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Perinatal Outcome of Intrahepatic Cholestasis of Pregnancy (ICP) in CMH Nowshera: A Prospective Cohort Study

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Abstract

Introduction: Intrahepatic cholestasis of pregnancy (ICP) is a common liver disorder in late pregnancy, characterized by itching and elevated bile acids, affecting 0.3% to 15% of pregnancies. This study aimed to compare foetomaternal outcomes between ICP patients and a control group at CMH Nowshera.

Methodology: This prospective cohort study was conducted from September 2023 to May 2024, involving 80 pregnant women (40 with ICP and 40 controls). Participants were enrolled using nonprobability sampling. Data collection included demographics, clinical presentation, laboratory findings, and obstetric history. Outcomes measured were preterm delivery, stillbirth, neonatal respiratory distress syndrome (RDS), NICU admission, low birth weight, Apgar scores, and maternal complications. Statistical analysis was performed using SPSS version 27.0.

Results: The mean age of participants was 30.19 years. ICP patients had significantly higher ALT levels (mean = 146.32 U/L) compared to controls (mean = 61.42 U/L). The ICP group had a higher incidence of C-sections (60% vs. 30%), preterm births, NICU admissions (72.5% vs. 22.5%), neonatal respiratory distress syndrome (27.5% vs. 7.5%), and meconium-stained fluid (23.75% vs. 7.5%). The ICP group had lower gestational ages at birth and birth weights. The analysis revealed significant differences between the groups in Apgar scores ($p<0.034$, RR = 8.0, 95% CI: 1.05 to 61.05) and preterm labor ($p=0.001$, RR = 7.5, 95% CI: 1.83 to 30.68).

Conclusion: ICP significantly impacts maternal and neonatal health, increasing the risk of preterm births, C-sections, and NICU admissions. Vigilant monitoring and tailored clinical strategies are essential to improve outcomes for this high-risk group.

Introduction

Intrahepatic cholestasis of pregnancy (ICP) is a liver disorder that typically occurs during the late stages of pregnancy, presenting with maternal pruritus and increased bile acid concentrations. The reported global prevalence ranges between 0.3% and 15%, depending on population and region. Although the precise cause of ICP is not completely understood, research suggests that genetic predisposition, hormonal influences, and environmental triggers play major roles in its development [1][2].

Pregnancies complicated by ICP are known to carry a higher risk of unfavorable perinatal outcomes, including premature delivery, fetal distress, and increased perinatal morbidity and mortality. The incidence of ICP shows considerable geographic variation, from approximately

0.1–1.5% in Europe and North America to 1.5–4% in Chile and Bolivia, with reports of a rising trend in India over the past decade from 0.79% to 2.73% [3].

Although the exact pathophysiology remains uncertain, studies have implicated hormonal factors and mutations in the MDR3 gene in bile acid transport dysfunction. In most cases, both symptoms and biochemical abnormalities resolve after childbirth. The use of ursodeoxycholic acid (UDCA) has been shown to reduce itching, improve liver function test results, and help prolong gestation [4][5]. Nonetheless, previous ICP diagnosis has been linked to a greater risk of future hepatic disorders and abnormal liver function [6]. Therefore, women who experience ICP should be closely monitored postpartum for possible liver-related complications [7].

There is ongoing debate regarding optimal prenatal management and the most suitable timing of delivery in ICP. While no fetal monitoring approach has reliably predicted or prevented adverse fetal outcomes, existing guidelines differ: the Royal College of Obstetricians and Gynaecologists discourages routine early delivery, whereas the American College of Obstetricians and Gynecologists supports timely induction protocols for selected patients [8]. Risk factors for ICP include pre-existing liver disease, a personal or family history of cholestasis during pregnancy, and advanced maternal age. Evidence suggests that patients with severe ICP, defined by serum bile acid levels ≥100 μmol/L, are more likely to experience complications such as stillbirth [9].

A recent cross-sectional study from Pakistan found an ICP prevalence of 1.6%, with a corresponding increase in cesarean deliveries and adverse neonatal outcomes such as fetal distress, intrauterine growth restriction, and low birth weight [10]. Given the increasing prevalence of ICP in Pakistan and its significant maternal and fetal implications, this study aims to assess and compare perinatal outcomes in women with ICP and those with uncomplicated pregnancies.

