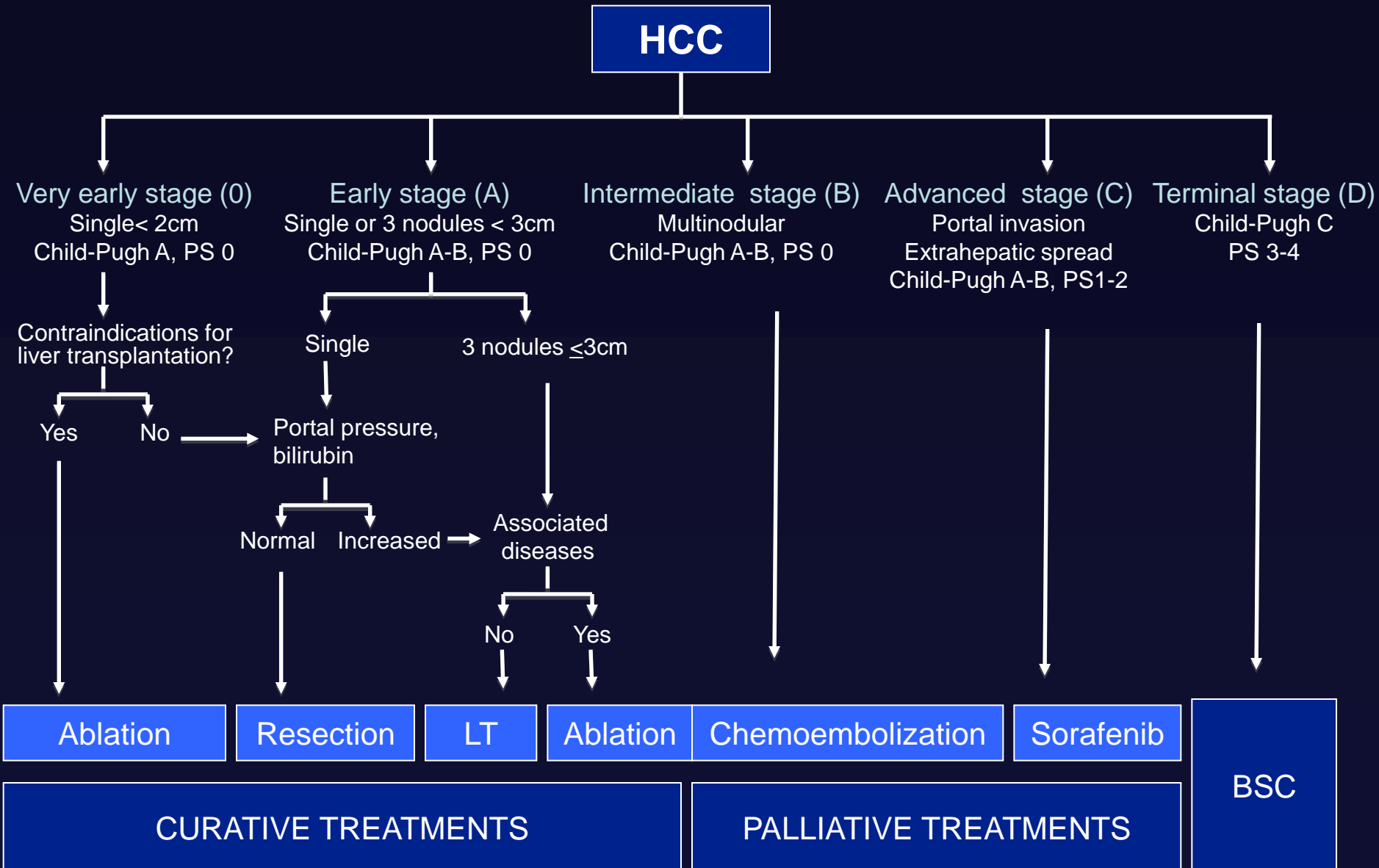


4 YEARS SURVIVAL OF 100 HCC PATIENTS TREATED WITH DC BEAD: A RETROSPECTIVE ANALYSIS

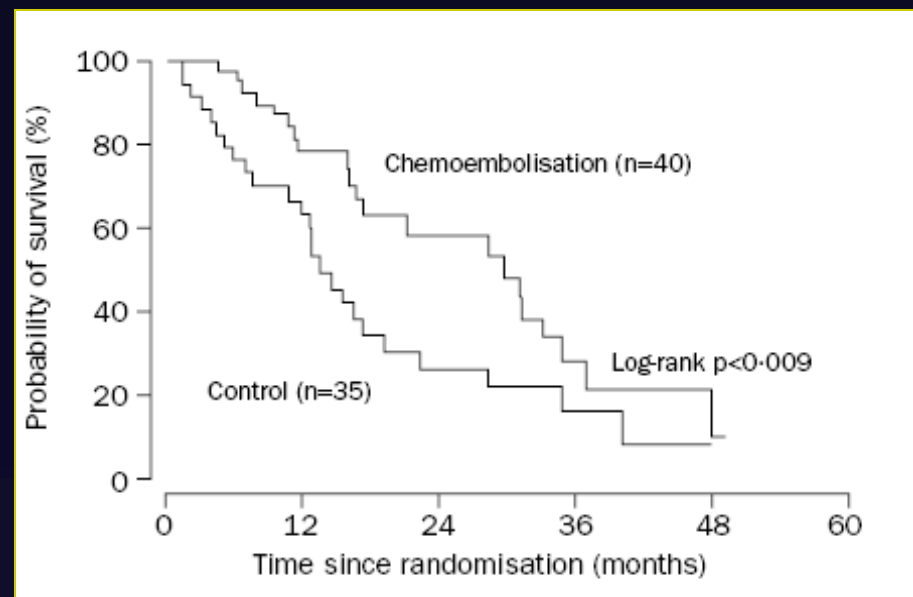
