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Correlative analysis between ursodeoxycholic acid and cardinal symptoms of intrahepatic cholestasis of pregnancy: a randomized controlled study

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ABSTRACT

Objective. The present study investigated the correlation between ursodeoxycholic acid and the cardinal symptoms of intrahepatic cholestasis of pregnancy (IHCP). This study also investigated the dose-dependent effect of ursodeoxycholic acid (UDCA) in reducing adverse maternal and foetal outcomes.

Materials and Methods. In this randomized controlled study, a comparative analysis of various treatment regimens was done by administering varied treatment medications to pregnant women having IHCP. Blood investigations, such as complete blood count and liver function tests, were done to evaluate the efficacy of UDCA. Moreover, maternal and foetal outcomes were assayed to determine the effective UDCA dose in treating IHCP.

Results. The prevalence of IHCP in our study was 9.7%. Out of 101 singleton pregnant women, 8 had mild IHCP, 32 had moderate and 61 had severe IHCP. A very highly significant difference in the serum bile acid levels ($p < 0.0001$) as well as in the score of pruritus ($p < 0.0001$) was observed in enrolled subjects who were treated with UDCA. Additionally, adverse maternal and foetal outcomes were significantly reduced in subjects receiving UDCA treatment.

Conclusions. This study demonstrated that UDCA significantly improved the patient's subjective and clinical state, reduced laboratory markers, such as elevated SGOT, SGPT, and bile acid levels as well as improved fetomaternal outcomes. It also concluded that a 300 mg BD dose of UDCA is the most effective dose in reducing bile acid levels and in treating IHCP.

INTRODUCTION

IHCP (intrahepatic cholestasis of pregnancy) is the most prevalent form of hormonally induced cholestasis. It is one of the most common gesta-

tional liver diseases unique to pregnancy that adversely affects maternal well-being and fetal outcomes [1]. It usually occurs in the later phase of the second trimester or early phase of the third trimester [2]. This disease has a genetic propen-

sity that usually occurs in the later phase of pregnancy [3] and disappears after the birth of the baby. Geographical location and ethnicity have a greater impact on its incidence [4]. Although the exact cause of IHCP is unknown, however, the presence of hormonal, environmental, and genetic factors allude to a multifactorial origin [5]. It is believed that one of the genetic causes of IHCP is mutations in the MDR3 gene, which codes for canalicular Phosphatidylcholine Translocase. Additionally, there are clinical shreds of evidence suggesting that progesterone and estrogen play a pivotal role in the development of IHCP [4, 6]. Furthermore, environmental factors such as decreased levels of selenium concentration and glutathione peroxidase activity in winter make the anti-oxidation pathway defective as both of them are required for the antioxidant mechanism and thus play a crucial role in the development of IHCP [7].

Ursodeoxycholic acid is the first choice of drug in the treatment of IHCP [8]. It increases the flow of bile [9] strengthens the bicarbonate environment that shields cholangiocytes from damage [10] and shields the liver from apoptosis spurred on by increased bile acid levels [10]. This treatment has anti-inflammatory properties [11] and could lower the elevated serum bile acid levels in the foetus [12], possibly through increased placental bile acid export. Ursodeoxycholic acid is considered safe even though it is not approved during pregnancy. The most frequent side effect is gastrointestinal distress; however, no serious side effects have been reported to date [13, 14]. Therefore, this drug is considered the most promising and effective drug for treating IHCP. Usually, a dose of 15-25 mg/kg/day in divided doses is recommended for its treatment.

The relationship between several IHCP risk factors and foeto-maternal outcomes, as well as the relationship between maternal bile acid levels and liver function test variables, are not well documented. To improve obstetrical outcomes without endangering perinatal outcomes, this study was conducted to evaluate the relationship between the severity of IHCP and foeto-maternal outcomes. Additionally, this study investigated the efficacy and safety of ursodeoxycholic acid (UDCA) in reducing adverse foeto-maternal outcomes. Furthermore, the dose-dependent effect of UDCA was monitored and it also provides the most effective dose for producing favourable results.

MATERIALS AND METHODS

Study design and setting

This randomized controlled study was conducted on pregnant women who visited the Department of Obstetrics and Gynaecology, SGT Hospital from July 2023 to July 2024.

Sample size calculation

The sample size was calculated using the G-Power statistical analysis program using the required variables such as the power of the study, α -value, and type of statistical test. Using these variables, the sample size (n) came to be 98. Considering the percentage of dropouts to be 10%, the adjusted sample size came to 101. But in our study, there was no dropout.

