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Outcome and Determinants of Directly observed Short-Course Treatment for Tuberculosis Patients

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ABSTRACT

Background: The Directly Observed Treatment Short Course (DOTS) is a well-established and cost-effective strategy for treating Tuberculosis. It efficiently transforms infectious cases into non-infectious ones, effectively interrupting the transmission cycle of the disease. **Objectives:** Measure the treatment outcomes in TB patients during 2016-2020, describe the socio-demographic and clinical profile of TB patients and evaluate the performance of the National TB program in Babil governorate based on WHO indicators. **Methods:** A descriptive cross-sectional study was done. All TB patients in the NTP Center of Babil governorate under the DOTS program from 2016 to 2020 were included. A form was developed to compile socio-demographic data, clinical presentation, and treatment outcomes. **Results:** A total number of cases was 1723. The mean age was 40.0 (± 21.0) years. The female constituted 53.8% of cases. The patients aged ≥ 65 years had the highest percentage of total cases 279 (16.2%). Pulmonary tuberculosis (PTB) constituted 56.1% of the cases 50.5% of them had smear-positive. The most common site for extrapulmonary tuberculosis (EPTB) was lymph nodes 41.1%. Treatment success was attained in 93.7%, while 3.3% of patients dead. The patients aged ≥ 65 years have the lowest success rate and highest treatment unsuccess rate opposite to young age groups (p 0.002). **Conclusion:** The treatment outcome target planned by WHO was achieved. The case detection rate of all form was low. The age and the site of TB significantly affected the outcome of treatment.

Keywords: DOTS, TB, treatment, outcome, Babylon.

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INTRODUCTION

It is estimated that about a quarter of the world's population, roughly 1.7 billion people, were infected with latent tuberculosis (LTBI), but only 5%–10% develop the disease, with an estimated ten million people falling ill with TB worldwide in 2019. Tuberculosis (TB) remains a significant global health concern. According to data from 2019, TB was among the top 10 causes of death worldwide, leading to approximately 1.4 million fatalities. It underscores the importance of continued efforts in prevention, diagnosis, and treatment of TB (Chakaya et al., 2021; Suleman & Rahman, 2020; Suleman & Mohamed, 2019).

The World Health Organization (WHO) announced TB as a global emergency in 1994 and subsequently Directly observed short treatment course (DOTS) was globally recommended by the WHO as the strategy for control of TB, ensures the cure and decrease the number of deaths due to TB. It's also reduced of the prevalence of TB by reducing the pool of infectious cases and curtailing the disease transmission (Lange et al., 2018; Suleman et al., 2023; Suleman et al., 2021; Suleman, Mohamed & Ahmmed, 2020)

The strategy that the Iraqi NTP has followed over the years 1998-2005 is expanded during the period 2006-2015 to the strategy of stop TB and then to the strategy of end TB since 2016. The Iraq depends on the globally accepted indicators for evaluating the performance of NTP which are; case detection rate (CDR) ≥ 70% treatment outcome indicators as (treatment success rate ≥ 89%, case fatality rate ≤ 5%, treatment failure ≤ 5%, Defaulter rate ≤ 1%), and other indicators (Iraq Ministry of Health, 2015)

The assessment of TB treatment outcomes is a pivotal metric for evaluating the effectiveness of a National TB program. It serves as a crucial method in TB control efforts, offering valuable insights to refine and enhance TB control strategies and programs in a given region. This study was undertaken with the intent of shedding light on treatment outcomes and providing valuable input towards the improvement of TB control measures in the study area. The findings from this research are likely to inform targeted interventions and policy decisions to further strengthen the management of tuberculosis in the region.

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METHODOLOGY

A descriptive cross-sectional study. the study was done in the National TB Center of Babil governorate / Iraq, which is called Chest and Respiratory Diseases Consultation Clinic (CRD-CC)) during the period from 1st April to 1st August 2021.

