Adjuvante Therapie des HCC
Endlich „ready for prime time“?

13 Okt 2023
Gemeinsame Jahrestagung der DGHO, OeGHO, SGMO und SGH

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CCCIT Center for Clinical Cancer and Immunology Trials
LIMCR Laboratory for Immunological and Molecular Cancer Research

UNIVERSITÄTSKLINIK FÜR INNERE MEDIZIN III
MIT HÄMATOLOGIE, INTERNISTISCHER ONKOLOGIE, HÄMOSTASEOLOGIE, INFEKTIOLOGIE, RHEUMATOLOGIE UND ONKOLOGISCHES ZENTRUM

Offenlegung Interessenskonflikte

Employment: University Hospital Salzburg, Austria.

Leadership: Head of Colorectal Cancer Branch, Austrian Breast and Colorectal Cancer Study Group (ABCSG)

Stock and Other Ownership Interests: none

Honoraria: Amgen, Astellas, BMS, Daiichi-Sankyo, Lilly, Merck, MSD, Novocure, Pierre Fabre, Servier

Consulting or Advisory Role: Amgen, Astellas, BMS, GSK, Lilly, Merck, MSD, Novocure, Pharmamar, Pierre Fabre, Roche

Speakers' Bureau: none

Research Funding: Novocure, Roche, Servier

Patents, Royalties, Other Intellectual Property: none

Expert Testimony: none

Travel, Accommodations, Expenses: AstraZeneca, Merck, Pierre Fabre, Roche, Servier

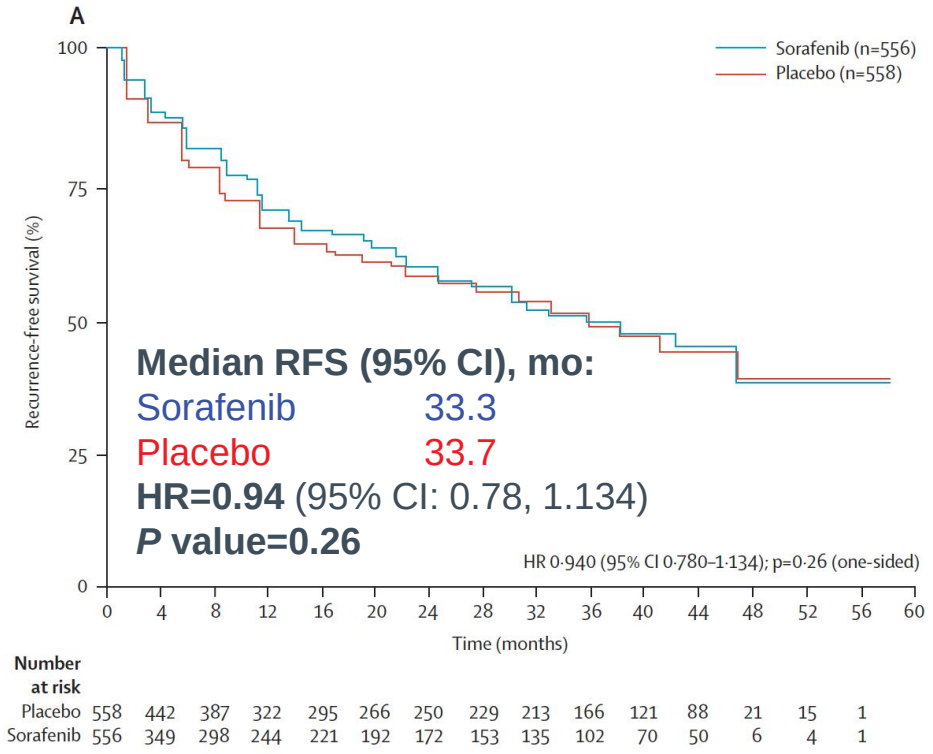
Other Relationship: none

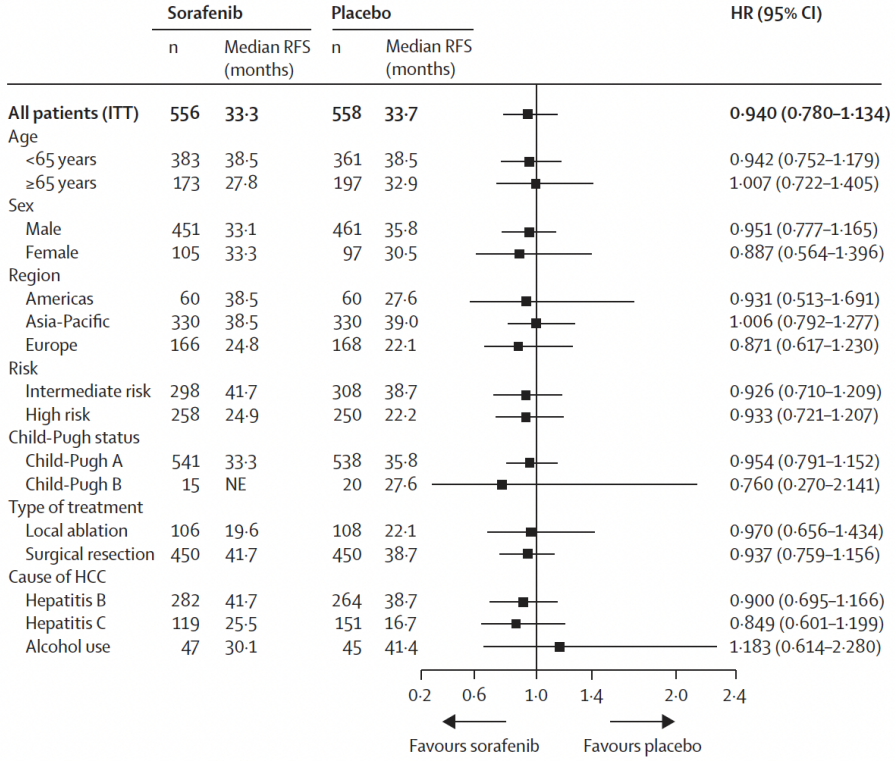
*Oct 2020 to Oct 2023

Background

STORM – Recurrence Free Survival

Phase 3 RCT
N=1,114
No benefit for adjuvant Sorafenib





Briux J et al. Lancet Oncol. 2015 Oct;16(13):1344-54.

Adjuvant Immunotherapy Trials

Adjuvant Phase 3 Trials

- CheckMate 9DX
- EMERALD-2
- KEYNOTE 937

} Data expected for 2024

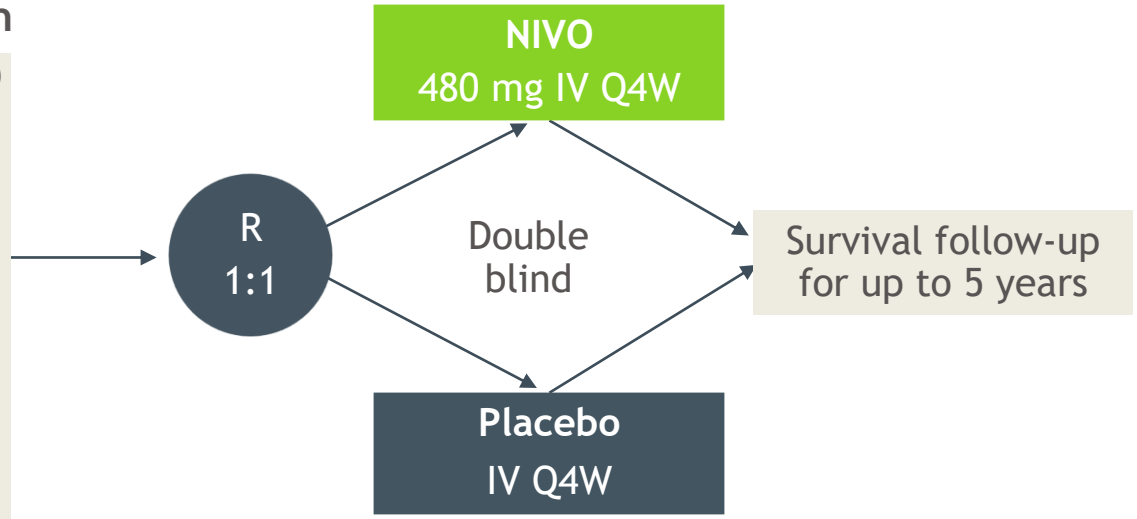
- **IMbrave 050**

CheckMate 9DX – Study Design

Hepatectomy or local ablation

Key eligibility criteria N = 530

- Patients aged ≥ 18 years with a first diagnosis of HCC (any etiology)
- Curative resection or complete ablation
- High risk of recurrence
- Child-Pugh score of 5 or 6
- ECOG PS ≤ 1
- No macrovascular invasion or metastatic disease



Treat until recurrence (by BICR), unacceptable toxicity, consent withdrawal, or for maximum 1-year total duration

Primary endpoint:

- RFS

Selected secondary and exploratory endpoints:

- OS
- Time to recurrence
- Safety and tolerability
- Biomarkers
- Pharmacokinetics
- Cancer-related QOL

Start date: April 2018
Estimated study completion date: December 2025
Estimated primary completion date: December 2023
Status: Active, not recruiting
Study sponsor: Bristol Myers Squibb

1. ClinicalTrial.gov NCT03383458. Accessed August 2022. 2. Exposito MJJ et al. Poster presentation at ESMO; October 19–23, 2018; Munich, Germany. Poster 783TiP.

EMERALD-2 – Study Design

In patients with newly diagnosed, confirmed HCC with a high-risk of recurrence after successful completion of hepatic resection or ablation
Estimated Enrollment = 888

Arm A	Arm B	Arm C
Durvalumab 1120 mg IV (Q3W) + Bevacizumab 15 mg/kg IV (Q3W)	Durvalumab 1120 mg IV (Q3W) + Placebo IV (Q3W)	Placebo IV (Q3W) + Placebo IV (Q3W)

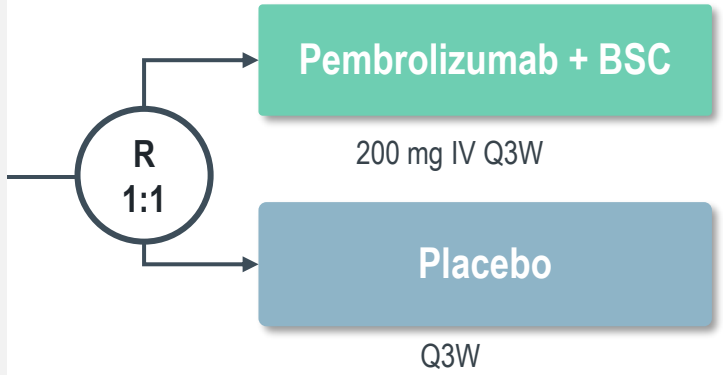
Primary Endpoint	Secondary Endpoints
• RFS for Arm A vs Arm C[a]	• RFS Arm B vs Arm C[a] • OS for Arm A vs Arm C and Arm B vs Arm C • RFS2/PFS2, RFS24 and RFS36 for Arm A vs Arm C and Arm B vs Arm C • TTR for Arm A vs Arm C and Arm B vs Arm C

Study NCT03847428. ClinicalTrials.gov website.

