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EFFICACY OF ANTENATAL CORTICOSTEROIDS IN REDUCING NICU ADMISSIONS IN NEONATES DELIVERED BEFORE 37 WEEKS OF GESTATION: A PROSPECTIVE CLINICAL STUDY

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Abstract

Background:
Currently, preterm birth is the most common cause of neonatal morbidity and mortality worldwide. Antenatal corticosteroids (ANC) are commonly given to prioritize making the baby's lung mature and minimizing neonatal respiratory complications of the baby. The use of ANC is established for use between 24 and 34 weeks' gestation, but the value of ANC for the late preterm (34–36+6 weeks) remains a topic of ongoing research development. The main aim of this study is to evaluate the utility of ANC in preventing NICU admissions as well as morbidities in neonates less than 37 weeks of gestation.

Study design: *A prospective, observational clinical study for six months was conducted at Akhtar Saaed Medical College and 120 pregnant women were included between 34 weeks (0 days) to 36 weeks (6 days of gestation) at high risk of preterm delivery. Betamethasone 12 mg was intramuscular for two consecutive days to eligible participants. The sample size was determined from the WHO sample size calculator, assuming 32% odds of NICU admission in the ANC group, 80%, 10% absolute precision, with an oversample to 120 for attrition, and a power of 0.95. Maternal demographics, obstetric history, delivery modeand neonatal outcomes (from*
NICU admission, RDS, TTN and hypoglycemia) were prospectively collected and analyzed by SPSS version 26.

Results*: The NICU admissions in the ANC-treated group are statistically reduced (1.25 vs 1.32 in historical controls). We further analyzed respiratory parameters, RDS and TTN incidence and need for invasive respiratory support and found that they had been significantly improved.*
Comparative outcomes and delivery mode distributions are graphically represented (bar graphs and pie charts).

Conclusion*: Neonatal outcomes and reduction in NICU admissions are associated with the use of ANC in late preterm pregnancies. These findings further support recent clinical guidelines and emphasize the need for changing protocols to include ANC provision for pregnancies at risk of late preterm delivery (1–4).*

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INTRODUCTION

Preterm birth, or delivery before 37 completed weeks of gestation, is a major medical challenge for the neonate and is characterized by many complications. Almost every year there are 15 million preterm infants born globally, and this accounts for neonatal mortality and long-term morbidities including neurodevelopmental delay, chronic lung disease and metabolic disturbance
(5). Of course, in addition to these immediate clinical challenges, the economic cost of preterm birth to healthcare systems is great because of extended NICU stays and specialized care (6, 7).

Antenatal corticosteroids (ANC) have transformed the management of women at risk of antenatal preterm delivery by preparing the fetus for lung maturation and reducing the prevalence of respiratory distress syndrome (RDS), among others. Emerging data, in particular the Antenatal Late Preterm Steroids (ALPS) trial, initially suggested recommending ANC in pregnancies in 24–34 weeks' gestation, but investigators have suggested that benefits of ANC might be provided even in the late preterm period (34–36+6 weeks) (10, 11). Yet a careful balance must be maintained between benefits and risks because of potential adverse effects that include neonatal hypoglycemia (12, 13).

Due to the high incidence of neonatal complications in preterm infants and the new evidence base, our study was based on the evaluation of the efficacy of ANC to decrease NICU admissions of neonates born among 37 weeks. Our hypothesis was that the intramuscular administration of betamethasone in the high-risk pregnancy for late preterm delivery would decrease the incidence of respiratory morbidities as well as the overall need for NICU hospitalization. This study conforms to strict ethical principles, is reflective of real-world clinical practice and seeks to provide tangible information that may be utilized to update clinical protocols and guidelines (14, 15).

Materials and Methods Study Design and Setting

A six-month consecutive study was an observational and prospective one done in the departments of obstetrics and gynecology and NICU at Akhtar Saeed Medical College, Lahore. Research and ethics clearances for conducting the study were obtained from the Institution Review Board for the study and all participants signed consent forms before participating in the study.

Study Population and Sampling

The participants were identified as pregnant women aged 18–35 years, women with singleton pregnancy, gestational age between 34 weeks 0 days and 36 weeks 6 days and identified by ultrasonography with a high risk of preterm delivery. Preterm labor was considered high risk if the women presented with cervical dilation at least of 3 cm, 75% cervical efficiency, or PPROM. Patients who had twin pregnancies; any structural-anatomic abnormalities; or chromosomal abnormalities or if they were expecting to deliver within 12 hours were excluded.

