ORIGINAL ARTICLE

FACTORS INFLUENCING THE SURVIVAL OF PATIENTS WITH PLEURAL EFFUSION WITHOUT CLEAR ETIOLOGY

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ABSTRACT

BACKGROUND: Undiagnosed pleural effusion is a common cause of respiratory distress worldwide and contribute to morbidity and mortality. OBJECTIVE: The aim of this study is to evaluate factors affecting mortality and determine the 30 day and 90 day survival of patients with pleural effusion undergoing medical thoracoscopy. METHODS: This prospective study was conducted on patients with pleural effusion of unknown etiology who were over 18 years old and underwent medical thoracoscopy in Dr. Cipto Mangunkusumo National General Hospital, a tertiary care hospital in Jakarta, Indonesia. The study included 57 patients with pleural effusion who underwent medical thoracoscopy from January 2023 to May 2024. Patients were monitored up to 90 days after medical thoracoscopy. Kaplan-Meier and Cox proportional hazard analysis was used to analyze the data. RESULTS: The 90-day survival rate was 74.63% (CI 66.36-82.88). Analysis using the cox proportional hazard showed male gender [HR 2.108 (CI 0.732-6.076), p=0.167)] and poor ECOG PS [HR 3.822 (CI 0.863-16.928), p=0.077] were factors directly influencing the 90-day mortality of patients with pleural effusion of unknown etiology undergoing medical thoracoscopy. CONCLUSION: The 90-day survival rate of patients with pleural effusion with unknown etiology undergoing medical thoracoscopy is 74.63% (CI 66.36-82.88). Patients with pleural effusion of unknown etiology undergoing medical thoracoscopy who were male and with worse ECOG PS were associated with a higher risk of mortality within 90 days post procedure.

Keywords: Pleural effusion, medical thoracoscopy, survival, mortality

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Introduction

Pleural effusion remains a significant cause of respiratory distress worldwide and one of the leading causes of pulmonary mortality and morbidity.[1] It is estimated that 1.5 million new cases of pleural effusion is found in the United States and 200,000-250,000 in the United Kingdom each year.[2,3] DeBiasi et al. reported an overall mortality rate of 21% at 30 days and 51% at 1 year.[4] This study also reported higher mortality in patients with malignant pleural effusion (37% at 30 days, 77% at 1 year) and in patients with bilateral pleural effusion compared to unilateral effusion, regardless of etiology (47% mortality within 30 days, 69% within 1 year). In 1999-2011 as many as 62,9% of patients with malignancy presented with pleural effusion and in 2019 a total of 174 patients with malignant pleural effusion underwent thoracentesis in Dr. Cipto Mangunkusumo National General Hospital, Jakarta, Indonesia.[5] In 2012, up to 52,4% of malignant pleural effusion was found in Persahabatan Hospital, Jakarta, Indonesia.[6,7]

Although the initial modality in the diagnosis of pleural effusion is thoracosentesis, in some cases, the diagnosis cannot be established, necessitating other modalities such as pleural biopsy.[8–10] Medical thoracoscopy is a well-tolerated procedure that can provide visualization of the entire pleural surface. This procedure uses local anesthesia and can be a less invasive, more economical, and safer modality compared to surgical biopsy for diagnosing the etiology of pleural effusion.[11,12] From 47 previous studies, mortality was reported in 16 out of 4736 cases of pleural effusion (0.34%, 95% CI 0.19% - 0.54%). From 28 studies on diagnostic thoracoscopy, no mortality was found among 242 subjects, whereas 19 other studies reported a combined mortality from pleurodesis with talc in 16 out of 2315 (0.69%, 95% CI 0.40% - 1.12%).[13]

Early diagnostic procedures to diagnose the etiology of pleural effusion are important for patient management, contributing to both short-term and long-term patient outcomes. Previous studies in Indonesia shows no data presenting the survival of patients with pleural effusion patients with unknown etiology. Several factors are suspected to influence the mortality of patients with pleural effusion, including age, gender, Eastern Cooperative Oncology Group Performance Status (ECOG PS), bilateral pleural effusion, malignancy condition, serum albumin levels, exudative effusion, and the role of definitive therapy after diagnosis. This study is designed to determine the survival and factors affecting patients with pleural effusion without a clear etiology.