KEYNOTE 937 – Study Design

Patients (N≈950)

- HCC diagnosis by radiological criteria and/or pathological confirmation
- Eligibility scan confirming complete radiological response ≥4 weeks following complete resection or local ablation
- No radiologic evidence of disease prior to enrollment
- ECOG PS 0–1
- Controlled HBV
- Child-Pugh Class A[a]
- AFP <400 ng/mL within 28 days prior to Cycle 1, Day 1



Stratification: Region, prior local therapy, risk of recurrence, AFP level

Continue until: Up to 17 cycles, disease recurrence,[b] intolerable toxicity, investigator/patient decision to withdraw

Primary End Points

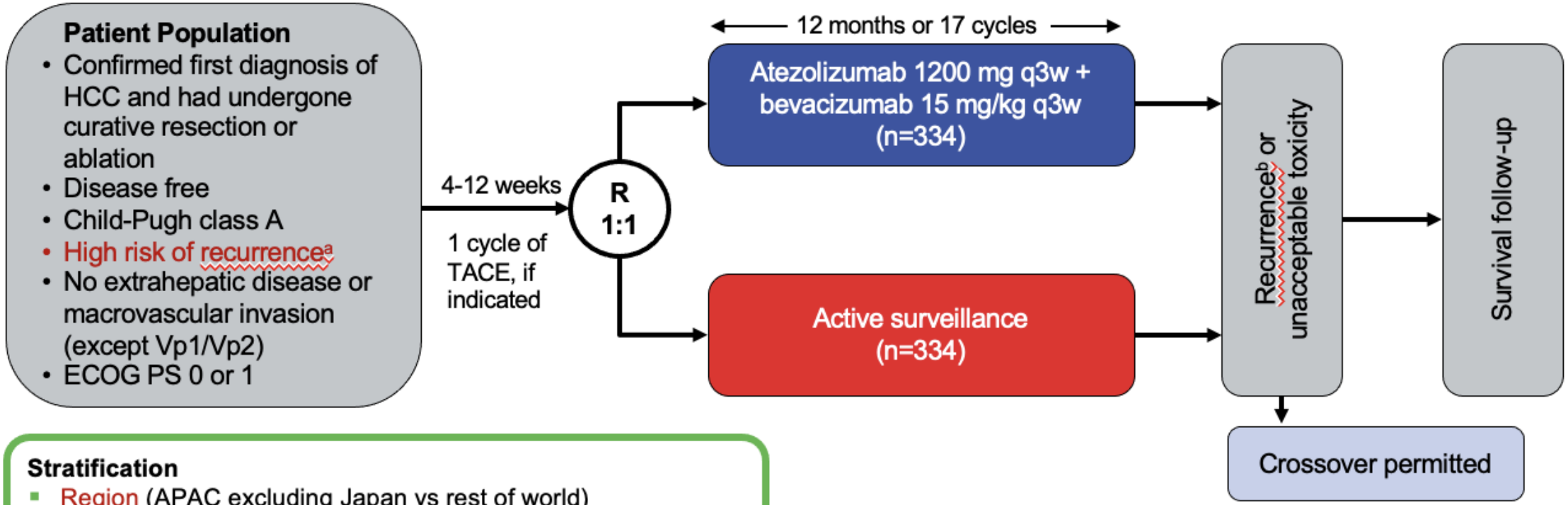
RFS by BICR, OS

Key Secondary End Points

Safety and tolerability, HRQoL

1. clinicaltrials.gov/ct2/show/NCT03867084. Accessed March 1, 2023. **2**. Goyal L et al. Presented at BASL 2021.

Imbrave050 – Study Design



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Imbrave050 – High Risk Features

Curative treatment	Criteria for high risk of HCC recurrence
Resection	▪ ≤3 tumors, with **largest tumor >5 cm** regardless of vascular invasion,[a] or poor tumor differentiation (Grade 3 or 4) ▪ **≥4 tumors**, with largest tumor ≤5 cm regardless of vascular invasion,[a] or poor tumor differentiation (Grade 3 or 4) ▪ ≤3 tumors, with largest tumor ≤5 cm with **vascular invasion**,[a] and/or **poor tumor differentiation** (Grade 3 or 4)
Ablation[b]	▪ 1 tumor >2 cm but ≤5 cm ▪ Multiple tumors (≤4 tumors), all ≤5 cm

Chow P et al. AACR 2023

Imbrave050 – Statistics

Study endpoints

Primary endpoint

- Recurrence-free survival (RFS) assessed by independent review facility (IRF)

Secondary endpoints

- RFS assessed by investigator (INV)
- Time to recurrence assessed per IRF
- Overall survival (OS)

Other endpoints

- Safety

Overall Type I error 0.05 (2-sided) hierarchical testing

IRF-assessed RFS
(interim analysis)

Number of events = 243
Stopping boundary (*P* value) = 0.0195
Target HR = 0.73

If RFS is positive:

OS
(1st interim analysis)
Information fraction = 14.7%
Expected[a] information fraction = 33.5%

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IMbrave050 – Baseline Characteristics

Characteristic	Atezo + bev (n=334)	Active surveillance (n=334)
Median age (range), years	60 (19-89)	59 (23-85)
Male sex, n (%)	277 (82.9)	278 (83.2)
Ethnicity, n (%)		
Asian	276 (82.6)	269 (80.5)
White	35 (10.5)	41 (12.3)
Other	23 (6.9)	24 (7.2)
Geographic region, n (%)		
Asia Pacific excluding Japan | rest of world	237 (71.0) | 97 (29.0)	238 (71.3) | 96 (28.7)
ECOG PS score, n (%)		
0 | 1	258 (77.2) | 76 (22.8)	269 (80.5) | 65 (19.5)
PD-L1 status, n (%)[a,b]		
≥1% | <1%	154 (54.0) | 131 (46.0)	140 (50.2) | 139 (49.8)
Etiology, n (%)		
Hepatitis B	209 (62.6)	207 (62.0)
Hepatitis C	34 (10.2)	38 (11.4)
Non viral | unknown	45 (13.5) | 46 (13.8)	38 (11.4) | 51 (15.3)
BCLC stage at diagnosis, n (%)		
0	2 (0.6)	3 (0.9)
A	287 (85.9)	277 (82.9)
B	25 (7.5)	32 (9.6)
C	20 (6.0)	22 (6.6)

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IMbrave050 – Baseline Characteristics

Characteristic	Atezo + bev (n=334)	Active surveillance (n=334)
Resection, n (%)	293 (87.7)	292 (87.4)
Longest diameter of the largest tumor at diagnosis, median (range), cm[a]	5.3 (1.0-18.0)	5.9 (1.1-25.0)
Tumors, n (%)		
1	266 (90.8)	260 (89.0)
2	20 (6.8)	29 (9.9)
3	4 (1.4)	2 (0.7)
4+	3 (1.0)	1 (0.3)
Adjuvant TACE following resection, n (%)	32 (10.9)	34 (11.6)
Any tumors >5 cm, n (%)	152 (51.9)	175 (59.9)
Microvascular invasion present, n (%)	178 (60.8)	176 (60.3)
Minor macrovascular invasion (Vp1/Vp2) present, n (%)	22 (7.5)	17 (5.8)
Poor tumor differentiation (Grade 3 or 4), n (%)	124 (42.3)	121 (41.4)
Ablation, n (%)	41 (12.3)	42 (12.6)
Longest diameter of the largest tumor at diagnosis, median (range), cm	2.5 (1.2-4.6)	2.6 (1.5-4.6)
Tumors, n (%)		
1	29 (70.7)	31 (73.8)
2	11 (26.8)	8 (19.0)
3	1 (2.4)	3 (7.1)

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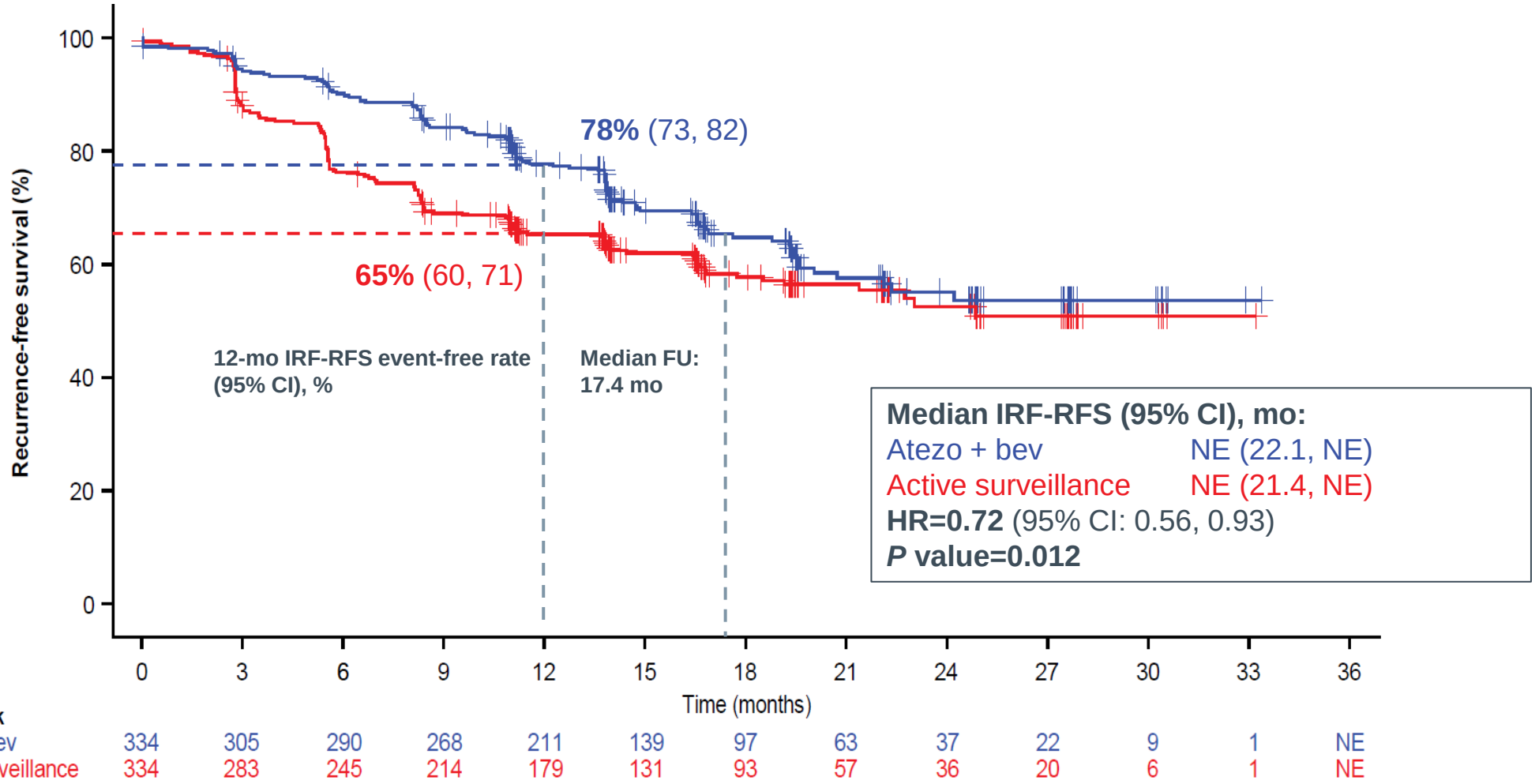
IMbrave050 – Recurrence Free Survival

IRF



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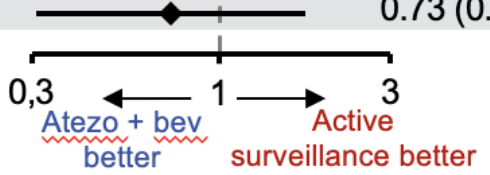
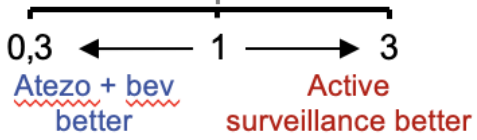
IMbrave050 – RFS by subgroups

Baseline risk factors	No. of patients	Unstratified HR (95% CI)
All patients	668	0.74 (0.57, 0.95)
<65 years old	427	0.80 (0.58, 1.08)
≥65 years old	241	0.64 (0.41, 1.00)
Male	555	0.74 (0.56, 0.98)
Female	113	0.73 (0.38, 1.40)
Asian	545	0.75 (0.56, 0.99)
White	78	0.59 (0.28, 1.25)
Other race	45	0.91 (0.36, 2.29)
ECOG PS 0	527	0.65 (0.48, 0.87)
ECOG PS 1	141	1.13 (0.67, 1.91)
PD-L1 ≥1%	294	0.82 (0.55, 1.20)
PD-L1 <1%	270	0.62 (0.43, 0.91)
Unknown PD-L1	104	0.82 (0.39, 1.71)
1 high-risk feature[a]	311	0.74 (0.48, 1.14)
≥2 high-risk features[a]	274	0.77 (0.55, 1.08)
BCLC 0/A	569	0.78 (0.59, 1.04)
BCLC B	57	0.44 (0.18, 1.08)
BCLC C	42	0.73 (0.31, 1.73)

