Straight Versus Coiled Peritoneal Dialysis Catheters: A Randomized Controlled Trial

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Rationale & Objective: Despite a recent meta-analysis favoring straight catheters, the clinical benefits of straight versus coiled peritoneal dialysis catheters remain uncertain. We conducted a randomized controlled study to compare the complication rates associated with these 2 types of double-cuffed peritoneal dialysis catheters.

Study Design: Multicenter, open-label, randomized, controlled trial.

Setting & Participants: 308 adult continuous ambulatory peritoneal dialysis patients.

Intervention: Participants were randomly assigned to receive either straight or coiled catheters.

Outcomes: The primary outcome was the incidence of catheter dysfunction requiring surgical intervention. Secondary outcomes included time to catheter dysfunction requiring intervention, catheter migration with dysfunction, infusion pain measured using a visual analogue scale, peritonitis, technique failure, and peritoneal catheter survival.

Results: 153 patients were randomly assigned to straight catheters; and 155, to coiled catheters. Among randomly assigned patients who underwent peritoneal dialysis, during a mean follow-up of 21 months, the primary outcome of catheter dysfunction or drainage failure occurred in 9 (5.8%) patients who received a coiled catheter and 1 (0.7%) patient who received a straight catheter. Straight catheters had 5.1% lower risk for catheter dysfunction (95% CI, 1.2%-9.1%; $P = 0.02$). The HR of the primary outcome for coiled versus straight catheters was 8.69 (95% CI, 1.10-68.6; $P = 0.04$). Patients who received a coiled catheter had similar risk for peritonitis but reported higher infusion pain scores than those who received straight catheters.

Limitations: Generalizability to other peritoneal dialysis centers with lower volumes and other races and nationalities.

Conclusions: Use of straight Tenckhoff catheters compared with coiled catheters reduced the rate of catheter dysfunction requiring surgical intervention.

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Despite the improved connectology of peritoneal dialysis (PD), successful creation of PD access for PD patients remains a major challenge.[1,2]

The best choice for a PD catheter, straight versus coiled, is controversial. No international guidelines have endorsed one type of intraperitoneal catheter design over another.[2,3] Limitations of previous studies on the influence of PD catheter type on complication rate and catheter survival have been highlighted in a recent systematic review and meta-analysis: catheter insertion using the percutaneous technique instead of the open method, omitting prophylactic antibiotics in some studies, incomplete data for catheter survival, and short length of follow-up.[4]

Eight randomized clinical trials[5-12] with sample size from 24 to 189 patients compared the outcome of PD catheters based on the difference in the intraperitoneal segment: straight versus coiled catheters. Although a coiled intraperitoneal segment has been thought to reduce infusion pain,[13] results from recent studies appear to be in favor of straight catheters, as reflected by the catheter malfunction rate.[11,12] However, these published studies are underpowered. Equipoise was also noted in the most updated International Society for Peritoneal Dialysis (ISPD) guideline on PD access,[14] which recommends the use of catheters with either a straight or coiled tip.

We designed a study powered to compare straight with coiled PD catheters with respect to catheter function and outcomes.

Methods

Objectives

The primary objective of the present study was to evaluate the a priori hypothesis that straight PD catheters would improve the treatment outcomes of PD.

Patients and Study Design

We enrolled consecutive adult patients who needed Tenckhoff catheter insertion in 2 dialysis centers, namely Prince of Wales Hospital and Alice Ho Miu Ling Nethersole Hospital. This prospective, open-label, randomized, controlled study was designed and conducted in compliance with the principles of Good Clinical Practice guidelines of the International Conference on Harmonisation.

The study was reviewed and approved by the local ethics committees (CREC Ref. No. 2015.197).

Patients who participated in the trial provided written informed consent before PD catheter insertion. Patients had to be 18 years or older and required insertion of a Tenckhoff catheter for long-term PD. Exclusion criteria included known contraindication to PD or participation in another interventional study within last 30 days of randomization. Patients requiring reinsertion of catheters were allowed. Recruitment took place from June 2015 through March 2017 at the 2 study centers.

Patients underwent randomization and were assigned in a 1:1 ratio to either straight or coiled PD catheters. A computer-generated treatment assignment by sealed envelopes was used. Treatment allocation was not blinded to investigators.

