Case report

Effectiveness and safety of a modified short-term regimen of antimycobacterial therapy to treat rifampicin-resistant tuberculosis in elderly patients with concomitant diabetes (a clinical case)

O. M. Raznatovska*, R. M. Yasinskyi, A. V. Fedorets

Zaporizhzhia State Medical University, Ukraine

Aim. To analyze the effectiveness and safety of a modified short-term regimen (mSTR) of antimycobacterial therapy (AMBT) for rifampicin-resistant tuberculosis (RR-TB) in a 71-year-old patient with type 2 diabetes mellitus (T2DM) on the clinical case example of own observation.

Materials and methods. A clinical case from own observation of the patient who was treated at the clinical base of the Department of Phthisiology and Pulmonology of Zaporizhia State Medical University – Pulmonary Tuberculosis Department No. 2 of the Communal Non-profit Organization “Zaporizhzhia Regional Phthisio-Pulmonology Clinical Treatment and Diagnostic Center” is presented.

Results. The presented case demonstrates the high safety and efficacy of all oral mSTR, including Lfx-Bdq-Lzd-Cfz-Cs, in the elderly person with RR-TB and concomitant decompensated T2DM who was smear-negative after 4 months as a result of treatment with 9-month mSTR AMBT (Lfx, Bdq, Lzd, Cfz, Cs). Positive radiological dynamics were observed all the time and residual changes in the lungs after tuberculosis were diagnosed at the end of the treatment course. These results complement indications for the use of mSTR, including Lfx-Bdq-Lzd-Cfz-Cs, in RR-TB patients.

Conclusions. mSTR AMBT (Lfx, Bdq, Lzd, Cfz, Cs) is effective and safe in elderly patients with RR-TB and concomitant decompensated type 2 diabetes mellitus when adequate treatment of diabetes and timely correction of antimycobacterial drug side effects are undertaken.

Keywords:
- modified short course regimen
- antimycobacterial therapy
- rifampicin-resistant tuberculosis
- elderly
- diabetes mellitus.

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E-mail: raznatovskaya@gmail.com

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Conflict of interest. The authors declare that there is no conflict of interest.

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Keywords: modified short course regimen, antimycobacterial therapy, rifampicin-resistant tuberculosis, elderly, diabetes mellitus.
The high effectiveness of such sSTR in patients with MDR-TB/RR-TB is evidenced by the data of a prospective observational study by Q. Nie et al. [8]. High-dose Gfx-based sSTR was used in comparison with previous studies. The authors also emphasize that severe adverse reactions, above all, hepatotoxicity and QT interval prolongation, should not be ignored when using this regimen.

Significantly higher efficacy of STR (9–12 months) was indicated in patients with MDR-TB compared to the standard treatment (20–24 months) as results of study by E. Zhdanova et al. [1].

Adverse factors influencing outcome of sSTR MDR-TB/RR-TB treatment were studied in a retrospective cohort study by A. Y. Soeroto et al. [6]. So, the researchers have found that significant independent factors that reduced the chances of successful treatment completion were a history of previous TB treatment, culture conversion for more than 2 months, and malnutrition in patients. At the same time, D. M. Kokebu et al. [7] have found that the predictors for Standardized Treatment Regimens of Anti-tuberculosis drugs for Multidrug-Resistant Tuberculosis (STREAM) sSTR failure in MDR-TB patients were: male sex, a significantly positive baseline smear degree, MDR-TB/HIV co-infection, and the presence of costo-diaphragmatic obliteration.

Souleymane M. B. et al. [13] investigated the use of all-oral mSTR, including bedaquiline and linezolid (Bdq/Lzd), in patients with RR-TB. The authors have found high safety, efficacy, and adherence to this regimen, confirming its continuity in the practice of the treatment for RR-TB patients. The effectiveness and safety of all-oral mSTR in patients with MDR-TB was also studied by T. Avaliani et al. [4]. The authors have determined that good treatment outcomes were achievable in people with fluoroquinolone-sensitive TB. Schwbel V. et al. [11] also have noted that RR-TB patients with initial resistance to fluoroquinolones had a lower efficacy of mSTR and an increased risk of any adverse treatment outcome.

Kendall E. A. et al. [9] examining the effects of a 9-month MDR-TB regimen have concluded that this approach to antitubercular therapy (AMBT) would double access to treatment (by saving resources or capacity) and ensure long-term effectiveness.

