Maternal and Fetal Complications in High-Risk Pregnancies: A Prospective Study to Evaluate and Mitigate Adverse Outcomes Through Pharmacist-Led Counselling

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Abstract:

Introduction: *High-risk pregnancies continue to account for a major proportion of maternal and neonatal morbidity in developing countries. This study evaluated common maternal and fetal complications and examined the effect of pharmacist-led counselling in mitigating adverse outcomes.*

Methods: *A prospective observational study was conducted over 15 months (February 2024–April 2025) in two tertiary hospitals in Bengaluru. 222 pregnant women enrolled in the study and 185 were identified as high-risk pregnancy. Clinical profiles, complications, and newborn outcomes were documented. Structured pharmacist counselling sessions were provided, and outcomes were compared before and after intervention. Sample size was determined using a single-proportion formula ($p = 0.49$, $d = 0.05$), yielding $n \approx 183$. Data were analysed using SPSS v27.*

Results: *The individual prevalence of the co morbidities that includes 41.4% of anemia, 3.2% of pregnancy induced hypertension, 3.6% of Gestational diabetes mellitus, 17.6% of hypothyroidism, 31.1% of previous lower segment caesarean section, 2.3% of twin/multiple pregnancy, 34.2% bad obstetric history, 1.4% of young gravida, 4.5% of elderly gravida, 6.8% of Rh incompatibility, 5.9% of low-lying placenta, 0.4% of HCV positive and 0.4% of HbSAg positive. Common fetal outcomes included low birth weight (6.3%), preterm delivery (9%), and neonatal complication. No serious drug-related adverse events were observed.*

Conclusion: *Pharmacist participation in antenatal care significantly improved awareness and adherence among high-risk mothers, suggesting that multidisciplinary collaboration can enhance pregnancy outcomes in resource-limited settings*.

Keywords: Antenatal care and Newborn outcomes, High-risk pregnancy, Maternal complications, Pharmacist counselling.

1. INTRODUCTION

Pregnancy is a profound and life-changing experience. It is characterized by a cascade of intricate physiological, hormonal, and metabolic adaptations that guarantee optimal fetal development and protect maternal well-being. Although most pregnancies are uncomplicated, others are designated as high-risk due to medical, obstetric, or social conditions that raise the risk of complications for the mother, fetus, or both (Williamson et al., 2023). These risky pregnancies remain a critical public-health problem worldwide, especially in low- and middle-income countries. The World Health Organization (2023) reports that approximately 15–20% of all pregnancies fall into the high-risk category and that most maternal deaths take place in developing countries where quality care is still not accessible.

India also carries a significant burden of this cross-border responsibility. Even with improvements in obstetric care and country-wide initiatives of maternal health, the nation continues to have a high maternal mortality rate (MMR) of approximately 88 deaths per 100,000 live births according to Sample Registration System, 2023. The majority of these deaths are avoidable and are due to conditions like anaemia, hypertensive disorders, gestational diabetes mellitus, thyroid disorders, and unbalanced nutrition. The above is further aggravated by practices such as early marriage, short birth intervals, late antenatal registration, and poor counselling. All of these factors add to the increasing number of high-risk pregnancies and resultant maternal and fetal complications.

In this study, the classification of the high-risk conditions is based on Pradhan Mantri Surakshit Matritva Abhiyan.

According to the guidelines of Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA), high-risk pregnancies are the following conditions:

- Severe Anemia (Hb less than 7gm/dl)
- Pregnancy-induced hypertension [PIH], pre-eclampsia and pre-eclamptic toxemia.
- Syphilis/ HIV Positive
- Gestational Diabetes Mellitus [GDM]
- Hypothyroidism
- Young primigravid (less than 20 years) or Elderly gravida (more than 35 years)
- Twin / Multiple pregnancy
- Malpresentation
- Previous history of lower segment cesarean section
- Low-lying placenta, Placenta previa
- Positive Bad obstetric history (History of stillbirth, abortion, congenital malformation, premature birth, and obstructed labor)
- Rhesus incompatibility (Sharma et al.,)

Anaemia still continues to be one of the most prevalent and chronic conditions among pregnant Indian women. Iron deficiency is the most prevalent cause and, if not treated, can lead to preterm or low-birth-weight baby, blood transfusion (if she loses a significant amount of blood during delivery), Postpartum depression, baby with anemia, child with developmental delays. Untreated folate deficiency can increase risk of having preterm or low-birth-weight baby and baby with a serious birth defect of the spine or brain (neural tube defects). Untreated vitamin

B12 deficiency can also raise the risk of having a baby with neural tube defects (Uscher J 2025). Research indicates that Indian pregnant women are nearly half anaemic, making it an ongoing problem despite supplementation programs. Pre-eclampsia and eclampsia are the hypertensive disorders of pregnancy and are a major cause of maternal and neonatal morbidity. They can cause Maternal – HELLP syndrome, ARDS, Renal failure, Pulmonary edema, DIC. Fetal- IUGR, IUD, Fetal distress, prematurity. Gestational diabetes mellitus (GDM) is also increasingly found in India because of alterations in dietary habits, lifestyle changes, and genetic predisposition. Undiagnosed and poorly controlled GDM can lead to Maternal- Polyhydramnios, pre-eclampsia, prolonged labor, obstructed labor, C-section, uterine atony, PPH, infection. Fetal- Abnormal fetal growth (macrosomia/growth restriction), spontaneous abortion, IUD, stillbirth, congenital malformation, birth injuries, neonatal hypoglycemia, IRDS. Thyroid disease, particularly hypothyroidism, is also underdiagnosed in pregnant women. These disorders are associated with Maternal: Recurrent miscarriages, stillbirths, incidence of pre-eclampsia, and incidence of abruptio placentae. Fetal: Premature delivery; IUGR (Sharma et al.,)

Besides medical determinants, a number of demographic and social determinants add to the risk profile of pregnancy. Both extremes of maternal age—less than 18 or more than 35 years—are thought to elevate the risk of obstetric complications. Short birth intervals, high parity, poor nutrition, and low knowledge regarding reproductive health also contribute significantly to this condition. In rural and semi-urban settings, unavailability of skilled healthcare workers and less frequent antenatal care are still significant hindrances. Illiteracy, socio-cultural beliefs, and economic limitations usually deter women from reporting in time to seek proper treatment, leading to further worsening of outcomes that could have been avoided with early screening and counselling. The effects of high-risk pregnancies are not just experienced by the mother but also by the newborn. Fetal and neonatal conditions commonly seen in such situations are low birth weight, prematurity, neonatal jaundice, respiratory distress, and intrauterine growth restriction. According to the National Neonatal Health Programme (2022), almost half of the neonatal deaths in India result from complications of preterm birth and low birth weight. Poor antenatal surveillance and late detection of maternal conditions frequently result in these avoidable consequences. Building up antenatal and postnatal care by way of early diagnosis and education of patients can significantly enhance survival and health opportunities for both child and mother.

While some national schemes like the Janani Suraksha Yojana and the Pradhan Mantri Surakshit Matritva Abhiyan try to limit maternal and neonatal deaths, numerous gaps remain in the effective implementation of the programmes. Health counselling and education, being an integral component of antenatal care, are usually not attended to owing to heavy patient numbers, lack of adequate staff, and poor communication between patients and healthcare professionals. Research has demonstrated that the majority of women drop supplements prescribed or do not adhere to dietary and lifestyle modifications because they are not well aware of the significance. These are areas of concern underlining the pressing need for routine, individualized counselling during pregnancy.

In recent years, the clinical pharmacist's role has increased immensely in healthcare systems across the globe. Pharmacists are specifically educated in drug safety, dose optimization, and patient counseling—all integral parts of maternal care. Their active involvement in antenatal clinics can reduce medication errors, enhance compliance, and increase patient knowledge regarding prescribed treatment. In India, where doctors and nurses are sometimes overwhelmed by their workload, incorporating pharmacists into maternal-care teams can reinforce the

continuum of care by being a source of credible information, reaffirming medication directives, and clarifying patient misconceptions well.

Therefore, the present study is designed with the following objectives:

Primary Objectives:

- To assess the prevalence of high-risk pregnancies
- To evaluate the effect of high-risk pregnancies on newborns

Secondary Objective:

- To improve the quality of life of pregnant women

2. MATERIALS AND METHODS

The study was conducted in the Department of Obstetrics and Gynaecology at Unity Lifeline Hospital, Nagarbhavi, Bengaluru, and Suresh Hospital and Maternity Home, Hegganahalli Cross, Bengaluru. Both hospitals are well-established maternity and obstetric care centers catering to a diverse patient population from urban and semi-urban areas of Bengaluru, making them suitable for conducting a community-representative clinical study. The research was designed as a prospective observational study that aimed to assess the prevalence of high-risk pregnancies and evaluate their impact on newborn outcomes. In addition to determining prevalence and clinical effects, the study also sought to contribute toward improving the quality of life of pregnant women through early identification and better management of high-risk conditions. The study was carried out over a continuous period of 14 months, extending from February 2024 to March 2025. During this time, all eligible pregnant women attending prenatal clinics and maternity wards were screened and recruited based on predefined inclusion and exclusion criteria.

The sample size for the study was estimated using a systematic two-step approach to ensure statistical adequacy and representativeness. In the first step, the Single Proportion or Danial Formula, applicable for populations greater than 10,000, was used to calculate the required number of participants. The formula applied was $\left(n = \frac{Z^2 \times P(1-P)}{d^2}\right)$, where n represents the sample size, Z denotes the Z statistic corresponding to a 95% confidence interval (1.96), P indicates the estimated prevalence (49.4% or 0.494), and d represents the margin of error or precision (0.05). Substituting these values yielded an initial calculated sample size of 372. In the second step, this sample size was adjusted according to the study period and the expected number of patients available during that time. The adjustment was made using the formula $\left(SS = \frac{n}{1+\frac{n-1}{pop}}\right)$, where pop represents the survey size or the target population (360). Substituting these values provided an adjusted sample size of 183. However, during the actual course of the study, a total of 222 pregnant women fulfilling all eligibility criteria were enrolled, which ensured adequate statistical power and improved reliability of the study findings.

