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Tuberculosis Diagnosis with Rapid Molecular Tests of Stool Samples in Adults with Severe Mental Illness (Review)

Tuberculosis is one of the leading causes of death worldwide. Early detection of tuberculosis is crucial for prompt initiation of treatment. Early detection of drug-resistant strains of *Mycobacterium tuberculosis* is particularly important to prevent their spread. However, early diagnosis can be difficult if respiratory specimens are not available for testing, such as in children, the elderly or patients with severe mental illness.

Objective — to investigate the effectiveness of rapid molecular tests of stool samples in adults in diagnosis of drug-resistant tuberculosis of the lungs.

Materials and methods. This study analyses literature from PubMed, namely 23 literature sources, and presents the results of our own observations about effectiveness of rapid molecular tests of stool samples in 2 adult patients with severe mental illness the diagnosis of drug-resistant tuberculosis.

Results and discussion. In our own observational data, patients with severe mental illness had to be empirically prescribed first-line antituberculosis treatment due to the inability to obtain respiratory specimens for drug susceptibility testing. This treatment was not effective enough and resulted in early relapse of active tuberculosis. Obtaining respiratory specimens in patients with severe mental illness is often impossible, so finding alternative non-invasive methods of investigation is extremely important for such patients. Testing of stool samples from both patients allowed the diagnosis of multidrug-resistant tuberculosis, and adequate anti-tuberculosis treatment regimens were prescribed.

Conclusions. Testing of stool samples with rapid molecular tests, namely XpertMTB/RIF and XpertMTB/XDR, is an effective alternative for diagnosis of drug-resistant tuberculosis in adult patients with inability to provide respiratory specimens, including patients with severe mental illness.

Keywords

Rapid molecular tests, tuberculosis diagnosis, mental illness.

Tuberculosis (TB) is one of the leading causes of death worldwide [22]. Early detection of TB is crucial for the prompt initiation of treatment. Early detection of drug-resistant strains of *Mycobacterium tuberculosis* (MTB) is particularly important to prevent their spread. However, early diagnosis can be difficult if respiratory specimens are not available for testing, such as in children, the elderly or patients with severe mental illness.

The «gold standard» for TB diagnosis is culture, as it is the most sensitive method and allows drug susceptibility testing. However, the wait time for culture results is usually long, lasting 4—6 weeks [2]. Rapid molecular tests (RMTs) can provide results for the presence of MTB DNA in the sample within hours and can also perform genotypic drug susceptibility testing [3]. RMTs demonstrate high sensitivity and specificity [15]. In 2010, WHO introduced the rapid molecular Xpert tests into national TB control programmes [19].

The most commonly used material for the detection of MTB is sputum [11]. However, patients with

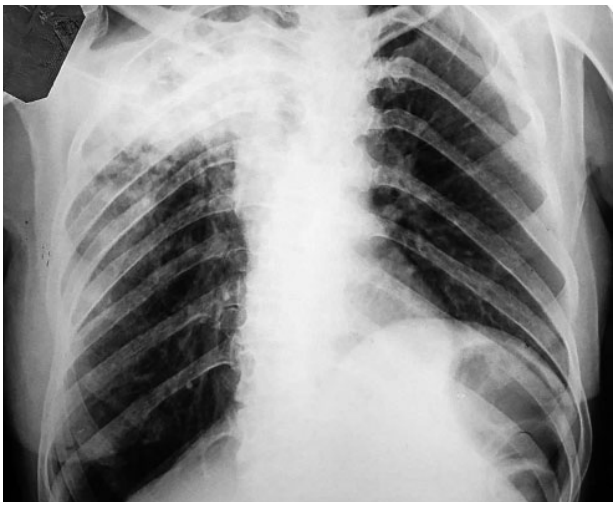

Fig. 1. **A 51-year-old woman with X-ray pathology revealed during medical check-up: nonhomogeneous infiltration of moderate intensity in the right lung**

