Downstaging disease in patients with hepatocellular carcinoma outside of Milan criteria: strategies using deb chemoembolization

SIR-RFS Journal Primer
**Quick Summary**

**BOTTOM LINE**
- 17 out of 22 patients (77%) with Stage T3 N0 M0 HCC were downstaged to meet Milan Criteria after treatment with DEB TACE

**MAJOR POINTS**
- 17 out of 22 patients deemed to have unresectable HCC because tumors were multifocal, unfavorably located, or patients had advanced liver failure were successfully downstaged meet Milan Criteria after treatment with DEB TACE
- 2 out of 7 patients who received transplant had recurrence within 28 days
- Only 2 out of 5 (13%) with 1 year progression free survival

**CRITICISM**
- Small sample size: n = 22 at a single institution
- Short follow-up period: 28 days (similar studies have required patients to meet Milan Criteria for 6 months in order to be considered downstaged)
- Imaging response assessment with mRECIST is more favorable than WHO criteria used in comparable trials
- Study population not exclusively transplant-eligible resulting in 6 out of 17 downstaged patients progressing beyond Milan Criteria prior to transplant
SINGLE CENTER RETROSPECTIVE REVIEW

- 239 patients treated with Doxorubicin-Eluting Bead (DEB) TACE: Sept 2008 – December 2011

INCLUSION CRITERIA

- Age 18-89
- HCC diagnosed by biopsy or imaging according to criteria by AASLD and UNOS
- UNOS Stage T3 N0 M0 Disease

EXCLUSION CRITERIA

- No follow up imaging obtained
- Follow up imaging was performed less than 28 days after treatment
- Follow up imaging showed ill-defined tumor margins
To assess downstaging rates in patients with UNOS T3 N0 M0 HCC treated with DEB TACE to meet Milan Criteria for liver transplant

**UNOS Stage T3N0M0 HCC**
- One tumor > 5 cm
- Two or three tumors with at least one > 3 cm
- No imaging evidence of vascular invasion
- No imaging evidence of extrahepatic metastatic disease

**Milan criteria**
- One tumor ≤ 5 cm
- Two or three tumors ≤ 3 cm
- No imaging evidence of vascular invasion
- No imaging evidence of extrahepatic metastatic disease
All subjects had unresectable HCC
Pre-procedural Bilirubin range: 0.9 to 3.6 mg/dL

Tumor Evaluation:
  » Baseline recorded as:
    1. Not meeting UCSF or Milan criteria
    2. Meeting UCSF but not Milan

Tumor Response on follow up CT / MR was evaluated according to the longest enhancing axial dimension of each tumor per mRECIST Criteria

LC Bead Sizes:
  » 8 Procedures: 100 – 300 µm beads
  » 18 Procedures: 100 – 300 µm and 300 – 500 µm beads
  » 15 Procedures: 300 – 500 µm beads
  » 7 Procedures: 300 – 500 µm and 500 – 700 µm beads

Arterial Selection:
  » 11 Procedures: Lobar Hepatic Artery
  » 37 Procedures: Segmental or Sub-segmental Hepatic Artery

Mean Doxorubicin dose: 104 mg (Range: 19 – 150 mg)

Embolization endpoints were operator dependent

Repeat Chemoembolization:
  » Single Chemoembolization: 7 patients
  » Two Chemoembolizations: 4 patients
  » Three Chemoembolizations: 11 patients
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FULL CITATION: