



ASSESSMENT OF FETOMATERNAL OUTCOMES IN CASES OF INTRAHEPATIC CHOLESTASIS OF PREGNANCY

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ABSTRACT

Background: Intrahepatic cholestasis of pregnancy (ICP) is the most common liver disorder unique to pregnancy and is characterized by pruritus, elevated serum bile acid levels and deranged liver function tests. Although maternal morbidity is generally limited, ICP has important fetal and neonatal implications, including preterm birth, fetal compromise and neonatal intensive care admission.

Objective: The present study was conducted to assess the fetomaternal outcomes in cases of intrahepatic cholestasis of pregnancy and to evaluate the association between disease severity and pregnancy outcomes.

Methods: This prospective observational study was conducted in the Department of Obstetrics and Gynaecology at National Institute of Medical Sciences and Research, Jaipur, over a period of 18 months. A total of 61 pregnant women in the third trimester presenting with pruritus and elevated serum bile acid levels were included. Detailed clinical history, examination and investigations including liver function tests and serum bile acids were performed. Patients were followed till delivery and maternal outcomes such as mode of delivery, gestational age at delivery and postpartum complications, along with fetal outcomes including birth weight, Apgar score and NICU admission were recorded. Statistical analysis was carried out using SPSS software with significance considered at $p < 0.05$.

Results: The mean maternal age was 26.89 ± 4.58 years, with 68.86% aged 21–30 years. Multigravida women constituted 78.7% of the cohort and 70.5% were from rural areas. The mean gestational age at presentation was 35.15 ± 3.35 weeks, and 86.9% presented between 35 and 39 weeks. The mean serum bile acid concentration was 27.88 ± 12.13 $\mu\text{mol/L}$; most participants had mild biochemical disease, with 40.9% having bile acids < 20 $\mu\text{mol/L}$ and 57.4% having concentrations of 20–40 $\mu\text{mol/L}$. Full-term vaginal delivery occurred in 62.3%, preterm vaginal delivery in 21.3% and caesarean delivery in 16.4%. Overall, 34.5% of pregnancies resulted in preterm birth. NICU admission was required for 16.4% of neonates. The mean Apgar score increased from 6.36 ± 0.68 at 1 minute to 8.05 ± 0.80 at 5 minutes. Higher bile acid categories were significantly associated with gestational outcome and Apgar scores, whereas the association with NICU admission was not statistically significant. ROC analysis showed an AUC of 0.962 for intrauterine death and 0.621 for NICU admission.

Conclusion: Intrahepatic cholestasis of pregnancy is associated with a higher incidence of preterm delivery and neonatal morbidity; however, with timely diagnosis, close monitoring and appropriate management, most pregnancies result in favorable maternal and neonatal outcomes. Early identification and regular antenatal surveillance are essential to reduce adverse fetomaternal complications.

KEYWORDS: Intrahepatic Cholestasis of Pregnancy, Bile Acids, Pruritus, Preterm Birth, Apgar Score, Fetomaternal Outcome.

Introduction

Intrahepatic cholestasis of pregnancy (ICP), also referred to as obstetric cholestasis, is the most common hepatobiliary disorder specific to pregnancy[1]. It is characterized principally by pruritus, particularly involving the palms and soles, accompanied by elevation of serum bile acids and variable abnormalities in liver function tests. Symptoms and biochemical abnormalities generally resolve after delivery[2, 3].

The global prevalence of ICP ranges from 0.1-2% with marked regional variation rates as high as 5-15% in Chile, 0.5-1.5% in Scandinavian countries and up to 6.06% in China attributable to differences in genetic susceptibility, environmental factors and seasonal influences. In India, the prevalence ranges from 0.02% to 5% with the Asian Indian population demonstrating an average of approximately 1.2-1.5%; tertiary care centres consistently report higher rates (up to 4.08% in North India and 3.3% in East India) due to referral concentration of cases from peripheral facilities. The risk is further amplified in multiple gestations with ICP affecting approximately 20-22% of twin pregnancies and recurrence in subsequent pregnancies has been documented in nearly 30% of affected Indian women, while under-recognition at peripheral centres continues to result in an underestimation of the true disease burden in the general Indian obstetric population[1, 2].

