence to an externally controlled dialysis schedule result in a reduction of the individual patient's quality of life. Also, despite these advances, the mortality rate for dialysis patients remains unacceptably high.

In an effort to improve the quality of life in a cost-effective manner, a novel way of delivering HD was pioneered in the early 1990s in Toronto, Ontario, Canada, called home nocturnal hemodialysis (NHHD). It soon became obvious that the treatment worked well and subsequent studies and experience have confirmed that it improves both mortality and morbidity and provides the best quality of life and other benefits for dialysis patients.

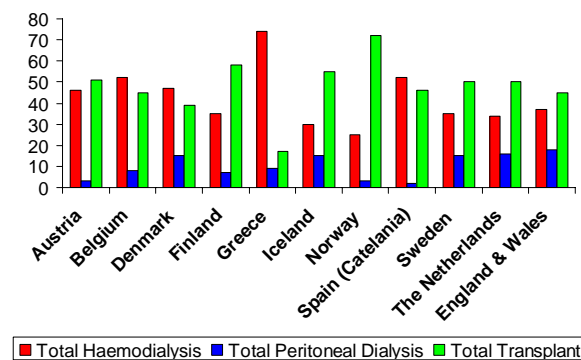


Figure 1: Percentage of patients by therapy and country on December 2002 (Source: Eurostat)

Home hemodialysis in Greece is indisputably at an early stage. Only one end stage renal disease (ESRD) patient out of about 9000 is on home hemodialysis (Source: YSE). Hemodialysis units are hardly sufficient for all the Greek ESRD patients. Moreover, transplants (living and cadaveric) in the European Union are least frequent in Greece - 10 per million (Fig.1).

Nocturnal home hemodialysis

NHHD is a home-based hemodialytic therapy during which patients are trained to receive their hemodialysis at home. The treatment is performed overnight, while the patient is sleeping, allowing freedom from treatment during the day.

Because of the extended time for dialysis, both blood flows (QB) and dialysate flows (QD) can be reduced. In NHHD, blood flows (QB) are generally 200-300 ml/min, and dialysate flows (QD) of 300 ml/min are usual. The smoother rates of hemodialysis result in disappearance of all dialysis-related symptoms, such as cramp, vomiting and 'flats'. The frequency and length of NHHD (although not rigid) range from 5-7 nights a week, and 6-10 hours per night, depending on the individualized dialysis prescription. High or low flux dialyzer membranes have been used for this therapy, with similar results.

There is increasing evidence confirming that nocturnal home hemodialysis improves clinical outcomes in a cost-efficient manner and reports from many studies indicate that patient's quality of life, measured with several questionnaires, improves markedly [1-6].

There is no fluid and food restriction. It gives patients a lot more control over their therapy and life. The effects of NHHD on blood pressure control are excellent. Many patients assume full-time employment and dialysis-related symptoms and anorexia disappear. Thinking clears and memory function improves. Sleep apnea lessens or disappears [2,7].

NHHD is done in the absence of medical personnel. On-line distant monitoring can be used to approximate the degree of supervision available in a dialysis center. Remote monitoring of patients while on nocturnal hemodialysis can be achieved through a telephone or an

Internet connection in order to follow up their vital signs and keep a record of the frequency of dialysis at home.

Moisture sensors, which are taped onto the needle sites, provide warning in cases of bleeding or needle dislodgement. Safety devices preventing air embolism or disconnection of the catheters are mandatory [1]. There are electrode sensors to detect dialysate fluid leakage from the machine and a similar alarm to detect blood leaks from the fistula. Additional moisture sensors should be placed on the floor of the room to warn the patient against potential blood and dialysate leakage on the floor.

Nocturnal dialysis delivers between 36 and 60 hours of dialysis per week, compared to 10 to 16 hours with conventional HD. By increasing the dialysis duration, phosphate clearance is significantly enhanced. After one month of NHD, most patients have experienced a reduction of phosphate binders while enjoying an unrestricted phosphate diet. Additionally, many patients become hypophosphatemic, necessitating addition of sodium phosphate to the dialysate, as a supplement. Very quickly (less than one month), all fluid and dietary restrictions are removed. This includes fluid, potassium and sodium restrictions [7].

Over the first three months of NHD, there is a trend toward an improvement of hypertension control. In fact, 75% of patients requiring anti-hypertensive medications before the conversion to nocturnal hemodialysis are able to discontinue these medications within three months. The mechanism by which this occurs has not been determined, but likely involves interplay between achieving the restoration of normal vascular tone, and possibly, a reduction of other medications, particularly erythropoietin [1,2,8].

