

# Safety, Effectiveness, and Manipulability of Peritoneal Dialysis Machines Made in China: A Randomized, Crossover, Multicenter Clinical Study

Xue-Ying Cao<sup>1</sup>, Ya-Ni He<sup>2</sup>, Jian-Hui Zhou<sup>1</sup>, Shi-Ren Sun<sup>3</sup>, Li-Ning Miao<sup>4</sup>, Wen Chen<sup>5</sup>, Jing-Ai Fang<sup>6</sup>, Ming Wang<sup>7</sup>, Nian-Song Wang<sup>8</sup>, Hong-Li Lin<sup>9</sup>, Jian Liu<sup>10</sup>, Zhao-Hui Ni<sup>11</sup>, Wen-Hu Liu<sup>12</sup>, Yu Na<sup>13</sup>, Jiu-Yang Zhao<sup>14</sup>, Zhi-Yong Guo<sup>15</sup>, Hong-Guang Zheng<sup>16</sup>, Wei Shi<sup>17</sup>, Geng-Ru Jiang<sup>18</sup>, Guang-Yan Cai<sup>1</sup>, Xiang-Mei Chen<sup>1</sup>

<sup>1</sup>Department of Nephrology, Chinese People's Liberation Army General Hospital, Chinese People's Liberation Army Institute of Nephrology, State Key Laboratory of Kidney Diseases (2011DAV00088), National Clinical Research Center for Kidney Diseases, Beijing 100853, China

<sup>2</sup>Department of Nephrology, Daping Hospital, Army Military Medical University, Chongqing 400042, China

<sup>3</sup>Department of Nephrology, Xijing Hospital, The Fourth Military Medical University, Xi'an, Shaanxi 710032, China

<sup>4</sup>Department of Nephrology, Second Hospital of Jilin University, Changchun, Jilin 130041, China

<sup>5</sup>Department of Nephrology, Hainan Provincial Agricultural Reclamation General Hospital, Haikou, Hainan 570311, China

<sup>6</sup>Department of Nephrology, First Affiliated Hospital of Shanxi Medical University, Taiyuan, Shanxi 030001, China

<sup>7</sup>Department of Nephrology, Hangzhou First People's Hospital, Hangzhou, Zhejiang 310006, China

<sup>8</sup>Department of Nephrology and Rheumatology, Affiliated Sixth People's Hospital, Shanghai Jiao Tong University, Shanghai 200233, China

<sup>9</sup>Department of Nephrology, First Affiliated Hospital of Dalian Medical University, Dalian, Liaoning 116011, China

<sup>10</sup>Department of Nephrology, The First Affiliated Hospital of Xinjiang Medical University, Urumqi, Xinjiang 830054, China

<sup>11</sup>Department of Nephrology, Renji Hospital, Shanghai Jiao Tong University, Shanghai 200127, China

<sup>12</sup>Department of Nephrology, Beijing Friendship Hospital, Capital Medical University, Beijing 100050, China

<sup>13</sup>Department of Nephrology, The 306<sup>th</sup> Hospital of People's Liberation Army, Beijing 100101, China

<sup>14</sup>Department of Nephrology, The Second Affiliated Hospital of Dalian Medical University, Dalian Medical University, Dalian, Liaoning 116023, China

<sup>15</sup>Department of Nephrology, Changhai Hospital, The Second Military Medical University, Shanghai 200433, China

<sup>16</sup>Department of Nephrology, People's Liberation Army General Hospital of Shenyang Military Region, Shenyang, Liaoning 110016, China

<sup>17</sup>Department of Nephrology, Guangdong General Hospital, Guangdong Academy of Medical Sciences, Guangzhou, Guangdong 510080, China

<sup>18</sup>Department of Nephrology, Xinhua Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai 200092, China

Xue-Ying Cao and Ya-Ni He both contributed equally to this work.

## Abstract

**Background:** Automated peritoneal dialysis (APD) can cater to individual needs, provide treatment while asleep, take into account the adequacy of dialysis, and improve the quality of life. Currently, independent research and development of APD machines made in China are more conducive to patients. A randomized, multicenter, crossover study was conducted by comparing an APD machine made in China with an imported machine. The safety, effectiveness, and manipulability of the two machines were compared.

**Methods:** Two hundred and sixty patients who underwent peritoneal dialysis (PD) on a regular basis in 18 centers between August 2015 and February 2016 were included. The inclusion criteria include age  $\geq 18$  years and PD  $\geq 30$  days. The exclusion criteria were as follows: hemodialysis; exit site or tunnel infection; and peritonitis  $\leq 30$  days. The patients were randomly divided into Group A, who were first treated with a FM machine made in China, then changed to an imported machine; and Group B, who were treated using the reverse sequence. APD treatment was performed with 10 L/10 h and 5 cycles of exchange. After 72 h, the daily peritoneal Kt/V, the accuracy of the injection rate, accuracy of the injection temperature, safety, and manipulability of the machine were assessed. Noninferiority test was conducted between the two groups.

