(aHR $_{0.39}0.57_{0.83}$, p=0.004; 92.2% vs 84.4% one-year survival post-decision). Within one year of decline, 7.9% died and 39.3% received a whole liver. **Conclusion:** Accepting grafts for a split liver transplant could substantially improve survival for small children and adults on the waitlist.

Table 1a. Pediatric candidate factors associated with mortality following the decision to accept versus decline the split liver offer.

Pediatric characteristic	aHR	p
Accepted vs declined; ≤7 kg	$_{0.17}0.37_{0.80}$	0.01
Accepted vs decline; >7 kg	$_{0.63}1.07_{1.82}$	0.8
Per year of age	$_{0.93}0.99_{1.06}$	0.8
Per unit of PELD/MELD	$_{1.00}1.02_{1.04}$	0.04
Status 1	$_{1.33}3.96_{11.80}$	0.01
Diagnosis		
Biliary atresia	Reference	-
Metabolic disease	$_{0.34}0.78_{1.75}$	0.5
Hepatoblastoma	$_{0.81}1.81_{4.05}$	0.1
Other	$_{1.02}1.87_{3.43}$	0.04

Table 1b. Adult candidate factors associated with mortality following the decision to accept versus decline the split liver offer.

Adult characteristic	aHR	p
Accepted vs declined	$_{0.39}0.57_{0.83}$	0.004
Per year of age	$_{1.01}1.02_{1.04}$	<0.001
Biologic sex	$_{0.69}0.91_{1.21}$	0.5
Race		
Causasian	Reference	-
African American	$_{0.56}0.82_{1.23}$	0.4
Hispanic	$_{0.68}0.90_{1.18}$	0.4
Other	$_{0.77}1.13_{1.68}$	0.5
Diagnosis		
Hepatitis C	Reference	-
NASH	$_{0.82}1.19_{1.72}$	0.4
Hepatocellular carcinoma	$_{0.73}1.01_{1.39}$	0.9
Alcoholic cirrhosis	$_{0.82}1.12_{1.53}$	0.5
Other	$_{0.78}0.99_{1.30}$	0.9
Height, per cm	$_{0.97}0.99_{1.01}$	0.2
Weight, per kg	$_{1.00}1.01_{1.02}$	0.001

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EARLY LIVER TRANSPLANTATION FOR SEVERE ALCOHOLIC HEPATITIS NOT RESPONDING TO MEDICAL TREATMENT: RESULTS OF THE FRENCH-BELGIAN PROSPECTIVE STUDY QUICKTRANS

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Background: Although some convincing data exist to support early liver transplantation (eLT) for severe alcoholic hepatitis (SAH) as an emerging therapy, this strategy that must be evaluated in prospective controlled studies with a rigorous study design to bring reliable data to experts. **Methods:** The purpose of this prospective controlled trial (NCT01756794) is to compare the following 3 groups: A: patients with SAH not responding to medical treatment selected for eLT using a dedicated score designed for the study (patient qualified for liver transplantation if score≥220/250), based on social and addiction parameters; B: patients candidates for transplantation for alcohol-related cirrhosis with at least 6 months of abstinence; C: patients with SAH not responding to medical treatment denied for eLT (score <220/250). Primary analysis was restricted to transplanted patients (groups A and B), to assess the non-inferiority of A versus B on 2-year alcohol relapse after LT using the alcohol timeline follow back (ATLFB) method and a pre-specified margin of 10%. Secondary outcomes were pattern of alcohol relapse and survival after LT. A secondary analysis was restricted to all patients of groups A and C to assess the benefit of eLT in SAH on 2-year survival. **Results:** We included 155 patients with SAH: 78 selected for eLT (group A, median Lille score=0.86), 77 denied for eLT (group C, median Lille score=0.81). 129 patients were included in group B. Primary analysis: 68 (A) and 93 patients (B) were transplanted and included. MELD score at inclusion in groups A and B were 30.6 vs. 22.3, p<0.001. The non-inferiority of A versus B was not demonstrated with a 2-year alcohol relapse of 33.8 (A) and 24.7% (B, figure), absolute difference of 9.1, one-sided 95% confidence interval, -∞ to 21.1%. Regarding secondary outcomes, 2-year heaving drinking relapse rate was higher in group A (22.1 vs. 5.4%, p<0.001). In heavy drinking relapsers, median percentage of time spent to drink during the follow-up was 10 (A) vs. 5.9% (B). Two-year survival in groups A and B was similar (89.7 vs. 88.1%). Secondary analysis: 2-year survival was higher in group A (patients transplanted or not, n=78) than in group C (n=77): 82.8 vs. 28.2%, p<0.001. **Conclusion:** In the first controlled study in this field, relapse rate is of 33.8% in patients early transplanted for SAH as compared to 24.7% in patients with alcohol-related cirrhosis.

