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Characterization and frequency of failure of the Peritoneal Dialysis technique in diabetic patients

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ABSTRACT

Background: Diabetes is defined as a disease caused by alterations in carbohydrate metabolism with multi-organ complications; diabetic nephropathy is one of the main causes of End-Stage Chronic Kidney Disease in Mexico and the world, having a 10-fold increased risk of nephropathy.

PD is an option in low-income countries, as it is cost-effective when performed at home vs. in health institutions with similar benefits for the first 1 to 2 years.

However, despite its benefits, PD is not without complications, one of the main ones being FT, defined as the transfer of the patient to HD due to the ineffectiveness of PD in maintaining adequate renal replacement therapy. FT can be caused by a variety of factors such as recurrent peritoneal infections, mechanical catheter problems, and complications related to ultrafiltration.

Due to the constant increase in the incidence of DM and ESCT as well as the controversy in the literature on the outcomes of patients living with diabetes in PD, it is important to be able to characterize and calculate the frequency of TF in PD in diabetic patients, in order to be able to seek a route of improvement in actions at different levels. both institutional, health personnel and family members.

Objective: The aim of the study is to evaluate the outcome in the subgroup of diabetic patients who started PD between 2020-2021 and to detect the frequency of PD in order to characterize and detect associated risk factors.

Material and Methods: We designed an observational, retrospective, analytical, and longitudinal study, whose objective was to obtain the incidence of PD in diabetic patients with ESRD in a tertiary hospital, in order to identify risk factors. Inclusion criteria: Adults over 18 years of age with a diagnosis of Type 2 Diabetes Mellitus prior to the diagnosis of ESRD, who have started renal replacement therapy in the PD modality at the Tertiary Level Hospital, between 2020 and 2021; (N=131). For the

Absolute frequencies and percentages were calculated for qualitative variables; for quantitative variables, such as age, normal distribution was determined using the Kolmogorov-Smirnov test ($p > 0.05$), so mean and standard deviation were used. To know the differences in the characteristics based on the failure or not of the technique, the $\chi 2$ test (Fisher's exact test in case of having a square with an expected count <5) and for the numerical variable Student's t-test for independent samples were used. A value of $p < 0.05$ was considered to be of statistical significance. To identify the risk factors associated with failure of the technique, an unadjusted logistic regression model was performed and adjusted for the same variables (PD modality, PD-associated infection, type of hospitalization), with the intro method, and odds ratio (OR) and 95% confidence interval (95% CI) were obtained.

Results: The average age was 54 years; with the following distribution of percentage of type of schooling, primary 52.7% and secondary 35.2%. The main comorbidity found is Systemic Arterial Hypertension with a frequency of 98%, followed by diabetic/hypertensive retinopathy in 90.1%.

A dialysis emergency reason for admission was 58.2% of patients at the time of peritoneal dialysis catheter placement. Of the total sample (N=91), 70.3% had failure of the peritoneal dialysis technique; The main etiology was catheter-associated infection (41.8%), followed by mechanical dysfunction (16.5%). The most commonly used type of dialyzer solution was dialysis solution with 1.5% glucose (78%).

The risk factors associated with FT are IPD in the unadjusted model (OR of 20.8; CI 4.52-95.88, $p<0.001$) and in adjusted multivariate model) OR 35.96; CI 6.81189.64, $p< 0.001$) and catheter-associated infection with an OR of 16.07 (CI 3.5-73.67, $p<0.001$) and multivariate adjustment OR of 29.35 (CI 5.48-157.62 $p<0.001$) remaining risk factors for technique failure.

Conclusions: PD in PD in diabetic patients has a statistically significant relationship with the IPD modality, as well as catheter-associated infection in unadjusted and multivariate adjustment analysis.

The choice of dialyzer solution in diabetic patients should be personalized and with a tendency to use glucose-free solutions to improve peritoneal functionality in PD.
Education of patients, family members, and personnel in charge of managing PD modalities is an area of opportunity for constant improvement of PD and reducing FT.