The inclusion criteria comprised all pregnant women visiting the hospital for routine prenatal check-ups, those aged above 18 years, and individuals who voluntarily provided informed consent to participate in the research. Exclusion criteria included pregnant women diagnosed with hemolytic diseases that could confound the study outcomes. Each participant was thoroughly informed about the purpose and procedures of the study, and written informed consent was obtained before enrollment. The study adhered strictly to ethical standards and

good clinical practice guidelines. Ethical approval for the study was obtained from the Institutional Ethical Committee of Unity Lifeline Hospital, Nagarbhavi, Bengaluru, and Suresh Hospital and Maternity Home, Hegganahalli Cross, Bengaluru.

Data for the study were collected using structured and validated data collection forms designed specifically for this research. The forms captured detailed demographic, obstetric, and clinical information from the patients. In addition, the informed consent process and patient information leaflets were used to ensure that participants had a clear understanding of their role and rights in the study. Data sources included patient case sheets, medical records, and personal interviews with pregnant women during their hospital visits. Each patient interview was conducted in a private and comfortable setting to encourage open communication and to obtain accurate information regarding medical history, ongoing treatments, and pregnancy-related complications. The collected data were then verified, cross-checked, and compiled for statistical analysis to determine the prevalence of high-risk pregnancies and their effects on neonatal outcomes.

Thus, this study, conducted with appropriate ethical clearance and meticulous methodology, provided a reliable and systematic approach to understanding high-risk pregnancies within the selected hospital settings. The comprehensive data collection, prospective design, and adherence to ethical protocols ensured that the study outcomes were both clinically relevant and scientifically valid, ultimately aiming to enhance maternal and neonatal health care quality in the study population.

2.1 Study procedure:

Method of collection of data: A hospital based prospective study was conducted in the Department of Obstetrics and Gynaecology, Unity Lifeline Hospital, Nagarbhavi, Bengaluru and Suresh hospital and Maternity Home, Hegganahalli Cross, Bengaluru. The study included 222 Pregnant women who met the study criteria for 6 months and pregnant women who were unwilling to participate and who did not meet the study criteria were excluded. An informed consent was obtained before including them in the study after getting IEC approval. Data was collected using a self-designed data collection form. Detailed history presenting complaints, general, systemic and obstetrical examination findings, Complete Blood Count (CBC), Serological examinations, Thyroid function test, blood pressure (BP), fasting blood sugar (FBS), random blood sugar (RBS) and oral glucose challenge test (OGCT) reports were recorded. All participants received antenatal education tailored to their health conditions, medications, and lifestyle changes aimed at enhancing the quality of life for pregnant women. This was achieved through the distribution of a validated Patient Information Leaflet (PIL), with particular attention given to expectant mothers classified as high risk, emphasizing the necessary precautions to be observed during pregnancy. All pregnant women were followed up from baseline to delivery to check for their symptomatic betterment or progress in the health status from their first visit. The results were compared between baseline and follow-up to access the betterment in pregnant women's quality of life and impact of counselling. And also, the neonatal outcomes/complications were measured after the delivery of the baby.

- **Validation of PIL**

  A patient information leaflet (PIL) was also provided to improve the adherence and lifestyle modification after proper validation and evaluation of the same.

I. **Lawshe's content validation:** The development of the PIL involved a comprehensive approach, beginning with the use of Lawshe's content validity ratio for expert assessment of PIL's content. The content validation of the PIL was assessed by a panel of experts who evaluated the relevance of each item in the PIL. The item includes what is high risk pregnancy, conditions included in high-risk pregnancy, disease-based counselling, drug-based counselling, lifestyle modification and when to report to the physician immediately. The content of the PIL was translated into the local language, Kannada with the help of a language expert.

II. **Readability test:** The readability of the PIL was calculated using Flesch's reading ease (FRE) and Flesch-Kincaid Grade Level (FK-GL) online readability calculators to gauge how easy a piece of text is to understand. The FRE score ranges from (0-100) were a score less than 50, text is considered to be difficult to read. FK-GL computes the US grade level required to read the text.

III. **PIL design:** Baker Able Leaflet Design (BALD) Index was adapted to access the PIL's graphic design and visual appeal. This index was adapted to appropriate values and adjustments were made to align with specific criteria or standards.

2.2 ETHICAL STATEMENT

Ethical clearance was taken in Unity Lifeline Hospital, Nagarbhavi, Bengaluru; Suresh Hospital and Maternity Home, Hegganahalli cross, Bengaluru

2.3 STATISTICAL ANALYSIS

I. **Statistical methods:** The methodology employed in this study involved utilizing various statistical tools to analyze and interpret the gathered data. Data frequency and percentage tables were employed to provide a descriptive overview. For univariate presentation, simple column charts and pie charts were utilized, while multivariate presentations utilized cluster column charts. To assess the significance the chi square test was applied. Throughout these analyses, a 5% significance level was assumed, and the tests were conducted with an 80% power level.

II. **Statistical software:** Microsoft Excel was used to compile the data and SPSS version 27 was used to analyse the data

RESULTS

5.1 Demographic details:

Table no 1. Categorization according to age

Age Interval	Frequency	Percentage (%)
<20 years	3	1.4
20-25 years	70	31.5
26-30 years	99	44.6
31-35 years	40	18.0
> 35 years	10	4.5
Total	222	100.0

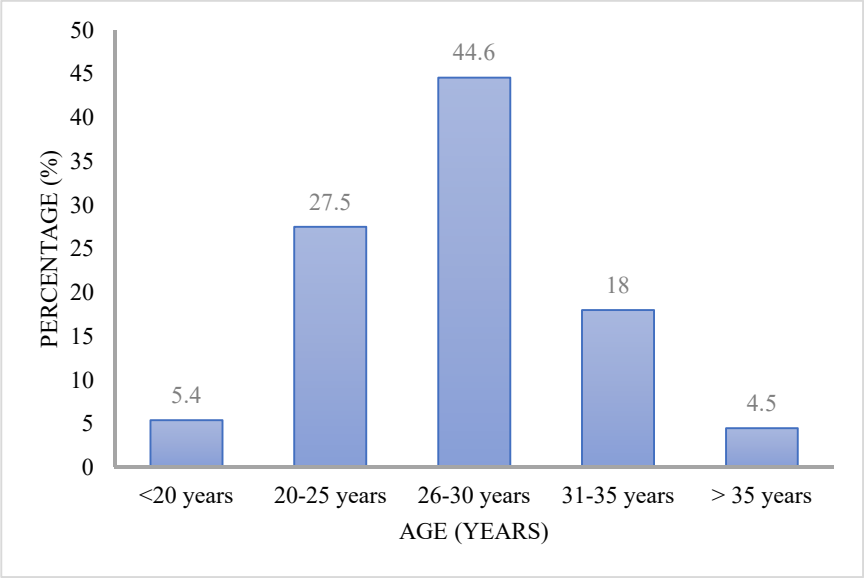

Figure 1. Categorization according to age

Table No. 01 and figure No.01 shows the age distribution of the pregnant women who took part in the study was as follows: there were 3 participants under 20 years of age, 70 participants aged between 20 and 25 years, 99 participants in the 26 to 30 years age group, 40 participants aged 31 to 35 years, and 10 participants over 35 years.

Table 2. Pregnant women's education level

Women Education	Frequency	Percentage (%)
No Education	3	1.4
Schooling	32	14.4
HSC	44	19.8
Graduated	113	50.9
Post Graduated	30	13.5
Total	222	100.0

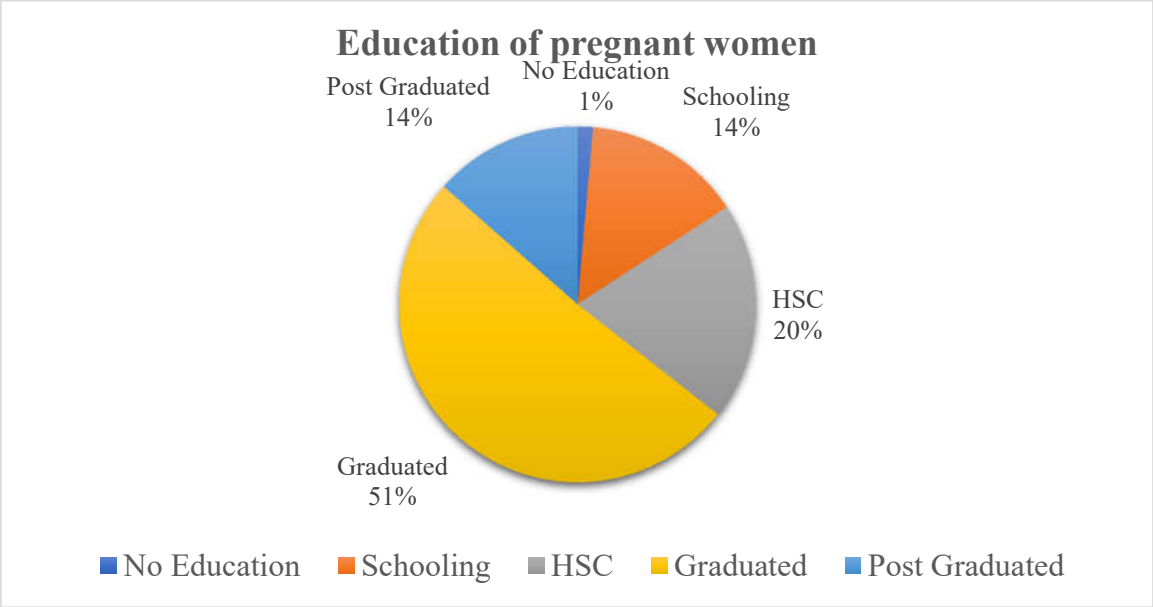

Figure 2. Pregnant women's education level

Table No. 02 and Figure No. 01 shows the educational backgrounds of the pregnant women surveyed revealed that 3 had no formal education, 32 had completed their schooling, 44 had finished higher secondary school (HSC), 113 participants held a bachelor's degree, and 30 had obtained a postgraduate degree.

