Peritoneal Dialysis International, Vol. 38, pp. 104–112
www.PDIConnect.com

0896-8608/18 $3.00 + .00

RANDOMIZED CONTROLLED TRIAL COMPARING OPEN VERSUS LAPAROSCOPIC PLACEMENT OF A PERITONEAL DIALYSIS CATHETER AND OUTCOMES: THE CAPD I TRIAL

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♦ ***Objective:*** **To determine the best operation technique, open versus laparoscopic, for insertion of a peritoneal dialysis (PD) catheter with regard to clinical success. Clinical success was defined as an adequate function of the catheter 2 – 4 weeks after insertion.**

♦ ***Methods:*** **All patients with end-stage renal disease who were suitable for PD and gave informed consent were randomized for either open surgery or laparoscopic surgery. A previous laparotomy was not considered an exclusion criterion. Laparoscopic placement had the advantage of pre-peritoneal tunneling, the possibility for adhesiolysis, and placement of the catheter under direct vision. Catheter fixation techniques, omentopexy, or other adjunct procedures were not performed. Other measured parameters were in-hospital morbidity and mortality and post-operative infections.**

♦ ***Results:*** **Between 2010 and 2016, 95 patients were randomized to this study protocol. After exclusion of 5 patients for various reasons, 44 patients received an open procedure and 46 patients a laparoscopic procedure. Gender, age, body mass index (BMI), hypertension, current hemodialysis, severe heart failure, and previous an abdominal operation were not significantly different between the groups. However, in the open surgery group, fewer patients had a previous median laparotomy compared with the laparoscopic group (6 vs 16 patients; $p = 0.027$). There was no statistically significant difference in mean operation time (36 ± 24 vs 38 ± 15 minutes) and hospital stay (2.1 ± 2.7 vs 3.1 ± 7.3 days) between the groups. In the open surgery group 77% of the patients had an adequate functioning catheter 2 – 4 weeks after insertion compared with 70% of patients in the laparoscopic group (p = not significant [NS]). In the open surgery group there was 1 post-operative death (2%) compared with none in the laparoscopic group (p = NS). The morbidity in both groups was low and not significantly different. In the open surgery group, 2 patients had an exit-site infection and 1 patient had a paramedian wound infection. In the laparoscopic group, 1 patient had a transient cardiac event, 1 patient had intraabdominal bleeding requiring reoperation, and 1 patient had fluid leakage that could be managed conservatively. The survival curve demonstrated a good long-term function of PD.**

♦ ***Conclusion:*** **This randomized controlled trial (RCT) comparing open vs laparoscopic placement of PD catheters demonstrates equal clinical success rates between the 2 techniques. Advanced laparoscopic techniques such as catheter fixation techniques and omentopexy might further improve clinical outcome.**

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Received 9 February 2017; accepted 16 October 2017.

Perit Dial Int 2018; 38(2):104–112 epub ahead of print: 31 Jan 2018
https://doi.org/10.3747/pdi.2017.00023

KEY WORDS: RCT; CAPD; peritoneal dialysis; operation; laparoscopic; open surgery; CAPD I trial.

Peritoneal dialysis (PD) was first successfully used in 1959 by Richard Ruben (1). Popovich and Moncrief developed continuous ambulatory PD, which gave a boost to the use of PD (2). Subsequently, the introduction of catheters into the abdominal cavity was modified, and the open procedure, the percutaneous, the peritoneoscopic, and the laparoscopic technique were then introduced (3–5).

These techniques were introduced to have fewer surgical traumas during the placement and/or improve functional outcome. Functional outcome of the catheter is the most relevant outcome parameter for patients. Dialysis exchanges should be relatively short without leakage and without infections. To improve functional outcome, several authors favor the laparoscopic placement over the open procedure and, in non-randomized trials, they could demonstrate a clear advantage of laparoscopically placed catheters (6–8).

In the 3 randomized controlled trials (RCTs) published on open versus laparoscopic placement of the PD catheter thus far, only Tsimoyiannis *et al.* showed an advantage for laparoscopically placed catheters on functional outcome (9). In this trial, the catheter was fixed with a suture into the pelvis. This trial was relatively small and randomized 50 patients. The other 2 trials, with 50 patients and 77 patients included, did not show any benefit on functional outcome (5,10). Catheters in these latter trials were not fixed, nor were any forms of omental fixation techniques performed. Meta-analyses at that time also did not show clear benefit for the laparoscopic procedure on functional outcome (11,12).

Gadallah *et al.* reported an RCT with 148 patients on peritoneoscopic placement versus surgical placement and demonstrated a benefit in functional outcome for the

peritoneoscopic placement (13). Catheters were not fixed nor was the omentum fixed in this trial. Thus far, there is conflicting evidence on which PD catheter placement technique to prefer. The open technique is easier to use, faster, and has only 1 incision. However, a failure rate of up to 33% has been reported with this technique (13). The laparoscopic technique uses more incisions and consumes more operation time but has the advantage of direct visual placement of the catheter and the ability of adhesiolysis if necessary. The laparoscopic technique can also be performed with a fixation technique of the catheter and/or the omentum but this consumes more operation time and is regarded as an advanced laparoscopic technique. In our institution, the laparoscopic technique is preferred because of the possibilities of pre-peritoneal tunneling, performing adhesiolysis when necessary and optimal placement of the catheter in the peritoneal cavity under direct vision. We hypothesized that these additional features of the laparoscopic technique would result in a higher clinical success rate (less mechanical dysfunction) and therefore conducted the present, largest European RCT of open versus laparoscopic placement of a PD catheter.

