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Risk factors for multidrug-resistant tuberculosis treatment failure

The standard treatment of a new case of multidrug-resistant tuberculosis according to WHO recommendations in the Republic of Moldova is performed since 2005 and shows a low treatment succes. Actually the treatment success rate increased due to excluding of MDR-TB patients from the general cohort. The major rate of patients with low outcome is represented by the treatment failed and lost to follow-up cases.

Objective — to assess the risk factors for MDR-TB treatment failure.

Materials and methods. A retrospective selective, descriptive study targeting social, demographic, economic and epidemiological peculiarities, case-management, diagnosis radiological aspects and microbiological characteristics of 131 patients with pulmonary MDR-TB registered in Chisinau city from 2010 to 2015 with different outcomes was performed.

Results and discussion. It was established that the major risk factors for loss to treatment failure were patient's social vulnerability and disease related charctersitics: extensive forms of pulmonary tuberculosis and involving more than 3 lung segments.

Conclusions. Raising awareness among all MDR-TB patients about treatment compliance and earlier diagnosis will improve disease outcome.

Key words

Multidrug-resistant tuberculosis, risk factors.

Tuberculosis represents a major global health problem decalred by World Health Organization as an public health emergency of international concern [7]. The standard treatment for new patients presumed or known to have drug-susceptible tuberculosis according to WHO recommendations is used since 1993 and lasts 6 months. It consists in a two phase regimen with four first-line drugs: isoniazid (H), rifampicine (R), ethambutol (E) and pyrazinamide (Z) in the intensive phase and two first-line drugs: isoniazid and rifampicine in the continuation phase. Previously treated patients are treated during 8 months with a two phase regimen consisted of five first-line drugs: H, R, E, Z and streptomycine (S) followed the continuation phase during 5 months consisted of H, R and E [10]. It costs in average US$ 40 per person and must achieve at least 85 % treatment success rate. Tuberculosis-related death without treatment occurs in average 2 years. In the top of causes of death worldwide tuberculosis was placed on the 5th place in lower-middle income countries in 2015 [9]. The quality of disease control activities is showed by the rate of multidrug-resistant tuberculosis (MDR-TB) at the regional level [3, 6]. MDR-TB is an infection caused by *Mycobacterium tuberculosis* that are resistant to at least two of the most first-line bactericidal drugs: isoniazid and rifampicine. An associated resistance to second-line drugs such as aminoglicozides (amikacyne (Am), kanamycine (Km) and capreomycin (Cm)) and any fluoroquinolone (levofloxacine (Lx) or moxifloxacine (Mx)) is called extensively drug-resistant (XDR-TB) tuberculosis [10]. Globaly in 2015 there were estimated 580.000 new MDR-TB cases, but only 125.000 received DOTS-Plus regimen designed for its treatment [9]. For a better drug resistance surveillance in Republic of Moldove rapid molecular test such as GeneXpert MTB/Rif machines were procured for 15 Moldovan Health Care Specialized Insti-

tutions offering positive results in average 45 % patients with pulmonary tuberculosis. The treatment of the rifampicin-resistant and MDR-TB, defined as DOTS-Plus regimen requires second-line drugs, classified in groups: A — Fluoroquinolones:-levofloxacin (Lfx), moxifloxacin (MFX), gatifloxacin (Gfx); B — second-line injectable agents: amikacin (Am), capreomycin (Cm), kanamycin (Km); C — other core second-line agents: ethionamide/prothionamide (Eto/Pto), cycloserine/terizidone (Cs/Trd), linezolid (Lzd), clofazimine (Cfz) [10]. Patients with MDR-TB are treated with different combination of second-line drugs for 18 months or more according to the national diseases programmes. High rate of poor MDR-TB treatment success rates, significant potential for adverse events, long duration inhibit good treatment compliance and contribute to high rate of therapeutic failure, drop out and death [2, 4, 5]. All related factors associated to high costs contributed to the development of a shorter MDR-TB regimen lasting less than 12 months with a lowered costs (< 1.000 $ per patient). The shorter MDR-TB regimen showed promising results in selected MDR-TB patients and WHO updated its treatment guidelines in May 2016 by including the recommendation to use in patients with non-complicated tuberculosis. The WHO emphasized that the regimen should not be applied in confirmed resistance to at least one drug included in the shorter MDR-TB (except isoniazid resistance), exposure to more than 1 second-line drugs for more than 1 month, intolerance to more than 1 second-line drugs, at least one drug not available in the national programme [10]. In case of therapeutic failure, drug intolerance, return after interruption more than 2 months, appearance of any exclusion criteria the shorter MDR-TB regimen should be replaced by individualised (conventional) MDR-TB regimen with a duration of at least 18 months.

