Ablative interventionelle Therapien: Geeignete Patientinnen und Methoden

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DIRK ARNOLD, DOI 2019-2023

Remunerated *Advisory Boards (A*) and/or *Education Activities/ Honoraria for Presentations (H)*

Industry:

Amgen (H), Astra Zeneca (A, H) Bayer (A,H), BMS (A,H), Boston Scientific (A,H) , Eli Lilly (A), GSK (H), Gilead (A,H)

Merck Serono (A,H), MSD (A), Roche (A,H), Sanofi (A,H), Servier (A,H), Seagen (A, H) Sirtex (A,H),

CME providers:

Art Tempi (H), PriME Oncology (H), onkowissen (H), TRM Oncology (H)

Travel support

Industry: Astra Zeneca, BMS, MSD, Roche, Sanofi

Research funding to institute

Astra Zeneca, InCyte, MSD, Roche, Sanofi

Non-remunerated activities:

Advisory Role and/or PI function: Oncolytics, Phanes

Lokal ablative Therapie: Empfehlungen

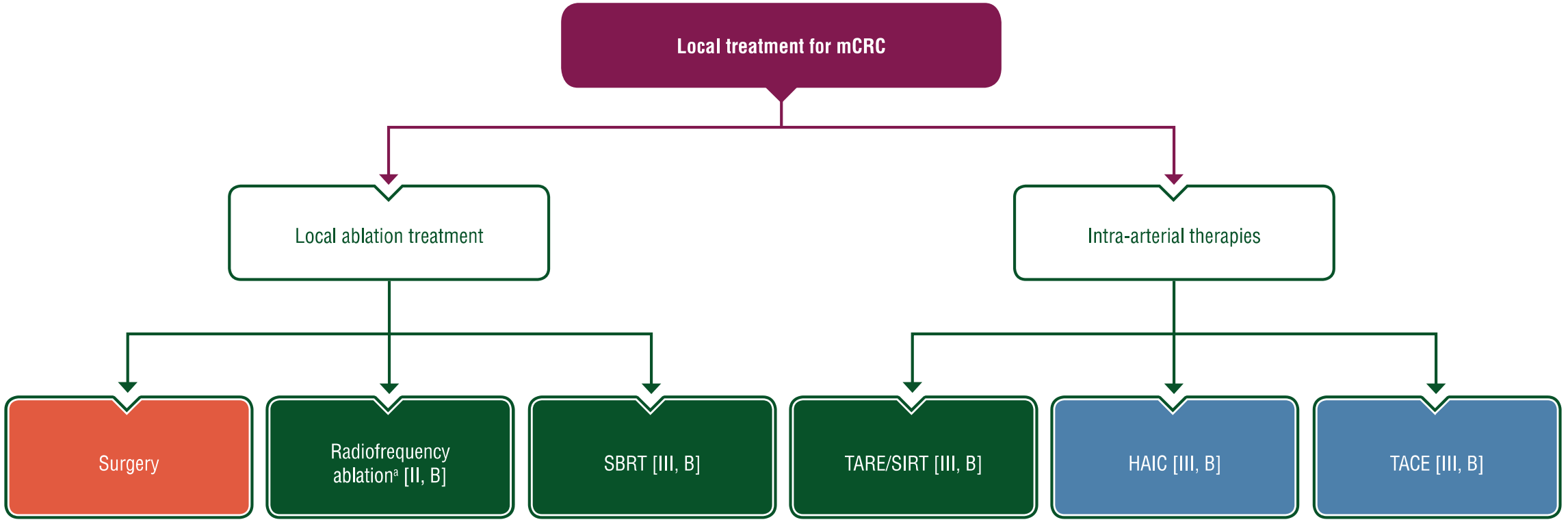
9.38.	Evidenzbasierte Empfehlung	2017
Empfehlungsgrad 0	Lokal ablative Verfahren können eingesetzt werden, wenn nicht resektable Metastasen vorliegen oder der Allgemeinzustand des Patienten eine Resektion nicht zulässt, insbe
Level of Evidence 3b	Quellen: [1184-1
	Starker Konsens

9.39.	Evidenzbasierte Empfehlung	2017
Empfehlungsgrad 0	Eine SIRT kann zur Behandlung von disseminierten Lebermetastasen bei KRK bei solchen Patienten eingesetzt werden, für die keine andere gleichwertige Therapie-option in Frage kommt.
Level of Evidence 2b	Quellen: [1205]
	Starker Konsens

S3 Leitlinie, 2017 (Version 2.1 update 2019)

Metastatic colorectal cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up☆

A. Cervantes[1,2], R. Adam[3], S. Roselló[1,2], D. Arnold[4], N. Normanno[5], J. Taïeb[6,7], J. Seligmann[8], T. De Baere[9,10,11], P. Osterlund[12,13], T. Yoshino[14] & E. Martinelli[15], on behalf of the ESMO Guidelines Committee*



Cervantes et al., Ann Oncol 2023

Lokal ablative Therapie beim mKRK: Empfehlungen

- Für wen?
- Wann?
- Was?
- (und warum nicht öfter?)

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Generally, a traditional clinical definition of OMD is:

- **One to five** metastatic lesions
  - occasionally more if complete eradication is possible
- Up to **two metastatic sites**
- Controlled primary tumor (optionally resected)
- All metastatic sites must be safely **treatable by LT .**

Cervantes et al., Ann Oncol 2023

Metastatic colorectal cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up☆

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- OMD status has therefore been established **by radiological appearances** and **clinical judgement**.
- Notably, OMD status can occur in **multiple clinical scenarios** in the **continuum of care** e.g. during different treatment lines.
  - Therefore, careful and continuous re-assessment is recommended.

Cervantes et al., Ann Oncol 2023

Metastatic colorectal cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up☆

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- OMD status has therefore been established by radiological appearances and clinical judgement.
- Notably, OMD status can occur in multiple clinical scenarios in the continuum of care e.g. during different treatment lines.
  - Therefore, careful and continuous re-assessment is recommended.

- Currently, **biological factors do not contribute** to this definition
  - this may change considering, for example, molecular subtypes with specific prognostic background and/or treatment implications.

Cervantes et al., Ann Oncol 2023

Understanding biology of metastasation

Local tumour → oligometastasation → diffuse mets. → terminal disease

Paget et al., Lancet 1898; Halstead et al., Ann Surg 1907

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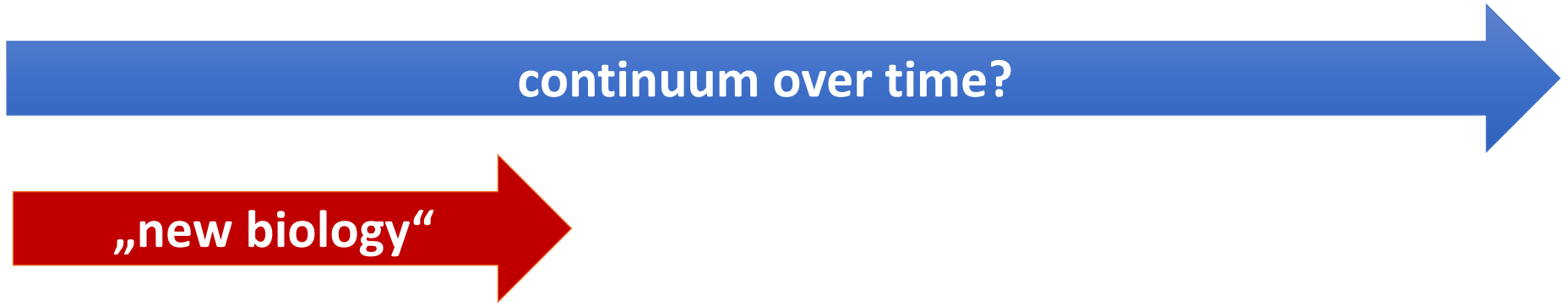

Paget et al., Lancet 1898; Halstead et al., Ann Surg 1907

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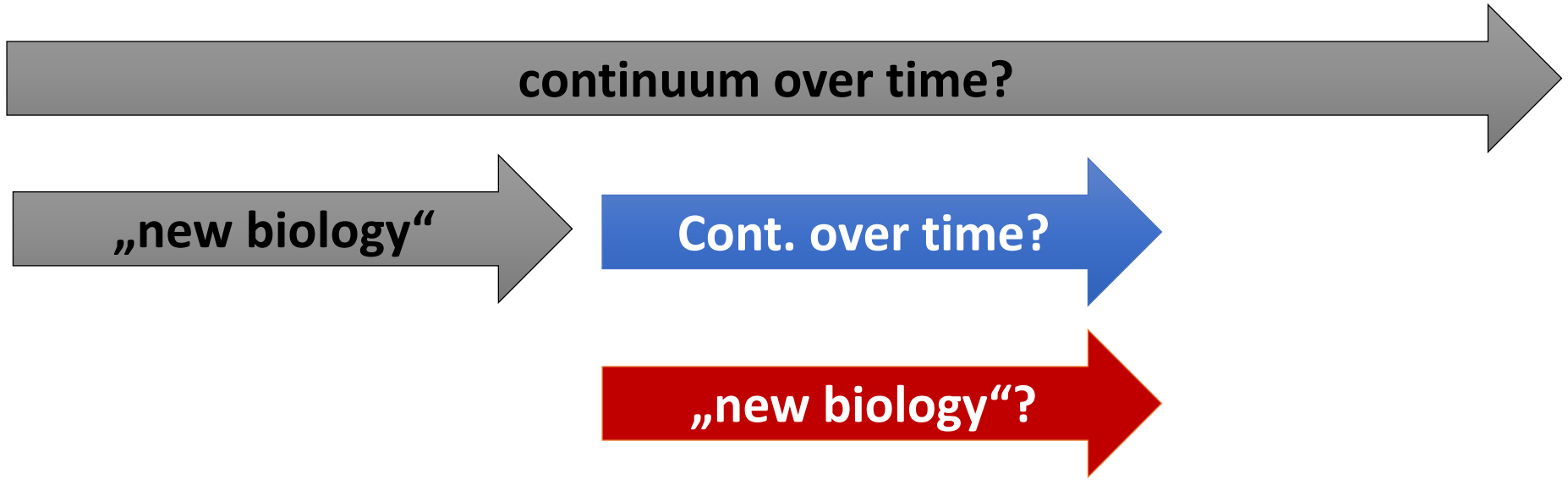
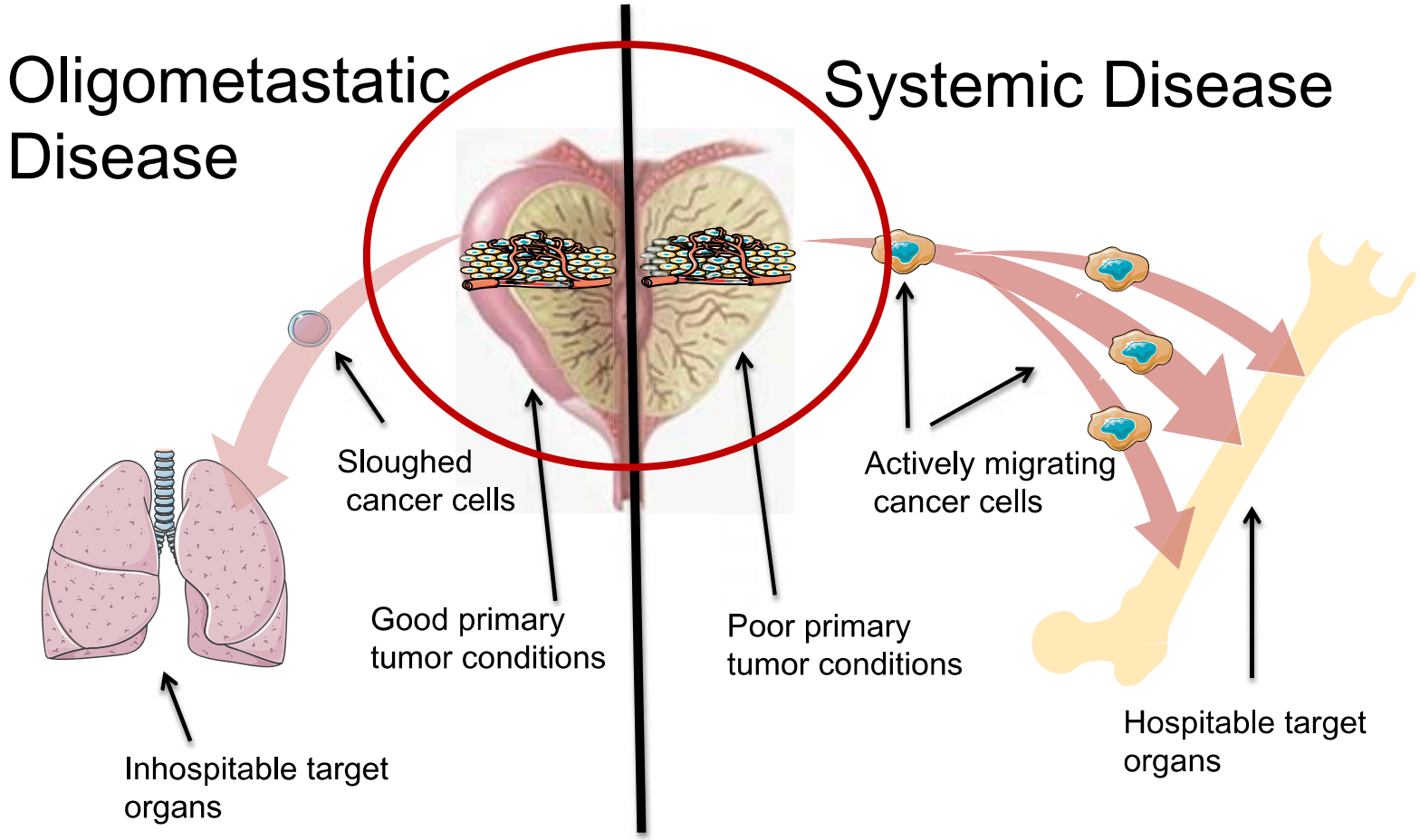


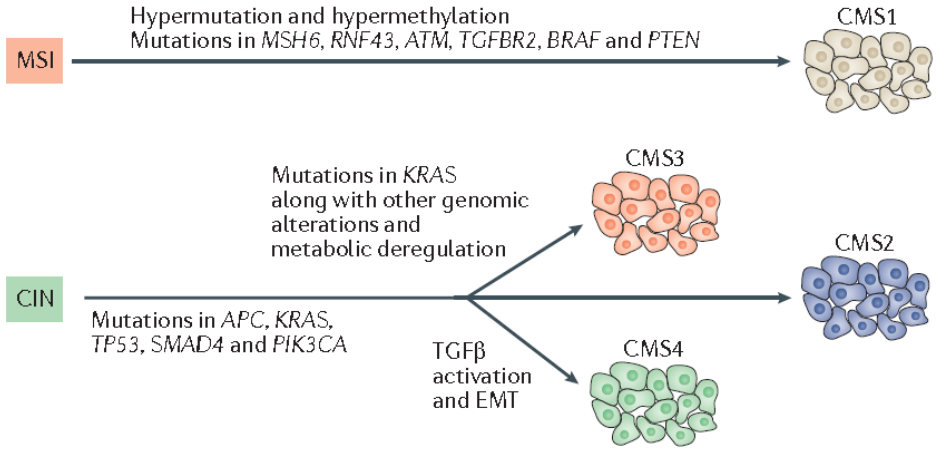
Paget et al., Lancet 1898; Halstead et al., Ann Surg 1907

