A Comparative Study of Two Small-Bore Pleural Drainage Systems

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Abstract

The aim of our study was to compare the efficacy of a closed drainage system (a bedside procedure) to that of an ultrasound-guided drainage system. 29 patients with pleural effusion were randomly assigned to undergo either ultrasoundguided small-bore pleural catheter placement (Pigtail® group, n=15) or catheter placement without ultrasound-guidance (Pleuracan® group, n=14). Data on indications for tube placement, drainage volume, mean duration of catheter stay, complications, and effectiveness of drainage were collected. Findings for the two groups were compared. The Pleuracan® group included 9 males and 5 females (mean age: 59.2±23.4 years), the Pigtail® group included 10 males and 5 females (mean age: 49.4±22.5 years). There were no statistically significant differences between the groups regarding sex distribution, age or catheter calibers used. The most common diagnosis was complicated parapneumonic effusion (34%). The other indications for tube placement were malignancy (21%), hemorrhagic effusion (21%), transudate (21%) and hemothorax (3%). The patients with Pleuracan® catheters showed trends towards shorter catheter stay and larger drainage volume than Pigtail® group (2.5±1.4 days vs. 3.8±2.5 days and 2436±1905 ml vs. 1388±598 ml, respectively), but the differences were not statistically significant (p:0.06 and p:0.07, respectively). Three (10%) of the 29 patients developed pneumothorax, but no other complications were observed in either group. In both systems, the patients with complicated parapneumonic effusion had a higher complication rate and were more likely to require lung decortication. The results showed that small-diameter chest drain kits that do not require ultrasound guidance for placement can be used effectively to drain pleural fluid similar to the conventional ultrasound-guided drainage system. The study also revealed that closed system chest drain kits for percutaneous placement of small-diameter tubes are as safe as ultrasound-guided systems.

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Introduction

In patients with pleural effusion, the underlying disease can usually be identified by analyzing the fluid collected by thoracentesis. This procedure is diagnostic in approximately 75% of the patients and can be used for therapeutic purposes in another 25% of the cases (1). Techniques for therapeutic thoracentesis include serial therapeutic thoracentesis and tube thoracostomy. For these treatments, chest tubes are inserted into the pleural space by three methods: tube thoracostomy with a guide-wire and dilators (small-bore catheters); tube thoracostomy with a large-bore catheter; and surgical tube thoracostomy. Use of small-bore catheters is a less invasive way to achieve fluid drainage. In addition to the older methods, commercial kits that facilitate small-bore catheter placements are now available (2-4).

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Clinical experience to date suggests that the use of small-bore catheters for chest drainage is effective, safe, and well-tolerated (4-10). Although the published results have been encouraging, the studies involved relatively small numbers of selected patients and the technique is not yet widely accepted. The efficacy of the various types of small-bore catheters also remains unclear. In this study we report our initial results with therapeutic thoracentesis using two different small-bore pleural catheters in patients with symptomatic pleural effusion, and comparing the efficacy of a closed drainage system (a bedside procedure) to that of an ultrasound-guided drainage system.

Materials and Methods

This prospective study was approved by the Başkent University Ethics Committee, and was carried out between January 1999 and December 2000. The procedure was carefully explained to each patient, and written consent was obtained. We randomly assigned 29 patients with radiographically confirmed pleural effusion to undergo either ultrasound-guided pleural catheter placement (Pigtail® group, n=15) or catheter placement without ultrasound-guidance (Pleuracan® group, n=14). For each patient, we recorded demographic data, the type of chest tube inserted, indication(s) for therapeutic thoracentesis, drainage volume, mean duration of catheter stay, local pleural treatments (such as intrapleural fibrinolytic or sclerosing agents), and the effectiveness or complications of drainage based on comparison of pre- and post- drainage chest x-rays. The data for the two groups were compared, and the patients' comfort level with the tube in place was evaluated as well.