Methodology

This prospective cohort study was approved by the institutional ethical committee (Ref No: 12 Ethical Committee/DME dated 12-03-2024) and conducted at CMH Nowshera between September 2024 and May 2025. The objective was to compare maternal and neonatal outcomes between women diagnosed with intrahepatic cholestasis of pregnancy (ICP) and those with uncomplicated pregnancies.

A total of 80 participants were enrolled using a non-probability sampling technique. Subjects were assigned to two equal groups: 40 women with confirmed ICP and 40 healthy controls. The required sample size was estimated using the WHO sample size calculator, assuming a significance level (α) of 0.05, statistical power (1–β) of 90%, and anticipated proportions for induced labor of 82.1% in the case group and 18.4% in the control group [5]. Although the minimum calculated requirement was 11 participants per arm, the sample size was expanded to 80 (40 per group) to strengthen statistical reliability and ensure more generalizable results.

Inclusion Criteria

Pregnant women receiving antenatal care at CMH Nowshera were eligible if they had singleton pregnancies and were diagnosed with ICP based on clinical presentation and biochemical findings (elevated serum bile acids and/or abnormal liver function tests). Eligible participants were between 30 and 36 weeks of gestation at diagnosis and provided written informed consent to participate.

Exclusion Criteria

Women with multiple gestations, known chronic liver disease, major systemic comorbidities, incomplete records, or those who were lost to follow-up were excluded from the study.

Data Collection

Data were gathered through a semi-structured questionnaire developed to capture both maternal and fetal information comprehensively. Maternal parameters included demographic

characteristics (age, gravidity, parity), presenting symptoms (itching, jaundice), gestational age at diagnosis, and laboratory results such as serum bile acids and alanine aminotransferase (ALT). Treatment information—including use, dose, and duration of ursodeoxycholic acid—was also documented. Obstetric outcomes such as mode of delivery, preterm labor, and maternal complications (e.g., preeclampsia) were recorded.

Fetal and neonatal data comprised gestational age at birth, birth weight, Apgar scores at one and five minutes, and complications such as meconium-stained amniotic fluid, fetal distress, intrauterine fetal demise, neonatal respiratory distress syndrome (RDS), and need for NICU admission.

Outcome Measures

Primary outcomes included preterm delivery (before 37 weeks of gestation), stillbirth, neonatal RDS, NICU admission, low birth weight (<2500 g), and Apgar score <7 at five minutes. Maternal parameters included mode of delivery, liver enzyme levels, and obstetric complications.

Statistical Analysis

Data were analyzed using SPSS version 27.0. Continuous variables were summarized as mean ± standard deviation (SD) and categorical variables as frequencies and percentages. Between-group comparisons were performed using the Chi-square test for categorical variables and the Mann–Whitney U test for continuous variables. Relative risk (RR) with 95% confidence intervals (CI) was computed to estimate the likelihood of adverse outcomes in the ICP group compared to controls. A p-value of <0.05 was considered statistically significant.

Ethical Considerations

Written informed consent was obtained from each participant prior to inclusion. Confidentiality was maintained through anonymization of patient identifiers and secure storage of data. Study procedures were carried out in accordance with the Declaration of Helsinki. Data accuracy was verified through double entry and periodic monitoring to ensure adherence to the approved research protocol.

Limitations in Design

Although the study design minimized bias through prospective data collection, potential limitations such as recall bias, reliance on self-reported symptoms, and loss to follow-up were recognized and mitigated through repeated follow-up and verification of clinical records.

Results

A total of 80 pregnant women were included in the study and divided equally into two groups: 40 participants diagnosed with Intrahepatic Cholestasis of Pregnancy (ICP group) and 40 healthy controls.

The mean maternal age for the overall cohort was 30.19 ± 5.96 years, with an average age of 30.68 ± 5.74 years in the ICP group and 29.70 ± 6.20 years among controls. Gravidity ranged from 1 to 5 (mean = 2.79 ± 1.20, median = 3.0, IQR = 2.0), while parity ranged from 0 to 4 (mean = 1.46 ± 1.14, median = 1.0, IQR = 1.0).

