

Assessment of Directly Observed Therapy Short Course (DOTs) Program Therapy in Treatment of Tuberculosis in Al-Sader City 2003-2005

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المستخلص:

الهدف: تقييم اداء برنامج العلاج القصير الامد تحت الاشراف المباشر المعد من قبل منظمة الصحة العالمية والمطبق في مدينة الصدر. **المنهجية:** ثلاثة مجاميع من مرضى التدرن الرئوي الذين يتابعون العلاج والمسجلين في معهد التدرن في بغداد ومركز التدرن في مدينة الصدر. شملت المجموعة الأولى 314 حالة لسنة 2003 والمجموعة الثانية 327 حالة لسنة 2004 والمجموعة الثالثة 321 حالة لسنة 2005. تم تحليل البيانات التي جمعت عن الحالات لغرض احتساب المعدلات الناتجة المعالجة للحالات الجديدة وحالات اعادة المعالجة، معدلات نجاح المعالجة ومعدلات نجاح اعادة المعالجة.

النتائج: أظهرت الدراسة بأن معدل كشف الحالات (73,36% ، 64,24% ، 71,49%) على التوالي في حين لاحظنا معدلات نتائج المعالجة للحالات الجديدة (71,7% شفاه ، 12,7% أتمام المعالجة ، 10,2% الانقطاع ، 3,5% فشل المعالجة ، 1% الوفاة ، 1% النقل) (71,7% ، 12,7% ، 10,2% ، 3,5% ، 1% ، 1%) ، (64,8% ، 19,9% ، 0,9% ، 7% ، 0,6% ، 6,7%) و (61,4% ، 24% ، 3,1% ، 5,9% ، 0,6% ، 5% respectively). معدلات نجاح المعالجة للحالات الجديدة (55,6% شفاه ، 7,9% أتمام المعالجة ، 6,6% الانقطاع ، 15,2% فشل المعالجة ، 4% الوفاة ، 10,6% النقل) (55,6% ، 7,9% ، 6,6% ، 15,2% ، 4% ، 10,6%) ، (44,9% ، 7,7% ، 2,6% ، 21,8% ، 4,5% ، 18,6%) و (41,8% ، 14,6% ، 11,4% ، 19,6% ، 1,9% ، 10,8% respectively). معدلات نجاح المعالجة (84,39% شفاه ، 84,7% أتمام المعالجة ، 85,35% الانقطاع) (84,39% ، 84,7% ، 85,35%) ، (63,57% ، 52,56% ، 56,32% respectively).

التوصيات: زيادة معدل اكتشاف الحالات من خلال زيادة الوعي الصحي للمجتمع حول طريقة انتقال وخطورة من مرض التدرن ، تكثيف تدريب الكوادر الصحية لكي يتمكنوا من متابعة المرضى في المنزل، زيادة متابعة المتعثرين لتكون قادرة على التعامل معها ويوصى دراسة لحالات الانتكاس.

Abstract:

Objectives: Assessment outcome of DOTs (Directly observed therapy short course) program in Al-Sader City Sector that was established by the WHO.

Methodology: Three cohorts groups of patients attending Baghdad TB institute and TB center in Al-Sader city were followed retrospectively. The 1st cohort included (314) patients registered in year (2003), the 2nd cohort included (327) patients registered in year (2004), the 3rd cohort included (321) patients registered in year (2005). The collected data were analyzed for case detection, treatment outcomes, retreatment outcomes, treatment success, and retreatment success in regard to time, age and sex.

Results: The following rates were extracted for the three cohort: Case detection rate within 1st, 2nd, and 3rd cohort were (73.36%, 64.24%, and 71.49% respectively). Treatment outcomes (cured, completed treatment, defaulters, treatment failure, died and transfer out) of new smear positive patients within the 1st, 2nd and 3rd cohort were (71.7%, 12.7%, 10.2%, 3.5%, 1%, 1%), (64.8%, 19.9%, 0.9%, 7%, 0.6%, 6.7%) and (61.4%, 24%, 3.1%, 5.9%, 0.6%, 5% respectively). Retreatment outcomes (cured, completed treatment, defaulters, treatment failure, died and transfer out) within 1st, 2nd and 3rd cohort were (55.6%, 7.9%, 6.6%, 15.2%, 4%, 10.6%), (44.9%, 7.7%, 2.6%, 21.8%, 4.5%, 18.6%) and (41.8%, 14.6%, 11.4%, 19.6%, 1.9%, 10.8% respectively). Treatment success rate within the 1st, 2nd and 3rd cohort were (84.39%, 84.7%, and 85.35%) respectively. Retreatment success rate within the 1st, 2nd and 3rd cohort was (63.57%, 52.56%, and 56.32%) respectively.

