EVALUATION OF PERINATAL OUTCOMES IN OBSTETRIC CHOLESTASIS AND THEIR ASSOCIATION WITH MATERNAL OBSTETRIC AND BIOCHEMICAL PARAMETERS

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ABSTRACT

Objective: To assess perinatal outcomes in obstetric cholestasis and associate them with maternal obstetric and biochemical parameters.

Study Design: A cross-sectional study

Place and Duration: This study was carried out at Karachi Metropolitan University Abbasi Shaheed Hospital Karachi Pakistan between April 2025 to April 2026.

Methods: 124 pregnant women diagnosed with obstetric cholestasis were included. Obstetric and biochemical parameters of the mother were documented, such as total bile acids, ALT, AST, GGT, and bilirubin. Perinatal outcomes measured were preterm labor, meconium-stained liquor, fetal distress, Apgar scores, admission to NICU, IUGR, respiratory distress syndrome, and stillbirth. Data were statistically analyzed using SPSS version 26, and associations were evaluated using appropriate tests ($p<0.05$). To assess ALT as a predictor of adverse perinatal outcomes, ROC curve analysis was performed.

Results: Preterm birth rates were 40 cases (32.3%), meconium-stained liquor was seen in 36 cases (29.0%), and fetal distress was noted in 38 cases (30.6%). NICU admission was required in 34 neonates (27.4%), and low Apgar scores at 1 and 5 minutes were observed in 30 (24.2%) and 18 (14.5%) cases, respectively. IUGR was detected in 28 pregnancies (22.6%), and stillbirth was seen in 6 cases (4.8%). In the adverse outcome group, total bile acids ($p < 0.05$), ALT ($p < 0.05$), AST ($p < 0.05$), and GGT ($p < 0.05$) were all significantly elevated. ROC analysis demonstrated good predictive value for adverse outcomes with an AUC of 0.81, sensitivity of 78.2% and specificity of 72.5% for ALT ≥ 55 U/L.

Conclusion: There is a significant association between obstetric cholestasis and adverse perinatal outcomes, and a close correlation between worsening biochemical parameters and fetal morbidity. ALT can be used as a supportive marker alongside bile acids to assist in risk stratification and improve antenatal management.

Keywords: Obstetric Cholestasis, Intrahepatic Cholestasis of Pregnancy, Perinatal Outcomes, Total Bile Acids.

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INTRODUCTION

Intrahepatic cholestasis of pregnancy (ICP), also known as obstetric cholestasis, is a hepatobiliary disorder that occurs during pregnancy and is characterized by the presence of intense itching, primarily on the palms and soles, and by elevated serum total bile acids (TBA) and transaminases [1]. It typically develops in the late second or third

trimester and quickly resolves post-delivery. Current evidence argues that ICP is not a benign pruritic condition, but a dose-dependent fetal risk disorder with a close relationship between biochemical severity (such as serum TBAs, and not only liver transaminases) and perinatal outcome [2]. A Bile acid > 40 µmol/L is considered clinically significant, and a strong association of Bile acid > 100 µmol/L with a stillbirth risk has been previously reported even when the obstetrician is actively monitoring the pregnancy [3].

The estimated global prevalence of ICP is approximately 2.9%, with geographic variability [4]. Differences exist due to ethnic factors, diagnostic criteria, and socioeconomic factors, with higher rates observed in developing areas [4]. The prevalence reported in Pakistan has ranged from 1.38% to 3.1% in hospital-based studies, higher than many Western figures [5, 6]. Factors associated with ICP include multiparity, multiple gestations, maternal age (<25 years or ≥35 years), pre-pregnancy underweight, inadequate gestational weight gain (GWG), lower educational attainment, IVF conceptions, and genetic variants in bile acid transporters like ABCB4 [4, 7]. Maternal complications include a higher incidence of preeclampsia, gestational diabetes, postpartum hemorrhage, and cesarean section, and perinatal complications include preterm delivery, low birth weight, respiratory distress syndrome, and rare stillbirth [8].

The underlying mechanisms of ICP are now known to be a multifactorial transportopathy, in which the bile salt export pumps of hepatocytes are compromised by estrogen and progesterone metabolites, and genetic polymorphisms increase susceptibility. In addition to hepatic retention, high bile acid levels have direct fetotoxic effects by causing placental vasoconstriction, oxidative stress, and alterations in myometrial contractile function [7, 9]. In addition, bile acids may induce oxytocin receptor activation, suggesting a mechanism for spontaneous preterm labor, independent of obstetric intervention [9].

