The Role of Radio-embolization in the Management of Hepatocellular Carcinoma

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19th May 2017, JW Marriot Hotel Hong Kong

SGH – Surgery

National Cancer Centre Singapore
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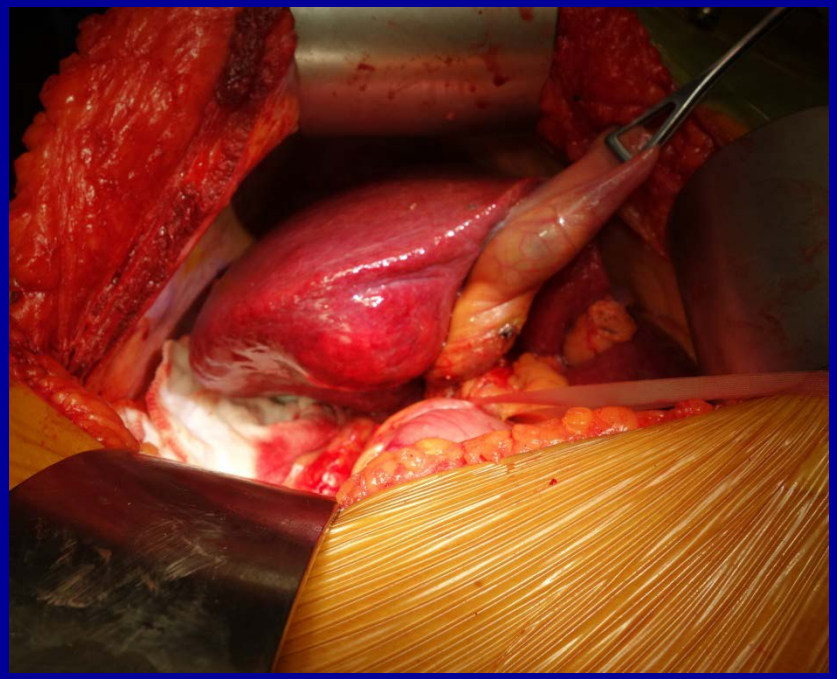
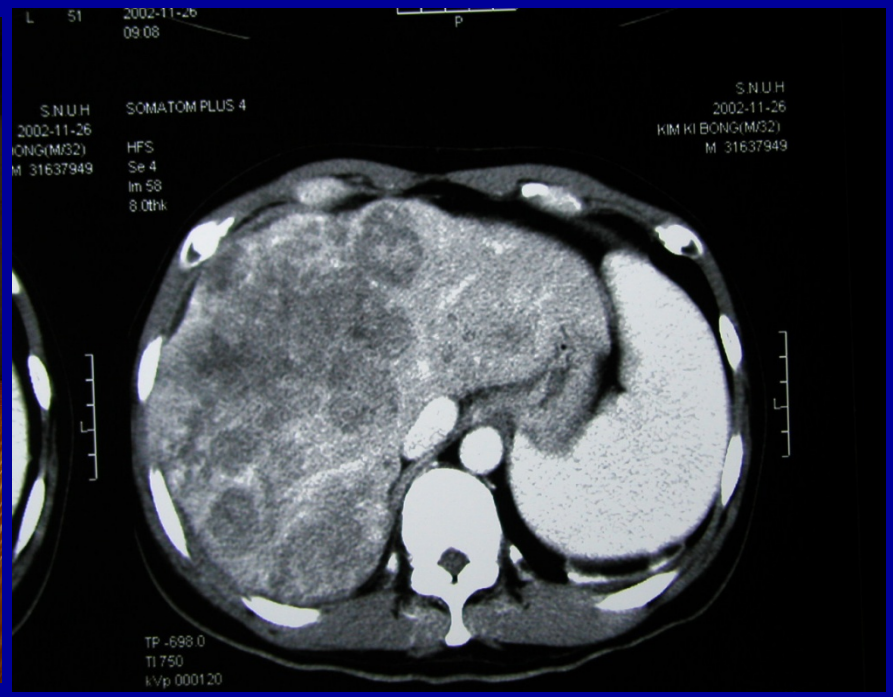
The challenge of HCC

Surgery is potentially curative in <u>early</u> HCC

But 80% are either not <u>early</u> HCC, have <u>poor function</u>



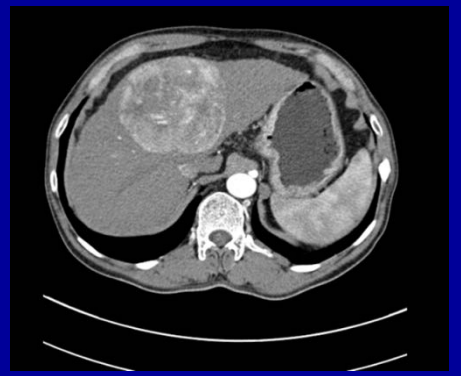


Inadequate future liver remnant is a common cause of Inoperability

Stages of Liver Cancer

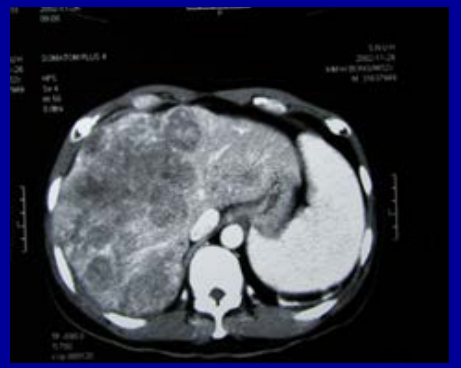
Early Stage HCC

- Lesions within the Milan Criteria
- criteria:
  - *Solitary tumour ≤ 5cm* OR *≤ 3 tumours, each < 3cm* AND *No invasion of blood vessels* and no distant spread



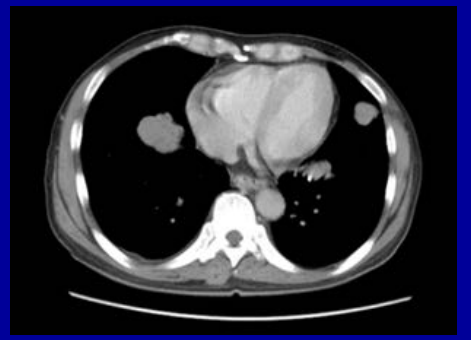
Locally Advanced HCC

- Lesions confined to the liver that are outside of the Milan criteria with or without vascular invasion



Metastatic HCC

- With good liver function (Child-Pugh A or early B)
- With poor liver function

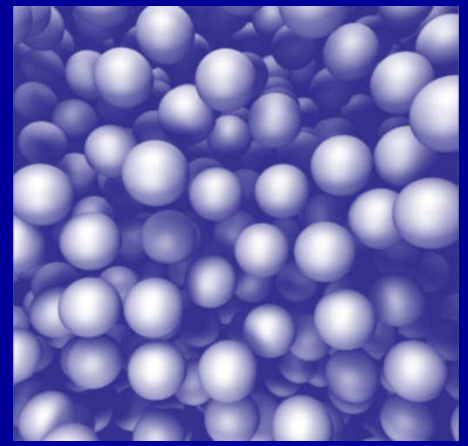


National Cancer Center Singapore Guidelines on Liver Cancer

http://www.nccs.com.sg/PatientCare/ComprehensiveLiverCancerClinic/Documents/CLCC guideline Final Ver to upload PDF 26092014.pdf

Main Loco-regional Therapies

- **Trans-arterial chemo-embolisation (TACE):**
  - widely used - disease control **approx 40%**
  - used mainly in *HCC*, *NETs* (includes DC Beads)
- **Selective Internal Radiation Therapy (SIRT):**
  - higher disease control **(approx 80%)**
  - Suitable for portal vein invasion
  - SIR-Sphere®, Thera-Sphere®



SIR-Spheres®

TheraSphere®

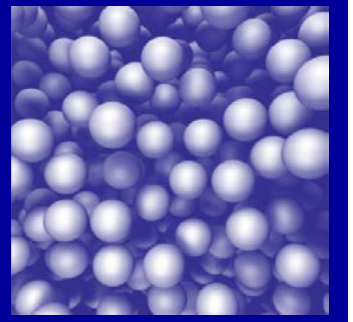
Trans-arterial Route

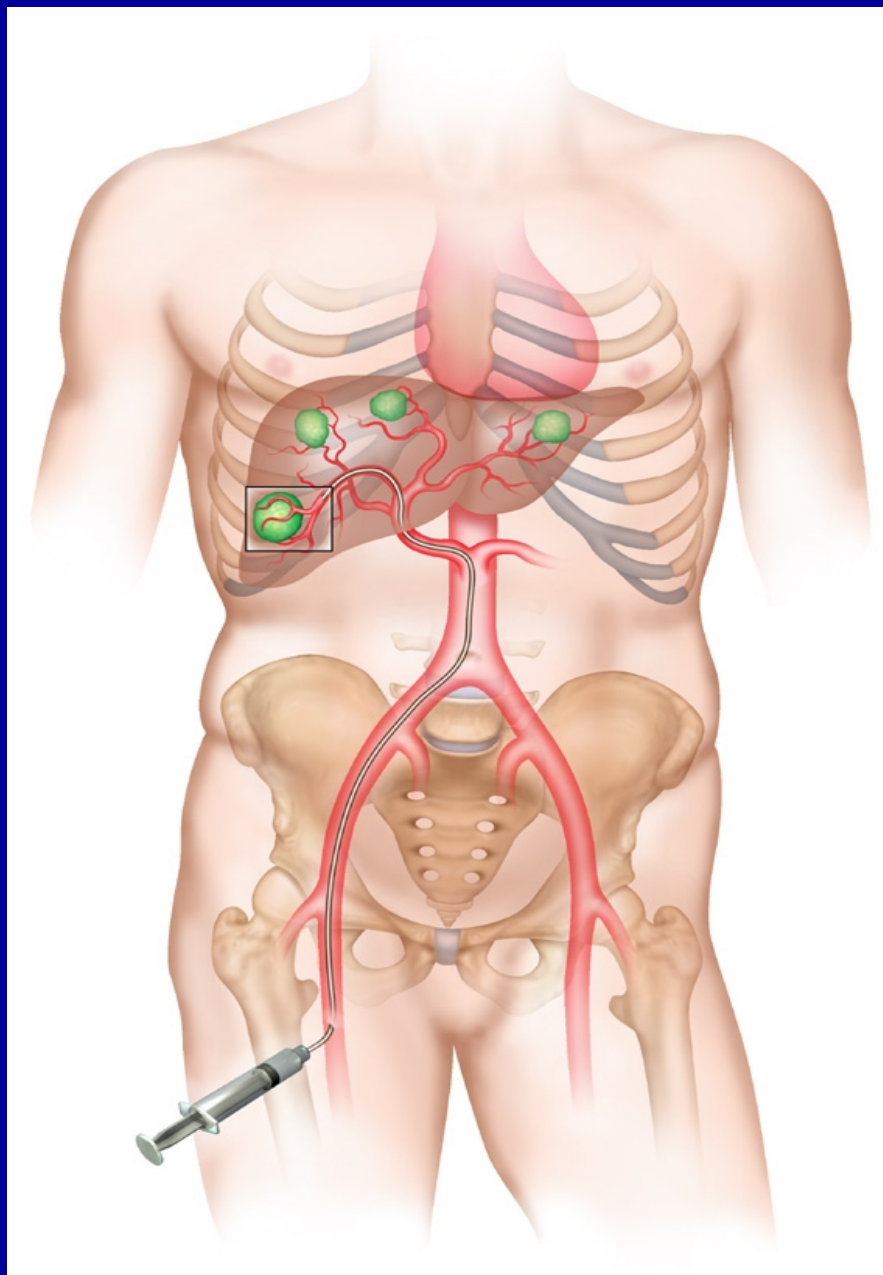
SIR-spheres:

- 20 – 40 μm diameter
- High-energy beta rays 0.9367 MeV
- 64.2 hrs (2.67 days) half-life
- Penetration:
- average penetration 2.5mm
- maximum range 11.0mm

