

Management of pulmonary tuberculosis in health clinics in the Gombak district: How are we doing so far?

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Abstract

This audit report assessed the structure, processes and outcome of the pulmonary tuberculosis (PTB) management in adults conducted at eight government health clinics within the high TB burden Gombak district. All newly diagnosed PTB patients from November 2012 to November 2013 were identified from the tuberculosis registry. Patients less than 18 years old, were transferred out or extrapulmonary tuberculosis was excluded from the study. The assessment criteria for PTB were defined according to the latest Malaysian TB clinical practice guidelines (TB CPG) 2012. A total of 117 patients were included in this report and data were extracted and analysed using SPSS version 20.0. The mean age of patients was 40.4 ± 14.4 SD. Majority was men (63.2%). Out of 117 patients, 82.1% were Malaysian citizens and 17.9% were foreigners. Malays were the majority (65%) followed by 7.7% Chinese, 10.3% Indian and 17.1% others. The most common clinical feature was cough (88.0%) followed by loss of weight (58.1%), loss of appetite (57.3%), fever (56.4%), night sweat (30.8%) and haemoptysis (32.5%). Acid-fast bacilli (AFB) smear was positive in 94% of cases. Chest X-ray and human immunodeficiency virus (HIV) screening results were available for 89.1 and 82.1% cases respectively. The results for the sputum culture were available in 27.4% of patients and 54.7% were documented as done but pending results. The clinics have a successful directly observed therapy (DOT) program with 94.0% patients documented under DOT. Out of 53 patients on maintenance phase, 47.2% were identified as cured. Cure rate for those completed treatment was 100%. The defaulter rate was 17.1%. This audit demonstrated the attempt made by the clinics to adhere to the recommended guidelines. However, improvements are to be made in the documentation of medical records, tracing of investigation results and reduction of the number of defaulters.

Introduction

Tuberculosis (TB) remains a major global health concern. Despite extensive control programs, there is a resurgence of the disease and a cause of global high mortality. In 2012, there were approximately 8.6 million incidences of TB cases globally and 1.3 million deaths among HIV-negative TB cases.¹

The stop TB strategy was recommended by the World Health Organization (WHO) in 2006 with the global target of 50% reduction in the 1990 prevalence and mortality rate by 2015.² Malaysia has a long history of combat with TB. Since the establishment of national TB control program (NTP) in 1961, it has been working hard to improve the TB outcome in Malaysia.³

Despite this commitment, incidence of TB in Malaysia is rising and has reached 81.4 per 100,000 population in 2010.⁴ The number of notified new TB cases increased from 15,000 in 2005 to 21,851 cases in 2012.¹ The state of Selangor has the highest incidence of TB within peninsular Malaysia with the Pulmonary TB (PTB) as the most common form.⁵

Malaysia faces various challenges in its attempt to tackle the problem of TB. HIV infection is on the rise and contributes to Malaysia's inability to reduce its TB burden.⁶ The rising rate of patients with diabetes mellitus and growing number of smokers pose a threat to the number of latent TB reservoir.⁷ This could lead to latent TB activation and cross-infection within the

general public. Incomplete treatment, high default rate and development of resistant strain also perpetuate the persistent TB transmission in the community.^{8,9} Lack of knowledge about the TB-causing organism and mode of transmission render the people at risk, unaware and unable to take measures to prevent transmission.¹⁰ There was also a problem of delay in diagnosis and start of treatment among TB patients.^{11,12}

In view of these challenges and the aim to combat TB, in November 2012, The Ministry of Health Malaysia (MOH) launched a revised 3rd edition tuberculosis clinical practice guideline (TB CPG) in order to standardise the management of TB at all levels and improve the patient care. Compared to the 2002 TB CPG, improvement was made in the collection of sputum smear for the diagnosis of sputum-positive PTB. The new recommendation requires two sputum smears with at least one of them being a morning sputum sample. Previously, clinics had to collect three sputum samples. The new CPG specified the diagnostic TB investigations for PTB to include sputum AFB smear, sputum culture for mycobacterium and chest X-ray. The tuberculin test (Mantoux) has been reserved for TB contact screening rather than for diagnostic purpose and erythrocyte sedimentation rate (ESR) was no longer mentioned as a useful investigation for PTB. The pharmacological treatment regime remains unchanged and the role of DOT clinic is emphasised in the new CPG to ensure better compliance and reduce the number of defaulters.