There have also been major transformations in diagnostic methods in recent years. At present, serum total bile acid levels are regarded as the diagnostic and prognostic gold standard, although pruritus is the earliest clinical marker [10]. Management usually includes ursodeoxycholic acid (UDCA) for symptom relief and improvement of biochemical results, but there is some doubt about its direct fetal benefit. Fetal surveillance involves monitoring for distress, and delivery is often scheduled close to 37 weeks to balance risk, especially in high disease burden [8, 10].

Although there is a known relationship between ICP and adverse fetal outcomes, precise integration of patterns of perinatal outcomes to maternal biochemical and obstetric parameters has not been clinically used. Early biochemical severity assessment in combination with obstetric risk profiling is crucial for predicting potential fetal compromise, preventing adverse events like stillbirth and preterm delivery, and enabling early obstetric intervention [8, 9]. Therefore, the current research aims to assess the perinatal outcomes in obstetric cholestasis and their association with obstetric and maternal biochemical parameters.

METHODOLOGY

This cross-sectional study assessed perinatal outcomes among women with obstetric cholestasis and their association with maternal obstetric and biochemical parameters. The sample size was determined to be 124 using the WHO sample size determination formula, with an expected prevalence of adverse perinatal outcomes in obstetric cholestasis, a 95% confidence level, and a margin of error of 5%. The study included pregnant women with obstetric cholestasis (pruritus without rash, mostly nocturnal and affecting the palms and soles, with elevated serum bile acid levels> 10 µmol/L). The participants were singleton or multiple pregnancies and gave informed consent. Participants were excluded from analysis if they had previously known chronic liver disease, viral hepatitis, cholelithiasis, multiple gestations with other confounding comorbidities, major fetal anomalies identified antenatally, or if they refused to participate or were lost to follow-up before the date of delivery.

Maternal obstetric data collected included age, parity, delivery age at diagnosis, body mass index (BMI), previous history of ICP, mode of conception, and comorbidities, including gestational diabetes or hypertension. Biochemical parameters monitored included total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyl transferase (GGT) and TBA. Perinatal outcomes assessed included gestational age at delivery, mode of delivery, preterm birth (<37 weeks), meconium-stained amniotic fluid (MSAF), low birth weight (<2500g), Apgar scores at 1 and 5 minutes, neonatal respiratory distress syndrome (RDS), NICU admission, and stillbirth. APGAR scores were noted specifically in reference to the immediate neonatal adaptation.

Once the diagnosis was made, all patients were given ursodeoxycholic acid (UDCA) treatment. Weekly fetomaternal monitoring included maternal serum liver function tests and a modified biophysical profile. Mothers kept daily fetal kick count charts. Non-stress cardiotocography (CTG) and umbilical artery Doppler studies were performed when requested. The pregnancy was maintained until 38 weeks for those who had reassuring fetal surveillance; a few patients arrived

at the later stages due to poor compliance with the follow-up.

SPSS version 26 was used for statistical analysis. Chi-square test for categorical variables, and the independent sample t-test for continuous variables were utilized. A p-value <0.05 was regarded as statistically significant. ROC curve analysis was used to investigate the relationship between ALT levels and essential perinatal outcomes, and to calculate optimal cut-off values for prediction.

RESULTS

A total sample size of 124 pregnant women diagnosed with obstetric cholestasis was analyzed. The majority of participants were aged 26–30 years (n=42, 33.9%), followed by 31–35 years (n=34, 27.4%), 18–25 years (n=28, 22.6%), and >35 years (n=20, 16.1%). Most women were multigravida (n=72, 58.1%), while primigravida accounted for 52 cases (41.9%). Regarding gestational age at diagnosis, the highest proportion was observed between 33–36 weeks (n=58, 46.8%), followed by 28–32 weeks (n=36, 29.0%) and >36 weeks (n=30, 24.2%). Serum bile acid levels were predominantly in the mild category <40 µmol/L (n=54, 43.5%), followed by moderate levels 40–99 µmol/L (n=48, 38.7%) and severe levels ≥100 µmol/L (n=22, 17.7%). Elevated ALT levels were observed in 54 patients (43.5%), while AST elevation was seen in 48 cases (38.7%). Caesarean section was performed in 56 women (45.2%), whereas 68 women (54.8%) delivered vaginally (Table 1).