Bada F. O. et al. [3] compared the cost of 9-month sSTR (including the second-line injectable drugs) with 20-month standard MDR-TB/RR-TB treatment in Nigeria. They have concluded that sSTR models such as the 9–12-month outpatient model and the model when patients were hospitalized during the first 4 months of treatment reduced the cost of MDR-TB/RR-TB treatment by approximately 5470 US dollars.

Kohler S. et al. [12] studying the costs of purchasing and importing drugs for 20-month, 9-month and 4–6-month AMBT regimens have concluded that the introduction of shorter AMBT regimens could reduce the cost of high-drug resistance TB control programs.

Trauer J. M. et al. [10] have found in their study that shorter MDR-TB treatment regimens could reduce the transmission of Mycobacterium tuberculosis (MBT) resistant strains. Han W. M. et al. [2] also indicated that STR helped to reduce the number of new cases of MDR-TB and the percentage of resistance among new infections.

Thus, the use of sSTR and mSTR in patients with MDR-TB/RR-TB has high safety, efficacy, and adherence. At the same time, such regimens are cost-effective (reduce the cost of MDR-TB/RR-TB control programs), provide long-term effectiveness and lower the transmission of resistant MBT strains. But there is no evidence in the literature about the safety and efficacy of sSTR and mSTR in older RR-TB patients with concomitant type 2 diabetes mellitus (T2DM), which served as the basis for writing this article.

Aim

To analyze the effectiveness and safety of mSTR AMBT in a 71-year-old patient with T2DM on the clinical case example of own observation.

Materials and methods

A clinical case from own observation of the patient who was treated at the clinical base of the Department of Phthisiology and Pulmonology of Zaporizhzhia State Medical University – Pulmonary Tuberculosis Department No. 2 of the Communal Non-profit Organization “Zaporizhzhia Regional Phthisio-Pulmonology Clinical Treatment and Diagnostic Center” of Zaporizhzhia Regional Council (CNO ZRRPCCTDC ZRC) is presented.

Case report

Patient М., male, 71 years old.

From anamnesis. He did not have a history of prior tuberculosis. He was diagnosed with hypertension in 1995 and took antihypertensive drugs from 2003; T2DM was diagnosed in 2006, and he was prescribed constant use of Glymepiride, insulin therapy was administered in February 2022. Worsening of the condition was noted after hypothermia in November 2021. The patient repeatedly consulted a family doctor and received non-specific antibacterial therapy for left-sided pneumonia treatment. The therapy was not effective, as negative dynamics were determined on a control chest X-ray examination dated 03.03.2022 (Fig. 1).

A sputum analysis by using GeneXpertUltra molecular genetic (MG) method was done due to radiological changes.

Fig. 1. Chest X-ray from 03.03.2022. There are focal and infiltrative shadows, consolidated in some areas, with destructions from 0.5 up to 2.0 cm in diameter. The left lung hilum is infiltrated, there are no changes in the right lung.
Table 1. Blood tests of the clinical case in dynamics

<table>
<thead>
<tr>
<th>Blood indicators, units</th>
<th>10.03.2022</th>
<th>07.04.2022</th>
<th>04.05.2022</th>
<th>13.06.2022</th>
<th>11.07.2022</th>
<th>12.08.2022</th>
<th>08.09.2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb, g/l (RV = 110–160)</td>
<td>99</td>
<td>107</td>
<td>100</td>
<td>98</td>
<td>111</td>
<td>108</td>
<td>115</td>
</tr>
<tr>
<td>Er, x1012/l (RV = 3.6–5.3)</td>
<td>3.25</td>
<td>3.48</td>
<td>3.26</td>
<td>3.16</td>
<td>3.5</td>
<td>3.44</td>
<td>3.75</td>
</tr>
<tr>
<td>WBC, x109/l (RV = 4–9)</td>
<td>9.6</td>
<td>9.3</td>
<td>7.9</td>
<td>7.7</td>
<td>9.1</td>
<td>7.3</td>
<td>5.0</td>
</tr>
<tr>
<td>pl, x109/l (RV = 150–390)</td>
<td>347</td>
<td>257</td>
<td>226</td>
<td>217</td>
<td>301</td>
<td>288</td>
<td>221</td>
</tr>
<tr>
<td>Ef, % (RV = 2–4)</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Hb, % (RV = 1–4)</td>
<td>27</td>
<td>22</td>
<td>19</td>
<td>17</td>
<td>2</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>s/n, % (RV = 52–72)</td>
<td>60</td>
<td>62</td>
<td>66</td>
<td>70</td>
<td>76</td>
<td>74</td>
<td>67</td>
</tr>
<tr>
<td>Lt, % (RV = 19–37)</td>
<td>3</td>
<td>10</td>
<td>7</td>
<td>18</td>
<td>14</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>m, % (RV = 3–10)</td>
<td>10</td>
<td>5</td>
<td>7</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>AsAt, mmol/l/h (RV = 1–10)</td>
<td>57</td>
<td>64</td>
<td>43</td>
<td>45</td>
<td>16</td>
<td>48</td>
<td>12</td>
</tr>
</tbody>
</table>

