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Clinical Profile and Perinatal Outcomes in Intrahepatic Cholestasis of Pregnancy: An observational study from Tripura, India

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ABSTRACT

Background

Intrahepatic cholestasis of pregnancy (IHCP) is a liver disorder in pregnancy linked to maternal discomfort and adverse perinatal outcomes.Despite existing studies, data from Tripura remain unavailable. This study evaluated the clinical profile and perinatal outcomes of IHCP in this region.

Methods

A prospective observational study was conducted from July 2022 to June 2023 at Tripura Medical College & Dr. BRAM Teaching Hospital. Eighty singleton pregnant women beyond 28 weeks gestation diagnosed with IHCP based on clinical features, elevated liver enzymes, and serum bile acid levels were enrolled. Patients received ursodeoxycholic acid (UDCA) therapy and were monitored until delivery and 14 days postpartum. Maternal and neonatal outcomes, including delivery mode, fetal distress, birth weight, APGAR scores, neonatal intensive care unit admissions, and early neonatal deaths, were recorded and analyzed.

Results

The mean maternal age was 27.4 ± 4.9 years, with 61.2% primigravida. The mean serum bile acid level at diagnosis was 38.6 ± 17.3 µmol/L, indicating predominantly mild IHCP. Labor was induced in 70% of cases, and caesarean section was performed in 58.8%. Intrapartum fetal distress occurred in 30% of pregnancies. The mean gestational age at delivery was 37.5±1.6 weeks. Neonatal outcomes showed a mean birth weight of 2.8±0.4 kg, with 13.7% low birth weight. Resuscitation was required in 32.5% of neonates, and 32.5% required SNCU admission. Early neonatal death occurred in 6.3% of cases. Neonatal complications included birth asphyxia, meconium aspiration syndrome, respiratory distress syndrome, and neonatal jaundice.

Conclusion

IHCP in Tripura presents with clinical and biochemical profiles consistent with existing literature. Perinatal morbidity and mortality remain significant, underscoring the importance of close fetal monitoring and individualized delivery planning based on serum bile acid levels. Further large-scale studies are needed to optimize management and outcomes in this population.

Key-words: bile acids, feto-maternal outcome, Intrahepatic cholestasis of pregnancy, perinatal complications, Tripura

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INTRODUCTION

Intrahepatic cholestasis of pregnancy (IHCP) is the most common cause of liver disease in pregnancy and is characterized by itching in the absence of skin lesions, disturbances in liver function, and impaired bile acid metabolism. It has a variable incidence due to geographical variation; factors such as advanced age, multiple pregnancy, family history, and history of cholestasis in previous pregnancy have shown increased prevalence in these patients.[1,2]This condition typically manifests during the second and third trimesters and is associated with significant maternal and fetal complications.[1] IHCP carries clinically important risks for both mother and fetus, with consistent evidence demonstrating increased rates of preterm birth, fetal distress, and stillbirth.[3,4] Neonatal complications are also more common, including respiratory distress syndrome, meconium-stained amniotic fluid, higher rates of neonatal intensive care unit admission, and perinatal death. Overall, in utero and perinatal mortality occurs in approximately 0.5% of affected pregnancies.[5] The severity of cholestasis plays a critical role in determining fetal risk, as markedly elevated bile acid concentrations are strongly associated with a greater likelihood of adverse fetal outcomes.[5] Maternal manifestations such as severe pruritus, disturbed sleep, and biochemical evidence of liver dysfunction can substantially impair quality of life during pregnancy. Management with ursodeoxycholic acid has been shown to reduce pruritus, improve liver test abnormalities, and support prolongation of pregnancy when clinically appropriate. Notably, both symptoms and biochemical derangements usually resolve rapidly after delivery, and maternal prognosis is generally excellent.[6,7]Management is challenging, as ursodeoxycholic acid improves maternal symptoms and biochemical parameters but its impact on perinatal outcomes is less certain. Optimal timing of delivery is controversial, with guidelines differing internationally: the Royal College of Obstetricians and Gynaecologists advises against routine early delivery, whereas the American College of Obstetricians and Gynaecologistssupports active induction protocols.[8,9] Intrahepatic cholestasis of pregnancy (IHCP) has been widely studied across various regions of India, with evidence highlighting its association with adverse maternal and fetal outcomes. However, there is a notable lack of region-specific data from Tripura. Given the geographical, ethnic, and healthcare delivery variations that may influence disease presentation and outcomes, the absence of local evidence represents an important knowledge gap. Generating data from this region is essential to understand the clinical profile of IHCP and its fetomaternal implications within the local context and to inform regionally relevant obstetric care strategies.