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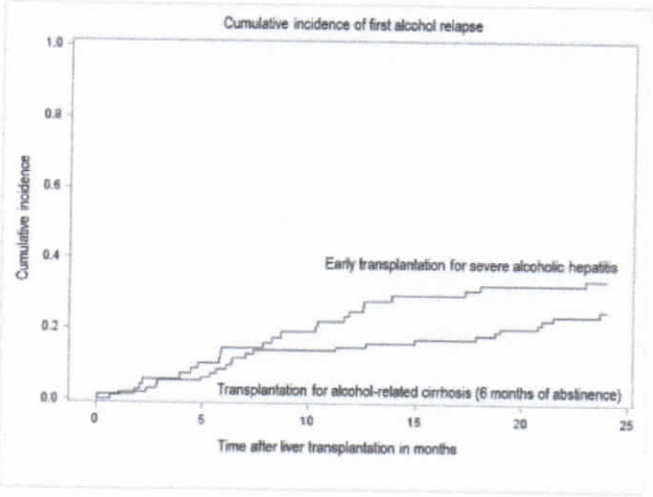
Using a pre-specified margin of 10%, we cannot conclude to non-inferiority. Heavy drinking is more frequently seen after early liver transplantation for severe alcoholic hepatitis than in patients transplanted for blank alcohol-related cirrhosis. Early liver transplantation induces a drastic improvement of survival in patients with severe alcholic hepatitis not responding to medical therapy.



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FECAL MICROBIOTA TRANSPLANT IMPROVES LONG-TERM OUTCOMES IN PATIENTS WITH ALCOHOL USE DISORDER

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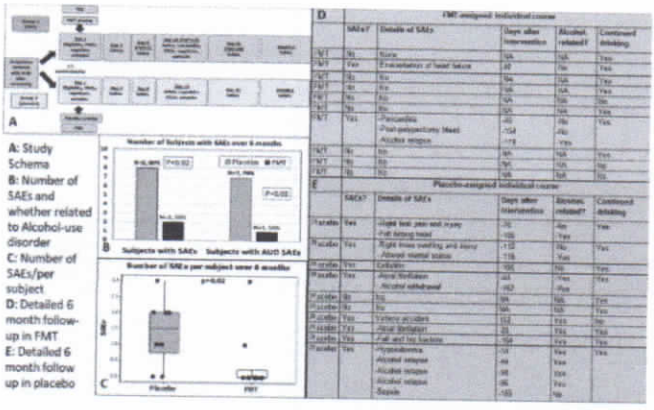
Background: Alcohol use disorder (AUD) is associated with an altered gut-liver-brain axis. Microbial modification to improve outcomes need to be studied. Fecal microbiota transplant (FMT) can improve outcomes in hepatic encephalopathy and in alcoholic hepatitis. In a randomized trial, we found that short-term alcohol craving reduced in cirrhotics randomized to FMT compared to placebo, but the long-term impact is unclear. **Aim**: Define long-term safety and impact of FMT compared to placebo in AUD patients with cirrhosis. **Methods:** In a Phase 1 trial, double-blind, placebo-controlled trial under IND, we 1:1 randomized AUD pts with cirrhosis with AUDIT-10>8 with multiple unsuccessful attempts at abstinence into placebo or one FMT enema from a donor enriched in beneficial Lachnospiraceae and Ruminococcaceae (Fig A). We found a reduction in alcohol craving and microbiota composition at day 15 post-intervention. Patients were then followed for 6 months for serious adverse events (SAEs), which were hospitalizations/ER visits. The data safety monitoring board determined "relatedness" to FMT. SAEs were divided into AUD-related/not. **Results:** 20 men with AUD-related cirrhosis [65±6.4 years, MELD 8.9±2.7] with similar demographics, cirrhosis and AUDIT-10 scores were included. All had undergone rehabilitation median 2 (2-5 IQR) times prior. Age (FMT 67.1±5.2 vs placebo 62.9±7.1 years, p=0.15) and racial distribution were comparable (7 White/3 Black in placebo vs 6 White/4 Black in FMT). All were on proton pump inhibitors, following Western non-vegetarian diet and were without recent antibiotic/probiotic use. Craving reduced significantly in 90% of FMT versus 30% in placebo at day15(p=0.02). Till day 30 there were no changes in liver enzymes, MELD score or other safety labs. At 6 months, patients with any SAEs (8 vs 2, p=0.02) were lower in the FMT group, which extended patients with AUD-related SAEs (7 vs 1, p=0.02, Fig B). The median SAEs per patient were also lower in the FMT group compared to placebo [median (IQR),1.5(1.25) vs 0(0.25) in FMT, p=0.02] Fig C. Individual patient course is shown in figure D and E, where AUD-related SAEs ranged from falls, car crashes, relapse, withdrawals and atrial fibrillation in the placebo-group, while only one SAE related to alcohol relapse was seen in FMT group. None of the SAEs were related to cirrhosis. None of the SAEs were deemed FMT-related by the monitoring group. Three patients in the FMT-assigned group and 1 person in the placebo-assigned group stopped problem drinking at 6 months. **Conclusion:** In this Phase 1 trial FMT in men with cirrhosis is safe, associated with reduction in short-term craving , which was associated with lower total and AUD-related SAEs over long-term follow-up and a trend towards reduction of harmful drinking in the FMT-assigned group. These results support larger trials to determine the impact of beneficially altering gut-brain axis in patients with AUD.



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