## **Original Article**



# Investigation of the CO-RADS system as a new approach based on the CT scan assessment scheme for Covid-19 patients referred to Razi, Golestan, and Imam Khomeini hospitals in Ahvaz in 2021

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#### ABSTRACT

The use of chest CT scans for the diagnosis of Covid-19 is controversial. Covid-19 Reporting and Data System (CO-RADS) classification for measuring the clinical suspicion of Covid-19 might improve diagnostic performance for pulmonary involvement in Covid-19 patients. This study aims to evaluate the diagnostic performance of the CO-RADS system as a new approach based on the CT-scan assessment scheme for Covid-19 patients. This retrospective study was conducted on Covid-19 patients referred to Razi, Golestan, and Imam Khomeini hospitals in Ahvaz in 2021. For this, 108 chest CT scans were gathered from clinically suspected Covid-19 patients undergoing Reverse Transcription Polymerase Chain Reaction (RT-PCR) testing. Using the CO-RADS classification, four radiologists assessed the pulmonary involvement in chest CT images of Covid-19 patients and reported the involvement rate based on a six-point scale ranging from 1 (very low) to 6 (very high). The Interobserver Agreement (IOA) was measured using the intraclass correlation coefficient (ICC). Ultimately, the area under the curve (AUC) results in relation to the CO-RADS classification were compared with those results obtained from RT-PCR and the clinical diagnosis of Covid-19. A significant correlation was observed between the diagnostic performance of observers (p<0.0001). The mean ICC value for evaluating the CT images of observers was 0.954 (CI: 95%; 0.929-0.989; p< 0.0001). Likewise, the mean AUC value was 0.846 (CI: 95%; 0.763-0.908; p<0.0001) for predicting RT-PCR outcome and 0.924 (CI: 95%; 0.857-0.996) for the clinical diagnosis.

The results of this study indicate the efficacy of the CO-RADS classification assessment scheme for the pulmonary involvement in Covid-19 in predicting Covid-19 in patients with moderate to severe symptoms using chest CT images, as supported by a significant IOA value.

Keywords: Computed tomography (CT), Covid-19, CO-RADS

### Introduction

The definite diagnosis of Covid-19 is generally carried out in the laboratory using reverse transcription polymerase chain reaction (RT-PCR) testing. However, the clinical sensitivities reported for diagnoses vary from 42% to 83%, depending on how prolonged symptoms last, viral load, and the quality of the test sample [1-5]. In many cases, RT-PCR further yields a positive test result after several negative results, while the patients show typical clinical symptoms and imaging results which indicate the

presence of Covid-19 infection [6, 7]. Still, RT-PCR testing takes several hours or even several days and, under some conditions, is not possible to be performed for some patients [8].

Concerning the above issues, the role of chest CT scans in clinically-suspected Covid-19 patients is constantly altering due to little scientific evidence. Additionally, there is a significant disagreement on the time and method of using CT scans for making clinical decisions or dispensing the right treatment [9]. Again, some guidelines, such as that provided by the American College of Radiology (ACR), do not recommend using CT scans in the initial stage of patient evaluation [10, 11]. Nevertheless,

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-Non Commercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms. the Fleischner Society has recently confirmed CT scan as the main evaluation technique under various conditions, such as when the symptoms are worsening or where access to RT-PCR resources is highly restricted [12].

CT scan results for Covid-19 overlap with the results obtained for other conditions, particularly viral infections, but still provide distinctive features that are less common in other areas [13]. Thus, it has widely attempted to standardize CT reporting in patients with clinically-suspected Covid-19 [14]. For example, the Dutch Society for Radiology (NVvR) launched a Covid-19 network on March 2, 2020, to facilitate the development and dissemination of information and tools related to Covid-19 across the Netherlands. NVvR further developed a standardized assessment plan, namely Covid-19 Reporting and Data System (CO-RADS), for classifying the pulmonary involvement in clinically-suspected Covid-19 patients based on chest CT images [8, 15]. CO-RADS is intended for use in patients with moderate to severe Covid-19 symptoms and evaluates the level of pulmonary involvement in Covid-19 that spans from 1 (very low) to 6 (very high). The IOA value for CO-RADS has also been reported to be appropriate and high [8].