All catheters are double cuffed with straight intercuff segments (Covidien). Lengths of straight and coiled catheters were 47 and 62 cm, respectively. They were inserted by nephrologists using an open dissection surgical technique, as previously reported.[15-17] Ten primary operators who had qualified as nephrologist specialists were responsible for the insertion of Tenckhoff catheters; each had experience inserting at least 50 catheters. Patients with extreme obesity and expected to require laparoscopic adhesiolysis, rectus sheath tunneling, and omentopexy were not recruited in the study.

Patients received a shower on or before the day of the procedure with chlorhexidine soap wash of the planned surgical site. The procedure was carried out in either a dedicated ward-based procedure room or operating room. Intravenous cefazolin was routinely administered as prophylactic antibiotic except for patients with penicillin or cephalosporin allergy. Catheter insertions are preceded by urinary bladder emptying. Skin preparation for the operation was performed using povidone iodine and standard draping.

After a midline or paramedian subumbilical incision, subcutaneous fat dissection was carried out, with or without diathermy, until reaching the sheath of the abdominal rectus muscle. The anterior rectus sheath was opened in layers and the muscle fibers were pulled aside or bluntly separated. The posterior sheath was then cut and the peritoneal cavity was opened after peritoneum dissection. After insertion of either a straight or coiled Tenckhoff catheter (with or without a malleable stylet) into the peritoneal cavity, the peritoneum and posterior rectus sheath were closed with continuous absorbable sutures. The internal cuff was secured in the rectus sheath, within the muscle tissue or just below, at the level of the insertion incision. An absorbable purse-string suture completed the closure at the posterior rectus sheath level. Free drainage of PD fluid was tested. A subcutaneous tunnel was then created by artery forceps to the preferred exit site after repair of the anterior rectus sheath with continuous sutures. The external cuff was placed subcutaneously at 2 to 4 cm from the exit site, and all exit sites were created in a downward-facing direction. The peritoneal cavity was flushed with 1,000 mL of dialysis fluid until clear after placement of the catheter. The wound and exit site were covered with absorbent dressings.

Patients stayed supine for the initial 24 hours after catheter insertion. Ambulatory PD was delayed for at least 3 weeks after catheter insertion; a 1-L volume of dialysis solution was used for supine PD exchanges if immediate dialysis was needed. Subsequent Tenckhoff catheter care was undertaken by trained PD nurses according to standard protocols. Treatment of peritonitis was carried out as suggested by the ISPD guidelines.[18]

End Points

All patients and catheters were followed up for at least 1 year. We examined mechanical and infectious catheter complications. PD-related peritonitis and exit-site infection were defined in the conventional manner.[18] Catheter survival was calculated from the day of catheter insertion. Catheter survival refers to the time that a PD catheter can be preserved before it has to be abandoned because of infection or mechanical malfunctioning. Data were censored at the time of kidney transplantation, recovery of kidney function, or end of the study.

The primary outcome measure of this study was the incidence of catheter dysfunction that requires surgical intervention. Catheter dysfunction refers to drainage failure, as defined by the inability to drain peritoneal dialysate effluent reliably within 45 minutes. Intervention includes catheter repositioning or reinsertion, either by an open surgical method or laparoscopically.[19] Temporary catheter dysfunction that resolved with treatment by laxative or fibrinolytic therapy was not counted as an event in the analysis.

Secondary end points included time to catheter dysfunction requiring intervention, infusion pain, risk for peritonitis, technique failure, and peritoneal catheter survival. Infusion pain was measured with the use of a visual analogue scale that ranges from 0 to 10. Study participants were questioned on infusion pain around 1 month after starting PD. Subgroup analysis was performed to see the complication rate between incident PD patients and those with previous catheter insertion.

Analyses were made according to the intention-to-treat and per-protocol populations. The intention-to-treat population included all participants who underwent random assignment. The per-protocol population included all participants who received PD after Tenckhoff catheter insertion.

