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## Mode of delivery and clinical findings in COVID-19 infected pregnant women in Northern Italy. --Manuscript Draft--

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<b>Abstract:</b>	<p>Summary</p> <p>Background: Limited data are available on pregnant women with COVID-19, their gestational age and mode of delivery, and vertical transmission of the virus. We report here the experience of a network of 12 northern Italian centres during the recent outbreak of SARS-Cov-2 infection.</p> <p>Methods: This is a retrospective study of women with COVID-19 who were delivered during the period 1-20 march 2020. Women with COVID-19 confirmed within 36 hours</p>

post-partum were also included. Data were collected from clinical chart.

Findings: During the period under investigation, 42 women with COVID-19 delivered at our centres. Of these, 24(57%) delivered vaginally. An elective cesarean section was made in 18/42 (43%) cases: in 8 cases the indication was unrelated to COVID-19 infection. In 10 cases the indications were worsening dyspnoea or other COVID-19 related symptoms. Pneumonia was diagnosed in 19/42(45%) cases: of these 7/19(37%) required oxygen support and 4/19(21%) were admitted to a critical care unit. Spontaneous preterm birth occurred in five cases. In two women with COVID-19 diagnosed in the post partum period and breastfed without mask, the new-borns had positive test for SARS-Cov-2 infection. In another case the new-born had a positive test after vaginal operative delivery.

Interpretation: : These findings suggest that COVID-19 syndrome in pregnancy is often mild or moderate. Although post-partum infection cannot be excluded, these findings suggest that vaginal delivery may be associated with a low risk of intrapartum SARS-Cov-2 transmission to the new-born. In consideration of the diagnosis of maternal SARS-Cov-2 infection during the post partum period, and hence to be infected but asymptomatic, in areas characterized by a high prevalence of infection, it may be safe to consider for the protection of health care providers, all delivering asymptomatic women as at risk to transmit the SARS-CoV-2.

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# Mode of delivery and clinical findings in COVID-19 infected pregnant women in Northern Italy.

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## **Research in context**

### Evidence before this study

Few cases of pregnant women delivered while suffering of COVID-19 respiratory syndrome have been reported . Most of these cases were delivered by cesarean section. Due to this limited number of cases, information on the risk of severe maternal complications, of preterm birth, of vertical/intrapartum transmission, and the risk of breast-feeding are scanty.

### Added value of this study

We retrospectively reviewed clinical records and laboratory findings of 42 pregnant women with laboratory confirmed COVID-19 infection who delivered in a network of hospitals in Northern Italy. Twenty-three cases suffered of mild symptoms, and 19 were diagnosed with interstitial pneumonia. In 11 cases respiratory support was required. Twenty-four of these pregnant women delivered vaginally. Spontaneous preterm birth occurred in five cases. In 5/42 women the diagnosis of COVID-19 infection was made during the post-partum period. In two of these women and breastfed without mask, the new-born had positive test for COVID-19 infection, but an additional new-born had a positive test after vaginal operative delivery.

### Implications of all the available evidence

Although based on limited numbers, this study suggests that the COVID-19 respiratory syndrome late in pregnancy is in most cases mild to moderate, but in some cases respiratory support or intensive care may occur. The observed occurrence of COVID-19 symptoms only after delivery suggests that, in areas characterized by a high prevalence of infection, safe procedures for midwives and doctors are to be recommended in any labour and to adopt mask and safe procedures in all breastfeeding women.

## Summary

**Background:** Limited data are available on pregnant women with COVID-19, their gestational age and mode of delivery, and vertical transmission of the virus. We report here the experience of a network of 12 northern Italian centres during the recent outbreak of SARS-Cov-2 infection.

**Methods:** This is a retrospective study of women with COVID-19 who were delivered during the period 1-20 march 2020. Women with COVID-19 confirmed within 36 hours post-partum were also included. Data were collected from clinical chart.