**Address for correspondence:** Dr. Xiang-Mei Chen,

Department of Nephrology, Chinese People's Liberation Army General Hospital, Chinese People's Liberation Army Institute of Nephrology, State Key Laboratory of Kidney Diseases (2011DAV00088), National Clinical Research Center for Kidney Diseases, Beijing 100853, China  
E-Mail: xmchen301@126.com

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

**For reprints contact:** reprints@medknow.com

© 2018 Chinese Medical Journal | Produced by Wolters Kluwer - Medknow

### Access this article online

#### Quick Response Code:



**Website:**  
www.cmj.org

**DOI:**  
10.4103/0366-6999.246079

**Received:** 02-08-2018 **Edited by:** Yuan-Yuan Ji

**How to cite this article:** Cao XY, He YN, Zhou JH, Sun SR, Miao LN, Chen W, Fang JA, Wang M, Wang NS, Lin HL, Liu J, Ni ZH, Liu WH, Na Y, Zhao JY, Guo ZY, Zheng HG, Shi W, Jiang GR, Cai GY, Chen XM. Safety, Effectiveness, and Manipulability of Peritoneal Dialysis Machines Made in China: A Randomized, Crossover, Multicenter Clinical Study. Chin Med J 2018;131:2785-91.

**Results:** The daily peritoneal Kt/V in the APD machine made in China and the imported APD machine were 0.17 (0.14, 0.25) and 0.16 (0.13, 0.23), respectively. There was no significant difference between the groups ( $Z = 0.15$ ,  $P = 0.703$ ). The lower limit of the daily Kt/V difference between the two groups was 0.0069, which was greater than the noninferiority value of  $-0.07$  in this study. The accuracy of the injection rate and injection temperature was 89.7% and 91.5%, respectively, in the domestic APD machine, which were both slightly better than the accuracy rates of 84.0% and 86.8% in the imported APD machine (89.7% vs. 84.0%,  $P = 0.2466$ ; 91.5% vs. 86.8%,  $P = 0.0954$ ). Therefore, the APD machine made in China was not inferior to the imported APD machine. The fuselage of the imported APD machine was space-saving, while the APD machine made in China was superior with respect to body mobility, man-machine dialog operation, alarm control, and patient information recognition.

**Conclusions:** The FM machine made in China was not inferior to the imported APD machine. In addition, the FM machine made in China had better operability.

**Trial Registration:** Clinicaltrials.gov, NCT02525497; <https://clinicaltrials.gov/ct2/results?cond=&term=NCT02525497&cntry=&state=&city=&dist=>

**Key words:** Automated Peritoneal Dialysis; Effectiveness; Peritoneal Dialysis; Peritoneal Dialysis Machine; Safety

## INTRODUCTION

Peritoneal dialysis (PD) is safe, effective, convenient, efficient, and suitable for home treatment.<sup>[1,2]</sup> Specifically, PD meets the needs of a large number of patients in China and helps relieve the economic burden.<sup>[3]</sup> Automated PD (APD) ensures the adequacy of dialysis and saves time, which is the best choice for treatment.<sup>[4]</sup> The widespread use of APD has been limited in China due to the reliance on an automatic circulatory machine for PD and the expensive special equipment and technology. Most current dialysis centers use APD for supplementary treatment. With the continuous improvement in our social security system and medical treatment, APD will be an increasingly popular in-home treatment modality in the future. Under such circumstances, it is imperative to produce APD equipment with good performance and an affordable price.

This study was conducted to verify the clinical safety, effectiveness, and operability of the FM-II PD machine (Jilin Province Morestep Medical Equipment Co., Ltd., Changchun, China) in comparison with the imported Homechoice PD machine (Baxter, USA).

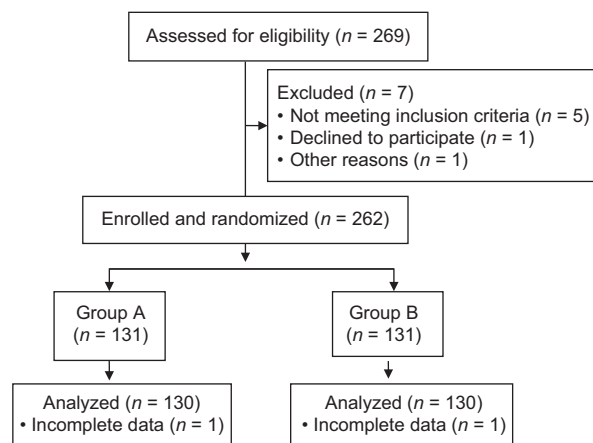
## METHODS

### Study design and ethical approval

This study was a prospective, randomized, crossover, multicenter clinical trial (Clinicaltrials.gov, NCT0252497). From August 2015 to February 2016, we selected 260 cases of PD adult patients from 18 dialysis centers nationwide [Figure 1]. The study was conducted in accordance with the *Declaration of Helsinki* and was approved by the Ethics Committee of Chinese People's Liberation Army General Hospital (No. 2014027). Informed written consent was obtained from all patients before enrollment in the study. Before enrollment, all researchers underwent training regarding the study protocol and passed the evaluation.

