Saudi Journal of Biological Sciences 28 (2021) 2041–2048

Contents lists available at ScienceDirect

Saudi Journal of Biological Sciences

journal homepage: www.sciencedirect.com

Original article

The possible impact of socioeconomic, income, and educational status on adverse effects of drug and their therapeutic episodes in patients targeted with a combination of tuberculosis interventions

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ARTICLE INFO

Article history:
Received 21 December 2020
Revised 26 January 2021
Accepted 1 February 2021
Available online 14 February 2021

Keywords:
Tuberculosis
DOTS
RNTCP
Socioeconomic Status
Education
Income

ABSTRACT

First-line antituberculosis (anti-TB) compounds have been considered as proven components of the Directly Observed Treatment-Short course (DOTS). Drug therapy against tuberculosis has been categorized as I, II, or III following the Revised National Tuberculosis Control Program guidelines. Anti-TB are drugs are quite common and show limited adverse effects. However, first-line anti-TB compounds mediated DOTS therapy and were found with several complications. Thus, those drugs have been discontinued. Therefore, the present study was designed to find out the possible impact of socioeconomic, income, and educational status on the adverse effects of drugs and their therapeutic episodes in patients targeted with a combination of tuberculosis intervention. This study found that an increased incidence of tuberculosis was found in patients who have finished high school, contributing to a high percentage of adverse effects. Notably, adverse events were shown maximally in poor patients compared with rich- or high-income patients. On the contrary, a high prevalence of adverse events was shown to be increased in partially skilled workers compared with full-skilled workers. Consequently, adversely considerable events were implicated to be raised in patients associated with minimal socioeconomic class. Such interesting factors would help in monitoring such events in experimental patients.

1. Introduction

Tuberculosis, known as the globally deadliest infectious killer, is caused by *Mycobacterium tuberculosis* which may be considered as the major culprit for disease occurrence. The most commonly affected organs are the lungs (World Health Organization (WHO). Global Tuberculosis Report, 2020). Moreover, it is projected that 40% of the population in India fosters *M. tuberculosis* (MTB) infection. At the international level, India has been ranked as the top 5 countries with the highest occurrence of tuberculosis (TB) (World Health Organization (WHO). Global Tuberculosis Report, 2020; RNTCP (Revised National Tuberculosis Control Programme). National strategic plan for tuberculosis:, 2025). In 2019; India confirmed 24 lakh TB cases and over 79,000 mortalities (Chopra, 2020). Moreover, TB is the biggest killer in India compared to Covid-19 (Chopra, 2020). In addition, India has now made a promising commitment to expel TB from the country by 2025. At the global level, the World Health Organization (WHO) also planned for the elimination of TB by the end of 2030 (India, 2020). Moreover, 20% and 8% of Indian TB cases were attributed to diabetes and tobacco usage, respectively (India, 2020; World Diabetes Day, 2019). The current work recommends that TB should be closely monitored on a nationwide level following social and economic indicators than the degree of occurrence (Oxlade et al.,

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Peer review under responsibility of King Saud University.

Production and hosting by Elsevier

https://doi.org/10.1016/j.sjbs.2021.02.004
1319-562X/

2009; Dye et al., 2009). Several reports have conflicting outcomes (Schoeman et al., 1991; Boccia et al., 2009). However, extreme levels of analyzed data have endorsed the positive mediation between ordinary and poverty areas in similar distinct set points such as Brazil (de Alencar Ximenes, et al., 2009), South Africa, Zambia (Harling et al., 2008; Boccia et al., 2011); and Vietnam (Hoa et al., 2011). Among the environmental, social, and biological elements of TB, several prominent and prevalent factors in the poor and rich groups likely contribute to a complex web of poverty-based risk factors that is difficult to separate. Thus, programs to control TB and the assertiveness of the community toward the execution of such programs are empirical. Consequently, alarming signals show that these strains could spread globally, emphasizing the need for supplementary control measures (e.g., new diagnostic methods, better treatment drugs, and a more effective vaccine). Meanwhile, patients harboring multidrug-resistant strains of *M. tuberculosis* necessitates alternate treatment schedules relating to second-line drugs and/or compounds, which are more expensive, more toxic, and less effective (Gaude et al., 2014). M. tuberculosis drug resistance has been characterized by a number of mutations in genes involved in drug metabolism such as Mutations in the *katG* genes, *rpoB* genes, *and embB* gene Isoniazid, Rifampicin, and Ethambutol respectively. Therefore, the present study aims to find out the possible impact of socioeconomic, income, and educational status on the adverse effects of drugs and their therapeutic episodes in patients targeted with a combination of tuberculosis intervention.

