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Review article

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Microbiological evaluation of the safety cap on peritoneal dialysis

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Evaluación microbiológica del tapón de seguridad en diálisis peritoneal

Resumen

En los pacientes con enfermedad renal crónica terminal, que reciben terapia dialítica bajo la modalidad de diálisis peritoneal, se ha descrito que las complicaciones infecciosas como la peritonitis, permanecen como la principal causa de pérdida de la terapia, aún después de lograr disminuir las tasas de presentación de esta complicación. Los factores etiológicos asociados son múltiples y van desde la condición clínica del paciente, su adherencia al protocolo de realización de la terapia, su estado socioeconómico y el sistema utilizado para el aporte de los líquidos al peritoneo. Tomando como objetivo estos factores, decidimos estudiar la adherencia al protocolo de conexión de diálisis,el comportamiento microbiológico y su asociación altapón de seguridad del cambio anterior del sistema de diálisis peritoneal BenY®, en pacientes previamente clasificados según su adherencia al protocolo de conexión a diálisis. Se evaluó la técnica del paciente para la conexión a su terapia según la escala de 9 pasos fundamentales y puntos adicionales, y se tomaron cultivos de dispositivos nuevos y usados por los pacientes. En nuestro estudio no se evidenció asociación clínicamente significativa del dispositivo evaluado en el desarrollo de peritonitis, comparado con otros existentes para la misma finalidad.

Palabras clave: Diálisis peritoneal, peritonitis, tapón de seguridad del cambio anterior (fuente DeCS).

Microbiological evaluation safety cap in peritoneal dialysis

Abstract

In patients with end-stage renal disease treated with peritoneal dialysis, peritonitis remains as a main cause of complications and therapy loss, even after reducing peritonitis appearance rate. Etiological factors which have been associated are multiple, including clinical conditions of patient, adherence to the clinical protocol of the therapy, socioeconomic status and the system used to deliver fluid to peritoneal cavity. Considering all these factors, we decided to study the adherence to the protocol of connection in dialysis, its microbiological behavior and its association to the safety cap of the previous exchange of peritoneal dialysis system BenY®, in patients who were previously classified according to their adherence to the protocol of connection in dialysis. Patients' technique of connection to their therapy was assessed through nine key steps and some additional remarks, and then cultures of new and used devices were collected. In our study, there is no evidence of a clinically significant correlation of evaluated devices and peritonitis, compared to other devices designed for the same aim.

Key words: Peritoneal dialysis, Peritonitis, Safety lock (MeSHsource).

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Introduction

Ambulatory peritoneal dialysis, in its manual and automated modes, is considered a therapeutic option for patients with end-stage renal disease with renal replacement requirement, providing clinical outcomes comparable to and even higher than hemodialysis[1-6] in terms of survival.

Their choice depends on the patient's preference, the geographical location of the patient and the hemodialysis unit, the special conditions of comorbidity and the discretion of the physician. However, despite complications have declined markedly, peritonitis is the main acute complication of peritoneal dialysis, causing hospitalization, catheter loss, abandonment of technique and transfer to hemodialysis, and mortality[7-12]. Bacteriological etiology is diverse[13-23]. Its diagnosis, treatment and prognosis are usually clearly defined[24-28] and prognosis is variable[29-33].

Among the "individual" factors which have been associated with peritonitis in peritoneal dialysis are the following, which are considered non-modifiable: race, female gender, chronic obstructive pulmonary disease, coronary artery disease, congestive heart failure, cardiovascular disease, hypertension, antibodies for hepatitis C, diabetes mellitus, lupus nephropathy and absence of residual renal function. Also, we have identified modifiable factors such as malnutrition, overweight, smoking, immunosuppression, psychosocial factors, low socioeconomic status, dialysis therapy against the patient's will and hemodialysis as the previous mode (as evidenced by Kerschbaum et al.12), and hypokalemia (according to other authors).

Additionally, factors related to the "system or dialysis technology" were described as associated to the development of peritonitis, finding that those used for connecting systems which are Y-sets and flush-before-fill double bag decrease the appearance rates of peritonitis compared to the spike type[34-36].

Because it is so multifactorial, many preventive strategies have been proposed as the main support in the development of episodes of peritonitis[37-45].

