Hepatocellular Carcinoma and Cholangiocarcinoma Up-date

MLS Denver
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S. Lindsey Davis, MD

Cancer Center

NCI-DESIGNATED COMPREHENSIVE
CANCER CENTER

Outline

- Hepatocellular Carcinoma Up-Dates
  - Adjuvant Therapy
  - Advanced Disease
- Biliary Tract Cancer Up-Dates
  - Advanced Disease

Outline

- **Hepatocellular Carcinoma Up-Dates**
  - **Adjuvant Therapy**
  - Advanced Disease
- Biliary Tract Cancer Up-Dates
  - Advanced Disease

Adjuvant Therapy for HCC

- **IMbrave050: Adjuvant atezolizumab/bevacizumab improves recurrence free survival vs active surveillance**
  - Phase 3 randomized trial
  - 668 patients with HCC following curative resection or ablation
    - Randomized 1:1 to atezolizumab 1200mg / bevacizumab 15mg/kg q3w or active surveillance
    - **High risk features** including
      - Tumor >5cm
      - >3 tumors
      - Microvascular invasion
      - Segmental portal vein invasion
      - Right anterior or posterior portal vein invasion
      - Grade 3/4 pathology
    - No extrahepatic disease or significant macrovascular invasion
    - Patients with Child Class B or C liver disease excluded

Chow; Proceedings of AACR Annual Meeting 2023, Abstr CT003

IMbrave 050

- **Primary endpoint was met** at time of prespecified interim analysis
  - Recurrence rate was 33% in the atezolizumab/bevacizumab group vs 40% in the active surveillance group
    - **HR 0.72** (95% CI: 0.56, 0.93; p=0.012)
    - Median RFS not met for either group
    - Median follow-up **17.4 months**

Chow; Proceedings of AACR Annual Meeting 2023, Abstr CT003

IMbrave 050

- First study to demonstrate RFS improvement for adjuvant therapy following curative intent resection or ablation
- Limitations
  - Short follow up
  - Lack of mature OS data
- Will await longer term follow-up before broadly adopting into practice

Chow; Proceedings of AACR Annual Meeting 2023, Abstr CT003

Adjuvant Therapy for HCC

- Additional ongoing studies evaluating adjuvant immunotherapy and combinations

Trial	Treatment Arm(s)	Comparison
IMbrave050	Atezolizumab/bevacizumab	Active surveillance
CheckMate 9DX	Nivolumab	Placebo
Keynote-937	Pembrolizumab	Placebo
EMERALD-2	Durvalumab/bevacizumab Durvalumab/placebo	Placebo
JUPITER 04	Toripalimab (anti-PD-1)	Placebo

Zhu, Genes and Diseases, 2020

Outline

- **Hepatocellular Carcinoma Up-Dates**
  - Adjuvant Therapy
  - **Advanced Disease**
- Biliary Tract Cancer Up-Dates
  - Advanced Disease

Systemic Therapy for HCC: First Line

National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2023
Hepatocellular Carcinoma

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PRINCIPLES OF SYSTEMIC THERAPY

First-Line Systemic Therapy

Preferred Regimens

- Atezolizumab + bevacizumab (Child-Pugh Class A only) (category 1)[a,b,c,1]
- Tremelimumab-actl + durvalumab (category 1)[b,2]

Other Recommended Regimens

- Sorafenib (Child-Pugh Class A [category 1] or B7)[d,e,3,4]
- Lenvatinib (Child-Pugh Class A only) (category 1)[5,6]
- Durvalumab (category 1)[b,2]
- Pembrolizumab (category 2B)[b,7]

Useful in Certain Circumstances

- Nivolumab (Child-Pugh Class B only)[b,8]
- Atezolizumab + bevacizumab (Child-Pugh Class B only)[9]
- For TMB-H tumors:
  - Nivolumab + ipilimumab (category 2B)[10]

