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PleurX drain use in the management of malignant ascites: safety, complications, long-term patency and factors predictive of success

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Objectives: The aim of this article was to assess the success, safety, complication profile and factors associated with long-term patency of tunnelled peritoneal drains (PleurX) in the treatment of refractory malignant ascites.
Methods: Over a 4-year period, 28 consecutive patients (32 drain insertions) with refractory malignant ascites were treated with a PleurX drain. The study group comprised 7 males and 21 females (mean age, 61 years). A combination of fluoroscopic and ultrasound guidance was used to insert 4 drains; the remaining 28 drains were inserted under ultrasound guidance alone. Patient history, biochemical profiles, pathological and procedural records and clinical follow-up until death were reviewed. Statistical analysis included multivariate logistic regression analysis and Kaplan–Meier curves ($p<0.05$ was considered significant).
Results: There was a 100% technical success rate for the insertion of the drain; there were no procedure-related deaths and no major complications. Only minor complications were reported: three (10%) immediate; three (10%) early; and two (7%) late. Factors significantly associated with these complications included current chemotherapy, low haemoglobin levels, low albumin levels, high white cell count and high c-reactive protein levels. The length of time the drains remained *in situ*, and therefore patent, ranged from 5 to 365 days (mean, 113 days). Out of the original 28 tunnelled drains, 24 (86%) remained *in situ* and functioning until the patients' death. Four (14%) drains dislodged and a subsequent PleurX drain was inserted on the opposite side of the abdominal wall. These new drains remained patent until the patient's death. The annual event rate was 0.45 events per year. A comorbid diagnosis of renal disease or chemotherapy was significantly related to a decreased length of patency.
Conclusion: The use of tunnelled peritoneal drains is safe and effective and we would advocate their use as a first-line approach in patients with refractory malignant ascites. Care and regular follow-up is indicated following insertion of the drain in all patients, especially those on chemotherapy and those with a pre-procedure diagnosis of renal disease.

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The development of ascites is usually a manifestation of terminal metastatic malignancy with anticipated life expectancy ranging from 1 to 4 months [1]. Intractable ascites is usually caused by peritoneal infiltration, liver metastases causing secondary portal venous compression, lymphangitic carcinomatosis, lymphatic obstruction or a combination of these factors. Distressing symptoms include tense abdominal distension, early satiety, nausea and vomiting, reflux oesophagitis, shortness of breath, lower limb oedema, fatigue and reduced mobility. 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 [2–4]. These approaches can have a significant impact on patients' remaining quality of life.

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Various studies have found that the PleurX catheter is an effective option for the management of malignant ascites with a low complication rate [5–7]. The PleurX drain is a tunnelled indwelling peritoneal catheter that can be managed at home to remove small (500 ml) aliquots of ascites on a regular basis or when it becomes symptomatic. Once the patient and their family have been shown how to use the drainage system and vacuum bottles, and how to recognise complications, patients can control and manage their ascites safely at home with minimal district nurse input. This also allows patients to limit the potential complications and frequent hospital admissions previously required for repeated paracentesis.

The aims of this study were to assess the success, long-term patency and complications associated with the use of PleurX drains in the management of malignant ascites. Furthermore, we wanted to assess the number of interventions and repeat hospital admissions required to maintain patency of the indwelling catheter. A secondary aim was to identify predictors of successful long-term catheter patency.

Methods and material

Our hospital research and ethics committee granted approval for this service evaluation. A prospective database of all cases of tunnelled long-term drain (PleurX; UK Medical, Sheffield, UK) insertion is kept in our department. Consecutive patients with malignant refractory ascites who had undergone this procedure were included in this study.

Although there are no strict guidelines, patients who had at least three recent standard ascitic drainages with the two most recent drainages less than 6 weeks apart (*i.e.* requiring frequent drainages) were considered suitable for this procedure. All of these patients were being treated for palliative/end of life care. In addition, if ascites was the main problem for a patient receiving chemotherapy, and a multidisciplinary team (MDT) review felt it would benefit a patient, then a tunnelled long-term drain was offered and inserted. All cases were performed by one of two consultant interventional radiologists between July 2005 and July 2009.