The rapid increase in the prevalence of Covid-19 in Iran necessitates the use of an accurate, straightforward, accessible, and fast evaluation technique for the clinical identification and management of clinically-suspected Covid-19 patients. Furthermore, concerning the positive results reported in recent studies indicating the efficacy of the CO-RADS based on CT scans in assessing the severity of pulmonary involvement in patients with clinically-suspected Covid-19 infection [8, 16], this study investigates the RADS-CO index based on CT scan in clinically-suspected Covid-19 patients referred to Razi, Golestan, and Imam Khomeini hospitals in Ahvaz.

## Materials and Methods

This retrospective study was conducted on clinically suspected Covid-19 patients referred to the emergency department of Razo, Golestan, and Imam Khomeini hospitals in Ahvaz (Iran) in 1400. Clinically suspected Covid-19 patients over 20 years undergoing RT-PCR testing for whom chest CT scan images were available in the files were included in the study. Patients with incomplete data in the files were excluded from the study. The participants were randomly and sequentially sampled, and the sample size was equal to 108, as instructed in [8].

Data on the patients' characteristics, including age, gender, comorbidities, Covid-19 diagnosis results (e.g., clinical diagnosis and positive/negative RT-PCR results), and the duration of the symptoms were extracted from the patient's electronic file and recorded in the data collection checklist.

The CT scans were retrieved from the image archive system and assessed by the CT scan browser system in three orthogonal views. Then, the pulmonary involvement in Covid-19 was evaluated based on the CO-RADS classification and reported from 0 to 6 [8] **(Table 1)**. CT images were assessed by four observers, including radiologists experienced in the field of chest CT who were not aware of the characteristics of the patients and the RT-PCR results. For this, CT images were assessed using tools such as mean or maximum projections, adaptation level window-width window, panning, and zooming.

Table 1. The CO-RADS classification and the rate of suspected pulmonary involvement in the Covid-19 infection [8]								
CO-RADS	The rate of pulmonary involvement in	Description						
classification	Covid-19							
0	Uninterpretable	Chest scanning is not technically appropriate for evaluating the scores.						
1	Very low	Normal or non-infectious						
2	Low	The presence of typical symptoms for other infections but not for the Covid-19						
		involvement						
3	Moderate	Symptoms indicating involvement with Covid-19 and other conditions						
4	High	Suspected to Covid-19						
5	Very high	Typical for Covid-19						
6	Confirmed	RT-PCR is positive for Covid-19						
CO-RADS: Cumulative Covid-19 Reporting and Data System								

#### Ethical considerations

The protocol of this study was approved by the Ethics Committee of Ahvaz University of Medical Sciences (AUMS) under the ethical approval code of IR.AJUMS.REC.1401.212. All the provisions of the Declaration of Helsinki for ethical considerations in research and the confidentiality of patient information were observed during all the phases of the study.

#### Statistics and analyses

Data were analyzed in SPSS version 22 (SPSS Inc., Chicago, IL, U.S.A.) and MedCalc version 13 (MedCalc Software Bvba) and described using mean, standard deviation (SD), frequency, and percentage indices. The relationship between variables was

investigated using Spearman's rank correlation coefficient. The IAO value was calculated using the intraclass correlation coefficient (ICC) by comparing the score of each observer with the mean of the results reported by the three other radiologists. The diagnostic performance of the CO-RADS system compared to the two standard indices for Covid-19 diagnosis (i.e., RT-PCR and clinical diagnosis) was measured by plotting the receiver operator characteristics curve and calculating the area under the curve (AUC) at the CI of 95%. The sensitivity, specificity, and positive and negative predictive value of CO-RADS for disease diagnosis were further determined. The results with a p-value less than 0.05 were considered to be statistically significant.