Table 3. Total number of gravida or gravidity of the pregnant women

Total gravida	Frequency	Percentage (%)
One	77	34.7
Two	93	41.9
Three	39	17.6
Four	9	4.1
Five or more	4	1.8
Total	222	100.0

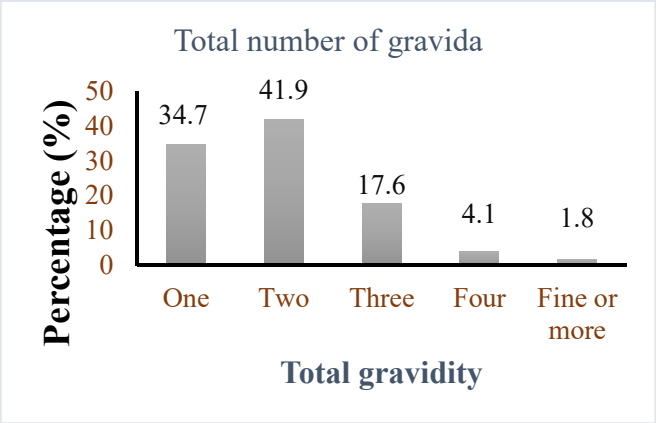

Figure 3. Total number of gravida or gravidity

Table No. 03 and Figure No. 03 shows the frequency of pregnancies among women is as follows: 77 women became pregnant once (primi), 93 women became pregnant twice, 39 women became pregnant three times, 9 women became pregnant four times, and 4 women became pregnant more than four times.

Table 4. Participant's and husband's blood group

Blood group	Women's		Husband's	
	Frequency	Percentage (%)	Frequency	Percentage (%)
A-	3	1.4	2	0.9
A+	45	20.3	41	18.5
AB-	2	0.9	2	0.9
AB+	15	6.8	21	9.5
B-	4	1.8	2	0.9
B+	48	21.6	64	28.8
O-	8	3.6	5	2.3
O+	97	43.7	85	38.3
Total	222	100.0	222	100.0

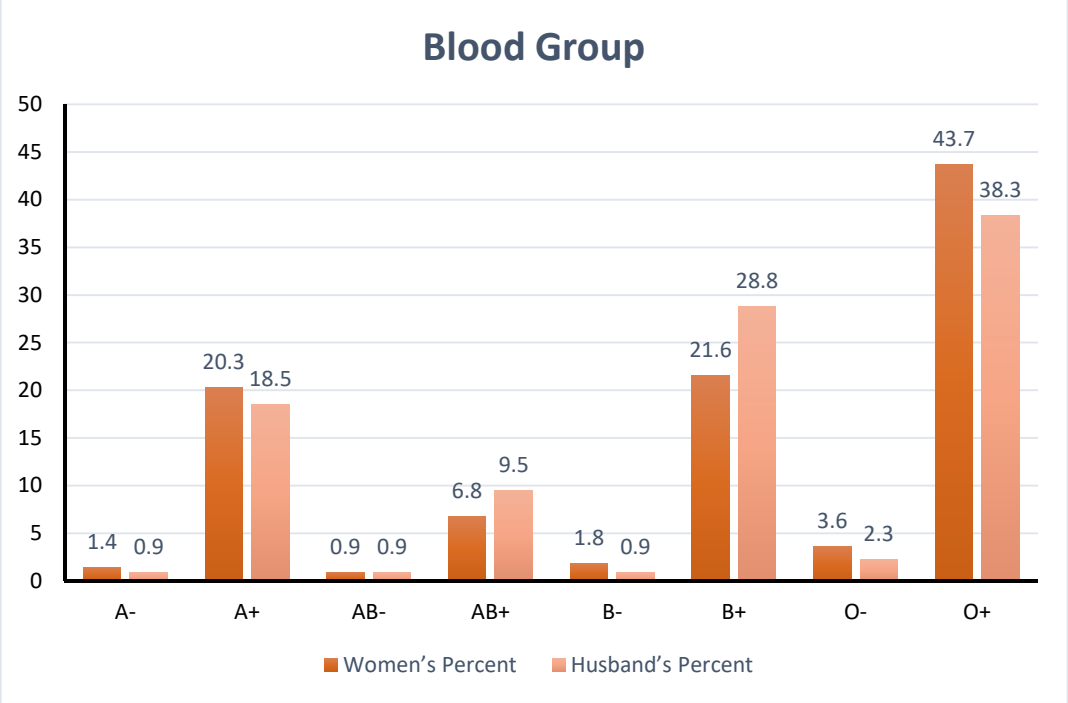

Figure 4. Participant's and husband's blood group

Table No. 04 and Figure No. 04 shows the data illustrates the various blood types of pregnant women alongside those of their husbands. Among the pregnant women, there were 3 with A-, 45 with A+, 2 with AB-, 15 with AB+, 4 with B-, 48 with B+, 8 with O-, and 97 with O+. In comparison, the husbands had 2 with A-, 41 with A+, 2 with AB-, 21 with AB+, 2 with B-, 64 with B+, 5 with O-, and 85 with O+.

5.2 Prevalence of high-risk pregnancy

Table 5. Prevalence of high-risk pregnancy

Summary	Frequency	Percentage (%)
High Risk Pregnancy	185	83.3
Non high risk	37	16.7
Total	222	100.0

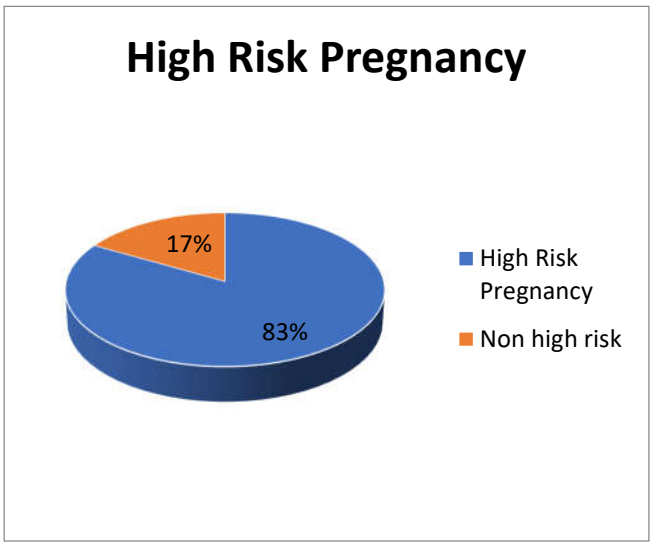

Figure 5. Prevalence of high-risk pregnancy

Table No.05 and Figure No: 05 indicates the prevalence of high-risk pregnancy where 185 are considered as high-risk pregnant women among 222 participants

Table 6. Number of co-morbidities in pregnant women

Number of co morbidities	Frequency	Percentage (%)
No Co-morbidities	37	16.7
One	88	39.6
Two	70	31.5
Three	25	11.3
Four	2	0.9
Total	222	100.0

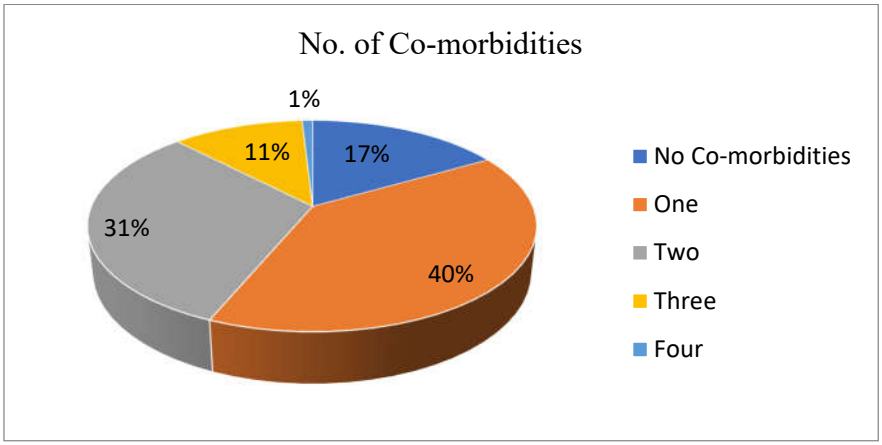

Figure 6. Number of co-morbidities in pregnant women

Table No.06 and Figure No. 06 indicates the number of co-morbidities of pregnant women who participated in the study. The co-morbidities that include are anemia, hypertensive disorders, gestational diabetes mellitus, hypothyroidism, syphilis or HIV positive, young primigravida and elderly gravida, twin/multiple pregnancy, malpresentation, previous history of lower segment caesarean section, low lying placenta, placenta previa, positive bad obstetric history, rhesus incompatibility, history of any current systemic illness/past history of illness

Table 7. Prevalence of individual co-morbidities

Co-morbidities	Frequency	Percentage (%)
Anemia	92	41.4
Hypertension	7	3.2
DM	8	3.6
Hypothyroidism	39	17.6
Previous LSCS	69	31.1
Multiple Gestation	5	2.3
BAD History	76	34.2
Young gravida	3	1.4
Elderly gravida	10	4.5
Rh incompatibility	15	6.8
Low Lying Placenta	13	5.9
HCV	1	0.4
HbSAg	1	0.4