Data collected included patient demographics, current and past medical records, details of the procedure, technical success, site of the drain, complications during and following insertion, follow-up imaging and intervention and clinical details prior to their death. Biochemical data at the time of the procedure were also collected and included haemoglobin level, white cell count, platelets, prothrombin time, activated prothrombin time, c-reactive protein, bilirubin, alkaline phosphatase, aspartate transaminase and albumin. All patient records were reviewed retrospectively from the initial procedure until their death.

Technical success was defined as successful placement of the drain and drainage of ascites at insertion. Complications were classified into three groups: immediate, occurring less than 24 h from the procedure; early, occurring 24 h to 30 days from the procedure; and late, occurring ater 30 days from the procedure. The 30-day mortality and overall mortality were calculated. Procedural mortality was defined as death attributed directly to the procedure.

Procedural technique

The insertion of a tunnelled long-term abdominal drain (PleurX; Figure 1) was contra-indicated if any of the following were present: multiloculated ascites, non-correctable coagulopathy or infected peritoneal cavity. In our practice, we use a single dose of prophylactic intravenous cefuroxime (750 mg) and metronidazole (500 mg) given 30 min–1 h before the procedure. An aseptic technique is used and a prior ultrasound examination of the abdomen is used to identify a suitable location (*i.e.* the largest collection of ascites with no significant vascular structures nearby). Furthermore, patient comfort has to be considered and an appropriate tract that will not interfere with a patient's clothing and belt line is taken.

Given that a 16-French introducer needs to be introduced over the wire, it is safer to perform this procedure when there is a moderate amount of ascites. A site 6–10 cm below the costal margins lateral to the midline is chosen. Lidocaine (1%) is injected subcutaneously at the site of the drain and along the proposed track of the tunnelled line. Conscious sedation with 1–2 mg of midazolam can be used if requested by the patient. An 18-guage needle attached to a syringe is inserted obliquely through the abdomen and ascites aspirated. A guidewire is inserted through the needle and the needle is subsequently removed. A small incision is made into the skin at the guidewire insertion site and then a further incision is made 5–8 cm superiorly and medially. The fenestrated end of the catheter is attached to the tunneller, which is passed subcutaneously from the second incision to the guidewire insertion site. The catheter is drawn through the tunnel until the polyester cuff is approximately 1 cm inside the second incision (Figure 2). The tunneller is removed from the catheter and a 16-Fr introducer is placed over the guidewire into the peritoneal cavity. Once the guidewire and the dilator from the introducer sheath have been removed, the fenestrated end of the catheter can be introduced into the abdomen through the peel-away introducer until all the fenestrations are within the peritoneal cavity. The catheter is then clamped closed. The incisions are sutured closed and the catheter is sutured to the skin.

The drainage of ascites is performed by inserting the access tip from a PleurX drainage bottle (UK Medical) into the PleurX catheter valve, which clicks into place (Figure 3). The vacuum bottle will exert negative pressure and will drain 500 ml of fluid. Once the drainage bottle is removed from the valve it can be wiped clean and the catheter can be looped and secured to the patients abdomen with an adhesive dressing.

We initially drain the ascites into a catheter bag to allow a large amount of ascites to be drained while in

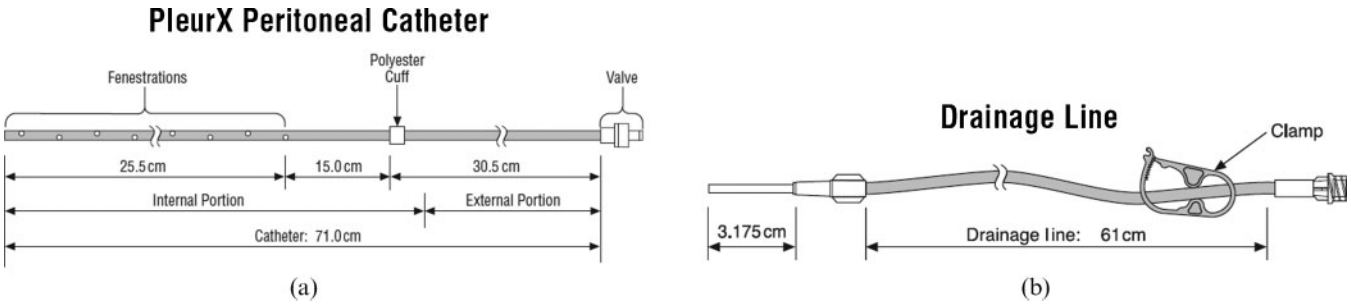

Figure 1. (a) Dimensions and location of various components of the PleurX peritoneal catheter (UK Medical, Sheffield, UK), (b) Dimensions of the drainage line. (Figure reproduced courtesy of CareFusion Corporation or one of its subsidiaries, 2010. All rights reserved.)

