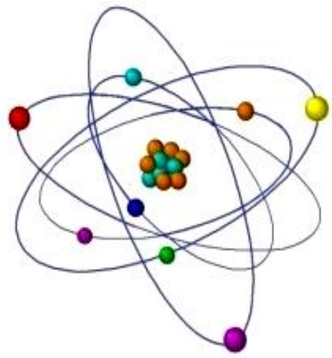
METHODOLOGICAL ISSUES OF "JUSTIFICATION" OF CHEST CT IN THE FEMALE POPULATION OF GEORGIA



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ABSTRACT: *To further refine the criteria for justifying chest computed tomography (CT) scanning in Georgia, taking into account its specific characteristics, this study analyzes the diagnostic value and clinical feasibility of chest CT scanning upon hospital admission of COVID-19 patients. Data on COVID-19 incidence, hospitalization, and mortality in Georgia for 2020–2021 were obtained from the First University Clinic of Tbilisi State Medical University (Georgia) and the National Center for Disease Control and Public Health (NCDC). Prognostic values for the incidence of radiogenic breast cancer among women with COVID-19 hospitalized in 2021 and undergoing chest CT scanning were obtained from our previous work.*

In the risk-benefit analysis, clinical benefit was defined as the difference between the risk of severe complications or mortality without CT scanning and the residual risk of the same outcomes with CT scanning. This was determined using binary logistic regression methods, receiver operating characteristic (ROC) curve analysis, and Monte Carlo simulations within a Bayesian approach.

It was found that, although the results of CT scanning have virtually no effect on the prognosis of complications of the disease, in the group of seriously ill patients they significantly improve the prognosis of a fatal outcome of the disease (sensitivity (with specificity = 0.05) is 0.89 taking into account the results of CT and 0.78 without taking into account the results of CT).

Based on these data, the age structure of excess mortality in COVID-19 patients in the Georgian population associated with the lack of use of computed tomography was estimated.

A comparative analysis was conducted between this excess mortality and the prognostic incidence of radiogenic breast cancer in female COVID-19 patients who underwent chest CT. The results indicated that for patients under 40 years of age, excess mortality and breast cancer incidence are approximately equivalent. However, in the 40–59 age cohort, excess mortality exceeds the radiation-induced breast cancer incidence by 80 times, and for patients over 60 years of age, by 1800 times. From these positions, CT examination for COVID-19 patients under 40 years of age at the time of hospitalization cannot be considered "justified", in the age range of 40-60 years - desirable, and in patients over 60 years - necessary.The results we obtained practically do not differ from the recommendations of international professional organizations, however, they clearly demonstrate the relevance of quantitative analysis of the "benefit/ risk" in computed tomography from the point of view of radiation protection of the population and indicate promising directions for its methodological provision.

Keywords: Chest computed tomography, radiation protection, "justification"

INTRODUCTION

The rapid advancement and integration of nuclear and radiation technologies in medical practice, along with the objective and potential health risks associated with medical radiological procedures, and the swift increase in the population exposed to such procedures, have necessitated the development of qualitatively new methodological approaches to radiation protection for both patients and medical personnel. In medicine, the contemporary ideology of radiological protection is founded on the principle of minimizing doses that are clinically unjustified [1-4].

One of the main tools for its implementation is the "justification" of medical radiological procedures, a fundamental principle of radiation protection stating that any exposure to ionizing radiation should do more good than harm. The conceptual model of "justification" can be expressed as the ratio of expected benefit to expected harm:

$$\text{Net Benefit} = \text{Clinical Benefit} - \text{Radiation Risk} - \text{Other Harms}.$$

The methodological challenges in the justification of medical radiological procedures lie in the fact that each component of this model is measured in different ways and defined with varying degrees of "uncertainty." To assess and minimize this uncertainty, it is crucial to conduct a thorough analysis of data from areas such as clinical epidemiology, medical physics, radiobiology, bioethics, evidence-based medicine, and others [5].

The challenges in this field primarily involve decision-making under uncertainty, utilizing risk-benefit analysis methods. To enhance methodological research in this area, new directions in mathematical statistics and probability theory, based on Bayes' conditional probability theorem, are currently being developed intensively.

The main advantages of this Bayesian approach compared to classical (frequentist) statistics include the following: it allows for the incorporation of prior information from various fields of knowledge, which simplifies working with small samples; it enables continuous updating of prior information; it provides a quantitative assessment of analytical uncertainties; and it simplifies the handling of hierarchical and multilevel models. This approach is particularly appealing for biomedical research and clinical trials because it addresses the question, "How probable and how large is the effect?" instead of the frequentist focus on whether the detected effect is statistically significant, assuming the hypothesis is true [6].