Table 1: Maternal Demographic, Obstetric, and Biochemical Characteristics (n = 124)

Variable	Category / Mean ± SD	Frequency (n)	Percentage (%)
Age (years)	18–25	28	22.6
	26–30	42	33.9
	31–35	34	27.4
	>35	20	16.1
Mean age (years)	29.4 ± 5.8	—	—
Parity	Primigravida	52	41.9
	Multigravida	72	58.1
Gestational age at diagnosis	28–32 weeks	36	29.0
	33–36 weeks	58	46.8
	>36 weeks	30	24.2
Mean gestational age (weeks)	34.2 ± 2.8	—	—
Serum bile acids (µmol/L)	<40 (mild)	54	43.5
	40–99 (moderate)	48	38.7
	≥100 (severe)	22	17.7
Mean bile acids (µmol/L)	62.8 ± 28.4	—	—
ALT (U/L)	Normal/mild elevation	70	56.5
	Elevated (>40 U/L)	54	43.5
AST (U/L)	Normal/mild elevation	76	61.3
	Elevated (>40 U/L)	48	38.7
Bilirubin	Normal	98	79.0
	Elevated	26	21.0
Alkaline phosphatase	Normal/raised physiologic	124	100
Mode of delivery	Vaginal	68	54.8
	Caesarean section	56	45.2

Preterm birth was observed in 40 cases (32.3%), while term deliveries accounted for 84 cases (67.7%). Meconium-stained liquor was present in 36 neonates (29.0%), and fetal distress on CTG was documented in 38 cases (30.6%), indicating significant intrapartum compromise. NICU admission was required in 34 newborns (27.4%). Low APGAR scores (<7) were recorded in 30 neonates (24.2%) at 1 minute and 18 cases (14.5%) at 5 minutes, reflecting transient to persistent neonatal depression. Respiratory distress syndrome occurred in 22 cases (17.7%). IUGR was identified in 28 pregnancies (22.6%), while stillbirth occurred in 6 cases (4.8%).

Table 2: Perinatal Outcomes in Obstetric Cholestasis

Perinatal Outcome	Category	n	%
Gestational outcome	Term delivery	84	67.7
	Preterm birth (<37 weeks)	40	32.3
Meconium-stained liquor	Yes	36	29.0

	No	88	71.0
Fetal distress (CTG abnormality)	Yes	38	30.6
	No	86	69.4
NICU admission	Yes	34	27.4
	No	90	72.6
APGAR score (1 min)	<7	30	24.2
	≥7	94	75.8
APGAR score (5 min)	<7	18	14.5
	≥7	106	85.5
Respiratory distress syndrome	Yes	22	17.7
	No	102	82.3
IUGR	Yes	28	22.6
	No	96	77.4
Stillbirth / IUFD	Yes	6	4.8
	No	118	95.2

Adverse outcomes were observed in 68% of cases, while normal perinatal outcomes were seen in 32% of cases, indicating a significantly higher burden of fetal complications.