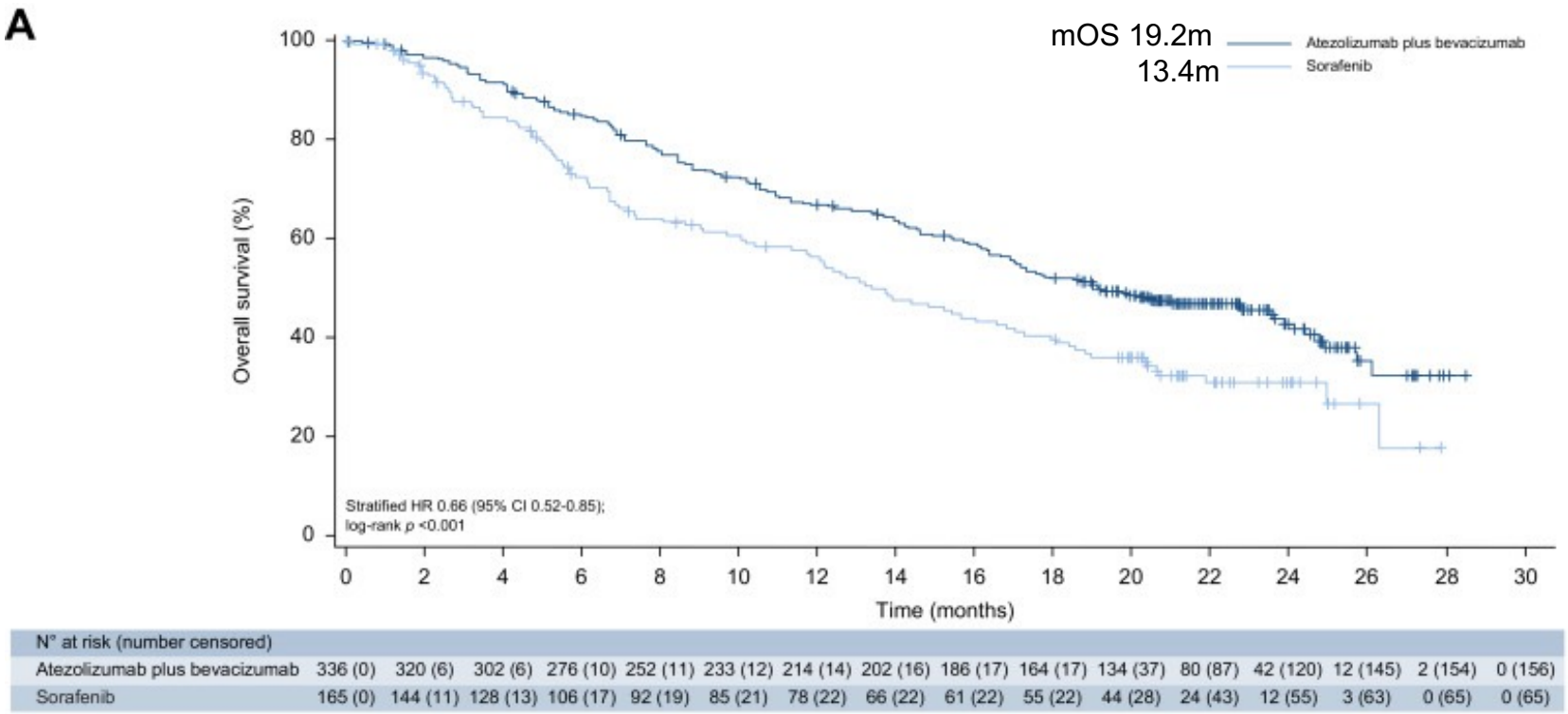
NCCN Guidelines, Hepatocellular Carcinoma, version 2.2023

Systemic Therapy for HCC: First Line

- **IMBrave 150: Atezolizumab / bevacizumab improves survival vs sorafenib**
  - Phase 3, open-label, randomized trial
  - 501 patients with unresectable hepatocellular carcinoma who had not received prior systemic therapy
    - Randomized 2:1 to atezolizumab 1200mg / bevacizumab 15 mg/kg q3 weeks or sorafenib 400mg BID
    - Patients with Child Class B or C liver disease excluded
    - Patients with history of autoimmune disease, prior liver transplant, hepatitis B/C co-infection, **high-risk varices excluded**

Finn; NEJM 2020, 1894

IMBrave 150



N° at risk (number censored)																
Atezolizumab plus bevacizumab	336 (0)	320 (6)	302 (6)	276 (10)	252 (11)	233 (12)	214 (14)	202 (16)	186 (17)	164 (17)	134 (37)	80 (87)	42 (120)	12 (145)	2 (154)	0 (156)
Sorafenib	165 (0)	144 (11)	128 (13)	106 (17)	92 (19)	85 (21)	78 (22)	66 (22)	61 (22)	55 (22)	44 (28)	24 (43)	12 (55)	3 (63)	0 (65)	0 (65)

Cheng; J Hepatol 2022, 862

IMBrave 150

Table 1. Clinical response by independent review facility-assessed RECIST 1.1.

	Atezolizumab plus bevacizumab (n = 326)	Sorafenib (n = 159)
Objective response, n (%) [95% CI]	97 (30) [25-35]	18 (11) [7-17]
Complete response, n (%)	25 (8)	1 (<1)
Partial response, n (%)	72 (22)	17 (11)
Stable disease, n (%)	144 (44)	69 (43)
Disease control rate, n (%)	241 (74)	87 (55)
Progressive disease, n (%)	63 (19)	40 (25)
Patients with ongoing response, n (%)	54 (56)	5 (28)
Duration of response, median (95% CI), months*	18.1 (14.6-NE)	14.9 (4.9-17.0)
Range, months	2.5-25.6†	2.5†-21.8
Responders with duration of response, %		
≥12 months	69	65
≥18 months	51	22

*The Kaplan–Meier method was used to estimate the duration of response in confirmed responders for each treatment arm with 95% CIs.
†Censored.

