RESEARCH PAPER

Evaluating the Effectiveness of Ursodeoxycholic Acid (UDCA) in Reducing Bile Acid Levels and Preventing Stillbirth in Intrahepatic Cholestasis of Pregnancy (ICP)

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ABSTRACT

Background: Intrahepatic cholestasis of pregnancy remains a striking hepatic disorder experienced amid the last-mentioned half of development, checked by pruritus and lifted serum bile corrosive concentrations. Whereas ursodeoxycholic corrosive has long been endorsed for symptom relief and biochemical improvement, its part in averting unfavourable fetal results, especially stillbirth, proceeds to be wrangled about. This trial looked for to decide whether Ursodeoxycholic Corrosive UDCA organization genuinely brings down bile acid levels and decreases the frequency of stillbirth among ladies analyzed with ICP at a tertiary care office in Pakistan.

Objective: To assess the therapeutic impact of ursodeoxycholic acid on serum bile acid reduction and stillbirth prevention in pregnant women with intrahepatic cholestasis, compared with standard obstetric care alone.

Methods: A single enter, open name randomized controlled trial was conducted at Department of Medicine/Gastroenterology and Department of Obstetrics & Gynecology, Al-Aleem Medical College, Gulab Devi Hospital, Lahore -Pakistan from February 2025 to October 2025. A add up to of 160 pregnant women diagnosed with ICP (serum bile acids10 µmol/L with pruritus) between 24 and 36 weeks of development were randomly apportioned to either the UDCA gather (n=80; 15 mg/kg/day in separated measurements) or the standard care gather (n=80; schedule antenatal observing without UDCA). The essential result was the alter in add up to serum bile corrosive levels from pattern to conveyance. Auxiliary results included stillbirth rate, preterm delivery, meconium-stained amniotic liquid, neonatal seriously care unit confirmation, and maternal side effect alleviation assessed through a approved pruritus scoring framework.

Results: The UDCA group demonstrated essentially more noteworthy decrease in cruel serum bile corrosive levels compared to standard care (cruel contrast: 14.6 µmol/L; 95% CI: 18.2 to 11.0; $p<0.001$). Stillbirth occurred in 1 case (1.25%) within the UDCA arm versus 5 cases (6.25%) within the control arm (relative chance: 0.20; 95% CI: 0.02 “1.68; $p=0.09$). Preterm delivery was essentially lower within the UDCA gather (16.3% vs 31.3%; $p=0.03$). Pruritus scores progressed particularly among UDCA treated members (cruel decrease: 4.8 vs 1.2 points; $p<0.001$). Rates of meconium-stained alcohol and NICU confirmations were too lower within the mediation arm, in spite of the fact that not all comparisons came to routine measurable importance.

Conclusion: Ursodeoxycholic acid treatment in ladies with intrahepatic cholestasis of pregnancy was related with significant biochemical change and striking diminishments in antagonistic perinatal results. In spite of the fact that the decrease in stillbirth did not accomplish measurable significance in this test, the in general slant nearby diminishments in preterm birth and indication burden underpins UDCA as advantageous intercession in ICP administration. Bigger multicentre trials are justified to confirm these perceptions.

Keywords: Intrahepatic Cholestasis of Pregnancy, Ursodeoxycholic Corrosive, Bile Acids, Stillbirth, Randomized Controlled Trial, Perinatal Outcomes

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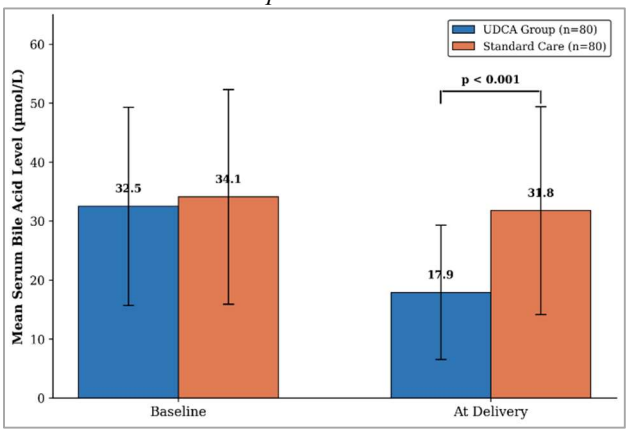
INTRODUCTION

