PROSPECTIVE RANDOMIZED STUDY COMPARING A SINGLE-CUFF SELF-LOCATING CATHETER WITH A SINGLE-CUFF STRAIGHT TENCKHOFF CATHETER IN PERITONEAL DIALYSIS

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◆ **Objectives:** Peritoneal dialysis (PD) catheters are critical to the success of the technique. However, few studies provide evidence about which design helps to reduce complications. Self-locating catheters (SLCs) are used to avoid displacement of the catheter tip. The incidence of mechanical and infectious complications and catheter survival rate were assessed in Tenckhoff PD catheters.

◆ **Design:** The prospective randomized study compared drainage problems in 40 incident PD patients using a single-cuff SLCs and 38 patients using a single-cuff, straight Tenckhoff catheter (TC).

◆ **Results:** No significant differences were observed in the number of complications in the Pre period (from the insertion of the catheter to the start of the technique); however, the number of complications was lower in the SLC group during Post ($p = 0.021$) and Total period ($p = 0.048$). The number of problems related to catheter malfunction for each period: Pre, Post, and Total, was significantly lower with SLCs vs TCs ($p = 0.018$, $p = 0.001$ and $p = 0.003$, respectively). Problems were solved more easily with SLCs, using laxatives, with less need for fluoroscopic placement and no need for surgical replacement, as opposed to the TC group: Pre (not significant), Post ($p = 0.007$), and Total ($p = 0.011$).

Median survival was 39.6 months (30.9 – 48.3) for SLCs and 30.1 months (22.6 – 37.5) for TCs, which is not a significant difference. However, SLCs have a higher malposition-free survival rate. Multivariate logistic regression models only included the variable “type of catheter” as a predictor of malfunction during the Pre period (odds ratio [OR] = 4.154). The Post period included the variables, “type of catheter” (OR = 7.701) and “age” (OR = 1.047), and the Total period only included the variable “type of catheter” (OR = 4.487), which indicates an increased probability of malfunction with the use of TCs vs SLCs. The variables (gender, previous intra-abdominal surgery, body mass index (BMI) and diabetes mellitus) did not add predictive value to the models ($p > 0.05$).

◆ **Conclusion:** The study confirms the hypothesis that TCs have more malfunctions and a lower malposition-free survival rate than SLCs, and TCs are considered as the highest risk factor for malfunction during all study periods.

Perit Dial Int 2016; 36(1):52–59 epub ahead of print: 02 Sept 2014
<http://dx.doi.org/10.3747/pdi.2013.00315>

KEY WORDS: Peritoneal dialysis; continuous ambulatory peritoneal dialysis; catheter; malposition; event-free survival.

Peritoneal dialysis (PD) catheters are critical to the success of the technique as well as to patient survival. Despite design improvements, catheter-related complications such as infections, obstructions or leaks are still frequent (1–2). Several prospective studies are designed to compare and find out which catheters have fewer mechanical problems, particularly migration, obstruction and entrapment, and a higher catheter survival rate (3–8). Clinical experience shows that Tenckhoff catheters (TCs) are the most commonly used internationally, with several variations of both subcutaneous and intra-abdominal segments to prevent displacement (9–12). Self-locating catheters (SLCs) are similar to TCs, but the end of the catheter is heavier and includes a small tungsten cylinder at the distal end (13,15). The weight of the tip (12 g) is intended to prevent catheter displacement when floating in the peritoneal fluid or as a result of bowel loop movement. Although the incidence of malfunction with SLCs is lower when compared to other types of catheters, (14,16–23), current prospective studies are limited and there is no record of randomized studies.

OBJECTIVES

The main objective of this study is to compare a SLC and a TC to confirm the hypothesis that SLCs have less drainage failures and a higher survival rate than TCs,

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Received 20 June 2014; accepted 25 June 2014.

and that dislocations are more easily solved in SLCs than in TCs.

