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ORIGINAL ARTICLE

Influence of the intra-peritoneal segment of the swan neck peritoneal catheter on infectious and mechanical complications and technique survival

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Abstract

Background There is no consensus about the preferable type of catheter for successful peritoneal dialysis. Intra- and extra-peritoneal catheter configuration may be associated with mechanical and infectious complications affecting technique survival. The objective of this study was to compare the mechanical and infectious complications of coiled versus straight swan neck (SN) peritoneal dialysis catheters.

Methods A prospective randomized trial was performed to compare mechanical (tip migration with dysfunction) and infectious (peritonitis and exit site infection) complications between catheters randomly divided into two groups: swan neck straight tip and swan neck coiled tip. The follow-up was 1 year.

Results A total of 49 catheters, in 46 patients, were included from April 2015 to February 2016. The catheters groups were constituted as: 25 coiled tip SN and 24 straight tip SN. The baseline demographics were similar among the groups. Kaplan–Meier survival estimates were not different for time to first exit site infection, peritonitis and time to first catheter tip migration (log-rank test, $p=0.07$, $p=0.54$ and $p=0.83$, respectively). Catheter survival and method survival were also similar (log-rank $p=0.88$ and $p=0.91$, respectively).

Conclusions The two types of intra-peritoneal segments of SN catheters studied presented similar infectious and mechanical rates with no differences in catheter and technique survival curve. These results were consistent with the recommendations of the International Society for Peritoneal Dialysis.

Keywords Peritoneal dialysis · Catheter migration · Peritonitis · Swan neck

Introduction

Chronic kidney disease (CKD) is considered a global public health problem. The number of patients increases progressively, but there is a disproportion in the modalities of therapies implemented, with a much more significant increase in hemodialysis (HD) in relation to peritoneal dialysis (PD) [1].

One possible reason for that includes the difficulties with catheter peritoneal insertion [2]. A large proportion of PD patients are transferred to HD every year and the main cause for it is the infectious and mechanical complications related to the dialysis catheter [3].

Translocation (tip migration) is the most frequent mechanical complication and consists of spontaneous migration of the intra-peritoneal catheter tip out of the pelvis. In most cases, this causes difficulty in draining the dialysate. This malposition causes malfunction of the catheter [4].

The most widely used PD catheter is the Tenckhoff catheter. Although there are many variations of the classic model, there is no evidence of the superiority of any particular type regarding the risk for infection or survival of the catheter [5–8].

The swan neck (SN) catheter was born in 1985 and has the extra-peritoneal curved segment with a fixed memory.

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In this way, as long as its shape memory was respected at the time of implant and tunnel construction, it would not interfere with the risk for translocations. At that time, the intra-peritoneal segment presented a straight configuration. The SN tip coil emerged in 1990 with the aim of reducing the pain that some patients presented at the time of dialysate infusion with the straight tip catheter—jet effect [9].

The different types of extra- and intra-peritoneal configurations of the catheters could be associated with the risk of complications (migrations and infections) and, consequently, the survival of the catheter. The systematic review with a meta-analysis published in 2014 [10] did not find differences in the incidence of: exit site infections (ESI), peritonitis, translocations, catheter failure and catheter survival at 1- and 2-year follow-up when the number of cuffs and the extra-peritoneal configuration were evaluated. When the intra-peritoneal segment was evaluated, there was benefit in the use of straight intra-peritoneal configuration in 2-year catheter survival.

Therefore, the aim of the present study was to evaluate the impact of two intra-peritoneal configurations: straight and coiled SN catheters on infectious and mechanical complications besides catheter and technique survival.

Materials and methods

This single center, prospective, randomized trial was approved by the ethics committee of Brazil Plataform, under number: 17086413.3.0000.5411. The participants provided their written informed consent to participate in it at the time of enrollment.

The study was conducted according to good clinical practices and the Declaration of Helsinki and its Trial Registration number is ISRCTN 15,159,688.

Study population

Between April 2015 and February 2016, all chronic kidney disease (CKD) consecutive patients, older than 18 years who started PD at Botucatu Medical School, Sao Paulo, Brazil were recruited. Patients who did not wish to participate in the study were excluded.