MATERIALS AND METHODS

PATIENT SELECTION

All consecutive patients with end-stage renal disease who were enrolled for PD treatment were asked to participate in this study at the outpatient clinic. Furthermore, patients who needed a second-time or third-time PD catheter (re-implantations) were asked to participate. Previous abdominal operations, such as hernia repair or bowel resections, were not considered exclusion criteria. Patients were excluded if life expectancy was less than 1 year or if they had a malignant process involving the abdominal cavity. Moreover, patients not willing to participate were excluded, as well as patients needing a combined procedure in the abdominal cavity not related to the PD catheter insertion. Patients could only participate once in this study. Patients received written information about the study at the outpatient clinic and were informed by both surgeon and nephrologist or PD nurse. Informed consent was obtained and signed at least 1 week after the outpatient clinic visit.

RANDOMIZATION

After informed consent was obtained, patients were randomized to the open surgery or laparoscopic surgery arm. Randomization was performed with sealed, opaque envelopes. At the start of the study, 100 envelopes were divided into 2 groups (50 each) and a letter was inserted with the desired procedure, open surgery versus laparoscopic surgery in a 1:1 ratio. Subsequently, envelopes were sealed and put in a closed box and mixed. On the day of the operation a person who was not involved with the surgical procedure drew an envelope from this box. Dressings applied at the end of the operation were the same for both procedures. However, the additional incisions and the different position of the incisions of the laparoscopic procedure meant that, post-operatively, blinding of the procedure for patients, PD nurses, and other staff was not possible.

PROCEDURE DETAILS

All procedures were performed by the first author or Dr. Peppelenbosch, both experienced laparoscopic vascular surgeons who had performed more than 20 laparoscopic PD catheter placement operations before the study commenced.

The desired exit site of the PD catheter was marked pre-operatively by the PD nurse. All patients received 1 g of intravenous cefazolin preoperatively. In all procedures, the catheter used was a 2-cuffed straight pigtail catheter (straight catheter with 2 cuffs and a curled intra-abdominal portion). The catheter was not fixed intra-abdominally with sutures. After sterile exposition, the catheter was placed on the abdomen of the patient, the cuffs were marked on the skin, and the bend of the catheter was also marked. All catheters faced downwards, and at the end of the operation, a functional test was performed by instillation of 1.25 L of 4% icodextrin. Approximately 200 mL was aspirated with a syringe to test the catheter function. The remaining solution was left intra-abdominally in order to minimize the risk of adhesions. Postoperatively, all patients received an X ray to confirm the position of the catheter. The X ray was not used to intervene at that time. The PD catheters were not flushed afterwards and were used after 2 – 4 weeks postoperatively with low volumes (250 mL).

Laparoscopic Technique: The laparoscopic procedure consisted of an open subumbilical introduction of a Hasson trocar. A pneumo-peritoneum of 12 – 14 mmHg was created. Inspection for adhesions was performed and the optimal position for the catheter was determined. The left lower abdominal cavity was the preferred spot. Only in case of adhesions were other spots preferred. If there was no available spot in the lower abdomen, adhesiolysis was performed. A second 7-mm trocar was used which was introduced at the position of the bend of the catheter and vertically tunneled through the rectus sheath and positioned preperitoneally. The trocar was then positioned more horizontally and, from this point, tunneled for several centimeters over the preperitoneal space and finally introduced into the abdominal cavity at the position where the deep cuff should be placed. Patients were placed in the Trendelenburg position before the catheter was introduced through the 7-mm trocar using a stylet. Under direct vision, the catheter was placed at the desired position in the abdominal cavity. The deep cuff was introduced into the abdominal cavity. The 7-mm trocar was then removed and the deep cuff of the catheter was retrieved into the preperitoneal space. The proximal cuff was placed in the subcutaneous layer more than 2 cm from the exit site, which was usually also at the left side of the abdominal wall. Adhesiolysis was not routinely performed.

Only in case of insufficient space in the lower abdomen for a good position of the catheter was adhesiolysis performed. There were no adjunct procedures performed, such as omental fixation or fixation of the catheter.

Open Technique: The open technique consisted of a 3- to 5-cm paramedian incision, predominantly at the left side, at the position where the deep cuff should be placed. No adhesiolysis was performed. The patient was positioned in the Trendelenburg position and the catheter was then placed with a stylet into the abdominal cavity. The distal cuff was fixed between both rectus sheaths in such a way that the catheter passed from the abdominal cavity to the posterior sheath most caudally and from the anterior sheath to the subcutaneous layer most cranially. This ensured fixation of the catheter. The proximal cuff was situated in the subcutaneous layer more than 2 cm from the exit site. The fascia layers were closed with vicryl sutures and the skin with resorbable sutures.

Both operation techniques have been described by our group in more detail previously (14). However, we have made some adjustments in our technique since. For the laparoscopic procedure, we switched to a 30-degree scope instead of a 0-degree scope. Moreover, the introduction of the 7-mm trocar is no longer performed at the exit-site position but on the bend of the catheter to ensure a downward position of the catheter. For the open technique, we currently use a paramedian incision instead of a midline incision.

OUTCOME MEASURES

At 2 – 4 weeks after insertion, the catheters were tested at the outpatient clinic and training of the patients was started. As per protocol, catheters were tested with low volumes (250 mL). Injection of fluid through the catheter and aspiration was first tested. Leakage from the wounds was then monitored. Volumes were increased to normal volumes if there were no leaks and the catheter showed no mechanical problems. This was considered a clinical success and the primary endpoint of this study. In case of leakage, we waited 2 more weeks before PD was started. If PD was then further uneventful, this was still considered as adequate function and scored as clinical success.

