Efficacy and safety of chemoembolisation using 40μm Doxorubicin-eluting microspheres in hepatocellular carcinoma
Disclosure of conflict of interest

Speaker name: Ulf Teichgräber, MD, MBA

Potential conflicts of interest related to the presentation:

- Research grant: Boston Scientific

Potential conflicts of interest not related to the presentation:


- Master research agreements with Siemens Healthineers, GE Healthcare

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Key Points

Objective:
Evaluation of the efficacy and safety of doxorubicin-loaded 40 µm sized Tandem Embozene™ microspheres in the treatment of patients with HCC

Design:
Retrospective, Monocentric Data Analyses

Therapy Response:
measured by mRECIST in mint lesion software

Endpoint classification:
Safety and Efficacy of Embozene™ TANDEM microspheres (Boston Scientific)
Embozene Microspheres

- Hydrogel Core
- Surface Nano Coating: Polyzene-F-shell
- Precise calibration: tight size distribution
- Highly biocompatible
- Minimize inflammatory response
- Stable suspension: no aggregation, no catheter clotting
- Highly elasticity and structural integrity

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Calibration

➢ Tight size distribution allows better steerable vessel occlusion

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Principle

- Aim: Embolization of pre-capillary bed
- Better and deep tutor vessel penetration
- Particle size ≤75µm

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Study Population

83 patients: 75 men, 8 women, mean age 64.7 years

Observation period: May 2012-May 2017
a total of 141 interventions were performed

Mean number of treatments per patient: 1.7

<table>
<thead>
<tr>
<th>DEB-TACE cycle (n)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>patients (n)</td>
<td>49</td>
<td>20</td>
<td>7</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>
Mean time between CT/MRI examination before treatment and TACE: 23.0 +/- 18.2 days
Software: Mint Lesion for therapy response evaluation

All pre- and post-treatment images were analyzed

282 imaging examinations (255 CT+27 MRI)

All lesions with arterial enhancement were circumnavigated in each axial slice
Therapy Response

Evaluation was based on the treated lesions declared to be „target lesions“, other not treated lesions= „findings“

Analysis according to mRECIST criteria

**Evaluation results:**

- Complete response (CR)
- Partial response (PR)
- Stable Disease (SD)
- Progressive Disease (PD)
Results

CR = complete remission > disappearance of all lesions
PR = partial remission > 30% decrease in sum of all target lesions in longest axis measurement
SD = stable disease > no significant decrease or increase in the size of target lesions
PD = progressive disease > an increase of at least 20% in the sum of the LD of targeted lesions
Results

Response Rate = CR + PR = 63.12%
Results

Disease Control Rate = CR+PR+SD = 95.74%
### Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>Postembolization-Syndrome (PES)</th>
<th>Pancreatitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>n=5</td>
<td>n=2</td>
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</tbody>
</table>

### Prolonged Hospitalization & Death

<table>
<thead>
<tr>
<th></th>
<th>Prolonged Hospitalization ¹</th>
<th>Death ³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>n=25 ²</td>
<td>n=1</td>
</tr>
</tbody>
</table>

¹ duration of hospital stay > 3 days

² increased liver parameters (n=9), increased infect parameters (n=3), increased liver and infect parameters (n=1), abdominal pain (n=5), nausea (n=2), fever (n=3), hematoma (groin) (n=1), hypertensive derailment (n=1)

³ patient died 16 days after DEB-TACE intervention, cause: acute liver failure

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Mint lesion

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1. Case Example

Baseline Imaging

longitudinal axis: 44,2 mm
short axis: 38,5 mm
volume: 27,0 cm^3

evaluation with mRECIST criteria

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1. Case Example
Follow-up Imaging (42 days between BL and FU)

- Longitudinal axis: 35.1 mm
- Short axis: 11.4 mm
- Volume: 5.8 cm³

Result: SD

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Circumnavigation in Mint Lesion
Mint lesion
2. Case Example

longitudinal axis: 32,0 mm
short axis: 28,7 mm
volume: 10,7 cm^3

evaluation with mRECIST criteria

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2. Case Example
Follow-Up Imaging (92 days between BL and FU)

longitudinal axis: 0.0 mm
short axis: 0.0 mm
volume: 0 cm^3

circumnavigation in Mint Lesion
Result: CR

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Conclusion

- DEB-TACE with 40 µm sized Tandem Embozene microspheres is an effective procedure with a response rate of 63% and disease control rate of 96%

- Superselective embolization in combination with small sized microspheres lead to an effective and deep tumor vessel penetration

- The superiority of small sized microspheres should be assessed with a prospective head-to-head trial against the conventional TACE with Lipiodol
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