Randomization procedure

Patients were divided into two groups randomly. Randomization was performed by lot using sealed envelopes. The randomized groups determined the tip type (coiled or straight) of peritoneal catheter implantation.

Intervention

All the catheters were implanted using Seldinger technique [11] by the same team of nephrologists, at operating room of the dialysis unit. Furthermore, all the patients used chronic topical antibiotics at the catheter ES, as dictated by the protocol of antibiotic prophylaxis service with gentamicin cream.

Operation procedure

All patients underwent prophylactic antibiotics (intravenous cefazolin 1 g) at the time of implantation. We performed blind placement based on the Seldinger technique using local anesthesia (2% lignocaine).

A horizontal paramedian incision, 2- to 3-cm long, was made, followed by blunt dissection of subcutaneous tissue until the fascia of the rectus muscle. The peritoneum was punctured using a 16-gauge needle from the Quinton catheter placement kit. A peel-away sheath and introducer were inserted over the guidewire. The introducer was removed along with the guidewire leaving the peel-away sheath in situ. The catheter was advanced through the peel-away sheath and directed caudally toward the left iliac fossa thus splitting the peel-away sheath. The inner cuff of catheter stayed on top of the fascia of the rectus muscle. An 8- to 12-cm subcutaneous tunnel for the catheter was fashioned using a stylet. The proximal end of the catheter was pulled through the exit site and positioned in a manner that the inner cuff was located at the peritoneal entry at the fascia of the rectus muscle, and the second cuff was 2 cm away from the exit site. The original incision was then closed and the catheter was flushed with 2 L of 1.5% dialysis solution to confirm catheter patency. If the drainage of the solution occurred without problems, the catheter was considered to be properly functioning and well-positioned. Fluoroscopy could not be used to check tip position because the procedures were performed in the dialysis unit operating room.

Follow-up and concepts

After PD initiation, patients were evaluated on a monthly basis in the clinic and immediately when an acute event occurred. In the follow-up, if the patients presented difficulty in dialysate drainage (catheter malfunction), a contrast X-ray was performed. Migration catheter (catheter malposition) was defined as catheter tip located outside the pelvis and it was documented by contrast radiography and diagnosed by the same team of nephrologists. In this case, as medical management, the patients used oral laxatives (mannitol) for two consecutive days. New contrast X-ray of the abdomen after this period was made to evaluate the possible relocation of the catheter (peristaltic effect of stimulus-induced laxative). In the failure of relocation using laxatives, the catheter was subjected to an attempt to reposition it using a guidewire under fluoroscopy at the surgery center. To enable this procedure (for guidewire passage), the patients underwent removal of subcutaneous segment of the catheter (tunnel track). If the relocation with guidewire was successful, the catheter was placed back in the same previous tunnel track and ES. In this case, the catheter was counted as continuation of catheter survival and technique survival. However, if the patient needed to replace the catheter, the position of the ES was determined by sequence randomization and a new study protocol was initiated.

Replaced catheters were counted as continuation of technique survival, but survival failure of previous catheter. Technique failure occurred when the PD catheter needed to be removed and the patient transferred to HD.

Patients with exit-site infection (ESI) or peritonitis received the recommended treatment (use of oral, intra-peritoneal and/or intravenous antibiotics) according to the recommendations of ISPD [12]. ESI was diagnosed if signs of redness and purulent discharge were present. Tunnel infection included in duration or redness over the subcutaneous course of the catheter, associated with pain, with or without abscess formation [12]. Peritonitis was defined clinically as abdominal pain and a cloudy dialysate yielding a leukocyte count greater than $100/mm^3$ with greater than 50% polymorphonuclear cells [12].

Removal of peritoneal catheters for refractory peritonitis was performed if no improvement was noted within 5 days of starting appropriate antibiotic treatment. Recrudescence of peritonitis by the same organism within 4 weeks of completing antibiotic therapy led to the removal of peritoneal catheters for relapsing disease [12]. Episodes of ESI and peritonitis were counted as separate events if the episode occurred more than 4 weeks after stopping antibiotic therapy or if the infection was caused by a different organism.