Prevent and conquer cancer. **Together**.

Cheng; J Hepatol 2022, 862

Table 4. Adverse Events with an Incidence of More Than 10% in Either Group.

Event	Atezolizumab–Bevacizumab (N = 329)		Sorafenib (N = 156)	
	Any Grade	Grade 3 or 4	Any Grade	Grade 3 or 4
	number (percent)			
Hypertension	98 (29.8)	50 (15.2)	38 (24.4)	19 (12.2)
Fatigue	67 (20.4)	8 (2.4)	29 (18.6)	5 (3.2)
Proteinuria	66 (20.1)	10 (3.0)	11 (7.1)	1 (0.6)
Aspartate aminotransferase increase	64 (19.5)	23 (7.0)	26 (16.7)	8 (5.1)
Pruritus	64 (19.5)	0	15 (9.6)	0
Diarrhea	62 (18.8)	6 (1.8)	77 (49.4)	8 (5.1)
Decreased appetite	58 (17.6)	4 (1.2)	38 (24.4)	6 (3.8)
Pyrexia	59 (17.9)	4 (1.2)	15 (9.6)	2 (1.3)
Alanine aminotransferase increase	46 (14.0)	12 (3.6)	14 (9.0)	2 (1.3)
Constipation	44 (13.4)	0	22 (14.1)	0
Blood bilirubin increase	43 (13.1)	8 (2.4)	22 (14.1)	10 (6.4)
Rash	41 (12.5)	0	27 (17.3)	4 (2.6)
Abdominal pain	40 (12.2)	4 (1.2)	27 (17.3)	4 (2.6)
Nausea	40 (12.2)	1 (0.3)	25 (16.0)	1 (0.6)
Cough	39 (11.9)	0	15 (9.6)	1 (0.6)
Infusion-related reaction	37 (11.2)	8 (2.4)	0	0
Weight decrease	37 (11.2)	0	15 (9.6)	1 (0.6)
Platelet count decrease	35 (10.6)	11 (3.3)	18 (11.5)	2 (1.3)
Epistaxis	34 (10.3)	0	7 (4.5)	1 (0.6)
Asthenia	22 (6.7)	1 (0.3)	21 (13.5)	4 (2.6)
Alopecia	4 (1.2)	0	22 (14.1)	0
Palmar–plantar erythrodysesthesia syndrome	3 (0.9)	0	75 (48.1)	13 (8.3)

