Management outcome of pulmonary tuberculosis: A nine year review in Ilorin.

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Summary

Objective: **This study evaluates the management outcome of patients with pulmonary tuberculosis (PTB) over a nine year period. Essentially the cure rate, rate of default and fatality rate were all estimated. Factors predisposing to poor drug compliance were also reviewed.**

Methods: **This was conducted by analysing the medical records of all newly diagnosed cases of PTB. Patients' demographic data, their social and past medical histories were obtained from their records. The extents of the lung lesions were determined from their chest X-rays.**

Criteria were set to define those that were (a) cured, (b) defaulted (c) transferred (d) had treatment failure and (e) died. The chi-square test of significance was used to estimate the difference between those that were cured and those that defaulted therapy. Multiple regression models were used to determine the level of interplay among the various factors contributing to patients' poor therapy compliance; the best of these was recorded.

Results: **Out of the 1,741 cases of PTB treated over the studied period, 43.7% were cured, 0.3% had treatment failure, 44.2% defaulted therapy, 0.2% were transferred to other treatment centers while a fatality rate of 11.6% was recorded. Male gender, old age (≥) 65 years), unmarried status, and previous default from therapy were found associated with poor therapy compliance. Others were unemployment, cigarette smoking and the use of alcohol.**

***Conclusion*: The cure rate of PTB in this study was very low, while the rate of default from therapy was quite high. These are in contrast to WHO target for TB control. To improve on these, directly observed therapy short course (DOTS) strategy for treating TB has to be adopted and implemented at all our treatment points for PTB. There should be emphasis on the Primary health Care (PHC) centers, because majority of PTB patients are grass root people and PHC set-ups are closer to them.**

Keywords: ***Pulmonary tuberculosis, Outcome, DTS.***

Résumé

Objectif: Cet étude met en relief le résultat de la prise en charge des patients atteints de tuberculose pulmonaire (PTB) au cours d'une période de neuf ans. Essentiellement, la cadence de la guérison, cadence de la défaillance et la cadence de la fatalité ont été toutes évaluées. Des facteurs responsables d'une mauvaise observation de la drogue ont été également examinés.

Méthodes: Cet étude été effectuée à travers une analyse des dossiers médicaux de tous les noveaux cas de PTD diagnostiqués. Les données démographiques des patients, leurs histories socio-médicaux du passé ont été recensés grâce à leur dossiers. La mesure de la lésion du poumon a été notée à travers la radiographie de leurs poitrines. Des critères ont été établis afin de décider: (a) ceux qui ont été soignés, (b) les défaillants, (c) patients envoyés dans un autre hôpital, (d) faillite de traitement et (e) morts. L'importance du test de chi-carré a été adopté afin d'évaluer la difference entre ceux qui ont été soignés et ceux qui ont recensé un échec avec la thérapie. Des Modèles Régressions Multiples ont été utilisés afin d'évaluer le niveau d'interaction parmi des facteurs diverses qui contribuent au mauvaise réaction des patients en matière de la thèrapie, le meilleur de ceux-ci était recensé.

Résultat: Entre 1,741 de cas de PTB soignés au cours de la durée de cet étude, 43,7% ont été soignés, 0,3% avaient un échec pendant le traitement, 44,2% n'ont pas réussi avec la thérapie, 0,2% ont été envoyés pour aller aux autres centres hospitaliers tandis que la cadence de la fatalité de 11,6% était recensé. Mâle, la vieillesse (≥ 65 ans) statut non marié et le défaut précédent de la thérapie ont été notés associés à une mauvaise observation de la thérapie. D'autres étaient chômage, fumeurs, et l'utilisation d'alcool.

