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Management of Intermediate Stage HCC

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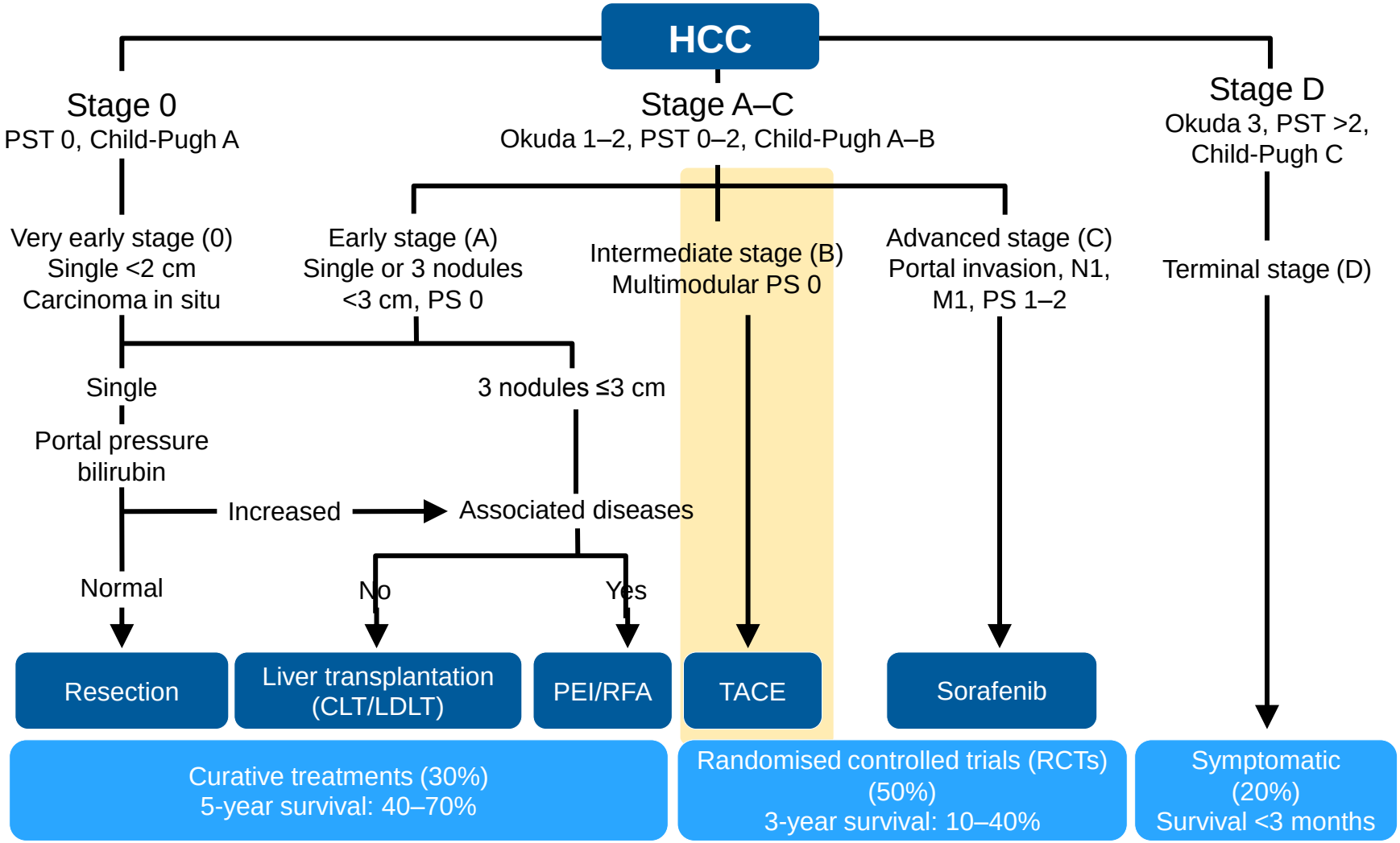
Outline

- What is Intermediate Stage HCC?
- Guideline: TACE for Intermediate Stage HCC
- Clinical Practice is Different
- Intermediate Stage HCC is a Heterogeneous Disease
- What should We Treat after TACE Failure or Refractoriness
- Summary and Conclusion

Proposed AASLD-JNCI modification of BCLC staging: unresectable HCC



Llovet JM, et al. *J Natl Cancer Inst* 2008;100(10):698–711

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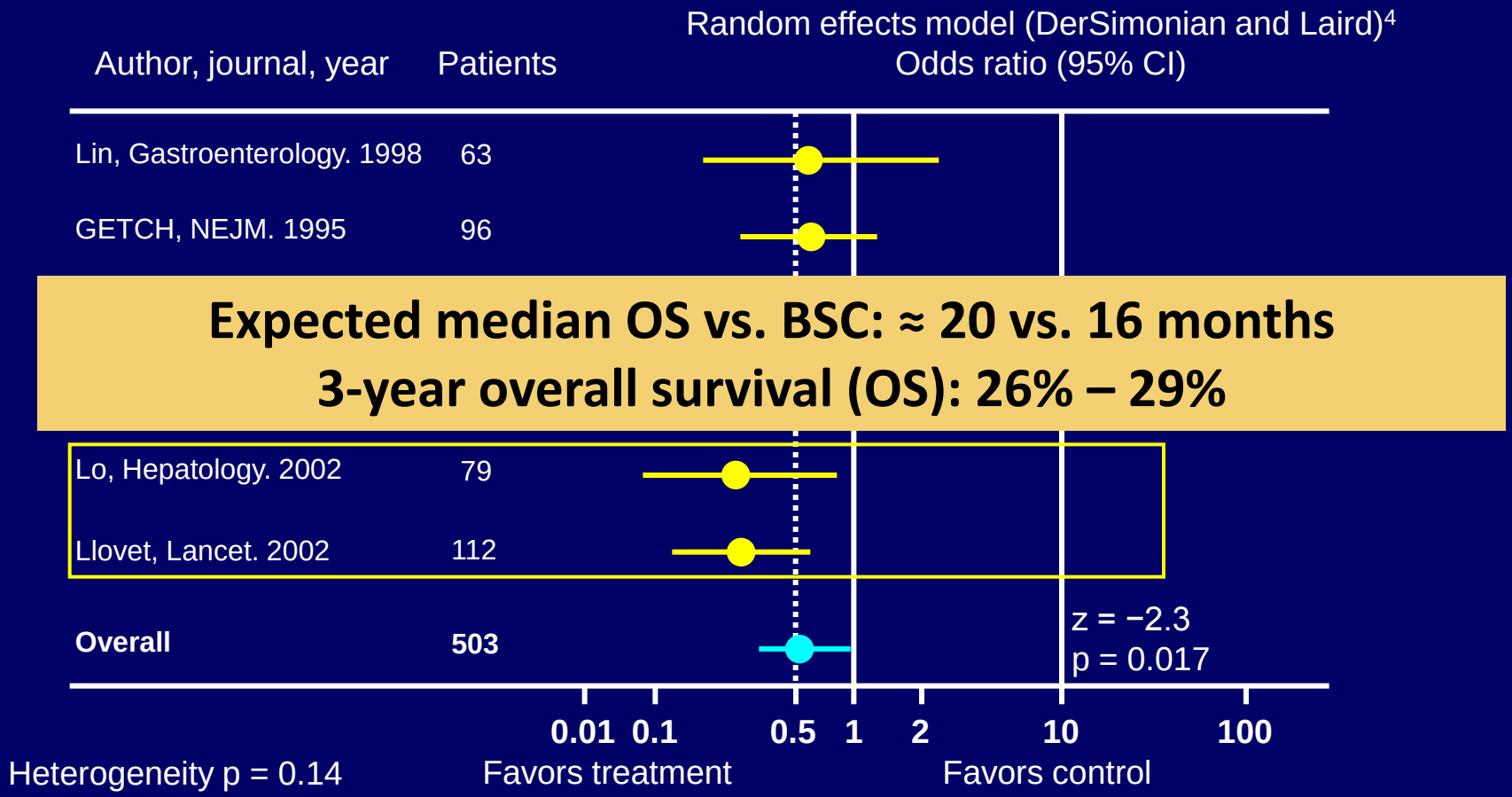
Meta-analysis of randomized controlled trials comparing 2-year survival of TAE/TACE versus best supportive care[1]



1. Llovet JM, et al. Lancet. 2003;362:1907-17.
2. Lo CM, et al. Hepatology. 2002;35:1164-71.
3. Llovet JM, et al. Lancet. 2002;359:1734-9.
4. DerSimonian R, Laird N. Controlled Clin Trials. 1986;7:177-8.

TAE = transarterial embolization.

TACE for intermediate HCC

- Significant survival benefits demonstrated in multiple RCTs[1,2]
  - TACE induces extensive tumour necrosis in more than 50% of patients
  - in responders, survival improvement ranges from 20% to 60% at 2 years
- Currently regarded as the standard of care for patients with localized unresectable intermediate HCC[2,3]
- Careful patient selection necessary to avoid significant toxicity
  - those with well-preserved liver function and multinodular HCC without vascular invasion or extrahepatic spread are best target
- Not appropriate for patients with tumours that occlude portal venous vessels or are more than minimally metastatic[3]

1. Llovet J, Bruix J. *Hepatology* 2003;37:429–42
2. Briux J, Sherman M. *Hepatology* 2005;42:1208–36
3. O'Neil B, et al. *Oncologist* 2007;12:1425–32

EASL-EORTC Guideline

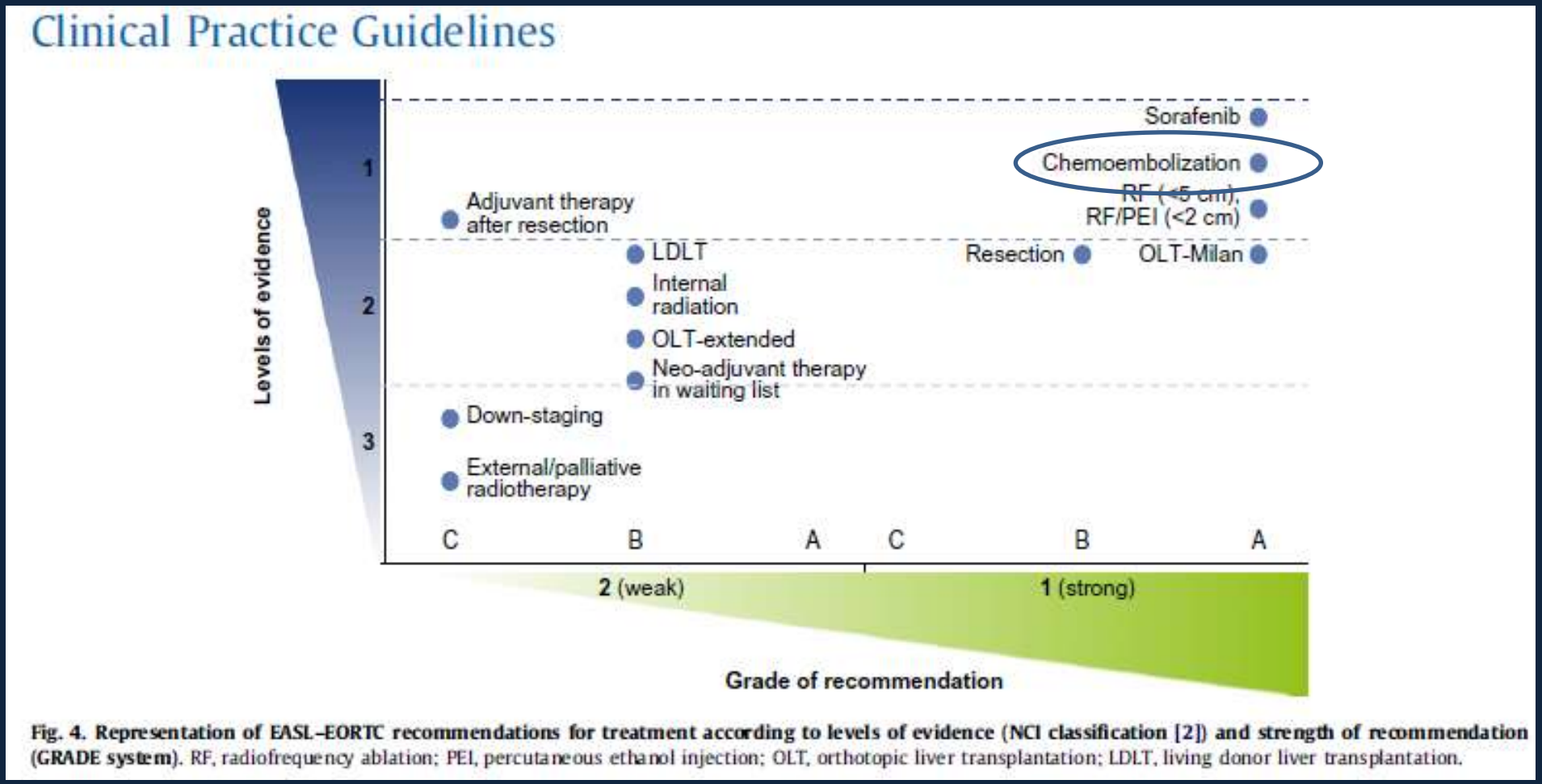


Fig. 4. Representation of EASL–EORTC recommendations for treatment according to levels of evidence (NCI classification [2]) and strength of recommendation (GRADE system). RF, radiofrequency ablation; PEI, percutaneous ethanol injection; OLT, orthotopic liver transplantation; LDLT, living donor liver transplantation.