Baseline risk factors	No. of patients	Unstratified HR (95% CI)
Hepatitis B etiology	416	0.87 (0.63, 1.20)
Hepatitis C etiology	72	0.65 (0.30, 1.40)
Non-viral etiology	83	0.70 (0.34, 1.42)
Unknown etiology	97	0.45 (0.23, 0.89)
Resection	585	0.75 (0.58, 0.98)
Ablation	83	0.61 (0.26, 1.41)
In patients who underwent resection		
1 tumor	526	0.77 (0.58, 1.03)
>1 tumors	59	0.60 (0.28, 1.27)
Tumor size >5 cm	327	0.66 (0.48, 0.91)
Tumor size ≤5 cm	258	1.06 (0.65, 1.74)
mVI present	354	0.79 (0.56, 1.10)
mVI absent	231	0.69 (0.45, 1.06)
Poor tumor differentiation	245	0.76 (0.51, 1.12)
No poor tumor differentiation	340	0.74 (0.52, 1.07)
Received TACE	66	1.21 (0.57, 2.59)
Did not receive TACE	519	0.71 (0.53, 0.94)





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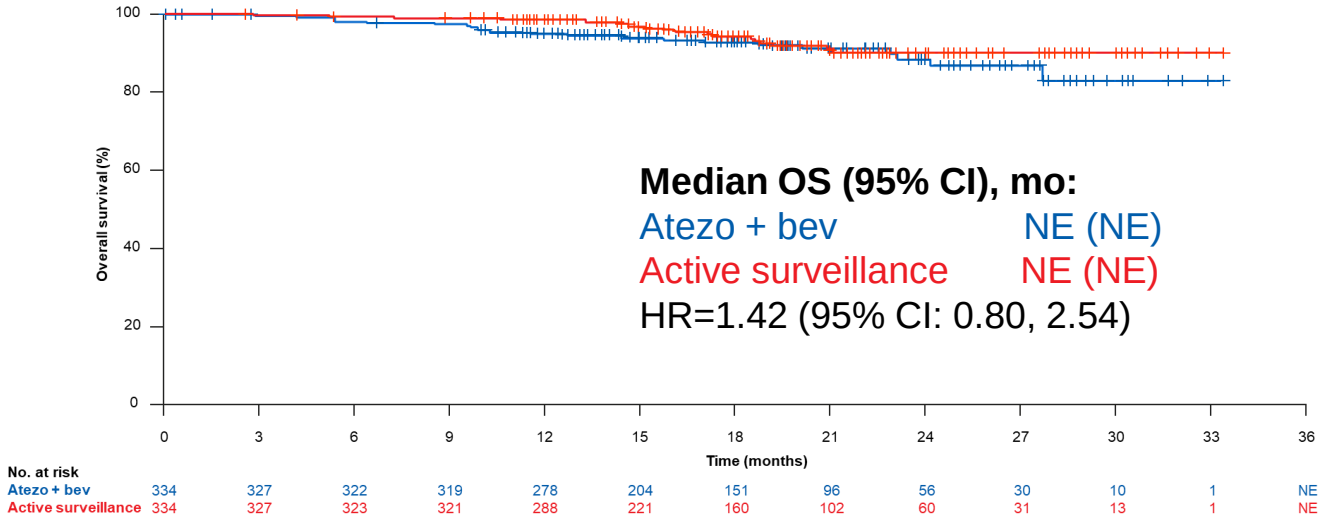
IMbrave050 – Overall Survival

- **OS is highly immature, with a 7% event-patient ratio (n=47).** There were:
  - 7 more deaths in the atezo + bev arm (27 vs 20)
  - Similar number of deaths due to HCC recurrence
  - 3 COVID-19-related deaths within 1 year of randomization, all in the atezo + bev arm
- Patients in the active surveillance arm were allowed to cross over to receive atezo + bev either directly after IRF-confirmed recurrence or following a second resection or ablation

- Of the 133 patients with an RFS event during active surveillance, **81 (61%) crossed over to atezo + bev**



n (%)	Atezo + bev (n=334)	Active surveillance (n=334)
All deaths	27 (8.1)	20 (6.0)
Progressive disease	17 (63.0)	16 (80.0)
Adverse events	6 (22.2)	1 (5.0)
Other	4 (14.8)	3 (15.0)

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IMbrave050 – Safety

WARNING
CROSS TRIAL COMPARISON

	Atezo + bev (n=332)	Active surveillance (n=330)	IMbrave150[1,2] (n=329)
Treatment duration, median, mo	Atezo: 11.1 Bev: 11.0	NA	Atezo: 7.4 Bev: 6.9
Patients with ≥1 AE, n (%)	326 (98.2)	205 (62.1)	323 (98.2)
Treatment-related AE	293 (88.3)	NA	276 (83.9)
Grade 3/4 AE, n (%)	136 (41.0)	44 (13.3)	186 (56.5)
Treatment-related Grade 3/4 AE	116 (34.9)	NA	117 (35.6)
Serious AE, n (%)	80 (24.1)	34 (10.3)	125 (38.0)
Treatment-related serious AE	44 (13.3)	NA	56 (17.0)
Grade 5 AE, n (%)	6 (1.8)	1 (0.3)	15 (4.6)
Treatment-related Grade 5 AE	2 (0.6)[a]	NA	6 (1.8)
AE leading to dose interruption of any study treatment, n (%)	155 (46.7)	NA	163 (49.5)
AE leading to withdrawal from any study treatment, n (%)	63 (19.0)	NA	51 (15.5)

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IMbrave050 – Safety

AE of any grade ≥10%

Event, n (%)	Atezo + bev (n=332)		Active surveillance (n=330)	
	Any grade	Grade 3 or 4	Any grade	Grade 3 or 4
Proteinuria	154 (46.4)	29 (8.7)	12 (3.6)	0
Hypertension	127 (38.3)	61 (18.4)	10 (3.0)	3 (0.9)
Platelet count decreased	66 (19.9)	15 (4.5)	22 (6.7)	4 (1.2)
Aspartate aminotransferase increased	52 (15.7)	3 (0.9)	18 (5.5)	2 (0.6)
Alanine aminotransferase increased	47 (14.2)	2 (0.6)	18 (5.5)	3 (0.9)
Hypothyroidism	47 (14.2)	0	1 (0.3)	0
Arthralgia	40 (12.0)	1 (0.3)	8 (2.4)	1 (0.3)
Pruritus	40 (12.0)	1 (0.3)	3 (0.9)	0
Rash	40 (12.0)	0	1 (0.3)	0
Blood bilirubin increased	34 (10.2)	1 (0.3)	23 (7.0)	1 (0.3)
Pyrexia	34 (10.2)	0	7 (2.1)	0

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IMbrave050 – Conclusions

- 1st positive trial demonstrating RFS improvement
- RFS benefit consistent across key clinical subgroups
- at prespecified interim analysis, OS was highly immature longer follow-up for OS is needed
- safety profile generally consistent with previous reports

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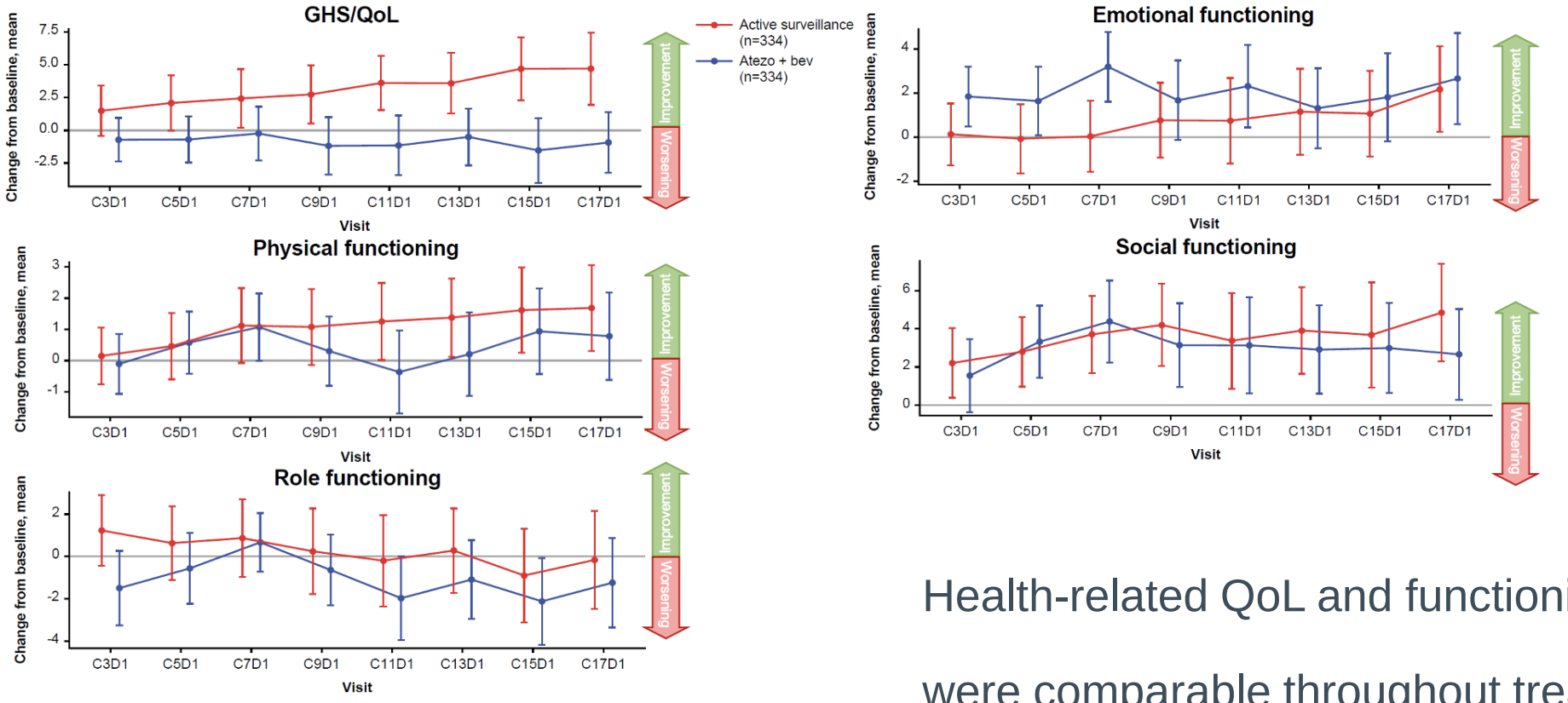
IMbrave050 – Patient Reported Outcome

