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TRANSPLANTATIONS ZENTRUM KÖLN

DKG KREBSGESELLSCHAFT Zertifiziertes Leberkrebszentrum

ESSURE

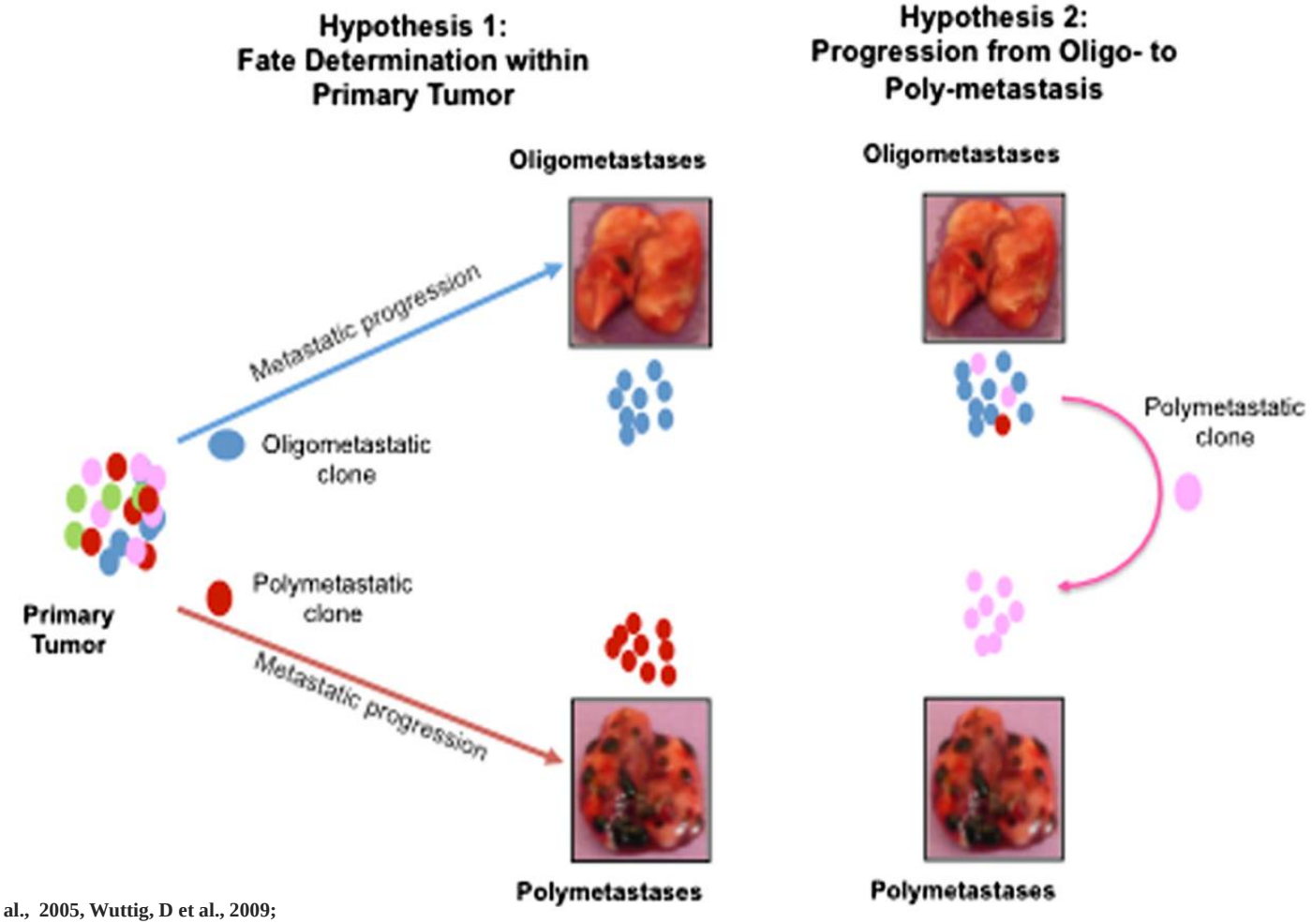
Die Oligometastasierung: moderne lokal ablative Verfahren und ihr Stellenwert

Priv.-Doz. Dr. med. Roger Wahba, FEBS

Leiter des Leberkrebszentrums

13. Brustkrebskongress, Köln 18.01.2020

Oligometastasis vs polymetatasis: illusion or reality?



Kosari, F et al., 2005, Wuttig, D et al., 2009;
Lussier, YA et al., 2011, Uppal , A et al., 2014

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ESSURE

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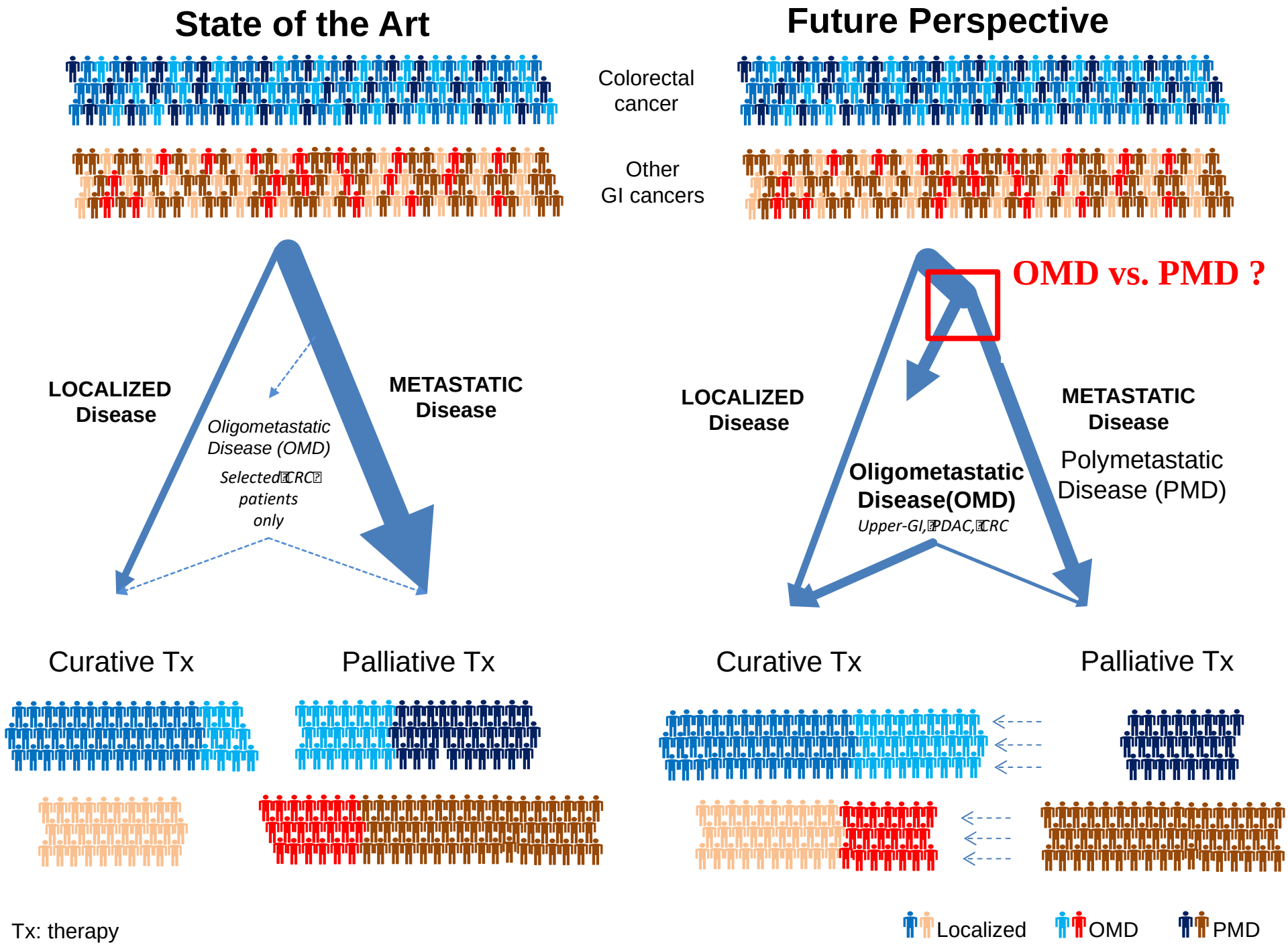
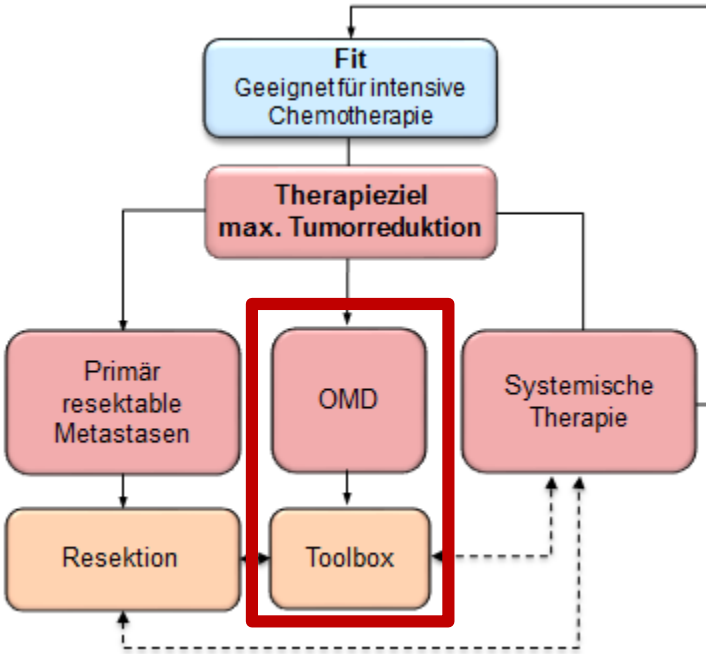

State of the Art
Future Perspective
Colorectal cancer
Other GI cancers
LOCALIZED Disease
METASTATIC Disease
Oligometastatic Disease (OMD)
Selected CRC patients only
OMD vs. PMD ?
LOCALIZED Disease
METASTATIC Disease
Oligometastatic Disease(OMD)
Upper-GI, PDAC, CRC
Polymetastatic Disease (PMD)
Curative Tx
Palliative Tx
Curative Tx
Palliative Tx
Tx: therapy
Localized
OMD
PMD

Definitionsversuch S3-Leitlinien
- Oligometastasierung mCRC -



„Definition“

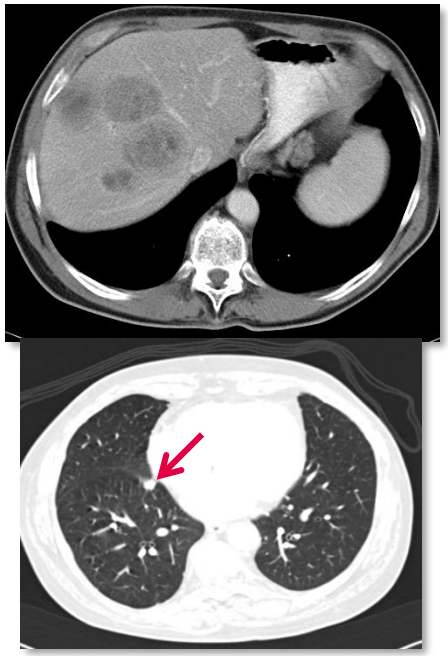
- Limitierte Ausbreitung auf z.B. 1-5 Metastasen und wenige Organsysteme (1-3 Organe, nicht Lymphknoten, Gehirn, Knochen)
- Potentiell resektabel oder lokal interventionell angehbare Metastasierung
- Unter **günstigen Voraussetzungen** kann bei OMD von ein kurativer Behandlungsansatz (möglichst chirurgisch) in Betracht gezogen werden
- Der Einsatz der lokal ablativen oder resezierenden Verfahren kann eine Unterbrechung der Systemtherapie ermöglichen

S3-Leitlinie Kolorektales Karzinom, Langversion 2, 2017
S3-Leitlinie Kolorektales Karzinom, Version 2.1, 2019

Definition von Subgruppen nach klinischen Situationen/Therapiezielen

1. **Bestehen einer kurativen Behandlungsoption**
   a. Resektable Erkrankung
   b. Potenziell resektable Erkrankung

