# Sigmoid cancer and liver metastases

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Bernard Nordlinger, Paris, F

Stefan Rauh, Differdange, LU

ESMO community oncologists working group

# Disclosures / conflicts of interest

- Gunnar Folprecht:
  - Study grant – Merck
  - Lecture honoraries - Merck, Roche, Amgen
  - Advisory boards - Merck, Roche, Sanofi-Aventis, BMS
- Bernard Nordlinger:
  - nothing to disclose
- Stefan Rauh:
  - nothing to disclose

# 41 y/o woman, abdominal pain

- Upper right  abdominal pain for 4 weeks
- 3kg weight loss
- No relevant medical history
- Clinical examination:
  - WHO PS 1
  - no jaundice
  - liver 8 cm below the costal rim

# Laboratory workup

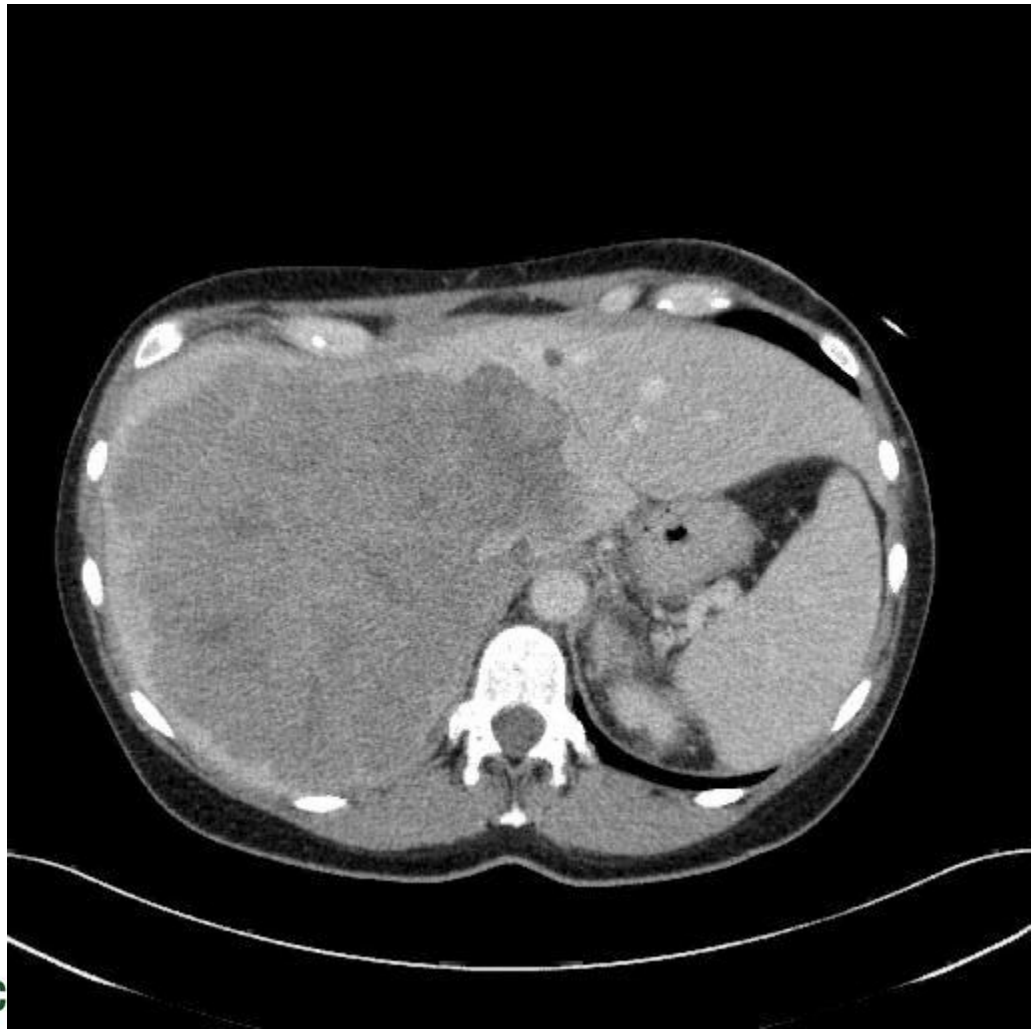
| | | | |
|---|---|---|---|
| • Hemoglobin | 4.6 | mmol/l | (7.4 mg/dl) |
| • MCV | 65 | fl | (normal: 80-96) |
| • Leukocytes | 13.4 | $x10^9/l$ | |
| • LDH | 58.4 | µmol/(l*s) | (16 x UNL) |
| • Alkaline phosph. | 3.2 | µmol/(l*s) | (1.87 x UNL) |
| • Cholinesterase | 53 | µmol/(l*s) | (0.59 x LNL) |
| • ALAT | 1.8 | xULN | |
| • ASAT | 8 | xULN | |
| • CEA | 31532 | ng/ml | |
| • CA 19-9 | 3682 | ng/ml | |
| • CRP | 253 | mg/l | |
| • Normal: Bilirubine, AFP, PTT, TT | | | |

# CAT scan

# Further results

- Fine needle biopsy (liver): Poorly diff. adenocarcinoma
- Colonoscopy: sigmatumor at 37 cm
- Histology: Adenocarcinoma intermediate-poorly differentiated
- Gastroscopy: no tumor

# CT SCAN July 2010



# PET SCAN July 2010

# Further results

- Fine needle biopsy (liver): Poorly diff. adenocarcinoma
- Colonoscopy: sigmatumor at 37 cm
- Histology: Adenocarcinoma, K-ras wild type
  intermediate-poorly differentiated
- CT: Large liver metastasis
- PET: No further distant metastases
- Gastroscopy: no tumor

# Would the audience consider:

1. liver metastases resectable?
2. resection of the primary, then start chemo?
3. palliative chemotherapy and reserve surgery for emergency situations?
4. upfront chemotherapy, and in case of response: followed by surgery of primary and liver?

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# Multidisciplinary discussion in my hospital

- Tumor pain = rapidly progressive disease
- Extent of metastatic infiltration, touching the vena cava and G3 plead against liver metastasis resection
- Start palliative chemotherapy up to best response
- Re-consider liver resection in case of major response
- Resect the primary in case of occlusion

# Patient's reaction

- She insists on the option of surgical removal of all tumor sites
- She wants a second opinion
- She has heard of a surgeon in Paris «who can operate in any situation»

# Dr. Nordlinger:

- Is this technically resectable disease?
- What are relevant prognostic factors?
  - How high would you estimate her chance of a 3 year DFS?
- What would be your next step?

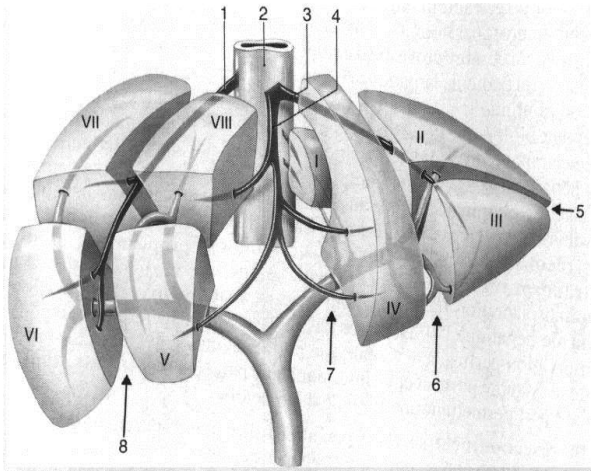
# Prof. Bernard Nordlinger

Hôpital Ambroise Paré
Assistance Publique-Hôpitaux de Paris
UVSQ, France

# Criteria for resectability

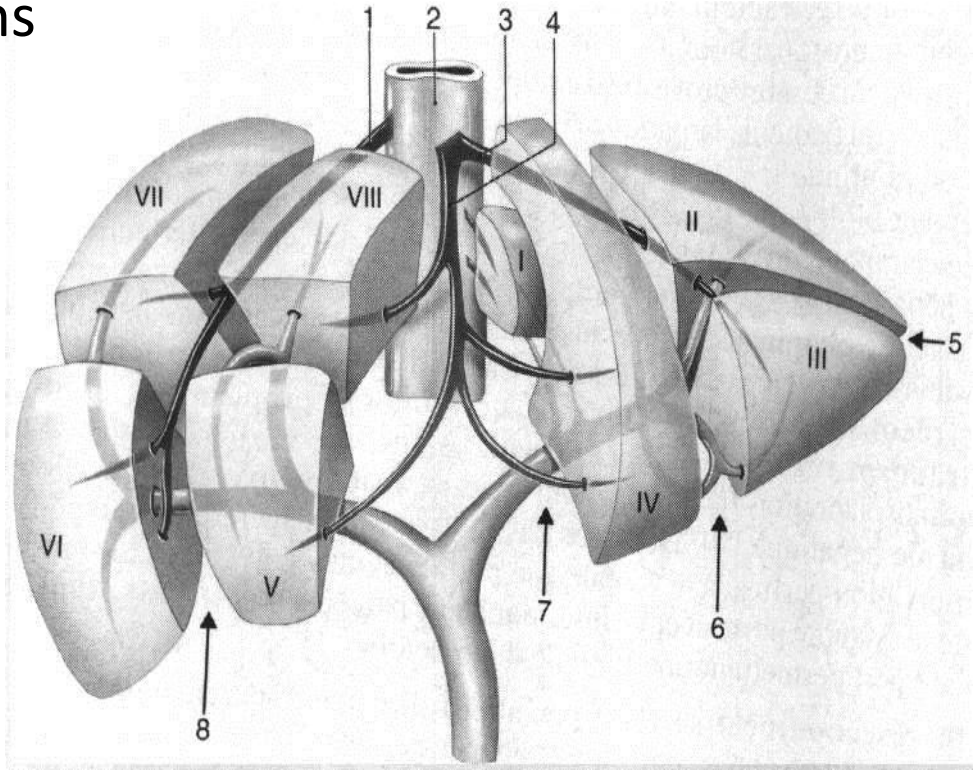
- Complete resection (± ablation) of tumour
- Free resection clearance
- Preservation of at least 1 of 3 hepatic veins
- Homolateral portal pedicle
- Future remnant liver parenchyma ≥25 %

Resectability does not depend on the number of metastases



# This metastasis is NOT resectable

- Involves right liver + segment I
- Involves portal vein bifurcation
- Involves the  3 hepatic veins
- Surrounds the IVC



# This patient has a “poor risk” metastasis

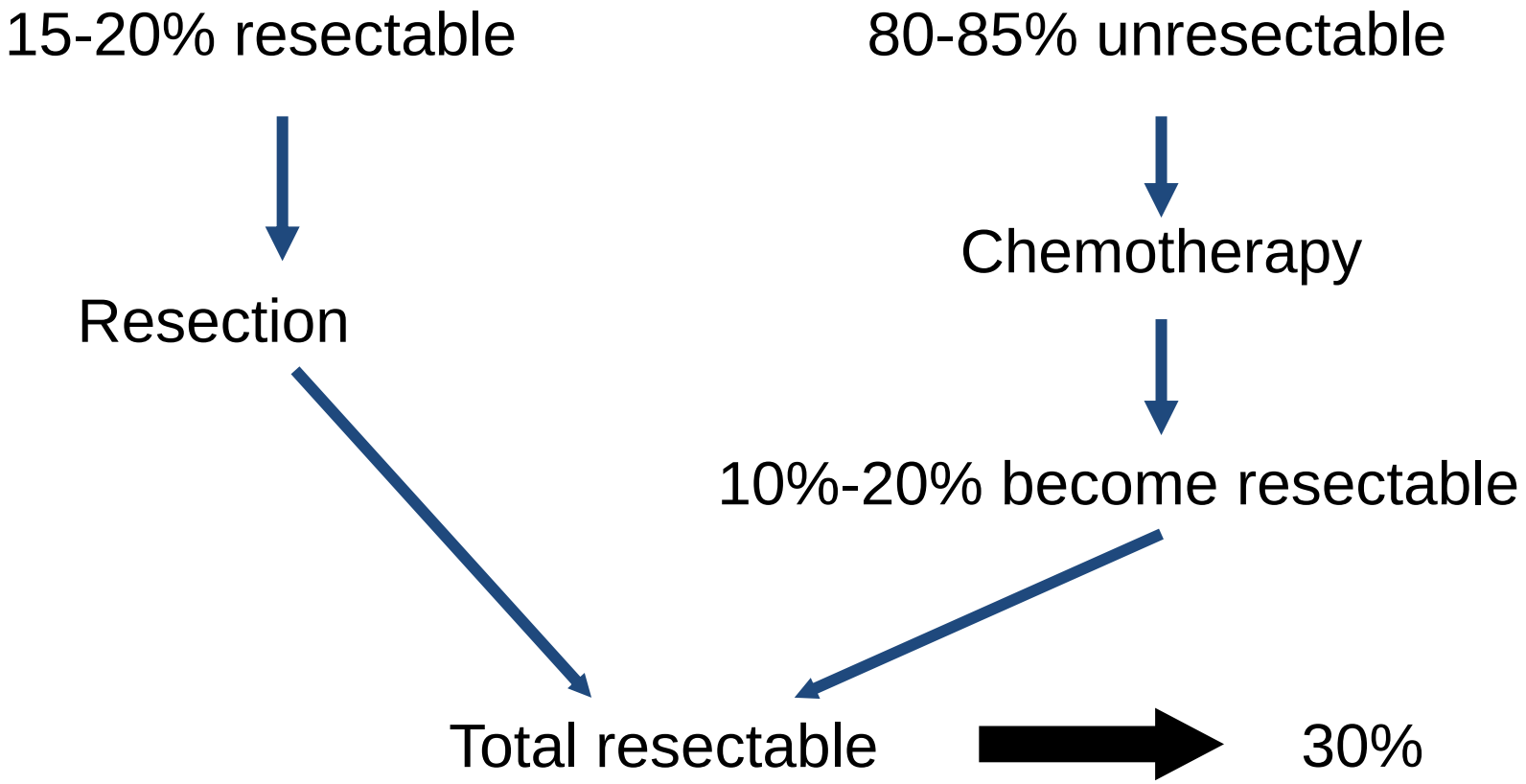
Surgery alone is not sufficient; cancer relapses in two thirds of patients[1]

| Life expectancy according to clinical risk score for tumour recurrence[2] | | | | | | |
|---|---|---|---|---|---|---|
| | Survival (%) | | | | | Median |
| **Score** | **1-yr** | **2-yr** | **3-yr** | **4-yr** | **5-yr** | **(mo.)** |
| **0** | **93** | **79** | **72** | **60** | **60** | **74** |
| **1** | **91** | **76** | **66** | **54** | **44** | **51** |
| **2** | **89** | **73** | **60** | **51** | **40** | **47** |
| **3** | **86** | **67** | **42** | **25** | **20** | **33** |
| **4** | **70** | **45** | **38** | **29** | **25** | **20** |
| **5** | **71** | **45** | **27** | **14** | **14** | **22** |



[1]Nordlinger B, *et al.* Cancer 1996; 77:1254-62;
[2]Fong Y, *et al.* Ann Surg 1999;230:309-18; discussion 18-21.

