

The use of the PleurX catheter in the management of non-malignant pleural effusions

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Abstract

Purpose: To evaluate the effectiveness of the PleurX catheter in the management of recurrent non-malignant pleural effusions. **Methods:** All subjects who underwent a PleurX catheter placement between 2003 and 2009 were evaluated. General demographic data, time to pleurodesis, complications, and a satisfaction questionnaire were collected. The subjects were divided into two groups. Group I included patients with non-malignant effusions and group II included patients with malignant effusions. **Results:** A total of 64 subjects were included in the final data analysis. A total of 23 subjects were included in group I and 41 subjects were included in group II. The diagnoses in group I included congestive heart failure (CHF; 13), hepatic hydrothorax (8), traumatic bloody (1), and idiopathic exudative (1). The diagnoses in group II included lung cancer (20), breast cancer (11), colon cancer (5), prostate cancer (2), B-cell lymphoma (2), and mesothelioma (1). The time to pleurodesis was 36 ± 12 days for group II compared to 110.8 ± 41 days for group I ($p < 0.0001$). The mean satisfaction score was similar in both groups (3.8 ± 0.4). Time to pleurodesis was significantly shorter in hepatic hydrothorax compared to CHF (73.6 ± 9 days vs. 113 ± 36 days, $p = 0.006$). There was one case of exit site infection in a patient with hepatic hydrothorax. Among subjects who were alive at 3 months after the catheter removal, none had recurrence of their pleural effusion. **Conclusion:** The Denver catheter was effective in achieving pleurodesis in non-malignant pleural effusions. The complication rate was low and patient satisfaction was high.

Keywords

Pleural, non-malignant, PleurX, Denver, pleurodesis

Introduction

Recurrent non-malignant pleural effusions are a fairly common problem in clinical practice, and sometimes difficult to treat.¹ The first step in the management of these effusions is treating the underlying cause. Sometimes these effusions persist despite optimal treatment of the underlying condition, and further management may involve repeated thoracenteses, chest tube placement with chemical pleurodesis, or even surgical pleurodesis.^{2–10} Some of the above procedures involve admission to an inpatient setting that can result in significant morbidity, discomfort, and pain.^{2,3,7}

The PleurX catheter (Denver Biomedical, Golden, CO, USA) has been used to treat recurrent malignant pleural effusions on an outpatient basis. It is placed

under local anesthesia with or without conscious sedation. It is tunneled subcutaneously for about 5 cm and then inserted into the pleural cavity.^{11–13} With the help of a family member or a health care professional, the catheter can be connected to a vacuum bottle on a daily or every other day basis to drain 500 ml of pleural fluid. In malignant pleural effusions, this device usually

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achieves auto-pleurodesis in approximately 6 weeks, and it can then be removed using local anesthesia.^{11,14,15}

There is very limited experience with the use of the PleurX catheter in the management of non-malignant pleural effusions, and the available data from a small case series suggest a high complication rate.¹⁶ The purpose of this study is to evaluate the effectiveness of the PleurX catheter in achieving pleurodesis in subjects with recurrent non-malignant pleural effusions.

Materials and methods

All patients who underwent a PleurX catheter for recurrent pleural effusions between 2003 and 2009 were evaluated. The following data were collected: age, sex, diagnosis (etiology of the pleural effusion), time to pleurodesis, number of thoracenteses prior to the PleurX catheter placement, and complications. Complications related to the PleurX catheter were divided into two main categories. Immediate complications defined as pneumothorax, bleeding or pain at the insertion site or unsuccessful placement of the catheter; and delayed complications defined as wound infection, empyema, bleeding at the extraction site, and electrolyte disturbances in patients with benign pleural effusions, or hypotension. Patients with benign pleural effusions and PleurX catheter had multiple blood tests for electrolytes and liver function testing by their referring physicians. The results of those blood tests as well as the medication list of every patient were reviewed during each follow-up visit. In addition, subjects were asked to complete a satisfaction questionnaire developed by the investigators for quality assurance purposes. The satisfaction questionnaire was graded 1 (I was not happy with the procedure and I will never have it again); 2 (I was not happy with the procedure but I may have it again if needed); 3 (I was happy with the procedure and I may have it again if needed); and 4 (I was very happy with the procedure and I will have it again if needed). The patients were asked to complete the questionnaire during their follow-up visit after the catheter was removed.

