УДК 547.828

CLINICAL COURSE AND EFFICACY OF TB TREATMENT DURING THE EPIDEMIC OF TUBERCULOSIS IN THE KHARKIV REGION

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Tuberculosis remains one of the most common infectious diseases in Ukraine. In recent times there are strains of Mycobacterium tuberculosis that are resistant to the action of TB drugs. In the past few years the incidence of tuberculosis in Ukraine stabilized [1].The number of patients with acutely progressive (APPT) pulmonary tuberculosis remains considerable.

In this regard endogenous intoxication syndrome (EISs) is one of the most important clinical indicators. Level of endogenous intoxication (EI) is an indirect measure of general severity of the patient. EI can be defined using a variety of systems (SOFA, SAPS, APACHE, etc.), but the process is quite time-consuming and technically difficult [2, 3].

The most important condition for improving the epidemic situation is increase in the treatment effectiveness. Another important condition is the isolation of pulmonary tuberculosis patients from possible contact with healthy people. In Ukraine, TB patients used to be treated at the hospital until the termination of their bacterial excretion and closing of cavities [4]. However, this approach has been revised since the start of the epidemic of tuberculosis in 1995.

Objective: To study the features of the clinical course of pulmonary tuberculosis, and the effectiveness of its treatment during the TB epidemic in the Kharkiv region.

Materials and Methods

413 patients (266 men and 147 women) of Kharkov City clinical TB hospital № 1 in the period from 2007 to 2009.. The main part of the group was of the working age: 206 people - up to 40, 114 - 40 to 50 years, 93 - over 50 years, 9 of them - over 70. Distribution of patients according to the clinical form of tuberculosis is shown in Table 1.

Table 1. The distribution of patients according to clinical TB forms.

TB-forms	TB-patients (group 1)
-total	413
- Focal TB	27
- disseminated TB	12
- infiltrative TB	286
- cheesy pneumonia	12
- miliary TB	2
- TB-pleurisy	11
- fibro-cavernous TB	45
- cirrhotic TB	7
- other TB-forms	11

The comparison group consists of 115 patients who were treated at the same hospital during the period 1993-1994 (up to the announcement of the TB epidemic in Ukraine).

All patients were thoroughly examined by radiographic and laboratory methods.

Statistical analysis of the study was performed with SPSS 20.

Descriptive statistics are presented as mean (M) and the error of the mean (m).

The critical level of statistical significance was assumed to be 0.05. The check sampling for distribution "normality" was performed using the Kholmogorov-Smirnov test. Univariate analysis of variance (ANOVA) was performed for normal distribution samples. When the null hypothesis between the groups deviated in ANOVA, the post-hoc Duncan test for identifying significant differences between the groups was used. If the samples were not subject to the "normal" distribution, we used the Kruskal and Wallis H-test method. Contingency table analysis was carried out using Pearson's xi-square test.

Results and discussion

In recent years the TB incidence in the Kharkiv region (as well as in Ukraine) tends to decrease. However, the epidemic situation remains difficult. Among first-time TB cases, the number of those who have bacterial excretion and destruction of lung tissue remains significant. Obviously, there is a strong intoxication syndrome in this case. In the presence of endogenous intoxication developing general condition of patients with TB can be defined as highly variable. In this regard, it is important to consider the condition of the patient, age, degree of defense reactions (non-specific and specific), and the presence of comorbidities [2] The correct choice of detoxification, as well as a reasonable forecast of the disease is almost impossible without an objective assessment of the level of endogenous intoxication. Level of endogenous intoxication can be defined (in points) with some tests.

Hematological toxicity index (HTI) was obtained on the basis of an extended blood count.