Method

This study was a prospective cohort, **a sub-study of the larger research project "Medical Thoracoscopy in Transudative and Exudative Pleural Effusion without Clear Etiology.** We included subjects with pleural effusion occupying more than half the hemithorax with unidentified etiology that underwent medical thoracoscopy in Dr. Cipto Mangukusumo National General Hospital, a tertiary care hospital in Indonesia. Subject were recruited from January 2023 through to May 2024.

Inclusion criterias for this study are patients aged $\geq$ 18 years with pleural effusion involving at least half of the right or left hemithorax, with unidentified etiology, and undergoing medical thoracoscopy. Exclusion criterias are pregnant and breastfeeding women, patients on non-invasive ventilation and mechanical ventilators, and pleural effusion (both transudative and exudative) with a clinical and supportive examination indicating chronic heart failure, chronic kidney disease, or hepatic cirrhosis with hepatic hydrothorax.

In this study, we analyzed the 30-day mortality rate as well as the 90-day mortality rate for patients with pleural effusion of unclear etiology. We also assessed several factors that may be related to mortality, which were age, gender, ECOG Performance Status (ECOG PS),

distribution of pleural effusion (unilateral or bilateral), presence of malignancy, serum albumin levels, exudate or transudate fluid analysis, and lack of definitive therapy post-diagnosis.

The procedure for sample recruitment and retention is conducted through consecutive sampling. All patients with recurrent pleural effusion of unclear etiology, presenting with pleural effusion involving ½ of the hemithorax, whether as outpatients (polyclinic) or admitted through the emergency department or electively for procedures, are included. Patients underwent thoracentesis twice. If the effusion recurs and the etiology remains unclear with negative cytology results, informed consent for thoracoscopy is obtained. Data collected included age, gender, ECOG Performance Status (ECOG PS), distribution of pleural effusion, evaluation of the presence of malignancy, serum albumin levels, pleural fluid analysis (exudate or transudate), and whether definitive therapy was received after diagnosis. Evidence of malignancy was proven through histopathological and cytological examinations. Distribution of pleural effusion was based on radiological examinations, including chest X-ray and chest CT scan.

Outcomes being measured were 30-day mortality rate as well as the 90-day mortality rate post-medical thoracoscopy. Statistical analysis was performed using the SPSS version 25.0 computer program, with survival and multivariate analysis using the Cox regression model to produce Kaplan-Meier curves and hazard ratios (HR). Continuous variables were presented with mean and standard deviations (SD), or median and interquartile range (IQR). Survival analysis for each variable was conducted using the Kaplan-Meier method and Log-rank test. Variables with p-value < 0.25 were included in the multivariate analysis using the Cox regression model to produce Kaplan-Meier curves and ratio of hazard rates of independent variables was presented in hazard ratios (HR).

Result

A total of 57 subjects were recruited during the time period January 2023 to May 2024. The average age of the subjects was 47.79 years, with a higher proportion of subjects below the age of 60 (80.7%). The majority of the subjects were male (52.6%), had secondary education (61.4%), and one-third (31.6%) were exposed to smoking, either as active smokers or with a history of active smoking. Additionally, the majority of subjects had good ECOG PS status (94.7%), unilateral pleural effusion (71.9%), had no initial malignancy (77.2%), and had serum albumin levels < 3.5mg/dL (75.4%). A total of 77.2% of subjects had exudatif pelural effusion, and 70.2% did not receive additional therapy after medical thoracoscopy.

Mortality assessment was conducted on the 30th and 90th day post-medical thoracoscopy. The 30-day mortality rate was 17%, and it increased to 30.2% by the 90th day. The mean 30-day survival rate for patients with pleural effusion of unknown etiology was found to be 27.51% (CI 25.29 – 29.72), and the mean 90-day survival rate was 74.63% (CI 66.36 – 82.88). Variables such as age ≥ 60 years [HR 0.444 (0.055 – 3.556), p=0.445], presence of malignancy [HR 0.888 (0.184 – 4.277), p=0.882], and exudative pleural fluid [HR 0.900 (0.187 – 4.337), p=0.896] showed a protective value against 30-day mortality. Other variables such as gender, ECOG PS, bilateral pleural effusion, and hypoalbuminemia increased the risk of 30-day mortality but were not statistically significant. Bivariate analysis showed that not receiving definitive therapy increased the risk of 30-day mortality [HR 4.066 (0.508 – 32.532), p=0.186].

