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E.V. Lesnic[1], L.D. Todoriko[2]

[1] State University of Medicine and Pharmacy «Nicolae Testemiţanu», Chişinău, Republic of Moldova

[2] Bukovinian State Medical University, Chernivtsi, Ukraine

Criteria for Distinguishing Pulmonary Tuberculosis from Community-Acquired Pneumonia of Moderate to Severe Course and Associated with COVID-19. Part 1

The COVID-19 pandemic has significantly changed the spectrum of lung pathology. As the lungs are the main organs affected by the SARS-CoV-2, as well as by community-acquired and *Mycobacterium tuberculosis* infections, their differentiation based on specific clinical, radiological and laboratory tests should be done properly for early initiation of treatment and follow-up.

Objective — to establish the distinguishing clinical, radiological and laboratory differential diagnostic criteria between COVID-19-associated pneumonia, moderate to severe community-acquired pneumonia (CAP) and pulmonary infiltrative tuberculosis in the frame of a prospective longitudinal study.

Materials and methods. A prospective case-control study was conducted from 1 January 2020 to 31 December 2022. It included 255 patients, distributed into the 1st group — 70 patients diagnosed with SARS-CoV-2 pneumonia, the 2nd group — 65 patients with CAP and the 3rd group — 120 patients with pulmonary infiltrative TB. All patients were aetiologically confirmed through the conventional microbiological or molecular genetic tests and clinically managed in specialised clinical services. Statistical analysis was carried out using quantitative and qualitative tests in SPSS Statistics 23.0 software, in which paired sample T-test, Anova and Chi-square tests were performed. The differences were considered statistically significant with a confidence level of more than 95 % and $p < 0.05$.

Results and discussion. The demographic characteristics of the patients showed no significant differences; however, male sex was identified as a high-risk factor for developing TB (Odds Ratio (OR) = 7.6; 95 % Confidence Interval (CI): 3.7—14.9; risk difference: 46 %; $\chi^2 = 37$; $p < 0.001$) compared to SARS-CoV-2 pneumonia. Additionally, male sex was found to be a moderate risk factor for severe CAPs (OR = 2.4; 95 % CI: 1.3—4.8; risk difference: 21 %). Young age (<45 years) was identified as a high-risk factor for developing TB (OR = 8.1; 95 % CI: 3.6—17.2; risk difference: 20 %). In contrast, age over 45 years was a significant risk factor for severe CAPs (OR = 6.6; 95 % CI: 3.1—14.2; $\chi^2 = 32$; $p < 0.001$; risk difference: 41 %) and SARS-CoV-2 pneumonia (OR = 7.4; 95 % CI: 3.2—8.1; $\chi^2 = 27$; $p < 0.001$; risk difference: 37 %).

Conclusions. Demographic characteristics of patients in all study groups showed that male gender was likely a high-risk factor for developing tuberculosis compared with SARS-CoV-2-associated pneumonia. Male gender was found to be a moderate-risk factor for severe community-acquired pneumonia. Young age (<45 years) was identified as a high-risk factor for developing tuberculosis; age over 45 years was a significant risk factor for severe community-acquired pneumonia and SARS-CoV-2-associated pneumonia.

Keywords

Tuberculosis, COVID-19, community-acquired pneumonia, risk factors, age, gender.

The lower respiratory tract infections, including bronchitis, bronchiolitis and community-acquired pneumonia (CAP) are often erroneously diagnosed in patients with pulmonary tuberculosis (TB), which worsens the epidemiological situation at the community level and increases the risk for complications, prolongs treatment and results in an unfavorable outcome [5, 10]. The World Health Organization (WHO) listed TB and CAP among the 10 global causes of death [12]. The case fatality rate (CFR) in TB, meaning the proportion of patients who developed and died from TB is in the range of 12—15 % globally [11]. In comparison, the CFR in patients with severe CAP varies depending on the the causative agent, with the highest rates for Influenza A H1N1 CAP) — 17 %, *Pseudomonas aeruginosa* CAP — 14 %, *Haemophilus influenzae* CAP — 12 %, *Klebsiella pneumoniae* CAP — 7 %, atypical bacteria (*Chlamydia pneumoniae, Mycoplasma pneumoniae, Legionella species*) CAP and *Streptococcus pneumoniae* (*pneumococcal* CAP) — 3—35 % [2]. The SARS-CoV-2 pneumonia achieved the 4—40 % CFR rate during the outbreak (2020—2022), with the peak in patients older than 65 years, with concurrent cardiovascular or cerebrovascular diseases and immunosuppressive conditions [9].

