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

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Presented by Dr. Roberto Iezzi

Monday, September 14 2020

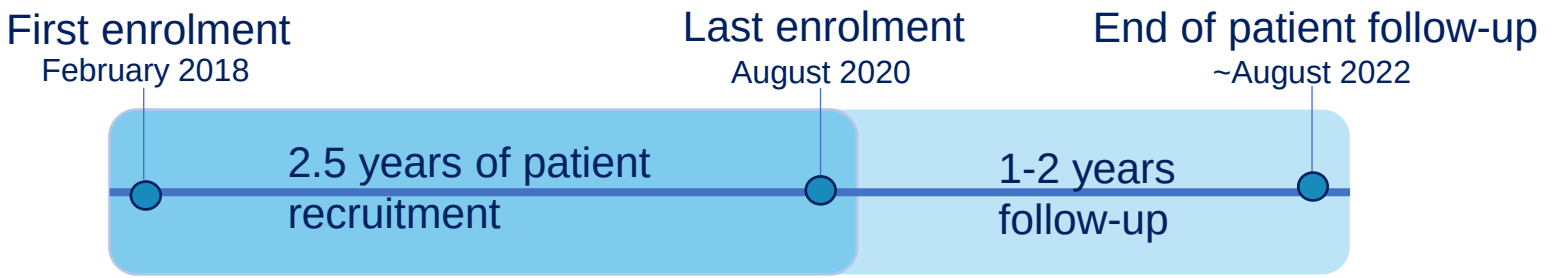
CIREL CIRSE Registry for LifePearl Microspheres

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 Pereira [1], Dirk Arnold [2], Thierry de Baère [3], Fernando Gomez [4], Thomas Helmberger [5], Roberto Iezzi [6], Geert Maleux [7], Hans Prenen [8], Bruno Sangro [9], Anders Nordlund [10], Bleranda Zeka [11], Robert Bauer [11], Nathalie Kaufmann [12], Olivier Pellerin [13], Julien Taieb [14]

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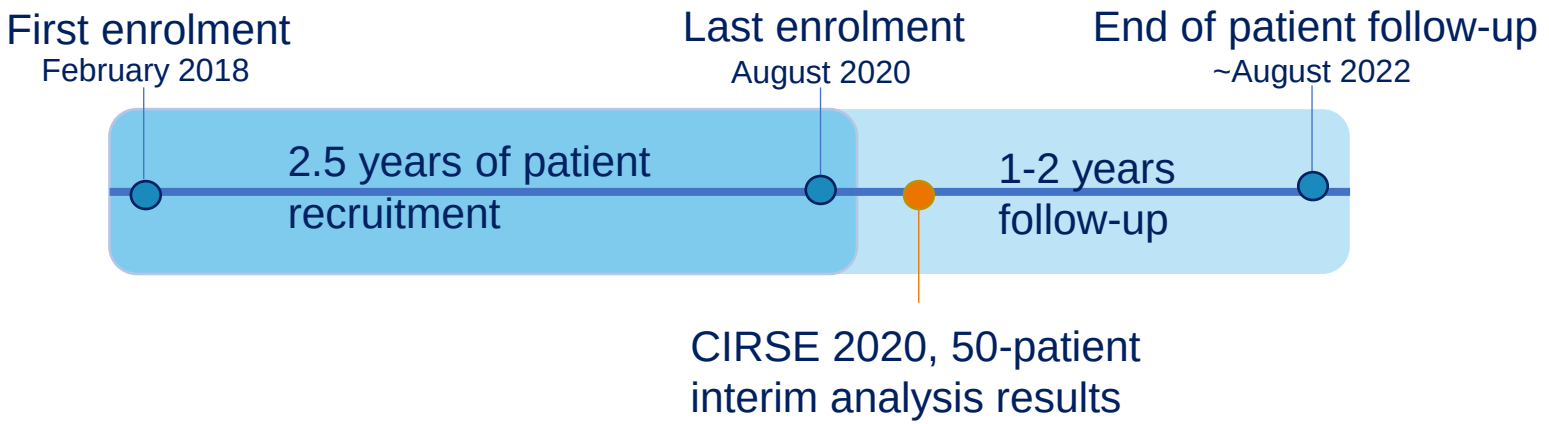
CIREL – CIrse REgistry for LifePearl microspheres:

