Прогнозирование исходов при лабораторно верифицированном COVID-19 по данным компьютерной томографии органов грудной клетки: ретроспективный анализ 38 051 пациента

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Обоснование. В условиях сложившейся эпидемиологической ситуации компьютерная томография органов грудной клетки (КТ ОГК) играет важную роль в диагностике заболевания. Клинические и КТ-данные позволяют врачам в короткие сроки установить вероятность наличия и прогноз у пациентов с COVID-19.

Цель — прогнозирование исходов у лабораторно верифицированных больных COVID-19 по данным КТ ОГК с помощью полуколичественной визуальной шкалы степени поражения лёгочной паренхимы (шкала КТ0–КТ4).

Материал и методы. Выполнен ретроспективный анализ выгрузки историй болезни из Единого медицинского информационного-аналитического сервиса (ЕМИАС) и протоколов из Единого радиологического информационного сервиса (ЕРИС) в период с 01.03.2020 по 30.07.2020. В исследование включены истории болезней пациентов с диагнозом U07.1 по МКБ-10 (лабораторно верифицированная коронавирусная инфекция), которым с 1 марта по 30 июля 2020 г. включительно проведена КТ ОГК по направлению врача-терапевта при подозрении на внебольничную пневмонию, вызванную COVID-19; максимально допустимый срок между лабораторной верификацией и КТ ОГК — не более 5 дней. Срок наблюдения за каждым пациентом — не менее 30 сут от даты проведения КТ. Исследования были выполнены в 48 медицинских организациях, оказывающих первичную медицинскую помощь взрослому населению Москвы. Не вошли в исследование пациенты, у которых результаты теста полимеразной цепной реакции на COVID-19 были отрицательными к 30.07.2020. Шкала КТ0–КТ4 рекомендована к применению в Российской Федерации для оценки объёма поражения паренхимы лёгкого при подозрении на COVID-19.

Результаты. Итоговый объём выборки — 38 051 пациент. По результатам исследования выявлено, что для категории КТ4 риск смерти выше в 3 раза по сравнению с категорией КТ0. По кривым Каплана–Мейера для анализа выживаемости доля выживших пациентов в категории КТ3 почти в 3 раза ниже (HR = 2,94), чем в категориях КТ0–КТ2. Кроме того, установлено, что чем выше исходная категория КТ, тем ниже риск ухудшения. Время до госпитализации снижалось при увеличении категории по данным КТ ОГК.

Заключение. Визуальная шкала КТ0–КТ4 может быть использована в качестве предиктора исходов (госпитализаций и летальных исходов) у пациентов, которым при подозрении на COVID-19 выполнена КТ ОГК на базе первичного звена здравоохранения.

Ключевые слова: COVID-19; внебольничная пневмония; компьютерная томография.

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Chest computed tomography for outcome prediction in laboratory-confirmed COVID-19: A retrospective analysis of 38,051 cases

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BACKGROUND: In the current epidemiological situation, computed tomography (CT) of chest organs plays an important role in disease diagnosis. Clinical and CT data allow physicians to quickly establish the probability of the presence and prognosis of patients with coronavirus disease 2019 (COVID-19).

AIMS: This study aimed to predict outcomes in patients with laboratory-confirmed COVID-19 based on chest CT and a semi-quantitative visual pulmonary lesion grading system (CT 0–4).

MATERIALS AND METHODS: A retrospective analysis of the Unified Medical Information and Analytical Service and Unified Radiological Information Service records from March 01, 2020 to July 30, 2020 was performed. The inclusion criteria were as follows: patients diagnosed with U07.1 (laboratory-verified coronavirus infection) from March 01, 2020 to July 30, 2020 and referred for a chest CT by a physician with suspected community-acquired pneumonia caused by COVID-19; the maximum period between laboratory verification and CT was not more than five days. The observation period for each patient was at least till 30 days from the date of CT. CT was performed in 48 medical organizations providing primary medical care to adults in Moscow. The exclusion criterion was a negative reverse transcription-polymerase chain reaction results by July 30, 2020. The CT 0–4 scale is recommended for use in the Russian Federation to estimate the volume of lung parenchyma lesions when COVID-19 is suspected.

RESULTS: The total sample volume was 38,051 patients. In this study, the risk of death was three times higher for CT-4 than for CT-0. In the Kaplan–Meier survival curve, the survival rate of patients in the CT-3 category was almost three times lower (hazard ratio = 2.94) than in the CT 0–2 categories; in addition, the higher the initial category of CT, the lower the risk of deterioration. The time for hospitalization decreased with the increase in the CT grade.