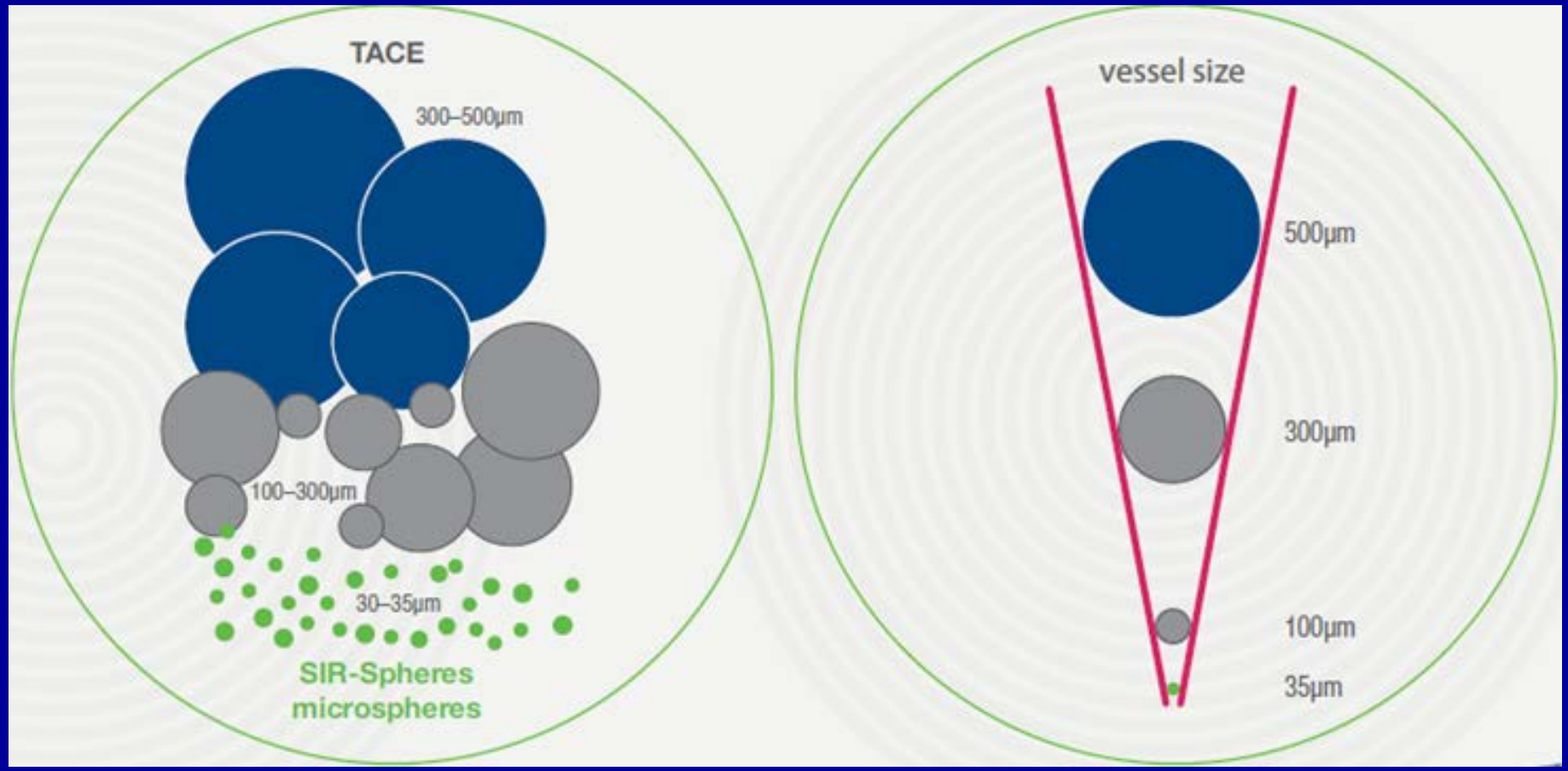
Ideal for Brachy-therapy

Yttrium-90



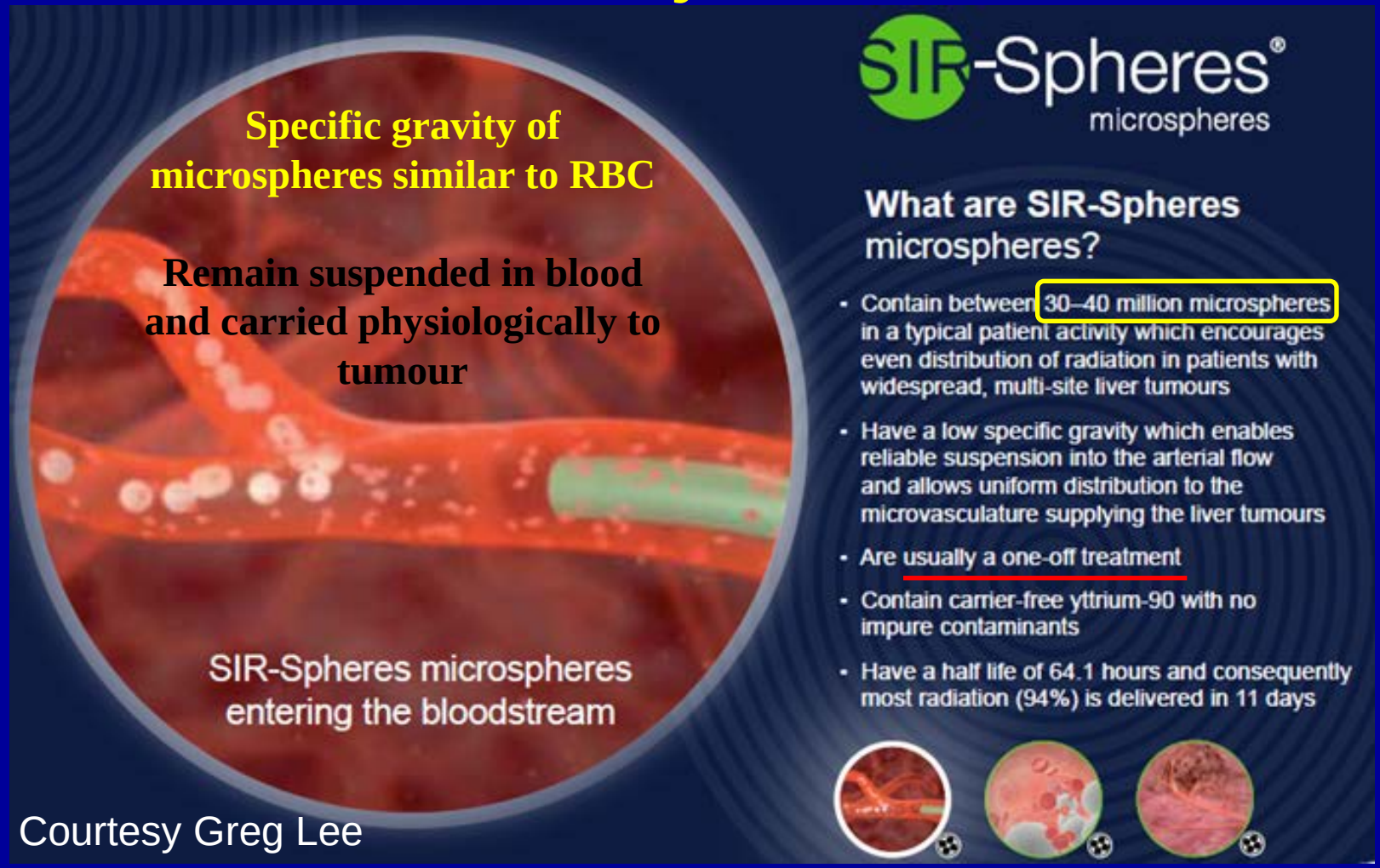


SIR-Spheres microspheres are much smaller than particles in cTACE or DEB



Courtesy Greg Lee

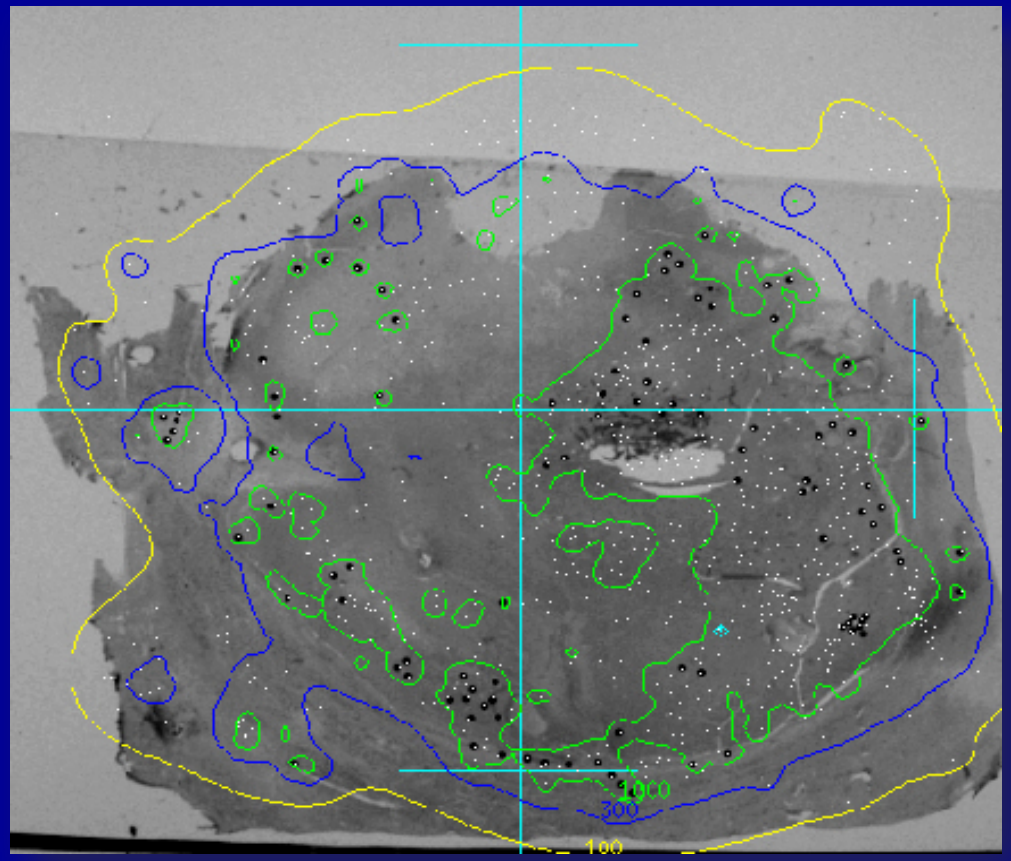
SIRT is fundamentally different from TACE



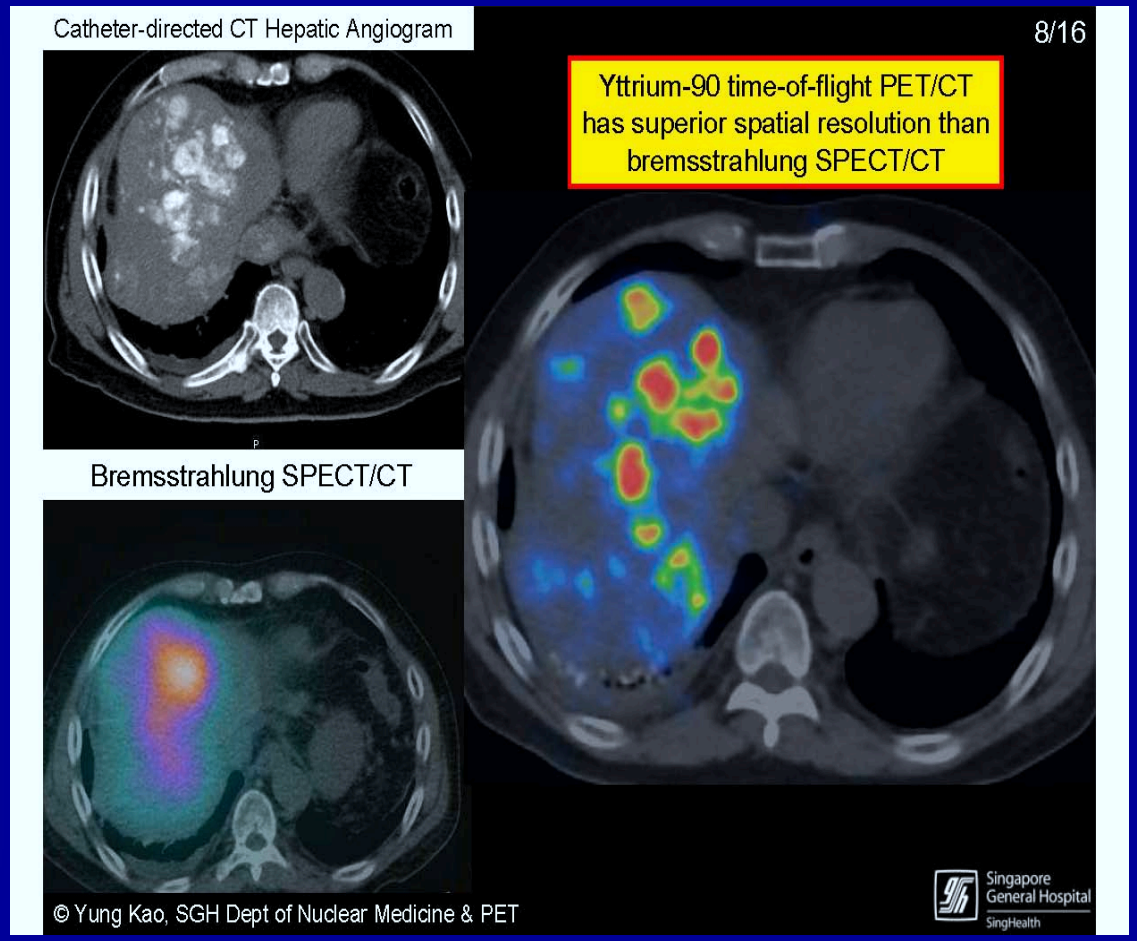
Courtesy Greg Lee

In Brachytherapy occlusion of vessels is **not desired** because oxygen is required to generate oxygen radicals which damage tumour DNA – **suitable for PVT**

Implantation of SIR-Spheres microspheres in pre-capillary vessels



Kennedy AS, Nutting C, Coldwell D, et al. Int J Radiat Oncol Biol Phys. 2004; 60:1552-63.



Evidence for SIRT in HCC

- **Retrospective Studies**
  - Western patients — *Saleem 2011, Hilgard 2010, Sangro 2011*
  - Asian patients — *Khor 2014, She 2015*

- **Prospective Studies**

• Phase II SiRSa	Chow	2014	
• Phase III SIRveNIB	Chow	closed	**ASCO 2017**
• Phase III SARAH	Vilgraine	closed	**EASL 2017**

AHCC06: SIRT Yttrium-90 versus Sorafenib in patients with locally advanced HCC (SIRveNIB)

Investigator-initiated

Asia-Pacific, Phase III, open-label, randomized-controlled study

Closed on 25th May 2016

Eligibility criteria
- Locally advanced HCC
- Child–Pugh <8 pts
- ECOG PS 0 – 1

Exclusion criteria
- Distant metastases
- Complete main portal vein thrombosis

Randomisation 1:1 (n=360)

- Sorafenib® 400mg b.i.d.
- SIRT Yttrium-90

Endpoints

Primary
- OS

Secondary
- TTP
- QoL
- Downstaging to curative therapies

ECOG PS = Eastern Cooperative Oncology Group Performance Status
OS = overall survival; TTP = time to tumour progression