Clinical data are the first differential criteria, and the main evidence suggesting pulmonary TB were gradual onset with symptoms developing over several weeks to months, while in *pneumococcal* and SARS-CoV-2 pneumonia usually had an acute onset over several days [5, 9, 10]. Night sweats, haemoptysis, weight loss and loss of appetite were suggestive of pulmonary TB, while high fever, chills, intense cough, chest pain and dyspnoea were typical for bacterial and COVID-19 pneumonia [1—3, 9, 11].

Because the lungs are the main organs affected by SARS-CoV-2, community-acquired respiratory infections and TB, the distinctive criteria should be properly identified for early onset of adequate treatment [1, 3, 5, 10]. Based on the results of the specialised literature, the main differential criteria of the listed diseases are clinical presentation, laboratory data and radiological findings. As clinical data are the first differential criteria to be evaluated by healthcare workers, the main evidence suggesting pulmonary TB is gradual onset with symptoms developing over several weeks to months, while in *pneumococcal* and SARS-CoV-2 pneumonia usually have an acute onset over several days [4]. Night sweats, haemoptysis, weight loss and loss of appetite are more suggestive of pulmonary TB, while high fever, chills, intense cough, chest pain, and dyspnoea are more typical for *pneumococcal* and COVID-19-associated pneumonia [3]. Radiographic patterns characteristic of TB — infiltrates, nodules and parenchymal lesions/cavities — are localised in the upper lobes and posterior segments, while *pneumococcal* CAP is most often localised in a lobar distribution, affecting the lower lobe [2, 3, 5, 10].

Some studies denoted that the rate of misdiagnosed TB cases increased during the COVID-19 pandemic, when mobility restrictions caused limited access to specialised healthcare services [2, 5, 9, 10]. As a consequence, the TB notification rates decreased globally by 30 %, with a slight recovery in the late stage of the COVID-19 outbreak [11]. The diagnosis of *pneumococcal* CAP, which is the most common, is based on Gram staining, identifying Gram-positive diplococci (*S. pneumoniae)* in the red and grey stages, while for COVID-19 pneumonia, reverse transcription polymerase chain reaction and rapid antigen tests are the gold standard diagnostic tools [4, 6, 11]. Differential diagnosis of the listed diseases plays a crucial role in the diagnostic process, and the criteria on which it is based are essential tools for clinicians to identify and distinguish between various conditions with similar presentations [6— 8]. The role of these criteria is to provide a systematic approach to evaluating patients' symptoms, signs and investigation results; distinguishing between diseases with similar presentations; guiding further investigations; improving diagnostic accuracy; and recognising when multiple conditions may be present simultaneously [4, 8]. This is important because many patients may have several diagnoses. The major challenge and seriousness of this issue are determined by the epidemiological danger that TB patients pose to the healthy population. Summarising above data, it was pointed out that the diagnosis of TB and CAP, including COVID-19 pneumonia, poses major challenges under current epidemiological conditions, and that the main peculiarities and risk factors need to be revised for a more individualised clinical approach.

Objective — to establish the distinguishing clinical, radiological and laboratory differential diagnostic criteria between COVID-19-associated pneumonia, moderate to severe community-acquired pneumonia and pulmonary infiltrative tuberculosis within the frame of a prospective longitudinal study.

Materials and methods

A prospective case-control study was conducted from 01.01.2020 to 31.12.2022 and included 25 patients who were registered and managed during the initial phase of the COVID-19 pandemic in clinical services in the Chernivtsi region and the Republic of Moldova.

