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

A Randomized Trial

Bernd G. Stegmayr, MD, PhD, Wolfgang Sperker, MD, Christina H. Nilsson, RN, Christina Degerman, RN, Sven-Erik Persson, MD, PhD, Jan Stenbaek, MD, and Conny Arnerlöv, MD, PhD

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 not clarified if this results in a benefit.

The primary aim of this study was to perform a randomized investigation to clarify if the use of a self-locating peritoneal dialysis (PD) catheter would result in different flow problems than a straight Tenckhoff catheter.

A total of 61 insertions were made who were randomized and recovered either a straight Tenckhoff (n = 32) or a self-locating Wolfram catheter (n = 29).

A previously described operation technique allowed immediate postoperative start of dialysis. Seven straight Tenckhoff catheters had to be changed into self-locating catheters, and none vice versa, due to flow problems (P = 0.011). An early leakage resulted in temporarily postponed PD in 4 patients.

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.

Abbreviation: PD = peritoneal dialysis.
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 (Homburg, 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.

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

<table>
<thead>
<tr>
<th>Reason for kidney failure:</th>
<th>Standard N (%)</th>
<th>Wolfram N (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic nephropathy</td>
<td>12 (37)</td>
<td>7 (24)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Glomerulonephritis</td>
<td>7 (22)</td>
<td>6 (21)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Nephrosclerosis</td>
<td>7 (22)</td>
<td>9 (31)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Polycystic kidney disease</td>
<td>2 (6)</td>
<td>4 (14)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Other reasons</td>
<td>4 (12.5)</td>
<td>3 (10)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Reasons for drop out:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Died</td>
<td>5 (16)</td>
<td>2 (7)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Converted to HD</td>
<td>14* (44)</td>
<td>6* (21)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Transplanted</td>
<td>3 (9)</td>
<td>12 (41)</td>
<td>0.008</td>
</tr>
<tr>
<td>Continued PD</td>
<td>10 (31)</td>
<td>9 (31)</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

HD = hemodialysis, n.s. = not significant, PD = peritoneal dialysis,
*5 due to catheter problems
*11 with pleural effusion.

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
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.


RESULTS

Start of peritoneal dialysis was initiated directly postoperatively in all 61 insertions (100%). Median follow-up was 10 months (range 1–76, mean 15 ± 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)
The self-locating catheter may favor that more patients will accept to start on PD with the described insertion technique and 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