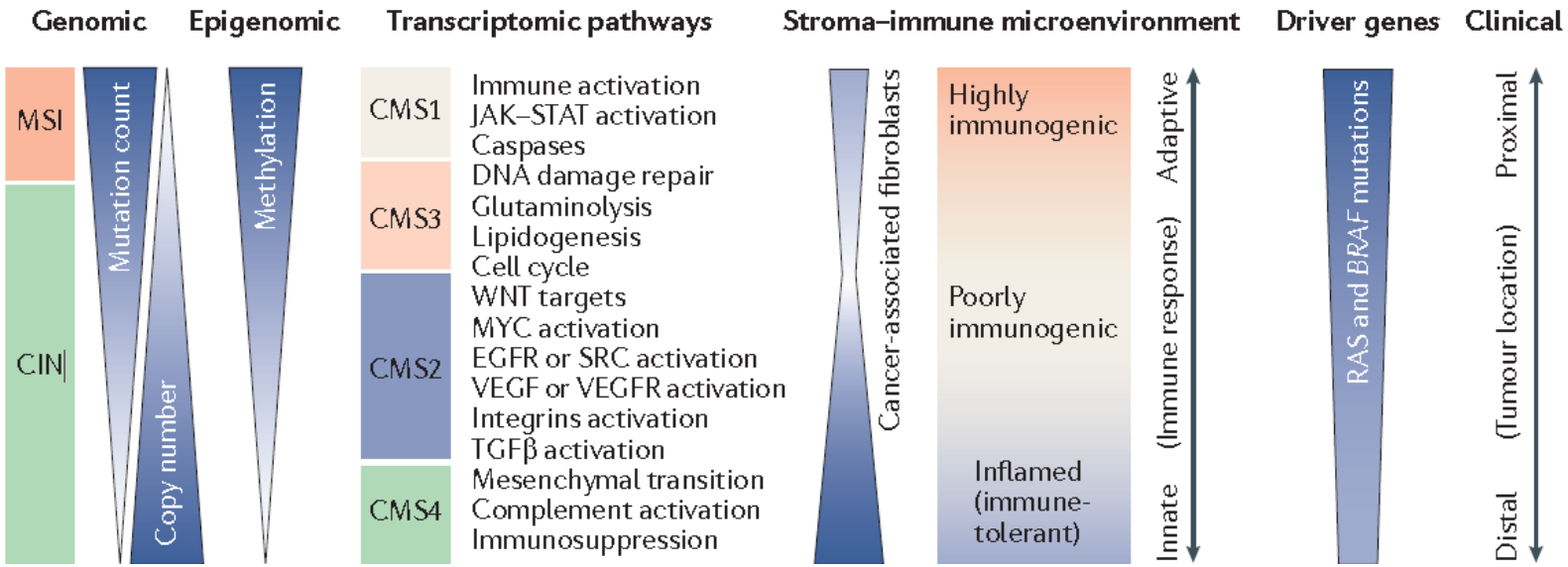
Oligometastatic vs. (widespread) systemic disease



adapted from: Reyes et al., Oncotarget 2015

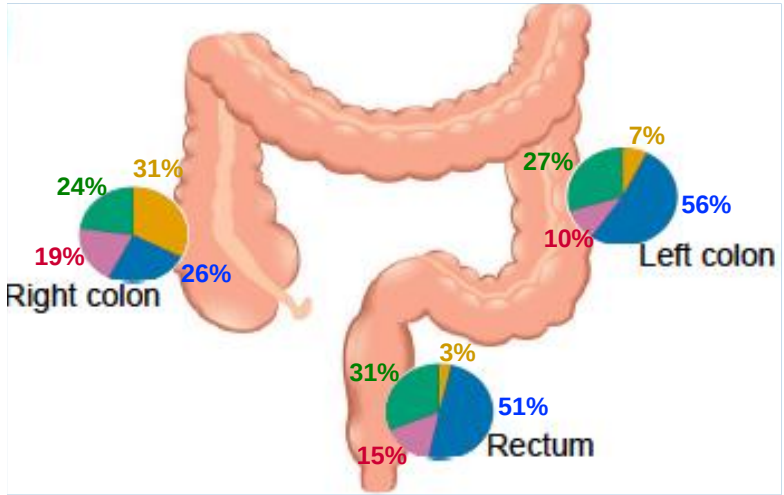
Consensus molecular subtypes of CRC

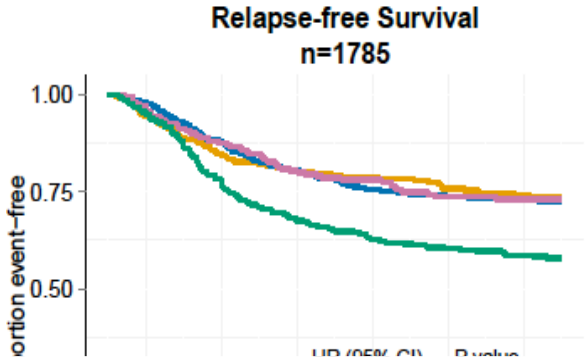


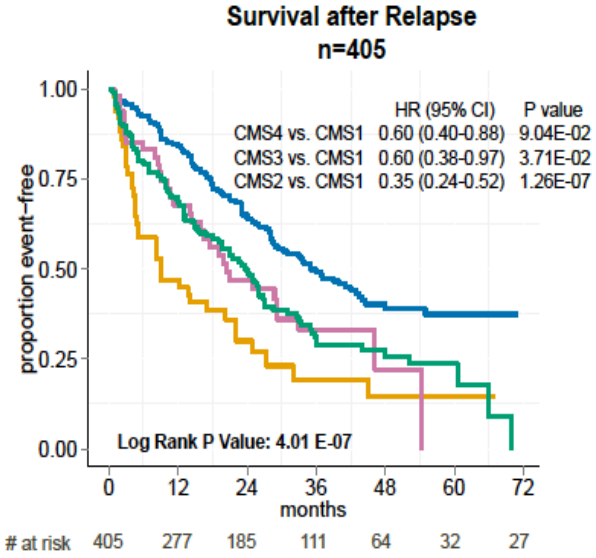


Consensus molecular subtypes of CRC

CMS1 MSI Immune	CMS2 Canonical	CMS3 Metabolic	CMS4 Mesenchymal
MSI, CIMP high Hypermutation	SCN high	Mixed MSI status SCNA low, CIMP low	SCN high
BRAF mutations		*KRAS* mutations	
Immune infiltration and activation	WNT and MYC activation	Metabolic deregulation	Stromal infiltration TGF beta activation Angiogenesis







Dienstmann et al., Ann Oncol 2018

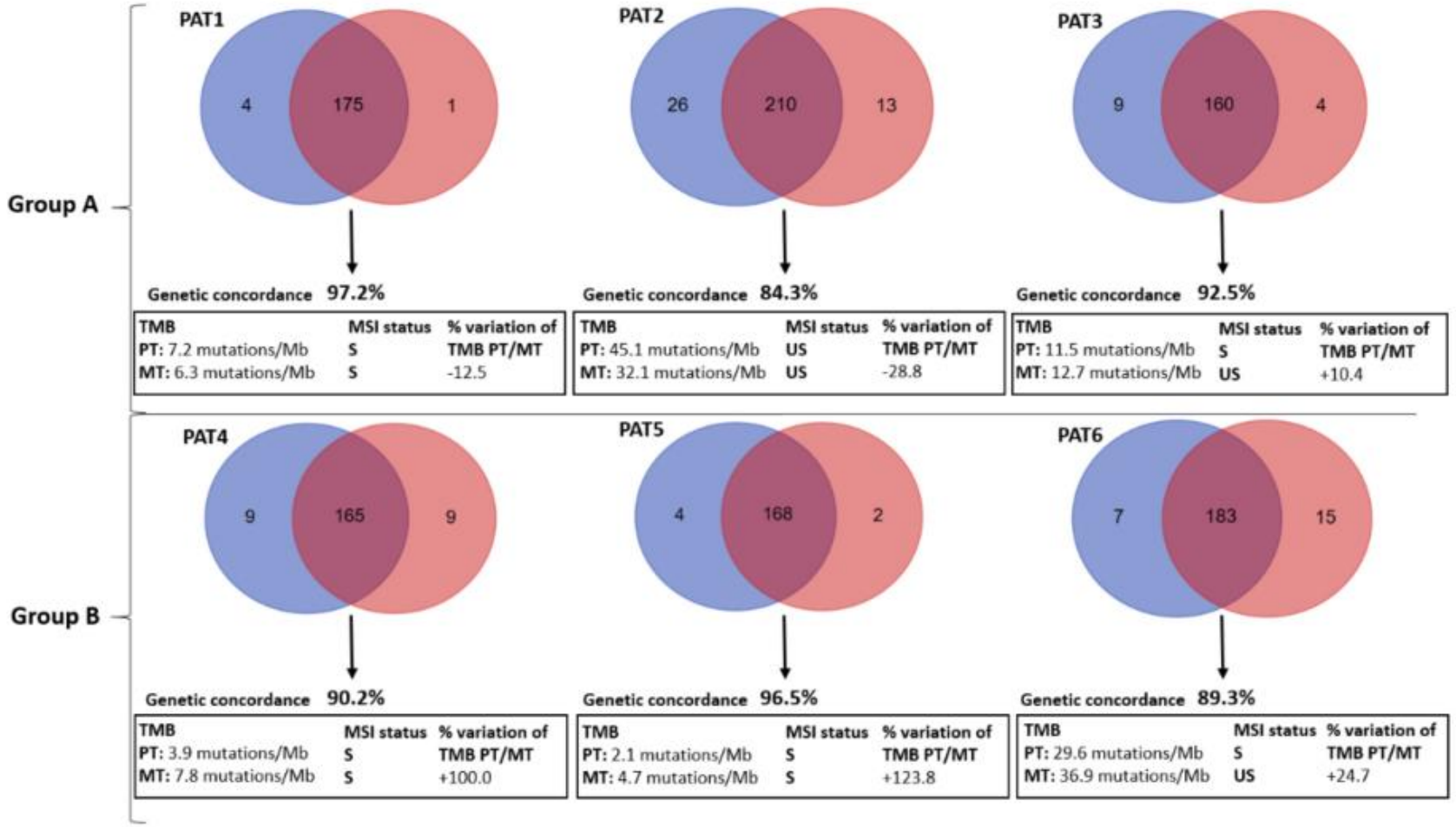
Mutational pattern of oligometastatic mCRC

6 out of 98 patients liver oligometastases

(≤3 lesions)

(A) without recurrence at 3y follow-up

(B) recurred within 1y



Ottaiano et al., Cancers (Basel) 2020

Mutational pattern of oligometastatic mCRC

Biomarker	Clinical Significance
Loss of *KRAS* and *SMAD4* alterations from primary to metastatic lesions. High granzyme-B+ T-cell infiltration into metastatic tumor.	The patients with these characteristics remain with liver-limited OMD for long time.
Gain in *KRAS*, *PIK3CA* and *SMAD4* alterations. Scarce granzyme-B+ T-cells infiltration.	The patients with these characteristics develop poly-metastatic widely diffusive disease.
KRAS regression from primary to metastatic lesions. HLA-C7 aplotype.	The patients with these characteristics remain oligometastatic for long time.

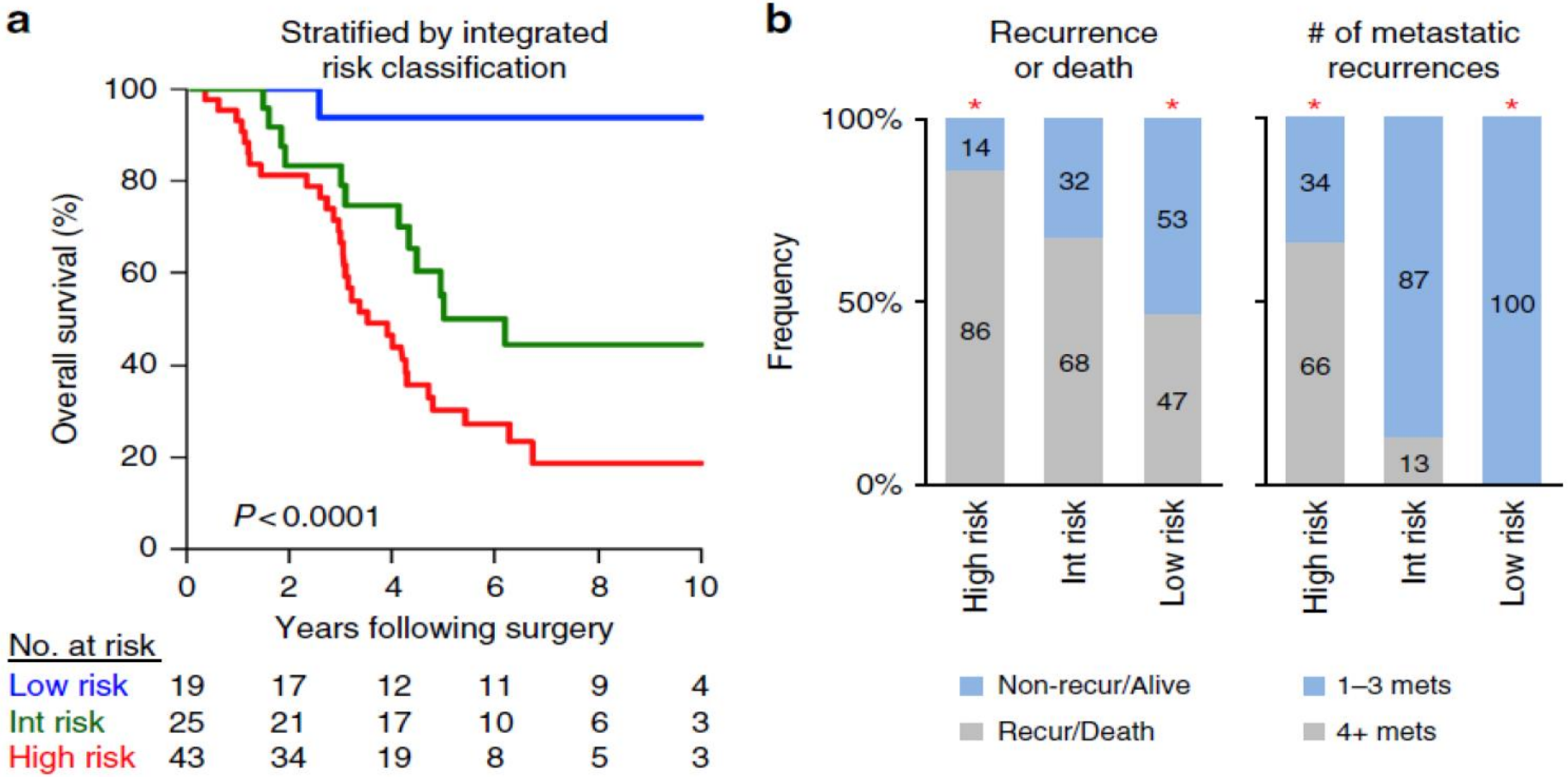
Ottaiano et al., Cancers (Basel) 2020; Ottaiano et al, Front Immunol 2022

Integrated molecular subtyping defines a curable oligometastatic state in colorectal liver metastasis

