Indwelling Peritoneal Catheters for Managing Malignancy-Associated Ascites

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Abstract / We investigated use of the tunnelled catheter in a large palliative population with malignancy-associated ascites employing retrospective analysis of a prospectively maintained patient database of tunnelled peritoneal catheter insertions for refractory malignancy-associated ascites or new rapidly accumulating ascites. We found that a 100 percent procedural success rate was achieved with 395 tunnelled catheters inserted in 386 patients. Catheters remained in situ for 66 days, on average. In a total of 22 cases (5.57 percent), complications developed. Nonfatal infections occurred most commonly — in 15 cases (3.80 percent). Ascites stopped reaccumulating in 16 cases (4.05 percent), leading to catheter removal. The mean Baseline Dyspnea Index was 3.79 (95 percent confidence interval [CI], 3.64-3.94); the mean Transitional Dyspnea Index postinsertion was 5.14 (95 percent CI, 4.94-5.34). In all, 13 patients completed serial European Organisation for Research and Treatment of Cancer Quality of Life Questionnaires. Postinsertion, overall quality of life improved significantly ($p<0.05$), as did all functional domains and fatigue, pain, dyspnea, and appetite symptoms. The tunnelled peritoneal catheter is feasible and safe and causes minimal complications. Its use results in significant improvement in dyspnea and improvement in overall quality of life for a small number of patients.

Résumé / Nous avons analysé l'utilisation du cathéter à demeure chez un grand nombre de patients admis dans un service de soins palliatifs et souffrant d'ascites associées à une tumeur maligne. Nous avons fait l'analyse rétrospective des dossiers de patients inscrits dans une base de données, où les renseignements avaient été recueillis auprès des patients dans une optique prospective. Les patients avaient tous été traités par l'insertion de cathéter à demeure pour une ascite maligne symptomatique liée au cancer ou pour une ascite à accumulation rapide d'eau. Nous avons relevé un taux de succès de 100 pourcent pour l'insertion de 395 cathéters chez 386 patients. Les cathéters sont demeurés "in situ" en moyenne environ 66 jours. On note que des complications sont survenues dans 22 cas (5.57 pourcent). Des infections mineures et sans conséquence fatale sont survenues dans 15 cas (3.80 pourcent). La re-accumulation d'eau a cessé dans 16 cas (4.05 pourcent) conduisant ainsi à la décision de retirer le cathéter. Après l'insertion du cathéter la qualité de vie des patients dans son ensemble a augmenté de façon significative ($p<0.05$) tout comme l'indice fonctionnel, et il y a eu une amélioration marquée au niveau de la fatigue, de la douleur, de la dyspnée et des symptômes reliés à l'appétit. La sonde à demeure est une option faisable et sécure qui comporte très peu de complications. Son utilisation améliore la dyspnée de façon significative de même que la qualité de vie chez un petit nombre de patients.

INTRODUCTION

Of all patients with ascites, 7 percent have malignancy-associated ascites (1). Its presence typically signifies advanced progression of terminal cancer and an anticipated life expectancy of one to four months after diagnosis (2). The mechanisms underlying the pathogenesis of malignancy-associated ascites vary depending on the type of malignancy involved. They include: invasion of the peritoneum with resultant increased vascular permeability and blockage of lymphatic drainage, otherwise known as peritoneal carcinomatosis (53 percent); portal hypertension secondary to massive liver metastases, hepatocellular carcinoma with cirrhosis, or Budd-Chiari syndrome (26 percent); a combination of all these factors (13 percent); and chylous ascites resulting from lymph node obstruction seen in lymphoma (7 percent) (3). Malignancy-associated ascites is often recurrent and causes a variety of abdominal, respiratory, and constitutional symptoms that compromise the quality of life of patients.

Many approaches can be taken to the palliative management of malignancy-associated ascites. For patients with ovarian or certain gastrointestinal cancers, intraperitoneal chemotherapy or targeted

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biologic therapy may be an option, but these have a brief benefit and treatment resistance often develops in the setting of recurrent disease (4). Diuretics appear to be somewhat helpful in cases of ascites caused by portal hypertension, but supporting data is based on surveys stating that 45 percent of prescribing clinicians have found this modality effective (2). Mechanical drainage of ascites remains the mainstay of palliation, with therapeutic paracentesis being the most common and effective method. However, this modality requires frequent hospital or clinic visits, repeated needle punctures, and a small but serious risk of infection, bowel perforation, and hemorrhage (5). Peritoneovenous shunts may help to minimize frequent paracenteses, but they are of limited utility as few patients are candidates for this surgical procedure, and many complications can arise — including pulmonary edema, shunt occlusion, pulmonary embolism, infection, and disseminated intravascular coagulation (4, 6). Additionally, one study (n=89) demonstrated that the level of complications could be high — affecting as many as 49 percent of study participants— and 13 percent of participants died within 30 days of placement due to placement complications (6). Nontunnelled pigtail drainage catheters are generally not considered because they are associated with high rates of infection (35 percent), blockage (30 percent), and leakage (20 percent) (7).

In the last decade, use of the indwelling tunnelled peritoneal catheter as an alternative for managing malignant ascites has been reported to be effective; its complication rates are clinically insignificant and it has been associated with symptom improvement and greater convenience for outpatient management in home care nursing (4, 5). However, the studies reporting such benefits have small sample sizes, and only one small study has evaluated symptom management and quality-of-life outcomes after catheter insertion (8). The objective of this study was to evaluate a large population of cancer patients with malignancy-associated ascites who received an indwelling tunnelled peritoneal catheter. Technical success, complications, symptom management, and quality-of-life outcome measures were assessed.

MATERIALS AND METHODS

Study Design and Setting

We conducted a retrospective analysis of a prospectively maintained database of patients who underwent indwelling tunnelled peritoneal catheter insertion (PleurX® catheter, CareFusion Corporation) for malignancy-associated ascites at The Ottawa Hospital (TOH). The investigational protocol was reviewed and approved by TOH's research ethics board (protocol number 20130375-01H).

Participants

In this retrospective study, data on patients who underwent PleurX® catheter insertion were collected from a prospectively maintained database in TOH's chronic ascites and recurrent effusion (CARE) clinic. This database includes data for all patients with malignancy-associated ascites who underwent catheter insertion. It was created without any influence or financing from the manufacturer of the PleurX® catheter. Patients were consecutively recruited, regardless of patient setting. We included both inpatients and outpatients who had a PleurX® peritoneal catheter inserted beginning in November 2007 (the inception of the drainage program for malignancy-associated ascites) and continuing over a five-year period with a minimum follow-up period of one year. Patients were assessed and considered eligible for the procedure if they had malignancy-associated ascites, were refractory to chemotherapy and diuretics, had reported symptomatic benefit from therapeutic paracentesis, and experienced rapid reaccumulation requiring repeat drainage within two weeks; also included were those with newly diagnosed malignancy-associated ascites with rapid accumulation and discomfort and a poor quality of life such that serial paracenteses would be inconvenient. No exclusion criteria were used. All eligible patients were offered this procedure.

After informed consent was obtained from the patient or the patient's decision maker, the PleurX® peritoneal catheter was inserted according to a previously described protocol (9). In brief, all catheters were placed under ultrasound guidance once the largest pocket of fluid was identified. The site for insertion was marked, and patients were prepped and draped in sterile fashion. Local anaesthesia was achieved with approximately 20 cc of 1 percent lidocaine; no periprocedural antibiotics were used for our patient population. An 18-gauge needle was then advanced into the peritoneal space, and once ascitic fluid was aspirated, a guidewire was put into the peritoneal cavity. Using a number 11 scalpel, a small incision, approximately seven millimetres long, was made around the guidewire, ensuring its free mobility. This was the entry site for the catheter into the peritoneal cavity. A second incision, five millimetres long, was made superior and medial to the initial incision. This second incision was the exit site for the catheter.

The 15.5 French PleurX® catheter was then tunnelled between the two incisions and retrieved adjacent to the guidewire. The polystyrene cuff was pulled through the tunnel until it was no longer visible at the exit site. A fascial dilator with a peel-away sheath was then advanced over the guidewire and inserted into the peritoneal cavity. The guidewire and the fascial dilator were subsequently removed, and the catheter was advanced into the peritoneal cavity through the peel-away sheath. The peel-away sheath was then removed, ensuring that the entire length of the tunnelled catheter was adequately advanced into the peritoneal cavity and that there were no kinks that could hinder drainage. Both the insertion site and the exit site were sutured with nonabsorbable 2-0 silk suture. A sterile dressing was applied and covered with a transparent adhesive film. Vital signs were monitored before and after the procedure.

Insertion was performed at the bedside if the recipient was an inpatient at TOH, or in the CARE clinic if the recipient was an outpatient or referred from a satellite hospital. Postinsertion management was carried out as per TOH and community nursing policies and procedures, which are similar to those described by the manufacturer (10); care was provided for inpatients at TOH and satellite hospitals by hospital nursing staff, and for outpatients by home care nursing staff supplied by the Community Care Access Centre (CCAC). Both inpatients and outpatients had their catheter drainage performed at least three times per week by the respective nursing staff; this was done at the bedside for inpatients and at home for outpatients. Those who had their catheters inserted as inpatients either remained in hospital or were discharged home to be cared for by CCAC staff, depending on their clinical state.