Current recommendations for TACE as the standard of care in intermediate HCC

Guideline	Recommendation	Contraindications
AASLD[1]	1st-line non-curative for non-surgical patients with large/multifocal tumours	EHS, vascular invasion
EASL–EORTC[2]	BCLC-B, multi-nodular asymptomatic tumours, without vascular invasion or EHS	Decompensated cirrhosis, advanced liver dysfunction, MVI or EHS
ESMO[3]	BCLC-B, excellent liver function and multinodular asymptomatic tumours without MVI or EHS	Decompensated cirrhosis, MVI, EHS
APASL[4]	1st first-line treatment for patients with unresectable, large/multifocal HCCs without MVI or EHS	Decompensated cirrhosis, MVI, EHS

AASLD, American Association for the Study of Liver Diseases; BCLC, Barcelona Clinic Liver Cancer; EASL, European Association for the Study of the Liver; EHS, extrahepatic spread; EORTC, European Organisation for Research and Treatment of Cancer; ESMO, European Society for Medical Oncology; APASL, Asian Pacific Association for the study of the Liver, MVI, microvascular invasion, EHS, extrahepatic spread

1. Bruix J, Sherman M. Hepatology 2011;53:1020–2; full guidelines available at: http://www.aasld.org/practiceguidelines/Pages/SortablePracticeGuidelinesAlpha.aspx; 2. EASL–EORTC Clinical Practice Guidelines: Management of hepatocellular carcinoma. J Hepatol 2012;56:908–43; Available at: http://www.easl.eu/assets/application/files/d38c7689f123edf_file.pdf;
3. Verslype C et al. ESMO guidelines. Ann Oncol 23(Suppl 7):vii41–8 ; 4.
4. Omata et al. APASL recommendations on Hepatocellular Carcinoma. Hepatol Int. 2010; 4:439–474

Outline

- What is Intermediate Stage HCC?
- Guideline: TACE for Intermediate Stage HCC
- How about Real life Clinical Practice?
- Intermediate Stage HCC is a Heterogeneous Disease
- What should We Treat after TACE Failure or Refractoriness
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Surprisingly, clinical practice is different

BRIDGE Study*: BCLC Stage at Diagnosis by Region

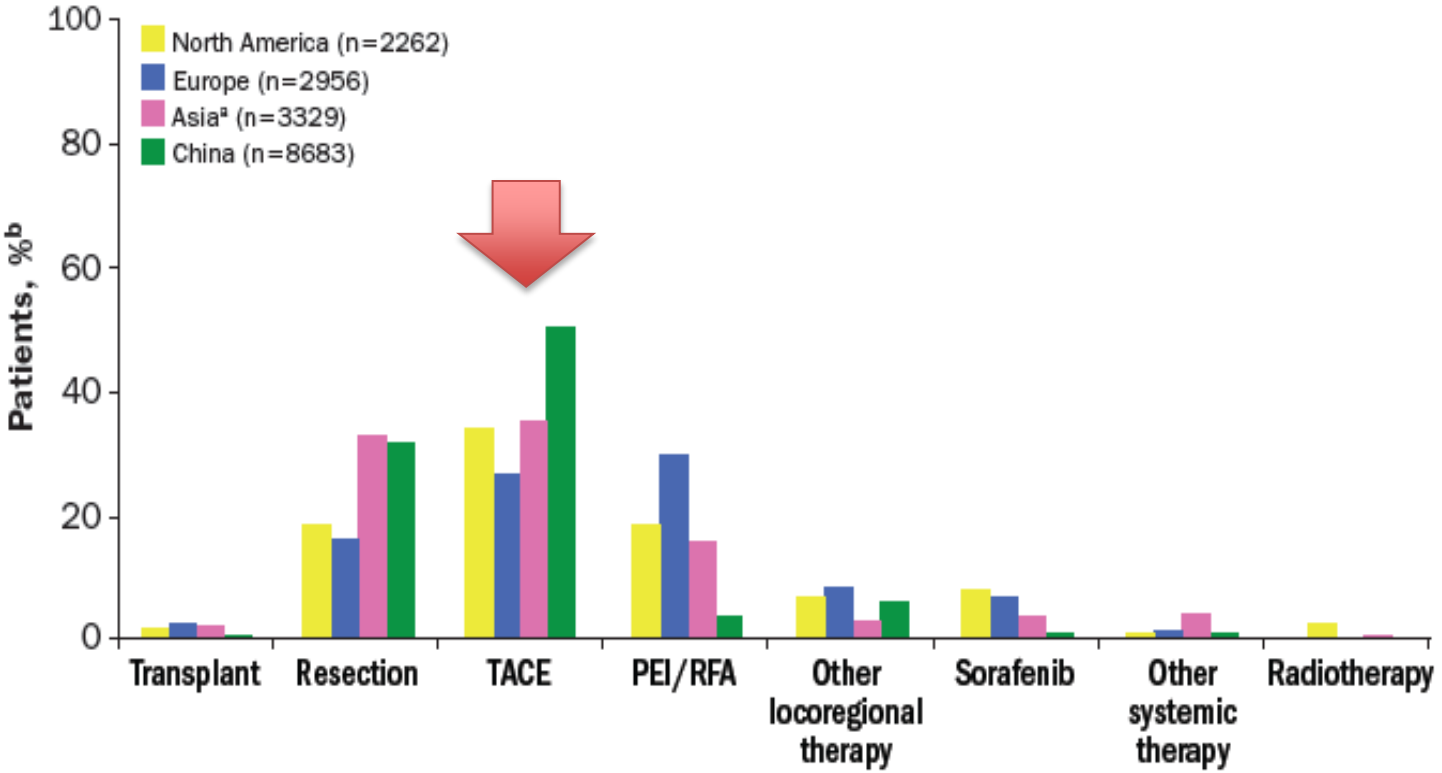
Only 10-13% of patients present with BCLC stage B at diagnosis in North America, Europe, and China

Variable/group[a]	North America n = 2262	Europe n = 2956	Asia[b] n = 3329	China n = 8683
BCLC stage, n (%)	n = 1507[c]	n = 1987[c]	n = 3023	n = 6480
0	105 (7)	69 (4)	399 (13)	191 (3)
A	465 (31)	526 (27)	1289 (43)	1969 (30)
B	156 (10)	234 (12)	384 (13)	590 (9)
C	626 (42)	999 (50)	908 (30)	3590 (55)
D	155 (10)	159 (8)	43 (1)	140 (2)
Child-Pugh status, n (%)	n = 1944	n = 2225	n = 3144	n = 7841
A	1411 (73)	1593 (72)	2721 (87)	6804 (87)
B	428 (22)	559 (25)	390 (12)	956 (12)
C	105 (5)	73 (3)	33 (1)	81 (1)

[a]Statistics based on patients with known values.
[b]Includes patients from Taiwan (n = 1585; 48%), South Korea (n = 1226; 37%), and Japan (n = 518; 16%).
[c]Data missing in >30% of patients.

*Park JW, et al. ASCO 2012 abstract #4033

BRIDGE Study*: TACE was the most frequently used first recorded HCC treatment in North America, China, and the other Asian countries



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[b]Percentages are based on percentage of population with known values.

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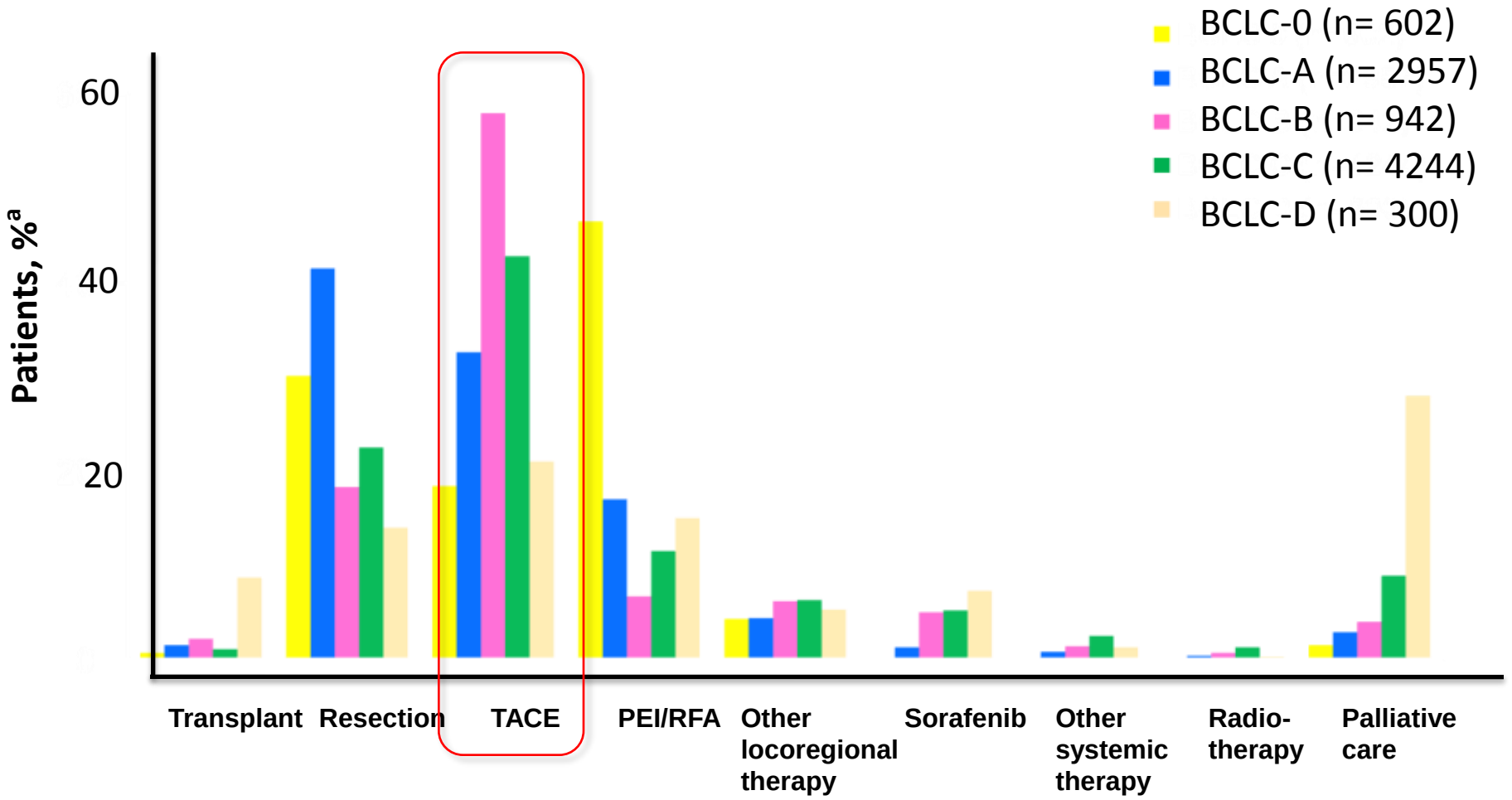
BRIDGE Study: First Recorded HCC Treatment by BCLC Status



[a]Percentages are based on percent of population with known values.
PEI/RFA, percutaneous ethanol injection/radiofrequency ablation; TACE, transarterial chemoembolization.

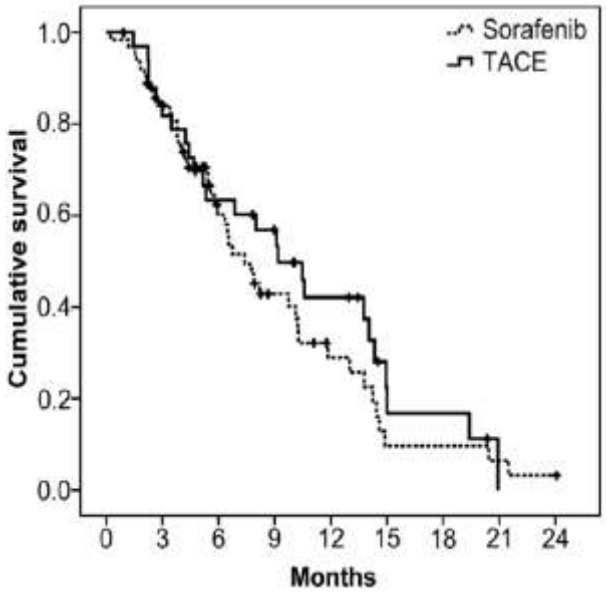
Sherman, et al. ILCA 2012

TACE also in BCLC C-Patients?