The selected patients weredivided into 3 groups: the 1st group included 70 patients diagnosed with SARS-CoV-2 pneumonia; and 2nd group —

Table 1. **Distribution of the patients by demographic data (n = 266)**

Indices	**Indices**	**1st Group (n = 70)**	**2nd Group (n = 65)**	**3rd Group (n = 120)**
Gender	Men	25 (35 %)*°	41 (63 %)	97 (80 %)
	Women	45 (65 %)*°	24 (37 %)	23 (20 %)
Age groups	18—24 years	0	1 (2 %)	8 (7 %)
	25—34 years	2 (3 %)°	5 (8 %)	24 (20 %)
	35—44 years	8 (11 %)°	2 (2 %)##	37 (31 %)
	45—54 years	14 (20 %)	13 (20 %)	31 (26 %)
	55—64 years	25 (36 %)°	18 (28 %)#	15 (12 %)
	≥65 years	31 (44 %)°	26 (40 %)##	5 (4 %)
Age categories	18—44 years	10 (14 %)*°	11 (17 %)##	69 (57 %)
	≥45 years	60 (86 %)*°	54 (83 %)##	51 (42 %)

Note. * $p < 0.001$ comparing 1st and 2nd groups; ° $p < 0.001$ comparing 1st and 3rd groups; # $p < 0.05$, ## $p < 0.001$ comparing 2nd and 3rd groups; Statistical test: Chi-square.

65 patients diagnosed with severe CAPs and the 3rd group — 120 patients with pulmonary infiltrative TB, registered as new cases.

All patients were aetiologically confirmed through the conventional microbiological or molecular genetic tests and clinically managed in clinical services during the initial phase of the COVID-19 pandemic (01.01.2020—31.12.2022). The study was approved by the ethics committee (approval No. 16 dated 21.04.2020) and the consent forms were signed.

Including criteria for patients in the study were: age over 18 years; the 1st group — SARS-CoV-2 pneumonia diagnosed through nucleic acid amplification test (RT-PCR), antigen test and radiological investigations (chest X-ray and high-resolution computed tomography, HRCT); the 2nd group — severe CAP diagnosed aetiologically through Gram smear staining and culture with antibiogram (susceptibility testing against conventional antibiotics), radiological investigations (chest X-ray, HRCT); the 3rd group — pulmonary infiltrative TB, diagnosed through sputum smear Ziehl—Neelsen staining, culture with drug-sensitivity testing (DST), nucleic acid amplification tests (GeneXpert MTB/Rif) and chest X-ray.

Severity of CAPs was assessed using major criteria: respiratory failure, tachypnea (rate ≥ 30 breaths), hypotension (< 90/60 mmHg), hypothermia (< 36 °C), confusion, plasma urea nitrogen ≥ 20 m/dL, platelet count < $100 \cdot 10^3$/μL and leucocyte count < 4000/mm^3. The results of bacterial culture on conventional growth media and DST established *S. pneumonia* in 22 (34 %), *H. influenzae* in 11 (17 %), methicillin-susceptible *S. aureus* — 4 (6 %), *S. pyogenes, M. pneumonia* and *P. mirabillis* — in 3 (5 %) cases respectively, *P. aeruginosa* and *Enterobacter sp.* — in 2 (3 %) patients respectively and *Klebsiella sp.* — in 4 (6 %) cases. In 12 (18 %) patients the viral aetiology of CAP was confirmed through polymerase chain reaction and rapid antigen detection tests.

Statistical analysis was carried out using quantitative and qualitative methods with SPSS Statistics 23.0 software, in which paired sample T-test, Anova and Chi-square tests were performed. Differences were considered statistically significant with a confidence level of more than 95 % and $p < 0.05$.

Results

According to the distribution by gender, the male-to-female ratio was 0.5 : 1.0 in the first group, 2 : 1 in the second group and 4 : 1 in the third group.. The rate of men affected by TB and severe bacterial CAP was statistically higher than in SARS-CoV-2 pneumonia ($\chi^2 = 21$; $p < 0.001$).

Repartition of patients into age groups, according to the WHO recommendations, identified that the largest subgroups in the 1st group were patients aged between 45 and 64 years and those older than 65 years (86 %); in the 2nd group — between 55 and 64 years and older than 65 years (68 %); and in the 3rd group — between 25 and 54 years, constituting two thirds (77 %).