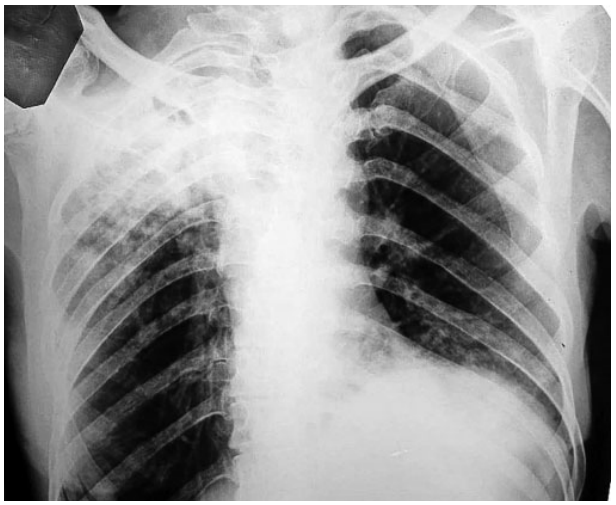

Fig. 2. **A 51-year-old woman; chest X-ray after anti-pneumonic treatment shows no change**

severe mental illness often do not follow instructions, which makes it impossible for them to collect sputum. Such patients swallow sputum more often than cough it up. Procedures such as sputum induction or bronchoscopy are also difficult to perform, especially since they are more unpleasant for these patients due to their lack of understanding. Therefore, the TB diagnosis in patients with severe mental illness is mainly based on chest X-ray and clinical symptoms and signs, so it is important to provide more reliable laboratory results to confirm the presence of TB in this special group of patients [18]. Therefore, non-invasive studies with the possibility of easily obtaining of material for examination are a priority for patients with severe mental illness. This is also in line with the WHO End TB strategy, which states the importance of integrated, patient-centred care to end the TB epidemic by 2030 [23]. Furthermore, early detection of TB in patients with severe mental illness is particularly critical, as these patients are less likely to adhere to treatment and therefore treatment of severe forms of TB in such patients may be more difficult [12]. At the same time, late initiation of treatment may lead to rapid spread of TB if patients are in closed facilities or if they do not practise cough hygiene.

Objective — to investigate the effectiveness of rapid molecular tests of stool samples in adults in the diagnosis of drug-resistant tuberculosis of the lungs.

Materials and methods

This study analyses literature from PubMed, namely 23 literature sources, and presents the results of our own observations about the effectiveness of rapid molecular tests of stool samples in 2 adult patients with severe mental illness for the diagnosis of drug-resistant TB.

Results

A 51-year-old woman with severe mental illness caused by brain damage and dysfunction was admitted to the hospital for a medical check-up. Chest X-ray showed nonhomogeneous infiltration of moderate intensity in the right lung (Fig. 1).

The patient underwent a course of anti-pneumonic treatment (Cefepime Hydrochloride 1 mL intravenously twice a day for 10 days). Chest X-ray after anti-pneumonic treatment showed no change (Fig. 2).

The patient did not follow instructions, so it was impossible to collect a sputum sample of perform bronchoscopy. According to clinical and X-ray data, active TB disease was diagnosed in the patient.

A standard treatment regimen was prescribed. The intensive phase of the standard treatment regimen lasted for 2 months and included:

- Isoniazid — 300 mg per day;
- Rifampicin — 450 mg per day;
- Ethambutol — 1200 mg per day;
- Pyrazinamide — 1500 mg per day.

After the intensive treatment phase, the patient's condition improved. She became more active and gained 5 kg of weight. However, the control chest X-ray did not show any change (Fig. 3).

The patient was transferred to the supportive treatment phase, which lasted for 4 months and included:

- Isoniazid — 300 mg per day;
- Rifampicin — 450 mg per day;
- Ethambutol — 1200 mg per day.

The control chest X-ray at the end of the supportive treatment phase also did not reveal any change (Fig. 4). However, given the improvement in the patient's state, the treatment was completed.