Currently, radiology referral guidelines and appropriateness criteria, such as those developed by the American College of Radiology (ACR) and the Royal College of Radiologists (RCR), are widely used as evidence-based frameworks to assist physicians in selecting the most appropriate, accurate, cost-effective, and safe imaging modality for a given clinical condition, thereby minimizing unnecessary radiation exposure and reducing healthcare costs.

It is important to note that directly applying recommendations developed for a specific population and country to other populations and countries can lead to significant inaccuracies.

This is due to variations in disease spectrum, disease risk and outcomes, overall mortality, radiosensitivity, and the healthcare system's capacity, among other factors.

One of the main research areas at the Radiation Safety Problems Laboratory of the Beritashvili Centre of Experimental Biomedicine, in collaboration with Tbilisi State Medical University and the First University Clinic, is the development of a methodological framework for assessing radiogenic health risks in the Georgian population [7-10].

This study applies a Bayesian approach to analyze the elements of justification underlying the appropriateness of chest computed tomography (CT) examinations in a population of female patients with COVID-19 in Georgia.. The findings may aid in developing a justification framework to support decision-making regarding the appropriate use of chest CT procedures in a broader clinical context in Georgia.

MATERIAL AND METHODS

Data were collected from 108 laboratory-confirmed COVID-19 patients of both sexes and varying ages admitted to the First University Clinic of Tbilisi State Medical University (Georgia) between April 1, 2020, and May 1, 2020. COVID-19 confirmation was based on positive results from SARS-CoV-2 nucleic acid testing via real-time reverse transcription-polymerase chain reaction (RT-PCR). Additionally, population-level data regarding COVID-19 morbidity, hospitalization, and mortality rates in Georgia for the 2020–2021 period were obtained from the National Centre for Disease Control and Public Health (NCDC). Prognostic values for the incidence of radiogenic breast cancer among female COVID-19 patients hospitalized in 2021 who underwent chest CT were derived from our previous work [8].

In the risk-benefit analysis, clinical benefit was defined as the difference between the risk of developing severe complications or mortality without inpatient CT scanning and the residual risk of these same outcomes when CT diagnostics were performed. Risks distributions were estimated using a Bayesian approach, employing a binomial distribution for the likelihood and an uninformative Beta distribution for the prior. Monte Carlo simulation techniques were applied to calculate the risk differences [11-13].

The diagnostic sensitivity of the predictor set served as a parameter for the binomial distribution. Logistic regression was used to identify the causal relationship between the values of the selected predictors and the likelihood of disease severity or lethality:

$$\boldsymbol{P}(+) = \frac{\boldsymbol{EXP(Z)}}{\boldsymbol{1+EXP(Z)}} \quad (1)$$

where P (+) is the probability that a particular patient with specific characteristics falls into the category of severe patients. Only linear combinations of individual parameters were considered at this stage:

$$\boldsymbol{Z = b_0 + b_1 X_1 + b_2 X_2 + \ldots + b_n X_n} \quad (2)$$

where $\boldsymbol{b_i}$ - regression coefficients; $\{\boldsymbol{X_i}\}_{\boldsymbol{i=1}}^{\boldsymbol{n}}$ - $\boldsymbol{n}$ values of $\boldsymbol{i}$ indicators.

The diagnostic sensitivity of the selected predictors was assessed based on receiver operating characteristic (ROC) curve analysis.

The following variables were utilized as outcome predictors: 1) Demographic characteristics (age and sex), Comorbidities (heart failure), Blood oxygen saturation, time interval from symptom onset to hospitalization and CT scores.

Because the primary complication among all deceased patients was acute respiratory distress syndrome (ARDS)—though not all patients who developed ARDS succumbed to the disease—the cohort was stratified into three classes: 1) Patients who did not develop ARDS (mild/moderate), 2) Patients who developed ARDS (severe/very severe), 3) Patients who died.

We used nonparametric statistical methods (Mann-Whitney U test, Kruskal-Wallis ANOVA & Median test) to assess the statistical significance of differences between the distributions of characteristics across patient groups.

For calculations and visualization of results, the mathematical software STATISTICA-12 MATLAB R2021 was used.

RESULTS AND DISCUSSION

When "justifying" the appropriateness of a radiological examination, it is useful to have answers to the following questions: 1) Is it medically indicated? (will it affect the patient's care?); 2) Is it necessary now? 3) Is this the best investigation method? (are there other tests that could answer the clinical question); 4) Has this been done already? (avoid unnecessary repetition of tests).

