



Klinik und Poliklinik für
Innere Medizin I

Systemtherapie des Pankreaskarzinoms

Aktuelle Leitlinien

Sophie Rauschenberg

14.05.2025

LIVING GUIDELINE

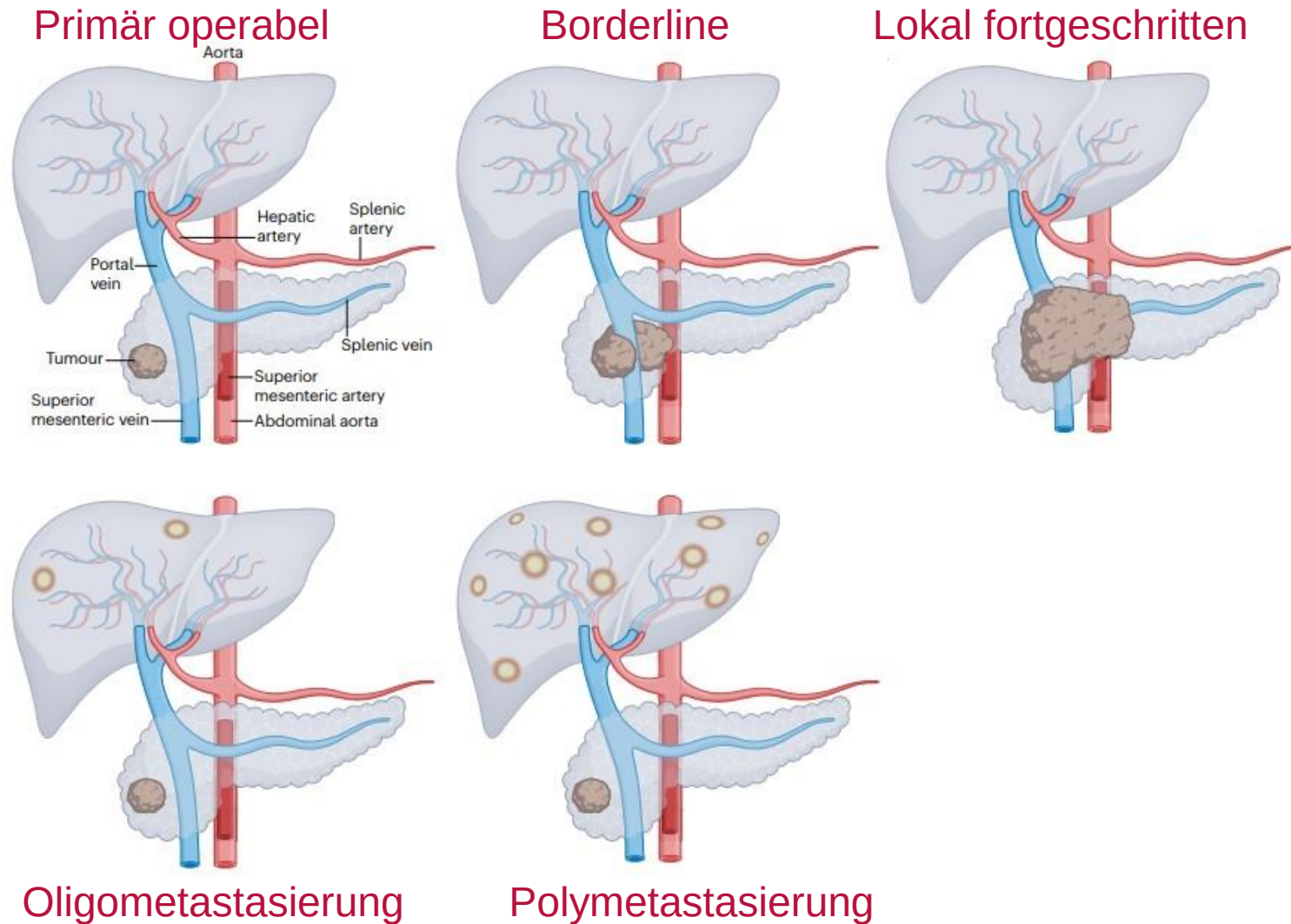


S3-Leitlinie Exokrines Pankreaskarzinom

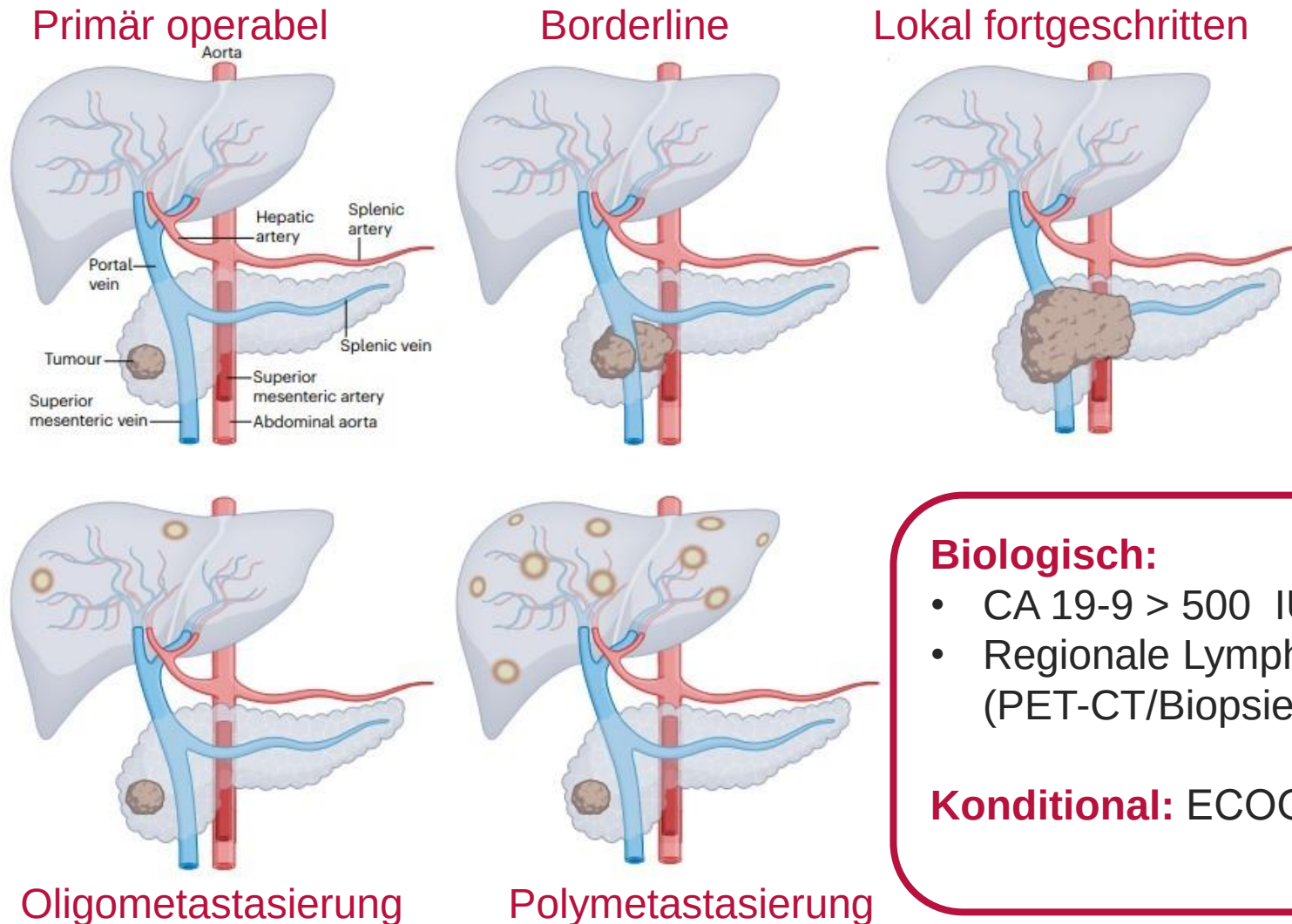
Version 3.1 – September 2024
AWMF-Registernummer: 032-010OL



ANATOMISCHE STADIENEINTEILUNG DES PANKREASKARZINOMS



STADIENEINTEILUNG DES PANKREASKARZINOMS

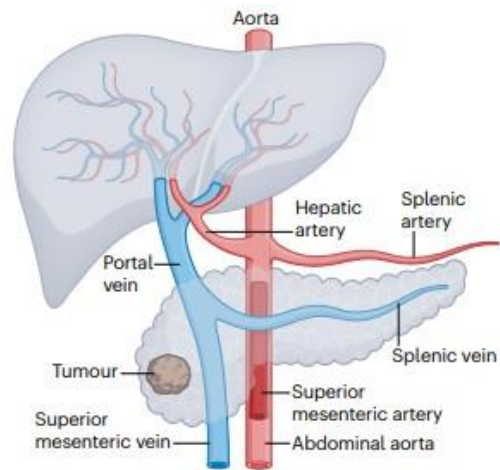


Biologisch:

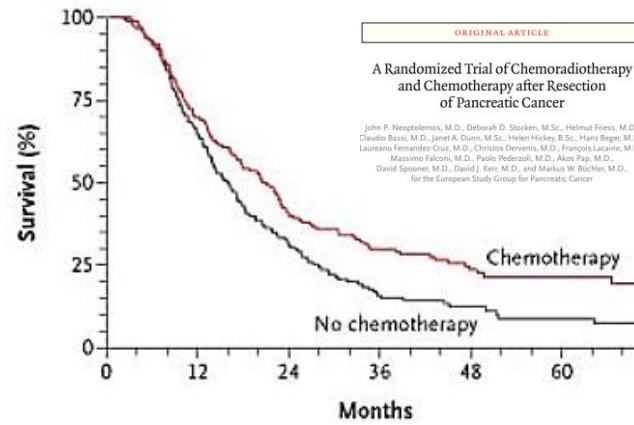
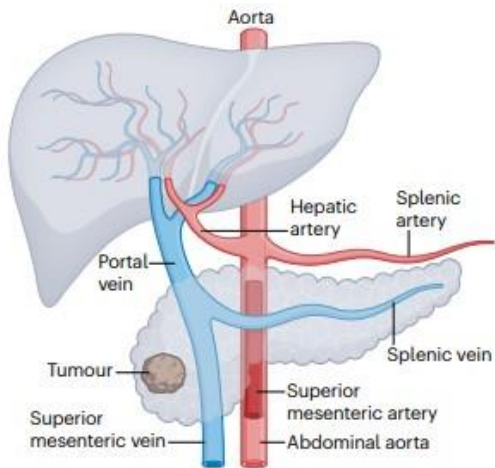
- CA 19-9 > 500 IU/l
- Regionale Lymphknotenmetastasen (PET-CT/Biopsie)

Konditional: ECOG ≥ 2

■ DAS PRIMÄR OPERABLE PANKREASKARZINOM



DAS PRIMÄR OPERABLE PANKREASKARZINOM



No. at Risk						
No chemotherapy	142	89	41	18	11	7
Chemotherapy	147	99	56	38	22	11

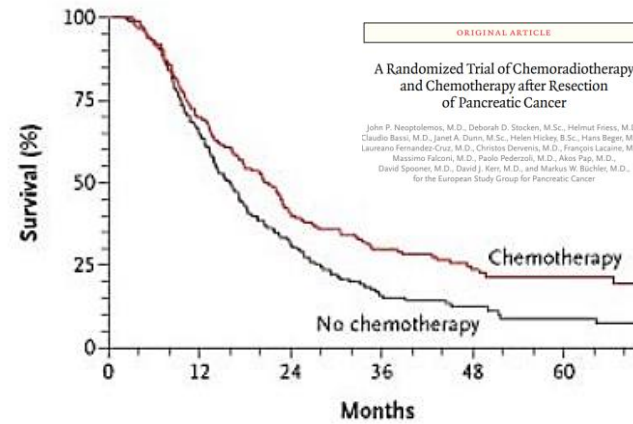
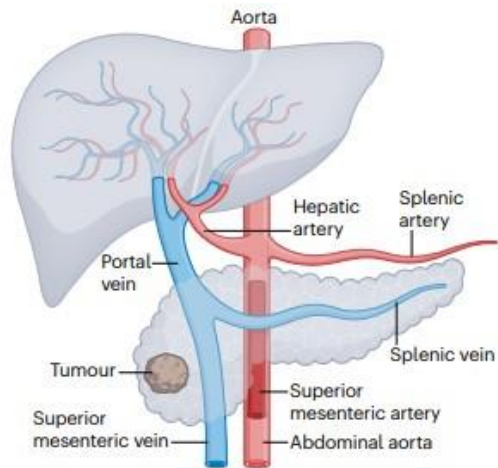
Neoptolemos JP et al. N Engl J Med. 2004