## **Results and Discussion**

This study investigated chest CT scans of 108 clinically suspected Covid-19 patients with a mean age of 59.14  $\pm$  06.47 years (22 to 80 years). Out of all the patients, 60 (55.6%) were males, and 48 (44.4%) were females. The mean duration of symptoms in the patients was 6.56  $\pm$  3.45 days (2 to 12 days). A total of 65 (62.2%) patients were diagnosed with underlying diseases like diabetes, hypertension, lung conditions, and cardiovascular disease.

Positive RT-PCR results were observed in 51 (47.2%) patients, and the clinical diagnosis for Covid-19 was positive in 58 (53.7%) patients. Negative RT-PCR results with positive clinical diagnoses were observed in 7 patients, while positive RT-PCR results with negative clinical diagnoses were observed only in one patient. Clinical diagnosis and RT-PCR results were similar in the remaining cases.

**Figure 1** shows the mean CT scores reported by different observers based on the clinical diagnosis of Covid-19. As can be seen, all cases with a CO-RADS score of 5 indicate the clinical diagnosis of Covid-19. Likewise, all the patients with a CO-RADS score of 1 and 2 (except for three cases in each group) were diagnosed to be healthy, i.e., not being affected by Covid-19.



**Figure 1.** The frequency of clinically-diagnosed Covid-19 based on the CT scoring system

**Figure 2** depicts the results from comparing CT scoring based on the CO-RADS system by four different observers. Investigation of the IOA values in CT scoring revealed that the mean ICC of observers is 0.954 (CI: 95; 0.989-0.929; p<0.0001). Spearman's correlation test results revealed a strong and significant relationship between the scores provided by different observers (p < 0.0001).



Figure 2. Comparing the CT scoring based on the CO-RADS index by different observers

The results of comparing the diagnostic performance of the CO-RADS scoring system with those results obtained from the clinical diagnosis of Covid-19 and RT-PCR are given in **Table 2** and **Figure 3**. The mean AUC of the CO-RADS system for predicting the clinical diagnosis of Covid-19 was 0.924. The sensitivity, specificity, positive predictive value, and negative predictive value of the CO-RADS scoring system were respectively 82.76%, 92%, 92.3%, and 82.1%. Likewise, the mean AUC of the CO-RADS system for predicting the RT-PCR of Covid-19 was 0.846. The sensitivity, specificity, positive predictive value of the CO-RADS scoring system for predictive value, and negative predictive value of the CO-RADS system for predicting the RT-PCR of Covid-19 was 0.846. The sensitivity, specificity, positive predictive value, and negative predictive value of the CO-RADS scoring system for predicting the RT-PCR results were 80.39%, 70.70%, 78.8%, and 82.1%, respectively.

	0					0		
Evaluation method	Observer	AUC	95% CI	p-value	Sensitivity	Specificity	PPV	NPV
CO-RADS vs clinical diagnosis	Observer 1	0.919	0.851-0.963	< 0.0001	82.76	92.00	92.3	82.1
	Observer 2	0.924	0.857-0.966	< 0.0001	82.76	92.00	92.3	82.1
	Observer 3	0.924	0.857-0.966	< 0.0001	81.03	92.00	92.2	80.7
	Observer 4	0.912	0.842-0.958	< 0.0001	82.76	92.00	92.3	82.1
	Total	0.966	0.857-0.966	< 0.0001	82.76	92.00	92.3	82.1
CO-RADS vs RT- PCR	Observer 1	0.841	0.758-0.904	< 0.0001	80.39	80.70	78.8	82.1
	Observer 2	0.846	0.763-0.908	< 0.0001	80.39	80.70	78.8	82.1
	Observer 3	0.844	0.762-0.907	< 0.0001	88.24	71.93	73.8	87.2
	Observer 4	0.835	0.752-0.900	< 0.0001	80.39	80.70	78.8	82.1
	Total	0.846	0.763-0.908	< 0.0001	80.39	80.70	78.8	82.1
CO-RADS: Cumulativ	ve coronavirus dise	ase 2019 (CC	VID-2019) Reportin	g and Data System	; RT-PCR: Reverse ti	ranscription polymeras	e chain reaction;	PPV: positive
			predictive value	s; NPV: negative p	redictive values			

