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

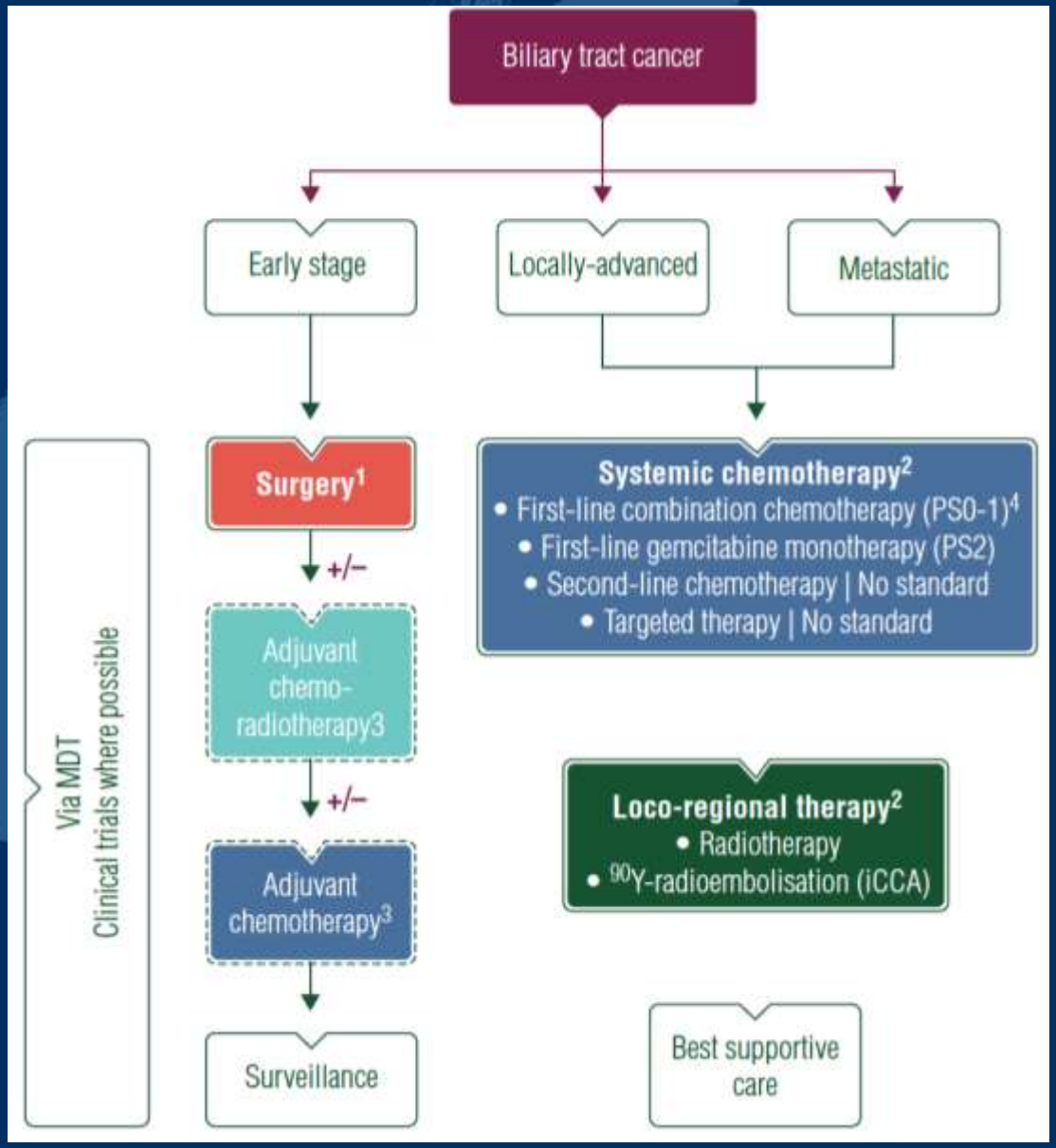
Intrahepatic cholangiocarcinoma (ICC)