Change from baseline in IL42–EORTC QLQ-C30 scales



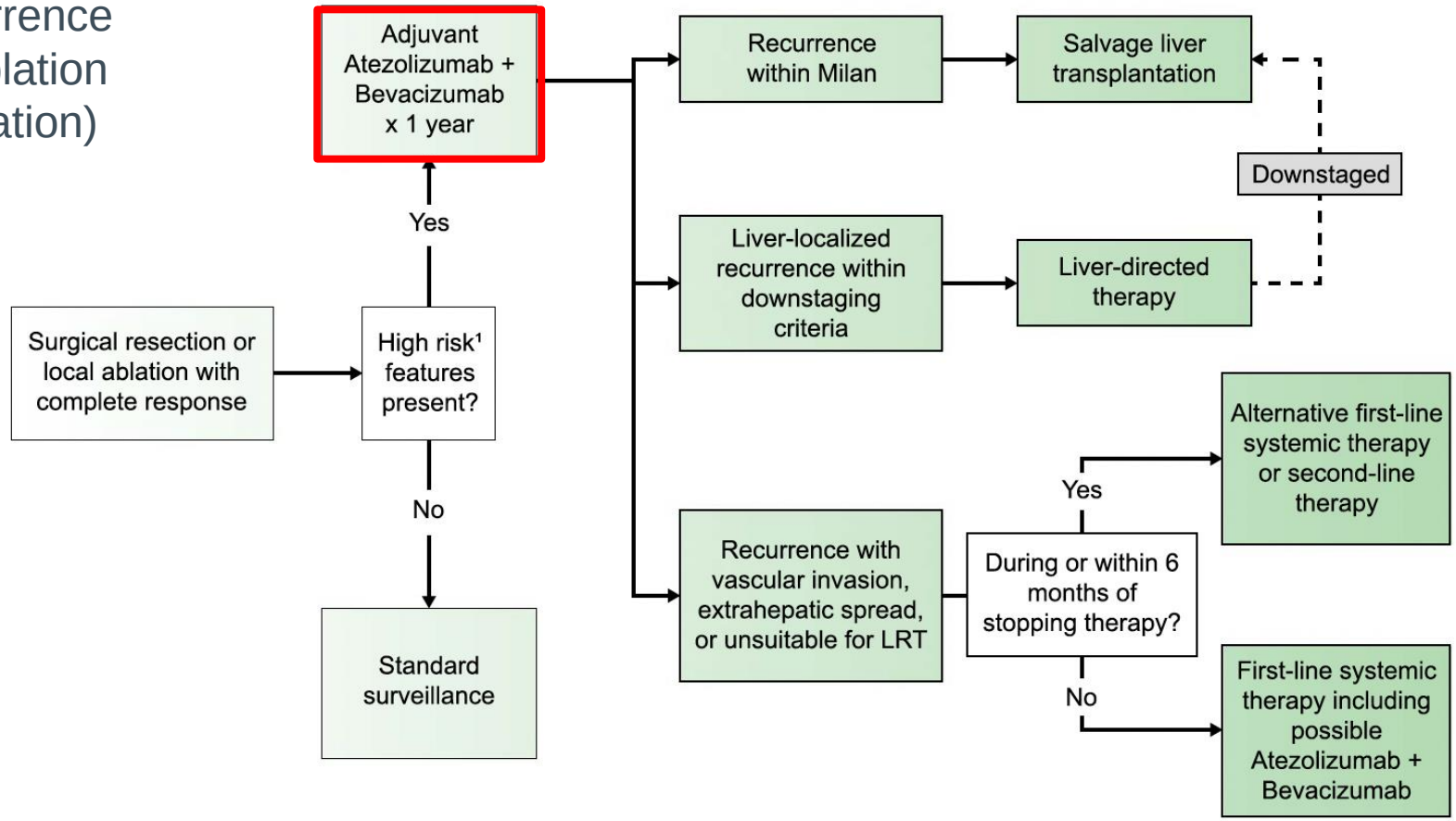
Health-related QoL and functioning scores were comparable throughout treatment

Chow P et al. AACR 2023

Whom to treat?

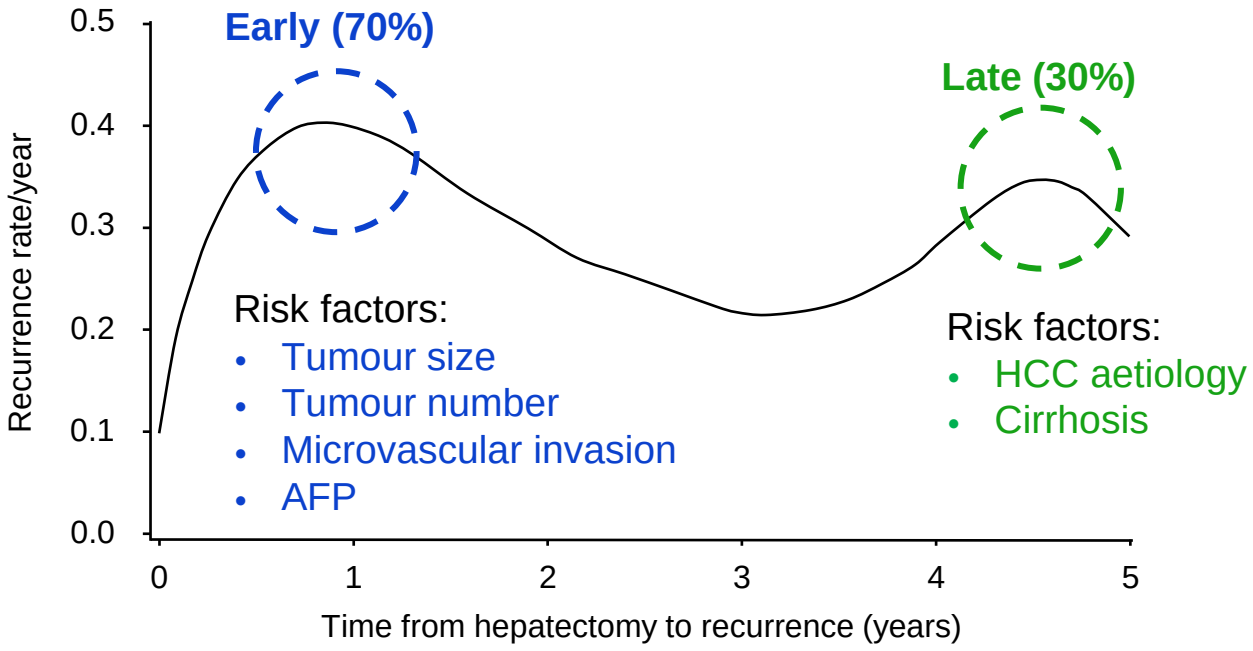
AASLD Guidelines 2023

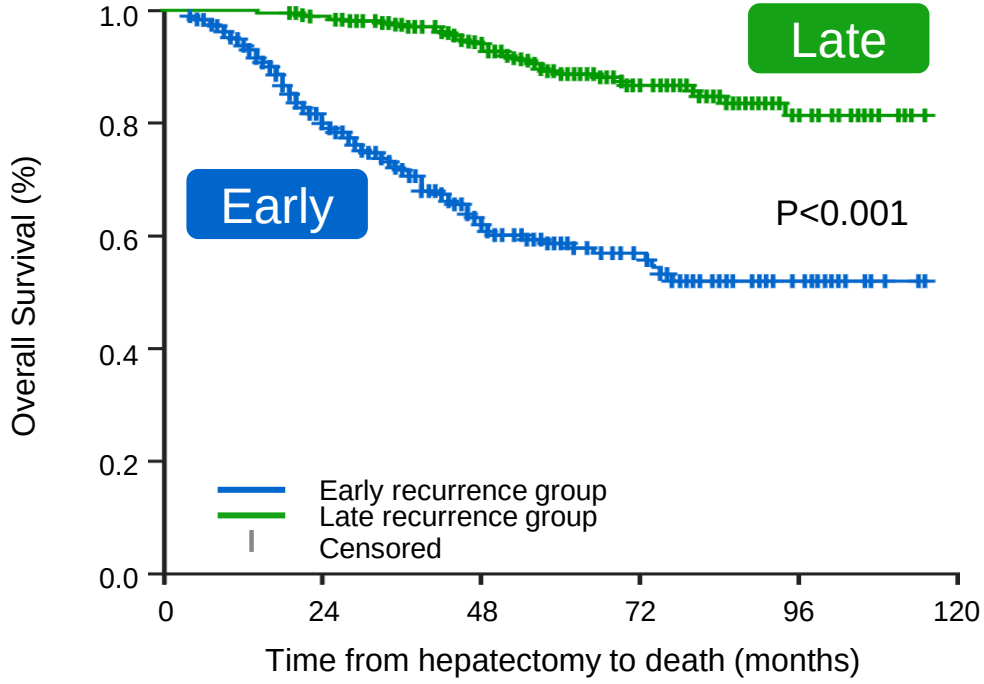
AASLD recommendation
for adjuvant Atezolizumab & Bevacizumab
in patients at high risk of recurrence
after liver resection or local ablation
(Level 2, Strong Recommendation)



Singal AG et al. Hepatology. 2023.

Bimodal recurrence after HCC resection





1. Reig et al. J Hepatol 2022; 2. Guo et al. Cancer Manag Res 2018; 3. Torzilli et al. Arch Surg 2008; 4. Imamura et al. J of Hepatology 2003; 5. Jung et al. J Gastrointest Surg 2019

Types of Recurrence

1.) near treated areas[1]
may occur in the same Couinaud segment as the treated HCC

60–70% of recurrences

2.) de novo intrahepatic recurrence[2]
i.e. multicentric HCC

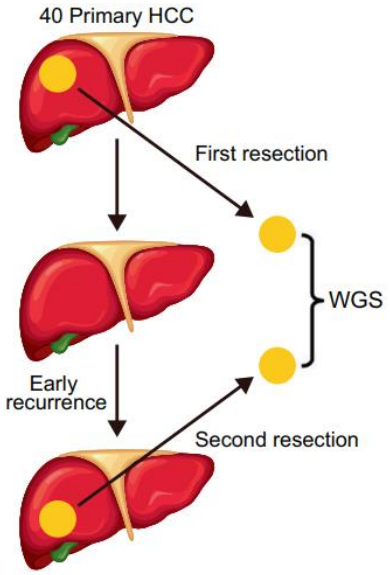
30–40% of recurrences

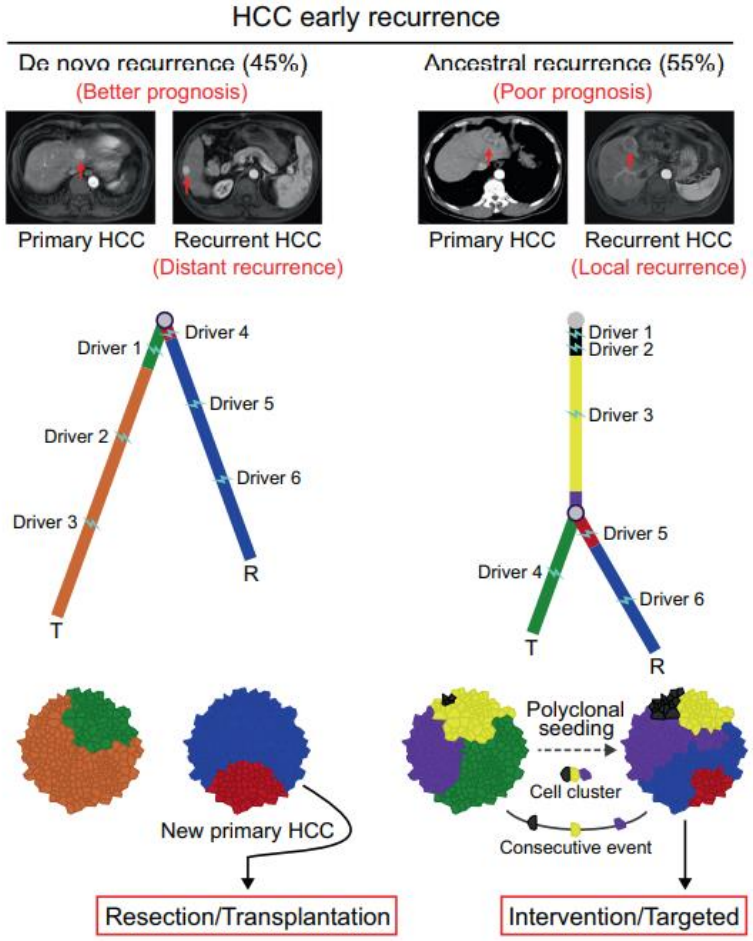
1 Minagawa M et al. Ann Surg. 2001 Mar; 233(3): 379–84.

