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Patient-Centered Outcomes Following Thoracentesis

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Abstract

Background—Pleural effusions impact over 1.5 million people annually in the United States and cause significant morbidity. Although therapeutic thoracentesis is associated with improvement in respiratory parameters, unanswered questions remain regarding its impact.

Objective—The purpose of this study was to investigate patient-centered outcomes, the need for additional pleural interventions, and mortality in the 30 days following thoracentesis.

Methods—This prospective observational cohort study was performed in a tertiary care academic medical center between December 2010 and December 2011. Adult patients referred for thoracentesis were offered enrollment. The following characteristics were evaluated both before and at 30 days postprocedure: dyspnea using modified BORG (mBORG), physical and mental quality of life (QoL) using the short form 12, and basic activities of daily living (BADLs). The primary outcomes included changes in these parameters 30 days after thoracentesis. Secondary outcomes included the need for additional pleural procedures and mortality within 30 days of the thoracentesis. Multivariable logistic regression was used for analysis.

Results—Of the 284 patients who underwent thoracentesis, 80 (28.2%) died within 30 days of the procedure. Of the 163 patients comprising the analytical cohort, 35 (21.5%) patients required an additional pleural intervention within 30 days of the index procedure. Patients who survived more than 30 days following thoracentesis had a sustained improvement in dyspnea and mental QoL, but a minority had improvement in physical QoL or BADLs. Surviving patients demonstrated no significant associations between bilateral and unilateral thoracentesis, volume of fluid removed, or the etiology of the effusion (malignant vs nonmalignant) and improvement in QoL, dyspnea, and BADLs. Relative to nonmalignant etiology, the presence of a malignant effusion was strongly associated with the need for an additional intervention, yielding an odds ratio (95% confidence interval [95% CI]) of 16.92 (5.47-52.37). Patients with hepatic hydrothorax

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and infectious etiologies of their effusion were also likely to require additional pleural interventions.

Conclusion—The majority of patients in this cohort demonstrated sustained improvement in dyspnea and the mental aspect of QoL 30 days following thoracentesis, independent of the etiology and regardless of the volume of pleural fluid removed. A minority experienced sustained improvements in the physical aspect of QoL and BADLs. Although 28.2% of patients died within 30 days, nearly 1 in 5 survivors required an additional pleural intervention. These results emphasize the significant clinical impact, morbidity, and mortality experienced by patients who undergo thoracentesis for pleural effusions.

Keywords

pleural effusion; thoracentesis; dyspnea; quality of life

Introduction

Pleural effusions occur in 1.5 million people in the United States annually, of which 178 000 undergo thoracentesis.¹ Therapeutic thoracentesis is associated with improvements in oxygenation,² pulmonary mechanics, gas exchange,³ spirometry, the 6-minute walk test,⁴ and sleep.⁵ The management of pleural disease has recently undergone a paradigm shift, whereby patient-centered outcomes, including hospital readmissions, morbidity, and mortality, are paramount. Although the availability of biochemical data in pleural effusions allows physicians to fine-tune individualized patient management, future effusion analysis may allow us to predict outcomes.⁶ Whether the amount of pleural fluid drained during thoracentesis is associated with clinically significant symptomatic benefit is questioned and debated among practitioners, and an evidenced-based answer does not exist. Other vexing questions include the clinically relevant degree and duration of benefit a patient receives following thoracentesis.

We performed a prospective study in an effort to address some of these unanswered questions. Using patients who underwent a clinically indicated thoracentesis to treat symptomatic pleural effusions, we characterized the effusion by laterality, volume, etiology, and by the temporal nature of the effusion defined as requirement for recurrent pleural procedures within 30 days of the index thoracentesis. We studied patient-centered outcomes on the day of the procedure and 30 days postprocedure with primary outcomes including severity of dyspnea, quality of life (QoL), and ability to perform basic activities of daily living (BADLs). Secondary outcomes included the need for additional pleural interventions within 30 days of mortality.

