INTRAHEPATIC CHOLANGIOCARCINOMA (ICC) TREATED WITH DSM-TACE



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Patient

- 84 year old female
- Stage III N0 M0 intrahepatic cholangiocarcinoma (ICC) involving segments IV-V-VI-VII diagnosed in August 2019
- Starting oral Capecitabine therapy in September 2019
- Lab Parameters: HB 11.5 g/dl | PLT 164.000 µl | ALT 31 U/l | AST 53 U/l, Serum bilirubin 1.2 mg/dl | Creatinine 0.8 mg/dl | INR 1.14
- Abdominal follow-up CT-scan showed disease progression in December 2019 | Fig 1a-c
- Tumor board decision:
 - DSM-TACE with 50 mg Doxorubicin
 - Monolobar treatment planned (two treatments at 2-month interval; first treatment was targeted to posterior segmental branch of right hepatic artery, feeding segments VI-VII (lobes more involved by disease), second treatment targeted to anterior segmental branch feeding segments IV-V)

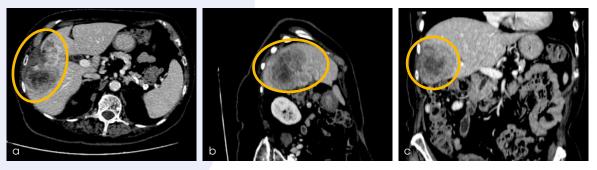


Figure 1: Abdominal follow-up CT before DSM-TACE showing disease progression



DSM-TACE Procedure

- Procedure was performed in an angiographic suite, during patient monitoring and anesthesiological assistance under local anesthesia
- Anatomy of hepatic artery and possible branches to non-target structure was confirmed by common hepatic artery selective angiography, via transfemoral retrograde approach | Fig 2
- Super-selective lobar catheterization was performed using 1.9 Fr microcatheter
- Under fluoroscopic guidance, a solution of 450 mg in 7.5 ml of microspheres type EmboCept® S DSM 50 µm mixed with 50 mg Doxorubicin and 21 ml non-ionic contrast medium was slowly infused in two steps:
 - Drug uptake: 50 mg of Doxorubicin diluted in 10 ml of saline solution plus 3.5 ml EmboCept® S DSM 50 µm plus 15 ml non-ionic contrast medium was injected
 - 4 ml of EmboCept[®] S DSM 50 µm plus 6 ml non-ionic contrast medium was injected to obtain stasis
- Endpoint for both steps was the delivery of the full planned dose with the achievement of an arterial stop-flow, which was achieved in all cases using EmboCept[®] S DSM 50 μm

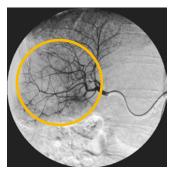


Figure 2: Hepatic artery selective angiography





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Outcome

- Partly transient elevation of hepatic enzymes (AST 90 U/I | ALT 19 U/I) and serum bilirubin (<2 mg/dl) at 1 day from procedure with return to normal values in three days without medical treatment
- Patient experienced mild nausea and abdominal pain, controlled and solved within 8 hours after procedure with standard medical therapy
- Patient was regularly dismissed after 48 hours, without any pain or periprocedural complications
- Partial response was apparent after second DSM-TACE (at 3-month follow-up) | Fig 3
- Tumor board decision was to continue the treatment
- **Complete response** with full necrosis of ICC with significant downsizing of residual liver parenchymal alteration after third DSM-TACE (at 6-month CT follow-up) | Fig 4 a-c

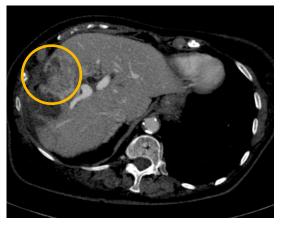
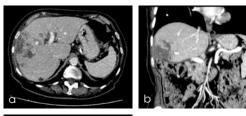
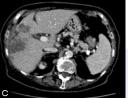


Figure 3: CT indicating partial response after second DSM-TACE at 3-month follow-up









CONCLUSION

- EmboCept® S DSM 50 µm causes a temporary occlusion with a short ischemic period, allowing for an **optimal drug uptake**
- Technical success was achieved in all DSM-TACE procedures using EmboCept® S DSM 50 µm
- DSM-TACE allows repetitive treatment with an optimal safety profile and low drug related toxicities
- The use of EmboCept® S DSM 50 µm offers a very effective treatment option in ICC patients not being eligible for surgery or refractory to standard chemotherapy regimen
- **DSM** Degradable Starch Microspheres
- ICC Intrahepatic cholangiocarcinoma
- TACE Transarterial chemoembolization

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