All of these questions can be combined into a single inquiry: What is the risk of diagnostic and prognostic errors, as well as their associated costs, with and without CT examination? In the context of COVID-19, this question can be formally stated as follows:

$$\Delta \boldsymbol{R}^{Covid\ Outcome} = \boldsymbol{R}^{Outcome}_{Without\ CT} - \boldsymbol{R}^{Outcome}_{With\ CT} \quad \ldots \quad (\mathbf{3})$$

While assessing $\boldsymbol{R}^{Outcome}_{With\ CT}$ is straight forward, based on both the literature and our available information, assessing $\boldsymbol{R}^{Outcome}_{With\ CT}$ based on actual data is virtually impossible, as the literature lacks data on specific indicators of complication and mortality dynamics among COVID-19 patients that would be determined solely by the absence of an initial CT scan, as the scan itself is merely a diagnostic tool and not a treatment method. Based on the above, the only way to estimate $\boldsymbol{R}^{Outcome}_{Without\ CT}$ is to model it based on the studied cohort of patients under certain assumptions.

It is important to consider here that patients differ in both the severity of the course of the disease and the risk and pace of exacerbation, and in severe patients, the probability of a lethal outcome. The severity of a disease, as well as the risk of exacerbation and fatal outcomes, is influenced by various factors that possess specific characteristics. This study aims to determine the additional informative value of CT examinations for different patient groups categorised by these factors, which can be analysed using ROC curves. It is also essential to consider the distribution of these patient groups within the overall population, as their prevalence may vary significantly across different countries, regions, or districts. Consequently, the effectiveness and feasibility of CT examinations can differ accordingly. This research is particularly relevant in light of the unique circumstances in Georgia concerning the justification of radiological procedures.

Mortality rates among hospitalised patients with COVID-19 typically range from 10% to 15%. Literature and official guidelines from organizations like the National Institutes of Health (NIH) highlight that demographic factors, comorbidities, and blood oxygen saturation levels play crucial roles in assessing the severity of illness, prognosis, and treatment decisions [14]. It is important to note that one of the primary causes of fatal outcomes in COVID-19 patients is diagnostic errors or delays in diagnosis. Research indicates that up to 23% of patients who require transfer to intensive care or who die in the hospital have experienced delayed or missed diagnoses. In the context of COVID-19, cognitive biases—such as viewing COVID-19 as the sole possible diagnosis—have led to missed cases of conditions like pulmonary embolism, strokes, and acute myocardial infarctions. Diagnostic errors related to COVID-19, especially in the absence of chest computed tomography, are often due to false-negative results from PCR tests or incorrect diagnoses of other viral or bacterial pneumonias. Such misdiagnoses can delay critical medical interventions [15],

Based on the above information, it was deemed appropriate to first identify a minimally sufficient criterion for assessing the severity of the disease. In our cohort, various types of complications were recorded, including sepsis, septic shock, acute kidney and liver injury, thromboembolism, acute coronary syndrome, and hemorrhagic stroke. However, only Acute Respiratory Distress Syndrome (ARDS) was noted in all deceased patients. It is important to mention that not all patients who developed ARDS died (see Figure 1).

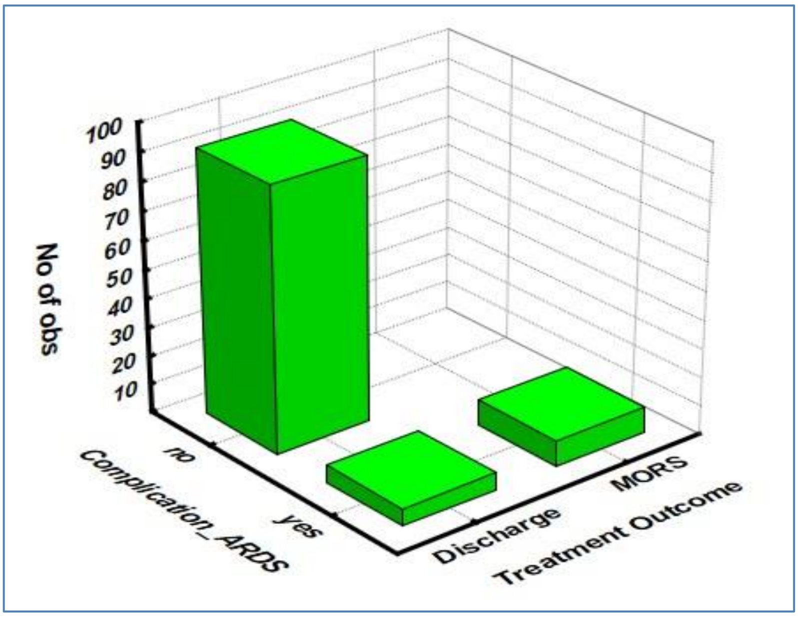

Figure 1. 3D distribution of patients in the study cohort according to the severity of complications and lethal outcome.

