Ann Ist Super Sanità 2020 | Vol. 56, No. 3: 378-389
DOI: 10.4415/ANN_20_03_17

ORIGINAL ARTICLES AND REVIEWS

Coronavirus and birth in Italy: results of a national population-based cohort study

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[Early release]

Abstract

Introduction. The study was implemented to provide guidance to decision-makers and clinicians by describing hospital care offered to women who gave birth with confirmed SARS-CoV-2 infection.

Materials and methods. National population-based prospective cohort study involving all women with confirmed SARS-CoV-2 infection who gave birth between February 25 and April 22, 2020 in any Italian hospital.

Results. The incidence rate of confirmed SARS-CoV-2 infection in women who gave birth was 2.1 per 1000 maternities at a national level and 6.9/1000 in the Lombardy Region. Overall one third of the women developed a pneumonia and 49.7% assumed at least one drug against SARS-CoV-2 infection. Caesarean rate was 32.9%, no mothers nor newborns died. Six percent of the infants tested positive for SARS-CoV-2 at birth.

Conclusions. Clinical features and outcomes of COVID-19 in women who gave birth are similar to those described for the general population, most women developing mild to moderate illness.

Key words

- pregnancy
- SARS-CoV-2
- pregnancy outcome
- COVID-19
- cohort studies

INTRODUCTION

Following the Chinese epidemic, Italy is currently one of the European countries reporting the highest number of clinical cases. From the H1N1 influenza, SARS, and MERS outbreaks, we learned that pregnant women are at higher risk of developing respiratory complications as well as worse maternal and neonatal outcomes [1]. Although there is no conclusive information with regards to an increased susceptibility of pregnant women to the SARS-CoV-2 illness, the currently available data suggest that it is analogous to that of the general population [1, 2].

To date, there have been several published case series of deliveries among women affected by COVID-19 [3-6]. Available data come primarily from China, and the UK [4].

There is a critical need to develop clinical guidance for obstetric providers and neonatologists, and this should be based on rigorously collected data. The Italian Obstetric Surveillance System (ItOSS) [7] is convenient for establishing a national prospective population-based cohort study on COVID-19 in pregnancy, birth and postpartum in Italy.

This paper describes hospital care of pregnant women with confirmed SARS-CoV-2 infection admitted to Italian hospitals for childbirth. Possible transmission of the SARS-CoV-2 virus from mothers to newborns is also addressed.

MATERIALS AND METHODS

The ItOSS national population-based cohort study collects information on all women who gave birth in any Italian hospital with a SARS-CoV-2 infection confirmed during pregnancy. The methods set forth in the study protocol for the diagnosis includes: reverse transcriptase-polymerase chain reaction (RT-PCR) testing for the SARS-CoV-2 virus through a nasopharyngeal swab and/or chest X-ray or computer tomography (CT) features of COVID-19 pneumonia and/or antibody response to SARS-CoV-2 from maternal peripheral blood.

The study's core outcomes include incidence rate of SARS-CoV-2 infection estimate, COVID-19 pneumo-

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nia, preterm birth, mode of delivery, invasive respiratory support, intensive care unit (ICU) admission, and maternal and neonatal severe morbidity and mortality.

The ItOSS network of trained reference clinicians working in Italian public and private maternity units covering 91% of total births [7] has been extended to reach nationwide coverage for the present study. Through this system, cases are rapidly notified and data on maternal and neonatal management collected. Informed consent to the participation is acquired from any woman at study enrolment.

A multidisciplinary expert group of clinicians has revised the data entry form and its online version has been pre-tested. The form is designed to collect information regarding the woman's socio-demographic characteristics, medical and obstetrical history, pneumonia diagnosis and treatment, mode of delivery, and maternal and neonatal outcomes.

In case of maternal death from SARS-CoV-2 infection, the ItOSS maternal mortality surveillance system will allow verification and provide further information.

Since this is an observational study, the cohort size depends on the incidence of the disease; therefore, a formal power calculation has not been performed.

The data are collected and processed by personnel responsible for ensuring confidentiality and security. This analysis reports hospitalized cases from February 25 to April 22, 2020, for whom complete data have been received by April 11, 2020.

