Samrakshan: An Indian Radiological and Imaging Association program to reduce perinatal mortality in India

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Abstract

Context: India has a high perinatal mortality rate. The Indian Radiological and Imaging Association (IRIA) is supplementing efforts to address perinatal mortality in India through the Samrakshan program. **Aims:** To describe various elements of the Samrakshan program that aims to reduce perinatal mortality in India. **Methods:** Samrakshan focuses on two priority areas, preeclampsia (PE) and fetal growth restriction (FGR). Samrakshan aims at technical skill upgradation, specifically focused on improved interpretative ability, prognostic and therapeutic efficacy using Doppler studies, a free online learning platform and offline continuous medical educations (CMEs), building an evidence base from the program to develop policy and guidelines, and improving synergy with the RAKSHA program of IRIA and other fetal care stakeholders. **Results:** Two courses on Doppler studies focused on first trimester and third trimester, supplemented by case discussions and journal articles, have started on the online platform with 230 registrants. The first statewide CME was held at Indore. Samrakshan screening identified 10 (17.24%, 95% CI: 8.59, 29.43) women at high risk for preterm PE and 29 (50.00%, 95% CI 36.58, 63.42) women at high risk for FGR in the first trimester. Ten fetuses (7.63%, 95% CI: 3.72, 13.59) including 9 with stage 1 FGR were identified in the third-trimester screening. **Conclusions:** Samrakshan is a flagship program of IRIA that aims to reduce perinatal mortality in India through a synergistic, holistic approach that complements and supplements existing efforts in India.

Key words: Doppler ultrasound; fetal growth restriction; India; perinatal mortality; preeclampsia; screening

Introduction

Perinatal deaths include stillbirths or fetal demise that occur after 7 months of gestation and early neonatal deaths

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or deaths of live-born babies within the first 7 days of life. Perinatal mortality rate is estimated as the number of perinatal deaths per 1,000 pregnancies of 7 or more months duration. The National Family Health Survey-4 (NFHS-4), a nationally representative survey carried out in 2015-16 in India, reported a perinatal mortality rate of 36 per 1000 pregnancies with large variations by states, urban-rural locations, and socio-demographic factors such as maternal schooling, household wealth index, and inter-pregnancy intervals.[1] The perinatal mortality rate ranged from 8 per 1,000 pregnancies in Kerala to 56 per 1,000 pregnancies in Uttar Pradesh.[1] NFHS-4 reported a stillbirth rate of 0.7% and a neonatal mortality rate of 30 per 1000 live births in India, and a birth weight <2500 grams in 18.2% of live births.[1] A major proportion (41.77%) of neonatal deaths in India are attributable to prematurity and low birth weight.[2] The maternal mortality ratio in India has shown a steady decline[3] and was reported as 130 per 100,000 live births in 2014-16 and pregnancy-induced hypertension remains a major cause for maternal mortality, preterm deliveries, fetal growth restriction (FGR), and low birth weight in India.

The NFHS-4 reported an increasing utilization of antenatal care (ANC) with 82.7% pregnant women reporting at least one ANC visit including 58.6% women in the first trimester of pregnancy.[1] The NFHS-4 also reported an increasing trend for institutional deliveries and ultrasound exams during pregnancy. An estimated 79% of all deliveries were institutional deliveries and 61% of all pregnancies had received at least one ultrasound exam during pregnancy.[1]

Fetal radiology has evolved from a conventional diagnostic approach focused on congenital and structural malformations and serial growth assessments to a more holistic preventative and prognostic approach focused on optimizing therapeutic interventions and fetal outcomes. Current radiology and imaging techniques that include multimodality sequential exams allow radiologists to recommend and provide evidence-based therapeutic and prognostic information based on early identification and earlier intervention besides providing confirmatory evidence for the presence or absence of factors that may affect fetal or maternal well-being.

The Indian Radiological and Imaging Association (IRIA) launched a nationwide program in June 2019, Samrakshan, which aims to utilize the experience and expertise of radiologists in India to complement existing efforts to address perinatal mortality in India and achieve the sustainable development goal targets for the country. In this manuscript, we discuss the various elements of the Samrakshan program launched by IRIA and provide information on the progress made in the initial couple of months of the program.

Methods

Samrakshan was designed to focus initially on two priority areas, based on the perinatal statistics of India and the potential for influencing therapeutic interventions, which can provide maximum impact on the perinatal mortality rates of India. Preeclampsia (PE) and FGR were chosen as the priority areas for Samrakshan.

