

Outcome of treatment of pulmonary tuberculosis in Switzerland in 1996

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Summary

Principles: Adequate treatment of pulmonary tuberculosis cures patients and reduces transmission. The study assesses treatment outcomes under current conditions in Switzerland.

Methods: Retrospective cohort study including all TB cases with positive sputum cultures notified to the national surveillance system between July 1996 and June 1997. Ten months after notification, treating physicians reported the outcomes using WHO categories.

Results: Of 265 patients, 209 (79%) completed at least 6 months' treatment, 3 (1%) were treatment failures, 23 (9%) died, 8 (3%) defaulted from treatment and 22 (8%) left the country. The proportion of successful treatments did not significantly differ between the 103 Swiss-born (80%) and the 162 foreign-born (78%) patients. There were 19 deaths (18%) in the Swiss-born and 4 (2%) in the foreign-born groups; death was caused by TB in two patients, 10 died of other causes (cause

unknown in 11). In the foreign-born group there were 31 (19%) potentially unsatisfactory outcomes (treatment failure, default from treatment, transfer abroad) and in the Swiss-born group 2 (2%). Default from treatment involved 8 patients, 6 of whom were asylum seekers. In a multivariate analysis potentially unsatisfactory outcomes were not significantly associated with foreign origin but with status as a foreigner of irregular or unknown legal status (adj. OR 8.8; 95% CI 1.4 to 53.7).

Conclusions: Overall treatment success rates are satisfactory and similar to those of other western European countries. Potentially unsatisfactory outcomes are more common in foreign-born persons of irregular legal status. Tracking of non-adherent patients by health workers could further improve outcomes.

Key words: tuberculosis; treatment outcome; surveillance; cohort analysis; Switzerland

Introduction

Correct treatment of tuberculosis (TB) aims at curing the individual patient, interrupting transmission of TB to other persons, and preventing bacilli from becoming drug resistant. These aims are not achieved in many regions of the world even when antituberculosis drugs are available [1]. The main reasons are death of the patients during treatment, default before the scheduled end of treatment or resistance to the drugs prescribed. Patient non-adherence to treatment is interpreted as a failure of the health care system to cope with the natural tendency of humans to quit treatment as soon as they feel subjectively better, or better without treatment if adverse drug events supervene [2].

Treatment outcome results serve as a proxy of the quality of TB treatment provided by a health care system. Recommendations on how to evaluate treatment outcomes using standardised categories have been issued by the World Health Or-

ganization (WHO) in conjunction with the European Region of the International Union Against Tuberculosis and Lung Disease (IUATLD) [3]. These categories were defined to assess the risk of future relapse and drug resistance. Ideally, treatment outcomes in all patients should be routinely monitored by the epidemiological surveillance system. This would make it possible to recognise and amend system failures before the incidence and proportion of resistant isolates rise.

In Switzerland, notification of TB cases to the health authorities is mandatory for both physicians and laboratories, and laboratories are required to report the results of testing of susceptibility to the four first-line antituberculosis drugs. Outpatient treatment of TB is predominantly in the hands of private practitioners in Switzerland. Treatment guidelines of the Swiss Lung Association exist [4]. Contrary to WHO/IUATLD recommendations, however, TB treatment outcome results do not

have to be reported under the current regulations. The notification rate decreased to a historical low of 9 cases per 100'000 population in the year 2000 [5]. The proportion of strains resistant to isoniazid remained 6% between the years 1996 and 2000, and the proportion of multidrug-resistant strains, i.e. strains resistant at least to isoniazid and rifampicin, between 1% and 2% [5, 6]. Resistances were predominantly observed in foreign-born patients having already received treatment for tuberculosis in the past [6]. The TB situation in Switzerland is similar to that in several other European countries [7–9].

Local surveys had prompted suspicion that

WHO targets for treatment outcomes were not being met in Switzerland, but data representative for the whole country were lacking [10, 11]. The objectives of the present study therefore were to ascertain the treatment outcomes in possibly contagious TB patients countrywide, identify groups at risk for unsatisfactory outcomes, obtain treatment outcome results for immigrants subject to the Federal screening programme, and evaluate the feasibility of routine monitoring of treatment outcomes. This would ultimately orient public health authorities and practitioners regarding the possible need for additional measures.