DFS 5J: 21% vs. 8%

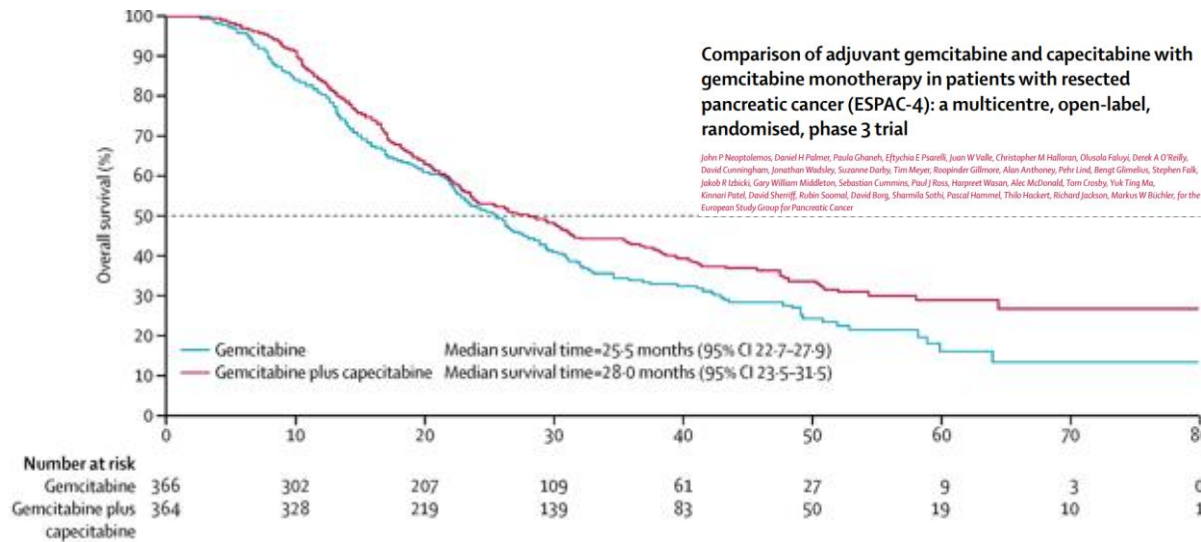


DAS PRIMÄR OPERABLE PANKREASKARZINOM

Neoptolemos JP et al. N Engl J Med. 2004
Neoptolemos JP et al. Lancet. 2017

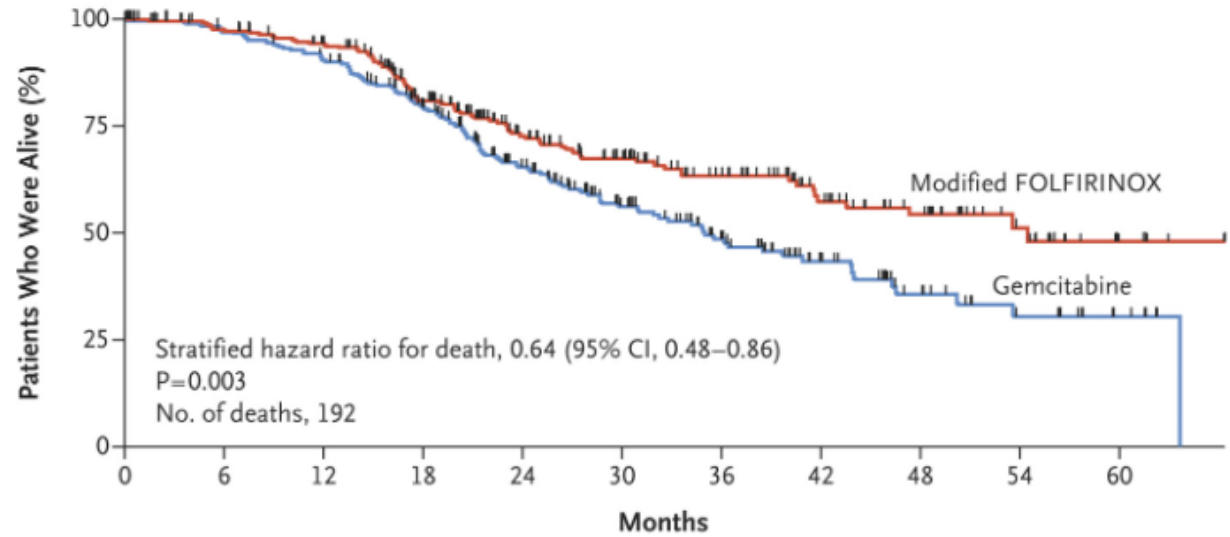
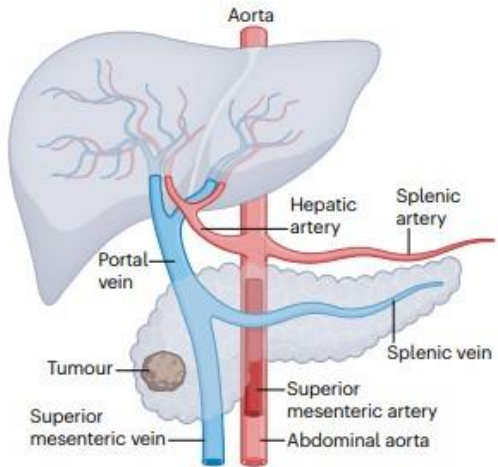


No. at Risk						
No chemotherapy	142	89	41	18	11	7
Chemotherapy	147	99	56	38	22	11



DFS 5J: 30,7% vs. 18,4%

■ DAS PRIMÄR OPERABLE PANKREASKARZINOM



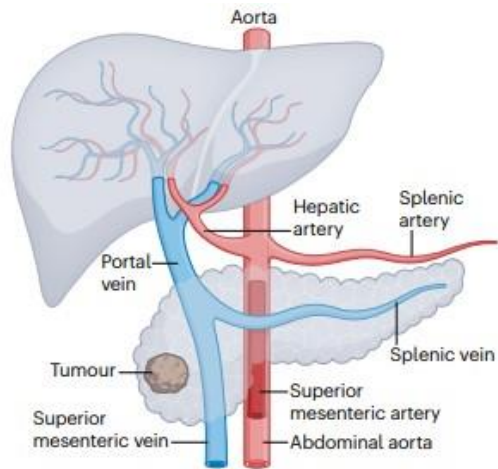
Conroy T et al. N Engl J Med. 2018

No. at Risk
Modified FOLFIRINOX
Gemcitabine

247	223	210	165	119	91	68	46	32	16	4
246	233	215	171	120	81	55	33	18	9	4

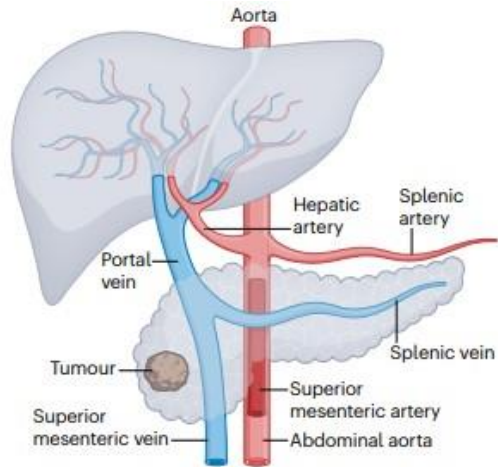
mDFS: 21.4 Mo vs. 12.8 Mo
DFS 5J: 26.1% vs. 19%
mOS 53.5 vs. 35.5
Alle Subgruppen profitieren

■ DAS PRIMÄR OPERABLE PANKREASKARZINOM



Adjuvante Systemtherapie
Standard nach Resektion

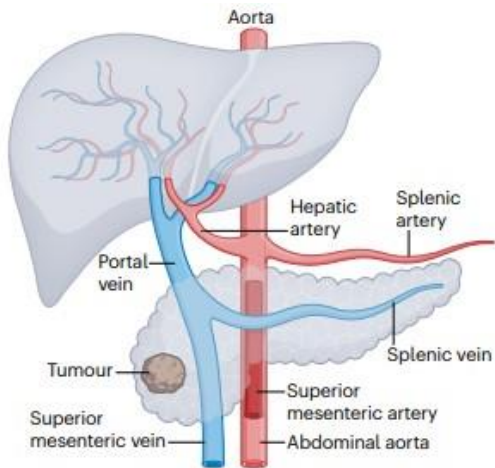
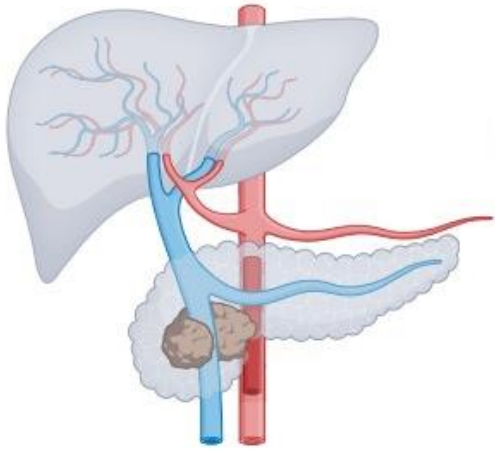
■ DAS PRIMÄR OPERABLE PANKREASKARZINOM



Adjuvante Systemtherapie Standard nach Resektion

- 12 Wochen postoperativ
- Dauer 6 Monate
- Auswahl nach Allgemeinzustand:
 - ECOG 0-1: mFOLFIRINOX
 - ECOG > 1-2:
Gemcitabin+Capecitabin/Gemcitabin/ 5-FU
bei Unverträglichkeit

■ BORDERLINE

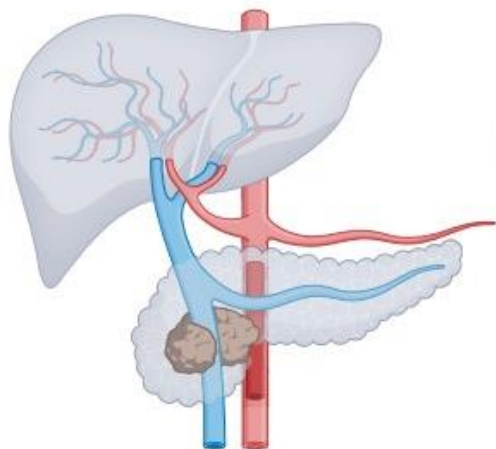


Primär operabel

CA19-9 < 500 UI/l oder ECOG $\geq$ 2

Borderline resektabel

■ BORDERLINE – ROLLE DER NEOADJUVANTEN CHEMOTHERAPIE



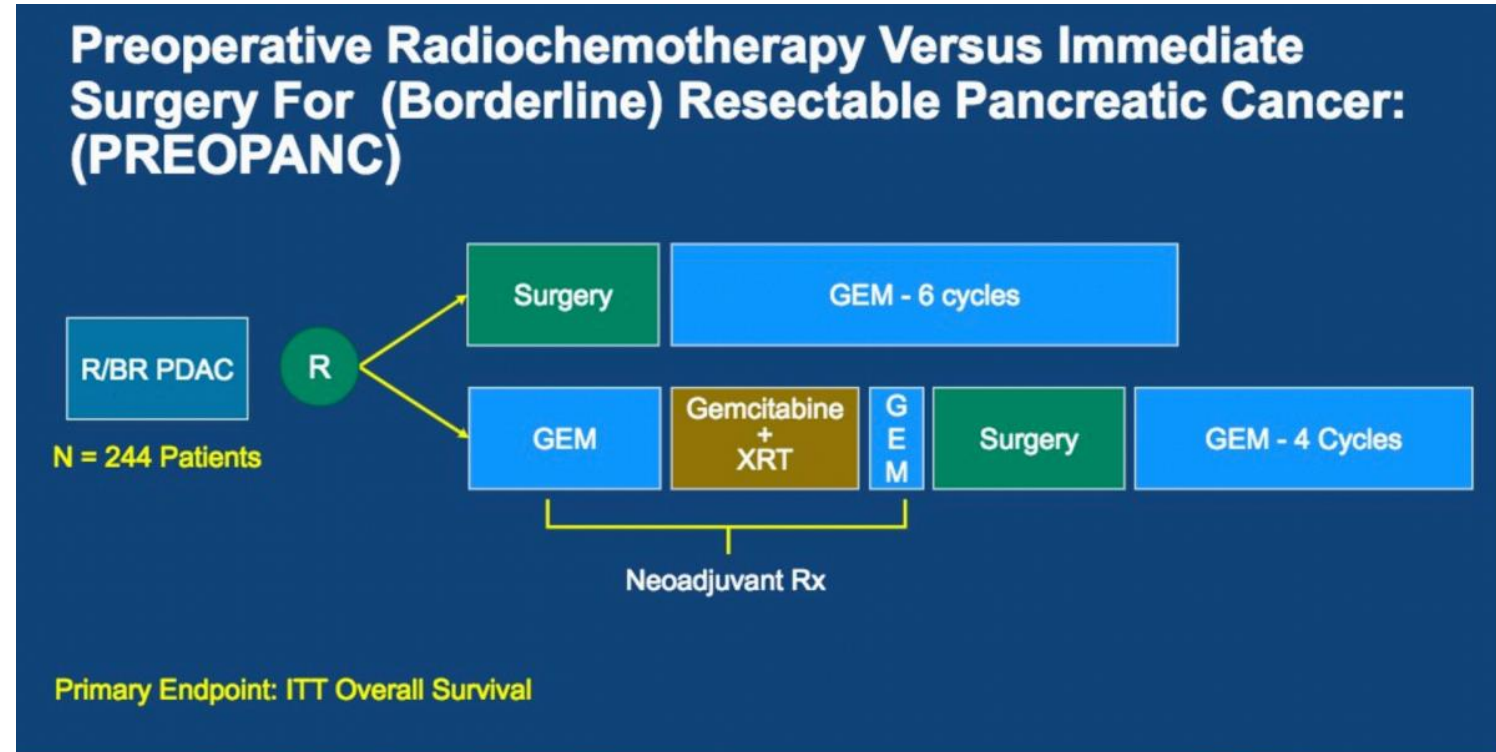
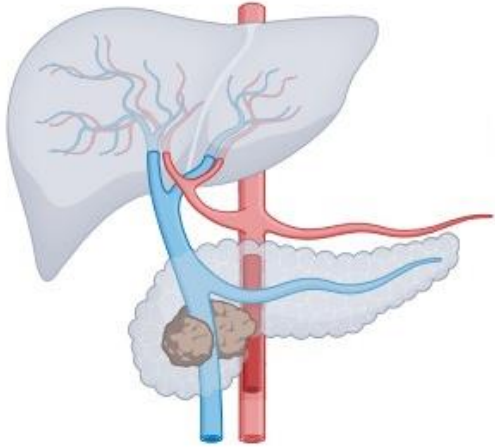
Meta-analysis comparing upfront surgery with neoadjuvant treatment in patients with resectable or borderline resectable pancreatic cancer

E. Versteijne¹ , J. A. Vogel², M. G. Besselink², O. R. C. Busch², J. W. Wilmink³, J. G. Daams⁴, C. H. J. van Eijck⁵, B. Groot Koerkamp⁵ , C. R. N. Rasch¹ and G. van Tienhoven¹, on behalf of the Dutch Pancreatic Cancer Group

Departments of ¹Radiation Oncology, ²Surgery and ³Medical Oncology, Cancer Centre Amsterdam, Academic Medical Centre, and ⁴Medical Library, Academic Medical Centre, Amsterdam, and ⁵Department of Surgery, Erasmus Medical Centre, Erasmus University Rotterdam, Rotterdam, The Netherlands

Correspondence to: Dr E. Versteijne, Department of Radiation Oncology, Cancer Centre Amsterdam, Academic Medical Centre, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands (e-mail: e.versteijne@amc.uva.nl)

■ BORDERLINE – ROLLE DER NEOADJUVANTEN CHEMOTHERAPIE



PRESENTED AT: 2018 ASCO ANNUAL MEETING

#ASCO18
Slides are the property of the author;
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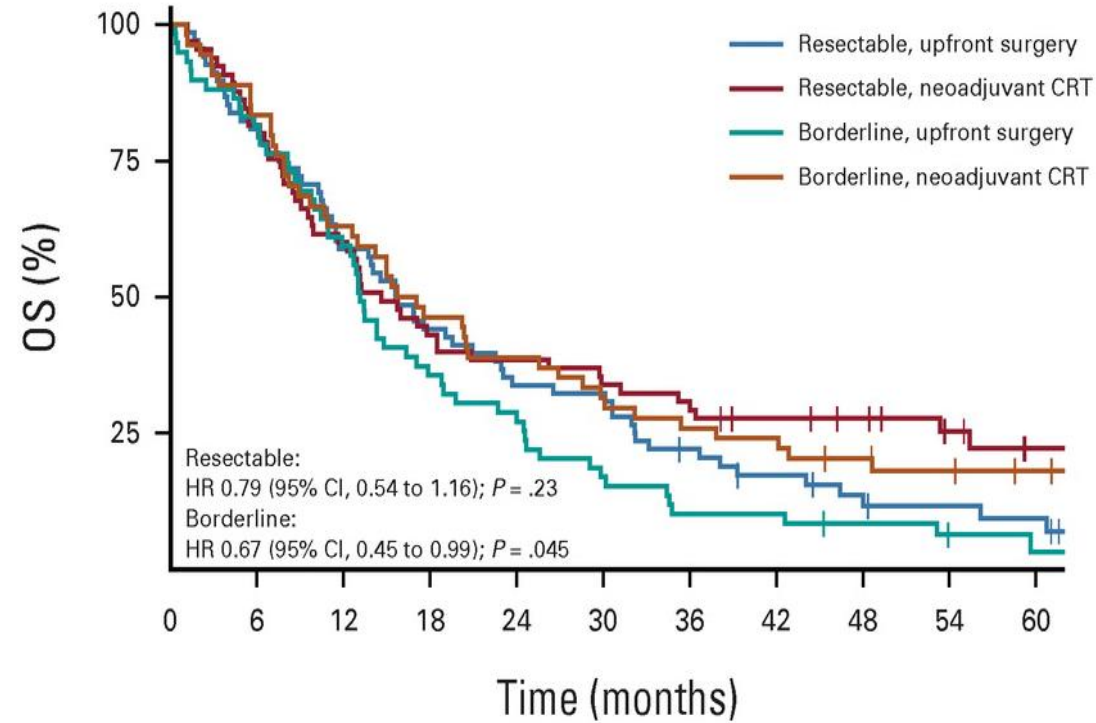
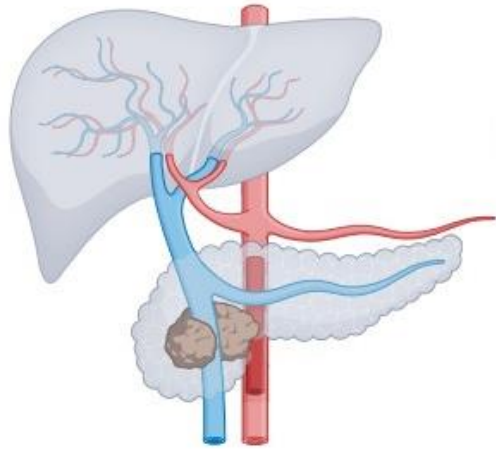
PRESENTED BY: Colin D. Weekes, MD, PhD