Samrakshan focuses on four areas relating to PE and FGR. These include technical skill upgradation to improve the use and interpretative ability and therapeutic effectiveness of Doppler studies, improving the reach of the program among radiologists through a 24 × 7 online presence, improving the evidence base through data-based evaluation from the program and development of policy guidelines, and improving synergy with other stakeholders including the RAKSHA program, and neonatologists, obstetricians, and others involved in the care of pregnant women.

Samrakshan utilizes a two-pronged approach for the technical skill upgradation of Radiologists in India. These include an offline approach through statewide continuous medical education (CME) programs and workshops and the utilization of an online learning management portal to deploy specific courses. The state chapter of IRIA, in coordination with the CME subcommittee of Samrakshan, will decide the number of CMEs in each state based on the size of the state and administrative divisions within the state. Each CME will include didactic lectures, workshops to demonstrate techniques of Doppler studies, panel discussions and involve synergistic stakeholders.

The online portal, accessible for Radiologists in India through user credentials and a password, will provide access to specific courses pertinent to Samrakshan. The courses include content pertinent to the trimester-specific identification of women at high-risk for preterm PE and FGR. The courses aim to familiarize and optimize use of Doppler studies and maximize the use of globally accepted risk estimators for preterm PE and FGR based on competing risk models and Bayesian algorithms.[4-8] Tutorials specific to the measurement of mean arterial pressures, uterine artery Doppler studies, umbilical artery Doppler studies, middle cerebral artery Doppler studies, and the estimation of cerebroplacental ratio are offered through the online platform. The courses also provide a 24 × 7 platform to standardize images and forums to discuss cases and share recent research articles in fetal radiology. The course work includes quizzes and assignments that can be accessed and submitted online. Samrakshan has a subcommittee of instructors that aims to include representation from all states and union territories of India to develop state-level teams of instructors. The online presence of Samrakshan is provided through a web link that leads to a dedicated page on the IRIA website and through a dedicated app for

Android devices developed and deployed by the digital team of Samrakshan.

Building an evidence base that can direct further improvements in the care provision as well as programmatic elements is an integral part of Samrakshan. The program aims to develop state-level evidence for India on the various measurement parameters that underpin the screening algorithms,[4-8] a continuous assessment of the effectiveness of the screening algorithms used in Samrakshan,[4-8] the number of practitioners who submit screening forms, and the number of women screened and identified as high risk for preterm PE and FGR. Women identified in the first trimester as high risk for preterm PE are recommended a daily low-dose aspirin regime (150 mg daily) to be initiated before 16 weeks of pregnancy.[5] A fetal staging and management protocol will be used to manage fetuses identified in the third trimester of pregnancy with growth restriction.[8] The program links antenatal screening with outcomes of birth to determine changes in the perinatal mortality.

Dedicated trimester-specific forms, based on the variables of interest, have been developed and can be downloaded from the dedicated Samrakshan page online or through the Samrakshan App. The forms can be completed offline, stored with the case records, and subsequently transcribed to an online form that is available on the dedicated Samrakshan page and in the Samrakshan App for android devices. The forms are anonymized for patient identifiers to protect the privacy of patients. The forms submitted online are exported to an online database stored in a password protected folder that is accessible only on approval by the national coordinator of Samrakshan. The forms are currently developed for singleton pregnancies. The forms for multiple pregnancies are under development.

Data analysis of the major parameters of the form is automated and is updated in real time. A set of basic parameters for the evaluation of basic parameters of Samrakshan will be used to develop monthly reports for dissemination [Table 1]. These functions will be performed by the evaluation subcommittee of Samrakshan that aims to include members from all states and union territories and representation from teaching faculty and practitioners. The evidence will be used to develop problem-specific tutorials as well as for the development of nationally relevant guidelines for fetal radiology, especially focused on Doppler studies.