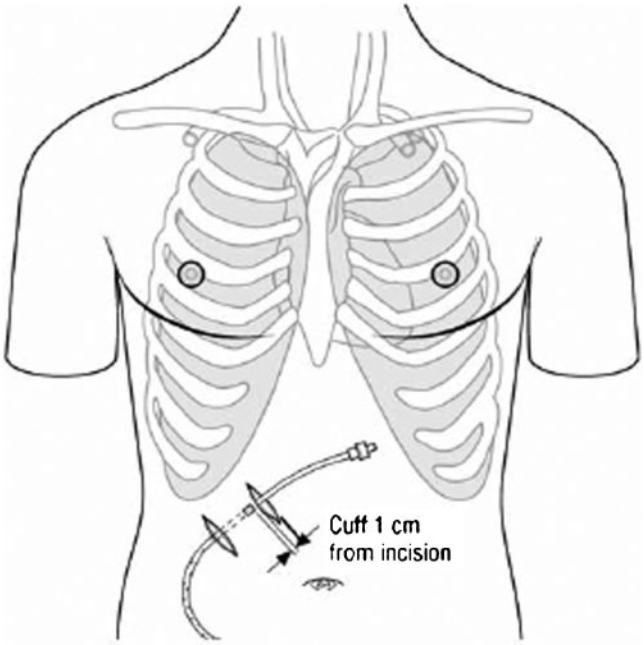

Figure 2. Ideal location of the tunnelled drain indicating the site of the incisions and the location of the cuff. (Figure reproduced courtesy of CareFusion Corporation or one of its subsidiaries, 2010. All rights reserved.)

hospital under supervision. The patient remains in the department for 30 min and is monitored closely for the next 2 h. They then remain as an inpatient for up to 24 h or until the initial abdominal ascites is drained. Once the patient knows how to use the device, they are allowed home with a stock of vacuum bottles for drainage. We advise that a patient does not drain more than 500 ml (one standard vacuum bottle) every 12 h. This avoids hypovolaemia and hypokalaemia. The patient is advised to drain early and frequently rather than wait till their abdomen becomes distended and uncomfortable. A district nurse (trained in the aftercare of these drains) visits the patient on a regular basis as part of their overall care. In our practice, the patients are given a direct phone number to contact a specialist nurse in our department if they experience any problems with the drains.

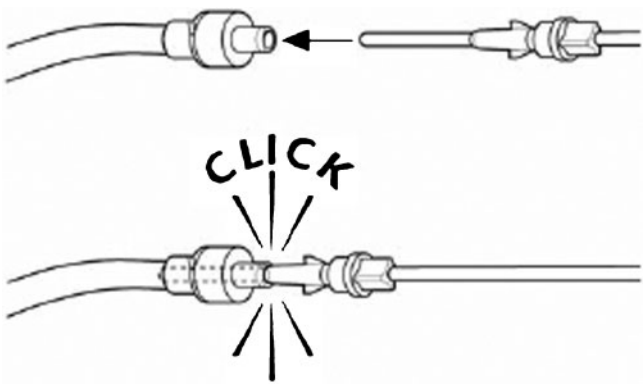

Figure 3. Simple mechanism for attaching the end of the tunnelled drain into one of the 500 ml drainage bottles. (Figure reproduced courtesy of CareFusion Corporation or one of its subsidiaries, 2010. All rights reserved.)

Statistical evaluation

Statistical analysis was performed with SPSS V.14 [IBM Corporation (formerly SPSS Inc.), Armonk, NY]. Kaplan–Meier curves and multivariate logistic regression analyses were performed. A p-value of <0.05 was considered to indicate a significant difference.