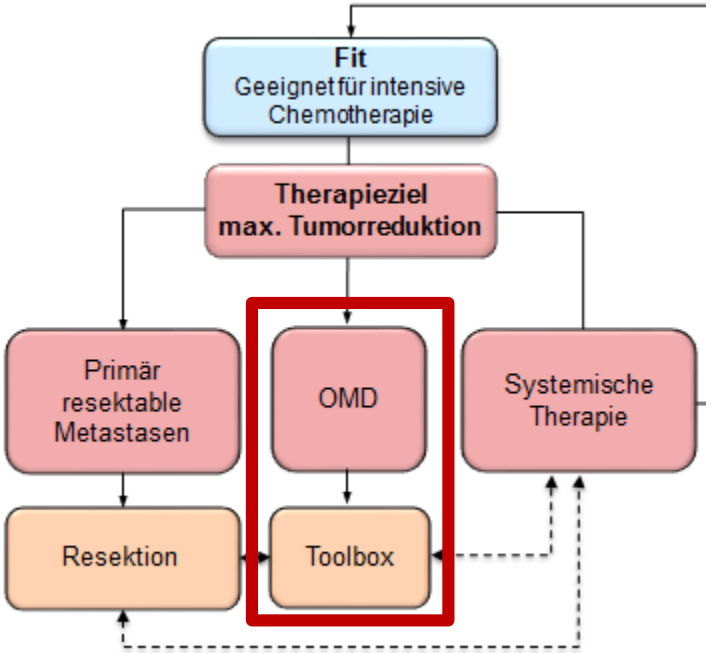
2. **Eher palliative Therapieausrichtung**
   a. Oligometastasierung
   b. Wahrscheinlich nicht/nie resektable, disseminierte Erkrankung



S3-Leitlinie Kolorektales Karzinom, Langversion 2, 2017

S3-Leitlinie Kolorektales Karzinom, Version 2.1, 2019

Definitionsversuch Brustkrebs



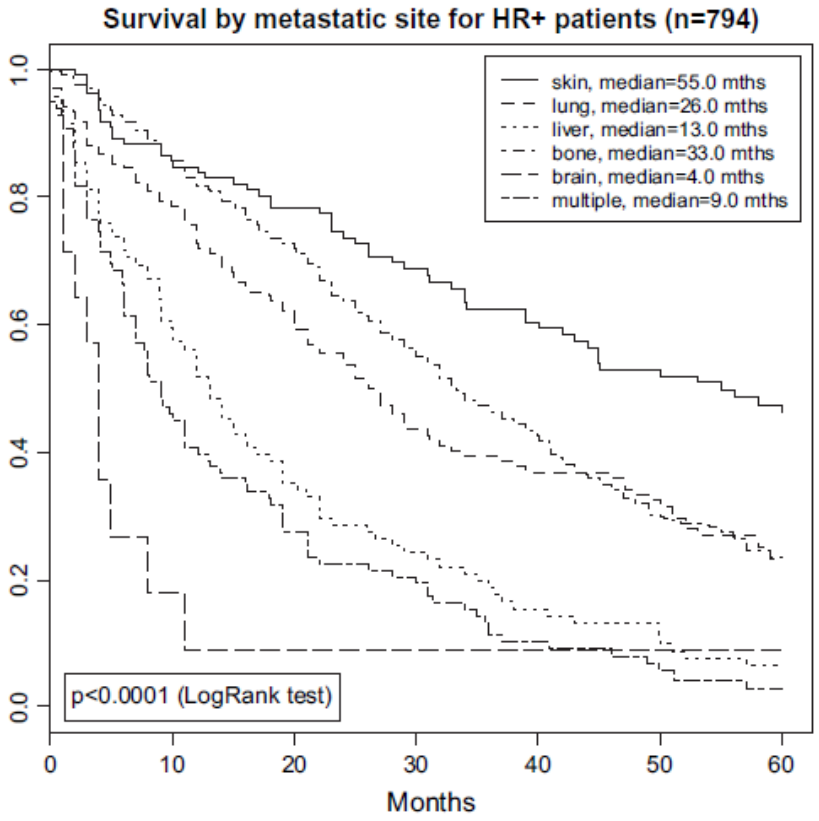
„Definition“

- “A small but very important subset of MBC patients, for example, those with a solitary metastatic lesion, can achieve complete
- remission and a long survival. More aggressive and multidisciplinary approach should be considered for these
- selected patients. A clinical trial addressing this specific situation is needed”

European School of Oncology (ESO)-MBC Task Force. Metastaticbreast cancer. Recommendations proposal from the European School of Oncology (ESO)-MBC Task Force. Breast. 2007;16:9–10.

Prognostic factors in women with metastatic breast cancer

- 1038 women
- Time period 1975-2005
- Multiple or visceral site of metastasis
- median survival >22 months
- Non-visceral sites
- median survival of >33months
- No „adjuvant“ local treatment



Largillier et al, Prognostic factors in 1038 women with metastatic breast cancer, Annals of Oncology 19: 2012–2019, 2008, doi:10.1093/

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Oligometastatic Disease - Evidence

Stereotactic ablative radiotherapy versus standard of care palliative treatment in patients with oligometastatic cancers (SABR-COMET): a randomised, phase 2, open-label trial

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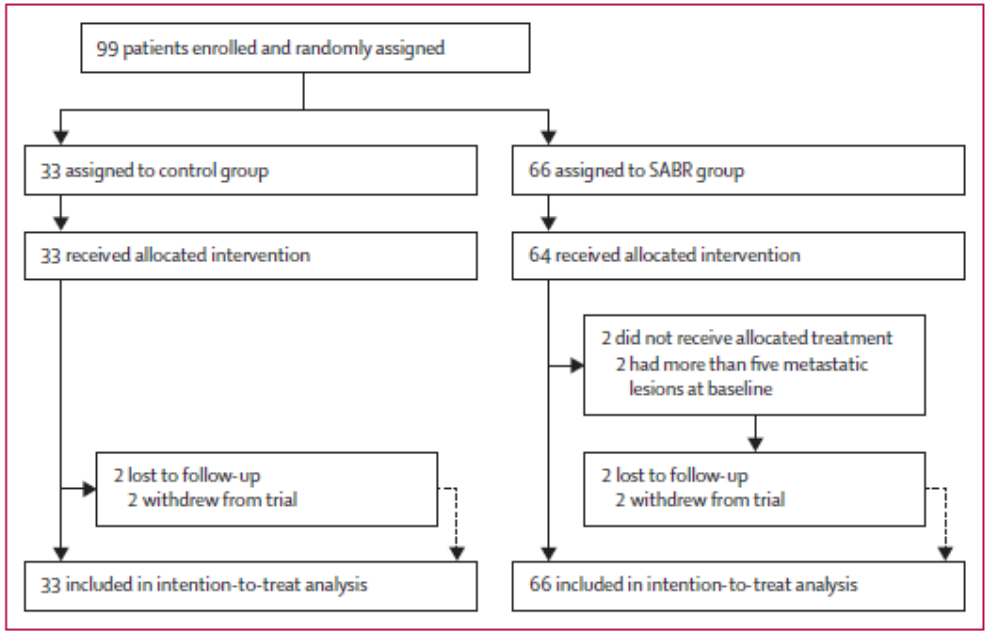

Lancet 2019; 393: 2051–58
Published Online
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http://dx.doi.org/10.1016/S0140-6736(18)32487-5

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	Control group (n=33)	SABR group (n=66)
Age	69 (64–75)	67 (59–74)
Sex		
Men	19 (58%)	40 (61%)
Women	14 (42%)	26 (39%)
Site of original primary tumour		
Breast	5 (15%)	13 (20%)
Colorectal	9 (27%)	9 (14%)
Lung	6 (18%)	12 (18%)
Prostate	2 (6 %)	14 (21%)
Other	11 (33%)	18 (27%)
Time from diagnosis of primary tumour to randomisation (years)	2·3 (1·3–4·5)	2·4 (1·6–5·3)
Number of metastases		
1	12 (36 %)	30 (46%)
2	13 (40%)	19 (29%)
3	6 (18%)	12 (18%)
4	2 (6%)	2 (3%)
5	0 (0%)	3 (5%)
Location of metastases		
Adrenal	2/64 (3%)	7/127 (6%)
Bone	20/64 (31%)	45/127 (35%)
Liver	3/64 (5%)	16/127 (13%)
Lung	34/64 (53%)	55/127 (43%)
Other*	5/64 (8%)	4/127 (3%)

Data are n (%), n/N (%), or median (IQR). SABR=stereotactic ablative radiotherapy. *Other comprises brain (n=3 lesions in control group; n=1 lesion in SABR group), lymph nodes (n=1 lesion in control group; n=3 lesions in SABR group), and para-renal (n=1 lesion in control group).

Table 1: **Baseline characteristics**

	All patients (n=99)	Control group (n=33)	Stereotactic ablative radiotherapy group (n=66)	p value
Adverse event grade ≥2	55 (56%)	15 (46%)	40 (61%)	0·15
Related adverse event grade ≥2	22 (22%)	3 (9%)	19 (29%)	0·026
Adverse event associated with death (grade 5)	3 (3%)	0	3 (5%)	0·55
Fatigue*	--	--	--	0·45
Grade 2	6 (6%)	2 (6%)	4 (6%)	--
Grade 3	1 (1%)	1 (3%)	0	--
Dyspnoea*	--	--	--	1·00
Grade 2	1 (1%)	0	1 (2%)	--
Grade 3	1 (1%)	0	1 (2%)	--
Pain (any type)*	--	--	--	0·14
Grade 2	5 (5%)	0	5 (8%)	--
Grade 3	3 (3%)	0	3 (5%)	--

Data are n (%). * Treatment related.

Table 2: **Summary of adverse events**

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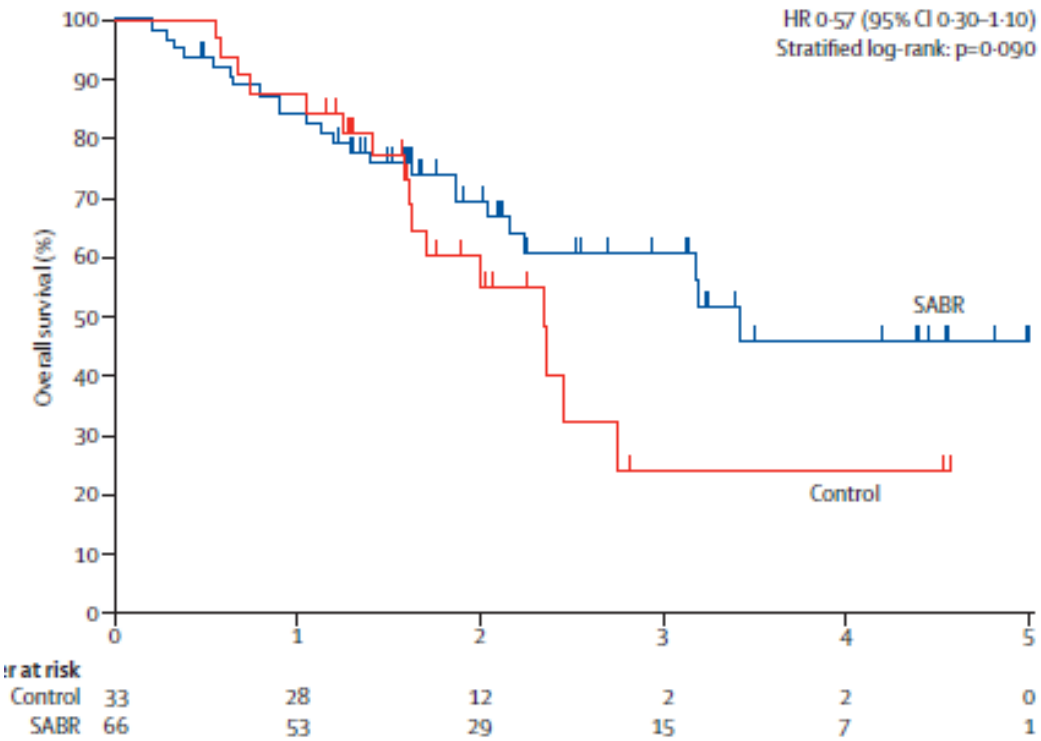

Median Overall survival: >41 vs 28 months !

