

Role of meteorological factors in the spread of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) pandemic in Italy

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Abstract. – OBJECTIVE: Understanding the evolutionary dynamics of the Coronavirus disease 2019 (COVID-19) pandemic in the coming months is a matter of great importance and urgency for governments worldwide, making fundamental decisions based on what is known about the transmission mechanisms of the virus and its survival in the environment. The present study aimed to evaluate the impact of demographic variables, solar radiation and relative humidity on the spread of the COVID-19 pandemic of the various regions in Italy.

MATERIALS AND METHODS: The retrospective longitudinal study was conducted, and data used in this study was obtained from the Italian Health Ministry. Descriptive statistics included mean, frequency, and percentage, and results presented by graphs were calculated.

RESULTS: The infection trend was investigated by comparing it with the demographic situation and the irradiation indices of solar ultraviolet light that are detected with the changing seasons. The present study reported that the geographic areas with higher population density and lower solar radiation during the autumn and winter months were most affected by SARS-CoV-2.

CONCLUSIONS: The analysis carried out can provide a predictive model for the future phases of the COVID-19 pandemic in Italy, regardless of the adoption of lockdown measures and behavioral factors.

Key Words:

COVID-19, Epidemiology, Health and safety, UV-Index, Population density, Lockdown.

Introduction

Exploring the evolutionary dynamics of the COVID-19 pandemic in the coming months is a matter of great importance and urgency for gov-

ernments worldwide, which will have to make fundamental decisions based on what is known about the transmission mechanisms of the virus and its survival in the environment. The coronavirus named SARS-CoV-2, which first emerged in China in December 2019, quickly spread to the Northern Hemisphere, moving from east to west, in regions with a cool and temperate climate, typical of the winter season. All this may suggest a climatic susceptibility of the virus and raise concerns about the next cold seasons where, if confirmed, a new recovery of infections will probably occur¹⁻³. Most respiratory viruses, including the flu, exhibit a seasonal tendency to infection, with incidence peaks during the winter season and space-time transmission strongly associated with meteorological factors, such as atmospheric temperature and humidity⁴⁻⁸. Beginning in February 2020, the spread of the virus began to move outside of China to reach more and more countries worldwide. Immediately after China, Italy was the most affected country. The COVID-19 pandemic officially began in Italy on February 21st, 2020, with the first case registered in the Lombard municipality of Codogno. Since the first few weeks, there was an uneven spread of the infection, both in the northern regions (most affected at that stage) and during the spread of the contagion in the second half of 2020, which has affected the entire nation. Hence, a link between climatic factors and the spread of the virus has been thought to be very likely. The northern regions of the country, such as Lombardy, Veneto, and Emilia Romagna have been struck much harder than the centre and the south. A study reported that the winter weather that characterized the city of Wuhan in 2020 was very similar to

that observed between February and March 2020 in Milan, Bergamo, and Brescia, the Italian provinces most heavily affected by the COVID-19 pandemic⁹.

Several studies have also tried to identify specific temperature and humidity ranges conducive to the spread of the virus. It was observed that, between January and March 2020, there was a greater growth in cases in the cold regions of the Northern Hemisphere and less spread in warmer or drier regions¹⁰. On the other hand, recent work carried out in collaboration between several research organizations and not yet subject to peer review has evaluated how temperature, humidity, exposure to ultraviolet rays, and other climatic factors have influenced the rate of contagiousness of the virus RT in almost 4000 locations around the world. Although high temperature and increased exposure to ultraviolet rays were found to have a modest effect on the spread of SARS-CoV-2, the study concludes that these are not enough to control the evolution of the pandemic¹¹.

The present study aimed to evaluate the impact of demographic variables that influenced the development of the pandemic, regardless of lockdown measures, and behavioural factors. The second goal was to explore the impact of solar radiation on the spread of COVID-19 pandemic in the various regions in Italy, which can be reduced to the ultraviolet index (UV-Index) based on its variation in the northern and southern parts of the country.