13

Presented By Colin D. Weekes, MD, PhD at 2018 ASCO Annual Meeting

■ BORDERLINE – ROLLE DER NEOADJUVANTEN CHEMOTHERAPIE

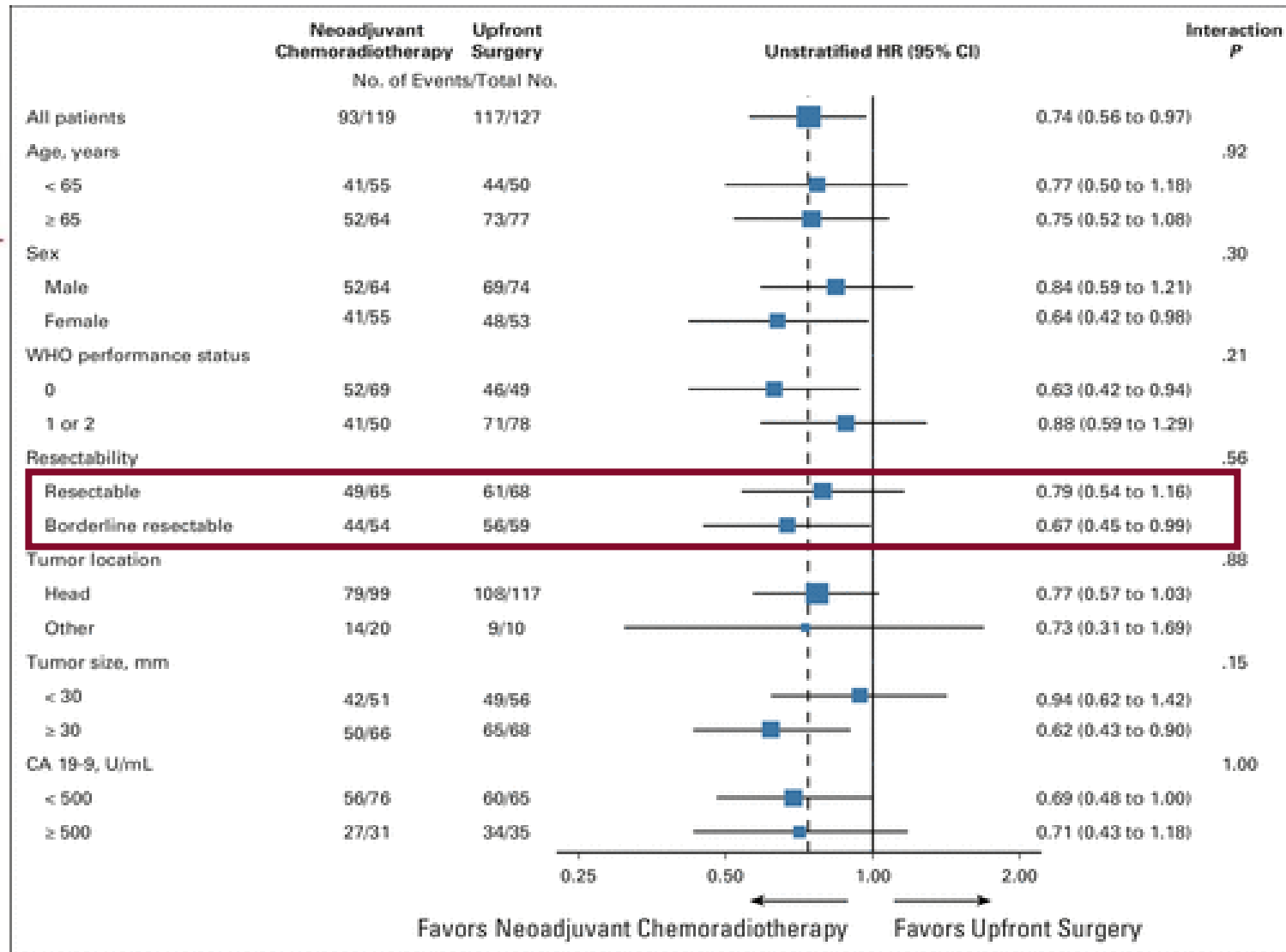
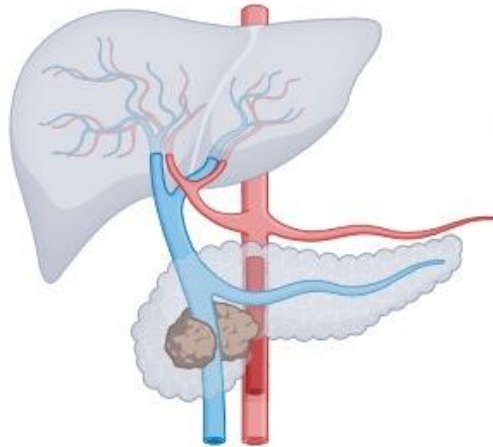


Neoadjuvant Chemoradiotherapy Versus Upfront Surgery for Resectable and Borderline Resectable Pancreatic Cancer: Long-Term Results of the Dutch Randomized PREOPANC Trial

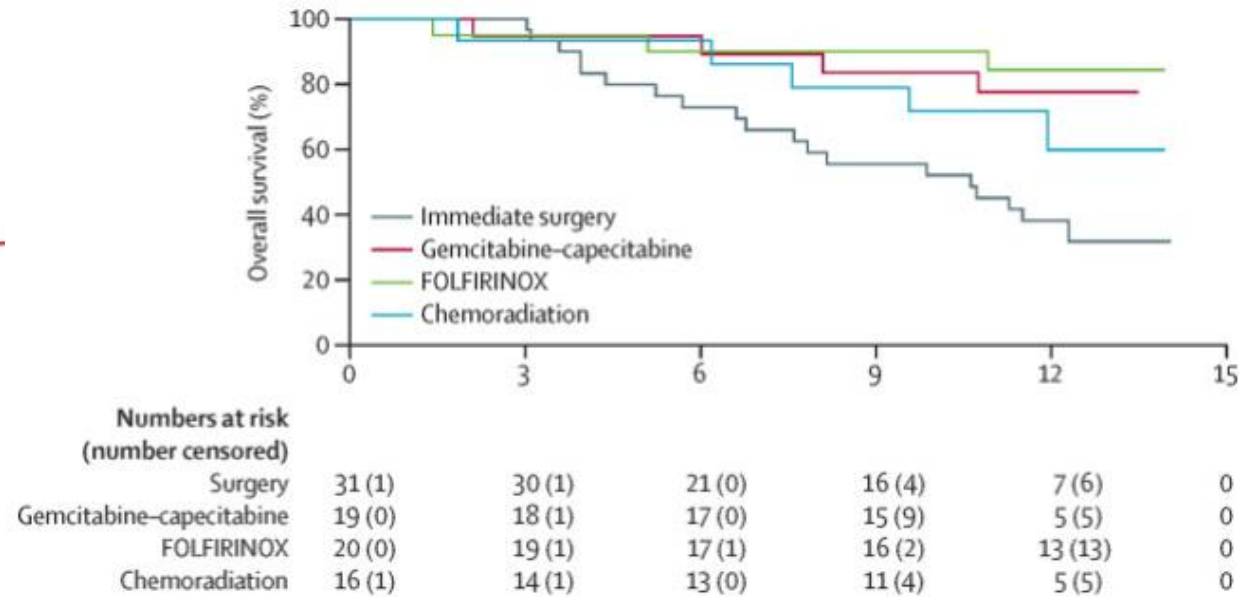
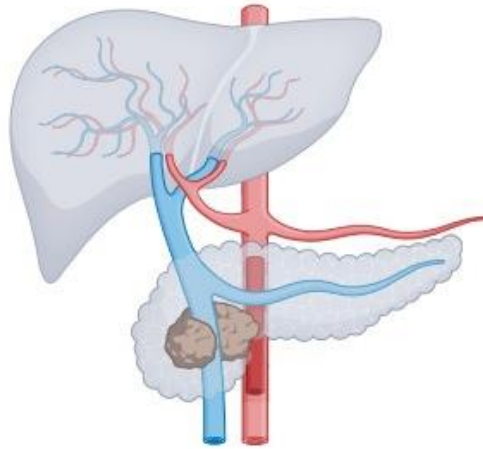
Eva Versteijne¹, Jacob L van Dam², Mustafa Suker², Quisette P Janssen², Karin Groothuis³, Janine M Akkermans-Vogelaar³, Marc G Besselink⁴, Bert A Bonsing⁵, Jeroen Buijsen⁶, Olivier R Busch⁴, Geert-Jan M Creemers⁷, Ronald M van Dam^{8,9,10}, Ferry A L M Eskens¹¹, Sebastiaan Festen¹², Jan Willem B de Groot¹³, Bas Groot Koerkamp², Ignace H de Hingh¹⁴, Marjolijn Y V Homs¹⁵, Jeanin E van Hooft^{15,16}, Emile D Kerver¹⁷, Saskia A C Luelmo¹⁸, Karen J Neelis¹⁹, Joost Nuytens²⁰, Gabriel M R M Paardekooper²¹, Gijs A Patijn²², Maurice J C van der Sagen²³, Judith de Vos-Geelen²⁴, Johanna W Wilmink²⁵, Aeilko H Zwinderman²⁶, Cornelis J Punt²⁷, Geertjan van Tienhoven¹, Casper H J van Eijk²; Dutch Pancreatic Cancer Group

Versteijne E et al. J Clin Oncol. 2022

BORDERLINE – ROLLE DER NEOADJUVANTEN CHEMOTHERAPIE



■ BORDERLINE – ROLLE DER NEOADJUVANTEN CHEMOTHERAPIE



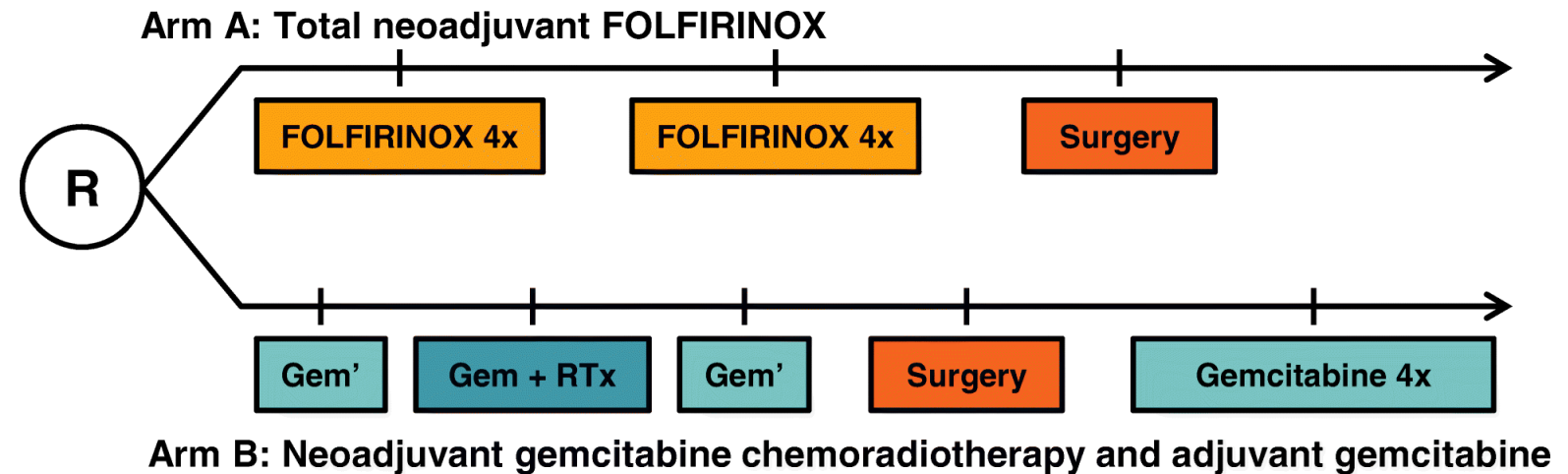
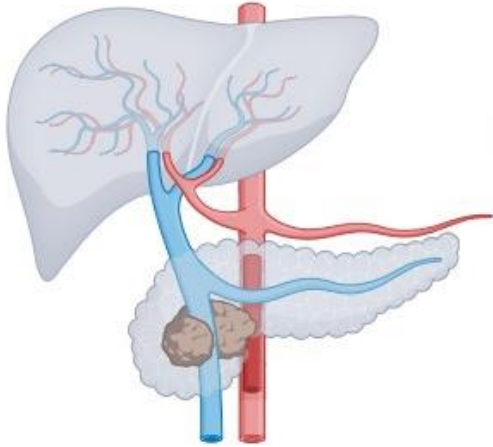
Immediate surgery compared with short-course neoadjuvant gemcitabine plus capecitabine, FOLFIRINOX, or chemoradiotherapy in patients with borderline resectable pancreatic cancer (ESPAC5): a four-arm, multicentre, randomised, phase 2 trial

Paula Ghaneh, Daniel Palmer, Silvia Cicconi, Richard Jackson, Christopher Michael Halloran, Charlotte Rowcliffe, Rajaram Sripadam, Sumathi Mahalingam, Zahir Swaminathan, Jonathan Winkley, Ahmed Al-Mukhtar, Evan Dickson, Janet Graham, Long Jia, Margaret S. Wain, Ian S. Tat, Anders Prochutsky, Paul Ross, Juan W Valle, Derek A O'Reilly, Bilal Al-Sarraf, Sarah Gayther, Hani Ahmed, Kate Connolly, Keen-Long Yin, David Cunningham, Thomas Armstrong, Caroline Archer, Keith Roberts, Yik Ting Ma, Christoph Springfeld, Christine Tjader, Thilo Hackert, Markus W Buehler, John P Neoptolemos, for the European Study Group for Pancreatic Cancer

Ghaneh P et al. Lancet Gastroenterol Hepatol. 2022



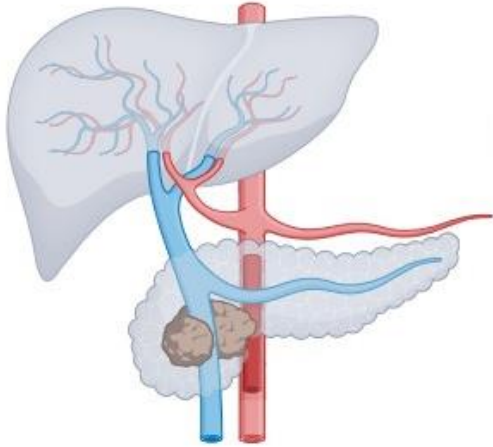
BORDERLINE – ROLLE DER NEOADJUVANTEN CHEMOTHERAPIE/ RADIOCHEMOTHERAPIE?



