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The Use of Electrolyzed Solutions for the Cleaning and Disinfecting of Dialyzers

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Abstract: Recently, the use of electrolyzed solutions has attracted considerable interest in Japan. This study investigates the efficiency of electrolyzed solutions as disinfecting agents (DA) in the reuse of dialyzers and compares their efficiency to that of other disinfectants currently in use. The following 3 methods were employed. First, the rinsing time and rebound release of reused dialyzers were measured and compared after electrolyzed solutions, electrolyzed strong acid aqueous solution (ESAAS) and electrolyzed strong basic aqueous solution (ESBAS), made from reverse osmosis (RO) water (ESAAS, ESBAS; Generating apparatuses: Super Oxseed α 1000, Amano Corporation, Yokohama, Japan), 2% Dialox-cj (Teijin Gambro Medical, Tokyo, Japan), and 3.8% formalin were used as DAs. This involved performing dialysis with 2 types of dialyzers: a cellulose acetate membrane (CAM) dialyzer and a polysulfone membrane (PSM) dialyzer. The dialyzers were cleaned and disinfected using the different DA and left for 48 h. Next, after performing dialysis the dialyzer membranes were cleaned with a saline solution (0.9% NaCl) and RO water and then cleaned with the various DA. These membranes were observed using a scanning electron microscope (SEM) to check for the presence of physical and biological contaminants. Finally, in vitro tests were performed to determine the level of dialyzer clearance when PSM dialyzers were reused after having been cleaned and disinfected with the electrolyzed solutions. The rinsing time results for both the CAM and PSM dialyzers showed the electrolyzed solutions (ESBAS and ESAAS) as being undetectable within 10 min. With regard to the rebound release, for both the CAM and PSM dialyzers, the electrolyzed solutions were undetectable at all checking times between 30 and 240 min. Observation by SEM showed that cleaning with both ESAAS and ESBAS left the fewest contaminants, and cleaning with 2% Dialox-cj left the highest level of contaminants in the CAM dialyzers. With regard to experiments concerning use in vitro, no major changes in the dialyzer clearance were noticed after 6 uses. In every experiment, the previous investigations showed the electrolyzed solutions to be superior to 3.8% formalin and 2% Dialox-cj DA for the reuse of dialyzers. **Key Words:** Electrolyzed strong acid aqueous solution—Electrolyzed strong basic aqueous solution—Cellulose acetate membrane dialyzer—Polysulfone membrane dialyzer—Formalin—Dialox-cj.

When an electrolyzed solution is formed by adding 500 to 1,000 ppm NaCl to tap or reverse osmosis (RO) water, and electrolyzing it in a container partitioned with a polyester membrane, a strong acidic electrolyzed solution is generated on the anode side with a pH of 2.3 to 2.7, an oxidation-reduction potential (ORP) of +1,000 mV, and an available chlorine content of 10 to 50 ppm. Simultaneously, a strong alkaline electrolyzed solution is generated on the cathode side with a pH of more than 11, an ORP of −800 mV, and an available chlorine content of 0.1 to 2 ppm.

Electrolyzed strong acid aqueous solution (ESAAS) has an especially strong bactericidal ability (1–3). We tested and compared the bactericidal effectiveness of this strong acidic disinfecting agent with 0.1% sodium hypochlorite and 2% Dialox-cj against 11 types of bacteria, 2 types of candida, and 4 types of viruses (4). ESAAS proved to be the most effective (Table 1).