Objective

The present study was undertaken to evaluate the maternal and neonatal outcomes among pregnant women diagnosed with intrahepatic cholestasis of pregnancy in Tripura.

METHODOLOGY

Study design, duration, and setting: This prospective observational study was conducted over a one-year period, from July 2022 to June 2023, within the Department of Obstetrics and Gynecology at Tripura Medical College & Dr. BRAM Teaching Hospital, Agartala.

Study population and selection criteria: Study population consisted of all the pregnant women attending the OPD of OBG department with the complaint of pruritis in the palm and sole after 28 weeks of pregnancy and diagnosed with intrahepatic cholestasis of pregnancy based on abnormal liver function test and bile acid levels.

All singleton pregnant women beyond 28 weeks period of gestation (POG) who were diagnosed with IHCP and consented to participate were enrolled in the study.Mothers who were not willing to provide consent, those with chronic liver diseases, obstructive jaundice, dermatological conditions presenting with itching and rash, hemolysis-elevated liver enzymes-low platelet count (HELLP) syndrome, or multiple pregnancies were excluded.

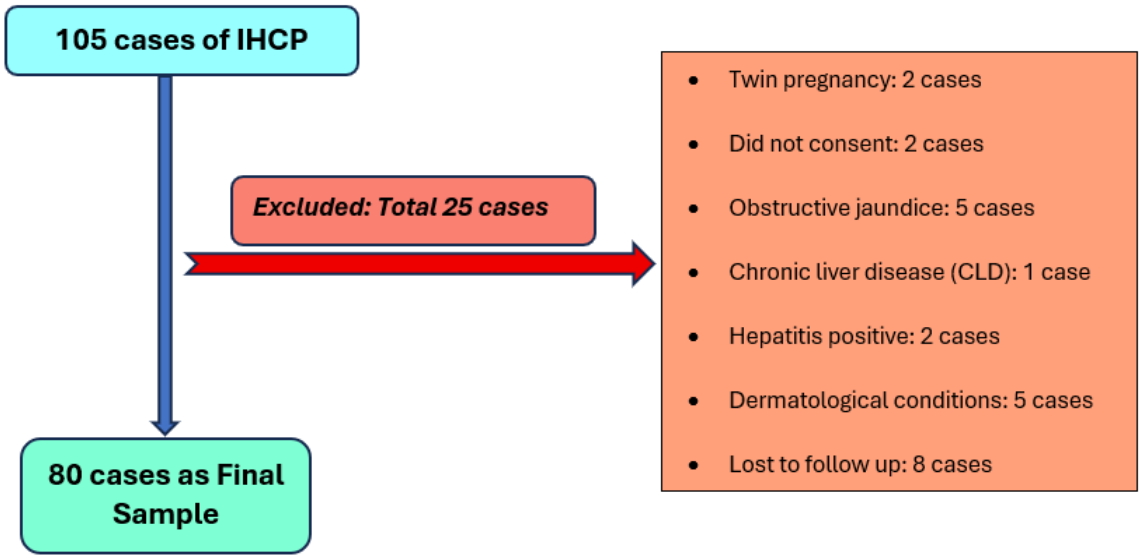
Study procedure: A comprehensive history was gathered, covering age, parity, obstetric history, family history of diabetes, hypertension, or IHCP, and any recent changes in medication. An obstetric examination was conducted. A dermatological cause for the itching was excluded through expert consultation.

The criteria for diagnosing IHCP included clinically noticeable unexplained itching, particularly on the palms and soles, without any skin lesions, which intensified at night, along with abnormal transaminase enzyme levels exceeding twice the normal range and serum bile acids over 10 µmol/L.