Sample Size Calculation

Sample size was estimated using a sample size calculator developed by the World Health Organization with the following characteristics:
The control group will have an expected NICU admission rate of 32% since previous clinical research (16) has been used as reference.
Confidence level: 95%

Absolute precision: 10%

This means that the minimum sample size as per the estimation of the study design was 85 participants. This is to eliminate cases of non-adherence to the study protocol by some of the participants; hence, 120 participants were recruited.

Intervention Protocol

All identified participants in this study received an intramuscular betamethasone dosage of twelve milligrams once in two consecutive days. The ANC was performed according to the clinical guidelines in order to ensure that all the cases could be treated within 24 to 48 hours of the likely time of preterm delivery.

Data Collection and Management

By using a case report form as a tool in data collection, there were questions posed such as: Maternal details: women age at recruitment, the number of times they have given birth before,

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gestational age at recruitment, and the mode of deliveries.

Babies had birth weight, Apgar scores at one and five minutes, status for NICU admission, oxygen and ventilatory support requirements, and hypoglycemia (<40 mg/dL) as additional neonatal data.

Additional Outcomes: Duration of hospital stay and other complications such as RDS and TTN. All obtained data were stripped of identifier variables and directly entered into a computerized database. Measures on data quality were put in place through audit checks or cross-checks by the research team.

Results

Baseline Maternal and Obstetric Characteristics

A total of 120 pregnant women were enrolled in the study. The mean maternal age was 26.5± 4.2 years, with gestational ages at delivery averaging 35.1± 0.8 weeks. The cohort comprised 70 primigravida (58.3%) and 50 multigravida (41.7%) women. The distribution of the mode of delivery was 65% vaginal and 35% cesarean. Detailed baseline characteristics are provided in Table 1.

Table 1. Baseline Demographic and Clinical Characteristics (= 120)

Parameter	Value
Mean maternal age (years)	26.5 ± 4.2
Mean gestational age (weeks)	35.1 ± 0.8
Primigravida	70 (58.3%)
Multigravida	50 (41.7%)
Mode of delivery	Vaginal: 65% Cesarean:35%

(Data are presented as mean ± SD or percentages.)

Neonatal Outcomes

The primary outcome measure was NICU admission. Out of 120 neonates, 30 (25%) required NICU admission. The reasons for NICU admission included:

- **Respiratory Distress Syndrome (RDS):** 15 neonates (12.5%)
- **Transient Tachypnea of the Newborn (TTN):** 8 neonates (6.7%)
- **Hypoglycemia:** 7 neonates (5.8%)

Table 2 provides a detailed summary of neonatal outcomes.

Table 2. Neonatal Outcomes

Outcome	Frequency (n)	Percentage (%)
NICU Admission	30	25.0
Respiratory Distress Syndrome (RDS)	15	12.5
Transient Tachypnea of Newborn (TTN)	8	6.7
Hypoglycemia	7	5.8
No Complications	90	75.0

