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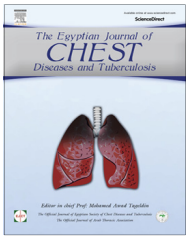

Evaluation of treatment failure outcome and its predictors among pulmonary tuberculosis patients in Sharkia Governorate, 2013–2014

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KEYWORDS

TB control program;
Treatment failure outcome;
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Abstract *Background:* Picking up tuberculosis (TB) treatment failure cases and its determinants is urgently needed in resource-limited developing countries. This work shows incidence and probable leading factors of TB treatment failure among patients who were managed by a TB control program.

Aim and objectives: This study aims to promote the TB control program at the ministry of health and population (MOHP) chest hospitals, Sharkia Governorate with the following objectives: (1) Determine the incidence of TB treatment failure. (2) Assess probable factors of TB treatment failure.

Patients and methods: A retrospective cohort study was carried out at MOHP chest hospitals, Sharkia Governorate. The study sample included all registered TB patients ($n = 480$) during the study period (2013–2014). There were 30 TB patients (Failed cases) with a positive sputum smear after 5 months of treatment (Group 1). Cured cases were 384 TB patients whose sputum smear was positive at the beginning of the treatment but became smear-negative at the end of treatment and on at least one previous occasion (Group 2). Both groups were compared to evaluate leading factors of treatment failure.

Results: Of the 480 TB patients registered during the study period (2013–2014), the incidence of treatment failure was 6.25%. Treatment failure cases were significantly more likely to have: positive sputum smears at 2 months of TB treatment ($p < 0.01$), cavities on the baseline chest radiograph ($P < 0.01$), extensive disease on the baseline chest radiograph ($P < 0.001$). Also, retreatment case ($P < 0.01$) and CAT 11 treatment category were ($p < 0.001$).

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Conclusion: This study showed that the treatment failure rate in our locality is relatively high. Positive sputum smear at 2 months of TB treatment, radiological findings and retreatment patients were found to be predictors of TB treatment failure that should be recognized early and closely followed up.

Introduction

Tuberculosis (TB) leads to 1.8 million deaths every year. Most of cases were present in low to middle income countries, this is further supported by studies carried out in both high and low income countries which demonstrate significantly higher rates of TB in their poorer populations [1].

The control of tuberculosis (TB) remains a challenge worldwide, more so in developing countries like Egypt where treatment target has not yet been met. TB control aims to detect at least 70% of the sputum smear positive cases and to cure at least 85% of the sputum smear positive cases. If these goals are achieved, there is a decrease in prevalence, incidence, transmission and drug resistance to TB [2].

The proportion of pulmonary TB cases whose sputum smear or cultures are positive after 5 months or later during the course of treatment is an important point recommended by the WHO for the monitoring of TB control success [3].

These patients are defined as treatment failure cases. Treatment failure is a serious problem because cases tend to have higher morbidity and mortality compared with those who are cured. Also, they carry the risk of being infectious for a long time; hence, reflects the level of risk to close contacts of the patients as well as high rates of multidrug-resistant TB have been found among treatment failure cases especially in developing countries [4,5].

Few studies have shown that predictors of TB treatment failure may include social, radiological, laboratory and treatment-related factors, but these factors can vary in different populations and it is important to assess the situation in specific settings [6].

Aim and objectives

This study aims to promote the TB control program at the ministry of health and population (MOHP) chest hospitals, Sharkia Governorate with the following objectives: (1) Determine the incidence of TB treatment failure. (2) Assess probable factors of TB treatment failure.

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Data were gathered from TB registry and medical records from the Sharkia Health Directorate. Identification and review of the documents and records which evaluate plan/guidelines, the input processes and output data of studied patients who were under cover of the MOHP national tuberculosis control program were revised. The collected data included TB registration code, patient number in the TB registry, name, age, sex, residence, history of previous treatment, diagnosis, culture results, regimen of treatment given, results of sputum examination (at 0, 2, 3 months, at the end of the initial phase, and at the end of treatment), and treatment outcome at the end of treatment. The study included a total number of 480 patients.