**Findings:** During the period under investigation, 42 women with COVID-19 delivered at our centres. Of these, 24(57%) delivered vaginally. An elective cesarean section was made in 18/42 (43%) cases: in 8 cases the indication was unrelated to COVID-19 infection. In 10 cases the indications were worsening dyspnoea or other COVID-19 related symptoms. Pneumonia was diagnosed in 19/42(45%) cases: of these 7/19(37%) required oxygen support and 4/19(21%) were admitted to a critical care unit. Spontaneous preterm birth occurred in five cases. In two women with COVID-19 diagnosed in the post partum period and breastfed without mask, the new-borns had positive test for SARS-Cov-2 infection. In another case the new-born had a positive test after vaginal operative delivery.

**Interpretation:** : These findings suggest that COVID-19 syndrome in pregnancy is often mild or moderate. Although post-partum infection cannot be excluded, these findings suggest that vaginal delivery may be associated with a low risk of intrapartum SARS-Cov-2 transmission to the new-born. In consideration of the diagnosis of maternal SARS-Cov-2 infection during the post partum period, and hence to be infected but asymptomatic, in areas characterized by a high prevalence of infection, it may be safe to consider for the protection of health care providers, all delivering asymptomatic women as at risk to transmit the SARS-CoV-2.

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## **INTRODUCTION.**

Most of the information on the effect of COVID-19 infection during pregnancy are substantially based on data of other highly pathogenic coronaviruses (i.e., severe acute respiratory syndrome (SARS) and the Middle East respiratory syndrome) <sup>1</sup>.

Recently Chen et al. <sup>2</sup> have reported in *Lancet* nine cases of deliveries in women with COVID-19 pneumonia. In that study all the nine patients had a caesarean section in their third trimester. The neonatal outcome were favourable and all neonatal throat swabs performed tested negative for the virus. Another clinical series of 11 women with COVID 19 infection who had successful deliveries (10 cesarean and 1 vaginal) has been reported: in all the new-borns the 2019-nCoV nucleic acid test was negative<sup>3</sup>.

Chen et al concluded their paper underlining that “there is currently no evidence for intrauterine infection caused by vertical transmission in women who develop COVID-19 pneumonia in late pregnancy” <sup>2</sup>. This finding is, however, based on very few reported cases, particularly for vaginally delivered newborns<sup>4</sup>.

Due to the recent outbreak of the infection in Italy, particularly in Lombardy, a number of infected women have already delivered. Due to the limited data available on pregnant infected women and their new-borns, we considered that even basic clinical data of this cohort could be usefully reported and shared with the scientific and clinical community of healthcare providers. As realistically stated by Remuzzi and Remuzzi in *Lancet* “Countries that have been unfortunate enough to have been exposed to this disease already have, paradoxically, very valuable lessons to pass on” <sup>5</sup>.

Regione Lombardia has settled a network of six designated COVID-19 maternity hospitals in order to offer adequate assistance and epidemiological surveillance to symptomatic infected pregnant women.

We report here the experience of the participating centers, with specific focus on mode of delivery and immediate neonatal outcome.

## **METHODS.**

This is a retrospective multicenter study of COVID-19 infected women who were admitted and delivered during the period 1-20 march 2020. Most of deliveries occurred in the designated COVID-19 hubs while some

were attended in the spokes for non-transferable active phase labor. Designated Hub-Maternity Hospitals were: Milan-Mangiagalli and Sacco, Bergamo-Pope Giovanni XXIII; Brescia-Civil Hospital; Monza-S. Gerardo Hospital/MBBM Foundation; Pavia-San Matteo. Spokes Maternity Hospitals were: Milan-Melloni and S. Giuseppe; Seriate-Bolognini; Treviglio-Civil Hospital. The Maternity Hospital of Padua and the Maternity Hospital of Modena also reported their cases.

Criteria for eligibility were the following:

- pregnant women with a confirmed diagnosis of COVID-19 infection prior or within 36 hours after delivery;
- who delivered during the study period.

The investigators reported all women consecutively observed who met the inclusion criteria.

The clinical triage was performed according to WHO guidelines<sup>6</sup>. Diagnosis of COVID 19 infection was based on the results of maternal and child throat swab samples according to the Italian National Procedures<sup>7</sup>.