Keywords: Type 2 Diabetes Mellitus, Peritoneal Dialysis, Technique Failure, Chronic Kidney Disease.

INTRODUCTION

Background

"A people that does not know its history cannot understand the present or build the future" -Helmut Kohl-.
Diabetes is defined by the American Diabetes Association (ADA) as a group of alterations in carbohydrate metabolism, whose main factors are low utilization of glucose as an energy source and its inappropriate production through gluconeogenesis and glycogenolysis, which together produce hyperglycemia (1). But as we will see later, the damage and impact of this chronic disease goes beyond glycocentrism.
According to the Global Burden of Disease study, published in the journal Lancet, in 2021 there were an estimated 529 million people with diabetes in the world and an increase in the prediction for 2050 to 1.31 billion people who will live with diabetes (2).
Mexico has statistics from the 2021 National Health and Nutrition Survey (ENSANUT) with a prevalence of 12 million 400 thousand Mexicans with diabetes, 9.8% of the national population (3) and Mexican projections are similar to those worldwide, since according to the first 2024 report of the Hospital Epidemiological Surveillance System for Type 2 Diabetes Mellitus (SVEHDMT2 for its acronym in Spanish), there was an increase in the first quarter of 2024 of 68.5% compared to the same period in the previous two years (4).
In Mexico, Systemic Arterial Hypertension (SAH) is the main comorbidity in 60.5% of diabetics, obesity as the second with 13.43% and ESRD in third place with 12.93%. (4), which implies the combination of two major health problems for the future of our country, the increase in people living with diabetes and therefore with ESRD.
The impact of diabetes includes increased cardiovascular risk and multi-organ damage; it is estimated that 20-40% of diabetic patients will develop diabetic nephropathy, being in some countries the main cause of End-Stage Chronic Kidney Disease CKD (5). According to reports by R, Yarragudi et al., the risk of nephropathy increases 10-fold vs. non-diabetics (6), Grzywacz, A. et al. document the synergistic effect of DM and ESCT, with an increase in the relative risk of 1.48 of death from any cause and an increase in cardiovascular mortality (7).
Another factor to take into account in these patients is insulin resistance and its consequent hyperinsulinism, affecting the lipid pathway and renal insulin receptors type 1 (IRS1), blocking the inhibition of gluconeogenesis, in addition to stimulating the tubular IRS2 to retain sodium and consequently hypertension and edema. At the podocyte level, the integrity of filtration and glucose reabsorption is altered, these effects are especially in those who receive high concentrations of glucose in the PD dialyzer pockets, causing a greater risk of peritonitis and mechanical damage of the peritoneal membrane, which are associated with high levels of mortality (8)
ESRD is also a global health problem, having an impact on quality, lifestyle and economic impact for the patient and the state. Villarreal-Ríos et al. estimate that the average annual cost of ERCT in Mexico is more than $200,000 Mexican pesos, with a lifetime cost of more than one million pesos, which impacts the expenditure of 1.47-1.73% of the annual institutional budget (9).
Taking into account that 56% of the Mexican population, according to INEGI data, is without a type of social security (10), the decision on the type of renal replacement therapy to choose will depend on psychosocial and economic factors.
Contrasting which renal replacement therapy is better if Hemodialysis (HD) or Peritoneal Dialysis (PD), has always been controversial, however, the results are dependent on the variables and subgroups that we analyze. In EF's meta-analysis, Vonesh, et al., which included 9 studies in four countries from 1994-2000, reported better overall survival in PD in the first 1 to 2 years. They also report the following independent mortality factors: age, number of comorbidities, wear and tear and the presence of diabetes, since diabetic adults over 55 years of age have better outcomes with HD Vs diabetics under 55 years of age with greater survival with PD, which may be due to a greater number of cardiovascular and metabolic comorbidities. (11)
Although the overall survival of patients with CKD has improved over the last few years, so has the survival of the PD technique, with a marked tendency to use personalized modalities and increase the opportunity for overall survival, however, diabetic patients in PD are still considered a subgroup with greater failure of the Technique and despite the fact that homogeneity has not been found in the related factors. these change depending on the population, country or institution (12); here lies the importance of characterizing diabetic patients in PD and the frequency of risk factors associated with Technical Failure (TF) in our population and enriching actions aimed at comprehensive management.