CONCLUSION: The visual CT 0–4 scale can be used to predict outcomes, such as hospitalizations and deaths, in patients suspected of COVID-19 who underwent chest CT in primary health care.

Keywords: COVID-19; community-acquired pneumonia; computed tomography.

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基于胸部CT的实验室验证COVID-19预后预测：38,051例患者的回顾性分析

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论证：在目前的流行病学情况下，胸部器官CT（胸部器官的计算机断层扫描）在该病的诊断中起着重要的作用。临床和CT数据使医生能够快速判断COVID-19患者的存在概率和预后。

目的：预测实验室证实的COVID-19患者的结果，基于胸部器官CT，使用肺实质损伤程度半定量视觉量表（CT0—CT4量表）。

材料与方法。对2020年3月1日至2020年7月30日期间从统一医疗信息和分析服务处（UMIAS）和从统一放射信息服务处（ERIS）卸载的医疗记录和协议进行了回顾性分析。本研究纳入了根据ICD-10诊断为U07.1患者的病历（实验室确诊新型冠状病毒感染病例）。从2020年3月1日至7月30日，这些患者在疑似COVID-19引起的社区获得性肺炎的内科医生的指导下接受胸部器官CT检查；实验室检查和胸部器官计算机断层扫描之间最长允许的时间不超过5天。每位病人的随访期由CT日期起计最少为30天。这项研究是在向莫斯科成年人口提供初级医疗保健的48个医疗机构中进行的。本研究不包括截至2020年7月30日COVID-19聚合酶链反应试验结果为阴性的患者。CT0-CT4量表推荐在俄罗斯联邦用于评估疑似COVID-19病例肺实质损害的程度。

结果。样本量为38,051例。根据研究结果，CT-4类患者的死亡风险比CT-0类患者高3倍。Kaplan-Meyer 生存曲线显示，CT-3类患者的存活比例比CT0-CT2类患者低3倍（HR = 2.94）。此外，发现了CT的初始类别越高，恶化的风险越低。根据胸部器官CT显示，住院时间随类别的增加而减少。

结果。CT0-CT4的视觉尺度可用于预测疑似COVID-19患者的预后（住院和死亡），如果患者在初级卫生保健的基础上接受了胸部器官CT检查。

关键词：COVID-19；社区获得性肺炎；计算机断层扫描

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INTRODUCTION

On March 11, 2020, the World Health Organization declared COVID-19 caused by the SARS-CoV-2 virus a pandemic [1]. According to official data, by the third quarter of 2020, there were more than 29 million confirmed cases and more than 940 thousand deaths worldwide [2].

Given the current epidemiological situation, chest computed tomography (CT) plays an essential role in diagnosing the disease. Clinical and CT data allow doctors to establish the probability and prognosis in patients with COVID-19 within a short time [3]. It should be noted that there are no specific signs of COVID-19 in chest CT, but bilateral peripheral ground-glass opacities are most often visualized, with a predominantly basal involvement [4,5]. Besides, quantitative chest CT analysis allows for COVID-19 patient triage [6]. Thus, Colombi et al. presented a quantitative assessment of pulmonary parenchyma lesions using an open-source software and established a high correlation between preserved, well-ventilated pulmonary tissue and outcomes (transfer to the intensive care unit or death) [7]. The extent of pulmonary lesions in COVID-19 can be fully and automatically assessed using machine learning algorithms [8].

Due to the epidemiological situation, it is necessary to create and critically evaluate prognostic models based on clinical data [9]. In the Russian Federation, due to the large patient flow, an "empirical" visual scale is recommended for the rapid and standardized assessment of lung lesions detected by chest CT [10].

This study aimed to predict the outcomes of laboratory-confirmed COVID-19 patients from their chest CT data using a semi-quantitative visual scale for grading pulmonary lesions.

MATERIALS AND METHODS

The Independent Ethical Committee of the Moscow Regional Branch of the Russian Society of Radiologists approved this retrospective study. Informed consent was not required due to the retrospective design of the study (absence of the prospective part of the study intervening in the treatment or diagnosis). A total of 240985 patients were selected from UMIRAS and Unified Radiological Information Service (URIS). We excluded 202934 patients due to lack of laboratory confirmation or data on the CT0–4 scale.

