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Original Research Article

Correlation of Serum Bile Acids and Transaminases with Fetomaternal Outcomes in Intrahepatic Cholestasis of Pregnancy: A Prospective Study

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Abstract

Background: Intrahepatic cholestasis of pregnancy (ICP) is a common pregnancy-specific liver disorder associated with adverse fetal outcomes. Serum bile acids are considered the most sensitive marker, while the role of transaminases in predicting outcomes remains unclear.

Methods: This prospective observational study included 50 pregnant women diagnosed with ICP at a tertiary care center over 18 months. Diagnosis was based on pruritus with elevated serum bile acids (>10 µmol/L) and/or transaminases. Patients were categorized by bile acid severity (mild >19 µmol/L, moderate >20-40 µmol/L, severe > 40 µmol/L). Maternal and fetal outcomes were recorded and correlated with biochemical parameters using appropriate statistical tests.

Results: Most patients had mild ICP (64%), though transaminase elevation was common (AST 54%, ALT 68%). Preterm birth occurred in 40%, predominantly iatrogenic (26%). NICU admission (22%), meconium-stained liquor (18%), and RDS (12%) were frequent. Severe bile acid levels (≥40 µmol/L) were significantly associated with RDS (60%, p=0.001) and higher rates of iatrogenic preterm birth and NICU admission. Transaminases showed weaker and inconsistent associations with outcomes.

Conclusion: Serum bile acids are superior to transaminases in predicting adverse fetal outcomes in ICP. Their estimation is crucial for risk stratification and guiding timely obstetric intervention to improve perinatal outcomes.

Keywords: Intrahepatic Cholestasis Of Pregnancy, Bile Acids, Transaminases, Fetal Outcomes, Preterm Birth.
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Introduction

Intrahepatic cholestasis of pregnancy (ICP) is the most common pregnancy-specific liver disorder, characterized by generalized pruritus without rash—predominantly affecting the palms and soles and worsening at night—along with elevated serum bile acids (>10 µmol/L) and/or abnormal transaminases [1,2]. It typically presents in the second or third trimester and resolves spontaneously after delivery, with normalization of biochemical parameters [3,4]. ICP has been described by various terms including obstetric cholestasis, hepatosisgestationalis, and recurrent jaundice of pregnancy [2].

The prevalence of ICP varies widely across populations, reflecting genetic, hormonal, and environmental influences. It ranges from 0.7% in England to 2.4% in Chile, with even higher rates (up to 5%) among specific ethnic groups such as Araucanian women [5,6]. Seasonal variation, with higher incidence in winter months, and increased risk in twin pregnancies, advanced maternal age (>35 years), assisted reproductive techniques, and prior history of cholestasis or biliary disease further support its multifactorial etiology [7]. The underlying mechanism involves impaired hepatocellular bile excretion, leading to accumulation of bile acids in maternal circulation and deposition in the skin, causing pruritus [2].

While maternal prognosis is generally benign, ICP is associated with significant fetal risks. Adverse outcomes include preterm delivery (19–60%), fetal distress (22–33%), meconium-stained liquor, respiratory distress syndrome, and intrauterine fetal demise (1–2%) [8]. Elevated bile acids are implicated in these complications through mechanisms such as increased myometrial oxytocin

receptor sensitivity leading to preterm labor, vasoconstriction of placental chorionic veins causing fetal hypoxia, and direct cardiotoxic effects resulting in fetal arrhythmias [9]. Notably, serum bile acid levels >40 μmol/L have been consistently associated with higher rates of adverse fetal outcomes [8].

Although serum bile acids are considered the most sensitive marker for diagnosis and prognostication, liver transaminases (AST and ALT) are frequently elevated and reflect hepatocellular injury. However, their correlation with disease severity and fetal outcomes remains inconsistent across studies [10]. In many clinical settings, especially resource-limited ones, transaminases are more readily available than bile acid estimation, underscoring the need to evaluate their predictive utility. Given the variability in clinical presentation and outcomes, correlating serum bile acid and transaminase levels with maternal and fetal outcomes may help identify reliable prognostic markers. This study aimed to assess these correlations and determine their relative utility in predicting adverse outcomes in ICP, thereby aiding in timely diagnosis and optimal management strategies.

Materials and Methods

Study Design and Setting: This hospital-based prospective observational study was conducted in the Department of Obstetrics and Gynaecology at Artemis Health Institute, Gurgaon, over a period of 18 months (November 2017 to May 2019), after approval from the Institutional Ethics Committee.