# Liver metastases 2012



# Improving outcome

- Convert patients with initially unresectable liver metastases to resection with a hope for cure

- Increase the number of patients becoming resectable
  - By intensifying chemotherapy
  - By adding biologics to chemotherapy

- Reduce cancer relapse

# Resection margin

- Resection margin is one of the prognostic factors used to identify the patients who might benefit most from liver resection; it is one of the few modifiable factors
- Adverse impact of leaving gross residual disease at the time of resection (R2) is well documented
- The prognostic implications of a microscopically positive surgical margin (R1) and of the width of a microscopically negative surgical margin (R0) remain controversial

# Impact of a positive (R1) margin on survival

- 5-year survival following a R0 resection (microscopically negative) range from 37% to 64%
- 5-year survival rate after an R1 resection is less than 20%*
- Question: Is the R1 margin status an independent predictor of survival ( cancer cells at the surgical margin ) or an indicator
  - of more aggressive disease
  - or more extensive disease making resection of the tumor with negative margins more difficult.



*Poultsides et al. HPB 2010

# Impact of a R1 margin on cancer relapse

- Recurrence at the surgical margin:
  - 3–8% of cases following an R0 resection
  - 9–55% following an R1 resection *[1]
- Any-site recurrence in the liver:
  - 22–78% following an R1 resection
  - 14–38% following an R0 resection *[2]

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*[1] Pawlik *et al. Ann Surg* 2005
Kokudo *et al. Arch Surg* 2002
de Haas *et al. Ann Surg 2008*
Nuzzo *et al. Surgery. 2008*
Wakai *Ann Surg Oncol 2008*

*[2] Pawlik *et al.* Ann Surg 2005
Cady *et al. Ann Surg* 1998
de Haas *et al. Ann Surg 2008*
Nuzzo *et al. Surgery 2008*
Hughes *et al.* Surgery 1986

# Treatment options in synchronous metastases

- Up-front treatment is controversial
- Chemotherapy : which timing ?
  before or after surgery
- Surgery of the primary tumor +/- radiation or chemoradiation

# The argument for up-front primary tumor resection

- The rationale for up-front resection is to avoid potential complications related to the primary tumor such as bleeding, obstruction, or tumor perforation during chemotherapy particularly with bevacizumab.
- The majority of US patients undergo primary tumor resection

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* Chang et al,JCO 2012; Hapani et al, Lancet Oncol, 2009; Costi et al. Ann Surg Oncol 2007

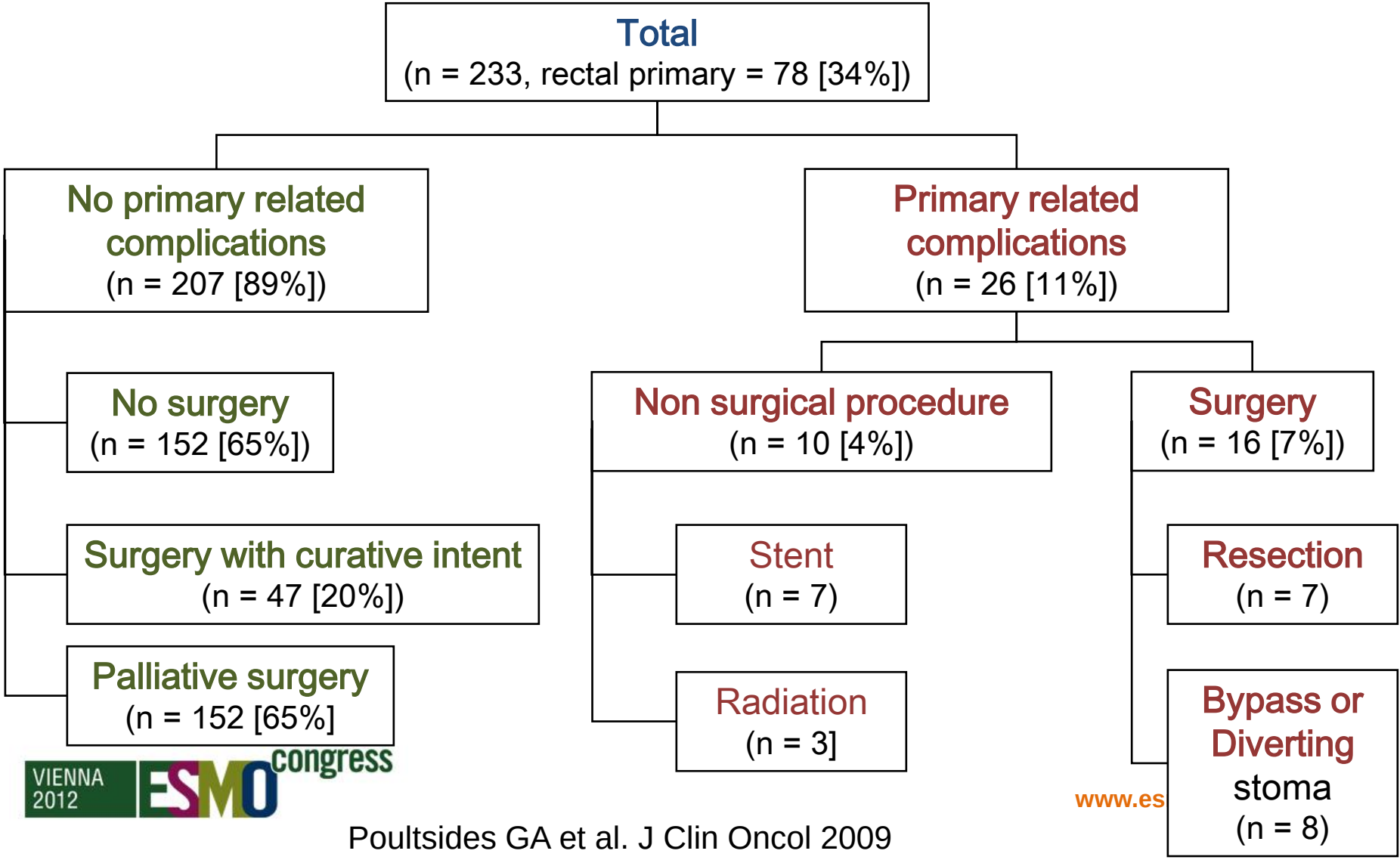
# The argument for up-front systemic chemotherapy

- Retrospective studies have observed low rates of primary tumor–related complications during treatment in patients with initially asymptomatic disease. *



* Poultsides et al, JCO, 2009;

# Primary related complications and stage IV CRC treated by sytemic chemotherapy








Poultsides GA et al. J Clin Oncol 2009

# Can primary tumor resection improve survival when combined with systemic therapy?

- In a comparative multi-institutional retrospective analysis , median survival was:
  - 30.7 months with colectomy prior to chemotherapy
  - 21.9 months with chemotherapy alone (*P* .031)*
- The analysis of cumulative data from 4 randomized trials showed a survival benefit for patients with prior resection of primary (HR 0,63; p=0,0001).**
- These analysis are retrospective and potentially biased (patients selected for resection having more limited metastatic disease)



*Karoui et al. DCR, 2011; **Faron et al. ASCO 2012 abst 3507

# The argument for up-front systemic chemotherapy

- The median survival duration of patients with unresectable metastases has increased to up to 24 months with modern cytotoxic +/- biologic treatments.
- Metastases can become resectable
- Systemic chemotherapy is active on liver metastases but also on the primary tumor and can even induce complete response.*
- It is the essential treatment modality to prolong survival in these patients** and should be started as soon as possible



*Karoui et al. DCR, 2011;
Schrag et al. JCO 2010; **Grothey et al. JCO 2008

# The argument for up-front systemic chemotherapy

- The overall complication rates for primary resection in patients with unresectable distant metastases was 11.8% (major) and 20.6% (minor) *
- These complications of surgery prolong recovery and delay or preclude administration of chemotherapy.



* Scheer et al. Ann Oncol 2008

# NSABP C-10: ph. II prospective, single-arm study primary CT ( mFOLFOX6 + bev) for patients (n=86) with asymptomatic primary intact unresectable stage IV colon cancer

- The majority of patients could be managed without primary tumor (PT) intervention, (primary endpoint of the study )
  - 86% of patients had no major morbidity related to the intact P
  - Median overall survival :19.9 months
- The investigators conclude that avoiding resection of the asymptomatic PT did not result in an unacceptable rate of PT–related complications and did not compromise survival
- 73.3% of the patients had not required PT resection at the time of death or last follow-up.


McCahill LE,et al. JCO.2012

# Dr. Folprecht:

- Does the patient require pre-operative chemotherapy?
- What's the preferred regimen? Alternatives?
- Assuming, this patient had only minor response to 1st line treatment, would you:
  - Go for resection, if still borderline feasible
  - Switch the regimen for better response / resection