Pregnancy brings around a cascade of physiological adaptations over numerous organ frameworks, and the hepatobiliary hub is no exemption. Among the liver related complications unconventional to incubation, intrahepatic cholestasis of pregnancy stands out as the most commonly encountered condition, regularly showing within the moment or third trimester. The hallmark highlights incorporate generalized pruritus frequently most troublesome on the palms and soles went with by biochemical prove of cholestasis, most dependably reflected by lifted add up to serum bile acid concentrations. Whereas the condition is by and large kind for the mother and resolves instantly after conveyance, its centrality lies within the potential for genuine fetal harm, including spontaneous preterm birth, meconium section in utero, fetal trouble, and within the most serious occasions, intrauterine fetal end. The worldwide prevalence of ICP changes considerably with topography and ethnicity, extending from less than one percent in most European populations to figures as high as fifteen percent in certain South American and South Asian communities. In Pakistan, in spite of the fact that exact epidemiological information stay restricted, clinical involvement proposes the condition isn't uncommon, especially within the Punjab and Sindh areas where consanguineous marriages and specific dietary designs may contribute to a better vulnerability. The clutter places a unbalanced burden on obstetric administrations in asset limited settings, where fetal surveillance capabilities may be lacking and opportune conveyance is not always attainable.

The pathogenesis of ICP is not entirely understood, but current prove focuses toward a multifactorial etiology including genetic inclination, hormonal impacts, and environmental triggers. Changes and polymorphisms in hepatobiliary transport proteins particularly those encoded by the ABCB4, ABCB11, and ATP8B1 qualities have been implicated in familial clustering of the malady. Raised estrogen and progesterone levels amid pregnancy appear to disable canalicular bile emission, driving to amassing of hydrophobic bile acids within the maternal circulation. These bile acids cross the placental barrier and collect within the fetal compartment, where they can incite cardiomyocyte damage, vasoconstriction of chorionic veins, and unusual contractility of the myometrium, each of which has been proposed as a component basic the watched fetal dangers. The administration of ICP has generally cantered on two targets: alleviating maternal side effects and moderating fetal chance. Symptomatic treatment with emollients, antihistamines, and cholestyramine gives limited advantage. Ursodeoxycholic corrosive, a hydrophilic bile corrosive actually displays in little amounts in human bile, risen within the 1990s as the most promising pharmacological specialist for this condition. Its proposed components of activity are multi fold: it uproots poisonous hydrophobic bile acids from the circulating pool, fortifies hepatocellular and cholangiocyte secretion, and may apply direct cytoprotective impacts on trophoblast cells. Different observational ponders and littler randomized trials over the past two decades have appeared steady enhancements in pruritus severity and serum bile corrosive concentrations taking after UDCA organization.

Figure 1

Comparison of Serum Bile Acid Levels Between UDCA and Standard Care Groups



In any case, the address of whether UDCA really prevents the most dreaded complication of ICP stillbirth has remained disagreeable. The point of interest PITCHES trial, an expansive multicentre placebo-controlled consider distributed in 2019, reported no measurably critical advantage of UDCA over fake treatment for a composite perinatal result that included stillbirth. This finding incited a reappraisal of clinical rules in a few nations, with a few educate scaling back their support of UDCA treatment. Pundits of the trial, in any case, have pointed out methodological concerns, including the consideration of ladies with only gently raised bile acids and a composite endpoint that will have weakened the effect on person extreme results. Subsequent metanalyses have yielded blended conclusions, and the talk about endures within the obstetric literature. In Pakistan and other South Asian nations, where the clinical profile of ICP may vary from Western cohorts in terms of severity, gestational age at presentation, and standard bile corrosive levels, locally produced probiotics are especially valuable. The display ponder was in this manner conceived to address a particular clinical address inside our possess population: does treatment with ursodeoxycholic corrosive, when started at the time of ICP determination and proceeded until conveyance, result in a important decrease in serum bile corrosive levels and, more importantly, does it translate into a lower hazard of stillbirth compared with

standard antenatal care alone? We outlined a randomized controlled trial at a single tertiary care middle to examine these questions with the thoroughness that the clinical instability requests.