This is a retrospective study. All women were treated according to the National Guidelines for COVID-19 in pregnancy and treatment was then tailored according to the individual evolution of signs, symptoms, laboratory data and radiologic findings. These patients did not undergo any additional obstetric diagnostic procedures or monitoring other than the normal clinical practice, plus a confirmative chest x-ray, a 48 hours monitoring of white blood cell formula and CRP.

Foetal growth and well-being were assessed at admission and foetal heart rate was monitored continuously during labour and delivery.

When the positive infected status of the mother was known at delivery, breast feeding was allowed according to international guidelines<sup>8</sup> if the mother was asymptomatic or pauci-symptomatic. Women were instructed how to wear and dispose surgical masks in combination with frequent hand-cleaning with alcohol-based hand rub or soap and water.

Data were collected from clinical records using a common questionnaire on maternal general characteristics, any medical or obstetric co-morbidity, course of pregnancy, clinical signs and symptoms, treatment of COVID 19 infection, mode of delivery, neonatal data and breastfeeding. For the purpose of this report, as regards the neonatal outcome we recorded only positive or negative test for COVID-19. Women and new-borns were followed up until discharge from hospital or till March 20<sup>th</sup>, whatever comes before.

For the considered variables, averages, range or proportions were calculated, as appropriate. Statistical significant differences among groups were tested using the common chi square test for heterogeneity.

The study protocol was approved by the Institutional Review Boards.

## **RESULTS.**

A total of 42 women delivered in the participating centres.

Diagnosis of COVID-19 infection was known before admission to hospital for delivery in 10 cases, diagnosis was made in the delivery room in 27 cases and in 5 cases diagnosis was made during the postpartum hospital admission within 36 hours following delivery.

A total of 24/42 (57%) women delivered vaginally with three cases undergoing induction of labour for obstetric reasons.

An elective cesarean section was performed in 18/42 (43%) cases: in 8 cases the indication was unrelated to COVID-19 infection, but in 10 cases the indications were worsening dyspnoea or other COVID-19 related symptoms.

The characteristics, signs, symptoms and treatment of COVID-19 infection of this cohort are presented in table 1 according to the mode of delivery

In this cohort, the mean age was 32.9 (range 21-44). Fever was the most common symptom reported. Pneumonia was diagnosed in 19/42 (45%) cases: of these 7/19 (37%) required oxygen support and 4/19 (21%) were admitted to a critical care unit.

Pneumonia was more common in women who delivered by cesarean section due to COVID-19 related infection (chi-square=7.45, p-value= 0,024).

Table 2 considers the course of pregnancy and the neonatal outcome. Gestational diabetes was reported in 6/42 cases (14%) without any significant difference between the three groups.

A total of 30/42 (71%) women delivered at term. Spontaneous preterm birth occurred in 5 cases and in 6 cases elective cesarean section was performed.

Only 2 very preterm new-borns had a 5min Apgar score <7.

In 10 cases breastfeeding was allowed with surgical mask. In two women who had diagnosis of COVID-19 infection in the post-partum period and breastfed without surgical mask the new-borns had positive test for COVID-19 infection at day one and three, respectively.

In another case after vaginal delivery the new-born of an infected woman had a positive test

This case deserves additional details. The newborn from a COVID-19 mother delivered vaginally at term in good conditions, was immediately separated for a severe maternal postpartum hemorrhage. Within a few hours he developed gastrointestinal symptoms, after three days he developed respiratory symptoms and was transferred to NICU where he recovered after one day of mechanical ventilation. The first test for SARS-CoV-2 was doubtful few hours after delivery, and positive three days later.

The mother did not breastfeed and no health care provider had a confirmed diagnosis of COVID-19 infection.

No other positive test was found among the new-borns.

## **DISCUSSION.**

This paper reports the obstetric outcome of a cohort of COVID-19 affected pregnant women and the rate of SARS-CoV-2 positive new-borns according to the mode of delivery and breastfeeding.

