Bundesweite Onkologische Qualitätskonferenz

ADT Arbeitsgemeinschaft Deutscher Tumorzentren

Versorgungssituation bei Pankreas- und periampullären Karzinomen

Louisa Bolm Ulrich Wellner UKSH Campus Lübeck

Next generation clinical evidence – klinische Evidenz aus versorgungsnahen Daten der Krebsregister

10. Bundesweite Onkologische Qualitätskonferenz 2024

Periampulläre Karzinome : Datenbasis

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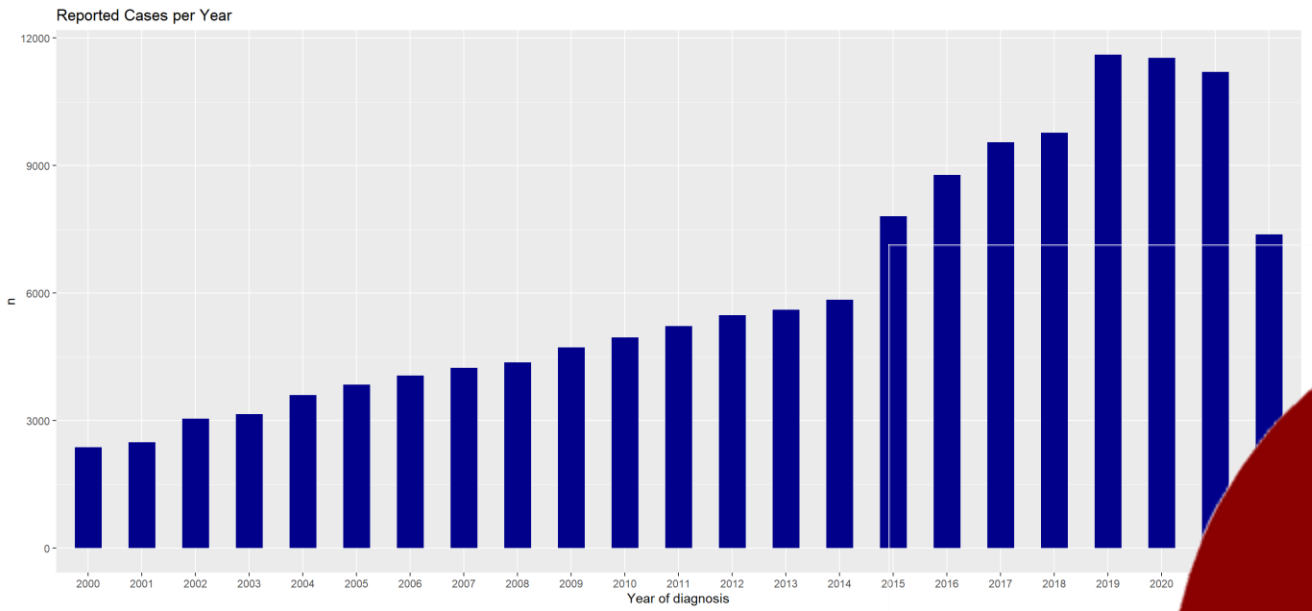

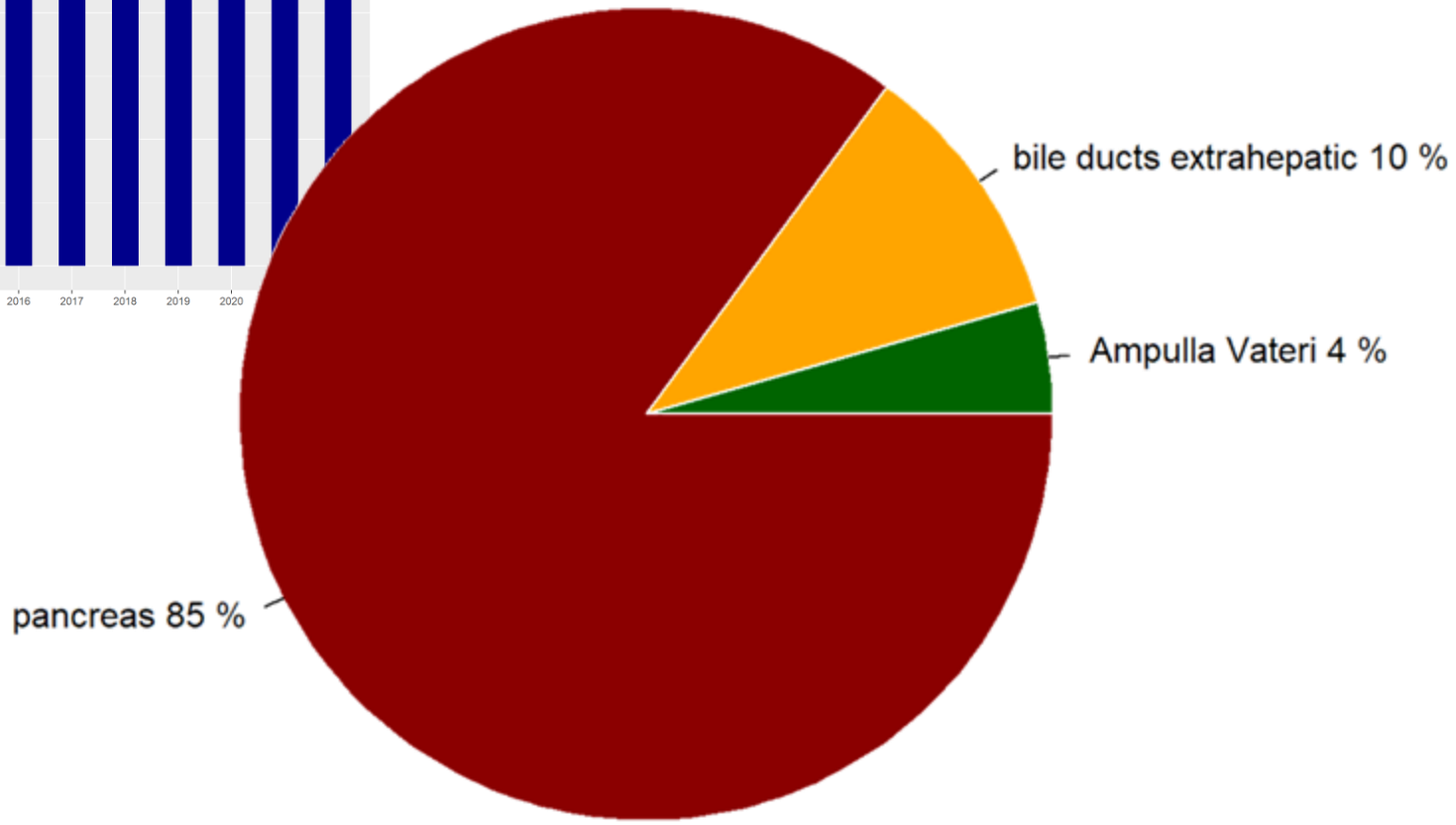

Wellner, Bolm et al, unpublished

Pankreaskarzinom : Therapie

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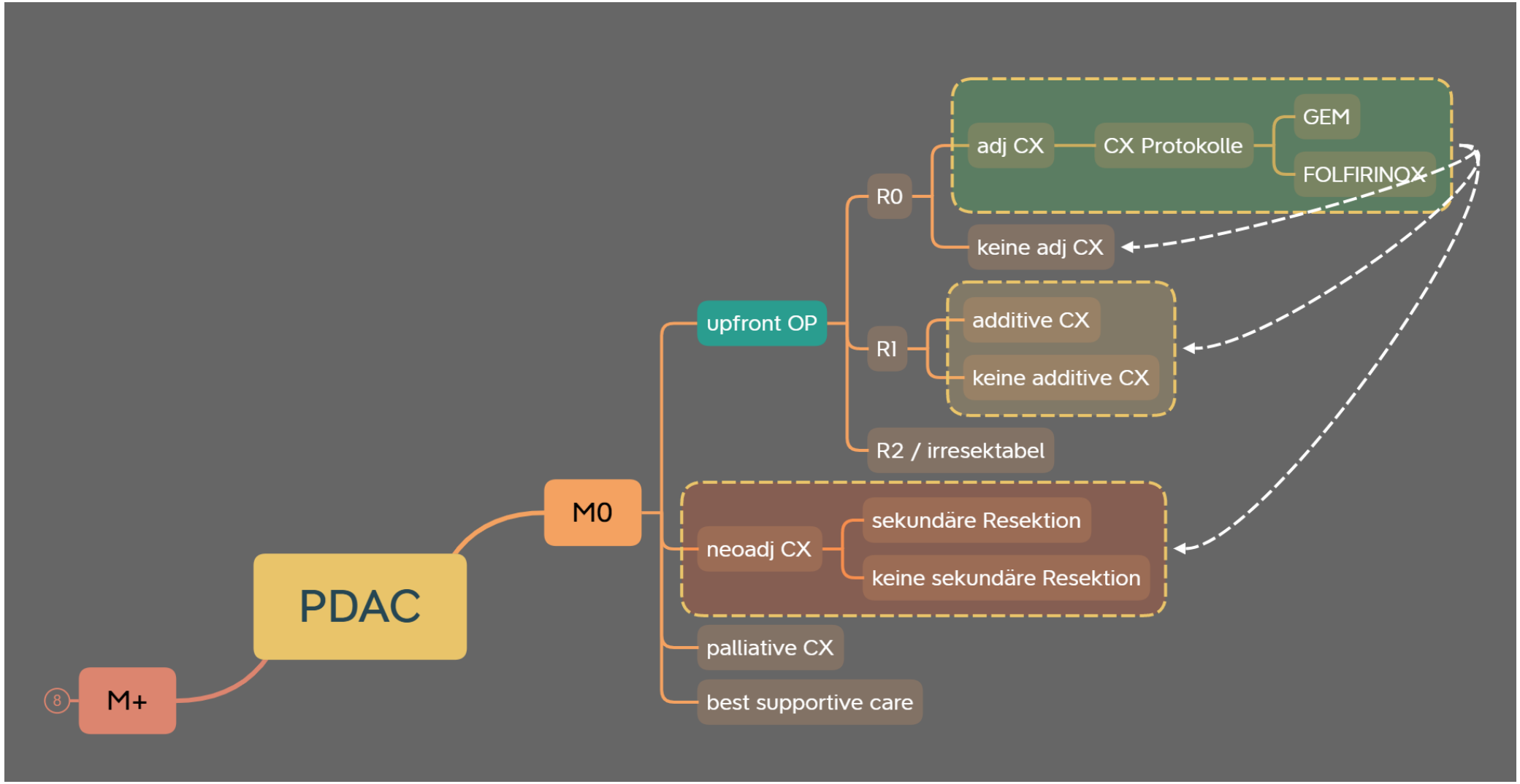
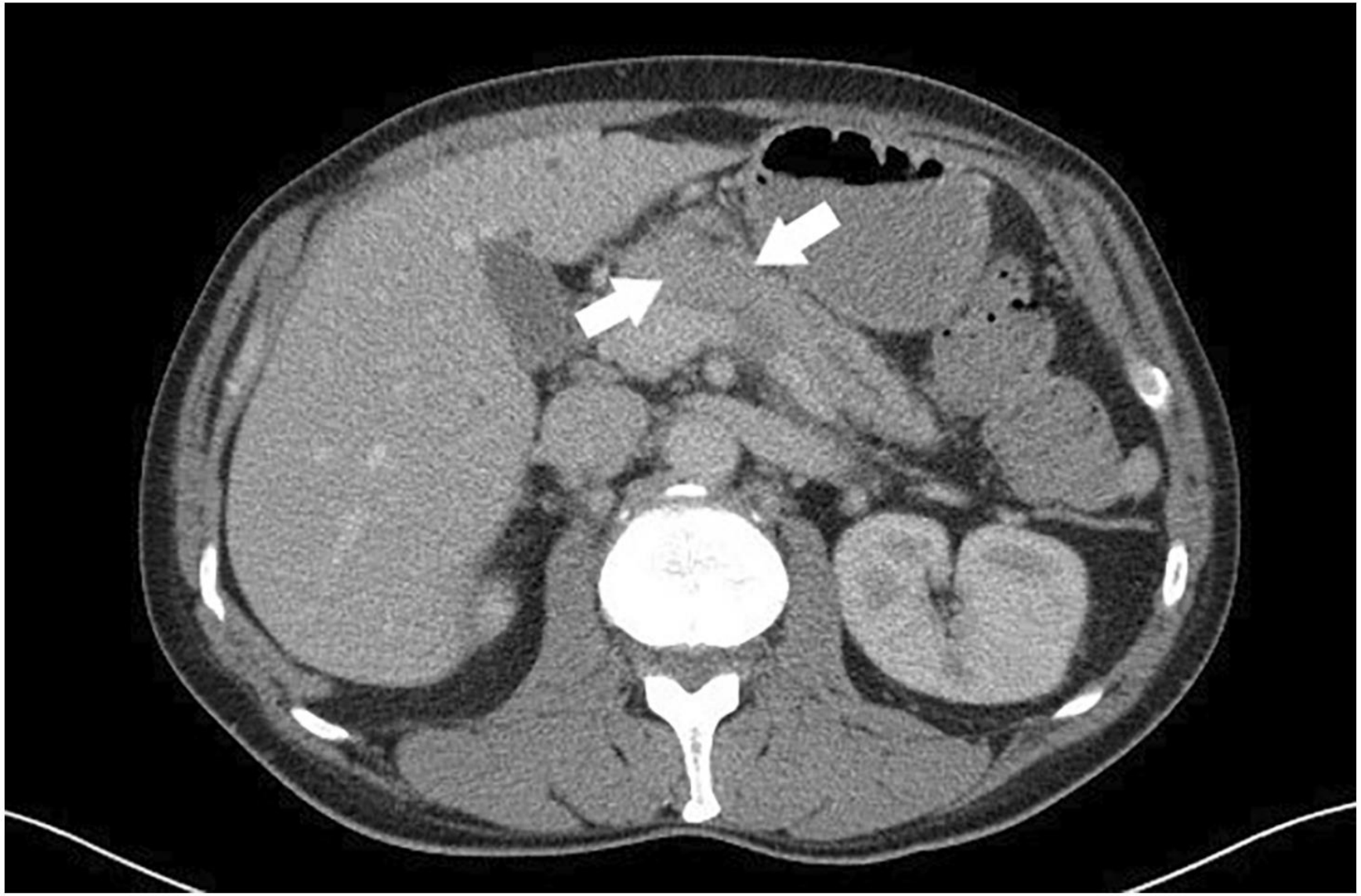


Wellner, Bolm et al, unpublished



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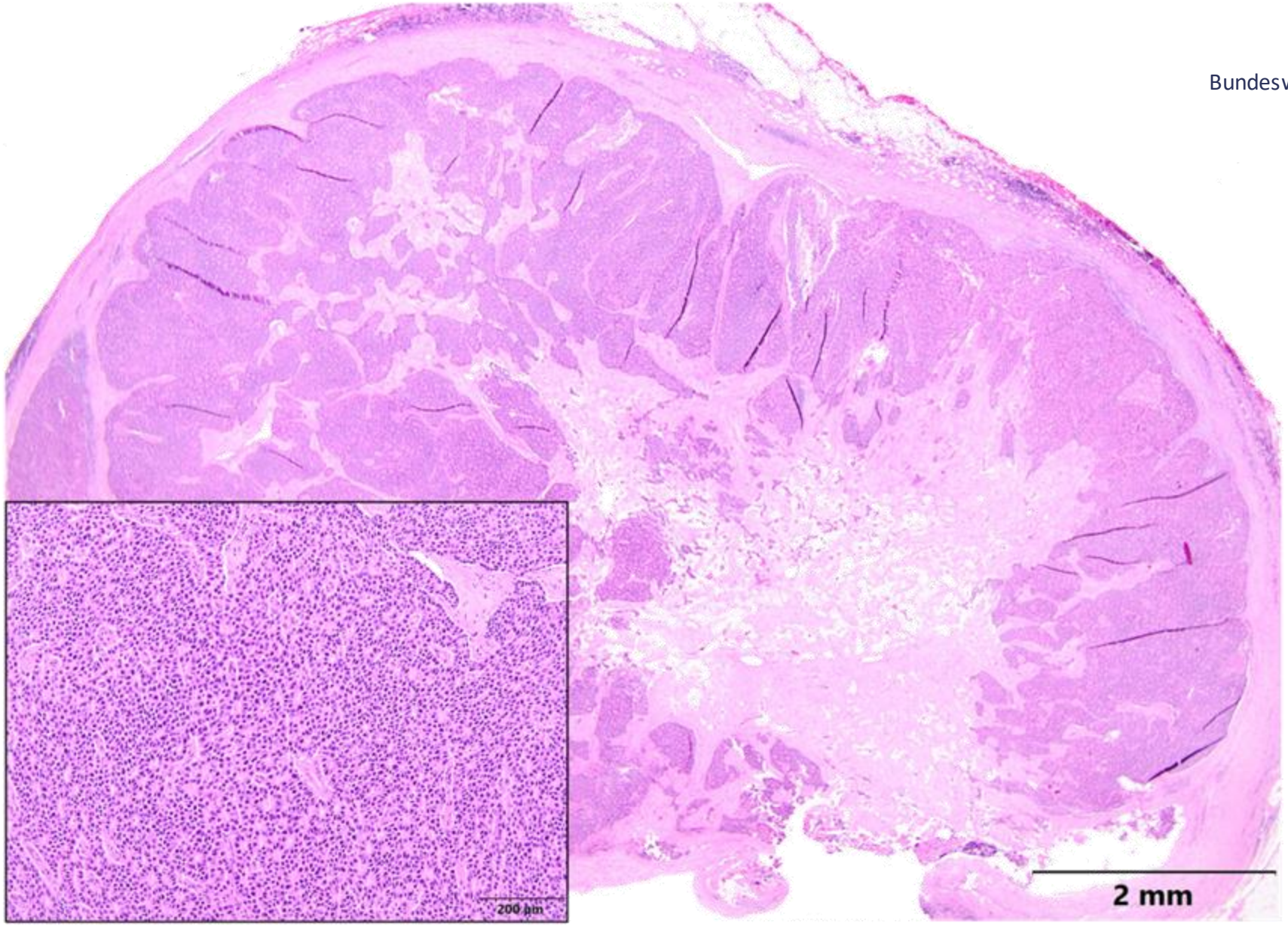
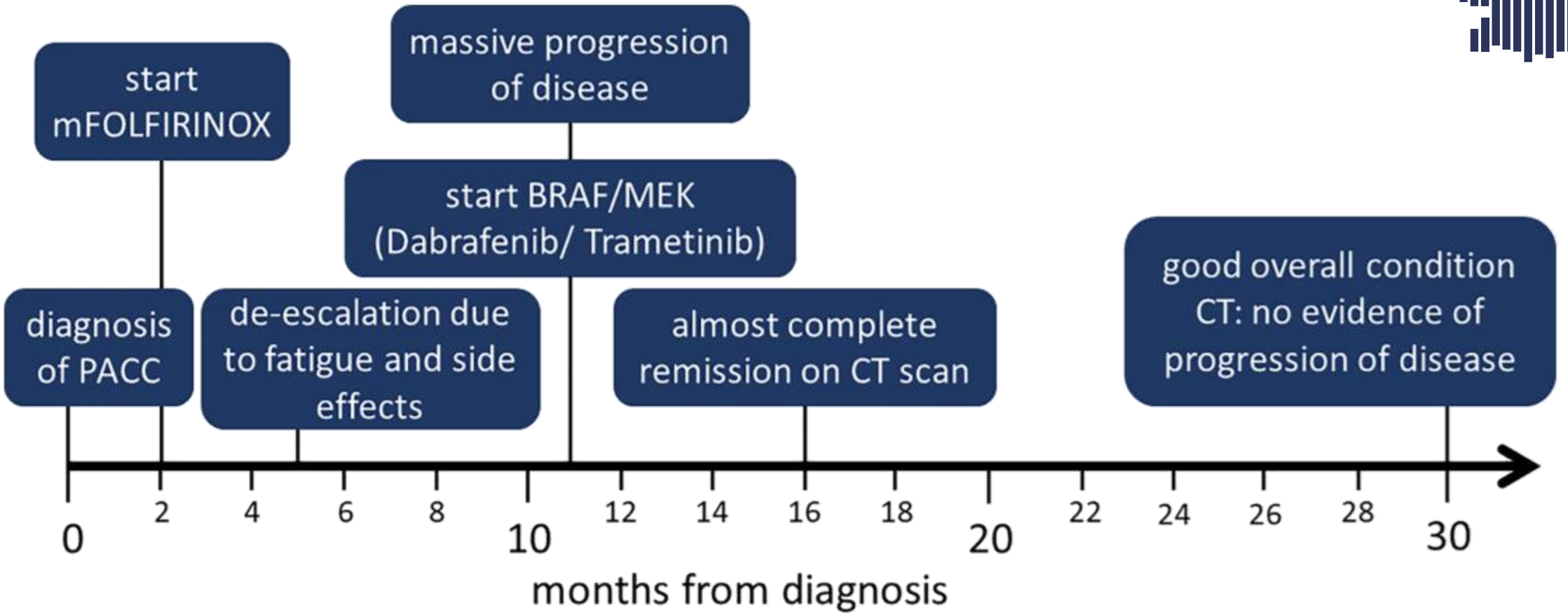
Freiherr von Fritsch-Seerhausen et al 2024