### Subjects

According to the design scheme of a prospective randomized cross-over study, we selected 260 cases of PD adult patients from 18 dialysis centers nationwide who received treatment



**Figure 1:** Schematic flow of this study.

for >30 days and divided the patients into two groups. The exclusion criteria were as follows: (1) combined hemodialysis, acute or chronic exit or tunnel infection, peritonitis, and catheter mechanical malfunction; (2) known to be HIV positive and allergic to liquor dialysis intraperitoneal; (3) comorbid severe diseases such as residual or malignant tumors, systemic infections, cirrhosis, congestive heart failure, anemia (Hb <70 g/L), malnutrition (SAlb <28 g/L), and intractable hypertension; and (4) poor compliance, pregnancy, lactation, alcoholism, and a drug abuse history. The PD machine uses the principle of a gravity-driven design. The main structural and performance indicators of the PD machine are consistent with similar foreign products. Product features and innovations are reflected in the system control, man-machine operation, and information management. Regarding safety, the PD machine also meets relevant requirements. The product obtained a medical device product registration certificate in September 2016 (registration certificate number: Jiji Machinery Note 20162450209).

### Procedure

The two groups were treated with the domestic FM-II and imported Homechoice PD machines with a standard dose of 10 L/d. Group A was treated with the domestic FM PD machine treatment in the first cycle. After 24 h (a washout period), the second cycle of treatment was carried

out with the Homechoice PD machine. In Group B, the Homechoice PD machine was used first and changed to the domestic FM PD machine. A physical examination, routine examination, detection of dialysis adequacy, peritoneal function, and transport status were monitored during the period of treatment, and the complications and adverse events were recorded. The total observation time was 72 h.

To verify the efficacy and safety of the domestic FM PD machine, we compared the daily peritoneum Kt/V, injection accuracy, injection temperature, serum sodium, potassium, calcium, phosphorus, carbon dioxide binding capacity, creatinine, and urea nitrogen after the treatment with the two machines. According to the patient's subjective feelings, the safety index, fuselage characteristics, and operational characteristics were evaluated based on a subjective rating scale.

### Outcomes

The primary endpoints of this study were as follows: (1) patient death; (2) inability to continue treatment because of severe changes in vital signs; and (3) machine failure.

The primary outcome measure was daily peritoneal Kt/V of patient. The secondary outcome measures included injection accuracy, injection temperature, and serum sodium, potassium, calcium, phosphorus, carbon dioxide binding capacity, creatinine, and urea nitrogen.

Safety evaluations included adverse and severe adverse events, marked changes in vital signs, and laboratory test results. Evaluation of product quality included the safety index, fuselage characteristics, and operational characteristics after treatment with the two machines.

### Randomization

Patients were centrally randomized 1:1 to Groups A or B using a randomization chart generated to clinical treatment. Each patient was randomized only once. All procedures were performed under the supervision of an independent clinical research organization.

### Sample size and statistical analysis

A noninferiority test was used in the present study. The primary outcome measure was daily peritoneal Kt/V. According to a previous study<sup>[5]</sup> and preexperimental research results, the noninferiority value was 0.07, the one-sided  $\alpha$  for the *t*-test was 0.025, and the  $\beta = 0.8$ . Two hundred thirty-five patients were required. With a 10% dropout rate, 260 patients were enrolled in the study.

Data were shown as mean  $\pm$  standard deviation, median ( $Q_1$ ,  $Q_3$ ), or *n* (%). Demography and baseline data were analyzed by *t*-test, Chi-square test, and Wilcoxon rank-sum test according to data types. The main effect index of daily peritoneal Kt/V was compared by variance analysis, and a noninferiority test was used with analysis of variance. The noninferiority margin was  $-0.07$ . The difference between the accuracy of the injection rate and the accuracy of the injection temperature was compared according to the two classification variables in a cross design test. Indices, such

as serum sodium, potassium, calcium, phosphorus, carbon dioxide binding power, creatinine, and urea nitrogen, were analyzed using an analysis of covariance model according to data distribution characteristics. Double factor analysis of variance was used to compare the intergroup differences in the comprehensive operability score. The incidence of adverse and serious adverse events was checked by a Chi-square test.  $P < 0.05$  was considered statistically significant. SAS 9.3 (SAS Institute Inc., North Tustin, USA) was used for the statistical analyses.