In order to define the contribution of the connection system in the genesis of contamination of the peritoneal cavity of patients, a descriptive, pragmatic study was conducted to assess the sterility of the safety device of the previous exchange (Figure 1) of PiSA® BenY system® (Figure 2) and PD Pacífica in both manual and automated peritoneal dialysis patients, adjusting for adherence to the technique of connection by the patient, as the main condition that causes variability.

Methodology

4 dialysis centers were chosen in Bogota, following the methodology of convenience randomization, and in these, 30 patients were selected, 23 on manual peritoneal dialysis and 7 on automated peritoneal dialysis. "Home delivery" distribution channel of

Figure 1.
Safety cap of the previous exchange

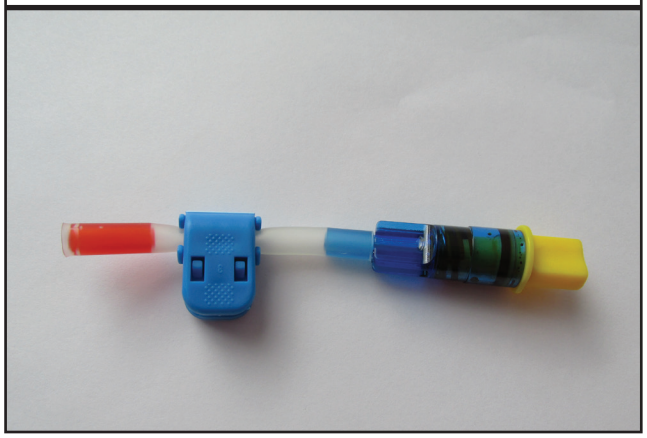
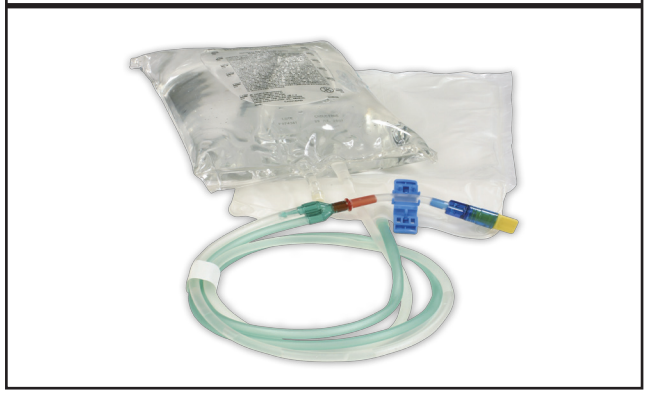


Figure 2.
BenY® system



PiSA® products for performing peritoneal dialysis therapy at home was checked.

Patients included were previously trained according to PiSA® methodology, and adherence was assessed through the application of a checklist where nine key steps are described (Annex 1), each of which had a score of 3. In the absence of one of them, the patient was considered not adhering. Patients who fulfilled the 9 key steps were considered adhering and, additionally, obtained more than 50 points when combined with the other criteria of the scale used for the technical evaluation (Annex 1).

All patients were questioned about symptoms associated with peritonitis at the time of inclusion in the study, and the physical characteristics of dialysate (color, turbidity) and presence of abdominal pain and fever were evaluated.

Together with the Microbiology team of San Ignacio University Hospital, the technique for identification, collection, transport and processing of samples as part of the research protocol (Annex 2) were defined.

Each patient included in the study was required 2 samples of the safety cap of the previous exchange; the sampling, in patients with continuous ambulatory peritoneal dialysis was made by 2 professional nurses trained for this purpose in the areas of replacement of the participant renal units; in the case of patients in automated peritoneal dialysis, all samples were collected at patients' home by the same professional staff.

All equipment used to collect the sample and the procedure to be followed by each person involved in the process is defined in Annex 2.

The samples were labeled according to a numerical system from 001-1 to 030-2; where samples labeled as 1 correspond to plugs from exchanges made by the patient at home and with a variable permanence of between 8 and 12 hours. The samples labeled as 2 correspond to plugs from exchanges made by the nurse at the renal unit in the case of patients with continuous ambulatory peritoneal dialysis with permanence variables between 4 and 12 hours.

All samples were analyzed at the laboratory of San Ignacio University Hospital, where 2 new caps and solutions of 20 bags randomly selected from available lots in PiSA® national distribution center, located in the municipality of Tocancipá, Cundinamarca, were also evaluated following the previously defined protocol.

The results were analyzed using descriptive statistics (frequencies), through Stata 12 software.

Results

The measurement of patient adherence to the technique of connection showed that 26 patients (87%) met the criteria to be considered adhering (Figure 3).

