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Original Research Article

Study of association of serum bile acid levels with fetomaternal outcomes in cases of intrahepatic cholestasis of pregnancy: a case control study

Himanshi Jain[1]*, Manisha Sharma[1], Rekha Jain[1], Ravindra Kumar[2], Rajiv Ranjan[3]

[1]Department of Obstetrics and Gynecology, Hindu Rao Hospital and NDMC Medical College, Delhi, India
[2]Department of Pediatrics, Hindu Rao Hospital and NDMC Medical College, Delhi, India
[3]Department of Biochemistry, Hindu Rao Hospital and NDMC Medical College, Delhi, India

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***Correspondence:**
Dr. Himanshi Jain,
E-mail: jain93himanshi@gmail.com

ABSTRACT

Background: This study was done to find out the association of serum bile acid level with fetomaternal outcome in patients with intrahepatic cholestasis of pregnancy (IHCP) and to determine the level of bile acids at which immediate intervention will be required to obtain good fetomaternal outcome.
Methods: An observational case control study was conducted on 60 women with IHCP as cases and 60 women without IHCP as controls in the department of obstetrics and gynecology at Hindu Rao Hospital and NDMC Medical College from March 2023 to December 2023 and statistical analysis was done using SPSS version 21.0. Quantitative variables were compared using Mann-Whitney test. Qualitative variables were calculated from the receiver operating characteristic curve. The p value of <0.05 was considered statistically significant.
Results: The most common symptom of IHCP was itching over whole body seen in 50% cases. Most of the cases (90% cases) were diagnosed with IHCP at 32-37 weeks of gestation. Recurrence was seen in 36.7% cases. 48.3% cases versus 71.7% controls went into spontaneous onset of labour while induction of labour was done in 51.7% cases versus 28.3% controls and augmentation of labour was required in 32.7% cases versus 52.5% controls with statistically significant difference. Preterm delivery was seen in 16.7% cases versus 3.3% controls. 43.3% cases versus 16.7% controls were delivered by cesarean section (p value <0.5). The liquor was meconium stained in 53.3% cases versus 10% controls with a statistically significant difference. 20% cases versus 1.7% controls landed up into PPH at the time of delivery (p value <0.5). There was no statistically significant difference in the fetal outcome, need of NICU admission and birth weight of the babies. The cut-off of 33.7µmol/l bile acid level at the time of diagnosis of IHCP was predictive of MSL, 64.19 µmol/l was the cut off of bile acid for predicting IUD/perinatal death with optimum sensitivity and specificity. 32.85µmol/l was the cut off of bile acid for predicting NICU admissions. A positive correlation was found between the levels of serum bile acid and level of ALT (r value of 0.355 and p value of 0.005), AST levels (r value 0.383 and p value of 0.003), total bilirubin levels (r value 0.355, p value 0.005) and direct bilirubin (r value 0.145, p value 0.271).
Conclusions: Significantly higher number of adverse fetomaternal outcomes occurred in the cases of intrahepatic cholestasis of pregnancy as compared to the controls. Increase in the level serum bile acid was associated with increased incidence of adverse fetomaternal outcomes. Serum bile acid levels can be used to predict those adverse fetomaternal outcomes. The adverse fetomaternal outcomes need to be predicted well in time so as to prevent them. Management can be optimized by timely prediction of adverse fetomaternal outcomes with the help of monitoring serum bile acid levels among pregnant women with IHCP.

Keywords: Bile acid, Fetomaternal outcomes, Intrahepatic cholestasis, Pregnancy

INTRODUCTION

Intrahepatic cholestasis of pregnancy also known as cholestatic hepatosis, pruritis gravidarum, pregnancy dermatoses or recurrent jaundice of pregnancy is the reversible cholestatic disease of pregnancy characterized by itching predominately on palms and soles presenting in the second to third trimester of pregnancy with elevated serum bile acids (≥10 µmol/l) or elevated serum aminotransferase with spontaneous relief of laboratory abnormalities and symptoms promptly after delivery but no later than one month postpartum.[1,2] The serum bile acids ≥10µmol/L is the most sensitive and specific marker for the diagnosis of IHCP.[3]