This audit aimed to assess the structure, processes including documentation of risk factors, clinical features, investigations and treatment, as well as outcome for the management of PTB within the health clinics in Gombak district that were set against the recommended criteria defined by the new Malaysian tuberculosis clinical practice guidelines.

Methodology

Study design and population

This was an audit, which was conducted in eight government healthcare clinics within the Gombak district, Selangor from 2012 to 2013. Selangor was chosen because it had

second highest number of new TB cases after Sabah.⁵ A total of eight government health clinics in Gombak were selected based on their known high TB burden with number of cases ranging from 3 to 10 new cases per month. These eight health clinics also shared similar characteristics in terms of infrastructure, facilities, healthcare services and staffing. Patients were selected from the TB registry in the respective health clinics.

Sampling method

All newly diagnosed PTB patients within a period of one year from 1st November 2012 to 1st November 2013 were identified from the tuberculosis registry. The audit period was purposefully chosen to coincide with the launching of the new CPG in November 2012. The inclusion criteria were adult patients (>18 years old) and those diagnosed with PTB who were seen and treated at the health clinics. Patients diagnosed with other forms of TB such as extra-pulmonary TB, those who were followed-up and treated outside the eight government clinics were excluded from the study.

Study tool and statistical analysis

The investigators prepared an audit protocol to assess the structure, processes and outcome of PTB management. The structure included the availability of TB registry and TB team within the clinics. The process included the practice of the clinics in delivering care for PTB including documentation for risk factors, clinical features, investigations and treatment. The outcome of PTB was measured by the cure rate and defaulter rates. 'Cure' was defined as a condition when the patient was smear-negative in the last month of treatment and on at least one previous occasion⁴. For monitoring, the AFB sputum smear was conducted at 2 months post starting treatment and at 4 and 6 months.⁴

A check list form was prepared and divided into seven itemised parts, which included patient's demographic details and diagnosis, TB risk factors, clinical features of PTB, investigation, treatment and outcome. The criterion for each item such as diagnosis, TB risk factors, clinical features, investigation, treatment and outcome were determined according to the Malaysian TB CPG.

Required information was obtained from the patients' medical records. The clinics use paper medical records and have no electronic medical records. Initially, patients' medical records were scrutinised to assess the documentation of each check list item performed by the clinic and identify whether the investigation results were available in the patients' notes. The items were documented as "done", "not done" or "not documented".

Following the 1991 World Health Assembly, Malaysia has set objectives of 85% cure rate and to detect 70% of sputum smear-positive TB cases.⁴ Data were entered and analysed using statistical package for social science (SPSS version 20.0 Chicago, IL, USA).

Results

There were 545 notified cases of TB within the Gombak district during the period of data collection. A total of 117 patients were included in the study based on the inclusion and exclusion criteria.

All of the health clinics had an identifiable TB structure in place, which included a TB registry, a named person in charge for TB who is either a nurse or a medical officer and a team that manages TB patients. All of the clinics were equipped with a laboratory, which was able to perform sputum AFP smear and baseline bloods investigation such as full blood count, liver function test, renal profile test and HIV rapid test. All clinics were also equipped with a radiological service to perform chest X-ray.

Table 1 contains the demographic details of patients. There was a male predominance compared to female. Most cases were reported amongst Malays and Malaysians.

Table 1. Demographic details

Variables	Frequency (%)	Mean (SD)
All subjects, <i>n</i> (%)	117 (100)	
Age		40.4 (14.4)
<i>^aGender</i>		
Male	74 (63.2)	
Female	43 (36.8)	
<i>^aRace</i>		
Malay	76 (65.0)	
Chinese	9 (7.7)	
Indian	12 (10.3)	
Others	20 (17.1)	
<i>^aNationality</i>		
Malaysian	96 (82.1)	
Non-Malaysian	21 (17.9)	
<i>^aDuration to start treatment from diagnosis</i>		
≤3 days	89 (76.1)	
3–7 days	16 (13.7)	
>7 days	12 (10.3)	