Improving the reach and uptake of research in fetal radiology in India with a specific focus on developing India specific data and protocols at the national, regional, and state levels is a goal of Samrakshan. Samrakshan is developing standard research protocols that can be utilized by teaching faculty for their academic research, by

Table 1: Evaluation parameters for Samrakshan

Categories	Parameters
CME (By State)	Number of CME
	Number of participants
	Participant distribution by district, urban-rural location, and by teaching faculty, practitioner or resident
Online Courses	Number of trimester-specific courses
	Mentors
	Quizzes
	Image Evaluations
	Course Completions
	Number of research articles shared through learning modules
	Number of trimester-specific cases discussed
	Number of registrations on the online portal
Form submission	Number of forms submitted
	Number of practitioners submitting forms
	Number of participating states and districts.
	Trimester Specific Reports on clinically relevant screening parameters
	Faculty/Resident/Practitioner use of the Samrakshan database for research
	Research Publications or Dissertations by state
	Research Projects by state
Online Presence	Visits to Samrakshan page
	App download
	Telegram channel subscribers
Synergistic programs	Number by State

residents for their dissertation, and by practitioners, either individually or as collaborative studies.

Addressing synergy with other programs including the flagship RAKSHA program of IRIA and reach out to other stakeholders in the care of pregnant women and newborn babies including obstetricians and neonatologists is another goal of Samrakshan. This synergy will be improved through dedicated reach out initiatives, involvement of stakeholders in the CME programs and through promotional activities aimed at increasing awareness.

Samrakshan will generate monthly reports on its activities that will be submitted to the various subcommittees of Samrakshan and to the digital team of IRIA for further dissemination to members of the IRIA through its e-newsletter.

Results

Samrakshan has activated 7 subcommittees since its launch in June 2019 [Table 2]. The online presence of Samrakshan was established through the dedicated Samrakshan page and App, through the online portal for courses, and through a dedicated Telegram channel to post updates.

Two-trimester specific courses, first trimester and third trimester, with registration of learners (n = 230) have started [Table 3]. The course content in the first trimester course currently focuses on the use of Doppler studies

Table 2: Subcommittees of Samrakshan IRIA program

Subcommittees	Number of members
Promotional Campaign	6
Online Instruction	17
State CME programs	12
Evaluation and Audit	9
Raksha & PCPNDT synergy	2
Reach out to Obstetricians and Neonatologists	2
Policy, Guidelines, Documentation	2

Table 3: Performance of Samrakshan for period July 1, 2019, to September 1, 2019

First Trimester	n, %
Number of Women Screened	58
High risk for PE (*n*, %)	10 (17.24%)
High risk for FGR (*n*, %)	29 (50%)
Recommended Low dose Aspirin (*n*, %)	30 (51.72%)
Third Trimester Singletons	
Number of women Screened	131
Women with PE (*n*, %)	2 (1.53%)
Prior high risk for PE (*n*, %)	2 (1.53%)
EFW centiles <3 (*n*, %)	6 (4.58%)
EFW Centiles 3-10 (*n*, %)	8 (6.11%)
FGR stage 1 (*n*, %)	9 (6.87%)
FGR stage 2 (*n*, %)	0
FGR stage 3 (*n*, %)	1 (0.76%)
FGR stage 4 (*n*, %)	0
No FGR (*n*, %)	121 (92.31%)
EFW 3-10 centile with normal Doppler (*n*, %)	6 (75%)
EFW 10-50 centile with abnormal Doppler	20 (46.51%)
Mean UtA PI >95th centile	21 (16.03%)
CPR <5th centile	21 (16.03%)
Online courses	
Number of registrants first trimester	214
Number of registrants third trimester	37
Number case discussions posted	3
Number Instructors	17
Number research articles shared	7
IRIA Samrakshan page visits	2047 (1994 from India)
Research protocols developed for Faculty/ Resident/Practitioner studies	7
State-level CME	1

for the identification of women in the first trimester of pregnancy at high risk for preterm PE, the standard method for measurement of mean arterial pressure, the use of an online risk estimator calculator to determine the risk for preterm PE and FGR, and tutorial on the completion of first trimester forms. The third trimester course currently focuses on the use of Doppler studies in the third trimester with a focus on FGR, early dating scans, planning of biometry planes and endpoints, growth charts and basic steps of growth assessment, the use of an online risk estimation calculator to stage fetal growth incorporating Doppler

findings, and the completion of third trimester forms. Trimester specific case discussions and sharing of research articles pertinent to the cases presented are ongoing in the online forum [Table 3].