Patients

The analysis of the Unified Medical Information and Analytical Service (UMIAS) and URIS protocols for the period from 01/03/2020 to 30/07/2020 inclusive was performed. The study included patients according to the following criteria: patients diagnosed with U07.1 (laboratory-confirmed coronavirus infection) and referred for a chest CT by a physician due to suspected community-acquired pneumonia caused by COVID-19; the maximum allowable period between laboratory verification and CT less ≤5 days. The observation period for each patient was at least 30 days from the CT scan in the outpatient clinic. We excluded patients without any typical coronavirus-associated chest CT changes, patients not assessed by the CT0–CT4 system, and patients with a negative polymerase chain reaction test as of 30/07/2020.

Equipment and CT protocol

The scanning was performed on 48 CT scanners, including Toshiba Aquilion 64 (Canon, Japan), Toshiba Aquilion CXL (Canon, Japan), and General Electric HiSpeed (GE, USA). For all studies, the standard protocol was used: voltage, 120 kV; tube current is adjusted automatically depending on the topogram; scanning direction—from the diaphragm to the lung apex; the field of view (FOV), 350 mm; slice thickness ≤ 1 mm; reconstruction kernel—lung, for Toshiba (Canon)—FC50/FC51/FC52/FC53, for GE—LUNG. Scanning was performed on breath-hold at an inspiration depth.

Evaluation of chest CT data

The initial assessment of the chest CT was performed using URIS by the outpatient CT center radiologists with 8–22 years of work experience. All the examinations were reviewed using URIS by on-duty experts of the Moscow Reference Radiology Center, with no other software used. Within 30 minutes after completing each primary protocol, an expert of the reference center with experience in thoracic radiology of ten years performed the audit and, if necessary, corrected the CT0–4 grade. Thus, the category was changed almost immediately, without saving the primary data. According to the audit reports, the percentage of discrepancies using the CT0–CT4 scale was up to 5%.

According to the Interim Methodological Recommendations of the Russian Society of Radiologists and the Russian Association of Ultrasound Diagnostics in Medicine, the so-called "empirical" visual scale is recommended to evaluate changes in the lungs detected by chest CT. It is based on a visual evaluation of the approximate volume of affected lung tissue [11]. This scale has five gradations, beginning at 0 and then with intervals of 25%. The Moscow Department of Health uses methodological recommendations, according to which the severity assessment of pulmonary lesions in COVID-19 should be based on the percentage of pulmonary tissue affected regardless of the semiotic phase of the process (ground-glass, crazy paving, consolidation) or their combination. This parameter is assessed separately for each lung. The category of changes is determined by the lung with the most extensive lesion (regardless of postoperative changes) [10].

Study hypotheses

The following questions were asked to conduct the study:

1. Is there a relationship between the CT0–CT4 grade in laboratory-confirmed patients and the risk of death?
2. Is there a relationship between the CT0–CT4 grade in laboratory-verified patients and survival rate?
3. Is there a relationship between the transition time for different grades and the initial CT0–CT4 category in the laboratory-confirmed patients?
4. Is there a relationship between the CT0–CT4 grade in laboratory-verified patients and the number of days from primary CT to hospitalization?

Statistical methods

The data analysis included all patients with a laboratory-confirmed diagnosis of COVID-19, for whom valid data was available on the dates of hospitalization and the dates of at least one CT scan. The result and date of the first CT scan that was used for the evaluation were taken as the baseline level and CT evaluation date: for 36,958 patients, this was the first CT scan; for 1,049 patients, the second CT scan; for 41 patients, the third CT scan; and for 3 patients, the fourth CT scan.

A logistic regression model was used to analyze data on patient deaths. Patient sex and age, as well as the CT severity grade, were used as the model factors. For each factor, the odds ratio (OR) of death, and the 95% confidence interval (CI) for OR, were estimated.

We applied the Kaplan–Meier method and Cox regression to analyze the time-to-event data (overall survival, time to CT deterioration, time from the baseline CT scan to hospitalization), patient sex and age, and the baseline CT severity grade as the model factors.

For the dependent variable, i.e., the number of hospitalizations, Poisson regression was performed using the above factors as covariates. The incidence rate ratio (IRR) and the corresponding 95% CI were estimated for each factor.

For data on the total duration of hospitalization (number of days) and the number of days from the date of baseline CT scan to laboratory confirmation of the diagnosis, a multivariate regression model was employed, which used sex, age, and CT severity grade as factors. For each factor, regression coefficient values were given with the 95% CI. Statistical analyses were performed using Stata 14 software.

