

The CIREL cohort: a prospective controlled registry studying the real-life use of irinotecan-loaded chemoembolisation in colorectal cancer liver metastases: First interim analysis.

Philippe L. Pereira, Roberto Iezzi, Riccardo Manfredi, Francesca Carchesio, Zoltan Bánsághi, Elias Brountzos, Stavros Spiliopoulos, Javier J. Echevarria-Uraga, Belarmino Gonçalves, Riccardo Inchingolo, Michele Nardella, Olivier Pellerin, Maria J. Sousa, Dirk Arnold, Thierry de Baère, Fernando Gomez, Thomas Helmberger, Geert Maleux, Hans Prenen, Bruno Sangro, Bleranda Zeka, Nathalie Kaufmann, Julien Taieb

Presented by Dr. Roberto Iezzi

Monday, September 14 2020

Conflict of interest

- No conflict of interest to declare

CIREL – Cirse REgistry for LifePearl microspheres:

- Multi-centre, non-randomized, observational study on real-life use of LifePearl microspheres loaded with irinotecan (LP-IRI) in colorectal cancer liver metastases.



> *Dig Liver Dis.* 2020 Aug;52(8):857-861. doi: 10.1016/j.dld.2020.05.051. Epub 2020 Jun 30.

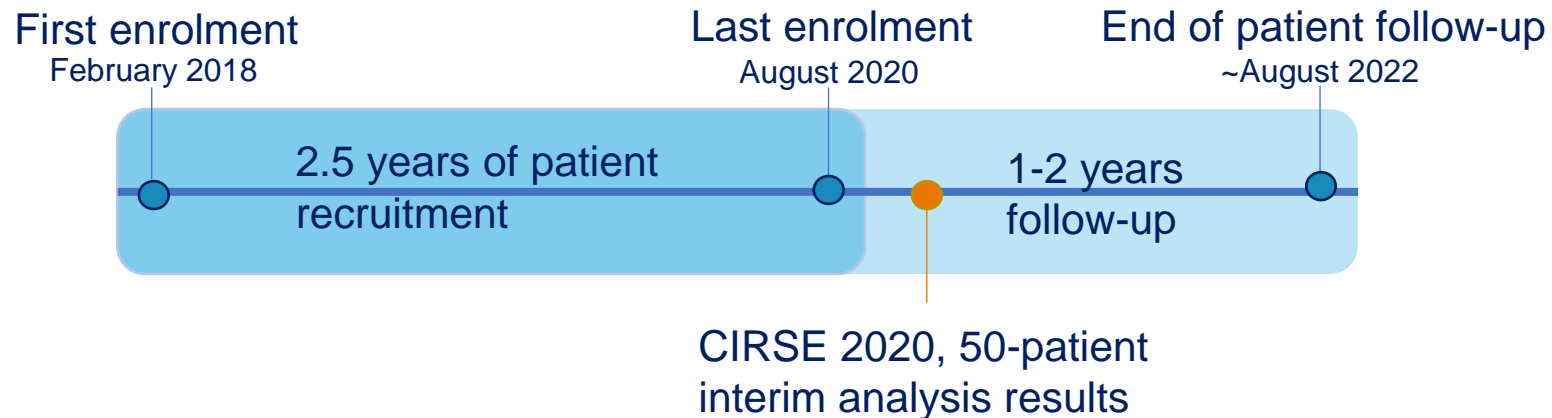
A multicentre, international, observational study on transarterial chemoembolisation in colorectal cancer liver metastases: Design and rationale of CIREL

Philippe L Pereira¹, Dirk Arnold², Thierry de Baère³, Fernando Gomez⁴, Thomas Helmberger⁵, Roberto Iezzi⁶, Geert Maleux⁷, Hans Prenen⁸, Bruno Sangro⁹, Anders Nordlund¹⁰, Bleranda Zeka¹¹, Robert Bauer¹¹, Nathalie Kaufmann¹², Olivier Pellerin¹³, Julien Taieb¹⁴

CIREL – Cirse REgistry for LifePearl microspheres:

50-patient interim analysis

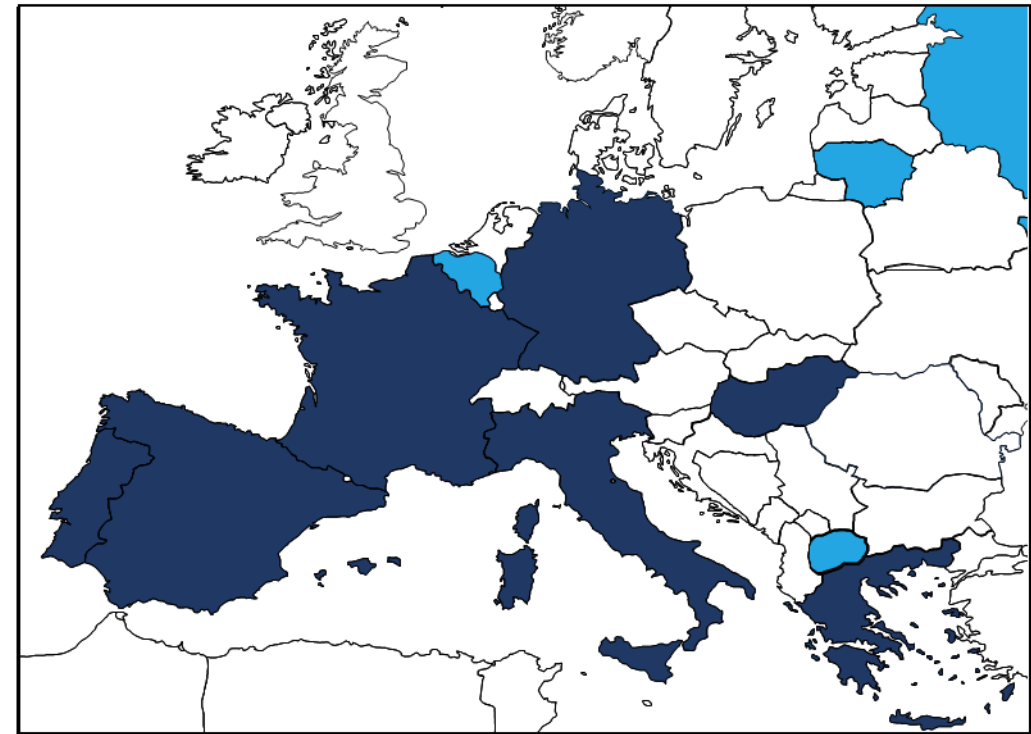
- Multi-centre, non-randomized, observational study on real-life use of LifePearl microspheres loaded with irinotecan (LP-IRI) in colorectal cancer liver metastases.
- Interim analysis focusing on feasibility, baseline, safety and quality of life.



CIREL – Countries included in interim analysis

Country	Number of centres	Number of patients
Italy	2	15
Germany	2	11
Hungary	1	9
Greece	1	8
Portugal	1	5
France	1	1
Spain	1	1

Countries included in CIREL



■ Included in 50-patient interim analysis

CIREL Objectives analysed for the interim analysis

- **Primary Objective**

The primary objective of CIREL is to **prospectively capture the real-life use** of LP IRI in colorectal cancer liver metastases by applying **predefined categories of treatment intention**.

- **Secondary Objectives**

Secondary Objective	Measured according to
1. Safety	• CTCAE 4.03 and 5.0
2. Quality of Life	• EORTC scoring manual v 3.0 for EORTC QLQ-C30

Patient demographics and prior hepatic treatments



50 patients

- Male: 29 (58%)
- Median age: 66y
- Synchronous (<6 months): 34 (68%)
- Metachronous (>6 months): 16 (32%)
- ECOG:
 - 0: 36 (72%)
 - 1: 7 (14%)
 - 2: 3 (6%)

