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IP International Journal of Medical Microbiology and Tropical Diseases

Journal homepage: <https://www.ijmmt.org/>

Original Research Article

Correlation between clinical symptomatology and RT-PCR results in the diagnosis of COVID-19: An analysis using routine data in Burkina Faso

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ARTICLE INFO

Article history:

Received 05-11-2022

Accepted 15-11-2022

Available online 19-04-2023

Keywords:

Diagnosis

Symptoms

Correlation

COVID-19

SARS-CoV-2

RT-PCR

ABSTRACT

Background: This study aimed to evaluate the correlation between suspected COVID-19 symptoms and RT-PCR results in the diagnosis of SARS-CoV-2 infection in Burkina Faso.

Materials and Methods: We analyzed SARS-CoV-2 RT-PCR routine diagnostic data in Burkina Faso. Data were collected from March 9, 2020 to September 30, 2020 in the framework of the COVID-19 surveillance. Sensitivity, specificity, predictive values, and Kappa concordance were used to check the correlation between COVID-19 symptoms and the RT-PCR results.

Results: A total of 2217 participants were tested for COVID-19 using RT-PCR, of them 779 COVID-19 positive. The mean age of the participants was 38.7± 17.69 years. Suspected symptoms presented by participants were fever (40.4%), cough (38.6%), asthenia (27.3%), headache (23.6%), dyspnea (20.8%), and odynophagia (16.3%). The sensitivity of presence of at least a clinical sign compared to RT-PCR results was 62.13% and the specificity was 39.85%. The kappa agreement between the presence of COVID-19 suspected symptoms and RT-PCR results was 0.017. The presence of aguesia and/or anosmia in patients induced a positive predictive value of RT-PCR of 91.30%.

Conclusion: The correlation between the COVID-19 symptoms and RT-PCR results in the diagnosis of COVID-19 was very weak. The present study confirms that most clinical signs associated with SARS-CoV-2 infection are not specific to COVID-19, hence the need to always combine RT-PCR or other biological tests with the clinical diagnosis. However, aguesia and anosmia are of interest with a high degree of RT-PCR positivity when present in a COVID-19 suspected patient.

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1. Introduction

The occurrence of several cases of pneumonia of unknown etiology in Wuhan, China, in December 2019 led Chinese authorities to alert WHO on December 31, 2019, about these cases of illness.^{1,2} Research on the causative agent of these illnesses resulted in the identification of a virus

named SARS-CoV-2.³ The respiratory disease for which it is responsible has been named "Coronavirus Disease 2019 (COVID-19)".⁴ This human-to-human transmission was associated with rapid spread in China and around the world. As of October 12, 2022, there were

619,161,228 confirmed cases of COVID-19 and 6,537,636 deaths worldwide.⁵ The African region, particularly Burkina Faso, seems to be relatively spared by the pandemic compared to the rest of the world.⁶ In

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Burkina Faso, as of the same date, the number of COVID-19 officially reported cases was 21,631, including 387 deaths.⁷

In view of the rapid expansion of the disease, a global strategy to fight COVID-19 has been developed with the main goal that all countries control the pandemic by reducing its transmission and mortality.⁸ Preparedness and response plans against the disease were therefore implemented in each country, adapted, and revised according to the pandemic evolution.

The confirmatory diagnosis of SARS-CoV-2 infection is based on the identification of the virus using real-time RT-PCR performed on respiratory specimens.⁹ This technic is also used in Burkina Faso.¹⁰ Covid-19 has several clinical forms including symptomatic (non-specific), pauci-symptomatic and asymptomatic cases.¹¹ In some populations, the measurement of the asymptomatic proportion has been performed, with variable results, ranging from 18% to 88%.¹² COVID-19 patients with functional signs, polymorphous and nonspecific symptoms such as fever, dry cough, dyspnea, muscle pain, or fatigue, and less frequent symptoms such as taste and smell disorders were reported.^{13–16} Several studies have shown high prevalence's of co-infections between SARS-CoV-2 and other bacterial, fungal¹⁷ or viral pathogens¹⁸ that may cause similar symptoms, making it difficult to attribute various clinical symptoms to SARS-CoV-2 infection.

