Original Article

Glycaemic Control and Insulin requirements during pregnancy in women with Type-1 Diabetes Mellitus and Pregnancy Outcome

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ABSTRACT

Objectives: The objectives of the study are to evaluate the pattern of insulin requirements and glycaemic control throughout pregnancy in women with Type 1 diabetes mellitus, and to assess the association of maternal glycaemic control with maternal and neonatal outcomes.

Methodology: This is a Retrospective cohort study. Medical records of 135 pregnancies complicated by Type 1 diabetes mellitus (T1D) were scrutinized, and 71 medical records fulfilled the inclusion criteria. Collected data was assessed for patients' demographics, blood glucose records, insulin requirements in each trimester, and maternal and neonatal outcomes.

Results: Average insulin requirements pre-pregnancy were 56.3 units, which peaked to 62.9 units between 6-8 weeks gestation, and between 9-13 weeks (47.1units), and a second peak between 32-36 weeks (94.4 units) and again at 38 weeks (87.4 units) onwards, the sharpest increment was observed from week 14 to week 32 Maternal complications included impaired awareness of hypoglycemia in 5.6%, ketoacidosis in 2.8%, and pregnancy-induced hypertension/pre-eclampsia in 11.3%. Premature delivery (<37 weeks) occurred in 33.8% of cases. Most births were through c-section, with an average age of 36.5 ± 2.2 weeks and a birth weight of 2425-3100 grams. The neonatal complications included neonatal hypoglycemia in 8.45%, respiratory distress syndrome in 22.54%, congenital anomalies in 11.27%, and intrauterine death (IUD) in 1.4%. There was a significant association between poor pre-pregnancy glycaemic control and congenital anomalies ($p < 0.05$), but there was no association between maternal glycaemic control, prematurity, neonatal hypoglycaemia, and birth weight (p=NS).

Conclusion: In pregnant women with Type 1 diabetes mellitus, insulin requirements changed with three successive changes of direction. Poor glycaemic control in T1D patients is further complicated by higher rates of maternal and neonatal complications.

KEY WORDS: Type-1 Diabetes Mellitus, Insulin requirements, Pregnancy, Glycemic Control, Maternal Outcomes, Neonatal Outcomes.

INTRODUCTION

The prevalence of diabetes in pregnancy has been increasing worldwide.[1] Diabetes confers significantly to maternal and fetal risk largely related to the degree of hyperglycemia but also related to chronic complications and comorbidities of diabetes.[2] In women with diabetes mellitus, precise metabolic control is important both

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Access this Article Online

URL:
https://jpes.org.pk/index.php/jpes/article/view/68

Submitted: November 19, 2025 **Revision Received:** December 19, 2025

Accepted for Publication: December 27, 2025

How to cite this: *Jamali A, Sheikh A, Kazi M, Awan S, Sheikh L, Islam N. Glycaemic Control and Insulin requirements during pregnancy in women with Type 1 Diabetes Mellitus and Pregnancy Outcome. JPES. 2025;2(2):55-60.*

before and during pregnancy to reduce pregnancy complications.[3] Maintenance of good glycaemic control is difficult because insulin requirement (IR) is continuously changing. The changes include a decrease in Insulin requirement in the first trimester, an increase in the second half of pregnancy,[4] and falling in insulin requirements in the third trimester.[5]

The unexpected perinatal outcome has been associated with poor glycaemic control for congenital malformations, miscarriage, perinatal mortality, pre-eclampsia, increased birth weight, neonatal hypoglycaemia, and respiratory distress among others.[6]

This study aimed to determine glycaemic control and insulin requirements of women with Type 1 diabetes mellitus throughout pregnancy and to correlate maternal glycaemic control with maternal and perinatal outcomes. Thus, the knowledge of the expected course of insulin requirement in pregnant women with type 1 diabetes mellitus would help them to achieve metabolic goals and reduce pregnancy complications.