HTI was calculated by the formula of V. Vasiliev et al. (1984) with the multiplication of leukocytic intoxication index (LII) to the level of white blood cells (K_{WBC}), ESR (K_{ESR}) [5], the level of red blood cells (K_{RBC}), and platelets (K_P) [6].

$$HTI = LII \times K_{WBC} \times K_{ESR} \times K_{RBC} \times K_P.$$

$K_{WBC} = 1$ when the WBC number is from 4.0 to $8.0 \cdot 10^9$/l. K_{WBC} increases by 0.1 with WBC number increasing 1.0×10^9/l above the norm.

$K_{ESR} = 1$ when the ESR is from 2 to 15 mm/hour. K_{ESR} increases by 0.1 when ESR increases by every 5 mm above the norm. K_{ESR} increases by 0.2 whereas ESR exceeds 30 mm/hour.

$K_{RBC} = 1$ when the number of red blood cells is more than 4.0 but less than 5.5×10^{12}/l. K_{RBC} increases by 0.1 when reducing the amount of RBC to 0.1×10^{12}/l below normal.

K_P is 1 when the number of platelet is more than 180 but less than 320×10^9/l. Due to the decrease in platelet count 10.0×10^9/l below normal K_P increases by 0.2.

$K = 1$ if it was impossible to calculate it.

Normal HTI = 0.2 - 1.2 (average - 0.61 ± 0.025) data were established from clinical blood tests for 144 healthy individuals.

HTI values were found and analyzed for 413 patients with various forms of tuberculosis. It was found that 235 patients (56.9%) had the destruction of lung tissue, respectively, 178 (43.1%) patients did not have it. We determined the value of the HTI before treatment and at 3 and 6 months into the study.

Table 2. HTI of TB patients with the lung tissue degradation and with none

Hematologic toxicity index	Destruction presence	Before treatment (patients, mean and variance)	During treatment	
			After 3 months (patients, mean and variance)	After 6 months (patients, mean and variance)
HTI	Destr -	178 1.80±0.37	154 0.97±0.22	123 0.81±0.07
	Destr +	235 3.59±0.43	172 2.81±0.48	134 2.88±0.57

It was found that in patients with the presence of lung tissue destruction pre-treatment HTI were significantly different from pre-treatment HTI in patients without destruction (p <0.01). The average HTI in patients without destruction was found to be normal after three months of treatment, and in patients with destruction it was still higher than normal. After 6 months of treatment HTI in patients with destruction was significantly higher than normal (p <0.05) and accounted for 80.22% of the pre-treatment HTI rate.

We studied several groups of patients (with a total size of destruction to 3 cm, from 3.0 cm to 5 cm, more than 5 cm as well as a group of patients without the destruction of lung tissue). Thus we have found the existence of a certain relationship between the size of lung destruction and HTI.

Table 3. HTI dependence versus lung tissue destruction

Total size of destruction	HTI	Before treatment (patients, mean and variance)	During treatment	
			After 3 months (patients, mean and variance)	After 6 months (patients, mean and variance)
0 (Destr-)	HTI	178 1.71±0.35	154 0.97±0.21	123 0.81±0.07
Up to 3 cm.	HTI	164 2.52±0.39	120 2.19±.59	90 1.34±0.22
3.1cm to 5 см	HTI	28 3.62±0.84	20 2.64±1.35	16 1.15±0.34
> 5 см	HTI	43 7.73±1.61	32 5.12±0.96	28 8.50±2.35

Significant difference HTI (p <0.01) was found when comparing HTI levels in patients with lung tissue destruction size greater than 5cm and HTI in patients with total size of destruction less than 5 cm. After six months of chemotherapy HTI was recorded in the normal range in patients with no destruction, as well as those who had the size of destruction more than 3.0cm but less than 5cm. HTI slightly exceeded the upper limit of normal in patients with lung destruction of up to 3cm.

TB endointoxication is caused not only by lung tissue destruction and catabolism increasing, but also liver and kidney dysfunction, due to the influence of both the disease and the side effects of chemotherapy. Especially these processes are expressed in patients with MDR TB where Mycobacterium tuberculosis (MBT) are resistant to the two most active TB drugs - isoniazid and rifampicin.