The statistical threshold was reached when comparing the subgroups aged 35—44 years, which predominated in the 3rd group, with the 1st and 2nd groups, and subgoups of patients between 55—64 years and the over 65 years, which predominated in the 1st group *vs.* 2nd and 3rd groups ($\chi^2 = 15$; $p < 0.001$). Regrouping the patients in two age groups — younger and older than 45 years — showed that younger patients statistically predominated in the 3rd group compared to the 1st and those older than 45 years predominated in the first and second groups compared to the third group ($\chi^2 = 34$; $p < 0.0001$) (Table 1).

Analysing statistical data, it was found that the male sex was a high-risk factor for developing active

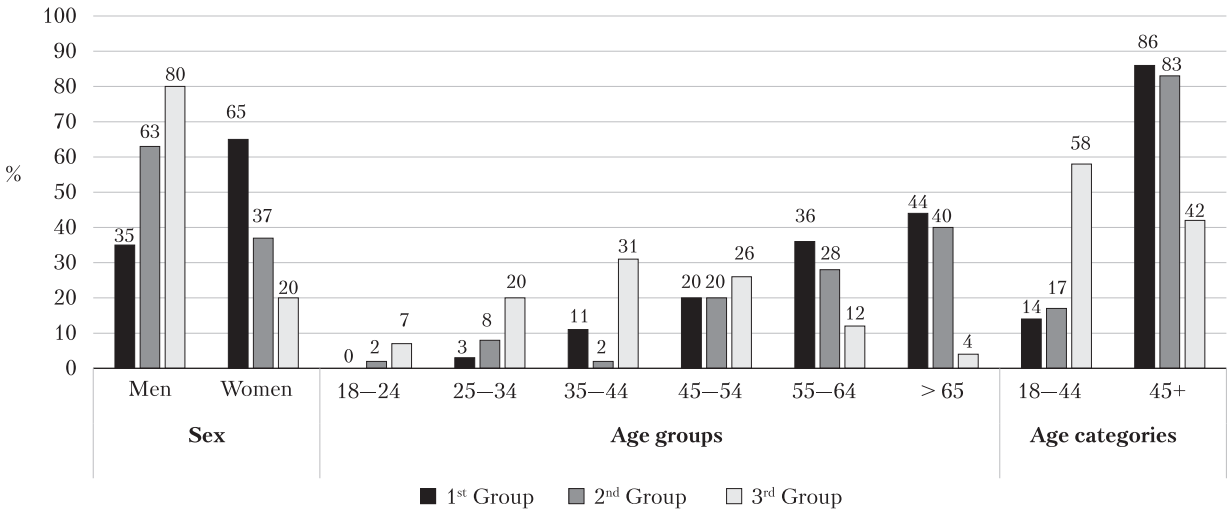

Fig. 1. **Distribution of the patients by demographic data**

TB (OR = 7.6; 95 % CI 3.7—14.9; risk difference 46 %; $\chi^2 = 37$; $p < 0.001$) compared to SARS-CoV-2 pneumonia and a moderate-risk factor for severe CAP (OR = 2.4; 95 % CI 1.3—4.8; risk difference 21 %). Young age (< 45 years) was a high-risk factor for developing TB (OR = 8.1; 95 % CI 3.6—17.2; risk difference 20 %) and age over 45 years was a high-risk factor for severe CAP and SARS-CoV-2 pneumonia (OR = 6.6; 95 %; CI 3.1—14.2; $\chi^2 = 32$; $p < 0.001$; risk difference 41 %) and OR = 7.4; 95 % CI 3.2—8.1; $\chi^2 = 27$; $p < 0.001$; risk difference 37 %) (Fig. 1).

The primary epidemiological risk factor for TB is contact with an active source of infection, which was identified in one third of patients in the 3rd group (43 patients, 33 %), including 33 patients (26 %) from family outbreaks.

One third of patients with SARS-CoV-2 pneumonia had returned from abroad while ill, and one fifth of TB patients had recently returned from labour migration within the past three months.

All patients with SARS-CoV-2 pneumonia, 61 (93 %) patients with severe CAP, and 68 (56 %) cases of pulmonary TB had underlying comorbid conditions.

The combination of the associated diseases was assessed using the Euler circles. The combintation of 5 diseases was detected in 19 (27 %) cases, of 4 diseases in 24 (34 %) and of 3 diseases in 27 (36 %) patients with SARS-CoV-2 pneumonia.