Maternal Clinical and Laboratory Characteristics

Pruritus was reported by 47.5% of women in the ICP group, whereas none of the controls reported itching. Jaundice was observed in 7.5% of the ICP group and was absent in controls. The mean alanine aminotransferase (ALT) level was significantly elevated in the ICP group (146.32 ± 80.29 U/L) compared to controls (61.42 ± 36.72 U/L).

Obstetric and Neonatal Characteristics

The mean gestational age at delivery was 36.05 ± 2.22 weeks for the entire sample. Women with ICP delivered at a mean gestational age of 35.25 ± 2.44 weeks, significantly earlier than the control group (36.85 ± 1.66 weeks).

Mean birth weight for all neonates was 2483.86 ± 444.09 g, with infants in the ICP group weighing an average of 2346.15 ± 487.62 g, compared with 2621.56 ± 348.02 g in the control

group.

Mode of delivery also differed between the two groups: in the ICP cohort, 60% of women delivered by cesarean section and 40% had vaginal deliveries, whereas in the control group 30% underwent cesarean section and 70% delivered vaginally. This reflects a higher rate of operative delivery among women with ICP.

Neonatal Outcomes

NICU admission was required for 72.5% of neonates born to mothers with ICP, compared with 22.5% of those in the control group. Neonatal respiratory distress syndrome (RDS) occurred in 27.5% of the ICP group and 7.5% of the controls. Meconium-stained amniotic fluid was observed in 23.75% of the ICP group versus 7.5% among controls.

The mean Apgar score at one minute was 6.88 ± 0.86 overall; 6.45 ± 0.94 in the ICP group and 7.30 ± 0.64 in controls

Comparative Analysis

The ICP group demonstrated significantly higher frequencies of:

NICU admission (72.5% vs. 22.5%; $p < 0.001$)

Neonatal respiratory distress syndrome (27.5% vs. 7.5%; $p = 0.025$

Meconium-stained amniotic fluid (23.75% vs. 7.5%; $p = 0.031$)

Elevated maternal ALT levels (mean 146.32 U/L; $p < 0.001$)

Additionally, gestational age at delivery and neonatal birth weight were significantly lower in the ICP group (both $p < 0.001$).

Relative risk (RR) analysis showed higher likelihoods of:

NICU admission

Respiratory distress

Meconium-stained amniotic fluid

among neonates born to ICP mothers.

A significant difference was found in Apgar score groups using a cutoff of <7 ($p = 0.034$; RR = 8.0, 95% CI: 1.05–61.05).

Regarding preterm labor, the Chi-square test indicated a strong association with ICP ($p = 0.001$; RR = 7.5, 95% CI: 1.83–30.68).

Table 1: Maternal and Pregnancy Characteristics

Characteristics	ICP Group (n=40)	Control Group (n=40)	p-value
Age (years, mean ± SD)	30.68 ± 5.74	29.70 ± 6.20	0.487
Gravida (mean ± SD)	2.89 ± 1.21	2.69 ± 1.19	0.515
Parity (mean ± SD)	1.53 ± 1.14	1.38 ± 1.15	0.583
Gestational Age at Birth (weeks, mean ± SD)	35.25 ± 2.44	36.85 ± 1.66	<0.001
Birth Weight (grams,	2346.15 ± 487.62	2621.56 ± 348.02	<0.001

mean ± SD)			
ALT Levels (U/L, mean ± SD)	146.32 ± 80.29	61.42 ± 36.72	<0.001

Table 2: Neonatal Outcomes

Outcomes	ICP Group (n=40)	Control Group (n=40)	p-value	Relative Risk (95% CI)
Admission to NICU (%)	72.5	22.5	<0.001	3.22 (2.02 - 5.15)
Neonatal Respiratory Distress Syndrome (%)	27.5	7.5	0.025	3.67 (1.09 - 12.34)
Meconium-Stained Fluid (%)	23.75	7.5	0.031	3.17 (1.12 - 8.97)
Apgar Score at 1 Minute (mean ± SD)	6.45 ± 0.94	7.30 ± 0.64	<0.001	
Apgar Group (Low Apgar group) (%)	21.5	2.5	0.034	8.0 (1.05 to 61.05)
Delivery Group (Preterm delivery) (%)	37.5	5	0.001	7.5 (1.83 - 30.68)
Mode of delivery	60	30	0.007	2.0 (1.17, 3.43)

