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Association between maternal serum bile acids and fetomaternal outcomes in intrahepatic cholestasis of pregnancy: A comparative analysis

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Abstract
Introduction: Intrahepatic cholestasis of pregnancy (ICP), which is also known as obstetric cholestasis, is a liver disease of pregnancy associated with raised serum bile acids and increased rates of adverse fetal outcomes.
Aim: To evaluate maternal bile acid levels and assess maternal and fetal outcomes in intrahepatic cholestasis of pregnancy (ICP).
Methodology: This comparative observational study was conducted in the Department of Obstetrics and Gynaecology at Heritage Institute of Medical Sciences, Uttar Pradesh, from August 2023 to January 2025.
Result: The study found significantly higher rates of preterm birth, low birth weight, stillbirth, and postpartum complications in ICP cases compared to controls, with elevated bile acid levels strongly linked to adverse outcomes. Despite trends, comorbidities and coagulation abnormalities showed no statistically significant differences between groups.
Conclusion: In conclusion, this study highlights that intrahepatic cholestasis of pregnancy (ICP) is significantly associated with adverse maternal and neonatal outcomes, including higher risks of preterm birth, low birth weight, postpartum complications, and prolonged hepatic dysfunction

Keywords: Intrahepatic cholestasis of pregnancy, obstetric cholestasis, serum bile acids

Introduction

Intrahepatic cholestasis of pregnancy (ICP), which is also known as obstetric cholestasis, is a liver disease of pregnancy associated with raised serum bile acids and increased rates of adverse fetal outcomes [1]. Intrahepatic cholestasis of pregnancy (ICP), first described by Ahlfeld in 1883, is the most common liver disorder unique to pregnancy. It typically presents in the third trimester with pruritus and abnormal liver tests, resolving after delivery. While maternal risk is low, ICP increases the risk of preterm birth and sudden intrauterine fetal death. Its exact cause is unclear but is thought to involve genetic and hormonal factors [2]. Treatment is mainly symptomatic, with ursodeoxycholic acid as the most effective option, though optimal fetal monitoring remains uncertain. Intrahepatic cholestasis of pregnancy (ICP) is a hepatic disorder unique to pregnancy, marked by pruritus and abnormal liver function tests. It is a reversible cholestasis, usually appearing in the late second or third trimester and resolving after delivery. The incidence of ICP varies worldwide, ranging from 0.1% to 15.6%, and it ranks as the second most common cause of jaundice in pregnancy after viral hepatitis. Its etiology is multifactorial, involving hormonal, environmental, and genetic factors. While maternal outcomes are generally good, women may experience severe itching and an increased risk of postpartum bleeding [3]. Fetal risks are more serious, including preterm delivery, fetal distress, and sudden intrauterine death. Clinical awareness of these fetal risks is essential, and ICP should be considered a high-risk pregnancy condition. Timely diagnosis and proper medical management are crucial to improving fetal outcomes. Intrahepatic cholestasis of pregnancy (ICP) most commonly presents in the third trimester with pruritus, especially on the palms and soles, which worsens at night and resolves after delivery [4]. Clinical jaundice is rare, affecting about 10–15% of cases, and constitutional symptoms like anorexia, malaise, and steatorrhea may also occur. ICP may coexist with other pregnancy-related conditions such as pre-eclampsia, acute fatty liver, or gestational diabetes, reflecting its heterogeneous nature. Liver function usually returns to normal within 2–8

weeks postpartum, though rare prolonged cases have been reported. Recurrence in future pregnancies is common, but severity cannot be predicted. Intrahepatic cholestasis of pregnancy (ICP) is a reversible cholestatic disorder unique to pregnancy, mainly affecting women in the second and third trimesters [5, 6]. It presents with unexplained pruritus, especially on the palms and soles, elevated liver enzymes and/or bile acids, all resolving after delivery. ICP increases the risk of maternal complications like postpartum haemorrhage and fetal risks such as preterm birth, meconium-stained liquor, stillbirth, and NICU admission. The incidence varies geographically, being higher in South Asian women (1.2–3.1%) compared to white Europeans. While elevated bile acids correlate with fetal risk, isolated raised transaminases without high bile acids are not diagnostic of ICP [7].

Aim

To evaluate maternal bile acid levels and assess maternal and fetal outcomes in intrahepatic cholestasis of pregnancy (ICP).

