Delayed Dialyzer Reprocessing for Home Hemodialysis

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Although dialyzer reuse for home hemodialysis (done by patients at home) has been in practice since the 1960s, it is now almost completely abandoned. The need for dialyzer reuse resurfaced with the renewed interest in daily/nightly forms of home hemodialysis and the associated increase in operating costs. We describe a method of dialyzer reuse based on reprocessing of dialyzers at the center, after they had been stored in a refrigerator at home for 1 week by the patient. Transportation of the dialyzers by either the patient or a transportation service was acceptable to the patients. Despite the lower number of reuses, possibly related to the delayed processing, dialyzer reuse in this setting provided significant financial benefits. Experience with this process for 3 years has not disclosed any negative effects after the initial logistical issues related to dialyzer transportation were resolved.

In summary, weekly dialyzer reprocessing at the center provides a solution to the need for dialyzer reuse for the home hemodialysis patient.

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Key words

Dialyzer reuse, home hemodialysis, daily hemodialysis, nocturnal hemodialysis

Introduction

In the early days of dialysis, dialyzer reuse was begun out of necessity; the original dialyzers were not disposable. Dialyzers were disassembled and rebuilt after each dialysis [1]. The same dialyzer was used by more than 1 patient, but fresh dialyzing membranes and tubing were used for each dialysis; the parts in contact with blood were sterilized with formaldehyde. A process for reuse without rebuilding was developed for patients at home and allowed for three treatments, requiring disassembly and cleaning only during the weekend [1]. Therefore, dialyzer reuse was practiced for the convenience of patients.

The first reuse — in the conventional sense — at home started in 1966 at the University of Washington Home Dialysis Program [1]. Introduction of disposable dialyzers simplified dialysis, but at the same time increased the cost. Therefore, dialyzer reuse was necessary to maintain the same cost of dialysis since, at that time, dialysis in the U.S. was not funded federally. After the introduction of federal funding for dialysis, reuse at home was not financially essential but it helped provide other services to patients. No longer a necessary procedure, dialyzer reuse became optional; its prevalence decreased in the early 1980s to 62% of the Northwest Kidney Center (Seattle, WA, U.S.A.) home patients [1]. Dialyzers were reused an average of 3.2 times, with automatic discontinuation at 6 reuses. Patients practiced manual reuse, which included blood tubing. Automated reuse for home dialysis was also introduced with machines such as the HPR (Renal Systems, Minneapolis, MN, U.S.A.), the Echo (Mesa Laboratories, Wheat Ridge, CO, U.S.A.), and the HR-3000 (Colorado Medical, Evergreen, CO, U.S.A.) [2]. Since then, home dialyzer reuse has decreased further, almost to extinction. The reasons for this decline included the lack of absolute financial necessity, the extra time burden imposed by the procedure, psychological factors, perceived hazards from chemical exposure, esthetics, the fear of possible decrease in dialyzer performance [1], and most importantly, the perceived need for immediate reprocessing of dialyzers. Although reprocessing of dialyzers at home has almost disappeared, the Sacred Heart Kidney Center in Spokane, Washington, still has 18 patients who practice reuse at home using the HR-3000 automated machine (personal communication, J. Stevens, 2000), despite the fact that the machines are no longer produced. Bleach and formaldehyde are used for reprocessing and the dialyzers are reused an average of 4.5 times.

The need for dialyzer reuse at home has resurfaced with the renewed interest in short daily dialysis and long nightly hemodialysis [3], and the increased cost imposed by these methods related to the high dialysis frequency. In the present paper we describe the method of delayed dialyzer reprocessing for home nocturnal hemodialysis that we practiced at the Wellesley Hospital in Toronto.

