A New Automatic Coil Dialyzer System for ‘Daily’ Dialysis

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INTRODUCTION

Within the past decade, maintenance dialysis, with the passive-flow artificial kidney, has progressed from once a week 20 to 24 hour continuous dialysis (Hegstrom et al, 1961) to a twice a week dialysis schedule of 10 to 16 hours in an effort to curtail progressive neuropathy (Hegstrom et al, 1962). With the introduction of dialysis in the home, treatment was increased to three times weekly for about 8 hours per dialysis with the 2 layer Kiil dialyzer (Curtis et al, 1965). Sophisticated automatic equipment was developed to allow the patient to sleep overnight while on haemodialysis (Eschbach et al, 1966), and the length of dialysis remained 8 to 10 hours thrice weekly because peripheral neuropathy and difficulty in controlling hypertension in several patients occurred when less dialysis time per week was used (Eschbach et al, 1967). The total number of hours of dialysis per week at home was similar to the less frequent dialytic treatment, but the pre-dialysis BUN and serum creatinine values were generally lower with three times weekly dialysis than with twice weekly dialysis, and the patients were able to eat a more liberal diet in protein and sodium (Eschbach et al, 1967). This experience indicated that more frequent dialyses of the same total time per week was more effective clinically. Additionally, Bell and his associates (1965) in an analogue simulation of dialysis length and frequency concluded that daily short dialyses were very effective in lowering the average concentration of substances which rapidly equilibrate between the intracellular and extracellular fluid compartments.

The present study was performed using initially an automatic fluid delivery system with 2 layer Kiil dialyzer to clinically evaluate the concepts and effectiveness of frequent short dialyses with this system and secondly an automatic patient operated fluid delivery system for coil type dialyzer was
built to permit frequent short coil dialyses and, as a necessary economy measure, to re-use the coil dialyzer in a similar manner as that for the Kiil (Pollard et al, 1967) but modified so that dialysis 'start-up' and 'clean-up' times would be minimized.

'DAILY' DIALYSIS

PATIENT EXPERIENCE
Our home haemodialysis training unit began in March 1967, and 23 patients have been trained in home haemodialysis techniques utilizing a 2 layer Kiil dialyzer (Cole et al, 1963) and MAKS/900 [Bio/Systems, Inc., Santa Monica, California, USA] fluid delivery system (DePalma et al, 1968) to perform 8 to 10 hours three times a week evening or overnight unattended haemodialysis. Beginning in August 1968, selected patients already on home dialysis or being trained for thrice weekly dialysis, were advised to dialyze 4 to 5 hours five times a week. Seven patients were placed on 5 times a week dialysis with Kiil re-use techniques rather than 3 times a week unattended overnight dialysis because of the following reasons:

1. Dialysis dys-equilibrium: with recurrent severe headache and increasing blood pressure beginning in the latter half of haemodialysis which were only partially relieved by medication (patient G.M.).

2. Cannula malfunction and/or clotting: not remedial by surgical revision or Warfarin anti-coagulation, and exacerbated by hypovolaemia from usual ultrafiltration (patients D.T. and C.T.).

3. Hypotension: recurrent, severe, and associated with necessary ultrafiltration:
   a. One patient post bilateral nephrectomy with hypotension and oedema (K.B.).
   b. One patient with partial paraplegia secondary to industrial accident (K.C.).
   c. One patient chronically unable to tolerate more than minimal degree of ultrafiltration, cause unknown (G.L.).


