



## Research Article

# Risk factors and incidence rate of complications originated as a consequence of the acute SARS-CoV-2 infection or the treatments performed. A longitudinal study in general medicine from March 15, 2020 to October 31, 2022 in Toledo, Spain

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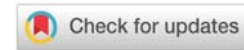
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## Abstract

**Background:** The epidemiological data on complications originated as a consequence of the acute infection of COVID-19 or the treatments performed are not well known.

**Objectives:** To estimate the incidence rate and the risk factors of complications originating as a consequence of the acute infection of COVID-19 or the treatments performed in general practitioner consultation.

**Methodology:** A prospective study of patients with COVID-19 in a general practice setting in Toledo, Spain, from March 15, 2020, to October 31, 2022.

**Results:** 687 positive cases of acute COVID-19 were diagnosed. Of these, 36 (36% were women and 39% had  $\geq 65$  years old) presented complications, which represents a gross incidence rate of 5%. In  $\geq 65$  years old, the incidence rate was 23%. The incidence rate of complications was much higher in 2020 vs. 2021 and 2022 (21%, 5%, and 1% cases, respectively). The only statistically significant risk factors were aged  $> 65$  years (RR = 2.46), having presented moderate-severe severity of primary infection (RR = 14.54) having chronic diseases (RR = 3.11), and specifically of the circulatory system (RR = 1.98).

**Conclusion:** In the context of general medicine in Toledo (Spain) incidence rate of complications originated as a consequence of acute infection of COVID-19 or the treatments performed, was higher in cases with acute infection in 2020, and in  $\geq 65$  years old, and are risk factors having presented moderate-severe severity of primary infection, having chronic diseases, and specifically of circulatory system, and being  $\geq 65$  years old.

## Introduction

Clinical evolution of infection by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19), is highly variable and can cover a wide clinical spectrum, from being asymptomatic or mild symptoms to severe respiratory failure requiring

supplemental oxygen and/or mechanical ventilation and even fatal respiratory failure [1].

Although most people recover well, in addition to its possible severity, there is a wide range of COVID-19-related illnesses and organ damage, creating a complex prognostic picture [2]. In severe cases of patients hospitalized with COVID-19, high

mortality rates are experienced, ranging from 10% to 30% [3]. And of the patients discharged from the hospital, more than one in 10 will die within six months [4].

Typical coronavirus symptoms, at least in the early stage of the pandemic, included fever, cough, and shortness of breath. Less known are the complications of the disease. The vast majority of these complications appear to stem from pneumonia caused by damage to the lungs. This causes respiratory malfunction and the entry of other pathogens that aggravate pneumonia. There may be a chronification of pneumonia. Also, pneumonia can continue with sepsis. Problems can occur in other organs affected by the virus, including other infectious complications, lipid disorders and diabetes, obesity, thromboembolism, bleeding, and coagulation disorders. COVID-19 may also lead to septic shock associated with low blood pressure and decreased urine output with acute renal failure and chronic kidney disease, muscular atrophy secondary to assisted ventilation and prolonged hospitalization, and cardiac problems such as heart failure, cardiac arrest, ventricular fibrillation, acute myocardial infarction, myocarditis, pericarditis, and hypertension; Significant neurological damage has even been recorded. This has a great weight not only when overcoming the disease, but also once the patient has left the hospital [5-12].

It is currently known that COVID-19 is a multisystemic disease, which can occur with complications at the time of presentation or develop during the acute phase of the disease. These complications can be respiratory, cardiovascular, renal, gastrohepatic, thromboembolic, neurological, cerebrovascular, and autoimmune, among others [13-15].

Since the outbreak of the COVID-19 pandemic, great efforts have been made to identify the possible determinants of increased risk of contracting the infection and developing its serious clinical manifestations within various demographic factors and medical conditions [16]. Initial data seemed to indicate that 81% of cases are mild, 14% severe, and 5% critical, with a 15% risk of death in people over 80 and 8% in people of more than 70 years [17]. On the other hand, age and underlying pathologies seem to be the most established risk factors [18,19]. Also, a history of geriatric disease, obesity, and chronic disease are classified as risk factors for adverse outcomes of COVID-19 [20].