The most common combination in patients with SARS-CoV-2 pneumonia involved cardiovascular diseases such as arterial hypertension, atherosclerotic heart disease and congestive heart failure, along with chronic respiratory diseases, observed in 51 (73 %) patients.

Additionally, glucose metabolism disorders were present in 24 (34 %) patients diagnosed with SARS-CoV-2-associated pneumonia. In every second patient with severe CAP (31 (48 %) were more often diagnosed with 2 associated diseases, 27 (41 %) with 3 comorbidities and in 7 (11 %) with only one associated disease.

The most frequent combination, observed in approximately one third of patients (23 cases, 35 %), was an infectious complication on a chronic respiratory condition (such as chronic bronchitis, chronic obstructive pulmonary disease, bronchiectasis or lung fibrosis) combined with cardiovascular diseases.

Immunocompromised state due to HIV infection (AIDS), immunosuppressive therapy and chronic respiratory diseases was identified in 6 (10 %) cases. Regarding the 3rd group, post-tuberculosis lung disease was diagnosed only in TB patients, including bronchiectasis in 5 (4 %) cases, calcifications in 19 (16 %), pleural adhesions in 22 (18 %) and pulmonary hypertension in 2 (1 %) patients.

One of the most frequent comorbidities was the type 2 diabetes mellitus (DM), which was diagnosed in 17 (24 %) patients with SARS-CoV-2 pneumonia, 8 (12 %) with severe CAP and 11 (9 %) patients with TB. Overweight/obesity (body mass index (BMI) greater than 25—30 kg/m^2) was established in 65 (93 %) COVID-19 patients and 36 (55 %) severe cases with CAP.

Malnutrition (BMI < 20 kg/m^2) was detected in 86 (72 %) and cachexia (BMI < 18 kg/m^2) in 34 (29 %) TB patients (Table 2).

Active tobacco smoking was detected in the majority of TB patients, 98 (82 %), and in patients with CAP — 39 (60 %). The rate were statistically higher compared to the group with SARS-CoV-2 pneumonia ($\chi^2 = 63$; $p < 0.001$).

Alcohol abuse or chronic alcoholism statistically predominated among the patients with TB and CAPs ($\chi^2 = 13$; $p < 0.001$).

Table 2. **Risk factors distribution among patients (n = 255)**

Indices	Indices	1st Group (n = 70)	2nd Group (n = 65)	3rd Group (n = 120)
Epidemiological	TB contact	0	0$^{\#\#}$	43 (33)
	Recently returned from abroad	25 (35 %)**	0$^{\#\#}$	16 (20 %)
Biological	Co-morbidities	70 (100 %)°°	61 (93 %)$^{\#\#}$	68 (56 %)
	HIV-infection	1 (1 %)°	5 (8 %)$^{\#}$	22 (18 %)
	Alcohol abuse	0 (0 %)**°°	11 (17 %)	28 (23 %)
	Tobacco smoking	16 (23 %)**°°	39 (60 %)$^{\#}$	98 (82 %)
	Drug use	0 (0 %)*°	5 (8 %)	10 (8 %)
	Obesity/overweight	49 (70 %)**°°	62 (95 %)$^{\#\#}$	0 (0 %)
	Undernutrition/cachexia	0 (0 %)°°	0 (0 %)$^{\#\#}$	110 (92 %)
Social economical	Vulnerable	12 (17 %)**°°	6 (9 %)$^{\#\#}$	107 (89 %)
	Stable	58 (83 %)**°°	59 (91 %)$^{\#\#}$	13 (11 %)

Note. * p < 0.01, ** p < 0.001 comparing 1st and 2nd groups; ° p < 0.01, °° p < 0.001 comparing 1st and 3rd groups; $^{\#}$ p < 0.01, $^{\#\#}$ p < 0.001 comparing 2nd and 3rd groups; Statistical test: Chi-square.

Socially and economically vulnerable state was established in a statistically higher proportion in the TB group compared with other groups (χ^2 = 17; p < 0.001).

Analysing statistical data, it was concluded that the major risk factors for active TB were: socially vulnerable state (OR = 39.1; 95 % CI 24—46), alcohol abuse (OR = 18.4; 95 % CI 4.7—26.1), undernourishment (OR = 15.6; 95 % CI 14—19), tobacco smoking (OR = 8.1; 95 % CI 6.2—9.7) and recent contact with an active source of infection (OR = 5.9; 95 % CI 4.3—7.2).

