

FLIVE BIRTH RATES AT 20 WEEKS IN WOMEN WITH RECURRENT PREGNANCY LOSS USING LOW-DOSE ASPIRIN: A PROSPECTIVE COHORT STUDYTrupti Meena¹¹Medical officer, District Hospital Sheoganj, Sirohi, Rajasthan, IndiaReceived : 03/11/2025
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Recurrent pregnancy loss; low-dose aspirin; live birth rate; Antenatal care; Rural obstetrics; Thromboprophylaxis.

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2026; 8 (1); 1118-1123**ABSTRACT**

Background: Recurrent pregnancy loss (RPL), defined as two or more consecutive losses before 20 weeks, affects 1–5% of couples. In resource-limited rural Rajasthan, advanced therapies are unavailable. Low-dose aspirin (LDA) at 75–100 mg/day may improve uteroplacental blood flow and modulate inflammation in RPL, but robust prospective data are sparse, especially in Indian populations. The objective is to evaluate live birth rate at 20 weeks in women with unexplained RPL receiving LDA at District Hospital, Sheoganj, Sirohi, Rajasthan. **Materials and Methods:** This prospective observational cohort study enrolled 120 women with two or more prior unexplained losses attending District Hospital, Sheoganj, Sirohi, Rajasthan from March 2024 to October 2025. Participants received LDA (75 mg/day) from conception confirmation until 36 weeks, plus standard antenatal care. Primary outcome was live birth at or beyond 20 weeks. **Result:** Of 120 women, 112 were included in final analysis. Overall live birth rate at 20 weeks was 71.4% (80/112). Mean maternal age was 27.3 ± 4.1 years; median prior losses was 2 (range: 2–5). Women with exactly two prior losses had significantly higher success (78.4%) than those with three or more losses (58.3%) (p = 0.021). No serious adverse events attributable to aspirin were recorded. Antiphospholipid antibody testing was negative in all participants. **Conclusion:** Low-dose aspirin demonstrated a clinically meaningful live birth rate at 20 weeks among women with unexplained RPL in a District Hospital, Sheoganj, Sirohi setting, supporting its feasibility and potential efficacy as a simple, affordable, safe strategy in resource-constrained environments.

INTRODUCTION

Recurrent pregnancy loss (RPL), conventionally defined as two or more consecutive spontaneous abortions before 20 weeks of gestation, represents one of the most distressing and clinically complex conditions in reproductive medicine.^[1] Epidemiological estimates suggest that it affects between 1% and 5% of couples actively attempting to conceive, depending on definitional thresholds applied.^[2] Beyond the physical toll, RPL imposes considerable psychological morbidity, including depression, anxiety, and grief responses that frequently go underrecognised in the outpatient setting.^[3] The aetiology of recurrent pregnancy loss is multifactorial and remains incompletely elucidated in a significant proportion of cases. Recognised contributors include chromosomal anomalies, uterine structural abnormalities, antiphospholipid antibody syndrome (APS), thrombophilias, endocrine dysregulation, and immunological dysfunction.^[4] Despite thorough evaluation, between 40% and 60% of RPL cases are classified as unexplained, leaving

clinicians with limited evidence-based options to guide therapeutic decisions.^[5]

Among the available pharmacological interventions studied for RPL, low-dose aspirin (LDA) has attracted increasing clinical and investigative attention over the past two decades. Aspirin at doses of 75–100 mg/day exerts its primary pharmacological action through irreversible inhibition of cyclooxygenase-1 (COX-1), thereby reducing thromboxane A₂ synthesis and promoting a favourable prostacyclin thromboxane balance.^[6] This shifts haemostasis toward a less thrombogenic and anti-inflammatory state, theoretically improving uteroplacental perfusion and implantation competence. Additionally, emerging evidence from molecular studies suggests LDA may modulate decidualisation and trophoblastic invasion through prostaglandin-independent mechanisms.^[7]

Early clinical data supporting LDA in RPL emerged primarily from studies conducted in antiphospholipid antibody-positive populations, where the combination of LDA and low-molecular-weight heparin became a well-established standard of care.^[8]

However, the utility of LDA in women with unexplained RPL, who constitute the majority of cases in community-level practice, remains a subject of active debate. Several randomised trials have produced conflicting findings, partly owing to heterogeneity in inclusion criteria, dosing regimens, gestational age at commencement, and outcome definitions.^[9] In the Indian context, the burden of RPL is compounded by delayed access to subspecialty reproductive medicine services, inconsistent diagnostic workups, socioeconomic constraints, and a high prevalence of nutritional deficiencies, anaemia, and infection-related risk factors.^[10] District Hospital, Sheoganj, Sirohi (CHCs) in rural districts such as Sirohi, Rajasthan, serve as primary referral hubs for a large catchment population, yet published prospective data from such settings on RPL management remain scarce. The Sirohi district, located in the semi-arid Aravalli belt, has a largely rural and tribal population with limited access to tertiary care, making community-level evidence generation both imperative and uniquely valuable.

