

[M19] PROMISES study: a prospective feasibility study of salivary progesterone as a test for detecting risk of preterm birth in rural community settings in India

Priyanka Garg, Jia Dai Mi, Nishtha Kathuria, Paul T Seed, Pankhuri Sharma, Simi Khan, Mohan Ghule, Ritu Dargan, Archana Sarkar, Atul Tayade, V B Shivkumar, Sunil Mehra, Poonam Varma Shivkumar, Rachel M Tribe
Department of Women and Children's Health, King's College London, UK

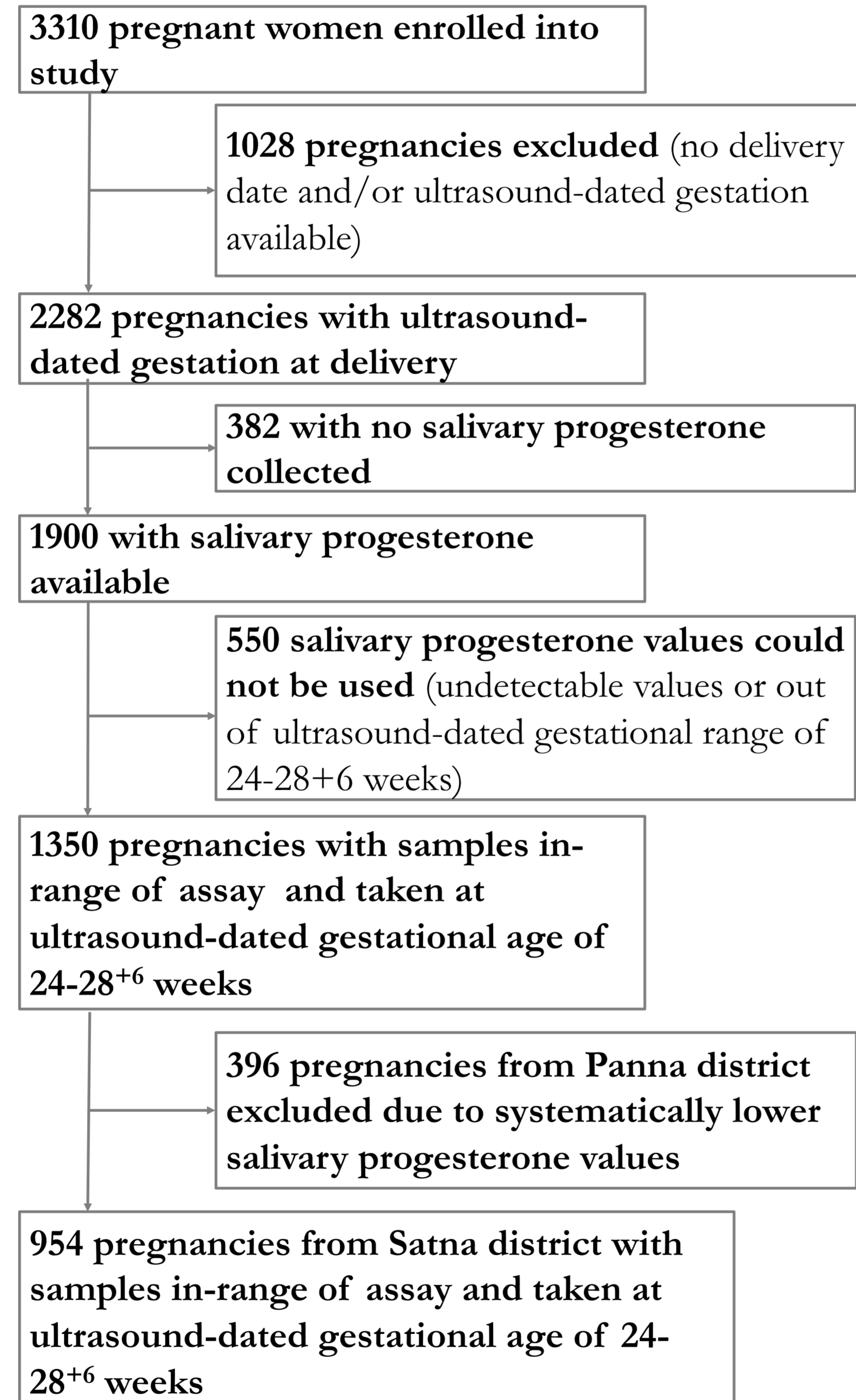
Introduction

The potential of salivary progesterone as a biomarker for preterm birth prediction remains controversial, with some studies suggesting low progesterone levels may indicate preterm birth risk in asymptomatic women.

The PROMISES study aimed to assess the feasibility and efficacy of salivary progesterone (collected between 24-28+6 weeks' gestation) as a low-cost biomarker for preterm birth risk prediction in rural community settings in Madhya Pradesh, India.