50-patient interim analysis

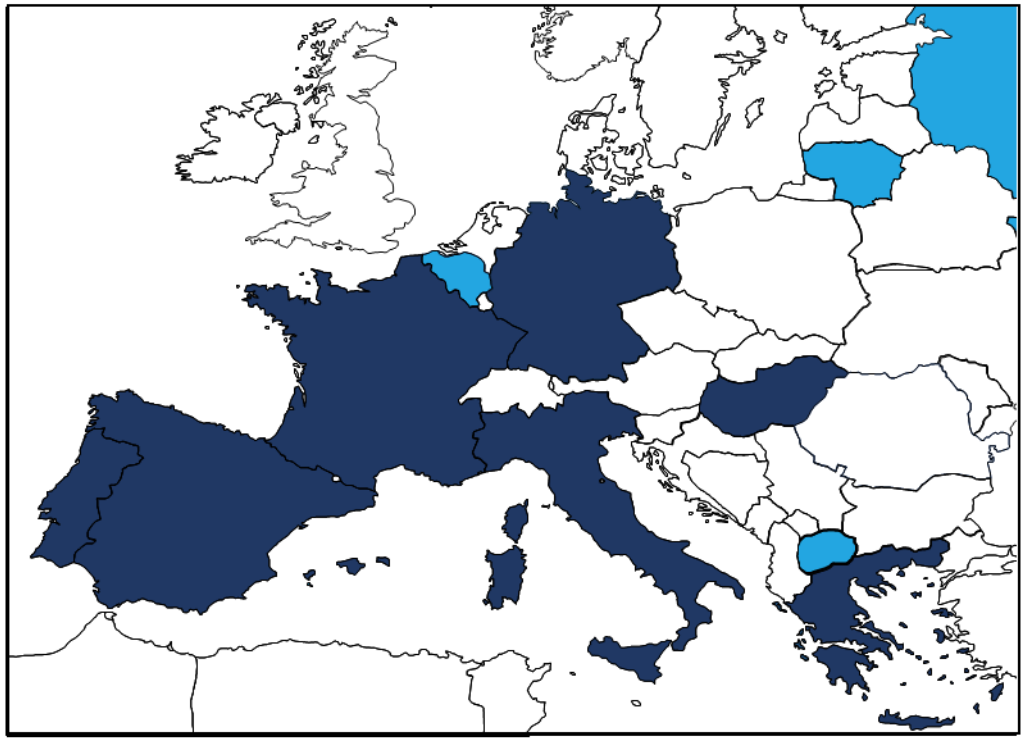
- Multi-centre, non-randomized, observational study on real-life use of LifePearl microspheres loaded with irinotecan (LP-IRI) in colorectal cancer liver metastases.
- Interim analysis focusing on feasibility, baseline, safety and quality of life.



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

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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%)**

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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%)