The protocol was interrupted when patients required replacement or removal of the PD catheter, change of dialysis method, or had completed 12 months of follow-up with the same catheter.

Statistical analysis

Considering alpha error as 5%, beta error as 20%, statistical power of the test as 80% and detecting a difference of 30% in infectious or mechanical complications between the two groups, the sample size for each group was 25 patients.

Normally distributed data are presented as mean ± standard deviation, and the Student *t* test was used to assess the significance of differences. Non-normally distributed data are presented as medians with interquartile range, and the Wilcoxon rank sum test was used to assess the significance of differences. For categorical data, the Pearson Chi square test was used to assess the significance of differences between groups. Catheter survival and technique survival were performed using life-table analyses and Kaplan–Meier analyses with a log-rank test. A *p* value lower than 0.05 was considered significant. All analyses were performed using the SPSS software application (version 16:0: SPSS, Chicago, IL, USA).

For catheter and technique failure, the following events were censored: renal function recovery, death, renal transplantation, psychosocial conditions and severe immediate extravasation.

Translocations requiring catheter replacement, refractory peritonitis, and refractory ESI were considered criteria for catheter failure.

Results

From April 1, 2015 to February 28, 2016, 49 catheters were implanted in 46 patients. The two groups were formed as follows: 24 straight tip SN catheters were implanted in 22 patients and 25 coiled tip SN catheters were implanted in 24 patients.

Figure 1 show the flowchart of the catheters in the study.

Table 1 shows that the groups were similar in relation to patients' age, gender, members of unplanned PD, dialysis mode, body mass index, frequency of reinsertion catheters, side of the abdomen where the implant was performed and frequency of diabetes mellitus, which was the main underlying disease of the patients in both groups.

Mechanical complication

Catheter dysfunction due to tip migration was the most common non-infectious complication, occurring in 9 of the 49 catheters (18.3%). There was no statistically significant difference in the frequency of translocations between the two groups: straight tip (4 of 24 catheters) vs coiled tip (5 of the 25 catheters), $p = 0.76$.

In addition, there was no difference in the time to first episode of translocation (Fig. 2).

Catheter-related infectious complications

In our study, the most common infectious complication was peritonitis: 19 episodes in 16 patients (34.7% of total number of patients). 10 episodes occurred in the straight tip group (in this group one patient had three peritonitis episodes) and 9 episodes in the coiled tip group (one patient had two peritonitis episodes), $p = 0.68$. They presented, in total, an overall incidence of 0.58 episodes per