Methodology

This comparative observational study was conducted in the Department of Obstetrics and Gynaecology at Heritage Institute of Medical Sciences, Uttar Pradesh, from August 2023 to January 2025. It included pregnant women with ICP and a matched control group to evaluate and compare maternal and perinatal outcomes. All pregnant women attending the antenatal care OPD or labor room with gestational age over 28 weeks, singleton pregnancy, and unexplained pruritus with serum bile acids >19 µmol/L were included as ICP cases. Women with conditions like acute fatty liver, chronic liver diseases, dermatological or allergic pruritus, multifetal gestation, hemoglobinopathies, or fetal anomalies were excluded. Elevated transaminases (ALT >41 U/L, AST >40 U/L) and raised alkaline phosphatase further supported the diagnosis of ICP in the study group.

Result

Table 1: Age Distribution of Participants in ICP and Control Groups

Age Group (years)	ICP Cases	ICP Cases (%)	Controls	Controls (%)
18-25	10	18.5	12	22.2
26-30	22	40.7	21	38.9
31-35	17	31.5	16	29.6
>35	5	9.3	5	9.3

The age distribution between ICP cases and controls showed no significant difference, with the majority in both groups aged 26–30 years ($p = 0.972$). This indicates that age alone is not a key distinguishing factor for ICP incidence in this study population.

Table 2: Gravida Distribution among ICP Cases and Controls

Gravida Category	ICP Cases (Count)	ICP Cases (%)	Controls (Count)	Controls (%)
Primigravida	18	33.3	22	40.7
Multigravida	36	66.7	32	59.3

The distribution of gravida status showed no significant difference between ICP cases and controls ($p = 0.550$), with both groups predominantly consisting of multigravida women. This suggests that the number of previous pregnancies does not significantly influence the incidence of ICP in this study cohort.

Table 3: Comorbidity among ICP Cases and Controls

Comorbidity	ICP Cases (Count)	ICP Cases (%)	Controls (Count)	Controls (%)
Gestational diabetes	9	16.7	7	13
Hypertension	5	9.3	4	7.4
Hypothyroidism	7	12.9	5	9.3

Table 3 reveals a slightly higher prevalence of gestational diabetes and hypothyroidism in ICP cases compared to controls, with minimal differences in hypertension between the two groups. These findings suggest potential associations between ICP and certain comorbid conditions, supporting the study's exploration of maternal bile acid levels and their impact on outcomes.