Prior treatments for liver metastases	n (%)
Systemic chemotherapy	41 (82%)
1 line	9 (18%)
2 lines	6 (12%)
3 or more lines	26 (52%)
Targeted therapy	24 (48%)
Anti-angiogenic targeted therapy	18 (36%)
Anti-EGFR targeted therapy	10 (20%)
Surgery	10 (20%)
Adjuvant fluoropyrimidine	2 (4%)
Adjuvant oxaliplatin	2 (4%)
Adjuvant irinotecan	2 (4%)
Ablation	5 (10%)
Intra-arterial treatment	6 (12%)

Patient demographics and prior hepatic treatments

Liver Metastases Characteristics	n (%)
Location	
Whole Liver	26 (52%)
Left liver lobe only	7 (14%)
Right liver lobe only	17 (34%)
Liver Tumor Burden	
< 25%	33 (66%)
25-50%	13 (26%)
> 50%	4 (8%)
Number of Lesions	
1	8 (16%)
2-3	16 (32%)
4-10	15 (30%)
> 10	11 (22%)

LP-IRI treatments' characteristic

129 treatment sessions	n (%)
Unilobar treatment	
Median number of sessions (min, max)	2 (1, 4)
Right lobe	39 (75%)
Left lobe	13 (25%)
Bilobar treatment	
Median number of sessions (min, max)	2,6 (1, 5)
Right lobe	45 (58%)
Left lobe	32 (42%)
Bead Size	
100	111 (86%)
>100	18 (14%)
Treatment	
Treatment technically successful	129 (100%)
Complete stasis	45 (36%)
Complete delivery of the dose	82 (64%)