	Subtype 1 Canonical	Subtype 2 Immune	Subtype 3 Stromal
Frequency	33%	29%	39%
Molecular signature	↓Immune and stroma E2F/MYC signaling DNA damage and cell cycle	↑Immune Interferon signaling p53 pathway	↑Stroma KRAS signaling EMT and angiogenesis
Specific mutations	NOTCH1 and PIK3C2B	NRAS, CDK12, and EBF1	MAD3
Met. reccurences	Many	Few	Many
Overall survival	Intermediate	Favorable	Unfavourable

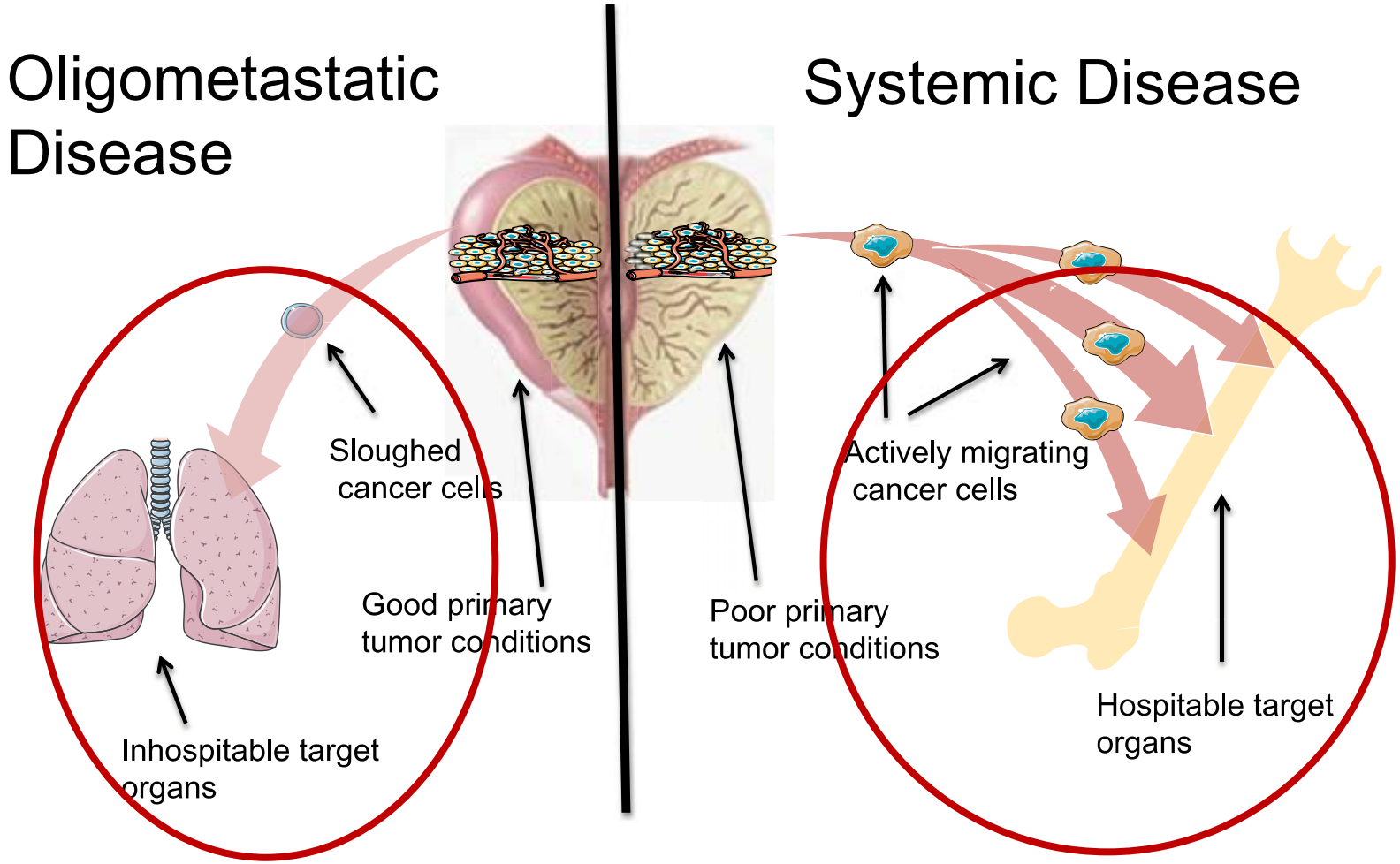
Pitroda et al., Nature Communications 2018

Integrated molecular subtyping defines a curable oligometastatic state in colorectal liver metastasis



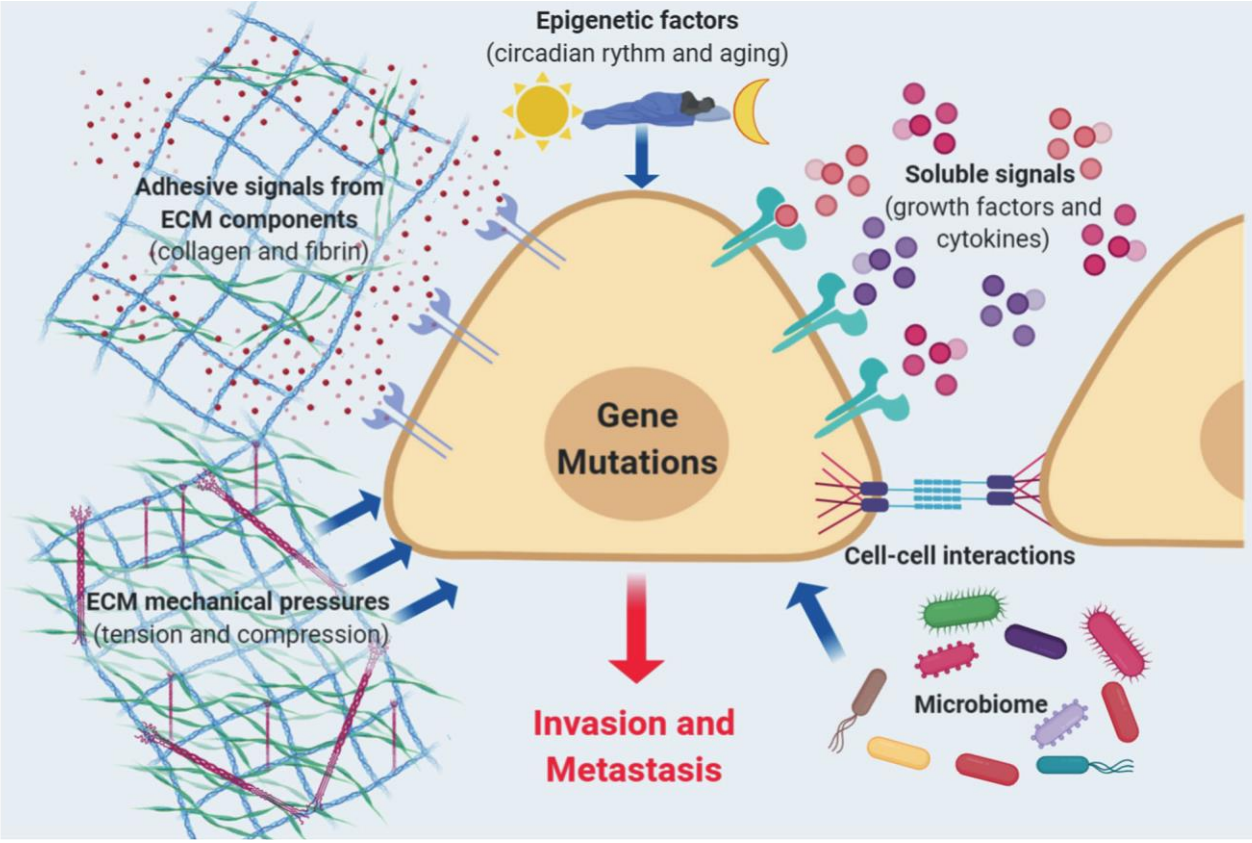
Pitroda et al., Nature Communications 2018

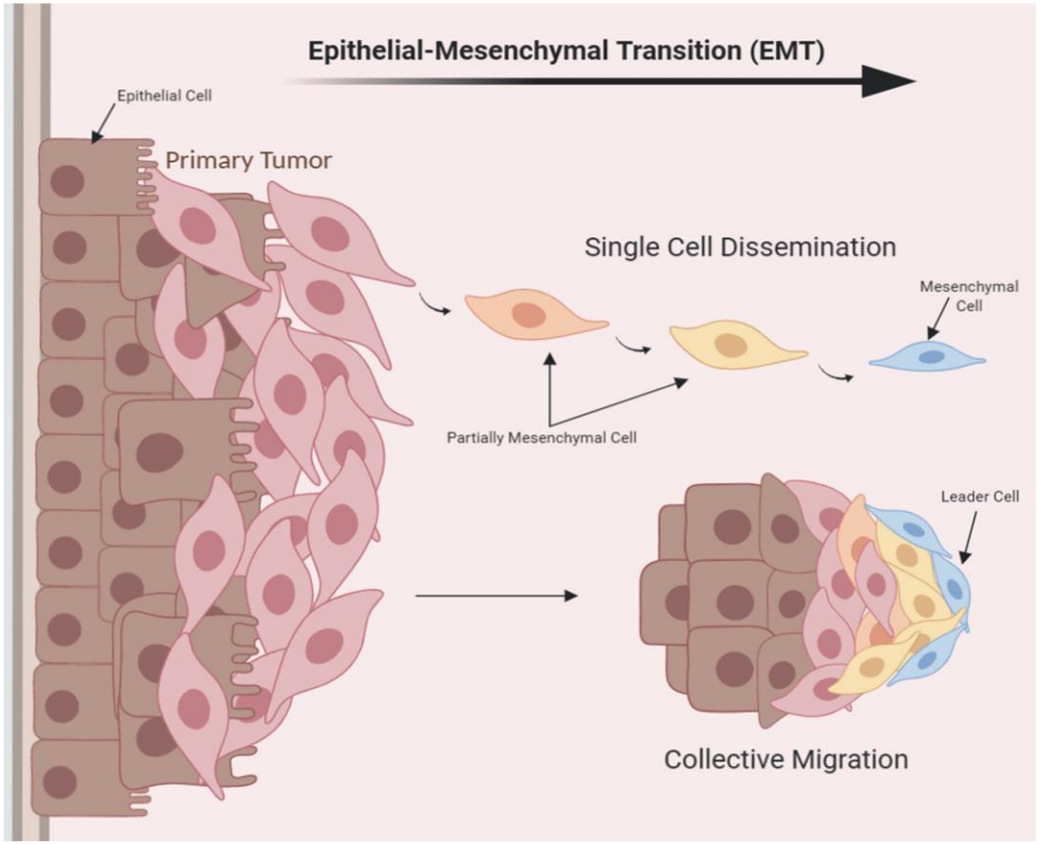
Oligometastatic vs. (widespread) systemic disease



