Tunneled Peritoneal Drainage Catheter Placement for Refractory Ascites: Single-center Experience in 188 Patients

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ABSTRACT

Purpose: To assess the success and safety of tunneled peritoneal drainage catheters for the management of ascites refractory to medical management.

Materials and Methods: A total of 188 consecutive patients (83 male, 105 female; average age 59 y) with refractory ascites were treated with tunneled peritoneal drainage catheters from January 1, 2006, to August 10, 2012. A combination of fluoroscopic and ultrasound guidance was used to insert all catheters. Patient history, procedural records, and clinical follow-up documents were retrospectively reviewed. Clinical data (malignancy, renal disease, chemotherapy, neutropenia, albumin levels) were compared with respect to patency and complication rates with the use of odds ratios. Catheter survival curves were generated with the Kaplan–Meier method and life-table analysis for the cumulative and infection-free survival of primary and secondary catheters.

Results: A total of 193 catheter placements or interventions were performed in 188 patients with refractory ascites: 170 catheters (93%) were placed for malignant etiologies and 13 (7%) for nonmalignant etiologies. The most common malignancies were ovarian (22%), pancreatic (12%), and breast (11%). The most common nonmalignant etiologies were end-stage liver disease ($n = 7$) and heart failure ($n = 6$). There was a 100% technical success rate for catheter insertion; no procedure-related deaths or major placement complications were identified. Catheter survival ranged from 0 to 796 days (mean, 60 d), with a total of 11,936 cumulative catheter-days. Fourteen postplacement complications were identified: five patients experienced catheter malfunction, four had leakage of ascites at the incisional site requiring suture placement, three had cellulitis of the tunnel tract, and two developed peritonitis. The annual complication event rate was 0.43 events per year (ie, 0.12 events per 100 catheter-days). Pancreatic malignancy was associated with a significantly increased rate of catheter malfunction (ie, occlusion).

Conclusions: Radiologic insertion of tunneled peritoneal drainage catheters demonstrated a 100% technical success rate for insertion and an acceptable complication rate for the management of refractory ascites.

The development of refractory ascites is commonly a manifestation of terminal metastatic malignancy with an anticipated life expectancy of 1 to 4 months (1). Intractable ascites is often related to peritoneal infiltration by tumor, liver metastases causing portal venous compression, lymphangitic carcinomatosis, lymphatic obstruction, or a combination of these factors (2). Symptoms include tense abdominal distension, early satiety, nausea and vomiting, reflux esophagitis, shortness of breath, lower-extremity edema, fatigue, and reduced mobility (2). Current treatment strategies for the palliation of these symptoms include repeated paracentesis, placement of indwelling intraperitoneal catheters, peritoneovenous shunting, intraperitoneal chemotherapy, diuretic treatment, and dietary restrictions (2–9). These approaches can have a varying, but substantial, impact on patients' remaining quality of life.

Patients with advanced liver disease or end-stage heart failure and refractory ascites have a limited range of options for palliation, including diuretic therapy, repeated large-volume paracentesis, and, in the case of liver failure, creation of a portosystemic shunt or liver transplantation (10–16). Patients with cirrhotic ascites may become refractory to or intolerant of diuretic therapy, yet prove to be poor candidates for transjugular intrahepatic portosystemic shunts (17,18).

Indwelling tunneled peritoneal drainage catheters may be an effective option for the management of ascites,

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with a low complication rate (2,3,4,7). These catheters can be managed at home to remove ascites on a regular basis or when the patient experiences discomfort related to the ascites. This approach also allows patients to limit the potential complications and frequent hospital or clinic visits previously required for repeated paracentesis. Small series have been published describing the experience and outcomes with this procedure (2,3,19,20). The purpose of the present study is to retrospectively assess the technical success, long-term patency, and complications associated with the use of tunneled peritoneal drainage catheters (PleurX; CareFusion, San Diego, California) in the management of refractory ascites in a large academic medical center. A secondary aim was to identify predictors of successful long-term catheter patency with analysis of clinical and laboratory data.

MATERIALS AND METHODS

Institutional review board approval and a waiver of consent were granted for this study. The study was a retrospective review of the electronic medical records of consecutive patients in whom tunneled peritoneal drainage catheters were placed at a single institution by the interventional radiology division between January 1, 2006, and July 31, 2012. Patient history, procedural records, and clinical follow-up documents were reviewed.