- 2 nd 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

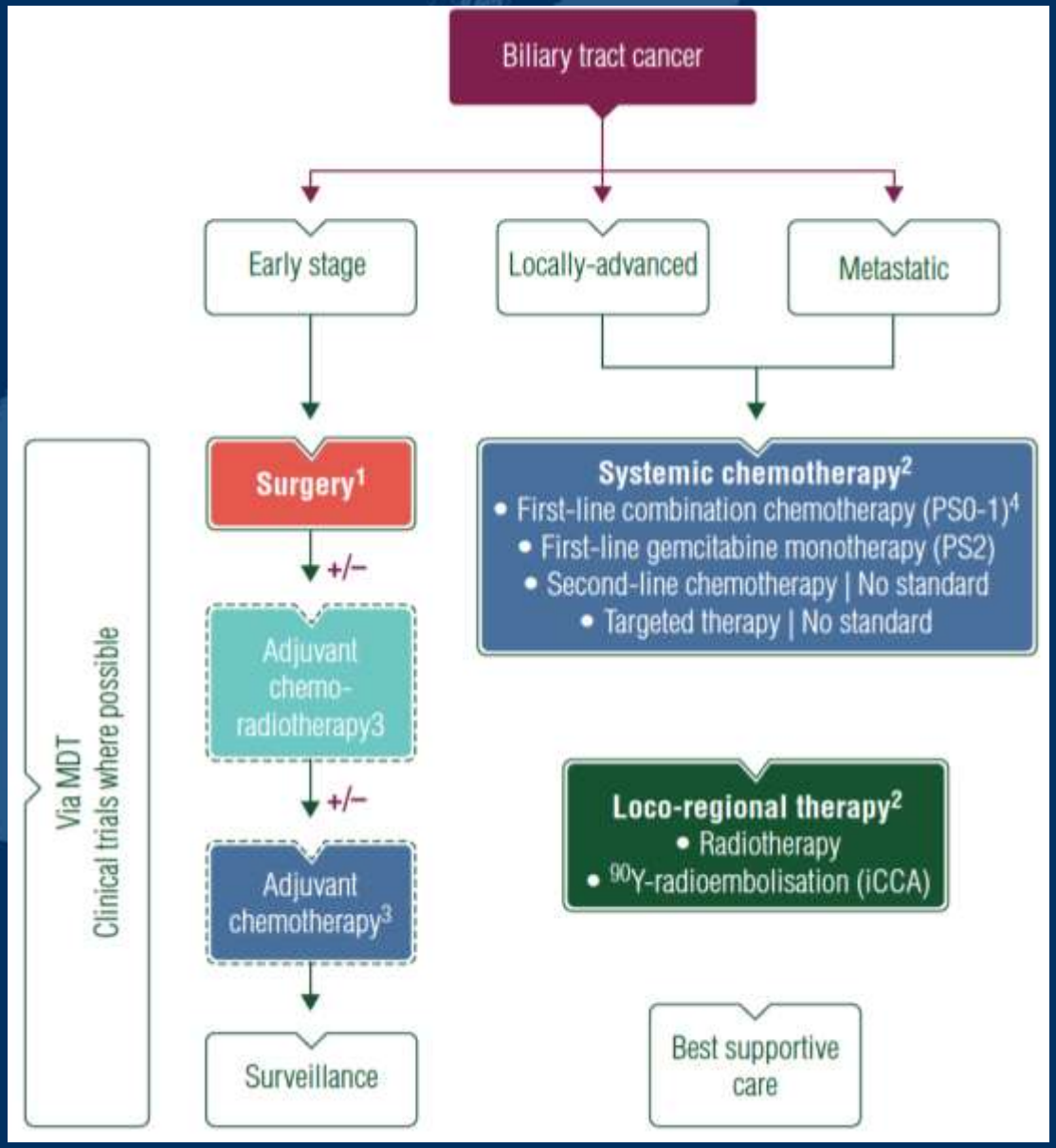
1 Roayaie S et al. Aggressive surgical treatment of intrahepatic cholangiocarcinoma: predictors of outcomes. J Am Coll Surg 1998
2 Valle J et al. Cisplatin plus gemcitabine versus gemcitabine for biliary tract cancer. N Engl J Med 2010 Apr 8
3 Ray CE et al. Metaanalysis of survival,Complications... Chemotherapybased transarterial therapy in patients with unresectable ICC. J Vasc Interv Radiol August 2013;

