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Abstract

Aim The aim of this study was to assess the impact of the community-integrated Samrakshan model on perinatal mortality and morbidity in the Guna district of Central India Methods The trimester-specific Samrakshan protocols were used to screen pregnant women in the first, second, and third trimesters of pregnancy and to stratify risk for preterm preeclampsia (PE) and fetal growth restriction (FGR) in the screened population. Low-dose aspirin was recommended for women identified at high risk in the first trimester screening. Fifty training programs were conducted over the duration of the program for district health workers including Anganwadi workers, Accredited Social Health Activist (ASHA) personnel, and women and child health staff. Data on the development of PE, stages of FGR, preterm births (PTBs), birthweight, neonatal mortality, and perinatal mortality were collected and compared with the baseline year to assess trends.

Results The program covered 168 Anganwadi centers and screened 1,021 women in the first trimester, 870 women in the second trimester, and 811 women in the third trimester of pregnancy from 2019 to 2022 and obtained details on childbirth outcomes from 1,219 women. PE did not occur in 71.58% of pregnant women identified at high risk for PE and occurred in only 2.37% of pregnant women identified at low risk for PE. The incidence of PE reduced from 9.36 to 1.61%, stage 1 FGR from 18.71 to 11.83%, PTB from 19.49 to 11.25%, and birthweight less than 2,500 g from 33.66 to 21.46% from 2019 to 2022. The neonatal mortality rate reduced from 26 to 7.47/1,000 live births from 2019 to 2022 and the perinatal mortality rate reduced from 33.90 to 18.87/1,000 childbirths from 2019 to 2022 in the Samrakshan program area at Guna.

Conclusion The community-integrated model of Samrakshan in the Guna district has led to a significant reduction in perinatal morbidity and mortality in the program area.

Kevwords

- antenatal ultrasound
- ► fetal Doppler
- ► Guna
- neonatal mortality
- perinatal mortality
- ► Samrakshan

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Introduction

The Central Indian state of Madhya Pradesh is a major contributor to the perinatal mortality statistics of India. The maternal mortality rate (MMR) of Madhya Pradesh was 173/100,000 live births in 2017 compared with the national MMR of 113/100,000 live births for India. 1,2 The decline of maternal deaths was lower in Madhya Pradesh (5.8%) compared with the national reduction (7.5%) reported for India in 2017.³ The neonatal mortality rate (NMR) showed a smaller decline in Madhya Pradesh (0.6%) compared with the national reduction (3.8%) reported for India in 2018.³ The NMR was 35/1,000 live births in Madhya Pradesh compared with 23/1,000 live births reported for India in 2018. 1,2 Guna is a district in the Gwalior division of the state of Madhya Pradesh in Central India. The district has seven tehsils and five blocks with a population of nearly 1.2 million people that is predominantly rural (n = 928,171; 74.80%). The public sector district hospital at Guna is a secondary care center with 400 beds with special neonatal care units and postnatal care services. Other public sector hospitals in the district provide primary care services.

Samrakshan is a national program of the Indian Radiological and Imaging Association (IRIA) that focuses on the reduction in perinatal mortality and morbidity through an approach that integrates fetal Doppler studies with routine antenatal ultrasound assessments during pregnancy. ^{4,5} The program was started in July 2019 in India and the district of Guna in Madhya Pradesh was one of the first participants in the program. In this manuscript, we present the impact of the Samrakshan program in the district of Guna for the period 2019 to 2022.

