The experience in tuberculous spondylitis treatment taking into account the susceptibility of mycobacteria tuberculosis to antibacterial medicines

Objective — to increase the effectiveness of treatment of patients with tuberculous spondylitis (TS), to improve the etiological diagnosis and operative treatment of patients with TS.

Materials and methods. The data of 60 patients with active TS of the thoracic and lumbar vertebrae, operated in the osteoartikular tuberculosis department of Kharkiv Regional Antituberculosis Dispensary No. 1 and Traumatology and Orthopedics department of Kharkiv Municipal Clinical Emergency Care Hospital named after A.I. Meshchaninov in the period 2014—2019. Patients were divided into the main and control groups (n = 30). The main group includes patients with TS operated with the use of a telescopic titanium cage for ventral interbody spondylodesis after necrosequestrectomy. The group II (control group) included patients treated with using traditional approaches to TS treatment.

Results and discussion. Bacteriological confirmation of the diagnosis was obtained in 40.0 % of patients of the control group, of which 20.0 % of mycobacterium tuberculosis (MBT) were isolated only by culture, 13.3 % only by bacterioscopy, and in 6.7 % of cases positive results were obtained using two methods. In patients of the control group, the largest number of positive results was obtained from the contents of abscesses — in 30.0 % of patients, with pus on tampons and secretions from fistulas — in 6.7 % (p < 0.01), from operative material (granulations and caseous masses) — in 16.7 %.

Among the patients of the control group, bacteriological confirmation was obtained in 10 (33.3 %) patients. Diagnostic puncture biopsy of vertebral bodies, used in 17 diagnostic patients, made it possible to diagnose cancer metastasis in the vertebral body in one (5.9 %) case, in three (17.6 %) — primary tumors of the spine, in 9 (52.9 %) patients — tuberculosis and 4 (23.6 %) — non-specific osteomyelitis of the spine. This study was performed by the method of diagnostic percutaneous trepanobiopsy of the vertebral bodies with the help of electronic-optical converter through the posterior access through the root of the affected vertebral arch.

The long-term results of TS treatment were studied in 26 patients of the main group (86.7 %) and in 25 patients of the control group (83.3 %) in the period from 1 to 10 years. Long-term results of treatment were evaluated using a generally accepted scoring scale.

Conclusions. The new method of TS treatment in the main group compared to traditional standards of surgical interventions in the control group allowed: 1) to avoid the progression of TS, the development of complications of the disease (p < 0.05) and complications related to the transplant (fractures, displacement of the autograft, cage) (p < 0.05), in the early postoperative period; 2) significantly increase the effectiveness of treatment due to an increase in excellent results (46.7 and 26.7 %, respectively) and a decrease in satisfactory (13.3 and 23.3 %) and unsatisfactory (0.0 and 10.0 %; p < 0.05) of the results in the remote terms of observation; 3) significantly shorten the inpatient stage of treatment ((96 ± 12) and (190 ± 21) bed-days; p < 0.001).

Keywords
Etiological diagnosis of tuberculous spondylitis, bacteriological studies, anterior spondylodesis with a sliding titanium cage, results of operative treatment of tuberculous spondylitis.
In Ukraine the share of extrapulmonary localizations of tuberculosis is approximately 10% in the overall structure of tuberculosis cases. In today’s epidemiological situation, osteoarticular tuberculosis (OATB) takes the first place in the structure of the incidence of extrapulmonary tuberculosis in our country and spinal tuberculosis takes the first place in the structure of bones and joints lesions [2, 5].

Tuberculous spondylitis (TS) in the structure of OATB in adults occupies a leading position and reaches the level of 40.0–61.5%. The main manifestations of a specific inflammatory process in the spine are the vertebrae destruction, which leads to the spine stability violation, the development of its deformations, chronic back pain, and general somatic reactions. In 40–75% of cases, spinal inflammatory diseases occur with neurological complications of varying severity degrees [1–5, 8, 10].