A leakage resulting in revision surgery to treat the problem was scored as a poor function.

A malfunction of the catheter, e.g., no fluid injection possible through the catheter or failure to aspirate, related to a malposition was first managed conservatively with laxatives. An X ray was conducted to observe the catheter's tip position. If conservative treatment resulted in an adequate function of the PD catheter, this was considered a clinical success. If conservative treatment did not improve catheter function and more invasive treatment modalities were necessary, this was considered a failure with regard to the primary endpoint of the study.

The first invasive treatment step was radiological repositioning. The interventional radiologist was consulted for repositioning the catheter with different guide wires and stiff wires under fluoroscopy. This technique can be time-consuming and was done in an interventional radiologic suite. If this failed, surgical techniques were used to improve the position and thus enhance function of the catheter, such as omentectomy and fixation of the catheter, as has earlier been described by our group (15).

If an infection of the catheter, tunnel tract, or exit site occurred in the postoperative period, antibiotics were given. If the catheter had an adequate function and PD was continued and the infection was successfully treated with antibiotics, this was considered a clinical success with regard to the primary endpoint.

Catheter infections, exit-site infections or peritonitis resulting in removal of the catheter or discontinuing PD were considered a failure with regard to the primary endpoint. Other primary outcome measures were in-hospital mortality and morbidity and postoperative infections. The latter was arbitrarily defined up to 4 weeks after operation, the latest time-point the catheters were tested at the outpatient clinic.

Secondary outcome parameters consisted of peritonitis, infections of the catheter, the exit site, or the tunnel tract after 4 weeks, removal of the catheters by any cause after 4 weeks, and survival of the catheter.

STATISTICAL ANALYSIS

Patients were treated on an intention-to-treat basis. Continuous variables are expressed as means with standard deviation (SD). Differences were calculated using the Mann-Whitney U test or the chi-squared test when appropriate. Survival analysis was performed using the Kaplan-Meier method. Follow-up periods are expressed as median and range. A p value < 0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 23 (IBM Corporation, Armonk, NY, USA).

POWER ANALYSIS

A power analysis was conducted before the start of this study. The literature on this subject at that time showed a failure rate of 20 – 38% for open surgery (6,9,13,16). For the laparoscopic placement of PD catheters, the failure rate ranged from 0 to 21% (6,9,16). With an alpha set at 0.05 and a beta at 0.20 and a failure rate of open PD catheters of 36% versus 12% for laparoscopic PD catheters, we calculated we needed 46 patients per group (total of 92 patients). To make this study more robust we decided to include 100 patients. At the end of the trial we encountered an inclusion drop mainly related to a change in reimbursement of PD treatment in the Netherlands. Therefore, the trial was ended after the inclusion of 95 patients.

DUTCH TRIAL REGISTER

The local ethics committee approved the abovementioned protocol and this study was recorded in the Dutch trial register (www.trialregister.nl) with number NTR2066. This trial abides by the Declaration of Helsinki.

RESULTS

From March 2010 until March 2016, 111 patients were assessed for eligibility. Sixteen patients were excluded. The main reason for exclusion was refusal to participate (5 patients) and patients who did not meet the inclusion criteria (9 patients). Two patients were excluded for other (logistical) reasons. All excluded patients were treated laparoscopically (Figure 1).

Ninety-five unique patients were randomized in this trial. Forty-six patients were randomized to open PD catheter insertion and 49 patients to laparoscopic PD catheter insertion. All patients received the procedure they were assigned to. There were no cross-over patients from 1 arm to the other. Five patients (2 with an open procedure and 3 with a laparoscopic procedure) violated the protocol because the catheters were not tested after 2 – 4 weeks. One emigrated and was lost to follow-up before the primary endpoint was achieved, 2 received a kidney transplantation before start of PD and 2 were still not on PD although they received the catheter more than 1 year before the end of this study. Since their catheters were not tested and training of the PD catheter with low volumes was not performed, it is unknown whether these catheters were functioning, and the primary outcome could not be established. They were therefore excluded.

Of the 90 remaining patients 44 patients received an open procedure and 46 patients received a laparoscopic procedure. Patient characteristics are listed in Table 1. Patients were predominantly male, and mean age (± SD) was comparable in the 2 groups. In both groups, there was a high incidence of (treated) high blood pressure. Also, the number of patients with diabetes was equal in both groups. The rate of severe heart

