

A Comparative Study of Sterility Levels in Continuous Ambulatory Peritoneal Dialysis System

Sabine Kyoko Saito¹, Tetsuya Kashiwagi¹, Hideyasu Miyahara²,
Yasuhiko Iino¹ and Yasuo Katayama¹

¹Department of Neurological, Nephrological, and Rheumatological Science, Graduate School of Medicine, Nippon Medical School

²Research and Development, JMS Co., Ltd.

Abstract

Introduction: Peritonitis remains a serious risk associated with continuous ambulatory peritoneal dialysis (CAPD), although better patient education programs and such technological advances as improved automated connecting devices have greatly decreased its incidence over the past 20 years. The automated devices have a good resistance to contamination, but they rely on an external electrical power source and are not easily portable. There has, therefore, been a need for a highly sterile nonelectric manual connecting device to complement the automated devices already in use. Such a manual device has recently been developed. We compared the level of sterility after touch contamination in this new device with levels in 2 other connecting devices: a conventional device with a manual cap (JMS Co. Ltd., Hiroshima, Japan), and a powered total containment device (JMS Co. Ltd.).

Method: Five bacteria frequently causing CAPD-related peritonitis (*Staphylococcus aureus*, *Staphylococcus epidermidis*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Candida albicans*) were separately applied to the tip of each connecting device, and peritoneal washing fluid was injected as in a routine exchange. We used a membrane filter method to determine whether the route had been contaminated by the washing fluid.

Results: In the conventional device with a manual cap, 3 to 4 colony-forming units (CFUs) of *S. aureus* were detected in 2 of 10 drainage samples, 8 CFUs of *E. coli* in 1 of 10 drainage samples, and 1 CFU of *E. coli* in the injection fluid. In contrast, no contamination was detected in the automated connecting device or the new manual cap device.

Conclusion: This study confirmed that the new device has a risk of touch contamination lower than that of the conventional manual cap device and equal to that of the automated device. Being easily portable and not reliant on an external power source, the new device should be useful in various situations.

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Key words: peritonitis, continuous ambulatory peritoneal dialysis, connecting device, touch contamination

Correspondence to Sabine Kyoko Saito, Division of Neurology, Nephrology, and Rheumatology, Department of Internal Medicine, Nippon Medical School, 1-1-5 Sendagi, Bunkyo-ku, Tokyo 113-8603, Japan

E-mail: s2037@nms.ac.jp

Journal Website (<http://www.nms.ac.jp/jnms/>)

Introduction

Continuous ambulatory peritoneal dialysis (CAPD) is still associated with a risk of peritonitis^{1,2}. The causes of CAPD-related peritonitis include contamination of the dialysate, infection via the catheter outlet, tunnel infections, and endogenous infections, such as intestinal and hematogenous infections¹. The incidence of peritonitis caused by contamination of the dialysate or infection via the catheter outlet has been reduced by more than two-thirds over the last 20 years or so (1986: 1 episode/22.1 patient months; 2005: 1 episode/73.5 patient months), owing mainly to technological advances, such as improved connecting devices, better training of care providers, and promotion of patient education³.

The development of automated connecting devices with sterile connectors and ultraviolet light flash has played a particularly important role in the decreased incidence of peritonitis³⁻¹⁰. Most of the causative microorganisms in CAPD-related peritonitis are thought to gain entry to the peritoneal cavity following touch contamination of a connecting device during bag exchange^{1,2}.

The automated device is a completely closed structure in which sterility during bag exchange is maintained with high heat (320°C) or an electrically generated ultraviolet flash. Therefore, contamination of the inner route followed by the dialysate is extremely unlikely.

The high sterility levels of automated devices have been confirmed in many studies, but a few limitations remain⁴⁻⁸: the devices are too heavy to be easily portable; an external electrical power source is required; and mechanical failure is a possibility. Because such limitations would make these devices unusable during natural disasters and other emergencies, there is a need for a highly sterile and easily portable manual-cap connecting device that can function without an external electrical power source and can minimize the risk of contamination of the dialysate route.

Such a device (hereinafter, the new device) has recently been developed by JMS Co. Ltd. (Hiroshima,

Japan). In this study, we compared 3 connecting devices in terms of sterility level and utility: the new device; a conventional device with a manual cap (JMS Co. Ltd.) (hereinafter, the conventional device); and a powered total containment device (JMS Co. Ltd.) (hereinafter, the TCD device).

Materials and Methods

Subjects

The following 2 manual-cap devices and 1 automated device were compared.

(1) The conventional device (**Fig. 1**) was a double-cylindrical structure with internal and external cylinders connected by a luer access device.