The incidence of intrahepatic cholestasis of pregnancy ranges from <1% to 27.6% worldwide and its prevalence is influenced by genetic and environmental factors and varies between populations.[4] Increased prevalence of IHCP is seen in women with advanced age, multiple pregnancy, family history and history of cholestasis in previous pregnancy.[5]

The cause of IHCP is still unknown. Its etiopathogenesis is believed to be multifactorial due to complex interactions between genetic, environmental and hormonal factors. The homozygous mutations in gene encoding biliary proteins leads to progressive familial cholestasis (PFIC) and benign recurrent cholestasis (BRIC).[6] Homozygous mutation in ABCB4 gene which encodes MDR3 (multi drug resistant) glycoprotein results in PFIC type 3.[7] Genetic mutations in BSEP (bile salt export pump) encoded by ABCB11 has also been reported in IHCP. BSEP is located exclusively in hepatocytes canalicular membrane and is a primary export pump for bile acid. The increased levels of monosulfated and disulfated isomers of progesterone are seen in the serum and urine of women with IHCP and it is because of impaired excretion of these metabolites at the canalicular membrane or abnormal synthesis.[8] Both increases and decreases in sex steroid levels is implicated in the etiopathogenesis of IHCP. Estrogens and bile acids cause oxidative stress and it has been proposed that reduced serum selenium levels may contribute to the etiology of IHCP and may also provide an explanation for the geographic variation in the prevalence of IHCP.

The main symptom of IHCP is itching which is predominately on palms and soles occurring in late second or early third trimester with typical worsening at night. Most of the women present with the symptoms of IHCP in the third trimester when the levels of estrogen and progesterone are the highest.[9] IHCP can lead to meconium staining of liquor, prematurity, fetal distress, meconium aspiration, respiratory distress (RDS), sudden intrauterine fetal death, still birth.[10-14]

Various guidelines are proposing different gestational age at which termination of pregnancy should be offered to the pregnant women with IHCP in order to get good fetomaternal outcome and they have been changing over last few years. The proposed study was conducted to find out the association of serum bile acids with fetomaternal outcome. It may also help us to determine the level of bile acids at which immediate intervention will be required to obtain good fetomaternal outcome.

METHODS

An observational case control study was conducted in the department of obstetrics and gynecology from March 2023 to December 2023 in collaboration with the department of biochemistry and the department of pediatrics at Hindu Rao Hospital and NDMC College, Delhi. After obtaining clearance with the scientific and the ethical committee of our hospital. 60 antenatal women in the third trimester of pregnancy who presented with generalized pruritis especially on palms and soles without any skin rash and raised serum bile acids ≥10 µmol/l were selected as cases and 60 antenatal women in third trimester of pregnancy without IHCP and matching demographic profile were selected as controls. Detailed history regarding the symptoms of IHCP and history of fever, loose stools, vomiting, yellowish discoloration of eyes and skin, pain abdomen were asked to rule out hepatitis A and E infections, history of raised BP records to rule out pre-eclampsia, eclampsia, history of sonographic evidence of liver or gall stone disorder, history of bone disease were asked and patients were excluded from the study. Clinical examination including general physical examination from head to toe, systemic examination and per abdominal examination of the patient was done. Laboratory investigations which were specific to study (serum bile acid which was measured in clinical lab of biochemistry using fully automatic Biochemistry analyzer, HBsAg, anti HCV, coagulation profile, liver function tests, ultrasound of upper abdomen to rule out liver or gall bladder diseases and for fetal wellbeing and routine ANC profile (CBC with peripheral smear, blood group, urine routine and microscopy, OGTT, HIV, thyroid profile, HPLC) were done.

The exclusion criteria were pregnant females with pre-eclampsia, HELLP, acute fatty liver of pregnancy, multifetal gestation, other acute or chronic liver or kidney disease, history of gallstones, skin disease with rash, hemolytic anemia, alcohol and drug addictions, any other comorbid medical disorders in pregnancy. Serum bile acid level was measured at initial diagnosis and repeated every 1-2 weekly interval as required and at the time of termination of pregnancy. Monitoring of fetal wellbeing was done as per hospital protocol. Termination of pregnancy was done at 37 weeks of gestation or earlier if indicated according to the institutional protocol. Testing for normalization of serum bile acids was done at 4 weeks postpartum.