Analysis of 90-day mortality showed that subjects aged ≥60 years [HR 1.205 (0.388 – 3.739)], presence of bilateral pleural effusion [HR 0.970 (0.313 – 3.008), p=0.970], presence of malignancy [HR 1.010 (0.326 – 3.132), p=0.987], exudative pelural fluid analysis [HR

1.111 (0.316 – 3.900), p=0.870], and not receiving definitive therapy after diagnosis [HR 1.581 (0.510 – 4.906), p=0.428] increased the risk of 90-day mortality, but none of these five factors were statistically significant. Meanwhile, male subjects [HR 2.205 (0.703 – 5.835), p=0.191], poor ECOG PS [HR 3.928 (0.887 – 17.392), p=0.071], and hypoalbuminemia [HR 2.444 (0.555-10.762), p=0.237] significantly increased the risk of mortality in patients with pleural effusion of unknown etiology.

Multivariate analysis using Cox regression was performed on independent variables with $p < 0.25$ or $HR \geq 1.5$ from the bivariate test results. This analysis showed that not receiving definitive therapy increased the risk of 30-day mortality [HR 4.066 (0.508 – 32.532), p=0.186] and poor ECOG PS [HR 3.928 (0.887 – 17.391), p=0.071] increased the risk of 90-day mortality, although both were not statistically significant.

Discussion

This study aims to determine the survival of patients with pleural effusion of unclear etiology and the factors influencing it. A total of 71.9% of the study subjects experienced unilateral pleural effusion, with 77.2% of the study subjects having exudative pleural effusion that was not malignant. DeBiasi et al. also reported that 80.2% of their study subjects had unilateral pleural effusion, with 74.5% being non-malignant and 66.3% being exudative.[4] In a study conducted at Persahabatan Hospital (2012), it was also reported that 87% of the cases were exudative pleural effusions, primarily caused by malignancy (42.8%) and tuberculosis (42%).[6]

Various studies conducted in countries with high TB prevalence generally report a much higher incidence of exudative effusions compared to transudative effusions. The highest cause of pleural effusion in countries with low TB prevalence is malignancy, as reported by Heidari et al. with 41% of pleural effusion etiology being malignancy and 33% caused by TB infection.[14] Similar findings were reported by Porcel et al.[15] and Gonlugur et al.[16] A study by Puchalski et al. reported that the most common etiology of exudative pleural effusion is a combination of two etiologies (30%), which may include congestive heart failure/malignancy, congestive heart failure/autoimmune, malignancy/hypoalbuminemia, and others, followed by malignancy (26%).[17]

In this study, the survival rates of patients with pleural effusion of unclear etiology at 30 and 90 days post-medical thoracoscopy were 83.0% and 69.8%, respectively. These survival rates are lower compared to the study conducted by Kookoolis et al., which showed mortality rates of 15% and 32% at 30 days and 1 year, respectively, in 140 patients with pleural effusion treated in the hospital, whether thoracentesis was performed (89.4%) or not (10.6%).[18] The study involved a majority of subjects with heart, lung, kidney diseases, and malignancies, with a mean age of 73 years (SD 16.6) and 68 years (SD 15.9) for subjects who did not receive and received thoracentesis, respectively. The difference in mortality outcomes may be due to the severity of the disease, as subjects in this study required therapeutic thoracentesis, whereas in the study by Kookoolis et al., only 10.6% underwent thoracentesis.[18]

Another study by Markatis et al. reported a higher overall 30-day mortality outcome of 22.6%, involving 508 pleural effusion patients with a higher mean age of 78 years.[19] Verma et al. conducted a study on 41 patients who underwent medical thoracoscopy for biopsy and therapeutic pleurodesis using talc (36.6%), with a 30-day mortality outcome similar to this study, at 17.1%.[20] The 90-day mortality outcome differed from this study, with a mortality rate of 39% compared to 30.2% in this study. The study involved a majority of patients with malignancy (58.5%) and

tuberculosis (22%) with an average age of 65 years. It was reported that the mortality rate was not caused by the thoracoscopy procedure. However, the higher 90-day mortality outcome might be influenced by the higher mean age of the study subjects (65 years). The study by Verma et al. also showed that the success rate of medical thoracoscopy in diagnosing the etiology of pleural effusion of unknown cause reached 77.8%. Our study reported a diagnostic success rate of 96.5%, with malignant pleural effusion accounting for 38.6% and 12.3% diagnosed as TB pleurisy, and 45.6% of non-malignant effusion consistent with underlying disease. Non-diagnostic results may be contributed to difficulties obtaining histopathological samples and made up 3.5% of subjects, arising from 2 subjects with histopathological examination results showing pleural fat tissue and lipoma.