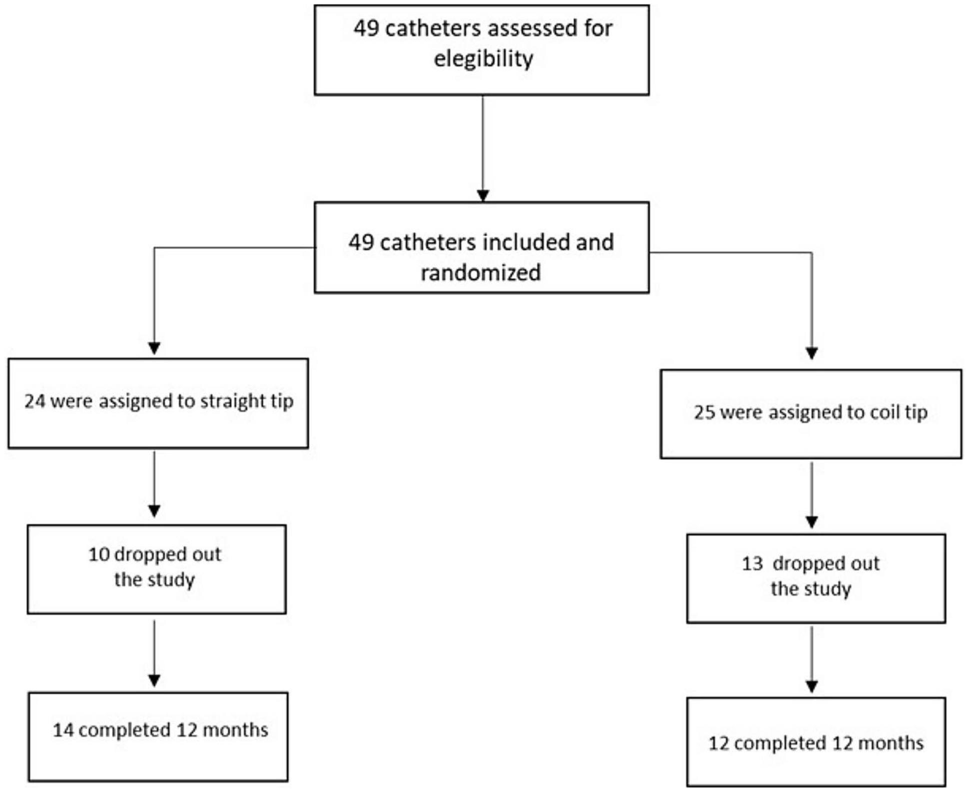

Fig. 1 Study flowchart

Table 1 Baseline patients characteristics by SN catheter type

	Straight tip	Coiled tip	*p*
Catheters number	24	25	
Patient number	22	24	
Men, sex (%)	12 (50)	19 (76)	0.06
Diabetics, *n* (%)	13 (54)	13 (52)	0.88
Age, years	66 (48–71)	66 (48–74)	0.6
Body mass index, kg/m^2	25 (23–29)	22 (20–25)	0.11
Members of unplanned PD, *n* (%)	15 (62.5)	16 (64)	0.91
Reinserted catheters, *n* (%)	7 (29)	7 (28)	0.92
Implant of the left side of the abdomen, *n* (%)	18 (75)	22 (88)	0.28
Dialysis mode APD (%)	23 (96)	23 (92)	0.57
Primary disease, *n* (%)			0.8
Diabetic nephropathy	11 (46)	11 (44)	
Hypertensive nephropathy	5 (21)	8 (32)	
Chronic glomerulonephritis	3 (12)	2 (8)	
Others	5 (21)	4 (16)	

patient-year. Separately, we had 0.65 episodes patient-year in the straight tip group and 0.52 episodes patient-year in the coiled tip group, $p = 0.54$.

The incidence of the ESI infection was 13 episodes in 10 patients (21.7% of total number of patients), three patients presented two episodes each. The straight tip group presented nine episodes and the coiled tip group four episodes, $p = 0.23$.

There were no significant differences in the time to first episode of peritonitis between the groups ($p = 0.54$) as the Fig. 3 shows.

Catheter survival and technique survival

During the 1-year follow-up, a total of 23 catheters dropped out of the study (were removed). The causes for drop out are

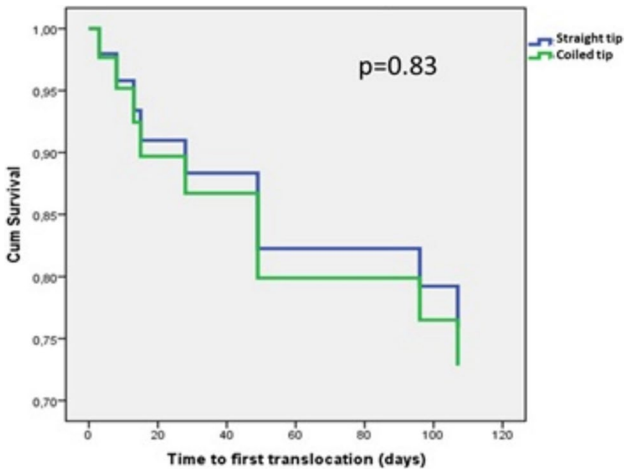

Fig. 2 Survival curve of time free to first tip migration according to the SN catheter tip