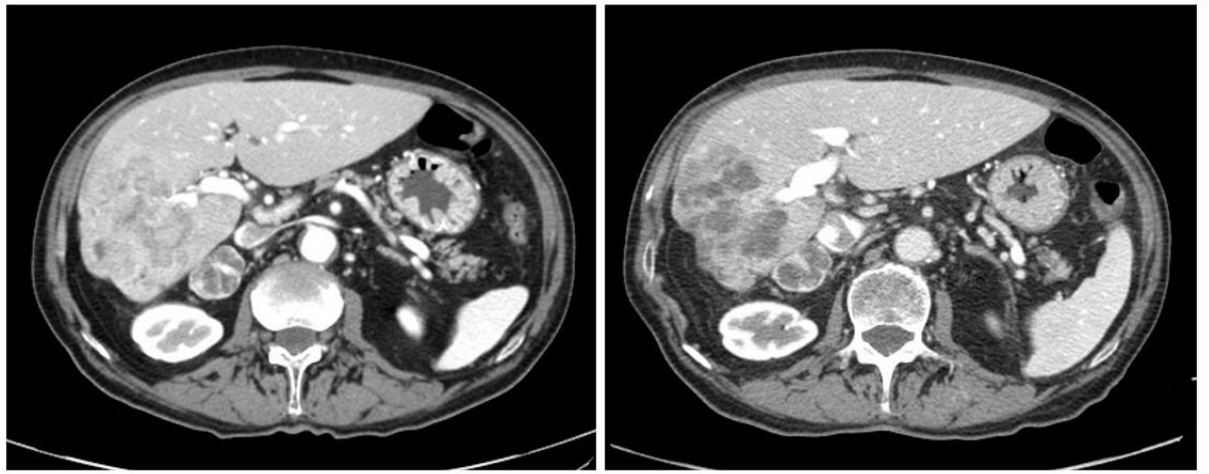
Treatment intentions of LP-IRI

Salvage treatment in progressive patients

n=21

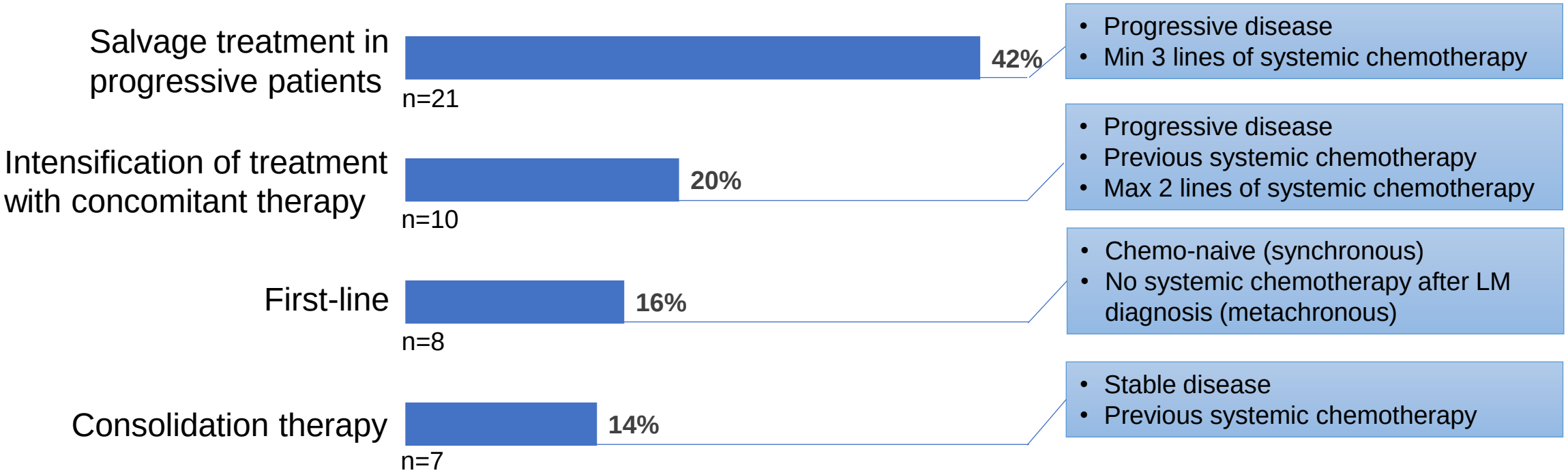
- Progressive disease
- Min 3 lines of systemic chemotherapy