Methods

(1) **Patients' history:** All patients' data that were gathered from records sheets of Sharkia Health Directorate included:
- Age and sex.
- Residence (rural or urban).
- Education level (illiterate, primary, secondary, tertiary and university level).
- Marital status (married, single, widowed or divorced).
- Occupations (employed or unemployed).
- Special habits {smoking (cigarette or goza), alcohol and drug abuse}.
- Human immune deficiency (HIV) positive cases.
- History of medical co-morbidity {diabetes mellitus (DM), hypertension (HPN), ischemic heart disease (IHD), liver diseases, and chronic obstructive pulmonary diseases (COPD)}.
- History of contact to tuberculous cases.
- History of previous anti-tuberculous treatment:
  - Number of treatment courses.
  - Regularity in the treatment (regular and irregular) and if the patient continues treatment or defaulted.

- **Type of treatment (CAT1 or CAT2):**
  - **CAT1 (regimen1) (for all new cases with sputum smear positive)**: Treatment regimens have an initial (or intensive) phase lasting 2 months and a continuation phase usually lasting 4 or 6 months. Initial phase, consists of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol or Streptomycin. Continuation phase consisting of isoniazide and rifampicin.

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– **CAT2 (regimen2) (for patients with previous anti-tuberculos treatment or treatment after interruption)**: Treatment regimen consists of 5 drugs in the initial phase (2 months) and 3 drugs in the continuation phase (4–6 months). Three of the drugs isoniazide, rifampicin and ethambutol are given throughout the treatment [7].

(2) **Medical data:** All recorded data of general and local examinations that were done for all patients at the time of admission.
(3) **Plain Chest X-ray (CXR) and CT chest:** Plain CXR was done monthly for all patients at the time of admission and end of treatment (target point). Pathological findings depending on radiology (plain CXR and CT): Extensive disease, infiltration, cavitation, miliary lesion, consolidation, collapse, fibrosis, effusion, hydropneumothorax, pneumothorax and lymph node.
(4) **Laboratory investigations:**
   1. **Routine laboratory investigations including:** Complete Blood Count (CBC), Erythrocyte Sedimentation Rate (ESR), serum creatinine and blood urea, ALT and AST, random blood glucose level. They were done at admission, monthly and at end of treatment besides at any time the patient developed new symptoms or signs.
   2. **Sputum Ziehl–Neelsen stain studies:** The reagents used are Ziehl–Neelsen carbolfuchsin, acid alcohol and methylene blue. Acid-fast bacilli will appear bright red after staining. It was done monthly for all patients [8].
   3. **Sputum culture on Lowenstein–Jensen (L.J.) medium:** Lowenstein–Jensen (LJ) Medium is used for the isolation and cultivation of Mycobacteria as bases for selective, differential and enriched media for Mycobacteria. It was repeated monthly for all patients [9].
   4. **Screening of T.B drug susceptibility testing (DST)**.
      - The drugs used for susceptibility testing should not include those additionally used for treatment. They must be taken from pure compounds that are available only from the manufacture.
      - For DST, the identical method is used where at least two sputum specimens should be submitted to the laboratory for AFB microscopy (smear) and culture. One of the two cultures can then be used for DST.

Definitions

Patient with positive sputum smears for acid-fast bacilli after 5 months of continuous category I treatment had treatment failure. A patient with initial treatment success after TB therapy of sufficient length (9 months for severe disease, 6 months for all others) that developed recurrent TB had treatment relapse. Treatment default was defined as interruption of treatment for $\geqslant 2$ consecutive months. Treatment success was defined as treatment completion or cure. Retreatment patients were those receiving their first retreatment regimen after relapse, failure, or default.

Data management

Collected data were computerized and statistically analyzed using SPSS program (Statistical Package for Social Science) version 20.0. Qualitative data were represented as frequencies and percentages. Chi-square test (X^2) was carried out for comparing the qualitative data and the Fisher's exact test was used for an expected cell value frequency less than five. Quantitative data were compared using student's t-test. The test results were considered significant when p-value < 0.05. Logistic regression analysis was carried out to identify significant predictors for TB treatment failure.