2. Study design and methodology

2.1. Study design

The present study is a questionnaire-based study investigating the correlation of socioeconomic, income, and educational status on the adverse effects of drugs and their therapeutic episodes in patients targeted with a combination of tuberculosis intervention at defined locations of the Revised National Tuberculosis Control Program (RNTCP) under Lala Ram Sarup (LRS) Institute of Tuberculosis and Respiratory Diseases, Sri Aurobindo Marg, Mehrauli, New Delhi, India. Moreover, in the current study, 1,011 patients of all categories, i.e., I, II, and III, were screened from the six centers at defined RNTCP locations under LRS for the detection of any untoward reactions after drug administration. Of the 1,011 patients, 351 reported adverse events during Directly Observed Treatment-Short course (DOTS) therapy.

2.2. Methodology

2.2.1. Enrolment procedure

All patients enrolled for the outpatient department were thoroughly examined for their health status followed by physical and clinical investigations including sputum examination and approved as TB cases. Based on the aforementioned observation, patients with TB registered for standard DOTS therapy at DOT centers of the defined RNTCP areas under the LRS Institute of Tuberculosis and Respiratory Diseases were enrolled in the current study. Enrolment was done from April 2008 to December 2008 (9 months) recognizing any untoward reactions after drug administration. Moreover, adverse events were examined and recorded whenever it arises during their particular set of therapy, i.e., categories as I and III (180 days) and category II (240 days). The improvements at the clinical stage of the patients when cured or completing full-course TB therapy were also recorded as evaluated by a physician.

2.2.2. Adverse events reporting for OPD patients

Any unwanted events during the course of therapy is called adverse event (AE) which may or may not be related to drug therapy. If it is related to drug therapy and confirmed by rechallenge and dechallege then it is called adverse drug reaction (ADR). The physician recommended DOTS to the patients in later stages. Thereby, the patients were asked to visit the nearest DOTS center for the initiation of DOTS therapy and verify consent. The patients who visited the DOTS center were also evaluated with the probability of ADR owing to anti-TB therapy postdosage at regular intervals without any interference. Consequently, targeted patients were inquired about specific events of negative effects due to DOT therapy during visiting hours (Naranjo et al., 1981; Hartwig et al., 1992). Investigations at basal levels were also quantified based on both physical and clinical examinations including sputum determination.

3. Results

3.1. Category-wise enrolment of patients

This paper enrolled 1,011 patients from all six specified centers at defined RNTCP locations under LRS. Moreover, enrolled patients were selected and categorized into three treatment categories (I–III) based on treatment guidelines provided by RNTCP. In category I, nearly 550 (53.9%) patients were considered for TB therapy. In contrast, nearly 225 (22.25%) patients were considered for therapy in category II. Finally, 241 (23.83%) patients were registered as last proposed in category III (Fig. 1).

3.2. Distribution of adverse events According to age group and Gender

Of the 351 patients of the present study, 200 (56.98%) and 151 (43.02%) were males and females, respectively. Therefore, the possible prevalence of such events was also observed to be at high levels in male patients compared with female TB patients being targeted with therapeutic interventions (Table 1). The correlation paradigm between age groups and adverse events was also examined in the present study in experimental patients. Therefore, patients were distributed into different age groups according to the standard guideline. Thus, TB prevalence has been evident in

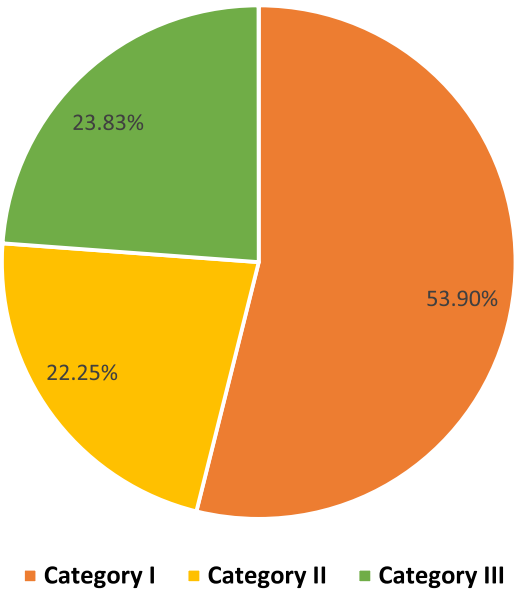

Fig. 1. Category-wise enrolment of patients for DOTS therapy.