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



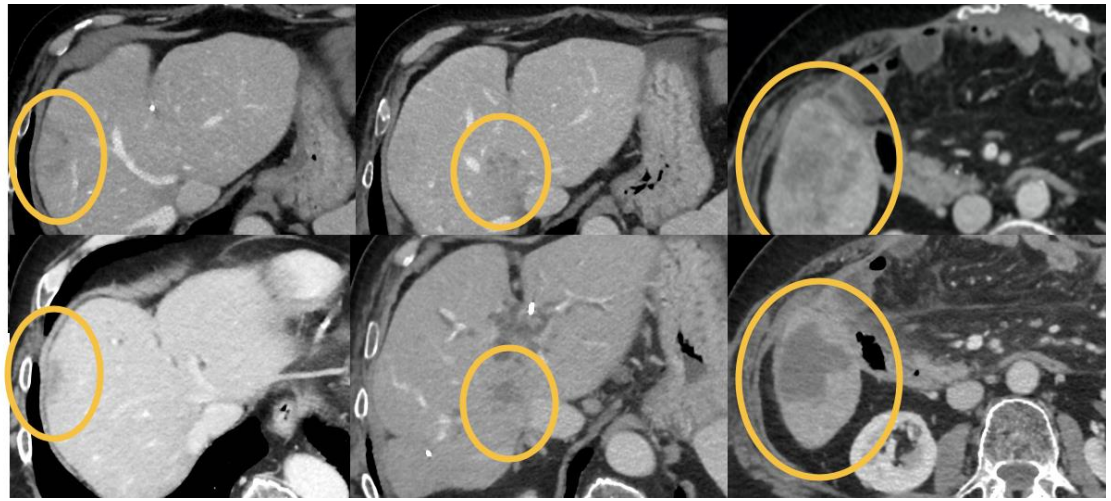
Pre-treatment ***6mo F-U***

Treatment intentions of LP-IRI



Treatment intentions of LP-IRI

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