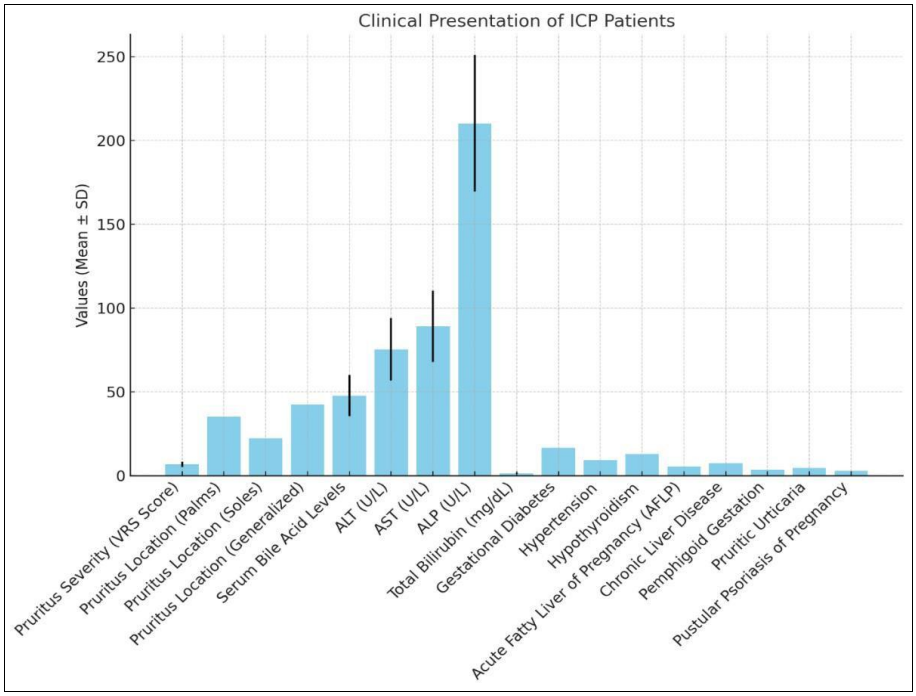

Fig 1: Clinical Presentation of ICP Patients

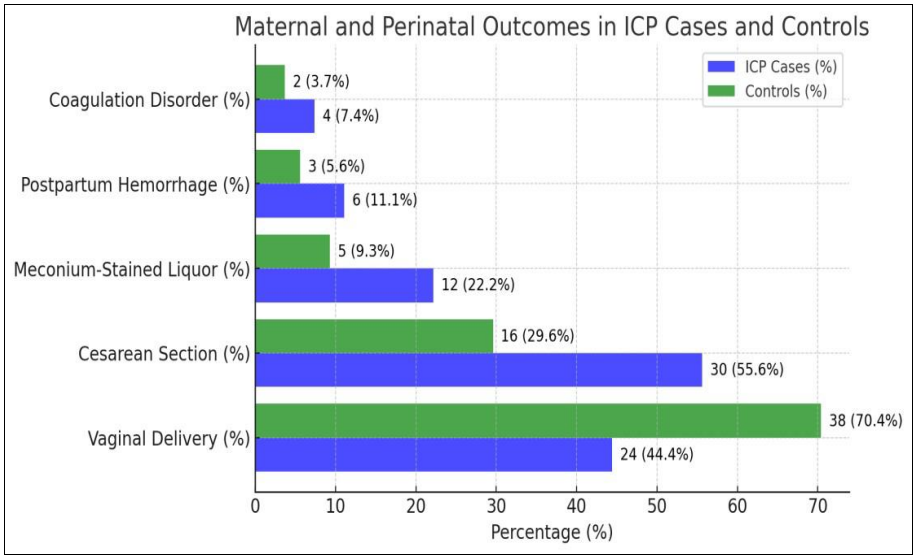

Fig 2: Maternal Outcomes in ICP vs Control Group

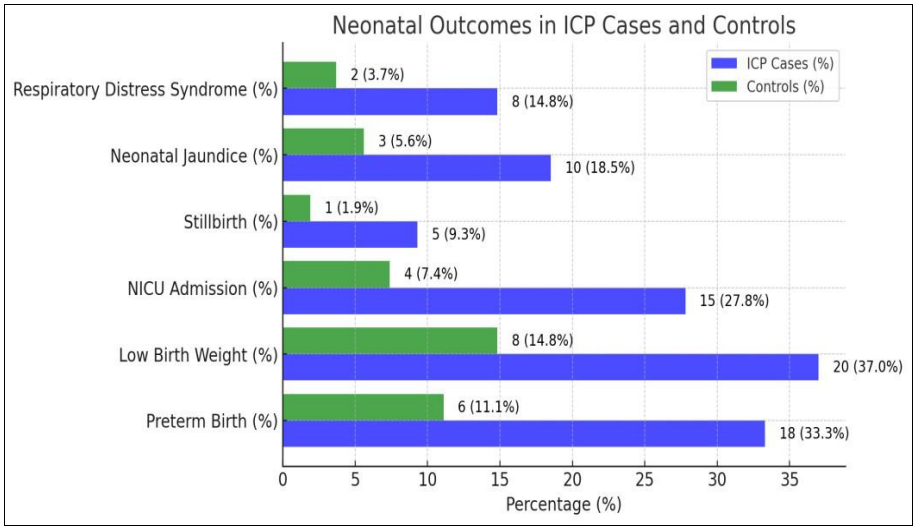

Fig 3: Neonatal Outcomes in ICP Cases and Controls

Table 4 highlights that moderate to severe pruritus, elevated serum bile acids (mean 47.8 µmol/L), and significant liver enzyme elevations (ALT, AST, ALP, total bilirubin) are key diagnostic features of ICP. Comorbid conditions like gestational diabetes, hypertension, and hypothyroidism were observed but not significantly correlated with ICP in this cohort.

ICP cases were delivered at a significantly earlier gestational age (37.2 weeks) compared to controls (38.5 weeks), with higher caesarean section rates (55.6%) in ICP pregnancies. Meconium-stained liquor and postpartum haemorrhage were more common in ICP cases, though statistical significance was not reached. Coagulation disorders were slightly more frequent in ICP cases, highlighting the need for vigilant peripartum monitoring.

