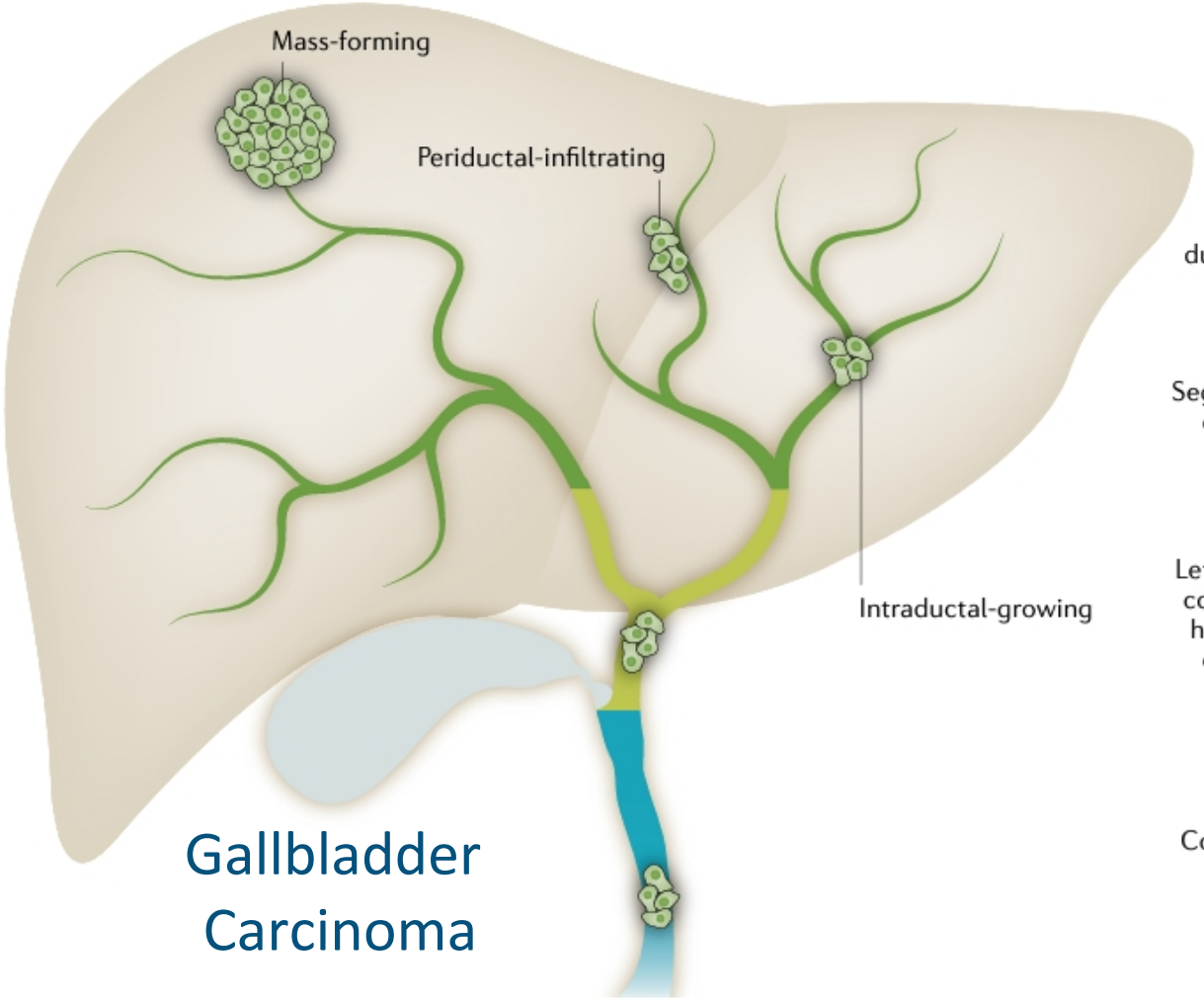
Oncology Review 2025: Biliary Tract Cancers

Gentry King, M.D.

Associate Professor, Medical Oncology

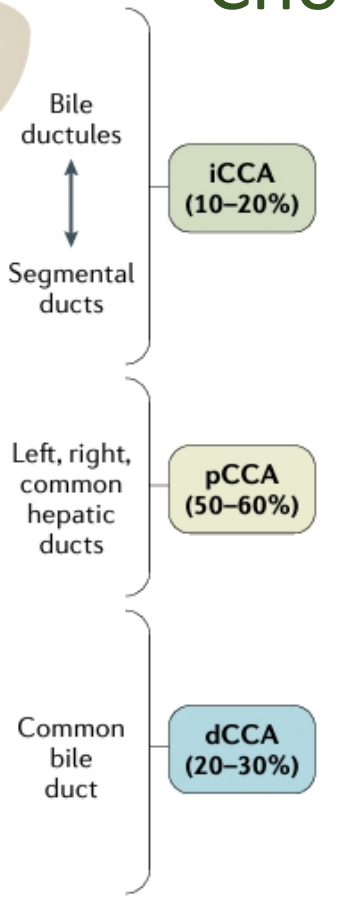
Fred Hutchinson Cancer Center, University of Washington

Distinct Anatomic Subtypes



Gallbladder Carcinoma

Cholangiocarcinoma



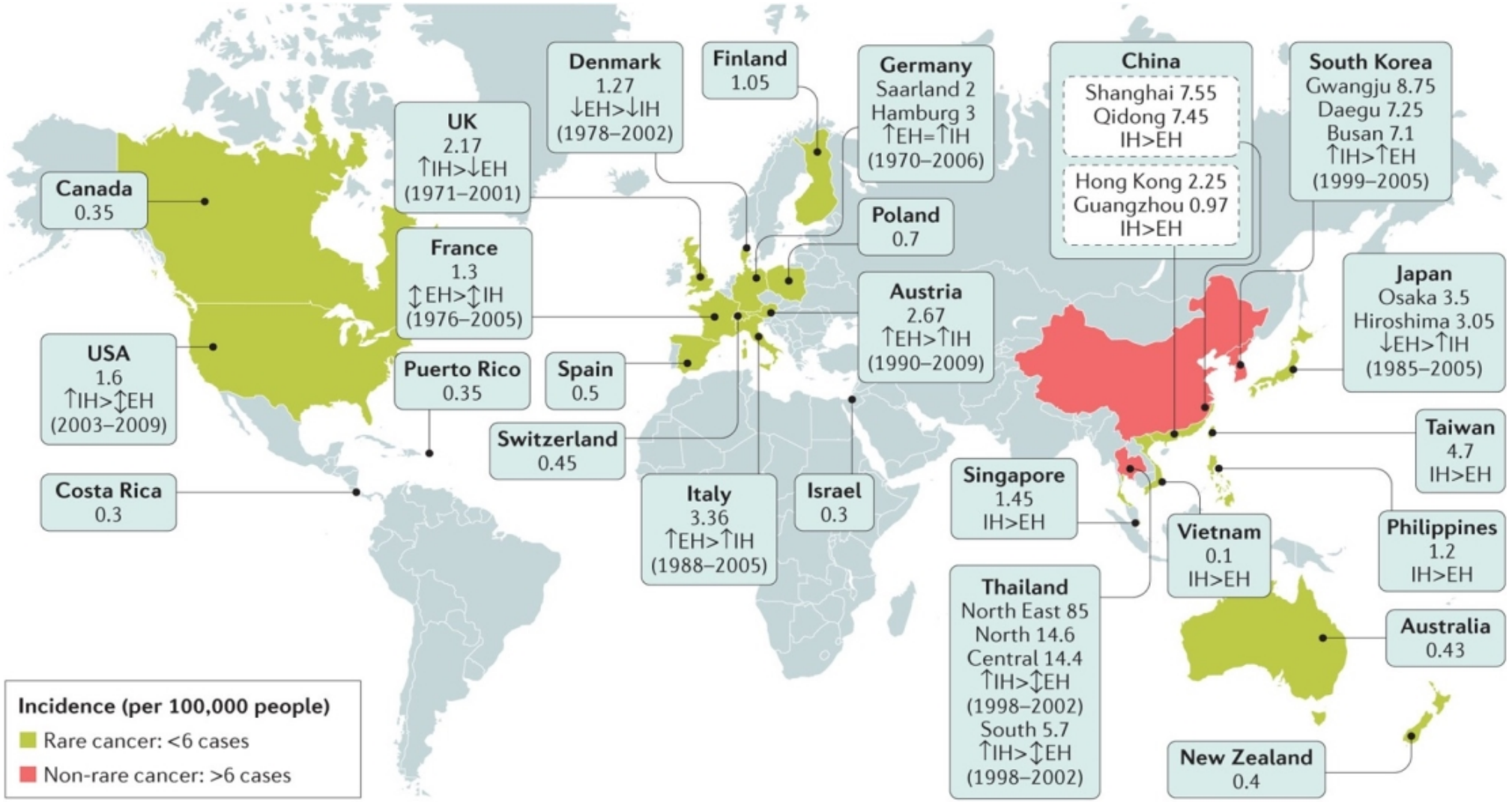
Intrahepatic CCA

Perihilar CCA (Klatskin Tumor)

Distal CCA

Banales et al Nature Reviews Gastroenterology, 2020

Cholangiocarcinoma: Low Incidence in West, Higher in East



Nature Reviews | Gastroenterology & Hepatology

*Banales, J.M., Marin, J.J.G., Lamarca, A. et al. Cholangiocarcinoma 2020: the next horizon in mechanisms and management. Nat Rev Gastroenterol Hepatol **17**, 557–588 (2020)*

Cholangiocarcinoma Risk Factors: East vs West

Great for clinical vignettes

West	East
Primary Sclerosing Cholangitis (pCCA) (15% lifetime risk)	**Liver Fluke infestation** **Opisthorcihis viverini* **Clonorchis sinensis* *Schistosoma japonicum*
Congenital Fibropolycystic Disease (Caroli Syndrome, choledochal cyst) (pCCA) (15% lifetime risk)	**Hepatolithiasis** (SEA, Taiwan)
Cirrhosis / Hepatitis, Obesity, DM, Etoh	**Recurrent Cholangitis**

**Group 1: definite human carcinogen*

GBC Risk Factors: Chronic Inflammation

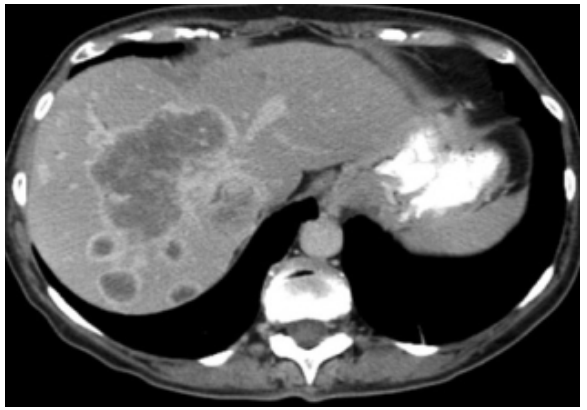
Chronic Cholecystitis **Chronic Salmonella Typhi**

CCA Clinical Presentation: Depends on Location

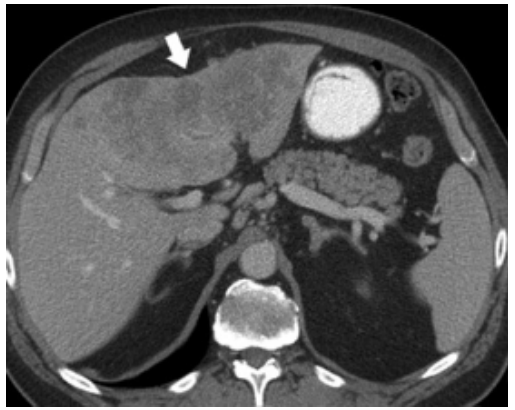
- **Intrahepatic CCA:**
  - **Mass-forming tumor**
  - **Incidental finding**, tumor of uncertain primary
  - Abd pain, anorexia, weight loss
  - Alk Phos high, Bili often normal