In Japan, ESAAS is being used increasingly for both oral and general rinsing and disinfection in medical care (6) and has attracted interest as a

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TABLE 1. *The results of disinfecting tests using various disinfectants for 60 s*

Sample bacteria or viruses		Amount	Time (s)							
			ESAAS (RO water)			ESAAS (tap water)			0.1% sodium hypochlorite solution	DIALOX
			α 1000	OXC–10M	AT–250	α 1000	OXC–10M	AT–250		
Pseudomonas aerugeninosa	27853	7.30×10^5	<5	<5	<5	<5	<5	<5	<5	<5
Xanthomonas maltopihilia	13697	3.88×10^5	<5	<5	<5	<5	<5	<5	<5	<5
Escherichia coli	O–157	4.60×10^5	<5	<5	<5	<5	<5	<5	<5	<5
Escherichia coli	25922	2.92×10^5	<5	<5	<5	<5	<5	<5	<5	<5
Serratia marcescens	81000	1.56×10^6	<5	<5	<5	<5	<5	<5	<5	<5
Acinetobacter calcoaveticus	23055	2.40×10^5	<5	<5	<5	<5	<5	<5	<5	<5
Staphylococcus aureus	25923	1.36×10^5	<5	<5	<5	<5	<5	<5	<5	<5
Staphylococcus aureus (MRSA)	Clinical strain	4.70×10^5	<5	<5	<5	<5	<5	<5	<5	<5
Streptococcus pneumoniae	JOM2876	4.00×10^4	<5	<5	<5	<5	<5	<5	<5	<5
Streptococcus pyogenes	12344	1.30×10^5	<5	<5	<5	<5	<5	<5	<5	<5
Bacillus cereus	14579	4.20×10^4	>60	>60	>60	>60	>60	>60	>60	>60
Candida tropicalis	13803	1.00×10^5	<5	<5	<5	<5	<5	<5	<5	30
Candida albicans	11006	6.00×10^4	<5	<5	<15	<5	<15	<5	30	30
Coxsackievirus type B1	Conne.5 Strain	$10^{5.5}$	<10	<10	<10	<10	<10	<10	a	a
Echovirus type 7	Wallace Strain	$10^{6.5}$	<10	<10	<10	<10	<10	<10	a	a
Herpes simplex type 1	HF Strain (oral)	$10^{5.0}$	<10	<10	<10	<10	<10	<10	a	a
Herpes simplex type 2	UW268 Strain (genital)	$10^{5.0}$	<10	<10	<10	<10	<10	<10	a	a

The testing procedures are as described in *The Effect of Electrolyzed Strong Acid Aqueous Solution on Hemodialysis Equipment* (4).

The six types of ESAAS were made from tap and RO water using 3 ESAAS generating apparatuses: Éø1000 (Amano Corporation, Yokohama, Japan), OXC–10M (Miura Denshi Co. Ltd., Akita, Japan), AT–250 (Aiken Industrial Co. Ltd., Kochi, Japan), 0.1% sodium hypochlorite (chlorine concentration 1,000 ppm), 2% Dialox-cj (Teijin Gambro Medical, Tokyo, Japan) were chosen as samples and their bactericidal /antiviral effect were compared. ESAAS worked faster.

The numbers were given by ATCC (American Type Culture Collection).

a: A cytopathic effect was impossible due to the toxicity caused by the sample in the culture cells.

promising replacement for conventional disinfecting agents (DA).

However, in comparison to ESAAS, little research has been done on electrolyzed strong basic aqueous solution (ESBAS). Its general dissolving effect on proteins is well known and was reported to be especially strong at high pH (7).

Being interested in the bactericidal ability of ESAAS, we purchased electrolyzed solution producing equipment from 3 manufacturers and, in September 1994, formed a research group to study the use of electrolyzed solutions in the disinfecting of dialysis system pipelines. Good results were obtained with regard to its effectiveness, safety, and operational costs (8–10). We also reported the effectiveness of ESAAS for the disinfecting and cleaning of the surgical wounds of dialysis patients, general wounds, hands, and surgical tools (11).

In this study, we investigated the effectiveness of ESAAS and ESBAS as cleaners and disinfectants in the reuse of dialyzers.

METHODS AND MATERIALS

Rinsing time and rebound release

Two kinds of dialyzer were used: A cellulose acetate membrane (CAM) dialyzer (FB-150A, 1.5 m^2, Nipro Inc., Osaka, Japan) and a polysulfone membrane (PSM) dialyzer (PS-1.6UW, 1.6 m^2, Kawasumi Laboratories Inc., Tokyo, Japan).

