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Abstract Discussion Forum **(0)**

Number: Mo1547

COMPARING THE SAFTEY AND EFFICACY OF SECOND LINE THERAPIES FOR PBC WITH OBETHICOLIC ACID: A NETWORK META-ANALYSIS

Society: AASLD

Track: Biliary Tract Diseases

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Introduction:

Ursodeoxycholic acid (UDCA), the gold standard therapy for Primary Biliary Cholangitis (PBC) slows disease progression by improving biochemical markers of liver function, particularly alkaline phosphatase (ALP) levels. However, this therapy is often poorly tolerated by patients and fails to achieve optimal response. The second-line therapy, obeticholic acid (OCA), provides an alternative but is associated with significant adverse effects, including pruritus, a debilitating symptom of PBC. Recent studies suggest the potential efficacy of alternative treatment regimens. This study aims to conduct a network meta-analysis comparing Elafibranor, Seladelpar, and Saroglitazar with OCA to evaluate their effectiveness and safety as superior second-line options.

Methods:

A systematic search was conducted across the Cochrane Library, ClinicalTrials.gov, EMBASE, and PubMed databases for relevant literature up to July 2024. We identified eight randomized controlled trials (RCTs) and included seven trials which were placebo-controlled. All included RCTs were conducted in patients who were either intolerant or resistant to UDCA therapy. The Network Analysis was conducted using R version 4.4.1, to calculate odds ratios (ORs) and 95% confidence intervals (CIs).

Results:

We analyzed 7 RCTâ€™s comprising a total of 712 patients among which female accounted for 91.1 % (649) of population. Comparison was done between different doses of OCA (5 mg, 10 mg, 50 mg), Elafibranor (80 mg), Seladelpar (10 mg) and Saroglitazar (2 mg and 4 mg) against placebo. The patients included in these trials were either UDCA intolerant or non-responders. The primary endpoint was achieving a biochemical response, defined as an ALP level less than 1.67 times the upper limit of the normal range and a reduction of at least 15% from baseline. The secondary endpoint was a reduction in pruritus severity. Forest Plot analysis for biochemical response proved Elafibranor to be superior to placebo, with OR 26.46 (95% CI 6.13-114.21). OCA at 5 mg, 10 mg and 50 mg was also superior to the placebo with OR 8.21 (95% CI 3.32 - 20.31), OR 8.18 (95%CI 3.3-20.3) and OR 10.5 (95% CI 1.82-60.45), respectively. Regarding pruritus, Elafibrinor 80 mg Phase 3 trial with OR 0.71 (95% CI 0.33 - 1.54) was superior to placebo and OCA monotherapy with OR 28.12 (95% CI 3.12 - 253.48) at 50 mg and OR 4.38 (95% CI 1.21 - 15.81) at 10 mg. While Seladelpar and Saroglitazar were superior to placebo, were inferior to Elafibranor overall.

Conclusion:

Elafibranor demonstrates superior outcomes in achieving biochemical response and improvement in pruritus symptoms when compared to OCA. Additionally, OCA worsened pruritus in PBC patients. Our findings highlight the need for additional randomized controlled trials (RCTs) investigating Elafibranor as effective second line therapy and a potential first line monotherapy for PBC.

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