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Identification of clinical factors predicting Pleur$_x$® catheter removal in patients treated for malignant pleural effusion☆

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Abstract

Objective: The objective of the study was to review the clinical records of patients undergoing insertion of a Pleur$_x$® catheter in the management of malignant pleural effusions. In particular, clinical parameters were analyzed for their influence on catheter removeability. **Methods:** Between January 1998 and July 2006, 263 patients underwent insertion of 295 Pleur$_x$® catheters for malignant pleural effusion(s). Patients were allocated to one of four groups based upon the site of the primary tumor: group 1 (breast), group 2 (lung), group 3 (gynecologic), and group 4 (all others). A history of prior chest irradiation, cytologic analysis (positive or negative for malignant cells), and incidence of trapped lung were also studied to determine if, in addition to the primary site, these influenced the incidence of pleurodesis. **Results:** Overall, 58.6% of Pleur$_x$® catheters were removed prior to death. The incidence of spontaneous symphysis and catheter removal in groups 1 (69.6%) and 3 (72.5%) was significantly higher than in groups 2 and 4 ($p < 0.001$). In addition, absence of a history of chest wall irradiation, cytologic positivity and a trapped lung all influenced catheter removeability to a significant degree ($p < 0.001$). **Conclusions:** Pleur$_x$® catheters effectively relieve patients of dyspnea by evacuating the pleural space. Spontaneous pleural symphysis and catheter removal is more likely in patients with breast or gynecologic primary tumors, absence of chest wall irradiation, cytologic positivity, and complete re-expansion of the underlying lung.

Keywords: Pleural diseases; Malignant pleural effusion; Pleur$_x$® catheter; Trapped lung

1. Introduction

The development of a malignant pleural effusion is a common complication of advanced malignancies of many types, but especially breast, lung and ovarian carcinoma. For many patients, common symptoms such as fatigue, weight loss, and pain can be well-controlled using conventional chemotherapy and analgesics. However, for many patients the symptoms of dyspnea, and the associated risk of pneumonia, pose serious limitations to palliative care, and often require repeated hospitalizations. We have reported elsewhere on our clinical experience with a large group of patients with diverse malignancies complicated by symptomatic pleural effusions managed with the goal of providing palliative care in an outpatient setting using the Pleur$_x$® catheter (Cardinal Health Systems, McGaw Park, IL, USA). This review is an attempt to identify those clinical factors which can best predict which patients are most likely to have complete and spontaneous symphysis of the pleural space allowing for subsequent removal of the catheter.

2. Materials and methods

2.1. Patient population

The clinical records of patients undergoing placement of a Pleur$_x$® catheter during the period 1998–2006 were reviewed. For the purposes of this study, only patients having a Pleur$_x$® catheter inserted into the pleural space with an underlying diagnosis of advanced malignancy were included. Those patients having placement of the catheter into the peritoneal space for the relief of ascites, who had recurring pleural effusions from congestive failure (but were not suspected of having an underlying malignancy) or who had a chylothorax were excluded.

Patients were chosen based on the following selection criteria:

(1) established underlying diagnosis of malignancy,
(2) symptomatic pleural effusion,
(3) patient expected to survive beyond 30 days based on their clinical status,
(4) no underlying contraindications of coagulopathy, thrombocytopenia, or empyema.

No patient was denied placement of a catheter on the basis of skin implants of tumor, radiation-induced ulcera-

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tion or loculation of the effusion. Positive cytology on pleural fluid was not a prerequisite for offering a Pleur$_x$® catheter insertion. In cases where it was questionable whether or not the pleural effusion was responsible for the dyspnea (as opposed to an underlying pulmonary or cardiac condition), the patient underwent a diagnostic thoracentesis, but preoperative fluid drainage was not routinely performed.

2.2. Insertion technique

In all cases, the Pleur$_x$® catheters were inserted under sterile conditions in the operating room under local anesthesia occasionally with supplemental sedation and monitoring as the clinical condition merited. As discussed elsewhere, the Seldinger insertion technique we used avoided tunneling which is recommended by the manufacturer. Tunneling the catheter through the subcutaneous chest wall tissue was reserved for those patients in whom a loculated effusion could not be accessed through the axilla, who had cachexia such that there was minimal subcutaneous tissue, and those with extensive ulceration of the skin, especially in the axilla. In these cases, the catheter was tunneled to an exit site that was accessible to the patient, avoiding the posterior chest wall whenever possible.