MATERIALS AND METHODS

A prospective, randomized study was performed from December 2007 to February 2013, in which 78 consecutive incident patients were allocated to a SLC group ($n = 40$) or to a TC group ($n = 38$), both single-cuff and straight (Figure 1). The method of allocation generation was a table of random numbers. Simple randomization was designed to achieve a 1:1 ratio. Initially, we used a double-cuff SLC which was modified by the removal of the external cuff and subsequently sterilized, until the commercialization in 2011 of a single-cuff SLC, as suggested by our team.

Inclusion criteria were PD incident patients older than 18 years of age and exclusion criteria were having a life expectancy of less than 6 months. A patient was excluded due to prostatic neoplasia with metastasis and another patient was excluded due to her small size as she required a short SLC, which was not available (Figure 2). The study protocol followed the ethical standards on human experimentation according to the Helsinki Declaration. All patients gave their written informed consent prior to enrolment in the study.

CATHETER INSERTION TECHNIQUE

Catheters were surgically inserted by the same surgical team of 2 surgeons using local anesthesia and sedation. Previously, an abdominal examination was performed to detect the presence of hernias; laxatives and prophylactic vancomycin (1 g IV) were given the day before surgery. An underumbilical transverse incision was made through the abdominal rectus muscle, in most patients on the right side. The length of the wound was 4 – 5 cm. The subcutaneous tissue and rectus were dissected to expose the peritoneal membrane. A 1-cm-long incision was made in the parietal peritoneum. The catheter was inserted through a purse string suture into the small hole and guided towards the Douglas pouch using a stiff guidewire. The catheters had a single deep cuff located within the rectus muscle, were guided in a rectilinear path, and their exit site was adjacent to the incision. The skin exit site was perpendicularly directed.

After the catheter was inserted, proper operation was checked by performing filling and drainage maneuvers using 2 L of peritoneal fluid solution. Likewise, similar washing and healing procedures were performed weekly in the exit site (ES) during the healing and training period, until the start of PD (Pre period).

Figure 1 — Types of catheters used in this study. Straight single-cuff Tenckhoff catheter and single-cuff, self-locating catheter with distal counterweight of 12 g of tungsten. (Characteristics: self-locating catheter: B. Braun-Carex SpA, Mirandola, Italy, internal portion of 16 cm and internal diameter of 2.6 mm with a tungsten cylinder of 12 g coated with Silastic at distal end. Tenckhoff catheter: internal portion of 22 cm and internal diameter of 2.6 mm).

DATA COLLECTION

The following information was collected: demographic and anthropometric data, renal disease etiology, previous intra-abdominal surgery, days of the Pre period (days from the insertion of the catheter to the start of PD), months of the Post period (months of PD), and months of the Total period using the catheter (Pre + Post). Dialysis effectiveness was assessed using creatinine clearance every 2 months and the modified peritoneal equilibration test (PET) every 6 months, according to Twardowski (24).

The frequency of complications associated with the use of both types of catheters was assessed: bleeding, leakage, peritonitis, tunnel and exit-site infection, hernias and cuff extrusion and malfunction due to dislocation and slow drainage, defined as a slow or insufficient infusion or drainage flow for the dialysis therapy.

Likewise, the primary objective was to study the frequency of malfunction of both types of catheters and secondary objectives included the number of treatments with laxatives (sennosides A and B), fluoroscopic replacements when laxatives failed or surgical replacements if fluoroscopic replacements failed, as well as the results obtained during each period: Pre, Post, and Total.

STATISTICAL ANALYSIS

Data were analyzed using SPSS software v.15.0 (SPSS, Chicago, IL, USA). The Kolmogorov-Smirnov test was

Figure 2 — Flow chart of study patients.

performed to verify if the variables studied followed a normal distribution. Self-locating catheters and TCs were compared with qualitative variables using a chi-square test, and with quantitative variables using the Student *t*-test for independent samples. Quantitative variables were described as median and interquartile range (IQR). The sample size calculation for this study was based on the number of drainage failure complications of previous studies. We assumed a disfunction event prevalence of 25% and a minimum expected effect size of 10%. The required sample size was 73 patients.