Recommendation : Increase case detection rate through increase health awareness to the community about the mode of transmission and risk of TB disease, Increase the training of health team so that they can follow up of patients at home, Increase follows up of defaulters to be able to deal with them and a study for relapses cases is recommended.

Key words: Tuberculosis, Directly Observed Therapy Short course (DOTs), Al-Sader City.

Introduction:

Tuberculosis is one of the top 10 causes of the global mortality and morbidity ^[1]. Tuberculosis is a bacterial disease caused by mycobacterium tuberculosis and occasionally by other species of mycobacterium tuberculosis complex that includes mycobacterium bovis, Mycobacterium africanum and mycobacterium canettii^[2]. Transmission occurs through airborne spread of infectious droplets. Sometime the disease transmitted by unpasteurized milk from infected animal but rarely^[3].

An individual's risk of infection depends on the extent of exposure to droplet nuclei and the susceptibility to infection. Mycobacterium tuberculosis causes annually about 10 million new of active tuberculosis^[4]. Three million deaths case yearly this mean 8250 death daily or 343 death/hr. Incidence rate of tuberculosis in Iraq has increased about 50 case positive yearly /100,000 person from population ^[5]. While incidence rate of TB in the Iraq expected from WHO in the year 2005 is the 167 case/100.000 person from population some of them 75 case positive smear sputum/100,000 person from population^[6]. TB can affect almost any part of the body but is mainly an infection of the lungs ^[7]. The disease characterized by night sweating, weight loss, fatigue, chest pain, hemoptemesis, cough with sputum at 2-3 weeks or more^[5] TB usually diagnosed by Chest X-ray. Sputum examination and culture, Tuberculin skin test chest CT. and biopsy^[8]. Once infected with M. tuberculosis a person remains infected for many years, probably for life the bacillus can remain dormant for many years. Under-normal circumstances only 10% of the infected persons will develop TB disease at some point in their life. When under nourishment and immune-suppressive condition, like (AIDS), or other disease sufficiently weaken the immune system, active TB disease may develop, under the natural course of progression of TB disease without treatment, 5 years after the onset of the disease, 50% of pulmonary TB patients will die as a result of the disease, 25% will be healthy, spontaneously cured by strong immune defense, and 25% will remain ill with chronic infectious TB^[9].

Treatment of pulmonary TB consist of an initial (intensive) phase lasting 2 months and a continuation phase usually lasting 4-6 months, and one year treatment of extra pulmonary TB. There are about 13 drugs act on TB bacilli in different manners, some are bactericidal, some are bacteriostatic and some of them have a sterilizing effect as well. But the essential and currently used drugs are, Rifampicin®, Pyrazinamide (Z), Streptomycin(S), Ethambutol (E), Isoniazide (H)^[10]. Tuberculosis program have failed to achieve control, because they have not cured enough patients particularly the infectious smear positive cases^[11]. Directly Observed Therapy Short course (DOTS), stated by WHO .Millions of TB deaths could be prevented through the widespread use of DOTS an inexpensive strategy for the detection and treatment of TB. The strategy can detect and cure TB even in the poorest countries ^[12]. The world health assembly adopted (DOTS) strategy for the control of TB and formulated global targets for the year 2000, namely to detect 70% of infectious new cases and to cure 85% of the detected infectious cases. It was documented in 1993 that DOTS is one of the most cost effective health interventions available and TB finally made a comeback in the global health agenda^[13]. The HIV/TB co-epidemic and the rise of multiple Drug Resistant – TB (MDR-TB) which is defined as, resistance to at least two of the most potent first – line anti-TB drugs, isoniazid (H) and rifampicin® many countries have now adopted the DOTS strategy . The 2003 WHO report shows that by the end of the year 2001. 155(74%) countries, out of a total of 210, were implementing DOTS. During the same period, 61% of the world's population lived in countries providing DOTS. DOTS program notified 2.4 million new cases, of which 1.2 million (50%) were smear-positive over 10 million patients have been diagnosed and treated in DOTS program since 1995^[14].

