

Challenges and Solutions for Keeping Maternity and Gynecology Services Functioning Comprehensively in Secondary Level Health Care Facility in COVID-19 Pandemic Situation Using a Clinical Approach

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ABSTRACT

OBJECTIVE: With the nationwide lockdown in India, and with a near-exclusive focus on the novel coronavirus disease (COVID-19) there has been a great deal of neglect in the management of other illnesses leading to significant mortality and morbidity. We aimed to assess the feasibility of keeping obstetrics & gynecology services in a secondary care hospital functioning (in terms of regional experiences and comprehensive patient care measures) in the COVID-19 pandemic situation using a clinical approach.

STUDY DESIGN: All policies of the World Health Organization and other international obstetrics- gynecological recommendations or guidelines were followed in keeping the services functional. Hospital data of obstetrics and gynecology services were maintained and compared with the previous year's data of the corresponding period (January to December) through a retrospective observational study.

RESULTS: Compared to figures for 2019, in-patient admissions, surgeries, and daycare procedures performed, and deliveries conducted were reduced in total but almost approached previous levels. The number of out-patient attendance and gynecologic laparoscopic surgeries were significantly reduced mostly in the initial month of lockdown (April 2020) and thereafter. Only limited COVID-19 testing was done and there was no mortality in patients or health care workers (HCW) in the obstetrics and gynecological department.

CONCLUSION: COVID-19 pandemic had caused an unprecedented global healthcare crisis. The experience and data collected from our hospital in the study period validate the 'clinical' working protocol that enables comprehensive maternity and gynecology care at secondary level care centers even in a pandemic situation without adverse outcomes on patients or the hospital staff.

Keywords: Aerosol generating procedures, Clinical approach, COVID-19 pandemic, Maternity and gynecology services, Standard safety precaution, Telemedicine

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Introduction

World Health Organization (WHO) has officially declared the outbreak of COVID-19 a pandemic on 11 Mar 2020 bringing unique unprecedented challenges in provisioning comprehensive health care. The pandemic has exploded to 167,492,769 cases and 3,482,907 deaths by 26 May 2021 (1). The functioning of health care facilities especially maternity and gynecological services has been tremendously impacted. Many studies were published in early pandemic stages including mathematic models to study the effectiveness of non-pharmacological interventions (NPIs) in controlling the COVID-19 spread. These models predicted an exponential increase in the number of cases with resultant overwhelming of available healthcare facilities. Mitigation efforts including hand washing and sanitation, face mask usage, social distancing, quarantine of suspected cases, and isolation of confirmed cases were advocated which were projected to considerably reduce the burden on the healthcare system and render the pandemic 'manageable' (2).

Exuberant mass media coverage and hype created an environment of fear among all strata of society. All possible preparedness was adopted by administrative and public health authorities with a near-exclusive focus to suppress the pandemic in the early stages ('flattening of the curve'). The primary aim was to protect the vulnerable population including pregnant ladies from getting infected until a steady-state for the pandemic was achieved either by herd immunity or through a vaccine (3).

The Government of India (GoI) imposed a nationwide lockdown in March 2020 to implement NPIs to limit the increase in the number of cases overwhelming the healthcare facilities and to utilize the time in preparedness. However, the lockdown comes with great medical, social, economic, and cultural costs (4).

There has been utter disorientation among medical professionals with ever-changing strategies and administrative involvement in disease management. The very basics of infectious diseases, transmission dynamics of acute respiratory diseases, application of standard precautions, the role of diagnostic testing, and the role of community medicine were considerably negated and overshadowed by directives and guidelines issued by administrative authorities. Often it appeared that medical professionals were constrained to endorse these measures since these could not be refuted with hard scientific data.

An exclusive focus on COVID-19 led to the neglect of other essential services of healthcare, including maternal and childcare, immunization, emergency, and trauma care, oncology care, and other critical medical services.

However, the imperatives of provision of comprehensive medical care in hospitals led us to explore ways and means to keep maternity and gynecologic services in this secondary care hospital fully functional in this pandemic situation (while also following the existing directives as mandated by all authorities).

In this setting, based on our experience in 2020, we set out to study the patient care outcomes and staff safety profile while keeping all services related to obstetrics and gynecology fully functional in the hospital using a working paradigm characterized by hospital management decisions taken using clinical judgment. The idea was to generate data that would validate this alternative protocol.