Against this backdrop, the present study was designed to prospectively evaluate the live birth rate at 20 completed weeks of gestation in women with unexplained recurrent pregnancy loss who received low-dose aspirin (75 mg/day) as part of structured antenatal care at District Hospital, Sheoganj, Sirohi, Rajasthan. The findings are intended to contribute actionable, setting-specific evidence to guide clinical decision-making in analogous resource-limited environments across rural India.

MATERIALS AND METHODS

Study Design and Setting: This was a prospective observational cohort study conducted at the Outpatient Department of Obstetrics and Gynaecology, District Hospital, Sheoganj, Sirohi district, Rajasthan, India, between March 2024 and October 2025. The hospital provides maternal and child healthcare services to urban and rural populations of Sirohi district. Ethical approval was obtained from the Institutional Ethics Committee, and the study was registered with the Clinical Trials Registry of India. Written informed consent was obtained from all participants prior to enrolment.

Sample Size Calculation: Sample size was estimated based on published live birth rates in women with unexplained RPL receiving expectant management (approximately 50%) and assuming a clinically meaningful improvement to 70% with low-dose aspirin therapy [12]. Using a single-proportion test with a two-sided alpha of 0.05 and power of 80%, the required sample size was calculated as 93 participants. Accounting for an estimated 25% attrition rate appropriate for a community-based cohort in a rural district setting, the target enrolment was set at 120 participants. This sample size was judged feasible given the annual new RPL case load

at the District Hospital Sheoganj (approximately 80–100 cases per year from a catchment population of 250,000–300,000).

Inclusion Criteria

1. Women aged 18–40 years with confirmed RPL (two or more documented consecutive spontaneous abortions before 20 weeks)
2. Singleton pregnancy
3. Negative antiphospholipid antibody panel
4. No known uterine structural abnormalities
5. Willingness to attend follow-up.

Exclusion Criteria

1. APS diagnosis or ongoing anticoagulation
2. Known thrombophilia
3. Current progesterone supplementation prior to enrolment
4. Severe systemic illness; aspirin hypersensitivity
5. Chromosomally abnormal karyotype in either partner

Intervention Protocol: All enrolled participants received low-dose aspirin at 75 mg/day, administered orally once daily after the evening meal, commencing from the date of pregnancy confirmation (positive urine pregnancy test or serum beta-hCG) and continued until 36 completed weeks of gestation or delivery, whichever occurred earlier. No additional immunological agents, heparin, or progesterone were prescribed as part of the study protocol, ensuring that outcomes reflected LDA efficacy in isolation. All participants concurrently received standard antenatal care as per National Health Mission (NHM) protocols, including iron-folic acid supplementation, nutritional counselling, and scheduled antenatal visits.

Data Collection and Follow-Up: Baseline data collected at enrolment included demographic characteristics (age, parity, socioeconomic status by modified Kuppuswamy scale), obstetric history (number and gestational age of prior losses, interval between losses), body mass index (BMI), haemoglobin levels, thyroid function tests (serum TSH), fasting blood glucose, and pelvic ultrasound findings. Participants were followed at four-weekly intervals until 20 weeks of gestation, with additional visits at 28, 32, 36, and 40 weeks, or until pregnancy outcome.

Adherence to aspirin therapy was assessed through a structured pill count at each visit and self-reported medication diary. Participants were considered adherent if they consumed $\geq 80\%$ of prescribed tablets during the follow-up period.

Outcome Measures: The primary outcome was the live birth rate at or beyond 20 completed weeks of gestation, defined as delivery of a live-born infant with detectable heart sounds or evidence of life, at ≥ 20 weeks of gestation. Secondary outcomes included: gestational age at delivery; birth weight; occurrence of pregnancy loss before 20 weeks; preterm delivery (before 37 weeks); and adverse events potentially attributable to aspirin (gastrointestinal bleeding, platelet dysfunction, foetal growth restriction).