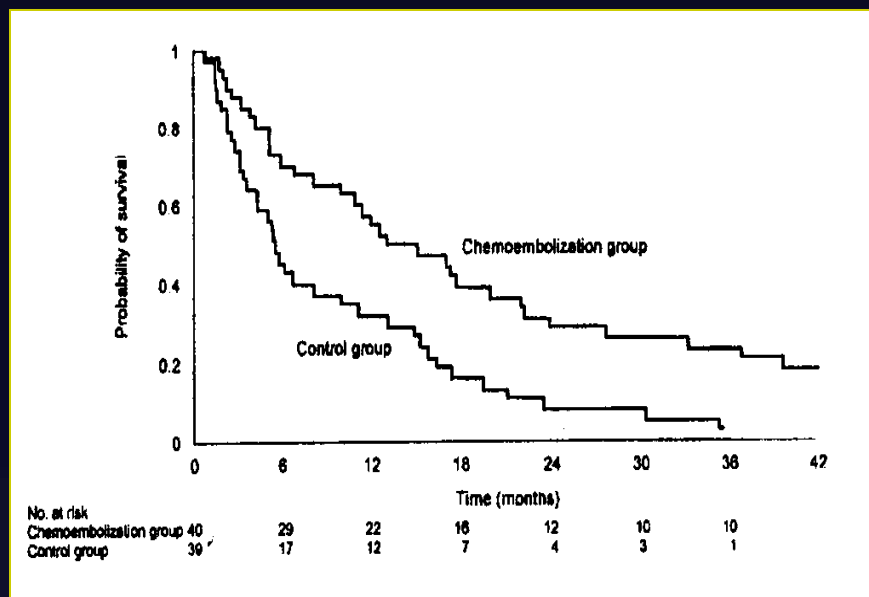
Marta Burrel
Vascular Interventional Unit
Barcelona Clinic Liver Cancer Group (BCLC)
Hospital Clínic, Barcelona