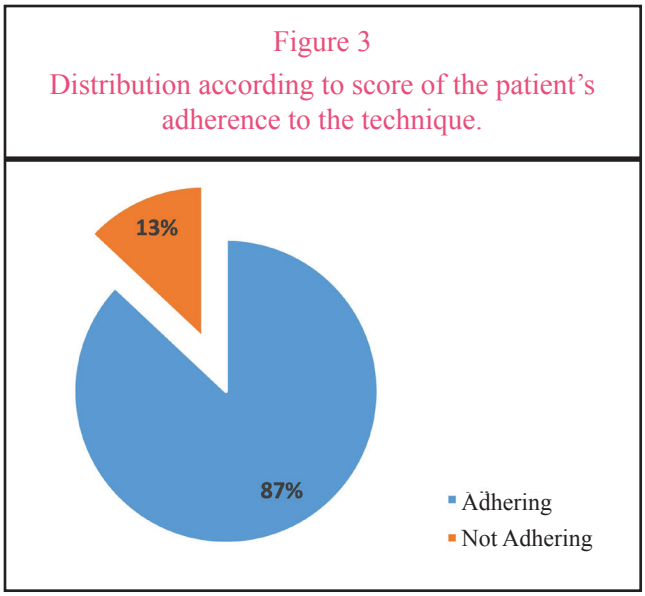
From the microbiological analysis of solutions and devices samples collected from the new inputs from PiSA® national distribution center, 100% were reported as negative (Table 1).

Of the 60 cultures taken from the patients' caps, 98.4% were negative and one positive, corresponding to 1.6% of the sample, and multisusceptible Escherichia Coli was isolated without presenting clinical association with active episode of peritoneal infection (Table 2).

Discussion

Having found sterility in new devices confirms appropriate quality standards and good manufacturing practices of inputs for conducting the therapy.

Figure 3
Distribution according to score of the patient's adherence to the technique.



In our review, an 87% of adherence to the technique of connection was found, which evidences training and continuous education with the patient. Non-adherence is 13%, similar to the 10% reported in the literature[46-52].

It was not possible to establish a direct relationship between patient non-adherence to the protocol of the connection technique and the positive culture result found, which may be related to multifactoriality and whose identification exceeds the scope of this study.

Conclusions

Our findings confirm the microbiological sterility of the elements used in the practice of the therapy in a heterogeneous group of patients, using inputs provided by PiSA® Pharmaceutical.

13% of patients were rated as not adhering to protocol, a similar proportion to 10% of non-adherence reported in the literature4; the positive result found in one culture does not clinically correlate with the peritoneal infection.

Ethical section

As a descriptive study, this is considered a safe research, in compliance with Article 11 of Resolution 8430 of 1993. Our study used techniques and methods of retrospective documentary research and those where no intentional intervention or modification of biological, physiological, psychological or social variables of the participants are performed. Each renal unit was requested informed consent, and they participated voluntarily and, in turn, informed their patients about the study. This study respects all international standards of clinical research.

Acknowledgements

The authors wish to thank the participant renal units and patients, as well as the Laboratory of Microbiology at Pontificia Universidad Javeriana.

Table 1.

Microbiological Analysis. Solution and Cap from factory.

Sample identification	Result	Sample identification	Result
918095	Negative (5 incubation days)	918114	Negative (5 incubation days)
918096	Negative (5 incubation days)	918115	Negative (5 incubation days)
918097	Negative (5 incubation days)	918116	Negative (5 incubation days)
918098	Negative (5 incubation days)	918117	Negative (5 incubation days)
918099	Negative (5 incubation days)	918118	Negative (5 incubation days)
918100	Negative (5 incubation days)	918119	Negative (5 incubation days)
918107	Negative (5 incubation days)	918120	Negative (5 incubation days)
918108	Negative (5 incubation days)	918121	Negative (5 incubation days)
918110	Negative (5 incubation days)	918122	Negative (5 incubation days)
918111	Negative (5 incubation days)	918123	Negative (5 incubation days)
918113	Negative (5 incubation days)	918124	Negative (5 incubation days)

Limitations of the study

Because it was a descriptive study with a limited sample, a causality analysis was not able to be performed. However, it allowed us to propose hypotheses that are in the process of being tested in a cohort study.