To date, disability due to TS among all localizations of OATB is 53.5% [1, 3, 7, 11].

It is known that a fundamentally important condition for the successful treatment of TS is the timely diagnosis of this disease before the development of such formidable complications: neurological deficit, overflow abscesses, fistulas, spinal deformity and etc. [2, 6, 9].

The diagnosis of spinal tuberculosis is based on the comparison of clinical, laboratory, bacteriological, radiological data and the results of new methods of diagnostic radiology [1, 2, 8, 11].

All diagnostic methods can be divided into two main types: detection of characteristic changes in the tissues of the musculoskeletal system and detection of the tuberculosis causative agent. Direct and indirect diagnostic methods are distinguished respectively. To detect characteristic changes in the tissues of the locomotor apparatus, direct methods are morphological and X-ray methods, indirect methods are classical methods of examining the patient, laboratory studies, methods of functional diagnostics. To detect the causative agent and its identification, direct diagnostic methods as microscopy, culturing media, molecular diagnostics are used and indirect — tuberculin diagnostics, antigens determination, determination of anti-tuberculosis antibodies — enzyme-linked immunosorbent assay (ELISA).

The introduction of surgical methods of treating spondylitis into practice did not provide a significant reduction in the duration of treatment and a reduction in disability, which is caused primarily by the duration of preoperative antibacterial therapy (ABT) against the background of strict bed rest for 3–6 months, insufficient radicalism of resection of the focus of destruction, the duration of postoperative bed rest up to 2–4 months.

With existing treatment methods, the length of stay of patients with limited forms of TS in the hospital reaches 6–8 months and the formation of a bone block between the resected vertebral bodies ends after 1.5–2.0 years [1, 2, 4, 7, 9, 10].

It is necessary to search for ways of shortening the period of patients preoperative preparation, as well as the possibility of their early activation after surgical intervention, which will make it possible to significantly reduce the inpatient stage of treatment. The question of the necessary and sufficient duration of preoperative treatment, the possibility of using modern methods of anterior spondylodesis remains unresolved; the influence of modern specific ABT on the course of tuberculous spondylitis has not been fully studied.

**Objective** — to increase the effectiveness of treatment of patients with tuberculous spondylitis, to improve etiological diagnosis and operative treatment of patients with tuberculous spondylitis.

### Materials and methods

Clinical research material — protocols of clinical and radiological examination, the analysis of treatment results of 60 patients with active tuberculous spondylitis of the thoracic and lumbar vertebrae, operated on at the clinical bases of the Department of Traumatology and Orthopedics of KhNPU in the osteoarticular tuberculosis department of Kharkiv Regional Antituberculosis Dispensary N 1 and Traumatology and Orthopedics department of Kharkiv Municipal Clinical Emergency Care Hospital named after A.I. Meshchaninov in the period 2014–2019 (patients without bacterial contamination, without fistulas, connecting tuberculous lesions of the lungs). The treatment of TS in all patients was carried out with the consultative assistance of a phthisiologist and included preoperative preparation, performing radical decompressive and stabilizing operations: necrosequestrectomy, decompression of the neural and vascular structures of the spinal canal followed by interbody spondylodesis.

Depending on the approaches to preoperative preparation and the method of surgical stabilization of the spine destructive specific process, 60 patients were divided into the main and control groups (n = 30). The group I includes patients with TS operated with the use of a telescopic titanium cage for ventral interbody spondylodesis after necrosequestrectomy. A feature of the preoperative preparation of patients of the I group was mandatory etiological diagnosis before the start of treatment with the determination of the susceptibility of *mycobacterium tuberculosis* (MBT) to antibacterial medicines (ABM), the prescription of a short-term preoperative course of specific ABT taking into account the
results of etiological diagnosis within 2—3 weeks, followed by surgical intervention. The basis for such a short period of preoperative preparation was the results of our experimental study [2].