Objective — to assess the risk factors for multidrug-resistant tuberculosis treatment failure registered in the period 2010—2015 in Chisinau. Objectives were: 1. Assessment of tuberculosis treatment outcome dynamics in pulmonary MDR-TB cases registered in Chisinau during 2011—2015. 2. Assessment of general, socio-economic and epidemiological risk factors of pulmonary tuberculosis patients with DOTS-Plus treatment failure. 3. Evaluation of case-management, diagnosis, radiological aspects and microbiological characteristics of patients with with DOTS-Plus treatment failure.

Materials and methods

It was performed a retrospective selective, descriptive study targeting social, demographic, economic and epidemiological pecualiarities, case-management, diagnosis radiological aspects and microbiological characteristics of 130 patients with pulmonary MDR-TB cases registered in Chisinau city. The electronic system for monitoring and follow-up of tuberculosis cases (SIME TB) was used for the patients selection. Data were extracted from the statistic templates F089/1-e «Declaration about patient's established diagnosis of new case/relapse of active tuberculosis and restart of the treatment and its outcomes» and F090/e «Declaration and follow up of multidrug-resistant tuberculosis». Inclusion criteria were: age > 18 years old, treatment failed case in the study group, cured new case in the control group, signed informed consent. New case is considered the patient never treated for TB or has taken anti-TB drugs less than one month. The investigational schedule included demographic, social and epidemiological data: sex (male/female ratio), age (distribution in age groups), demographic characterstics (urban/rural residence), educational level, socio-economic status (employed, unemployed, retired, disabled, student), health insurance status (uninsuranced, insuranced), migrational and detention history, presence of high risk (close contact with an infectious source, comorbidities, type of infectious cluster, patient's screening methods. All selected patients were diagnosed and managed according to the National Clinical Protocole 123 «Tuberculosis in adults». Enrolled patients were distributed in two groups: 1st group was constituted from 69 pulmonary tuberculosis patients registered with DOTS-Plus treatment failure (TFG) and treated according to the standard MDR-TB regimen in the period 01.01.2010—31.12.2015, 2nd group — control group (2) was constituted of 61 new pulmonary tuberculosis cases registered in 01.01.2014—31.12.2015 and cured with the standard DOTS-Plus regimen. First group was constituted from 36 (52.17 %) new cases, 15 (21.74 %) relapses, retreated for a previous treatment failure 12 (17.39 %) and retreated after a previous treatment default were 6 (8.69 %). New cases were considered patients never treated or treated with anti-tuberculosis drugs for less than 1 month. Relapses were previously treated patients, declared cured or treatment completed, than diagnosed with a recurrent episode of tuberculosis. Treatment failure was considered the patients whose treatment failed. Failure of drug susceptible tuberculosis was considered microbiological positive smear patient at the end of 5th month. Failure of MDR-TB regimen was defined as the lack of smear conversion by the end of the intensive phase, or bacteriological reversion in the continuation phase after conversion to negative, or evidence of acquired resistance to