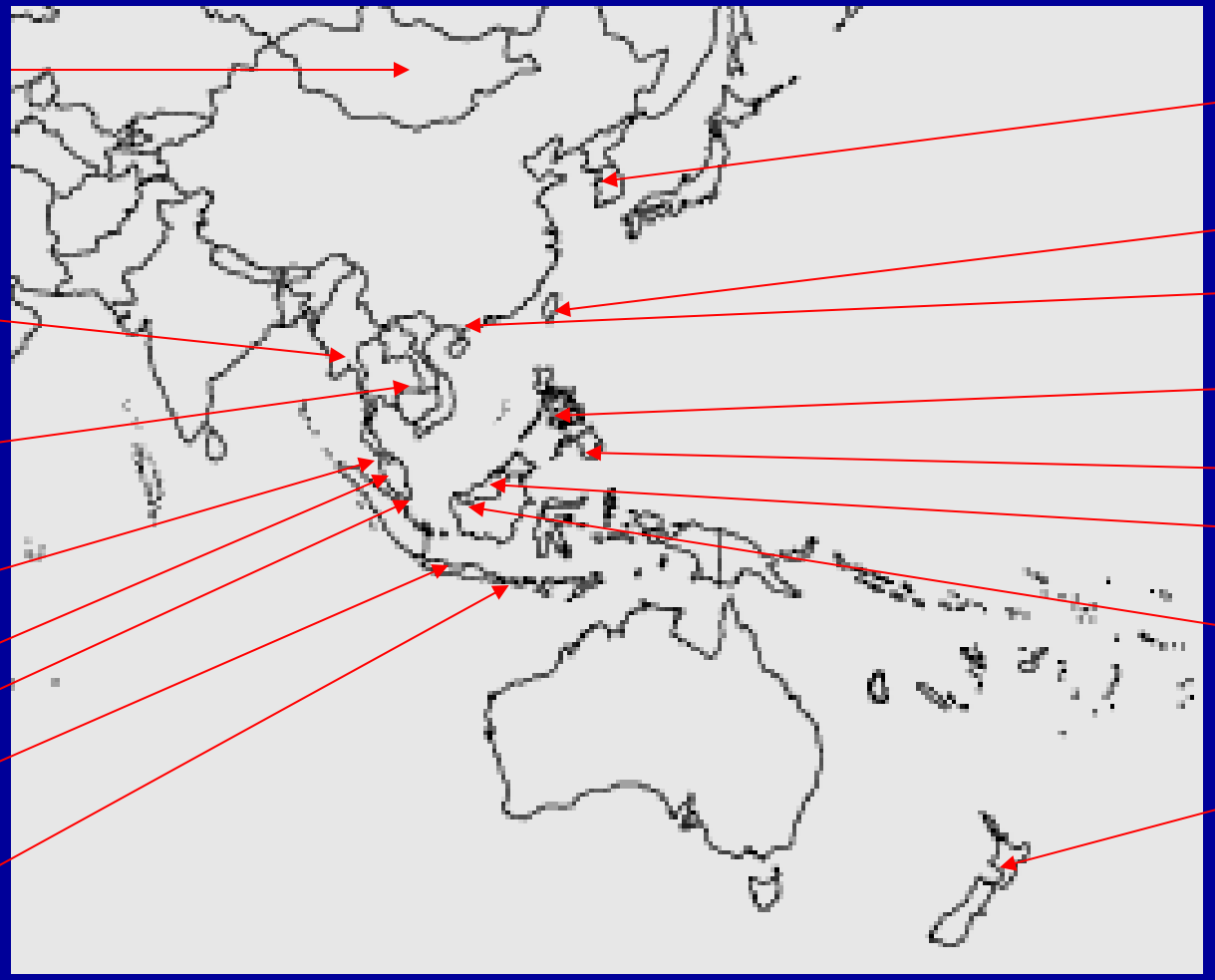
Eligible: *Previous surgery, RFA, TACE*

DUKE NUS GRADUATE MEDICAL SCHOOL SINGAPORE

THE Asia-Pacific Hepatocellular Carcinoma Trials Group

Asia-Pacific HCC Trials Group 2016

SIRveNIB – will be presented at ASCO 4th June 2016



27 centers 11 Countries

SGH – Surgery

National Cancer Centre Singapore
SingHealth

National Cancer Centre Singapore
SingHealth

SINGAPORE CLINICAL RESEARCH INSTITUTE

American Society of Clinical Oncology (ASCO) publishes abstract of SIR*ve*NIB, an Investigator-led Asia Pacific Primary Liver Cancer Study to be presented at ASCO Annual Meeting in Chicago, 4 June 2017

The SIR*ve*NIB abstract published on-line in the *Journal of Clinical Oncology* states that treatment of locally advanced Hepatocellular Carcinoma (HCC) with a single treatment of SIR-Spheres® Y-90 resin microspheres results in Overall Survival not significantly different from twice-daily oral sorafenib, but with significantly better tumour response and fewer and less severe adverse events

TRR - 16.5% vs 1.7%; $p < 0.001$

The study was conducted by The Asia-Pacific Hepatocellular Carcinoma Trials Group (AHCC) in collaboration with the National Cancer Centre Singapore and Singapore Clinical Research Institute (SCRI) and supported by the National Medical Council Singapore and Sirtex Medical Limited

Media release 18th May 2017 Singapore

Impact of SIRveNIB and SARAH

- **SIRveNIB** **360 patients** **28.6%** assigned to SIRT did not receive therapy
- **SARAH** **467 patients** **26.6%** assigned to SIRT did not receive therapy
- On ITT Analysis in neither trials were there significant difference in OS
- On ITT Analysis both trials showed significantly better **tumor response rate** (TTR) in the SIRT arms
- On ITT Analysis both trials showed significantly less **AE and SAE** in the SIRT arms

- **SIRveNIB** and **SARAH** established the efficacy and safety of SIRT in intermediate stage HCC with or without PVT
- SIRT is a good alternative to sorafenib in locally advanced HCC

Liver Cancer

Liver Cancer 2016;5:162–174
DOI: 10.1159/000367766
Published online: May 3, 2016

2235-1795/16/0053-0162$39.50/0
www.karger.com/lic

Consensus Guidelines

Consensus for Radiotherapy in Hepatocellular Carcinoma from The 5th Asia-Pacific Primary Liver Cancer Expert Meeting (APPLE 2014): Current Practice and Future Clinical Trials

Hee Chul Park[a,b] Jeong Il Yu[a] Jason Chia-Hsien Cheng[c]
Zhao Chong Zeng[d] Ji Hong Hong[e] Michael Lian Chek Wang[f]
Mi Sook Kim[g] Kwan Hwa Chi[h] Po-Ching Liang[i] Rheun-Chuan Lee[j]
Wan-Yee Lau[k] Kwang Hyub Han[l] Pierce Kah-Hoe Chow[m]
Jinsil Seong[n]

APPLE 2014 Guidelines – *Park 2016*

Liver Cancer

Liver Cancer 2016;5:97–106
DOI: 10.1159/000367759
Published online: March 17, 2016

2235-1795/16/0052-0097$39.50/0
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Consensus Guidelines

National Cancer Centre Singapore Consensus Guidelines for Hepatocellular Carcinoma

Pierce K. H. Chow [a,b,h] Su Pin Choo [c] David C. E. Ng [d]
Richard H. G. Lo [e] Michael L. C. Wang [f] Han Chong Toh [c]
David W. M. Tai [c] Brian K. P. Goh [b] Jen San Wong [b]
Kiang Hiong Tay [e] Anthony S. W. Goh [d] Sean X. Yan [d]
Kelvin S. H. Loke [d] Sue Ping Thang [d] Apoorva Gogna [e]
Chow Wei Too [e] Farah Gillian Irani [e] Sum Leong [e]
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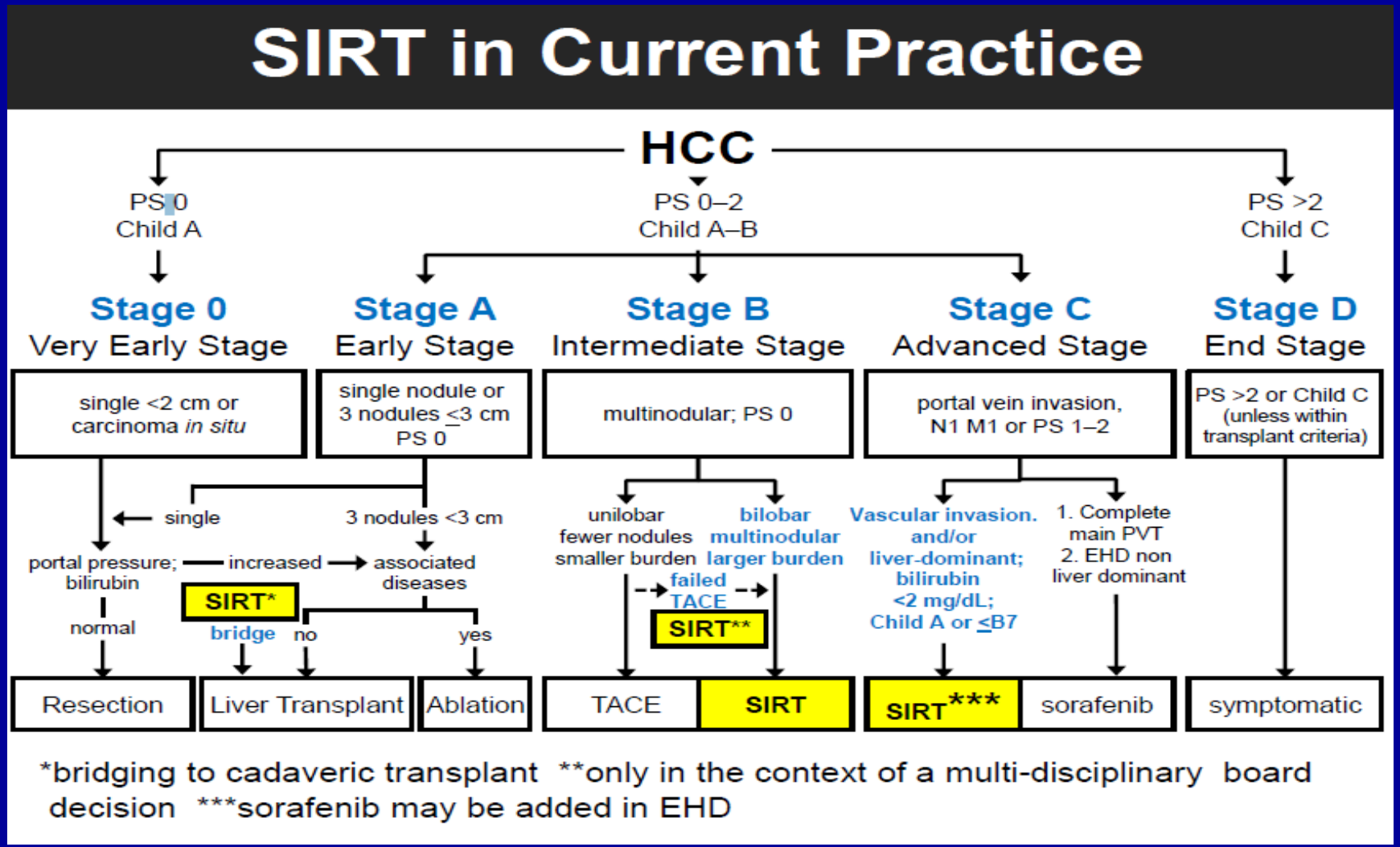
[a]Division of Surgical Oncology, National Cancer Centre Singapore, [b]Department of Hepatopancreato-biliary/Transplantation Surgery, Singapore General Hospital, [c]Division of Medical Oncology, National Cancer Centre Singapore, [d]Department of Nuclear Medicine & PET, Singapore General Hospital, [e]Department of Diagnostic Radiology, Singapore General Hospital, [f]Department of Pathology, Singapore General Hospital, [g]Division of Oncologic Radiology, National Cancer Centre Singapore, [h]Office of Clinical Sciences, Duke-NUS Graduate Medical School, Singapore, Singapore

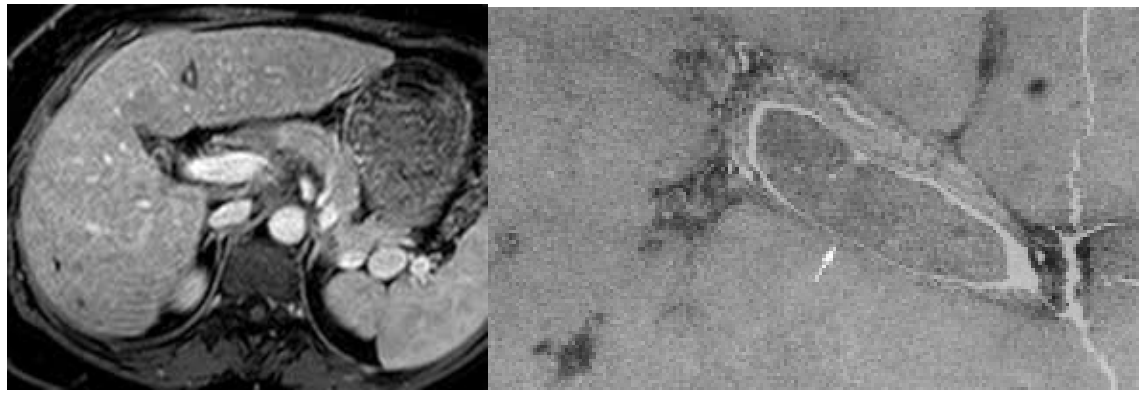
Updated : Evidence –based Multi-disciplinary Practice Guidelines

Key Words
Diagnosis · Hepatocellular carcinoma · Practice guidelines · Radiation therapy · Surgery

Integration of Evidence: APPLE 2014



HCC with Portal Vein Tumour Thrombosis



Courtesy Kenneth Chin BSc(Hon) MD

APPLE recommendations for SIRT 2014

- **first- line therapy** in Advanced HCC with vascular invasion and/or which are liver dominant with bilirubin <2 mg/dL and which are Child-Pugh A or <B7 . (Level B1). In this context sorafenib may be added in patients with extra-hepatic disease. (Level B2)
- **first-line therapy** in multi-focal or bilobar HCC with high disease burden. (Level B1)
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PLOS ONE

Multicenter Phase II Study of Sequential Radioembolization-Sorafenib Therapy for Inoperable Hepatocellular Carcinoma

Pierce K. H. Chow[1,2,3]*, Donald Y. H. Poon[2], Maung-Win Khin[4], Harjit Singh[5], Ho-Seong Han[6], Anthony S. W. Goh[1], Su-Pin Choo[2], Hee-Kit Lai[1], Richard H. G. Lo[1], Kiang-Hiong Tay[1], Teong-Guan Lim[1], Mihir Gandhi[3,7], Say-Beng Tan[3,7], Khee-Chee Soo[1,2,3], for the Asia-Pacific Hepatocellular Carcinoma Trials Group

1 National Cancer Centre, Singapore, Singapore, **2** Singapore General Hospital, Singapore, Singapore, **3** Duke-NUS Graduate Medical School, Singapore, Singapore, **4** Yangon Gastrointestinal and Liver Centre, Yangon, Myanmar, **5** Selayang Hospital, Selangor, Malaysia, **6** Seoul National University Bundang Hospital, Bundang, South Korea, **7** Singapore Clinical Research Institute, Singapore, Singapore

Abstract

Background: The safety and tolerability of sequential radioembolization-sorafenib therapy is unknown. An open-label, single arm, investigator-initiated Phase II study (NCT0071279) was conducted at four Asia-Pacific centers to evaluate the safety and efficacy of sequential radioembolization-sorafenib in patients with hepatocellular carcinoma (HCC) not amenable to curative therapies.

Methods: Sorafenib (400 mg twice-daily) was initiated 14 days post-radioembolization with yttrium-90 (^{90}Y) resin microspheres given as a single procedure. The primary endpoints were safety and tolerability and best overall response rate (ORR) using RECIST v1.0.Secondary endpoints included: disease control rate (complete [CR] plus partial responses [PR] and stable disease [SD]) and overall survival (OS).