Pinter *et al.*, Radiology 2012; 263: 590

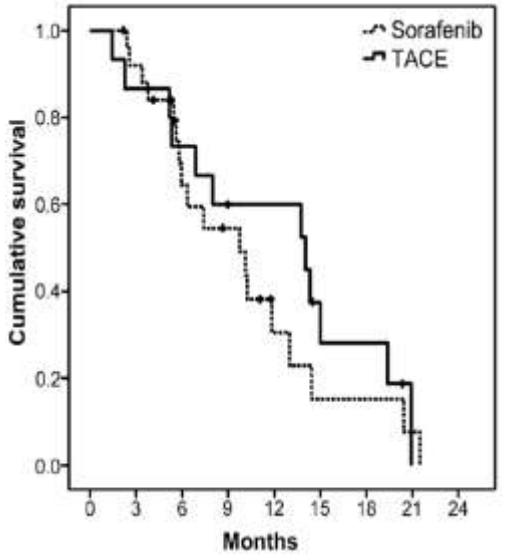
- 228 TACE-patients, Medical University of Vienna
- 144 Sorafenib-Patients, 11 Centers Austria
  - Exclusion: OLT, resection, TACE (Sorafenib-group)
  - BCLC C, retrospective: 34 TACE vs. 63 Sorafenib

Whole Cohort



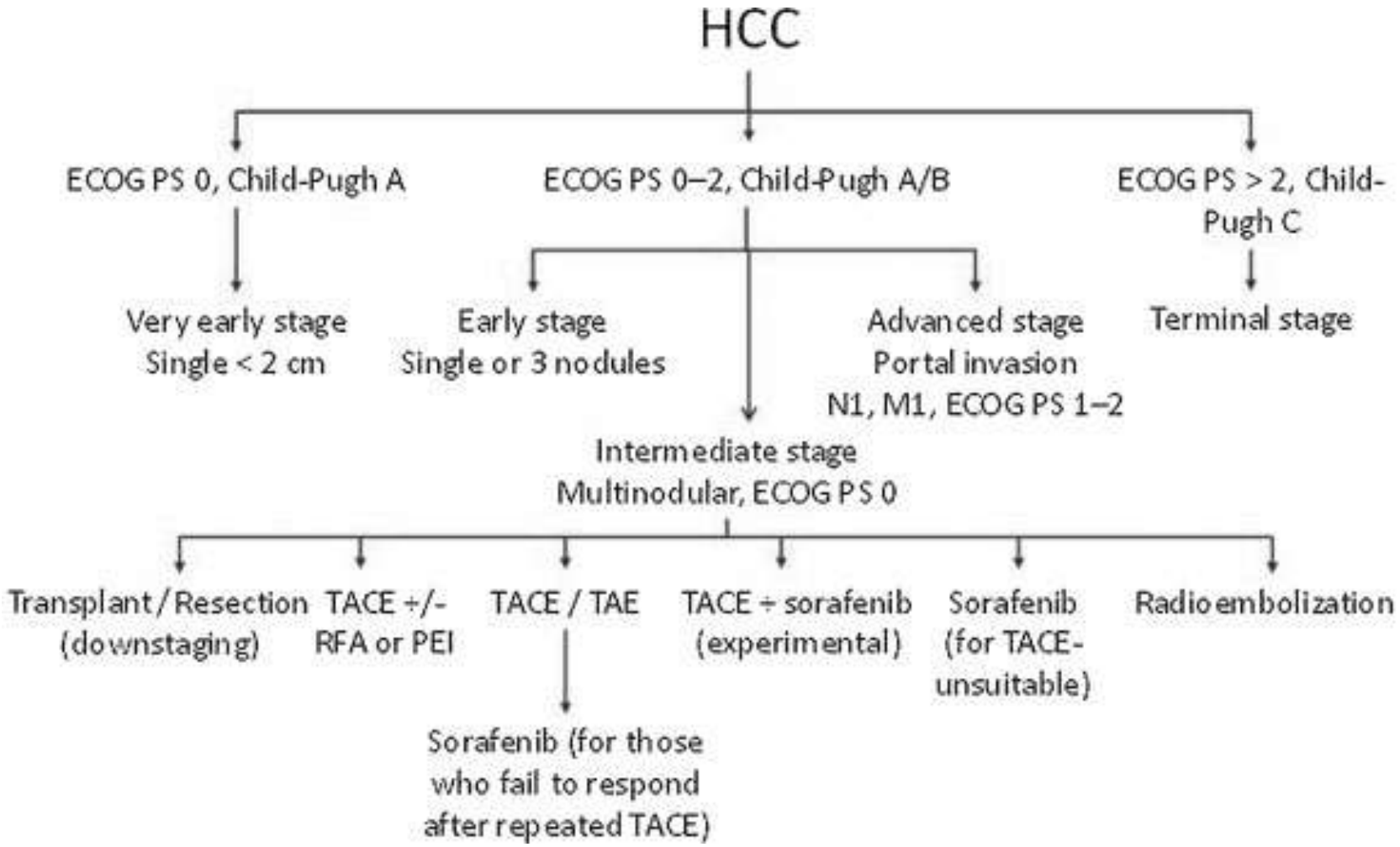
Survival T vs. S: 9.2 *vs.* 7.4 months, p=0.377

CP A + MVI, EHS (T 15 vs. S 26 pat.)



14 *vs.* 9.7 months, p=0.49

Treatment options in intermediate hepatocellular carcinoma patients.



Bolondi L et al., Semin Liver Dis 2012;32:348–359.

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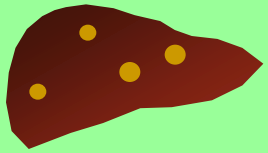
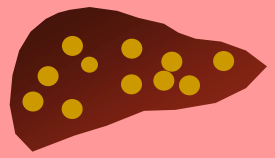
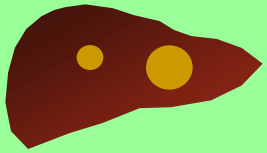
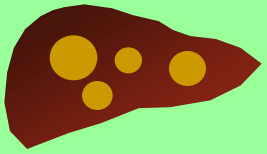
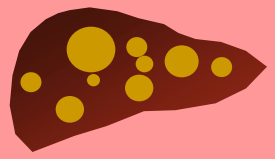
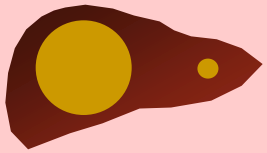
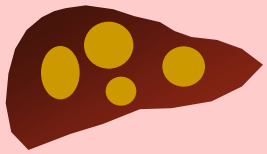
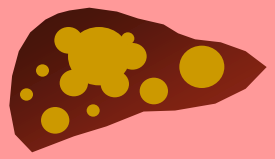
Heterogeneity of Intermediate HCC

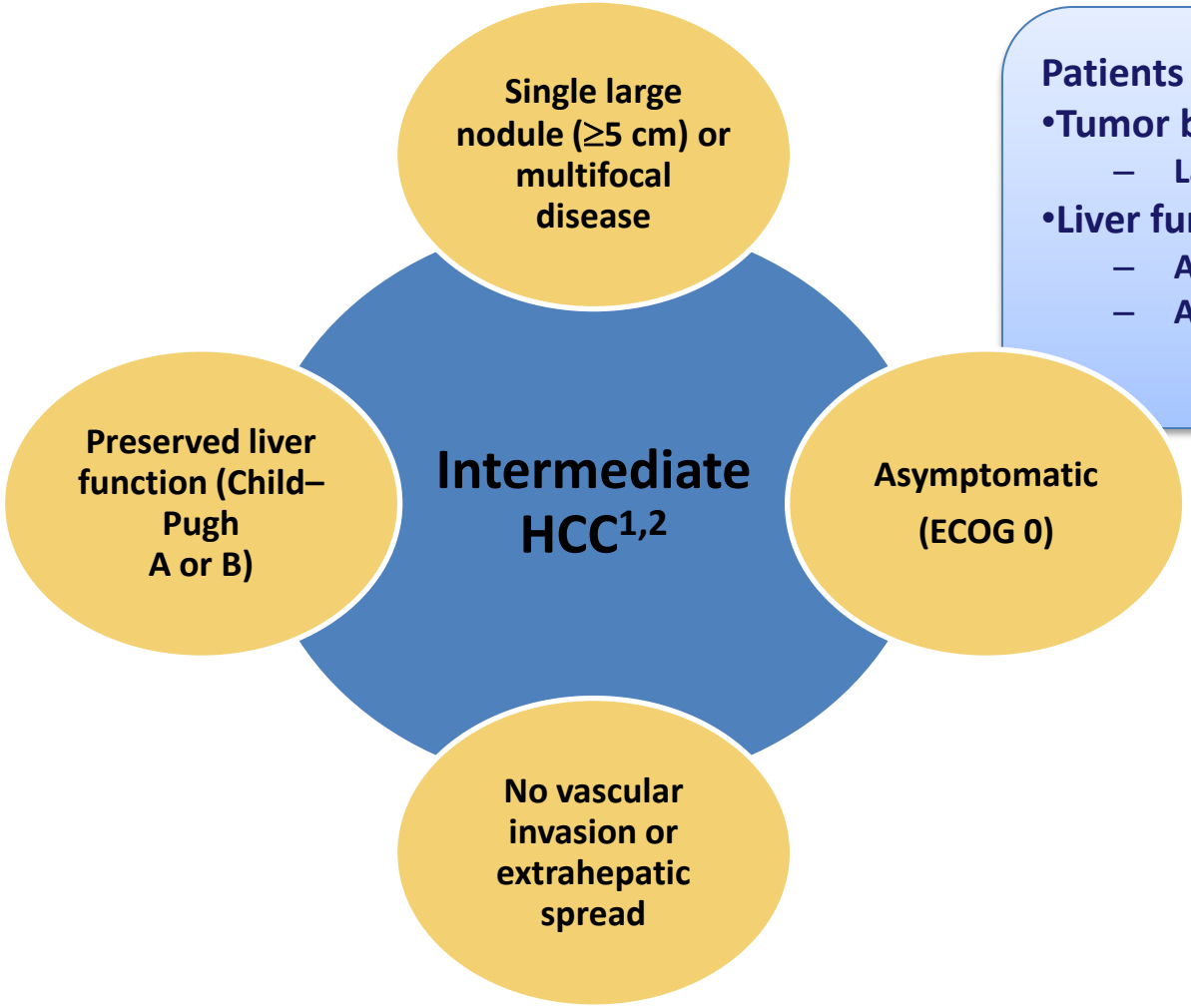
N0
M0
VP0,Vv0

>3 nodules

Size \ Number	≤3 nodules	Multiple(≤4)	Multiple（>4-10）
≤3cm	Resection・RFA		
Large (>3 cm)			
Huge **（>7-10 cm?）**			

>3cm

Even intermediate HCC itself is a heterogeneous patient population



Patients may vary widely in terms of:

- **Tumor burden**
  - **Large unresectable or multinodular HCC**
- **Liver function: Child–Pugh A and B**
  - **A5–B9**
  - **Ascites, encephalopathy**

HCC, hepatocellular carcinoma

1. Forner A et al. Lancet 2012;379:1245–55; 2. Piscaglia F et al. Dig Liver Dis 2010;42(Suppl 3)S258–63

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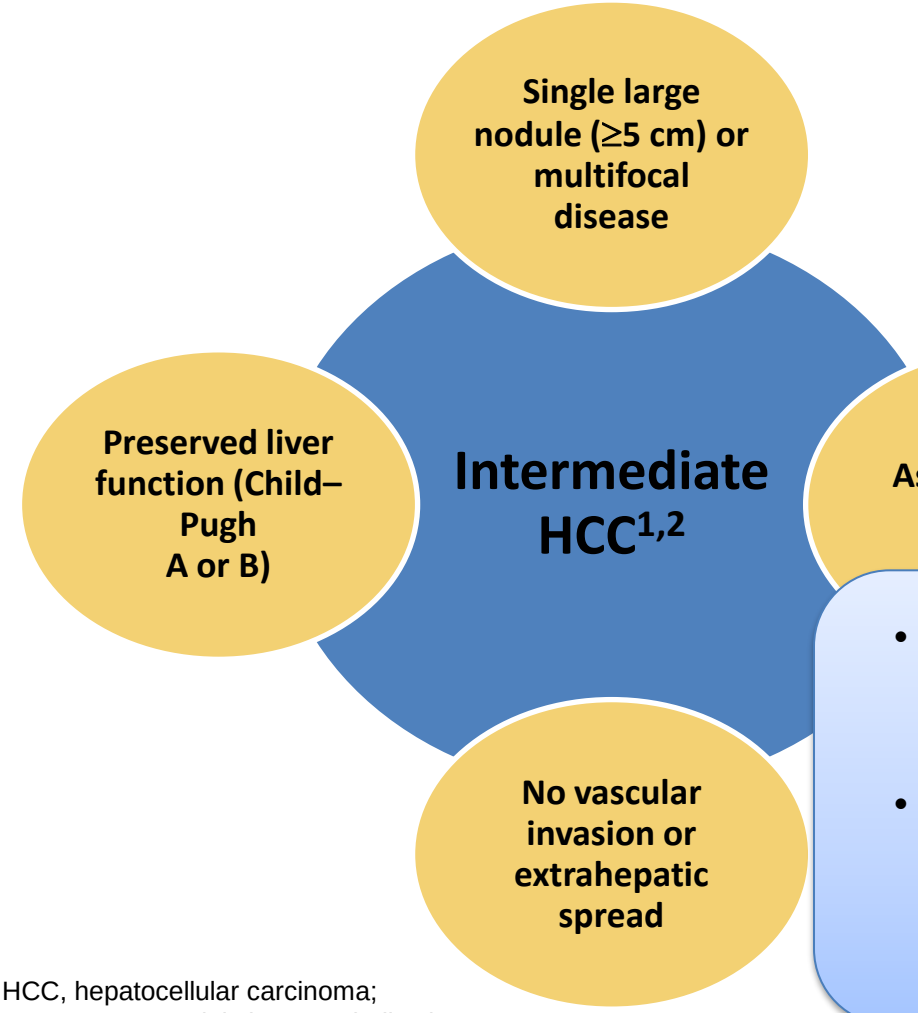

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- **Not all patients with intermediate HCC are suitable for TACE[4]**
- **Evidence of TACE efficacy in intermediate HCC is limited; most studies carried out in the 'pre-staging' era with highly heterogeneous protocols[3]**