Methodology: This study is done in Baghdad governorate in Al-Sader city sector for the years (2003-2004-2005). Al-Sader city sector include 20 health centers for distribution the drugs to the tuberculosis patients. The data taken from archives of TB institute in Baghdad governorate (institute of respiratory and chest

disease) and TB center in Al-Sader city this institute and TB center in Al-Sader city contain information about people infected with tuberculosis disease. The archives include information about patients such as, name, age, sex, geographic area, laboratory diagnosis and result the treatment with DOTS programs. Three cohort of pulmonary TB patient were followed retrospectively. The first cohort included 314 patients attending The TB center in Al-Sader city in year 2003. The second

cohort included 327 patients attending TB center in Al-Sader city in year 2004. The third cohort included 321 patients attending TB center in Al-Sader city in year 2005. The collected data were analyzed for indicators of case.

Statistical analysis: doing by using (Chi-square and multiple Z-test) test of significant to found the differences between rates among different population.

Results:

Table 1. Distribution of pulmonary tuberculosis patients registered for DOTS program according to Age and Gender 1st cohort in 2003

Age groups(years)	Gender		Total
	Male	Female	
0 – 14	0 (0%)	2 (0.6%)	2 (0.6%)
15 – 24	52 (16.6 %)	14 (4.5%)	66 (21.1%)
25 – 34	50 (15.9%)	18 (5.7%)	68 (21.6%)
35 – 44	80 (25.5%)	42 (13.4%)	122 (38.9%)
45 – 54	14 (4.5%)	15 (4.8%)	29 (9.3%)
55 – 64	13 (4.1%)	12 (3.8%)	25 (7.9%)
≥ 65	1 (0.3%)	1 (0.3%)	2 (0.6%)
Total	210 (66.9%)	104 (33.1%)	314 (100%)

% = Percent

This table presents Shows the distribution of pulmonary TB patients registered for DOTS program according to age and Gender 1st cohort in 2003. from 314 patient ,210 were male and 104 were female ,the common age groups include in this study between 35-44 years old then 15 to 24 year old then ages from 25-34 years old and other age groups are less.

Table 2. Distribution of pulmonary tuberculosis patients registered for DOTS Program according to age and gender 2nd cohort in 2004

Age groups(years)	Gender		Total
	Male	Female	
0 – 14	7 (2.1%)	8 (2.4%)	15 (4.5%)
15 – 24	63 (19.3%)	40 (12.2%)	103 (31.5%)
25 – 34	80 (24.5%)	16 (4.9%)	96 (29.4%)
35 – 44	31 (9.5%)	14 (4.3%)	45 (13.8%)
45 – 54	19 (5.8%)	12 (3.7%)	31 (9.5%)
55 – 64	17 (5.2%)	6 (1.8%)	23 (7 %)
≥ 65	11 (3.4%)	3 (0.9%)	14 (4.3%)
Total	228 (69.8%)	99 (30.2%)	327 (100%)

% = Percent

This table shows Distribution of pulmonary TB patients registered for DOTS Program according to age and gender 2nd cohort in 2004 (show the common age group effected is between 25-34 years old then 15-24 years old then age group from 45-54 years old and other age groups are less.

Table 3. Distribution of pulmonary TB patients registered for DOTS program according to age and gender 3rd cohort in 2005

Age groups(years)	Gender		Total
	Male	Female	
0 – 14	3 (0.9%)	7 (2.2%)	10 (3.1%)
15 – 24	47 (14.6%)	47 (14.7%)	94 (29.3%)
25 – 34	75 (23.4%)	35 (10.9%)	110 (34.3%)
35 – 44	23 (7.2%)	13 (4 %)	36 (11.2%)
45 – 54	11 (3.4%)	16 (5 %)	27 (8.4%)
55 – 64	17 (5.3%)	10 (3.1%)	27 (8.4%)
≥ 65	7 (2.2%)	10 (3.1%)	17 (5.3%)
Total	183 (57%)	138 (43%)	321 (100%)

% = Percent

This table Show the distribution of pulmonary TB patients registered for DOTS program according to age and gender 3rd cohort in 2005 also show the common age group effected is between 25-34 years old then 15-24 years old then age group from 45-54 years old and other age groups are less.

