The Efficacy of Jackson Drain in the Application to Be a Tunnel Pleural Catheter (TPC) in the Management of Malignant Pleural Effusion

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Background: *Malignant pleural effusion (MPE) is a common clinical problem in patients with advanced cancer and portends a poor prognosis, which means survival of less than six months. In June 1997, the US-FDA approved an indwelling TPC with a one-way drainage valve to be used in the management of MPE. Although popularity of this TPC has increased over the past few years, the experience with this device remains limited in Thai patients. One of the reasons is its high cost.*
Objective: *Assess the efficacy and the safety of customary indwelling TPC by using Jackson drain in the management of patients with symptomatic MPE.*
Material and Method: *Ten patients with symptomatic MPE were receiving these catheters (18 Fr Silicone catheters with 25cm fenestrated length) to drain effusion via plastic vacuum bottles (250ml) every other day or as needed to relieve dyspnea. The patient's dyspnic respiration, quality of life, and comfort during the catheter's application were quantified with a Borg score, the St. George Respiratory Disease Questionnaire (SGRQ), and the comfort's score, respectively. These parameters were recorded at initial (before insertion) and 2-week follow-up visit. Pain after 24 hours of each insertion was quantified by visual pain analogue scale (VPAS). Patients were followed until either death or catheter removal.*
Results: *The Borg score, SGRQ, and comfort's score showed significant improvement at 2-week visit ($p < 0.05$). Mean VPAS was 2.44. There was no early (2-week) complication, but the catheters were obstructed in three patients (mean = 60 days) and slipped out in two (day18, day 50).*
Conclusion: *This modified Jackson drain was effective in the treatment of MPE as a TPC without early complications.*

Keywords: *Tunneled pleural catheter (TPC), Malignant pleural effusion, Jackson drain*

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Malignant pleural effusions (MPEs) are a common clinical problem in patients with neoplastic disease, especially in the advanced stage. It can develop in virtually all malignancies, which leads to significant morbidity and impairment in quality of life. Lung and breast cancers are the most and second most common neoplastic causes of MPE[1], although in 5-10% of cases, no primary tumor is identified[2,3]. Except for certain tumors such as lymphoma, MPE portends a poor prognosis, which means survival of < 6 months[4]. In the majority of cases, the MPE does not resolve or recurs after initial drainage. Thus, the ideal management approach should offer immediate and long-term relief of symptoms, avoid hospitalization, be applicable to the majority of patients, have minimal side effects, and avoid repeated uncomfortable procedures. None of the current MPE treatment options has all of these characteristics.

There are several approaches to MPE management, with the objective of each procedure to drain the pleural space and to relieve respiratory symptoms. Initial drainage customarily occurs with standard thoracentesis to confirm the presence of malignant pleural disease and to provide symptomatic relief. If the MPE recurs, several approaches can be taken for further control such as repeat thoracentesis, placement of an indwelling, cuffed, tunneled pleural catheter (ICTPC), tube thoracostomy with pleurodesis, medical pleuroscopy or video-assisted thoracoscopic surgery (VATS) with pleurodesis[5]. Each method carries with it certain advantages and disadvantages.

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The use of tunneled pleural catheter (TPC) has gained popularity over the past few years. However, the overall experiences with this approach in Thai patients remain limited. One of the reasons is the high cost of the device when compared with other approaches to MPE management.

The primary objective of the present study was to evaluate, at two weeks, the efficacy of a modified Jackson drain used as a TPC, the rate of various complications, and comfort of the patients. The same assessments after two weeks were done as the secondary objective.

Material and Method

A case series was conducted to assess the treatment of symptomatic MPE with an indwelling pleural silicone catheter. The Institutional Review Board of Siriraj Hospital approved the present study protocol. The written informed consent to participate in the present study was obtained from each patient, in accordance with relevant guidelines. The patients received the indwelling catheter for the treatment of symptomatic MPE.

