



Clinical characteristics and economic burden of tuberculous-destroyed lung in Korea: a National Health Insurance Service-National Sample Cohort-based study

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Background: Tuberculous destroyed lung (TDL) contributes to patient mortality via acute exacerbation and combined medical comorbidities. This study characterized the clinical characteristics and economic burden of patients with TDL using large scale database, Health Insurance Review and Assessment Service (HIRA) data.

Methods: We searched the HIRA national database to identify patients diagnosed with TDL from January 01, 2011 to December 31, 2015. The clinical characteristics of the patients were collected and the 5-year claims data were analyzed.

Results: In total, 645,031 patients (55% male, mean age, 59.6 years) were enrolled over the 5 years. During the study period, 98.5% of the patients visited a primary care clinic and 71.1% and 93.2% visited secondary and tertiary hospitals, respectively. Patients spent a median of 5 days for inpatient services, and were admitted to the hospital a median of 0.62±1.2 times per person annually. Annual total cost per person was \$1,838 and half of the total cost was expended for inpatient services. About 68.9% of the patients were prescribed respiratory medications, and \$12 million was paid. Oral bronchodilators (46.5%) and methylxanthine (35.2%) were used more frequently than inhaled corticosteroids (ICSs)/long-acting β 2 agonist (LABA) combination agents (11.6%) or inhaled long-acting muscarinic antagonists (LAMAs) (7.5%).

Conclusions: TDL imposes a high medical economic burden in Korea. The estimated economic costs were mainly made up of inpatient services and outpatient medication prescriptions. Interventions to prevent acute disease exacerbations and progression of comorbid conditions should be accompanied to alleviate the clinical and economic burden of TDL.

Keywords: Tuberculosis; chronic obstructive lung disease; economic burden

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Introduction

The incidence of tuberculous (TB) in Korea was 25–99/100,000 people in 2016 (1), which is relatively high compared to Western countries (2). TB is a risk factor for chronic obstructive pulmonary disease (COPD) because bronchiectasis and airflow limitations are caused by endobronchial involvement and destruction of lung parenchyma (3). Tuberculous-destroyed lung (TDL) defines patients who have extensive parenchymal destruction after a pulmonary TB infection with or without anti-TB treatment (4–6).

The definition and clinical characteristics of TDL patients have been studied since early 19th century, for recent 20 years. TDL can cause a progressive decline in lung function with frequent exacerbations (4,5,7). Korean multicenter retrospective studies showed that TDL patients had experienced acute exacerbations 0.4 times per year and the frequency of acute exacerbations were correlated with the severity of the airflow limitation, and pulmonary function was negatively correlated with the number of lobes involved (5,8). These retrospective studies have revealed the negative effects of TDL on lung function and patient prognosis as an independent respiratory disease from COPD. About the treatment of TDL, a multicenter double-blind clinical trial was recently published in patients with TDL receiving inhaled indacaterol. That study revealed that inhaled indacaterol provides significant symptom and lung function improvement (6). An inhaled bronchodilator benefits patients diagnosed not only with COPD but also TDL. However, little is known about the current status of physicians' prescriptions and the economic burden of patients with TDL. In order to detect and appropriately treat TDL patients, we designed a clinical study using nationwide database system.

This study evaluated the baseline characteristics, healthcare utilization, and costs of patients diagnosed TDL in Korea for 5 years using Health Insurance Review and Assessment Service (HIRA) data. Globally, this is the first large-scale report showing the nationwide social economic burden of TDL.