Material and Method

Study design and place of study with the study period

The retrospective observational study for the period of January to December 2020 was conducted in a 627 bedded secondary level care multispecialty hospital catering to local service personnel as well as their dependents (including out-station ones) and that of veterans.

Protocols of the hospital and the department of obstetrics & gynecology

At the onset of the pandemic various directives, advisories and guidelines were issued by multiple agencies (medical and administrative) including the WHO, International Federation Gynecology and Obstetrics (FIGO), Ministry of Health and Family Welfare (MoH&FW), local civil and service administration outlining hospital and out of hospital measures to contain the pandemic. This hospital and adhere to all mandatory measures as applicable (5-9).

A separate 'feto-maternal unit' was established with segregated enclosure for a newborn baby is made in the COVID-19 ward for 'confirmed case' and another similar unit in the original maternity ward for 'suspect case' is also maintained. Intensive care unit (ICU) and high dependency unit (HDU) were also available for severe cases for all specialties. Appropriate standard precautions were observed in both COVID-19 as well as non-COVID patient care by all health care workers (HCW) as per risk assessment (10,11).

The departmental outpatient (OPD) facility was functional in the original location without any disruption of services. Patients requiring admission were sent to a respective ward and appropriate treatment started without any delay. No patient was refused outpatient or inpatient treatment in the department or hospital at any time (Table I).

Nasopharyngeal swab for reverse transcriptase-polymerase chain reaction (RT-PCR) test at civil Government medical facility was used for detecting COVID-19. However, RT-PCR testing was not done for all cases, even for cases admitted for delivery on a routine basis as results of the testing were not available before 4-10 days from available resources. There was no mandatory testing before the discharge of COVID-19 patients (12).

The standard precautions principally constituted of use of face masks (N-95/ 3- ply surgical masks), usual hand hygiene measures, face shields, and limited enforcement of social distancing were followed due to the imperatives of large numbers of patients, infrastructure limitations, and behavioral trends.

Safe abortion services and all surgeries including elective obstetrics and gynecology surgeries were performed regularly maintaining all guidelines. Immunization of children and pregnant ladies as per the National Immunization Program was continued uninterrupted (13,14).

However, implementation of telemedicine and social media platform was done for primary health care facilities opted for such consultations for clientele and HCWs posted there as per FIGO statement (15).

Data collection

Data were obtained from hospital medical records which included the out-patient and in-patient (IPD) workload of the department, surgeries performed, and deliveries conducted.

Table I: Measures implemented for maternity and gynecology services during the COVID-19 pandemic at this hospital

| Patient group | Measures | |
|--|--|--|
| Maternity OPD services including contraception and abortion services | Maintained; In original place after screening/ triage at 'Cough clinic' at hospital entry | Standard precautions continued as described in material and method; Other clinical management protocols were continued as per clinicians; All kinds of surgeries continued including laparoscopic surgeries. |
| Gynecology OPD services including infertility services | Maintained; In original place after triage at 'Cough clinic' at hospital entry | |
| IPD services (all kinds of maternity & gynecology services) | Maintained; In original ward | |
| Acute obstetrics & gynecology services | Maintained as usual | |
| Cancer patient | Maintained as usual; Transferred to tertiary care center on a case-to-case basis after initial pharmacological imaging evaluation | |
| Confirmed COVID-19 patients | Managed at 'Feto-maternal unit' of 'Confirmed COVID-19 ward' of hospital | |
| Suspected COVID-19 patients | Managed at 'Feto-maternal unit' of original maternity/ gynecology ward of the hospital | |

Data of confirmed and suspected COVID-19 was also obtained.

Morbidity/ mortality data (including maternal mortality and stillbirths) were separately obtained.

Wherever relevant, corresponding data from the previous year (2019) was used for analysis using IBM SPSS (Statistical package for social sciences) version 21.0 software (IBM Corp., Armonk, NY, USA).

The significant statistical difference is considered when the p-value is <0.05.

Results

The total number of OPD and IPD patients treated in the department in the years 2019 and 2020 are shown as per figure 1 and table II.

The total surgical workload in years 2019 and 2020 is shown in table III.

Total laparoscopic gynecological surgeries performed in 2019 and 2020 are shown as per figure 2.

Total daycare procedures (like 1st-trimester abortion procedures, gynecological cancer screening, Hysterosalpingogram, etc.) in 2019 and 2020 are shown in table IV.

