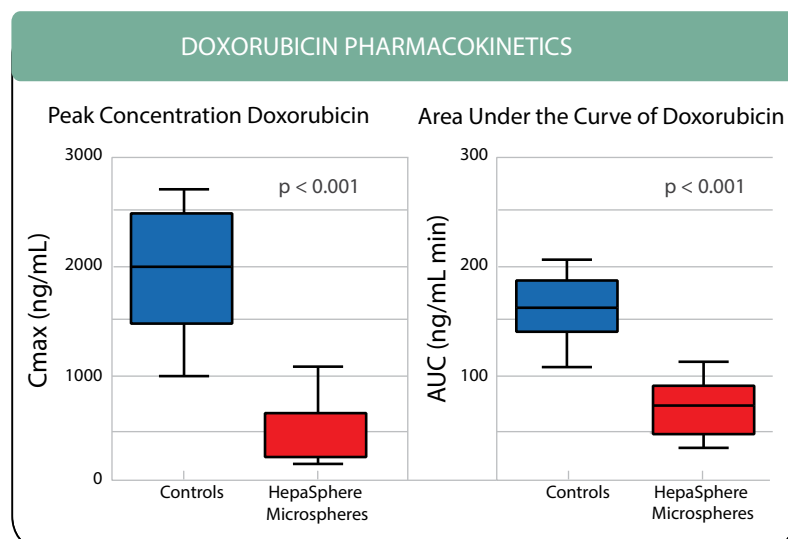
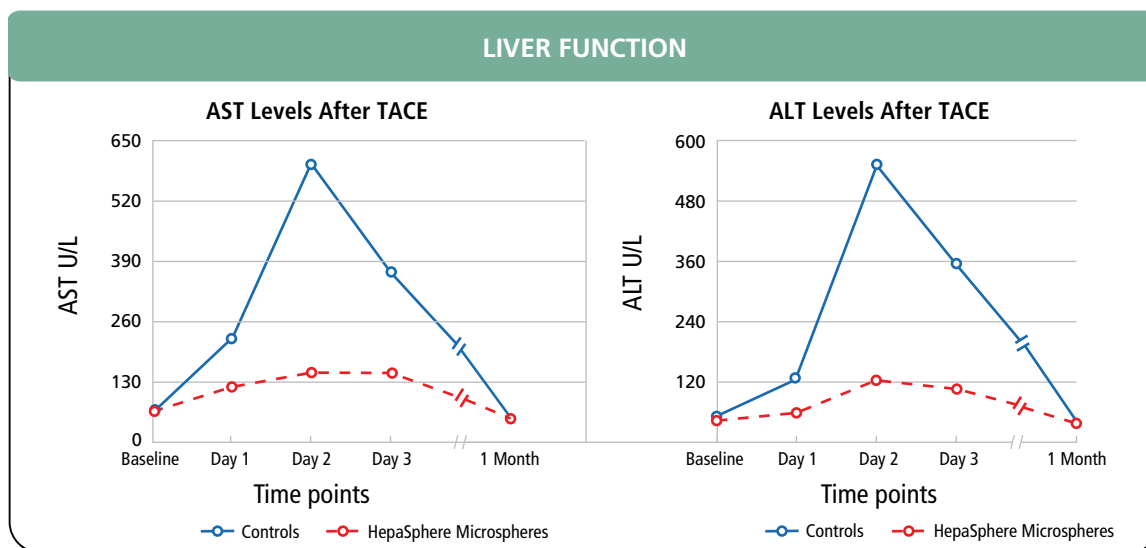


Clinical Experience: Increased Efficacy, Reduced Systemic Exposure

A Randomized Phase II Study of Transarterial Chemoembolization with Doxorubicin Eluting HepaSphere Microspheres in Patients with Hepatocellular Carcinoma

Validating preclinical studies of hqTACE, clinical experience with doxorubicin-loaded HepaSphere Microspheres demonstrates that hqTACE provides high efficacy, reduced systemic exposure and lower complication rates, while minimizing the impact on normal liver function.

