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Brief Research Report

Establishment of permanent peritoneal PleurX catheter as palliative treatment of malignant ascites

Marie Riis Mortensen[1], Tue Duy Ngyuen[2], Hans Henrik Madsen[3] & Michelle Meier[2]

1) Department of Gastrointestinal Surgery, Copenhagen University Hospital – Hvidovre Hospital, 2) Department of Gastrointestinal Surgery, Aarhus University Hospital, 3) Department of Radiology, Aarhus University Hospital, Denmark

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ABSTRACT

INTRODUCTION. Refractory malignant ascites (RMA) is a manifestation of end-stage cancer disease with a major impact on quality of life due to the symptom burden and need for repeated hospitalisations. We previously described the implantation of the permanent PleurX catheter as a treatment of RMA. The present study aimed to evaluate and describe our experience with the permanent PleurX catheter system in the largest cohort to date.

METHODS. A total of 97 consecutive patients had a PleurX catheter implanted from 2015 to 2021. We retrieved retrospective data on patients and procedures using the patient's medical records.

RESULTS. A total of 96 (99%) of implantations were successful, and all patients had symptom relief. Six patients (6%) experienced minor or moderate adverse events: three due to infection, two due to leakage and one because of hypotension. The mean residual lifetime was 77 days.

CONCLUSIONS. We established that implantation of the permanent peritoneal PleurX catheter is a safe and efficient treatment of RMA. We emphasise the importance of early detection and intervention in the management of RMA by implantation of a permanent peritoneal catheter.

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Refractory malignant ascites (RMA) poses a major clinical challenge. RMA is associated with reduced quality of life due to the symptom burden and the need for repeated hospitalisations [1].

In 2015, we described our first experience with implantation of the permanent PleurX catheter system for treating RMA in 20 patients [2]. This tunnelled, indwelling catheter provides a direct connection between the peritoneal cavity and an external drainage system, enabling continuous removal of accumulated ascites. In this small study population, we showed that the permanent PleurX system is a minimally invasive and effective procedure in an outpatient setting with only minor adverse events and a high rate of catheter patency.

The aim of this study was to evaluate the treatment of RMA by implantation of the permanent system in the largest cohort to date.

Methods

This was a retrospective study of terminal cancer patients with a permanent PleurX (CareFusion Catheter System, McGaw Park, IL, USA) catheter implanted for RMA palliation from August 2015 to January 2021.

A total of 97 consecutive patients were identified (**Table 1**). Contraindications for implantation were non-correctable coagulopathy and peritonitis. No patients declined to have a permanent PleurX catheter implanted. All patients, including liver cancer patients, had signs of carcinomatosis on CT.

TABLE 1 Demographics and distribution of primary cancers (N = 97).

	n (%)	Median (range)
Demographics		
Female:male	63:34	
Age, yrs		72 (37-92)
Type of cancer		
Ovarian	25 (26)	
Bile duct	9 (9)	
Breast	9 (9)	
Pancreas	8 (8)	
Colon	7 (7)	
Liver	7 (7)	
Lung	10 (10)	
Renal cell carcinoma	3 (3)	
GI cancer	7 (7)	
Melanoma	1 (1)	
Unknown primary cancer	10 (10)	

GI = gastrointestinal.

Data were collected from medical records. The follow-up period ran from the date of PleurX placement to the end of data collection in April 2021 or until death.

Technical success was defined as the successful placement of the PleurX catheter with prompt drainage of ascites. Adverse events (AEs) were categorised according to the time they appeared: 1) intraprocedural AEs, 2) early AEs occurring during the first seven post-procedural days and 3) late AEs occurring after more than seven days. Procedure-specific AEs were graded according to the Common Terminology Criteria for Adverse Events – version 4.0 [3].

We have previously described the procedure of implanting a permanent PleurX catheter [2]. In brief, accumulation of ascites and an optimal placement of the PleurX catheter was established by ultrasonography. Two skin incisions were made, one for guidewire insertion and one for catheter exit. Over the tunnelling guidewire, the catheter was placed subcutaneously. By introducer, the catheter was further inserted into the peritoneal cavity. Lastly, the catheter was connected to a catheter bag, ensuring free flow and successful catheter placement. No prophylactic antibiotics were administered. The international normalised ratio (INR) was measured before implantation.

Trial registration: not relevant.

Results

A total of 97 (63 female, 34 male) patients with RMA were treated (Table 1), all on indication of RMA. Forty patients (41%) had more than five paracenteses before catheter implantation (**Table 2**). Pre-procedural symptoms of RMA included abdominal discomfort (87%), nausea (33%) dyspnoea (30%), oedema of lower extremities (13%), vomiting (11%) and constipation (7%).