Study Population and Sample Size: All antenatal women presenting with pruritus and biochemical evidence suggestive of intrahepatic cholestasis of pregnancy (ICP) were screened. Diagnosis was based on pruritus without rash, along with serum bile acid levels >10 μmol/L and/or serum transaminases (AST/ALT) ≥2 times the pregnancy-specific upper limit, after exclusion of other causes of liver dysfunction. Sample size was calculated using the formula $n = Z^2p(1-p)/m^2$, assuming 5% prevalence, 95% confidence level, and 6% margin of error, yielding a minimum sample size of approximately 50 participants.

Inclusion Criteria were Singleton pregnancy at any gestational age; Pruritus without rash; and Serum bile acid >10 μmol/L or elevated transaminases. Exclusion Criteria included Multiple pregnancy; Pre-existing or concurrent liver disease (e.g., hepatitis, gallbladder disease, acute fatty liver); Dermatological causes of pruritus; Diabetes mellitus, pre-eclampsia; Congenital fetal anomalies; and Unwillingness to participate

Data Collection and Clinical Evaluation: After obtaining written informed consent, detailed demographic and clinical data were recorded in a predesigned proforma. All patients underwent thorough clinical and systemic examination. Ultrasound of the upper abdomen was performed to exclude hepatobiliary pathology. Fasting venous blood samples were collected and analyzed for liver function tests using dry chemistry (Vitros-350) and serum bile acids using enzyme cycling method. Serial monitoring of bile acids and transaminases was performed at presentation, periodically during pregnancy, and prior to delivery. The highest recorded values were used for analysis. Patients were categorized based on bile acid levels into mild (10–19 μmol/L), moderate (20–39 μmol/L), and severe (≥40 μmol/L).

Management and Follow-up: All patients were managed as per institutional protocol, including administration of ursodeoxycholic acid (10–15 mg/kg/day, titrated up to 30 mg/kg/day). Fetal surveillance included growth scans, Doppler studies, and non-stress tests/biophysical profile as indicated. Delivery was planned at 37 weeks or earlier depending on clinical severity. Patients were followed through antepartum, intrapartum, and postpartum periods, with repeat liver function tests at 2 weeks postpartum.

Outcome Measures: Maternal outcomes included disease severity and mode of delivery. Fetal outcomes assessed were preterm birth (<37 weeks), meconium-stained liquor, fetal distress, low Apgar score (<7 at 1 minute), birth weight, respiratory distress syndrome, NICU admission, and intrauterine fetal demise.

Statistical Analysis: Data were analyzed using Microsoft Excel and SPSS 20.0. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequencies and percentages. Normality was assessed using the Kolmogorov–Smirnov test. Parametric data were analyzed using Student's t-test/Z-test, and non-parametric data using Kruskal–Wallis and Mann–Whitney U tests. Categorical variables were compared using Chi-square or Fisher's exact test. Correlation between serum bile acids, transaminases, and outcomes was assessed using correlation coefficients. A p-value <0.05 was considered statistically significant.

Ethical Considerations: Ethical approval was obtained prior to study initiation. Written informed consent was taken from all participants. Confidentiality and privacy were maintained, and participants were free to withdraw at any stage without affecting their medical care.

Results

The majority of participants were aged 31–35 years (46%), followed by 26–30 years (34%), with a mean age clustering in the early thirties.

Primigravida constituted 62% of the study population, while 38% were multigravida. Among multiparous women (n=19), 36% had a history of ICP in previous pregnancies. Prior use of oral contraceptive pills was reported in only 4% of patients, whereas 20% received progesterone during pregnancy. Overall, the study population predominantly comprised primigravid women in the third decade with a relatively low prevalence of prior hormonal exposure (Table 1).

Table 1: Baseline Maternal Characteristics of the Study Population (n=50)

Variable	Category	Frequency (%)
Age (years)	≤25	3 (6)
	26–30	17 (34)
	31–35	23 (46)
	>35	7 (14)
Parity	Primigravida	31 (62)
	Multigravida	19 (38)
History of ICP (n=19 multipara)	Yes	7 (36)
	No	12 (64)
OCP use	Yes	2 (4)
	No	48 (96)
Progesterone use	Yes	10 (20)
	No	40 (80)

ICP – Intrahepatic cholestasis of pregnancy; OCP – Oral contraceptive pills

Most patients had mild ICP with serum bile acid levels of 10–19 µmol/L (64%), followed by moderate (26%) and severe disease (10%). Elevated AST levels (>60 IU/L) were observed in 54% of cases, while ALT elevation (>68 IU/L) was more frequent, seen in 68% of patients. These findings indicate that although bile acid elevation was predominantly mild, transaminase abnormalities were common, particularly ALT (Table 2).