The incidence rates of women with confirmed SARS-CoV-2 infection who gave birth with a 95% confidence interval (CI) were estimated at a national level, by geographical area, and for the Lombardy Region. Denominator estimates are based on the national Birth Registry providing the most recent available data on deliveries (year 2018) assuming an annual reduction of 3% in births. The data analysis focuses on descriptive statistics stratified by the occurrence of pneumonia. Significant differences between the two groups were assessed through the Pearson's Chi-squared test or the Fisher's exact test for categorical variables and the Mann-Whitney U test for continuous variables. Data analyses were performed at the Italian National Health Institute using the Statistical Package Stata/MP 14.2.

The Ethics Committee of the Italian National Institute of Health approved the project (Prot. 0010482 CE 01.00, Rome 24/03/2020).

This study has not received any funding.

RESULTS

From February 25 to April 22, 2020, 146 women who gave birth in any Italian Obstetric Unit with confirmed SARS-CoV-2 infection during pregnancy were notified to ItOSS. The diagnosis of SARS-CoV-2 infection was confirmed for 142 patients by RT-PCR testing through nasopharyngeal swab and in 4 cases through chest X-ray.

Out of the total cases, 126 (86.3%) were notified by 5 Regions and 2 Autonomous Provinces located in the North of the country. Among the cases reported in the North, 84 (57.5%) were identified in the Lombardy Region.

Among an estimated 70 343 maternities that took place over the same study period in Italy, the incidence rate of confirmed SARS-CoV-2 infection in women who gave birth was 2.1 per 1000 (CI 95% 1.8-2.4) maternities at a national level, 3.9/1000 (CI 95% 3.2-4.6) in Northern, 1.0/1000 (CI 95% 0.6-1.6) in Central, and 0.2/1000 (CI 95% 0.1-0.5) in Southern Italy. The rate in Lombardy was 6.9/1000 (CI 95% 5.5-8.5) maternities.

During the 14 days prior to diagnosis, 41.1% of the women reported having had contact with a probable case (32.9%) or entering health care facilities with confirmed SARS-CoV-2 cases (13.7%).

Table 1 describes the socio-demographic characteristics of the cohort stratified by COVID-19 pneumonia occurrence. Women's median age is 32 years (q1-q3 = 29-36). Women without Italian citizenship are 18.5% of the entire cohort, respectively 27.7% and 14.4% of the group with and without pneumonia (p-value = 0.049). Previous comorbidities were significantly higher (p-value = 0.023) amongst the pneumonia group (34.0%) compared to unaffected women (17.2%), obesity being the most frequent condition. None of the women smoked until the end of pregnancy, and foetal growth restriction was diagnosed in 2.0% of the cases.

As reported in *Table 2*, multiparas are 69.2% of the cohort and 67.1% of the mothers gave birth vaginally, 25.5% under epidural analgesia. Caesarean section (CS) rate was 32.9% overall, 48.9% among the pneumonia group and 25.3% among the unaffected group (p-value = 0.004). COVID-19 indication to CS concerned 7.5% of the entire cohort. General anaesthesia was performed in 5 cases.

Overall, 19.2% of the cohort gave birth preterm, 12.3% due to spontaneous onset of preterm delivery (n = 18), and 6.9% due to iatrogenic labour induction (n = 3) and urgent/emergency CS (n = 7). Preterm birth <37 weeks concerned 31.9% of the women affected by pneumonia compared to 13.1% of the unaffected (p-value = 0.007). Among preterm births, the majority were late preterm (*Table 2*).

On hospital admission, 28.1% of the women were asymptomatic. The onset of clinical symptoms occurred in 9.5% of the cases on the day of delivery, and in 90.5% before it, the median value being 8 days (range 1-52 days). Overall, fever (47.9%), cough (46.6%), and general weakness (35.6%) were the most common symptoms at presentation. *Table 3* highlights the higher percentage of symptoms amongst women affected by pneumonia, 31.9% reporting dyspnoea *vs* 5.1% of the unaffected (p-value <0.001).

One third of the women developed COVID-19 pneumonia; oxygen saturation <95% and abnormal results of blood gas test concerned respectively 27.7% and 35.6% of the women with pneumonia compared to 4% of the unaffected.