Methods

A prospective cohort study was conducted at Yale-New Haven Hospital between December 2010 and December 2011 wherein all patients referred to the interventional pulmonary program for thoracentesis were eligible to participate. Yale-New Haven hospital is a tertiary care, urban, 1000-bed academic hospital. Approval for the study was obtained from the Yale University School of Medicine Institutional Review Board (Human Investigation Committee

[HIC] number 1307012325), and all participants provided informed consent for both the procedure and for research participation. The interventional pulmonary program performs a majority of thoracenteses in this hospital environment. Indications for thoracentesis included the need to define an etiology by analyzing the characteristics of the effusion and for symptomatic relief of dyspnea. Inclusion criteria included age \geq 18 years, radiographic evidence of pleural effusion, and a clinically justified need for thoracentesis. Patients were excluded if they refused enrollment or were lost to follow-up for any reason within 30 days postprocedure, usually due to death. Most patients were inpatient, predominantly on medical rather than surgical floors, or in the medical intensive care unit.

Demographics and medical history were obtained from the patient or their surrogate on the day of the index thoracentesis using supplemental information abstracted from the medical records. Ultrasound (SonoSite S-ICU, Bothell, Washington) was used to locate and mark the pleural effusions at the time of thoracentesis. The intent of every thoracentesis was complete evacuation of the pleural space, and this was accomplished by manual aspiration. For this, fluid was actively aspirated into a syringe and flushed into a bag. A vacuum bottle was not used. The procedure was aborted if the patient complained of severe pain or otherwise could not tolerate the procedure. Pleural manometry was not used. If bilateral effusions were evident on preprocedural chest X-ray, both sides were always drained simultaneously per our practice protocol. Pleural fluid was subsequently sent for routine analysis including cell count, protein, lactate dehydrogenase, pH, cultures, and cytology. Flow cytometry was performed when there was a clinical suspicion of a lymphoproliferative disorder. A CXR was routinely performed following the procedure.

Following data collection using the results of the pleural fluid analysis as well as clinical data, the etiology of the pleural effusions was determined by 2 physicians using predefined criteria.⁷ Effusions were only considered to be secondary to malignancy if cytology demonstrated malignant cells or flow cytometry was positive. A recurrent pleural effusion was defined as that requiring additional pleural intervention within 30 days of initial thoracentesis.

The primary outcomes included dyspnea, physical and mental QoL, and BADLs. These were assessed at the time of the index procedure and 30 days postprocedure with the following validated instruments: the modified BORG (mBORG) score,⁸ the short form 12 (SF-12) questionnaire,⁹ and Katz BADLs.¹⁰ Questions were asked in person on the day of the procedure using these instruments by an investigator not performing the procedure. At the time of follow-up, questions were asked by telephone. The degree of dyspnea was assessed at the time of the procedure and on the day of follow-up, whereas QoL and BADL questions referred to the 2 to 4 weeks preceding the procedure and in the 30 days following the procedure.

Secondary outcomes included the need for an additional pleural intervention within 30 days of the index thoracentesis and mortality. These were assessed during the follow-up patient telephone interview and by review of medical records. Additional pleural intervention consisted of any of the following procedures: repeat thoracentesis, placement of tunneled pleural catheter or chest tube, and thoroscopic evaluation (including pleurodesis).

Statistical Analysis

Demographics and procedural characteristics of those patients undergoing and those not undergoing additional pleural intervention within 30 days postprocedure were compared with input from a statistician (TM). Multivariable models of 4 dichotomous outcomes were evaluated. These outcomes were comprised of indicators of the following events within 30 days postprocedure: additional pleural intervention and improvement in physical QoL, mental QoL, dyspnea, and BADLs. Of note, there is a statistical rule of thumb stating that multi-variable logistic regression models should draw from 10 outcome events for each term included.^{11,12} In this regard, the model of need for additional pleural intervention was limited in its power to detect associations by the small number of patients. As such, we employed backward selection with the retention of only the strongest model terms to abide by this rule.