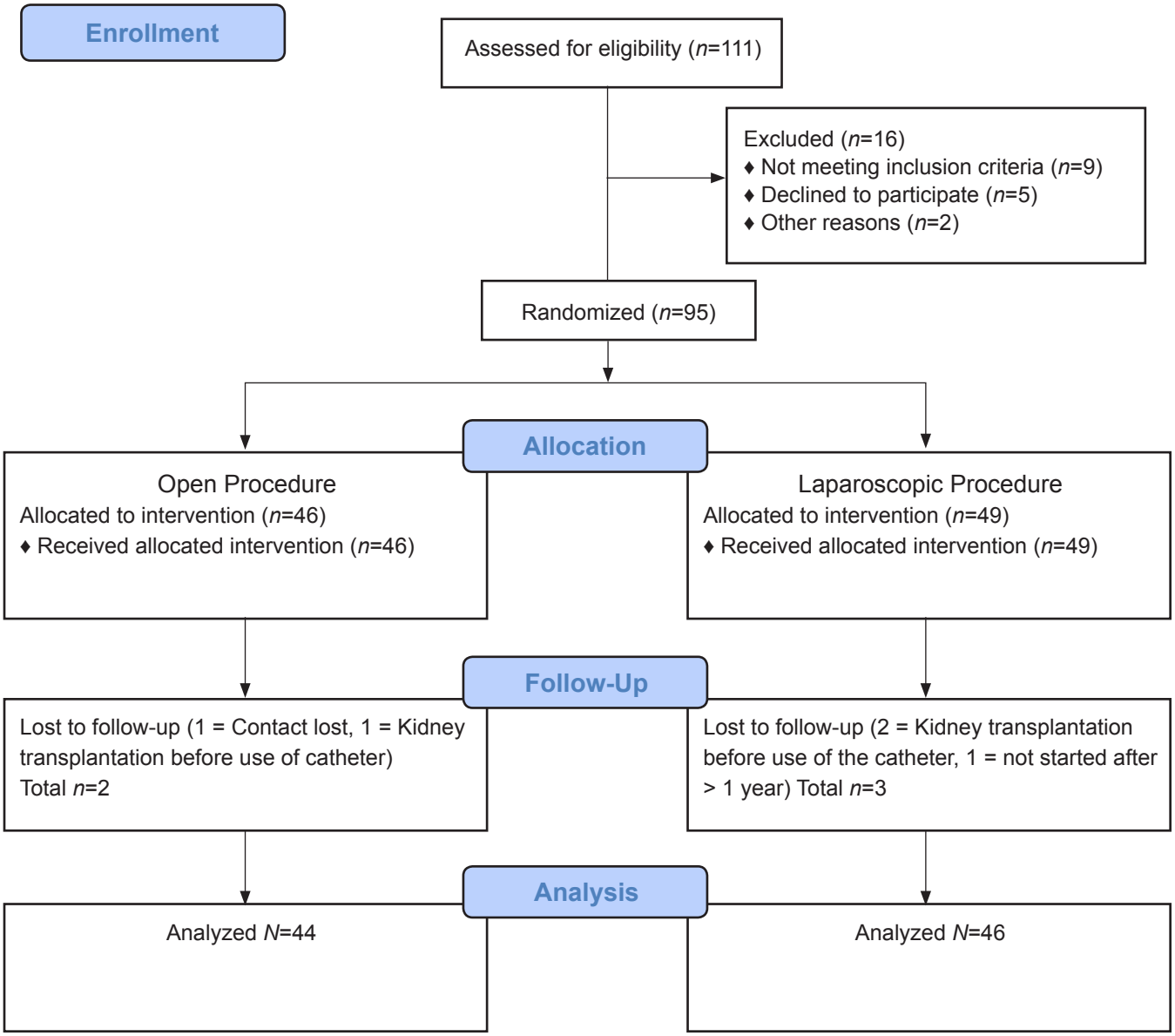


Figure 1 — Flow Diagram CAPD I Trial. CAPD = continuous ambulatory peritoneal dialysis.

failure was not significantly different between the groups. The mean creatinine level was comparable in the 2 groups, as was mean body mass. Previous abdominal operation was not statistically different for both groups with 23 patients (52%) in the open surgery group and 22 patients (48%) in the laparoscopic group. However, when previous abdominal surgery was further analyzed we did find a statistically significant difference between the groups in patients with a previous median laparotomy. In the open surgery group, 6 patients (14%) had had a median laparotomy, while the number was 16 patients (35%) in the laparoscopic group ($p = 0.027$). The number of patients already on hemodialysis before placement of the PD catheter was not significantly different between the groups. The number of patients who received a second or third PD catheter in this study was rather high, with 6 patients (14%) in the open surgery group and 8 patients (17%) in the laparoscopic group. All parameters were statistically not significant except for a median laparotomy in the previous history.

Operative and postoperative details are listed in Table 2. The mean operation time was comparable for the 2 groups. Nine patients received adjunctive procedures (hernia repair or adhesiolysis) during the operation. The mean hospital stay was 2.1 days for the open surgery group versus 3.2 for the laparoscopic group. There were no statistically significant differences for the above-mentioned outcome parameters. There was 1 postoperative death in the open surgery group. This patient was known to have severe heart failure with an ejection fraction of 20% and died 4 days after catheter insertion because of cardiac failure not related to the procedure. Postoperative morbidity was relatively low. In the open surgery group, 3 patients suffered from an infection of the paramedian wound (1 patient) or exit site (2 patients). There were no catheter infections, tunnel tract infections, or postoperative peritonitis. Treatment with antibiotics was sufficient in all 3 patients. In the laparoscopic group, 1 patient had a cardiac event and recovered uneventfully. A second patient had fluid

TABLE 1
Patient Characteristics

		Open surgery group	Laparoscopic group	*P* value
Patients	*N*	44	46	
Male	*N*	24 (55%)	29 (63%)	0.52
Age (years)	Mean±SD	64.5±14.1	62.6±14.1	0.55
Hypertension	*N* (%)	30 (68%)	35 (76%)	0.34
Diabetes	*N* (%)	13 (30%)	13 (28%)	1.0
Heart failure (EF<40%)	*N* (%)	10 (23%)	6 (13%)	0.28
Creatinine (µmol/L)	Mean±SD	469±136.2	551.3±253.6	0.32
Body mass index (kg/m^2)	Mean±SD	26.05±4.65	26.50±5.06	0.72
Previous abdominal surgery	*N* (%)	23 (52%)	22 (48%)	0.83
Previous median laparotomy	*N* (%)	6 (14%)[a]	16 (35%)[a]	0.027
Hemodialysis	*N* (%)	10 (23%)	12 (26%)	0.81
Previous PD catheter	*N* (%)	6 (14%)	8 (17%)	0.77

EF = ejection fraction; PD = peritoneal dialysis.
[a] p=0.027.