Table 1
Distribution of Adverse Events According Gender.

DOTS Center	Male		Female		Total	
	Number	Percent	Number	Percent	Number	Percent
Bersarai	52	14.81	47	13.39	99	28.20
LRS Institute	42	11.97	28	07.98	70	19.94
PHC Mehrauli	26	07.41	28	07.98	54	15.39
Chattarpur	41	11.68	29	08.26	70	19.94
Fatehpur	19	05.41	13	03.70	32	09.12
Mahipalpur	19	05.41	7	01.99	26	07.41
Total	**200**	**56.98**	**151**	**43.02**	**351**	**100**

the population of the constructive age group. Notably, the maximum number of patients obtained more competence in adverse events. Such patients were males and considered as critically linked with the productive and/or constructive age group.

3.3. Distribution of adverse events According to age group

TB is more prevalent in the population of the productive age group. The current study found that a high number of male patients were considered as critically linked with the productive and/or constructive age group. Consequently, adverse events were quantified with the male–female ratio in all the experimental patients. This ratio was observed as a higher rate in all chosen centers for data collection. In younger patients, adverse events were also reported at higher episodes. A large number of patients (n = 127; 36.18%) in the 20–29 years old age group had adverse events. Furthermore, 63 (17.95%) and 56 (15.95%) patients who showed adverse events are in the 30–39 and 15–19 years old age groups (Table 2).

3.4. Incidence of adverse events According to education and income

Many of the TB patients have low income or poor. In the current study, TB was most prevalent in patients who finished high school (n = 404) followed by patients who finished intermediate (n = 187) and primary (n = 178) school (Table 3). An incremented percentage (42.17%) of adverse events was also noticed in patients who finished high school. Furthermore, the patients were recorded as illiterate (18.2%), graduated primary school (16.24%), and graduated high school (15.39%). Conversely, a declined percentage of adverse events were evident in professional/PG and higher, i.e., 1.42% (Table 3).

3.5. Incidence of adverse events According to income group and Occupation

Many of the TB patients have low income or poor. In the current study, TB with a maximum rate of adverse events (n = 209; 59.54%) were noted in patients having an income range of ₹2,041–6,100 followed by ₹6,101–10,160 (n = 93; 26.50%) and ₹10,160–15,820 (n = 27; 7.69%). Moreover, this study selected and included 103 semiskilled workers as patients. Also, 55 unskilled workers have an income range of ₹2,041–6,100. Adverse events were observed in 93 patients (44 semiskilled workers, 20 skilled workers, and 11 unemployed) with an income range of ₹6,101–10,160 (Table 4).

3.6. Incidence of adverse events According to Occupation and education

The current study declared that an occurrence of adverse events was higher in semiskilled workers (159 patients). Similarly, 71 unskilled workers were also considered as TB patients. Also, 71 patients who are skilled workers were considered. Furthermore, 159 patients were semiskilled workers. In addition, adverse events were also reported in patients who finished high school (n = 76) and primary school (n = 28; Table 5). Of the 351 patients, 71 (20.23%) patients who are unskilled workers have shown adverse events, and 25, 24, and 19 patients had education up to high school, illiterate, and primary school, respectively (Table 5).

Table 2
Adverse Events According to Age and Gender.

