Original research

Cohort Profile: The Rajarata Pregnancy Cohort (RaPCo)

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Abstract

Purpose: The Rajarata Pregnancy Cohort (RaPCo) is designed to provide evidence for context-specific practices and to understand the broader socio-demographic, economic, and psychological factors underlying maternal morbidity and mortality in rural Sri Lanka.

Participants: RaPCo included 3374 pregnant women in their early pregnancy (median gestation period of eight weeks) registered with the national pregnancy care program from July to September 2019 in Anuradhapura district, Sri Lanka. The sample included almost 90% of the study population. Baseline data collection included socio-demographic, economic, anthropometric, blood and urine biochemistry, comprehensive mental health, and social capital assessment. Pregnancy outcome data were collected from 96.6% of the entire cohort. The follow-up infant cohort was established with 2400 infants of RaPCo cohort women who are still residing in the area. This cohort profile summarizes the major finding so far as well.

Key findings: The study found that adolescent pregnancies were high (22%) and associated with social factors, undernourishment, and anxiety. Anaemia was prevalent (14.4% in the first trimester), and minor hemoglobinopathies (23%) were found in anaemic pregnant women. The study also revealed high out-of-pocket expenditure for the first antenatal clinic visit ($8.12). Miscarriage was more prevalent than previously reported (24%). Gestational diabetes was prevalent even in the first trimester (15%), and fasting plasma glucose in the first trimester was a good predictor of large for gestational age neonates. Fatty liver grades were identified as significant risk factors for early pregnancy miscarriage (RR12.5), and a valid fatty liver index was developed as a screening tool. The prevalence of metabolic syndrome was 6%, but individual metabolic derangement was higher than expected.

Future plans: This unique dataset and bio samples with population-based early pregnancy enrolment and a low attrition rate and the linked neonatal cohort (70% of the original cohort) will be used to generate evidence on the impact of complex social and mental factors, and biological factors in pregnancy on child health. Further analysis of bio samples will also be carried out to understand the causes and correlates of maternal morbidity.

Keywords: Pregnant women, Cohort studies, RaPCo, Sri Lanka, Morbidity

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Introduction

Global maternal health authorities continue to face challenges concerning ending preventable maternal mortality (EPMM)(1), with a maternal mortality ratio of 211 per 100,000 live births in 2017 [2]. This number accounts for 810 daily maternal deaths. Of these, 94% occur in low- and middle-income countries (LMICs), showing gross inequality as an underlying determinant of maternal deaths [3]. The total estimated number of maternal deaths not representing the estimated maternal near misses, which is around 1867 per 100,000 live births showing that for each maternal death reported, around nine more pregnant or postpartum women go through a near-death experience [4].

In countries such as Sri Lanka, where the maternal mortality ratio (MMR) is relatively low (38 per 100,000 live births) and the actual number of maternal deaths is around 100 per year, focusing only on maternal deaths will not provide adequate information on improving high-quality maternal care. Beyond maternal deaths, near-misses, and severe maternal morbidity, the actual burden of maternal morbidity is not explored extensively in LMICs. Previous small-scale studies have shown that the highest impact on pregnant and postpartum women's daily life could not be due to severe maternal illnesses but to the often neglected minor ailments [5-7]. With the obstetric transition in Sri Lanka, the causes of maternal deaths are shifting from communicable diseases and direct obstetric causes, such as sepsis, haemorrhage, and pulmonary embolism (phase 1), to non-communicable diseases and indirect causes (phases 4 and 5) [8]. In phase 4 of the obstetric transition, the Sri Lankan maternal care program needs to focus on preventing non-communicable diseases and indirect factors that adversely affect pregnancy outcomes. Social development is also critical to further reducing maternal mortality in the later phases of the obstetric transition.

Currently, the Sri Lankan health sector and the global maternal health agenda primarily focus on medical interventions; this approach does not directly address the role of social determinants and social interventions as root causes of the more proximal factors influencing pregnancy outcomes. Although evidence-based interventions focusing on tackling the above priorities are essential, there is a dearth of evidence from LMICs, as most of the baseline normative data and prospective analysis have been generated from high-income countries (HICs). Against this evidence vacuum, the Rajarata Pregnancy Cohort (RaPCo) study was designed to generate local evidence to address these foreseen gaps in EPMM.

Methodology

Cohort description

Details of the study participants, eligibility criteria, study settings, tools used, and other methodology-related details were extensively discussed in the published study protocol [9]. RaPCo is a population-based, prospective cohort study. The study was conducted in Anuradhapura, Sri Lanka, the largest (geologically) district in Sri Lanka with a predominantly rural population.