Results

Over a 4-year period, 28 patients were treated in our institution with a long-term tunnelled abdominal drain for refractory malignant ascites; 4 patients had 2 drains inserted, giving a total of 32 long-term drains inserted. The study group included 7 males and 21 females (age range 43–91 years; mean, 61 years). The primary tumour was gastrointestinal in origin in 7 cases, lung in 3 cases, gynaecological in 10 cases, pancreatic in 5 cases and breast in 3 cases. Three patients had their drain inserted under conscious sedation. Four patients had a comorbid diagnosis of significant renal disease (glomerular filtration rate $<60\,ml\,min^{-1}\,1.73\,m^{-2}$), seven had a diagnosis of hypertension (medically managed currently normotensive), seven had a diagnosis of ischaemic heart disease (three patients who had a history of myocardial infarction and four patients with medically managed angina) and seven had diabetes (all Type 2 and on medical management).

The technical success rate was 100%. There were no vessels injured during drain insertion, no bowel perforations and no procedure-related deaths. Of the 32 insertions, 9 were to the left side of the abdomen and 23 were to the right side. Four procedures were performed with a combination of fluoroscopic and ultrasound guidance and the remaining 28 with ultrasound guidance only. Patients had an average of 5000 ml of ascites (range 3500–7000 ml) drained before they returned home to continue drainage as per the protocol above. Hospital inpatient stay was less than 1 day.

Length of time in situ

The length of time the drain remained *in situ* ranged from 5 to 365 days (mean 113 days, 95% confidence interval 70–157 days) (Figure 4a). The cumulative number of days the drains were *in situ* in all patients was 3152 days. Out of the original 28 tunnelled drains, 24 (86%) remained *in situ* and functioning until the patients' death. The drains of 4 (14%) patients were dislodged and a new drain was inserted into the opposite side of the abdomen without complication. This gave an annual event rate of 0.45 events per year. These episodes happened at 23 days, 29 days, 40 days and 42 days post-insertion. The second drains inserted remained *in situ* until the patients' death. A co-morbid state of renal failure and concurrent or recent (within the past 3 months) chemotherapy use was statistically significantly related to a decreased length of time *in situ* (Figure 4b,c).

Complications

No deaths were caused by drain insertion or related to a complication of drain insertion. The 30-day mortality