Participant flow chart

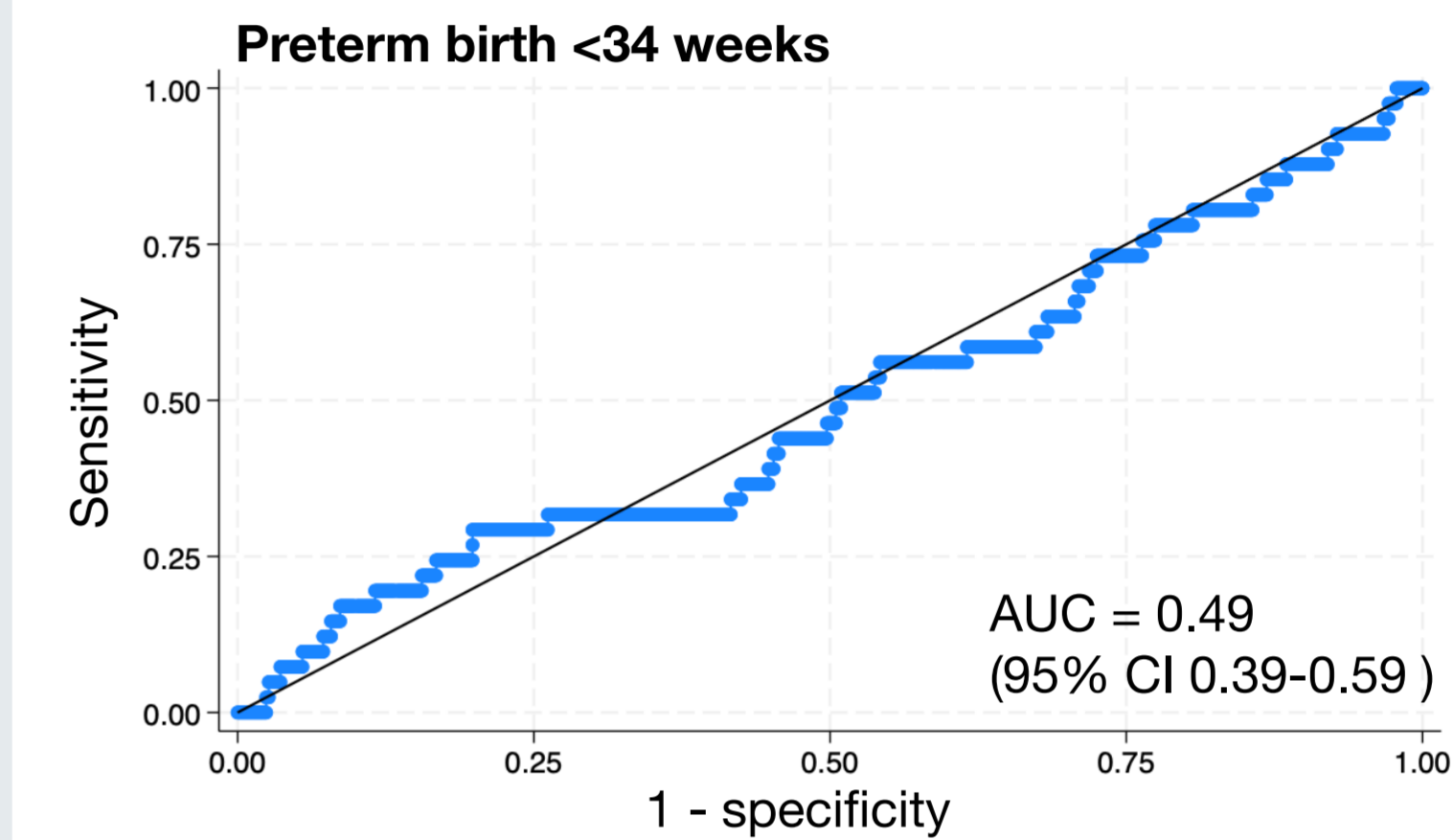


Sociodemographic characteristics of mother by birth outcome

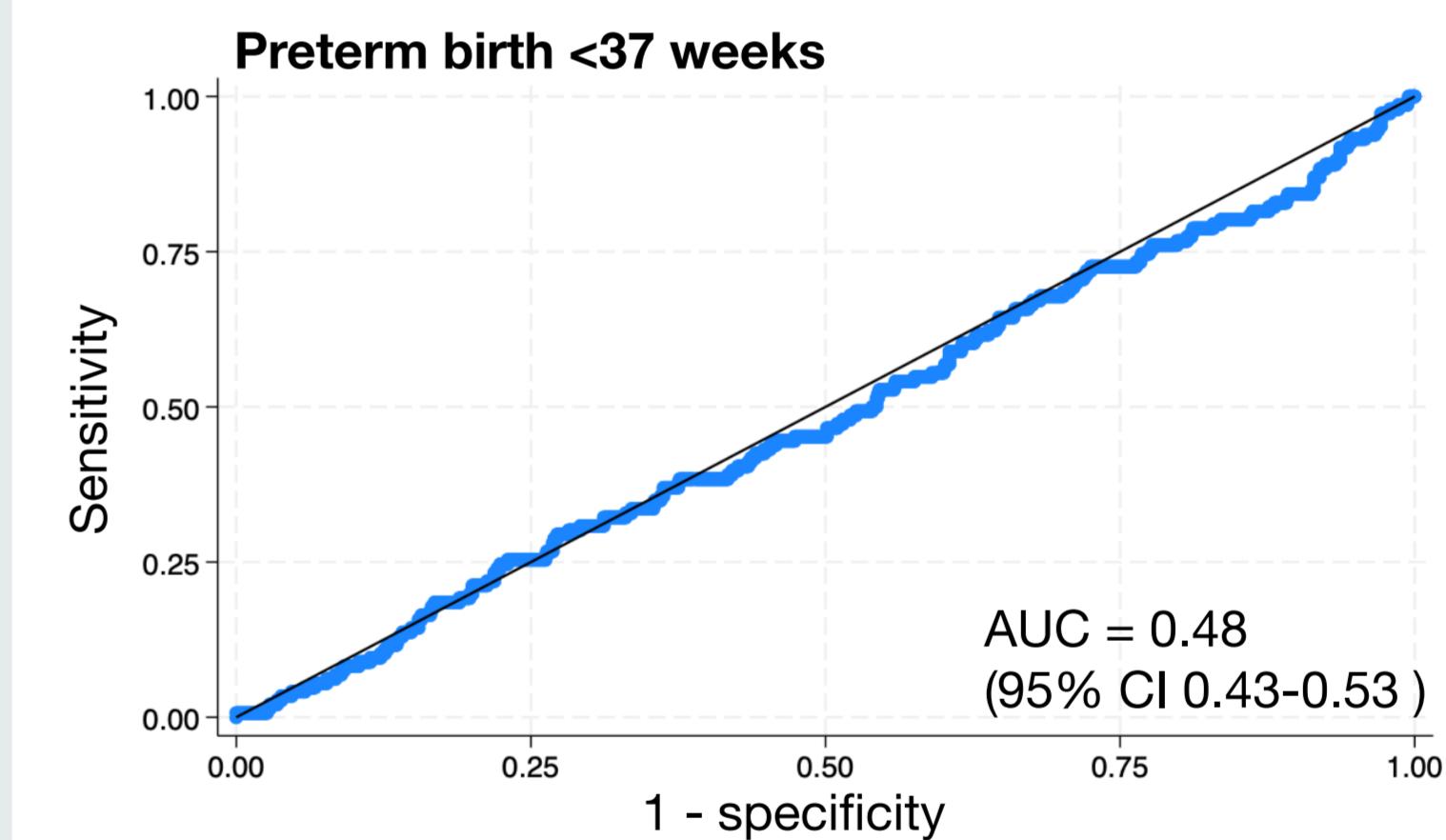
	Preterm (n=459)	Term (n=1823)
Age, years	23.93 (3.24)	23.82 (3.12)
Education, years		
0-5	103 (22.4%)	417 (22.9%)
6-12	331 (72.1%)	1276 (70.0%)
13+	25 (5.4%)	130 (7.1%)
Occupation		
Housewife	387 (84.3%)	1501 (82.3%)
Daily wage earner	60 (13.1%)	281 (15.4%)
Agriculture	5 (1.1%)	6 (0.3%)
Other	6 (1.3%)	19 (1.0%)
Monthly income		
< Rs. 2500	324 (70.6%)	1241 (68.1%)
Rs. 2501-5000	108 (23.5%)	481 (26.4%)
Rs. 5001-7500	19 (4.1%)	65 (3.6%)
Rs. 7501-10000	5 (1.1%)	20 (1.1%)
> Rs. 10000	3 (0.7%)	16 (0.9%)
Caste		
Scheduled Caste	156 (34.0%)	697 (38.2%)
Scheduled Tribe	39 (8.5%)	191 (10.5%)
General	71 (15.5%)	260 (14.3%)
Other	193 (42.0%)	675 (37.0%)