Table 2: Biochemical Profile and Severity Distribution of ICP

Parameter	Category	Frequency (%)
Serum bile acid levels (µmol/L)	Mild (10–19)	32 (64)
	Moderate (20–39)	13 (26)
	Severe (≥40)	5 (10)
AST elevation (>60 IU/L)	Yes	27 (54)
	No	23 (46)
ALT elevation (>68 IU/L)	Yes	34 (68)
	No	16 (32)

AST – Aspartate aminotransferase; ALT – Alanine aminotransferase

The majority of patients were diagnosed between 28–32 weeks of gestation (38%), followed by 32–37 weeks (34%). Only 14% were diagnosed beyond 37 weeks. Regarding delivery, 60% of patients delivered at term (≥37 weeks), while 34% delivered between 34–36.6 weeks and 6% before 34 weeks. These findings suggest that ICP is commonly diagnosed in the late second to early third trimester, with a majority achieving term delivery (Table 3).

Table 3: Gestational Age at Diagnosis and Delivery

Parameter	Category	Frequency (%)
Gestational age at diagnosis (weeks)	<24	2 (4)
	24–28	5 (10)
	28–32	19 (38)
	32–37	17 (34)
	>37	7 (14)
Gestational age at delivery (weeks)	30–33.6	3 (6)
	34–36.6	17 (34)
	≥37	30 (60)

GA – Gestational age

Preterm birth occurred in 40% of cases, with a higher proportion being iatrogenic (26%) compared to spontaneous (14%). The predominant mode of delivery was cesarean section, with emergency LSCS accounting for 52% and elective LSCS for 12%. Instrumental deliveries constituted 16%, while only 20% had normal vaginal delivery. Overall, there was a high rate (80%) of operative deliveries in the study population (Table 4).

Table 4: Preterm Birth and Mode of Delivery

Parameter	Category	Frequency (%)
Preterm birth (n=20)	Spontaneous	7 (14)
	Iatrogenic	13 (26)
Mode of delivery	Elective LSCS	6 (12)
	Emergency LSCS	26 (52)
	Instrumental	8 (16)
	Vaginal delivery	10 (20)

LSCS – Lower segment cesarean section

The mean birth weight distribution showed that 40% of neonates weighed between 2.6–3.0 kg, while 28% had low birth weight (<2.5 kg). Preterm birth was the most common neonatal outcome (40%), followed by NICU admission (22%), meconium-stained liquor (18%), hyperbilirubinemia (16%), and RDS (12%). Intrauterine death was observed in 4% of cases. These findings highlight a substantial burden of adverse neonatal outcomes in ICP pregnancies (Table 5).

Table 5: Neonatal Outcomes and Birth Weight Distribution

Parameter	Category	Frequency (%)
Birth weight (kg)	<2.5	14 (28)
	2.6–3.0	20 (40)
	>3.0	16 (32)
Neonatal outcomes	Preterm birth	20 (40)
	Meconium-stained liquor	9 (18)
	Respiratory distress syndrome	6 (12)
	Hyperbilirubinemia	8 (16)
	NICU admission	11 (22)
	Intrauterine death	2 (4)

RDS – Respiratory distress syndrome; NICU – Neonatal intensive care unit; IUD – Intrauterine death

Maternal age, parity, history of ICP, and gestational age at diagnosis were comparable across mild, moderate, and severe bile acid groups (p>0.05). Although gestational age at delivery and birth weight were lower in the severe group, the differences were not statistically significant. Among fetal outcomes, iatrogenic preterm birth increased with severity (15.6% in mild vs 60% in severe; p=0.05). Notably, RDS showed a significant association with bile acid severity, being highest in the severe group (60%; p=0.001). Other outcomes, including meconium-stained liquor, NICU admission, and LSCS rates, were higher in severe ICP but did not reach statistical significance. These findings suggest that increasing bile acid levels are associated with worsening fetal outcomes, particularly respiratory morbidity (Table 6).

