

CLINICAL CHARACTERISTICS OF PULMONARY TUBERCULOSIS PATIENTS FROM A SOUTHERN TAIWAN HOSPITAL-BASED SURVEY

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This study aimed to identify the clinical characteristics of culture-positive pulmonary tuberculosis (TB) patients from a southern Taiwan hospital-based survey between August 1, 2003 and July 31, 2006. Demographics, symptoms, susceptibility patterns, sputum acid-fast bacilli (AFB) stain status and treatment outcomes were recorded. The medical records of 154 patients who presented to the Kaohsiung Municipal Hsiao-Kang Hospital were analyzed retrospectively. The mean age of patients was 59.5 years; 115 patients were male and 39 were female. Diabetes mellitus (48/154; 31.2%) was the most frequent risk factor for pulmonary TB infection. Nearly all patients (139/154; 90.3%) had a cough. Fever was only seen in 27.9% and hemoptysis in 14.9% of patients. The combined resistance rates of *Mycobacterium tuberculosis* to the tested first-line agents were as follows: isoniazid, 3.2%; rifampin, 7.8%; ethambutol, 5.8%; and streptomycin, 2.6%. The combined resistance rate to any one of four first-line drugs was 12.3%. The combined resistance rate to ofloxacin was 3.9%. The combined resistance rate of multidrug resistant-TB was 1.9%. Sputum AFB stains were positive in 68.2% of cases. Analysis of treatment outcomes showed overall treatment success at 76.6%. The proportions of patients who died, defaulted treatment or in whom treatment failed were 16.2%, 3.9% and 0.0%, respectively. In conclusion, our study showed: (1) a higher frequency of pulmonary TB in male subjects than in other areas of Taiwan; (2) a higher frequency of cough and lower frequency of fever and hemoptysis than previous studies; (3) that the combined resistance rates to isoniazid and streptomycin were lower than both average levels in Taiwan and the global combined drug resistance rate; and (4) a higher proportion of patients responding to treatment and lower proportions of patients suffering mortality, defaulting treatment or not responding to treatment compared with other areas of Taiwan. With regard to resistance rates, the combined resistance rate to ethambutol was similar to the average level in Taiwan and higher than the global combined drug resistance rate. However, the combined resistance rate to rifampin was higher than both the average level in Taiwan and the global combined drug resistance rate. The combined resistance rates to at least any one of four first-line drugs and multidrug resistant-TB were lower than the average levels in Taiwan and higher than the global combined drug resistance rate. Our results may help to identify local variations in the disease and improve the effectiveness of TB infection control programs.

Key Words: pulmonary tuberculosis, resistance, symptom, Taiwan, treatment outcome
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Although the prevalence of tuberculosis (TB) has declined significantly in Western countries during the past several decades, TB remains one of the most common infectious diseases in developing countries [1]. In Taiwan, TB has remained the leading notifiable communicable disease for years. In 2004, the incidence rate was 74.1 per 100,000 people and the mortality rate was 4.23 per 100,000 people. TB accounted for 0.72% of the total deaths and TB ranked 13th among the leading causes of death. Among notifiable communicable diseases, TB has remained the number one killer for years [2].

We believe a description of the clinical characteristics of pulmonary TB serves two important purposes. First, it provides a contemporary description that may be valuable to clinicians, public health officials and agencies to screen for active TB. Second, a subgroup analysis will provide insight as to which groups may present atypically with the disease. In addition, the epidemiology of pulmonary TB has changed, raising the question of whether the clinical characteristics described in the past remain valid today.

Global surveillance of drug resistance has shown that a substantial proportion of TB patients are infected with drug-resistant *Mycobacterium tuberculosis* strains [3]. In Taiwan, the incidence of drug resistance among *M. tuberculosis* isolates and the associated mortality have remained high despite recent advances in anti-TB therapy and an understanding of well-known TB control strategies [2]. Variations in susceptibility data, due to the use of different methods in studies from different regions of Taiwan and the lack of a program for the nationwide surveillance of drug resistance using a uniform and standard method, has made data on the resistance patterns in Taiwan unclear [4].