Patients and methods

The dialysis technique

Nocturnal hemodialysis began at the Wellesley hospital in Toronto, Canada, in April 1994. The project was transferred to the Humber River Regional Hospital in 1998. The method is described in detail elsewhere [4]. Briefly, it is a form of home hemodialysis done by the patient or a helper. It lasts 6 –

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10 hours nightly and is done 6 – 7 times per week during sleep. Central venous catheters, arteriovenous fistulas, and grafts have been used [5]. Remote "live" monitoring of machine functions has been used. In view of the hemodynamic stability of the method, a partner was not required. During the period of the study, the blood flow during dialysis was kept relatively high (250 – 350 mL/minute) to prevent clotting, while dialysate flow was low (100 mL/min) as a way to prevent "excessive dialysis." Currently, wide ranges of blood and dialysate flows are used [6]. During the study, we used the Fresenius 2008H dialysis machine (Fresenius Medical Care, Lexington, MA, U.S.A.) and small surface area polysulfone dialyzers (Fresenius F40 and F50). Currently, larger dialyzers are also used (Fresenius F80).

Dialyzer reuse

TRANSPORTATION LOGISTICS AND SAFETY MEASURES

Dialyzer reuse was instituted in 1995 as a method of containing the cost of nightly dialysis. Patients were instructed to rinse their dialyzers in the morning after dialysis with heparinized saline using the remaining heparin in the heparin pump. The dialyzers were then stored in a small refrigerator at home, provided to the patients free of charge. Once per week, the dialyzers (six or seven) were placed in a bag labeled with the patient's name (Fig. 1) and taken by the patient to the local outlet of a collaborating network of laboratories (MDS Laboratories, Toronto, ON, Canada). Patients would also deliver blood or dialysate samples to the laboratory as required. The bag was exchanged with another bag waiting at the laboratory outlet, which contained the same patient's reprocessed dialyzers. The bag containing the unprocessed dialyzers was in turn transported to the Wellesley Hospital, Toronto, using the pre-existing laboratory sample transportation system of MDS Laboratories. At the hospital, the bag was exchanged with another bag of reprocessed dialyzers of the same patient. Thus, three dialyzer bags were rotated between the home of the patient, the laboratory, and the hospital. The use of the laboratory transportation system obviated the need for patients to visit the hospital on a weekly basis. Patients were also supplied with a small number of unused dialyzers for use in case of failure of the transportation system.

Microbiological cultures and limulus amebocyte lysate (LAL) endotoxin assays were done from samples taken from the contents (normal saline) of the stored used dialyzers after the delayed transportation, but prior to the next reprocessing. In order to ensure that patients were using their own dialyzers and that these dialyzers were indeed reprocessed, the following measures were taken:

1. All dialyzers were labeled with the patient's name and were processed prior to the first use.
2. The dialyzer bag was labeled with the patient's name.
3. A double-faced card in the transparent sleeve of the dialyzer bag described the destination of the bag (laboratory or hospital). The card was turned to display the appropriate destination.
4. A red disposable plastic seal was attached to the zipper of the bag at the hospital, after the reprocessed dialyzers were packed and the zipper was closed (Fig. 1). The seal had a serial number identifying the technician responsible for the reprocessing of the dialyzers. A broken seal upon arrival to the patient would indicate that the bag did not contain processed dialyzers.
5. A paper seal was attached around each end cap of the dialyzer. A broken or absent seal would suggest that the dialyzer had not been reprocessed (Fig. 2).

FIGURE 1 Dialyzer bag.

DIALYZER REPROCESSING

Dialyzers were reprocessed at the Wellesley Hospital with Renalin, using the automated Renatron System and the Renalog computerized database (Minntech Corp., Minneapolis, MN, U.S.A.). Standard procedures and

FIGURE 2 Reprocessed dialyzer with intact paper seal.

precautions were followed in adherence to the Association for the Advancement of Medical Instrumentation (AAMI) standards [7]. Briefly, reprocessing included a "preclean" and a "clean" cycle. The dialyzers were acceptable if they maintained more than 80% of the original volume, the pressure test was successful, and they had good appearance without evidence of excessive clotting. The water treatment system operation was monitored daily, microbiological cultures and LAL endotoxin assays were monitored monthly, and the system was cleaned and disinfected quarterly. The volume test verification was performed daily and logged, and the presence of sterilant was tested and recorded on all reprocessed dialyzers. All dialyzer and patient data were entered in the computer and labels were produced for each dialyzer.