Table 6: Association of Bile Acid Severity with Maternal and Fetomaternal Outcomes

Parameter	Mild (n=32)	Moderate (n=13)	Severe (n=5)	p-value
	Frequency (%)/mean ± SD			
Maternal age (years)	31.62±3.44	31.77±4.40	31.2±5.12	0.962
Parity				
Primipara	17 (53.1)	10 (76.9)	3 (60)	0.389
Multipara	14 (43.8)	3 (23.1)	2 (40)	
History of ICP	4 (12.5)	2 (15.4)	1 (20)	0.907
Gestational age at diagnosis (weeks)	32.08±4.06	29.35±5.83	30.06±5.30	0.195
Gestational age at delivery (weeks)	36.79±1.74	36.58±2.06	35.64±0.49	0.402
Birth weight (kg)	2.84±0.39	2.69±0.46	2.59±0.25	0.278
Spontaneous preterm	4 (12.5)	1 (7.7)	2 (40)	0.190
Iatrogenic preterm	5 (15.6)	5 (38.5)	3 (60)	0.050
Meconium-stained liquor	5 (15.6)	2 (15.4)	2 (40)	0.418
RDS	3 (9.4)	0 (0)	3 (60)	0.001
Hyperbilirubinemia	6 (18.8)	2 (15.4)	0 (0)	0.550
IUD	0 (0)	2 (15.4)	0 (0)	0.055
NICU admission	6 (18.8)	2 (15.4)	3 (60)	0.100
LSCS	22 (68.8)	7 (53.8)	3 (60)	0.628

RDS – Respiratory distress syndrome; IUD – Intrauterine death; LSCS – Lower segment cesarean section

Adverse outcomes were observed across all biochemical markers. Spontaneous preterm birth occurred in 18.5% (AST), 17.6% (ALT), and 14% (bile acids), whereas iatrogenic preterm birth was highest with elevated bile acids (26%). Meconium-stained liquor and RDS were comparably distributed across AST and ALT groups but were relatively lower in bile acid group. NICU admission was slightly higher in the ALT group (26.4%) compared to AST (25.9%) and bile acids (22%). Operative delivery rates were similar across all groups (AST 62.9%, ALT 58.8%, bile acids 60%). Overall, both transaminases and bile acids showed comparable trends in predicting adverse outcomes, with bile acids showing relatively stronger association with iatrogenic preterm birth (Table 7).

Table 7: Comparison of Fetomaternal Outcomes by Serum Transaminases and Bile Acids

Outcome	AST >60 (n=27)	ALT >68 (n=34)	Bile Acid >10 (n=50)
	Frequency (%)/mean ± SD		
Spontaneous preterm	5 (18.5)	6 (17.6)	7 (14)
Iatrogenic preterm	4 (14.8)	4 (11.7)	13 (26)
Meconium-stained liquor	6 (22.2)	6 (17.6)	9 (18)
Hyperbilirubinemia	4 (14.8)	5 (14.7)	8 (16)
RDS	5 (18.5)	6 (17.6)	6 (12)
IUD	2 (7.4)	2 (5.8)	2 (4)
NICU admission	7 (25.9)	9 (26.4)	11 (22)
Mode of delivery			
Operative delivery	17 (62.9)	20 (58.8)	30 (60)
Normal delivery	10 (37.0)	14 (41.2)	20 (40)

AST – Aspartate aminotransferase; ALT – Alanine aminotransferase; RDS – Respiratory distress syndrome; IUD – Intrauterine death; NICU – Neonatal intensive care unit.

Discussion

This prospective observational study evaluated the relationship between serum bile acids, serum transaminases, and fetomaternal outcomes in intrahepatic cholestasis of pregnancy (ICP). The findings demonstrate that while most patients had mild biochemical disease, there was a substantial burden of adverse fetal outcomes, and increasing bile acid levels—more than transaminases—were associated with worsening neonatal morbidity.