Methods

Study population and design

We used a dataset provided by HIRA corresponding to approximately 51 million subjects with national claims data from nearly the entire Korean population. Korea is

compulsorily covered by medical insurance, 98% of the total population are covered and 99% of claims are electronically submitted by healthcare service providers. The changes of missing claims are highly unlikely (9). The healthcare system in Korea has two components, health insurance and medical aid. The national health insurance system provides coverage to all citizens and medical aid component provides support to lower income groups (10). HIRA research data consists of 6 files: (I) general information file; (II) healthcare services file including inpatient prescription; (III) the diagnosis file; (IV) the outpatient prescription file; (V) the drug master file; and (VI) the provider information file (9). Disease diagnoses held in the general information file are coded based on the International Codes of Disease 10th Edition Clinical Modification (ICD-10-CM). We searched the database to identify patients diagnosed with TDL using ICD codes B90 and J984 for the period from January 01, 2011 to December 31, 2015. Patients who had the ICD code for TDL as the primary to fifth sub-diagnosis among patients aged >40 years old were included. The cohort database included age, sex, insurance type (health insurance and medical aid), comorbidities, drug prescription data (drug name and rate of prescription), billing code, and healthcare services provided to beneficiaries such as procedures, diagnostic tests, treatment, and inpatient prescriptions. The provider information file carries information about healthcare providers such as the provider ID; practice location; provider type (i.e., primary, secondary, or tertiary); the number of beds; and inception date of institution (9). We collected and retrospectively analyzed 5 years of drug prescription and healthcare visit claims data from 2011 to 2015. Days of healthcare use were analyzed separately according to outpatient and inpatient services. Days of outpatient service utilization were analyzed only for patients who used such a service. Days of inpatient service utilization were analyzed only for patients who used an inpatient service, including the emergency room (ER) or intensive care unit (ICU). The total number of days utilizing healthcare were analyzed for all patients who used outpatient or inpatient services. Percentage of TDL patients who took any of respiratory drugs at least one time during the study period was calculated. Frequencies of medication prescriptions were expressed as a percentage of the patients who had prescribed each drug at least one time in the total number of TDL patients (allowed duplication). Moreover, costs for healthcare utilization and respiratory medications were analyzed with the billing code and rate of prescription in Korean won (KRW) and converted into US dollars (USD)

according to the exchange rate (\$1 USD =1,126 KRW) on November 20, 2018.

Statistical analyses

All statistical analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC, USA). Results are expressed as mean \pm standard deviation for continuous variables and proportions for categorical variables.

Ethics statement

To protect the patients' information and identity, all patients received an anonymous identification code in the HIRA sample data. The authors could not identify any patients included in the sample data. This study was approved by the Institutional Review Board of Seoul St. Mary's Hospital, which waived the requirement for informed consent (KC18ZESE0458).

Results

Baseline characteristics

Table 1 shows the baseline characteristics of all included patients. In total, 645,031 patients were diagnosed with TDL over the 5 years. Among them, 55.8% were male, the mean age was 59.6 \pm 11.9 years old, and the most common age group was 50–60 s. About 11% of the patients received medical aid. During the study period, 98.5% of the patients used primary care hospitals, 71.1% used secondary hospitals, and 93.2% used tertiary hospitals. The comorbid medical diseases are summarized in Table 1, showing that gastroesophageal reflux disease (74.9%), hyperlipidemia (68.0%), and hypertension (53.5%) were the most common. In addition, diabetes mellitus was found in 46.3% of the patients and cardiovascular comorbidities, such as ischemic heart disease (13.7%) or congestive heart failure (11.0%), were also included.

Healthcare utilization

The frequencies of healthcare utilization are presented in Table 2, and expended costs and service days are included in Tables 3,4. During the study period, 475,804 (73.8%) patients visited the ER or were hospitalized. Annual frequencies of ER visits or hospital admissions were 0.62 \pm 1.2 per person. About 8.1% (0.28 \pm 0.2 times/year/person) of

Table 1 Baseline characteristics of total patients (N=645,031)

