EXPERIENCES WITH ASSISTED PERITONEAL DIALYSIS IN CHINA

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◆ **Objective:** About half the patients on peritoneal dialysis (PD) in China need to be assisted by family members or home assistants. We explored whether these patients have a higher risk for peritonitis and death compared with self-care PD patients.

◆ **Methods:** We prospectively followed 313 incident PD patients until death or censoring. This cohort was divided into assisted and self-care PD groups according to the independence of bag exchange. Data on baseline demographics, Charlson comorbidity index, biochemistry, and residual renal function were recorded during the first 3–6 months. The outcome variables were first episode of peritonitis and all-cause mortality.

◆ **Results:** Of the 313 patients in this cohort study, 122 needed assistance in performing bag exchanges (86 from a family member, 36 from a home assistant); the remaining 191 patients did not need assistance. During a follow-up period averaging 44.5 months, 122 patients developed a first episode of peritonitis, and 135 patients died. Compared with patients having a family assistant, those with a home assistant had similar peritonitis-free and survival times, but a higher risk of mortality after adjustments for variables such as age, sex, Charlson comorbidity score, hemoglobin, serum albumin, and residual renal function. Furthermore, compared with self-care patients, assisted patients overall had a similar peritonitis-free time, but a higher risk of mortality, even after adjusting for covariates.

◆ **Conclusions:** Based on our single-center experience in China, we conclude that assisted PD is a good option for patients with poor self-care ability. This result provides evidence for recruiting patients who need assistance to PD programs in China.

KEY WORDS: Assisted peritoneal dialysis; peritonitis; mortality.

Although peritoneal dialysis (PD) has many advantages, such as ease of training and accommodation, simple facilities, and good mobility, the procedure is difficult for patients who are physically disabled or noncompliant. Many studies have demonstrated that self-care difficulties contribute to the underutilization of PD as a kidney replacement therapy (1–3). Accordingly, assisted PD provides a good alternative in Europe. Lobbedez *et al.* (4) found that, compared with self-care patients, patients with nurse assistance had a higher peritonitis rate and a lower technique survival rate. Povlsen *et al.* (5) reported a higher risk of peritonitis and mortality in assisted patients than in autonomous patients, all of whom were elderly (>65 years) and receiving automated PD.

The reasons that may potentially lead to unfavorable outcomes in assisted PD include inconsistent home care and inadequate training and education for assistants (6). However, in the past few years in our PD patient pool, patients and their home care providers have both been trained at dialysis initiation to be familiar with the procedures of bag exchange, volume control, and blood pressure and glucose monitoring. The major sources of home care providers are stable and provide good training.

We conducted the present study to examine the risk factors for peritonitis and death under two different conditions: PD assisted by trained home care providers and self-care PD. We hypothesized that in China, assisted PD by well-trained and compliant assistants can be as good as self-care PD with regard to peritonitis. We explored this issue in a cohort study. Answering this question was expected to help generate evidence for the enrolment of patients who need assistance into the PD program.

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METHODS

PATIENTS

Our single-center cohort study enrolled 313 incident patients who started PD in our unit from July 2002 to February 2007. Demographics and comorbidities were recorded within the first 3 – 6 months, including age, sex, height, weight, body mass index (BMI), Charlson comorbidity index, presence of diabetes, presence of home helper (family member or home assistant paid by the family). Other variables—including serum albumin, hemoglobin, and residual renal function (RRF) at baseline—were also collected. Biochemical profile, including hemoglobin and serum albumin, was examined using an automatic Hitachi chemistry analyzer (Hitachi, Tokyo, Japan). The RRF calculation was based on urea and creatinine clearances from a 24-hour urine collection. All patients were dialyzed with lactate-buffered glucose dialysate, in a twin-bag connection system (Baxter Healthcare, Guangzhou, China). Prophylactic cefazolin was administered before Tenckhoff catheter placement in all cases. Catheter and exit-site care in the postoperative period followed recommended practices (7). Patients with severe fluid overload, acid–base imbalance, or hyperkalemia received prompt intermittent PD after catheter placement, with a fill volume of 500 – 800 mL, a dwell time of 3 – 4 hours, and frequency of 2 – 4 times daily according to the RRF of the individual patient. Otherwise, PD initiation occurred 1 – 2 weeks after catheter placement. Generally, in the subsequent 1 – 2 weeks, an appropriate PD regimen was gradually achieved.

