Real-world outcomes of durvalumab plus GemCis or GemCis in patients with advanced biliary tract cancer in the US

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Objective

- This real-world study describes characteristics, clinical outcomes, and treatment patterns of patients in the US with advanced biliary tract cancer (aBTC) treated with durvalumab plus gemcitabine and cisplatin (D + GemCis) or GemCis using claims-based data

Conclusions

- To our knowledge, this is the first study in the US utilizing comprehensive claims data to describe real-world clinical outcomes in patients with aBTC treated with D + GemCis or GemCis
- These results are consistent with other real-world studies showing numerical improvement in overall survival (OS), consistent with the clinical efficacy profile seen in the TOPAZ-1 study[1,2]

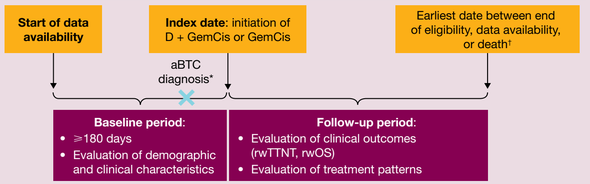
Introduction

- Findings from the Phase 3 TOPAZ-1 study (NCT03875235) support D + GemCis as a standard of care treatment for patients with aBTC, and D + GemCis is now considered a first-line (1L) regimen for patients with aBTC[3,4]
- Real-world studies are increasingly being used to support results of clinical studies, so that clinical data may be applicable to a more heterogenous population. Multiple real-world studies have been supportive of the TOPAZ-1 efficacy results[1,5,6]
- To date, no real-world study of D + GemCis has been conducted in a US population using a US health database

Methods

- This retrospective, observational study used Optum's de-identified Market Clarity data (Optum Market Clarity®) from adult patients diagnosed with *de novo* or recurrent aBTC receiving 1L D + GemCis, on or after March 11, 2022 (date of addition to NCCN Clinical Practice Guidelines in Oncology [NCCN Guidelines®]), or GemCis, on or after January 1, 2019, to February 28, 2025
- Patients needed to have ⩾2 diagnosis codes in the electronic health record or claim codes (inpatient or non-diagnostic outpatient) for BTC 1–90 days apart to be eligible
- Patients were followed until the earliest date between end of eligibility, data availability, or death (**Figure 1**)
- **Primary objective:** to describe the baseline demographics and clinical characteristics of patients receiving D + GemCis or GemCis
- **Exploratory objectives:** assessment of real-world time to next treatment (rwTTNT) and real-world OS (rwOS) were both estimated using the Kaplan-Meier (KM) method without direct comparisons

Figure 1. Study design



De novo or recurrent aBTC. †End of eligibility included health plan disenrollment. Data were available up to March 31, 2025.

aBTC, advanced biliary tract cancer; D, durvalumab; GemCis, gemcitabine and cisplatin; rwOS, real-world overall survival; rwTTNT, real-world time to next treatment.

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Disclosures

JJH reports a consulting or advisory role for, and research funding from, AstraZeneca. VS is a consultant for AstraZeneca. SJV and YJ are employees and shareholders of AstraZeneca. AE and MZ are employees of AstraZeneca. FD reports contracted research from AstraZeneca.

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Results and interpretation

- A total of 636 patients met eligibility and were included in the study: 210 patients treated with D + GemCis and 426 patients treated with GemCis
  - 367 patients treated with GemCis were included in this analysis prior to March 2022
- Demographics and baseline characteristics were similar in each cohort (**Table 1**)
  - Most patients were diagnosed with *de novo* aBTC (D + GemCis, 85.7%; GemCis, 86.6%) and intrahepatic cholangiocarcinoma (D + GemCis, 76.2%; GemCis, 68.5%)
  - Median time from treatment initiation to the end of follow-up was 6.9 months for D + GemCis and 8.7 months for GemCis
- At last follow-up, 26.2% of patients receiving D + GemCis remained on their current 1L treatment, as did 7.7% of patients on GemCis. Among those who discontinued either treatment, 30.0% and 46.2% of patients on D + GemCis or GemCis, respectively, switched to a second line of therapy (**Table 2**)
- Median (95% confidence interval [CI]) rwTTNT was 10.3 (8.0–15.8) months for D + GemCis and 7.5 (6.6–8.5) months for GemCis (**Figure 2**)
- KM landmark estimates (95% CI) for rwTTNT (**Table 3**) were:
  - 0.44 (0.36–0.54) and 0.32 (0.22–0.46) at 12 and 24 months, respectively, for patients who received D + GemCis
  - 0.31 (0.26–0.37) and 0.19 (0.14–0.26) at 12 and 24 months, respectively, for patients who received GemCis
- Median (95% CI) rwOS was 14.6 (12.9–19.0) months for D + GemCis and 11.9 (10.3–14.5) for GemCis (**Figure 3**)
- KM landmark estimates (95% CI) for rwOS (**Table 4**) were:
  - 0.58 (0.51–0.66) and 0.38 (0.31–0.47) at 12 and 24 months, respectively, for patients who received D + GemCis
  - 0.49 (0.45–0.54) and 0.28 (0.24–0.33) at 12 and 24 months, respectively, for patients who received GemCis

