

RANDOMIZED PROSPECTIVE COMPARISON OF LAPAROSCOPIC AND OPEN PERITONEAL DIALYSIS CATHETER INSERTION

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◆ **Objective:** To compare laparoscopic and conventional peritoneal dialysis catheter insertion with respect to post operative discomfort, complication rates, and catheter survival.

◆ **Design:** Randomized prospective study.

◆ **Setting:** Tertiary referral renal unit.

◆ **Patients:** Fifty patients commencing peritoneal dialysis.

◆ **Intervention:** Catheters were implanted laparoscopically or by a conventional surgical technique.

◆ **Main Outcome Measures:** The duration of surgery, hospital stay, pain scores, and analgesic requirements were recorded. Complications (early/late) and catheter survival were compared.

◆ **Results:** The conventional procedure was faster than the laparoscopic (14.3 vs 21.9 minutes, $p < 0.0001$). There was no difference in any other parameter assessed.

◆ **Conclusions:** The data suggest that the insertion techniques are equivalent, and that laparoscopic insertion does not reduce early complication rates.

KEY WORDS: Laparoscopy; catheter insertion techniques.

Peritoneal dialysis (PD) has been an effective method for treating end-stage renal failure over the past 20 years. Despite this, complications related to the peritoneal catheter such as exit-site infection, pain, or mechanical dysfunction causing failure of fluid drainage remain troublesome. It has been suggested that a laparoscopic insertion technique may reduce the incidence of these complications (1-3). Laparoscopic insertion allows a smaller abdominal incision and direct visualization of the location of the catheter tip. Previous comparisons have been retrospective (4), not randomized (5), or lacking in detail. We hypothesized that the smaller incision of the laparoscopic method may cause less discomfort and/or a lower incidence of early complications.

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Received 28 January 1999; accepted 12 May 1999.

SUBJECTS AND METHODS

The local ethics committee approved the study and informed consent was obtained from all patients. Fifty patients starting PD were randomized to either conventional (CI) or laparoscopic (LI) insertion. All were considered fit enough for general anesthesia. Because catheter survival is better after insertion by an experienced surgeon (6), one consultant (BJ) with an interest in access surgery performed all operations.

Randomization was by sealed envelopes containing cards with "laparoscopic" or "conventional" written on them. These cards were stored in the theater anesthetic room and one envelope opened after each patient was anesthetized, thus blinding the patient to the procedure performed.

The single-cuffed Quinton Curlcath (Quinton Instruments, Bothell, WA, U.S.A.) was used for all patients. All procedures were performed under general anesthetic in the operating theater. All patients received 2 g of vancomycin intravenously prior to surgery as prophylaxis. The conventional technique employed a single midline infraumbilical incision 4 - 6 cm in length. The catheter was passed through this incision on a straight introducer into the well of the pelvis. The tube was secured with a purse-string suture of 20 Vicryl (Ethicon, Edinburgh, U.K.) in the parietal peritoneum, which tethered the Dacron cuff of the tube in the extraperitoneal plane. The linea alba was closed snugly around the tube with a 1 polydioxanone suture; the catheter was then tunneled to an exit site in the iliac fossa and the wound closed with subcuticular 30 Monocryl (Ethicon).

The laparoscopic technique employed a 1.5-cm infraumbilical incision through which a Veress needle was introduced and a 3-L carbon dioxide pneumoperitoneum created. The Veress needle was then replaced with a 10-mm port and a preliminary laparoscopy was performed to look for adhesions or other anatomical abnormalities that could hinder flow. A 2.5- to 3-cm

midline incision was made midway between the umbilicus and pubis, and a disposable trochar and peel-apart plastic sheath were introduced into the peritoneum under direct vision. The Curlcath was passed through the sheath and the tip guided into position in the well of the pelvis under direct vision through the laparoscope. The catheter was secured and the midline wound closed as for the conventional operation. The laparoscope was then removed and the pneumoperitoneum evacuated before closing the umbilical port wound with 1 polydioxanone suture to the linea alba and subcuticular 30 Monocryl (Ethicon).

After the operation, dressings were applied to the same positions for all patients in order to blind the ward staff to the technique used. The duration of the operation from first incision to completed skin closure was documented. On return to the ward, all analgesics administered were noted and the patients rated their discomfort using a visual analogue scale (7) at 6-hour intervals. The duration of the hospital stay was noted. On return from theater, all catheters were cleared with four 500-mL flushes of PD fluid and capped for a period of 2 weeks before PD training began.

