

# *Le Bulletin de la Dialyse à Domicile*

## **WHY DO WE HAVE TO USE NEW LOW FLUX DIALYSIS MACHINE FOR DAILY HOME DIALYSIS**

**Pourquoi faut-il utiliser les nouveaux générateurs à bas débit de dialysat pour l'hémodialyse à domicile quotidienne (HDQ)**

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### **Résumé**

L'hémodialyse à domicile après un déclin fin des années 1990-2000, retrouve un second souffle. Ce renouveau n'est pas propre à la France, mais aussi aux USA et en Europe de l'Ouest (Angleterre, Italie, Espagne).

Quelques études confirment que les nouveaux générateurs/cycleurs à bas débit dialysat assurent une épuration efficace, basée sur la Saturation élevée du dialysat et permettent un taux d'ultrafiltration horaire réduit. La fréquence permet d'éviter un intervalle interdialytique long.

Mais ils sont aussi simples d'utilisation, permettent une facilité de gestion des séances avec une flexibilité et une mobilité.

L'hémodialyse quotidienne à bas débit dialysat répond à des objectifs nouveaux ou non encore atteints : une amélioration de la qualité de vie, une amélioration des paramètres cardiovasculaire et une diminution du temps de récupération post dialyse.

Ils permettent, grâce à une plus grande adhésion des patients, de diminuer les freins au développement de cette thérapie.

Ils représentent aujourd'hui une opportunité pour l'amélioration de la qualité de la dialyse. Le rôle du patient, partenaire-décideur du soin reste déterminant.

**Mots clés :** hémodialyse à domicile, HDQ, Hémodialyse quotidienne, dialysat bas débit

### **Abstract**

After a decline at the end of 90's, Home Hemodialysis recently found a second breath. This renewal doesn't only concern France, but also the US and Western Europe (GB, Italy and Spain).

Several studies confirm that low flux dialysat machines deliver adequate dialysis dose, based on high dialysat saturation and low daily ultrafiltration rate. Frequent sessions avoid long interdialytic interval.

They also are easy to use, allow easier session management with more flexibility and mobility.

Daily hemodialysis with low dialysat flux responds to new goals: improving quality of life reaching better cardiovascular parameters and reduce recovery time post dialysis.

Better patient adhesion to the treatment with low flux dialysat machines allows a decrease in barriers to home hemodialysis development.

It gives a good opportunity today to improve dialysis quality. The role of patient care partner is determinant

**Keywords :** home hemodialysis, daily hemodialysis, low dialysate flow rate

## INTRODUCTION

After a decline in the late 1990s and the 2000s, home hemodialysis found its second wind. This renewal was not unique to France; it also occurred in the USA and Western Europe (England, Italy, Spain). Only Australia, New Zealand and Northern Europe have maintained their home hemodialysis rates. The renewal is due to the conjunction of several factors: 1- a morbi-mortality rate that remains high in conventional hemodialysis; 2- patient care partners looking for an improvement in their quality of life; and 3- a demographic increase in hemodialysis patients in the world in the face of limited resources.

### WHAT CHALLENGE FOR DAILY HOME DIALYSIS

Several surveys of dialysis patients show that the ranking of priorities for patients is different from that of caregivers. In the EPOCH-RRT study, the ranking of patient preferences is as follows: 1- keeping the most independence and autonomy possible; 2- quality of life; and 3- flexibility of dialysis hours (1).

When it comes to the features of the home-based machines that patients prefer, they are: portable, silent, easy to start (on/ off), usable with or without help, allow processing flexibility, and quick to get started and clean. They do not look like medical devices and are not imposing.

International competition has accelerated, particularly since 2015, for the development of home appliances with new features. This «effervescence» contrasts with the «stagnation» of the offers of conventional generators. Several generators or cyclers are now available. Some use bags, others reverse osmosis or microfiltration or a cartridge for the regeneration of water.