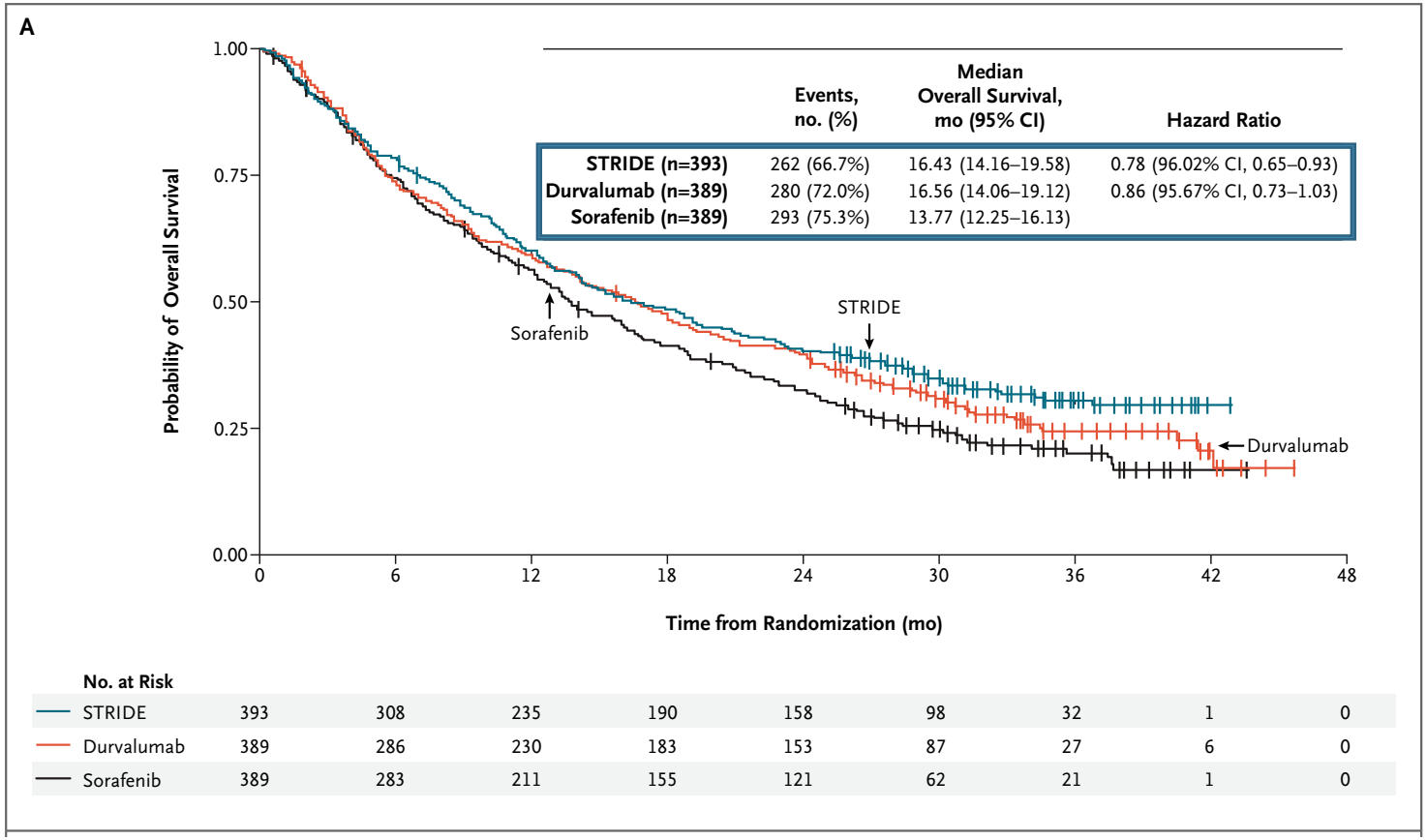
Finn; NEJM 2020, 1894

Systemic Therapy for HCC: First Line

- **HIMALAYA: durvalumab +/- tremelimumab improves survival vs sorafenib**
  - Phase 3, open-label, randomized trial
  - 871 patients with unresectable hepatocellular carcinoma who had not received prior systemic therapy
    - Randomized to tremelimumab 300mg x1 / durvalumab 1500 mg q4 weeks or durvalumab monotherapy 1500 mg q4 weeks or sorafenib 400mg BID
      - Primary endpoint: OS for tremelimumab + durvalumab vs sorafenib
      - Secondary objective: OS for durvalumab vs sorafenib
    - Patients with Child Class B or C liver disease excluded
    - Patients with history of autoimmune disease, prior liver transplant, **main portal vein thrombosis excluded**

Abou-Alfa, NEJM Evidence, 2022

HIMALAYA



	STRIDE imAE	STRIDE No imAE	D imAE	DNo imAE
n	139	249	64	324
mOS (95% CI), mo	23.2 (19.1–32.4)	14.1 (11.6–17.9)	17.8 (13.8–25.1)	16.5 (13.1–19.4)
OS HR (95% CI)		0.73 (0.56–0.95)		1.14 (0.82–1.57)
OS rate (95% CI), %				
6 mo	81.3 (75.1–88.0)	77.1 (72.1–82.5)	82.8 (74.1–92.6)	71.8 (67.1–76.9)
12 mo	69.1 (61.8–77.2)	55.2 (49.4–61.8)	60.9 (50.1–74.1)	58.2 (53.1–63.8)
24 mo	48.9 (41.3–58.0)	35.3 (29.8–41.8)	39.1 (28.8–53.0)	39.3 (34.3–45.0)

Abou-Alfa, NEJM Evidence, 2022
Lau, J Clin Oncol, 2023, suppl

HIMALAYA

Table 2. Response Outcomes in the Intent-to-Treat Population (Confirmed).*

Parameter	STRIDE (n=393)	Durvalumab (n=389)	Sorafenib (n=389)
Response — no. (%)			
Objective†	79 (20.1)	66 (17.0)	20 (5.1)
Complete	12 (3.1)	6 (1.5)	0
Partial	67 (17.0)	60 (15.4)	20 (5.1)
Stable disease — no. (%)	157 (39.9)	147 (37.8)	216 (55.5)
Disease control rate — %	236 (60.1)	213 (54.8)	236 (60.7)
Duration of response — mo‡			
Median	22.34	16.82	18.43
IQR	8.54–NR	7.43–NR	6.51–25.99
Time to response — mo			
Median	2.17	2.09	3.78
95% CI	(1.84–3.98)	(1.87–3.98)	(1.89–8.44)

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Abou-Alfa, NEJM Evidence, 2022

Table 3. Summary of Treatment-Emergent Adverse Events in the Safety Analysis Population.*