Study procedure

The subjects were first screened based on the diagnostic criteria of IHCP [6] which are mentioned below:

- pruritus with or without papules on the skin
- serum bile acid level of more than 10 micromole/L

The screened subjects were then enrolled in the study based on the inclusion and exclusion criteria. The inclusion and exclusion criteria were as follows:

Inclusion criteria:

- Singleton pregnant women with at least 20 weeks of gestational age and had pruritus and serum bile acid level of 10 micromole/L or more
- Willingness to participate

Exclusion criteria

- Multi-foetal pregnancies
- Maternal/foetal heart disorders
- Liver disorder: Hepatitis C, Hepatitis B, Cholelithiasis
- Medication for any dermatological disease, which can cause itching
- Any hormonal contraceptive or oestrogen-containing drugs

Evaluation

The informed consent of recruited subjects was taken before their enrolment in this study. Enrolled subjects were either divided into 3 groups (mild, moderate, and severe) based on the severity of IHCP or into 6 groups (no treatment, UDCA, UDCA+Levocetirizine, UDCA+Calamine lotion, UDCA+Levocetirizine+Calamine lotion, LCZ/Calamine lotion or both) based on the treatment regimens they received. Subjects were then evaluated

using the following algorithm (the set of instructions or procedures followed in the study, detailed below).

History

The patient's age, parity, and history of previous pregnancies were asked. All the vitals were recorded.

Examination

The patient's general examination like blood pressure, weight, height, and pulse rate were also noted at the time of enrolment and during follow-up visits. Other investigations and features suggestive of IHCP were also examined such as Complete blood count (Platelets and Hb count), and liver function test (bile acid, SGPT, SGOT, ALP, bilirubin) at the time of enrollment and termination of pregnancy. The maternal and foetal outcomes were also assessed during the study.

The assessed maternal and foetal parameters outcomes were as follows:

- Maternal parameters:
- Onset of pruritus and severity of IHCP
- Gestational age at the time of diagnosis and termination of pregnancy
- Associated morbidities such as thyroid, blood pressure, diabetes, etc.
- Mode of delivery, need for blood transfusion, or post-partum complications
- Blood investigations during enrolment and termination of pregnancy
- Efficacy of investigational drug during the study

Foetal parameters:

- Birth weight
- Stillbirth/ Neonatal death/ preterm birth [15]
- Meconium-stained liquor
- Neonatal admission
- APGAR score at 5 minutes [16]
- Jaundice in neonate.

General questions

Enrolled subjects were asked a set of validated questionnaires.

Drug administration

Every enrolled subject was subsequently treated with varied treatment regimens based on the severity of IHCP. Group I received no treatment (n = 8), Group II received UDCA (n = 55), Group III received UDCA+Levocetizine (n = 7), Group IV received UDCA+calamine lotion (n = 14), Group V received UDCA+Levocetizine+calamine lotion (n = 14), and Group VI received Levocetizine / ca-

lamine lotion or both (n = 3). Liver enzyme tests were performed at the time of enrolment and termination of pregnancy. All enrolled subjects were followed up and clinically assessed in high-risk prenatal clinics. Various routine examinations such as foetal surveillance, modified biophysical profile, and ultrasonography were done as per the hospital's protocol. Each enrolled subject without spontaneous preterm birth was admitted to the hospital by 37 weeks of POG and was delivered by the appropriate method as per the protocol of the hospital. Several foeto-maternal outcomes such as POG of termination of pregnancy, onset of labour, pregnancy outcome, mode of delivery, post-partum complication, weight of baby at the time of birth, neonatal intensive care unit admissions, APGAR score at 5th minute, and other foetal and neonatal morbidity were recorded.

Data collection

All antenatal care (ANC) OPD and labour room patients diagnosed with IHCP were recruited in this study. Since this was a randomized controlled study, the data of recruited subjects was collected and recorded in the validated questionnaire for analysis.

Outcomes

The primary outcome of the study was the change in the pruritus score and bile acid levels with the administration of UDCA. The secondary outcomes were maternal (hypertension, maternal age, and gravida) and foetal (stillbirth, APGAR score, birth weight) outcomes.

Statistical analysis

The collected data were tabulated in Microsoft Excel and analysed using Prism-GraphPad version 10.2.3 [14]. Continuous variables were described as mean, range, and standard deviation, while categorical variables were presented as percentages. Comparisons of categorical variables were analysed using the Chi-square test or, Fisher's exact test. Continuous variables were analysed using the 2-way ANOVA to calculate P-values. A P-value < 0.05 was considered statistically significant.