adapted from: Reyes et al., Oncotarget 2015

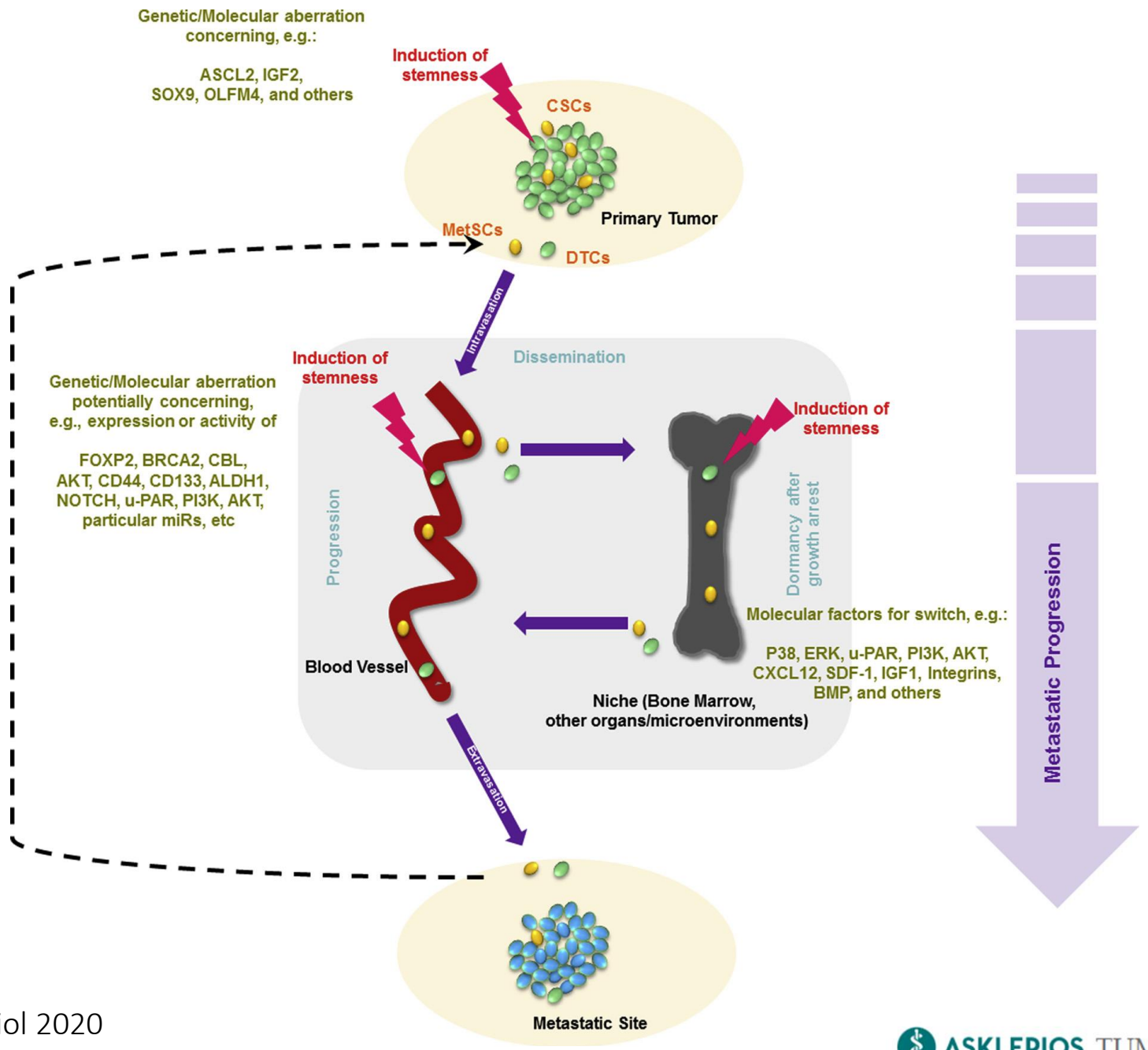
„A Hallmark of Cancer Revisited…“



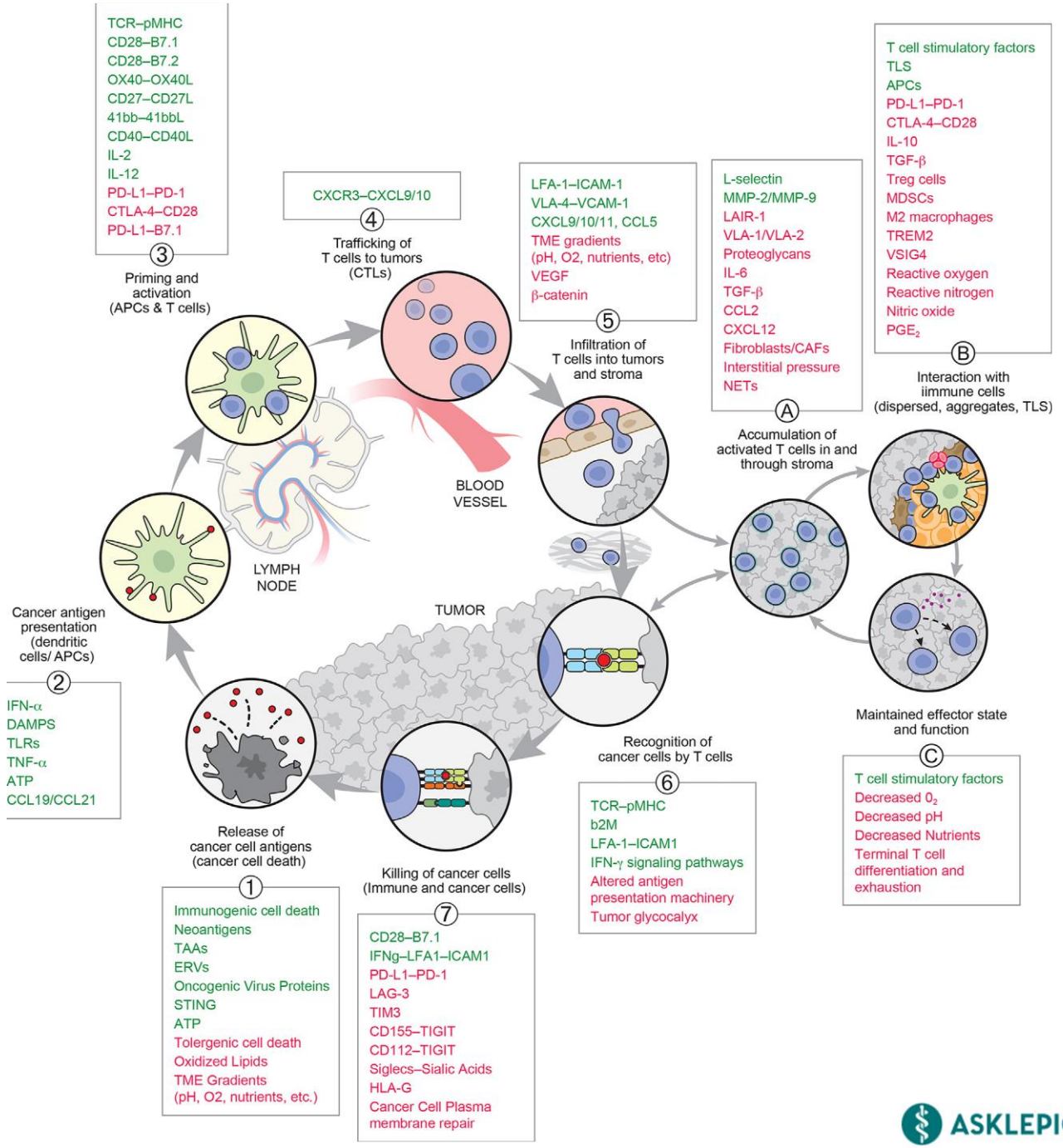


Fares et al., Signal Transduction and Targeted Therapy 2020

The oligometastatic phenotype

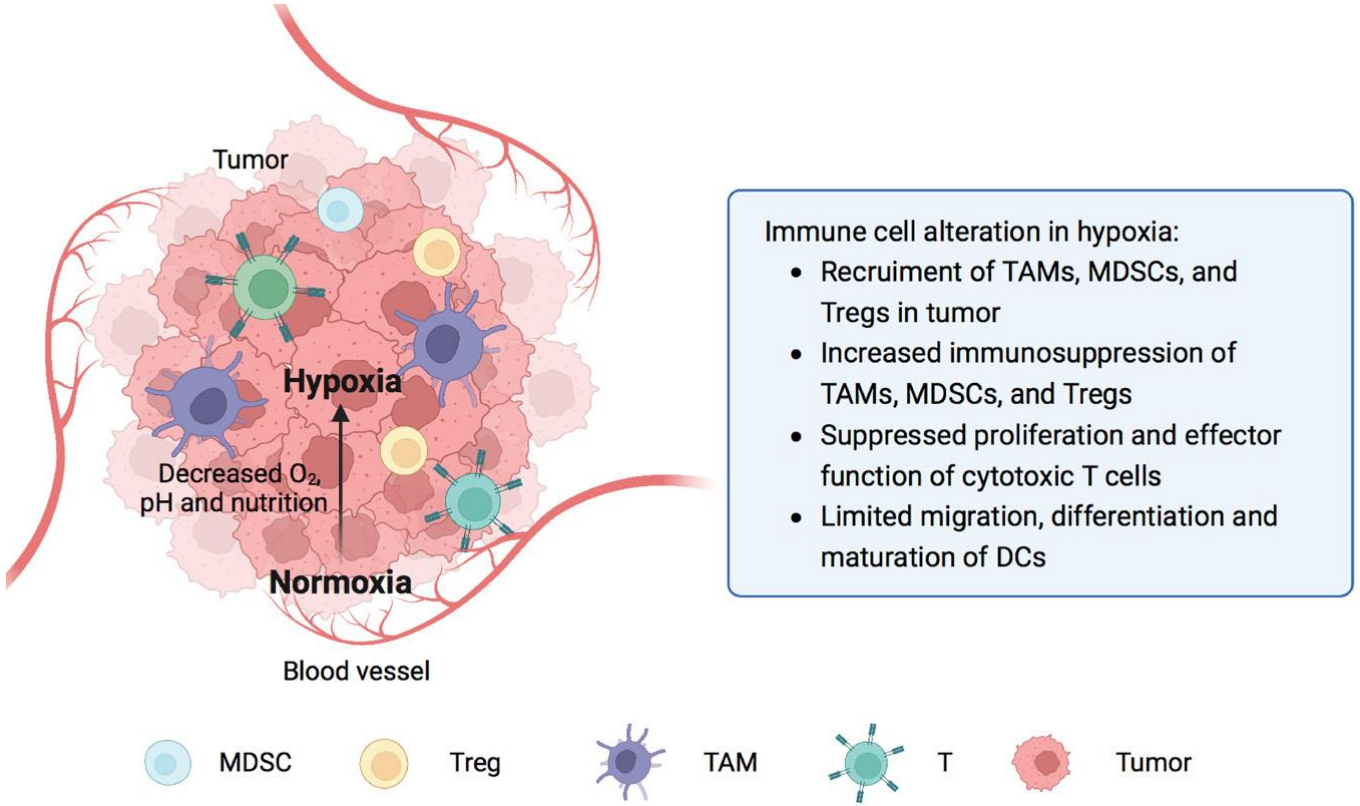


Allgayer et al., Semin Cancer Biol 2020



Melmann et al., Immunity 2023

Tumour microenvironment (TME)

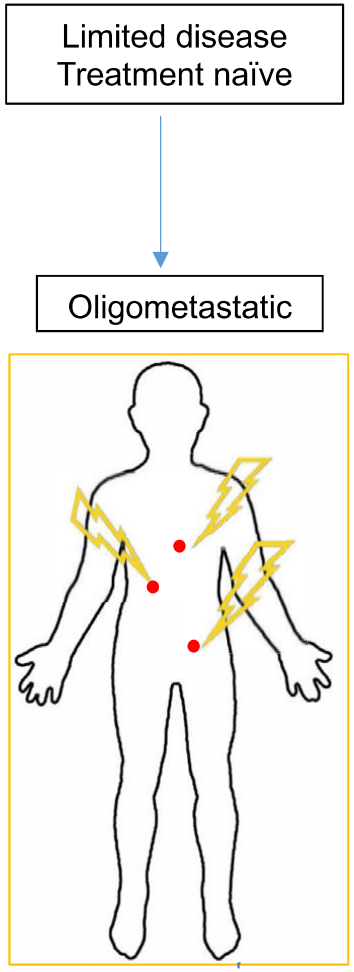


The TME includes

- immune cells,
- extracellular matrix,
- other cells, like fibroblasts
- (blood vessels)

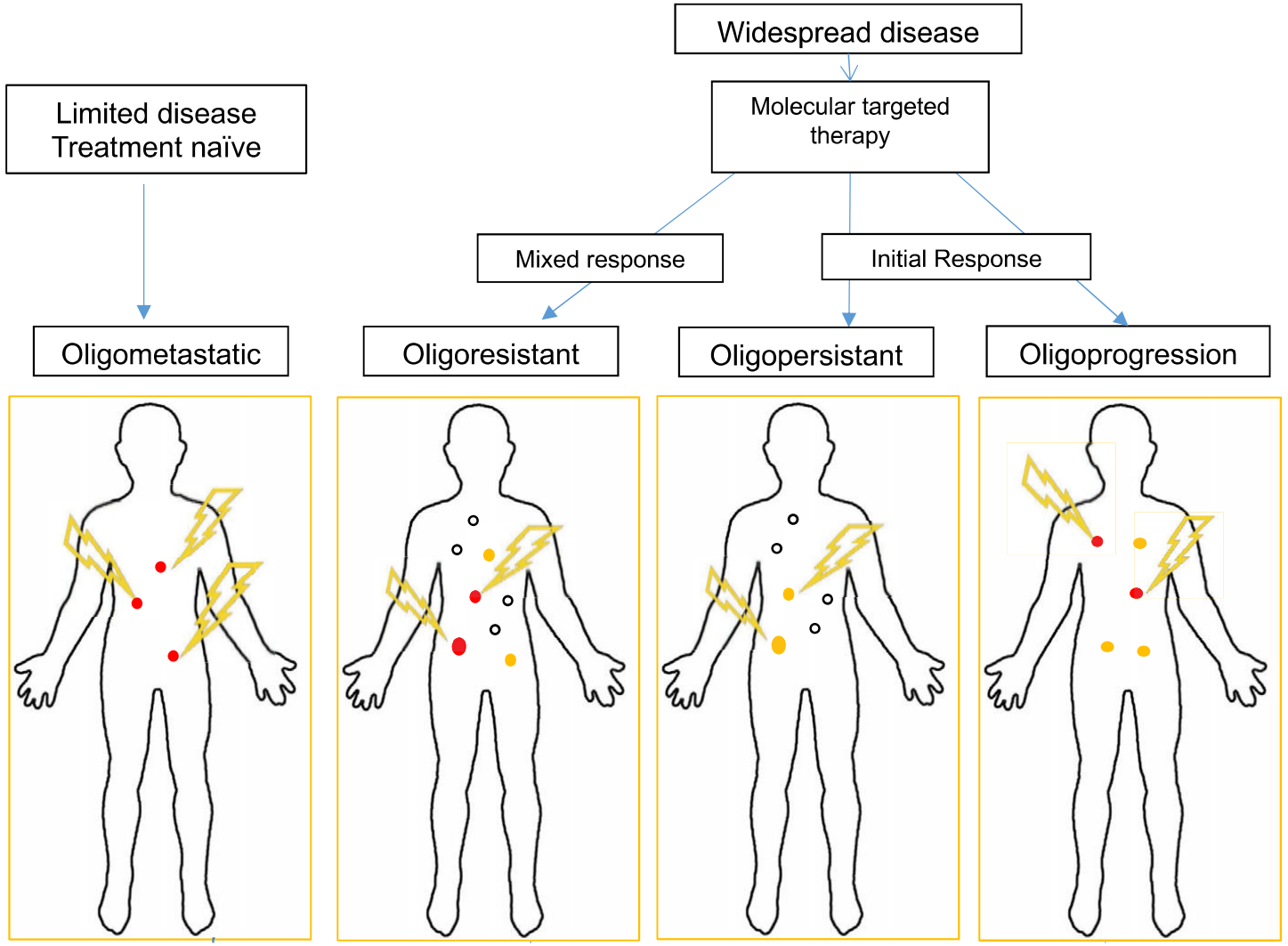
Zhu et al., Organoids 2022

Oligometastatic disease and LAT: What can be improved?



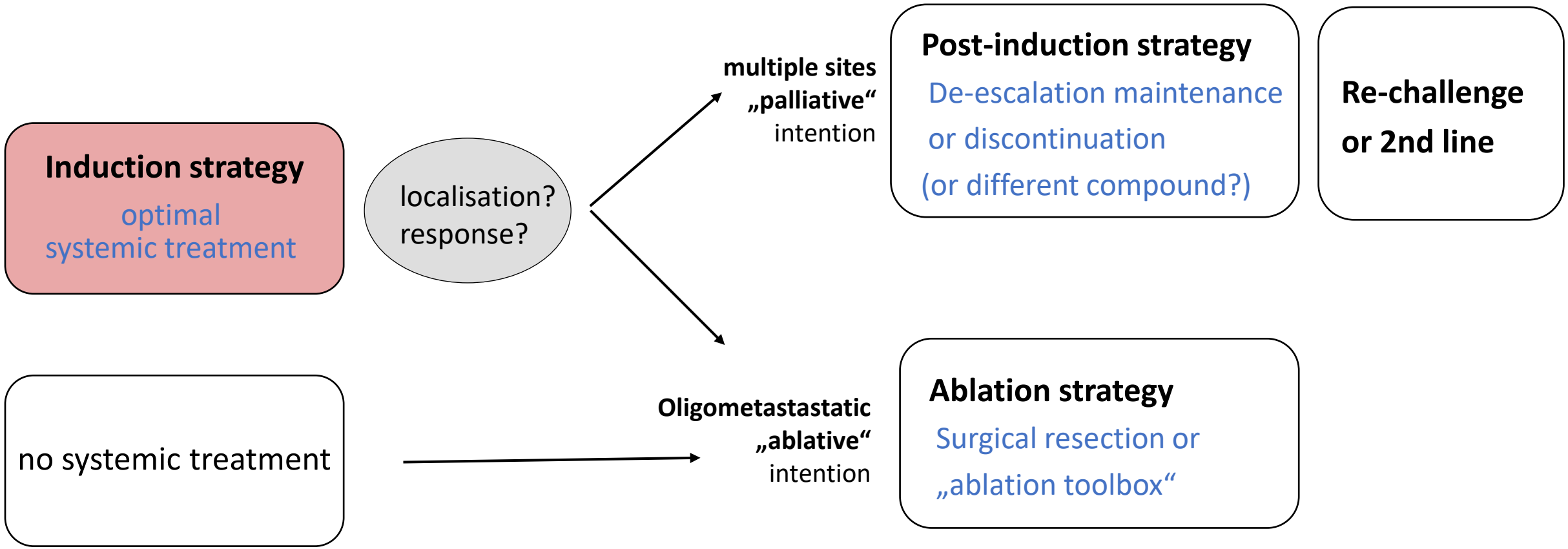
Patel et al., Clinical Oncology 2019

Oligometastatic disease and LAT: What can be improved?