The Intermittent Peritoneal Dialysis (IPD) modality is currently in disuse in many parts of the world due to long-term complications, as well as longer time with elevated toxins, (13) however, in the hospital environment of Mexico, it is still used for reasons of institutional input and patient resources.
PD is an option in low-income countries, as it is cost-effective when performed at home vs. in health institutions, (14), however, it is necessary to be able to understand all the flats of this method to ensure an adequate and efficient technique.
The known benefits of PD are reported in the systematic review by B. Budhram et al., finding results in quality of life, less physical and emotional limitation, as well as functionality, pain, burnout due to ESRD, impact on day-to-day, sexual function and financial quality as they are more productive. Other authors report better control of blood pressure, hemodynamic stability, continuous and gradual clearance of fluids, improvement in the preservation of renal function and less myocardial stress; while HD obtained better results in sleep, body image and general health (15). These results are not conclusive throughout the literature, due to different economic, social and educational variables of health personnel and patients.
However, despite its benefits, PD is not exempt from complications, one of the main ones being FT, defined as the transfer of the patient to HD due to the ineffectiveness of PD in maintaining adequate renal replacement therapy [(16).] FT can be due to a variety of factors such as recurrent peritoneal infections, mechanical catheter problems, and complications related to ultrafiltration [(17).]
There are no systematized studies that characterize diabetic patients in PD and FT, however, Couchoud et al. report an average frequency of diabetics in PD between 9-61%. (18) and the risk of FT in these occurred within 11 months, with a 10-fold higher risk than HD, with infection being the main causes of FT (19).
Continuous contact with glucose-based hypertonic solutions in PD is related to submesothelial thickening, cellular hypertrophy, vacuolization and loss of microvilli, as well as angiosclerosis and angiogenesis in the peritoneal tissue, which perpetuate a state of inflammation coupled with diabetes, with the consequence of peritoneal tissue fibrosis and FT in PD. (20)
To address a problem, the population must be identified or characterized in order to find and direct improvement actions in the population studied. In the meta-analysis and systematic review by Daniel J. Devoe et al., they highlight the importance of patient education, as it is a sine qua non formula for success in PD, as it is performed at home. They also report that making an informed decision has a strong association with improvement and adherence to the technique. (21)

Problem Statement
Peritoneal dialysis is a viable and effective alternative for patients with end-stage chronic kidney disease (CKD), not only providing a relatively simple and less invasive technique, but also allowing them to maintain greater autonomy and quality of life compared to HD [(22 and 23).] PD is especially beneficial in regions with limited access to hemodialysis centers, as it can be performed in the patient's home, significantly reducing the need for advanced medical infrastructure [(24).]
It is important to carry out exclusive studies in this subgroup to assess the effect of microvascular damage and insulin resistance on PD functionality, we know that a higher hbA1c is related to higher mortality, however, this is not recommended as a goal in ESRD due to its easy intervention with anemia due to chronic disease and malnutrition. similarly, a goal of glycemia or HbA1c has not been recommended in them (5).
Due to the constant increase in the incidence of DM and ESCT as well as the controversy in the literature on the outcomes of patients living with diabetes in PD, it is important to be able to characterize and calculate the frequency of TF in PD in diabetic patients, in order to be able to seek a route of improvement in actions at different levels. both institutional, health personnel and family members.