The primary explanatory variables included bilateral effusion, volume of fluid removed, and presence of a malignant effusion. Covariates included age, gender, race, and number of comorbidities. Associations between explanatory variables and the outcomes are presented as odds ratio (OR) and 95% confidence interval (95% CI). The SAS 9.4 statistical software was utilized, and in all cases, a *P* value < .05 was considered significant.

Results

Patient demographics and clinical characteristics are shown in Table 1. Patients had a mean of 2 underlying chronic medical problems, including obstructive lung disease, heart failure, liver disease, renal failure and others. The most common indications for performing thoracentesis included evaluation for malignancy or infection and an effort to provide symptomatic relief of dyspnea felt due to the effusion. A total of 320 patients were initially enrolled, and 163 patients were ultimately assessed at 30 days postprocedure. Of the 121 patients in which 30-day follow-up was not completed, 80 died and the majority of the others were unable to answer the questions satisfactorily due to altered mental status or other medical conditions. Of the 163 patients who had complete analysis, 128 (78.5%) required only the index thoracentesis whereas 35 (21.5%) required additional pleural intervention within 30 days due to recurrence of their effusion and associated symptoms. Additional pleural intervention within 30 days of the index thoracentesis was most commonly needed for patients with malignant effusion, infection, or liver disease (hepatic hydrothorax). The number of patients who underwent thoracentesis and subsequent pleural procedures is shown in Figure 1.

Rates of Improvement in Patient-Centered Outcomes

Of the patients who survived 30 days and had complete follow-up, the majority (60.1%) experienced a clinically significant improvement in dyspnea, as shown in Table 2. A majority of these same patients (56.3%) also exhibited improvement in the mental component of the SF-12. A minority of patients reported improvements in the physical component of the SF-12 (45.7%) and in their BADLs (19.4%).

Multivariable Analyses

Table 3 presents the associations calculated between the explanatory variables and the patient-centered outcomes. No significant associations were demonstrated between improvement in patient-centered outcomes (dyspnea, QoL, and BADLs) and the following: the performance of bilateral versus unilateral thoracentesis, the volume of fluid removed, or effusion etiology (malignant vs nonmalignant). As none of the explanatory variables showed significant associations with improvement in BADLs, these results are not included in Table 3. The need for additional pleural intervention was limited in its power to detect associations by the small number of patients ($n = 35$). The 3 terms retained in the model of need for additional pleural intervention were the explanatory variables of primary interest, that is, bilateral versus unilateral thoracentesis, amount of fluid removed, and malignant effusion. Relative to unilateral thoracentesis, patients who underwent bilateral thoracentesis were less likely to need an additional pleural intervention within 30 days of the index thoracentesis, yielding an OR (95% CI) of 0.10 (0.01-0.89) with $P = .04$. Although the total amount of fluid removed was not associated with need for additional pleural intervention, the diagnosis of a malignant effusion was strongly associated with the need for additional pleural intervention within 30 days of the index procedure, yielding an OR (95% CI) of 16.92 (5.47-52.37) with $P = <.01$.

Discussion

The removal of pleural fluid by thoracentesis is felt to facilitate greater lung expansion, improve the ventilation-perfusion ratio, and augment lung mechanics through relief of restrictive ventilation. For larger effusions, reduced pressure on the diaphragm enables the inspiratory muscles to operate on a more advantageous portion of their length-tension curve.^{13,16} Mechanoreceptors that detect changes in stretch, cough, and lung volume are believed to contribute to a person's sensation of dyspnea.¹⁷ The body's physiologic response to fluid in the pleural space may be sensitive to small volumes, and our data suggests that patients with small- or moderate-sized effusions may still benefit symptomatically from drainage of the fluid. Despite what is known about physiological impacts of thoracentesis, there is limited information on how patients fare during the 30 days postprocedure. Our study attempts to provide insight into this critical period of time.