Values displayed as mean (SD) or n (%)

Salivary progesterone does not predict preterm birth



The study observed a preterm birth rate of 20.11% for births <37 weeks, and 8.26% births <34 weeks.



No significant correlations between low salivary progesterone levels and an increased risk of preterm birth was observed.

For preterm birth <34 weeks, OR 0.90 (95% CI 0.46-1.79).

For preterm birth <37 weeks, OR 1.19 (95% CI 0.79-1.78).

Acknowledgements and references

We are grateful to the field study team including the local ASHA workers and outreach workers. This study was approved by both MAMTA Health Institute for Mother and Child (MAMTAHIMC) Ethical Review Board (MERB/Dec-2016/002) and the Institutional Review Board of Mahatma Gandhi Institute of Medical Science (MGIMS/IEC/OBGY/289/2016). Funding for this project was provided by the Biotechnology Industry Research Assistance Council, Dept. of Biotechnology India, and Bill and Melinda Gates Foundation.



PROMISES protocol paper



Acceptability of salivary progesterone testing

Conclusions

Successfully delivered a complex pregnancy study, and report preterm birth rates, within a rural setting in India.

Demonstrated there is poor predictive value in salivary progesterone for risk of preterm birth in this cohort. Suggest the need for integration of additional biomarkers to enhance the accuracy of preterm birth risk prediction models.

We emphasise the critical importance of maintaining sample integrity through proper cold chain management during transportation.

Future research must continue to focus on developing and validating accessible and cost-effective tools for early preterm birth risk assessment, particularly in resource-constrained settings.