Therefore, patients were divided into three classes: patients who did not develop ARDS (mild and moderate severity), patients who developed ARDS (severe/very severe), and patients who died.

Figures 2-6 present the values of characteristics related to complications and lethal risk across different severity strata of patients, along with the statistical significance of the differences observed.

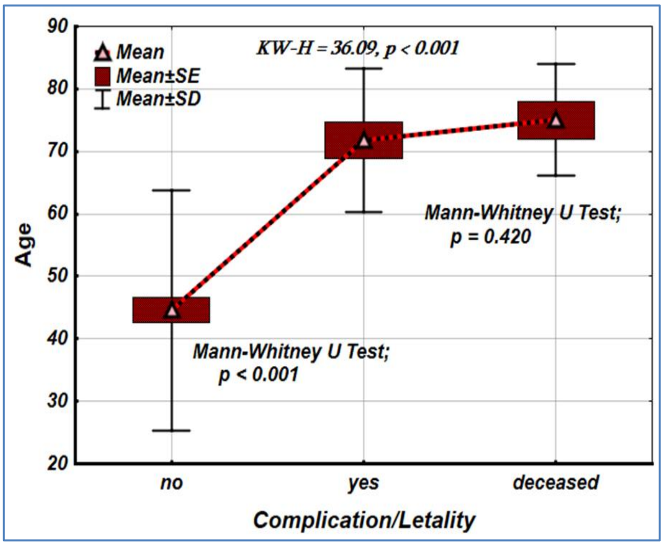

Figure 2. Comparison of mean age between patients with varying degrees of disease severity

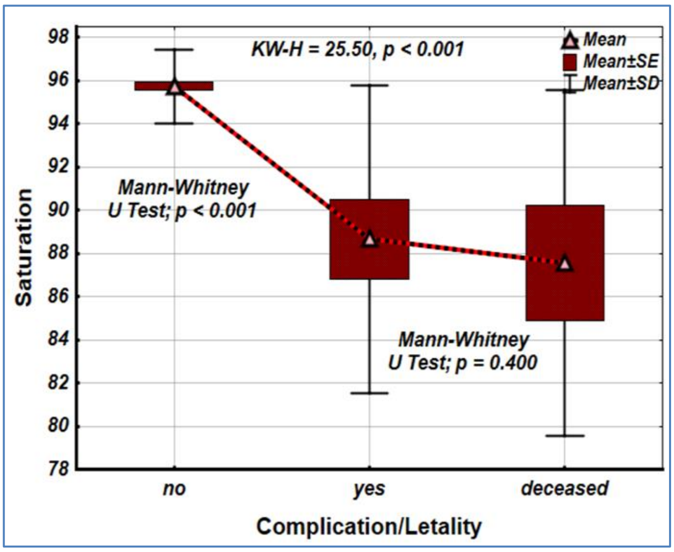

Figure 3. Comparison of mean oxygen saturation levels at hospital admission between patients with varying degrees of disease severity

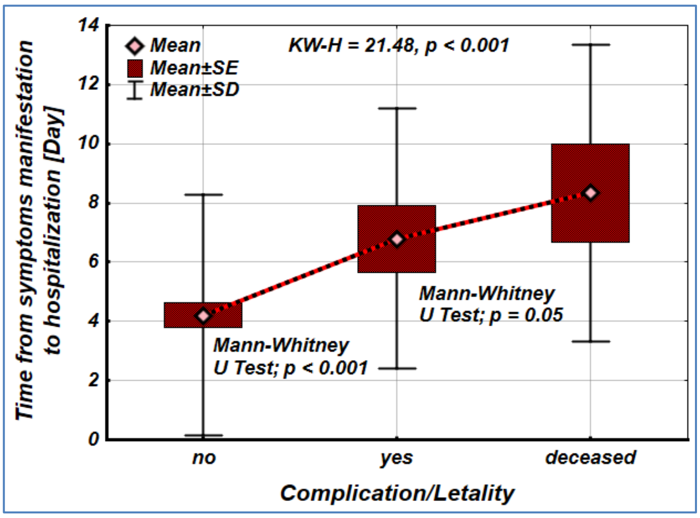

Figure 4. Comparison of mean Time from manifestation of symptoms to hospitalization between patients with varying degrees of disease severity