There has been only one previously published study on the prevalence of drug-resistant TB in southern Taiwan from 1996 to 2000 [5]. However, that survey did not precisely distinguish between newly diagnosed and re-treatment cases, only the combined resistance rate. Thus, we undertook this study to evaluate the prevalence of drug-resistant isolates of pulmonary TB at Kaohsiung Municipal Hsiao-Kang Hospital in southern Taiwan in the last 3 years, including primary (resistance among new cases), acquired (resistance among re-treatment cases), and combined (resistance among new and re-treatment cases) drug resistance. We also present an approach to the subgroup analysis of treatment outcomes of

pulmonary TB cases from a hospital-based survey performed in southern Taiwan.

METHODS

This study was conducted at Kaohsiung Municipal Hsiao-Kang Hospital, which is a 500-bed, university-affiliated teaching hospital that serves as a tertiary referral center and a primary-care facility in southern Taiwan. From a retrospective review, 154 consecutive adult patients with pulmonary TB detected in the period from August 1, 2003 to July 31, 2006 were selected. Cases were identified from the hospital coding system and microbiology department records. Patients who were younger than 18 years and those who were not Taiwanese were excluded. The diagnosis of pulmonary TB was based on at least one sputum culture that was positive for *M. tuberculosis*. Patients included outpatients and inpatients at initial visit. Re-treatment cases and newly diagnosed cases were also enrolled in the study. Sputum samples were obtained by spontaneous morning expectoration, saline solution induction, tracheal aspiration, or bronchoscopy with bronchoalveolar lavage. Repeated isolates with the same antibiogram from the same patient during the same diagnosis course were regarded as one strain. This study was reviewed and approved by the human experiment and ethics committee of Kaohsiung Municipal Hsiao-Kang Hospital.

All patients had a medical chart and microbiology results. Patients were interviewed by the same trained nurse case manager using a structured questionnaire and the completed questionnaires were then reviewed by the physician investigator. Demographic information included age, sex and body mass index. We recorded risk factors for TB infection, including a history of TB infection, exposure to an individual with TB, alcoholism, substance abuse, long-term glucocorticoid medication, immunosuppressive drug use and other comorbidities, such as diabetes mellitus, end-stage renal disease, cancer, human immunodeficiency virus infection, silicosis and post-gastrectomy. Clinical symptoms included the presence of cough, expectoration, weight loss, fever, shortness of breath, anorexia, hemoptysis, chest pain, fatigue and night sweats.

All sputum smears were concentrated and stained with Ziehl-Neelsen stains by trained microbiology technicians. Each sputum sample was prepared in

Löwenstein-Jensen culture medium and Middlebrook 7H11 selective agar, and maintained for at least 8 weeks to detect the presence of growing organisms. Susceptibility of *M. tuberculosis* isolates to four first-line antimicrobial agents, isoniazid, rifampicin, ethambutol and streptomycin, and one second-line agent, ofloxacin, was determined by the proportion method using Middlebrook 7H10 medium. Although this is a retrospective study, quality control was usually performed during susceptibility testing using a reference strain provided by the College of American Pathologists and the national reference laboratory. The concentrations of the drugs used were as follows: isoniazid, 1 µg/mL; rifampin, 1 µg/mL; ethambutol, 10 µg/mL; streptomycin, 10 µg/mL; and ofloxacin, 2 µg/mL. Tested isolates were considered resistant if the proportion of the tested isolate was >1% of the control population. Drug resistance was defined as either single or any resistance to anti-TB drugs. Multidrug resistance (MDR) was defined as resistance towards at least isoniazid and rifampicin. In patients who had not previously received anti-TB drugs, the bacterial resistance was classified as primary. Acquired drug resistance was defined as resistance among re-treatment cases. Combined drug resistance was defined as resistance among new and re-treatment cases.