2 Takayama T et al. Lancet 1990 Nov 10;336(8724):1150-3

Types of Recurrence

Whole Genome Sequencing
hepatitis B virus related HCC
N=40





de novo recurrence:
- developed genetically independently of the primary tumor
- carries different HCC drivers

Shao-Lai Zhou et al Signal Transduct Target Ther 2022 Jan 26;7(1):24

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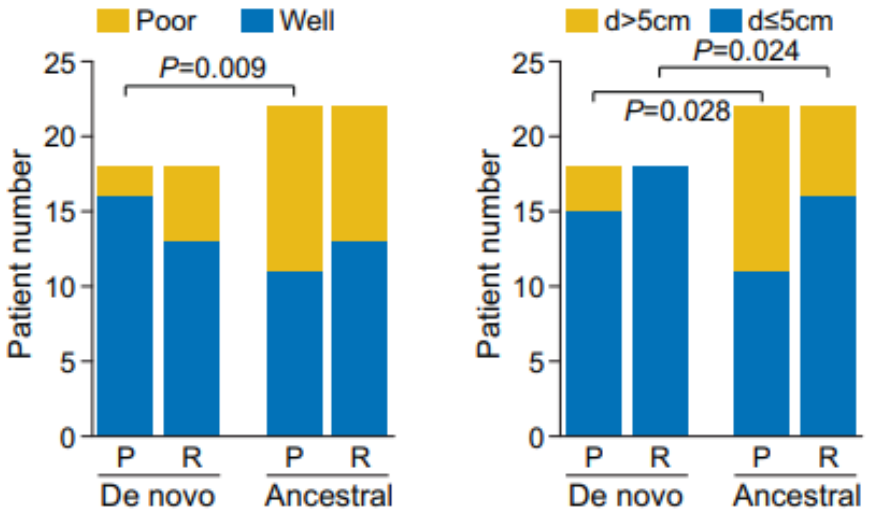
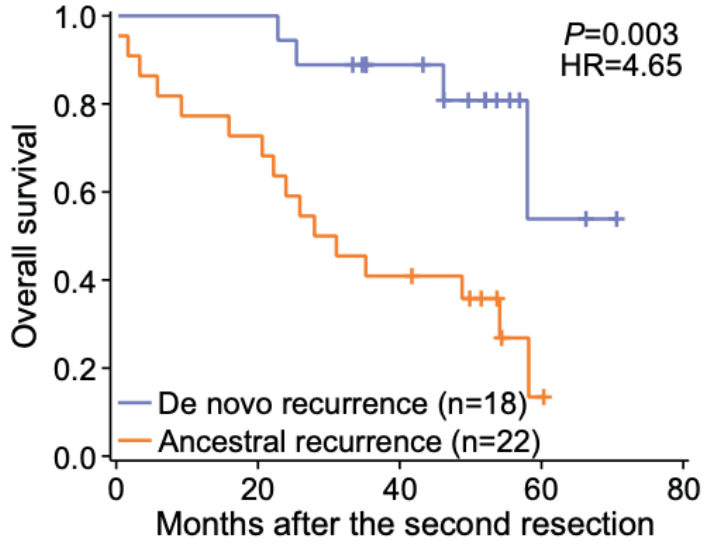


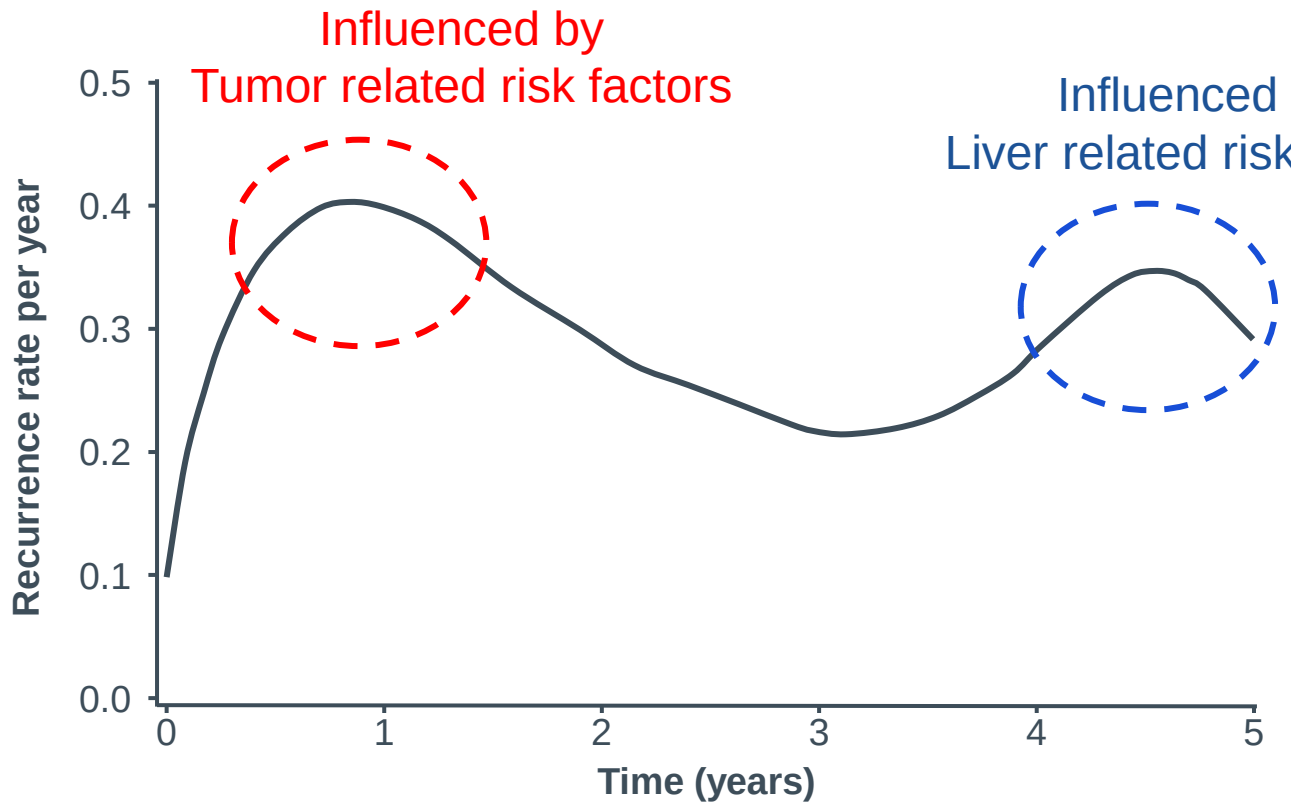
relapse of ancestral origin:
bigger size & higher grade



relapse of ancestral origin:
shorter OS

Shao-Lai Zhou et al Signal Transduct Target Ther 2022 Jan 26;7(1):24

Bimodal recurrence after HCC resection

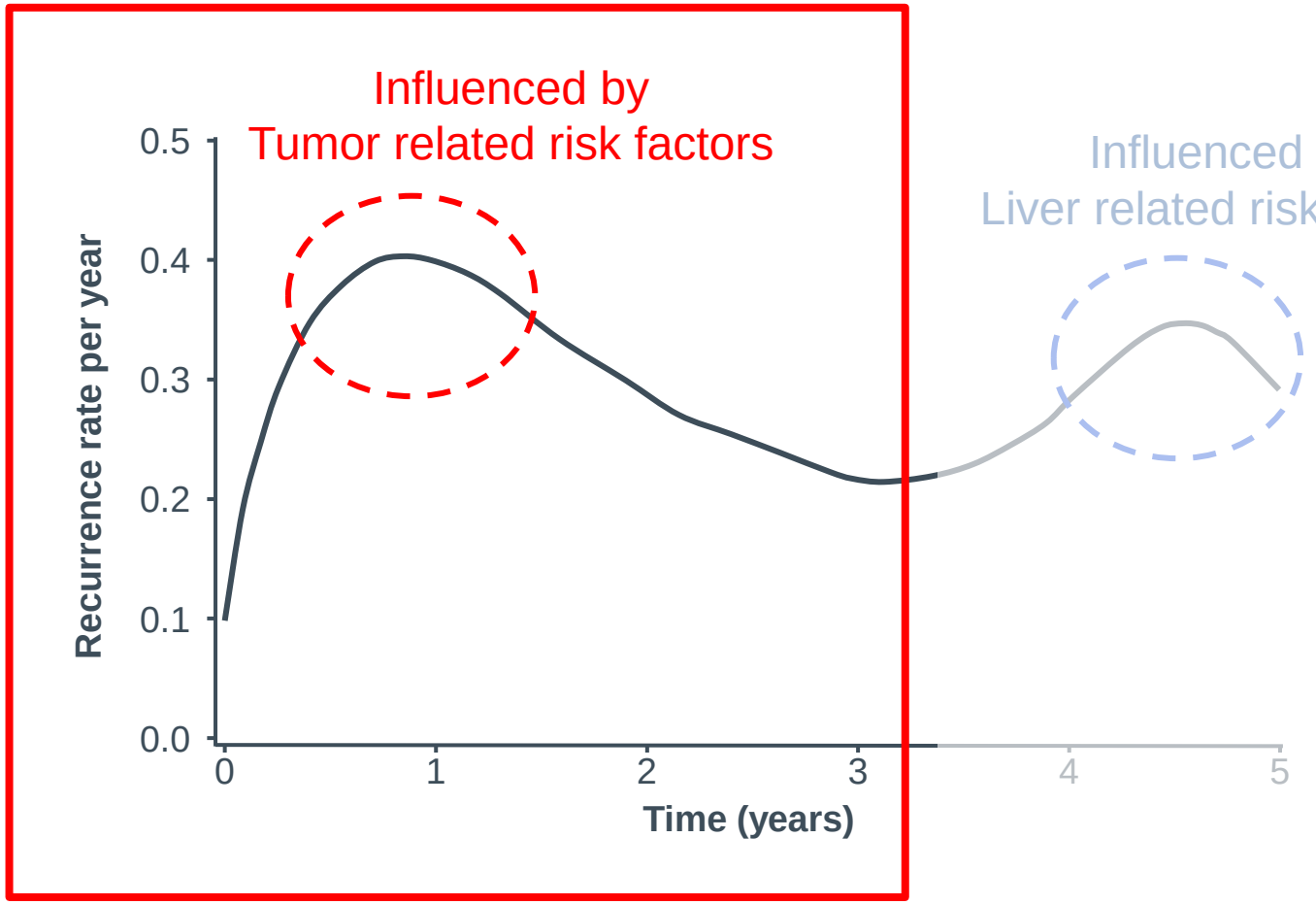


1st recurrence peak at **1 year** after resection[1]
> from **micro-metastases**

2nd peak at **4-5 years**[1] after resection
> **de novo tumors** associated with underlying liver disease[2]

1. Imamura et al. J Hepatol 2003. 2. Yao et al. Ann Surg Oncol 2022.

Effect of adjuvant therapy?