Statistical Analysis

We determined sample size on the basis of our previous experience that the incidence of catheter dysfunction with migration after insertion of coiled peritoneal catheters was ∼15%, in keeping with most of the reported studies of catheters inserted using the open surgical method.[5,10,11] The trial was powered to distinguish a clinically meaningful reduction in complications to an incidence of 7%. We determined that a sample size of 264 would achieve 80% power to detect the difference between groups with a significance level (alpha) of 0.05 using a 2-sided 2-sample t test. This sample size was estimated using Power Analysis and Sample Size for Windows software (PASS 2000; NCSS).

Numerical data were expressed as mean ± standard deviation. Treatment outcome and data between treatment groups were compared using log-rank test, t test, or Mann-Whitney U test, as appropriate. Percentages between groups were compared using χ^2 test; outcome measures with events numbering fewer than 10 were compared using Fisher exact test. Survival analysis was compared using Kaplan-Meier analyses with log-rank test. $P < 0.05$ was considered statistically significant. We also performed sensitivity analyses to explore whether final results were significantly affected by using time from actual PD to catheter dysfunction. Calculation was performed using SPSS for Windows software, version 24.0 (SPSS Inc).

Results

The study randomly assigned 308 patients to receive either straight or coiled Tenckhoff catheter insertion (Fig 1), after excluding 8 patients who were referred for laparoscopic catheter insertion due to severe obesity. The intention-to-treat population included all patients who underwent randomization; 153 received straight catheters and 155 received coiled catheters. The number of patients included in the per-protocol population was 306 because 2 in the straight catheter group had incorrect placement into the urinary bladder and preperitoneal space.

Baseline characteristics of the 2 treatment groups were comparable with respect to age, baseline albumin level, body size, and comorbid conditions (Table 1). More than half had diabetes mellitus (58%) and 27% of all patients had previous abdominal surgery before catheter insertion. Four (2.6%) patients in the straight catheter group and 5 (3.2%) in the coiled catheter group had a body mass index > 35 kg/m^2. No patients were lost to follow-up during the trial. Less than 10% of patients required immediate dialysis; otherwise, patients received training for PD at 4 to 6 weeks after catheter insertion. The peritonitis rate was 0.37 episodes per year.

In the intention-to-treat analysis, the incidence of catheter dysfunction or drainage failure did not differ between the coiled and straight catheter groups (5.8% and 2.0%, respectively; difference, 3.9 percent points; $P = 0.1$).

After excluding 2 cases with catheter misplacement, the per-protocol population consisted of 306 patients. At the end of follow-up, there were 10 (3.3%) episodes of catheter dysfunction or drainage failure requiring intervention, our primary end point of mechanical complication. Open surgical repositioning (8 episodes) or laparoscopic intervention (2 episodes) confirmed catheter migration, with the catheter being wrapped by the omentum or small-bowel loops in all cases. None of these episodes occurred in patients who received re-insertion of Tenckhoff catheters. With the exception of 3 patients receiving coiled catheters, most of the complications occurred more than 8 weeks after catheter insertion. Of the 7 cases of catheter dysfunction more than 8 weeks after catheter insertion, complications occurred at median interval of 7.5 months after catheter insertion. As shown in Table 2, 9 of 155 (5.8%) patients receiving coiled catheters had catheter dysfunction versus 1 of 151 (0.7%) receiving straight catheters. The difference in risk for catheter dysfunction (coiled minus straight catheter) was 5.1 (95% confidence interval [CI], 1.2-9.1) percentage points ($P = 0.02$).