Routine antenatal tests, including liver function and fasting serum bile acid tests, were performed. All patients received treatment with ursodeoxycholic acid (UDCA) tablets at a dosage of 10-15 mg/kg/day, with a maximum of 300 mg every 8 hours orally. Liver enzymes were monitored weekly or biweekly until delivery. All participants were clinically observed and followed up in high-risk antenatal clinics on a weekly basis. Fetal monitoring was conducted using non-stress tests and obstetric ultrasounds according to hospital protocol. Patients who did not experience spontaneous preterm labor were admitted between 37 and 37^{+6} weeks of gestation and delivered by the appropriate method as per institutional and standard guidelines. They were subsequently monitored until 14 days postpartum. The maternal and fetal outcomes were documented, including gestational age at pregnancy termination, labor onset, delivery method, pregnancy outcome, postpartum complications, APGAR score at 1 minute, birth weight, NICU admissions, occurrence of neonatal jaundice and early neonatal death. Neonates were monitored up to till the course of hospital stay.

Sample size: A total of 105 cases of IHCP attended the OPD during the study period. But among them, considering the selection criteria only 80 were selected as final sample size and analysis was done on them. Non-probability sampling was employed to select the participants.

Figure 1: Schematic Flowchartof Sample Selection



Data collection and analysis: All relevant data were collected in a predesigned proforma. All the data collected were entered in Microsoft excel and analysed using SPSS version 26. Continuous variables were expressed as mean±SD and categorical variables were summarized as frequency and percentages.

Ethical consideration: The study was approved by the Institutional Ethics Committee of Tripura Medical College (Approval No. SFTMC/09(Sub-1)/3540). All participants were informed about the purpose of the study, and written informed consent

was obtained prior to enrolment. Patient management and treatment were carried out in accordance with standard clinical guidelines.

Results

The mean age of participants was 27.4 (±4.9) years, with majority in the age group of 26-30 years. Majority (61.35) were primigravida. At the time of diagnosis, the mean serum bile acid was 38.6 (±17.3) µmol/L. Nearly three-fourth of the participants had mild IHCP (SBA: 10-39 (µmol/L)), while only 23.8% had moderate IHCP (SBA: 40-99 (µmol/L)).Detailed baseline characteristics of the participants are depicted in Table 1.

Table 1: Baseline characteristics of participants (n=80)

Variable	Subgroup	Frequency	Percentage
Age (Years)	≤20	2	2.5%
	21-25	29	36.2%
	26-30	31	38.8%
	>30	18	22.5%
Pariti	Primipara	49	61.2%
	Multipara	31	38.8%
Serum bile acid level (µmol/L)	10-39	61	76.2%
	40-99	19	23.8%
Total bilirubin (mg/L)	<1	74	92.5%
	≥1	6	7.5%
Alanine aminotransferase (IU/L)	<40	17	21.2%
	≥40	63	78.8%
Aspartate aminotransferase (IU/L)	<40	15	18.8%
	≥40	65	81.2%
Alkaline phosphatase (IU/L)	<150	14	17.5%
	≥150	66	82.5%

At the time just before the delivery when parameters were last recorded, most patients had serum bile acid levels between 19-39 µmol/L (68.8%), with a smaller proportion having levels below 19 µmol/L (28.8%) and very few in the 40-99 µmol/L range (2.5%). Nearly all patients (97.5%) had total bilirubin levels less than 1 mg/L, while only 2.5% had levels of 1 mg/L or more. For alanine aminotransferase (ALT), 58.8% had elevated values of 40 IU/L or greater and 41.3% had levels below 40 IU/L. Regarding aspartate aminotransferase (AST), 56.3% had levels 40 IU/L or above, while 43.8% had values less than 40 IU/L. Lastly, alkaline phosphatase was raised (≥150 IU/L) in 68.8% of patients, and 31.3% had values below 150 IU/L. The mean POG at the time of delivery was 37.5 (±1.6) weeks. Among the vaginal delivery in two cases ventouse was required. Details of the

perinatal parameters are shown in **Table 2**.

