ORIGINAL ARTICLE

An Audit of Sputum Smear Negative Pulmonary Tuberculosis Cases in Kinta District, Perak, in 2011

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Abstract

58 cases of sputum smear negative pulmonary tuberculosis (PTB) were reported to Kinta Health Department between January and June 2011. It was found that 47 cases (81%) were sputum smear negative cases. Six cases (10.3%) were actually sputum smear positive but were wrongly reported as smear negative. Five cases (8.6%) were misdiagnosed as tuberculosis. Majority of these patients (82.7%) sought consultation and treatment after two weeks of having cough. Only 6.9% sought treatment for cough that was less than two weeks old. Accurate diagnosis of PTB is crucial and the Perak State Health Department needs to quickly adopt steps to improve the situation.

Introduction

Tuberculosis is now creating a new crisis globally.[1] It remains the leading cause of death attributed to infectious diseases. Recent statistics have reawakened awareness on the magnitude of the problem caused by the disease.[2] According to World Health Organization (WHO), there are approximately 20 million active cases in the world today infecting 50-100 million people annually. Mortality due to the disease is approximately 3 million annually, of which at least 80% are in the developing countries.[2]

Sputum smear microscopy using Ziehl-Neelsen (ZN) staining for detecting acid fast bacilli (AFB) is currently the most feasible microbiological method for diagnosing PTB especially in developing countries due to its efficiency, low cost and high positive predictive value for mycobacterium tuberculosis.[3,4] The smear positivity for AFB is a variable. Positive smears indicate large bacterial load in the lung lesions compared with negative cases which show less bacterial load.[3] Sputum smear negative cases are less infectious but are still capable of transmitting the disease. Therefore, sputum smear negative cases present a challenge to tuberculosis management.[3,5]

In Kinta District, Perak, it was found that there was an increase in the number of sputum negative pulmonary tuberculosis cases between January and June 2011. There were 58 cases as compared with 40 in the same period in 2010 and 48 cases in 2009.[6] The primary objective of the study was to ascertain the reason for an increase in the number of sputum smear negative pulmonary tuberculosis cases between January to June 2011. The secondary objective was to determine the socio-demographic factors, underlying co-morbidities, duration of symptoms prior to diagnosis, chest X-ray changes, symptoms experienced and venue of diagnosis, previous PTB contacts, as well as the documentation of the sputum AFB direct smear results on the TBIS 10A-1

form (Ministry of health TB treatment data collection form.

Methods

This was a retrospective case review analysis. The study was conducted at the record office of Hospital Raja Permaisuri Bainun (HRPB) Ipoh, Perak, where we reviewed patients' folders as well as the TBIS 10A-1 forms from the chest clinic at HRPB, two government health clinics and the private hospitals in Ipoh between January and June 2011. The case review and data analysis were conducted over a period of one month. All cases of sputum smear negative PTB with or without extra-pulmonary involvement were included. All cases of sputum smear positive PTB were excluded. Microsoft Excel 2010 software was used for data entry and data analysis.

Results

A total of 178 cases of PTB was reported between January and June 2011, of which 79 (44.4%) were sputum smear positive, 58 (32.6%) were sputum smear negative and 41 (23.0%) were extra-pulmonary tuberculosis. Polymerase chain reaction tests were not conducted for the sputum smear negative cases. Out of the 58 sputum smear negative cases, 8 had concurrent extra-pulmonary tuberculosis cases. It was found that out the 58 cases, 47 (81%) were sputum negative. It was found that the spectum Smear results were not recorded in the TBIS 10A-1 form in 11 cases (19.0%). Of these, five cases (8.6%) were misdiagnosed as tuberculosis (two were lung carcinoma, two were finally not pulmonary tuberculosis and one was diagnosed as chronic lung disease) and six cases (10.3%) were sputum smear positive. Almost half of the patients (46.5%), were aged 40 to 59 years old. Majority of patients with sputum smear negative PTB were males (69%); 44.8% were Malays, 36.2% Chinese, 17.2% Indians and 1.7% Japanese. Majority of the patients with sputum smear negative PTB (74%) were treated in HRPB Ipoh while 26% were treated at the government health clinics or district hospitals.