Genetic mutations in hepatocanalicular transport proteins particularly those encoded by the ABCB4, ABCB11 and ATP8B1 genes have been implicated in predisposed individuals. Elevated estrogen and progesterone metabolites during late pregnancy are thought to further impair bile acid excretion, precipitating the cholestatic state[1,2,4]. Serum bile acid concentration has therefore emerged as an important marker for clinical risk stratification. Previous studies have reported progressively higher rates of adverse fetal outcomes with increasing bile acid concentrations[5].

Although maternal disease is usually self-limiting, the fetal consequences are of greater clinical concern. ICP has been associated with spontaneous and iatrogenic preterm birth, meconium-stained liquor, fetal distress, low Apgar scores, neonatal respiratory morbidity and NICU admission. Severe disease, particularly with high maternal serum bile acid concentrations, has been associated with an increased risk of stillbirth. Large observational studies have particularly emphasized the association between severe ICP and preterm birth, meconium-stained liquor, lower Apgar scores and perinatal morbidity[6,7].

Despite increasing recognition of ICP, locally relevant data from Indian tertiary-care centres remain important because patient characteristics, referral patterns, disease severity and obstetric management may differ between populations. The present study was undertaken to characterize women with ICP presenting to a tertiary-care centre in Jaipur and to evaluate maternal and neonatal outcomes, with particular emphasis on the relationship between disease severity and pregnancy outcomes.

Materials and Methods

Study Design and Settings

This prospective, observational study was carried out in the Department of Obstetrics and Gynaecology, National Institute of Medical Sciences and Research, Jaipur, Rajasthan. The study was conducted over a period of 18 months. Institutional Ethics Committee approval (Ref. no.: NIMSUR/IEC/2024/1003, dated: 10/05/2024) was obtained before commencement of the study. Written informed consent was obtained from all participants.

Study Participants

Pregnant women in the third trimester presenting with pruritus and biochemical evidence suggestive of ICP, attending in the Department of Obstetrics and Gynaecology at the study centre were screened for eligibility.

Inclusion Criteria

- Pregnant women in third trimester.
- Pruritis on the palm and soles along with deranged LFT
- Raised Serum Bile Acids levels {mild (peak bile acids 19-39 micromol/L), moderate (peak bile acids 40-99 micromol/L) and severe (peak bile acids 100 micromol/L or more)}
- Those who are willing to give consent to participate in the study.

Exclusion Criteria

Women who declined consent or had dermatological causes of pruritus, viral hepatitis, HELLP (Haemolysis, elevated liver enzymes, low platelet count) syndrome, acute fatty liver of pregnancy or obstructive jaundice were excluded.

Sample Size:

Sample size was calculated using formula:

$$N = \frac{Z^2_{\alpha/2} * p * (1-p)}{d^2}$$

$$= \frac{1.96 * 0.0373 * (1-0.0373)}{(0.05)^2}$$

$$= 55.18 \approx 55$$

Where,

N = Sample size.

$Z_{\alpha/2}$ = inverse probability of normal distribution at 95% confidence interval. p= incidence rate of intrahepatic cholestasis of pregnancy

d= Margin of error (5%) considered

The calculated sample size was 55.18, which was rounded to 55 and increased by 10% to account for potential loss to follow-up, giving a final target sample of 61 participants.

Study Procedure

Participants underwent detailed clinical and obstetric evaluation, including assessment of the onset and severity of pruritus, obstetric history, medical and drug history, general examination and obstetric examination. Routine antenatal investigations were undertaken according to institutional protocol. Liver function tests and serum bile acid concentrations were additionally measured for diagnosis and assessment of disease severity. Investigations were repeated as clinically required. Participants were managed according to standard institutional clinical practice and followed until delivery. Maternal variables included age, parity, gestational age at diagnosis/presentation, gestational age at delivery, mode of delivery and maternal complications. Neonatal variables included Apgar scores at birth and the need for NICU admission. Data were recorded using a structured proforma.

Study Endpoints

The primary endpoint was to assess fetomaternal outcomes among women with ICP. The secondary endpoints were to assess maternal outcomes according to type of delivery and gestational age at delivery and to evaluate fetal outcomes including preterm birth, Apgar score at birth and the need for NICU admission.

Statistical Analysis

Data were entered into a Microsoft Excel and analysed using SPSS v.25. Descriptive statistics were used to summarize demographic, clinical, biochemical and obstetric variables. Associations between serum bile acid categories and categorical pregnancy outcomes were assessed using the Chi-square (χ^2) test. A p-value <0.05 was considered statistically significant. ROC analysis was performed to assess the discriminatory ability of serum bile acid concentration for intrauterine death and NICU admission.