The NTP in Babylon governorate was based on five TB management units called Chest and Respiratory Diseases Units (CRD-Us), one in each district. These units are under supervision of chest and respiratory diseases consultation clinic (CRD-CC) which is a specialized center in the field of the national program to control TB and managing some other respiratory diseases. The facility is equipped with essential departments including a laboratory, radiology unit, and pharmacy unit. Its primary function is to dispense anti-TB medications, demonstrating a focused commitment to tuberculosis diagnosis and treatment. This setup ensures comprehensive care for individuals affected by TB, covering diagnostic, imaging, and pharmaceutical needs within the facility. More than 110 primary health care centers are responsible for patient care, follow up and giving them free charge anti-TB treatment.

All TB patients under DOTS program in the NTP of Babil governorate from 2016 to 2020 were involved in the study. The data was obtained using a data collection questionnaire form adopted after a review of similar articles. The collected data were organized and arranged categorically. The data were presented in the form of tables. Descriptive statistics were determined, using frequencies and percentages. Including estimated TB incidence rates for the years 2016–2020. Also determined the rate of smear-positive and negative, and percentage of clinical features of the patients.

The comparison of PTB and EPTB patients was done by gender and age group. The statistical association for the outcome of TB and gender, age groups, and site of TB was examined in the chi-square test. The Microsoft Excel software 2016 and statistical package for the social sciences SPSS (version 23) were used for both data entry and statistical analysis. The p-value <0.05 was considered statistically significant.

The study underwent a proposal process and was subsequently granted approval by the scientific committee of the College of Medicine at the University of Baghdad. Additionally, it received endorsement from the Babylon Health Directorate under the Iraqi Ministry of Health.

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This formal approval underscores the credibility and ethical adherence of the study, Verbal contest was taken from each patient.

RESULTS

Table 1: *The total TB cases (notified), notification rate and case detection rate in Babylon Governorate over 2016-2020 (N=1723)*

Variable		years				
		2016	**2017**	**2018**	**2019**	**2020**
Population		1953184	1958230	1971265	2038296	2065042
Total TB cases in districts	Hilla-1	81	70	67	65	42
	Hilla-2	108	74	62	65	44
	Mussaib	93	102	64	62	42
	Mahaweel	86	48	57	50	23
	Hashemia	97	88	76	91	66
Total TB cases (notified)		465	382	326	333	217
Notification rate/10^5/year		24	20	17	16	11
Estimation rate /10^5/year (by WHO)		43	43	42	41	41
Case detection rate (% of all form)		55%	47%	40%	39%	27%

This table shows that the total number of TB cases (notified) was decline during the study year in all districts.

Table 2: *Socio-demographic distribution of TB cases in Babil governorate over 2016-2020*

characteristics		Notification number of all cases (new and relapse)					
		2016	2017	2018	2019	2020	Total
Gender	Male	209 (44.9%)	201 (52.6%)	150 (46 %)	135 (40.5%)	101 (46.5%)	796 (46.2%)
	Female	256 (55.1%)	181 (47.4%)	176 (54%)	198 (59.5%)	116 (53.5%)	927 (53.8%)
Age group	1-14	46 (9.9%)	34 (8.9%)	39 (12%)	48 (14.4%)	30 `13.8%)	197 (11.4%)

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	15-24	57 (12.3%)	62 (16.2%)	53 (16.3%)	46 (13.8%)	45 (20.7%)	263 (15.3%)
	25-34	76 (16.3%)	57 (14.9%)	56 (17.2%)	50 (15.0%)	26 (12.0%)	265 (15.4%)
	35-44	65 (14.2%)	59 (15.4%)	57 (17.5%)	58 (17.4%)	25 (11.5%)	264 (15.3%)
	45-54	66 (14.2%)	62 (16.2%)	38 (11.7%)	36 (10.8%)	31 (14.3%)	233 (13.5%)
	55-64	65 (14.0%)	46 (12.0%)	37 (11.3%)	49 (14.7%)	25 (11.5%)	222 (12.9%)
	≥65	90 19.4%	62 (16.2%)	46 (14.1%)	46 (13.8%)	35 (16.1%)	279 (16.2%)