RESULTS

The present study was conducted over one year. Total deliveries during the study period were 1,037,

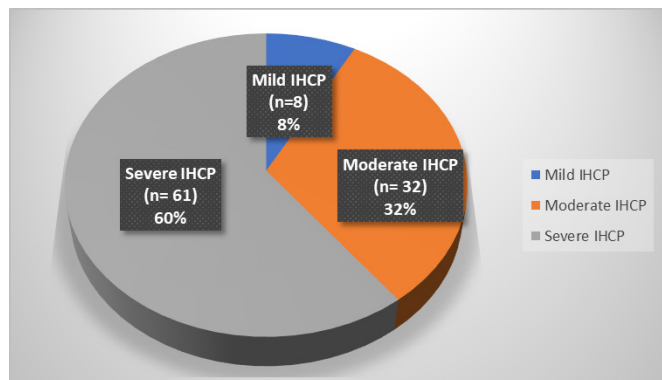


Figure 1. Pie chart representing % and number (n) of mild, moderate, and severe IHCP cases.

out of which 101 were IHCP cases. The prevalence of IHCP in our study was 9.7%. Out of 101 singleton pregnant subjects, 8 (7.92%) had mild IHCP (score of pruritus ≤ 1), 32 (31.68%) had moderate IHCP (1 < score of pruritus ≤ 2), and 61 (60.39%) had severe IHCP (score of pruritus > 2) [17] (**Figure 1**). Only one case of stillbirth was reported in our study out of 101 enrolled subjects.

The maternal demographic profile of enrolled subjects was adjusted, and all the subjects were divided into three groups based on the severity of IHCP *i.e.* mild, moderate, and severe. All the data

related to maternal demography was then presented as mean ± standard deviation. Tukey’s multiple comparisons test of the Two-way ANOVA model was used to compare categorical variables (**Table 1**). It was observed that there was no significant difference found in terms of maternal age, BMI, Gravida, and diastolic pressure. However, clinically significant differences were observed in the period of gestation (POG) at diagnosis and in the systolic pressure.

Enrolled subjects were divided into 6 groups based on the treatment regimen they received and the score of pruritus and bile acid levels was then measured. The score of pruritus was presented as mean ± standard deviation on the 1st, 5th, 9th, and 14th day of the treatment (**Table 2**), and the change in serum bile acid levels before and after varying treatment regimens was also presented as mean ± standard deviation (**Table 3**) and the P-value and levels of significance were recorded. A clinically significant difference in the pruritus score at day 14 was observed in Group II (n = 55) which received UDCA treatment as compared to Group I, III, IV, V, and VI (n = 46) which received treatment other than UDCA. In contrast, no significant difference was observed when other treatments or adjuvants

Table 1. Effect of severity of IHCP on maternal demography.

S.No.	Maternal demography	Tukey's multiple comparisons test			Statistical results	
		Mild (n = 8)	Moderate (n = 32)	Severe (n = 61)	P-value	Significance
1	Maternal age (Years)	24.37±4.0	26.70±4.4	27.18±4.51	0.6357	ns
2	POG at diagnosis (days)	271.50±6.7	260.84±9.2	261.65±8.65	0.0001	***
3	BMI	32.75±11.1	28.31±9.9	27.65±3.14	0.1937	ns
4	Gravida	1.25±1.0	1.25±0.9	1.19±0.82	0.9990	ns
5	Systolic pressure (mm/Hg)	124.25±12.6	117.78±8.2	117.08±6.88	0.0095	**
6	Diastolic pressure (mm/Hg)	77.75±10.2	76.5±7.15	74.11±6.23	0.8771	ns

Data represented as mean ± standard deviation, data were analysed by two-way ANOVA followed by Tukey’s multiple comparisons test. **Very significant, ***highly significant difference; ns: not significant difference.

Table 2. Change in the score of pruritus with different treatment groups.