In addition to symptomatic cases, the transmission of COVID-19 can occur through asymptomatic patients^{19,20} and knowledge of the most suggestive symptoms could help practitioners better manage SARS-CoV-2 infection. Hence, it is of interest to know how the SARS-CoV-2 infection symptoms and real-time RT-PCR positivity are linked in a respiratory infection endemic country like Burkina Faso. The purpose of this study was to investigate the correlation between clinical symptomatology and real-time RT-PCR results in the diagnosis of COVID-19 in Burkina Faso.

2. Materials and Methods

2.1. Type and period of study

This study was an analysis of SARS-CoV-2 RT-PCR routine diagnostic data in Burkina Faso collected from March 9 to September 30, 2020.

2.2. Study data

The data used in this analysis included individuals of both sexes (male and female) of all age groups, symptomatic and asymptomatic patients who completed the SARS-CoV-2 test during the study period. Individuals with SARS-CoV-2 negative or positive RT-PCR diagnostic results were included in the analysis. All individuals with an undetermined RT-PCR result were not included in the analysis.

The data analyzed consisted of all persons who were tested for SARS-CoV-2 instead SARS6CoV2 (excluding control tests), during the study period and who had an available RT-PCR result. Following this selection criteria, a total of 2217 individuals were included in the analysis (Figure 1).

As sociodemographic, clinical, and biological data were collected from the COVID-19 case, notification forms filled out during the investigation in search of exposure factors or clinical signs in the persons who took a sample for the diagnosis of COVID-19. Sociodemographic data included age, sex, occupation, and residence. The clinical data consisted essentially of symptoms present at the time of diagnosis, comorbidities, and exposure and travel during the 14 days preceding the sampling (notion of contact with a positive case of COVID-19). The biological data concerned the results of the diagnostic test for COVID-19 by RT-PCR, which was either negative or positive.

2.3. Method of SARS-CoV-2 diagnosis in laboratories

The molecular diagnosis of COVID-19 was performed using real-time RT-PCR method. For detection of SARS-CoV-2, viral RNA was isolated from the sample by extraction and then analyzed using real-time RT-PCR. The extracted RNA contains both the genetic material of the individual and, if present, the RNA of the virus. It has then been converted into cDNA during reverse transcription, using a specific enzyme and primer. If the virus is present in the sample, the amplification of cDNA was carried out in real time RT-PCR thermocycler.²¹

2.4. Study variables

Outcome variable: we considered as outcome variables the results of RT-PCR test which were coded 0 if the results were negative and 1 if the results were positive. We considered as a confirmed case of COVID-19, any person in whom the RT-PCR test for SARS-CoV-2 was positive.

Independent variables: The main exposure variable was the presence or absence of clinical symptoms. An asymptomatic subject is the one enrolled for a COVID-19 diagnostic test and who had no clinical symptoms at the time of the RT-PCR diagnostic test. To be classified as asymptomatic in our database, any participant had to have (i) the modalities "no" and/or "NA" with the variables "cough," "Covid-19 other symptoms," "nausea/vomiting," "sore throat," "irritability/confusion." (i) the variables "Cough", "Nausea/Vomiting", "Sore Throat", "Irritability/Confusion", "History of Fever/Chills", "General Weakness", "Shortness of Breath/Difficulty of Breathing/Lack of Air", "Runny Nose", "Chest Pain", "Muscle Pain", "Joint Pain", "Abdominal Pain", "Diarrhea", "Headache"; (ii) the modalities "Asymptomatic", "None", "No signs", "Not applicable", "Asymptomatic

patients", "Nothing to report SIR (iii) "Not applicable", "External/domicile" modalities at the "COVID Patient Status" variable. As other variables of interest, we used age, sex, occupation, place of residence, type of clinical symptoms, and contact with a confirmed case of COVID-19.

2.5. Statistical analysis

Data were cleaned using Microsoft Excel. The data were analyzed using the statistical programming and analysis software "R". Sensitivity, specificity, positive and negative predictive values were calculated with their 95% confidence intervals. Statistical comparisons were made using the Chi-square test with a significance level of 5%. The Kappa coefficient of agreement between the presence of symptoms and the RT-PCR result was calculated according to the criteria of Landis and Koch (1977).²² Thus, a kappa agreement test ≤ 0 indicated no agreement; 0.01-0.20 indicated no slight agreement; 0.21-0.40 indicated moderate agreement; 0.41- 0.60 meant that there was moderate agreement; between 0.61-0.80 substantial agreement; and between 0.81-1.00 almost perfect agreement.