Treatment intentions of LP-IRI

Salvage treatment in
progressive patients
n=21

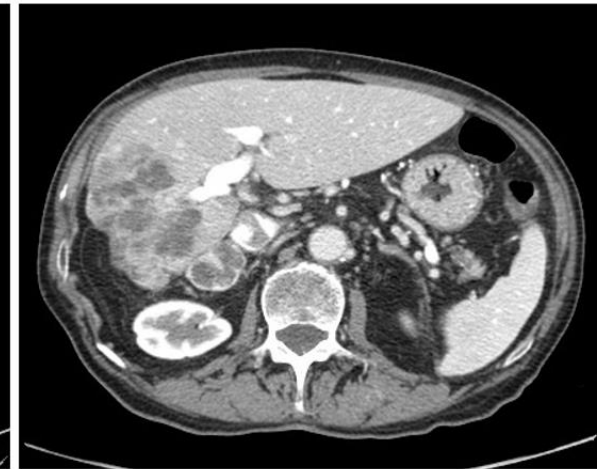


- Progressive disease
- Min 3 lines of systemic chemotherapy

♂ 76 yo
Unilobar Disease
/Refractory to
3 lines of CHT

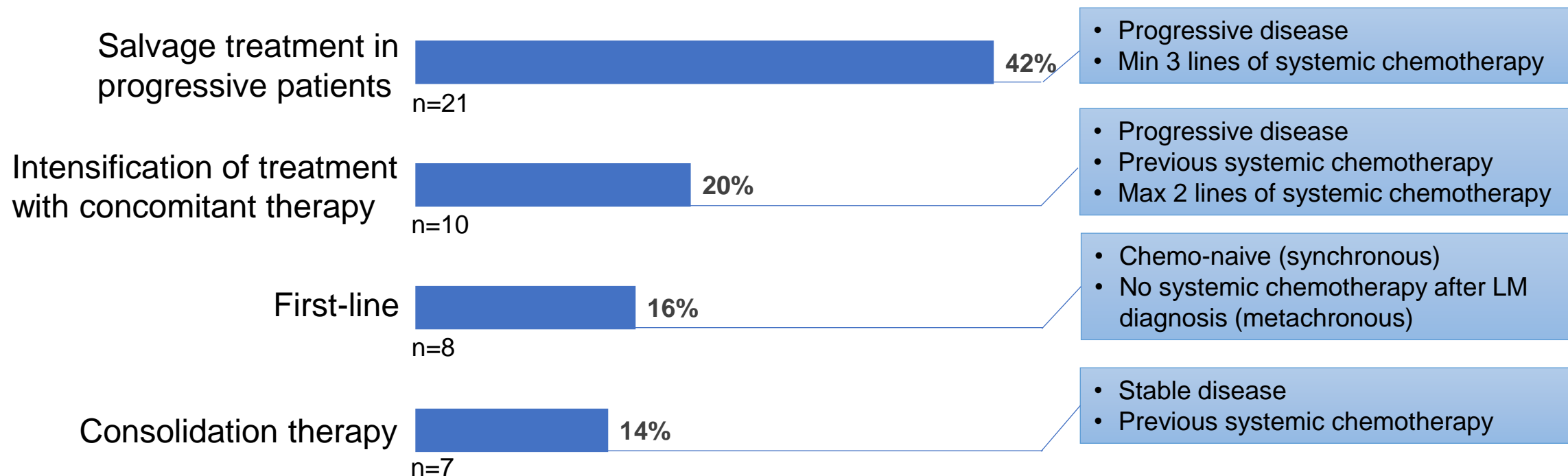


Pre-treatment



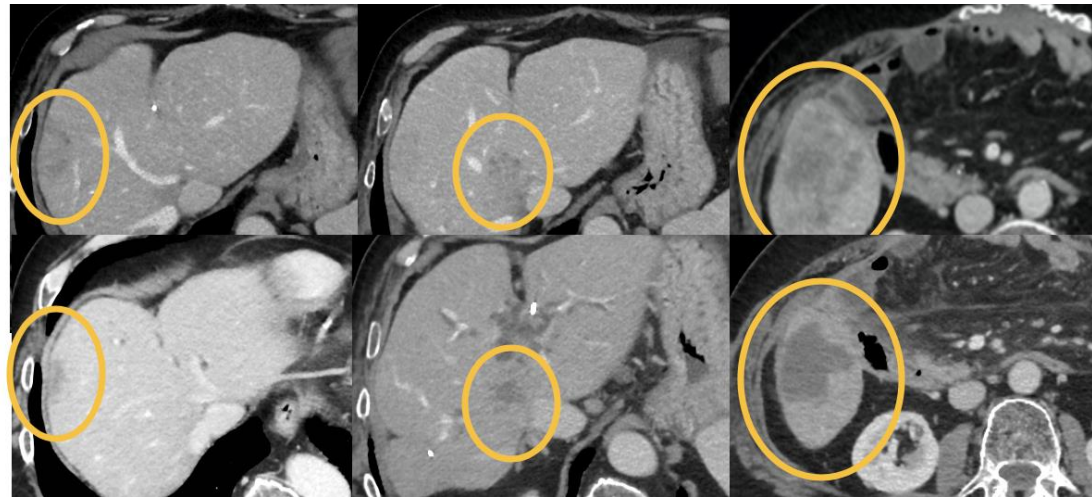