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Local Therapy Options

- Liver resection
- Radiofrequencyablation (RFA)
- Microwaveablation (MWA)
- Irreversible electroporation (IRE, NanoKnife)
- 3D-navigated resection/ablation, ICG-navigated resection
- Stereotatic radiation (Cyberknife)
- Laparoscopic liver resection, Robotic liver resection
- SIRT (selective intern radiotherapy), Radioembolisation
- Liver resection following SIRT
- Transarterial Chemoembolisation

Resektion nicht-kolorektalen, nicht-(neuro)endokrinen Lebermetastasen

- 4735 Abstracts → 120 Manuskripte → 73 Manuskripte gewählt
- 3596 Patienten mit u.a.:

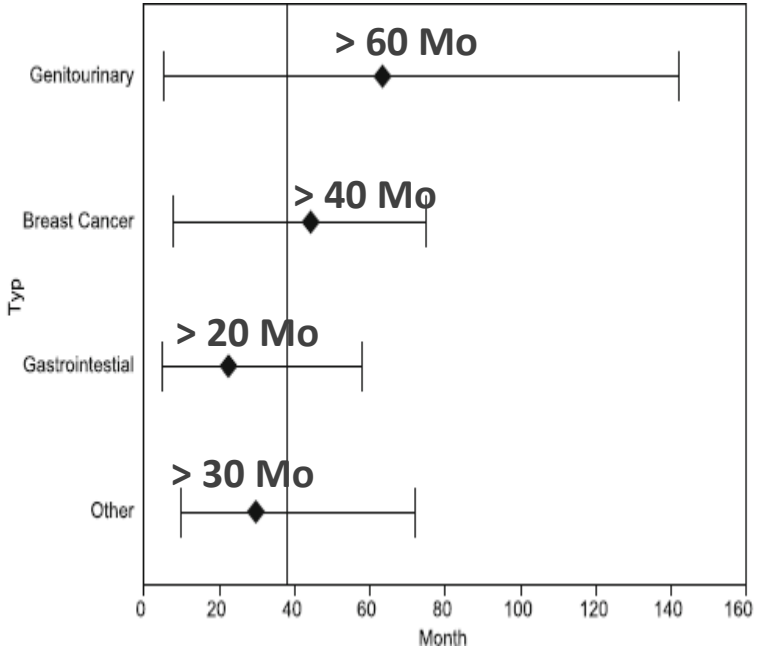
  - n=1281 Brustkrebs
  - n=119 Ov-Ca
  - n=153 Keimzelltumor
  - n=90 Nebennierenkarzinom
  - n=28 Dünndarmtumor
  - n=21 Gallenblasenkarzinom, n=13 Cholangiokarzinom
  - n=38 Duodenalkarzinom, n=55 Pankreaskarzinom
  - n=481 Magenkarzinom, n=23 Ösophaguskarzinom
  - n=106 GIST
  - n=189 Sarkom
  - n=643 Melanom

Fitzgerald TL et al. Langenbecks Arch Surg 2014

Resektion nicht-kolorektalen, nicht-(neuro)endokrinen Lebermetastasen

- Resektion ist sinnvoll bei NCRNNE Lebermetastasen
- Der Überlebensvorteil wird on der Art des Primärtumors bestimmt
- Größter Überlebensvorteil = Urogenitale Tumore (Keimzelltumore, OV-Ca, NCC)
- Resektion isolierter LM bei Mammakarzinom
  - Überlebensvorteil
  - CTx-Response und Hormonrezeptorstatus
- Geringerer Überlebensvorteil bei LM von GI-Tumoren, HNO-Tumoren, Sarkomen, Bronchialkarzinomen etc.
- Ausnahme: metachronen, isolierten LM bei Magenkarzinom, < 5cm, ohne Serosabezug

Erwartetes medianes Überleben bei Resektion von NCRNNE-LM aus Studien 1990-2013



Fitzgerald TL et al. Langenbecks Arch Surg 2014

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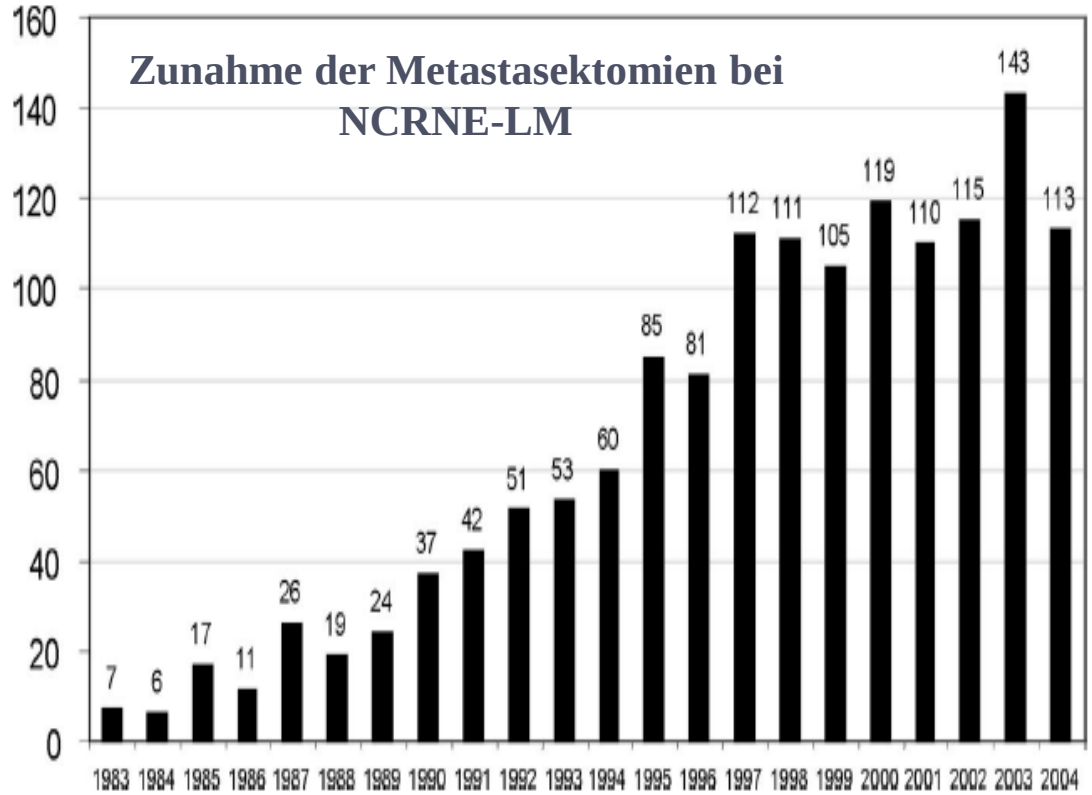
Hepatic Resection for Noncolorectal Nonendocrine Liver Metastases

Analysis of 1452 Patients and Development of a Prognostic Model

1452 Patienten, 41 Zentren, 1983-2004

- Solitäre Metastasektomie in 56%
- Unilaterale Metastasektomie in 71%
- Mittlere Metastasengröße =50.5 mm
- Extrahepatische Manifestation in 22%
- Tumorentitäten:
  - Mammakarzinom =32%
  - GI-Tumore =16%
  - Urologische Tumore =14%
- R0-Resektion in 83%
- Tumorrezidive in 67%



Adam R et al. Ann Surg 2006

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Study Population	No.	5-Year Survival (%)	Median Survival (mo)
All patients	1452	36	35
Group 1: 5-yr survival >30%			
Adrenal	28	66	63
Testicular	78	51	82
Ovarian	65	50	98
Small bowel	28	49	58
Ampullary	15	46	38
Breast	454	41	45
Unknown	28	38	30
Renal	85	38	36
Uterine	43	35	32
Group 2: 5-yr survival 15%–30%			
Gastric adenocarcinoma	64	27	15
Exocrine pancreatic	40	25	20
Cutaneous melanoma	44	22	27
Choroid melanoma	104	21	19
Duodenal	12	21	34
Group 3: 5-yr survival <15%			
Gastroesophageal junction	25	12	14
Pulmonary	32	8	16
Esophageal	20	32*	16
Head and neck	15	24*	18

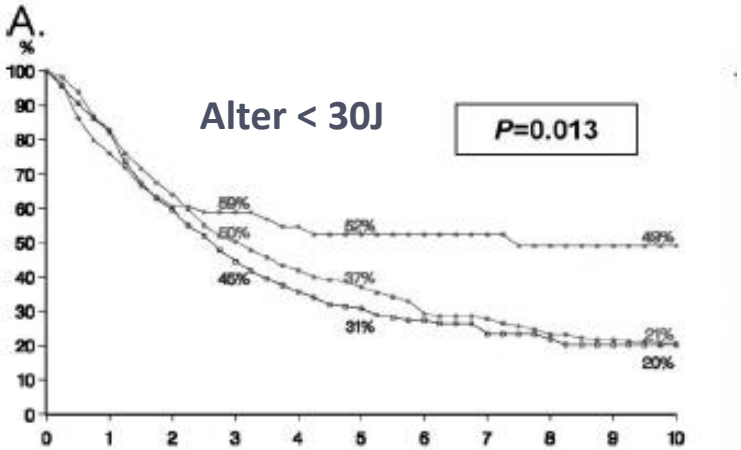
46 %

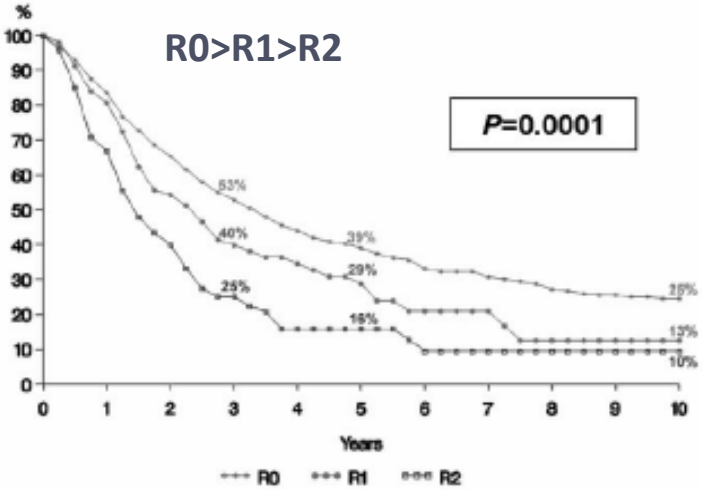
23 %

19 %

*Three-year survival.

Prognostische Faktoren





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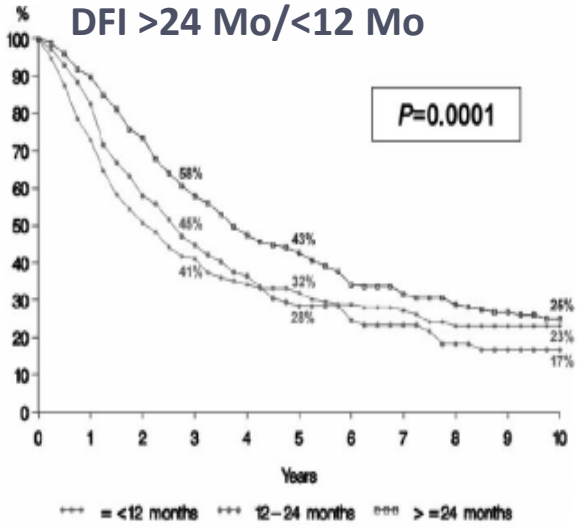
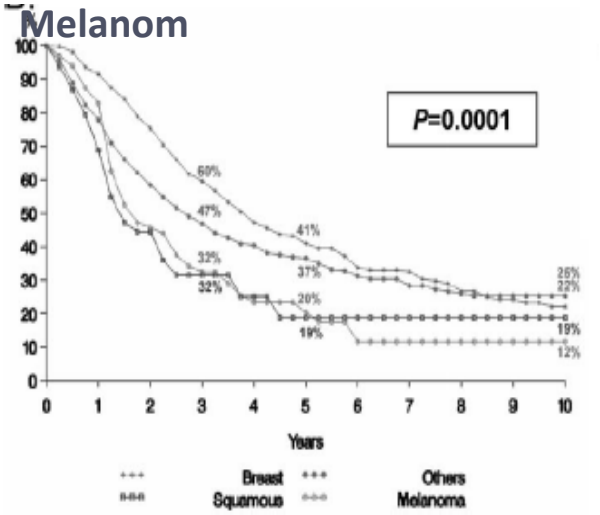
DFI >24 Mo/<12 Mo



Mamma > Plattenepithel > Melanom



Prognostisches Modell:

- Extrahepatische Manifestation
- R-Status
- > 2 Segment
- Alter
- DFI
- Tumorlokalisation/Histologie

