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Review article

COVID-19 and pregnancy: A comparison of case reports, case series and registry studies

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ABSTRACT

Background: Selection, outcome and publication biases are well described in case reports and case series but may be less of a problem early in the appearance of a new disease when all cases might appear to be worth publishing.
Objective: To use a prospectively collected database of primary sources to compare the reporting of COVID-19 in pregnancy in case reports, case series and in registries over the first 8 months of the pandemic.
Study design: MEDLINE, Embase and Maternity and Infant Care databases were searched from 22 March to 5 November 2020, to create a curated list of primary sources. Duplicate reports were excluded. Case reports, case series and registry studies of pregnant women with confirmed COVID-19, where neonatal outcomes were reported, were selected and data extracted on neonatal infection status, neonatal death, neonatal intensive care unit admission, preterm birth, stillbirth, maternal critical care unit admission and maternal death.
Results: 149 studies comprising 41,658 mothers and 8,854 neonates were included. All complications were more common in case reports, and in retrospective series compared with presumably prospective registry studies. Extensive overlap is likely in registry studies, with cases from seven countries reported by multiple registries. The UK Obstetric Surveillance System was the only registry to explicitly report identification and removal of duplicate cases, although five other registries reported collection of patient identifiable data which would facilitate identification of duplicates.
Conclusions: Since it is likely that registries provide the least biased estimates, the higher rates seen in the other two study designs are probably due to selection or publication bias. However even some registry studies include self- or doctor-reported cases, so might be biased, and we could not completely exclude overlap of cases in some registries.

Contents

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Introduction

Primary sources such as case registries, case series and case reports, provided early data regarding the impact of SARS-CoV-2 infection in pregnancy. The influence of publication bias, selection bias and reporting bias is likely to differ between these data sources; it is anticipated that conventional case reports and series are more influenced by bias than data from registry studies. These data sources are more commonly retrospective in nature predisposing them to recall bias, information bias and greater subjectivity [1] and authors have greater autonomy regarding selection of cases to report resulting in significant reporting bias (Table 1).

Although registry studies are often considered to be the 'gold standard', potential for bias exists if no efforts are made to disambiguate data. This results in publication of overlapping and duplicated cases amplifying certain outcomes.

Early in the COVID-19 pandemic most publications were case reports or small case series documenting information from either a single or a limited number of cases. The outcomes of these pregnancies varied with some of the papers reporting severe cases of SARS-CoV-2 infection. This uncertainty influenced obstetricians to employ measures such as mother-baby isolation, caesarean birth and formula or expressed milk feeding. Later studies suggested that these practices were not necessary due to low rates of vertical transmission [2]. By assessing the extent to which outcomes reported by data sources differ and the degree of overlap and duplicated studies in registry studies, more informed clinical decisions can be made.

A secondary aim is to investigate the extent to which registries have endeavoured to avoid duplication and overlap of cases.

Methods

A systematic review written in accordance with the guidelines set out by PRISMA 2009 [3]. It used the same methods as Walker et al [2] summarised below. No ethics approvals were required. The study followed a protocol, but the protocol was not registered.

Case reports, case series or registry data, of pregnant women with confirmed COVID-19 infection based on a positive swab, or high clinical suspicion were eligible for inclusion. No restriction was applied on language.

A curated list of all scientific reports of COVID-19 in pregnancy since 22 March 2020, was created, based on a daily PubMed search (Appendix A) supplemented by alerts from colleagues on social media. After 8 April 2020 this was supplemented by formal weekly searches by KO and KW. The search was conducted from 8 April 2020 to 5 November 2020 through the following electronic bibliographic databases (Medline, Embase and Maternity and Infant Care Database) and citation tracking on relevant studies. The search terms were based on MeSH terms.

'Titles and abstracts were assessed for inclusion by two reviewers (KFW, KO), and if there was a disagreement the full text was obtained. Disagreements were resolved by discussion, and if agreement could not be reached the study was independently assessed by a third reviewer (JGT).' [2] Data for the first 170 reports was extracted independently by two authors (KFW, KO), data for the subsequent reports was extracted independently by two authors for each study, by a team of three (YK, JS and EY).

A registry was defined as a study which aimed to report every case in a defined geographical area, a case report as a report of a single case and a case series as more than one case but not every case in a defined geographical area.

The following data were collected: number of children, number of deliveries, number of ongoing pregnancies, infection status of mother and neonate, gestational age at delivery, maternal death, maternal critical care unit admission, NICU admission, stillbirth, neonatal death and study type classification. For registries with multiple data updates we used the last update prior to 5 November 2020.