TABLE 2
Operative Characteristics and Complications

		Open surgery group	Laparoscopic group	*P* value
Total patients	*N*	44	46	
Operation time (min)	Mean±SD	36.4±24.9	38.3±15.3	0.15
Additional procedures performed	*N* (%)	3 (7%)	6 (13%)	0.57
Adhesiolysis	*N* (%)	—	4 (7%)	0.24
Hernia repair	*N* (%)	3 (7%)	2 (4%)	0.67
Hospital stay (days)	Mean±SD	2.1±2.8	3.2±7.5	0.39
Mortality	*N* (%)	1 (2%)	—	0.49
Morbidity (in-hospital)	*N* (%)	3 (7%)	3 (7%)	1.0
Wound infection		1 (2%)	—	0.49
Exit-site infection		2 (5%)	—	0.24
Bleeding		—	1 (2%)	0.49
Cardiac event (non-fatal)		—	1 (2%)	0.49
Wound leakage		—	1 (2%)	0.49

leakage from the wounds. This was successfully treated by drainage of the intra-operatively instilled fluid. A third patient suffered from an intra-abdominal bleeding, which needed a re-operation and removal of the catheter. This patient started with hemodialysis afterwards.

Table 3 lists clinical success, which was the primary endpoint of this study. We found no statistically significant difference between the 2 groups. An adequate functioning catheter was found in 34 patients (77%) in the open surgery group and in 32 patients (70%) in the laparoscopic group. In terms of previous surgery, in the open surgery group, 76% of patients without any abdominal previous surgery and 78% of those with previous surgery had a functioning catheter vs 63% and 77%, respectively, in the laparoscopic group. In patients with a previous laparotomy, we observed a further decline in the success rate in the open surgery group compared with the laparoscopic group. However, because of the small numbers we could not observe a trend in this difference (3/6 of patients, 50% in the open surgery group versus 11/16 of patients, 69% in the laparoscopic group; $p = 0.62$). As previously described by our group, when revision techniques were used, we could increase the overall rate of adequate functioning catheters up to 90% in both groups (15).

In Table 4, the reasons for catheter failure are listed. In the open surgery group, a total of 10 patients had a non-functioning catheter. Four patients had omentum wrapped around the catheter, 3 others had a malposition of the catheter caught between bowels, 1 patient had failure because of adhesions and another had peritonitis and an infected catheter, which had to be removed (> 6 weeks from the operation). The tenth patient was the patient who died as mentioned earlier. In the laparoscopic group, a total of 14 patients experienced failure of the catheter. Half of these patients suffered from omental wrapping, 3 patients had failure due to malposition of the catheter between the bowels. Other reasons for failure were dialysate leakage to the groin, adhesions, bleeding, and peritonitis not responding to antibiotic treatment (1 patient each).

Of these 10 patients in the open surgery group, 8 underwent revision surgery. In 5 patients, an omentectomy and fixation of the catheter was performed and in 1 patient adhesiolysis and fixation of the catheter. One patient had catheter removal and a new catheter placed laparoscopically in a second procedure. The last patient had just repositioning of the catheter with no fixation. Of these 8 patients, 6 had a good function of the catheter afterwards. Of the 14 patients in the laparoscopic group, 8 patients underwent revision surgery. Here also, 5 patients had an omentectomy and fixation of the catheter. Two patients had just repositioning with fixation of the catheter and 1 patient had catheter removal and a new catheter placed in a second procedure. Thereafter, 6 of these 8 patients had a good functioning catheter.

Univariate analysis did not demonstrate a statistically significant difference between successful outcome and morbidity, mortality, previous PD catheter placement, hemodialysis, or cardiac failure.

Median (range) follow-up time for the open surgery group was 11 months (0–56) and for the laparoscopic group 5 months (0–44). The 1-year catheter survival for the open procedure group was 70% and for the laparoscopic group 60%. Figure 2 shows the survival plot of the open and laparoscopic groups. There was no statistically significant difference between the 2 groups.

DISCUSSION

This RCT demonstrated equal clinical success rates between open and laparoscopic PD catheter insertion. An adequately functioning PD catheter 2 weeks after insertion was found in

TABLE 3
Clinical Success of PD Catheter Insertion

		Open surgery group	Laparoscopic group	*P* value
Total	*N*	44	46	
Functioning catheter	*N* (%)	34 (77%)	32 (70%)	0.48
Needing revision	*N* (%)	10 (23%)	14 (30%)	0.48
Virgin abdomen	*N*	21	24	
Functioning catheter	*N* (%)	16 (76%)	15 (63%)	0.36
Needing revision	*N* (%)	5 (24%)	9 (37%)	0.36
Previous abdominal operation	*N*	23	22	
Functioning catheter	*N* (%)	18 (78%)	17 (77%)	1.0
Needing revision	*N* (%)	5 (22%)	5 (23%)	1.0
Previous median laparotomy	*N*	6	16	
Functioning catheter	*N* (%)	3 (50%)	11 (69%)	0.62
Needing revision	*N* (%)	3 (50%)	5 (31%)	0.62
Previous implantation of PD catheter	*N*	6	8	
Functioning catheter	*N* (%)	5 (83%)	7 (88%)	1.0
Needing revision	*N* (%)	1 (17%)	1 (12%)	1.0

PD = peritoneal dialysis.