Freiherr von Fritsch-Seerhausen et al 2024



Freiherr von Fritsch-Seerhausen et al 2024

TABLE 1 Cases of pancreatic acinar cell tumor treated with BRAF-/MEK-inhibitor, described in the literature.

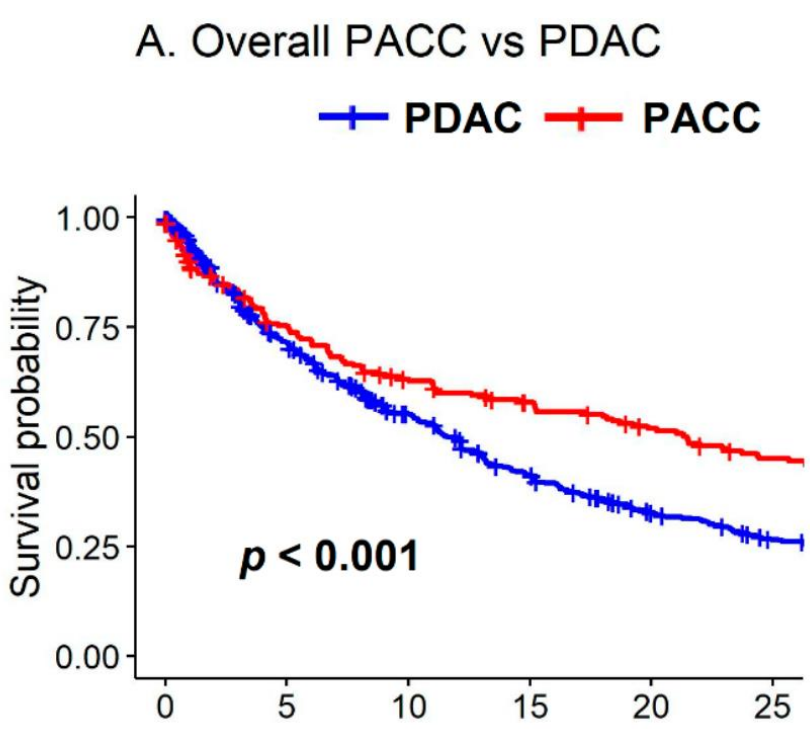
Authors	Busch et al.[9] (2020)	Cramer et al.[10] (2020)	Barrichello et al.[11] (2021)
Patient	27-year-old male	15-year-old female	73-year-old male
Symptoms at presentation	Abdominal pain, weight loss, nausea, fatigue	Abdominal pain, weight loss, fatigue, severe dysphagia	Abdominal pain, weight loss
Tumormarker	AFP	AFP	No information
Initial finding	Retroperitoneal tumor with mediastinal lymphadenopathy	Central mesenteric adenopathy with cervical and mediastinal lymphadenopathy, scattered lung nodules	Tumor pancreas head with portocaval, interaortocaval, mesenteric, and bilateral common iliac space lymphadenopathy
Molecular pathology	*BRAF*^{V600E}-mutation *PALB2*-mutation	*BRAF*^{V600E}-mutation *MLL3*-mutation	*BRAF*^{V600E}-mutation
Treatment	1. FOLFIRINOX (discontinued after side effects) 2. BRAF/MEK 3. Operation 4. Adjuvant treatment with BRAF/MEK	1. Gemcitabine, nab-paclitaxel (progression of disease and side effects) 2. BRAF/MEK	1. FOLFIRINOX 2. OperationAdjuvant treatment with capecitabine, radiotherapy, FOLFIRINOX, and nab-paclitaxel 3. BRAF/MEK
Outcome	Progression of disease, patient deceased 21 months after diagnosis	Complete remission for 24 months	Initial partial response to BRAF/MEK-inhibitor. After progression of disease, treatment was suspended and the patient deceased

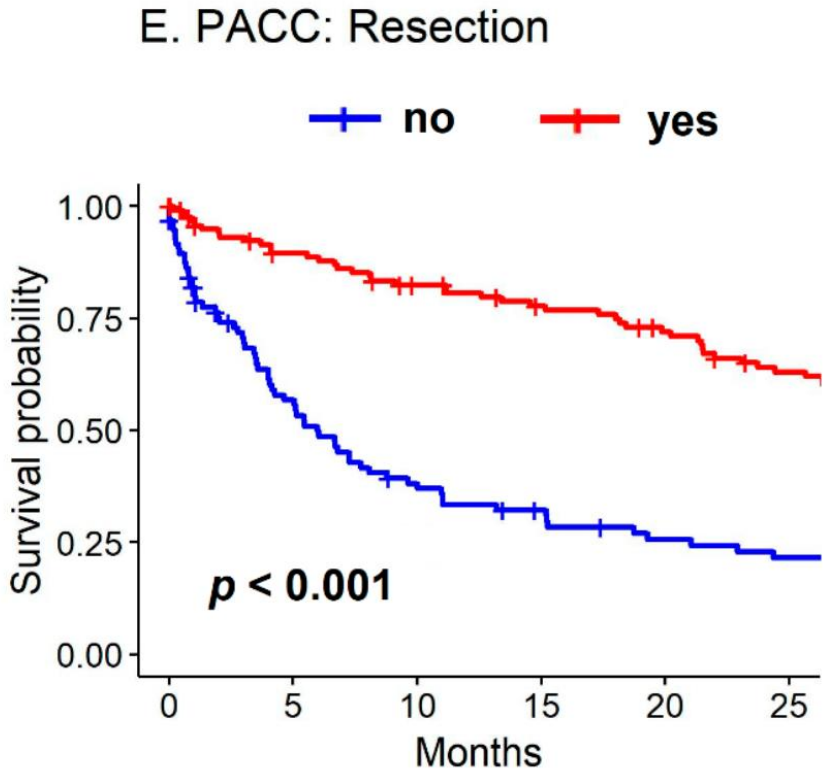
Abbreviation: AFP, alpha-fetoprotein.

Table 1. Univariable analysis PACC versus PDAC.

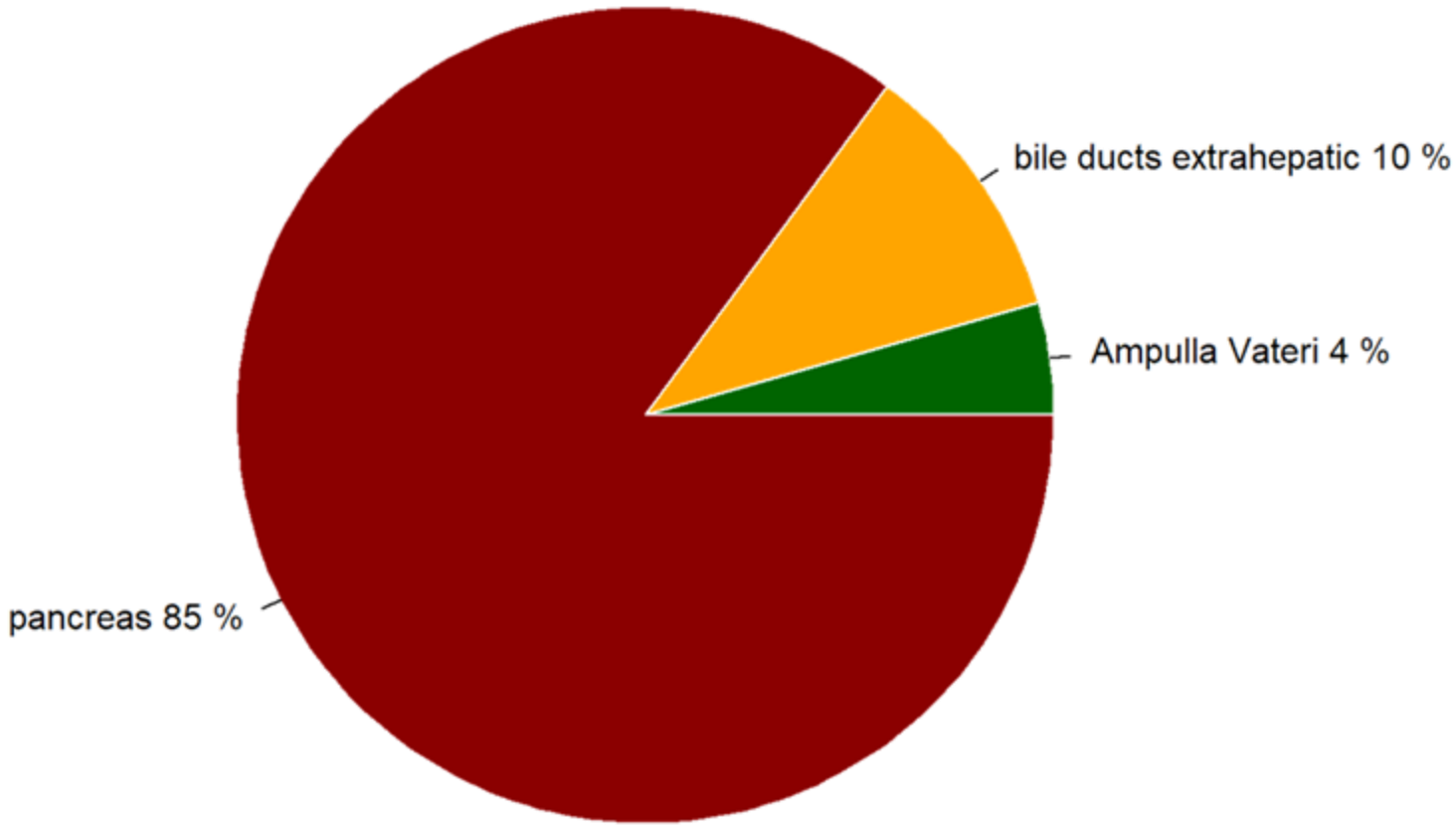
Parameter	*N* (% of Total)/Median (IQR)		*p*-Value
	PACC	PDAC	
All Patients			
Total number	233 (100)	37,940 (100)	
Sex			
male	154 (66.1)	20,225 (53.3)	
female	79 (33.9)	17,712 (46.7)	<0.001
missing	0 (0)	3 (<0.001)	0.978
Median age [years]	66 (17)	70 (14)	<0.001
Age			
≤67 years	128 (54.9)	15,863 (41.8)	
>67 years	105 (45.1)	22,077 (58.2)	<0.001
Distant metastases			
M0	106 (45.5)	12,964 (34.2)	
M1	79 (33.9)	15,177 (40)	0.002
Mx	48 (20.6)	9799 (25.8)	0.003
Treatment			
none	59 (25.3)	15,249 (40.2)	
Operation alone	80 (34.3)	10,139 (26.7)	<0.001
neoadjuvant + operation	2 (0.9)	299 (0.8)	0.448
operation + adjuvant	49 (21)	4304 (11.3)	<0.001
(Radio-)chemotherapy	43 (18.5)	7949 (21)	0.095
Operation	131 (56.2)	14,742 (38.9)	<0.001

Petrova et al 2021





Petrova et al 2021



Wellner, Bolm et al, unpublished

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Capecitabine compared with observation in resected biliary tract cancer (BILCAP): a randomised, controlled, multicentre, phase 3 study

John N Primrose, Richard P Fox, Daniel H Palmer, Hassan Z Malik, Raj Prasad, Darius Mirza, Alan Anthony, Pippa Corrie, Stephen Falk, Meg Finch-Jones, Harpreet Wasan, Paul Ross, Lucy Wall, Jonathan Wadsley, Jeff T R Evans, Deborah Stocken, Raaj Praseedom, Yuk Ting Ma, Brian Davidson, John P Neoptolemos, Tim Iveson, James Raftery, Shihua Zhu, David Cunningham, O James Garden, Clive Stubbs, Juan W Valle, John Bridgewater, on behalf of the BILCAP study group