## RESULTS

### Baseline demographic and main clinical characteristics

The average age of patients undergoing maintenance PD was  $49.3 \pm 15.3$  years (158 males and 102 females). The mean dry abdominal weight was  $65.7 \pm 13.2$  kg, the mean systolic blood pressure was  $145.5 \pm 20.2$  mmHg, and the diastolic blood pressure was  $87.4 \pm 12.7$  mmHg [Table 1].

### Main evaluation index

All of the patients were treated with two different machines. The daily peritoneal Kt/V in the domestic APD group was 0.17 (0.14, 0.25) and 0.16 (0.13, 0.23) in the imported APD group. The results showed that there was no significant difference between the groups ( $Z = 0.15$ ,  $P = 0.703$ ). The lower limit of the daily Kt/V difference between the domestic and imported APD treatment was 0.0069, which was greater than the noninferiority value of  $-0.07$  in this study. Therefore, daily peritoneal Kt/V results indicated that the domestic APD treatment was not inferior to the imported APD. No significant difference existed about the total Kt/V and Kt/V of the remnant kidney after two cycles of treatment between the two kinds of machines.

### Secondary evaluation index

Serum urea nitrogen, creatinine, and electrolytes (potassium, sodium, calcium, and phosphorus) and carbon dioxide

**Table 1: Baseline characteristics of the patients undergoing maintenance PD in the entry group (*n* = 260)**

Characteristics	Values
Age (years)	$49.3 \pm 15.3$
Gender, male, <i>n</i> (%)	158 (60.8)
Height (cm)	$166.5 \pm 8.1$
Weight (kg)	$65.7 \pm 13.2$
History of cardiovascular disease, <i>n</i> (%)	
Normal	239 (91.9)
Abnormal	21 (8.1)
Systolic pressure (mmHg)	$145.5 \pm 20.2$
Diastolic pressure (mmHg)	$87.4 \pm 12.7$
CAPD during the screening period (6 L/d), <i>n</i> (%)	
No	15 (5.8)
Yes	245 (94.2)

Data were shown as mean  $\pm$  SD, or *n* (%). SD: Standard deviation; CAPD: Continuous ambulatory peritoneal dialysis; PD: Peritoneal dialysis.

binding before and after treatment were not statistically different between the two groups [Table 2].

The difference between the actual amount of irrigation and the dosage in the prescription was <2% (40 ml). The difference between the actual temperature and the setting temperature was <2°C, which indicated that the injection temperature was accurate. The accuracy of the injection rate and injection temperature was 89.7% and 91.5%, respectively, in the domestic APD machine, which were both slightly better than the accuracy rates of 84.0% and 86.8% in the imported APD machine (89.7% vs. 84.0%,  $P = 0.2466$ ; 91.5% vs. 86.8%,  $P = 0.095$ ). Compared with the logistics model of cross design, there was no difference between the accuracy of the injection rate and the accuracy of the injection temperature when the two machines were used in APD treatment.

### Safety and operability

The 260 patients were treated with two different APD machines. One case of intestinal tract gas and one case of urinary retention occurred in the domestic APD group. One

case of abdominal pain and one case of dialysis occurred in the imported APD group. All of the patients were able to complete the treatment after the intervention. The incidence of adverse events was 0.19% in the two groups [Table 3].

The imported APD machine had a more economic fuselage, while the domestic APD machine had an automatic cycle of liquor dialysis intraperitoneus and facilitated improvements in body movement, dialysate storage, storage battery, and man-machine dialog function. Moreover, the touch screen function made the operation easier and more convenient, which provided a better treatment experience [Tables 4 and 5].

### DISCUSSION

The prevalence of chronic kidney disease (CKD) in the adult Chinese population is 10.8%.<sup>[6]</sup> Thus, in the large population of China, there are nearly 130 million individuals with CKD, among whom approximately 2% will develop end-stage kidney disease (ESRD). In 2010, the number of ESRD maintenance hemodialysis patients reached 2,618,000 globally, and the number increases by 7% per

**Table 2: Removal of serum creatinine, urea, and correction of electrolyte and acid-base balance disorders before and after treatment ( $n = 260$ )**