Study population

The inclusions were adult (18 year old and older) patients diagnosed of MPE. Patients were required to have MPE (proven by cytologic or pathological examination of the fluid) with at least a moderate sized pleural effusion and dyspnea relieved after therapeutic thoracentesis. Exclusion criteria included chylothorax, previous lobectomy or pneumonectomy on the affected side, previous attempts at pleurodesis, immunodeficiency syndrome, Karnofsky performance status score < 50, bilateral moderate or larger pleural effusions, multiple loculations, pleural infection, or abnormal coagulation profile.

Study participants were not allowed to receive concurrent intrapleural chemotherapy or radiation therapy to the ipsilateral chest. Patients were allowed to receive systemic chemotherapy or mediastinal radiation.

Chest X ray (CXR) evaluation[6]

Pleural effusions were semi-quantified by CXR as follows, 1) No effusion, 2) Effusions only detected on decubitus films, 3) Blunting of the costophrenic angles, 4) Moderate effusion fluid between the costophrenic angle and hilar level, 5) Large effusion fluid above hilar level but not completely opacified, and 6) Complete opacification.

Description of Indwelling Pleural Catheter Apparatus

The apparatus for the indwelling pleural catheter set consisted of the catheter and a drainage plastic vacuum bottle with an access tip matched to the catheter (Fig. 1, 2). The pleural catheter was an 18 Fr silicone rubber catheter, 72 cm in length, with fenestrations along the proximal 25 cm. The catheter had a double-click clamp in set. This clamp worked as a valve preventing fluid or air from passing in either direction through the catheter unless it was opened after being accessed with the matched drainage tip of the vacuum bottle inserted into the distal end of the catheter. The pleural fluid was drained by inserting the access tip (with a one-way valve) of the vacuum bottle into the catheter and then only draining the fluid via an external part of catheter into vacuum bottles.

The negative pressure in the vacuum bottle was created by hand after it was squeezed. The pressure in the bottle after being compressed and then relieved (the opening was occluded by a plastic stopper at the same time) was about 25 cmH2O.

Protocol for catheter insertion

With the patient lying on the lateral decubitus position (contralateral to the lesion) in an imaginary triangle (the pectoris major, the lattissimus dorsi, and the diaphragm were the sides of this triangle) and after local anesthesia with 10 ml of 1% lidocaine, the trocar was inserted through the ipsilateral chest wall into the pleural cavity under the ultrasonographic guided method at the appropriate level of effusion. A catheter was inserted through trocar. A chest wall tunnel (about 5 cm in length) created a lead to the counter incision, which was anterior to the first incision. The distal end of the catheter was pulled through this tunnel to exit at the second incision. These incisions were closed primarily, and the catheter was secured to the skin medially with a suture.

After catheter insertion, up to 1,000 ml of pleural fluid was initially drained. If the effusion was not drained completely, as evaluated with the chest radiograph, then another 500 ml of fluid were drained every six hours until drainage was complete and confirmed by the chest radiograph. The drainage of the pleural fluid was done every 3 to 7 days depending on each patient's need.

Pain was recorded as visual analogue pain score at 24 hours after the procedure. Complications as well as any ipsilateral pleural procedures required post-TPC placement were also recorded.