Materials and Methods

We employed retrospective longitudinal study and data were obtained from the Italian Health Ministry. During the evolution of the SARS-CoV-2 epidemic, a comparison was made between the data of total infections and new daily cases in a few Italian regions, also evaluating the different trend over time. For the metropolitan cities / provinces examined, the cases per 100,000 inhabitants as of 31st December 2020 were considered, while for the national data, reference was made to the total number of cases, of new monthly and daily ones, of positive subjects for each period screened. The comparison between each region was based on monthly and daily infected case count. In particular, the situations that emerged in the northern regions, that turned out to be the most affected, were compared with what emerged in Campania, a large southern

region with a high population density, especially in the metropolitan city of Naples. For the same places, the population densities were verified, as well as the trends of the solar ultraviolet radiation indices during the alternation of the seasons, in order to evaluate the existence of a relationship between the same variables and the spread of the COVID-19 disease. The time intervals of the year 2020 taken into consideration were the ones coinciding with the first epidemic peak and the consequent adoption of the lockdown measure, the summer months characterized by the greatest solar radiation and the October-December quarter, largely corresponding to the autumn season, and marked by the second increase in the contagion curve. The descriptive statistics included calculation of mean, frequency and percentage, and the results were presented in graphs.

Patient and Public Involvement

The study did not include patient involvement. As this was a longitudinal retrospective study, no patients were involved in the design and data collection phase.

Results

During the first two months of monitoring carried out on a daily basis by the Civil Protection and disclosed by the Ministry of Health, the COVID-19 pandemic was characterized by a main outbreak that spread to Lombardy, with further outbreaks in Veneto and in Emilia Romagna. At that stage, the secondary involvement of other regions was mostly attributed to minor outbreaks resulting from import cases. Over the weeks, the inequalities in the number of infections between the north and the south of the country were progressively increasing. On 16th March 2020 Lombardy and Campania respectively presented a total number of 14,469 vs. 400 cases (Figure 1). On that same day, the total number of cases in Italy was 27,980 with + 3233 new cases per day, 23,073 subjects positive to the virus. After another month, on 16th April 2020 Lombardy counted 63,094 total cases, against 3887 in Campania. Referring to other large regions, 16th April saw 21,486 total cases in Emilia-Romagna, 19,108 in Piedmont, 14,990 in Veneto, with a total national number of 168,941 with + 3786 new cases per day, and 106,607 positives¹². The curve of the total cases of Lombardy, starting from the first few days of March, assumed an exponential trend,

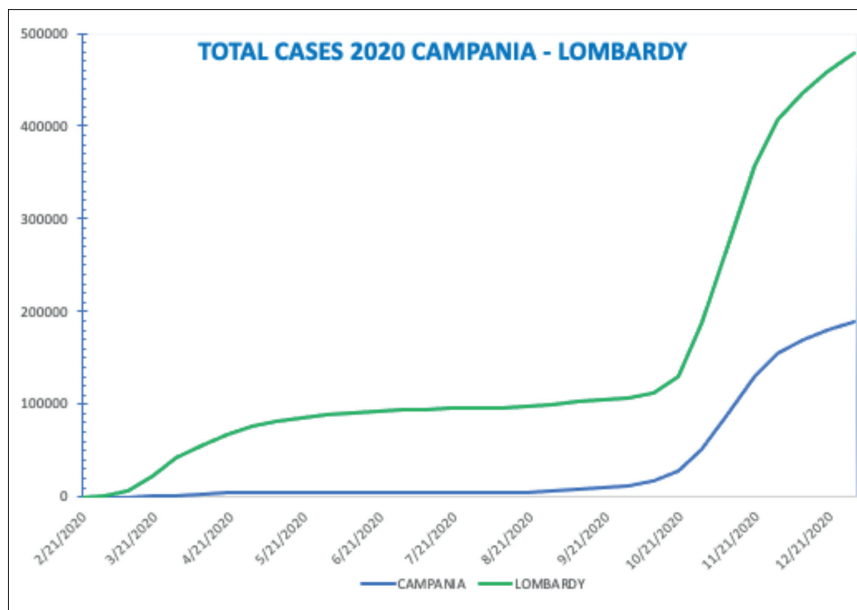


Figure 1. Epidemic curves comparing Campania and Lombardy during the year 2020 of the COVID-19 pandemic.

while that of Campania diversified due to a very slow growth, which persisted for the entire first epidemic phase.

