

Impact of COVID-19 infection on emergency obstetric and gynecological transport

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Abstract. The spread of COVID-19 affected emergency medical care worldwide. Studies have observed various impacts of COVID-19, depending on the intensity of infection control measures, the number of medical facilities and the demographic composition of the region. However, reports on the impact on emergency medicine in rural cities or in the field of obstetrics and gynecology are limited. Therefore, the present study examined the impact of COVID-19 infection on the emergency transfer of patients with obstetric and gynecological diseases, where medical resources are limited. A cross-sectional study was conducted using a publicly available database. From 2019 to 2021, there were 635 obstetrics and gynecology transfers, which were divided into obstetric and gynecological diseases. The year 2019 was defined as the pre-pandemic period, while the other 2 years were labeled as the post-pandemic period. The number of transports, post-transportation outcomes and the percentage of transfers and the time required for transport were examined. The number of transfers did not change significantly during the post-pandemic period. In obstetric diseases, the number of transported patients who did not require hospitalization increased, and transfers from primary facilities decreased during the post-pandemic period. There was no change in severity or transport type for gynecological diseases, nor in the time required for transport for both obstetric and gynecological cases. The impact of infectious diseases on emergency transfers for obstetric and gynecological cases was considered

low. Whether the increase in COVID-19 cases not requiring hospitalization and the decrease in transfers in obstetrics cases were due to the impact of infectious diseases remains unclear; thus, further studies are required.

Introduction

The COVID-19 epidemic began in China at the end of 2019, and became a pandemic by 2020 (1). The first case of infection in Japan was reported on January 14, 2020 (2). As the number of infected individuals increased rapidly, the government and municipalities called for voluntary restraints on events that could increase the risk of infection, such as cross-prefecture travel and dining, affecting numerous areas, including public administration, medical facilities and educational institutions. Medical facilities took measures such as postponing routine medical examinations and non-urgent surgeries. To reduce the risk of infection, patients began to avoid visits to doctors, particularly for pediatrics and otolaryngology in Japan (3). In emergency transport, an increase in the number of difficult cases and a longer time spent at the scene were noted (4). Similarly, Taiwan and Germany experienced a decline in the number of emergency transport requests (5,6), making it challenging to find suitable facilities for certain cases (7).

The present study examined the impact of COVID-19 infection on the emergency transfers of patients with obstetric and gynecological diseases in Kochi Prefecture, Japan. Kochi Prefecture has a population of ~680,000. In 2021, the percentage of older adults aged ≥ 65 years was 35.2%, markedly higher than the national average of 28.4% (8). Surrounded by the Pacific Ocean and the Shikoku Mountains, Kochi Prefecture is situated in a difficult location for receiving medical care beyond the prefectural border, apart from some areas, and the provision of medical care must be completed within the prefecture. The numbers of physicians and hospital beds per 100,000 individuals have exhibited a steady decline in Kochi Prefecture. However, it is still higher than the national average, partly owing to the decline in the population in Kochi. As of 2022, there were 313.9 physicians (national average, 253.6) and

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1,105.2 general hospital beds (national average, ~701.4) per 100,000 individuals (9). According to the Fire and Disaster Management Agency of the Ministry of Internal Affairs and Communications, there were about 40,000 emergency medical calls per year, with 581.5 calls per 10,000 individuals in 2021. In the same year, the national figure was 491.2 dispatches per 10,000, and Kochi Prefecture had a higher number of dispatches per population than the national average (10).

As of 2021, seven general hospitals, six clinics and one midwifery center were handling childbirth deliveries in Kochi Prefecture. Of note, ~30% of deliveries in Kochi are performed at clinics. Owing to the aging of obstetricians and gynecologists, more temporary facilities have suspended deliveries in recent years. Thus, obstetric and gynecological care, particularly perinatal care, is not robust. Although the number of deliveries is decreasing with the declining birthrate, the number of high-risk pregnancies is increasing owing to the higher age of pregnant women, patients with complex social backgrounds and pregnancies complicated by psychiatric disorders. Moreover, the number of cases that require individualized care is increasing.