Pimrose et al 2019

2006-2014

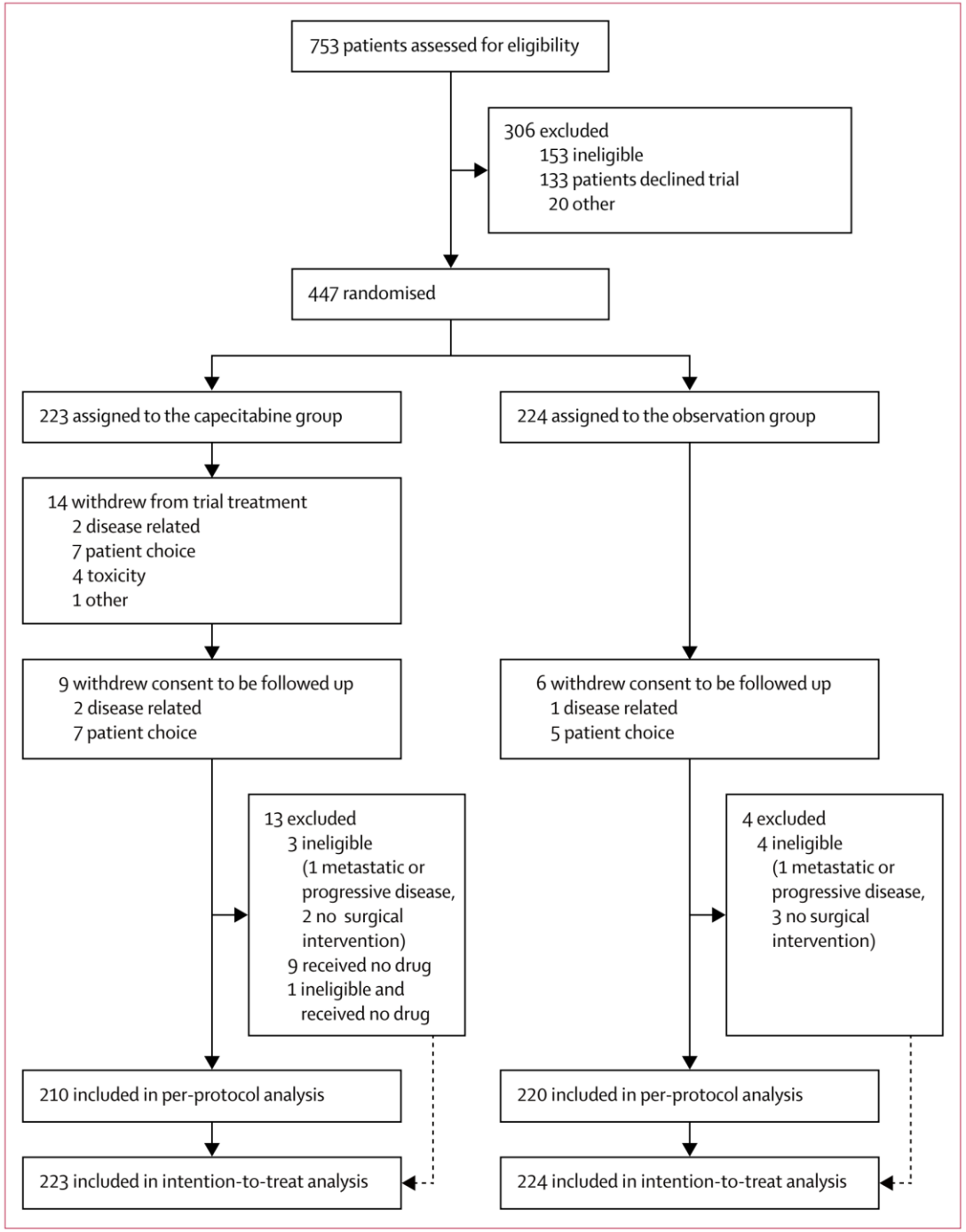

Figure 1: **Trial profile**

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Pimrose et al 2019

2019

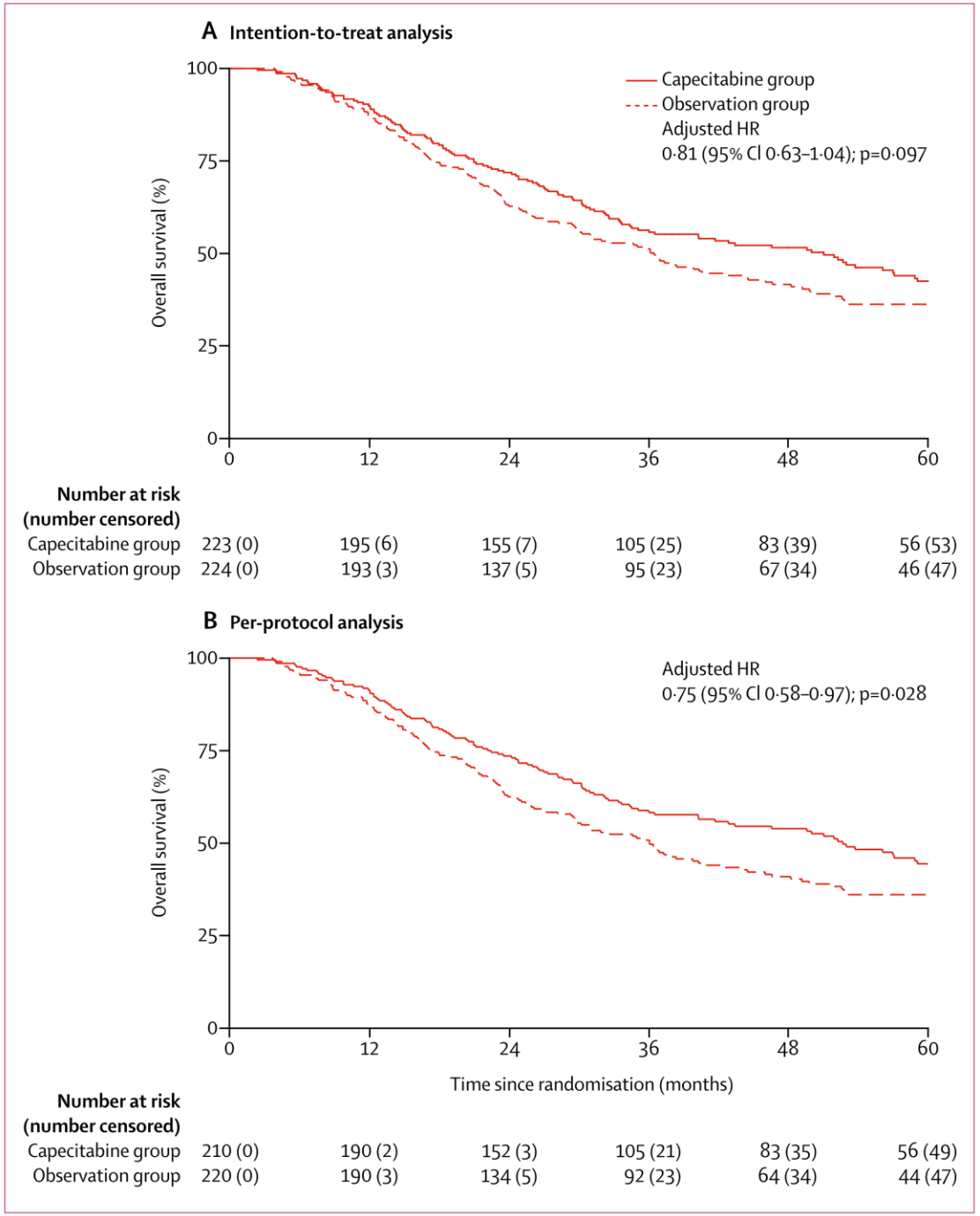

Figure 2: **Overall survival by intention-to-treat (A) and per-protocol (B) analyses**

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Pimrose et al 2019

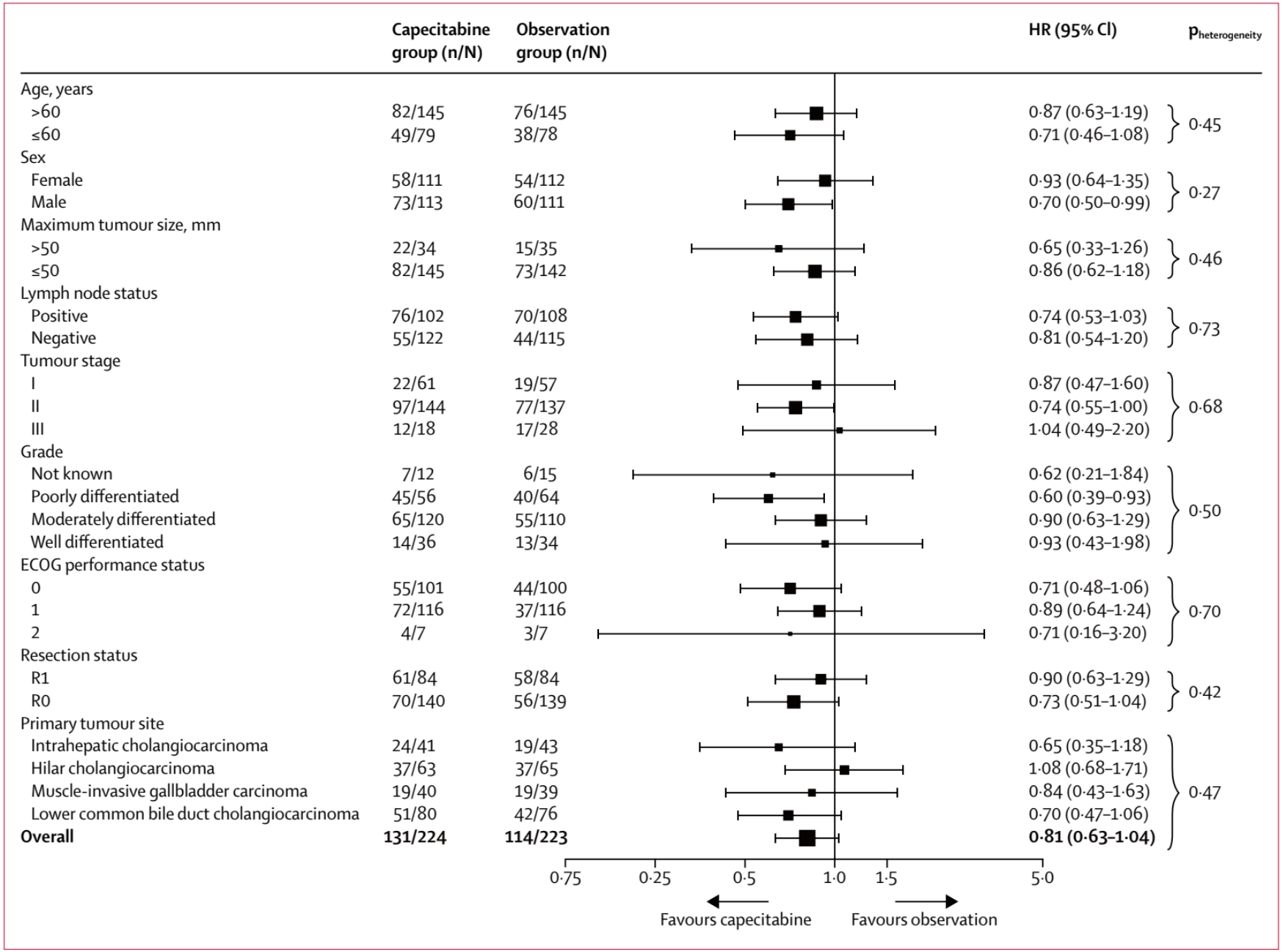

***Figure 4:* Subgroup analyses of overall survival in the intention-to-treat population**

Heterogeneity assessed through fitting of interactions terms in Cox survival models. ECOG=Eastern Cooperative Oncology Group. HR=hazard ratio. R0=negative resection margin. R1=positive resection margin.

Pimrose et al 2019

Der Effekt von adjuvanter Chemotherapie (AC) bei distalen Cholangiokarzinomen

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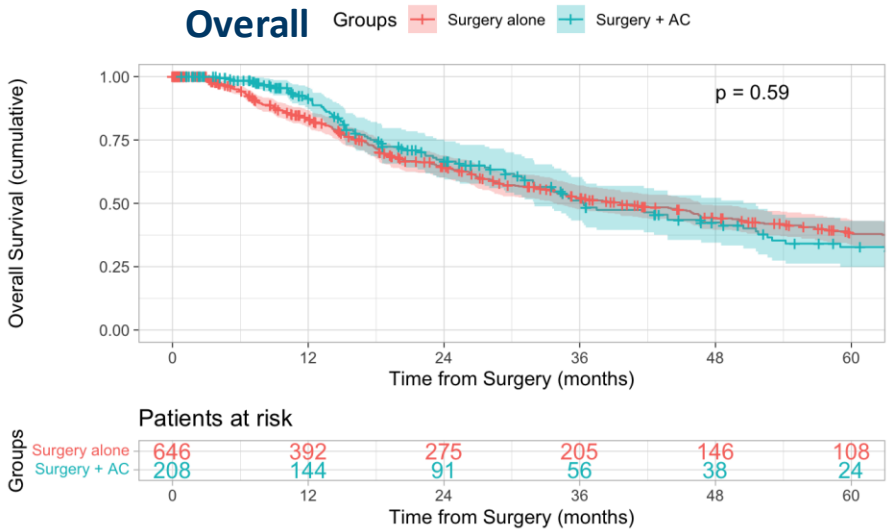
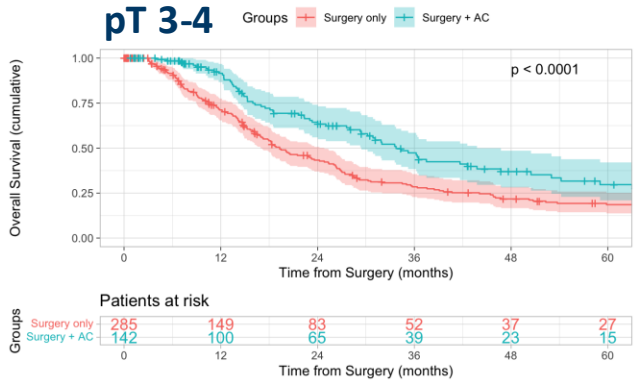
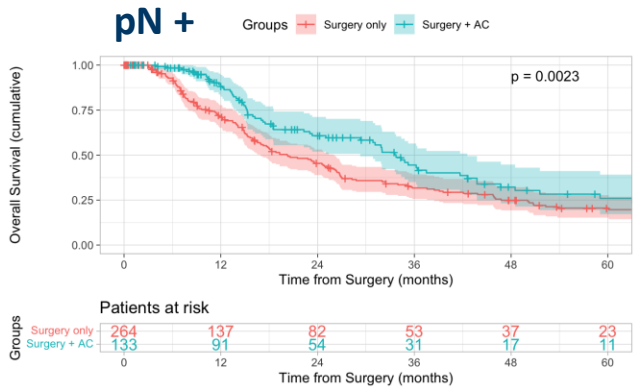
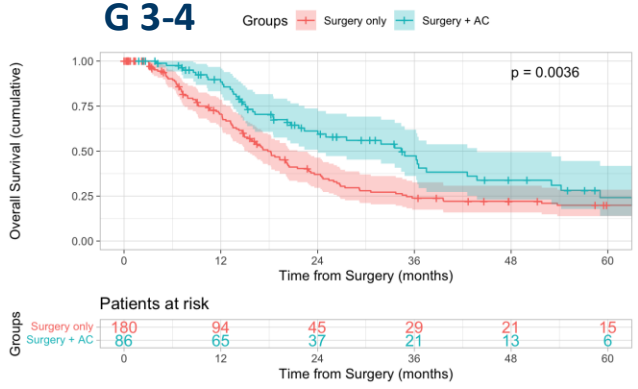
- Patienten mit primär resezierten distalen Gallengangskarzinomen (ICD-10: 24.1)
- Ausschluss von Patienten mit 90d postoperativer Mortalität

- n = 1093 → 230 Patienten (21.2 %) mit AC









- ✓ In der Gesamtkohorte kein Überlebensvorteil nach adjuvanter Chemotherapie
- ✓ Identifikation von Patienten mit fortgeschrittenen Tumoren (pT 3-4, pN+, G 3-4) profitieren von adjuvanter Chemotherapie

- ➢ Erste Populations-basierte Analyse zum Effekt adjuvanter Chemotherapie in distalen Cholangiokarzinomen
- ➢ Genauere Patientenselektion erforderlich?
- ➢ Prospektiv-randomisierte Studien dringend benötigt, aber sehr herausfordernd bei geringer Inzidenz.

Duhn, Bolm et al., unpublished

Invasive IPMN : bessere Prognose bei Resektion

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- Patienten mit primär resezierten invasiven IPMN oder PDAC entsprechend der ICD-O3 Klassifikation selektiert
- $n_{(PDAC)} = 5974$ // $n_{(invasive\ IPMN)} = 217$

✓ Signifikant niedrigere Tumorstadien in invasiven IPMN

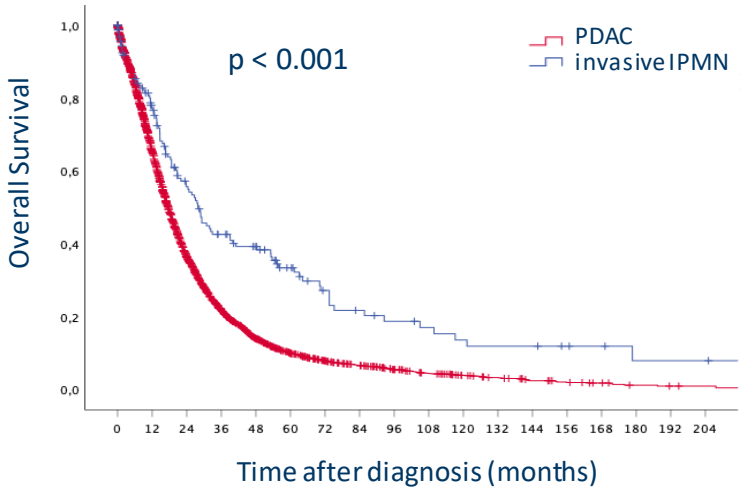
✓ Besseres Gesamtüberleben, v.a. in niedrigen Tumorstadien

✓ Weniger Lokal- und Fernrezidive in invasiven IPMN

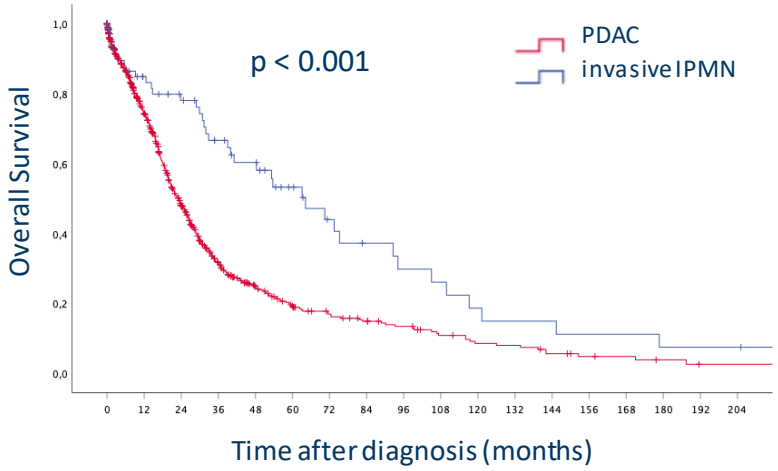
✓ Unterschiedliches Metastasierungsmuster / mehr isolierte Lungenmetastasen in invasiven IPMN (?)