HCC, hepatocellular carcinoma;
TACE, transarterial chemoembolization

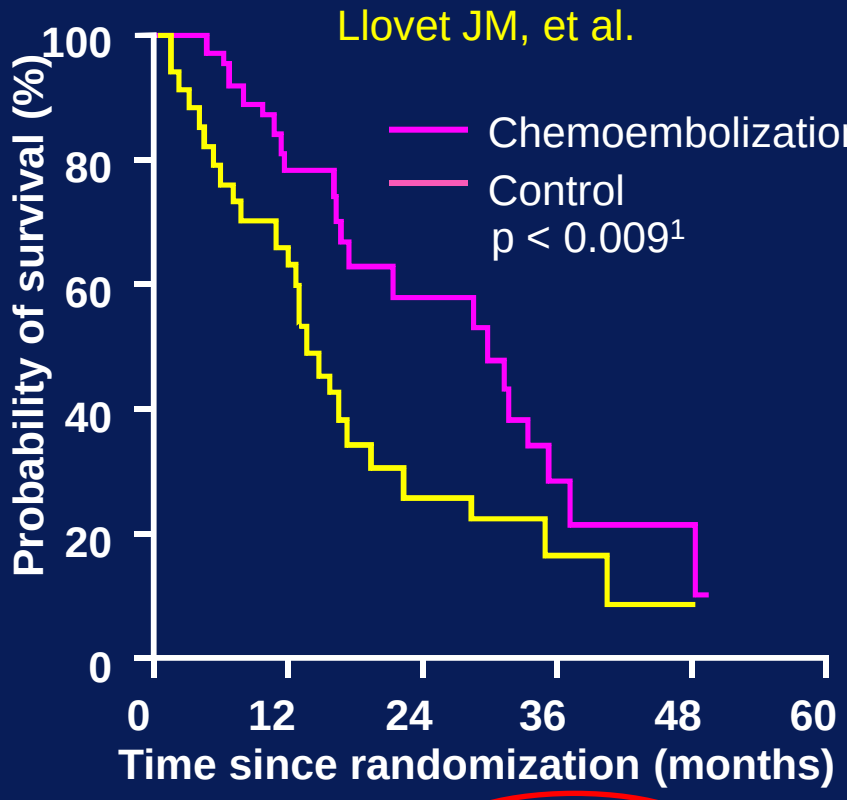
1. Forner A et al. Lancet 2012;379:1245–55; 2. Piscaglia F et al. Dig Liver Dis 2010;42(Suppl 3)S258–63;
3. Llovet JM, Bruix J. Hepatology 2003;37:429–42; 4. Bruix J, Sherman M. Hepatology 2011;53:1020–2; full guidelines available at:
http://www.aasld.org/practiceguidelines/Pages/SortablePracticeGuidelinesAlpha.aspx

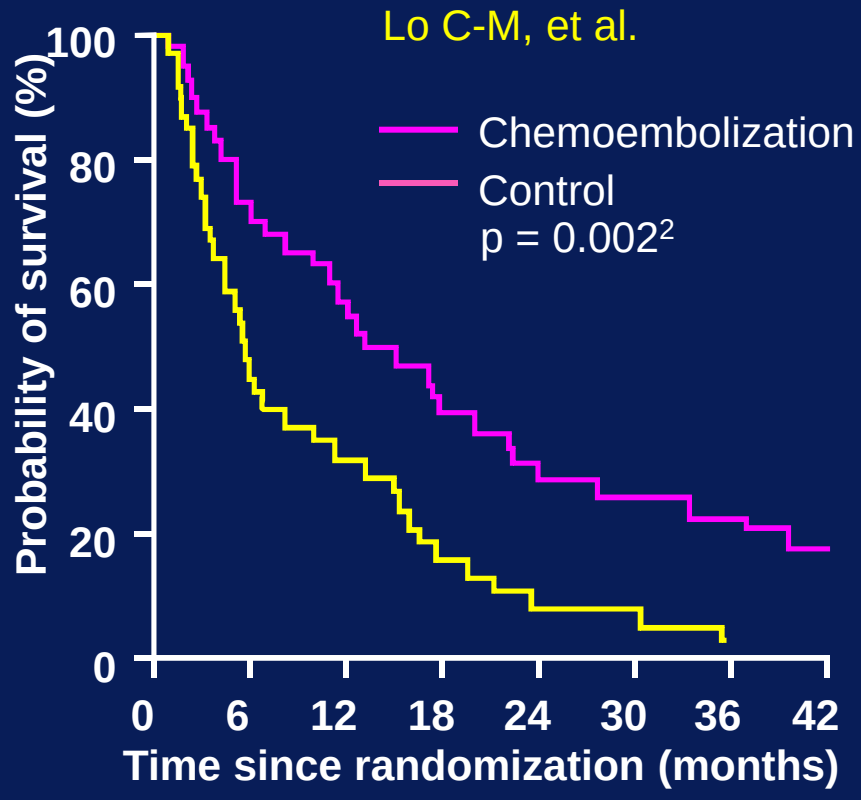
Not only a patient population, but also

TACE procedures are heterogeneous!

Overall survival in selected TACE studies

TACE: long-term survival outcomes are unsatisfactory

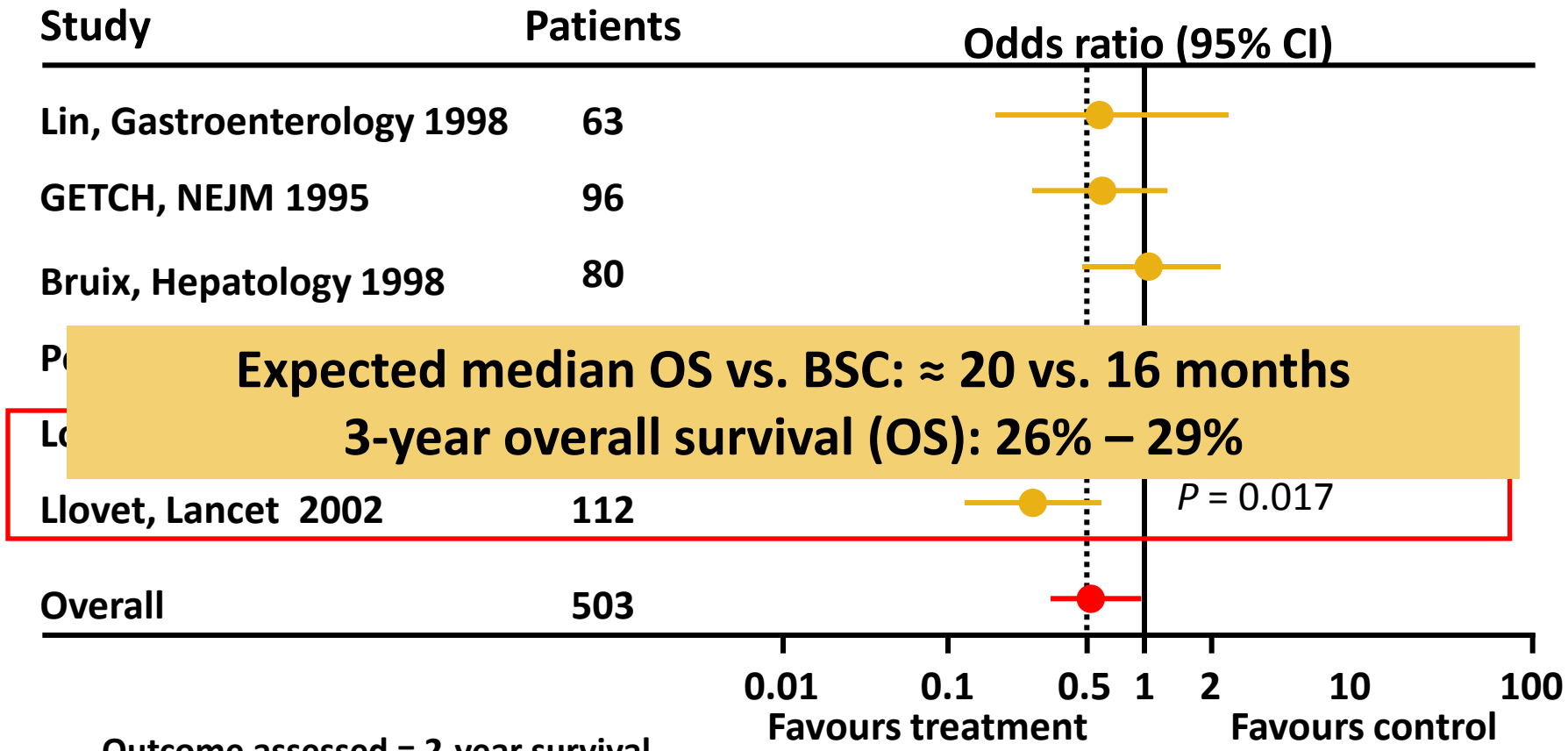




- 3-Year overall survival: 26%[2]–29%[1]
- Sustained objective response rate (3–6 months): 35%[1]–39%[2]
- No difference in survival of intention-to-treat population between non-responders and control[1]

1. Llovet JM, et al. Lancet. 2002;359:1734-9.
2. Lo C-M, et al. Hepatology. 2002;35:1164-71.

Meta-Analysis of TACE for HCC



Expected median OS vs. BSC: ≈ 20 vs. 16 months

3-year overall survival (OS): 26% – 29%

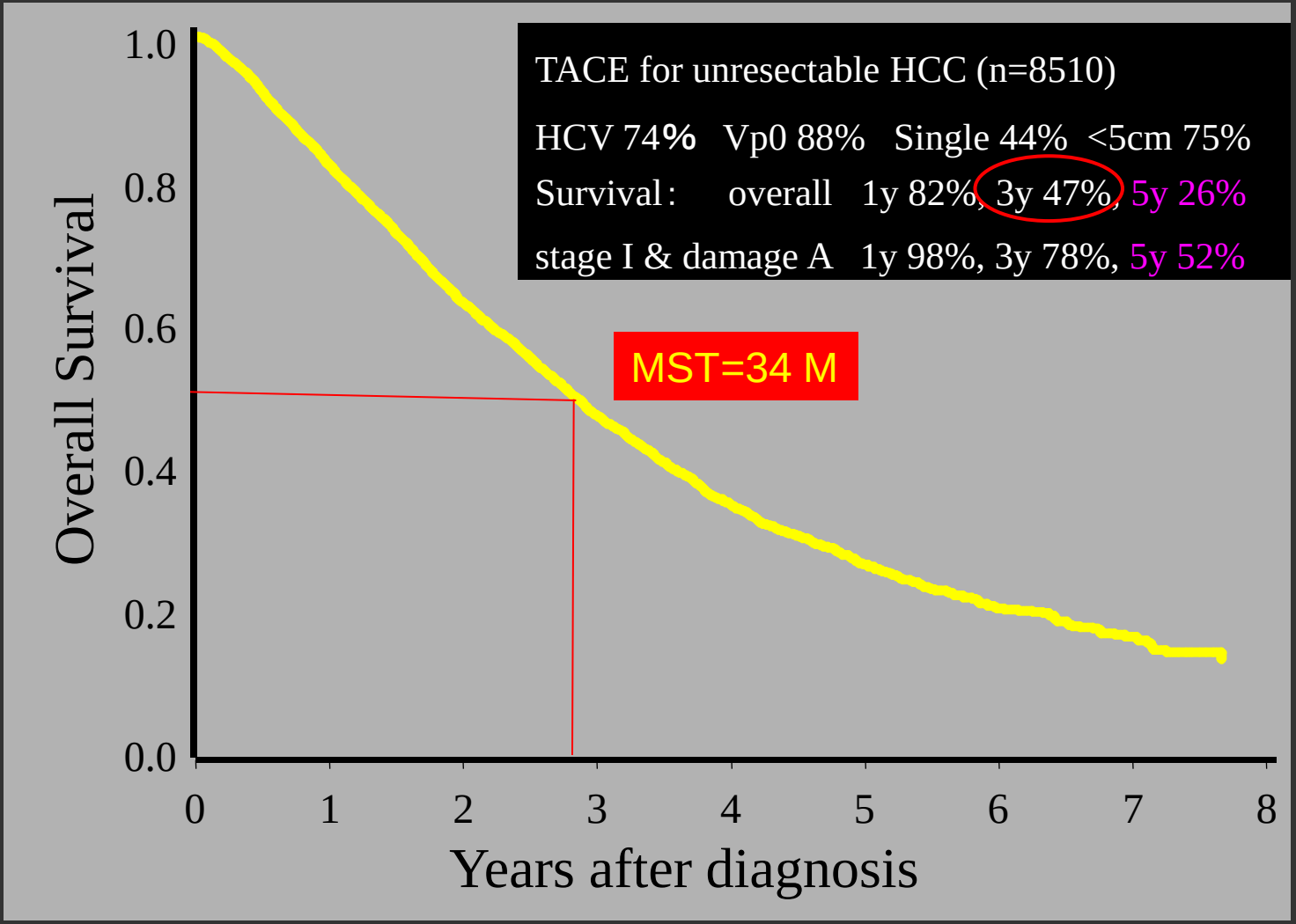
OR = 0.53 [95% CI, 0.32–0.89] *P* = 0.017

- Child-Pugh B <10 % of all patients
- Around 10% had tumor portal vein thrombosis
- In most trials no selective TACE

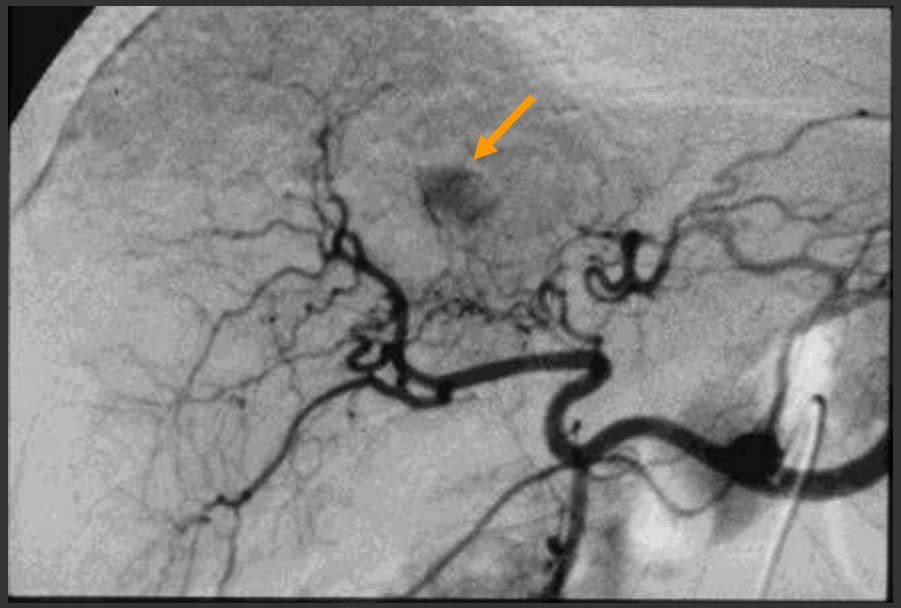
Llovet JM, et al. Lancet 2003; 362: 1907–1917