Although these results are impressive, arguably the biggest benefit of NHD is the improvement in how patients are feeling. There have been both qualitative and quantitative studies done with this population, and the consensus confirms improvement in the quality of life, and an increased rate of return to work for eligible patient populations.

Cost analysis

The evidence is overwhelmingly in favour of lower total costs for NHD compared with conventional hemodialysis and it appears to be cost-effective [3,8-10].

Despite the initial high costs of NHD, due to set-up and training costs, the payback period is approximately 14 months [11]. The principal reason for this is the lower staffing requirements of NHD. It offers clear cost advantages by avoiding high-cost nursing and infrastructure expenditure. Although consumable and equipment costs are higher, the savings on wage and infrastructure far outweigh this added expenditure. Moreover NHD may save on patient travel cost and the saving may be considerable if they live far from the base unit.

Compared with in-centre dialysis, people on home dialysis have fewer hospital admissions, live longer, are more likely to be in full-time work, receive less medication and experience fewer intradialytic adverse events, such as headaches and cramps. Home hemodialysis may improve the well-being of patients and allow them, by dialyzing at a time suitable to them, to maintain employment [12].

Materials and Methods

Along with survival and other types of clinical outcome, the functioning and well-being that characterize ESRD patients are important indicators of the effectiveness of the medical care that they receive. The importance of measuring the quality of life of ESRD patients' lies in not only providing the absolute survival but also the quality of that survival.

This study describes how 146 patients (99 males and 47 females, mean age $57 \pm 15,7$ years) perceived their quality of life. The questionnaires have been distributed on-site in 10 hemodialysis centers all over Greece. The answers from 146 patients have been collected and analysed within a semester period. Most of the patients were unable to complete the questionnaire without assistance and so it is characterised as an interviewer-administered survey.

They were all interviewed using questionnaires composed of two parts. The Kidney Disease Quality of Life short form instrument (KDQOL-SFTM, Greek version 1.2) and an additional part which contains an informative leaflet on NHD, followed by a short questionnaire in order to assess willingness, motivations and concerns of participating in a potential NHD program and also gather additional data such as demographic, age, gender, marital, economical and educational status. The generic core of KDQOL-SFTM is the SF-36TM health survey for the evaluation of health dimensions generic in nature. KDQOL-SFTM comprises of 80 items, 43 of which are kidney disease-targeted items. This instrument was developed specifically for individuals with kidney disease on dialysis.

Results

The 146 ESRD patients who participated in this survey age between 17 to 84 years old and the majority of them (69%) are older than 50 years old (Fig.2). Mean age is $57 \pm 15,7$ years.

The duration of years the patients are on hemodialysis is shown on Fig.3. Most of them (73%) have started HD during the last five years. (Mean years of duration $4,8 \pm 3,2$).

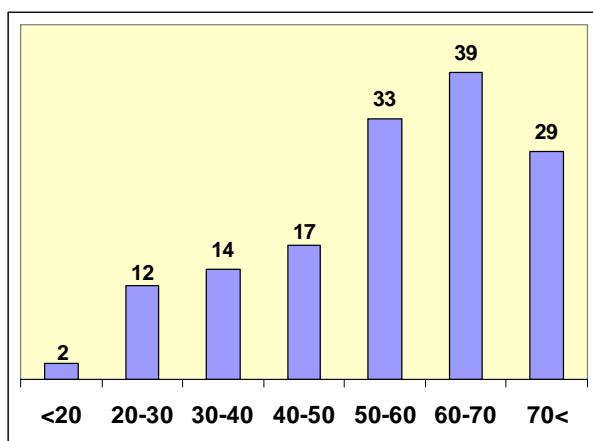


Figure 2: Age (years) of ESRD patients (n=146)

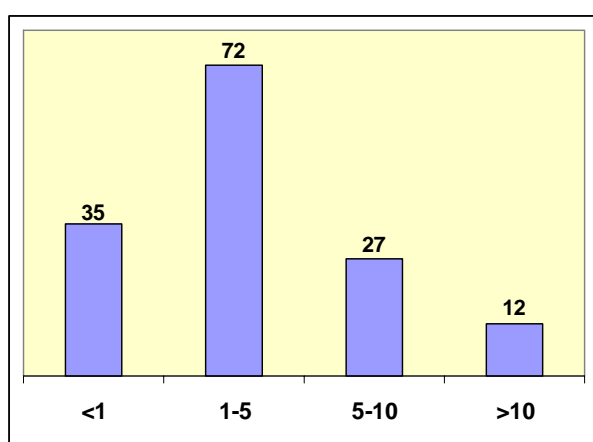


Figure 3: Duration of years ESRD patients practice conventional hemodialysis (n=146)

Diabetes mellitus is the most common (20%) primary kidney disease and a high percentage of patients (30%) are not aware of the reason that led to their end stage renal failure (Table 1).

