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BIRTH, RISE, DECLINE AND REVIVAL OF HOME HEMODIALYSIS - FRENCH EXPERIENCE

NAISSANCE, CROISSANCE, DECADENCE ET RENAISSANCE DE L'HEMODIALYSE A DOMICILE

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Alain MEYRIER[1]

[1]Professor emeritus (Néphrology), UUniversité Paris-Descartes and Hôpital Européen Georges Pompidou, 75015 Paris, France.

Résumé

La première publication sur l'hémodialyse de suppléance, en 1960 fut suivie en 1963 des premiers cas d'hémodialyse à domicile. La mise au point d'appareils délivrant un mélange d'électrolytes et d'eau assortis de dispositifs de sécurité fut à l'origine de machines individuelles compatible avec la dialyse à domicile. On démontra en 1964 que la dialyse peut être nocturne et sans assistance. Cela conduisit à une augmentation progressive du nombre des dialysés à domicile dont le % en France était de ≈20% pour un total de ≈ 6 000 hémodialysés vers la fin des années '70. Le déclin fit suite à la création d'unités dites d'autodialyse qui incita une majorité de patients à quitter la dialyse à domicile et une majorité de néphrologues à abandonner cette option. La renaissance de la dialyse à domicile peut être datée de 2012, avec l'apparition du dialysat en poches permettant une dialyse quotidienne à bas débit, avec une efficacité et une tolérance remarquables. Le nombre de dialysés à domicile augmenta de 307 en 2014 à 374 en 2016 et à 448 à la fin de 2018, ce qui était essentiellement dû à la dialyse quotidienne dont le nombre passa de 55 à 374 et atteint 448 aux mêmes périodes. Certes ce nombre est faible au regard des ≈46 000 hémodialysés en France, mais la tendance se fait vers une renaissance de l'hémodialyse à domicile, majoritairement quotidienne

Mots clés : hémodialyse à domicile, fistule, shunt, histoire

Abstract

The first publication in 1960 on maintenance hemodialysis was followed in 1963 by sparse reports on dialysis in the home. The introduction of proportioning pumps and concentrated electrolyte solutions led to developing single-patient machines and safety devices that made home hemodialysis possible. It was demonstrated in 1964 that home hemodialysis can be done overnight, unattended. This led to a steady rise in the number of patients treated at home. The percentage in France was ≈20% by the end of the seventies, out of a total of ≈6 000. The decline began when Public Health authorities authorized a program of ''limited – care'' units. A loophole in the regulations led to a massive transfer of patients to these units and a rapid decline of home dialysis. The revival can be dated to 2012 with the development of disposable dialysate bags that make low flow daily home dialysis feasible. Efficacy and tolerability are such that the total number of patients treated at home rose from 307 in 2014 to 374 in 2016, owing to those on daily hemodialysis - an increase from 55 in 2014 to 374 in 2016 and 448 by the end of 2018. Currently, ≈ 46 000 patients are hemodialyzed in France. The % of those treated at home is still low but the trend is to a steady increase.

Keywords : home dialysis, fistula, shunt, history

Correspondance :
Pr Alain Meyrier -Service de Néphrologie
Hôpital Georges Pompidou
20 rue Leblanc 75015 Paris
Email : alain.meyrier@gmail.com

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BIRTH

Every nephrologist knows that Clyde Shields was the first patient who survived from end-stage kidney disease in 1960, thanks to Belding Scribner who made long-term maintenance hemodialysis possible with an arteriovenous shunt that allowed a permanent access to the circulation [1]. This treatment had been undertaken in a hospital setting. John P. Merril's team in Boston's Peter Bent Brigham Hospital is credited with the first successful endeavor to hemodialyze a patient at home in 1963, using a Travenol machine that comprised a 100 liter tank for preparing the dialysate which was delivered to a dialyzer made of a spool of cellophane, the ''coil-kidney ''. (fig.1) The home dialysis session was supervised by a physician assisted by a nurse [2]. After one year during which three new patients had been treated in the home with the same method, Merrill & al. realized that the procedure could be carried out without the doctor and nurse's assistance by replacing them by the patient's spouse [3]. The main motivation of dialyzing in the home with this cumbersome installation was in fact the shortage of dialysis stations in the hospital, along with the cost of in-center renal replacement therapy (RRT), a cost that amounted to 10,000 $ compared to 5,000 $ per year for a patient dialyzed at home. [For the European reader, in order to translate these figures into the current rates of the euro multiply them by 20 and also be aware of the high cost of medical procedures in the United States].