RESULTS

A total of 240,985 patients were selected from UMIAS and URIS. On the other hand 202,934 patients were excluded from the study due to the lack of laboratory confirmation and data on the CT0–4 scale. The study sample consisted of 38,051 patients, including 21,888 men (57.5%) and 16,163 women (42.5%). The mean age was 50 ± 14.7 years. The total number of deaths was 182. The sampling process flowchart is shown in Figure 1. Following the baseline scan, most patients were classified as CT1 (Table 1).

For grade CT-4 patients, the risk of death was three times higher ($p = 0.010$). No statistically significant differences were found for CT-2 and CT-3 grades. Similar results were obtained in the overall survival analysis. In Kaplan–Meier survival curves, the survival rate of patients in the CT-3 category was almost three times lower (HR = 2.94) than that of the patients in the CT0-2 categories (Fig. 2).

The analysis of the time to chest CT deterioration by one or more grades relative to the baseline was performed. The results showed that the higher the baseline level, the lower the risk of deterioration ($p < 0.001$) (Fig. 3).

Also, it was found that the time to hospitalization decreased as the chest CT severity grade increased ($p < 0.001$) (Fig. 4).

In the analysis of the interval between the first and second CT scans ($N = 12726$), the mean time-lapse between them was 25.1 ± 21.9 days (95% CI 24.7–25.5), while the median time was 20 days. As for the time between the first and third CT scans ($N = 2847$), the time-lapse was 36.6 ± 28.8 days (95% of CI 35.4–37.5), while the median was 30 days. In the analysis of the interval between the first and fourth CT scans ($N = 582$), the mean time-lapse was 44.6 ± 26.5 days (95% of CI 42.4–46.7), while the median was 40 days.

Table 1. Distribution of patients by baseline CT0–CT4 grade

Baseline CT grade	Number of patients	Proportion (%)
0	8,112	21.3
1	18,704	49.2
2	8,180	21.5
3	2,773	7.3
4	282	0.7
Total	38,051	100.0

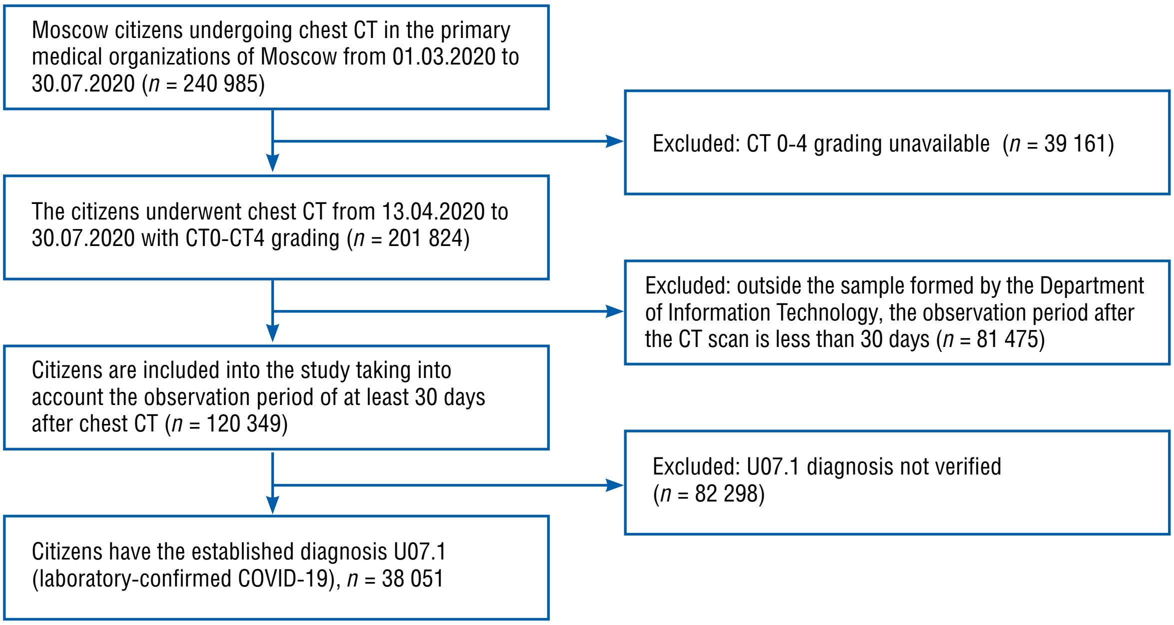

Figure 1. Sampling process flowchart.

