Clinical Application of TARE in Hepatic Malignancies in Europe: first results from the prospective multicentre observational study CIRSE Registry for SIR-Spheres Therapy (CIRT)

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Conflicts of interest

NONE

First European-wide prospective, observational, multicentre study on Y90 resin microspheres

CIRT addresses the need for real-life data on Y90 resin microspheres:

- Prospective observational data in the European context
- Indications in HCC, ICC or mCRC and beyond

Independently conducted by CIRSE

- First international trial driven by a scientific society

Primary objective: real-life application

To observe the real-life clinical application of TARE with Y-90 resin microspheres and the impact of the treatment in clinical practice

1. Type of liver cancer
2. Intention of treatment
3. Locoregional procedures before to TARE
4. Associated systemic therapy
5. Locoregional procedures after TARE

Secondary objectives

Effectiveness: OS, PFS, hepatic-PFS, imaging response

Safety: treatment complications, adverse events, laboratory assessments

Technical considerations: treatment planning and administration, procedure-related outcomes

Quality of life: change in QoL from baseline (QLQ-C30 with HCC Module)

Methods

Site selection criteria

- Upon invitation
- Experienced centres: minimum 10 cases in the last 12 months and 40 overall cases

Inclusion criteria

- 18 years or older
- To be treated with Y-90 resin microspheres for primary or metastatic liver tumours
- No specific exclusion criteria

Enrolment period

Patient distribution

Representativeness

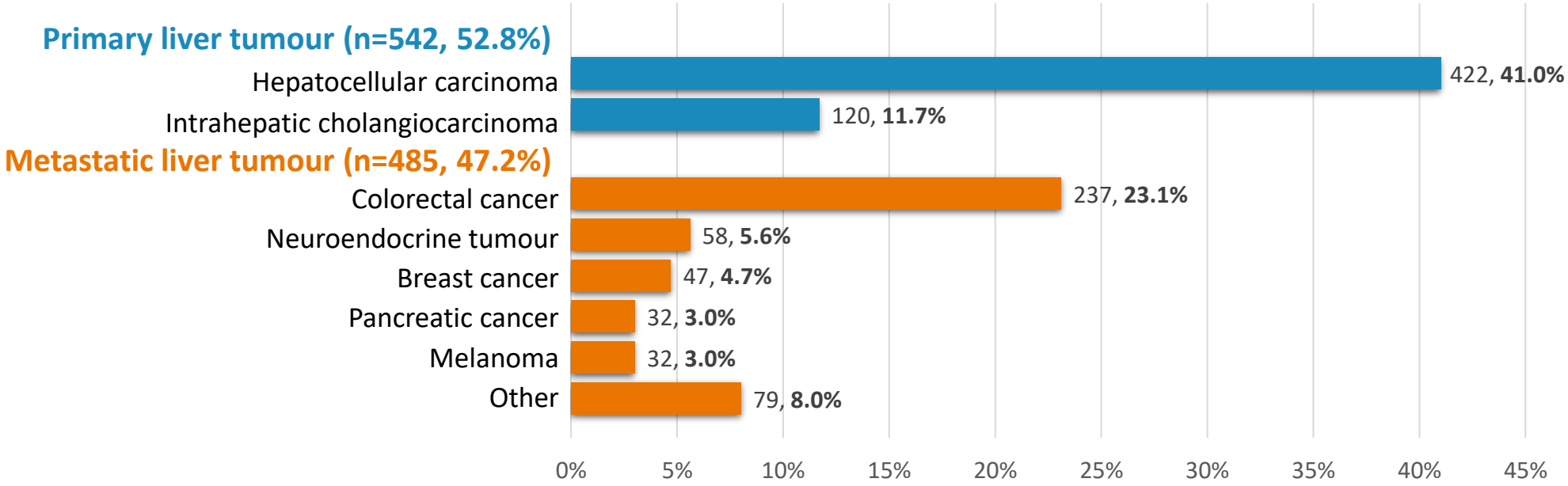
- 8 countries
- 27 hospitals
- 1027 patients