Table I is a list of the several parameters compared in these seven patients. Six patients for a total of 36 patient-months have been maintained on 4 hours 5 times a week. These patients had been formerly maintained from 2 to 22 months by 8 hour 3 times a week haemodialysis. The seventh patient was placed on 5 hours 5 times a week for the past 4 months to compensate for the 10 hours 3 times a week dialysis he formerly was on and to compensate for persistent poor cannula blood flow and intermittent clotting. The average pre-dialysis serum creatinine taken 48 hours following the last
TABLE I. Frequency and Length of Dialysis

<table>
<thead>
<tr>
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<th>8-10 hr 3x/wk</th>
<th>4-5 hr 5x/wk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysis time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dialyzer Blood Flow rate, mean</td>
<td>190 ml/min</td>
<td>188 ml/min</td>
</tr>
<tr>
<td>BP, Standing Pre-dialysis, mean</td>
<td>160/100</td>
<td>147/91</td>
</tr>
<tr>
<td>Weight, Pre-dialysis, mean</td>
<td>150 lbs</td>
<td>154 lbs</td>
</tr>
<tr>
<td>Serum Creatinine, Pre-dialysis, mean</td>
<td>12.2 mg%</td>
<td>13.2 mg%</td>
</tr>
</tbody>
</table>

Dialysis on 3 times a week dialysis was 12.2 mg%. Standing blood pressures pre-dialysis decreased in 6 of 7 patients and the seventh (J. O.) remained modestly hypertensive at blood pressures of 160/110. There was a mean weight increase of 5 lbs with a moderate decrease in the mean blood pressure. It is possible, therefore, that the pre-dialysis serum creatinine on 5 times a week dialyses of 13.2 mg% reflects increased muscle mass rather than less effective dialysis. Three of the patients, K.C., C.T. and G.L. who were trained and then sent home on 5 times a week dialysis increased their serum albumins to greater than 5 g% and gained an average of 11 lbs within six months on home dialysis.

Diet
Only minimal dietary restrictions were placed upon these patients. They were instructed to avoid the use of salt and large amounts of dairy products and were advised to supplement their diet with fresh fruits or other potassium containing food because of the frequency of hypokalaemia. The use of supplemental water soluble vitamins was advocated.

Pre- and post-dialysis time with the Kiln Dialyzer
'Start-up' time using the Kiln and an automatic fluid delivery system with reuse of the Kiln 5 times continued to consume 45 minutes to an hour in preparation. 'Clean-up' time with the help of a spouse or relative varied from half to one-and-a-half hours. Rebuilding a 2 layer Kiln dialyzer either with two persons or solo, wet or dry, averaged one to one-and-a-half hours per week.

The additional time necessary to perform these two additional dialyses including preparation and clean-up approximated the amount of extra time on dialysis with thrice weekly haemodialysis. Because of the excessive demands made on patient's time and since 5 of the 7 patients were working a minimal 40 hour week, and in some instances 50 to 60 hours, studies were initiated to investigate the possibility of using at home a pumped coil dialyzer and to develop a fluid delivery system which would allow rapid use and re-use of coil artificial kidneys.

28
CLINICAL EVALUATION OF THE ULTRA-FLO 100 COIL DIALYZER
[Travenol Laboratories, Morton Grove, Illinois, USA]

Clearance Data
The Ultra-flo 100 was tested in vitro and in vivo and compared with the performance characteristics of the 2 layer modified Kil1 dialyzer. Table II lists the results of the clearance data of the two dialyzers and indicates that at similar dialyzer blood flow rates the clearance of BUN, creatinine and phosphate are significantly greater with the coil dialyzer when both dialyzers are tested in single pass dialysate systems.

<table>
<thead>
<tr>
<th>Ultra-flo 100 coil</th>
<th>2 layer Kil1</th>
<th>P</th>
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<tbody>
<tr>
<td>$Q_D$ 500</td>
<td>550 ml/min</td>
<td></td>
</tr>
<tr>
<td>$Q_B$ 191 ± 22</td>
<td>176 ± 62 ml/min</td>
<td>&gt; .05</td>
</tr>
<tr>
<td>$C_{BUN}$ 113 ± 20</td>
<td>84 ± 27 ml/min</td>
<td>&lt; .05</td>
</tr>
<tr>
<td>$C_{CR}$ 93 ± 16</td>
<td>68 ± 27 ml/min</td>
<td>&lt; .05</td>
</tr>
<tr>
<td>$C_{HPO4}$ 76 ± 22</td>
<td>49 ± 17 ml/min</td>
<td>&lt; .05</td>
</tr>
</tbody>
</table>