Results

Maternal Demographic & Clinical Details

The mean maternal age was 26.89±4.58 years. Women aged 21–25 and 26–30 years each represented 34.43% of the cohort, while 22.95% were aged 31–35 years. Only 4.92% were aged ≤20 years and 3.27% were >35 years. Most participants were multigravida (78.7%), while 21.3% were primigravida. The majority were booked cases (91.8%), and 70.5% were from rural areas. All the study participants had itching over the palms and soles. Table 1 summarizes the demographic details and clinical characteristics of the study participants.

Gestational Age and Biochemical Findings

The mean gestational age at presentation was 35.15±3.35 weeks. Most participants (86.9%) presented between 35 and 39 weeks, whereas 9.84% presented at 31–35 weeks and 3.27% at ≤30 weeks. The mean SGOT concentration was 167.51±141.23 IU/L, with values ranging from 53 to 609 IU/L. The mean SGPT concentration was 168.51±111.86 IU/L, ranging from 48 to 403 IU/L. The mean serum bile acid concentration was 27.88±12.13 µmol/L. According to the descriptive bile-acid table, 25 women (40.9%) had concentrations <20 µmol/L, 35 (57.4%) had concentrations of 20–40 µmol/L, one (1.64%) had a concentration of 40–100 µmol/L and none had concentrations >100 µmol/L (Table 2).

Table 1: Demographic & Clinical Characteristics of the Study Participants

Characteristics	No. of Participants [N = 61]
Age (years) Mean ± SD: 26.89±4.58 years	≤20
	21-25
	26-30
	31-35
	>35
Residence	Rural
	Urban
Booking Status	Booked
	Unbooked
Gravidity	Primigravida
	Multigravida
Palmoplantar pruritis	Present

Table 2: Gestational Age and Biochemical Findings of the Study Participants

Variable	Result
Mean gestational age at presentation $\pm$ SD	35.15 $\pm$ 3.35 weeks
Presentation $\leq$ 30 weeks	2 (3.27%)
Presentation 31–35 weeks	6 (9.84%)
Presentation 35–39 weeks	53 (86.9%)
Mean SGOT $\pm$ SD	167.51 $\pm$ 141.23 IU/L
Mean SGPT $\pm$ SD	168.51 $\pm$ 111.86 IU/L
Mean serum bile acid $\pm$ SD	27.88 $\pm$ 12.13 μ mol/L
Bile acid <20 μ mol/L	25 (40.9%)
Bile acid 20–40 μ mol/L	35 (57.4%)
Bile acid 40–100 μ mol/L	1 (1.64%)
Bile acid >100 μ mol/L	0 (0%)

Mode of Delivery

Full-term vaginal delivery was the most frequent mode of delivery, occurring in 38 women (62.3%). Preterm vaginal delivery occurred in 13 women (21.3%), while 10 women (16.4%) underwent caesarean delivery. Thus, vaginal delivery accounted for 83.6% of all deliveries. Among caesarean deliveries, previous caesarean section and obstetric indications were the principal reasons for operative delivery. The reported indications included previous LSCS with scar tenderness, previous two LSCS, twin pregnancy, PROM with DCDA twins/IVF conception and preterm labour with meconium-stained liquor (Table 3 & 4).

Neonatal Outcomes

NICU admission was required in 10 neonates (16.4%), while 51 (83.6%) did not require NICU admission. At 1 minute, the mean Apgar score was 6.36 $\pm$ 0.68; 33 neonates (54.0%) had a score of 7 and 28 (46.0%) had a score of 6. At 5 minutes, the mean score increased to 8.05 $\pm$ 0.80, with 22 neonates (36.1%) scoring 8, 21 (34.4%) scoring 9 and 18 (29.5%) scoring 7. Serum bile acid category was significantly associated with gestation ($p=0.001$), Apgar score at 1 minute ($p=0.048$) and Apgar score at 5 minutes ($p=0.042$). Table 5 summarizes neonatal outcomes according to serum bile acid levels.