Groups	Number of Subjects (n)	Treatment Regimen	Tukey's multiple comparisons test				Statistical results	
			Score of Pruritus				P-value	Significance
			Day 1	Day 5	Day 9	Day 14		
I	8	No treatment	1.0±0.0	1.0±0.0	0±0.5	0.0±0.5	>0.9999	ns
II	55	Ursodeoxycholic acid (UDCA)	2.6±0.7	2.0±0.7	1.2±0.6	0.34±0.47	<0.0001	****
III	7	UDCA+ Levocetrizine (LCZ)	3.1±0.3	2.4±0.4	1.7±0.4	0.57±0.49	<0.0001	****
IV	14	UDCA+ Calamine lotion	2.9±0.4	2.0±0.3	1.5±0.6	0.6±0.61	<0.0001	****
V	14	UDCA+ LCZ+ Calamine lotion	3.2±0.5	2.4±0.6	1.78±0.55	0.78±0.55	<0.0001	****
VI	3	LCZ/ Calamine lotion or both	1.3±0.4	1±0	1±0	1±0	0.9045	ns

Data represented as mean ± standard deviation, data were analysed by two-way ANOVA followed by Tukey’s multiple comparisons tests. ****Very highly significant difference; ns: not significant difference.

Table 3. Change in the serum bile acid levels before and after varying treatment regimens.

Groups	Treatment regimen	Tukey's multiple comparisons test		Statistical results	
		Change in Bile acid levels (micromol/L)		P-value	Significance
		Before treatment	After treatment		
I	No treatment	29.80±16.08	25.75±16.97	>0.9999	ns
II	Ursodeoxycholic acid (UDCA)	74.98±49.77	24.65±20.23	<0.0001	****
III	UDCA+ Levocetirizine (LCZ)	67.17±53.63	55.00±51.89	0.9944	ns
IV	UDCA+ Calamine lotion	90.90±54.07	70.70±50.60	0.6931	ns
V	UDCA+ LCZ+ Calamine lotion	87.76±49.58	64.35±44.70	0.5736	ns
VI	LCZ/ Calamine lotion or both	19.44±15.19	16.11±14.94	>0.9999	ns

Data represented as mean ± standard deviation, data were analysed by two-way ANOVA followed by Tukey's multiple comparisons test. ****Very highly significant difference; ns: not significant difference.

Table 4. Change in the laboratory variables before and after the treatment

S.No.	Laboratory investigation	Sidak's multiple comparisons test		Statistical results	
		Before treatment	After treatment	P-value	Significance
1	Serum bile acid	73.09±52.04	24.60±12.70	<0.0001	***
2	SGOT	150.63±150.63	152.49±122.54	0.0433	*
3	SGPT	152.49±152.49	145.02±124.40	0.0246	*
4	ALP	327.73±126.78	327.73±126.78	>0.9999	ns
5	Platelet count	1.759±0.38	1.75±0.38	>0.9999	ns
6	Hb	11.10±1.55	11.76±1.66	>0.9999	ns
7	Bilirubin	0.99±0.52	0.99±0.52	>0.9999	ns

Data represented as mean ± standard deviation, data were analysed by two-way ANOVA followed by Sidak's multiple comparisons tests. *Significant, **very significant, ***highly significant difference; ns: not significant difference.

Table 5. Comparison of foetal outcomes based on the severity of IHCP.

S.No.	Foetal outcomes	Sidak's multiple comparisons test			Statistical results	
		Mild IHCP (≤ 40 µmol/L)	Moderate IHCP (40-100 µmol/L)	Severe IHCP (> 100 µmol/L)	P-value	Significance
1	POG at diagnosis (days)	243.7±21.77	231.86±61.5	250.40±15.78	0.173	*
2	POG at termination (days)	266±33.15	264.4±9.77	257.20±40.38	0.969	ns
3	Apgar Score	7.76±1.44	7.73±0.67	7.95±0.52	>0.9999	ns
4	Birth weight (Kg)	2.71±0.53	2.75±0.73	2.77±0.39	>0.9999	ns

Data represented as mean ± standard deviation, data were analysed by two-way ANOVA followed by Sidak's multiple comparisons test. *Significant difference; ns: not significant difference. No significant difference was found in foetal outcomes in mild and severe IHCP.

such as antihistaminic (Levocetirizine or calamine lotion) were added to UDCA treatment.

Furthermore, the serum bile acid levels of enrolled subjects were also assessed with varying treatment regimens. A clinically significant difference was observed in the serum bile acid levels when the subject received UDCA treatment. In contrast, no significant difference was observed when other treatments or any adjuvant such as antihistaminic (Levocetirizine or calamine lotion or both administered to Group III, IV, V, and VI) was added to UDCA treatment.