However, sometime after the COVID-19 pandemic began in 2019, little is known about the complications of SARS-CoV-2 infection, which appear to be common in hospitalized patients, but the spectrum of symptoms in milder cases needs further investigation [21]. Thus, overall, the data on the risk of presenting complications from COVID-19 are limited, as well as the importance of comorbidities in COVID-19 with serious complications [20].

In this context, we present an observational, longitudinal, and prospective study of patients with complications originated as a consequence of the acute infection of COVID-19 or the treatments performed, whose objectives were: 1. Estimate Incidence Rate (IR) of complications originated as a consequence of the acute infection of COVID-19 or the

treatments performed; and 2. Identify the risk factors for complications that originated as a consequence of the acute infection of COVID-19.

## Material and methods

### Design and emplacement

An observational, longitudinal, and prospective study of patients with complications originated as a consequence of the acute infection of COVID-19 or the treatments performed was carried out from March 15, 2020, to October 31, 2022, in a family medicine office at the Health Center Santa Maria de Benquerencia, Toledo (Spain), which has a list of 2,000 patients > 14 years of age (in Spain, the general practitioners [GPs] care for people > 14 years of age, except for exceptions requested by the child's family and accepted by the GP).

### Objectives

1. Estimate IR of complications originated as a consequence of the acute infection of COVID-19 or the treatments performed in GP consultation. IR was calculated by dividing the number of cases of complications that originated as a consequence of the acute infection of COVID-19 by the primo infection of COVID-19 in the follow-up time (from March 15, 2020, to October 31, 2022) [22]. Similarly, the data on the incidence of complications that originated as a consequence of the acute infection of COVID-19 were extrapolated to the entire population that attended the consultation (N = 2,000 people) [23].

2. Identify the risk factors for complications that originated as a consequence of the acute infection of COVID-19. In this sense, the variables collected were compared by calculating the Relative Risk (RR) as the incidence of risk factors in those exposed to complications originated as a consequence of the acute infection of COVID-19 / incidence of risk factors in those not exposed to complications originated as a consequence of the acute infection of COVID-19. The RR was interpreted as follows [24]: From 0 to 0.5: protection factor effectively; from 0.6 to 0.8: true benefits; from 0.9 to 1.1: not significant; from 1.2 to 1.6: weak risk; from 1.7 to 2.5: moderate risk; more than 2.5: strong risk.

### Inclusion criteria

The inclusion and exclusion criteria in this study have already been previously published [25]. Complications were considered health problems that originated as a result of acute COVID-19 infection or the treatments performed. Complications due to COVID-19 were defined as those cases presenting acute respiratory infection, dyspnea (oxygen saturation less than or equal to 92%), tachypnea, and clinical and/or radiological signs of pneumonia. In addition, those who required hospitalization (including admission to the intensive care unit) and death from COVID-19 [26] were considered. Specific sequelae of acute COVID-19 infection were excluded: when there were persistent symptoms or pathologies during acute infection or after apparent recovery from acute COVID-19 infection, which is not part of acute COVID-19 infection [27].

## Diagnosis of COVID-19

The diagnosis was performed with reverse transcriptase Polymerase Chain Reaction (PCR) oropharyngeal swab tests or antigen testing. Spain had not initially devised an intensive testing strategy for suspected cases of COVID-19 infections [28]; since the beginning of the pandemic in mid-March 2020, PCR tests were only performed in the hospital context until mid-May 2020, date when they began to be performed in general medicine as well. In mid-December 2020, rapid antigen tests began for symptomatic patients with less than 5 days of evolution. The PCR tests were performed both in symptomatic patients and in asymptomatic contacts. An Asymptomatic confirmed case with active infection was considered to be any person with a clinical picture of sudden onset acute respiratory infection of any severity that occurs, among others, with fever, cough, or feeling of shortness of breath. Other symptoms such as odynophagia, anosmia, ageusia, muscle pain, diarrhea, chest pain, or headache, among others, were also considered symptoms of suspected SARS-CoV-2 infection according to clinical criteria; plus, a positive PCR or rapid antigen test positive [29].