PATIENT EDUCATION

Patients were trained to follow the reuse process, with special emphasis on the following points:

1. After dialyzer use and prior to bag delivery to the laboratory
   i. discard dialyzers with poor appearance or other obvious defects, and
   ii. ensure that the destination label on the dialyzer bag is the hospital's.
2. When picking up dialyzer bags at the laboratory, ensure that
   i. the destination label on the bags received shows the laboratory's address,
   ii. your name appears on the label of the received bag,
   iii. the red safety seal on the bags received is not broken, and
   iv. the bag is opened and contents are inspected before leaving.
3. Prior to dialyzer use, ensure
   i. proper appearance of the dialyzer,
   ii. correct patient name is on dialyzer,
   iii. intact paper seal on the dialyzer cap (Fig. 2), and
   iv. absence of Renalin in the dialyzer.

Patients

Forty patients have been trained and, currently, 30 patients are on nocturnal hemodialysis at home. Six patients were on nocturnal hemodialysis when the reuse program was introduced, and 19 patients when the reuse program was discontinued 3 years later. Details of patient characteristics have been described elsewhere [4].

Results

Prior to program implementation, bacteriological studies and endotoxin assays of dialyzer contents stored in the refrigerator for 1 week met AAMI standards [7]. The average number of reuses, using Fresenius F40 and F50 dialyzers, was 5.09 ± 3.92. After the early period of implementation, no significant problems were encountered. The reuse program was discontinued in 1998 at the time of transfer of the nocturnal hemodialysis program to the Humber River Regional Hospital in Toronto. The decision to discontinue reuse was made following an attractive purchase contract that made reuse less financially significant.

The only complications occurred during the early phases of program implementation, and were related to gaps in the organizational process that were subsequently corrected. In three cases, patients received their own unprocessed dialyzers. In two of these cases, the patients used their own, unprocessed dialyzers. In one case, this resulted in a S*taphylococcus epidermidis* bacteremia treated successfully with antibiotics and catheter removal. In yet another case, a patient received another patient's dialyzers, but this was readily identified and the dialyzers were not used. After the initial period and full implementation of the above rules, no further problems were encountered. No clinical problems or laboratory changes were identified as related to dialyzer reuse.

The decrease in the yearly cost of nocturnal hemodialysis due to dialyzer reuse is depicted in Fig. 3. Although the specific amounts may differ in different centers, it is apparent that most of the financial benefits are realized by the first few reuses of the dialyzers. Therefore, the number of reuses achieved using delayed reprocessing of the dialyzers provided most of the possible financial benefits.

Discussion

Dialyzer reuse is practiced widely in the U.S. and less frequently in Canada and elsewhere. Although dialyzer reuse involving reprocessing of the dialyzers at home by patients has been done in the past, the practice has been almost completely abandoned. The process was relatively complex and increased the workload of the patients. At this time, there is no simplified system for dialyzer reuse at home. In view of the declining prevalence of home hemodialysis and the reluctance of patients or providers to consider home

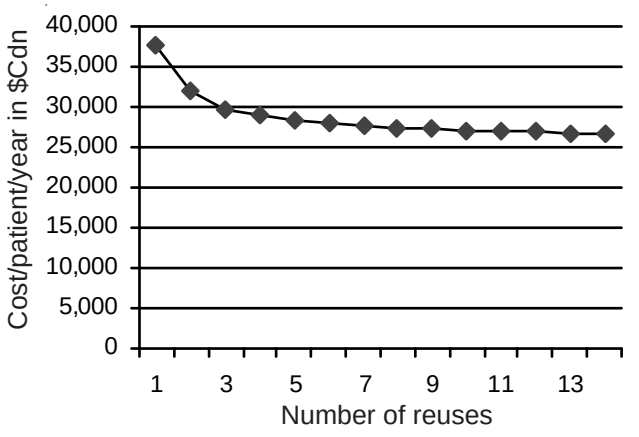

FIGURE 3 Yearly cost of nocturnal hemodialysis, per patient, with increasing number of dialyzer reuses.

hemodialysis as the selected treatment, dialyzer reuse at home would make the choice of home hemodialysis even less attractive. Lastly, the lower cost of home hemodialysis compared to in-center hemodialysis provides little financial incentive for such an approach. The idea of a fully automated dialysis machine performing dialyzer reprocessing *in situ* has been discussed in the past [2]. Such a machine is currently under development but not yet available [8].