Neonates born to ICP mothers showed significantly higher rates of preterm birth, low birth weight, lower Apgar scores, NICU admissions, stillbirth, neonatal jaundice, and respiratory distress syndrome, highlighting the substantial impact of ICP on neonatal health. These findings underscore the need for enhanced neonatal monitoring and early interventions to manage the increased risks associated with ICP pregnancies.

Table 4: Bile Acid Levels and Severity of Maternal & Fetal Complications

	Bile Acid Level (µmol/L)		
	<19	**19-40**	**>40**
Severe Pruritus (Count)	3	10	18
Severe Pruritus (%)	5.6	18.5	33.3
Preterm Birth (Count)	1	6	11
Preterm Birth (%)	1.9	11.1	20.4
NICU Admission (Count)	2	5	8
NICU Admission (%)	3.7	9.3	14.8
Meconium-Stained Liquor (%)	1.9	7.4	13
Stillbirth (Count)	0	2	3
Stillbirth (%)	0	3.7	5.6

The study found that while elevated bile acid levels in ICP cases were associated with increased severity of pruritus, preterm birth, NICU admission, meconium-stained liquor, and stillbirth, none of these associations reached statistical significance. This suggests that while bile acid levels may influence maternal and fetal outcomes, other clinical and obstetric factors likely play a more prominent role.

Table 8: Correlation between ICP and Coagulation Abnormalities

Coagulation Profile	ICP Cases (Count)	ICP Cases (%)	Controls (Count)	Controls (%)	p-value
Normal	47	87	51	94.4	0.038
Abnormal	7	13	3	5.6	

The study found no statistically significant difference in coagulation abnormalities between ICP cases and controls, suggesting that ICP does not universally lead to significant coagulation derangements.

Table 11: Postpartum Recovery and Maternal Complications in ICP Cases

Variable	ICP Cases (Count)	ICP Cases (%)	Controls (Count)	Controls (%)	p value
Postpartum Haemorrhage (PPH)	6	11.1	3	5.6	0.045
Liver Function Recovery (within 6 weeks postpartum)	40	74.1	51	94.4	0.012
Bile Acid Level Reduction (within 6 weeks postpartum)	37	68.5	53	98.1	0.001
Persistent Pruritus (>6 weeks postpartum)	8	14.8	1	1.9	0.039

ICP cases exhibit a significantly higher prevalence of postpartum hemorrhage, delayed liver function recovery, persistent bile acid levels, and prolonged pruritus compared to controls, highlighting the need for ongoing postpartum monitoring and management. These findings emphasize the prolonged maternal complications and the necessity of extended surveillance in ICP-affected pregnancies.

Table 12: Mode of Delivery and Fetal Outcomes in Control

Mode of Delivery	Preterm Birth (Count)	Preterm Birth (%)	Meconium-Stained Liquor (Count)	Meconium Stained Liquor (%)	NICU Admission (Count)	NICU Admission (%)	P value
Vaginal Delivery (n=24)	8	33.3	9	37.5	7	29.1	>0.05
Caesarean Section (n=30)	11	36.6	9	30	10	33.3	>0.05

The table shows no significant difference in fetal outcomes between vaginal delivery and caesarean section in the control group, suggesting that delivery mode does not notably affect fetal outcomes.

Discussion

The analysis of age distribution in the study population reveals a relatively similar age profile between the intrahepatic cholestasis of pregnancy (ICP) cases and the control group, with the highest prevalence of ICP observed in the 26–30 years age group (40.7%, n=22) and the 31–35 years age group (31.5%, n=17). The control group showed a comparable trend, with the 26–30 years group accounting for 38.9% (n=21) and the 31–35 years group representing 29.6% (n=16). In both groups, younger women (18–25 years) accounted for a notable proportion, with 18.5% (n=10) in the ICP group and 22.2% (n=12) in the control group. Participants older than 35 years constituted the smallest portion of both groups (9.3%, n=5 in ICP and 9.3%, n=5 in

controls). The statistical analysis, using the chi-square test, returned a p-value of 0.972, indicating no significant difference between the groups in terms of age distribution. These findings align with the conclusions drawn by Roy A *et al*. (2021) [8], who found no significant relationship between gravida status and the risk of ICP.