The end of the so-called “first wave”, in late spring, was marked by a prevalence of total cases in northern Italy, with decreasing order in Lombardy, Piedmont, Emilia-Romagna and Veneto, while central Italy witnessed a moderate spread of the infection. The least affected regions were the southern ones, the major islands and the northern regions/autonomous provinces with low population density.

Two thousand and twenty was a leap year, so the summer solstice occurred on June 20th. On that date the number of new daily cases in Lombardy was + 165 out of 92,840 total cases, + 27 out of 31,215 total cases in Piedmont, + 28 out of 28,198 total cases in Emilia-Romagna, + 3 out of 19,238 total cases in Veneto. In all of Italy there were 238,275 total cases with + 262 new cases daily and 21,212 positive subjects. In many regions the new cases did not exceed some units. In others, including Campania, none emerged. The new national cases registered in June 2020 were 7,559, 240,578 total cases, with 15,563 positive subjects as of June 30th. A spread of the endemic COVID-19 infection was therefore observed, a situation that lasted for the entire summer season, albeit with a minimal increase in the numbers of infected people that emerged in the last decade of August and which also marked the first weeks of September. At this stage, the incidence of the

demographic factor can be considered small, as even the very populated regions with a high population density have been affected by a very low number of daily cases.

SARS-CoV-2 is characterized by an inter-human type of transmission, direct or indirect, therefore contagion is much more likely the higher the number of individuals in confined environments and communities. The near zeroing of the national epidemic curve during the summer revealed that the virus is characterized by a seasonal trend, as it is already known for the other coronaviruses that infect humans^{13,14}. The second variable that was taken into consideration, regardless of containment strategies and collective behavior, was the level of ultraviolet solar radiation in the Italian regions, called “UV-Index.” The universal index of solar UV radiation (Ultraviolet Index or UV-Index) is a dimensionless number, generally between 1 and 12, a unit of measurement of the intensity of UV radiation that reaches the Earth’s surface. It varies depending on the latitude, increasing with the approach of the Equator. Other factors that influence UV radiation levels are the height of the sun, the degree of sky coverage, altitude, ozone level, reflection from the Earth’s surface. The UV-Index during the calendar year in Italy presents a geographic variability linked to the above factors.

Therefore, it assumes maximum values during the spring-summer and in the southern regions (Table I). Looking at 16th July 2020, the number

Table I. Annual variation of the average monthly UV index in the different regions of Italy.

UV index in Italy												
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Aosta	1	2	1	1	2	3	4	3	2	2	2	1
Trento	2	2	3	3	4	5	5	4	3	3	2	1
Sondrio	2	1	2	2	3	4	4	3	2	2	2	1
Bergamo	2	2	3	4	5	6	5	5	4	3	2	1
Torino	2	2	4	3	5	6	6	5	4	3	2	1
Milano	2	2	4	4	5	6	6	6	5	3	2	1
Brescia	2	3	4	4	5	6	6	6	5	3	2	1
Piacenza	2	3	4	4	5	6	6	6	5	3	2	1
Padova	2	3	4	4	5	6	6	6	5	4	2	1
Firenze	2	2	3	4	5	6	6	5	5	4	2	1
Bologna	2	3	4	4	5	6	6	6	5	4	2	1
Roma	3	3	4	5	5	6	7	6	6	5	4	2
Cagliari	3	3	4	4	5	6	7	6	6	5	4	3
Napoli	3	3	4	5	5	6	7	6	5	5	4	2
Palermo	3	3	4	5	5	6	7	7	6	5	4	3
Lecce	4	4	5	5	6	6	7	7	6	5	4	3
Ragusa	4	3	4	5	6	7	7	7	6	5	4	3

