

The placement of peritoneal dialysis catheters: a prospective randomized comparison of open surgery versus “Mini-Perc” technique

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Abstract

Purpose Currently, most ESRD patients are treated with open surgical technique or with laparoscopic technique. In this study, we examined the role of the ureteroscopy-assisted “Mini-Perc” technique versus the modified open surgery in the treatment of ESRD in a prospective randomized manner.

Methods A total of 72 patients with chronic renal failure were prospectively randomized for the ureteroscopy-assisted “Mini-Perc” technique or modified open surgery. Intraoperative and postoperative morbidity, incision size, dose of local anesthesia, operative time, hospital stay, and initial catheter survival and follow-up were compared for both methods.

Results “Mini-Perc” group was associated with shorter incision size, operative time, and hospital stay, with lower dose of local anesthesia and incidence of bloody ascites. Two of five patients with the history of abdominal surgery in “Mini-Perc” group required adhesiolysis under direct vision of telescope. All adhesions were easily dissected. All complications of leakage (8.1 %) and incisional hernia (2.7 %) occurred in the open surgery group, but a difference of no significant value with “Mini-Perc” group

($p = 0.2400$, $p = 1.0000$). There was no any other significant difference in common complications between two groups. After 2 years of follow-up, 54 patients (75 %) survived with their initial PD catheter. The overall death was 5 (6.9 %).

Conclusions Compared to modified open surgical technique, the ureteroscopy-assisted “Mini-Perc” technique can be used to achieve the same clinical efficacy for placement of peritoneal dialysis catheters in ESRD patients, and it carries minimal morbidity.

Keywords Mini-Perc · Open surgery · Peritoneal dialysis · Catheter

Introduction

Continuous ambulatory peritoneal dialysis (CAPD) is a widely accepted method of treatment for patients with ESRD. An estimated 120,000 patients worldwide are using peritoneal dialysis for renal replacement therapy [1]. Compared to hemodialysis, the main advantages of CAPD for patients are an improved mobility and less dietary restrictions. Catheter malfunction, commonly seen in peritoneal dialysis, is a major cause for PD technique failure. Ever since the first permanent silicone catheter was introduced in the 1970s, a wide variety of catheters and placement techniques have been developed to attempt to eliminate catheter malfunction [2–6]. Today, debate about the ideal catheter and the optimal technique for catheter placement is still ongoing [5, 7–15].

Since laparoscopic technique was introduced and used for the placement of catheters in the early nineties of the last century [16–19], laparoscopic technique has proven to be superior to the open techniques in many medical centers,

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by reducing morbidity, length of hospital stay, and postoperative pain [20–22]. Currently, most ESRD patients are treated with open surgical technique or with laparoscopic technique. The main advantage of laparoscopic peritoneal dialysis catheter insertion, compared to the conventional open surgery, is the ability to insert the catheter under direct vision [23]. Several laparoscopic techniques have been described, most of them using 2–4 ports [17–19]. However, each port entry creates a weak abdominal site where a hernia or leaking could occur later [24]. Basically, those procedures require general anesthesia and special equipments. In the literature, up to 35 % catheter failure has been described when using the open technique and only 13 % for the laparoscopic technique [17, 25–27].

We have used various catheters and surgical methods for catheter placement since a PD program was established in our department in 1997. Previously, we have reported a new ureteroscopy-assisted “Mini-Perc” technique with a 16-Fr Peel-Away sheath in placing peritoneal dialysis catheters under local anesthesia [28]. And also, we have developed a new open surgery method for implanting a straight Tenckhoff catheter [29]. In this study, we examined the role of the ureteroscopy-assisted “Mini-Perc” technique versus the modified open surgery in the treatment of ESRD in a prospective randomized manner.

Materials and methods

Patients and inclusion criteria

Between March 2010 and March 2013, 72 patients with chronic renal failure were treated at our center. All patients gave their informed consent, and the ethics committee in our university approved the study protocol. A total of 72 patients were randomly treated with “Mini-Perc” technique [35] or open surgery [36]. Randomization was done on the day of intervention using the closed envelope method. The inclusion criteria of patients are: (1) diagnosed with chronic kidney disease 5 (CKD5), age <70 years old, (2) no history of abdominal trauma or surgery (open group), while patients with history of appendectomy, nephrectomy, cholecystectomy, and cesarean section can be included in “Mini-Perc” group, (3) no history of serious lung and chest disease, (4) with body mass index (BMI) <25, (5) without serious abnormalities of coagulation tests, (6) no tumor, psychosis, drug addiction, alcoholism, and other special status, and (7) can live independently.