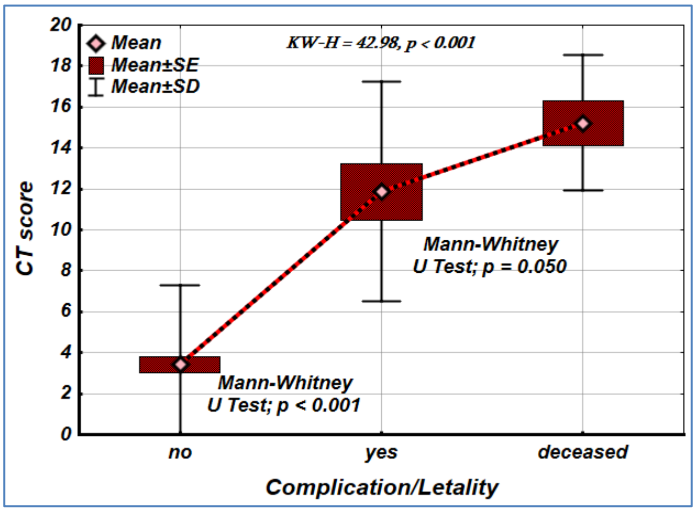

Figure 5. Comparison of mean CT severity score at hospital admission between patients with varying degrees of disease severity

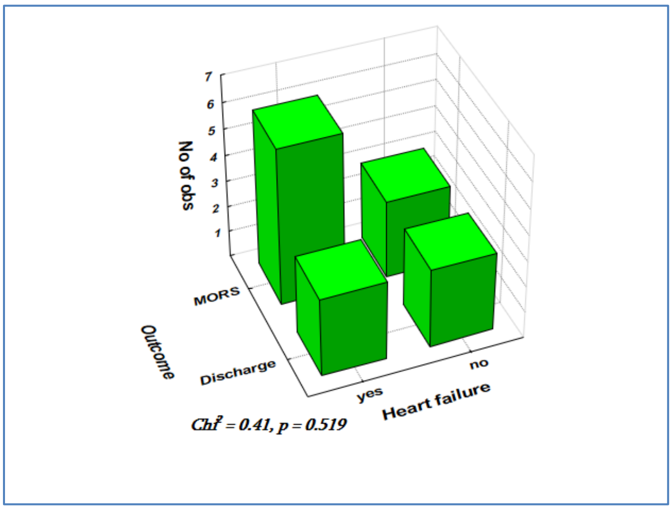

Figure 6. 3D contingency histogram between comorbidity (Heart failure) and treatment outcome

As shown in the graphs, patients who developed ARDS during hospitalisation differed significantly from those with mild and moderate severity across all statistical parameters considered. Differences between the severe and deceased cohorts were significant only in the time interval from symptom onset to hospitalisation and in CT scores. Although the p-level is at the limit of reliability, these data indicate with a high degree of certainty the leading role of delayed diagnosis in the occurrence of a lethal outcome in the studied cohort, which can only be predicted by CT examination. This pattern is also clearly reflected in the ROC curves. Figures 7 and 8 show the difference in the information value of features with CT data (blue) and without them (red) in terms of predicting of severe complications and mortality.

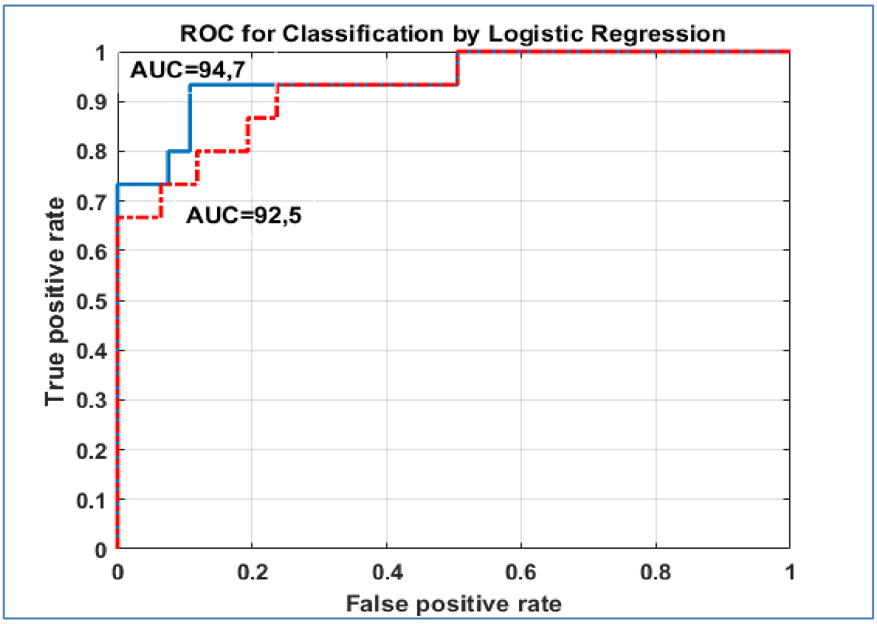

Figure 7. The difference in the information value of features with computed tomography data (blue) and without them (red) in terms of prognosis of severe complications