of new daily cases in Lombardy was + 80 out of 95,316 total cases, + 7 out of 31,522 total cases in Piedmont, + 46 out of 29,035 total cases in Emilia-Romagna, + 29 out of 19,470 total cases in Veneto, + 4 out of 4,791 total cases in Campania. As of July 31st, 2020, 6959 new monthly infections were recorded in Italy, 247,537 total cases, and 12,422 positive subjects. During the month of July, the average UV Index in Italy was between 6-7.

With the arrival of the autumn season, there was a reversal of the epidemic trend. On 22nd September 2020, the date of the autumn equinox, the new national daily case number was + 1391 out of 300,897 total cases, Lombardy reported + 182 out of 105,030 total cases, Emilia-Romagna + 56 out of 34,511 total cases, Piedmont + 84 out of 34,480 total cases, Veneto + 119 out of 26,004 total cases, Campania + 156 out of 10,659 total cases. At the end of the month, 45,647 new national cases were ascertained in thirty days, as well as 314,861 total cases and 51,263 positive subjects. The average Italian UV Index was 5 for September. The spread of the COVID-19 infection subsequently underwent a rapid worsening. On 1st October 2020, the new cases were + 2548 out of 317,409 total cases, and 52,647 positives, the most affected region was Veneto which counted + 445 out of 27,896 total cases, Campania following

with + 390 out of 13,132 total cases, Lombardy + 324 out of 107,051 total cases, then Piedmont + 110 out of 35,512 total cases, and eventually Emilia-Romagna + 103 out of 35,414 total cases. On 31st October 2020, the new national case number was + 31,758 out of 679,430 total cases, with a monthly increase of 364,569 cases, while the positive subjects got to 351,386. On that date Lombardy enumerated + 8,919 new infections out of 195,744 total cases, Campania + 3,669 out of 55,740 total cases, Piedmont + 2,887 out of 70,636 total cases, Veneto + 2,697 out of 56,953 total cases, Emilia-Romagna + 2,046 out of 55,841 total cases (Table II). The average Italian UV Index for October was 4 (Figure 2).

The month of November 2020 was highlighted for the peak of new national cases, detected on the 13th when + 40,902 were counted, and the total cases were 1,107,303, with 663,926 positives. On 30th November 2020, the new monthly case number was 922,124 out of 1,601,554 total cases, with 788,471 positives. The tests taken in that month were 6,160,638, with an average 205,354 per day. The average UV-Index in Italy is 3 for November. Coming to the end of 2020, on New Year's Eve, the new monthly cases were 505,612 out of 2,107,166 total cases, with 569,896 positives, and 4,653,508 people taking a test, an

Table II. Number of new daily cases (NC) and total cases (TC) registered at the end of each month during the year 2020 in the Italian regions examined.