Patients with pleural effusions who require thoracentesis are quite ill. We have previously demonstrated a high mortality rate in patients with malignant and benign effusions,¹⁸ as well as in hospitalized patients undergoing thoracentesis.¹⁹ The fact that 28.2% of patients in this study died and an additional 21.5% of those who were capable of providing follow-up information required an additional pleural intervention within 30 days of the initial thoracentesis emphasizes the need for aggressive management in this time period.

Our study suggests that dyspnea and the mental aspect of QoL are sustained in the majority of patients who underwent thoracentesis and who were alive after 30 days. This is likely in part because of the thoracentesis, but certainly due to other factors as well. Medical management targeted to the etiology of the effusion contributes to ongoing symptom relief, including optimized medical management of heart failure, fluid management in renal failure, treatment of infection, and multimodality support in malignancy. In our study, the majority

of patients with either congestive heart failure or renal failure (96.2%) did not require additional pleural intervention in the next 30 days, likely reflecting an ability to medically manage these patients. Similarly, 95.7% of patients with other causes of their effusion, mainly postoperative, did not require additional pleural intervention within 30 days. Why mental QoL is improved is difficult to determine, although possibly reflects feeling better from improvement in dyspnea and/or the underlying medical problem.

Although improvements in dyspnea were sustained, a minority of patients experienced improvement in the physical aspect of QoL and BADLs. These patients often have many comorbidities and due to this, require a multisystem therapeutic approach. Our study brings attention to physical impairments and difficulties performing BADLs that persist in patients with pleural disease. Given the marked mortality, the high rate of recurrent pleural interventions, and the ongoing disabilities, we suggest that pleural disease may be a marker of severe illness requiring aggressive comprehensive interventions.

A greater percentage of patients requiring additional pleural intervention had malignant or paramalignant effusions (57.1%), compared to those only requiring the index thoracentesis (15.6%). Although it is known that patients with malignant effusions often require additional pleural procedures, the fact that so many had symptomatic recurrence within 30 days is important clinical information. Should patients with malignant effusions undergo more definitive intervention at the time of diagnosis? What is the ideal follow-up for pleural disease in this population? Additional studies to address this are required. Notably the subgroup of patients requiring additional pleural intervention within 30 days was also characterized by a larger proportion of patients with incomplete follow-up, explainable by the high morbidity and progressive nature of these diseases that often result in hospitalization and mortality. Interestingly, patients who underwent bilateral thoracentesis were significantly less likely to require another pleural intervention.

Limitations of our study include that it was conducted at a single center and involved predominantly medical, not surgical patients. Figure 1 indicates that a large number of patients were excluded from analysis, mostly because of death but also because of poor health that limited their ability to provide data at 30 days postprocedure. We did not specifically monitor the overall medical care provided for these patients, including changes in medications, therapy, or rehabilitation. We cannot isolate the impact of thoracentesis from this other care provided for these patients and thus can only address what clinicians may expect of their patients within 30 days of thoracentesis. Finally, 30 days is a relatively short period of time. Dyspnea, QoL, and BADLs are dynamic processes that may change dramatically over different points in time.

Conclusion

The 30-day period following thoracentesis for pleural effusion is a critical time in patient management. We suggest that pleural effusions may be a marker of severe illness. A large number of patients die or require additional pleural interventions during this time. Although the majority of patients who survive have sustained improvements in dyspnea regardless of the volume of pleural fluid removed, multidisciplinary care directed at multiple

comorbidities is required. Despite improvements in dyspnea, patients undergoing thoracentesis often fail to improve in physical conditioning and their ability to perform BADLs, suggesting a much needed area for future research.

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Biographies

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Margaret A. Pisani is an associate professor of Medicine, fellowship director of the Pulmonary and Critical Care fellowship at Yale University. She mentors many investigators in clinical research and has a particular interest in ICU outcomes.