This table showed that the total number of cases was 1723; 927 (53.8%) were female. The age group was ≥ 65 years had the highest percent of TB cases, 279 (16.2%)

Table 3: *Distribution of TB cases according to the anatomical site of occurrence of disease*

Tuberculosis site		Notification number of all cases (new and relapse)					
		2016	2017	2018	2019	2020	Total
Pulmonary TB (PTB)		320 (68.8%)	238 (62.3%)	160 (49.1%)	151 (45.3%)	98 45.1%)	967 (56.1%)
	pulmonary (smear -ve)	178 (55.6%)	121 (50.8%)	73 (45.6%)	62 (41.1%)	45 (45.9%)	479 (49.5%)
	pulmonary (smear +ve)	142 (44.4%)	(117 (49.2%)	87 (54.4%)	89 (58.9%)	53 (54.1%)	488 (50.5%)
Extra-Pulmonary TB (EPTB)		145 (31.2%)	144 (37.7%)	166 (50.9%)	182 (54.7%)	119 (54.8%)	756 (43.9%)
Extra pulmonary TB	Lymph nodes	60 (41.3%)	57 (39.6%)	69 (41.6)	79 (43.4)	46 (38.7)	311 (41.1%)
	Bone and Joint	17 (11.7%)	29 (20.1%)	28 (16.9%)	24 (13.2%)	26 (21.8%)	124 (16.4%)
	Pleura	26 (17.9%)	16 (11.1%)	25 (15.1%)	29 (15.9%)	19 (16.0%)	115 (15.2%)
	Gastro intestinal tract	13 (9.0%)	10 (6.9%)	14 (8.4%)	14 (7.7%)	4 (3.4%)	55 (7.3%)
	Meninges	11 (7.6%)	11 (6.7%)	7 (4.2%)	7 (3.8%)	6 (5.0%)	42 (5.6%)
	Skin	4 (2.8%)	1 (0.7%)	10 (6.0%)	6 (3.3%)	4 (3.4%)	25 (3.3%)
	Genito urinary tract	1 (0.7%)	3 (2.1%)	4 (2.4%)	5 (2.7%)	2 (1.7%)	15 (2.0%)
	Pericardium	4	3	1	2	2	12

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		(2.8%)	(2.1%)	(0.6%)	(1.1%)	(1.7%)	(1.6%)
	Others	9 (6.2%)	14 (9.7%)	8 (4.8%)	16 (8.8%)	10 (8.4%)	57 (7.5%)

The table above showed that there is an increased frequency of EPTB 756 (43.9%) while Pulmonary tuberculosis (PTB) constituted 967 (56.1%) of the cases, 50.5% of them had smear-positive. the most common site for extrapulmonary tuberculosis (EPTB) was lymph nodes 41.1%, followed by Osteoarticular TB 124 (16.4%)

Table 4: *Distribution of TB cases according to the gender, age group, and seasonal occurrence with site of disease.*

characteristic	variable	PTB N.	PTB .%	EPTB N.	EPTB %	P-value
Gender	Male	488	61.3	308	38.7	<0.001
	Female	479	51.7	448	48.3	
Age group	1-14	49	24.9	148	75.1	<0.001
	15-24	156	59.3	107	40.7	
	25-34	144	54.3	121	45.7	
	35-44	141	53.4	123	46.6	
	45-54	149	63.9	84	36.1	
	55-64	134	60.4	88	39.6	
	≥65	194	69.5	85	30.5	

The table above showed that the PTB cases constituted 61.3% of male cases compared to 51.7% of female cases, while EPTB constituted 48.2% of female cases compared to 38.7% of male cases ($p \leqslant 0.001$). The age group 1-14 years had the highest percent of EPTB 75.1%, while the age group ⩾ 65years had highest percent of PTB 69.5% (p =<0.001).