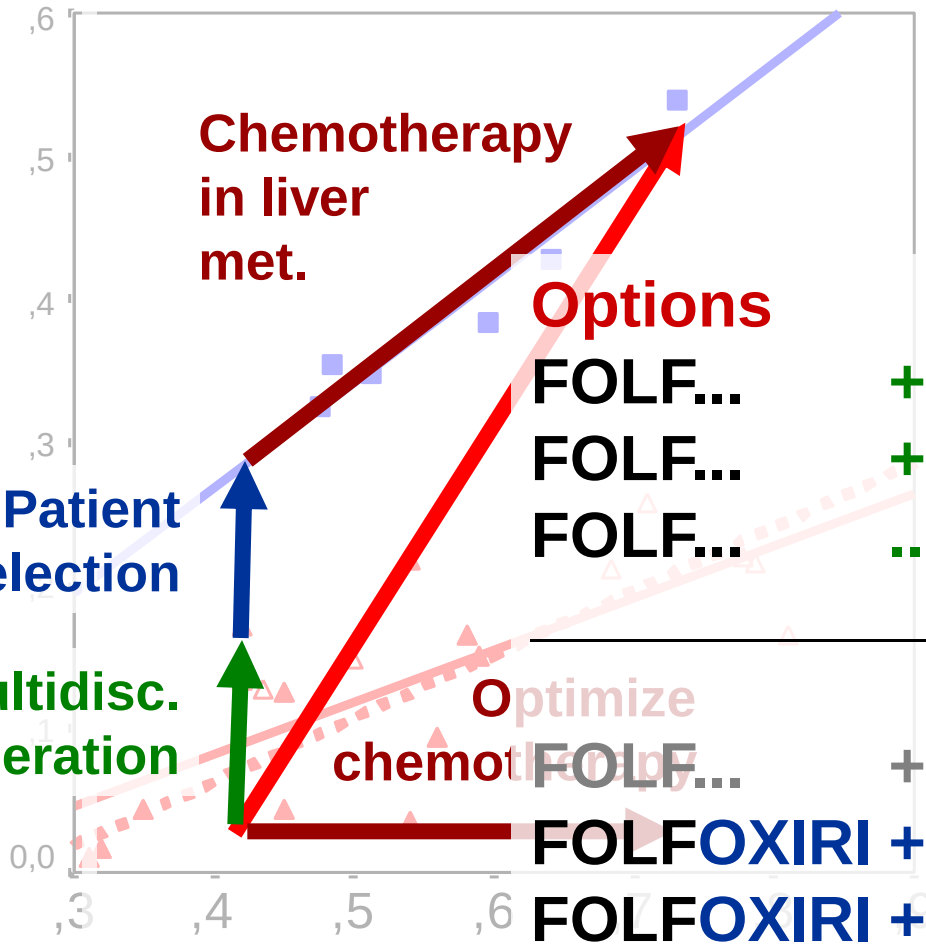
# Gunnar Folprecht

University hospital Carl Gustav Carus

University Cancer Center / Med. Dpt. I

Dresden, Germany

# Resection and response




- **Studies with neoadjuvant focus**
  („liver metastases“)
  r=.96, p=.002

**Options**

**FOLF... + Cetuximab**

**FOLF... + Bevacizumab**

**FOLF... ...OXIRI**

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**FOLF... + 2 antibodies**

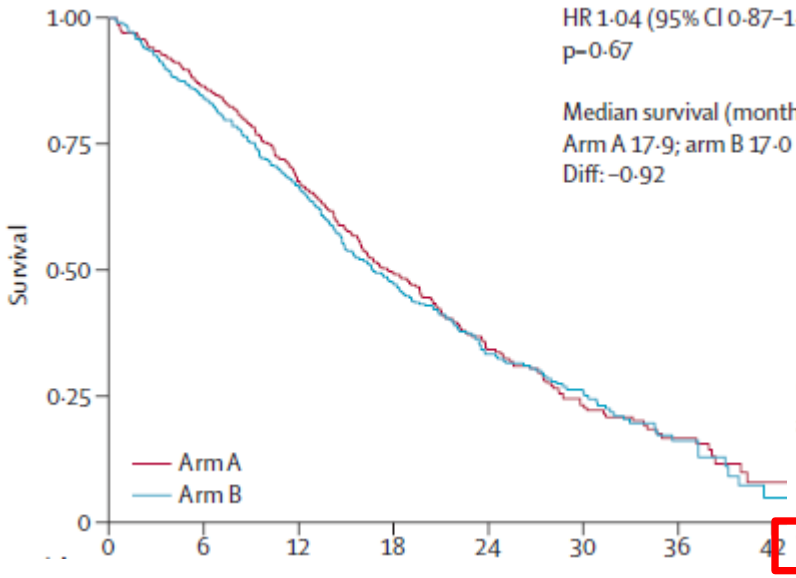
**FOLFOXIRI + Bevacizumab**

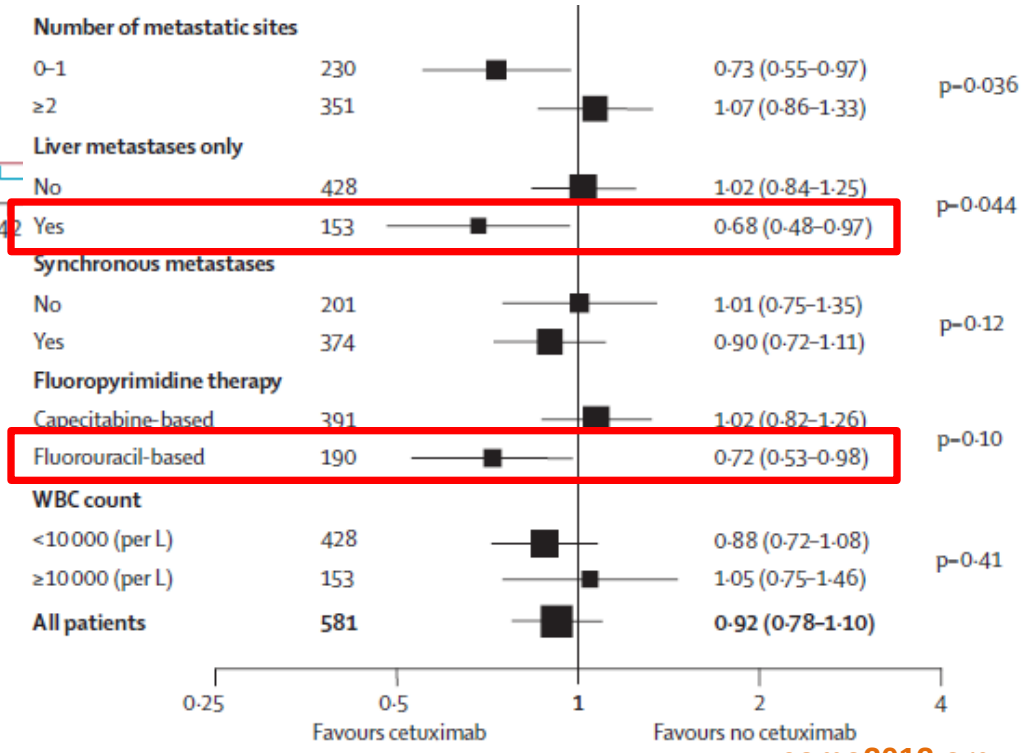
**FOLFOXIRI + Cetuximab**

# EGFR antibodies in first line therapy

| K-ras wild type | n | RR | R0-Resections |
|---|---|---|---|
| **FOLFIRI+Cetuximab** | 316 | **57%** | **5.1%** |
| **FOLFIRI** | 350 | **40%** | **2.0%** |
| „CRYSTAL“, Van Cutsem, JCO 2011 | | p<0.0001 | p=0.03 |
| **FOLFOX+Cetuximab** | 97 | **57%** | **7.3%** |
| **FOLFOX** | 82 | **34%** | **3.1%** |
| „OPUS“, Bokemeyer AnnOncol 2011 | | p<0.01 | Van Cutsem, ASCO-GI 2011 |
| **...OX+Cetuximab** | 367 | **64%** | |
| **...OX** | 362 | **57%** | |
| „COIN“, Maughan Lancet 2011 | | p=0.049 | |
| **FLOX+Cetuximab** | 97 | **46%** | |
| **FLOX** | 97 | **47%** | |
| „Nordic VII“, Tveit ESMO 2010 | | | |
| **FOLFOX+Panitumumab** | 325 | **55%** | **8.3%** |
| **FOLFOX** | 331 | **48%** | **7.0%** |
| „PRIME“, Douillard, JCO 2010 | | p=0.07 | |

# „COIN“ Oxaliplatin/Fluoropyrimidin ± cetuximab

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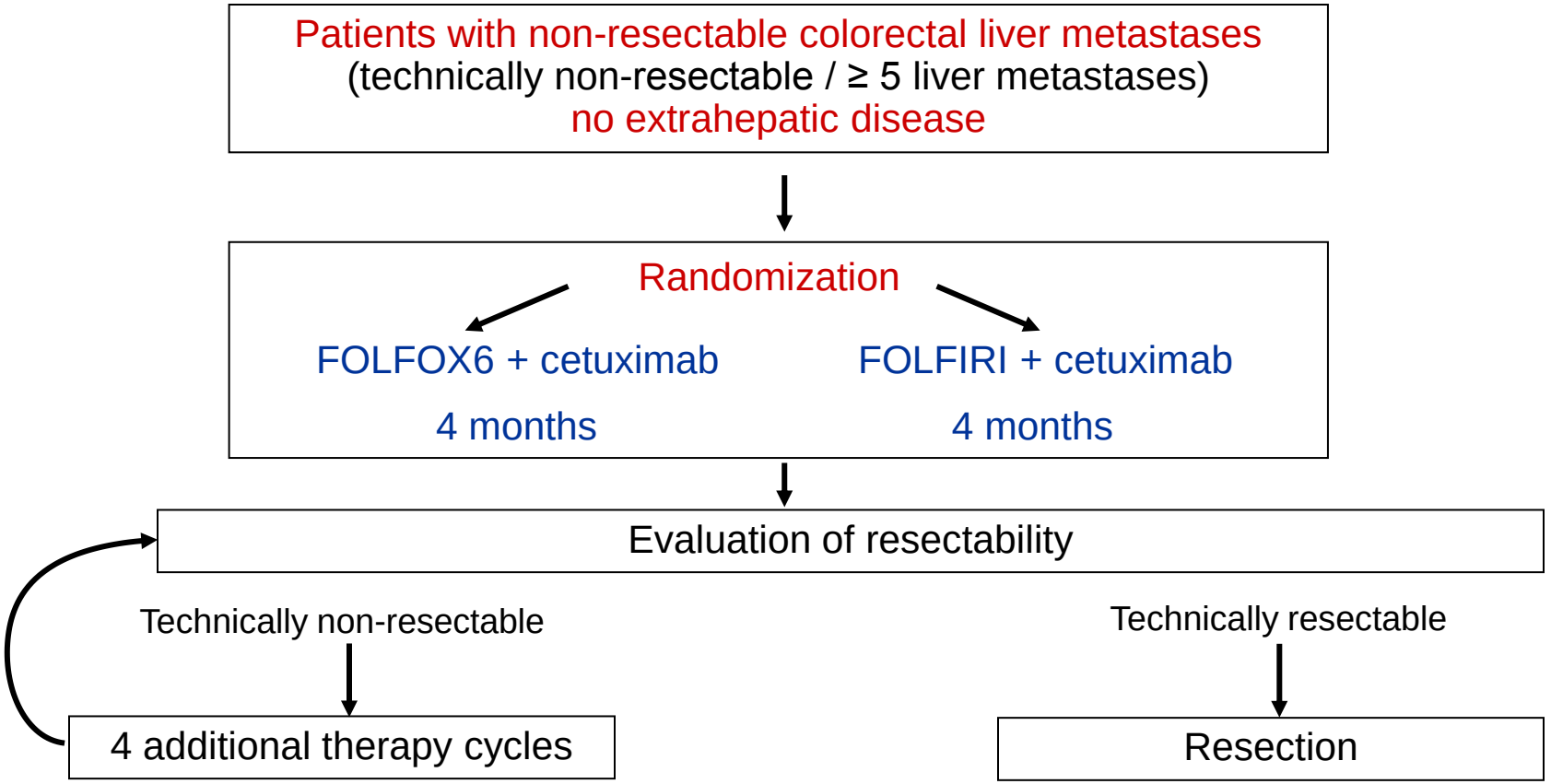
Maughan Lancet 2011

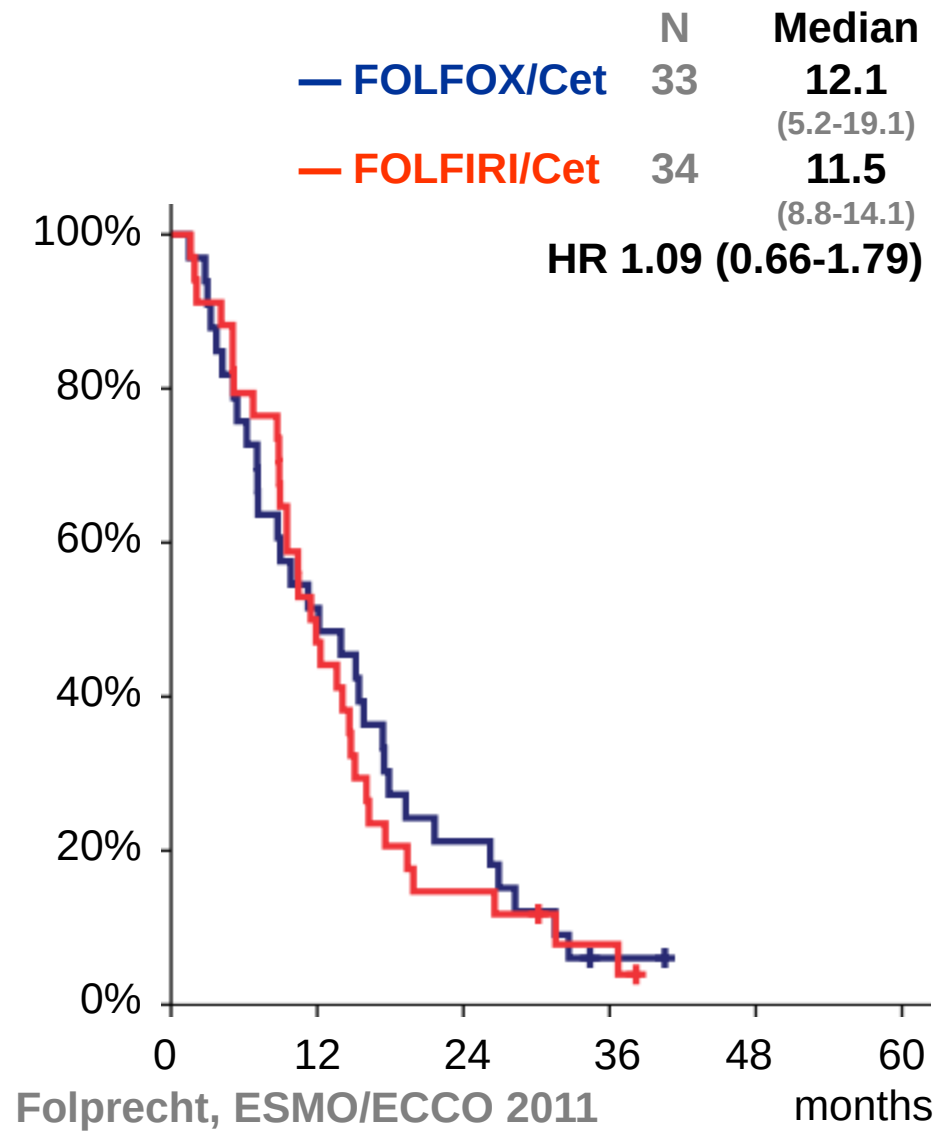



| | n | RR | R0 Resection |
|---|---|---|---|
| **All patients** | 106 | **62%** | **34%** |
| **K-ras wild type** | 67 | **70%** | **33%** |

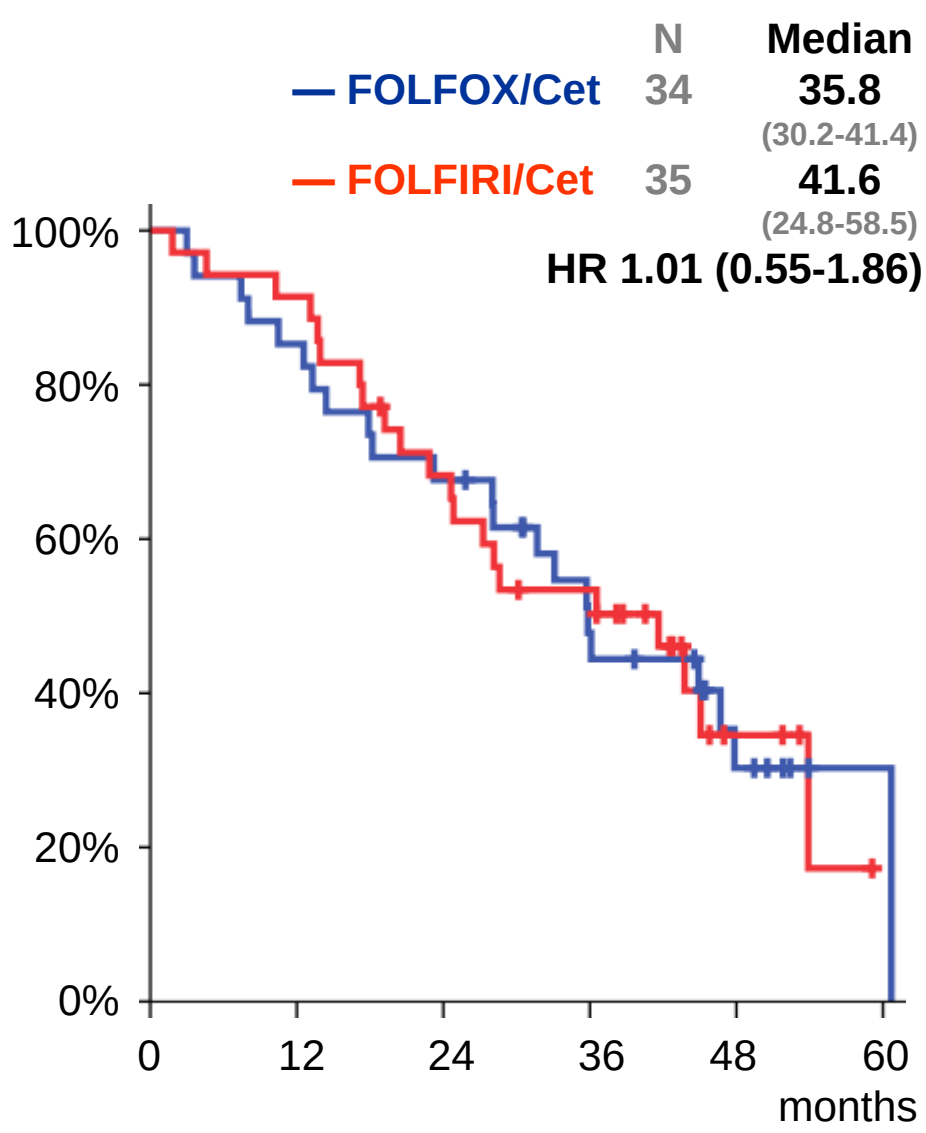
„CELIM“ Folprecht et al, Lancet Oncol 2010

