

Real-world characteristics, costs, and outcomes with best supportive care vs anticancer therapy in patients with advanced BTC

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Objective

- This real-world study characterized baseline demographics and clinical characteristics, healthcare costs, and outcomes of patients with advanced biliary tract cancer (BTC) receiving best supportive care (BSC) and anticancer therapy (ACT) in the US

Conclusions

- To our knowledge, this is the first comprehensive analysis describing US patients with advanced BTC receiving BSC versus ACT. Patients receiving BSC were older and generally in poorer health at baseline compared with patients receiving ACT
- Overall, total healthcare costs were higher and real-world overall survival (rwOS) was numerically shorter in patients who received BSC versus ACT, highlighting an unmet need for this population
- These findings reinforce the need to reduce healthcare costs and improve outcomes for patients with advanced BTC. This may be achieved by educating healthcare professionals to consider more patients for systemic therapy and by providing patient advocacy and support as early as possible after diagnosis, to improve patient understanding of treatment options and facilitate shared decision-making
- Future research will focus on evaluating which patients receiving BSC may benefit from receiving ACT

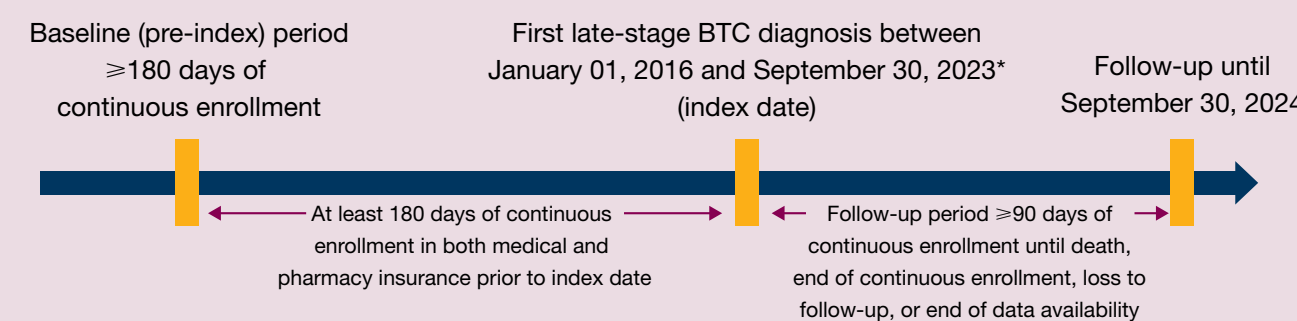
Introduction

- Patients with BTCs often have delayed diagnosis at an advanced stage, resulting in limited therapeutic options and poor prognosis¹⁻³
- Although immunotherapy combined with the chemotherapies gemcitabine and cisplatin is considered standard of care for late-stage BTC, BSC remains a viable option¹
- There is limited research examining patient and clinical characteristics, healthcare costs, and outcomes of patients receiving BSC in the US

Methods

- This retrospective, observational study analyzed US-based Optum's de-identified Market Clarity Data (Optum® Market Clarity) of adults diagnosed with late-stage BTC from January 2016–September 2023 (Figure 1)
- Patients were followed from the index date (date of initial BTC diagnosis) for at least 90 days of continuous enrollment in both medical and pharmacy insurance until death, end of continuous enrollment, loss to follow-up, or end of data availability (September 30, 2024), whichever occurred first
- The BSC group received no chemotherapy, immunotherapy, targeted, liver-directed, or radiation therapy, or BTC-related surgical resection; the ACT group received one or more of the above therapies, excluding resection, on or after initial BTC diagnosis
- This study reports baseline characteristics, healthcare costs calculated per patient per month (PPPM), and rwOS (time from index to death) estimated using Kaplan-Meier methods
- As this was an exploratory analysis without adjustment for potential confounders, comparisons between ACT and BTC groups should be considered hypothesis-generating only

Figure 1. Study design



Patients were included if they had ≥2 BTC diagnosis codes 1–90 days apart present in any patient records, with ≥1 diagnosis of late-stage BTC on or after the initial BTC diagnosis. Where data regarding American Joint Committee on Cancer disease stage at diagnosis were not clearly recorded, claims-based proxies were used to extrapolate stage at diagnosis. *Late-stage BTC includes cancer that has spread to nearby tissue or lymph nodes (i.e., Stage IIIA) and advanced / metastatic which is defined as cancer that has spread to the large vessels that carry blood to the organs in the abdomen, to one or more nearby lymph nodes, or to other parts of the body, such as the liver, lungs, or abdomen (i.e., Stage IIIB to Stage IV BTC). BTC, biliary tract cancer.

