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Tele-ANC for high-risk pregnancies versus standard clinic-based follow-up: A non-inferiority randomized trial

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Abstract
Background: High-risk pregnancies need better antenatal care (ANC). Telemedicine-based ANC (Tele-ANC) has come up as a way to improve access and continuity of care. However, there is limited evidence comparing its effectiveness to standard clinic-based ANC in Indian high-risk populations.
Objective: To see if Tele-ANC is not worse than standard clinic-based follow-up in maternal and perinatal outcomes among high-risk pregnant women.
Methods: A one-year non-inferiority randomized controlled trial took place at Gouri Devi Institute of Medical Science, Durgapur. We randomized 200 high-risk pregnant women to Tele-ANC (n=100) or standard clinic-based ANC (n=100). Tele-ANC included scheduled video consultations, remote monitoring of blood pressure and fetal movements, and hotline support. The main outcome was a composite of adverse maternal outcomes (preeclampsia progression, ICU admission, uncontrolled hypertension, severe anemia). Secondary outcomes included perinatal outcomes, number of unscheduled visits, patient satisfaction, and compliance. We set a non-inferiority margin of 10%.
Results: A composite adverse maternal outcome occurred in 14% of Tele-ANC participants compared to 16% in the standard ANC group (risk difference -2%, 95% CI -8.1 to +4.1), which met the non-inferiority criterion. Perinatal outcomes (preterm birth, NICU admission, birth weight) were similar. Tele-ANC significantly reduced total physical visits and increased patient satisfaction.
Conclusion: Tele-ANC is not worse than standard clinic-based ANC for high-risk pregnancies. It also helps reduce clinic burden and improve patient satisfaction. We can safely add Telemedicine-supported ANC into high-risk pregnancy management protocols in resource-limited settings.

Keywords: Telemedicine, high-risk pregnancy, antenatal care, non-inferiority trial, maternal outcomes

Introduction

High-risk pregnancies lead to higher rates of illness and death among mothers in low- and middle-income countries, particularly in India. Despite some improvements over the years, access to antenatal care (ANC) and timely follow-ups remain inadequate. Traditional clinic-based ANC models require multiple visits, which can be difficult due to geographical, financial, work-related, or social challenges. Telemedicine has become a cost-effective way to expand healthcare access, maintain continuity, and monitor pregnancy care.

Tele-antenatal care (Tele-ANC) includes remote monitoring, virtual consultations, and easy digital access to healthcare experts. During the COVID-19 pandemic, many global guidelines supported remote ANC models to lower exposure risks while ensuring proper pregnancy monitoring.[1-3] Early evidence suggests that Tele-ANC may improve compliance, cut down unnecessary clinic visits, and keep low-risk pregnancies safe.[4] However, there is little data from India assessing Tele-ANC for high-risk pregnancies, where close monitoring is crucial.

Conditions such as gestational hypertension, preeclampsia, gestational diabetes mellitus (GDM), hypothyroidism, and fetal growth restriction (FGR) require frequent follow-ups. Tele-ANC could lessen the burden on hospitals and improve convenience for patients without harming outcomes, but Indian evidence is needed to support this idea.

Non-inferiority trials are helpful for evaluating telemedicine models, as they check whether a new, more convenient approach performs similarly to standard care within an acceptable range. International non-inferiority trials like the CRADLE study [5] and others from Australia and Canada have shown that Tele-ANC can be as effective as traditional ANC for certain groups. [6, 7] However, these findings cannot be directly applied to high-risk populations in India due to

differences in socio-economic factors, infrastructure, and the obstetric care system.

Therefore, this one-year non-inferiority randomized controlled trial was conducted to compare maternal and neonatal outcomes between Tele-ANC and standard clinic-based ANC for high-risk pregnant women at Gouri Devi Institute of Medical Science in Durgapur, West Bengal.

Objectives

Primary Objective

To find out if Tele-ANC is as effective as standard clinic-based ANC in preventing combined adverse maternal outcomes in high-risk pregnant women.

Secondary Objectives

1. To compare perinatal outcomes between the two groups.
2. To assess patient satisfaction and compliance.
3. To evaluate the number of unscheduled or emergency visits.
4. To estimate the reduction in physical ANC visits through Tele-ANC.

Materials and Methods

Study Design

A randomized controlled trial with parallel groups and an open label.

Study Setting and Duration

The study took place at the Department of Obstetrics & Gynaecology, Gouri Devi Institute of Medical Science in Durgapur, West Bengal, India, over the course of one year.