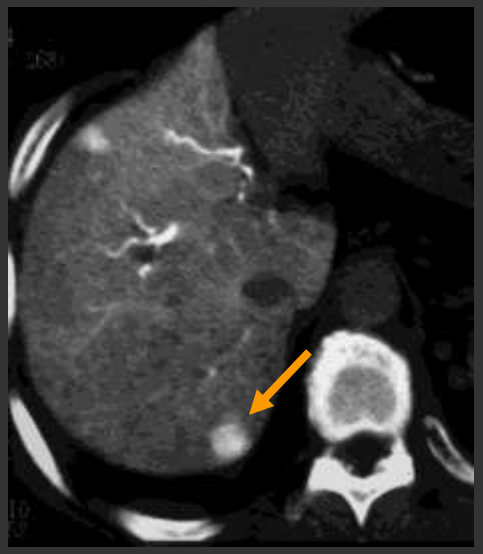
LCSGJ TACE Study

Takayasu K et al. Gastroenterology 2006



Targeted TACE with a superselective catheterization

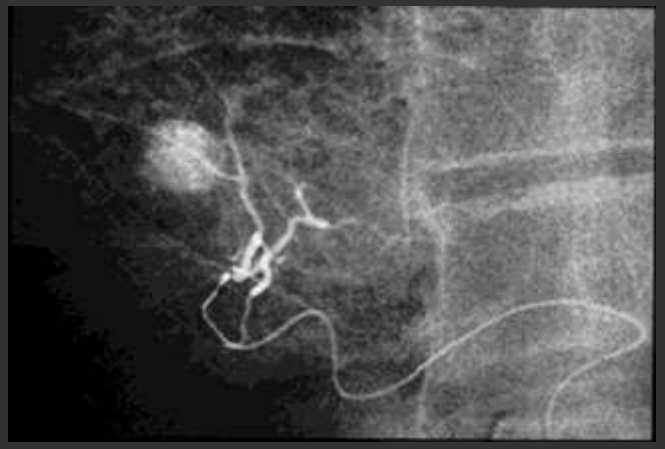




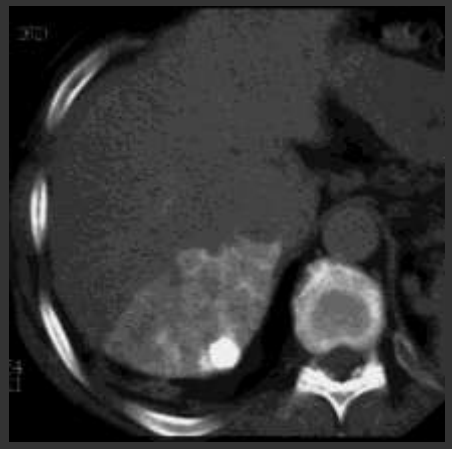
CTHA

HCC, 63F

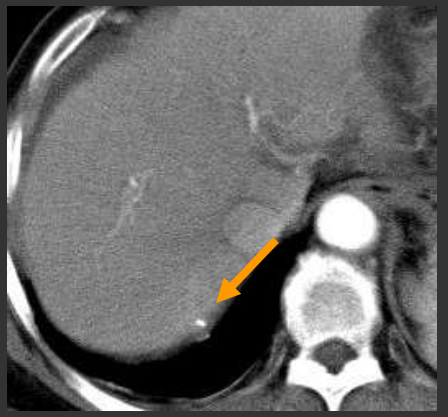
S7, 1cm,



A7, microcatheter

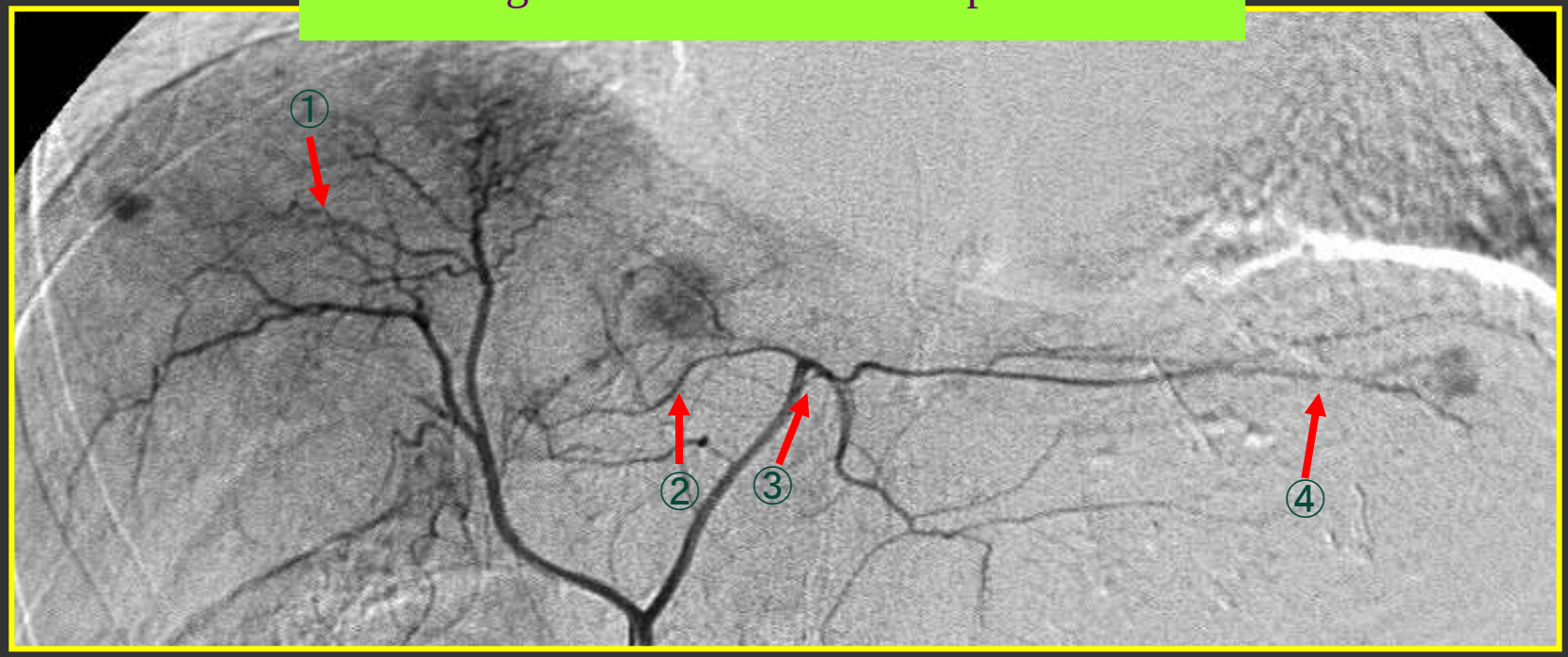


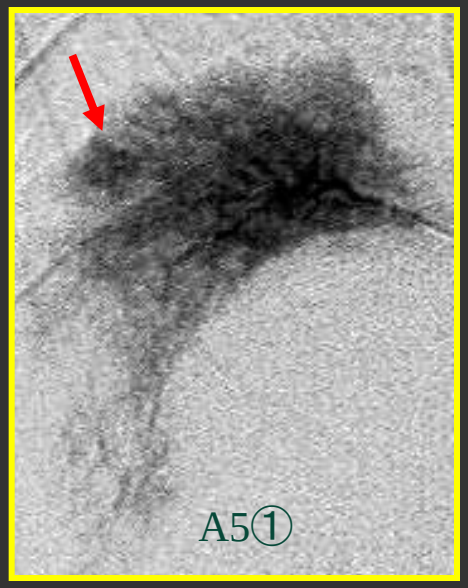
Lip CT

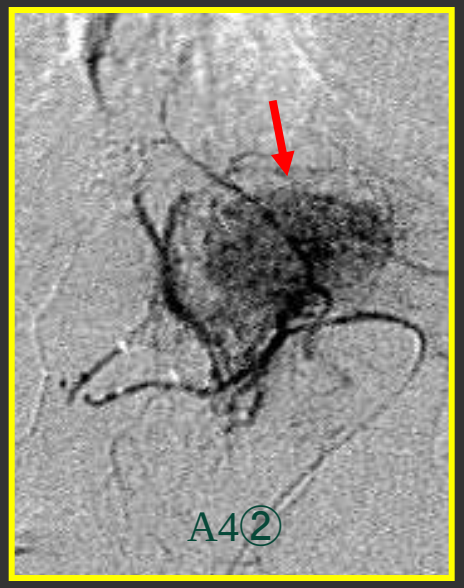


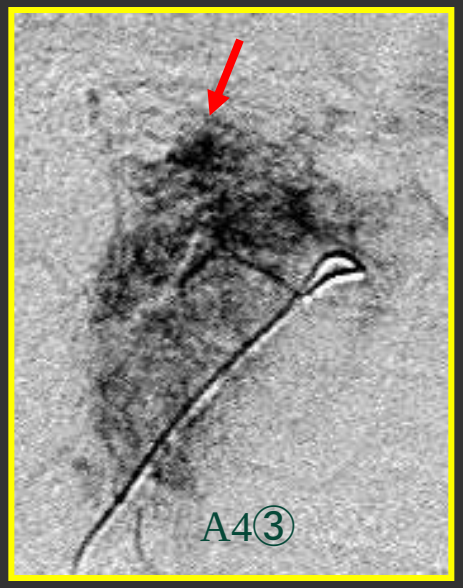
13mo, no local recurrence

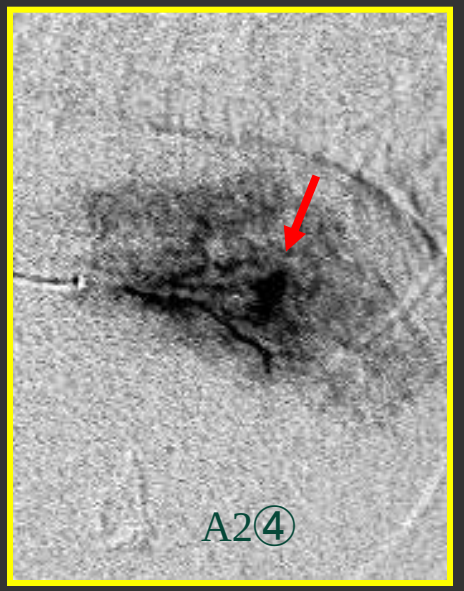
Subsegmental TACE for Multiple HCCs







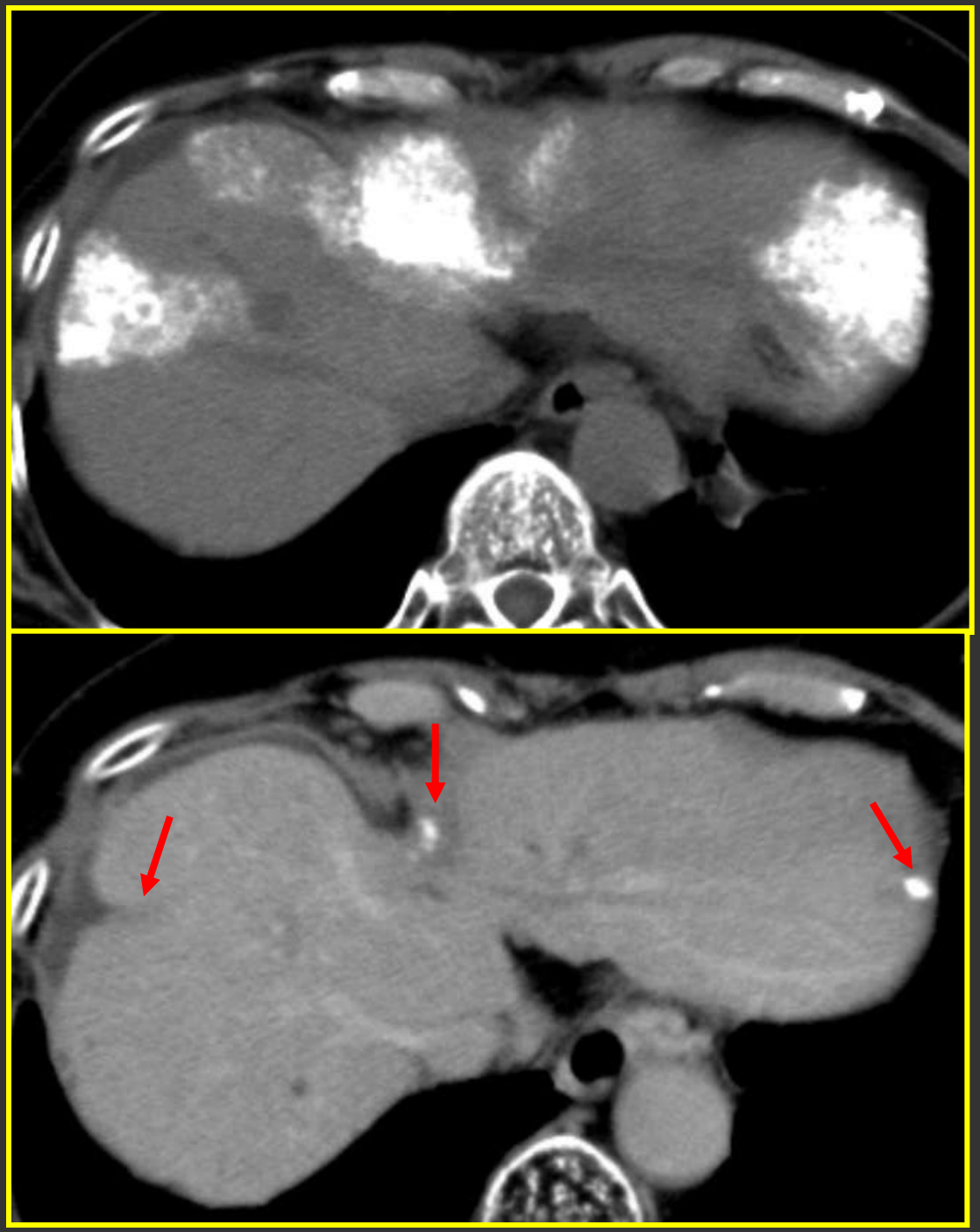




One week after multiple TACEs

Subsegmental TACE for Multiple HCCs

25 months after TACE



Formula for Successful TACE

Radiological tumor response↑

+

Preservation of liver function↑

=

Patient benefit (overall survival)↑

TACE, transarterial chemoembolization

So, how should we select patients for TACE ?

