503: Epidemiological Characterization Of Biliary Tract Cancer Patients From The Spanish RETUD Registry

T Macarulla[1], F Castet[1], A Castillo[2], R Vera[3], R Vidal-Tocino[4], AJ Muñoz[5], P García-Alfonso[5], A Fernández[6], M Lobo[7], RM Rodríguez-Alonso[8], E Aranda[8], M Granja[9], J Adeva[10], A Modrego-Sánchez[10], R Álvarez[11], J Martínez-Galán[12], T García[13], E Martínez de Castro[14], I Alés[15], A La Casta[16]

[1]Medical Oncology Department, Hospital Clínic, Barcelona, Spain. [2]Medical Oncology Department, Hospital Universitario Central de Asturias, Asturias, Spain. [3]Medical Oncology Department, Hospital Universitario de Navarra, Navarra, Spain. [4]Medical Oncology Department, Hospital Universitario de Salamanca, IBSAL, Salamanca, Spain. [5]Medical Oncology Department, Hospital General Universitario Gregorio Marañón, Madrid, Spain. [6]Medical Oncology Department, Complejo Hospitalario Universitario de Ourense, Ourense, Spain. [7]Medical Oncology Department, Consorcio Hospital General Universitario de Valencia, Valencia, Spain. [8]Medical Oncology Department, Hospital Universitario Reina Sofía, Córdoba, Spain. [9]Medical Oncology Department, Hospital Clínico San Carlos, Madrid, Spain. [10]Medical Oncology Department, Hospital Universitario 12 de Octubre, Madrid, Spain. [11]Medical Oncology Department, Hospital Universitario HM Sanchinarro, Madrid, Spain. [12]Medical Oncology Department, Hospital Universitario Virgen de las Nieves, Granada, Spain. [13]Medical Oncology Department, Hospital Universitario Santa Lucía, Cartagena, Spain. [14]Medical Oncology Department, Hospital Universitario Marqués de Valdecilla, Santander, Spain. [15]Medical Oncology Department, Hospital Regional Universitario de Málaga, Málaga, Spain. [16]Medical Oncology Department, Hospital Universitario de Donostia, San Sebastián, Spain

Background

- Biliary tract cancer (BTC) is a heterogeneous group of tumors, including cholangiocarcinoma (intra and extrahepatic) and gallbladder carcinoma (GC).[1]
- BTC account for ~3% of gastrointestinal cancers.[2,3] Age-standardized incidence rate for GC and BTC in Spain (2019) is 6.9 cases per 100,000 inhabitants.[4]
- In this study, we aimed to describe the epidemiology of BTC patients from the RETUD registry.

Methods

- Patients included in this analysis were diagnosed with BTC between January 1st, 2017, and May 30th, 2025.
- Patients were analyzed in two different populations as shown in **figure 1**. Patients could be included in both populations.

Figure 1. Definition of patient populations for the analysis

Resectable disease population (RD)

✓ Patients with neoadjuvant therapy as first therapeutic approach

Advanced disease population (AD)

✓ Patients from RD population with tumor relapse

✓ First line systemic treatment as first therapeutic approach

- Analysis comprised demographic and clinical data, tumor molecular profile, therapeutic procedures and efficacy outcomes. Time to relapse (TTR), progression-free survival (PFS) and overall survival (OS) were estimated using the Kaplan-Meier method. P-value < 0.05 was considered statistically significant. All analysis were done using statistical software SAS v9.4.

Results

- 1756 patients from 40 different hospitals were included in the study and analyzed per population, as described in **table 1**. Main findings for the whole population are shown in **table 2**.

Table 1. Patient disposition

Variable	N = 1,756[1]
Resectable disease population	695 (39.6%)
Advanced disease population	1450 (82.6%)
Population	
Advanced disease only	1061 (60.4%)
Resectable and Advanced disease	389 (22.2%)
Resectable disease only	306 (17.4%)

[1]n (%)

Table 2. Demographic and clinic characteristics

Variable	N = 1,756[1]
Age at primary tumor diagnosis [median (Q1, Q3)]	68.6 (61.2, 74.9)
Sex (female)	978 (55.7%)
Location of primary tumor	
Intrahepatic	931 (53.0%)
Gallbladder carcinoma	272 (15.5%)
Extrahepatic distal	253 (14.4%)
Extrahepatic hiliar	226 (12.9%)
Ampulla of vater	47 (2.7%)
Other	27 (1.5%)
Chemotherapy	1586 (90.3%)
Immunotherapy	188 (10.7%)
Targeted therapy	111 (6.3%)
Clinical trial	136 (7.7%)

[1]n (%)

This large multicenter real-world study provides a comprehensive **characterization of biliary tract cancer** epidemiology in Spain. Treatment patterns observed, specifically those with **immunotherapy** and **targeted therapies**, reflect a **progressive uptake** of these innovative treatments in **standard of care** therapies.