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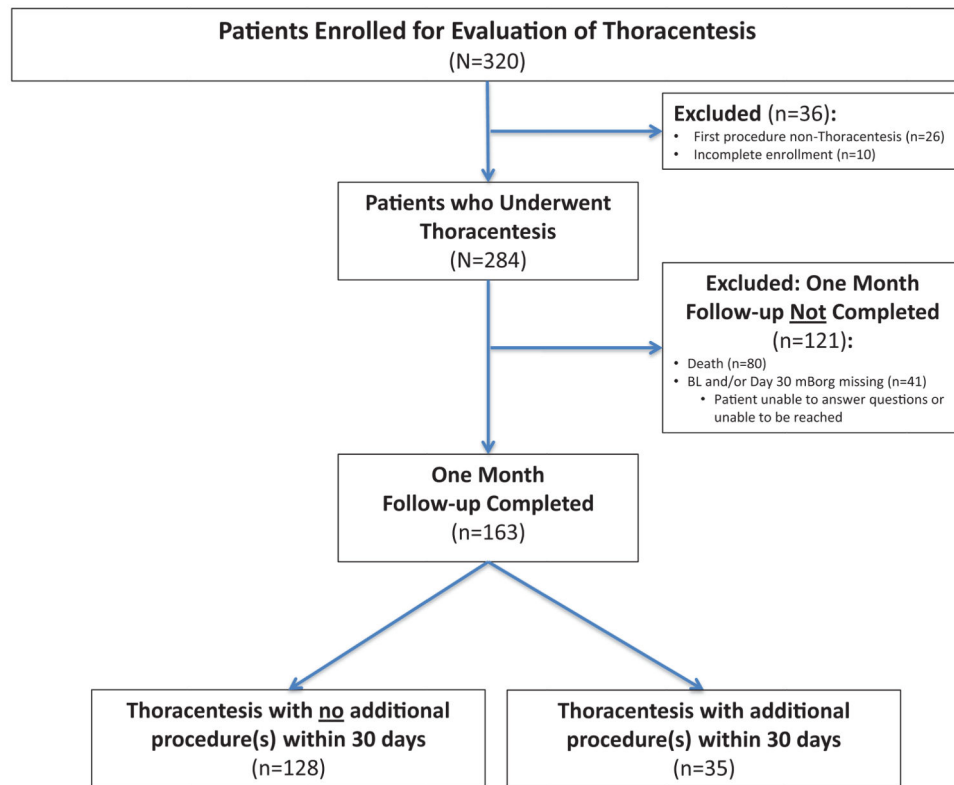


Figure 1.
Patient enrollment and follow-up.

Table 1

Baseline Characteristics of Patients Who Undergoing Thoracentesis by Need for Additional Pleural Procedure Within 30 days.^{a,b}

| Explanatory Variable | Analytical Cohort | No Additional Pleural Procedure | Additional Pleural Procedure | P Value ^c |
|---|-------------------|---------------------------------|------------------------------|----------------------|
| | (N = 163) | (n = 128) | (n = 35) | |
| Age, mean (SD) | 67.0 (15.0) | 67.0 (14.6) | 67.1 (16.6) | .97 |
| Male, n (%) | 76 (46.6) | 63 (49.2) | 13 (37.1) | .20 |
| Nonwhite race, n (%) | 25 (16.0) | 18 (14.9) | 7 (20.0) | .47 |
| Inpatient, n (%) | 131 (80.4) | 103 (80.5) | 28 (80.0) | .95 |
| Number of chronic medical conditions, mean (SD) | 4.3 (1.9) | 4.3 (2.0) | 4.2 (1.9) | .70 |
| Unilateral thoracentesis, n (%) | 140 (85.9) | 106 (82.8) | 34 (97.1) | .03 |
| Etiologies for index thoracentesis, n (%) | 140 (85.9) | 106 (82.8) | 34 (97.1) | |
| CHF | 17 (10.4) | 16 (12.5) | 1 (2.9) | .12 |
| Renal failure | 9 (5.5) | 9 (7.0) | 0 (0) | .21 |
| Liver failure | 13 (8.0) | 9 (7.0) | 4 (11.4) | .48 |
| Pneumonia | 19 (11.7) | 14 (10.9) | 5 (14.3) | .56 |
| Malignant | 22 (13.5) | 6 (4.7) | 16 (45.7) | <.0001 |
| Paramalignant | 18 (11.0) | 14 (10.9) | 4 (11.4) | 1.0 |
| Multiple etiologies | 26 (16.0) | 24 (18.8) | 2 (5.7) | .07 |
| Other ^d | 23 (14.1) | 22 (17.2) | 1 (2.9) | .03 |
| Unknown | 16 (9.8) | 14 (10.9) | 2 (5.7) | .53 |

Abbreviations: SD, standard deviation; CHF, congestive heart failure.