Adverse Drug Events Among Various Age Groups Patients									
DOTS Center	Gender	<15	15–19	20–29	30–39	40–49	50–59	≥60	Total
Bersarai	Male	4	8	20	9	4	3	4	52
	Female	5	6	15	7	6	4	4	47
	Total	**9**	**14**	**35**	**16**	**10**	**7**	**8**	**99**
LRS Institute	Male	1	5	15	12	5	2	2	42
	Female	6	6	9	4	2	1	0	28
	Total	**7**	**11**	**24**	**16**	**7**	**3**	**2**	**70**
PHC Mehrauli	Male	1	3	8	6	2	3	3	26
	Female	5	6	10	4	2	1	0	28
	Total	**6**	**9**	**18**	**10**	**4**	**4**	**3**	**54**
Chattarpur	Male	3	9	14	7	3	3	2	41
	Female	4	7	12	4	2	0	0	29
	Total	**7**	**16**	**26**	**11**	**5**	**3**	**2**	**70**
Fatehpur	Male	1	2	6	4	4	0	2	19
	Female	0	1	5	2	2	1	2	13
	Total	**1**	**3**	**11**	**6**	**6**	**1**	**4**	**32**
Mahipalpur	Male	0	1	13	3	2	1	0	20
	Female	1	2	0	1	0	1	1	6
	Total	**1**	**3**	**13**	**4**	**2**	**2**	**1**	**26**
GRAND TOTAL		**31**	**56**	**127**	**63**	**34**	**20**	**20**	**351**

Table 3
Incidence of Adverse Events According to Education and Income.

Education	Patient	ADE Number (%)	Mean Income (INR) (Mean ± SD)	Income (INR) <2,040	2,041–6,100	6,101–10,160	10,161–15,820	15,821–20,360	20,361–40,700
Professional/PG and higher	28	05 (1.42)	16,642.86 ± 5,062.793	0	0	0	4	0	1
Graduate	75	23 (6.55)	9,500.00 ± 4,333.938	0	5	14	2	1	1
Inter or Post High School Diploma	187	54 (15.39)	7,492.79 ± 3,248.684	0	26	21	7	0	0
High School Completion	404	148 (42.17)	5,660.12 ± 3,248.512	5	89	43	9	1	1
Primary School	178	57 (16.24)	5,122.31 ± 2,955.489	3	34	13	4	2	1
Illiterate	139	64 (18.23)	4,308.00 ± 3,176.853	5	48	9	1	1	0
	1,011	**351**		**13**	**202**	**100**	**27**	**5**	**4**

L Lower class, *LM* lower middle class, *M* middle class, *H* higher middle class, *H* higher class, *INR* Indian rupees

Table 4
Incidence of Adverse Events According to Income Group and Occupation.

Income Range	TB Patients	ADEs Percent	Mean Income Mean ± SD	Occupation P	SP	CSF	SW	SSW	USW	UE	Total
<2,040	45	13 (3.70)	1,753.33 ± 390.730	0	0	0	0	4	7	2	13
2,041–6,100	564	209 (59.54)	4,190.00 ± 1,111.336	0	2	11	13	103	55	25	209
6,101–10,160	223	93 (26.50)	8,180.90 ± 1,486.292	0	1	9	20	44	8	11	93
1,016–15,820	89	27 (7.69)	13,134.62 ± 1,571.990	2	2	7	7	7	1	1	27
15,821–20,360	57	05 (1.42)	19,333.33 ± 1,154.701	0	0	2	2	0	1	0	5
20,361–40,700	33	04 (1.14)	29,666.67 ± 8,962.886	0	0	2	1	0	0	1	4
	1,011	**351**		**2**	**5**	**31**	**43**	**158**	**72**	**40**	**351**

P Professional, *SP* semiprofessional, *CSF* clerk/shopkeeper/farmer, *SW* skilled worker, *SSW* semiskilled worker, *USW* unskilled worker, *UE* unemployed

Table 5
Incidence of Adverse Events According to Occupation and Education.