The risk factors with medium impact were labour migration in the last 3 months (OR=3.6; 95 % CI 2.1—4.7) and immunosuppression due to HIV/AIDS (OR = 2.2; 95 % CI 1.2—4.7). For SARS-CoV-2 pneumonia and severe CAPs the major risk factors were the comorbid background (OR = 21; 95 % CI 19—38) and (OR = 186; 95 % CI 144—196) respectively), overweight (OR = 4.9; 95 % CI 2.4—6.2) and OR = 18; 95 % CI 14—26) (Fig. 2).

The demographic characteristics of the patients showed no significant differences; however, male sex was identified as a high-risk factor for developing TB (OR = 7.6; 95 % CI: 3.7—14.9; risk difference: 46 %; χ^2 = 37; p < 0.001) compared to SARS-CoV-2 pneumonia. Additionally, male sex was found to be a moderate-risk factor for severe CAP (OR = 2.4; 95 % CI: 1.3—4.8; risk difference: 21 %). Young age (< 45 years) was identified as a high-risk factor for developing TB (OR = 8.1; 95 % CI: 3.6—17.2; risk difference: 20 %). In contrast, age over 45 years was a significant risk factor for severe CAPs (OR = 6.6; 95 % CI: 3.1—14.2; χ^2 = 32; p < 0.001; risk difference: 41 %) and SARS-CoV-2 pneumonia (OR = 7.4; 95 % CI: 3.2—8.1; χ^2 = 27; p < 0.001; risk difference: 37 %).

While the demographic characteristics of the patients did not differ between the groups, their risk

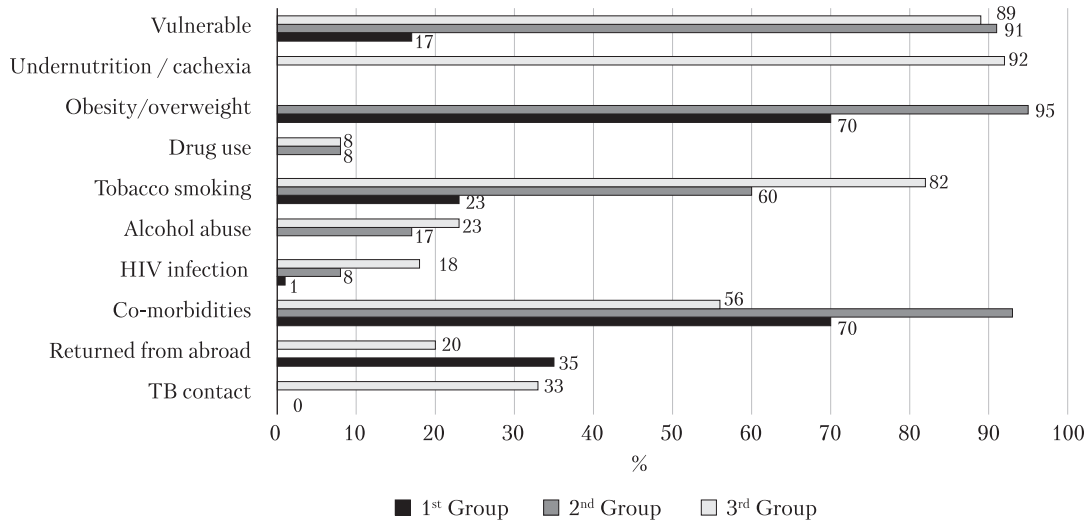

Fig. 2. **Distribution of risk factors among patients**

factors, clinical presentation, case management and aetiological examination results were contrasting. Similar aspects were identified in other international research [1—6, 9—11].

Conclusions

1. The demographic characteristics of patients across all study groups indicated that male sex was a high risk factor for developing TB compared with SARS-CoV-2-associated pneumonia.

2. Male sex was a moderate-risk factor for severe community-acquired pneumonia.

3. Young age (< 45 years) was identified as a high-risk factor for developing TB, whereas age over 45 years was a significant risk factor for both or severe community-acquired pneumonia and SARS-CoV-2-associated pneumonia.