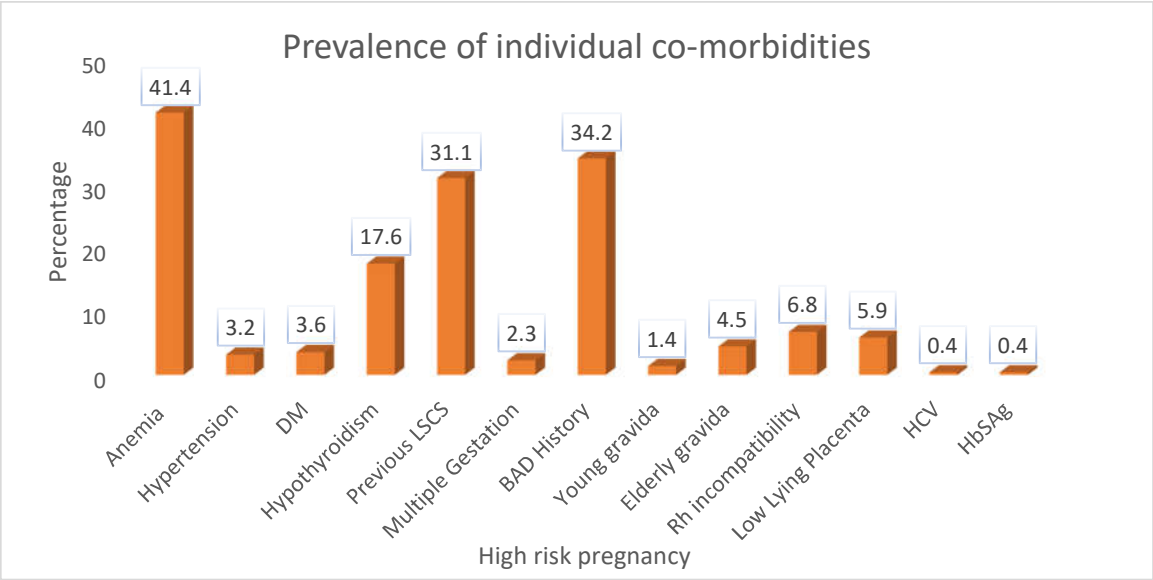

Figure 7. Prevalence of individual co-morbidities

Table No.07 and figure No. 07 shows that the individual prevalence of the co morbidities that includes 41.4% of anemia, 3.2% of pregnancy induced hypertension, 3.6% of Gestational diabetes mellitus, 17.6% of hypothyroidism, 31.1% of previous lower segment caesarean section, 2.3% of twin/multiple pregnancy, 34.2% bad obstetric history, 1.4% of young gravida, 4.5% of elderly gravida, 6.8% of Rh incompatibility, 5.9% of low-lying placenta, 0.4% of HCV positive and 0.4% of HbSAg positive

Table 8. Prevalence of Anemia

Haemoglobin	Frequency	Percentage (%)
>11g/dl (normal)	130	58.6
10-10.9g/dl (mild anemia)	51	23.0
8-9.9g/dl (moderate anemia)	36	16.2
<8g/dl (severe anemia)	5	2.2
Total	222	100.0

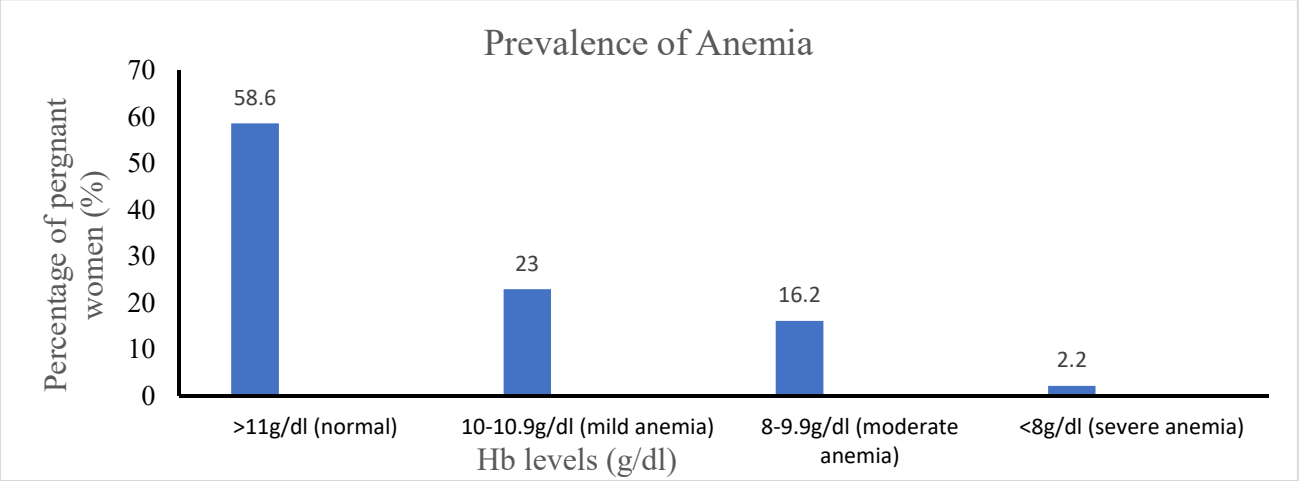

Figure 8. Prevalence of Anemia

Table no.08 and Figure No. 08 data indicates the prevalence of anemia, which is categorized according to haemoglobin levels. A haemoglobin level exceeding 11 g/dl is deemed normal, while a level below 11 g/dl is classified as anemia where the haemoglobin is further classified into mild anemia (10-10.9g/dl), moderate anemia (8-9.9g/dl), severe anemia (<8g/dl)

Table 9. Prevalence of Rhesus incompatibility

Rh incompatibility	Frequency	Percentage (%)
No	207	93.2
Yes	15	6.8
Total	222	100.0

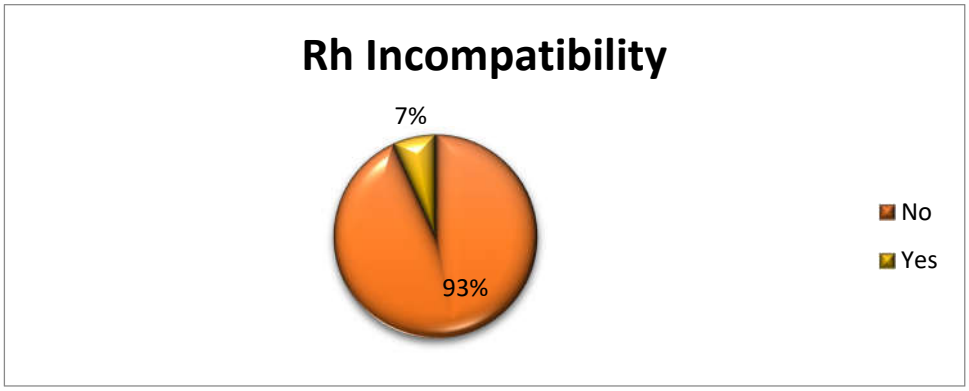

Figure 9. Prevalence of Rhesus incompatibility

Table No:09 and Figure No:09 data indicates occurrences of Rhesus incompatibility, particularly when the pregnant woman has a Rh-negative blood type and her partner has a Rh-positive blood type. In the population examined, 6.8% of pregnant women faced Rh incompatibility, whereas 93.2% did not.

Table 10. Prevalence of syphilis, HIV and hepatitis

Serology	Frequency	Percentage (%)
HIV	No	0
VDRL	No	0
HCV	1	0.4
HbSAg	1	0.4
Normal	220	99.2
Total	222	100.0

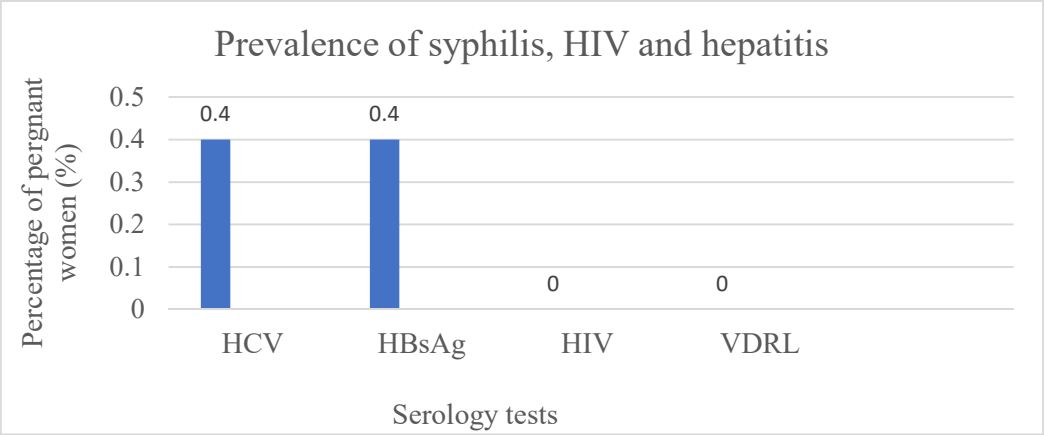

Figure 10. Prevalence of syphilis, HIV and hepatitis

Table No.10 and Figure No: 10 shows the serology positive and negative participants. The serology test includes human immunodeficiency virus (HIV), venereal disease research laboratory (VDRL), hepatitis C virus (HCV), hepatitis B surface antigen (HBsAg) where 0.4% of pregnant women had HCV positive and 0.4% of pregnant women had HBsAg positive.

