Internal Medicine: Open Access

Reyes-Marín, et al., Intern Med 2014, 4:4
DOI: 10.4172/2165-8048.1000159

Research Article Open Access

Urgent Peritoneal Dialysis Initiation: is it Better to Wait a Few Days than to Use the Catheter Immediately After its Implantation? A Randomized Controlled Trial

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Received date: March 28, 2014, **Accepted date:** May 28, 2014, **Published date:** June 3, 2014

Abstract

Background: High-grade evidence for recommendations about the appropriate lag-time from implantation to utilization of the catheter regarding urgent PD is lacking. The objective of this study was to compare immediate and delayed utilization of the Tenckhoff catheter in urgent PD.

Methods: 160 patients beginning urgent automated peritoneal dialysis (APD) were randomized into two groups of 80 patients each. In the immediate utilization group (I), the catheter was used immediately after the surgical implantation; in the delayed utilization group (D), the catheter began to be used 3-5 days after the surgical implantation. The catheter function and complications in the two groups were compared after a one-year follow-up.

Results: Patients in I and D were aged 42.5±18.5 and 49.2±19.6 years and their BMI was 25±2.5 and 25±3 kg/m^2, respectively. The lag-time from implantation to utilization of the catheter was shorter in I (4±2 h) than in D (79.5±35.7 h; $p < 0.01$). Both groups had similar frequency of overall complications: 10 patients (12.5%) in I and 12 patients (15%) in D developed catheter related complications within 12 months. Group I complications were leakage (2), migration (2), and peritonitis (2); group D complications were leakage (3), migration (4), and peritonitis (2). Actuarial survival of the catheter showed no differences between the two groups at one year.

Conclusions: Immediate utilization of a surgically implanted Tenckhoff catheter is feasible and safe, since it is not associated with an increased frequency of complications.

Keywords: Randomized controlled trial; Peritoneal dialysis; Peritoneal catheter placement; Tenckhoff catheter; Technique survival; Per catheter leakage

Introduction

The appropriate time to initiate non-urgent peritoneal dialysis (PD) after a Tenckhoff catheter (TC) insertion is not clear from the literature [1-3]. Recent clinical guidelines for peritoneal access recommend to wait at least 2 weeks after catheter implantation before starting PD and to use smaller dialysate volumes in the recumbent position if dialysis is required earlier, but acknowledge that the strength of the recommendation is weak and the quality of the evidence level is moderate [4].

A widely sustained opinion is that immediate initiation of PD should not be recommended as a standard approach because it is reasonable to believe that a break-in period of some weeks may reduce the risk for early complications [5].

Complications such as dialysate fluid leaks, exit site infection or peritonitis have been reported to occur if PD is initiated too soon after the catheter insertion [6]. Some studies recommend a delayed initiation of the catheter utilization, but do not test different delay intervals [7]. Other studies report a very low leak incidence after a short break-in period, provided that tight catheter securing is performed [8,9].

It is accepted that there is insufficient evidence to formulate a guideline regarding the appropriate lag-time from implantation to utilization of the TC, and that further research is required [1,2].

The rationale for recommending a two weeks delay of the TC utilization in non-urgent PD is the general belief that leakage rates will be higher if PD is initiated during the first 10 days after PD catheter implantation because this is the time considered as necessary to allow an appropriate tissue cicatrization [10]. The 2 to 4 week break-in period would require bridge hemodialysis in some patients that need urgent dialysis therapy [9,11]. In some developing countries, such as in Mexico, there may not be availability of bridge hemodialysis, making it necessary to initiate the utilization of the TC immediately after its placement. In many Mexican dialysis centres, such as in ours, most of the incident patients with chronic kidney disease (CKD) arrive to the hospital with urgent dialysis requirement, because of uremic symptoms, fluid overload, congestive heart failure, or electrolyte and/or acid-base imbalance.