The study cohort was divided according to the independence of bag exchange into assisted PD (care by a family member or a home assistant) and self-care PD groups. Family members and home assistants who helped patients to perform PD exchanges were selected according to education (a health care background was not required, but they had to be able to read and write), cognition, and hands-on skills. Only competent assistants were appointed. All home assistants were paid by their employer. The study was approved by the medical ethics committee of Peking University. Written informed consent was obtained from each patient.

DEFINITION OF OUTCOME EVENTS

We examined technique survival, patient survival, and peritonitis-free survival. Technique survival was defined as inadequate dialysis, ultrafiltration insufficiency, exit-site or tunnel infection, conversion to hemodialysis because of peritonitis, and the presence

of any mechanical problem; patient and peritonitis-free survival corresponded to death as the outcome event and first episode of peritonitis respectively. In each analysis, patients were censored when PD was stopped for any other reason, including transfer to hemodialysis, renal transplantation, or study end date (April 2010).

TRAINING AND RETRAINING PROGRAMS

Patients and their caregivers were trained by nurses in the dialysis clinic following a standard initial training program that lasts approximately 3 – 5 days or 5 – 7 sessions (about 1 – 2 hours for each session). The initial training includes bag exchange procedures, exit-site care, salt and fluid restriction, blood pressure and glucose monitoring, dietary education, noninfectious complications related to the catheter, and rehabilitation. The pace and the length of training depend on the individual learner's situation. For bag exchange training, the patient or the assistant is allowed to practice until the procedure can be skillfully performed. After learning all of the steps, the patient or assistant then has to pass a test on bag exchange procedures. Details of this bag exchange training were previously published (8).

The retraining program procedures include

- reiteration of bag exchange protocols. Assistants are re-trained if peritonitis develops or if improper operation is suspected at this step.
- education for the individual, based on the actual situation, in exit-site care, salt and fluid restriction, blood pressure and glucose monitoring, dietary management, noninfectious complications related to the catheter, and rehabilitation.
- periodic group meetings held by nurses, dietitians, and physicians that focus on specific topics. For example, salt and fluid restriction are emphasized by primary nurses and dietitians when congestive heart failure repeatedly occurs. The points being emphasized focus on timing of the administration of phosphorus binder and avoidance of foods containing high phosphate when hyperphosphatemia cannot be adequately controlled.

PERITONITIS

Peritonitis was defined as the presence of at least 2 of the following conditions: abdominal pain or tenderness; presence of white blood cells (≥ 100 cells/mL) in the peritoneal effluent, with at least 50% polymorphs; and positive dialysate culture results. The peritonitis rate calculation divides the total treatment period for a study group by the incidence of peritonitis in that group.

Peritonitis was treated using the standard recommended antibiotic protocol. In general, initial antimicrobial therapy for peritonitis consisted of intraperitoneal administration of a third-generation cephalosporin plus cefazolin according to the guidelines suggested by the International Society for Peritoneal Dialysis (7).

STATISTICAL ANALYSES

Statistical analyses were performed using the SPSS software package (version 13.0: SPSS, Chicago, IL, USA). Parametric data are presented as mean $\pm$ standard deviation. Nonparametric data are presented as median values, with their 25th – 75th percentile intervals. Categorical variables are expressed as a percentage or ratio. Values of categorical variables were compared using the chi-square test; the Mann–Whitney U-test was used for continuous variables. A multivariate Cox proportional hazards analysis was used to predict the risk for first-episode peritonitis or for mortality in assisted PD after controlling for age, sex, BMI, diabetes, Charlson index, hemoglobin, albumin, and RRF. The Kaplan–Meier method and log-rank test were used to examine survival by comparing family-assisted PD with “assistant”-assisted PD, and assisted PD overall with self-care PD. All of the reported *p* values are two-tailed, and statistical significance was set at 0.05.