Country	Hospitals	Patients
Belgium	4 (14.8%)	100 (9.7%)
France	1 (3.7%)	56 (5.5%)
Germany	12 (44.4%)	421 (41.0%)
Israel	1 (3.7%)	14 (1.4%)
Italy	5 (18.5%)	174 (16.9%)
Spain	1 (3.7%)	30 (2.9%)
Switzerland	1 (3.7%)	109 (10.6%)
Turkey	2 (7.4%)	123 (12.0%)

Patient characteristics

1027 patients

- **Male, 667** (64.9%)
- **Age, median 65 years** (IQR 56-72)



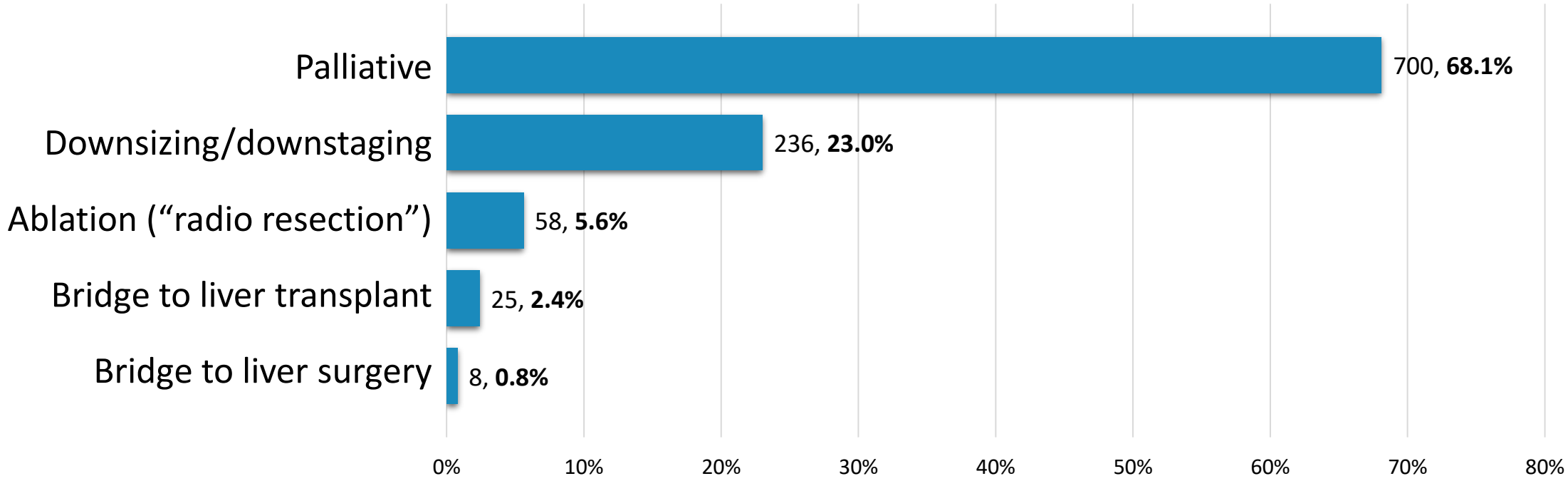
Patient characteristics

Patient characteristics	N (%)
ECOG	**1016 (98.9%)**
0	600 (58.4%)
1	336 (32.7%)
2	80 (7.8%)
Extra-hepatic disease	**1027 (100%)**
No	722 (70.3%)
Yes	305 (29.7%)
Ascites	**1027 (100%)**
No	925 (90.1%)
Yes	102 (9.9%)
Cirrhosis	**1027 (100%)**
No	706 (68.7%)
Yes	321 (31.3%)