Over 80% of the women who developed pneumonia received at least one pharmacological treatment (*Table 3*), hydroxychloroquine was the most frequently administered drug alone (4.3%) and in combination with other medical therapies (69.6%). The most frequently adopted therapeutic scheme included hydroxychloroquine in association with antivirals and antibiotics concerning 13.8% of the cohort and 37.0% of the group

Table 1
Women's socio-demographic characteristics by occurrence of COVID-19 pneumonia

Characteristics	Total (N = 146)		No COVID-19 pneumonia (N = 99)		COVID-19 pneumonia (N = 47)		p-value
	n	%	n	%	n	%	
Maternal age[a]							
<30	40	(28.0)	23	(24.0)	17	(36.2)	0.174
30-34	53	(37.1)	35	(36.5)	18	(38.3)	
≥35	50	(35.0)	38	(39.6)	12	(25.5)	
Citizenship							
Not Italian	27	(18.5)	14	(14.1)	13	(27.7)	0.049
Italian	119	(81.5)	85	(85.9)	34	(72.3)	
Country of birth							
Italy and western Europe	112	(76.7)	83	(83.8)	29	(61.7)	0.010
East Europe	10	(6.8)	7	(7.1)	3	(6.4)	
Africa	9	(6.2)	4	(4.0)	5	(10.6)	
South/Central America	11	(7.5)	4	(4.0)	7	(14.9)	
Asia	4	(2.7)	1	(1.0)	3	(6.4)	
Educational level							
≤8 years	18	(12.3)	10	(10.1)	8	(17.0)	0.469
>8 years	86	(58.9)	59	(59.6)	27	(57.4)	
Missing	42	(28.8)	30	(30.3)	12	(25.5)	
Previous comorbidities							
No	113	(77.4)	82	(82.8)	31	(66.0)	0.023
Yes	33	(22.6)	17	(17.2)	16	(34.0)	
Obesity	*22*	*(15.1)*	*11*	*(11.1)*	*11*	*(23.4)*	0.067
Autoimmune disease	*4*	*(2.7)*	*2*	*(2.0)*	*2*	*(4.3)*	0.387
Diabetes	*6*	*(4.1)*	*4*	*(4.0)*	*2*	*(4.3)*	0.649
Hypertension	*5*	*(3.4)*	*1*	*(1.0)*	*4*	*(8.5)*	0.042
Other	*3*	*(2.1)*	*2*	*(2.0)*	*1*	*(2.1)*	0.691
Smoking in pregnancy							
Never	118	(80.8)	78	(78.8)	40	(85.1)	0.719
Quit before or during pregnancy	14	(9.6)	11	(11.1)	3	(2.1)	
Missing	14	(9.6)	10	(10.1)	4	(8.5)	

[a] 3 missing values in "No COVID-19 pneumonia" group

with pneumonia. Among women with pneumonia, the subgroup at higher risk of worse outcomes – defined by the presence of at least one previous comorbidity or C-reactive protein >10mg/100ml or dyspnoea – received more often the combination of the three drugs. The women belonging to this subgroup, compared to those at lower risk, registered the longest hospital stay (median value 13 days), received more often invasive ventilatory support due to severe morbidity and were admitted more frequently to ICU.

Antenatal corticosteroids for foetal lung maturation were administered respectively to 10.9% and 4.0% of the groups with and without pneumonia.

Severe adverse maternal outcomes have been rare, affecting almost exclusively the group with pneumonia, as described in *Table 4*. Seven women (4.8%) were in critical conditions due to severe morbidity (2 acute respiratory distress syndromes, 1 respiratory failure, 1 preeclampsia, 2 postpartum haemorrhages, and one thrombosis). Invasive ventilatory support concerned 11 women (7.5%), orotracheal intubation 2 mothers (1.4%). ICU admission regarded 7 patients (4.8%), on average for 7 days. None required extracorporeal membrane oxygenation and none died. Two percent of the women were transferred from another hospital, and 18 were still hospitalized at the end of the study period. The median hospital stay was respectively 10 and 4 days for the women with and without pneumonia (p-value <0.001).

