



Original Article

Cost-Effectiveness Study of the Diagnosis of Pleural Effusion in Chest Diseases Outpatient Clinic

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ABSTRACT

Objective: To evaluate the diagnostic efficacy of pleural procedures, safety, delay and cost of the diagnosis of pleural effusion (PE) by analysing the parameters that are dependent on the area of patient management (outpatient or inpatient).

Patients and Methods: Prospective non-randomized study. Two groups were established depending on whether they were managed in a specific outpatient unit or as a conventional hospital inpatient, with the rest of the criteria being the same for the study of the PE.

Results: We included 60 outpatients and 34 inpatients. The median number of visits as an outpatient was 2 (range 2-3), and the time an inpatient was hospitalized was 13 (range 7.7-25.2) days. The number of analytical and imaging studies was significantly higher in the inpatient group. There were no differences in the number of cytology and pleural biopsies, or complications between groups. There were no differences in time to performing computed tomography. The number of days until the pleural biopsy and the time until to obtain a diagnosis was lower in the outpatient group. Mean total cost for an outpatient was € 1.352 and € 9.793,2 for inpatients.

Conclusions: Management of ambulatory diagnosis of PE patients is highly cost-effective. The effectiveness and safety of forms of the study is at least similar. In this study, the mean cost for a hospitalised inpatient for a PE was 7.2 times higher than outpatient management.

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Estudio de coste-efectividad del manejo diagnóstico del derrame pleural en una unidad de patología pleural ambulatoria

RESUMEN

Objetivo: Analizar la eficacia diagnóstica de los procedimientos, seguridad, demora y costes del estudio diagnóstico del derrame pleural (DP) analizando estos parámetros en función del ámbito de manejo del paciente (ambulatorio u hospitalizado).

Material y métodos: Estudio prospectivo no aleatorizado. Se establecieron 2 grupos según su manejo se realizó de forma ambulatoria en una unidad específica o en régimen de hospitalización convencional, sin otro criterio de ingreso diferente al del propio estudio del DP, comparando las variables mencionadas en función del ámbito del estudio diagnóstico.

Resultados: Se incluyeron 60 pacientes ambulatorios y 34 hospitalizados. La mediana de visitas en los pacientes manejados de forma ambulatoria fue de 2 (RIQ = 2-3) días y la de días de estancia en los ingresa-

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dos de 13 (7,7-25,2) días. El número de analíticas y estudios radiológicos fue significativamente mayor en el grupo de pacientes hospitalizados. No observamos diferencias en el número de citologías ni de biopsias pleurales, ni en las complicaciones entre ambos grupos. No hubo diferencias significativas en el tiempo hasta la realización de la tomografía computerizada pero sí en el número de días hasta la realización de la biopsia pleural que fue menor en los pacientes del grupo ambulatorio al igual que el necesario hasta la obtención de un diagnóstico. El coste medio total por paciente ambulatorio fue de 1.352 € y en el ingresado de 9.793,2 €.

Conclusiones: El manejo diagnóstico de forma ambulatoria de pacientes con DP es altamente coste-efectivo. La efectividad y la seguridad de ambas formas de estudio son al menos similares. En este estudio el coste medio por paciente estudiado por DP en régimen hospitalizado fue 7,2 veces superior al que supone el manejo ambulatorio.

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Introduction

Pleural effusion (PE) is a very prevalent pathology that tends to be managed differently by different medical specialties. In recent years, several groups have attested to the convenience of offering comprehensive assistance to these patients in specialized units. Such a unit would appear to provide reduced technical morbidity, superior efficiency of diagnosis, and better definition of prognoses and treatment.^{1,2} Due to the need for semi-invasive technical procedures for the study of this condition (thoracentesis, pleural biopsy...), PE patients are usually hospitalized, which can mean an increase in procedural costs and elevated rates of inadequate hospital stays in a significant portion of patients.³ However, some evidence suggests that many patients could be safely managed as outpatient cases.⁴ In a comprehensive literature review, we have found no study that specifically analyzes the cost-effectiveness of outpatient management of PE in a specialized centre as opposed to the regimen of conventional hospitalization. Nor is this aspect specifically mentioned in the guidelines on diagnosis and treatment of PE recently published by the Spanish society of pneumology and thoracic surgery (SEPAR)¹ nor in European or North American recommendations that were published earlier.^{5,6}

Our hypothesis is that PE evaluation in an outpatient pleural pathology unit could diminish health costs (especially those derived from hospitalization), maintaining diagnostic effectiveness and without increasing the number of complications, compared to the results produced by performing this process with hospitalized patients. The primary objective of this study is to verify the diagnostic efficiency of the various necessary procedures, their safety, and associated costs and length of time, as well as analyze all of these parameters with respect to outpatient versus inpatient management whenever the only reason for hospitalization was for diagnostic study of PE.