Our first consideration in deciding to compare immediate (within hours) and delayed (2-5 days) initiation of the TC utilization was the context of the study, with all the patients needing urgent beginning of the dialysis therapy. Recent guidelines [4] recommend leaving the catheter untouched for at least 5 days after its placement. In Mexico, many surgeons recommend not using the catheter in the first 5 days after the implantation. A 2-5 days period may be not enough to assure a complete wound healing, but we considered that there could be a

significant difference between 0 and 2-5 days, regarding wound cicatrisation.

The objective of this study was to compare immediate (within hours) and delayed (2 to 5 days) utilization of the TC in urgent PD in a randomized controlled trial (RCT).

Methods

Patients

One hundred and sixty adult patients from a single dialysis centre (Hospital Regional ISSEMYM, Tlalnepantla, México) with chronic kidney disease (CKD) and indication of urgent renal replacement therapy with PD (residual glomerular filtration rate±6 ml/min/1.73 m2) were randomly assigned to one of the two arms of the study: the immediate utilization group (I), in which the catheter was used immediately after the surgical implantation (n = 80), and the delayed utilization group (D), in which the catheter began to be used 2-5 days after the surgical implantation (n=80). Assignment was done using a computer-generated list, with a 1:1 ratio. Randomization was done before catheter placement, after the signing of the informed consent. The surgical team did not know to which group the patients were allocated. Allocation concealment was assured since only one of the authors (ARM) knew the allocation sequence and he only revealed the patients' study group to the rest of the team at the moment of dialysis initiation. Patients with systemic infection, severe protein-energy wasting (BMI<15kg/m^2), severe obesity (BMI>40 kg/m^2), and underlying medical conditions such as severe congestive heart failure, myocardial infarction, malignant hypertension, and stroke were excluded.

All the patients signed an informed consent form in order to participate in the study. The Institutional Review Board approved the protocol. The protocol was not inscribed in a RCT registry since it does not involve comparison of commercial drugs or devises, and it was not supported by external funds. All the invited patients accepted to participate in the study. Only patients who met all the eligibility criteria underwent randomization. All of the randomized patients began the study and concluded it. There were no deaths or loss to follow-up during the one-year observation period.

Surgical tc insertion

A coiled, double-cuffed, straight-neck TC was inserted by open surgery under general anaesthesia, without any use of prophylactic antibiotics.

The same technique was used in all the patients. Briefly, a paramedical line approach is used. A vertical 1-2 cm skin incision is made besides the umbilicus. The subcutaneous tissue and muscle layers are dissected. The peritoneum is opened by a 1 cm incision, and a purse-string suture is made around it. TC is introduced and advanced towards the inferior left quadrant until the deep cuff reaches the fascia. TC function is tested by infusing 500 mL dialysate into the peritoneal cavity. The dialysate is immediately drained and if the flow is good, the purse-string suture is tightened. The internal cuff of the catheter is left over the fascia. A subcutaneous tunnel is created by dissecting the subcutaneous tissue with a Kelly clamp. The TC is exteriorized through a small orifice approximately the diameter of the catheter on the right flank, 10-12 cm away from the umbilicus. The outer cuff is placed at a distance of 5-8 cm from the exit site. Finally, the incision is closed, leaving the exit site without stitches.

The catheters were placed by general surgery residents under the direct supervision of one of five general surgeons of the surgery department. All these general surgeons have at least 15 years of experience placing PD catheters.

Patients with percutaneously or laparoscopically inserted TCs were not included, because these techniques are not used habitually at our centre. A 1 L watery enema within 30 min before beginning the surgical procedure was used in all the patients. No other bowel preparation was possible because of the urgent need for catheter placement.

Peritoneal dialysis protocol

For group I patients, full dialysate volume was instilled immediately after the TC placement. The typical dialysate volume was 2000 mL, with four exchanges per day, but in patients with body weight ±50 kg, the infusion volume was reduced to 1000 mL. For group D patients, 500 mL dialysate was infused and drained out after the surgical procedure. When it was considered that the patient conditions allowed it, the catheter was closed, and reopened at the 5th day. Otherwise, four or more 500 mL dialysate cycles were performed, depending on the patient´s hyperazoemic status and the presence of uremic symptoms; the dwell volume was gradually increased, reaching 2000 mL 48-72 hours after the TC instalment.