Results: Twenty-nine patients with Barcelona Clinic Liver Cancer (BCLC) stage B (38%) or C (62%) HCC received a median of 3.0 GBq (interquartile range, 1.0) ^{90}Y-microspheres followed by sorafenib (median dose/day, 600.0 mg; median duration, 4.1 months). Twenty eight patients experienced ≥1 toxicity; 15 (52%) grade ≥3. Best ORR was 25%, including 2 (7%) CR and 5 (18%) PR, and 15 (54%) SD. Disease control was 100% and 65% in BCLC stage B and C, respectively. Two patients (7%) had sufficient response to enable radical therapy. Median survivals for BCLC stage B and C were 20.3 and 8.6 months, respectively.

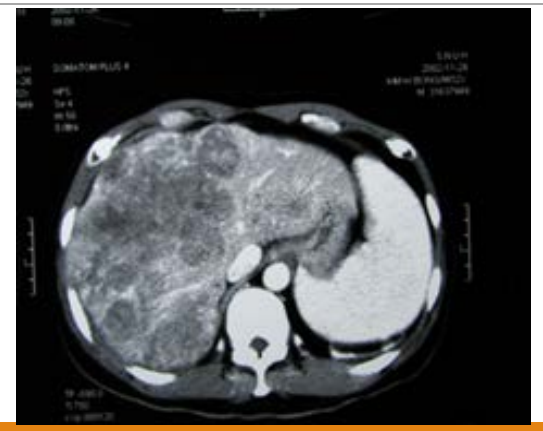
Conclusions: This study shows the potential efficacy and manageable toxicity of sequential radioembolization-sorafenib.

Trial Registration: ClinicalTrials.gov NCT00712790.

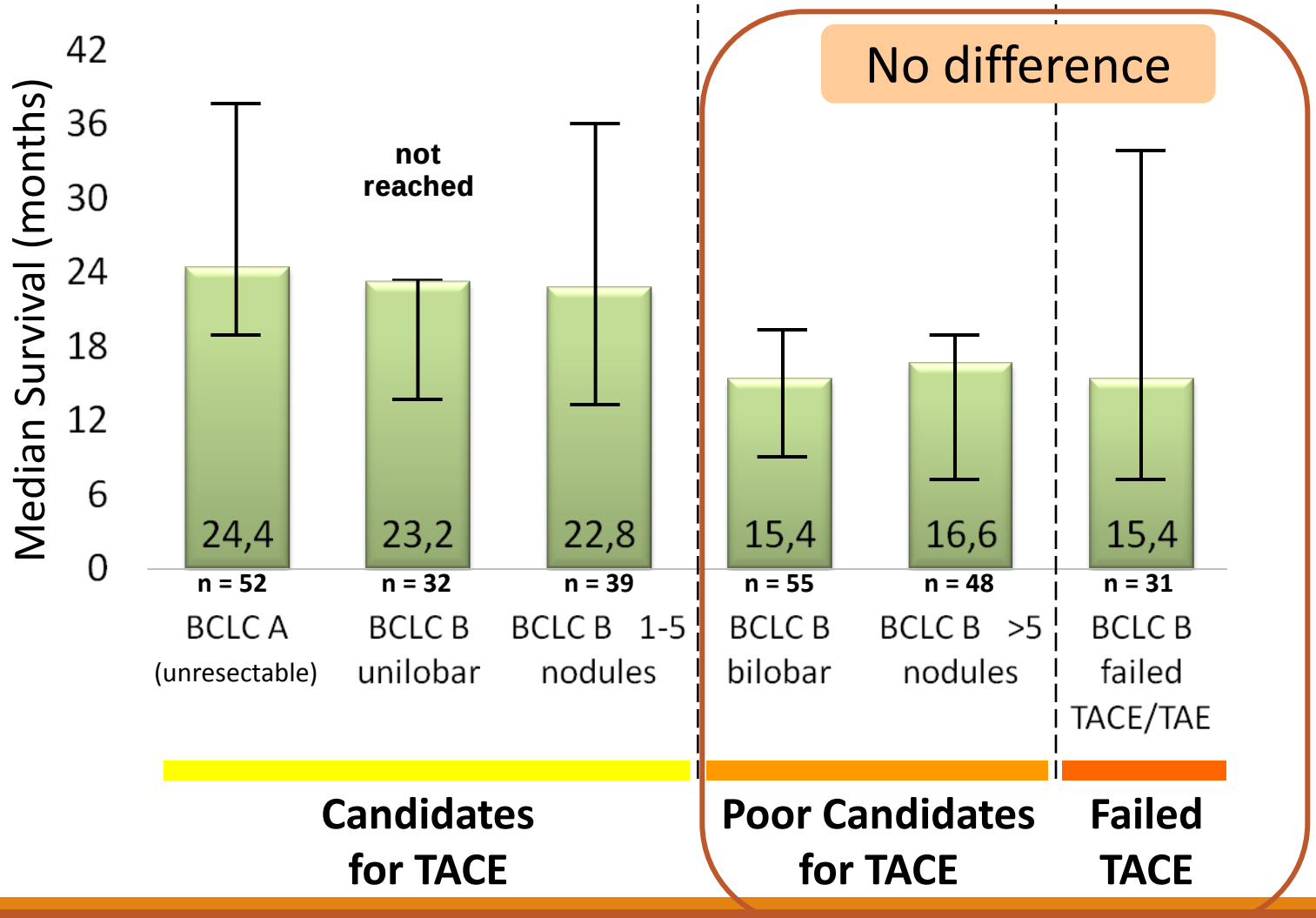
Citation: Chow PKH, Poon DYH, Khin M-W, Singh H, Han H-S, et al. (2014) Multicenter Phase II Study of Sequential Radioembolization-Sorafenib Therapy for Inoperable Hepatocellular Carcinoma. PLoS ONE 9(3): e90909. doi:10.1371/journal.pone.0090909

Bilobar and/or Large Volume HCC

TACE is not efficacious in large volume HCC



Patient Outcomes According to Suitability for TACE in the ENRY Series



Sangro et al., Hepatology 2011;54:868-878

APPLE recommendations for SIRT 2014

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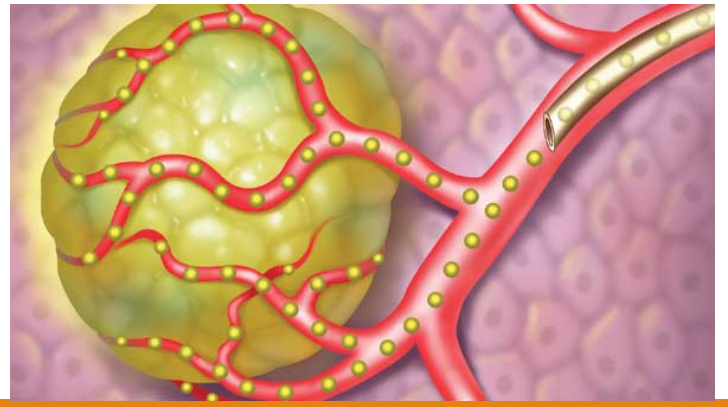
Failed/Progressed on TACE

Should we persist with TACE when tumour fails to respond?



APPLE recommendations for SIRT 2014

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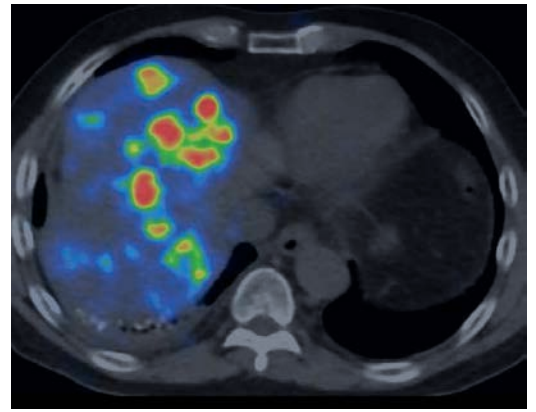
Bridging for Transplant

prevention of disease progression while on waiting list



Downstaging with SIRT or TACE in HCC

Study	Treatment	Number	Overall survival months	TTP months	Response[a], %		Downstaged/ transplanted %	Days in hospital[b]
					WHO/RECIST	EASL		
Lewandowski et al. [41] (2009)	TARE (glass)	43	35.7	33.3	61	86	58[c]	0[c]
	TACE	43	18.7	18.2	37	71	31	3
Kooby et al. [42] (2010)	TARE (resin)	27	6	NR	11	NR	NR	1.7[c]
	TACE	44	6		6			6
Carr et al. [43] (2010)	TARE (glass)	99	11.5[d]	NR	41	NR	NR	NR
	TACE	691	8.5		60			
Salem et al. [44] (2011)	TARE (glass)	123	20.5	13.3	49	72	25	0[c]
	TACE	122	17.4	8.4	36	69	36	1.8

Most studies used a chemotherapy combination of mitomycin/doxorubicin/cisplatin with lipidol for TACE. In Carr et al. [43], cisplatin was used alone with lipidol.

TTP = Time to tumor progression; NR = not reported; WHO = World Health Organization tumor response criteria.

[a] Response: patients with complete or partial response. [b] Mean days in hospital per treatment. [c] Significant difference, $p < 0.05$.

Lau, 2013

APPLE recommendations for SIRT 2014

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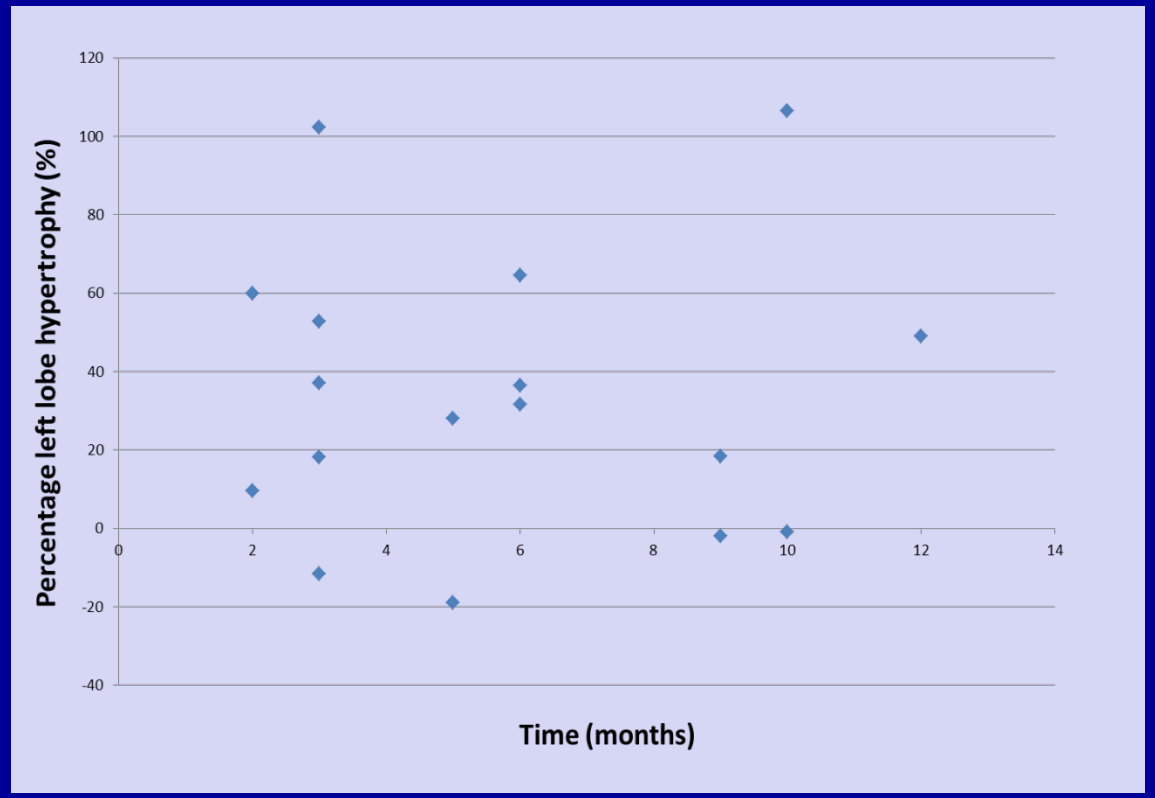
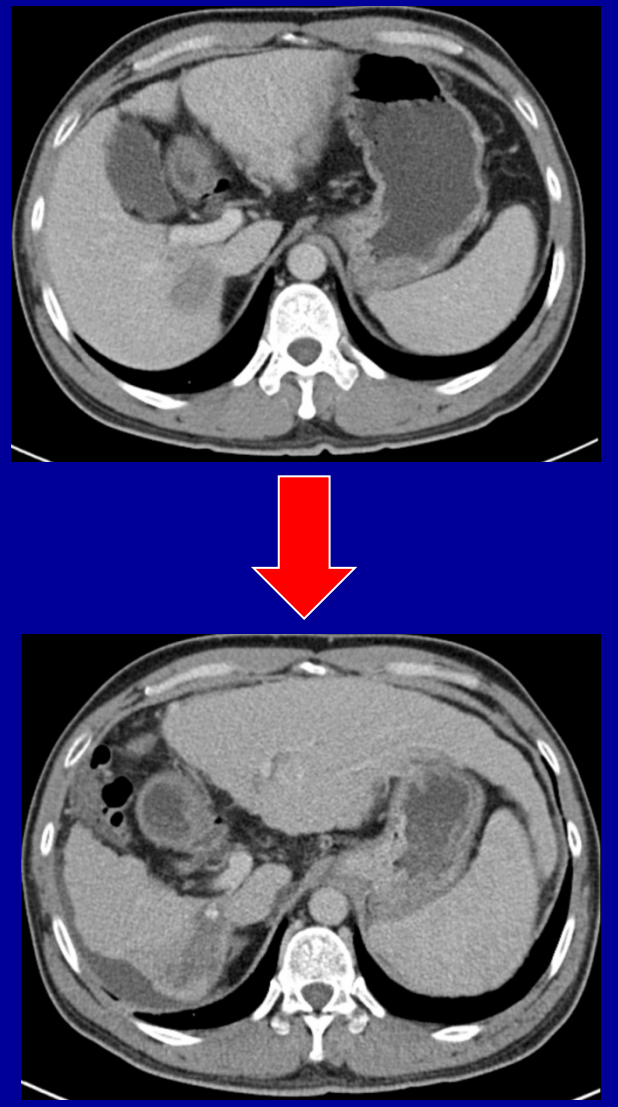
Unique Feature:

Hepatic hypertrophy of contra-lateral lobe after SIRT





Left-lobe hypertrophy *mean* ***34.2% (SD±35.9%)***
median ***31.7% (range -19.0 – 106.5%)***

SGH – Surgery

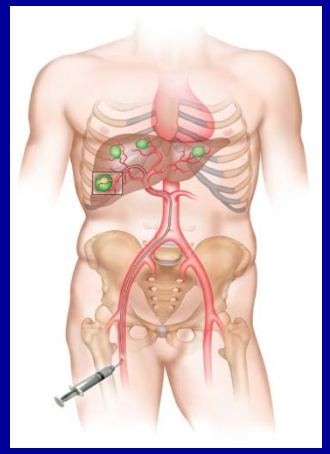
Compensatory hypertrophy

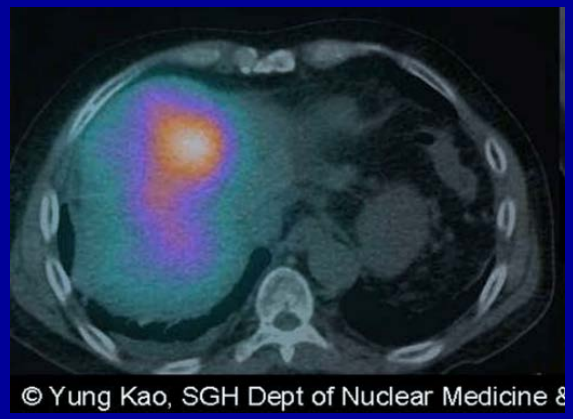
Teo 2014

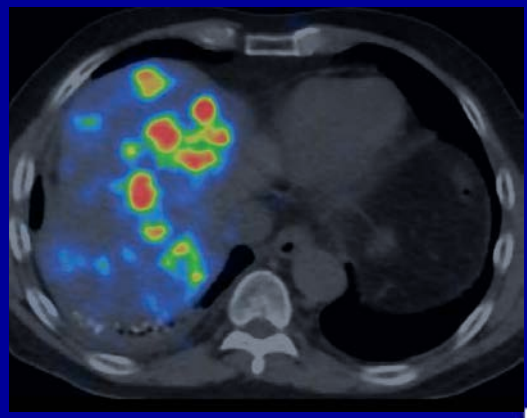
Of interest to surgeons……

1. High utility of SIR-Spheres for down-staging of locally advanced HCC
2. compensatory hypertrophy of contra-lateral lobe which increases Future Liver Remnant

…and the potential for resection/transplant of previously unresectable/untransplantable patients



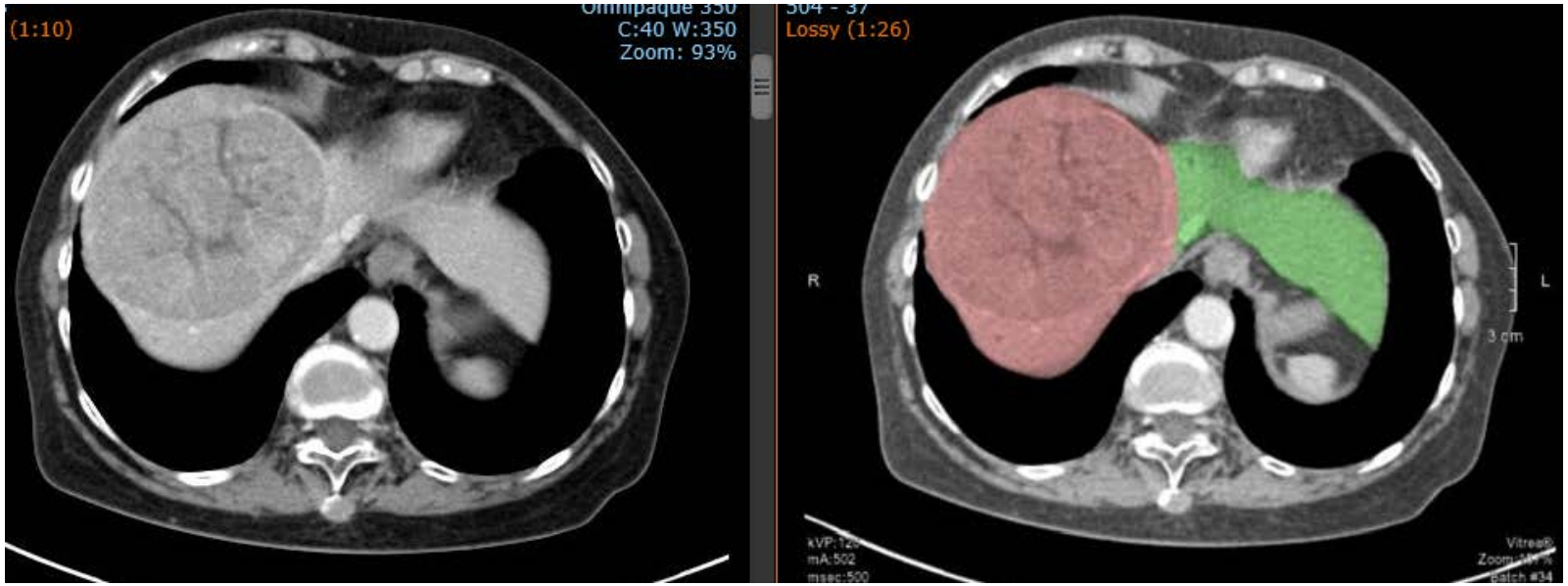




Example 1: Insufficient future liver remnant (FLR) for safe resection

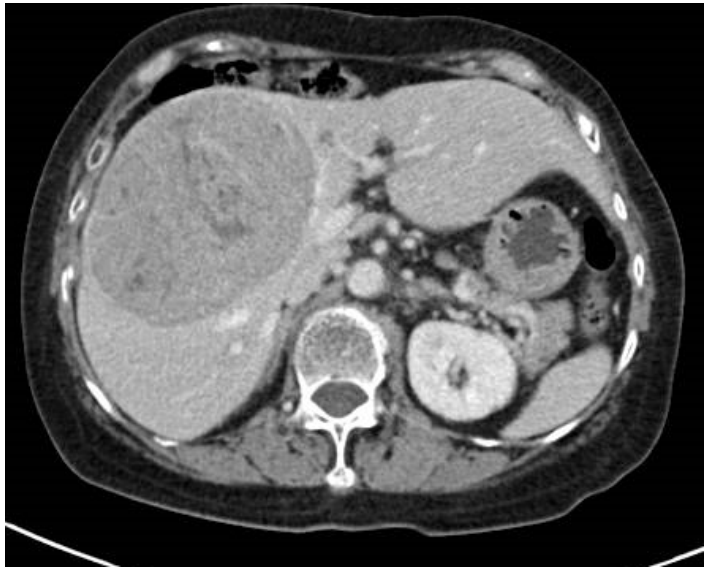
70 year old lady, Hep B +ve Child Pugh A

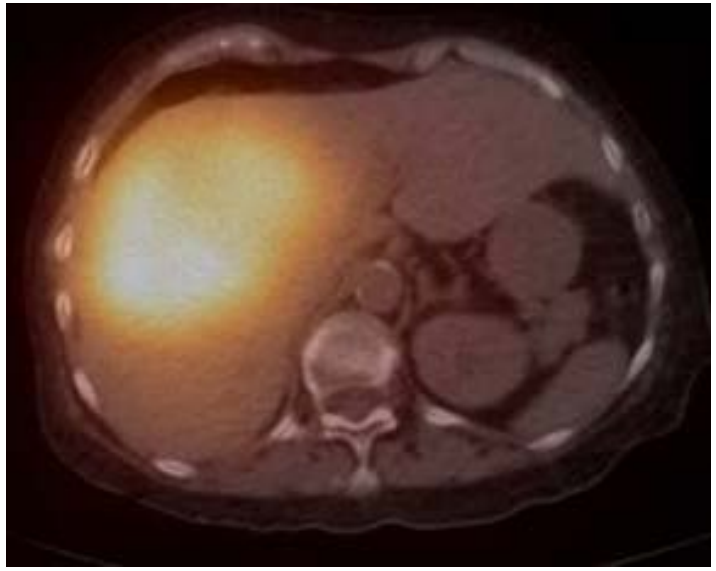
- CT Liver (11th May): 11.1cm HCC in Segment 5/8 with encroachment to segment 4, tumour abuts right and middle hepatic vein
- extended right hepatectomy required
- Liver Volumetry – future liver remnant: 27%, ICG 15mins – 16%



Selective Internal Radiation Therapy with Resin Microspheres

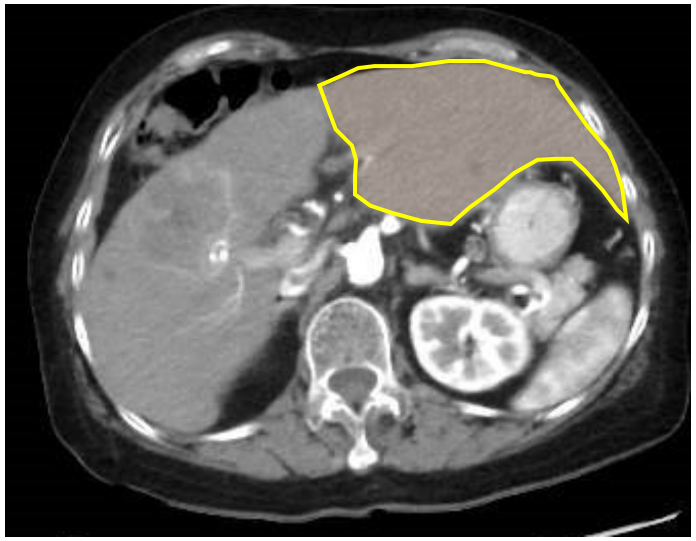
- 31st May





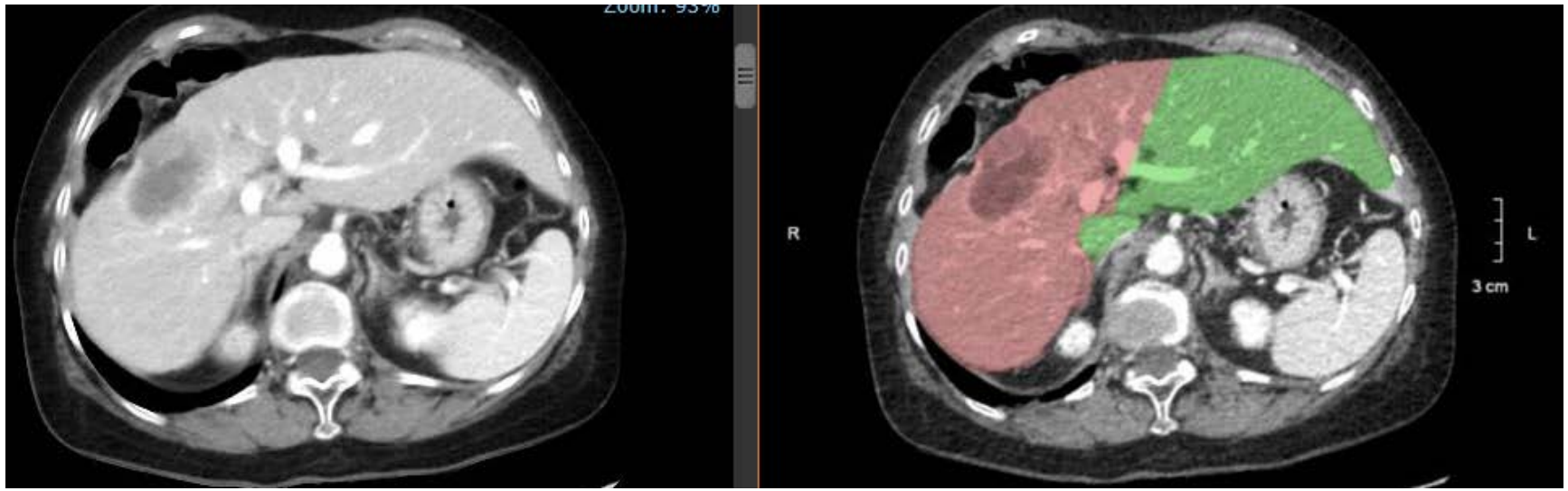
Progress August

- Underwent Hepatic embolization Y-90 in 31st May
- Follow Up (25th Aug): Interval decrease in size from 11.1 cm to 7.6 cm with areas of viable tumour as evidenced by nodular arterial enhancement with washout



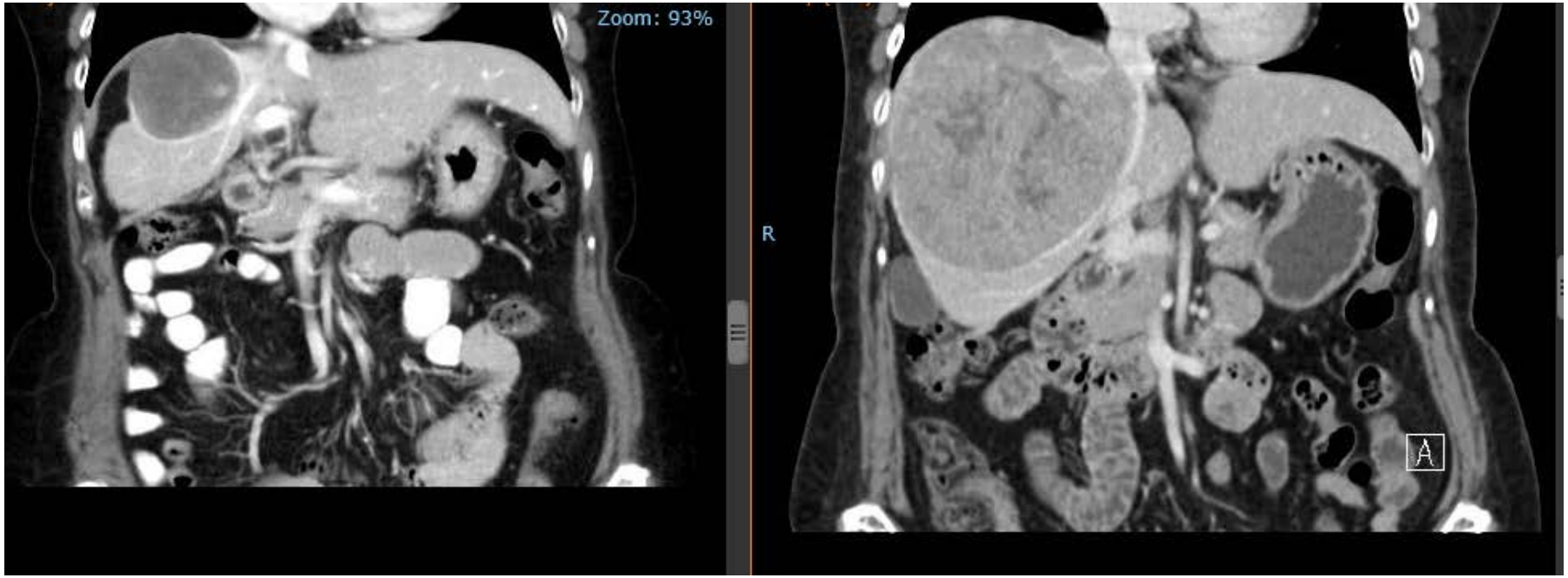
Progress November

- CT Liver (24th Nove 2016): regressed from
  - from 11.1 cm to 7.6 cm to 5.5 cm
- Liver Volumetry – future liver remnant: 43%, ICG 15mins – 13%