TABLE 2 Number of paracenteses prior to implantation of permanent PleurX catheters and treatment of primary cancer[a] (N = 97).

	n (%)
Paracenteses prior to permanent catheter	
≤ 5	50 (52)
> 5	40 (41)
None/unknown	7 (7)
Treatment of primary cancer	
Chemotherapy	76 (78)
Surgery	21 (22)
Radiation therapy	6 (6)
Biological treatment	6 (6)
TACE/RFA	3 (3)
None	12 (12)

RFA = radiofrequency ablation; TACE = transcatheter arterial chemoembolisation.
a) Some cancers were treated with > 1 treatment.

In 96 of 97 patients (99%), implantation was successful. The one unsuccessful implantation was due to a lack of ascites. All catheter procedures were performed during hospital admission with a median hospitalisation length of one day (range: 1-27 days). For 85 patients, the median drainage volume of RMA 24 h after the procedure was 3,800 ml (range: 700-12,100 ml). All patients experienced immediate symptom relief. Most patients were subsequently admitted to the hospital due to issues with their cancer disease; only six (6.2%) patients were re-admitted due to issues with their PleurX catheter (**Table 3**). Among these six patients, reasons for admission were infection around the catheter site (n = 2), leakage from the catheter site (n = 2), hypotension (n = 1) and pain around the catheter site (n = 1). Two catheters had to be removed without re-implantation, two catheters were removed with reimplantation of a new permanent PleurX catheter, one catheter was adjusted and one catheter was left in place with no further intervention.

TABLE 3 Characterisation of adverse events and catheter patency (N = 97).

Adverse event	Grade[a]	n (%)
Early		
Catheter dislocation	3	1 (1)
Late		
Hypotension	1	1 (1)
Leakage from catheter site	1	1 (1)
Infection at catheter site	2	3 (3)

a) According to the Common Terminology Criteria for Adverse Events. Version 4.0 [3]: Grade 1: minor; Grade 2: moderate; Grade 3: severe; Grade 4: life-threatening; Grade 5: death.

Four patients (4.1%) were alive at the end of the follow-up period; their catheters were still functioning with a median implantation period of 60 days (range: 33-87 days). A total of 93 patients (96%) died during the follow-up period. All deaths were due to malignant disease. Mean residual lifetime after implantation with a functioning catheter was 77 days (range: 1-1,147 days).

Discussion

This study establishes the safety and efficacy of implanting a permanent PleurX catheter for treatment of RMA in terminal cancer patients in the most extensive study cohort reported to date.

In total, 97 PleurX catheters were implanted with a technical success rate of 99% (n = 96). The same high technical success rates have been shown in other studies [2, 4-6].

Six patients (6%) experienced AEs; two had a minor AE due to leakage from the catheter site, which was successfully treated with catheter adjustment. In two patients, moderate AEs were noted due to infection, and both were treated successfully with antibiotics. One patient had re-infection, and the peritoneal catheter was

removed permanently. The incidences of leakage, catheter-related infections and incidence of hypotension (1%) and pain (1%) are all comparable to results by Richard et al., Stukan and Macken et al. [4, 7, 8]. Peritonitis is a dreaded complication in regards to implantation of a permanent catheter into the abdominal cavity, but it was not seen in our population of 97 patients or a study comprising 28 patients by Trapping et al. [5].

In our data, the initial observation of immediate symptom relief for all patients following implantation of the PleurX catheter is noteworthy. After discharge, subsequent registrations of symptom relief were not performed systematically, but persisting symptom relief was presumed as no further hospital contacts were registered.

It was not possible for us to estimate catheter patency. The vast majority of the patients in our study died within a short time and with a well-functioning catheter. However, some patients lived with a functioning catheter for more than 100 days. In one patient, the catheter remained in situ and functioning for 1,137 days. Our findings indicate that the permanent PleurX catheter has a patency that exceeds the life expectancy of patients with terminal cancer disease.

Our study showed a mean residual lifetime with a functioning catheter of 77 days; similar to results found in previous studies [2, 4, 9]. This relatively short residual lifetime underlines the advanced stage and terminal nature of the patient's disease and emphasises the importance of early detection and intervention.

Two major strengths of the present single-centre study are the high number of consecutive patients included and the completeness of follow-up data owing to the data recorded in the Danish National Patient Registry.

The retrospective design holds some reservations in terms of interpretations of results, introducing a potential risk of selection and information bias. However, a randomised trial would, in our opinion, be unethical in these terminal cancer patients with very short life expectancy.

For future studies, we suggest a systematic follow-up for patient-reported outcomes that exceed the immediate post-implantation period. This may ensure exact data on symptoms, catheter comfort and functionality, and overall quality of life.

Conclusions

We established that implantation of the permanent peritoneal PleurX catheter is a safe and efficient treatment of RMA. We emphasise the importance of early detection and intervention in managing RMA by the implantation of a permanent peritoneal catheter.

Correspondence *Marie Riis Mortensen*. E-mail: marieriis@live.dk

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