Objectives:

1. To evaluate the pattern of insulin requirements and glycaemic control throughout pregnancy in women with Type 1 diabetes mellitus.
2. To assess the association of maternal glycaemic control with maternal and neonatal outcomes.

METHODOLOGY

This is a Retrospective cohort study. An investigation was carried out at the Aga Khan University Hospital's Department of Endocrinology. The research followed the Declaration of Helsinki and GCP guidelines along with all relevant regulatory requirements. An ethical review exemption was given by Aga Khan University's Ethical Review Committee, while data privacy and ERC regulatory authorizations were obtained. A non-probability convenience sampling technique was used. Medical records of 135 pregnancies complicated by Type 1 diabetes mellitus (T1D) delivered at Aga Khan University Hospital from Jan 2012 to Dec 2022 were scrutinized, and 71 medical records fulfilled the inclusion criteria. All women with a diagnosis of Pre-existing Type 1 Diabetes Mellitus, single pregnancy, available record of self-monitoring blood glucose (SMBG), and delivered at AKUH were included in the study. Women with incomplete follow-up and miscarriage before 20 weeks were excluded from the study. Data was collected from the HIMS (Health Information Management System) department of Aga Khan University Hospital. Collected data was assessed for patients' demographics, blood glucose records, insulin requirements during each trimester, and maternal and neonatal outcomes.

The primary outcome was Insulin dose at end of each trimester, change in insulin requirements per trimester, correlate maternal glycaemic control (pre conception and in each trimester) with maternal outcome (pregnancy induce hypertension, preeclampsia, operative delivery, diabetic emergency) and correlate maternal glycaemic control (pre conception and in each trimester) with neonatal outcome (prematurity, small for gestational age, large for gestational age, congenital anomalies, neonatal hypoglycaemia, acute respiratory distress syndrome or NICU admission).

After getting permission from the ERC of Aga Khan University Hospital, the data was collected with the