Occupation	Adverse Events	Mean Income	Education Professional/PG and Higher	Graduate	Inter or Post High School Diploma	High School	Primary School	Illiterate
	Number (%)	Mean ± SD	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)
Professional	2 (0.57)	13,500.00 ± 2,121.320	2 (0.57)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Semiprofessional	5 (1.42)	8,900 ± 3,398.529	1 (0.28)	0 (0.00)	3 (0.85)	1 (0.28)	0 (0.00)	0 (0.00)
Clerk, farmer, shopkeeper	31 (8.83)	10,564.52 ± 7,575.995	2 (0.57)	2 (0.57)	9 (2.56)	14 (3.99)	0 (0.00)	4 (1.14)
SW	43 (12.25)	9,035.71 ± 4,883.263	0 (0.00)	13 (3.7)	9 (2.56)	17 (4.84)	3 (0.85)	1 (0.28)
SSW	159 (45.3)	5,627.67 ± 2,569.734	0 (0.00)	11 (3.13)	25 (7.12)	76 (21.65)	28 (7.98)	19 (5.41)
USW	71 (20.23)	4,064.29 ± 2,399.519	0 (0.00)	0 (0.00)	3 (0.85)	25 (7.12)	19 (5.41)	24 (6.84)
Unemployed	40 (11.4)	5,675 ± 3,954.144	0 (0.00)	2 (0.57)	2 (0.57)	16 (4.56)	10 (2.85)	10 (2.85)
Total	**351**		**5**	**28**	**51**	**149**	**60**	**58**

3.7. Tuberculosis patients and adverse events According to socioeconomic class

TB was more prevalent in the lower middle class. Of the 1,011 patients, 712 (70.43%) belonged to the lower middle class, followed by 231 patients from the middle class. Moreover, the maximum percentage of adverse events (i.e., 72.65%) were reported in the lower middle-class and middle-class socioeconomic status (Table 6).

3.8. Advised by the pharmacist for treatment adherence and compliance

Compliance is a prerequisite for disease management and is quite important for managing infectious diseases like tuberculosis. Noncompliance leads to drug resistance that is more challenging to treat (i.e., compounds or drugs that are highly intolerable, high treatment onset, and more expensive drugs). The overall compliance evaluated in the current study was more prominent at

Table 6
Adverse Events According to Socioeconomic Class among Tuberculosis Patients.

Socioeconomic Class	Patients Number	Percent	Adverse Events Number	Percent
Lower Class	12	01.19	5	01.42
Lower Middle Class	712	70.43	255	72.65
Middle Class	231	22.84	68	19.37
Upper Middle Class	56	05.54	23	06.55
Upper Class	0	00.00	0	00.00
Total	**1,011**	**100**	**351**	**100**

88.43%. According to the WHO recommendations, about 85% of cure rate is achieved in all prognosed new sputum TB cases with positive onset. For better achievement, the aforementioned cure rate focused on an 85%–90% compliance rate. Compliance was recorded as 84.25% at the LRS Institute DOT center (center 3). Moreover, the LRS is a well-reputed TB institute and most patients are more likely to go for DOT therapy at an LRS DOT center. After diagnosis, patients were referred to the nearest center for DOT therapy outside the center for patient convenience and better compliance (data not shown).

3.9. Incidence of ADR in TB patients According to socioeconomic status

The maximum number of TB patients were poor or lower middle class, which contributes to a high rate of the adverse drug**.** This is followed by middle-class patients**. Of the** 712 **(**70.43**%)** low- and middle-class TB patients, 80 **(**7.91**%)** reported ADRs**.** Of the 231 **(**22.84**%)** TB patients, only 15 **(**1.48**%)** patients were found to be with reported ADRs**.** Consequently, ADRs were not recorded in patients from the upper-class status**.** Thus, the probable trend of ADRs decreases as socioeconomic status advances, which is especially found in TB patients **(**Table 7**).**

3.10. Incidences of ADR in TB patients According to education status

In the current study, TB incidence was found to be maximum in patients who graduated high school, intermediate, and primary school. Of the 1,011 TB patients, 404, 187, 178, 139, 75, and 28 patients had an education up to high school, inter- or post-high school diploma, primary school, illiterate, graduate, and professional/PG and higher, respectively (Table 8). Of the 404 TB patients educated up to high school, 41 patients experienced ADRs. Conversely, of the 187 TB patients educated up to inter- or post-high school, only 12 patients reported ADRs (Table 8).

