The Journal of Obstetrics and Gynecology of India (July-August 2021) 71(4):361–368
https://doi.org/10.1007/s13224-021-01537-3

ORIGINAL ARTICLE

Preliminary Results from the FOGSI's National Registry on Pregnancy with COVID-19

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Received: 20 May 2021 / Accepted: 2 August 2021 / Published online: 31 August 2021

Abstract

Background/purpose of the study The obstetric population is believed to be more susceptible to adverse consequences of coronavirus disease COVID-19 as compared to the general populace. Clinical characteristics and outcomes data related to COVID-19 infection in obstetric cases are limited and evolving. Most importantly, studies reporting Indian data are strikingly few and of single centre. The objective of our study was thus to address these lacunae using data registered in the FOGSI's National registry on COVID-19 infection in pregnancy (FOGSI COVID registry).

Methods We conducted an observational study using data retrieved from the FOGSI COVID registry. Fifty-three hospital departments participating in the registry populated data related to laboratory confirmed and hospitalized COVID-19 obstetric patients. Data for the period of 28 April 2020 to 28 August 2020 were extracted from the registry. A subset of the data was formatted, curated, standardized and harmonized. Descriptive analysis was carried out, and results reported.

Results Of the 989 cases analyzed, 956 women were pregnant and 33 women were in the postpartum period. A total of 569 women (61.71%, $n=922$) were multi-gravida, and 713 women (72.98%, $n=977$) belonged to the 21–30 years age group. A total of 492 cases (52.73%, $n=966$) had a gestational age > 37 weeks. A total of 754 women (83.41%, $n=904$) were asymptomatic, and 32 cases (3.54%, $n=904$) had severe acute respiratory infection (SARI). Fifty-six women (7.19%, $n=779$) required critical care and ten women (1.01%, $n=989$) died. A total of 771 pregnant women (97.23%, $n=793$) gave birth of which 455 cases (59.01%) underwent a lower segment caesarean section (LSCS). There were 749 cases (95.17%, $n=771$) of live birth that included eight cases of twin deliveries. 195 infants (28.34%, $n=688$) were admitted to the NICU, and 13 infants (2.99%, $n=435$) tested COVID-19 positive in the neonatal period. Twelve infants (1.54%, $n=779$) died.

Conclusion 83.41% pregnant women were asymptomatic. COVID-19 infection in obstetric cases from India led to 59.01% LSCS procedures which are lower than many other countries. COVID-19 infection led to a higher maternal mortality and IUFD rate as compared to pregnant women that did not have COVID-19 infection in India. Vertical transmission rate is 2.99% and at par with other countries.

Keywords COVID-19 · Pregnancy · India · Registry · FOGSI

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Introduction

Apart from being a novel infection, the COVID-19 pandemic has spread with a disruptive and exponential scale. Healthcare organizations worldwide have been grappling to understand and manage it with limited resources and data. While each member of the world populace is at considerable risk of COVID-19 infection, the obstetric population (pregnant women, women in labor—especially if they are acutely ill) is believed to be more susceptible. Their susceptibility is higher due to the mechanical, physiological and immunological changes that take place during pregnancy [1–4]. Pregnant women are also known to be disproportionately

affected by respiratory infections. They are not only at a higher risk of developing symptoms but also related morbidity and mortality. This risk is more pronounced in the presence of pre-existing comorbidities, pregnancy-related complications, limited care in the time of lockdown and social distancing, as well as due to the fact that COVID 19 virus is associated with severe illness [2, 5–7].

Past data point towards the adverse impact of severe acute respiratory syndrome-related coronavirus (SARS-CoV) and middle east respiratory syndrome coronavirus (MERS-CoV) epidemics on pregnant women [2, 3]. These apprehensions are further enhanced as reliable data related to prevention, disease progression, management, risks, complications, outcomes of COVID-19 infection in pregnant women are limited and evolving [3, 6, 8–14]. Where data is available, their utility is limited by characteristics like small sample size, short duration of study period and lack of enough follow-up data [7]. Additionally, there is a paucity of data related to neonates born to these mothers [4]. Most importantly, studies reporting Indian data are strikingly few, and where available, they either have a small sample size and involve a few participating sites or are region-specific [15, 16]. This limits the ability of healthcare workers and policy makers to develop a better understanding of the disease and effectively design and apply preventive as well as clinical strategies [7].

In light of these facts and challenging times, The Federation of Obstetric and Gynaecological Societies of India (FOGSI) working group recognized the urgent need to rapidly collect data related to obstetric cases diagnosed and hospitalized with COVID-19 in India and guide clinical care and healthcare policy. They responded by designing and deploying the FOGSI's National registry on COVID-19 infection in pregnancy (FOGSI COVID registry) in April 2020.

The purpose of this study is to describe the clinical characteristics as well as obstetric and perinatal outcomes of obstetric cases diagnosed and hospitalized with COVID-19 in India and registered in the FOGSI COVID registry.

Material and Methods

Registry Information

The FOGSI COVID registry is an ongoing national registry initiated in April 2020 by FOGSI. The registry was designed to: (1) facilitate prospective, online data collection from multiple hospital departments across India in a uniform manner and (2) facilitate research studies using the data collected, whose findings would then guide clinical and policy decisions.

The FOGSI COVID registry working group designed the data collection form and selection criteria after performing literature review and consulting other similar global efforts. Members of the FOGSI working group designed the online data collection form using Google forms [17]. It captures data related to patient demographics, clinical presentation, history, diagnosis and investigations, management, obstetric and perinatal outcomes. It captures data related to 126 variables.

Study Design

We conducted an observational study using data retrieved from FOGSI COVID registry—a prospective national registry.

Study Population and Participants

We extracted registry data related to all obstetric cases diagnosed (laboratory-confirmed) and hospitalized with COVID-19 at hospital departments participating in the FOGSI COVID registry from 28 April 2020 to 28 August 2020.

Data Collection

A total of 53 hospital departments were invited to contribute data into the FOGSI COVID registry. Each participating hospital department was advised to populate consecutive obstetric cases meeting the following selection criteria: pregnant or women in their postpartum period hospitalized with laboratory-confirmed COVID-19 infection. Patients with unconfirmed COVID-19 infection are not populated in the registry. Competent obstetricians affiliated to the hospital departments participating in the FOGSI COVID registry managed each patient by using applicable clinical protocols and clinical judgement. Each obstetrician or his/her authorized representative manually abstracted data from in-patient department forms (IPD forms) related to each eligible patient and populated it into the online registry. It takes approximately 15 min to populate data into the online registry form.

Study Management

The FOGSI sponsored this study. The FOGSI working group coordinates data collection efforts, manages access to the resulting registry database and carries out follow-up with member hospital departments to address data quality issues. The FOGSI working group circulated instructions related to populating data into the registry and a link to the data collection form to the participating hospital departments. A total of 53 hospital departments voluntarily agreed to participate in the registry and contribute data without any remuneration. Data collection began on 28 April 2020 and is currently ongoing.

Data Analysis

Members of the FOGSI working group extracted data that met the inclusion and exclusion criteria of this study and shared the resulting dataset with the data analysis team. Next, the data analysis team formatted, curated, standardized and harmonized the resulting dataset. Duplicate and empty records were excluded from the study. Where possible, FOGSI working group members made attempts to populate missing data by coordinating with participating hospital departments. Attempts were also made to derive missing data from other related variables within the dataset. For the purpose of this observational study, we analyzed a subset of the registry variables. These included demographic, clinical, medical history, diagnostic, therapeutic, perinatal and neonatal outcome variables. The data analysis team carried out descriptive analysis of the data. Categorical variables are reported using absolute frequencies and percentages (where applicable) after deducting missing records.