Material and Methods

We performed a non-randomized, prospective study that included all PE cases attended at a tertiary hospital with a reference population of 250,000 inhabitants. The study period was between 1 July 2007 and 31 December 2009. Patients were evaluated in the emergency department or in a specialized care at the hospital, and the attending physician decided whether to admit the patients or refer them to the pleural pathology outpatient unit.

Two groups of patients were established according to the management of their condition (outpatient at a specialized unit or the conventional hospital care), with no other criteria for inclusion in addition to the evaluation of PE.

The evaluation of pleural effusion in the outpatient unit was performed following the SEPAR protocol¹ at a multidisciplinary unit coordinated by pneumologists with the collaboration of a radiologist and a pathologist. The decision of the order and priority of tests for the patients admitted was made by the attending physician.

When necessary, closed pleural biopsy was performed with an Abrams needle, and always before performing a thoracoscopy. The closed pleural biopsies were performed by the pneumologists working at the outpatient clinic.

The diagnostic criteria were those recommended by SEPAR.¹ We included patients with non-neoplastic PE of an unknown cause: PE due to unknown cause in patients with any of these criteria: 1) non-specific pleuritis observed by thoracoscopy, thoracotomy, or necropsy (idiopathic PE); 2) Lack of symptoms or recurrence of PE at a 1-year radiological-clinical follow-up (inflammatory PE).^{7,8}

The following variables were registered for all patients:

- a. Clinical and epidemiological characteristics.
- b. Extent of PE based on thoracic radiography, classified as: severe PE when the PE occupied more than 2/3 of the corresponding hemithorax, moderate PE when occupying between 1/3 and 2/3, and small when less than 1/3.
- c. Comorbidity quantified using the Charlson comorbidity index.⁹
- d. General condition of the patient using the Karnofsky index.¹⁰
- e. Outpatient or inpatient (hospital) study.
- f. Number and type of tests needed for diagnosis.
- g. Number of hospital days in hospitalized patients and number of consultations in outpatient cases.
- h. Costs derived from thoracentesis, pleural biopsy, imaging techniques, and other complementary studies and hospital days in hospitalized patients, and number of consultations for outpatient cases, in which we used the rates established by the regional Galicia Health Service.¹¹
- i. Safety of pleural procedures. We registered complications that arose from the various pleural techniques used and their severity and ulterior consequences.
- j. Time spent during the patient PE evaluation, analyzing the following intervals: 1. Start of the evaluation (date of the first consultation in outpatient cases and date of hospitalization for the others) until obtaining a diagnosis. The cost analysis study considered "diagnosis obtained" to be the moment in which a specific cytohistological diagnosis was made, the physician decided to perform a clinical-radiological follow-up, or a Thoracic Surgery consultation was required for a diagnostic videothoracoscopy. 2. Start of the evaluation until the date of imaging tests (thoracic CT). 3. Start of the evaluation until the

date of the pleural biopsy, in the cases where one was performed.

We did not randomize the cases, and the level of care where the patient was evaluated depended on the specialty and experience of the faculty responsible for the patient exams, day of the week, and availability of resources at that time.

None of the various procedures prescribed (thoracentesis, pleural biopsy, thoracic CT...) were prioritized at any time during the study period with regard to the environment in which the diagnostic procedure was performed, and these were carried out in the order that the request arrived at the unit.

We compared the diagnostic results, the type of tests performed and their level of safety, and the delays and costs associated with the diagnostic process for PE patients according to how the case was handled (outpatient or conventional hospitalization).

Patients who fulfilled any of the following criteria were excluded from the study:

- Patients with parapneumonic pleural effusion, empyema, or hemothorax that required hospital treatment (intrathoracic drainage or intravenous antibiotics).
- Patients with acute or chronic respiratory failure.
- Patients with a Karnofsky scale general health value under 50%.
- Patients with a mental or social status or comorbidity that would make outpatient care impossible
- Patients that refused to participate in the study.