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Disclosures

MM reports consulting fees from AstraZeneca. SR, MF-K, JM, EC, LC, and YJ are employees and / or shareholders of AstraZeneca.

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Results and interpretation

Baseline demographics and clinical characteristics

- In total, 1576 patients with late-stage BTC were included in this analysis (Table 1)
 - The BSC group included 431 patients
 - The ACT group included 1145 patients
- Baseline demographics were generally similar between groups; however, the BSC group was older than the ACT group (median age: 73 years vs 64 years) (Table 1)
- The BSC group had a greater prevalence of cardiovascular disease (48.7% vs 37.6%), diabetes (37.6% vs 30.0%), higher mean CCI score (2.2 vs 2.0), and more adverse liver function (ALBI Grade 3: 22.3% vs 8.2%) compared with the ACT group (Table 1)

Table 1. Baseline demographics and clinical characteristics

	BSC (N=431)	ACT (N=1145)	Overall (N=1576)
Age, years, median (Q1–Q3)	73 (63–81)	64 (57–72)	66 (59–75)
Female patients, n (%)	232 (53.8)	597 (52.1)	829 (52.6)
Race, n (%)			
Caucasian (White)	307 (71.2)	880 (76.9)	1187 (75.3)
African American	63 (14.6)	131 (11.4)	194 (12.3)
Asian	20 (4.6)	50 (4.4)	70 (4.4)
Unknown / missing	41 (9.5)	84 (7.3)	125 (7.9)

Site of primary tumor recorded at earliest BTC diagnosis, n (%)*

Intrahepatic CCA	262 (60.8)	799 (69.8)	1061 (67.3)
Gallbladder cancer	108 (25.1)	204 (17.8)	312 (19.8)
Extrahepatic CCA	84 (19.5)	150 (13.1)	234 (14.9)
Other	65 (15.1)	140 (12.2)	205 (13.0)
Ampulla of Vater	14 (3.3)	35 (3.1)	49 (3.1)

CCI score during baseline, mean (SD)[†]

	2.2 (2.1)	2.0 (1.7)	2.0 (1.8)
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Comorbid conditions of interest and risk factors of BTC during baseline, n (%)*

Cardiovascular disease	210 (48.7)	430 (37.6)	640 (40.6)
Any diabetes mellitus (type 1, type 2, drug-induced, etc)	162 (37.6)	344 (30.0)	506 (32.1)
Obesity (using ICD diagnosis codes or BMI values)	134 (31.1)	368 (32.1)	502 (31.9)
Liver cirrhosis	53 (12.3)	122 (10.7)	175 (11.1)

Signs and symptoms of BTC during baseline, n (%)*

Jaundice	91 (21.1)	165 (14.4)	256 (16.2)
Biliary obstruction	62 (14.4)	174 (15.2)	236 (15.0)

ALBI grade, n (%)[†]

Grade 1 (≤-2.60)	45 (10.4)	217 (19.0)	262 (16.6)
Grade 2 (>-2.60 and ≤-1.39)	133 (30.9)	331 (28.9)	464 (29.4)
Grade 3 (>-1.39)	96 (22.3)	94 (8.2)	190 (12.1)
Missing	157 (36.4)	503 (43.9)	660 (41.9)

*Not mutually exclusive. [†]The CCI score was calculated after excluding primary malignancies and metastatic solid tumors. [†]ALBI scores were calculated for each patient using albumin (measured in g/L) and bilirubin (measured in μmol/L) values recorded within ±8 weeks of each other during the 6-month baseline period. ALBI score = (log10 bilirubin × 0.66) + (albumin × -0.085). ACT, anticancer therapy; ALBI, albumin-bilirubin; BMI, body mass index; BSC, best supportive care; BTC, biliary tract cancer; CCA, cholangiocarcinoma; CCI, Charlson Comorbidity Index; ICD, International Classification of Diseases; Q1–Q3, first quartile to third quartile; SD, standard deviation.