Bacterial excretion (MBT+) was detected in 250 of 413 patients (60.5%), of which 118 patients (47.2%) had the sensitivity to TB drugs («resistant»). 13 patients

(5.2%) were resistant to one of TB drugs (mono-resistant), 98 patients (39.2%) had MDR TB, 21 (8.4%) - were resistant to more than one anti-TB drug (of the first line) except both isoniazid and rifampicin (MDR-TB multi-resistant) [7]. HTI values in patients were determined prior to treatment and after 3 and 6 months of chemotherapy.

Table 4. Haematological indexes in pulmonary tuberculosis patients depending on their MBT sensitivity

MBT sensitivity	HTI before treatment	HTI during treatment	
		After 3 months (patients, mean and variance)	After 6 months (patients, mean and variance)
MBT (Resist 0)	168 1.26±0.13	146 0.82±0.13	117 0.74±0.07
MBT+ (Resist-)	118 2.70±0.57	88 2.46±0.80	64 1.16±0.27
Monoresistant TB	13 6.43±3.61	9 0.86±0.13	2 0.64±0.49
PolyresistantTB	21 3.63±1.19	14 1.38±0.30	12 1.90±0.75
MDR-TB	98 4.87±0.81	73 3.72±0.68	64 4.70±1.11

Prior to treatment, mono-resistant patients had the highest average level of HTIs. But it was normal after three months of chemotherapy and after 6 months HTI decreased even more. The slowest involution was recorded in the MDR-TB group. Although HTI fell slightly after three months of chemotherapy, but rose again after six months of treatment.

Statistical analysis using non-parametric methods revealed significant differences between the average levels of HTI in patients with sensitive MTB strains and MDR-TB patients.

Thus, it may be noted that in recent years the destructive pulmonary tuberculosis was torpid. This is caused not only by the vast lung tissue destruction and immunologic disorders, but also by the increasing number of chemoresistant MBT strains primarily MDR-TB ones.

Patients with acutely progressive pulmonary tuberculosis are the most difficult group. Acutely progressive pulmonary tuberculosis (APPT) is a term, that describes some different clinical respiratory system TB-forms. APPT is characterized by the acute disease onset, severe progressive course, pronounced intoxication syndrome aswell as the prevalence of exudative caseous tissue reaction, extensive lesions and the rapid formation of of lung tissue destruction [8].

Typically the clinical picture of the disease is characterized by severe intoxication syndrome, severe manifestations of bronchopulmonary disease, respiratory failure, deep disturbances of all homeostasis functional systems, as well as rapid progress, often leading to death. Often unfavorable outcome of APPT is determined by the severity of intoxication syndrome [9].

Table 5. The distribution of APPT patients depending on the clinical TB forms

TB-forms	group 2 (years 2006 to 2009)	group 1 (years 1993 to 1995)
- total	100	115
- disseminated TB	13	11
- infiltrative TB	75	74
- cheesy pneumonia	12	30

Intoxication syndrome was identified in all TB-patients. Average pre-treatment HTI was different from the average normal (p <0.001) significantly. We analyzed the value of HTI in patients with different clinical TB-forms before treatment as well as after 3 and 6 months of treatment. The results are summarized in the following table.

Table 6. HTI dynamics in patients with different TB-forms during chemotherapy

TB-forms, experimental group		HTI before treatment	HTI after 3-month treatment	HTI after 6-month treatment
disseminated TB	Group 1	2.46±0.26	1.89±0.16	0.83±0.09
	Group 2	3.35±1.06	1.80±0.53	2.46±1.18
infiltrative TB	Group 1	2.76±0.28	1.17±0.13	0.84±0.13
	Group 2	5.25±0.90	2.40±0.67	1.71±0.33
cheesy pneumonia	Group 1	7.95±1.29	3.25±0.46	0.72±0.06
	Group 2	6.03±1.21	3.38±1.09	10.41±4.81

Pre-treatment degree of EI was noted the same in both groups of patients - with disseminated tuberculosis and caseous pneumonia. It was recorded II degree of pre-treatment EI (HTI - 2.76 ± 0.28) in group of patients with infiltrative TB treated in 1993-1995, and III degree of EI (HTI - 5.25 ± 0.90) in patients treated in 2006-2009 respectively.