Figure 1 : 100 L Travenol tank and twin coil artificial kidney

In 1963 the age constraints for accepting a patient in a dialysis program were very strict and the indications were warranted by a jury of sorts, that comprised a panel of physicians and of members of the civil society including of course (''in God we trust'') among citizens of various classes a clergy minister [4].

It was considered that a patient under 18 years of age was not suitable for being treated by dialysis, until the time when Scribner admitted in 1964 a 15 year-old girl with end-stage renal failure. She had been denied RRT by the hospital administration [5]. At that time the Nephrology department of Seattle hospital was equipped with only four dialysis machines. The dialysate was prepared with batches of electrolyte concentrate poured in tanks filled with tap water, a mixture achieved by stirring with a canoe paddle.

With the help of Albert Babb, Professor of engineering at the University of Washington, a proportioning pump was designed, that produced a mixture of water and concentrate, (that is, dialysate) which was delivered in line to each in-center dialysis station [5].

Babb knew the father of the young girl. He was urged by Scribner to elaborate a miniature model of the hospital proportioning machine equipped with safety devices. This ''kidney machine'' became the prototype of all those currently used for hemodialysis, in particular for dialyzing at home [6]. The young girl commenced a treatment at home by means of a Teflon arteriovenous shunt (Figure 2) and a Kiil kidney (figure 3) from June 1964 to 1968, she followed a regular academic course and she died, not of renal failure nor of complications of hemodialysis but from the development of systemic lupus that had been the cause of her kidney disease.

Rapid progress followed: as soon as 1966 the hemodialysis hardware had benefitted from these improvements [7] and Washington University treated eight patients at home with two or three 8 to 10-hour hemodialyses per week. Five patients were dialyzed overnight. The cost was down to 4,000 $ per year.

In Europe credit for undertaking self-dialysis in the hospital goes to Stanley Shaldon in London. At a time when he had 10 patients treated in this fashion he embarked on a program of home hemodialysis in

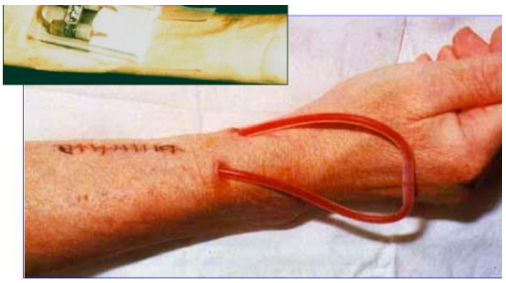

Fig. 2 : Quinton Scribner Shunt. Picture availabe on http://www.medicinhistoriskasyd.se/Bildspel/Dialys2011/

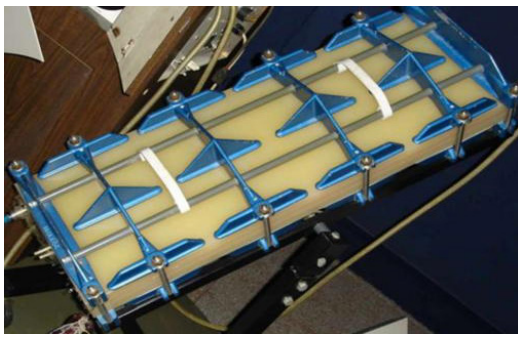

Fig. 3 : Kiil artificial Kidney (from the name of the urologist who designed it/

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1954 and as soon as October the same year he started to convince his patients to dialyze at home, overnight and unattended. Shaldon presented his experience at a meeting of dialysis physicians in Seattle at the beginning of 1965 [8]. The American nephrologists were so impressed that they started to define home RRT as a standard of adequate dialysis, preferably carried out at night. It did not take long before 90% of patients at Seattle were treated at home thrice weekly and preferably overnight.
An interesting observation is noteworthy: some patients chose to dialyze five times per week and told their nephrologist that in so doing they had a feeling of increased wellness-– an anticipation of daily hemodialysis in the future.

