

# A New Reality: Extracorporeal Home Hemodialysis with a Revolutionary System

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## Abstract

Home extracorporeal hemodialysis (HD), which had aroused great interest in the past, did not keep the promises expected due to the complexity and family commitment in managing the treatment. The portable NxStage One system was proposed from the United States, also marketed in Italy and designed for home use. 9 patients on chronic hemodialysis, 5 males and 4 females, after a period of about 15 days of training, with a partner deemed suitable, were initiated for home HD treatment with the NxStage System : 5/6 weekly dialysis sessions lasting about 150/180 minutes. In all patients, weekly clearance was evaluated according to the Leypoldt formula for Standard Kt/V, in addition to bimonthly control of the main tests. Blood control (Hospital HD vs Home HD), performed 6 months after starting home HD then compared to the same last values checked during the period in hospital HD, showed no difference in the amount of cleansing as shown by weekly KT / V, while a significant reduction was shown as regards serum urea, creatinine, uric acid, phosphorus and calcium (not significant increase) with reduction of the dosages of phosphorus binders (Sevelamer and Calcium Carbonate) and a significant increase of serum bicarbonate and hemoglobin even with reduction of doses of erythropoietin (darboepoietin). We conclude that the dialysis efficiency of home HD is comparable to hospital treatment, with a reduction in metabolic parameters and an increase in hemoglobin values. This method undoubtedly improves the patient's psycho-physical well-being, increases their autonomy and self-image.

**Keywords:** Creatinine; Hemodialysis; Sevelamer

**Abbreviations:** HD: Hemodialysis; PD: Peritoneal Dialysis.

## Background

Chronic terminal uremic patients require dialysis treatment to purify uremic toxins, which would otherwise lead to death. Purifying treatments can be of two types: a) Peritoneal Dialysis (PD) uses the peritoneum as a purifying membrane and an intracorporeal circulation system b) Hemodialysis (HD) which exploits the purifying capabilities of synthetic membranes and an extracorporeal circulation system.

While PD treatment is easily manageable even by subjects who are not particularly experienced in dialysis techniques

and therefore also by the patients themselves, HD has always encountered technical difficulties that only professionals were able to manage. As a result of this, PD has always been chosen as a technique, easy and quick to learn, for sending patients to their home. However, there are limitations to its use: the availability of a partner is mandatory; no previous surgery on the abdomen, etc., therefore not all subjects may be suitable for this treatment. In addition, another limitation is the duration of the technique over time (about 3 - 4 years) linked to the exhaustion of the peritoneum.

Despite these problems HD has encountered resistance and learning difficulties which only in very rare cases have made it possible to perform at home. Therefore, in the latter case, the patient's dependence on hospitals and doctors in dialysis

centers is total. It is therefore obvious that dependence on one's own hospital dialysis center results in the need for three-weekly transfers from one's home to the hospital and vice versa with any weather and health conditions, with even more inconvenient implications for those who live in disadvantaged areas. To this are added long periods (at least 4-5 hours) of stay in the dialysis center that take away freedom and management of one's free and working time. All this significantly limits the quality of life of patients. An innovative technological platform for Home HD has overcome and solved the limits of the traditional technical approach which until now has shown many critical aspects. The simplicity of use, the reliability of the technique, the management of vascular access and the simplification of materials seem resolved [1-3].

The portable NxStage One system was proposed from the United States, also marketed in Italy and designed for home use. At this regard a group of patients in Home HD was evaluated, already for an average period of about one year, comparing the previous period of Hospital HD to the period of Home HD to evaluate the efficacy and safety, over time, of a method that could be extended over time to more patients. The possibility of expanding the method to all those

who might be able to manage it would undoubtedly lead to substantial economic savings, taking into account that the average cost / patient- of Hospital HD is around 60,000 euros / year against 27-30000 euros / year of Home HD [3].