Adam R et al. Ann Surg 2006

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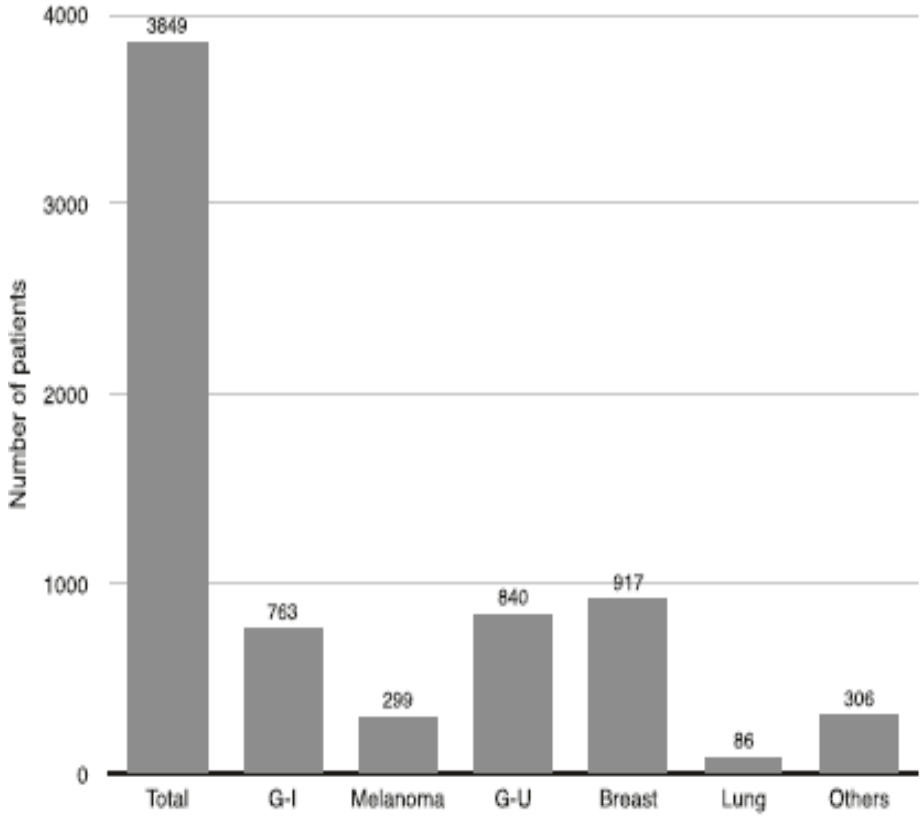
Metastatic liver disease from non-colorectal, non-neuroendocrine, non-sarcoma cancers: a systematic review

- **30 full texts (25 single-center and 5 multicenter studies), 1995 – 2015**
- **N = 3849 patients with NCNNNS liver metastases, 83% of these subjects were resected**



- **Entscheidender Vorteil für:**
  - **Urogenitale Tumore und Mammakarzinom**
  - **Metastasengröße ≤ 5 cm**
  - **R0 Resektion**
  - **DFS ≥ 12 Monate**

Uggeri, F et al. W J Surg Oncol 2015

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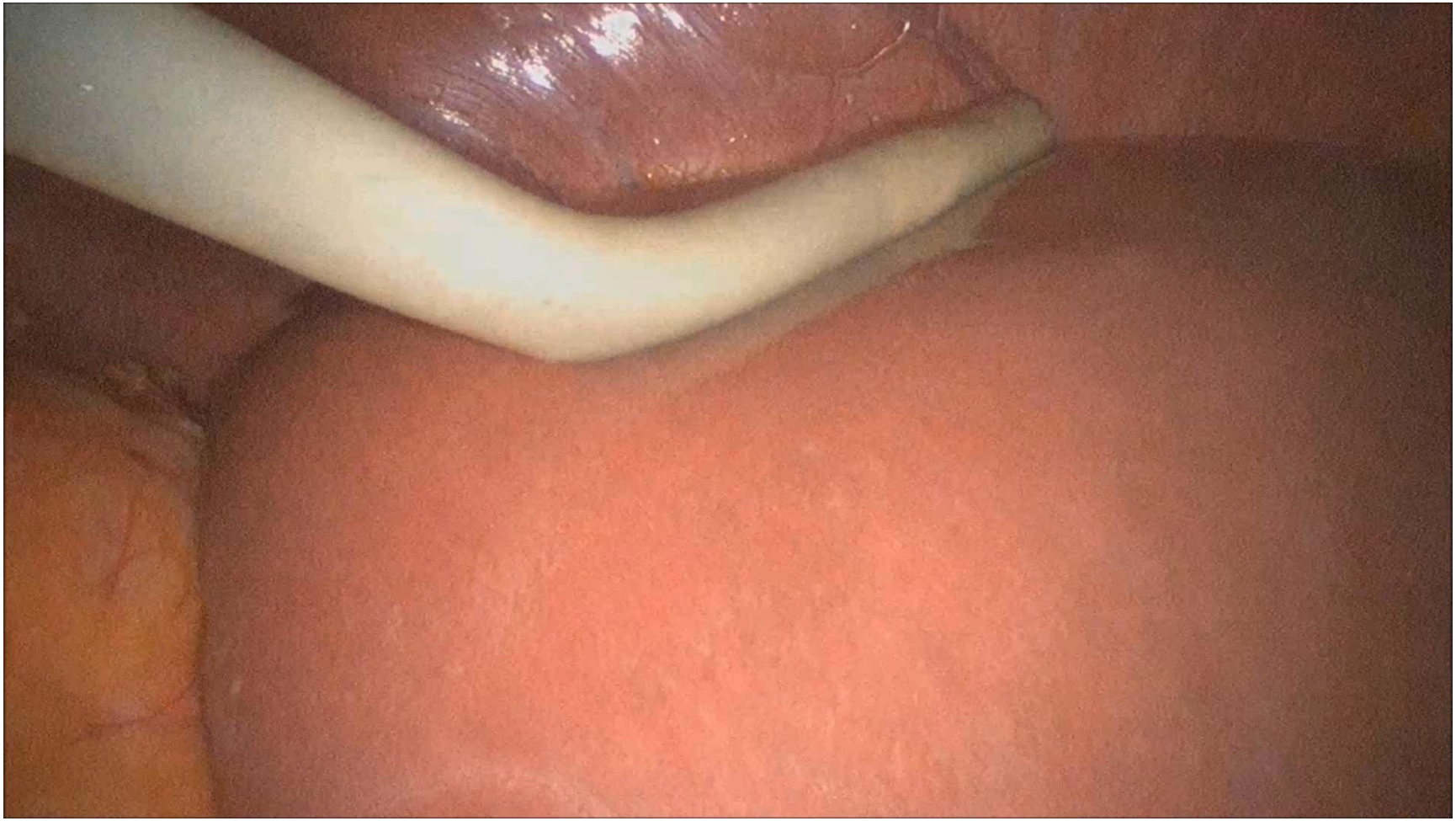
Hepatic Resection for Noncolorectal Nonendocrine Liver Metastases

Analysis of 1452 Patients and Development of a Prognostic Model

- **The results of this study suggest that the dogma that "there is no role for the surgical treatment of liver metastases from noncolorectal nonendocrine tumors" is no longer valid.**
- **However, in contrast to the treatment of colorectal liver metastases where surgery has the key role and chemotherapy acts as an adjuvant treatment, it is likely that the reverse situation is currently observed for noncolorectal nonendocrine metastases, where systemic chemotherapy plays the key role and surgery acts as an adjuvant therapy.**
- **In current practice, liver surgery for noncolorectal nonendocrine metastases should be considered only when the metastatic disease is well controlled or responding to systemic therapy.**

Adam R et al. Ann Surg 2006

Laparoskopische Leberresektion



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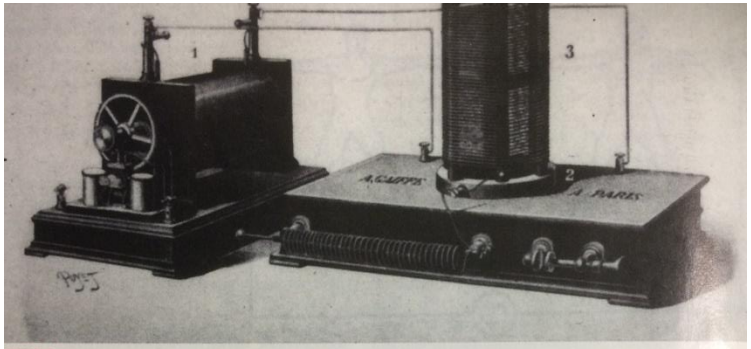
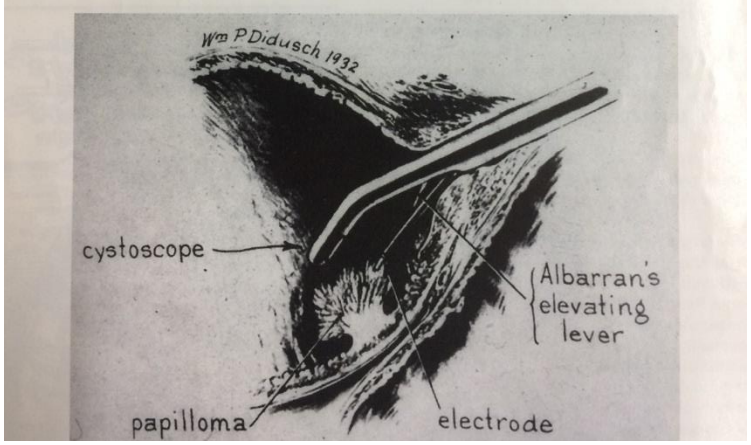
Interventional tumor treatment - History



IGURE 4 This is the first high-frequency electrical apparatus used in a medical setting. It was designed by d'Arsonval and wa sed in the Hôtel Dieu in Paris in 1896.



Siperstein et al, History and technological aspects of radiofrequency thermoablation, The Cancer Journal, Vol 6, S293-S303, 2000

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Thermische Ablationsverfahren – Mikrowellenablation (MWA) vs Radiofrequenzablation (RFA)

	MWA	RFA
	Mikrowellen 2.4 GHz	Elektromagn. Feld (450KHz)
Gewebeerwärmung / Geschwindigkeit	Erwärmung durch Induktion	Wärmetransport durch Konduktion (6 x schneller)
max. Nekrose Ø	7-8cm	6-7cm
Zeitdauer für max Ø	15min	25–40min
Zeitdauer für 2cm Ø	5min	10-15min
Heat sink	+	+++
Variabilität der Ablationszone	+	+++

Interventionelle Strategien -Mikrowellenablation

Solero - MWA System

Stippel, Wahab Bruns, Perisghell, Image-guided, minimally invasive surgery and other local therapeutic procedures for primary liver tumors], der Chirurgr, 2018
Ng KKC, Chok KSH, Chan ACY et al (2017) Randomized clinical trial of hepatic resection versus radiofrequency ablationforearly-stagehepatocellular carcinoma.Br JSurg104:1775–1784

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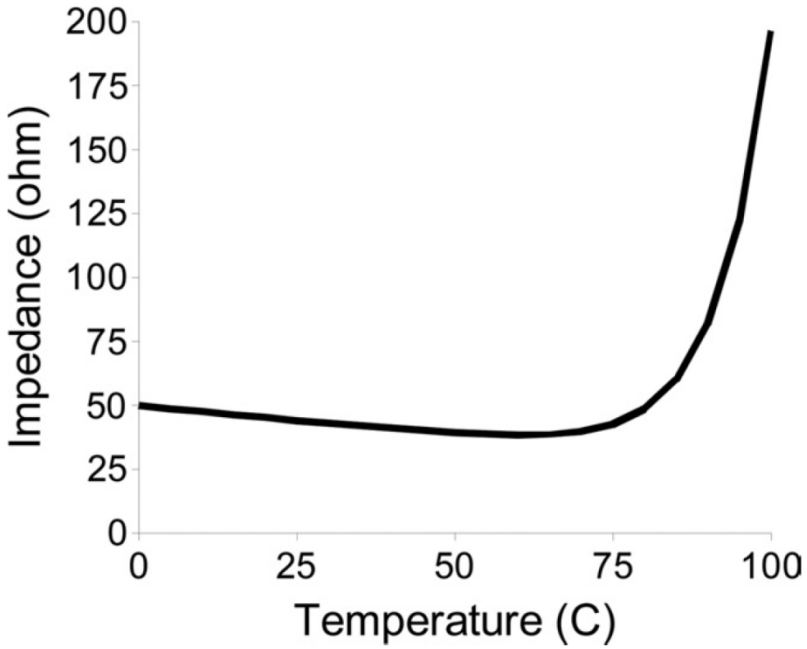
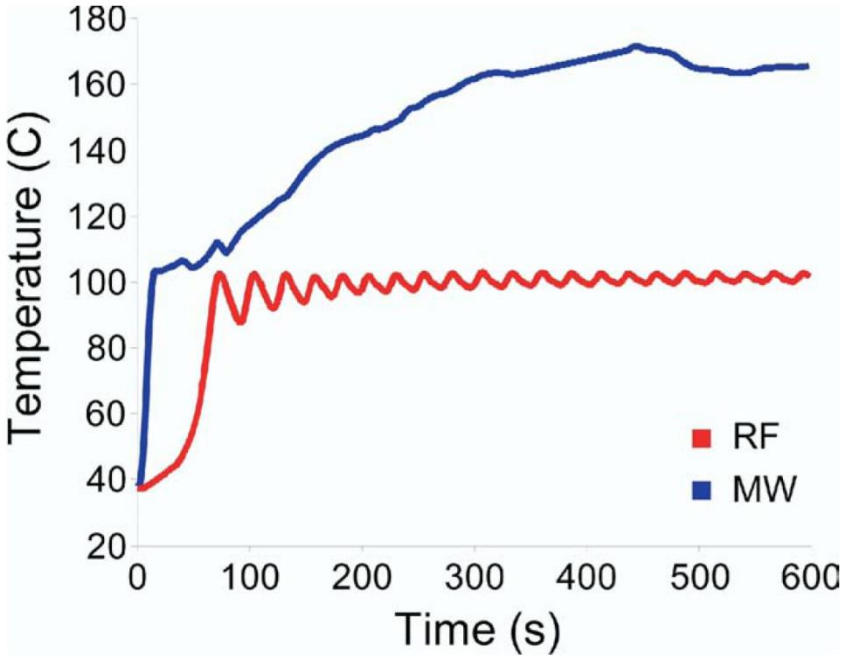
Vorteile Mikrowelle