RESULTS

PATIENT DEMOGRAPHICS

Among the 313 incident PD patients in the study group (133 men, 180 women; mean age: 59.7 ± 14.1 years; RRF: 4.0 ± 4.5 mL/min; BMI: 23.4 ± 3.8 kg/m²; diabetes prevalence: 40.1%), 122 needed assistance (“assisted PD group”) in performing bag exchanges (86 by a family member, 36 by a home assistant). The remaining 191 patients were in the self-care PD group. Patients with a home assistant were older, more likely to be female, and less likely to have diabetes than were PD patients with a family assistant (Table 1). Compared with self-care PD patients, assisted PD patients were, overall, older and more likely to have diabetes and a higher Charlson score at baseline ($p < 0.001$). They also had lower levels of hemoglobin ($p < 0.05$) and serum albumin ($p < 0.001$, Table 1).

FOLLOW-UP

Follow-up was 43.5 ± 21.0 months (range: 1 – 88 months). During the observation period, 135 patients died, 28 patients transferred to hemodialysis (19 in the self-care group), and 30 patients underwent kidney transplantation (28 in the self-care group).

TABLE 1

Baseline Demographic, Clinical, and Outcomes Data^a for the Self-Care and Assisted Peritoneal Dialysis (PD) Groups

Variable	Assisted PD group			Self-care PD group (C)	<i>p</i> Value	
	Family assisted (A)	“Assistant” assisted (B)	All assisted (A+B)		(A) vs. (B)	(A+B) vs. (C)
Patients (<i>n</i>)	86	36	122	191		
Age (years)	65.7 $\pm$ 10.4	71.1 $\pm$ 8.7	67.3 $\pm$ 10.2	54.8 $\pm$ 14.2	0.007 ^b	<0.0001 ^b
Sex, male [<i>n</i> (%)]	43 (50)	10 (27.8)	53 (43.4)	80 (42.1)	0.02 ^c	0.93
Body mass index (kg/m ²)	23.5 $\pm$ 4.0	24.7 $\pm$ 4.5	23.8 $\pm$ 4.2	23.1 $\pm$ 3.5	0.14	0.08
Charlson comorbidity index	6 (4–9)	6 (4–10)	6 (4–9)	4 (2–7)	0.567	<0.0001 ^b
Diabetes [<i>n</i> (%)]	51 (59.3)	15 (41.7)	66 (54.1)	59 (30.9)	0.04 ^c	<0.0001 ^b
Hemoglobin (g/L)	99.9 $\pm$ 19.3	100.2 $\pm$ 17.2	99.4 $\pm$ 18.6	104.0 $\pm$ 15.5	0.745	0.017 ^c
Albumin (g/L)	33.3 $\pm$ 3.9	34.3 $\pm$ 4.0	33.6 $\pm$ 4.0	36.8 $\pm$ 3.8	0.217	<0.0001 ^b
Residual renal function (mL/min)	4.4 $\pm$ 5.6	3.1 $\pm$ 2.4	4.0 $\pm$ 4.9	3.9 $\pm$ 4.2	0.194	0.908
Follow-up (months)	39.2 $\pm$ 20.5	36.0 $\pm$ 17.4	38.2 $\pm$ 19.6	46.8 $\pm$ 21.3	0.411	<0.0001 ^b
Died [<i>n</i> (%)]	57 (66.3)	28 (77.8)	85 (69.7)	50 (26.2)	0.208	<0.0001 ^b
GPP-free duration (months)	43.7 $\pm$ 6.0	34.8 $\pm$ 6.0	42.1 $\pm$ 4.7	43.5 $\pm$ 3.6	0.543	0.989
Overall P-free duration (months)	24.4 $\pm$ 3.2	21.9 $\pm$ 4.3	23.5 $\pm$ 2.5	23.4 $\pm$ 2.0	0.685	0.968
Survival duration (months)	45.5 $\pm$ 2.9	39.0 $\pm$ 3.6	43.8 $\pm$ 2.3	69.8 $\pm$ 2.1	0.184	<0.0001 ^b

GPP = gram-positive peritonitis; P = peritonitis.

^a Mean $\pm$ standard error of the mean, median (25th – 75th percentile), or absolute numbers with percentages.

^b $p < 0.01$.

^c $p < 0.05$.

Among the 313 study patients, 21 occurrences of technique failure were observed during the study period: 17 because of conversion to hemodialysis after peritonitis, 1 because of severe pulmonary infection, 1 because of hernia, and 2 because of ultrafiltration failure. Kaplan–Meier analysis showed that technique survival was not significantly different between family-assisted and “assistant”-assisted PD patients (74.8 ± 2.3 months vs. 69.8 ± 2.0 months, $p = 0.65$) or between assisted PD patients overall and self-care patients (75.2 ± 2.0 vs. 82.4 ± 1.4 months, $p = 0.81$).