In Spain, since April 28, 2022, there was a new "Surveillance and Control Strategy Against COVID-19" that included the non-performance of diagnostic tests, which were focused only on those over 60 years of age, immunosuppressed and pregnant women, health workers, and serious cases, as well as the elimination of contact tracing [30].

## Definition of cases and controls

Patients with complications originated as a consequence of the acute infection of COVID-19 or the treatments performed were considered "cases." "Control" patients were those with acute COVID-19 without complications originating as a consequence of the acute infection of COVID-19 or the treatments performed. Control data were obtained from previous studies in the same consultation, with the same population attended, and carried out by the same researcher [31-34].

## Collected variables

The variables collected and their definitions and criteria have been previously published [25]. These variables were: Age; sex; if the patient was a healthcare professional, acute COVID-19 infection date; complications originated as a consequence of the acute infection of COVID-19 or the treatments performed (as defined above), chronic diseases (defined as "any alteration or deviation from normal that has one or more of the following characteristics: is permanent, leaves residual impairment, is caused by a non-reversible pathological alteration, requires special training of the patient for rehabilitation, and / or can be expected to require a long period of control, observation or treatment" [35], classified according to the International Statistical Classification of Diseases and Health-Related Problems, CD-10 Version: 2019 [36]; vaccination status against COVID-19 at the date of acute infection; and severity of the disease (mild cases: clinical symptoms are mild and no manifestation of pneumonia can be found on images; moderate cases: with symptoms such as

fever and respiratory tract symptoms, and the manifestation of pneumonia can be seen on the imaging tests; and severe cases: respiratory distress, respiratory rate  $\geq 30$  breaths / min., pulse oxygen saturation  $\leq 93\%$  with room air at rest, arterial partial pressure of oxygen / oxygen concentration ration  $\leq 300$  mmHg.) [37]. To simplify the comparison, moderate and severe cases were counted together.

## Epidemiological and statistical analysis

The calculation of the IR and RR were performed as explained above (subsection "Objectives") [22-24]. The classes that classify the age groups were made taking into account mid-decade to mid-decade [38]. As much as possible, excessive fragmentation of the data was avoided to avoid low numbers of classes to be compared. The age of 65 years was used as the beginning of old age [39,40].

The bivariate comparisons were performed using the Chi-Square test ( $X^2$ ) with Yates correction or Fisher Exact Test when necessary, (according to the number of the expected cell totals) for percentages.

## Ethical issues

No personal data of the patients were used, but only group results, which were taken from the clinical history.

## Results

687 positive cases of acute COVID-19 were diagnosed in the general medicine consultation. Of these, 36 cases (36% were women and 39% had  $\geq 65$  years old) presented complications originated as a consequence of the acute infection of COVID-19 or the treatments performed, which represents a gross IR of 5% cases x March 15, 2020, to October 31, 2022. In  $\geq 65$  years old, IR was of 23 % cases x March 15, 2020 to October 31, 2022. IR of complications with respect to COVID-19 cases was much higher in 2020 (21% cases) versus in 2021 and 2022 (5% and 1% cases, respectively) (Table 1). IR of complications originated as a consequence of the acute infection of COVID-19 or the treatments performed with respect to the total population attended in that office (N = 2,000), from March 15, 2020, to October 31, 2022, was 1.8 %. The only statistically significant risk factors for complications originated as a consequence of the acute infection of COVID-19 or the treatments performed were aged  $\geq 65$  years [RR = 2.46 (95% CI: 1.3, 4.67). Moderate risk;  $X^2 = 8.8539$ .  $p = .002925$ ], having presented moderate-severe severity of primary infection [RR = 14.54 (95% CI: 8.68, 24.37). Strong risk;  $X^2 = 108.4104$ .  $p < 0.00001$ ], having chronic diseases [RR = 3.11 (95% CI: 1.38, 7). Strong risk;  $X^2 = 8.5601$ .  $p = .003436$ ], and specifically having chronic disease of the circulatory system [RR = 1.98 (95% CI: 1.29, 3.05). Moderate risk;  $X^2 = 10.7329$ .  $p = .001052$ ] (Tables 2,3).