Overall, 2 stillbirths were detected respectively at 30 and 35 weeks of pregnancy (*Table 5*). There were 143 singletons and 3 sets of twins, 85.0% of the newborns weighed ≥2500 gr, 3.4% <1500 gr. Median Apgar index

Table 2
Obstetric characteristics by occurrence of COVID-19 pneumonia

Characteristics	Total (N = 146)		No COVID-19 pneumonia (N = 99)		COVID-19 pneumonia (N = 47)		p-value
	n	%	n	%	n	%	
Parity							
Nulliparae	45	(30.8)	32	(32.3)	13	(27.7)	0.569
Multiparae	101	(69.2)	67	(67.7)	34	(72.3)	
Multiple pregnancy							
No	143	(97.9)	97	(98.0)	46	(97.9)	0.691
Yes	3	(2.1)	2	(2.0)	1	(2.1)	
Mode of delivery							
Vaginal	98	(67.1)	74	(74.7)	24	(51.1)	0.001
Elective CS	12	(8.2)	9	(9.1)	3	(6.4)	
Urgent/emergency CS due to maternal/foetal indication	25	(17.1)	14	(14.1)	11	(23.4)	
Urgent/emergency CS due to COVID-19	11	(7.5)	2	(2.0)	9	(19.1)	
PPROM[a]							
No	134	(95.0)	90	(94.7)	44	(95.7)	0.587
Yes	7	(5.0)	5	(5.3)	2	(4.3)	
Gestational age at birth							
≤32	6	(4.1)	2	(2.0)	4	(8.5)	0.017
33-36	22	(15.1)	11	(11.1)	11	(23.4)	
≥37	118	(80.8)	86	(86.9)	32	(68.1)	
Median (q1-q3)	38	(37-39)	38	(37-40)	38	(36-39)	

CS: Caesarean Section; PPROM: Preterm Premature Rupture of Membranes; q1: 25% percentile; q3: 75% percentile.
[a] 5 missing values (4 in "No COVID-19 pneumonia" group and 1 in "COVID-19 pneumonia" group).

was 9 at 1 minute and 10 at 5 minutes; at 5 minutes, 1 infant had Apgar index <4 (*Table 4*). Admission to neonatal intensive care unit (NICU) concerned 23 newborns (15.6%), 18 of whom were preterm, including 6 <32 weeks of gestation. Four infants developed severe morbidity (1 interstitial pneumonia and 3 respiratory distress syndrome). Two were breeches, one affected by spina bifida, and one was macrosoma. None of them tested SARS-CoV-2 positive at birth and, overall, no neonatal death was recorded.

Nine newborns (6.1%) tested positive for SARS-CoV-2, 5 were tested on the day of delivery, 1 the day after, and 3 after 6-9 days from birth. Out of the 5 newborns with positive swabs collected within 24 hours from birth, 4 were delivered vaginally and 1 by pre-labour CS. Three of the positive infants were admitted to NICU, and none of them developed a severe illness.

DISCUSSION

The incidence rates of SARS-CoV-2 positive women who gave birth in Italy (2.1/1000), in the North (3.9/1000), the Centre (1/1000) and the South of the country (0.2/1000) as well as in the Lombardy Region (6.9/1000) reflect the same variation in circulation of the virus among geographical areas as that detected in the general population [10]. This observation impacts on the present different seroprevalence and susceptibility of the population. In the current phase, following the lockdown, the early identification of new cases and their contact traceability and isolation will be decisive for the containment of the virus circulation.

Compared to the reference population of women giving birth in Northern Italy [8, 9], the higher proportion of multiparas (69% *vs* 50%) among the women with SARS-CoV-2 infection confirms the hypothesis of greater circulation of the virus in families with children who are often asymptomatic.

Clinical features of the detected pneumonia are similar to those described by previous studies [2, 6, 11, 12]. The majority of cases are mild/moderate, and similarly to the UKOSS study [4] previous comorbidities are significantly associated with pneumonia (p-value = 0.023).

In Italy, black and minority ethnicities are present in a lower proportion than in the UK where a significative association with COVID-19 has been detected [4]. Hospitalized women without Italian citizenship develop significantly more often pneumonia than the Italians (p-value = 0.049), probably due to delayed access to healthcare services.