Table 2: Distribution of perinatal parameters

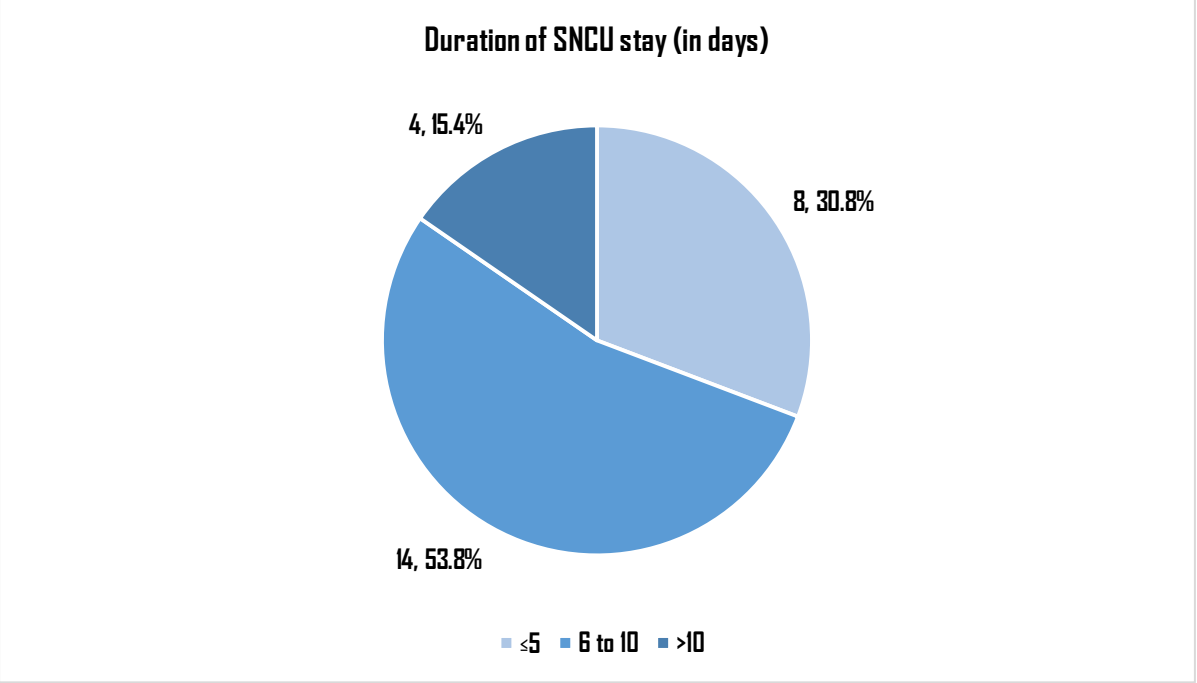
Parameters	Subgroup	Frequency	Percentage
Intrapartum Fetal Distress	Absent	56	**70.0%**
	Present	24	**30.0%**
POG at delivery	28 to 31 weeks	2	**2.5%**
	32 to 36 weeks	9	**11.3%**
	37 to 39 weeks	66	**82.5%**
	≥40 weeks	3	**3.8%**
Onset of delivery	Spontaneous	24	**30.0%**
	Induced	56	**70.0%**
Mode of delivery	Vaginal Delivery	33	**41.3%**
	CS	47	**58.8%**
Type of CS (n=47)	Elective	26	**55.3%**
	Emergency	21	**44.7%**
Colour of liquor	Clear	51	**63.8%**
	Meconium stained	29	**36.3%**

The mean birthweight was 2.8 (±0.4) kg. The mean APGAR score at 1 minute was 7.7 (±1.8).Mean duration of SNCU stay was 7.4 (±3.8) days. Details of neonatal outcomes are depicted in **Table 3** and **Figure 2**.

Table 3: Distribution of neonatal outcomes (n=80)

Variable	Subgroup	Frequency	Percentage
Birth Weight (in Kg)	<2.5	11	13.7
	≥2.5	69	86.3
Resuscitation	Not required	54	67.5
	Required	26	32.5
Neonatal Jaundice	Absent	42	52.5
	Present	37	46.3
Neonatal Sepsis	Absent	64	80
	Present	15	18.8
SNCU admission	Not required	54	67.5
	Required	26	32.5
Early Neonatal Death (within 7 days)	No	75	93.8
	Yes	5	6.3
Outcome	Discharged	71	88.8
	Died/Referred	9	11.2

Figure2: Duration of SNCU stay (in days)



Perinatal and neonatal outcomes were comparable between women with mild and moderate IHCP (Table 4). Intrapartum fetal distress occurred in 29.5% of the mild group and 31.6% of the moderate group. Most deliveries in both groups occurred at 37–39 weeks of gestation, while preterm delivery before 32 weeks was infrequent. Labour was predominantly induced in both categories, and caesarean section was the commonest mode of delivery. Clear liquor was observed in nearly two-thirds of cases in each group. With respect to fetal outcomes, the majority of neonates had a birth weight ≥2.5 kg. The requirement for neonatal resuscitation, incidence of neonatal jaundice and sepsis, and need for SNCU admission were similar across severity groups. Early neonatal death within seven days was uncommon. Overall, most neonates were discharged in stable condition, and no meaningful differences in perinatal or neonatal outcomes were observed between mild and moderate IHCP.