Notably, access to and the quality of medical care in Japan is high by global standards, and the disparity between regions in the country is the lowest worldwide (11). However, the regional cities in Japan are experiencing a declining population and an uneven distribution of medical facilities and physicians. The challenges in rural areas, where medical resources and medical institutions are limited, could differ from those in urban areas, where there are many medical institutions or major medical departments, such as internal medicine.

When a situation such as the recent pandemic occurs and causes a prolonged disruption to the medical field, making the most of limited medical resources is an important issue. The present study first examined the extent to which the pandemic caused confusion in the medical field, focusing on the field of obstetrics and gynecology, which is not directly related to the practice of COVID-19 medical care. As regards making the most of limited medical resources, by focusing on departments with limited resources, the present study provides insight that may be useful during emergencies. The changes in emergency transfers for obstetric and gynecological cases in Kochi Prefecture in the pre- and post-pandemic period were compared in an aim to discover clues with which to solve the issue of facilitating emergency medical care in an emergency situation.

Subjects and methods

Study design and setting. This cross-sectional study was conducted by extracting data on emergency transport of obstetric and gynecological diseases in Kochi Prefecture from January, 209 to December, 2021 from the database 'Kochi-Iryo-Net' (<https://www.kochi-iryo-net/>).

Japan has a nationwide fire/ambulance service that can be availed by dialing the emergency number 119. This taxpayer-funded service is available to anyone, anytime and anywhere at no charge. When an individual calls 119 during an emergency, the nearest fire station dispatches an ambulance to the patient, locates a receiving hospital based on the chief complaint and condition of the patient, and subsequently transfers the patient to medical personnel. Fire stations are operated

and managed by municipal governments, and each station is equipped with fire engines and ambulances according to the size of the local population. As of 2021, there were 41 fire stations in Kochi Prefecture.

The Kochi-Iryo-Net is a database established in 2015 as part of the medical and disaster information system of Kochi Prefecture. The database contains information about fire and ambulance dispatches and crew details, dates and times of calls, destination medical institutions and distance between patients from the fire department. Upon arrival at the destination (medical institution), an attending doctor recorded pertinent information regarding institution names, locations where patients were collected, types and degrees of conditions or urgency in the institutional medical record database. The Kochi Prefectural Government then integrated this information into the Kochi-Iryo-Net database. The data that support the findings of the present study are available from the Kochi Prefecture database. However, these data are not publicly available as they report the surveillance conducted by Kochi Prefecture Healthcare Policy Division Department for monitoring emergency medical care.

Study participants. From the Kochi-Iryo-Net, data were extracted on transports made between January, 2019 and December, 2021 that indicated obstetrics and gynecology as the disease classification. Since the disease name was written in a free description format by the receiving physician, it was additionally converted to the ICD-10 code for the corresponding disease name.

The period from January to December, 2019 was defined as the pre-expansion period of COVID-19 infection (pre-pandemic), and that from January, 2020 to December, 2021 was considered as the expansion period of COVID-19 infection (during the post-pandemic period).

In order to protect patient privacy, all data were anonymized by the Kochi Prefecture Medical Policy Division. The data obtained were already in an anonymized state. The study protocol was approved by the Ethics Committee of Kochi University School of Medicine (approval no. 2021-142). The present study was conducted in accordance with the Ethical Guidelines for Medical and Biological Research Involving Human Subjects by the Ministry of Education, Culture, Sports, Science and Technology; the Ministry of Health, Labour and Welfare; and the Ministry of Economy, Trade and Industry and the Declaration of Helsinki (2013 amendment).

Variables. Only the cases classified as obstetrics and gynecology diseases were included in the present study. Cases classified as 'O: Pregnancy, delivery, and postpartum' by the ICD-10 code were classified as obstetric cases, and those with other codes were classified as gynecological cases. Newborns who were transported together with their mothers for out-of-hospital deliveries (n=4), cases with unknown diseases (n=7), and those with incorrectly entered or incompletely recorded transport dates and times (n=9) were excluded from the study (Fig. 1).

The type of transport was examined separately for transfers and non-transfers. The time required for transport was examined in terms of the time required to arrive at the scene, time spent at the scene, and time from the emergency call to the transfer to the physician at the receiving facility.

