

Comparative Study of Feto-Maternal Outcome of Antenatal Cases as per the Standard WHO Guidelines vs Revised Antenatal Visit Schedule during COVID 19 Pandemic

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ABSTRACT

Background: Good antenatal care helps a woman face labour in good health and optimum conditions. The National Institute for Health and Care Excellence (NICE) and WHO guidelines suggest 15 visits in the whole pregnancy. Keeping in view the COVID-19 pandemic to reduce the exposure of pregnant ladies the number of antenatal visits was reduced to 7 milestone visits and outcome was noted. This study aimed to do a comparative study of feto-maternal outcome in antenatal cases at our centre using standard WHO protocol vs. revised antenatal protocol during COVID-19 pandemic.

Subjects and Method: This was an observational study done at a tertiary care center of an Armed forces hospital with target population as pregnant ladies attending antenatal care Out patient department of the hospital during COVID19 pandemic Vs Antenatal cases in previous 1 year. A comparative analysis of pregnancy outcome, maternal variables during pregnancy and delivery along with neonatal variables was done.

Results: There were lesser deliveries by 41.7% as compared to non-COVID times. There was an increase in the caesarean delivery rate and instrumental delivery rate during COVID times by 11% and 53% respectively. There was increase in Vaginal birth after caesarean (VBAC) by 26.6%. The incidence of fetal growth restriction, placental abruption, maternal anaemia and gestational diabetes mellitus, oligohydramnios and polyhydramnios was low. The incidence of spontaneous abortions was also low in our study. In contrast, the incidence of pre-term deliveries doubled from 7.4% to 13.4%. Neonatal morbidity and mortality indicators like Neonatal Intensive care unit (NICU) admissions showed a rising trend of 1.7% during the COVID (14.6% to 16.3%) with a minimal rise in early neonatal deaths by 0.2%.

Conclusion: Our model doesn't show an increase in maternal, neonatal morbidity, and mortality. This model can be used as a standard of care for Antenatal patients during Pandemics. It reduces the risk exposure of the gravid mother without any significant increase in maternal and neonatal morbidity and mortality.

Keywords: antenatal care, COVID-19 pandemic, revised antenatal schedule.

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Cite this as:

Bhardwaj B, Menon A, Prajapati VK, Kathi AS, Singh R (2023). Comparative Study of Feto-Maternal Outcome of Antenatal Cases as per the Standard WHO Guidelines vs Revised Antenatal Visit Schedule during COVID 19 Pandemi. J Matern Child Health. 08(01): 125-133. <https://doi.org/10.26911/thejmch.2023.08-01.12>.



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BACKGROUND

The care of pregnant woman to achieve a

healthy pregnancy and delivery of a healthy baby would come under the perspective of

antenatal care. Good antenatal care helps a woman face labour in good health and optimum conditions. Proper antenatal care check-up provides necessary care to the mother and helps to identify any complications of pregnancy such as anaemia, hypertension etc. in the mother and slow/ inadequate growth of the fetus. Antenatal care provides an opportunity to prepare a birth plan identify the facility for delivery and referral in case of complications. Data from various observational studies suggest that good ante-natal care can reduce maternal and neonatal mortality and morbidity. The number of antenatal visits and period of gestation at which antenatal care has been started has a strong bearing on the outcome of pregnancy after controlling confounding factors like length of gestation (Kaunitz et al., 1984; Dowswell et al., 2015). However, there is no definite guideline to suggest the minimal number and frequency of these antenatal visits, and what all is to be included as the essential content of these visits.

In the United States and even in India the usual practice as per the WHO NICE guidelines is approximately 15 prenatal visits for nulliparous women with uncomplicated pregnancies which includes 4 weekly visits till 28 weeks of gestation, then every 2 weekly visits from 28 to 36 weeks, and then every week until 40 weeks/ delivery (Kilpatrick et al., 2017). Parous women with a low-risk profile may be advised less frequent visits in OPD. High-risk women depending upon the nature of risk factors may be seen more frequently in OPD. As per this schedule, even a woman with a low-risk pregnancy with the first visit at six weeks of gestation and the last visit at 40 weeks will still have 15 prenatal visits.