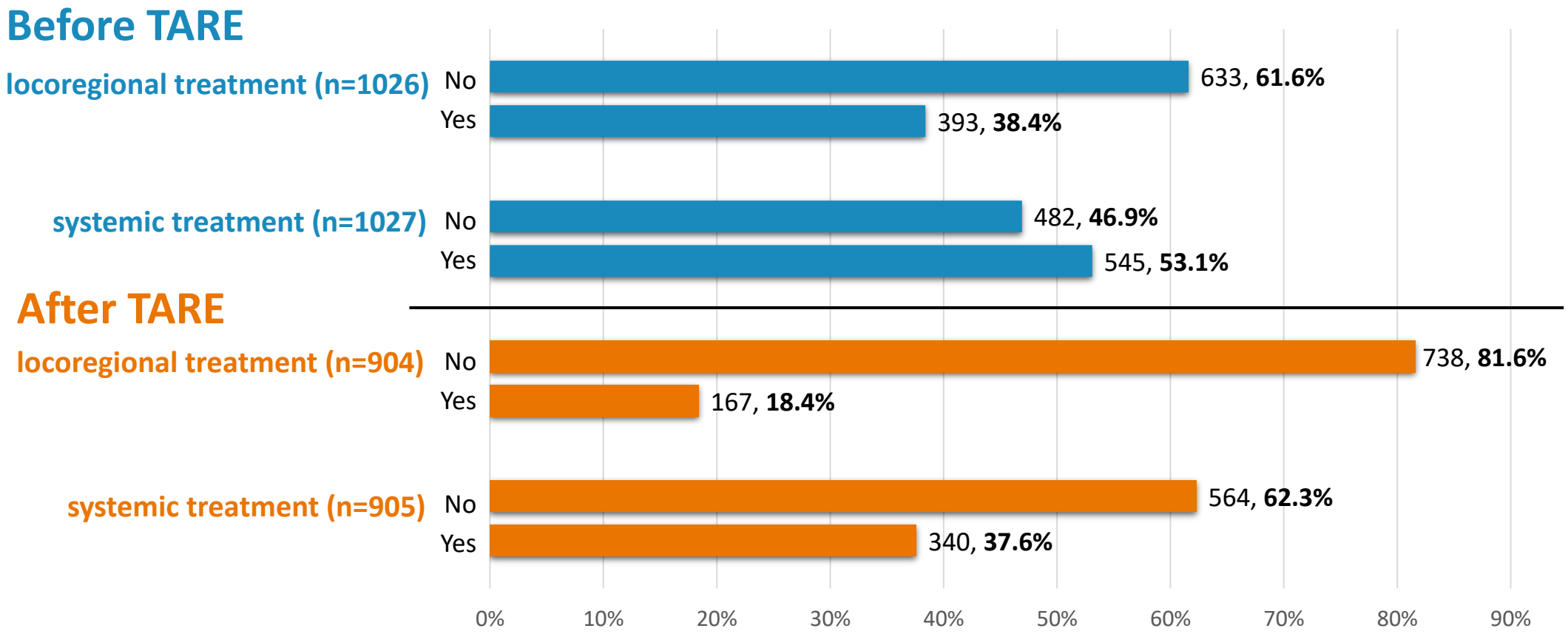
Patient characteristics	N (%)
Location of liver tumours	**1027 (100%)**
Bilobar	587 (57.2%)
Right	100 (9.7%)
Left	339 (33.0%)
Portal vein	**1027 (100%)**
Patent	849 (82.7%)
Segmental thrombosis	105 (10.2%)
Lobal thrombosis	47 (4.6%)
Main thrombosis	26 (2.5%)

Primary end point: Application of TARE in clinical practice

Intention of treatment (n=1027)