4. Discussion

The current study was carried out on patients targeted with a combination treatment for TB management registered in the DOTS program at various DOTS centers of the defined RNTCP areas under the LRS. Sixteen DOTS centers were affiliated under LRS (ten, located at government dispensaries; six, under nongovernment organizations). Of the ten government dispensaries, six centers were chosen for patient enrolment. This study screened 1,011 patients from all six centers of the defined RNTCP areas under the LRS for the identification of any untoward reactions after drug administration. Among the 1,011 patients, 351 reported adverse events. This accounts for nearly one-third of the patients screened for adverse events that may be either related or unrelated to the drugs. Few patients were identified with at least one adverse event while most of the patients reported more than one event for the entire stage of this study. On average, one patient displayed 2.03 maximal adverse events. TB occurrence and its analytical trend may help examine its associated risk concerns and possible targeted medications for defense. However, it is key for identifying a possible and seasonal pattern in the occurrence of disease events. In addition, conceptual understanding may be utilized to assume the future set of health issues to establish a reflective public health event, plan major aims, and employ the possible availability and its connected resources at major levels (Rios et al., 2000).

The demographic detail of the patients includes age, gender, weight (kg), height (cm), and body mass index. Janmeja et al. reported that the majority of the subjects were young adults (mean age, 31.79 ± 11.13 years) (Janmeja et al., 2005). Another study done in Maulana Azad Medical College, New Delhi reported that the mean value of a subject in the study was found to be 35.30 ± 12. 00 years (Sharma et al., 2010). Consequently, global TB disease occurrence was higher in men compared with women. One probable clarification for such male predominance may be that men are more engaged in social and labor activities compared with women in most of the countries, therefore promoting disease transmission. Furthermore, previous reports also suggest that TB stimuli initiate different responses between men and women. Barriers to primarily TB detection and its treatment may be greater in women compared with men (Holmes et al., 1998). Another implication done by Sharma et al. revealed that TB prevalence was more in males compared with females (Sharma et al., 2007). This is because males have major risk factors including smoking, alcoholism, and drug addiction (Leung et al., 2004; Lonroth et al., 2008). Smoking is also included as a maximum risk factor for TB in 32.8% and 8.6% males and females, respectively (Leung et al., 2004).

This study has shown that the maximum number of male patients had a great experience with adverse events related to the consecutive age distribution (20–29 years old). The lowest percentage of such adverse events were seen in patients < 15 years old. Following the study conducted by Sharma et al., TB has been extensively prevalent in the productive age group (Sharma et al., 2010). Also, the effects of the disease have been perceived by their children and families. Additionally, infection-mediated TB progression may be more rapid in the reproductive age of women compared with men of similar age (Murray, 1991). Nonetheless, authorities in public health quantified the male–female ratio as 2:1 and correlated it with the notable number of TB cases. Most of the TB patients were from the low-income population. In the present study, TB was observed to a great extent in patients who finished high school, intermediate school, and primary school. Moreover, the prevalence of TB was found to be minimum in professional/PG and higher. The highest percentage of adverse events were reported in patients educated up to high school, inter- or post-high school diploma, primary school, illiterate, and graduates. Conversely, the lowest percentage of adverse events were reported in patients educated up to professional/PG and higher. Similar findings were reported in a study conducted by Pandit and Choudhary where 50% of the patients were educated up to primary school and 23% were illiterate (Pandit and Choudhary, 2006). A survey has reported that educated patients have more concepts of TB and have less chance to acquire the disease, and males have a higher probability of acquiring TB infection. This may be due to the exposure of

Table 7
Incidences of ADR in TB According to Socioeconomic Status.

S. No.	Socioeconomic Class	TB Patients		ADRs	
		Number	Percent	Number	Incidence
1	Lower	12	01.19	4	0.49
2	Lower Middle	712	70.43	80	7.91
3	Middle	231	22.84	15	1.48
4	Upper Middle	56	05.54	3	0.30
5	Upper	0	00.00	00	00
	Total	**1,011**	**100**	**102**	**10.09**

Table 8
Incidences of ADR in TB Patients According to Education Status.