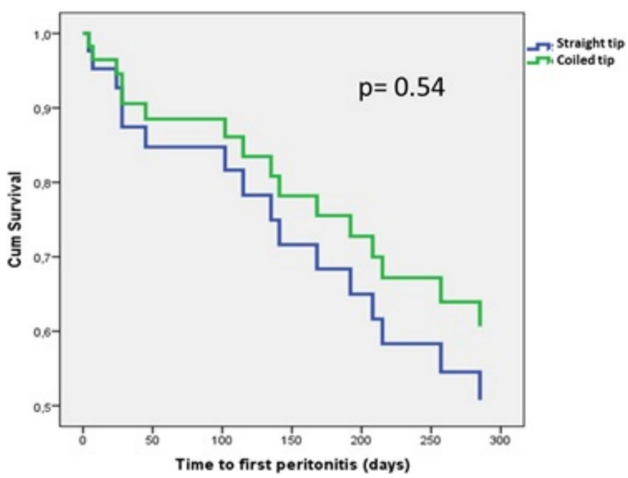

Fig. 3 Survival curve of time free to first peritonitis according to the SN catheter tip

summarized in Table 2 and were not significantly different between the straight tip group and coiled tip group.

In Table 3 are included the tip migrations (with catheter malfunction), refractory peritonitis and refractory ESI that were the causes of failure of the technique in each of the studied groups. In the straight tip group of three catheters that needed to be removed due to tip migration, two were successfully replaced and the patients continued in PD. Similarly, in the coiled tip group of four catheters, three were successfully replaced and the patients continued in the PD therapy.

A comparison of catheter survival rates in the two groups using Kaplan–Meier analysis showed no significant differences in 1 year follow-up, as Fig. 4 shows.

Figure 5 shows the survival curve of PD technique according to the SN catheter tip type. In 1 year follow-up, the survival of the technique did not differ between the two types of tips (90.5% in coiled tip group and 89% in straight tip group, log-rank $p=0.91$).

Discussion

A coiled intra-abdominal segment is generally believed to reduce inflow pain and catheter migration; however, the results of previous prospective randomized studies comparing straight and coiled catheters have been controversial [13]. As a result, the ISPD does not provide definitive guidelines for choice of catheter [14].

Our study evaluated prospectively in a follow-up of 1 year the main outcomes associated with two different intra-peritoneal parts: straight tip or coiled tip in SN peritoneal catheter. Infectious and mechanical complications rates were similar with no differences in catheter and technique survival curve.

Hagen et al. [10] in a systematic review with a meta-analysis also looked at the intra-peritoneal segment:

Table 2 Causes for drop out of the study before 12 months

	Straight tip ($n=24$)	Coiled tip ($n=25$)
Tip migration (with catheter malfunction)[a]	3	4
Refactory peritonitis[a]	0	1
Refactory ESI[a]	1	0
Kidney transplantation	0	3
Renal function recovery	0	1
Death	0	2
Transfer to hemodialysis due to psychosocial conditions	3	2
Transfer to hemodialysis due to severe extravasation	3	0
Total	10	13

[a]The catheters were removed (replacement of the catheter or permanent withdrawal of the catheter and transfer of the patient to hemodialysis)

Table 3 Causes of technique failure

	Straight tip ($n=24$)	Coiled tip ($n=25$)
Tip migration (with catheter malfunction)[a]	1	1
Refactory peritonitis[a]	0	1
Refactory ESI[a]	1	0
Total	2	2