Downward EI trend was observed in both groups after 3 months of treatment. However, after 6 months of treatment in the first group all patients HTI decreased to the normal, while in the group of patients with infiltrative tuberculosis HTI slightly exceeded the norm while maintaining the overall downward EI trend.

EI was determined depending on the pre-treatment HTI taken in both groups. We have studied the HTI dynamics in groups of patients with varying EI degrees during treatment. The observations can be seen in Table 7.

Table 7. HPI dynamics in group of TB-patiens with varying degrees of EI during the treatment

Experimental group, EI –degree		Before treatment (patients, mean and variance) n x±$S_{x)}$	During treatment	
			After 3 months n x±$S_{x)}$	After 6 months n x±$S_{x)}$
I EI degree	Group 1	11 1.51±0.16	11 0.67±0.05	8 0.66±0.03
	Group 2	17 1.13±0.09	15 1.51±0.52	12 2.49±0.93
II EI degree	Group 1	60 2.96±0.33	56 1.3±0.12	47 0.91±0.13
	Group 2	49 2.15±0.08	36 1.55±0.27	29 1.34±0.45
III EI degree	Group 1	44 6.25±1.08	40 1.98±0.29	34 0.72±0.06
	Group 2	32 9.62±1.10	23 4.23±1.56	19 4.51±2.11
IV EI degree	Group 1	0 -	0 -	0 -
	Group 2	2 38.65±7.75	1 1.01±0	0 -

I-st, II-nd and III-rd degree of EI were recorded in the first group of patients. In the I-st EI degree group HTI was normal after 3 months of treatment, in 2-nd and 3-rd grade EI groups HTI normalized after 6 months of chemotherapy.

EI of all four degrees was found in the second group of patients. There was not HTI normalization at neither 3 nor 6 months after treatment. However, there was a downward HTI trend in 2-nd degree EI group after 3 months of treatment. After 6 months of treatment the HTI was found below then its pre-treatment level (p <0.05). After 3 months of anti-TB therapy in group of patients with first EI degree HTI rose, matching the 2-nd EI degree, and it became even higher after 6 months of treatment.

Thus, there has been rapid regression of intoxication syndrome in group of APP-TB patients treated in 1993-1995. After 6 months of chemotherapy HTI significantly decreased to normal. It was observed slow regression of intoxication syndrome in group of APP-TB patients treated in 2006-2009. Thus, EI remained after 6 months of treatment and HTI was higher than normal. After 3 and 6 months of chemotherapy in group of patients with first before-treatment EI degree EI increased, corresponding to the second degree of EI.

In modern epidemiological conditions where morbidity and mortality rates remain significant, the main organizational form of treatment is treatment in hospital. That hospital has the most favorable conditions for examination and confirmation of the diagnosis, clarify the activity of tuberculosis, determine the treatment plan and its implementation. For a long time it was considered necessary to continue treatment in the hospital until smear-negative result and closing of cavities [10].

We examined the effectiveness of in-patient treatment, depending on the clinical TB-forms (Table 8). The conclusions on improving the condition of the patient were made on the basis of clinical data (complaints and objective condition of the patient, the degree of intoxication syndrome), X-ray data (closing or reducing the size of lung tissue destruction, resorption or decrease: focal, infiltrative, or fibrosis) and laboratory data (cease of smear-positive, normalization or improvement in blood count). Conclusions about the unchanged patient's condition ("no changes") or a worsening of the patient have been made based on the same parameters. The recovery group included patients who were discharged from the hospital with the ending of the temporary disability and a work-resumption permit.