In our cohort, most of pregnant women affected by the COVID-19 respiratory syndromes suffered of mild or moderate conditions. Fever, cough and mild dyspnoea were the most common symptoms, from 70% to 80%. Thanks to this clinical condition, more than half of consecutive reported cases were delivered vaginally. However, radiological confirmed pneumonia was diagnosed in 42% of cases and four of these 19 cases required admission to a critical care unit. As previously suggested (9), the findings of our cohort support the hypothesis that COVID-19 respiratory syndrome may be less severe for the maternal prognosis than SARS and MERS.

Lymphopenia and high CRP values were part of the clinical scenario that induced clinicians to deliver patients by cesarean section.

Of note, two cases were delivered < 34 weeks of gestation because of worsening respiratory syndrome. Further, five women delivered spontaneously before term (one before 34 weeks of gestation). This observation suggests that acute infection does not markedly increase, if any, the risk of preterm birth. This is also consistent with the findings of previously published series showing no case of preterm birth before 33 weeks of gestation<sup>4</sup>.

Vertical and intrapartum transmission are among the most serious complications of viral diseases during pregnancy. In the previously quoted published series, delivery occurred in all cases, except one, by cesarean section for a total of 30 women: no new-born infection was reported (for the series of Zhang et al. we have considered only data reported in the abstract<sup>10</sup>). Likewise, in a review (including the above quoted series) Schwartz et al.<sup>4</sup> reported 37 cases: no vertical infection was reported.

Vertical transmission did not seem to occur also after other pathogenic coronaviruses – SARS-CoV and MERS-CoV- infection in pregnancy, although it has been suggested that coronaviruses may cause early pregnancy losses<sup>11,12</sup>. Furthermore, no evidence of transmission through genital fluids has been recently reported<sup>13</sup>.

Among the 24 women who delivered vaginally one new-born was infected probably due to post-partum contamination (see below). In a second cases after vaginal delivery a potential intrapartum infection may have occurred, but it was not possible to exclude other sources of infection in the immediate post-partum.

It should be underlined that, due to the recent outbreak of COVID-19 infection we are reporting from Northern Italy, we can consider mainly the risk of transmission among women who were infected during the third trimester or at term and the risk of intrapartum transmission.

We reported 5 cases who were diagnosed to be COVID-19 positive due to fever in the post-partum period. In two cases in which skin to skin contact after birth and breastfeeding was allowed without mask, the COVID test of the new-born was positive at day 1 and 3 after birth. Although no viral load has been detected in breast milk by Chan et al.<sup>2</sup>, close maternal contact may represent a potential route of transmission. In these two cases, because viral testing was not made immediately after birth, a vertical transmission cannot be excluded.

To our knowledge, other two cases of SARS-CoV-2 infected new-borns have been reported in which the diagnosis was made 36 hours following delivery and at 17 days of life. In both cases a postpartum neonatal infection acquired through an infected contact was suggested <sup>4</sup>.

In all these cases, because viral testing was not performed immediately after birth, the route of transmission cannot be completely explained.

The frequency of COVID-19 symptoms and positive laboratory and radiologic findings observed in this cohort is in line with the fact that this syndrome is generally mild or moderate in pregnancy and very likely many pregnant women are totally asymptomatic or might develop symptoms only after delivery. This stands for safe procedures for midwives and doctors in any labour and delivery room such as wearing appropriate personal protective equipment (PPE) during labour (surgical mask for the labouring woman, her accompanying person and the midwife and/or doctor) and more strict PPE during delivery, since the efforts of pushing in case of unknown positive women might diffuse infected droplets.

Finally, we considered all consecutive positive women delivered or admitted in the post-partum COVID-19 ward for being symptomatic and tested positive to the nasopharyngeal sampling. We called all spokes of the COVID-network in Lombardy and related Units of Padua and Modena to be sure to include all cases. Although few might have slipped through this network and not reported, overall the reported cases represent approximately 0.6% of the number of deliveries occurring in the same area in these 20 days.

In conclusion, this study reports the early experience in Italy regarding the delivery of SARS-CoV-2 infected women. This clinical experience may be useful to colleagues of other countries which may be involved in the next weeks in the obstetric care of SARS-CoV-2 infected delivering women.