*^aNumbers not equal to *n* = 117 due to missing data.*

Table 2. Results of risk factors documented in the medical notes of the PTB patients

Risk factors for TB	Yes, <i>n</i> (%)	No, <i>n</i> (%)	Not documented, <i>n</i> (%)
Contact with TB	24 (20.5)	74 (63.2)	19 (16.2)
Diabetes mellitus	19 (16.2)	68 (58.1)	30 (25.6)
HIV	3 (2.6)	80 (68.4)	34 (29.1)
Drug abuse	2 (1.7)	69 (59.0)	46 (39.3)
Smoker	20 (17.1)	63 (53.8)	34 (29.1)

The results from Table 2 show that the majority of patients did not present with risk factors. Out of those who were identified with risk factors, the most common was contact with TB (20.5%) followed by the underlying diabetes mellitus (16.2%) and smoking (17.1%). Only 2.6% of patients had underlying HIV infection and 1.7% had a history of drug abuse. Non-documentation of risk factors was high. Non-documentation for HIV was 29.1%, drug abuse was 39%, smoking was 29.1% and presence of T2DM was 25%. The highest documentation was for contact with TB (83.8%).

The results from Table 3 demonstrate patients presenting with clinical features of PTB. The most common feature was cough (88%), followed by loss of weight (58.1%), loss of appetite (57.3%), fever (56.4%), night sweats (48.7%) and haemoptysis (32.5%). There was a high percentage of non-documentation. The most complete documentation was for clinical feature of cough (91.4%). Non-documentation was high for haemoptysis (28.2%), night sweats (30.8%), loss of weight (17.9%), loss of appetite (17.9%) and fever (23.1%).

Table 3. Results of clinical features documented in the medical notes of the PTB patients

Clinical features of TB	Yes, <i>n</i> (%)	No, <i>n</i> (%)	Not documented, <i>n</i> (%)
Cough	103 (88.0)	4 (3.4)	10 (8.5)
Haemoptysis	38 (32.5)	46 (39.3)	33 (28.2)
Night sweat	57 (48.7)	24 (20.5)	36 (30.8)
Loss of weight	68 (58.1)	28 (23.9)	21 (17.9)
Loss of appetite	67 (57.3)	29 (24.8)	21 (17.9)
Fever	66 (56.4)	24 (20.5)	27 (23.1)

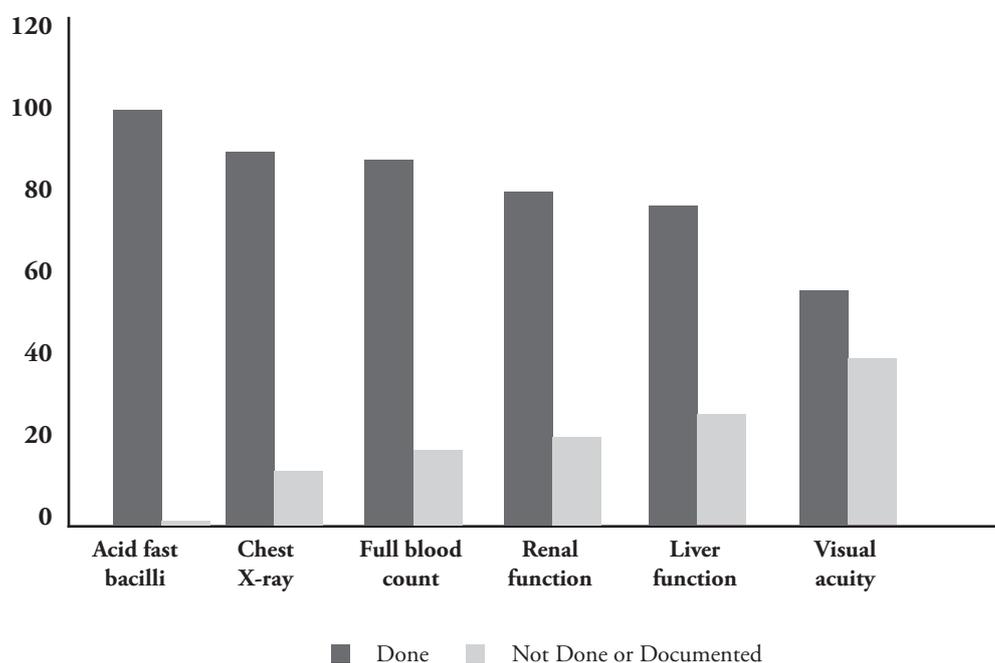


Figure 1. Percentage of investigations performed

Figure 1 demonstrates the percentage of basic investigation that was done for patients according to the recommendation of the CPG. AFB sputum smear test was conducted in almost all of the patients (99.1%) and positive sputum smear was identified in 94% of the cases, achieving above the national standard of 70%. Other investigations