Characteristics	No. (%)
Male	360,165 (55.8)
Age (years), mean \pm SD	59.6 \pm 11.9
<40	21,619 (3.4)
40–50	123,278 (19.1)
50–60	184,365 (28.6)
60–70	169,587 (26.3)
70–80	115,624 (17.9)
\geq 80	30,558 (4.7)
Insurance type	
Medical aid	70,147 (10.9)
Type of hospital use	
Primary	635,311 (98.5)
Secondary	458,332 (71.1)
Tertiary	601,117 (93.2)
Comorbidities	
Ischemic heart disease	88,514 (13.7)
Congestive heart failure	70,868 (11.0)
Hypertension	344,786 (53.5)
Diabetes mellitus	298,952 (46.3)
Hyperlipidemia	438,624 (68.0)
Gastroesophageal reflux disease	483,310 (74.9)
Osteoporosis	203,548 (31.6)
Depressive disorder	159,222 (24.7)
Arthritis	94,915 (14.7)
Pneumothorax	9,822 (1.5)
Anemia	30,123 (4.7)

patients were admitted to the ICU. Patients diagnosed with TDL had received 0.56 \pm 0.6 chest X-rays, 0.30 \pm 0.2 chest computed tomography (CT) scans, and 0.42 \pm 0.5 pulmonary function test (PFT)s per person annually.

The summarized costs for healthcare utilization are shown in Table 3. Total cost per person during the 5-year study period was >\$6,907 USD; half (\$2,739 USD) was expended for medications, 10% for medical examinations, and 7% for radiological examinations. When these costs were divided according to whether they were inpatient or

Table 2 Healthcare utilization of tuberculosis-destroyed lung patients

Healthcare utilization	No. (%)	Number/ year/person, mean ± SD
ER visit or hospitalization	475,804 (73.8)	0.62±1.2
Intensive care unit care	52,184 (8.1)	0.28±0.2
Performed studies		
Chest X-ray	344,462 (53.4)	0.56±0.6
Chest computed tomography	34,829 (5.4)	0.30±0.2
Pulmonary function test	290,739 (45.1)	0.42±0.5

Table 3 Costs of total TDL-related healthcare utilization for 5 years

Cost of total TDL-related healthcare utilization	KRW/USD, mean ± SD
Outpatient service	
Medical examination	524,907.7±533,636.9/466.2±473.9
Radiologic examination	328,682.8/291.9±332,384.8/291.9±295.2
Medication	3,082,411.2±6,390,207.4/2,737.5±5,673.1
Others	1,712,105.4±1,712,105.4/1,520.5±1,520.5
Total cost	5,659,761.6±7,411,745.8/5,026.4±6,582.4
Inpatient service	
Medical examination	310,435.0±794,767.4/275.7±705.8
Radiologic examination	201,292.0±668,010.5/178.8±593.3
Medication	755,891.8±4,114,227.0/671.3±3,653.8
Others	1,604,352.8±4,309,093.4/1,424.8±3,826.9
Total cost	2,871,971.4±7,355,507.4/2,550.6±6,532.4
Total services	
Medical examination	835,342.7±1,044,053.9/741.9±927.2
Radiologic examination	529,974.8±793,058.2/470.7±704.3
Medication	3,084,441.4±6,392,522.1/2,739.3±5,677.2
Others	3,328,112.6±4,862,326.2/2,955.7±4,318.2
Total cost	7,777,871.5±10,072,607.3/6,907.5±8,945.5

TDL, tuberculous-destroyed lung.

Table 4 Costs and service days of TDL-related healthcare utilization

TDL-related healthcare utilization	USD/year/person, mean ± SD or days/year/person
Cost, USD/year/person	
Outpatient service	617.6±983.1
Cost for outpatient medication	414.0±829.2
Inpatient service	806.5±1,813.0
Total	1,838.1±2,436.8
TDL-related service days, days/year/person	
Outpatient service	25.1±23.5
Inpatient service	5.3±17.5
Total service	30.4±30.2

TDL, tuberculous-destroyed lung.

outpatient services, the costs for outpatient services were twice as much as those for inpatient services (5,026 vs. 2,550 USD) over the 5 years.

Analysis results for the annual cost and service days for TDL-related healthcare utilization per person are shown in *Table 4*. Patients diagnosed with TDL received services for about 30.4±30.2 days per year, and 25 days were in the outpatient clinic. Annual total costs were \$1,838 USD per person, \$806 USD for inpatient services, \$617 USD for outpatient services, and \$414 USD for outpatient medications. Forty-three percentage of the annual costs analyzed individually were expended for inpatient services.