“Mini-perc” technique procedure

One surgeon (YAN X) with an interest in mini-percutaneous surgery performed all operations. Patients were placed

in a supine position. The Peritoneal Catheter Kit (Quinton Instrument Company, Seattle, Washington, USA) was used for catheter placement. All patients were eligible to receive local infiltration anesthesia with 20 % lidocaine hydrochloride. Our patients were administered 40 mg Parecoxib (COX-2 selective inhibitor, Pfizer) half an hour before operating.

A 15-mm incision was made 2 cm left of and 3 cm inferior to the umbilicus. Blunt dissect the subcutaneous fat and incise the rectus sheath (8 mm), and insert the aeroperitonea needle from this incision, and it is this needle that acts as a port. The subcutaneous pocket was used for placing the deep cuff. This port serves for the pneumoperitoneum installation and the introduction of the camera system. We insufflate about 1 l filtered air with disposable syringe (50 ml) to achieve an undersaturation pneumoperitoneum. A guide wire is introduced through the aeroperitonea needle (Richard-Wolf, Knittlingen, Germany), and the needle is removed.

A 16-Fr Peel-Away sheath with a dilator (Cook, Bloomington, IL) was passed over the guide wire in a caudal direction (at a 45° angle) into the peritoneal cavity, and the guide wire is then removed. The dilator was removed, and a 9.8-Fr rigid ureteroscope (Karl Storz, Tuttlingen, Germany) was advanced through the sheath into the true pelvis. The Peel-Away sheath was subsequently introduced into the true pelvis with rotating motion along the rigid ureteroscope. Removed the camera system, meanwhile, the Peel-Away sheath should stay at a stable position. The Swan-neck catheter was passed through the Peel-Away sheath over a stylet into the true pelvis. The distance between the rectus sheath and the entrance of Peel-Away sheath is measured using a sterile ruler. The catheter is then withdrawn from the Peel-Away sheath, and the intra-abdominal segment is trimmed and shortened to a length that is about 3 cm longer than the measured distance between the rectus sheath and the out hole of Peel-Away sheath. With the aid of the stylet, the trimmed catheter is then placed back into the pouch of Douglas.

The inner cuff was placed into the rectus sheath, and the stylet was then removed. To make sure there was no kinking, patency was checked by small amounts of peritoneal fluid flushed through the catheter’s lumen (in–out test). With the aid of the tunneling stylet of the catheter kit, a subcutaneous tunnel is created in a latero-caudal direction, taking care to leave the outer cuff at a distance of 2–3 cm from the exit site. In the end, the incision was sutured.

Open technique procedure

Open surgery was performed by Zhu and Jiang. Traditional open surgery procedure has been described elsewhere [30]. In our center, we developed a new open surgery method for

implanting a straight Tenckhoff catheter [29]. The major differences between the new technique and conventional open surgery are that

- The main incision site is set in the paramedial area 7 cm above the pubic symphysis and 2–2.5 cm lateral to the midline.
- The length of the intra-abdominal portion of the catheter is set during operation based on a real-time measurement of the distance from the opening in the peritoneum to the pouch of Douglas. Briefly, after a purse-string suture is placed in the peritoneum, the catheter, with metal stylet, is inserted into the pouch of Douglas. The distance between the peritoneal opening and the inner cuff is measured using a sterile ruler. The catheter is then withdrawn from the abdominal cavity, and the intra-abdominal segment is trimmed and shortened to a length that is about 1 cm longer than the measured distance between the peritoneal opening and the inner cuff. With the aid of the stylet, the trimmed catheter is then placed back into the pouch of Douglas.
- An additional 1-cm transverse skin incision, which serves as a “jump site,” is made at a point 6 cm just above the upper margin of the main incision. The catheter is then pulled through the “jump site” to create a long, straight, upward subcutaneous tunnel, with the outer cuff staying in the tunnel.
- A curved subcutaneous tunnel is made for the exit site by using a tunneler in a lateral downward direction, resulting in a 5–6-cm uncuffed catheter segment within the subcutaneous tunnel.