Primary end point: Application of TARE in clinical practice



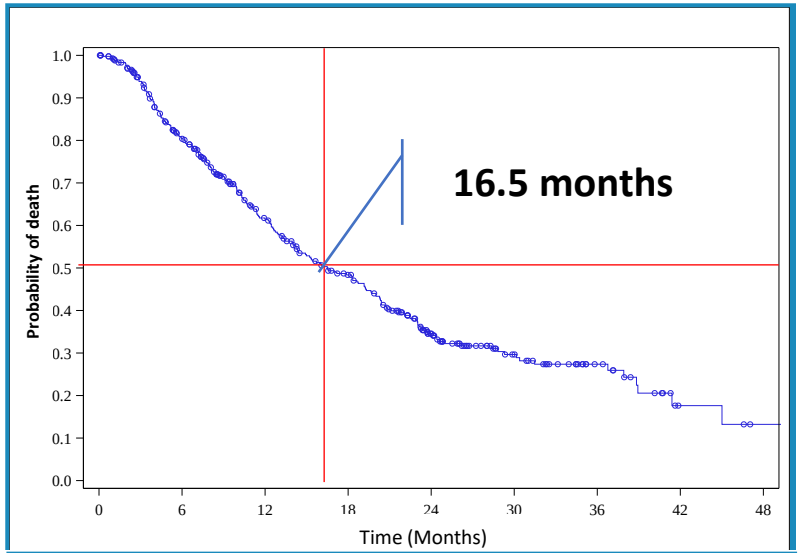
Safety

SAE (grade 3, 4) @ 30 days **< 2.5 %**

Serious adverse events within 30 days after treatment		All (n=1027)
Deceased	Within 30 days	10 (1.0%)
AE Grade 3 or higher	Abdominal Pain	25 (2.4%)
	Fatigue	14 (1.4%)
	Fever	2 (0.2%)
	Nausea	5 (0.5%)
	Vomiting	2 (0.2%)
	Radiation Cholecystitis	**2 (0.2%)**
	Radioembolisation-Induced Liver Disease (REILD)	**5 (0.5%)**
	GI Ulceration	**4 (0.4%)**
	Gastritis	**3 (0.3%)**
	Other	51 (5.0%)

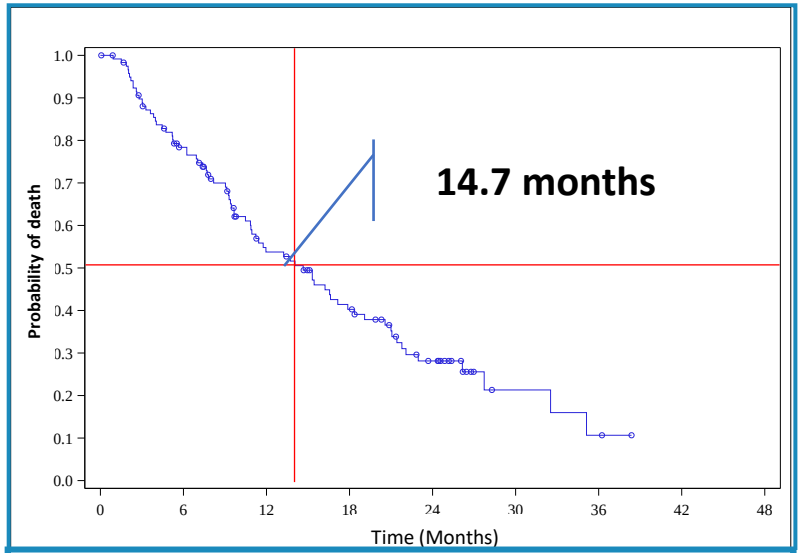
Overall survival

HCC (n=422)



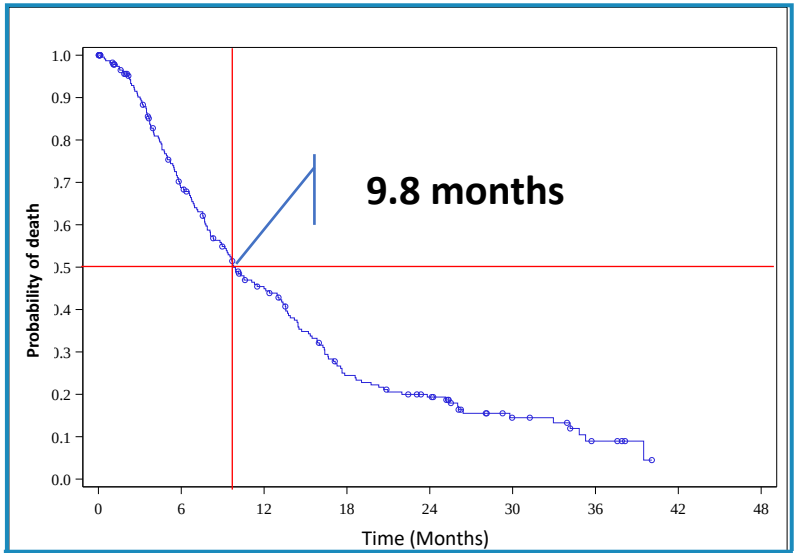
Median OS: 16.5 months
95% CI: 14.2-19.3 months