All patients included in the study signed an informed consent document and the project was approved by the Galicia Ethics Committee (Consellería de Sanidade, Xunta de Galicia).

Statistical Analysis

The overall results are expressed as percentages and absolute frequencies for qualitative variables and as median and interquartile range (IQR) for numerical variables. We used chi-squared or Fisher's

tests for the comparison of discrete variables. We used the Mann-Whitney test for the analysis of quantitative variables, given that the majority of these variables did not present a normal distribution, except for costs, which were calculated as total values and patient mean values.

We used SPSS version 15.0 software (Chicago, IL, USA) for all statistical analyses.

As in previous studies, we determined medical costs of the diagnosis by multiplying the number of procedures and other aspects of medical care by their individual costs, including hospital costs, both in hospitals and outpatient clinics, medical and nursing attention, treatments administered, and medical procedures performed. In the case of hospitalized patients, the number of hospitalisation days was multiplied by the cost per day of hospitalization. We designed a system for calculating sample size that allowed for establishing significant differences in mean cost per patient of PE evaluation in both groups, based on a database of retrospective data from the 100 PE cases treated at our centre. This analysis produced the following results: mean cost of 5,640 € for the hospital evaluation group (mean cost of 470 € per day, mean stay of 12 days), and a mean cost of 1,800 € for the outpatient study group. For the calculation of the sample size, we established predetermined criteria: a 1:1 relationship between the size of each group with a statistical power of 99% (β error = 1%) and a 99% confidence level (α error = 1%). With all of these assumptions, the necessary sample size was 56 patients (28 in each group).

Results

Between June 2007 and December 2009, a total of 94 patients were included in the study: 60 outpatient and 34 conventional hospitalizations.

Table 1 describes the epidemiological, radiological, comorbidity, and general condition characteristics for the patients included in each group. We only found differences in the level of comorbidity calculated by the Charlson index.

Table 2 describes PE aetiologies, showing no difference between the 2 patient groups.

Table 1
Clinical characteristics of the patients

	Outpatient care n = 60	Hospital care n = 34	P
Age ^a	60 (36-73.7) years	64 (47.5-81) years	0.1
Sex	39 (65%)	21 (61.8%)	0.8
Karnofsky index	100-80: 54 (90%) 70-50: 6 (10%)	100-80: 30 (88.2%) 70-50: 4 (11.8%)	0.9
Charlson index ^a	0 (0-2)	2 (0-3)	0.01
Level of pleural effusion	Severe 6 (10%) Moderate 32 (53.3%) Small 22 (36.7%)	Severe 8 (23.5%) Moderate 18 (52.9%) Small 8 (23.5%)	0.2

^aExpressed as median (interquartile range).

Table 2
Pleural effusion aetiology

	Outpatient care n = 60	Hospital care n = 34	P
Tuberculous PE	16 (26.7%)	10 (29.4%)	0.8
Malignant PE	21 (35%)	13 (38.2%)	0.8
Parapneumonic PE	7 (11.7%)	3 (8.8%)	0.7
Idiopathic PE	3 (5%)	4 (11.8%)	0.2
Inflammatory PE	9 (15%)	3 (8.8%)	0.5
Transudate	4 (6.7%)	1 (2.9%)	0.6

PE indicates pleural effusion.

Table 3
Number of procedures performed in each group

	Outpatient care n = 60	Hospital care n = 34	P
No. lab analyses ^a	3 (1-3.75)	5.5 (4-7)	0.0001
No. thoracenteses ^a	1 (1-2)	1 (1-2)	0.9
No. cytological studies ^a	2 (1-2)	2 (1-2)	0.4
No. closed pleural biopsies ^a	1 (0-1)	1 (1-1)	0.1
No. radiographies ^a	2 (2-3)	3 (2-5)	0.01
No. CT scans ^a	1 (1-2)	1 (1-2)	0.0001

CT indicates computerized tomography; No., number.

^aExpressed as a median (interquartile range).

Table 4
Time taken for the evaluation of patients with pleural effusion

	Outpatient care n = 60	Hospitalized care n = 34	P
Days until a thoracic CT was performed ^a	6 (2-9.5)	4 (1-8)	0.5
Days until a closed pleural biopsy was performed ^a	3 (2-6)	6 (3-7)	0.03
Days until a diagnosis was obtained ^{ab}	9 (4.2-15.7)	13 (7.7-25.2)	0.01

CT indicates computerized tomography.