Variables	FM-APD	HC-APD	<i>t</i>	<i>P</i>
BUN (mmol/L)				
Before	18.55 ± 6.06	18.41 ± 5.91	0.26	0.7952
After	17.26 ± 5.62	16.92 ± 5.36	0.71	0.4768
Serum creatinine (μmol/L)				
Before	882.16 ± 317.14	869.13 ± 314.77	0.47	0.6390
After	837.78 ± 304.06	827.84 ± 302.69	0.37	0.7101
Na (mmol/L)				
Before	140.55 ± 3.62	140.59 ± 3.48	-0.01	0.9930
After	140.55 ± 3.42	139.76 ± 9.22	1.34	0.1796
K (mmol/L)				
Before	3.91 ± 0.61	3.88 ± 0.59	-0.05	0.9598
After	3.91 ± 0.61	3.91 ± 0.61	-0.47	0.6359
Ca (mmol/L)				
Before	2.22 ± 0.23	2.25 ± 0.24	-0.99	0.3233
After	2.57 ± 0.28	2.26 ± 0.21	-0.73	0.4653
P (mmol/L)				
Before	2.43 ± 0.43	1.45 ± 0.44	1.01	0.3119
After	1.55 ± 0.47	1.46 ± 0.45	-0.22	0.8242
CO <sub>2</sub> (mmol/L)				
Before	26.33 ± 3.33	27.20 ± 3.97	-0.64	0.5227
After	26.52 ± 3.40	30.78 ± 4.21	-1.24	0.2163

FM-APD: Domestic FM peritoneal dialysis machine; HC-APD: Homechoice peritoneal dialysis machine; BUN: Blood urea nitrogen.

**Table 3: Comparison of occurrence and frequency of different machine adverse events ( $n = 260$ )**

Items	FM-APD		HC-APD		Total	
	Cases	Incidence (%)	Cases	Incidence (%)	Cases	Incidence (%)
Finding intestinal tract	1	0.38	0	0	1	0.19
Abdominal pain	0	0	1	0.38	1	0.19
Urinary retention	1	0.38	0	0	1	0.19
Backache	0	0	1	0.38	1	0.19

FM-APD: Domestic FM peritoneal dialysis machine; HC-APD: Homechoice peritoneal dialysis machine.

**Table 4: Comparison of the fuselage characteristics of two kinds of PD machines (*n* = 260)**

Items	FM-APD	HC-APD	$\chi^2$	<i>P</i>
Fuselage space, <i>n</i> (%)				
Space-saving	108 (41.9)	218 (83.9)	102.8308	<0.0001
Requires part of the space	148 (57.4)	38 (14.6)		
Requires a lot of space	2 (0.8)	4 (1.5)		
Any noise in the fuselage, <i>n</i> (%)				
No noise	144 (55.8)	156 (6.0)	3.139	0.2082
Mild noise	114 (44.2)	102 (39.2)		
Obvious noise	0 (0)	2 (0.8)		
Convenience, <i>n</i> (%)				
Inconvenient	3 (1.2)	139 (53.5)	178.0038	<0.0001
Convenient	255 (98.8)	121 (46.5)		
Continued dialysate liquid storage space, <i>n</i> (%)				
No	2 (0.8)	168 (64.6)	239.3773	<0.0001
Yes	256 (99.2)	92 (35.4)		
Storage function after power failure, <i>n</i> (%)				
No	30 (11.6)	75 (28.9)	23.7553	<0.0001
Yes	228 (88.4)	185 (71.2)		
Convenient and clean fuselage, <i>n</i> (%)				
No	0 (0)	4 (1.5)	4.0001	0.0455
Yes	258 (100)	256 (98.5)		

FM-APD: Domestic FM peritoneal dialysis machine; HC-APD: Homechoice peritoneal dialysis machine; PD: Peritoneal dialysis.

**Table 5: Comparison of the operating characteristics of two kinds of PD machines (*n* = 260)**

Items	FM-APD	HC-APD	$\chi^2$	<i>P</i>
Set the operating prompt clearly, <i>n</i> (%)				
Very clear	249 (96.5)	195 (75.0)	48.9989	<0.0001
Sometimes not clear	9 (3.5)	64 (24.6)		
Vague	0 (0)	1 (0.4)		
Man-machine dialog clearly at the alarm, <i>n</i> (%)				
Clear Chinese prompt	245 (95.0)	203 (78.1)	31.7274	<0.0001
Code prompt	13 (5.0)	56 (21.5)		
No prompt	0 (0)	1 (0.4)		
Set comprehensively, <i>n</i> (%)				
No	0 (0)	25 (9.6)	26.8151	<0.0001
Yes	258 (100)	235 (90.4)		
Adjusted alarm sound, <i>n</i> (%)				
No	3 (1.2)	35 (13.5)	28.8151	<0.0001
Yes	255 (98.8)	225 (86.5)		
Changed during the process, <i>n</i> (%)				
No	34 (13.2)	129 (49.6)	79.7249	<0.0001
Yes	224 (86.8)	131 (50.4)		
Identified multiple information sources, <i>n</i> (%)				
No	2 (0.8)	129 (49.6)	163.4915	<0.0001
Yes	256 (99.2)	131 (50.4)		

FM-APD: Domestic FM peritoneal dialysis machine; HC-APD: Homechoice peritoneal dialysis machine; PD: Peritoneal dialysis.

year. The number of ESRD patients in China also increases by 20–30% each year.<sup>[7]</sup> Indeed, it has been predicted that the number of patients with ESRD will double to 5,439,000 worldwide<sup>[8]</sup> in 2030, and Asia will have the greatest proportion of ESRD patients. China will face the severe challenge that accompanies such a large number of patients with renal failure.