Ultrasound-guided intervention

Real-time ultrasound (US) (Hitachi, Japan) guidance was used to insert a Pigtail® catheter in 15 patients. After the exact location of the fluid was identified by US, local anesthesia was achieved by injecting approximately 10 ml of 1% lidocaine into the skin, the periosteum of the rib and the parietal pleura. We did not routinely administer atropine to prevent vasovagal reactions, nor did we routinely give analgesics, sedatives, or tranquilizers prior to the procedure unless the patient showed excessive anxiety.

The catheter placement procedures were all performed by the same interventional radiologist (FB). A skin incision just large enough to allow easy passage of the needle was made, and a single-lumen locking Pigtail® catheter (Flexima, Boston Scientific, USA) was placed within the dependent portion of the fluid collection. The drain size varied from 10 to 16 French (F), but 12 F drains were used in most cases. After the first catheter dilator was removed, the chest tube containing the inserter was threaded over the guidewire. Once the catheter was in position, the inserter and the guidewire were withdrawn. The tube was then clamped until

it was attached to the chest drainage system. The device was anchored in place by means of a long suture that was tied around the tube and secured to the skin. The surgical site was then cleaned and covered with plain 4x4 cm gauze pads.

Each drain was connected to a water-seal drainage bottle, and was irrigated daily with sterile saline solution to maintain patency. No more than 1500 ml of pleural fluid was removed daily. This was a precaution because patients occasionally develop re-expansion pulmonary edema or hypovolemia after thoracentesis. A daily chest radiograph was obtained in all cases during the course of pleural drainage to monitor for pneumothorax. Patients with complicated parapneumonic effusion and hemorrhagic effusion whose x-rays showed significant amounts of remaining fibrinous or suppurative fluid were given intrapleural fibrinolytic (IPFL) therapy. Our definition of a "significant" amount of fluid was subjective. In most cases, the decision to begin IPFL treatment was made in the first or second day after drainage.

For the irrigation procedure, 250 000 U of urokinase (UK) was dissolved in 100 ml of normal saline solution to achieve a final concentration of 1000 U/ml. The 1000 U/ml concentration was used initially in patients who required fibrinolysis. The solution was injected into the chest tube via a stopcock attached to the luer-lock connector of the catheter. Once injected, the catheter was clamped and the patient was instructed to intermittently change from the supine position to both lateral decubitus positions in order to facilitate mixing of the irrigant with the pleural fluid. After 3 to 4 hours, the catheter was unclamped, and as much fluid as possible was aspirated and the net output was recorded. If necessary, three separate UK irrigations were done to achieve complete pleural drainage.

Patients with a history of repeated and resistant malignant pleural fluid were evaluated for pleurodesis. The treatment for pleurodesis was 500 mg tetracycline hydrochloride dissolved in 50 ml saline and instilled into the pleural space via the catheter. After the solution was injected, the tube was clamped for 3-4 hours, during which time the patient was instructed to change position at 30-minute intervals to ensure adequate dispersal. Then, suction (-20 mmHg) was applied until almost all pleural fluid was removed. The standard criteria used to determine when to remove the chest drain were as follows: 1) Almost complete pleural fluid drainage confirmed by radiographic evaluation or 2) no more than 50 ml of net drain output over the 24 hours preceding tube removal.

Closed-system drainage

Closed-system drainage (Pleuracan® catheter) was used in 14 patients, and all these bedside procedures were

Table 1. Some characteristics of the Pleuracan® and Pigtail® catheter groups				
	Pleuracan® (Bedside, n=14)	Pigtail [®] (US-guided, n=15) 10/5		
Sex distribution (M/F)	9/5			
Age (years)	59.2±23.4	49.4±22.5		

10-16 F

performed by pulmonary specialists (ŞA, ÖK, NÇ, FÖE). Prior to placement, each patient's recent chest x-rays were reviewed and a physical examination of the chest was done. Local anesthesia was achieved as described above, and thoracentesis was attempted where tactile fremitus was lost and the percussion note became dull. A Pleuracan® catheter (14F, Braun, Germany) was inserted into the pleural space, and with the exception of a small skin incision made with a scalpel, the procedure for this was similar to that described for US-guided catheter placement. The sharp hollow needle containing the catheter was advanced percutaneously to the pleural space and then removed. The pleural fluid was drained into ambulatory bags. If necessary, pleurodesis or IPFL therapy was carried out as described above. The criteria for Pleuracan® removal were the same as those detailed above for the Pigtail® catheters. Seldinger's technique was used in cases where two small-bore catheters were placed.