➢ Histologischer Subtyp relevant für Prognose von Patienten
➢ Frühes Erkennen invasiver IPMN entscheidend für Überlebensvorteil
➢ Unterschiedliches Metastasierungsmuster
→ Beachtung in der Nachsorge

Overall Cohort



T1-2 N0



	HR	95% CI	*p*
Age > 65 vs. < 65	1.341	1.26 – 1.43	< 0.001
Sex male vs. female	1.097	1.03 – 1.16	0.002
Tumor Size T2 vs. T1	1.589	1.32 – 1.91	< 0.001
Tumor Size T3-4 vs. T1	1.537	1.29 – 1.84	< 0.001
Lymph Node Mets pN+ vs. pN0	1.413	.131 – 1.51	< 0.001
Resection margins R+ vs. R0	1.463	1.40 – 1.56	< 0.001
Histology PDAC vs. IPMNi	1.484	1.22 – 1.80	< 0.001

Abdalla, Duhn et al, unpublished

Muzinöser Subtyp ist ein unabhängiger positiv prognostischer Faktor nach Resektion

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- Patienten mit primär resezierten muzinösen Adenokarzinomen (MACP) oder PDAC entsprechend der ICD-O3 Klassifikation selektiert
- $n_{(PDAC)} = 8959$ // $n_{(MACP)} = 345$

✓ Signifikant niedrigere Tumorstadien in MACP

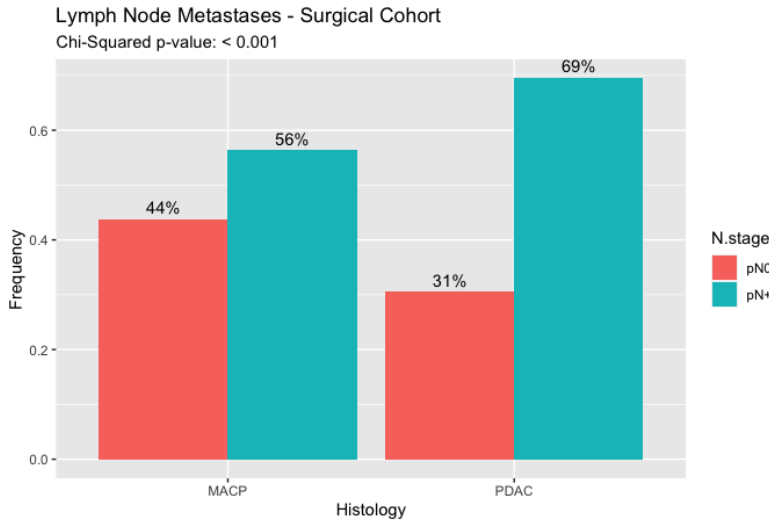
✓ Besseres Gesamtüberleben unabhängig vom Tumorstadium

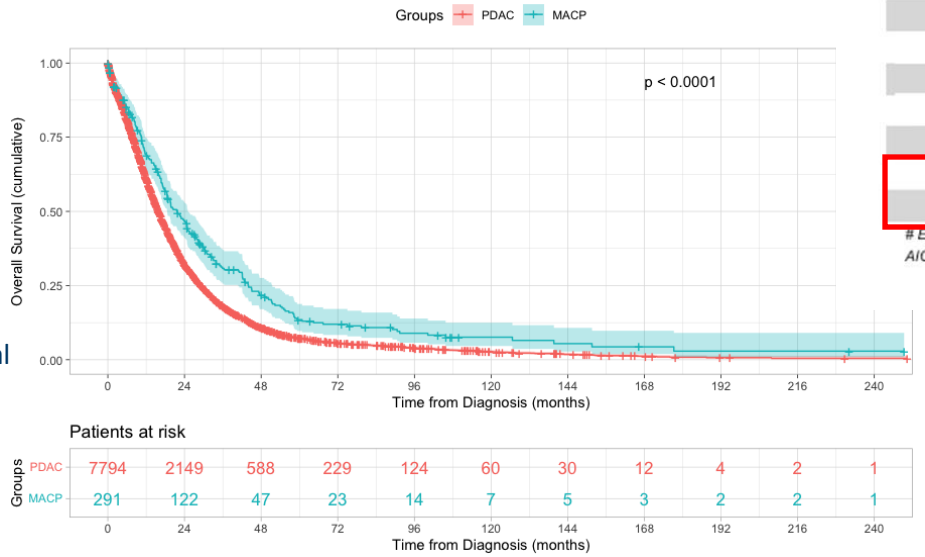
✓ MACP-Histologie als unabhängiger positiv-prognostischer Faktor für Gesamtüberleben

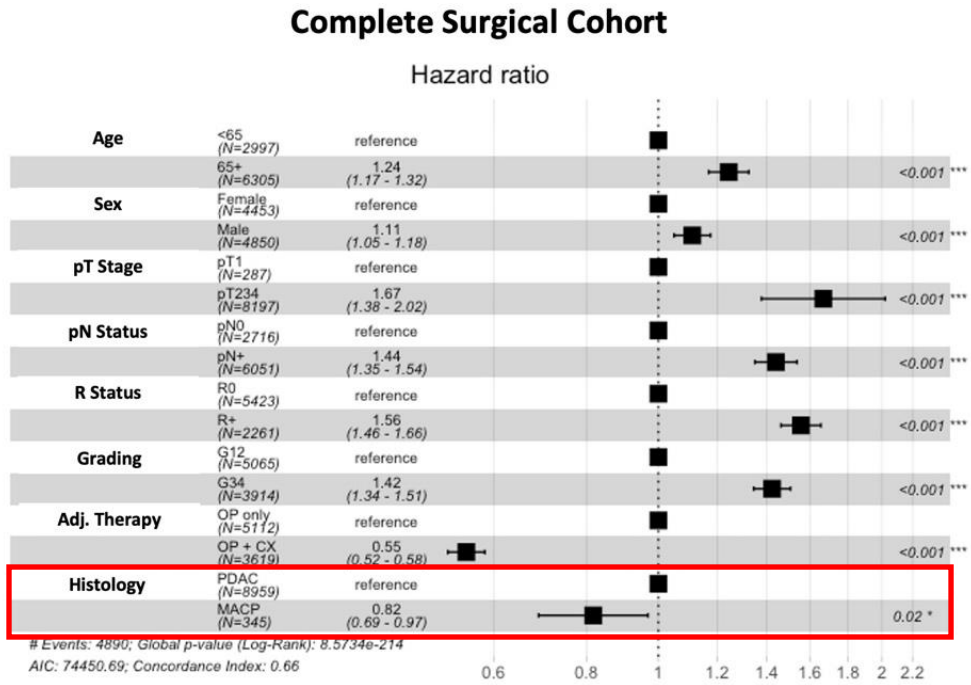
✓ Verlängertes Gesamtüberleben nach adjuvanter Chemotherapie in MACP-Patienten

➢ Histologischer Subtyp relevant für Prognose von Patienten

➢ Bestätigung kürzlich publizierter Daten der National Cancer Database → Cross-Validation







Duhn, Braun et al., unpublished

Metastasierungsmuster beim PankreasCA

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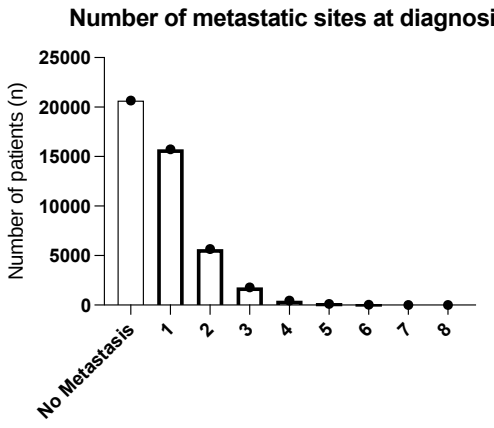
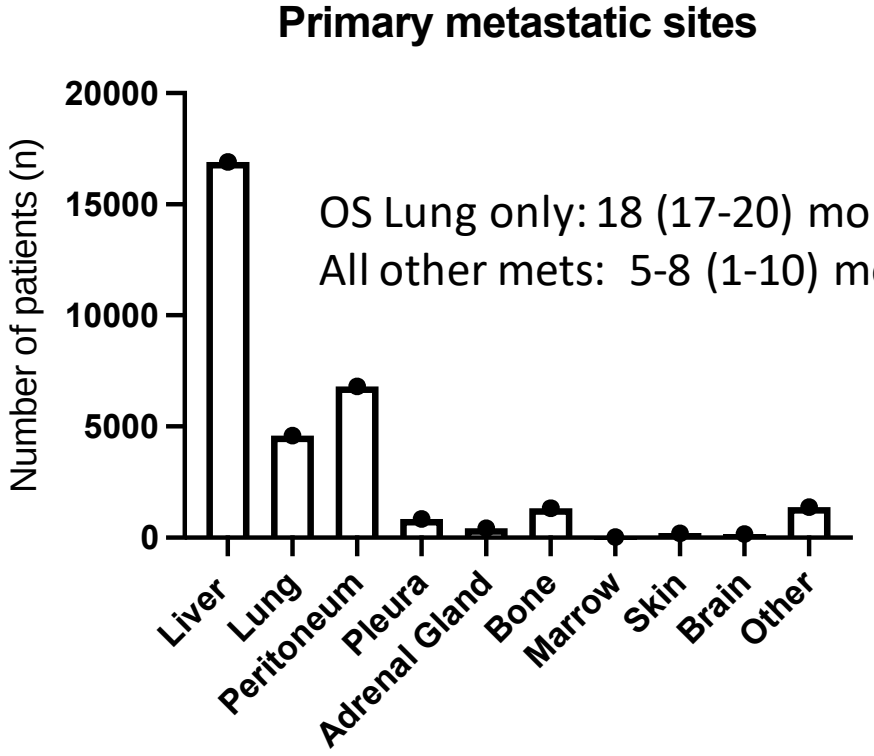
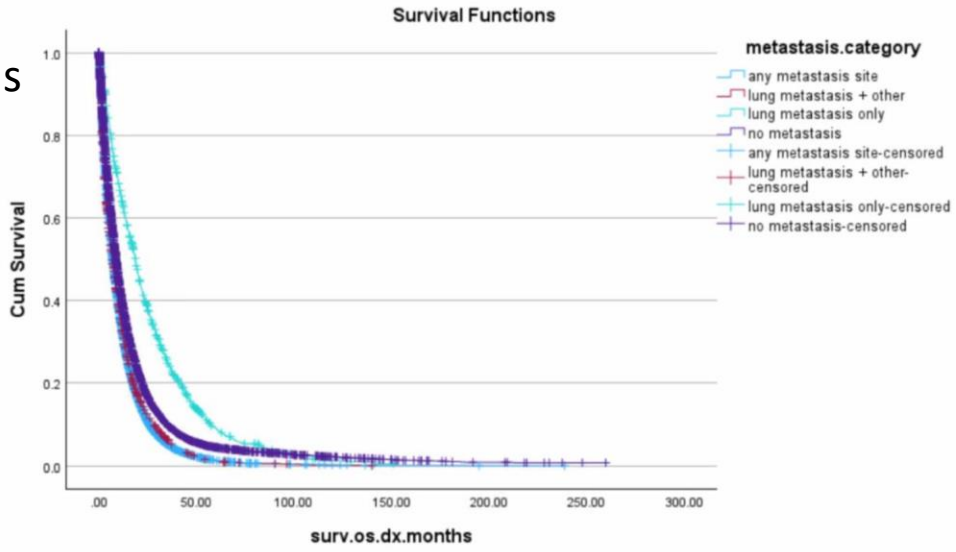
53% metastatic at diagnosis





OS Lung only: 18 (17-20) months
All other mets: 5-8 (1-10) months



Key Message: Mindestens die Hälfte der Patienten mit duktalem Pankreaskarzinom werden im metastasierten Stadium diagnostiziert. Aktuell werden diese Patienten einer palliativen Chemotherapie zugeführt und haben dementsprechend ein sehr schlechtes Überleben. Wir konnten zeigen, dass Patienten mit Lungenmetastasen ein vergleichbares Überleben, wie Patienten mit resektablem Pankreaskarzinom haben, sodass diese Patienten möglichweise von einem kurativem Behandlungskonzept profitieren würden. Dieses sollte in klinischen Studien untersucht werden.

Honselmann et al, unpublished

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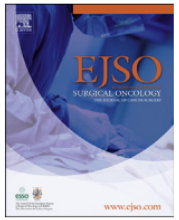

Metastases or primary recurrence to the lung is related to improved survival of pancreatic cancer as compared to other sites of dissemination. Results of a systematic review with meta-analysis

Francesco Guerra [a, *], Viola Barucca [b], Diego Coletta [c]

[a] Ospedali Riuniti Marche Nord, Pesaro, Italy
[b] San Camillo-Forlanini Hospital, Rome, Italy
[c] Hepatopancreatobiliary Surgery, IRCCS Regina Elena National Cancer Institute, Rome, Italy

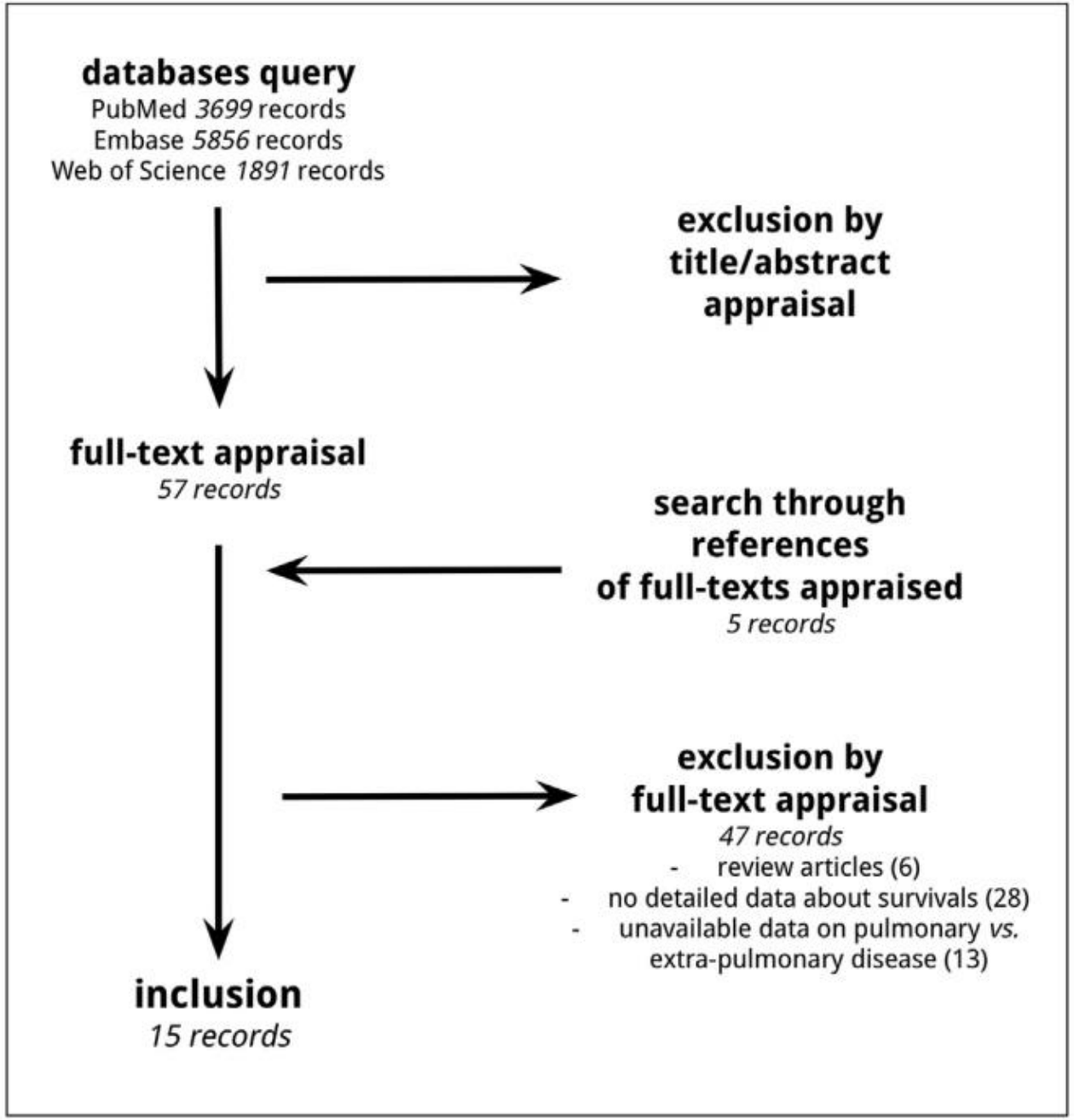

Fig. 1. The PRISMA diagram illustrating the selection process.

Table 1
Included studies with general characteristics, PDAC: pancreatic ductal adenocarcinoma, PR: pancreatic resection. RCT randomized controlled trial

Author	Recruitment Period	Origin	Study Design	Patients included	Patients with pulmonary metastasis
Ariake et al. 2017 [22]	2006-2014	Japan	Retrospective cohort of recurrence after PR	186	25
Chen et al. 2015 [23]	1997-2010	US	Retrospective cohort of recurrence after PR	213	37
Decoster et al. 2016 [24]	2007-2013	France	Retrospective cohort of metastatic PDAC	74	37
Groot et al. 2018 [2]	2000-2013	US	Retrospective cohort of recurrence after PR	877	93
Jones et al. 2019 [25]	2008-2014	Europe	RCT on adjuvant therapy after PR	479	52
Kim et al. 2017 [26]	2011-2015	Australia	Retrospective cohort of recurrence after PR	82	18
Kim et al. 2019 [27]	2000-2014	South Korea	Retrospective cohort of recurrence after PR	1346	23
Kurahara et al. 2020 [28]	2000-2017	Japan	Retrospective cohort of recurrence after PR	121	16
Liu et al.2019 [29]	2010-2016	Taiwan	Retrospective cohort of metastatic PDAC	654	22
Liu et al. 2020 [30]	2010-2014	US	Retrospective analysis of SEER database on PDAC	7156	740
Nakagawa et al [31]	2006-2011	Japan	Retrospective cohort of recurrence after PR	95	26
Sahin et al. 2018 [15]	2004-2014	US	Retrospective cohort of recurrence after PR	149	47
Wangjam et al. 2015 [32]	1998-2007	US	Retrospective cohort of recurrence after PR	174	28
Watanabe et al. [33]	1996-2015	Japan	Retrospective cohort of recurrence after PR	90	11
Zheng et al. 2017 [34]	1994-2013	Japan	Retrospective cohort of recurrence after PR	220	24
Total				***11 916***	***1 199***