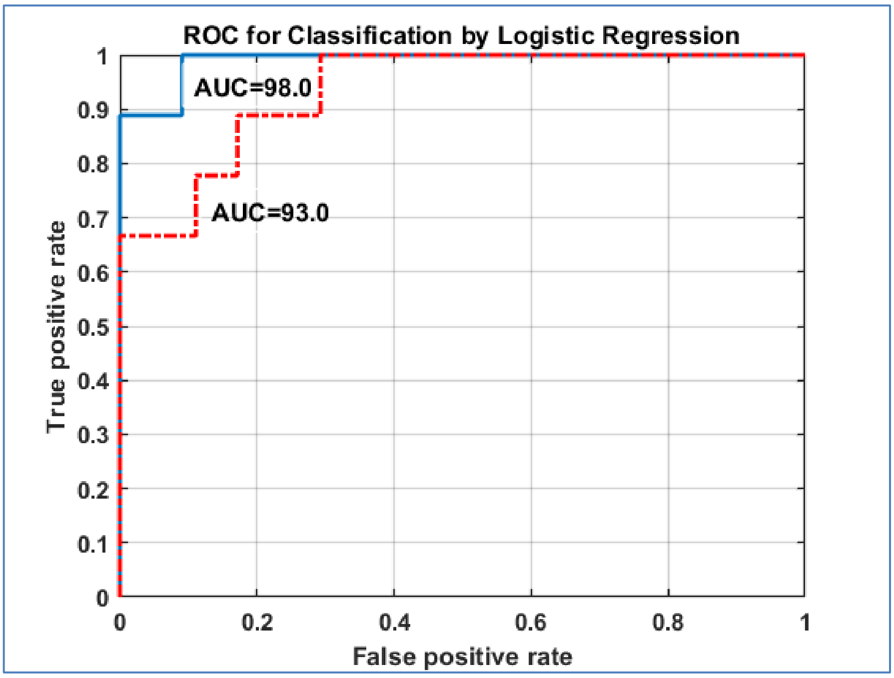

Figure 8. The difference in the information value of features with CT data (blue) and without them (red) in terms of predicting mortality

While CT findings have a modest impact on prognosticating disease complications (sensitivity 0.73 with a specificity of 0.05, including CT findings, and sensitivity 0.68 without CT findings) (see Figure 8), they can significantly improve prognosis for critically ill patients in terms of mortality. In this group, sensitivity increases to 0.89 when CT findings are included, compared to 0.78 when these findings are not taken into account (see Figure 8).

Given that delayed or misdiagnosis in the critically ill group is statistically significantly associated with mortality, it is highly likely that the difference in sensitivity of patient diagnostic/prognostic criteria with and without CT scan results reflects the additional mortality associated with diagnostic error in the absence of CT scan results.

As for the probability of survival (or lethal outcome), it is a random variable and is described by a binomial distribution:

$$\boldsymbol{R^{I}}_{\textbf{likelihood}} \infty\ \boldsymbol{p^{n(I)}\left(1-p^{N(I)}\right)}\ \ldots(\mathbf{4})$$

The index (I) corresponds to the prognostic values of disease complications or lethal outcomes based on the use or non-use of computed tomography data. To evaluate the range of risk uncertainty and simplify the interpretation of the results, we opted to adopt Bayesian statistics. In this approach, the beta function is used as the prior distribution for the risk of lethality.

$$\boldsymbol{R^{I}}_{\boldsymbol{prior}}(\boldsymbol{p}) = \boldsymbol{Beta}(\boldsymbol{\alpha},\boldsymbol{\beta}) = \frac{\Gamma\,(\boldsymbol{\alpha}+\boldsymbol{\beta})}{\Gamma(\boldsymbol{\alpha})\Gamma(\boldsymbol{\beta})} * \boldsymbol{p^{\alpha-1}} * (\mathbf{1}-\boldsymbol{p})^{\boldsymbol{\beta-1}} \ldots \quad (\mathbf{5})$$

In Bayesian statistics, the Beta function is the uncorrelated prior function of the binomial function, the a posteriori function obtained by synthesizing which will also have the form of a Beta distribution:

$$\boldsymbol{R^{I}}_{\textbf{posterior}} \infty\ \boldsymbol{Beta}(\boldsymbol{n}+\boldsymbol{\alpha};\boldsymbol{N}-\boldsymbol{n}+\boldsymbol{\beta})\ \ldots \quad (\mathbf{6})$$

At this stage, the Beta non-informative prior (uniform prior) function was used to describe the a priori distribution of risks, for which - α=1,β = 1.