Table 1: Primary kidney disease of 146 ESRD patients

All	Primary kidney disease	male	female
29	Diabetes mellitus	21	8
17	Hypertension	14	3
12	Glomerulonephritis	6	6
43	Unknown	32	11
45	Other	26	19

As shown in figure 4, 45% of the patients have to travel a distance greater than 20 km (up to 200km) in order to achieve in-center hemodialysis (mean distance above 20km: 43,5 km ± 28,3km.)

Willingness to participate in NHHD was expressed by 75 out of 146 patients (51%) who answered “quite a bit” or “extremely” in the corresponding question posed to them (Table 2). Among the age groups, more willing to participate in NHHD program were patients younger than 35 years old (74%), followed by patients aging

between 35 and 60 years old (58%) and less willing were patients older than 60 years old (40%).

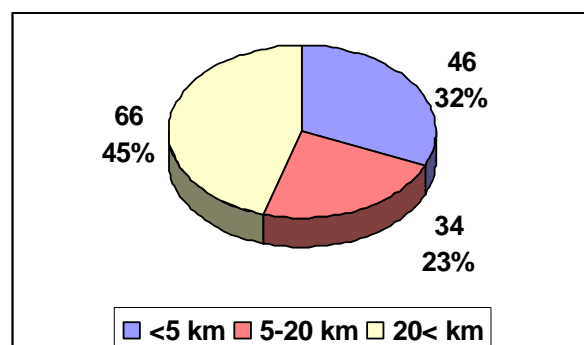


Figure 4: Distance (km) ESRD patients travel in order to have conventional hemodialysis (n=146)

Table 2: Willingness of participating in a potential NHHD program (n=146) and categorisation of age groups.

Willingness	All	Age 0-35	Age 35-60	Age above 60
Not at all	23	1	8	16
Slightly	23	3	5	15
Moderately	23	1	12	10
Quite a bit	37	6	16	14
Extremely	40	8	18	13

The most prevalent barriers the patients expressed about NHHD were fear of dialysing without direct supervision, fear of failure to perform self-care dialysis adequately, fear of change (concerning mainly patients above 65 years old) and fear of social isolation. Additional barriers were needle phobia, lack of space at home, and unwillingness to be seen by other members of the family during hemodialysis.

Concerning patient’s marital status, 105 were married (with mean value of children 2±1), 26 were not married and 15 were widowers and widows.

Only 19 out of 146 patients graduated university (13%), 51 high school (35%), 54 primary school (37%) and 22 had no education at all (15%).

Only 32 (22%) ESRD patients have maintained employment. The rest 114 (78%) patients suffer from disease-specific symptoms, diminished physical working capacity, inability to pursue full-time employment, difficulties in coping with family responsibilities and social lives.

The quality of life of the 146 ESRD patients is qualified from the KDQOL-SF questionnaire and the statistics from the answers given are shown on table 3.

Some of the scales used in this study assess effects of kidney disease (extent that patient is bothered in his/her daily life by issues such as fluid restriction and dietary restriction, feeling dependent on doctors and other medical staff, and stress or worries caused by kidney disease), burden of kidney disease (extent to

which kidney disease interferes too much with patient's life, takes too much of patient's time, makes patient feel frustrated dealing with it, makes patient feel like burden on his/her family), degree of patient satisfaction with care received for kidney dialysis, perceived dialysis staff encouragement (extent to which staff encourage patient to be independent and support patient in coping with kidney disease), and perceived social support (satisfaction with togetherness and support from family and friends).

Each of these scales is scored 0–100, with higher scores indicating more positive psychosocial outlook. A p value of less than or equal to 0.05 was considered statistically significant. All significance tests are two-tailed.