Results

A total of 53 hospital departments participating in the FOGSI COVID registry contributed data from 28 April 2020 to 28 August 2020. Data related to 1012 pregnant or postpartum women diagnosed and hospitalized with COVID-19 infection were populated in the registry during this period. Of the 1012 records in the dataset, 19 sets of records were duplicates, and two sets of records were triplicates. After their removal, the final dataset consisting of 989 records was used for analysis.

Of the 989 cases, 956 women were pregnant and 33 women were in their postpartum period when they were diagnosed and hospitalized with COVID-19 infection. A total of 569 women (61.71%) were multi-gravida, and 713 women (72.98%) belonged to the 21–30 years age group. A total of 839 (89.92%) pregnant women were in their third trimester of pregnancy, and 492 cases (50.93%) had a gestational age of more than 37 weeks.

Of the 989 cases, data for comorbidities were available for 68 cases. Of these, 18 cases (26.47%) each had a chronic history of hypertension and thyroid disorders, respectively. Nine cases (13.24%) had a history of diabetes, while seven cases (10.29%) had a history of more than one pre-existing comorbidity. Of the 598 cases where data related to pregnancy-related complications were available, 226 cases (37.79%) suffered from Anemia. Forty-three cases (7.19%) reported other maternal complications that included pre-eclampsia (4 cases), eclampsia (2 cases), oligohydramnios (7 cases), placenta accreta (1 case), placenta previa (4 cases), threatened preterm delivery (6 cases), post datism (3 cases), premature rupture of the membranes (PROM) (15 cases) and obstructed labor (1 case). 61 cases (10.20%) had more than one pregnancy-related complication. (Table 1).

Of the 904 cases where relevant data were available, 754 women (83.41%) were asymptomatic when diagnosed and hospitalized with COVID-19 infection. Thirty-two cases (3.54%) had severe acute respiratory infection (SARI), of which 29 cases (3.21%) had a milder version. Notably, 31 cases (3.43%) had multiple presenting symptoms (Table 2).

Of the 188 cases where data related to X-ray imaging were available, 15 cases (7.98%) were diagnosed with 'Radiological abnormality with Pneumonia and Pneumonia like features.' Similarly, of the 29 cases where computerized tomography (CT) scan data were available, five cases (17.24%) were diagnosed with Pneumonia. Data related to C-reactive protein (CRP) diagnostic tests were available for 173 cases, of which 54 cases (31.21%) had a CRP value of more than 10 mg/L. Data related to symptomatic treatment were available for 454 cases. Of these, 191 cases (42.07%) received a combination of various interventions [IV fluids, non-steroidal anti-inflammatory drugs (NSAIDs), oxygen, paracetamol) as a part of symptomatic treatment. Data related to specific treatment were available for 575 cases. Of these, 247 cases (42.96%) were treated with antibiotics, and 203 cases (35.30%) were treated with 'Hydroxychloroquine + Azithromycin'. Fifty-six women (7.19%, $n = 779$) required critical care of which two women required mechanical ventilation and 23 patients were administered oxygen. In all ten women (1.01%, $n = 989$) died (Table 3).

Data for obstetric outcomes were available for 787 cases. Sixteen women (1.98%) had a pregnancy loss (Abortion or ectopic pregnancy). Of the remaining 771 women who gave birth, only 749 women (95.17%) had a live birth, and intrauterine fetal death (IUFD) was reported for 22 cases (2.72%) (15 cases of fresh stillbirth and 7 cases of macerated stillbirth). Apart from these, 22 women (2.72%) had an ongoing pregnancy. Of the 771 women who gave birth. 455 cases (59.01%) underwent a Lower segment Caesarean section (LSCS), and 307 cases (39.82%) had a vaginal delivery. There were eight cases of twin deliveries. Of the 757 live birth cases, 93 infants (11.50%) were delivered preterm (Table 4).