Event	STRIDE (n=388)	Durvalumab (n=388)	Sorafenib (n=374)	T75+D (n=152)
Treatment-emergent adverse events of any cause				
Any	378 (97.4)	345 (88.9)	357 (95.5)	145 (95.4)
Any serious	157 (40.5)	115 (29.6)	111 (29.7)	52 (34.2)
Any grade 3 or 4	196 (50.5)	144 (37.1)	196 (52.4)	60 (39.5)
Leading to discontinuation	53 (13.7)	32 (8.2)	63 (16.8)	23 (15.1)
Leading to dose delay	134 (34.5)	95 (24.5)	178 (47.6)	58 (38.2)
Leading to death	30 (7.7)	26 (6.7)	27 (7.2)	12 (7.9)
Immune-mediated requiring high-dose steroids	78 (20.1)	37 (9.5)	7 (1.9)	29 (19.1)
Any grade 3 or 4 immune-mediated	49 (12.6)	25 (6.4)	9 (2.4)	19 (12.5)
Immune-mediated leading to death	6 (1.5)	0	0	0
Any grade 3 or 4 hepatic SMQ	54 (13.9)	54 (13.9)	39 (10.4)	26 (17.1)
Treatment-related adverse events				
Any	294 (75.8)	202 (52.1)	317 (84.8)	106 (69.7)
Any serious	68 (17.5)	32 (8.2)	35 (9.4)	28 (18.4)
Grade 3 or 4	100 (25.8)	50 (12.9)	138 (36.9)	32 (21.1)
Leading to discontinuation	32 (8.2)	16 (4.1)	41 (11.0)	13 (8.6)
Leading to dose delay	83 (21.4)	54 (13.9)	144 (38.5)	42 (27.6)
Leading to death	9 (2.3)†	0	3 (0.8)‡	2 (1.3)
Grade 3 or 4 immune-mediated	49 (12.6)	24 (6.2)	9 (2.4)	18 (11.8)
Any immune-mediated leading to death	6 (1.5)§	0	0	0
Grade 3 or 4 hepatic SMQ	23 (5.9)	20 (5.2)	17 (4.5)	15 (9.9)

Abou-Alfa, NEJM Evidence, 2022

Systemic Therapy for HCC: First Line

First Line	Child Class	Primary Endpoint	Result	ORR
Atezo/bev v sorafenib	A	OS and PFS	19.2 v 13.4 m HR 0.66 6.9 v 4.3 m HR 0.65	27% v 12%
Durva/treme v sorafenib	A	OS	16.4 vs 13.8 HR 0.78	20% v 5%
Durvalumab v sorafenib	A	OS	16.6 v 13.8 HR 0.86, NIM 1.08	17% v 5%

Systemic Therapy for HCC: First Line

First Line	Child Class	Primary Endpoint	Result	ORR
Atezo/bev v sorafenib	A	OS and PFS	19.2 v 13.4 m HR 0.66 6.9 v 4.3 m HR 0.65	27% v 12%
Durva/treme v sorafenib	A	OS	16.4 vs 13.8 HR 0.78	20% v 5%
Durvalumab v sorafenib	A	OS	16.6 v 13.8 HR 0.86, NIM 1.08	17% v 5%
Lenvatinib v sorafenib	A	OS Non-inferiority	13 v 12.3 m HR 0.92, NIM 1.08	24% v 9%
Sorafenib v placebo	A Safe in B	OS	10.7 v 7.9 m HR 0.69	2% v 1%
Nivolumab v sorafenib	A Safe in B	OS	16.4 v 14.7 m HR 0.85	15% v 7%

Systemic Therapy for HCC: Second Line

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Hepatocellular Carcinoma

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Subsequent-Line Systemic Therapy if Disease Progression[f,g,h]

Options

- Regorafenib (Child-Pugh Class A only) (category 1)[11]
- Cabozantinib (Child-Pugh Class A only) (category 1)[12]
- Lenvatinib (Child-Pugh Class A only)
- Sorafenib (Child-Pugh Class A or B7)[d,e]

Other Recommended Regimens

- Nivolumab + ipilimumab (Child-Pugh Class A only)[b,i,13]
- Pembrolizumab (Child-Pugh Class A only)[b,i,j,14-16]

Useful in Certain Circumstances

- Ramucirumab (AFP ≥400 ng/mL and Child-Pugh Class A only) (category 1)[17]
- Nivolumab (Child-Pugh Class B only)[b,i,18-21]
- For MSI-H/dMMR tumors
  - Dostarlimab-gxly (category 2B)[b,i,k,22,23]
- For *RET* gene fusion-positive tumors:
  - Selpercatinib (category 2B)[24]
- For TMB-H tumors:
  - Nivolumab + ipilimumab (category 2B)[b,i,l,10]

NCCN Guidelines, Hepatocellular Carcinoma, version 2.2023

Outline

- Hepatocellular Carcinoma Up-Dates
  - Advanced Disease
  - Adjuvant Therapy
- **Biliary Tract Cancer Up-Dates**
  - **Advanced Disease**