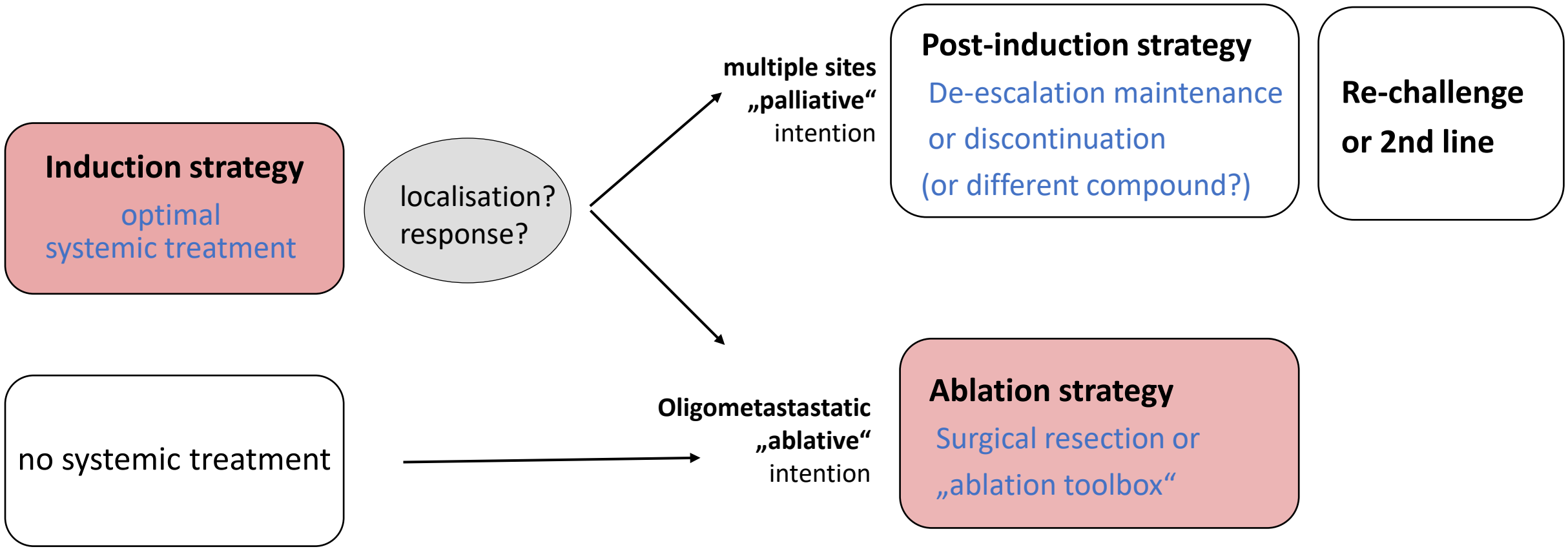
Patel et al., Clinical Oncology 2019

Principles in mCRC management



Arnold; ESMO GI Educational Session 2022

Principles in mCRC management

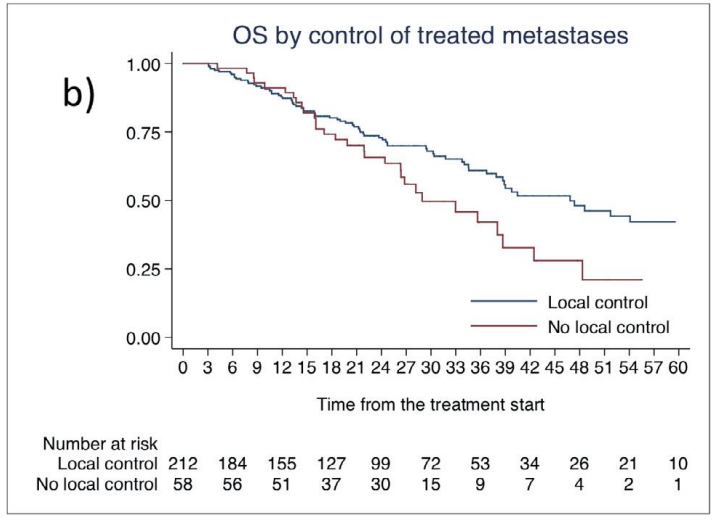


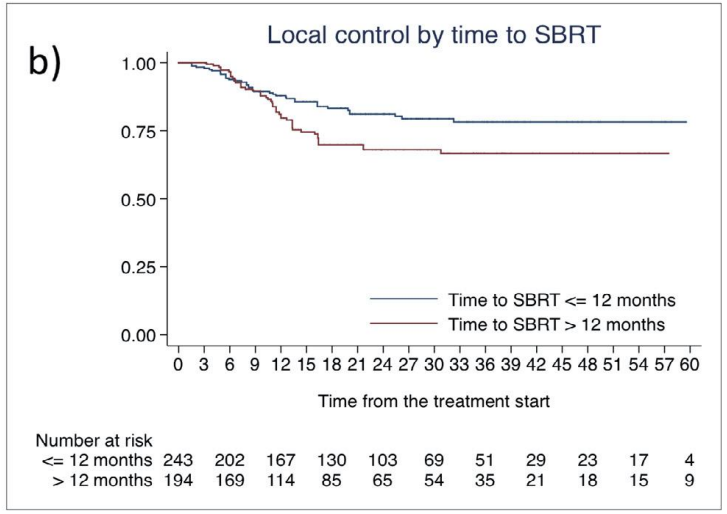
Arnold; ESMO GI Educational Session 2022

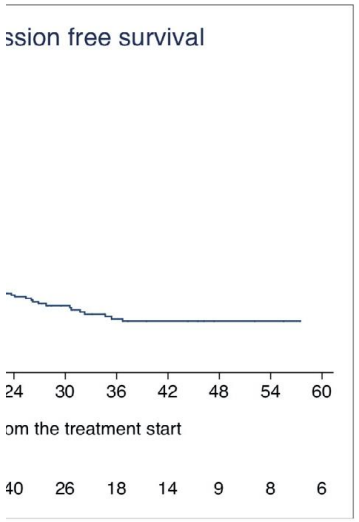
Bekannte Faktoren: Zeit, Kontrolle, Vollständigkeit

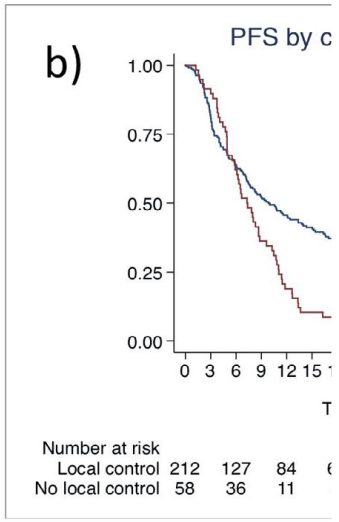
Original Article

Predictive factors for survival of oligometastatic colorectal cancer treated with Stereotactic body radiation therapy





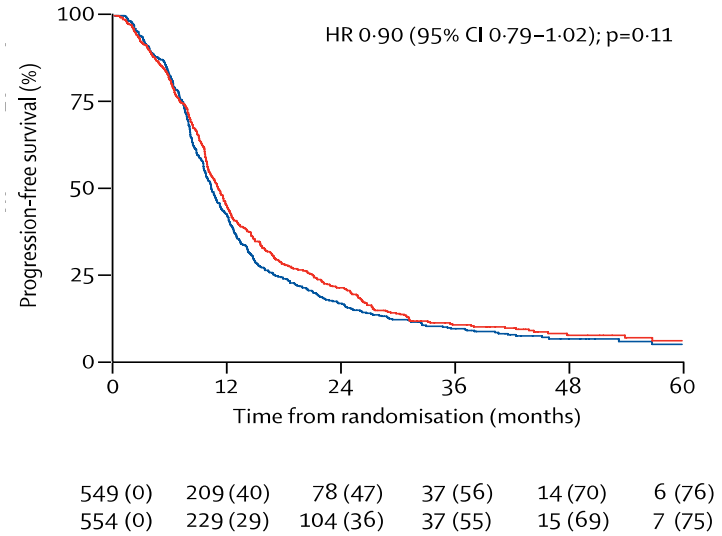




Franzese et al., Radiotherapy Oncol 2019

Beispiel: transarterielle Radioembolisation beim KRK

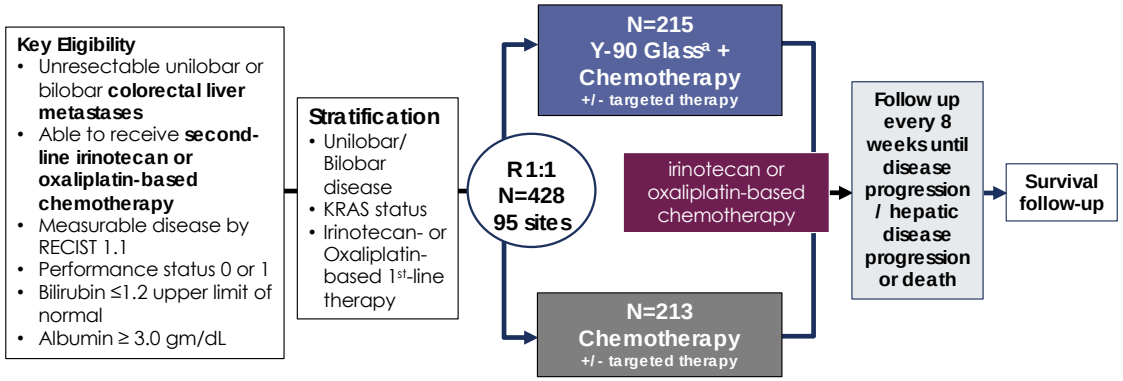
First-line selective internal radiotherapy plus chemotherapy versus chemotherapy alone in patients with liver metastases from colorectal cancer (FOXFIRE, SIRFLOX, and FOXFIRE-Global): a combined analysis of three multicentre, randomised, phase 3 trials



1st line, upfront TARE

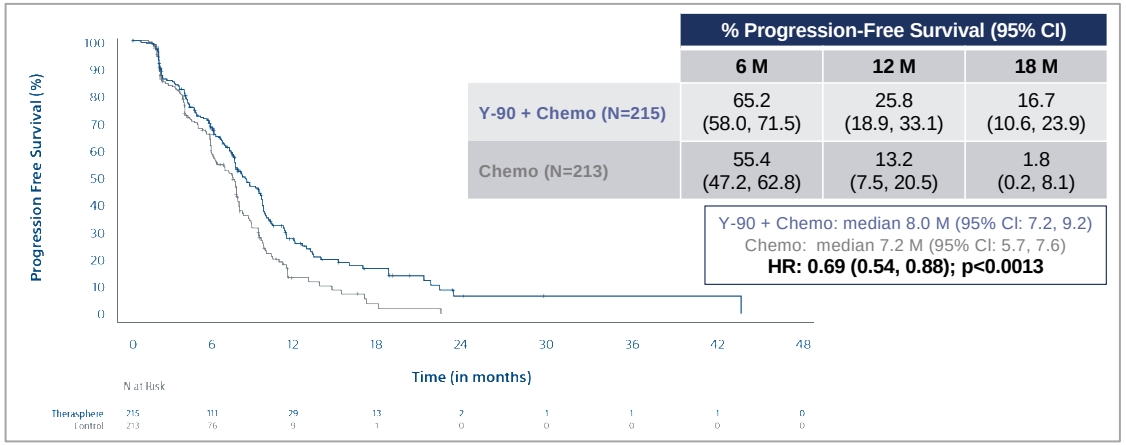
Wasan et al., Lancet Oncol 2017; Mulcahy et al., J Clin Oncol 2021

EPOCH Studie: 2nd line Chemo mit TARE



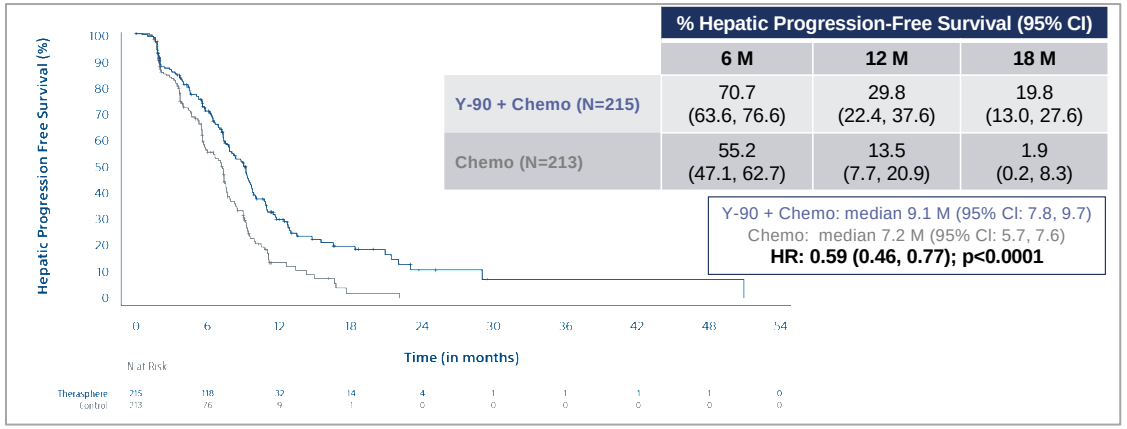
[a] TARE with Y^{90} glass microspheres (TheraSphere™, Boston Scientific Corporation). Cycle 1= chemotherapy, Y-90 TARE replace Cycle 2, Cycle 3 resume chemotherapy ± targeted therapy.

Chauhan N, Mulcahy MF, Salem R, et al. JMIR Res Protoc. 2019;8(1):e11545. doi: 10.2196/11545.



	% Progression-Free Survival (95% CI)		
	6 M	12 M	18 M
Y-90 + Chemo (N=215)	65.2 (58.0, 71.5)	25.8 (18.9, 33.1)	16.7 (10.6, 23.9)
Chemo (N=213)	55.4 (47.2, 62.8)	13.2 (7.5, 20.5)	1.8 (0.2, 8.1)

Y-90 + Chemo: median 8.0 M (95% CI: 7.2, 9.2)
Chemo: median 7.2 M (95% CI: 5.7, 7.6)
HR: 0.69 (0.54, 0.88); p<0.0013



	% Hepatic Progression-Free Survival (95% CI)		
	6 M	12 M	18 M
Y-90 + Chemo (N=215)	70.7 (63.6, 76.6)	29.8 (22.4, 37.6)	19.8 (13.0, 27.6)
Chemo (N=213)	55.2 (47.1, 62.7)	13.5 (7.7, 20.9)	1.9 (0.2, 8.3)

Y-90 + Chemo: median 9.1 M (95% CI: 7.8, 9.7)
Chemo: median 7.2 M (95% CI: 5.7, 7.6)
HR: 0.59 (0.46, 0.77); p<0.0001

Mulcahy et al., ESMO 2021; Mulcahy et al., J Clin Oncol 2021

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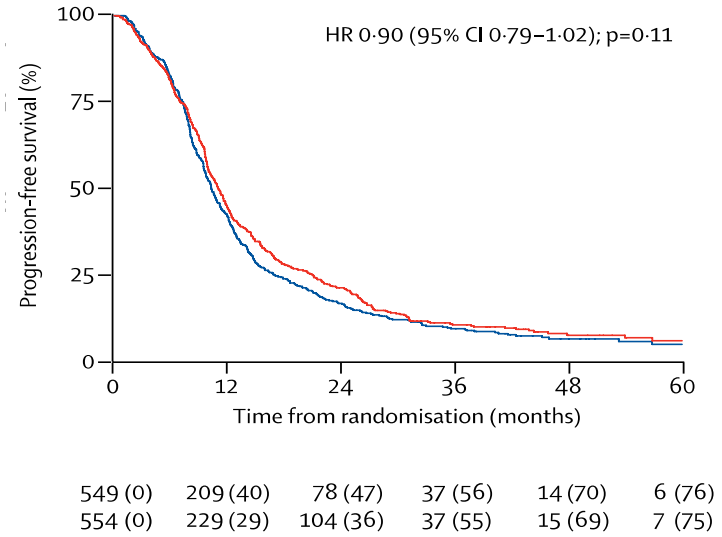
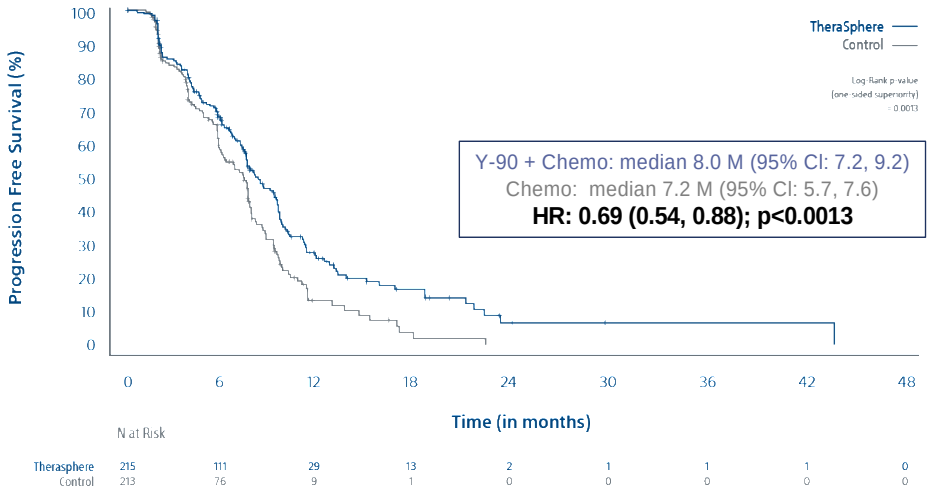