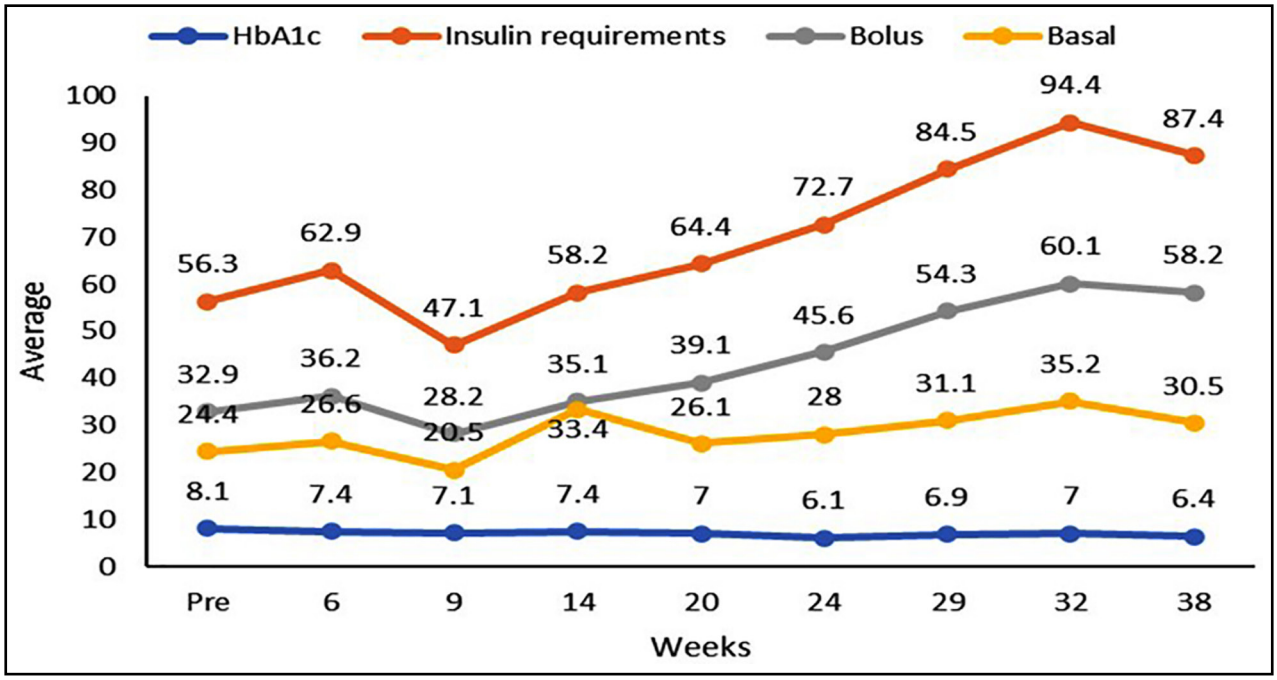

Fig.1: Insulin requirement during pregnancy in Type 1 DM.

help of information from the Department of HIMS. Data collection in Google form was done by the healthcare professionals themselves.

The data was accumulated by a unique identification number so the patients' identities were protected. Throughout the research process, all the data collected was kept in a database that was isolated and free from personal identity. It should be noted that data with sensitive personal information was never physically shifted out of the facility or electronically taken to any non-secure location. Additionally, an exemption from the ERC of AKUH had been attained.

Quantitative data were first entered into SPSS version for detailed examination and interpretation. The data cleaning and ordering were done before any analysis to ensure the accuracy and precision of the results. In this study, the mean ± SD was calculated for continuous variables. In contrast, categorical variables were assessed as percentages. Either a chi-square test or independent t-test was applied for detecting the relation between various variables. The level of significance was set at a p-value of less than 0.05, and hence any relation below this value is considered meaningful and relevant.

RESULTS

The study population consisted of 71 consecutive women who met the inclusion criteria. Mean maternal age was 29.1 years with a median duration of diabetes of 12 years. Noteworthy history included previous miscarriages (9.9%), low birth weight babies (8.5%), and cesarean sections (40.8%). Family histories revealed 70.4% with diabetes mellitus and 53.5% with hypertension. The mean pre-pregnancy weight was 62.2 kg, and the mean BMI was 26.7 kg/m². The mean pre-pregnancy HbA1c was 8.1%, while the median insulin dose was 56 units/day (Table-I).

The mean pre-pregnancy insulin requirements were 56.3 units, which reached a peak of 62.9 units between 6-8 weeks of gestation, a trough between 9-13 weeks (47.1units), and a second peak between 32-36 weeks (94.4 units) and again a trough at 38 weeks (87.4 units) onwards, the sharpest increment was observed from week 14 to week 32.

DISCUSSION

This retrospective cohort study conducted among women with T1D throughout pregnancy offer important insights on glycemic control and insulin

Table-I: characteristics of study population (n=71).

Maternal age (Years)	29.1 ± 4.8
Height (cm)	157.1 ± 6.0
Duration of diabetes (years)	12(7.5-18)
Previous history of 2 Miscarriages	7(9.9)
Previous history of Low-Birth-Weight Baby (<2.5 Kg)	6(8.5)
Previous history >3.5 Kg Birth Weight Baby	2(2.8)
History of Congenital Anomaly in the Previous Pregnancy	4(5.6)
History of Pre-eclampsia in previous pregnancy	4(5.6)
History of pregnancy-induced hypertension in previous pregnancy	2(2.8)
Previous history of C-Section	29(40.8)
History of thyroid disorder	18(25.4)
Family history of Diabetes Mellitus	50(70.4)
Family history of Hypertension	38(53.5)
Pre-Pregnancy Body Weight (Kg)	62.2 ± 15.7
Pre-Pregnancy BMI (Kg/m2)	26.7 ± 10.5
Hba1c Before Pregnancy	8.1 ± 1.4
Average Insulin Dose Before Pregnancy (Units/Day)	56(39-70)
History of nephropathy	2(2.8)
History of retinopathy	2(2.8)

Results are reported as n(%) or mean ± *

requirement, which influence maternal and neonatal outcomes. Our investigation emphasizes the dynamic nature of changes in insulin requirements during pregnancy and the crucial attention to be paid to the maintenance of optimal glycemic levels to minimize adverse outcomes.