MATERIALS AND METHODS

Study Design and Setting

This investigation was organized as a single enter, open name, parallel gather randomized controlled trial carried out at the Department of Medicine/Gastroenterology and Department of Obstetrics & Gynecology, Al-Aleem Medical College, Gulab Devi Hospital, Lahore -Pakistan from February 2025 to October 2025. The healing centre caters to a mixed urban and peri urban population and oversees around 8,00 conveyances yearly. Moral clearance was received from the Institutional Review Board. Composed educated assent was obtained from all members after careful explanation of the think about strategies, potential dangers and benefits, and the intentional nature of cooperation.

Participants and Eligibility

Pregnant women presenting to the antenatal clinic or conceded to the obstetric ward between from February 2025 to October 2025 were screened for eligibility. The diagnosis of intrahepatic cholestasis of pregnancy was built up on the basis of the taking after inclusion criteria: singleton pregnancy between 20 and 36 completed weeks of gestation, presence of pruritus without an identifiable dermatological cause, and a fasting serum bile acid concentration of 10 µmol/L or over. Woman were avoided on the off chance that they had pre-existing liver illness (counting viral hepatitis B or C, immune system hepatitis, or known gallstone illness), different incubation, major deadly peculiarities recognized on ultrasonography, concurrent preeclampsia or gestational diabetes at the time of enrolment, known hypersensitivity to ursodeoxycholic corrosive, or ongoing treatment with any hepatoprotective or bile acid binding specialist.

Randomization and Allocation

Eligible members who given consent were randomly allocated in a 1:1 proportion to either the intercession bunch (UDCA) or the control group (standard care). Randomization was performed employing a computer-generated random number grouping with permuted squares of variable measure (4 and 6), arranged by a free analyst not included in quiet care or result appraisal. Allotment concealment was kept up through successively numbered, fixed murky envelopes that were opened as it were after the member had been formally selected. Due to the nature of the intervention, blinding of members and treating clinicians was not doable; be that as it may, the research facility staff dissecting bile corrosive tests and the analyst performing the ultimate data analysis were kept ignorant of bunch assignments.

Intervention Protocol

Members distributed to the UDCA have gathered verbal ursodeoxycholic acid at a measurement of 15 mg/kg body weight per day, isolated into two or three dosages taken with meals. Treatment was started on the day of randomization and proceeded until conveyance. The pharmaceutical was apportioned by the clinic drug store, and adherence was observed through pill tallies at each take after up visit and self detailed pharmaceutical journals. Members within the standard care gather received schedule antenatal administration as per institutional conventions, which included standard fetal heart rate observing by cardiotocography, serial ultrasonographic evaluation of fetal development and amniotic liquid volume, and guiding with respect to fetal development checking. Both bunches received indistinguishable obstetric reconnaissance, and the timing and mode of conveyance were decided by the going to obstetrician based on clinical signs, with a common arrangement of advertising delivery by 37 to 38 weeks of development in affirmed ICP cases.

Outcome Measures

The primary result was the alter in total serum bile corrosive concentration from pattern (at enrolment) to the final estimation obtained inside 48 hours earlier to conveyance. Bile corrosive levels were measured utilizing an enzymatic colorimetric measure on a Cobas c501 analyser. Auxiliary results included: (a) frequency of stillbirth, characterized as fetal passing at or after 24 weeks of development; (b) rate of preterm conveyance some time recently 37 completed weeks; (c) nearness of meconium recoloured amniotic liquid at the time of film burst or delivery; (d) neonatal seriously care unit affirmation inside the primary 48 hours of life; (e) Apgar score at 5 minutes; and (f) maternal pruritus severity, evaluated employing a approved 10point visual simple scale managed at standard, week after week interims, and at conveyance.