Table 5 and *Figure 1* show the frequencies and costs of respiratory medications during the study period. A total of 68.9% of the patients were prescribed respiratory medications and \$12 million USD (\$18 USD per person annually) were paid for the medications. The most frequently prescribed medications were oral systemic bronchodilators (46.5%) and methylxanthine (35.2%). The most frequently prescribed inhalers were short-acting β₂ agonists (19.1%). An inhaled corticosteroid (ICS)/long-acting β₂ agonist (LABA) combination was used in 11.6%, and ICS only in 10.0%, of patients. Long-acting muscarinic antagonists (LAMAs) and LABAs were used in 7.5% and 1.4%, individually. Annual cost per person was highest for ICS/LABA (\$10 USD) and LAMA (\$9 USD).

Discussion

This is the first large-scale study showing the economic

Table 5 Frequencies and costs of respiratory medications during study period

Respiratory medications	No. (%)	USD	USD/year/person, mean \pm SD
Any respiratory medications	444,610 (68.9)	12,093,410.7	18.7 \pm 74.8
Systemic bronchodilator	300,189 (46.5)	703,835.9	1.1 \pm 7.2
Theophylline	227,148 (35.2)	1,382,353.8	2.1 \pm 9.1
ICS	64,789 (10.0)	471,298.9	0.7 \pm 7.2
ICS/LABA	74,548 (11.6)	6,571,132.7	10.2 \pm 49.6
LABA	9,052 (1.4)	351,135.5	0.5 \pm 7.5
LAMA	48,346 (7.5)	5,985,786.0	9.3 \pm 62.2
LABA/LAMA	2,821 (0.4)	48,961.1	0.1 \pm 1.4
SAMA	68,657 (10.6)	277,490.7	0.4 \pm 4.2
SABA	123,047 (19.1)	390,690.2	0.6 \pm 5.3
SAMA + SABA	562 (0.1)	2,340.5	0.003 \pm 0.2
LTRA	200,768 (31.1)	3,864,585.9	6.0 \pm 28.2
PDE4	2,584 (0.4)	123,712.1	0.2 \pm 4.7

ICS, inhaled corticosteroid; ICS/LABA, inhaled corticosteroid/long-acting β 2 agonist; LABA, long-acting β 2 agonist; LAMA, long-acting muscarinic antagonist; SAMA, short-acting muscarinic antagonist; SABA, short-acting β 2 agonist; LTRA, Leukotriene receptor antagonist; PDE4, Phosphodiesterase E4.