^aExpressed as a median (interquartile range).

^bCytohistological diagnosis, decision for clinical-radiological exams, or interconsultation in thoracic surgery for a diagnostic thoracoscopy.

The median number of visits in outpatient cases was 2 (IQR = 2-3) days. Median length of hospitalization in the other group of patients was 13 (7.7-25.2) days, with a mean of 16.2 days. Patients were admitted to the following departments: 20 in pneumology (58.8%), 12 in internal medicine (35.5%) and 2 in medical oncology (5.9%).

Table 3 describes the number of procedures performed in each group. The number of lab analyses and radiological exams was greater in the hospitalized group.

We found no differences between the two groups in the number of complication described ($P = 0.9$). Five of the patients in the specialized outpatient unit presented complications (8.3%): three presented post-pleural biopsy pneumothorax, 1 a post-thoracentesis pneumothorax, and 1 a post-pleural biopsy vagal lesion. Three cases produced complications (8.8%) in the hospitalized patients: one suffered a post-pleural biopsy pneumothorax, 1 a post-thoracentesis hemothorax, and 1 a post-pleural biopsy subcutaneous emphysema. Only one subject in each group required intrathoracic drainage ($P = 0.9$).

With respect to the diagnostic methods, no differences existed between the two groups in the percentage of cases diagnosed using cytological studies or closed pleural biopsy. In the outpatient group, 36.6% of cases were diagnosed by closed pleural biopsy, and in the hospitalized group, 32.3% ($P = 0.6$). 9.9% of cases were diagnosed by pleural liquid cytology in the outpatient group, and 11.7% of cases in the hospitalized group ($P = 0.7$). The length of time for the PE evaluation is summarized in table 4. The outpatient group experienced a longer delay until a CT scan was taken, but there were no significant differences when compared to the hospitalization group. However, the time until pleural biopsy was significantly lower in the outpatient group, as well as the length of time needed to obtain a diagnosis. Although we observed no significant differences in the number of days until receiving a CT scan in patients admitted to the Pneumology Department as compared to other specialties (3 days [IQR = 0.75-6.5] versus 7 days [IQR = 3-11.75]; $P = 0.06$), or in the time until performing a pleural biopsy (5 days [IQR = 2-6.7] versus 7 [IQR = 4-21]; $P = 0.7$), or in the time needed until obtaining a diagnosis (11.5 days [IQR = 7.2-25] versus 15 [IQR = 7.7-26.5]; $P = 0.6$), the tendency was for the evaluated time spans to be lower in patients admitted to the Pneumology Department.

Table 5
Costs (mean cost per patient) derived from complementary tests and consultations/hospitalization

	Outpatient care ^a n = 60	Hospitalized care ^a n = 34
Lab analyses	364.2	833.5
Cytological studies	253.8	280.5
Closed pleural biopsies	180.5	228.7
Radiographies	88.8	131.7
CT scans	219.3	437.9
Outpatient consultations/hospital stay	245.4	7,880.9
Total	1,352	9,793.2

CT indicates computerized tomography.

^aMean cost per patient in Euros.

The mean costs incurred from the different complementary tests performed are presented in table 5. One hundred and fifty-five consultations were performed in the outpatient group (95 of which were second visits), implying a total cost of 14,729.9 € (mean cost per patient of 245.4 €). The total amount of hospitalized time was 552 days. This implies a total cost of 267,951.8 € (mean cost per patient of 7,880.9 €) (table 5).