The maternal outcomes were seen in terms of need for induction of labour, mode of delivery, meconium-stained liquor, postpartum hemorrhage, need for blood transfusion and fetal outcomes were seen in terms of prematurity, fetal

distress, intrauterine fetal death, still birth, 5 minutes APGAR score, respiratory distress, meconium aspiration syndrome, neonatal intensive care unit admission and perinatal mortality.

RESULTS

The mean age of our study group was 26.62±3.81 years for cases and 25.20±3.95 for controls. 36.7% cases and 53.3% controls were primigravida and 63.3% cases and 46.76% controls were multigravida. The most common complaint of the patients was itching over whole body seen in 50% cases. The mean period of gestation for diagnosis of IHCP was 34.87±2.01 weeks. 36.7% cases had history of IHCP in previous pregnancy. 16.7% cases had serum bile acid level between 10-19.9 µmol/l, 53.3% cases had serum bile acid level between 20-39.9 µmol/l, 30% patients had serum bile acid level ≥40 µmol/l. 13.3% cases developed gestational hypertension and 8.3% cases developed preecclampsia during the course of study. 48.3% cases had spontaneous onset of labour, induction of labour was done in 51.7% cases while 71.7% controls had spontaneous labour and induction of labour was done in 28.3% controls. The difference was statistically significant (p value 0.01). Augmentation of labour was not required in 67.3% cases while 47.5% controls did not require augmentation (p value 0.03). The mean gestational age of termination of pregnancy/onset of labour was 37.50±1.20 weeks for cases and 38.77±1.19 weeks for controls. The difference was statistically significant (p value <0.001). 56.7% cases and 83.3% controls were delivered vaginally while 43.3% cases and 16.7% controls were delivered by caesarean section (p value <0.01). In 26.7% cases and 3.3% controls LSCS was done because of MSL and the difference was statistically significant (p value <0.01). The colour of liquor was clear in 43.3% cases and 90% controls. The liquor was meconium stained in 53.3% cases and 10% controls and it was tobacco juice coloured in 3.3% cases and 0% controls. The difference was statistically significant (p value <0.001). 80% cases and 98.3% controls had average blood loss during the delivery while 20% cases and 1.7% controls had more than average blood loss (PPH) during the delivery. In our study 16.7% cases had serum bile acid level between 10-19.9 µmol/l, 53.3% cases had serum bile acid value between 20-39.9 µmol/l, 30% patients had serum bile acid level ≥40 µmol/l. The serum bile acid level of one patient (1.7%) was >100 µmol/l and another one patient (1.7%) had serum bile acid level >200 µmol/l.

Table 1: Association of serum bile acids level with fetomaternal outcome.

Maternal outcome	Bile acid 10-19.9 µmol/l (n=10) (%)	Bile acid ≥20 µmol/l (n=50) (%)	P value
Mode of delivery			
VD	8 (80)	26 (52)	<0.00001**
LSCS	2 (20)	24 (48)	<0.00001
Induction of labour	6 (75)	25 (53.2)	<0.0012*
Need of augmentation	5 (62.5)	13 (27.7)	<0.00001*
Meconium-stained liquor	5 (50)	27 (54)	0.56*
Fetal distress	0	10 (20)	<0.00001**
PPH	0	12 (24)	0.<0.00001**
IUD	0	2 (4)	0.04**
Fetal outcome			
Prematurity	1 (10)	9 (18)	0.1**
Neonatal intensive care unit admission due to MAS and RDS	0	9 (18.8)	<0.00001**

*Chi square test or **fisher exact test applied

Table 2: Receiver operating characteristics curves of bile acid level for predicting MSL, IUD and NICU admissions.

	MSL	IUD/perinatal death	NICU admission
Area under curve (AUC)	0.59 (0.44-0.74)	0.95 (0.90-1.0)	0.50 (0.32-0.68)
Standard error	0.07	0.02	0.09
p-value	0.20	<0.01	0.96
Cut-off	33.7	64.19	32.85
Sensitivity (95% CI)	53.12 (34.74-70.91)	100% (29.3-100)	22.2 (2.81-60.01)
Specificity (95% CI)	71.43 (51.33-86.78)	91.2% (80.7-97.1)	55.1 (40.23-69.33)
PPV (95% CI)	68 (52.09-80.59)	37.5 (20.62-58.1)	8.33 (2.51-24.29)
NPV (95% CI)	57.14 (46.27-67.36)	100 (93.15-100)	79.41 (71.48-85.58)

Table 1 shows association of serum bile acid levels with maternal and fetal outcome in cases of IHCP.

