P-45 – REAL-WORLD OUTCOMES OF PATIENTS WITH HCC TREATED WITH TARE: RESULTS FROM CIRT, A LARGE EUROPEAN PROSPECTIVE MULTICENTER OBSERVATIONAL STUDY

F. KOLLIGS[1], D. ARNOLD[2], T. HELMBERGER[3], G. MALEUX[4], B. PEYNIRCIOGLU[5], N. SCHAEFER[6], M. PECH[7], R. GOLFIERI[8], T. PFAMMATTER[9], M. RONOT[10], N. DE JONG[11], B. SANGRO[12]

1. Department of Internal Medicine and Gastroenterology,Helios Klinikum Berlin-Buch, Berlin, DE
2. Oncology and Hematology, Asklepios Tumorzentrum Hamburg, AK Altona, Hamburg, DE
3. Department of Radiology, Neuroradiology and Minimal-Invasive Therapy, Klinikum Bogenhausen, Munich, DE
4. Radiology, Universitair Ziekenhuis Leuven, Leuven, BE
5. Department of Radiology, School of Medicine, Hacettepe University, Sihhiye Campus, Ankara, TR
6. Service de médecine nucléaire et imagerie moléculaire, Inselspital Hospital Lausanne, Lausanne, CH
7. Department of Radiology and Nuclear Medicine, University of Magdeburg, Magdeburg, DE
8. Radiology Unit, Department of Experimental, Diagnostic and Speciality Medicine, Sant'Orsola Hospital, University of Bologna, Bologna, IT
9. Institut für Diagnostische und Interventionelle Radiologie, Universitätsspital Zürich, Zürich, CH
10. Department of Radiology, University Hospitals Paris Nord Val de Seine, APHP, Beaujon, Clichy, Hauts-de-Seine, FR
11. Next Research, Cardiovascular and Interventional Radiological Society of Europe, Vienna, AT
12. Liver Unit, Clínica Universidad de Navarra; IDISNA and CIBEREHD, Pamplona, ES

ILCA conference
The world's leading liver cancer meeting
2 - 5 September 2021
WWW.ILCA2021.ORG

CIRT

INTRODUCTION

Trans-arterial radioembolization (TARE) is a treatment option for patients with metastases limited to the liver. However, there is a **lack of large prospective observational cohorts** on the clinical application of TARE for patients with hepatocellular carcinoma (HCC).

AIM

- **The CIRSE Registry for SIR-Spheres Therapy** (CIRT) was set up to evaluate the **clinical context and outcomes of patients treated with Y90 resin microspheres**
- The primary objective of this subgroup analysis was to investigate outcome in terms of **overall survival (OS)** following TARE in patients with HCC.
- Secondary endpoints were progression-free-survival, hepatic-progression-free survival, quality of live and potential **prognostic factors of survival** after TARE in HCC patients.

METHOD

- Prospective observational multi-centre study
- Adult HCC patients treated with Y90 resin microspheres as standard of care.
- No exclusion criteria.
- Enrolment period Jan 2015 – Dec 2017.
- Follow-up period 24 months.
- Data collected on baseline characteristics, clinical context and dosimetry, OS, PFS, hepatic PFS, safety and QoL.
- Prospective collection of investigator-assessed treatment intention.
- Univariate and multivariate analyses performed to determine prognostic factors for OS, PFS, and hPFS.
- Further investigation comparing the results of dosimetry models Partition model with BSA/mBSA is ongoing.

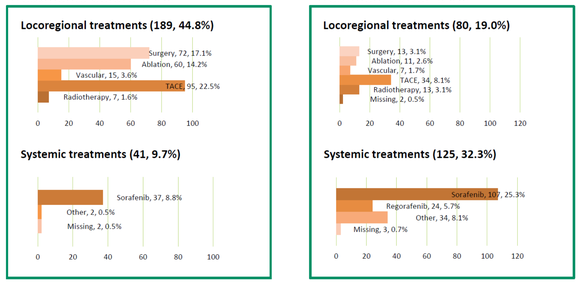
RESULTS

Baseline

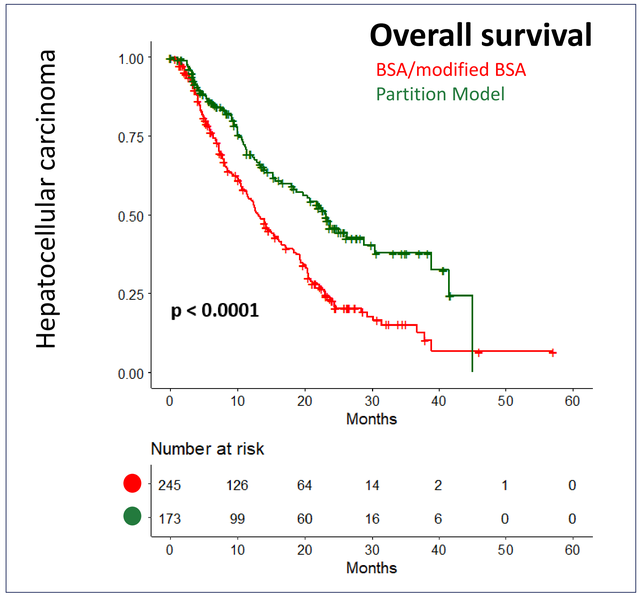
- 1027 patients in the CIRT study
- 422 patients with HCC