To measure the residual contaminants, formaldehyde under the acetyl acetone method (sensitivity 0.5 ppm) was used for the 3.8% formalin, chlorine residuals under the ortho-tolidine method (sensitivity 0.05 ppm) were used for ESAAS, and hydrogen peroxide under the peroxide test (Merck, Darmstadt, Germany) (sensitivity 0.5 ppm) was used for the 2% Dialox-cj.

Prerinsing preparation

After dialysis, blood inside the dialyzer was conveyed back to the patient. The blood compartments were rinsed with 500 ml of saline solution (0.9% NaCl) at a pump speed of 350 ml/min.

Rinsing time

Both the blood and dialysate compartments were cleaned with RO water for 15 min at a pump speed of 500 ml/min. In the case of the 3.8% formalin and 2% Dialox-cj, both the blood and dialysate compartments were filled and left for 48 h. In the case of the electrolyzed solutions, both the blood and dialysate compartments were flushed (single-pass) with ESBAS for 1 min and then filled and left for 5 min. This was followed by a single-pass flush with ESAAS for 1 min, after which they were filled and left for 48 h. Forty-eight hours later, the DA were cleared. The blood and dialysate compartments were rinsed with a saline solution and dialysate, respectively, at a pump speed of 500 ml/min. Every 10 min, the

amounts of formaldehyde, hydrogen peroxide, and chlorine residuals were measured until they became undetectable.

Rebound release

After the previously mentioned rinsing was completed (40 min for 3.8% formalin and 20 min for ESAAS and 2% Dialox-cj), the residual contaminants in the blood and dialysate compartments were measured. The dialysate compartment was clamped, and the blood compartment was filled with saline solution (0.9% NaCl) and circulated in a closed circuit for 240 min at a pump speed of 250 ml/min, during which the amount of dissolved contaminants was measured. The total volume was set at 230 ml for each experiment. Dialysate was inserted in the dialysate compartment, the inlets and outlets were closed, and the pump remained turned off. The saline solution (0.9% NaCl) was sampled during circulation at 30 min intervals up to 240 min, and the amount of dissolved matter was measured.

Scanning electron microscope

The same dialyzer types as those in the previous tests were used: The low-flux membrane cellulose acetate membrane dialyzer and the high-flux membrane polysulfone membrane (PSM) dialyzer. All the sampled dialyzers were used for a 4 h period of dialysis and then chosen at random. The cleaning method was carried out as follows. Immediately after the completion of dialysis, the blood compartment of the dialyzer was rinsed using 500 ml of saline solution (0.9% NaCl). Then, after the dialyzer was reset in the blood circuit, both the blood and dialysate compartments were cleaned with RO water at a pump speed of 300 ml/min for 5 min. Furthermore, as shown in Table 2, Group A was cleaned with RO water only; Group B was cleaned with RO water and ESAAS; Group C was cleaned with RO water, ESAAS, and ESBAS; Group D was cleaned with RO water and 3.8% formalin; and Group E was cleaned with RO water and 2% Dialox-cj. A new dialyzer was used as the control group. The blood and dialysate compartments of the dialyzers were cleaned at a pump speed of 300 ml/min. Each DA was kept in the line for 48 h, and then both compartments were rinsed with RO water for 5 min. The central part of the dialyzer fibers was cut in cross-section and fixed using a phosphate buffer solution. The cleaning effectiveness was then observed by measuring the amount of residual contaminants and comparing them with those of a new control group dialyzer.

In vitro test of dialyzer clearance after reuse

The dialyzer used was the PSM dialyzer (PS-1.6UW, 1.6 m^2, Kawasumi), and the clearances of urea and creatinine were measured. A special grade of creatinine and urea was used. A new dialyzer was connected to the "blood" circuit, and priming was performed with 1,000 ml of saline solution (0.9% NaCl). The reagents urea and creatinine were dissolved in the 40 L of dialysate at concentrations of 100 mg/dl and 10 mg/dl, respectively, to produce a test solution. Both the arterial blood tubing inlet and venous blood tubing outlet of the closed blood circuit were submerged in the test solution. Dialysis was performed for 4 h with the test solution at a pump speed of 180 ml/min. The dialysate, after a single pass, was pumped into the dialysate compartment at 500 ml/min. Just after the start and at the end of dialysis, the amount of urea and creatinine at the dialyzer inlet and outlet ports was measured, and the level of clearance was calculated. After 4 h of dialysis, the dialyzer was cleaned with ESBAS and ESAAS and then reused. This was performed the same way as previously described.