6mo F-U

Treatment intentions of LP-IRI



Treatment intentions of LP-IRI

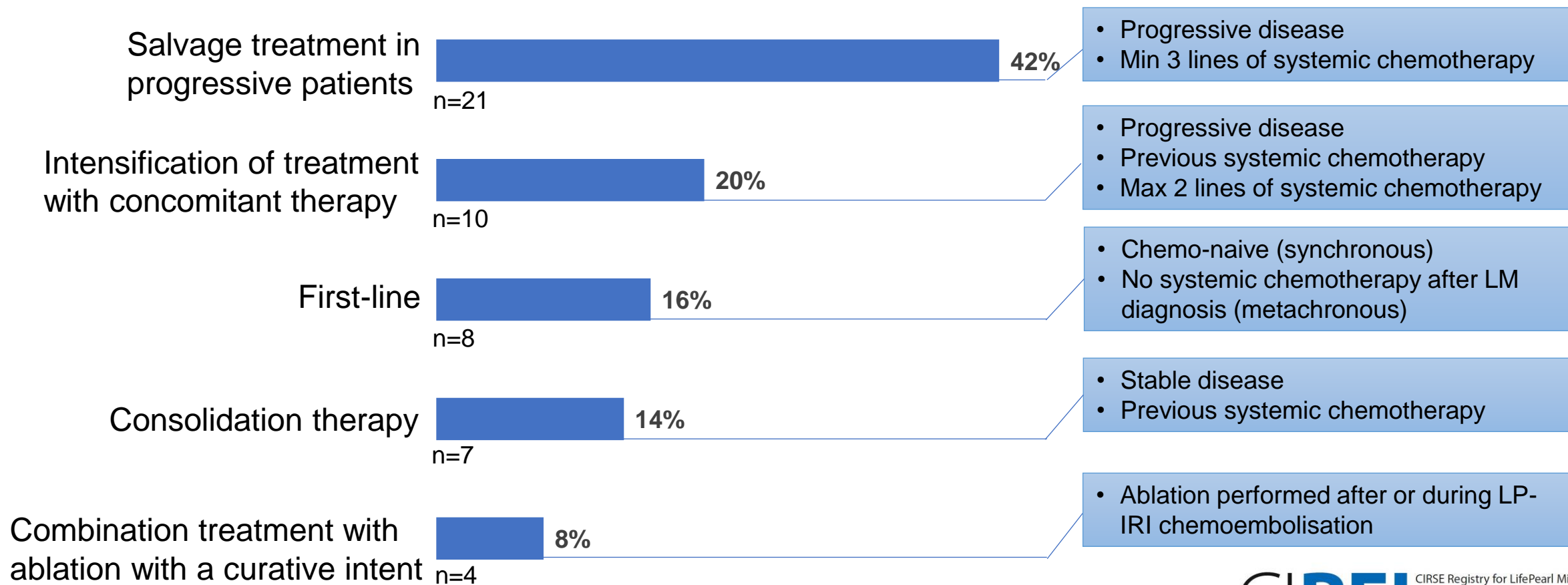
♀ 67yo SD > 3 months in
2-lines CHT asking for a
ChemoHolidays/Break



Consolidation therapy  14%
n=7

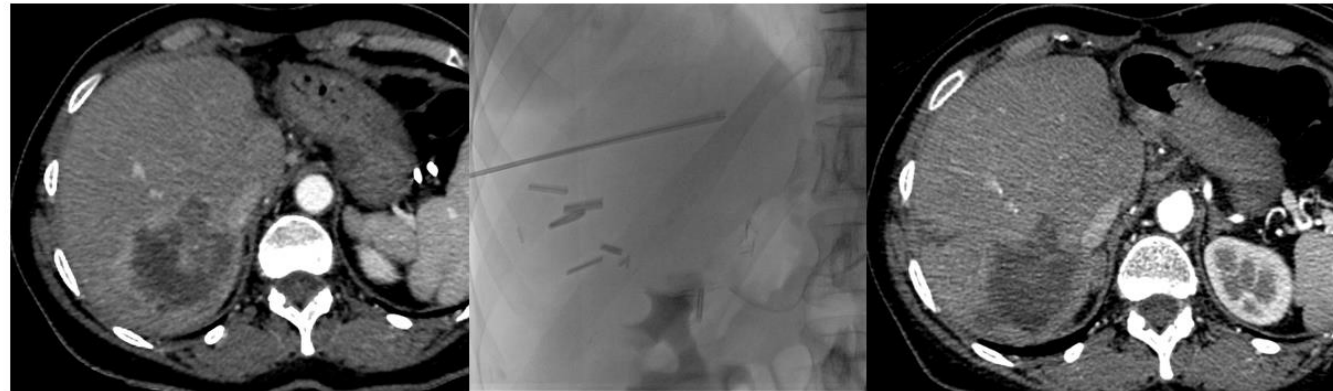
- Stable disease
- Previous systemic chemotherapy