Catheter survival was assessed using the Kaplan-Meier test (log rank). Logistic regression models were used to assess risk factors that predicted catheter malfunction during the Pre, Post, and Total period. The forward Wald method was used for different variable profiles. Final models had the best predictive capability for malfunction risk, using the odds ratio (OR) of the model variables and leaving the OR adjusted for the other factors included in

each profile. Values of $p < 0.05$ were considered statistically significant.

RESULTS

DEMOGRAPHIC AND BASAL CHARACTERISTICS

Seventy-eight patients participated in the study: 53.8% were males, 38 patients used a TC and 40 patients used a SLC. No significant differences were observed in demographic and basal characteristics, nor in the number of days (Pre period) or months (Post and Total periods) for both groups, except for the body mass index (BMI) ($p < 0.023$). The catheter follow-up period for our patients was 1,544.83 patient-months (Table 1).

No significant differences were observed in the number of diabetic patients, basal renal disease or previous surgery, between both groups. Urea Kt/V values and peritoneal creatinine clearance (pClCr) were slightly

lower in the TC group vs the SLC group, although the differences were not significant. All our patients started continuous ambulatory PD (CAPD), and 13 patients were transferred to automated PD (APD) during the catheter follow-up period.

We analyzed the frequency of bleeding, leakage, hernias, exit-site infection (ESI), peritonitis and extrusion depending on the type of catheter during Pre, Post, and Total periods (Table 2). We identified 29 episodes of peritonitis in the SLC group (0.42 peritonitis/year) and 28 in the TC group (0.44 peritonitis/year). *Staphylococcus coagulasa-negative* infectious agents were the most common and were isolated in 19 cultures. Other frequent microorganisms were *Streptococcus* spp ($n = 7$), *Corynebacterium* ($n = 3$), *Staphylococcus aureus* ($n = 3$) and *Pseudomonas* spp ($n = 3$). No significant differences were observed in the mechanical and

infectious complications and a significant difference was observed only for malfunctions ($p = 0.003$), which were higher in the TC group. The comparison of the average number of complications per patient with SLCs and TCs was not significantly different in the Pre period ($p = 0.432$); however, significant differences were observed in the Post ($p = 0.021$) and Total ($p = 0.048$) periods that favor the use of SLCs, with fewer complications observed. Problems related to catheter malfunction during each period, Pre, Post, and Total (Table 3) were significantly higher with TCs vs SLCs ($p = 0.018$, $p = 0.001$ and $p = 0.003$, respectively). In any case, for patients with drainage problems, we tried to address the problem using laxatives (Sennosides A and B) in the first place, and if laxatives failed, we tried fluoroscopic replacement and only 2 patients required surgery (Table 3).

TABLE 1
Patient Demographics

	SLC	TC	<i>p</i>
Catheters	40	38	
Gender (Male/Female)	21/19	21/17	NS
Age (Years)	55.4±14.8	59.1±13.2	NS
BMI kg/m ²	25.7±4.3	28.1±4.0	0.023
Days until start of PD (Pre period)	46.3±37.7	45.6±22	NS
Months after start (Post period)	19.0±16.7	17.3±13.7	NS
Months in the 2 periods (Total period)	20.5±16.6	19.1±14.0	NS
Follow-up (patient-months)	820	724	NS
DM patients/non-DM patients	11/29	9/29	NS
Etiology of renal failure	40	38	NS
Nephroangiosclerosis	7	8	
Glomerulonephritis	10	8	
Interstitial nephropathy	4	6	
Diabetes mellitus	11	9	
Hereditary nephropathy	5	5	
Others	3	2	
Previous intra-abdominal surgery	7	6	NS
Appendicectomies	3	1	
Hysterectomy ^a	2	0	
Eventration	2	0	
Transplantation	1	3	
Nephrectomy	0	1	
Cholecystectomy	0	1	
Residual renal function	9.62±6.1	10.98±5.2	NS
4-hour D/P creatinine	0.758±0.14	0.754±0.14	NS
Peritoneal Kt/V	1.59±0.67	1.33±0.42	NS
Renal Kt/V	1.57±0.91	1.47±0.82	NS