Catheter

PleurX tunneled peritoneal drainage catheters were used in all patients in the present series. The PleurX peritoneal drainage catheter is a 15.5-F, 66-cm fenestrated silicone catheter with a one-way valve mechanism and a polyester cuff. After the catheter is placed, patients or their caregivers (trained to perform fluid drainage by using this system) can drain ascites when required. This process involves attaching the vacuum bottle to the catheter and draining fluid from the peritoneal cavity; after drainage, the bottle is disconnected and the catheter is coiled and kept underneath a dressing.

Procedures

Tunneled peritoneal drainage catheter insertions were performed in the interventional radiology suite by a total of seven interventional radiology physicians with experience ranging from 3 to 25 years. Informed consent was obtained for all patients before the procedure. Patients were evaluated and referred to the interventional radiology service for tunneled peritoneal drainage catheter placement by the clinical oncology or gastroenterology clinical services. There were 83 men and 105 women in the study population, with an average age of 59 years. Patient preparation included evaluation and confirmation of appropriate hematologic parameters, including platelet count at least 50,000/L, hemoglobin level at least 8 g/dL, and International Normalized Ratio no greater than 1.5. Whereas an abnormal coagulation profile was considered a relative contraindication, absolute contraindications to the procedure included clinical or laboratory evidence of active infection. Prophylactic intravenous antibiotic infusion was used for all catheter placements (cefazolin 1 g or clindamycin 600 mg). Before patient preparation, ultrasound assessment of ascites volume was performed. The right lower quadrant was the preferred site. The abdominal access site was surgically prepared with 2% chlorhexidine gluconate and 70% isopropyl alcohol (ChloraPrep; CareFusion) and draped in sterile fashion. Initial transperitoneal puncture was performed with an 18-gauge needle by using real-time sonographic guidance. Serial tract dilation was then performed to accommodate the appropriate introducer sheath. The subcutaneous tunnel was fashioned in the midabdomen in standard fashion. The catheter (PleurX peritoneal catheter drainage system, CareFusion) was advanced into the peel-away introducer sheath and positioned in the dependent aspect of the abdomen or pelvis; positioning the catheter tip in the most dependent portion of the peritoneal cavity is desirable to maximize drainage in the sitting or supine positions. The insertion site was closed with a single 2–0 absorbable buried suture and further secured with 2-octyl cyanoacrylate (Dermabond; Ethicon, Norwood, Massachusetts). The catheter was sutured to the skin near the exit site with 2–0 nylon sutures. After the procedure, catheter course and tip position was documented in the interventional radiology suite with a supine anteroposterior abdominal image.

Definitions

Technical success was defined as the insertion of the catheter in a satisfactory intraperitoneal position with establishment of initial successful ascites drainage. Endpoint (date) was defined as the time of catheter removal, patient death, or last clinical note present in the electronic medical record. Catheter-days were defined as the number of days the catheter was properly functioning with no interventional radiologic or medical catheter salvages. The reporting standards and recommendations of the Society of Interventional Radiology were used to report procedural and catheter-related complications (21).

Statistical Analysis

The data were analyzed by using Statistical Package for Social Sciences software (version 19; SPSS, Armonk, New York) and Stata 12C (StataCorp, College Station, Texas). Correlation of complication rates with cancer type were performed by using Pearson χ^2 test, and statistical significance was determined at the 95% confidence interval. P values lower than .05 were considered statistically significant. Catheter survival curves were generated by

using the Kaplan–Meier method for the cumulative and infection-free survival of primary and secondary catheters.

RESULTS

There was a 100% technical success rate for insertion of the tunneled peritoneal drainage catheter; no procedure-related deaths or complications were identified. A total of 193 catheter placements or interventions were performed in 188 patients with refractory ascites. A total of 170 catheters (88%) were placed for malignant etiologies, and 13 (12%) were placed for nonmalignant etiologies (Table 1). The most common malignancies were ovarian (n = 42; 22%), pancreatic (n = 22; 12%), and breast (n = 20; 11%); the most common nonmalignant etiologies were end-stage liver disease (n = 7; 4%) and heart failure (n = 6; 3%).