## Materials and Methods

9 patients on chronic HD, 5 males and 4 females, with a mean age of  $55 \pm 5$  years, dialysis age  $102 \pm 135$  months, after a period of about 15 days of training, with a partner deemed suitable, were initiated to Home HD treatment with the NxStage System ( $9 \pm 6$  months): 5/6 weekly dialysis sessions lasting about 150/180 minutes (Table 1). In all patients, the weekly KT / V according to the Leypoldt formula [4] and the control blood tests ( serum Urea , Creatinine , Uric Acid , Ca , P , Na , K , PTH , Hb ) as well as other parameters such as the use of weekly Erythropoietin and the daily use of Phosphorus Chelators, Calcium Carbonate and Oral Iron were evaluated 6 months after the start of home HD. The data were then compared to the same last values checked during the period in hospital HD, in this case we considered the iron administered intravenously. Statistical significance between the two periods was evaluated with Student's T for paired data.

Membrane	5 pts Polysulphone 4 pts polyamide	9 pts Polyethersulphone
Dialyzer surface	5 pts 2,5 m <sup>2</sup> 4 pts 2,1 m <sup>2</sup>	9 pts 1,6 m <sup>2</sup>
Dialysis hrs/ week	12 $\pm$ 0,5	13,5 $\pm$ 1,5
QB ml/min	300	250
QD ml/min	600	150
Buffer concentration mEq/l	Bicarbonate 35	Lactate 40

**Table 1:** Characteristics of the treatments in the 9 patients (QB = blood flow ,QD = dialysate flow )during the two periods.

## Results

Blood control (hospital HD vs. home HD) performed six months after starting home HD (Table 2) did not show differences in the amount of the weekly KT / V. On the contrary home HD showed a significant reduction of serum Urea, Creatinine, Uric Acid, Phosphorus and Hemoglobin .This last parameter improved despite a slight reduction in weekly doses of Darboepoietin (Table 3). Ca and PTH improved even if not significantly with a maintenance or a reduction in the dosages of phosphorus binders (Sevelamer and Calcium Carbonate) (Table 3). In addition serum Bicarbonate improved significantly. With regard to martial therapy, intravenous iron gluconate was administered during the period of hospital HD, while for HD at home we preferred to prescribe oral liposomal iron. This is for a better convenience of drug administration, since intravenous iron is unsuitable and safe for intravenous administration at home, by untrained people and therefore in the absence of doctors or nurses.

	Hospital HD	Home HD	P
Weekly KT/V	2,3 $\pm$ 0,5	2,2 $\pm$ 0,7	NS
Urea mg/dl	161 $\pm$ 31	136 $\pm$ 29	0,05
Creatinine mg/dl	11,2 $\pm$ 1,7	9,7 $\pm$ 1,4	0,05
Uric Acid mg/dl	6,5 $\pm$ 1	5,2 $\pm$ 1,2	0,03
Na mEq/l	139 $\pm$ 1,9	139 $\pm$ 1,2	NS
K mEq/ l	5,4 $\pm$ 1,6	5,2 $\pm$ 1,2	NS
Ca mg/dl	8,5 $\pm$ 0,8	9,6 $\pm$ 0,6	NS
P mg/dl	5,8 $\pm$ 1,4	5,0 $\pm$ 1,1	0,05
Hb gr/l	10,3 $\pm$ 1,3	11,7 $\pm$ 1,5	0,05
PTH pmol/l	74 $\pm$ 91	61 $\pm$ 88	NS

**Table 2:** Comparison between Blood Tests at the end of the Period in Hospital HD and 6 Months after the Transition to Home Hd in 9 Patients.