- Energieeintrag unabhängiger von Gewebetemperatur und Wassergehalt





Brace L Cardiovasc Intervent Radiol 2012

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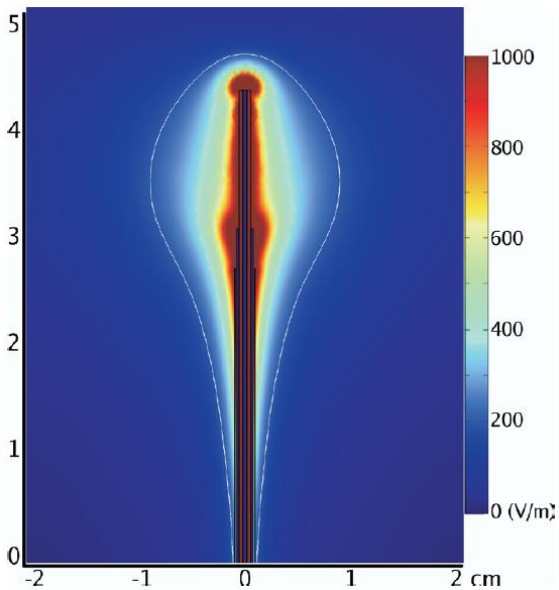
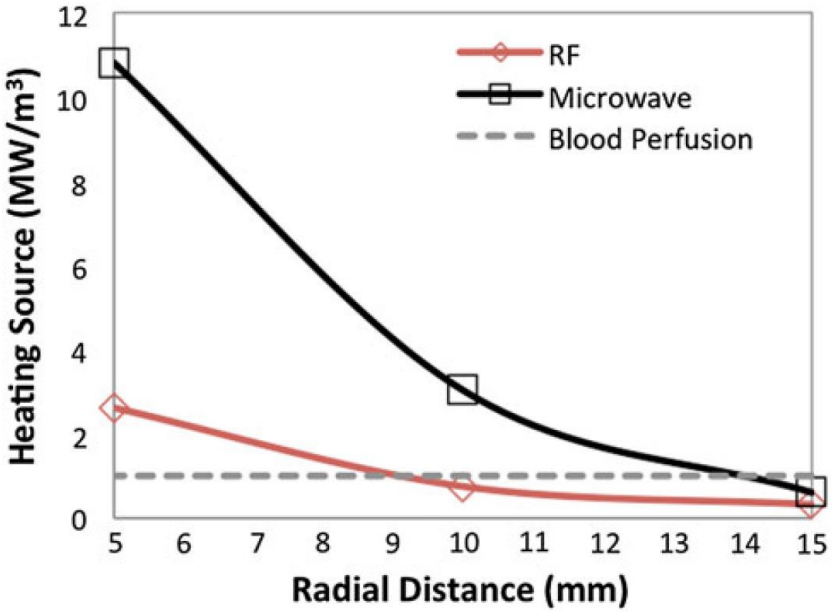
Vorteile Mikrowelle

Wärmeentstehung nicht nur direkt neben dem Applikator

- Karbonisierung kein Problem
- geringere Abhängigkeit von der konduktiven Wärmeausbreitung
- Ablationszone konstant





Brace L Curr Probl Diag Rad.: 2000; Cardiovasc Interv Radiol. 2012

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Interventionelle Strategien -Radiofrequenzablation

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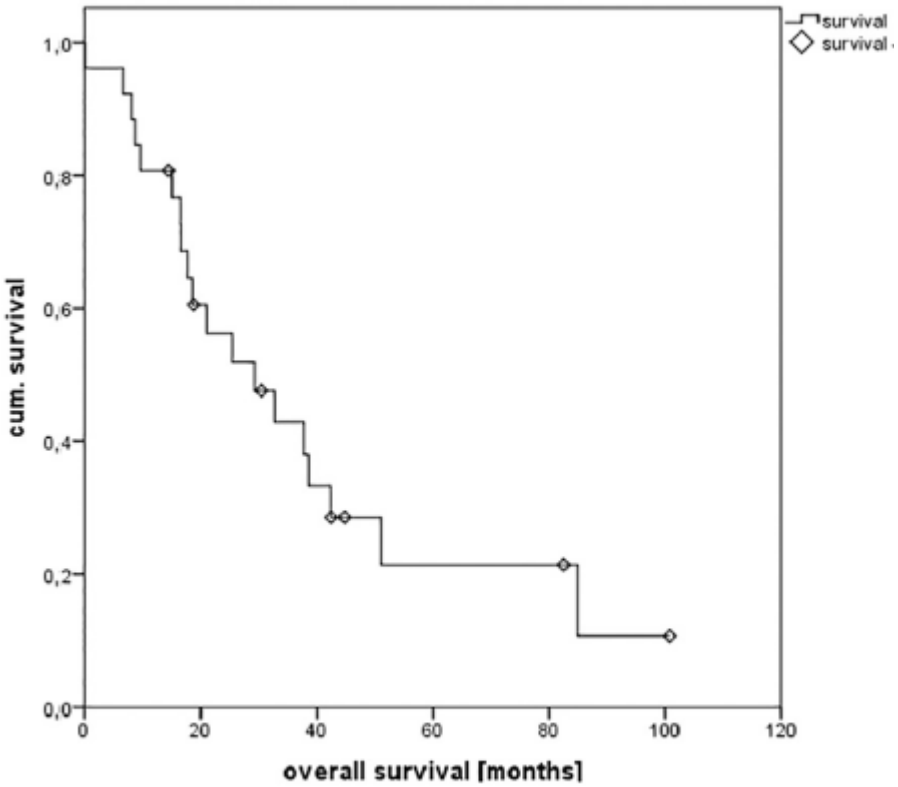
Radiofrequencyablation for Breast Cancer Liver Metastases



Number at risk

26	14	7	3	3	1	0

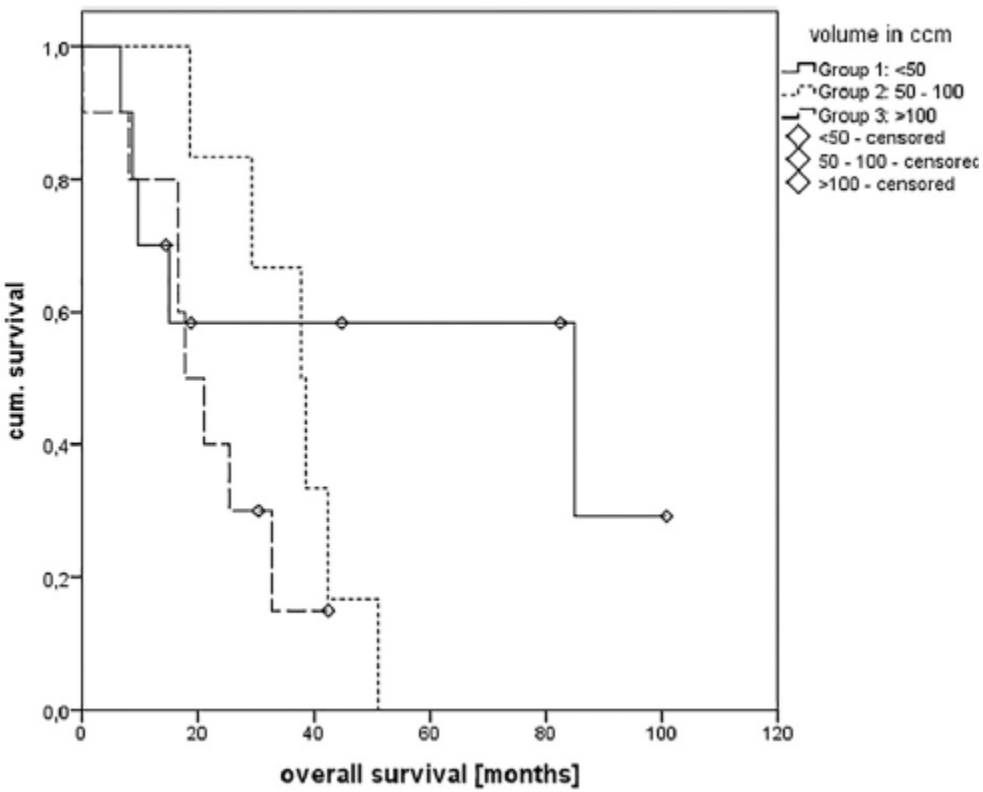


Figure 1. The median estimated OS of all 26 patients was 29.3 months ± 8.9 (mean, 38.7 mo).

Bale at al, Stereotactic Radiofrequency Ablation for Breast Cancer Liver MetastasesJ Vasc Interv Radiol 2018; 29:262–267,

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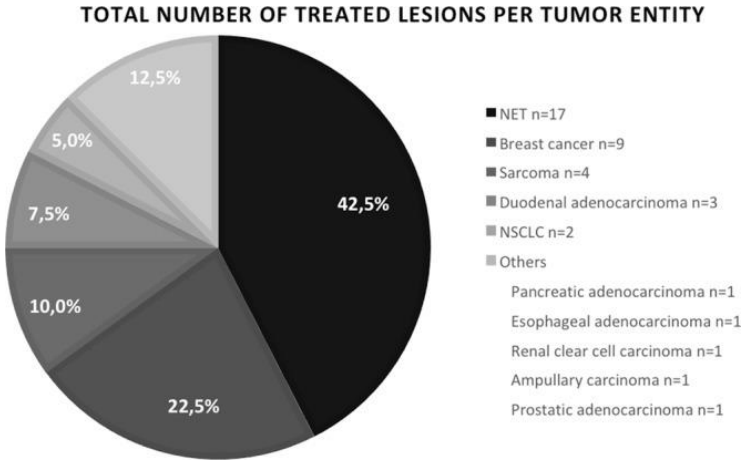
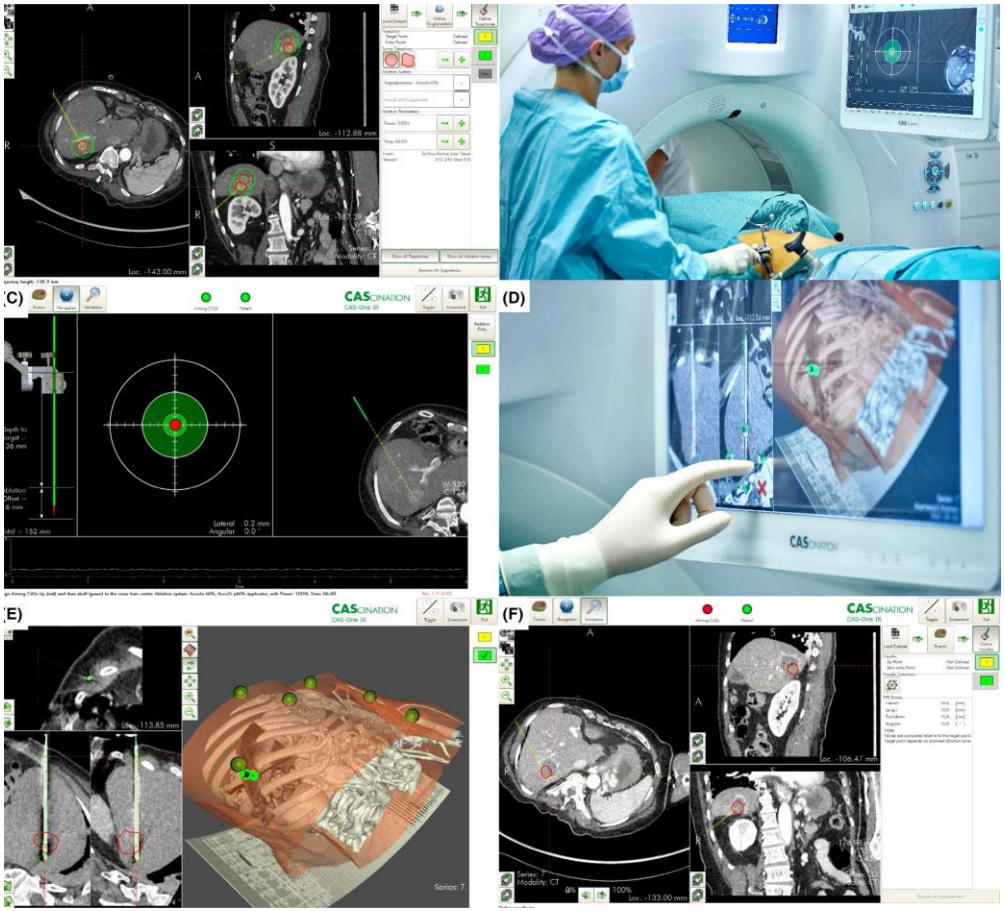
Computer-assisted stereotatic percutaneous 3D-navigated microwave ablation