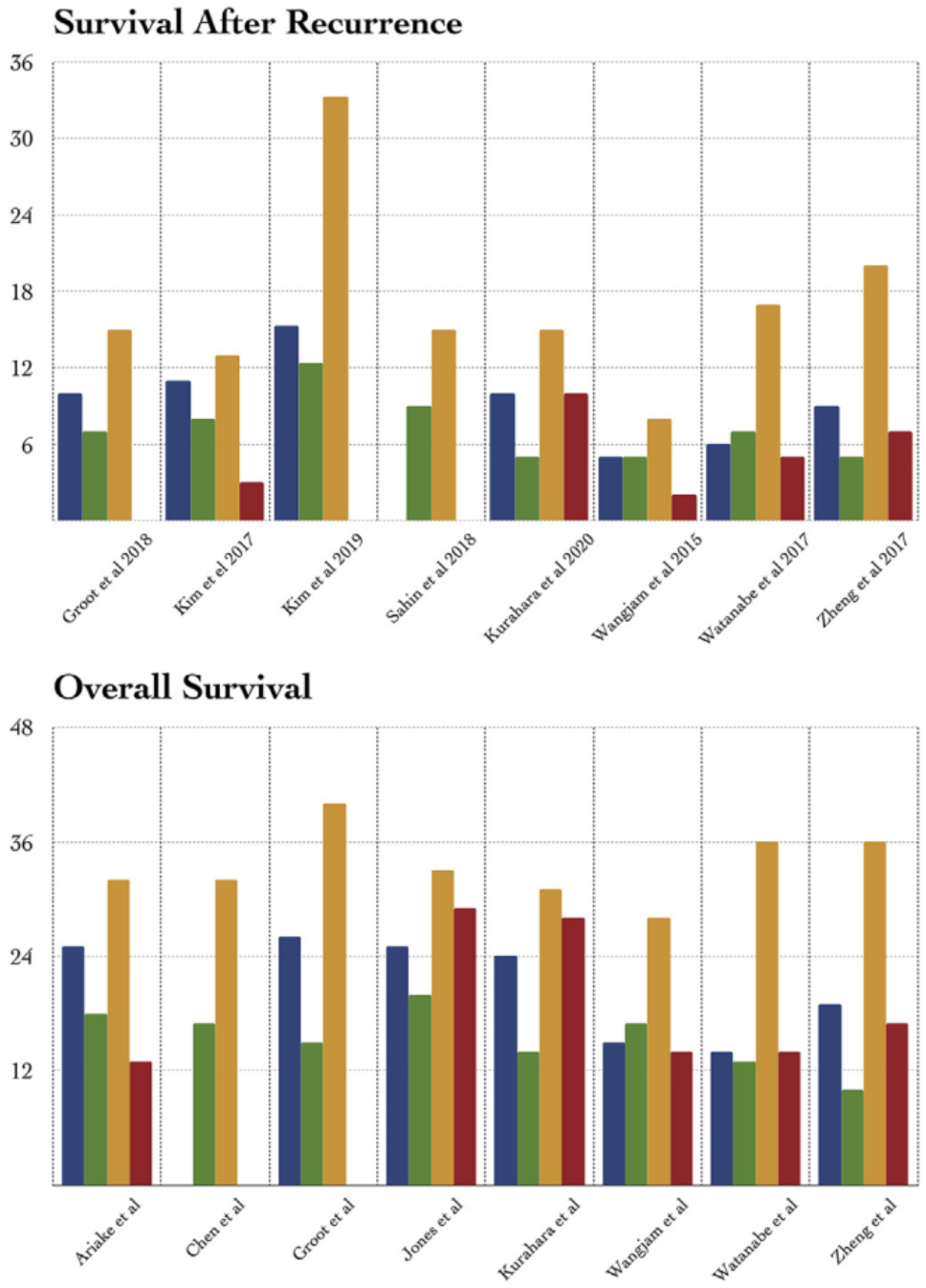

Fig. 2. Median survivals according to the site of PDAC recurrence (months).

A B S T R A C T

There are demonstrations that the prognosis of patients with isolated pulmonary dissemination of pancreatic cancer is more favorable than that of patients with other patterns of disease progression. The aim of this systematic review with meta-analysis was to evaluate the oncological outcomes of pulmonary *vs*. non-pulmonary metastasis of patients with pancreatic cancer. A total of 11 916 patients with secondary spread of pancreatic cancer were included from 15 primary reports. In the setting of single-organ disease dissemination, the lung demonstrated a significant survival advantage over hepatic, locoregional, or peritoneal localization. In particular, patients who recurred in the lung after pancreatectomy, showed a significant survival benefit as compared to those patients with hepatic and locoregional relapse in terms of disease-free survival, survival after recurrence and overall survival.

PankreasCA

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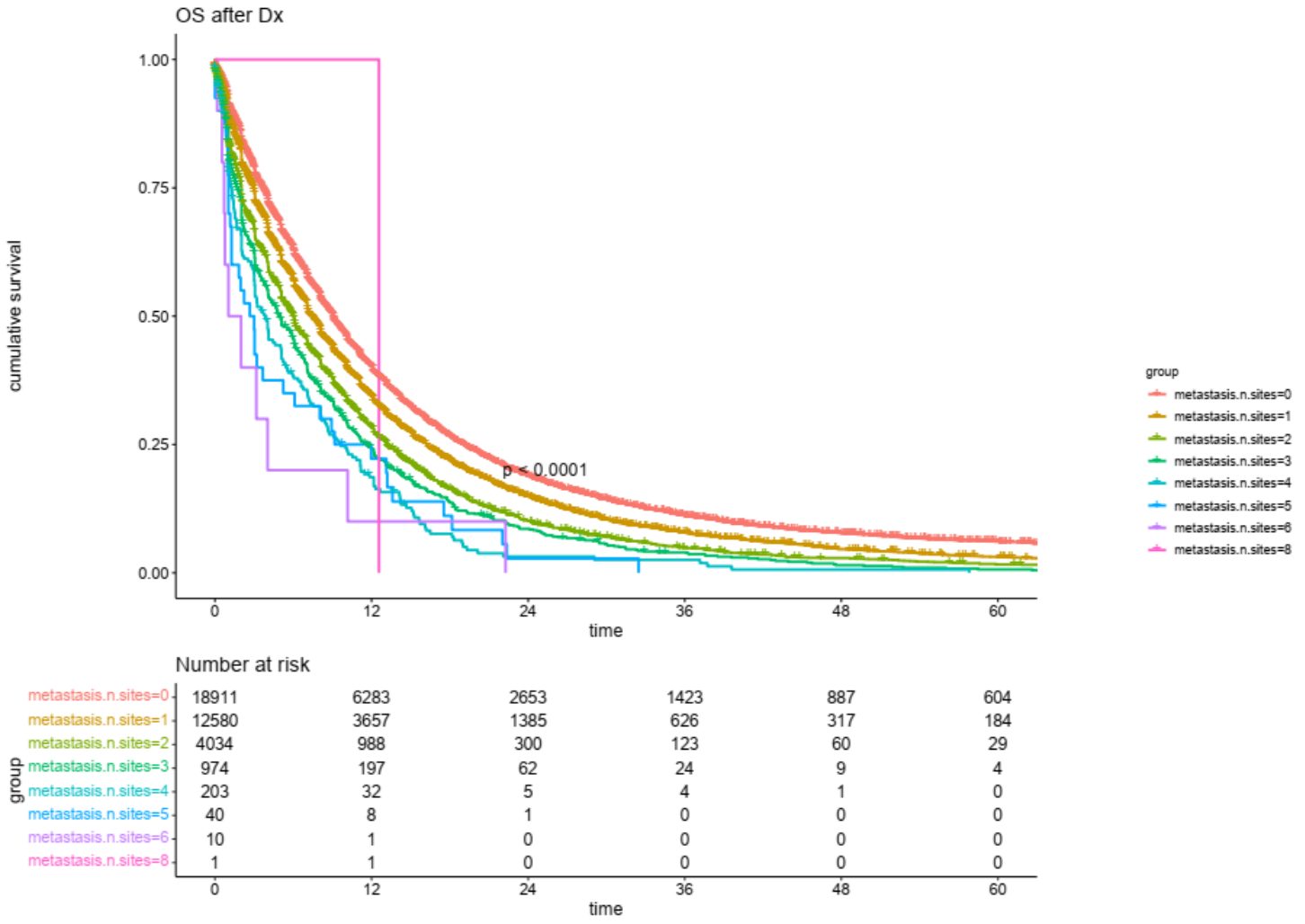

Honselmann et al, unpublished

PankreasCA

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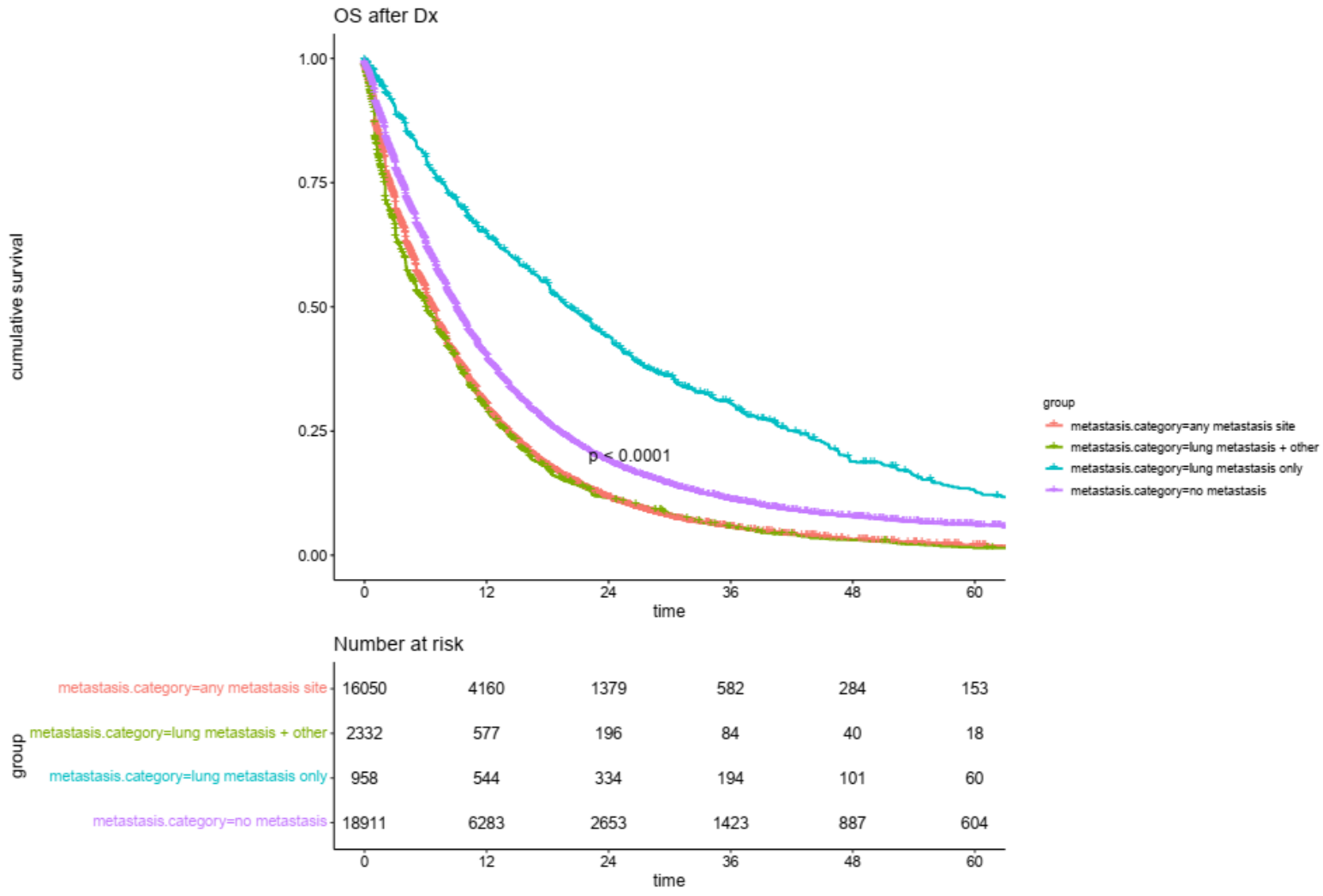

Honselmann et al, unpublished

PankreasCA

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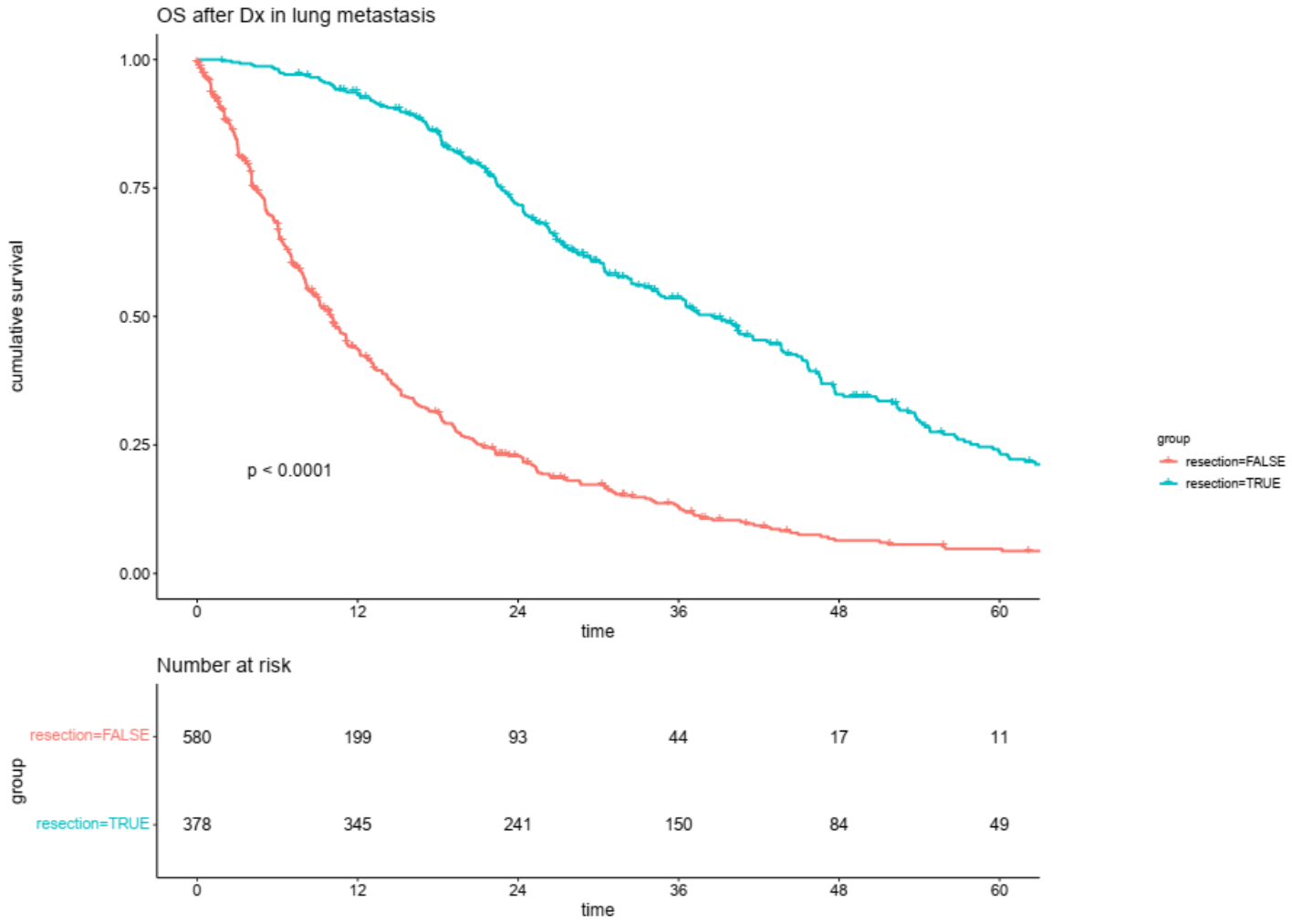


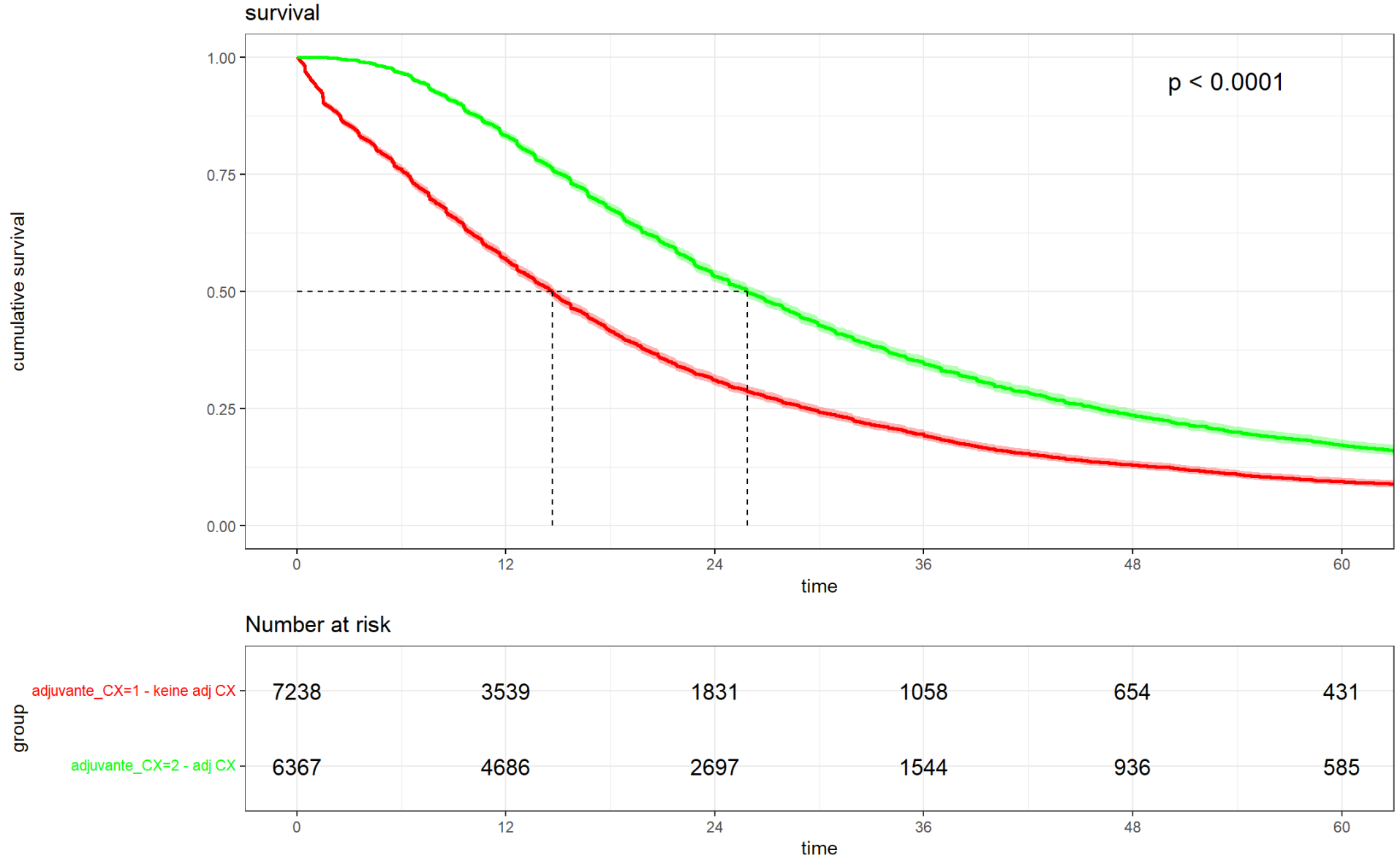
Honselmann et al, unpublished

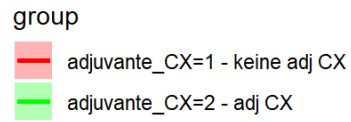
5.15.	Konsensbasierte Empfehlung	modifiziert 2021
EK	Eine kontrastmittelgestützte Computertomographie der Lunge und des Abdomens/Beckens soll erfolgen, wenn eine Evaluation der Tumorausbreitung notwendig ist und keine Kontraindikationen für ein CT vorliegen.	
	Starker Konsens	

Hintergrund

Internationale Leitlinien empfehlen zur prätherapeutischen Ausbreitungsdiagnostik die Durchführung einer kontrastmittelgestützten Untersuchung von Lunge und Abdomen mit Becken [161, 162] . Für die vorliegende Leitlinie (Version 2.01) wurde keine systematische Literaturanalyse bzgl. dieser Fragestellung durchgeführt.