3. Results

A total of 28631 records (fully or partially) were performed for a COVID-19 diagnostic test by RT-PCR. After applying our inclusion criteria, we retained 2217 records with known RT-PCR results which were used in our analysis. The flow diagram of the study participants is shown in Figure 1.

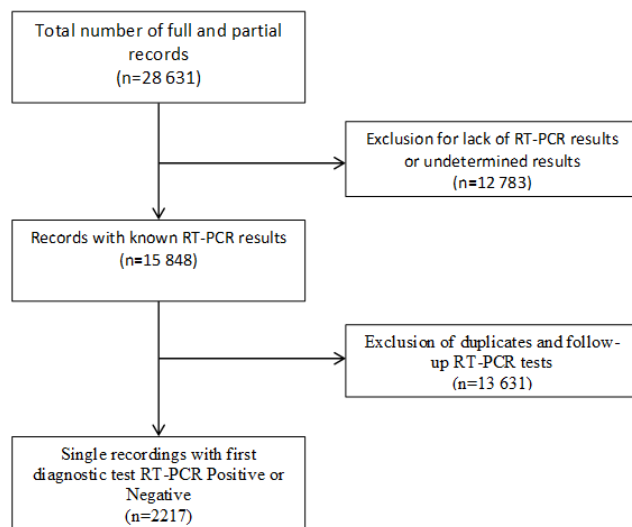


Fig. 1: Flow chart of the data; (Nb: (i) Duplicates are patients recorded more than once for the same RT-PCR test, (ii) Control tests are tests repeated until cured as part of the follow-up of patients who had a first positive test, or tests repeated as part of the follow-up of contact cases who had a first negative test)

3.1. Socio-demographic characteristics of participants

The mean age of participants was 38.7 ± 17.69 years. It was 41.79 ± 17.22 years for participants with a positive RT-PCR result and 37 ± 17.73 years for those with a negative RT-PCR result. Males accounted for 64.3% of the SARS-CoV-2 infected participants and 62.7% of the negative cases. Health workers and students accounted for 12.3% and 15.8% of the RT-PCR positive cases and 16.7% and 12.4% of negative cases, respectively. More than 18% of the RT-PCR positive participants had been in contact with a confirmed and/or suspected COVID-19 case and 25.0% did not have contact with an infected person. Twenty eight percent (28%) of the RT-PCR negative subjects reported being in contact with a confirmed COVID-19 cases. Respectively, 82% and 73.5% of the SARS-CoV-2 infected and uninfected subjects resided in urban areas. The results are presented in Table 1.

3.2. Symptoms recorded at the time of data collection

During enrollment, 61.0% of participants had at least one symptom suspicious for COVID-19. Among 779 participants tested positive for SARS-CoV-2 RT-PCR, 295 were asymptomatic (37.9%). Symptomatology in the positive tested participants was dominated by fever (40.43%), cough (38.64%), asthenia (27.34%), headache (23.62%), dyspnea (20.80%), and odynophagia (16.30%). Fever/history of fever, odynophagia, chest pain, aguesia/dysgeusia, anorexia, and anosmia were the symptoms most associated with positive RT-PCR results ($p < 0.05$), whereas headache, chest pain, and odynophagia were more found in RT-PCR negative test subjects ($p < 0.05$). The results are presented in Table 2.

3.3. Clinical symptoms based diagnostics compared with RT-PCR

Out of a total of 779 patients tested positive for SARS-CoV-2 using RT-PCR, 488 were symptomatic, giving a sensitivity of symptoms of 62.13%. The specificity of symptoms was estimated at 39.85% (865/1435 RT-PCR negative). The positive (PPV) and negative (NPV) predictive values for the presence of at least one symptom at the time of diagnosis were 35.88% and 66.01%, respectively. Overall, the agreement between the presence of symptoms and RT-PCR in the diagnosis of COVID-19 is 0.017. The accuracy of a diagnosis based on the presence of symptoms among participants was 47.7% (Table 3).