SLC = self-locating catheter; TC = Tenckhoff catheter; NS = not significant; BMI = body mass index; PD = peritoneal dialysis; DM = diabetes mellitus; D/P = dialysate/plasma.

^a One patient had hysterectomy and eventration.

In our study, 12 catheters were removed, 2 due to ultrafiltration failure that prevented the performance of the technique, 2 SLCs and 1 TC due to pericatheter leak, 2 SLCs and 2 TCs due to peritonitis, and 1 SLC due to a complicated hernia. The presence of recurrent malfunctions that prevented the performance of PD forced us to substitute TCs in 2 cases.

The median survival time was 39.6 months (30.9 – 48.3) for SLCs and 30.1 months (22.6 – 37.5) for TCs, which is not a significant difference. However, Figure 3 shows a higher malposition-free survival rate with SLCs: 31.7 months (19.0 – 44.5) compared to TCs, 17.9 months (15.6 – 20.3).

Logistic regression models (Table 4) that predict the risk of malfunction for catheters (in the Pre, Post, and Total periods) depending on the profiles of the variables introduced as potential risk factors of malfunction (age, gender, previous intra-abdominal surgery, BMI, diabetes mellitus and type of catheter) only included the variable “type of catheter” in the Pre period (OR = 4.154), which indicated a malfunction risk 4.154 times higher for TCs. During the Post period, 2 variables were incorporated: “type of catheter” (OR = 7.701) and “age” (OR = 1.047), and during the Total period, only the variable, “type of catheter,” was incorporated (OR = 4.487), which indicated an increased probability of malfunction with the

TABLE 2
Type and Number of Complications During Each Study Period: Pre, Post, and Total

	Pre period ^a	Post period ^a	SLC	Total period ^a TC	<i>p</i>
No complications	49	31	21	8	NS
Peritoneal bleeding	4	9	7	6	NS
Leakage	8	8	9	7	NS
Drainage failure	16	30	12	25	0.003 ^b
Hernia	0	7	7	7	NS
Peritonitis	0	57	31	26	NS
Exit-site infection	3	11	7	7	NS
Cuff extrusion	0	0	0	0	NS

SLC = self-locating catheter; TC = Tenckhoff catheter; NS = not significant.

^a Some patients have drainage problems as well as other concomitant problems

^b Between SLC and TC groups in total period.

TABLE 3
Number of Complications and Solutions During Each Study Period: Pre, Post, and Total

	Pre period			Post period			Total Period		
	SLC	TC	<i>p</i>	SLC	TC	<i>p</i>	SLC	TC	<i>p</i>
Complication ^a									
Malfunctions	4	12	0.018	8	22	0.001	12	25	0.003
Solutions ^b									
No problem	36	26		32	16		28	13	
Sennosides	2	9	0.071	6	16	0.007	8	17	0.011
Fluoroscopy	2	2	NS	2	5		4	6	
Surgery	0	1		0	1		0	2	

SLC = self-locating catheter; TC = Tenckhoff catheter; NS = not significant.

^a It should be noted that while the variable “Total Malfunctions” is defined as YES or NO, 11 patients experienced malfunction both in the Pre and in the Post period and, therefore, the total number of malfunctions is not 37 but 46.

^b It should be noted that while the variable “Solutions Total Period” is defined as “No Complications” or using a treatment (laxative, fluoroscopic, surgery), there are patients who received treatment with laxatives (Sennosides A and B) and fluoroscopic replacement both in the Pre and the Post period, and therefore, the total number of treatments is not the arithmetic sum of the treatments in the Pre and Post periods.

