Case Report.

DSM-TACE OF UNRESECTABLE PERIHILAR CHOLANGIOCARCINOMA

Author: ***Andreas H. Mahnken, MD, MBA, MME***
Philipps-University, Marburg, Germany

Patient

- 78 year old female
- Histology proven, unresectable perihilar cholangiocarcinoma (pCCA), Bismuth 4
- Course of disease and prior treatment:
  - 11/2019: onset of symptoms and diagnosis
  - 03/2020: complicated ERCP and biliary stent placement
  - 04/2020: laparotomy with gall bladder resection and hilar lymph node resection
  - 05-08/2020: Palliative chemotherapy (gemcitabine, oxaliplatin)
  - 08/2020: Multifocal tumor progression with multiple bilobar mass like lesions, histology proven as pCCA
- Lab parameters: **Alkaline phosphatase** 203 U/l | **GGT** 192 U/l | **eGFR** 61 ml/min/1.73m^2 **Ferritin** 78.9 ng/ml
- Tumor board decision:
  - **DSM-TACE** with EmboCept® DSM 50 µm and cisplatinum and gemcitabine
  - Adjuvant capecitabine

DSM-TACE Procedure

- 3 sessions of DSM-TACE at 6 weeks intervals
- Procedures were performed in angiographic suite under local anesthesia
- Premedication with granisetron, piritramid and cefuroxime
- Right femoral approach (5F), diagnostic angiogram revealed stenosis of the celiac trunk and distinct collaterals from the superior mesenteric artery, microcatheter (2.7F) placement in the proper hepatic artery for **whole liver treatment** due to rapid tumor growth and multicentricity | *Fig 1*
- Stepwise application of **300 mg EmboCept® S DSM 50 µm, 75 mg/m2 Cisplatin PlatiCept, 1000 mg/m2 gemcitabine**
  - Step 1: 100-150 mg EmboCept® S DSM 50 µm in 0.9% NaCl until massive flow reduction, but maintained antegrade flow is reached
  - Step 2: sequential slow infusion of chemotherapeutic agents over a 30 minute period using a rate-controlled syringe pump with intermittend administration of DSMs after angiographic control of hepatic artery flow
  - Step 3: via a 3-way stopcock the remaining EmboCept® S DSM 50 µm is administered in a way to maintain the massively reduced, but antegrade hepatic artery flow
- Endpoint for successful treatment was defined as delivery of the full planned dose

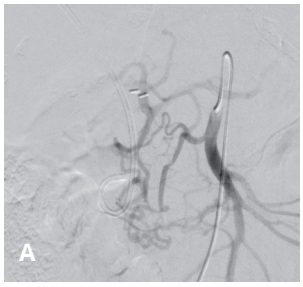

Figure 1: Diagnostic catheter angiogram shows a fixed high grade stenosis of the celiac trunk with distinct collaterals from the superior mesenteric artery (A). For whole liver treatment a microcatheter was placed in the proper hepatic artery (B).

Outcome

- Patient experienced no major adverse events, except for an transient elevation of **AST** and **ALT**. Renal function improved over time with a current **eGFR** 73 ml/min/1.73m^2
- Patient experienced mild fatigue for about a week after the procedure without any limit in the personal activity level
- At the current 8 month follow-up MR imaging after the first DSM-TACE procedure the **tumor became almost undetectable.** The patient is doing well without any limitations to her daily life | *Fig 3*

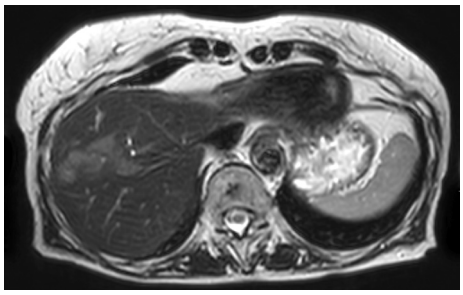

Figure 2: Pre-DSM-TACE MRI depicts a rapidly progressive map like lesion in the right liver lobe. This lesion was histology proven as a part of the pCCA.

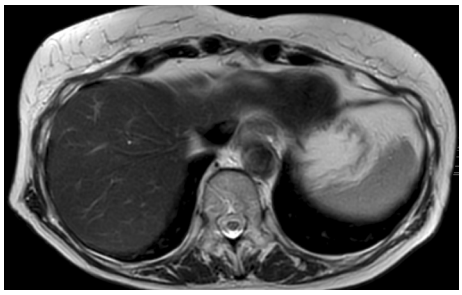

Figure 3: Eight months after the first DSM-TACE there is an excellent response. According to RECIST 1.1 she has partial response with only very little tumor left.

Outlook

- Tumor board decision:
  - 3 month "treatment holiday"
  - Restaging in 3 months by means of MRI
  - Continue DSM-TACE in case of tumor progress

CONCLUSION

- EmboCept® S DSM 50 µm is an **effective, safe and easy to use embolic agent**
- As degradable agent EmboCept® S DSM 50 µm can be used for **whole organ treatments with low toxicity,** even if the organ function is compromised. The same feature permits repeat use via the same vessels
- DSM-TACE with EmboCept® S DSM 50 µm can be **freely combined with any chemotherapy suited for transarterial administration**
- The properties of EmboCept® S DSM 50 µm **facilitate embolization procedures** for a broad range of interventional oncology applications

DSM *Degradable Starch Microspheres*
TACE *Transarterial chemoembolization*
pCCA *perihilar cholangiocarcinoma*

Magle PharmaCept GmbH, Cicerostrasse 2, 10709 Berlin, Germany
Phone: +49-(0)30–7565985-0 · info@maglepharmacept.com

20231106-01/2023