On one hand, the most sensitive single symptoms compared to RT-PCR in the diagnosis of COVID-19 were fever ($Se=40.44\%$), cough ($Se=36.4\%$), headache ($Se=31.14\%$), asthenia (27.34%), and dyspnea (20.80%), with specificities range from 63% to 80%. On the other hand, aguesia/dysgeusia, anosmia, and anorexia, with very low sensitivity ($Se < 3\%$), were the most specific clinical

signs in the diagnosis with specificity greater than 98% (Table 4). These clinical signs were also those with the highest positive predictive values in the diagnosis of COVID-19 cases (PPV ranged from 59.10 to 74.06%).

In association, aguesia with anosmia and fever had a sensitivity of 1.5% with, however, the highest specificity (99.72%) and positive predictive value (75%). It is followed by the association "cough, fever, and asthenia" more sensitive (25.35%) and less specific (81.90%) with a positive predictive value estimated at 44.37% (Table 4).

4. Discussion

In our study, we found a sensitivity of 62.13% for the symptomatologic presence and a specificity of 39.85%. We obtained a positive predictive value of 35.88% and a negative predictive value of 66.01%, with a kappa agreement of 0.016. According to the kappa concordance classification scale, there is a very weak correlation between the presence of symptoms and the result of the RT-PCR diagnostic test. Taking each single symptom, we found that fever/chills had the higher sensitivity (40%), followed by cough (36.44%), headache (31%), and dyspnea (20%). These proportions correspond to the probability that these clinical signs are present in a person with COVID-19. This is consistent with the results of a systematic review that reported that among the COVID-19 patients confirmed by positive PCR results, most of them showed fever or cough as the primary clinical signs.¹⁶ However, the probability that the absence of these signs among individuals without SARS-CoV-2 infection (specificity) in our study population varied from 63.45% for headache to 86.93% for odynophagia. These results show that clinical signs are not sensitive and are not specific to COVID-19. Moreover, the frequency and sensitivity of these signs may vary according to the severity of the disease.^{23–25} In severe cases admitted to intensive care, the authors revealed that half of them presented with fever with a temperature greater than 38°C, and more than 80% of them presented with cough and/or breathlessness, accompanied by tachypnea.²⁶ In patients with subclinical COVID-19, on the other hand, only 40% had fever with nonspecific symptoms, such as cough and sore throat.²⁷ This study did not report any cases of dyspnea, whereas in our study the sensitivity of dyspnea was 20.80% with a specificity of 35%.

The combination of "aguesia with anosmia and fever" at the time of RT-PCR diagnosis had a low probability of identifying an infection (1.54%), but the probability that the absence of this combination of signs would rule out COVID-19 infection was very high (99.72%). Moreover the probability that a subject with the combination of the three signs is infected with COVID-19 is greater than 75%, which is also much higher than that of "cough, fever, and asthenia" (PPV=44.37%, p=0.02). Some authors had already reported similar results. Ozcan et al in Turkey²⁸

found a highly significant correlation between the presence of anosmia and/or aguesia in a patient and RT-PCR positivity. Anosmia/aguesia, fever, and myalgia were the strongest independent predictors of positive RT-PCR tests for COVID-19 in the study by Fan-Yun et al. among healthcare workers in the United States.²⁴ The positive predictive value of this association of clinical signs, which corresponds to the probability that a person presenting with this association of symptoms is actually infected with SARS-CoV-2, is 75%. Other authors, although not finding significant differences between the clinical signs of RT-PCR positive and negative patients, reported a relatively high specificity for dysgeusia (84%) and anosmia (85%) with a positive predictive value of the dysgeusia-anosmia association of 82.5%.²⁹

4.1. Strengths and limitations of the study

We performed an analysis of the data from routine surveillance of COVID-19 in Burkina Faso. Many records were not carefully completed, which might cause information bias. There are also a potential recall bias for some variables, for instance, like the history of contact with COVID-19 patient or comorbidities. Despite these limitations, we think that this study provides useful information on the link between symptoms and RT-PCR test for COVID-19 in a context of limited resources and endemic of many similar infectious diseases.