Who is unsuitable for TACE?

Reported absolute contraindications to TACE

Decompensated cirrhosis (Child-Pugh B ≥8) including:

- Jaundice
- Clinical encephalopathy
- Refractory ascites
- Hepato-renal syndrome

Extensive tumor with massive replacement of both entire lobes

Severely reduced portal vein flow (e.g. non-tumoral portal vein occlusion or hepatofugal blood flow)

Technical contraindications to hepatic intra-arterial treatment (e.g. untreatable arteriovenous fistula)

Renal insufficiency (creatinine ≥2 mg/dL or creatinine clearance <30 mL/min)

Reported relative contraindications to TACE

Tumor size ≥10 cm

Comorbidities involving compromised organ function:

- Active cardiovascular disease
- Active lung disease

Untreated varices at high risk of bleeding

Bile-duct occlusion or incompetent papilla due to stent or surgery

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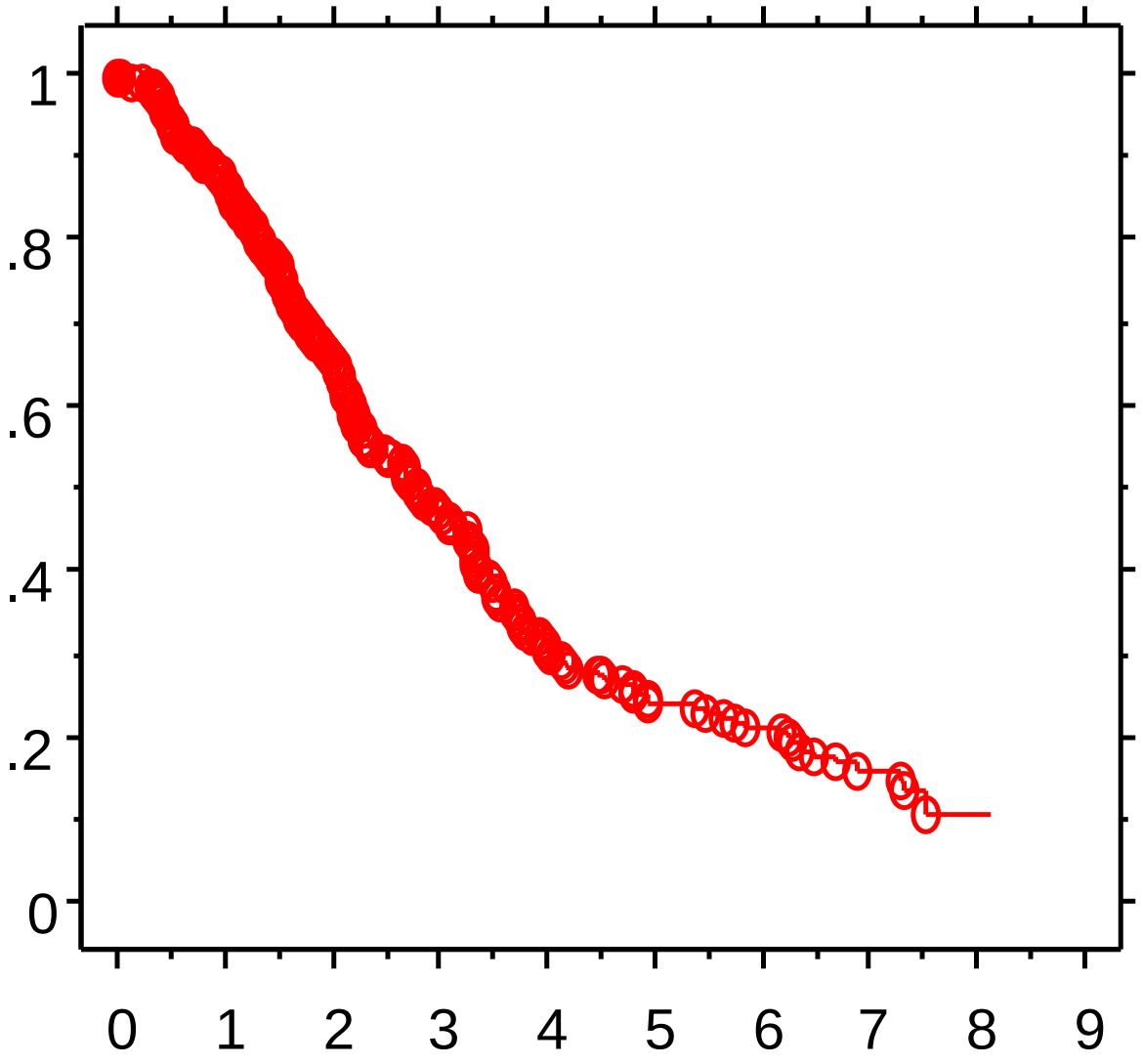
Raoul JL, et al. Cancer Treat Rev 2011; 37: 212–220

OS in All TACE Patients (n=325)



Yamakado K, et al. on behalf of the Japan TACE Study Group

Sub-classification of TACE Patients and Overall Survival

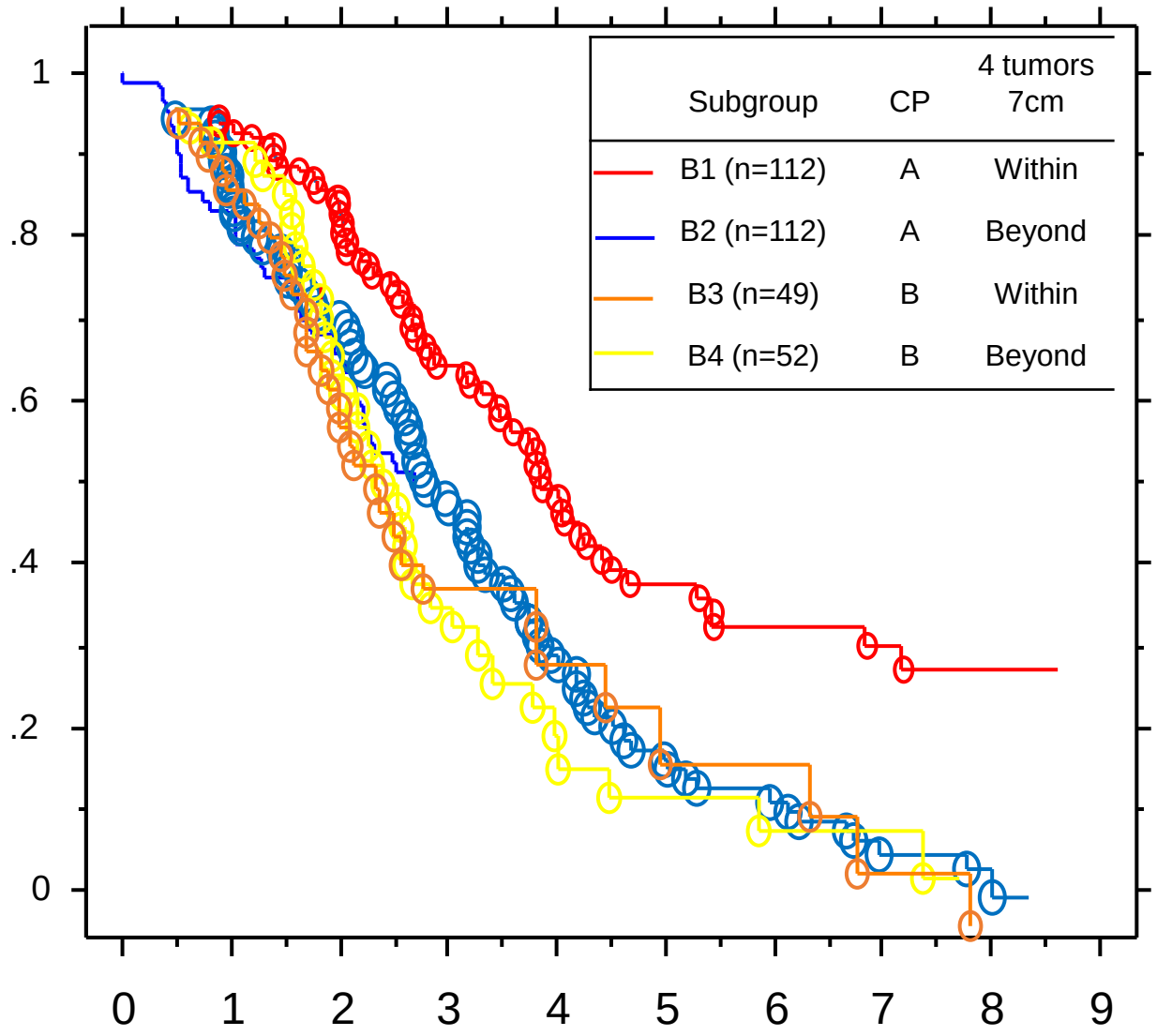
	standardised partial regression coefficient	P-value
≦4 tumors ≦7cm (within)	0.618	0.0008
Child-Pugh grade (A)	0.644	0.0036

Yamakado K, et al. on behalf of the Japan TACE Study Group

Subgrouping of Intermediate stage HCCs

Subgroup	CP	4 tumors 7cm
B1 (n=112)	A	Within (≤4 and ≤7cm)
B2 (n=112)	A	Beyond (>4 or >7 cm)
B3 (n=49)	B	Within (≤4 and ≤7cm)
B4 (n=52)	B	Beyond (>4 or >7 cm)

OS based on Child-Pugh grade and 4 tumor-7cm criterion



Yamakado K, et al. on behalf of the Japan TACE Study Group

Heterogeneity of Patients with Intermediate (BCLC B) Hepatocellular Carcinoma: Proposal for a Subclassification to Facilitate Treatment Decisions

Luigi Bolondi, MD[1] Andrew Burroughs, MBChBHons, FMedSci[2] Jean-François Dufour, MD[3]
Peter R. Galle, MD, PhD[4] Vincenzo Mazzaferro, MD[5] Fabio Piscaglia, MD, PhD[1]
Jean Luc Raoul, MD, PhD[6] Bruno Sangro, MD, PhD[7]

Semin Liver Dis 2012;32:348-359

Unanswered Questions Relating to Transarterial Chemoembolization

Schedules for Repeat Sessions and Stopping Transarterial Chemoembolization

Key Points of Unmet Clinical Needs of Intermediate Hepatocellular Carcinoma Patients

	Current Issues with BCLC staging for Intermediate HCC
1	The BCLC staging system does not account for the heterogeneity of the intermediate HCC population. This has both prognostic and therapeutic implications and hinders determining the best treatment algorithm. As in the early-stage HCC (BCLC stage A), a subclassification of intermediate HCC based on tumor burden and functional status is required.
2	ECOG PS is subjective, difficult to define, and does not discriminate between cancer-or cirrhosis-related symptoms.
3	TACE is the only recommended first-line treatment for intermediate HCC, although it does not seem to benefit all BCLC B patients. As a consequence, various other treatments are employed in the real world on an empirical basis, as first-line therapeutic alternatives for patients unsuitable for TACE or as second-line treatments.
4	Current recommendations for TACE in intermediate HCC are based on limited data derived from old studies lacking reliable prognostic characteristics and including both early-stage and advanced HCC patients.
5	TACE is not the optimal treatment for many patients with intermediate HCC. In some subgroups of intermediate HCC patients, there is an increased risk of major complications with TACE, which are further elevated repeated TACE sessions.
6	Liver resection and transplantation can produce long survival in well-selected patients with intermediate HCC (i.e., limited tumor burden, within the up-to-7 rule or after downstaging). Therefore, this treatment option should be considered for patients who have no extrahepatic contraindications for this procedure.
7	Sorafenib has shown to be effective and relatively well tolerated in patients with Child–Pugh class A status, both in the intermediate and advanced settings.
8	Deviations from current guidelines are very frequent in clinical practice. An efficient and evidence-based stratification of intermediate HCC patients may limit arbitrary decisions and make practice more consistent.

HCC, Hepatocellular carcinoma; BCLC, Barcelona Clinic Liver Cancer; TACE, transarterial chemoembolization.