The process was repeated, and dialysis was performed again. Dialysis was performed 7 times in total. The level of clearance of urea and creatinine before and after dialysis was calculated for the third, fifth, and seventh times. The method of calculation for the clearance was calculated as follows: clearance (ml/min) = [dialyzer IN (mg/dl) – dialyzer OUT (mg/dl)/dialyzer IN (mg/dl)] × flow rate (ml/min).

TABLE 2. *Disinfecting method of the dialyzer sample that was observed by a scanning electron microscope (SEM)*

	RO water cleaning	Disinfecting agent	Soaking time	RO water cleaning
Group A	5 min	None	48 h	5 min
Group B	5 min	ESAAS (10 min)	48 h	5 min
Group C	5 min	ESBAS (5 min), ESAAS (5 min)	48 h	5 min
Group D	5 min	3.8% Formalin (5 min)	48 h	5 min
Group E	5 min	2% Dialox-cj (5 min)	48 h	5 min
Control Group	Unused dialyzer			

Observations were made on cellulose acetate and polysulfone dialyzers after 4 h of dialysis.

For each group of dialyzers, the central part of the dialyzer fibers were extracted and fixed using a phosphate buffer solution. The contaminants were then observed through SEM and compared with the new dialyzers. The pump speed for cleaning Groups A, B, C, D, and E was 300 ml/min.

RESULTS

Rinsing time

Residual amounts of ESAAS and ESBAS were undetectable in both compartments of the CAM and PSM dialyzers after only 10 min of rinsing and remained undetectable.

For 3.8% formalin, 0.7 ppm was detected in both the blood and dialysate compartments at 10 min with the CAM dialyzers and became undetectable after 20 min. With the PSM dialyzers, 3.8% formalin was undetectable at all check times. The 2% Dialox-cj was undetectable at all check times for both the CAM and PSM dialyzers.

Rebound release

The results for each DA are shown in Tables 3 and 4. As shown, ESAAS and ESBAS were undetectable after 30 min of circulation in both the CAM and PSM dialyzers and remained undetectable.

The dissolution concentration for 3.8% formalin with CAM dialyzers was 27.7 ppm at 30 min, 36.1 ppm at 60 min, 45.3 ppm at 120 min, 54 ppm at 180 min, and 55.3 ppm at 240 min. With the PSM dialyzers, the results showed concentrations of 4.7 ppm, 6.4 ppm, 8.4 ppm, 9.6 ppm, and 10.1 ppm at the same respective check times. For the 2% Dialox-cj with the CAM and PSM dialyzers, the results showed dissolution of 0.5 ppm after 30 min of circulation, and the same 0.5 ppm after 120 min and 240 min.

SEM observations

As shown in Table 5, no biological contaminants were observed on the unused dialyzers, and only slight physical contaminants were detected. For Group A, biological and physical contaminants were observed more on the CAM dialyzers than on the PSM ones. For Group B, more biological contaminants were detected on the CAM dialyzers than on PSM ones while a medium level of physical contaminants was observed on both dialyzers. For Group C, the biological and physical contaminants were the lowest among all groups, and the internal condition was the best for both the CAM and PSM dialyzers. For Group D, biological contaminants were low on the CAM dialyzers; however, it was ineffective in the prevention of biological contaminants on the PSM dialyzers and physical contaminants on the CAM and the PSM dialyzers. For Group E, the level of biological and physical contaminants was high on the CAM dialyzers but low on the PSM dialyzers.