Table 3: KDQOL statistics for n=146 ESRD patients

Scale (number of items in scale)	Mean	Stand. Dev.	n
Symptom/problem list (12)	4,85	2,84	146
Effects of kidney disease (8)	79,44	15,01	146
Burden of kidney disease(4)	63,06	17,92	145
Work status (2)	49,02	24,00	146
Cognitive function (3)	31,03	40,43	145
Quality of social interaction(3)	84,00	19,20	145
Sexual function (2)	76,92	19,44	145
Sleep (4)	46,38	38,42	138
Social support (2)	64,09	24,34	145
Dialysis staff encouragement (2)	89,20	17,74	145
Overall health (1)	92,21	10,60	146
Patient satisfaction (1)	56,97	24,95	145
Physical functioning (10)	86,07	17,29	146
Role limitations-physical (4)	60,68	28,96	146
Pain (2)	36,47	44,64	146
General health (5)	72,10	28,48	145
Emotional well-being (5)	43,97	19,87	146
Role limitations-emotional(3)	58,22	20,98	146
Social function (2)	53,42	46,56	146
Energy/fatigue (4)	60,79	32,91	146
SF-12 Physical Health Composite	54,18	18,14	146
SF-12 Mental Health Composite	39,85	9,74	145

Discussion

In NHHD patients need to be able to learn to perform the entire treatment, from setting up the system to the after-treatment clean up and troubleshooting, either themselves or with the help of a partner. In

addition, patients are expected to wake up to the alarms and be able to respond in a timely manner. Therefore, the most important criteria in order to participate in a NHHD program is willingness and motivation to achieve independence.

Only 9 out of 146 ESRD patients (6%) were aware of nocturnal home hemodialysis. The majority of the rest and especially the younger ones expressed great interest for getting information about this new modality of hemodialysis and their willingness to participate in a potential NHHD program was higher than expected.

Regarding patient selection, several studies on NHHD have selected highly motivated ESRD patients who have been stable on conventional or home hemodialysis [13,14]. This type of selection automatically excludes patients who undergo significant intradialytic hypotension, or patients who suffer from severe congestive heart failure, diabetes, cardiovascular disease, blindness or lack of manual dexterity. Usually patients who are HIV or Hepatitis B positive are also excluded because financial reasons oblige reuse of the equipment.

The psychological effects of NHHD on patients should also be considered in the selection of candidates for this modality, as they will be required to adjust to changes caused by the new treatments, such as needing to handle the responsibility of self-care, and dealing with the loss of interactions with other patients, as would occur in a treatment center.

The impact on and the reaction of the patient's family members living in the house should also be considered. Besides the patients' ability to be trained and subsequently perform the hemodialysis process alone, other selection criteria may prove important, such as home environment, patient's vascular access type and location, availability of a partner, patient's compliance, and psychological well being [1]. The rate of patient eligibility for training on NHHD worldwide is currently estimated at 15% to 20% of patients.

There has been a significant effort by industry to produce patient-friendly machines for home hemodialysis. These HD machines are highly effective for long 8-hour dialysis. They are ergonomically suitable for use in a home setting, easier to use and deliver smoother dialysis with better cardiovascular stability than conventional dialysis machines. They economize on use of dialysers, tubing, and dialysate, allow remote monitoring, and appear to result in superior patient survival. The exceptional cleanliness and biocompatibility they offer is a great advantage to patients. The full automatization saves the patient one hour every night and 30 minutes every morning. They also economize on filters and dialysate and are good for the environment [15,16].

Conclusions

NHHD is a modality that provides high quality dialysis in a cost-effective manner compared to conventional HD modalities. The intensive dose of dialysis delivered is associated with substantial

improvements from the perspective of the patient, including a significant reduction of medication use, a reduction in hospitalization days, an elimination of dietary restrictions, and an improved quality of life.

NHHD offers significant improvement in life-style, rehabilitation, work capacity, biochemical stability, dietary and fluid freedom and moreover enhances self-determination.

The results from the KDQOL-SF questioners revealed that Greek ESRD patients have a relatively good quality of life, besides their mental health, cognitive function and working status rates which are rather diminished compared to general population [17].

A significant fact that studies have shown is that when patients can themselves make the choice between treatment modalities, it improves their quality of life [6]. Expanding NHHD services in Greece may provide a method of coping with increasing numbers of people requiring renal replacement therapy, with less additional resources required than would otherwise be needed to expand conventional hemodialysis services and more importantly will result to a number of symptom-free patients who have returned to work or recreation and are able to contribute to society without the signs or stigma of their disease.

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