Figure 2 shows that there is a positive correlation between levels of serum bile acid and ALT/ SGPT in IHCP cases.

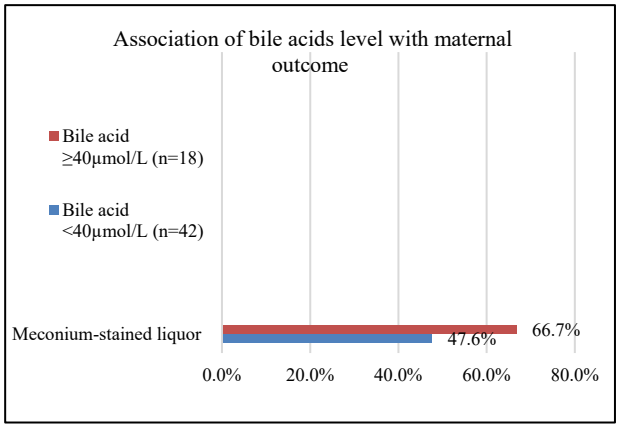

Figure 1: Association of bile acid levels with maternal outcome.

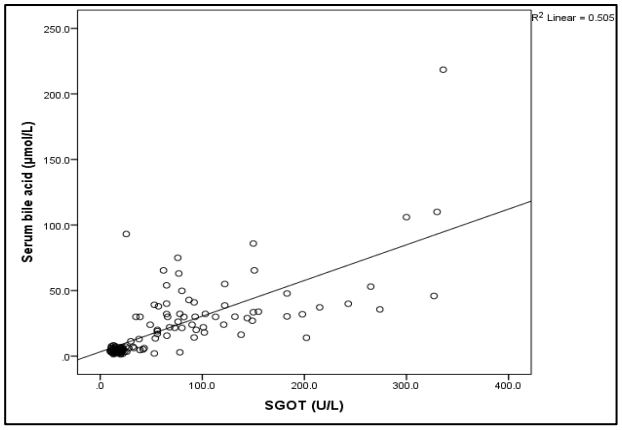

Figure 2: Scatterplot showing correlation of serum bile acid level with ALT/ SGPT in IHCP cases.

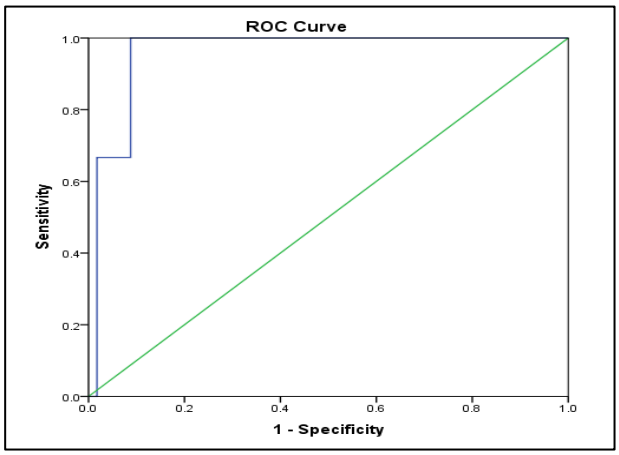

Figure 3: Receiver operating characteristics curve of bile acid level for predicting IUD/perinatal death.

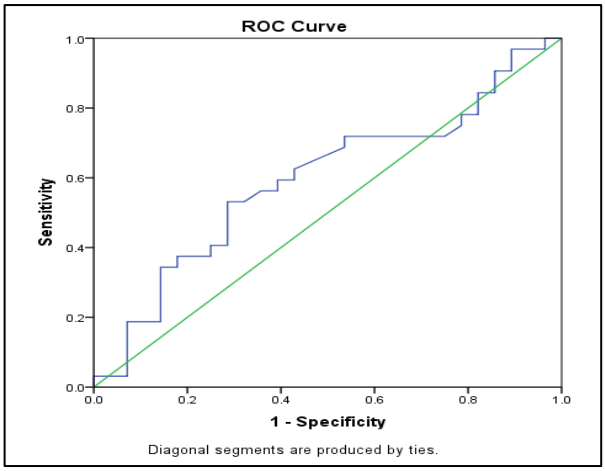

Figure 4: Receiver operating characteristics curve of bile acid level for MSL.