Preterm birth, which is one of the feared outcomes of COVID-19, was overall 21.2% in the UK cohort [4], 17.4% in the WHO review [6], and 19.2% in Italy compared to the 7% figure among women who gave birth in northern Italy [8, 9].

Table 3
Diagnosis and medical therapy by occurrence of COVID-19 pneumonia

Characteristics	Total (N = 146)		No COVID-19 pneumonia (N = 99)		COVID-19 pneumonia (N = 47)		p-value
	n	%	n	%	n	%	
Symptoms							
Fever	70	(47.9)	39	(39.4)	31	(66.0)	0.003
Cough	68	(46.6)	38	(38.4)	30	(63.8)	0.004
Tiredness	52	(35.6)	25	(25.3)	27	(57.4)	<0.001
Muscle/joint pain	28	(19.2)	14	(14.1)	14	(29.8)	0.015
Sore throat	27	(18.5)	16	(16.2)	11	(23.4)	0.261
Rhinorrhea	23	(15.8)	17	(17.2)	6	(12.8)	0.528
Dyspnea	20	(13.7)	5	(5.1)	15	(31.9)	<0.001
Headache	16	(11.0)	7	(7.1)	9	(19.1)	0.024
Vomiting/Diarrhea	14	(9.6)	5	(5.1)	9	(19.1)	0.005
Chest pain	5	(3.4)	3	(3.0)	2	(4.3)	0.650
Conjunctivitis	3	(2.1)	3	(3.0)	0	(0.0)	0.553
No symptoms	41	(28.1)	37	(37.4)	4	(8.5)	<0.001
Imaging techniques							
No exams	62	(42.5)	62	(62.6)	0	(0.0)	<0.001
Chest X-ray	51	(34.9)	26	(26.3)	25	(53.2)	
Chest CT	6	(4.1)	2	(2.0)	4	(8.5)	
Lung ultrasound	6	(4.1)	5	(5.1)	1	(2.1)	
Association of different techniques	21	(14.4)	4	(4.0)	17	(36.2)	
Vital signs and laboratory reports							
Body temperature >37.5 °C	34	(23.3)	11	(11.1)	23	(48.9)	<0.001
Lymphopenia (<1500 mm3)	73	(50.0)	40	(40.4)	33	(70.2)	0.008
CRP values >10mg/100ml	34	(23.3)	17	(17.2)	17	(36.2)	0.077
Oxygen saturation <95%	17	(11.6)	4	(4.0)	13	(27.7)	<0.001
Blood gas test [a]							
Not performed	96	(67.6)	80	(82.5)	16	(35.6)	<0.001
Performed. normal results	26	(18.3)	13	(13.4)	13	(28.9)	
Performed. abnormal results	20	(14.1)	4	(4.1)	16	(35.6)	
Drugs administered[b]							
HCQ + Antivirals + Antibiotics	20	(13.8)	3	(3.0)	17	(37.0)	<0.001
HCQ + Antibiotics	14	(9.7)	6	(6.1)	8	(17.4)	
Empirical antibiotics	14	(9.7)	12	(12.1)	2	(4.3)	
HCQ + Antivirals	8	(5.5)	1	(1.0)	7	(15.2)	
HCQ alone	8	(5.5)	6	(6.1)	2	(4.3)	
Antivirals + Antibiotics	5	(3.4)	1	(1.0)	4	(8.7)	
Targeted antibiotics	2	(1.4)	2	(2.0)	0	(0.0)	
Antivirals alone	1	(0.7)	1	(1.0)	0	(0.0)	
No pharmacological treatment	73	(50.3	67	(67.7)	6	(13.0)	
Antenatal corticosteroids	9	(6.2)	4	(4.0)	5	(10.9)	0.132

CRP: C-reactive protein; *CT*: Computed tomography; HCQ: hydroxychloroquine.
[a] 4 missing values (2 in "No COVID-19 pneumonia" group and 2 in "COVID-19 pneumonia" group).
[b] 1 missing value in "COVID-19 pneumonia" group.