BCLC Staging and Treatment Strategy, 2011



Lipiodol TACE improves survival in a selected group of HCC patients



Survival probability

	TACE	Control
1 year	57%	32%
2 years	31%	11%

Survival probability

	TACE	Control
1 year	82%	63%
2 years	63%	27%

35% objective response \geq 6 months
Independent prognostic factor

Cumulative meta-analysis of 6 RCT: TACE vs control

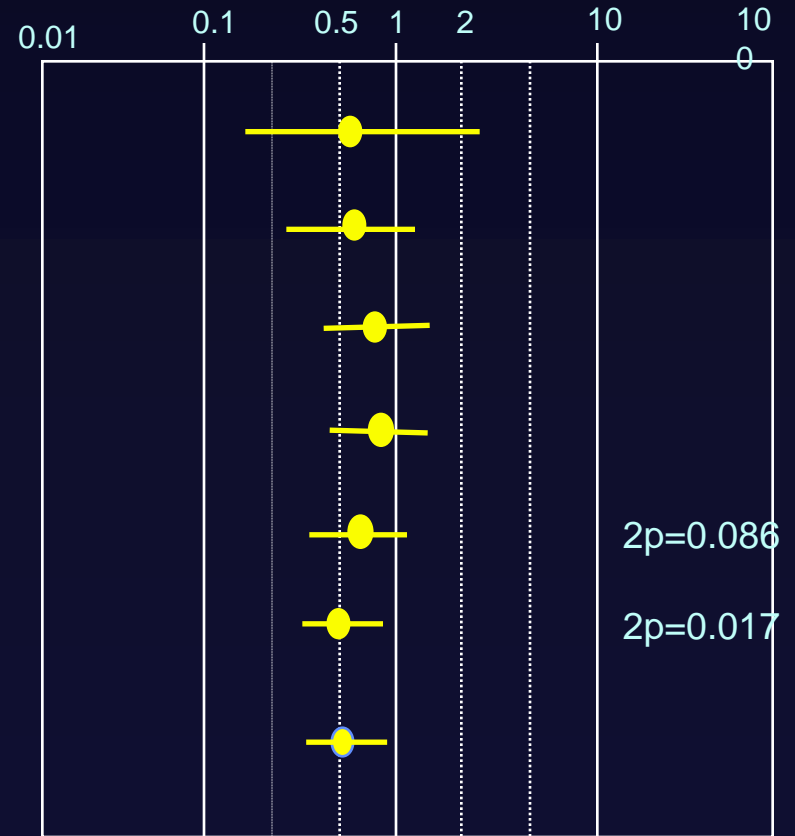
Median survival : ~ 20 months

Author, Journal year Cumulative (pts)

Lin , Gastroenterology 1988	63
GETCH, NEJM 1995	159
Bruix , Hepatology 1998	239
Pelletier, J Hepatol 1998	312
Lo, Hepatology 2002	391
Llovet, Lancet 2002	112
OVERALL	503

Heterogeneity: Q:7.73 P=0.14

Random effects model (DerSimonian & Laird).OR (95% IC)