Overall catheter survival ranged from 0 to 796 days (mean, 60 d), with a total of 11,903 cumulative catheter-days (Figure); one patient was discharged to hospice within 24 hours of the procedure, and the date of death could not be confirmed for this patient. In total, seven catheters were in patients still alive at last clinical follow-up, 157 catheters were placed in patients who had since died, 17 catheters were removed or replaced, and 12 were in patients who were discharged to hospice/home without a date of death confirmed; in 12 patients (6%), the date of death could not be determined, and the date they were discharged to hospice care was instead used as the endpoint. Fourteen complications were identified: five patients experienced catheter malfunction, four had leakage of ascites at the incisional site requiring suture placement, three had cellulitis of the tunnel tract, and two developed peritonitis (Table 2). Leakage of ascites occurred at an average of 11.25 days after catheter placement and was managed in all cases with suture placement around the tunnel. The annual event rate was 0.43 events per year (or 0.12 per 100 catheter-days).

Pancreatic cancer was associated with a statistically greater catheter complication rate ($P = .007$; odds ratio, 4.7; 95% confidence interval, 1.399–15.511). Complications in the pancreatic cancer group included four catheter occlusions that were addressed via catheter replacement and one case of cellulitis treated successfully with antibiotic therapy. No significant association of catheter complications were found based on other cancer types, presence of neutropenia, hypoalbuminemia, renal dysfunction, or chemotherapy (Table 1).

Catheters placed in patients with refractory ascites caused by a benign etiology (n = 13) accounted for a total of 1,071 cumulative catheter-days (mean, 82 d). One case of peritonitis was found in this group after 258 catheter-days. The annual event rate was 0.34 (0.1 per 100 catheter-days). There was no statistically significant difference among the nonmalignant disease types or clinical data associated with catheter complications (Table 1).

Table 1. Pathophysiology of Refractory Ascites and Relevant Clinical Data in Catheter Patient Population from Retrospective Chart Review Between 2006 and 2012

Primary Disease	Incidence	*P* Value
Benign		
Congestive heart failure	6 (3)	.31
End-stage liver disease	7 (4)	.48
Malignant		
Ovarian	42 (22)	.9
Pancreatic	22 (12)	.01†
Breast	20 (11)	.77
Hepatocellular	16 (9)	.91
Unknown primary lesion	10 (5)	.39
Colorectal	9 (5)	.42
Cholangiocarcinoma	6 (3)	.48
Endometrial	7 (4)	.48
Melanoma	6 (3)	.51
Mesothelioma	6 (3)	.51
Gastric	5 (3)	.55
NSCLC	5 (3)	.55
Neuroendocrine	4 (2)	*
Renal	4 (2)	*
Fallopian	2 (1)	*
Teratoma	1 (1)	*
Lymphoma	1 (1)	*
Adrenal	1 (1)	*
Appendiceal	1 (1)	*
Bladder	1 (1)	*
Cervical	1 (1)	*
Esophageal	1 (1)	*
Gallbladder	1 (1)	*
GIST	1 (1)	*
Testicular	1 (1)	*
Thyroid	1 (1)	*
Clinical/laboratory data		
Renal dysfunction (serum creatinine > 1.3 mg/dL)	74 (39)	.28
Hypoalbuminemia (< 3.5 g/dL)	178 (95)	.51
Neutropenia (WBC < 3.2×10^9)	15 (8)	.54
Chemotherapy (< 30 d catheter placement)	108 (57)	.97

Values in parentheses are percentages.
P value reflects Pearson χ^2 correlation with catheter complications.
GIST = gastrointestinal stromal tumor, NSCLC = non–small-cell lung cancer, WBC = white blood cell.
*Number of patients insufficient for meaningful statistical analysis.
†Significant at $P < .05$.

DISCUSSION

The present study is one of the largest series to date examining the application and safety of tunneled ascites drainage catheter implantation. The data presented here support the radiologic insertion of tunneled peritoneal