Sample Size Calculation

The test estimate was assessed based on the essential result. Distributed writing suggests a cruel decrease in bile acid levels of around 1015 µmol/L with UDCA treatment, with a pooled standard deviation of around 18 µmol/L. To identify the least clinically critical difference of 10 µmol/L between the two bunches, with a two-sided alpha of 0.05, statistical control of 80%, and an expected dropout rate of 10%, a add up to of 160 members (80 per arm) was required.

Data Collection and Follow Up

Standard demographic and obstetric information were recorded at enrolment using a organized case report frame. Factors included maternal age, equality, gestational age at determination, body mass file, and important restorative and obstetric history. Blood tests for add up to bile acid estimation were drawn at enrolment, fortnightly amid the treatment period, and within 48 hours before delivery. All members were taken after up through conveyance, and neonatal results were recorded from the delivery enrol and

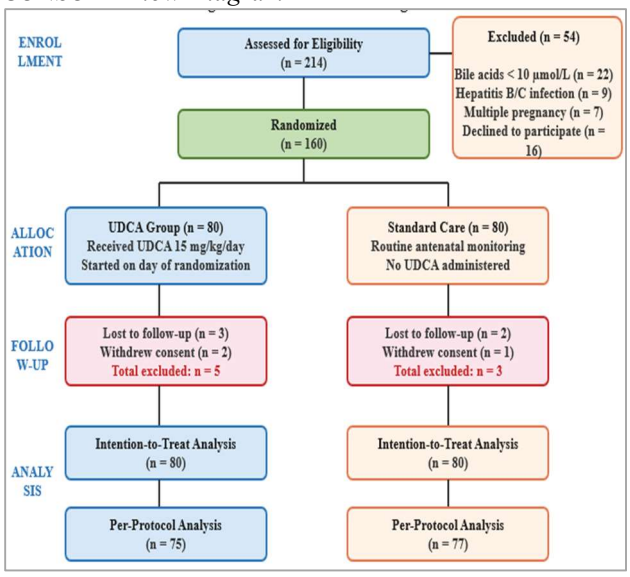
neonatal unit records. Members who pulled back assent, were misplaced to take after up, or required a alter in treatment due to clinical deterioration were reported.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using SPSS version 26.0. Continuous variables were expressed as mean ± standard deviation or median with interquartile range depending on the distribution assessed by the Shapiro-Wilk test. Categorical variables were presented as frequencies and percentages. Between group comparisons for continuous outcomes were made using the independent samples T-test or Mann Whitney U test as appropriate, while the chi-square test or Fisher's exact test was applied for categorical variables. The primary outcome was analysed using analysis of covariance (ANCOVA) adjusting for baseline bile acid levels. Relative risks with 95% confidence intervals were calculated for binary secondary outcomes. A two tailed p value of less than 0.05 was considered statistically significant. The analysis was conducted on an intentionn to treat basis.

Figure 2

CONSORT Flow Diagram



RESULTS

Participant Flow and Baseline Characteristics:

During the study period, a total of 214 pregnant women with suspected intrahepatic cholestasis were screened for eligibility. Of these, 38 did not meet the inclusion criteria (22 had bile acid levels below 10 µmol/L, 9 had coexisting hepatitis B or C infection, and 7 had multiple pregnancies) and 16 declined to participate. The remaining 160 women were randomized, with 80 assigned to the UDCA group and 80 to the standard care group. Five participants in the UDCA group and three in the control group were lost to follow up or withdrew consent before delivery, yielding 75 and 77 evaluable subjects respectively for per protocol analysis. All 160 participants were included in the intention to treat analysis. The two groups were well matched at baseline with respect to maternal age, parity, gestational age at enrolment, body mass index, and initial serum bile acid concentrations, as presented in Table 1.