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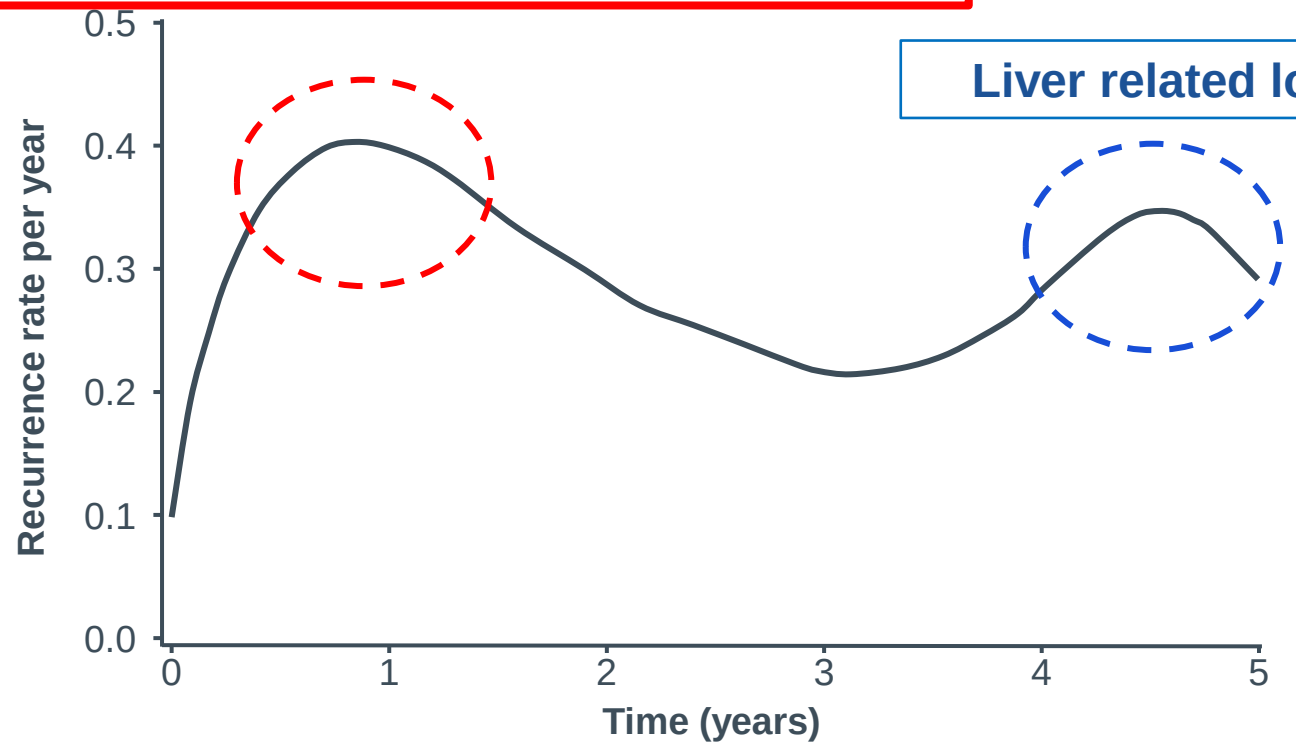
Ideal cancidate for adjuvant therapy?

Tumor related high risk



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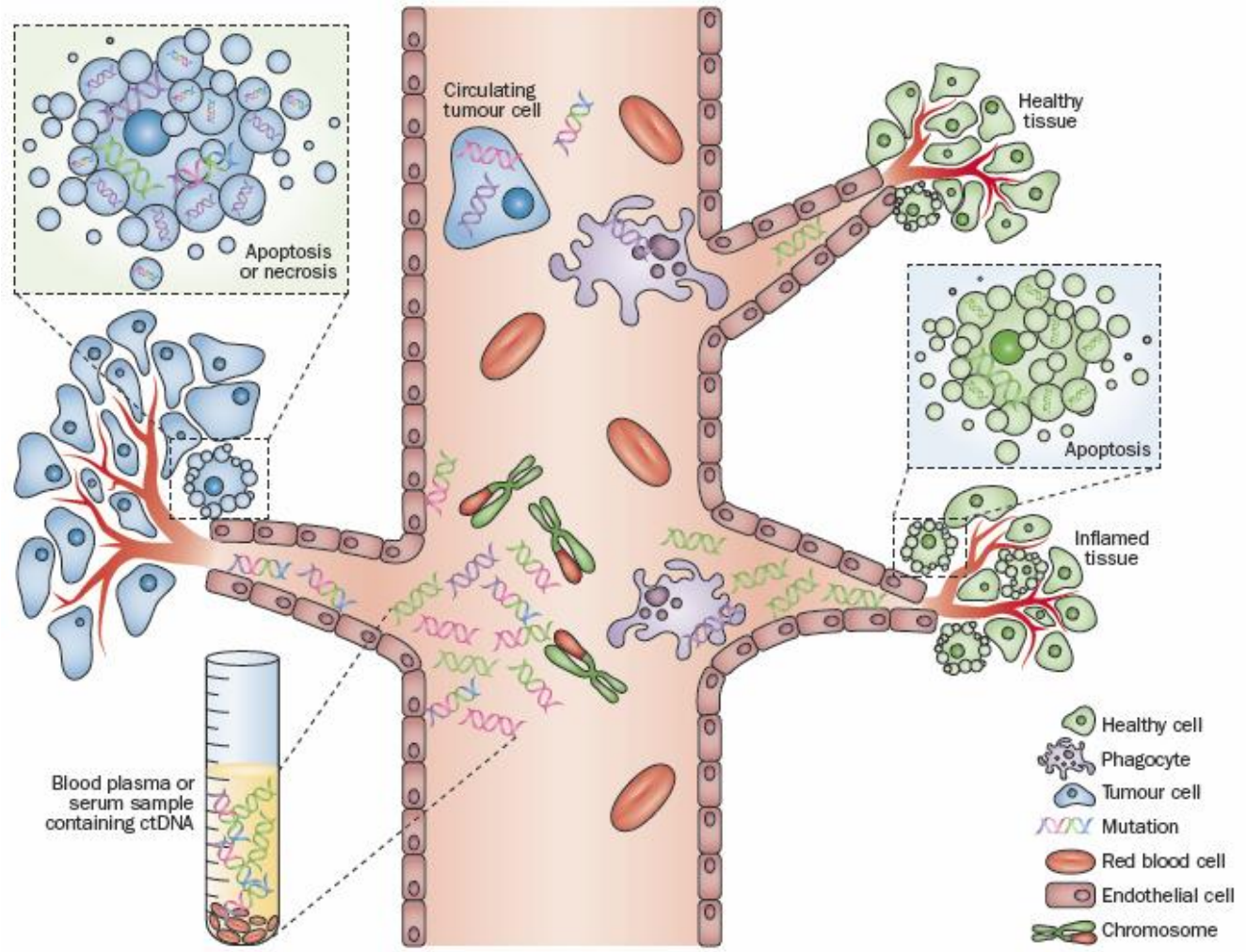
Ablation[b]	▪ 1 tumor >2 cm but ≤5 cm ▪ Multiple tumors (≤4 tumors), all ≤5 cm

> How will trials without high risk selection perform?

Chow P et al. AACR 2023

Circulating Tumor DNA (ctDNA)

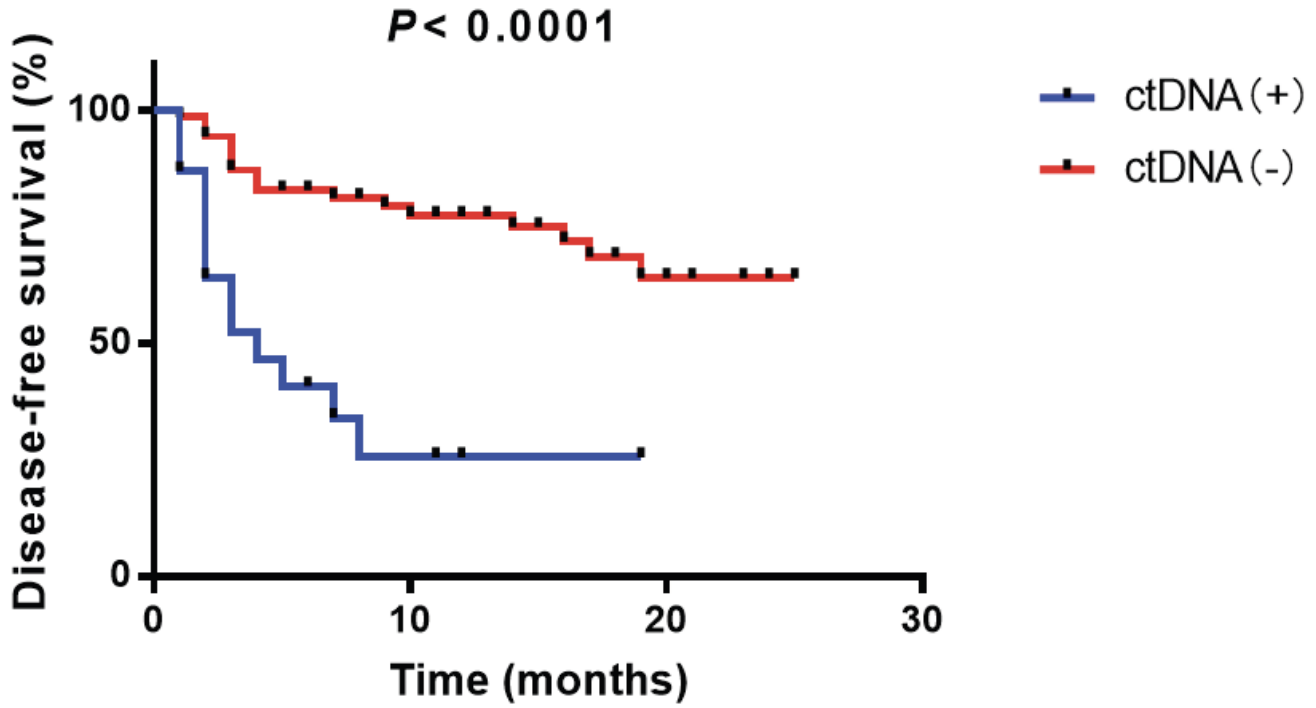


Liquid biopsy: monitoring cancer-genetics in the blood
Emily Crowley, Federica Di Nicolantonio, Fotios Loupakis and Alberto Bardelli
Nature Reviews Clinical Oncology 10, 472-484 (August 2013) | doi:10.1038/nrclinonc.2013.110

Postoperative ctDNA

HCC, N=96
all underwent radical resection

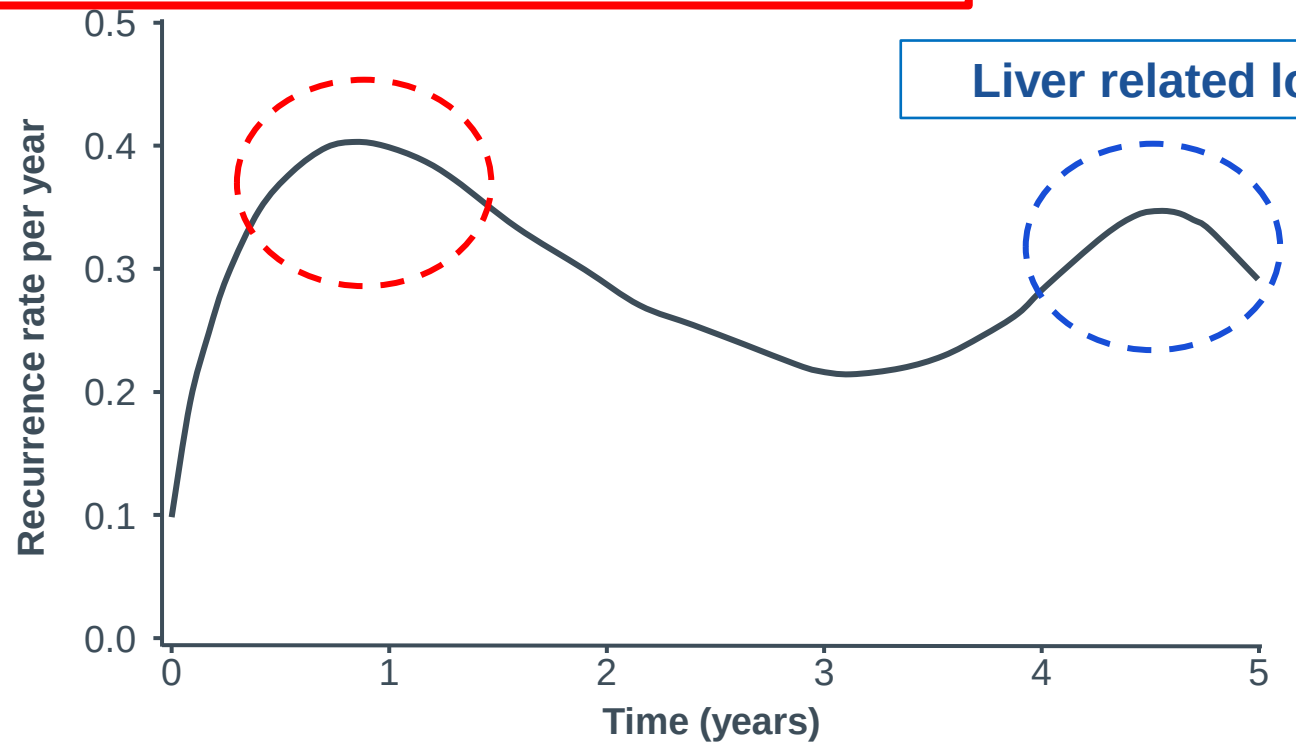
“tumor informed approach“
ctDNA+ based on mutational profile of resected HCC



Ye K et al. Front Oncol. 2022 Mar 4:12:834992.