In addition to NxStage® used for more than 10 years on the American market and in France since 2012 and S3® by Physidia, used since 2013 in France with a European development program begun in 2017, we note the Quanta® used in England, including the launch of the European program which has been postponed to 2018–2019. The Outset Tablo® has been used in home testing in the USA since 2016. Easydial's Dharma® has been on the market since 2017, and Clinical Trial and Infomed's Dimi® has been CE marked and is scheduled for clinical trials in 2018–2019. Finally, do not forget Awak®, whose program was relaunched

in the USA and Singapore with the participation of Debiotech.

### OPERATING MODE AND PRESCRIPTION

The two generators/cyclers used in France in low-flow dialysate (NxStage® and S3® Physidia) have very similar operating modes. They use 5-liter bags, a dialysate flow rate that varies between 150 and 200 ml/min, and a blood pump flow rate of about 300 ml/min, which can be accelerated up to 450 ml/min on the NxStage®. Dialysis baths in sterile bags are based on lactate or bicarbonate for S3. The number of bags per session varies between 4 (20 liters) and more depending on the need. The number of sessions per week cannot be less than 5, defined as daily dialysis, but is preferably 6 sessions, especially if the weight is greater than 60 kg and/or the weight gains are greater than 1 liter/day. In the case of 5 sessions per week, it is not recommended that the 2 days «off» be successive. The recommended duration of sessions is from 2h to 2h30. It is estimated that a duration that exceeds 2h30 is not reasonable, because of its impact on the weight of treatment, and can be a source of burnout.

The prescription is simple, and is made on a weekly basis, rather than per session. As in conventional hemodialysis, there is no objective of  $kt/v$  to be attained in each session.

- The number of sessions per week (5 or 6) can be determined by the daily weight gain. The objective is not to exceed a maximum ultrafiltration rate of 700 ml/h. Weight gain/week relative to the desired maximum ultrafiltration rate gives the number of hours of dialysis per week.

- Meanwhile, the volume of dialysate per session can be adapted to the results of weekly  $kt/v$ , but it can vary between 20 liters if weight <70 kg, 25 liters up to 100 kg, and 30 liters beyond.

### HOW CAN LOW-FLOW DIALYSATE DELIVER HIGHER CLEARANCE THAN CONVENTIONAL DIALYSIS?

The operating principle of low dialysate flow is based on the high saturation of the dialysate, which optimizes the removal of low-, medium and high molecular weight molecules.

For urea, the saturation of the dialysate with a flow rate <200 ml/min is greater than 90% (2) and that of phosphorus 85%. This contrasts with the saturation of the dialysate at a flow rate of 500 ml/min, which is 55% for urea and only 35% for phosphorus. The amount of phosphorus purified per week by conventional

hemodialysis is about 3.2 g, while it is 8.1 g for night hemodialysis, assuming 6 nights, and 4.6 g for frequent-dialysate hemodialysis (3).

Thus, the elimination of phosphorus in frequent dialysis is improved thanks to: better saturation of the dialysate with a low dialysate flow; more treatments per week; and an increase in the total dialysis time (an increase of 15 mn dialysis time per day increases phosphorus removal by 8%).

### **KT/V SESSION, STANDARDIZED KT/V (std) OR FREQUENCY OF SESSIONS?**

We should not forget that the 2 largest international studies whose objective was to observe the effect of the increase in kt/v on the morbidity and mortality of hemodialysis, the European MPO and the American Hemo Study (4 and 5), did not reveal any difference between the high-dose dialysis group and the standard-dose group in their main criterion and to general surprise.

The total dialysis dose per week takes into account dialysis time per week and frequency (standardized kt/v). It makes it possible to compare the different methods of dialysis. The KDIGO 2015 set a Kt/vstd > 2.1, synonymous with adequacy (6).

Another important study (7) compared 2 groups of patients: the first in conventional dialysis centers, and the second in home dialysis 5 times/week. Here, 51% of at-home patients had a kt/vstd < 2.1, versus 27% in centers. Despite this, cardiovascular complications, deaths, and hospitalizations were significantly lower in the at-home dialysis group! This confirms the kt/v limit as the sole criterion of adequacy.