Complications were divided into "early" (up to 6 weeks after the operation date) and "late" (more than 6 weeks post operation).

STATISTICS

All values are quoted as mean \pm SD (standard deviation) unless otherwise stated. Normally distributed data were compared using *t*-tests; non-Gaussian data with the Mann-Whitney U-test. Complication rates were compared using the chi-square test with Yate's correction. Catheter survival figures were compiled using data from a median of 18.5 (range 7 - 26) months of follow-up. Survival analysis used the Kaplan-Meier technique with tube "losses" following death or successful transplantation censored.

RESULTS

Four laparoscopic procedures required conversion to the conventional method in theater (three because of technical difficulties in creating a pneumoperitoneum and one because the patient was too obese for the laparoscope to reach his peritoneal cavity). One patient undergoing the conventional procedure suffered a fractured neck of femur 2 days after the operation. This led to a protracted hospital stay and hemodialysis. These five cases were excluded from further analysis, leaving 21 patients in LI and 24 in CI.

Demographic data (Table 1) show no difference in age, sex, body mass index, or previous abdominal sur-

gery. The duration of the operation was significantly shorter for CI (14.3 ± 3.3 minutes) than LI (21.8 ± 2.9 minutes, $p < 0.0001$). The duration of hospital stay, pain scores, and analgesic requirements were not different, although CI tended to have higher pain scores than LI after the first 6 hours (Figure 1).

Table 2 shows that there was no difference in early or late complication rates for the two groups. Peritonitis recurring within 1 month with the same organism was considered a relapse rather than a new episode. Peritonitis rates were 1 per 19 patient-months for LI and 1 per 17 patient-months for CI. Exit-site infection was associated with peritonitis in several patients. Eight patients (4 LI, 4 CI) had more than one episode of peritonitis. Catheters were removed for relapsing or resistant peritonitis in 9 patients (3 LI, 6 CI), reflecting our policy of early tube removal in this situation. Eleven patients in LI and 13 in CI remained free of catheter-related infection throughout follow-up. Only two exit-site leaks occurred, both in LI. They were not associated with exit-site infection and resolved spontaneously with delay in the start of PD.

Half of the tubes (12 LI, 13 CI) were still in use at last follow-up, the remainder having been removed because of successful transplantation (1 LI, 2 CI), death (4 LI, 3 CI), or treatment failure (1 LI: resistant fluid overload).

Figure 2 shows catheter survival for each group. All of the catheters were used to commence PD successfully. The earliest catheter removal was performed for pseudomonas peritonitis 1 month after starting dialysis. Patient death, ultrafiltration failure, and peritonitis caused the other catheter losses within 6 months of insertion. Of those patients experiencing early infection, only two (1 CI, 1 LI) ultimately lost their tubes because of peritonitis, both with different organisms than their original cultures and more than 10 months into treatment.

DISCUSSION

Our results suggest that the laparoscopic insertion technique is not superior to the conventional method. Previous studies have used the peritoneoscopic Y-Tec insertion system (3) which differs from our technique in that the laparoscope is passed through the insertion sheath and used to guide the end of this sheath into the pelvis. The pelvis can still be examined, but adhesions cannot be divided and the catheter tip is not directly observed during insertion. Previous studies suggest a low number of early complications with this system (3,4). The number of complications in our CI group was considerably lower than that reported in earlier series (6,8). These high complication rates originally provoked the development of the peritoneo-

TABLE 1
Demographic Details of Patients Enrolled in the Study (Mean ±SD)

	Age	Sex M:F	BMI (kg/m ²)	Previous surgery	Duration of operation (minutes) ^a	Duration of hospitalization (days)
Conventional (n=24)	49.3±20.2	15:9	25.3±3.5	5	14.3±3.3	2.4±0.8
Laparoscopic (n=21)	46.4±14.8	14:7	27.7±7.9	11	21.8±2.9	3.1±1.9

BMI = body mass index.

^a *p* < 0.0001.