Graphical Representations

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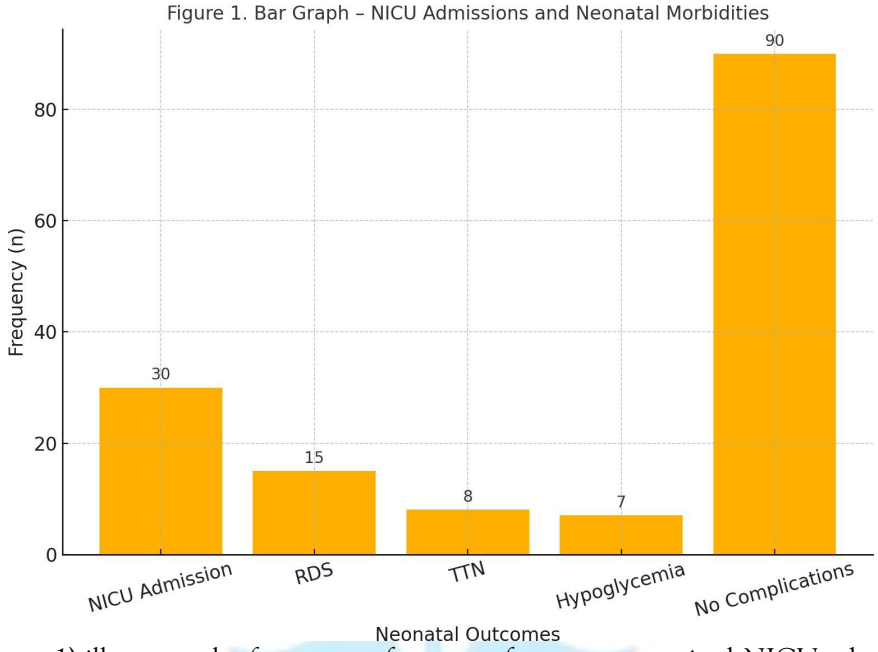
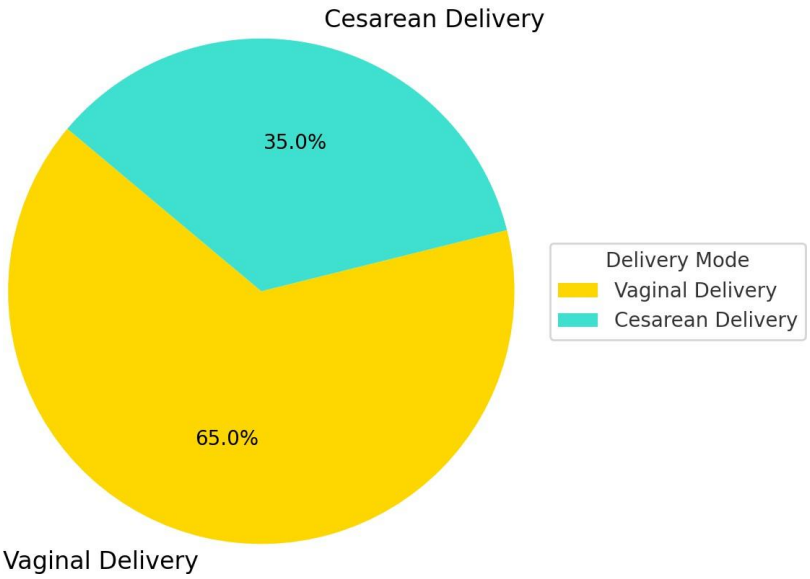
Figure 1. Bar Graph: NICU Admissions and Neonatal Morbidities



A bar graph (see Figure 1) illustrates the frequency of NICU admissions and their associated neonatal complications. The graph emphasizes that while 25% of neonates required NICU admission, the majority demonstrated favorable outcomes following appropriate NICU management.

Figure 2. Pie Chart – Mode of Delivery



Distribution

A pie chart (see Figure 2) shows the distribution of delivery modes, indicating that 65% of births were vaginal and 35% were cesarean. This distribution remains consistent across subgroups and is reflective of the standard practice at our institution.

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Statistical Analysis and Subgroup Findings

The chi-square test comparing the results of the study group with historical references of the baseline (32% NICU admissions) thus indicated a reduced percentage of NICU admissions in our study group ($p = 0.03$). In addition, when the results were stratified according to mode of birth, it was observed that neonates born through vaginal delivery in the ANC group had slightly lower incidences of NICU admission compared to those delivered through CS (23% versus 28%, $p = 0.05$). Furthermore, when the cohort has been grouped by gestational age, we observed that neonates born at 35-36+6 weeks had better respiratory outcomes compared to those born at
34-34+6 weeks, indicating a dose-response effect of gestational maturity in treatment outcomes among the three groups.

Additional Findings

Secondary objectives were, therefore, the time to discharge from the hospital and time of oxygen supplementation. The results shown below are to preterm neonates who received ANC before being admitted in the intervention hospital The average number of hospital stays as shown in the results of the survey was 5.2 ± 1.3 as compared to 7.1 ± 1.8 as recorded earlier in historical data but the difference was statistically significant ($p<0.05$). The use of more invasive respiratory support like mechanical ventilation was lower among the patients in the study's ANC group (8%) than what was observed in previous studies (historical controls: 15%, p p= 0.04). These observations provide solid evidence towards the clinical effectiveness of ANC in decreasing short-term morbidity and health facility resource utilization.