Studies to determine length of dialysis
Figure 1 illustrates the derived BUN and creatinine data of 10 patient studies. Blood samples were drawn pre- and post-dialysis, at 20, 40 and 60 minutes, and at 2, 3, 4, 5, 6 hours from the arterial line of the coil dialyzer. Samples were analyzed for BUN and creatinine and the percent change of BUN and creatinine were calculated for each of these time points using as 100% the difference in creatinine or BUN between the pre-and post-dialysis blood samples. The average dialysis time was 7 hours and 12 minutes. There was no statistical difference between the percent change in BUN or creatinine at any given time interval, so that these data were combined and illustrated at a single point plus or minus one standard deviation. Excluding rebound (Shackman et al, 1963) this graph reflects the percent per time total of BUN and creatinine removed. A mean of some 57% of BUN and creatinine is removed after only 3 hours of a 7 hour and 12 minutes dialysis, and a mean of 70% after 4 hours. In a similar manner the percent change of BUN and creatinine in some 10 Kil1 dialyses with blood samples drawn at 0, 1, 2, 3, 4 and pre- and post-dialysis were analyzed for an average dialysis length of 7 hours and 48 minutes. There was no significant difference in percent change per time of BUN and creatinine between the coil and Kil1 dialyses. These data would seem to indicate that 2 to 3 hour 5 times a week coil dialysis might equal the results obtained with a Kil1 dialyzer 4 hours 5 times a week and that
in either instance short frequent dialysis would very effectively remove the measured solutes.

Coil re-use technique
Re-use of the coil dialyzer at least 5 times is necessary to permit the coil dialyzer to economically compete with the Kiil. Prior to permitting patient dialysis re-use of coils the following study was performed:

1. Following haemodialysis using a continuous infusion of at least 1,000 units per hour of Heparin, the coil was rinsed for 2 minutes with 98% tap water at 500 cc/min or until the outflow from the dialyzer outflow line was clear.

2. A 500 ml graduate cylinder of 1-1/2% Purex [Purex Corporation, Ltd., Lakewood, California, USA] (sodium hypochlorite, 500 ppm) was pumped through the arterial blood line, coil and venous tubing and allowed to remain in the coil for a timed 15 minutes.

3. The coil was then again rinsed with tap water for 15 minutes and filled with 2% Formalin and stored in the canister of the fluid delivery system.

4. The canister was drained of Formalin before initiating dialysis. (Dialysis was initiated in the usual manner as with Formalin stored Kiils.)

Nine coils were rinsed in the above manner after being used on patients. They were stored at least 24 hours, rinsed, tested for residual Formalin, filled with canine blood and the outflow dialyzer pressure elevated to 200 mm Hg. The dialysate was then checked with a Hemastik 10 minutes after initiation of dialysis and if the test for blood was negative the coil was rinsed, stored
again and retested until the coil had been re-used 5 times. At the end of 5 re-uses the coil was unwrapped and inspected. Of the coils used only one ruptured on the first re-use. The 8 coils re-used 5 times, on inspection showed no unusual evidence of accumulation of blood or blood products more than is seen in re-used Kiil dialyzers. All bacteriological cultures of these coils were negative.

AN AUTOMATIC HOME COIL DIALYZER SYSTEM

PRINCIPLES
An automatic patient operated fluid delivery and monitoring system for use with any type of coil dialyzer and designed for rapid 'start-up' and 'clean-up' was built and clinically evaluated. The principles of safety, man-machine interface, man-machine monitoring, machine logic, and sterilization for the machine are similar to those discussed by the authors in a recent communication (DePalma et al, 1968). Changes in the present system were made to:

1. mechanically simplify the machine
2. permit modular replacement of the basic components
3. further simplify the presentation of the controls to the patient
4. permit the use of a blood pumped coil system with safety similar to a pumpless system.