Light's criteria were used to distinguish exudative from transudative pleural effusions.^{17,18} Malignant pleural effusions were defined by the presence of malignant cells in the pleural fluid on cytologic examination. The patients were selected to have the PleurX catheter placement if they fulfilled the following criteria; at least two therapeutic thoracenteses within 4 weeks time, and significant symptomatic relief following each thoracentesis. Subjects with trapped lung

were excluded. Trapped lung was defined as the failure of the lung to fully expand after thoracentesis or chest tube placement. There were three subjects with lung cancer and trapped lung who had the PleurX catheter but were not included in the data analysis.

During their follow-up visit after the PleurX catheter placement, the patients and their family members were instructed on drainage techniques and infection control. The subjects with no family members, or whose family members were unwilling or unable to perform the drainage, had arrangements for visiting nurse services. The subjects were drained every day up to 500 cc until the drainage was less than 100 cc; then they were drained every other day until the drainage was less than 25 cc.

Time to auto-pleurodesis was defined as the time from the insertion of the PleurX catheter to the first time the patient reported fluid drainage less than 25 cc on three consecutive drainages. Clinically, relevant recurrence was defined as an ipsilateral pleural effusion that occurred after the removal of the PleurX catheter and required drainage for symptomatic relief. The PleurX catheter was placed using the Seldinger technique under local anesthesia with conscious sedation. The patients were positioned in a 45° sitting position. The catheter was placed in the fifth intercostal space between the mid and anterior axillary lines. The subjects were divided into two groups. Group I included patients with non-malignant pleural effusions, whereas group II included patients with malignant pleural effusions. The study was a retrospective chart review analysis and it was approved by the Institutional Review Board.

Statistics

Descriptive data analysis was performed with SPSS 14 for windows (SPSS Inc., Chicago, IL, USA). Data were presented as mean \pm SD (standard deviation) unless otherwise specified. Two-tailed *p* values were reported. A *p* value of <0.05 indicated a statistically significant difference between groups.

Results

Demographic and baseline characteristics

A total of 64 subjects were included in the final data analysis. A total of 23 subjects were included in group I (non-malignant pleural effusions) and 41 subjects were included in group II (malignant pleural effusions). There were 13 men and 10 women in group

Table 1. Outcomes of patients with malignant versus non-malignant pleural effusions^a

	Non-malignant (I)	Malignant (II)	p Value if applicable
Number of patients	23	41	
Age (years)	76 ± 13	71 ± 13	NS
Men, n (%)	13 (57)	18 (44)	NS
Women, n (%)	10 (43)	23 (56)	NS
Time to pleurodesis (days)	110.8 ± 41	36 ± 12	<0.0001
Complications	1	0	NS
Recurrence	0	0	NS
Satisfaction score	3.8 ± 0.4	3.8 ± 0.4	NS

NS: non-significant, recurrence: recurrence at 3 months follow-up.

^a Results are mean ± standard deviation.

Table 2. Outcomes of patients with congestive heart failure compared to hepatic hydrothorax^a

	CHF	Hepatic hydrothorax	p Value
Number	13	8	NS
Men, n (%)	8 (62)	6 (75)	NS
Women, n (%)	5 (38)	2 (25)	NS
Age (years)	77.8 ± 10	56 ± 5	0.002
Right effusions, n (%)	12 (92)	8 (100)	NS
Left effusions, n (%)	1 (8)	0 (0)	NS
Time to pleurodesis (days)	113 ± 36	73.6 ± 9	0.006
Thoracenteses prior to PleurX insertion	3.2 ± 0.8	3.5 ± 0.9	0.8

NS: non-significant, CHF: congestive heart failure.

^a Results are mean ± standard deviation.

I (57% and 43%, respectively) compared to 18 men and 23 women in group II (44% and 56%, respectively; Table 1). The mean age was not statistically different between the two groups (76 ± 13 years for group I compared to 71 ± 13 years for group II). The diagnoses in group I included congestive heart failure (CHF; 13), hepatic hydrothorax (8), traumatic bloody (pleural fluid to serum hemoglobin ratio less than 50%; 1), and idiopathic exudative effusion (1). The diagnoses in group II included lung cancer (20), breast cancer (11), colon cancer (5), prostate cancer (2), B-cell lymphoma (2), and mesothelioma (1).

