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Title: National Control for Tuberculosis: Does Primary Health Care System Have a Crucial Role for Fight?

Short title: Fight Against Tuberculosis

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Abstract

OBJECTIVE: To analyze the tuberculosis control studies in a primary healthcare center, and to observe the changes throughout the years.

MATERIAL AND METHODS: Obtained data of patients followed-up between 2005-2014 in Elazig Dispensary were investigated retrospectively.

RESULTS: Of the total 1,251 patients, 51.6% was male. Majority of the patients were between the ages 15-24 (19.9%), 25-35 (18.5%) and 65+ (14.4%). While the rate of sputum smear examination was 71.6%, the positivity rate for Acid-Fast Bacilli was 55.5%. It was detected that drug sensitivity test has been applied in only 25.8% of all patients. Treatment success of all patients was 85.8%. Cure rate of smear- positive cases was found to be 26.35%. The rate of the relapsing patients was 9.1%. Overall treatment response rate was found to be 87.4%.

CONCLUSION: The control of tuberculosis in primary healthcare is partially successful; yet, not enough. The rate of smear -positive defaulters was found to be high in young adult individuals which indicates that contamination is probably still going on dangerously. Furthermore, the overall rate of microscopic examination, sputum culture and drug sensitivity tests performed to patients in primary healthcare system is low and should be improved immediately.

Keywords: Tuberculosis, control, dispensary.

INTRODUCTION

Tuberculosis (TB) is still one of the most fatal disease both in our country and also in the world. Successful treatment of TB infection is essential for disease control. It is estimated that in 2014, 9.6 millions of people in the world suffered from tuberculosis and 1.2 million of them died because of this disease (1). Likewise the overall situation in the world, also in Turkey, tuberculosis is a disease that should be fought decisively and systematically which is a major threat for the overall health of the society. Dispensaries play the most important role for TB treatment in our country. As a primary healthcare center, they perform the main operations which enables all individuals or patients to benefit from the best preservation techniques and also diagnosis and treatment by itself or the contribution of the other institutions, regarding the Strategy of Stop TB and International Standarts for TB care (2).

In the world, for tuberculosis there is a global control program for tuberculosis which is run by World Health Organization; In Turkey, there is a tuberculosis control program which has the same standards and parallels. (2). In our country, starting from the year 2010, the actions regarding the

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establishment of dispensaries for each city, at least one, has started and each of them will be serving to at least 500,000. Currently, the number of active dispensaries is 179, in our country. The studies are coordinated by Elazığ dispensary, which locates in the city center, are still going on. In the districts of Elazığ, there aren't any tuberculosis dispensaries. (3) Therefore the patients who have contributed to the studies represent the overall of Elazığ. Since the data about the patients were recorded in the related registers properly, reaching the data was simple and also trustworthy. It is beneficial to see worth 10 years data together and show the alterations throughout the years. The city where the studies are run is in the Eastern Anatolian Region of Turkey and has a population of worth 568 753 according to the 2014's data (4).

In the light of this aim, we have investigated the data of Tuberculosis Dispensary in Elazığ.

MATERIAL AND METHODS

Data Collection and Analysis

The Ministry of the Health is publishing a report regarding the control of tuberculosis in Turkey by analyzing the data of the patients who are registered to the dispensaries of tuberculosis. In this scope, we have shaped our study by taking this report as a major reference. This study is based on all the records of the dispensaries of the tuberculosis control in Elazığ. We have examined the data of the clients retrospectively which were recorded in Tuberculosis Dispensary of Elazığ between the years 2005-2014. Patient information was collected including age, gender, form of TB (pulmonary and extrapulmonary), type of TB (smear- positive or negative), category of TB (new cases, relapse or retreatment cases) and treatment outcomes. The diagnosis of TB was based upon ATS guideline for TB diagnosis. The recommendation of ATS is: Acid-fast bacilli (AFB) smear microscopy be performed, rather than no AFB smear microscopy, in all patients suspected of having pulmonary TB (strong recommendation, moderate-quality evidence). Testing of 3 specimens is considered the normative practice pervasive issue of poor sample quality (5).