Laboratory investigations were done at the time of enrolment of the subject as well as at the termination of pregnancy. The data were presented as mean ± standard deviation. Sidak's multiple comparisons test of two-way ANOVA was done to analyse the data (Table 4). A clinically significant difference was observed in serum bile acid levels, SGPT, and SGOT. In contrast, no significant difference was found in other laboratory investigations. The comparison of foetal outcomes based on the severity of IHCP in terms of serum bile acid levels was also assessed during the study (Table 5). All

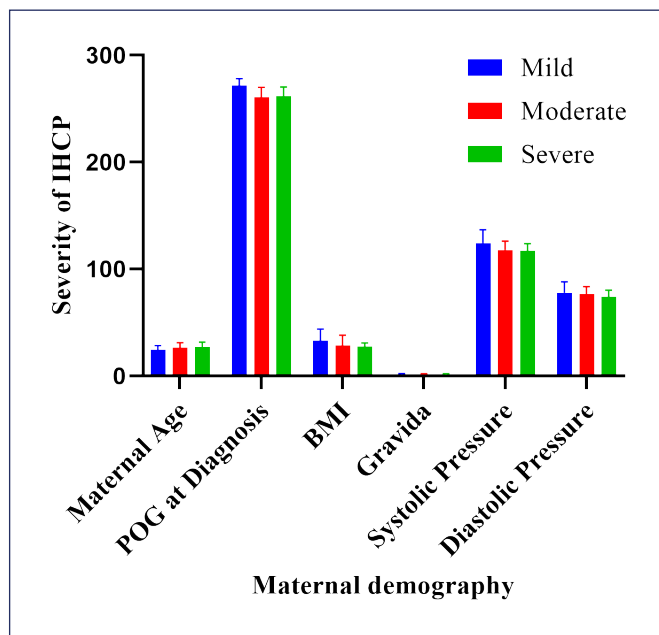


Figure 2. Comparison of enrolled subjects based on the severity of IHCP in terms of maternal demography.

the data related to foetal outcomes were presented as mean ± standard deviation. Sidak’s multiple comparisons test of two-way ANOVA was used to interpret the results. It was observed that a clinically significant difference was found in the period of gestation at delivery however no significant difference was found in other foetal outcomes based on the severity of IHCP.

The dose-related efficacy of ursodeoxycholic acid was also assessed by dividing the subjects into various groups based on the dose they consumed. The serum bile acid levels were compared before and after the administration of the test drug, *i.e.*, UDCA. The data was then presented as mean ± standard deviation (Table 6). Tukey’s multiple comparisons test of the two-way ANOVA model

was used to compare categorical variables. A clinically significant difference was observed in serum bile acid levels on administration of 300 mg BD and 300 mg TDS. However, no significant difference was found after the administration of the remaining doses.

DISCUSSION

IHCP is a pregnancy-specific disease having a varied incidence of 0.2-2% worldwide [6]. The prevalence of IHCP in our study was 9.7% which was much greater than previous studies [18, 19]. The incidence varies significantly depending on area and ethnicity [20, 21]. Earlier studies also reported that IHCP affects Asian women about twice in comparison to European women [22]. However, there is a lack of data on the prevalence of IHCP in India. The exact causes of this variance are unknown; however, population and ancestry studies point to a genetic influence [23, 24].

Maternal demography

The subjects were divided into three major groups based on the severity of IHCP (Figure 2). It was observed that there was no significant difference between maternal age and IHCP which is consistent with the findings of Hochler *et al.* [25]. Furthermore, no correlation was found between gravida and IHCP which is consistent with the findings of previous studies despite there being an increased incidence of IHCP in a multifetal pregnancy [5, 26]. However, there was a highly significant difference in POG at diagnosis and a very significant difference in systolic pressure of enrolled subjects. These findings are consistent with a study done by Brouwers *et al.* [27].

Table 6. Dose-related efficacy of Ursodeoxycholic acid based on serum bile acid levels.

Group	Number of subjects	Dose of UDCA	Tukey’s multiple comparisons test		Statistical results	
			Serum bile acid levels		P-value	Significance
Before treatment	After treatment					
I	1	150 mg OD	75.6±0	54±0	0.996	ns
II	11	150 mg BD	36.16±24.79	18.90±16.04	0.9286	ns
III	2	150 mg TDS	142±0	100.50±11.50	0.9202	ns
IV	2	300 mg OD	34±0	18±0	0.9995	ns
V	42	300 mg BD	69.38±50.25	34.14±44.82	0.0018	**
VI	35	300 mg TDS	100.22±47.23	68.25±42.67	0.0153	*

Data represented as mean ± standard deviation, data were analysed by two-way ANOVA followed by Tukey’s multiple comparisons tests. *Significant, **very significant difference; ns: not significant difference.