ICC - Guidelines



ESMO Guidelines
Biliary Cancer 2016

ICC - Guidelines



„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]

1 Mouli S, et al. Yttrium-90 radioembolization for intrahepatic cholangiocarcinoma: safety, response, and survival analysis. J Vasc Interv Radiol 2013
2 Shridhar R et al. Shortterm outcomes of intrahepatic cholangiocarcinoma treated with glass based yttrium 90 microspheres. J Vasc Interv Radiol 2012

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

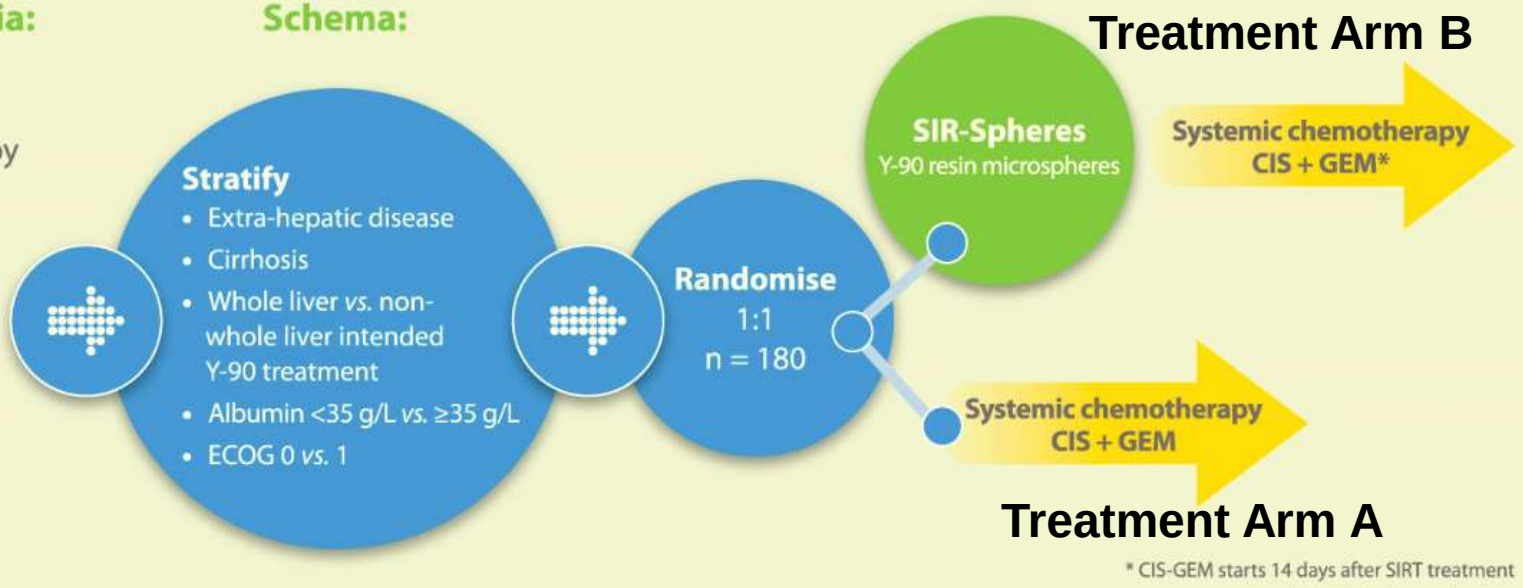
- Liver-specific Progression Free Survival (PFS)
- PFS at any site
- Objective Response Rate (RECIST)
- Overall Survival
- Liver surgical resection and ablation rate
- Safety and tolerability
- Quality of life

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:



Treatment Arm A:

- Cisplatin 25 mg/m²
- Gemcitabine 1000 mg/m²

	Cycle 1			Cycle 2			Cycle 3			Cycle 4 onwards		
Week	1	2	3	4	5	6	7	8	9	10	11	12
Day	1	8		1	8		1	8		1	8	
Cisplatin	x	x		x	x		x	x		x	x	
Gemcitabine	x	x		x	x		x	x		x	x	

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 ^{99m}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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