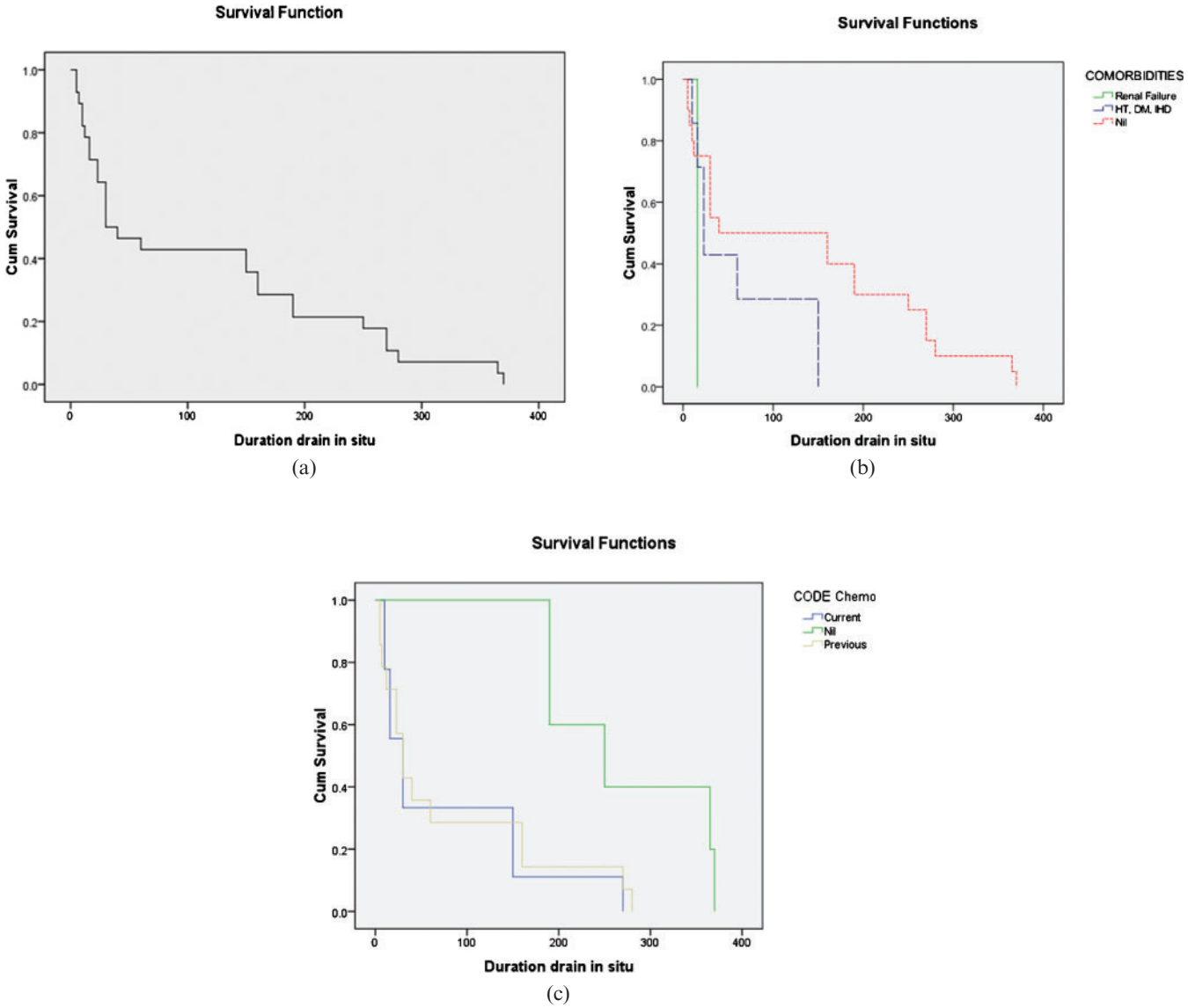

Figure 4. Kaplan–Meier patient survival curves showing (a) the interval between drain placement and drain failure or patient death, (b) comorbid factors (Log rank $p=0.041$) and the interval between drain placement and drain failure or patient death and (c) chemotherapy status (Log rank $p=0.022$) and the interval between drain placement and drain failure or patient death. DM, diabetes mellitus; HT, hypertension; IHD, ischaemic heart disease.

was 11 patients (39%), which was attributed to the underlying medical diagnosis and its advanced state.

There were no procedural complications during drain insertion and there were no major complications during follow-up. Minor complications were divided into immediate (<24 h), early (24 h to 30 days) and late (>30 days).

There were three (10%) immediate minor complications, which included a leak from the puncture site that was treated by application of a colostomy bag. The leak ceased after drainage of the ascites over the following week and did not return. The district nurse visited this patient daily. There were two cases of discomfort, erythema and small exudative discharge around the catheter entry site. These were swabbed and a positive culture grown. There was no evidence of systemic infection or peritonitis. These cases were treated with a 7-day course of oral antibiotics.

There were three (10%) minor early complications reported, which included three cases of erythema and discharge from the wound entry site without any systemic features of infection (swab positive growth obtained). All cases were treated with oral antibiotics for 7 days.

There were 2 (7%) late minor complications, which included an incisional site hernia occurring 310 days from drain insertion. The patient did not have any complications from this and it was not repaired.

Multivariate regression analysis revealed that the independent factor significantly associated with immediate, early and late complications was current chemotherapy use ($p=0.003$, $p=0.004$ and $p<0.001$, respectively). Early complications were related to low haemoglobin levels ($p=0.004$), low albumin levels ($p=0.037$), high c-reactive protein ($p=0.02$) and high white cell count ($p=0.037$).

Discussion

The use of a tunnelled indwelling peritoneal drain in patients with refractory symptomatic malignant ascites is feasible and well tolerated, with low levels of complications. We treated 28 patients and they were able to drain the accumulated fluid at home following a simple treatment guideline. There were low levels of re-interventions and re-admission to hospital. Although a cost analysis was not performed in this study, we believe the use of an indwelling tunnelled catheter provides a superior and cost-effective alternative to repeat inpatient paracentesis.