Methods

The details of the Samrakshan program have been published earlier.⁴ Briefly, the program integrates fetal Doppler measurements with routine antenatal ultrasound assessments in the first, second, and third trimesters of pregnancy. The first trimester screening at 11 to 14 gestation weeks includes collection of a detailed clinical and demographic history including prior pregnancy and comorbidity, determination of mean arterial blood pressure with simultaneous measurement of blood pressure in both upper arms using a digital blood pressure machine, ultrasound-based dating of the pregnancy, estimation of the crown rump length, measurement of the mean uterine artery (UtA) pulsatility index (PI), and the determination of an individualized risk for preterm preeclampsia (PE) and fetal growth restriction (FGR).⁴⁻⁹ A value of 1 in 150 was used as the cutoff to stratify risk for the pregnant woman. 4-9 Pregnant women considered as high risk based on the cutoff value were recommended low-dose aspirin 150 mg once daily at bedtime till 36 weeks, development of preterm PE, or childbirth, whichever was earlier.4,10,11 The second trimester assessment was done between 20 and 24 gestation weeks and included the integration of fetal Doppler studies with routine ultrasound assessment, targeted imaging for fetal anomalies scan, estimation of risk for preterm PE, and assessment of fetal growth.⁴ The third trimester assessments from 28 weeks included fetal Doppler studies for the UtA PI, umbilical artery (UA) PI, middle cerebral artery (MCA) PI, and the cerebroplacental ratio (CPR).^{4,12} The presence of any one of mean UtA PI more than 95th percentile and/or UA PI more than 95th percentile and/or MCA PI less than 5th percentile and/or CPR less than 5th percentile was considered an abnormal Doppler study.^{4,12} The fetal weight was estimated based on fetal biometry assessments and using the Hadlock III formula. Fetal growth was staged using the Barcelona protocol as stages 1 to 4 FGR, small for gestational age (SGA), and no FGR.¹² SGA was defined as estimated fetal weight (EFW) between 3rd and 10th percentile with a normal Doppler study. 12 Stage 1 FGR was defined as EFW less than 3rd percentile with or without an abnormal Doppler study or EFW 3rd to 10th percentile with an abnormal Doppler study.¹² The diagnosis of PE was ascertained from the obstetric medical records of the women. Details of childbirth including gestational age and birthweight at delivery, live births, still births, and neonatal mortality were collected from the obstetric services.

The Samrakshan model in Guna district additionally included health education for the district health workers including Anganwadi workers, ASHA personnel, and women and child health department (WCD) staff. The training programs were initially provided in a lecture-presentation format by author LKS. The training covered concepts of preconception care; antenatal care; common comorbidity in pregnancy with a specific focus on pregnancy-induced hypertension, FGR, infections, and anemia; dating of pregnancy; the importance of early identification and compliance with interventions; nutritional counseling; postconception care; and the importance of documentation and maintenance of records. Fifty training programs were conducted over the duration of the program. The presentations were followed up with regular interaction and demonstration of antenatal care concepts during patient assessments as part of dedicated evening clinics. The health workers were encouraged to counsel the patients under the supervision of LKS in these dedicated clinics. LKS also conducted daily education sessions for patients and their families. A dedicated WhatsApp group that included the WCD workers and staff, district program personnel, and the radiology center staff was created to communicate, guide, and monitor trimester-specific assessments of pregnant women registered at the Anganwadi centers. All training programs and interactions were provided in Hindi, the local language.

The program covered 168 Anganwadi centers that provided services to a population of nearly 220,000 people. The program provided walk-in services for pregnant women from other parts of the district through the clinical radiology clinic. All pregnant women were assessed using the Samrakshan protocols and high-risk pregnant women were referred to the appropriate obstetric service at the district hospital after the fetal assessments. Pregnant women were provided free nutritional and antenatal counseling services and were provided multivitamin supplements free of cost. Antenatal

Table 1 Trends in the proportion of women at high risk for preterm preeclampsia and fetal growth restriction in 1,021 pregnant women in the first trimester screened from 2019 to 2022

High-risk parameter	2019 (n = 107)	2020 (n = 143)	2021 (n = 383)	2022 (n = 388)
Preterm preeclampsia: n (%)	34 (31.78%)	42 (29.37%)	81 (21.15%)	53 (13.66%)
Fetal growth restriction: n (%)	38 (35.51%)	34 (23.78%)	83 (21.67%)	67 (17.27%)

care services were organized at regular intervals in the Anganwadi centers in addition to the services provided at the base center.

Interactive sessions were conducted for other important stakeholders in childcare, especially obstetricians and neonatologists. LKS, who provided the primary imaging and clinical radiology services, discussed the results of fetal assessment of all high-risk cases with the obstetricians and neonatologists at the district hospital. LKS personally interacted with the obstetricians at the tertiary care level to inform them about the fetal assessment findings for all referral cases. The management and monitoring of complex cases was discussed with authors RMC and PKN on a regular basis through a dedicated WhatsApp group. Regular interactions were conducted with the district health administration and staff to sensitize and update on the progress of the Samrakshan initiative in the district.

All pregnant women in the program were assigned a unique program identification number for sequential follow-up. The data of all pregnant women were collected using the Samrakshan forms and were initially entered into an MS Excel spreadsheet for local reference and subsequently entered in an online Google Form database after anonymizing personal information. The anonymized data were aggregated into a specific password-protected database and subsequently exported to STATA Version 13.0 (College Station, Texas, United States) for statistical analysis. The data of the year 2019 were considered as the baseline data to assess the trends in the perinatal morbidity and mortality statistics.

