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**TITLE:** Impact of intensive enteral nutrition in association with corticosteroids in the treatment of severe alcoholic hepatitis: a multicenter randomized controlled trial

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**ABSTRACT BODY: Abstract Body (Oral or Poster Submission):** Introduction. Severe alcoholic hepatitis (AH) is associated with a high risk of short-term mortality. Although adequate nutritional support is recommended in these patients, the recommended protein-caloric intake is often difficult to achieve orally in this population. Our objective was to evaluate the impact of intensive enteral nutrition in addition to steroid therapy on 6-month survival in patients with severe AH.

**Methods.** This multicenter randomized, controlled trial was performed in 18 Belgian and 2 French hospitals. Two groups were included: 1) intensive enteral nutrition and methylprednisolone (intensive group) or 2) conventional nutrition and methylprednisolone (control group). In the intensive group, enteral nutrition was given using a feeding tube for 14 days and patients received Fresubin HP Energy® (1.5 kcal/ml, 7.5 g prot/100 ml) as it follows: 1L/day if body weight (BW) < 60 kgs, 1.5L if BW between 60 and 90 kgs, 2L if BW>90 kgs. Nutrition intake was recorded for 14 days in both groups.

**Results.** A total of 136 patients with a severe biopsy-proven AH (Maddrey discriminant function [mDF]  $\geq 32$ ) were randomized, 68 in each group. At baseline, there were no significant difference between the two groups (intensive vs. control) for age (49.5 $\pm$ 8.7 vs. 51.5 $\pm$ 8.6), male gender (69.1 vs. 58.8%), bilirubin (13.3 [8.9-23.5] vs. 11.9 [6.9-21.5] mg/dL), INR (1.8 [1.6-2.1] vs. 1.8 [1.6-2.1]), mDF (52.3 [40.9-70.2] vs. 54 [42-68.5]) and MELD score (22.8 [21.4-26.3] vs. 22.4 [20.2-25.1]). Mean kcal intake was 2206 $\pm$ 754 vs. 1754 $\pm$ 656 kcal/day (p=0.001) and mean protein intake was 106 $\pm$ 37 vs. 80 $\pm$ 32 g/day (p<0.001). In intention-to-treat (ITT) analysis, 6-month survival was not statistically different between the two groups: 55.9 vs. 47.0% (p=0.316). In the intensive group, 43/68 (63.2%) patients received at least 80% of the planned kcal intake defined by the protocol, and were considered in the per-protocol analysis. In per-protocol analysis, 6-month survival was higher in the intensive group: 69.8 vs. 46.8% (p=0.015). In addition, mean

kcal intake/kg/day > 26.4 (median value) was associated with a higher 6-month survival (68.3 vs. 42.4%, p=0.002). In ITT multivariable analysis, a mean kcal intake/kg/day > 26.4, baseline mDF, serum sodium, MELD and the Lille scores remained independently associated with 6-month survival.

Conclusions. Intensive enteral nutrition by feeding tube does not improve 6-month survival in patients with severe AH. However, adequate nutritional support is associated with a better short-term prognosis. Adequate nutritional intake should be targeted in AH patients treated with corticosteroids.

(No Image Selected)

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