Lachenmayer et al, Percutaneous stereotactic image-guided microwave ablation for malignant liver lesions, SciRep 2019, March 2019

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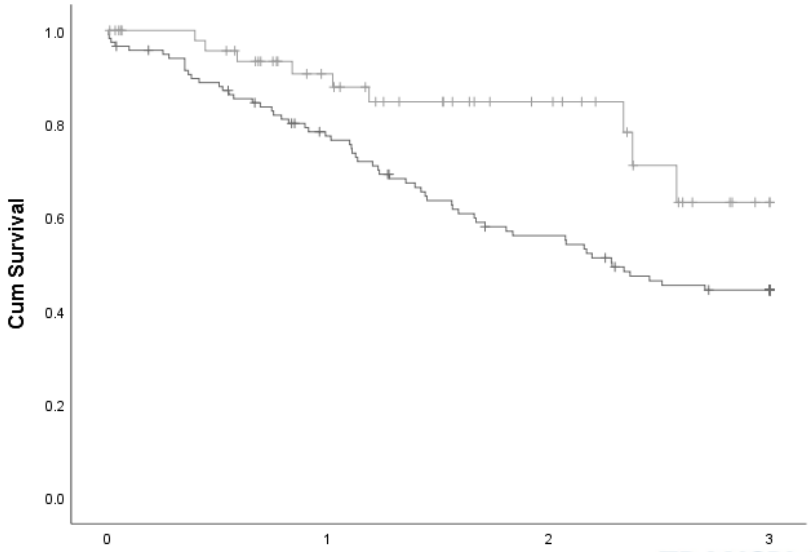
Mikrowellenablation vs. Radiofrequenzablation – eine klinische Verlaufsstudie bei primär und sekundären Lebertumoren

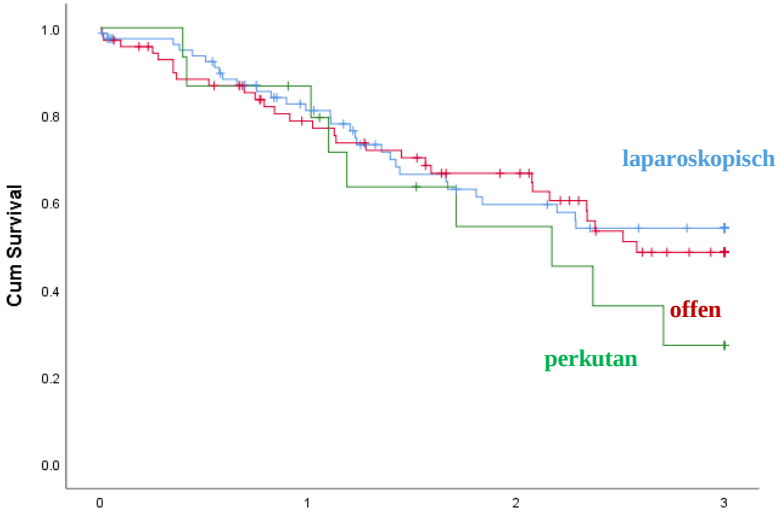
184 Patienten (131 prim LT, 53 sek. LT), Zeitraum 2001-2017, verschiedene Zugangsmodalität: perkutan/laparoskopisch/offen

→Ziel: Lokalrezidivrate nach 1 Jahr gemeinsam mit Radiologie herausarbeiten

MWA vs RFA - 3 Jahres Patientenüberleben nach primärer Ablationstherapie



Zugangsmodalität - 3 Jahres Patientenüberleben



Wahba et al, unpublished data 2020

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Navigated laparoscopic microwave ablation of tumor mimics in pig liver - an ex-vivo study -

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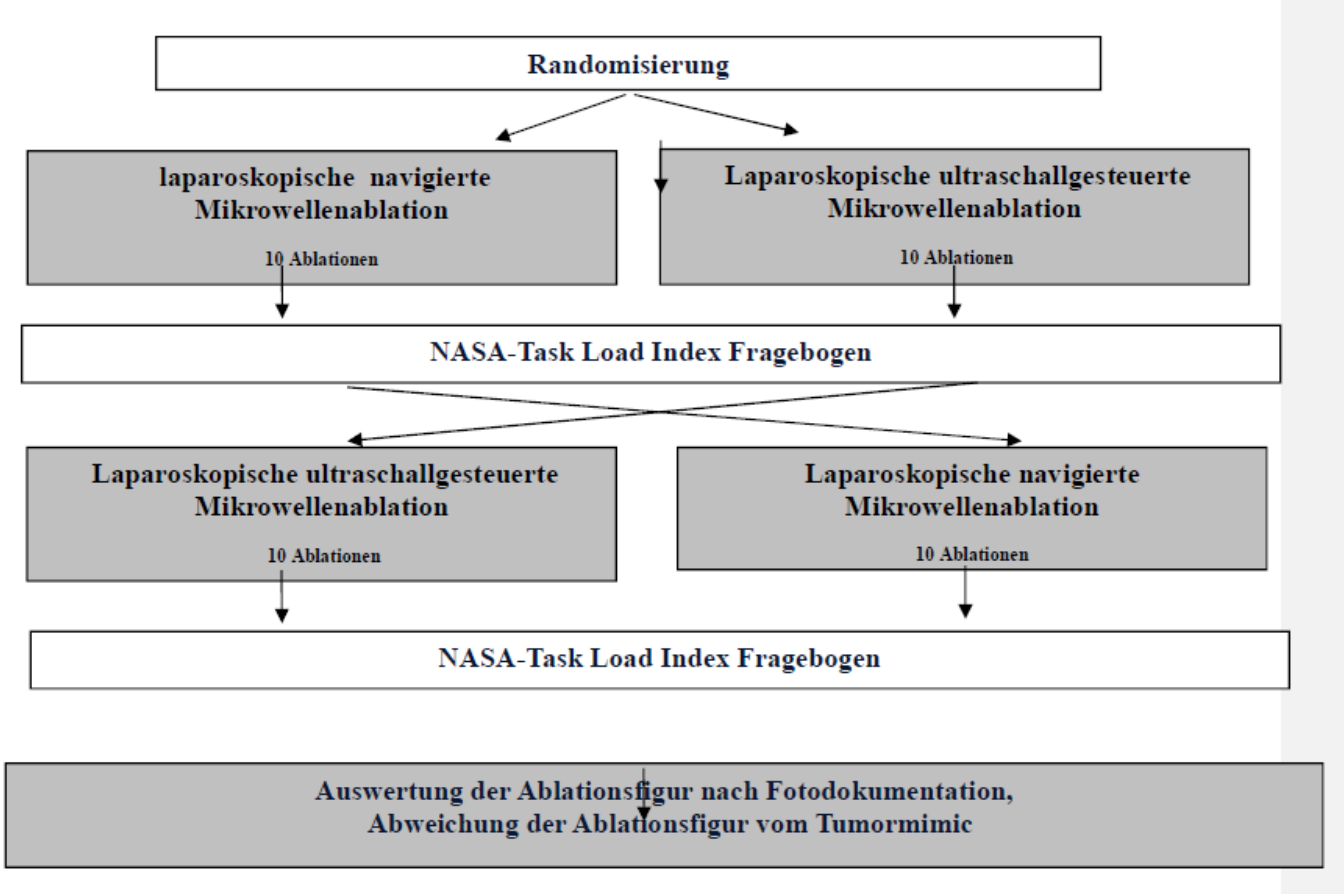
Navigated laparoscopic microwave ablation of tumor mimics in pig liver - an ex-vivo study – NCT04106453



Thomas, Stippel, Wahba, clinicaltrials.gov NCT 0410653, unpublished data 2019

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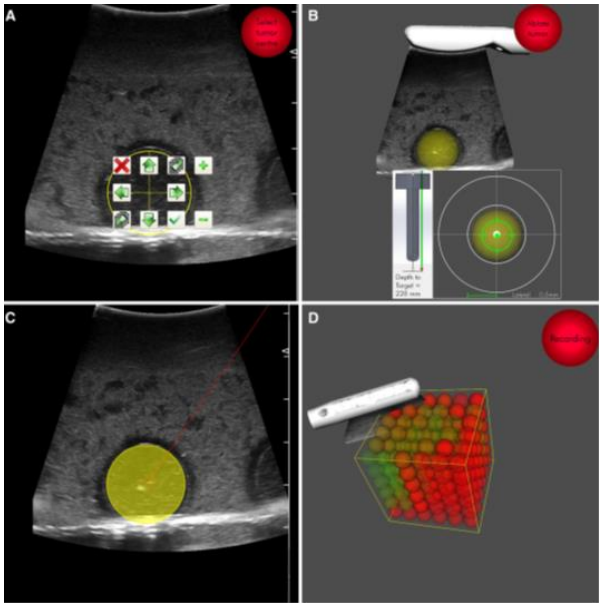
Navigated laparoscopic microwave ablation of tumor mimics in pig liver - an ex-vivo study -



Thomas, Stippel, Wahba, clinicaltrials.gov NCT 0410653, unpublished data 2020

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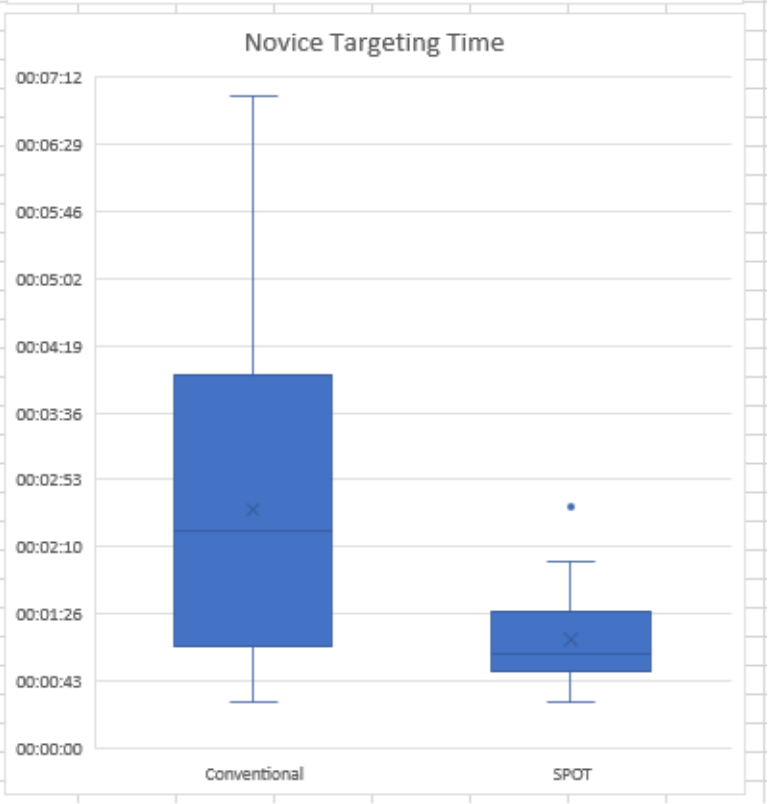

