Few Outflow Problems With a Self-locating Catheter for Peritoneal Dialysis
A Randomized Trial

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Abstract: We developed a technique for direct start of peritoneal dialysis. Using a coiled or straight Tenckhoff catheter often results in obstruction of flow. A self-locating Wolfram catheter is on the market. It is often difficult to start acute peritoneal dialysis 1 because of the need for a break-in period (no peritoneal dialysis) of 14 days postoperatively for most operative techniques used. 2 The reason to use a delayed start is to avoid leakage and outflow obstruction. Although the use of a swan neck catheter versus a straight outer part of the Tenckhoff catheter does not differ, 3 the use of a coiled inner part causes more complications than when using a straight inner part. 4–7 The coiled catheters are more frequently caught by the omentum and dislocated.

To avoid dislocations a “self-locating” catheter was invented. 8 The catheter contains a tip with a tungsten (Wolfram) weight. This catheter is meant to be self-locating toward the fossa and thereby avoid dislocation. Beneficial data have been shown in several observational studies. 5–11 The benefit was also shown in an Italian multicenter study. 8 After detailed explanation and information, patients were invited to choose between the 2 types of catheter. With rare exceptions, the same surgeon in each center implanted the catheters. Insertion techniques could vary between the centers.

As we have a surgical technique using 3 purse string sutures, we start peritoneal dialysis directly postoperatively both in acute and chronic dialysis settings. 12,13 The technique results in few problems with leakage. 14 However, obstructive episodes occur intermittently requiring adjustment using either a bended stylet 15,16 or reoperation.

The primary aim of the study was to analyze if the Wolfram catheter would perform better than the straight peritoneal dialysis catheter regarding filling and outflow problems when starting peritoneal dialysis.

INTRODUCTION

It is often difficult to start acute peritoneal dialysis 1 because of the need for a break-in period (no peritoneal dialysis) of 14 days postoperatively for most operative techniques used. 2 The reason to use a delayed start is to avoid leakage and outflow obstruction. Although the use of a swan neck catheter versus a straight outer part of the Tenckhoff catheter does not differ, 3 the use of a coiled inner part causes more complications than when using a straight inner part. 4–7 The coiled catheters are more frequently caught by the omentum and dislocated.

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MATERIAL AND METHODS

We had previously established the benefit using a straight double cuff Tenckhoff before a coiled catheter. 4 Thereafter, at our hospital, insertions were performed using either a straight or a self-locating Wolfram catheter. To clarify if there was a benefit using one or the other we decided to perform a systematic quality assessment study using randomization. If failure would occur the other type of catheter should be used. All patients were informed and consented to participate in the setting. All patients started their dialysis program using peritoneal dialysis (PD). The study started February 2007 and ended June 2013. A peritoneal dialysis nurse made randomization from envelopes and provided the surgeon with the respective catheter. Once the patient was accepted for peritoneal dialysis by the physician in charge, there were no exclusion criteria for randomization. The study has attained local ethical committee approval (Ethical Committee, Umeå, Sweden, 2012-181-31 M at June 5, 2012) and the ClinicalTrials.gov Identifier: NCT02347592.
As numerous patients are unaware of their chronic uremic condition when they are confronted with health care for the first time they need to start dialysis rather acute. Other patients postpone the dialysis start until late by other reasons. If they start acute using hemodialysis few will change to PD later. Starting directly (acute) with PD results in lesser drop out off PD. The terminology acute in this text refers to both acute and chronic kidney disease patients. In this study only chronic patients were included.

A total of 61 insertions were performed either to a straight Tenckhoff (n = 32, 53% men) or a self-locating Wolfram catheter (n = 29, 69% men). The study was performed on a University Hospital. The mean age of the group randomized to straight Tenckhoff did not differ with the group of patients with a self-locating catheter (Table 1). The various diagnoses for chronic kidney disease are given in Table 1.

Catheters used were from Fresenius Medical Care (Hamburg, Germany), either a straight double-cuffed Tenckhoff or a double-cuffed Wolfram (tungsten, heavy tip) catheter by Di Paolo.