The patients received dialysis in the recumbent position during the first 24 h after the TC placement. The first dialysis exchanges in both arms were done manually. Patients in the I arm switched to APD on the second night after the catheter placement. Patients in the D arm who could not wait 5 days without dialysis switched to APD the night of the day in which full volume was reached. For patients in the D arm who could wait 5 days without dialysis, only one 2 L exchange was done manually to verify patency and leaks before starting on APD. The typical APD prescription was 2 cycles overnight of 6 L (1.5%) each, with a 2 L wet day. Patients' education for home self-care began immediately after switching to APD and was completed within 2 weeks. All patients began with APD program after 2 weeks of surgical placement of peritoneal catether.

Data collection

Patients were followed-up and checked for catheter complications for 12 months after starting PD, with medical visits every 2 months. Peri catheter leakage was defined as leakage of dialysate from the incision wound or exit site, or tunnel oedema. Fluid leaks were assessed for glucose content to ensure it was dialysate and not just serous drainage. Diminished outflow volume was diagnosed when the difference of inflow minus outflow volume was ±200 ml, without evidence of peri catheter leakage. Migration was diagnosed when the outflow was poor, and the catheter tip was outside the true pelvis on an abdominal X-ray plain film. Peri catheter infection was defined as infection of either the exit site or the tunnel. The criteria to diagnose peri catheter infection were purulent discharge, peri catheter swelling, redness or tenderness. Ultrasonography was not used for diagnosing tunnel infection. Peritonitis was diagnosed when two or more of the following data were present: abdominal pain, turbid dialysate, a dialysate white blood cell count greater than 100/μL, or a positive dialysate culture [12]. Time elapsed from the TC placement to the moment in which the full dialysate volume was reached was measured and registered. Also, an exercise was done to identify the patients who would have been sent to hemodialysis as a bridge therapy, provided

that such an option was available. The criteria were one or more of the following: severe acidosis (arterial blood pH±7.2, or arterial blood bicarbonate concentration±10 mmol/L), hyperkalemia (serum K concentration ±7.5 mEq/L), and uraemia (uremic encephalopathy – lethargy, confusion, obtundation, fasciculations, hyperreflexia–, nausea, vomiting, or severe anorexia). Patients in the D arm who met these criteria initiated the dialysis therapy without waiting for the 5 days rest period.

Statistical analysis

Continuous variables are reported as mean±standard deviation (SD). Categorical variables are reported as frequencies and percentages. Chi-squared test and independent t-test were used to determine the significance of differences between proportions and mean values respectively. Actuarial freedom from catheter related complications within one year was determined by the Kaplan-Meier method and a comparison was done for the immediate and delayed groups using the log-rank test. Intention-to-treat analysis was used to compare variables between groups. Statistical analysis was performed using the statistical package SPSS v13.0 (SPSS Inc., Chicago, Il, USA).

Sample size was calculated to test the hypothesis of a 20% difference between utilization early vs late of peritoneal dialysis in the two groups, in a two sided distribution, with ±=0.05, and power (1 – ±)=0.80. The calculated sample size was 80 patients per group (Power & sample size calculations. v 2.1.31, NJ, USA).

Results

The randomization procedure rendered two comparable groups. Table 1 shows the demographic data and clinical features of the patients in both groups.