To follow this standard prenatal visit schedule requires significant effort and planning on the part of both the doctor and the patient without clear evidence of benefits at

times. Comparing women who had more than 10 prenatal visits with those who had 10 or fewer prenatal visits did not reveal any differences in neonatal intensive care unit admissions, five-minute Apgar score <7, neonatal demise, or small for gestation in a Cohort study of 7200 women with low-risk profile (Carter et al., 2016). Thirty three per cent rise in induction rates and 50% higher caesarean delivery rates were seen in the high utilization group than the women in the low utilization group, but no significant data is available to prove this causal relationship (Carter et al., 2016). In patients with high-risk pregnancies as per various criteria, enhanced prenatal care including extra office visits, health education, home visits, telephone contact, psychosocial support) have not reported significantly improved outcomes compared with standard care (Klerman et al., 2001; Villar et al., 1993).

The National Institute of Health and Clinical Excellence (NICE) emphasises reduced ANC visits. NICE Guidelines emphasised the need for 10 ANC visits for nulliparous patients 7 ANC visits for parous women with a specific purpose/ goal of each visit (Antenatal care: Routine care for the healthy pregnant woman, 2008). This approach takes into account the cost and time constraints of modern society and the lack of proven efficacy of frequent prenatal visits in randomized trials.

During the phase of COVID infection from April 2020 during the lockdown by the government, our hospital decided to restrict the number of ANC visits to 7 visits to provide optimal antenatal care and reduce the risk of COVID-19 infection to patients, relatives and hospital staff as well. The study aimed to do a comparative study of feto-maternal outcome in antenatal cases at our centre using standard WHO protocol Vs Revised antenatal protocol during COVID-19 pandemic.

SUBJECTS AND METHOD

1. Study Design

It was an observational study. This study conducted 1 year from 1 April 2020 to 31 March 2021. Period of study was 1 year.

2. Population and Sample

Study population: All pregnant ladies attending antenatal care OPD in a tertiary care centre of Armed Forces during COVID-19 pandemic from 1 April 2020 to 31 March 21 vs antenatal cases of the previous year (2019 during non-COVID times).

Inclusion criteria: a) All low-risk pregnancies registered in first-trimester; b) Age limit- 20-35 years.

Exclusion criteria: a) teenage pregnancy; b) Advanced Maternal Age; c) Patients with medical disorders.

3. Study Variable

Pregnancy Outcome: live birth, abortion

Mode of Delivery: normal delivery, caesarean delivery, instrumental delivery, vaginal birth after caesarean

Maternal complications: anaemia, hypertensive disorders of pregnancy, gestational diabetes, oligohydramnios, polyhydramnios, Prelabour rupture of membranes, preterm prelabour rupture of membranes, abruption, intrahepatic cholestasis of pregnancy, maternal mortality.

Fetal outcome: low birth weight, NICU admissions, still born, early neonatal deaths.

4. Operational Definition of Variables

Live birth was the term used to record a birth whenever the new born at or sometime after birth breathes spontaneously or shows any other sign of life such as a heartbeat or definite spontaneous movement of voluntary muscles.

Abortion was spontaneous or induced termination of pregnancy before fetal viability

Normal delivery was spontaneous in onset, low-risk at the start of labor and remaining so throughout labor and delivery. The infant is born spontaneously in the

vertex position between 37 and 42 completed weeks of pregnancy. After birth, mother and infant are in good condition.

Caesarean delivery was delivery of a fetus through surgical incisions made through the abdominal wall (laparotomy) and the uterine wall (hysterotomy).

Instrumental delivery was vaginal delivery accomplished with the aid of instruments which can be vacuum or forceps.

Vaginal birth after caesarean was vaginal delivery in a woman who has given birth via caesarean section in a former pregnancy.

Anemia was Hb values less than 11gm/dl.

Hypertensive disorder of pregnancy was new onset of systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg on at least 2 occasions 4 hours apart after 20 weeks of gestation in a previously normotensive individual.

Gestational diabetes was any degree of glucose intolerance with onset or first recognition during pregnancy i.e DIPSI > 140 mg/dl.

Oligohydramnios was Amniotic fluid index (AFI) ≤ 5 cm or single deepest pocket (SDP) < 2 cm.

Polyhydramnios was AFI ≥ 24 cm or SDP ≥ 8 cm.

Preterm prelabour rupture of membranes (PPROM) was PROM before 37+0 weeks of gestation.

Prelabour rupture of membranes (PROM) was membrane rupture before the onset of uterine contractions after 37 weeks of gestation.

Intrahepatic cholestasis of pregnancy (IHCP) was total serum bile acid concentration > 10 ng/dl.

Abruption was premature separation of the placenta from the decidua at or after 20 weeks gestation.

Maternal mortality was the death of a patient while pregnant or within 42 days of

termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

Low birth weight was birth weight less than 2500 grams.