Of the 728 infants whose birth weight data were available, 503 infants (69.09%) weighed more than 2.5 kg at birth. Out of eight twin deliveries, six twins (75%) weighed between 2 and 2.5 kg. Of the 656 infants whose isolation data were available, 397 infants (60.52%) (included seven twins) were isolated from their mother post-birth. Of the 688 infants whose NICU admission data were available, 195 infants (28.34%) (included five twins) were admitted to the NICU during the neonatal period. Of the 435 infants who were tested for COVID-19 infection, only 13 infants (2.99%) tested positive. Finally, of the 694 infants whose data related to feeding methods in

Table 1 Characteristics of pregnant women with laboratory confirmed COVID19 infection and admitted to hospitals in India, 28 April 2020 to 28 August 2020

Variable	Categories	Number of pregnant women
Age (years) ($n=977$)	< = 20 years	99 (10.13%)
	21–30 years	713 (72.98%)
	31–40 years	161 (16.48%)
	> 40 years	4 (0.41%)
Parity ($n=922$)	Multigravida	569 (61.71%)
	Primigravida	353 (38.29%)
Gestational age at diagnosis (weeks) ($n=966$)	< 22 weeks	71 (7.35%)
	22–27 weeks	32 (3.31%)
	28–33 weeks	77 (7.97%)
	34–37 weeks	261 (27.02%)
	Above 37 weeks	492 (50.93%)
	Post-natal	33 (3.42%)
Pregnancy related complications ($n=598$)	Ectopic pregnancy	1 (0.17%)
	Fetal anomaly	3 (0.50%)
	Fetal complication (Distress/IUGR)	11 (1.84%)
	Maternal complication: gestational diabetes mellitus	8 (1.34%)
	Maternal complication: gestational hypertension	16 (2.68%)
	Maternal complications (Others)	43 (7.19%)
	Anemia	226 (37.79%)
	Liver disorders	5 (0.84%)
	Thrombocytopenia	3 (0.50%)
	More than one complication	61 (10.20%)
	None	221 (36.96%)

Table 2 Clinical symptoms of pregnant women with laboratory confirmed COVID19 infection on hospital admission

Variable	Categories	Number of pregnant women
Maternal clinical symptoms on admission ($n=904$)	Asymptomatic (met testing criteria due to contact/exposure/travel and others)	754 (83.41%)
	Fever	72 (7.96%)
	Gastrointestinal symptoms	5 (0.55%)
	Generalized symptoms (Body ache, headache, backache, fatigue, myalgia, chills, rigors)	10 (1.11%)
	Mild SARI	29 (3.21%)
	Severe SARI	3 (0.33%)
	Multiple presenting symptoms	31 (3.43%)

Table 3 Hospital management of pregnant women with laboratory confirmed COVID-19 infection in India, 28 April 2020 to 28 August 2020

Variable	Categories	Number of pregnant women
Specific treatments ($n=575$)	Antivirals only	10 (1.74%)
	Hydroxychloroquine + Azithromycin only	203 (35.30%)
	Antibiotics only	247 (42.96%)
	Combination therapy	115 (20.00%)
Required critical care ($n=779$)		56 (7.19%)
Maternal mortality ($n=989$)		10 (1.01%)

the neonatal period were available, 415 infants (59.80%) (included two twins) received breastfeeding only. Twelve infants (1.54%) died in the neonatal period. (Table 5).

Table 4 Pregnancy outcomes of pregnant women with laboratory confirmed COVID-19 infection and admitted to hospitals in India, 28 April 2020 to 28 August 2020

Pregnancy outcomes	Categories	Number of pregnant women
Obstetric outcomes ($n=787$)	Abortion (Missed/Incomplete/Complete/MTP/D&C/ Early pregnancy failure)	13 (1.65%)
	Ectopic pregnancy	3 (0.38%)
	IUFD—fresh still birth	15 (1.91%)
	IUFD—macerated stillbirth	7 (0.89%)
	Live birth[a]	749 (95.17%)
Mode of birth ($n=771$)	Lower segment caesarean section (LSCS)	455 (59.01%)
	Normal vaginal delivery	307 (39.82%)
	Instrumental delivery	9 (1.17%)
Perinatal outcomes ($n=779$ that includes 8 twins)	IUFD (fresh stillbirth/ macerated stillbirth)	22 (2.82%)
	Full term live birth (includes 8 twin births)	652 (83.70%)
	Preterm live birth	93 (11.94%)
	Neonatal death after day 1	3 (0.39%)
	Neonatal death on day 1	1 (0.13%)
	Preterm live birth and neonatal death after day 1	6 (0.77%)
	Preterm live birth and neonatal death on day 1	2 (0.26%)