Conclusion: Le taux de la guérison pour le PTB dans cet étude était très inférieur, tandis que le taux de défaut en matière de la thérapie était très élevé. Ces registres sont par contraste avec le cible du WHO en matièré du contrôle du TB. Pour pouvoir améliorer sur cet situation implique l'utilisation de la stratégie d'une observation directe de la thérapie à court terme (DOTS) pour le traitement du TB doit être utilisé et introduit partout dans nos centre de traitement de PTB. C'est nécessaire d'appuyer sur des centres de soins de la santé primaires (PHC), parce que la plus grande partie de patients de PTB sont des gens de base et l'institution de (PHC) doit être à la portée de tout le monde.

Introduction

One of the most dramatic medical changes in the last 50 years has been the revolution in the management of patients with pulmonary tuberculosis (PTB). This used to be a tragic situation in which two out of every three patients with confirmed PTB died[1]. The outlook has now been converted to one in which permanent recovery is ensured for all newly diagnosed cases[1]. This is based on the efficacy of a two-phase multi drug anti-tuberculosis chemotherapy.

Bacteriological cure has been established at well over 95%, if patients adhere strictly to a treatment regimen prescribed by a qualified medical personnel[2]. however, drug compliance is usually very poor and this has become one of the important factors to be considered in Tuberculosios (TB) control programme.

It has been shown that greater than 50% of patients with PTB would not comply with treatment by the 12th month of a standard regime[3]. This has led to the introduction of the short course chemotherapy regime. This is in an attempt to improve patients' compliance with therapy[4], because poor compliance with therapy could lead to emergence of multi-drug resistant TB. In light of this, we decided to review the outcome of man-

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agement of PTB cases in our center between 1991-1999 with emphasis on drug compliance rate and factors that may encourage non-compliance with therapy.

Method

The case files of all the new cases of PTB seen at the medical Outpatient Department of University of Ilorin Teaching Hospital, Ilorin (U.I.T.H) between January 1991 and December 1999 were retrieved from the medical record for analysis. These were the files of patients confirmed to have PTB by at least 2 positive smears of sputum for AAFB and they had short course anti-TB therapy of either 6/12 regimen comprising intensive phase of 2 months of Rifampicin, Isoniazid, Ethambutol and Pyrazinamide. Then 4 months of Isoniazid and Rifampicin in the maintenance phase, or 9 months regimen of Isoniazid, Rifampicin and Ethambutol in the intensive phase and 7 months maintenance phase of Rifampicin and Isoniazid. The following data were obtained from their records; age, sex, marital status, level of education, place of residence (Living within or outside Ilorin), social life style (cigarette smoking and alcohol ingestion). Information on associated medical conditions such as HIV infection; diabetes mellitus or chronic obstructive pulmonary disease (COPD) as well as history of previous default from TB treatment programme were also sought. Others included severity of the pulmonary lesion based on the radiological assessment. The type of care (in-patients or outpatient or both) and evidence of assistance from the hospital in form of free supply of anti-TB drugs, free hospital admission and exemption from paying for diagnostic and follow-up test. The patients were then divided into 5 groups: (a) cured patients, those that completed the prescribed term of treatment and were AAFB free at the end of the treatment; (b) treatment failure, those still excreting AAFB in their sputum five months into their treatment; (c) treatment defaulters, those that completed at least one month of treatment and possibly returned for treatment after at least 2 months' interruption of treatment, (d) transferred patients, these were patients that were referred to other institutions equipped with resources to manage TB due to one reason or the other (e) patients that died, either of TB or TB related conditions during treatment[5].

Statistical analysis

Cured patients and defaulters were compared for a number of variables that could have encouraged non-compliance with therapy. The statistical significance of these variables was estimated using chi-square test in stratified tables to remove potential confounding factors. P-values less than 0.05 were taken as significant. Odds ratio (OR) that is an indicator of the degree of association between non-compliance and a predictor variable was estimated with 95% confidence limit. All the variables that were significantly related to poor drug compliance from the univariate analysis were entered simultaneously into a multiple regression model for any possible interaction. Each of these variables was then excluded one at a time by a backward elimination procedure until the remaining variables contributed significantly to the model. At each step, the variable with the smallest contribution to the model (i.e the largest P value) was removed. The regression coefficients (regression coeff) that indicate the predicted increase in non-compliance for each unit increase in each of the predictor variables and the regression mean square (RMS) that indicate the influence of each of the variables on non-compliance were estimated. F-statistic (F) and the degree of freedom (df) were used to determine the best regression model.