Conflict of interest

This study was funded by PiSA® Pharmaceutical Laboratories of Colombia SA. Dr. Carlos Hernan Mejia serves as a medical scientific advisor of PiSA® Nephrology Line. Dr. Luis Felipe Cano Silva is a medical advisor at PiSA® Laboratories. The coordinator of the Nephrology Line is Maribel Herrera and the technical director is Hernan Rodriguez.

Table 2.

Results from microbiological analysis of cap.

Sample identification	Culture 1	Sample identification	Culture 1	Sample identification	Culture 1	Sample identification	Culture 1
001-1	Negative	016-1	Negative	001-2	Negative	016-2	Negative
002-1	Negative	017-1	Negative	002-2	Negative	017-2	Negative
003-1	Negative	018-1	Negative	003-2	Negative	018-2	Negative
004-1	Negative	019-1	Negative	004-2	Negative	019-2	Negative
005-1	Negative	020-1	Negative	005-2	Negative	020-2	Negative
006-1	Negative	021-1	Negative	006-2	Negative	021-2	Negative
007-1	Negative	022-1	Negative	007-2	Negative	022-2	Negative
008-1	Negative	023-1	Negative	008-2	Negative	023-2	Negative
009-1	Negative	024-1	Positive *Escherichia coli*	009-2	Negative	024-2	Negative
010-1	Negative	025-1	Negative	010-2	Negative	025-2	Negative
011-1	Negative	026-1	Negative	011-2	Negative	026-2	Negative
012-1	Negative	027-1	Negative	012-2	Negative	027-2	Negative
013-1	Negative	028-1	Negative	013-2	Negative	028-2	Negative
014-1	Negative	029-1	Negative	014-2	Negative	029-2	Negative
015-1	Negative	030-1	Negative	015-2	Negative	030-2	Negative

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Annex 1

CHECKLIST FOR ADHERENCE TO CONNECTION TECHNIQUE

Prepare the necessary items.	Immediately twist and remove the safety device of the previous exchange from the extension line.
Check concentration, expiration date, characteristics of the dialysis solution and condition ofthe outer bag.	With your free hand, take the blue connector by its flat side.
Control the environment.	Connect and twist the blue connector smoothly to the top avoiding contamination.
Perform simple hand washing.	Place the clamp on the infusion line close to the Y.
Put on mask correctly.	Break the green seal on the Y.
Clean the worktop with Exsept 50% (500 ml) as indicated.	Hang solution bag / put drain bag on the floor.
Clean the protection bag of the solution before removing it.	Open drainage line, perform drain, verify characteristics of dialyzed fluid.
Place the bag on the table avoiding contamination.	Once drain stops, close the drainage line.
Clean the blue peritoneal clamp before placing it on the table.	Remove peritoneal dialysis clamp from the infusion line, count to 5 seconds and clamp drain line.
Clean Exsept bottle 50% (200 ml) according to taught technique.	Open drainage line allowing the income of solution to the peritoneal cavity.
Remove the extension line of the catheter from the bandage and verifies it is closed.	Once the solution is in, close drainage line.
Perform surgical scrub according to taught technique.	Close unbreakable lock.
Repeat scrub.	Clamp the two lines.
Perform pressure test to the bag (fold the bag).	Put down empty solution bag.
Verify cap color, break green connector, red clamp line, solution bag and characteristics of solution.	Break red connection clamp.
Put the lines apart so that they don't cross, without lifting them and avoiding contamination.	Place the line inside the protective bandage.
Disinfect hands.	Check the characteristics of the drained fluid.
Loosen the colored cap of the new BenY® system and immediately … (text missing).	Wash with water and soap, and dry the blue clamp, place it in lidded container.
Place the blue connector of the new BenY® system between index and middle fingers.	Organize the items for next exchange.
Place the drainage line connector between index finger and thumb.	Wash your hands.
Then remove the cap (yellow, green, red) by twisting it off the new BenY® system.	