(C-section) (%)				
Preeclampsia (%)	15	5	0.136	3.0(0.64-13.98)

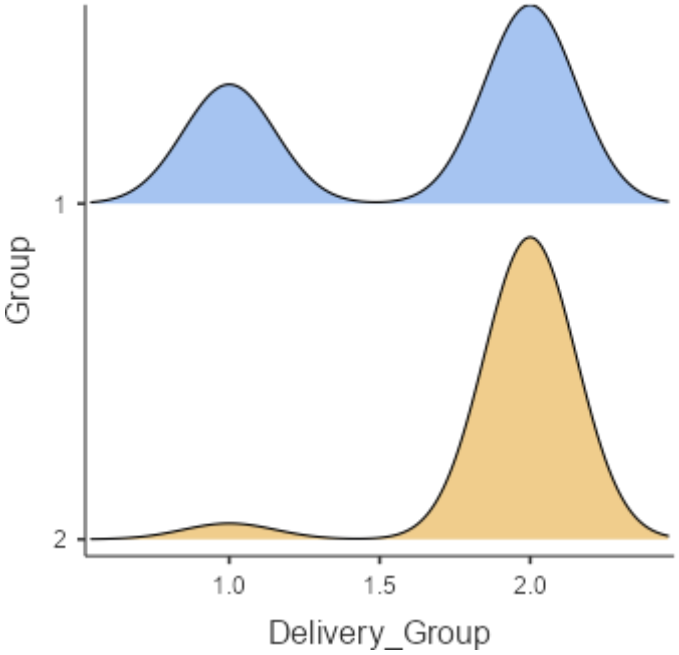


Figure I: Comparison of Preterm vs Term deliveries in the ICP and Control Groups

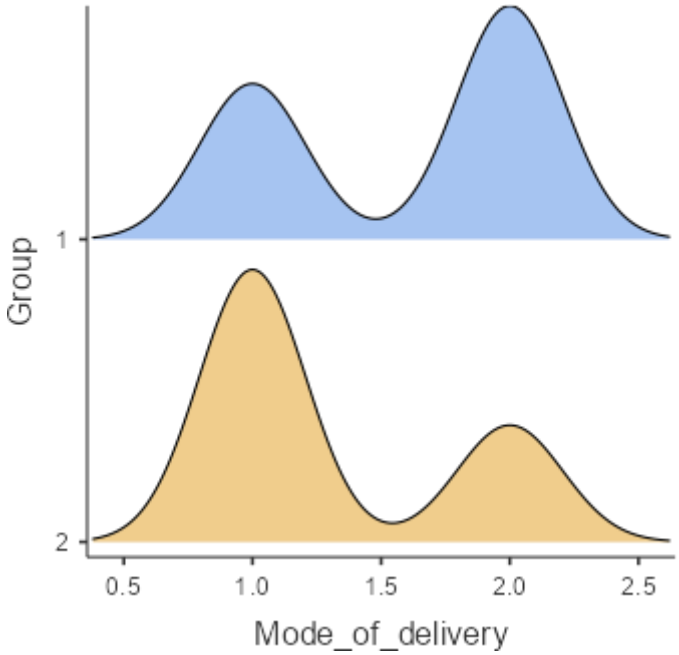


Figure II: Comparison of mode of delivery in ICP and control groups

Discussion

Intrahepatic cholestasis of pregnancy (ICP) is the most common liver disorder occurring during pregnancy, typically manifesting in the third trimester with pruritus and elevated bile acid or

alanine aminotransferase levels. Symptoms usually resolve after delivery, but recurrence in subsequent pregnancies is common [11]. The exact etiology of ICP remains uncertain, though genetic, hormonal, and environmental factors are believed to play contributory roles. Mutations in the hepatobiliary transport protein *MDR3*, which is essential for biliary phospholipid secretion, have been identified as key contributors to the pathogenesis of ICP [12].