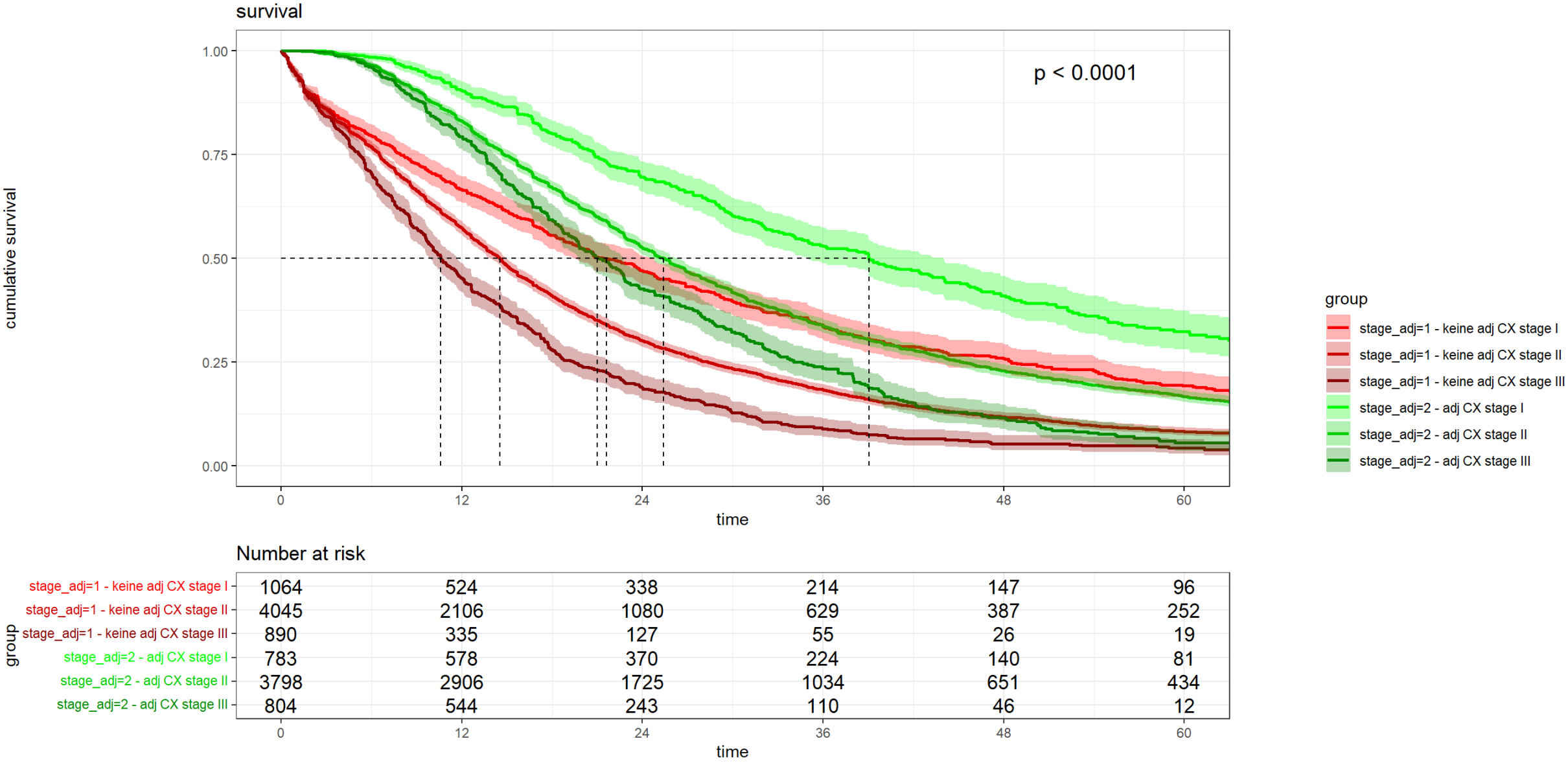
PDAC M0 upfront R0 – adjuvante Therapie





Wellner, Bolm et al, unpublished

PDAC M0 upfront R0 – adjuvante Therapie



Wellner, Bolm et al, unpublished

PDAC M0 upfront R0 : adjuvante Tx ?

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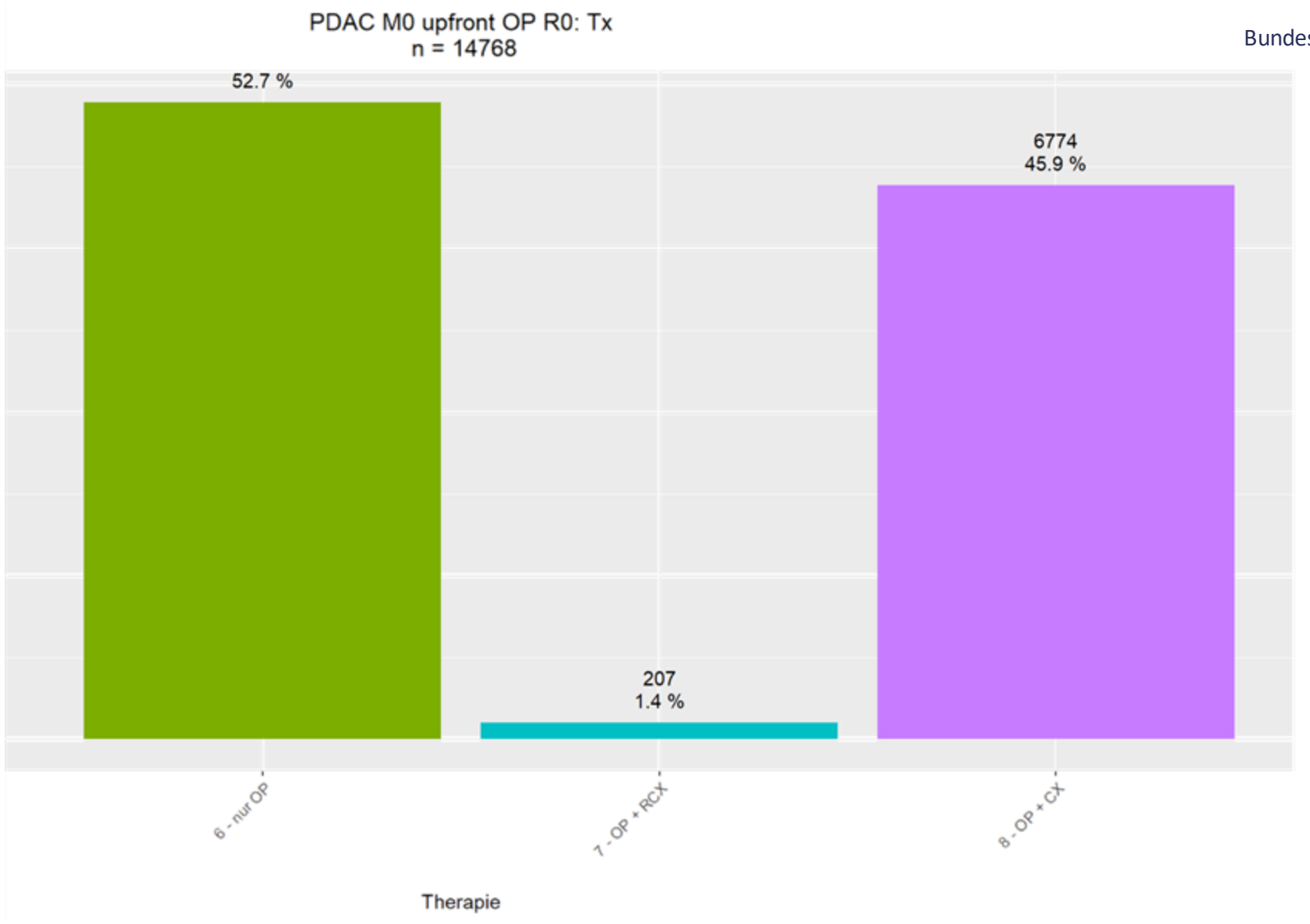

Wellner, Bolm et al, unpublished

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FOLFIRINOX or Gemcitabine as Adjuvant Therapy for Pancreatic Cancer

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ABSTRACT

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PATIENTS

Patients 18 to 79 years of age who had histologically confirmed pancreatic ductal adenocarcinoma, who had undergone complete macroscopic (R0 [no cancer cells within 1 mm of all resection margins] or R1 [cancer cells present within 1 mm of one or more resection margins]) resection within 3 to 12 weeks before randomization, and who had no evidence of metastatic disease, malignant ascites, or pleural effusion were eligible for inclusion. Other inclusion criteria were full recovery from surgery, a World Health Organization (WHO) performance-status score of 0 or 1 (on a 5-point scale, with higher numbers indicating greater disability), and adequate hematologic function (absolute neutrophil count, ≥1500 per cubic millimeter; platelet count, ≥100,000 per cubic millimeter; and hemoglobin level, ≥10 g per deciliter), liver function (serum total bilirubin level, ≤1.5 times the upper limit of the normal range), and renal function (creatinine clearance, ≥50 ml per minute). Patients with nonductal pancreatic tumors, incomplete (R2) resection, a serum CA 19-9 level of more than 180 U per milliliter within 21 days before randomization, receipt of previous chemotherapy or radiotherapy, or symptomatic heart failure or coronary heart disease were ineligible.

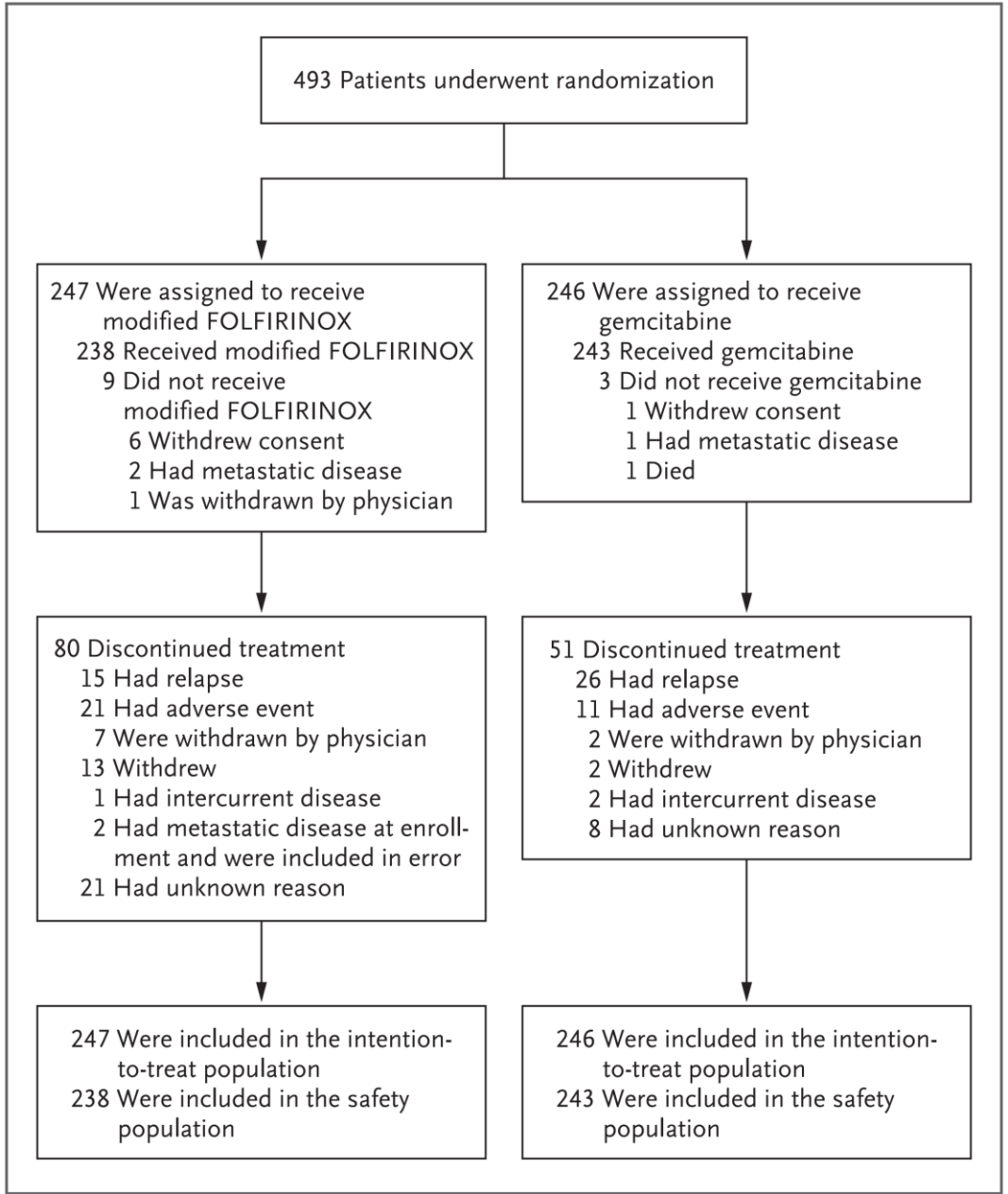

Figure 1. Randomization and Treatment of the Patients.

The modified FOLFIRINOX regimen consisted of fluorouracil (without bolus), leucovorin, irinotecan, and oxaliplatin.

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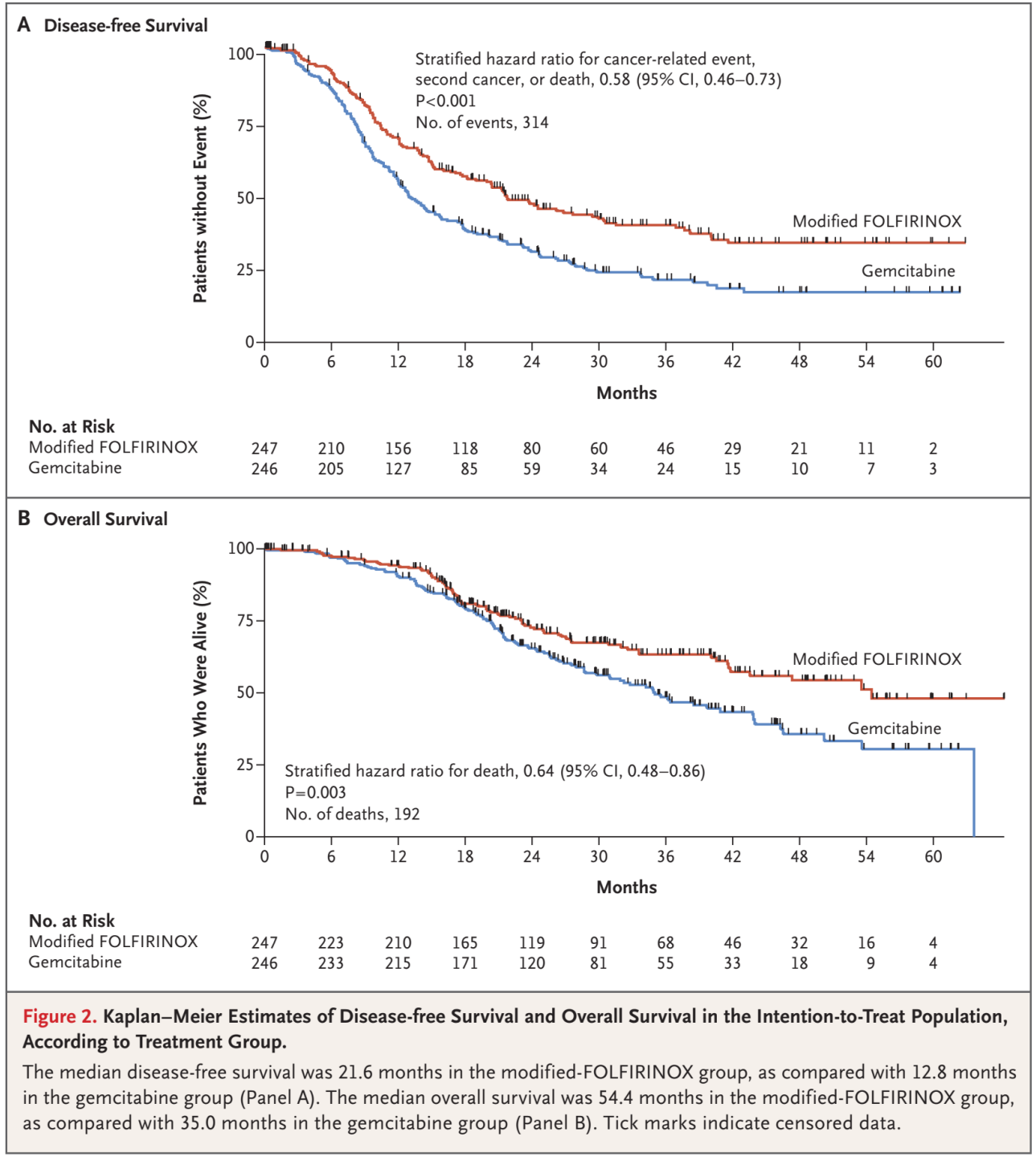

Figure 2. Kaplan–Meier Estimates of Disease-free Survival and Overall Survival in the Intention-to-Treat Population, According to Treatment Group.