Treatment regimen and evaluation of treatment outcomes

Treatment is based on four major drugs. All patients were treated with Isoniasid (300 mgr /day), Rifampicin (600 mgr /day), Pyrazinamide (2000 mgr/day) and Ethambutol (1500 mgr/day) according to 'National TB programme' recommended doses (6). The standard anti-TB treatment with four drugs was continued for 2 months initially and maintenance therapy was made with Isoniasid and Rifampicin for minimum 4 months. All cases were followed up at TB dispensary and treated with partial or total directly observed treatment (DOT) . The treatment response was evaluated according to microbiological, radiological and clinical findings. Smear conversion was estimated as the time(in weeks) from initiation of treatment to the first two consecutive negative smears for AFB. Treatment

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outcomes were categorized according to WHO criteria (1). a) Cured: A pulmonary TB patient with bacteriologically-confirmed TB at the beginning of treatment who was smear- or culture- negative in the last month of treatment and on at least one previous occasion. b) Completed treatment :A TB patient who completed treatment without evidence of failure but with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable. c) Died:A patient who died from any kind of reason during the course of treatment d)Treatment failure :At the end of fifth month or longer during treatment, smear remains or becomes positive for AFB . e)Treatment defaulter:Any patient who has interrupted treatment for two consecutive months or more after the date of the last attendance during the course of treatment. f) Transfer –out: A patient who was transferred to another center during treatment and ultimate treatment response is not known. All the subjects provided written informed consent.

Study design

A case descriptive study is performed focusing on data of TB patients followed in Elaziğ dispensary between the years 2005-2014 and basically dispensary reports are used. This is a national , retrospective and non- interventional study.

Statistical Analysis

All the statistical analysis were performed by using SPSS software version 24.0 IBM , Chicago, by mainly using descriptive statistics.

RESULTS

The 51.6% of the patients is male and the 48.4% of them is female. When the target organ involvement of TB is evaluated, the 57.1% of them was pulmonary and 42.9% of them were extra pulmonary. While the number of the male patients had the tendency of decrease throughout the years, the number of the female patients was variable, and also it had the tendency of decrease in 4 years (Table-1).

It was determined that, in the distribution of the ages, the majority of the patients were between the ages 15-24 (19.9%), 25-35 (18.5%) and 65+ (14.4%) .When the distribution of the patients' case definitions were considered, it was found out that 90.9% percent of the patients didn't get a TB treatment before (new cases).

It was found out that 4.9% of the cases were relapsing and 3% of the cases were treatment defaulters. 1% and 0.1% of cases were found to be treatment failures and cases with chronic TB infection respectively (Table-1).

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According to the microbiological evaluations, of the 714 pulmonary tuberculosis patients, 511 (71.6%) have been performed sputum smear and 396 (55.5%) of them were found to be smear positive cases. Sputum culture has been obtained from 337 (52.8%) patients and positivity rate was 35.4% with 253 patients. Only 175 (25.8%) patients have been done drug sensitivity test (Table-2). While calculating the microbiological examinations on pulmonary tuberculosis cases, we have based our calculations on the overall number of the pulmonary cases (Table-2). We think that, in the evaluation of the tuberculosis control programmes, the real calculation of the microbiological examination in practice should be based on this way which is parallel to the National TB control report.

When the treatment results of all cases were evaluated, the success of the treatment rate was 85.8%, treatment defaulter rate was 9.3%, failure of the treatment rate was 0.9% and the death rate was 4%. There is an increase on the percentage of success of treatment, decrease in the percentage of treatment defaulters within years. (Table-3). The cure rate in smear- positive pulmonary TB cases is 26.3% however, treatment success (cured + treatment completed cases) rate is 87.4%. The rate of treatment defaulters was 9.1% and the rate of death was 2.5% (Table-4).