	Immediate	Delayed
N	80	80
Age (years)	42.5±18.5	49.2±19.6
Gender (female/male)	45/35	48/32
Weight (kg)	62±5	66±8
Height (m)	1.62±5	1.68±3
BMI (kg/m2)	25±2.5	25±3
Previous abdominal surgery	5% (4)	6.3%(5)
Systolic BP (mmHg)	130±5	135±10
Diastolic BP (mm Hg)	80±10	70±5
Antihypertensive medication	100% (80)	100%(80)
-Prazosin	60%(48)	66%(53)
-β-blocker	40%(32)	34% (27)
Comorbidities		
Heart failure	5% (4)	5% (6)
Hypertension	80% (64)	85% (68)
Neuropathy	7% (6)	5% (4)
CKD Diagnosis		
-Diabetes Mellitus	40% (32)	47% (38)
-Nephrosclerosis	13% (10)	10% (8)
-Other or unknown	47% (38)	43% (34)
Hemoglobin (g/dL)	10.5±1	11±2
Hematocrit (%)	30±1	31±2
Leukocytes (/mm3)	8000±2000	9000±1000
Glucose (mg/dL)	140±20	130±10
Albumin (g/dL)	3.8±0.5	4±0.2
Creatinine (mg/dl)	8±2	9±1.8
rGFR (ml/min/1.73 m2)*	3.65±1.6	4.1±2.01
Proteinuria (g/24 h)	1.1±200	1.3±300
Residual urine volume (ml/day)	600±350	650±300

BMI = body mass Index; BP = blood pressure; CKD = chronic kidney disease; *rGFR = residual glomerular filtration rate (mean of urea and creatinine clearances).

Table 1: Baseline clinical characteristics and laboratory values in the two groups

The patients in I group had 600+350 ml/day and patients in D group had 650+300 ml/day of baseline residual urine volume at initiation of PD (p>0.05).

A similar proportion of patients who would have been sent to hemodialysis as a bridge therapy before initiating the APD program was seen in both groups: 42 (53%) in I vs. 45 (56%) in D (p>0.05). The time elapsed between TC placement and the moment in which the full dialysate volume was reached was significantly shorter in I (4±2 h) than in D (79.5 ±35.7 h; p < 0.01). For the D arm patients, mean dialysate volume in the day of catheter placement was 281.3±142.4 ml per exchange, in the 2nd day the mean dialysate volume was 496.1±261.7 ml, and by the 3rd day the mean volume was 2 l in all patients.

After the catheter placement in all the 80 patients receiving immediate dialysis the mean dialysate volume was 992.2±492.5 ml in the first day, in the 2nd day the mean dialysate was 2 L per exchange. Total (renal+peritoneal) creatinine clearance (Cr CL) and total (renal +peritoneal) Kt/V was measured at the 2nd month medical visit. Total Cr CL was 70±2 and 69±1 L/week/1.73 m2 (p>0.05) and total Kt/V was 1.95±0.1 and 2.0±0.2 (p>0.05) in groups I and D respectively.

Catheter complications

Overall, 10 patients (12.5%) in I and 12 patients (15%) in D developed catheter related complications within 12 months of starting APD. Two patients (2.5%) in I and three patients (3.75%) in D developed peri catheter dialysate leakage. Two patients (2.5%) in I and 4 patients (5%) in D experienced migration of the catheter tip out of the true pelvis. One patient (1.25%) in I and 2 patients (2.5%) in D had hemoperitoneum, 3 patients (3.75%) in I and 1 (1.25%) in D had peri catheter infection and 2 patients (1.25%) in I and 2 patients (2.5%) in D had peritonitis within 12 months of starting APD (Table 2).

Complications	Immediate	Delayed	p value
Mechanical complications	12.5% (10)	15% (12)	>0.05
-Leakage	2.5% (2)	3.75% (3)	>0.05
-Migration	2.5% (2)	5% (4)	>0.05
-Hemoperitoneum	1.25% (1)	2.5% (2)	>0.05
Infectious complications			>0.05
-Peri catheter infection	3 .75%(3)	1.25% (1)	>0.05
-Peritonitis	2 epis/80 pt m	2 epis/80 pt m	>0.05

Table 2: Catheter-related complications within a twelve months follow-up period

Actuarial freedom from catheter related complications within 12 months was not different in I and D (Figure 1).