Annex 2

SAMPLE COLLECTION PROTOCOL OF SAFETY DEVICE OF THE PREVIOUS EXCHANGE

PiSA® FARMACEUTICA MEXICANA	NURSING PROTOCOLS	Elaboration date: 01/03/2015
	PERITONEAL DIALYSIS PROGRAM	Page 1 of 4
	SAMPLE COLLECTION PROTOCOL OF SAFETY DEVICE OF THE PREVIOUS EXCHANGE	

Required material:

Sterile tube with breeding ground

Sterile cytobrush

Sterile pair of gloves No. 2

Mask

Surgical cap

Rack

500 ml 50% Exsept

200 ml 50% Exsept in spray

Sterile gauze

Sterile field

Transport (cooler)

BenY® system

Sterile scalpel blade

Identification of tubes with cultures:

The identification of the tubes with culture will be as follows:

001-1 001-2	0011-1 0011-2	0021-1 0021-2
002-1 002-2	0012-1 0012-2	0022-1 0022-2
003-1 003-2	0013-1 0013-2	0023-1 0023-2
004-1 004-2	0014-1 0014-2	0024-1 0024-2
005-1 005-2	0015-1 0015-2	0025-1 0025-2

- 1 ending corresponds to the first sample of each patient.

- 2 ending corresponds to the second sample of each patient.

At the beginning of the sample collection, all tubes will be labeled taking into account the previous nomenclature.

Then each pair of tubes will be placed in a plastic bag and will be identified by a color, just as patients will be recognized by color.

Personnel involved in the procedure:

Patient

Nurse #1, who performs the bag exchange, qualified personnel trained in BenY® system by PiSA®.

Nurse #2, who collects the sample, trained for its collection by the laboratory conducting the sample processing.

Context:

The connection technique of BenY® system or technical connection to the PD Pacífica are procedures that every patient on peritoneal dialysis program performs at home. For this reason, patients must take into account the recommendations given by the renal unit during training.

In this case, the connection procedure to BenY® System will be held in an exchange room at the renal unit (controlled environment) and will be performed by a trained nurse in PiSA® connection system. Additionally, the nurse who is in charge of collecting the sample for cultures will be in all cases the same, with the purpose of standardizing all samples to grow.

As for patients on automated peritoneal dialysis, samples will be taken at the home of the participating patients, and the procedure will be performed by a trained nurse in PiSA® connection system. Additionally, the nurse who is in charge of collecting the sample for cultures will be in all cases the same, with the purpose of standardizing all samples to grow.

Roles of participants:

The patient enters the exchange room, performs a simple hand washing and places his mask correctly.

Nurse #1: performs simple hand washing, wears cap covering earlobes, wears the mask correctly. Nurse #1 disinfects the safety device of the previous exchange, and immediately performs connection technique of BenY® system to the patient as per protocol (Annex 1).

At the time of performing disinfection of the elements to exchange the bag, N#1 disinfects the work area in order to handle the material for sample collection.

N#1 disinfects rack, disinfects outside of the tube containing the culture medium, disinfects Cytobrush wrap.

Nurse #2: 10 minutes before starting the connection method, places the culture medium at room temperature.

Nurse #2 verifies that all necessary equipment is complete.

N#2 performs simple hand washing, wears cap covering earlobes, wears mask correctly. N#2 prepares for sample collection of the safety device of the previous exchange.

Sampling procedure:

By the time Nurse # 1 is checking the solution bag according to the protocol (Annex 1), Nurse # 2 proceeds to perform surgical scrub, and prepares the material, unwraps the two pairs of sterile gloves, the surgical field, the gauze pack and the scalpel blade.

N#2 disinfects hands with Exsept 50%.

N#2 wears the sterile gloves and extends the sterile field on the work area. At this time, the 2 nurses synchronize so that Nurse # 1 performs patient's connection to PiSA® connection system, and places the safety device of the previous exchange on the sterile field, immediately disinfects hands using Exsept 50%, puts on sterile gloves, unwraps the cytobrush with the help of the scalpel blade and delivers it to Nurse # 2.

Nurse # 2 takes the cytobrush and, protecting with a short sterile gauze, cuts the excess, presses it with right hand, then takes the safety device of the previous change with left hand and proceeds to perform the sampling (introduces the cytobrush through spiral movements to the top of the device and removes with a single movement, without turning).

Simultaneously:

Nurse #1 uncovers the culture medium, according to the indication of Nurse #2.

Nurse #2 places cytobrush in the culture medium.

Nurse #1 immediately covers the culture medium and places it in the rack for transport to the laboratory.

Sample Transportation:

Place the rack with culture samples in a portable cooler which contains batteries for temperature maintenance.

Complete the Examination Order form required for the entry and processing of samples in clinical laboratory.

These samples will be taken to the laboratory where they will be processed in a time not exceeding two hours.

Unsuccessful sample:

A sample is considered not able to be processed when:

The protocol is not followed.

The times set by the protocol are not met.

Sample contamination by external agents.

Problems in the transport of the sample.

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