2.3. Drainage protocol

Up to 1500 cc was drained immediately upon placement of the catheter, but drainage was stopped when the patient experienced either pleuritic chest pain, or an irresistible urge to cough. There was no incidence of perioperative re-expansion, pulmonary edema, bleeding, cardiac arrhythmias, or hypotension. A chest X-ray was taken in the recovery room after catheter insertion.

Preoperatively, patients were given an instructional videotape and clinical counseling on the management of these catheters. Postoperatively, they were provided with 30 vacuum drainage kits and dressings. They were instructed to drain up to 600 cc every day for the first 7 days (in order to evacuate the pleural space completely). Thereafter, they were asked to drain the pleural space every other day, until the drainage subsided to less than 50 cc/day (100 cc/every other day). Once this criterion was met, the offer was made to remove the catheter in the office under local anesthesia. It should be noted, however, that some patients demurred from having the catheter removed due to a fear that the fluid would re-accumulate, or due to transportation difficulties. Nevertheless, the date entered was the date the catheter was actually removed, not the date upon which this criterion for removal was met. When the catheter was removed, the catheter site was secured with a suture and the patients returned 1 week later.

2.4. Putative factors predicting catheter removal

Demographics, complications from the catheter (including chest wall infection, empyema and tumor growth along the catheter tract), length of time the catheter was in place, and the incidence recurrence of the pleural effusion after the catheter was removed were all noted.

The chart of each patient was also reviewed for four variables thought to be possible determinates of successful catheter removal. These determinates were: (1) the site of the underlying primary malignancy, (2) cytologic analysis of the pleural fluid (positive or negative for malignant cells), (3) presence or absence of history of thoracic irradiation, and (4) presence or absence of a trapped lung (incomplete re-expansion of the lung) by chest X-ray taken approximately 1 week after catheter insertion.

It was the focus of this paper to evaluate four factors thought to be possible predictors of catheter removal. A χ^2 analysis was used to determine if catheter removal was associated with the origin of the primary tumor, history of chest wall irradiation, cytologic analysis and radiologic evidence of a trapped lung (failure of the lung to re-expand after evacuation of the pleural effusion). Multivariate logistic regression analysis was used to determine if any of the four variables were predictive of Pleur$_x$® catheter removal.

3. Results

Over this period of time, 263 patients underwent insertion of 295 Pleur$_x$® catheters. Only one Pleur$_x$® catheter was inserted into a pleural space at any one time; 263 patients had a single catheter inserted, and 16 patients had bilateral catheters placed over the study period. There were no intraoperative complications, but not included were 11 patients in whom insertion was attempted but not possible either because a fluid pocket could not be found (10 cases) or because frankly purulent fluid was found (1 case). In the former cases, it was presumed that the fluid had become gelatinous or otherwise had become loculated and undrainable using either the Pleur$_x$® catheter or a chest tube. Seven of these cases went on to undergo a video-assisted thoracoscopy to debride the pleural space with insufflation of sterile talc to cause pleurodesis. The patient with the empyema was treated with antibiotics and drainage using a 32 Fr. thoracostomy tube.

Postoperative complications included catheter blockage (3.7%), superficial chest wall infection (1.3%), empyema (0.3%) and growth of tumor out the catheter tract (0.3%)(Table 1).

Over this period of observation, 173 of the 295 pleural catheters were removed after the drainage subsided to less than 50 cc/day (58.6%). The average period of time for the catheter to be left in place was 29.4 days. Once this criterion for catheter removal was met and the catheter was removed, these patients were followed by chest X-ray, and, if indicated, by a chest CT scan to re-evaluate the pleural space. Although it was a frequent radiologic finding to find some blunting of the costophrenic angles, over a 6-month period of observation, only 5/173 (2.9%) pleural spaces re-accumulated a pleural effusion accompanied by dyspnea. In all five cases, patients were offered alternative drainage options, including video-assisted thoracoscopic surgery, but opted for insertion of another Pleur$_x$® catheter.

The patients were broken into four groups based upon the primary site of the neoplasm (Table 2). Group 1 consisted of patients with breast carcinoma. This group was by far the largest in this series, consisting of half of the patients.