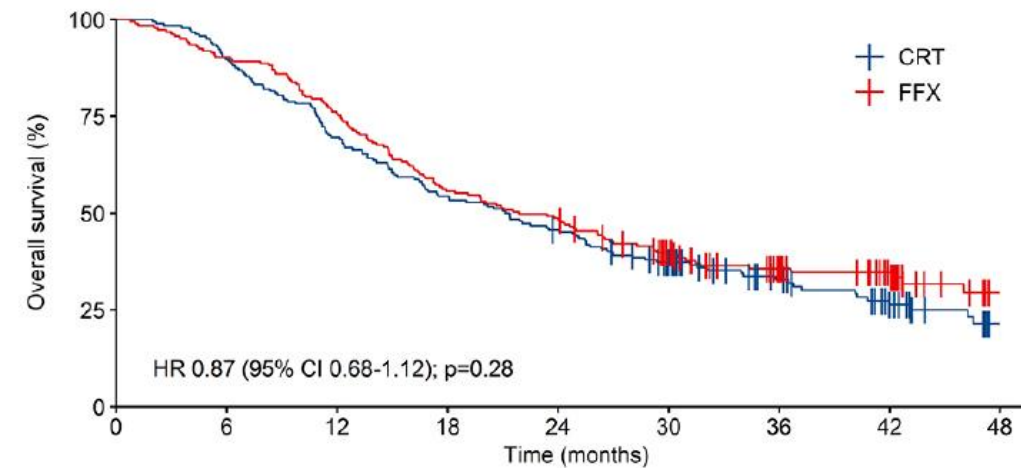
Janssen Q.P. et al. BMC Cancer. 2021



BORDERLINE – ROLLE DER NEOADJUVANTEN CHEMOTHERAPIE/ RADIOCHEMOTHERAPIE?



Overall Survival



Number at risk

CRT	184	165	128	100	83	61	39	24	7
FFX	185	167	140	103	90	64	43	28	9

Median OS

FFX	21.9 (17.7-27.0)
CRT	21.3 (16.8-25.5)

1-year OS

FFX	75.7%
CRT	69.6%

2-year OS

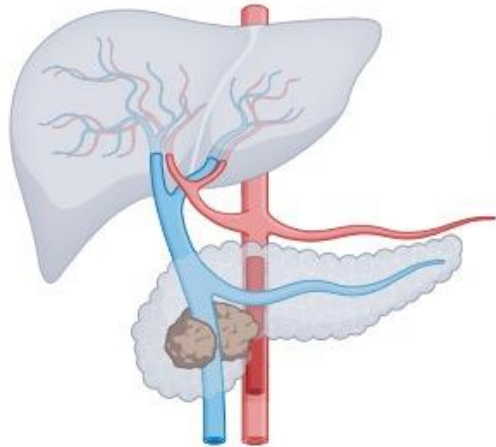
FFX	48.6%
CRT	45.7%

3-year OS

FFX	35.6%
CRT	32.8%

Overall survival was not improved with neoadjuvant FOLFIRINOX versus gemcitabine-based chemoradiotherapy in the PREOPANC-2 trial (ESMO Congress 2023, LBA83)

BORDERLINE – ROLLE DER NEOADJUVANTEN CHEMOTHERAPIE/ RADIOCHEMOTHERAPIE?



Pancreas Cancer

PANDAS/PRODIGE 44

2

Phase II



Randomized

Borderline resectable pancreatic cancer (BRPC)

• N= 110

4 Courses mFOLOFIRINOX
(2 months)

R 1:1

2 Courses mFOLFIRINOX

2 Courses mFOLFIRINOX

**CRT 50.4Gy
+Capecitabine**
830 mg/m² 5/7d (5w)

Arm A

Arm B

Surgery

6 Courses mFOLFIRINOX 3 months

LBA62 - Preoperative modified FOLFIRINOX (mFOLFIRINOX) with or without chemoradiation (CRT) in borderline resectable pancreatic cancer (BRPC): Results from the randomized phase II trial PANDAS/PRODIGE 44 (ESMO 2024)

Oncology.me

Primary endpoints

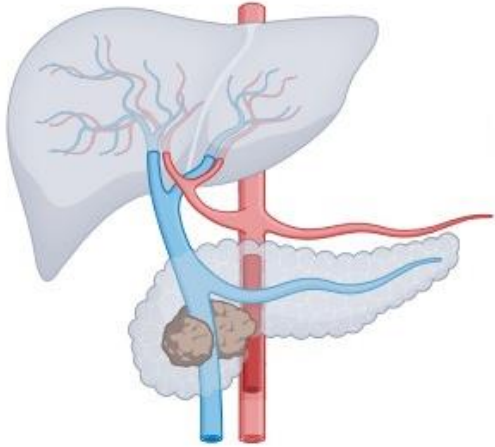
R0 resection rate in (ITT) population

Secondary endpoint

OS, LR-RFS, MFS, and Safety

This educational material is exclusively directed for healthcare professionals treating cancer patients

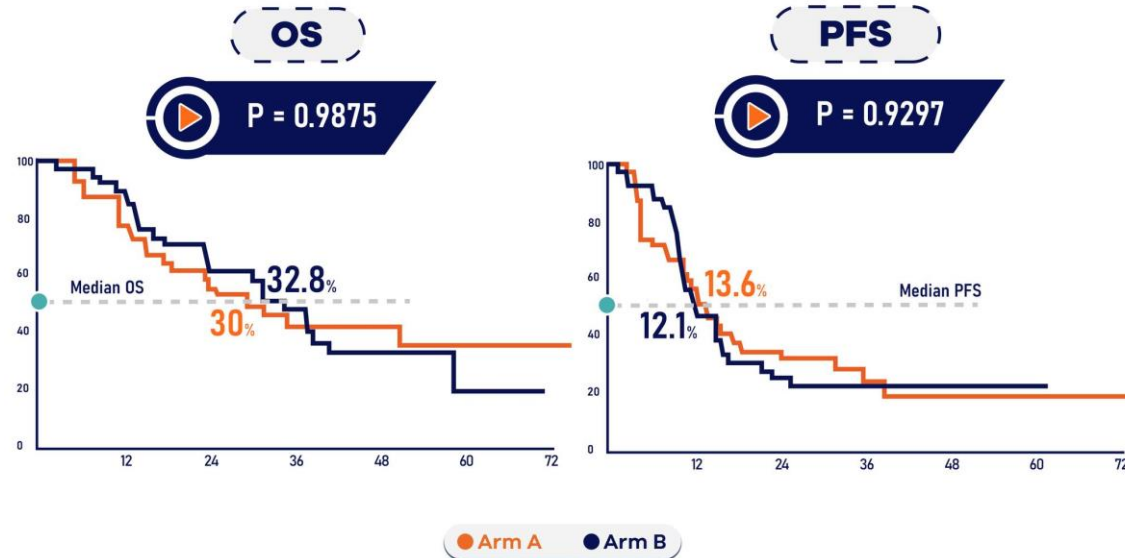
BORDERLINE – ROLLE DER NEOADJUVANTEN CHEMOTHERAPIE/ RADIOCHEMOTHERAPIE?



PANDAS/PRODIGE 44



NO improvement in OS or PFS

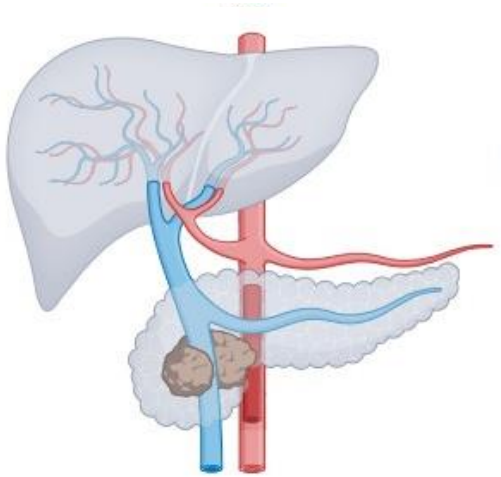


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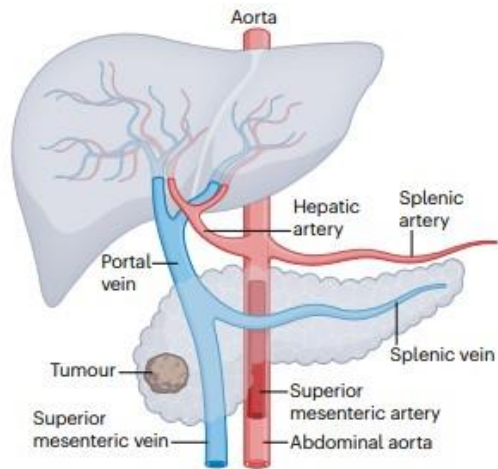
■ BORDERLINE - ZUSAMMENFASSUNG



Präoperative Therapie empfohlen

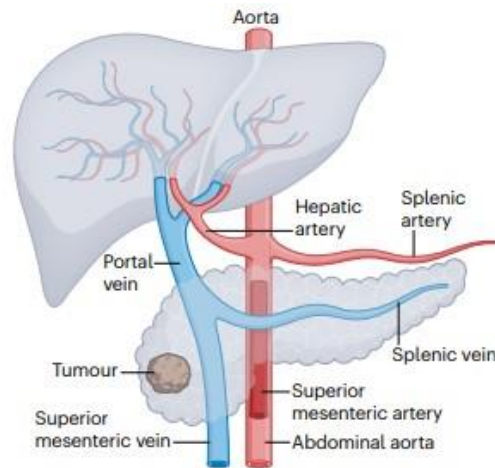
- Neoadjuvante Chemotherapie (bis zu 4 Monaten?) oder Chemostrahlentherapie

■ DAS PRIMÄR OPERABLE PANKREASKARZINOM



Rolle der Neoadjuvanz?

DAS PRIMÄR OPERABLE PANKREASKARZINOM – ROLLE DER NEOADJUVANZ?



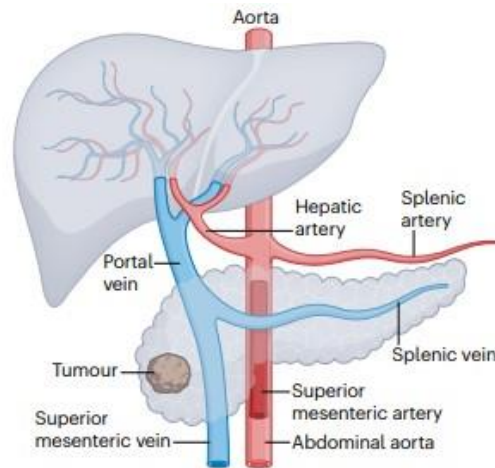
	Patient population	Groups	Number of cycles of neoadjuvant chemotherapy	Number of patients	Patients completing neoadjuvant chemotherapy by ITT	Median overall survival, months
SWOG1505 ⁶	Resectable	Neoadjuvant modified FOLFIRINOX vs neoadjuvant gemcitabine and abraxane	6 vs 3	55 vs 47	46 (84%) vs 40 (85%)	23.6 vs 23.2
Prep-02/JSAP-05 ⁷	Resectable and borderline resectable	Neoadjuvant gemcitabine plus S-1 vs upfront surgery	2 vs NA	182 vs 180	Not reported	36.7 vs 26.6
NEONAX ^{8*}	Resectable	Neoadjuvant gemcitabine and abraxane vs upfront surgery	2 vs NA	59 vs 59	53 (90%)	25.5 vs 16.7
PREOPANC-1 ⁹	Resectable and borderline resectable	Neoadjuvant gemcitabine and radiotherapy vs upfront surgery	3 vs NA	119 vs 127	81 (68%)	15.7% (20.5)† vs 14.3% (6.5)
PANACHE01 PRODIGE48 ¹⁰	Resectable	Neoadjuvant modified FOLFIRINOX vs neoadjuvant FOLFOX vs upfront surgery	4 vs 4 vs NA	70 vs 50 vs 26	62 (88%) vs 42 (84%)	30.6 vs 31.3 vs >36
PREOPANC-2 ¹¹	Resectable and borderline resectable	Neoadjuvant full-dose FOLFIRINOX vs neoadjuvant gemcitabine and radiotherapy	8 vs 3	185 vs 184	115 (62%) vs 149 (81%)	21.9 vs 21.3
NORPACT-1 ¹²	Resectable	Neoadjuvant full-dose FOLFIRINOX vs upfront surgery	4 vs NA	77 vs 63	36 (46%)	25.1 vs 38.5

FOLFIRINOX=fluorouracil, leucovorin, irinotecan, and oxaliplatin. FOLFOX=fluorouracil, leucovorin, and oxaliplatin. NA=not applicable. *Primary endpoint not met. †5-year overall survival.

Table: Select studies evaluating neoadjuvant treatment in resectable pancreatic ductal adenocarcinoma

Henault D et al. Lancet Gastroenterol Hepatol. 2024

DAS PRIMÄR OPERABLE PANKREASKARZINOM – ROLLE DER NEOADJUVANZ?



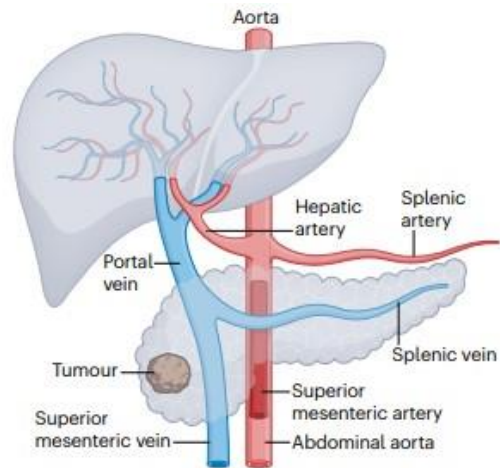
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Henault D et al. Lancet Gastroenterol Hepatol. 2024

DAS PRIMÄR OPERABLE PANKREASKARZINOM – ROLLE DER NEOADJUVANZ?