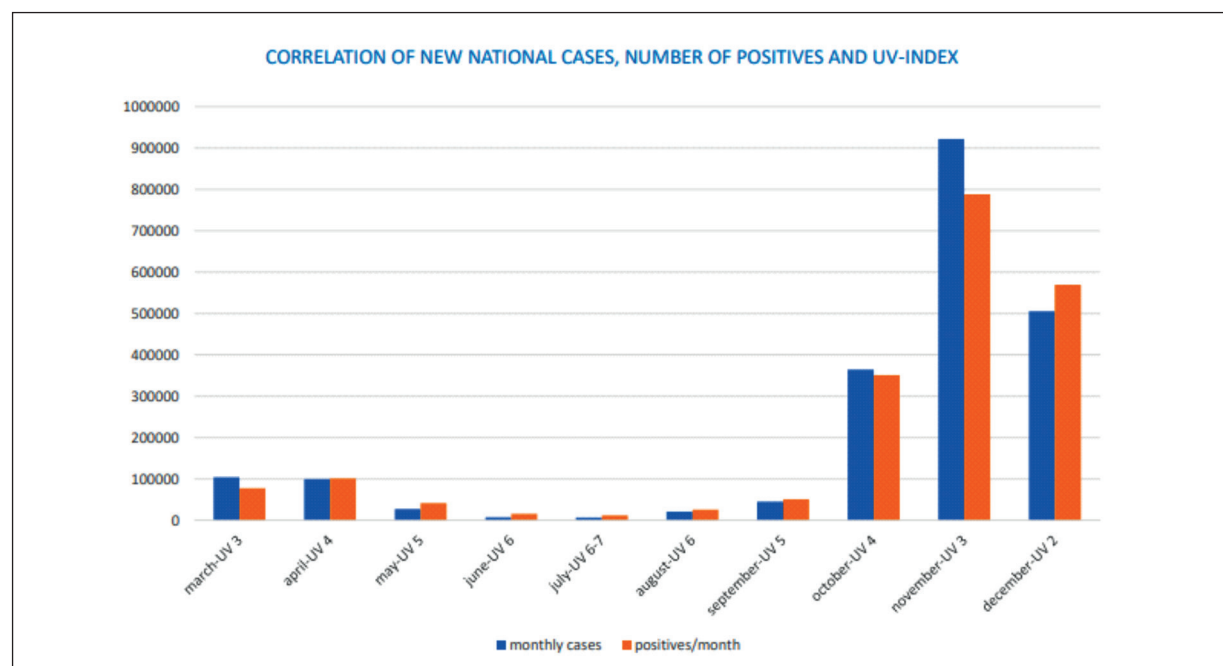
	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Lombardia (NC)	1047	598	210	62	77	135	201	8919	1929	3859
Lombardia (TC)	43.208	75.732	88.968	93.901	96.219	100.075	106.727	195.744	407.791	478.903
Piemonte (NC)	589	428	54	11	21	37	170	2.887	1.185	1.367
Piemonte (TC)	9301	26.289	30.637	31.349	31.667	32.881	35.402	70.636	167.516	197.828
Emilia R. (NC)	543	259	31	20	36	117	101	2.046	2.041	2.116
Emilia R. (TC)	14.074	25.436	27.790	28.492	29.670	31.922	35.311	55.841	123.073	171.512
Veneto (NC)	431	135	6	8	117	65	155	2697	2.003	4.800
Veneto (TC)	9155	17.960	19.152	19.286	20.120	22.929	27.451	56.953	145.592	253.875
Campania (NC)	140	13	5	24	9	184	287	3.669	1.626	1.554
Campania (TC)	2092	4423	4.802	4690	4.999	7066	12.742	55.740	155.319	189.673

average 150,113 per day. The average UV-Index in our country is 2 for December (Table I).

Further data observed was the incidence of cases per 100,000 inhabitants for each metropolitan city/province in question, reported as 31st December 2020. Referring to the two metropolitan cities with the highest population density, Naples had 3745 cases per 100,000 inhabitants from the beginning of the pandemic, whereas Milan had 5305. The metropolitan city of Turin, with a much lower population density than the previous ones, recorded 4,626 cases per 100,000 inhabitants. Examining the same data

relating to some northern provinces severely affected by SARS-CoV-2, despite the low population density values, that of Padua counted 4935 cases per 100,000 inhabitants, Brescia 3308 cases per 100,000 inhabitants, that of Piacenza 5174 cases per 100,000 inhabitants. However, the latter was the province with the lowest population density among those mentioned, meaning 110.27 inhabitants / km², and placed only 78th in Italy in the ranking ordered by population density (Figure 3).

On the other hand, it should be emphasized that coronavirus is notoriously more active within cer-


Figure 2. Correlation between the average monthly UV index for the national territory, new cases of COVID-19, and the number of positive subjects at the end of each month on 31.12.2020.