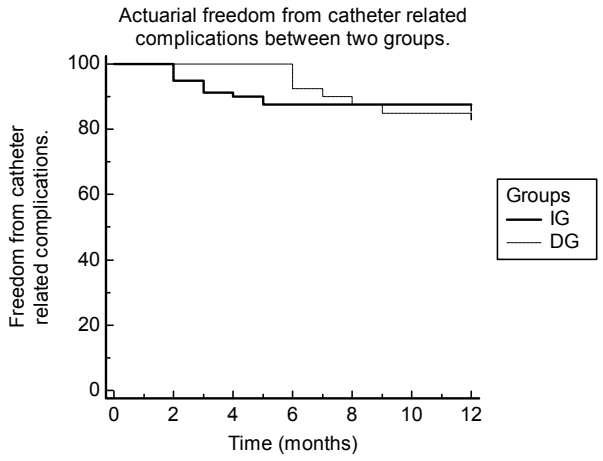

Figure 1: Actuarial freedom from catheter related complications by the Kaplan-Meier method. There are no statistically significant differences of immediate (solid line) and delayed (dashed line) groups regarding overall catheter related complications up to 12 months after PD initiation.

Five patients (6.3%) in I and 8 patients (10%) in D were transferred to HD (NS) because they presented malfunctioning with the peritoneal catheter. At the end of study, after 12 months of follow-up, 75 patients (93.7%) in I and 72 patients (90%) in D were still on APD (Table 3).

Clinical outcome	Immediate (n=80)	Delayed (n=80)	p
Death	0% (0)	0% (0)	---
Loss to follow-up	0% (0)	0% (0)	---
Still on APD	93.7% (75)	90% (72)	>0.05
Transfer to HD	6.3% (5)	10% (8)	>0.05

Table 3: Patients' outcomes in both groups

HD: Hemodialysis; APD: Automated Peritoneal Dialysis

Discussion

We decided to perform this study in order to clarify if is it preferable to wait a few days than to use the catheter immediately after its implantation, because in many of our former patients in which PD initiation could not be delayed because of the severity of the CKD manifestations and the recommendation of waiting 5 days after the insertion before using the TC could not be followed.

The main finding of this study is that variations in the time elapsed from insertion to utilization of catheters, within the range studied have a neutral effect on mechanical and/or infectious catheter related complications. Thus, patients can immediately use surgically implanted TCs instead of waiting for a 5-days break-in period, eliminating the need for bridge hemodialysis.

Existing data suggest that the access routes at the beginning of the dialysis treatment may be of crucial importance for technique and patient survival in both hemodialysis and PD [13]. Laparoscopic PD catheter insertion technique may be preferable over the conventional open technique, since catheter survival at one year is higher and the incidence of catheter migration is lower in the laparoscopic group, resulting in higher patient comfort, lower hospital costs and better overall PD results [14]. However, the open technique, as used in the present trial, is still the most frequently used one all over the world [15]. It has been suggested that starting APD in the recumbent position, with a large intraperitoneal volume right after catheter placement, may increase the risk of catheter displacement due to catheter flotation [3]. Since there is no time to wait for catheters to migrate back to the correct position, the risk for mechanical complications may be increased in urgent starters. However, the results of the present study do not support such a speculation. Several studies address the issue of early initiation of PD therapy [3,9,11,16-20]: A single-centre randomized controlled trial compared 21 patients, in whom exchange volume was gradually increased from 500 mL per 3 hours to full-volume exchange over 13 days to 38 patients, who received full-volume exchange per 6 hours from the day of catheter implantation. One-year catheter survival was very similar in the 2 groups: 84.2% and 85.7% respectively, the study provided no evidence that immediate full-volume exchange causes more short- or long-term complications compared to the stepwise volume increment method [16]. Another observational prospective study of 41 patients reported low frequencies of peri catheter leak (4.8%), peritonitis (2.4%), or other complications; PD was started on average on day 6 after PD catheter insertion, similarly to the delayed-start group of the present report [17]. A prospective observational study of 51 consecutive patients initiating peritoneal dialysis, immediately after catheter insertion without a break-in procedure carried out in two university-based hospitals, reported a very low incidence of mechanical or infectious catheter-related complications, similarly to I group of the present study [9]. In a prospective observational study, 16 of 34 patients needing urgent PD initiated acute inpatient APD shortly (median, 4 days) after surgical placement of a PD catheter. Two of the 16 patients (12.5%) presented dialysate leak that was adequately resolved by postponing the catheter utilisation for 2 weeks. Comparing patients who started acute automated PD with those who started delayed PD, technique survival, patient survival, peritonitis rates, and residual glomerular filtration rates at 12 months were not significantly different [18].