We were able to reach the data of DOT just after 2009 September and we have accepted year 2010 as the initiation point. It has been observed that within years the application of DOT has reached nearly 100%. Also the percentage of DOT applied by health care workers is currently increasing (Table-5). In 2009 Ministry of Health issued a circular letter announcing DOT strategy. In this letter, related forms and application methods are explained in details.

Totally 43 (3, 4%) patients who were registered to the dispensary were recognized to be over diagnosed as TB during follow-up durations. Therefore treatment outcomes of this group is not given in the study.

When the case notification rate of TB according to age groups was analyzed during 10 years, it was realized that the majority of the patients are young. When the graph of case notification rate of TB regarding the age groups was observed, there happened a sudden increase between the ages 15-24, and within the elder age groups and the increase continued with a few fluctuations on the line (Figure-1).

DISCUSSION

Global and national fight for tuberculosis infection is essential with a knowledge of epidemiologic features such as the age groups which are more likely to have tuberculosis, areas with higher rates of tuberculosis and the patients' socioeconomic characteristics. Having knowledge about the situation of tuberculosis in society enables to fight effectively with the disease.

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We have compared Elazığ's data of 10 years with the data of 2011 which was stated in the Report of Tuberculosis Fight in Turkey which was published by Ministry of Health. Since the year 2005, the ministry is reporting each year's data of the country, annually.

In our study, within all the cases, 51.6% of them are male and 48.4% of them are female. Throughout the years, the cases of the females have increased from 44.3% to 67.3%. Our country results revealed , 58.6% male and 41.4% of female TB patients (3). When involvement of systems with TB infection is evaluated in our study 57.1% was pulmonary ,42.9% was extrapulmonary. It was also observed that pulmonary tuberculosis has decreased; however, extra pulmonary tuberculosis has increased within years. All along the years, according to Elazığ data extrapulmonary TB rate has increased from 38.8% to 54.9% ultimately. In a study which was performed among dispensaries of Çorum, it was reported that the rate for pulmonary TB was 63.7% and 36.3% for extrapulmonary tuberculosis. Similar studies performed in different regions such as Isparta, Istanbul and Şanlıurfa, extrapulmonary TB rates were found as 21.7%,20.9% and 28.8 % respectively (7-10). The relatively higher rates of extrapulmonary TB cases in Elazığ reveals that the contamination of infection has partially decreased with the help of the control programme. "Effective TB control programmes applied as a national approach might have relatively reduced the pulmonary involvement" is our subjective opinion about this rate.

It is observed that the accumulation in age groups between the ages 15-24 is 19.9%, between the ages 25-35 is 18.5%, and over the age 65 is 14.4%. The similar age groups were focused in Çorum study and the rates of TB was found as 14.4%, 17.1 %and 16.8 % respectively (7). Also a study performed in İstanbul rates were found to be 36%, 27%, 2,9 % (9). When the graph of case speed regarding the ages is observed, it is vivid that there is a sudden increase between the ages 15-24, and the increase is maintained with a few fluctuations. The reason for that is the majority of the population consists of young individuals (4). The age distribution resembles with countries which applies successful control programs, has low rate of incidence, and the disease is seen in old individuals; and it also resembles with countries which has high rate of incidence and the disease is seen in young adults. This situation shows us that the epidemic of tuberculosis is still an ongoing issue in Elazığ and there is a partial success in tuberculosis control. When the years 2005 and 2014 is compared, while in the year 2005 the rate was 27.9% in the age group between 15-24, in the year 2014, the rate is decreased to 17.3%; in 2005, the rate of the age over 65 was 7.5% which has increased up to 22.1% in the year 2011.