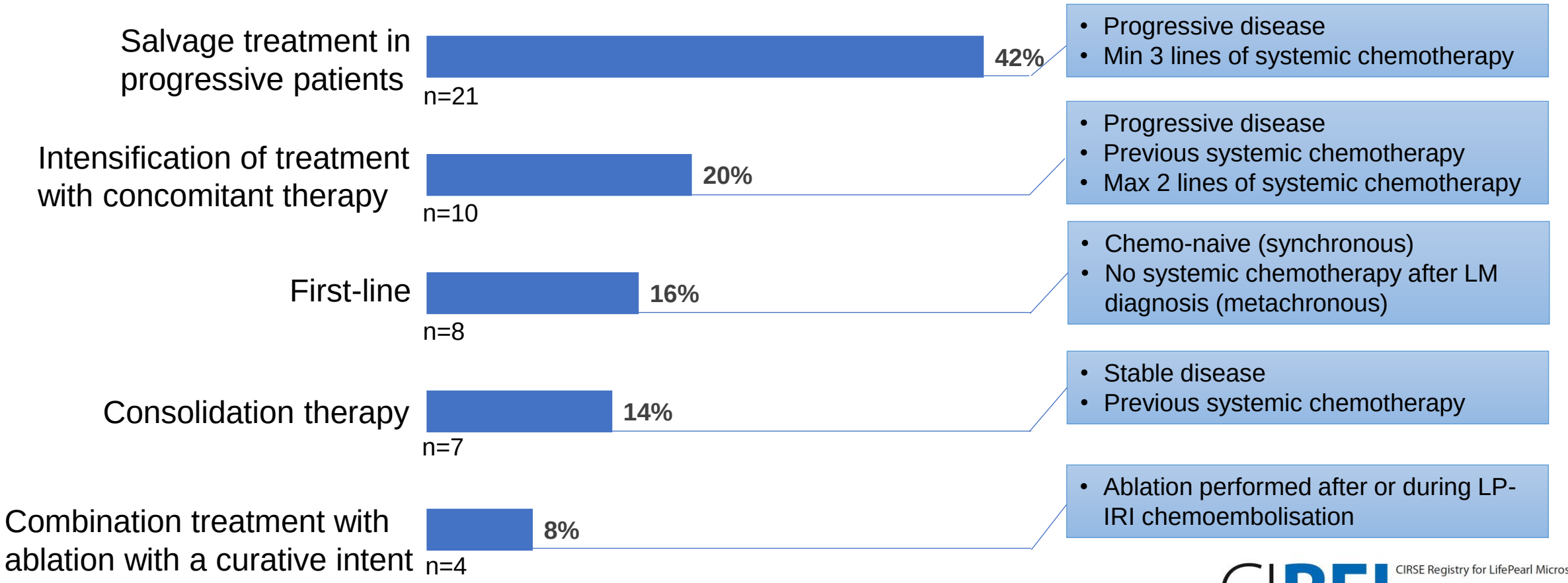
Consolidation therapy

14%

n=7

- Stable disease
- Previous systemic chemotherapy

Treatment intentions of LP-IRI



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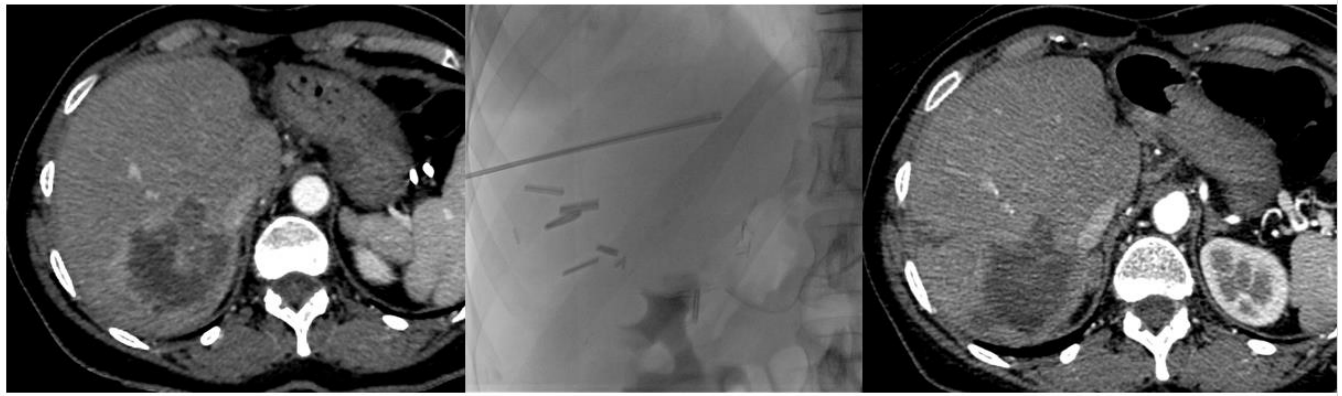
Treatment intentions of LP-IRI