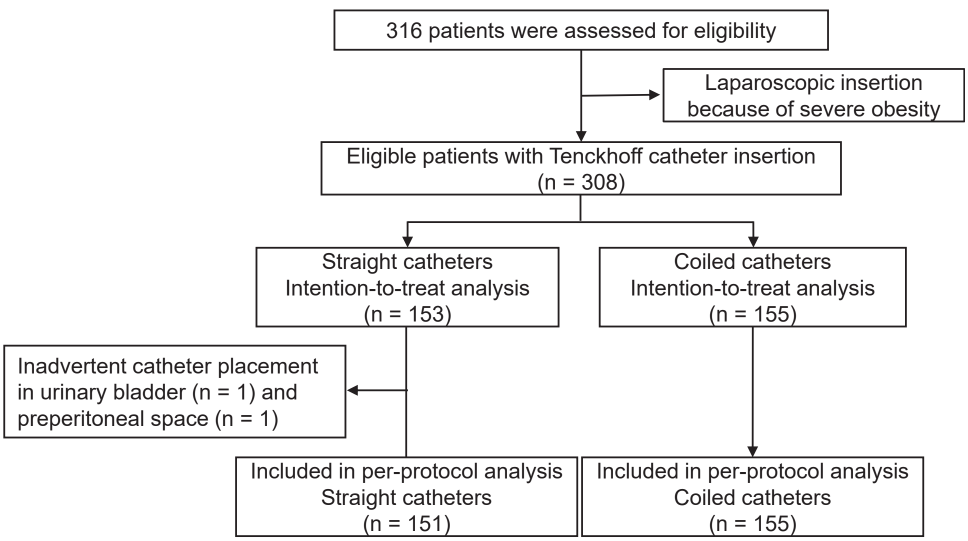

Figure 1. Flow diagram of the number of patients recruited, randomly assigned, followed up, and analyzed.

Table 1. Baseline Demographic Characteristics in the Intention-to-Treat Population

	Straight Catheter (n = 153)	Coiled Catheter (n = 155)	*P*
Age, y	61 ± 13	61 ± 14	0.9
Female sex	50 (32.7%)	59 (38.1%)	0.3
Body weight, kg[a]	65.4 ± 14.6	67.4 ± 13.3	0.2
Body mass index, kg/m^2	24.9 ± 4.6	25.5 ± 4.4	0.2
Serum albumin, g/L	33.4 ± 6.7	33.7 ± 6.3	0.7
Diabetes mellitus	81 (52.9%)	96 (61.9%)	0.1
Primary kidney disease			0.2
Glomerular disease	36 (23.5%)	26 (16.8%)	
Diabetic kidney disease	69 (45.1%)	83 (53.5%)	
Polycystic kidney disease	3 (2.0%)	1 (0.6%)	
Hypertensive nephrosclerosis	22 (14.4%)	12 (7.7%)	
Obstruction	2 (1.3%)	5 (3.2%)	
Unknown	15 (9.8%)	18 (11.6%)	
Miscellaneous	6 (3.9%)	10 (6.5%)	
Previous abdominal surgery			0.4
Cholecystectomy	4 (2.6%)	3 (1.9%)	
Gastrectomy	2 (1.3%)	0 (0%)	
Hemicolectomy	2 (1.3%)	0 (0%)	
Cesarean delivery	6 (3.9%)	3 (1.9%)	
Kidney transplantation	6 (3.9%)	6 (3.9%)	
Nephrectomy	20 (13.1%)	2 (1.3%)	
Appendectomy	1 (0.7%)	3 (1.9%)	
Tenckhoff catheter insertion	27 (17.6%)	14 (9.0%)	
Hysterectomy	1 (0.7%)	1 (0.6%)	
Ischemic heart disease	28 (18.3%)	28 (18.1%)	0.9
Cerebrovascular accident	20 (13.1%)	26 (16.8%)	0.4
Planned catheter insertion	129 (84.3%)	135 (87.1%)	0.5
Automated peritoneal dialysis	10 (6.5%)	20 (12.9%)	0.08

[a]Mean ± standard deviation.

With respect to the primary end point of catheter dysfunction or drainage failure, the Kaplan-Meier event-free survival probability for the Tenckhoff catheters is shown in Figure 2. Coiled catheters had significantly increased risk for catheter dysfunction or drainage failure; the hazard ratio (HR) for the primary outcome was 8.69 (95% CI, 1.10-68.6; P = 0.04). Log-rank test for the difference in event-free survival curves indicated the superiority of straight catheters (P = 0.01). In sensitivity analyses assessing event-free survival from the time of starting dialysis, instead of catheter insertion, results were similar.

To assess the association of catheter types with secondary outcomes, there was no association of coiled catheters with risk for peritonitis (HR, 0.87; 95% CI, 0.60-1.27; P = 0.5) and catheter survival (HR, 0.95; 95% CI, 0.73-1.23; P = 0.7).