Extent of Regression 31st May – 24th Nov

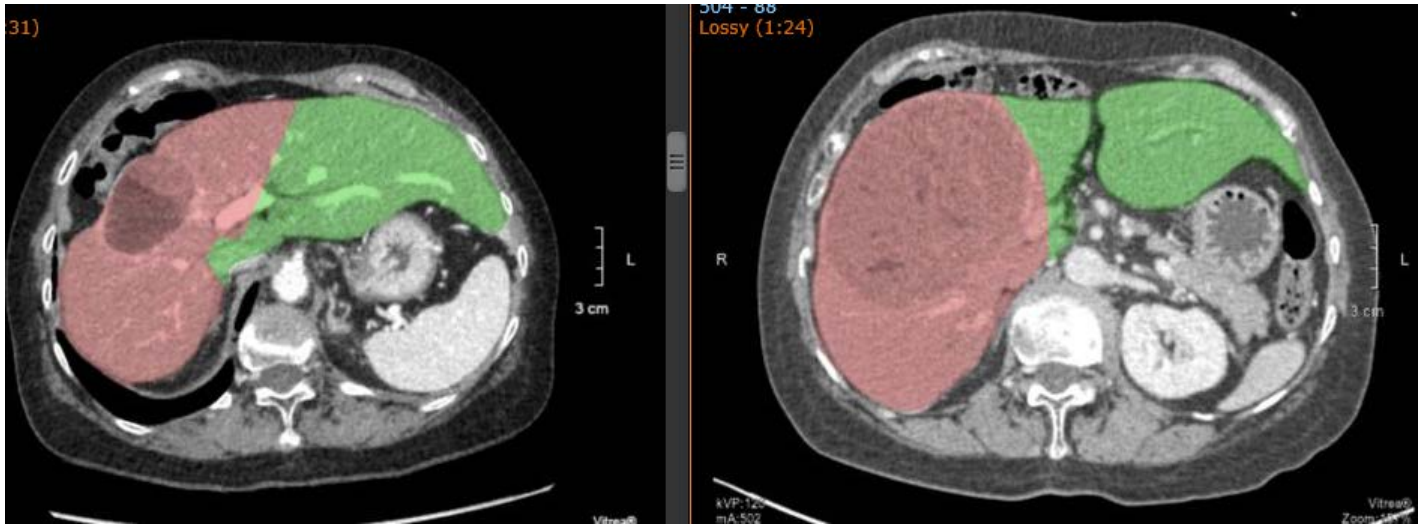
- Regressed from 11.1 cm to 7.6 cm to 5.5 cm



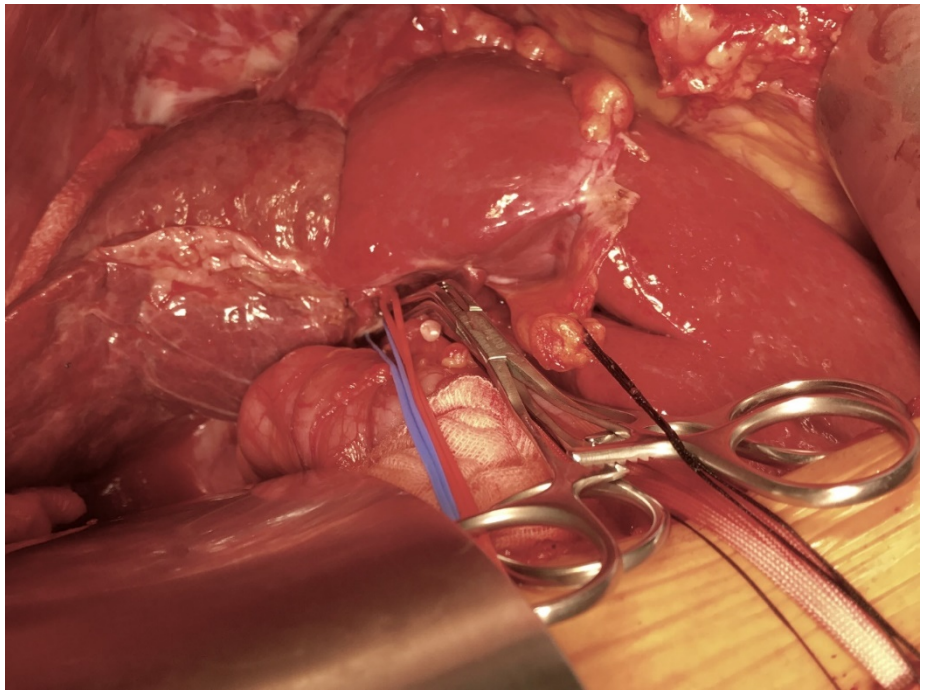
There is now sufficient future liver remnant (FLR) for safe resection

Extent of Contralateral hypertrophy 31st May – 24th Nov

- Liver Volumetry – future liver remnant: from 27% to 43%

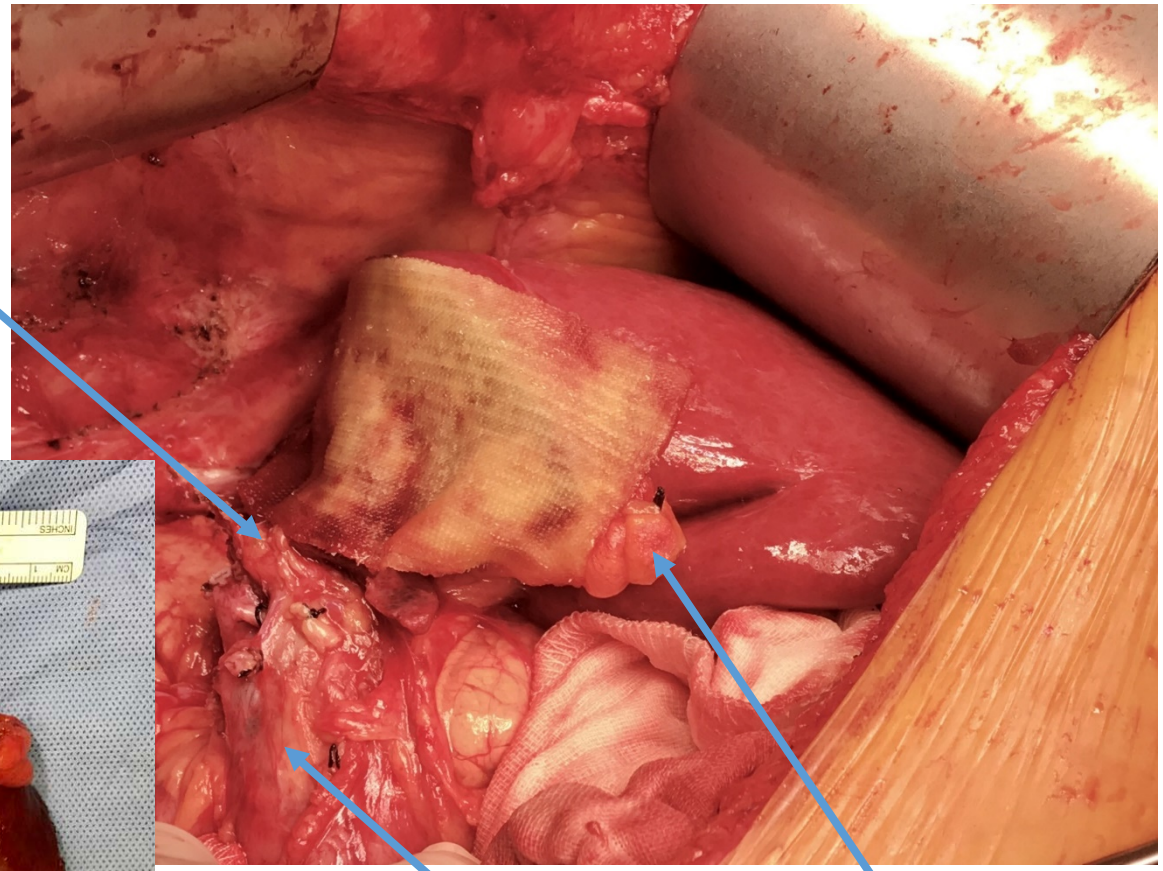


Safe Resection with excellent future liver remnant (FLR): Extended right hemi-hepatectomy



Safe Resection with excellent future liver remnant (FLR)