**Operation Technique (Figure 1 A–H)**

A few experienced surgeons, specialized in general and vascular surgery, performed catheter insertions. A strict protocol for the operative technique was used. The insertion technique is the same for both types of double cuffed peritoneal dialysis catheters, whereas the difference is at the inner end of the Wolfram catheter, holding a metal weight. The insertion of the catheter is performed in the operation theatre in local anesthesia, and often mild sedation of the patient. Incision of the skin and the right anterior rectus sheath is performed. The fibers of the rectus abdominal muscle are separated and a small hole is made in the posterior rectus sheath. Thereafter, the peritoneal membrane is identified and a small incision of the membrane allows the catheter to be located into the left lower fossa. The location of the catheter is facilitated using a stiff slightly bended stylet with a blunt end. The stylet is placed within the catheter and withdrawn when the catheter is in the right location. The inner cuff is placed outside the peritoneum and beneath the posterior rectus sheath and angulated toward the left lower fossa with 2 purse string sutures. The first suture tightens the membranes around the catheter and the second suture further tightens the membranes around the cuff causing a watertight seal. The outer fascia is closed around the catheter with the third row of sutures within the channel created. The location of the catheter between the peritoneal opening and the inner fascia is in direction toward the left lower abdomen and the curve of the subcutaneous tunnel is smooth to avoid kinking of the catheter. During the operation the location of the catheter tip in the left lower fossa is usually verified by x-ray. In addition filling and emptying the abdomen before placing the final sutures tested the function of the catheter (see also Appendix). Based on a randomized study, in the first postoperative dialysis bag, instilled directly after return from operation, cefuroxime (250 mg/L) is used as antibiotic prophylaxis. The patient is kept in a supine position for 2 h, before allowed to walk around. When the patient is out of bed with PD-fluid in the abdominal cavity a surgical girdle is used during the first 2 to 4 postoperative days to avoid distension of the wound Figure 1.18

Primary outcome measures: problems related to the type of catheter were considered to be filling and outflow dysfunction. Outflow dysfunction was defined as inability to repeatedly drain >500 mL PD fluid within 40 min. An x-ray investigation of the location of the catheter was performed to decide if reoperation should be performed or not.

Secondary outcome measure: early and late leakages were considered as problems related to the operation technique in the tissue area (not enabling tightness between abdominal cavity and exit).

When outflow failure occurred, repeated attempts were made to overcome the problem. Initially the patient was informed to change into various positions, using laxatives. When dysfunction remained, x-ray was performed. If omental wrapping was not obvious attempts were made using fibrinolytic agents such as heparin and even attempts were made using correction with a bended stylet. Thereby the stylet is inserted into the catheter to try to correct the position of the catheter without surgery.

If total obstruction was present or if outflow or inflow dysfunction remained and surgery was decided this was defined as outflow failure (death of catheter in the survival analysis).

Early and late leakages were used as the secondary outcome variable as leakage is 1 important reason for interruption of the dialysis process. As the self-locating catheter has a wider tip it needs a larger entry hole through the peritoneum than a regular catheter. This larger hole may increase the risk for early leakage.

**Statistics**

Sample size was estimated by assuming at least 30% differences between groups. Interim results were obvious due to an open study design. Clinical differences urged for an

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**TABLE 1. Baseline Data of Patients Who Either Receive a Double Cuff Tenckhoff (Standard, N = 32) or a Self-Locating Wolfram Catheter (Wolfram, N = 29) and Reasons for Ending PD**