- **Perihilar / Extrahepatic CCA**:
  - **Biliary obstruction**: jaundice, cholangitis
  - Perihilar mass or stricture (pCCA)
  - Sometimes initially thought to be pancreas cancer (distal CCA)
  - **PSC patients: rising CA 19-9**

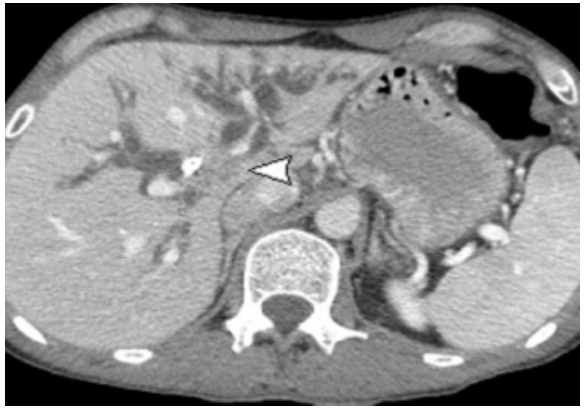
Mass forming: fibrotic enhancement



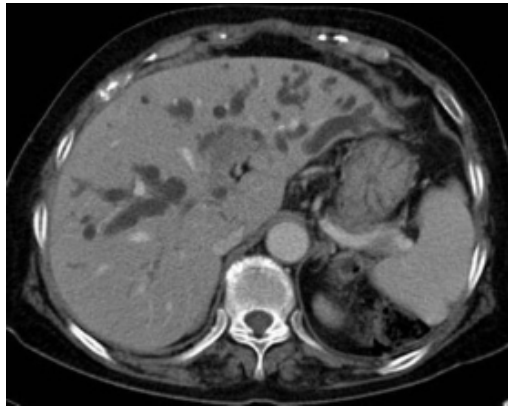
Capsular retraction



Klatskin tumor, bilateral bil dil



Intraductal growth

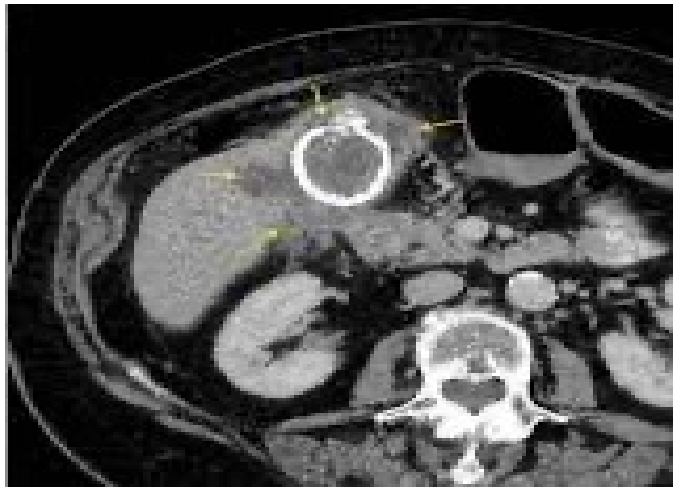


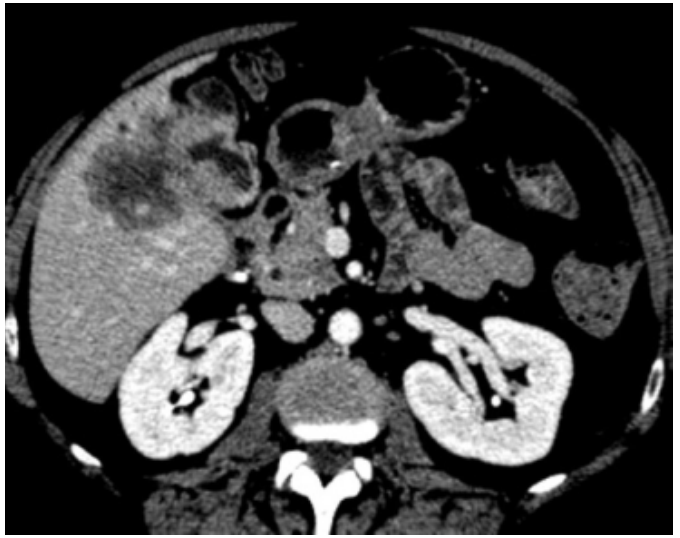
https://liveratlas.org/

One of the GI cancers that present as hypercalcemia of malignancy (hypercalcemia, hypophosphatemia, low parathyroid hormone levels, and low vitamin D levels)

Clinical Presentation: Depends on Location

- **Gall Bladder** Carcinoma:
  - Most common presentation is **incidental** cancer found on routine cholecystectomy (1-2% of cholecystectomies)
  - Otherwise, typically advanced on presentation
  - **Porcelain gall bladder:** risk of GB CA





http://www.svuhradiology.ie/case-study/porcelain-gallbladder-with-carcinoma/ https://liveratlas.org/

BTC Staging (AJCC 8th): Depends on type

	Intrahepatic	Perihilar	Extrahepatic	Gallbladder
T1	1 tumor w/o vascular invasion and is , T1a = ≤5 cm, T1b = ≥5 cm	Confined to bile duct	Bile duct wall invasion <5 mm	T1a: Invade lamina propria **T1b: Invade muscularis propria**
T2	One tumor w/ **vascular invasion** or **Multiple tumors** +/- vascular invasion	T2a/b: Invades adipose or liver tissue	Bile duct wall invasion 5-12 mm	T2a/b: Invades perimuscular connective tissue
T3	Any tumor perforating visceral peritoneum	Invades unilateral branches portal v or hepatic aa	Bile duct wall invasion >12 mm	Involvement of serosa or invasion of liver or adjacent organs
T4	Any tumor with direct invasion of local extrahepatic structures	Invades main PV or bilateral branches or CHA	Involves celiac axis, SMA, and/or CHA	Invades portal v, hepatic aa, or two or more extrahepatic organs
N1	**Any + regional nodes**	1-3	1-3	1-3
N2	N/A	≥4	≥4	≥4

Surgical Management

- **Intrahepatic**: Hepatic resection +/- portal LN dissection
- **Perihilar CCA**: Bile duct resection or **liver transplant**
- **Distal CCA**: Bile duct resection + cholecystectomy + **Whipple**
- **Gallbladder:** Cholecystectomy + **hepatic segmental resection (IVB/V), lymphadenectomy,** possible bile duct excision.

Resectable GBC: T1b and above is high risk

- **T1a:** no invasion of muscularis propria:
  - 75-100% long term survival
  - **Only simple cholecystectomy** needed, no adjuvant therapy
- **T1b:** muscle invasive disease
  - High risk of recurrence
  - **Cholecystectomy + hepatic segmental resection (segments IVB/V), lymphadenectomy, possible bile duct excision + adjuvant chemo**

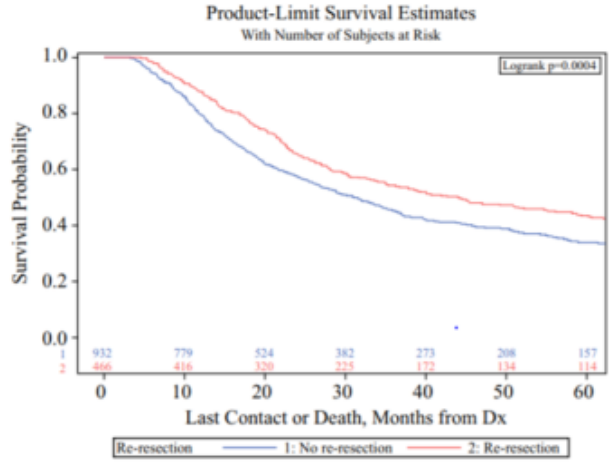
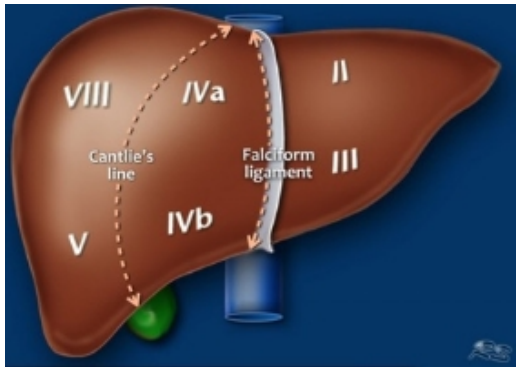


FIG. 5 Kaplan-Meier survival curves for gallbladder adenocarcinoma patients who did and did not undergo re-resection after matching

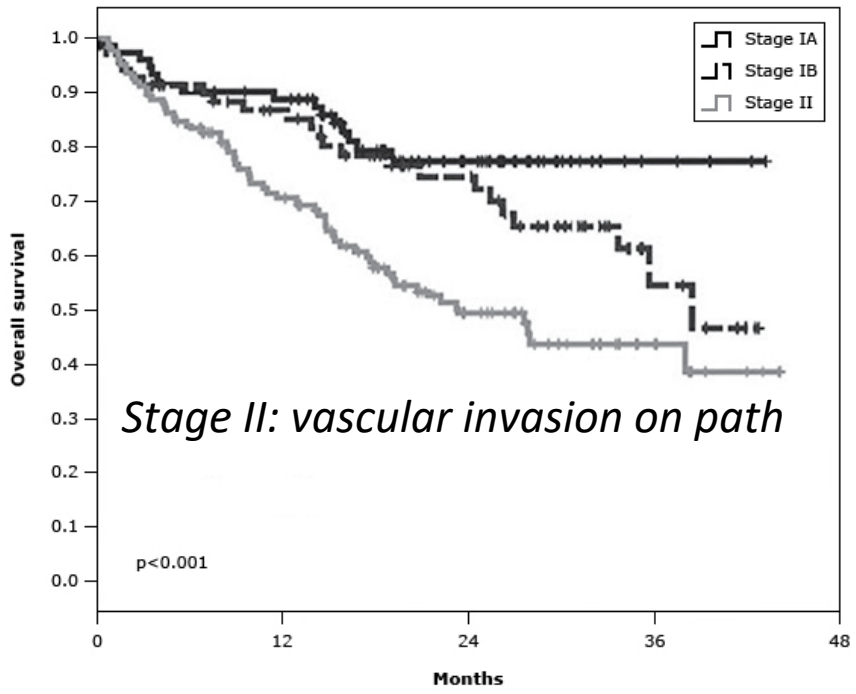


Papageorge MV, et al. Ann Surg Oncol (2021) 28:2949–2957

High Risk Features for Recurrence

Main factors are stage, **nodal** involvement and **margin**

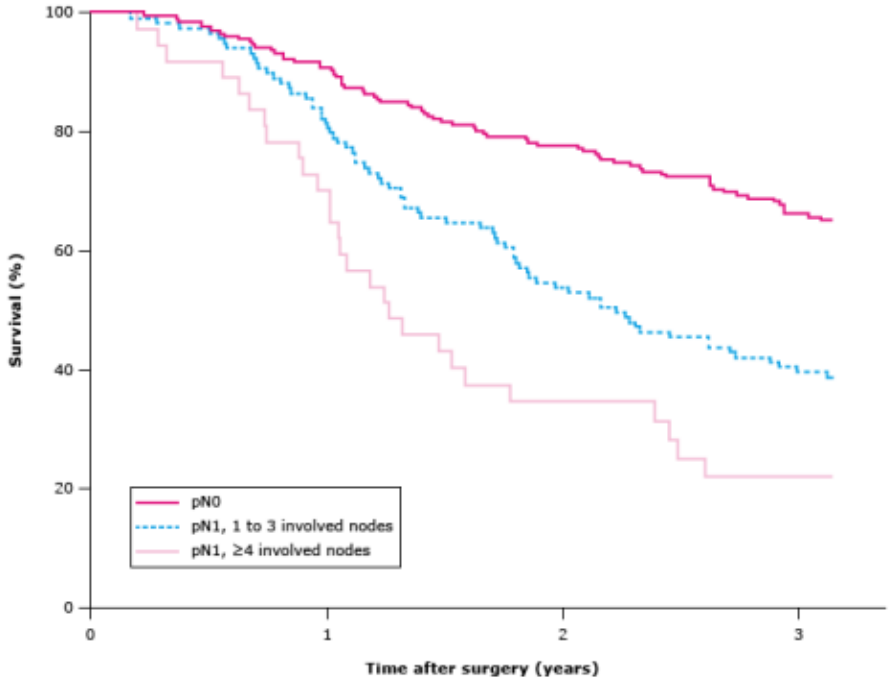
Stratification for survival in a series of 861 patients with intrahepatic cholangiocarcinoma based on revised AJCC/UICC 8th edition definitions for stage IA, IB, and II disease