In a recent retrospective study, 226 patients who started CAPD ≤ 14 days after implantation were compared to 84 patients starting CAPD>14 days after implantation. Catheter-related complications within 6 months were no different between early and late groups (14.6 vs. 13.1% respectively) [11].

A single centre non-randomized study compared 18 patients with urgent PD need to 9 patients who started non-urgently on PD. The number of leaks was higher in the urgent-start group than in the non-urgent-start group. The urgent-start group had 2 (11.1%) major leaks and 4 (22.2%) minor leaks, and the non-urgent-start group had no major leaks and 1 (11.1%) minor leak [19]. A prospective observational case-series of 11 patients requiring urgent-start PD followed for a short period reported no peritonitis and no leaks. Catheters were inserted by laparoscopy, dialysate volumes were 1 L per exchange, always in the recumbent position; if the patients needed to sit or stand, dialysate was completely drained before changing position [20].

Currently, there is an ongoing RCT designed to determine the safest and shortest time interval between surgical placement of a TC and starting PD, mainly in the non-urgent setting [21].

The authors of all the mentioned reports [3,9,11,16-20] showed that a shortened break-in period for initiating the utilization of a TC is feasible and safe. However, the studies have substantial differences in their design and results. Most importantly, the studies have different times elapsed from insertion to initiation of the TC utilization. Only one of the studies is a RCT [16], 3 are comparative retrospective studies with unmatched controls [3,11,19], and 4 are prospective observational studies without a comparison group [9,17,18,20]. The technique for TC placement was percutaneous in 4 [9,16,17,19], surgical in 2 [3,11], laparoscopic in 1 (20), and non-specified in 1 [18]. The results of the 4 comparative studies are also discrepant. In the RCT [16] and the largest comparative retrospective study [11] there were no differences in the frequency of dialysate leaks between the two groups, results that are similar to those of the present trial. In the remaining 2 comparative retrospective studies [3,19], and in the non-published study (Winch P.), a higher frequency of peri catheter leaks in the early initiation group was reported. The number of patients cared-for in each dialysis centre may contribute to explain these discrepancies [22,23].

Some of the articles highlight the importance of using low volumes and maintaining the supine position during the initial dialysate exchanges to avoid complications [3,9,16,20]. In the present study, no special precautions were taken regarding these issues after switching to APD. Since the automated exchanges in APD are done during the night time, patients are expected to spend most of the period in the recumbent position, but they were allowed to sit or stand as needed. No special recommendations regarding position were made for the wet-day.

The main weaknesses of the present study were that this is an open label, single centre study with a short follow-up period of only one year. Exclusion of patients with severe protein-energy wasting, severe obesity, and comorbid conditions probably eliminated the subjects most at risk for peri catheter leaks. These results may be not generalizable to facilities with fewer PD patients, since centres with more patients consistently report better outcomes than the less experienced ones [22,23]. Age and BMI of the patients included in the present study are lower than those of the typical patients on PD in developed countries, reflecting the demography of the Mexican PD population [24-26]. This difference is a limitation for the external validity of the study. There are reports that high BMI is an independent risk factor for peritoneal leak [27], but in a recent study BMI do not appear to be a risk factor for PD technique survival [28]. The design of the present work as a parallel RCT is a strength of the study.

We can conclude that immediate utilization of a surgically implanted TC is feasible and safe, since it is not associated with increased frequency of complications.

Acknowledgments

The study was supported with resources of the ISSEMYM. No external support was required.

Disclosures

All the authors state that they have no financial conflicts of interest to declare.

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