performed and documented were chest X-ray (89.7%), full blood count (88%), renal function (78.6%) and liver function (75.2%). Visual acuity test was only documented in 54.7% of patients and was either not done or documented in 45.3% of patients.

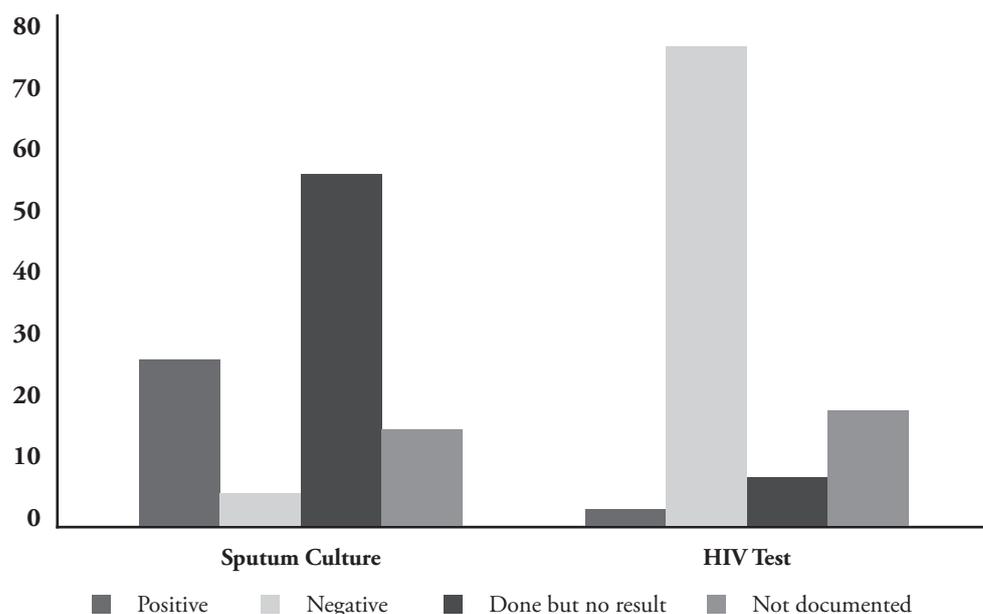


Figure 2. Percentage of patients with HIV and sputum culture performed and the results

Figure 2 demonstrates the percentage of patients with HIV and sputum culture test conducted. Although, in majority of patients (86.4%) sputum samples were collected for *Mycobacterium tuberculosis* detection, 54.7% of results were still unavailable in the patient’s notes, 27.4% were culture -positive and 4.3% were culture -negative.

HIV test was conducted in 82.1% of patients and most patients had negative results (73.5%) and only 2.6% had positive results. HIV test was either not done or documented in 17.9% of patients.

Table 4. Association between stage of PTB treatment and cure rate

Treatment stage	Total number of patients (N)	Patients cured, n (%)	Patients not cured, n (%)	Chi-square test (p<0.01)
Initiation stage	31	0 (0.0)	31 (100)	0.001
Maintenance stage	53	25 (47.2)	28 (52.8)	
Completed treatment	33	33 (100)	0 (0.0)	
Total	117 (100)	58 (49.6)	59 (50.4)	

All patients were started on the initial recommended treatment regime. DOT was well established within the health clinics where 94% of patients were documented under DOT and only 7% were undocumented. The default rate was 17.1% (20 patients). Contact tracing was documented in 62.4% of patients and not done or documented in 37.6%. As shown in Table 4, all patients who completed treatment were cured hence, achieving the national standard of more than 85%.