Table 11. Effectiveness of counselling on Anemia

Haemoglobin	Baseline		Follow-up	
	Frequency	Percentage (%)	Frequency	Percentage (%)
Normal (>11g/dl)	130	58.6	166	74.8
Mild anemia (10-10.9g/dl)	51	23.0	45	20.2
Moderate anemia (8-9.9g/dl)	36	16.2	11	5.0
Severe anemia (<8g/dl)	5	2.3	-	-
Total	222	100.0	222	100.0
Chi-square statistic = 133.574, p-value<0.001 (significant association)				

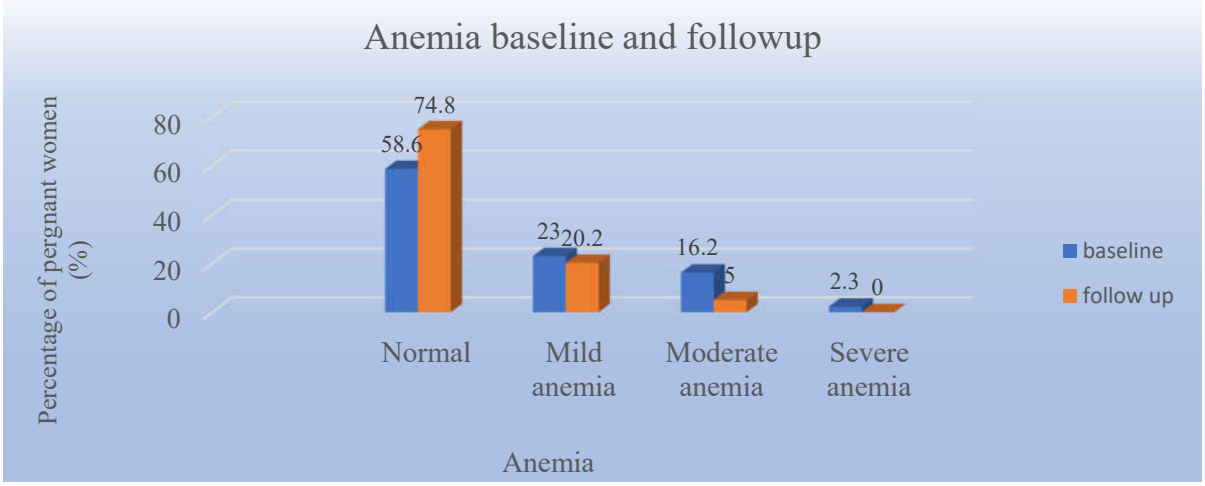

Figure 11. Effectiveness of counselling on Anemia

Table No.11 and Figure No.11 data outlines the baseline and follow-up hemoglobin levels, employing the chi-square test to evaluate the relationship between them. The chi-square statistic reveals a significant difference in hemoglobin levels between the baseline and follow-up evaluations. After counseling, there was a 16.2% increase in the proportion of participants reaching normal hemoglobin levels. The time frame between the baseline and follow-up measurements was one month. Furthermore, there was a significant decline in the number of pregnant women experiencing mild, moderate, and severe anemia, with reductions of 2.8%, 11.2%, and 2.3%, respectively.

Table 12. Effectiveness of counselling on Gestational diabetes mellitus

Sugar level	Baseline		Follow-up	
	Frequency	Percentage (%)	Frequency	Percentage (%)
Elevated (>140mg/dl)	8	3.6	1	0.5
Normal (<140mg/dl)	214	96.4	221	99.5
Total	222	100.0	222	100.0
Chi-square statistic = 26.871, p-value<0.001 (significant association)				

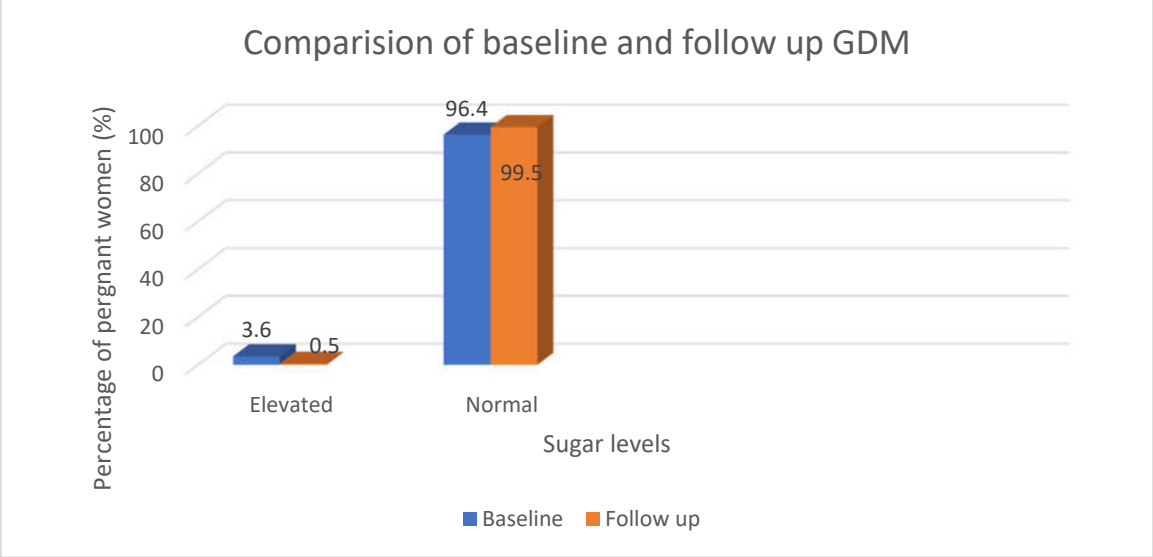

Figure 12. Effectiveness of counselling on Gestational diabetes mellitus

Table No.12 and Figure No.12: The data outlines the initial and follow-up measurements of blood sugar levels, which were evaluated using fasting blood sugar (FBS) and the oral glucose tolerance test (OGCT). There was a one-month gap between the baseline assessment and the follow-up. At the start, 3.6% of pregnant women had elevated blood sugar levels; however, after receiving counseling and undergoing a follow-up assessment, this figure dropped to 0.5%. This represents a decrease of 3.1% in elevated sugar levels from the baseline to the follow-up. A chi-square test was performed to assess the significance of these results, indicating a statistically significant difference in blood sugar levels between the two assessments.

Table 13. Effectiveness of counselling on pregnancy induced hypertension

Blood pressure	Baseline		Follow-up	
	Frequency	Percentage (%)	Frequency	Percentage (%)
Elevated (>120/90 mmHg)	7	3.2	0	0.0
Normal (<120/90 mmHg)	215	96.8	222	100.0
Total	222	100.0	222	100.0
Cannot be estimated due to zero count.				

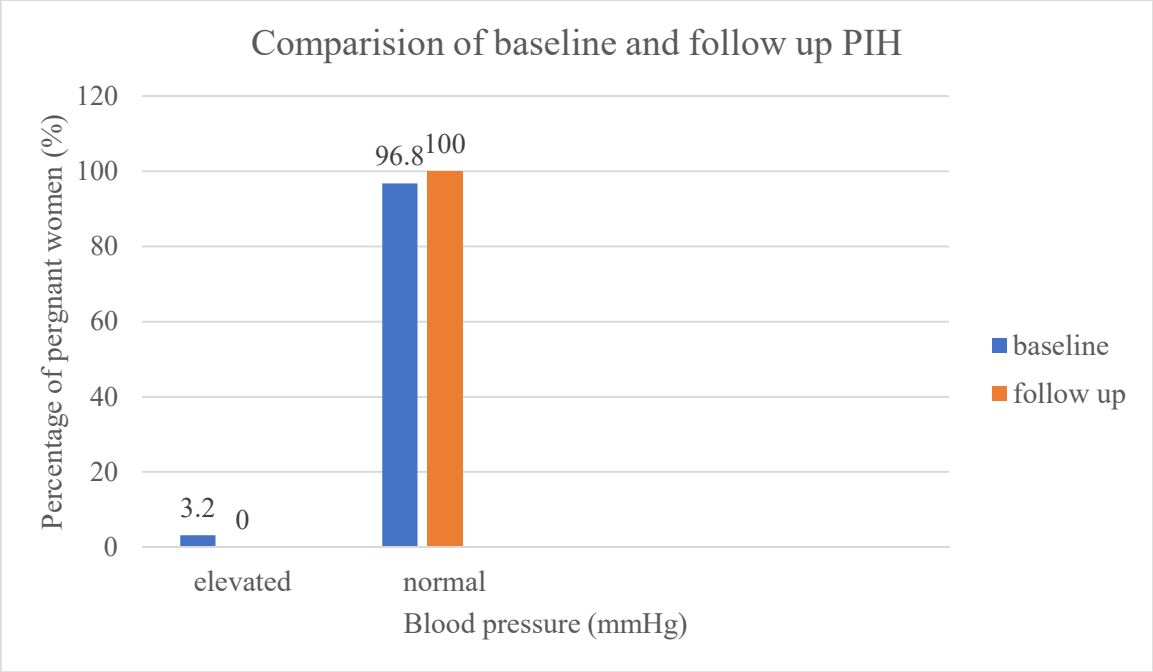

Figure 13. Effectiveness of counselling on pregnancy induced hypertension (PIH)

Table No.13 and Figure No.13: The data presents the initial and later blood pressure readings, with a one-month gap between the baseline and follow-up assessments. At the start, 3.2% of pregnant women had elevated blood pressure, defined as readings above 120/90 mmHg. After counseling, follow-up measurements showed a complete reduction, with no pregnant women exhibiting elevated blood pressure. This indicates a significant decrease in blood pressure levels.