High medical expenditures are an incentive for the Chinese to break the monopoly of foreign brands and develop domestic

medical devices to offer satisfactory treatment at a low cost to uremic patients.<sup>[9,10]</sup> In recent years, some domestic dialysis supplies have reached the market and produced social and economic benefits. The domestic high-performance mini-automated PD machine in this study is a better choice for patients.

In recent years, APD therapy has developed rapidly. The flexibility of dialysis time,<sup>[2]</sup> the adequacy of dialysis,<sup>[4]</sup> and the low incidence of peritonitis<sup>[11]</sup> have been widely



recognized. Greater than 60% and >70% of Canadian<sup>[12]</sup> and US<sup>[13]</sup> PD patients use APD, respectively. According to the CNRDS report in China, <1.5% of PD patients are treated with APD.<sup>[9]</sup>

An APD machine can automatically control dialysate circulation in and out of the abdomen.<sup>[4]</sup> Based on the parameters of PD set in advance, the machine runs automatically by computer and exchanges PD fluid continuously. The APD machine can monitor and record the temperature, perfusion, and drainage time of the dialysate at the same time. An alarm system monitors the entire process of treatment and terminates the treatment immediately when danger arises to improve safety. Therefore, the ideal APD machine needs to not only complete the treatment program but also offer friendly usage. Imported APD machines have been a priority for APD treatment for a long time. In this study, two kinds of APD machines were compared regarding dialysis adequacy, dose and temperature accuracy, safe operation, and operation characteristics so that the effectiveness and safety of the domestic PD machine could be evaluated.

The removal of small molecules of solute and water is the most important indicator of dialysis adequacy in current research. The International Peritoneal Dialysis Association and the European Best Practice Guidelines set the total Kt/V1.7 as the minimum standard of dialysis adequacy, but do not clearly point out the adequacy standard of APD.<sup>[14]</sup> In this study, two groups of daily peritoneal Kt/V were reached the lowest standard of total KT/V1.7 per week. Therefore, both domestic and imported APD machines do not affect the adequacy of PD. The adequacy is mainly determined by peritoneal function and transport characteristics.<sup>[15,16]</sup>

As a dialysate exchange tool, an APD machine must possess accurate measurement and temperature control of the injected liquid. The APD machine should be able to accurately calculate the amount of dialysate in the abdominal cavity and assess water balance over time.<sup>[17]</sup> Therefore, APD has a set of measurement devices which can accurately determine the dialysate into and out of the abdominal cavity. According to the manufacturing industry standards of the PD machine and the patient's subjective experience, the actual amount of peritoneal fluid filled with prescription treatment volume difference of less than  $\pm 2\%$  (40 ml) is considered as the injection quantity standard. The machine is suggested to be equipped with temperature control and temperature control devices. The temperature of the dialysate is approximately 37°C, which makes the patient comfortable when introduced into the abdominal cavity. The actual temperature injected and temperature difference of less than  $\pm 2^\circ\text{C}$  are considered to be the proper injection temperature. The accuracy of the injection rate and injection temperature were 89.67% and 91.47%, respectively, in the domestic APD machine, which were both slightly better than the accuracy rates of 84.01% and 86.82% in the imported APD machine. The accuracy of the injection process of the APD machine met the expected standard.

It is also advised that the APD machine be equipped with a complete automatic monitoring and alarm device to ensure the safety of the treatment,<sup>[17,18]</sup> which includes a temperature control system, dialysate measurement system, dialysate sequential flow control system, pressure sensing control system, and liquid discharge alarm system. Safety is the most important requirement for the PD machine. When the alarm sounds, it can automatically terminate the work and send out a warning signal. In this study, the two kinds of APD machines sent out alarm signals accurately, and slow drainage and insufficient flow rate were the main causes for the alarm. In addition, the display interface of the domestic APD machine was more convenient by using a graphic method to guide patients to complete alarm processing.