The median disease-free survival was 21.6 months in the modified-FOLFIRINOX group, as compared with 12.8 months in the gemcitabine group (Panel A). The median overall survival was 54.4 months in the modified-FOLFIRINOX group, as compared with 35.0 months in the gemcitabine group (Panel B). Tick marks indicate censored data.

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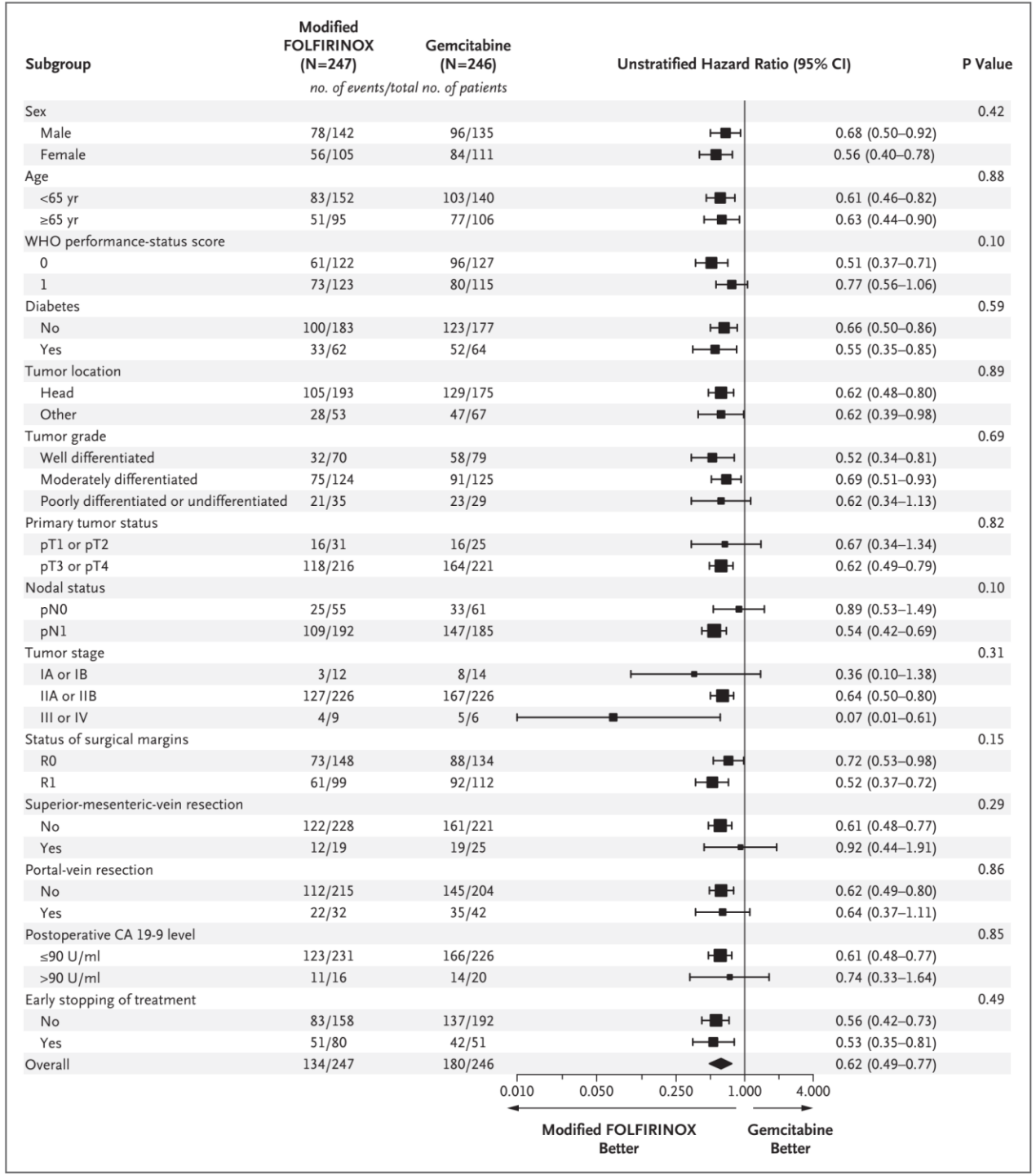

Subgroup	Modified FOLFIRINOX (N=247)	Gemcitabine (N=246)	Unstratified Hazard Ratio (95% CI)	P Value
	no. of events/total no. of patients			
Sex				0.42
Male	78/142	96/135	0.68 (0.50–0.92)	
Female	56/105	84/111	0.56 (0.40–0.78)	
Age				0.88
<65 yr	83/152	103/140	0.61 (0.46–0.82)	
≥65 yr	51/95	77/106	0.63 (0.44–0.90)	
WHO performance-status score				0.10
0	61/122	96/127	0.51 (0.37–0.71)	
1	73/123	80/115	0.77 (0.56–1.06)	
Diabetes				0.59
No	100/183	123/177	0.66 (0.50–0.86)	
Yes	33/62	52/64	0.55 (0.35–0.85)	
Tumor location				0.89
Head	105/193	129/175	0.62 (0.48–0.80)	
Other	28/53	47/67	0.62 (0.39–0.98)	
Tumor grade				0.69
Well differentiated	32/70	58/79	0.52 (0.34–0.81)	
Moderately differentiated	75/124	91/125	0.69 (0.51–0.93)	
Poorly differentiated or undifferentiated	21/35	23/29	0.62 (0.34–1.13)	
Primary tumor status				0.82
pT1 or pT2	16/31	16/25	0.67 (0.34–1.34)	
pT3 or pT4	118/216	164/221	0.62 (0.49–0.79)	
Nodal status				0.10
pN0	25/55	33/61	0.89 (0.53–1.49)	
pN1	109/192	147/185	0.54 (0.42–0.69)	
Tumor stage				0.31
IA or IB	3/12	8/14	0.36 (0.10–1.38)	
IIA or IIB	127/226	167/226	0.64 (0.50–0.80)	
III or IV	4/9	5/6	0.07 (0.01–0.61)	
Status of surgical margins				0.15
R0	73/148	88/134	0.72 (0.53–0.98)	
R1	61/99	92/112	0.52 (0.37–0.72)	
Superior-mesenteric-vein resection				0.29
No	122/228	161/221	0.61 (0.48–0.77)	
Yes	12/19	19/25	0.92 (0.44–1.91)	
Portal-vein resection				0.86
No	112/215	145/204	0.62 (0.49–0.80)	
Yes	22/32	35/42	0.64 (0.37–1.11)	
Postoperative CA 19-9 level				0.85
≤90 U/ml	123/231	166/226	0.61 (0.48–0.77)	
>90 U/ml	11/16	14/20	0.74 (0.33–1.64)	
Early stopping of treatment				0.49
No	83/158	137/192	0.56 (0.42–0.73)	
Yes	51/80	42/51	0.53 (0.35–0.81)	
Overall	134/247	180/246	0.62 (0.49–0.77)	

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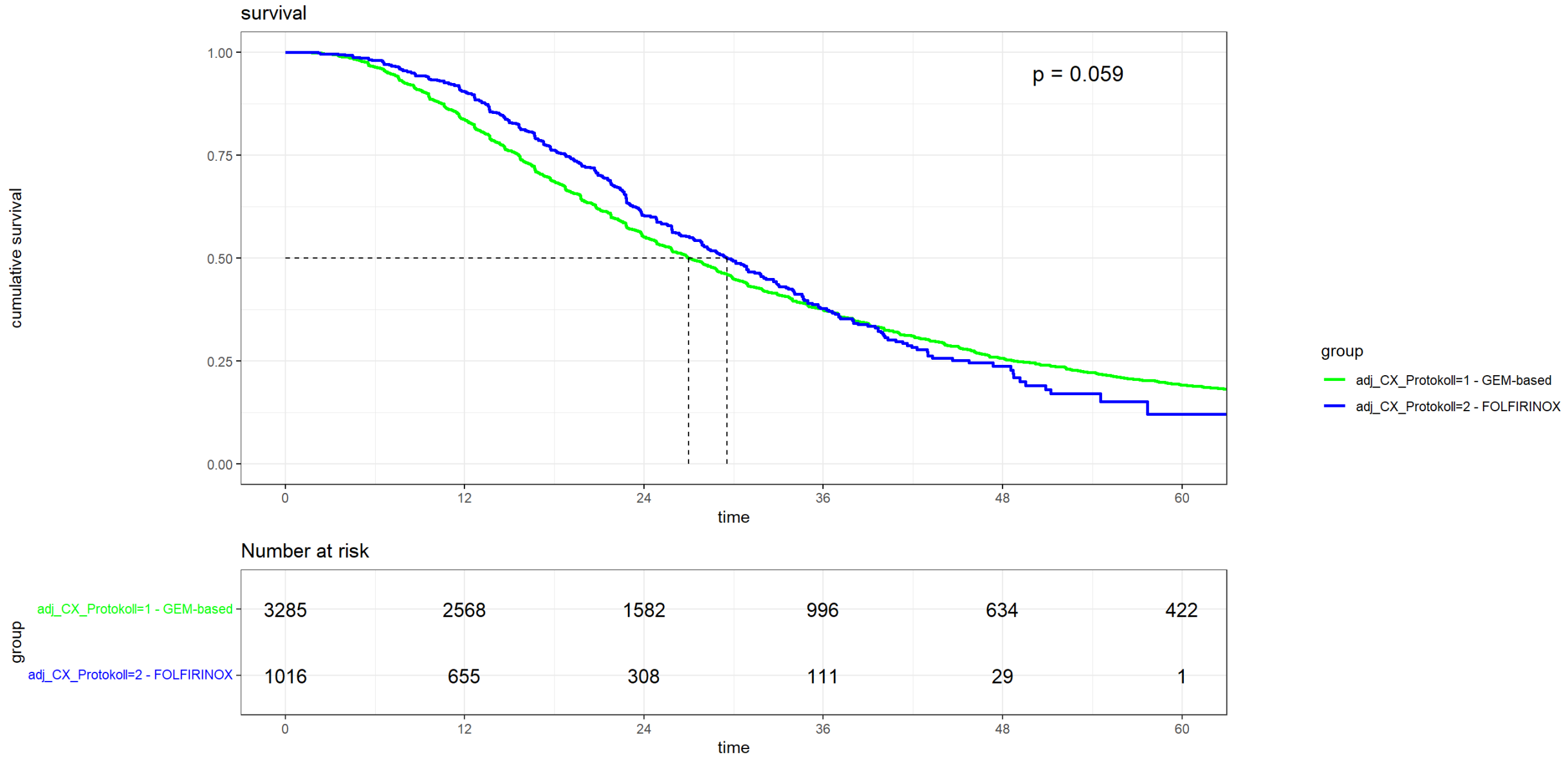
PDAC M0 upfront R0 – adjuvantGEM vs FOLFIRINOX



Wellner, Bolm et al, unpublished

Pankreaskarzinom : Therapie

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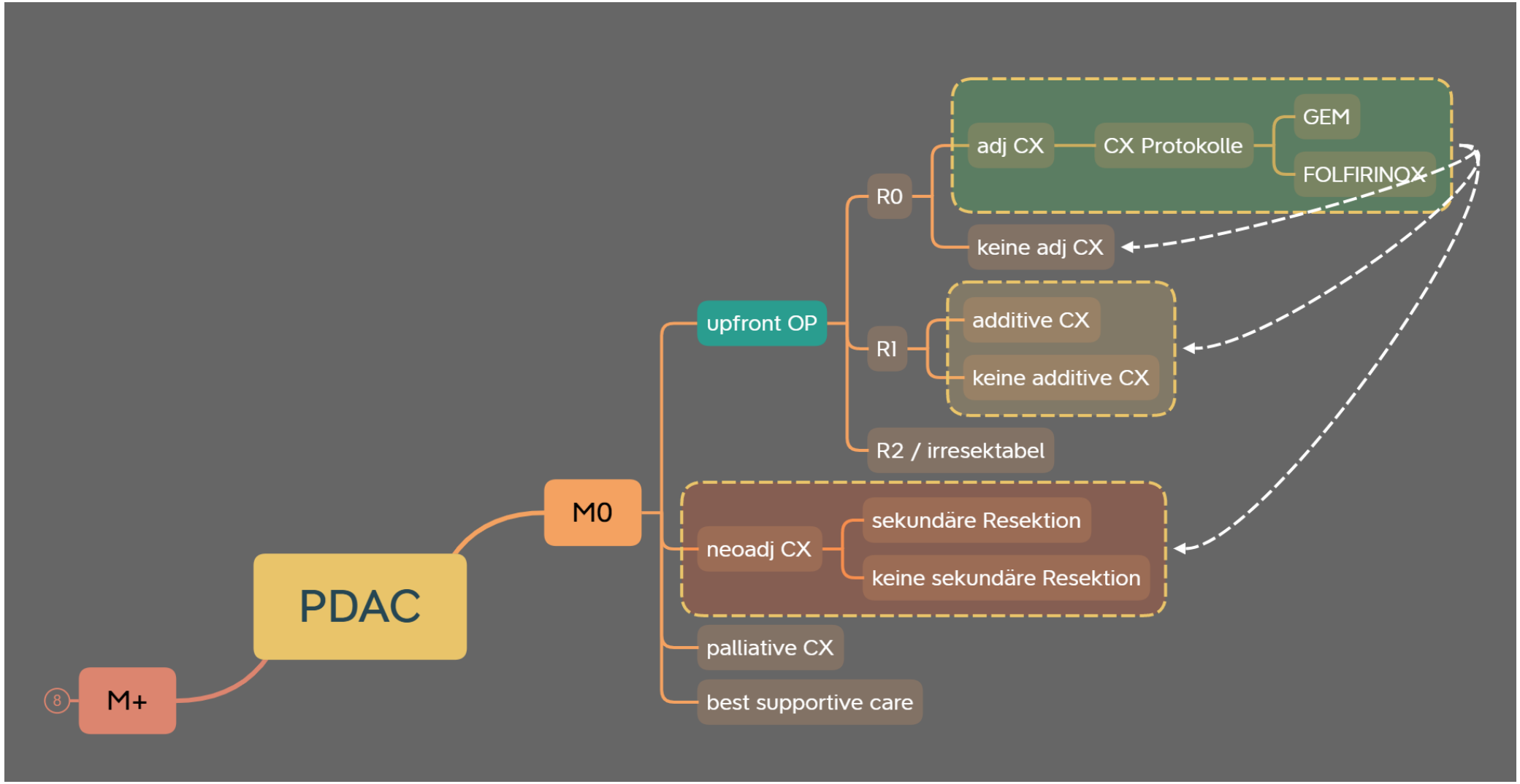
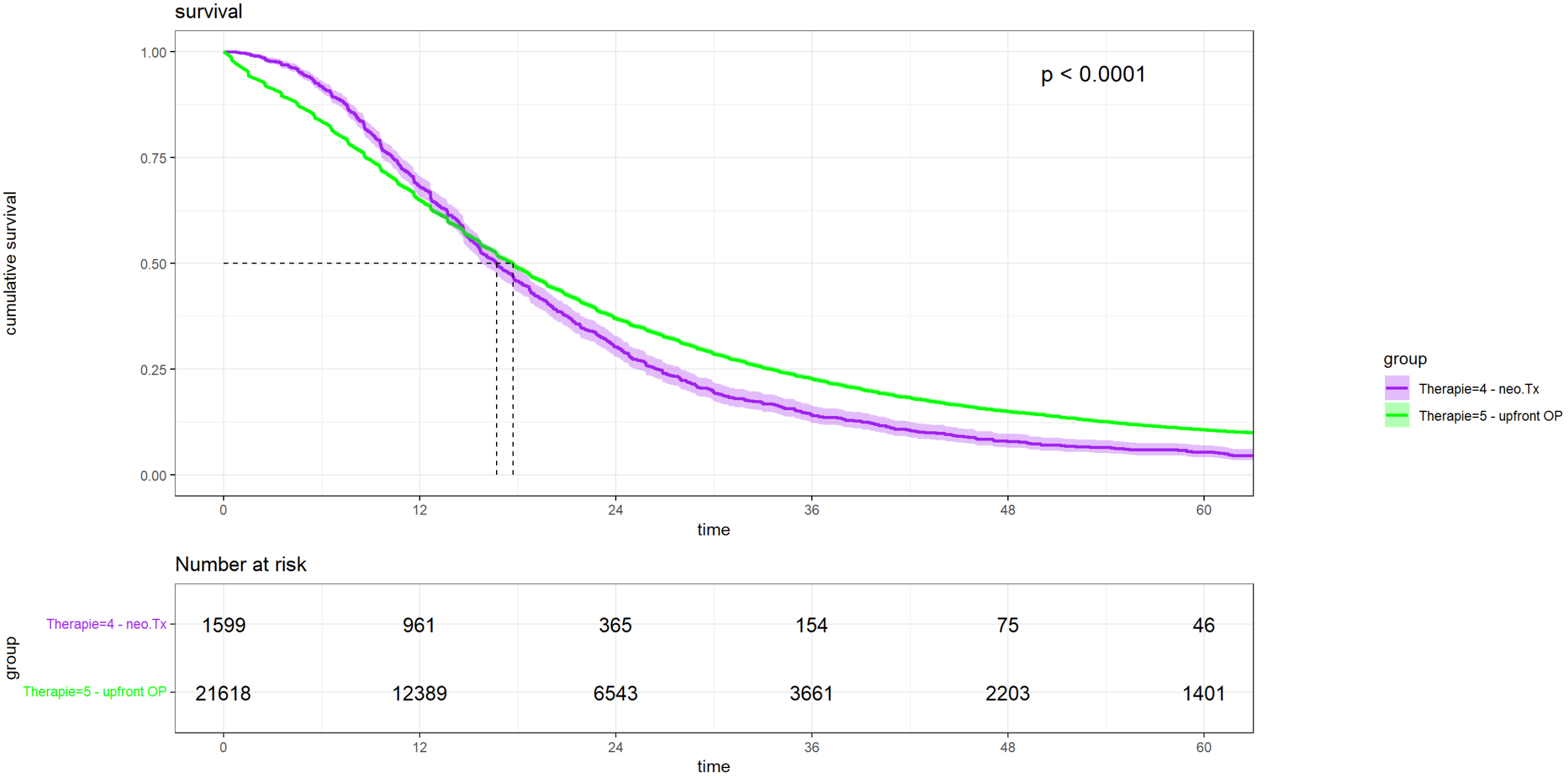