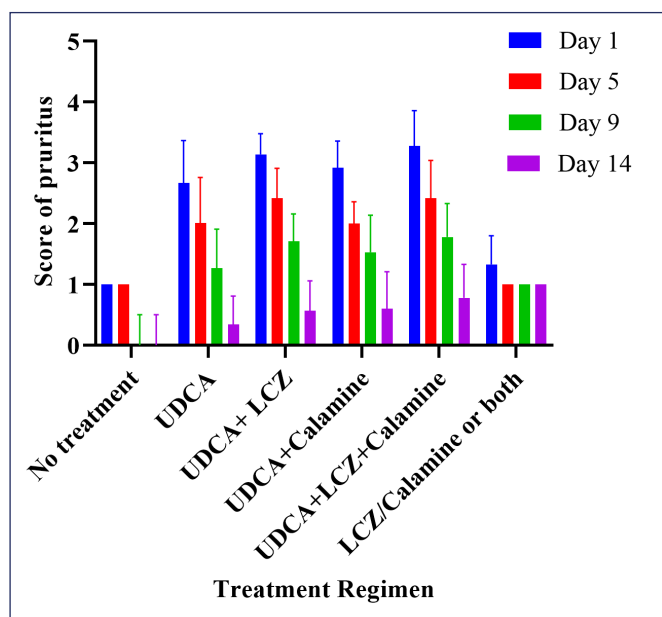


Figure 3. Comparison in varying treatment regimens in terms of the score of pruritus measured at days 1, 5, 9, and 14.

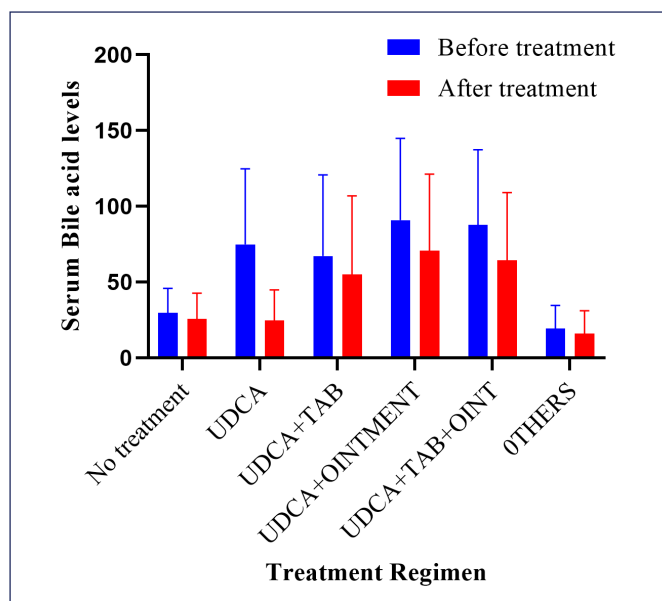


Figure 4. Change in the serum bile acid levels before and after varying treatment regimens.

Table 7. Dose-related efficacy of Ursodeoxycholic acid based on serum bile acid levels.

S.No.	Characteristic	Severity of pruritus	Pruritus score
1	No itching	No itching	0
2	Light itching with scratching	Mild	1
3	Itching on without relieving after scratching	Moderate	2
4	Itching on after scratching with hurting skin	Severe	3
5	Dysphoria	Very severe	4

Data represented as mean ± standard deviation, data were analysed by two-way ANOVA followed by Tukey's multiple comparisons tests. *Significant, **very significant difference; ns: not significant difference.

Cardinal symptoms of IHCP

The two important cardinal symptoms of IHCP are pruritus and elevated serum bile acid levels. These two parameters were evaluated by dividing the enrolled subjects into various groups based on the treatment they were taking. The score of pruritus as well as serum bile acid levels were measured appropriately. The score of pruritus was calculated using the pruritus scale (Table 7).

No significant difference was seen in the control group (Group I: no treatment received) and the group who were receiving only antihistaminic drugs (Figure 3). This indicates that antihistaminic drugs like levocetirizine and calamine lotion do not treat the problem of pruritus in IHCP patients. However, a very highly significant difference was observed in the groups receiving UDCA treatment as monotherapy as well as the group receiving UDCA and antihistaminic tablet/ointment or both. These findings suggested that both treatment regimens improved the score of pruritus. However, the combined treatment regimens had no additive effect on the score of pruritus. These findings are consistent with Binder *et al.* [28], Kondrackiene *et al.* [29] and Morton and Laurie [30].