Table 1

Baseline Characteristics of Study Participants

Variable	UDCA Group (n=80)	Standard Care (n=80)	p-value
Age (years), mean ± SD	27.4 ± 4.8	28.1 ± 5.2	0.38
Gestational age at enrolment (weeks)	30.6 ± 3.1	31.2 ± 2.9	0.22
Nulliparity, n (%)	34 (42.5%)	31 (38.8%)	0.63
BMI (kg/m²), mean ± SD	26.8 ± 3.6	27.3 ± 4.1	0.41
Baseline bile acids (µmol/L), mean ± SD	32.5 ± 16.8	34.1 ± 18.2	0.56
Severe ICP (bile acids ≥40 µmol/L), n (%)	28 (35.0%)	30 (37.5%)	0.74
Baseline pruritus score (VAS 0–10)	7.2 ± 1.6	7.0 ± 1.8	0.47

SD = standard deviation; BMI = body mass index; ICP = intrahepatic cholestasis of pregnancy; VAS = visual analogue scale.

Primary Outcome: Change in Serum Bile Acid Levels

At delivery, the mean total serum bile acid concentration in the UDCA group had decreased from 32.5 ± 16.8 µmol/L at baseline to 17.9 ± 11.4 µmol/L, representing a mean reduction of 14.6 µmol/L. In contrast, the standard care gather showed a humble decay from 34.1 ± 18.2 µmol/L to 31.8 ± 17.6 µmol/L, a cruel decrease of as it were 2.3 µmol/L. After adjusting for baseline bile corrosive levels utilizing ANCOVA, the between gather contrast remained profoundly critical (balanced mean contrast: 12.8 µmol/L; 95% CI: 16.4 to 9.2; p<0.001). The extent of participants achieving normalization of bile acids (underneath 10 µmol/L) at conveyance was 47.5% within the UDCA group compared with 12.5% within the standard care gather (p<0.001).

Secondary Outcomes: Perinatal Events

The incidence of stillbirth was lower in the UDCA group, occurring in 1 of 80 participants (1.25%) compared with 5 of 80 (6.25%) in the standard care group. The relative risk was 0.20 (95% CI: 0.02 to 1.68), and although the direction of effect favoured UDCA, the difference did not reach conventional statistical significance (p=0.09 by Fisher's exact test). All six stillbirths occurred at gestational ages between 34 and 37 weeks, and five of the six involved bile acid levels exceeding 40 µmol/L at the most recent measurement prior to fetal death.

Preterm delivery before 37 weeks occurred in 13 women (16.3%) in the UDCA group and 25 women (31.3%) in the control group (RR: 0.52; 95% CI: 0.29 to 0.94; p=0.03). Meconium staining of the amniotic fluid was observed in 11 cases (13.8%) in the UDCA arm and 21 cases (26.3%) in the control arm (RR: 0.52; 95% CI: 0.27 to 1.01; p=0.05). Neonatal intensive care unit

admission within 48 hours of birth was required for 9 neonates (11.3%) in the UDCA group and 18 (22.5%) in the standard care group (RR: 0.50; 95% CI: 0.24 to 1.04; p=0.06). The mean 5minute Apgar score was 8.6 ± 0.9 in the UDCA group and 8.1 ± 1.3 in the control group (p=0.006). A summary of all perinatal outcomes is provided in Table 2.

Table 2

Perinatal Outcomes in UDCA and Standard Care Groups

Outcome	UDCA (n=80)	Control (n=80)	RR (95% CI)	p-value
Stillbirth, n (%)	1 (1.25%)	5 (6.25%)	0.20 (0.02–1.68)	0.09
Preterm delivery <37 weeks, n (%)	13 (16.3%)	25 (31.3%)	0.52 (0.29–0.94)	0.03*
Meconium-stained liquor, n (%)	11 (13.8%)	21 (26.3%)	0.52 (0.27–1.01)	0.05
NICU admission, n (%)	9 (11.3%)	18 (22.5%)	0.50 (0.24–1.04)	0.06
5min Apgar <7, n (%)	3 (3.8%)	9 (11.3%)	0.33 (0.09–1.19)	0.07