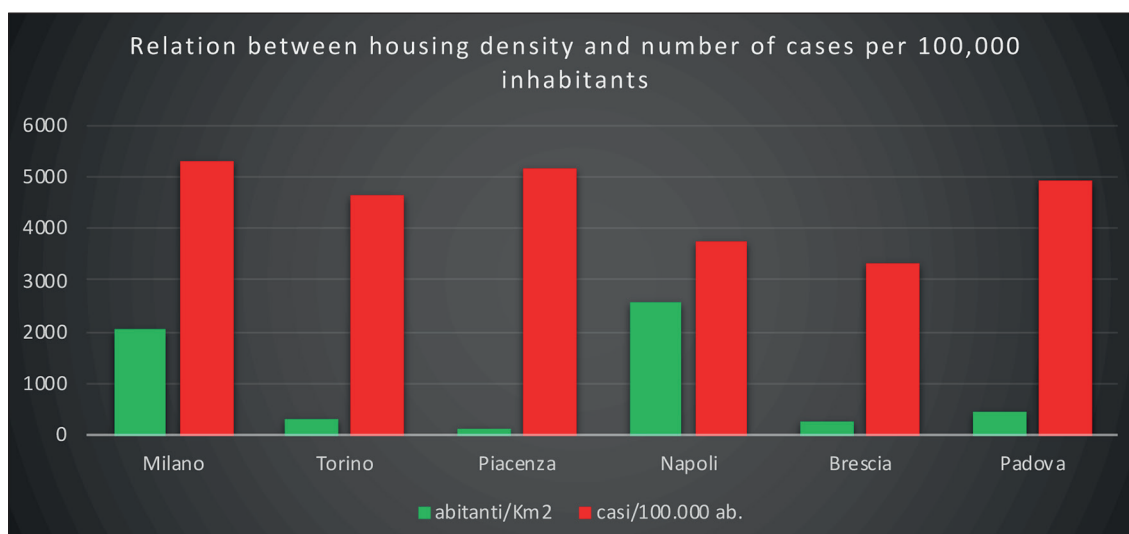


Figure 3. Relationship between population density in different Italian provinces and metropolitan cities and the number of cases of COVID-19 per 100,000 inhabitants as of 31.12.2020.

tain ranges of temperature and humidity. Previous studies had already shown that the relationship between viral inactivation and relative humidity was not monotonous, since it was faster at intermediate values (50% RH), slower at low values (20% RH) and high values (80% RH), while growing progressively with increasing room temperature according to a monotonous dependence¹⁵. Recent studies concerning the permanence of the virus on surfaces carried by microscopic drops of saliva have shown that their survival has a trend called “reverse U” in relation to relative humidity, with increased inactivation of virions at intermediate values^{16,17} (Table III). Further study has shown that, even at high temperatures (30°C), and in conditions of high relative humidity (90%), a significant increase in the total number of droplets of contaminated saliva is observed, which can spread over a long distance, increasing the persistence of the virus in the air.

Discussion

The SARS-CoV-2 pandemic in Italy in the year 2020 was an example of a “spreading epidemic,” generated by an agent initially transmitted by one or more primary cases, spreading overtime to receptive individuals that constitute the secondary cases. The evolution of the infection, therefore, depended on numerous variables. Among those not attributable to human behavior and lockdown strategies, one of the most important is the population density, which undoubtedly favored the spread of the infection, considering how the pathogen was transmitted. During the first phase, which officially began on 21st February 2020 with the identification of the outbreak in Codogno, in the province of Lodi, ten municipalities belonging to the territories of Lombardy and Veneto were isolated with the establishment of a

Table III. Monthly averages of relative humidity values [%] recorded during the year 2020 in different cities in southern and northern Italy.