Evaluation at follow-up

Postoperative treatment and follow-up

All patients were hospitalized with wound dressing every other day to keep the incision dry and clean. Patients after discharge should come back for wound dressing at least once in every 2 days within 2 weeks. The wound should be kept dry and clean. Before discharge from hospital, all patients received training in operating the dialysis catheter themselves. After discharge, professional nurses 24 h online to provide the instruction of dialysis procedure. The patient's PD program was usually commenced on the second day after catheter placement, with the patient in a supine position during the 1 week after surgery. Low volume (1,000 ml each time) exchange of 1.5 or 2.5 % Baxter's dialysis fluid glucose lactate with double-pipe system was practiced for 7 days prior to the initiation of regular dialysis (2,000 ml each time). Prophylactic antibiotics, usually a cephalosporin, were administered prior to the procedure.

Follow up monthly for at least 1 year. The outcome measures are success rate of procedure, intra-operative anesthetic dose, the average operation time, the bleeding and blood transfusion rate, the number of cases of postoperative catheter migration, catheter blockage, fluid leaking, infections of exit site or tunnel, and loss of function.

Statistical analysis

Data were processed using SPSS-10 for Windows (SPSS, Inc., Chicago, Illinois). Statistical analysis of the means of continuous variables was performed with the unpaired Student's *t* test. Analysis of the significance of categorical variables was performed using the Chi-square test with differences resulting in $p < 0.05$ considered statistically significant.

Results

Both groups were comparable regarding age, sex, serum creatinine, body mass index, history of surgery, and primary disease. Detailed demographic and clinical data are described in Table 1. The study included 46 men and 26 women, with an average age of 55.3 ± 15.4 years. No significant differences were found between two groups, except that five patients with history of abdominal surgery were included in “Mini-Perc” group. Of the 72 patients, 32 had primary glomerulonephritis, 18 had diabetic nephropathy, 13 had hypertensive arteriosclerosis, and nine had other diseases.

Table 1 Preoperative characteristics of both treatment groups

Patient characteristics	“Mini-Perc”	Open	<i>p</i> value
Patients (<i>n</i>)	35	37	
Mean pts age \pm SD	54.3 \pm 16.2	56.8 \pm 14.7	0.4947
Sex (<i>n</i> male/female)	21/14	25/12	0.5040
Mean μ mol/l serum creatinine \pm SD	1,225 \pm 186	1,180 \pm 221	0.3545
No. pts with history of surgery	5	0	0.0232
Appendectomy	2		
Cesarean section	1		
Nephrectomy	1		
Cholecystectomy	1		
Body mass index (kg/m ²)	23.2 \pm 3.8	22.7 \pm 4.3	0.6036
Primary disease (<i>n</i>)			0.9313
Glomerulonephritis	15	17	
Diabetic nephropathy	8	10	
Hypertension	7	6	
Other causes	5	4	

The mean incision size of “Mini-Perc” was obviously shorter than total size of open surgery (1.6 vs 4 cm, $p < 0.0001$). The mean operative time of the “Mini-Perc” group (43.3 ± 15.6 min) was significantly lower than that of the open surgery group (86.4 ± 16.8 min, $p < 0.0001$). Local anesthesia was tolerated well by all patients. The mean total dose of local anesthesia in “Mini-Perc” group (12.2 ± 8.5 ml) was lower than in open surgery group (18.5 ± 10.4 ml, $p = 0.0065$). Five patients (14.3 %) had the history of abdominal surgery in “Mini-Perc” group. Patients with history of abdominal surgery were excluded from open surgery group. Only two of five patients required adhesiolysis under direct vision of telescope. The extent of adhesion was mild in two cases. All adhesions were easily dissected with a pair of grab scissors or holmium laser fiber inserted through the working channel of the ureteroscope. Mean hospital stay was significantly shorter in “Mini-Perc” group (2.6 ± 1.6 vs 4.2 ± 2.4 days, $p = 0.0015$).