When the distribution of the patients' case definition is observed, the rate of new cases was found out to be 90.9%. The rate of relapsing cases was 4.9%, the rate of treatment defaulters was 3% and the rate of treatment failure and chronic cases was 1% and 0.1% respectively. A remarkable difference between the relapsing cases was found in a study performed in İstanbul with a rate of 7.5% (9). According to the overall data of Turkey in 2011, the rate of new cases is 92%, relapse is 6.3%, the rate of treatment defaulter is 1.1%, the rate for treatment failure is 0.6% and the chronic

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patients is 0.03%. We think that since the rate of “treatment failure” and “chronic cases” has decreased , we are running a partially successful program in Elazığ (3).

When the microbiological examinations, which were performed for 714 pulmonary tuberculosis patients, are examined; it is found that the rate of microscopic examination is 71.6%, otherwise diagnosis was based upon clinical and radiological suspicion. The microscopic examination rate was higher in Çorum dispensaries (83.5%). AFB positivity rate in sputum was 55.5%; the application of sputum culture rate was 52.8%, the sputum culture positivity rate is 25.8%. The rate of the application of microscopic examination, sputum culture and drug sensitivity test was substantially low. Throughout the years these rates have decreased evidentially. In the calculations of Reports of Fight of Tuberculosis (2007-2010), the rates of pulmonary tuberculosis are mentioned and included (6,11,12).

The inefficiency in while diagnosis should be eliminated and also the microbiological treatments should be used wisely in diagnose and the treatment. Primary healthcare facilities should be widened for more microbiological approaches. Education and awareness of healthcare workers is an essential issue .

When the treatment results are evaluated, the city based success rate is 85.8%, it is lower than the average of the country. The success rate is 89.2% in the Turkey (3). Also, in Turkey 2010, defaulters rate within all the cases is 2.7% (3). In the city of Elazığ, this rate is 9.3%. Even though the rate of treatment defaulters, starting from the year 2005, has decreased, it is not still below the average of Turkey. In a previous study of Sahile and Zinatsa et al; they declared that non-adherence to TB treatment was a major problematic issue with the need for DOTS service providers and more training (13,14).

In the city of Elazığ, the cure rate for smear- positive pulmonary TB is 26.3%, the success rate of treatment (cured + treatment completed cases) is 87.4%. When the overall look of the country is evaluated, within the all data that was recorded to the dispensaries in 2010, the rate of cure of smear- positive pulmonary TB is 59.1%, the success rate of treatment is 88.2% (3). It is a great problem to have a low rate of cure around the region for tuberculosis control. Microbiological treatment should be used for diagnose, follow -up and ending the treatment; this problem should be improved emergently. Within the all cases and also smear-positive pulmonary TB cases, treatment defaulter rate is 9.9% which is high and creates a major problem for tuberculosis control. Non-adherence to treatment is a major problem in our country as well as other countries. In our study, the quit of treatment among young adult clients is high that indicates defaulters change their cities and lives to seek for new seasonal jobs out of the region. Also migration is another problematic issue that ruins the treatment and follow-up schedule. Our results are contrary to the study of Annunnatsiri et al which revealed other than young clients , people older than 60 years were found to be defaulters or failures (15).

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In general, sputum culture is an important tool to confirm noncontagious TB patients. Also the use of serial sputum examination has been described as the most definite, cost-effective and dependable test for accurate diagnosis of pulmonary TB (16).

The rate of application of microscopic evaluation, sputum culture and drug sensitivity test for the patients with pulmonary tuberculosis in primary healthcare centers was found not to be enough and should be developed. Microbiologic diagnostic approaches should be focused and more confirmation of diagnosis rather than clinical suspicion should be an initiation point for therapy in daily practices of dispensaries. The rate of defaulters was found to be high in young adult patients which indicates that contamination is probably still going dangerously. Since young people are located in the middle of social life, close contact and relationship with their partners, children and friends, this group of patients should be focused for an efficient TB fight. The percentage of the patients who have quitted the treatment is high. The influential factors (age, gender, social-economic situation, etc.) should be evaluated in a more detailed way and DOT application by healthcare workers is a necessary issue for TB control. Aforementioned lacking points in our study should be considered, and eliminated immediately.