	Jen	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec
Napoli	70	68.7	68.4	64.3	58.2	62.9	58	64.6	61.2	74.6	75.8	77.5
Salerno	59.9	60.8	57.2	54.4	51.2	61.2	57.3	59.4	56	66.3	65.9	75.1
Milano	84.6	67.4	68.2	54	62.5	68.4	65.1	67.4	70.4	83.7	90	95.8
Torino	71.4	57	65.1	58.1	67.1	70.6	66.1	68.1	68.5	80.8	80.9	86.5
Brescia	85.4	73.1	77.8	67.7	67.7	69.4	61.8	65	65.5	79.2	82.9	87.3
Bergamo	76.5	61.3	68.4	55.9	65.7	70	65.8	69.5	72.3	82.5	84.4	93.9
Varese	82.8	65.4	68.1	59.5	66.1	70.8	65.7	64.5	71.7	81.8	85.1	92.7
Piacenza	89.8	64.8	67.8	51.2	59.8	64.1	58.8	63.6	66.9	83.9	94.1	99.4

“red zone”, corresponding to a total population of 50,000 quarantine inhabitants. With the spread of COVID-19 cases in the following days, on the evening of March 9th 2020, the quarantine was extended nationwide with the closure of all public activities, except grocery stores, supermarkets, pharmacies, and other businesses considered “distributors of necessities”¹⁸.

Therefore, thanks to the lockdown that lasted 69 days, the highest concentration of cases took place precisely in the areas where the first outbreaks were identified in February. The absent or extremely reduced mobility determined the containment of the contagion in central and southern Italy. At the same time, the great northern regions have witnessed an exponential growth in cases of COVID-19, contributing to a predominant extent to fuel the so-called “first wave”. At the end of this period in the history of the pandemic, on May 18th 2020, there were 225,886 total cases, of which 160,855 were cumulatively calculated in the most affected northern regions. Lombardy had registered 85,019 cases, Piedmont 29,619, Emilia-Romagna 27,267, and Veneto 18,950 cases. The least affected region was Basilicata, with 392 cases. At this stage, the extent of the infection was obviously influenced by the restrictions imposed by the lockdown, although some noticeable differences between regions emerged over the weeks. Analyzing the growth curves of the contagion, at the end of March, there were 43,208 total cases in Lombardy, and only 2092 in Campania. On 30th April 2020, the total cases in Lombardy were 75,732 with 13,772 deaths, 4,423 in Campania, with 359 deaths. The population density of Lombardy is 423.4 inhabitants/km², that of Campania 423.2 inhabitants/km² - basically identical. In March, the average monthly UV-Index in Lombardy is 3; in Campania, it assumes the value of 4. During April, the same indices go to a monthly average value of 4 in Lombardy and 5 in Campania. Moreover, after the peak of national cases on 21st March 2020, the Italian epidemic curve showed a rapid decline in April, when the monthly average UV-Index assumes a value greater than or equal to 4 over most of our country.

In the spring-summer period of 2020, from 19th May to 21st September, the new national cases diagnosed were 73,620, with a daily average for this period of 584.2 new cases. There was, therefore, a trend of the new disease of an endemic type, that is, with a uniform manifestation over time and with few cases. This evidence

supports the seasonality of SARS-CoV-2, as already largely demonstrated by Nickbaskh et al¹⁹ for coronaviruses endemic to humans, CoV-229E, CoV-OC43 and CoV-NL63, most active from early autumn to early spring, with an average peak between January and March. In fact, compared to the monthly average values on a national scale, for May, we find a UV-Index equal to 5. In June the value is 6, in July it is between 6 and 7, in August it is 6, in September it drops to 5. The greater ultraviolet irradiation destabilizes the droplets that carry SARS-CoV-2 in aerosols and on contaminated surfaces, through the increase in temperature, thanks to the faster evaporation²⁰.

Regarding the same period of the year, Nicastro et al^{21,22} have shown that the relatively high efficiency of the solar pump led to a drastic reduction in contagion during the first six months of the SARS-CoV-2 pandemic in Italy. From 22nd September to 31st December 2020, 1,807,660 new national cases were registered. With the arrival of autumn already on 1st October, the ascent of the epidemic curve was clear with + 2548 new cases per day. Over the same month, during which the national average UV-Index was equal to 4, our study found a growth in the average daily infection 20.1 times higher than the summer average. For November, with a national average UV-Index of 3, the increase in new daily cases was on average 52.6 times greater than the average value for the summer. During this period, on November 6th, the “Red Zones” came into force, which introduced strategic measures to contain the transmission of the infection that was definitely looser than during the March lockdown²³.