Treatment intentions of LP-IRI



Treatment intentions of LP-IRI

***P.M.T. 68 yo ♀ -
Unresectable
mCRC (PD CHT)***



***Unresectable
mCRC (Ø 6cm)***

***RFA &
LP-IRI***

F-U

Combination treatment with
ablation with a curative intent 8% n=4

- Ablation performed after or during LP-IRI chemoembolisation

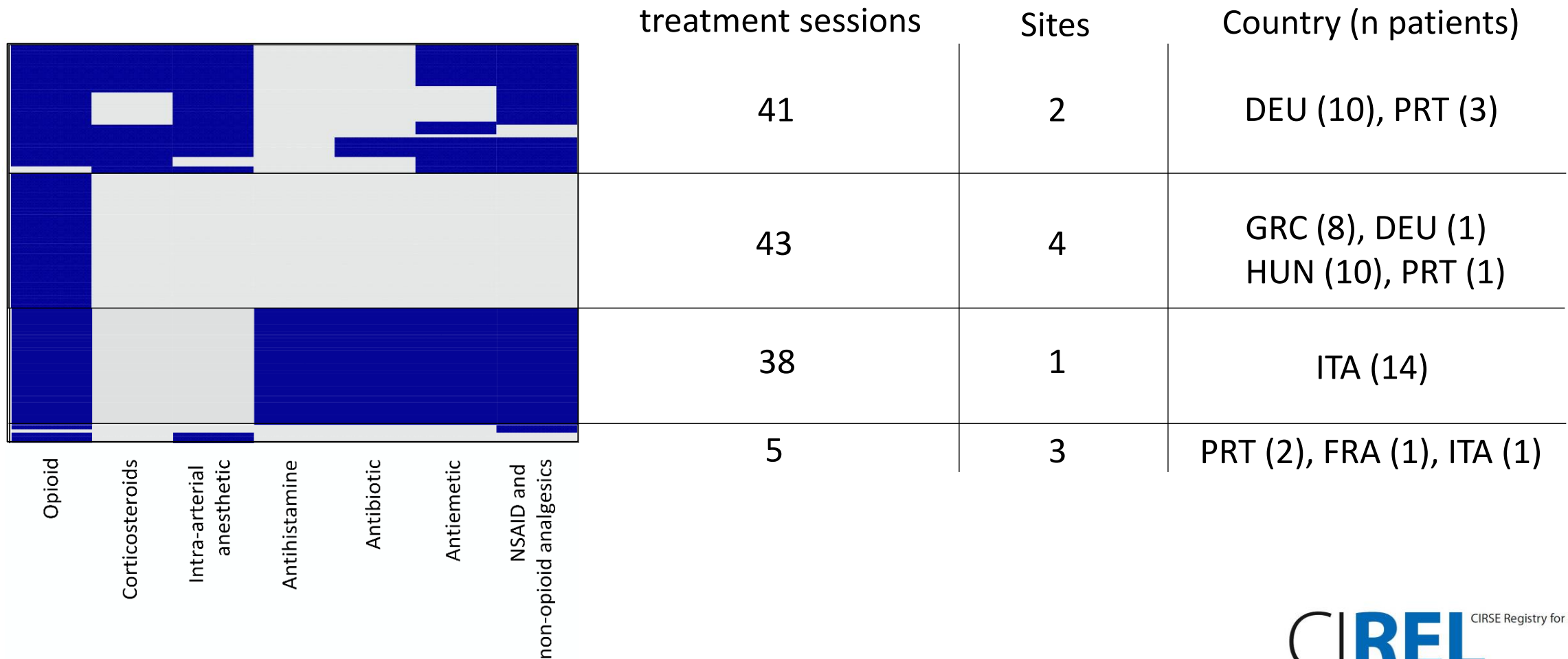
Safety and toxicity

- 0% mortality in the first 30 days
- Most common AE: Grade 1-2 Post-embolization Syndrome (Pain)

	Peri-interventional	<30 days
Total AEs	33	24
Total grade 3 + 4 AEs	2	7
Patients with at least one AE (%)	13 (26%)	10 (20%)
Patients with at least one grade 3 + 4 AE (%)	2 (4%)	5 (10%)