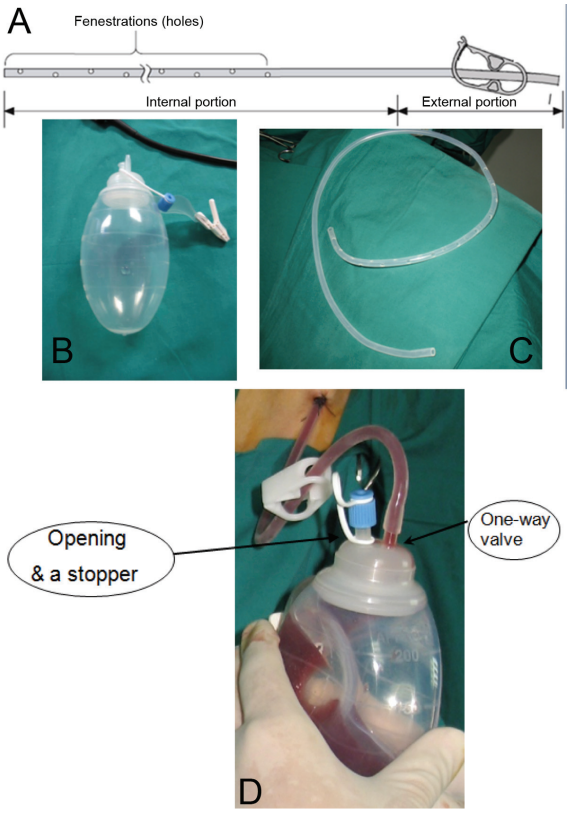

Fig. 1 The apparatus for the indwelling pleural catheter set is shown. A, C shows the outline of the catheter parts. B shows the drainage plastic vacuum bottle. D shows the application of the pleural catheter with the drainage bottle

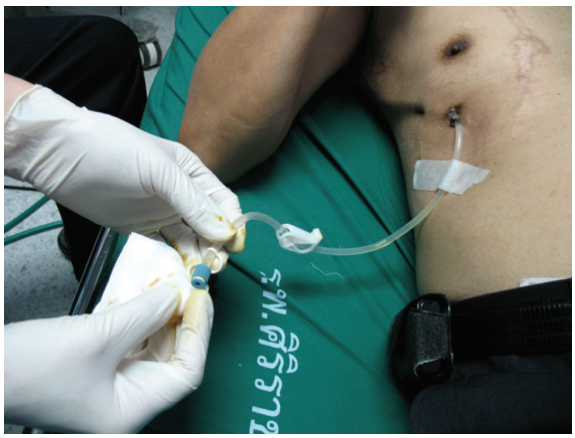

Fig. 2 The indwelling pleural catheter is shown. The distal end of the pleural catheter is closed except when the double click clamp and the access tip of the drainage line are opened

Follow-up procedures

Follow-up clinic visits were scheduled at 1, 2, 4, 8 and 12 weeks. Chest radiograph, interval history, and physical examination were obtained at each clinic visit. The patient's dyspnea was quantitated with a Borg score, and their quality of life was assessed by the St. George's Respiratory Questionnaire (SGRQ)[7]. Comfortability was assessed by using the scale with 0 = very uncomfortable, 1 = uncomfortable, 2 = slightly uncomfortable, 3 = comfortable, 4 = satisfactory, 5 = very satisfied. Karnofski Performance score (KPS) was also recorded. Patients were followed until either death or catheter removal. They were advised to return for a follow-up visit sooner if there was $\leq$ 50 ml of pleural fluid drainage on three consecutive occasions. The catheter was removed when pleurodesis had occurred.

Patients were followed until either death or catheter removal or for 10 months if the patients were still alive.

Data collection

Other data recorded for each patient were gender, age, primary malignancy, side and size of the effusion on CXR pretreatment and two weeks post-procedure, dates of insertion, removal of TPC, death, pleural procedures performed ipsilateral side prior to or following insertion of the TPC, complications, and symptom control.

Statistical analysis

The data were presented as the mean $\pm$ standard deviation when the data were distributed normally and as the median with the range when the data were not distributed normally. The data at 2, 4 and 8 weeks follow-up were compared by using paired t-tests. If the data failed the normality test, then the results were compared by using the Wilcoxan signed rank test. Differences in the results were considered significant when $p < 0.05$. When the treatment results were analyzed, only the patients who received the appropriate treatment without protocol violation were included.

Results

Ten patients were enrolled in the present study. All of them received the indwelling pleural catheter.

The demographics data of the patients are shown in Table 1. Most common primary malignancy was lung cancer (70%) The mean initial size of the effusions was estimated in grade 6.

Table 1. Demographic data of the patients

Patient No.	Age (yr)	Sex	Diagnosis (side of MPE)	Prior treatment	TPC in-placed (day)
1	52	F	Lung cancer (Rt)	Serial thoracentesis	85
2	56	F	Lung cancer (Rt)	Serial thoracentesis	55
3	36	F	Lung cancer (Rt)	-	19
4	66	M	Lung cancer (Rt)	-	166
5	62	M	Rectal cancer (Lt)	-	45
6	52	F	Breast cancer (Lt)	-	37
7	75	M	Lung cancer (Rt)	ICD	19
8	76	M	Lung cancer (Rt)	-	50
9	61	F	Breast cancer (Lt)	Serial thoracentesis	46
10	72	M	Lung cancer (Rt)	-	33

Half of our patients received the pleural catheter placement in an out-patient setting; the others were placed when the patient was admitted due to other non-procedure related indications. Overall, TPC remained in place for a median of 45.5 days (19-166 days).