Methods

The study included all TB patients notified to the Swiss Federal Office of Public Health between 1 July 1996 and 30 June 1997 for pulmonary TB with a positive sputum smear or a positive culture from sputum.

Ten months after notification, standardised questionnaires were sent, via the cantonal public health authorities, to the treating physicians who had notified the cases. Treatment outcome at 6 months after the start of treatment was the study endpoint. If a patient continued treatment with another physician, the questionnaire was also sent to the latter until the information was available for at least the first 6 months of treatment. Patients who continued treatment beyond 6 months were classified as having completed treatment. To ensure that the duration of treatment was assessed correctly, information on the total duration of treatment with each antituberculosis drug was sought. In the event of non-response a reminder was sent to the physician, followed by a telephone contact.

The information gathered in this study was linked on a case-by-case basis to that from physicians and laboratories already existing in the national TB database. Pre-existing information concerned geographic origin, legal status, previous antituberculosis treatment, organs affected

and antituberculosis drug resistance. Geographic origin of patients was defined by country of birth [12], and if unknown by nationality. Patients who had been treated in the past were known either from the current notification or from a previous patient record in the national TB registry.

The outcome categories of the WHO and IUATLD working group were used [3]. There being no national TB programme supervising treatment and routinely collecting treatment results in Switzerland, adaptations in the definitions of some outcomes were necessary (table 1). The treatment outcomes were further grouped into three summary categories (table 1): "successful", i.e. the treatment was such that the risk of relapse is minimal; "death"; and "potentially unsatisfactory", i.e. associated, or potentially associated, with a higher risk of relapse or resistance [3]. This separates the category "death" from the other two, as deaths in low incidence countries are more often deaths with TB as a second diagnosis than deaths due to TB [8, 9]. The two remaining categories are epidemiologically relevant: cases with "successful outcomes" are likely not to be transmitting TB any longer and cases with "potentially unsatisfactory outcomes" may transmit a TB strain that has possibly become resistant.

Table 1
Outcome categories and definitions.

Category	definitions of outcomes for culture confirmed TB (WHO/IUATLD) [3]	study adaptations of WHO/IUATLD definition [rationale for adaptation]	summary categories (WHO/IUATLD)
Cured	documented conversion of culture during the continuation phase	same as WHO	successful
Treatment completed	documented treatment completion, but no documented culture conversion	documented completion of 6 months' treatment, but no documented culture conversion [at ten months' follow-up some patients were still on treatment]	
Death	death of the patient irrespective of cause at any time before scheduled end of treatment	same as WHO	death
Treatment failure	culture remaining or again becoming positive at 5 months of treatment or later	same as WHO	potentially unsatisfactory
Treatment interrupted	patient off treatment for 2 consecutive months or more or failure to complete treatment within 9 months for a 6-month or within 12 months for a 9-month regimen or drug intake <80%	patient interrupted treatment without notice [intended regimen is not known and interruption time cannot be reliably sought from physicians]	
Transfer out	a patient referred to another clinician for treatment on whom information on treatment outcome cannot be obtained	patient went abroad, with or without indication as to continuation of treatment, and no further information available [information on all patients remaining in Switzerland was available]	

As the treatment of tuberculosis is in the hands of private physicians, there is currently no legal or mandatory control on the management of the disease (control of adherence to treatment, bacteriological control during treatment, tracing of non-compliant patients). Therefore, the study reflects current conditions in Switzerland.

Logistic regression was used to test the effects of age, sex, geographic origin, and legal status on treatment outcome at 6 months. The dependent variable was “poten-

tially unsatisfactory treatment outcome” (n = 33). Deaths were excluded from the analysis (n = 23). In the first phase only one predicting variable was included in the model. Then a main effects model including all predictors was estimated. All interaction terms additionally included in the main effects model were insignificant. The results are presented as odds ratios and their 95% confidence intervals (95% CI). These computations were done by *Splus 2000* for Windows NT (MathSoft, Seattle, WA, USA).