Ideal cancidate for adjuvant therapy?

Tumor related high risk



1st recurrence peak at **1 year** after resection[1]
> from **micro-metastases**

2nd peak at **4-5 years**[1] after resection
> **de novo tumors** associated with underlying liver disease[2]

1. Imamura et al. J Hepatol 2003. 2. Yao et al. Ann Surg Oncol 2022.

Risk of recurrence (de novo tumors) = Risk of HCC?

HIGH RISK

LOW RISK

cirrhosis

no cirrhosis

chronic viral hepatitis

ALD

West J et al. Aliment. Pharmacol. Ther 45, 983–990 (2017).

HCC & etiology

HCC, N=1,051
treated at 2 big US centers

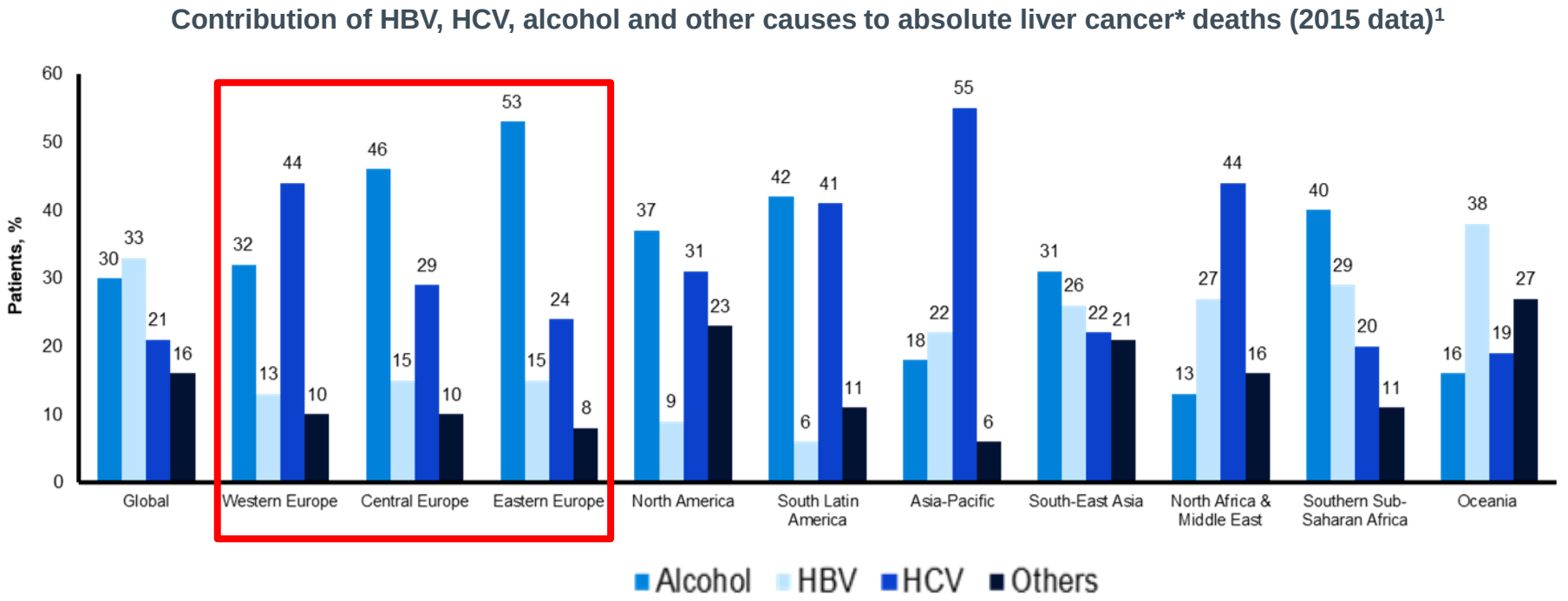
Factor	NASH (n=92)	ALD (n=153)	HCV (n=719)	HBV (n=87)	*P* Value
Child-Pugh score, n (%)					<.001
A	56 (60.9)	45 (29.4)	341 (47.4)	52 (59.8)	
B	27 (29.3)	71 (46.4)	285 (39.6)	28 (32.2)	
C	9 (9.8)	37 (24.2)	93 (12.9)	7 (8.0)	
Cirrhosis, n (%)					<.001
No	15 (16.3)	8 (5.2)	48 (6.7)	13 (14.9)	
Level 1 noncirrhosis (% of no)	13 (86.7)	4 (50.0)	25 (52.1)	9 (69.2)	
Level 2 noncirrhosis (% of no)	2 (13.3)	4 (50.0)	23 (41.9)	4 (30.8)	
Yes	77 (837)	145 (94.8)	671 (93.3)	74 (85.1)	

ALD	Alcohol-associated Liver Disease
NASH	Non-Alcoholic SteatoHepatitis
HCV	Hepatitis C Virus
HBV	Hepatitis B Virus

Hester CA et al. J Natl Compr Canc Netw. 2019 Apr 1;17(4):322-329

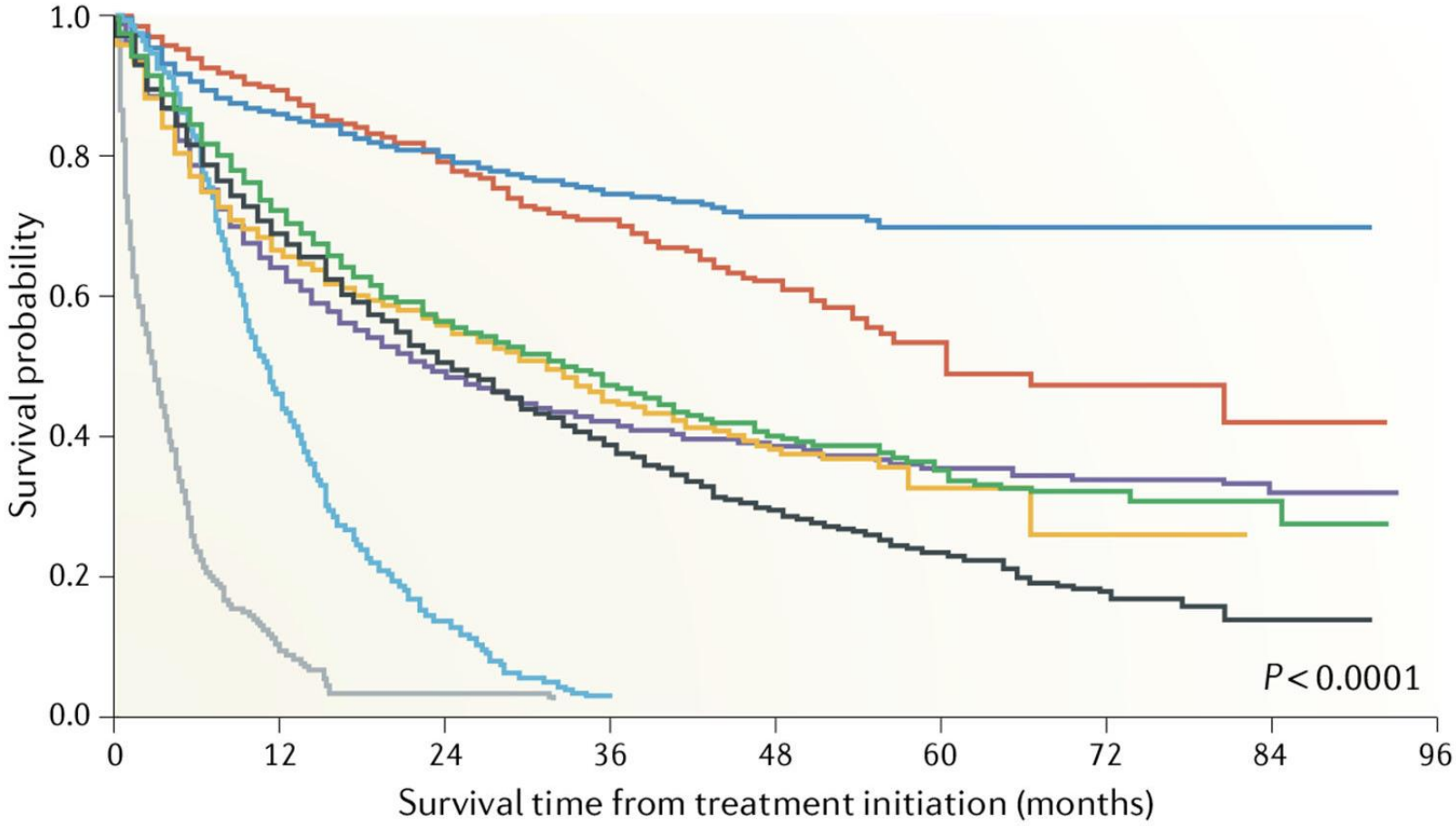
Regional Differences

Leading causes of incident cases of HCC and deaths



Singal et al. J Hepatol 2020: 72(2):250-261

OS in HCC – Global Variation

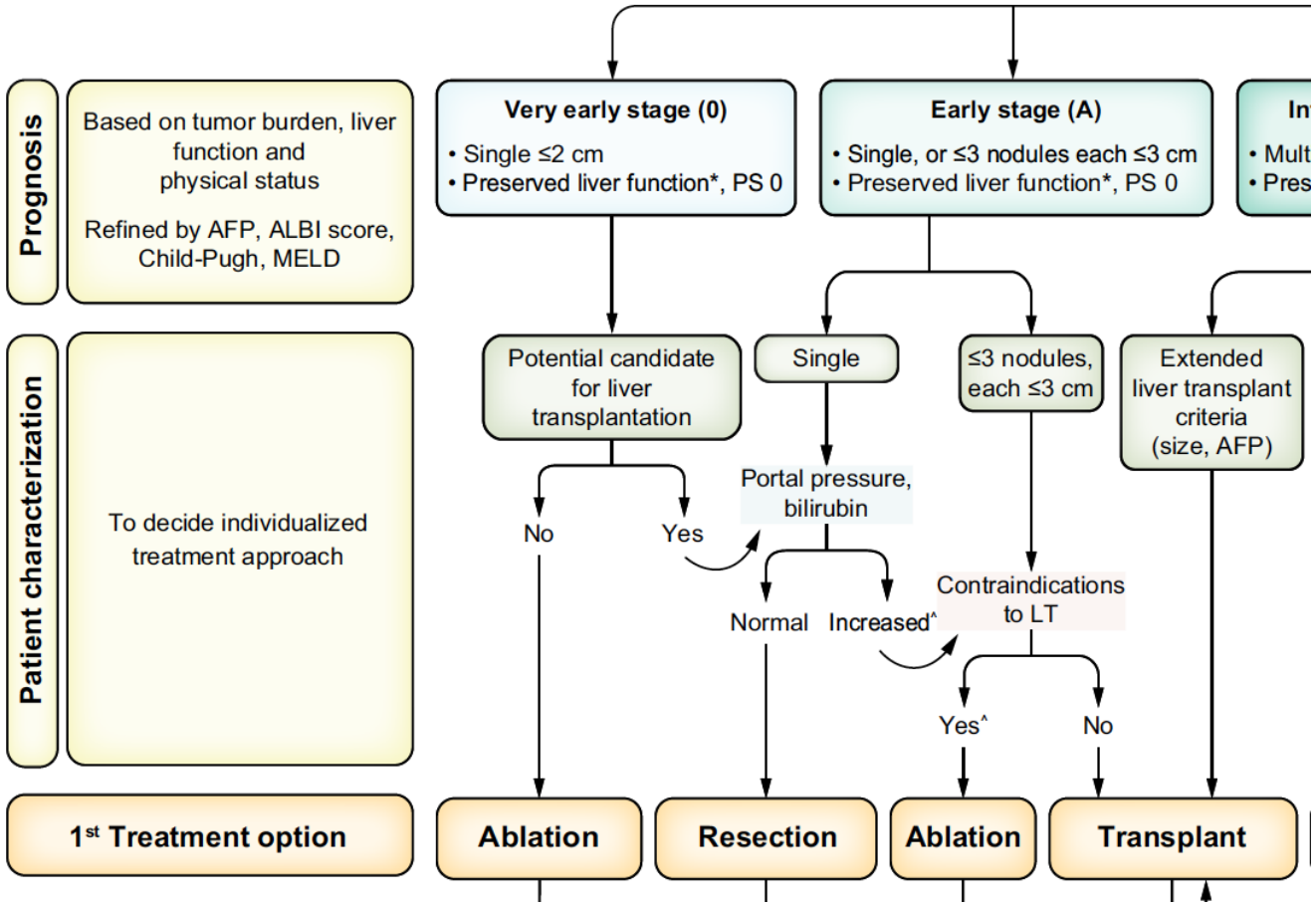


Countries	Median survival (months)
Taiwan	Not reached
Japan	60
North America	33
South Korea	31
Europe	24
China	23
Egypt	11
Other African countries	3