Stapled Right hepatic vein



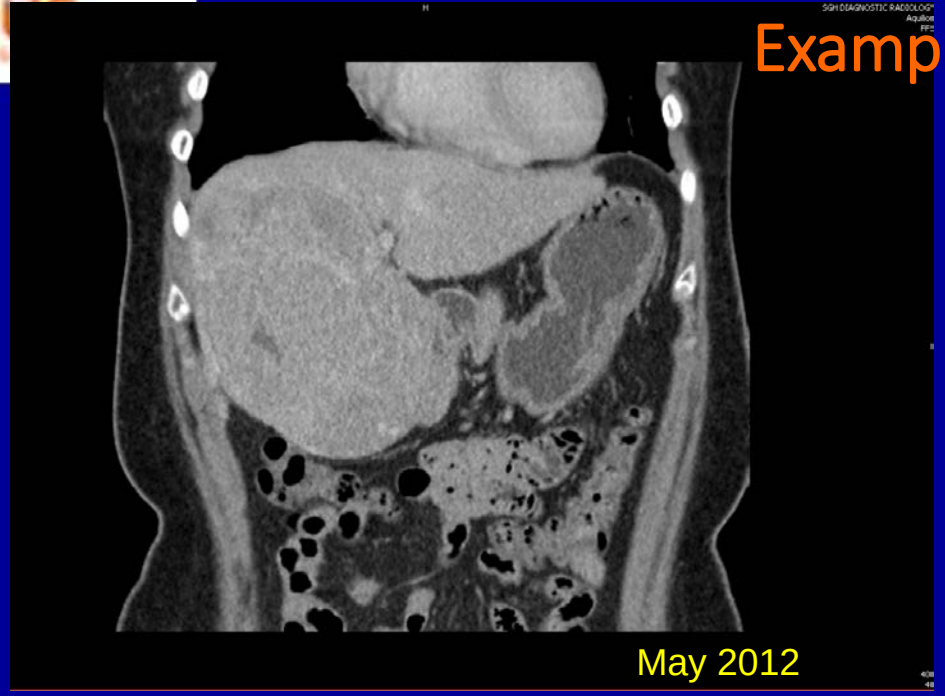
Ligamentum teres

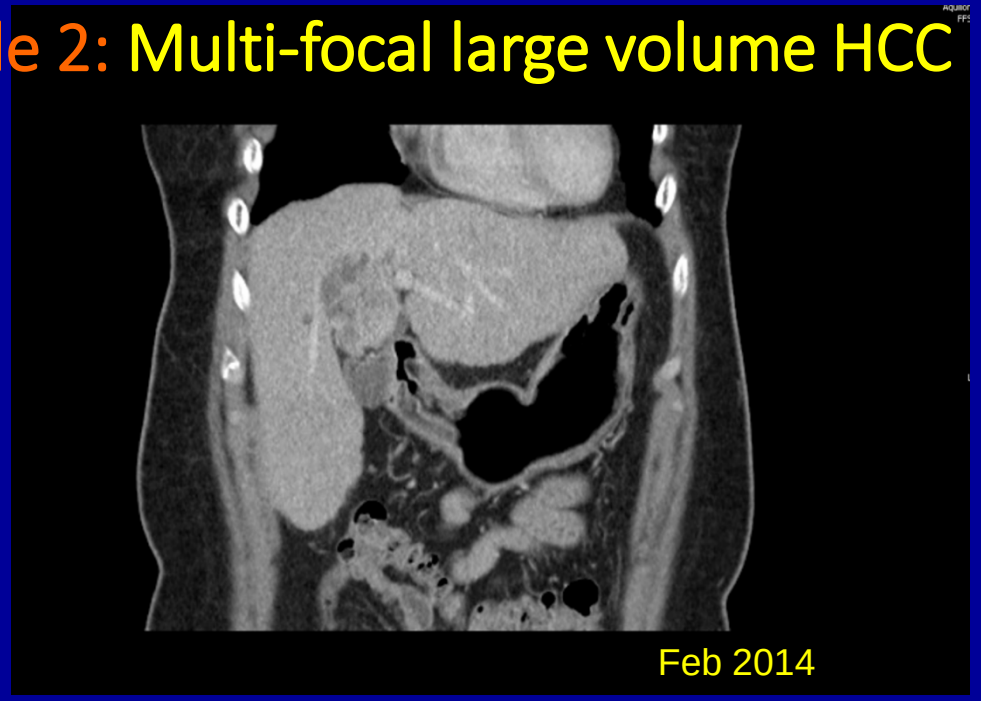
Inferior Vena Cava

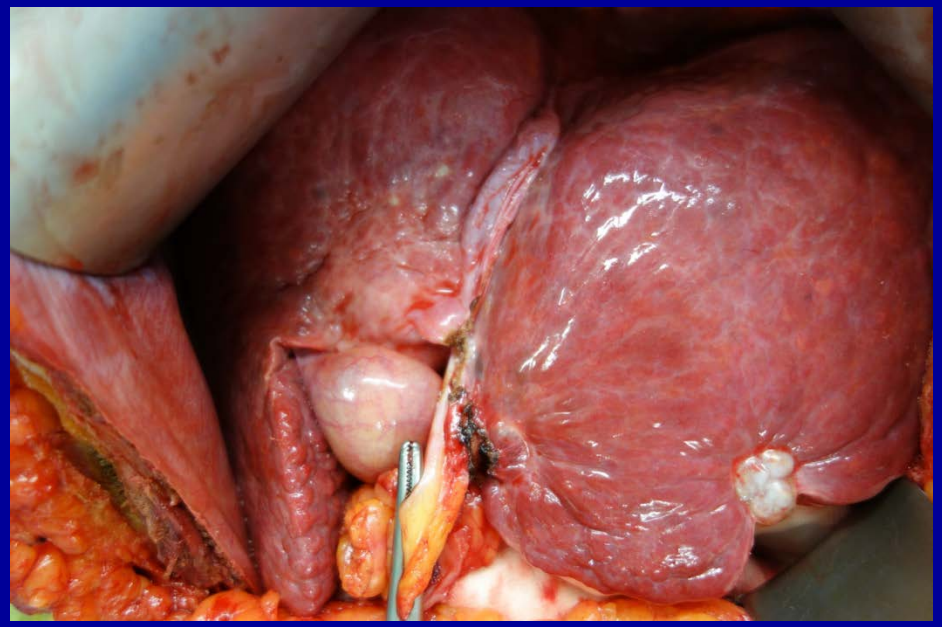
Histology

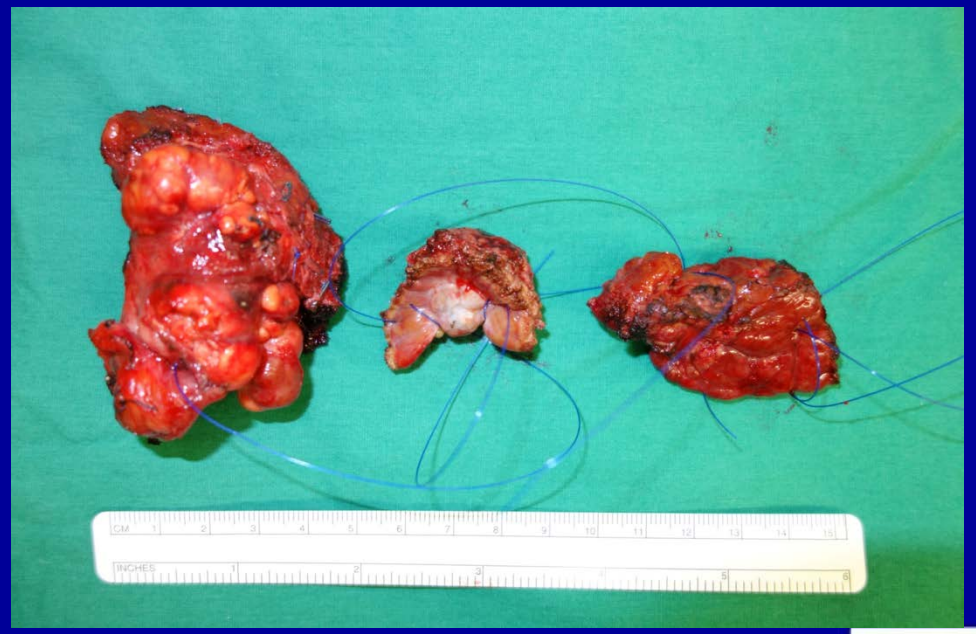
- Extended right hemi-hepatectomy specimen weighing 445gm and measuring 14 x 15 x 6 cm
- Well circumscribed tumour measuring **6 x 5 x 5 cm**
- **Viable tumour** HCC Grade 2, moderately differentiated, **2.3cm**, margins clear, closest margin – liver capsule 0.5mm away
- Staging
  - **pT1N0M0**

Example 2: Multi-focal large volume HCC









Down-staging to curative resection – 5-year survival

P4S Study

- **Retrospective Post SIR-Spheres Surgery in Previously Unresectable Hepatic Malignancy Study (P4S)** is an international, multicentre, retrospective study to assess outcomes of liver resection or transplant

- To meet the absence of robust data on down-staging with SirSphere Y90, the P4S data were analysed to evaluate **safety** and **outcomes** of liver resection or transplantation following SIRT in patients with unresectable hepatocellular carcinoma (HCC)

In press

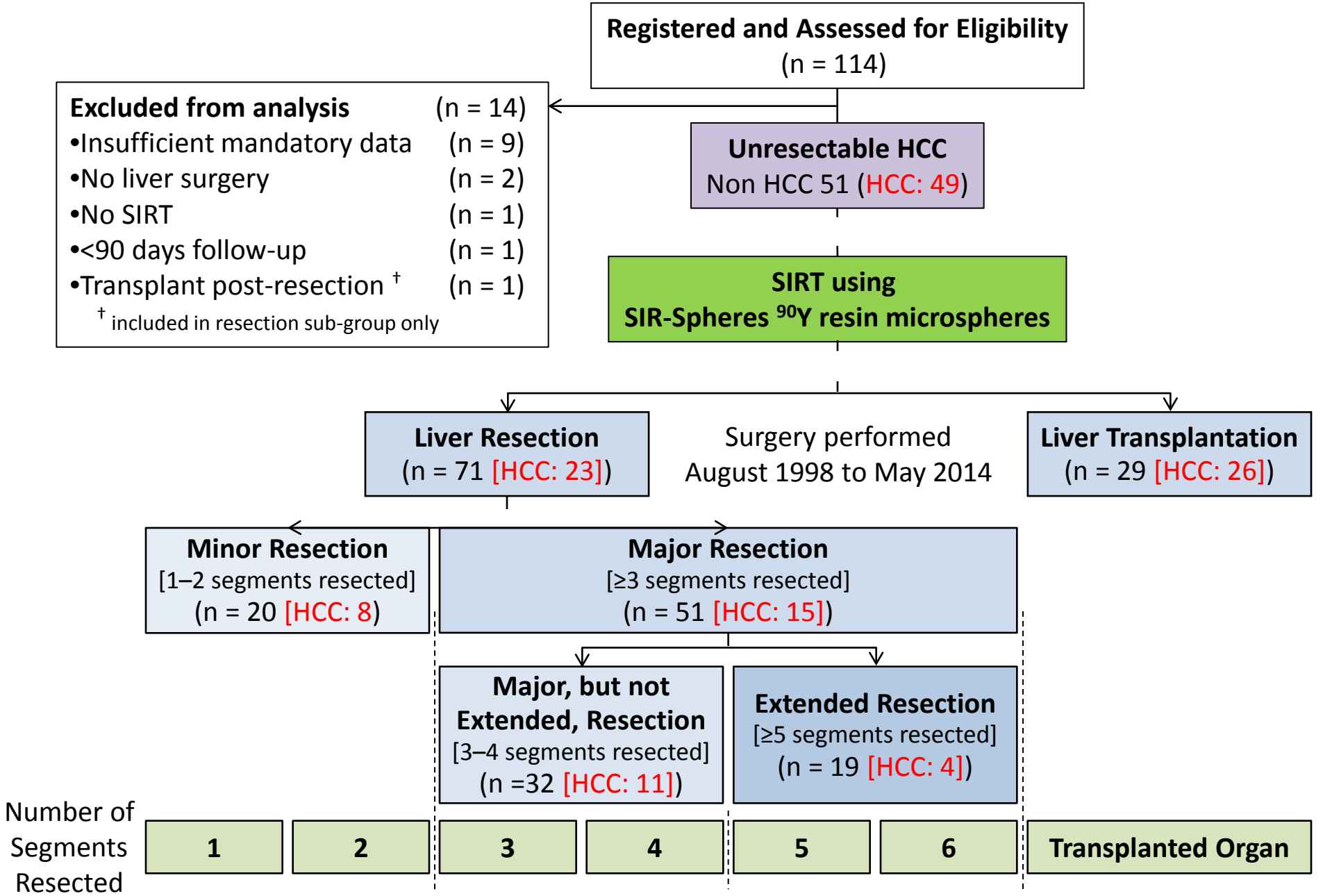
P4S Global Study

- Clinica Universidad de Navarra, Pamplona, Spain: Fernando Pardo, Bruno Sangro, J Ignacio Bilbao
- Klinikum Karlsruhe, Karlsruhe, Germany: Michael R Schön, Konstantinos Kouladouros
- Taipei Veterans General Hospital, Taipei, Taiwan: Lee Rheun-Chuan
- Newcastle Hospitals, Newcastle, UK: Derek Manas
- Methodist Dallas Medical Center, Dallas TX, USA: Dhiresh Rohan Jeyarajah,
- Hôpital Erasme & Institut Jules Bordet, Brussels, Belgium: Georgios Katsanos, Vincent Donckier
- UZ Gasthuisberg, Leuven, Belgium: Geert Maleux
- University of Bologna, Sant Orsola-Malpighi Hospital, Bologna, Italy: Antonio D Pinna, Giorgio Ercolani
- St. Vincent's Hospital, Sydney, NSW, Australia: Lourens Bester
- St George Hospital, University of New South Wales, Kogarah, NSW, Australia: David L Morris, Frances Chu
- Carolinas Medical Center, Charlotte NC, USA: David Iannitti
- **National Cancer Center, Singapore**: Pierce KH Chow
- Wakefield Clinic, Wellington, New Zealand: Richard Stubbs
- Austin Hospital, Heidelberg, VIC, Australia: Paul J Gow
- Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy: Lucio Urbani, Caterina Vivaldi, Gianluca Masi, Irene Bargellini
- Saint Francis Hospital, Tulsa OK, USA: Kevin T Fisher
- The Chinese University of Hong Kong, Shatin, New Territories, Hong Kong: Wan-Yee Lau

Methods

- International, multi-centre retrospective study on the outcomes of liver resection or transplantation following SIR-Spheres ^{90}Y resin microspheres (Sirtex Medical; Sydney, Australia) in patients with either:
  - **Primary liver cancer**
  - **Metastases in the liver**
- Primary endpoints:
  - Peri-operative & 90-day post-operative morbidity
  - 90-day post-operative mortality
- Secondary endpoints:
  - Post-operative hospital days
  - Overall survival
  - Timing of surgery relative to SIRT
- 16 SIRT centers in Asia-Pacific, Europe and USA
- Data were captured on baseline characteristics, prior treatment including SIRT, liver surgery and follow-up
- Analysis used standard statistical methods

Study Design



Pre-Surgery Characteristics

Characteristic		Liver Resection (N = 23)	Liver Transplant (N = 26)
ASA score:	Median (IQR)	3.0 (1.0)	3.0 (1.0)
	ASA score ≥3	14 (61%)	21 (81%)
Total Bilirubin Grade ≥1:		4 (17%)	16 (62%)
Co-morbidities pre-surgery:			
	Any	16 (70%)	20 (77%)
	Cardiopathy	6 (26%)	5 (19%)
	COPD	1 (4%)	1 (4%)
	Diabetes	9 (39%)	11 (42%)
	Hypertension	13 (57%)	12 (46%)
	Other	2 (9%)	9 (35%)
Future Liver Remnant had received SIRT:		5 (22%)	na
Time from last SIRT to surgery			
	Median (IQR):	8.0 months (4.4)	7.4 months (7.7)
	>6 months, n (%):	16 (70%)	16 (62%)

n (%) unless stated; na: not applicable; SIRT: Selective Internal Radiation Therapy.

Peri-/Post-Surgical Complications

Complication	Clavien-Dindo (CD) grade	Liver Resection (N = 23)	Liver Transplant (N = 26)
Any:	CD grade ≥1 CD grade ≥3	4 (17%) 1 (4%)	13 (50%) 4 (15%)
Liver failure:	CD grade ≥1 CD grade ≥3	0 0	1 (4%) 0
Wound-specific:	CD grade ≥1 CD grade ≥3	0 0	1 (4%) 0
Cardiovascular-specific:	CD grade ≥1 CD grade ≥3	1 (4%) 0	1 (4%) 0
Pulmonary-specific:	CD grade ≥1 CD grade ≥3	0 0	1 (4%) 0
Renal-specific:	CD grade ≥1 CD grade ≥3	1 (4%) 0	2 (8%) 0
Other complications:	CD grade ≥1 CD grade ≥3	1 (4%) 1 (4%)	10 (39%) 4 (15%)

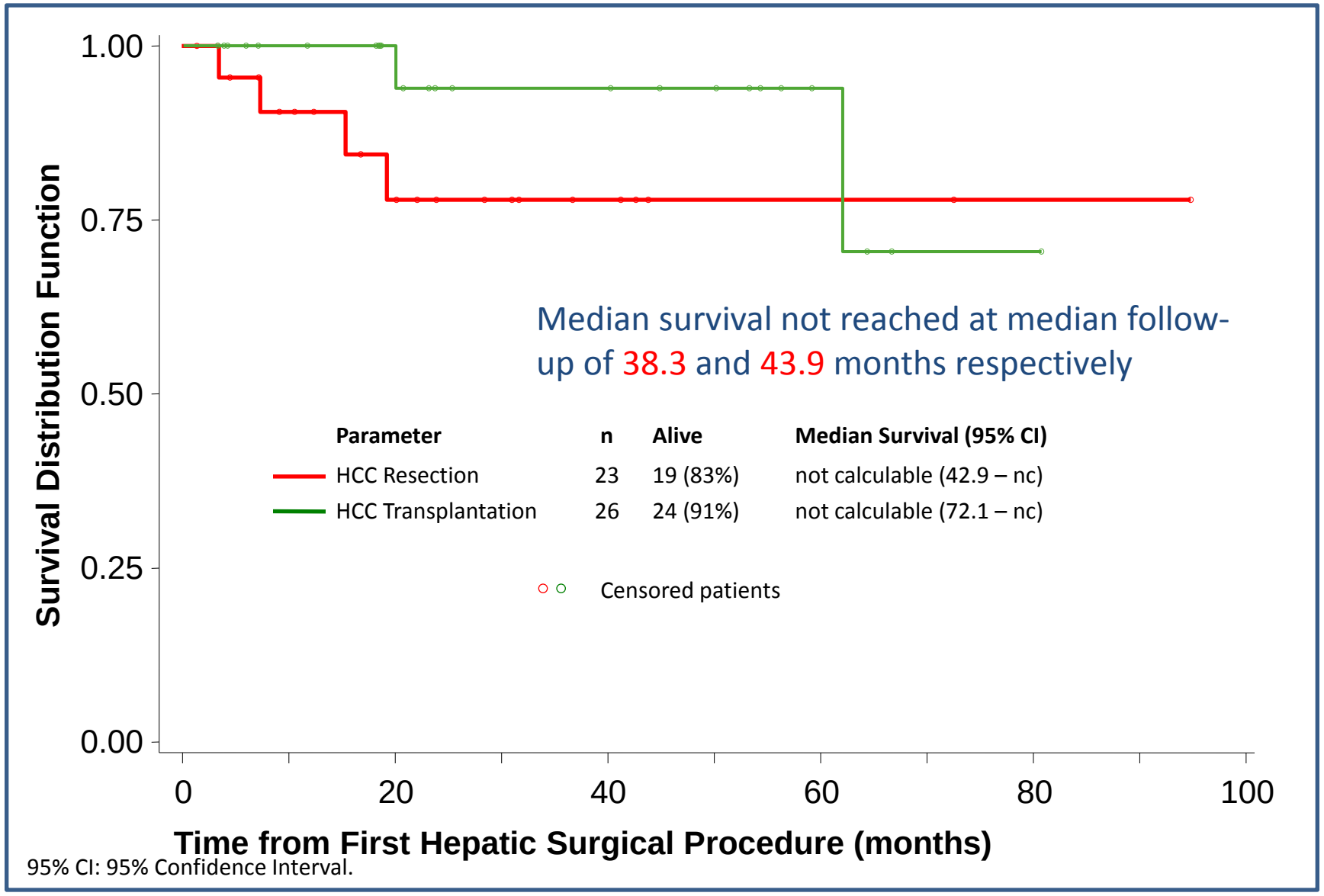
n (%) unless stated; CD: Clavien-Dindo scale;.