Table 4: Distribution of outcomes across severity of IHCP

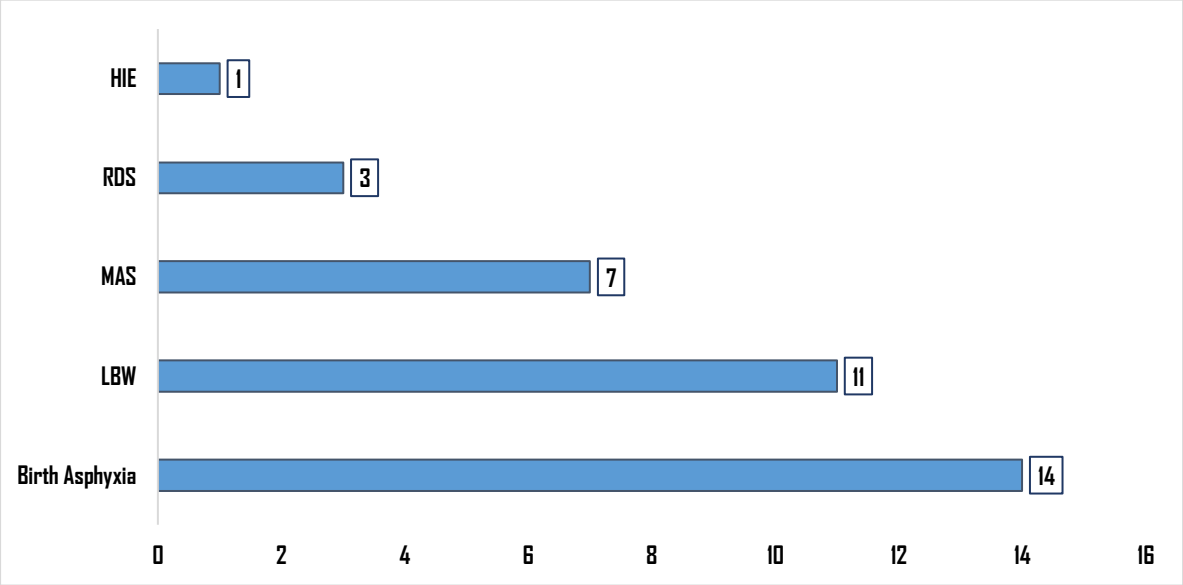
Outcome	Subgroup	Mild IHCP (n=61)	Moderate IHCP (n=19)
Perinatal outcome			
Intrapartum fetal distress	Absent	43 (70.5)	13 (68.4)
	Present	18 (29.5)	6 (31.6)
Period of gestation at delivery	28–31 weeks	2 (3.3)	0 (0.0)
	32–36 weeks	7 (11.5)	2 (10.5)
	37–39 weeks	49 (80.3)	17 (89.5)
	≥40 weeks	3 (4.9)	0 (0.0)
Onset of delivery	Spontaneous	20 (32.8)	4 (21.1)
	Induced	41 (67.2)	15 (78.9)
Mode of delivery	Vaginal delivery	26 (42.6)	7 (36.8)
	Caesarean section	35 (57.4)	12 (63.2)
Colour of liquor	Clear	39 (63.9)	12 (63.2)
	Meconium stained	22 (36.1)	7 (36.8)

Neonatal outcome			
Birth weight (kg)	**<2.5**	8 (13.1)	3 (15.8)
	≥2.5	53 (86.9)	16 (84.2)
Neonatal resuscitation	**Not required**	42 (68.9)	12 (63.2)
	Required	19 (31.1)	7 (36.8)
Neonatal jaundice	**Absent**	32 (52.5)	10 (52.6)
	Present	29 (47.5)	9 (47.4)
Neonatal sepsis	**Absent**	49 (80.3)	15 (78.9)
	Present	12 (19.7)	4 (21.1)
SNCU admission	**Not required**	42 (68.9)	12 (63.2)
	Required	19 (31.1)	7 (36.8)
Early neonatal death (≤7 days)	**No**	57 (93.4)	18 (94.7)
	Yes	4 (6.6)	1 (5.3)
Outcome	**Discharged**	54 (88.5)	17 (89.5)
	Died/Referred	7 (11.5)	2 (10.5)