TABLE 4
Reasons for Failure of the PD Catheter

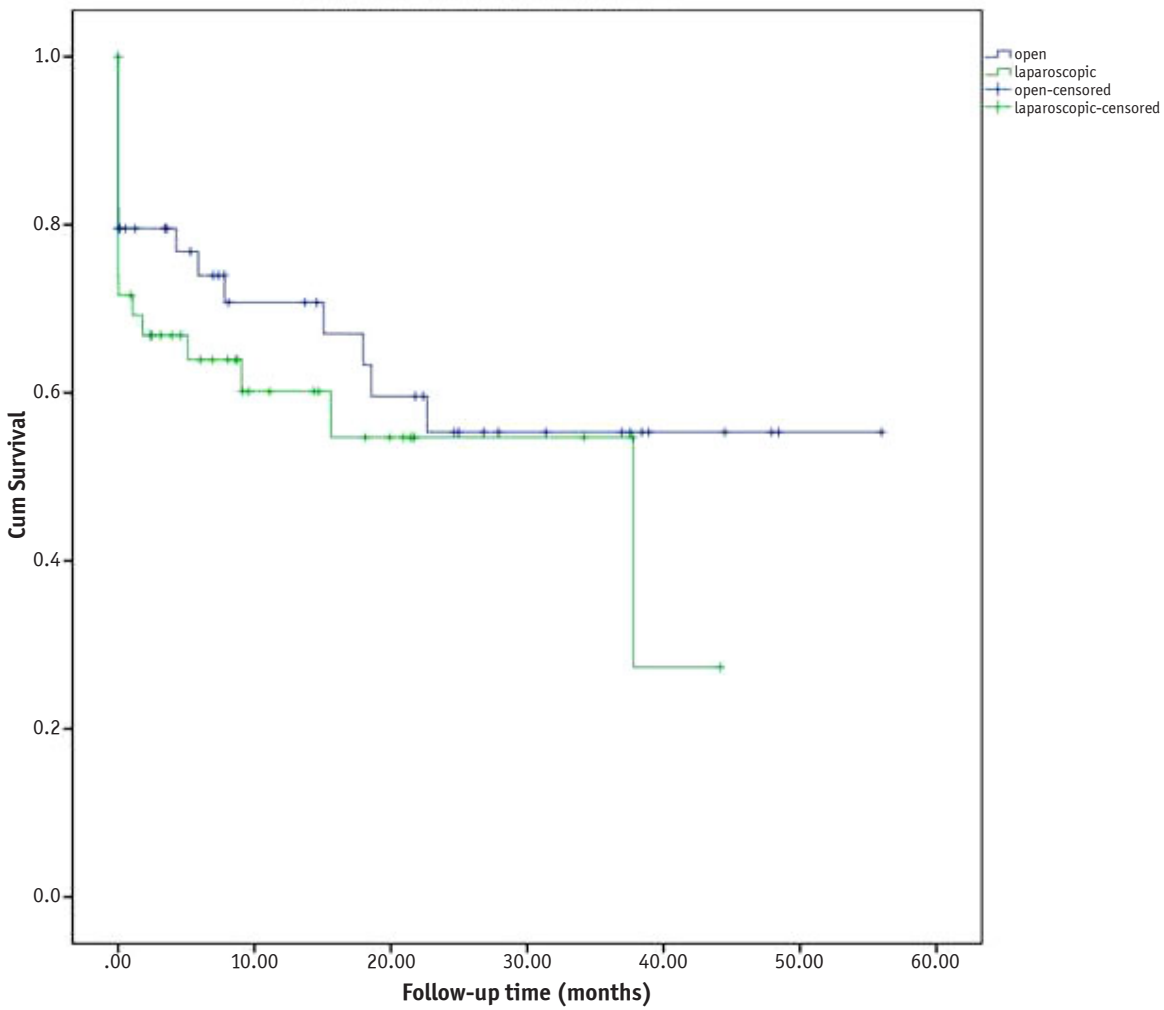
		Open surgery group	Laparoscopic group
Total	*N*	10	14
Omental wrapping	*N*	4	7
Malpositioning of catheter between bowels	*N*	3	3
Adhesions	*N*	1	1
Peritonitis (>6 weeks from operation)	*N*	1	1
Bleeding (and removal of catheter)	*N*	—	1
Dialysate leakage	*N*	—	1
Death	*N*	1	—

PD = peritoneal dialysis.

77% of patients in the open surgery group and 70% of patients in the laparoscopic group in our study. Our study included consecutive patients and "all-comers" without selection and therefore represented a real-world population of PD patients. This is indeed reflected by the advanced age of our patient groups, the inclusion of patients with re-implantations of PD catheters, and the substantial number of patients with a previous abdominal operation.

The results of our open surgery group are in line with the other 3 prospective randomized trials. Failure of the PD catheter occurred in 23% in the open surgery group in our RCT and this figure ranged between 16 – 33% in the other 3 RCTs (5,9,10).

In contrast, the failure rate in our laparoscopic group seems to be higher than in the previously mentioned trials. Although the 30% failure rate in our laparoscopic group is in line with the RCT from Wright *et al.*, where 28% of the patients had a failed catheter, it is much higher than the failure rates of Jwo *et al.* and Tsimoyiannis *et al.*, who had failure rates of 16% and 0%,



Number at risk (N)					
Months	0	10	20	30	40
Open procedure	44	22	17	9	4
Laparoscopic procedure	46	14	8	4	1

Figure 2 — Survival plot of the open and laparoscopic groups.

respectively (5,9,10). However, in the latter trial, an alternative laparoscopic fixation technique was used, which may (partly) explain this difference.