Thomas, Stippel, Wahba, clinicaltrials.gov NCT 0410653, unpublished data 2019

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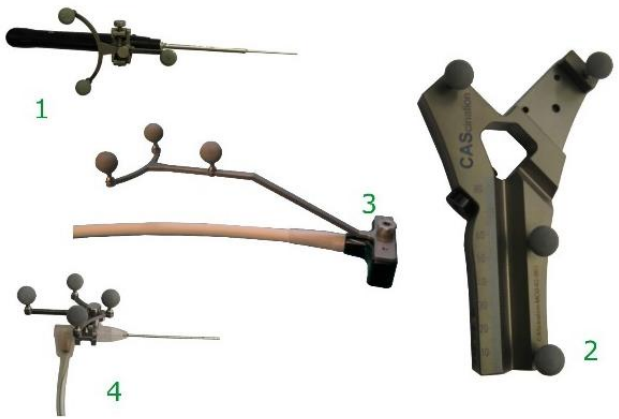
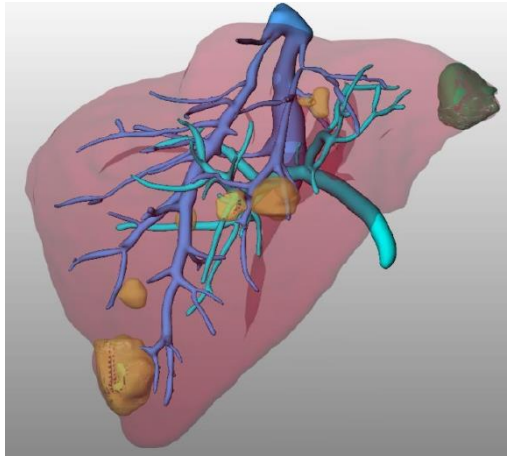
Computer-assisted 3D-navigated liver resection/ablation stereotactic ultrasound assisted





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Computer-assisted 3D-navigated liver resection/ablation

- Due multiple liver resections during the life time of patient with liver tumors 3D-Navigation could lead to a benefit by providing parenchyma-sparing resection
- Major challenge : high number of disseminated lesion in both liver lobes, that could not be targeted by anatomical resection or resection only (without intraoperative ablation techniques)
    - R0-resction
    - Preserving sufficient future liver remnant
    - Finding, visualization an treatment of **all** liver lesion
    - Orientation “in” the liver(e.g. variation of standard anatomy)
    - Optimized combination of resection and ablation
    - “Ghost” metastasis

➡ Pushing the ´Limits

1 Banz VM et al, Intraoperative image-guided navigation system: development and applicability in 65 patients undergoing liver surgery, Langenbecks Arch Surg. 2016 Jun;401(4):495-502

Stereotaktische Bestrahlung

Hyperfraktionierte Einzeitbestrahlung

12 – 24 Gy (Summe 30 - 100Gy)

Verschiedene Techniken der Bewegungskompensation

–Bodyframe,
Gating
(Novalis, Brainlab)

–Bewegungskompensation,
Referenzierung durch
injizierte Partikel
(Cyberknife)

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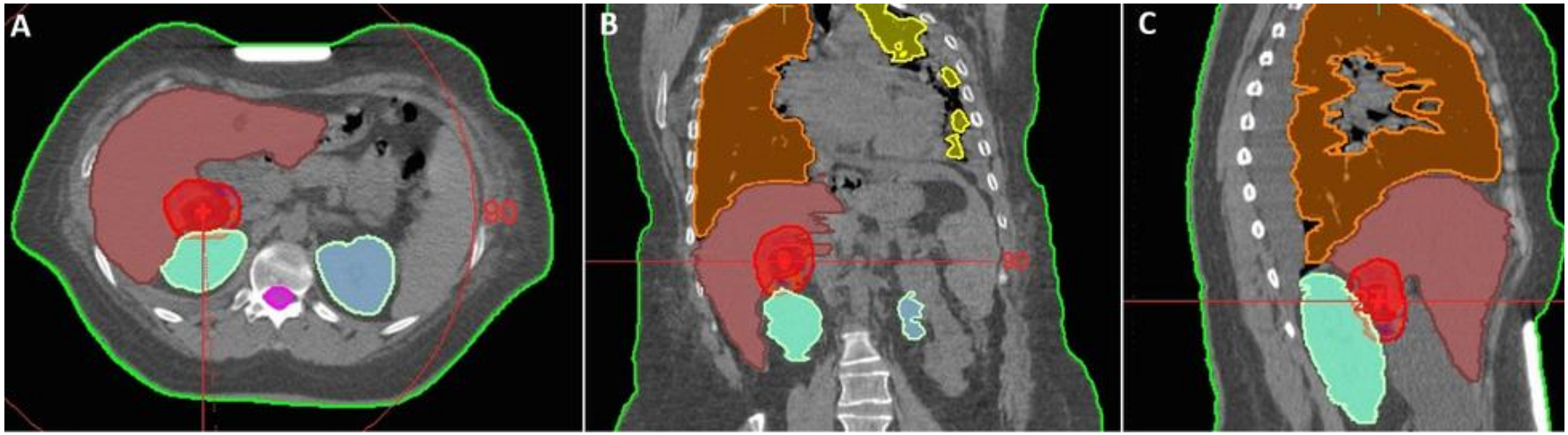
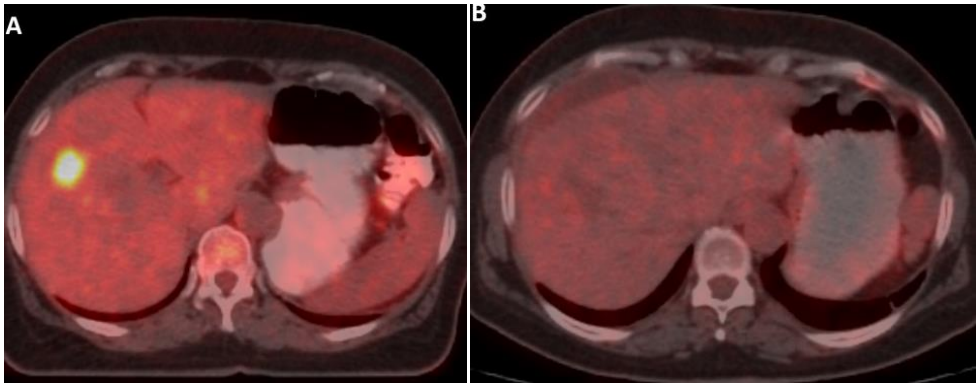
SBRT of Breast Cancer Liver Metastases





Onal et al, Treatment outcomes of breast cancer liver metastasis treated with stereotactic body radiotherapy, The Breast , 2018, 42, 150-156

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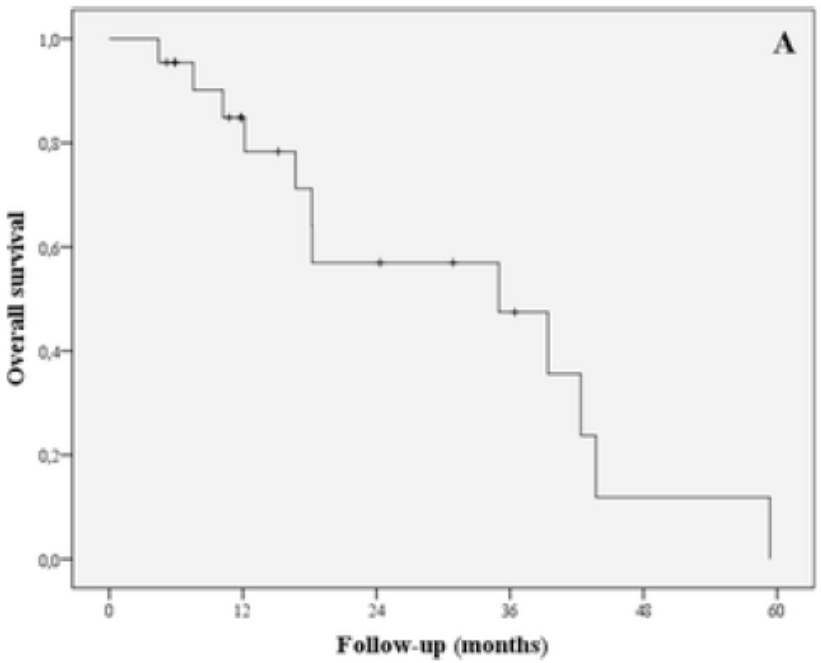
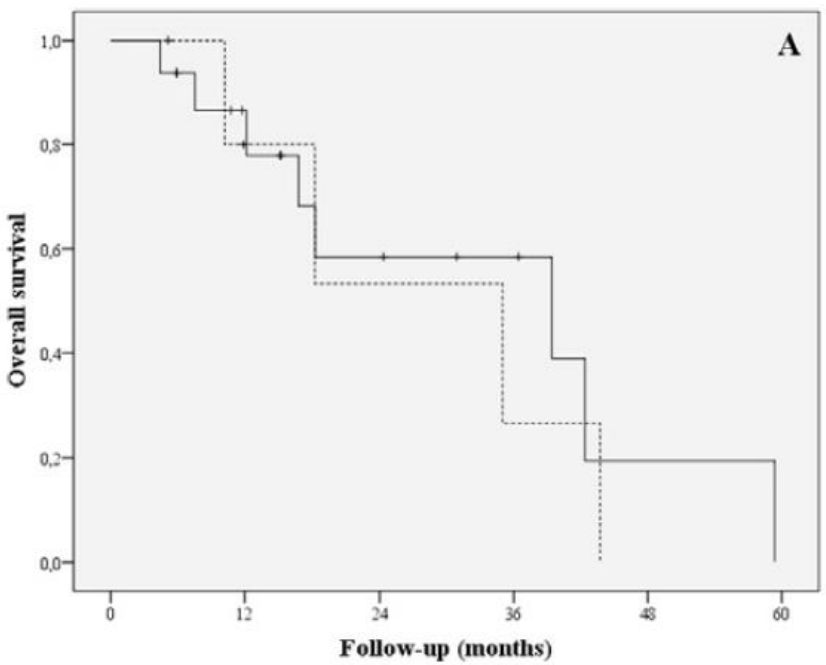
SBRT of Breast Cancer Liver Metastases





1-year survival 85%,
2-year survival 57%

Solid line: liver only
Broken line: multiple organ metastasis

Onal et al, Treatment outcomes of breast cancer liver metastasis treated with stereotactic body radiotherapy, The Breast , 2018, 42, 150-156

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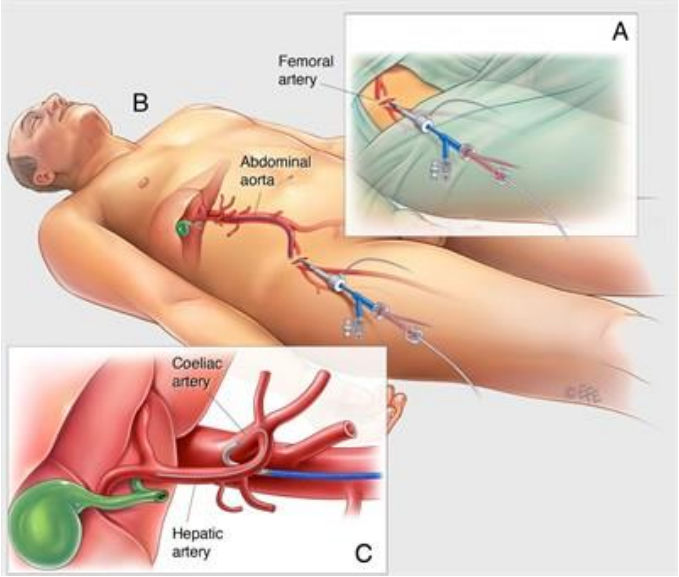
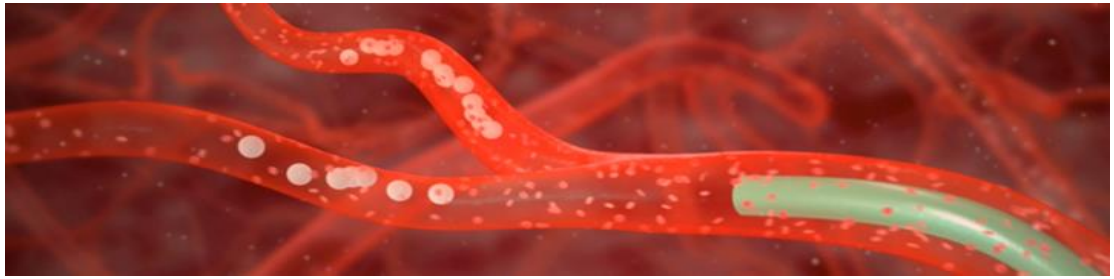
SIRT with SIR-Spheres Y-90 resin microspheres – a tool to conversion to resectability ?