Healthcare costs during follow-up period

- For patients with available healthcare cost data during the follow-up period, the BSC group (288 / 431) incurred higher total healthcare costs than the ACT group (1111 / 1145), with a mean (SD) PPPM cost of \$32,257 (\$42,085) versus \$27,438 (\$24,736), respectively (Table 2)
- Higher total healthcare costs for patients receiving BSC versus ACT were mainly driven by inpatient costs (mean [SD]: \$26,387 [\$36,753] vs \$13,462 [\$20,292], respectively) (Table 2)

Table 2. All-cause healthcare resource utilization and costs during follow-up period (\$US 2024 PPPM)

	BSC (N=431)	ACT (N=1145)	Overall (N=1576)
Patients with available data, n (%)	288 (66.8)	1,111 (97.0)	1,399 (88.8)
Healthcare costs, mean (SD)			
Total healthcare costs [†]	32,257 (42,085)	27,438 (24,736)	28,430 (29,210)
Total inpatient costs [†]	26,387 (36,753)	13,462 (20,292)	16,123 (25,131)
Total outpatient costs [†]	3,951 (11,150)	8,106 (8,984)	7,250 (9,614)
Total ED costs [†]	638 (1,783)	540 (1,398)	560 (1,485)
Total pharmacy costs [†]	1,281 (7,130)	5,331 (8,039)	4,497 (8,027)

Patients were followed from the index date until death, end of continuous enrollment, loss to follow-up, or end of the data availability (September 30, 2024), whichever came first. [†]One patient in the BSC group and one patient in the ACT group were not included in the cost calculations, as they had negative cost values recorded. [†]Includes inpatient, ED, outpatient, and pharmacy costs among patients with at least one inpatient / outpatient / ED visit or pharmacy fill. [†]Costs are the mean cost PPPM, calculated as the costs incurred over the follow-up period divided by the patient-months of observation, standardized to the 2024 US dollar. ACT, anticancer therapy; BSC, best supportive care; ED, emergency department; PPPM, per patient per month; SD, standard deviation.

Real-world overall survival

- With a median follow-up of 1.6 months, the BSC group had a median (95% CI) rwOS of 2.2 (2.0–2.4) months (Figure 2A)
- With a median follow-up of 8.6 months, the ACT group had a median (95% CI) rwOS of 11.4 (10.7–12.6) months (Figure 2B)

Figure 2A. rwOS in patients receiving BSC

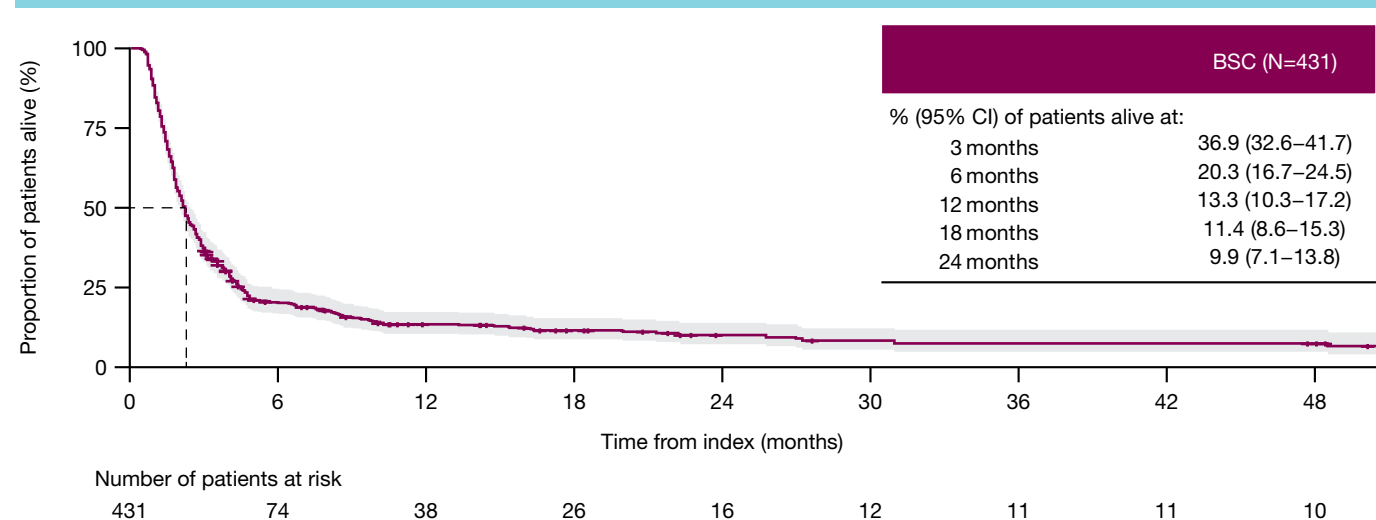
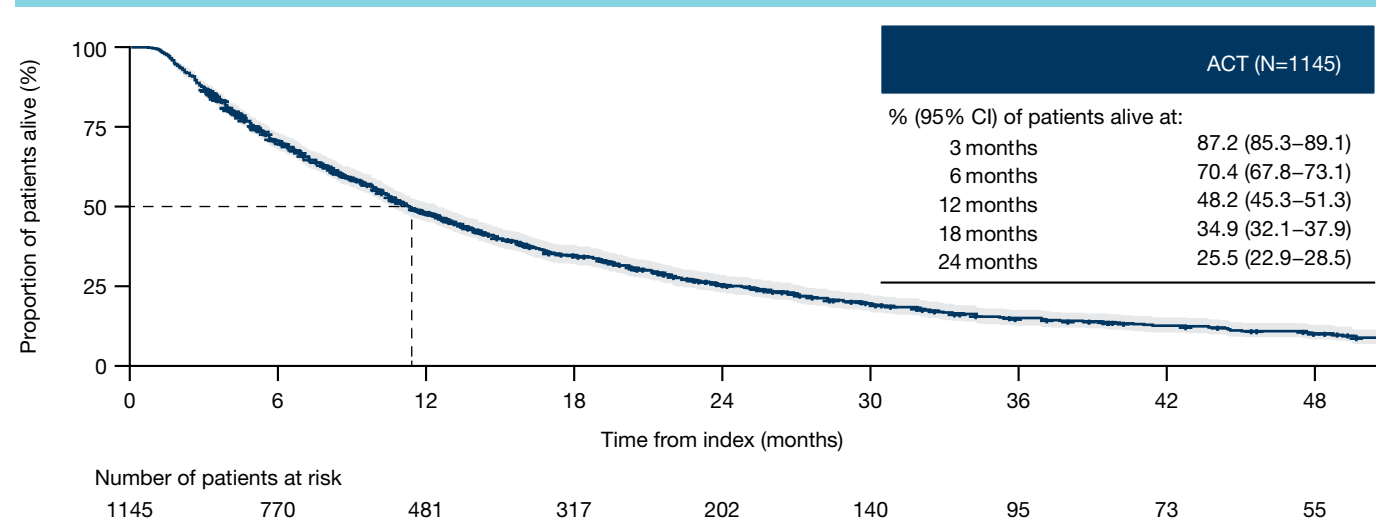