NB: 1. Patient that defaulted during the course of the treatment and were brought back to complete the treatment regimen were considered under cured or treatment failure category as determined by the excretion of AAFB in the sputum.

2. Extent of disease[6] (classification) was taken as (a) minimal lesion when there were soft densities without demonstrable cavitations affecting one or both lungs, the total extent of which, regardless of distribution, did not exceed the volume of lung on one side that was above the 2nd chondrosternal junction and the spine of the 4th or the body of the 5th thoracic vertebral. (b) Advanced lesion: Soft densities on one or both lungs, the total extent of which was not more than the volume of one lung or dense and confluent opacities with cavitation of less than 4cm in diameter, the total extent limited to one third the volume of one lung.

Results

In the nine-year period, 1741 new cases came under treatment, 776(44%) of them completed their treatment. Seven hundred and sixty-one (43.7%) patients were certified cured, while 5(0.3%) had treatment failure see Table 1. About 975 (56%) patients did not complete their treatment. 769 (44.2%) of them defaulted, while 4(0.2%) were transferred to other centers and 202 (11.6%) patients died of PTB of PTB-related complications.

Table 2 shows the demographic data of both the patients that complied with treatment and were cured and those that did not comply. The age specific distribution of cases was similar

Table 1 Outcome of PTB treatment from 1991 - 1999

	Completed treatment		Did not complete treatment			
Year	Cured	Treatment failure	Defaulted	Transfer	Died	Total
91	83	–	72	–	12	167
92	94	–	78	–	10	182
93	77	–	80	–	17	174
94	76	–	74	2	20	172
95	100	–	62	–	27	189
96	102	–	97	1	26	226
97	92	1	83	1	34	211
98	74	2	119	–	32	227
99	59	2	104	–	28	193
Total	761	5	769	4	202	1741

Table 2 Demographic data of compliant and non-compliant PTB patients

Variable	Compliant patients (n= 761) (%=100)	Non compliant patients (n = 769) (%=100)
Age (in years)		
15-24	176(23)	269(35)
25-34	233(31)	185(24)
35–44	157(20)	112(15)
45-54	113(15)	82(11)
55–64	44(6)	25(3)
≥ 65	38(5)	96(12)
Sex		
Males	346(46)	449(58)
Females	415(51)	320(42)
Occupation		
Professional workers	51(7)	40(5)
Intermediate workers	58(8)	85(11)
Skilled manual workers	95(12)	89(12)
Semi skilled manual workers	146(19)	110(14)
Unskilled manual workers	165(22)	123(16)
Unemployed	246(32)	322(42)
Educational status		
University	33(4)	27(4)
Professional (OND, HND, NCE)	82(11)	81(10)
Secondary	116(15)	104(14)
Primary	90(12)	70(9)
Non formal	203(27)	218(28)
Nil	237(31)	269(35)
Marital status		
Married	459 (60)	296(39)
Single	231(30)	324(44)
Others	71(10)	131(17)
Distance from the clinic		
Living within Ilorin	536(70)	509(66)
Living outside Ilorin	225(30)	260(34)

Table 3 Medical history of the compliant and non compliant PTB patients

Variable	Compliant patients (n= 761) (%=100)	Non compliant patients (n = 769) (%=100)
Type of care		
Only in-patient	13(2)	-
Both in and out-patient	200(26)	208(27)
Only out-patient	548(72)	561(73)
Previous default from TB treatment		
Yes	268(35)	414(54)
No	493(65)	355(46)
Extent of disease at diagnosis		
Minimal lesion	278(37)	458(60)
Advance lesion	483(63)	311(40)
Associated Medical condition		
Diabetes mellitus	29(4)	7(1)
Chronic heart failure	17(2)	5(1)
COPD/bronchial Asthma	23(3)	13(2)
HIV-scropositive	51(7)	14(2)
HIV-negative	641(84)	730(94)
Assistance from Hospital (free anti-TB drugs & free investigation		
Yes	402(52)	379(49)
No	359(48)	390(51)
Life style		
Alcohol ingestion		
Yes	307(40)	512(67)
No	454(60)	257(33)
Cigarette smoking		
Yes	293(38)	386(51)
No	468(62)	383(49)