Table 1. **Distribution of MDR-TB patients by demographic data, p (%)**

Indices		TFG (1) (n = 69)	CG (2) (n = 62)	p_{value}
Sex	Men	58 (84.06)	44 (70.96)	> 0.05
	Women	11 (15.93)	18 (29.03)	> 0.05
Age groups	18—34 years	27 (39.13)	15 (24.19)	< 0.05
	35—54 years	26 (37.68)	22 (35.48)	> 0.05
	> 55 years	16 (21.18)	25 (40.32)	< 0.05
Residence	Urban	39 (56.22)	44 (70.96)	> 0.05
	Rural	30 (43.47)	18 (29.03)	> 0.05

Note. Applied statistical test: paired simple T — test; P — probability.

fluoroquinolones or second-line injectable drugs (acquired XDR-TB). Statistic analysis was carried out using the quantitative and qualitative research methods. Statistical survey was performed using Microsoft Excel XP soft.

Results and discussion

According to the published data by the Moldovan National Centre for Management in Health during the period 2011—2015 it was registered an important treatment failure decline among new cases with 24 % in Chisinau: 2010 — 26.9 %, 2011 — 23.6 %, 2012 — 18.2 %, 2013 — 6 %, 2014—2.8 % and with 16.4 % in Republic of Moldova: 2010 — 19.6 %, 2011 — 17.0 %, 2012 — 16.4 %, 2013 — 3.8 % and 2014 — 3,2 % due to the improving of the treatment quality and changes in treatment outcomes. The treatment success rate increased (+33.7 %) from 2010 to 2014 in the positive acid fast bacilli patients: 2010 — 45 %, 2011 — 56.7 %, 2012 — 57.5 %, and in bacteriological confirmed cases 2013 — 70.3 %, 2014 — 78.7 % [1].

Clinical study established the prdominance of men in the treatment failed group (TFG) comparing with cured group (CG) without achieving statisical difference. The sex distribution identified a male/female ratio = 5.27/1 in TFG and 2.44/1 in CG. Repartition of the patients into three age groups, identified that the largest represented was 18—34 years old in TFG and patients more than 55 years in CG. Comparing the groups it was established that the rate of young (18—34 years) patients, economical and reproductive active people predominated in the TFG: 27 (84.06 %) *vs.* 15 (24.19 %) in CG. Patients aged more than 55 years predominated in the CG 25 (40.32 %) vs 16 (21.18 %). So, distributing patients according to the biological characteristics it was argued that men and young age individuals have a bigger probability to fail the tuberculosis treatment and must be targed by the risk reduction measures. Demographic distribution identified that all the enrolled patients were originary from the Republic of Moldova and patients from urban area were more frequently cured than those from villages (table 1).

Distributing patients according to the economic status, it was established that employed persons were contributing to the health budget by paying taxes, health insurance policy and social taxes predominated in the CG comparing with the TFG. A low rate of disease disabled patients in all groups demonstrated that most of them had no social protection and financial income, despite the fact that multidrug-resistant form of tuberculosis permits social financial income. High rate of retired patients in the CG was due to the high rate patients aged more than 55 years. One student was identified in the CG. Unemployed patients were the majority of both groups, but statistically predominated in the TFG. Health insurance represents the major condition for accessing health care in the Republic of Moldova. Patients without inssurance were the majority of both groups but statisticaly predominated in the TFG. So, economical vulnerability of MDR-TB patients enhanced by the lack of health insurance and social protection must be corrected for improving treatment outcome (table 2).

Assessing the educational level it was established that most of the patients from both groups graduated general school or lyceum. More over other educational levels were similar distributed among groups. So, awareness and information about the importance of the adequate treatment compliance must be performed targeting all groups of patients (table 3).