ICC (n=120)



Median OS: 14.7 months
95% CI: 10.9-17.9 months

mCRC (n=237)



Median OS: 9.8 months
95% CI: 8.3-12.9 months

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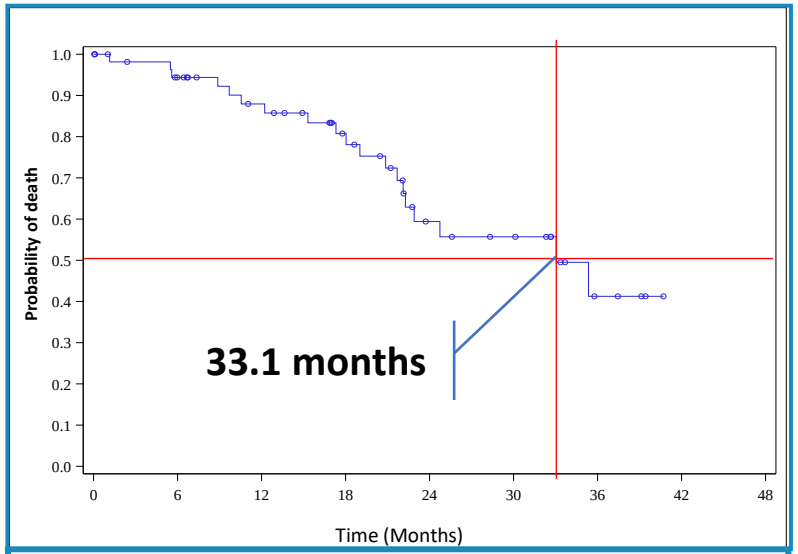
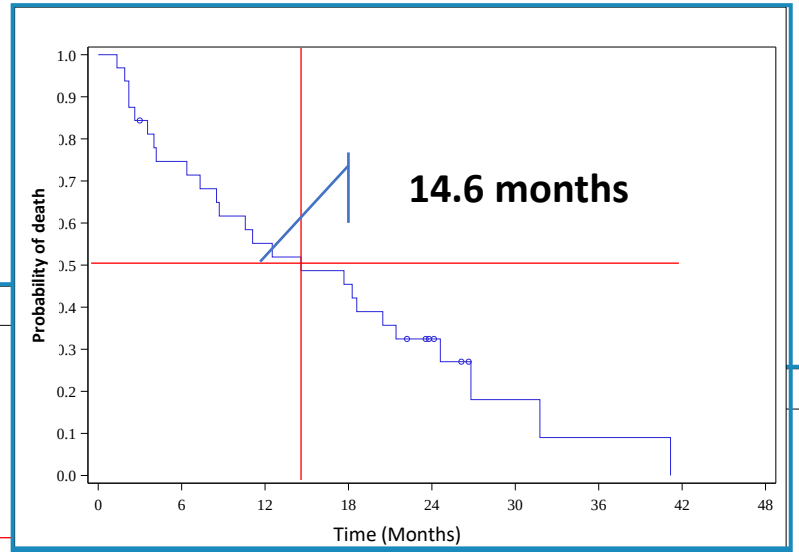
Overall survival

NET (n=58)