1st line, upfront TARE

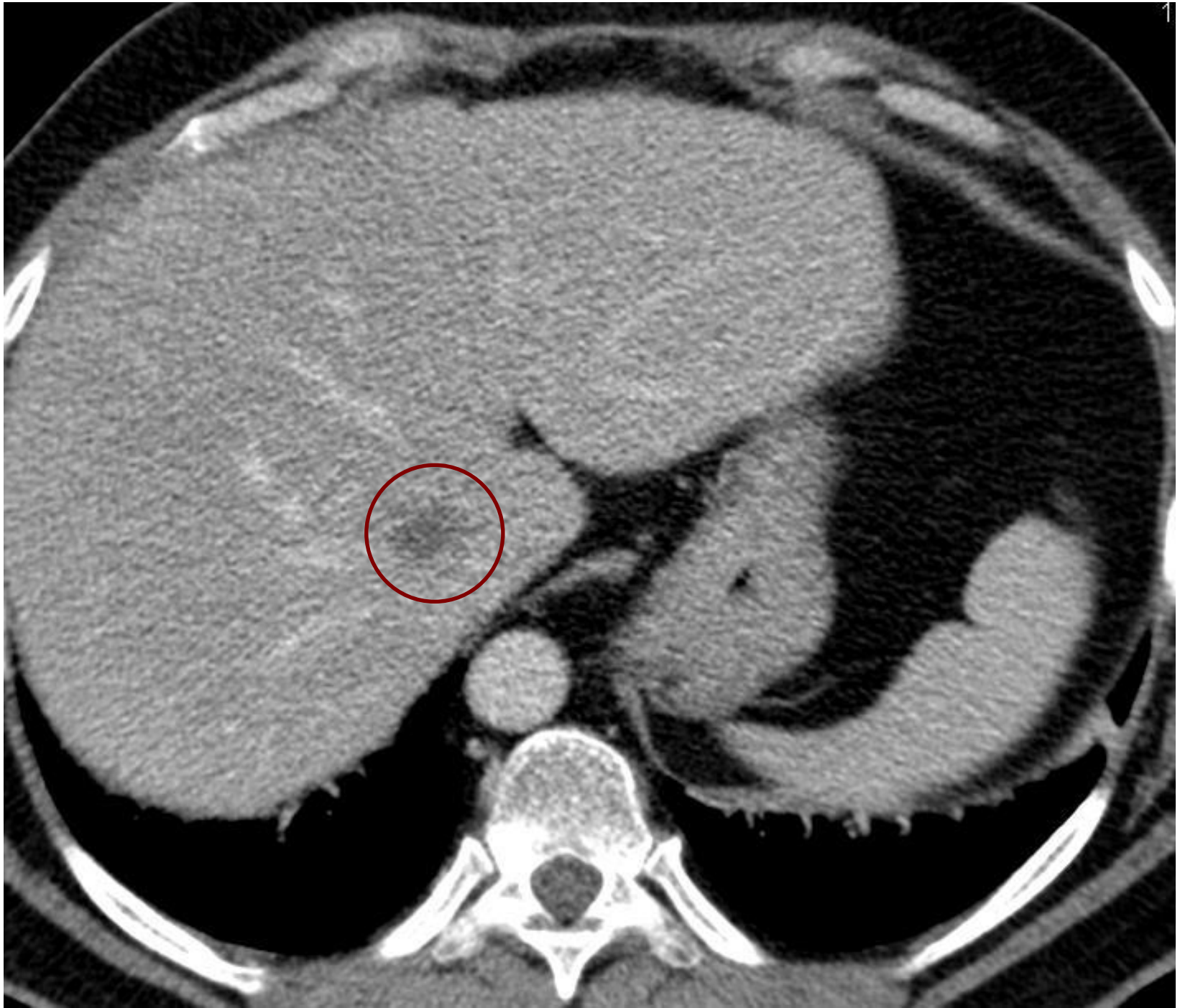
Radioembolization with Chemotherapy for Colorectal Liver Metastases: a randomized, open-label, international, multicenter, phase 3 trial

EPOCH study



2nd line, oligomets.

Wasan et al., Lancet Oncol 2017; Mulcahy et al., J Clin Oncol 2021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Resection: Long-term survival proven

Table 1 Hepatic metastasectomy: Large retrospective studies

Ref.	Patients, *n*	Median overall survival (mo)	5-yr survival	10-yr survival	20-yr survival
Rees *et al*[19], 2008	929		36%	23%	
Choti *et al*[17], 2002	226	46	40%	26%	
Fong *et al*[22], 1999	1001	42	37%	22%	
Nordlinger *et al*[18], 1996	1568		28%		
Scheele *et al*[20], 1995	434	40	33%	20%	17%

Table 3 Retrospective studies including ⩾ 100 patients with resectable lung metastases from colorectal cancer

Ref.	Year	*n*	median survival (mo)	5-yr survival rate (%)
Borasio *et al*[66]	2011	137	36.2	55
Hwang *et al*[67]	2010	125	37	48
Riquet *et al*[68]	2010	127	45	41
Watanabe *et al*[69]	2009	113	NA	68
Welter *et al*[70]	2007	169	47.2	39
Yedibela *et al*[71]	2006	153	43	37
Inoue *et al*[72]	2004	128	49	45
Kanemitsu *et al*[73]	2004	313	38	38
Pfannschmidt *et al*[74]	2003	167	40	32
Saito *et al*[75]	2002	165	NA	40
Zink *et al*[76]	2001	110	41	32

Vatandoust et al., World J Gastroenterol 2017

Oligometastases and SBRT

Study (Year), Type	No. of Patients	Lesions	Dose/Fraction, Gy	BED	Size, mm	Median Follow-up (Months)	Local Control at 1 Year (%)	Local Control at 2 Years (%)	Overall Survival at 1 Year (%)	Overall Survival at 2 Years (%)	Median Progression-Free Survival (Months)	Toxicity ≥ CTCAE Grade 3 (%)
Van der Pool et al (2010), phase I/II[49]	20	31	37.5–45/3 #	–	7–60 (median, 23)	26	100	74	100	83	11	15 (2 hepatic events)
Chang et al (2011), phase I[36]	65	102	22–60/1–6 #	40.5-180 Gy	30 mL	14.4	67 84 (≥ 42 Gy)	55 66 (≥ 42 Gy)	72	38	–	6 (2 hepatic, 2 gastrointestinal events)
Kress et al (2012), retrospective[48]	11	14	16–42/2–5 #	28-110.8 Gy	–	21	72	–	–	25.7	16.1	9
Doi et al (2017), retrospective[32,72]	24	39	45–72 in 4–33 #	71.7-115.5 Gy	≤ 30 30–50 > 50	16	67.2	35.9	81.3	67.1	–	8 (authors describe alternate causes of toxicity)
Joo et al (2017), retrospective[71]	70	103	45–60 in 3–4 #	60-180 Gy	< 30 ≥ 30	34.2	93	73		75	–	0
McPartlin et al (2017), phase I and II[50]	60	105	22.7–62.1 in 6 # over 2 weeks	—	6-21	28.1	49.8	32 (26 at 4 years)	63	26 (9 at 4 years)	16.0	1.7

Abbreviations: BED, biologically effective dose; CTCAE, Common Terminology Criteria for Adverse Events.

Studies including stereotactic radiotherapy cases for liver metastases from primary cancers other than colorectal cancer are not listed in this table.

Gill et al., J Clin Oncol Suppl. (ASCO ED Book) 2018

Oligometastases and RFA

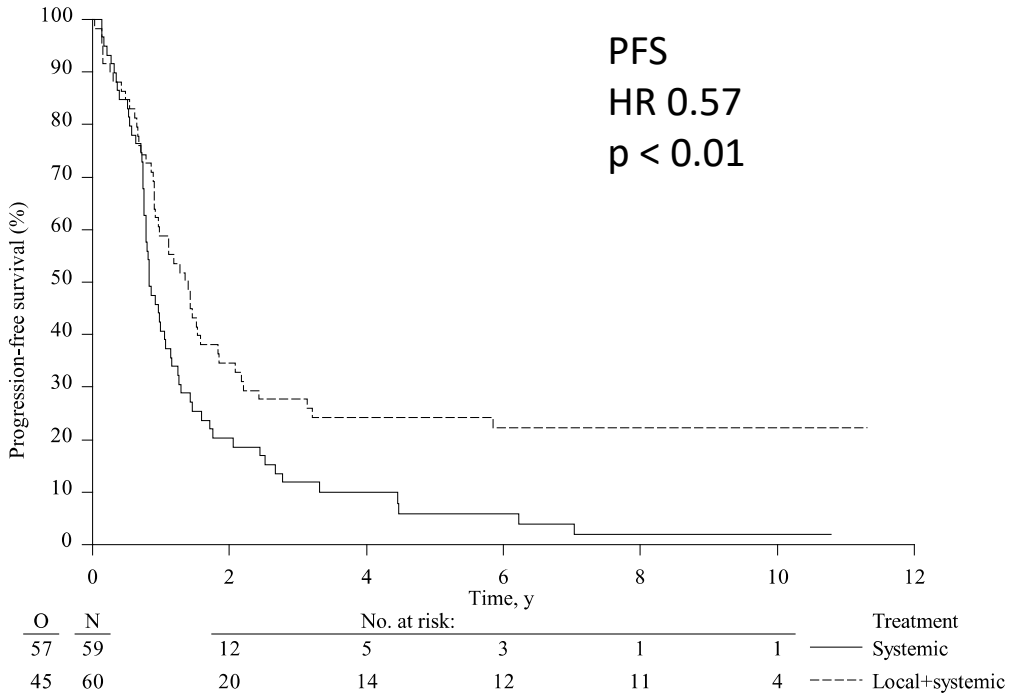
Study (Year)	No. of Patients	Approach	Median/Range No. of Tumors	Mean/Median Diameter, cm	Extrahepatic Disease, %	5-Year Survival, %	Comment
Ruers et al (2017)[30]	119	Percutaneous laparoscopic	4 (1–9)	< 4 cm (NR)	0	43.1	8-year survival: 39.5%; RCT*
Imai et al (2017)[33]	31	Hepatect (Paviour) + RFA	5 (2–25; total) 2 (1–4; RFA)	29 (7–90; total) 1.3 (0.4–3.0; RFA)	0	57	
Agcaoglu et al (2013)[32]	395	Laparoscopic	3 (1–11)	3.4	8	17	Extension of RFA during resection
Bale et al (2012)[25]	63	Percutaneous	2 (1–14)	2 (0.5–13)	0	27	
Gillams et al (2009)[26]	123	Percutaneous	2.1 (1–5)	2.9(0.9–5)	0	24	
Hamada et al (2012)[27]	101	Percutaneous	1.7	2.3 (0.5–9)	27	21	
Kim et al (2011)[34]	595	Open percutaneous	1.6	2.1 (0.5–6.2)	0	51 (< 3 cm)	
Machi et al (2006)[29]	100	Open percutaneous laparoscopic	3.5	3	20	31	
Van Tillborg et al (2011)[35]	38	Open percutaneous	2.4	2.4 (0.2–8.3)	–**	36	8-year survival: 24%
Hammill et al (2011)[28]	101	Laparoscopic	2.6	3-4		18–49†	
Solbiati et al (2012)[31]	99	Percutaneous	2	2.2 (0.8–4)	7	48	7-year survival: 25%

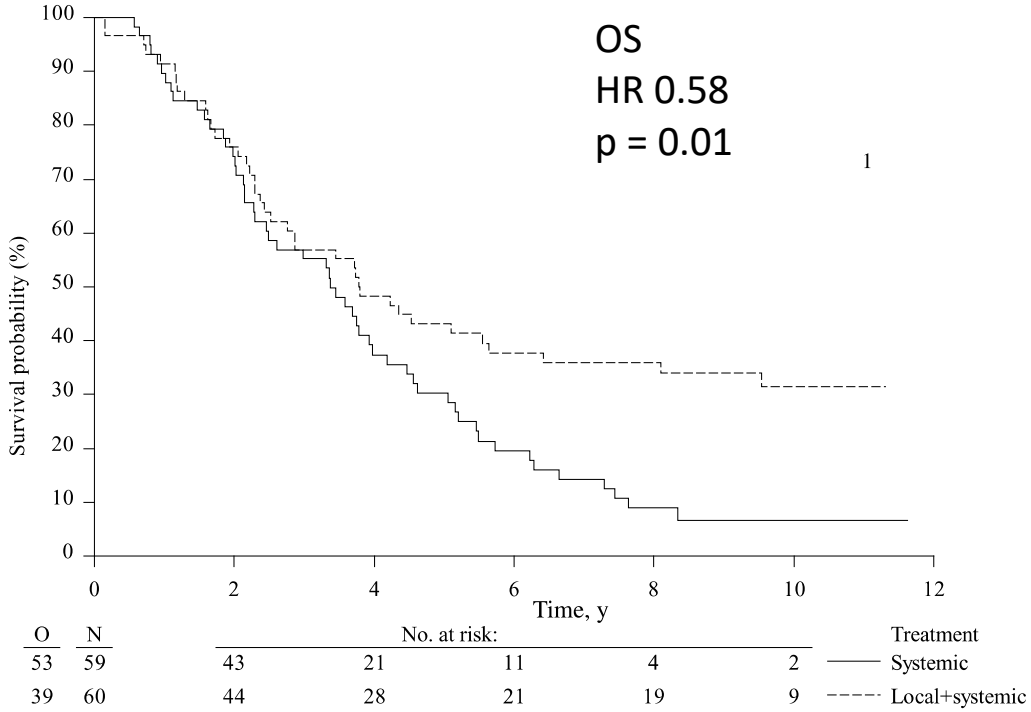
*The only prospective randomized controlled trial to date.

Gill et al., J Clin Oncol Suppl. (ASCO ED Book) 2018

Local Treatment of Unresectable Colorectal Liver Metastases: Results of a Randomized Phase II Trial

119 pts., “liver only” met disease; not suitable for resection; <10 lesions





CLOCC Trial, Ruers et al., JNCI 2017

Median follow-up 9.7 yrs

How can we eradicate metastases?

Local ablative treatments of metastases

- Surgery
- Local ablation techniques
- Intra-arterial therapies
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*Depends on: size, localisation, physical effects (cooling,....), and:....