Finally, using expression (3) for the risk difference, we obtain an expression that can be considered as the probability distribution of additional deaths associated with failure to perform CT examination during hospitalization.:

$$\begin{aligned}\Delta\boldsymbol{R}^{\boldsymbol{Covid\ Outcome}} &= [\boldsymbol{Beta}\left(\boldsymbol{n}^{\boldsymbol{With\ CT}}+\mathbf{1};\boldsymbol{N}^{\boldsymbol{With\ CT}}-\boldsymbol{n}^{\boldsymbol{With\ CT}}+\mathbf{1}\right)\\ &\quad -\boldsymbol{Beta}\left(\boldsymbol{n}^{\boldsymbol{Without\ CT}}+\mathbf{1};\boldsymbol{N}^{\boldsymbol{Without\ CT}}-\boldsymbol{n}^{\boldsymbol{Without\ CT}}+\mathbf{1}\right)]\ \ .\ .\ \ (\mathbf{7})\end{aligned}$$

In general, the difference between two independent beta random variables does not follow a beta distribution. The exact probability density function (PDF) requires complex mathematics, such as generalized hypergeometric functions.

Typically, when the output variables are determined by a complex nonlinear function of the input variables, and their probability density function cannot be derived analytically, Monte Carlo methods are employed to estimate the uncertainty [11-13]. For each input variable X_1 and X, (M) random vectors X_{1j} and X_{2j} (where j = 1, ….., M) are generated. This results in M pairs of numbers. The value of M is determined by the condition $\boldsymbol{M}=\mathbf{10^4}(\mathbf{1}-\boldsymbol{p})$, where 100***p** represents the coverage probability of the output variables. In this case, we use a coverage probability of 90%, so (p = 0.90), which means M must be at least 200,000.

The j-th element of the measurement model corresponds to the random numbers X_{1j} and $X_{2j\_}$ according to the uncertainty distribution density. The output values $Y_{j\_}$ (for j = 1, …, M)) must be organized into a histogram, with the interval determined by the required accuracy of the estimates. This ordered model represents the discrete distribution function of (Y), from which standard statistical indicators can be calculated (Figure 9.).

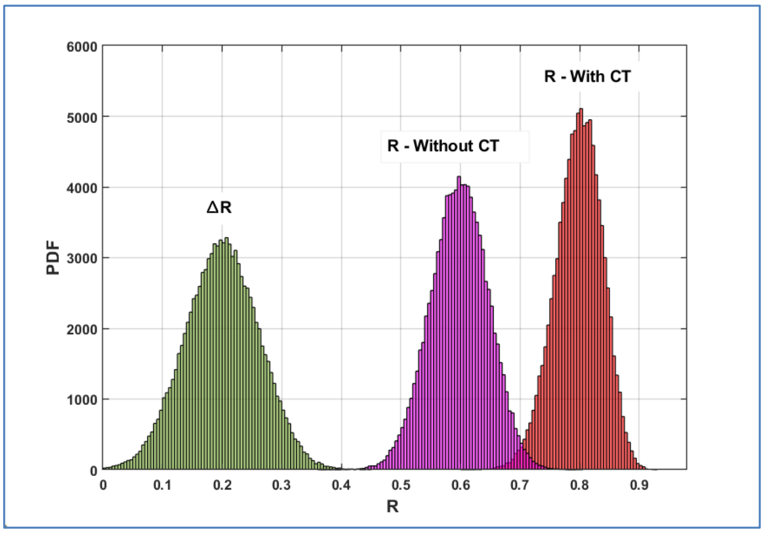

Figure 9. Unnormalized mortality probability density functions in critically ill patients estimated using with (R-with CT) and without CT (R-without CT) data, and the probability distribution function of the additional risk (ΔR).

Assuming that delayed or incorrect diagnoses result in an increase in mortality by a similar amount across all age groups, we can estimate the total number of additional deaths and their age distribution in the absence of computed tomography:

$$P(N_\tau) = \Delta R^{Covid\ Outcome} * N(\tau) \; . \; . \; . \; . \; (8)$$

Where N(τ) is the age structure of mortality from COVID-19 among the female population of Georgia. Figure 10 illustrates the age structure of excess mortality estimated using expression (6) and the age structure of COVID-19 mortality in the female population of Georgia in 2021