Notes: CT — computed tomography; CT 0-4 — semi-quantitative visual scale of the pulmonary parenchyma damage

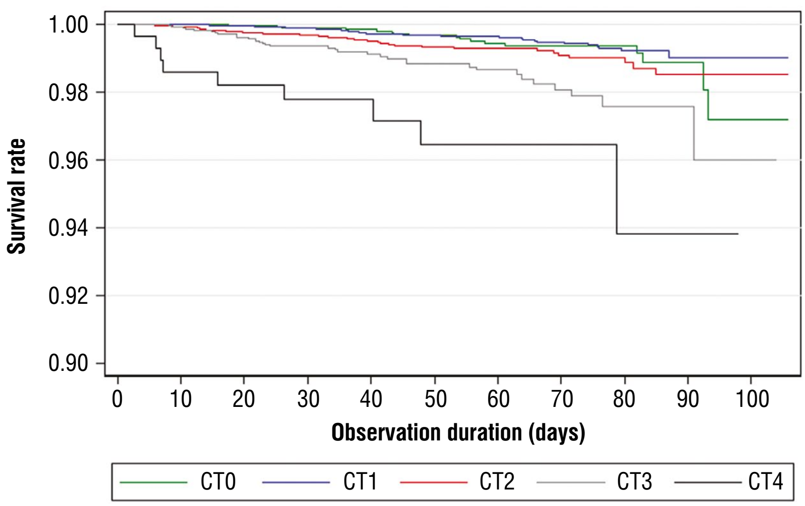

Figure 2. Overall survival curves for CT1-4 grades ($p < 0.0001$)

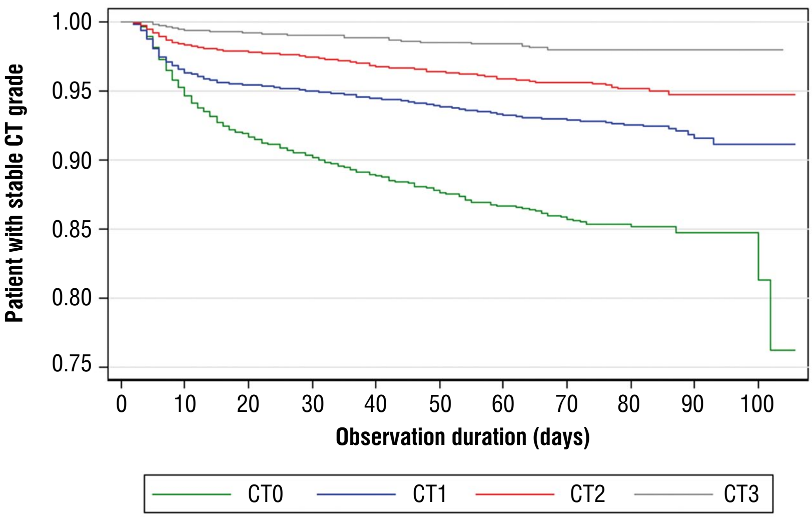

Figure 3. Kaplan–Meier curves for the time to deterioration by one or more grades relative to the baseline ($p < 0.0001$).

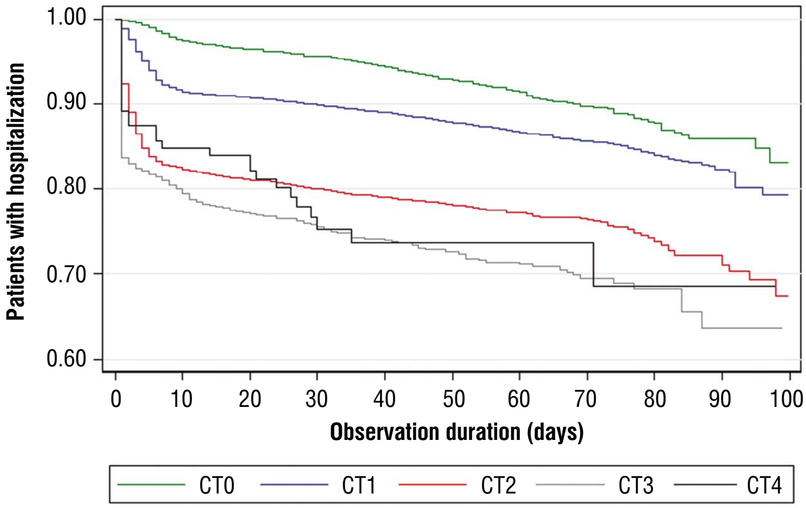

Figure 4. Kaplan–Meier curves for the time from the baseline CT to hospitalization ($p < 0.0001$)