Favors treatment

Favors control

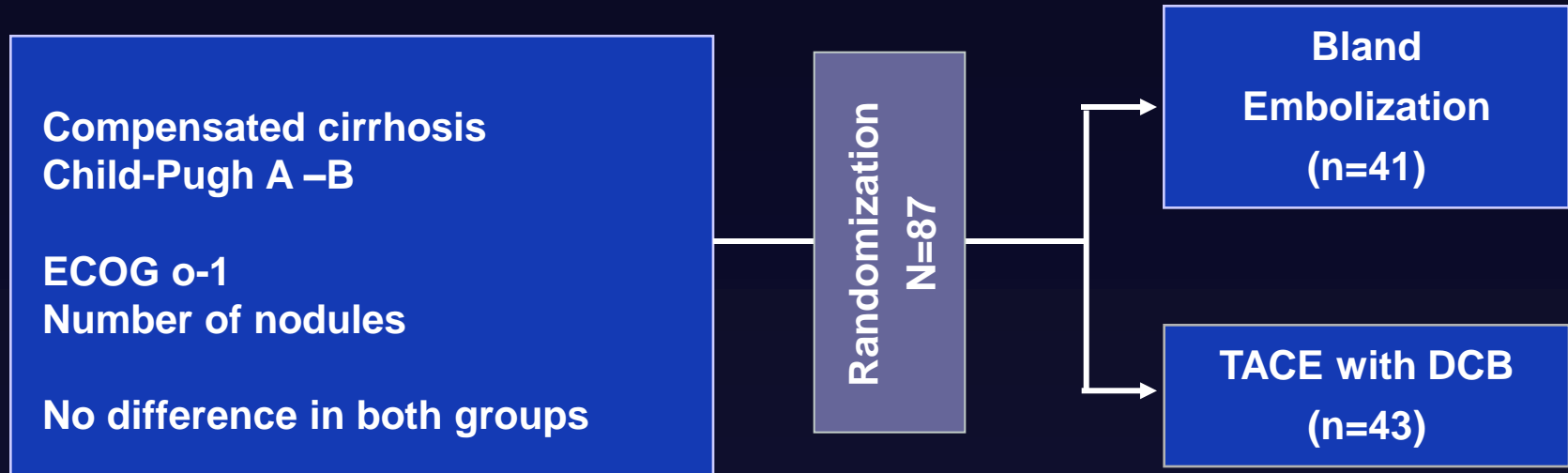
Cohort studies with TACE-DC Beads



- . Improved Objective Response
- . Better tolerance

	Varela 2007 <i>J Hepatology</i>		Poon 2007 <i>Clin Gast Hepatol</i>		Malagari 2008 <i>CVIR</i>		
# patients	27		35		62		
Tumor size (mm)	46 (8-150)		76 (25-220)		56 (30-90)		
Tumor response	CR 29% PR 75% OR (IT) 66,6%		CR 14,3% OR 42,9%		CR 12,2% OR 80,7%		
Survival (months)	12 m 92,5%	24 m 88,9%			12 m 97%	24 m 91%	30 m 88%

Chemoembolization vs Bland Embolization



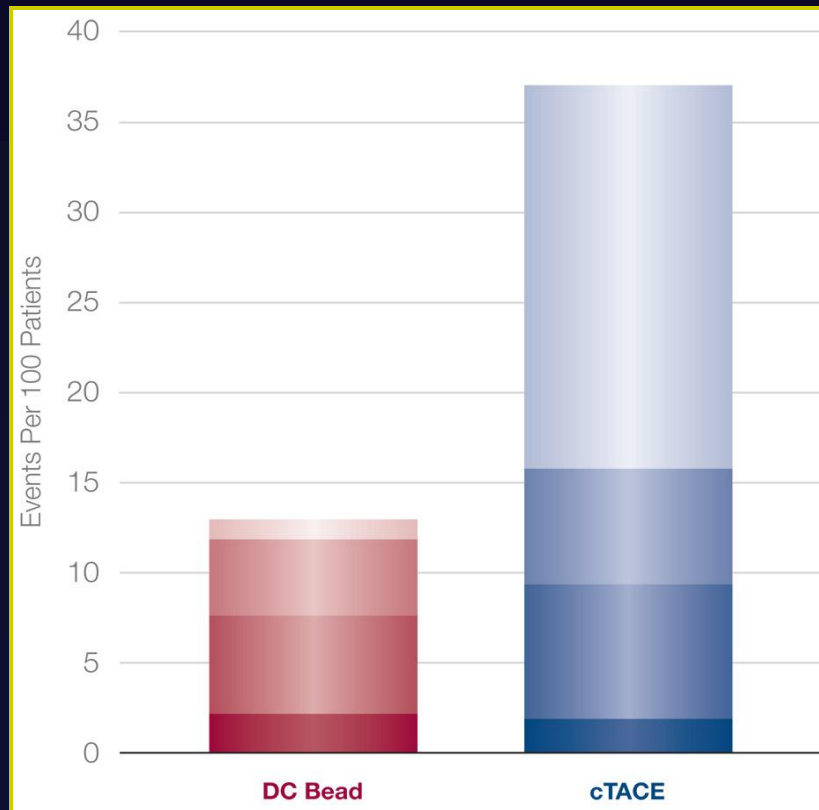
TACE-DEB better than Bland Embolization

- Local response. Overall Response (p=0.04)
- Fewer recurrence at 9 months (p=0.002)
- Longer TTP (p=0.008)

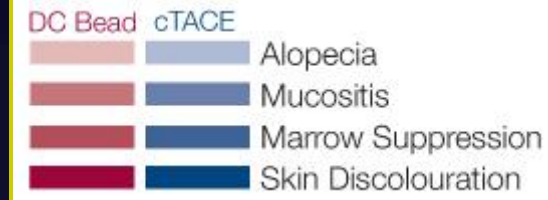
Lipiodol TACE vs TACE-DC Beads

Randomised Multiinstitutional Study: Precision V Trial

- . End Point: Negative
- . Significant better tolerance



Doxorubicin-Related Side Effects:



Phase II trial (Precision I): Conclusion in 2007

- **DEB-TACE is effective and safe (caution with abscess) for the treatment of HCC.**
- **Pharmacokinetic profile is favorable with reduced systemic exposure.**

Summary.-

DEB TACE is potentially superior to conventional TACE.