The influence of sex steroids on ICP development is supported by its higher incidence in multiple pregnancies and in women using oral contraceptives. Estrogen, progesterone, and their metabolites peak during the third trimester, and while the exact mechanism remains unclear, 17-β-D-estradiol and sulfated progesterone metabolites have demonstrated specific cholestatic effects [13].

Our study aimed to compare maternal and neonatal outcomes between women with ICP and those without. The results demonstrated significant differences between the two groups. Previous research comparing perinatal outcomes from two birth cohorts showed that the ICP group had higher incidences of abnormal amniotic fluid and preterm births (all $P < .05$), indicating that ICP has a notable impact on pregnancy outcomes [14]. Our findings corroborate these results, with significant differences observed in similar perinatal parameters between the ICP and control groups.

A retrospective analysis of perinatal data (2011–2017) reported that women with ICP were nearly six times more likely to undergo labor induction and experienced higher rates of moderate preterm births, though overall maternal and neonatal outcomes remained favorable [15]. In our study, the rate of preterm births was found to be 7.5 times higher in the ICP group compared to the control group.

A recent systematic review and meta-analysis of 21 studies revealed that ICP significantly increases the risk of cesarean delivery (OR: 1.42, $p < 0.001$), preeclampsia (OR: 2.64, $p < 0.001$), NICU admission (OR: 2.1, $p < 0.001$), and preterm birth (OR: 2.64, $p < 0.001$). However, it showed no significant association with postpartum hemorrhage (OR: 1.31, $p = 0.13$), small-for-gestational-age infants (OR: 0.87, $p = 0.07$), or stillbirth (OR: 1.49, $p = 0.29$) [16]. Our findings align with these results, and no cases of stillbirth were reported in our cohort, emphasizing that careful and regular monitoring can effectively prevent such outcomes.

A population-based study reported cesarean section rates of 53.3% in the ICP group and 40.5% in controls [17], whereas our study observed rates of 60% and 30%, respectively. This variation may reflect differences in clinical decision-making by patients and obstetricians at presentation. Another meta-analysis reported an ICP incidence of 1.7% (OR: 0.021; 95% CI: 0.012–0.027) and a higher likelihood of cesarean birth (OR: 2.938; 95% CI: 1.467–5.881) [18]. This is consistent with our findings, where the risk of cesarean delivery was approximately double in the ICP group. Similarly, a retrospective study from Nepal reported a preterm delivery rate of 15.2% and a cesarean delivery rate of 69.5% in ICP patients [19], which closely parallels our results.

Preeclampsia is another adverse perinatal outcome associated with ICP. A retrospective cohort study demonstrated that women with ICP were significantly more likely to develop preeclampsia (aOR = 16.74; 95% CI: 5.29–52.98) than controls [20]. Furthermore, a systematic review and meta-analysis found that women with ICP had higher risks of gestational diabetes (OR = 2.19; 95% CI: 1.58–3.03) and preeclampsia (OR = 2.58; 95% CI: 2.37–2.81)[21]. In contrast, our study did not find a significant difference in the incidence of preeclampsia between the ICP and control groups.

Overall, our findings align with previous studies demonstrating that ICP is associated with adverse maternal and fetal outcomes during pregnancy[22–24]. Women with ICP showed higher incidences of cesarean delivery, gestational diabetes, and preterm labor compared to those without ICP.

Conclusion

Vigilant monitoring and appropriate management of intrahepatic cholestasis of pregnancy are crucial to minimizing its adverse effects on maternal and neonatal health. The increased risks of preterm birth and NICU admission highlight the importance of individualized clinical strategies aimed at improving outcomes in this high-risk population. Future research should focus on uncovering the precise mechanisms underlying ICP and developing targeted interventions to optimize care for affected women.

Limitations of the Study

1. The study was conducted at a single hospital, which may limit the generalizability of the findings to other populations or settings.

2. Despite its prospective design, potential biases in patient selection and data reporting cannot be excluded.

3. The study focused solely on immediate maternal and neonatal outcomes, lacking long-term follow-up to assess extended effects of ICP.

4. Some potential confounding factors influencing outcomes may not have been fully controlled.

5. The study population may not represent other geographical or demographic groups, which could affect the external validity of the results.

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