Drug	Hospital HD	Home HD
Darboepoietin mcg/week	34,2 ± 10	33,3 ± 10
Intravenous iron mg / week	46,9 ± 28,3	-
Oral iron mg / week	-	168,3 ± 158,1
Ca Carbonate gr / day	10,5 ± 6,3	9,3 ± 7
Sevelamer mg / day	32,2 ± 14,5	34,2 ± 14,2

**Table 3:** Dosages of the main drugs taken during the two periods.

## Discussion

Today many difficulties of home HD seem to be overcome thanks to new technologies, such the NxStage System (Figures 1 & 2). This equipment allows frequent dialysis sessions, avoiding long periods between sessions and allowing the organism a nearly continuous purification. The NxStage System One was developed to address these challenges. The system is an innovative, flexible device that can deliver hemodialysis, hemofiltration, and/or ultrafiltration therapies to patients with renal failure or fluid overload. The unique characteristics of this system include a highly automated system design with a drop-in cartridge to facilitate training and simple operation; portable size and independence from dedicated infrastructure to minimize practical barriers to where therapy may be administered; use of high-quality premixed treatment fluids to enable capture of the potential clinical benefits of fluid purity without the hassles of local water treatment; and wide operating ranges to allow clinician flexibility in patient therapy prescriptions.



**Figure 1:** Small portable machine with wheeled trolley. There are pre – packaged dialysate bags containing lactate on the road.



**Figure 2:** Pre – packaged kit containing dialyzer filter and blood lines.

Most conventional hemodialysis uses bicarbonate-based dialysate, which typically uses acetate as an acid concentrate. Therapies using prepackaged fluids, such as PD or the NxStage System One, use lactate based dialysate. Lactate provides a practical buffer alternative, as it is converted by the patient rapidly to bicarbonate on a 1:1 basis primarily by the liver and also the skeletal muscle. Lactate should not be confused with acetate in terms of patient tolerance and cardiovascular stability. Acetate has known vasodilatory effects that far exceed lactate. Clinicians prescribing hemodialysis with the NxStage System One have observed that lactate-buffered dialysate is well-tolerated by patients. Data shown at the 2004 American Society of Nephrology Annual Meeting showed that moderate elevation of serum lactate levels at the end of treatment is less than that observed in low to moderate physical exertion and returns to baseline levels soon after treatment. Premixed, 5-liter dialysate bags are portable along with the System One. This offers patients the freedom to travel, with a physician prescription, without interrupting their treatment schedule. Usage by the patient has been simplified. The physician determines the number of bags the patient requires; the patient simply hangs and connects the bags for treatment [11]. As regard home HD our data confirm a better control, compared to hospital HD, of many serum parameters, as already reported in previous works, considered to worsen during uremic syndrome [1-4]. All this with the goal of improving the quality of life of the patient undergoing hemodialysis treatment, treating him in his own family environment, reserving the diagnostic and therapeutic aspects for the most complex clinical situations to the hospital environment. Reducing the need to resort to the hospital environment, for situations that can be easily controlled at home. Increasing collaboration with the Family Doctors for the care and follow-up of the chronic uremic patients undergoing dialysis treatment. Experimenting with

innovative solutions for those in need of more intensive care, through the spread of new forms of home care services. Reducing management costs for hemodialysis: transport, therapies, examinations, hospital staff, etc [6-10]. In this context the FREEDOM clinical study [5] showed 85% reduction in recovery times after hemodialysis, 30% reduction in depressive symptoms, 6-17% improvement in quality of life, significant reduction in the use of antihypertensive drugs (33% fully terminated and 56% reduced by 50%), 40% reduction in expected mortality. In addition two of our works highlighted an improvement in the quality of life and nutritional status of patients on home HD with respect to hospital HD [9,10].

## Conclusion

So in conclusion the dialysis efficiency of home HD is comparable to hospital treatment, with a reduction in metabolic parameters and an increase in hemoglobin values. This method undoubtedly improves the psycho-physical well-being of the patient, increases their autonomy and self-image [6-10]. The problem of duration, over time, and compliance of home HD remains open. The relationship between the patient and the reference staff of the dialysis center is fundamental. In our opinion, periodic returns of the patient to the dialysis center must be considered physiological to allow the care giver the possibility of a sort of rest and therefore detoxification from the responsibility of the health and life of their loved one.

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