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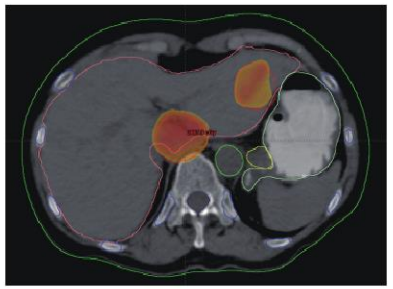
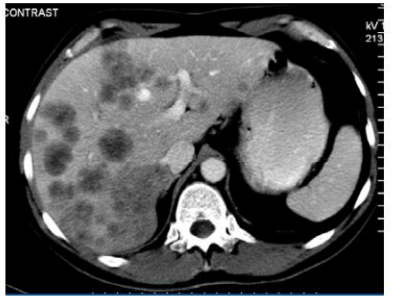
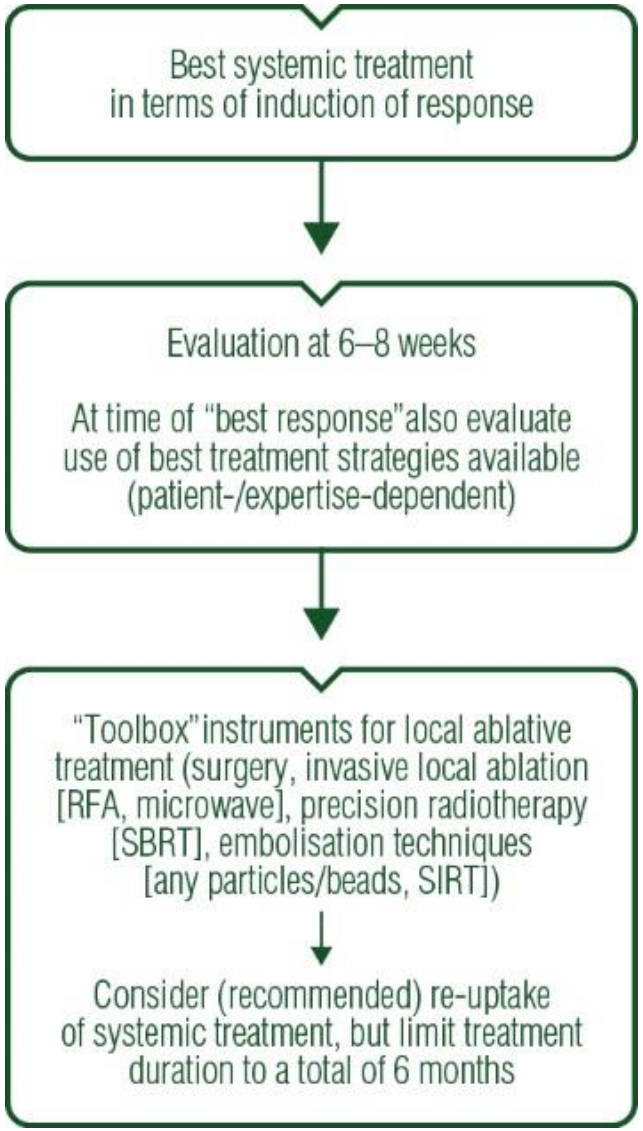
Which local treatment „the best“?





- Toolbox of ablative treatments
  - Local treatments
    - Thermal devices
      - Radiofrequency ablation or cryoablation
      - Microwave ablation
    - Non-thermal devices
      - Brachytherapy electroporation
      - External Body Radiotherapy with high-precision RT
  - Locoregional treatments
    - Embolic devices
      - Radioembolisation SIRT
      - Chemoembolisation TACE/Beads
    - Local chemotherapy

Van Cutsem et al., ESMO Consensus Guidelines mCRC., Ann Oncol 2016

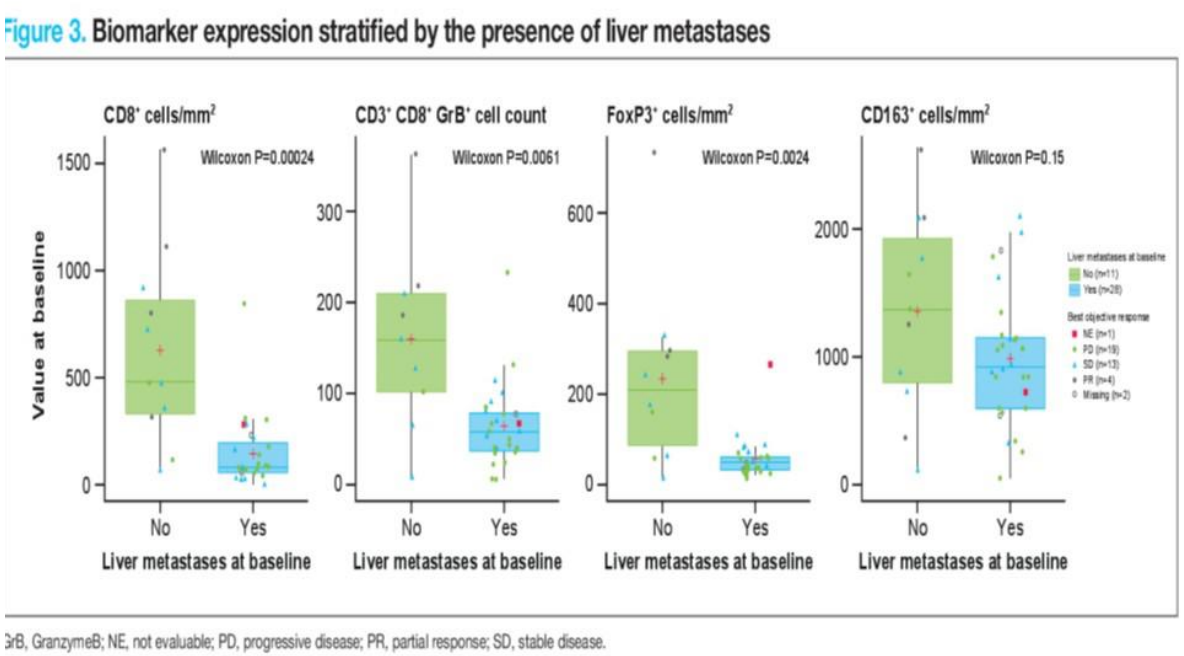


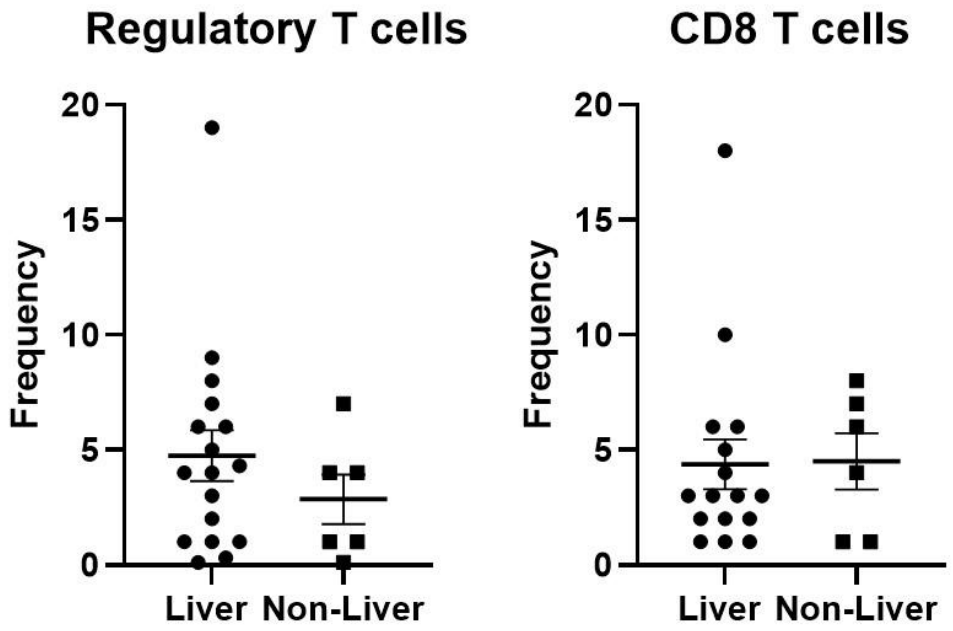
Local ablative treatments....should be selected…..according to

- localisation,
- treatment goal ('the more curative the more surgery'/higher importance of local/complete control),
- treatment-related morbidity,
- local expertise and availability,
- patient-related factors.

Van Cutsem E et al., ESMO Consensus 2016; Ann Oncol 2016

Biological characteristics of colorectal liver metastases





Fakih M et al., ASCO 2022; Kim R et al., Eur J Cancer 2022

Analysis of ICI + TKI efficacy in MSS CRC w/o liver metastasis.

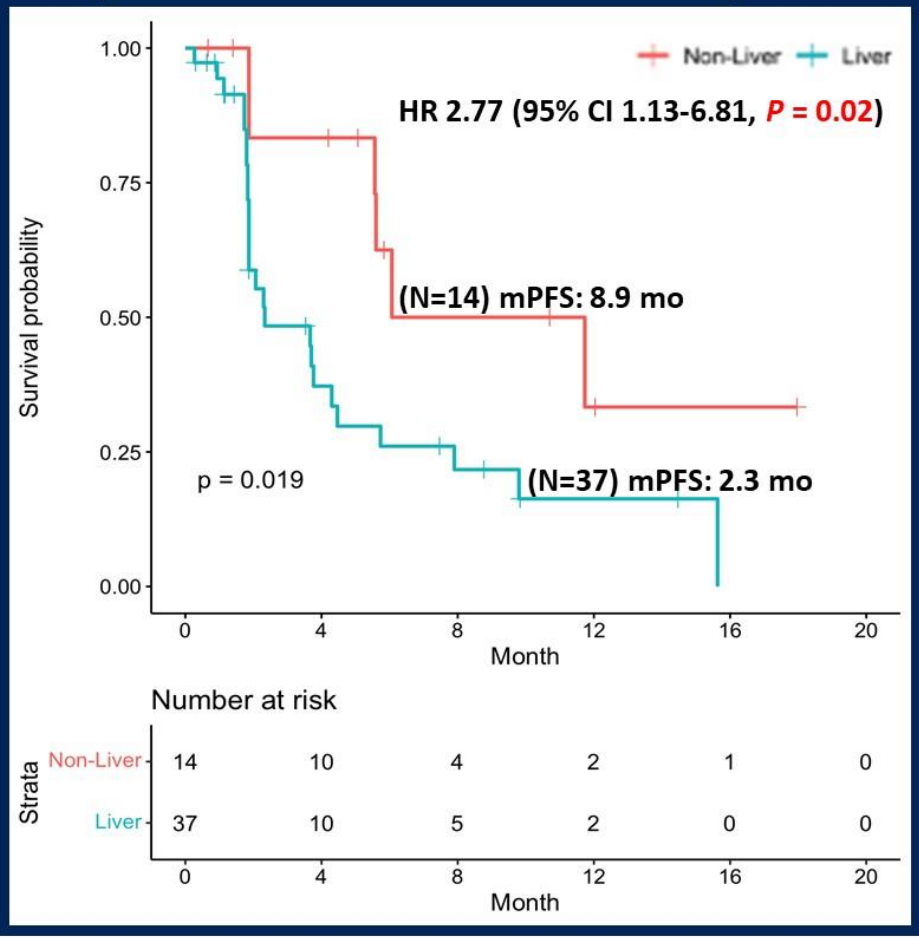
Phase, Drug	Size, MSI status	Metastatic sites (%)	Affects of liver mets to ICI efficacy	Autor, NCT
Phase Ib (REGONIVO), Nivolumab + Regorafenib	25pts (96% MSS, 4% MSI-H)	Liver mets (52%) Lung mets (64%)	ORR with liver vs lung mets: 8.3% vs 63.6%	Fukuoka et al. NCT03406871[1]
Phase Ib, Nivolumab + Regorafenib	52pts (100% MSS)	Liver mets (27%) Lung mets (17%) Both Liver&Lung mets (46%)	ORR with liver vs lung mets: 3.6 % vs 37.5 %	Kim et al. NCT03712943[2]
Phase II, Nivolumab + Regorafenib	70 pts (100% MSS)	Liver mets (67%)	ORR without vs with liver mets: 22% vs 0% DCR without vs with liver mets: 57% vs 30% PFS without vs with liver mets: 3.5 mo vs 1.8 mo OS without vs with liver mets: 12.0 mo vs 10.8 mo	Fakih et al. NCT04126733[3]
Phase I/II, Pembrolizumab + Regorafenib	73 pts (100% MSS)	Liver mets (78%)	PFS without liver mets vs overall cohort: 4.3 mo vs 2.0 mo Live-mets subgroup PFS N/A	Barzi et al. NCT03657641[4]
Phase II (BACCI), Atezo + Bev + Cap (arm 1) vs Bev + Cap (arm 2)	82 pts in arm 1 (84% MSS, 11% MSI-H, 5% Unknown)	Liver mets (84%) in arm 1	In arm 1, ORR without vs with liver mets (23% vs 6%, *P*=.0408) Benefit of atezolizumab for OS without vs with liver mets (HR, 0.33; 0.11-1.02 vs 1.14; 0.72-1.81, *P*= .04)	Mettu et al. NCT02873195[5]

Abbreviation: Atezo, Atezolizumab; Bev, Bevacizumab; Cap, Capecitabine; CRC, Colorectal cancer; DCR, Disease control rate; Mets, Metastasis; Mo, Months; MSI-H, Microsatellite instability-high; MSS, Microsatellite stable; N/A, Not available; ORR, Overall response rate; OS, Overall survival; PFS, Progression-free survival; Pts, Patients.