[a]including full term, preterm live birth and neonatal death (on and after day 1)

Table 5 Neonatal outcomes among live born babies of pregnant women with laboratory confirmed COVID-19 infection and admitted to hospitals in India, 28 April 2020 to 28 August 2020

Variable	Categories	Number of cases
Birth weight of infant ($n=728$)	Less than 2 kg	42 (5.77%)
	2 to 2.5 kg	183 (25.14%)
	Above 2.5 kg	503 (69.09%)
Birth weight of infant (Baby2 in 8 twin deliveries)	Less than 2 kg	1 (12.50%)
	2 to 2.5 kg	6 (75.00%)
	Above 2.5 kg	1 (12.50%)
Infants that required NICU admission ($n=688$ that includes 8 twins)		195 (28.34%)
Infants that were isolated from their mother ($n=656$ that includes 8 twins)		397 (60.52%)
Infant feeding method ($n=694$ that includes 8 twins)	Breast feeding only	415 (59.80%)
	Top feeding only	272 (39.19%)
	Combination	7 (1.01%)
Infants infected with COVID-19 (vertical transmission) ($n=435$ that includes 5 twins)		13 (2.99%)

Discussion

To the best of our knowledge, this is the first observational study based on a national registry that captured data related to obstetric cases diagnosed and hospitalized with COVID-19 across India.

We noted that more than half of the cases in our study had a gestational age of more than 37 weeks (50.93%). Two recent studies involving obstetric cases with COVID-19 infection and conducted in India [16] and China [14], respectively, report similar observations. On the contrary, two recent studies involving obstetric cases with COVID19 infection from the USA [12] and UK [9] observed a lower proportion of pregnant women with gestational age of more than 37 weeks. Notably, only one of these three studies had a large sample size and was derived from a population-based cohort study [9]. Other recent studies involving obstetric cases with COVID-19 infection from China and the USA did not report relevant data [8, 18].

More than half of the cases (63.04%) in our study had a history of pregnancy-related complications. Anemia, PROM, gestational hypertension and gestational diabetes were common pregnancy-related complications observed in

our study. The latter (gestational diabetes) was also reported by two recent studies as a common pregnancy-related complication [9, 19]. In cases where data were available, we observed that hypertension, thyroid disorders and diabetes were common pre-existing comorbidities. Apart from these disorders, asthma was also reported as a common pre-existing comorbidity by other recent studies reporting data related to COVID-19 infection in obstetric cases [8, 9]. A recent SRMA of seven studies reporting prevalence of comorbidities in patients infected with SARS CoV-2, reported diabetes and hypertension [20] as common pre-existing comorbidities.

In common with results reported by recent studies from India [16, 21], more number of cases (83.41%) in our study were asymptomatic. Using data derived from six recent studies that universally tested all pregnant women, a recent review observed that the rates of asymptomatic infection were high (Range: 43.5–92%, three studies from the USA: 43.50%, 66% and 88%, respectively, One study from the UK: 89%, One study from Italy: 67% and One study from Portugal: 92%) [22]. Additionally, other recent studies from the USA reporting data related to COVID-19 infection in obstetric cases also observed a high rate of asymptomatic and mild/asymptomatic cases respectively [23, 24].

We observed that 7.19% cases in our study required critical care. This is in contrast with 1.85% cases reported by a large nationwide, prospective cohort study involving pregnant and recently pregnant women infected with COVID-19 in the USA [8]. On the other hand, a higher rate (9.3%) of admission to intensive care unit was reported by a recent systematic review and meta-analysis (SRMA) which analyzed 32 obstetric cases with COVID19 infection [25]. A recent review involving 1287 obstetric cases with COVID-19 infection, noted that 111 cases (0–18%) had severe disease and 50 cases (0–5%) had critical disease [22].