To classify the pleural fluids as either transudates or exudates, Light's criteria were used (11). The term complicated parapneumonic effusion was used to refer to parapneumonic effusions that do not resolve without tube thoracostomy. Diagnosis of malignant pleural effusions was based on a positive cytological analysis. A hemothorax was considered to be present only when the hematocrit of the pleural fluid was at least 50% of the peripheral blood (12).

Statistical analysis

Catheter caliber

The data were not normally distributed, therefore nonparametric tests were used in the analyses. The Mann-Whitney U test was used to compare quantitative variables between two groups. A p value of \leq 0.05 was accepted to indicate statistical significance. The analysis was done using the statistical software SPSS for Windows (Chicago, IL, USA) (13).

Results

Patient characteristics

Some characteristics of the Pleuracan[®] (bedside) and the Pigtail[®] (US-guided) groups are given in Table 1. The Pleuracan[®] group included 9 males and 5 females of mean age 59.2±23.4 years (range, 13-86 years). The Pigtail[®] group included 10 males and 5 females of mean age 49.4±22.5 years (range, 19-81 years). There were no statistically significant

	All patients (n)	Bedside (n)	US-guided (n)
Complicated parapneumonic effusion	10 (34)	3	7
Malignancy	6 (21)	3	3
Hemothorax	1 (3)	1	0
Hemorrhagic effusion	6 (21)	2	4
Transudate	6 (21)	5	1
Total	29 (100)	14 (49)	15 (51

differences between the two groups regarding sex distribution, age, or catheter caliber.

Indications for drainage and intrapleural therapy

The indications for therapeutic thoracentesis in this series and their distribution in the two patient groups are listed in Table 2.

The most common diagnosis leading to the intervention was complicated parapneumonic effusion, which was identified in 10 of the 29 patients (34%). All 3 of the complicated parapneumonic effusion patients treated with the Pleuracan® system required IPFL therapy. Fluid drainage was successful in 2 (67%) of these cases, but the third patient (33%) required decortication. Of the 7 complicated parapneumonic effusion patients in whom Pigtail® catheters were used, 6 (86%) required intrapleural UK instillation. Ultimately, 3 of these IPFL patients (43% of the complicated parapneumonic effusion patients with Pigtail® catheters) required decortication after 6 weeks of follow-up. Intrapleural UK instillation was successful in the other 3 (43% of the complicated parapneumonic effusion patients with Pigtail® catheters).

In the 6 patients with malignant pleural effusion, histological subtyping identified non-small cell lung carcinoma in 5, and chondrosarcoma in 1 case. Of the 3 patients with malignancy, 3 underwent Pigtail® intervention, 2 required pleurodesis treatment with tetracycline. Both types of drainage systems successfully recovered pleural fluid in all patients with malignant effusions.

One of the 29 patients had developed hemothorax from hemorrhagic diathesis caused by aplastic anemia. In this case, a Pleuracan[®] catheter and IPFL therapy with UK drained the chest successfully.

Of the 6 patients with hemorrhagic effusion related to CRF, Pleuracan® catheters were inserted in 2 (33%) and these

Table 3. Comparison of two performance parameters for the catheter systems

	Pleuracan [®]	Pigtail [®]	P value
Variable			
Drainage volume (ml)	2436±1905	1388±598	0.07
Mean duration of catheter stay (days)	2.5±1.4	3.8±2.5	0.06

patients recovered with no complications. The effusions in the remaining 4 patients (67%) were drained by Pigtail® catheters, and 2 of these individuals required intrapleural UK instillation to lyse fibrin bands secondary to CRF. Of the 4 patients in whom Pigtail® devices were used, 3 recovered completely and 1 (25%) required decortication.