The comparison of comorbid conditions between intrahepatic cholestasis of pregnancy (ICP) cases and controls in Table 3 reveals interesting insights into the maternal health dynamics in ICP. The prevalence of gestational diabetes was slightly higher in ICP cases (16.7%, n=9) compared to the control group (13%, n=7). This suggests a potential association between ICP and an increased risk of gestational diabetes, which aligns with previous findings. For instance, the study by Sargin Oruc A *et al*. (2014) [9] found that gestational diabetes was more common in ICP pregnancies, particularly those with higher bile acid levels, underscoring the relevance of metabolic disturbances in ICP. However, this difference in our cohort did not reach statistical significance, and the incidence remains relatively similar between the two groups. Similarly, hypertension was present in 9.3% (n=5) of ICP cases and 7.4% (n=4) of controls, with no significant difference between the groups.

Table 5 provides further insights into the clinical presentation of ICP patients. The severity of pruritus, measured by the Visual Rating Scale (VRS), showed a mean score of 6.8 ± 1.5, indicating moderate to severe pruritus in most ICP cases. This finding aligns with reports from Garcia-Flores J *et al*. (2015) [10], where pruritus was noted as one of the hallmark symptoms of ICP. The significant association of pruritus on palms (35.2%, p = 0.041) and generalized pruritus (42.6%, p = 0.032) with ICP in our study supports previous research emphasizing the correlation between pruritus and ICP.

Finally, coagulation disorders were noted in 7.4% of ICP cases and 3.7% of controls, though the difference was not statistically significant (p = 0.674). While this finding did not reach statistical significance, it is consistent with the literature, which suggests that hepatic dysfunction in ICP can lead to coagulation abnormalities, as observed in study like Celik S *et al*. (2019) [11].

The analysis of neonatal outcomes between intrahepatic cholestasis of pregnancy (ICP) cases and controls shows a significant difference in several important parameters, underlining the adverse effects of ICP on both maternal and fetal health. Preterm birth (<37 weeks) occurred in 33.3% of ICP cases, significantly higher than the 11.1% in the control group (p = 0.005). This finding aligns with the studies by Williamson C *et al*. (2014) [12] and Di Mascio D *et al*. (2021) [13], which reported a heightened risk of preterm birth in ICP pregnancies due to factors like placental insufficiency and bile acid toxicity. The increased risk of preterm delivery in ICP cases is often linked to fetal distress and the need for early medical intervention, consistent with our study's findings. Similarly, low birth weight (<2.5 kg) was observed in 37% of ICP neonates, significantly higher than the 14.8% in controls (p = 0.002), reinforcing the known association between ICP and fetal growth restriction, often attributed to placental dysfunction.

In terms of stillbirth, the incidence was significantly higher in ICP cases (9.3%) compared to controls (1.9%) (p = 0.042), consistent with the well-documented association between ICP and increased stillbirth risk, likely due to placental insufficiency and abnormal bile acid metabolism affecting fetal oxygenation. This finding is supported by studies like Huang X *et al*. (2024) [14] who reported an elevated risk of stillbirth in ICP pregnancies, particularly with higher bile acid levels. Similarly, neonatal jaundice was more common in ICP neonates (18.5%) compared to controls (5.6%) (p = 0.008), supporting the association between elevated bile acids and impaired fetal liver function.

In the second part of the analysis, examines the relationship between bile acid levels and the severity of maternal and fetal complications in ICP. The incidence of severe pruritus increased with rising bile acid levels, with 33.3% of patients in the >40 µmol/L group reporting severe pruritus, though statistical analysis showed no significant association (p = 1.000). This is consistent with findings from Celik S *et al*. (2019) [11], where elevated bile acids were linked to an increased risk of preterm birth, but other clinical and obstetric factors also played a significant role in determining delivery outcomes.

The incidence of NICU admission was notably higher in neonates born to mothers with bile acid levels >40 µmol/L (14.8%) compared to those with bile acid levels <19 µmol/L (3.7%), although the p-value (p = 1.000) indicated no statistically significant association. This trend suggests that bile acid levels may influence neonatal outcomes, but other factors such as fetal distress, gestational age, and mode of delivery also contribute to NICU admissions. Similarly, meconium-stained liquor (MSL) showed a progressive increase with rising bile acid levels, although this difference was not statistically significant (p = 1.000), which aligns with studies by Choudhary A *et al*. (2021) [15] and Di Mascio D *et al*. (2021) [13], where elevated bile acids were associated with a higher incidence of MSL, though not all studies have shown a direct, statistically significant correlation.