Five states, Kerala, Tamil Nadu, Jharkhand, Bihar, and Madhya Pradesh have started the online submission of data forms. Samrakshan has screened 51 first trimester pregnant women and 131 third trimester pregnant women till August 30, 2019. The screening identified 10 (17.24%, 95% CI: 8.59, 29.43) women at high risk for preterm PE and 29 (50.00%, 95% CI 36.58, 63.42) women at high risk for FGR in the first trimester. Ten fetuses (7.63%, 95% CI: 3.72, 13.59) were identified with FGR in the third-trimester screening [Table 3].

The first state CME of Samrakshan was held on September 1, 2019, at Indore, Madhya Pradesh and was attended by 200 participants. The CME had a detailed panel discussion that involved other stakeholders including local obstetricians and neonatologists, besides didactic interactive lectures on the first and third-trimester screening protocols and forms, familiarization with the online applications and demonstration of Doppler techniques.

Discussion

Samrakshan has several strengths from a program perspective. Samrakshan can draw upon the collective wisdom and experience of approximately 17,000 radiologists in India who have trained in various imaging techniques and have a good understanding of the medical physics that drive imaging machines and algorithms. The program runs through the national professional body of Radiologists in India, the IRIA. The program works synergistically, complementing existing efforts aimed at reducing perinatal mortality rates in India.

The program addresses two major health priorities, preterm PE and FGR, which can lead to maximum impact on perinatal mortality rates in India. These conditions are important health problems in India as judged by the incidence, severity, and long-term consequences of these conditions. The epidemiology of these two conditions are understood and there is robust evidence about the association between several risk factors and the risk of serious or treatable disease.[9-15]

There are simple, safe, precise, and validated screening protocols available for the identification of pregnant women at high risk for PE in the first through third trimester of pregnancy, and to identify women in the first trimester of pregnancy at high risk for FGR, and to stage fetal growth and initiate fetal staging based management in the third trimester.[4-8] These protocols are already used in diverse populations globally and the distribution of test values are

known in the global context.[8,16-19] The protocols provide evidence-based, clearly defined, and agreed cut-off levels to optimize management and follow-up.[8,16-19] There is an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.[8,16-19]

There are effective interventions for patients identified through screening, with evidence that intervention at an early presymptomatic phase leads to better outcomes for the screened individual compared with usual care.[5,8,16-19] The guidelines for interventions including optimal timing, dosage, and frequency of follow-up are based on evidence gathered through several studies in global populations.[5,8,16-19] The complete screening program (test, diagnostic procedures, treatment/intervention) is clinically, socially, and ethically acceptable to health professionals and the public.

However, there are several challenges to the success of Samrakshan. India is a country with a large population with diverse sociodemographic characteristics even within states. There were an estimated 27 million births in 2017. The NFHS-4 reported suboptimal utilization of ultrasound exam services and ANC during pregnancy.[1] Improving ultrasound coverage for pregnant women is both a challenge and an opportunity.

Standardizing techniques and ensuring the uniform application of standard measures is a challenge for any nationwide program, especially in a country the size of India. Samrakshan aims to address this challenge through a mix of online and offline programs, data documentation and audits, and image standardization exercises. Strict onsite visits to assess standardization may not be feasible and is a pragmatic limitation. Several aspects of the risk prediction model including past history of PE, maternal history of PE, previous birth weight, date of previous delivery may be subject to recall bias or a lack of reliable information. This is a pragmatic limitation that may affect the results of screening. Radiologists can recommend low-dose aspirin to women identified as high risk in the first trimester; however, the actual prescription of low-dose aspirin is dependent on the managing physician. Nonprescription, nonusage, and less than optimal dosage of low-dose aspirin may influence the outcomes after screening.

The results in a large program of this nature may be impacted by differing sociodemographic and test characteristics, as well as inter- and intra-observer variations. We do not have previous evidence from India to determine the potential influence of these factors on detection rates. Samrakshan offers an opportunity to explore these factors within the context of diversity in India.

A major benefit from Samrakshan, besides the potential impact on perinatal mortality rates, is the possibility of deriving India specific data at state and district levels that can lead to further in-depth research protocols and guidelines that can reduce perinatal mortality rates in India to sustainable levels. Samrakshan can shift fetal radiology in India from a predominantly diagnostic model to a preventative, prognostic, and therapeutic model to optimize fetal outcomes, working synergistically with other stakeholders in fetal healthcare.

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Conflicts of interest
There are no conflicts of interest.

References

1. International Institute for Population Sciences (IIPS) and ICF. National Family Health Survey (NFHS-4) 2015-16: India. Mumbai: IIPS; 2017.