We aimed to recruit all pregnant women in their early pregnancy (before 13 weeks of gestation (PoG)) permanently residing in the Anuradhapura district and registered in Pregnant Mothers' Registers by the Public Health Midwives (PHM) (grass-root level public health care workers providing maternal and child health services in Sri Lanka). As soon as the pregnancy was informed to the PHM (the routine practice in Sri Lanka), she referred the pregnant woman to the next available RaPCo clinic in the area. RaPCo clinics replaced the routine booking visit of the system and provided all routine services in addition to the study-specific data and sample collection. Clinics were held once a week or fortnight based on the estimated numbers in the particular area.

From 1st July to 31st September 2019, we conducted 226 recruitment clinic sessions in 22 Medical Officer of Health (MOH) areas (basic functional unit of the public health system in Sri Lanka) in the district representing 283 PHM areas. From these sessions, 3405 pregnant women participated in the clinic, and 31 were not included in the cohort due to ineligibility (already registered and completed the booking visit with a baseline assessment and gestation period>13 weeks) or due to missing baseline data. The final dataset included 3374 pregnant women. As this study was conducted parallel to the routine maternal care program in the district and all the baseline investigations were incorporated into the study, we allowed recruitment of all pregnant women who were coming for their booking visit, even if it was after 13 weeks of PoG. This added a small group of pregnant women (n=228, 6.8%) in their early second trimester to the cohort. Of the main cohort, 1770 (52.5%) were recruited at or before eight

weeks of PoG, and another 1376 (40.8%) between 9-13 weeks of PoG. At the time of recruitment, the PoG was approximated to the period of amenorrhea since the majority had not undergone the dating scan or were not yet at the optimal age for a dating scan. However, the PoG was later confirmed and corrected using the USS findings.

As shown in Table 1, the total number of eligible women, as reported in the national pregnancy care program, was 3652. However, during the data comparison and validation process, 148 pregnant women were identified as eligible by PHM and referred to RaPCo clinics but did not participate. They were later documented as having very early miscarriages in PHM records. After the adjustment for very early miscarriages, 3144(89.1% of the total study population were recruited for the study. One of our observations was that in Nuwaragampalatha East (NPE), the district's only "urban" area had the lowest participation rate, with only 75% of the eligible participants recruited to the study. Of the 22 MOH divisions, 20 had >80% participation.

Participants were followed-up at three months (during the second trimester), 6-8 months (after delivery), and 20 months (one year postpartum) after enrollment. The original protocol included follow-up visits during the second and third trimesters. However, the follow-up visits were affected by the COVID-19 pandemic. As a result, follow-up visits in the second trimester were completed for 1450 (43.0%) pregnant women, and in-person follow-up visits in the third trimester were conducted for only 331 (9.8%) pregnant women. However, the main outcome variable, pregnancy outcome data (at least one outcome variable),was collected for 3259 (96.6%) participants. The outcome data collection included reviewing labour room and hospital records and delivery records of PHMs of the entire district. In addition, a telephone interview was conducted among all recruited women(10). For neonatal data collection, child health development records (CHDR) of all recruited mothers were collected through another round of field visits after 20 months of delivery. The characteristics of the study participants are summarized in Table 2.

Patient and Public Involvement statement

The RaPCo protocol was developed using a Participatory and Partnership in Engagement (PPIE) approach, which involved extensive consultations with pregnant women, public health midwives, medical officers of health, and other healthcare providers over more than two years. The PPIE approach ensured that the priorities and perspectives of pregnant women were taken into account in developing the protocol. This included the inclusion of social, neighbourhood, and community-level socio-economic and cultural determinants. In addition, three pregnant colleagues were included as co-investigators to provide a critical perspective on the protocol and process. The protocol was also reviewed by pregnant women and other stakeholders to ensure that it was appropriate and relevant to the needs of pregnant women.

During the research process, pregnant women from different stages of gestation were included to provide their perspectives, priorities, and issues related to the research problem and process. This was done while ensuring the privacy and confidentiality of participant information and empowering participants to be involved in the research process. Pregnant and postpartum women were also involved in preparing public awareness programs and communication.