Stage II: vascular invasion on path

AJCC 8th Ed

Survival after potentially curative resection in a multi-institutional series of 370 patients undergoing pancreaticoduodenectomy for a distal bile duct cancer



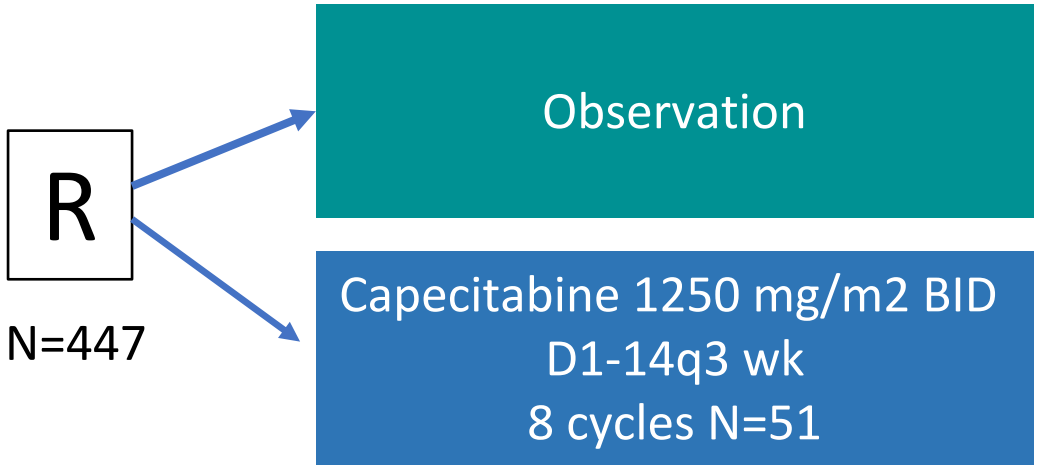
Kiriyama M, Ebata T, Aoba T, et al. Br J Surg 2015; 102:399.

Adjuvant Therapy: BILCAP

something is better than nothing

- Randomized open-label multi-center UK ph III trial: Cape vs Obs
- Took 10 years to complete

CCA or muscle-invasive GBC cancer macroscopic complete resection
ECOG 0-2
Within 16 weeks of surgery



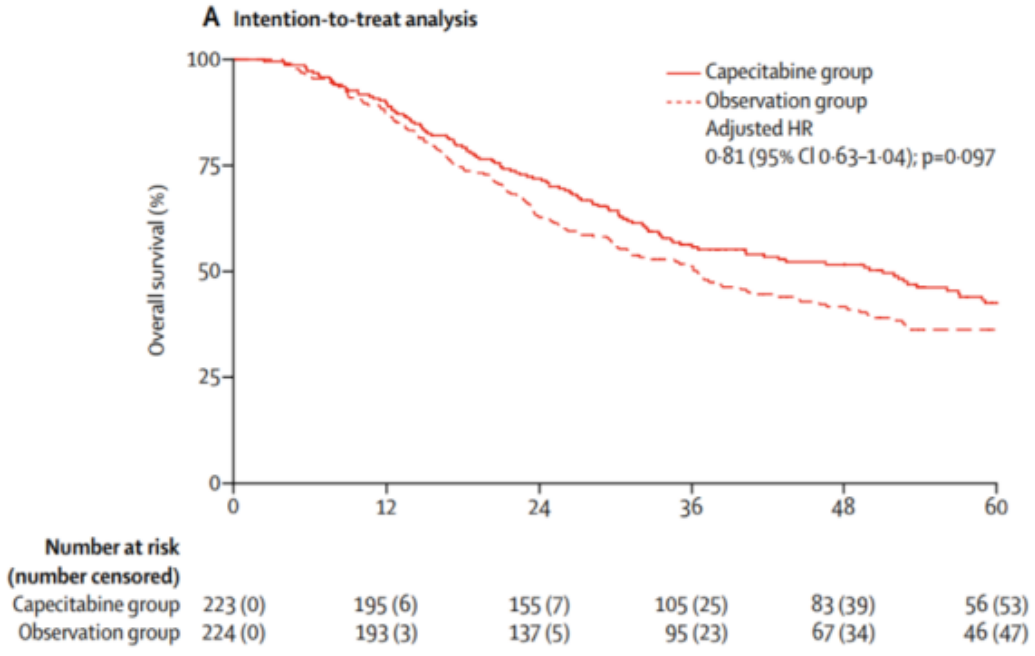
Primary: Overall survival (OS) by **intention-to-treat**

Secondary: Outcome by **per-protocol analysis**
Relapse free survival (RFS)
Toxicity, Quality of life, Health economics

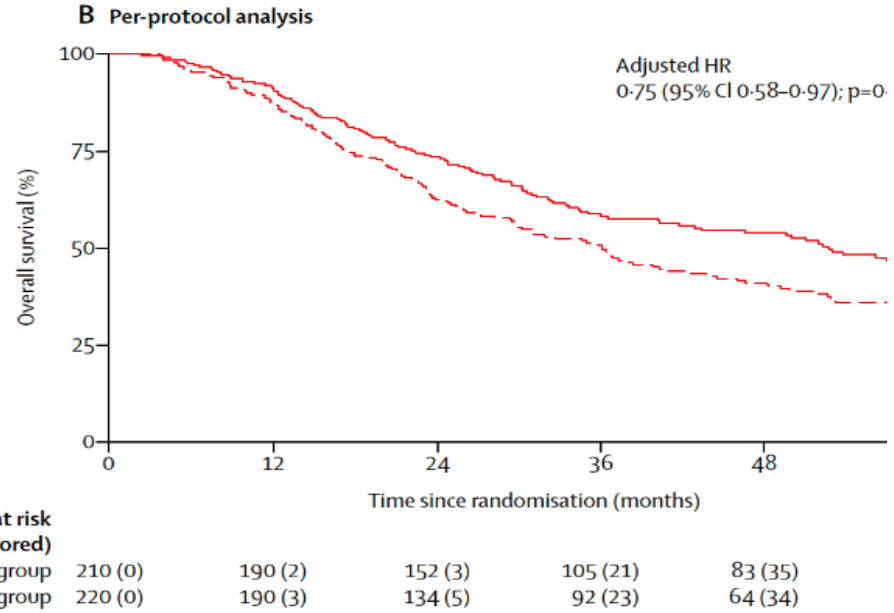
Primrose JN et al. Lancet Oncol 2019; 20: 663-73

BILCAP: Highest level of evidence in adjuvant tx

Intention-to-treat analysis



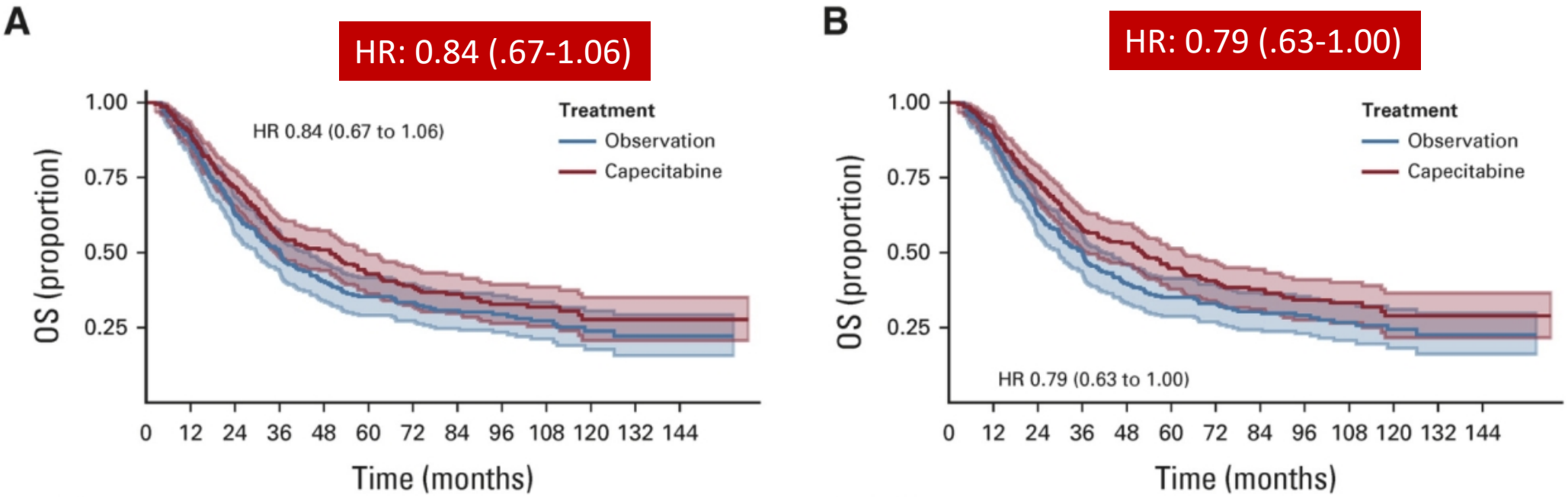
Per-protocol analysis



- No OS benefit in ITT analysis, but **OS benefit seen in Per-protocol Analysis**
- Difference of 17 patients ineligible/withdrawal of consent prior to starting treatment
- **Median OS: 53 mo vs 36 months**
- **Median RFS: 25.9 mo vs 17.5 mo (similar for both ITT and per-protocol analysis)**

Primrose JN et al. Lancet Oncol **2019**; 20: 663-73

BILCAP: 8 year follow up: still meh



- Planned sensitivity analyses in the **ITT** population showed an **OS HR for capecitabine of 0.74 (0.59 to 0.94), after ADJUSTING** for the effect of identified prognostic factors (nodal status, grade of disease, and sex, in addition to the minimization variables site of disease, resection status, and ECOGPS).