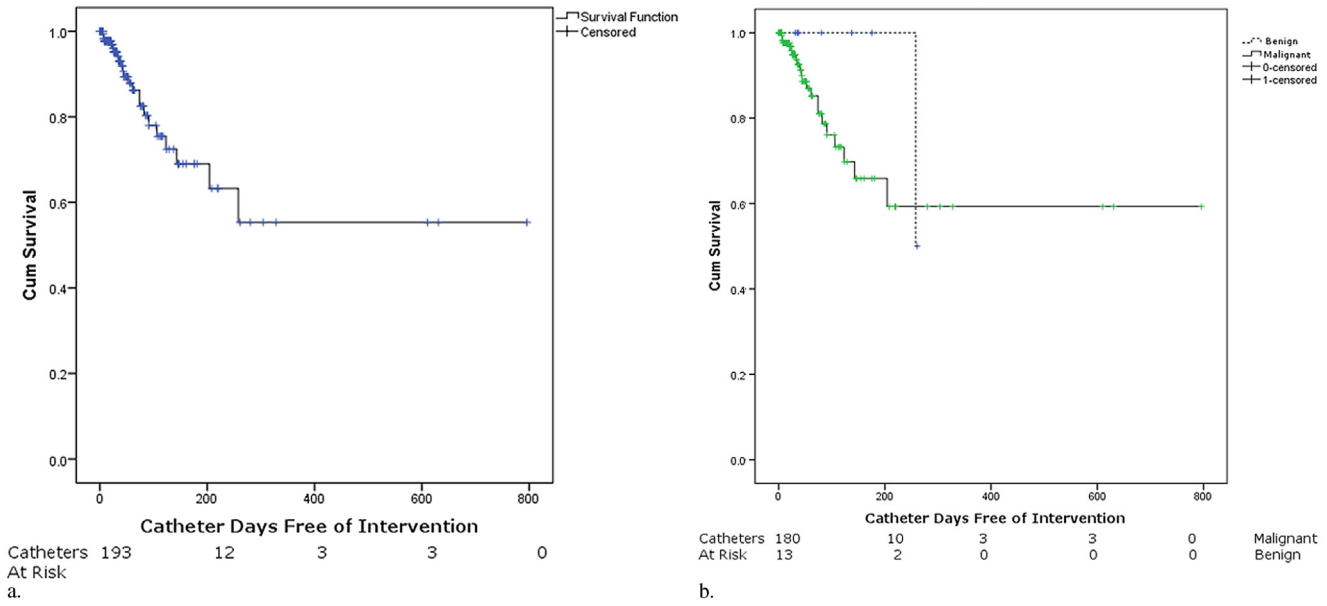

Figure. Kaplan–Meier survival curves for **(a)** all peritoneal drainage catheters placed between 2006 and 2012 and **(b)** separated by patients with benign and malignant ascites, respectively, for all catheters placed between 2006 and 2012. Cum = cumulative. (Available in color online at *www.jvir.org*.)

Table 2. Complications of Catheters from Retrospective Chart Review of Catheter Placement between 2006 and 2012

Complication	No. of Cases	Total Catheters (%)	Average Time after Placement (d)	Intervention
Peritonitis	2	1.0	182	Catheter removed, antibiotics
Leakage	4	2.0	11.25	Tunnel suture placement
Malfunction	5	2.5	92.2	Catheter removed and replaced
Cellulitis	3	1.5	50.7	Catheter removed (n = 2); catheter left in place, antibiotics (n = 1)
Total	14	7.0	–	–

drainage catheters for the management of patients with refractory ascites.

Findings of this analysis are in concordance with those of other series. White et al (22) reviewed nine studies with a total of 180 patients, with a reported 100% technical success rate for tunneled peritoneal drainage catheter placement in patients with malignant ascites. Tapping et al (2) described 28 patients treated with tunneled peritoneal drainage catheters for refractory malignant ascites over a 4-year period, also revealing a 100% technical success rate for the insertion of the drain, with no major complications and an annual event rate of 0.45 per year, similar to the findings of the present study. Factors these authors (2,22) found to be significantly associated with complications included current chemotherapy, low albumin levels, high white blood cell count, and renal dysfunction. The present study, in contrast, found none of these reported clinical data to be significantly associated with catheter complications, but that pancreatic malignancy was significantly associated with a fourfold greater risk of tunneled peritoneal drainage catheter malfunction. One can hypothesize this to be an inherent difference in composition of the ascites in pancreatic malignancy (eg, more prone to fibrin sheath formation), but we are aware of no literature to date supporting this hypothesis. Instead, the true pathophysiology underlying an increased tendency for catheter malfunction in this population compared with ascites caused by other malignancies is unknown.