Ethical considerations

This cohort study has several ethical considerations related to service, data, and bio samples. First, the cohort was integrated with the routine service provisions, and because of the cohort baseline assessment, the routine evaluation was not done by the MOH clinic. Since the original cohort aimed at women in their early pregnancy, a group of women (n=216) were coming for the first time (booking visit) later in their pregnancy. As a service requirement, we included them also in the cohort and provided all investigations and assessments through the cohort. Written informed consent was obtained from all pregnant women before the enrolment. For the minors, consent was obtained from the parent/ legal guardian. All procedures performed were in accordance with the ethical standards of the institution and the 1964 Helsinki declaration. Ethical clearance for the RaPCo study was obtained from the ethics review committee of the Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka (ERC/2019/07).

Table 1. Completeness of the Cohort

MOH Area	Pregnant women registered in the system			Pregnant women included in the Cohort			
	<8weeks	<12 weeks*	Total	<13 weeks	Completeness	Abortions among non participants	Completeness adjusted for abortions
Medawachchiya	175	17	192	189	98.4	5	101.1
Padaviya	78	5	83	83	100.0	0	100.0
Palugaswewa	36	15	51	46	90.2	5	100.0
Galenbidunuwawe	183	25	208	200	96.2	6	99.0
Rajanganaya	120	24	144	135	93.8	7	98.5
Mahawilachchiya	84	14	98	90	91.8	4	95.7
Palagala	146	18	164	150	91.5	4	93.8
Mihintale	130	21	151	133	88.1	9	93.7
Rambewa	139	24	163	143	87.7	10	93.5
Kekirawa	243	38	281	251	89.3	8	91.9
Horowpothana	135	27	162	135	83.3	14	91.2
Galnewa	151	21	172	152	88.4	5	91.0
NuwaragamPalatha Central	219	28	247	213	86.2	11	90.3
Thambuttegama	163	24	187	163	87.2	4	89.1
Ipalogama	156	29	185	160	86.5	3	87.9
Kahatagasdigiliya	153	20	173	145	83.8	6	86.8
Nachchaduwa	94	12	106	84	79.2	7	84.8
Nochchiyagama	187	30	217	174	80.2	7	82.9
Thalawa	211	30	241	188	78.0	9	81.0
Thirappane	104	9	113	88	77.9	4	80.7
Kebithigollewa	84	20	104	73	70.2	11	78.5
NuwaragamPalatha East	157	53	210	151	71.9	9	75.1
Total	3148	504	3652	3146	86.2	148	89.8

*In the national maternal care program <12 weeks is documented.

Measurements

Table 3 shows the measures and variables included in the study.

Findings to date

The detailed methodology underlying the establishment of the cohort is published as a protocol paper [9], which includes all details related to the data collection and methods. In addition to the primary cohort protocol, protocols relating to RaPCo study subcomponents, including sub-studies focused on heart disease complicating pregnancy [11], anaemia in pregnancy [12], and out-of-pocket expenditure in pregnancy [13] are also published.

Table 2. Characteristics of the cohort

Age at conception (years)	n	%
<20	254	7.5
20-24	685	20.3
25-29	1168	34.6
30-34	818	24.2
35-39	376	11.1
40-44	70	2.1
>44	3	0.1
Ethnicity		
Sinhala	2938	87.1
Moor/Malay	392	11.6
Other	44	1.3
Religion		
Buddhists	2905	86.1
Islam	402	11.9
Catholic/Christian	50	1.5
Hindu	17	0.5
Highest grade completed in school		
Up to grade 10	371	11.1
Grade 11	1642	49.2
Grade 12-13	1326	39.7
Marital status		
Currently married	3306	98.0
Currently not married	68	2.0
Gravidity		
1	1041	30.9
2	1059	31.4
3	830	24.6
4	312	9.3
5 or more	128	3.8
Self reported pre-existing medical conditions		
Asthma	223	6.6
Hypertension	200	6.1
Hyperglycemia	98	3.0
Hypothyroidism	77	2.3
Dyslipidemia	56	1.7
Depression	15	0.4

One of the first papers published from the baseline data of the cohort showed that 7.5% of all pregnancies were adolescent pregnancies [14]. More importantly, an especially high rate of adolescent pregnancies among the 1037 primigravida mothers (n=233; 22.4%) was reported. Social factors such as maternal and paternal low education level, unmarried, and recently married were significantly associated with adolescent pregnancies. This analysis also revealed that adolescent pregnant women were more undernourished, did not use the available health services, and had significantly higher anxiety levels during the first trimester than non-adolescent pregnant women. Of the adolescent primigravidae, 47.6% had unplanned pregnancies.