## Discussion

### Main findings

The main results of our study were:

1. The incidence rate of complications originated as



**Table 1:** Incidence rates of complications originated as a consequence of the acute infection of COVID-19 or the treatments performed in general medicine (Toledo, Spain) from March 15, 2020 to October 31, 2022.

Variables	Complications originated as a consequence of the acute infection of COVID-19 or the treatments performed N = 36	Acute COVID-19 without complications originated as a consequence of the acute infection of COVID-19 or the treatments performed N = 651	Incidence rates of complications originated as a consequence of the acute infection of COVID-19 or the treatments performed from March 15, 2020 to October 31, 2022 N = 687
Total	36 (100)	651 (100)	5 % cases x March 15, 2020, to October 31, 2022
> = 65 years	14 (39)	46 (7)	23 % cases x March 15, 2020, to October 31, 2022
>45 and < 65 years	18 (50)	184 (28)	9 % cases x March 15, 2020, to October 31, 2022
= < 45 years	4 (11)	421 (65)	1 % cases x March 15, 2020, to October 31, 2022
Women	13 (36)	319 (49)	4 % cases x March 15, 2020, to October 31, 2022
Men	23 (64)	332 (51)	6 % cases x March 15, 2020, to October 31, 2022
COVID-19 date in 2020	22 (61)	84 (13)	21% cases x March 15, 2020, to October 31, 2022
COVID-19 date in 2021	12 (33)	251 (39)	5% cases x March 15, 2020, to October 31, 2022
COVID-19 date in 2022	2 (6)	316 (48)	1% cases x March 15, 2020, to October 31, 2022

( ): Denotes percentages.

**Table 2:** Risk factors of complications originated as a consequence of the acute infection of COVID-19 or the treatments performed.

Risk Factors	Complications N = 36	Acute COVID-19 Without Complications N = 188	Statistical Significance	Relative Risk (RR)
> = 65 years	14 (39)	32 (17)	X2 = 8.8539. p = .002925. Significant at p < .05.	RR = 2.46 (CI 95%: 1.3, 4.67). Moderate risk
Women	13 (36)	101 (54)	X2 = 3.7501. p = .052804. NS	RR = 0.55 (CI 95%: 1.07, 0.28). Protection factor effectively
Men	23 (64)	87 (46)	X2 = 3.7501. p = .052804. NS	RR = 1.83 (CI 95%: 0.93, 3.6). Moderate risk
Health Care Workers	4 (11)	31 (16)	X2 = 0.6629. p = .415531. NS	RR = 0.68 (CI 95%: 2.62, 0.18). True benefits
Moderate-severe severity of primary infection	26 (72)	8 (4) [pneumonia]	X2 = 108.4104. p < 0.00001. Significant at p < .05.	RR = 14.54 (CI 95%: 8.68, 24.37). Strong risk
Chronic diseases	30 (83)	108 (57)	X2 = 8.5601. p = .003436. Significant at p < .05.	RR = 3.11 (CI 95%: 1.38, 7). Strong risk
Vaccinated COVID-19 with 1, 2, or 3 doses at the time of acute covid-19	16 (44)	88 (47)	X2 = 0.0679. p = .794432. NS	RR = 0.92 (CI 95%: 7.1, 0.12). Not significant
Not vaccinated at the time of acute covid-19	20 (56)	100 (53)	X2 = 0.0679. p = .794432. NS	RR = 1.08 (CI 95%: 0.16, 7.12). Not significant

( ): Denotes percentages; NS: Not significant.