Early neonatal death was death of a neonate within first 7 days of birth.

Still born was birth at ≥ 20 weeks of gestation with no signs of life.

5. Study Instrument

All antenatal cases visiting the OPD of the tertiary centre of Armed Forces were screened for inclusion criteria and registered for this study. The visit schedule of the patients was revised during the COVID-19 Pandemic and the maternal and fetal outcomes of these patients were studied at the end of 1 year and the data was compared with the traditional 15 visits model as recommended in WHO guidelines 2016 on antenatal care. Keeping in view the COVID-19 pandemic, the frequency of antenatal visits was decreased to 7 compared to the standard 15 visits as per the WHO visit schedule which included Visits POG:

- I. Detection of pregnancy in the first trimester
- II. 11-13 weeks for Level I scan
- III. 8-20 weeks for Level II scan
- IV. 24- 28 weeks for DIPSI, CBC, Urine examination
- V. 32 weeks Level III scan
- VI. 36 weeks for follow up
- VII. 40 weeks for admission and delivery

6. Data Analysis

The research data analysis method is frequency (N) and percentage (%).

RESULTS

A comparative analysis of the delivery room data of 2 years was done i.e., April 2019 to Mar 2020 (Pre COVID pandemic) Apr 2020 to March 2021 (COVID pandemic) for the variables (complications arising during pregnancy). The data collected was converted to a percentage by using the variable as the numerator and total deliveries as the denominator. Changes in percentages were compared as either increased incidence from the pre-COVID period or decreased incidence from pre-COVID time and interpretations were made accordingly.

Table 1. Comparison of Mode of delivery during Pre COVID 19 vs COVID 19 times

| Delivery and Mode | Pre COVID 19 | COVID 19 | Change (%) |
|--------------------------------|--------------|-------------|------------|
| Total Deliveries | 2081 | 1212 | -41.7 |
| Normal deliveries | 1333 (64.1%) | 649 (53.5%) | -10.6 |
| Caesarean deliveries | 685 (32.9%) | 532 (43.9%) | +11 |
| Instrumental deliveries | 32 (1.5%) | 8 (0.7%) | -0.8 |
| VBAC | 31 (1.5%) | 23 (1.9%) | +0.4 |

As shown in Table 1, there was a reduction in total deliveries by 41.7% as compared to normal times. In our revised schedule, the caesarean section rate increased by 11% compared to the standard WHO schedule. The caesarean delivery rate increased from 32.9% in pre-COVID time to 43.9% during the COVID pandemic. Instrumental deliveries were reduced by

almost 53% and the rate decreased from 1.5% to 0.7 % of the total deliveries. Although there was an increase in the incidence of caesarean deliveries during the COVID19 pandemic, there was also an increase in VBAC by 26.6% in the same period from 1.5% to 1.9% of the total deliveries.

On comparing hypertensive disorders of pregnancy and Eclampsia, as shown in

table 2, the figures were nearly the same during both pre-COVID and COVID times. However, the incidence of fetal growth restriction, placental abruption, maternal anaemia and gestational diabetes mellitus showed decreasing trends in our study.

DISCUSSION

Traditional antenatal care includes fifteen visits, as recommended by WHO in 2016 guidelines. However, during this pandemic, to reduce the risk of exposure of mother and healthcare personnel, considerations for reducing the number of recommended prenatal visits for low-risk pregnancies were adopted. We planned the follow up in antenatal OPD to cover all the landmark visits as described in the methodology.

The optimal timing, frequency and indication of visits should be determined according to the needs and risk status of each pregnant female or her fetus. Before the COVID-19 pandemic, our ANC follow-up protocol had first visit between 6-8 weeks and subsequent visits 4 weekly till 28 weeks, 2 weekly follow up from 28 to 36 weeks and weekly then after till 40 weeks which used to make 15 visits in total till delivery. During the revised protocol of follow up, we called the patients for only important milestones during pregnancy starting with the first visit at 6- 8 weeks as shown in Table 4. The patients were subsequently called for follow up at 12-14 weeks for NT/NB scan and aneuploidy screening, then anomaly scan at 18 to 20 weeks, OGTT, CBC, Urine R/E, M/E at 24-28 weeks, Level III scan at 32 weeks, then 36 weeks finally 40 weeks delivery. A focused ANC model was recommended by the WHO in 2002, particularly in low- and middle-income countries [LMICs]. It suggested four ANC visits with the first visit at 8 and 12 weeks, then between 24 and 26 weeks, at 32 weeks and

last between 36 and 38 weeks. Villar et al. (1993) in one of their multicentric RCTs reiterated that there were no disadvantages of fewer visits as compared to the standard visit schedule (Carroli et al., 2001).