When the Borg scores and the SGRQ scores were re-evaluated at the 2-week follow-up, by comparing with each score before treatment, means improvements were statistically significantly different in both scores ($p = 0.007$ and $p = 0.008$ for the Borg score and the SGRQ scores, respectively) (Fig. 3C, 3D). In the same way, the KPS scores showed a similar improvement at the 2-week follow-up visit ($p = 0.007$) (Fig. 3A). By the CXR graded score, the radiographic alteration also improved significantly ($p = 0.005$) (Fig. 3B).

The degree of comfort, quantified by a score that has six grades (from 0-5), experienced in these patients after the 2-week follow-up visit had a range from grade 3 to 5 with the median grade being 4, which had a statistically significant improvement ($p = 0.008$) when compared with this score evaluated after the first 24 hours of the procedure (median = 3; range from 3-4) (Fig. 3E).

Morbidity and complications

The degree of pain, quantified by the visual analogue scale, experienced in these patients after the first 24 hours of the procedure was 2.44 ± 0.527 (range 2-3). All patients received opiate for analgesia during the procedure, only two patients had received opiate after the procedure; the main reason for this post-procedure opiate was due to pain at other sites (such as bone pain). All patients received acetaminophen for analgesia during the first 24 hours after the procedure. No pain at insertion site was noted beyond three days after the procedure.

In the 2-week follow-up period, there were no complications in any patients. Pain during fluid drainage was reported by all patients for a few days just after initiation of intervention. No serious morbidity, such as pneumothorax, misplacement of

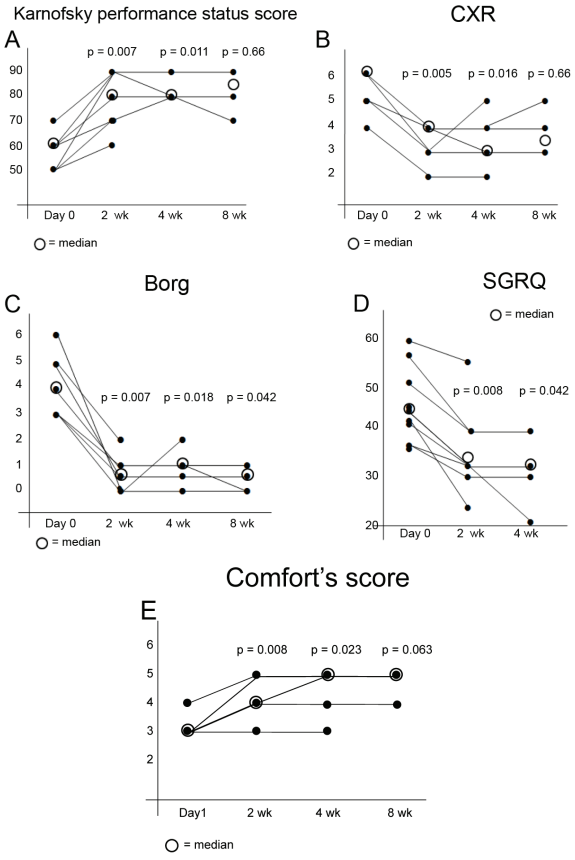

Fig. 3 Treatment results

catheter, re-expansion pulmonary edema and hypercapnic respiratory failure secondary to over-sedation, occurred.

The KPS scores and the Borg scores were re-evaluated at the 4-week and 8-week interval. The SGRQ scores were re-evaluated only at the 4-week interval. The results were compared with each score before treatment, and the mean degree of improvement had statistical significance at the 4-week follow-up visit in all scores ($p = 0.011$, $p = 0.018$ and $p = 0.042$ for the KPS score, the Borg score and the SGRQ scores, respectively). In the same way, the CXR graded score also showed statistically significant improvement ($p = 0.016$).