The corrected COVID-19 infection fatality rate derived from sero-prevalence data ranges from 0 to 1.54% [26]. The number of maternal deaths (10 cases, 1.01%) observed in our study was lower as compared to data reported by a single site, retrospective, observational study conducted in India (2.12%) [16]. On the contrary, it was higher as compared to the national maternal mortality rate for India (2014-16, 0.13%, 130 per 100000 live births) [27]. Data related to COVID-19 infection in obstetric cases from a large Italian case series (617 pregnant women with COVID-19) and a large nationwide UK-based cohort study reported a lower (0.2%) [28] and similar maternal mortality rate (1%) [9], respectively. While Di Mascio D et al. [25] did not report any maternal death in their SRMA; eight maternal deaths (0.62%) were reported in a review of 60 articles carried out by Pettiroso et al. [22]. In our study, cause of death data was available for four cases of which three patients died from respiratory failure, and one patient died due to complications arising out of attempted suicide through hanging.

More than half of the cases (59.01%) in our study were delivered by caesarean section. In a recent SRMA of six articles reporting data related to COVID-19 infection in 41 obstetric cases, caesarean section was carried out in 92.68% cases [25]. Additionally, in a review of 60 articles reporting data related to COVID-19 infection in 1287 obstetric cases, Pettiroso et al. [22] reported that caesarean section was carried out for more than 40% pregnant women except in five studies. Data related to mode of delivery, obstetric and perinatal outcomes are not available for 180 cases in our study. We believe that absence of this data probably indicates that these cases continued their pregnancy.

The preterm live birth (PTB) rate in our study was 13.34%. Although this rate is similar to the Indian national preterm live birth rate (13·6%) reported by Chawanpaiboon et al. [29], it is lower than the data (14.9%) reported by Bhatnagar et al. [30]. It should be noted that the former national PTB rate was derived from modelled national estimates while the latter was based on a hospital-based cohort study (GARBH-Ini) involving 1,662 live births at a single site in India. Recent studies reporting outcomes of obstetric cases with COVID-19 infection data from the USA, UK and France report a higher PTB rate (14.6%, 25% and 27.6%, respectively) [9, 28, 31]. Finally, Pettiroso et al. [22] observed a PTB rate ranging from 10 to 100% in 22 of the 60 articles included in their review.

Nearly one-fourth (28.34%) of the infants in our study required admission to the neonatal intensive care unit (NICU). Although data related to the exact cause of admission to NICU are not available in our dataset, we believe that these were preventive in nature due to the prevailing uncertainty regarding prognosis of children born to COVID-19 positive mothers. Recent data from India reported a lower NICU admission rate (18.32%) for infants born to COVID-19 infected mothers primarily due to low birth weight [16]. At the same time, cohort studies reporting data related to COVID-19 infection in obstetric cases from the USA (25.7%) [31] and UK (25%) [9] report similar infant NICU admission rates.

Thirteen infants (2.99%) in our study were diagnosed with COVID-19 infection in their neonatal period. Our observations are aligned with those reported in a recent review that analyzed data related to 655 infants born to pregnant women infected with COVID-19 across ten studies (2.90%) [22]. On the contrary, recent data from India reported a lower COVID-19 infection rate in infants born to mothers infected with COVID-19 (2.29%) [16].

In our study, we observed 22 cases (2.82%, 28/1000) of IUFD and 12 cases (1.54%, 15/1000) of neonatal mortality. The IUFD rate is higher than the prevalent Indian IUFD rate (10/1000) [32] as well as recent data (1.07%, 10.68/1000)

reported by Pettiroso et al. [22] in their review article. The neonatal mortality rate is lower as compared to the early neonatal mortality rate (18/1000) [33] and neonatal mortality rate (23.5/1000 live births) prevalent in India in 2017 [34]. On the contrary, it is higher than the neonatal mortality rate (0.92%) reported by Pettiroso et al. [22] in their review article involving 655 infants born to pregnant women infected with COVID-19 across ten studies.