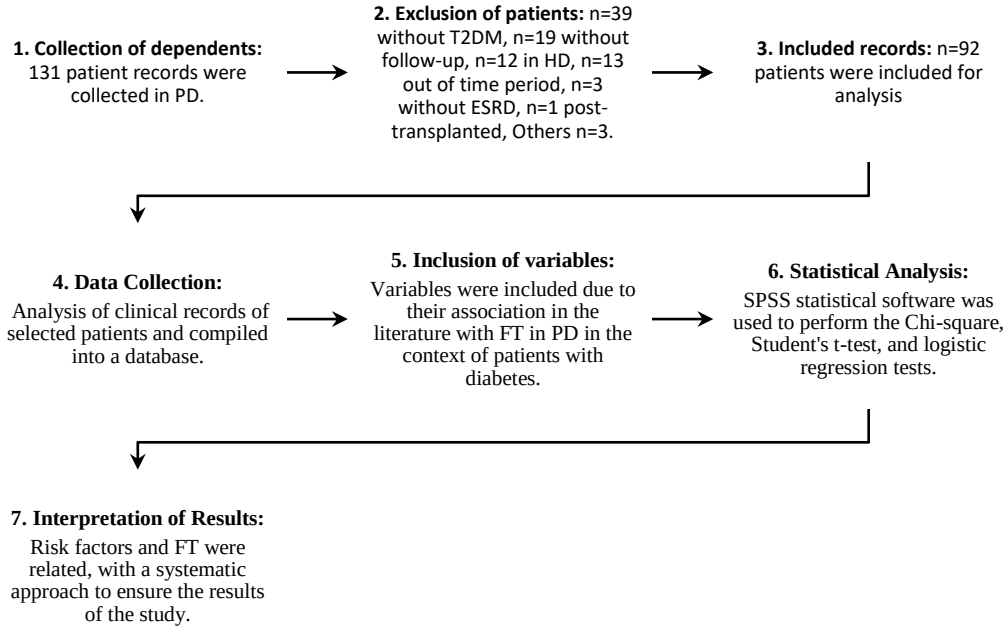
Objective: The aim of the study is to evaluate and characterize the subgroup of diabetic patients who started PD between 2020-2021 and to detect the frequency of PD and associated risk factors.

Material and Methods: We designed an observational, retrospective, analytical, and longitudinal study, whose objective was to obtain the incidence of PD in diabetic patients with ESRD in a tertiary hospital, to identify risk factors. Given the objectives of the study, the type of study allows us to analyze the elements of the failure of the technique in diabetic patients with ESRD
Inclusion criteria: Adults over 18 years of age with a diagnosis of Type 2 Diabetes Mellitus prior to the diagnosis of ESRD, who have started renal replacement therapy in the PD modality at the Tertiary Level Hospital, between 2020 and 2021. Records that had loss of follow-up after 365 days that were incomplete or illegible were not incorporated for an adequate analytical process, as well as those that did not meet the inclusion criteria.
Based on the previously mentioned criteria, all the records of patients treated in the Internal Medicine and Nephrology services during the period from January 2020 to December 2021, in a tertiary level hospital (N=131) were included. Clinical and demographic variables necessary to characterize the diabetic patient

population were included, as well as the factors that have an impact on TF. For the qualitative variables, absolute frequencies and percentages were calculated; for quantitative variables, such as age, normal distribution was determined using the Kolmogorov-Smirnov test ($p > 0.05$), so mean and standard deviation were used. To know the differences in the characteristics based on the failure or not of the technique, the χ^2test (Fisher's exact test in case of having a square with an expected count <5) and for the numerical variable Student's t-test for independent samples were used. A value of $p < 0.05$ was considered to be of statistical significance. To identify the risk factors associated with failure of the technique, an unadjusted logistic regression model was performed and adjusted for the same variables (PD modality, PD-associated infection, type of hospitalization), with the intro method, and odds ratio (OR) and 95% confidence interval (95% CI) were obtained; and thus use these results to improve clinical practice and allow the development of strategies for the survival of the patient. technique and reduce the incidence of complications associated with PD in diabetic patients.

The ethical principles established in the Declaration of Helsinki and the health research regulations of Mexico were followed, so the confidentiality of the data in the clinical record is protected. The data was used solely for research and analysis purposes, without personally identifying the patients involved.