Results

The program screened 1,021 women in the first trimester, 870 women in the second trimester, and 811 women in the third trimester of pregnancy from 2019 to 2022 and obtained details on childbirth outcomes from 1,219 women. The program included only singleton pregnancies. Most preg-

nant women (>99%) had spontaneous/natural conceptions, 56.32% of women were nulliparous, and 1.37% had chronic hypertension in the first trimester screening. The prevalence of diabetes mellitus was very low (<0.5%) in this population. The overall incidence of women identified at high risk for preterm PE and FGR in the first trimester screening was 20.57% (n = 210) and 21.74% (n = 222), respectively, from 2019 to 2022. One hundred and twenty-four women (12.14%) were identified at high risk for both preterm PE and FGR, 86 (8.42%) women were identified at high risk for preterm PE alone, and 98 (9.60%) women were identified at high risk for FGR alone from 2019 to 2022. Low-dose aspirin was recommended for 298 (29.19%) high-risk women in the first trimester and 713 (69.83%) women were considered at low risk in the first trimester from 2019 to 2022. The first trimester screening showed significant declining trend in the proportion of women identified with high risk for preterm PE and FGR from 2019 to 2022 (►Table 1). The screening of 870 pregnant women in the second trimester identified 3.79% women (n=33) at high risk for preterm PE, 2.07% (n=18)with early FGR, and 0.72% (n=2) with fetal structural abnormalities from 2019 to 2022.

Stage 1 FGR was identified in 123 (15.17%), stage 2 FGR in 5 (0.62%), stage 3 FGR in 19 (2.34%), and stage 4 FGR in 2 (0.25%) of the 811 fetuses screened in the third trimester. Forty-five fetuses (5.55%) were classified as SGA and 617 (76.08%) fetuses were classified as without growth restriction. An abnormal fetal Doppler study was present in 261 (32.18%; 95% confidence interval: 28.96 to 35.40%) of the 811 pregnant women screened in the third trimester from 2019 to 2022. -Table 2 presents the distribution of the fetal Doppler studies in this population. An abnormal Doppler study was present in 72.45% of fetuses with EFW less than 3rd percentile, 50.55% of fetuses with EFW between 3rd and 10th percentile, 26.38% of fetuses with EFW between 10th and 50th percentile, and 19.13% of fetuses with EFW more than 50th percentile.

Table 2 Distribution of abnormal fetal Doppler studies in 811 pregnant women screened in the third trimester

Parameter	n (%)	95% CI
Mean uterine artery PI > 95th centile	132 (16.28%)	13.90–18.97
Umbilical artery PI > 95th centile	30 (3.70%)	2.60-5.23
Middle cerebral artery PI < 5th centile	109 (13.44%)	11.26-15.96
Cerebroplacental ratio < 5th centile	168 (20.72%)	18.07-23.64
Any one abnormal Doppler study	261 (32.18%)	28.96-35.40%

Abbreviations: CI, confidence interval; PI, pulsatility index.

Table 3 Incidence of preeclampsia, fetal growth restriction, preterm births, and birthweight <2,500 g in the program population in 2022 compared with the baseline year 2019

Parameter	2019	2022	<i>p</i> -Value
Preeclampsia	9.36%	1.61%	< 0.001
Stage 1 FGR	18.71%	11.83%	0.001
No FGR	68.42%	82.80%	< 0.001
Preterm births	19.49%	11.25%	< 0.001
Birthweight < 2,500 g	33.66%	21.46%	< 0.001

Abbreviation: FGR, fetal growth restriction.

PE did not occur in 71.58% of pregnant women identified at high risk for PE in the program. PE occurred in only 2.37% of pregnant women identified at low risk for PE. ►Table 3 presents the trends in the distribution of PE, FGR, preterm births (PTBs), and birthweight less than 2,500 g by year in this population. There was 1 maternal death, 9 neonatal deaths, and 14 stillbirths in the program population from 2019 to 2022. The NMR reduced to 7.47/1,000 live births from 2019 to 2022 compared with the NMR of 26.0/1,000 live births in the baseline year 2019 from the Samrakshan program area in Guna. The perinatal mortality rate (PMR) reduced from 18.87/1,000 childbirths from 2019 to 2022 compared with the PMR of 33.90/1,000 childbirths in the baseline year 2019 from the Samrakshan program area in Guna.

Discussion

The results of the Samrakshan program show a significant improving trend in the perinatal morbidity and mortality rates for the region from 2019 to 2022. The NMR and PMR in the program area are better than the national average for India. This change assumes great importance considering that Guna is a predominantly rural district in the state, Madhya Pradesh, that is still a major contributor to the poor perinatal statistics of India. The improvement in perinatal statistics in Guna highlights the potential for the program to impact on the perinatal mortality statistics of the entire state if implemented in a systematic manner.