Delayed dialyzer reprocessing, as practiced by our group and later adopted by others, provided a solution to the need for dialyzer reuse for home dialysis. To our knowledge, such an approach has not been described before. In our experience, patients do not consider the minimal increase in their workload, including a weekly visit to the local laboratory outlet or the hospital for exchange of their dialyzer bags, a burden. This visit is often necessary to deliver blood samples for routine laboratory tests. Fears concerning the safety of such a process were not substantiated. This method of reuse was followed in our center for 3 years, with only one complication with proper labeling and dialyzer transportation in the early stage of policy and procedure development. This prompted improvement, and no significant complications were encountered later. The quality of nocturnal hemodialysis was very high and dialyzer reuse did not appear to have any appreciable negative effects on patients or their laboratory test results. The problems we encountered were related to the need for measures to ensure that the patients received their own dialyzers, and that these dialyzers had indeed been reprocessed. These problems were resolved during the early period of the reuse method by implementing the rules described above. We incorporated an intermediate step in the delivery of the dialyzers through the use of a pre-existing laboratory sample transportation system. This became necessary in view of the large distances within the city of Toronto. This step is not necessary if patients can exchange the dialyzers directly at the reprocessing center. This simpler process would also minimize the probability of errors.

The number of dialyzer reuses achieved was relatively low — fewer than six. This small number of reuses may have been related to delayed reprocessing. The financial benefits from dialyzer reuse are realized from the first few reuses; therefore, the financial impact of reuse on the yearly cost of the method was substantial. In Canada, the savings related to dialyzer reuse, as well as the lower personnel cost and other center-related expenses, decreased the operating cost of nocturnal hemodialysis to levels below the cost of in-center hemodialysis. With the move of the nocturnal hemodialysis program to the Humber River Regional Hospital, Toronto, dialyzer reuse was discontinued. The absence of an established dialyzer reuse facility in the new hospital, the excellent deal with the supplier of the consumable supplies for dialysis, as well as the increasing costs of dialyzer transportation, made dialyzer reuse less attractive.

In summary, we have demonstrated that a delay in reprocessing used and refrigerated dialyzers for up to 1 week is feasible and safe. The storage and weekly transportation of dialyzers to the hospital was well accepted by patients. Despite the relatively low number of reuses achieved, delayed dialyzer reprocessing can help decrease the cost of daily and nightly hemodialysis, depending on the cost of dialyzers and reprocessing.

References

1 Sawer TK. Dialyzer reuse: Home patient considerations. In: AAMI Standards and Recommended Practices. Vol 3: Dialysis. Arlington, VA: Association for the Advancement of Medical Instrumentation, 1995; 244–6.

2 Boag JT. Reuse in the home: Some considerations for automated systems. In: AAMI Standards and Recommended Practices. Vol. 3: Dialysis. Arlington, VA: Association for the Advancement of Medical Instrumentation, 1995; 243.

3 Pierratos A. Daily hemodialysis: Why the renewed interest? Am J Kidney Dis. 32(suppl 4):S76–82, 1998.

4 Pierratos A, Ouwendyk M, Francoeur R, Vas S, Raj DS, Ecclestone AM, Langos V, Uldall R. Nocturnal hemodialysis: Three-year experience. J Am Soc Nephrol. 9:859–68, 1998.

5 Pierratos A, Goluboff D, Ouwendyk M. Vascular access for nocturnal hemodialysis. J Am Soc Nephrol. 10(September): 215A, 1999.

6 Pierratos A. Nocturnal home haemodialysis: An update on a 5-year experience (Abstract). Nephrol Dial Transplant. 14:2835–40, 1999.

7 AAMI Committee. Reuse of hemodialyzers. In: AAMI Standards and Recommended Practices, Vol. 3: Dialysis. Arlington, VA: Association for the Advancement of Medical Instrumentation, 1995; 93–118.

8 Kenley RS. Tearing down the barriers to daily home hemodialysis and achieving the highest value renal therapy through holistic product design. Adv Ren Replace Ther. 3:137–46, 1996.