Wellner, Bolm et al, unpublished

PDAC M0 : neoadjuvant vs upfront OP



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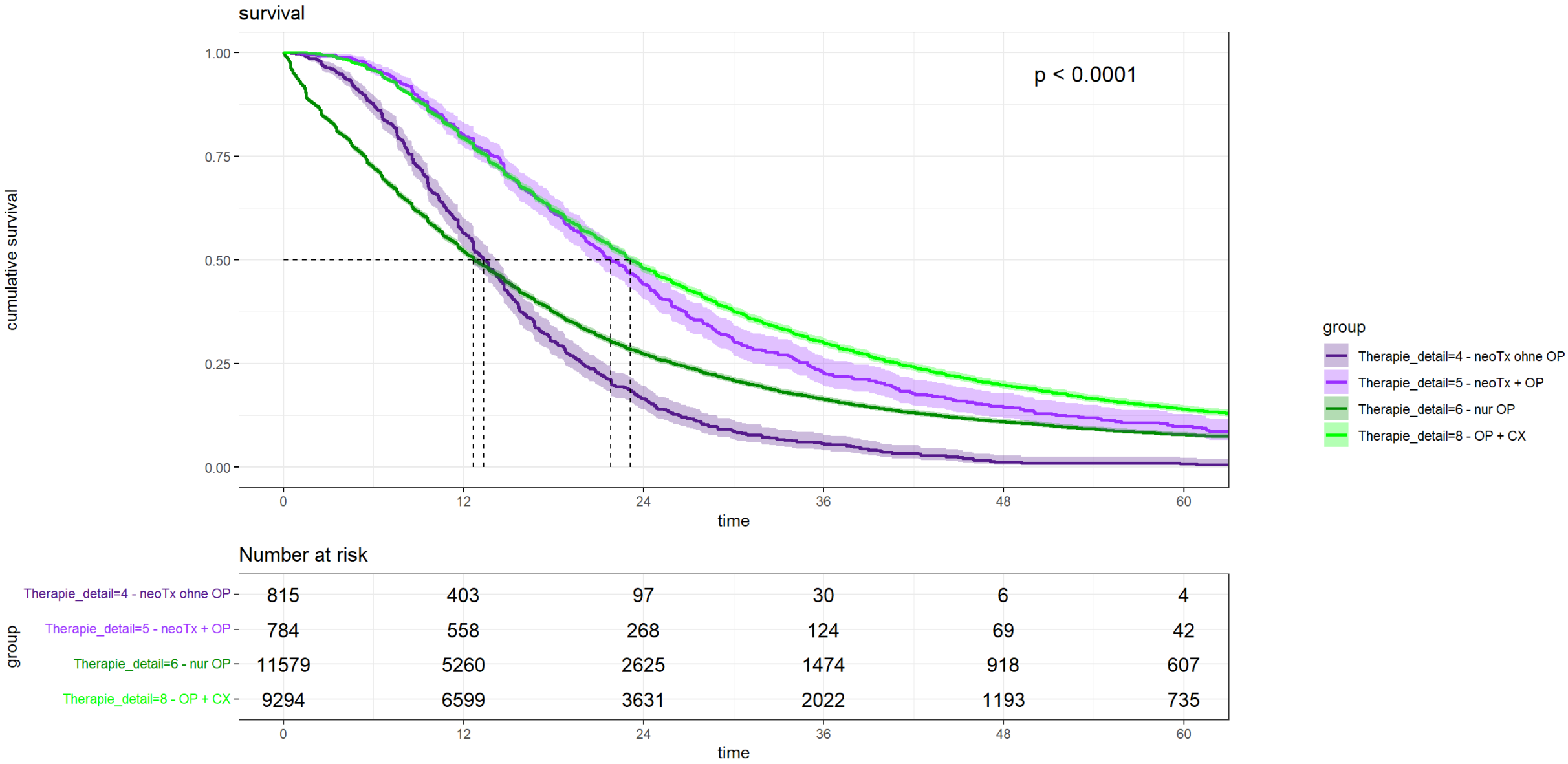
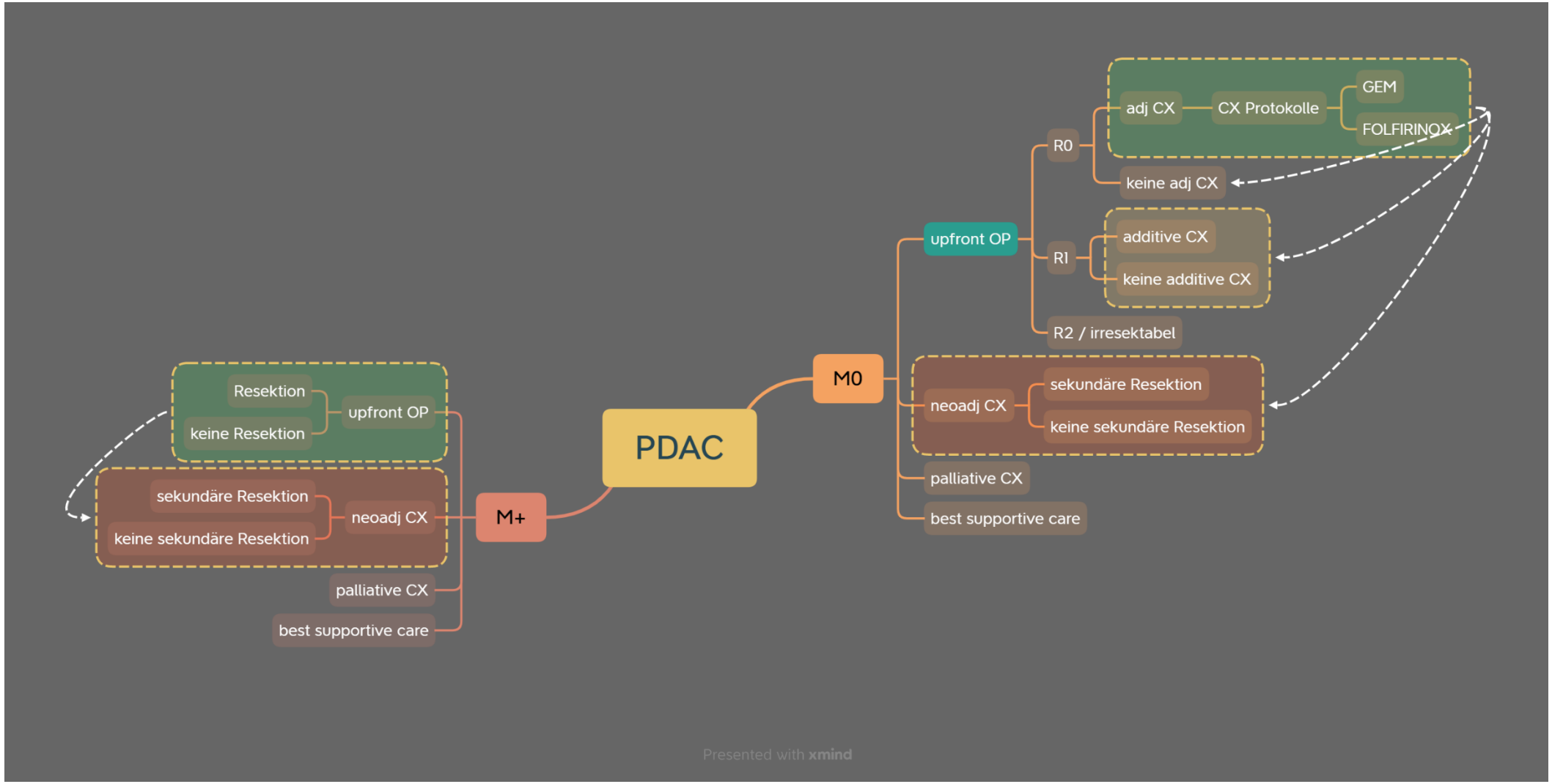
PDAC M0 : neoadjuvant vs upfront OP



Wellner, Bolm et al, unpublished



Wellner, Bolm et al, unpublished

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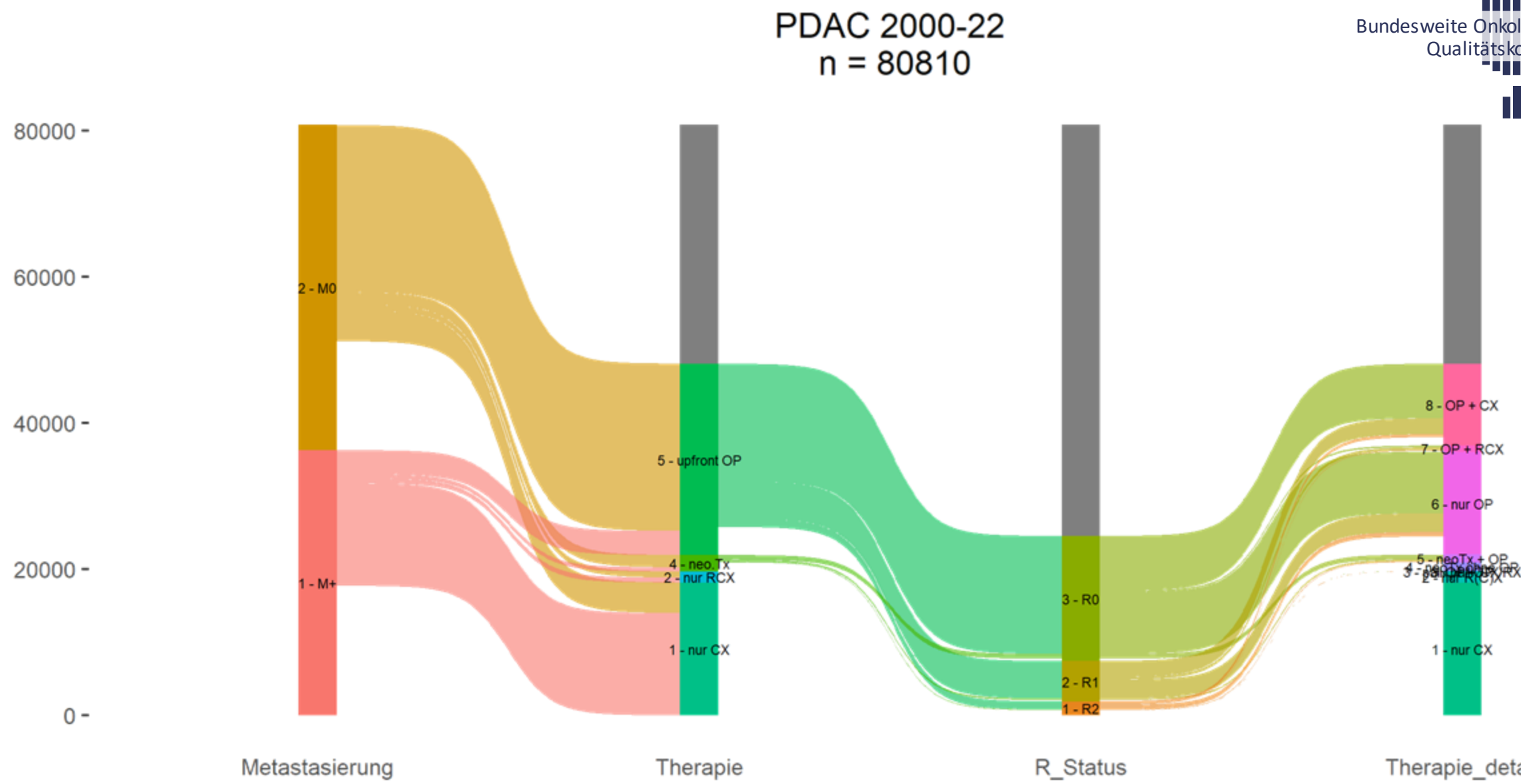

Wellner, Bolm et al, unpublished

PDAC M+ : neoadjuvant vs upfront OP

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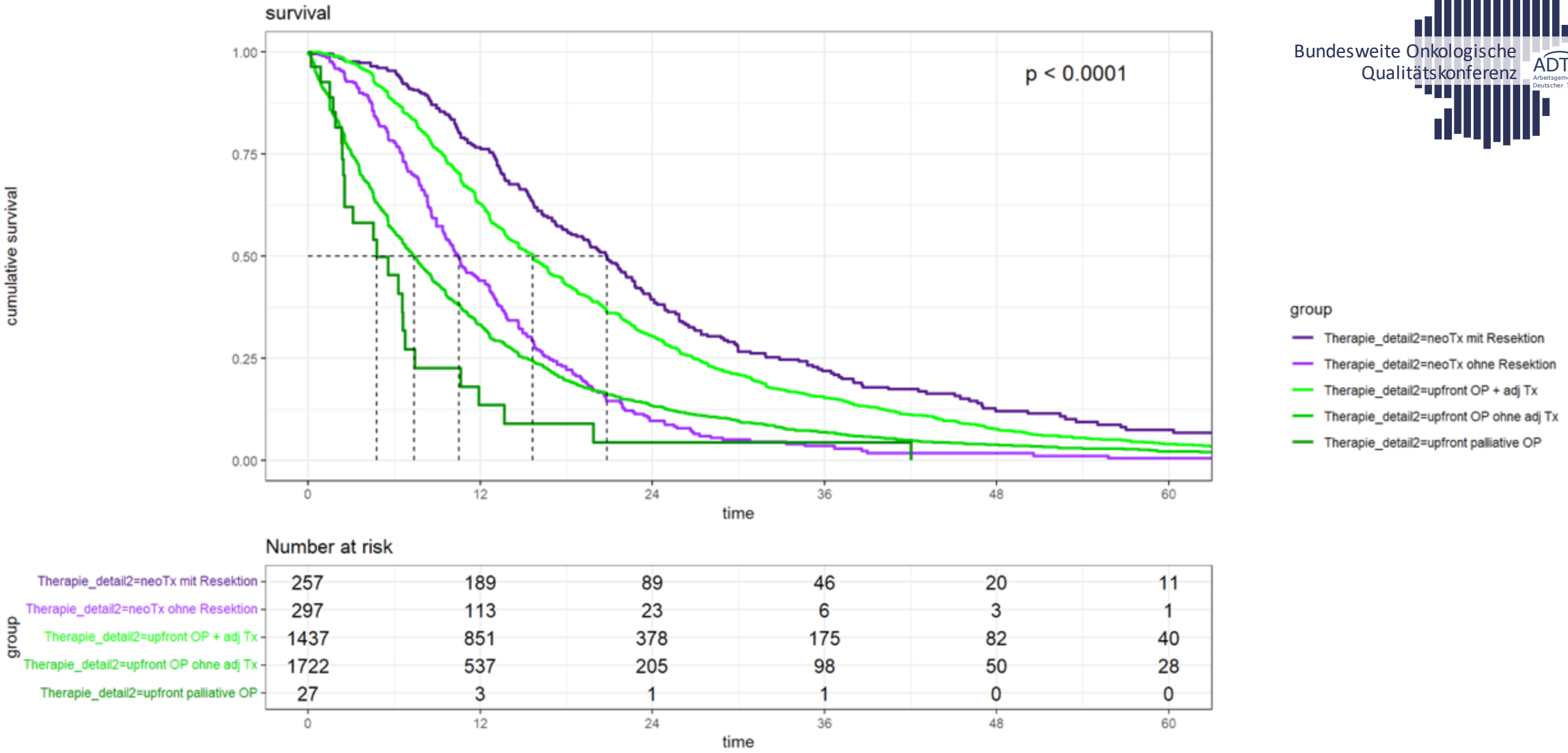

Wellner, Bolm et al, unpublished

Fazit

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Interpretation für Pankreaskarzinom:

- die beste Therapie ist **multimodal**: Resektion UND Chemotherapie
  - nur **ca. 40%** der Patienten erhalten adjuvante / additive Tx
  - -> periOP 90-Tages Mortalität (>5%) als Surrogat für periOP Komplikationen
  - -> neoadjuvant als Alternative ?

- **neoadjuvante Tx**: mindestens gleichwertig zur adjuvanten Tx
  beim lokal fortgeschrittenen PankreasCA sinnvoll
  biologische Selektion für Resektion im Stadium IV

Die klinischen Krebsregister

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Vorteile

- „Real World Data“

Nachteile

- retrospektive Daten
- Selection Bias (z.B. bei Vergleich von Therapieschemata)
- Reporting Bias (?)

Validierung

- Vergleich mit prospektiven Daten (Literatur, andere Register)

Die klinischen Krebsregister

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Ausblick / Potential beim Pankreaskarzinom

klinische Untersuchung

- multimodaler Therapie
- Second / Third line Therapieschemata
- palliativer Therapie / natürlicher Verlauf
- seltener Entitäten (z.B. Tumorsubtypen)

translational

- Verknüpfung (z.B. biologische Daten)
- Precision Medicine: z.B. Selektionskriterien gemäß DTE

Herzlichen Dank

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Auswertungsteam

Prof. Dr. med. Richard Hummel
Prof. Dr. med. Dr. h.c. Tobias Keck

Dr. med. Thaer Abdalla
Dr. med. Louisa Bolm
PD Dr. med. Rüdiger Braun
Dr. med. Jannis Duhn
Dr. med. Freiherr von Fritsch-Seerhausen
PD Dr. med. Steffen Deichmann
PD Dr. med. Kim Honselmann

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Campus Lübeck

Danke an die....

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Arbeitsgruppe Klinische Krebsregister

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Prof. Dr. med. Sylke R. Zeissig
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