**Contributors**

FP, EF, IC and LF each led aspects of the contact investigation and provided overall leadership and guidance to the investigation.

FM, GZ and GM were the pediatricians in charge of treatment of the newborn babies in the main collaborating centres.

LF, VS, SB, FF, MTG, EI, AK, BM, LP, FeP, DS, AS, GT, PV, MV, AV completed the investigation of cases and 7 or collected epidemiological data, and provided clinical care to the patients and assisted with clinical descriptions.

FP and EF drafted the manuscript  
IC revised the manuscript.

All authors reviewed and approved the final manuscript.

**Declaration of interests**

We declare no competing interests.

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**Data sharing**

With the permission of the corresponding authors, we can provide data without names and identifiers. The corresponding authors have the right to decide whether to share the data or not based on the research objectives and plan provided.

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Table 1. Maternal characteristics and symptoms.

	Elective Cesarean section for conditions determined by COVID-19 respiratory syndrome (No.= 10)	Elective Cesarean section for obstetric reasons unrelated with COVID-19 respiratory syndrome (No.=8)	Vaginal delivery <sup>°</sup> (No.=24)
<b>Maternal characteristics</b>			
Maternal age (mean, range)	30.9 (21-40)	30.5 (27-44)	34.6 (29-43)
Nulliparous women	4(40%)	2(25%)	9 (38%)
<b>Sign and symptoms of SARS-Cov-2-infection</b>			
Fever before delivery	7(70%)	4(40%)	9(38%)
Fever only in the post partum	-	1(13%)	5(21%)
Myalgia/malaise	5(50%)	-	2(8%)
Cough	8(80%)	2(25%)	8(33%)
Dyspnoea	7(70%)	-	1(4%)
Diarrhoea	-	1(13%)	1(4%)
Pneumonia	8(80%)	4(50%)	7(29%)
<b>Treatment</b>			
Oxygen support (nasal cannula, CPAP)	4(40%)	1(13%)	2(8%)
Admission to critical care unit (yes)	2(20%)	1(13%)	1(4%)
<b>Laboratory findings</b>			
High leukocyte count (>9.5 × 10 <sup>9</sup> cells per L) <sup>°°</sup>	3(30%)	2(25%)	11(46%)
Lymphopenia (<10 <sup>9</sup> cells per L) <sup>°°</sup>	3(30%)	1(13%)	2(8%)
Elevated C-reactive protein (>10 mg/L) <sup>°°</sup>	7(70%)	4(50%)	6(25%)
Elevated ALT (>45 U/L) or AST (>35 U/L) <sup>°°</sup>	2(20%)	-	3(13%)

<sup>°</sup> In 3 cases labour was induced for obstetric indication unrelated with COVID 19 respiratory syndrome.

<sup>°°</sup>6 cases missing

Table 2. Pregnancy, delivery and neonatal outcome.

	Elective Cesarean section for conditions determined by COVID-19 respiratory syndrome (No.= 10)	Elective Cesarean section for obstetric reasons unrelated with COVID-19 respiratory syndrome (No.=8)	Vaginal delivery (No.=24)
<b>Pregnancy and delivery</b>			
<u>Gestational diabetes (yes)</u>	2(20%)	-	4 (17%)
<u>Weeks of gestation at delivery</u>			
>37	5 (50%)	7(88%)	18( 78%)°
>34-37	3 (30%)	-	4 (17%)
<=34	2 (20%)	1 (13%)	1 (4%)
<b>New-born</b>			
Birth weight (grams; mean, range)°°	2730(840-4040)	3100(2770-3430)	3226(2450-3740)
Apgar score (5min)>7	8(80%)	8(100%)	24(100%)
NICU admission (Yes)	-	1 (13%)°°°	2(8%)°°°
Positivity to SARS-Cov-2 (Yes)	0	1(13%)	2(8%)
<b>Breastfeeding (Yes)</b>	0	1(12%)	10(42%)

NICU: Neonatal Intensive Care Unit.

°1 case missing

°°5 cases missing

°°° for preterm birth/respiratory distress