**RV:** reference values; **Hb:** hemoglobin; **Er:** erythrocytes; **WBC:** leukocytes; **pl:** platelets; **Ef:** eosinophils; **s/n:** band neutrophils; **Lt:** lymphocytes; **m:** monocytes; **ESR:** erythrocyte sedimentation rate.

Table 2. Biochemical blood analyses of the clinical case in dynamics

<table>
<thead>
<tr>
<th>Biochemical blood indicators, units</th>
<th>10.03.2022</th>
<th>07.04.2022</th>
<th>04.05.2022</th>
<th>13.06.2022</th>
<th>11.07.2022</th>
<th>12.08.2022</th>
<th>08.09.2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin, mmol/l (RV = up to 21)</td>
<td>12.48</td>
<td>8.6</td>
<td>9.75</td>
<td>8.9</td>
<td>9.7</td>
<td>8.8</td>
<td>9.9</td>
</tr>
<tr>
<td>ThT, units (RV = up to 4)</td>
<td>4.09</td>
<td>4.6</td>
<td>5.11</td>
<td>4.55</td>
<td>4.7</td>
<td>4.12</td>
<td>4.55</td>
</tr>
<tr>
<td>AAl, mmol/l/h (RV = 0.16–0.44)</td>
<td>0.59</td>
<td>0.48</td>
<td>0.35</td>
<td>0.85</td>
<td>2.11</td>
<td>1.56</td>
<td>1.55</td>
</tr>
<tr>
<td>AsAt, mmol/l/h (RV = 0.91–1.75)</td>
<td>0.39</td>
<td>0.26</td>
<td>0.27</td>
<td>0.67</td>
<td>1.65</td>
<td>0.86</td>
<td>0.89</td>
</tr>
<tr>
<td>TP, g/l (RV = 64–85)</td>
<td>82.9</td>
<td>69.6</td>
<td>80.4</td>
<td>68.8</td>
<td>76.4</td>
<td>71.5</td>
<td>72.5</td>
</tr>
<tr>
<td>Creatinine, µmol/l (RV = 62–115)</td>
<td>103.2</td>
<td>73.6</td>
<td>108.5</td>
<td>124.2</td>
<td>146.3</td>
<td>127.6</td>
<td>96.1</td>
</tr>
<tr>
<td>Urea, mmol/l (RV = 2.5–8.3)</td>
<td>8.81</td>
<td>8.4</td>
<td>8.7</td>
<td>8.13</td>
<td>7.22</td>
<td>7.45</td>
<td>8.65</td>
</tr>
<tr>
<td>RHN, µmol/l (RV = 12.5–25.0)</td>
<td>4.11</td>
<td>3.9</td>
<td>4.0</td>
<td>3.8</td>
<td>3.37</td>
<td>3.4</td>
<td>4.04</td>
</tr>
<tr>
<td>α-amylase, g/l × h (RV = 2–4)</td>
<td>8.47</td>
<td>2.96</td>
<td>11.0</td>
<td>2.55</td>
<td>3.49</td>
<td>8.26</td>
<td>2.35</td>
</tr>
<tr>
<td>Potassium, mmol/l (RV = 2–4)</td>
<td>5.21</td>
<td>5.98</td>
<td>5.52</td>
<td>4.03</td>
<td>4.32</td>
<td>5.15</td>
<td>4.0</td>
</tr>
<tr>
<td>Sodium, mmol/l (RV = 2–4)</td>
<td>133.1</td>
<td>132.5</td>
<td>130.7</td>
<td>140.3</td>
<td>139.7</td>
<td>141.4</td>
<td>138.7</td>
</tr>
<tr>
<td>Chlorine, mmol/l (RV = 2–4)</td>
<td>92</td>
<td>96.4</td>
<td>95.0</td>
<td>101.9</td>
<td>103.0</td>
<td>104.5</td>
<td>104.2</td>
</tr>
<tr>
<td>Magnesium, mmol/l (RV = 2–4)</td>
<td>0.93</td>
<td>1.07</td>
<td>1.02</td>
<td>0.96</td>
<td>0.91</td>
<td>0.89</td>
<td>0.88</td>
</tr>
</tbody>
</table>