The demographic profile in the present study showed a predominance of women in the 26–35 year age group with a mean age in the early thirties, consistent with Indian studies by Sumangali et al., and Kohli et al., which reported peak incidence in the third decade [11,12]. A higher proportion of primigravida (62%) was observed, similar to findings by Juusela et al., although study by WikströmShemer et al., reports higher recurrence and thus greater multiparity association [13,14]. Notably, 36% of multiparous women had a prior history of ICP, supporting the well-established recurrence risk of 40–60% reported globally, suggesting a strong genetic and hormonal predisposition [14]. Biochemically, the majority of patients had mild bile acid elevation (64%), yet transaminase elevation—particularly ALT (68%)—was more frequent. This aligns with studies by Fan et al., and Kushner et al., which suggest that transaminases may be elevated even in less severe disease, but lack specificity in predicting outcomes [15,16]. In contrast, bile acids remain the most sensitive and clinically relevant biomarker. The present findings reinforce that although transaminases reflect hepatocellular injury, they do not reliably stratify fetal risk [16].

ICP was most commonly diagnosed between 28–32 weeks of gestation, consistent with global observations that the disease typically manifests in the late second or third trimester. Despite this, 60% of patients delivered at term, reflecting effective antenatal surveillance and timely intervention. However, the preterm birth rate was high (40%), with a predominance of iatrogenic preterm deliveries (26%), similar to reports by Ekiz et al., and Hagenbeck et al., where early delivery is often planned to mitigate the risk of sudden intrauterine fetal demise [17,18].

A key finding of this study is the high operative delivery rate (80%), predominantly emergency cesarean sections (52%). This is comparable to Indian studies by Mitra et al., and Rizvi et al., which attribute higher cesarean rates to fetal distress and clinician preference for early intervention in ICP [19,20]. The increased incidence of meconium-stained liquor (18%) and fetal distress further supports this trend, reflecting the adverse intrauterine environment associated with elevated bile acids [20].

Neonatal outcomes in the present study indicate significant morbidity, with preterm birth (40%), NICU admission (22%), and RDS (12%) being the most common complications. These findings are in agreement with cohort studies by Gupta et al., and Misra et al., which demonstrated increased risks of preterm birth, NICU admission, and respiratory complications in ICP [21,22]. The incidence of

intrauterine death (4%) in this study is slightly higher than the 1–2% reported by Palmer et al., possibly reflecting the relatively small sample size or referral bias in a tertiary care setting [23].

Importantly, stratification by bile acid severity revealed a clear trend toward worsening outcomes with increasing levels. Severe ICP (≥40 μmol/L) was associated with higher rates of iatrogenic preterm birth (60%), NICU admission (60%), and notably RDS (60%), with the latter showing a statistically significant association (p=0.001). This finding is consistent with the meta-analysis byCapatina et al., which identified bile acid levels >40 μmol/L as a critical threshold for adverse fetal outcomes, and levels >100 μmol/L as markedly increasing stillbirth risk [24]. The pathophysiological basis includes bile acid–induced fetal cardiotoxicity, placental vasoconstriction, and surfactant dysfunction, explaining the increased incidence of RDS and fetal compromise [25]. In contrast, serum transaminases (AST and ALT) showed comparable but less distinct associations with adverse outcomes. Although elevated transaminases were associated with increased rates of preterm birth, NICU admission, and operative delivery, the trends were less pronounced compared to bile acids. This supports existing studies by AyasOzkan et al., and Saadi et al. suggesting that transaminases are poor predictors of fetal risk and should not be used in isolation for clinical decision-making [26,27]. Studies by Jhirwal et al., and Ahuja et al., similarly concluded that bile acids correlate more strongly with fetal outcomes than liver enzyme levels [28,29].

Limitations

This study was conducted at a single tertiary care center with a relatively small sample size, which may limit generalizability. Absence of a control group restricts comparative inference. Serial bile acid measurements were performed, but peak levels were used for analysis, potentially overlooking dynamic trends. Additionally, confounding factors influencing fetal outcomes could not be completely excluded despite strict criteria. Long-term neonatal follow-up was not assessed.

Conclusion

Intrahepatic cholestasis of pregnancy is associated with significant fetal morbidity despite relatively benign maternal outcomes. This study demonstrates that elevated serum bile acids, particularly ≥40 μmol/L, correlate more strongly with adverse fetal outcomes such as respiratory distress syndrome, NICU admission, and iatrogenic preterm birth compared to serum transaminases. While transaminases are frequently elevated, they show limited prognostic value. These findings emphasize the importance of serum bile acid estimation as a key tool for risk stratification. Early identification, close fetal surveillance, and timely intervention, including planned delivery, are essential to optimize perinatal outcomes in pregnancies complicated by ICP.

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