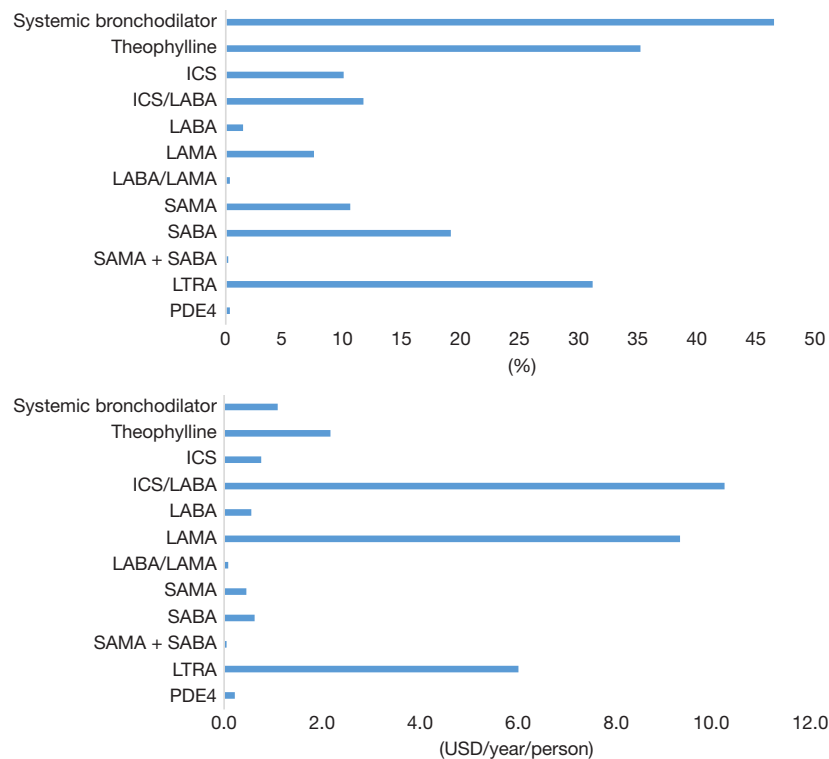


Figure 1 Frequencies and costs for respiratory medications during study period. ICS, inhaled corticosteroid; LABA, long-acting β 2 agonist; LAMA, long-acting muscarinic antagonist; SAMA, short-acting muscarinic antagonist; SABA, short-acting β 2 agonist; LTRA, Leukotriene receptor antagonist; PDE4, Phosphodiesterase E4.

burden of patients with TDL using a nationwide database. Patients with TDL were admitted to the hospital 0.6 times including 0.28 times per person annually for ICU care. The total costs for 5 years were mainly produced by outpatient services, which were larger than those for inpatient services including medication prescription and medical or radiological examinations. Among the total 30 days of TDL-related services, 5 days were spent for inpatient services, 1/5 of outpatient service per person annually. That is, 5-day individual cost per month for inpatient services made 43% of the total costs. In addition, 68.9% of the patients had been prescribed respiratory medications for TDL. Oral bronchodilators and methylxanthine were favored rather than inhaled bronchodilators and corticosteroids.

The first description of destroyed lung after pulmonary TB was in the 1960s, but TDL only began to be analyzed in the early 2000s. Lee *et al.* reported a decline in lung function with chronic airflow obstruction (CAO) due to TDL in 2003 (4). They compared 21 patients with CAO and parenchymal damage in more than one-half of one lung to 11 patients with COPD. PFTs showed that patients with CAO had a lower forced vital capacity (FVC) and post-bronchodilator forced expiratory volume for 1 s (FEV₁) than those with COPD. Patients with CAO who wheezed were more responsive to a bronchodilator than those who did not. Patients with TDL could have a CAO pathophysiology that is different from that of COPD, and bronchodilator therapy may be useful for treating CAO.

A large-scale retrospective review of clinical and radiographic findings of TDL was conducted in 2012, including 169 patients followed for 15 years from a single tertiary center (7). The authors found a median of 1 (range, 0–11) hospitalization during the median 31-month follow-up period. The clinical respiratory events were pneumonia (56.8%), hemoptysis (21.9%), and spontaneous pneumothorax (14.2%). Overall mortality was 27.8% with a median survival duration of 39 (range, 0–176) months. About 60% of patients had been prescribed respiratory medications, 46% used inhaled anticholinergic drugs, and 40% used oral methylxanthine. The prognostic factor contributing to mortality associated with TDL was a field score >3, denoting a percentage of parenchymal injured lung area >51% (P=0.004).

Rhee *et al.* studied 595 patients with TDL from 21 university hospitals in Korea over 6 years and reported that 76.8% of the patients had an airflow obstruction (FEV₁/FVC <0.7) with 0.4 exacerbations per year (5). Interestingly, the number of annual exacerbations in patients with TDL

was similar to those in patients with COPD (0.4±0.05 *vs.* 0.32±0.03, P=0.062); however, the rates of LAMA or LABA/ICS prescriptions were significantly lower in patients with TDL compared to those with COPD (LAMA 50.0% *vs.* 73.9%, P<0.001, ICS/LABA 45% *vs.* 84.2%, P<0.001). Based on this large-scale review of patients with TDL, physicians recognized that these patients had a poor prognosis with acute exacerbations similar to COPD. Moreover, despite the effects of airflow obstruction on the mortality rate of patients with TDL, airflow obstruction is under-recognized and less often treated with long-acting inhaled bronchodilators.