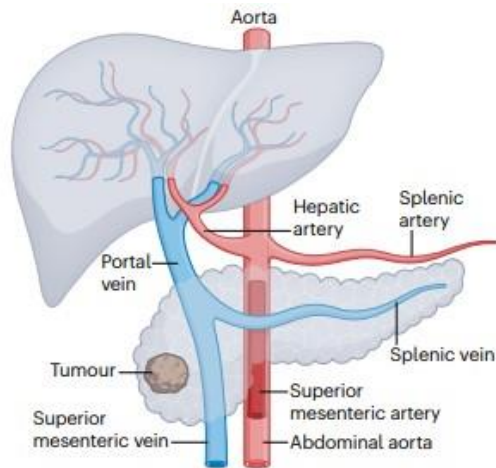


7.2 Neoadjuvante Therapien

7.12	Evidenzbasierte Empfehlung	geprüft 2021
Empfehlungsgrad B	Eine neoadjuvante Strahlenchemotherapie, Strahlentherapie oder Chemotherapie sollte Patienten mit einem resektabel eingeschätztem Pankreaskarzinom außerhalb von Studien nicht angeboten werden.	
Level of Evidence 1, 2, 4	[484] , [485] , [486] , [487] , [488] , [489] , [490] , [491] , [492] , [493] , [494] , [495] , [496] , [497]	
	Starker Konsens	

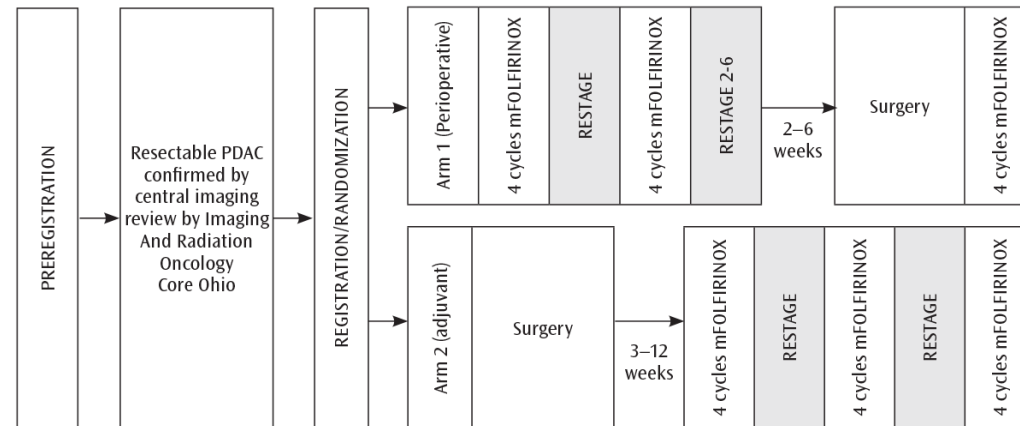
S3-Leitlinie Exokrines Pankreaskarzinom
Version 3.1 – September 2024

DAS PRIMÄR OPERABLE PANKREASKARZINOM – ROLLE DER NEOADJUVANZ?

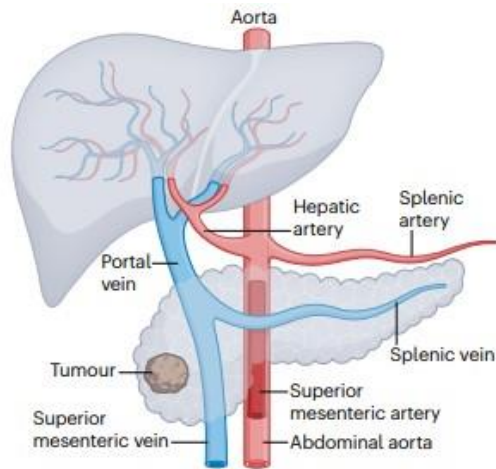


SWOG/ALLIANCE A021806

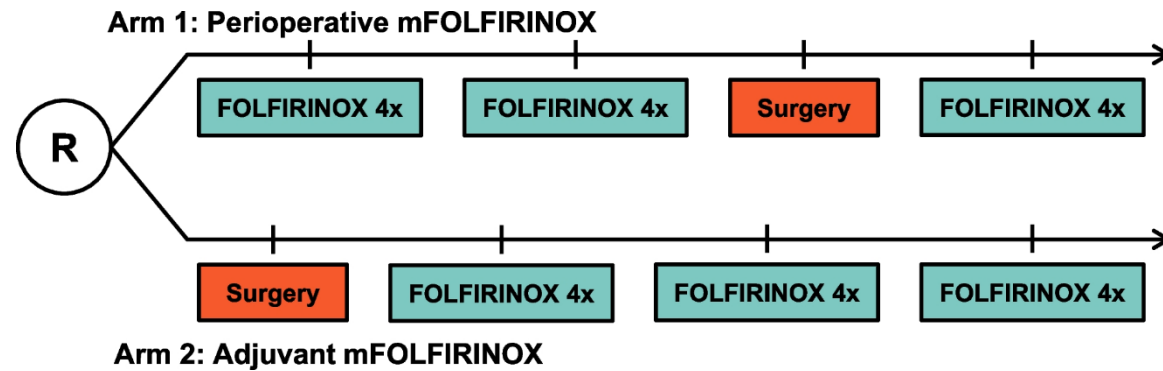
CTSU/A021806, "A Phase III Trial of Perioperative Versus Adjuvant
Chemotherapy for Resectable Pancreatic Cancer." Dr. Noel. Activated:
7/1/20.



DAS PRIMÄR OPERABLE PANKREASKARZINOM – ROLLE DER NEOADJUVANZ?

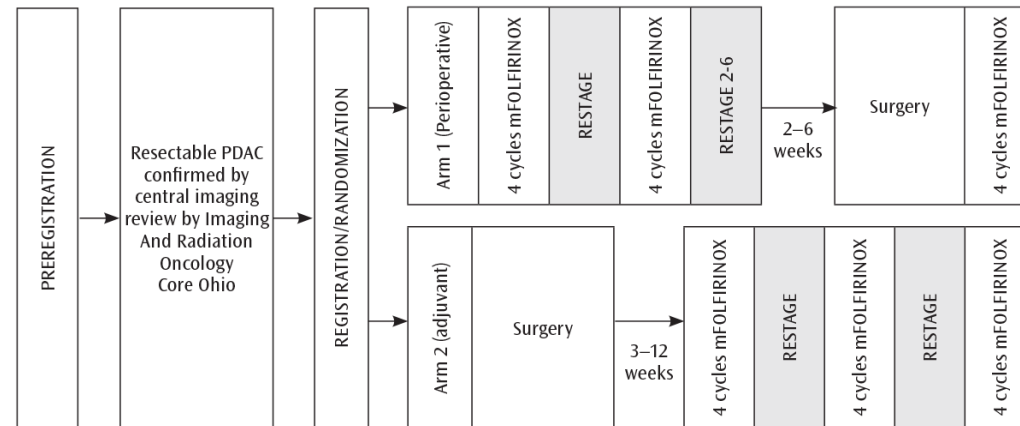


PREOPANC 3

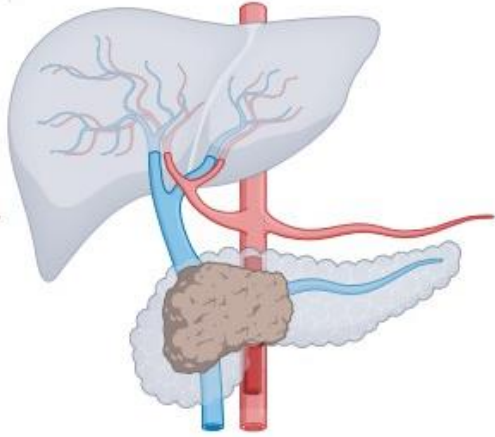


SWOG/ALLIANCE A021806

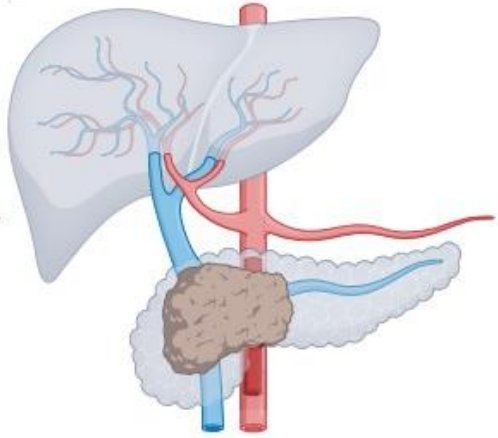
CTSU/A021806, "A Phase III Trial of Perioperative Versus Adjuvant
Chemotherapy for Resectable Pancreatic Cancer." Dr. Noel. Activated:
7/1/20.



■ LOKAL FORTGESCHRITTEN (LAPC) – PRIMÄR NICHT RESEKTABEL

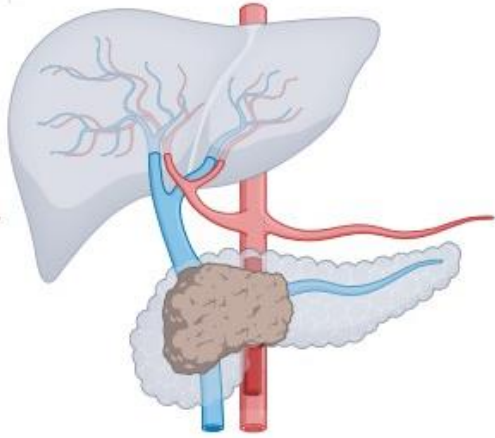


■ LOKAL FORTGESCHRITTEN (LAPC) – PRIMÄR NICHT RESEKTABEL



(palliative) Systemtherapie entsprechend des
Allgemeinzustandes

■ LOKAL FORTGESCHRITTEN (LAPC) – PRIMÄR NICHT RESEKTABEL

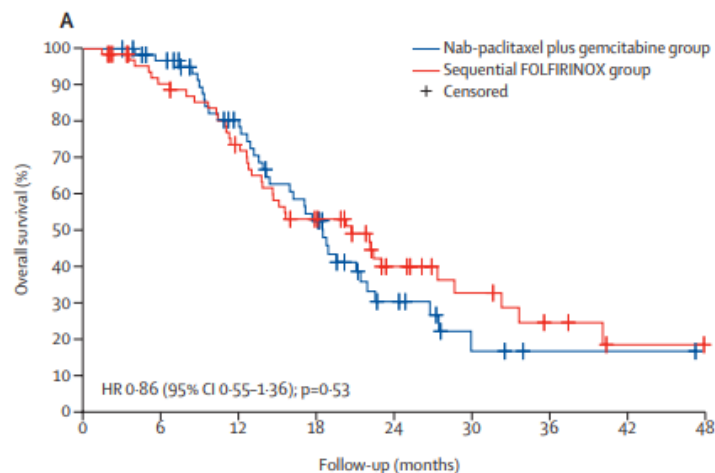
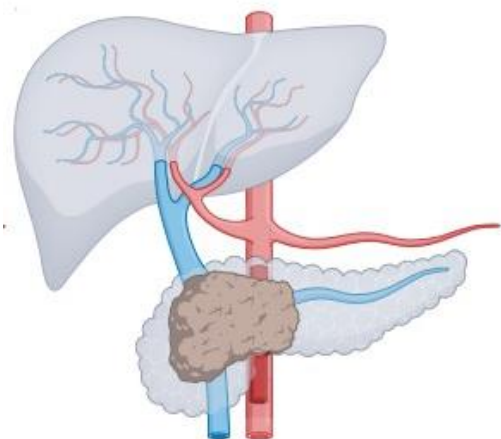


(palliative) Systemtherapie entsprechend des
Allgemeinzustandes

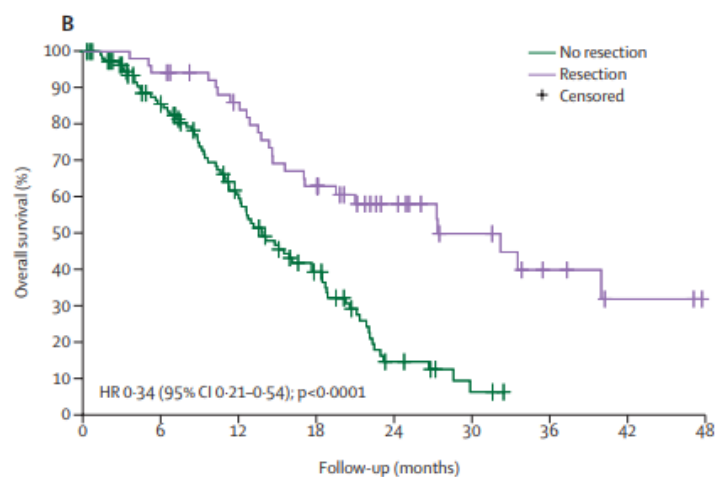


Sekundäre Resektabilität

LOKAL FORTGESCHRITTEN (LAPC) – NEOLAP – STUDIE



Number at risk (number censored)	0	6	12	18	24	30	36	42	48
Nab-paclitaxel plus gemcitabine group	64 (0)	58 (4)	41 (12)	26 (13)	10 (20)	3 (24)	1 (26)	1 (26)	0 (27)
Sequential FOLFIRINOX group	66 (0)	55 (5)	43 (7)	29 (9)	15 (17)	9 (21)	5 (23)	2 (25)	2 (25)

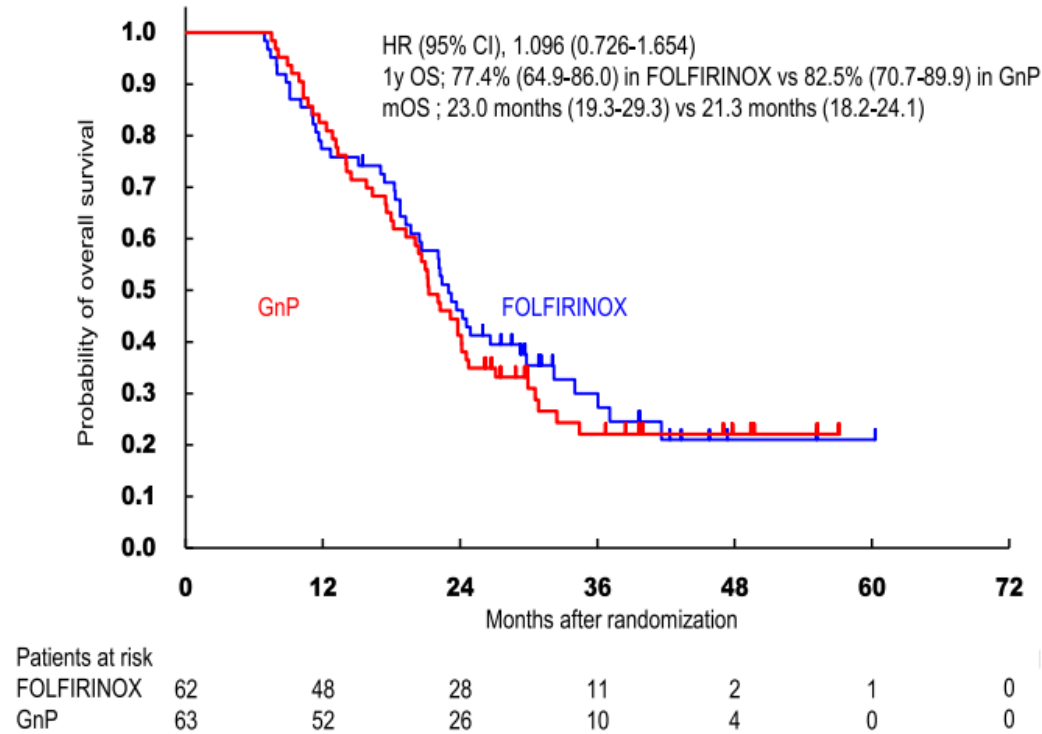
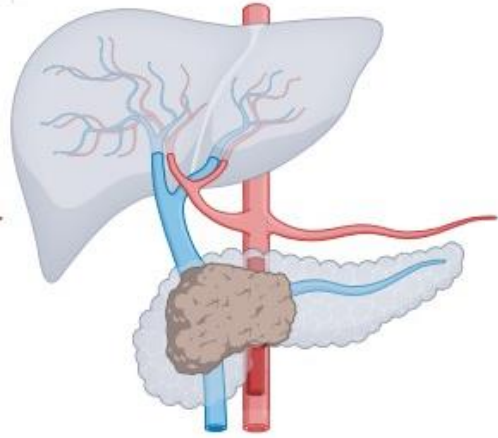