Table 4. Case detection of new smear positive cases comparison between. 1st, 2nd and 3rd cohort

Follow up period	Total number of new pulmonary TB cases	New smear positive cases	Percent
1 st cohort Year 2003	428	314	73.36%
2 nd cohort Year 2004	509	327	64.24%
3 rd cohort Year 2005	449	321	71.49%

% = Percent

This table Case detection of new smear positive cases comparison between 1st, 2nd and 3rd cohort. Show total No. of. of new pulmonary TB cases and No. of new smear positive cases more in 2nd cohort Year 2004 then 3rd cohort Year 2005 then 3rd cohort Year 2005 then 1st cohort Year 2003

Table 5. Treatment outcomes of new smear positive patients Comparison between 1st, 2nd and 3rd cohort

Treatment outcomes	1 st cohort Year 2003		2 nd cohort Year 2004		3 rd cohort Year 2005	
	F	(%)	F	(%)	F	(%)
1- Cure	225	(71.7)	212	(64.8)	197	(61.4)
2- Completed treatment	40	(12.7)	65	(19.9)	77	(24)
3- Defaulter	32	(10.2)	3	(0.9)	10	(3.1)
4- Treatment failure	11	(3.5)	23	(7)	19	(5.9)
5- Died	3	(1)	2	(0.6)	2	(0.6)
6- Transfer out	3	(1)	22	(6.7)	16	(5)

F = Frequency; % = Percent

This table Treatment outcomes of new smear positive patients Comparison between 1st, 2nd and 3rd cohort.(show most patients cure in 1st, 2nd and 3rd cohort 72.7%

,64.8% ,and 62.4% respectively while Treatment failure are 3.5% ,7% and 5.9% respectively and died patients is 7 patients 3 in 1st cohort 2 patients in 2nd cohort and 2 patients in 3rd cohort

Table 6. Treatment outcomes of retreatment smear positive patient's comparison between 1st, 2nd and 3rd cohort

Treatment outcomes	1 st cohort Year 2003		2 nd cohort Year 2004		3 rd cohort Year 2005	
	F	(%)	F	(%)	F	(%)
1- Cure	84	(55.6)	70	(44.9)	66	(41.8)
2- Completed treatment	12	(7.9)	12	(7.7)	23	(14.6)
3- Defaulter	10	(6.6)	4	(2.6)	18	(11.4)
4- Treatment failure	23	(15.2)	34	(21.8)	31	(19.6)
5- Died	6	(4)	7	(4.5)	3	(1.9)
6- Transfer out	16	(10.6)	29	(18.6)	17	(10.8)

F = Frequency; % = Percent

This table Treatment outcomes of retreatment smear positive patients comparison between 1st, 2nd and 3rd cohort. (Cure patients 48, 70 and 66 patients respectively. While completed treatment 12, 12 and 23 patients respectively. Treatment failures were 23, 34 and 31 patients respectively. Died patients 6, 7 and 3 patients respectively).

Table 7. Treatment success of new smear positive Patients comparison between 1st, 2nd and 3rd cohort

Follow up period	Total number of new smear positive patients	Treatment success	
		F	%
1 st cohort Year 2003	314	265	84.39%
2 nd cohort Year 2004	327	277	84.7%
3 rd cohort Year 2005	321	274	85.35%

F = Frequency; % = Percent

This table obvious that the successful treatment among the 1st , 2nd and 3rd cohort number were 265 from 314 patients(84.39) , 277 from327 (84.7%) ,274 from 321(85.35%) respectively.

Table 8. Treatment success of retreatment smears positive patient's comparison between 1st, 2nd and 3rd cohort

Follow up period	Total number of new smear positive patients	Treatment success	
		F	%
1 st cohort Year 2003	151	96	63.57%
2 nd cohort Year 2004	156	82	52.56%
3 rd cohort Year 2005	158	89	56.32%

F = Frequency; % = Percent

This table presents Treatment success of retreatment smear positive patients comparison between 1st, 2nd and 3rd cohort. Show treatment success 63.57% in 1st

cohort, 52.56% in 2nd cohort and 56.32% in 3rd cohort while other patients are failure or not respond to treatments.