In the bivariate analysis, only three variables were statistically significantly associated with 90-day patient mortality outcomes: gender, hypoalbuminemia and poor ECOG PS. Male patients had a significant influence (HR 2.205) on pleural effusion mortality outcomes within 90 days. This result contrasts with several other studies, including the study conducted by Kookoolis et al.[18], which showed that the male gender variable was a non-significant protective factor for 30-day [HR 0.60 (CI 0.18-2.00)] and 90-day [HR 0.79 (CI 0.38-1.66)] mortality outcomes. Markatis et al. also showed similar results where female gender is a risk factor for mortality outcomes [HR 1.092 (CI 0.58-1.96)], but the results were not significant.[19] The study by DeBiasi et al. showed that the male gender acted as a protective factor for 30-day mortality outcomes [OR 0.96 (CI 0.58-1.60)], but was a risk factor for 1-year mortality outcomes [OR 1.07 (CI 0.77-1.40)].[4]

These differing results might be explained based on the predilection for pleural effusion in each country, which can differ from Indonesia. The study by Adeoye et al. in Nigeria showed that malignancy was the leading cause of exudative pleural effusion in women, whereas tuberculosis was the leading cause in men, correlating with higher mortality outcomes in women.[21] Similarly, in this study, 22.8% (n = 13) of subjects had malignancy at the start, with 76.9% (n = 10) being women and 23.1% (n = 3) being men. However, mortality outcomes were higher in men (68.75%, n = 11) compared to women (31.25%, n = 5). This could be influenced by the higher risk of acute respiratory failure in men, which increases mortality outcomes. Acute respiratory failure and mortality outcomes, especially those documented in hospitals, were higher in men (66.9%) with the highest underlying disease being pneumonia (58.7%), followed by COPD (25.5%), pulmonary tuberculosis (25.2%), and lung cancer (16.5%). Several studies conducted in Indonesia show that pleural effusion occurs more frequently in men due to higher predisposition factors such as smoking and working outside the home compared to women in Indonesia. This supports the risk of anatomical changes in the lungs due to greater exposure to irritants compared to women.

This study reports that 75.4% of subjects had serum albumin levels < 3.5 mg/dL. A similar finding was reported by Pilling et al., where 66% had hypoalbuminemia (serum albumin < 3.5 mg/dL) among 278 patients with malignant pleural effusion.[22] The most commonly found types of malignancy in their study were breast cancer (28.9%), followed by mesothelioma (27.5%), lung cancer (13.2%), and ovarian cancer (8.9%). In this study, low levels of albumin were significantly related [HR 2.444 (CI 0.555-10.762), p=0.237] to the 90-day mortality outcomes of patients with pleural effusion of unknown etiology who underwent medical thoracoscopy. Similar findings were observed in a study conducted by Ford et al. involving 326 patients with malignant pleural effusion, which showed that low albumin levels were significantly associated with higher

mortality rates at 1 month and 3 months.[23] Pilling et al. reported that 278 patients with malignant pleural effusion showed a significant difference in mean survival time between patients with albumin levels >35 g/L and <35 g/L, being 667 days (CI 449-885) and 114 days (CI 87-141), respectively.[22] Multivariate analysis in a study by Bernard et al. found that low serum albumin levels (≤60 g/L) were significantly correlated with higher mortality rates in patients with malignant pleural effusion (p=0.03).[24]

The results of this study indicate that patients with poor ECOG performance status (ECOG PS) have a 3.928-fold increased risk (CI 0.887-17.392) of 90-day mortality outcome. However, multivariate analysis showed that this association was not statistically significant and did not predict 90-day mortality in patients with pleural effusion without clear etiology undergoing medical thoracoscopy. These findings align with Jeba et al.'s study on 48 patients with malignancy-related pleural effusion, which demonstrated a significant correlation between poor ECOG PS and shorter survival duration; ECOG PS scores 0, 1, 2, 3, and 4 sequentially had mean survival durations of 8 months, 4.5 months, 4 months, 2 months, and 1 month.[25] The majority of patients in that study had pleural effusion due to lung cancer (41.7%) followed by breast cancer (27.1%). Additionally, a systematic review and meta-analysis by Peng et al. (2022) also showed similar results, indicating a significant correlation between high ECOG PS scores (poor ECOG PS) and prognosis in patients with malignant pleural effusion [HR 2.35 (CI 1.83-3.00)].[26]

Conclusion

This study provides important insights into the characteristics and factors affecting mortality in patients with pleural effusion of unclear etiology undergoing medical thoracoscopy, particularly in terms of gender and ECOG PS.