Beginning in November 2010, patients who had their PleurX® peritoneal catheters inserted in the CARE clinic were also given the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire version 3.0 (QLQ-C30) to complete at baseline visit and within 12 weeks of follow-up (11) to assess their quality of life and symptoms.

Data Collection

We collected baseline demographic data, including: age, gender, patient setting (inpatient/outpatient), type of malignancy, Eastern Cooperative Oncology Group (ECOG) Performance Status Scale score, prior and current cancer treatments, medical comorbidities (history of cardiac, renal, and hepatic dysfunction), and history of previous therapeutic paracentesis. For each patient, the date of PleurX® peritoneal catheter insertion, initial drainage volume and ascitic fluid cytology status, length of time catheter remained in-situ, death status, and date of death were also collected. Complications occurring within 24 hours of the procedure and adverse events occurring more than 24 hours after catheter insertion and noted on follow-up were recorded.

Dyspnea Assessment

As part of measuring symptom management, we collected data on dyspnea using Baseline Dyspnea Indices (BDIs) and Transitional Dyspnea Indices (TDIs) within two weeks after catheter insertion (12). These tools are validated instruments for assessing dyspnea. The BDI rates dyspnea severity at the initial visit using a questionnaire that the patient completes at clinic visits; it has three domains, each graded from 0 (very severe) to 4 (no impairment) and therefore ranges from 0 to 12. Similarly, the TDI measures changes in dyspnea severity from the BDI; it has three domains, each graded from -3 (major deterioration) to +3 (major improvement) and therefore ranges from -9 to +9. A TDI of one unit or more is considered a minimally important clinical difference (13).

Quality-of-Life Assessment

Quality-of-life and symptom data were collected, as described earlier, using the EORTC QLQ-C30, which consists of multi- and single-item scales. There are 30 questions — each presented on a Likert-type scale (1 to 4, or 1 to 7) — assessing global health status, functional scales, and various symptoms. A raw score is determined for each scale of interest and then linearly transformed to standardize the scores from 0 to 100, with higher values signifying a higher or better level of functioning or a higher or worse level of symptoms (14). Minimal clinically important difference is based on patients' perceived changes to their quality of life as derived from the Subjective Significance Questionnaire (14), and change in scores of 5 to 10, 10 to 20, and greater than 20 corresponds to a little change, moderate change, and very much change, respectively.

Outcomes

The primary outcome for this study was the rate of technical success of the PleurX® peritoneal catheter insertion, as defined by evidence of drainage and the patient being comfortable and not experiencing dry pain during and after insertion. Secondary outcomes included: the number of days the catheter remained in situ, the rate of

immediate complications after catheter insertion, the rate of adverse events and catheter-related interventions, the mortality rate, changes in sensation of dyspnea as recorded by BDIs and TDIs, and the quality-of-life scores collected from the EORTC QLQ-C30. Outcomes expressed as percentages were determined based on the total number of catheters inserted, as some patients may have had catheter reinsertions.

Statistical Analysis

Descriptive statistics were used to measure the aforementioned rates. BDIs and TDIs were expressed as mean values including 95 percent confidence intervals. Two-sided paired t-tests were used to evaluate mean scores derived from the various scales of the EORTC QLQ-C30; a p-value of less than 0.05 was considered statistically significant.

Table 1 / Patient Characteristics

Median age (interquartile range), years	65	56
	No.	**%**
Sex		
Male	147	38
Female	239	62
Patient type		
Inpatient	180	46
Outpatient	214	54
Tumour type		
Ovarian	81	21
Pancreatic	57	15
Colon	50	13
Breast	43	11
Cancer of unknown primary	29	8
Hepatocellular	27	7
Gastric	15	4
Cholangiocarcinoma	12	3
Esophageal	10	3
Other	62	16
Comorbidities		
Cardiovascular	43	11
Renal	21	5
Liver	29	8
Prior therapies		
Surgery	164	42
Radiotherapy	96	24
Chemotherapy	289	73
Hormonal	31	8
None	71	18
Ascitic fluid cytology		
Positive for malignancy	168	43
Negative for malignancy	222	57
Prior therapeutic paracentesis	197	51
Eastern Cooperative Oncology Group ECOG Performance Status Scale score		
1	8	2
2	60	16
3	167	43
4	151	39

RESULTS

Patient demographic data are described in Table 1. Over a five-year period beginning in November 2007, 386 patients with malignancy-associated ascites had PleurX® peritoneal catheters inserted. Five patients had two catheter insertions during this period, and two patients had three catheter insertions; five patients' prior catheters had been discontinued due to lack of drainage. Participants' median age was 65 years, and 180 (47 percent) were inpatients at the time of catheter insertion. The top three tumour types in this population were ovarian cancer (21 percent), pancreatic cancer (15 percent), and colon cancer (13 percent). Prior therapeutic paracenteses were performed for 197 patients (51 percent).