Table 4 Relationship betweeen Bio-data, Life style, medical history and risk of non-compliance

Variable	Non-compliant	Compliant	OR	95% CI	P-value
Younger age	269	176	1.79	1.42-2.25	<0.001
Old age	96	38	2.71	1.81-4.09	<0.001
Male sex	449	346	1.68	1.37-2.07	<0.001
Unemployment	322	246	1.51	1.22-1.87	<0.001
Unmarried patient	473	302	2.43	1.97-3.00	<0.001
Living outside Ilorin	260	225	1.22	0.97-1.52	0.08
Previous default	414	268	2.15	1.74-2.65	<0.001
Mild disease	458	278	2.56	2.07-3.16	<0.001
Alcohol ingestion	521	307	3.11	2.51-3.85	<0.001
Cigarette smoking	386	293	1.61	1.31-1.98	<0.001

in both groups except at the two extremes of life where there were more cases of non-compliance. In the younger age group, 15-24 years, 176 (23%) patients complied while 269(35%) did not. Five hundred and forty-seven (72%) of the adult population, 25-64 years complied with therapy while 404 (53%) did not. Among the elderly ≥ 65 years only 38 (5%) patients complied with treatment while 96 (12%) of them did not. The sex ratios for the two groups are M.F 0.8:1 for the compliant group and 1.4:1 for the non-compliant group.

Greater than one half (54%) of the non-compliant patients had previous exposure to anti-TB drugs, while only 35% had previous exposure among the compliant patients Table 3. Majority of the patients diagnosed with advanced disease (63%), complied with treatment, while 60% of those with mild disease did not comply with drug treatment regimen Table 3.

Patients' access to free drugs and free diagnostic tests did not have impact on compliance as only 52% of those that had the access complied, while 49% of them did not. A greater proportion of non-compliant patients used alcohol and smoked cigarettes, 67% and 51% respectively Table 3.

Some of the factors encouraging patients non-compliance with the anti-TB drug are shown in Table 4; alcohol (OR, 3.11, 95% C12.51-3.85) mild disease (OR, 2.56, 95% C12.07-3.16) unemployment (OR, 1.51, 95% C11.22-1.87) old age (≥ 65 years) (OR, 2.71, 95% C1 1.81–4.09), male sex (OR, 1.68, 95% C1 1.37-2.07), single patients (OR, 2.43,95% C1 1.97-3.00), history of previous default from treatment (OR, 2.15, 95% CI 1.74-2.65). They all have significant P-values. The regression model shows interaction among some of these variables table 5, while table 6 shows the best regression model. This was expressed as a combination of the interactive efforts of alcohol (regression coeff 54.4%), old age (regression coeff. 33.4%), mild disease (regression coeff 7%), unmarried status (regression coeff. 19.7%) and previous default from therapy (regression coeff. 26.4%). Although they all have $p<0.05$ their independent contribution to non-compliance was a weak one save for alcohol as shown by their respective regression coefficients table 5. Patients' level of education (OR, 0.84,95% CI 0.84-1.05), access to free drugs (OR, 0.87, 95% CI 0.71 – 1.07) and the place of residence of the patients (OR, 1.22,95% CI 0.97-1.52) did not have any statistically significant impact on their level of compliance. Some of the possible causes of death (not confirmed by autopsy) are shown in table 7 with advanced disease and HIV/AIDs accounting for most of them.