A medical check-up in 6 months showed deterioration of the patient's state: weight loss of 6 kg, cough and haemoptysis. Chest X-ray showed negative dynamics: enlargement of the infiltration in the right lung with destruction and the appearance of infiltration in the left lung (Fig. 5).

Given the early relapse of TB, the Central Medical Advisory Commission suggested that the patient had drug resistance, which had resulted in insufficient effectiveness of the treatment with first-line antituberculosis drugs. As it was impossible to collect sputum or another respiratory sample from the patient due to severe organic brain damage, which led to pronounced intellectual deficit, it was proposed to perform a rapid molecular tests of stool samples, namely XpertMTB/RIF and XpertMTB/XDR.

Tests revealed MTB DNA and resistance to Isoniazid, Rifampicin and Kanamycin. Multidrug-resistant TB (MDR-TB) was diagnosed in the patient. The 6-months BPaL treatment regimen was started and included:

- Bedaquiline — 200 mg per day for 8 weeks, then 100 mg per day;
- Pretomanid — 200 mg per day;
- Linezolid — 600 mg per day.

Throat swabs were used to monitor treatment effectiveness. On an empty stomach, a swab was taken from the posterior pharyngeal wall, then dipped in a tube with 1 ml of saline and delivered to the laboratory for microscopy and culture. At the 3rd month of treatment, the patient had a positive microscopy result (5/100 visual fields), but all culture results were negative. Clinical symptoms and signs had reduced by the end of the 2nd month of treatment.

Chest X-ray after the end of treatment showed positive changes (Fig. 6). The treatment was completed.

A 35-year-old man was admitted to the hospital for a medical check-up. Chest X-ray showed signs of exudative pleurisy (Fig. 7).

Microscopy and XpertMTB/RIF of pleural fluid did not reveal MTB. Pleural fluid analysis showed leukocytes covering 1/4 of field of vision with predominance of lymphocytes and presence of fibrous clots. Active TB disease was diagnosed and a four-month treatment regimen was started. The intensive phase of treatment lasted for 2 months and included:

- Isoniazid 300 mg per day;
- Rifapentine 600 mg per day 2 times a week;
- Pyrazinamide 1000 mg per day;
- Moxifloxacin 400 mg per day.

Chest X-ray at the end of the intensive treatment phase showed positive changes (Fig. 8).

The patient was transferred to the supportive treatment phase, which lasted for 2 months and included:

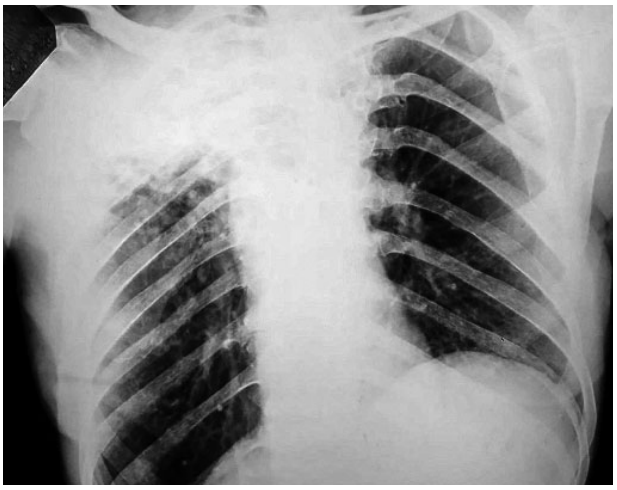

Fig. 3. **A 51-yaer-old woman; chest X-ray at the end of the intensive treatment phase shows infiltration in the right lung, indicating absence of radiological improvement**