Table 1
Complications of Pleur$_x$® catheters

Primary site	Infection	Blocked	Tumor growth along catheter tract	Recurrence of effusion after catheter removal
Breast	3/148 = 2.0%	3/148 = 2.0%	0/148 = 0%	3/103 = 2.9%
Lung	0/66 = 0%	8/66 = 12.1%	0/66 = 0%	0/29 = 0%
Gynecologic	1/40 = 2.5%	0/40 = 0%	0/40 = 0%	1/29 = 3.4%
Miscellaneous	1/41 = 2.4%	0/41 = 0%	1/41 = 2.4%	1/12 = 8.3%
Overall	5/295 = 1.7%	11/295 = 3.7%	1/295 = 0.3%	5/173 = 2.9%

Table 2
Primary sites of malignancy

Primary site	No. of patients	No. of catheters
Breast	133	148
Lung	60	66
Gynecologic	32	40
Miscellaneous	38	41
Overall	263	295

Table 4
Assessment of pleural space

Primary site	Irradiated lung	Cytology positive	Trapped lung
Breast	83/148 = 56.1%	112/148 = 75.7%	15/148 = 10.1%
Lung	55/66 = 83.3%	51/66 = 77.3%	18/66 = 27.2%
Gynecologic	0/40 = 0%	33/40 = 82.5%	3/40 = 7.5%
Miscellaneous	8/41 = 19.5%	18/41 = 43.9%	4/41 = 9.7%
Overall	146/295 = 49.5%	214/295 = 72.5%	40/295 = 13.6%

Overall, 69.6% of patients in this group had the catheter removed. The average indwelling period was 26.7 days (Table 3). Overall, 56.1% of history of chest wall irradiation, patients with a malignant pleural effusion and breast cancer had a history of chest wall irradiation over the hemithorax in question. Upon cytologic analysis of the fluid submitted at the time of catheter insertion, 75.7% were found to contain malignant cells (Table 4). Upon reviewing the chest X-rays in these patients, 10.1% were initially assessed to have incomplete re-expansion of the underlying lung (trapped lung).

Group 2 consisted of patients with an underlying diagnosis of lung cancer. The 30-day mortality was much higher in this group than in group 1 (25.0% vs 12.0%). Only 43.9% had the catheter removed. In this group of patients, the average indwelling time was 30.4 days. The incidences of chest irradiation (83.3%) and positive cytology (77.3%) were high. The incidence of trapped lung was much higher than in group 1 (27.2% vs 10.1%).

Group 3 consisted of patients who had an underlying gynecologic malignancy, the majority of which were ovarian carcinoma (Table 5). Overall, 72.5% of patients had the catheter removed after an average indwelling time was 41.6 days. The incidence of positive cytology in this group was 82.5%. In this group, the incidences of thoracic irradiation (0%) and trapped lung (7.5%) were much less than in groups 1 or 2.

Group 4 consisted of patients having a wide variety of malignancies exclusive of those included in groups 1–3 (Table 6). Patients who had had a lymphoma or leukemia were under good control usually with no obvious residual disease apart from a chronic and recurring pleural effusion which was not chylous. Drainage of this fluid by thoracentesis led to symptomatic relief until recurrence of the effusion. In this group of patients, 29.3% had catheter removal. The average indwelling time was 30.1 days. In this diverse group of tumors, some patients had had high dose irradiation to the chest (lymphoma, laryngeal carcinoma). However, as a group, only 19.5% of patients had some degree of irradiation to the hemithorax. Positive cytology was noted in only 43.9% of cases. The overall incidence of trapped lung was 9.7%.

Table 5
Gynecologic primary sites

Primary site	No. of patients	No. of catheters
Ovary	26	34
Fallopian tube	1	1
Endometrium	3	3
Cervix	2	2
Overall	32	40

4. Statistical analysis

Primary tumor sites, history of chest irradiation, cytologic analysis of the pleural fluid (positive or negative for malignant cells) and incomplete re-expansion of the lung were each studied for their ability to predict which patients were likely to have their catheter removed. Upon

Table 3
Outcomes of patients with Pleur$_x$® catheters

Primary site	Died within 30 days	Died with 1 or 2 catheters in place	Catheter removed	Average indwelling time
Breast	16/133 = 12.0%	40/133 = 30.1%	103/148 = 69.6%	26.7 days
Lung	15/60 = 25.0%	34/60 = 56.7%	29/66 = 43.9%	30.4 days
Gynecologic	1/32 = 3.1%	9/32 = 28.1%	18/40 = 72.5%	41.6 days
Miscellaneous	11/38 = 28.9%	27/38 = 71.1%	12/41 = 29.3%	30.1 days
Overall	43/263 = 16.3%	110/263 = 41.4%	173/295 = 58.6%	29.4 days

Table 6
Miscellaneous primary sites of malignancy

Primary site	No. of patients	No. of catheters
Leukemia	6	6
Lymphoma	6	6
Pancreas	8	8
Kidney	5	6
Colon	3	4
Stomach	2	3
Mesothelioma	2	2
Soft tissue sarcoma	2	2
Larynx	2	2
Prostate	1	1
Bile duct	1	1
Overall	38	41

combining groups 1 and 3 and comparing the outcomes of groups 2 and 4, patients with a primary tumor of the breast or female genital tract were much more likely to have the catheters removed than those at other sites ($p < 0.001$, $\chi^2 = 18.68$, dl = 1).