Table 14. Effectiveness of counselling on hypothyroidism

TSH	Baseline		Follow-up	
	Frequency	Percentage (%)	Frequency	Percentage (%)
Elevated (>4mIU/L)	39	17.6	4	1.8
Normal (<4mIU/L)	183	82.4	218	98.2
Total	222	100.0	222	100.0
Chi-square statistic = 19.114, p-value<0.001 (significant association)				

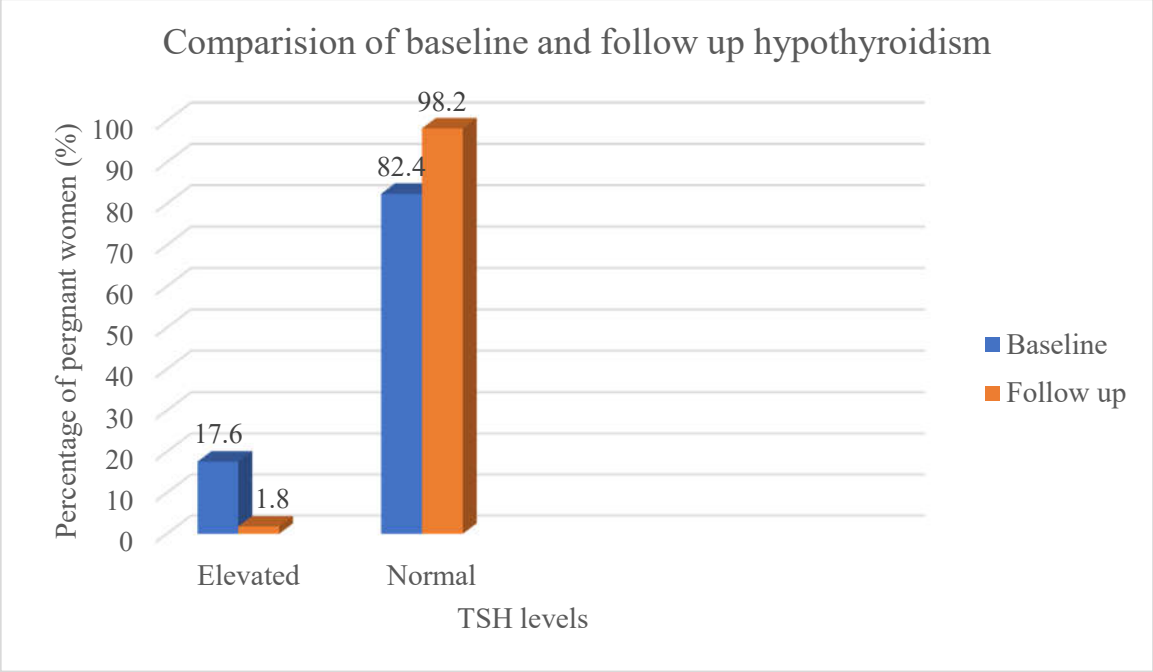

Figure 14. Effectiveness of counselling on hypothyroidism

Table No.14 and Figure No 14: The data presents the baseline and follow-up TSH levels for individuals diagnosed with hypothyroidism. Hypothyroidism classification is based on these TSH levels. Initially, 17.6% of pregnant women exhibited elevated TSH levels, categorizing them as hypothyroid patients at baseline. Following counseling, TSH levels were reassessed after a one-month interval, revealing that only 1.8% of the pregnant women had elevated TSH levels. This represents a significant reduction of 15.8% in the number of pregnant women with elevated TSH levels. The significance of this change was determined using the chi-square test, which indicates a notable difference in hypothyroidism levels when comparing baseline and follow-up assessments.

Table 15. Assessment of neonatal birth weight

Neonatal birth weight	Frequency	Percentage (%)
Normal (2.5-4kg)	204	91.9
LBW (<2.5kg)	14	6.3
Terminated	4	1.8
Total	222	100.0

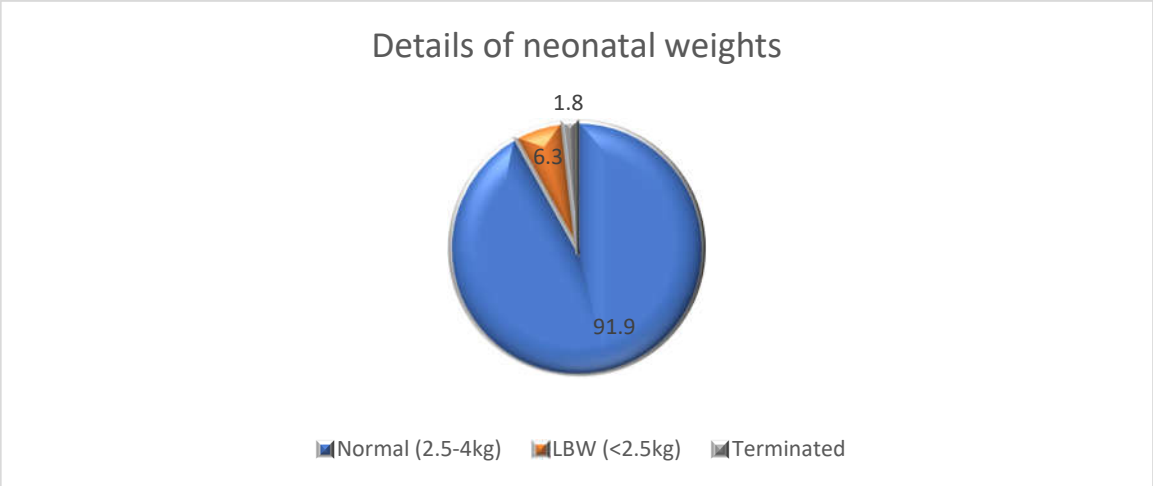

Figure 15. Assessment of neonatal birth weight

Table No.15 and Figure No.15: The delivery details are presented, encompassing the birth weight, instances of fetal termination. Among the delivered infants, 91.9% were classified as having a normal birth weight, whereas 6.3% were identified as having low birth weight. Additionally, 1.8% of pregnant women experienced fetal termination due to the absence of a heartbeat

Table 16. Gestational age at delivery of neonates (according to WHO)

Gestational age at delivery	Frequency	Percentage (%)
Full term (39-42 weeks)	90	40.55
Early term (37-38 weeks)	111	50
Late pre-term (34-36 weeks)	20	9
Moderately pre-term (29-33 weeks)	1	0.45
Total	222	100.0

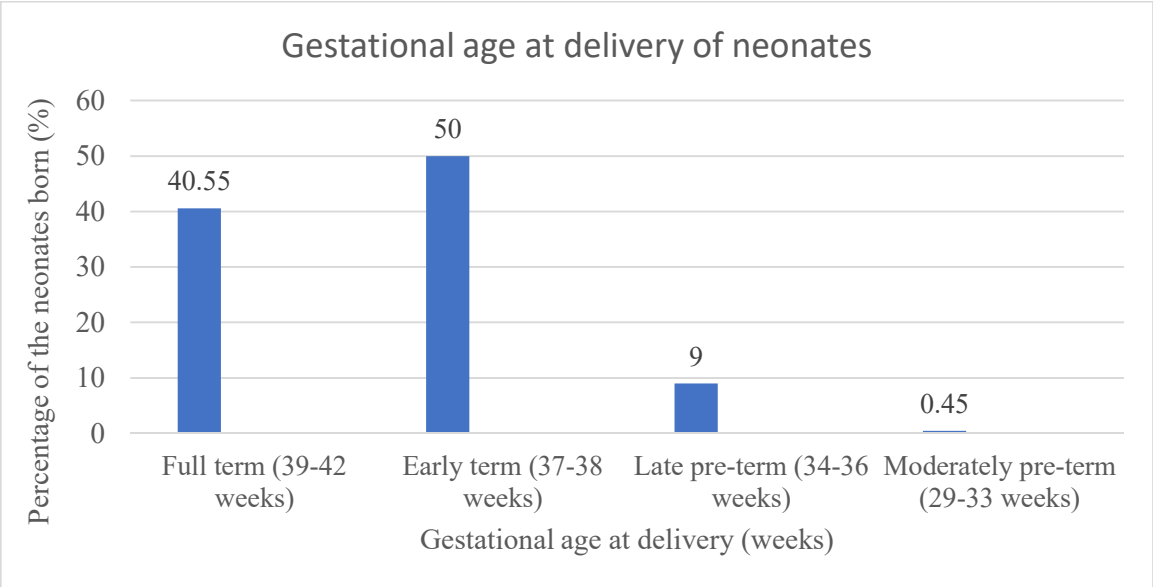

Figure 16. Gestational age at delivery of neonates

Table No.16 and figure No.16: The gestational age at delivery is categorized into several classifications: full term, early term, late pre-term, and moderately pre-term, corresponding to the ranges of 39-42 weeks, 37-38 weeks, 34-37 weeks, and 29-33 weeks, respectively. Among the neonates, 40.55% were born full term, 50% were born early term, 9% were born late pre-term, and 0.45% were born moderately pre-term.