Results

During the period considered, 271 patients were notified with positive sputum results, i.e. either a positive microscopy or culture or both. Their treating physicians could be located and all eventually responded (response rate 100%). Of the 271 cases, 265 were confirmed by culture for *M. tuberculosis* complex in at least one of the specimens received by the laboratory, and were thus analysed. Six cases were excluded because the cultures were negative.

176 patients (66%) were male and 89 (34%), female. 150 were born in a foreign country and 81

in Switzerland, while in 34 patients information on geographic origin was lacking; 22 of the latter had Swiss nationality and 12 were foreign nationals. Recoding the 34 “country of birth unknown” using nationality, 162 (61%) were considered foreign-born and 103 (39%) Swiss-born. The median age was 38 years (range 1–99 years) overall. It was 67 years in Swiss-born subjects (range 1–94) and 30 years in foreign-born subjects (range 4 to 99). Direct sputum microscopy was positive in 177 cases (67%) and negative in 42 (16%); no information available in 46 (17%). An extrapulmonary site was additionally affected in 52 patients (20%). There were 193 new cases, 30 were relapses and information on prior treatment was unavailable in 42.

Overall, treatment outcome at 6 months after the start of treatment was successful in 209 patients (79%) (table 2). There were 23 deaths either before or within six months following the start of treatment. In three patients cultures were still positive after five months’ treatment or later. Eight patients defaulted from treatment. Overall, 22 patients left the country either before (n = 11) or after (n = 11) the start of treatment; an intention to begin treatment abroad was known for one patient.

Patients with a history of a previous treatment

Table 2
Treatment outcome at 6 months after the start of antituberculosis treatment.

Outcome (adapted from WHO/IUATLD)	N	%	(95% CI)
Total	265	100	
Successful	209	79	(73 to 84)
cured	78	29	(24 to 35)
treatment completed	131	49	(43 to 56)
Death	23	9	(6 to 13)
Potentially unsatisfactory	33	12	(9 to 17)
treatment failure	3	1	(0 to 4)
treatment interrupted	8	3	(1 to 6)
transfer out	22	8	(5 to 12)

Table 3
Treatment outcome by history of previous TB treatment and sex.

Outcome	new cases	recurrent cases	previous treatment unknown	male	female
Successful	156 (81%)	23 (77%)	30 (71%)	137 (78%)	72 (81%)
Death	15 (8%)	3 (10%)	5 (12%)	19 (11%)	4 (4%)
Potentially unsatisfactory	22 (11%)	4 (13%)	7 (17%)	20 (11%)	13 (14%)
Total	193 (100%)	30 (100%)	42 (100%)	176 (100%)	89 (100%)

Table 4
Outcome by age (quartiles of age distribution).

Outcome	age group (years)			
	1 to 27	28 to 39	40 to 66	67 to 99
Successful	56 (81%)	55 (80%)	55 (87%)	43 (67%)
Death	0 (0%)	0 (0%)	5 (8%)	18 (28%)
Potentially unsatisfactory	13 (19%*)	14 (20%*)	3 (5%)	3 (5%)
failure	1 (1%)	1 (2%)	0	1 (2%)
interrupted	3 (4%)	5 (7%)	0	0
transfer out	9 (13%)	8 (12%)	3 (5%)	2 (3%)
Total	69 (100%)	69 (100%)	63 (100%)	64 (100%)

for TB were analysed separately. There were no significant differences of outcome depending on a history of previous treatment or sex (table 3).

The proportion of successful treatment outcomes was similar in all age groups (table 4). The remaining outcomes differed: potentially unsatisfactory outcomes were more frequent below age 40 than above. More deaths occurred above age 39. The age range of the 23 deaths was 41–94 years with a median of 74 years. Of the five deaths in the age group between 40 and 66, three were foreign-born patients. In the age group above 66 years, all deaths except one occurred in Swiss-born patients. One Swiss-born patient (aged 68) died from TB and one foreign-born (aged 41) died of HIV-TB. Ten patients died from other diseases than TB and in 11 patients the cause of death was unknown.

The proportions of successful outcomes were similar in Swiss and foreign-born patients (table 5).

The proportion of deaths was higher in Swiss-born patients, whereas potentially unsatisfactory outcomes occurred more frequently in the foreign-born.