No OS benefit in ITT analysis, but **OS benefit seen in Per-protocol Analysis…but barely made the cut and the benefit mostly in the first 2 years**

STAMP: More Adjuvant Chemo not better for eCCA

Multicenter, open-label, randomized Ph II, 3 Korean centers

Extrahepatic CCA (pCCA,dCCA)
Adenocarcinoma histology
Macroscopic Resection (R0, R1)
≥1 regional LN met
ECOG 0-1

R

N=101

Gemcitabine 1000mg/m2
Cisplatin 25mg/m2, D1,8
8 cycles N=50

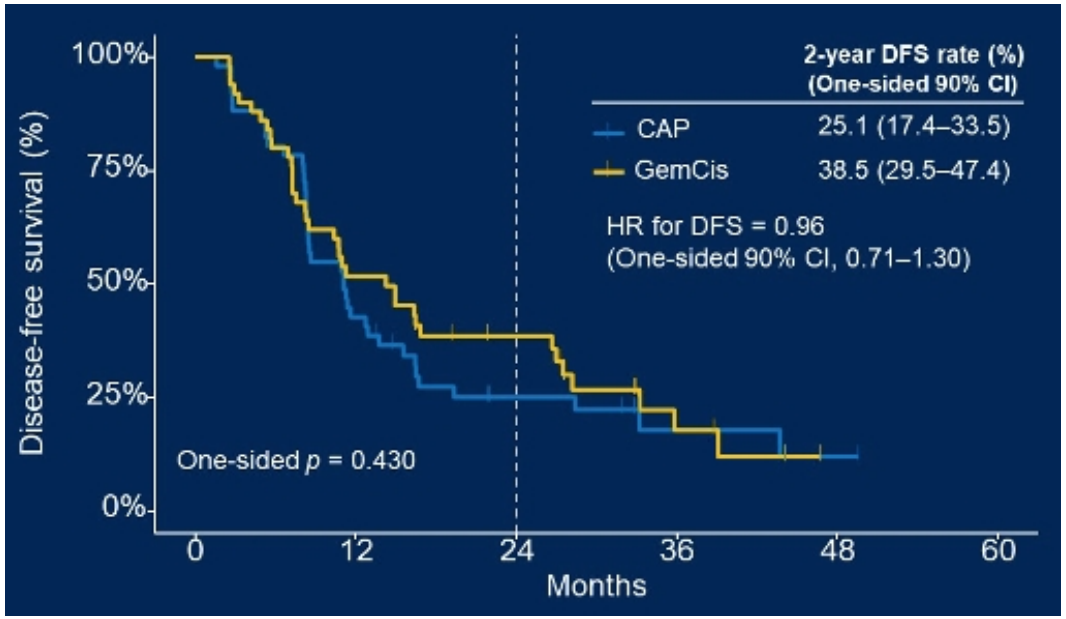
Capecitabine 1250 mg/m2 BID
D1-14q3 wk
8 cycles N=51

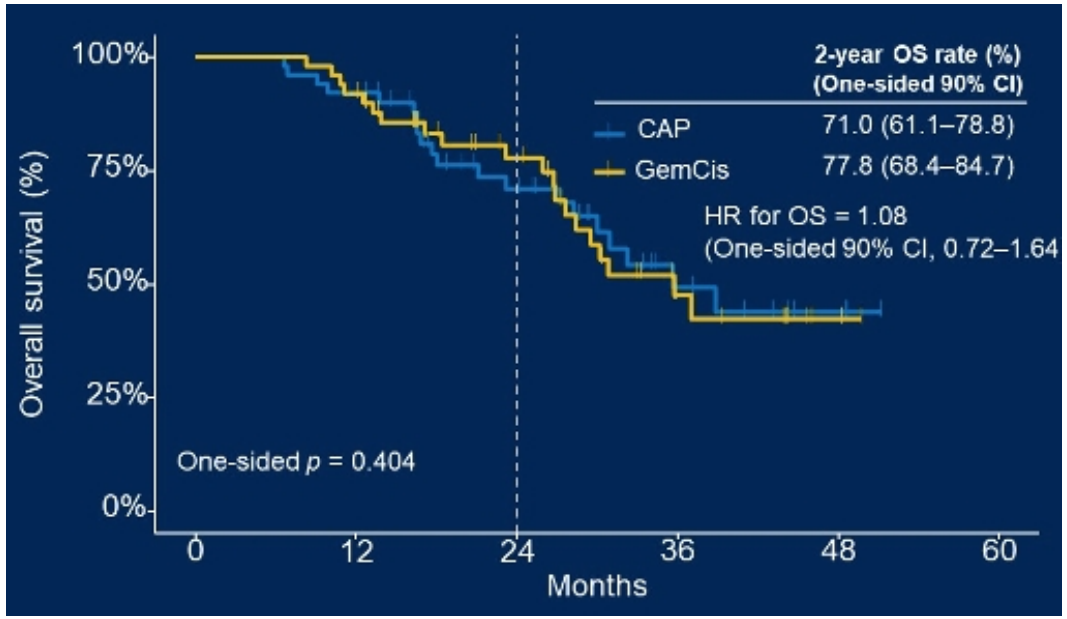
Primary Endpoint: DFS
Secondar Endpoint OS, Safety, EORTC QLQ

Yoo et al Journal of Clinical Oncology 2022 40:16_suppl, 4019-4019

Adjuvant Therapy: More not Better for eCCA

STAMP: Multicenter, open-label, randomized Ph II, 3 Korean centers





Negative study: no statistical difference in PFS or OS
No trends in subgroup analysis
More grade 3 AE with GemCis (42%) vs Cape (16%), mostly cytopenias

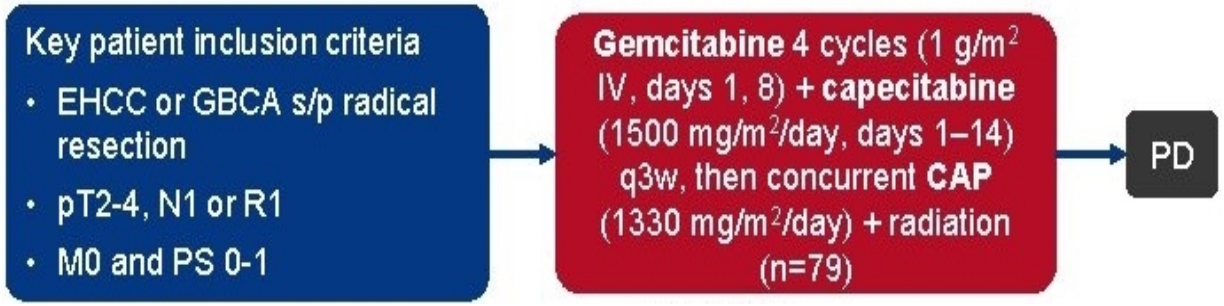
Unknown for iCCA

Yoo et al Journal of Clinical Oncology 2022 40:16_suppl, 4019-4019

Prospective Data: SWOG 0809 for eCCA /GBC

Phase II trial, single arm trial attempted to establish a standard practice (2014) for adjuvant therapy of **eCCA & GBC**, N=79 pT2-4 AND either N+ or R1 resection

4 cycles Gem/Cape → cape chemoradiation 54-59 Gy



	All pts (%, 95% CI)	Extrahepatic	Gallbladder
2-yr OS	65 (53-74)	**68 (54-79)**	**56 (35-73)**
2-yr DFS	54 (40-66)	**54 (39-66)**	**48 (28-66)**
2-yr LR	11 (4-18)	13 (4-22)	8 (0-19)

Primary endpoint: OS
Secondary Endpoints: DFS, Safety

86% completed therapy
mOS 34 months
Applicability limited due to single arm

Ben-Josef E et al. J Clin Oncol, 2014;33:261-2622

Systemic Therapy for BTC: Rapidly Evolving

First-line

Gemcitabine Cisplatin
ABC-02 (included ampullary)
ORR: 26% (vs 21%), mOS: 11mo
2010

Gemcitabine Cisplatin Durvalumab
TOPAZ-1
ORR: 26.7% (vs 18.7%) ,mOS 12.8mo
2022

Gemcitabine Cisplatin Pembrolizumab
Keynote 966
ORR: 29% ,mOS 12.7mo
2023

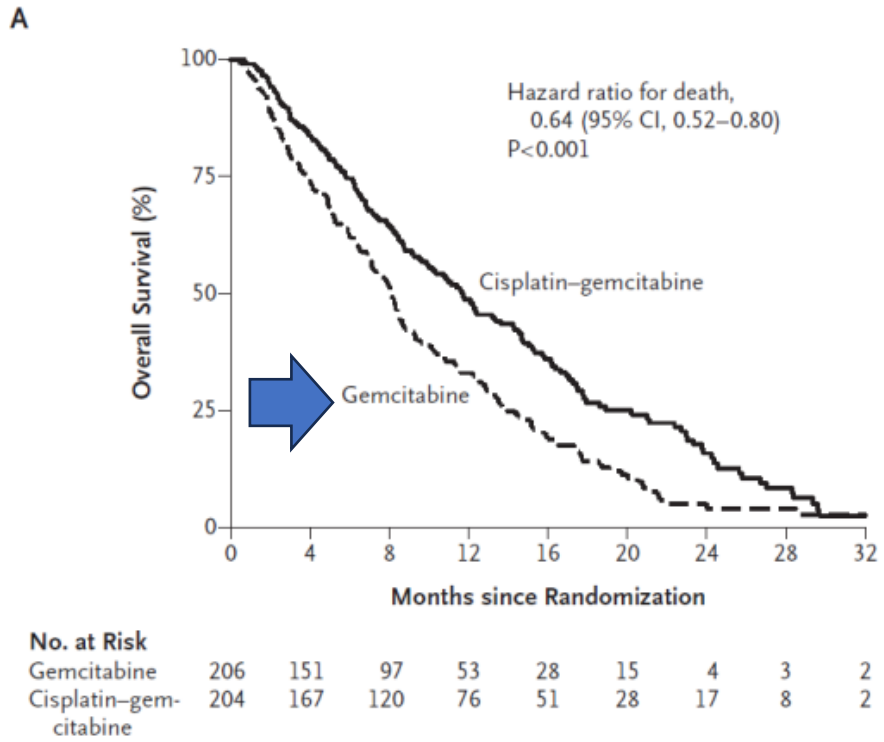
Gemcitabine Cisplatin
Nab-Paclitaxel ? SWOG 1815 was negative

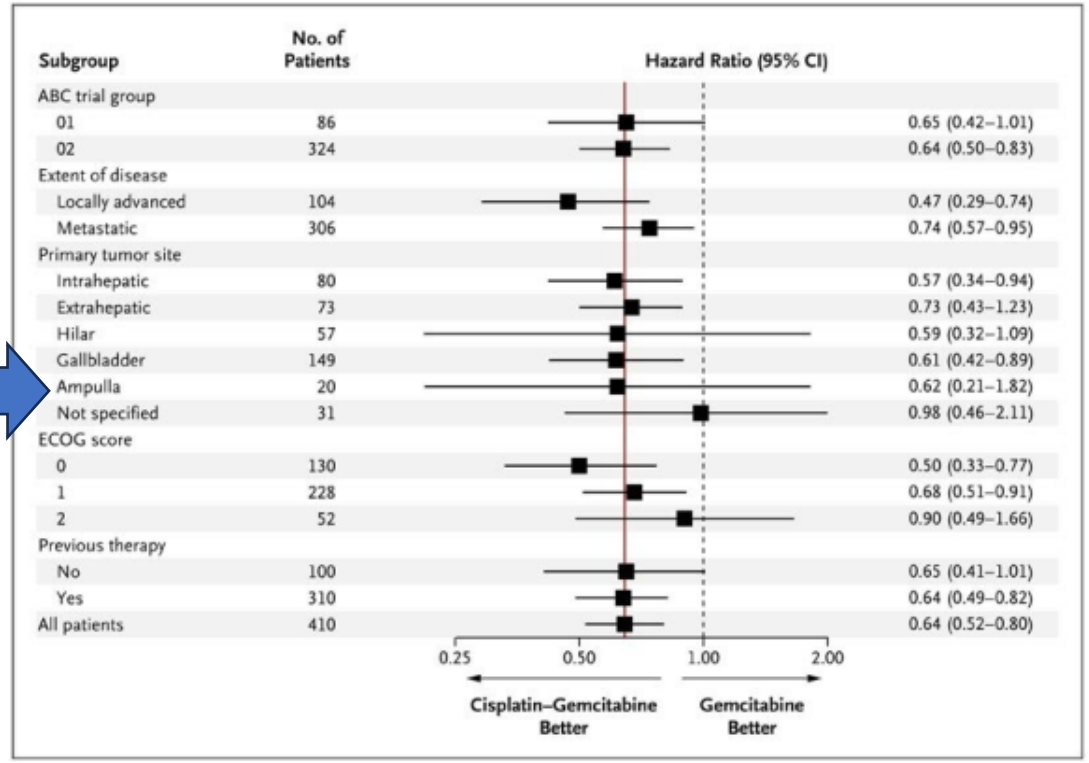
Second-line

No Targets	**FOLFOX** ABC-06 ORR: 5%, mOS 6.2mo	2018	**5-FU Nal-IRI** Nifty ORR: 14.8%, mOS 8.6mo	2021
FGFR2 fusion	***Pemigatinib** FIGHT-302 ORR: 35.5%, mOS 21.2mo	2020	***Futibatinib** FOENIX-CCA2 ORR: 42%, mOS 21.7mo	2022
IDH-1 mutation	**Ivosidenib** ClarIDHy ORR: 2%, mOS 10.3	2022		
BRAF V600E	**Dabrafenib/Trametinib** ROAR tissue agnostic, ORR: 36%, DCR 76%	2022		
ERBB2 amplification HER 2 “positive’	**⁺Trastuzumab/Pertuzumab** MyPathway, ORR: 40%		**T-Dxd (Enhertu)** DESTINY Pan-Tumor02 ORR:22%, mOS 7mo	
MSI-H	**Pembrolizumab** KEYNOTE cohorts ORR:39.6%	2017	**Dostarlimab-glxy** GARNET ORR: 41.6%	2021
NTRK fusion	**Larotrectinib** LoxoTRK, SCOUT, NAVIGATE ORR: ~60-70%	2018	**Entrectinib** STARTRK1,2 ORR: 57%	2019
RET Fusion	**⁺Pralsetinib** BLU-667, tumor agnostic, 2B rec	2022		