Table 3: Mode of Delivery of the Participants

Mode of Delivery	Participants, n (%) [N=61]
Full-term gestation	40 (65.5%)
Preterm gestation	21 (34.5%)
FTVD	38 (62.3%)
PTVD	13 (21.3%)
LSCS	10 (16.4%)

Table 4: Indications for Caesarean Delivery

Indications	No. of Participants, n (%) [N=10]
Elective Caesarean Section	
Previous 1 LSCS	2 (20%)
Emergency Caesarean Section	
PROM, DCDA twins, IVF conception	1 (10%)
Preterm labor pain with MSL	2 (20%)
Previous 1 LSCS with scar tenderness	2 (20%)
Previous 2 LSCS	1 (10%)
Twin pregnancy (DCDA)	2 (20%)

Table 5: Neonatal Outcomes According to Serum Bile Acid Levels

Neonatal Outcomes < 20		Bile Acid Level ($\mu\text{mol/L}$)			Total (N=61)	p-Value
		20-40	> 40-100			
Gestation	Full-term	0 (0%)	13 (100%)	0 (0%)	13 (21.3%)	0.001*
	Preterm	0 (0%)	43 (89.6%)	5 (10.4%)	48 (78.7%)	
NICU Admission	Yes	0 (0%)	4 (40%)	6 (60%)	10 (16.4%)	0.198
	No	0 (0%)	47 (92.1%)	4 (7.9%)	51 (83.6%)	
APGAR Score at 1 min	5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.048*
	6	0 (0%)	21 (75%)	7 (25%)	28 (46%)	
	7	0 (0%)	30 (90.9%)	3 (9.1%)	33 (54%)	
APGAR Score at 5 mins	7	0 (0%)	15 (83.3%)	3 (16.7%)	18 (29.5%)	0.042*
	8	0 (0%)	16 (72.7%)	6 (27.3%)	22 (36.1%)	
	9	0 (0%)	20 (95.2%)	1 (4.8%)	21 (34.4%)	

* Significant ($p < 0.05$) ROC Analysis

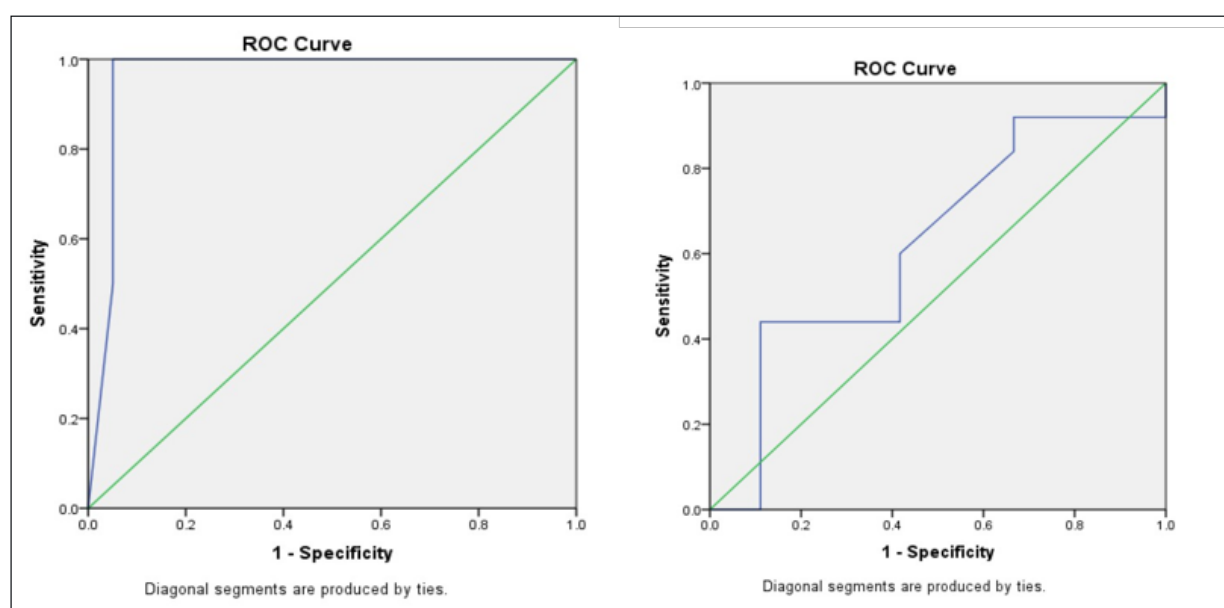
ROC Analysis

Serum bile acid concentration showed excellent discrimination for intrauterine death, with an area under the ROC curve of 0.962 (standard error 0.026; $p=0.027$). The reported cut-off was 49.085 $\mu\text{mol/L}$, corresponding

to 100.0% sensitivity and 94.9% specificity. For NICU admission, the AUC was 0.621 (standard error 0.075; $p=0.110$). The reported cut-off was 30.50 $\mu\text{mol/L}$, with 44.0% sensitivity and 88.9% specificity, indicating limited discriminatory performance (Table 6 & Figure 1).