Table 17. Neonatal complications

Neonatal complications	Frequency	Percentage (%)
Breathlessness	8	3.6
Jaundice	30	13.52
NICU admission	10	4.5
Nothing significant	174	78.38
Total	80	100.0

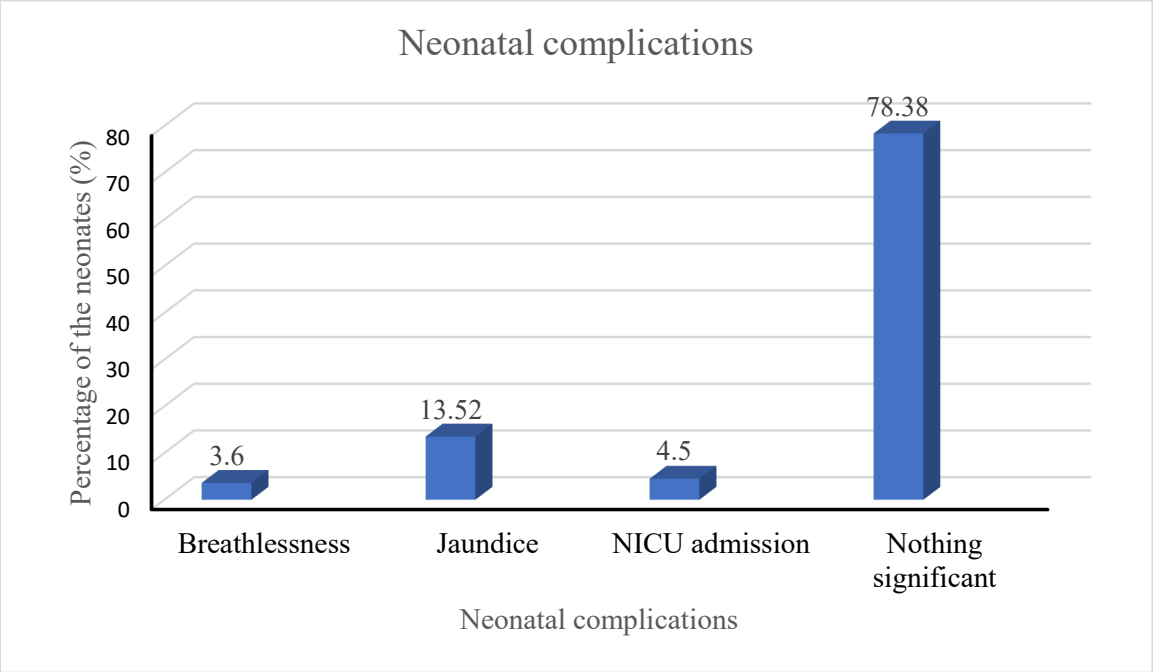

Figure 17. Neonatal complications

Table No.17 and Figure No.17: The neonatal outcomes presented include instances of breathlessness, jaundice, NICU admissions, and cases without complications. Specifically, 3.6% of neonates experienced breathlessness, 13.52% were diagnosed with jaundice, and 4.5% were admitted to the NICU due to breathlessness and low birth weight. Notably, 78.38% of neonates did not encounter any complications.

5.3 Validation of patient information leaflet (pil)

I. Content validation:

Table 18. Panel of expert agreement on the items of PIL

Number of items	Items	Number in agreement	Content Validity Index (CVI)
1	What is high risk pregnancy?	8	1
2	Conditions included in High-risk pregnancy	7	0.875
3	Disease based counselling	7	0.875
4	Drug based counselling	8	1
5	Lifestyle changes	8	1
6	When to report immediately to the doctor	8	1

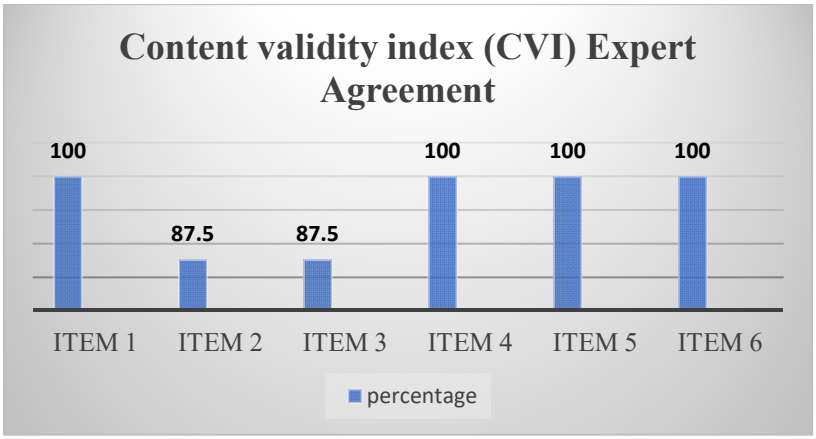

Figure 18. Panel of expert agreement on the items of PIL

The above Table No.18 and figure No. 18 shows the frequency and percentage of the items on the patient information leaflet agreed by the experts for the evaluation of the content validity according to Lawshe's scale. CVI scores for the items were above the 0.83 so all the content is kept in leaflet

II. DESIGN AND LAYOUT VALIDATION

Table 19. Design characteristics of PIL

Design characteristics	Value	
	English version	Kannada version
Lines 50-89 mm long	1	1
Separation between the lines	0	0
Lines unjustified	0	1
Serif typeface	2	2
Type size	3	3
Italics	2	2
Positive advice	2	2
Headings standout	2	2
Numbers all Arabic	0	0
Boxed text	1	1
Pictures	2	2
Number of colours	2	2
White space	2	2
Paper quality	3	3
Total	22	23

Table No.19 represents the Baker able leaflet design [BALD] method used to assess the layout and design characteristics of the PIL. BALD index was 22 for English version and 23 for Kannada version

III. READABILITY TEST:

Table 20. PIL readability test scores [Final version]

Readability tests	Sentences	Words	Syllables	Score	Grade
Flesch reading ease [FRE]	16	175	268	66.17	8-9th grade
Flesh Kincaid Grade level [FK-GL]	16	175	268	6.75	6th grade

Table No.20 represents the readability scores assessed using the online readability calculator FRE and FK-GL. The best FRE score was above 60 and the FK-GL score was 6.1 indicating it is in plain English and can be easily understood by 13–15-year-old students.

6. DISCUSSION

A hospital-based prospective study was conducted at two hospitals in Bengaluru. Most of the earlier studies conducted were only on prevalence of high-risk pregnancies and its outcomes, there was only fever studies which focuses on antenatal education and counselling. But our study was focused to evaluate the maternal and fetal complications associated with high-risk pregnancies and to identify key factors contributing to adverse outcomes. Furthermore, the study seeks to assess the effectiveness of early interventions and counseling in reducing these risks, ultimately improving the health and well-being of both mother and newborn by providing them a validated PILs.

Prevalence of high-risk pregnancies: The findings from this prospective study on maternal and fetal complications in high-risk pregnancies provide significant insights into both the prevalence of complications and their impacts on the health of the newborn. The analysis of high-risk pregnancies revealed that 83.3% (n=185) of the pregnant women in the study were categorized as high-risk [Table no.05, fig no.05]. This high percentage emphasizes the importance of early identification and appropriate management of these pregnancies to improve maternal and fetal outcomes. Prajapati et al. (2022) conducted a study in Uttar Pradesh, where 40.5% of women were classified as high-risk pregnancies under the Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA) scheme. Arjariya R and Tiwari P (2021) found a prevalence of 16.54% in a study conducted in a tertiary care centre in Madhya Pradesh. In Majella et al. (2019), the prevalence of high-risk pregnancies in Puducherry was 18.3%. This figure is lower compared to our study, possibly reflecting differences in population health and access to healthcare interventions.

Demographic details of the study participants: The demographic distribution shows that the majority of the participants 44.6% (n=99) [Table no.01, fig no.01] were aged between 26 and 30 years. In comparison, studies such as those by Saravade, et al. (2021) also highlight that women in their late 20s are generally more likely to have successful pregnancies but may also encounter complications depending on other factors like health conditions and previous medical history. This suggests that while this age group is associated with a high likelihood of normal pregnancy outcomes, there is still a notable prevalence of high-risk conditions among women in this demographic. Therefore, the findings from both our study and the literature

reinforce that the 26-30 age group represents a balanced risk for both normal and high-risk pregnancies, influenced by a combination of sociodemographic factors and medical history. Educationally, 50.9% (n=113) of the participants had graduated [Table no.02, fig no.02]. The higher level of education among these women suggests better health literacy, which could have contributed to better pregnancy management and outcomes.

Gravidity and other co-morbidities: Most women in our study 41.9% (n=93) were experiencing their second pregnancy, with 34.7% (n=77) being primigravida [Table no. 03, fig no.03]. Gravidity influences the risk of complications, as women with multiple gravidities are more likely to face conditions such as placenta previa or previous cesarean sections. Ticconi et al. (2020) found that women with recurrent pregnancy loss also had increased risks of complications, including gestational diabetes mellitus (GDM) and anemia, further supporting the findings in our research. More than half of the participants (55.8%) reported at least one co-morbidity, with anemia 41.4% (n=92), previous lower segment cesarean sections 31.1% (n=69), and bad obstetric history 34.2% (n=76) being the most common. Anemia, in particular continues to be a major concern in maternal health in India, which aligns with other studies showing a high prevalence of iron-deficiency anemia among pregnant women. These conditions significantly contribute to adverse pregnancy outcomes, and the study stresses the importance of early diagnosis and intervention to mitigate their effects. The prevalence of pregnancy-induced hypertension (3.2%, n=7) and gestational diabetes mellitus (3.6%, n=8) were relatively lower than expected, yet these conditions require strict management protocols due to their potential to escalate into severe complications. A significant proportion of participants were diagnosed with hypothyroidism (17.6%, n=39) is comparable to findings from Kumar et al. (2023) in Northern India, where thyroid dysfunction was found to be prevalent among pregnant women. These conditions are known contributors to maternal and fetal morbidity, with hypothyroidism increasing the risks of premature birth and cognitive impairment in the child. Additionally, 2.3% of pregnancies involved multiple gestations, which inherently carry higher risks of preterm delivery, IUGR (Intrauterine Growth Restriction), and neonatal complications [Table no. 06 and 07, fig no. 06 and 07]. The conditions like, 6.8% (n=15) participants with Rhesus incompatibility [Table no.16, fig.no16] and 5.9% (n=13) with low lying placenta [Table no.17, fig no.17] was found.

Anemia baseline vs follow-up: At baseline, 58.6% (n=130) of the pregnant women were diagnosed with anemia, categorized into mild (23%, n=51), moderate (16.2%, n=36), and severe (2.3%, n=5) [Table no.19]. Following counseling and intervention, the prevalence of anemia decreased significantly. The proportion of women with normal hemoglobin levels (>11 g/dL) increased from 58.6% at baseline to 74.8% at follow-up, a 16.2% improvement. Meanwhile, the prevalence of moderate anemia dropped from 16.2% to 5%, and severe anemia was completely resolved by the follow-up [fig no.19]. This significant reduction underscores the effectiveness of targeted dietary recommendations, supplementation, and patient education in managing anemia during pregnancy. This is consistent with Barut A and Mohamud DO (2023), who studied Somali women and found a high prevalence of anemia, concluding that anemia was a major contributor to maternal and fetal complications. Their study showed a similar need for iron supplementation and education for pregnant women.