Of the 6 patients with transudates, Pleuracan® placement was palliative in 5 cases and Pigtail® placement was palliative in 1 individual.

Catheter stay and drainage volume

Mean duration of tube stay and total volume drained are given in Table 3. Although the patients with Pleuracan[®] catheters showed trends towards shorter catheter stay and larger drainage volume, the differences between the groups were not statistically significant (p> 0.05).

Complications

We calculated the complication rate for each group based on findings of vasovagal reaction, pneumothorax, pleural infection and bleeding. Three (10%) of the 29 patients developed pneumothorax, with 1 case (3%) in the Pleuracan® group and 2 (7%) in the Pigtail® group. Large-tube thoracostomy was not required in any of these 3 cases of pneumothorax. None of the other complications noted above were observed in either of the groups. In addition to complication rates, we also evaluated the patients' comfort state following catheter placement. In all cases, patients reported no discomfort with their catheters.

Discussion

Many different types of chest tubes can be inserted to evacuate pleural fluid. These devices range in size from 8.0 to 36.0 F, and commercial kits for 8.0 to 16.0 F tubes are the best systems for facilitating catheter placement. These systems are associated with minimal morbidity compared to serial therapeutic thoracentesis or large-tube thoracostomy (6). Our study shows that small-bore chest drain kits that do not require US guidance for placement can be used as effectively as the US-guided drainage system to drain pleural fluid. As described, we examined patients with pleural effusion who underwent either US-guided pleural catheter placement (Pigtail® group) or catheter placement without

US guidance (Pleuracan® group). Although they conflict with other researchers' findings, our results show that closedsystem chest drain kits for percutaneous placement of small diameter tubes (14 F) are at least as safe as US-guided systems in patients with pleural effusion. Other published reports have concluded that image-guided drainage is a safer and more effective method of collecting pleural fluid compared to closed-system drains (14-17). We believe that the disparity between our results and those of other studies may be explained by the fluid levels in our patients' chests. Most cases in our study involved medium- or large-sized effusions. It is true that US is significantly superior to closed thoracentesis for sampling small and loculated effusions. However, blind thoracentesis based on chest films can be successful in patients with large effusions, especially when an experienced clinician performs the procedure.

It is always important to obtain a chest radiograph after therapeutic thoracentesis in order to verify that pneumothorax has not occurred. The only series in the literature that examines both US-guided and bedside drain placement, showed pneumothorax as the most frequent complication (18). The 10% incidence of pneumothorax in our study corroborates these findings and is comparable to the rates that have been documented in prospective studies of bedside thoracentesis. Seneff et al. reported a 15.5% rate (19), and Grogan and colleagues reported a 30.3% rate of pneumothorax in thoracenteses performed by house officers (15). All the thoracentesis procedures in our study were performed by doctors who had specialized in chest diseases. Regarding other potential complications of this technique, we encountered none of the relatively minor problems (vasovagal reaction, cough, or bleeding) in our patients. Our data showed that similar catheter diameters were used in the Pigtail® and Pleuracan® groups; thus, it is not surprising that there were no differences in complications or patient comfort related to the chest-tube size.

Previously published studies have investigated small-bore *vs* large-bore chest tubes for treatment of symptomatic pleural effusions. Parulekar *et al* found that small-bore catheters may be as effective for treating malignant pleural effusions as large-bore catheters (6). Clementsen *et al* also concluded in their studies that in patients with recurrent malignant pleural effusion, therapeutic thoracentesis with small percutaneous catheters (Cystofix[®], Braun, Germany) can yield an effect similar to that achieved with large-bore chest tubes and with less patient discomfort (4). Many studies have established that small-bore chest tube placement for drainage of symptomatic malignant effusions is a well-accepted and well-tolerated palliative procedure (3,20).