Figure 2B. rwOS in patients receiving ACT



rwOS and rwOS landmark rates were estimated using Kaplan-Meier methods. Median rwOS and 95% CI were reported separately for each BSC and ACT subgroup. rwOS was calculated as the time from diagnosis of late-stage BTC (index date) to the date of death from any cause, defined as an event. Death dates were captured in the data at month-year granularity. For recorded deaths, the last day of each month was imputed. Patients with no evidence of death were censored at the end of their health insurance enrollment or the end of data availability, whichever came first. ACT, anticancer therapy; BSC, best supportive care; CI, confidence interval; rwOS, real-world overall survival.

Plain language summary



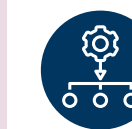
Background: Why did we perform this research?

- Biliary tract cancers (BTCs) are cancers of the bile ducts, often diagnosed in the advanced stage when they are harder to treat. As a result, patients have limited treatment options and poor outcomes
- While immunotherapy (drugs that target the immune system to help the body fight cancer) combined with chemotherapy is the standard treatment given to patients with late-stage BTC (cancer that has spread to nearby tissues and / or lymph nodes, as well as other parts of the body), some patients receive best supportive care (BSC), focused on relieving symptoms and improving comfort, rather than controlling the cancer
- However, there is a lack of research into the characteristics, healthcare costs, and outcomes of patients receiving BSC in the US



Methods: How did we perform this research?

- Patients were enrolled in the Optum® Market Clarity database between January 2016 and September 2023
- We looked at data from all adult patients with late-stage BTC who received either BSC or anticancer therapy (ACT), which included treatments such as immunotherapy and surgery



Results: What were the findings of this research?

- Compared with the patients who received ACT, patients who received BSC were older and had more comorbidities such as heart disease and worse liver function
- Patients who received BSC had higher overall healthcare costs compared with those who received ACT, largely due to higher inpatient costs
- Following their BTC diagnosis, and after starting their treatments, half of all patients receiving BSC were still alive at 2.2 months and half of all patients receiving ACT were alive at 11.4 months



Conclusions: What are the implications of this research?

- This is the first study in the US using healthcare claims data to describe the characteristics of people with late-stage BTC receiving BSC. Compared with those who received ACT, patients who received BSC were older and generally in poorer health, with higher healthcare costs, and lived for a shorter length of time after diagnosis
- These results highlight opportunities to improve care and outcomes in patients receiving BSC, including through initiatives such as expanded patient advocacy. Future studies will look at identifying which patients receiving BSC may benefit from receiving ACTs

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Poster

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