Methodological steps:



RESULTS

The population analyzed was N=91, the demographic characteristics are exemplified in Table 1. Data are presented in frequency, percentages, mean and standard deviation.

The average age was 54 years; with the following distribution of percentage of type of schooling, primary 52.7% and secondary 35.2%.

The main comorbidity found is Systemic Arterial Hypertension with a frequency of 98%, followed by diabetic/hypertensive retinopathy in 90.1%.

It was found that 58.2% of the patients had dialysis emergency as a reason for admission at the time of placement of the peritoneal dialysis catheter. The proportion of the sample is homogeneous in relation to CAPD and IPD, represented by percentages in 53.8% and 46.2% respectively. No statistical difference was found in relation to the method of placement of the PD catheter. 8

Of the total sample (N=91), it was found that 70.3% had failure of the peritoneal dialysis technique; The main etiology was catheter-associated infection, frequently represented in a percentage of 41.8%, followed by mechanical dysfunction with 16.5%. The most commonly used type of dialyzer solution was the dialytic solution with 1.5% glucose, which represents 78% of the sample, it was identified that 40.7% had a catheter replacement due to previous dysfunction.

The characteristics of the population when comparing patients with and without FT are shown in tables 3 and 4. The comparison of the PD modality in patients with or without FT (Table 5); statistical significance was found for CAPD and IPD with $p < 0.001$. In relation to complications associated with peritoneal dialysis catheters, catheter-associated infection was significantly statistical for FT in 94.7% with $p < 0.001$.

Table 5 shows the factors associated with FT; in the unadjusted model, the IPD had an OR of 20.8 (CI4.52-95.88, p<0.001), identifying other risk factors such as catheter-associated infection with an OR of 16.07 (CI 3.5-73.67, p<0.001), without identifying another factor with associated statistical significance.
When performing the multivariate model adjusted for these same variables, the IPD had an OR of 35.96 (CI 6.81189.64, p< 0.001), and catheter-associated infection with an OR of 29.35 (CI 5.48-157.62, p<0.001) remained as risk factors for failure of the technique.

Analysis of results

The demographic characteristics of the population studied are relevant for the analysis of the results in failure of the PD technique; more than 50% of our population does not have basic schooling and only 35.2% has completed secondary school, making it difficult to understand the underlying pathology and its complications.
The main associated comorbidity was systemic arterial hypertension in 98% of patients, consistent with national reports released in the Hospital Epidemiological Surveillance System for Type 2 Diabetes Mellitus (SVEHDMT2) of 2024 and visual weakness was considered the main disability in diabetic patients (4). The frequency of visual impairment in the studied group was 90.1%, this is a social factor that affects the adequate PD technique at home, as well as the need for a good support network for PD placement.
According to the ADA in its 2024 recommendations, the referral of patients in stage KDIGO 4 to nephrology has been related to a reduction in costs and better quality of treatment, as well as a delay in the dialysis requirement (5). In the case of our population, 58.2% had a hospital admission with dialysis urgency at the time of placement without having a timely referral to an Internal Medicine or nephrology service.
70.3% of the patients had failure of the peritoneal dialysis technique; the main etiology was catheter-associated infection, frequently represented in a percentage of 41.8%, followed by mechanical dysfunction with 16.5%, consistent with national reports of the SVEHDMT2 where the main cause of admission in insulin-dependent patients was infection (4), likewise, in the meta-analysis by Nelveg-Kristensen et al, they report that diabetic patients have a higher risk of catheter-associated infection with an HR of 1.34 (p< 0.001), this being the second cause of mortality and the main cause of dysfunction or FT (25); as found in this study. The comparison of the PD modality in patients with or without FT is statistically significant for CAPD and IPD with p < 0.001. catheter-associated infection was significantly statistical for FT in 94.7% with p < 0.001.
Statistical significance in relation to FT and IPD was found both in the analysis without adjustment OR of 20.8 (CI4.52-95.88, p<0.001), and in the multivariate model adjusted for these same variables OR 35.96 (CI 6.81189.64, p< 0.001) remaining as a risk factor, the same situation with the relationship between FT and the risk of catheter-associated infection with an OR of 16.07 (CI 3.5-73.67, p<0.001) and in the adjusted multivariate OR model of 29.35 (CI 5.48-157.62 p<0.001) being true associated risk factors found in the study population.
The analysis of dialyzer solutions is an area of opportunity in the future of PD, although some authors such as Paniagua R, Et. Improvements in hyperinsulinism, glycemic and lipid control, and fewer adverse events were found with glucose-free solutions adjusted to patient characteristics (26), randomized controlled studies such as IMPENDIA-EDEN showed no statistical significance in insulin requirement and little significance in lipid control, however, they report that greater absorption of peritoneal glucose has a higher risk of mortality and FT in the first two years (27). The type of dialyzer solution most commonly used in patients (n=78%) was the dialytic solution with 1.5% glucose, with little variability and access to other types of solutions.
As mentioned by Bonomini, M et. The use of new dialyzing solutions is crucial for the future of PD (21), as well as finding strategies to reduce their toxicity and their personalized choice to reduce the risk of PD dysfunction.
The importance of finding risk factors associated with TF in diabetic patients lies in finding ways to improve the education of patients and personnel in charge of PD management. In the systematic review by Idier, L. et al., patient education improves adherence to treatment, management of the technique, greater satisfaction with the modality and quality of life of patients (28).