Our study has some limitations since it is retrospectively designed, and totally based on data of dispensary which was reported primarily by health care providers. Subjective approaches and alterations in health care professionals might have affected the data collection.

In our study no data were obtained in means of etiological factors for extrapulmonary involvement, so this situation can be attributed as our retrospective data limitation.

CONCLUSION

TB in the world and also in our country is a lethal but a preventable disease that needs probably struggling decisively, globally and systematically not only in present but also in the future. Accurate detection and treatment of smear-positive and latent TB patients are major components of TB control and prevention. Dispensaries play the most important role for TB treatment in our country. As a primary healthcare center, dispensaries perform the main operations which enables all individuals or patients to benefit from the best preservation techniques and also diagnosis and treatment by itself or the contribution of the other institutions. In the city of Elazığ, the control of tuberculosis is partially successful, yet, not enough. The rate of smear-positive defaulters was found to be high in young adult individuals which indicates that contamination is probably still going on dangerously. Microscopic examination, sputum culture and drug sensitivity tests performed to patients in primary healthcare centers is low and should be improved immediately. If these problems are solved in region, we won't probably face such issues in general. Therefore making such studies based in regions will direct and highlight national control programmes.

Conflict of Interest : The authors declare that they have no conflict of interest.

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Table 1: The Distribution of the Gender and Site of Involvement According to Years and The Distribution of the Patients According to Case Descriptions

	Male	Female	Pulmonary	Extrapulmonary	New Cases	Relapsing	Treatment Defaulter	Treatment Failure	Chronic TB Infection	Total
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n
2005	112(55,7)	89 (44,3)	123 (61,2)	78 (38,8)	173(86)	9(4,5)	11(5,5)	7(3,5)	1(0,5)	201
2006	75 (52,8)	67 (47,2)	92 (64,8)	50 (35,2)	133(93,7)	6(4,2)	3(2,1)	-	-	142
2007	81	59	81	59 (42,1)	132(94,3)	7(5)	1(0,7)	-	-	140

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7	(57,9)	(42,1)	(57,9))))))))
2008	73 (61,3)	46 (38,7)	71 (59,7)	48 (40,3)	104(87,4)	7(5,9)	8(6,7)	-	-	119
2009	61 (50,4)	60 (49,6)	71 (58,7)	50 (41,3)	113 93,4)	7 (5,8)	1 (0,8)	-	-	121
2010	63 (48,5)	67 (51,5)	71 (54,6)	59 (45,4)	124 95,4)	3 (2,3)	3 (2,3)	-	-	130
2011	48 (51,6)	45 (48,4)	56 (60,2)	37 (39,8)	88 (94,6)	3 (3,2)	2 (2,2)	-	-	93
2012	58 (53,7)	50 (46,7)	49 (45,3)	59 (54,7)	90(83,3)	8(7,4)	4(3,7)	6(5,6)	-	108
2013	41(44, 1)	52(55, 9)	53 (56,9)	40(43,1)	88(94,6)	3(3,2)	2(2,2)	-	-	93
2014	34 (32,7)	70 (67,3)	47(45,1)	57(54,9)	92(88,5)	9(8,6)	3(2,9)	-	-	104
Total	646(51 ,6)	605(48 ,4)	714 (57,1)	537(42,9)	1.137(90 ,9)	62(4,9)	38(3)	13(1)	1(0,1)	1.251

Table 2. The Results of Microbiological Findings of the Tuberculosis Cases Within Years