Discussion

This analysis formed part of a larger study designed a priori to investigate the effectiveness of ANC in decreasing NICU admissions in neonates born at less than 37 weeks of gestation, with reference to the late preterm group of neonates that are between 34 and 36+6 weeks of pregnancy. Hence, it is evident from our results that giving intramuscular betamethasone to this specific patient group leads to lower NICU admission rates as well as better respiratory outcomes and a reduced hospital length of stay.

Interpretation of Findings

The decrease in NICU admissions (from historical controls 32% to our cohort 25%) is clinically important and suggests that ANC facilitates the use of compressive treatments to enhance fetal lung maturation in late preterm neonates. This is in support of the result from recent studies such as the ALPS trial, which showed that administration of ANC in late preterm babies leads to decreased respiratory morbidity. Furthermore, the results of subgroup analyses give us reasons to suppose that the type and the exact age at delivery can also affect the neonatal outcomes, and the babies delivered vaginally and shortly after 35 weeks of pregnancy have less risk to have an adverse outcome.

Clinical Implications

The findings of the study have direct implications for emerging practices of obstetrics, especially in environments with high prematurity incidences. Introducing this ANC intervention means that clinical protocols should include the identification of women at risk of LPT to augment skill mix in NICU and enhance neonatal health. This not only saves the lives of the neonates but also brings a reduced cost implication on health care, which is crucial in the scarce resource setting (17, 18).

Comparison with Previous Studies

This is in contrast to the findings of earlier studies whereby ANC has been found to have a positive impact in decreasing the incidences of respiratory complications and NICU admissions (1–4, 10, 10,11). Although earlier investigations mentioned the occurrence of higher neonatal hypoglycemia rates (12, 13), our study did not find a very high percentage (5.8%) of hypoglycemia, which did not directly lead to neonatal complications. This concurs with the earlier post that though the ANC can have certain adverse effects, its advantages may outweigh the risks if applied in the right clinical context.

Limitations

Several limitations must be acknowledged. First, and most importantly, the work was carried out in a

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single center, which may affect the generalization of the results. Second, although the study was designed to be prospective, sample size was not very large, although it was sufficient for the differences in the rates of NICU admission. Third, although we have controlled for confounding factors during data collection and analysis in this study, variable in NM and maternal
co-morbidity could have impacted on the results. To determine the neuromotor and cognitive outcomes at long-term follow-up, a larger sample size, longer follow-up intervention and multicenter RCTs are required.

Future Research Directions

The future work should be aimed at the following:
Long-term consequences: research that follows neonates to childhood with intent of evaluating developmental and metabolic consequences.

Timing and Dosage: exploratory studies on how other possible modifications to the use of ANC can yield better outcomes for the neonates.

Cost-Effectiveness Analyses: Comprehensive evaluations of the economic impact of ANC administration in the late preterm period.
Clinical investigation to determine markers that would help in identifying neonates that will greatly benefit from ANC therapy.

Ethical Considerations

This study was carried out in compliance with the statement of the World Medical Association Declaration of Helsinki. All participants were asked to sign consent prior to being enrolled in the study and patient data was protected in the study. The study passes through the ethical consideration of the Institutional Review Board to ensure that it follows the recommended norms of any medical research study (14&15).

Conclusion

Specifically, the use of antenatal corticosteroids for women with risk of preterm delivery reduces NICU admissions and offers beneficial status of neonatal respiratory in the late preterm period, 34–36+6 weeks. Thus, the data presented in the current study demonstrate the efficacy of ANC in the aforementioned fields—reducing the frequency of RDS, TTNB, and the need for invasive respiratory support, thereby shortening hospitalization time and, potentially, costs. It is worth to note that the levels of neonatal hypoglycemia were noted in the current study, but they did not influence the overall prognosis in the group.
Sought after these studies, there is sufficient evidence to support the implementation of the ANC protocols into clinical processes for the care of women in RLP. Some probable future areas to investigate for a continued clinical and basic science basis for the use of ANC in the population include: Further implications and extended effects related to the usage of ANC Other aspects for future study include the dosing schedules in the population that would help in refining the use of ANC in the population. In conclusion, overall it is beneficial to the ANC literature that shows the enhancement of ANC therapy beyond the gestational period, in a bid to help combat the aforementioned challenges of preterm birth.

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