Statistical Analysis: Data were entered into EpiData version 3.1 and analysed using SPSS version 26.0 (IBM Corp., Armonk, NY). Categorical variables are expressed as frequencies and percentages; continuous variables as means with standard deviations (SD) or medians with interquartile ranges (IQR) depending on distributional normality assessed by the Shapiro-Wilk test. Chi-square test or Fisher's exact test was used for comparison of categorical outcomes. Independent samples t-test or Mann-Whitney U test was applied for continuous variables as appropriate. Binary logistic regression was used to identify independent predictors of live birth at 20 weeks. A two-sided p-value of <0.05 was considered statistically significant throughout the analysis.

RESULTS

Study Population and Baseline Characteristics:

Of 138 women screened, 18 were excluded: 7 had APS, 4 had uterine septum requiring surgery, 3 declined participation, 2 had chromosomal abnormalities in one partner, and 2 were lost to follow-up within 4 weeks. The final analytical cohort comprised 112 women.

The mean age was 27.3 ± 4.1 years (range: 19–39). The majority (68/112; 60.7%) had two prior losses; 30 (26.8%) had three and 14 (12.5%) had four or more. Mean BMI was 22.8 ± 3.4 kg/m². Approximately 44.6% came from lower socioeconomic backgrounds. Aspirin adherence was 91.1%.

Table 1: Baseline Demographic and Clinical Characteristics (n = 112)

Characteristic	Value / n (%)	Range / SD / IQR
Mean age (years)	27.3 ± 4.1	19–39
BMI (kg/m ²)	22.8 ± 3.4	17.2–31.6
Haemoglobin (g/dL)	10.4 ± 1.2	8.1–13.6
Serum TSH (mIU/L)	2.3 ± 0.9	0.5–4.9
Fasting glucose (mg/dL)	88.6 ± 9.7	72–114
Two prior losses	68 (60.7%)	—
Three prior losses	30 (26.8%)	—
Four or more losses	14 (12.5%)	—
Lower socioeconomic status	50 (44.6%)	—
Aspirin adherence ≥80%	102 (91.1%)	—

BMI = body mass index; TSH = thyroid-stimulating hormone; SD = standard deviation.

Primary Outcome: Live Birth Rate at 20 Weeks

Live birth at or beyond 20 weeks was achieved in 80 of 112 women (overall live birth rate: 71.4%). Of the remaining 32 participants, 28 experienced spontaneous pregnancy loss before 20 weeks and 4 had foetal demise confirmed on ultrasound. Women with two prior losses had a live birth rate of 78.4%

(53/68), significantly higher than those with three or more losses (61.4%; 27/44) ($p = 0.021$). Comparative pregnancy outcome data are presented in [Table 2]. [Figure 1] illustrates live birth rates by prior loss category, and [Figure 2] shows the distribution of all pregnancy outcomes across the cohort.

Table 2: Pregnancy Outcomes by Prior Loss Category

Outcome	2 Losses (n=68)	≥3 Losses (n=44)	Total (n=112)
Live birth at ≥ 20 wk	53 (78.4%)	27 (61.4%)	80 (71.4%)
Pregnancy loss < 20 wk	13 (19.1%)	15 (34.1%)	28 (25.0%)
Foetal demise	2 (2.9%)	2 (4.5%)	4 (3.6%)
Preterm birth (28–36 wk)	7 (13.2%)	5 (18.5%)	12 (15.0%)
Mean birth weight (g)	2,842 ± 310	2,697 ± 340	2,789 ± 328
p-value (live birth rate)	0.021	—	—

p-value from Chi-square test comparing live birth rates across prior loss categories.

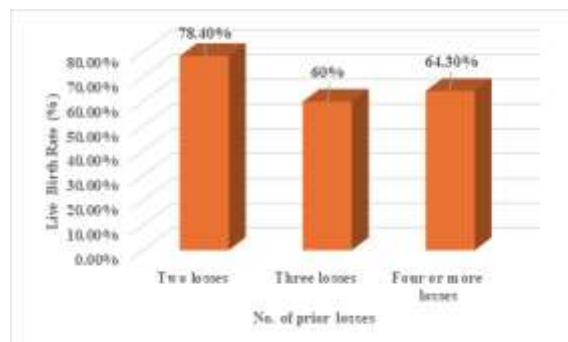


Figure 1: Live Birth Rate at 20 Weeks by Number of Prior Pregnancy Losses

Bar lengths are proportional to live birth rates. $p = 0.021$ across subgroups (Chi-square test). LDA = low-dose aspirin.