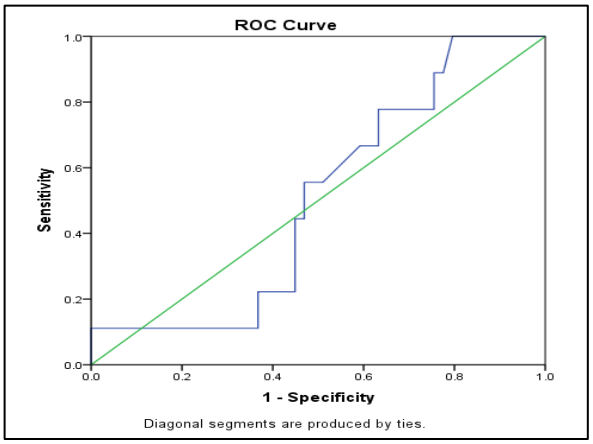

Figure 5: Receiver operating characteristics curve of bile acid level for NICU admission.

DISCUSSION

The mean age of cases and controls was 26.62±3.81 years and 25.20±3.95 years respectively which is comparable to the study conducted by Naga et al[15] where mean age of study group was 27.37±3.8 years for cases and 25.2±4.5 years for controls.[15] 36.7% cases versus 53.3% controls were primigravida and 63.3% cases versus 46.76% controls were multigravida which is comparable to each other and comparable to the study group of Jhirwal et al where 37.5% patients were primigravida and 62.5% patients were multigravida.[16] Pruritis was the main symptom in all the patients which is similar to the study conducted by Kenyon et al.[17] The mean period of gestation for diagnosis of IHCP was 34.87±2.01 weeks which is comparable to study of Jhirwal et al where 92.1% patients were diagnosed with IHCP at a period of gestation of >32 weeks and hence proving the fact that IHCP occurs in third trimester.[16] 36.6% cases had history of IHCP in previous pregnancy which is similar to that reported by Arora et al where history of cholestasis was seen in 30% cases.[18] This recurrence of IHCP is seen because of mutations in various