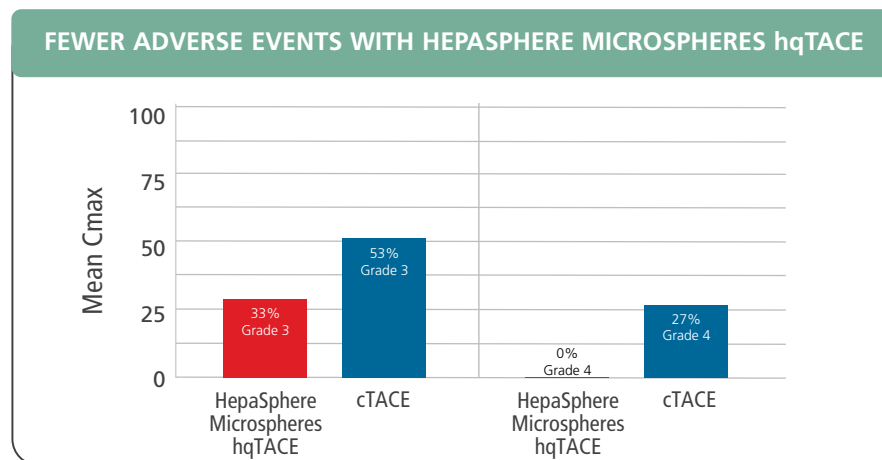
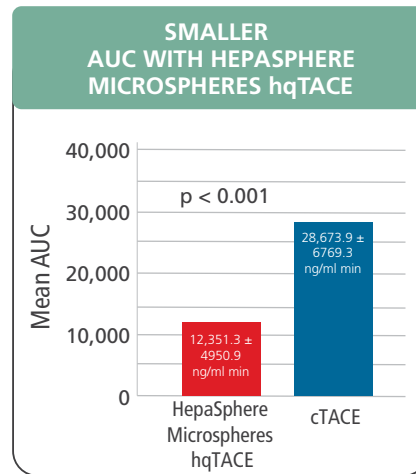
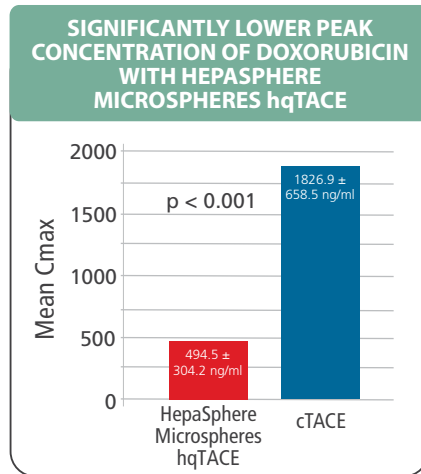
- **30 HCC patients were randomized**
 - 14 patients received lipiodol and doxorubicin (cTACE, control group)
 - 16 patients received doxorubicin delivery HepaSphere Microspheres (hqTACE)
- **The doxorubicin levels were assessed to determine**
 - Peak concentration of doxorubicin (C_{max})
 - Area under the curve of doxorubicin (AUC) up to 3 hours after infusion
- **Liver function was analyzed**
 - AST (at day 1, 2 and 3 and after 1 month)
 - ALT (at day 1, 2 and 3 and after 1 month)
- **Side-effects were reported**
 - Following the Common Toxicity Criteria



Results and Conclusion

Results

- **Minimal impact on normal liver function**
 - Significantly lower peak concentration of doxorubicin and smaller AUC (area under curve) in patients receiving HepaSphere Microspheres compared to cTACE ($p < 0.001$)
 - Serum liver enzyme analyses showed better preserved liver function
- **Reduced systemic exposure**
 - hqTACE shown to have less systemic effect of doxorubicin than cTACE
- **Fewer adverse events**
 - Significantly fewer grade 3 and 4 adverse events in the HepaSphere Microspheres group ($p = 0.027$)



Conclusion

hqTACE with doxorubicin delivery HepaSphere Microspheres leads to low circulating plasma levels of the antimitotic drug and reduces toxicity.

Reference: van Malenstein H, Maleux G, et al. A randomized phase II study of drug-eluting beads versus transarterial chemoembolization for unresectable hepatocellular carcinoma. *Onkologie* 2011; 34(7):368-76.



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