

Hepatic arterial infusion of Doxorubicin-loaded microsphere for treatment of hepatocellular cancer: a multi-institutional registry.

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Source

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Abstract

BACKGROUND:

Hepatic intra-arterial therapy for unresectable hepatocellular cancer (HCC) has been shown to improve overall survival, but can have significant toxicity. A recent prospective randomized controlled trial demonstrated superior response rates and significantly less morbidity and doxorubicin-related adverse events with drug-eluting beads with doxorubicin (DEBDOX) compared with conventional chemoembolization. The aim of this study was to confirm the efficacy of DEBDOX for the treatment of unresectable HCC.

STUDY DESIGN:

This open-label, multicenter, multinational single-arm study included 118 intermediate-staged HCC patients who were not candidates for transplantation or resection. Patients received DEBDOX at each treatment. Complications and response rates to treatment were analyzed.

RESULTS:

There were 118 patients who received a total of 186 DEBDOX treatments with a median total treatment dose of 75 mg (range 38 to 150 mg), and median overall total hepatic exposure of 150 mg (range 150 to 600 mg). Five lesions were targeted, with a median size of 5.3 cm (range 1.0 to 16.9 cm). Severe adverse events related to liver dysfunction were seen after 4% of treatments. Overall survival was a median of 14.2 months (range 5 to 30 months), with progression-free survival of 13 months and hepatic-specific progression-free survival of 16 months. Okuda class less than 1 at time of treatment, reduction of alpha-fetoprotein of 1,000 ng/mL at the first post-treatment evaluation, delivery of more than 200 mg doxorubicin, and less than 25% liver involvement were all predictors of favorable overall survival assessed by multivariable analyses.

CONCLUSIONS:

Hepatic intra-arterial injection of DEBDOX is safe and effective in the treatment of HCC, as demonstrated by a minimal complication rate and robust and durable tumor response.