Only the Borg scores showed statistically significant improvement at 8-week follow-up visit ($p = 0.042$).

The degree of comfort experienced in these patients at the 4-week follow-up visit had a median grade of 5 (3-5), which indicated statistically significant improvement ($p = 0.023$) when compared with the score evaluated after the first 24 hours of the procedure. But this score did not show statistical significant improvement at the 8-week follow-up visit ($p = 0.063$).

Morbidity and complications

The catheters occluded in three patients (mean day 60) and slipped out in two patients (at day 19 and day 50).

Two patients developed catheter-related infection but responded promptly to local wound care and administration of oral antibiotics.

Spontaneous pleurodesis

No spontaneous pleurodesis occurred in the present study. However, one patient had suspected spontaneous pleurodesis because the drained volumes were 80 ml and 75 ml at the 40-day and 36-day follow-up visits. Finally, the TPC was removed and the effusion did not recur.

Survival

There was no death in the 2-week follow-up visit; although three patients died at day 18, day 45, and day 55 after catheter placement, however; all deaths were non-catheter related.

Discussion

Pleural effusion is a common and frequently difficult complication of advanced malignancy. The development of MPE, in general, portends poor prognosis. Therefore, the primary therapeutic goal in MPE is effective palliation of associated dyspnea and chest discomfort. Thoracentesis is not reliably effective for long-term symptomatic control. In recent years, palliative therapy for MPE has largely focused on chemical sclerosis of the pleural space to achieve pleurodesis, using agents such as talc, doxycycline, and bleomycin.

In June 1997, the USA Food and Drug Administration approved an ICTPC with a one-way drainage valve to be used in patients with MPE[5] (Fig. 4). The ICTPC can be accessed and drained with a negative pressure drainage bottle at home and is designed for insertion even for an outpatient basis.

Several groups have reported that spontaneous pleurodesis can occur in 42 to 58% of patients within 4-6 weeks of placement, thereby allowing for ICTPC removal[8-19].

In the present report, a series of patients with MPE for whom placement of a permanent pleural catheter that derived from the Jackson drainage set to be a tunnel pleural catheter (TPC) to drain recurrent pleural fluid demonstrated a convenient, effective alternative option to the procedures currently in use. Patients generally reported good symptomatic relief following catheter placement and all patients showed good acceptance (comfort score) with this device.

Most patients experienced complications (55%) that were relatively high compared with other

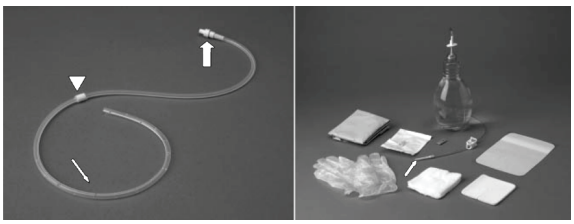

Fig. 4 ICTPC kit and supplies[5]. Left: The ICTPC (Pleurx; Denver BioMedical, a Subsidiary of Cardinal Health; Golden, CO) is composed of an intrapleural end that contains fenestrations for fluid drainage (thin arrow), a polyester cuff that resides in a subcutaneous tunnel to help reduce infection risk and to secure the catheter (arrowhead), and a proximal end that remains extracorporeal and contains a one-way valve to allow for drainage (thick arrow). Right: The ICTPC drainage system with integrated drainage line vacuum bottle system that allows for home drainage. The arrow marks the end that inserts into the one-way valve (thick arrow, left panel) to allow for drainage

studies. Catheter-related infection is a potentially serious complication for which patients should be vigilantly monitored. The present study reported two catheter-related infections (20%), but both responded promptly to wound care and oral antibiotics. These occurrences only happened in the first two patients.

Three of the presented patients experienced catheter occlusion and the catheter slipped out in two patients (30% and 20% respectively). Two of three occlusions were accompanied by catheter infection. This relationship may show the association of similar causes

Although, no spontaneous pleurodesis occurred in this study, one TPC was removed after 40 days of follow up interval because the drained volume was minimal (80 ml and 75 ml, respectively), the chest radiography did not change and no significant respiratory symptoms such as dyspnea were reported.

In Thailand, the commercial ICTPC device has only a limited role in malignant pleural effusion management due to the principal reason, its cost. With this modified Jackson drain set, cost is much lower (The local price of commercial ICTPC is 34,000 Baht compared to 354 Baht for Jackson drain set).The present report showed the same direction of efficacy in the management of malignant pleural effusion when compared with the other studies. Although the complications of this device were high compared to other studies, no catheter related death was observed in the present study.

Conclusion

The modified Jackson drain to use as TPC may be effective for the malignant pleural effusion management. This device showed its safety without complications, at least in the 2-week follow-up visit.

Potential conflicts of interest

None.

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ประสิทธิภาพของการประยุกต์ใช้ Jackson drain แทนอุปกรณ์ท่อฝังใต้ผิวหนังสำหรับดูดสารน้ำมะเร็งในการรักษาสารน้ำมะเร็งในช่องเยื่อหุ้มปอด

แจ่มศักดิ์ ไชยคุนา, ปรีชา ธำรงไพโรจน์, ศุภฤกษ์ ดิษยบุตร

ภูมิหลัง: *สารน้ำมะเร็งในช่องเยื่อหุ้มปอดเป็นผลแทรกซ้อนที่พบได้บ่อยในโรคมะเร็งระยะท้าย และบ่งถึงการพยากรณ์โรคที่ไม่ดีอัตราการรอดชีวิตประมาณ 6 เดือน ในเดือนมิถุนายน ปี พ.ศ. 2538 FDA ของประเทศสหรัฐอเมริกาได้อนุมัติให้ใช้อุปกรณ์ท่อฝังใต้ผิวหนังสำหรับดูดสารน้ำมะเร็งออกจากช่องเยื่อหุ้มปอด ซึ่งอุปกรณ์ดังกล่าวเป็นที่นิยมใช้มากขึ้นในระยะหลังนี้ ประสบการณ์การใช้อุปกรณ์นี้มีน้อยในประเทศไทยเนื่องจากมีราคาสูง การศึกษานี้จึงพยายามดัดแปลงอุปกรณ์ Jackson drain ซึ่งมีราคาถูกกว่ามาใช้แทน*

วัสดุและวิธีการ: *ผู้ป่วย 10 รายที่มีสารน้ำมะเร็งในช่องเยื่อหุ้มปอดถูกนำมาใส่สายที่ดัดแปลงมาจาก Jackson drain โดยสายจะถูกใส่ค้างไว้กับตัวผู้ป่วยโดยทำการดูดสารน้ำออกผ่านทางขวดที่มีแรงดันลบภายในจนสารน้ำนั้นหมด ได้ทำการติดตามผู้ป่วยจนไม่มีสารน้ำและนำท่อออกจากตัวผู้ป่วยหรือผู้ป่วยเสียชีวิต ที่สัปดาห์ที่ 2, 4 และ 8 ได้ทำการวัดอาการเหนื่อย ความพึงพอใจในการใช้ท่อ Borg score และ St. George Respiratory Disease Questionnaire*

ผลการศึกษา: *พบว่าค่า Borg score St. George Respiratory Disease Questionnaire และความพึงพอใจดีขึ้นอย่างมีนัยสำคัญทางสถิติที่สัปดาห์ที่ 2 และ 4 ไม่มีผลแทรกซ้อนใน 2 สัปดาห์ อย่างไรก็ตามพบว่าเกิดการอุดตันของท่อ 3 ราย และมีการเลื่อนหลุดของท่อ 2 รายในวันที่18 และวันที่ 50 หลังใส่ท่อตามลำดับ*

สรุป: *การใช้ท่อที่ดัดแปลงจาก Jackson drain แทนอุปกรณ์ท่อฝังใต้ผิวหนังสำหรับดูดสารน้ำมะเร็งออกจากช่องเยื่อหุ้มปอดสามารถใช้ได้ผลดีในช่วง 2 สัปดาห์แรก*