(2) The new device (**Fig. 2**) was an improved (compared with the conventional device) double-cylindrical structure with a manual cap. It is difficult for the internal cylinder of the connector to make contact with the external cylinder, the most likely site of contact contamination in the connecting operation. In addition, the new device shields the tip of the internal cylinder of the connector on the patient side with a silicon rubber valve (septum).

(3) The TCD device (**Fig. 3**) was an automated device in which the tubes are melted and connected directly by a copper plate electrically heated to 320°C. Because heat ensures sterile connections in a completely closed structure, contamination of the inner route followed by the dialysate is extremely unlikely.

Materials

The microorganisms used for the test were 1 fungus that causes intractable peritonitis (*Candida albicans*; *C. albicans*) and 2 Gram-positive bacteria (*Staphylococcus aureus*; *S. aureus* and *Staphylococcus epidermidis*; *S. epidermidis*) and 2 Gram-negative bacteria (*Escherichia coli*; *E. coli* and *Pseudomonas aeruginosa*; *P. aeruginosa*) known to cause dialysis related peritonitis^{3,12,13}. Bacterial cultures of 10⁶ colony-forming units (CFUs)/mL were prepared with 0.01% Tween 80 saline for *Staphylococcus* spp., and with saline for the other bacteria.

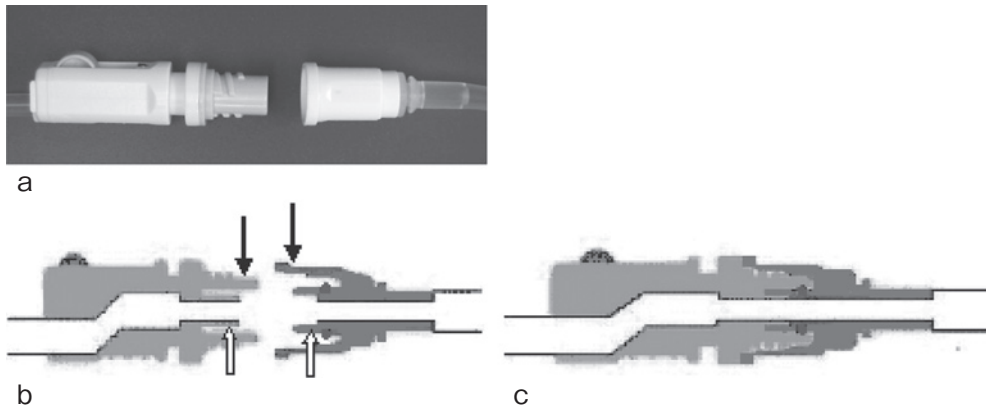


Fig. 1 Conventional device

- a Left: Patient-side connector
Right: Dialysate-side connector
- b Longitudinal section
A double cylindrical structure with internal (↑) and external cylinders (↓).
- c Longitudinal section (connected status)

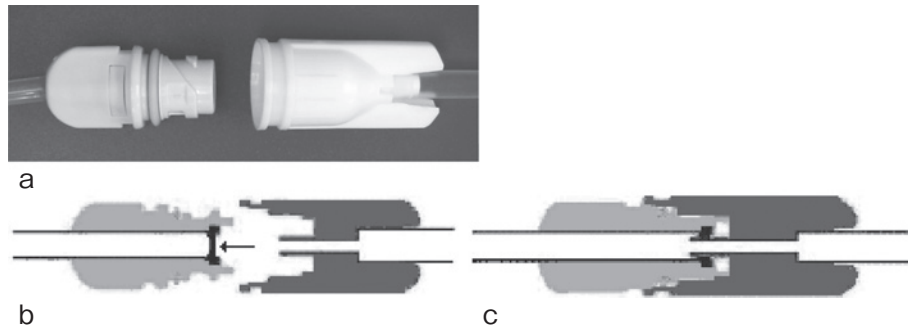


Fig. 2 New device

- a Left: Patient-side connector
Right: Dialysate-side connector
- b Longitudinal section
An improved double cylindrical structure.
The lumen of the patient-side connector is closed with a silicon rubber valve (←).
- c Longitudinal section (connected status)
Flow path is prepared only by connection with the dialysate-side connector.