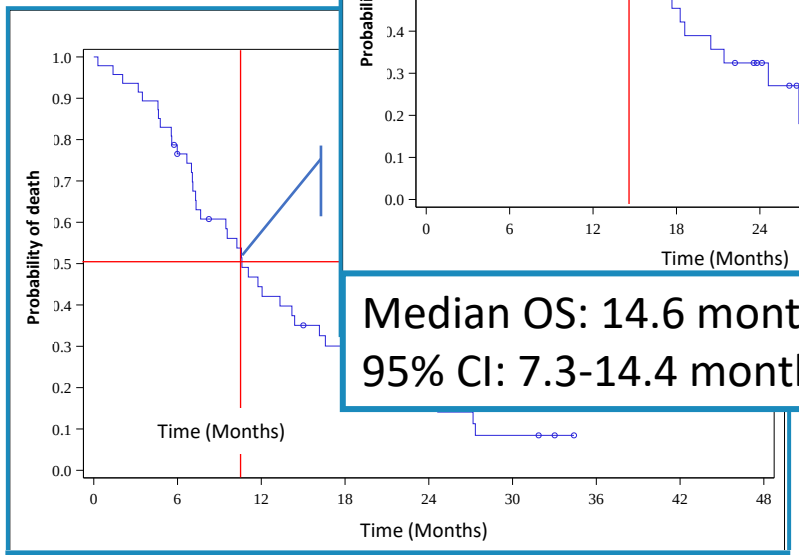
Median OS: 33.1 months
95% CI: 22.1-nr months

Melanoma (n=32)



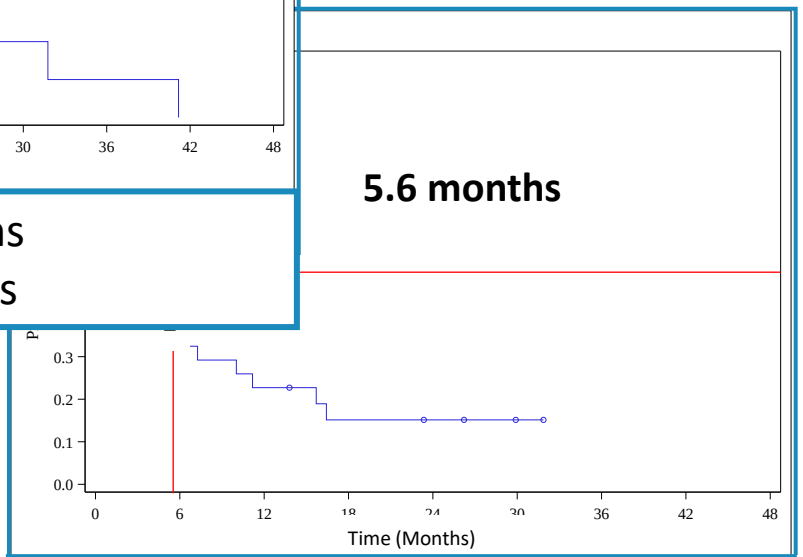
Median OS: 14.6 months
95% CI: 7.3-14.4 months

Breast (n=47)