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

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Safety and toxicity

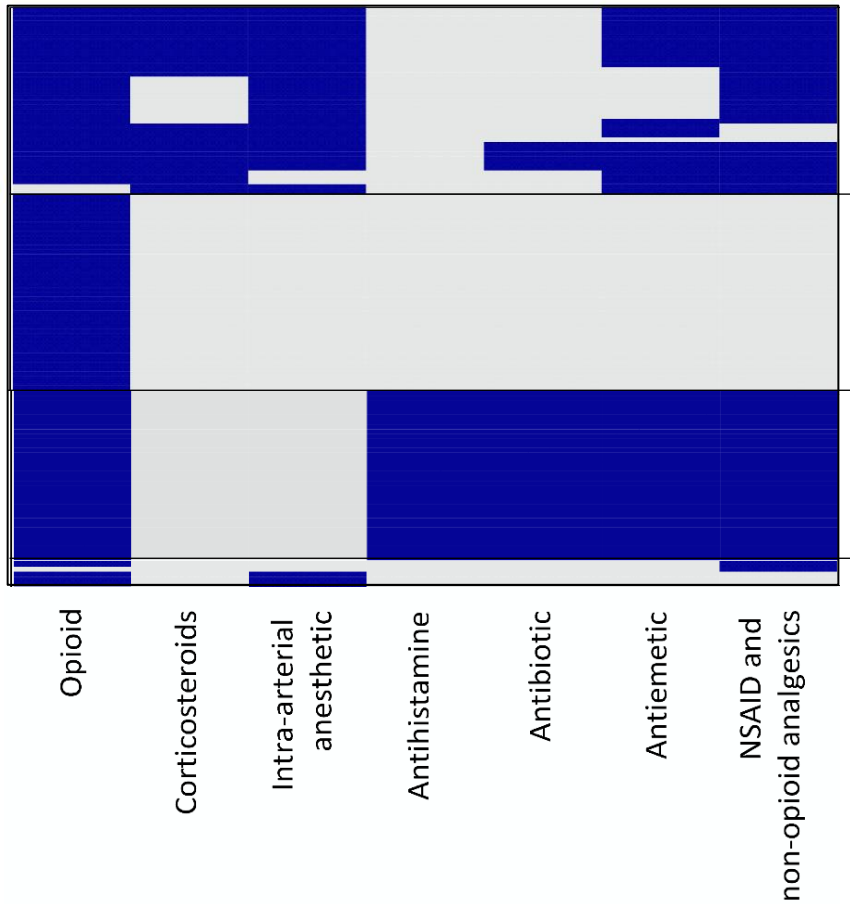
- 0% mortality in the first 30 days
- Most common AE: Grade 1-2 Post-embolization Syndrome (Pain)

	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
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

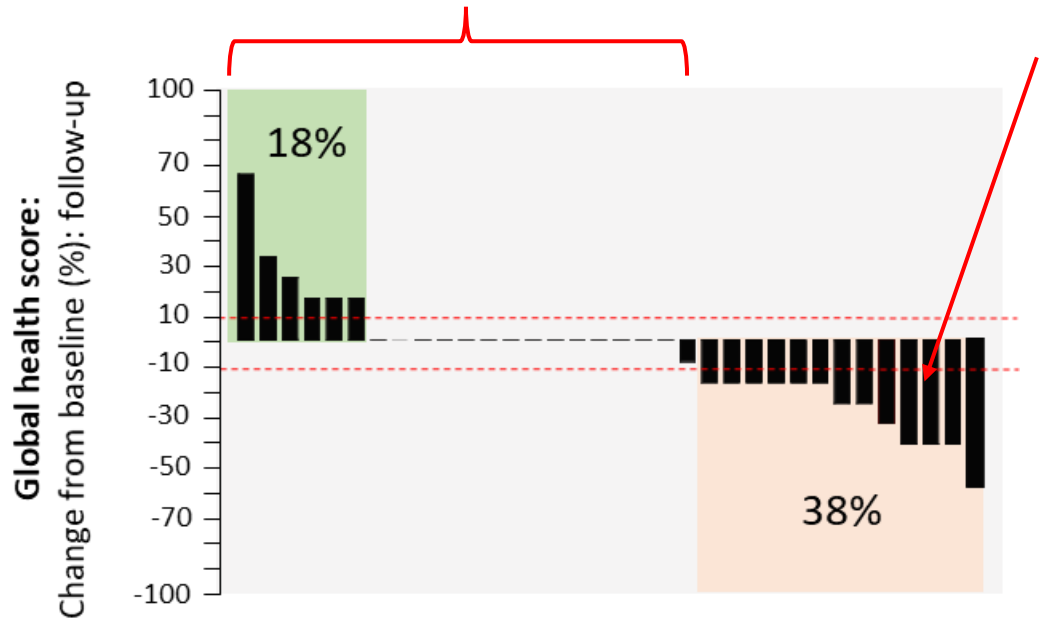


treatment sessions	Sites	Country (n patients)
41	2	DEU (10), PRT (3)
43	4	GRC (8), DEU (1) HUN (10), PRT (1)
38	1	ITA (14)
5	3	PRT (2), FRA (1), ITA (1)