Table 6: Receiver operating characteristics curves of bile acid level for predicting IUD and NICU admission

Parameter	Intrauterine death (IUD)	NICU admission
AUC	0.962	0.621
Standard error	0.026	0.075
p-value	0.027	0.110
Cut-off ($\mu\text{mol/L}$)	49.085	30.50
Sensitivity	100.0%	44.0%
Specificity	94.9%	88.9%



**Figure 1.(a) ROC diagram of bile acid level for predicting IUD;
(b) ROC diagram of bile acid level for predicting NICU admission**

Discussion

The present study was undertaken to assess the fetomaternal outcomes associated with this condition in a tertiary care setting. Various clinical, biochemical and obstetric parameters were evaluated to understand the pattern of disease presentation and its impact on pregnancy. The findings of this study are discussed in light of existing literature to highlight similarities, differences and the clinical relevance of observed outcomes.

In the present study, the mean age of patients with intrahepatic cholestasis of pregnancy (ICP) was 26.89 ± 4.576 years with the majority of cases (68.86%) concentrated in the 21–30-year age group, reflecting peak reproductive age as the most affected category. Anjum et al. (2024), in their prospective observational study from West Bengal, India, reported a mean age of 24.91 ± 4.23 years among 100 ICP patients with the 21–25-year age group forming the largest cohort (42%)[8]. Similarly, Nasir et al. (2025) reported a mean age of 26.42 years with approximately 71.8% of participants aged under 30 years[9]. Jhirwal et al. (2022) found ICP predominantly affecting women in the 21–30-year age bracket in a tertiary care setting.[10] Mitra et al. (2020) and Yadav et al. (2021) similarly documented peak ICP incidence in the reproductive age group of 20–30 years across their Indian study populations[11, 12].

In the present study, 70.5% (n=43) of ICP patients were from rural areas and 29.5% (n=18) from urban areas, indicating the predominantly rural catchment of this tertiary referral institution. Jhirwal et al. (2022) from AIIMS Jodhpur, Rajasthan, reported that a large proportion of their ICP patients belonged to rural and peri-urban backgrounds, consistent with the rural predominance seen in the present study[10]. Similar patterns were observed in comparable Indian tertiary care studies, including studies by Upreti (2024), Anjum et al. (2024)[8,13].

In our study, multigravida women comprised 78.7% (n=48) and primigravida 21.3% (n=13) of ICP patients. This multigravida predominance is in contrast with the findings of Anjum et al. (2024), who reported that 68% of their 100 ICP patients 74 were primigravidae, suggesting that ICP affected first-time mothers more frequently in their Kolkata-based cohort[8]. Nasir et al. (2025) noted that ICP in their cohort predominantly affected primigravida women, consistent with the conclusion that ICP predominantly affected younger, overweight primigravida patients[9]. Wikström Shemer et al. (2013), in their large 12-year Swedish cohort of 5,477 ICP cases, identified first pregnancy as one of the associated demographic factors for ICP, suggesting that in Western populations, primigravid women may carry a relatively higher risk[14].

The mean gestational age at diagnosis/presentation was 35.148 ± 3.348 weeks with the majority of patients (86.9%, n=53) presenting between 35–39 weeks and only 3.27% (n=2) at ≤ 30 weeks and 9.84% (n=6) at 31–35 weeks. This

is consistent with the well-established clinical pattern of ICP presenting predominantly in the third trimester. Jhirwal et al. (2022) reported that the majority (70.39%, n=107) were diagnosed at 32–36.6 weeks of gestation and 21.05% (n=32) at 37–39.6 weeks; only 7.89% (n=12) were diagnosed as early as 28–31.6 weeks[10]. Granese et al. (2023), in their 10-year Italian retrospective study of 129 ICP patients, reported that most ICP patients delivered between 32 and 37 weeks (16.3% preterm), compared to controls who delivered mostly between 38 and 40 weeks ($p=0.001$)[15].

In the present study, 100% of patients (n=61) presented with itching over the palms and soles as the defining presenting complaint, consistent with the diagnostic criterion applied - all patients were enrolled based on the presence of palmoplantar pruritus with confirmatory biochemical testing. Wikström Shemer et al. (2013) and Geenes et al. (2014) both defined ICP by the presence of pruritus (predominantly palmoplantar) with biochemical confirmation, making itching an inherent 100% criterion in their study[14,16].