Discussion

A particular area of concern highlighted from this audit report was the incomplete documentation

of patients’ medical notes. TB is a notifiable disease and undergoes regular auditing, hence, requiring complete and concise documentation to ensure that the patients receive appropriate and optimum level of care as recommended by the national TB CPG. Incomplete documentation could be due to the use of paper-based record as a study had shown that the use of electronic medical record was more complete and accurate compared to paper based record.¹³ The use of check list items as well as regular training of clinical staff may improve documentation. Measures to improve documentation are necessary to ensure and maintain high standards of patient care.

There were more men with PTB compared to women and this finding was similar to other Malaysian studies.^{14,15} Social, biological and behavioural factors had been postulated as causes for higher TB incidence in men.¹⁶ In general, there is often a delay in seeking medical help following the onset of TB symptoms and women tend to delay longer as compared to men.^{17,18} The number of undiagnosed women may contribute to this gender discrepancy.¹⁷ More public health education in recognising clinical features of TB is needed to improve health seeking behaviour among the public.

The risk factors associated with PTB are well known. Compared to TB contact studies¹⁹ and another audit conducted in Ipoh, Perak (another state in Malaysia),¹⁵ the presence of risk factors and co-morbidities in these patients were low. This was most likely due to under-reporting and non-documentation. Close contacts are determined by proximity and persistence of the contact between the person infected with TB and those who are at risk (19). Patients with active TB and smear-positive are more infectious compared to those with latent or smear-negative TB²⁰ hence, documentation and rigorous contact tracing is important to prevent the spread of this disease. Risk factors such as HIV,²¹ drug use,²² smoking²³ and Diabetes⁷ are associated with higher risk of developing TB and were identified in this audit.

Productive cough is the most common clinical presentation in PTB cases although it is known that patients with PTB may present with non-PTB symptoms.²⁴ The investigations recommended by the TB CPG should be properly adhered as a part of patient assessment and monitoring. In general, most investigations were reasonably conducted and adhered by the clinics except for visual acuity test which was only recorded in 50% of cases. The first line recommended treatment for PTB is the combination of ethambutol, isoniazid, rifampicin and pyrazinamide.⁴ Optic neuritis is a well-known complication of ethambutol and isoniazid treatment.^{24,25} The TB CPG recommends routine screening for visual acuity prior to starting treatment and documentation of this procedure is essential in order to detect this complication.

This audit found that although laboratory confirmation for sputum culture was sent in majority of the patients but results were unavailable in the medical notes. The sputum culture taken for mycobacterium tuberculosis at the health clinic was sent to a centralised

laboratory and results become available after 8 weeks. This delay might affect the initiation of treatment in smear-negative TB patients leading to further transmission.²⁶ Laboratory bacteriological confirmation is important because positive culture have been identified in smear-negative cases.²⁷ A systematic tracing system is required to ensure that results of the culture and sensitivity are tracked down and recorded in the patient's notes.

The cure rate within Gombak district was commendable. However, defaulters were still posing a challenge to the district. This could be due to population fluidity where there was a constant influx and exodus of patients. Malaysia has a robust DOTS program to trace and refer patients from different parts of the country and has been practiced since the late 1990s.²⁸ However, the implementation of this system requires a dedicated and experienced team and is dependent upon the adequate staffing of the clinics.

Limitations

This study was based on a retrospective scrutiny of patient's medical records and was conducted to reflect practices within the health clinics with regards to PTB management. The main limitation was the absence of data due to non-documentation. The study was also timed to immediately coincide with the launching of the new TB CPG and there might be insufficient time for the dissemination of information in order to implement the changes.

Conclusion

The management of PTB in assessing risk factors, clinical presentation, investigation, treatment and outcome of PTB within government health clinics in Gombak adhered to the recommended criteria set by the Malaysian TB CPG 2012. However, gaps were identified in the documentation of patient's medical records within each items assessed. Improvements in documentation are crucial to ensure fair assessment can be conducted and appropriate clinical care can be given to patients. Tracing of investigation results, especially for sputum culture is recommended to ensure diagnostic confirmation. The clinics should be commended for their implementation of DOT and a high cure rate. Defaulter tracing can be improved as a measure in reducing treatment failure and complications such as multi-resistant drug TB (MDR-TB).

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Conflict of interest

None to declare.

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