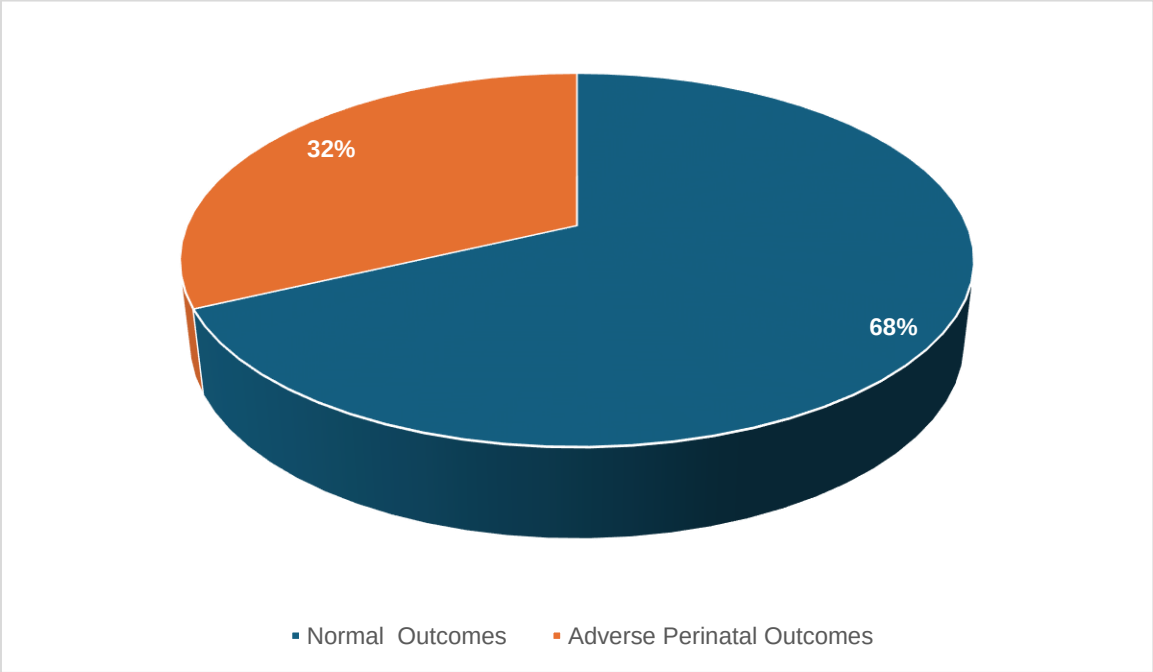

Figure 1: Comparison of Perinatal Outcomes in Obstetric Cholestasis

A clear association was observed between maternal biochemical derangements and adverse perinatal outcomes in obstetric cholestasis. Total bile acid levels were significantly higher in the adverse outcome group (78.9 ± 35.2 µmol/L) compared to the normal outcome group (38.6 ± 12.4 µmol/L), with a strong statistical significance ($p < 0.001$). Similarly, ALT levels were elevated in the adverse group (68.7 ± 25.6 U/L) versus the normal group (32.4 ± 10.8 U/L) ($p = 0.002$). AST showed a comparable pattern, with higher mean values in adverse outcomes (64.3 ± 22.1 U/L) compared to normal outcomes (30.1 ± 9.6 U/L) ($p = 0.003$). GGT levels were also significantly raised in adverse cases (55.9 ± 20.4 U/L vs 28.5 ± 11.2 U/L, $p = 0.01$). Total bilirubin followed the same trend, being higher in adverse outcomes (1.8 ± 0.7 mg/dL vs 0.9 ± 0.3 mg/dL, $p = 0.02$). Overall, worsening biochemical profiles showed a strong and consistent correlation with poorer perinatal outcomes (Table 3).

Table 3: Association of Maternal Biochemical Parameters with Perinatal Outcomes

Biochemical Parameter	Normal Perinatal Outcomes	Adverse Perinatal Outcomes	p-value
Total Bile Acids (µmol/L)	38.6 ± 12.4	78.9 ± 35.2	<0.001
ALT (U/L)	32.4 ± 10.8	68.7 ± 25.6	0.002

AST (U/L)	30.1 ± 9.6	64.3 ± 22.1	0.003
GGT (U/L)	28.5 ± 11.2	55.9 ± 20.4	0.01
Total Bilirubin (mg/dL)	0.9 ± 0.3	1.8 ± 0.7	0.02

ROC analysis showed ALT has good predictive value for adverse perinatal outcomes (AUC=0.81). A cut-off ≥55 U/L gave 78.2% sensitivity and 72.5% specificity, indicating ALT is a significant marker for fetal risk stratification in obstetric cholestasis.

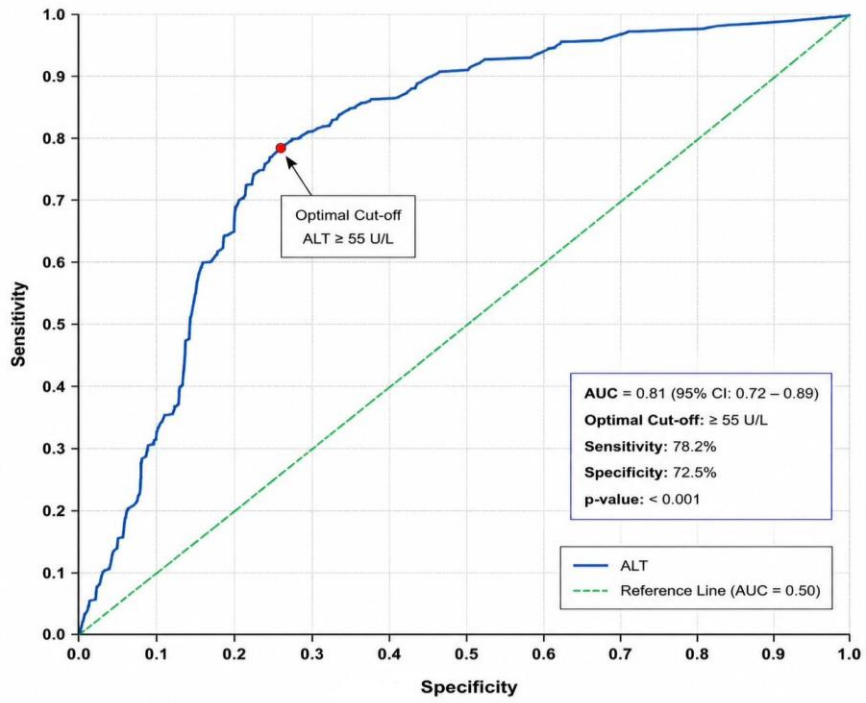

Figure 2: ROC curve of serum ALT for prediction of adverse perinatal outcomes in obstetric cholestasis