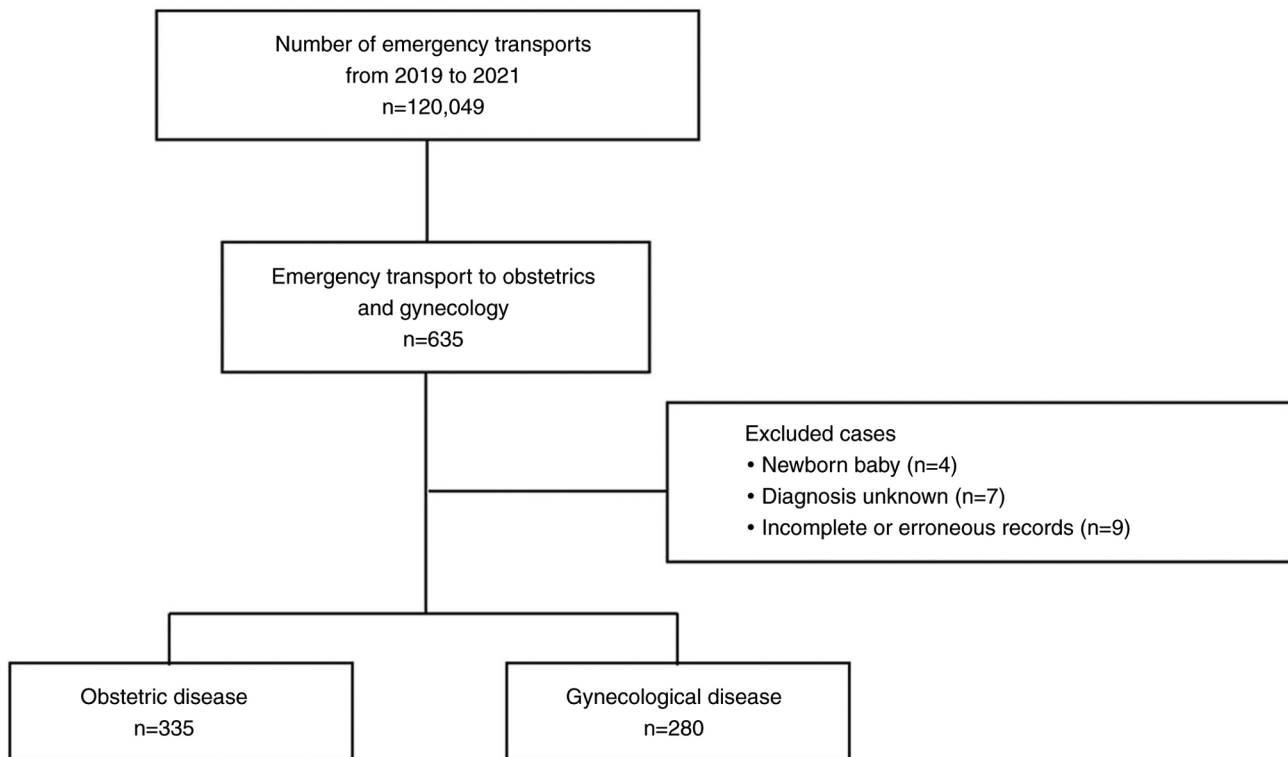


Figure 1. Extraction of target cases. Kochi Prefecture had 120,049 emergency transports between 2019 and 2021, of which 635 cases were transported to obstetrics and gynecology departments. Newborns, cases with unknown disease names, and cases with incorrect or incomplete record entries were excluded. The remaining cases were classified by disease name into obstetric (n=335) and gynecological (n=280) diseases.

Statistical analysis. All analyses were performed using Stata/MP 16.0 software (StataCorp LLC). Chi-squared tests were performed to evaluate the number of transports, severity and type of transport, and the P-values obtained were corrected using the Bonferroni method. A Kruskal-Wallis test was performed to examine age and transport time. A two-sided P-value <0.05 was considered to indicate a statistically significant difference.

Results

Between January, 2019 and December, 2021, a total of 120,049 emergency cases were transported in Kochi Prefecture, of which 635 were sent to obstetrics and gynecology departments (Fig. 1).