**Table 3:** Chronic diseases risk factors in complications originated as a consequence of the acute infection of COVID-19 or the treatments performed.

Chronic Diseases (WHO, ICD-10 GROUPS)	Complications N = 36	Acute COVID-19 Without Complications N = 188	Statistical Significance	Relative Risk (RR)
-I Infectious	0	0	Fisher exact test = 1. NS	RR = NaN
-II Neoplasms	4 (4)	9 (3)	Fisher exact test = 0.3158. NS	RR = 1.52 (CI 95%: 0.37, 6.26). Weak risk
-III Diseases of the blood	1 (1)	5 (1)	Fisher exact test = 1. NS	RR = 0.81 (CI 95%: 3.74, 0.18). True benefits
-IV Endocrine	20 (22)	65 (19)	X2 = 0.5733. p = .448957. NS	RR = 1.19 (CI 95%: 0.68, 2.08). Not significant
-V Mental	5 (6)	24 (7)	X2 = 0.2089. p = .647628. NS	RR = 0.83 (CI 95%: 4.37, 0.16). True benefits
-VI-VIII Nervous and Senses	4 (5)	34 (10)	X2 = 2.5652. p = .109237. NS	RR = 0.49 (CI 95%: 1.34, 0.18). Protection factor effectively
-IX Circulatory system	24 (27)	44 (13)	X2 = 10.7329. p = .001052. Significant at p < .05.	RR = 1.98 (CI 95%: 1.29, 3.05). Moderate risk
-X Respiratory system	7 (8)	23 (7)	X2 = 0.1525. p = .696205. NS	RR = 1.15 (CI 95%: 0.21, 6.37). Not significant
-XI Digestive system	11 (12)	43 (12)	X2 = 0.0013. p = .971485. NS	RR = 0.99 (CI 95%: 1.14, 0.86). Not significant
-XII Diseases of the skin	0	11 (3)	Fisher exact test = 0.1306. NS	RR = 0 (CI 95%: Infinity, 0). Protection factor effectively
-XIII Musculo-skeletal	7 (8)	46 (13)	X2 = 1.9962. p = .157698. NS	RR = 0.61 (CI 95%: 1.34, 0.28). True benefits
-XIV Genitourinary	6 (7)	40 (12)	X2 = 1.778. p = .182394. NS	RR = 0.37 (CI 95%: 0.78, 0.17). Protection factor effectively
TOTAL chronic diseases**	89 (100)	344 (100)	---	---

( ): Denotes percentages; NS: Not Significant; NaN: Not a Number (result impossible to calculate); \*Patients could have more than one chronic disease; the percentages of chronic diseases are over the total of chronic diseases.

a consequence of the acute infection of COVID-19 or the treatments performed were high or very high in >=65 years old (23% cases x March 15, 2020, to October 31, 2022). On the other

hand, the IR of complications was much higher in 2020 versus 2021 and 2022 (21%, 5%, and 1% cases, respectively).





During 2020, variants of the original Wuhan virus predominated in Spain [38]. In the period from March to April 2020, in Spain the A lineage of the coronavirus predominated, especially the SEC7 and SEC8, and from summer to December 2020, the 20E (EU1) variant [41,42]. In the period from January 2021 the alpha variant predominated and from the summer-autumn of 2021 the delta variant [43,44]. From January 2022 to October 2022, the omicron variant predominated [45-47].

Therefore, the data used in our study, which included information on the different epidemiological waves of the pandemic during 2020, 2021, and 2022, yield results that suggest that the Asian original virus strains are a much higher cause of serious complications than other later variants. Although it can also be influenced by the vaccination rate; it must be remembered that vaccination began in 2021. In any case, this data coincides with other publications that indicate that in 2022 cases rose 230%, but deaths barely 20% [48].