DISCUSSION

This study assessed the perinatal outcome of obstetric cholestasis in relation to maternal obstetric and biochemical parameters. The results confirm that obstetric cholestasis is a significant risk factor for adverse perinatal outcomes. The 32.3% preterm birth rate in our cohort is similar to the result of Jafarei et al., who reported a 24.32% preterm birth rate in ICP pregnancies, frequently resulting from both spontaneous and iatrogenic factors associated with active surveillance [11]. The findings of meconium-stained liquor (29.0%) and fetal distress (30.6%) in the present study are consistent with current mechanistic evidence linking bile acids to placental function and fetal cardiomyocyte activity [12]. Excessive bile acid accumulation alters uteroplacental blood flow and increases fetal intestinal motility, which can lead to meconium passage and abnormal CTG patterns [13]. Huang et al. noted that ICP pregnancies had significantly more meconium-stained amniotic fluid and fetal distress, especially when bile acids were >40 µmol/L, which is considered moderate to severe [14].

Most importantly, in this study, IUGR and stillbirth further support the concept of placental dysfunction as a factor in ICP. Ovadia et al. have shown that the risk of a stillbirth is relatively low in mild ICP but higher in severe ICP (bile acids ≥100 µmol/L), implying a stratified risk model rather than a uniform risk in all patients [8]. These findings are clinically relevant, as they demonstrate that fetal risk is not solely driven by symptoms but is strongly associated with biochemical severity.

The findings from this study suggest that total bile acid, ALT, AST, GGT, and bilirubin were significantly increased in the adverse outcome group and that there was a consistent dose–response relationship between hepatobiliary dysfunction and fetal compromise ($p < 0.05$). Ovadia et al. showed that higher levels of bile acids in the blood were directly linked to an increased risk of spontaneous preterm birth, meconium-stained liquor, and stillbirth, especially when the level of bile acids rises above 40 µmol/L [8]. Similarly, ALT and AST were raised significantly in pregnancies with adverse outcomes in the present study. Transaminases do not directly indicate fetal outcome, but studies suggest

they can serve as markers of the severity of hepatocellular injury and may be incorporated into composite risk prediction models [15]. Huang et al. found a moderate correlation between liver enzymes and adverse neonatal outcomes, with lower specificity than bile acids [14].

At a mechanistic level, high concentrations of bile acids have direct fetotoxic effects: vasoconstriction, generation of oxidative stress, and impairment of fetal cardiomyocyte function. Zhan et al. reported that the biological plausibility of sudden fetal compromise in ICP pregnancies has been demonstrated by bile acid accumulation in association with fetal cardiac dysfunction and arrhythmogenic potential [16]. This explains the observed increase in adverse outcomes in pregnancies with higher biochemical derangement in the present study. It is worth noting that modern guidelines focus on biochemical stratification to guide clinical decision-making. In view of the strong association between bile acids and fetal outcomes, the Society for Maternal-Fetal Medicine and recent EASL-based analyses suggest that bile acid levels should be used to guide delivery timing [17].

In the present study, the serum ALT level showed good predictive value for adverse perinatal outcomes in obstetric cholestasis, with an AUC of 0.81. This observation is consistent with a study conducted in Turkey, which showed that transaminase-related parameters are strongly associated with adverse perinatal outcomes in ICP, thereby indicating the clinical significance of ALT in adverse outcome prediction systems [18]. Likewise, a recent cohort study revealed that elevated ALT levels were significantly associated with higher rates of both preterm delivery and neonatal complications, especially when elevated bile acids were also present, thereby suggesting a combined-marker prediction model [19]. These findings suggest that ALT, although not a specific diagnostic marker, could be used to identify early risk when bile acid testing is not readily available in resource-limited settings.

The research was performed at a tertiary care hospital and may not be generalizable to other populations. The cross-sectional design limits the examination of the temporal causality between biochemical severity and perinatal outcomes. Further, long-term neonatal outcomes were not assessed.

CONCLUSION

This study found that obstetric cholestasis is significantly associated with adverse perinatal outcomes and high rates of preterm birth, fetal distress, and NICU admissions. Clinically, there was a clear dose-dependent relationship between maternal biochemical worsening and poor neonatal outcomes, especially in the presence of elevated levels of total bile acids, ALT, AST, GGT, and bilirubin. ALT showed moderate predictive power for unfavorable outcomes, contributing to its use as an adjunct marker in risk stratification. This study highlights the need for combined biochemical and fetal monitoring techniques for early identification of risk and prompt obstetric management in high-risk pregnancies.

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