Previous management prior to PleurX catheter placement

For patients with malignant pleural effusions, the PleurX catheter was the initial procedure if the patients fulfilled the inclusion criteria described in materials and methods. The patients with non-malignant pleural effusions, in addition to the inclusion criteria, must have been optimized medically as documented by their

referring physicians. For subjects with hepatic hydrothorax and CHF, the referring physician documented failure of maximal medical therapy before referring the patients for further management of their pleural effusions.

Pleurodesis and recurrence

The time to pleurodesis was 36 ± 12 days in group II (malignant pleural effusions) compared to 110.8 ± 41 days in group I (non-malignant pleural effusions; $p < 0.0001$). All patients who did not die during the follow-up period achieved pleurodesis (see below for cause of death). Among patients with non-malignant pleural effusions, those with hepatic hydrothoraces were significantly younger than those with pleural effusions secondary to CHF (56 ± 5 years vs. 77.8 ± 10 years). Furthermore, the time to pleurodesis in hepatic hydrothoraces was significantly shorter than the time to pleurodesis in CHF (73.6 ± 9 days vs. 113 ± 36 days, $p = 0.006$; Table 2). In subjects who were alive at 3 months after the catheter removal, no patients in either

group had a clinically significant recurrence or required drainage of the pleural fluid.

Complications

Except for post procedure pain, there were no occurrences of immediate complications related to the PleurX catheter placement (pneumothorax, bleeding, or unsuccessful placement). Post procedure pain was present in 12 patients: 8 patients with malignant pleural effusions and 4 patients with non-malignant pleural effusions. The pain lasted from 2 days to a maximum of 6 days, and was easily controlled with a combination of acetaminophen and tramadol. There was one case of exit site infection in a patient with hepatic hydrothorax. The subject had local symptoms of itching and redness; signs included erythema and slight edema at the exit site. There was no evidence of systemic inflammatory response, such as fever, tachycardia, tachypnea, or increased or decreased white cell count. The evaluation of pleural fluid revealed no evidence of infection. The pleural fluid remained transudative by LDH, and protein ratio criteria, and the blood as well as the pleural fluid cultures were negative. The infection was successfully treated with oral combination of amoxicillin and clavulanate (10 days course), and topical application of 2% mupirocin cream. The catheter should not be removed before successful pleurodesis. There were 3 deaths in group I and 10 deaths in group II. None of the deaths were related to pleural effusions or catheter-related complications. In group I, three deaths occurred before the removal of the PleurX catheter. One patient died of myocardial infarction and resulting cardiogenic shock, and two patients died of respiratory failure related to hepatic encephalopathy. In group II, three deaths occurred before the catheter removal and seven deaths occurred between the time of catheter removal and 3 months. All deaths in group II were related to terminal malignancy.

There was no incidence of significant electrolyte disturbance requiring intervention other than adjusting potassium supplementations in five subjects with benign pleural effusions. There were no documented episodes of hypotension, nor there were any changes in the patients' diuretics use after the PleurX catheter was placed.

Patients' satisfaction

A total of 58 subjects (20 subjects with benign pleural effusions and 38 subjects with malignant pleural

effusions) completed the satisfaction questionnaire. Patients' satisfaction was high in both groups. The mean satisfaction score was similar in both groups (3.8 ± 0.4).

Discussion

Our results show that the PleurX catheter is effective in achieving auto-pleurodesis in non-malignant as well as malignant pleural effusions. This is the second largest case series to evaluate the usefulness of the PleurX catheter in the management of recurrent non-malignant pleural effusions.¹⁹ Although most patients with CHF or pleural effusions related to end stage liver diseases can be adequately managed medically, some fail medical management and the physician is confronted with symptomatic patients that require recurrent thoracenteses for symptomatic relief. Besides therapeutic thoracenteses, treatment options are limited to chest tube placement with chemical pleurodesis^{6,7,20} or less commonly surgical pleurodesis.^{9,10} In the case of hepatic hydrothorax, closure of diaphragmatic holes if present is also performed during the surgical exploration.^{6,21} Another therapeutic option for recurrent hepatic hydrothoraces is placement of transjugular intrahepatic portosystemic shunts (TIPS).^{22,23} In addition, few small series have reported on the use of pleuro-peritoneal shunts or pleuro-venous shunts for the treatment of refractory non-malignant pleural effusions.²⁴⁻²⁷