Table 4
Maternal outcomes by occurrence of COVID-19 pneumonia

Characteristics	Total (N = 146)		No COVID-19 pneumonia (N = 99)		COVID-19 pneumonia (N = 47)		p-value
	n	%	n	%	n	%	
Severe morbidity	7	(4.8)	3	(3.0)	4	(8.5)	0.215
Non invasive respiratory support	28	(19.2)	6	(6.1)	22	(46.8)	<0.001
Invasive respiratory support	11	(7.5)	2	(2.0)	9	(19.1)	0.001
Orotracheal intubation	2	(1.4)	1	(1.0)	1	(2.1)	0.544
ICU admission	7	(4.8)	2	(2.0)	5	(10.6)	0.035
Extracorporeal membrane oxygenation	0	(0.0)	0	(0.0)	0	(0.0)	-
Maternal death	0	(0.0)	0	(0.0)	0	(0.0)	-

ICU: Intensive Care Unit.

Table 5
Foetal and neonatal outcomes by occurrence of COVID-19 pneumonia

Characteristics	Total (N = 149)		No COVID-19 pneumonia (N = 101)		COVID-19 pneumonia (N = 48)		p-value
	n	%	n	%	n	%	
Stillbirth	2	(1.3)	1	(1.0)	1	(2.1)	0.542
Livebirth	147	(98.7)	100	(99.0)	47	(97.9)	
Neonatal birthweight (g)							
<1500	5	(3.4)	3	(3.0)	2	(4.3)	0.267
1500-2499	17	(11.6)	9	(9.0)	8	(17.0)	
≥2500	125	(85.0)	88	(88.0)	37	(78.7)	
Apgar 1 min >7	128	(87.1)	91	(91.0)	37	(78.7)	0.039
Apgar 5 min >7	140	(95.2)	98	(98.0)	42	(89.4)	0.022
NICU admission	23	(15.6)	10	(10.0)	13	(27.7)	0.007
Neonatal morbidity	4	(2.7)	1	(1.0)	3	(6.4)	0.106
Neonatal death	0	(0.0)	0	(0.0)	0	(0.0)	
Neonatal positive SARS-CoV-2 test							
No	138	(93.9)	94	(94.0)	44	(93.6)	0.594
Positive test <24 hrs of age	5	(3.4)	4	(4.0)	1	(2.1)	
Positive test ≥24 hrs of age	4	(2.7)	2	(2.0)	2	(4.3)	

NICU: Neonatal Intensive Care Unit

Mothers requiring critical care were 9% in the UK [4] and 7.5% in Italy. NICU admissions concerned respectively 26% in the UK [4], 6.2% of the infants described by the WHO review [6], and 4.8% of the Italian newborns (*Table 4*) but this variability could be related to different local admission policies to NICU regarding quarantine or neonatal observation. The UK cohort reported 5 maternal and 2 neonatal deaths compared to zero deaths reported in Italy and China. The interpretation of these differences is not straightforward even though the lower prevalence of minority ethnicities could play a role as well as the different pattern of drug prescriptions.

The data are preliminary and collection is still ongoing; nevertheless, they confirm a better course of the disease compared to H1N1 flu and SARS and MERS epidemics [1, 2].

The observation that almost 60% of the enrolled women did not have risky contacts during the 14 days prior to symptom onset raises the challenge of the impact of asymptomatic infections and the opportunity to consider screening policies for pregnant women at hospital admission, currently available in few Italian Regions and/or hospitals.

The proportion of women with pneumonia receiving pharmacological treatment against SARS-CoV-2 infection in this study is high, 73.9% receiving hydroxychloroquine alone or in association with antivirals and/or empirical antibiotics (*Table 3*). Lopinavir amongst antivirals is the most frequently used, probably due to the experience of its use in HIV positive women. No differences on maternal and neonatal outcomes have

been detected according to the drugs administered. Conversely, among the UKOSS cohort hydroxychloroquine was not administered at all and 2% of the women received antivirals [4]. At the end of May, the Italian Medicines Agency (AIFA) suspended the authorization for the prescription by the National Health Service of hydroxychloroquine and lopinavir/ritonavir for COVID-19, except for use in clinical studies. It is necessary to study safety and effectiveness of medications used in pregnant women to guide decision-making about treatment options for COVID-19 disease and associated complications.

Antenatal corticosteroids for foetal lung maturation have been prescribed as recommended [2] to 4 women <34 weeks and to 5 women at 34-35 weeks of gestation.