The total load of deliveries conducted (vaginal and cesarean section) in 2019 and 2020 is shown in table V.

Total 229 patients and 23 HCWs were tested for COVID-19 RT-PCR tests in the hospital including only 4 in the department. Out of 2 patients, a patient was 'suspect case' transferred in from primary center being in contact with positive COVID-19 confirmed case, and both patients were delivered by cesarean section for an obstetric reason. Comparing the positivity rates, there is no statistically significant difference between HCWs and patients (Table VI).

The hospital COVID-19 mortality rate is 4.17% (8 deaths in total 192 confirmed COVID-19 cases admitted). There was no mortality due to COVID-19 among HCWs and amongst any patients managed by the department.

There was no maternal mortality in 2019 and 2020, whereas numbers of stillbirths were reduced from 9 in 2019 to 6 in 2020.

Table II: Month-wise IPD attendance in 2019 and 2020

| Year | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Total | |
|------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-------|--------------------------------|
| 2019 | 437 | 328 | 263 | 347 | 386 | 415 | 591 | 424 | 423 | 473 | 432 | 462 | 4981 | t-value-1.54; p-value-0.136 |
| 2020 | 367 | 343 | 368 | 276 | 325 | 353 | 448 | 377 | 373 | 463 | 398 | 376 | 4467 | |

Table III: Total surgeries performed in years 2019 and 2020

| Year | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Total | |
|------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-------|--|
| 2019 | 93 | 80 | 91 | 67 | 69 | 80 | 107 | 106 | 102 | 101 | 96 | 111 | 1103 | <i>t</i> -value-1.87; <i>p</i> -value-0.074 |
| 2020 | 91 | 87 | 79 | 76 | 77 | 75 | 88 | 84 | 77 | 97 | 77 | 88 | 996 | |

Table IV: Daycare procedures performed in years 2019 and 2020

| Year | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Total | |
|------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-------|---|
| 2019 | 40 | 39 | 32 | 36 | 35 | 36 | 61 | 44 | 26 | 20 | 23 | 38 | 430 | <i>t</i> -value-0.279; <i>p</i> -value-0.071 |
| 2020 | 33 | 42 | 27 | 25 | 33 | 27 | 35 | 29 | 23 | 23 | 23 | 30 | 349 | |

Table V: Deliveries conducted in 2019 and 2020

| Year | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Total | |
|--|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-------|---|
| VAGINAL DELIVERY | | | | | | | | | | | | | | <i>t</i> -value-1.02; <i>p</i> -value-0.318 |
| 2019 | 96 | 63 | 63 | 67 | 69 | 76 | 131 | 70 | 66 | 106 | 67 | 69 | 943 | |
| 2020 | 71 | 57 | 57 | 44 | 57 | 55 | 97 | 83 | 73 | 103 | 83 | 64 | 844 | |
| CESAREAN SECTION | | | | | | | | | | | | | | <i>t</i> -value-0.253; <i>p</i> -value-0.803 |
| 2019 | 38 | 33 | 47 | 31 | 27 | 36 | 41 | 47 | 56 | 67 | 58 | 61 | 542 | |
| 2020 | 43 | 35 | 36 | 42 | 41 | 35 | 42 | 51 | 52 | 58 | 48 | 46 | 529 | |
| TOTAL DELIVERIES- 2019: 1485 and 2020: 1373 | | | | | | | | | | | | | | |

Table VI: COVID- 19 RT-PCR Testing data in the hospital (Department of Obstetrics and Gynecology)

| Category | Total tests | Positive | Negative | <i>p</i> (Chi-Square test) |
|-------------------------|-------------|----------|----------|----------------------------|
| Patients excluding HCWs | 229 (2) | 135 (1) | 94 (1) | 0.821 |
| HCWs | 23 (2) | 13 (1) | 10 (1) | |