Treatment outcomes were analyzed and defined according to the World Health Organization (WHO) recommendations [6]. "Cure" was defined as a patient who was sputum smear-negative in the last month of treatment and on at least one previous occasion. "Treatment completed" was defined as a patient who had completed treatment, but who did not meet the criteria to be classified as a cure or a failure. "Treatment success" included both of these categories. "Treatment failure" was defined as a patient who was sputum smear-positive at 5 months or later during treatment. "Died" was defined as a patient who died for any reason during the course of treatment. "Default" was defined as a patient whose treatment was interrupted for 2 consecutive months or more. "Transfer out" was defined as a patient who was transferred to another recording and reporting unit, and for whom the treatment outcome was not known.

Statistical analysis

Data in the text and illustrations correspond to mean ± standard deviation (continuous variables) or

to frequencies and percentages (non-continuous variables). All analyses were performed using SPSS version 12.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

Demographic information

One hundred and fifty-four culture-positive pulmonary TB patients were enrolled in the study. Eighty outpatients and 74 inpatients at initial visit were identified. Mean age was 59.5±18 years (range, 20–91 years). Patients aged ≥65 years comprised 42.9% of the patient group, which was followed by people aged between 45 and 64 years (36.4%). One hundred and fifteen patients were male (74.7%) and 39 were female (25.3%). Demographic information is presented in Table 1.

Risk factors

Risk factors are depicted in Table 2. Diabetes mellitus was the most frequent risk factor for pulmonary TB infection ($n=48$, 31.2%). Twenty-one patients were re-treatment cases (13.6%). No patients had any of the following risk factors for pulmonary TB infection in this study: substance abuse, long-term glucocorticoid medication, immunosuppressive drug use, human immunodeficiency virus infection, silicosis or post-gastrectomy.

Table 1. Demographic information on 154 pulmonary tuberculosis cases

| | <i>n</i> (%) |
|--------------------------------------|------------------|
| Age (yr) | |
| 20–44 | 32 (20.8) |
| 45–64 | 56 (36.4) |
| ≥65 | 66 (42.9) |
| Mean (SD) | 59.5 (18.0) |
| Median (range) | 61 (20–91) |
| Body mass index (kg/m ²) | |
| Mean (SD) | 20.4 (3.6) |
| Median (range) | 20.6 (14.5–31.4) |
| Sex | |
| Male | 115 (74.7) |
| Female | 39 (25.3) |
| Patient type | |
| Outpatients | 80 (51.9) |
| Inpatients | 74 (48.1) |

SD = standard deviation.

Table 2. Risk factors in 154 pulmonary tuberculosis (TB) cases

| Risk factor | n (%) |
|--|-----------|
| History of TB infection | 21 (13.6) |
| History of exposure to an individual with TB | 8 (5.2) |
| Alcoholism | 14 (9.1) |
| Diabetes mellitus | 48 (31.2) |
| End-stage renal disease | 3 (1.9) |
| Cancer | 10 (6.5) |

Table 3. Clinical symptoms of 154 pulmonary tuberculosis (TB) cases

| Symptom | n (%) |
|---------------------|------------|
| Cough | 139 (90.3) |
| Expectoration | 111 (72.1) |
| Weight loss | 51 (33.1) |
| Fever | 43 (27.9) |
| Shortness of breath | 39 (25.3) |
| Anorexia | 34 (22.1) |
| Hemoptysis | 23 (14.9) |
| Chest pain | 19 (12.3) |
| Fatigue | 12 (7.8) |
| Night sweats | 11 (7.1) |

Clinical symptoms

Table 3 shows the percentages of patients with each symptom. The most common presenting symptoms were cough (90.3%), expectoration (72.1%) and weight loss (33.1%). Other presenting complaints were fever (27.9%), shortness of breath (25.3%), anorexia (22.1%), hemoptysis (14.9%), chest pain (12.3%), fatigue (7.8%) and night sweats (7.1%).