Comparison of our data with Villar et al. (1993) multicentre study was done in Table 5 and the comparison results were suggesting that the FANC model proposed by WHO during the pandemic times (in our case it was COVID 19 pandemic) or planning a reduced number of antenatal visits covering all the landmark visits as in our study doesn't lead to any significant increase maternal neonatal mortality or morbidity.

There was an increase in the incidence of Caesarean delivery during COVID, similar results were found in various other studies conducted during the COVID with standard follow-up protocols followed. With regards to the pregnant population in general, fears of contracting COVID-19 at healthcare centres as well as difficulties in transportation during lockdown periods has contributed to a reluctance in timely referrals to emergency care units. All these factors have contributed towards delay in the management of obstetrical complications thereby increasing the rate of preterm deliveries, with a propensity for increased C-section NICU admissions (Khalil et al., 2020; Elsaddig and Khalil, 2021). On the other hand, some obstetricians are reluctant when it comes to exposing themselves, trainees and midwives to pregnant patients whose PCR status is unknown, with a tendency towards pursuing C-sections for labouring women who would normally have better chances for delivering vaginally; obstetricians lowered the C-section threshold during COVID-19 pandemic in general, intending to reduce inpatient maternal stays, cross-infection and the use of protective equipment (Qi et al., 2020).

Table 4. Landmarks Visits in Proposed Model

| Period of Gestation | Investigation | Intervention |
|---------------------|--|---|
| 6 - 8 weeks | Booking visit investigations | Folic Acid started Inj. dT, 1 st dose |
| 12 - 14 weeks | NT/NB Scan, aneuploidy screening | Cap Iron, Folic Acid, Calcium, Vit D3 started |
| 18 – 20 weeks | Anomaly scan | Inj. dT, 2nd dose |
| 24 – 28 weeks | Haemoglobin, oral glucose tolerance test, urine routine examination | |
| 32-34 weeks | Third trimester scan, biometry for fetal assessment Haemoglobin repeated | DFMC advised |
| 36 - 38 weeks | Fetal growth and well-being assessment, Sonography if complication suspected RT PCR at 38 weeks | |
| 40 Weeks | | Admission for Delivery |

Table 5: Comparative analysis with Villar et al. (2022)

| Variable | Pre-COVID Incidence (%) (WHO 2016 model) | Incidence during COVID (%) (FANC model) | Villar et al. (2022) | |
|-----------------------|--|---|---------------------------------|----------------------|
| | | | 12 or more antenatal visits (%) | 6-8 antenatal visits |
| Caesarean Delivery | 32.9 | 43.9 | 14.1 | 14.1 |
| Instrumental Delivery | 1.5 | 0.7 | 3.8 | 3.7 |
| VBAC | 1.5 | 1.9 | - | - |
| Abortions | 4.5 | 1.4 | -3.1 | - |
| Anaemia | 11.6 | 5.4 | - | - |
| GDM | 31.9 | 16.7 | | |
| HDP | 11.5 | 9.0 | 3.4 | 5 |
| Eclampsia | 0.2 | 0.2 | 0.07 | 0.08 |
| Abruption | 1.4 | 0.8 | 0.7 | 0.6 |
| FGR | 6.4 | 4.1 | 6.7 | 7.2 |
| IHCP | 1.6 | 2.7 | - | - |
| Oligo-hydramnios | 2.7 | 2.1 | - | - |
| Poly-hydramnios | 0.6 | 0.7 | - | - |
| PPROM | 2.5 | 2.9 | - | - |
| Preterm deliveries | 7.4 | 13.4 | 7.7 | 7.9 |
| PROM | 4.9 | 5.5 | 1.4 | 1.3 |

The number of spontaneous abortions were significantly low (reduced 7.35 times) during the COVID 19 with revised protocol. The likely explanation for the above can be attributed to lockdown restrictions during COVID and hence low reporting of patients

to the hospital for any earliest sign of threatened abortion. Many patients might have reported to their nearest facilities/ would have taken OTC medications for their symptoms and management. However, the studies suggested that the fre-

quency of miscarriage didn't increase above baseline, but data on first and second-trimester infections are limited (Rotshenker-Olshinka et al., 2021).