At that time, in the USA the access to vessels was provided by a Teflon shunt, evidently easier for achieving the connection to the dialyzer than puncturing an arteriovenous fistula (AVF), an elegant technique of vascular access published by Cimino and Brescia in 1966 [9] and that implied a venipuncture. For the patients the easiest way of performing a connection to the dialyzer without an aid was the Thomas shunt implanted at the groin between the femoral artery and the femoral vein. This shunt was easily manipulated with both hands. The blood flow was in the order of 300-500 ml/min. The Thomas shunt was still used in the dialysis center of Montpellier, France in 1975 [10, 11]. However this shunt required meticulous aseptic manipulations and careful dressings. Complications could occur [12] and nephrologists avoided this type of vascular access in a possibly suicidal patient, as a young girl had chosen a mode of demise inspired by ancient Rome, that is, opening up her Thomas shunt in a warm bath.

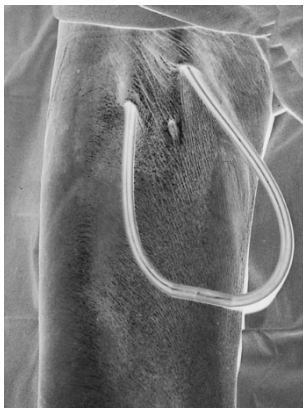

Fig 4 : Thomas Shunt at the right thigh (photo from Francisco Coronel et al. Nephrol Dial Transplant -2001 16: 1845±1849)

A paradox stems from the opposite advantages of the AVF versus the Teflon-silastic shunts. The former was a definite progress in terms of vessel-access viability over the years but the fear of venipunctures hampered the patients' acceptance of treatment at home. This drawback was and still is a hindrance to the development of home hemodialysis. The ''Button-hole'' does not seem to entail a definite advantage on that score [13].

In 1970 Scribner and his team published their experience with home hemodialysis, essentially using Teflon shunts [14]. Two patients only had commenced to dialyze with an AV fistula. Fifty-two patients had been trained to perform their dialysis unattended and by night. They were followed up over six to 64 months. Of note, the death toll was as high as 31%. The morbi-mortality was not a consequence of renal failure but of the treatment with dialysis. More than 80% of the patients had resumed their previous professional activity. Thirty-five per cent of this population had some evidence of psychologic disorders. The 65 % extant patients agreed on feeling well with home dialysis. The major difficulties were linked to the Teflon cannula, to complications of anticoagulants and to mechanical breakdowns. The cost was low and this saving was also explained by the re-use of dialyzers.

RISE

Meanwhile home hemodialysis was rapidly developing in France. At Tassin Dialysis Center in Lyon, France, Guy Laurent transferred in 1968 a first dialyzed patient to her home in Eastern France. She inaugurated a series of about 80 patients that over the years were treated at home using Kiil kidneys for long nightly dialysis.
At about the same time Charles Mion in Montpellier launched an ambitious program of home hemodialysis, using mainly AV fistulas although some patients still used a Thomas shunt. Each patient was equipped with his own Kiil kidney that was sterilized and reused several times, which reduced cost and was perfectly safe in terms of viral contamination. In 2002 Mion had been treating at home about 800 patients with terminal renal failure. Of note, the gist of home dialysis for Mion was not only to suppress the problem of distance between the home and the in-center but first and foremost to allow living a normal life and pursuing a professional work in daytime. Therefore dialyses were long and performed overnight.

Beyond the fear of venipuncture the drawbacks with regard to home hemodialysis were – and still are – numerous. Interestingly, on a whole they are the same in France and in the United States [15]. Their list is long and not limitative: the need of a dwelling with a space for medical care and room for stockpiling the disposable commodities; a spouse accepting to don the nurse's coat; fear of an accident (from a hematoma at the puncture site to air embolism - - - you name it); anxiety from being far for a medical environment in case of emergency. In any

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event the progression of home hemodialysis followed a steady rise until the late 70s [Table 1].

DECLINE

The decline started around 1980, with the appearance of ''self'' (or ''limited care'') dialysis facilities. Their legal requirements were specified in a brief from the Ministry of Public Health. They had to comply with the following:
- To be a substitute to dialysis in the home
- To comprise one station per patient
- To limit acceptance to young patients with complete autonomy
- To assign one registered nurse for supervising the dialysis procedures.

Without delay ''Self dialysis'' almost fatally jeopardized the progression and even the mere existence of home hemodialysis.