Outcomes for HCC in PS4 Study

Outcome	Liver Resection (N = 23)	Liver Transplant (N = 26)
Median (IQR) duration to hospital discharge, days:	8.0 (4.0)	11.0 (8.0)
90-day readmission rate:	1 (4%)	7 (27%)
All-cause mortality at: 30 days 90 days	0 0	0 0
Median follow-up from: 1st SIRT Surgery	38.3 months **28.5 months**	43.9 months **23.7 months**

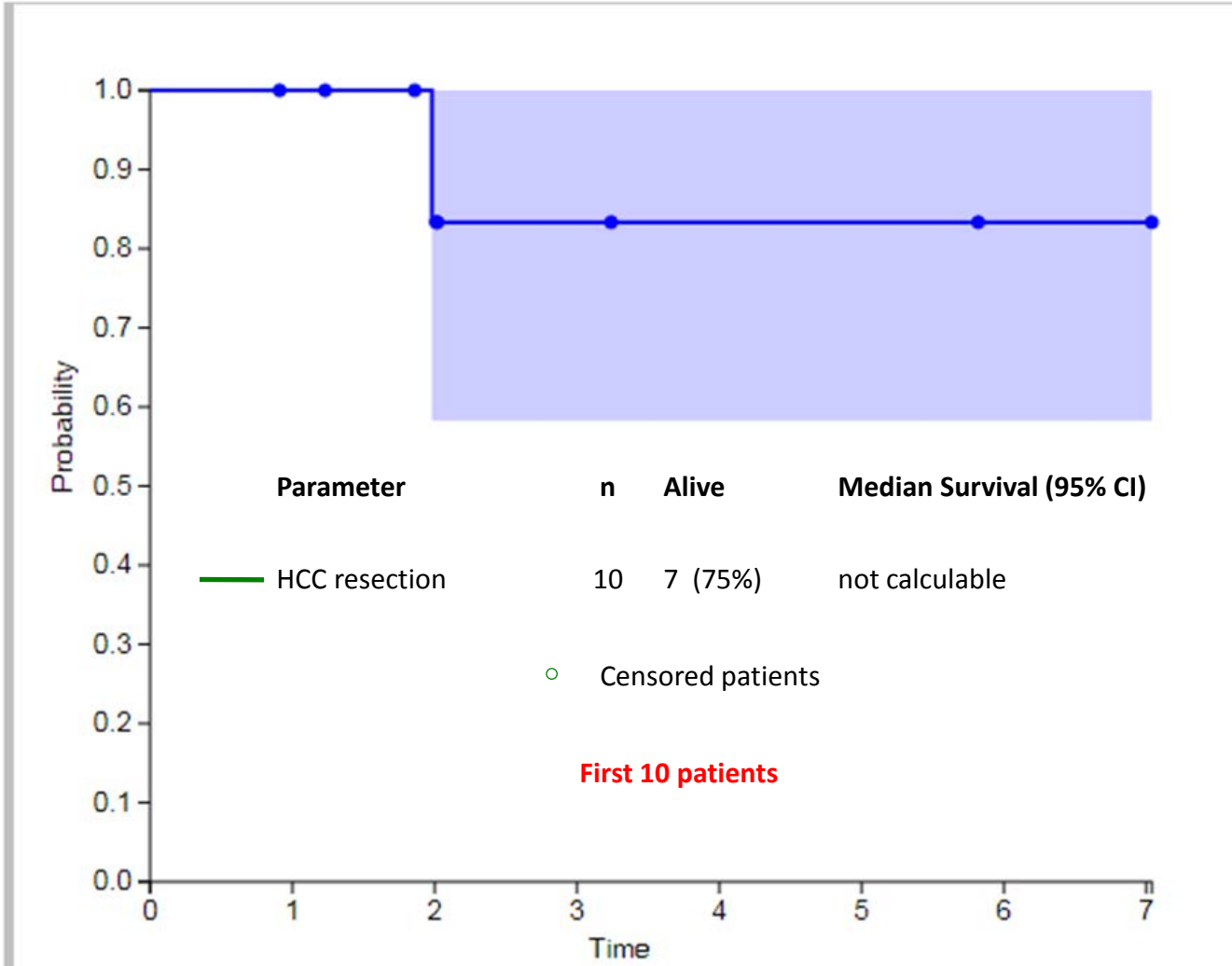
n (%) unless stated.

Survival from surgery for HCC, stratified by procedure



95% CI: 95% Confidence Interval.

Survival from SIRT and surgery for HCC
The experience of the NCCS/SGH



Time from First SIRT (years)

The basis for sustained response - Longitudinal Blood collection

Pre Y90
n=19
(**n=10 NR**
n=9 R)

Y90

Post Y90
(~1 month: 37-53d)
n=10

Post Y90
(~3 month: 75-146d)
n=12

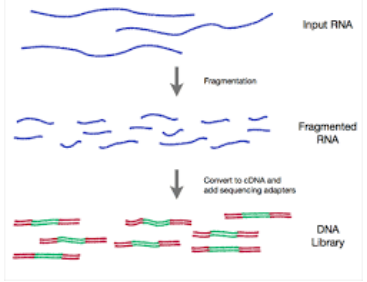
Post Y90
(~6 month: 157-233d)
n=7

Resection
n=3
+ n=3 Post Y90 cases (w/o blood)

Tissue collection

Resection
n=6
(Stage and viral status matched treatment naive cases)

CyTOF
RNA sequencing

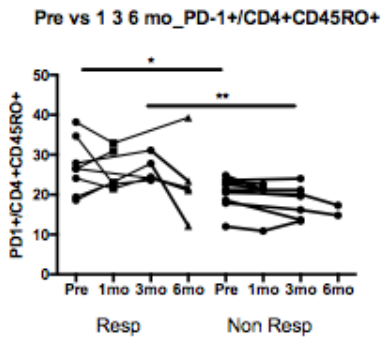


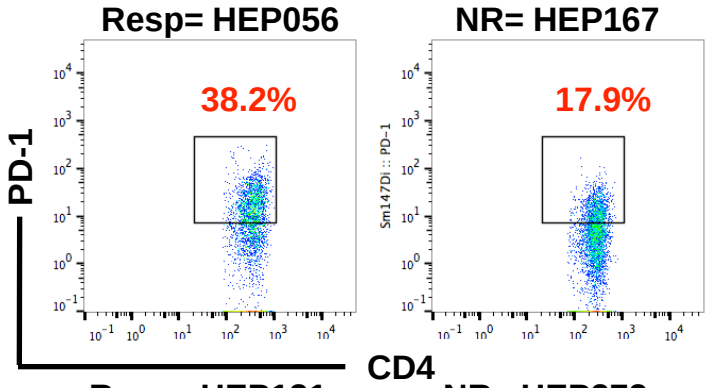
Aims:

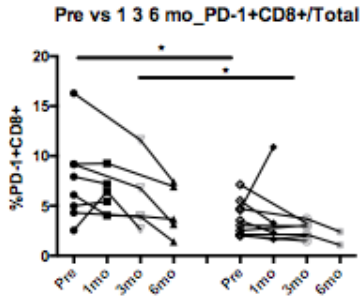
1. Capture the "abscopal effect" in the peripheral blood
2. Identify biomarkers for responders to Y90
3. Understand the mechanisms for immune response to Y90
4. Improve the therapeutic strategies in combination with Y90

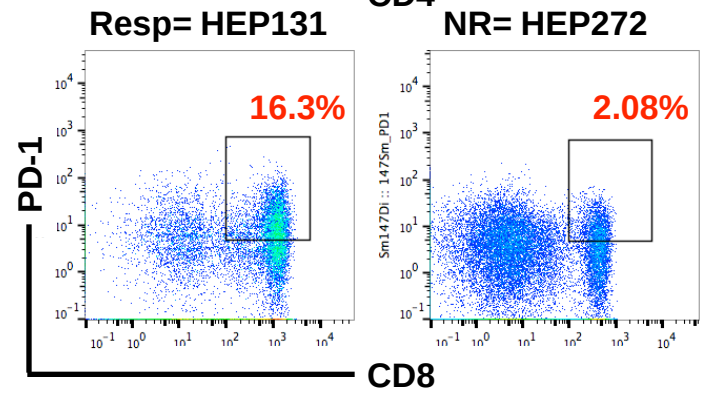
Courtesy:
Valerie Chew
PhD

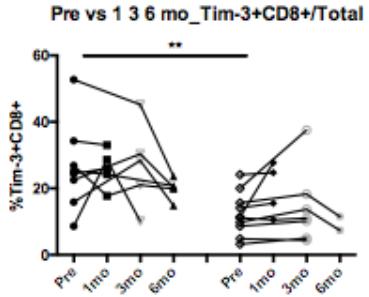
Checkpoint markers are higher in responders vs non-responders to Y90

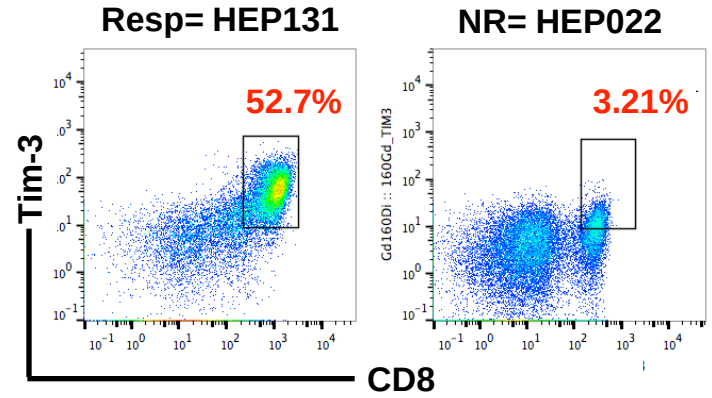












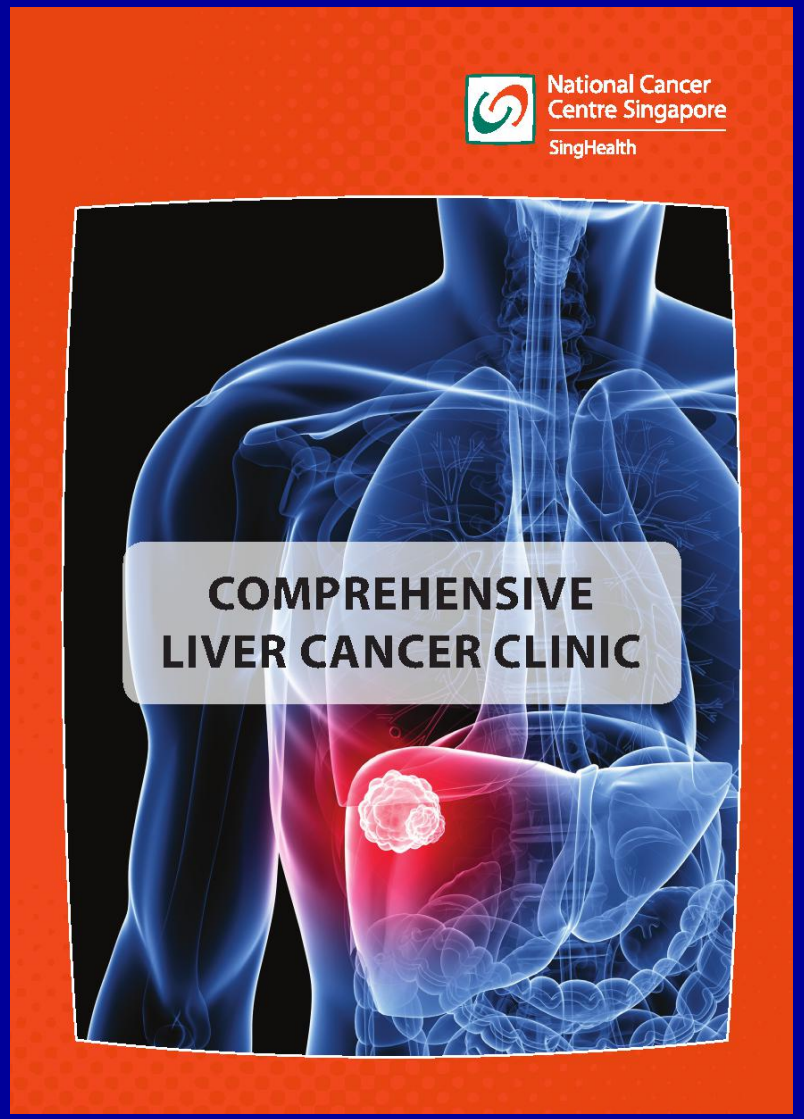
Responders defined as: no additional new HCC lesions develop:
An Abscopal effect

In press

The Role of Radio-embolization in the Management of HCC

- SIRT requires tertiary facilities and expertise, most patients with intermediate stage HCC are in the 3rd world
- TACE will remain the most common therapy for intermediate stage HCC

- **Roles of Radioembolization (SIRT) in tertiary centers**
  - HCC with PVT, Large volume HCC, HCC that have failed TACE
  - Bridge to transplantation
  - Down-staging of inoperable HCC to resection/RFA/Transplantation
  - Potential combination therapy with check-point inhibitor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Thank You!

APPLE 2017 Singapore

the 8th Asia-Pacific Primary Liver Cancer Expert Meeting

Date: 14 – 16 July 2017 **Venue**: The Grand Copthorne, Singapore

Theme : The Science and Art of Conquering Liver Cancer