The legal status of TB cases is routinely collected in the national TB database, as there are Federal screening programmes for asylum seekers, refugees, and foreign labour. The proportion of successful outcomes was similar among Swiss nationals, foreign labour and asylum seekers/refugees (table 6). It was lower among foreigners of other (visitors, students, retired persons, etc.) or unknown legal status. Patients of the last-mentioned legal category had the highest proportion of potentially unsatisfactory outcomes: all 16 were "transfers out" abroad, two known to be involuntary. Among the eight asylum seekers or refugees with a potentially unsatisfactory outcome, six defaulted from treatment by disappearing.

Table 5

Treatment outcome by geographical origin of patients.

Outcome	Swiss-born			foreign-born		
	N	%	(95% CI)	N	%	(95% CI)
Successful	82	80	(71 to 87)	127	78	(71 to 84)
Death	19	18	(11 to 27)	4	2	(1 to 6)
Potentially unsatisfactory	2	2	(0 to 7)	31	19	(13 to 26)
Total	103	100		162	100	

Table 6

Treatment outcome and legal status.

Outcome	Swiss nationality		asylum seekers and refugees		foreign workers		foreigners of other or unknown status	
	N	(%)	N	(%)	N	(%)	N	(%)
Successful	91	(81%)	42	(81%)	56	(89%)	20	(54%)
Death	19	(17%)	2	(4%)	1	(2%)	1	(3%)
Potentially unsatisfactory	3	(3%)	8	(15%)	6	(10%)	16	(43%)
Failure	1	(1%)	1	(2%)	1	(2%)	0	
Default	1	(1%)	6	(12%)	1	(2%)	0	
Transfer out	1	(1%)	1	(2%)	4	(6%)	16	(43%)
Total	113	(100%)	52	(100%)	63	(100%)	37	(100%)

Table 7

Predictors of potentially unsatisfactory outcomes in logistic regression models.

		univariate crude OR 95% CI			multivariate adj. OR 95% CI		
		OR	95% CI	OR	95% CI		
Age (years)	1 to 27	1		1			
	28 to 39	1.1	(0.5 2.5)	1.4	(0.5 3.6)		
	40 to 66	0.2	(0.1 0.9)	0.4	(0.1 1.6)		
	67 to 99	0.3	(0.1 1.1)	0.7	(0.1 3.1)		
Sex	female	1		1			
	male	0.9	(0.6 1.3)	0.9	(0.6 1.4)		
Geographic origin	Swiss-born	1		1			
	foreign-born	3.2	(1.5 6.5)	1.8	(0.7 5.1)		
Legal status	Swiss	1		1			
	foreign workers	3.2	(0.8 13.4)	1.1	(0.2 7.2)		
	asylum seekers and refugees	5.8	(1.5 22.8)	1.9	(0.3 12.9)		
	others and unknown	24.3	(6.5 90.8)	8.8	(1.4 53.7)		

The logistic regression models confirmed the above findings. In the simple models age, geographic origin and legal status were significant predictors of a potentially unsatisfactory outcome (table 7). In the 40–66 age group, a potentially unsatisfactory outcome was 0.2 times (95% CI 0.1–0.9) less likely than in the reference age group 0–27 years. When adjusted for all other predictors the age effect became weaker (0.4; 95% CI 0.1–1.6) and no longer significant. Sex was not a predictor of treatment outcome either in the simple or multivariate model. Foreign-born patients were 3.2 times more likely to have a potentially unsatisfactory outcome than Swiss-born (95% CI 1.5–6.5).

This effect became insignificant in the multivariate analysis. “Legal status” was the strongest predictor of a potentially unsatisfactory outcome. “Legal status” was, however, closely associated with age, sex and geographic origin. Two categories of legal status accounted for most of this effect: “other and unknown”, a category including irregular aliens, and “asylum seekers and refugees”. These effects became less marked in the multivariate analysis, and only “other and unknown legal status” remained significant (adj. OR: 8.8; 95% CI 1.4–53.7). These changes in the effect estimates indicate multi-collinearity in the predicting variables.

Discussion

This study is the first in Switzerland to assess the nationwide results of treatment for TB, the prime measure of TB control. Overall, the proportion of successful treatment outcomes (79%) is reassuring. However, specific problems in some segments of the foreign-born population exist, such as a 12% default rate among asylum seekers and a 43% transfer rate among foreigners of other status than asylum seekers and foreign labour.