[a]The catheters were removed and the patients were transferred to hemodialysis

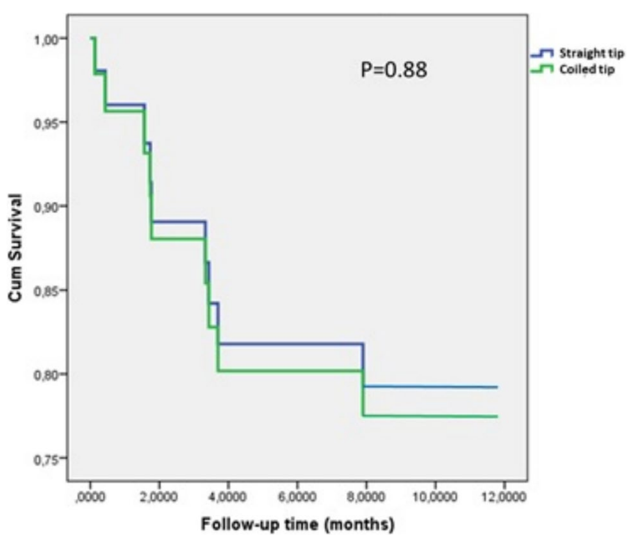

Fig. 4 Survival curve of the SN catheter according to the catheter tip

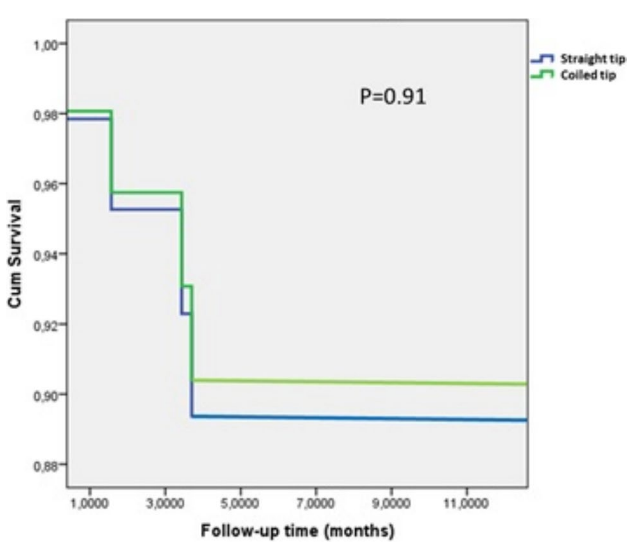

Fig. 5 Survival curve of the technique according to the SN catheter tip

coiled versus straight in a total of 454 patients and did not observe statistically significant differences in infection rates (ESI and peritonitis), incidence of translocations, leakage or catheter removal. Already when he evaluated the survival of the catheter in 2 years after insertion, there was a significant difference in favor of straight catheter (HR 0.22, 95% CI 0.35–0.08, $p=0.001$). Similarly, Johnson et al. [15] also observed a difference in catheter survival between the groups with a significant difference in favor of straight tip catheter.

Patient maintenance in the PD technique is strongly related to peritoneal catheter survival. According to the guideline [14], the catheter survival rate should be higher than 80% in 1 year. In our study, the survival of both types of catheters in one year of follow-up was very similar and practically reached that target of survival: straight tip catheter: 79% and coiled tip catheter: 77%.

The guideline [14] also recommends that the rate of catheters that have dysfunction and require surgical manipulation is less than 20%. Total catheter dysfunction due to tip migration requiring surgical manipulation in our study also reached this target of recommendation (18.3%).

In the literature, depending on the type of catheter, there are records of occurrences of translocations of 5–35%. Xie et al. [16] in a RCT also compared possible mechanical and infectious complications between straight tip SN and coiled tip SN with 40 patients in each group randomly divided. The results were meta-analyzed with other RCTs of coiled versus straight catheters. Their results suggested that coiled catheters may be more likely to have higher migration rates.

Our study has some limitations. It was performed in a single center and the sample size was small, and therefore, the results cannot be generalized. We do not perform fluoroscopy to check tip position at the time of implantation; although rare, there may be intra-peritoneal catheter tip out of the pelvis with well-functioning catheter. Moreover, the follow-up period was only 1 year, shorter than that of previous studies.

Finally, this study, despite the above-mentioned limitations, was the first randomized prospective study from Latin America that compared the effect of two types of intra-abdominal segments: straight and coiled on the risk of the main complications associated with PD failure.

In conclusion, in SN catheters the two types of tips studied presented similar infectious and mechanical rates with no differences in catheter and technique survival curve. This result confirms the recommendations of the ISPD.

Compliance with ethical standards

Conflict of interest The authors have declared that no conflict of interest exists.

Human rights This study was approved by the ethics committee of Brazil Plataform, under number: 17086413.3.0000.5411.

Informed consent The participants provided their written informed consent to participate in it at the time of enrollment. The study was conducted according to good clinical practices and the Declaration of Helsinki and its Trial Registration number is ISRCTN 15,159,688.

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