In revised protocol, the incidence of hypertensive disorders of pregnancy reduced to 9.5% compared to 11 % in the standard WHO protocol. Although not many studies have been done to compare the difference in the prevalence of hypertensive disorders of pregnancy during COVID19, the incidence of gestational hypertension and preeclampsia was found to be more in COVID affected mothers 8.4% as compared to mothers without COVID infection (5.4%) (Villar et al., 2022). The incidence of eclampsia remained almost the same in both ANC protocols i.e., 0.2%.

The incidence of preterm birth during the COVID pandemic has been increased in many studies but not all (Khalil et al., 2020). We observed an increase in the incidence of Preterm deliveries by 44 % during the revised protocol. Increases in preterm births could also be related to higher stress during the pandemic and changes in maternity services (Shah et al., 2021). In three large cohort studies of pregnant patients with COVID-19 in the United States, the overall preterm delivery rates were 7.2% (compared with 5.8% in patients without COVID-19) (Jering et al., 2021) 12.9% (compared with a national rate of 10.1%, and 14.8% (compared with 10.2% in patients without COVID-19) (Hamilton, Martin and Osterman, 2021).

There was a slightly low incidence of low-birth-weight newborns or stillborns in the revised (FANC) protocol as compared to standard WHO protocol. A study from the US is unable to identify an association between stillbirths, placental pathology and SARS-CoV-2 as the majority of the stillbirths were seen in patients other than maternal SARS-CoV-2 infection.

However, hypoxia and vascular insults to the placenta are known effects of COVID-19 infection. These two factors may not directly contribute to fetal death but may have caused continuous microinsults to the placenta during the period of fetal development, thereby increasing the chances of stillbirth and other adverse pregnancy outcomes. Hence, this subset of patients demands extra antenatal surveillance (Bunnell et al., 2021). Munjanja et al in 1996, over the 2 years, recruited 15,994 women and assessed the difference in feto-maternal outcome in standard 14 visits and new lesser 6 visits. An antenatal care programme with fewer more objectively oriented visits can be introduced without adverse effects on the main outcome pregnancy variables. The proportion of antenatal referrals was also lower (13.6 vs 15.3%; OR=0.87 [95%CI= 0.79 to 0.95]). Nevertheless, there were significantly fewer labour referrals for severe hypertension or eclampsia (2.1 vs 2.6%; OR=0.81 [95%CI= 0.66 to 1.00]). The risk for preterm (<37 weeks) delivery was significantly lower for women on the new programme (10.1 vs 11.5%; OR=0.86 [0.78 to 0.96]). There were no other significant differences between the programmes in other major indices of pregnancy outcome, including antenatal referrals for other causes, labour referrals, obstetric interventions, low birth weight, and perinatal and maternal mortality and morbidity.

Despite tremendous improvements in maternal and newborn care in recent years, the health of the mother baby has always been the prime concern in Obstetrics globally. ANC visits are a means to reinforce maternal education and compliance, and thereby provide an opportunity for timely detecting the warning signs of pregnancy complications and their treatment. Besides this, ANC visits provide a

window for health workers to teach young mothers about warning signs of complications during pregnancy, labour, and delivery and to motivate them for safe institutional deliveries (Vogel et al., 2013; Bloom et al., 1999).

For HDP, placental abruption, FGR, Oligo-hydramnios and Poly-hydramnios, both models of standard care and revised (FANC) model had the almost same outcome without any increase in maternal morbidities. Revised (FANC) model showed an increased incidence of caesarean deliveries but it can be attributed to bias due to COVID pandemic with unknown status of many patients till negative RT-PCR report is available. However, there is an increased incidence of preterm deliveries with this revised (FANC) model which may be due to subclinical infection from COVID in preceding months however this requires further investigations to arrive at a definite conclusion. Conclusion in this study is our Revised (FANC) model doesn't increase neonatal morbidity, mortality or increased incidence of low-birth-weight deliveries as compared to the standard ANC care model recommended by WHO. This Revised (FANC) model can be used as a standard of care for Antenatal patients during the Pandemics. This model reduces the risk of exposure to the gravid mother without any significant increase in maternal and neonatal morbidity and mortality.

AUTHOR CONTRIBUTION

Bikram Bhardwaj wrote and compiled study design and review of literature. Aruna Menon reviews of literature and discussion. Vipin Kumar Prajapati do data analysis. Apphia S Kathi and Dr Randeep checked and evaluated data collection.

ACKNOWLEDGMENT

None.

FUNDING AND SPONSHORSHIP

None.

CONFLICT OF INTEREST

Authors declare no conflict of interest.

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