5. Conclusion

The correlation between the presence of clinical signs and RT-PCR results in the diagnosis of COVID-19 remains very weak. The present study confirms that most of the clinical signs associated with SARS-CoV-2 infection are not specific to this infection, hence the need to always associate RT-PCR or antigen rapid test to the diagnosis. However, it is shown that aguesia and anosmia appear to be strongly associated with COVID-19 infection with a very high level of RT-PCR positivity when present in a patient. These two clinical signs could therefore be considered pathognomonic of COVID-19 in subjects in an epidemiological context. This work provides guidance to health professionals in the presumptive diagnosis of COVID-19, while maintaining the role of RT-PCR as a confirmatory test.

6. Authors' Contributions

HGO: Conceptualization, Methodology, Investigation, Results interpretation, Writing – original draft, Writing – review & editing, NP, KC: Investigation, Formal analysis, Writing – review & editing, OO, AAZ, DBY, SZ, EAD, TS: Writing – review & editing. All authors commented on the manuscript. All authors reviewed and approved the final manuscript to be published.

Table 1: Socio-demographic characteristics of patients according to RT-PCR results.

Socio-demographic characteristics	Total (n=2217)	RT-PCR positive (n=779)	RT-PCR negative (n=1438)	p value
Age (mean± sd in years)	38.69 ± 17.69	41.79 ± 17.22	37.0 ± 17.73	<0.001
Age groups n (%) (in years)				
< 15	159 (7.17)	27 (3.47)	132 (9.18)	<0.001
15 - 30	516 (23.27)	181 (23.23)	335 (23.30)	
30 - 45	792 (35.72)	256 (32.86)	536 (37.27)	
45 - 60	467 (21.06)	194 (24.90)	273 (18.98)	
≥60	283 (12.76)	121 (15.53)	162 (11.26)	
Gender n (%)				
Female	802 (36.18)	278 (35.69)	524 (36.44)	0.61
Male	1402 (63.24)	501 (64.31)	901 (62.66)	
Not specified	13 (0.58)	-	13 (0.90)	
Occupations n (%)				
Health workers	336 (15.16)	96 (12.32)	240 (16.69)	0.006
Student	302 (13.62)	123 (15.79)	179 (12.45)	0.03
Other	1579 (71.22)	560 (71.89)	1019 (70.86)	0.61
Notion of contagage n (%)				
Yes	544 (24.54)	142 (18.23)	402 (27.96)	0.01
No	1002 (45.20)	442 (56.74)	560 (38.94)	
Without recall	671 (30.26)	195 (25.03)	476 (33.10)	
Place of residence n (%)				0.005
Urban	1693 (76.36)	636 (81.64)	1057 (73.50)	
Rural	136 (6.13)	35 (4.49)	101 (7.02)	

sd : standard deviation

Table 2: Distribution of subjects according to the presence of symptoms.

Symptoms	Overall (n=2217)	RT-PCR positive (n=779)	Negative RT-PCR (n=1438)	P value
Symptomatic cases n (%)	1353 (61.02)	484 (62.13)	869 (60.43)	0.61
Asymptomatic cases n (%)	864 (38.97)	295 (37.87)	569 (39.57)	
Frequency of reported symptoms				
Cough	826 (37.3)	301 (38.64)	525 (36.51)	0.32
Fever/history of chills	793 (35.8)	315 (40.43)	478 (33.24)	0.001*
Headaches	589 (26.6)	184 (23.62)	405 (28.16)	0.02*
Asthenia	561 (25.3)	213 (27.34)	348 (24.20)	0.11
Dyspnea	453 (20.4)	162 (20.80)	291 (20.24)	0.76
Odynophagy	428 (19.31)	127 (16.30)	301 (20.93)	0.008
Nasal discharge	354 (16)	110 (14.12)	244 (16.97)	0.08
Muscle pain	273 (12.3)	110 (14.12)	163 (11.34)	0.06
Chest pain	267 (12)	79 (10.14)	188 (13.07)	0.04*
Arthralgia	205 (9.2)	75 (9.62)	130 (9.04)	0.65
Diarrhea	122 (5.5)	35 (4.49)	87 (6.05)	0.12
Abdominal pain	91 (4.1)	30 (3.85)	61 (4.24)	0.66
Aguesia	29 (1.31)	21 (2.79)	8 (0.56)	<0.0001**
Anosmia	27 (1.22)	20 (2.57)	7 (0.49)	<0.0001**
Anorexia	22 (0.99)	13 (1.67)	9 (0.63)	0.02*
Total n (%)	2217 (100)	779 (35.14)	1438 (64.86)	