(Figures in parenthesis indicate percentages)

Among the newborns, 54 were healthy, while the remainder presented with one or more clinical conditions. The most frequently observed condition was birth asphyxia (n = 14), followed by low birth weight (n = 11), meconium aspiration syndrome (n = 7), respiratory distress syndrome (n = 3), and hypoxic-ischemic encephalopathy (n = 1)(Figure 3).

Figure 3: Distribution of neonatal complications#



HIE: hypoxic-ischemic encephalopathy; RDS: respiratory distress syndrome; MAS: meconium aspiration syndrome; LBW: low birth weight
#Conditions are mutually inclusive

DISCUSSION

The present study examined maternal and neonatal outcomes among women diagnosed with intrahepatic cholestasis of pregnancy (IHCP) in Tripura. The demographic profile observed aligns broadly with previously published evidence while providing region-specific insights. The mean age of participants in our cohort was 27.4 ± 4.9 years, with a notable predominance of primigravida women (61.2%). These characteristics mirror trends

described in earlier Indian studies. For example, Upreti and colleagues also described comparable age profiles, noting a mean maternal age of 27.5±5.8 years, although only half of their study population were primigravida.[10]A study from Rajasthan by Jhirwal et al. similarly documented a mean maternal age of 27.63±3.91 years among women diagnosed with IHCP.[11]International findings show similar observations. Celik et al. reported a mean maternal age of 27.7±5.3 years, closely aligning with our results.[12] In contrast, Kant et al. from northern India reported a slightly higher mean maternal age (29.88±4.35 years) and an even higher proportion of primiparous women (79.54%).[7]Aftab et al. also presented comparatively higher mean age (31.7±5.9 years), suggesting variability in demographic patterns across populations.[13]Collectively, these comparisons reinforce the demographic consistency of our findings while highlighting important contextual differences across settings.

The predominance of mild IHCP in our cohort, reflected by mean serum bile acid levels of 38.6±17.3 µmol/L, aligns with the moderate severity range described by Williamson and Geenes, who highlighted the association between bile acid concentration and fetal risk.[2]The maternal biochemical profile, characterized by heightened levels of liver enzymes (ALT, AST) and an increase in alkaline phosphatase in the majority of participants, aligns with previous findings, confirming the typical liver dysfunction observed in IHCP.[1,11] Management with ursodeoxycholic acid (UDCA), administered at dosages in line with standard recommendations, resulted in symptomatic relief and improvement in biochemical markers. These outcomes corroborate the reports of Lee et al., who reported similar benefits with respect to pruritus reduction and normalization of liver function, while noting that UDCA's influence on perinatal outcomes continues to be a subject of ongoing discussion.[6]

Perinatal outcomes

Perinatal outcomes in our study demonstrated notable obstetric challenges, with intrapartum fetal distress occurring in 30% of cases, a 70% rate of labor induction, and a caesarean section rate of 58.8%. These findings parallel the elevated intervention rates described by Arthuis et al. and Odutola et al., who reported similar associations between IHCP and increased fetal compromise, often necessitating operative delivery.[4,5] The mean gestational age at delivery (37.5 weeks) reflects the clinical challenge of balancing risks of prematurity and stillbirth, a controversy also highlighted in international guidelines from RCOG and ACOG, which differ on timing of delivery.[8,9] Comparable observations have been documented in other Indian studies. Kant et al. reported a slightly lower mean gestational age of 36.63 ± 2.57 weeks, while Upreti et al. found an average of 37 ± 1.2 weeks, with 36.9% of cases requiring induction of labor and 33% undergoing cesarean delivery.[7,10] In their cohort, fetal distress emerged as the leading indication for emergency cesarean section, accounting for 39.1% of procedures.[10] Collectively, these findings reinforce the consistent pattern of increased obstetric interventions and fetal monitoring needs among women affected by IHCP.The analysis demonstrated that perinatal outcomes were largely comparable between women with mild and moderate IHCP. Rates of intrapartum fetal distress, gestational age at delivery, onset of labour, and mode of delivery showed minimal variation across the two groups. Labour induction and caesarean section were common in both categories, reflecting a cautious obstetric approach rather than differences in disease severity. These findings are consistent with earlier reports suggesting that although IHCP is associated with increased obstetric intervention, distinctions between mild and moderate disease may not be clearly evident, particularly in smaller cohorts. Williamson and Geenes highlighted the strong association between markedly elevated serum bile acid levels and adverse fetal outcomes, while noting that moderate elevations may have a variable and less predictable impact.[2] However, few studies observed increased obstetric interventions in IHCP, without clear stratification by disease severity.[5,7]

