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Poster Number: **EP 167** Name: **Dr. Pikee Saxena**

Title: **Phase III, Prospective Multicentric, Clinical Study in the Management of Pregnancy Induced Cholestasis to Evaluate the Efficacy and Safety of Ursodeoxycholic Acid (PICTURE Study)**

Introduction

Intrahepatic cholestasis of pregnancy (ICP) is the most common liver disorder specific to pregnancy and is associated with adverse perinatal outcomes.[1,2]

Objectives

Primary objective – To evaluate the efficacy of UDCA in terms of improvement in pruritus at 2-week intervals using VAS scores.

Secondary /Exploratory objective –

1)To evaluate reduction in serum bile acid, transaminases, GGT, and bilirubin levels from baseline until the time of delivery.

2)Safety assessment including fetomaternal outcomes

3)Treatment emergent adverse effects (TEAE) w.r.t UDCA

Materials & methods

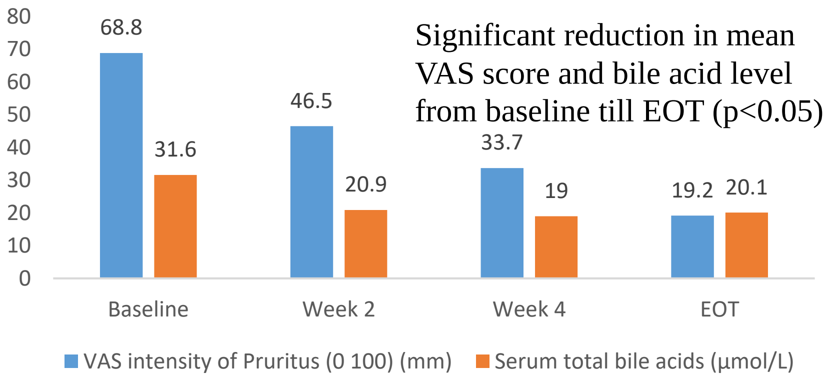
- **Study design:** Prospective, multicentre, open-label, single-arm, Phase III clinical study.
- **Sites:** 15 centres across India
- **Sample size:** Assuming baseline pruritus score of 60, expecting 20-point reduction in pruritus score post 2-week therapy, a sample size of 96 was calculated with 90% power, alpha error of 5%. Taking 20% dropout rate, total 120 subjects were recruited.

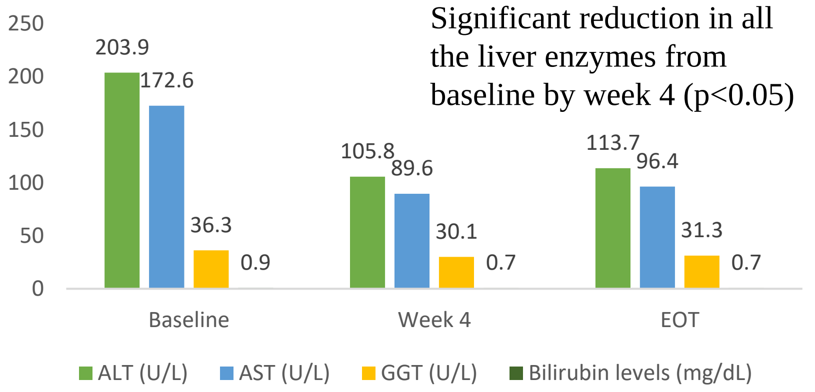
Study drug: UDCA 300 mg TID until delivery.

Inclusion criteria: Women with GA of ≥22 weeks but ≤35 weeks.
Confirmed diagnosis of ICP[3]: Consistent pruritus in soles & palms, ALT >40 U/L or AST >37 U/L and raised serum bile acids (≥10 µmol/L)
Exclusion criteria: History or current diagnosis of Hepatitis A, B, C, and E virus related liver diseases, dermatologic diseases, AFLP, USG abdomen showing liver or gall bladder pathology, alcohol abuse, other causes of cholestasis.

Results

Gestational age of subjects at baseline – 30.4 wks.
Mean duration of UDCA - 45.3 days
Mean gestational week at delivery - 37.2 wks.
Mode of delivery: CS in 48%, Vaginal in 52%





Safety assessment

Fetomaternal Outcome: 28% preterm births, 0.97% Gest.HT, 1.9% MSL, 0.97% NICU admission, 1.9% FGR,0.97% Stillbirth, 1 Early neonatal death- Unrelated (Reported to DCGI)

TEAE: 85% subjects experienced no TEAEs. Most TEAEs (GI symptoms – Nausea, Diarrhea) were mild in severity and not related to study drug. There was no study discontinuation due to TEAEs.

Conclusion: Study findings suggests that UDCA in subjects with ICP is significantly reduce pruritus and liver enzymes (p<0.05) and is well-tolerated.

References:

1. Mikolasevic I et al Liver Disease During Pregnancy: A Challenging Clinical Issue. Med Sci Monit. 2018 Jun 15;24:4080-4090
2. Roy A, Premkumar M, Mishra S, Mehtani R, Suri V, Aggarwal N, Singh S, Dhiman RK. Role of ursodeoxycholic acid on maternal serum bile acids and perinatal outcomes in intrahepatic cholestasis of pregnancy. European Journal of Gastroenterology & Hepatology. 2021 Apr 1;33(4):571-6.
3. Arora, Anil, et al. "Indian National Association for the Study of the Liver—Federation of Obstetric and Gynaecological Societies of India position statement on management of liver diseases in pregnancy." *Journal of clinical and experimental hepatology* 9.3 (2019): 383-406.