The disappointing results in our laparoscopic group could also be partly due to the baseline patient characteristics in our RCT. Compared with the study of Jwo *et al.* and Wright *et al.*, our patients were older, they had a higher body mass index, and there were more patients with previous abdominal surgery (5,10). Moreover, we had more re-implanted catheters and more patients with previous abdominal surgery than patients in the Tsimoyiannis *et al.* study (9). All the above-mentioned patient characteristics, which provide a realistic reflection of our practice, could have negatively influenced our clinical success rates of PD catheter insertion.

Gadallah *et al.* performed an RCT in which a different technique was used (13). A peritoneoscopic placement technique was compared with open surgical placement of a PD catheter. The advantage of this peritoneoscopic technique is the ability to place the catheter under direct vision at the desired spot. Moreover, a fixation of the catheter in the rectus sheath was performed, directing the catheter downwards into the abdomen. This trial mimics our laparoscopic procedure technique, in which rectus sheath tunneling is changed to pre-peritoneal tunneling. In this trial, the failure rate in the open surgery group was 33%, comparable with our group. In contrast, the peritoneoscopic group had a failure rate of 13%, which is less than the failure rate of 30% in our laparoscopic group. However, patients in the publication of Gadallah *et al.* were younger, and all patients had a PD catheter implanted for the first time. In comparison, 16 % of our patients in the laparoscopic group had had a PD catheter implanted previously. Nevertheless, in the group of patients with a previous PD catheter implantation, we achieved a favorable success rate of more than 80%. This shows that a previous PD catheter should not be a contraindication for PD catheter re-implantation.

There are other reports of laparoscopic PD catheter placement describing excellent results. However, in all these reports, adjunct techniques are used to perform a more advanced laparoscopic placement of the PD catheter. The adjunct procedures described are mostly fixation of the catheter or fixation of the omentum. Crabtree and Fishman published a large series with more than 200 patients who received selective prophylactic omentopexy and selective adhesiolysis resulting in an adequate functioning catheter in over 99% of patients (17). Oğünç *et al.* even reported a 100% success rate using a laparoscopic fixation technique, although they also described a rather high incidence of infections of up to 25% (exit-site and peritonitis combined) (6). Stitches to fix the catheter have been used by other groups, with reported success rates of 94% and 100% (7,9). A report by Ko *et al.* also showed a favorable outcome when a prolene suture was used to fix the catheter at the lower abdominal wall. In their report, only 1 late migration of the catheter occurred (2.6%). Regretfully, there were no details on the patients provided (18).

A report by Krezalek *et al.* describes a change in practice. They retrospectively reviewed their 235 procedures of open PD catheter placement, basic laparoscopic procedures with selective adhesiolysis, and advanced laparoscopic procedures utilizing rectus sheath tunneling with selective adhesiolysis and selective omentopexy. The catheter dysfunction rate was statistically lower for the advanced laparoscopic group, with a failure rate of only 4.4%. This is in contrast with the open repair, which had a failure rate of 32% (19).

A report by Cox *et al.* describes a large database of over 3,000 patients in which a PD catheter was placed. More than 700 patients received an open procedure and over 2,400 patients a laparoscopic procedure. The univariate analysis appeared to show a benefit for the laparoscopic procedure. However, after correcting for confounding variables, both techniques had the same outcome (20).

In the last decade, several meta-analyses have been published on this subject (11,12,21–23). Three of them showed a benefit for the laparoscopic technique and 2 did not. The included studies vary from RCTs to prospective cohort studies and retrospective studies. The difference in favor of laparoscopic procedures is mainly described in the prospective cohort studies and the retrospective studies. What is particular in these studies is that advanced laparoscopic procedures have been described with selective omentopexy, adhesiolysis, colopexy, salpingectomy, and fixation of the catheter.

In an RCT to prevent bowel adhesions, the use of icodextrin demonstrated favorable results (24). For the same reason, we used icodextrin in our study in both the open and laparoscopic group. This could, however, not have improved our results, as this is speculative and has not been subject of any study in PD catheter placement so far.

Our study has several weaknesses, which have to be taken into account. First of all, despite randomization, there was a statistically significant difference in patients with a previous median laparotomy in favor of the laparoscopic group. This could have negatively influenced the clinical success rate in the laparoscopic group and makes the comparison between open and laparoscopic surgery more hazardous. A second reason for the lack of an advantage in our laparoscopic group compared with the open surgery group could be related to the fact that, in both groups, a technique was used to direct the catheter downwards into the abdomen. In the open surgery group, we fixed the catheter in the rectus sheath, and in the laparoscopic group, the catheter was tunneled pre-peritoneally with the same goal. We could therefore argue that the only advantage of laparoscopic placement was adhesiolysis if necessary and the placement of the catheter under direct vision. However, adhesiolysis was only performed in 4 patients, despite a rather high proportion of patients in the laparoscopic group with a previous median laparotomy. A final difficulty of this trial was the relatively long inclusion period challenging the strict following of any protocol.

CONCLUSION

This RCT shows equal clinical success rates regarding functional outcome between an open surgical and “simple”

laparoscopic PD catheter insertion procedure. Advanced laparoscopic PD catheter insertion techniques using catheter fixation or omentopexy are likely to improve functional outcome. To provide solid proof on this subject we initiated CAPD II Trial comparing standard laparoscopy with advanced laparoscopy (starting in 2018).