Table 5: *Treatment outcome of TB patients under DOTS over 2016-2020*

Outcomes		Year 2016	2017	2018	2019	2020	Total
Treatment success		437 94.0%	364 95.2%	310 95.1%	314 94.3%	190 87.6%	1616 93.7%
	Cured	132 28.4%	107 28.0%	78 23.9%	81 24.3%	44 20.3%	442 25.6%

DOI: 10.48165/sajssh.2023.4604

	Treatment completed	305 65.6%	257 67.2%	232 71.2%	233 70.0%	146 67.3%	1173 68.1%
Treatment un success 74 (4.3%)	Death	17 3.7%	12 3.1%	10 3.1%	8 2.4%	9 4.1%	56 3.3%
	Failure	4 0.9%	0.0	0.0	2 0.6%	1 0.5%	7 0.4%
	Lost to follow up	3 0.6%	3 0.8%	2 0.6%	2 0.6%	1 0.5%	11 0.6%
Others (unknown) 34 (1.9%)	Transfer out	4 0.9%	3 0.8%	4 1.2%	7 2.1%	0.0	18 1.0%
	Incomplete treatment	0.0	0.0	0.0	0.0	16 7.4%	16 0.9%

The table showed that the treatment success (cured and treatment completed) was achieved in 1615 (93.7%) patients, 56 (3.3%) patients dead. treatment failure 7 (0.4%), transfer out 18 (1.0%), Lost to follow up 11 (0.6%), and treatment incomplete in 16 (0.9%) patients.

Table 6: *Distribution of TB cases according to gender, age group with the outcome of the disease*

characteristics		Treatment outcome						P-value
		Treatment success N.	%	Unsuccess (death, failure, defaulter) N.	%	Others N.	%	
Gender	Male	740	92.7	37	4.6	19	2.4	0.405
	Female	875	94.3	37	4.0	15	1.6	
Age group	1-14	189	95.9	7	3.6	1	0.5	0.002
	15-24	256	97.3	6	2.9	1	0.4	
	25-34	253	95.5	5	1.9	7	2.6	
	35-44	252	95.1	9	3.4	4	1.5	
	45-54	212	91.4	13	5.6	6	2.6	
	55-64	206	92.8	10	4.5	6	2.7	
	≥65	246	88.2	24	8.6	9	4.1	
TB site	PTB	904	93.5	53	5.5	10	1.0	< 0.001
	EPTB	711	94.0	21	2.7	24	3.2	

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This table showed that the distribution of TB cases according to gender, age group, and TB site with the outcome of the disease. The age groups ≥ 65 have the lowest success rate and highest treatment unsuccess rate (p 0.002). Also, patients with PTB have a higher treatment unsuccess rate compared to EPTB (p<0.001), and there was no significant association in the outcome of TB and gender.

DISCUSSION

The incidence rate of TB in Iraq which it's estimated by WHO was declined from 43/105 in 2016 to 41/105 in 2020. It is still higher than that of neighboring countries, as Turkey (16/105), Iran (13/105), Saudi Arabia (10/105) and Jordan (6/105) (Merza, 2020); this decline in incidence rate is not occurring quickly enough to reach to the End TB Strategy targets in contrast to that the WHO reported in 2017 the European regions have experienced the largest declines in TB incidence, 19% since 2015 (Sotgiu et al., 2017; Guha & Kumari, 2023).

The current study in table 1 showed that there is a gradual decrease in total TB cases (notified cases) from 465 (24/105) in 2016 to 217 (11/105) in 2020 with an average of 18/105 that led to decrease in case detection rate (CDR) lower than WHO target which is 70% and these results were observed in all districts.