Hierarchy of risk groups according to the widest rate of patients identified that the biggest impact on the developing MDR-TB treatment failure determined the patient's vulnerable economic status and living in poor conditions — 43 (62.32 %) followed by the comorbid state in 16 (23.18 %) cases and history of imprisonment identified in 14 (20.29 %) patients (table 4). Extreme poverty and history of migration during the last year predominated in the CG comparing with TFG, without achieving statistical threshold. Low rate of family

Table 2. **Socio-economic status of MDR-TB patients, p (%)**

Economic indices	State	TFG (1) (n = 69)	CG (2) (n = 62)	p_{value}
Stable	Employed	12 (17.39)	18 (29.03)	> 0.05
	Disable	3 (4.35)	4 (6.45)	> 0.05
	Retired	2 (2.89)	8 (29.03)	< 0.001
	Student	1 (1.45)	0	> 0.05
Vulnerable	Unemployed	51 (73.91)	32 (51.62)	< 0.001
	Lack of inssurance	51 (73.91)	32 (51.62)	< 0.001

Table 3. **Distribution of MDR-TB patients according to the last graduated level, p (%)**

Educational level	Educational status	TFG (1) (n = 69)	CG (2) (n = 62)	p_{value}
Illiteracy	No school attendance	3 (4.35)	3 (4.83)	> 0.05
Primary level	Primary & general incomplete school	15 (21.74)	18 (29.03)	> 0.05
Secondary level	Completed general school	40 (57.91)	35 (56.45)	> 0.05
	Profesional school	10 (14.49)	5 (8.06)	> 0.05
Higher education	Superior studies	1 (1.45)	1 (1.61)	> 0.05

Table 4. **Rate of high risk groups of MDR-TB patients, p (%)**

Risk groups		TFG (1) (n = 69)	CG (2) (n = 62)	p_{value}
SG	Poor living conditions	43 (62.32)	35 (56.45)	> 0.05
	Homelessness	6 (8.69)	11 (17.74)	> 0.05
	Migration	6 (8.69)	10 (16.13)	> 0.05
	History of detention	14 (20.29)	3 (4.83)	< 0.01
EG	Closed contact	5 (7.25)	5 (8.06)	> 0.05
MBG	Associated diseases	16 (23.18)	11 (17.74)	> 0.05
	HIV-infection	5 (7.25)	3 (4.84)	> 0.05

Note. SG — social group; EG — epidemiological group; MBG — medico-biological group.

TB clusters affiliated to each investigated patient in all groups was due to the low quality of epidemiological cross-examination. Patients with associated diseases were 16 (23.18 %) in TFG and 11 (17.74 %) in CG. Among associated diseases, HIV infection was established in 3 (7.25 %) cases of the TFG and 3 (4.84 %) cases in the CG.

So, the distribution of patients with pulmonary MDR-TB with different outcomes established the primary target groups in frame of which must be performed awareness, education, and improvement of health behavior are social and economical vulnerable groups, comorbid groups and individuals with history of imprisonment.

Studying case-management it was identified that general medical staff (National Primary Health Care) was involved in the detection of one half of both groups. The rate of patients identified using the microscopic examination of the symptomatic cases was similar in both groups. The rate of high risk groups investigated through active screening by general practitioners and pneumologists was low in both groups, fact demonstrating low disease control in vulnerable populations. Direct addressing to the hospital specialized services was used in a similar proportion of patients from both groups due to the lack of health insurance and accessibility in the primary health care sector (table 5).

Identifying the clinical radiological forms of pulmonary tuberculosis it was established that pulmonary infiltrative tuberculosis was diagnosed in the most of patients from both groups. Other radiological forms such as disseminated tuberculosis and fibro-cavernous tuberculosis predominated in a lower proportion the TFG. Distributing patients according to the number of the affected lungs it was established that one lung was involved in two third of the CG and both lungs were affected in two third of the TFG. Infiltrative opacities and destructive forms of pulmonary tuberculosis were identified in a similar proportion of both groups, but extensive forms of pulmonary tuberculosis predominated in the TFG (table 6).