To minimise differences due to different health care systems we excluded case reports and case series from countries (Dominican Republic, Israel, Turkey, Portugal, Australia, Canada, Peru, Iran, Japan, Morocco, Denmark, The West Indies, Jordan, Nigeria, Sri Lanka, Norway, Saudi Arabia, Oman, Estonia, the Republic of Ireland and India) in which at the time there was no registry. We also excluded case series, case reports and registries with no data on pregnancy outcomes. For this reason, 10 registries [7–16] were not included in the comparison of adverse outcomes between different data sources and 57 case series and 10 case reports were excluded from the study as shown in Fig. C.1.

Table 1
Number of Each Study Type Found

Study Type Classification	Number of Studies Identified	Study References
Registry	21	[7–29]
Borderline Registry/ Case Series	3	[30–32]
Case Series	74	[33–106]
Case Reports	47	[107–153]

Table 2
Comparison of Incidence of Severe Outcomes in Registries, Case Series and Case Reports

Study Type Classification	No. of studies (N)	Neonates (N)	Infected Neonates N (%)	Stillbirth and Neonatal Death N (%)	Neonatal Intensive Care Unit Admission N (%)	Preterm Birth N (%)	Pregnant Women (ongoing pregnancy and delivered) (N)	Maternal Death N (%)	Maternal Critical Care Unit Admission N (%)
Registry	12	6396	85, (1.3)	57, (0.89)	506, (7.9)	823, (13)	33844	43, (0.13)	365, (1.1)
Case Series	74	2141	38, (1.8)	26, (1.2)	338, (16)	289, (13)	2840	6, (0.21)	168, (5.9)
Case Report	47	49*	6, (12)	2, (4.1)	25, (51)	24, (49)	47	1, (2.1)	19, (39)

Table 3
Rates of Severe Outcomes in Prospective Registries

Country	Registry	Type of study	Neonates (N)	Infected Neonates N (%)	Stillbirth and Neonatal Death N (%)	Neonatal Intensive Care Unit Admission N (%)	Preterm Birth (%)	Pregnant Women (ongoing pregnancy and delivered) (N)	Ongoing Pregnancies (N)	Maternal Death N (%)	Maternal Critical Care Unit Admission N (%)
UK	UK Obstetric Surveillance System (UKOSS) (26)	Prospective	268	12, (4.5)	5, (1.9)	67, (25)	66, (25)	427	161	5, (1.2)	40, (9.4)
US	Centres for Disease Control and Prevention (CDC) (28,29)	Prospective	4527	16, (0.35)	29, (0.64)	279, (6.2)	506, (11)	30,415	309	34, (0.11)	245, (0.81)
	Pregnancy Coronavirus Outcomes Registry (PRIORITY) (17,24)	Prospective	179	2, (1.1)	0, (0)	31, (1.7)	21, (12)	594	not reported	not reported	11, (1.9)
	COVID-NET (21)	Prospective and Retrospective	453	not reported	7, (1.5)	not reported	56, (12)	598	139	2, (0.33)	44, (7.4)
Spain	Obs COVID Registry (20)	Prospective	246	3, (1.2)	3, (1.2)	23, (9.3)	34, (14)	246	0	0, (0)	5, (2.0)
	Sociedad Española de Neonatología (seNeo) (23)	Prospective	40	40, (100)	0, (0)	8, (20)	10, (25)	not reported	not reported	not reported	not reported
Netherlands	Netherlands Obstetric Surveillance System (NethOSS) (19)	Prospective	155	0, (0)	0, (0)	27, (17)	15, (9.7)	431	258	1, (0.39)	7, (1.6)
Italy	Italian Obstetric Surveillance System (ItOSS) (18)	Prospective	149	5, (3.4)	2, (1.3)	23, (15)	28, (19)	146	0	0, (0)	7, (4.8)

We explored the extent of overlap between registries where multiple registries reported cases in the same country. Authors classified studies as retrospective or prospective based on the description of each study author, but the methodology section of each paper was checked to make sure the author's description fit with the described study design as per the protocol, and disagreements were resolved with a third author (JGT). Registry methodologies were studied for details of any efforts to identify and remove duplicated cases. Where there was available data we also calculated percentages of total cases identified as duplicates.

Results

Full texts for three studies could not be accessed and were excluded. The study flow chart is shown in Fig. C.1.

Main Findings

The rates of major adverse outcomes estimated from the three study designs is shown in Table 2. In comparison to registry studies and case series, case reports documented the highest incidence of adverse outcomes for all outcomes investigated.

The rates in prospective and retrospective studies are shown in Tables 3 and 4. Retrospective studies reported higher incidences than prospective studies for all six severe outcomes. For two registries (GROG [25] and National Health Commission of China [31]) it could not be determined if they were prospective or retrospective in nature and so these were not included in this comparison.