Patient outcomes are reported in Table 2. Technical success of catheter insertion was achieved in 100 percent of patients; the median drainage of ascitic fluid was five litres. A total of 305 patients (79.02 percent) died with the catheter in situ. The median period for the PleurX® peritoneal catheter remaining in situ was 31 days. Ascites had stopped accumulating in 16 patients (4.05 percent), leading to catheter removal. By 12 weeks, 255 patients (66.06 percent) had died; and, overall, 346 patients (89.64 percent) had died by the time of data analysis. Living status was unknown for 19 patients (4.92 percent). Immediate complications following

Table 2 / Patient Outcomes Following PleurX® Insertion[a]

	No.	**%**
Technical success	386	100
Median initial drain (L) (interquartile range)	5	3
Median number of days catheter inserted (interquartile range)	31	56
	No.	**%**
Immediate complications	12	3.04
Oozing at catheter site	11	2.78
Hypotension	1	0.25
Catheter interventions	38	9.62
Catheter removed	16	4.05
Total adverse events	22	5.57
– Infections	15	3.80
– Catheter fell out	2	0.51
– tPA[b] for blockage	1	0.25
– Valve leakage	1	0.25
– Patient suicidal	1	0.25
– Catheter migration	1	0.25
– Pain requiring removal	1	0.25
Mortality		
12 weeks	255	66.06
Overall	346	89.64
Catheter in situ at death	305	79.02
Unknown	19	4.92

[a] Reported in number of patients, unless otherwise stated.
[b] Tissue plasminogen activator.

Table 3 / **European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire Version 3.0 (QLQ-C30) Mean Outcomes of 13 Patients**[a]

	Baseline (mean ± SD[b])	Interval (mean ± SD)	Change (mean with 95% CI[c])	p-value
Global health status	26 ± 22	45 ± 21	19 (7 to 30)	0.007
Functional scales				
Physical	33 ± 16	51 ± 23	18 (8 to 26)	0.003
Role	17 ± 19	36 ± 27	19 (10 to 28)	0.001
Emotional	63 ± 31	80 ± 19	17 (3 to 32)	0.039
Cognitive	64 ± 24	76 ± 27	12 (0 to 23)	0.082
Social	19 ± 24	40 ± 33	21 (6 to 35)	0.019
Symptoms				
Fatigue	72 ± 15	55 ± 22	-17 (-29 to -4)	0.022
Nausea/vomiting	18 ± 19	17 ± 20	-1 (-16 to 14)	0.870
Pain	71 ± 25	36 ± 30	-35 (-49 to -20)	0.001
Dyspnea	67 ± 27	44 ± 28	-23 (-40 to -6)	0.022
Insomnia	46 ± 35	41 ± 36	-5 (-26 to 16)	0.636
Appetite loss	59 ± 31	23 ± 28	-36 (-53 to -19)	0.002
Constipation	38 ± 36	23 ± 25	-15 (-38 to 8)	0.213
Diarrhea	15 ± 17	23 ± 28	+8 (-7 to 23)	0.337
Financial difficulties	23 ± 28	15 ± 29	-8 (-19 to 3)	0.190

[a] Reported in scores of 0 to 100; a higher score indicates a higher response level.
[b] Standard deviation.
[c] Confidence interval.

catheter insertion included: oozing of ascitic fluid around the insertion site in 11 patients (2.78 percent), which spontaneously resolved within two weeks; and the development of hypotension in 1 patient (0.25 percent), which resolved after a bolus intravenous fluid resuscitation. Adverse events were noted for 22 patients (5.57 percent). The most common occurrence was infection — this occurred for 15 patients (3.80 percent) but in no case was fatal. Cellulitis at the catheter exit site was noted in 4 patients (1.01 percent). Bacterial peritonitis was noted in 10 patients (2.53 percent), necessitating catheter removal, and bacteremia was noted in 2 patients (0.51 percent).