Figure 3 — Analysis of malposition-free Kaplan-Meier survival by comparing self-locating catheters (dotted line) and Tenckhoff catheters (solid line). Cumulative survival rate was significant between the groups (Log Rank test, $p=0.0329$)

use of TCs vs SLCs in both periods. Odds ratio for risk factors introduced in the models (type of catheter and age) were adjusted for the variables excluded from the models, which did not add predictive value to logistic regression models ($p > 0.05$).

DISCUSSION

The history of PD is linked to the continuous search for the optimal peritoneal catheter. Currently, the most commonly used catheters are the double-cuff TCs (47 – 65%) (6,13), followed by swan-neck (26%) (6,13). Recent use in adult PD patients in Italy of Di Paolo catheters is estimated at 15.1% (13).

The intramural segment of double-cuff Tenckhoff catheters is tunneled subcutaneously, producing an angle with the intraperitoneal segment at the internal cuff. In our initial experience with double-cuff Tenckhoff and swan-neck catheters, it was difficult to replace and guide malfunctioning catheters fluoroscopically. For this reason, we decided to use single-cuff straight Tenckhoff and SLCs (Figure 1) as the intramural rectilinear path allows guiding the catheters with rigid guidewires moving them on the preperitoneal cuff, which allows for better results.

Several authors, such as Flanigan and Gokal (25), state that single-cuff catheters with a cuff deep either within the rectus muscle or abutting the preperitoneal

TABLE 4
Probability of Malposition with SLCs and TCs
(Taken as a Reference)

Study periods	OR (CI 95% of OR)
Pre	TC: 4.154 (1.203–14.339)
Post	TC: 7.701 (2.008–15.062) Age: 1.047 (1.006–1.09) ^a
Total	TC: 4.487 (1.732–11.627)

SLC = self-locating catheter; TC = Tenckhoff catheter; OR = odds ratio; CI = confidence interval.

^a Increased risk of 4.47% with each year of age.

fascia may become the preferred design. There is strong evidence that single-cuff catheters are as durable as two-cuff designs when the single cuff is placed deep at an intramuscular location, and has fewer pericatheter leaks and hernias. Eklund *et al.* (26), in a prospective, randomized trial, found similar results with single- or double-cuff straight TCs for complications such as peritonitis, ESI, and catheter survival. Strippoli *et al.* found no differences between the catheters with respect to these issues (27). In our study, we also confirmed the absence of significant differences in the incidence of leaks, peritonitis, or ESI between the different catheters.

Some prospective studies (3–8) show mixed results regarding catheter malfunction and survival when comparing catheters with a straight or spiral intraperitoneal segment or with any other device. At the time of writing this study, we were aware of only observational, non-randomized studies that compare SLCs with CTs, generally double-cuff (15–22).

Age and gender are similar to other studies (17–19). Body mass index medians were significantly different between groups but it was not clinically relevant. There were only 4 decimals difference between BMI medians. Both groups had their median and central values in the range of overweight but not obesity. The percentage of diabetic patients was higher than in other studies with an approximate average of 15% to 18.5% (19,21,22) and it was lower than the number of diabetic patients (32%) in the De Toro *et al.* study population (16).

Some studies exclude patients with previous surgery (22), but other studies did not find previous surgery to affect the PD catheter survival. From our experience, previous intra-abdominal surgery was not a determining factor of catheter malfunction and, therefore, it was not considered as a cause of exclusion. Parameters of residual renal function and dialysis dose were similar in both groups; however, there was a trend towards

higher peritoneal excretion of urea and creatinine with SLCs vs TCs. Di Paolo *et al.* observed that the peritoneal function was reduced in the presence of dislocation ($p = 0.0007$) (14).