Furthermore, this study founs that patients who did not receive definitive therapy after diagnosis had a higher 30-day mortality rate [HR 4.066 (0.508 – 32.532)], although the result was not significant. Regarding 90-day mortality outcomes, not receiving therapy increased the risk of mortality by up to one and a half times [HR 1.581 (CI 0.510-4.906)]. This study achieved a diagnostic value of 96.5%, with malignant pleural effusion confirmed by histopathological examination of pleural tissue in 38.6% of cases and diagnosis of TB pleuritis in 12.3%. Definitive therapy after diagnosis was defined as new treatments given to subjects in whom pleural effusion etiology was identified based on pleural visualization results, laboratory biomarker tests, and cytological or histopathological examination of tissue biopsy obtained from medical thoracoscopy.

Based on the diagnostic results obtained, 29.8% (N = 17) of subjects received therapy after medical thoracoscopy. The therapies provided included anti-tuberculosis drugs (41.2%, n = 7), chemotherapy (41.2%, n = 7), pleurodesis (5.9%, n = 1), radiation (5.9%, n = 1), and surgery (5.9%, n = 1). Among the 6 subjects diagnosed with TB pleuritis from medical thoracoscopy, 6 (85.7%) out of 7 subjects initiated anti-tuberculosis drugs, and 10 (45.5%) out of 22 subjects received therapy for malignancy. The proportion of subjects not given additional therapy after thoracoscopy was 38 (66.6%) subjects, of whom 13 (22.8%) died and thus did not continue with definitive therapy. A total of 5 (8.7%) subjects continued the therapy they had previously been given, which included chemotherapy, anti-tuberculosis drugs, and immunosuppressive agents in cases of SLE.

However, the unmet sample size and the differing baseline characteristics of the study subjects compared to previous studies limit the optimal analysis of this study. Further large-scale, multicenter studies are needed to refine the results, making them representative of the Indonesian population and producing

prognostic factors beneficial to patients and clinicians.

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Conflict of Interest
Authors declare no conflict of interest.

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Figure 4.2 Kaplan-Meier Curve for 30-day Mortality Outcomes in Patients with Pleural Effusion of Unknown Etiology

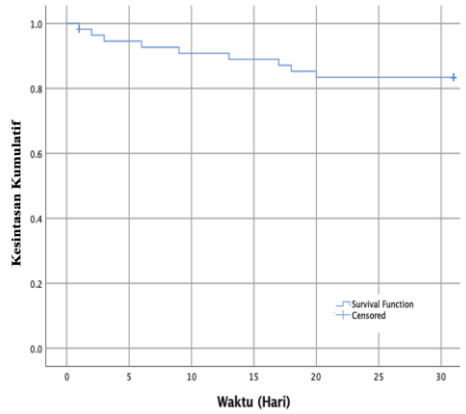

Figure 4.3 Kaplan-Meier Curve for 90-day Mortality Outcomes in Patients with Pleural Effusion of Unknown Etiology