More than 15 years ago:

Table I : number of dialysed patients living in France on December 31 from 1972 to 1978 (EDTA registry)

Number of patients			
Years	In center haemodialysis	Home haemodialysis	Percentages ratio Home HD/total HD
1972	2040	226	10
1973	2565	325	11.2
1974	3228	332	9.3
1975	4067	583	12.5
1976	4872	778	13.8
1977	5539	1061	16.1
1978	5630	1234	18

The conclusion of an a nalysis performed more than 15 years ago was eloquent, at a time when more than 25 000 patients were treated with hemodialysis in France (16): ''*The number of self-dialysis units that allow to relieve the patients' burden on in-center facilities is fully developing. Currently nephrologists have almost completely ceased to persuade renal patients to start hemodialysis at home and they kindly persuade them to be treated in self-dialysis units. This policy leads to a definite advantage of self-dialysis over home dialysis. However we have observed that these so-called ''self-dialysis'' facilities rarely comply with official government regulations. In fact few of these units undertake treatment of young and autonomous patients. We have even found invalid patients treated in these facilities. Moreover the number of self-dialysis units that comply with the legal rule of one kidney machine per patient is increasingly dwindling. These unlawful derogations of self-dialysis units result on the one hand from the lack of adequacy between official agreements to authorize the creation of new dialysis centers, and on the other from the regional dialysis requirements along with financial constraints*''.

Sadly the lure of gain did not spare the hemodialysis circles. The loopholes in regulations paved the way to profitable schemes. A substantial number of ''pseudo-selfcare'' dialysis units allowed some nephrologists to look without qualms at their personal expenses.

This was how the number of end-stage renal patients treated with home hemodialysis steadily declined between the 90s and 2013. The ''R.E.I.N.'' French registry indicated that in 2005 283 patients were treated at home and no more than 286 in 2012.

Analyzing data of 1978 (Table 1) reveals 1 234 home dialysis patients (18% of the total number of patients dialyzed in France). The data of Dec. 31, 2016 that include 384 patients treated at home out of a total of 41 000 patients from all French regions, leads to considering that this mode of RRT had been reduced to a trifle.

A first indication that home dialysis might revive perked up from the first endeavors of daily dialysis, and more specifically of low flux dialysis.

REVIVAL

I cannot resist to cite the first Medline-indexed publication [17] entitled ''Daily hemodialysis'' in 1970. This paper described the case of a young patient with end-stage renal failure, who worked nearby Tenon Hospital in Paris. Following her afternoon occupation as a secretary, she would be admitted from Mondays to Saturdays to the dialysis center around 6 PM and was dialyzed with a coil-kidney six days per week after the afternoon patients' shift by one of the nurses, who all volunteered to work three extra hours without compensation.

The results on blood pressure, calcium and phosphate metabolism and nutritional status were remarkably satisfactory. The only snag was persisting anemia as the wash-back of coil kidneys was poor in term of blood restitution and pharmaceutical erythropoietins did not exist.

In fact, a decade later daily hemodialysis became the subject of a keen interest, but for treating acute rather than chronic renal failure [17], in particular when oliguria was accompanied by severe hypercatabolism. With regard to home hemodialysis, credit goes to Traeger in Lyon, France, for being among the first renal physicians who practiced daily home dialysis by the end of the '90s. He demonstrated – as did other nephrologists – with a personal experience of up to 11 years, that the patients' survival when treated by daily RRT was superior to that of patients dialyzed with the classical schedule of three sessions per week. In particular Traeger showed that the daily-dialysis population demonstrated a superior nutritional status [19].

A focus on the situation by the end of 2018 discloses that,

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as in the past, technical progress is the main factor that stimulates the progression of hemodialysis at the home. The year 2012 marks the time of such progress, that stemmed from simple idea that the dialysate generator could be replaced by disposable bags of dialysate, ready for use and perfectly safe in terms of composition and sterility, both factors contributing to correct the ‘’unphysiology of dialysis’’ [20]. With this technique patients were able to commence daily dialysis in the home with a low dialysate flux. From 2014 to 2016 the number of patients treated at home rose from 307 to 374, owing mainly to the new method that was credited of an input that started with 55 patients and reached a figure of 143. By the end of 2018 there were about 440 patients treated in this fashion.

There is no doubt that the material used for this form of dialysis still requires substantial storage space. Likewise the issue of venipuncture remains a possible drawback. Nevertheless dialysis tolerability, quality of blood chemistries improvement and the wellbeing of patients who monitor their dialysis sessions on tablets and are followed up by remote surveillance are hopefully predictive of a home dialysis revival. In any case, in this field as in the political realm ‘’ One need not hope in order to undertake, nor succeed in order to persevere’’ [William the Silent, Prince of Orange, 1568-1584].

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