Therefore, the results show that contaminants were fewest when cleaning was performed with ESAAS and ESBAS, physical contaminants were high on both CAM and PSM dialyzers with 3.8% formalin, and both types of contaminants were high on CAM dialyzers with 2% Dialox-cj. Figure 1 shows the physical contaminants on the PSM dialyzers in Groups C and D, and Fig. 2 shows their biological contaminants. Figure 3 shows the biological contaminants on the CAM dialyzers in Groups C and E.

TABLE 3. *Detected levels of DAs*

Time	Disinfecting agent		
	ESBAS, ESAAS (n = 4)	3.8% Formalin (n = 4)	2% Dialox-cj (n = 4)
30 min	Undetectable	27.7 ppm	0.5 ppm
60 min	Undetectable	36.1 ppm	
120 min	Undetectable	45.3 ppm	0.5 ppm
180 min	Undetectable	54.0 ppm	
240 min	Undetectable	55.3 ppm	0.5 ppm

Rebound release in a reused cellulose acetate membrane dialyzer with the residual amount of each disinfecting agent at different rinsing times.

TABLE 4. *Detected levels of DAs*

Time	Disinfecting agent		
	ESBAS, ESAAS (n = 4)	3.8% Formalin (n = 4)	2% Dialox-cj (n = 4)
30 min	Undetectable	4.7 ppm	0.5 ppm
60 min	Undetectable	6.4 ppm	0.5 ppm
120 min	Undetectable	8.4 ppm	0.5 ppm
180 min	Undetectable	9.6 ppm	0.5 ppm
240 min	Undetectable	10.1 ppm	0.5 ppm

Rebound release in a reused polysulfone membrane dialyzer with the residual amount of each disinfecting agent at different rinsing times.

In vitro test of dialyzer clearance after reuse

The level of clearance after dialyzer reuse is shown in Table 6. The level of clearance just after the start of the first dialysis was 177 ml/min for urea and 126 ml/min for creatinine, and just before the end of dialysis was 179 ml/min for urea and 144 ml/min for creatinine. The level of clearance just after the start of the third dialysis was 175 ml/min for urea and 136 ml/min for creatinine, and just before the end of the third dialysis was 179 ml/min for urea and 126 ml/min for creatinine. The level of clearance just after the start of the fifth dialysis was 177 ml/min for urea and 135 ml/min for creatinine, and just before the end of the fifth dialysis was 179 ml/min for urea and 130 ml/min for creatinine. There was no change from the initial measurements. The level of clearance just after the start of the seventh dialysis was 167 ml/min for urea and 115 ml/min for creatinine, and just before the end of the seventh dialysis was 159 ml/min for urea and 116 ml/min for creatinine. As the Table 6 shows, a decrease in dialyzer perfor-

TABLE 5. *Contamination observed in dialyzers using a SEM*

	Membrane	Biological contaminant	Physical contaminant	Notes
Group A	Cellulose acetate	+ – + +	+ – + +	Excessive biological and physical contaminant present
	Polysulfone	+	+	Biological and physical contaminant present
Group B	Cellulose acetate	+ – + +	± – +	Moderate biological and physical contaminant present
	Polysulfone	± – +	± – +	Moderate biological and physical contaminant present
Group C	Cellulose acetate	± – +	± – +	Few contaminants present
	Polysulfone	±	±	Only trace amount of contaminants present
Group D	Cellulose acetate	+	+ – + +	Biological contaminant present; excessive physical contaminant present
	Polysulfone	+ – + +	+ – + +	Excessive biological and physical contaminants present
Group E	Cellulose acetate	+ – + +	+ – + +	Excessive contaminant present
	Polysulfone	±	±	Small amount of contaminants present
Control group	Cellulose acetate	–	±	Few physical contaminants present
	Polysulfone	–	±	Few physical contaminants present

Only trace contaminants (±), few contaminants (± – +), moderate contaminants (+), excessive contaminants (+ +).
SEM: scanning electron microscope.
Observations were made on cellulose acetate and polysulfone dialyzers after 4 h of dialysis. After each dialyzer was pretreated with saline solution (0.9% NaCl) and RO water, they were cleaned by the methods given for Groups A through E in Table 2. Then, each DA was kept in the line for 48 h, after which both compartments were rinsed with RO water. The central part of the dialyzer fibers were extracted and fixed using a phosphate buffer solution. The contaminants were then observed through SEM.

mance of 5.65% for urea and 8.73% for creatinine was found to have occurred from the first dialysis.