Results

During the two-year period (2013–2014), there were 480 pulmonary tuberculosis (TB) cases notified in MOHP chest hospitals where these data were obtained from the Sharkia Health Directorate. There were 290 (60.4%) males and 190 (39.6%) females with a mean age of 35.7 ± 11.3 years. Most of the patients (40.0%) were within the age group 25–34 years. Only 24 patients (5.0%) were above 65 years. The majority of patients were married (54.2%) and living in rural areas (70.8%). They had average educational level (secondary school and above) (50.0%), with an overall rate of unemployment (58.3%) (Table 1).

Most of those patients were newly diagnosed pulmonary TB (n = 425; 88.5%) cases. About 62.5% of patients were known smokers, there were no HIV positive cases and about 36.4% of patients had medical comorbidities where diabetes mellitus was the most common disease (45.7%) (Table 1).

Treatment outcomes of all patients were overall 384 (80%) of the notified patients were cured: 30 defaulted patients (6.25%), 27 dead cases (5.6%), 30 patients had treatment failure (6.25%) and 9 cases were transferred out or missed (1.9%) (Graph 1).

The high percentage of the studied treatment failure patients were distributed at Abu Hamad (13.30%), Zagazig and Belbais (12.0%) as illustrated in Graph 2.

Baseline characteristics of treatment failure cases were significantly more likely to be old age ($p < 0.001$), male gender ($p < 0$ .01), rural residence ($p < 0.001$) lower educational level ($p < 0.001$) and unemployment ($p < 0.0001$) (Table 2).

By clinical data, treatment failure cases were significantly more likely to have positive sputum smears at 2 months of TB treatment ($p < 0.01$) cavities on the baseline chest radiograph ($p < 0.01$), extensive disease on the baseline chest radiograph ($p < 0.001$). Also, retreatment ($p < 0$ .01) and CAT 11 treatment category are ($p < 0.001$) as shown in (Table 3).

On Simple logistic regression analysis (Table 4); it was found that the most important predictors of TB treatment failure among patients in the Sharkia Governorate were positive sputum smear at 2nd month (O.R = 10.19), illiteracy (O.R = 106.45), rural residence (O.R = 80.01), radiology (O.R = 3.47), and retreatment cases (O.R = 1.06).

Discussion

The global goal of the World Health Organization (WHO) TB strategy is to achieve 2015 universal targets for decreasing the

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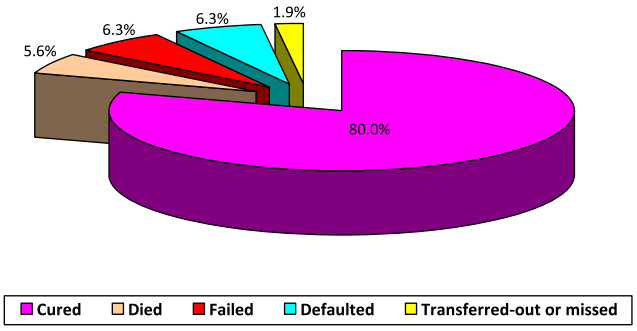
Table 1 Base line characteristics of the studied patients.

Characteristic	No. (n = 480)	Percent (%)
Age group		
15–24	48	10.0
25–34	192	40.0
35–44	168	35.0
45–64	48	10.0
> 65	24	5.0
Age (years)		
Mean ± SD	35.7 ± 11.3	
Sex		
Male	290	60.4
Female	190	39.6
Residence		
Rural	340	70.8
Urban	140	29.2
Education		
Illiterate	168	35.0
Primary	72	15.0
Secondary	96	20.0
University	144	30.0
Marital status		
Married	260	54.2
Single	200	41.7
Other (widowed, divorced)	20	4.1
Occupation		
Employed	200	41.7
Unemployed	280	58.3
Habits		
Cigarette smoking	190	39.6
Goza smoking	110	22.9
Alcohol use	25	5.2
Drug abuse	70	14.6
Type of patient		
New case	425	88.5
Retreatment case	55	11.5
HIV +ve cases	0	0.0
Medical comorbidities		
DM	80	16.7
HPN	25	5.2
IHD	30	6.3
Liver diseases	25	5.2
COPD	15	3.1
Total	175	36.5



Graph 1 The outcome of the studied cases.

burden of disease caused by TB. These targets are that incidence should be falling and that prevalence and incidence rates should be halved by 2015 in comparison to 1990 levels [8].