Systemic Therapy for BTC: The Early Days

ABC-02 trial: Randomized Ph III trial Gemcitabine vs Gemcitabine + Cisplatin in **first-line BTC**





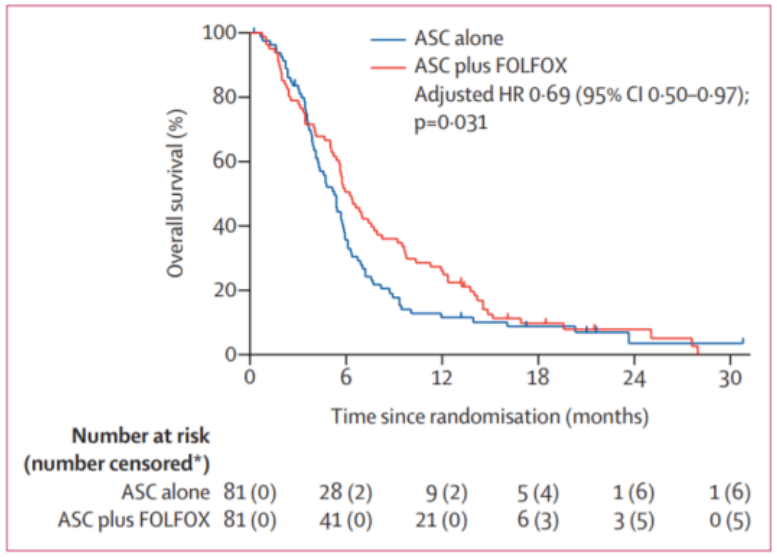
Improved DCR: 81.4% vs. 71.8% (p=0.049), ORR: 26% vs 21 %

mOS 11.7 vs. 8.1 months (p<0.001), Treatment compliance better with Gem Cis

Valle et al N Engl J Med 2010

Second-line: Options: which one?

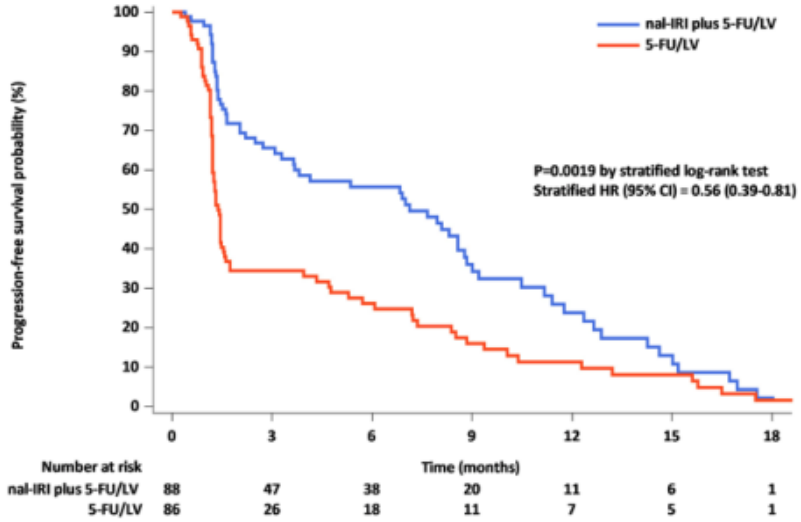
ABC-06: FOLFOX vs ASC (UK)



	FOLFOX	ASC
Median OS	**6.2 mo**	5.3 mo
Median PFS	4.0 mo	N/A
ORR	**5%**	N/A

Lamarca A, et al. Lancet Oncol 2021; 22:690-701.

NIFTY: 5-FU vs 5-FU+Nal-IRI (Korea)



	Nal-IRI+ 5-FU/LV	5-FU-/LV
Median OS	8.6 mo	5.5 mo
Median PFS	3.9 mo	1.6 mo
ORR	**14.8%**	**5.8%**

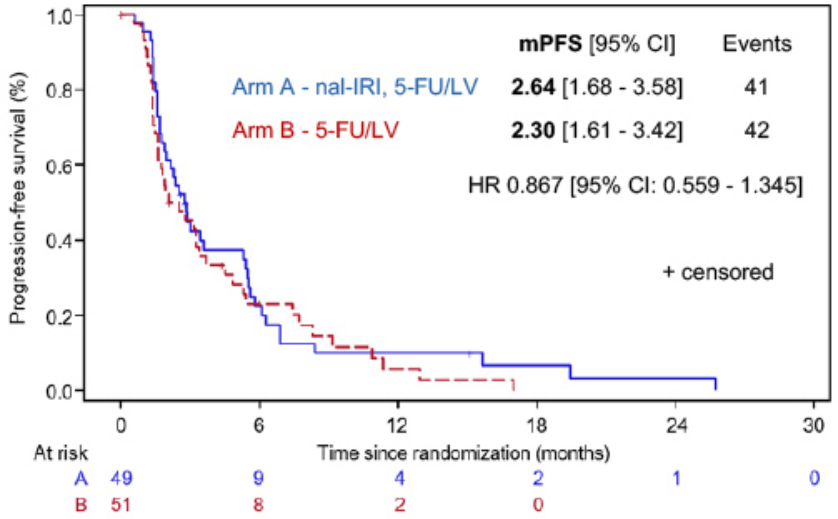
Yoo C, et al. Abstract 4006. 2021 ASCO Annual Meeting

NALIRICC: Different results in Germany

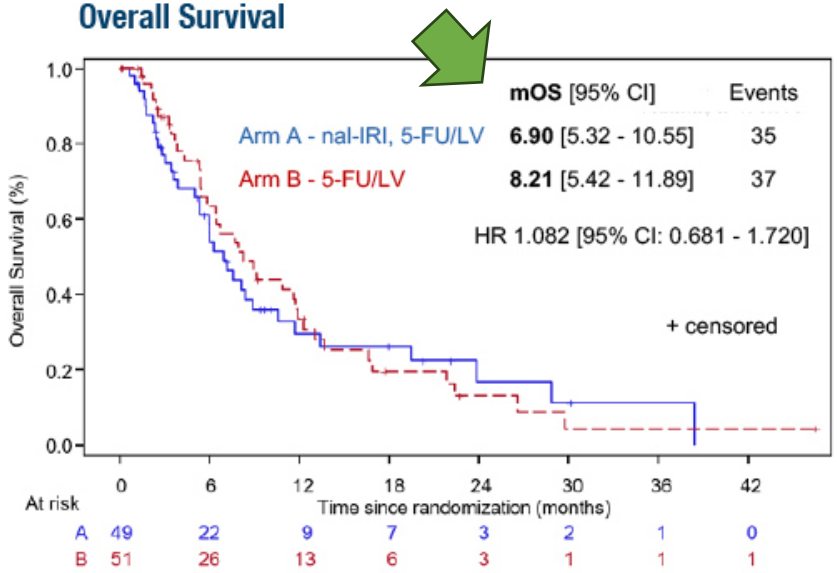
NALIRICC I Efficacy Results

Response was evaluated per RECIST v1.1, every 6 weeks

Progression-free survival



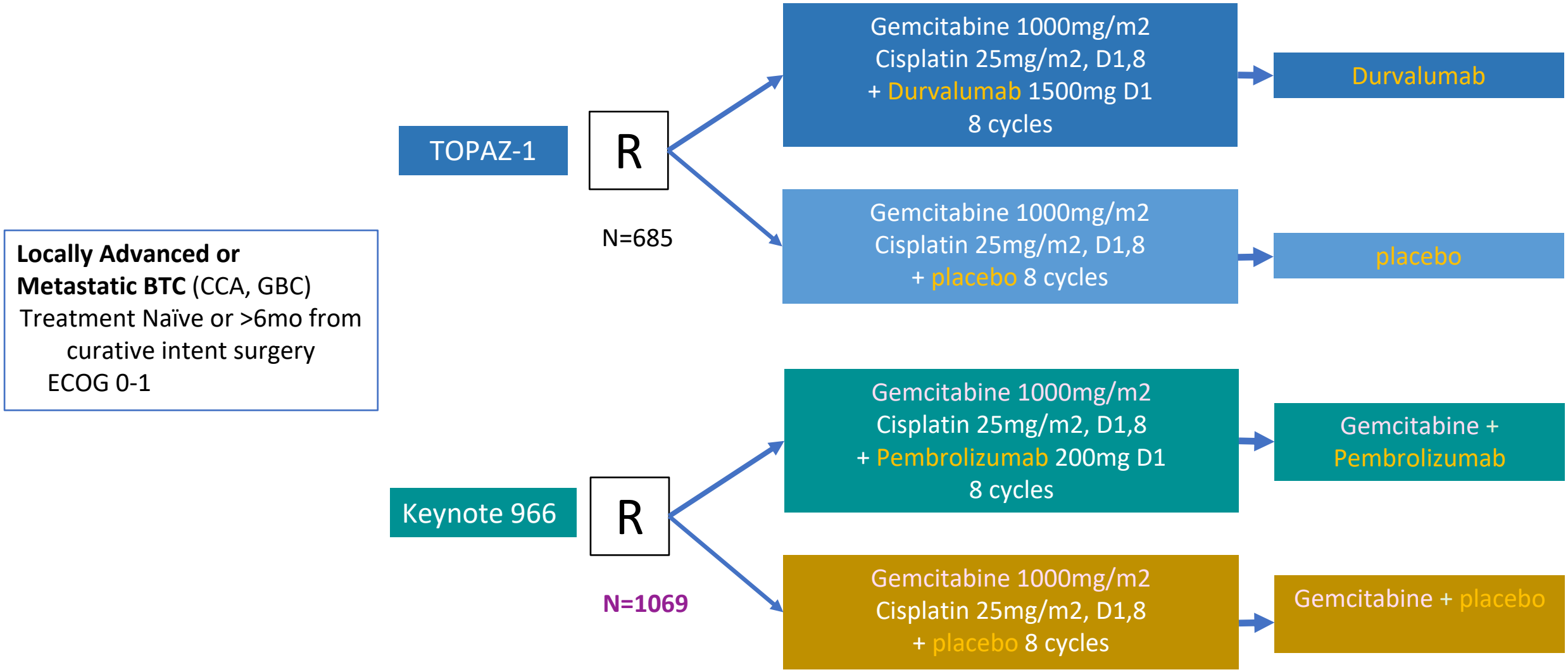
Overall Survival



		CR Complete remission	PR Partial remission	SD Stable disease	PD Progressive disease	Missing value	ORR	DCR
Arm A - Nal-IRI, 5-FU/LV	N = 49	1 (2.0%)	6 (12.2%)	18 (36.7%)	12 (24.5%)	12 (24.5%)	7 (14.3%)	25 (51.0%)
Arm B - 5-FU/LV	N = 51	1 (2.0%)	1 (2.0%)	21 (41.2%)	20 (39.2%)	8 (15.7%)	2 (3.9%)	23 (45.1%)