DISCUSSION

When tap water or RO water mixed with 500 to 1,000 ppm NaCl is electrolyzed in a container partitioned with a polyester membrane, ESAAS containing high levels of O_2 and Cl_2 are formed on the anode side, and ESBAS containing large amounts of H_2 are formed on the cathode side. About 15 years ago in Japan, the ESAAS that forms on the anode side was found to have a strong bactericidal effect (12) and since then has seen a great deal of use in the food industry (13), agriculture, and dentistry (5). Recently, it also was being used to prevent nosocomial infection (14) and to disinfect bed sores (11) and endoscopes (15). On the other hand, ESBAS, which formed on the cathode side, is weak at sterilization but effective at cleaning, particularly proteins (7). Accordingly, after using the dialyzer, ESBAS was used as a cleaner and then ESAAS as a sterilizer. We feel that these solutions are most suitable for cleaning and disinfecting when considering economic and environmental factors since they return to normal water after use.

The advantages of ESAAS are its instantaneous disinfecting qualities and its low toxicity when compared to other disinfectants. As for safety tests on animals, no toxicity of ESAAS was observed when ingested orally by mice, and no damage was observed on the mucus membrane of rabbits' eyes.

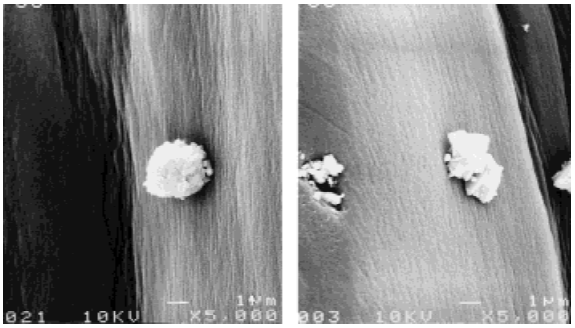

FIG. 1. Shown are the physical contaminants of the PSM observed through SEM. The photo on the left shows an ovoid structure attached to the inside of the membrane that was cleaned with the electrolyzed solution, and the photo on the right shows a crystalloid pattern attached to the inside of the membrane that was cleaned with 3.8% formalin.

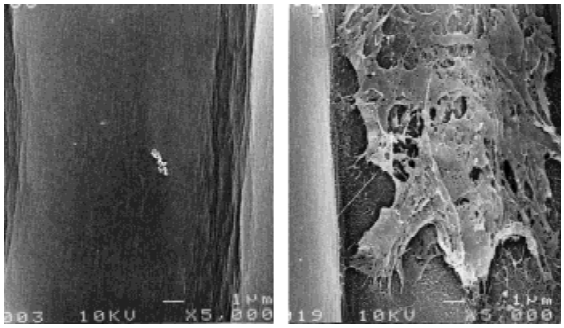

FIG. 2. Shown are the biological contaminants of the PSM observed through SEM. The photo on the left shows flocculation attached to the inside of the membrane that was cleaned with the electrolyzed solution, and the photo on the right shows a fibrous, dense mesh-type network attached to the inside of the membrane that was cleaned with 3.8% formalin.

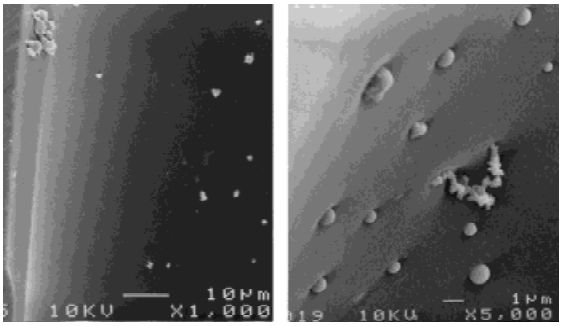

FIG. 3. Shown are the biological contaminants of the cellulose acetate membrane observed through SEM. The photo on the left shows a spotty dispersal of coarse granular particulates attached to the inside of the membrane that were cleaned with the electrolyzed solution, and the photo on the right shows flocculation attached to the inside of the membrane that was cleaned with 2% Dialox-cj.