Number at risk (number censored)	0	6	12	18	24	30	36	42	48
No resection	113 (0)	85 (13)	53 (22)	29 (28)	8 (33)	2 (36)	0 (38)	--	--
Resection	52 (0)	49 (0)	41 (4)	30 (4)	18 (14)	11 (19)	6 (22)	3 (24)	2 (25)

Nab-paclitaxel plus gemcitabine versus nab-paclitaxel plus gemcitabine followed by FOLFIRINOX induction chemotherapy in locally advanced pancreatic cancer (NEOLAP-AIO-PAK-0113): a multicentre, randomised, phase 2 trial

Volker Kunzmann, Jens T Siveke, Hana Algül, Eray Goekkurt, Gabriele Siegler, Uwe Martens, Dirk Waldschmidt, Uwe Pelzer, Martin Fuchs, Frank Kullmann, Stefan Boeck, Thomas J Eitrich, Swantje Held, Ralph Keller, Ingo Klein, Christoph-Thomas Germer, Hubert Stein, Helmut Friess, Marcus Bahra, Ralf Jakobs, Ingo Hartlapp, Volker Heinemann, on behalf of the German Pancreatic Cancer Working Group (AIO-PAK) and NEOLAP investigators

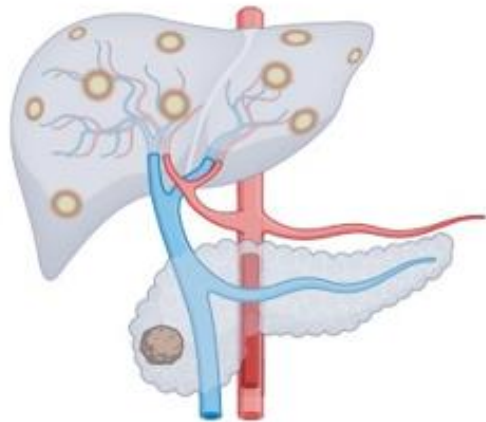
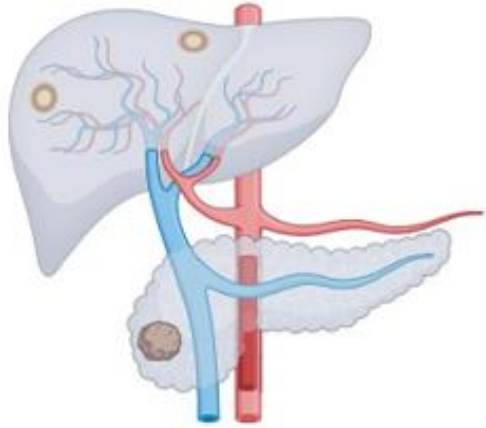
LOKAL FORTGESCHRITTEN (LAPC) – JCOG1407



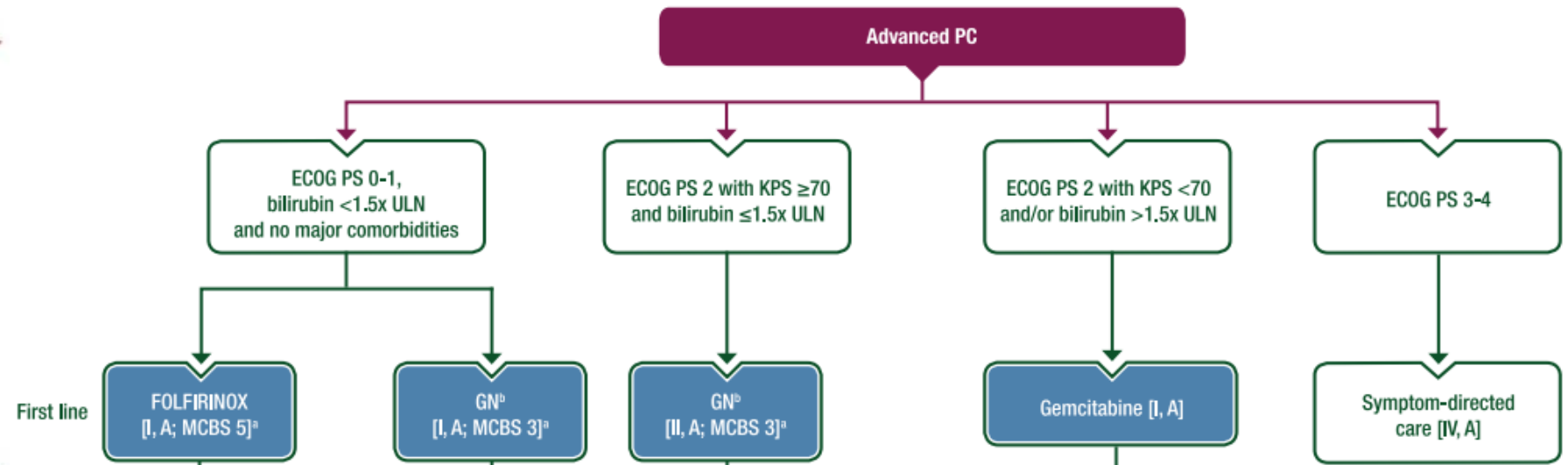
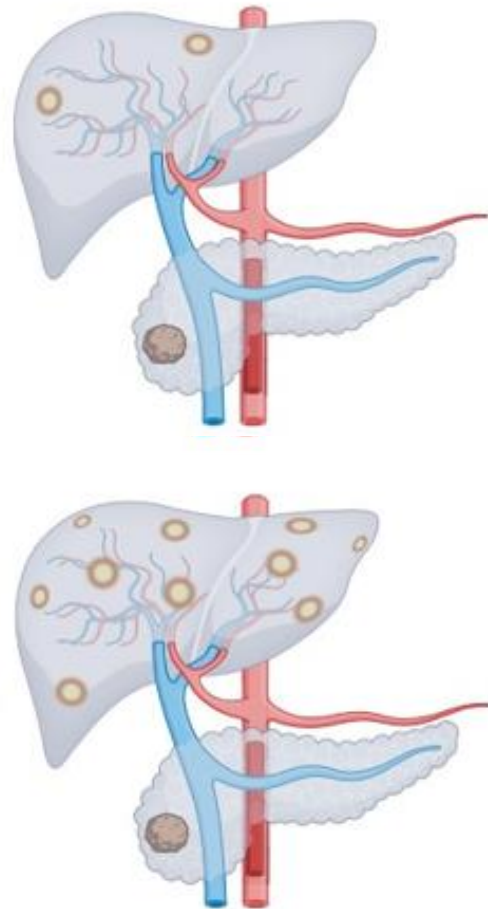
A randomised phase II study of modified FOLFIRINOX versus gemcitabine plus nab-paclitaxel for locally advanced pancreatic cancer (JCOG1407)[☆]

Masato Ozaka^{a,*}, Kohei Nakachi^b, Satoshi Kobayashi^c, Akihiro Ohba^d, Hiroshi Imaoka^e, Takeshi Terashima^f, Hiroshi Ishii^g, Junki Mizusawa^h, Hiroshi Katayama^h, Tomoko Kataoka^h, Takuji Okusaka^d, Masafumi Ikeda^e, Naoki Sasahira^a, Haruo Miwaⁱ, Eishiro Mizukoshi^f, Naohiro Okano^j, Nobumasa Mizuno^k, Tomohisa Yamamoto^l, Yoshito Komatsu^m, Akiko Todakaⁿ, Ken Kamata^o, Masayuki Furukawa^p, Nao Fujimori^q, Akio Katanuma^r, Yukiko Takayama^s, Hidetaka Tsumura^t, Haruhiko Fukuda^h, Makoto Ueno^c, Junji Furuse^{c,j}, Hepatobiliary and Pancreatic Oncology Group of Japan Clinical Oncology Group (JCOG)

■ FORTGESCHRITTES/ METASTASIERTES PANKREASKARZINOM

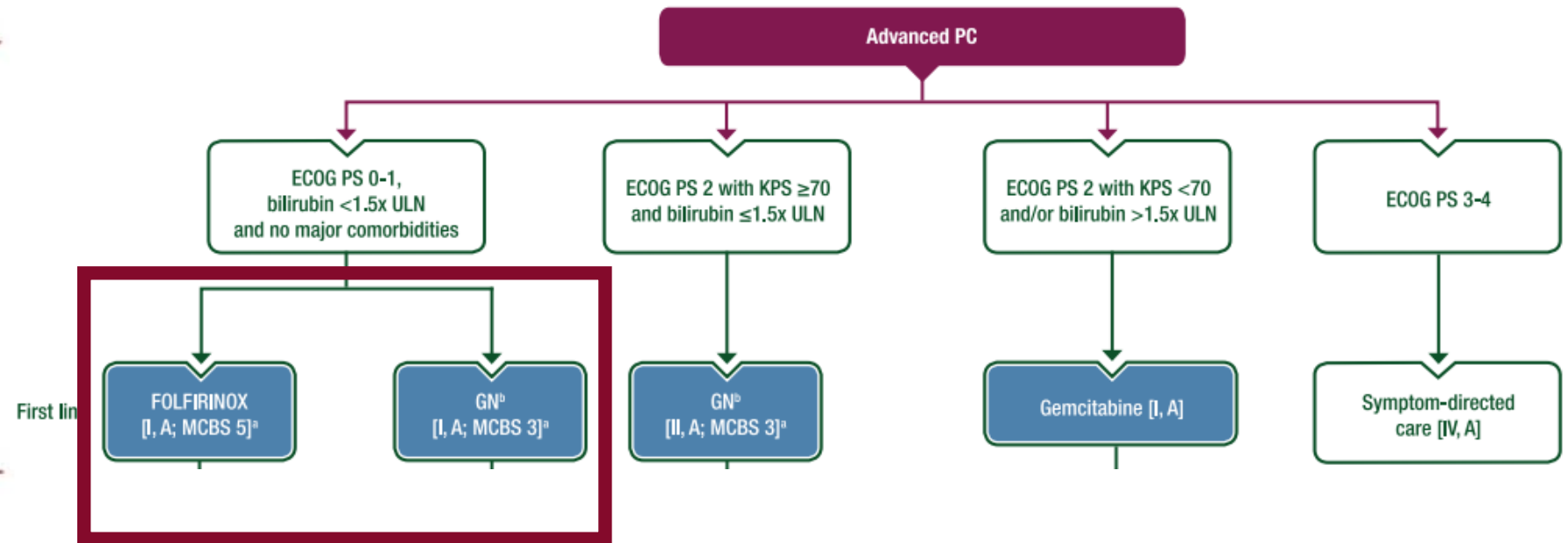
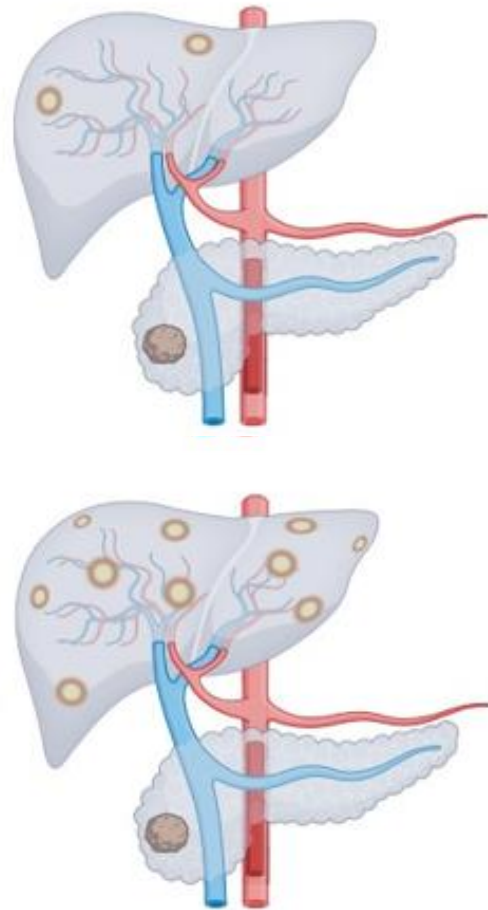