In this study, more than half of patients were males (60.4%) while females were 39.6% with a mean age 35.7 ± 11.3 years (Table 1). This in consistence with the epidemiology of tuberculosis, as males are more exposed to infection in the community than females. Also, the occupational and mental stress or social factors which may prevent females from seeking medical advice, resulting in inaccurate lowering of the incidence rate [8]. The mean age (35.7 ± 11.3 years) represents the period of physical, mental, and occupational stress. This was in agreement with those found by Mohamed [9], Kamal [10] and Fouad [11] who found near similar age groups. Most patients were from rural areas (70.8%). Near similar results were found in other studies conducted in different governorates of Egypt [12,13].

Poverty, close interaction within the community, as well as a low level of water supply and sanitation; may all explain the increased TB cases in rural areas. Drinking or handling contaminated milk and agricultural workers may acquire the disease when in close physical contact with potentially infected animals may also be other factors [14].

Regarding the occupation, there were 280 unemployed patients (58.3%) and 200 employed cases (41.7%) (Table 1). Near similar results were reported by Floyd et al. and Ladefoged et al. who notified that, a several-fold increase in the incidence of tuberculosis was noted among the unemployed compared to the employed among cases from different countries with varying degrees of TB disease [15].

Undoubtedly poverty due to poor diet or stress and greater difficulties in using health services contributes to the incidence of tuberculosis disease. Also, unemployment leads to behavior that increases the risk of tuberculosis, such as addiction or higher alcohol consumption, economic decline and homelessness [16].

Cigarette smoking was the most frequent special habit of the studied patients which represented 63.3% of cases. This is in consistence with Jee, Gajalakshmi and Lam TH who found that current smokers developed TB and subsequently died within the follow-up period more than non-smokers [17,18].

Factors that may contribute to the increased susceptibility of smokers to develop TB infection may be; Smoking damages the lungs and impacts the body's immune system and occurrence of TB has been shown to be linked to altered immune response of immune cells such as macrophages, monocytes and CD4 lymphocytes. Other mechanisms, such as mechanical disruption of cilia function and hormonal effects could also appear secondary to smoking [19].

Diabetes mellitus was by far the most common (45.7%) comorbidity of the studied patients. In agreement with Mc Cornick and colleagues who documented the association between diabetes mellitus and tuberculosis in 5000 TB patients. Using retrospective data they found that the co morbidity of TB-DM exceeded that of TB-HIV. Patients with TB and DM were older, more likely to have hemoptysis and pulmonary cavitation, were smear positive at diagnosis and remain positive at the end of the first and second month of treatment [20].

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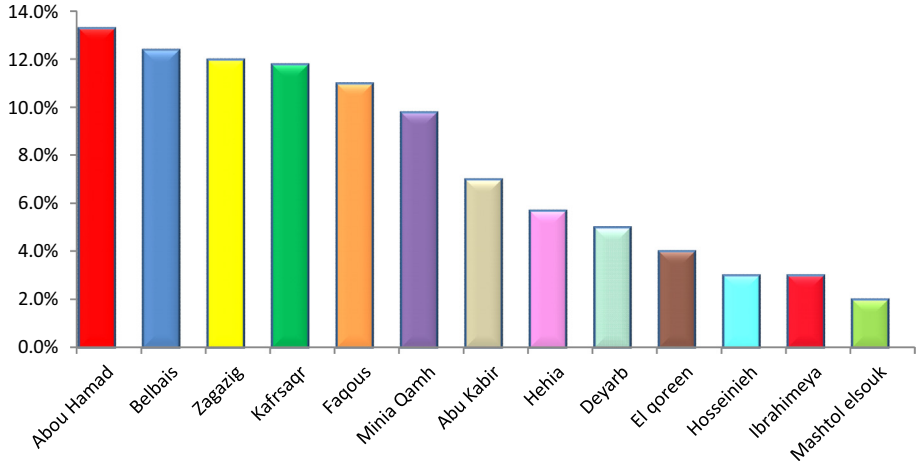

Graph 2 Geographic distribution of treatment failure patients' in the Sharkia governorate.