In the past, relatively large (26 to 30 F) have been recommended due to the belief that smaller tubes would

become obstructed with the thick fluid. However, there is abundant data indicating that such large tubes are unnecessary. Recent series in which patients with complicated parapneumonic effusions were treated with smaller catheters (8.3F-16F) demonstrate that these patients can be successfully managed with the small-bore catheters (21,22).

Our series were comparatively small and the diagnoses in the 29 patients with symptomatic pleural effusion varied from parapneumonic effusion to malignancy, hemorrhagic effusion, hemothorax or transudates. All of these conditions were considered as indication for therapeutic thoracentesis.

In complicated parapneumonic effusion, adequate drainage of the pleural space is at least as important as antimicrobial therapy in determining the outcome. Chest tubes should be inserted as soon as possible following a diagnosis of a complicated parapneumonic effusion, because the longer tube thoracostomy is delayed, the more difficult the pleural drainage becomes. As expected, compared to findings in patients with other illnesses, our patients with complicated parapneumonic effusion had a higher complication rate and more of them required lung decortication. Decortication is the procedure of choice for patients whose pleural effusion is not controlled by the less invasive measures of tube placement and intrapleural thrombolytic complicated In our patients with parapneumonic effusion, we administered 6 weeks of antibiotic therapy in addition to pleural drainage. However, in some cases the pleura remained thickened and pulmonary function was reduced to a level that limited the individual's activities. This was the stage at which decortication was considered.

There were more cases of complicated parapneumonic effusion and hemorrhagic pleural effusion in our study group who underwent US-guided drainage, a finding which explains why the requirement for decortication was higher in this group than in the Pleuracan® group. If the indications for therapeutic thoracentesis had been more evenly distributed between the two groups, the decortication ratios might have been different. In our opinion, closed-drainage systems are as effective and as safe as US-guided systems for patients with complicated parapneumonic effusion and hemorrhagic pleural effusion. We believe that small-bore catheter placement should be considered in any patient whose physical examination and chest x-ray findings reveal a large pleural effusion.

In the patients with malignant pleural effusion, we found that both the Pleuracan® and Pigtail® catheters were reasonably comfortable and safe, and that they were effective for pleurodesis treatment. These findings have also been

documented previously (4,17). In addition to complicated parapneumonic effusion and malignancy cases, we found both drainage systems to be useful in treating other chest conditions as well.

Regarding drainage volume and mean duration of catheter stay, we found no significant difference in the performance of the Pleuracan® and Pigtail® systems (p>0.05). This indicates that bedside catheters are effective means of palliative treatment for diseases of the pleural space. In addition to utility, these systems are considerably cheaper than the US-guided intervention because the sonography costs are eliminated. Our study was not designed to specifically address cost-effectiveness, so we can only make general statements about this aspect of the group comparison.

The main disadvantage of a commercial thoracentesis kit is that they are more expensive than the older methods. The principal advantage of the plastic catheter system is that there is no sharp needle in the pleural space that might lacerate the lung as it re-expands. Moreover, the patient can be re-positioned with the catheter in place to allow more complete pleural fluid removal. Both of the drainage systems we studied offer these technical benefits.

Research has shown that malignant effusion and complicated parapneumonic effusion are the conditions most commonly treated with small-bore tubes (4,7,8,16,20,23). However, other types of symptomatic effusions, such as transudates and hemorrhagic effusions, should also be drained by therapeutic thoracentesis. In each case under consideration, two criteria should be met before therapeutic thoracentesis is performed: first, the effusion must be symptomatic, and second, the patient's chest condition must be refractory to traditional medical therapy, or must be one for which no adequate therapy exists (1,24,25). All of our cases had both these features.

In conclusion, our results indicate that closed-system chest drain kits for percutaneous placement of small-diameter tubes are safe and promising tools for treating symptomatic pleural effusion. With the proper technique, the procedure is minimally invasive, avoids the cost of sonographic guidance, and can be easily performed by the clinician at the bedside. The strength of interpretation in this study was limited by the small number of patients that were treated with each system; thus, it is difficult to make strong conclusions. Further investigation is needed, preferably in the form of larger randomized prospective trials.

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