The detected rate of CS in the Italian cohort is 32.9%, higher compared to the rate of the Northern Regions (26%) but considerably lower compared to 59% of the UK cohort [4], 73.5% reported by the WHO review [6], and 85% of the Chinese series [3-6]. As reported in the UK, the majority of CS indications were not due to SARS-CoV-2 infection, which is not in itself necessarily an indication for delivery, nor for CS. The proportion of CS due to COVID-19 concerned in fact a minority of the total surgeries, 7.5% of Italian and 16% of UK cohort. Although international agencies are unequivocal in claiming that the disease is not an indication for CS and that the protection of birth physiology is a priority [2, 13, 14], clinical practice seem not to follow the current recommendations. Italy, which has historically recorded higher CS rates compared to the UK, on this occasion didn't show the same significant increase in CS as in other countries despite the early onset of the epidemic.

An issue still highly debated concerns the possibility of mother to foetus transmission of SARS-CoV-2 virus. The WHO review shows that 6.6% of the newborns tested as suspected to have COVID-19, the UK cohort reports 5% of positive infants, and the ItOSS cohort 6%. Although evidence is sparse, vertical transmission cannot be excluded [15, 16] but it appears to be rare and, for the most part, babies, who must be carefully monitored, have a good prognosis.

Many case reports and small case series have already been published on COVID-19 in pregnancy; however, there is a lack of population-based data that could allow incidence rates to be estimated and unbiased characteristics and outcomes to be described and compared [4]. The scientific community, as well as international journal peer review procedures, should better support the development and the dissemination of studies adopting population-based approaches to properly inform clinicians and decision-makers.

Pregnant women are often not included in clinical trials on drugs [17]. However, the good news is that recently the European Medicines Agency and Health Canada under the aegis of the International Coalition of Medicines Regulatory Authorities have agreed on three priority areas for cooperation on observational research during the outbreak of COVID-19 [18]. One area is devoted to research in pregnancy in order to examine the impact of both Coronavirus disease and the use of drugs on pregnant women infected with SARS-CoV-2 and their unborn babies. The different practices in prescribing hydroxychloroquine and antivirals observed in the UK and Italy promotes a reflection on the determining factors that guide clinicians in deciding whether and to what extent they should confidently prescribe drugs for which conclusive evidence is still unavailable.

The study's strengths are the national population-based prospective design and the opportunity to analyse data from the beginning of the epidemic. Another asset is the wealth of information contained in the data collection form. Limitations include the analysis of preliminary data while the pandemic is still underway and the constraints linked to the impossibility of generalizing the results without taking into account the different prevalence of the condition by geographical area. The lack of information regarding women infected in the early stages of pregnancy is also a limit of the study, but the ItOSS will follow-up affected women currently in the first trimester of pregnancy.

CONCLUSIONS

The clinical presentation of SARS-CoV-2 infection in women who gave birth appears to be similar to the general population. The lesson learned by reviewing hospital care offered to affected Italian women who gave birth, confirmed the current priority of physical distancing measures, the urgent need for stronger evidence on the safety and effectiveness of medical therapy and a continued commitment to face the challenge of respecting and protecting childbirth physiology. These findings confirm the primary importance of comparisons among population-based cohorts to support health professionals and decision-makers with evidence-based recommendations.

Acknowledgements

We thank Silvia Andreozzi and Mauro Bucciarelli for their valuable technical support and assistance to the operation of the web-based data collection system. We thank Clarissa Bostford for language editing.

Our heartfelt thanks go to all the clinicians working in the national network of maternity units (*Appendix*) for the assistance offered to women and for collecting the data, we thank all women who agreed to participate in the study.

Disclosure statement

The authors and the working group members report no conflict of interest.

Source of financial support

This study has not received any financial support.

Individual contribution to the manuscript

Alice Maraschini: conceptualization, methodology, software, formal analysis, writing-review and editing; Edoardo Corsi: methodology, investigation, data curation, writing-review and editing, project administration; Michele Antonio Salvatore: methodology, formal analysis, writing-review and editing; Serena Donati: conceptualization, methodology, formal analysis, writing original draft, supervision; Ilaria Lega: investigation,

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Received on 9 June 2020.
Accepted on 16 July 2020.

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