In addition to the basic functions and safety characteristics, easy manipulation, home-use convenience, and flexible treatment space are considerations in evaluation of the PD machine. The imported APD machine has been applied for nearly 20 years and been trusted by many PD patients. On the basis of the original functions, the domestic APD machine has made corresponding improvements which are more suitable for personalized habits and meets the specific needs of Chinese patients. Therefore, in this study, we also made a quantitative comparison of the manipulation through a questionnaire. Although the imported APD machine was more economic in the fuselage space, the domestic APD machine gained more appreciation from Chinese patients because of its easy mobility, dialysate placing space and storage function, man-machine conversation, temporary information adjustment, and patient information recognition. Recently, remote therapy management has the potential to improve the outcomes of patients undergoing APD at home.<sup>[19,20]</sup> APD machines can provide an ideal, safe, and effective renal replacement therapy for patients with uremia. Domestic APD machines benefit more and more PD patients with excellent performance.<sup>[21]</sup>

This study was intended to evaluate the efficacy of PD machines under the same peritoneal conditions. Since many factors may influence peritoneum during peritoneal dialysis treatment, differences exist among individuals, even in the same patient at different times. We chose cross-complete treatment observations within 72 h, mainly to eliminate the effects of peritoneal status during peritoneal dialysis treatment as much as possible. However, the use and observation time may be not sufficient enough to carry a detailed observation for a long-term operation of the peritoneal dialysis machine. Therefore, studies with longer term or more cyclical evaluation are suggested for a comprehensive verification of safety, therapeutic effects, and prognostic impact of the machine.

### Financial support and sponsorship

This work was supported by grants from National Key Research and Development Program of China (No. 2016YFC1103004), the Twelfth Five-Year National Key Technology Research and Development Program (No. 2015BAI12B06), the National Science & Technology Pillar Program in the

Twelfth Five-year Plan Period (No. 2011BAI10B08), and Funds for Clinical Scientific Research of Chinese Medical Association (No. 15020050593).

### Conflicts of interest

Morestep and Baxter Inc. support data collection for this research.

### REFERENCES

1. Diaz-Buxo JA, Suki WN. Automated peritoneal dialysis. In: Gokal R, Nolph KD, editors. *The Textbook of Peritoneal Dialysis*. Dordrecht: Kluwer; 1994. p. 399-418.
2. McComb J, Morton AR, Singer MA, Hopman WM, MacKenzie T. Impact of portable APD on patient perception of health-related quality of life. *Adv Perit Dial* 1997;13:137-40.
3. Lai KN, Lui SL, Chan DT. Automated peritoneal dialysis in Asia. *Perit Dial Int* 1999;19 Suppl 2:S125-9.
4. Bro S, Bjorner JB, Tofte-Jensen P, Klem S, Almqvist B, Danielsen H, *et al*. A prospective, randomized multicenter study comparing APD and CAPD treatment. *Perit Dial Int* 1999;19:526-33.
5. Vega ND, Gallego R, Oliva E, Henriquez F, Palop L, Divino Filho JC, *et al*. Nocturnal ultrafiltration profiles in patients on APD: Impact on fluid and solute transport. *Kidney Int Suppl* 2008;(108):S94-101. doi: 10.1038/sj.ki.5002609.
6. Zhang L, Wang F, Wang L, Wang W, Liu B, Liu J, *et al*. Prevalence of chronic kidney disease in China: A cross-sectional survey. *Lancet* 2012;379:815-22. doi: 10.1016/S0140-6736(12)60033-6.
7. Liu ZH. Nephrology in China. *Nat Rev Nephrol* 2013;9:523-8. doi: 10.1038/nrneph.2013.146.
8. Liyanage T, Ninomiya T, Jha V, Neal B, Patrice HM, Okpechi I, *et al*. Worldwide access to treatment for end-stage kidney disease: A systematic review. *Lancet* 2015;385:1975-82. doi: 10.1016/S0140-6736(14)61601-9.
9. Chen XM, Zhou JH. Current status and future of peritoneal dialysis technology in China (in Chinese). *Chin J Pract Internal Med* 2013;33:413-5.
10. Tang CH, Wu YT, Huang SY, Chen HH, Wu MJ, Hsu BG, *et al*. Economic costs of automated and continuous ambulatory peritoneal dialysis in Taiwan: A combined survey and retrospective cohort analysis. *BMJ Open* 2017;7:e015067. doi: 10.1136/bmjopen-2016-015067.
11. Nayak KS, Subramanyam SV, Pavankumar N, Antony S, Sarfaraz Khan MA. Emergent start peritoneal dialysis for end-stage renal disease: Outcomes and advantages. *Blood Purif* 2018;45:313-9. doi: 10.1159/000486543.
12. Moist LM, Fenton S, Kim JS, Gill JS, Ivis F, de Sa E, *et al*. Canadian organ replacement register (CORR): Reflecting the past and embracing the future. *Can J Kidney Health Dis* 2014;1:26. doi: 10.1186/s40697-014-0026-5.
13. United States Renal Data System. 2014 USRDS Annual Data Report: end-Stage Renal Disease [DB/OL]. Vol. 2. Bethesda, MD: US Department of Public Health and Human Services, National Institutes of Health; 2014. Available from: <http://www.usrds.org/links.aspx>. [Last accessed on 2015 Apr 08].
14. Dombros N, Dratwa M, Feriani M, Gokal R, Heimbürger O, Krediet R, *et al*. European best practice guidelines for peritoneal dialysis 7 Adequacy of peritoneal dialysis. *Nephrol Dial Transplant* 2005;20 Suppl 9:ix24-7. doi: 10.1093/ndt/gfi1121.
15. Samad N, Fan SL. Comparison of change in peritoneal function in patients on continuous ambulatory PD vs. automated PD. *Perit Dial Int* 2017;37:627-32. doi: 10.3747/pdi.2016.00101.
16. Beduschi Gde C, Figueiredo AE, Olandoski M, Pecoits-Filho R, Barretti P, de Moraes TP, *et al*. Automated peritoneal dialysis is associated with better survival rates compared to continuous ambulatory peritoneal dialysis: A Propensity score matching analysis. *PLoS One* 2015;10:e0134047. doi: 10.1371/journal.pone.0134047.
17. Fischbach M, Zaloszczyk A, Schaefer B, Schmitt C. Adapted automated peritoneal dialysis. *Adv Perit Dial* 2014;30:94-7.
18. Brandes JC, Packard WJ, Watters SK, Fritsche C. Optimization of dialysate flow and mass transfer during automated peritoneal dialysis. *Am J Kidney Dis* 1995;25:603-10. doi: 10.1016/0272-6386(95)90131-0.
19. Makhija D, Alscher MD, Becker S, D'Alonzo S, Mehrotra R, Wong L, *et al*. Remote monitoring of automated peritoneal dialysis patients: Assessing clinical and economic value. *Telemed J E Health* 2018;24:315-23. doi: 10.1089/tmj.2017.0046.
20. Drepper VJ, Martin PY, Chopard CS, Sloan JA. Remote patient management in automated peritoneal dialysis: A promising new tool. *Perit Dial Int* 2018;38:76-8. doi: 10.3747/pdi.2017.00054.
21. Petersson I, Lennerling A. Experiences of living with assisted peritoneal dialysis – A qualitative study. *Perit Dial Int* 2017;37:605-12. doi: 10.3747/pdi.2017.00045.