Yang JD et al. Nat Rev Gastroenterol Hepatol. 2019

Role of Local Treatment

BCLC Guidelines - (Very) Early Stage



Resection vs Ablation:

- resection is superior to ablation (RFS)
- non-inferior in small lesions (≤2cm)
- higher complication rate with surgery

> preoperative liver function assessment

> patient selection

Reig M et al. J Hepatol. 2022 Mar;76(3):681-693.

RFA *vs* Surgery – RCT

China, single center

HCC within Milan Criteria:

- 1 lesion ≤5 cm or 3 lesions ≤3 cm
- no evidence of gross vascular invasion

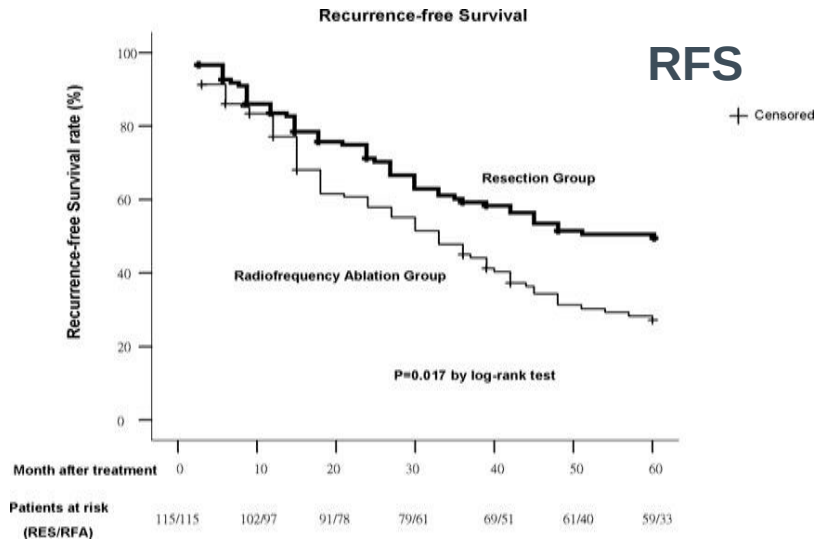
N=230

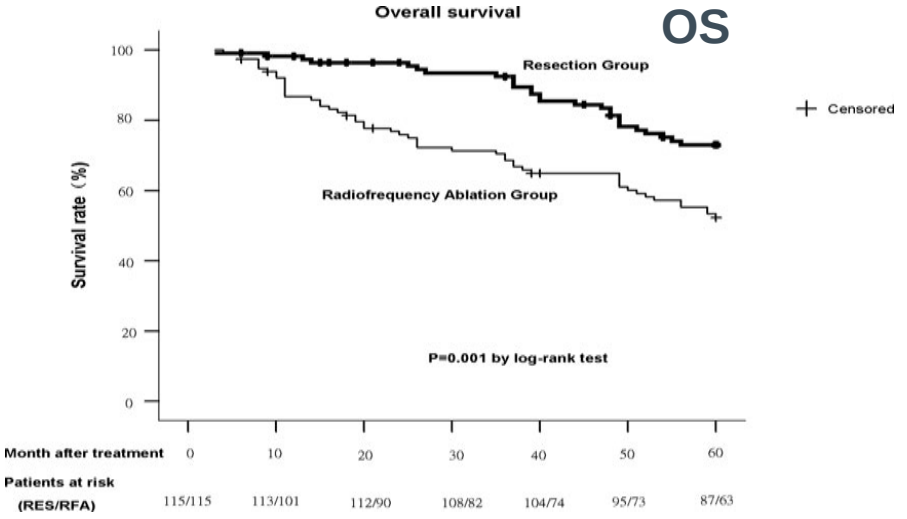
1° endpoint:
Overall survival (OS)

2° endpoints:
Recurrence free survival (RFS)
Overall Recurrence

TABLE 1. Clinical Characteristics of Patients in the 2 Study Groups

Group Variable	RES n = 115	RFA n = 115	*P* value
Age (year)	55.91±12.68	56.57 ± 14.30	$t = 0.373$ $P = 0.709$
Sex (men/women)	85/30	79/36	$\chi^2 = 0.765$ $P = 0.382$
HBV infected	104	101	$\chi^2 = 0.404$ $P = 0.525$
HCV infected	6	4	$\chi^2 = 0.105$ $P = 0.746*$
None-HBV and HCV	5	10	$\chi^2 = 1.783$ $P = 0.182$
Liver cirrhosis	75	67	$\chi^2 = 1.178$ $P = 0.278$
Solitary tumor size>/≤3cm	44/45	27/57	$\chi^2 = 5.342$ $\mathbf{P = 0.021}$
Tumor number 1/2/3	89/23/3	84/30/1	$\chi^2 = 0.583$ $P = 0.445^{\dagger}$





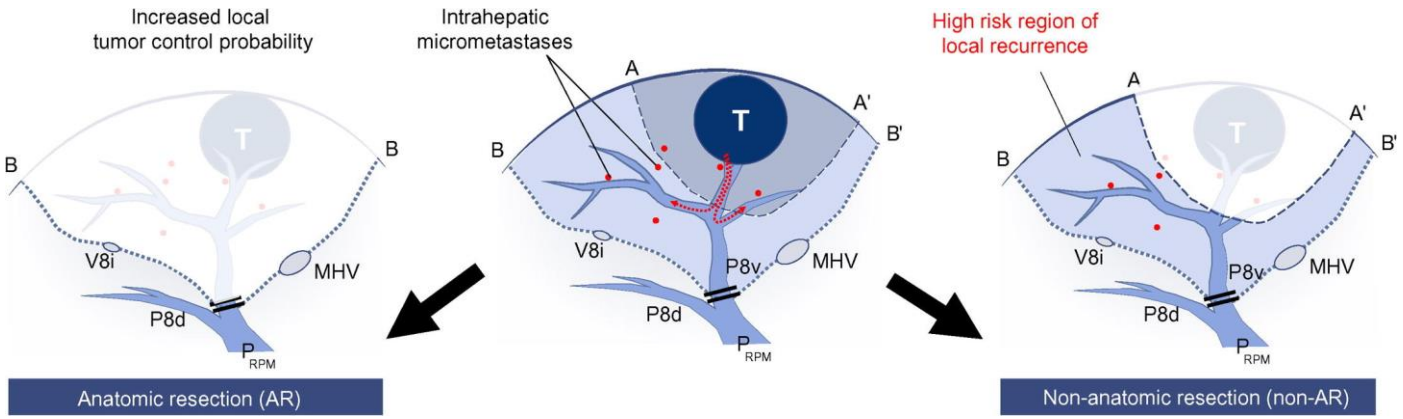
Huang J et al. Annals of Surgery 2010

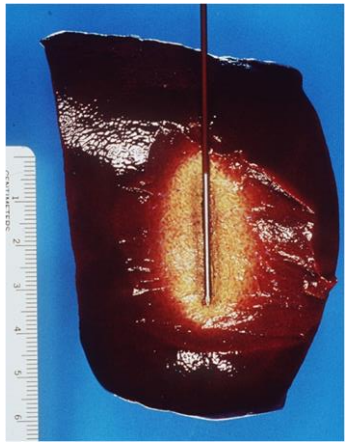
Extent of Treated Area

Anatomical Resection

Non-Anatomical Resection

RFA





by courtesy of Reto Bale

Shindo J et al. J Hepatol 2016

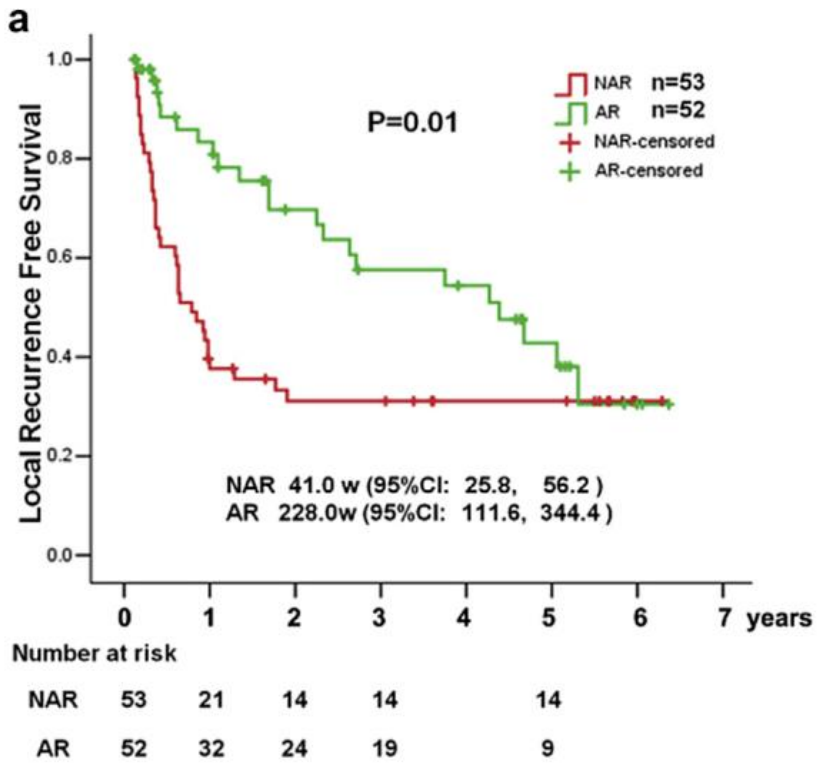
Anatomic *vs* Non-Anatomic Resection

Randomized Controlled Trial
Single center, China

Inclusion Criteria:
HCC diagnosis
Child–Pugh A & ICGR-15 <14%
≤2 tumors limited to one side of the liver

Exclusion Criteria:
≥ moderate portal hypertension
tumor invasion or thrombosis in major hepatic vessels
extrahepatic metastases
tumors located in the caudate lobe

Local recurrence-free survival better with anatomic resection



Xiaobin Feng et al. HPB (Oxford) . 2017 Aug;19(8):667-674.

summary

Ready for prime time?

IMbrave050
Atezolizumab & Bevacizumab

- 1st positive adjuvant therapy trial in HCC
- possibly practice changing
  (additional OS data?)

- patient selection is key
- more data in caucasian patients / non-viral HCC desirable

CANCER CLUSTER SALZBURG

ABCSG AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

COLORECTAL BRANCH ABCSG

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Salzburg Cancer Research Institute

CCCIT Center for Clinical Cancer and Immunology Trials

LIMCR Laboratory for Immunological and Molecular Cancer Research

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