This study confirms the well-documented pattern of insulin requirements during pregnancy in women with T1D: a rise in the second and third trimesters, peaking between 32-36 weeks of gestation. This pattern is in concert with physiological changes throughout pregnancy, including the progressive increase in insulin resistance driven by placental hormones such as human placental lactogen (HPL) and cortisol, known to oppose insulin action.[4,5,7] The observed troughs in insulin requirements during the first trimester and near term are consistent with prior studies, in which an early reduction in insulin requirements has been attributed to increased insulin sensitivity or the counter-regulatory response to hypoglycemia commonly observed early in pregnancy.[8,9] These findings emphasize the need for frequent monitoring and individualized adjustment of insulin therapy to maintain stable glycemic control.

The 77.6% incidence of cesarean sections in the present study is consistent with previous reports, indicating an increased risk of operative delivery in women with T1D due to macrosomia, fetal distress, or preeclampsia.[5,10] The high prevalence of hypoglycemic episodes (37.3%) underlines the difficulty in managing glycemic control, since frequent adjustments of insulin doses can cause both hypoglycemia and hyperglycemia.[11]

Preeclampsia (12.6%) and pregnancy-induced hypertension (11.9%) were recorded in higher numbers compared to the general obstetric population, which agrees with reports of T1D pregnant women having an increased risk of developing hypertensive disorders during pregnancy(2, 10). These findings underscore that pregnant women with T1D require vigilant antenatal care and close monitoring to prevent these complications.[12]

Neonatal outcomes in this study further underscore the risks associated with T1D in pregnancy. The most prevalent adverse outcome was preterm delivery before 37 weeks (33.8%), followed by respiratory distress syndrome (22.5%). These outcomes are consistent with findings in the literature, where preterm birth and respiratory complications are frequently reported in infants born to mothers with T1D.[5,13] Congenital anomalies occurred in 11.27% and were highly associated with poor pre-pregnancy glycemic control, as indicated by elevated HbA1c levels, which is a well-documented risk factor for fetal malformations.[10] SGA infants occurred in 10.2%, and neonatal hypoglycemia in 8.45%, underscoring the critical need to achieve optimal glycemic control to reduce these risks.

Notably, the complications in these cases included a relatively lower incidence of LGA infants at 5.4% and intrauterine death at 1.4%. These figures may suggest that strict glycemic control policies during the period of study were effective, but also that vigilant conduct of these pregnancies is still essential in order to avoid such major outcomes.