The number of transports, post-transportation outcomes and type of transport for obstetric diseases are presented in Table I. However, there was no significant difference in the number of transports before and after COVID-19. There were 88 transfers between hospitals (75.2%) before the spread of COVID-19 infection; however, the number decreased to 77 (72.6%) in 2020 and 68 (60.7%) in 2021. As regards post-transportation outcomes, 2.6% of cases were managed as outpatients before the spread of COVID-19 infection; however, after the spread of COVID-19 infection, the number of cases increased to 6 (5.7%) and 21 (18.8%) in 2020 and 2021, respectively. The number of cases admitted to the hospital after transport was 114 (97.4%) in 2019, 100 (94.3%) in 2020 and 91 (81.2%) in 2021, exhibiting a decreasing trend. During this period, no cases were deceased at the time of transport.

The numbers of childbirth deliveries and childbirth delivery facilities in Kochi Prefecture over the 3-year period are presented in Table II. The number of emergency transports for obstetric diseases as a percentage of the number of childbirth deliveries remained at a similar rate of 2.5-2.7% per year. The outcome, age of the patients, and time required for transport for the cases excluding transfers are presented in Table III. Significantly fewer cases were admitted to the hospital after transport, and more patients were managed as outpatients. The age of the patients transported did not differ significantly. The time required to arrive at the scene was 7-8 min, the time spent at the scene was 9-12 min, and the time elapsed from the emergency call to the physician at the receiving facility was 35-40 min; however, there was no significant difference in time to transport before and after the spread of COVID-19 infection.

The number of transports, post-transportation outcomes and type of transport for gynecological diseases are presented in Table IV. The outcome, age of the patient and time required for transport for the cases excluding transfers are presented in Table V. No significant differences were observed in outcomes, type of transport, the age of the patients and time required for transport.

Discussion

Using data on emergency transports in Kochi Prefecture, the present study examined the impact of COVID-19 infection on emergency obstetric and gynecological care. No marked changes were observed in the number of emergency transports, or the time required for transport, suggesting that the

Table I. Emergency transport of patients with obstetric diseases.

Parameter	Pre-pandemic		Post-pandemic		P-value
	All	2019	2020	2021	
Number of transports					0.98
All	120,049	41,740	38,585	39,724	
Obstetric disease	335	117	106	112	
Outcome, n (%)					<0.01
Outpatient	30	3 (2.6)	6 (5.7)	21 (18.8)	
Hospitalization	305	114 (97.4)	100 (94.3)	91 (81.2)	
Type of transport, n (%)					0.04
Transfer	233	88 (75.2)	77 (72.6)	68 (60.7)	
No transfer	102	29 (24.8)	29 (27.4)	44 (39.3)	

The table demonstrates the emergency transport of obstetric diseases in terms of severity and type of transport. (%) shows the percentage of each item in the number of transports with obstetric disease in that year. Significant differences were found in severity ($P<0.01$) of illness (deemed by the need for hospitalization or not) and type of transport ($P=0.04$). Statistical analyses were performed using the Chi-squared test.

Table II. Number of deliveries, delivery facilities and transports in Kochi Prefecture.

Parameter	2019	2020	2021
No. of childbirth deliveries in the prefecture	4,731	4,303	4,090
Facilities advocating obstetrics and gynecology	13	14	14
Childbirth delivery facility			
General hospital	7	7	7
Clinic	7	6	6
Maternity hospital	1	1	1
Transport	117	106	112
(per childbirth delivery)	2.5	2.5	2.7
Transfer	88	77	68
(per childbirth delivery)	1.86	1.79	1.66
No transfer	29	29	44
(per childbirth delivery)	0.6	0.7	1.1

The upper part of the table illustrates the number of childbirth deliveries and childbirth delivery facilities in Kochi Prefecture over a three 3 year period. On the lower part of the table, the percentage of emergency transports in relation to the number of childbirth deliveries is presented. The annual rate of emergency transports stands at 2.5-2.7% of the total childbirth deliveries, with a notable increase in the number of non-transfers in 2021.

measures taken to prevent infection had minimal impact on emergency care.