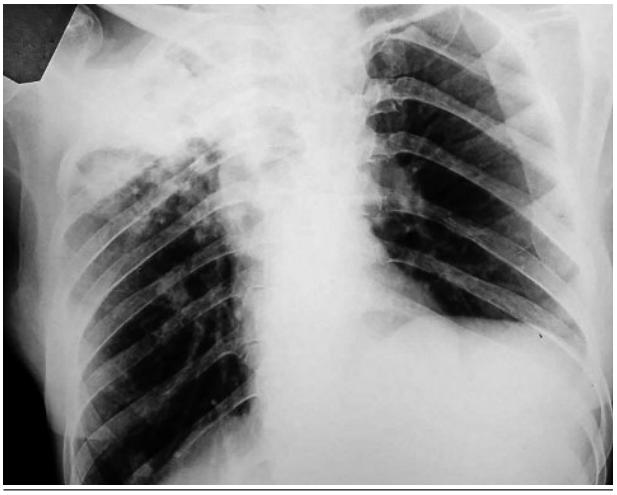

Fig. 4. **A 52-year-old woman; chest X-ray at the end of a six-month course of anti-tuberculosis treatment with 2INH RIF PZA EMB/4 INH RIF regimen shows no change**

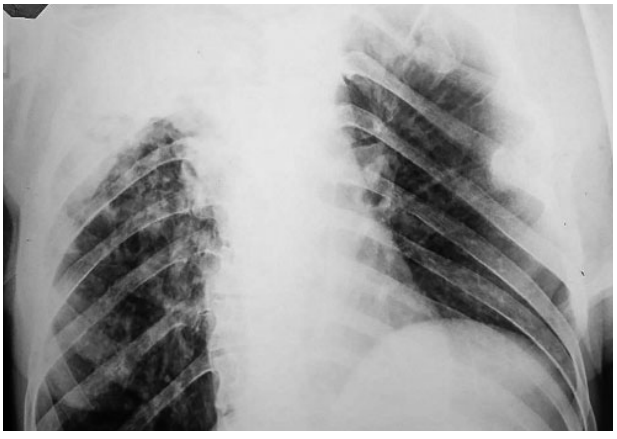

Fig. 5. **A 52-year-old woman — chest X-ray 6 moths after completion of anti-tuberculosis treatment**

Chest X-ray shows nonhomogeneous infiltration of moderate and high intensity in both upper pulmonary lobes and destruction in the right upper pulmonary lobe. The right pulmonary root is fibrosed and shifted upward.

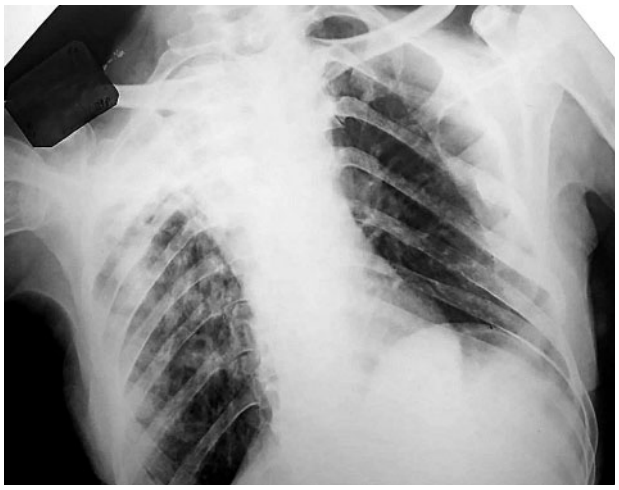

Fig. 6. **A 53-year-old woman; chest X-ray after a six-month BPaL treatment regimen shows positive changes in the form of consolidation of infiltration in the right upper pulmonary lobe and resorption of infiltration in the left upper pulmonary lobe**