Systemic Therapy for Cholangiocarcinoma: First Line

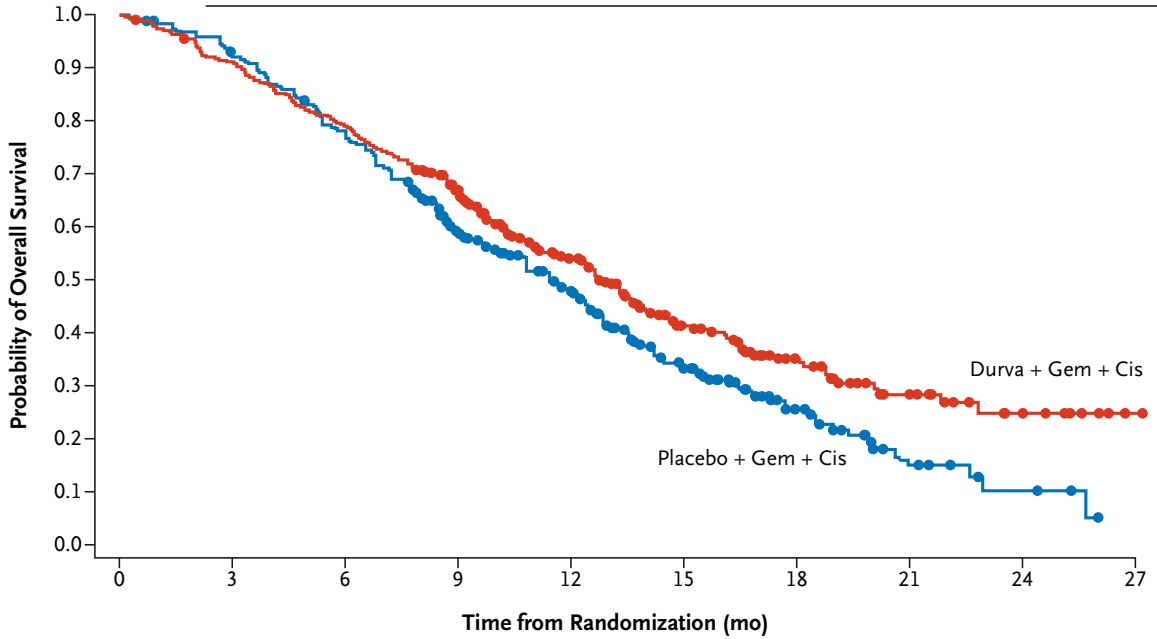
- **TOPAZ: Gemcitabine/cisplatin/durvalumab improves overall survival vs. gemcitabine/cisplatin**
  - Phase 3, randomized, double-blind, placebo-controlled trial
  - 685 patients with untreated locally advanced or metastatic disease
    - Cholangiocarcinoma and gallbladder cancer allowed to participate
    - Randomized 1:1 to durvalumab 1500 mg or placebo day 1 and gemcitabine 1000mg/m2 and cisplatin 25mg/m2 days 1 and 8 of a 21 day cycle **x 8 cycles, followed by durvalumab or placebo**

Oh; NEJM Evidence 2022, 1

TOPAZ

A

	Median Overall Survival, mo (95% CI)	Hazard Ratio (95% CI)	Stratified Log-rank P Value
Durva + Gem + Cis (n=341)	12.8 (11.1–14.0)	0.80 (0.66–0.97)	0.021
Placebo + Gem + Cis (n=344)	11.5 (10.1–12.5)		



No. at Risk

Durva + Gem + Cis	341	331	324	309	294	278	268	252	238	208	174	151	135	118	93	79	74	57	49	39	29	24	15	12	9	8	4	1
Placebo + Gem + Cis	344	337	329	317	299	283	261	242	220	183	159	143	125	97	78	65	52	40	29	21	15	10	8	4	4	3	0	0

Oh; NEJM Evidence 2022, 1

TOPAZ

Table 3. Summary of Safety Data in the Safety Analysis Set.

Parameter	Durvalumab plus Gemcitabine and Cisplatin (n=338)	Placebo plus Gemcitabine and Cisplatin (n=342)
Adverse events — no. (%)		
Any grade	336 (99.4)	338 (98.8)
Serious	160 (47.3)	149 (43.6)
Grade 3 or 4	256 (75.7)	266 (77.8)
Leading to discontinuation of any study treatment	44 (13.0)	52 (15.2)
Leading to death	12 (3.6)	14 (4.1)
Treatment-related adverse events — no. (%)		
Any grade	314 (92.9)	308 (90.1)
Serious	53 (15.7)	59 (17.3)
Grade 3 or 4	212 (62.7)	222 (64.9)
Leading to discontinuation of any study treatment	30 (8.9)	39 (11.4)
Leading to death*	2 (0.6)	1 (0.3)