In our study, catheter malfunction was the most common catheter-related complication. Some patients experienced other complications during the study periods (Pre, Post, and Total) (Table 2). Different authors report global complications associated with the use of SLCs and TCs (15–19,22). These data may be difficult to interpret as, in some cases, they describe complications (bleeding, leakage, ESI, peritonitis, hernias, or extrusion) that can be managed with peritoneal rest and conservative measures (15–17,22). Minguela *et al.* removed 20 catheters (3 SLC/17 TC) and described other complications in a ratio of 40/18 (18). The most important article by Di Paolo *et al.* describes 95 SLCs and 65 TCs with complications and 84/46 substitutions (19). In our study, 12 catheters were removed, only 2 due to malfunction in the TC group and none in the SLC group.

Catheter malfunction due to dislocation, omental entrapment or obstruction of drainage exit sites may prevent dialysis. Literature is difficult to interpret with the data provided. The studies consulted (15–22), do not mention the number of malfunctions for each type of catheter (SLC or TC), nor the procedures used to solve them, except, in some cases, catheter removal. De Toro *et al.* (16) replaced 1 SLC and 10 TCs and do not describe any catheter removal. Minguela *et al.* (18) do not mention the patient-months of treatment and removed 17 TCs out of 53 and 3 SLCs out of 105. Di Paolo *et al.* (19) collects data from 16 nephrology departments and describe 15 substitutions with SLCs and 19 with TCs. Lanuza *et al.* (21) lost 18 TCs out of 55, and 9 SLCs out of 258.

It was observed that the groups of SLCs described by these authors were sometimes disproportionately higher. However, the number of catheter malfunctions and losses was considerably lower in the SLC group vs the TC group. Finally, the groups in our study were established at random and the need to remove catheters due to malfunction was not that high as indicated by the data discussed. The percentage of failure in problem-solving and the need to remove the catheter was due, hypothetically, to improper manipulation of the catheter during the fluoroscopic replacement as double-cuff catheters form an angle with the intraperitoneal segment and the intramural and subcutaneous segments that prevents the use of rigid guidewires, which have been successful in the resolution of peritoneal drainage issues with single-cuff catheters, both SLC and TC. Rigid guidewires, slightly arched in their distal end, help to clean the intraluminal fibrin of the catheter, allow the rotation

of the intraperitoneal segment of the catheter at the entrance point into the peritoneum and the rotation of the proximal guide to achieve a circular rotation of the arched distal end of the guidewire. This may solve potential obstructions, adhesences, compressions, and slight entrapments. This conclusion is a hypothesis that requires further study.

Although the survival rate of SLCs was not significantly higher compared to TCs, malposition-free survival with SLCs was considerably higher compared to TCs. The main cause of drop-out from PD remains peritonitis, but other problems such as loss of residual renal function or loss of ultrafiltration are significantly associated with technique survival too.

The variables, type of catheter, previous intra-abdominal surgery, obesity, age, gender, and diabetes mellitus, were considered as potential risk factors for malfunction of SLCs and TCs, and multivariate logistic regression models showed that the only predictive relationship between malfunctions was the type of catheter studied during the Pre, Post, and Total periods, as well as age during the dialysis period (Post). Malfunction is 4 times more likely to happen with TCs (taken as a reference) than with SLCs.

We may conclude that our results confirm the hypothesis that TCs have more malfunctions from a qualitative point of view (chi square) than SLCs. On the other hand, both, the chi square test and the logistic regression test confirm that TCs increase the risk of malfunction compared to SLCs. Our study shows a higher malposition-free survival rate with SLCs vs TCs, and, finally, our study confirms the hypothesis that malfunctions are mainly solved with the use of laxatives, performing an “alpha maneuver” with a flexible guidewire or using rotation procedures with rigid guidewires. The success rate was high and only 2 patients required surgical replacement. Resolution of malfunction is essential for the patients as well as for the PD program.

DISCLOSURES

The authors declare that they have no potential conflicts of interest related to the contents of this article.

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