How should this be proven?

Should DCBeads be reimbursed?

**SURVIVAL DATA AFTER TACE IN PATIENTS
WITH HEPATOCELLULAR CARCINOMA (HCC) IN 2010:
IMPACT ON CLINICAL PRACTICE AND RESEARCH**

OBJECTIVES

- Evaluate the survival of HCC patients treated with TACE-DEB following a strict selection (preserved liver function, absence of cancer related symptoms, extrahepatic spread or vascular invasion)
- Evaluate causes of untreatable progression (UTP)

PATIENTS AND METHOD

HCC patients treated by TACE-DEB between February 2004 and June 2010

Retrospective review of:

- baseline characteristics
- development of treatment related adverse events
- overall survival

RESULTS

- 104 patients evaluated
- Median follow up 23.5 months (2.6-79.6)
- At the time of evaluation
 - 31 patients had died
 - 2 had received transplantation
 - 25 under treatment with Sorafenib because of progression not amenable for TAC
 - 1 under treatment with Intra-arterial Radiotherapy (contraindication for Sorafenib)

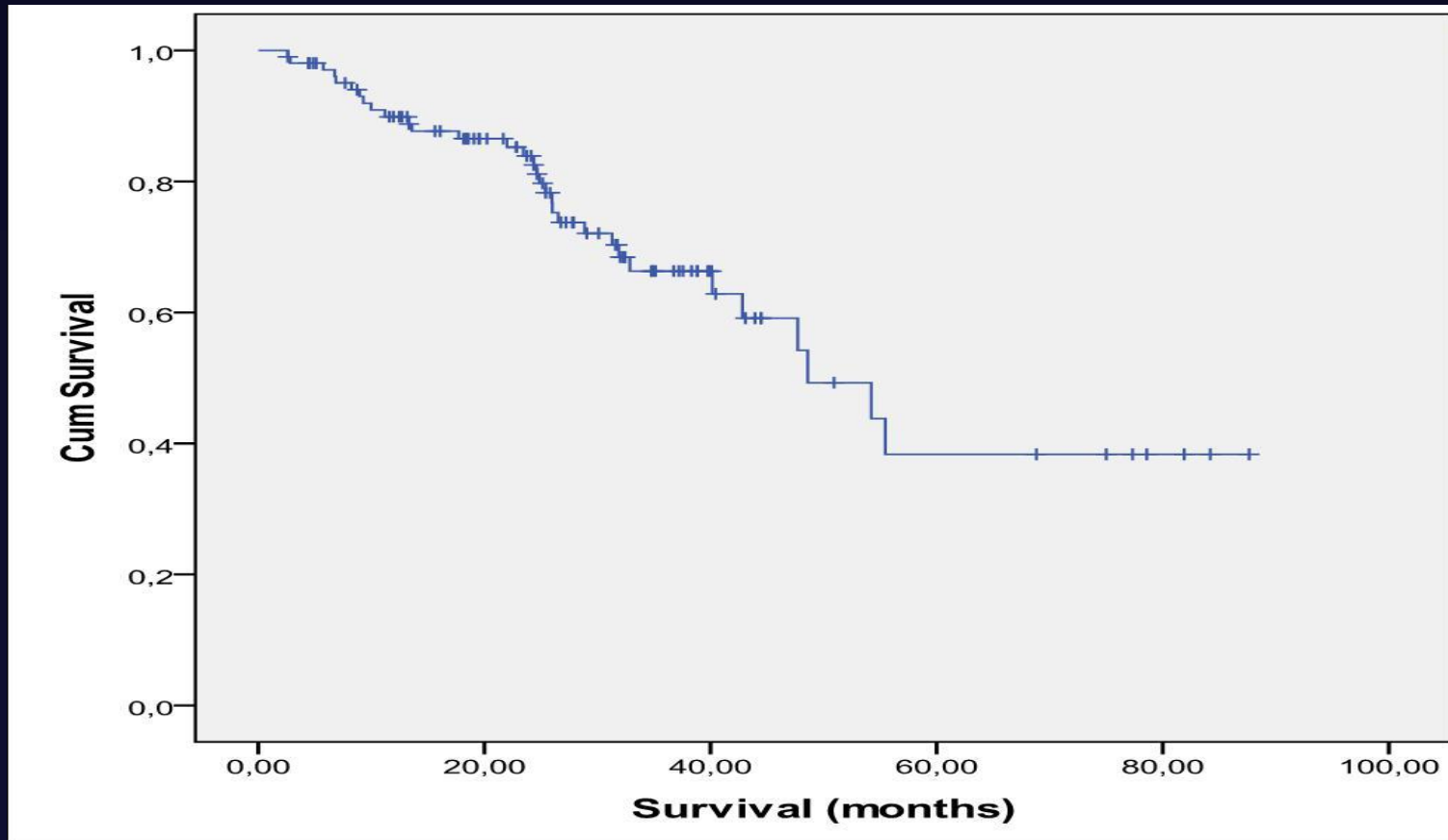
Results: Characteristics of patients

	Total cohort (n=104)	BCLC A (n=41)	BCLC B (n=63)	p
Age, median	68.2 [34-81]	68.2 [42-81]	66.1 [34-81]	ns
Male/Female, n	89/15	33/8	56/7	ns
Child-Pugh A/B, n	99/4*	40/1	59/3*	ns
BCLC, A/B, n	41/63	41/0	0/63	NA
Perf. status, 0 /1, n	104/0	41/0	63/0	ns
Prothr. time (%)	84 [55-100]	83 [55-100]	88 [57-100]	0.02
Bilirubin, (mg/dL)	0.95 [0.1-2.8]	1.1 [0.4-2.8]	0.85 [0.1-2.4]	ns
Albumin,, (g/dL)	41 [29-64]	40 [31-47]	42 [29-64]	ns
Creatinine, (g/dL)	0.9 [0.6-1.6]	0.9 [0.6-1.4]	0.9 [0.7-1.6]	ns
AFP, (IU/mL)	16 [1-78847]	12 [2-2422]	19.5 [1-78847]	ns

* One patient without cirrhosis

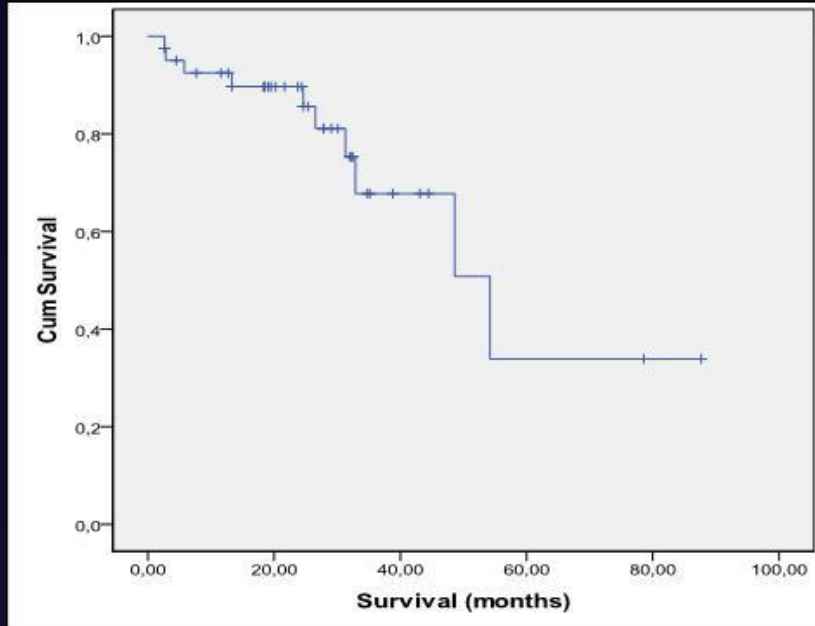
Results: Survival

Median whole cohort survival (n=104):
48.6 months (95% CI: 36.6-58.8)