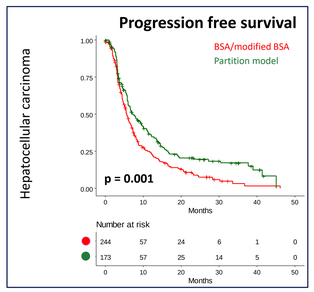
Variable		N (%)
Age (median, IQR)		68 (60-74)
Gender	Male	341 (80.8%)
	Female	74 (17.5%)
Cirrhosis	Yes	299 (70.9%)
	No	123 (29.1%)
BLCL stage	A	59 (14.0%)
	B	217 (51.4%)
	C	142 (33.6%)
	D	4 (0.9%)
Tumour location	Bilobar	150 (35.5%)
	Left	51 (12.1%)
	Right	221 (52.4%)
ALBI grade	A1	139 (32.9%)
	A2	219 (51.9%)
	A3	15 (3.6%)
	Missing	49 (11.6%)
ECOG	0	260 (61.6%)
	1	131 (31.0%)
	2+3	31 (7.3%)

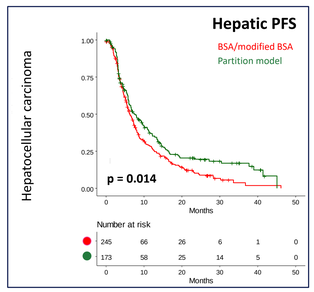
Treatment application



Dose methodology







Preliminary analysis *suggests that patients that received personalised dosimetry (partition model) showed an improved OS, PFS and hPFS compared to dose calculations using BSA or modified BSA*

Safety

Abdominal Pain	9 (2.1%)
Fatigue	6 (1.4%)
Fever	2 (0.5%)
Nausea	3 (0.7%)
Vomiting	2 (0.5%)
GI Ulceration	1 (0.2%)
Gastritis	0 (0.0%)
Radiation Cholecystitis	0 (0.0%)
Radioembolization-Induced Liver Disease	3 (0.7%)
Other	15 (3.6%)

1. *36.7% (n=155) of the patients had at least 1 adverse event*
2. *7.1% (n=30) of the patients had at least 1 SAE (grade 3-5)*
3. *30-day mortality rate: 0.7% (n=3)*

Multivariate analysis (OS)

Variable	Threshold (n,%)	HR (95% CI)	p value
ECOG	1 (131, 31.0%)	1.61 (1.18-2.19)	0.0027
	2+3 (31, 7.3%)	1.84 (1.08-3.13)	0.0252
Cirrhosis	Yes (299, 70.9%)	1.39 (1.00-1.93)	0.0522
Ascites	Yes (61 (14.3%)	1.63 (1.11-2.40)	0.0136
Location of tumor	Left (51, 12.1%)	0.64 (0.40-1.02)	0.0626
	Right (221, 52.4%)	0.55 (0.41-0.75)	0.0002
Extra-hepatic disease prior to treatment	Yes (36, 8.5%)	1.55 (1.01-2.37)	0.0460
Portal vein occlusion	Lobar (39, 9.0%)	1.42 (0.84-2.38)	0.1884
	Main (19, 4.5%)	2.52 (1.38-4.60)	0.0026
	Segmental (81, 19.2%)	1.49 (1.04-2.13)	0.0308
Treatment intention	Curative (XXX)	0.65 (0.48-0.88)	0.0056
Dose methodology vs partition model	BSA/mBSA (245, 58.1%)	1.57 (1.11-2.21)	0.0108
ALBI grade	A2 (219, 51.9%)	1.59 (1.17-2.15)	0.0032
	A3 (15, 3.6%)	2.86 (1.51-5.39)	0.0012

MVA shows that:

1. *Presence of ascites, extra-hepatic disease, portal vein occlusion, bilobar disease and ECOG > 0, are independent predictors of reduced OS*
2. *Partition model shows better OS outcomes than BSA/mBSA*
3. *ALBI grades are a good independent predictor of OS*

CONCLUSIONS

- TARE is generally applied according to guideline recommendations.
- Careful patient selection is essential to increase overall survival and (hepatic) progression-free survival.
- Personalised dosimetry calculation (partition model) may be associated with an improved OS, PFS and hPFS in TARE.
- Randomised controlled trials are needed to confirm the effect of personalised dosimetry on the effectiveness of TARE.

REFERENCES

- Helmberger T, et al. Clinical Application of Trans-Arterial Radioembolization in Hepatic Malignancies in Europe: First Results from the Prospective Multicentre Observational Study CIRSE Registry for SIR-Spheres Therapy (CIRT). Cardiovasc Intervent Radiol. 2021 Jan;44(1):21-35.
- Helmberger T, et al. Clinical Application of Radioembolization in Hepatic Malignancies: Protocol for a Prospective Multicenter Observational Study. JMIR Res Protoc. 2020 Apr 22;9(4):e16296.
- Galle PR, et al. EASL Clinical Practice Guidelines: Management of hepatocellular carcinoma. J Hepatol. 2018
- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines ®) Hepatobiliary Cancers, Version 3.2021. NCCN website. 15 June 2021. Accessed 12 August 2021. https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf
- Vilgrain V, et al. Efficacy and safety of selective internal radiotherapy with yttrium-90 resin microspheres compared with sorafenib in locally advanced and inoperable hepatocellular carcinoma (SARAH): an open-label randomised controlled phase 3 trial. Lancet Oncol. 2017.

INFORMATION

Conflict of interest

FK is on the Advisory Board/Speakers Bureau of Bayer, Bristol-Myers-Squibb, Lilly, Exact Sciences, Exelixis, Falk Foundation, Ipsen, and Roche

Funding information

The CIRSE Registry for SIR-Spheres Therapy was sponsored by the Cardiovascular and Interventional Radiological Society of Europe and funded by an unconditional research grant from Sirtex Medical Europe GmbH.

Contact information

Please contact N de Jong (dejong@cirse.org) for more information about the study

Click the QR code for the main results of the CIRT study

CIRSE