
CHEMOEMBOLIZATION
WITH DEGRADABLE STARCH MICROSPHERES
EMBOCEPT® S (AMILOMER, DSM 35/50)

NEW CLINICAL AND EXPERIMENTAL PUBLICATIONS

The increasing interest in local tumor therapy results as well from new publications which describe the actual advantages and benefits of the local therapy, as of the fact to include modern techniques and materials in this therapy.

One of the key-studies discussed with it, is the meta-analysis for chemoembolization of the HCC which is considered to be the pioneer for standardization of TACE. This study creates the basis of the following investigations with modern substances. The advantages of survival by a combined i.a./i.v. - therapy of liver metastases of CRC, first time published in 1999, had been achieved an increasing success in palliative therapy areas by modern chemotherapeutic agents.

Beside the classical application for TACE new fields of application - such as lung tumors - arise from that therapy. Nevertheless the scientific basis of the therapy also contributes to exploit new therapeutic options, such as gene-therapy or thermoablation with regional tumor-therapy.

The universal application of degradable starch microspheres for embolization convinces **“by the decisive advantage for the patient to prolong his life-time once again.”** (Vogl T. www.dradio.de/dlf/sendungen/sprechstunde/913587/)

Summary of the following publications

Authors: H Nishiofuku et al.

Source: J Vasc Interv Radiol 2013, 24:56-65

Title: Transcatheter arterial chemoembolization using cisplatin powder mixed with degradable starch microspheres for colorectal liver metastases after FOLFOX Failure: Results of a phase I/II Study.

The study enrolled 24 patients and shows that transcatheter arterial chemoembolization with cisplatin powder at a dose of 80mg/m² mixed with DSM is well tolerated and can produce a high response rate (61.1%) with a long survival time (21.1 months) for patients with unresectable colorectal liver metastases after failure of FOLFOX.

Authors: C Meyer et al.

Source: Eur J Nucl Med Mol Imaging 2013

Title: Feasibility of temporary protective embolization of normal liver tissue using degradable starch microspheres during radioembolization of liver tumours.

From Dec 2011 to July 2012 radioembolization was performed in 54 patients. Five of these patients underwent protective temporary embolization using DSM (EmboCept® S) of normal liver tissue that could not be excluded from the area treated by radioembolization through catheter repositioning. Temporary embolization using DSM was technically successful in all five patients. ^{99m}Tc-MAA SPECT/CT performed in the first two patients after DSM injections showed no increased pulmonary shunting compared to the MAA test injection without DSM. Temporary embolization with DSM before radioembolization can effectively protect areas of normal liver tissue from irradiation and avoid permanent embolization.

Authors: P Wiggermann et al.

Source: Cl. Hemorheol & Microcirculation 2012, 1–12

Title: Dynamic evaluation and quantification of microvascularization during degradable starch microspheres transarterial Chemoembolisation (DSM-TACE) of HCC lesions using contrast enhanced ultrasound (CEUS): A feasibility study.

DSM such as EmboCept® S were developed to overcome the limitation of TACE due to permanent occlusion of the hepatic artery and to provide a more effective treatment than TAI. To evaluate the time dependent changes in capillary microvascularisation of HCC lesions during DSM-TACE with EmboCept® S a total of 48 CEUS examinations were performed (1-5 MHz, convex probe) in 6 patients. Using quantitative perfusion analysis it was possible to quantify the transient embolizing effect of DSM-TACE.

Authors: T Yamasaki, S Hamabe, I Saeki et al.

Source: J Gastroenterol 2011, 46:359–366

Title: A novel transcatheter arterial infusion chemotherapy using iodized oil and degradable starch microspheres for hepatocellular carcinoma: a prospective randomized trial.

45 patients with HCC were randomly divided in 3 groups: TAI using mixture lipiodol with cisplatin, TAI using mixture DSM with cisplatin and TAI using mixture lipiodol with cisplatin followed by DSM. The response rates in the lipiodol group were 40%, in the DSM group 53.4% and in the lipiodol + DSM group 80%. The progression-free survival in the lipiodol + DSM group was significantly better than those in the DSM group (P=0.020) and the lipiodol group (P=0.35). There were no serious adverse effects among the 3 groups.

Summary of the following publications

Authors: TJ Vogl, NNN Naguib, NEA Nour-Eldin et al. **Source:** Eur Radiology 2010, 20:173-80

Title: Transarterial chemoembolization (TACE) with mitomycin C and gemcitabine for liver metastases in breast cancer.

208 patients with unresectable hepatic metastases of breast cancer were repeatedly treated with TACE at 4 weeks intervals (8mg/m² mitomycin C vs. 1000mg/m² gemcitabine vs. mitomycin C (MMC) + gemcitabine + Lipiodol and 200-450mg EmboCept®). The mean survival time from start of TACE was 30.7 months. Differences between the treatment groups: MMC: 24 months, gemcitabine: 22.3 months, MMC+gemcitabine: 35.5 months. TACE with a combined chemotherapy and the use of degradable starch microspheres is an optimal therapy for this indication.

Authors: TJ Vogl, T Gruber, NNN Naguib et al. **Source:** AJR 2009, 193:941-947

Title: Liver metastases of neuroendocrine tumors: Treatment with hepatic transarterial chemotherapy using two therapeutic protocols.

48 patients with liver metastases from neuroendocrine tumors underwent repetitive selective hepatic artery chemotherapy used 8mg mitomycin C alone or combined with 1000mg/m² gemcitabine chemotherapy agents in 4-week intervals. All patients in both groups received systemic chemotherapy followed by chemoembolization 200-450mg EmboCept®. Local tumor control evaluation resulted in: partial response (PR) for group 1: 11.1%, group 2: 23.33%; stable disease (SD) for group 1: 50%, group 2: 53.34%; and progressive disease (PD) for group 1: 38.9%, group 2: 23.33%. The survival rate from initial diagnosis to the fifth year for group 1 was 11.11% and for group 2 was 46.67%.

Authors: J Altomonte, R Braren, S Schulz et al. **Source:** Hepatology 2008, 48:1864-73

Title: Synergistic antitumor effects of transarterial viroembolization for multifocal hepatocellular carcinoma in rats.

Oncolytic virotherapy is a promising strategy for safe and effective treatment of malignancy. DSM is one of the embolic agent that is registered and that provides transient embolization of the therapeutic agent with high concentration at the tumor tissue. Oncolytic virus (VSV), when administered in combination with EmboCept®, results in enhanced tumor necrosis and synergistically prolongs survival when compared with VSV alone. This viroembolization regimen represents an innovative therapeutic modality that can augment the future development of transarterial oncolytic virus therapy for patients with advanced HCC.