# Survival in the k-ras wild type subset

## Progression free survival



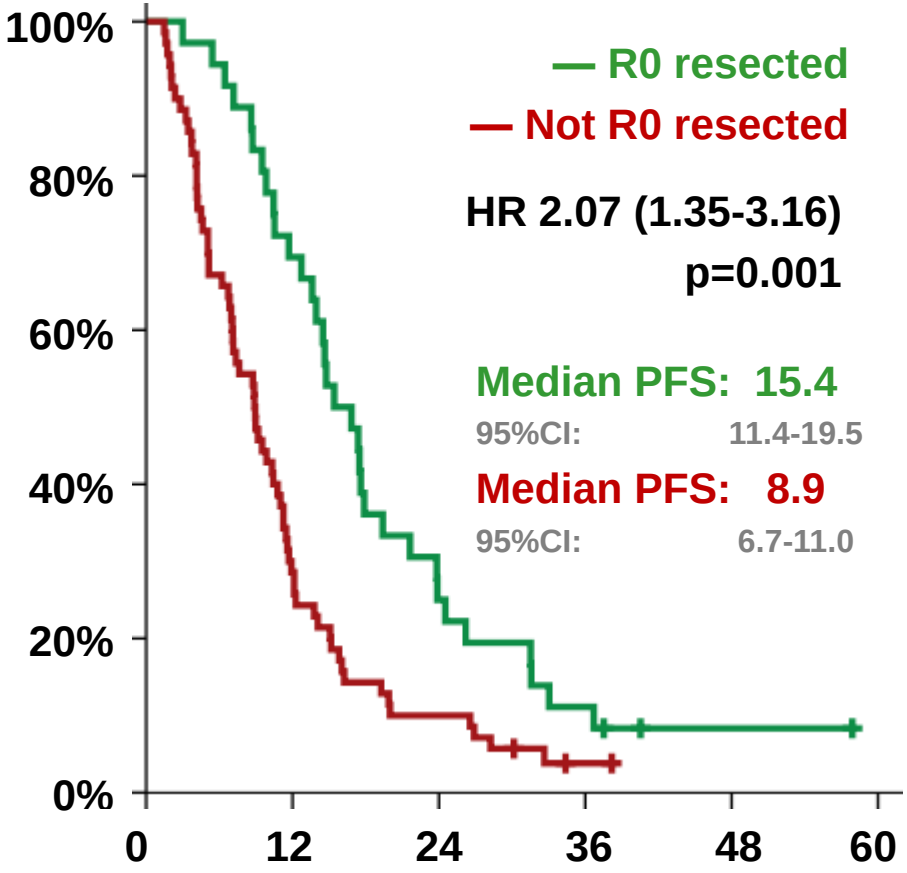

## Overall survival



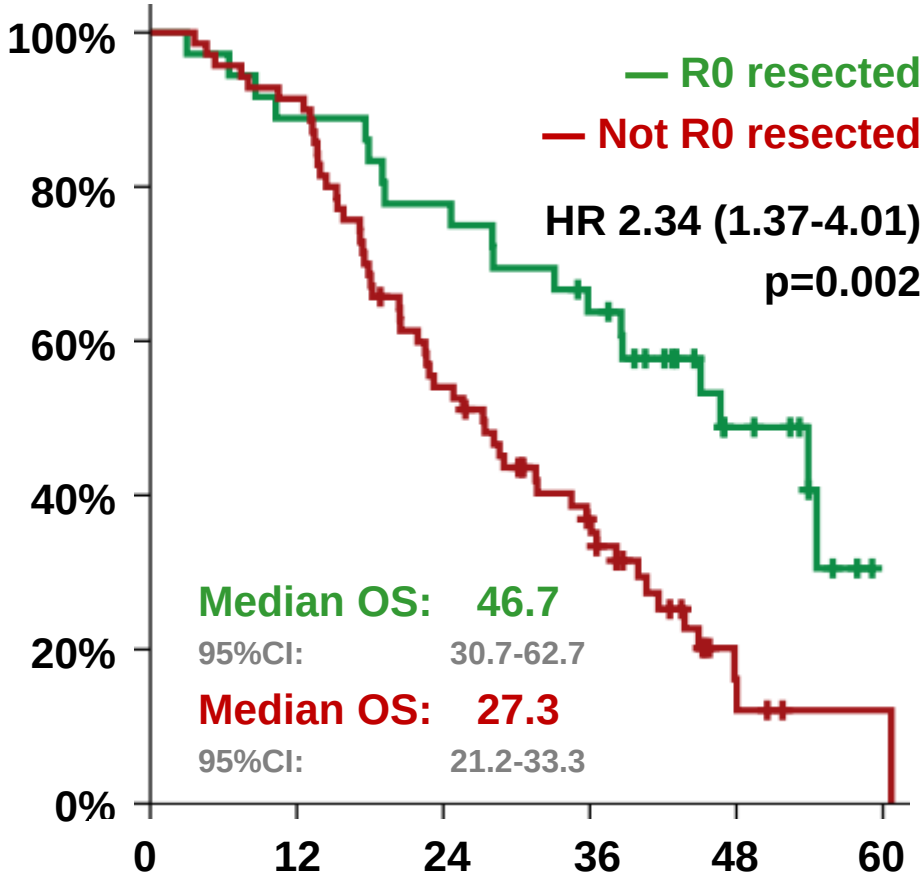

Folprecht, ESMO/ECCO 2011

# Survival and R0 resection

## Progression free survival




## Overall survival




| | | | | | |
|---|---|---|---|---|---|
| R0 resected, N=36 | 100 | 89 | 78 | 64 | 49% |
| not R0 resected, N=70 | 100 | 91 | 54 | 37 | 16% |

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Folprecht, ESMO/ECCO 2011

# Triple combinations in first line therapy

| | n | RR | R0-Resections |
|---|---|---|---|
| **FOLFOXIRI** | 122 | **60%** | **15%** |
| **FOLFIRI** | 122 | **34%** | **6%** |
| Falcone, JCO 2007 | | **p<0.0001** | **p=0.033** |

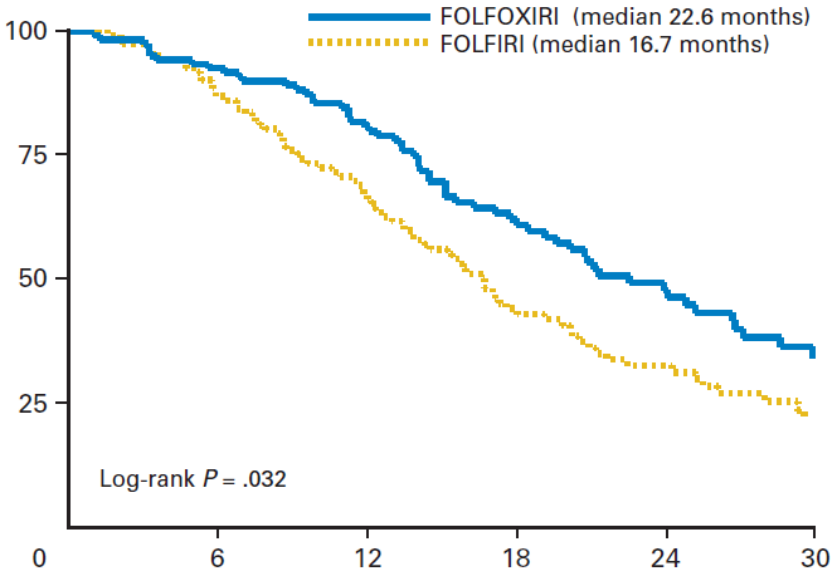
**FOLFOXIRI** — **85 oxaliplatin, 165 irinotecan, 200 LV, 3000 5-FU (46h)**

**FOLFIRI** — 65 oxaliplatin, 150 irinotecan, LV5FU2

Souglakos, BJC 2006

| **Grad 3/4** | **4drugs** | **3drugs** |
|---|---|---|
| **Neutropenia** | **50%*** | **28%** |
| **Diarrhea** | **20%** | **12%** |
| **Vomiting** | **7%** | **2%** |
| **Neurotox.** 2/3 | **20%** | **0%** |

**Overall survival**



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| **FOLFOXIRI** | 137 | 43% | |
| **FOLFIRI** | 146 | 34% | |
| Souglakos, BJC 2006 | | | |
| **IFL+Bevacizumab** | 411 | **45%** | |
| **IFL** | 403 | **35%** | **< 2%** |
| Hurwitz, NEJM 2004 | | | |
| **...OX+Bevacizumab** | 699 | **38%** | **8.4%** |
| **...OX** | 701 | **38%** | **6.1%** |
| Saltz, JCO 2008 | | | **p=0.1** |

# FOLFOXIRI / antibody

| | n | |
|---|---|---|
| **cmFOLFOXIRI / Cetux**<br>**"POCHER", Garufi BJC 2010** | **43** | Dose reduction:<br>Irinotecan, oxaliplatin, 5-FU |
| **FOLFIRINOX / Cetux**<br>**Assenat Oncologist 2011** | **42** | Full dose: irinotecan (180), oxaliplatin (85), 5-FU (400/2400)<br>52% diarrhea gr 3/4; 5% febrile neutropenia |
| **FOLFOXIRI / Cetux**<br>**"COFI", Folprecht ASCO-GI 2010** | **20** | phase I; FOLFOXIRI as Falcone,<br>MTD for irinotecan 125 mg/m$^2$ |
| **FOLFOXIRI / Bev**<br>**Masi Lancet Oncol 2010**<br>liver only: | **57**<br>30 | Falcone: FOLFOXIRI – response 66% |

# Morbidity with neoadjuvant CTx

| | FOLFOX + OP<br>n=159 | OP<br>n=170 |
|---|---|---|
| **Mortality** | **1 (1%)** | **2 (1%)** |
| **Complications** | **40 (25%)** | **27 (16%)** |
| **No resection due to liver toxicity** | **1 Pat** | |

EORTC 40983, Nordlinger Lancet 2008

**Does chemo harm resection?**

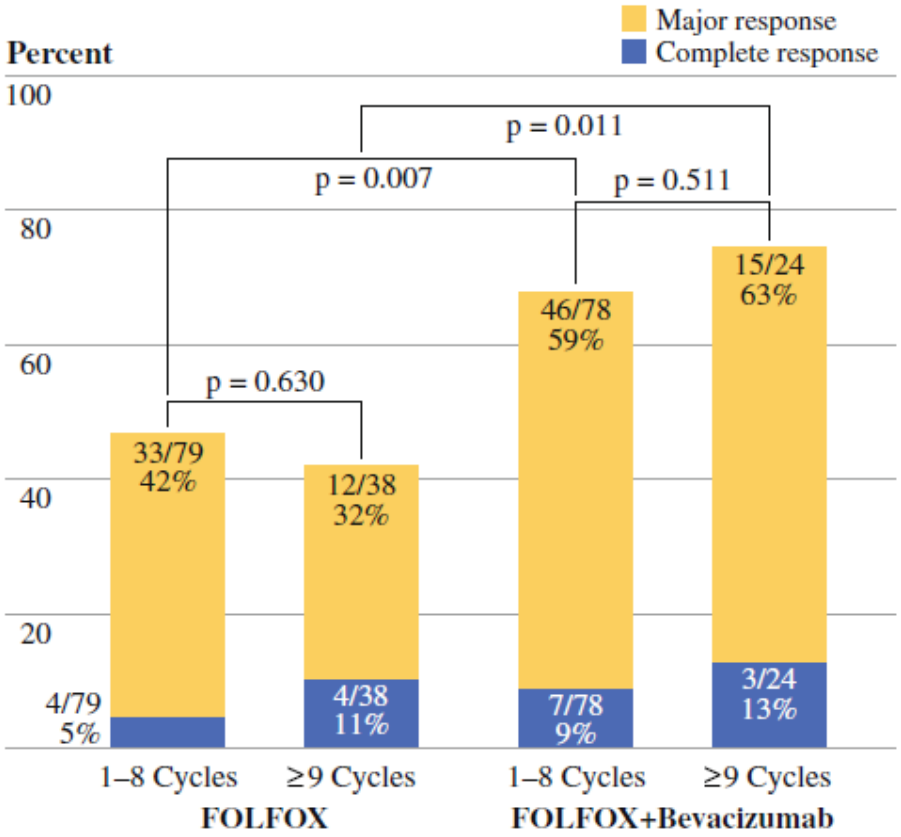
**Yes, 0.6%**

| CTX cycles | n | Morbidity |
|---|---|---|
| 0 | 22 | 14% |
| 1-5 | 21 | 19% |
| 6-9 | 11 | 45% |
| ≥ 10 | 13 | 62% |