Neonatal outcomes

In the present study, the mean birthweight was

2.8±0.4 kg, and only 13.75% of neonates had low birth weight (<2.5 kg), suggesting that IHCP in this setting was not uniformly associated with fetal growth restriction. This proportion is comparable to several studies, though proportion varied and supports the view that prematurity, rather than chronic placental insufficiency, is the dominant driver of impaired growth in IHCP pregnancies.[7,10,11,14]Perinatal adaptation and the need for immediate support at birth in this study are also broadly consistent with earlier literature. Resuscitation was required in 32.5% of neonates, and the mean SNCU stay of 7.4±3.8 days and an SNCU admission rate of 32.5% are similar to earlier work that has shown a two- to three-fold rise in NICU/SNCU admission among IHCP-exposed neonates compared with controls, driven by respiratory morbidity, jaundice, sepsis evaluation, and feeding difficulties. These concordant findings reinforce that IHCP is a marker of higher perinatal service utilization, even when absolute survival remains high.[5,7,15–18]Neonatal complications observed, including respiratory distress syndrome, meconium aspiration syndrome, and neonatal jaundice, concur with the spectrum reported in previous studies.[2,3,7,10,19]The early neonatal death rate of 6.3% in this cohort, while concerning, falls within the range of perinatal mortality rates linked to IHCP in systematic reviews, underscoring the severity of fetal risk associated with elevated bile acid levels.[20]Neonatal outcomes were also similar between the mild and moderate IHCP groups. Birth weight distribution, need for neonatal resuscitation, incidence of neonatal jaundice and sepsis, and rates of SNCU admission did not differ meaningfully by severity category. These findings align with observations by Upreti et al., who reported comparable neonatal outcomes across IHCP severity levels, underscoring the importance of close fetal surveillance and timely intervention irrespective of biochemical classification.[10] Comparable results have also been reported in other Indian and international studies, suggesting that while IHCP increases overall perinatal morbidity, the severity gradient does not always translate into substantially different neonatal outcomes.[7,12] Although systematic reviews, such as that by Di Mascio et al., have demonstrated a stronger association between high bile acid levels and perinatal mortality, the absence of significant differences in early neonatal death in the present study may be attributable to the small sample size, limited number of severe cases, and effective clinical management mitigating adverse outcomes.[20]

Overall, the findings indicate that serum bile acid levels are valuable for risk stratification in IHCP, and the observed neonatal morbidity and mortality underscore the importance of vigilant fetal monitoring and individualized delivery planning. The study's strengths include its prospective observational design and its contribution as the first IHCP data from Tripura, providing systematically collected regional evidence. However, the small sample size, non-probability sampling, absence of a control group,limited data about medicine compliance and limited neonatal follow-up may affect generalizability and limit the ability to fully assess the impact of different biochemical severity levels on outcomes.

CONCLUSION

This study offers important regional insight into IHCP in Tripura, reflecting clinical and biochemical patterns consistent with existing evidence and demonstrating the effectiveness of ursodeoxycholic acid in improving maternal symptoms. The findings underscore ongoing challenges in obstetric management, including the need to balance maternal and fetal risks, as neonatal outcomes indicated notable morbidity. Serum bile acid levels emerged as a key tool for risk assessment, highlighting the importance of close fetal surveillance and individualized delivery planning. While the studyprovided meaningful observations, its design and sample limitations warrant cautious interpretation. Further research with larger samples and longer follow-up is needed to strengthen understanding and guide improved perinatal care.

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