In December, we detected an average increase in infection 27.9 times higher than the summer average, although 1,507,130 fewer rhino-pharyngeal tests were performed this month than in November. The national average UV index for December was 2. Although there is a relationship between the population density of the most affected metropolitan cities/provinces and the number of infections, the metropolitan city of Naples, the most densely populated in Italy, recorded several cases per 100,000 inhabitants less than 29.5% on 31st December 2020, compared to that of Milan, as well as 19.1% lower than that of Turin, 24.1% lower than the province of Padua. The most striking data among those surveyed was the comparison between the metropolitan city of Naples and the province of Piacenza, as the number of cases per 100,000 inhabitants - in the first it was 27.6% lower than in the second,

even though the metropolitan city of Naples has a population density 23.4 times higher than that of the province of Piacenza. These observations can be explained under the noncausal profile, considering the variables regardless of the strategies to contain the transmission of SARS-CoV-2 and the behavioral factor in the detachment of the solar ultraviolet irradiation indices at various latitudes. We have verified that even the per capita health costs of the health systems of Lombardy and Campania (2019 data) do not diverge consistently so much as to suggest a difference in the expression of the pandemic. In Lombardy, per capita health expenditure in 2019 (latest data available) was 1.944,00 Euros while in Campania it was 1.848,00 Euros²⁴.

This study about the seasonality of the virus has several limitations. The data are strongly influenced by the short time window the data refer to and the fact that the first phase of the pandemic, which started in China, was limited to the northern regions of the hemisphere. The quality of the data and the different classification and reporting criteria for COVID-19 cases adopted by the various countries and in the specific case by Italy may have influenced the results. There could be several confounding factors related to the territory (and, therefore, to the temperature and climate) that could better explain the transmission of the virus and which are, however, very complex to measure and control in longitudinal studies. Among these, we have the type of health system, the containment measures adopted, the chance to access care, behavioral habits, movement flows within and outside the national territory and the blocking of air flights. Although evidence in the present study suggests a potential reduction in cases in the hottest months and with relative humidity with average values between 50% and 70% (Table III), we must be aware that these results are not sufficient to establish a causal link.

Conclusions

The present study demonstrated that COVID-19 was more active within certain ranges of temperature and relative humidity. For example, during the spring-summer period of 2020 (May 19th to September 21st), the new national screened cases were high, with a daily average for this period of 584.2 (new cases). The SARS-CoV-2 pandemic during the year 2020 was characterized by

an uneven development throughout the country, mainly affecting the more populated northern regions. Among the variables independent of the strategies to contain the transmission of infection and behavioral factors, there are population density and the differences in the UV-Index between the northern and southern areas of the country that were examined. Over time, the spread of the epidemic was seasonal, with two waves, the first corresponding to the period February-April, the second in the quarter October-December. In the months where the national average UV-Index assumes values between 5 and 6/7, we have seen a drastic reduction in the infection, with an endemic trend. This study provides clear evaluation elements for the possible future scenarios of the COVID-19 pandemic in Italy.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Authors' Contribution

Giulio Nittari and Paolo Marino designed the research, collected and analyzed data, wrote the manuscript, and conducted the analyses. Filippo Gibelli and Paolo Sossai analyzed data and conducted the analyses, Ascanio Sirignano and Giovanna Ricci contributed to manuscript writing.

Authors' Approval

All authors have read and approved the manuscript. All authors agree the work is ready for submission to a journal. All authors accept responsibility for the manuscript's contents.

Competing Financial Interests

All authors declare they have no actual or potential competing financial interests.

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Ethics Statement

No data from human patient studies nor data from animal studies were used in this study. For these reasons, the approval of an Ethics Evaluation Committee was not required.

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