The early identification of pregnant women at risk for preterm PE and FGR and the recommendation to start low-dose aspirin early during pregnancy has been an effective intervention for Samrakshan. The individualized estimation of risk using the freely available online Fetal Medicine Foundation algorithm and calculator was effective as only 2.37% of the low-risk pregnant women developed PE and PE was averted in 71.58% of high-risk pregnant women. The benefits of this approach are corroborated by the significant decline in the incidence of PE and FGR from 2019 to 2022. These results are consistent with the results of the Aspirin for Evidence-Based Preeclampsia Prevention (ASPRE) trial on the use of low-dose aspirin to prevent preterm PE. 10,11

The Barcelona protocol was used to stage FGR and for stage-based management of FGR in the program.¹² The

stage-based recommendations based on fetal Doppler assessments provided objective measures that helped to initiate interactive and continuous discussions with the obstetricians on the need and frequency of repeat assessments and to optimally plan for childbirth. Regular interactions with the obstetricians with objective fetal Doppler measures can help to reduce the PTB rates by differentiating the stages of FGR and identifying FGR and SGA fetuses that can be carried till term. The differentiation of FGR and SGA fetuses will help to reduce the proportion of fetuses that need intense surveillance as almost all SGA fetuses can be delivered at term unless there are additional complications.

The results of Samrakshan program show the importance of integration of fetal Doppler studies with trimester-specific ultrasound studies. It is important to study the UtA and MCA and estimate the CPR and not restrict fetal Doppler studies to the UA. There is a large pool of evidence from the global literature that SGA defined based on a normal UA PI has a large proportion of fetuses with worse perinatal outcomes than normal fetuses. 13-15 The MCA provides information about the brain vasodilatation and is a surrogate marker for fetal hypoxia and brain sparing effects. 12 The CPR provides information on even mild increases in placental resistance and mild reductions in fetal brain vascular resistance.¹² The study of the uterine, umbilical, and middle cerebral arteries and the estimation of CPR in addition to the UA can therefore provide a more objective assessment of fetal wellbeing as they assess different facets of fetal wellbeing. Abnormalities in UtA PI, MCA PI, and CPR were observed in 10 to 20% of the population of pregnant women screened in the third trimester and these were communicated to the obstetricians. Abnormal Doppler studies were also found in fetuses with an EFW more than 10th percentile suggesting that a certain proportion of Appropriate for Gestational Age (AGA) fetuses may benefit from more intense surveillance. Currently, intense surveillance is limited to fetuses with an EFW less than 10th percentile.

The community-integrated model with active involvement of the district health personnel at different levels has been a very useful add-on to the program. The involvement of Anganwadi workers, ASHA workers, and health workers at the primary care centers with nutritional and antenatal counseling helped to reinforce the need for continuous and systematic care to the pregnant women and their families. The involvement of these workers helped with increasing compliance to low-dose aspirin and adherence to antenatal schedules, to build and maintain rapport and trust with the pregnant women, and for identification of infectious diseases in pregnancy. These workers also helped with pre- and postconception care in the program areas, and the improvement in perinatal statistics in this program area can be attributed in part to the integration of these workers with the Samrakshan program.

Delays that impact maternal care^{16–19} are a major challenge for the provision of care in this rural district. Advanced tertiary care services are available at Bhopal or Gwalior and involve facilitation of travel of several hours. Delay in the identification of potential issues in pregnancy and childbirth, delay in communication and acceptance of the diagnosis,

delay in transportation and access to tertiary care facilities, and delay in access to resources once they reach healthcare facilities remain significant challenges that impact on PMRs in the district. Perinatal mortality could be attributed to delays in nearly 50% of the perinatal deaths in the program with the major drivers of delay being difficulty to arrange transportation and acceptance of the need for further care by the family. The single maternal death in the program duration was in the first year of the program and due to a delay in accessing tertiary care services after referral. The early identification of potential issues during pregnancy and childbirth, preventive strategies, and regular interaction with pregnant women and their families to improve compliance with care schedules and recommended interventions are important immediate measures that can minimize the impact of delays in fetal and maternal care.

Improvement in perinatal statistics of India needs a multidisciplinary synergistic approach that builds on the strength of each stakeholder. The Samrakshan model in Guna district focused on integrating the imaging skills of the radiologist that helped in objective assessments of fetal wellbeing with the skills of the health workers to provide and promote primary and preventive care, and the clinical skills of the obstetrician and neonatologists for childbirth and neonatal care. The significant improvement in perinatal statistics in this rural district using this approach provides a template that can be adapted by other districts in the state.

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Conflict of Interest None declared.

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