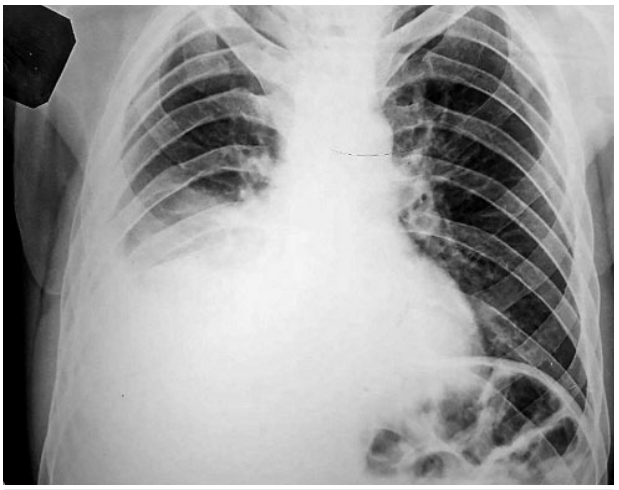

Fig. 7. **A 35-year old man; chest X-ray shows an intense shadow from the 3rd rib to the diaphragm on the right side**

The upper contour of the shadow is unclear. The right pulmonary root, costodiaphragmal sinus and diaphragm dome are not visualised against the background of the shadow.

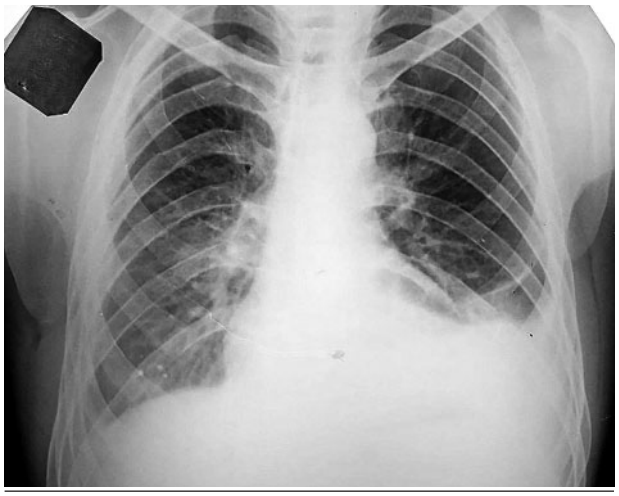

Fig. 8. **A 35-year-old man; chest X-ray shows positive changes after the intensive phase of anti-tuberculosis treatment, in form of resorption of the pleural effusion shadow**

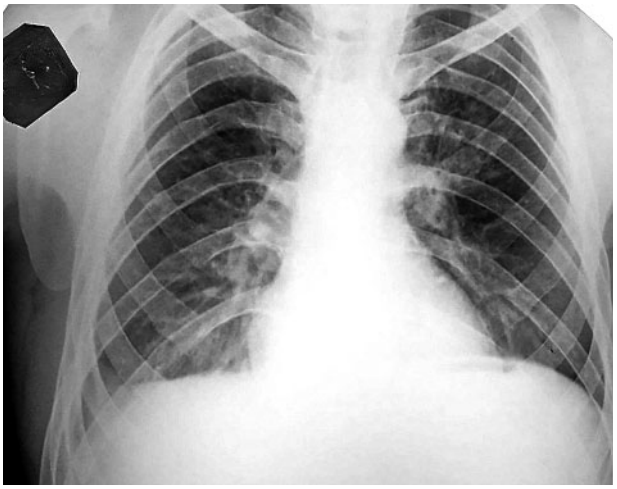

Fig. 9. **A 35-year old man; chest X-ray at the end of the supportive phase of anti-tuberculosis treatment**

- Isoniazid 300 mg per day;
- Rifapentine 600 mg per day twice a week;
- Moxifloxacin 400 mg per day.

Chest X-ray after the supportive treatment phase (Fig. 9) did not reveal any negative changes, and the treatment was completed.

A medical check-up in 6 months after the end of treatment showed clinical and radiological deterioration of the patient's state. The patient lost 4 kg of weight and experienced mild anemia, fatigue, malaise dry cough. Chest X-ray showed an intense shadow in the 3rd intercostal space in the left lung extending to the root (Fig. 10).