Finally, we examined the between-group difference in infusion pain measured using visual analogue scale. Study participants were questioned on infusion pain around 1 month after starting PD. Data were presented as box plots in Figure 3. We observed a slight but statistically lower pain score in the straight catheter group (Table 2). Overall, three-quarters of participants reported an infusion pain score ≤1 of 10.

Table 2. Clinical and Catheter Outcomes in Per-Protocol Analysis

	Straight Catheter (n = 151)	Coiled Catheter (n = 155)	% Difference (95% CI)	*P*
Primary end point: catheter dysfunction due to drainage failure	1 (0.7%)	9 (5.8%)	5.1% (1.2%-9.1%)	0.02
Secondary end point: infusion pain assessed by visual analogue scale ranging from 0-10[a]	0.0 [0.0-1.0][b]	1.0 [0.0-2.0][b]	NA	<0.001

Abbreviations: CI, confidence interval; NA, not applicable.
[a]Missing data in 4 patients receiving straight Tenckhoff catheters and 2 patients with coiled catheters.
[b]Median [interquartile range].

Discussion

The main objective of this randomized controlled trial involving patients with kidney failure who received Tenckhoff catheters for PD was to discern the effect of coiled versus straight Tenckhoff catheters with respect to catheter function. The clinical event of catheter dysfunction requiring surgical intervention was assessed during a mean follow-up of 21 months. The trial showed that use of a straight Tenckhoff catheter resulted in a significantly lower rate of catheter dysfunction or drainage failure than the rate with coiled catheters. Results extend the evidence base regarding the superiority of straight Tenckhoff catheters. A purely clinical outcome was chosen to be the primary outcome because it is the most meaningful to PD patients and, by extension, determines further dialysis pathways.

Previous studies (Table 3) were considerably smaller than the present study and most also had shorter follow-

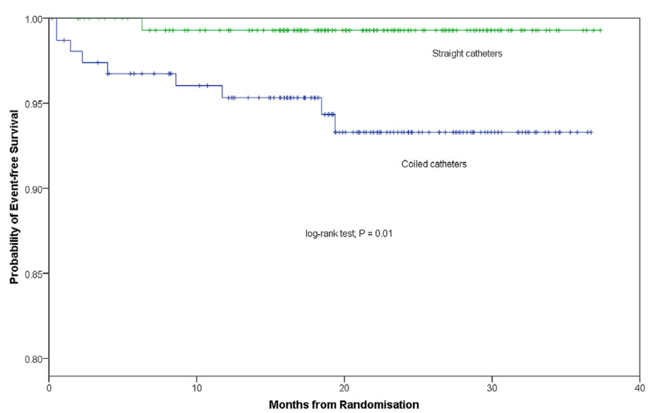

Figure 2. Kaplan-Meier curve for catheter survival probability with event free from the primary efficacy outcome of catheter dysfunction or drainage failure.

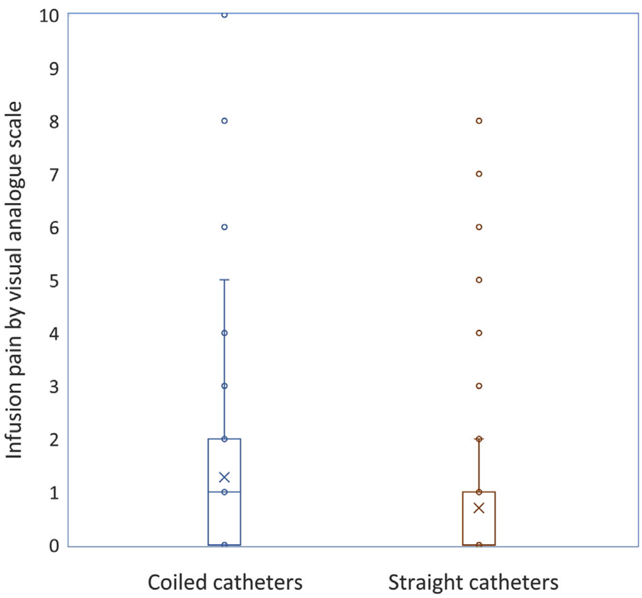

Figure 3. The effect of straight and coiled catheters on patient self-reported infusion pain based on a visual analogue scale from 0 to 10.