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Year	Total Pulmonary Cases	Performed Sputum smear	Positivity of Sputum smear	Performed Sputum Culture	Positivity of Sputum Culture	Performed Drug Sensitivity Test
	n	n (%)	n (%)	n (%)	n(%)	n(%)
2005	123	73 (59,3)	55 (44,7)	71 (57,7)	44 (35,8)	28 (22,7)
2006	92	59 (64,1)	49 (53,3)	51 (55,4)	38 (41,3)	28 (30,4)
2007	81	51 (63)	45 (55,6)	23 (28,4)	14 (17,3)	4 (4,9)
2008	71	55 (77,5)	43 (60,6)	31 (43,7)	25 (35,2)	18 (25,4)
2009	71	47 (66,2)	33 (46,5)	29 (40,8)	23 (32,3)	15 (21,1)
2010	71	46 (64,8)	36 (50,7)	31 (43,6)	17 (23,9)	13 (18,3)
2011	56	48 (85,7)	34 (60,7)	34 (60,7)	24 (42,9)	14 (25)
2012	49	45 (91,8)	39 (79,5)	34 (69,3)	22 (44,9)	17 (34,6)
2013	53	47(88,6)	27 (50,9)	39 (73,6)	20 (37,7)	14 (26,4)
2014	47	40 (85,1)	35 (74,4)	34 (72,3)	25 (53,1)	19 (40,4)
Total	714	511 (71,6)	396 (55,5)	377 (52,8)	253 (35,4)	170 (25,8)

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Table 3.Treatment Outcome Rates of All cases

	Number of cases n	Treatment success n(%)	Treatment defaulter n(%)	Treatment failure n (%)	Death n(%)
2005	193	156 (80,8)	25 (13,0)	2 (1,0)	10 (5,0)
2006	142	114 (80,3)	23 (16,2)	1 (0,7)	4 (2,8)
2007	139	119 (85,6)	19 (13,6)	-	1 (0,7)
2008	115	99 (86,1)	15 (13)	-	1 (0,9)
2009	120	103 (85,8)	11 (9,2)	-	6 (5)
2010	123	112 (91)	5 (4,1)	1 (0,8)	5 (4,1)
2011	93	81 (87,1)	3 (3,2)	4 (4,3)	5 (5,3)
2012	95	82 (86,3)	5 (5,3)	1 (1,1)	7 (7,4)
2013	84	74 (88,1)	4 (4,7)	2 (2,3)	4 (4,7)
2014	104	96 (92,3)	3 (2,9)	-	5 (4,8)
Toplam	1.208	1036 (85,8)	113 (9,3)	11 (0,9)	48 (4)

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Tablo 4. Treatment Outcomes of Smear- Positive Pulmonary TB cases

	Total Number of Cases n	Cured n (%)	Treatment Success n (%)	Treatment Defaulter n (%)	Treatment Failure n (%)	Death n (%)
2005	55	1 (1,8)	46 (83,6)	7 (12,7)	1 (1,8)	1 (1,8)
2006	49	1 (2)	42 (85,7)	6 (12,2)	-	1 (2,0)
2007	45	14 (31,1)	35 (77,3)	9 (20,5)	-	1 (1,3)
2008	43	-	37 (86)	6 (14)	-	-
2009	33	12 (36,4)	29 (87,9)	2 (6,1)	-	2 (6,1)
2010	36	27 (75)	31 (86,1)	2 (5,6)	1 (2,8)	2 (5,6)
2011	34	5 (14,7)	30 (88,2)	2 (5,9)	1 (2,9)	1 (2,9)
2012	39	15 (38,5)	34 (87,2)	2 (5,1)	1 (2,6)	2 (5,1)

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2013	27	14 (51,9)	27 (100)	-	-	-
2014	35	15 (42,9)	35 (100)	-	-	-
Total	396	104 (26,3)	346 (87,4)	36 (9,1)	4 (1)	10 (2,5)

Table 5. DOT Strategy

	Total Number of Patients	Patients DOT Not Applied	Number of Patients DOT Applied by HCW(*)	Number of Patients DOT Applied not by HCW(*)	DOT Application Percentage(%)	DOT Application Percentage by HCW(*) (%)
2010	130	7	45	78	94,6	34,6
2011	93	2	53	38	97,8	56,9
2012	108	3	63	42	97,2	58,3
2013	93	0	63	30	100	67,7
2014	104	0	68	36	100	65,3

