
The History of Home Hemodialysis: A View From Seattle

Christopher R. Blagg

Northwest Kidney Centers and Division of Nephrology, Department of Medicine, University of Washington, Seattle, Washington, U.S.A.

Home hemodialysis was first used for the treatment of end-stage renal disease in the early 1960s, primarily as a means of reducing the cost of treatment. It was soon found to be an effective form of treatment that provided patient independence, greater opportunity for rehabilitation, and better survival. In 1973, when the Medicare End-Stage Renal Disease Program began, some 40% of all U.S. dialysis patients were on home hemodialysis, but since then the percentage of patients on this treatment has steadily decreased. There are several reasons for this, one in particular being the lack of availability of suitable equipment.

There is now renewed interest in home hemodialysis sparked by the knowledge that new equipment specifically designed for this is being developed, that this is the modality with the best survival rate, greatest opportunity for adequate dialysis and best quality of life, and an interest in the use of daily (or nightly) home hemodialysis. Consequently, more than 30 years later, it appears that home hemodialysis may again become the preferred treatment for many more patients.

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History of hemodialysis, hemodialysis results

History is not what you thought. *It is what you can remember.*

R.J. Yeatman and W.C. Sellar, *1066 and All That* (1930), Compulsory Preface.

The Early Years: 1961–1973

In 1942, Willem Kolff, in Holland, developed the first clinically useful artificial kidney for the treatment of acute renal failure. Only a few years later, Nils Alwall

Correspondence to:

Christopher R. Blagg, MD, FRCP, Northwest Kidney Centers, 700 Broadway, Seattle, Washington 98122 U.S.A.

in Sweden tried glass cannulas, shunted and anticoagulated between dialyses, to allow long-term treatment of patients with chronic renal failure, but this was unsuccessful. It was not until 1960, when Belding Scribner and colleagues at the University of Washington in Seattle developed the Teflon arteriovenous shunt, that long-term intermittent hemodialysis for end-stage renal disease (ESRD) became a reality (1). Four patients were treated, but because of the expense, support from research funds was unlikely to be continued indefinitely. Once this ran out, the University Hospital would have been unable to withhold further treatment without adverse publicity. However, by early 1961, Scribner felt the technique was improved sufficiently to allow a feasibility study to show whether a community-supported and service-oriented artificial kidney center could function outside the hospital. He approached James Haviland, president of the King County Medical Society, asking for his and the Society's support.

The result was the Seattle Artificial Kidney Center (SAKC) — now the Northwest Kidney Centers — a medical school-conceived, medical society-sponsored community effort. A grant of \$250 000 was obtained from the John A. Hartford Foundation “for implementing a community hemodialysis center for treatment of chronic uremia and terminal renal failure.” Several Seattle hospitals wanted this facility, so a lay-dominated committee was appointed jointly by the Board of Trustees of the King County Medical Society and the Seattle Area Hospital Council to review their proposals. After much deliberation, the committee ruled that the SAKC was to be “attached to the Swedish Hospital in Seattle in a public trust arrangement as a research and demonstration project.” Thus the SAKC opened in early 1962 as the world's first free-standing outpatient dialysis unit (2).

The Teflon arteriovenous shunt made repetitive dialysis possible (3), and equipment modifications and the Kiil dialyzer (4) made hemodialysis for ESRD patients a relatively routine procedure. Until then,

nurses generally were not allowed to start intravenous infusions or to give blood transfusions, and starting dialysis was always a procedure performed by the physician. For the new center it was decided that dialysis would be a nurse/technician procedure and that nurses would administer blood and fluids as required, without the presence of a physician (5). This was a first step in reducing the cost of long-term dialysis. (It was another ten years before similar responsibilities were introduced for direct patient care by nurses in Washington State with the use of nurse practitioners in semiremote communities.)