Peri-interventional AEs	Grade 3	Grade 4
Infusion related reaction	1	
Hypertension	1	
<30days	Grade 3	Grade 4
Hepatic failure	1	
Liver abscess	1	
Renal failure + hyperkalemia	1	
Blood bilirubin increase	1	
Infection, CRP increasing	1	
Sepsis		1
Colonic obstruction		1

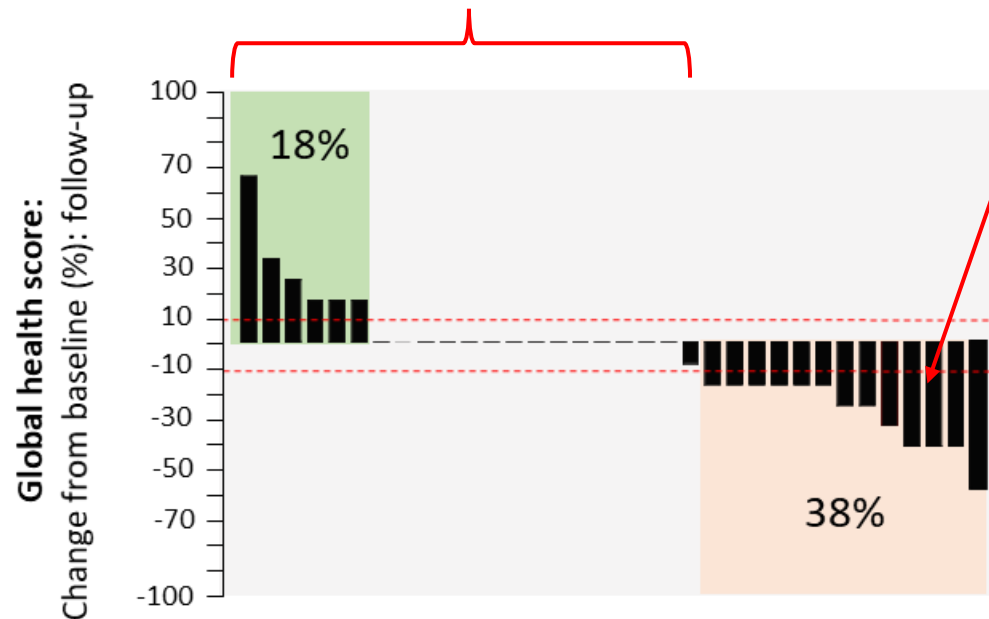
High variability in procedural medications