Drug resistances and sputum acid-fast bacilli stain status

Drug resistance to *M. tuberculosis* is shown in Table 4. The combined resistance rates of *M. tuberculosis* to the tested first-line agents were as follows: isoniazid, 3.2%; rifampin, 7.8%; ethambutol, 5.8%; and streptomycin, 2.6%. The combined resistance rate of *M. tuberculosis* to any one of the four first-line drugs was 12.3%. The combined resistance rate of MDR-TB was 1.9%. The combined resistance rate of *M. tuberculosis* to ofloxacin was 3.9%. Of the 154 culture-positive pulmonary TB patients, 105 were sputum acid-fast bacilli stain-positive (68.2%).

Table 4. Drug resistance of *Mycobacterium tuberculosis* isolates recovered from 154 pulmonary tuberculosis cases*

| | Primary (n = 133) | Acquired (n = 21) | Combined (n = 154) |
|-----------------------|----------------------|----------------------|-----------------------|
| Resistant to | | | |
| Isoniazid | 4 (3.0) | 1 (4.8) | 5 (3.2) |
| Rifampin | 7 (5.3) | 5 (23.8) | 12 (7.8) |
| Ethambutol | 9 (6.8) | 0 (0.0) | 9 (5.8) |
| Streptomycin | 2 (1.5) | 2 (9.5) | 4 (2.6) |
| Any drug [†] | 14 (10.5) | 5 (23.8) | 19 (12.3) |
| MDR | 2 (1.5) | 1 (4.8) | 3 (1.9) |
| Ofloxacin | 6 (4.5) | 0 (0.0) | 6 (3.9) |

*Data are presented as n (%); [†]resistance to any one of four first-line drugs, specifically: isoniazid, ethambutol, rifampin and streptomycin. MDR = multidrug resistance.

Table 5. Outcomes at the completion of anti-tuberculosis treatment

| Outcome | n (%) |
|--------------------|-------------|
| Cure | 45 (29.2) |
| Treatment complete | 73 (47.4) |
| Treatment success* | 118 (76.6) |
| Treatment failure | 0 (0.0) |
| Died | 25 (16.2) |
| Default | 6 (3.9) |
| Transfer out | 5 (3.3) |
| Total | 154 (100.0) |

*Defined as the sum of patients cured and those who completed treatment.

Outcomes of treatment

The outcomes at the completion of treatment are summarized in Table 5. Five patients were transferred out. Successful completion of therapy was achieved in 76.6% of patients. The proportions of patients who died, defaulted treatment, or in whom treatment failed were 16.2%, 3.9% and 0.0%, respectively.

DISCUSSION

In Taiwan, of the TB patients who died in 2003, 95.72% died of pulmonary TB while the remaining 4.28% died of TB related to other organs. The incidence rate increased with age [2]. In the present study, patients aged ≥ 65 years comprised 42.9% of the study group, which was followed by people aged between 45 and 64 (36.4%). This increase with age was similar to that observed in other areas of Taiwan. Since the aging of the

general population in Taiwan is expected to continue, it can also be expected that the caseload of TB will be increasingly associated with the elderly. The clinical presentation of disease in the elderly is often atypical [7,8]. Diagnosis and treatment are more often delayed in the elderly, and there is a higher incidence of treatment failure [9]. Therefore, physicians should give greater consideration to TB in the differential diagnosis of elderly patients with pulmonary symptoms or obscure fever, and promptly investigate suspected cases to allow earlier diagnosis and treatment.

In Taiwan, with regard to the gender of TB patients, a previous study showed that there were about 2.29 times more male than female patients, and that the incidence rate for males was 2.2 times the number for females in 2004 [2]. In our study, the incidence rate in male patients was almost three times higher than that in female patients. The reason for the higher frequency of TB in male subjects has not been sufficiently addressed. One possible explanation for this gender difference is that, in most countries, young men perform more social and labor-related activities than women, thus favoring the transmission of the disease. This hypothesis is in agreement with the higher prevalence of positive tuberculin test results in male subjects than in female subjects [10,11]. The higher rates of infection in young men could result in the higher frequency of the development of symptomatic TB. However, the presence of a biological factor conferring protection against infection and/or clinical development of TB in female subjects cannot be precluded, and deserves further investigation.