Table 2. The diagnostic performance of CO-RADS compared to the clinical diagnosis and RT-PCR results



Figure 3. Comparison of the diagnostic performance of the CO-RADS systems with the clinical diagnosis of Covid-19 and RT-PCR results

The results obtained from investigating the diagnostic performance of the CO-RADS scoring system based on chest CT scans with the clinical diagnosis of Covid-19 revealed that the mean AUC scores for this system are 0.846 (for predicting the RT-PCR results) and 0.924 (for predicting clinical diagnosis). The sensitivity, specificity, positive predictive value, and negative predictive value of the CO-RADS scoring system for predicting the RT-PCR results were respectively 82.76%, 92%, 92.3%, and 82.1%. Likewise, the sensitivity, specificity, positive predictive value, and negative predictive value of the CO-RADS scoring system for predicting the clinical diagnosis were 80.39%, 70.70%, 78.8%, and 82.1%, respectively. Moreover, a strong and significant correlation was observed between the CO-RADS scoring results reported by different observers. The IOA value based on the ICC index was equal to 0.954, which is excellent. These findings imply the accuracy of the CO-RADS system based on chest CT scans of Covid-19 patients in evaluating the pulmonary involvement in patients while having significant IOA values.

Covid-19 is a frightening infectious disease worldwide, which can lead to severe respiratory failure and even death, particularly in elderly patients and those with an underlying disease [17, 18]. The sensitivity of chest CT scans for Covid-19 diagnosis has been reported to vary from 80% to 90%, and its specificity to vary from 82.9% to 96% (higher than RT-PCR). This suggests the need for identifying, interpreting, and sharing pulmonary imaging findings [19]. Findings from precise imaging are critical for epidemiological assessments and the effective control of the pandemic. CT findings (e.g., consolidation, linear opacities, crazy-paving, bronchial wall thickening, and enhanced CT intensity scores) have been associated with poor disease prognosis and the necessity for special care [20]. The CO-RADS classification reported by the NVvR is a highly-accurate and straightforward interpretation technique yielding a very high concordance rate [8]. The wide acceptance of this system seems to entail the standardization of CT scans interpretations worldwide. However, evidence regarding this issue is still

inadequate. This study is the first attempt to confirm the efficacy of the CO-RADS system among the Iranian people.

Prokop et al. [8] were the first researchers who introduced the CO-RADS system in the Netherlands for use in the standard assessment of the pulmonary involvement of Covid-19 in unenhanced chest CT scans. In their study, eight observers assessed the CT scans of 105 patients suspected to be infected with Covid-19 and classified the obtained CT scans based on the CO-RADS system. They found a close agreement between the observers in 68.2% of cases. Moreover, the mean AUC score for this system was 0.91 (for predicting the RT-PCR results) and 0.95 (for predicting the clinical diagnosis). In another study in Japan, Fujioka et al. investigated the usefulness of using the CO-RADS system in 154 patients suspected to be infected with Covid-19 and reported the mean values of sensitivity, specificity, and AUC to be 87.8%, 66.4%, and 0.859, respectively. They further reported a high IOA value, with a mean ICC value of 0.840 [16]. In agreement with the present study, these results advocate that the CO-RADS system is an accurate evaluation technique for Covid-19 based on CT scans while yielding a very high IOA score.