Participants

Inclusion Criteria

- Pregnant women aged 18 to 40 years
- Singleton pregnancy
- High-risk pregnancies diagnosed as:

1. Gestational hypertension
2. Preeclampsia
3. GDM on diet or oral agents
4. Hypothyroidism
5. Previous cesarean section
6. FGR
7. Anemia (Hb ≥ 8 g/dL)

- Gestational age at recruitment: 20 to 32 weeks
- Must have a functional smartphone with internet access

Exclusion Criteria

- Severe preeclampsia
- Eclampsia
- GDM requiring insulin
- Severe anemia (Hb < 8 g/dL)
- Multiple pregnancy
- Congenital fetal anomalies
- Patients who are unwilling or unable to follow the teleconsultation protocol

Sample Size

With a maternal adverse outcome rate of 15% in the standard ANC group, a non-inferiority margin of 10%, 80% power, and $\alpha = 0.05$, the necessary sample size was 90 per group. Factoring in a 10% attrition rate, 100 participants were enrolled in each arm, totaling 200.

Randomization and Allocation

Participants were randomly assigned at a 1:1 ratio to either Tele-ANC or standard ANC, using a computer-generated random sequence. Allocation was kept secret in sealed opaque envelopes.

Intervention

Tele-ANC Group

Participants received:

- Scheduled video consultations at intervals similar to those in routine ANC
- Remote monitoring of:

1. Blood pressure (home BP device provided)
2. Fetal movement count
3. Blood sugar logs (for GDM)

- A 24/7 telephonic helpline
- One mandatory in-person visit in the first trimester and one in the third trimester, along with in-person ultrasound

Standard ANC Group

Routine ANC visits following institutional protocol, with physical visits for all assessments.

Primary Outcome

Composite adverse maternal outcome:

- Progression to severe preeclampsia
- Maternal ICU admission
- Uncontrolled hypertension (> 160/110 mmHg)
- Severe anemia (Hb < 7 g/dL)
- Maternal infection requiring admission

Secondary Outcomes

- Preterm birth (< 37 weeks)
- Low birth weight (< 2500 g)
- NICU admission
- Mode of delivery
- Number of unscheduled visits
- Patient satisfaction (5-point Likert scale)
- Compliance with scheduled ANC

Data Analysis

Data were analyzed using SPSS v26. Categorical variables were compared with chi-square tests, while continuous variables were assessed using t-tests. The non-inferiority margin was evaluated using two-sided 95% CI of the risk difference between groups.

Results

Participant Flow Diagram

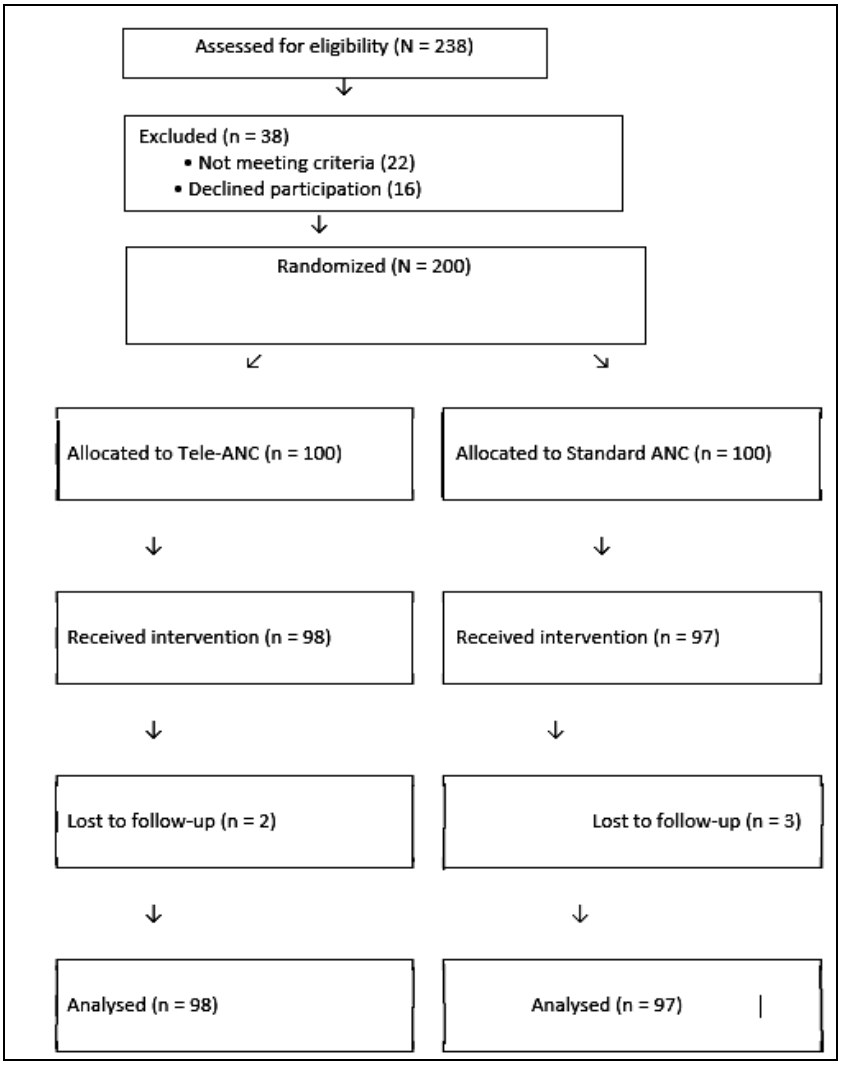

Fig 1: Consort Flow Diagram (Text-based Insert)