The same groups were taken, and their serum bile acid levels were measured at the time of enrolment and termination of pregnancy. A very highly significant difference was observed in the group receiving UDCA as a drug whereas other groups showed no significant difference (Figure 4). This finding is consistent with the study done by Bull and Vargas [31] and Qureshi *et al.* [2].

Based on the findings of our study, we can conclude that UDCA is the most effective drug for improving the pruritus score and reducing serum bile acid levels. Both of these are important cardinal symptoms for the occurrence of IHCP. Therefore, UDCA is regarded as the most efficacious and safest drug for treating IHCP.

Biochemical estimation

IHCP is a hepatobiliary disorder of pregnancy and deranged liver enzymes are often seen in this condition. Therefore, the liver function test is one of the diagnostics markers for its diagnosis. In the present study, the biochemical tests of enrolled subjects were done at the time of enrolment and at the time of termination of pregnancy. No significant difference was seen in ALP, platelet count, Hb, and bilirubin levels before and after the treatment with

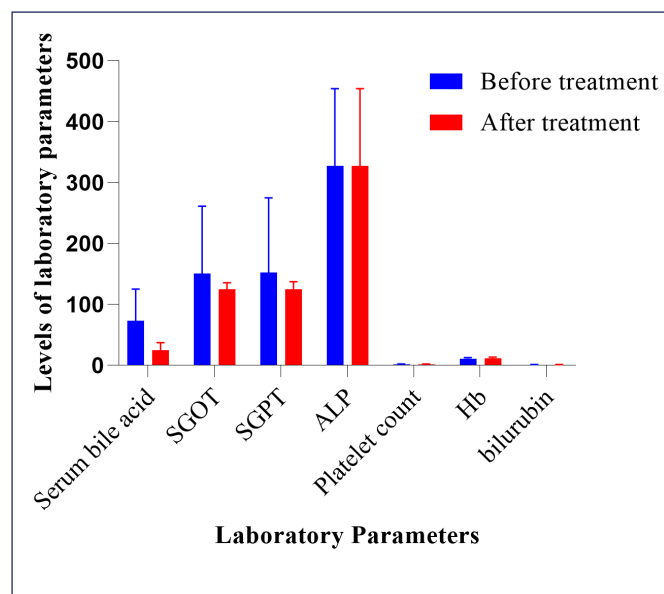


Figure 5. Change in the laboratory investigation before and after the treatment

UDCA (Figure 5). However, a very highly significant difference was observed in bile acid levels, and a significant difference was observed in SGOT and SGPT levels. These findings suggested that UDCA reduced the bile acid significantly and consequently reduced the adverse foetal outcomes. Furthermore, it also reduced the SGOT and SGPT levels and thus improved the liver profile of the patients treated with UDCA drug. Therefore, this drug might be the most recommended drug for treating IHCP.

Foetal outcomes

All the enrolled subjects were divided into three groups *i.e.* mild IHCP (≤ 40 micromol/L), moderate (41-100), and severe IHCP (> 100 micromol/L) based on their serum bile acid levels [5]. No significant difference was observed in POG at termination, birth weight, and APGAR Score. However, a clinically significant difference was found in POG at diagnosis (Figure 6). This suggested that UDCA treatment had beneficial effects in reducing adverse foetal outcomes as even in severe cases of IHCP, there were very less reported cases of preterm birth or underweight children. This is also supported by a meta-analysis done by Kong *et al.* [32].

Dose-dependent effect of UDCA in treating IHCP

Different doses of UDCA were recommended based on the severity of IHCP of individual subjects. Furthermore, the doses were titrated where needed. Subjects were divided based on the dose they were taking. No significant differences were found

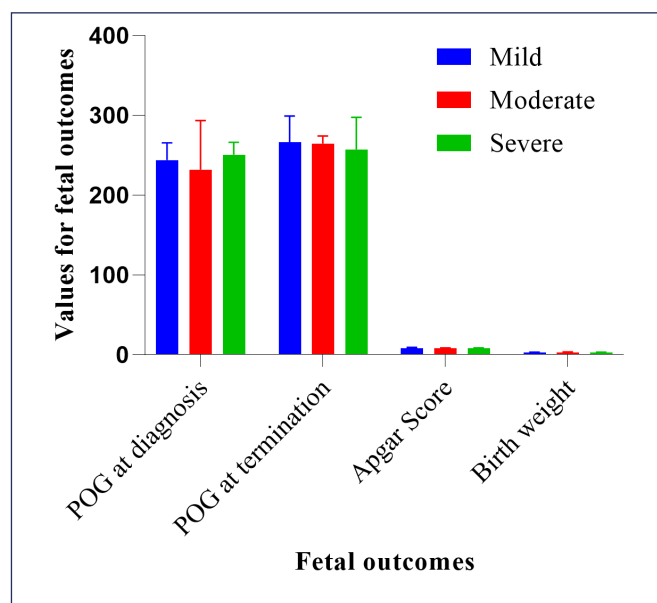


Figure 6. Change in the foetal outcomes with severity of IHCP.