The control group II included patients treated with using traditional approaches to TS treatment — preoperative preparation using 3—5 specific ABM of the first line without determining susceptibility for 2—3 months with subsequent surgical intervention — decompressive necrectomy of the affected vertebrae and anterior spondylodesis with an autograft from a rib fragment (thoracic access) or from the iliac bone wing (retroperitoneal access). The II group of patients was analyzed retrospectively (patients who were in the osteoarticular tuberculosis department of the Kharkiv Regional Tuberculosis Hospital N 1 in 2003—2008 and who were treated according to the Order of the Ministry of Health of Ukraine N 499 of 28/10/2003 current at that time).

Criteria for inclusion in the study: tuberculous spondylitis in the active phase (verified morphologically and/or bacteriologically).

Exclusion criteria from the study: age over 75 years; spinal operations in the anamnesis; the presence of decompensated accompanying (NOT tuberculous) lesions.

In terms of age, gender, number of affected vertebral motor segments, activity of the infectious inflammatory process, the patients of both groups are practically identical, so it is considered quite correct to compare the results of treatment of patients of both groups in the near (3 months) and distant periods (1—2 years).

In groups I and II 66.4 % (20) and 59.94 % (18) of male patients, 33.4 % (10) and 40.06 % (12) of women, respectively (Table 1).

The average age of patients in the main group and the comparison group was (38.2 ± 9.6) and (40 ± 10.8) years, respectively (p > 0.05).

When comparing the age indicators in both groups, the following feature was revealed. It has been established that young patients from 20 to 30 years old are significantly less susceptible to TS disease than people over 40 years old. In elderly patients the disease was also observed relatively rarely. Thus, the development of TS is most typical for persons of mature age.

The division of patients according to the location and the number of affected vertebrae is given in Table 2.

Connective tuberculous lesions were observed in 20.0 % of patients of the group I and 26.7 % of the group II. TS was accompanied by: pulmonary tuberculosis (10.0 and 16.7 % of cases, respectively), as well as tuberculosis of the genitourinary system, lymph nodes, and skin (3.3 % of observations in each of the groups for each localization).

Fistular form of TS was found in 16.7 % of patients in group I and in 20.0 % in group II.

In terms of age, gender, the number of affected spinal motor segments, the activity of the specific inflammatory process, the patients of both groups did not have a probable difference, therefore, the

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comparison of the results of the treatment of patients of both groups in the near (3 months) and distant periods (1–2 years) is considered quite correct.

During clinical studies, a standard orthopedic examination and study of the neurological status according to the ASIA clinical scale were performed [3, 4].

From the radiodiagnostic methods the survey spondylography in two projections, computed tomography (CT) and magnetic resonance imaging (MRI) were used. In the case of fistulas, fistulography was performed in a specialized anti-tuberculosis institution.

A puncture of an overflowing abscess, discharge from a fistula (for fistula forms of TS) were used for the etiological laboratory diagnosis of tuberculosis in both groups of patients, as well as in group I – pathological material taken during a percutaneous puncture and trepanation biopsy of the bodies of the affected vertebrae (9 patients). Punctures of para-vertebral abscesses were performed in 21 patients. Puncture biopsy of the vertebral bodies was performed under the control of the electron-optical converter (EOC) and X-ray, applied in 17 diagnostic patients. Puncture of retroperitoneal abscesses was performed under ultrasound control. The examination using surgical biopsy techniques from obtaining the material to establishing the diagnosis lasted from 2–3 days to 2 weeks.