As the patient did not follow the instructions due to severe mental illness, it was impossible to obtain a respiratory specimen for bacteriological analysis to detect MTB. Therefore, that a stool specimen was obtained from the patient for analysis.

XpertMTB/RIF and XpertMTB/XDR tests of the stool specimen detected MTB DNA with resistance to Isoniazid, Rifampicin and Ethionamide. Multidrug-resistant TB was diagnosed, and the BPaLM anti-tuberculosis treatment regimen was prescribed. At present, the patient is undergoing a six-month BPaLM treatment regimen, which includes:

- Bedaquiline 200 mg per day 3 times a week;
- Pretomanid 200 mg per day;
- Linezolid 600 mg per day;
- Moxifloxacin 400 mg per day.

The patient's tolerance of the regimen is satisfactory.

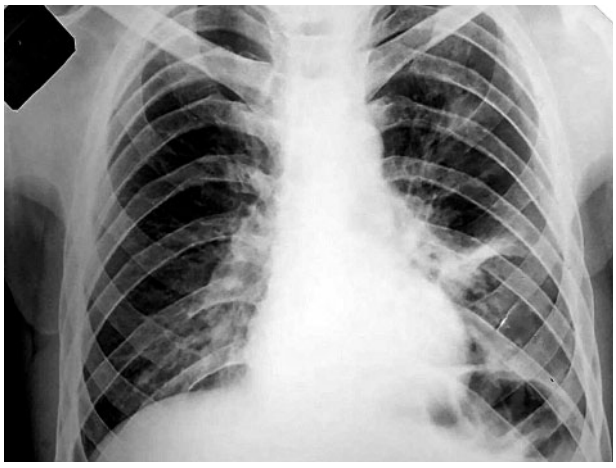

Fig. 10. **A 36-year-old man; chest X-ray a six-month after the end of anti-tuberculosis treatment shows negative changes the form of an intense shadow in the the 3rd intercostal space of the left lung extending to the pulmonary root**

Discussion

Given that people with severe chronic mental illness are at higher risk of developing active TB, timely case detection in this cohort of patients is an important challenge for the health system [18]. According to the WHO risk group classification for TB, patients with chronic mental disorders residing in long-term care facilities are at high risk for TB. Furthermore, such facilities may lack standard TB infection control practices and may be densely populated with people who have multiple risk factors for TB infection [4]. Screening for TB infection among people with various chronic psychiatric disorders, especially those residing in long-term care facilities, is very important for controlling TB transmission [6].

An alternative method for detecting MTB is the examination of a stool sample. Patients with pulmonary TB swallow sputum containing MTB. The mycobacteria pass through the gastrointestinal tract, and their DNA can be detected in stool using molecular tests. It is clear that a stool sample is easier to obtain than a sputum sample or material from invasive procedures. In addition, the collection of a stool sample does not require a mandatory visit to a medical facility for the procedure [16]. This method has already proven to be an effective alternative in children [20], but data on its effectiveness in adults remain insufficient.

The introduction of rapid molecular tests, namely Xpert tests, for the detection of MTB has been a breakthrough in the diagnosis of TB and has been approved by WHO for the detection of MTB in various specimens. Initially, tests were performed on sputum, lymph node aspirate, cerebrospinal fluid and gastric lavage fluids [21], and recently, studies have been conducted on stool samples. A study by Musisi et al. shows that the bacterial load of MTB in the stool of adults with pulmonary TB is high, which makes the examination of stool for the detection of MTB promising [10]. Data on the sensitivity of tests for the detection of MTB in stool samples vary, and according to different studies, sensitivity ranges from 32 to 83.3 % [9, 17]. According to meta-analyses, this variation in sensitivity is most likely due to different testing methods [5, 8]. Previous studies have shown that non-centrifugation stool processing is the simplest method with the lowest error rate (4.5 %). According to these studies, the best practice involves using 0.5 g of stool, shaking by hand, sedimentation for 30 minutes and processing at a 1 : 3.6 dilution with Xpert Specimen Processing Reagent [7]. Some studies have shown that pretreatment of the sample to remove inhibitors in faecal components, which often inhibit PCR amplification by inhibiting Taq DNA polymerase, is important for increasing the sensitivity of the method [14]. A standardized decontamination method is treatment with NALC-NaOH-Na-citrate solution [13].