at doses of 150 mg OD, 150 mg BD, 150 mg TDS, and 300 mg OD. However, a highly significant difference was found at a dose of 300 mg BD and a significant difference was found at a dose of 300 mg TDS (Figure 7). This finding revealed that a dose of 300 mg BD might be the most effective dose in reducing elevated serum bile acid levels. Based on these results, we can predict that UDCA has a $t_{1/2}$ of 12 hours and therefore after a gap of 12 hours, the subject needs to take another dose of UDCA to keep the serum bile acid levels in range.

Study strengths

To date, there has been no study reported about the comparative analysis of antihistaminic drugs *versus* UDCA. Furthermore, no study reported the dose-dependent effect of UDCA in treating IHCP.

Study limitations

Since we are constrained to only a single centre and the sample size is not good enough so these results might not be transferrable to real-world settings. Further studies are needed to assess the post-natal outcome by collecting all the problems of newborns after follow-up with the enrolled subjects till 6-8 weeks after discharge from the hospital.

CONCLUSIONS

IHCP is a hepatobiliary disease that occurs during the later phase of the second trimester and the ini-

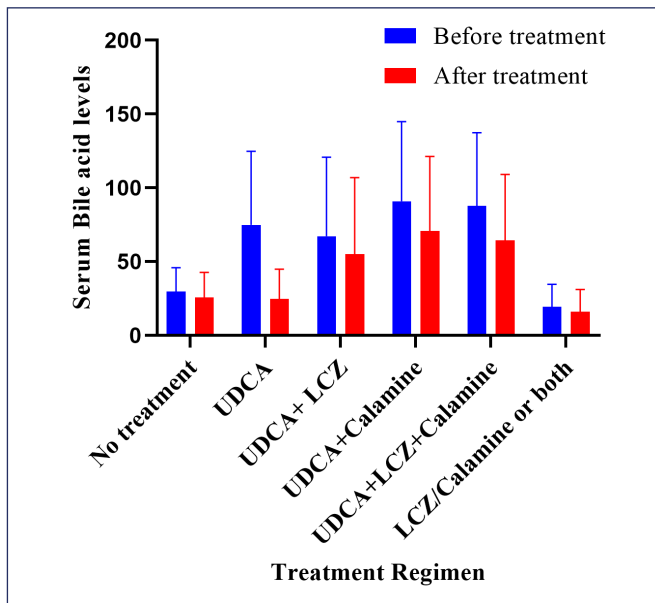


Figure 7. Dose-dependent effect of UDCA on serum bile acid levels.

tial phase of the third trimester. The present study aimed to perform a comparative analysis of foeto-maternal outcomes of enrolled subjects treated with UDCA or other treatment regimens. Furthermore, the study demonstrated that UDCA significantly improved the patient's subjective and clinical state, reduced laboratory markers, such as elevated SGOT, SGPT, and bile acid levels as well as improved foeto-maternal outcomes. Additionally, it was shown that the best dosage of UDCA for treating IHCP and lowering bile acid levels in human beings is 300 mg BD. In addition, a positive correlation was found between serum bile acid levels and termination of pregnancy but timely administration of UDCA to severe IHCP cases in our study reduces the rate of preterm birth, stillbirth, and neonatal death.

COMPLIANCE WITH ETHICAL STANDARDS

Authors' contributions

R.B.: Conceptualization, data curation, writing – review & editing, supervision. N.S.: Formal analysis, software, writing – original draft, resources. R.R.: Investigation, methodology, supervision, visualization, resources.

Funding

None.

Study registration

This study is registered in CTRI with registration number CTRI/2024/03/063580.

Disclosure of interests

The authors declare that they have no conflict of interests.

Ethical approval

The study protocol was approved by the Institutional Ethical Committee, FMHS, SGT University, Gurugram (IEC/FMHS/S/05/ /07/23-59).

Informed consent

Written informed consent was obtained from all the participants before their enrolment in the study.

Data sharing

Data are available under reasonable request to the corresponding author.

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