Methods of laboratory diagnostics, which were carried out in the certified laboratories of Kharkiv Regional Antituberculosis Dispensary N I together with a bacteriologist, included:

– the molecular-biological method of rapid determination of the presence of MBT in pathological material and susceptibility to ABM using polymerase chain reaction (PCR) was reformed only in patients of the main group. Studies for the detection of *M. tuberculosis*-complex DNA were conducted in 45 samples of pathological biopsy material taken from foci of destruction (in a number of cases, several samples were taken from one patient);

– methods of bacteriological examination of the pathological material of patients of both groups using direct microscopy of smears and microscopy of smears prepared after enrichment (centrifugation, flotation, microflotation) with subsequent Ziehl–Neelsen staining or fluorescent dyes;

– for histological studies, the surgical material of TS patients of both groups (bone sequestrations, necrotized areas of bone, granulations, pyogenic membranes of overflow abscesses, etc.) was fixed in a 10 % formalin solution. Then the soft tissues were embedded in paraffin and the bone tissue was decalcified in 5 % nitric acid solution and embedded in celloidin. Sections were stained with hematoxylin-eosin and picrofuchsin according to Van Gieson and light-optical research was performed.

For the treatment of TS patients on the basis of traditional approaches (control group), operative treatment methods were used, including the remediation of abscesses, resection or necroctomy of the focus of destruction, stabilization of the affected parts of the spine with the help of anterior or antero-lateral spondylosis with an autograft, immobilization and unloading of the spine in the pre- and postoperative period using bed rest.

The fundamental differences in the treatment of patients in the main group were as follows:

1) mandatory study of the pathological material of the focus of destruction with the determination of the susceptibility of MBT to ABT;

2) a short-term course of intensive ABT for 2–3 weeks, taking into account the sensitivity of the MBT to ABM;

3) during the surgical intervention, a sliding telescopic titanium cage was used instead of an autograft.

Telescopic body replacement implants allow to provide:

– restoration of the height of the interbody space;

– fixation and stabilization of the supporting columns of the spine;

– individually select ending parts according to the anatomy of the patient’s spine;

– to correct the sagittal deformation of the spine due to the possibility of distraction.

It is important to note that surgical interventions for patients of both groups were performed as a stage of treatment, after basic antibacterial and pathogenic therapy.

For surgical interventions on the thoracic and lumbar regions of the spine, preference was given to anterior approaches.

Below a clinical example of surgical treatment of TS in the lumbar spine using autografts in patients of the control group is provided (Fig. 1).

After the remedial stage of surgery, patients of both groups underwent anterior spondylosis using an autograft (the control group) or a sliding titanium cage (the main group).

Clinical examples of surgical treatment of TS in the lumbar spine using a sliding telescopic cage are given (Fig. 2).

**Results and discussion**

Results of etiological diagnosis. Bacteriological confirmation of the diagnosis was obtained in 40.0 % of patients of the control group, of which 20.0 % of MBT were isolated only by culture, 13.3 % only by
bacterioscopy, and in 6.7% of cases positive results were obtained using two methods.

The analysis of the informativeness of the results of bacteriological examination of various pathological material in patients of the control group showed that the largest number of positive results, both by the method of culture and bacterioscopic, was obtained from the abscesses content — in 30.0% of patients. Pus on tampons and discharge from fistulas had a significantly lower number of positive results — in 6.7% of cases (p < 0.01). Also, a low frequency of MBT separation was found in the operative material, including granulations and caseous masses — in 16.7%. Among the patients of the group I, bacteriological confirmation was obtained in 10 (33.3%) patients.

Thus, the conducted bacteriological studies confirm the data of other authors that a feature of any pathological material in OA TB is its oligobacillary nature [1, 8, 10]. This determines a great thoroughness in conducting microbiological research and the need to improve bacteriological methods of diagnosing OATB.

When carrying out etiological diagnosis in the patients of the main group, punctures of paravertebral abscesses were performed in 21 patients with a positive result in 52.4% of cases. The detection of bacterial flora or MBT (PCR or bacteriologically) in the punctate was considered a positive result, however, their absence could not testify against TS diagnosis.