- Biomarker information was provided in 591 (33.7%) patients, ESCAT-I alterations were found in 168 (28.4%) of them. Most frequent ESCAT-I alterations are presented in **table 3.** A total of 111 patients (6.3%), all of them from the AD population, were treated with targetable alterations. Targeted therapies increased median OS from 16.5 (95% CI 14.6-18.0) to 25.4 (95% CI 22.4-28.8) (p < 0.001) (**Figure 2**).

Table 3. Most frequent ESCAT-I alterations

ESCAT-I	Biomarker determination (N)	Alteration [N (%)]
IDH1 mutation	447	75 (16.8%)
FGFR2 fusion	401	32 (8.0%)
MSI	491	30 (6.1%)
HER2 amplification/overexpression	449	25 (5.7%)

- Main findings for **RD** and **AD** are described in **table 4** and **table 5** respectively.

Table 4. Resectable disease population characteristics

Variable	N = 695[1]
Age at primary tumor diagnosis [median (Q1, Q3)]	68.8 (61.6, 74.9)
Sex (female)	276 (39.7%)
Surgery for primary tumor	665 (95.7%)
Locoregional therapy	104 (15.0%)
Neoadjuvant treatment	27 (5.0%)
Adjuvant treatment	375 (68.9%)
Follow-up time (months) [median (Q1, Q3)]	23.9 (14.4, 39.5)
Median OS (months) (95% CI)	33.0 (30.2-38.9)
Median TTR (months) (95% CI)	19.4 (17.3-22.2)

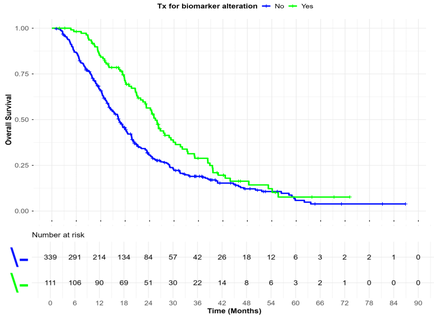
[1]n (%)

Table 5. Advanced disease population characteristics

Variable	N = 1450[1]
Age at primary tumor diagnosis [median (Q1, Q3)]	68.4 (61.0, 74.6)
Sex (female)	656 (45.2%)
First line treatment	1372 (96.4%)
CISGEM	923 (67.3%)
Second line treatment	606 (42.6%)
FOLFOX	201 (33.2%)
Thromboembolic events	158 (17.3%)
Follow-up time (months) [median (Q1, Q3)]	13.2 (6.7, 22.9)
Median OS (months) (95% CI)	10.4 (9.7-11.2)
Median PFS 1L (months) (95% CI)	5.3 (4.9-5.6)

[1]n (%)

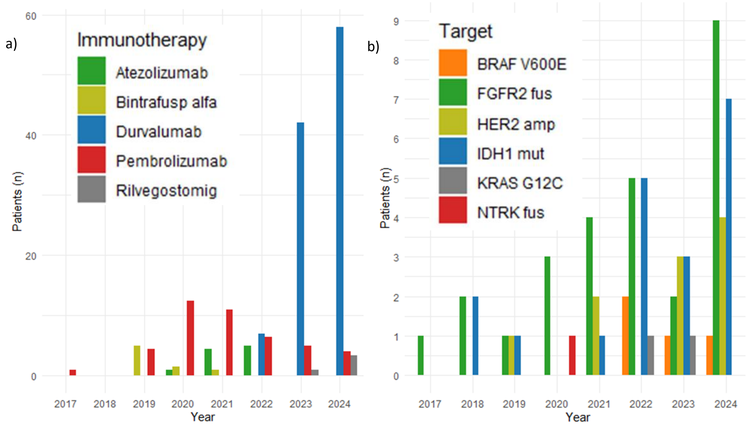
Figure 2. Overall survival for AD patients treated with targeted therapies vs other treatments



Targeted therapies	Median (95% CI)	Hazard Ratio (95% CI)	p-value
No	16.5 (14.6-18.0)	Reference	
Yes	25.4 (22.4-28.8)	0.64 (0.50-0.82)	0.0004

- Evolution of treatment with both immunotherapy and targeted therapies through the years is shown in **figure 3.**

Figure 3. Number of patients treated by year with: a) Immunotherapies and b) Targeted therapies against ESCAT-I alterations



- There were differences in mOS by age groups; 20.9 months (95% CI 16.8-26.9) in patients under 50 years old vs 16.3 months (95% CI 15.1-17.3) in patients of 50 or more years old (p = 0.033); but not for sex; 16.3 months (95% CI 14.9-17.9) in males vs 16.6 months (95% CI 15.1-17.9) in females (p = 0.444).

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Contact email: macarulla@clinic.cat

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