Two previous Swiss studies of TB treatment outcomes were each limited to one canton [10, 11]. Both showed a slightly lower proportion of successful outcomes (70% and 75% respectively). One of them showed a high proportion of defaulters (16%) and fewer than 1% of patients transferred out of the region; it also showed that foreign patients had an unsatisfactory outcome more often than Swiss patients [11]. The other study showed 4% defaulters and 7% transfer out [10].

In other western European countries and in the USA, the proportion of successful results was similar to that in this study [8, 13, 14]. A low proportion of proven cure is common. It is related to the difficulty of obtaining a sputum sample at the end of the treatment, as patients have stopped coughing. Therefore, most of the cases classified as “successful outcome” have only completed their treatment without final proof of cure. Nevertheless, based on these results, the future Swiss guidelines for the treatment of tuberculosis will include a firm recommendation to confirm the bacteriological cure of all cases with a positive sputum smear before treatment. It is also common in Western countries with a low incidence that the WHO target of 85% successful outcomes is missed due to a high proportion of deaths in native elderly patients, mostly due to causes other than TB [8]. In foreign-born patients, who are usually younger, the death rate is low but the target is missed due to a high proportion of patients leaving Switzerland before or during treatment. This is particularly the case among foreigners belonging to groups other than foreign labour and asylum seekers.

The methods used in this study comply with international standards, so that comparisons with other countries are possible [11]. As insufficient results of sputum microscopy are available from notification data, only cases with positive sputum cultures were enrolled and analysed. Two thirds of the cases in this group also had positive sputum microscopy, so these cases were likely to be the most infectious and thus most relevant for the spread of TB. As the cases with positive sputum smear but negative culture may have been infected with non-tuberculous mycobacteria, these were excluded from the analysis. As the specimens collected before the beginning of treatment were considered, this is probably not an effect of treatment.

Four out of five patients received at least 6 months' combined therapy within 10 months of the start of treatment. Treatment failures were rare, a fact possibly related to the low proportion of drug-resistant isolates. An underestimate of the number of treatment failures as defined by the WHO is possible if cultures were not performed after 5 months' treatment in suspicious cases, but should be a very rare event except in patients leaving the country and eluding further control. Defaulters were also rare, a fact which may reflect the high standard of care in the curative sector in combination with the nursing teams specialised in TB control in some parts of the country. However, specific problems are observable: defaulters are apparently met with mainly among asylum seekers. In the Netherlands, asylum seekers were also among the groups at higher risk for default [15]. Default from treatment ultimately reduces the effectiveness of the screening programme in place for this group, which is aimed at stopping transmission by early detection and treatment. More directly observed treatment (DOT) to ensure drug intake in this group is needed. As this group is also highly mobile within the country, it should be a focus for specialised nursing teams who establish a culturally sensitive relationship to ensure follow-up and drug intake until completion of treatment, if necessary with the aid of incentives (tickets for

transportation, free meals, etc.). It cannot be ruled out that some of the defaulters among the foreign population have actually left the country (voluntarily or by legal decision). If some stay illegally in the country, they may avoid all contact with the health care system. Patients leaving the country may contribute to the spread of TB elsewhere and to local drug resistance. Coordination of the different actors involved could also cut health care costs by reducing the number of physicians and hospitals involved in the course of a treatment.

The WHO recommends that data on treatment results be routinely collected at the local level as a part of epidemiologic surveillance [3]. Norway and the Czech Republic have implemented a system for mandatory notification of the results of TB treatment [16]. Experience with our study has shown that it is difficult for a central surveillance unit to retrospectively obtain follow-up data from private practitioners in Switzerland. It was less difficult wherever there was a local public health team

coordinating and following up patients under treatment. Public health structures are presently not sufficient to allow routine monitoring of TB treatment outcomes at the national level as recommended by the WHO [3, 17]. The main reasons are a Federal system with decentralised responsibilities in TB control and, in most parts of Switzerland, a lack of public health nurses specialised in TB to be responsible for routine follow-up of TB patients.

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