Of 245 episodes of peritonitis observed in the 313 patients during the study period, 121 were first episodes of peritonitis: 45 due to gram-positive organisms; 29, to gram-negative organisms; 2, to fungi. No first peritonitis episode was polymicrobial; 31 were culture-negative; and 14 returned no culture results. Table 2 shows the causative micro-organisms for all 245 peritonitis episodes. A higher proportion of gram-positive bacterial peritonitis episodes occurred in “assistant”-assisted patients, which was nonsignificant overall ($p = 0.274$ compared with family-assisted patients, $p = 0.68$ compared with self-care patients), but which became significant between the two assisted groups when *Staphylococcus* episodes specifically were considered ($p = 0.02$ compared with family-assisted patients, but $p = 0.24$ compared with self-care patients). The overall peritonitis rate was 1 episode in 55.5 patient–months. In 16 episodes of peritonitis, the patient was transferred to hemodialysis, and in 17 episodes, the patient died. Kaplan–Meier analysis showed that peritonitis-free

interval was not significantly different between family-assisted and “assistant”-assisted PD patients (24.4 ± 3.2 vs. 21.9 ± 4.3 months, $p = 0.69$, Figure 1). Assisted PD patients overall had a peritonitis-free interval similar to that for self-care patients (23.5 ± 2.5 months vs. 23.4 ± 2.0 months, $p = 0.93$, Figure 1). Even after adjustment for age, sex, BMI, presence of diabetes mellitus, Charlson score, serum albumin, hemoglobin, and RRF, “assistant”-assisted PD and assisted PD overall were still not independent predictors for first-episode peritonitis [“assistant”-assisted—hazard ratio (HR): 0.985; 95% confidence interval (CI): 0.44 to 2.21; $p = 0.97$; assisted overall—HR: 1.24; 95% CI: 0.78 to 1.96; $p = 0.37$; Table 3].

Among the 135 patients who died, the causes of death were cardiovascular disease ($n = 55$), other definite systemic or severe infection ($n = 50$), malnutrition ($n = 11$), and unknown causes or multiple organ failure ($n = 19$). We observed no significant difference in survival between family-assisted and “assistant”-assisted PD patients (45.5 ± 2.9 months vs. 39.0 ± 3.6 months, $p = 0.18$). However, after controlling for age, sex, BMI, presence of diabetes mellitus, Charlson score, serum albumin, hemoglobin, and RRF, “assistant”-assisted patients had higher risk of mortality (HR: 2.14; 95% CI: 1.20 to 3.81; $p = 0.01$; Table 4). Overall, assisted PD patients had a significantly higher mortality than did self-care patients (69.7% vs. 26.2%, $p < 0.0001$) and a significantly shorter survival (43.8 ± 2.3 months vs. 69.8 ± 2.1 months, $p < 0.0001$, Figure 2). Even after controlling for covariates, the higher risk of mortality for

TABLE 2
Micro-organisms Causing Peritonitis in Self-Care, Family-Assisted, and “Assistant”-Assisted Peritoneal Dialysis (PD) Groups

Organism	Self-care PD patients		Assisted PD patients			
	(n)	(%)	Family-assisted (n)	(%)	“Assistant”-assisted (n)	(%)
<i>Staphylococcus epidermidis</i>	23	15.5	5	7.8	4	12.1
<i>Staphylococcus aureus</i>	4	2.7	1	1.6	5	15.2
Other gram-positive bacteria	30	20.3	14	21.9	5	15.2
<i>Coli bacillus</i>	11	7.4	8	12.5	5	15.2
<i>Klebsiella</i>	3	2.0	4	6.3	0	0.0
<i>Corynebacterium</i>	7	4.7	3	4.7	2	6.1
<i>Pseudomonas aeruginosa</i>	2	1.4	0	0.0	0	0.0
Other gram-negative bacteria	13	8.8	2	3.1	2	6.1
Fungi	2	1.4	1	1.6	0	0.0
Culture-negative result	39	26.4	18	28.1	7	21.2
No culture result	14	9.5	8	12.5	3	9.1
TOTAL	148		64		33	

assisted PD patients remained (HR: 1.93; 95% CI: 1.26 to 2.97; $p = 0.003$, Table 4).