In addition to selective reporting that may have been carried out by participating sites, our study also has some other limitations. Firstly, multiple variables in our dataset had missing data. Abstracting data from IPD case records and populating them in the online registry under the current challenging circumstances is a daunting task. Although additional efforts were made to reach out to contributing sites and populate missing data in the dataset used for this study, they did not yield enough data for many variables. Secondly, the COVID-19 registry does not collect follow-up data which limits the types of analysis that can be carried out using available data.

Conclusion

83.41% pregnant women were Asymptomatic. COVID-19 infection in obstetric cases from India led to 59.01% LSCS procedures which are lower than many other countries. COVID-19 infection led to a higher maternal mortality and IUFD rate as compared to pregnant women that did not have COVID-19 infection in India. Vertical transmission rate is 2.99% and at par with other countries.

Acknowledgements We would like to acknowledge FOGSI and each hospital department participating in the FOGSI COVID registry. Specifically, we would like to acknowledge following FOGSI members: Dr. Reena Jatin Wani (reena.wani@rediffmail.com), Dr. Shrinivas Gadappa (gadappashrinivas@gmail.com), Dr. Samir Ramesh Pradhan (drsamirpradhan@gmail.com), Dr. Nozer Khursed Sheriar (nsheriar@gmail.com), Dr. Ajith S (drajiths@hotmail.com), Dr. Parul Tushar Shah (parulshah11@hotmail.com), Dr. Ajesh N Desai (andesai38@gmail.com), Dr. Ashish Vishnu Gokhale (dravgokhale@yahoo.com), Dr. Saroj Singh (drsarojsingh@hotmail.com), Dr. Rajesh Yashwant Mhatre (rmhatre120169@gmail.com), Dr. Raina Chawla (raina.chawla@gmail.com), Dr. Vineeta Gupta (vineetahims@yahoo.co.in), Dr. Vandana Kanumury (kanumuryvandana@gmail.com), Dr. Yamini Nilesh Trivedi (yamilesh2@yahoo.com), Dr.Ashvin Dayalal Vachhani (avachhani74@gmail.com), Dr. Jitesh Shah (avachhani74@gmail.com), Dr. Uma Pandey (uma.pandey2006@yahoo.com), Dr. Anita Kant (dranitakant@yahoo.com), Dr.Kasturi V Donimath (dkasturiv@rediffmail.com), Dr. Poonam Verma (poonam@mgims.ac.in), Dr. Anita Abhijeet Soni (anita.soni8@hotmail.com), Dr. Prabhadevi Kodey (drprabhakodey@gmail.com), Dr. Nidhi Gupta (drnidhigupta19@gmail.com), Dr. Sarita Agrawal (drsaritaagrawal@yahoo.com), Dr. Nalini Inderpal Anand (docnalini.anand@gmail.com), Dr. Vrunda Joshi (vrunda2007@rediffmail.com), Dr. Tripti Nagaria (triptinagaria@gmail.com), Dr. Kavita N. Singh (drkavitasingh67@gmail.com), Dr. Manpreet Kaur Tehalia (dr_mjtehalia@yahoo.co.in), Dr. Datta Manohar Panandikar (dattamp63@gmail.com), Dr. Bharti Maheshwari (bhartinalok123@gmail.com).

Funding This observational study did not receive any external funding.

Declarations

Conflict of interest No conflict of interest.

Ethical approval The corresponding author would like to state that this paper is compliant with ethical standards. There are no relationships or interests to be declared, financial or otherwise, that any of the authors hold which lead to any conflict of interest. No research grant has been released by any external funding agency for this study. No financial support has been sought from any programs for this study. All ethical guidelines as prescribed by the 1964 Helsinki declaration have been followed in the preparation of the manuscript. This study does not involve any research on animals.

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