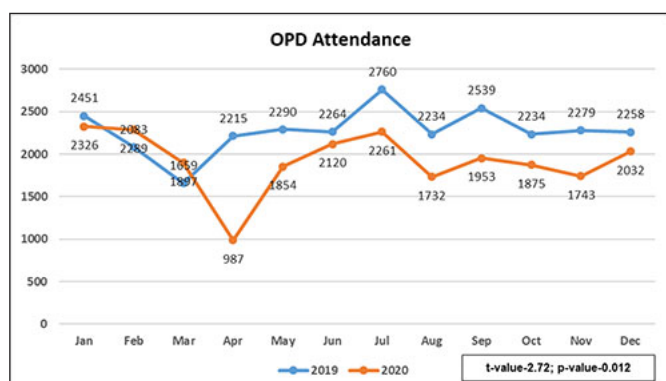


Figure 1: Month-wise OPD attendance in 2019 and 2020

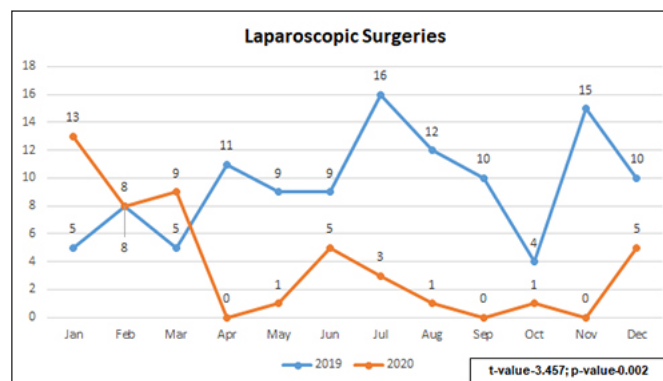


Figure 2: Laparoscopic gynecological surgeries performed in years 2019 and 2020

Discussion

Primum non-nocere (first do not harm) is one of the principal perceptions of medical ethics denoting non-maleficence that all healthcare professionals are taught. It reminds HCWs to consider the possible harm that any intervention might do with a less certain chance of benefit. This is relevant to the various NPIs instituted for the management of the COVID-19 pandemic situation.

The lockdown and NPIs considered in health care facilities to limit the spread of the pandemic has come at an obvious cost to the medical, economic, social, and cultural sectors. The measures were mostly being derived from the extrapolation of mathematical models and low-level medical evidence (16,17). Much of this evidence tends to ignore the crucial aspect of causal relationships and relies on observed associations.

Since the onset of the COVID-19 pandemic in India and concurrent ongoing lockdown, various hospitals across the country were facing the dilemma of restricting services to non-COVID patient care for managing COVID-19 patients. This amounts to medical negligence as it had led to numerous untoward consequences in patients with various acute and chronic diseases and malignancies including maternity and gynecological services because of the non-availability of adequate medical management; patients were practically left to ' fend for themselves' in large instances across the country.

The medical costs included the neglect of various essential maternity and child-care, immunization, oncology, contraception, and abortion services, etc. This has been compounded by the worsening of the general health of the population due to prolonged enforced undesirable lifestyle changes including lack of exercise and disruption of daily routine (18). Also, there has been an undesirable effect on personal immunity due to prolonged home isolation with its consequent distortion of exposure patterns to environmental microbes. Also, the long-standing stress-induced by anxiety about COVID-19 and by limitation of normal socialization and bonding has led to an increase in psychosomatic ailments and stress disorders (19). The overemphasis on sanitization has led to the distortion of surface microbiomes with consequent vulnerability to microbial infections.

The economic cost though considerable and obvious is outside the scope of this discussion.

The social cost is many but relevant to this discussion is the adverse impact on interpersonal relationships due to fear of transmission of COVID-19. This has led to a culture of 'name, blame and shame' in respect to COVID-19. This stigmatization has led to considerable unhappiness and stress not only in COVID-19 patients and attendants but also among HCWs (20). Also, there has been persistent and serious anxiety and stress amongst the general population.

The cultural cost includes perpetuation of a 'leper colony' mentality which has created undesirable cleavages in society manifesting in various ways including the ostracization of domestic and other workers. It has also adversely impacted the optimal provision of preventive healthcare measures in respect of other diseases (21).

In this scenario, maintaining full services was imperative, as closing down a major maternity and gynecology services in this center could not have been compensated by other hospitals in a 100 kilometers radius. OPDs were fully functional in their original places with the only modifications as described earlier. There were no restrictions on admissions for any disease. There was no protocol of mandatory prior testing for deliveries, elective and emergency surgeries, and for imaging facilities which would have delayed the institution of prompt management. Consequently, HCWs had to continue patient care even after being in close contact with confirmed COVID-19 cases.