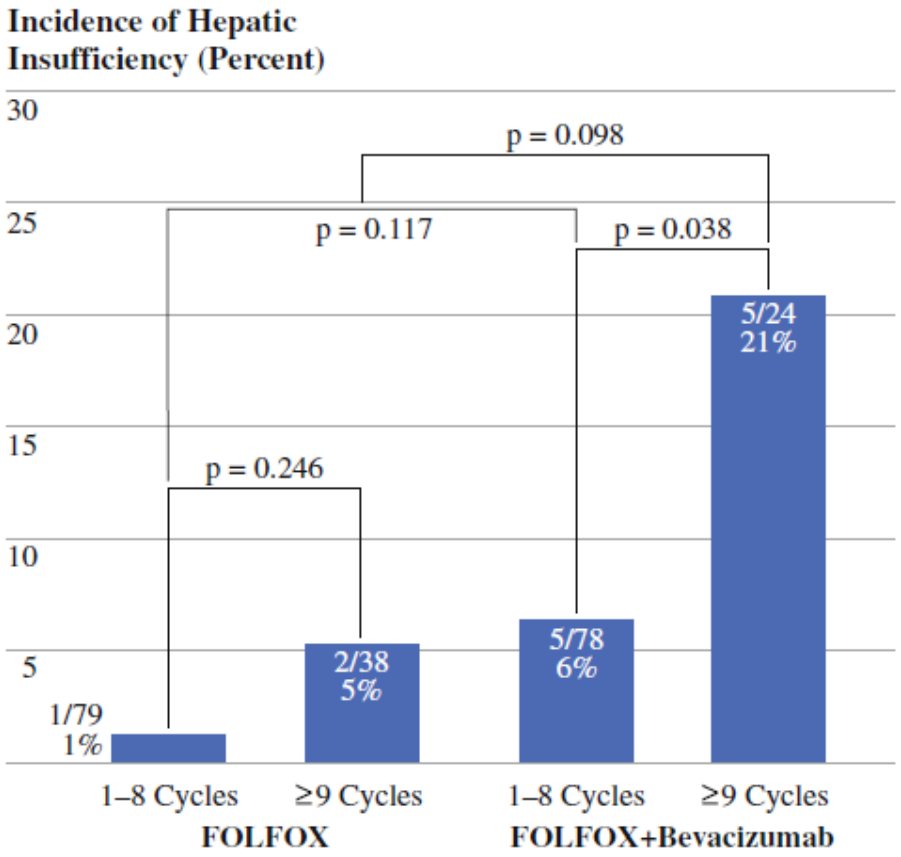
Karoui Ann Surg 2006

# Duration of chemotherapy

## Pathological response




## Complications

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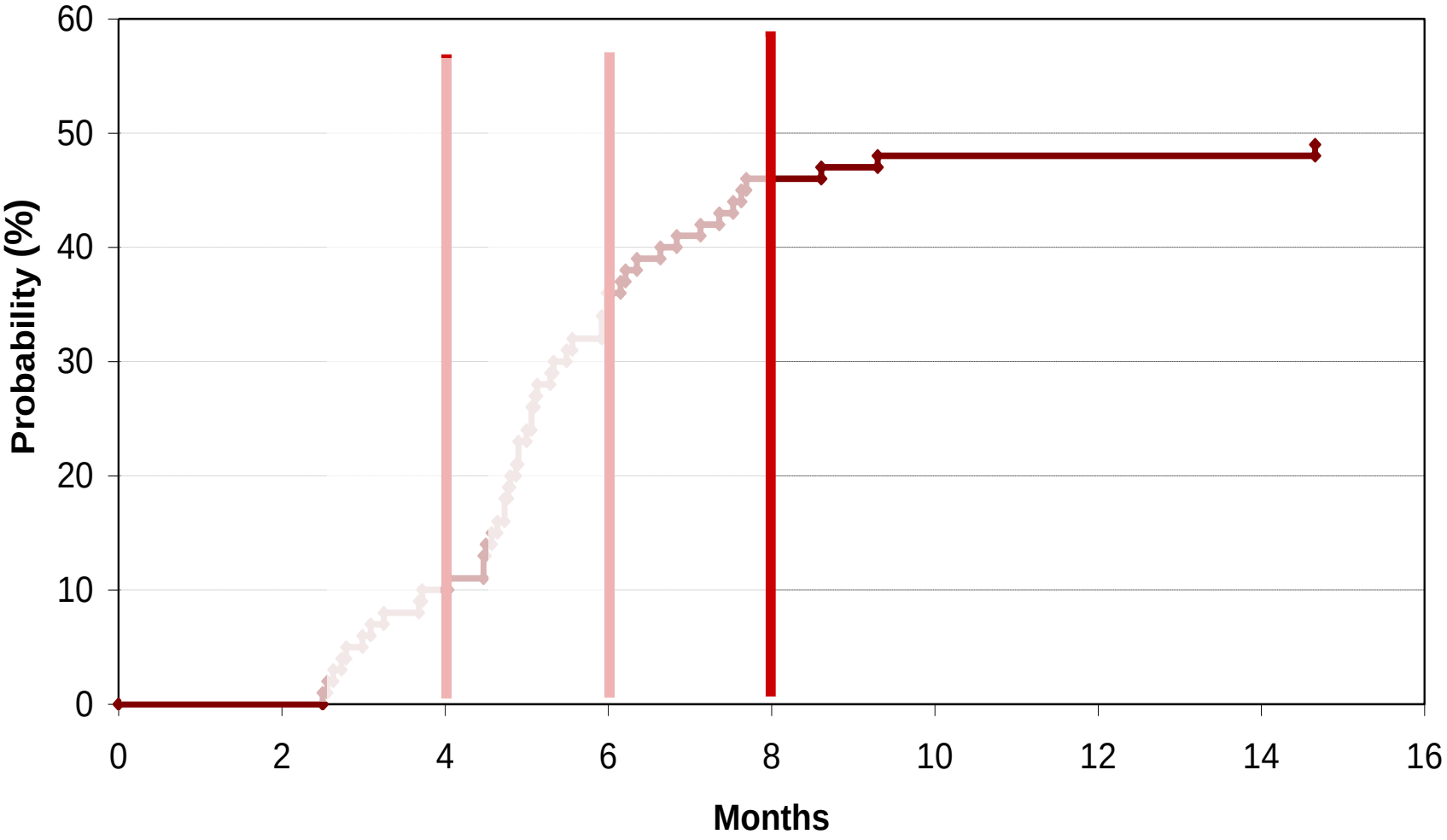
Krishi, Vauthey Ann Surg Oncol 2010

# Time to resection / intervention



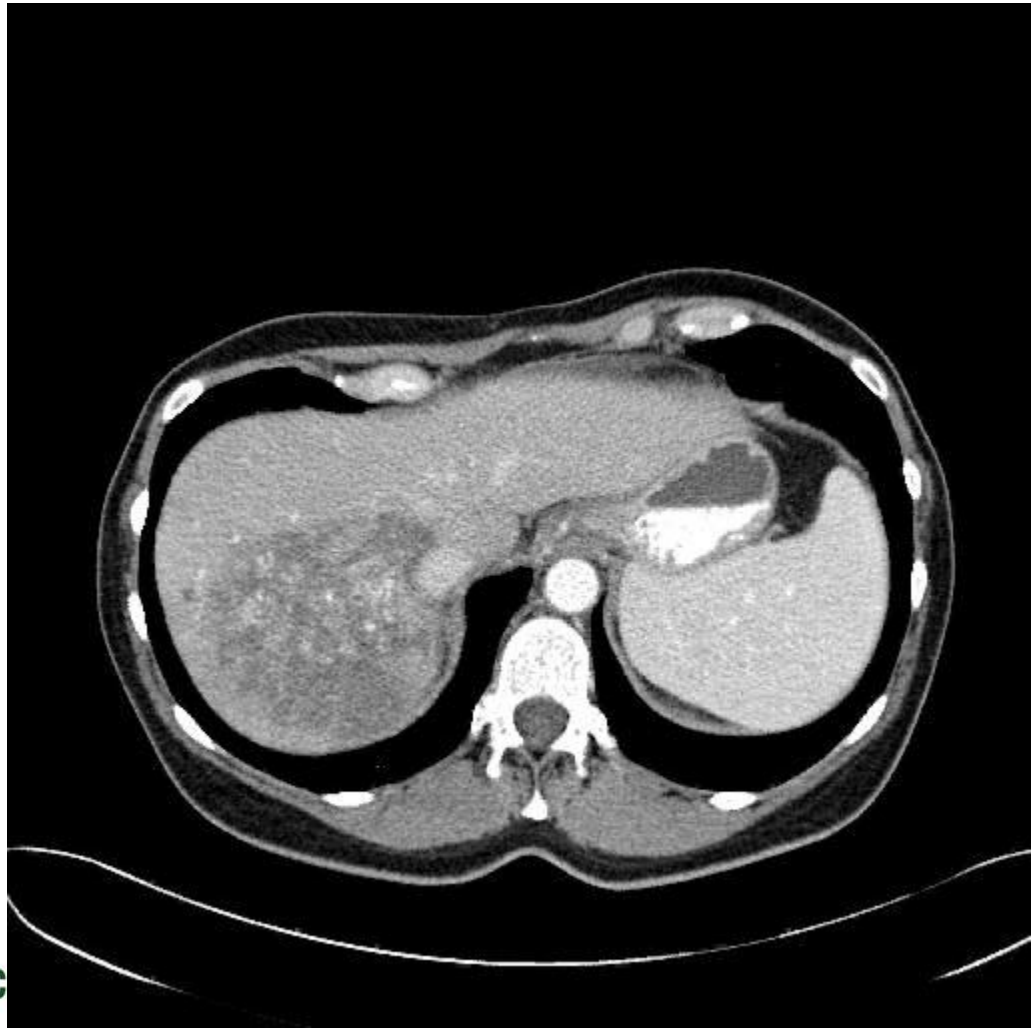



Folprecht et al, Lancet Oncology 2010

# Further course…

- 07/2010 Sigmoid cancer + liver metastasis
  - 07-11/2010 Cetuximab / FOLFOX

# CT SCAN Nov 2010



# Dr. Nordlinger:

- What would have been your decision?
- Liver first, primary first or simultanouesly – is it important?

# Surgical strategy: the “classical approach”

- Resection of primary →Resection of CLM →Chemotherapy
- Advantages:
  - No risk of primary related complications
- Limitations: risk of progression of resectable CLM during the treatment of primary in particular if complications of surgery delay other phases of treatment (++rectal primary)

# Surgical strategy: *simultaneous combined resections of primary and CLM*

- Advantages:
  - Only one operation
  - Resection of CLM not delayed by the treatment of the primary
- Limitations
  - Increased morbidity (major liver resection + major colorectal surgery)
  - No Increased morbidity (minor liver resection for example wedge resection on left lobe + intestinal resection)
  - Requires double surgical expertise
  - Depends on surgical access ( open +/- laparoscopy)



Reddy et al. Ann Surg Oncol 2007, De Santibanes et al. J Am Coll Surg 2003, Fujita et al, Jpn J Clin Oncol 2000, Tocchi et al, Int J Colorectal Dis 2004

# Surgical Strategy: The combined approach

| | Combined resection | Staged resection | P value |
|---|---|---|---|
| **Major Hepatectomy** | | | |
| **Mortality** | **6.1%** | **2.4%** | **0.009** |
| **Minor Hepatectomy** | | | |
| **Mortality** | **2.2%** | **0.5%** | **0.11** |



Nordlinger, Jaeck , Cancer 1996

# Surgical Strategy: the combined approach

| | Combined resection | Staged resection | P value |
|---|---|---|---|
| **Major Hepatectomy** | | | |
| **n** | **36** | **51** | |
| **Mortality** | **3 (8.3%)** | **0** | **0.07** |
| **Severe morbidity** | **13 (36.1%)** | **9 (17.6)** | **0.05** |
| **Minor Hepatectomy** | | | |
| **n** | **99** | **19** | |
| **Mortality** | **1 (1%)** | **0** | **0.83** |
| **Severe morbidity** | **14 (14.1%)** | **2 (10.5%)** | **0.73** |



Reddy SK et al. Ann Surg Oncol 2007

# Surgical Strategy: the reverse approach: liver surgery first

- Preoperative chemotherapy → Resection of CLM →Resection of the Primary Tumor
- Rationale:
  - Survival depends on progression of CLM rather than of the primary tumor
  - Prevents the risk of progression of CLM which could become unresectable during treatment of primary
  - primary related complications during treatment of CLM are rare
  - Primary tumor usually also responds to preoperative chemotherapy



Mentha G et al. Br J Surg 2006

# Further course…

- 07/2010 Sigmoid cancer + liver metastasis
  - 07-11/2010 Cetuximab / FOLFOX

# Further course…

- 07/2010 Sigmoid cancer + liver metastasis
  - 07-11/2010 Cetuximab / FOLFOX
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  - 02/2011 Resection of the sigmoid tumor