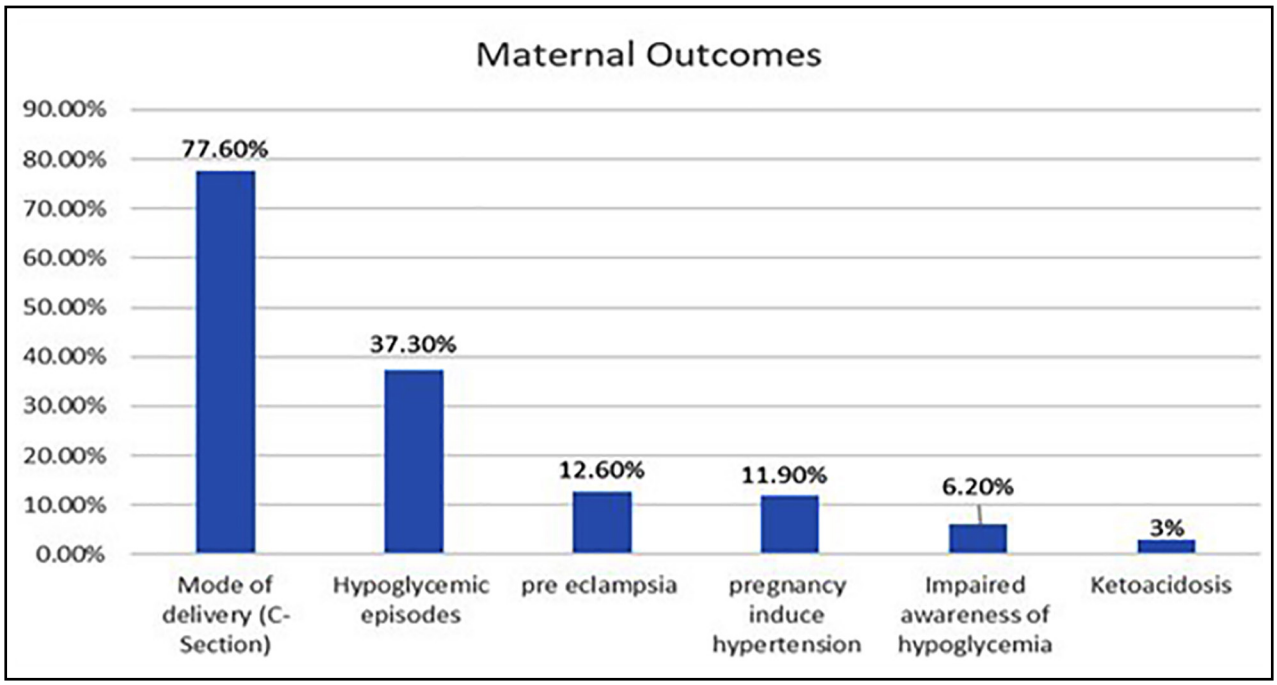

Fig.2: The maternal outcome indicated that 77.6% of the pregnancies resulted in cesarean sections. Hypoglycemic episodes were also 37.3% of the women, while 12.6% had pre-eclampsia and 11.9% had pregnancy-induced hypertension. Impaired awareness of hypoglycemia occurred in 6.2% of cases and ketoacidosis in 3%.