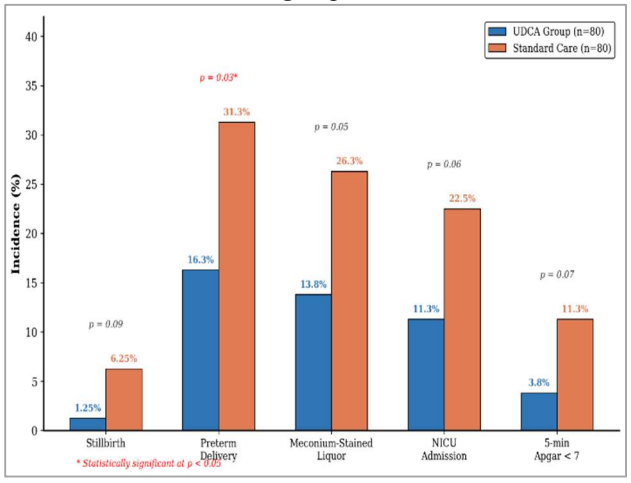
** Statistically significant at p<0.05; RR = relative risk; CI = confidence interval; NICU = neonatal intensive care unit.*

Maternal Symptom Relief

Pruritus severity, assessed by a visual analogue scale, showed significant improvement in the UDCA group over the course of treatment. The mean pruritus score decreased from 7.2 ± 1.6 at baseline to 2.4 ± 1.1 at the last assessment before delivery in the UDCA group, a reduction of 4.8 points. In the standard care group, the corresponding decrease was from 7.0 ± 1.8 to 5.8 ± 1.9, amounting to only a 1.2point reduction. The between group difference in pruritus score change was statistically significant (p<0.001). Additionally, sleep quality, assessed informally through patient reported outcomes at follow up visits, was subjectively better in the UDCA arm, with a majority of treated women reporting improved sleep after the first week of therapy.

Figure 3

Comparison of adverse perinatal outcames between UDCA and standard care groups



Subgroup Analysis: Severe ICP

A prespecified subgroup analysis was performed among participants with severe ICP, defined as baseline bile acid levels of 40 µmol/L or above. In this subgroup (n=28 in UDCA group; n=30 in standard care group), the mean bile acid reduction with UDCA was 22.4 µmol/L compared with 3.8 µmol/L in the control arm (p<0.001). Stillbirth occurred in 0 of 28 cases in the UDCA subgroup and 4 of 30 in the control subgroup (p=0.04 by Fisher's exact test), suggesting a more pronounced protective effect of UDCA in severe disease. Preterm delivery was also significantly lower in the severe ICPUDCA subgroup (21.4% vs 46.7%; p=0.04).

Table 3

Outcomes in Severe ICP Subgroup (Bile Acids ≥40 µmol/L)

Outcome	UDCA (n=28)	Control (n=30)	p-value
Bile acid reduction (µmol/L)	22.4 ± 9.6	3.8 ± 7.2	<0.001
Stillbirth, n (%)	0 (0%)	4 (13.3%)	0.04
Preterm delivery, n (%)	6 (21.4%)	14 (46.7%)	0.04
NICU admission, n (%)	5 (17.9%)	12 (40.0%)	0.06

** Statistically significant at p<0.05.*

Adverse Effects

Ursodeoxycholic acid was by and large well endured. Gentle gastrointestinal side effects, counting sickness and free stools, were detailed by 8 members (10%) within the UDCA bunch, but none required discontinuation of therapy. No genuine unfavourable medicate responses were recorded. Liver transaminase levels showed a trend toward more noteworthy change within the UDCA group, though this was not a prespecified outcomes.

DISCUSSION

The findings of this randomized controlled trial give prove that ursodeoxycholic corrosive, managed at a standard dose of 15 mg/kg/day, leads to a significant and factually critical decrease in serum bile corrosive levels among women with intrahepatic cholestasis of pregnancy. The size of the decrease observed in our think about a cruel diminish of around 14.6 µmol/L relative to the control gather is reliable with prior reports from both randomized and observational thinks about, strengthening the biochemical adequacy of the sedate in this clinical setting. The address of whether this biochemical change interprets into unmistakable fetal advantage, especially the anticipation of stillbirth, is the more significant and challenged issue. In our trial, the rate of stillbirth was

numerically lower within the UDCA gather (1.25% versus 6.25%), and the course of the relative chance gauge unequivocally favored treatment. Be that as it may, the distinction did not accomplish routine factual importance at the 0.05 level. This finding warrants cautious translation. The think about was fueled to detect a distinction in bile corrosive levels instead of stillbirth, and given the generally moo rate of fetal passing indeed in untreated ICP, a test estimate of 160 was insufficient to draw conclusive conclusions with respect to this endpoint. The observed slant, in any case, is clinically important and adjusts with the biological plausibility of lessening harmful bile corrosive presentation within the fetal compartment.