Table 3. Outcomes of Catheter Migration With Dysfunction in Studies Comparing Straight With Coiled Tenckhoff Catheters

Reference	Year	No. of Cases	Insertion Method	Incidence of Catheter Dysfunction
Akyol et al[5]	1990	Straight: 20 Coiled: 20	Open surgery	Straight: 10% Coiled: 10%
Rubin et al[6]	1990	Straight: 50 Coiled: 35	Open surgery	Straight: 10% Coiled: 14%
Nielsen et al[7]	1995	Straight: 38 Coiled: 34	Percutaneous insertion with trocar	Straight: 55% Coiled: 12%
Lye et al[8]	1996	Straight: 20 Coiled: 20	Open surgery	Straight: 0% Coiled: 0%
Stegmayr et al[9]	2005	Straight: 10 Coiled: 14	Open surgery	Straight: 0%[a] Coiled: 43%[a]
Johnson et al[10]	2006	Straight: 70 Coiled: 62	Open surgery	Straight: 14%[a] Coiled: 16%[a]
Xie et al[11]	2011	Straight: 40 Coiled: 40	Open surgery	Straight: 22.5% Coiled: 45%
Ouyang et al[12]	2014	Straight: 99 Coiled: 90	Open surgery	Straight: 7% Coiled: 18%
Current study	2018	Straight: 151 Coiled: 155	Open surgery	Straight: 0.7% Coiled: 5.8%

[a]Incidence of catheter dysfunction requiring surgical or laparoscopic rescue.

up. Our study aimed to address the concerns from a previous meta-analysis and systematic review calling for the need of a large high-quality randomized trial.[4,20] Notably, our findings differ from those of earlier studies in terms of event rates. For example, our drainage failure rate of 3.3% was considerably lower than that of 15.2% reported by another randomized trial.[10] A few factors may explain the discrepancy, among them the center effect.[21] Better outcomes and technique survival had been repeatedly demonstrated among more experienced centers with larger case volume. This study was carried out in Hong Kong, where all patients with kidney failure who require dialysis were treated with PD first unless they have a medical contraindication to do so.[22] Low complication rates may also explain the practice of catheter insertion by a dedicated team.[1] The Hawthorne effect was unlikely because the observed catheter drainage failure rate in the current trial was not significantly different from that of 2.0% as reported in a previous audit from our center.[16] The beneficial effect of straight catheters, in terms of less likelihood of catheter tip migration with dysfunction, as shown in the current study, aligned with findings from previous meta-analyses.[4,11] Despite these reassurances, we recognize that the relatively small numbers of events may affect the stability of the effect from a statistical significance standpoint. This was also a study from high-volume PD centers with nephrologists experienced in PD, so results may not be generalizable to other centers.

In addition, our study refuted the speculation that the design of a straight intra-abdominal tip increases dialysate inflow pain, presumably due to the jet effect of the dialysate from the end hole of the catheter. In contrast, we found a statistically significant lower infusion pain score reported by patients who received straight catheters than in those with coiled catheters. It should be emphasized that both types of catheters were well tolerated in terms of infusion pain; the choice of PD catheter should therefore not be dictated by a difference in infusion pain. However, the current study was not designed to study the influence of catheter design on drain pain. We chose not to examine drain pain because it is largely determined by the catheter insertion site and length of intraperitoneal tubing, rather than the choice of straight versus coiled tips.

Strengths of this trial include sample size and the ability to include >95% of PD patients. Our trial also has several limitations. First, it was, by necessity, conducted as an open label study. The open design might have introduced some level of ascertainment bias. However, the event of catheter dysfunction was based on an objective assessment and confirmed by surgical intervention and surgical findings. Second, advantages of straight catheters concluded from the current study in the Chinese population might not be generalizable to others, notably non-Asians with larger body habitus.

In summary, our adequately powered randomized controlled trial suggests that straight PD catheters are less prone to catheter dysfunction and drainage failure than coiled catheters.

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Data Sharing: Individual participant data collected during the trial will be shared, after deidentification, with researchers who provide methodologically sound proposals such as individual participant data meta-analysis. No other documents will be available. Requests should be made to the corresponding author and must be received within 24 months following publication.

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