| Reason for drop out:          | Standard N (%) | Wolfram N (%) | P |
|------------------------------|----------------|---------------|---|
| Men                          | 17 (53)        | 20 (69)       | n.s.|
| Age, years, mean (SD)        | 60 ± 18        | 58 ± 13       | n.s.|
| Diabetes mellitus            | 14 (44)        | 10 (34)       | n.s.|
| Reason for kidney failure:   |                |               |    |
| Diabetic nephropathy         | 12 (37)        | 7 (24)        | n.s.|
| Glomerulonephritis           | 7 (22)         | 6 (21)        | n.s.|
| Nephrosclerosis              | 7 (22)         | 9 (31)        | n.s.|
| Polycystic kidney disease    | 2 (6)          | 4 (14)        | n.s.|
| Other reasons                | 4 (12.5)       | 3 (10)        | n.s.|
| Reasons for drop out:        |                |               |    |
| Died                         | 5 (16)         | 2 (7)         | n.s.|
| Converted to HD             | 14* (44)       | 6‡ (21)       | n.s.|
| Transplanted                 | 3 (9)          | 12 (41)       | 0.008|
| Continued PD                 | 10 (31)        | 9 (31)        | n.s.|

HD = hemodialysis, n.s. = not significant, PD = peritoneal dialysis,
* 5 due to catheter problems.
† 1 with pleural effusion.
interim analysis after June 2013. Fisher’s test was used for the comparison of catheter patency. For mean value calculations, the Student $t$ test was used. Kaplan–Meier analyses were performed. A 2-tailed $P$ value of $<0.05$ was considered statistically significant. IBM SPSS software version 22 was used. Kaplan–Meier analyses were performed with R on an Apple MacBook Pro, System 10.10.1.

R Core Team (2014; R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/).

RESULTS
Start of peritoneal dialysis was initiated directly post-operatively in all 61 insertions (100%). Median follow-up was 10 months (range 1–76, mean $15 \pm 17$ months).

Primary Outcome Measure
Obstructions resulted in reoperation in 7 of 32 inserted straight Tenckhoff catheters and none of 29 self-locating Wolfram catheter insertions (Fisher’s test, 2-tailed, $P = 0.01$). These 7 straight Tenckhoff catheters were changed into self-locating catheters, and none vice versa ($P = 0.011$).

The survival curve of the catheters showed a worse outcome for the straight Tenckhoff (Breslow analysis, $P = 0.01$, Fig. 2), all problems happening during the early phase of PD. The flow problems arose within the first 2 months. If a straight Tenckhoff catheter was patent at that time there was no difference in patency between catheters. The catheters were thereafter functioning well with both techniques (Fig. 2).

The reasons for patients to end the PD program are given in Table 1.

Secondary Outcome Measure
Leakage was present in 4 (6.5%) of the placements during the first days (1 of those with self-locating catheter and 3 with the straight Tenckhoff). The patients were kept off PD (dry) for 6, 8, 14, and 17 days, respectively. Restart was without leakage. In general, their tissue was considered very soft by the surgeon. No late leakage developed.

A total of 7 surgeons had inserted catheters through the period. Three had inserted most ($\geq 5$ insertions/surgeon)
selected the self-locating catheter there might be a selection invited to choose between the 2 types of catheter. As 78% complain of a discomfort in the pelvis, probably caused by when the patient is moving. However, some patients may in the pelvis of the patient. This will protect from dislocation of the tip of the catheter caused for example by a patient that is in motion, bending forward and dislocating the catheter upward or an omentum catching and obstructing a catheter tip. By using the self-locating Wolfram catheter the weight at the tip keeps the catheter in a position when obstruction occurs, other measures than described in this study may also be tried if experience exists such as using single-port laparoscopy for salvaging outflow failure from omentum wrapping.

A limitation of the study was that the surgeon was not blinded to the catheters inserted. It is important the tip of the self-locating catheter is located right at start to avoid discomfort and invagination into the omentum. This is facilitated using the bended stylet described and a follow-up x-ray check preoperatively. The larger hole created in the peritoneum for insertion of the metal tip may increase the risk for early leakage although the operation technique was kept the same. If dislocation occurs it is trickier to adjust the position of the self-locating catheter with a stylet due to the weight at the tip.

In conclusion, this study showed that using the present operation technique the self-locating PD-catheter causes fewer obstruction episodes than a straight Tenckhoff catheter. This facilitates immediate postoperative start of PD.