Chest tube placement for hydrostatic pleural effusions may lead to confinement to hospital beds for prolonged periods of time resulting in increased risk of nosocomial infections, pressure skin ulcers, and other hospital-related complications.²⁸ This prolonged hospitalization likely results in a significant increase in the overall medical cost.²⁷ The PleurX catheter eliminates these complications since the procedure is performed on an outpatient basis. Our study demonstrated that not only was the PleurX catheter effective in achieving pleurodesis in all patients; it also had a low rate of catheter-related complications and high satisfaction scores. There was only one case of exit wound infection that was likely due to poor local care at home. The site infection was successfully treated with oral and topical antibiotics and local care. The catheter should not be removed prior to successful pleurodesis. There were no reported episodes of electrolyte imbalance or hypotension.

Our study is in agreement with a recent abstract by Borgeson et al.²⁹ that showed similar results. The

mean time to pleurodesis was 109 days, and the rate of infection was low at 8%. Our findings along with Borgeson's are in contradiction with the study by Herlihy et al.,¹⁶ where in a small series of five patients with CHF and PleurX catheter placement, two patients (40%) developed empyema. One of them died of sepsis and multiple organ failure.¹⁶ The very small size of Herlihy's series makes drawing conclusions very difficult. The difference could also be related to a different patient population, as well as to a different socioeconomic status and social support. With an average time to pleurodesis of over 100 days, local care and aseptic techniques during drainage play a major role in preventing septic complications. Possible explanations of the low rate of infection in our series could be related to the extensive counseling and teaching of the patients and their family members responsible for the drainage about infection control and the importance of sterile techniques. In addition, 36 subjects (56%) had trained visiting nurses perform the drainage.

Some earlier reports caution about continuous drainage in subjects with hepatic hydrothorax. The potential risks include hypotension, renal insufficiency, nutritional deficiency, and increased risk of infections secondary to increased loss of proteins and immunoglobulins by the continuous drainage.³⁰ In the present study, none of the patients with hepatic hydrothorax and PleurX catheter experienced any of the above described complications. There were no reported cases of hypotension, change in the diuretic regimens secondary to renal injury or reports of increased blood urea nitrogen or creatinine. One possible explanation for the lack of these adverse events is the intermittent nature and small amount of fluid drained at each session, never exceeding one bottle of 500 ml. In addition, the every-other-day regimen would probably allow enough time for restoration of intravascular volume before the next drainage. The placement of TIPS for recurrent hepatic hydrothoraces has been described. This therapeutic intervention seems attractive for controlling recurrent hepatic hydrothoraces. However, TIPS is expensive. It can thrombose or stenose frequently, and most importantly, is complicated by post-TIPS encephalopathy in 15%–30% of cases.^{31,32}

The mechanism by which the PleurX catheter achieves auto-pleurodesis is not well understood. It is possibly related to an inflammatory reaction that develops in response to a foreign object in the pleural space.^{14,33} With the inflammatory reaction at the pleural surfaces and the repetitive suctioning that occurs during vacuum drainage, spontaneous pleural

symphysis occurs. The shorter time to pleurodesis in patients with hepatic hydrothoraces compared to patients with CHF could be related to increased levels of circulating inflammatory mediators in subjects with cirrhosis favoring more rapid pleural symphysis. Described circulating inflammatory mediators in cirrhosis include tumor necrosis factor- α , interleukin 1 β , interleukin 10, interleukin 1 receptor antagonist, and interleukin 6.³⁴

One limitation of this study is the lack of a control group consisting of subjects with non-malignant pleural effusions that were treated with other definitive therapies (chest tube placement with chemical pleurodesis, surgical pleurodesis, or TIPS) for comparison of outcomes, complications, satisfaction, or economic considerations. Future studies should focus on identifying a control group of patients treated without the PleurX catheter and comparing the rate of complications, recurrence, medical costs, and overall patient satisfaction. Another limitation of this study is the satisfaction questionnaire that has not been validated in earlier studies. The questionnaire was developed as a quality assurance tool, and even though it was not validated, it does give a fair idea that most patients were satisfied with the procedure of placement of the PleurX catheter and its removal, and were willing to have it performed again if needed.

Conclusion

The PleurX catheter is a safe, effective, and well-tolerated treatment of recurrent non-malignant pleural effusions. It helps achieve auto-pleurodesis on an outpatient basis, and should be considered when treating patients with recurrent non-malignant pleural effusions that are refractory to optimum medical therapy.

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