**RV:** reference values; **ThT:** thymol test; **AAI:** alanine aminotransferase; **AsAt:** aspartate aminotransferase; **TP:** total protein; **RHN:** residual urea nitrogen.

Table 3. Urine analyses of the clinical case in dynamics

<table>
<thead>
<tr>
<th>Urine analysis indicators, units</th>
<th>10.03.2022</th>
<th>24.03.2022</th>
<th>07.04.2022</th>
<th>04.05.2022</th>
<th>06.05.2022</th>
<th>13.06.2022</th>
<th>11.07.2022</th>
<th>12.08.2022</th>
<th>08.09.2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein, g/l</td>
<td>0.33</td>
<td>0.132</td>
<td>0.033</td>
<td>traces</td>
<td>traces</td>
<td>traces</td>
<td>traces</td>
<td>traces</td>
<td>traces</td>
</tr>
<tr>
<td>Glucose, %</td>
<td>1.5</td>
<td>1.5</td>
<td>1.0</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
</tr>
<tr>
<td>Ketone bodies</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
<td>not detected</td>
</tr>
</tbody>
</table>

Mycobacteria tuberculosis (MBT+) resistant to rifampicin (Rif+) were detected.

Based on such results, the age (71 years) of the patient and concomitant T2DM, the patient was referred to CNO ZRPPCTDC ZRC, where an additional examination was performed.

Sputum analysis: genotypic drug sensitivity test (gDST) (XpertMTB/XDR) MG-, Cultural test (C) + (BACTEC), phenotypic (pDST) (-).

Blood tests of the clinical case in dynamics are demonstrated in Table 1, biochemical blood analyses – Table 2, blood glucose – Fig. 2, urine analysis – Table 3.

Blood test for HIV (rapid test): negative.

Blood test for HCV (rapid test): negative.

Electrocardiogram (ECG): voltage is sufficient, sinus rhythm, heart rate – 90/min, heart electrical axis (HEA) is not deviated, incomplete blockade of the right branch of the bundle of His. Signs of left ventricular myocardial hypertrophy. Diffuse changes in the myocardium of the ventricles, QTcF = 404 msec.

Conclusion of a therapist: Diabetic nephropathy. Arterial hypertension, stage II, degree I. I degree heart failure (HF), functional class (FC) II. Anemia of chronic disease, moderate degree.

Conclusion of an ophthalmologist: Initial cataract, retinal angiosclerosis OD, 1st degree myopia OS.

A diagnosis was made: Rifampicin-resistant TB (RR-TB) infiltrative of the left lung. Destruction +, MBT+ microscopy (Acid fast bacilli (AFB)) + MG+ Rif+ gDST (-) C + pHDST (-). Histology (Hist) 0 (Newly diagnosed tuberculosis (ndTB)). Cohort 1 (2022). Type 2 diabetes mellitus, mild severity, stage of decompen.sation. Diabetic nephropathy. Arterial hypertension, stage II, degree I. I degree HF, FC II. Anemia of chronic disease, mild degree.