The mode of delivery was as follows: full-term vaginal delivery (FTVD) in 62.3% (n=38), preterm vaginal delivery (PTVD) in 21.3% (n=13) and LSCS in 16.4% (n=10) giving a total vaginal delivery rate of 83.6% and caesarean section rate of 16.4%. Nasir et al. (2025) noted that ICP is associated with 1.5 times the caesarean section rate compared to normal pregnancies[9]. The comparatively lower LSCS rate of 16.4% in the present study is consistent with the predominantly mild ICP profile (98.36% of patients had bile acid $<40 \mu\text{mol/L}$) and is in agreement with Ghimire et al. (2016) from Nepal and Upreti (2024) from India, who reported similarly lower CS rates in mild-ICP predominant cohorts from South Asian tertiary care settings[13,17]. Sitaula et al. (2021) from Nepal and Senocak and Yilmaz (2019) from Turkey documented that vaginal delivery remained the predominant mode in their ICP cohorts, consistent with the findings of the present study[18,19].

In the present study, 16.4% (n=10) of neonates required NICU admission, while 83.6% (n=51) did not. This was comparable to rates reported by Anjum et al. (2024) (19%, West Bengal), Jhirwal et al. (2022) (approximately 15–20%, Rajasthan), and Granese et al. (2023) (18.6%, Italy), but substantially lower than the 52.56% reported by Nasir et al. (2025) in Lahore[8-10,15]. Previous studies have also suggested that NICU admission increases with increasing bile acid levels, particularly in severe ICP, with prematurity, respiratory distress, and meconium aspiration contributing to neonatal morbidity.

All neonates in the present study had an Apgar score ≥ 6 at 1 minute, with a mean of 6.36 ± 0.68 , which improved to 8.05 ± 0.80 at 5 minutes; all neonates scored ≥ 7 at 5 minutes. These findings indicate favourable early neonatal adaptation. In comparison, Anjum et al. (2024) and Nasir et al. (2025) reported 5-minute Apgar scores <7 in 9% and 16.67% of neonates, respectively[9]. Geenes et al. (2014),

Brouwers et al. (2015), and Wikström Shemer et al. (2013) reported poorer Apgar outcomes particularly among severe or preterm ICP cases, while Granese et al. (2023) observed lower 1-minute Apgar scores among ICP neonates, with improvement by 5 minutes[14-16,20].

Among the 10 LSCS cases (16.4%) in the present study, 2 were elective and 8 were emergency procedures, with previous LSCS, scar tenderness, meconium-stained liquor, twin pregnancy, PROM, and previous two LSCS being the main indications. Similar findings were reported by Jhirwal et al. (2022), where previous LSCS, fetal distress, and failed induction were the predominant indications. Granese et al. (2023) also reported a significantly higher rate of caesarean delivery for cardiotocographic abnormalities among women with ICP compared with controls ($p=0.005$)[10,15].

Serum bile acid levels were significantly associated with gestational age at delivery ($p=0.001$), Apgar scores at 1 minute ($p=0.048$) and 5 minutes ($p=0.042$), but not NICU admission ($p=0.198$). Preterm delivery was observed across the reported bile acid categories, including all cases in the $>40 \mu\text{mol/L}$ group. These findings are broadly consistent with studies by Geenes et al. (2014), Kong et al. (2016), and Herrera et al. (2018), which reported increased risks of preterm delivery, low Apgar scores, and NICU admission with severe ICP and higher bile acid concentrations[16,21,22].

However, this study was limited by its small sample size, single-centre observational design, purposive sampling, limited representation of severe ICP, relatively short follow-up, and absence of multivariable analysis. Treatment variations and maternal comorbidities were not extensively analysed, and neonatal outcomes were limited to immediate outcomes such as Apgar score and NICU admission, without long-term neonatal follow-up.

Conclusion

In this prospective cohort, ICP predominantly affected multigravidas and presented in late pregnancy, with most women having mild bile acid elevation. Higher bile acid levels were associated with gestational outcome and Apgar scores, while NICU admission was not significantly associated. These findings highlight the importance of early recognition, bile acid assessment, and close antenatal surveillance. Larger multicentre studies are needed to validate bile acid thresholds and predictors of adverse outcomes.

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None

Conflict of Interest

None

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