Table 3: Performance of symptomatology compared to RT-PCR in the diagnosis of COVID-19

Symptoms	RT-PCR Positive	RT-PCR Negative
Symptomatic case (presence of symptoms)	n=484	n=865
Asymptomatic (no symptoms)	n=295	n=573
Sensitivity (%)	62.13 (95%CI: 58.67-65.47)	
Specificity (%)	39.85 (95%CI: 37.35-42.4)	
Positive predictive value (%)	35.88 (95%CI: 33.36-38.47)	
Negative predictive value (%)	66.01 (95%CI: 62.8-69.09)	
Accuracy of diagnosis by symptoms (%)	47.68 (95%CI: 45.6-49.76)	
Likelihood ratio of positive test	1.033 (95%CI : 1.028 - 1.038)	
Likelihood ratio of negative test	0.9504 (95%CI : 0.9392 - 0.9616)	
Kappa concordance test	0.017 (95%CI :-0.019-0.053)	

Table 4: Performance of symptom types according to RT-PCR in the diagnosis of COVID-19

Clinical symptoms	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)	Kappa	p-value
Fever/shivering history	40.44	66.76	39.72	67.42	0.071	0.001**
Cough	36.44	65.64	38.64	63.49	0.021	0.32
Headache	31.24	63.45	23.62	71.84	-0.048	0.02*
Dyspnea	20.80	79.76	35.76	65.02	0.006	0.76
Odynophagy	16.30	79.07	29.67	63.56	-0.051	0.008**
Myalgia	14.12	88.66	40.29	65.59	0.032	0.06
Nasal discharge	14.12	83.03	31.07	64.09	-0.032	0.08
Asthenia	27.34	75.80	37.97	65.82	0.033	0.11
Chest pain	10.14	86.93	29.59	64.10	-0.034	0.04*
Arthralgia	9.63	90.96	36.59	65.01	0.007	0.65
Nausea/vomiting	6.80	93.60	36.55	64.96	0.005	0.71
Diarrhea	4.49	93.95	28.69	64.49	-0.019	0.12
Abdominal pain	3.85	95.76	32.97	64.77	-0.005	0.66
Aguesia/dysgeusia	2.70	99.44	72.41	65.63	0.027	<0.0001**
Anosmia	2.57	99.51	74.07	65.34	0.026	<0.0001**
Irritation/confusion	1.80	98.26	35.90	64.88	0.0007	0.92
Anorexia	1.67	99.37	59.10	65.10	0.013	0.02*
Symptoms associations						
Cough + fever + asthenia	25.35	81.90	44.37	65.84	0.079	0.002
Cough + fever + dyspnea	18.71	82.15	35.37	65.95	0.001	0.94
Cough + fever + headache	14.51	87.69	38.97	65.44	0.025	0.15
Aguesia + Anosmia + Fever	1.54	99.72	75.00	65.15	0.018	0.001

7. Data Availability

Data available from the corresponding author upon reasonable request.

8. Source of Funding

No funding received for this study

9. Conflicts of Interest

The authors declare that there are no conflicts of interests.

10. Acknowledgments

The authors thank all staff of the COVID-19 diagnostic center. They also thank all staff of the IRSS Biomedical Research Laboratory (LaReBio) for data compilation and entry.

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Cite this article: Ouedraogo HG, Nabia P, Cisse K, Ouedraogo O, Zoure AA, Yugbare DB, Zida S, Diendere EA, Sagna T. Correlation between clinical symptomatology and RT-PCR results in the diagnosis of COVID-19: An analysis using routine data in Burkina Faso. *IP Int J Med Microbiol Trop Dis* 2023;9(1):10-16.