There was no bleeding-related blood transfusion case in “Mini-Perc” group while two blood transfusion cases (5.4 %) in open surgery group. Slight bloody ascites presented in one patient (2.9 %) lasted for an average of 17 h (range 10–25 h) without significant decline in hemoglobin. The incidence of bloody ascites in open surgery group (21.6 %) was higher than in “Mini-Perc” group ($p = 0.0284$). One significant bleeding occurred in open surgery group with the rapid decreasing of hemoglobin. The patients underwent exploratory surgery of the abdomen. The catheter was replaced after the active bleeding was controlled.

After at least 1 year of follow-up, 54 patients (75 %) survived with their initial PD catheter. The overall death was 5 (6.9 %). There were 23 episodes of peritonitis, for an overall rate of 0.012 episodes per patient–month. Episodes of exit-site infection numbered seven for a rate of 0.003 episodes per patient–month. Catheter malfunction was the most important mechanical complication, seen in 4 (5.6 %) patients. There were also 3 (4.2 %) cases of leakage, 5 (6.9 %) cases of inflow or outflow pain, 2 (2.7 %) cases of catheter migration, 1 (1.4 %) case of catheter blockage, and 1 (1.4 %) case of incisional hernia. All complications of leakage (8.1 %) and incisional hernia (2.7 %) occurred in the open surgery group, but a difference of no significant value with “Mini-Perc” group ($p = 0.2400$, $p = 1.0000$). There was no any other significant difference in common complications between two groups. The comparison of data between two groups is shown in Table 2.

Discussion

Traditional open surgery for placement of peritoneal dialysis catheters had many disadvantages especially in those obese patients. Open surgery costs a longer operation time,

Table 2 Complications and clinical outcomes by two groups

Variable	“Mini-Perc”	Open	<i>p</i> value
Patients (<i>n</i>)	35	37	
Incision size (cm)	1.6 ± 0.3	4.0 ± 1.2	<0.0001
Operative time (min)	43.3 ± 15.6	86.4 ± 16.8	<0.0001
Dose of local anesthesia(ml)	12.2 ± 8.5	18.5 ± 10.4	0.0065
Hospital stay (days)	2.6 ± 1.6	4.2 ± 2.4	0.0015
Blood transfusion [<i>n</i> (%)]	0	2 (5.4)	0.4933
Bloody ascites [<i>n</i> (%)]	1 (2.9)	8 (21.6)	0.0284
Catheter blockage [<i>n</i> (%)]	1 (2.9)	0	0.4861
Fluid leaking [<i>n</i> (%)]	0	3 (8.1)	0.2400
Catheter migration [<i>n</i> (%)]	1 (2.9)	1 (2.7)	1.0000
Incisional hernia [<i>n</i> (%)]	0	1 (2.7)	1.0000
Inflow or outflow pain [<i>n</i> (%)]	2 (5.7)	3 (8.1)	1.0000
Peritonitis			
Episodes (<i>n</i>)	10	13	
Episodes/patient–month (%)	1.1	1.4	0.5551
Exit-site infection			
Episodes (<i>n</i>)	2	5	
Episodes/patient–month (%)	0.2	0.5	0.4523
Catheter malfunction [<i>n</i> (%)]	2 (5.7)	2 (5.4)	1.0000
Overall deaths [<i>n</i> (%)]	2 (5.7)	3 (8.1)	1.0000
Initial catheter survival [<i>n</i> (%)]	26 (74.3)	28 (75.7)	0.9017

more bleeding, too much pain, relatively inaccurate catheter position, and a larger trauma. The most common complications of CAPD catheter insertion are infection and leakage at the insertion site. Hemorrhage, visceral organ perforation, and incisional hernia are rare complications but most commonly occur in patients who have undergone previous abdominal surgery and have had recurrent peritonitis [31]. The rate of catheter malfunction with open surgery can be as high as 19.4 % [23, 32, 33]. The main cause of catheter malfunction was catheter migration. Catheter tip migration is a serious complication associated with the open surgical insertion technique. It was reported that the incidence of catheter tip migration was range between 16 and 54 % after the open surgical [34].

Laparoscopic-assisted techniques have been described by many centers, with early reports highlighting the potential for laparoscopic placement to reduce the morbidity associated with open surgical placement [35]. The most evident advantage of laparoscopic technique is putting the dialysis catheters into the true pelvis under direct vision. The disadvantages of those procedures are that it requires general anesthesia and special equipments. There are also studies showed that laparoscopy was more time-consuming without better catheter outcomes [27]. An explanation is that each port creates a site where a hernia or leaking could develop, and herniation often occurs through port sites larger than 10 mm in most procedures.