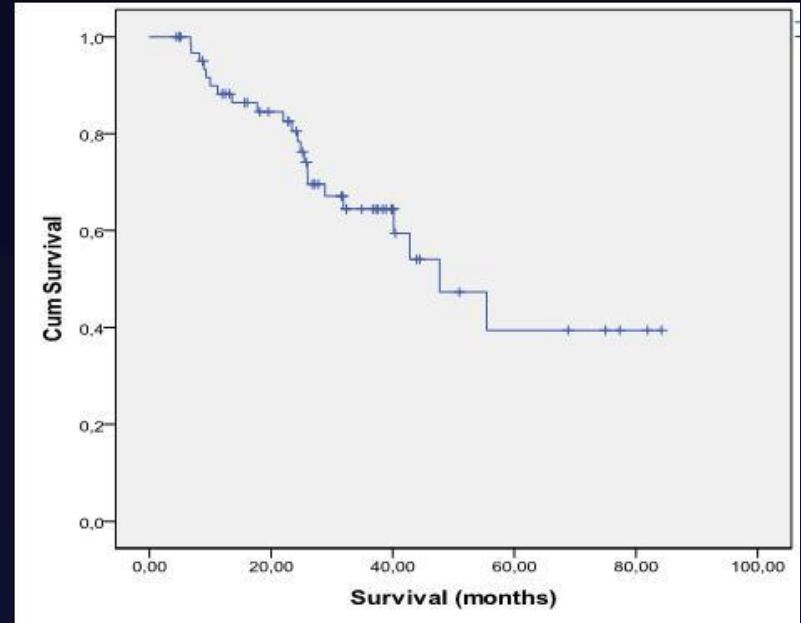


Results: Survival

BCLC A (n=41)



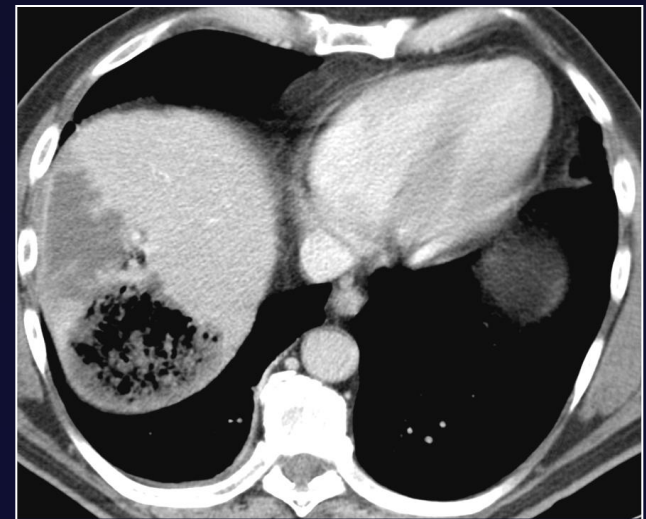
BCLC B (n=63)



OS 54.2 months (CI95%: 32.3 – 76.15) OS 47.7 months (CI 95%: 32.7- 62.7)