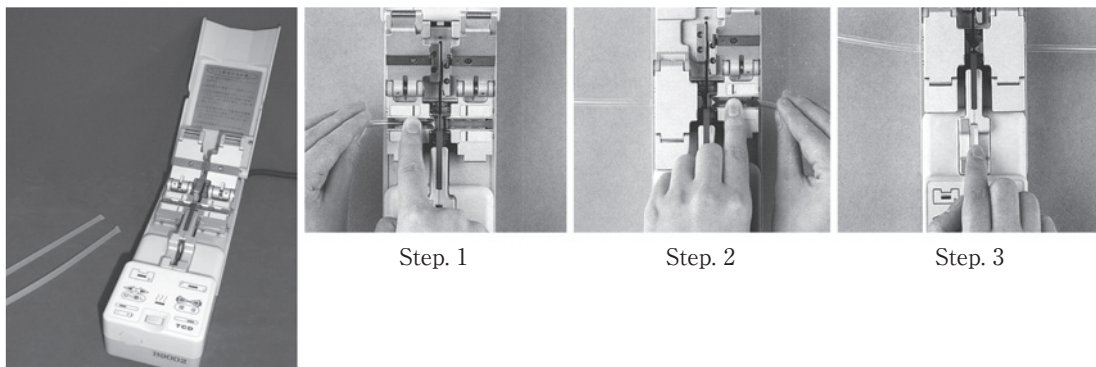


Fig. 3 TCD system

- Step. 1 Set the patient-side tube
 - Step. 2 Set the dialysate-side tube
 - Step. 3 Set a copper plate wafer
- After steps 1 to 3, the tubes are automatically melted and welded by pressing the button.

Method

(1) Two milliliters of the prepared bacterial culture was evenly applied to a 90-mm-diameter filter (No. 5C, Advantec Toyo Roshi Kaisha, Ltd., Tokyo, Japan) in a dish, and the tip of the connector on the patient side of each manual cap device was brought into contact with the filter for 3 seconds. The tip of the tube on the patient side of the automated device was contaminated in the same fashion.

(2) The contaminated patient-side connector (or tube) was jointed with the dialysate-side connector (or tube) similarly to usual dialysate bag change method. Then 100 mL of peritoneal washing fluid (Fluid D Rinsing Solution [FLUID DST], Sysmex bioMérieux, Lyon, France) was injected via syringe from the patient-side connector tube which was considered as a substitution of the effluent from a patient in the dialysis. The peritoneal washing fluid was collected by a 0.45- μ m-diameter cellulose membrane filter (100-mL Milliflex filter funnel unit, Millipore, Billerica, MA, USA) at the opposite end (dialysate end), and incubated on a soybean casein digest (SCD) agar medium (Milliflex Cassette prefilled with Tryptic Soy Agar, Millipore) at 30°C to 35°C for 1 to 2 days.

(3) One hundred milliliters of the peritoneal washing fluid was injected through the connecting device in the opposite direction to that in step 2 (i.e. from the dialysate end to the contaminated patient end). It was considered as a substitution of the dialysate, injected to a patient's abdominal cavity in the dialysis. The fluid was collected on a membrane filter and incubated on an SCD agar medium at 30°C to 35°C for 1 to 2 days.

(4) After being cultured for 1 to 2 days, the colonies were counted.

(5) Each contaminated connector or tube was soaked in 10 mL of the peritoneal washing fluid. The solutions were then vortexed for 30 seconds, applied to 3 SCD agar media (Sysmex bioMérieux) at 500 μ L per plate, and incubated at 30°C to 35°C for 1 to 2 days. The colonies produced were counted, and the mean number of bacteria was calculated from the 3 samples.

Results

The connector (n=10, mean \pm SD) of the conventional device was contaminated with 4,196 \pm 4,799 CFUs of *S. aureus*, 2,720 \pm 1,350 CFUs of *S. epidermidis*, 4,316 \pm 3,951 CFUs of *E. coli*, 18,990 \pm 21,796 CFUs of *P. aeruginosa*, and 1,529 \pm 1,139 CFUs of *C. albicans*. In the new system, the numbers of colonies were 4,716 \pm 5,078 CFUs of *S. aureus*, 3,273 \pm 2,129 CFUs of *S. epidermidis*, 5,247 \pm 5,173 CFUs of *E. coli*, 3,593 \pm 3,765 CFUs of *P. aeruginosa*, and 2,229 \pm 2,510 CFUs of *C. albicans*. In the TCD system, the numbers of colonies were 5,222 \pm 7,023 CFUs of *S. aureus*, 1,560 \pm 1,371 CFUs of *S. epidermidis*, 1,840 \pm 2,239 CFUs of *E. coli*, 7,040 \pm 7,113 CFUs of *P. aeruginosa*, and 2,402 \pm 2,873 CFUs of *C. albicans* (**Table 1**). In all cases, because bacteria were attached to the connector or tube in larger numbers than would be expected in clinical settings (60 to 470 CFUs), we judged the levels of contamination more than sufficient for testing contact contamination^{4,14}.