Quality of Life mostly deteriorating in Salvage therapy patients

Global health score

62% improving or remaining stable

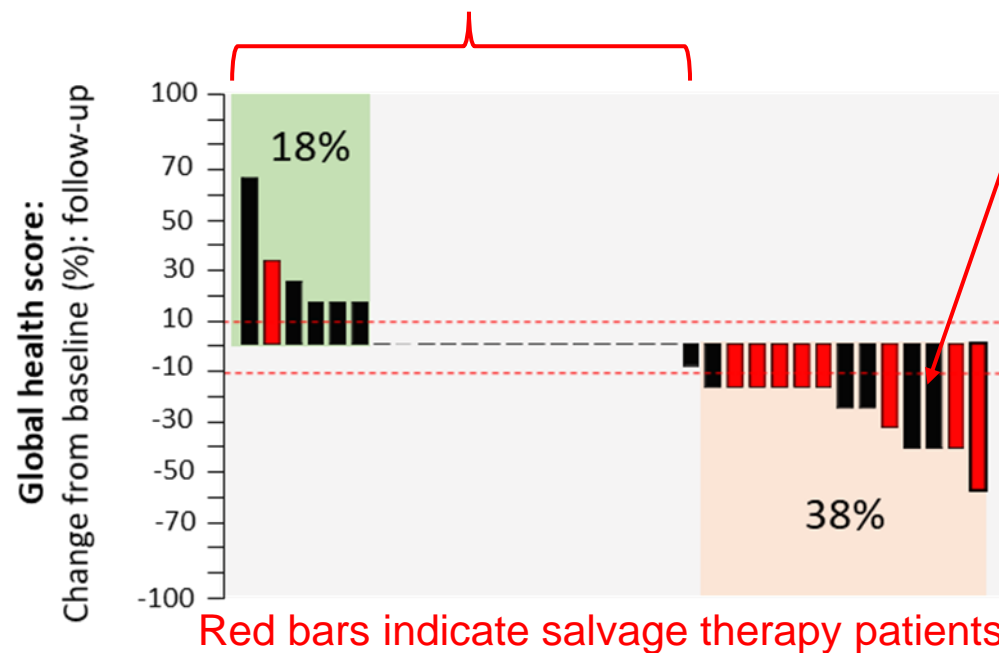


Global health quality of life score decreased in 38% of patients.

Quality of Life mostly deteriorating in Salvage therapy patients

Global health score

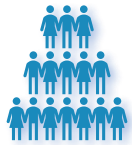
62% improving or remaining stable



Global health quality of life score decreased in 38% of patients.

A large proportion of patients with deterioration were salvage therapy patients (red bars).

Summary & Discussion



Treatment intention

Mainly used as **salvage or intensification therapy**

Suitable treatment options beyond guideline recommendations



Safety

4% of grade 3 + 4 adverse events peri-interventionally

10% of grade 3 + 4 adverse events within 30 days after treatment

Most common: grade 1-2 Post-embolization Syndrome (Pain)



Procedural medications

Vast differences in procedural medications reported

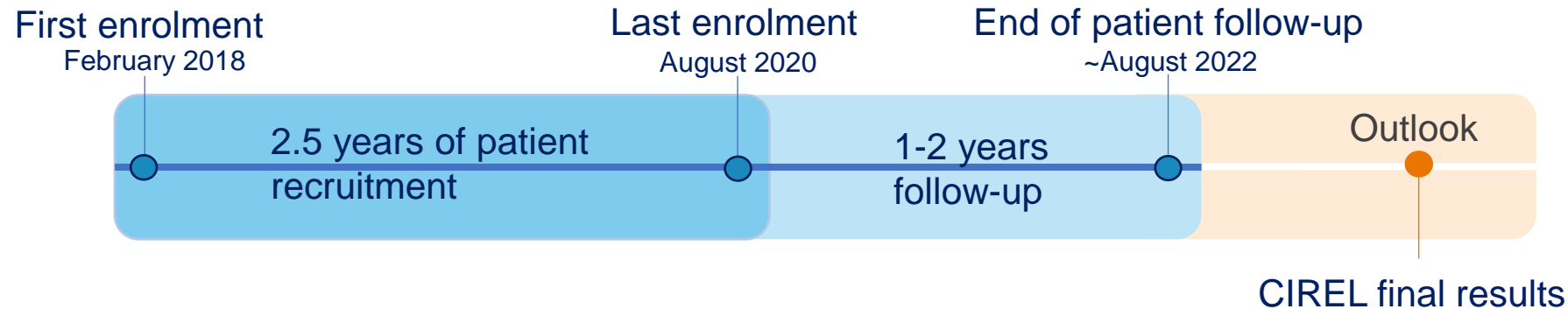


HRQOL

62% reported a stable or better global health score

54% of patients that reported worse HRQOL were treated as salvage-therapy patients

Outlook



The final results of CIREL will provide prospective data on:

- Overall survival and (hepatic) progression-free survival
- Objective response rate (Independent central image review by FFCD)
- Early tumour shrinkage at $\geq 20\%$ and $\geq 30\%$ at first tumour assessment
- Depth of response
- Quality of Life using a comprehensive questionnaire

Acknowledgements

- Terumo Europe NV



- CIREL Steering Committee

- Carole Déan



- All participating centres and personnel involved in CIREL

Thank you!

more information in

CVIR

“The CIREL cohort: a prospective controlled registry studying the real-life use of irinotecan-loaded chemoembolisation in colorectal cancer liver metastases: Interim analysis.”

Treatment intentions of LP-IRI