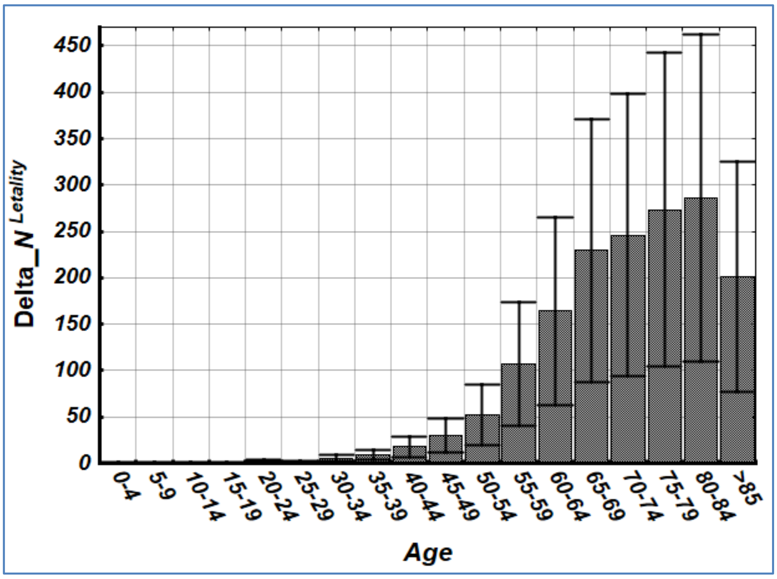

Figure 10. The age structure of excess mortality in the female COVID-19 patient population in 2021

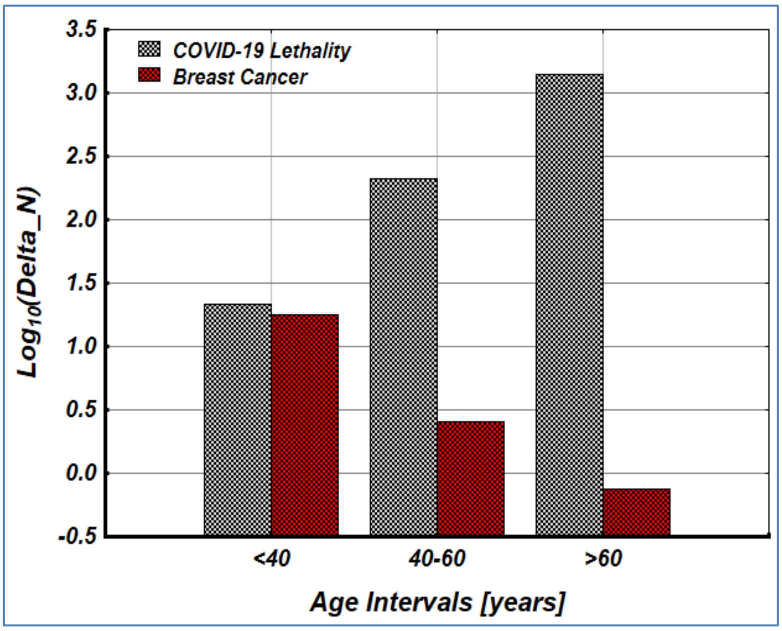

Figure 11. The logarithmic data for excess breast cancer cases associated with chest CT scans in the female COVID-19 patient population in 2021

Figure 11 shows the logarithmic data for excess breast cancer cases associated with chest CT scans in the female COVID-19 patient population in 2021 (data taken from our previous work), as well as excess COVID-19 mortality rates in the 0-39, 40-59, and over-60 age groups. The results indicated that for patients under 40 years of age, excess mortality and breast cancer incidence are approximately equivalent. However, in the 40–59 age cohort, excess mortality exceeds the radiation-induced breast cancer incidence by 80 times, and for patients over 60 years of age, by 1800 times. From these positions, CT examination for COVID-19 patients under 40 years of age at the time of hospitalization cannot be considered "justified", in the age range of 40-60 years - desirable, and in patients over 60 years - necessary.

STUDY LIMITATIONS

The study was conducted on a limited number of patients hospitalized in April and May. It is important to note that COVID-19 morbidity and mortality tend to follow a distinct seasonal pattern, with the highest rates of severe illness and deaths occurring consistently during the autumn and winter months.

In the studied cohort, fatal outcomes were observed only in patients who developed complications from acute respiratory distress syndrome (ARDS). Not all patients who experienced ARDS died; therefore, only those who developed ARDS during their hospitalization were categorized as having severe complications. This assumption is directly related to the small size of the cohort, and a more thorough analysis is needed to assess the related uncertainties.

The binary logistic regression employed an approximation of a linear combination of predictors that does not account for the interactions between these predictors. The validity of this assumption and the assessment of the associated uncertainties warrant further investigation.

CONCLUSION

The results we obtained practically do not differ from the recommendations of international professional organizations [16,17], however, they clearly demonstrate the relevance of quantitative analysis of the "benefit/ risk" in computed tomography from the point of view of radiation protection of the population and indicate promising directions for its methodological provision.

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