Quality of Life mostly deteriorating in Salvage therapy patients

Global health score

62% improving or remaining stable

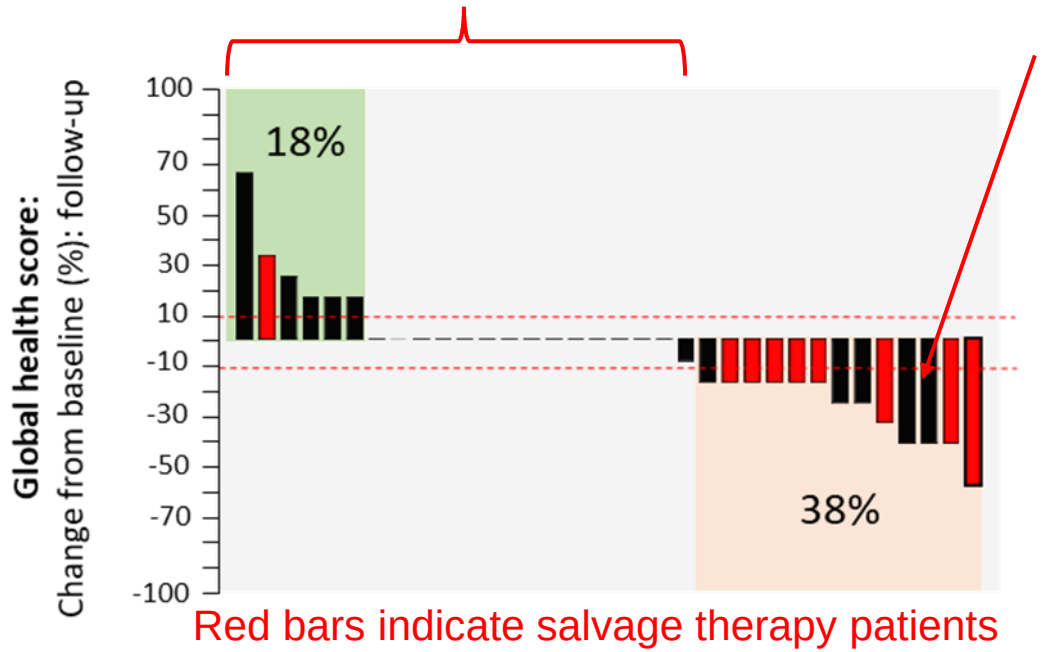


Global health quality of life score decreased in 38% of patients.

Quality of Life mostly deteriorating in Salvage therapy patients

Global health score

62% improving or remaining stable



Red bars indicate salvage therapy patients

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

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

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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)