Table 9. Comparison of performance indicators with the world health organization targets and multiple Z-tests to detect significant difference between rates and world health organization targets

Performance indicators	1 st cohort year 2003	2 nd cohort year 2004	3 rd cohort year 2005	WHO global target	MZ-test (P-value)
Case detection rate	73.36%	64.24%	71.49%	70%	10.49045 P < 0.05
Treatment success rate	84.39%	84.7%	85.35%	85%	0.1214838 P > 0.05
Retreatment success rate	63.57%	52.56%	56.32%	85%	30.7383 P < 0.05

% = Percent; P= probability level

This table presents a comparison of performance indicators with the WHO target and MZ-test to detect significant difference between rates and WHO targets. Case detection rate and treatment success rate within the 2nd cohort were lower than the WHO targets. Retreatment success rate within the 1st, 2nd and 3rd cohort were lower than the WHO targets. The lowest difference between the 1st, 2nd and 3rd cohort was in treatment success rate (84.39%, 84.7% and 85.35% respectively). Case detection rate have significant difference with WHO targets at (P < 0.05). Treatment success rate similar to WHO targets non significant at (P > 0.05) while retreatment success rate have significant difference with WHO target.

Discussion:

This study shows that there is higher rate of infection among age group (15-24) years old and the age group (25-34) years old which is usual risky group for TB infection. The age group which is mentioned above more exposed to TB in developing countries and that age group is more infected in last 5 years in Iraq which indicates decrease control measure of TB disease^[15].

In this study it was found that the registered patients were more males than females it might due to, the male patients have most active phase of life (student, worker, farmers, etc.) rendering them at increase risk of exposure to open cases^[16].

While for female patient the percentage of detection of disease decrease because the disease form social obstacles to female in addition poor health awareness in community and that prevent females from receiving treatment from PHC centers^[6].

This study shows that case detection rate within the 1st cohort exceeds that within the 2nd and 3rd cohort, 1st and 3rd cohort exceeds WHO targets (70%).

While 2nd cohort were lower than WHO targets and other EMRO countries like: Kuwait, Morocco and Djibouti (91.4%, 93.9%, and 90% respectively)^[17]. Treatment outcomes for the three cohort with regard to the following indicators (cured).Completed treatment and treatment failure. The achieved cure rate within the 1st, 2nd and 3rd cohort are evidently lower than those of many EMRO countries like Jordan and Oman and many global countries like China, Cambodia and Bangladesh (90.1%, 90%, 94%, 89% and 85.3% respectively)[18,19].

In three cohorts was (1%, 0.6% and 0.6%) of smear positive who received short course therapy died during treatment. This result was comparable with other result a death rate of 9.4% was recorded Uganda DOTS in 1996 and 7% death rate in Morocco in 1996^[17].

About (3.5%, 7% and 5.9%) of all smear positive pulmonary TB cases were failed to be treated in the 1st, 2nd and 3rd cohort, which was higher than that recorded in Syria 2% , Morocco 2% and Yemen 2% in 1996^[10-17]. About (10.2%, 0.9% and 3.1%) of smear positive patients were registered as defaulter in the 1st, 2nd and 3rd cohort this result was higher than other project for example it was 0.8% in Syria, 2nd cohort defaulter was similar in comparison to the other result such as 0.9% in Oman^[17].

This may due to follow up defaulters was poor due to transport difficulties. Also the rate of transfer out of 1st, 2nd and 3rd cohort was (1%, 6.7% and 5% respectively). The result 2nd and 3rd cohort higher than other projects such as in Syria it was 2.5% , 1st cohort transfer out similar in comparison to other result such as 1% in Iran^{[37][20]}.

The treatment success rate of new smear positive patient within 1st and 2nd cohort was less than the WHO target (85%). Contrasting local rates EMRO countries like Lebanon, Arab Emirates and Bahrain and may global like China, Vietnam, Nepal achieved higher success rate (96%, 96%, 95%, 96%, 85% and 85% respectively).

About (85.35%) of new smear positive patient were registered as treatment success rate in 3rd cohort were more than the WHO target (85%) and more than the result compared with others course chemotherapy programs for example 70% treatment success in Pakistan between the years 1995 and 1996 and 69% treatment success rate in South Africa in 1997^[21].

Recommendations:

1. Increase case detection rate through increase health education to community about the mode of transmission and dangerous of TB disease.
2. Increase training of health personals so that they can follow up patients at home.
3. Increase follows up of defaulters to be able to deal with them.
4. A study for relapses cases is recommended.

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