Upon analyzing the data on patients with and without a history of chest wall irradiation, those without a history of radiation were statistically more likely to have a Pleur$_x$® catheter removed than those who did ($p < 0.001$, $\chi^2 = 15.45$, dl = 1).

Unexpectedly, patients whose pleural fluid contained malignant cells were statistically more likely to have the Pleur$_x$® catheter removed than those whose pleural fluid did not ($p < 0.001$, $\chi^2 = 57.01$, dl = 1).

Not surprisingly, patients with complete re-expansion of the underlying lung 1 week after insertion of the catheter were more likely to have the catheter removed than those with a trapped lung ($p < 0.001$, $\chi^2 = 45.15$, dl = 1).

Multivariate analysis revealed that group classification (i.e. groups 1 and 3 vs groups 2 and 4) ($p = 0.0080$), cytology positive status ($p < 0.0001$), and the presence of trapped lung ($p = 0.001$) each were predictive of catheter removal (Table 6). The reported result for each effect was obtained after having controlled for the other three variables. This was in contrast to a history of radiation therapy ($p = 0.16$) which was not predictive of Pleurx® catheter removal after having controlled for the other three variables.

5. Discussion

In a patient with advanced malignancy, evacuation of a symptomatic pleural effusion often provides palliation. The duration of this palliation is almost entirely dependant upon control of the pleural space. A single thoracentesis rarely provides long-lasting relief and is viewed to be solely a diagnostic procedure. Insertion of a chest tube with evacuation of the fluid, followed by instillation of a sclerosing agent (such as doxycycline or sterile talc), caused a chemical sclerosis of the pleural space and has its advocates [1,2]. There have been concerns over systemic absorption of talc and the incidence of an ARDS-type clinical picture [3—6]. Moreover, this requires a hospital admission and the recurrence rate of symptomatic pleural effusion has been reported to be as high as 30% [1].

More recently, surgeons have advocated video-assisted thoracoscopy to completely evacuate the effusion, break down adhesions and to insufflate talc evenly over the pleural surface [7,8]. In many institutions this remains the preferred procedure of choice. However, it requires a general anesthetic, placement of a double-lumen tube and a hospitalization of these uniformly terminal patients.

An alternative strategy has been offered with the development of soft valved catheters allowing for the outpatient management of these patients. For many years, some have favored the use of the pleuroperitoneal shunt [8—10]. When placed, this catheter is completely subcutaneous and requires repeated compressions of the valved chamber. The only way to know if the catheter is functioning adequately is to document recurrence of the effusion. The only way to confirm that the pleural space is fused, or the catheter is blocked is to stop compressing the valve and watch for re-accumulation of fluid.

Others have explored the use of a pleural access port to allow for repeated thoracentesis at home using a visiting nurse [11]. Apart from the cost of a visiting nurse, a limitation is the size of needle that can be used to access the port. Repeated use of needles greater than 19 Ga. will cause damage to the port membrane.

Although some have used a Tenckhoff catheter inserted into the pleural space, the valve can be easily left open allowing air and bacteria to enter the pleural space [12]. Furthermore, the catheters themselves are uncomfortable to lie upon.

The introduction of the Pleur$_x$® catheter in 1997 provided an alternative to these soft catheters. It is inserted under local anesthesia usually as an outpatient, and the patient or family member performs the drainage procedure at home. The amount and the nature of the pleural fluid are recordable. When the drainage subsides, the catheter can be removed with an acceptably low risk [13—16] of re-accumulation of fluid.

In cost-analysis studies [17,18], the outpatient management of patients with these soft catheters was compared to chest tube insertion and pleural sclerosis. These studies concluded that there was a cost advantage to using Pleur$_x$® catheters even though, in one study, 40% of the catheters were inserted on an inpatient basis. In the current study, 74.6% of patients had the catheter inserted as an outpatient leading to further cost savings.

We and others proved this could be performed with minimal morbidity, and with a high incidence of removal of the catheter without a recurrent effusion [19,13—16]. In our experience, the incidence of catheter-related complications (infection: 2.2%, blocked: 4.8%, tumor growing out catheter tract: 0.3% and recurrence after catheter removal: 4.2%) were minimal. This stands in contrast with a recent article citing a 6.7% incidence of tumor growth through the catheter tract [20]. This may be explained by the low incidence of mesothelioma and primary lung cancer in our series. In our series, the one case encountered had a renal cell carcinoma. Even in those cases where the lung fails to re-expand and fill the pleural space (i.e. a trapped lung), patients can be palliated of their dyspnea, where sclerosis through a conventional thoracostomy tube would be doomed to failure.

The mechanism by which these catheters sometimes induce a pleural symphysis is unclear. Extensive studies have failed to prove any chemical or immune-related reactivity of medical grade silicone. However, several clinical observations are noteworthy. First, these catheters, unlike conventional polyvinyl chloride chest tubes, are mobile and migrate within the pleural space depending on the patient's position. This is evident in early chest X-rays taken in the upright and decubitus positions. Therefore, contact with the pleural space is much more widespread than that seen with chest tubes. Moreover, the draining fluid often changes from serous to serosanguinous, and the patient often experiences pleuritic pain at the end of the drainage, indicating an inflammatory response, perhaps on the basis of the presence of a foreign body. Thoracoscopy has been attempted on a few of these patients after successful pleurodesis and catheter removal and extensive adhesion formation has been observed.

In this study, we assessed the influence of primary site, history of radiation therapy, cytology status and presence of a trapped lung on the removeability of these catheters. It should be stressed that prior to catheter insertion, most patients wanted to know how soon it could be removed. However, once the catheter had been in place and the patients experienced palliation, many were reluctant to having it removed citing concerns that the fluid may re-accumulate or that the trip into the office for removal was not worth the minor inconvenience of caring for the catheter. While delay in catheter removal was not long and unlikely to skew the results, it does serve to emphasize the fact that these catheters were extremely well tolerated by patients overall. Moreover, there were very few complications, including infections and catheter blockage.

Although an attempt was made to avoid patients who were thought to have a survival of less than 30 days, it was instructive to see that 25—30% of patients with primary malignancies other than those of the breast or female genital tract died within 30 days. There was no reason to consider that the placement of the catheter hastened their demise. To the contrary, patients with breast and gynecologic malignancies fared very well, and, with the advent of newer chemotherapy, can survive longer than would otherwise be expected. Obviously, survival is a prerequisite for catheter removal.

At first glance, one may conclude that these catheters are not well suited for patients with effusions secondary to lung cancer. These patients experienced a shorter overall survival and a higher 30-day mortality than patients with breast and gynecologic malignancies. This more limited survival undoubtedly had an influence on the incidence of catheter removal. The incidence of a trapped lung was especially high in lung cancer patients, influencing the removeability. On the other hand, patients in this category had good palliation including in those patients with a trapped lung, which is unlikely to respond well to other treatment options. Moreover, 43.9% of the time the catheter was removed, without a single case of clinically significant re-accumulation.

Statistically, patients with breast or gynecologic malignancies were significantly more likely to have the catheter removed than those with lung or other primary tumors. According to this analysis, the presence of malignant cells in the pleural effusion, and the absence of a trapped lung each were statistically significant independent positive predictive factors in the likelihood of removing these catheters. The history (or absence of history) of radiation therapy was by itself not predictive of catheter removal. Many patients with locally advanced breast cancer had low-dose radiation to the chest wall; no attempt had been made to distinguish these patients from those with lung cancer having undergone high-dose radiation to the underlying lung. The predictive significance of cytologic analysis was somewhat unexpected and merits further study.

While these findings are interesting, it should be stressed that removal of the Pleur$_x$® catheter was not the goal of the treatment and the morbidity of prolonged catheter placement was minimal. Even those patients who continued to drain were well palliated of their presenting complaint of dyspnea, and remained comfortable as an outpatient.

Only two cases of mesothelioma were entered and the results are insufficient to draw conclusions. It is the authors' feeling however, that insertion of the Pleur$_x$® catheter in patients with this condition should be limited to those who are frail and have a short life expectancy, since the probability of leaving the patient with a trapped lung and a chronically draining catheter is high.

We conclude that Pleur$_x$® catheters effectively palliate patients with a malignant pleural effusion with an acceptably low incidence of complications. Overall, even without use of a sclerosing agent, 60% of patients can expect to have the catheter removed, usually a period of 30—45 days. This percentage is as high as 70% in patients with a gynecologic or breast malignancy. Finally, even in patients with a trapped lung, or with continued high outputs of pleural fluid, this catheter proves excellent palliation with acceptably low complications, where alternative strategies are unlikely to succeed.

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