To date, at least to the best of our knowledge, no study has examined emergency transport for obstetrics and gynecology cases on a regional basis. In Osaka, one of the largest cities in Japan, the number of cases of difficulty in transporting pregnant women was lower than that of other cases and remained the same even under pandemic conditions (12).

The present study covered the period from 2019 to 2021; 2019 was considered pre-pandemic, and 2020 and 2021 were during the post-pandemic period. Even during the COVID-19 pandemic, in 2020, unknown infectious diseases spread globally, infection control measures were in a state of flux, and medical practices underwent a period of great uncertainty (13).

In addition, numerous infected individuals were older adults with a high risk of serious illness if they became infected (13). By 2021, infection control measures had been established to a certain extent. The number of infected individuals was increasing, although the main source of infection was young individuals, and the number of severe cases decreased. During this period, the number of pregnant women infected with COVID-19 also increased, and infected pregnant women were at a high risk of developing severe illness (14). Thus, the situations of infected patients varied slightly during the pandemic.

As regards the impact of COVID-19 on obstetrics and gynecology during this period, in April 2020, the Japanese Society of Reproductive Medicine issued a statement on the postponement of fertility treatment (15), and the Japanese

Table III. Emergency transport patients other than those transferred owing to obstetric diseases.

Parameter	Pre-pandemic	Post-pandemic		P-value
	2019	2020	2021	
No. of transports	29	29	44	
Outcome, n (%)				0.03
Outpatient	3 (10.3)	6 (20.7)	19 (43.2)	
Hospitalization	26 (89.7)	23 (79.3)	25 (56.8)	
Age, years; median (quartile range)	30 (25-30)	30 (25-35)	30 (25-35)	0.07
Time of transport, min; median (quartile range)				
Time required to arrive on-site	7 (6-9)	8 (7-10)	8 (6-10)	0.34
On-site time	9 (6-13)	10 (7-13)	12 (7.5-16)	0.13
Time required for hospitalization	34 (27-44)	42 (28-49)	37 (31.5-45)	0.41

The outcome, age of the patients and time taken to transport the patient are presented. The (%) in the Outcome column indicates the percentage of each item in the number of transports for that year. The time taken for transport was examined in terms of the time from the emergency call to arrival at the scene, the time spent at the scene, and the time taken from the emergency call to the handover to the physician at the destination. No significant differences were found in either case. The χ^2 test was used to examine outcomes, and the Kruskal-Wallis test was used to examine age and time taken to transport.

Table IV. Emergency transport of patients with gynecological diseases.

Parameter	Pre-pandemic		Post-pandemic		P-value
	All	2019	2020	2021	
Number of transports					0.35
All	120,049	41,740	38,585	39,724	
Gynecological disease	280	108	81	91	
Outcome, n (%)					0.18
Outpatient	144	58 (53.7)	42 (51.9)	44 (48.4)	
Hospitalization	136	50 (46.3)	39 (48.1)	47 (51.6)	
Type of transport, n (%)					0.97
Transfer	56	21 (19.4)	16 (19.8)	19 (20.9)	
No transfer	224	87 (80.6)	65 (80.3)	72 (79.1)	

The table demonstrates the emergency transport of gynecologic diseases in terms of severity and type of transport. (%) shows the percentage of each item in the number of transports with gynecological disease in that year. No change was observed in severity of illness or type of transport. A Chi-square test was performed for data analysis.

Society of Surgery proposed the postponement of non-emergency surgery (16). In fact, according to a survey by the Japan Society of Obstetrics and Gynecology, the number of surgeries (for both benign and malignant diseases) and the number of patients seeking fertility treatment decreased (17). As regards prenatal check-ups, some facilities reported that they made efforts to provide remote medical care as an infection control measure (18,19); however, they were not requested to take measures such as reducing the number of patient visits.

However, there were calls for individuals to refrain from moving to other prefectures as a countermeasure against infection. As a result, some facilities refused to transfer patients from other prefectures for delivery, or requested that individuals stay at home for 2 weeks after moving.