Gestational diabetes mellitus baseline vs follow-up: Initially, 3.6% (n=8) of participants had elevated blood sugar levels (>140 mg/dL), while 96.4%(n=214) had normal levels. After gap of one month of follow-up, the percentage of women with elevated blood sugar dropped to 0.5%, and 99.5% of the women had normal glucose levels. This 3.1% improvement reflects the

success of dietary modifications, exercise, and medication compliance introduced through counseling, contributing to better glycemic control during pregnancy [Table no.20, fig no.20]. Comparatively, Li et al. (2020) in a study in Qingdao, China, found a higher incidence of GDM at 6.8%. They emphasized the importance of early intervention and dietary management, similar to the approach adopted in your study. Ejaz et al. (2023) also highlighted similar outcomes where counseling and lifestyle modifications were key factors in reducing GDM cases.

Pregnancy-induced hypertension (PIH) baseline vs follow-up: At baseline, 3.2%(n=7) of women were diagnosed with elevated blood pressure (>120/90 mmHg). Following intervention, all participants exhibited normal blood pressure levels during follow-up, reducing the prevalence of PIH completely [Table no.21, fig no.21]. This result highlights the critical role of early detection, lifestyle modification, and regular monitoring in controlling hypertension in pregnancy, thereby reducing risks such as preeclampsia. Rajbanshi et al. (2020) in Nepal reported a similar prevalence but did not observe as significant a reduction, suggesting that our interventions (including patient education and lifestyle changes) may have been more effective. Mathew et al. (2023) also studied hypertensive disorders in primigravida populations, emphasizing the need for regular monitoring, which our study also supports.

Hypothyroidism baseline vs follow-up: At the start of the study, 17.6% of pregnant women had elevated thyroid-stimulating hormone (TSH) levels (>4 mIU/L), indicating hypothyroidism, while 82.4% had normal levels. After counseling and appropriate medical management, the percentage of women with elevated TSH dropped to 1.8%, with 98.2% having normal thyroid function [Table no: 22, fig no:22]. This 15.8% reduction illustrates the importance of medication adherence and routine thyroid function monitoring in minimizing hypothyroidism-related pregnancy complications. This demonstrates the significant positive impact of early intervention, patient education, and structured counseling on managing high-risk conditions in pregnancy. By improving outcomes in anemia, GDM, PIH, and hypothyroidism, the study highlights the need for consistent prenatal care and patient engagement to prevent maternal and fetal complications.

Neonatal outcomes: In terms of neonatal outcomes, with 6.3% of babies being born with low birth weight (LBW) and 1.8% was terminated [Table no:23, Fig No:23]. This is a relatively low incidence of LBW compared to other studies, suggesting that the management strategies employed may have contributed to better fetal health. However, 13.5% of neonates developed jaundice, 3.6% developed breathlessness and 4.5% required NICU admission, indicating the ongoing need for monitoring and intervention [Table No:25, Fig No: 25]. Majella et al. (2019) conducted a study in Puducherry on high-risk pregnancies and reported 10.4% LBW and 1.7% stillbirths among neonates. This aligns with our study in terms of low stillbirth rates, though your LBW rate was slightly lower. Wahabi et al. (2024) in Saudi Arabia found that 23% of LBW neonates and 59.3% of very low birth weight (VLBW) neonates were admitted to the NICU, with complications such as Respiratory distress syndrome RDS being prevalent. In comparison, our NICU admission rate was lower, which may suggest that early intervention and counseling in our study helped reduce the severity of neonatal complications.

Patient Education and Lifestyle Modifications: The use of patient information leaflets (PILs) as part of the intervention strategy appears to have played a crucial role in improving patient understanding of their condition and adherence to prescribed treatment plans. The success of this intervention is reflected in the relatively lower rates of gestational diabetes and hypertension compared to the national averages and also significant symptomatic better from

baseline to next follow-up. This highlights the value of health education in managing high-risk pregnancies, particularly in ensuring that pregnant women follow prescribed medication regimens and adopt lifestyle modifications that could positively impact pregnancy outcomes. Similar outcomes were seen in the study conducted by Gultom AM on the impact of antenatal health education on healthy pregnancy and safe delivery in Indonesia (Gultom and A M R 2024).

Lawshe's content Validity: The development of the Patient information leaflet (PIL) involved a comprehensive approach, beginning with use of Lawshe's content validity index (CVI) for assessment of the PIL's content.

If the CVI score is more than 0.78, the text is considered relevant to all the constructs it aims to measure. A panel of experts reviewed the PIL content, and the results demonstrated high agreement. Overall, all the content items surpassed the 0.83 threshold, indicating strong validity for inclusion in the PIL [Table no:26, fig No:26]

This high CVI reflects the reliability of the PIL in providing relevant and understandable information to pregnant women, ensuring that the content meets expert expectations and patient needs.

Baker Able Leaflet Design (BALD): Additionally, the Baker able leaflet design (BALD) index was adapted to evaluate the PIL's graphic design and visual appeal. The results showed a BALD index score of 22 for the English version and 23 for the Kannada version, indicating a well-designed leaflet in terms of readability, visual appeal, and accessibility. Key factors evaluated included type size, use of serif typeface, separation between lines, and use of boxed text [Table No:27]. The design was particularly effective in ensuring headings stood out and in maintaining a clear structure, which enhances the ease of navigation for readers.

Flesch's Reading Ease Score (FRE) and Flesch-Kincaid Readability Test (FK-GL): The Flesch Reading Ease (FRE) score assesses how easy it is to understand the text in the PIL. The final score for the PIL was 66.17, placing it in the category of "Plain English," which means the leaflet can be easily understood by individuals with an educational level equivalent to an 8th to 9th grade student [Table No:28]. This is a suitable level for health communication, especially in a diverse population where health literacy levels may vary. A score above 60 is considered appropriate for public-facing health documents, ensuring that the intended audience can easily grasp the provided information. The FRE score highlights the effectiveness of the PIL in simplifying complex medical terms and instructions for the general population.

The Flesch-Kincaid Grade Level (FK-GL) indicates the educational level needed to understand the text. The PIL achieved an FK-GL score of 6.75, which suggests that it can be comprehended by individuals with a 6th-grade reading level [Table No: 28]. This further confirms that the PIL was written in an accessible and straightforward manner. By keeping the FK-GL score low, the researchers ensured that the leaflet could reach a broader audience, particularly those with lower literacy levels. This is critical in a healthcare setting where patients may not have advanced education but still need to fully understand medical guidance.

7. CONCLUSION

The study titled "Maternal and Fetal Complications in High-Risk Pregnancies: A Prospective Study to Evaluate and Mitigate Adverse Outcomes on Newborn Aimed in Providing Effective Counselling" concludes that high-risk pregnancies are a significant concern due to their potential to cause severe complications for both the mother and the fetus. The research identified that 83.3% of the participants experienced high-risk pregnancies, with anemia, hypothyroidism, gestational diabetes mellitus (GDM), and hypertensive disorders being the most prevalent conditions. Key findings highlight the necessity for early identification of risk factors and the implementation of appropriate interventions, such as iron and folic acid supplementation for anemia, insulin therapy or oral hypoglycemics for GDM, and antihypertensive medications for pregnancy-induced hypertension. Regular prenatal care, close monitoring, and effective patient counseling were emphasized as critical in improving maternal and fetal outcomes.

The study also emphasizes the importance of patient education through well-designed Patient Information Leaflets (PILs), which were evaluated using various readability and content assessment tools such as the Content Validity Index (CVI), Flesch Reading Ease (FRE), and Flesch-Kincaid Grade Level (FK-GL). The results demonstrated that the PILs were clear, accessible, and effective in communicating crucial health information to pregnant women.

Therefore, the study recommends that healthcare providers enhance patient education and counseling, especially for high-risk pregnancies, to reduce complications and improve the quality of maternal and neonatal care. The integration of accessible information tools like PILs can play a vital role in ensuring pregnant women are informed and supported throughout their pregnancies.

8. ACKNOWLEDGEMENT

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9. CONFLICT OF INTEREST

The authors declare no conflict of interest

10. FINANCIAL SUPPORT AND SPONSORSHIP

No funding received for this study.

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ABBREVATIONS

1. MMR: Maternal mortality ratio
2. PMSMA: Pradhan Mantri Surakshit Matritva Abhiyan
3. HIV: Human immunodeficiency viruses, PIH: Pregnancy induced hypertension
4. GDM: Gestational diabetes mellitus
5. HELLP: Hemolysis, Elevated Liver enzyme levels, and Low Platelet levels
6. ARDS: Acute respiratory distress syndrome
7. DIC: Disseminated intravascular coagulation
8. IUGR: Intrauterine growth restriction
9. IUD: Intrauterine death
10. IRDS: Infant respiratory distress syndrome
11. IEC: Institutional ethics committee
12. CBC: Complete blood count
13. RBS: Random blood sugar
14. FBS: Fasting blood sugar
15. OGCT: Oral glucose challenge test
16. BP: Blood pressure
17. PIL: Patient information leaflet
18. FRE: Flesch’s reading ease
19. FK-GL: Flesch-Kincaid grade level
20. BALD: Baker able leaflet design

21. HCV: Hepatitis c virus
22. HBsAg: Hepatitis B surface antigen
23. Rh: Rhesus, LBW: Low birth weight
24. NICU: Neonatal intensive care unit
25. VLBW: Very low birth weight
26. CVI: Content validity index