Bolondi L et al., Semin Liver Dis 2012;32:348–359.

Refinement of BCLC classification

- Subclassification of intermediate HCC (B1–B4) has been proposed based on factors that influence allocation of patients to TACE or alternative treatment:
  - Major and minor tumor burden
  - Liver function by Child–Pugh score and class, presence/absence of jaundice and ascites
  - Presence of PVT
- The proposed subgroups are linked to suggested first-line and alternative treatment options
  - In practice, treatment selection should always be based on careful evaluation of individual patients' characteristics by a multidisciplinary team

PVT = portal vein thrombosis.

Bolondi L et al., Semin Liver Dis 2012;32:348–359.

Substaging and treatment indications for patients at first observation with intermediate hepatocellular carcinoma

BCLC Sub-Stage	B1	B2	B3	B4
CPT score	5-6-7	5-6	7	8-9*
Beyond Milan and within Ut-7	IN	OUT	OUT	ANY
ECOG (Tumor Related) PS	0	0	0	0-1
PVT	NO	NO	NO	NO
1st option	**TACE**	TACE or TARE		**BSC**
Alternative	LT TACE + ablation	SOR	Research trials TACE SOR	LT**

Bold letters mean stronger scientific evidence.
*, with severe/refractory ascites and/or jaundice;
** only if Up-to-7 IN and PS0;
BSC, best supportive care; LT, liver transplantation; SOR, sorafenib;
TARE, transarterial radioembolization

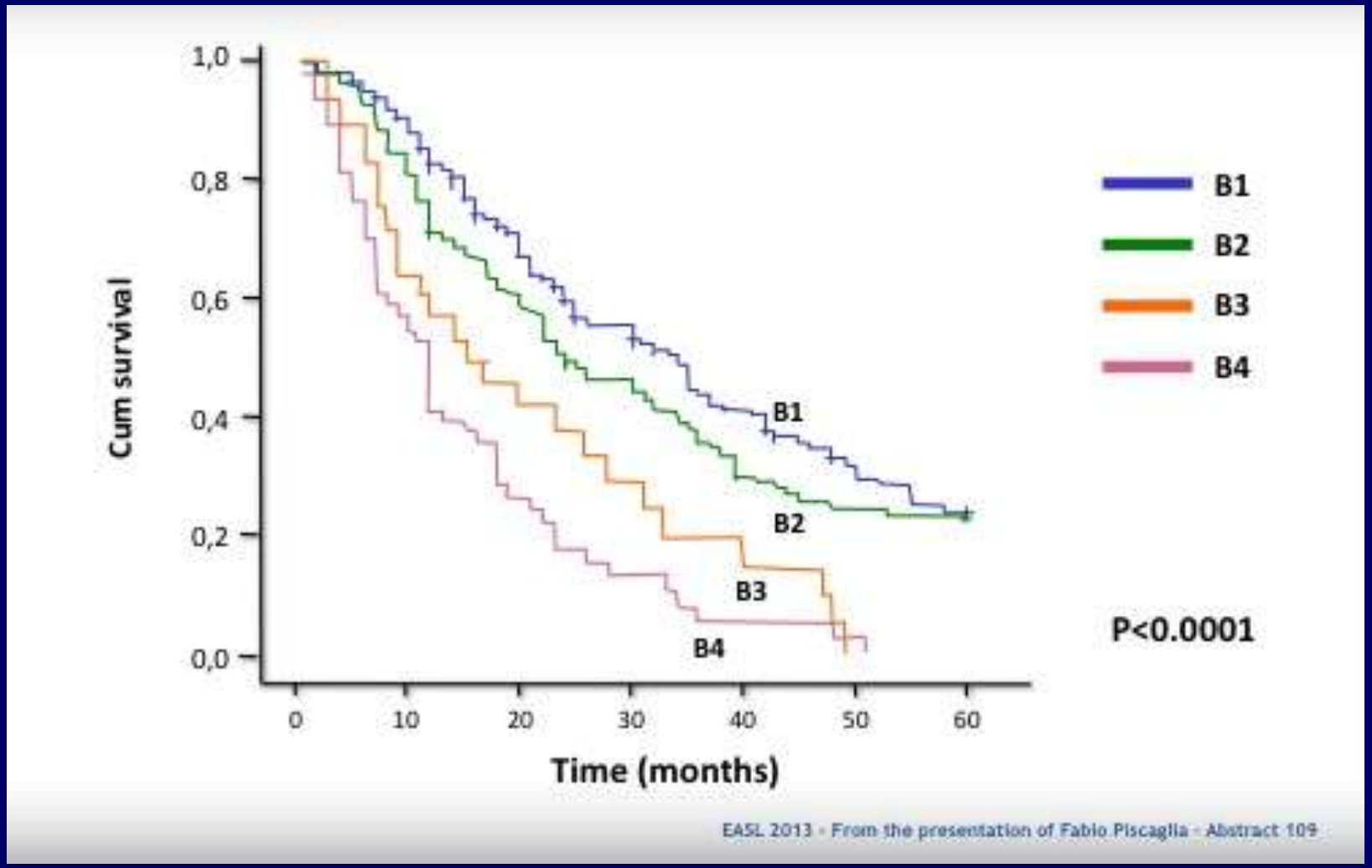
Bolondi L et al., Semin Liver Dis 2012;32:348–359.

Clinical Validation of a sub-staging proposal of patients with intermediate HCC (BCLC-B)

F. Piscaglia, A. Pecorelli, L. Venerandi, F. Farinati, P. Del Poggio, G. Rapaccini, M.A. Di Nolfo, L. Benvegnu, M. Zoli, F. Borzio, E. G. Giannini, E. Caturelli, M. Chiaramonte, F. Trevisani, L. Bolondi, for the ITALICA Study Group

F. Piscaglia et al., oral presentation at EASL 2013, Abst. No.O-109

Results. Survival



F. Piscaglia et al., oral presentation at EASL 2013, Abst. No.O-109

VALIDATION OF SUB-STAGING CLASSIFICATION OF PATIENTS WITH INTERMEDIATE HEPATOCELLULAR CARCINOMA (BCLC-B) TREATED WITH CONVENTIONAL TRANSARTERIAL CHEMOEMBOLIZATION

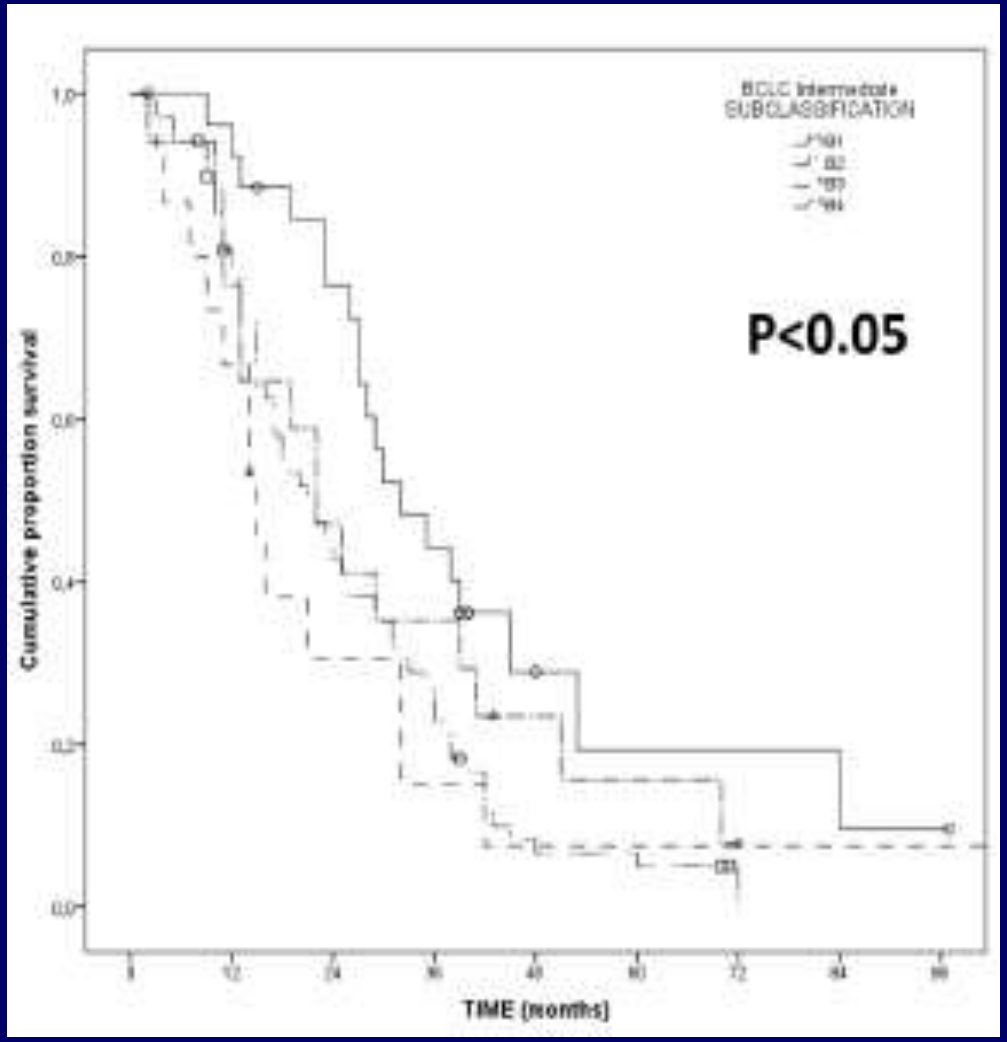
MARCO BIOLATO, ANDREA ZANCHE, VITTORIA VERO, SUMONA RACCO, ELEONORA B. ANNICCHIARICO, MASSIMO SICILIANO, MAURIZIO POMPILI, GIAN LUDOVICO RAPACCINI, ANTONIO GASBARRINI, ANTONIO GRIECO.

Hepatology Unit, Catholic University of Sacred Heart, Rome, Italy

Biolato M et al., poster presented at the 64th annual meeting of AASLD (2013)

RESULTS

- Mean overall survival of whole population was 31.5 months (95% C.I. 25 9-37.0).
- Number of patients in BCLC subgroup was
  - B1 = 27,
  - B2 = 69,
  - B3 = 15,
  - B4 = 17.
- Each stage appeared associated with different median overall survival ($p < 0.05$ between groups), namely
  - B1 = 32.0 months (95% C.I. 22.3-41.7)
  - B2 = 21.0 months (95% C.I. 15.5-26.5)
  - B3 = 15.0 months (95% C.I. 10.5-19.5)
  - B4 = 22.0 months (95% C.I. 13.9-30.0)
- The 3-years survival were:
  - B1 = 44.2 %
  - B2 = 22.9 %
  - B3 = 15.2 %
  - B4 = 35.3 % ($p<0.05$).



Biolato M et al., poster presented at the 64th annual meeting of AASLD (2013)

DISCUSSION / CONCLUSION

- The new substaging proposal is able to refine prognosis of intermediate patients with HCC treated with conventional TACE.

- The prognosis of patients in B2-B3 seems to related mainly on the tumor burden while that of patients in B4 on the underlying cirrhosis, so further studies are needed to confirm the actual prognostic gradient of these substages.

Biolato M et al., poster presented at the 64th annual meeting of AASLD (2013)

Outline

- What is Intermediate Stage HCC?
- Guideline: TACE for Intermediate Stage HCC
- Clinical Practice is Different
- Intermediate Stage HCC is a Heterogeneous Disease
- What should We Treat after TACE Failure or Refractoriness
- Summary and Conclusion

Definition of TACE Failure/Refractoriness

- JSH Definition (Kudo M. Dig Dis 2011)
- Park's Definition (Kim, Park. JGH 2011)
- Raoul's Definition (Raoul. Cancer Treat Rev. 2011)
- ART Score (Sieghart, Peck. Hepatology 2013)

HEPATOLOGY
Official Journal of the American Association for the Study of Liver Diseases

The ART of Decision Making: Retreatment With Transarterial Chemoembolization in Patients With Hepatocellular Carcinoma

Wolfgang Sieghart,[1]* Florian Hucke,[1]* Matthias Pinter,[1] Ivo Graziadei,[2] Wolfgang Vogel,[2] Christian Müller,[1] Harald Heinzl,[3] Michael Trauner,[1] and Markus Peck-Radosavljevic[1]

ART-score: Assessment for Retreatment with TACE

The ART score differentiated two groups (0-1.5 points; ≥2.5 points) with distinct prognosis (median OS: 23.7 versus 6.6 months; $P < 0.001$) and a higher ART score was associated with major adverse events after the second TACE ($P = 0.011$). These results were confirmed in the external validation cohort and remained significant irrespective of Child-Pugh stage and the presence of ascites prior the second TACE. *Conclusion:* An ART score of >2.5 prior the second TACE identifies patients with a dismal prognosis who may not profit from further TACE sessions. (HEPATOLOGY 2013;57:2261-2273)

The ART-Score to Predict Poor Survival after first TACE

Assessment for Retreatment with TACE: the ART score

- Developed by multivariate regression analysis of
  - baseline characteristics
  - radiological response after 1st TACE (EASL-response criteria)
  - changes of liver function after the 1st TACE
- Determined prior to 2nd TACE in BCLC-A*/B patients, who received ≥ 2x TACE
- Training cohort: n=107 (Vienna), validation cohort: n=115 (Innsbruck)