In the present study, emergency transport in the field of obstetrics and gynecology was examined separately for obstetric and gynecological diseases during the period when the above measures were taken in daily medical care. For gynecological diseases, the number of transports and the time required for transport did not change over the 3-year study period, and it is considered that the same operations carried out in peacetime were continued even in the pandemic situation.

By contrast, in Kochi Prefecture, there were two changes in obstetric conditions: A decrease in the proportion of transfers and a decrease in the number of patients admitted to hospital after emergency transport (Table I). Transfer to another hospital for obstetric disorders refers to the transfer of a pregnant woman who had been managed in a primary or secondary

Table V. Patients transported to emergency departments other than transfers owing to gynecological diseases.

Parameter	Pre-pandemic	Post-pandemic		P-value
	2019	2020	2021	
No. of transports	87	65	72	
Outcome, n (%)				0.71
Outpatient	54 (62.1)	42 (64.6)	43 (59.7)	
Hospitalization	33 (37.9)	23 (35.4)	29 (40.3)	
Age, years; median (quartile range)	35 (20-50)	35 (25-50)	37.5 (25-62.5)	0.40
Time of transport, min; median (quartile range)				
Time required to arrive on site	8 (7-10)	8 (6-10)	8 (6-9.5)	0.51
On-site time	13 (9-18)	14 (10-18)	14 (9-18)	0.95
Time required for hospitalization	36 (30-42)	36 (30-42)	39 (30.5-49.5)	0.54

The outcome, age of the patients and time required for transport are illustrated. The (%) in the Outcome column indicates the percentage of each item in the number of transports for that year. The time required for transport was examined in terms of time from emergency medical services call to arrival at the scene, time spent at the scene, and time from emergency medical services call to handover to the destination physician. No significant differences were found. The χ^2 test was used to examine outcomes, and the Kruskal-Wallis test was used to examine age and time taken to transport.

facility to a higher-level facility with a neonatal intensive care unit or maternal fetal intensive care unit owing to a sudden change in her condition. The decline in hospital transfers may be due to changes in the management of pregnant women, such as the early referral of patients who are at a high risk for preterm birth, etc., to higher-level facilities. In cases in which shortening of the cervical length or uterine contractions were observed during the preterm period at the primary facility, hospitalization management was previously administered at the primary facility and pregnant women were transported when the disease worsened. During this period, however, there was an increase in referrals to higher-level facilities at an early stage, rather than hospitalization management at primary facilities. This may have been due in part to a decrease in the number of primary facilities where hospitalization management could be provided. To avoid bringing infections into the hospital, patient hospitalizations other than those for delivery may have been avoided as much as possible.

Subsequently, the decrease in the number of cases requiring hospitalization after transportation was considered. Usually, pregnant women have a family doctor and receive regular check-ups. If there is a change in their condition, they first consult with their family doctor and ask whether they should schedule an appointment. The fact that pregnant women request an ambulance means that their condition has suddenly changed and they are not in a situation in which they can consult by phone. However, there was an increase in the number of cases not requiring hospitalization as they were judged to have been mild. This finding may be due to an increase in the number of cases that were undecided between hospitalization and careful outpatient management at the time of transport, and outpatient management was opted over hospitalization. This situation may have occurred as numerous facilities imposed visiting restrictions due to COVID-19, and patients preferred outpatient management, or as medical institutions avoided hospitalization due to a hospital bed shortage or to reduce the chance of

bringing COVID-19 into the hospital. However, it cannot be ruled out that there was an increase in the number of cases in which emergency calls were made even though the symptoms were mild. This could be due to the social unrest caused by COVID-19 or also since more facilities blocked deliveries and emergency calls made on holidays and during the night as the family doctor could not be reached. This point requires further investigation as countermeasures vary depending on the cause. In the former case, it is necessary to raise awareness about the proper use of ambulances. In the latter case, it is necessary to review the medical system. In addition, the indications and timing of therapeutic interventions, such as inpatient treatment, may differ depending on whether the patient is being treated at a primary or higher-level facility. Moreover, during this period, the pandemic may have affected the implementation of these interventions. Using a more objective measure of severity to confirm what changed (e.g., scoring urgency based on patient background, symptoms, laboratory findings) was also considered crucial. In addition, accumulating more detailed information on symptoms and findings may facilitate the future development of tools to assist diagnosis using artificial intelligence and other methods (20,21).