DISCUSSION

The population of elderly and diabetic patients is on a rapidly rising trend in China (9) and worldwide (10–14). This trend is increasing the demand for kidney replacement therapy. Peritoneal dialysis is considered an appropriate therapy for elderly and diabetic patients (3,15–18). However, it is well-known that older and diabetic dialysis patients are more likely to have weaker eyesight, impaired physical abilities, and cognitive dysfunction, all of which are often regarded as major

contraindications to performing PD. Given an inability to perform bag exchanges for themselves, these patients need home care helpers. Before increasing the PD penetration rate in these patients, it is extremely important to clarify the safety and effectiveness of assisted PD compared with self-care PD. Few studies have addressed this issue.

Three previous studies indicated an advantage for assisted PD given by family or nurses, but assisted patients were not compared with self-care patients (6,18,19). Two papers investigating differences between assisted and self-care PD showed that assisted patients had a higher risk of peritonitis (4,5) and lower rates of survival (5) and technique survival (4). However, one of those paper did not report on outcomes in the self-care patients (4), and the other included only elderly (>65 years) patients on automated PD. Recently, a report that included 1613 patients from the French-language peritoneal dialysis registry (Registre de dialyse péritonéale de langue française) showed that the type of assistance did not predict risk for peritonitis (20). Additionally, despite all of the foregoing results, no relevant data in Asian patients are available.

Our study was designed to compare rates of peritonitis and survival outcomes between assisted PD and self-care PD in Beijing, China. Results showed that assisted PD patients, whether assisted by family or a home care assistant, experienced a rate of peritonitis as low as that in self-care patients. This result clearly demonstrates that patients who need assistance can receive PD treatment safely in China. However, in accord with results from earlier studies (5,20), our assisted PD patients had a higher mortality rate that could not be explained by their older age, higher comorbidity scores, and lower serum albumin levels.

Figure 1 — Cumulative peritonitis-free survival for peritoneal dialysis (PD) patients assisted by a family member or by another helper and for self-care PD patients (family-assisted vs. “assistant”-assisted, $p = 0.69$; all assisted vs. self-care, $p = 0.93$).

TABLE 3
Risk for First-Episode Peritonitis by Multivariate Cox Proportional Hazards Analysis

Variable	Assisted by other vs. by family				Assisted PD vs. self-care PD			
	HR	Confidence limits	Lower	Upper	HR	Confidence limits	Lower	Upper
Type of assistant	0.985	0.440	2.206	0.971				
Need for assistance					1.237	0.780	1.961	0.366
Sex (male)	0.963	0.416	2.229	0.929	0.992	0.643	1.529	0.970
Age (per year)	0.983	0.944	1.023	0.406	0.976	0.960	0.993	0.006
Albumin (per 1 g/L)	0.969	0.896	1.048	0.433	0.990	0.936	1.048	0.730
Diabetes mellitus (present)	0.556	0.167	1.853	0.339	0.985	0.558	1.737	0.958
BMI (per 1 kg/m ²)	1.046	0.937	1.167	0.423	1.027	0.973	1.084	0.338
RRF (per 1 mL/min)	0.974	0.922	1.030	0.359	0.981	0.940	1.024	0.378
Hemoglobin (per 1 g/L)	0.999	0.970	1.028	0.937	0.999	0.985	1.014	0.916
CCI score (per point)	1.111	0.936	1.319	0.229	0.994	0.927	1.065	0.859

PD = peritoneal dialysis; HR = hazard ratio; BMI = body mass index; RRF = residual renal function; CCI = Charlson comorbidity index.