Table 5 Shows final backward regression model that best predict patients non-compliance with therapy

Variable	Regression coefficient	Standard error	T	P-value
Constant	-	.335	-17.776	0.000
Alcohol	.544	.124	2.020	0.000
Mild disese	.007	.112	10.198	0.004
Unmarried	.197	.079	11.157	0.0031
Default	.264	.094	22.039	0.0016
Old age	.334	.035	6.322	0.000

Table 6 Shows analysis of variance of the final regression model

Source of variation	Degree of freedom	Sum of square	Mean square	F-statistic
Regression of non-compliance on old age, default, alcohol, mild disease and unmarried status	6	1918.961	319.808	906.723
	762	268.763	.353	
Residual Total	768	2187.612	–	

Table 7 Possible causes of death

Cause of death	Number	Percentage
Complications of TB		
1. Advanced disease	35	17.1
2. Cor pulmonale	22	11
3. Diseminated disease	11	5.4
4. Massive Haemoptysis	11	5.4
5. Tuberculosis meningitis	9	4.5
6. Bilateral pneumothorax	8	4.0
7. Pyopneumothorax	6	3.0
8. Treatment failure (MDR)	4	2.0
Associated Medical condition		
1. HIV/AIDs	27	13.4
2. Poorly controlled diabetes mellitus	4	2.0
3. COPD	4	2.0
4. Heart failure	2	0.9
Drug reaction		
a. Steven Johnson syndrome	6	3.0
b. Acute renal faulure	3	1.5
c. Acute liver failure	1	0.5
Others		
1. Severe anaemia	14	7.0
2. Shock	8	4.0
3. Pulm, embolism	2	0.9
4. ? Cause	25	12.4
Total	202	100

Discussion

Modern chemotherapy appropriately prescribed and administered in regimen cures 98 to 99 percent of cases of previously untreated PTB if the disease is caused by drug-susceptible Mycobacterium tuberculosis[9]. Despite the availability of these effective treatment regimens for TB, cure rates remain unacceptably low in most developing and some developed countries[10]. This was the finding in the study where a cure rate of 43.7% was recorded, in almost equal proportion to the rate of defaulters, which was 44.2%. The main reason for this low cure rate was that patients did not take the prescribed medications with sufficient regularity and duration to achieve cure.

Multiple factors were observed in this study to be responsible for patients' non-compliance with anti-TB therapy. These were old age, male gender and previous history of treatment default. Others were unmarried status (single and separated), unemployment, cigarette smoking, the use of alcohol and those who had minimal lesion at diagnosis. Interplay of some of these factors (alcohol, previous default, old age and unmarrried status) was also observed. Surprisingly, patients' literacy level, access to free drugs and free diagnostic tests did not improve their compliance with therapy. Some reasons may be advanced for the patients' non-compliance with therapy. These could be separated into three categories:- health workers' factor, patients' factors and government factors.

Health workers factors

Adequate information as regards the duration of therapy and the consequence of poor drug compliance might not have been given to these patients. This may explain why literacy level and access to free drugs did not have impact on compliance[11]. There is therefore a need for continuous dissemination of updated information on TB management to all health institution and practicing physicians alike[12].

Patient factors

Some patients would not accord the treatment of TB the right priority it deserves because of some social demands. This may be the problem among those that use alcohol[13] or smoke cigarette. Some believe, albeit erroneously that they are cured once they are symptoms free as it usually happens during the intensive phase of therapy. This is common among the youth and those diagnosed to have mild form of TB. The society does not also help the matter because of the social stigma attached to TB. Patients with the disease enjoyed limited social interaction. This is probably borne out of the fact that majority of Nigerians are not well informed about PTB, though certain class of the population, especially the civil servants are quite aware of the disease others like the petty traders are not[14].

Government factors

Treatment of TB is often irregular because of poor economic power of the patients. This usually leads to inadequate anti-TB drugs procurement, thus poor compliance. This was evident among the unemployed patients. A study had earlier shown that more than 60% of the health institutions in one of the states of the federation recorded cases of treatment default and lack of finance was the major reason for these defaults[12]. The consequences of patients' non-compliance with effective anti-TB therapy have been highlighted in one of our studies[15].