On the other hand, it must be taken into account that the "denominator" of the IR [the total number of COVID-19 cases in the consultation (687 positive cases)] is probably underestimated. In Spain, since April 28, 2022, there was a new "Surveillance and Control Strategy Against COVID-19" that included the non-performance of diagnostic tests, that focused only on those over 60 years of age, immunosuppressed and pregnant women, vulnerable areas (socio-health workers) and serious cases, and the elimination of contact tracing [30]. Therefore, since that date, patients carried out self-diagnosis with antigen tests purchased at a pharmacy, although they usually informed the GP of their result if it was positive. In contrast, the IR "numerator" (cases with complications originated as a consequence of the acute infection of COVID-19 or the treatments performed) is probably valid, due to the characteristics of the complications themselves, which require assistance from the GP.

Consequently, it is possible that the IR of complications for the entire pandemic period is overestimated, but at the expense of the calculation for 2022 (when tests in general medicine were no longer carried out); Being so, this bias would not affect the years 2020 and 2021, dates where the cases with complications are concentrated, especially in the year 2020.

2. In our study, the following risk factors were statistically significant:

- Aged  $\geq$  65 years (Moderate risk)
- Moderate-severe severity of primary infection (Strong risk)
- Chronic diseases (Strong risk)
- Chronic disease of the circulatory system (Moderate risk)

### Comparison with other studies

A fact to take into account is the difficulty of comparison due to the fact that most researchers do not differentiate the terms "persistent symptoms", "sequels" and "complications" of COVID-19, using these words as interchangeable when in reality they are different concepts [26,27,49-60]. In any

case, excessive risks for complications have been observed preferentially in critically ill hospitalized patients [5]. In agreement with this data, we found that having presented moderate-severe severity of primary infection supposes a strong risk factor.

On the other hand, age over 65 years has been repeatedly pointed out as an important factor that contributes to the risk of hospitalization, pneumonia, and death from COVID-19. Relative risks for complications from COVID-19 have been reported according to age in  $> 30$  years of 1.28 (95%: 0.6 to 2.75) and in  $> 60$  years 2.04 (95%: 0.88 to 4.74). Although some studies have indicated that arrhythmias, gastrointestinal bleeding, and sepsis were more common in younger patients [61]. We found that being  $\geq 65$  years is a moderate risk factor.

Another established risk factor is the presence of chronic diseases: cardiovascular diseases and arterial hypertension, diabetes, chronic obstructive pulmonary disease, cancer, immunosuppression, other chronic diseases, smoking, and obesity. A relative risk for complications from COVID-19 in the presence of comorbidity of 2.94 (95%: 1.95 to 4.42) has been reported [7-10,26,53,54,62-68]. However, other studies have reported a relatively poor correlation between pre-existing risk factors and complications [61]. In our study, we found that presenting chronic diseases entails a strong risk, and specifically having chronic circulatory system disease a moderate risk. It has been reported that underlying heart disease can worsen the severity of any infection, including COVID-19 [16,65]. In this sense, COVID-19 is actually a multi-organ disease and several possible mechanisms underlying cardiac muscle injury have been proposed: direct cytotoxic damage, dysregulation of the renin-angiotensin-aldosterone system, endothelial inflammation, dysregulation of the immune response [69].

### Study limitations and strengths

1. Infections were not genetically sequenced; Thus, complications cannot be accurately ascribed to a certain variant of SARS-CoV-2.

2. The number of cases with complications was small.

3. Our prospective study based on continued GP care allowed a long follow-up time.

### Conclusion

In the context of general medicine in Toledo (Spain) incidence rate of complications originated as a consequence of the acute infection of COVID-19 or the treatments performed, was higher in cases with acute infection in 2020, and in  $\geq 65$  years old, and are risk factors having presented moderate-severe severity of primary infection, having chronic diseases, and specifically of circulatory system, and being  $\geq 65$  years old.

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