■ FORTGESCHRITTES/ METASTASIERTES PANKREASKARZINOM



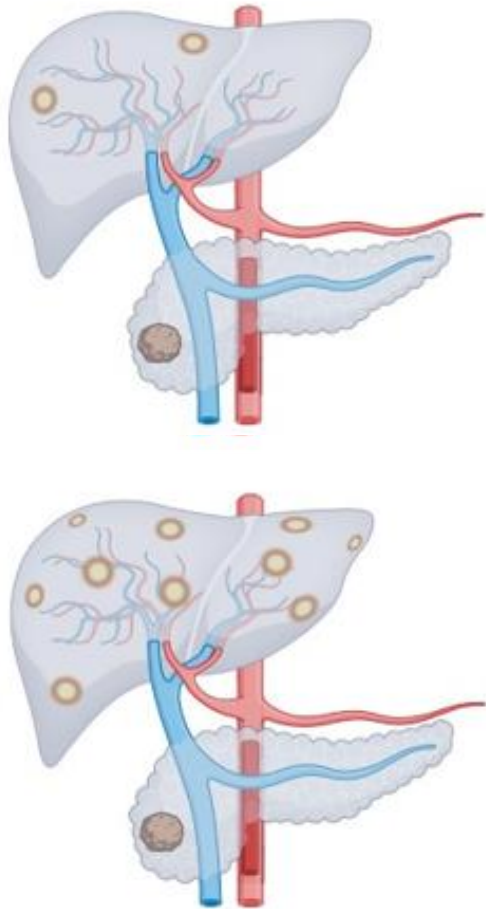
ESMO Guideline 2023

■ FORTGESCHRITTES/ METASTASIERTES PANKREASKARZINOM

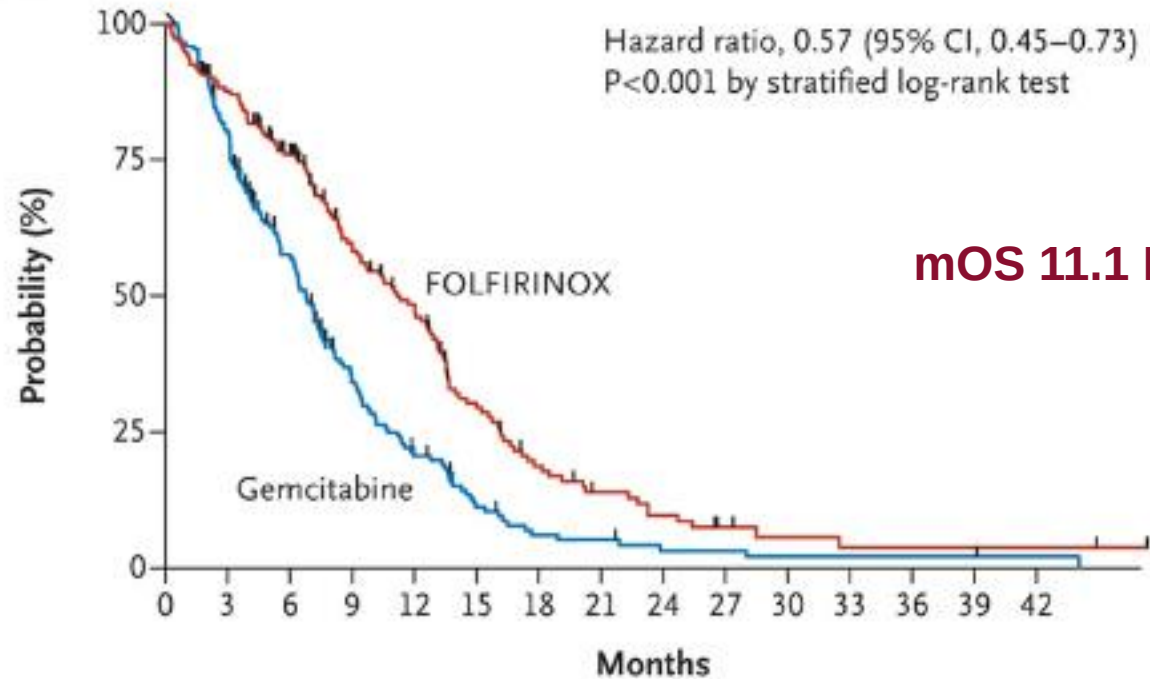




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A Overall Survival



mOS 11.1 Monate

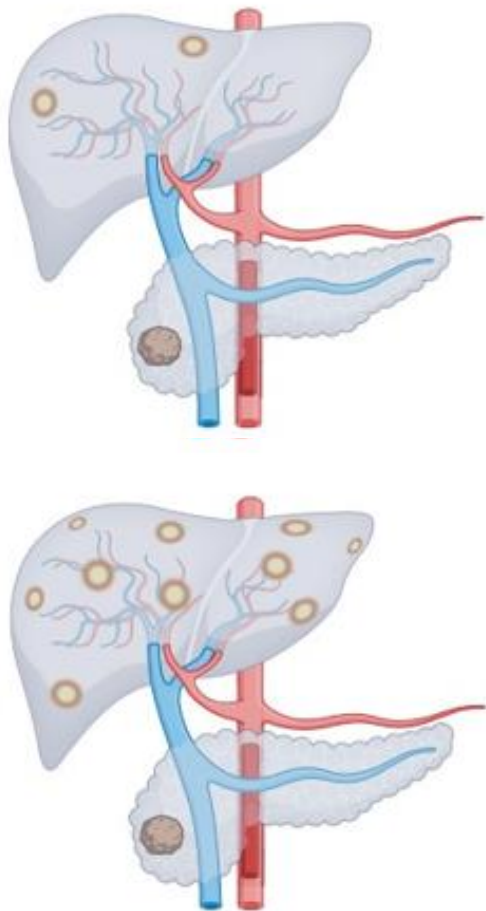
No. at Risk

Gemcitabine	171	134	89	48	28	14	7	6	3	3	2	2	2	2	1
FOLFIRINOX	171	146	116	81	62	34	20	13	9	5	3	2	2	2	2

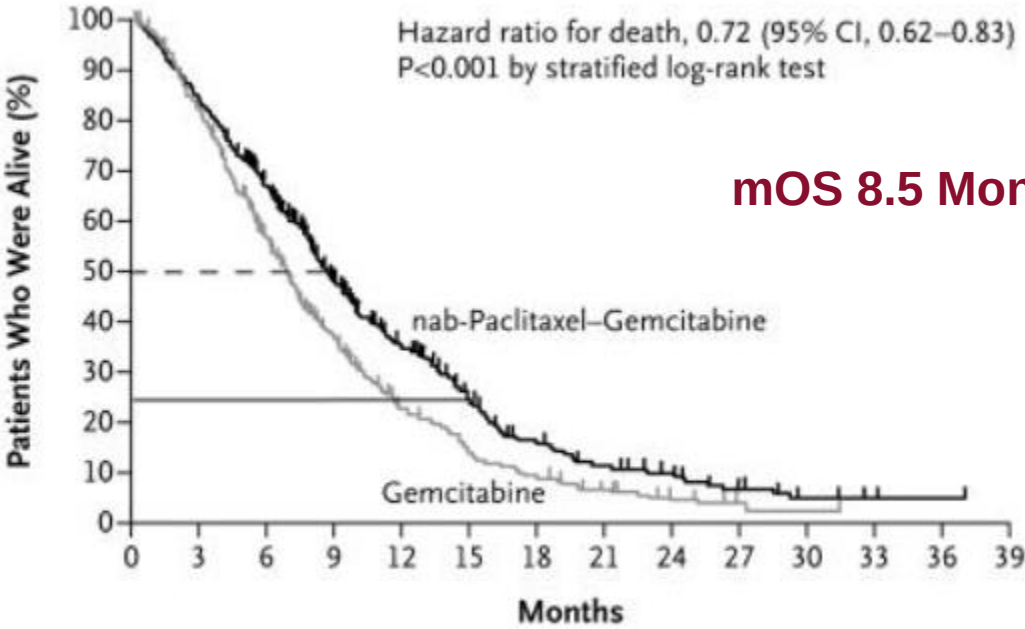
Conroy T et al. N Engl J Med. 2011



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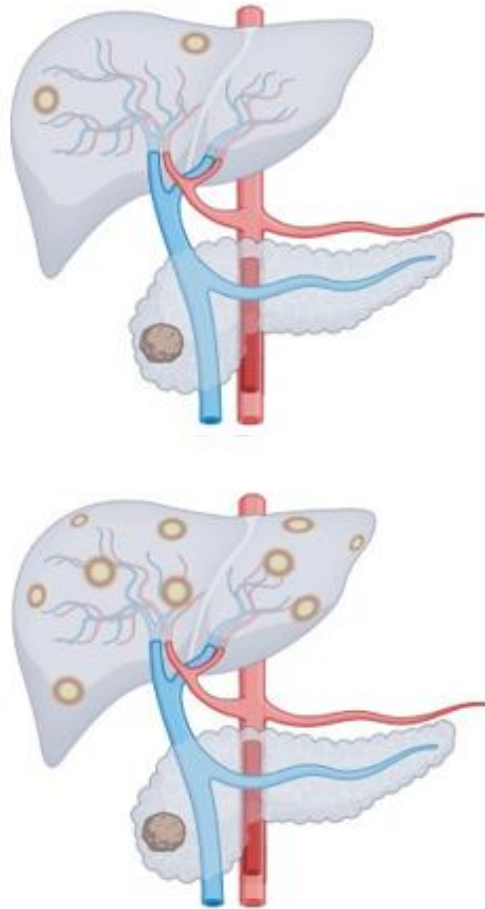
Overall Survival



No. at Risk														
nab-Paclitaxel–Gemcitabine	431	357	269	169	108	67	40	27	16	9	4	1	1	0
Gemcitabine	430	340	220	124	69	40	26	15	7	3	1	0	0	0

Von Hoff D et al. N Engl J Med. 2013

FORTGESCHRITTES/ METASTASIIERTES PANKREASKARZINOM



NAPOLI 3: Study design

N = 770
Key inclusion criteria

- Confirmed PDAC not previously treated in the metastatic setting
- Metastatic disease diagnosed ≤ 6 weeks prior to screening
- ≥ 1 metastatic lesions measurable by CT/MRI according to RECIST v1.1
- ECOG PS of 0 or 1

R1:1

Stratification

- ECOG PS 0/1
- Region
- Liver metastases

NALIRIFOX

Liposomal irinotecan 50 mg/m²
+ **5-FU** 2400 mg/m²
+ **LV** 400 mg/m²
+ **oxaliplatin** 60 mg/m²
Days 1 and 15 of a 28-day cycle

Gem+NabP

Gem 1000 mg/m²
+ **NabP** 125 mg/m²
Days 1, 8 and 15 of a 28-day cycle

Tumor assessment every 8 weeks per RECIST v1.1^a

Treatment until disease progression, unacceptable toxicity or study withdrawal^b

Follow-up every 8 weeks until death or study end^c

^aTumor assessments (RECIST v1.1) were performed at baseline and every 8 weeks until radiologically progressive disease or until the start of another anti-cancer treatment, whichever came first. ^bDose delays were permitted; if oxaliplatin was not well tolerated, patients in arm 1 could continue to receive liposomal irinotecan + 5-FU/LV. ^cThe study will be completed once all patients have discontinued the study treatment and at least 543 OS events have occurred in randomized patients. 5-FU, 5-fluorouracil; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; Gem, gemcitabine; LV, leucovorin; MRI, magnetic resonance imaging; NabP, nab-paclitaxel; OS, overall survival; PDAC, pancreatic ductal adenocarcinoma; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors.

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Cancers Symposium

#GI23

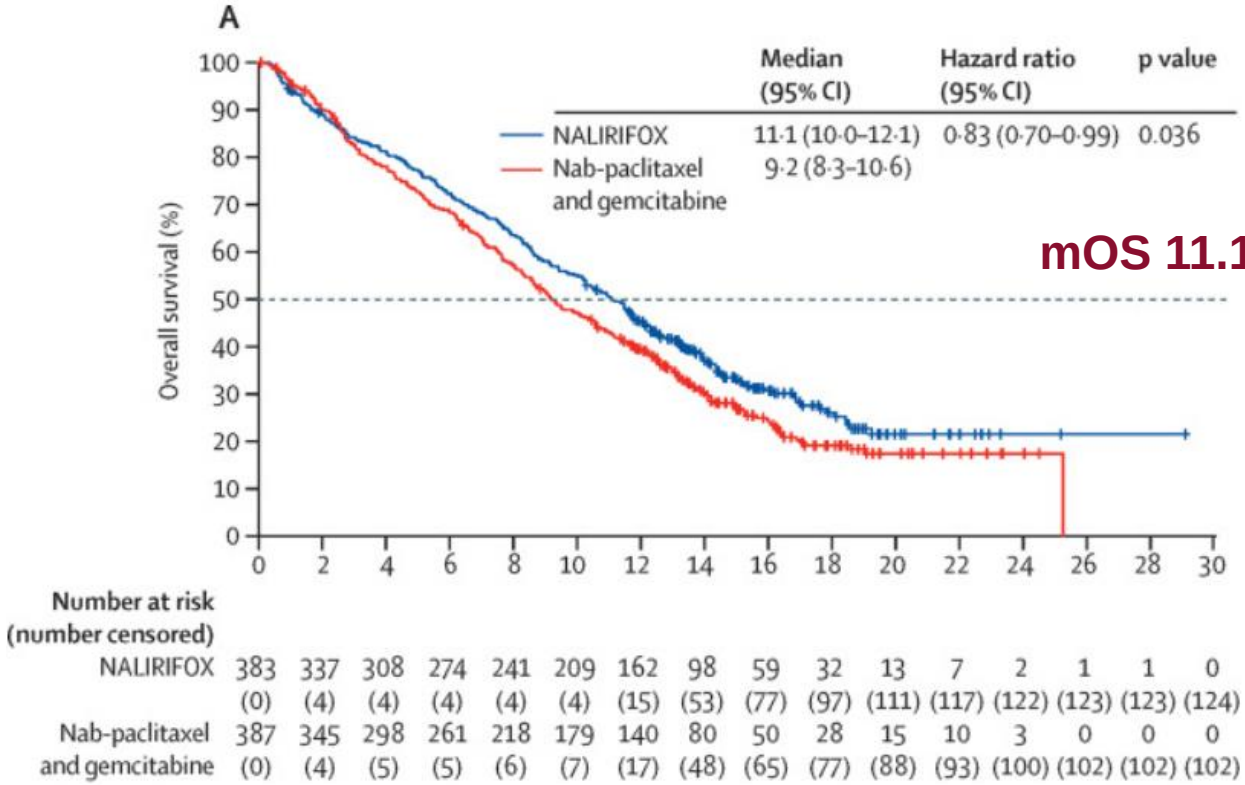
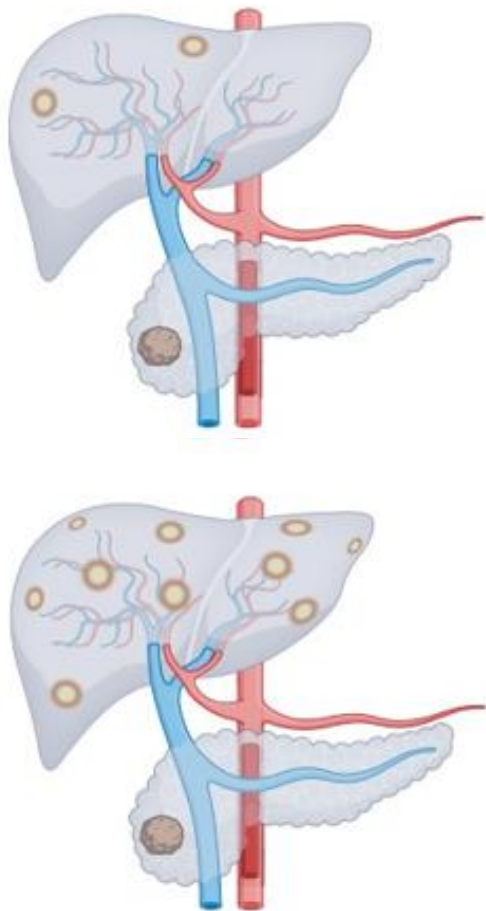
PRESENTED BY: Professor Zev A Wainberg

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CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