S. No.	Education Status	TB Patients		ADRs	
		Number	Percent	Number	Incidence
1	Professional/PG and higher	28	2.76	2	0.20
2	Graduate	75	7.42	11	1.09
3	Inter- or Post-High School Diploma	187	18.50	12	1.19
4	High School	404	39.96	41	4.06
5	Primary School	178	17.61	20	1.98
6	Illiterate	139	13.75	16	1.58
	Total	**1,011**	**100**	**102**	**10.09**

males at their work locations compared with females. In contrast, lower figures for such observations have been reported in earlier studies conducted in Delhi (Malhotra et al., 2002; Singh et al., 2002). Furthermore, a study has shown that US high school students have shown a variation in infection ubiquity. This is due to the education level of their parents and housing characteristics. Thus, developed countries have a lower prevalence and occurrence of TB, thereby reducing the concern of the general population in developed nations (Singh et al., 2002). Furthermore, many of the TB patients belonged to the low-income population. In the present study, the rate of adverse events was reported to be high (59.54%) in poor or low-income range (i.e., ₹2,041–6,100) patients followed by the range of income at ₹6,101–10,160 and ₹10,160–15,820. A study revealed that 42% and 55% were from low-income and middle-income groups, respectively (Janmeja et al., 2005). Of the 209 patients, 113 and 55 patients were semiskilled and unskilled workers, respectively, belonging to the income range of 2,041–6,100. Of the 93 (26.50%) patients, 44, 20, and 11 who showed adverse events were semiskilled workers, skilled workers, and unemployed, respectively. They belonged to the income range of 6,101–10,160. Consequently, the patients were classified according to their profession into two groups (unskilled and skilled profession), and it was reported that tuberculosis was more prevalent in unskilled professionals than skilled professionals (Chadha and Bhagi, 2000).

In the current study, the prevalence of the observed adverse events was shown to be maximum in semiskilled workers, and further events were displayed in the unskilled and skilled working groups. The highest levels of the percentage of adverse events were in patients educated in high school and primary school. It was corroborated that TB infections were quite high in laborers. The study conducted by Chadha and Bhagi (Chadha and Bhagi, 2000) classified the patients according to their education into three groups (illiterate, school educated, and college-educated). It also showed that TB was more frequent in school-educated and in illiterate and college-educated patients (Chadha and Bhagi, 2000). Of the 351 patients from the unskilled working group, 71 (20.23%) showed adverse events. Among the 71 patients, 25, 24, and 19 were educated up to high school, illiterate, and primary school or literate, respectively. TB as a disease state has been recorded to be maximum in the low- and middle-class socioeconomic status. Of all the 1,011 patients, 712 (70.43%) and 231 belonged to the lower middle-class and middle-class socioeconomic status (Chadha and Bhagi, 2000). Additionally, 82% of TB patients belonged to low socioeconomic status. In all the socioeconomic class, the highest percentage of adverse events were observed in the low- and middle-class socioeconomic status. Of the 1,011 patients registered for this study, 78.04% and 21.96% were enrolled as new cases (treated with DOTS therapy for the first time) and retreated patients (treated with DOTS therapy for the second time or more), respectively. The retreatment is due to relapse, default, and others. In all new cases (i.e., 789 patients), 40.68%, 15.08%, and 44.23% of the patients were considered as new positive cases, negative cases, and new extrapulmonary patients, respectively. In all retreated cases (i.e., 222 patients), 18.91%, 6.31%, and 37.84% of the patients were relapsed positive, failure positive, and default positive, respectively. Also, 36.94% were other category II patients.

The expected cure rate is < 85% according to RNTCP guidelines. Moreover, a study has reported that the cure rate was 91% and 73.3% in categories I and II patients, respectively. Such supporting investigations were also shown in the study by Arora et al. (Arora et al., 2003), Gaur et al. (Gaur et al., 2004), Filho et al. (Filho et al., 2007), and Pardeshi and Deshmukh (Pardeshi and Deshmukh, 2007). The expected mortality rate must be < 5% as provided in the RNTCP guideline. Inclusively, mortality was 0.89% from the new cases and is considered as significantly lower than the expected rate following the RNTCP guidelines (Central, 2009).

A declined rate was observed as slightly higher than the expected rate in new pulmonary positive patients. Nevertheless, the complete rate was found to be significantly diminished compared with the expected failure rate in new pulmonary TB and new extrapulmonary TB patients as well (Central, 2009). The default rate must be < 5% following the RNTCP guidelines. In new positive, negative, and extrapulmonary cases, the default rate was observed as 2.49%, 6.72%, and 2.01%, respectively. Consequently, the complete rate was observed at 2.92%.