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REFERENCES

1. Canadian CAPD Clinical Trials Group. Peritonitis in continuous ambulatory peritoneal dialysis (CAPD): a multi-centre randomized clinical trial comparing the Y connector disinfectant system to standard systems. Canadian CAPD Clinical Trials Group [see comments]. Perit Dial Int. 1989;9:159–163.
2. Stegmayr B. Advantages and disadvantages of surgical placement of PD catheters with regard to other methods. Int J Artif Organs. 2006;29:95–100.
3. Eklund BH, Honkanen EO, Kala AR, et al. Peritoneal dialysis access: prospective randomized comparison of the Swan neck and Tenckhoff catheters [see comments]. Perit Dial Int. 1995;15:353–356.
4. Stegmayr BG, Wikdahl AM, Bergstrom M, et al. A randomized clinical trial comparing the function of straight and coiled Tenckhoff catheters for peritoneal dialysis. Perit Dial Int. 2005;25:85–88.
5. Xie J, Kirelyuk K, Ren H, et al. Coiled versus straight peritoneal dialysis catheters: a randomized controlled trial and meta-analysis. Am J Kidney Dis. 2011;58:946–955.
6. Hagen SM, Lafranca JA, Ijzermans JN, et al. A systematic review and meta-analysis of the influence of peritoneal dialysis catheter type on complication rate and catheter survival. Kidney Int. 2014;85:920–932.
7. Johnson DW, Wong J, Wiggins KJ, et al. A randomized controlled trial of coiled versus straight swan-neck Tenckhoff catheters in peritoneal dialysis patients. Am J Kidney Dis. 2006;48:812–821.
8. Di Paolo N, Capotondo L, Sansoni E, et al. The self-locating catheter: clinical experience and follow-up. *Perit Dial Int.* 2004;24:359–364.

9. Bergamin B, Senn O, Corsenca A, et al. Finding the right position: a three-year, single-center experience with the “self-locating” catheter. *Perit Dial Int.* 2010;30:519–523.

10. Cavagna R, Tessarin C, Tarroni G, et al. The self-locating catheter: clinical evaluation and comparison with the Tenckhoff catheter. *Perit Dial Int.* 1999;19:540–543.

11. Vaccarisi S, Spadafora N, Bonaiuto E, et al. Laparoscopic placement of “self-locating catheter”: our experience and a review of literature. *Transplant Proc.* 2012;44:1873–1875.

12. Stegmayr B, Hedberg B, Sandzen B, et al. Absence of leakage by insertion of peritoneal dialysis catheter through the rectus muscle. *Perit Dial Int.* 1990;10:53–55.

13. Stegmayr BG. Three purse-string sutures allow immediate start of peritoneal dialysis with a low incidence of leakage. *Semin Dial.* 2003;16:346–348.

14. Stegmayr BG. Lateral catheter insertion together with three purse-string sutures reduces the risk for leakage during peritoneal dialysis. *Artif Organs.* 1994;18:309–313.

15. Stegmayr B. Various clinical approaches to minimise complications in peritoneal dialysis. *Int J Artif Organs.* 2002;25:365–372.

16. Stegmayr BG, Hedberg B, Norrgard O. Stylet with a curved tip to facilitate introduction of new Tenckhoff catheters and reposition of displaced ones. Surgical technique. *Eur J Surg.* 1993;159:495–497.

17. Wikdahl AM, Engman U, Stegmayr BG, et al. One-dose cefuroxime i.v. and i.p. reduces microbial growth in PD patients after catheter insertion. *Nephrol Dial Transplant.* 1997;12:157–160.

18. Engman U, Nilsson C, Bergström M, et al. A surgical girdle may be helpful to start PD patients. *Perit Dial Int.* 2000;20 (suppl 1):S84.

19. Kang SH, Lee DS, Park JW. Outflow failure caused by mesothelial cell lining sheet wrapping in a patient with peritoneal dialysis. *Clin Nephrol.* 2014;81:224–227.