Table 1. Patient demographics and clinical characteristics

	D + GemCis (n=210)	GemCis (n=426)
Age, years		
Median (Q1–Q3)	67 (60–73)	63 (57–70)
Female, n (%)	104 (49.5)	238 (55.9)
Race, n (%)		
Caucasian	161 (76.7)	326 (76.5)
African American	27 (12.9)	47 (11.0)
Asian / other / unknown	22 (10.5)	53 (12.4)
aBTC diagnosis, n (%)		
De novo	180 (85.7)	369 (86.6)
Recurrent	30 (14.3)	57 (13.4)
BTC subtype,* n (%)		
Intrahepatic CCA	160 (76.2)	292 (68.5)
Extrahepatic CCA	23 (11.0)	43 (10.1)
Gallbladder cancer	26 (12.4)	70 (16.4)
AoV / Other†	8 (3.8)	39 (9.2)
CCI score at baseline		
Median (Q1–Q3)	2.0 (2.0–3.0)	2.0 (2.0–3.0)
Time from treatment initiation to end of follow-up, months		
Median (Q1–Q3)	6.9 (3.6–12.5)	8.7 (4.4–16.4)

*Not mutually exclusive. †'Other' included patients with malignant neoplasms of the biliary tract (unspecified) or malignant neoplasms of overlapping sites of the biliary tract.

(a)BTC, (advanced) biliary tract cancer; AoV, Ampulla of Vater; CCA, cholangiocarcinoma; CCI, Charlson Comorbidity Index; D, durvalumab; GemCis, gemcitabine and cisplatin; Q, quartile.

Table 2. Real-world treatment characteristics

	D + GemCis (n=210)	GemCis (n=426)
Patients who switched to 2L therapy or died without initiating a subsequent line of therapy during the follow-up period, n (%)		
Yes	86 (41.0)	254 (59.6)
No	124 (59.0)	172 (40.4)
Reasons for end of 1L treatment, n (%)		
Died while on 1L	23 (11.0)	57 (13.4)
Discontinued 1L during follow-up (no subsequent line of therapy)	69 (32.9)	139 (32.6)
Remained on 1L at last follow-up	55 (26.2)	33 (7.7)
Switched to 2L	63 (30.0)	197 (46.2)

1L, first-line; 2L, second-line; D, durvalumab; GemCis, gemcitabine and cisplatin.

Table 3. KM estimates for rwTTNT

	D + GemCis (n=210)	GemCis (n=426)
KM landmark estimate (95% CI) of no. of patients event-free at:		
3 months	0.87 (0.82–0.92)	0.75 (0.71–0.79)
6 months	0.69 (0.62–0.76)	0.58 (0.53–0.63)
12 months	0.44 (0.36–0.54)	0.31 (0.26–0.37)
18 months	0.35 (0.26–0.48)	0.25 (0.20–0.31)
24 months	0.32 (0.22–0.46)	0.19 (0.14–0.26)

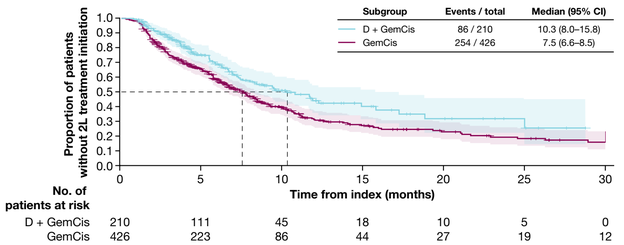
CI, confidence interval; D, durvalumab; GemCis, gemcitabine and cisplatin; KM, Kaplan-Meier; rwTTNT, real-world time to next treatment.