Diagnostic puncture biopsy of vertebral bodies, used in 17 diagnostic patients, made it possible to diagnose cancer metastasis in the vertebral body in one (5.9%) case, in three (17.6%) — primary tumors of the spine, in 9 (52.9%) patients — tuberculosis and 4 (23.6%) — non-specific osteomyelitis of the spine. This study was performed by the method of diagnostic percutaneous trepanobiopsy of the ver-
tebral bodies with the help of image intensifier through the posterior access through the root of the affected vertebral arch.

Thus, the use of surgical biopsy techniques in spondylitis and other spine diseases of uncertain etiology allows avoiding diagnostic errors in most observations and significantly shortens the period of preoperative examination to 2 weeks instead of 2–4 months with traditional dynamic observation of patients.

**Results of molecular biological methods of etiological diagnosis of spondylitis in patients of the main group.** *M. tuberculosis*-complex DNA was detected by the PCR method in 40 (88.9 %) of 45 samples of operative material of patients with a histologically confirmed diagnosis of TB (this number is caused by the fact that several samples were taken from one patient). In general, confirmation of TS diagnosis based on the results of PCR and cultural methods was obtained during the examination of surgical material samples in 28 (93.7 %) patients of the main group with a histologically verified TS diagnosis.

When comparing the diagnostic informativeness, the molecular genetic method showed an indisputable advantage over bacteriological methods (when sowing on dense and liquid nutrient media in total) — 88.9 % and 40.0 % of positive results, respectively (p < 0.05).

**Treatment results of TS patients.** For the clinical evaluation of treatment results of patients of both groups, a generally accepted point scale proposed by E.V. Ulrich, O.Yu. Mushkin was used [4]. The long-term results of TS treatment were studied in 26 patients of group I (86.7 %) and in 25 patients of group II (83.3 %) in the period from 1 to 10 years. The rest of the patients were residents of distant regions of Ukraine and it was not possible to trace the results of their treatment. Clinical, X-ray, neurological examination, as well as CT in the indicated cases did not reveal any recurrence of the disease.

At the same time, excellent results were obtained in 14 patients of the main group (54 %) and in 8 patients of the control group (32 %); good — in 71 (24.7 %) patients of the main group and in 7 (28 %) patients of the control group; satisfactory — in 4 (15.4 %) patients of the main group and in 7 (28 %) of the control group, unsatisfactory — in 3 (12 %) patients of the control group, there were no unsatisfactory results in the patients of the main group.

Analysis of the results of the standard approach to the treatment of TS patients from the control group revealed the following. Preoperative and postoperative periods against the background of strict bed rest with a total duration, depending on the localization of the process, from 2–3 to 4–6 months caused long-term hypodynamia with a negative impact on the functional state of organs and systems with the development of lymphostasis (30.0 %) and symptoms of venous insufficiency (36.7 %) of the lower extremities in the early postoperative period. A significant slowing down of the reparative processes in the bone tissue with the formation of a bone block in the spondylodesis area within 1 to 2 years has been established. The level of getting I and II disability groups by patients reached 90 %.

In the main group, where a new technique of TS surgical treatment was used, in 93.3 % of cases improvement or complete recovery of the patient’s lost ability to walk was achieved. Only 2 patients with lower paraplegia did not experience significant regression of neurological symptoms. Only 5 (16.7 %) patients changed their jobs, 23.3 % got III disability group, 53.3 % — II disability group, 2 (6.7 %) patients returned to their previous job after 6–8 months.

When analyzing postoperative complications of patients in both groups, 4 complications (13.32 %) from the total number of operations in patients of the main group and 10 complications (33 %) from the total number of operations in patients of the control group were found.

The applied method of treatment in the patients of the main group with the prescription of a short-term course of intensive specific ABT, taking into account the sensitivity of MBT to ABM in the preoperative period, allowed us to achieve compensation of the inflammatory process and carry out surgical intervention without the risk of generalization of the disease and carrying out surgical intervention using, after the reparative stage of spondylitis, surgery with with the help of a sliding cage (instead of an autograft) made it possible to carry out early rehabilitation of patients in the postoperative period, which contributed to the normalization of metabolic processes, acceleration of the formation of spondylodesis in the zone of specific inflammation, rapid recovery of the patient’s physical activity and, as a result, a significant reduction in the duration of treatment and made it possible to obtain a significantly better treatment results.