Throughout the 1960s, Scribner and colleagues described most of the medical complications and the social, financial, and ethical problems associated with ESRD treatment. The financial problems in particular highlighted the ethical issues and led directly to the development of home hemodialysis. In 1962, insurers and other funding sources did not cover treatment for ESRD, and demand far exceeded available financial resources. To deal with this problem, the SAKC and the King County Medical Society appointed an anonymous lay Admissions Committee to screen potential candidates for treatment (6). The committee, chaired by a clergyman, had members chosen from the community. Patients were reviewed by nephrologists first, and only those who met very strict medical criteria were referred to the Admissions Committee; the committee then decided who would be treated and who would have access to funding coming primarily from donations. The committee continued until 1971, by which time private insurance, the Division of Vocational Rehabilitation, and state funds had become sufficient to provide treatment for all patients being referred to the SAKC. This means of patient selection was a major factor in the development of the specialty of biomedical ethics and has been a fertile field for discussions by ethicists, social scientists, and physicians (7). However, in 1962 it was a practical response to the unprecedented difficulty of triage in a civilian population of patients who would inevitably die without treatment and who lacked the resources to pay for the treatment.

Age was a major criterion in the selection of patients for dialysis at the SAKC, so when the 15-year-old daughter of a friend of Dr. Albert Babb, Professor of Nuclear Engineering at the University of Washington, developed ESRD in 1963, was rejected by the committee. Babb and Scribner, already collaborating

on building an automated proportioning system to make dialysate for several dialysis stations at the University of Washington Clinical Research Center, decided to make a similar single-patient machine for home hemodialysis that incorporated various fail-safe monitors. This, the precursor of all proportioning hemodialysis equipment, was first used at home in 1964 by the girl aided by her mother (8).

She was not the first patient to be treated by home hemodialysis. In 1961, Yuki Nosé treated a Japanese patient at home using a coil dialyzer immersed in a domestic electric washing machine (9), and Scribner visited India in 1963 to train a physician to do home hemodialysis for a wealthy Madras businessman. In 1963–1964, two other programs were also looking at home hemodialysis as a less expensive alternative to outpatient treatment. In Boston, John Merrill and co-workers were using the twin-coil dialyzer for this, with a nurse going to the home to supervise the treatments (10). At the same time, Stanley Shaldon and his colleagues in London began home hemodialysis using a setup similar to the Seattle system, and they were the first to use overnight home hemodialysis (11). This was possible because of the monitoring by the equipment and because the Scribner shunt and low-resistance Kiil dialyzer allowed hemodialysis without a blood pump. Treatment was relatively inefficient, some 10–12 hours of dialysis two or three times weekly, so it was logical to use overnight dialysis, with the patient sleeping at least some of the time. Home hemodialysis proved to be as effective as outpatient hemodialysis and considerably less expensive, because it did not require the presence of staff. Consequently, Scribner and Shaldon pursued development of equipment to simplify the procedure in the home and to ensure maximum safety. The resulting fail-safe monitoring is now a feature of almost all single-patient hemodialysis equipment (12,13).

In 1966, a home hemodialysis training program was begun at the SAKC, and shortly thereafter it was decided that all new patients admitted to the Seattle program must be treated by home hemodialysis because the center was having serious financial difficulties. Resources were almost nonexistent to provide additional space, staff, and support of even the carefully selected patient population. Home hemodialysis allowed available funds to be used to treat the largest possible number of patients. Shortly thereafter, the 47 patients already dialyzing as outpatients at the

SAKC were encouraged, cajoled, and persuaded to change to home hemodialysis, and eventually 44 of these were successfully trained. This change was helped by the decision of the Washington State Department of Vocational Rehabilitation to support home hemodialysis by paying for the equipment and training, and for 6 months of supplies, equipment service, and other support for eligible patients.

One important change with home hemodialysis was how physician follow-up was provided. Originally, all dialysis patients were followed by physicians at the center. With home hemodialysis, patients were returned to the care of their referring physicians after completion of training and their return home.

Support for the home hemodialysis program at the SAKC came from Scribner, who had recently developed the University of Washington's Coach House facility by modifying several rooms in a local motel to become a free-standing home dialysis training unit. More than 50 patients from the SAKC and from elsewhere in the United States and abroad were trained for home hemodialysis here during the 1960s (14). Staff from the Coach House helped SAKC staff develop their training program. A very similar home hemodialysis program was developed at the dialysis unit at Sacred Heart Hospital in Spokane (15), so by 1970, more than 90% of all dialysis patients in Washington State were on home hemodialysis. The SAKC training program continued to grow and to develop, and in 1972, with the aid of an educational consultant, it pioneered the use of videotapes for home hemodialysis training. This shortened average training time significantly (16).