REFERENCES

1. Blagg CR. The early history of dialysis for chronic renal failure in the United State: a view from Seattle. *Am J Kidney Dis* 2007; 3:482–96.
2. Popovich RP, Moncrief JW, Nolph KD, Ghods AJ, Twardowski ZJ, Pyle WK, *et al*. Continuous ambulatory peritoneal dialysis. *Ann Intern Med* 1978; 88:449–56.
3. Allon M, Soucie JM, Macon EJ. Complications with permanent peritoneal dialysis catheters: experience with 154 percutaneous placed catheters. *Nephron* 1988; 48:8–11.
4. Ash S, Wolf GC, Bloch R. Placement of the Tenckhoff peritoneal dialysis catheter under peritoneoscopic visualization. *Dial Transplant* 1981; 10:383–5.
5. Wright MJ, Bel'eed K, Johnson BF, Eadington DW, Sellars L, Farr MJ. Randomized prospective comparison of laparoscopic and open peritoneal dialysis catheter insertion. *Perit Dial Int* 1999; 19:372–5.
6. Oğünç G, Tuncer M, Oğünç D, Yardimsever M, Ersoy F. Laparoscopic omental fixation technique versus open surgical placement of peritoneal dialysis catheters. *Surg Endosc* 2003; 17:1749–55.
7. Soontrapornchai P, Simapatanapong T. Comparison of open and laparoscopic secure placement of peritoneal dialysis catheters. *Surg Endosc* 2005; 19:137–9.
8. Gajjar AH, Rhoden DH, Kathuria P, Kaul R, Udupa AD, Jennings WC. Peritoneal dialysis catheters: laparoscopic versus traditional placement techniques and outcomes. *Am J Surg* 2007; 194:872–6.
9. Tsimoyiannis EC, Siakas P, Glantzounis G, Toli C, Sferopoulos G, Pappas M, *et al*. Laparoscopic placement of the Tenckhoff catheter for peritoneal dialysis. *Surg Laparosc Endosc Percutan Tech* 2000; 10:218–21.
10. Jwo SC, Chen KS, Lee CC, Chen HY. Prospective randomized study for comparison of open surgery with laparoscopic-assisted placement of Tenckhoff peritoneal dialysis catheter—a single center experience and literature review. *J Surg Res* 2010; 159(1):489–96.
11. Strippoli GF, Tong A, Johnson D, Schena FP, Craig JC. Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients. *Cochrane Database Syst Rev* 2004; (4):CD004680.
12. Xie H, Zhang W, Cheng J and He Q. Laparoscopic versus open catheter placement in peritoneal dialysis patients: a systematic review and meta-analysis. *BMC Nephrol* 2012; 13:69.
13. Gadallah MF, Pervez A, el-Shahawy MA, Sorrells D, Zibari G, McDonald J, *et al*. Peritoneoscopic versus surgical placement of peritoneal dialysis catheters: a prospective randomized study on outcome. *Am J Kidney Dis* 1999; 33(1):118–22.
14. Peppelenbosch AG, van Kuijk WH, Bouvy ND, van der Sande FM, Tordoir JH. Peritoneal dialysis catheter placement technique and complications. *NDT Plus* 2008; 1(Suppl 4):iv23–8.
15. Peppelenbosch AG, van Laanen J, Cornelis T, de Graaf R, Mees B, Tordoir J. Revision techniques for failed PD catheters: outcome in a University Hospital. *J Vasc Access* 2015; 16(Suppl 9):S93–5.
16. Lund L, Jønler M. Peritoneal dialysis catheter placement—is laparoscopy an option? *Int Urol Nephrol* 2007; 39:625–8.
17. Crabtree JH, Fishman A. A laparoscopic method for optimal peritoneal dialysis access. *Am Surg* 2005; 71:135–43.
18. Ko J, Ra W, Bae T, Lee T, Kim HH, Han HS. Two-port laparoscopic placement of a peritoneal dialysis catheter with abdominal wall fixation. *Surg Today* 2009; 39:356–8.
19. Krezalek MA, Bonamici N, Lapin B, Carbray J, Valasco J, Denham W, *et al*. Laparoscopic peritoneal dialysis catheter insertion using rectus sheath tunnel and selective omentopexy significantly reduces catheter dysfunction and increases peritoneal dialysis longevity. *Surgery* 2016; 160:924–35.
20. Cox TC, Blair LJ, Huntington CR, Prasad T, Kercher KW, Heniford BT, *et al*. Laparoscopic versus open peritoneal dialysis catheter placement. *Surg Endosc* 2016; 30:899–905.
21. Hagen SM, Lafranca JA, Steyerberg EW, IJzermans JN, Dor FJ. Laparoscopic versus open peritoneal dialysis catheter insertion: a meta-analysis. *PLOS One* 2013; 8(2):e56351.
22. Chen Y, Shao Y, Xu J. The survival and complication rates of laparoscopic versus open catheter placement in peritoneal dialysis patients: a meta-analysis. *Surg Laparosc Endosc Percutan Tech* 2015; 25:440–3.
23. Qiao Q, Zhou L, Hu K, Xu D, Li L, Lu G. Laparoscopic versus traditional peritoneal dialysis catheter insertion: a meta-analysis. *Ren Fail* 2016; 38:838–48.
24. Catena F, Ansaloni L, Di Saverio S, Pinna AD; World Society of Emergency Surgery. P.O.P.A. study: prevention of postoperative abdominal adhesions by icodextrin 4% solution after laparotomy for adhesive small bowel obstruction. A prospective randomized controlled trial. *J Gastrointest Surg* 2012; 16:382–8.