There has been progress in reducing the global incidence rate of Tuberculosis (TB), it's not happening at a pace rapid enough to achieve the 20% reduction target set for the period between 2015 and 2020. This highlights the ongoing challenges in TB control efforts and emphasizes the need for continued, concerted action to further decrease TB incidence rates. including a reduction of 2.3% between 2018 and 2019 (Fukunaga et al., 2021; Roy & Jose, 2023)

The decrease in TB cases may be due to funding and security instability and displacement of the population. The improvement in the economic state of the Iraqi people after 2003 may play a role in the improvement in the immunity of society and give them more protection from TB. Also, census accuracy was an important factor affected directly since no real census in Iraqi. The Severe declined in notified cases in 2020 may be attributed to the COVID-19 pandemic, which leads to the concentrate of pandemics and neglect of other diseases.

Females were dominant in TB cases as stated in table 2. This agrees with a study in Bane (Kurdistan) revealed the women had a high percent 58.5 to 41.5 for males (44). The contrast was

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in Iraq in 2016, WHO report about Iraq showed that 58.5% of TB cases were male and 41.5% were female another study in Pakistan revealed that the males were predominant (Kurdstan, 2017; Kadim et al., 2021).

According to the World Health Organization (WHO), the global diagnosis rates for TB show that nearly twice as many men have been diagnosed with TB compared to women. This gender disparity in TB diagnoses is an important consideration in understanding and addressing the impact of the disease (Feng et al., 2012). This might be attributed to increasing community awareness, a decrease of the social TB stigma, the demographic changes due to displacement during conflicts.

Patients aged ≥ 65 years constituted the largest group of cases as illustrated in table 2. In Singaporean, the study revealed that the majority of cases were observed in elderly patients aged 65 years and older, accounting for 31.9% of the total cases. This highlights the higher vulnerability of older individuals to the disease. (Muhsen et al., 2015) The contrast to that in Iraq, the study revealed the highest age group was (15-24) and (25-34) (Getahun et al., 2011) Also in Ethiopia, most patients were between 15 to 35 years and in Turkey, about 55% of patients age was between 21 to 40 years (Sunnetcioglu et al., 2015) This change might be due to social variation (demographic transition, conflicts, war) also before contracting TB in their early years, the geriatric population serves as the primary reservoir for TB infection. Factors such as compromised immunity, malnutrition, poverty, and limited access to healthcare services contribute to this vulnerability in older individuals. This underscores the importance of targeted efforts to address TB in this demographic., and an increased in comorbid illness especially DM in old age have all been linked to a higher risk of tuberculosis in the elderly (Jappar and Low., 2015)

The findings in table 3 show that the rate of EPTB was around half in study sample. Its higher than target which is (25-30%) from all TB cases) The rate of EPTB patients in Turkey is estimated as 39-45.1% [(11)] Another study in China During 2008–2017 in Beijing Chest Hospital revealed that There was a notable rise in the proportion of extrapulmonary TB cases, increasing from 29.8% to 31.4%. This shift highlights a growing significance of cases outside the lungs, underlining the importance of comprehensive diagnostic and treatment approaches for both pulmonary and extrapulmonary TB. (Pang et al., 2008)

The current study in table 3 revealed that, more than half of the patients presented with pulmonary TB >56%, about half of them had smear positive. The same results were obtained in another study

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in Ethiopia, while the study in Iraq showed that the number of pulmonary TB was as twice as the extra pulmonary TB and about two-thirds of them had smear-positive.

The proportion of PTB to EPTB varies according to geographical, social, ethnic, and economic parameters. On the other hand, several cases of EPTB and smear-negative PTB had no cultured confirmed and diagnosed based on clinical ground.

Lymph nodes were the most common site for extrapulmonary TB, the same results were obtained by other studies in Turkey, and the same results were obtained in China [13] While in Korea, pleura was the commonest site followed by lymph nodes (Lee, 2015).

In the current study table 4 displayed that there was a decrease in the percent of EPTP with age opposite to PTB. This might be Extrapulmonary tuberculosis (EPTB) is linked with immune suppression, which makes it more prevalent in children. This susceptibility arises from the fact that children have not yet fully developed their immune systems, rendering them more vulnerable to various infections, including EPTB. In contrast to that were observed in another study in China and excuse that trend by the dynamic immunological changes during aging as the Previous research has shown that there is a functional decline in monocytes and macrophages as individuals age. However, the production of proinflammatory cytokines by mononuclear cells in older individuals tends to be higher compared to younger individuals. This indicates that there are significant age-related changes in the immune system's responses and functions.