genes like ABCB4 gene, ABCB11. In our study 51.7% cases were being treated with tab UDCA. However, in the study conducted by Arora et al 88% patients received tab UDCA, 26% required local emollients and 4% required antihistaminic drugs.[18] Over the course of the study we found out that GHTN developed in 13.3% cases and 8.3% cases developed preecclampsia while the controls which developed GHTN or preecclampsia were excluded from the study. However, in the study conducted by Naga et al GHTN developed in 6.6% cases and 5% controls, pre-eclampsia developed in 31.6% cases and 3.3% control.[15] In our study 48.3% cases underwent into spontaneous onset of labour while induction of labour was done in 51.7% cases however, in the study conducted by Jhirwal et al induction of labour was done in 60.53% cases and 32.2% patients underwent into spontaneous labour.[16] Augmentation of labour was not required in 67.3% cases versus 47.5% controls. This statistically significant difference (p value 0.003) was found as the increased levels of bile acids are associated with increased expression of oxytocin receptors and increased sensitivity of myometrium to oxytocin. The mean period of gestation for termination of pregnancy/onset of labour in our study was 37.50±1.20 weeks for cases and 38.77±1.19 weeks for controls. In the study conducted by Jhirwal et al 2% cases were delivered between 28-31+6 weeks, 13.8% cases were delivered between 32-36+6 weeks, 82.2% patients were delivered between 37-39+6 period of gestation and 2% were delivered at or above 40 weeks of gestation.[16] We also found out that IHCP per say is not an indication of LSCS but increasing rates of LSCS are seen in the cases of IHCP because of meconium staining of liquor and fetal distress. In our study the meconium staining of liquor occurred in 53.3% cases and 10% controls. In the study conducted by Naga et al meconium staining of liquor was seen in 25% cases and 16.7% controls.[15] However, in the study conducted by Gupta et al meconium staining of liquor was seen in 24.7% cases.[19] Gupta et al observed that meconium staining of liquor was seen in 18.37% cases.[20] The meconium staining of liquor occurs in the cases of IHCP because raised bile acids increase the gut motility of fetus which results in the passage of meconium by the fetus. We also found that 20% cases versus 1.7% controls developed PPH during the delivery however, in the study conducted by Gupta et al PPH was observed in 9.18% cases and in the study conducted by Naga et al PPH was observed in 1.6% cases.[15,20] The increased rates of PPH are seen in the cases of IHCP due to vitamin K deficiency induced coagulopathy. In our study 3.3% cases were IUD (babies died in-utero) and 1.7% babies of cases died within 7 days of life due to RDS. Gupta et al observed that 3.06% babies died in-utero and 7.14% cases had neonatal death.[20] Jhirwal et al observed that still birth occurred in 1.32% cases.[16] Arora et al observed that intrauterine death occurred in 2% cases.[18] Intrauterine death occurs in the cases of IHCP as bile acids are cardiotoxic and cause fetal arrhythmia leading to sudden IUD. Also raised bile acids cause constriction of placental vasculature leading to sudden IUD. Neonatal death occurred because of meconium aspiration syndrome and RDS (respiratory distress syndrome). NICU admission was required in 15.5% cases and 5% controls however, Naga et al observed that NICU admission was required in 31.7% cases and 18.3% controls.[15] In the study conducted by Arora et al NICU admission was required in 2% cases and 3% controls.[18] In the study conducted by Gupta et al it was being observed that NICU admission was required in 20.41% cases.[20] The increasing rates of NICU admission are seen in the cases of IHCP as meconium staining of liquor results in meconium aspiration syndrome and RDS in baby.

We have also found a positive correlation between the levels of serum bile acid and level of ALT (r value of 0.355 and p value of 0.005), AST levels (r value 0.383 and p value of 0.003), total bilirubin levels (r value 0.355, p value 0.005), direct bilirubin (r value 0.145, p value 0.271). This finding is similar to the study conducted by Jhirwal et al where a significant positive correlation was found between maternal serum bile acid and total bilirubin (r=0.48, p value <0.001), aspartate aminotransferase (r=0.48, p value <0.001) and a weak correlation was found between serum bile acid with alkaline phosphatase (r=0.10, p value 0.22).[16,17] As shown in Table 2 and Figures 3-5 MSL can be predicted at 33.7 µmol/l bile acid cut off with optimum sensitivity (53.12%) and specificity (71.43%); IUD can be predicted at 64.19 µmol/l bile acid cut off with optimum sensitivity (100%) and optimum specificity (91.2%); and NICU admission can be predicted at 32.85 µmol/l bile acid with sensitivity (22.2%) and specificity (55.1%). For predicting preterm delivery, a cut-off value of 29.45 µmol/l had a sensitivity and specificity of 90% and 42% respectively.

At bile acid level ≥64.19 µmol/l early termination of pregnancy should be done after 34weeks in order to prevent IUD in cases of IHCP. At bile acid level ≥33.7 µmol/l termination of pregnancy should be done by 38 weeks to obtain optimal fetomaternal outcome and avoid MSL.

Limitations of this study are the study was conducted in a single centre which might not be a representative of the whole population. Small sample size could influence the results. Further, there could be variations according to the geographic and racial factors and use of ursodeoxycholic acid (UDCA).

CONCLUSION

Significantly higher number of adverse fetomaternal outcomes have been found in the cases of intrahepatic cholestasis of pregnancy as compared to the controls. Increase in the level serum bile acid is found to be associated with increased incidence of adverse fetomaternal outcomes. The adverse fetomaternal outcomes need to be predicted well in time so as to prevent them. Management can be optimized by timely prediction of adverse fetomaternal outcomes with the help of

monitoring serum bile acid levels among pregnant women with IHCP.

Recommendations

Bile acids level should always be done in every antenatal patient complaining of itching and IHCP should be considered as high risk pregnancy. Early termination of pregnancy may be considered in the patients with IHCP.

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