Table 8. The treatment effectiveness depending on dlinical TB-forms

TB-forms	Patients				
	total	recovery	no changes	deterioration	death
Focal TB	27 100%	23 85.2%	4 14.8%	0	0
disseminated TB	12 100%	6 50%	5 41.7%	0	1 8.3%
infiltrative TB	286 100%	206 72.0%	51 17.8%	8 2.7%	21 7.5%
cheesy pneumonia	12 100%	5 41.7%	4 33.3%	0	3 25%
miliary TB	2 100%	1 50%	0	0	1 50%
TB-pleurisy	11 100%	8 72.7%	3 27.3%	0	0
fibro-cavernous TB	45 100%	9 20%	20 44.4%	0	16 35.6%
cirrhotic TB	7 100%	4 57.1%	3 42.9%	0	0
other TB-forms	11 100%	4 36.4%	5 45.4%	0	2 18.2%
Total	413 100%	266 64.72%	95 22.63%	8 1.95%	44 10.70%

The treatment effectiveness of the patients with focal (85.2%), infiltrative tuberculosis(72.0%) and tuberculous pleurisy (72.7%) was significantly higher in comparison with other forms of pulmonary tuberculosis (p <0.05). The lowest efficiency was observed in patients with fibro-cavernous pulmonary tuberculosis.

The concept of the National Anti-TB Programme 2012-2016 provides for complete recovery 70% of newly diagnosed TB patients [11]. We examined the in-patient treatment effectiveness, depending on the TB type in the following groups of patients: newly diagnosed tuberculosis (ND-TB), relapse of tuberculosis (R-TB), chronic tuberculosis (C-TB) and the residual changes in tuberculosis (RC-TB) [12].

Table 9. The treatment effectiveness depending on the TB-type

TB-type	Patients					
	total	Full recovery	partial improvement	No changes	deterioration	death
ND-TB	274 100%	19 6.9%	190 69.3%	45 16.4%	4 1.5%	16 5.8%
R-TB	68 100%	4 5.9%	31 45.6%	21 30.9%	3 4.4%	9 13.2%
C-TB	60 100%	0	18 30.0%	24 40%	1 1.7%	17 28.3%
RC-TB	11 100%	0	4 36.4%	5 45.4%	0	2 18.2%
Всего	413 100%	23 5.56%	243 58.84%	95 23%	8 1.94%	44 10.66%

The table shows that the treatment effectiveness of ND-TB patients was significantly higher (69.3%) compared with R-TB, C-TB and RC-TB - 45.6%, 30.0% and 44.4%, respectively (p <0.05)

We believe that the achievement of the above goal of 70% recovery of patients is quite possible, if the in-patient treatment success will be fixed at the out-patient and health-resort treatment stages. At the same time, patients are discharged from the hospital without positive dynamics can be seen as a reserve for the treatment efficiency improvement, Thus, 22 such patients (group of 45 persons) were discharged for voluntary departure, 19 - transferred to other hospitals, and only 4 - to out-patient treatment.

247 patients with positive sputum (from the group of 250) were tested for sensitivity to TB drugs. The results of treatment in this group are summarized in Table 10.

Table 10. Effectiveness of the treatment depending on MTB sensitivity to TB drugs

MTB sensitivity	TB-patients				
	total	partial improvement	No changes	deterioration	death

sensitivity to all TB-drugs	117 100%	77 65.9%	30 25.6%	0	10 8.5%
Mono-resistant TB	13 100%	7 53.8%	3 23.1%	1 7.7%	2 15.4%
Poly-resistant TB	21 100%	9 42.9%	10 47.6%	0	2 9.5%
MDR-TB	96 100%	33 34.4%	34 35.4%	6 6.2%	23 24%
Total	247 100%	126 64.5%	77 31.2%	7 2.8%	37 15%

Among patients discharged from the hospital, significantly better efficacy was observed in patients with sensitivity to all TB drugs -77 (65.9%) as well as in patients with mono-resistant MBT - 7 (53.8%), compared with patients with poly-resistant MTB 9 (42.9%) and MDR-TB -33 (34.4%), respectively (p <0.05).