In Taiwan, the incidence of TB in patients with diabetes mellitus was 5.6 times higher than the overall incidence (363.0 *vs.* 64.8 per 100,000 people) in 2001 [12]. In the present study, diabetes mellitus was the most frequent risk factor for pulmonary TB infection (31.2%). Similar studies have revealed a higher percentage of pulmonary TB in individuals with diabetes mellitus [13–15].

Differences in the symptom prevalence noted in the present study might reflect local variations in the disease. The rate of cough (90.3%) in our study may also reflect the inclusion in our population of outpatients, a group almost invariably ignored in previous symptom studies. Although we were unable to find population-based studies of pulmonary TB, recent hospital-based studies have demonstrated cough rates of 50–77% [16–18]. Fever (27.9%) and hemoptysis

(14.9%) rates in our study were surprisingly lower than expected and than shown in previous studies [19,20], suggesting that atypical TB presentation may be more common than previously thought. This finding has implications for clinicians who we believe should not dismiss TB as a possibility in those who lack the more “classical” symptoms of the disease. The surprisingly low rate of people lacking the typical significant symptoms of TB may in part explain the delays in suspicion of TB disease [21,22]. Whether the symptomatic differences in studies of TB represent physiologic or cultural differences (or both) remains unclear.

Available historical data about drug resistance rates in Taiwan are not directly comparable because of different sampling methods and because different susceptibility testing methods have been applied in various hospital settings over time. Isoniazid was introduced for TB treatment in 1952. From 1990 to 2002, primary resistance to isoniazid ranged from 4.7% to 12%. The acquired resistance rate (25–63%) to isoniazid was significantly higher than the primary resistance rate. Chemotherapy regimens, which include rifampin, have been widely used in Taiwan since 1978. The primary resistance rate to rifampin has gradually increased from 0.7% to 5.9% during the last decade. The acquired resistance rate (17–46%) to rifampin was significantly higher than the primary resistance rate. The primary resistance rate to ethambutol was 1–6% and that to streptomycin was 4–11% from 1990 to 2002. The overall rates of primary MDR-TB were within 1–3% in the last decade. However, the rates (15–46%) of acquired resistance of MDR-TB were significantly higher than those of primary resistance [5,23–29]. Fluoroquinolones were introduced in Taiwan in 1986 for the treatment of mycobacterial and other bacterial diseases. Yu et al found in 1994–5 that primary resistance to ofloxacin was 0.8% and that acquired resistance to ofloxacin was 87.5% [30].

The Taiwan Center for Disease Control initiated the Taiwan Surveillance of Drug Resistance in Tuberculosis program in 2003. Since clinical data were not available, only combined (primary plus acquired) drug resistance rates were analyzed. That survey showed that the combined drug resistance rates were 9.5% to isoniazid, 6.4% to rifampin, 5.8% to ethambutol, 9.6% to streptomycin, 20.0% to any drug, and 4.0% to MDR-TB [31]. In the third global drug resistance surveillance report, the combined drug resistance was 6.6% to isoniazid, 2.2% to rifampin, 1.3% to ethambutol,

6.1% to streptomycin, 10.4% to any drug, and 1.7% to MDR-TB [3].

In our study, the combined resistance rates to the tested first-line agents were as follows: 3.2% to isoniazid, 7.8% to rifampin, 5.8% to ethambutol, 2.6% to streptomycin, 12.3% to any drug, and 1.9% to MDR-TB. The combined resistance rates to isoniazid and streptomycin were lower than both average levels in Taiwan and the global combined drug resistance rate. The combined resistance rate to ethambutol was similar to the average level in Taiwan and higher than the global combined drug resistance rate. However, the combined resistance rate to rifampin was higher than both the average level in Taiwan and the global combined drug resistance rate. The combined resistance rate to at least any one of four first-line drugs and MDR-TB was lower than the average level in Taiwan and higher than the global combined drug resistance rate. Differences in the bacteriology results noted in different studies might reflect local variations in disease.