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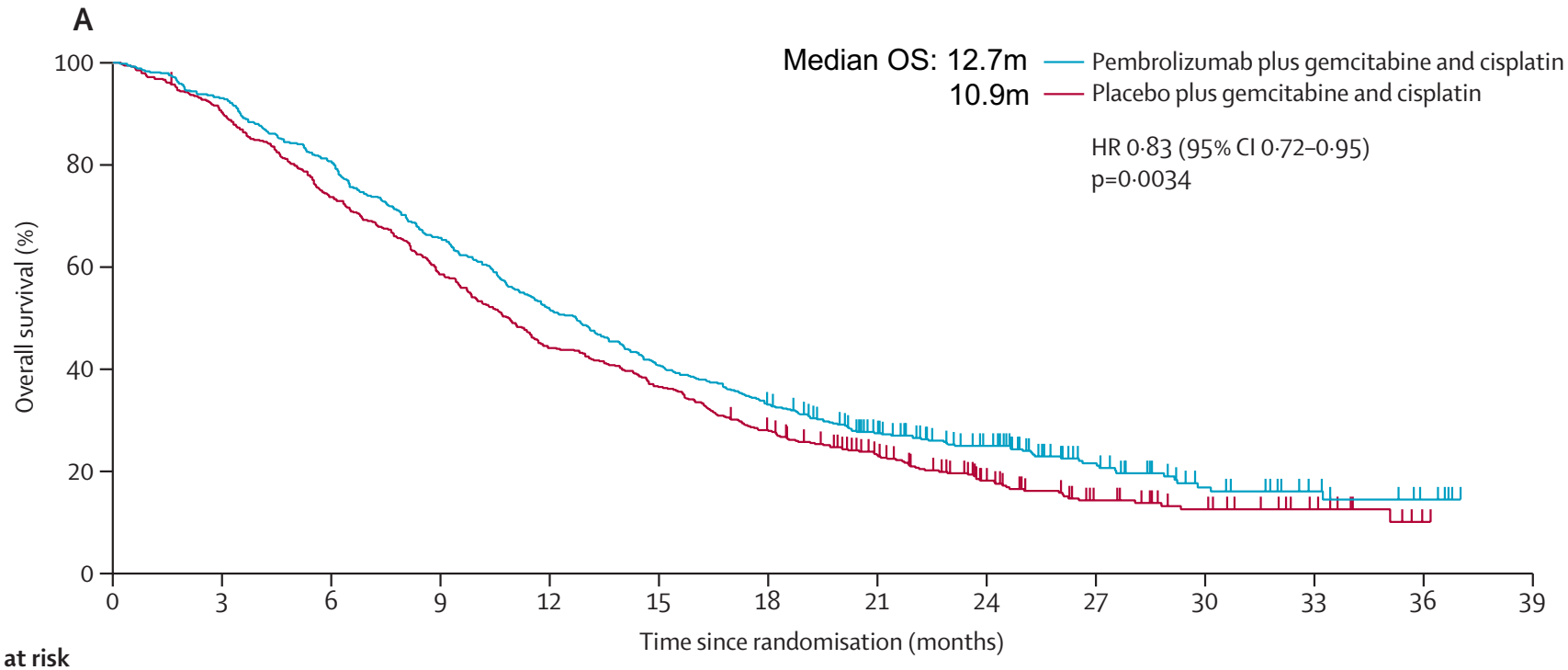
Oh; NEJM Evidence 2022, 1

Systemic Therapy for Cholangiocarcinoma: First Line

- **KEYNOTE-966: Gemcitabine/cisplatin/pembrolizumab improves overall survival vs. gemcitabine/cisplatin**
  - Phase 3, randomized, double-blind, placebo-controlled trial
  - 685 patients with untreated locally advanced or metastatic disease
    - Cholangiocarcinoma and gallbladder cancer allowed to participate
    - Randomized 1:1 to pembrolizumab 200 mg or placebo day 1 and gemcitabine 1000mg/m2 and cisplatin 25mg/m2 days 1 and 8 of a 21 day cycle
    - **Cisplatin limited to 8 cycles, pembrolizumab/placebo limited to 35 cycles, unlimited gemcitabine**

Kelley; Lancet 2023, 1853

KEYNOTE-966



Number at risk (number censored)														
Pembrolizumab plus gemcitabine and cisplatin	533 (0)	496 (0)	430 (0)	350 (0)	275 (0)	217 (0)	175 (1)	122 (26)	88 (50)	46 (83)	21 (100)	11 (109)	5 (114)	0 (119)
Placebo plus gemcitabine and cisplatin	536 (0)	483 (1)	394 (1)	313 (1)	236 (1)	195 (1)	148 (3)	97 (30)	59 (49)	32 (65)	20 (74)	10 (84)	1 (92)	0 (93)