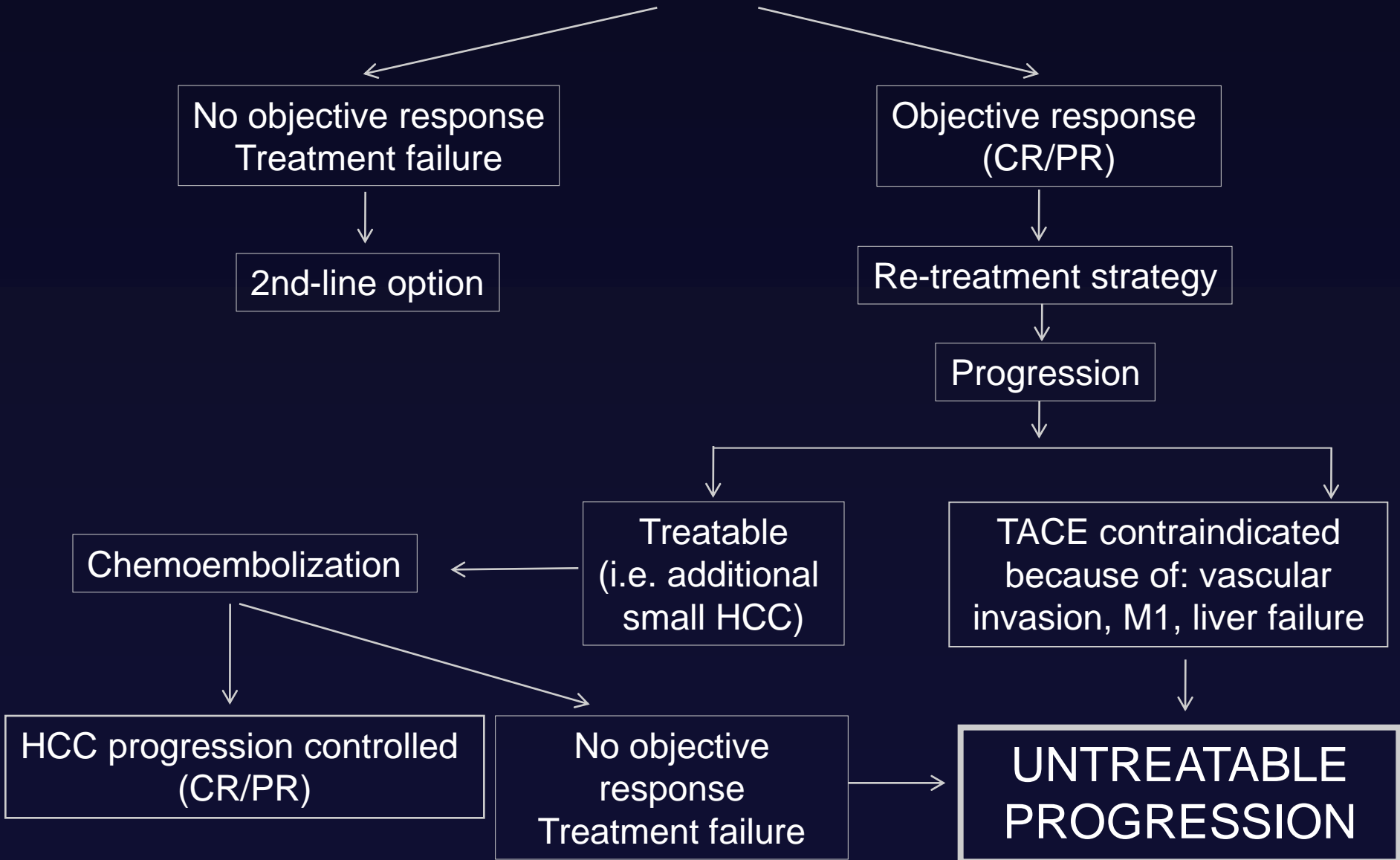
Results: Complications (n=104 patients)

Early (<1 month)	6
• Abscess	1
• Ischemic cholecystitis	1
• Subcapsular hematoma	1
• Severe pain	1
• Pancreatitis	1
• Hepatic artery dissection	1
Late (>1 month)	4
• Hepatic artery dissection	1
• Biliary dilatation	1
• Abscess	2
Related death (abscess)	1



The untreatable progression concept

Chemoembolization



Causes of untreatable progression

n=26

• Significant progression after TACE	10
• Increase in lesion size despite repeated sessions	4
• Biliary dilatation related to tumor	3
• Extrahepatic spread	5
• Technically not feasible	3
• Intolerance to previous TACE-DEB	1



Precision V: Potential patients with UTP

	DC Bead™ Group	cTACE Group
Baseline Assessments/Randomization	N=212	
Randomised	N=102	N=110
Received Treatment	N=93*	N=108*
Discontinued treatment	N=27	N=40
<i>Adverse event</i>	<i>N=12</i>	<i>N=14</i>
<i>Patient consent withdrawal</i>	<i>N=3</i>	<i>N=4</i>
<i>Post consent ineligibility</i>	<i>N=0</i>	<i>N=1</i>
<i>Lack of efficacy</i>	<i>N=2</i>	<i>N=8</i>
<i>Downstaged</i>	<i>N=5</i>	<i>N=8</i>
<i>Lost to Follow-up</i>	<i>N=2</i>	<i>N=1</i>
<i>Death</i>	<i>N=0</i>	<i>N=3</i>
<i>Other</i>	<i>N=3</i>	<i>N=1</i>
Analysed Population	N=93	N=108

CONCLUSIONS

At our institution, current survival of HCC patients treated with TACE-DEB within stages A and B is 48,6 months (47,7 months for BCLC B patients).

The survival data expose that current selection criteria and refined treatment application translate in a survival that exceeds 50% at 4 years.

The encouraging survival figures (also observed in other modern cohorts) should be considered when deciding treatment for patients fitting into controversial scenarios (e.c. expanded criteria for transplantation, resection of multifocal HCC or resection in patients with portal hypertension).