From March 11, 2022, the following treatment was prescribed:

– course of mSTR AMBT according to the scheme: levofloxacin (Lfx), bedaquiline (Bdq), linezolid (Lzd), clofazimine (Cfz), cycloserine (Cs);

– treatment of T2DM according to the scheme: Glyme piride + Humodar C25 100R, in the evening – Humodar C25 100R;
– pathogenetic and symptomatic therapy.
Sputum analysis from 08.04.2022: AFB- C-.
ECG from 11.04.2022: voltage is sufficient, sinus rhythm, heart rate – 90/min, HEA is not deviated, less expressed changes in the myocardium, QTcF = 427 msec.
Sputum analysis from 06.05.2022: AFB+ C-.
ECG from 10.05.2022: voltage is sufficient, sinus rhythm, heart rate – 77/min, HEA is not deviated, less expressed changes in the myocardium, QTcF = 428 msec.
After 3 months of the complex treatment with mSTR AMBT (Lfx, Bdq, Lzd, Cfz, Cs), the patient had positive radiological dynamics (Fig. 3).
ECG from 10.06.2022: voltage is sufficient. Atrial fibrillation, tachysystolic form, heart rate – 138/min, HEA is not deviated, QTcF = 403 msec.
Sputum analysis from 13.06.2022: AFB+ C-.
Conclusion of the therapist from 13.06.2022: Heart rhythm disturbance (atrial fibrillation). Anemia of chronic disease, mild degree. Symptomatic therapy was prescribed.
ECG from 21.06.2022: voltage is sufficient, sinus rhythm, supraventricular extrasystole, heart rate – 71/min, HEA is not deviated, QTcF = 435 msec.
Conclusion of a neurologist from 23.06.2022: Diabetic polyneuropathy of the lower extremities.
Sputum analysis from 11.07.2022: AFB- C (a growth of other flora).
ECG from 11.07.2022: voltage is sufficient, sinus rhythm, heart rate – 69/min. HEA is not deviated, incomplete blockade of the right branch of the bundle of His. QTcF = 428 msec.

Abdominal ultrasound (US) examination from 05.08.2022: There are signs of hepatomegaly, diffuse changes in the liver and pancreas. I degree calicocoeлиa. Bilateral renal microthiasis.

ECG from 10.08.2022: voltage is sufficient, sinus rhythm, heart rate – 68/min. HEA is not deviated, incomplete blockade of the right branch of the bundle of His. QTcF = 436 msec.

Sputum analysis from 12.08.2022: AFB-.

After 6 months of the complex treatment with mSTR AMBT (Lfx, Bdq, Lzd, Csf, Cs), the patient continued to present positive radiological dynamics (Fig. 4).

ECG from 07.09.2022: voltage is sufficient, sinus rhythm, heart rate – 64/min, HEA is not deviated, unchanged ECG pattern. QTcF = 420 msec.

Sputum analysis from 08.09.2022: AFB- C (a growth of other flora).

Abdominal US from 08.09.2022: There are signs of hepatomegaly, diffuse changes in the liver, pancreas and renal parenchyma (diabetic nephropathy). I degree calicocoeлиa. Bilateral renal microthiasis.

Sputum analysis from 12.10.2022: AFB- C.

Sputum analysis from 14.11.2022: AFB-.

Sputum analysis from 07.12.2022: AFB-.

9 months after completing the mSTR AMBT (Lfx, Bdq, Lzd, Csf, Cs) course, the patient had positive X-ray dynamics with the formation of residual changes after tuberculosis (Fig. 5).

Conclusions

Thus, the 71-year-old patient suffering from both RR-TB and decompensated type 2 diabetes mellitus when adequate treatment is studied the impact of new AMBT regimens for the treatment of MDR-TB/RR-TB patients with comorbidities.

However, the novelty is that the results of such study are presented for the first time in the elderly person with RR-TB and concomitant decompensated T2DM. There is no information in the literature about possible side effects of antimycobacterial drugs in such comorbid patients and methods for their correction. According to our study results, the patient with RR-TB and concomitant decompensated T2DM had the following adverse reactions to antimycobacterial drugs during treatment: anemia caused by Lzd (corrected with Heferol), increased AlAt and AsAt caused by Cfz Bdq Lfx – (corrected with hepatoprotectors), QTcF interval prolongation and arrhythmia caused by Cfz Bdq (corrected with Bisoprolol and Triductane), diabetic angioneuropathy progression caused by Lzd and Cs (corrected with vitamin B6 and Dialipon).

These results complement indications for the use of mSTR, including Lfx-Bdq-Lzd-Csf-Cs, in RR-TB patients.

Discussion

The presented case demonstrates the high safety and efficacy of all oral mSTR, including Lfx-Bdq-Lzd-Csf-Cs, in the elderly person with RR-TB and concomitant decompensated T2DM. These results are in agreement with those of M. B. Souleymane et al. [13], T. Avaliani et al. [4] and V. Schwbel et al. [11].