Discussion

The etiological study of PE is a frequent problem in pneumology departments, representing 4-10% of all pathologies.^{1,12} No clear recommendations exist on the level of care (outpatient or hospitalized) that should be given.^{1,4,5} In the majority of cases, the diagnosis of PE requires various pleural techniques such as thoracentesis and closed pleural biopsy and some radiological studies such as computerized tomography.^{1,4,5} Due to the potential risks of some of these tests and the delays that they can lead to, many PE patients are commonly admitted to hospitals in spite of being in a good condition and without any other justifying factors. Indeed, several recent studies have analyzed the inadequacy of hospital stays in pneumology departments, as the most frequent causes of this internal patient care were performing tests that could

have been taken care of in outpatient facilities, and waiting for diagnostic tests and their results.^{3,13} Due to the type of diagnostic procedures most commonly used in the evaluation of PE, both causes appear to be especially important in these patients. Until now, no studies specially designed for evaluating the cost-effectiveness of outpatient PE evaluation have been published, and we have found only one in which a Spanish group analyzed the efficacy and safety of PE evaluations performed in this field. Villena et al⁴ evaluated the results of outpatient care given to 100 patients with PE evaluations, following a protocol that included, among other tests, one or more pleural biopsies. The outpatient study was possible in spite of the patients' old age (44% were older than 70 years) and the level of PE (23% were large or massive). Of the 141 closed pleural biopsies performed, 8.5% experienced complications in the form of pneumothorax, although thoracic drainage was required in only 2.1%.

Although references do exist with respect to pathologies such as COPD¹⁴ and lung cancer,¹⁵ ours appears to be the first study that shows that outpatient treatment of select PE patients is just as safe, quicker, and much less costly for the health system (7.2 times cheaper in this case) than that given to hospitalized patients.

Given that we did not prioritize any of the procedures in terms of the environment in which they were performed, the shorter time required for outpatient PE evaluation could be explained by the delays produced in the daily activity at relatively large hospital centres and the high pressure produced in emergency situations such as ours: movement of patients to the unit from the emergency room and delay in processing the request for pleural procedures in the technical departments, among other causes. Even so, when the process is performed at specialized units attended by the same pneumologists who perform all procedures, this appears to be much more agile and coordinated. On this subject, several authors have attested to the convenience offered by comprehensive treatment of these patients.^{2,4} Antón and Sanchis performed a small study with hospitalized patients, demonstrating that specialization in pleural pathology increases clinical efficiency.² Our study combines this idea with outpatient processes, both of these elements being important for improving the management of pneumology department.¹⁶

This study presents various limitations. Since ours was not a randomized study, it is possible that the patients from the two groups were not comparable. In spite of this fact, we only found differences in the level of comorbidity as measured by the Charlson Index, which was significantly higher in the hospitalized group. However, this must be interpreted with caution, since although this difference was statistically significant, it seems to be fairly irrelevant from a clinical point of view. For instance, a patient with a gastric ulcer and CPOD, although under control by treatment, would have 2 points on the Charlson Index, and another with controlled cancer and diabetes mellitus with retinopathy or nephropathy, even just to a small degree, would have a Charlson index score of 4 points. However, in spite of the limitations of the study, the groups are homogeneous in the rest of the clinical and epidemiological characteristics, and in spite of the higher Charlson index, we believe that these patients could be treated as outpatient cases safely and effectively. It is possible that hospitalized patients required a greater number of tests due to the higher comorbidity in this group, which could overestimate the total cost of the process. However, this would imply a mean increase of 700 Euros, less than 10% of the total difference.

A second limitation is the possibility that outpatient care requires that more resources be available, primarily in the form of facultative personnel, which is an aspect that was not analyzed in our study. However, we annually performed 60 outpatient consultations (little more than once per week), which is an amount that we believe to be similar in the majority of pneumology departments. Furthermore, this type of care avoids hospital care and the resources necessary for it, which would compensate for the cost of outpatient care. According to the results of our study, the total savings of a hypothetical cohort of 100 PE patients attended at an outpatient pleural pathology unit would be over 700,000 €, resources that could be redistributed for establishing strategies such as those proposed here.

Lastly, performing a study such as ours in one single hospital could limit its validity. Indeed, the mean duration of hospital stay in the hospitalized group was excessive, and given the increased cost associated with hospital stays, the results at another centre could be quite different. As such, it is possible that the savings described in our study have been overvalued and would be less at other centres with a shorter mean hospital stay per patient. Indeed, our mean stay index adjusted for operations with respect to other departments is 1.19, and this number could be used as a correction factor.

In conclusion, and in light of the aforementioned limitations, we believe that outpatient diagnostic methods in PE patients at a specialized unit are highly cost-effective when compared to patients treated under the conventional hospitalization system. The effectiveness and safety of the two types of evaluation are fairly similar, although the outpatient method provides a shorter diagnosis time by performing fewer complementary tests and provides a significantly lower mean cost per patient.

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