In our center, we have established a new modified open surgery technique for straight Tenckhoff catheter placement that effectively reduced catheter malfunction during 2 years of follow-up. Recently, we have described another new ureteroscopy-assisted “Mini-Perc” technique with a 16-Fr Peel-Away sheath for insertion of peritoneal dialysis catheters [28]. The preliminary study showed that the “Mini-Perc” technique with a 16-Fr Peel-Away sheath for insertion of peritoneal dialysis catheters under direct visualization probably presents a lower rate of organ damage, catheter migration, bleeding, and dialysate leakage. Especially, some cases with mild to moderate adhesions can be easily dissected with a pair of grab scissors or laser fiber inserted through the working channel of the ureteroscope. Although a comparison of open surgery versus laparoscopic-assisted techniques has been reported in the literature [20, 22, 26], there are relatively few studies that compare two new modified techniques in a prospective randomized manner in one center.

Like other comparative study, our data showed that open surgery costs a longer operation time, larger incision, more bleeding, too much pain, and longer hospital stay. In this study, using the ureteroscopy-assisted “Mini-Perc” technique and a modified open surgical technique, we found that only 2 of 72 patients experienced catheter migration during at least 1 year of follow-up. In regard to the rate of migration, the “Mini-Perc” technique did not show any superiority. The associated rate of migration in this project was significantly lower than those of conventional open surgery reported by some medical center include ours [34]. Our result of the 2.7 % catheter migration with “Mini-Perc” technique suggests that the placing of the catheter tip deep into the pelvis under direct vision and minimizing the interference of the abdominal omentum might prevent catheter migration.

Our study proved that the most prominent advantage of “Mini-Perc” technique, compared to the conventional open technique, was the ability to insert the catheter under direct vision. Direct visual feedback during placement led to better positioning at the end of the operation with a lower rate of organ damage and bleeding [24–27]. In the present study, no bleeding-related blood transfusion was observed in “Mini-Perc” group, and the risk of bleeding in “Mini-Perc” group was lower than in open surgery group. And more important, some cases with mild to moderate adhesions can be easily dissected with a pair of grab scissors or laser fiber inserted through the working channel of the ureteroscope. Generally, patients with history of abdominal surgery were not suitable for placing catheter with open technique. In fact, we found that only two of five patients required adhesiolysis under direct vision of telescope.

Another common complication is dialysate fluid leakage with a reported incidence between 2.6 and 22 % [36], which

is not only associated with open surgery, but also with the conventional laparoscopic procedure. We did not have any cases of dialysate fluid leakage in “Mini-Perc” group, but have three cases in open surgery group (8.1 %). It was another prominent advantage of “Mini-Perc” technique. 16-Fr Peel-Away sheath fits the Swan-neck catheter very well, which could minimize the risk of potential abdominal wall hematoma or hemorrhage, incisional hernia formation, and postoperative leakage. In fact, we have never had any cases of incisional hernia too in “Mini-Perc” group.

Generally, the conventional laparoscopic procedure has to be done under general anesthesia. It is important that some patients with high risk factors for performing general anesthesia could also underwent the ureteroscopy-assisted “Mini-Perc” technique under local anesthesia. In this study, we accomplished insertion of peritoneal dialysis catheters under local anesthesia not only in open surgery group but also in “Mini-Perc” group. Patients were administered 40 mg Parecoxib half an hour before operating. Our experiences show that local anesthesia was tolerated well by the overwhelming majority of patients. Postoperative pain was mild, and analgesics were not used.

Conclusions

Although more convincing conclusions might be supported by further studies with larger sample numbers, performing peritoneal dialysis catheter insertion with “Mini-Perc” technique appeared to be less invasive than the open surgical procedure for the patients. In our opinion, compared to modified open surgical technique, the ureteroscopy-assisted “Mini-Perc” technique can be used to achieve the same clinical efficacy for placement of peritoneal dialysis catheters in ESRD patients, and it carries minimal morbidity.

Conflict of interest The authors have no financial conflicts of interest to declare.

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