Another study consisting of 10 patients with malignant ascites by Richard et al (7) reported a mean tunneled peritoneal drainage catheter survival time of 70 days. The present study reports that, in a cumulative analysis of 11,903 catheter-days in 188 patients, the mean catheter survival time was 60 days. Based on the 0.43 cumulative annual event rate in the present study, the true catheter survival time may actually be greater because the overwhelming majority of these catheters were placed for the management of refractory malignant ascites in patients with end-stage cancer, who commonly die with functioning catheters in place.

A large literature review (3) examined 15 publications over a period of 18 years that studied the complication rates of ascites drains and included a variety of tunneled and nontunneled peritoneal drainage catheters, including ports, nontunneled peritoneal drainage catheters, tunneled peritoneal drainage catheters, and peritoneal dialysis catheters (4,7,8,19,20,23). The heterogeneity and small individual numbers of the included catheter types limited the ability to draw firm conclusions regarding an optimal strategy for the management of refractory malignant ascites; the reported cumulative rate of peritonitis was 11% (3), and minor complications such as catheter occlusion (37%) or leaking (11%) (3) were also more common than reported in other studies of tunneled peritoneal catheters and the present study. Courtney et al (24) reported a prospective cohort of 34 patients and reported only one instance of peritonitis; 85% of patients in this study (24) were free of catheter interventions in 12 weeks of follow-up. In the largest study of tunneled peritoneal drainage catheters to date, Rosenberg et al (4) reviewed 40 patients, reporting only one case (2.5%) of peritonitis. In 193 catheters in 188 patients, the present study reported two cases of peritonitis (1%) and an overall minor complication rate of 7% (14 of 193), which includes catheter malfunction (ie, occlusion) and site leakage. These data further support an exceedingly low incidence of peritonitis in tunneled peritoneal drainage catheters.

In the analysis of tunneled peritoneal drainage catheter placement for nonmalignant disease, 13 patients were identified, seven with end-stage liver disease and six with congestive heart failure. Only one patient in this group experienced a major complication, which was a case of peritonitis in a patient with heart failure at 258 catheter-days. In this subgroup, the overall complication rate was 0.4 per year (ie, 0.1 per 100 catheter-days), which is comparable to accepted complication rates in peritoneal dialysis catheters (0.6 per year) (25). In some clinical practices, patients who are referred for tunneled peritoneal drainage catheter placement for benign ascites are often not candidates for alternative management such as transplantation or transjugular intrahepatic portosystemic shunt creation, and therefore repeated large-volume paracentesis remains the standard of care for palliative management of refractory ascites (26–28). This procedure, although safe, is inconvenient and uncomfortable for patients, as it often requires travel to a clinical setting for the procedure, sometimes multiple times per week. In addition, the major and minor complication rates have been reported to be as high as 2.5% for each procedure (26–28). Given the small sample size of patients with nonmalignant refractory ascites in the present study, these data suggest that future investigation may be warranted to evaluate tunneled peritoneal drainage catheter placement in this population as a potential alternative to large-volume paracentesis, or in certain cases, transjugular intrahepatic portosystemic shunt creation.

The present study has limitations. In 12 patients (6%), the date of death could not be determined, and the date each patient was discharged to hospice care was instead used as the endpoint; therefore, it is possible that the catheter survival days as well as complications were underestimated in these cases. A standardized grading system was not used to more objectively determine whether the tunneled peritoneal drainage catheter placement sufficiently addressed quality of life and comfort-related concerns; these are often among the primary clinical considerations when tunneled peritoneal drainage catheter placement is performed. Further investigation can be performed in a prospective manner to determine the degree of palliation from pain related to ascites. The exclusive use of the PleurX peritoneal drainage catheter system in all our tunneled peritoneal drainage catheter placements may limit applicability of our conclusions broadly to the use of other tunneled peritoneal drainage catheters. Finally, the present study is a retrospective analysis in a relatively small population.

In summary, the present study represents a large single-center experience with tunneled peritoneal drainage catheters for the management of refractory ascites. In this study, there was a 100% technical success rate and a low complication rate in the management of patients with refractory ascites with the use of tunneled peritoneal drainage catheters. Complications were not statistically correlated to the presence of neutropenia, current chemotherapy, renal dysfunction, or hypoalbuminemia; of all the malignancy types, pancreatic cancer was significantly associated with an increased rate of catheter malfunction (ie, occlusion). Further investigation is needed to evaluate tunneled peritoneal drainage catheter placement for palliative management in selected patients with nonmalignant etiology of refractory ascites.

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