Table 2 Comparison between Group 1 (Failed cases) and Group 2 (Cured cases) regarding demographic characteristics of treatment failure.

Characteristic	Group 1 (N = 30)		Group 2 (N = 384)		P
Age (years)					
Mean ± SD	55.5 ± 8.8		36.9 ± 12.0		0.00**
Sex					
Male	20	66.7	235	61.2	0.013*
Female	10	33.3	149	38.8	
Residence					
Rural	28	93.3	259	67.4	0.00**
Urban	2		125		
	2	6.7	125	32.6	
Education					
Illiterate	22	73.3	151	39.3	0.00**
Primary	6	20.0	58	15.1	
Secondary	0	0.0	85	22.1	
University	2	6.7	90	23.5	
Marital status					
Single	9	30.0	150	39.0	0.23
Married	19	63.3	225	58.6	
Other (widowed, divorced)	2	6.7	9	2.4	
Habits					
Goza smoking	5	16.7	90	23.4	0.39
Cigarette smoking	15	50.0	155	40.3	0.30
Alcohol use	1	3.33	13	3.38	1.0
Drug abuse	3	7.6	28	6.3	0.72
Occupation					
Employed	10	33.3	180	46.9	0.0005**
Unemployed	20	66.7	204	53.1	
Medical comorbidities	21	70.0	140	36.5	0.0007**

* Statistically significant.
** Statistically highly significant.

Treatment outcome among the studied patients revealed that 384 patients were cured (80%), 27 patients dead (5.6%), treatment failure patients were 6.25%, defaulter cases were 6.25% and transferred or missed cases constituted 1.9% of patients (Graph 1). The case detection rate in 2008, in Egypt was 78% (global target is 70%) and treatment success rate was 89% (global target is 85%) [21].

TB treatment failure in Egypt is a serious problem facing national tuberculosis control programs due to different risk factors regarding the disease. In Egypt, treatment failure

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Table 3 Comparison between Group 1 (Failed cases) and Group 2 (Cured cases) regarding clinical characteristics of treatment failure.

Characteristic	Group 1 ($N = 30$)		Group 2 ($N = 384$)		P
CXR findings					
Cavity on chest X-ray	19	63.3	0	0.0	0.0**
Extensive disease on CXR	11	36.7	0	0.0	0.00**
Sputum smear conversion to −ve after 2 months	14	46.7	284	73.95	0.01*
Weight gain after 2 months of treatment	9	30.0	350	91.1	0.00**
Treatment category					
CAT 1	4	13.3	315	82.0	0.00**
CAT 11	26	86.7	69	18.0	
Type of patient					
New case	23	76.7	344	89.6	0.019*
Retreatment case	7	23.3	40	10.4	

* Statistically significant.
** Statistically highly significant.

Table 4 Logistic regression analysis; for significant predictors of TB treatment failure among patients in the Sharkia Governorate during 2013–2014.

Independent factors	B	Wald	P	O.R (95% C.I)
Male gender	−0.072	.017	0.896	1.93 (0.52–0.2.74)
Illiteracy	4.668	14.978	0.000**	106.46 (10.01–113.91)
Rural residence	−4.633	15.548	0.000**	80.01 (11.00–214.09)
Radiology	1.243	5.962	0.015*	3.47 (1.28–9.41)
+ve sputum smear at 2nd month	−1.680	11.019	0.001**	10.19 (5.07–12.50)
DM	0.419	.401	0.527	1.52 (0.42–5.55)
Retreatment	0.062	6.327	0.012*	1.06 (1.01–1.12)
Unemployment	−0.379	3.766	0.052	0.68 (0.47–1.00)

B = beta coefficient; O.R = Odds ratio; Wald = chi-square.
* Statistically significant.
** Statistically highly significant.

accounts for 3–5% of the treatment outcome of new smear positive cases and 13–17% of re-treated cases [22]. Also, near similar results were found by Mohamed [10] who reported that treatment failure patients were 16.1% of his studied patients.