According to the most recent WHO annual report, the treatment success rate in the 2003 cohort was 82% globally [6]. Among the 14,486 TB patients who received anti-TB treatment in 2001 in Taiwan, 73.3% completed a full course of treatment, 20.1% died during treatment (not all related to TB), 5.6% defaulted treatment, and, in 0.36%, treatment failed [12]. Comparison of the treatment outcomes between our study and the TB annual report (Taiwan) revealed that the proportion of patients whose treatment was successful had increased, while the proportions who died, defaulted treatment or in whom treatment failed, had decreased.

Much of the persistence of the TB epidemic may be attributable to the failure to comply with treatment regimens and the lack of follow-up. The 3.9% rate of treatment default in this study is unacceptably high. These failures may be partially explained as being due to beliefs and attitudes toward TB infection by Taiwanese. The perception of social stigma placed on the infected individual and his/her family may lead patients to avoid or cease treatment. The inability to identify those patients likely to abandon therapy emphasizes the need to treat all patients with a directly observed therapy short-course (DOTS). As these cases have been identified as the most significant source of infection in a community, efforts should be immediately refocused on improving the cure rates in these groups.

In summary, we have described the contemporary clinical presentation, bacteriological results and treatment outcomes of persons with pulmonary TB in an Asian city. This retrospective study evaluated the epidemiology of pulmonary TB from a hospital-based survey in southern Taiwan during the period from August 1, 2003 to July 31, 2006. The results may help identify local variations in disease and improve the effectiveness of TB infection control programs.

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以南台灣某醫院為基礎之肺結核病患的 臨床特徵調查

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這篇研究是要辨別從 2003 年 8 月 1 日至 2006 年 7 月 31 日以南台灣某醫院為基礎之肺結核培養陽性病患的臨床特徵調查。我們記錄人口統計學，症狀，藥物感受性，痰抗酸性細菌染色狀態及治療結果，並且回顧性分析高雄市立小港醫院的 154 位病患的病歷資料。病患平均年齡±標準差是 59.5 ± 18 歲，包括 115 位男性 (佔 74.7%) 及 39 位女性 (佔 25.3%)。糖尿病是肺結核感染最常見的風險因子 (佔 31.2%)。幾乎所有病患有咳嗽 (佔 90.3%)，發燒只在 27.9% 的病患可見，另外咳血只佔 14.9%。第一線抗結核藥物的綜合抗藥性比率如下：isoniazid、3.2%；rifampin、7.8%；ethambutol、5.8% 和 streptomycin、2.6%。針對四種第一線抗結核藥物中的任一種的綜合抗藥性比率是 12.3%。針對 ofloxacin 的綜合抗藥性比率是 3.9%。多重抗藥性結核的綜合抗藥性比率是 1.9%。病患呈痰抗酸性細菌染色陽性有 68.2%。對治療結果的分析顯示，整體治療成功率達 76.6%，病患死亡、治療失落及治療失敗的比率各佔 16.2%，3.9% 和 0.0%。總而言之，我們的研究顯示：(1) 比臺灣其它地區的肺結核患者，男性佔更高的比率。(2) 比先前的研究，有更高的比率咳嗽，更低的比率發燒和咳血。(3) 對 isoniazid 和 streptomycin 綜合抗藥性比率，比臺灣的平均水準和全球性低；對 ethambutol 綜合抗藥性比率，與臺灣的平均水準是相似的，但比全球性高；但是，對 rifampin 綜合抗藥性比率，比臺灣的平均水準和全球性高；針對四種第一線抗結核藥物中之任一種的綜合抗藥性比率和多重抗藥性結核的綜合抗藥性比率，比臺灣的平均水準低，但比全球性高。(4) 比臺灣其它地區的肺結核患者，有更高的比率治療成功，更低的比率死亡、治療失落及治療失敗。這些結論可以幫助辨別疾病的本土性的差異及改進結核病感染控制計劃的成效。

關鍵詞：肺結核，抗藥性，症狀，台灣，治療結果

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