Table 4. KM estimates for rwOS

	D + GemCis (n=210)	GemCis (n=426)
KM landmark estimate (95% CI) of no. of patients event-free at:		
3 months	0.91 (0.87–0.95)	0.85 (0.81–0.88)
6 months	0.77 (0.72–0.83)	0.72 (0.68–0.77)
12 months	0.58 (0.51–0.66)	0.49 (0.45–0.54)
18 months	0.42 (0.35–0.51)	0.37 (0.33–0.43)
24 months	0.38 (0.31–0.47)	0.28 (0.24–0.33)

CI, confidence interval; D, durvalumab; GemCis, gemcitabine and cisplatin; KM, Kaplan-Meier; rwOS, real-world overall survival.

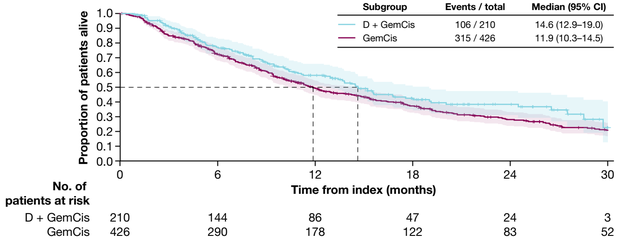
Figure 2. rwTTNT for D + GemCis and GemCis



rwTTNT was estimated using the KM method, with the median time to event and related 95% CI.

2L, second-line; CI, confidence interval; D, durvalumab; GemCis, gemcitabine and cisplatin; rwTTNT, real-world time to next treatment.

Figure 3. rwOS for D + GemCis and GemCis



rwOS was estimated using the KM method, with the median time to event and related 95% CI.

CI, confidence interval; D, durvalumab; GemCis, gemcitabine and cisplatin; rwOS, real-world overall survival.

Plain language summary

Background: Why did we perform this research?

- Advanced biliary tract cancers (aBTC) start in the bile ducts either within the liver (also known as intrahepatic cholangiocarcinoma) or outside the liver (known as extrahepatic cholangiocarcinoma) or in the gallbladder and then spread to other parts of the body. Based on previous clinical trial findings, durvalumab (a type of immunotherapy drug) plus gemcitabine and cisplatin (a type of chemotherapy) is an approved treatment for patients with aBTC
- Real-world studies can assess how patients are treated in everyday practice and provide information on the outcomes of treatment. Currently, real-world data are limited for patients with aBTCs in the US
- This study describes the characteristics of, and outcomes for, patients treated with durvalumab plus gemcitabine and cisplatin (D + GemCis) or GemCis who may or may not have met the medical standards for a clinical trial. The patient population in this analysis may be more representative of patients that physicians are treating

Methods: How did we perform this research?

- Data were taken from Optum's de-identified Market Clarity database (a database with information on patient medical and pharmacy claims) for patients diagnosed with aBTC between 2019 and 2025 and treated with D + GemCis or GemCis in the US

Results: What were the findings of this research?

- Data from 210 patients treated with D + GemCis and 426 patients treated with GemCis were included in the study
- Most patients treated with D + GemCis or GemCis were diagnosed with intrahepatic cholangiocarcinoma (>71% of patients), while about 10% of patients were diagnosed with extrahepatic cholangiocarcinoma
- More than half of patients treated with D + GemCis or GemCis lived for at least 12 months. The time it took for patients to move to the next treatment was, on average, >7 months for those treated with D + GemCis or GemCis

Conclusions: What are the implications of this research?

- To the best of our knowledge, this is the first study in the US utilizing healthcare data to describe real-world characteristics and outcomes in patients with aBTC treated with D + GemCis or GemCis
- These results are similar to those reported in other clinical and real-world studies that have reported positive patient outcomes with these treatments

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Poster presented at the Cholangiocarcinoma Foundation (CCF) Annual Conference 2026 by James J. Harding

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Poster

Poster presented at the Cholangiocarcinoma Foundation (CCF) Annual Conference 2026, Salt Lake City, UT, USA, May 1–3, 2026

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