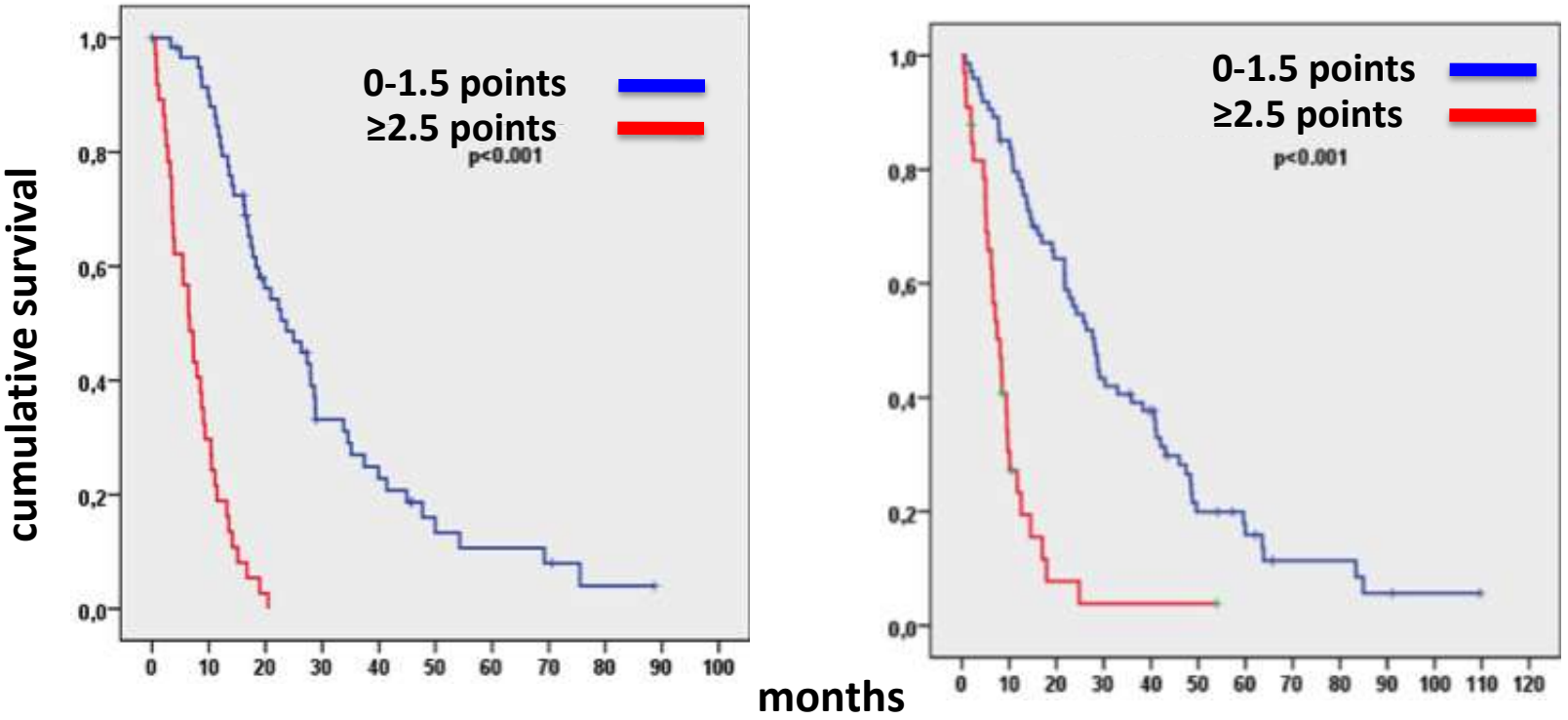
ART score category	**Points**
Absence of radiological tumour response	1 (0 if present)
AST increase >25%	4 (0 if absent)
Increase in CP score by 1 point	1.5 (0 if absent)
Increase in CP score by ≥2 points	3 (0 if absent)

*BCLC-A not suitable for liver transplantation/local ablative treatment

AST, aspartate transaminase; BCLC, Barcelona Clinic Liver Cancer; CP, Child–Pugh; EASL, European Association for the Study of the Liver; TACE, transarterial chemoembolization

Sieghart W et al. Hepatology 2013 Jan 12. doi: 10.1002/hep.26256

ART score validation



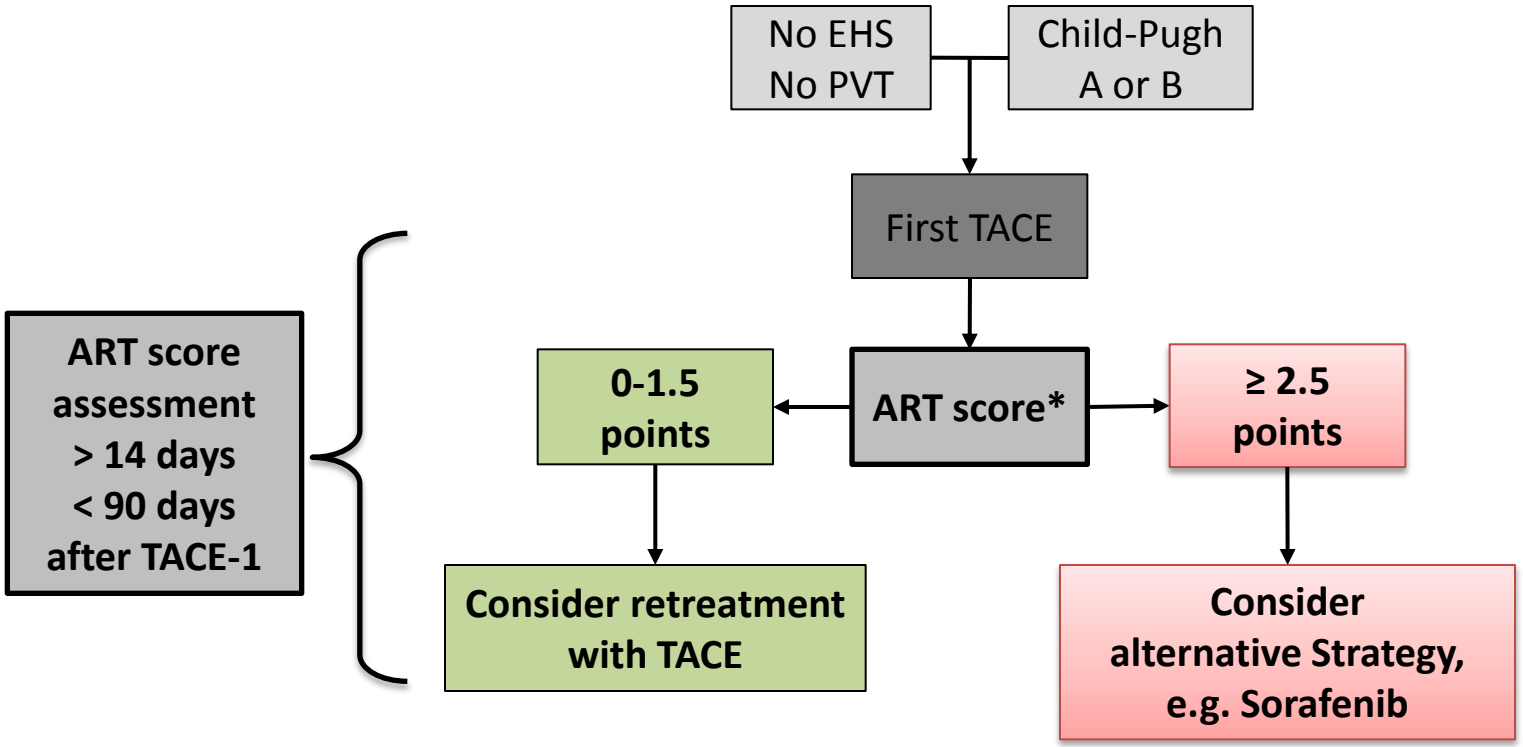
Training cohort

ART-Score
0-1.5: (n=60): 23.7 months (CI: 16-32)
≥ 2.5: (n=37): 6.6 months (CI: 5-9)
P=0.001

Validation cohort

ART-Score
0-1.5: (n=74): 28 months (CI: 23-33)
≥ 2.5: (n=37): 8.1 months (CI: 6-11)
P=0.001

Proposed ART-Score based Re-treatment Strategy for TACE



*

ART-score		Points	
Absence of radiologic tumor response		1	(0 if present)
AST increase >25%		4	(0 if absent)
Child Pugh score increase	1 point	1.5	(0 if absent)
	≥ 2 points	3	(0 if absent)

ART Score for Repeated Transarterial Chemoembolization in Patients with Hepatocellular Carcinoma

ART Score does not work for Japanese patients , who had repeated TACE

Kudo M, et al. Hepatology 2013 Epub Ahead of Print

A Total Numbers of Patients with Repeated TACE (2004.1.1 – 2011.12.31)

A total number of TACE	n=779
TACE : 2 or more	n=513

≤90 days	49	9.6%
≤120 days	129	25.1%
≤150 days	173	33.7%
≤180 days	214	41.7%
≤210 days	242	47.2%
≤240 days	266	51.9%
≤270 days	289	56.3%
≤300 days	306	59.6%

ART score	n
0	4
1	27
1.5	1
2.5	3
4	3
5	4
5.5	1
8	1
Unknown	5

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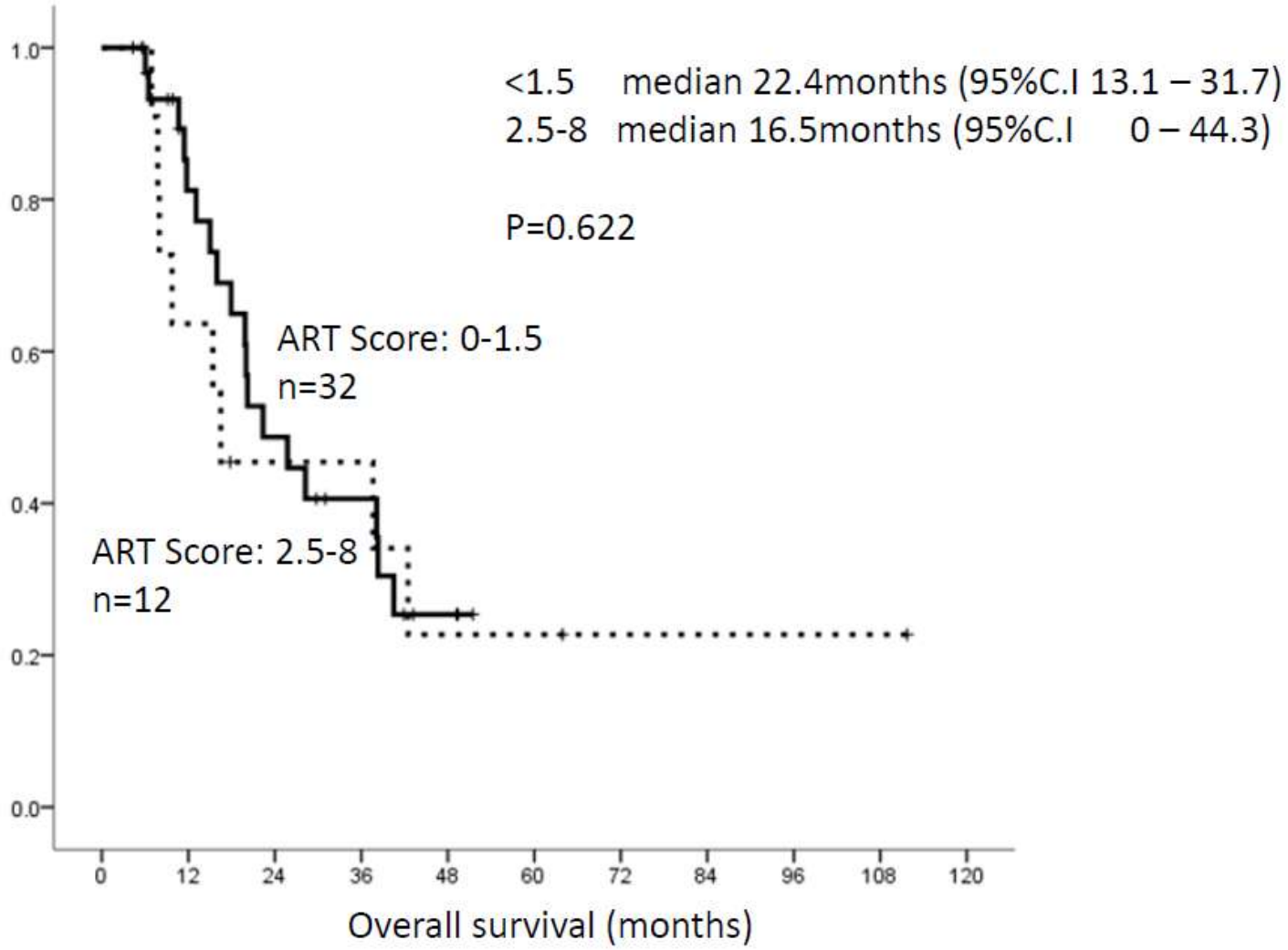
Overall Survival According to ART Score



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Limitation of ART Score as a Measure of TACE Refractoriness

- ART score can be applied only in < 10% of patients with repeated TACE in validation study.
- ART score did not have any impact on survival in patients with 2nd TACE within 90 days.
- ART score is not useful as a measure of TACE refractoriness since it is only applied to the patients who received 2nd TACE within 90 days.
- ART score is not universally applicable point system and not the definition of actual TACE refractoriness after several repeated TACE procedure.

Summary and Conclusion

- TACE is basically recommended for Intermediate stage HCC according to Guideline
- However, since intermediate stage HCC is a heterogeneous patient population, several treatment options are applied in the real world clinical setting
- Sub-staging of intermediate stage HCC is an urgent clinical needs
- Definition of TACE failure/refractoriness is also an important issue in intermediate stage HCC, but has not yet been established.


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Approach to HCC
4th
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