Machine Outline
Figure 2 is a line drawing of the components that make up this system. The cartridge heater is optional and would allow operation from a single cold water line, otherwise, the usual connections require hot and cold water sources with a drain source less than 20 inches above the floor level.

![FLUID SCHEMATIC, AUTOMATIC COIL DIALYZER SYSTEM](image)

Dialysate is prepared by a hydraulically operated proportioning unit combining a liquid concentrate and water, with the ability to adjust the dilution ratio ± 10% of the nominal 1:33. It is fully self-priming.

The conductivity monitor is fully temperature compensated with adjustable alarm points and is a direct reading unit with an expanded scale. Flushing and sterilizing of the system are accomplished without readjusting the high and low conductivity limits.

Fixed upper and lower temperature limits are incorporated at 95°F - 105°F (35°C - 40.6°C). These limits are shown in red on the front panel temperature indicator. While the value of the low temperature alarm limit is still moot, it was felt that the additional small cost was warranted to protect against the possibility of venous spasm with potential damage to the cannulated vein.

Dialysate delivery flow rate is set internally for constant operation at 500 ml/min. However, the system will permit operation at any flow rate between 300 cc/min and 1000 cc/min.

The use of the by-pass/operate valve is direct and simple. This 2-way plastic valve, when closed, electrically overrides the conductivity and temperature monitors permitting any fluid to run through the system and through the relief valve to drain. In this mode the flow rate, normally set at a fixed 500 cc/min for dialysis, switches to a high flow of over 1000 cc/min. This permits a rapid system start-up, flushing out sterilizing fluid with dialysate, and flushing out cooled water with warm. When both monitors are within limits this valve may be opened and the system then delivers dialysate at 500 cc/min.

Patient controls on the dialysate supply system have been reduced to what we feel may be an irreducible minimum. To start manufacture of dialysate the patient presses the on/off switch and turns the by-pass/operate valve to by-pass. When the temperature and conductivity are within limits he turns the valve to operate. No further steps need be taken. The system is now delivering the dialysate within the prescribed conductivity and temperature limits at the fixed flow rate.

To flush the system the patient replaces the concentrate container with a container of Formalin or sodium hypochlorite and presses the rinse switch. The system now automatically produces the prescribed sterilizing fluid at a high flow rate.

A self-sealing quick disconnect coupling is provided on the tempered water line (not shown) to provide warm water at a high flow rate for flushing the dialyzer for re-use.

Safety
The cardinal principle of safety was retained. The dialysate flow is immediately halted during dialysis unless the dialysate is within the prescribed
conductivity and temperature limits. The blood pump is electrically locked out when the machine is switched into the rinse mode.

Metal contact with dialysate (Matter et al., 1969) was avoided except as required for monitoring probes. Metal contact on the water side was minimally used. A simpler power loss alarm was retained.

Monitor alarm test before each dialysis was simplified by using momentary hold switches which sweep the meter needles across the alarm limits.

The overall system was divided into two basic modules: a dialysate supply module and a coil dialyzer module. The one unit delivers monitored dialysate to the other through a quick disconnect self-sealing coupling. Each module is readily handled separately and may be shipped by common carrier for exchange to remote locations.

The dialyzer module of this machine is a combination of the single pass coil apparatus developed in 1964 (Rubini et al., 1964), a roller blood pump, and associated arterial and venous pressure monitors. The unit packaging including the necessary blood tubing hangers, maintains the entire extracorporeal circuit in full view of the patient. The roller blood pump is electrically interlocked with the dialysate supply module, and cannot operate in the rinse mode, eliminating the possibility of dialysing blood against any fluid except monitored dialysate.

Figure 3. Spatial relationship of machine and patient
The relationship of the machine and its controls to the patient can be seen in Figure 3 which shows that the patient can both visually and manually operate his own dialysis. Some 12 patients have been dialyzed on this machine and a patient is now being trained for home dialysis with this machine. Training techniques continue to be evolved in efforts to decrease patient training time.

REFERENCES