Kelley; Lancet 2023, 1853

	Pembrolizumab plus gemcitabine and cisplatin group (n=529)				Placebo plus gemcitabine and cisplatin group (n=534)			
	Grade 1–2	Grade 3	Grade 4	Grade 5	Grade 1–2	Grade 3	Grade 4	Grade 5
Any event	73 (14%)	287 (54%)	133 (25%)	31 (6%)	83 (16%)	270 (51%)	130 (24%)	49 (9%)
Decreased neutrophil count	73 (14%)	167 (32%)	90 (17%)	0	74 (14%)	171 (32%)	82 (15%)	0
Anaemia	171 (32%)	150 (28%)	2 (<1%)	0	159 (30%)	150 (28%)	4 (1%)	0
Nausea	221 (42%)	12 (2%)	0	0	234 (44%)	12 (2%)	0	0
Decreased platelet count	117 (22%)	64 (12%)	30 (6%)	0	105 (20%)	67 (13%)	40 (7%)	0
Fatigue	161 (30%)	25 (5%)	1 (<1%)	0	150 (28%)	22 (4%)	0	0
Constipation	184 (35%)	2 (<1%)	0	0	187 (35%)	3 (1%)	0	0
Decreased appetite	137 (26%)	6 (1%)	1 (<1%)	0	140 (26%)	15 (3%)	0	0
Decreased white blood cell count	80 (15%)	57 (11%)	4 (1%)	0	80 (15%)	44 (8%)	3 (1%)	0
Pyrexia	127 (24%)	12 (2%)	0	0	99 (19%)	5 (1%)	0	0
Vomiting	108 (20%)	14 (3%)	0	0	121 (23%)	7 (1%)	0	0
Diarrhoea	92 (17%)	11 (2%)	0	0	87 (16%)	10 (2%)	0	1 (<1%)
Abdominal pain	82 (16%)	10 (2%)	0	0	103 (19%)	19 (4%)	0	0
Rash	87 (16%)	3 (1%)	0	0	47 (9%)	2 (<1%)	0	0
Increased aspartate aminotransferase	72 (14%)	16 (3%)	0	0	77 (14%)	19 (4%)	2 (<1%)	0
Increased alanine aminotransferase	75 (14%)	12 (2%)	0	0	99 (19%)	14 (3%)	0	0
Hypomagnesaemia	74 (14%)	5 (1%)	0	0	73 (14%)	5 (1%)	1 (<1%)	0
Pruritus	77 (15%)	0	0	0	51 (10%)	0	0	0
Asthenia	64 (12%)	10 (2%)	1 (<1%)	0	76 (14%)	19 (4%)	0	0
Peripheral oedema	73 (14%)	0	0	0	78 (15%)	7 (1%)	0	0

Data are n (%).

Table 3: **Adverse events of any cause that occurred in ≥15% of participants in either treatment group in the as-treated population at the final analysis**

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Kelley; Lancet 2023, 1853

Systemic Therapy for Cholangiocarcinoma: First Line

First Line	Disease Sites	Primary Endpoint	Additional Endpoints
Gemcitabine/cisplatin v gemcitabine	Intrahepatic, extrahepatic cholangio, gallbladder, ampullary	OS 11.7 v 8.1 m HR 0.64	PFS 8 v 5 m
Gemcitabine/cisplatin/ durvalumab v gemcitabine/ cisplatin	Intrahepatic, extrahepatic cholangio, gallbladder	OS 12.8 v 11.5 m HR 0.8	PFS 7.2 v 5.7 m
Gemcitabine/cisplatin/ pembrolizumab v gemcitabine/ cisplatin	Intrahepatic, extrahepatic cholangio, gallbladder	OS 12.7 v 10.9 m HR 0.83	PFS 6.5 vs 5.6 m

Systemic Therapy for Cholangiocarcinoma: Second Line

Second Line	Disease Sites	Primary Endpoint	Additional Endpoints
FOLFOX v active symptom control	Intrahepatic, extrahepatic cholangio, gallbladder, ampullary	OS 6.2 v 5.3 m HR 0.69	PFS 4m
Pemigatinib	Cholangiocarcinoma with **FGFR2 fusion/ rearrangement** (98% intrahepatic)	ORR 37%	PFS 7m OS 17.5 m
Infigratinib	Cholangiocarcinoma with **FGFR2 fusion/ rearrangement**	ORR 23.1%	PFS 7.3m OS 12.2m
Futibatinib	**Intrahepatic** cholangiocarcinoma with **FGFR2 fusion/ rearrangement**	ORR 42%	PFS 9m OS 21.7m
Ivosidenib	Cholangiocarcinoma with **IDH1 mutation** (90% intrahepatic)	PFS 2.7 v 1.4 m HR 0.37	OS 10.3 v 7.5m (5.1 w crossover adjustment)

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University of Colorado
Anschutz Medical Campus

Thank You!