Those groups of patients admitted with advanced TB or associated medical conditions like HIV/AIDs, or poorly controlled Diabetes mellitus or heart failure complied with therapy. This is probably because they were admitted for a longer period and received supervised management. Other categories of patients observed to comply included married individuals, those in employment, female gender, adult patients and those living closer to the clinic. The type of care (in patient or outpatient) given to the patient did not really influence outcome safe for only 13 patients with complication, that had a fully supervised anti--TB therapy throughout the course of their management. They were all cured despite the fact that most of them had previous history of default from anti-TB treatment. This underscores the fact that the most important determinant of the

outcome of treatment of TB patients is access to reliable diagnosis and treatment services organised within a national TB control programme (NTP) as part of Directly Observed Treatments Short Course ((DOTS); the name of the WHO recommended TB control strategy[16]. In Nigeria, there are manpower (Doctors, Nurses, Health Technologist, Community Health Officers etc) and facilities to make reliable diagnosis of TB. The problem lies with the means to achieve effective treatment as laid down by WHO. Anti-TB drugs are not supplied free, DOTS is not effectively practised while contact tracing is no longer given the desirable attention in most places. A cure rate of 43.7% and non compliance rate of 44.2% is a far cry from the effective TB control policy, which aims at a cure rate of 85% from smear cases. Incomplete treatment would lead to a situation where the same sets of patients are being recycled in the clinic and thereby adding to the pool of infectious cases[17]. It is therefore very important to recognised that poorly supervised or incomplete treatment for TB is worse than no treatment at all[18].

A formal transfer arrangement was made for 5 of our patients to other tertiary institution for continuation of their management. However, there was no feedback as to the final outcome of their management. Cases of treatment failure as earlier defined were seen but their resistance could not be determined because facilities for culture and sensitivity are not available in our center. The case fatality rate in this study was 11.6% and the major determinants of mortality were HIV seropositive status, previous default from TB treatment and advanced disease. Generally TB mortality is due to failure or delay in diagnosing the disease or to ineffective treatment (lack of compliance, resistant organism)[19]. In our study, lack of compliance featured prominently. Therefore, ensuring patients adherence to treatment is very vital to achieving the cure of smear positive cases, while avoiding drug resistance[20]. Various methods to monitor drug compliance have been tried (pill counting, testing urine for INH metabolites etc) but they can all be countered by the patients intent on non-compliance[21]. In fact some will still default even if they are on intermittent regimen of anti-TB therapy[22]. DOTS is probably the most effective way to ensure drug compliance[23], and it can significantly reduces the rates of relapse and drug resistance in the community[21]. DOTS is not cheap or easy to conduct, but in long term, by ensuring completion of treatment is cost effective.

In Nigeria tuberculosis is endemic. HIV infection has also reached an epidemic proportion. Cases of TB/HIV co-infection are therefore expected to be common, so are the drug resistant forms of TB[15]. Appropriate measures should now be put in place in order to meet the global targets for TB control. Some of these steps include collaborative efforts from all tiers of Government toward provision of needed resources for the Local Councils to implement DOTS in all Primary Health Centers and Specialised TB Units under their control. This is because TB treatment has shifted from the hospitals to the field and management of TB at this level could be arranged to the convenience of both the patient and the Health personnel. Home visits too could go along way to reduce the rate of defaulters[24]. Also supervised anti-TB drugs should be supplied free to patients at all treatment points. It would be preferable if these drugs were supplied in fixed dose combination and in slow-release formulations. It may also be appropriate to use monetary and other inducements to encourage compliance with outpatient therapy since the effective treatment of TB benefits the entire community. If the above measures are well implemented but prove ineffective in improving patient's drug compliance, the state public health powers may have to be employed as a last resort such as confinement to a residential facility until patient is certified cured[25]. This is because every community has the right to protect itself against an epidemic of a disease that threatens the safety of its members.

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