CONCLUSIONS

PD in PD in diabetic patients has a statistically significant relationship with the IPD modality, as well as catheter-associated infection in unadjusted and multivariate adjustment analysis.
The choice of dialyzer solution in diabetic patients should be personalized and with a tendency to use glucose-free solutions to improve peritoneal functionality in PD.
Education of patients, family members, and personnel in charge of managing PD modalities is an area of opportunity for constant improvement of PD and reducing FT.

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Annexes.

Table 1. Baseline characteristics of the population	
Variable	N=91 (100%)
Sex	
Female	39 (43)
Male	52 (57)
Age (years)[a]	54 ± 12
Schooling	
Primary	48 (52.7)
High school	32 (35.2)
High School or Bachelor's Degree	11 (11.1)
Comorbidities	
Systemic arterial hypertension	89 (98)
Diabetic or hypertensive retinopathy	82 (90.1)
Alcoholism	33 (36.7)
Smoking	24 (26.4)
Heart failure	13 (14.3)
Type of hospitalization	
Emergency admission	53 (58.2)
Scheduled entry	38 (41.8)

Data presented in frequency and percentages.
aData presented in mean and standard deviation

Table 2. General characteristics related to peritoneal dialysis	
Variable	N=91 (100%)
DP Modality	
Chronic ambulatory peritoneal dialysis	49 (53.8)
Intermittent peritoneal dialysis	42 (46.2)
Type of peritoneal dialysis catheter	
Tenckhoff espiral cateter	87 (95.6)
Straight Tenckhoff Catheter	4 (4.4)
Peritoneal Dialysis Catheter Placement Method	
Percutaneous	55 (60.4)

Laparotomy	35 (38.5)
Laparoscopic	1 (1.1)
Type of technical failure	
No failure	25 (27.5)
Failure of the technique	64 (70.3)
Catheter-associated infection	38 (41.8)
Mechanical dysfunction	15 (16.5)
Ultrafiltered alteration	3 (3.3)
Bleeding or bruising	1 (1.1)
Other unspecified	9 (9.9)
Type of solution used	
1.5%	71 (78)
1.5% and 2.5%	11 (12.1)
2.5%	9 (9.9)
Other variables	
PD catheter replacement	37 (40.7)
Previous abdominal surgery	28 (30.8)
Hernia abdominal o inguinal	2 (2.2)

Data presented in frequency and percentages.
aData presented in mean and standard deviation

Table 3. Baseline characteristics of the population in relation to the failure or failure of the technique