DISCUSSION

This study showed that for grade CT-4 patients, the risk of death was three times higher than for grade CT-0 patients. According to Kaplan-Meier curves, the proportion surviving patients in the CT-3 category was almost 3 times lower (HR = 2.94) than in the CT0-CT2 categories. Also, it was found that the higher the baseline CT grade, the lower the risk of deterioration. In Fig. 3, the CT-3 curve is the most stable in time, while the CT-0, CT-1, and CT-2 curves tend to degrade. Therefore, the lighter grades (CT-0, CT-1, and CT-2) require the same attention as the severe disease, as there is a greater risk of disease progression. The time to hospitalization decreased as the chest CT severity grade increased.

It should be noted that the decision to hospitalize depends on the clinical status of the patient, peculiarities of the organization of a specialized bed fund, and legal acts. Also, patients could be hospitalized outside the observation period or hospitalized in facilities that are not connected to UMIAS. A higher all-cause mortality rate was registered in June, which may be due to the health system's workload and the imperfection of medical care algorithms in a complicated epidemiological situation.

Previously, we conducted a retrospective study that revealed that the probability of death increased progressively from CT-0 to CT-4. The patient's age and CT-0 to CT4 grade were statistically significantly associated with the time to death from COVID-19. When moving from one CT grade to the next, the risk increased by an average of 38% [12]. However, the earlier study included patients without laboratory confirmation of the coronavirus infection, the follow-up period was significantly shorter, and only the relationship between CT grade and deaths was evaluated. This study improves on previous results and is based on a larger sample with laboratory-confirmed diagnoses and more detailed information about the outcomes.

It was found that chest CT enables to detect pulmonary abnormalities that are characteristic of COVID-19 and grade them, which is in line with the results obtained by other authors [13,14]. Yuan et al. developed a prognostic model of deaths from COVID-19 that considers CT data but uses a comprehensive segment-by-segment evaluation of the CT images [15]. Errors may be accumulated due to the multicomponent semi-quantitative evaluation in the model. Other limitations include the long time required for data analysis and its complexity in routine practice. The proposed method of evaluating chest CT data is easily applicable in practice, correlates with the risk of death from all causes, overall survival, and risk of clinical deterioration.

Petrikov et al. revealed a relationship between increased lung involvement detected by CT and clinical deterioration in patients [16]. In a retrospective multicenter observational study by Xu et al., a multivariate analysis of 703 laboratory-confirmed cases of COVID-19 was performed, which showed a correlation between death and the presence of comorbidities, leukocytosis, lymphopenia, and severe lung impairment as shown by CT [17]. The authors proposed a visual segment-by-segment semi-quantitative scale to evaluate lung impairment, where the affected segment was evaluated as 1 point regardless of lesion morphology. When 14 segments (70%) or more were involved, the risk of death increased three times. Colombi et al. presented a quantitative assessment of the lung involvement using an open-source software, which showed a high correlation between preserved, well-ventilated lung tissue and the outcomes (transfer to the intensive care unit or death) [7]. In the study by Xiong et al., a small sample of 42 patients showed a positive correlation between the number of affected lung lobes at baseline and the risk of pulmonary infiltration progression [18]. The results of these studies are comparable to ours. The main differences include the use of the original CT0–4 scale and the examined populations. In our case, these were only patients who independently applied for medical care in the primary health care system.

Our study has several limitations. First, the data were analyzed retrospectively. However, this design allowed the study to include many patients with a long follow-up period. Second, the authors did not review the chest CT scans, possibly affecting the patient grading using the CT0–4 scale. Given the large sample size, the impact of borderline cases under- or overestimating the severity of lung impairment was minimized. Also, all studies were reviewed by on-duty medical experts from the Moscow Reference Radiology Center. Third, the large sample formed semi-automatically limited the validation possibilities. However, high statistical significance and literature analysis results support the validity of the findings in this study.

CONCLUSION

The visual CT0–4 scale can be used to predict outcomes (hospitalizations and deaths) in patients suspected of COVID-19 who underwent chest CT scans in primary health care.

ADDITIONAL INFO

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Authors contribution. S.P. Morozov — research concept; V.Yu. Chernina — search for publications, editing the manuscript; I.A. Blokhin — preparing the dataset, writing the manuscript; V.A. Gombolevsky — expert assessment of study results. All authors made a significant contribution to the study and preparation of the article, read and approved the final version before publication.

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