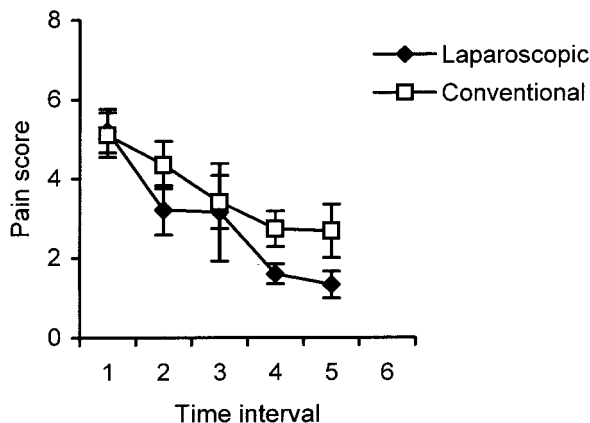


Figure 1 — Pain scores at 6-hourly intervals for patients in each group. The error bars represent SEM. The lines are not significantly different, but the laparoscopic group tended to have less pain after 18 hours.

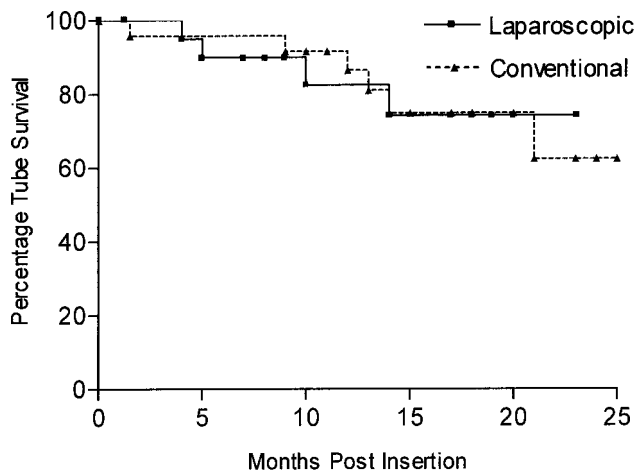


Figure 2 — Kaplan–Meier plot of catheter survival. Survival is not significantly different.

TABLE 2
Early (< 6 Weeks Post-Op) and Late (> 6 Weeks after Insertion) Complications of Catheter Insertion. Figures represent numbers of patients. Total follow-up: laparoscopic = 265 months, conventional = 361 months.

	Pain on drainage	Mechanical dysfunction	Fluid leak	Exit-site infection	Peritonitis
Laparoscopic (early)	3	0	2	2	3
Conventional (early)	2	0	0	4	1
Laparoscopic (late)	0	0	0	6	6
Conventional (late)	0	0	0	4	11

scopic technique. While the peritonitis rates were unusually high for our unit, other complications were so few that it would require a considerably larger study population to prove either technique superior. The possibility of a type II statistical error means that a study with several hundred patients in each arm would be required.

Thus, we have no evidence to suggest that laparoscopic insertion should be used as a routine. Indeed, the shorter operation time and simpler material requirements of the conventional technique make this theoretically more cost-effective in our hospital. This may not apply to all renal units, because

in the short term, it may be less costly for a nephrologist to perform catheter insertion percutaneously in a side-room under local anesthetic. If this is so, the peritoneoscopic approach represents a better option than more conventional “blind” insertion techniques, which have consistently returned inferior catheter survival data when compared to other forms of catheter insertion (6,9), although the risk of intestinal perforation exists with both.

We see the laparoscope as a useful tool for some patients. It is useful for repositioning displaced catheters which do not move in response to peristaltic stimulants. It has been useful for investigating pa-

tients with mechanical dysfunction when occult pelvic adhesions can be divided or partial omentectomy performed. In patients who have undergone previous abdominal surgery following peritonitis, the better views of the pelvic cavity and the ability to divide adhesions make the laparoscopic insertion technique a more attractive option.

Some centers use laparoscopic insertion with local anesthetic for patients at high risk for general anesthesia on the assumption that it is safer. We suggest that modern general anesthesia is safe for the vast majority of patients and allows a better view of the peritoneal cavity to be achieved. For those few patients who are still considered to be very high anesthetic risks, we are not aware of any study showing that a conventional catheter insertion under spinal anesthesia is less likely to succeed than a laparoscopic insertion.

In conclusion, this randomized prospective comparison of PD catheter insertion by conventional open surgery and a laparoscopically guided surgical technique showed no difference in postoperative discomfort or complication rates. The laparoscopic technique is more time consuming than the conventional. While laparoscopic guidance is useful in selected patients, we recommend a conventional approach for the majority of patients when complication rates are as low as those observed in this series.

ACKNOWLEDGMENT

We would like to thank Sister Susan Harvey, Sister Karen Hunt, and the patients and staff of Ward 50 and the operating theaters at Hull Royal Infirmary for their assistance with this study.

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