Experience with home hemodialysis soon showed its many advantages for patients. Besides a reduced risk of hepatitis and other infections, these included increased patient independence, a feeling of accomplishment, and a greater opportunity for rehabilitation than with outpatient dialysis. In contrast, patients treated in the facility very easily became dependent on the nursing staff. Similar advantages have since been reported after other treatment technologies were moved into the home.

While these developments with home hemodialysis were occurring, Scribner's group was also working on modifying peritoneal dialysis for use with ESRD patients. Fred Boen and Henry Tenckhoff developed a closed peritoneal dialysis fluid supply system to minimize the risk of peritonitis (17,18), and Tenckhoff devised the first effective indwelling

peritoneal catheter, still the mainstay for all forms of long-term peritoneal dialysis (19). As a result, home intermittent peritoneal dialysis (IPD) became possible for some patients. Tenckhoff followed this by developing an automated system for on-line preparation of peritoneal dialysate using reverse osmosis and ultraviolet light to sterilize the fluid (20). Even so, while some patients were successfully treated by IPD in Seattle and elsewhere, home peritoneal dialysis was not widely used prior to the introduction of continuous ambulatory peritoneal dialysis (CAPD) by Robert Popovich and Jack Moncrief in Austin, Texas, in 1976 (21). Since then, CAPD and modifications such as continuous cyclic peritoneal dialysis (CCPD) have become the most widely used forms of home dialysis in the United States and elsewhere.

Home Dialysis in the United States and the Medicare ESRD Program: 1973–1997

Home hemodialysis had proved to be both clinically effective and cost-effective and was being used by more than 40% of the 11 000 or so dialysis patients in the United States when the Medicare ESRD Program began in July 1973. However, shortly thereafter, the proportion of patients treated by home hemodialysis in the United States began to decline. There were several reasons for this.

With almost universal Medicare coverage, the composition of the dialysis patient population changed rapidly as compared with that of the 1960s (22) and has continued to change. For example, between 1977 and 1993, the median age of new patients increased from 54 to 60 years, and the number of new patients with ESRD due to diabetes increased from 7.7% to 35.2% (23,24). The number of Black and Native American patients also increased because of the very high incidence of hypertensive renal disease and diabetes in these populations. In 1993, Blacks comprised 12.5% of the U.S. population, but accounted for 29.1% of all new ESRD patients and, because of their lower mortality rate, 31.4% of the prevalent ESRD population (24). As a result of the changes in the patient population, there are now many more patients unsuited for home hemodialysis based on medical or social grounds. In addition, with ready access to dialysis facilities across the United States, patients have become much freer to select not only their modality of treatment but where and by whom this will be performed.

Availability of what was then generous funding from the government encouraged the development of many new dialysis units, so providing improved access to care. However, it also helped encourage development of for-profit outpatient dialysis facilities, and these now treat more than 58% of dialysis patients in the United States (24,25). In the past, for-profit units have been reluctant to encourage home dialysis (26), and this appears to be continuing. In addition, in 1973 the Medicare reimbursement to both the physician and the facility for outpatient dialysis was much better than for home dialysis. This was a significant financial incentive to expand outpatient hemodialysis units and to discourage patients from selecting home hemodialysis.

Physician bias regarding treatment modalities may also be important (27). A survey of selected U.S. nephrologists under the age of 50 showed most would prefer home hemodialysis to kidney transplantation or CAPD for themselves. Despite this, there was a marked disparity between what they preferred for their patients and their actual practice (28,29). In part, this reflects the relative complexity of home hemodialysis, which requires a structured training program lasting 3 – 8 weeks, as compared to a week or so for CAPD training. In addition, home hemodialysis requires an extensive support system to provide 24-hour availability of training staff for telephone consultation and ready maintenance and servicing of equipment as well as provision of supplies. Today, most nephrologists also lack personal experience with a home hemodialysis program and are therefore skeptical of its safety, effectiveness, and benefits.