The mean BDI at the time of PleurX® peritoneal catheter insertion was 3.79 (95 percent CI, 3.64-3.94), and TDI within two weeks of catheter insertion was 5.14 (95 percent CI, 4.94-5.34). Only 13 patients had completed the EORTC QLQ-C30 at both baseline and within 12 weeks of catheter insertion. In this subset, improvement in the global health status (mean change: +19) as well as in four of five dimensions of function (physical function: +18; role function: +19; emotional function: +17; and social function: +21) was statistically and clinically significant, as shown in Table 3. Improvement in fatigue (mean change: -17), pain (mean change: -35), dyspnea (mean change: -23), and appetite loss (mean change: -36) was also significant.

DISCUSSION

To our knowledge, this retrospective study evaluated the largest prospectively maintained database to date of patients undergoing PleurX® peritoneal catheter insertion for management of malignancy-associated ascites. Our study demonstrates that this procedure is quite technically feasible as a palliative measure for this group of patients. It also concurs with previous studies that had much smaller sample sizes (5, 7, 15, 16). Additionally, this study reaffirms the finding of these previous studies that indwelling catheters are safe — we found only minor complications and non-fatal adverse events. This finding has led to the avoidance of surgical intervention, intensive care unit stays, and catheter-related death. Admittedly, given that this was a retrospective study, we do not have comparative data on patients undergoing other palliative drainage treatments, such as large-volume paracenteses; a prospective design would have been preferable.

Slightly more than half of the patients in this study had prior large-volume paracenteses. This modality of mechanical drainage of ascites is highly effective, but it does entail well-documented risks of bowel perforation and hemorrhage with repeated needle punctures; in one study, the overall complication rate was 7.5 percent per patient (7). Furthermore, repetition of this procedure leads to frequent hospital visits, which are inconvenient for the patient, entail the use of more healthcare resources, and may lead to delays in drainage resulting in patients becoming progressively symptomatic in the terminal stages of their illnesses (5, 7). Given that over 80 percent of the patients in this study had poor performance status (an ECOG score of at least 3), in our clinic we used clinical judgment that the PleurX® catheter would benefit the

patient — rather than a history of therapeutic paracentesis — as another indication for catheter insertion. This was justified by the low rate of catheter removal (4.05 percent), as mentioned earlier.

Overall, patients' dyspnea scores improved by two weeks after catheter insertion, which is a clinically important outcome. We further evaluated symptoms and quality of life with the EORTC QLQ-C30, since this survey was developed, validated, and widely tested for oncology clinical trials, including one in which PleurX® catheters were used to drain malignant pleural effusions (17). However, one major limitation of this study was the fact that although improvement was inferred in quality of life, most aspects of functioning, and symptoms of fatigue, pain, dyspnea, and anorexia, only 13 patients completed baseline and interval surveys for this analysis. A major reason that these data were missing is that the EORTC QLQ-C30 was implemented in late 2010, which was beyond the midpoint of the period of this retrospective study. Patients had been asked to complete the questionnaire voluntarily. It has only been since the beginning of 2012 that use of the questionnaire has been an integral part of the clinical encounter. Also, the fact that 66 percent of patients died by 12 weeks after catheter insertion implies that this patient cohort was very ill. This posed significant challenges to completing the 30-question survey at subsequent visits. The data from the 13 patients are still useful, however, as they demonstrate a large and significant change in dyspnea, which is comparable to the TDIs. Furthermore, clinically important improvement in other aspects of the survey was at least moderate based on change in scores of 10 to 20, as mentioned earlier, but further study is required for any generalization to be made.

A cost-benefit analysis was not performed in this study. There are costs associated with PleurX® catheters and postinsertion care, especially in the outpatient setting, but these may be rivalled by costs associated with repeated hospital visits and supplies for paracentesis. Certainly, given the low rate of complications — which is comparable to that with repeated large-volume paracentesis (5) — we anticipate minimal economic impact related to complications. In addition, these palliative patients were able to remain at home with nursing care provided by those trained to offer care at the end of life. The United Kingdom's National Institute for Health and Care Excellence (NICE) has also recently endorsed the PleurX® catheter for malignancy-associated ascites drainage under the National Health Service due to the clinical benefits cited here and the estimated cost savings of £679 (CA$1,360) per patient, as compared to inpatient therapeutic paracentesis (18).

CONCLUSION

The indwelling peritoneal catheter is a technically feasible and convenient option for palliative management of malignancy-associated ascites; there is strong evidence to support that this procedure is safe and results in minimal, nonfatal complications. This catheter has been associated with significant improvement in dyspnea outcomes after insertion. In addition, our data suggest that its use is linked with an improvement in overall quality of life and functioning as well as improvement in other symptoms, but further study is warranted in a larger population of patients capable of participating in quality-of-life assessments.

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