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TITLE: A reduction in alkaline phosphatase levels is associated to improved prognosis in primary sclerosing cholangitis: A 14 year follow up of the Scandinavian ursodeoxycholic acid trial

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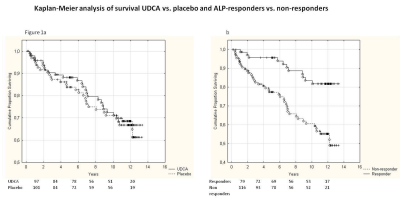
ABSTRACT BODY: BACKGROUND: Primary sclerosing cholangitis (PSC) has a poor prognosis and effective medical treatment is lacking. Ursodeoxycholic acid (UDCA) is widely prescribed in PSC but has never been proven to prevent disease progression. However, in patients with primary biliary cirrhosis excellent long-term survival has been shown in patients with biochemical response to UDCA (Pares et al 2006) AIMS: To study long-term survival in patients treated with medium dose (17-23 mg/kg/day) UDCA and to compare the clinical outcome between biochemical responders and non-responders. METHODS: From our previous 5-year randomized controlled trial of UDCA vs. placebo in PSC (Olsson et al 2005), we performed a follow up of all patients (n= 198) from end of the trial 2001 until 2010. Information on endpoints and treatment after end of the initial trial was collected. Clinical endpoints were defined as death, liver transplantation or development of cholangiocarcinoma. Data on biochemistry was retrieved from the original trial database. Patients were categorized as biochemical responders if levels of alkaline phosphatase (ALP) were normal or had decreased with 40% or more after 1 year in the trial. Endpoint-free survival was compared between the groups using the Kaplan-Meier method. RESULTS: No difference in endpoint-free survival between treated (n=97) and untreated (n=101) patients was seen (p=0.774 log rank), (figure 1a). Fifty-five patients reached an endpoint, 26 in the UDCA group and 29 in the placebo group. No differences in sex (73 % males vs. 70%), age at study entry (43 vs. 43 years), duration of PSC (7 vs. 5.6 years), associated IBD (85 % vs. 83%) or use of UDCA (47% vs. 50%) were found between patients that reached an endpoint and those who did not. However ALP-responders (n=79) had a significantly better long term survival compared with non-responders (n=116) (log rank 0.0001)(figure 1b). CONCLUSION: Treatment with medium dose UDCA does not improve the long term survival in PSC patients. A reduction in ALP is associated to a better prognosis, regardless of UDCA treatment.

(No Table Selected)



Co-Author Disclosure Status

The following authors have completed their AASLD 2012 disclosure:

Lina Lindström: Disclosure completed

Kirsten Boberg: Disclosure completed

Ingalill Friis-Liby: Disclosure completed

Rolf Hultcrantz: Disclosure completed

Annika Bergquist: Disclosure completed