There is no conflict of interest.
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Е.В. Леснік[1], Л.Д. Тодоріко[2]
[1] Державний університет медицини та фармації «Ніколая Тестеміцану, Кишинів, Республіка Молдова
[2] Буковинський державний медичний університет, Чернівці

Критерії для диференціації легеневого туберкульозу від позалікарняної пневмонії середнього та тяжкого перебігу, пов'язаної з COVID-19. Частина 1

Пандемія коронавірусної хвороби-2019 (COVID-19) суттєво змінила спектр легеневої патології. Оскільки легені є основними органами, що вражаються вірусом SARS-CoV-2, позалікарняною інфекцією та інфекцією, спричиненою мікобактеріями туберкульозу, їхня диференціація на основі специфічних клінічних, радіологічних і лабораторних досліджень має бути проведена належним чином для раннього початку лікування та подальшого спостереження.

Мета роботи — визначити клінічні, радіологічні та лабораторні критерії для диференційної діагностики пневмонії, асоційованої з COVID-19, позалікарняної пневмонії середнього й тяжкого ступеня та інфільтративного туберкульозу легень.

Матеріали та методи. Проведено проспективне дослідження типу випадок—контроль з 01.01.2020 р. до 31.12.2022 р. Було залучено 255 пацієнтів, яких розподілили на три групи — 70 хво-

рих на пневмонію, асоційовану з SARS-CoV-2, 65 хворих на позалікарняну пневмонію та 120 хворих на інфільтративний туберкульоз легень. У всіх пацієнтів діагноз етіологічно підтверджено за допомогою звичайних мікробіологічних або молекулярно-генетичних тестів. Хворі отримували лікування в спеціалізованих клінічних установах. Статистичний аналіз проводили за допомогою кількісних і якісних тестів програмного забезпечення SPSS Statistics 23.0 із використанням Т-критерію парної вибірки, ANOVA і тесту χ^2. Відмінності вважали статистично значущими з вірогідністю > 95 % ($p < 0,05$).

Результати та обговорення. Демографічні характеристики істотно не відрізнялися між групами, але чоловіча стать була визначена як чинник високого ризику розвитку туберкульозу (відношення шансів (ВШ) — 7,6, 95 % довірчий інтервал (ДІ) — 3,7—14,9, різниця ризиків — 46 %; $\chi^2 = 37$; $p < 0,001$), але не пневмонії, асоційованої із SARS-CoV-2. Установлено, що чоловіча стать є також чинником помірного ризику розвитку тяжких позалікарняних пневмоній (ВШ — 2,4; 95 % ДІ — 1,3—4,8, різниця ризиків — 21 %). Молодий вік (< 45 років) визначено як чинник високого ризику розвитку туберкульозу (ВШ — 8,1; 95 % ДІ — 3,6—17,2; різниця ризиків — 20 %), тоді як вік понад 45 років був чинником високого ризику розвитку тяжких позалікарняних пневмоній (ВШ — 6,6; 95 % ДІ — 3,1—14,2; $\chi^2 = 32$; $p < 0,001$, різниця ризиків — 41 %) і пневмонії, асоційованої із SARS-CoV-2 (ВШ — 7,4; 95 % ДІ — 3,2—8,1; $\chi^2 = 27$; $p < 0,001$; різниця ризиків — 37 %).

Висновки. Вивчення демографічних характеристик пацієнтів у всіх групах показало, що чоловіча стать, імовірно, є чинником високого ризику розвитку туберкульозу, але не пневмонії, асоційованої із SARS-CoV-2. Установлено, що чоловіча стать є чинником помірного ризику розвитку тяжкого перебігу позалікарняної пневмонії. Молодий вік (< 45 років) визначений як чинник високого ризику розвитку туберкульозу, а вік понад 45 років — як чинник високого ризику розвитку тяжких позалікарняних пневмоній і пневмонії, асоційованої із SARS-CoV-2.

Ключові слова: туберкульоз, COVID-19, позалікарняна пневмонія, чинники ризику, вік, стать.

Контактна інформація / *Corresponding author*

Тодоріко Лілія Дмитрівна, д. мед. н., професор
https://orcid.org/0000-0002-0117-6513
58002, м. Чернівці, пл. Театральна, 2
E-mail: pulmonology@bsmu.edu.ua

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