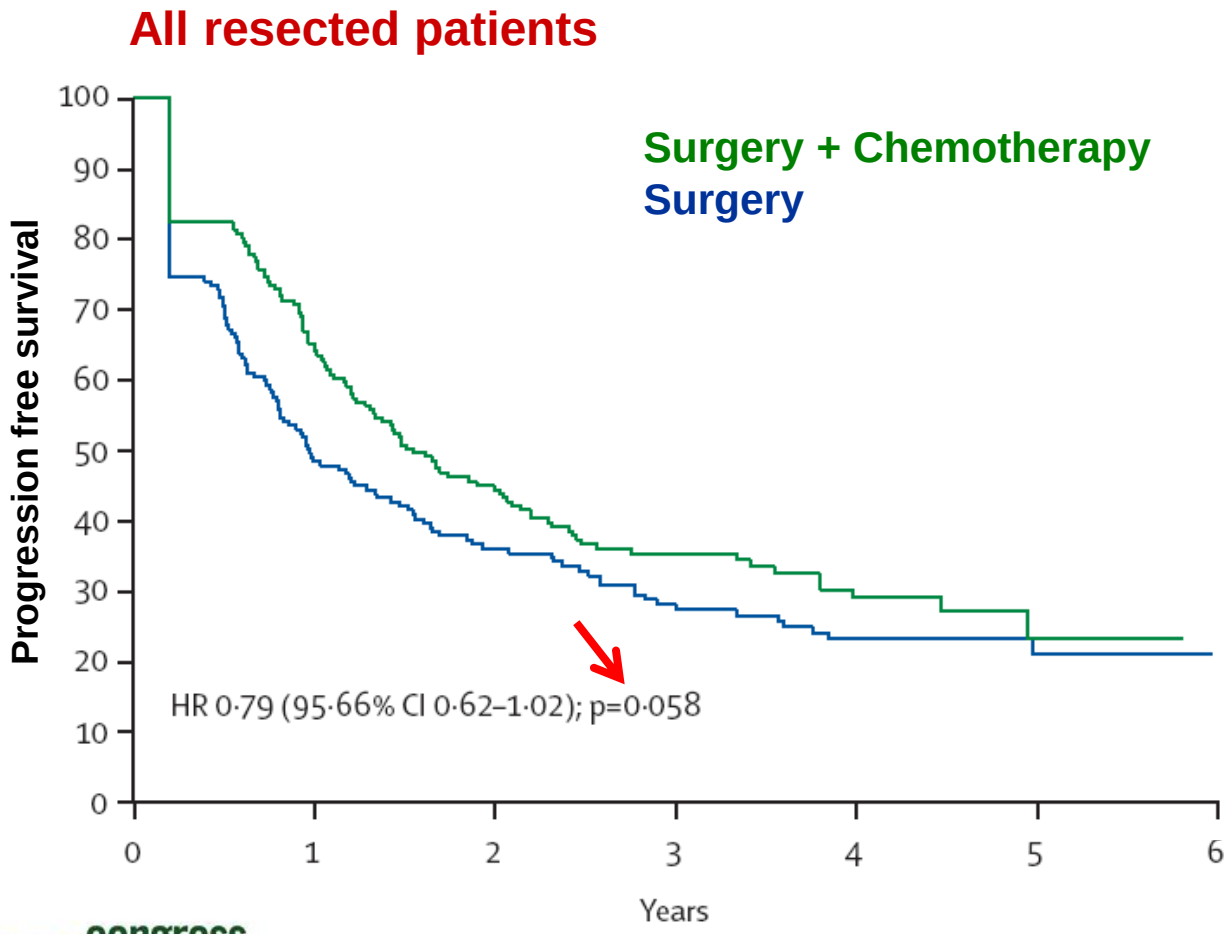
    pT3pN1(2/18)pM1L0V0Pn0R0

# Dr. Folprecht:

- Would you recommend adjuvant chemotherapy?

- If yes: which regimen, and who long?

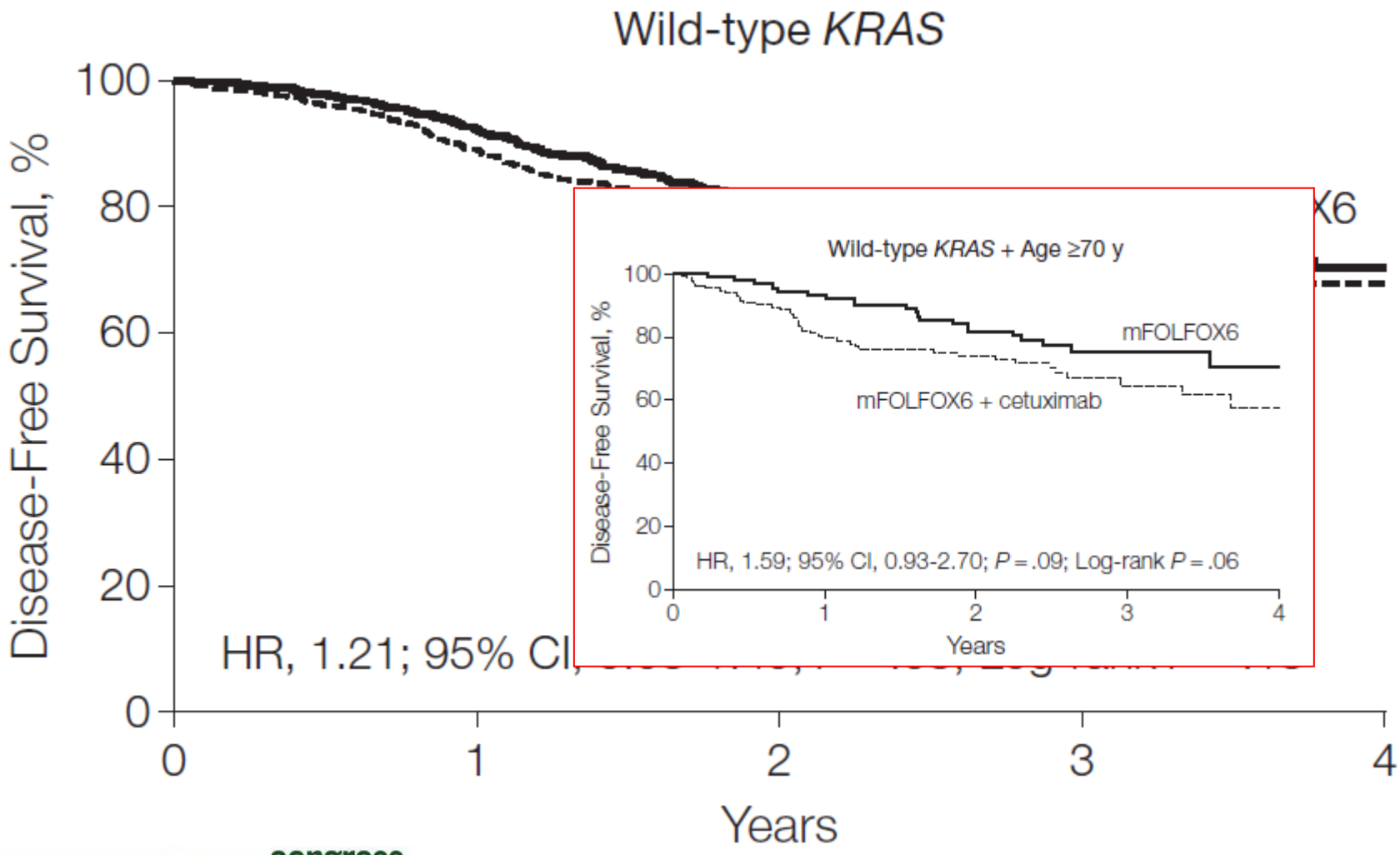
# EORTC 40983: Liver surg. +/- FOLFOX






Nordlinger Lancet 2008

# Adjuvant: FOLFOX +/- Cetuximab





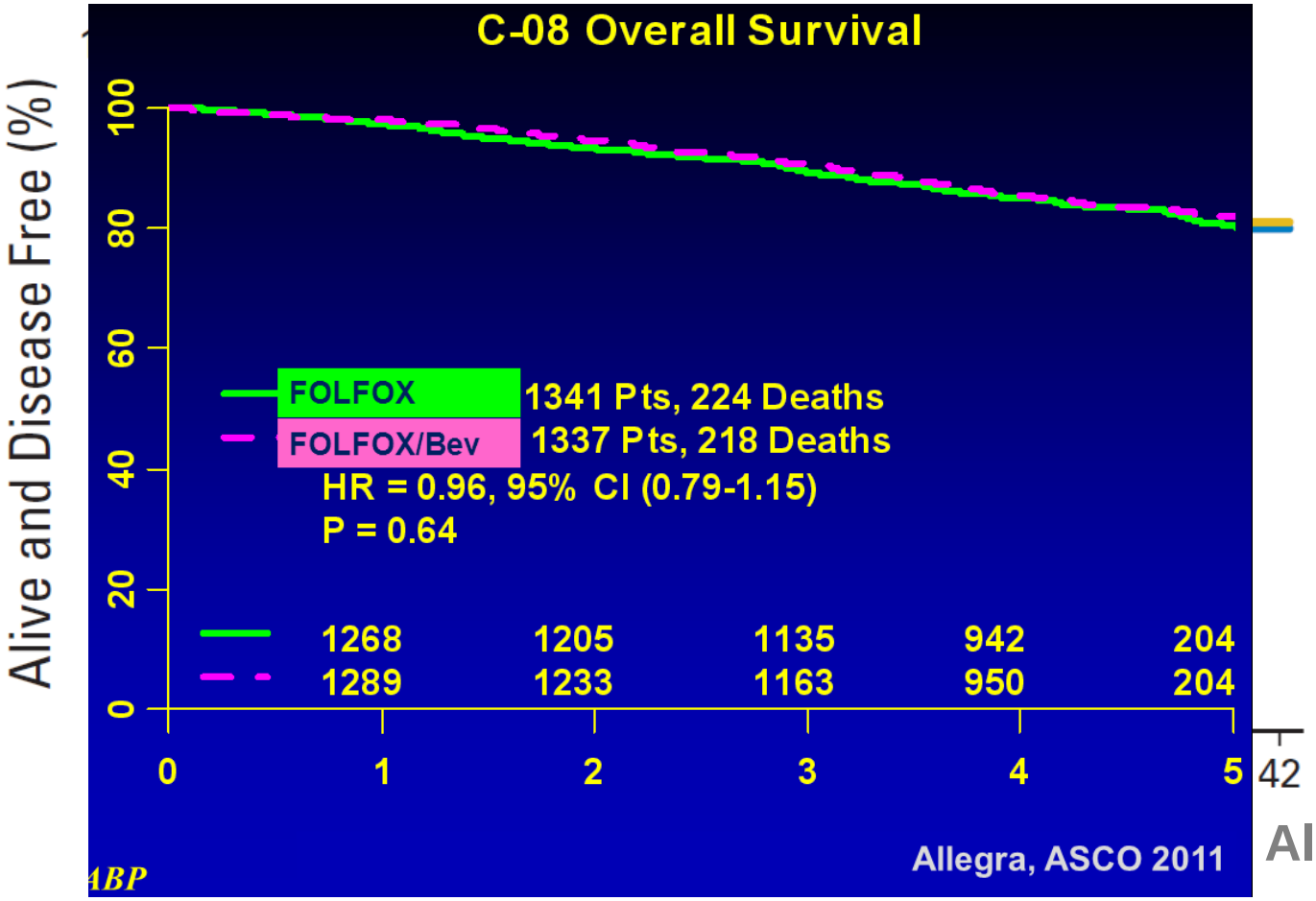

Alberts, JAMA 2012

# FOLFOX +/- Bevacizumab adjuvant

NSABP-C08

**CRC**
Stage II/III

- **FOLFOX**
- **FOLFOX + Bevacizumab (1 y.)**




Allegra, JCO 2011

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- 09/2011 Liver metastasis, segm 2

# CT SCAN Sep 2011

# Dr. Nordlinger:

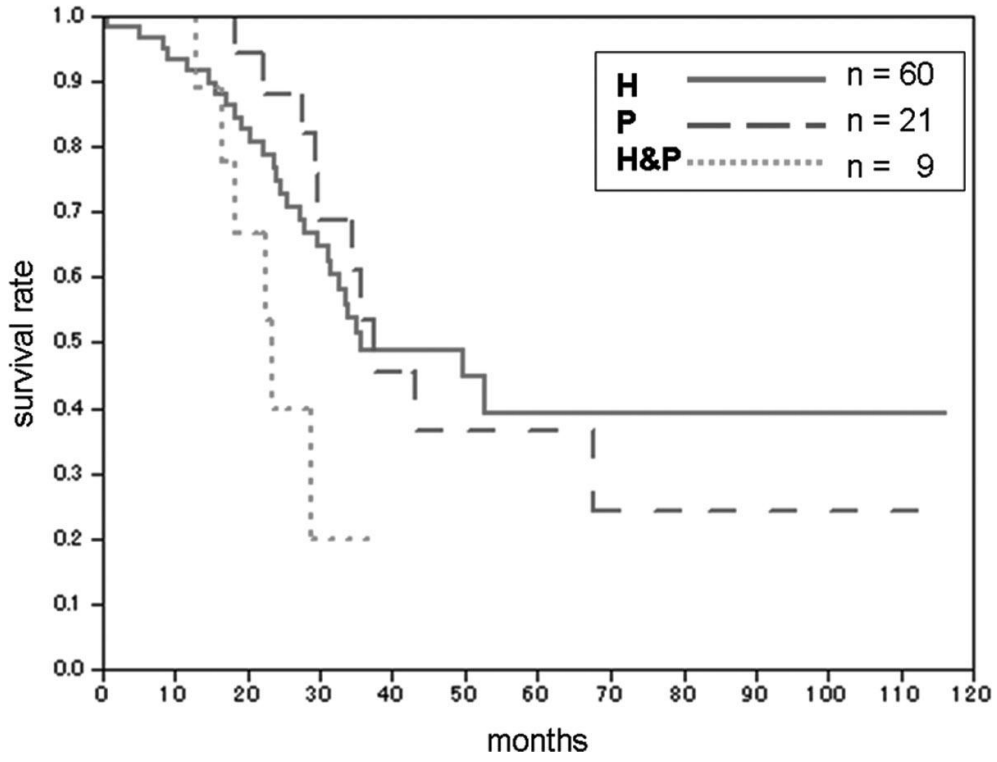
- Is this technically resectable disease?
- What is the prognosis for repeated resections of liver metastases?
  - How high would you estimate her chance of a 3 year DFS?
- What would be your next step?

# Dr. Folprecht:

A liver metastasis just two months after adjuvant therapy…

- Neoadjuvant therapy, if yes: which regimen?
- Palliative approach instead of surgery?