As a consequence of these and other factors, the proportion of patients treated by home hemodialysis in the United States declined throughout the 1970s and by 1980 was down to 4.6%. However, with the introduction of CAPD, home dialysis in total has increased, and between 1980 and 1993 the percentage of dialysis patients on some form of home dialysis increased from 6.2% to 16.3%. At the same time, the percentage of patients on CAPD and other forms of peritoneal dialysis increased from 1.6% to 16.1%, while that of patients on home hemodialysis declined from 4.6% to less than 1.3% (23,24). Thus the increased use of home dialysis in recent years has been solely due to the increase in various forms of home peritoneal dialysis. Elsewhere in the world, home hemodialysis has continued to be used, particularly

in Australia and New Zealand (17% of dialysis patients), the United Kingdom (8%), France (7%), and Canada and Germany (2%) (24). Only in Australia was there an increase in the absolute number of home hemodialysis patients between 1984 and 1993. It is interesting to speculate on reasons for these national differences in the approach to the treatment of ESRD.

By virtue of being a home treatment, CAPD provides many of the same advantages for the patient as home hemodialysis and is also less expensive than outpatient dialysis. Unfortunately, after 2 years, less than 40% of patients started on CAPD or CCPD remain on this modality, primarily because of problems with peritonitis, and very few of those who experience treatment failure are then trained for home hemodialysis. Consequently, these patients soon lose the benefits associated with home dialysis.

There remain isolated pockets of facilities offering home hemodialysis in various places in the United States. For example, in Washington State at the end of 1995, 10.2% of dialysis patients were on home hemodialysis and 14.6% on peritoneal dialysis; in the Northwest Kidney Centers' regional program, 14.5% of 882 dialysis patients were on home hemodialysis and 11.5% on peritoneal dialysis (30). Thus where dialysis programs remain committed to home hemodialysis, this option can still be used successfully.

One major change since the early years is the use of paid helpers to assist home hemodialysis patients, rather than a family member or friend, and this has proved extremely useful. Because of the success of such a program in Seattle, in 1980 the Health Care Financing Administration (HCFA) funded three multicenter studies of home hemodialysis using "paid aides." These studies showed that the number of patients choosing home hemodialysis could be increased significantly by providing funding for a dialysis aide or by paying a family member, and this was particularly effective in programs associated with nonprofit dialysis facilities. Although there was a significant variation in cost between different programs, home hemodialysis with an aide cost an average of \$119 per treatment, 17% of which was the cost of the aide. This home hemodialysis cost was 77% of the cost of outpatient dialysis at the same facility and 82% of the cost of outpatient dialysis at 23 "control" facilities (31). These studies showed that at that time it was possible to pay an aide or family member to help with home hemodialysis without the total cost exceeding

that of outpatient dialysis. Despite this, Congress introduced "composite rate" reimbursement in 1983, which pays the same for dialysis in a center or at home and specifically excludes payment for a home dialysis aide as a Medicare-allowable charge. As a result, a home hemodialysis program using paid aides has to pay for these separately.

Several years ago, Congress asked the HCFA to undertake a demonstration project looking at the advantages of providing staff-assisted home hemodialysis for patients with severe medical problems and a life expectancy of less than 6 months. Usually, such patients are best treated in a facility. Only some 90 patients meeting these criteria were entered into the study, and only 21 actually went home to do hemodialysis with an aide. These latter patients had a lower mortality than the controls, but the numbers were much too small to establish statistical significance (32).

In contrast to CAPD and other home treatments such as home respiratory therapy and parenteral nutrition (33), home hemodialysis so far has not been seen as a major revenue generator and, with one exception several years ago, has not generally attracted for-profit dialysis corporations. In fact, when the Medicare ESRD Program began in 1973, home dialysis was inadequately reimbursed, and only with the introduction of the composite rate in 1983 was reimbursement for home hemodialysis raised to the same level as for outpatient hemodialysis. This was intended to provide an incentive to encourage home dialysis, although the surplus generated was also intended primarily to offset any program losses with outpatient dialysis. Even today, when the cost of a home dialysis helper is excluded, home hemodialysis is the least expensive dialysis modality (34).

Recent developments: 1994–1997

The last three years have seen a revival of interest in home hemodialysis. At the 1994 American Society of Nephrology meeting, the late Robert Uldall reported on 6 patients treated by nightly home hemodialysis, and this work has been continued by Andreas Pierratos and his colleagues (35). This program has now treated 15 patients dialyzed for 8–10 hours during sleep, 5–7 nights weekly, using an Uldall–Cook Silastic jugular vein catheter as blood access and modified Fresenius dialysis equipment. Special precautions are taken to prevent accidental blood-line

separation. Monitoring of dialysis functions is carried out remotely by modem. Dialyzers are reused to minimize expense and patient effort. Dialysate flow is 100 or 200 mL/min, blood flow is 300 mL/min, and with a 0.4 m² polysulfone dialyzer there is greater than 90% equilibration of urea between plasma and dialysate effluent.