The present study used a database covering emergency transports within Kochi Prefecture. The number of individuals infected with COVID-19 is reported by prefecture (those diagnosed with COVID-19 are tabulated by prefecture and published on prefectural websites, etc.), which makes it easier to identify trends based on infection status than reports from a single center, which we believe is a strength of this study.

Despite its strengths, the present study has the following limitations: The names of diseases in the database were freely described, and for some cases, it was difficult to grasp the number of weeks of pregnancy and accurate diagnoses. There were also cases in which the outcome was unknown. In the field of obstetrics, maternal deaths, stillbirths, premature births and other complications have increased since the pandemic

occurred (22,23). Conversely, there have been reports of an increase in maternal transport, although the rate of premature births remained the same as before the pandemic (24). Details such as changes in diseases could not be evaluated in the present study. In addition, the present study evaluated the cases of difficult transportation only based on the time required for transportation. Difficult transportation is generally evaluated by the number of facilities that were requested to accept transportation and the extension of on-site stay time. However, owing to the unique circumstances of Kochi, these indicators may not be able to determine difficult transportation. First, the number of facilities contacted was not listed in the data used herein. In Kochi, the number of hospitals is limited, and the number of facilities that can accept transportation is limited. Therefore, the number of times transportation was requested was not an indicator of cases of difficult transportation even if it was listed. Second, on-site stay time was associated with the time it takes to determine the patient's destination, which is usually performed after the patient has been placed in an ambulance. However, Kochi Prefecture is geographically wide from east to west, and medical institutions are concentrated in the center of the prefecture. Therefore, in some areas, the time on site may not be an indicator of difficulty of transport, as patients often leave the site and head to the central part of the prefecture before a decision is made on where to transport them. The fact that hospitals could maintain normal medical functions to a certain extent in the department of obstetrics and gynecology, which was not directly affected by COVID-19 infection, was a factor that prevented major disruptions in emergency transport. With fewer facilities handling deliveries owing to a shrinking population, it is unclear whether facilities can maintain their medical functions when a new pandemic or other socially disruptive event occurs in the future. Furthermore, it has been predicted that Kochi Prefecture will be hit by a huge Nankai Trough earthquake in the near future, at which time medical treatment functions will be temporarily paralyzed, and will likely take some time to recover (25). In considering emergency obstetrics and gynecology care in rural areas, one future challenge is establishing a medical care system that does not disadvantage patients, such as by decreasing the number of delivery facilities, in an environment that changes year by year. To this end, strengthening cooperation between hospitals and clinics, applying artificial intelligence technology to support diagnoses, using information and communication technology, and broadening the area of medical cooperation are some of the measures that can be implemented.

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Availability of data and materials

The data supporting the present findings are under license from Kochi Prefecture and are not publicly available. The dataset is surveillance conducted by the Kochi Prefecture Healthcare Policy Division Department, for monitoring emergency medical care and is not publicly available, although its use may be permitted following ethical review.

Authors' contributions

TT was involved in the conceptualization and methodology of the study, and in the writing the original draft of the manuscript. MM and HM were involved in the study methodology. RN and KN were involved in the study methodology, and supervised the study. TT and MM confirm the authenticity of all the raw data. All authors (TT, MM, HM, RN, KN, NS, and NM) were involved in the interpretation of and in reporting the findings of the study. All authors were involved in the conceptualization of the study, contributed to, and have read and approved the final version of the manuscript.

Ethics approval and consent to participate

An opt-out recruitment was adopted to obtain consent in the present study on the Kochi-Iryo-Net website. There was no objection from participants to use their information. The present study was approved by the Ethical Review Committee of Kochi University School of Medicine in 2021 (no. 2021-142). The present study was approved by and complied with the Ethical Guidelines for Medical and Biological Research Involving Human Subjects of the Ministry of Education, Culture, Sports, Science and Technology; the Ministry of Health, Labour and Welfare; and the Ministry of Economy, Trade and Industry and the Declaration of Helsinki (2013 amendment).

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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