

Developments in TACE and SIRT treatment in patients

April 26 2013

Data from a number of clinical trials presented today at the International Liver Congress 2013 shed new light on the use of TACE and SIRT in the treatment of hepatocellular carcinoma (HCC).

Transarterial chemoembolization (TACE) is a technique in which small particles designed to block blood vessels mixed or coated with [chemotherapeutic drugs](#) are injected directly into an artery supplying the [tumour](#); it has become a standard treatment in selected [patients](#) with HCC.

New data presented today has identified a [scoring system](#) which defines those HCC patients who achieve the most benefit from TACE. An Assessment for Retreatment with TACE (or ART-score) was developed based on the impact of the initial TACE session on parameters of [liver function](#) and tumour response, and their impact on overall survival (overall survival; log rank test).

The ART-score differentiated two groups (0-1.5 points; ≥ 2.5 points) with distinct differences in prognosis (median overall survival: 23.7 months vs. 6.6 months; p

EASL Vice-Secretary, Prof. Markus Peck-Radosavljevic commented: "These findings represent an important discovery as they will enable physicians to identify and treat those HCC patients who will benefit from repeat TACE sessions. Furthermore, rounds of ineffective treatment, as well as any associated side effects and complications, can

be avoided for those patients who are not likely to respond."

While TACE is the standard-of-care treatment for intermediate-stage HCC, selective Internal Radiotherapy Treatment (SIRT) is more commonly used to treat patients with advanced-stage HCC, or those who are poor candidates for, or have failed TACE. However, data from SIRTACE, a separate, open-label, multi-centre [pilot study](#) suggest that a single-session of SIRT is as safe and effective as multiple sessions of TACE in a typical TACE patient cohort with unresectable HCC.

Patients were randomised to receive either TACE (n=15) or SIRT (n=13). Patients received a mean of 3.4 TACE interventions (median 2; range 1-11) or 1 SIRT procedure. Treatment response was assessed by local (using RECIST 1.0) and independent central (RECIST 1.1 and mRECIST) review. Median progression-free survival (RECIST 1.1) was 5.5 months (95%CI: 1.6- not reached) for TACE and 4.1 months (95%CI: 2.3-9.9) for SIRT (p=0.411). Overall survival did not differ by procedure (p=0.244).

The similar efficacy and safety of these two procedures presents a challenge for the design of a phase III trial for intermediate-stage HCC in terms of whether to use TACE or SIRT as the preferred treatment technique.

Finally, the SORAMIC European multicentre phase II clinical trial also showcased at the congress, evaluated the efficacy and safety of using a combination of SIRT and sorafenib for the [treatment](#) of HCC.

Data from the interim safety analysis has confirmed that SIRT as a sequential approach followed by an escalation scheme for sorafenib does not lead to increased toxicity. Interim analysis of the data showed a total number of adverse events of 196 and 220 in the combination and control arm, with grade 3-5 [adverse events](#) reaching 42 and 49, respectively

($p > 0.05$).

SORAMIC continues to recruit and investigators are hopeful that the combination of SIRT and sorafenib will be shown to significantly enhance survival over sorafenib alone without increasing toxicity thus enabling to design large Phase III clinical trials.

More information: References:

1 Sieghart W et al, THE ART OF DECISION MAKING: RETREATMENT WITH TACE IN PATIENTS WITH HEPATOCELLULAR CARCINOMA. Abstract presented at the International Liver Congress 2013

2 Kolligs FT et al, SIRTACE: A RANDOMISED MULTICENTRE PILOT TRIAL OF SELECTIVE INTERNAL RADIOEMBOLISATION (SIRT) WITH YTTRIUM-90 MICROSPHERES VERSUS TRANSARTERIAL CHEMOEMBOLISATION (TACE) IN PATIENTS WITH UNRESECTABLE HEPATOCELLULAR CARCINOMA (HCC). Abstract presented at the International Liver Congress 2013

3 Ricke J et al, SAFETY AND TOXICITY OF THE COMBINATION OF Y90-RADIOEMBOLIZATION AND SORAFENIB IN ADVANCED HCC: AN INTERIM ANALYSIS OF THE EUROPEAN MULTICENTER TRIAL SORAMIC. Abstract presented at the International Liver Congress 2013

Provided by European Association for the Study of the Liver

Citation: Developments in TACE and SIRT treatment in patients (2013, April 26) retrieved 20

September 2024 from <https://medicalxpress.com/news/2013-04-tace-sirt-treatment-patients.html>

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