- Permanent implant
- Resin microspehres loaded with yttrium-90
- Diameter 20-60 microns
- β-emitting isotope, maximum energy 2.27 MeV
- Max Range of emissions 11mm
- Half life 64.1h
- 94% of the radiation is delivered in 11 days





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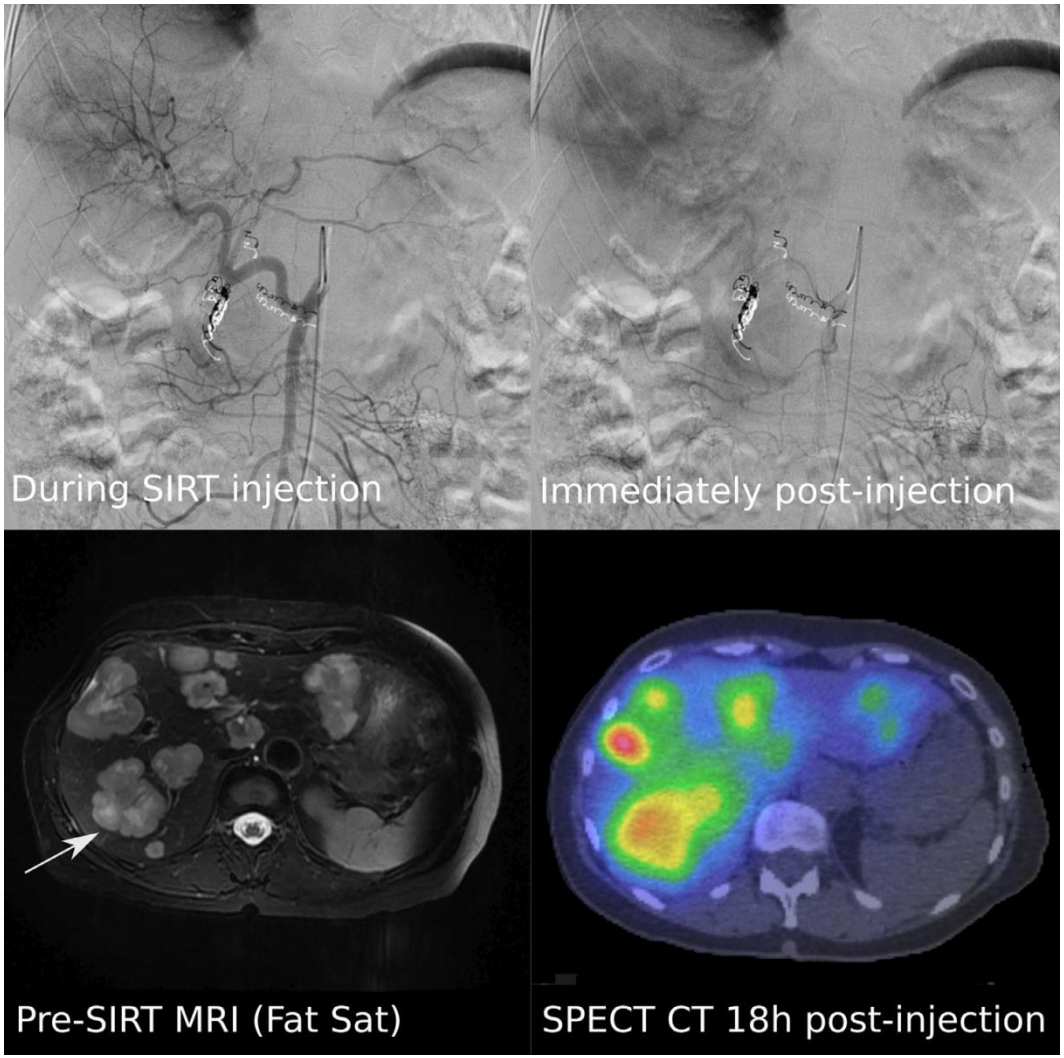
SIRT for



Lyon et al, Long-term radiological and histological outcomes following selective internal radiation therapy to liver metastases from breast cancer, Rad Cas rep 13, (2018), 1259-1266

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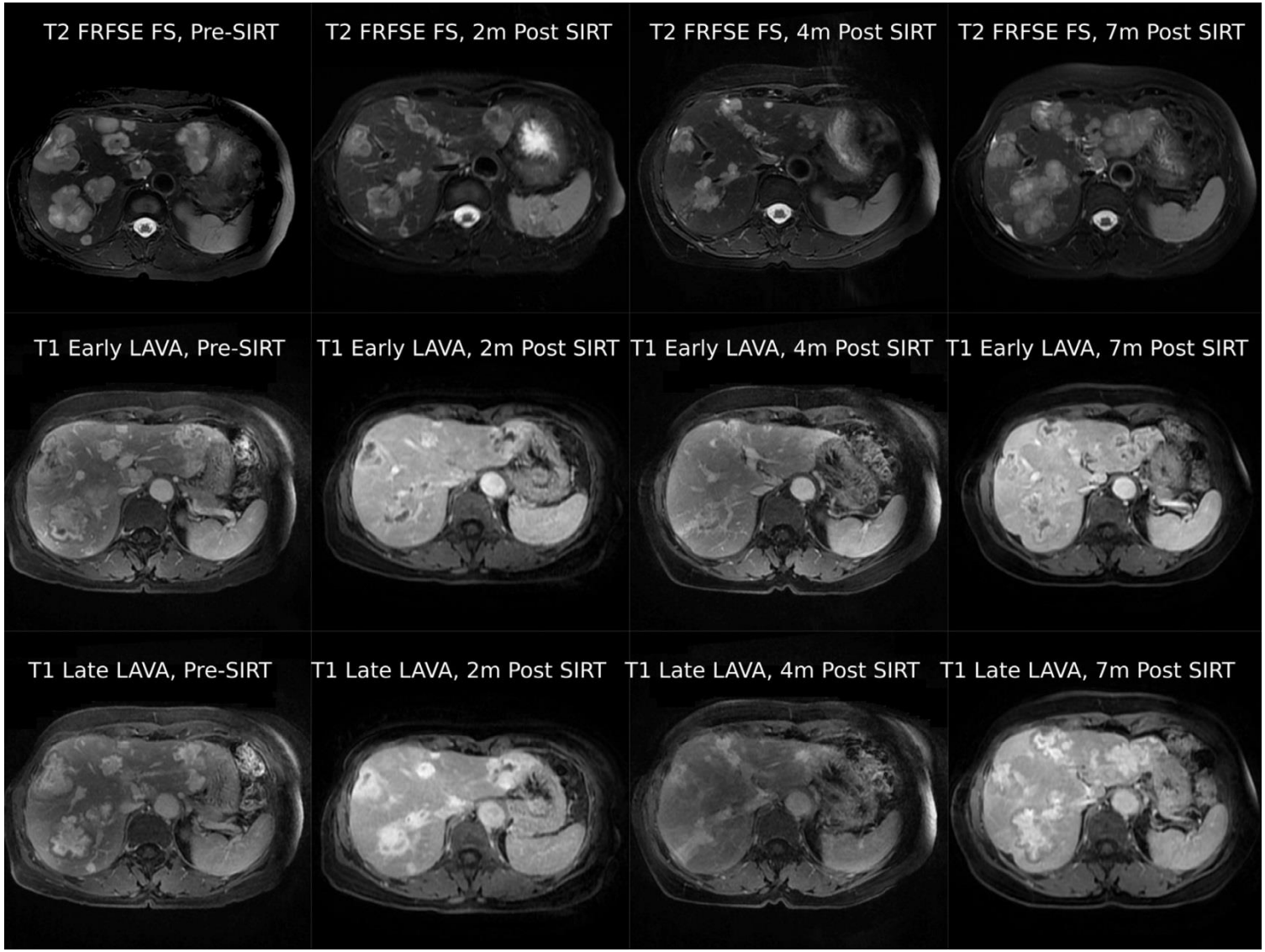

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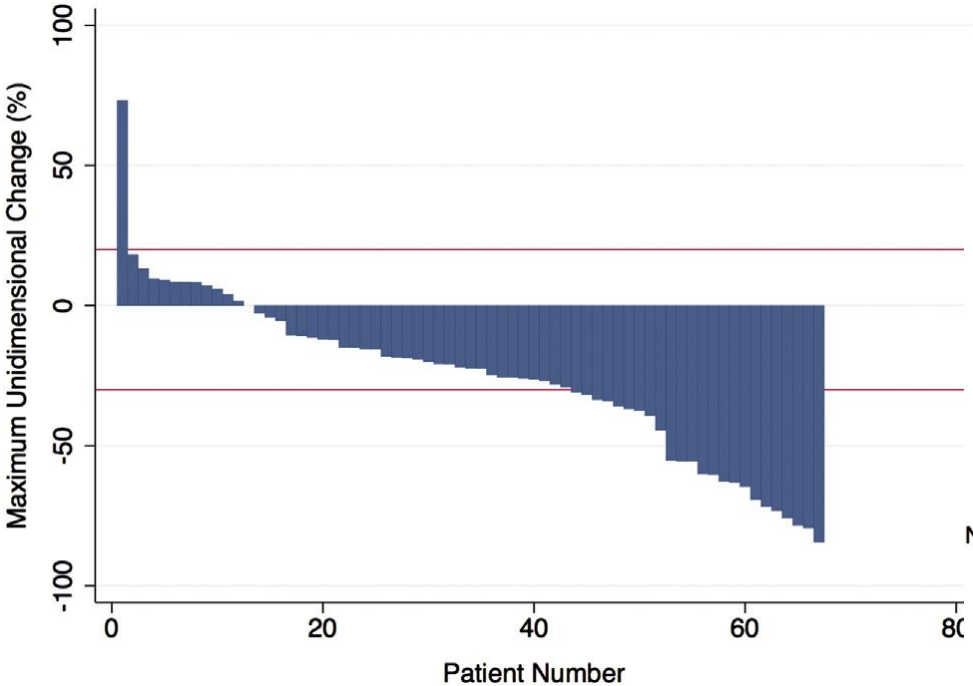
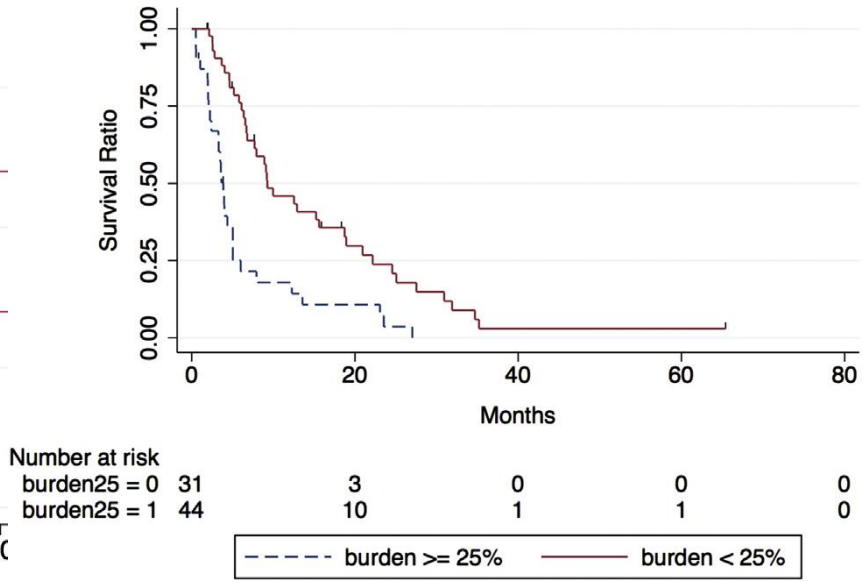
SIRT for Breast Cancer Liver Metastases
- without systemic treatment option
- without other local treatmnet options





Overall Survival: 6.6 months

Overall Survival 11 months, if hepatic tumor burden <25%

Gordon et al, Yttrium-90 Radioembolization Stops Progression of Targeted Breast Cancer Liver Metastases after failed chemotherapy, VascIntervRadiol2014;25:1523–1532

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Zusammenfassung

- Lokaltherapie kann zur Verlängerung des Überlebens im Stadium der Oligometastasierung bei metastasiertem Brustkerbs führen
- Standard der Lokaltherapie ist die chirurgische Resektion
- Interventionelle lokal ablative Verfahren stellen wirkungsvolle Therapiealternativen dar
- Die verschieden Verfahren sind im Rahmen einer individualisierten Therapie anzuwenden
- Ein hoher Grad an Interdisziplinarität optimiert die Behandlung

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Prof. Dr. Christiane Bruns


Priv.-Doz. Dr. Roger Wahba

Vielen Dank für ihre Aufmerksamkeit !