When assessing the laboratory features of the enrolled MDR-TB patients, it was identified that one third of patients were microscopic positive for

Table 5. **Case-management characteristics of MDR-TB patients, p (%)**

Health level	Detection ways	TFG (1) (n = 69)	CG (2) (n = 62)	p_{value}
PHC	Detected by GPs-symptomatics	27 (39.13)	28 (45.16)	> 0.05
	Detected by GPs -screening of HRG	12 (17.39)	9 (14.51)	> 0.05
Ambulatory specialised level	Detected by SP-symptomatics	11 (15.,94)	9 (14.51)	> 0.05
	Detected by SP-screening of HRG	3 (4.35)	8 (12.91)	> 0.05
Hospital level	Direct addressing	10 (14.49)	8 (12.91)	> 0.05
Other	Other ways	6 (8.69)	0	> 0.05

Table 6. **Radiological characteristics of MDR-TB patients, p (%)**

Parametres	Detection ways	TFG (1) (n = 69)	CG (2) (n = 62)	p_{value}
Forms of TB	PIT	57 (82.61)	55 (88.71)	> 0.05
	PDT	8 (11.59)	4 (6.45)	> 0.05
	FCVT	4 (5.79)	3 (4.84)	> 0.05
Localisation	1 lung	28 (40.58)	48 (77.42)	< 0.001
	Both lungs	41 (59.42)	14 (22.58)	< 0.001
Features	Infiltration	24 (34.78)	15 (24.19)	> 0.05
	Lung destruction	45 (65.22)	47 (75.81)	> 0.05
	Extensive forms	39 (56.22)	12 (19.35)	< 0.001

Note. PIT — pulmonary infiltrative tuberculosis; PDT — pulmonary disseminated tuberculosis; FCVT — pulmonary fibro-cavernous tuberculosis.

Table 7. **Microbiological features of MDR-TB patients, p (%)**

Characteristics		TFG (1) (n = 69)	CG (2) (n = 62)	p_{value}
Mo	Microscopic positive	27 (39.13)	22 (35.48)	> 0.05
	Culture positive	48 (69.56)	41 (66.13)	> 0.05
	GeneXpert MTB/Rif positive	45 (65.22)	36 (58.06)	> 0.05
M intensive phase	Microscopic or culture positive	56 (81.16)	0	N/A
Other	Acquired XDR-TB	3 (4.35)	0	N/A

Note. Mo — smear microscopy at the treatment onset; M intensive phase — smear microscopy at the end of the intensive phase of the MDR-TB treatment 6th—8th month; N/A — non available.

acid-fast-bacilli at the treatment onset, two third were identified to have positive culture results (on solid Lowenstein-Jensen either liquide MGIT BACTEC). The resistance to the rifampicine through GeneXpert MTB/Rif assay was established in 45 (65.22 %) cases of TFG and 36 (58.06 %) cases of the CG. During DOTS-Plus regimen 3 (4.35 %) patients of MDR-TB developed XDR-TB (established through the acquired resistance to kanamycin and levofloxacin). Data were shown in the table 7.

An important research outcome represents the relative risk (RR), odds ratio (OR), likehood ratio (LR) and attributable risk (AR) indices for identifying the priority subgroups for treatment faillure in the frame of which the specific interventions could have an optimal outcome. It was established that major risk factors for MDR-TB treatment failure were characteristics of patient's social vulnerability: unemployment, lack of health insurance and social protection, followed by the history of detention, that contributes to the lack of the supportive measures after detention releasing. Disease related charctersitics as extensive forms of pulmonary tuberculosis, involving more than 3 lung segments and tuberculosis of both lungs showed the major impact on the treatment failure development (table 8).

Attributable risk percent established that the highest excess risk was determined by the history of detention followed by the disease-related charcateristics. Considering the fact that the likehood ratio was more than 10 for extensive, both-lungs tuberculosis it was established a large probability that those patients will outcome in treatment failure. Young age determined a small degree of risk and probability for treatment failure, but must considered in special regions were the treatment failure is high.