A study from Delhi reported the treatment success rates at 91.0% and 73.0% in categories I and II patients, respectively (Chadha and Bhagi, 2000). Other studies also showed the same successive treatment in Mumbai by Yatin et al. (Yatin et al., 2000), Lucknow by Prasad et al. (Prasad et al., 2008), Bangladesh by Kumareson et al. (Kumareson et al., 1998), Delhi by Gaur et al. (Gaur et al., 2004); and Karnataka by Jagota et al. (Jagota et al., 1998). However, a study from Bangalore by Sophia et al. (Sophia et al., 2004) reported a treatment success of 67.9% in category I patients, which was likely due to the high default rate. Compliance in TB treatment is very important. Noncompliance leads to resistance provoked by the drug, which is more challenging to target because compounds or drugs are highly intolerable, the onset of treatment is not enough, and drugs are very expensive. The overall compliance aimed in the current investigation is an excellent fit and followed WHO guidelines. The WHO also recommends at least an 85% curative rate in all diagnosed TB cases. In the context of the curative rate, compliance should be in the range of 85%–90% (Murray, 1991). Similar findings were reported by Mweemba et al. in an earlier study conducted in Zambia (Mweemba et al., 2008). Another investigation reported that DOT compliance was found to be significant at a high rate in those having sound concepts on the several facets of the disease (Pandit and Choudhary, 2006). Consequently, a limited number of investigations also depicted similar factors including age, gender, work, and education. However, the correlated treatment was not displayed (Gad et al., 1997). Furthermore, Johansson et al. (Tekle et al., 2002) reported that the patient's economic situation is a prominent determinant of both compliance and noncompliance. DOT compliance was significantly high in those who have sound concepts of

health education in each aspect of the disease. Similar observations were also documented by other authors as well (Gad et al., 1997; Tekle et al., 2002; O'Boyle et al., 2002; Thomas, 2002). Several reasons were given why the patients fail to administer their medications. TB symptoms commonly conclude within 7 days before initiating TB treatment and several patients then capitulate motivation to further supplement their medication. Continuous follow-up is a key step to determine compliance and for the patients to demonstrate any developed adverse event with drug therapy. Patients need to be advised of the possible relevance of obtaining tablets at regular intervals and the importance of full treatment due to the risk of developing drug resistance. Any unwanted reaction possible due to drug therapy is called ADR. The maximum number of TB patients belonged to the low middle class and middle-class socioeconomic status, thereby contributing to the high number of ADRs. Of the 712 (70.43%) TB patients, 80 (7.91%) experienced ADRs in the lower middle-class socioeconomic status. Conversely, of the 231 (22.84%) TB patients, only 15 (1.48%) experienced ADRs in the middle-class socioeconomic status. Moreover, patients from the upper-class socioeconomic status also reported ADRs. The probability trends of ADRs decreases as socioeconomic status advances and which is especially visualized in TB patients. In the current study, TB was found to increase in patients educated up to high school, intermediate school, and primary school. Of the 1,011 TB patients, 404, 187, 178, 139, 75, and 28 patients have education up to high school, inter- or post-high school diploma, primary school, illiterate, graduate, and professional/PG and higher, respectively. Of the 404 TB patients educated up to high school, only 41 patients experienced ADRs. Conversely, of the 187 TB patients with education up to inter- or post-high school diploma, only 12 patients showed ADRs.

5. Conclusions

The possible occurrence of TB events was observed at high-extent patients whose education was up to high school. They also took part in the maximum percentage of adverse events. Moreover, such events were higher in low- compared with high-income patients. The incidence of adverse events was also reported at a higher rate in semiskilled compared with skilled workers. Furthermore, adverse events showed more proximity in patients from the lower socioeconomic class. The prevalence of ADRs with DOT therapy was quite lower. However, a serious issue in India concerns the overburden of TB at a national level. Therefore, regulating or modulating the possible ADRs, especially in patients at risk, as an integral core for good clinical practice and must be carried out at routine levels.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

The authors extend their appreciation to the Deanship of Scientific Research at King Saud University for funding this work through research group No (RG -1439-019)

Funding

The present study was funded by the Deanship of Scientific Research, King Saud University, Riyadh, Saudi Arabia, through the research group project (Research Group No: RG-1439-019).

Ethical approval

Ethical approval was obtained from the Human Research Ethics Committee, LRS Institute of Tuberculosis and Respiratory Diseases, with reference AMS/EC/2008/12038.

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