A significant association was observed in the current study in table 4 and 6 between the gender and site of TB, males had the highest percent of PTB comparing to females which had the highest percent of EPTB. The same results were obtained by another study in the United States (Qian et al., 2018). This gender effect is thought to be related to many factors, such as sex hormones, genetic factors, and nutritional status, and contact during work play roles in this disparity (Lin et al., 2013).

An important finding of the current study in table 5 and 6 was that the target of treatment outcome is within WHO targets. in Iraq In 2018, the WHO country profile re-ported a higher treatment success rate (93%) in comparison to the rates of neighboring countries reportedly, 89%, 87%, 86%, in Jordan, Turkey, and Iran. In Ethiopia, recent study reported a success rate of 88.2% and death by 4.8%, and treatment failure by 0.5%, and defaulter by 6.6%, in comparison with the current study (Abebe et al., 2019).

DOI: 10.48165/sajssh.2023.4604

The treatment success rate was optimal give an impression of patient's adherence to the instructions of the program and good follow up by health care providers to succeed in the treatment of patients in addition to free access to tuberculosis medication.

There was no significant association between the gender and outcome of the treatment, as within that in Ethiopia (Tesema et al., 2020). It is in contrast with that in Taiwan

The current study revealed that the age group was significantly associated with treatment outcomes. The younger patients had the highest percentage of treatment success and a low percent of treatment unsuccess rate, opposite to the old age group. In comparison, another study revealed that treatment success rates for all forms of tuberculosis decrease. Children had the highest treatment success rate, while the elderly had the lowest. The mortality rate was 4% for children, but significantly higher at 25% for the elderly.

This underscores the importance of tailored and vigilant healthcare strategies, particularly for the older population, in effectively managing tuberculosis. Treatment outcomes in older individuals may be influenced by a range of factors. These individuals often contend with concurrent chronic conditions, a natural decline in physiological functions due to aging, and may face challenges in accessing healthcare facilities and increase co-infection with other diseases, which could lead to a poorer treatment outcome. (Ncube et al., 2017)

The current study in table 5 revealed that the site of TB was significantly associated with treatment success. The highest percent of treatment success occurs in EPTB patients. In Ethiopia, the treatment success rates were 89.2%, 83.3% and 81.9% among PTB+, PTB- and EPTB patients, respectively (Gebrezgabiher et al., 2016), This agreed with another study which revealed that the highest percentage of successful treatment was among PTB (Obaid et al., 2023).

This discrepancy may be related to other affecting factors like age and underlying conditions. The BCG is currently the only licensed vaccine against TB which can reduced the incidence rate (Al Sa'ady et al., 2022).

LIMITATIONS

The primary limitation of this study is the absence of crucial patient data, including details about education, occupation, smoking history, nutritional status, family medical history, presence of

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underlying chronic diseases, and other sociocultural factors. These unrecorded variables could potentially have an impact on the treatment outcome, and their omission from the registry hinders a comprehensive understanding of the study's findings.

CONCLUSION

The treatment outcome target planned by WHO was achieved. The case detection rate (% of all form) was lower than target. The age and the site of TB significantly affected the outcome of treatment. The age and the gender significantly affected the site of TB.

RECOMMENDATIONS

1. Promotion of outreach TB screening and awareness campaigns to detect the active TB cases.
2. Organizing TB diagnostic clinic nearer high-risk regions especially poor marginalized regions may increase TB case detection in setting where prevalence of undiagnosed disease is high
3 Engagement of Private sectors in National TB program may help in detection of more TB cases
4 Further epidemiological studies about TB should be carried out by academic institutions in the upcoming years to obtain more details about the DOTS program in another governorate.

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