The clinical significance of inhaled bronchodilators for treating TDL was shown in a retrospective study (11) and a multicenter double-blind clinical trial (6). In the latter study, after a 2-month treatment, inhaled tiotropium led to a >10% improvement in FEV₁; inhaled indacaterol increased FEV₁ by 150 mL and controlled symptoms. More than half of patients with TDL have airflow obstructions and use of long-acting bronchodilators benefits lung function and symptom control. Although the positive effect of bronchodilator use in TDL patients has been shown recently in this multicenter double-blind clinical trial, prescription rates of the LAMA or LABA were remarkably low (7.5%, 1.4% respectively) in our study result. Clinical guidelines should be established to treat airflow obstruction in TDL patients.

In a global report published in 2016, direct costs for respiratory diseases made up approximately 6% of the total €800 billion healthcare budget of the European Union. The four major respiratory diseases, including COPD, asthma, pneumonia, and TB, had costs totaling €38.7, €17.7, €10.1, and €2.1 billion, respectively (12). In Korea, the mean annual cost for patients with respiratory disease was estimated to be \$8,853 per patient in 2012. The estimated percentages of each ailment among the 999 enrolled patients were of 5.6% for COPD, 31.8% for asthma, 55.7% for allergic rhinitis, and 6.9% for rhinosinusitis (13). Based on these results, the total annual costs of \$1,838 USD per person by patients with TDL in our study seem low (about 20% of \$8,853 USD) compared to those in patients with a respiratory disease. However, because TDL had not been defined in that study, it is possible that TDL patients could be missed or included as COPD or asthma. The economic burden of TDL would increase if underdiagnosed patients with TDL are re-assessed.

TDL is a chronic lung disease and the most important factors determining the economic and social costs are

disease severity, the presence of acute exacerbations, and comorbidities (14). The predominant healthcare cost item in a COPD cohort was hospitalization for exacerbations, which is associated with patient mortality (15). Our data also showed that most patients with TDL had comorbidities that needed to be treated and half of the annual costs were used for inpatient services, although the number of inpatient days was only 20% of the number of outpatient days. Interventions to prevent acute disease exacerbations and progression of comorbid conditions should be accompanied to alleviate the clinical and economic burden of TDL. Moreover, it is necessary to raise awareness of disease incidents, perform early diagnosis and disease control mediated by active treatment using bronchodilators.

This study has provided the first description of the nationwide TDL burden in Korea using HIRA data. Because South Korea has provided national medical health care services since 1989, HIRA data contain almost all of the claims data. Patients enrolled in our study represented the nationwide population of South Korea. The indirect costs for disability should be included because loss of productivity contributes to a significantly larger burden of disease than direct medical costs (13,16). As patients with COPD have different economic burdens on the healthcare system in Korea depending on disease severity (17), the healthcare burden of TDL should also be discussed in later research depending on disease severity. Moreover, HIRA data have limitations because of its nature, retrospective claims data. As the claims data are generated to reimburse healthcare services eligible for coverage, discrepancies occur between diagnosis entered in the data and diseases that a patient has in reality (9). Patients registered with ICD 10 codes could be over or underdiagnosed and make a bias. Lack of patients' clinical characteristics such as socioeconomic status and absence of control group could also be the limitation of this study.

Conclusions

TDL imposes a high medical economic burden. These economic costs were primarily made up of inpatient services and costs for prescribed medications, which were higher than those for medical or radiological examinations. Physicians in Korea mainly use oral bronchodilators or methylxanthine rather than inhaled long-acting bronchodilators. The treatment guidelines and definition of TDL disease should be established to prevent utilization of

healthcare and to lower the economic burden of TDL.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: This study was approved by the Institutional Review Board of Seoul St. Mary's Hospital, which waived the requirement for informed consent (KC18ZESE0458).

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