While analyzing the OPD and IPD workload numbers, it is seen that there has been some reduction in the total number of patients treated. This is due to reduced reporting to the hospital due to lockdown situations and due to hesitation in patients in approaching a hospital owing to fear of COVID-19 infection. However, there was a dip in April in the loads (statistically significant in IPD workload), but increased in the subsequent months, almost similar to 2019.

A similar trend can also be seen in the total number of surgeries and daycare procedures performed in the department.

There was a significant reduction in laparoscopic surgeries performed post lockdown since March, due to fear of contracting the disease being 'aerosol-generating procedures' mainly amongst patients and operating room assistants.

There is no significant difference between the total number of deliveries conducted when the corresponding period of the years 2019 and 2020 was compared. This is obviously because they had no other alternative and these cases could not have been deferred.

We performed limited COVID-19 testing as per the clinical dictum that an investigation was only performed in the hospital if the result would alter the clinical management plan.

HCWs are stated to be highly vulnerable to risk of infection scientifically and the national COVID-19 vaccination program for HCWs was started through emergency usage authorization (EUA) only in mid-January 2021 in India (22). Still, the COVID-19 positivity rate is seen to be similar in the general population and the HCWs (without any statistical difference) in the year 2020.

Out of the total of 192 confirmed COVID-19 cases in the

hospital, only 1 patient and 1 HCW from the department- both having only very mild symptoms and with no mortality. This is low as only the cases deemed to require in-patient care based on clinical condition were admitted. The hospital mortality rate of 4.17% must be seen in this light. A more liberal COVID-19 admission policy would have resulted in a lower mortality rate.

Also, it must be noted that in 2020 overall admissions were reduced as more emphasis was given to admissions to serious transferred- in cases from peripheral hospitals to this hospital. Cases with minor ailments were given treatment at primary care centers with help of teleconsultation.

The reason for low morbidity and no mortality in the HCWs may be presumed to be because of various factors and measures taken to boost the general health and immune status of the hospital personal. All HCWs were encouraged to take regular outdoor exercise. This included regular conduct of organized physical training and the use of masks while exercising was not mandated.

The absence of undue restriction on entry of patients into hospital campuses would have enhanced the low-level immune exposure to COVID-19. Such a concept of variolation to boost immunity is well known (23).

The limitations of ensuring foolproof usage of masks for one year are evident due to inherent issues in air-sealing of nose and mouth compounded by the high number of patients and attendants vis a vis limited resources. Therefore, over-emphasis on this aspect was avoided as a practical consideration. In any case, the evidence for justifying universal mask usage is very limited and debatable (24).

The limitations in enforcing social distancing in our hospital scenario are also obvious and therefore a realistic approach was adopted from the beginning. This also served to promote team bonding and avoid stigmatization of HCWs involved with COVID care. Overall, this facilitated optimal delivery of medical services during a challenging and stressful period.

We ensured the implementation of the time-tested practice of hand washing and sanitization as a standard safety precaution. However, it is also pertinent that indiscriminate use of antiseptics would lead to alteration in body surface microbiome with a detrimental effect on resistance to pathogenic micro-organisms.

Conclusion

Though COVID-19 caused an unprecedented global healthcare crisis, the experience and data collected from our hospital in the study period validate the 'clinical' working protocol, based on management decisions taken as per clinician's judgment, that enables comprehensive maternity and gynecology care at the secondary level health facility even in a pan-

demographic situation without adverse outcomes on patients or the hospital staff.

We recommend that this 'clinical based' protocol may be always applied to other hospitals in the interest of provision of appropriate care to maximum clientele.

This study had compared data of previous years in the same center, it would have been even better if studies can be done comparing data of other similar centers in the future to validate the statements notified.

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Informed consent and approval were obtained for retrospective study using data from hospital medical records before the study and as per the principles outlined in the Declaration of Helsinki (World Medical Association. Declaration of Helsinki: ethical principles for medical research).

Availability of data and materials: The data supporting this study is available through the corresponding author upon reasonable request.

Authors' contributions: JB and AN raised the presented idea. All authors designed the study. JB conducted the analyses. JB, PL, and AN developed the first draft of the manuscript. All authors contributed to the writing of the paper, and have read and approved the final manuscript. JB, PL, SP, VS, and AN participated in data analysis, interpretation, and draft revision. JB, PL, VS, and AN participated in data collection and result interpretation. All authors assisted with data collection and analysis. All authors designed the study and critically revised the manuscript. All authors read and approved the final manuscript.

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