Conclusions

The standard treatment for new case of MDR-TB according to WHO recommendations in Republic

Tabel 8. **Risk factors for the treatment failure of the DOTS-Plus regimen**

Factors		Statistical indices			
		RR	OR	AR, %	LR
Age	18—34 years	1.36 (0.099—1.866)	2.01 (0.946—4.29)	38	3.384
Social status	Unemployment and lack of insurance	2.25 (1.467—3.446)	4.25 (2.112—8.551)	30	2.097
	History of detention	1.72 (1.276—2.283)	5.006 (1.364—18.368)	81	7.489
Disease-related charcteristics	Involvement of both lungs	1.76 (1.275—2.421)	3.97 (1.824—8.659)	63	12.971
	Extensive tuberculosis	2.04 (1.479—2.812)	5.42 (2.459—11.931)	66	19.73

Note. RR — relative risk; OR — odds ratio; AR — attributable risk; LR — likelihood ratio.

of Moldova is performed since 2005, lasts at least 18 months and showas a low rate of success.

The high rate of patients with low outcome is represented by those with treatment failure.

Major risk factors for MDR-TB treatment failure were characteristics of patient's social vulnerability and disease related charctersitics: extensive forms of pulmonary tuberculosis and involving more than 3 lung segments.

Highest excess risk was determined by the history of detention.

Patient's young age must considered in special circumstances were the risk of treatment failure is high.

Raising awareness among all MDR-TB patients about treatment compliance and earlier diagnosis will improve disease outcome.

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Фактори ризику невдачі лікування туберкульозу з множинною лікарською стійкістю

Стандартне лікування нових випадків туберкульозу з множинною лікарською стійкістю (МЛС-ТБ) відповідно до рекомендацій ВООЗ в Республіці Молдова проводиться з 2005 року і показує низький результат лікування. Насправді рівень успішного лікування збільшується за рахунок виключення пацієнтів з МЛС-ТБ із загальної когорти. Основна частина пацієнтів з низькими показниками результатів лікування представлена лікуванням, яке не вдалося, і втрачене в наступних випадках.

Мета роботи полягала в тому, щоб оцінити фактори ризику невдачі лікування МЛС-ТБ.

Матеріали та методи. Проведено ретроспективне вибіркове дослідження соціальних, демографічних, економічних та епідеміологічних особливостей ведення хворих, діагностики радіологічних аспектів та мікробіологічних характеристик 131 пацієнта з легеневим МЛС-ТБ, зареєстрованого у місті Кишиневі з 2010 по 2015 рік, з різними результатами.

Результати та обговорення. Встановлено, що основними факторами ризику втрати ефективності лікування були соціальна вразливість пацієнта і захворювання, пов'язані з характеристиками: великі форми туберкульозу легень і за участі понад 3 сегментів легень.

Висновки. Підвищення обізнаності пацієнтів з МЛС-ТБ, дотримання режиму лікування та рання діагностика поліпшить результати лікування.

Ключові слова: туберкульоз із множинною лікарською стійкістю, фактори ризику.

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Факторы риска неудачи лечения туберкулеза со множественной лекарственной устойчивостью

Стандартная обработка новых случаев туберкулеза со множественной лекарственной устойчивостью (МЛУ-ТБ) в соответствии с рекомендациями ВООЗ в Республике Молдова проводится с 2005 года и демонстрирует низкую эффективность лечения. Фактически частота успешного лечения увеличилась из-за исключения пациентов с МЛУ-ТБ из общей когорты. Основная часть пациентов с низкими показателями результатов лечения представляет собой неудачное лечение и утраченное для последующих случаев.

Цель работы заключалась в оценке факторов риска неудачи лечения МЛУ-ТБ.

Материалы и методы. Проведено ретроспективное выборочное исследование социальных, демографических, экономических и эпидемиологических особенностей ведения больных, диагностики радиологических аспектов и микробиологических характеристик 131 больного легочным МЛУ-ТБ, зарегистрированного в городе Кишиневе с 2010 по 2015 год, с различными исходами.

Результаты и обсуждение. Установлено, что основными факторами риска утраты эффективности лечения являются социальная уязвимость пациента и связанные с заболеванием характеристики: обширные формы туберкулеза легких и вовлечение более 3 сегментов легкого.

Выводы. Повышение осведомленности пациентов с МЛУ-ТБ, соблюдение режима лечения и ранняя диагностики улучшит исход заболевания.

Ключевые слова: туберкулез со множественной лекарственной устойчивостью, факторы риска.

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