Also, no problems were reported in accumulative irritation tests on rabbits' skin or in sensitization tests (16).

If ESAAS is kept in the open air, the HClO contained within is activated and is released as chlorine gas. As this release continues and the concentration of chlorine in the solution decreases, its sterilizing ability is reduced. However, storage in an airtight and lightproof container allows its properties to be maintained for up to 1 month. Research reports on ESBAS are few; however, we encountered no change in pH levels when it was stored in airtight and lightproof containers. Nevertheless, as both solutions can be produced in large quantities and at low cost, we believe long-term storage is not an issue.

The frequency of dialyzer reuse differs depending on the country and the type of dialysis facility. In Japan, dialyzers are not reused; in Europe, the reuse of dialyzers is rare; and in the United States, the reuse of dialyzers is quite common.

If we bear in mind the merits previously mentioned and the environmental problems facing society today, we believe that dialyzers should be reused a certain number of times. Of course, this should be done while ensuring that the quality of the dialysis itself is not jeopardized; that is, the parameters for safe dialysis must be maintained.

TABLE 6. *The results of dialyzer clearance tests after dialyzer reuse*

	Urea clearance		Creatinine clearance	
No. of dialyses	Just after start	At end	Just after start	At end
First	177	179	126	144
Third	175	179	136	126
Fifth	177	179	135	130
Seventh	167	159	115	116

Q_B, 180 ml/min; Q_D, 500 ml/min; Clearance units, ml/min; Dialyzer: PSM (PS–1.6UW).

In general, formalin, sodium hypochlorite, peracetic acid disinfectant, and some other solutions are used as DA for the reuse of dialyzers. Residual formalin is known to bring about hemolytic anemia. It can trigger the formation of anti-N form antibodies (17,18). It also was reported that even less than 2 ppm formalin remaining in the dialyzer could produce antibodies (19,20).

In the United States, peracetic acid disinfectant recently has been employed for the reuse of dialyzers more often. The ratio of formalin to peracetic acid disinfectant use was 86 to 12% in 1985, and 40 to 51% in 1993. As shown, the use of peracetic acid disinfectant is overtaking that of formalin (21). A considerable amount of research on peracetic acid disinfectant has been reported. For example, it was reported that due to the use of Renalin (Minntech Renal Systems Inc., Minneapolis, MN, U.S.A.), the death rate increased (22) and the absorption capacity of B2-MG decreased to less than that of formalin or sodium hypochlorite (23). At the same time, Renalin is said to be more effective against bacillus subtilis and nontuberculous mycobacterium than 4% formaldehyde and has a less significant toxic risk to humans and fewer negative effects on the dialyzer (24).

It also was reported that in disinfecting for dialyzer reuse, peracetic acid disinfectant showed better biocompatibility than formalin and sodium hypochlorite (25). Subsequently, there are many reports supporting the use of peracetic acid disinfectant for dialyzer reuse.

Much research has been done on the use of sodium hypochlorite as a disinfectant for dialyzer reuse. For example, it was reported that 4% sodium hypochlorite causes neutropenia (26). While we investigated its bactericidal effect (4), we did not use it for dialyzer reuse.

In this study, we investigated the effectiveness of the electrolyzed solutions made by electrolysis as DA for dialyzer reuse and compared the results in terms of rinsing time, rebound release, and SEM observation. We also investigated the level of dialyzer clearance in vitro.

As explained earlier, dialyzer cleaning and disinfecting was performed with electrolyzed solutions (ESAAS and ESBAS), 3.8% formalin, and 2% Dialox-cj as the DA. The time required until the disinfectants became undetectable (rinsing time) then was measured for each DA. For the CAM dialyzers, 0.7 ppm of 3.8% formalin was still detected after 10

min of rinsing. However, in the PSM dialyzers, all the DAs were undetectable at the check times between 10 and 40 min.

