Use of a New Connector Decreases Peritoneal Dialysis–Related Peritonitis

The most common cause of peritoneal dialysis (PD)–related peritonitis remains infection by gram-positive organisms originating from contamination of the catheter during a fluid exchange. However, peritonitis rates have declined mainly because of technological advances such as improved connection devices and better training programs for caregivers and patients (1,2). Over time, the technology of PD therapy has been further modified in attempt to reduce rates of peritonitis (3). The PIN technology of the Stay•Safe system (Fresenius Medical Care, Bad Homburg, Germany) provides a closed-system disconnection that expels a pin and secures it firmly into the catheter extension, avoiding touch contamination.

In 2008, Fresenius Medical Care introduced to our center a PD transfer set (Stay•Safe Catheter Extension Luer Lock) with a deeply recessed cone on the connector side of the PD system to reduce even further the risk of touch contamination during patient connection. However, no clinical studies to date have investigated the effect of this transfer set on the prevention of peritonitis. The present study was designed to determine whether this new connector system in fact has the potential to lower the incidence of PD-related peritonitis.

METHODS

The study was approved by the local institutional review board. Between May and October of 2008, 37 consecutively treated adult patients dialyzed using the new connector were asked to participate in the study. Of those 37 patients, 5 refused to participate, and 2 transferred to hemodialysis after 3 months and were excluded from the study. The remaining 30 patients gave their informed consent to participation in the study (group II). Of 41 consecutive patients who were treated using the conventional connector in the same months of the preceding year, 36 agreed to the release of their medical information (group I).

Clinical, laboratory, and PD-related infection data were retrieved from electronic medical records. Peritonitis was defined according to International Society for Peritoneal Dialysis guidelines (1). Data are expressed as mean $\pm$ standard deviation unless otherwise specified. Comparisons between systems were made using chi-square tests for categorical data, Student t-tests for parametric data, and Mann–Whitney U-tests

for nonparametric data. Peritonitis-free survival was analyzed using the Kaplan–Meier life table method. Values of p less than 0.05 were considered to indicate statistical significance.

RESULTS

All basic demographic and clinical data were similar in the two groups; however, peritonitis rates were lower in group II than in group I (1 episode in 56.52 patient-months vs 21.76 patient-months, $p = 0.044$, Table 1). The 1-year peritonitis-free survival was estimated to be 72.36% for group I and 90.23% for group II ($p = 0.031$, Figure 1).

Of the 19 episodes of peritonitis in group I, 12 were caused by gram-positive organisms (4 cases each of *Staphylococcus aureus*, *S. epidermidis*, and *Streptococcus viridans*); 1, by a gram-negative organism (*Escherichia*

coli); and 6, by unknown organisms (culture-negative). Of the 6 episodes of peritonitis in group II, 5 were caused by gram-positive organisms (1 case each of *S. aureus*, *S. epidermidis*, and *Strep. agalactiae*, and 2 cases of *Strep. viridans*); and 1, by *Mycobacterium tuberculosis*. Table 2 shows the organism-specific peritonitis rates.

Multiple peritonitis episodes occurred only in 2 group I patients. One experienced 3 episodes: 1 caused by *Strep. viridans*, and 2 that were culture-negative. The other patient had 2 episodes: 1 caused by *S. epidermidis*, and 1 caused by *Strep. viridans*.

DISCUSSION

This is the first prospective study with historical controls to report a significant reduction in peritonitis with the new connector for the PD transfer set, the Stay•Safe Catheter Extension Luer Lock System, which is

TABLE 1
Demographic, Clinical, and Peritonitis Data for the Study Subjects

Parameter	Group I	Group II	p Value ^a
Patients (n)	36	30	
Mean age (years)	54.67±15.04	56.50±13.73	0.603
Sex (n men)	27	23	0.566
Body mass index	23.24±3.31	23.75±3.23	0.527
Nonsmokers (n)	26	23	0.796
Alcohol consumption (n)	6	5	0.907
Diabetic ESRD (n)	16	12	0.561
Serum albumin (mg/dL)	3.61±0.47	3.49±0.50	0.353
Comorbidities (n)			
Diabetes	16	13	0.751
Hypertension	32	28	0.814
Heart disease	17	15	0.952
Visual disturbance	18	13	0.438
Study period (days)	349.33±43.50	345.00±37.80	0.664
Peritonitis rate (eps/pt-mo)	21.76	56.52	0.044
Causative organisms (n)			
Gram-positive	12	5	0.551
Gram-negative	1	0	0.508
Others	0	1	0.116
Negative culture	6	0	0.302

ESRD = end-stage renal disease; eps/pt-mo = episodes per patient-month.

^a Determined using the Student t-test (parametric data), Mann–Whitney U-test (nonparametric data), or chi-square test (categorical data).

Figure 1 — Kaplan–Meier survival analysis of the first peritonitis-free interval in patients in groups I and II. The 1-year peritonitis-free survival rate was estimated to be 72.36% in group I and 90.23% in Group II ($p = 0.031$).

TABLE 2
Organism-Specific Peritonitis Rates, Episodes per Year at Risk

Organism	Peritonitis rate Group I	Peritonitis rate Group II
Gram-positive		
<i>Staphylococcus aureus</i>	0.12	0.04
<i>Staphylococcus epidermidis</i>	0.12	0.04
<i>Streptococcus viridans</i>	0.12	0.07
<i>Streptococcus agalactiae</i>	—	0.04
Gram-negative		
<i>Escherichia coli</i>	0.03	—
<i>Mycobacterium tuberculosis</i>	—	0.04
Culture-negative	0.17	—

protected by a pin and disinfection cap to minimize the risk of contamination.

Among the four means by which bacteria can be introduced to the body during dialysis, touch contamination of the intraluminal route is the most common, and this category of contamination is reduced by improvements in connection technology (4). Few studies on this topic have been published; only disconnect systems (the twin-bag and Y-set systems) were specifically proved to be effective compared with conventional spike systems (5).

Our data suggest that the new connection system has the potential to reduce PD-related peritonitis. Furthermore, our findings show a lower prevalence of gram-positive peritonitis—a surrogate index of the risk for touch contamination (3)—with use of the new connector, indicating that the new system might improve patient safety by reducing the probability of touch contamination.

The use of historical controls in the present study is an important limitation. Information bias could potentially lead to biased estimates of the effects of treatment. However, all controls were consecutively treated patients who were well matched with their counterparts in group II, and all had been enrolled during the same months of the previous year and had been followed for similar lengths of time, which might minimize the bias attributable to lack of randomization and use of historical data. Additionally, all participants in both groups were educated and managed by the same physicians and nurses under a well-established PD education program that has been running for more than 10 years at our center. Although a well-designed randomized controlled study is needed to properly address the issue, the manufacturer has decided to provide only the new connector system as of 2008.

Despite the suboptimal study quality attributable to the historical controls, our results suggest that catheter-related interventions can potentially reduce the risk of PD-related peritonitis.

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DISCLOSURES

The authors have no financial conflicts of interest to declare.

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