^aN = 163.

^bMissing data: race (n = 10; missing due to refusal or only ethnicity provided).

^cChi-square or Fishers exact test as appropriate for categorical variables and *t* test for continuous variables.

^dOther causes of pleural effusion included postoperative effusions, subdiaphragmatic infections or inflammation (pancreatitis), autoimmune disease, and others. The “unknown” effusions did not meet criteria defined for an associated etiology.

Table 2Rate of Improvement in Patient-Centered Outcomes in the 163 Patients Analyzed.^a

| Patient-Centered Outcome | n (percentage that improved) |
|-----------------------------|------------------------------|
| Dyspnea | 98 (60.1) |
| BADLs | 30 (19.4) |
| Physical component of SF-12 | 69 (45.7) |
| Mental component of SF-12 | 85 (56.3) |

Abbreviations: SF-12, short form 12; BADLs, basic activities of daily living.

^aMissing data: SF-12, physical (n = 12), SF-12, mental (n = 12), BADL (n = 8).

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Table 3

Results of Multivariable Analysis.^a

| Explanatory Variables | Patient-Centered Outcomes at 30 Days After Index Thoracentesis | | | | | | | |
|--|--|---------|------------------------|---------|---------------------|---------|------------------|-----|
| | Additional Pleural Procedure | | Improved SF12 Physical | | Improved Borg Score | | | |
| | OR (CI) | P value | OR (CI) | P value | OR (CI) | P value | | |
| Bilateral thoracentesis | 0.10 (0.01-0.89) | .04 | 1.60 (0.50-5.14) | .43 | 0.82 (0.26-2.59) | .74 | 0.94 (0.33-2.65) | .90 |
| Fluid removed (per 100 cm ³) | 1.03 (0.97-1.10) | .28 | 1.00 (0.95-1.06) | .99 | 0.97 (0.92-1.02) | .27 | 1.02 (0.97-1.07) | .44 |
| Malignant effusion | 16.92 (5.47-52.37) | <.01 | 0.55 (0.20-1.56) | .26 | 0.56 (0.24-1.76) | .40 | 0.50 (0.19-1.35) | .17 |
| Covariates ^b | | | | | | | | |
| Age, years | <i>c</i> | | 0.99 (0.97-1.02) | .55 | 1.02 (0.99-1.04) | .22 | 0.98 (0.96-1.01) | .14 |
| Male sex | <i>c</i> | | 0.78 (0.39-1.58) | .49 | 1.69 (0.83-3.46) | .15 | 1.07 (0.53-2.15) | .85 |
| Nonwhite | <i>c</i> | | 3.00 (1.07-8.43) | .04 | 2.96 (1.00- 8.73) | .049 | 0.51 (0.20-1.35) | .18 |
| Number of comorbidities (count) | <i>c</i> | | 1.15 (0.96-1.38) | .13 | 1.19 (0.99-1.43) | .07 | 0.92 (0.76-1.10) | .34 |

Abbreviations: SF-12, short form 12; OR, odds ratio; CI, confidence interval.

^aOnly 3 terms were permitted in the model due to the small number of outcome events (35). The presence of a malignant effusion had a high OR for needing another pleural procedure within 30 days, whereas patients who underwent bilateral thoracentesis had a low OR. Nonwhite patients improved in both mental and physical components of SF12.^bAll covariates omitted in backward selection.^cIndicate that these covariates were not considered in model selection for this outcome because of a small number of outcome events.