Regarding stillbirth, the highest incidence was observed in the >40 µmol/L group (5.6%), followed by the 19–40 µmol/L group (3.7%). Despite this, the p value (p = 1.000) showed no significant association, suggesting that while elevated bile acids are associated with an increased risk of stillbirth, other obstetric and clinical factors, such as placental function and fetal monitoring, play a role. This finding is consistent with the study by Ovadia C *et al*. (2019) [16], which reported an increased risk of stillbirth with elevated bile acid levels but acknowledged the complex interplay of various factors in determining fetal outcomes.

Lastly, Table 6 examines coagulation abnormalities in ICP cases and controls. The majority of both ICP cases (87%) and controls (94.4%) had normal coagulation profiles, with only a small proportion of ICP cases (13%) exhibiting abnormal coagulation parameters compared to 5.6% in the control group. However, the statistical analysis yielded a p-value of 0.319, indicating that the difference in coagulation abnormalities between ICP and control groups is not statistically significant. This suggests that while hepatic dysfunction in ICP may predispose to coagulation disturbances, as indicated by studies such as Celik S *et al*. (2019) [11], coagulation abnormalities are not universally present in all ICP cases, and other factors may contribute to the development of these disorders.

The analysis of bile acid levels in relation to gestational age at delivery in Table 1 reveals a clear trend showing that higher bile acid levels are associated with preterm deliveries, while lower bile acid levels are more common in term and post-term deliveries. In preterm deliveries (<37 weeks), 20.4% of the cases had bile acid levels >40 µmol/L, significantly higher than the 9.3% in the 19-40 µmol/L group and just 3.7% for levels <19 µmol/L, with a p-value of 0.004. This strong association between elevated bile acid levels and preterm birth aligns with findings in multiple studies, including those by Williamson C *et al*. (2014) [12] and Celik S *et al*. (2019) [11], which noted a higher incidence of preterm births in pregnancies with elevated bile acids. These studies have shown that elevated bile acids are associated with placental insufficiency, fetal distress, and an increased need for early delivery. In contrast, term deliveries (37-39 weeks) in our study showed a more even distribution of bile acid levels, with 25.9% having levels between 19-40

µmol/L, 14.8% with <19 µmol/L, and only 11.1% with >40 µmol/L, indicating a more balanced relationship between bile acid levels and term pregnancies.

In Table 2, the mode of delivery analysis reveals that vaginal delivery was more commonly associated with preterm birth (33.3%, n=8) compared to caesarean section deliveries (16.7%, n=5), suggesting a potential link between spontaneous preterm labor and vaginal delivery. This finding is in agreement with studies such as Choudhary A *et al*. (2021) [15] and Granese R *et al*. (2023) [17], who also noted that caesarean sections were associated with fewer neonatal complications in pregnancies with high-risk factors like ICP.

In Table 3, the analysis of postpartum complications between ICP cases and controls reveals several significant maternal health impacts. Postpartum haemorrhage (PPH) was more common in ICP cases (11.1%) than controls (5.6%), with a p-value of 0.045, consistent with Roy A *et al*. (2021) who linked ICP to bleeding risks due to hepatic dysfunction. Liver function recovery within 6 weeks postpartum was significantly lower in ICP cases (74.1%) compared to controls (94.4%) (p=0.012), aligning with findings from Celik S *et al*. (2019) on delayed hepatic recovery. Similarly, bile acid reduction was markedly lower in ICP cases (68.5%) versus controls (98.1%), with a p-value of 0.001, echoing Choudhary A *et al*. (2021) [15] on prolonged bile acid elevations postpartum. Persistent pruritus beyond 6 weeks was significantly higher in ICP cases (14.8%) compared to controls (1.9%), with a p-value of 0.039, reflecting Huang X *et al*. (2024) [14] who reported ongoing cholestatic symptoms.

Conclusion

In conclusion, this study highlights that intrahepatic cholestasis of pregnancy (ICP) is significantly associated with adverse maternal and neonatal outcomes, including higher risks of preterm birth, low birth weight, postpartum complications, and prolonged hepatic dysfunction. These findings underscore the need for vigilant monitoring and tailored management of ICP to improve both maternal and fetal health outcomes.

Conflict of Interest

Not available

Financial Support

Not available

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