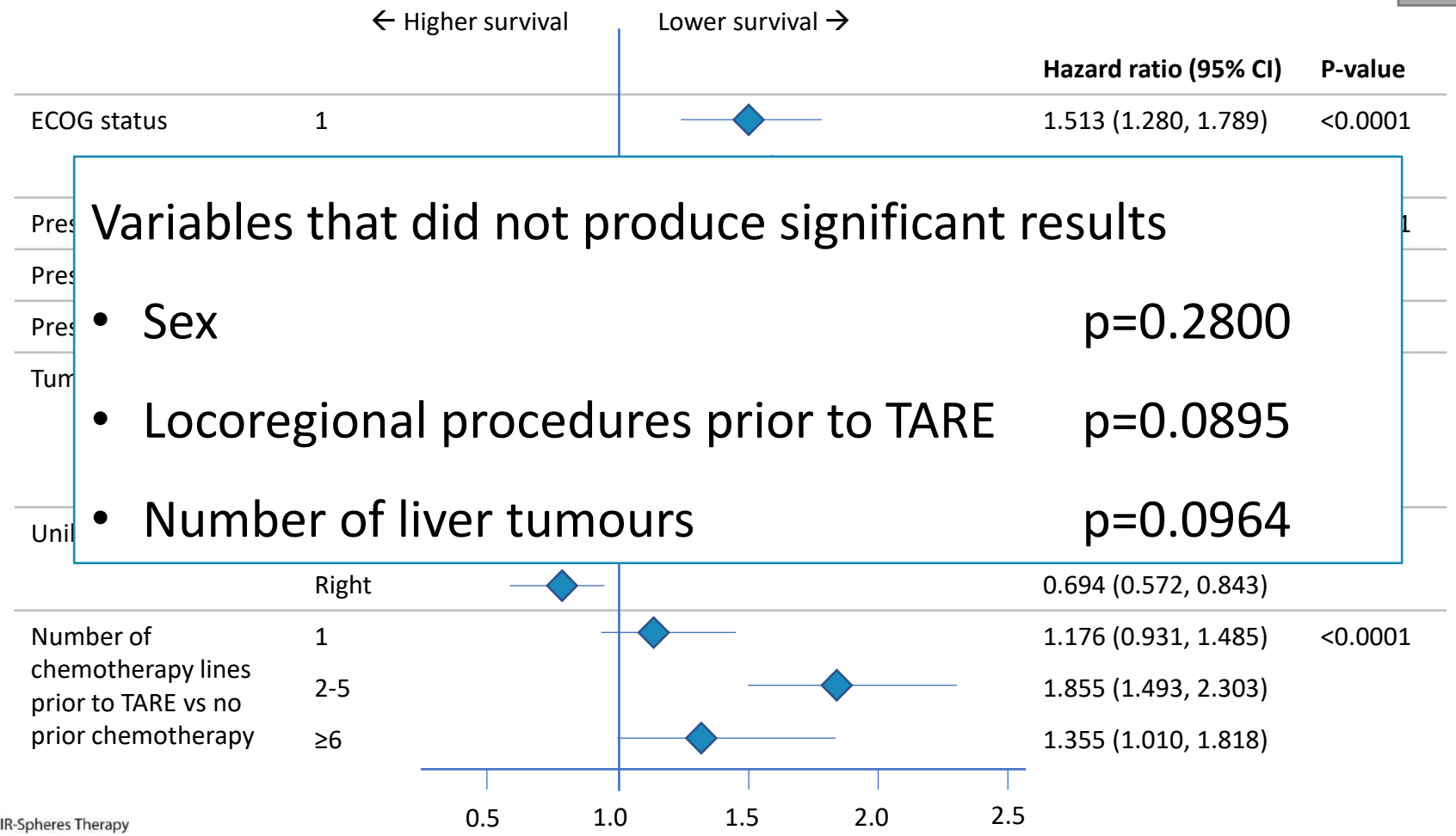
Median OS: 10.6 months
95% CI: 7.3-14.4 months

Pancreatic (n=32)



Median OS: 5.6 months
95% CI: 4.1-6.6 months

Prognostic factors associated with survival



Variables that did not produce significant results

- Sex p=0.2800
- Locoregional procedures prior to TARE p=0.0895
- Number of liver tumours p=0.0964

Take-home points

Representativeness

- With 1027 patients, 27 hospitals and 8 countries, CIRT is the largest prospective multicentre observational study on TARE

Key findings

- Palliative treatment strategy instead of early consolidation
- Confirms that findings from randomised trials are replicated in real-life
  - Safety
  - Overall survival
  - Prognostic factors
- CIRT confirms effective palliation in hepatic liver metastases from rarer indications such as NET, breast cancer, pancreatic cancer and melanoma

Take-home points

Limitations

- Observational design
- Relatively high lost-to-follow-up rate (33.9%)
- Differences in national guidelines and local standards of practices were not taken into account in this analysis

Further analyses

- Details concerning treatment application ???? What is meant
- Additional safety analyses
- Further effectiveness analyses
- Quality of life data
- A deeper look at data per indication

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