In our own observational data, patients with severe mental illness had to be empirically prescribed first-line antituberculosis treatment due to the inability to obtain respiratory specimens for drug susceptibility testing. This treatment was not sufficiently effective and resulted in an early relapse of active TB. Obtaining respiratory specimens from patients with severe mental illness is often impossible, so finding alternative non-invasive methods of investigation is extremely important for such patients.

Testing of stool samples from both patients allowed the diagnosis of multidrug-resistant TB, and adequate anti-tuberculosis treatment regimens were prescribed.

Conclusions

Testing stool samples with rapid molecular tests, namely XpertMTB/RIF and XpertMTB/XDR, is an effective alternative for the diagnosis of drug-resistant TB in adult patients unable to provide respiratory specimens, including those with severe mental illness.

There is no conflict of interest.
Authors' participation: concept and design of the article — O.S. Shevchenko, L.D. Todoriko; material collection and material processing — T.O. Synenko, V.P. Kiba, O.O. Pohorielova; writing and editing of the article — O.S. Shevchenko, L.D. Todoriko, T.O. Synenko, V.P. Kiba, O.O. Pohorielova; editing of the article — O.V. Pidverbetska.

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Діагностика туберкульозу за допомогою швидких молекулярних тестів зразків калу в дорослих із тяжкими психічними захворюваннями (огляд літератури)

Туберкульоз є однією з провідних причин смерті у світі. Раннє виявлення туберкульозу дає змогу вчасно розпочати лікування. Особливо важливе раннє виявлення лікарсько-стійких штамів *Mycobacterium tuberculosis*, щоб запобігти їхньому поширенню. Рання діагностика може бути ускладнена у випадках, коли неможливо отримати респіраторні зразки для дослідження, наприклад, у дітей, людей похилого віку або пацієнтів із тяжкими психічними розладами.

Мета роботи — вивчити ефективність швидких молекулярних тестів зразків калу в дорослих для діагностики лікарсько-стійкого туберкульозу легень.

Матеріали та методи. Проведено аналіз літературних джерел із бази даних PubMed (23 джерела). Представлено результати власних спостережень щодо ефективності швидких молекулярних тестів зразків калу в 2 дорослих пацієнтів із тяжкими психічними розладами для діагностики лікарсько-стійкого туберкульозу.

Результати та обговорення. У наших клінічних спостереженнях пацієнтам із тяжкими психічними розладами емпірично було призначено протитуберкульозне лікування першої лінії через неможливість отримання респіраторних зразків для дослідження лікарської чутливості. Це лікування виявилося недостатньо ефективним і призвело до раннього рецидиву активного туберкульозу. Отримання респіраторних зразків у пацієнтів із тяжкими психічними розладами часто є неможливим, тому пошук альтернативних неінвазивних методів діагностики для таких хворих є вкрай важливим. Дослідження зразків калу в обох пацієнтів дало змогу діагностувати туберкульоз із множинною лікарською стійкістю. Призначено відповідні схеми протитуберкульозного лікування.

Висновки. Тестування зразків калу із застосуванням швидких молекулярних тестів, зокрема XpertMTB/RIF та XpertMTB/XDR, є ефективною альтернативою для діагностики лікарсько-стійкого туберкульозу в дорослих пацієнтів, в яких неможливе отримання респіраторних зразків, зокрема в пацієнтів із тяжкими психічними розладами.

Ключові слова: швидкі молекулярні тести, діагностика туберкульозу, психічні розлади.

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