As for co-morbidities, 31.0% of these patients were smokers, 27.6% had diabetes mellitus, 17.2% had hypertension, 17.2% had HIV infection, 15.5% were intravenous drug users and 8.6% had hepatitis C infection. It was also found that majority of these patients (82.7%) sought consultation and treatment after two weeks of cough as compared with 6.9% who sought treatment for cough lasting less than two weeks. As for other symptoms, 53% experienced fever, 50% had loss of appetite, 38% had loss of weight, 26% had night sweats and, 3.5% had shortness of breath. More than half of these patients had moderately advanced or advanced chest X-ray changes (56.9%). From the analysis, five cases were infected as a result of contact with people with PTB and were diagnosed from contact tracing and screening.

Discussion

Diagnosing and managing sputum smear negative pulmonary tuberculosis cases have become increasingly challenging for clinicians. It requires a high clinical suspicion, good quality of sputum sample and meticulous radiological interpretation. This is because the clinical and radiological manifestations of PTB may be atypical as in the case of sputum smear negative PTB.[7]

The incidence of tuberculosis in Perak in 2011 was 53.6 per 100,000 people and in Kinta District was 43.4 per 100,000 people. The case detection rate of newly diagnosed sputum smear positive tuberculosis cases in Perak state in 2011 was 67% and in Kinta District was 43%. The CDR target for newly diagnosed patients with TB to have positive sputum smear is 70%.[8] This target was not achieved in Kinta District and Perak in 2011 due to an increase in sputum smear negative cases. This study found that there was an increase of 32.6% in sputum smear negative cases. Sputum smear positive cases were still high in terms of proportion - (44.4%). A study undertaken by Kedah Medical Centre in 2004 showed that sputum smear negative cases were proportionately higher (62.2%), compared with sputum smear positive cases,

(22.8%).[7] Another study in Lahore conducted in 2007 also found that there were sputum smear negative cases (60.0%) than sputum smear positive cases, (40.0%).[3] This study showed a higher proportion of sputum smear positive cases as compared with the above two studies probably because of the recent increase in emphasis on achieving the Millennium Development Goal *6C For The Control Of Tuberculosis*, especially attaining the target of case detection rate of more than 70%.[8]

Out of the 58 reported cases of sputum smear negative cases, 10.3% were sputum smear positive and were wrongly reported as smear negative. The documentation error was attributed to the inexperienced junior doctors at the tertiary hospital (five cases) and medical officers from the government health clinic (one case). It was also found that 19% of the TBIS 10A- 1 forms were not filled up and were assumed to be sputum smear negative cases. One patient was found to have no sputum sample as he had non productive cough and did not undergo a bronchoscopy. This patient was also as reported a case of sputum smear negative PTB.

We also found that majority of these patients (82.7%) sought consultation and treatment only after two weeks of having cough as compared with only 6.9% who sought treatment for cough lasting less than two weeks. According to the Millennium Development Goal *6C For The Control Of Tuberculosis* 2012, the target set for the state of Perak was to screen all patients at the outpatient clinics who have been coughing for more than a week; and to screen all patients with comorbidities, especially those with diabetes who have poor glycaemic control, lost weight and coughed for more than three days.[8] These were measures taken by the state to enhance early detection of PTB.

Following this audit, remedial measures were suggested and implemented by the Perak State Health Department. Doctors were informed of the importance of accurate and proper reporting and documentation particularly filling up the TBIS 10A-1 form as this will facilitate in retrieving accurate data for analysis as well as aid in improving clinical management of tuberculosis holistically. In addition, the health staff advised patients on how to provide good quality sputum sample in order to obtain a better yield of AFB. A study conducted in Chicago reported that a minimum of 5ml of sputum improves the sensitivity of acid fast smear for mycobacterium tuberculosis.[9] The technical guidelines of WHO International Union Against Tuberculosis and Lung Disease specify that PTB suspects are required to submit three sputum samples - the first and third are spot specimens taken at the centre, and the second should be an early morning sputum.[4]

Patients who could not produce sputum sample for examination but are symptomatic or have a highly suspicious radiological findings should have a bronchoscope arranged to enable lavage fluid smears examined for AFB.[10] Health staff were also reminded to improve public awareness via health education such as using the tuberculosis quick flip charts and medical campaigns to ensure patients with symptoms seek early medical assistance.

There are a few limitations in this study. The information obtained from the TBIS 10A-1 forms could only be verified with the source documents from (HRPB), Ipoh but not with the private hospitals. Another limitation is the lack of information on laboratory errors including unsatisfactory sputum specimen as this was a retrospective study and we were unable to retrieve some information from the TBIS 10A-1 forms as well as from the source documents at HRPB Ipoh.

In conclusion, there is potential for further study to evaluate the effectiveness of these remedial measures.

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