2. Million Death Study Collaborators, Bassani DG, Kumar R, Awasthi S, Morris SK, Paul VK, Shet A, *et al*. Causes of neonatal and child mortality in India: A nationally representative mortality survey. Lancet 2010;376:1853-60.

3. Niti Ayog, India. Maternal Mortality Ratio (per 100,000 live births). Available from: https://www.niti.gov.in/content/maternal-mortality-ratio-mmr-100000-live-births. [Last accessed on 2019 Sep 02].

4. Tan MY, Syngelaki A, Poon LC, Rolnik DL, O'Gorman N, Delgado JL, *et al*. Screening for pre-eclampsia by maternal factors and biomarkers at 11-13 weeks' gestation. Ultrasound Obstet Gynecol 2018;52:186-95.

5. Rolnik DL, Wright D, Poon LC, O'Gorman N, Syngelaki A, de Paco Matallana C, *et al*. Aspirin versus placebo in pregnancies at high risk for preterm preeclampsia. N Engl J Med 2017;377:613-22.

6. Litwinska M, Syngelaki A, Wright A, Wright D, Nicolaides KH. Management of pregnancies after combined screening for pre-eclampsia at 19-24 weeks' gestation. Ultrasound Obstet Gynecol 2018;52:365-72.

7. Panaitescu A, Ciobanu A, Syngelaki A, Wright A, Wright D, Nicolaides KH. Screening for preeclampsia at 35–37 weeks' gestation. Ultrasound Obstet Gynecol 2018;52:501-6.

8. Figueras F, Gratacós E. Update on the diagnosis and classification of fetal growth restriction and proposal of a stage-based management protocol. Fetal Diagn Ther 2014;36:86-98.

9. Malik A, Jee B, Gupta SK. Preeclampsia: Disease biology and burden, its management strategies with reference to India. Pregnancy Hypertens 2019;15:23-31.

10. Ghossein-Doha C, van Neer J, Wissink B, Breetveld NM, de Windt LJ, van Dijk AP, *et al*. Pre-eclampsia: An important risk factor for asymptomatic heart failure. Ultrasound Obstet Gynecol 2017;49:143-9.

11. Sharma D, Sharma P, Shastri S. Genetic, metabolic and endocrine aspect of intrauterine growth restriction: An update. J Matern Fetal Neonatal Med 2017;30:2263-75.

12. Sharma D, Shastri S, Sharma P. Intrauterine growth restriction: Antenatal and postnatal aspects. Clin Med Insights Pediatr 2016;10:67-83.

13. Sharma D, Farahbakhsh N, Shastri S, Sharma P. Intrauterine growth restriction-Part 2. J Matern Fetal Neonatal Med 2016;29:4037-48.

14. Sharma D, Shastri S, Farahbakhsh N, Sharma P. Intrauterine growth restriction-Part 1. J Matern Fetal Neonatal Med 2016;29:3977-87.

15. Khadilkar AV, Parthasarathy LS. Fetal growth restriction and cardiovascular health among adolescents. Indian Pediatr 2015;52:107-8.

16. O'Gorman N, Wright D, Poon LC, Rolnik DL, Syngelaki A, de Alvarado M, *et al*. Multicenter screening for pre-eclampsia by maternal factors and biomarkers at 11-13 weeks' gestation: Comparison with NICE guidelines and ACOG recommendations. Ultrasound Obstet Gynecol 2017;49:756-60.

17. Sotiriadis A, Hernandez-Andrade E, da Silva Costa F, Ghi T, Glanc P, Khalil A, *et al*. ISUOG practice guidelines: Role of ultrasound in screening for and follow-up of pre-eclampsia.

Ultrasound Obstet Gynecol 2019;53:7-22

18. Tan MY, Wright D, Syngelaki A, Akolekar R, Cicero S, Janga D, *et al*. Comparison of diagnostic accuracy of early screening for pre-eclampsia by NICE guidelines and a method combining maternal factors and biomarkers: Results of SPREE. Ultrasound Obstet Gynecol 2018;51:743-50.

19. Poon LC, Rolnik DL, Tan MY, Delgado JL, Tsokaki T, Akolekar R, *et al*. ASPRE trial: Incidence of preterm pre-eclampsia in patients fulfilling ACOG and NICE criteria according to risk by FMF algorithm. Ultrasound Obstet Gynecol 2018;51:738-42.