

**Table 5. Randomized controlled trials comparing TACE to supportive care in patients with hepatocellular carcinoma**

Study Country Setting Years of Enrollment	N subjects: T vs C	Inclusion and exclusion criteria	Sample characteristics; liver disease etiology (% T vs C)	Liver disease stage  (% T vs C)	Survival  (%T vs C)	Adverse events
Groupe d'Etude et de Traitement du Carcinome Hepatocellulaire, 1995 <sup>53</sup> France, Belgium, Canada 24 centers 1990-1992	50 vs 46	HCC with AFP >250ng/ml, excluded patients who were candidates for surgery, previous treatment, severe liver disease, vascular contraindications to chemoembo, increased creatinine, extrahepatic mets.	Mean age 63 vs 65 Male 96 vs 96 EtOH 76 vs 73  HBV 4 vs 7  HCV 9 vs 10  Primary hemochromatosis 11 vs 10	Okuda I 94 vs 84.8 Okuda II 6 vs 15.2	Unadjusted RR of death: 0.7, (95% CI 0.45-1.11, P=0.13) 1-year: 62 vs 43.5 2-year: 37.8 vs 26  Adjusted RR of death: 0.77 (95% CI 0.48-1.25, P=0.31)  adjusted for Karnofsky score, ascites, bilirubin, albumin, tumor type, tumor mass, portal obstruction AFP, chemoembolization	Trial stopped due to deaths in both groups (liver failure, GI hemorrhage, SBP). Chemoembolization led to <50% increase in survival after 8 months, therefore trial stopped. Abdominal pain 80% Vomiting 80% Fever 76% Death 2% Ascities 10% Encephalopathy 2% GI hemorrhage 8% Cholecystitis 4% Elevated AST/ALT ≥ 5x ULN 3 days after treatment 54% Increase in serum bilirubin ≥ 0.9mg/dL 58% Other complications 18%
Lo, 2002 <sup>55</sup> Hong Kong Single-center 1996-1997	40 vs 39	Patients with unresectable HCC. Excluded: poor hepatic function, elevated creatinine, history of prior tumor treatment of acute tumor rupture, presence of extrahepatic metastasis or vascular contraindications to chemoembolization, poor performance status	Mean age 62 vs 63 Male 90 vs 87 HBsAg pos 85 vs 74	Okuda I 47.5 vs 46.1, Okuda II 52.5 vs 53.9	Unadjusted: 1-year : 57 vs 32  2-year: 31 vs 11  3-year: 26 vs 3  RR of death 0.50 ( 95%CI 0.31-0.81, p=0.005)  Adjusted RR of death: 0.49 (95% CI 0.29-0.81, p=0.006), adjusted for symptoms, portal vein obstruction, Tumor size, Okuda, treatment with TACE	38 patients had treatment stopped because of progressive disease (12 patients), death (7 patients), poor liver function (6 patients), adverse effects (6 patients), patient refusal (3 patients), arteriovenous shunting (2 patients),  and hepatic artery thrombosis (2 patients). The most common clinical adverse effect was a self-limiting syndrome consisting of fever, abdominal pain, and vomiting.
Pelletier, 1990 <sup>54</sup> France 10 hospitals 1985-1988	21 vs 21	Consecutive patients with HCC were included. Excluded: resectable HCC, patients with spontaneous encephalopathy with associated poor survival rates, non-embolizable HCC due to portal vein thrombosis, or previous porto-caval anastomosis.	Age 64 vs 66 Male 91 vs 86 EtOH 71.4 vs 66.7  Non-EtOH 28.6 vs 33.3	Okuda I 28.6 vs 23.8 Okuda II 53.4 vs 52.4 Okuda III 19 vs 23.8	Unadjusted: 6 month 33 vs 52 1 year 24 vs 31 (no statistical difference)	Two severe complications of chemoembolization: death from acute renal failure in one patient, and a gastrointestinal hemorrhage from acute gastroduodenal ulcerations