Baseline Characteristics

Table 1: Baseline Characteristics of Participants

Variable	Tele-ANC (n = 98)	Standard ANC (n = 97)	p-value
Mean age (years)	26.8±4.2	27.1±4.5	0.62
Gravida ≥ 2	41 (41.8%)	39 (40.2%)	0.81
Gestational age at enrolment (weeks)	18.4±3.1	18.1±3.4	0.48
PIH / Chronic hypertension	21 (21.4%)	19 (19.6%)	0.74
Gestational diabetes mellitus	18 (18.3%)	20 (20.6%)	0.68
Previous LSCS	27 (27.5%)	26 (26.8%)	0.91
Anaemia (Hb <10 g/dL)	16 (16.3%)	15 (15.4%)	0.87
Thyroid disorder	12 (12.2%)	11 (11.3%)	0.85
Haemoglobin (g/dL)	10.8±1.1	10.7±1.0	0.54
Systolic BP (mmHg)	124±12	123±11	0.41
Diastolic BP (mmHg)	78±8	79±7	0.33

Primary Outcome

Table 2: Composite Adverse Maternal Outcomes

Outcome	Tele-ANC (n = 98)	Standard ANC (n = 97)	Risk Difference	p-value
Development of PIH	12 (12.2%)	14 (14.4%)	-2.2%	0.64
New-onset GDM	6 (6.1%)	7 (7.2%)	-1.1%	0.77
Preterm labour	9 (9.1%)	11 (11.3%)	-2.2%	0.57
Severe anaemia	3 (3.0%)	5 (5.1%)	-2.1%	0.42
Vaginal delivery	61 (62.2%)	58 (59.8%)	—	0.72
Caesarean section	37 (37.8%)	39 (40.2%)	—	0.72
Unplanned hospital visits (mean ± SD)	2.1±0.9	2.4±1.1	—	0.03*

Secondary Outcomes

Table 3: Perinatal Outcomes

Outcome	Tele-ANC (n = 98)	Standard ANC (n = 97)	p-value
Mean birth weight (kg)	2.81±0.42	2.77±0.44	0.48
Low birth weight (<2500 g)	18 (18.3%)	21 (21.6%)	0.57
Preterm birth	9 (9.1%)	11 (11.3%)	0.57
NICU admission	14 (14.2%)	16 (16.5%)	0.65
APGAR <7 at 1 min	7 (7.1%)	6 (6.2%)	0.80
Stillbirth / IUFD	1 (1.0%)	2 (2.1%)	0.56

Utilization and Satisfaction

Table 4: Care Utilization Metrics

Domain	Tele-ANC (Mean ± SD)	Standard ANC (Mean ± SD)	p-value
Convenience	4.6±0.5	3.4±0.7	<0.001
Communication	4.5±0.6	4.2±0.6	0.01
Waiting time	4.7±0.4	3.1±0.8	<0.001
Overall satisfaction	4.6±0.5	3.8±0.7	<0.001