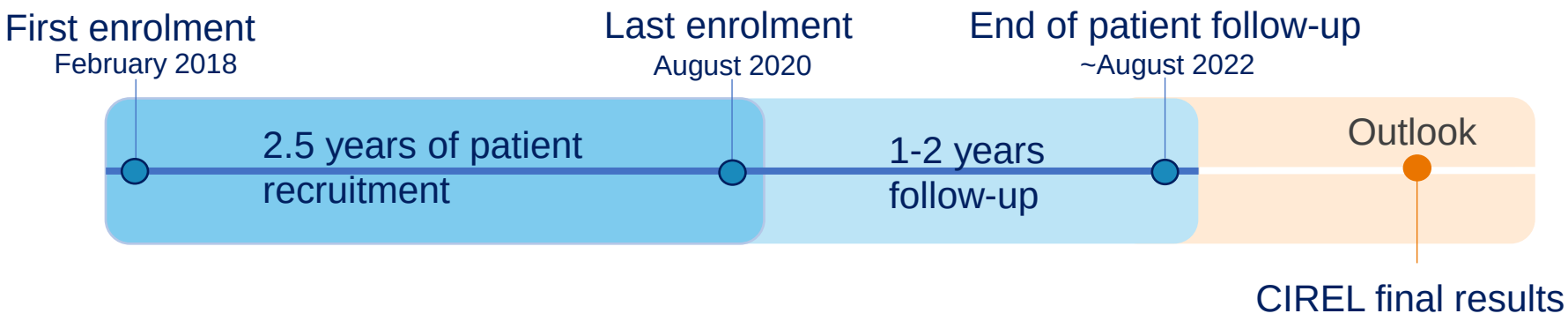
Procedural medications

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 ≥20% and ≥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

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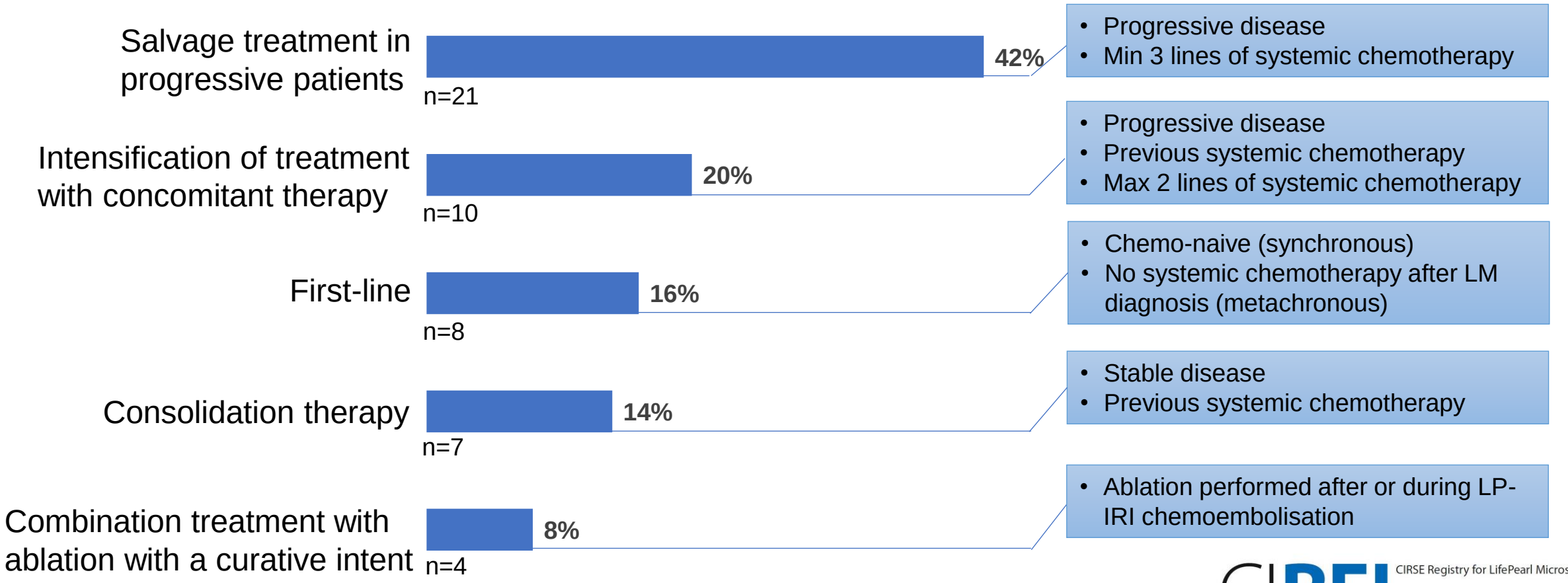
Treatment intentions of LP-IRI



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