Case Report.

DSM-TACE OF UNRESECTABLE MULTINODULAR BILOBAR HCC IN NAFLD CIRRHOSIS

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Patient

- 68 year old male
- Histologically confirmed **unresectable multinodular bilobar HCC G2-3** (>6 lesions, largest lesion 7 cm in hepatic segments IV-V) | *Fig 1a-f* nonalcoholic fatty liver disease (NAFLD) cirrhosis
- BCLC B, Child-Pugh: A5 – MELD 7. ECOG 0. No ascites – no portal hypertension.Comorbidities: diabetes and arterial hypertension
- Lab parameters: **AFP** 5 ng/dl | **Total bilirubin** 0.5 mg/dl | **PLT** 195 x 10^3/dl | **INR** 1.05 | **Albumin** 4.2g/dl | **Creatinine** 0.94 mg/dl
- Tumor board decision:
  - **DSM-TACE** with 50 mg Doxorubicin
  - **Bilobar treatment** (four treatments at 2-week interval; the first and third treatment were targeted to the lobe more involved by disease)

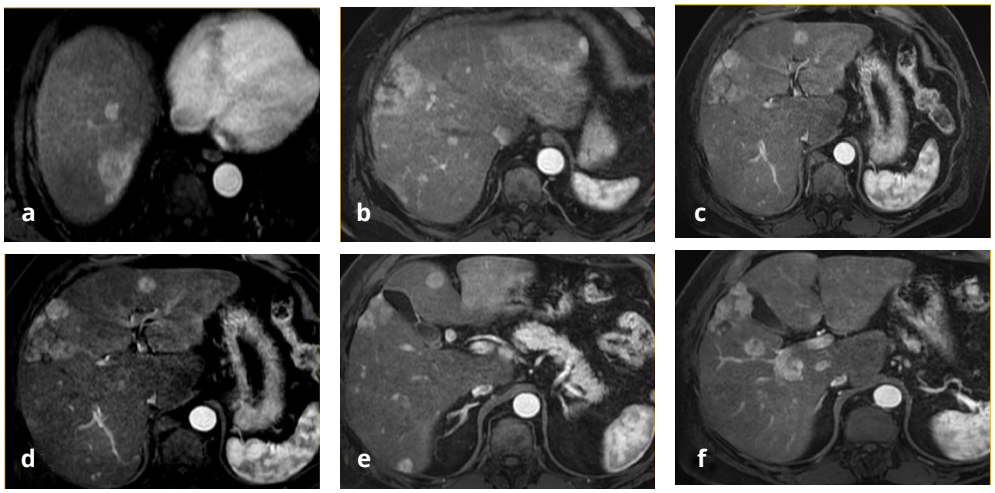


Figure 1: Pre-procedural CT scans show multinodular bilobar HCC lesions (up to 7 cm in size) (a-f)

DSM-TACE Procedure

- DSM-TACE procedures were performed in an angiographic suite, using patient monitoring and anesthesiological assistance under local anesthesia
- Selective lobar catheterization was performed with a coaxial technique placing a 2.7-Fr microcatheter in the right or left hepatic artery that was feeding the tumor lesions | *Fig 2*
- Solution of **450 mg in 7.5 ml of microspheres type EmboCept® S*** mixed with **50 mg of Doxorubicin** andnon-ionic contrast medium was slowly infused in two steps:
  - Drug uptake: a ready-to-use solution composed of 50 mg of Doxorubicin diluted in 5 ml of saline solution plus 3.5 ml of EmboCept® S* plus 15 ml for right lobe or 10 ml for left lobe of non-ionic contrast medium was injected
  - Stop flow: the last 4 ml of EmboCept® S* plus 6 ml of non-ionic contrast medium was injected
- A technical success was obtained; in particular, all the expected dose was infused and a final "stop flow" was obtained

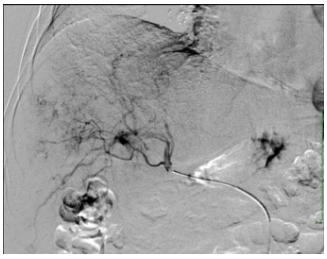
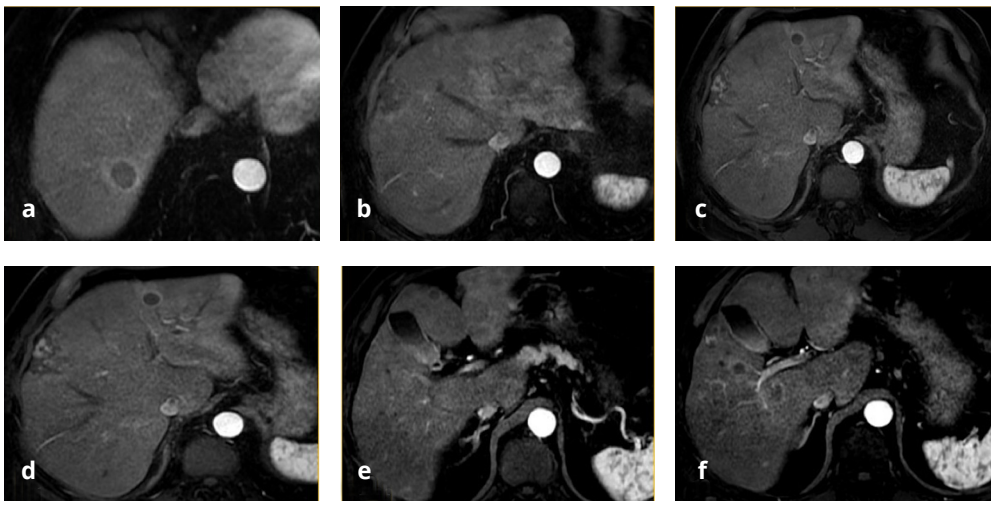


Figure 2: Angiogram shows lobar catheterization of right hepatic artery, using coaxial technique

Outcome

- Patient experienced no adverse events, with dismission after 24 hours, without any pain or periprocedural complications
- 3-month CT follow-up showed an **almost complete response with necrosis of almost all multinodular hepatic lesions** | *Fig 3a-f*



3-month post DSM-TACE CT scans show an almost complete response with necrosis of almost all hepatic lesions, without complications (a-f)

Outlook

- Based on 3-month follow-up result, patient will receive 2 more DSM-TACE sessions

CONCLUSION

- **DSM-TACE** with doxorubicin is a **safe, feasible, and effective option** in the treatment of patients with multinodular bilobar HCC, without drug-related toxicities
- Degradable Starch Microspheres cause a temporary occlusion, with a short ischemic period, allowing an **optimal drug uptake** with no post-embolic effects
- The transient vascular occlusion generated by **DSM allows to repeat treatment,** reducing the risk of liver toxicity that may occur when repeating cTACE or DEB-TACE
- DSM-TACE is used for **treatment of multinodular extensive intermediate HCC stage patients** where superselective TACE is not possible or could be characterized by a high risk of hepatic toxicities or adverse events. DSM-TACE is well-tolerated and effective for BCLC-B patients and BCLC-C patients

** Patient treated with EmboCept® S, which is equivalent to the successor and available product EmboCept® S DSM 50 µm [data on file]. EmboCept® and EmboCept® S manufactured by Serumwerk Bernburg AG*

DSM *Degradable Starch Microspheres*

TACE *Transarterial chemoembolization*

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