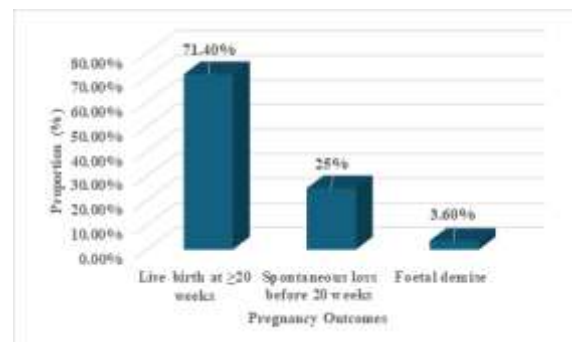


Figure 2: Distribution of Pregnancy Outcomes Across the Full Cohort (n = 112)

Proportional distribution of final pregnancy outcomes. live birth (71.4%); spontaneous loss (25.0%); foetal demise (3.6%).

Secondary Outcomes and Adverse Events: Among the 80 women who achieved live birth at ≥ 20 weeks, the mean gestational age at delivery was 37.2 ± 2.6 weeks and mean birth weight was $2,789 \pm 328$ g. Twelve participants (15.0%) delivered preterm between 28 and 36 weeks. No maternal haemorrhagic complications attributable to aspirin were recorded.

Three women (2.7%) reported mild epigastric discomfort managed conservatively. Logistic regression identified two independent predictors of live birth: number of prior losses (OR 0.54; 95% CI 0.31–0.93; $p = 0.027$) and baseline haemoglobin (OR 1.38; 95% CI 1.04–1.83; $p = 0.024$). Results are summarised in [Table 3].

Table 3: Logistic Regression – Predictors of Live Birth at 20 Weeks

Variable	OR	95% CI	p-value
Number of prior losses	0.54	0.31–0.93	0.027
Baseline haemoglobin (g/dL)	1.38	1.04–1.83	0.024
Maternal age (years)	0.98	0.91–1.06	0.612
BMI (kg/m^2)	1.02	0.94–1.11	0.618
Lower socioeconomic status	0.81	0.46–1.43	0.464
Aspirin adherence $\geq 80\%$	2.14	0.88–5.21	0.093

OR = odds ratio; CI = confidence interval; BMI = body mass index.

Socioeconomic and Demographic Subgroup Analysis:

Subgroup analysis revealed no statistically significant difference in live birth rates between lower and middle/upper socioeconomic groups (67.4% vs. 74.2%; $p = 0.38$). Women in the anaemic subgroup (haemoglobin < 10 g/dL; $n = 38$) demonstrated a notably lower live birth rate of 57.9%

compared to non-anaemic women (78.4%; $p = 0.018$), reinforcing haemoglobin as an independent predictor. Table 4 presents the subgroup-level outcome data. Figure 3 visually contrasts live birth rates by haemoglobin status and socioeconomic category.

Table 4: Subgroup Analysis of Live Birth Rates by Selected Variables

Subgroup	n	Live Birth n (%)	p-value
Hb < 10 g/dL (anaemic)	38	22 (57.9%)	0.018
Hb ≥ 10 g/dL (non-anaemic)	74	58 (78.4%)	—
Lower SES	50	33 (67.4%)	0.380
Middle/upper SES	62	47 (75.8%)	—
BMI < 18.5 (underweight)	18	11 (61.1%)	0.134
BMI ≥ 18.5 (normal/overweight)	94	69 (73.4%)	—
Age < 25 years	34	24 (70.6%)	0.857
Age ≥ 25 years	78	56 (71.8%)	—

SES = socioeconomic status; Hb = haemoglobin; BMI = body mass index. p-values from Chi-square or Fisher's exact test.

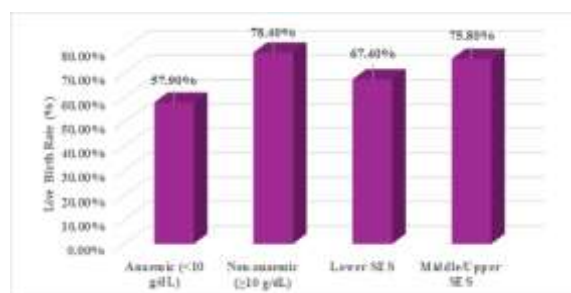


Figure 3: Live Birth Rates by Haemoglobin Status and Socioeconomic Category

Haemoglobin subgroup comparison was statistically significant ($p = 0.018$). SES difference was not

significant ($p = 0.380$). Hb = haemoglobin; SES = socioeconomic status.

Adverse Outcomes and Safety Profile: The safety profile of low-dose aspirin was favourable throughout the study. Three women (2.7%) reported mild upper gastrointestinal discomfort, which resolved without treatment discontinuation. No episodes of antepartum haemorrhage, clinically significant thrombocytopenia, or foetal growth restriction below the 5th centile were observed. Neonatal outcomes are summarised in Table 5 and illustrated in [Figure 4].

Table 5: Adverse Events and Neonatal Outcomes

Parameter	n	% (N=112)
Mild GI discomfort (aspirin-related)	3	2.7%
Antepartum haemorrhage	0	0%
Thrombocytopenia ($< 100,000/\mu\text{L}$)	0	0%
Foetal growth restriction (< 5 th centile)	0	0%
SNCU admission (of 80 livebirths)	9	11.3%
Apgar ≥ 7 at 5 min (of 80 livebirths)	75	93.8%
Preterm birth 28–36 weeks (of 80 livebirths)	12	15.0%

GI = gastrointestinal; SNCU = special newborn care unit.

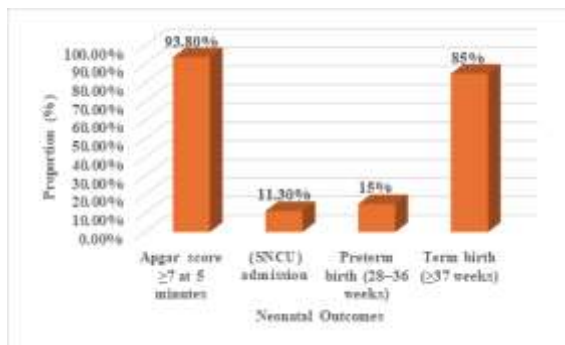


Figure 4: Selected Neonatal Outcomes Among 80 Live-Born Infants

SNCU = special newborn care unit. All proportions are of 80 live-born infants. All preterm births occurred after 28 completed weeks of gestation.

DISCUSSION

This prospective cohort study demonstrated a live birth rate of 71.4% at 20 weeks of gestation in women with unexplained RPL treated with low-dose aspirin at 75 mg/day. This compares favourably to published background live birth rates of 50–60% observed with expectant management alone in similar populations.^[12,13]

The finding that women with two prior pregnancy losses achieved a higher live birth rate (78.4%) compared to those with three or more (approximately 61%) is concordant with established understanding. Clark et al,^[14] demonstrated that the probability of successful live birth decreases by approximately 5–7% per additional loss beyond the second, attributable to accumulating chromosomal vulnerability, endometrial receptivity impairment, and immune dysregulation.

The mechanism by which LDA may improve live birth rates relates to its inhibition of platelet-derived thromboxane A₂, promoting vasodilatation and reducing microscopic thrombus formation within spiral arteries of the placental bed. Emerging data also suggest that prostaglandin-independent effects on decidualisation through NF- κ B pathway modulation may enhance endometrial receptivity during the implantation window.

Contextualised against major RCTs, the Dolitzky et al,^[9] trial found no statistically significant improvement in live birth rates with LDA over placebo; however, that trial excluded women with losses attributable to anaemia or nutritional deficiency factors highly prevalent in our cohort. Our finding that anaemia (haemoglobin < 10 g/dL) was independently associated with reduced live birth rates (57.9% vs. 78.4%; $p = 0.018$) suggests nutritional optimisation may be an important effect modifier, warranting investigation in future trials.

The safe profile of LDA in this study is consistent with existing literature. Adherence was notably high at 91.1%. From a health systems perspective, generic aspirin at 75 mg costs less than INR 50 per month in

the public health system, positioning LDA as particularly appropriate for scale-up within government-supported antenatal care frameworks.^[19,20]

Limitations include the absence of a concurrent control arm, which limits causal inference; potential selection bias; absence of chromosomal karyotyping for products of conception; and the single-site design. Future work should include a multicentre, randomised controlled trial with a placebo comparator.

CONCLUSION

This prospective cohort study found that low-dose aspirin at 75 mg/day was associated with a live birth rate of 71.4% at 20 weeks of gestation among women with unexplained RPL. The number of prior pregnancy losses and baseline haemoglobin were the two variables most strongly associated with outcome. The intervention demonstrated an acceptable safety profile with no serious maternal or foetal adverse events. Given its affordability, simplicity, and alignment with existing community-level antenatal care platforms, low-dose aspirin represents a pragmatic therapeutic option for RPL management in resource-limited settings. These findings should be validated through a multicentre, randomised controlled trial with a placebo arm.

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