(*)HCW: Health Care Workers

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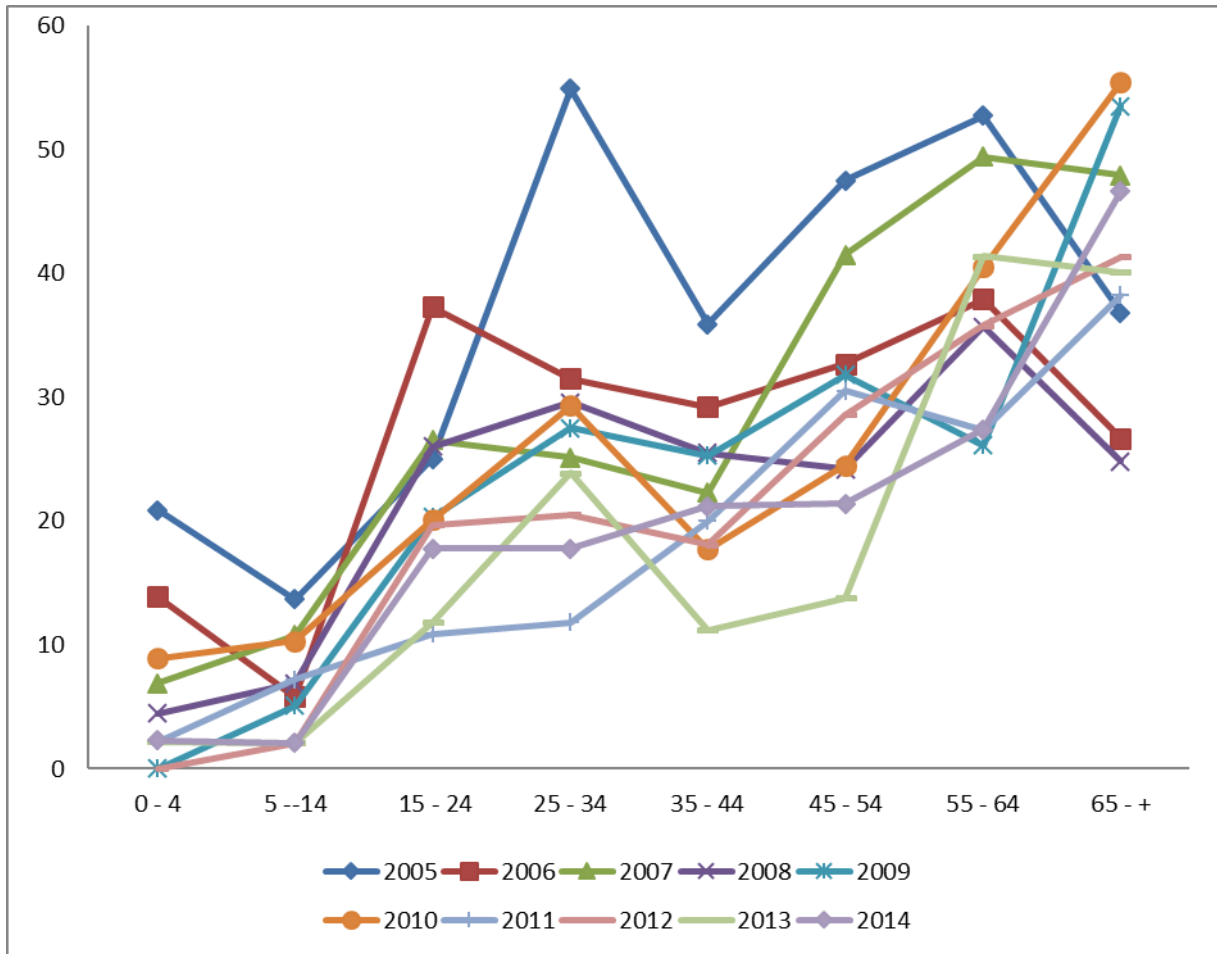
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Figure 1. Case Notification Rate Regarding the Ages of the TB Cases in Elazığ: 2005-2014

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