Anaemia was considered one of the major risk factors to study in relation to pregnancy [12]. RaPCo data showed that among 3127 participants analysed, 14.4% were anaemic [15]. Of them, 331 (10.6%) had mild anaemia. Microcytic, normochromic-normocytic, hypochromic-normocytic, and macrocytic anaemia was observed in 243 (54%), 114 (25.3%), 80 (17.8%), and two (0.4%) anaemic pregnant women, respectively. One of the most important findings of this study was that minor hemoglobinopathies were present in at least 23.3% (n=105) of anaemic pregnant women. We further demonstrated that the prevalence of iron deficiency, B12 deficiency, and Southeast Asian ovalocytosis among anaemic pregnant women was 41.9%, 23.8%, and 0.9%, respectively.

Additional analysis showed that provision of continuous care through the National Maternal and Child Health Programme protects against socioeconomic disparities that influence the development of early pregnancy anaemia [16]. However, the geospatial clustering of genetic, socioeconomic, and environmental risk factors for anaemia observed in this study indicated that controlling anaemia with blanket interventions could be unsuccessful [17]. Additional studies using RaPCo data demonstrated the impact of different cut-off values for anaemia detection in the first and second trimesters. These analyses revealed that two out of five women labelled as having anaemia in mid-pregnancy were not anaemic [18]. This analysis led to a policy change in Sri Lanka to change the threshold values for anaemia detection in pregnancy.

While Sri Lanka has a free health care system, the RaPCo data revealed that out-of-pocket expenditure (OOPE) for pregnancy is considerably high in some situations. A comprehensive analysis of OOPE(13)

showed that the first clinic visit among pregnant women costs approximately USD 8.12, accounting for 4.5% of the household expenditure [19].

Challenging the most recently published global data on miscarriage, our study showed that the actual rate of miscarriage among pregnant women might be as high as 23.8% [20]. However, most miscarriages are underreported in the literature due to a lack of early pregnancy registration systems. Our data showed the period of amenorrhea (PoA)-specific miscarriage risk among women registered at weeks 4–5, 6, and 7 of PoA as 23.8%, 19.9%, and 14.3%, respectively. In this analysis, we used PoA rather than PoG because the ultrasound confirmation of dates was not done for most of these women. We further showed that many (n=143, 3.7%) women had miscarriages within two weeks of the first sign of pregnancy.

Hyperglycemia is considered one of the most important medical conditions to screen for and monitor in pregnancy. In our cohort, the prevalence of gestational diabetes mellitus (GDM) in the first trimester was 15.0% [21]. Previously undiagnosed diabetes mellitus (DM) was detected in 2.5% of pregnant women. The relative risk of having a large for gestational age neonate among women with DM and GDM was 2.3 and 1.8, respectively. Our data showed that fasting plasma glucose in the first trimester was a good predictor of large for gestational-age neonates.

Associations between non-alcoholic fatty liver disease (NAFLD) and the development of GDM and early pregnancy miscarriage were investigated in a subsample of this cohort. The prevalence of fatty liver grade (FLG) II and I was 14% and 37%, respectively [22]. Pregnant women with FLG II had a relative risk (RR) of 12.5 for developing GDM compared with FLG 0. More importantly, FLG I (RR 2.1) and FLG II (RR 4.5) were identified as significant risk factors for early pregnancy miscarriage. We also demonstrated that FLG II remained the only independent predictor of miscarriage after adjusting for age, parity, body mass index, blood sugar, blood pressure, and haemoglobin level. In addition, we developed a valid fatty liver index, a tool to screen for NAFLD during routine pregnancy assessment [23].

Recent evidence from various studies shows that metabolic syndrome (MetS) in pregnancy is associated with many adverse pregnancy outcomes. However, the definitions used need to be more consistent. Among RaPCo participants, we estimated MetS using different criteria used in the literature [24]. The prevalence of MetS in RaPCo participants varied between 3.0% (95% CI=2.4%-3.7%) and 5.6% (95% CI=4.8%-6.5%) using different definitions. However, individual metabolic derangements in early pregnancy showed alarmingly high levels, with a mean (SD) levels of triglycerides (TG), total cholesterol (TC), high-density lipoprotein (HDL), low-density lipoprotein (LDL), fasting plasma glucose, and 2-hour oral glucose tolerance test of 87.71 (38.7), 172.2 (34.7), 49.6 (11.5), 122.6 (32.3), 82.2 (12.8) and 120.3 (11.5), respectively.

Given that malnutrition-related issues emerged from the COVID-19 pandemic and the ongoing economic crisis in Sri Lanka, we validated the Latin American and Caribbean Food Security Scale (*EscalaLatinoamericana y Caribena de Seguridad Alimentaria* - ELCSA) among pregnant women in the RaPCo study(25). The tool showed good internal consistency (Cronbach's alpha = 0.79) and a good model fit (Rasch infit statistic range: 0.85 to 1.07). Therefore, this tool was introduced to the national maternal care program for routine use.