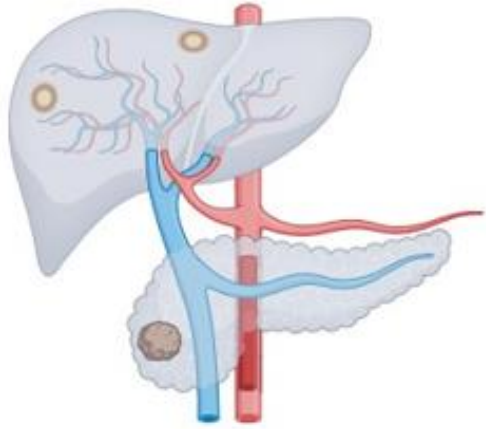


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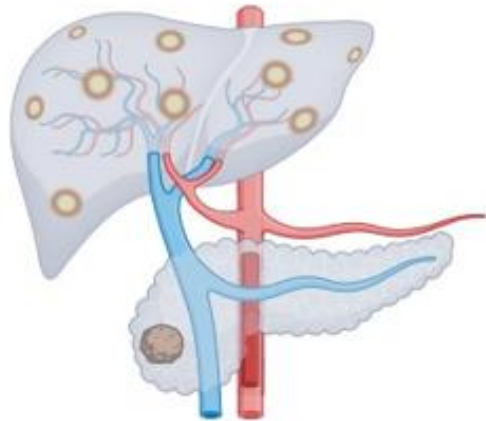
Wainberg ZA et al. Lancet. 2023

FORTGESCHRITTES/ METASTASIERTES PANKREASKARZINOM



NALIRIFOX versus nab-paclitaxel and gemcitabine in treatment-naïve patients with metastatic pancreatic ductal adenocarcinoma (NAPOLI 3): a randomised, open-label, phase 3 trial

Zev A Wainberg, Davide Melisi, Teresa Macarulla, Roberto Pazo Cid, Sreenivasa R Chandana, Christelle De La Fouchardière, Andrew Dean, Igor Kiss, Woo Jin Lee, Thorsten O Goetze, Eric Van Cutsem, A Scott Paulson, Tanios Bekaii-Saab, Shubham Pant, Richard A Hubner, Zhimin Xiao, Huanyu Chen, Fawzi Benzaghrou, Eileen M O'Reilly

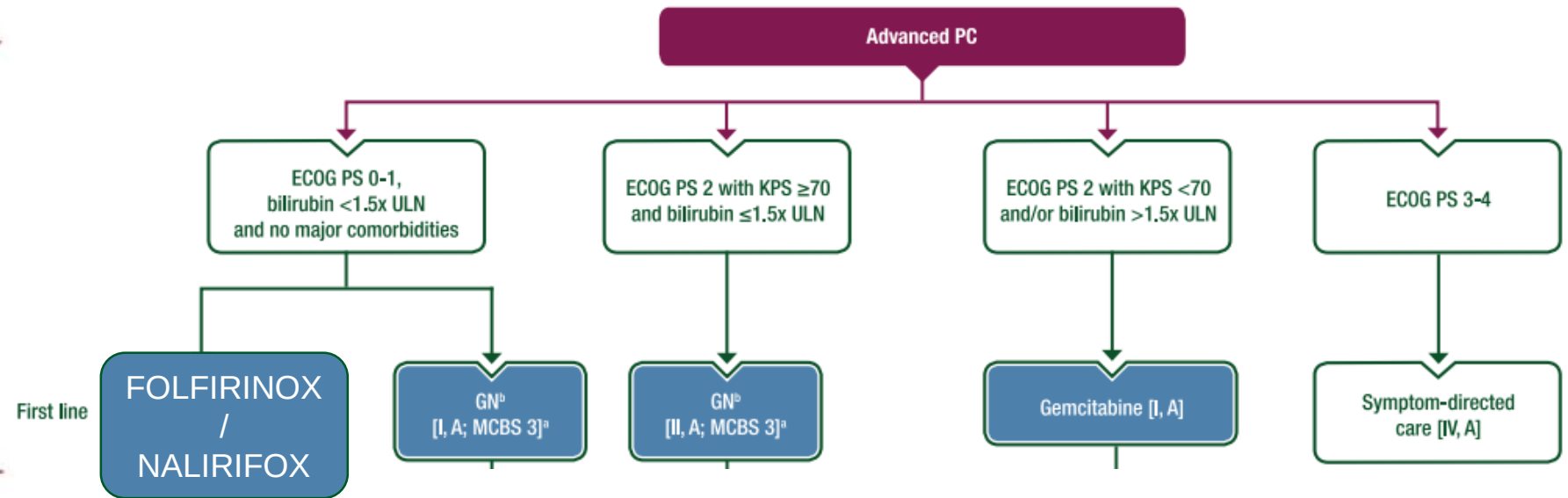
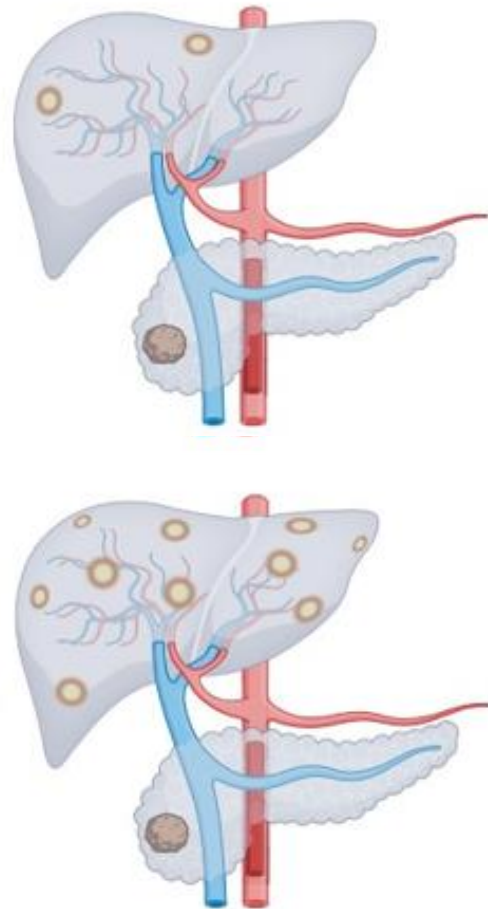


- Zulassung Ende April 2024 -> weitere Therapieoption in der Erstlinie
- Überlegenheit zu Gemcitabin/nab-Paclitaxel

Offene Fragen:

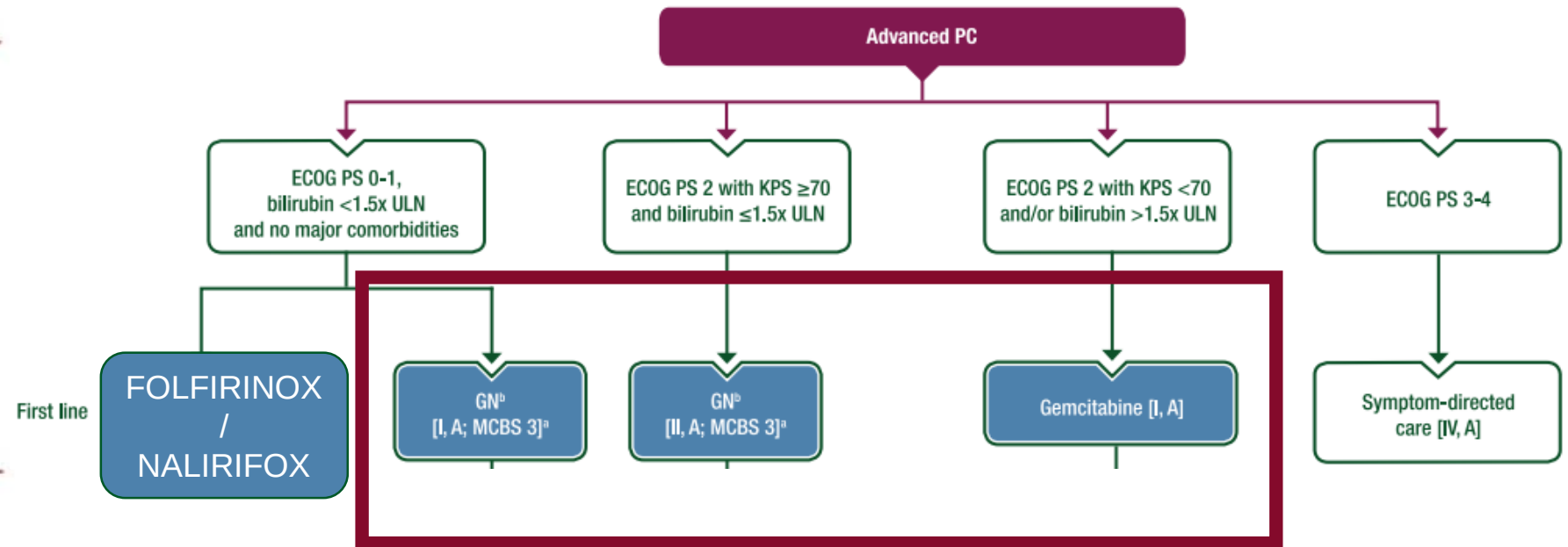
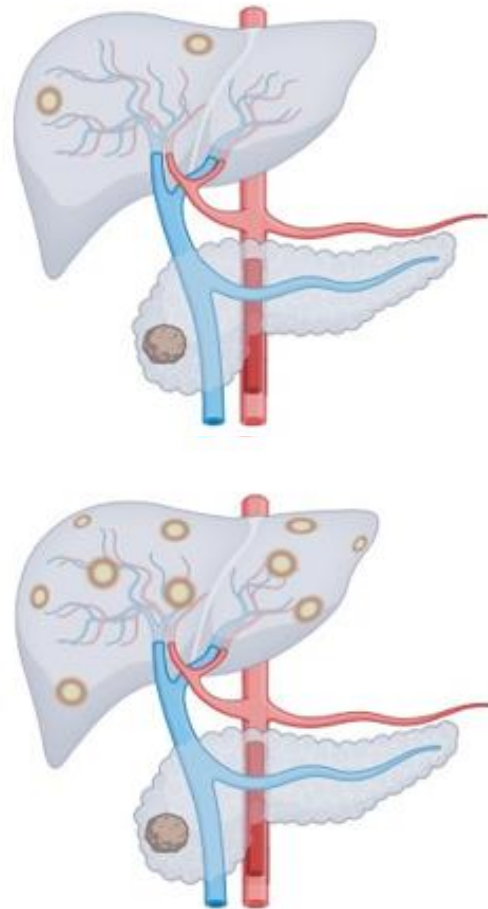
- Gleichwertigkeit zu FOLFIRINOX?
- Kosten gerechtfertigt?

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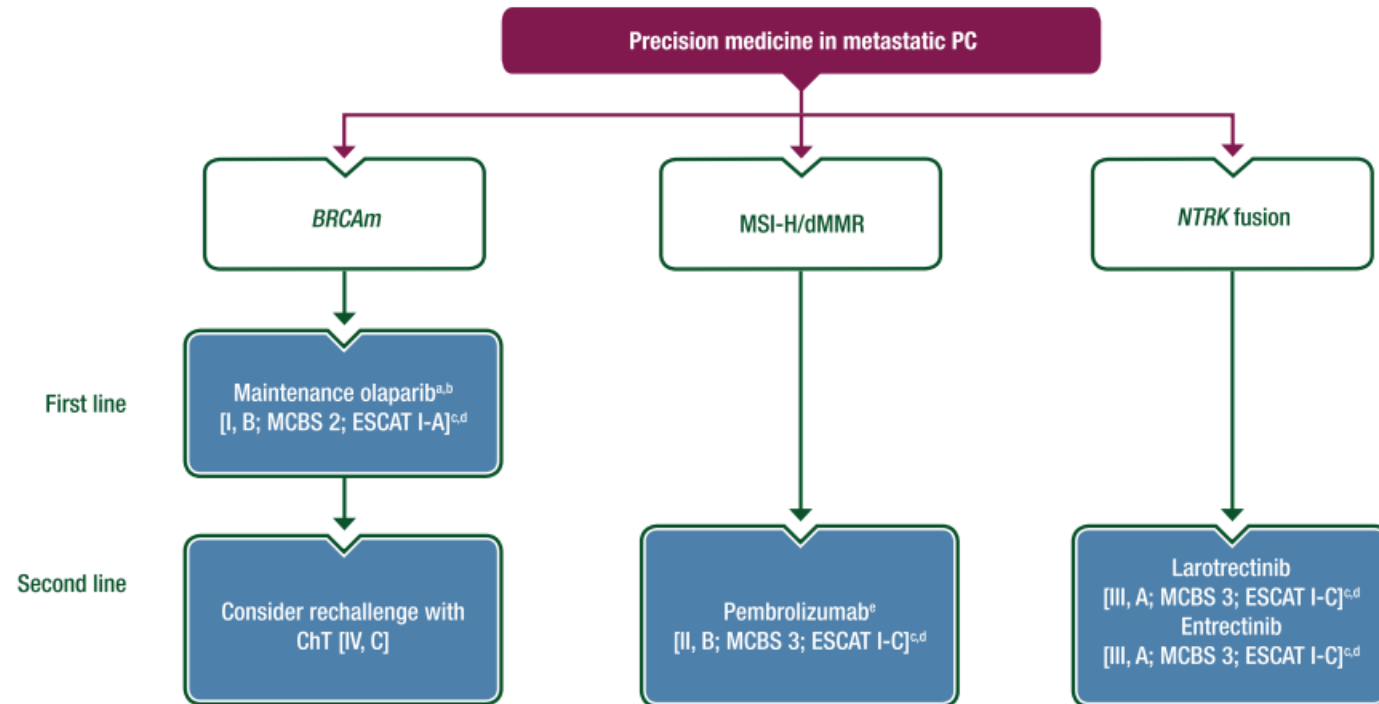
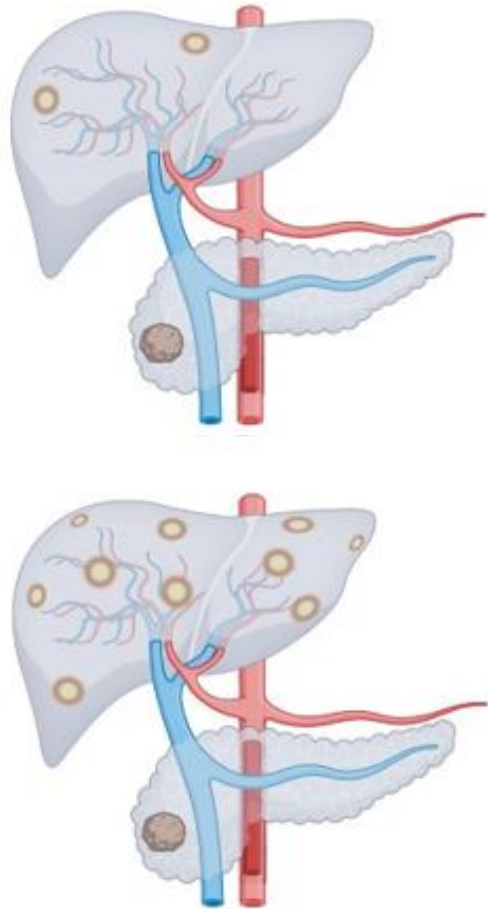
ESMO Guideline 2023

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ESMO Guideline 2023

Five-year survival for pancreatic cancer increased to 13%

MORE HOPE THAN EVER BEFORE FOR PANCREATIC CANCER PATIENTS

American Cancer Society, Cancer Facts and Figures, 2024

PANCREATIC
CANCER
ACTION
NETWORK



**VIELEN DANK FÜR IHRE
AUFMERKSAMKEIT**