For the rebound release, ESAAS was not detected with either the CAM or the PSM dialyzers at any check time. For 2% Dialox-cj, 0.5 ppm hydrogen peroxide (H_2O_2) was detected with both dialyzer types at all check times between 30 and 240 min. The dissolution of 3.8% formalin with the CAM dialyzers was 27.7 ppm at 30 min, increasing to 55.3 ppm at 240 min; with the PSM dialyzers, it rose from 4.7 ppm to 10.1 ppm at the same times, respectively.

According to another report on rinsing time and rebound release (27), formalin left more residual contaminants than peracetic acid disinfectant. This coincides with the results of this study, but since its experimental methods were different, they will not be discussed here.

As for the observation of the dialyzers by SEM, the contaminants found to adhere to the CAM and PSM dialyzers after their first use were divided into biological and physical contaminants. As shown in the Results, the cleaning and disinfecting by ESAAS and ESBAS left the fewest contaminants. The level of contaminants left by 2% Dialox-cj with CAM dialyzers was the highest.

The cleaning and disinfecting with 3.8% formalin resulted in a low level of biological contaminants with a high level of physical contaminants.

Furthermore, it was shown that disinfecting with the combination of ESAAS and ESBAS was more effective than disinfecting with only ESAAS in terms of eliminating contaminants. As a whole, the CAM dialyzers resulted in more contaminants than the PSM ones.

The distinction between biological and physical contaminants was made as follows. First, an unused dialyzer (control) was observed by SEM. The contaminants observed on this control dialyzer then were defined as physical contaminants while those that appeared after dialysis were defined as biological contaminants. However, we believe it is impossible to precisely determine the nature of the contaminants by observing only their configuration.

Further research based upon a multiple-approach technique, using analytical electron microscopy, x-ray microanalysis, and cell-chemistry analysis, among other methods, is necessary to make an overall assessment.

In the in vitro experiments, the level of dialyzer clearance was measured after the dialyzer was reused. The reduction of the level of dialyzer clearance was minimal, and virtually no changes were noticed from the first use of the dialyzer until the fourth use. However, from the sixth use, a slight drop in dialyzer performance was noticed with both urea and creatinine. The drop was small, however, with the clearance levels for urea and creatinine down 5.65% and 8.73%, respectively, compared to the initial performance.

Up to a 10% loss in clearance for urea and sodium is generally acceptable with dialyzer reuse (28). With the experiments we performed, in which electrolyzed solutions were used for dialyzer reuse, the urea clearance levels for the seventh dialysis were within 5.6% of that of the first dialysis, showing that seven dialyses, or even more, are within acceptable limits. However, in our experiments, we only took measurements up to the sixth dialysis, and therefore further experimentation for a greater number of dialyses is necessary. It also is necessary to perform the experiment under the same conditions for other cleaning solutions as well. Though not mentioned in the test results, there was virtually no change in the dialyzer volume measured from the first use to the sixth use.

All experiments in this study demonstrated that the ESAAS was the most effective disinfectant. However, more research is necessary to investigate the effectiveness of ESAAS with regard to the disinfecting of dialyzers used more than once. Until recently, the effectiveness of ESAAS as a disinfectant was said to be mainly due to the bactericidal effect of the hypochlorous acid, but now it is thought to be due to the synergies of HClO, Cl_2, OH, H_2O_2, and other components (29).

Of these, radicals such as OH and H_2O_2 in particular react with oxygen and destroy bacteria by damaging the cell lipid membrane, denaturing proteins, and preventing enzyme activation by severing the DNA (30). This differs from sodium hypochlorite, which contains only the active disinfectant HClO. Furthermore, sodium hypochlorite is known to have toxic effects such as irritation of the skin and mucus membranes and acute toxicity.

Further research is necessary, however, as the underlying mechanisms of electrolyzed solutions have not been fully elucidated.

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