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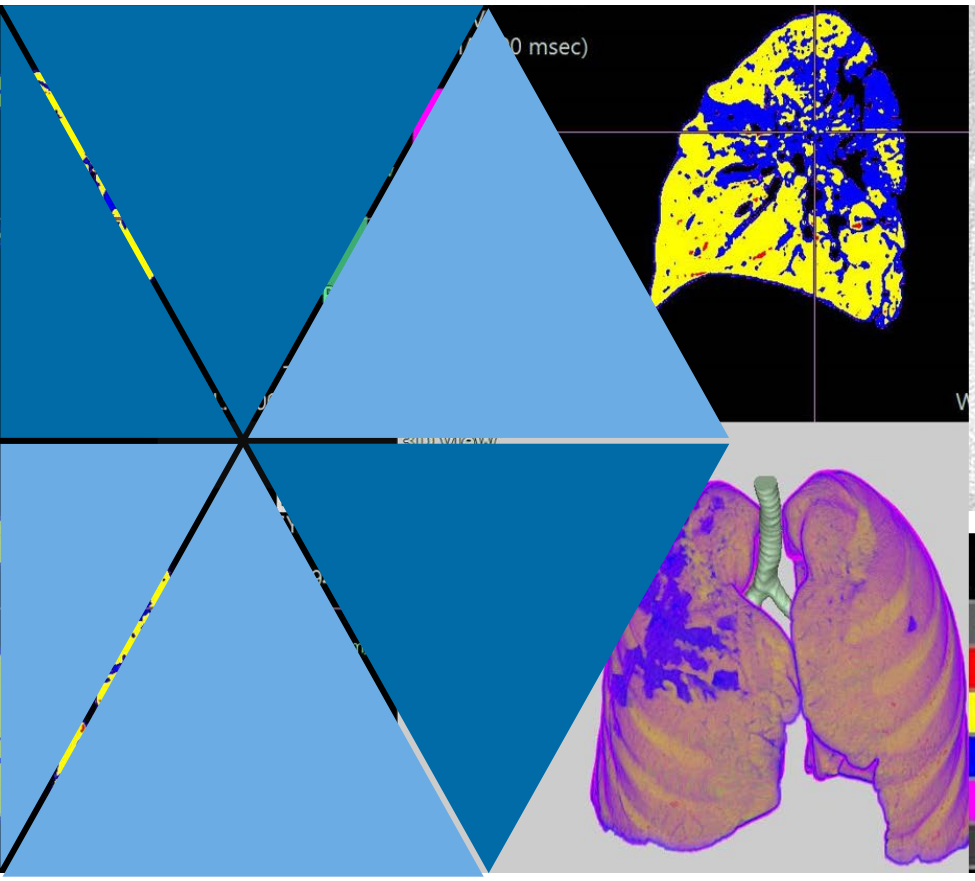
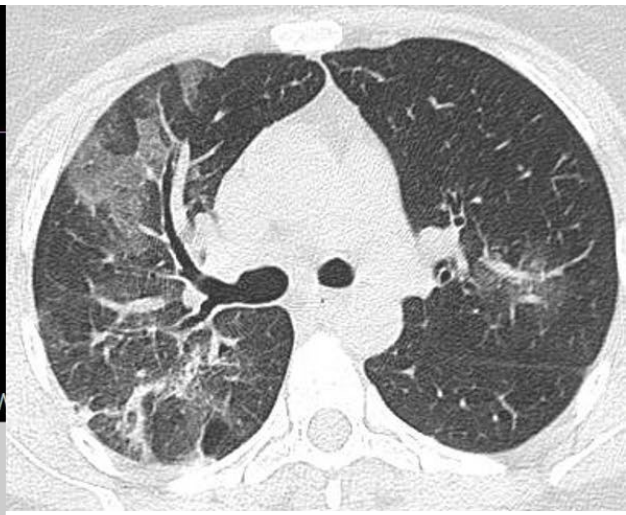
INTERNATIONAL CASE STUDY





Density list(Both lungs)

CT val.	(lower)	(upper)	Volume(ml)	%	%CF
	-1024	-950	26.7	1.0	1.0
	-949	-750	1948.7	72.9	73.9
	-749	-300	670.9	25.1	99.0
	-299	40	26.2	1.0	100.0
	Total		2672.6		

Synapse 3D

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Pisa University Hospital uses Synapse 3D toimprove patient management during the COVID19 pandemic

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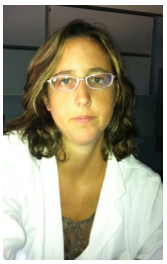

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Introduction

The novel Coronavirus infection (severe acute respiratory syndrome SARS-CoV-2), which has led to the spread of COVID-19 around the world, has upset normal workflow in hospitals, increasing their workloads and stress due to the necessity of increasingly safe and separate diagnostic pathways and the need to constantly monitor the development of the disease after its onset.

The rapid outbreak and brutal effect of this virus led to it being quickly classified as a global threat. Like other viruses, SARS-CoV-2 penetrates into human cells and causes various degrees of damage. At present, no countries are sufficiently prepared to control this new and unpredictable scenario, but we are able to adapt our behaviour on the basis of previous experience.