Renal functions during pregnancy undergo rapid changes, and the "normality" data are lacking, especially for the region and LMICs. Therefore, in this cohort, we evaluated the serum creatinine levels, and using the 97.5th percentile, thresholds for normal values were proposed. For 4-7, 8-9, 10-12, 24-27, and 28-30 weeks of gestation, thresholds were 72.4, 69.1, 70.0, 63.6, and 66.0 µmol/L, respectively.

Further exploration of medical conditions complicating pregnancy showed that 6.6% of pregnant women in this cohort were asthmatic, yet only 41.7% were on regular treatment. We further noticed that the prevalence of low birth weight was higher (16%) among those with asthma [26].

Beyond the medical and health-related findings, RaPCo helped the research community to understand the validity and feasibility of alternative survey methods [10]. Because of the COVID-19 pandemic, we employed a telephone-based survey method for follow-up data collection. However, in this rural community, contact ability using the numbers provided was reduced to less than 50% after nine months. Of those who were contacted, internet-based messaging apps were used by only one-third.

Table 3. Measures and variables included

Socio-demographic data	Pregnant women: age, ethnicity, religion, education, marital status, occupation/Husbands' age, ethnicity, religion, education, occupation/ details of household members, household assets
Pregnancy-related data	Period of amenorrhoea, gestation, parity, planned or not, pre-conceptional folic acid use, early pregnancy-related symptoms
Previous pregnancies data	Age at conception, outcome, mode of delivery, complications, details of family planning used (for each pregnancy separately)
Medical conditions	History of medical conditions and details, including family history,
Mental health/psychological variables	EPDS scores, happiness score, psychological distress (GHQ 10), fear of birth (FoB), emotional intelligence (EQ), Ten Item Personality Inventory (TIPI)
Anthropometric data	Height, weight, hip and waist circumference
General health data	Blood pressure, pulse rate, general examination findings, auscultation, and cardiovascular system examination findings
Blood biochemistry	Fasting plasma glucose, OGTT test second hour glucose value, full blood count (all red cell indices), serum LDL, HDL, triglycerides SGOT, SGPT, serum creatinine, GGT, serum cortisol
Urine biochemistry	Urine colour, sugar, urine proteins, crystals, organisms
Other variables/ measurements tools (sub samples of the cohort)	Social capital tool LSCAT-MH, Out-of-pocket expenditure details (monthly), productivity cost, food frequency, food plate, gender-based violence, physical activity, Fetal social capital, household food security (ELCSA),
Specific measurements for sub samples	2D-ECHO, ECG, USS abdomen (Liver)
Delivery and pregnancy outcome data	Period of Gestation, pregnancy outcome, birth weigh, birth length, Apgar score, details of delivery including complications
Infant data	Length and weight at each clinic visit

Strengths and limitations

The main strengths of this cohort include the community-based approach to participant recruitment. As illustrated in Table 1, 90% of the reference population was successfully recruited into the cohort. These data represent an unbiased population (not a sample) of pregnant women in rural Sri Lanka. Another major strength of this cohort is the early pregnancy recruitment and early baseline assessment, which is not seen in many pregnancy cohorts worldwide. Most RaPCo participants were recruited in their first trimester, and more than 1000 women were in early pregnancy (less than eight weeks of PoA).

Moreover, RaPCo being a prospective cohort, eliminates selection bias, which can occur in many studies when pregnant women are selected retrospectively through hospital registers. All data collection procedures were conducted according to established protocols by trained medical officers or research assistants under supervision. Hence, the data quality was maintained to optimal standards. In addition, we conducted all laboratory procedures to maintain quality control, and specialists conducted advanced investigation procedures such as haematological analyses and echocardiograms.

One major weakness of the study could be that unwanted pregnancies may not be included here. If a pregnancy was unwanted, the pregnancy may not have been registered by the PHM and thus may not have been considered for recruitment into the cohort. In addition, pregnancies leading to nontherapeutic miscarriages may not have been included in this cohort. Another weakness of the cohort was the effect of the COVID-19 pandemic, which prevented in-person data collection during delivery, which led to limitations on outcome data collection.

Collaboration

The investigators of RaPCo welcome collaborations and requests for data analysis, further investigations of biological samples, and follow-up cohort studies. The investigators consider all requests through a standard procedure involving a review of a brief proposal. Please

get in touch with the authors for the data or bio sample analysis requests.

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