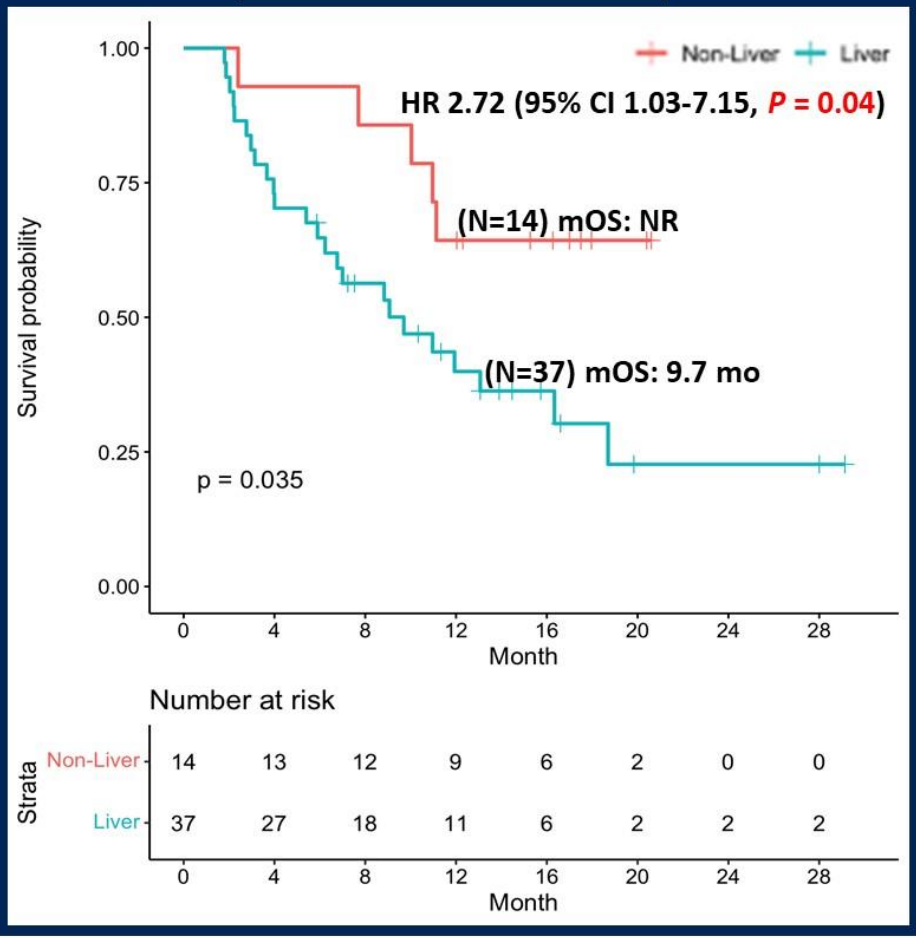
Kim R et al., ASCO 2022; Educational Session

PFS and OS by Presence and Lack of Liver Metastases in MSS MCRC

Progression Free Survival

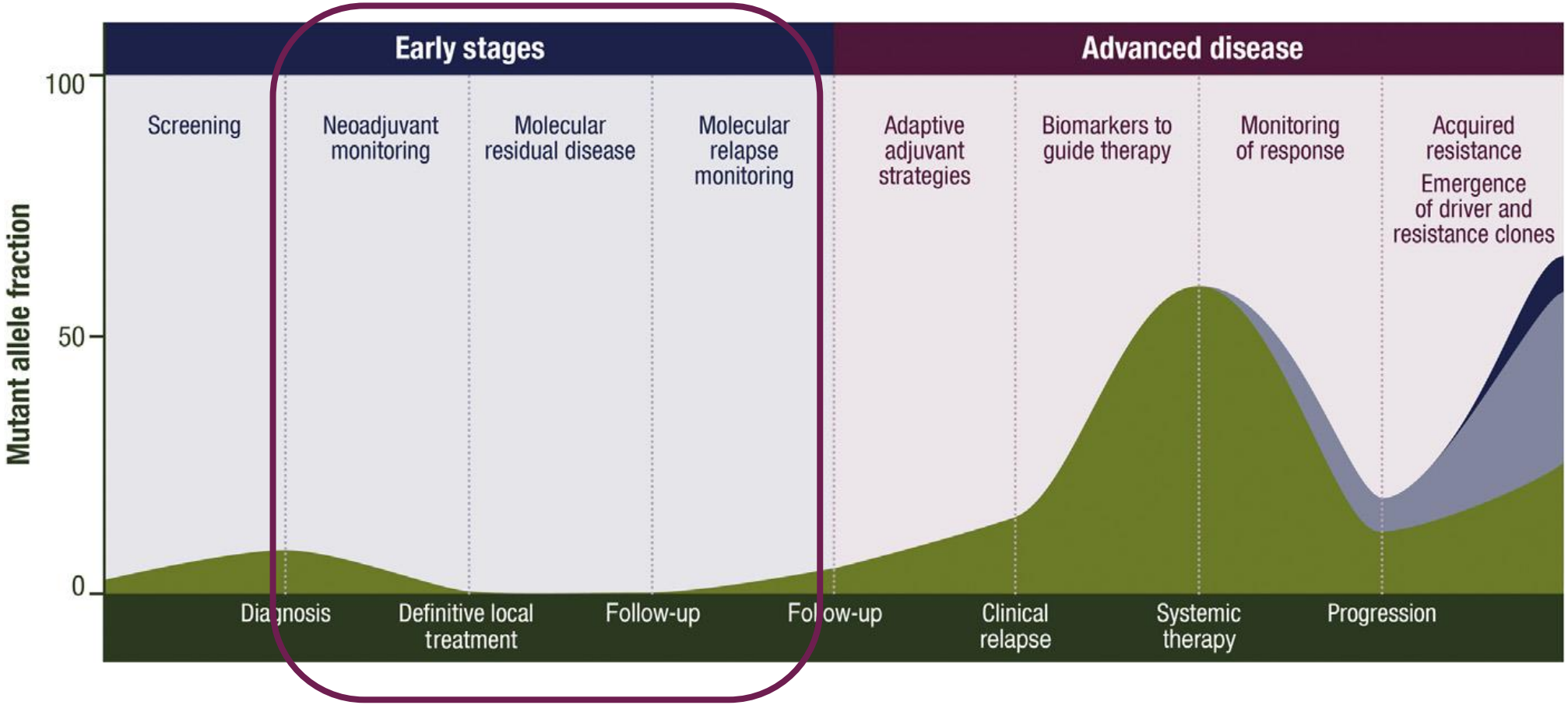


Overall Survival



Kim R et al., ASCO 2023

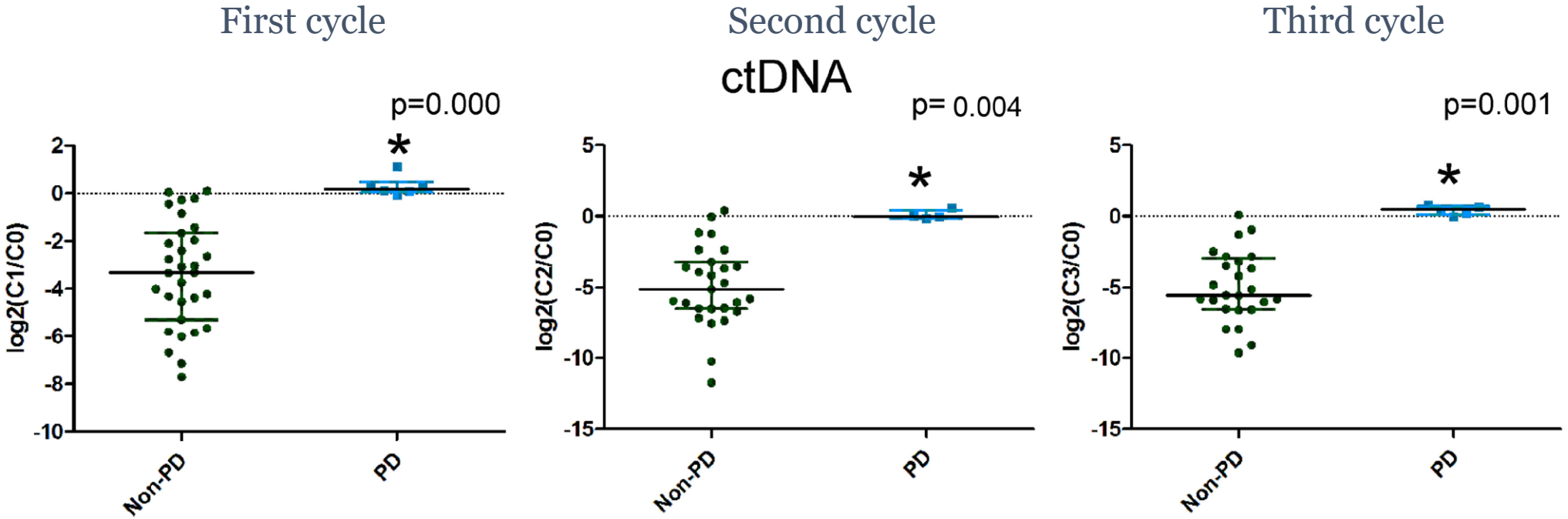
Clinical applications of ctDNA: Perspectives



ESMO recommendations on the use of circulating tumour DNA assays for patients with cancer: a report from the ESMO Precision Medicine Working Group

Pascual D et al., Ann Oncol 2022

ctDNA dynamics indicating response to systemic tx.



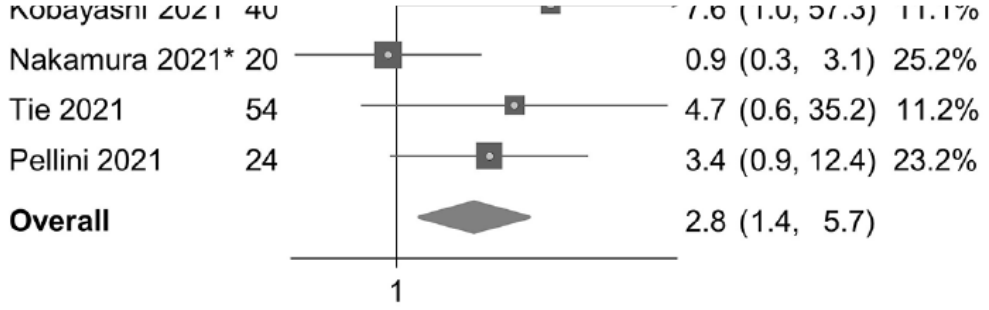
Variable	AUC	*p* value	Cutoff value	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	PPV (%) (95% CI)	NPV (%) (95% CI)	Accuracy (%) (95% CI)
ctDNA log2 (C1/C0)	0.978	0.000	−0.126	100.0 (54.1–100.0)	93.5 (78.6–99.2)	75.0 (34.9–96.8)	100.0 (88.1–100.0)	94.6 (81.8–99.3)
ctDNA log2 (C2/C0)	0.954	0.004	−0.655	100.0 (39.8–100.0)	92.6 (75.7–99.1)	66.7 (22.3–95.7)	100.0 (86.3–100.0)	93.5 (78.6–99.2)
ctDNA log2 (C3/C0)	0.992	0.001	−0.471	100.0 (47.8–100.0)	96.0 (79.7–99.9)	83.3 (35.9–99.6)	100.0 (85.8–100.0)	96.7 (82.8–99.9)

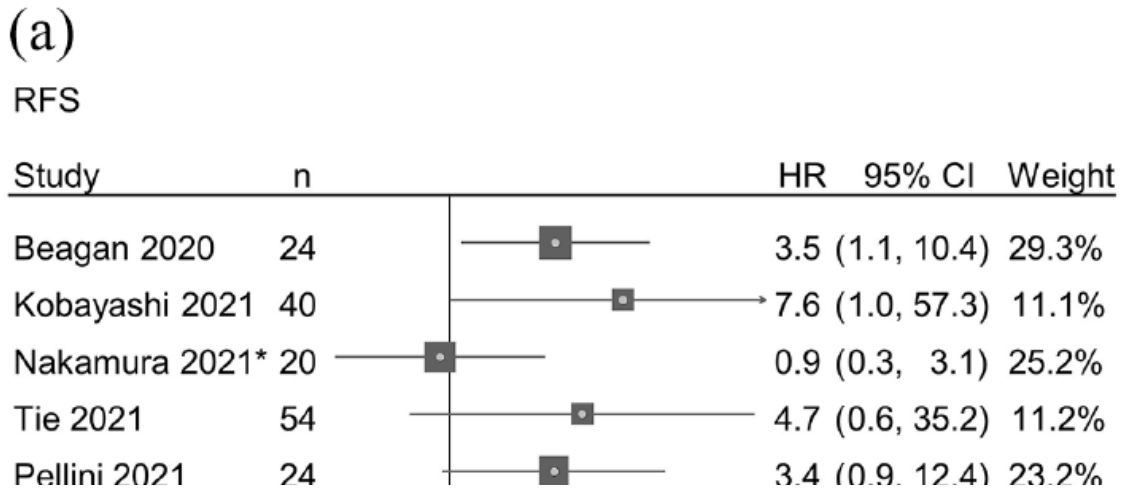
Jia et al., Front Genet 2021

Circulating DNA in patients undergoing loco-regional treatment of colorectal cancer metastases: a systematic review and meta-analysis

Louise B. Callesen, Tana Takacova, Julian Hamfjord, Florian Würschmidt, Karl J. Oldhafer, Roland Brüning, Dirk Arnold and Karen-Lise G. Spindler

in pre-ablation samples





Callesen et al., Ther Adv Med Oncol 2022

ASKLEPIOS TUMORZENTRUM HAMBURG

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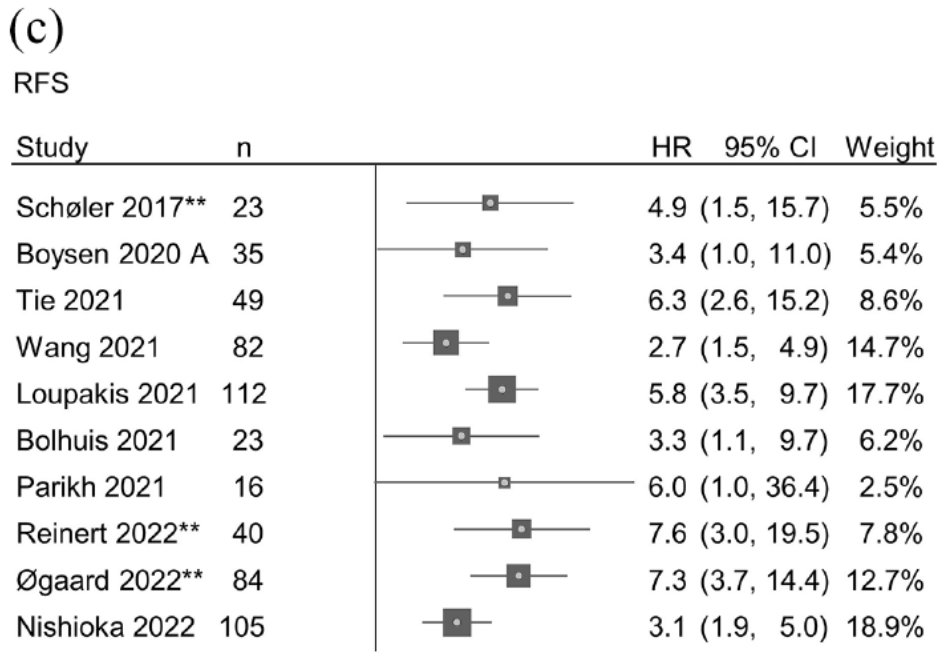

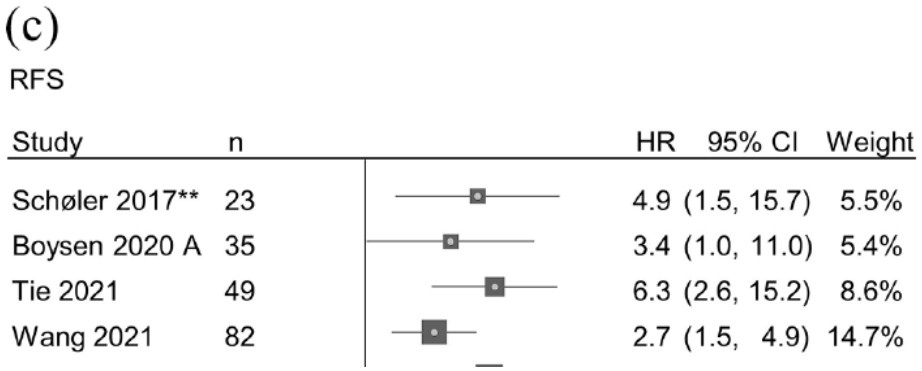

Callesen et al., Ther Adv Med Oncol 2022

ASKLEPIOS TUMORZENTRUM HAMBURG

Zusammenfassung

- Lokal ablative Therapie ergänzen das Spektrum – in der „last line“, der Ergänzung der operativen Resektion, und eventuell auch als Konsolidierung in früheren Therapielinien
- Patientinnenselektion: klinische Faktoren insuffizient – biologische „on the way“
- Verfahrensauswahl: nach Lokalisation und Expertise
- Neue Felder: Lebermetastasierungskontrolle, und Therapiesteuerung über ctDNA

Dirk Arnold

Asklepios Tumorzentrum Hamburg

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