In patients with MDR-TB, more often than other groups recorded deterioration of dynamics and a high mortality rate - in 6 (6.2%) and 23 (24%), respectively (p <0.05) (Table 3).

During the period of treatment of 232 patients admitted to hospital with lung tissue destruction, its closure was only reached in 135 (32.2%) patients. In this case, the closure of the destruction was achieved in 57 (47.1%) patients with MBT sensitivity to all TB drugs, in 5 patients (4.1%) with monoresist-TB, in 48 (39.7%) patients with poly-resistant TB and in 11 patients with MDR-TB (9.1%).

By the end of inpatient treatment sputum positive was recorded in 78 patients (31.2%).

Thus, it can be noted that in the last decade, during the TB-epidemic in the Kharkov region at low levels of a large part of the population some problems in the TB-treatment are retained.

The situation is aggravated by the prevalence of destructive TB-forms, MTB drug resistance to TB-drugs, and as a result - large proportion of MDR-TB.

Sputum positive patients as well as those who have lung tissue destruction are a significant portion of TB-patients to be hospitalized. By the end of inpatient treatment sputum negative group of patiens was 68.8%, closing the destruction was achieved in 58.2% of patients with the destruction of lung tissue.

Conclusions

1. During the TB-epidemic in the Kharkiv region tuberculosis is characterized by common destructive TB-forms (56.9%), increase in MBT resistance to TB drugs, a large proportion of MDR-TB(39.2).

2. Regression of intoxication syndrome in group of APTB-patients during the epidemic was recorded more slower than before the epidemic. Detoxification therapy for APTB-patients should be carried out continuously. Intensive detoxification therapy is needed not only for patients with severe intoxication syndrome, but also when it is poorly defined.

3. TB treatment in the hospital can achieve sputum negative result in the majority of patients (68.8%), closure of destruction can be achieved in

58.2% of patients with lung tissue destruction. The lowest treatment efficiency and the highest mortality rate were observed in patients with MDR-TB.

4. Hematologic Toxicity Index (HTI) is a very informative indicator, which does not require additional research and also has a high sensitivity that can detect the presence of even minor destructive processes in the lungs.

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CLINICAL COURSE AND EFFICACY OF TB TREATMENT DURING THE EPIDEMIC OF TUBERCULOSIS IN THE KHARKIV REGION.

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The subject of the study was the clinical course of tuberculosis and the treatment effectiveness of patients during the TB epidemic in the Kharkiv region. Hematological toxicity index was defined in 413 patients. The treatment effectiveness was studied in its relation to the clinical form of tuberculosis, the presence of destruction of lung tissue, bacterial excretion, as well as the presence of resistance to TB drugs.

Keywords Destructive pulmonary tuberculosis, endogenous intoxication, hematology toxicity, TB treatment efficacy

ОСОБЕННОСТИ КЛИНИЧЕСКОГО ТЕЧЕНИЯ И ЭФФЕКТИВНОСТИ ЛЕЧЕНИЯ БОЛЬНЫХ ТУБЕРКУЛЕЗОМ В ПЕРИОД ЭПИДЕМИИ В ХАРЬКОВСКОМ РЕГИОНЕ

Лебедь Л.В., Киреев И.В., Потейко П.И., Ляшенко А.А., Крутько В.С., Сокол Т.В.

Изучены особенности клинического течения и эффективности лечения больных туберкулезом в период эпидемии в Харьковском регионе. У 413 больных определен гематологический показатель интоксикации, изучена эффективность стационарного этапа лечения в зависимости от клинической формы туберкулеза, наличия деструкции легочной ткани, бактериовыделения и устойчивости к противотуберкулезным препаратам.

Ключевые слова Деструктивный туберкулез легких, эндогенная интоксикация, гематологический показатель интоксикации, эффективность лечения