Thus, the new method of TS treatment in the main group compared to traditional standards of surgical interventions in the control group allowed: 1) to avoid the progression of TS, the development of complications of the disease (p < 0.05) and complications related to the transplant (fractures, displacement of the autograft, cage) (p < 0.05); in the early postoperative period; 2) significantly increase the effectiveness of treatment due to an increase in excellent results (46.7 and 26.7 %, respectively) and a decrease in satisfactory (13.3 and 23.3 %, respectively) and unsatisfactory (0.0 and 10.0 %) respec-
The developed method of TS surgical treatment using telescopic titanium cages during spondylodiscitis after short-term intensive ABT based on etiological diagnosis is a promising direction of TS surgical treatment.

The use of a new method of TS surgical treatment allows, in comparison with the traditional approach, to significantly improve the treatment results due to a significant reduction in the stage of preparation for radical operations (2—3 weeks versus 2—6 months), a significant reduction in the number of complications, shortening the duration of inpatient treatment \((96 \pm 12) \text{ vs } (190 \pm 21) \text{ bed-days}) and social adaptation of patients.

All authors declare that they have no conflicts of interest.

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нам телескопічного титанового кейджа для вентрального міжтілового спондилодезу після проведення некрексвестектомії. У контрольній групі (n = 30) застосовано традиційні підходи до лікування ТС.

Результати та обговорення. Бактеріологічно підтверджено діагноз у 40,0% хворих контрольної групи, з них у 20,0% МБТ віділено лише методом посіву, у 13,3% — лише методом бактеріоскопії, у 6,7% — позитивні результати отримано двома методами.

У пацієнтів контрольної групи найбільша кількість позитивних результатів отримана із вмісту абсцесів — у 30,0% хворих, з гною на тампонах та виділень з нориць — у 6,7% (p < 0,01), з операційного матеріалу (трансплантати та кезезонні маси) — у 16,7%.

В основній групі бактеріологічне підтвердження отримано у 10 (33,3%) хворих. Діагностична пункційна біопсія тіл хребців, застосована у 17 хворих, дала змогу в 1 (5,9%) випадку діагностувати метастаз раку в тіло хребця, в 3 (17,6%) — первинні пухлини хребта, у 9 (52,9%) — туберкульоз, у 4 (23,6%) — неспецифічний остеоміеліт хребта. Це дослідження виконували методом діагностичної черезшкірної трансангінії тіл хребців за допомогою електронно-оптичного перетворювача заднім доступом крізь корінь дуги враженого хребця.

Віддалені результати лікування ТС вивчено у 26 (86,7%) хворих основної групи і 25 (83,3%) — контрольної групи у терміні від 1 до 10 років.

Висновки. Нова методика лікування ТС порівняно з традиційними стандартами хірургічних втручань дала змогу: 1) уникнути прогресування ТС, розвитку зваження захворювання (p < 0,05) та ускладень, пов’язаних із трансплантатом (переломи, зміщення автотрансплантата і кейджа) (p < 0,05), у ранній післяоперативній період; 2) суттєво підвищити ефективність лікування за рахунок збільшення відмінних результатів (46,7 і 26,7% відповідно) та зменшення задовільних (13,3 і 23,3%) i незадовільних (0,0 і 10,0%) результатів у віддаленій період; 3) суттєво скоротити станціонарний етап лікування ((96 ± 12) і (190 ± 21) ліжко-день; p < 0,001).

Ключові слова: етіологічна діагностика туберкульозного спондиліту, бактеріологічні дослідження, передній спондилодез розсувним титановим кейджем, результати оперативного лікування туберкульозного спондиліту.

Контактна інформація:

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