With this regimen, the weekly removal of urea, phosphate, and β_2 -microglobulin far exceeds that with thrice-weekly hemodialysis, and patients' serum urea and creatinine levels are close to normal throughout the week. Cumulative weekly Kt/Vs are some 7.7, compared with 5.0 with very adequate conventional hemodialysis. Patients are able to stop phosphate binders, increase their dietary phosphate intake, and stop taking angiotensin-converting enzyme inhibitors and calcium channel blockers, treating their hypertension with beta blockers only or, in some cases, without drugs. Patients sleep soundly, have greatly increased energy and stamina, and their days are free for work and other activities. With dialyzer reuse the cost of this treatment is no more than that of CAPD and less than that of thrice-weekly outpatient hemodialysis (36).

Also in the last 2 years, Rod Kenley of Aksys Ltd. has described the development of new equipment designed specifically for home hemodialysis (37). This is highly automated and will allow many patients to do home hemodialysis without a helper, what Belding Scribner has described as "a one button machine." The equipment should be available for testing next year and, if it fulfills its potential, will make home hemodialysis a readily available treatment option again.

The other developments have been several reports on patient survival with the various dialysis modalities based on data from a national study by the United States Renal Data System. Using a national random sample from patients starting ESRD treatment in 1986 and 1987 and a Cox proportional hazards model and adjusting for age, race, sex, diabetes as cause of renal disease and comorbid factors present before the onset of ESRD, the survival with home hemodialysis had a relative risk of 0.58 ($p = 0.03$) compared with the survival of patients dialyzed as outpatients (38). This confirms reports from individual dialysis programs (39–41). At the same time, concern has been growing over whether peritoneal dialysis as generally practiced provides adequate dialysis for many patients (42). The

hospitalization rate for peritoneal dialysis patients is 14% higher than for center hemodialysis patients, even after adjusting for comorbid conditions (43), and the relative risk (RR) of death, after adjusting for age, race, sex, diabetic status, and duration of dialysis, is higher in peritoneal dialysis patients than in center hemodialysis patients (RR = 1.19; $p < 0.001$) (44). This risk is greater in older patients than in younger patients and increased in diabetic patients compared with nondiabetic patients (RR = 1.38 vs 1.11; both $p < 0.001$) and in females compared with males (RR = 1.30 vs 1.11; both $p < 0.001$). In addition, after adjustment for demographic factors, deaths due to infections, myocardial infarction, withdrawal from dialysis, cerebrovascular disease, other cardiac causes, and "other causes" were significantly more frequent in peritoneal dialysis patients compared with hemodialysis patients (45). These results are particularly interesting since they all come from the same database. In light of these developments, now is an appropriate time to reexamine how to make home hemodialysis available on a wider scale through existing dialysis facilities and at a more economical cost. This could best be done by the development of regional centers for home hemodialysis training and support services.

History tends to repeat itself. More than 30 years ago the high cost of dialysis treatment led to the development of single-patient dialysis equipment primarily intended for home hemodialysis. This soon became the standard equipment for outpatient dialysis as well. For some 20 years or so, home hemodialysis, even with a paid helper, remained a cost-effective treatment, and outpatient hemodialysis, the most widely used treatment, also produced a substantial profit. However, because the composite rate was never increased, and in fact was decreased, profit margins for outpatient dialysis have steadily declined while the number of patients and the costs of salaries and supplies have steadily increased. The development of automated equipment and the interest in daily or nightly hemodialysis have revived interest in home hemodialysis. Fortuitously, this comes at a time when the problems of adequacy with long-term CAPD as well as with hemodialysis are being recognized, and at the same time the advantages of home hemodialysis are being rediscovered. As a result, the next 5 years should see home hemodialysis again achieve its rightful place as the optimum treat-

ment choice for many more patients than is the case now.

Plus ça change, plus c'est la même chose.

The more things change, the more they are the same.

Alphonse Karr, *Les Guêpes*, January 1849 (6th series, 1859), p. 305.

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