The most popular treatment method used by physicians to treat refractory ascites is repeated paracentesis [8] and although successful it has well-documented risks, which include infection, bowel injury and haemorrhage. The frequent trips to hospital required to maintain drainage and alleviate symptoms also make this method of treatment less than ideal. Furthermore, the associated morbidity of repeated peritoneal needle punctures and drainages, which include hypovolaemia and protein loss, contribute to patients' dissatisfaction with this technique. Patients often delay their visit to the hospital owing to the discomfort caused by the procedure, associated fatigue, dizziness and nausea following repeated paracentesis. Many patients wait and experience high levels of pain and discomfort before scheduling their next visit [9]. Such problems reported with repeated large volume paracentesis and caused by a significant reduction in serum protein have been shown to be reduced if small volume paracentesis is combined with a high protein diet [5, 10].

Peritoneovenous shunting is another technique used for draining ascites. However, this approach carries the risk of complications such as disseminated intravascular coagulopathy, cardiac failure and shunt malfunction [11]. In addition, the efficacy of intraperitoneal chemotherapy and immunotherapy are not well established [2, 3]. Diuretics and dietary restrictions are only effective in a small proportion of patients in whom the ascites is usually caused by portal venous compression. The use of non-tunnelled indwelling catheters is associated with a complication rate of 30% [12], which is greater than those seen in this series where we experienced four (14%) dislodgements requiring a further drain insertion and only minor complications.

This study demonstrated that 24 (86%) of the originally inserted drains were functioning and patent up until the patient's death. This compares well with the only other study to evaluate a similar number of patients with tunnelled peritoneal drains (85% patency at the time of death [6]). Furthermore, these authors emphasise that the protocol-specified objective performance criteria for drain patency is 35 days, and their results were superior with the lower limit of the 95% confidence interval at 86 days patency. Our results show a mean patency of 113 days and our 95% confidence interval of 70–157 days compares favourably with these results.

This study sought to identify factors associated with the length of time a drain remained *in situ* as well as factors associated with complications. We found that patients on chemotherapy were at a greater risk of complications. Furthermore, those on chemotherapy and those who had recently had chemotherapy had the drain *in situ* for a reduced length of time, and thus reduced drain patency, following insertion. Although no major complications occurred, minor complications required medical treatment (antibiotics for superficial infections). It is perhaps not surprising that patients on chemotherapy had more minor complications. This is probably due to the systemic side effects of the cytotoxic substances and reduced immunity. Owing to the relatively small number of patients in this study group, the exact regime of chemotherapy that produces most complications cannot be established. A consideration is to only perform the drainage procedure after the chemotherapy has finished. However, in our practice we agree to insert the drains following an MDT decision that the benefits outweigh the small increased risk of infection. All of the patients who were on chemotherapy had significant discomfort from their ascites and, although we did not perform an objective measure of satisfaction, the patients were more comfortable following drainage even with the added inconvenience of taking oral antibiotics for localised infections. Our considered decision is to continue offering tunnelled drains to patients on chemotherapy but to monitor them more closely at home with more frequent district nurse visits, especially in the first week following insertion. We will also emphasise the need for regular drain site monitoring to these patients and their families.

A further group of patients identified in this study as requiring more frequent follow-up are those patients with a pre-procedure diagnosis of renal disease. These patients had the drain *in situ* for a significantly shorter length of time. Although likely to be related to their advanced state of malignancy, this factor requires further research to establish a causal relationship and to identify the most appropriate follow-up of these patients.

Limitations

The authors acknowledge that this study has limitations. Although the procedure-related database is prospectively maintained and all complications are regularly logged by the district nursing staff, the authors did not contact the patients at home and no quality of life data were obtained. Furthermore, follow-up blood samples were not taken after the patient returned home. This is most important in the patients with renal disease and further studies here are required as this group might require closer follow-up. Unfortunately, there was no comparison group and a prospective randomised trial to fully assess the tunnelled peritoneal drains might be warranted.

Conclusions

The drainage of refractory malignant ascites with a tunnelled peritoneal (PleurX) drain is a safe, effective and relatively easy technique to perform. It is a feasible way for patients undergoing palliative treatment to spend as much time as possible at home. This has financial implications as well as implications relating to time and resource allocation. The simplicity of the equipment means that patients and/or their family or carers can use it. In addition to these benefits, 86% of patients had no drain failures and those who did were

treated with a second successful drain. Care and regular follow-up is required for patients on chemotherapy and those with renal disease. We would advocate a tunnelled peritoneal (PleurX) drain as the first-line approach in patients receiving palliative care for refractory malignant ascites.

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Conflict of interest

The authors have no financial interest in the companies mentioned in this paper.

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