### EDITORIAL COMMENTARY

Automated peritoneal dialysis machines made in China might benefit Chinese patients undergoing maintenance peritoneal dialysis in improved operability and reduced medical costs. Although the authors selected an observation period of 72 hours mainly considering the differences and variability of peritoneal function in this study, the editors and peer reviewers of *Chinese Medical Journal* think that the 72-hour observation period is not enough. Further evidence is encouraged to certify the efficacy and safety of the automated peritoneal dialysis machines made in China.

# 迈达FM自动化腹膜透析机随机、多中心、交叉对照研究

## 摘要

**背景:** 通过随机、多中心交叉对照研究, 评价迈达FM腹膜透析机用于维持性腹膜透析患者治疗的安全性、有效性和可操作性。

**方法:** 研究对象来自全国18家医院接受腹膜透析(PD)治疗的患者(年龄 $\geq 18$ 岁, PD $\geq 30$ 天; 排除联合血液透析、出口或隧道感染、腹膜炎后30天内的患者)。试验组选用迈达FM腹膜透析机治疗, 对照组选用Homechoice腹膜透析机治疗。采用随机、多中心交叉对照设计, 各进行1个周期的治疗。主要评价指标为每日腹膜Kt/V, 次要评价指标为注入准确率、注入温度准确率以及毒素电解质变化情况。采用问卷评分法比较两组的安全性和可操作性。将两组研究结果进行非劣效检验。

**结果:** (1) 共260例维持性腹膜透析患者参加本研究, 男性158例, 女性102例; 平均年龄(49.33 $\pm$ 15.26)岁; (2) 主要有效性评价指标: 试验组和对照组的每日腹膜Kt/V分别为0.17(0.14,0.25)和0.16(0.13,0.23)。P值为0.7029, 大于0.05, 差异无统计学意义; 且试验组与对照组每日Kt/V差值的95%CI下限为0.0069, 大于本研究的非劣效界值-0.07。; (3) 次要有效性评价指标: 试验组和对照组注入准确率(89.7%和84.0%)和注入温度准确率(91.5%和86.8%)无显著差异; (4) 安全性及可操作性: 两组治疗过程中患者生命体征平稳, 耐受性良好; 对照组机身较节省空间, 试验组的机身移动性、人机对话操作、报警控制和患者信息识别较好。

**结论:** 通过多中心随机交叉对照研究, 迈达FM腹膜透析机可操作性良好, 有效性、安全性达标, 不劣于Homechoice腹膜透析机。