# Resection of recurrent metastases

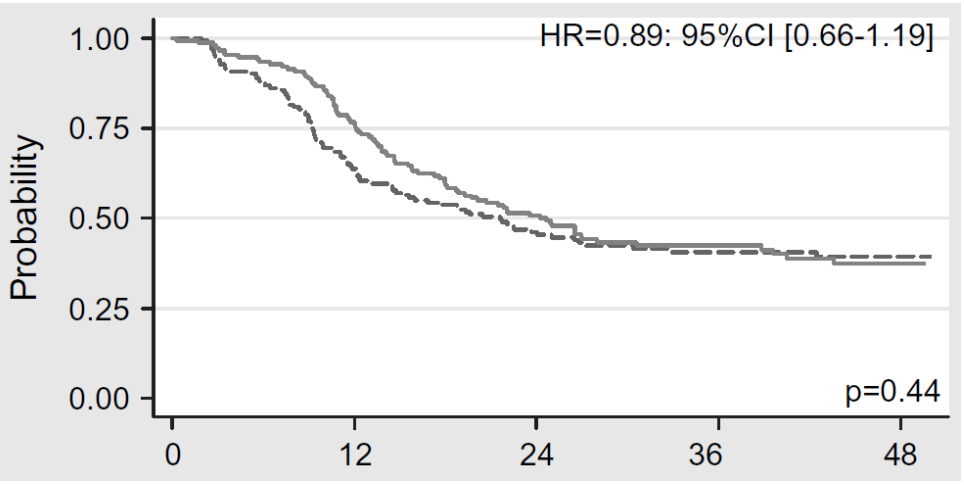




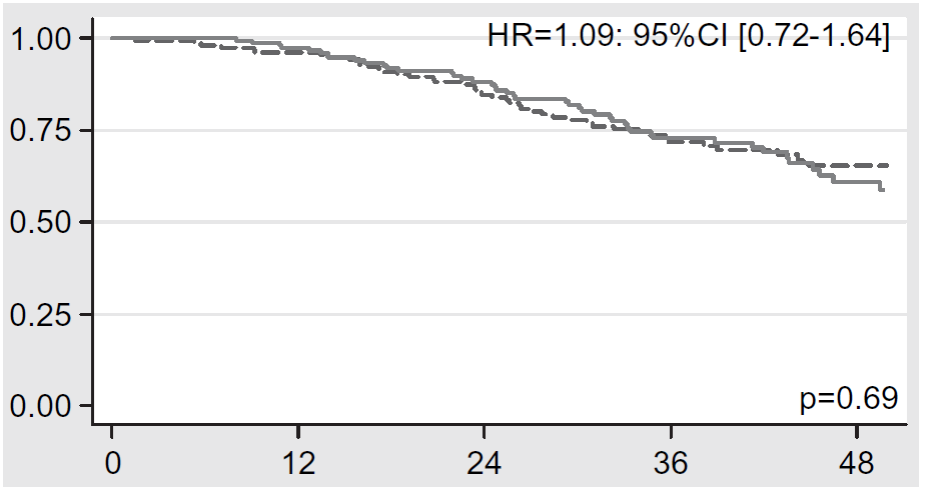

Mise et al, Ann Surg 2010

# Resectable liver met's: 5-FU vs FOLFIRI

## Disease free




## Overall survival






Ychou et al, Ann Oncol 2009

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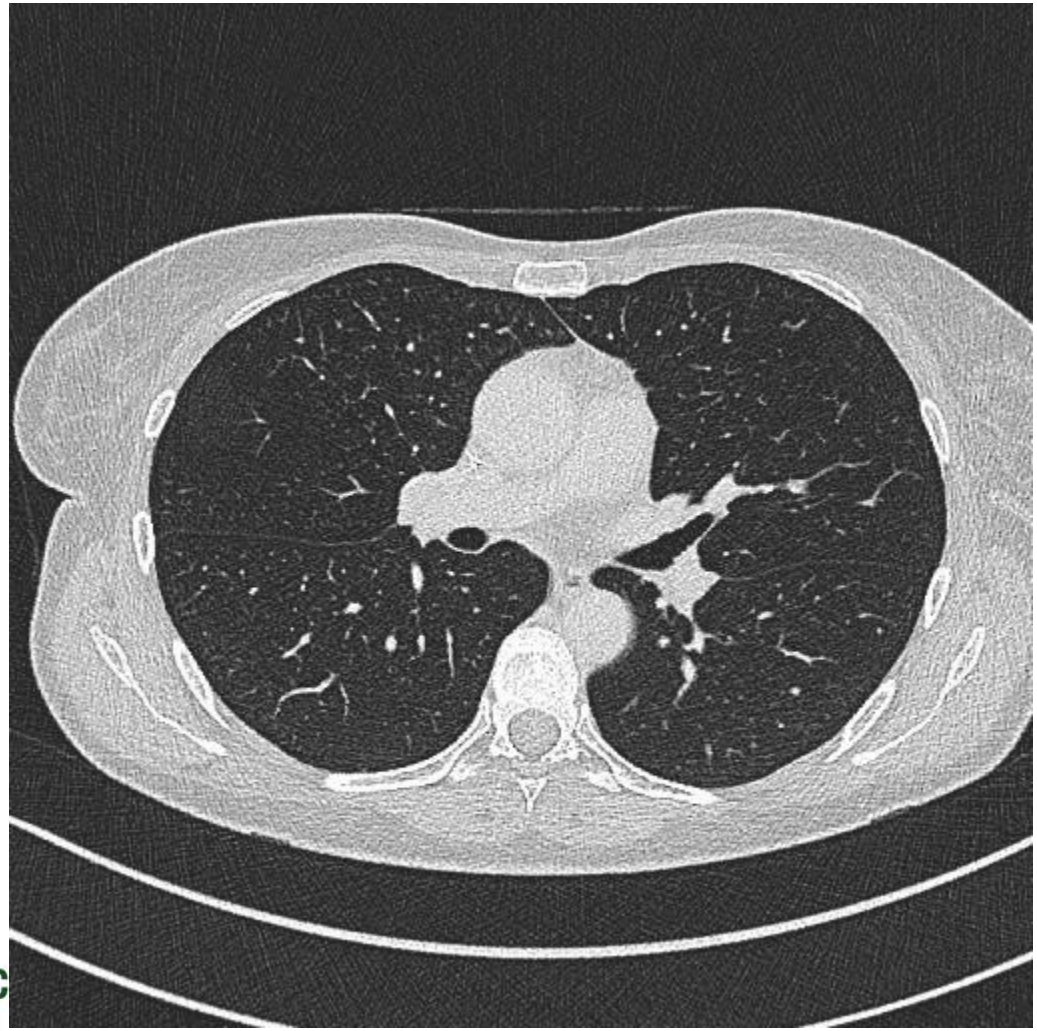
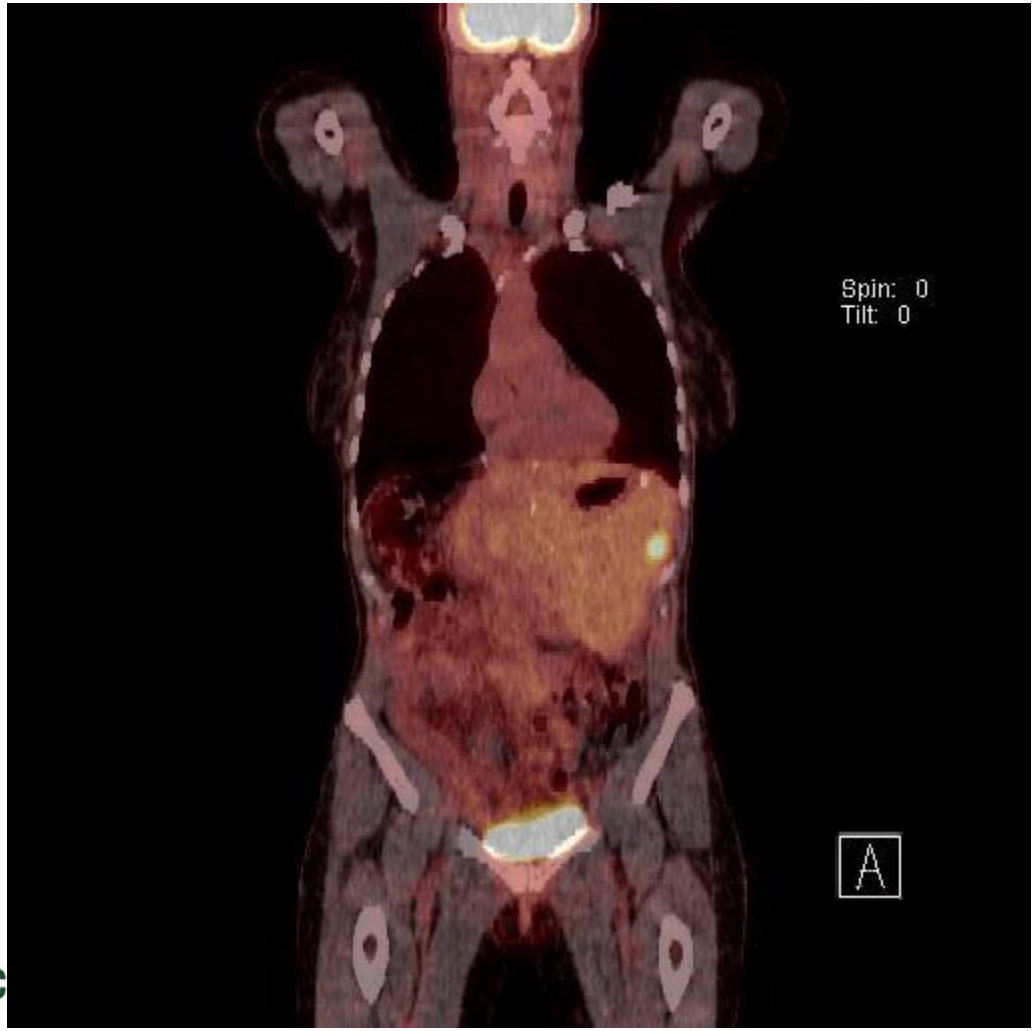
# CT May 2012

# CT May 2012



# PET-CT June 2012



# Dr. Nordlinger:

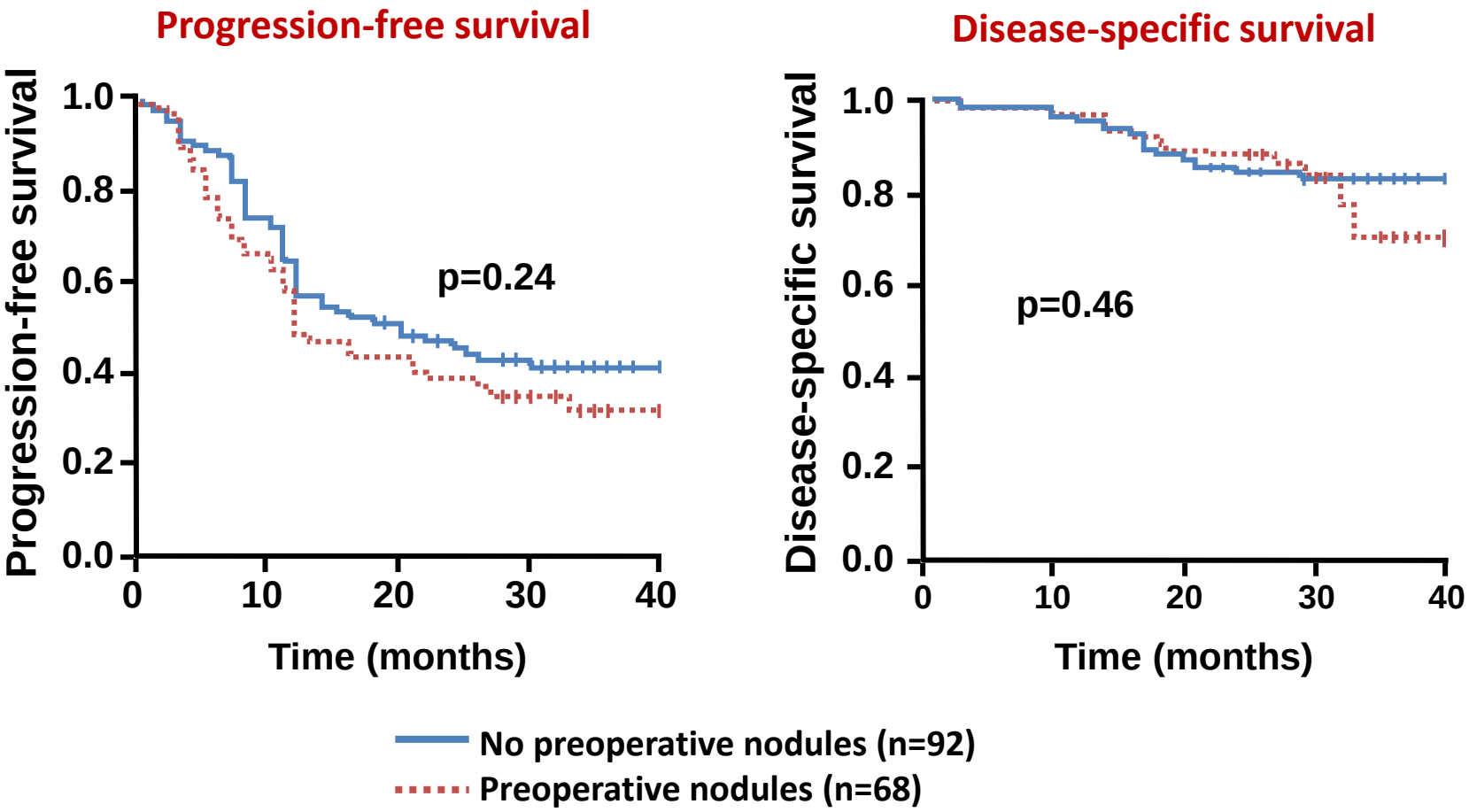
- Is this technically resectable disease?
- Do you think, it‘s an indication for surgery?
- What would be your next step?

# Dr. Folprecht:

We are one year after last chemotherapy.

- Is it an indication for neoadjuvant therapy, if yes: which regimen?
- There is a risk for multiple metastases and incurable disease.
  Therefore, palliative approach instead of surgery?