No bacterial contamination of the peritoneal washing fluid was found in the new or TCD devices. In the conventional device, however, 3 to 4 CFUs of *S. aureus* were detected in 2 of 10 drainage samples, 8 CFUs of *E. coli* in 1 of 10 drainage samples, and 1 CFU of *E. coli* in the injected fluid (**Table 1**).

Discussion

Peritoneal dialysis was introduced in 1981; in the succeeding years, the safety of this treatment in terms of resistance to contamination has been greatly increased by improved connecting devices for the dialysis bag, promotion of patient education, and better training of care providers. Consequently, the incidence of CAPD-related peritonitis found in a 1996 survey was significantly lower than that found in a similar 1986 survey¹. However, cases of refractory or even fatal CAPD-related peritonitis still occur. Automated devices have a good safety record, but limitations remain: the devices are too heavy to be easily portable; an external electrical power source is required; mechanical failure is a possibility; and the devices might be unusable during natural

Table 1 Results of the bacterial contamination test (into dialysate)

a Test results for Conventional type											(CFU)
Bacterial species	1	2	3	4	5	6	7	8	9	10	Laced bacterial count
<i>S. aureus</i>	-*/-	-/-	-/-	3/-	4/-	-/-	-/-	-/-	-/-	-/-	4,196
<i>S. epidermidis</i>	-/-	-/-	-/-	-/-	-/-	-/-	1/-	-/-	-/-	-/-	2,720
<i>E. coli</i>	-/-	-/-	-/-	-/-	-/-	8/1	-/-	-/-	-/-	-/-	4,316
<i>P. aeruginosa</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	18,990
<i>C. albicans</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	1,529
(Effluent/Dialysate)											
* -: negative											
b Test results for New type											(CFU)
Bacterial species	1	2	3	4	5	6	7	8	9	10	Laced bacterial count
<i>S. aureus</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	4,716
<i>S. epidermidis</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	3,273
<i>E. coli</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	5,247
<i>P. aeruginosa</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	3,593
<i>C. albicans</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	2,229
(Effluent/Dialysate)											
* -: negative											
c Test results for TCD											(CFU)
Bacterial species	1	2	3	4	5	6	7	8	9	10	Laced bacterial count
<i>S. aureus</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	5,222
<i>S. epidermidis</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	1,560
<i>E. coli</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	1,840
<i>P. aeruginosa</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	7,040
<i>C. albicans</i>	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	2,402
(Effluent/Dialysate)											
* -: negative											

disasters and other emergencies. To meet the needs of increasing numbers of elderly patients requiring dialysis and to ensure that treatment can continue during natural disasters, a safe, reliable, and easy-to-use device with a manual cap is required.

In this study, the level of contamination of a new device was compared with that of a conventional device and a TCD device. Because touch contamination is most likely to occur during dialysis bag exchange, the new device was designed with an improved closed structure featuring a silicon gum septum and an internal cylinder. This modified double-cylindrical structure makes touch

contamination of the dialysate route highly unlikely. The TCD system is also extremely resistant to contamination, because high heat (320°C) is used to directly connect the tubes. Our tests resulted in bacterial contamination of the peritoneal washing fluid only in the conventional device, indicating that it is less resistant to touch contamination than are the other 2 devices. However, this study probably overestimated the risk of bacterial contamination in the conventional device for 2 reasons: first, the connector was contaminated with a larger number of bacteria than would be expected in clinical settings;¹¹ second, the injection cap is normally

cleaned with povidone iodine before it is applied to the external cylinder of the connector, greatly reducing the risk of contamination. In this study, we contaminated the external cylinder of the connector on the patient side with bacteria. The connectors of both side have a double cylindrical structure with internal and external cylinder. The main reason why bacterial contamination was detected only in the conventional system is that the internal cylinder of the connector is located at a site that can more easily make contact with the bacterially contaminated external cylinder.

Nevertheless, our study shows that the new device is more resistant to touch contamination than is the conventional device and achieves sterility levels similar to those of the TCD device, whose high safety levels have been confirmed in other studies⁹. Therefore, we believe that its portability, ability to function without an external power source, mechanical reliability, and low price make the new device useful for a wide range of applications. Further development will no doubt lead to the production of a connection system that is even more resistant to contamination and more easily portable which can be used in adverse circumstances, such as natural disasters.

Conclusion

This comparative study of 3 CAPD devices indicates that the new device offers, in addition to various other advantages, a resistance to touch contamination similar to that of the TCD device and greater than that of the conventional device.

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