According to studies, CT scans play a critical role in diagnosing Covid-19 in epidemic areas owing to their high sensitivity, while merging RT-PCR and CT imaging enhances the diagnosis of Covid-19 [2, 6]. In this study, we attained a high diagnostic performance by using the results of chest CT of patients, as supported by 51 (47.2%) cases of positive Covid-19 diagnosis based on RT-PCR results, all of which were symptomatic. Nevertheless, the specificity and positive predictive value of the scoring of CT images have been reported to be lower in some areas with a lower prevalence of positive Covid-19. Thus, the usefulness of the CO-RADS system in diagnosing Covid-19 in non-epidemic areas needs to be further illustrated by more investigations [21]. Young adults with no underlying disease have also been reported to often be asymptomatic or have mild symptoms when infected with Covid-19 [16-22].

The study conducted in Belgium by de Smet *et al.* showed that the CT-based CO-RADS system both in symptomatic and

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asymptomatic Covid-19 patients exhibits good diagnostic performance, with AUC scores of 0.89 and 0.70, respectively, for "symptomatic" and "asymptomatic" Covid-19 patients. However, the sensitivity of this system was low in asymptomatic patients, hindering its use as a first-line screening method [23]. In the study conducted by Bernheim *et al.* in the USA, the chest CT imaging of 121 symptomatic Covid-1 patients showed that 56% of the patients undergoing CT imaging in the early stages of the disease (days 0 to 2 post-infection) had normal CT images. Accordingly, CT results may be negative in the early stages of the Covid-19 disease [24].

All the patients in this study (n=51) were diagnosed with Covid-19, as supported by the presence of suspected pneumonia clinical symptoms. However, 7 (12.3%) patients with Covid-19 symptoms had negative PCR results, and 3 (5.8%) patients had no CT-based findings supporting pneumonia. According to a similar study [8], CO-RADS scores of 1 and 2 in the early days of the disease need to be strictly interpreted, while scores of 3 and above indicate that CT alone can be useful for the diagnosis of Covid-19.

In this study, four patients with clinical symptoms of Covid-19 had a CT score of 4, probably implying community-acquired pneumonia. However, due to the overlap of Covid-19 pneumonia with imaging findings of various diseases (e.g., community-acquired pneumonia, interstitial pneumonia, eosinophilic pneumonia, and pulmonary edema), precise differential diagnosis of these findings is challenging even when using the CO-RADS system. Although CT findings are not specific to Covid-19 [13], they seem to accurately indicate the presence of the disease, as supported in this study with the absence of Covid-19 in patients with a CO-RADS score of 5 (i.e., the absence of false negatives).

The results of this study show a good performance of the CO-RADS system in predicting Covid-19 in patients with moderate to severe symptoms. Thus, this scoring system based on chest CT has addressed the demand for a structured and fast-reporting system. Nevertheless, whether this system is adequate for patients with mild or no symptoms is still unclear.

Ultimately, it is worth mentioning that this study suffered from some limitations. First, this was a retrospective study with a relatively small sample size. Thus, for these findings to be confirmed, it is necessary to conduct prospective studies with a larger sample size in the future. Second, this study was conducted in three centers. Thus, the images were taken from CT systems developed by various manufacturers, which can cause differences in the quality of the CT images and, consequently, the observers' diagnostic performance. Third, this study did not investigate the relationship between the findings of CT images and the severity and prognosis of the disease. And ultimately, it is suggested to conduct more studies for the precise examination of these relationships.

## Conclusion

The CO-RADS system is an assessment strategy for classifying the pulmonary involvement of Covid-19 using unenhanced chest CT images. This system exhibits good performance in predicting Covid-19 compared to standard references, i.e., RT-PCR results and clinical diagnoses in patients with moderate to severe symptoms. It further has a remarkably high IOA value. Thus, this CT-based scoring system can be used in the clinical field, particularly when access to RT-PCR for the diagnosis of Covid-19 is restricted.

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