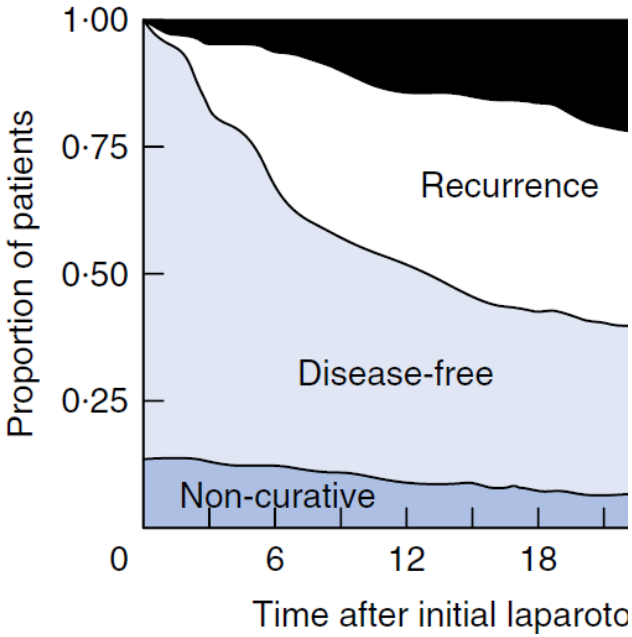
# Natural history of patients with subcentimeter pulmonary nodules present at time of liver resection for mCRC

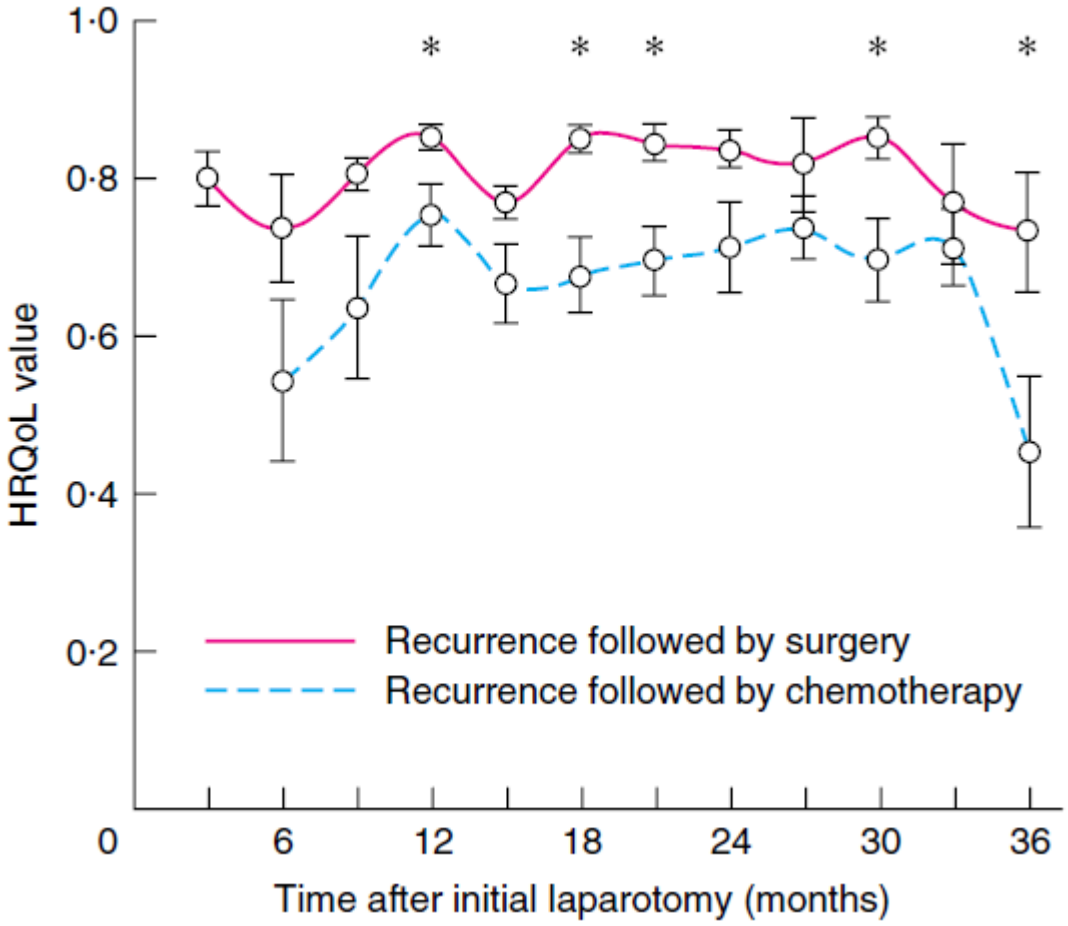





Maithel SK, et al. J Am Coll Surg 2010;210:31–38

# Resection and Quality of Life




VIENNA 2012 ESMO congress

www.esmo2012.org

Wiering et al, Br J Cancer 2010

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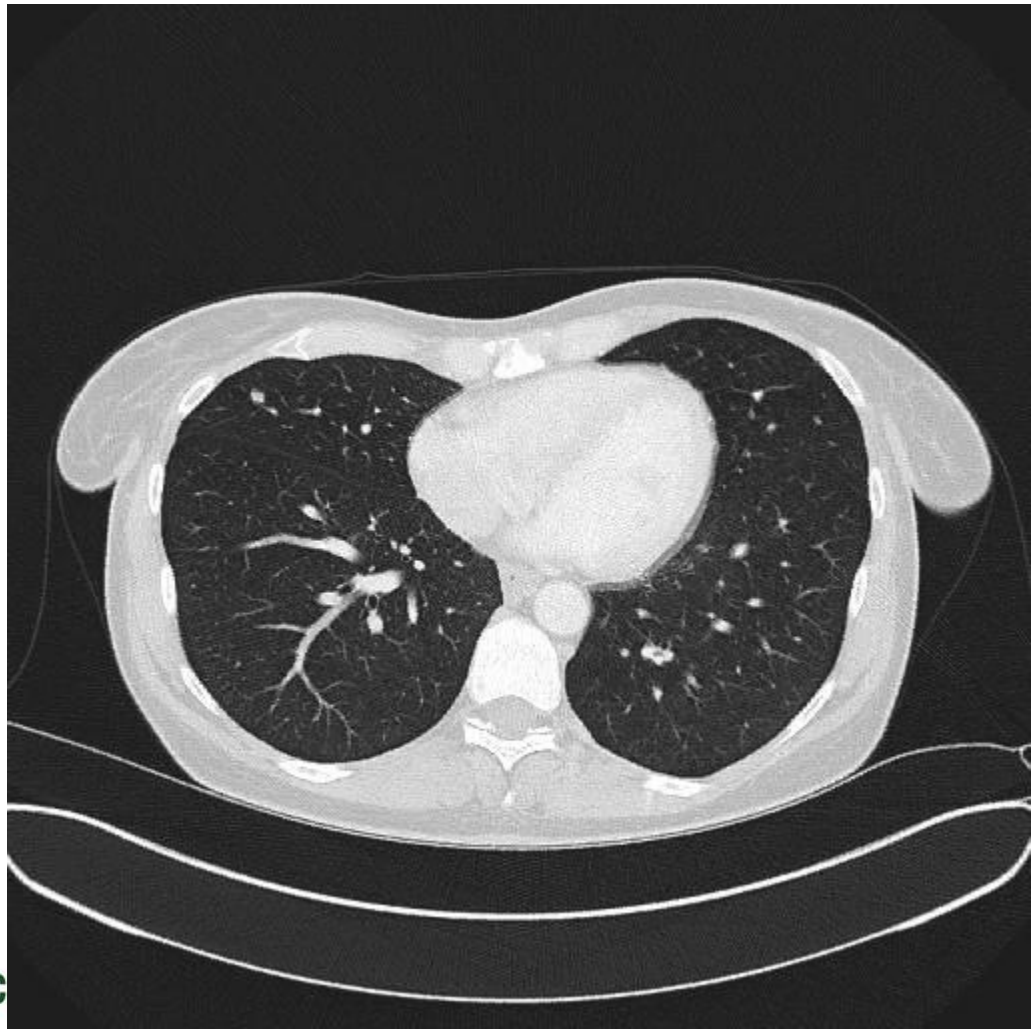
# CT July 2012

# CT July 2012



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- 09/2011 Liver metastasis, segm 2
  - 11/2011 Atypical resection
- 05/2012 3 liver met's, 3? pulmon. metastases
  - 06/2011 Atypical resection
- 07/2012 ≥ 10 small pulmonary metastases

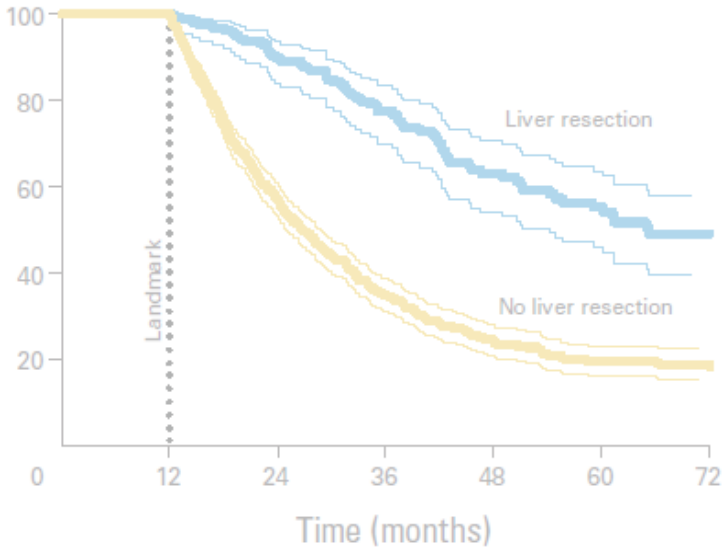
# Dr. Nordlinger, Dr. Folprecht:

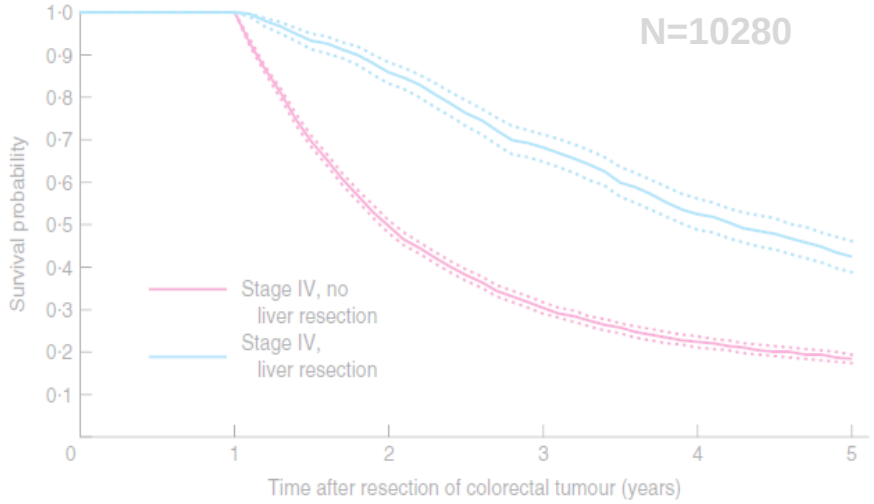
- What would you recommend?

## Mayo Clinic und MD Anderson

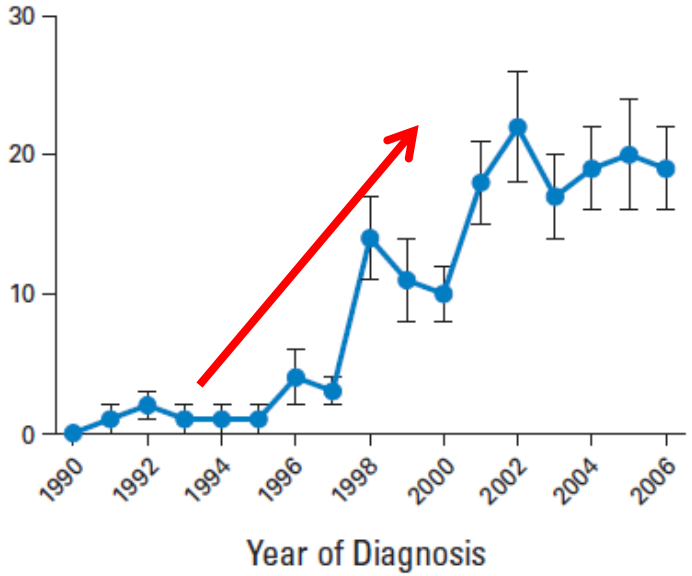
## England

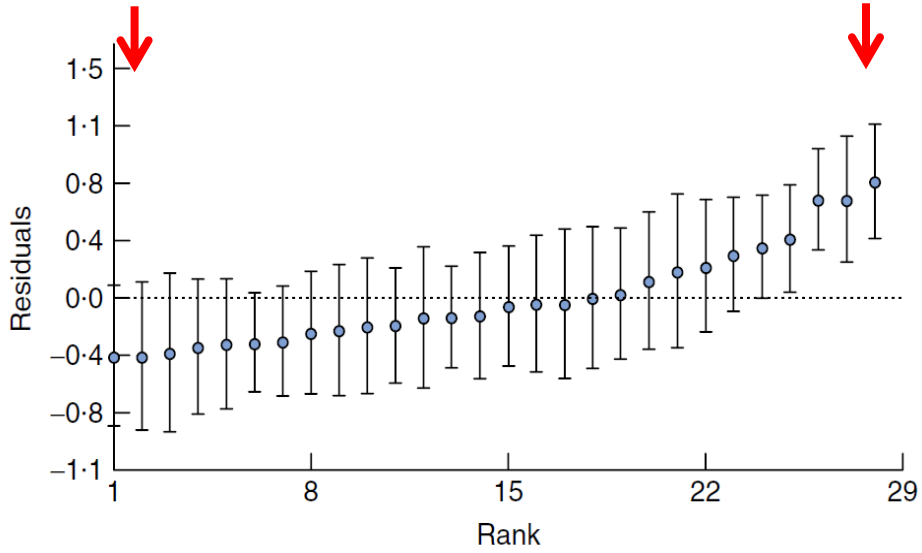
Überleben




% Pat. mit Leberresektion




Kopetz et al, JCO 2009

Morris et al, Br J Surg 2010

# Discussion