The University Hospital of Pisa was prepared when the epidemic reached Tuscany. Having seen what was happening in Lombardy and Veneto, the various specialists involved in managing these patients (such as infectious disease specialists, pulmonologists, intensive care and emergency medicine doctors) designed a procedure for treating patients with COVID-19. Entire areas of the hospital were prepared to house exclusively COVID patients, dividing the hospital into COVID zones and non-COVID zones and organizing the corresponding task forces. Levels of gravity of the COVID-19 disease were established with 3 hospitalization options: normal hospitalization for patients with mild pneumonia not requiring respiratory support, assessment by a pulmonologist or intensive care doctor for patients with moderate pneumonia to plan suitable respiratory support, if required, and, finally, intensive care assessment for patients with severe pneumonia with a view to transferring them to the intensive care unit. In addition to the clinical data (fever, cough, dyspnoea and increased respiratory rate) and the instrumental data, such as blood gas analysis, essential for the classification of these patients, the pulmonary involvement identified by the CT scan proved to be fundamentally important to establish their level of gravity.

A subjective assessment of the extent of this involvement is often imprecise and scarcely reproducible. Therefore, to satisfy this need of the emergency department and intensive care doctors, the radiologists devised a way to make this assessment automatically, using readily available and easy-to-use tools. In the meantime, the Italian Society of Medical and Interventional Radiology (SIRM) shared with its members several articles and operating procedures, including a letter in which the future president of the chest radiology division recommends the use of a quantitative CT analysis to assess pulmonary involvement in the management of patients during the COVID-19 pandemic.

In a CT image, COVID-19 appears as interstitial pneumonia characterized by widespread ground-glass opacity in the initial phases, together with areas of consolidation. The radiological image visual system (Fujifilm Synapse PACS) at our disposal in the hospital supports the use of some image processing tools (Synapse 3D). Of these, LungAnalysisAirway enables the lungs to be "isolated" from the rest of the chest and provides an analysis of the distribution of the pixels of the CT image, expressed as a percentage of the total lung volume, according to their density. This tool is normally used to assess the percentage

1 CT cannot perform differential diagnosis between the interstitial pneumonia caused by COVID-19 and that caused by other viruses

of emphysema (lower-density pixels), but it can also be used with other density ranges. To establish density ranges for quantifying the higher- density pixels typical of COVID-19 pulmonary involvement, we followed suggestions made by the SIRM and documented in scientific literature. Together with Fujifilm, we thus set the ranges in Synapse 3D manually, creating the COVID-19 dataset, which consists of 4 groups based on the following density ranges:

- From -1,024 HU to -950 HU (red), represents emphysema.
- From -949 HU to -750 HU (yellow), corresponds to healthy lung tissue.
- From -749 HU to -300 HU (blue), represents part of the pulmonary involvement caused by COVID-19, and corresponds to the part of the lung (as a percentage) that is more dense than a healthy lung. This group does not represent COVID-19 pulmonary involvement but can be used to quantify the higher-density (ground-glass) pixels, which, in viral interstitial pneumonia in an endemic area, corresponds to part of COVID-19 pulmonary involvement.
- From -299 HU to +40 HU (violet), this last group corresponds to a further increase in density, that is, in theory, to consolidation and the blood vessels. In most cases, however, this percentage is very low, close to 0%, because the automatic lung segmentation system also uses density ranges and generally identifies all areas with a density of over -200 HU as "non-lung", and therefore excludes them from the volume under examination.

To obtain the percentage of consolidation areas, they would have to be added manually, but this would make the analysis long and subject to variability. Under emergency conditions in which the analysis is conducted in real time, it is more important to have a fast, reproducible system that quantifies the percentage (e.g. 20%) of the lung with a high density, that is, with ground glass opacity. The example shown below shows how the automatic system analyses the CT image and gives an indication of the patient's pulmonary status, providing also a 3D model of the lung.

At present, when a suspected COVID-19 patient comes to the emergency department, the diagnostic procedure followed is to collect a nasopharyngeal swab on which a molecular test is performed by Real Time PCR.

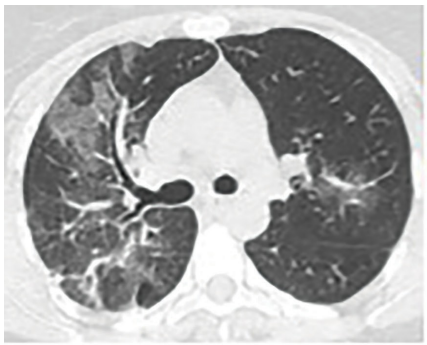
The patient also undergoes a chest x-ray and ultrasound scan and/or a CT scan without contrast medium.

The radiologist processes the images using Synapse 3D and, on the basis of the ranges assigned, produces output for assessing the density of the lung, and therefore the degree of the patient's pulmonary involvement.

The radiologist attaches the table with the percentages obtained to the diagnostic images of the lung and mediastinum, so as to provide the emergency and intensive care doctors with a more precise indication of the extent of the patient's interstitial involvement.

The CT scan and this procedure of quantitative analysis facilitate the hospital's workflow by providing a rapid, objective assessment of the patient's pulmonary involvement- which, together with the clinical and instrumental data, enables the patient to be classified in one of the levels of gravity mentioned previously. At the Pisa University Hospital, the radiology department put its instruments at the disposal of the intensive care, emergency, pulmonology and infectious disease departments, not only to the benefit of the doctors and the health system, but also, and above all, to the benefit of patients.

In fact, we have designed and implemented a work method that ensures an objective, quantitative assessment and that can be used in the future to detect and quantify the pulmonary involvement of patients that come to the emergency department.



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