### **CLINICAL RESULTS**

The European retrospective study (KIHDNEy) (8) gathered 182 patients from 5 different European countries, all treated at home with low-speed dialysate by NxStage®. They had shown a mean weekly rate of 2.6 at start-up, which was maintained at the same level at 6 months and at 1 year. This perfectly illustrates the efficiency of this method with a quality judged on the KDQI.

The average ultrafiltration rate was 6.8 ml/h/kg. This rate, which is well below 10 ml/h/kg, is one of the major effects of the frequency, with all the consequences that the reduction of ultrafiltration rate can have for the reduction of left ventricular

hypertrophy and arterial hypertension. The number of antihypertensives was significantly reduced from 1.5 to 0.9 drug/day (p < 0.001).

The rate of bicarbonate and the level of phosphorus was significantly corrected without stopping the phosphorus chelators, but merely reducing them (9).

The potassium level was maintained as normal, with no episodes of hyperkalemia observed.

Residual diuresis at 1 year was maintained in all patients who had diuresis > 500 ml/day. This result contrasts with the FHN study, which showed a significant reduction in diuresis at 6 months (50%) and at 1 year (67%) (10).

Training time was shorter on low-dialysate-flow machines (18.9 sessions) than on conventional machines (27.7 sessions).

The post-dialysis recovery time in the FREEDOM study was reduced from an average of 8 hours before daily dialysis on NxStage® to less than 1 hour to 4 months at 1 year of treatment (11).

Finally, the leading cause of NxStage® drop out is renal transplantation: 31% at 3 years. There is an extremely low mortality rate; deaths occur in only 10% of cases at 3 years, while 40% of patients continue their home treatment at that point. The output technique on this machine concerned 19% of patients at 3 years. It was 14% at 1 year, which shows that apart from an early drop out, there is perfect stability in the 1st year and a very high adherence to the technique over time (8).

### **ENVIRONMENT**

The emission of greenhouse gases is important in hemodialysis. It comes from medical equipment, energy used by generators, and patients' movements. The carbon footprint of conventional center machines has been evaluated at 3.8 tons of CO<sub>2</sub> equivalent (CO<sub>2</sub>e) per patient per year. It is only 1.8 tons of CO<sub>2</sub>e for NxStage®. Water consumption is 10 times less important for NxStage® than for conventional machines (7203 vs 82173 liters per patient per year). Finally, the cost of electricity is reduced by 80%.

### **PROVEN MODE OR EFFECTIVENESS EFFECT**

Several teams in France have started or reactivated home dialysis programs since 2013. Between 2015 and 2017, there was a 40% increase in HDQ, according to

the REIN registry and the manufacturers of 2 low-flow-rate machines.

Is it a fashion effect? Is it motivated by innovation and curiosity?

At Tenon Hospital, there has been a home dialysis tradition for almost 50 years. Between 2000, after the release of our last transplant patient, and 2012, we did not set up home treatment for any patients. Yet information regarding the choice of treatments has existed since 1995. From 2012, the same proposal has found the support of more and more patients. Between 2012 and the 1st quarter of 2018, we set up home treatment for 72 patients.

It is hard to think of a fashion effect. There is real reporting by the patients of better quality of life, to which is added an improvement of the clinical parameters, the flexibility of the treatment, and improved mobility.

## CONCLUSION

Daily low-flow-rate dialysate hemodialysis meets new or unmet targets: improved quality of life, improved cardiovascular outcomes, and decreased post-dialysis recovery time.

The new low-flow-rate dialysate throughput generators/cyclers provide efficient purification and reduced hourly ultrafiltration. The frequency makes it possible to avoid a long interdialytic interval. It also increases ease of use and ease of session management by improving flexibility and mobility. Thanks to greater patient support, the generators allow for reductions in the obstacles to the development of this therapy. Today, they represent an opportunity for improving the quality of dialysis. The role of the patient, a partner and decision-maker in the treatment, remains decisive.

## CONFLICTS OF INTEREST

*The author declares he has no conflict of interest for this publication*

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