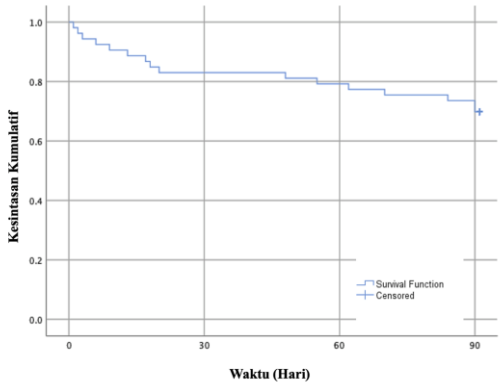

Table 1. Basic Characteristics of Subjects Studied

Characteristic	Total N (%) (n = 57)
Age, mean (SD)	47,79 (SB 14)
Age	
≥60 years	11 (19,3)
<60 years	46 (80,7)
Gender	
Men	30 (52,6)
Women	27 (47,4)
Pendidikan	
Primary School	7 (12,3)
Middle School	11 (19,3)
High School	24 (42,1)
University based	11 (19,3)
Smoking	
Yes	18 (31,6)
No	39 (68,4)
Comorbidities	
Yes	46 (80,7)
No	11 (19,3)
ECOG PS	
Poor	3 (5,3)
3	3 (5,3)
4	0
Good	54 (94,7)
0	1 (1,7)
1	27 (47,4)
2	26 (45,6)
Location of Pleural Effusion	
Bilateral	16 (28,1)
Unilateral	41 (71,9)
Malignancy	
Yes	13 (22,8)
No	44 (77,2)
Albumin	
≥3,5	14 (24,6)
<3,5	43 (75,4)
Pleural effusion	
Exudate	44 (77,2)
Transudate	13 (22,8)
Therapy	
No	40 (70,2)
Yes	17 (29,8)

Table 2 Proportion of Mortality in Patients with Pleural Effusion of Unknown Etiology

Outcome	Total, n (%)	Cumulative Survival
Mortality		
0-30 days	11 (17)	83,0%
61-90 days	16 (30,2)	69,8%

Table 3 Association of Risk Factors with 30-day Mortality in Patients with Pleural Effusion of Unknown Etiology

Variable	Mortality n (%)		HR (95% CI)	p-value
	Yes	No		
	9 (15,7)	48 (84,3)		
Age				
≥60 years	1 (9,1)	10 (90,9)	0,444 (0,055 – 3,556)	0,445
<60 years	8 (17,4)	38 (82,6)		
Gender				
Male	5 (16,7	25 (83,3)	1,079 (0,290 – 4,017)	0,910
Female	4 (14,8)	23 (85,2)		
ECOG PS				
Poor	1 (33,3)	2 (66,7)	2,865 (0,358 – 22,930)	0,321
Good	8 (14,8)	46 (85,2)		
Location of Pleural Effusion				
Bilateral	3 (18,8)	13 (81,3)	1,426 (0,356 – 5,707)	0,616
Unilateral	6 (14,6)	35 (85,4)		
Malignancy				
Yes	2 (15,4)	11 (84,6)	0,888 (0,184 – 4,277)	0,882
No	7 (15,9)	37 (84,1)		
Albumin				
<3,5	9 (20,9)	34 (79,1)	31,102 (0,047-204,933)	0,299
≥3,5	0 (0,0)	14 (100,0)		
Pleural Fluid				
Exudate	7 915,9)	37 (84,1)	0,900 (0,187 – 4,337)	0,896
Transudate	2 (15,4)	11 (84,6)		

Table 4 Association of Risk Factors with 90-day Mortality in Patients with Pleural Effusion of Unknown Etiology

Variable	Mortality n (%)		HR (95% CI)	p-value
	Yes	No		
	16 (28,1)	41 (71,9)		
Age				
≥60 years	4 (36,4)	7 (63,6)	1,205 (0,388 – 3,739)	0,747
<60 years	12 (26,1)	34 (73,9)		
Gender				
Male	11 (36,7)	19 (63,3)	2,205 (0,703 – 5,835)	0,191*
Female	5 (18,5)	22 (81,5)		
Location of Pleural Effusion				
Bilateral	2 (66,7)	1 (33,3)	3,928 (0,887 – 17,392)	0,071*
Unilateral	14 (25,9)	40 (74,1)		
Malignancy				
Yes	4 (25,0)	12 (75,0)	0,970 (0,313 – 3,008)	0,970
No	12 (29,3)	29 (70,3)		
Albumin				
<3,5	4 (30,8)	9 (69,2)	1,010 (0,326 – 3,132)	0,987
≥3,5	12 (27,3)	32 (72,7)		
Pleural Fluid				
Exudate	14 (32,6)	29 (67,4)	2,444 (0,555-10,762)	0,237*
Transudate	2 (14,3)	12 (85,7)		
Location of Pleural Effusion				
Bilateral	13 (29,5)	31 (70,5)	1,111 (0,316 – 3,900)	0,870
Unilateral	3 (23,1)	10 (76,9)		
Therapy				
No	12 (30,0)	28 (70,0)	1,581 (0,510 – 4,906)	0,428
Yes	4 (23,5)	13 (76,5)		

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