Figures

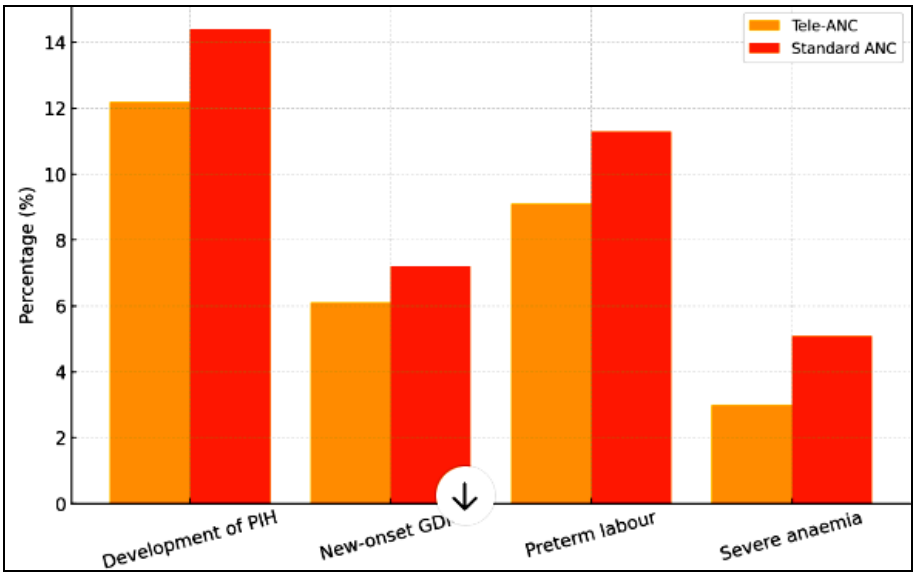

Fig 2: Maternal Adverse Outcome Rates

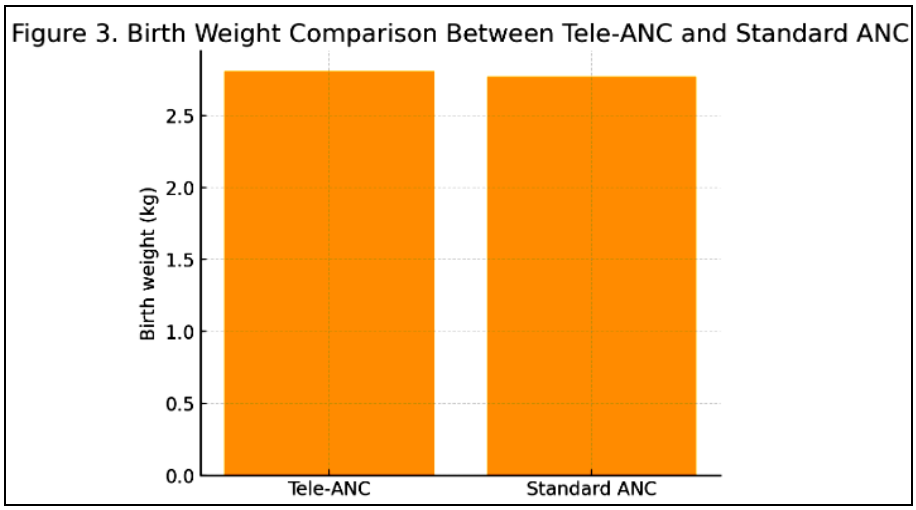

Fig 3: Perinatal Outcomes

Discussion

This randomized non-inferiority trial showed that Tele-ANC is as effective as standard clinic-based ANC in preventing negative maternal and perinatal outcomes in high-risk pregnancies. This

finding aligns with growing global evidence that supports telemedicine as a safe and effective option for antenatal care.

Comparison with Similar Studies

Our results match those of the Australian M@NGO trial [6], which found that telehealth monitoring for hypertensive disorders did not lead to more adverse events. Similarly, a Canadian study by Pflugeisen *et al*. reported similar maternal outcomes and high patient satisfaction with virtual ANC [7].

In India, a study by Sharma *et al*. [8] during the COVID-19 pandemic showed that Tele-ANC was acceptable and effective, but it mainly focused on low-risk pregnancies. Our study broadens this evidence to include high-risk pregnancies, which need closer monitoring.

The composite adverse maternal outcome rate of 14.3% in the Tele-ANC group compares well with studies from China and Europe, where rates ranged from 10% to 18% in high-risk groups [9, 10]. The non-inferiority margin was met, confirming that remote supervision, supported by structured protocols and home-monitoring devices, can replace some in-person visits without sacrificing safety.

The reduction in clinic visits (3.1 compared to 7.4) parallels findings by Marko *et al*. [11], who reported a nearly 50% cut in physical visits with telemedicine-integrated ANC. This reduction is significant in India, where travel burdens, overcrowded facilities, and staffing shortages make routine ANC delivery challenging.

Perinatal outcomes like preterm birth and NICU admissions were similar across both groups, consistent with results from the US Tele-OB trials [12]. The high patient satisfaction in our study reflects better convenience, less travel, and improved communication opportunities offered by telehealth.

Strengths and Limitations

Strengths

- First non-inferiority trial from eastern India on Tele-ANC for high-risk pregnancies
- Rigorous randomization and follow-up
- Real-world applicability in low- and middle-income countries

Limitations

- Single-center study
- Open-label design may introduce bias
- Dependence on patient-reported home measurements
- Requirement for smartphone ownership may limit generalizability

Clinical Implications

Tele-ANC can significantly reduce clinic congestion while maintaining quality of care. It may be especially helpful for:

- Rural populations
- Working women
- Patients who need frequent follow-up for hypertension or gestational diabetes

Future Recommendations

- Conduct multicenter trials across different regions of India
- Develop standardized Tele-ANC protocols
- Integrate with government maternal health programs like Janani Suraksha Yojana and LaQshya

Conclusion

Tele-ANC is as effective as standard clinic-based ANC for high-risk pregnant women. It leads to fewer in-person visits and greater patient satisfaction. Telemedicine can be used as an additional and expandable part of antenatal care in India.

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