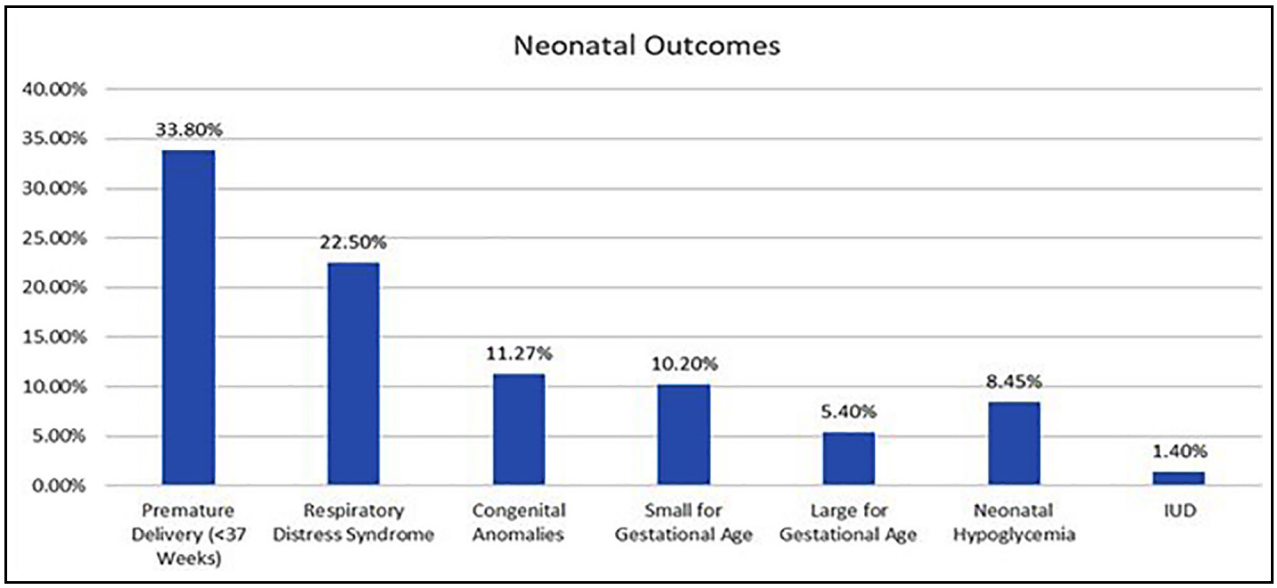

Fig.3: Neonatal outcomes included preterm delivery before 37 weeks in 33.8% of cases, respiratory distress syndrome in 22.5%, congenital anomalies in 11.27%, small for gestationa 10.2%, and neonatal hypoglycemia in 8.45%. Large for gestational age and intrauterine death were less common, occurring in 5.4% and 1.4% of cases, respectively. The pre-pregnancy poor glycaemic control was significantly associated with congenital anomalies only ($p < 0.05$), and no association was found in other parameters of outcome.

The results of this investigation emphasize the need for personalized insulin-therapy management during pregnancy, according to changing insulin requirements, in order to achieve and maintain optimum glycemic control.[14] Frequent monitoring and adjustments are quite necessary to minimize adverse maternal and neonatal outcomes.[15] These results also suggest that healthcare providers should be especially watchful for common complications such as preeclampsia and hypoglycemia and be prepared to address such issues without any delay. Besides, pre-pregnancy counseling and optimization of glycemic control are important for reducing the risk of congenital anomalies and other adverse outcomes.[16]

Although this study provides important insights, its limitations must be recognized. The potential for bias in the retrospective design and reliance on medical records reduces the ability to control for all possible confounding. In addition, the relatively small sample size and single-center feature of this study may reduce the generalizability of findings. Future research should be directed at larger, multi-center prospective studies that confirm these findings and provide insights into the mechanisms underlying fluctuations in insulin requirement and their impact on pregnancy outcomes. Further investigation will be required regarding the role of CGM and advanced insulin delivery systems in optimizing glycemic control in pregnancy.

CONCLUSION

In summary, this paper provides important insights into the insulin needs and associated outcomes of women with T1D during pregnancy. Understanding the patterns of insulin needs and their implications for maternal and neonatal health is crucial in optimizing management strategies and improving pregnancy outcomes in this high-risk population. This finding highlights the importance of individualized and vigilant care in ensuring the best outcome for both mother and child.

DECLARATIONS

Ethical Approval and Consent to participate: The study was carried out in accordance with the provisions of the Declaration of Helsinki and the guidelines on GCP, and all relevant regulatory requirements. The Ethics Review Committee (ERC) of Aga Khan University granted an ethical review exemption (ERC number 2022-7855-22331), and data privacy and ERC regulatory authorizations were obtained. All participants gave informed consent before data acquisition.

Consent for Publication: Not Applicable.

Availability of supporting data: Some or all data sets generated during and/or analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Competing interests: The authors do not have any competing interests.

Funding: The research did not receive any funding grant from any agency.

Acknowledgments: Not Applicable.

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Author's Contribution:

AJ: Conceptualization, study design, data collection, manuscript drafting.
AS: Supervision of data collection, editing and reviewing manuscript.
MK: Literature review, critical revision of the manuscript.
SA: Data analysis, interpretation of results, manuscript drafting.
LS: Statistical analysis, preparation of tables and figures.
NI: Supervision, critical review, final approval of manuscript
All authors meet the ICMJE criteria for authorship and have read and approved the final manuscript.

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