In this study, treatment failure patients were of an older age than the cured group (Table 2). Old TB patients may be at risk of increased physical disability resulting in increased delay in clearing the mycobacterium bacilli probably due to decreasing immunity. These results were unlike findings from Uganda and Egypt which showed no differences in age [3,23]

Also, this study showed that the male gender was significant with the treatment failure group than the cured one (Table 2). This is consistent with findings from Brazil [24], but unlike results in Uganda and Egypt. This suggests that male smear-positive TB patients need to be monitored closely for improved adherence during TB treatment [3,23].

Other socio-demographic data such as, residence, education and occupation were found to be associated with TB treatment failure group more than the cured one (Table 2). This may be explained by: living further from the TB clinics make patients not return for drug refills because of the longer distance. Low educational level and unemployment add further to poor adherence and loss of interest to complete the treatment course.

This is in consistence with Hasker et al. who studied socio-demographic factors including unemployment, education and distance to the clinic and published it as medical risk factors for treatment failure [25].

Unsuccessful sputum smear conversion at the 2nd month of the TB treatment course, retreatment TB cases and CAT11 regimen were found to be more significant with treatment failure patients than cured patients (Table 3). This is in agreement with results of Namukwaya et al. [23] and Chavez Pachas et al. [26].

After two months of tuberculosis treatment, sputum smear microscopy is routinely carried out in national TB programs. Thus, TB control programs consider patients who have smear positive after two months of tuberculosis treatment to be at-risk of treatment failure [27].

Our results were in consistence with Dooley et al. [28], who studied outcomes of retreatment cases with the Category II regimen which was suboptimal and they found that treatment failure among those patients was unacceptably high.

Among those more significant associated factors studied in (Tables 2 and 3), we found that, independent predictors for treatment failure were; sociodemographic factors; living in rural and illiteracy (Table 4). This association between treatment failure and rural patients may be due to lower awareness of TB treatment and the long distance between their residence and the treatment resources [29].

Illiteracy is usually associated with low socioeconomic status that makes personal and family adaptation to treatment

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more difficult. Also, illiteracy may be the reason patients often prefer to be treated away from their place of residence. Such conditions contribute to irregular treatment, which results in failure [24].

Clinical factors associated with treatment failure were; positivity of sputum smears at 2nd month of antituberculous drugs course, retreatment cases and radiology of patient (Table 4).

Positivity of sputum smear at 2nd month of TB treatment was found to be associated with treatment failure in this study. This is in agreement with findings in Peru and Uganda. Patients found to have persistent smear positivity after two months of treatment should be investigated further using sputum culture and be treated further based on drug sensitivity testing [30].

This study also found that, previous treatment for TB was a predictor of treatment failure (Table 4). Near similar results were reported by de Albuquerque et al. who found that a history of prior TB treatment was significantly associated with unsuccessful treatment outcomes. Similarly, Anunnatsiri et al. also found that a history of previous TB treatment was associated with treatment failure and death [24,31].

Prior to TB treatment, association with treatment failure is a clear indication of the importance of properly completing treatment and monitoring patients [32].

As regards CXR findings, our study showed that patients with cavities and advanced lesions will be in favor of treatment failure outcome (Table 4). This is in consistence with Bao et al. [33], who found that treatment failure outcome was more likely among patients with cavitations than those without. Also, another study by Talay et al. [34] showed that treatment failure outcome among patients with extensive lesions on chest X-rays was more than those with non-extensive lesions.

Our study did not find age, male gender and occupation to be independent risk factors of TB treatment failure and this is in consistence with Morsy et al. [3], and Namukwaya et al. [23] but in contrary to studies elsewhere [35].

Clinical factors previously described by other authors as risk factors for TB treatment failure including diabetes mellitus, persistent fever, weight loss and HIV sero-positivity were not significant in this work [36].

This study had some limitations. Data were retrospectively collected from TB treatment registers. This study does not have additional data to confirm or refute the findings. In addition, there is no information on participants' knowledge of TB, TB treatment adherence, quality of education given the patient and anti-TB drug side effects; these factors may affect TB treatment outcome.

Conclusion

This study showed that the treatment failure rate in our locality is relatively high. Positive sputum smear at 2nd month of TB treatment, radiological findings and retreatment patients were found to be predictors of TB treatment failure that should be recognized early and closely followed up.

Conflict of interest

The authors declare that they have no conflict of interest.

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