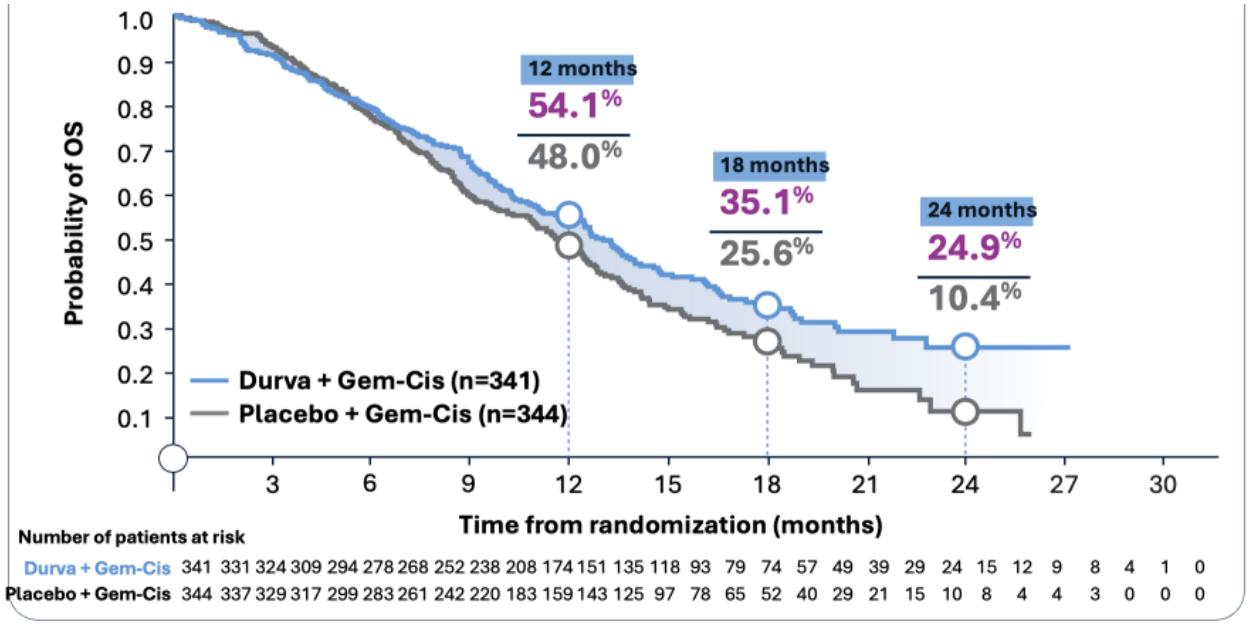
https://dailyreporter.esmo.org/esmo-congress-2022/upper-gi-tumours/second-line-chemotherapy-for-advanced-biliary-tract-provides-modest-efficacy-but-quality-of-life-benefit

New First-line treatment : ICI + Chemo



New First-line treatment : ICI + Chemo

TOPAZ-1

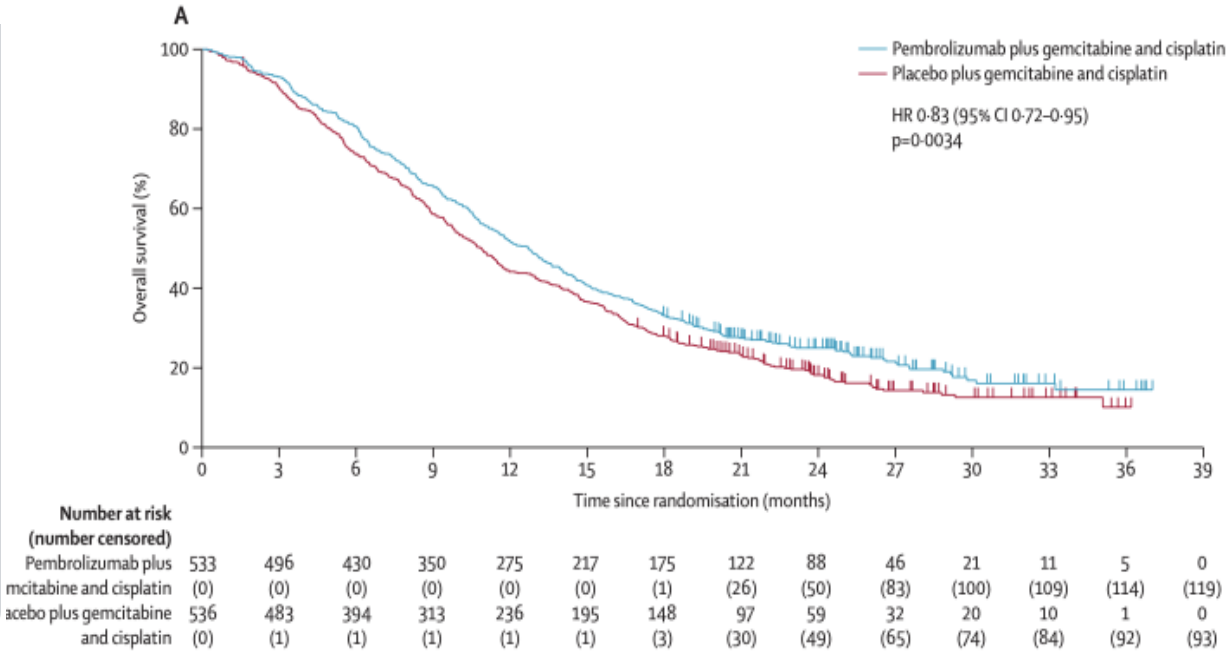


HR: 0.80 (95% CI O.66-0.97), P=0.021 (sig)
GC+ Durva: mOS: 12.8
GC+ Placebo: mOS: 11.5

1.3mo diff

Oh, D-Y. et al. Annals of Oncology, Volume 33, S565 - S566

Keynote-966



HR: 0.83 (95% CI O.72-0.95), P=0.0034 (sig)
GC+ Pembro: mOS: 12.7
GC+ PemPlac: mOS: 10.9

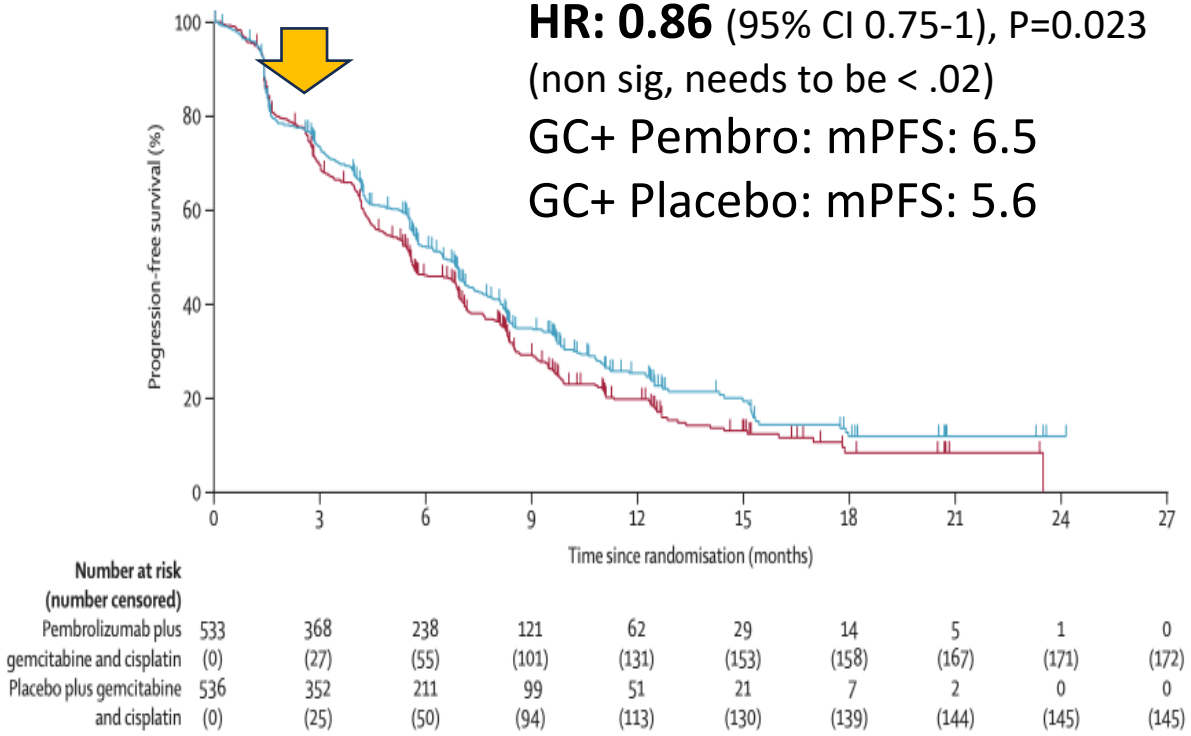
1.8mo diff

Kelley R.K. The Lancet, Volume 401, Issue 10391, 1853 - 1865

Benefit for those with response

Keynote-966

PFS: not stat sig (-), trend, separated early, sustained



HR: 0.86 (95% CI 0.75-1), P=0.023
(non sig, needs to be < .02)
GC+ Pembro: mPFS: 6.5
GC+ Placebo: mPFS: 5.6

Kelley R.K. The Lancet, Volume 401, Issue 10391, 1853 - 1865

Keynote-966 *Blinded central review*

	GC + Pembro	GC + Placebo
ORR	**29%**	**29%**
DoR	9.7	6.9
24mo ongoing OR	18%	6%

TOPAZ-1 *Investigator review*

	GC + Durva	GC + Placebo
ORR	**27%**	**19%**
DoR	6.4	6.2
>12mo ongoing OR	26%	15%

Oh, D-Y. et al. Annals of Oncology, Volume 33, S565 - S566

Who benefits? Additive / Synergistic?

Experience with ICI monotherapy

Original Investigation

FREE

April 30, 2020

A Phase 2 Multi-institutional Study of Nivolumab for Patients With Advanced Refractory Biliary Tract Cancer

Richard D. Kim, MD[1]; Vincent Chung, MD[2]; Olatunji B. Alese, MD[3]; et al

Author Affiliations | Article Information

JAMA Oncol. 2020;6(6):888-894. doi:10.1001/jamaoncol.2020.0930

N = 54, central review **ORR = 11%**

Meeting Abstract: 2023 ASCO Gastrointestinal Cancers Symposium

FREE ACCESS | Hepatobiliary Cancer | January 24, 2023

A multicenter, single-arm, phase II study of nivolumab in patients with biliary tract cancer with a PD-L1 combined positive score ≥ 1.