Variable	No technical flaw 27 (29.7)	With technical failure 64 (70.3)	p
Sex [to]			
Woman	9 (23.1)	30 (76.9)	0.233
Man	18 (34.6)	34 (65.4)	
Age [b]	54 ± 12	53 ± 12	0.995
Schooling [a]			
Primary	14 (30.4)	32 (69.4)	0.563
High school	8 (25)	24 (75)	
High School or Bachelor's Degree	5 (45)	6 (55)	
Comorbidities			
Systemic arterial hypertension	26 (29.2)	63 (70.8)	0.525
RD/RH	25 (30.5)	57 (69.5)	0.813
Alcoholism	7 (21.2)	26 (78.8)	0.166
Smoking	6 (25)	18 (75)	0.559
Heart failure	3 (23)	10 (77)	0.538
Type of hospitalization [a]			
Emergency admission	16 (30.2)	37 (69.8)	0.898
Scheduled entry	11 (28.9)	27 (71.1)	

[a] Values are presented in frequencies and percentages, $\chi 2$.
[b] Values are presented as mean and standard deviation, Student's T.

Table 4. Characteristics related to peritoneal dialysis and failure of PD technique

Variable	No technical flaw 27 (29.7)	With technical failure 64 (70.3)	p
Modality DP [a]			
Chronic ambulatory peritoneal dialysis	25 (51)	24 (49)	<0.001
Intermittent peritoneal dialysis	2 (4.8)	40 (95.2)	
Type of peritoneal dialysis [catheter b]			
Tenckhoff espiral cateter	25 (28.7)	62 (71.3)	0.363
Straight Tenckhoff Catheter	2 (50)	2 (50)	
Catheter placement method			
Percutaneous	18 (32.7)	37 (67.3)	0.628
Laparotomy	9 (25.7)	26 (74.3)	
Laparoscopic	0 (0)	1 (100)	

Complications associated with peritoneal dialysis catheter [to]			
Catheter-associated infection	2 (5.3)	36 (94.7)	<0.001
Initiation of dialysis emergency replacement therapy [a]			
Yes	19 (30.6)	43 (69.4)	0.766
Type of solution used [to]			
1.5%	17 (26.2)	48 (73.8)	0.519
1.5% and 2.5%	5 (46)	6 (54)	
2.5%	4 (44.4)	5 (55.6)	
Other variables			
DP to replacement	8 (21.6)	29 (78.4)	0.204
Pre-abdominal surgery	7 (25)	21 (75)	0.487
Hernia abdominal o inguinal [b]	1 (50)	1 (50)	0.497

[a] Values are presented in frequencies and percentages, $\chi 2$.
[b] Values are presented in frequencies and percentages, Fisher's exact test.

Table 5. Risk factors associated with technical failure.

Multiple logistic regression						
Variables	Hour	IC 95%	p	ORb	IC 95%	p
Intermittent peritoneal dialysis	20.8	(4.52-95.88)	<0.001	35.96	(6.81-189.64)	<0.001
Catheter-associated infection	16.07	(3.5-73.67)	<0.001	29.39	(5.48-157.62)	<0.001
Emergency admission	0.94	(0.37-2.35)	0.898	1.07	(0.28-4.11)	0.916
			R2 de Nagelkerke 0.615			<0.001

[a] Model 1 without adjustment.
[b] Model 2 adjusted for PD modality, associated catheter infection, and reason for hospitalization

Table 6. Additional findings and their relationship with or without failure to the technique

Variable	No technical flaw 27 (29.7)	With technical failure 64 (70.3)	P
Timely referral of nephrology [to]	7 (35)	13 (65)	0.58
Reason for discharge [b]			
Discharge due to improvement	26 (30.2)	60 (69.8)	0.533
Discharge due to death	1 (20)	4 (80)	

[a] Values are presented in frequencies and percentages, $\chi 2$.
[b] Values are presented in frequencies and percentages, Fisher's exact test.