Our results stand in fractional differentiate to the PITCHES trial, which found no significant advantage of UDCA for a composite perinatal endpoint. Be that as it may, a few highlights of our ponder populace may clarify the error. To begin with, the cruel standard bile corrosive level in our cohort (roughly 33 μmol/L) was significantly higher than in PITCHES, where a considerable extent of members had only gently raised levels. Moment, our subgroup investigation uncovered that the defensive impact of UDCA was most articulated among ladies with extreme ICP (bile acids over 40 μmol/L), in whom stillbirth was totally missing within the treatment arm versus 13.3% in controls. This perception echoes the discoveries of Ovadia and colleagues, who illustrated in a large person patient information meta-analysis that the hazard of stillbirth rises sharply above the 40 μmol/L edge, and suggests that the good thing about UDCA may be concentrated within the most noteworthy chance subset of patients. The significant decrease in preterm delivery watched within the UDCA group (16.3% versus 31.3%) is another critical finding. Preterm birth in ICP may happen spontaneously due to the impact of bile acids on myometrial contractility, or iatrogenic ally when clinicians select early delivery to relieve the chance of stillbirth. By bringing down bile corrosive concentrations, UDCA may decrease both pathways, permitting for more secure prolongation of pregnancy closer to term. The lower rates of meconium-stained liquor and neonatal seriously care unit admission within the treatment gather, whereas not all measurably noteworthy, paint a reliable picture of generally perinatal advantage. The advancement in maternal pruritus with UDCA treatment was significant and adjusts with essentially all earlier thinks about. The about five-point decrease on a ten-point visual simple scale is clinically important and ought to not be expelled as just a symptomatic advantage. Serious pruritus in ICP causes impressive trouble, rest hardship, and mental

A few limitations of this think about must be recognized. The open name plan presents the plausibility of performance and discovery predisposition, in spite of the fact that research facility results were surveyed by blinded work force. The single enters setting limits generalizability, in spite of the fact that it moreover guaranteed uniform clinical administration conventions. The test measure was satisfactory for the essential biochemical endpoint but underpowered for uncommon auxiliary results such as stillbirth. The study period of eight months may have presented regular variations in infection introduction that we may not account for. At last, long term neonatal take after up was not performed, clearing out open the address of whether the watched perinatal benefits endure past the immediate postnatal period. In spite of these confinements, the show think about contributes important prove from a South Asian populace that has been underrepresented within the existing writing on ICP administration. The consistency of our discoveries over different results biochemical, symptomatic, and perinatal strengthens the argument for UDCA as a clinically valuable intercession in this condition. Future inquires about ought to prioritize huge, multicentre trials with sufficient factual control to assess stillbirth as a primary endpoint, and ought to consider stratifying examinations by infection severity to superior characterize the persistent populace most likely to infer noteworthy advantage from treatment.

CONCLUSION

This randomized controlled trial demonstrates that ursodeoxycholic acid managed at 15 mg/kg/day to women with intrahepatic cholestasis of pregnancy produces a noteworthy and clinically pertinent decrease in serum bile acid concentrations compared with standard antenatal care alone. Treatment was also related with a critical diminishment in preterm conveyance and a marked advancement in maternal pruritus. In spite of the fact that the watched lower rate of stillbirth within the UDCA bunch did not reach measurable centrality in this test, the course of impact and the striking advantage seen within the serious ICP subgroup give bolster for the proceeded utilize of UDCA in clinical hone. These discoveries emphasize the importance of early identification and dynamic pharmacological administration of ICP, especially in settings where the condition is predominant and fetal observation resources are limited. Enough fueled multicentre trials stay required to resolve the extraordinary address with respect to the affect of UDCA on stillbirth avoidance.

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