TABLE 4
Risk for All-Cause Mortality by Multivariate Cox Proportional Hazards Analysis

Variable	Assisted by assistant vs. by family				Assisted PD vs. self-care PD			
	HR	95.0% Confidence limits		p Value	HR	95.0% Confidence limits		p Value
Type of assistant	2.143	1.204	3.813	0.01 ^a				
Need for assistance					1.933	1.258	2.972	0.003 ^b
Sex (male)	0.815	0.478	1.390	0.453	0.652	0.436	0.975	0.037 ^a
Age (per 1 year)	1.024	0.999	1.050	0.061	1.030	1.011	1.048	0.001 ^b
Albumin (per 1 g/L)	0.925	0.867	0.988	0.021 ^a	0.910	0.863	0.960	0.001 ^b
Diabetes mellitus (present)	2.479	1.288	4.770	0.007 ^b	1.664	1.023	2.707	0.04 ^a
BMI (per 1 kg/m ²)	0.950	0.889	1.015	0.131	0.987	0.935	1.041	0.621
RRF (per 1 mL/min)	0.990	0.942	1.041	0.693	1.003	0.965	1.042	0.890
Hemoglobin (per 1 g/L)	0.986	0.971	1.003	0.101	0.991	0.978	1.004	0.171
CCI score (per 1 point)	1.005	0.934	1.081	0.896	1.029	0.975	1.087	0.298

PD = peritoneal dialysis; HR = hazard ratio; BMI = body mass index; RRF = residual renal function; CCI = Charlson comorbidity index.

^a $p < 0.05$.

^b $p < 0.01$.

Figure 2 — Cumulative survival for peritoneal dialysis (PD) patients assisted by a family member or by another helper and for self-care PD patients (family-assisted vs. “assistant”-assisted, $p = 0.18$; all assisted vs. self-care, $p = 0.0001$).

There are several reasons for the low peritonitis rate in assisted PD patients. First, the higher risk of peritonitis in assisted PD as shown in previous studies may not imply that assistance itself was the causative factor; more possibly, that result is attributable to inconsistent home care help combined with inadequate training (6). In a situation different from that in Western countries, disabled PD patients in China are assisted mostly by one appointed family member or, occasionally, a long-term home care assistant—but not by a hired nurse. The predominance of family members (who have a higher degree of personal involvement), rather than inconsistent home care helpers, could possibly explain the better outcomes

observed in the present study. After the appointed family member or long-term home care assistant has received initial training, he or she is regularly re-evaluated during follow-up and usually accompanies the PD patient to all clinical visits. As reported by Verger *et al.* (6) in France, patients on automated PD assisted by a private nurse have a higher risk of developing peritonitis than do family-assisted patients, but when additional home visits were made by the training center (the equivalent of retraining), the best results were achieved by private nurses. Second, we also speculate that assistance by a family member could overcome not only physical inconvenience, but also psychological difficulties, which is an important predictor of peritonitis (21).

Our study found that assisted PD patients had a higher risk of mortality, even after adjustments for confounders. This result is consistent with results from a recently published study with a considerable sample size and long-term follow-up (20). We hypothesize that unknown confounding factors related to disabilities are also associated with mortality (22). In addition, only baseline characteristics, and not the change trend in clinical variables, were analyzed for the prediction of mortality during follow-up. This choice may possibly have influenced the reliability of the results.

Our findings have important implications for the PD community in China. The cultural tradition in China encourages spouses and children to help the family carry on with life in chronic diseases. Assistance by family members does not add extra costs to PD. Moreover, family support shows independent benefits for outcomes in

chronic conditions (23,24). The evidence provided by the present study therefore suggests more patients who need assistance can be recruited into PD programs, decreasing the cost burden on the health care system for the Chinese government (25).

Ours is the first study to investigate the efficacy of assisted PD, by assistance type, in Asian patients. However, our study has some limitations. First, it is a single-center study. A sufficiently large sample size (313 patients in total, more than in most of the earlier studies) and long-term follow-up (mean: 44.5 months) in the present study help to minimize that potential bias and to increase reliability. Second, the numbers of patients transferred to hemodialysis or transplantation were unbalanced between the assisted and self-care groups, which could create bias in group comparisons. Third, quality of life (QOL) was not compared for the assisted and self-care PD groups. Quality of life is a significant outcome for dialysis patients, and it has a significant influence on survival (26). However, we speculate that, if adjusted for QOL, the improved outcomes for the assisted PD patients would have been more obvious because of their conceivably lower QOL compared with QOL in self-care patients.

CONCLUSIONS

We conclude that assisted PD is a good option for patients with poor self-care ability in Beijing, China. Our study provides evidence for recruiting more patients who need assistance into PD programs in China.

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DISCLOSURES

The authors have no financial conflicts of interest to declare.

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