We found that extensive overlap is likely to be prominent in registry study data. Cases from seven countries were reported by multiple registries, (UK, US, France, Brazil, Spain, Italy, Sweden) with at least five registries reporting cases from the US. However, the extent of the overlap cannot be determined without further information regarding details of cases and the hospitals in which they were reported.

The only registry which made explicit reference to removal of duplicates was the British registry UKOSS [26]. However CDC (US) [28,29], PRIORITY (US) (17,24), Obs COVID Registry (Spain) [20], seNeo (Spain) [23] and ItOSS (Italy) [18] reported the collection of identifiable patient data which would facilitate identification of duplicate cases.

Discussion

Main Findings

Right from the start of the COVID-19 pandemic reported rates of adverse outcomes were higher in case reports than case series which themselves were higher than in registries. The former two study designs overestimate complication rates. Although they tend to provide the most data in the early stages, they should be interpreted with caution owing to this bias.

There are several reasons for the differences we observed. The choice to report a certain case or collection of cases with no predefined method for participant selection leads to a selection effect such that the resultant study population is unrepresentative of the population. Authors may choose to report incomplete data, leading to an outcome selection effect and a misleading representation of reality. Finally journal editors are incentivised to publish papers describing, 'interesting' or severe outcomes , so called publication bias.

Nevertheless case reports contribute valuable information to medical knowledge, highlight potential areas of research and can

Table 4
Rates of Severe Outcomes in Retrospective Registries and Bordeline Case Series

Country/ Region	Registry	Type of study	Neonates (N)	Infected Neonates N (%)	Stillbirth and Neonatal Death N (%)	Neonatal Intensive Care Unit Admission N (%)	Preterm Birth N (%)	Total Pregnant Women (ongoing pregnancy and delivered) (N)	Ongoing Pregnancies (N)	Maternal Death N (%)	Maternal Critical Care Unit Admission N (%)
22 Countries	World Association of Perinatal Medicine COVID-19 (22)	Retrospective	266	1, (0.38)	11, (4.1)	69, (26)	70, (26)	388	122	3, (0.77)	43, (11)
Kuwait	New-Jahra Hospital (30)	Retrospective	41	2, (4.9)	2, (4.9)	2, (4.9)	11, (27)	185	141	0, (0)	2, (1.1)
Sweden	Stockholm Hospitals (32)	Retrospective	68	3, (4.4)	2, (2.9)	12, (18)	14, (21)	67	0	0, (0)	4, (6.0)

[1]Registry method states that some data collection occurred retrospectively where cases occurred prior to the set-up of this registry, the remainder of the data collection was conducted in a prospective manner.
[2]Case Series were classed as borderline if it is likely that all cases in the respective regions at the time were identified.

help guide clinicians in novel situations where little is known about effects and course of a disease [4].

We also identified many overlapping cases in all types of study, which complicates epidemiological study of this disease. This problem merits further study.

Strengths of the review

Data collection for this study was carried out by five independent reviewers, KFW, KO, JS, YK and EY and was initiated prior to the commencement of this project. The curated dataset (appendix B or https://ripe-tomato.org/2020/05/15/covid-19-in-pregnancy-101-onwards/) which our group continue to update, remains the only publicly available such resource.

Weaknesses of the review

We could not access three potentially eligible papers. Case series and case reports from countries in which registries were not established, and studies with insufficient data on neonatal outcomes were also excluded Our combining of rates of adverse outcomes was mathematically crude, and we ignored the possibility of 'The Simpson's Paradox,' [5]. Some of the data used in analysis may have been outdated given that registries published reports at different times throughout the pandemic. Finally, a certain degree of ambiguity exists with regard to the classification of a registry. For the purpose of this study, a registry report has been defined as a paper which aimed to report every case in a defined geographical area resulting in the classification of 21 studies as registries. However, it could be argued that another classification of data source should have been included in this study to recognise the distinction between registries set up to report cases of COVID-19 in pregnancies and pre-existing surveillance systems. UKOSS (UK), CDC (US) and NethOSS (Netherlands) are examples of registries that could be classified under this category. Further differences in severity of outcomes and the influence of bias may have been detected had this distinction been made.

Comparison to other studies

Our findings confirm many previous studies in other disease setting [6]. However we are the first group to demonstrate this bias so early in the epidemiology of a new disease like COVID-19.

Conclusions

Implications for Clinical Practice

Clinicians resorting to case reports or cases series even early in a disease should recognise that such study designs overestimate severity.

Implications for Future Research

Further study of the phenomenon of duplicate reporting is needed.

Inclusion of news releases in comparison of data sources would also be an interesting line of study. Although professionals rely on scientific papers for information, the opinion of the general public is most often guided by the media. The abundance and accessibility of information can present new challenges for medicine, particularly if the media presents biased and unjustifiably severe cases to the public.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejogrb.2021.12.002.

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