Authors: Masayuki Furukawa, Makoto Ueno, Daisuke Sakai, Kota Ouchi, Yasuo Hamamoto, Hiroshi Aika, Masato Ozaka, ... SHOW ALL ..., and Junji Furuse | AUTHORS INFO & AFFILIATIONS

Publication: Journal of Clinical Oncology • Volume 41, Number 4_suppl • https://doi.org/10.1200/JCO.2023.41.4_suppl.533

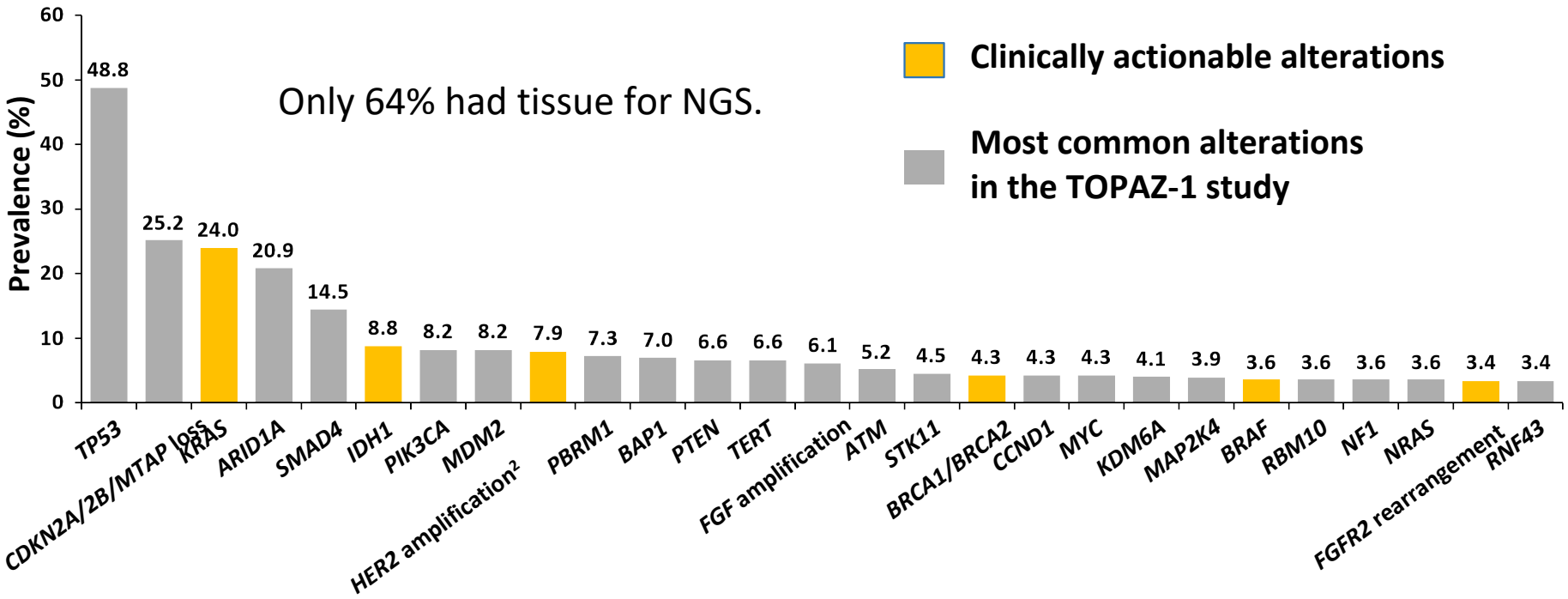
49

N=82 central assessment **ORR: 11%**

* One vial of 200mg Pemrbolizumab is ~ $23,000 …. Not including staff, infusion, overhead

Molecular subsets that benefit?

Exploratory Analysis of Prevalence of Genomic Alterations (≥3%) in TOPAZ-1

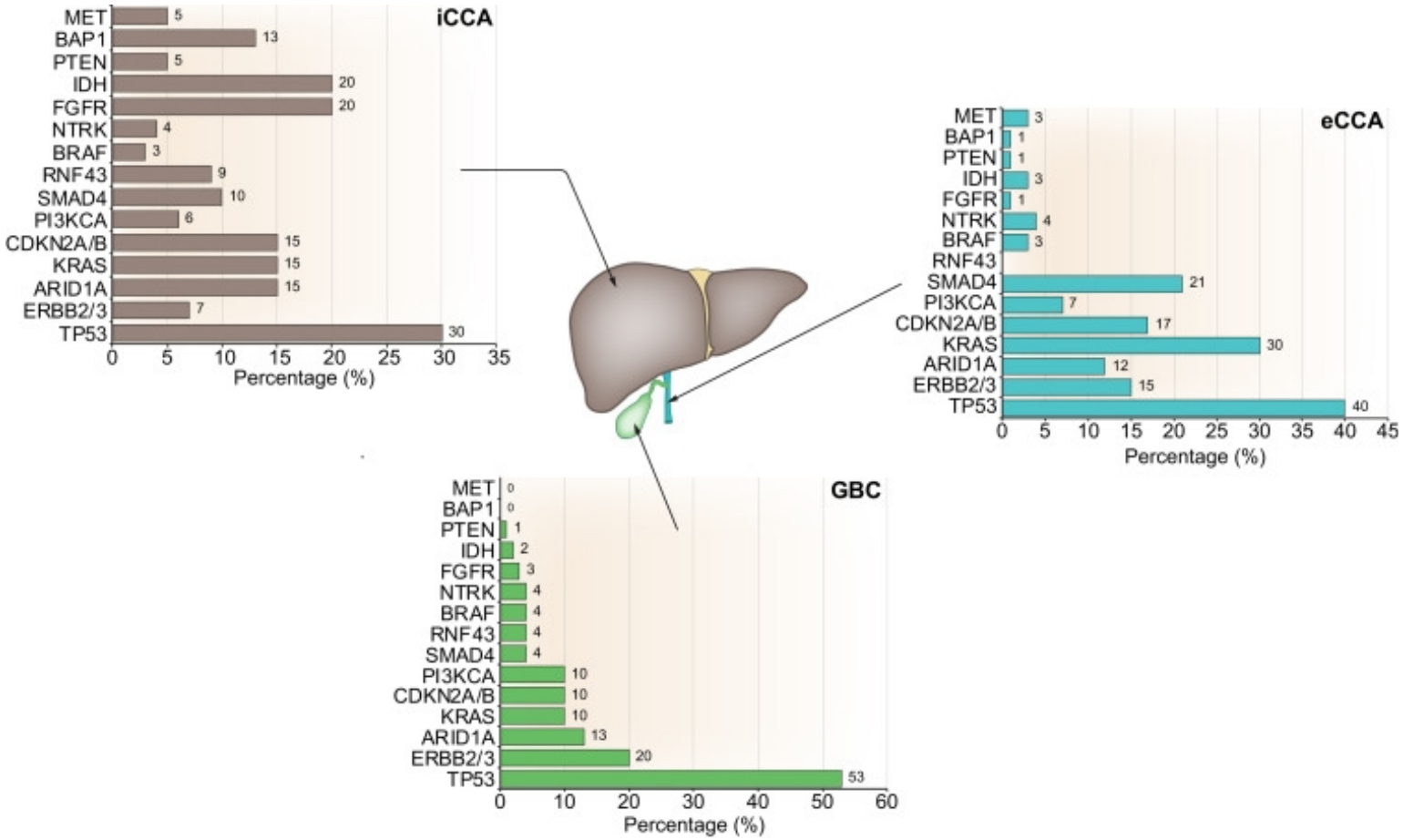


<u>Key point:</u> We do not have biomarkers that predict benefit to the addition of ICI. We need them!

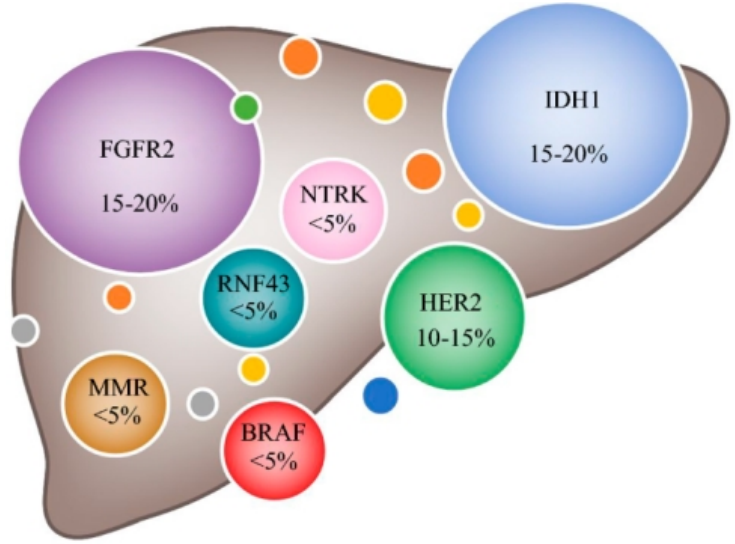
No significant correlation with outcomes for any subset
PD-L1 % did not predict benefit or lack thereof

Oh DY ESMO Asia 2022 Bridgewater JA, et al. Am Soc Clin Oncol Educ Book,. Oh DY, et al. NEJM Evid. Valle, J.W. et al. Annals of Oncology, Volume 33, S1457

Molecular Targets for Therapy in BTC



Lamarca et al J Hepatol. 2020 Jul;73(1):170-185



*Fong et al Ann Surg Oncol **28**, 2660–2674 (2021).*

Systemic Therapy for BTC: Rapidly Evolving

First-line

Gemcitabine Cisplatin
ABC-02 (included ampullary)
ORR: 26% (vs 21%), mOS: 11mo
2010

Gemcitabine Cisplatin Durvalumab
TOPAZ-1
ORR: 26.7% (vs 18.7%) ,mOS 12.8mo
2022

Gemcitabine Cisplatin Pembrolizumab
Keynote 966
ORR: 29% ,mOS 12.7mo
2023

Gemcitabine Cisplatin
Nab-Paclitaxel ? SWOG 1815 was negative

Second-line

No Targets	**FOLFOX** ABC-06 ORR: 5%, mOS 6.2mo	2018	**5-FU Nal-IRI** Nifty ORR: 14.8%, mOS 8.6mo	2021
FGFR2 fusion	***Pemigatinib** FIGHT-302 ORR: 35.5%, mOS 21.2mo	2020	***Futibatinib** FOENIX-CCA2 ORR: 42%, mOS 21.7mo	2022
IDH-1 mutation	**Ivosidenib** ClarIDHy ORR: 2%, mOS 10.3	2022		
BRAF V600E	**Dabrafenib/Trametinib** ROAR tissue agnostic, ORR: 36%, DCR 76%	2022		
ERBB2 amplification HER 2 “positive’	**⁺Trastuzumab/Pertuzumab** MyPathway, ORR: 40%		**T-Dxd (Enhertu)** DESTINY Pan-Tumor02 ORR:22%, mOS 7mo	
MSI-H	**Pembrolizumab** KEYNOTE cohorts ORR:39.6%	2017	**Dostarlimab-glxy** GARNET ORR: 41.6%	2021
NTRK fusion	**Larotrectinib** LoxoTRK, SCOUT, NAVIGATE ORR: ~60-70%	2018	**Entrectinib** STARTRK1,2 ORR: 57%	2019
RET Fusion	**⁺Pralsetinib** BLU-667, tumor agnostic, 2B rec	2022		

Clinical FGFR2 Inhibitors for CCA

FGFR Inhibitor	Class, Isoform Selectivity	Study population	Trial Phase	ORR	mDOR	mPFS	mOS
Pemigatinib (INC054828)	**Reversible** FGFR1–3 inhibitor	FGFR2 fusions n = 107 other FGFR alteration n = 20	Ph II	**Fusions: 35.5%** Other: 0%	**7.5 mos**	**Fusions: 6.9 mos** Other: 2.1 mos	**Fusions: 21.2 mos** Other: 6.7 mos
Infigratinib (BGJ398)	**Reversible** FGFR1–3 inhibitor	N =108 FGFR2 fusion n= 83	Ph II	**Overall : 23.1%** 2nd Line: 34% 3rd line: 13.8%	5.0 mos	**7.3 mos**	**19.2 mos**
Futibatinib (TAS-120)	**Irreversible** FGFR1–4 inhibitor	N=103 FGFR2 fusion n= 80	Ph II	**Overall 41.7 %**	9.7 mos	**9.0 mos**	**21.7 mos**

*Pemigatinib	*Futibatinib	**Inifgratinib
FIGHT-302	FOENIX-CCA2	PROOF
ORR: 35.5%, mOS 21.2mo	ORR: 34.3%, mOS 27.7	ORR: 27.3%, mOS 19.2mo
Abou-Alfa et al, Lancet Oncol. 2020.	*Goyal et al. AACR, 2021*	*Javle et al, ASCO 2021*

