SIRCCA trial: Radioembolisation as first line therapy in patients with inoperable intrahepatic cholangiocarcinoma

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Disclosure

I have the following potential conflicts of interest to report:

Consultant Somatex
Procotor SIRTEX
Intrahepatic cholangiocarcinoma (ICC)

- 2nd most common primary liver cancer
- 0.3 - 3.5 cases / 100,000 people

Median OS:
- w/o therapy\(^1\) 8 mo
- Gem-Cis\(^2\) 11.7 mo
- TACE\(^3\) 13.4 mo

3 Ray CE et al. Metaanalysis of survival,Complications... Chemotherapy-based transarterial therapy in patients with unresectable ICC. J Vasc Interv Radiol August 2013;

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ICC - Guidelines

Biliary tract cancer

Early stage

Surgery\(^1\) +/−

Adjuvant chemotherapy\(^3\)

Via MDT Clinical trials where possible

Loco-regional therapy\(^2\)

• Radiotherapy

• ⁹⁰Y-radioembolisation (icca)

Surveillance

Best supportive care

Locally-advanced

• Systemic chemotherapy\(^2\)

• First-line combination chemotherapy (PSO-1)\(^4\)

• First-line gemcitabine monotherapy (PS2)

• Second-line chemotherapy | No standard

• Targeted therapy | No standard

Metastatic

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ESMO Guidelines
Biliary Cancer 2016
Radioembolisation may be considered in patients with inoperable iCCA, usually after first-line chemotherapy; patients should be encouraged to participate in clinical trials“

ESMO Guidelines
Biliary Cancer 2016
SIRT in ICC

- 12 studies / 298 patients
- Median OS 15.5 month
  (w/o 8 m, ChTx 11.7 m, TACE 13.4)

- Conversion to resectable disease in up to 10 %\(^1\)

- 1y OS: 20.2 % 2nd line SIRT vs. 84.6 % 1st line SIRT\(^2\)

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A prospective, multicentre, randomised, controlled study evaluating SIR-Spheres® Y-90 resin microspheres preceding standard cisplatin-gemcitabine (CIS-GEM) chemotherapy versus CIS-GEM chemotherapy alone as first-line treatment of patients with unresectable intrahepatic CholangioCArcinoma.
SIRCCA Trial - Study Objectives:

Primary Endpoint
- Survival at 18 months

Secondary Endpoints
- Liver-specific Progression Free Survival (PFS)
- PFS at any site
- Objective Response Rate (RECIST)
- Overall Survival
- Liver surgical resection and ablation rate
- Safety and tolerability
- Quality of life
SIRCCA Trial

Key eligibility criteria:
- Unresectable ICC
- No prior chemotherapy
- ECOG PS 0–1
- Suitable for SIRT and systemic chemotherapy
- No or limited extra-hepatic disease

Schema:
- Stratify
  - Extra-hepatic disease
  - Cirrhosis
  - Whole liver vs. non-whole liver intended Y-90 treatment
  - Albumin <35 g/L vs. ≥35 g/L
  - ECOG 0 vs. 1

Randomise
1:1  n = 180

Treatment Arm A:
- Cisplatin 25 mg/m²
- Gemcitabine 1000 mg/m²

Treatment Arm B
- SIR-Spheres Y-90 resin microspheres
- Systemic chemotherapy CIS + GEM

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SIRCCA Trial

2-stage process for SIRT

• Work-up procedure:
  – Angiographic evaluation with prophylactic occlusion of extra-hepatic vessels (GDA, right gastric etc) if necessary
  – Injection of $^{99\text{m}}\text{Tc}$-MAA / gamma camera study to assess lung-shunt

• Treatment procedure:
  – Injection of SIR-Spheres microspheres 3 - 8 days after Work-up
  – No sequential lobar approach permitted

• Start Chemotherapy 14 days after SIRT
SIRCCA Trial

- Start World: Feb 2017
- Start Germany: 2019
- Participating centres: 45
- Planned no. of patients: 180
- Already included patients: 60
- Planned end of the trial: 2023
- Publication of the results: 2023/24
Conclusion

• SIRT is a promising therapy for ICC

• Maybe better in 1st therapy

• Results of the SIRCCA Trial 2023/24
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