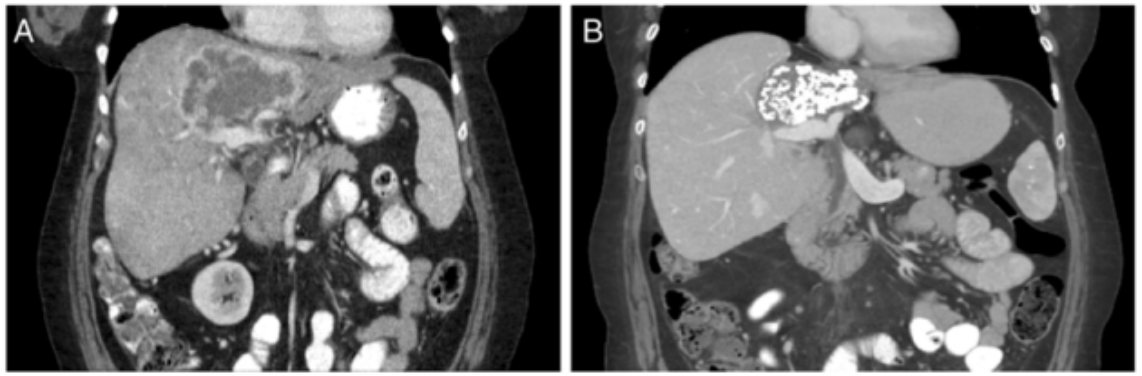
Key point: Benefit confined to FGFR2 fusions

*Conditional FDA approval pending confirmatory ph III
** QED did not file for approval

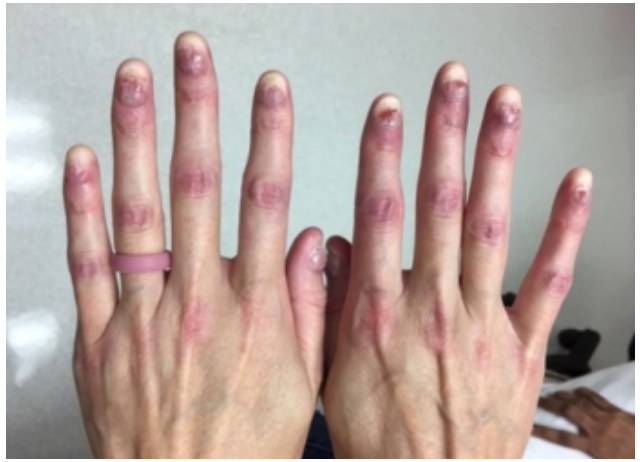
On/Off-Target Toxicity: these drugs aren't easy

	Grade 1–2	Grade 3	Grade 4
Hyperphosphataemia†	81 (55%)	0	0
Alopecia	67 (46%)	0	0
Dysgeusia	55 (38%)	0	0
Diarrhoea	49 (34%)	4 (3%)	0
Fatigue	45 (31%)	2 (1%)	0
Stomatitis	39 (27%)	8 (5%)	0
Dry mouth	42 (29%)	0	0
Nausea	34 (23%)	2 (1%)	0
Decreased appetite	34 (23%)	1 (1%)	0
Dry eye	30 (21%)	1 (1%)	0
Dry skin	22 (15%)	1 (1%)	0
Arthralgia	16 (11%)	6 (4%)	0
Palmar-plantar erythrodysaesthesia	16 (11%)	6 (4%)	0
Constipation	20 (14%)	0	0
Hypophosphataemia*	8 (5%)	10 (7%)	0

Abou-Alfa, Lancet Oncol. 2020.



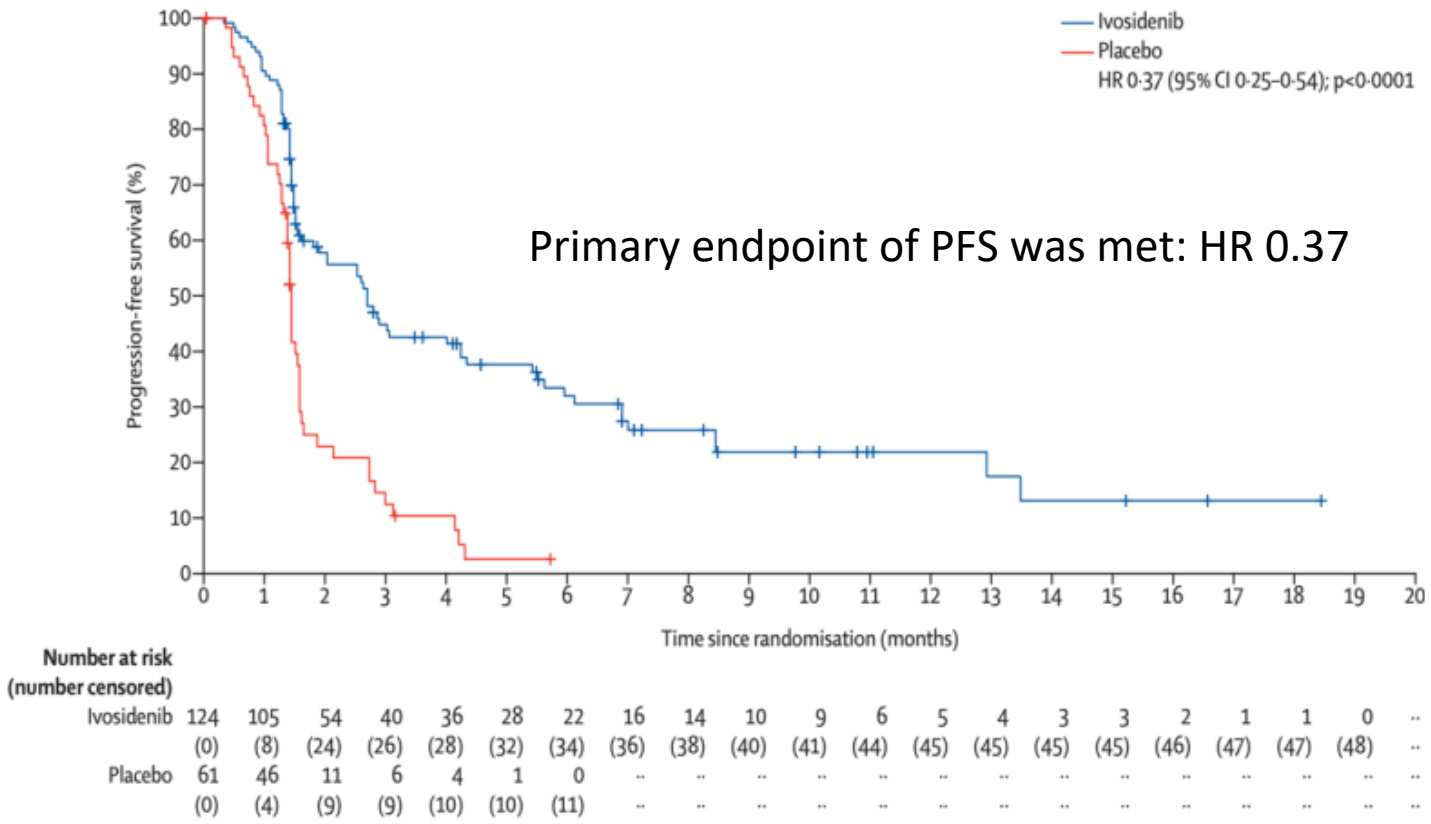
Ectopic tumor-related hepatic calcification on infigratinib. A. Before treatment B. On Treatment with response



Onycholysis and onychoclasis of the fingernails on a selective FGFR inhibitor

***King GK**, Javle M. Curr Oncol Rep 2021*

CLarIDHy: Mostly SD, PFS Benefit



Primary endpoint of PFS was met: HR 0.37

	Ivosidenib	Placebo
Median PFS	**2.7**	1.4
6-mo PFS%	32%	NE
12-mo PFS%	22%	NE
Disease Control (PR+SD)	53% (**2% PR**, 51% SD)	28% (0% PR, 28% SD)

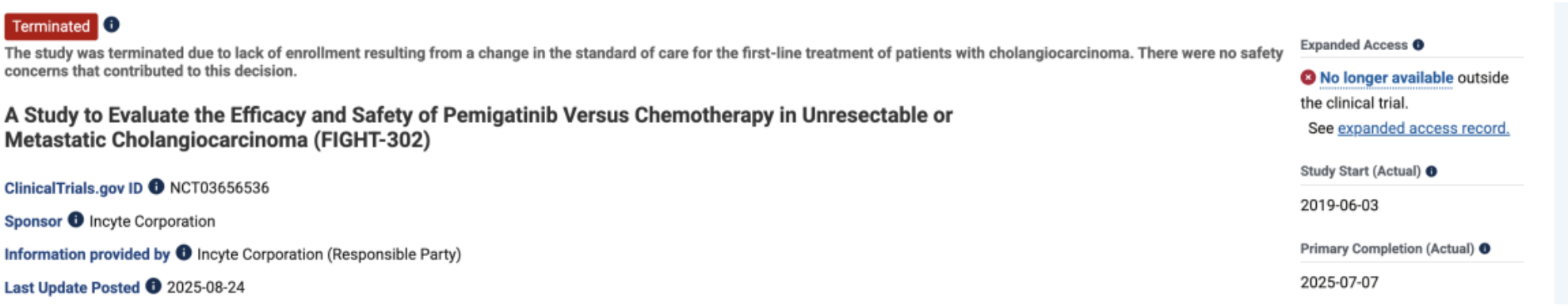
Abou-Alfa et al. Lancet Oncol 2020; 21: 796–807

Low Hanging Fruit Board Questions/Tips

- **Peculiar Toxicities of targeted therapies**
  - **FGFR2 Inhibitors (Pemigatinib, Futibatinib)**: Hyperphosphatemia, Retinal (Central Serous Retinopathy / Retinal Pigment Epithelium Detachment CSR/RPED)
  - **IDH inhibitors (Ivosidenib)**: myositis, QT prolongation
  - **Dabrafenib/Trametinib**: pyrexia, CSR/RPED
  - **Pertuzumab:** diarrhea
  - **Enhertu**: ILD
- What to avoid with liver dysfunction
  - Irinotecan
  - Targeted therapies (FGFR2i, IDHi, NTRKi): no data in severe liver dysfunction
- Avoid ICI: autoimmune disease
- Targeted therapies only indicated in 2nd line, chemo still 1st line

First-Line Trials of targeted therapy in BTC/CCA

Agent	Target	Phase	Arms	NCT	Status
Pemigatinib	***FGFR2 fus/rea***	***III***	***Pemigatinib vs GC***	***NCT03656536***	***Terminated (8/2025)***
Infigratinib	***FGFR2 fus/rea***	***III***	***Infigratinib vs GC***	***NCT03773302***	***Terminated (5/2024)***
Futibatinib	***FGFR2 fus/rea***	***III***	***Futibatinib vs GC***	***NCT04093362***	***Terminated (7/2024)***
Ivosidenib	IDH1mt	Ib/II	Ivo plus **GCD**	NCT06501625	Active
Zanidatamab	HER2 IHC+/Amp	III	Zani **GC+ICI** vs **GC+ICI**	NCT06282575	Active



Terminated

The study was terminated due to lack of enrollment resulting from a change in the standard of care for the first-line treatment of patients with cholangiocarcinoma. There were no safety concerns that contributed to this decision.

A Study to Evaluate the Efficacy and Safety of Pemigatinib Versus Chemotherapy in Unresectable or Metastatic Cholangiocarcinoma (FIGHT-302)

ClinicalTrials.gov ID NCT03656536

Sponsor Incyte Corporation

Information provided by Incyte Corporation (Responsible Party)

Last Update Posted 2025-08-24

Expanded Access

No longer available outside the clinical trial.

See expanded access record.

Study Start (Actual)

2019-06-03

Primary Completion (Actual)

2025-07-07

Low Hanging Fruit Board Questions/Tips

- Chemotherapy vignettes:
  - Avoid cisplatin in patients with significant kidney dysfunction
  - LATE Anaphylactic reactions can happen in patients who are receiving oxaliplatin or carboplatin for many months
  - 5-FU cardiac vasospasm
  - Gemcitabine associated HUS
  - All sorts of potential toxicity with cisplatin: kidney, hearing, hemorrhagic cystitis etc.

Good Luck!

Think like a question maker (not necessarily a clinician) for the boards