EFFECTIVENESS AND SAFETY OF DURVALUMAB IN UNRESECTABLE OR METASTATIC CHOLANGIOCARCINOMA

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BACKGROUND AND IMPORTANCE

Unresectable or metastatic colangiocarcinoma (CCUoM) is a type of biliary tract cancer with poor prognosis. Results from the pivotal trial "TOPAZ-1" suggest that adding durvalumab (anti-PD-L1) to standard therapy (platinum-gemcitabine(PtGem)) may improve survival outcomes.

AIM AND OBJECTIVES

Evaluate the effectiveness and safety of durvalumab in combination with PtGem (PtGemDur) as first-line therapy for CCUoM, comparing it with a historical cohort, PtGem, and results from TOPAZ-1.

MATERIALS AND METHODS

A retrospective descriptive study of patients with CCUoM

Two cohorts

Treated with PtGem

from 06/2018-06/2021

Treated with PtGemDur

from 06/2021-06/2024.

Data collected from Oncofarm® software and medical records:

Sex, Age and ECOG

Effectiveness:

- Survival (OS)
- Progression-free survival (PFS)

According to the Kaplan-Meier method, using SPSS® statistical software.

Safety:

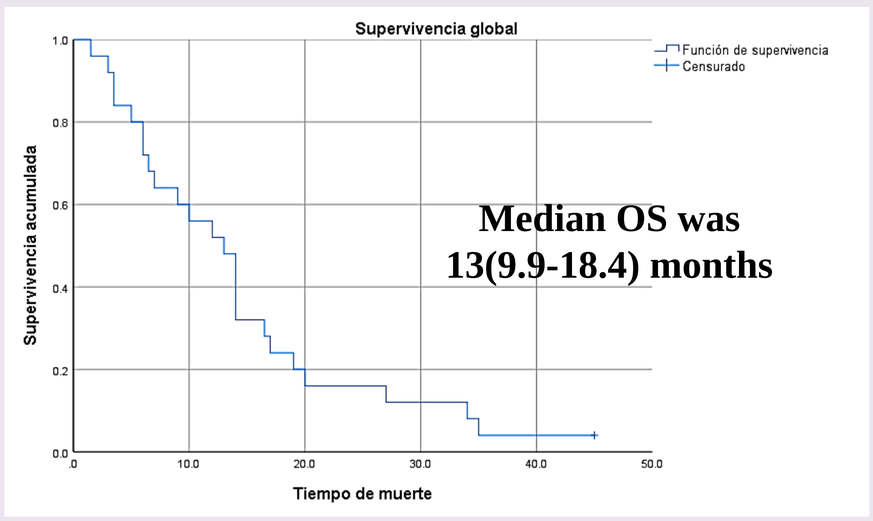
Type of adverse events (AEs) and discontinuations.

RESULTS

PtGem

25 received PtGem.

Median age 66(41-81) years, 64% men, ECOG1: 76%, rest ECOG0 and 76% intrahepatic.



Median PFS was 9(7.6-23.2) months.

92% had AEs of any grade

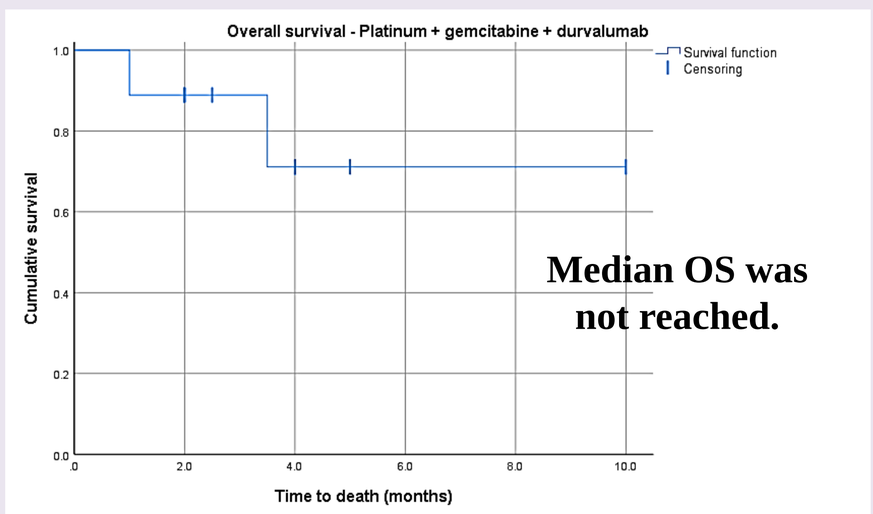
The most frequent AEs were hematologic 31% and digestive 13.8%.

Discontinuations were 68%.

PtGemDur

9 received PtGemDur.

Median age 70(49-80) years, 92% men, ECOG0: 55.6%, rest ECOG1 and 55.6% intrahepatic.



Median PFS was 9(8.8-10.2) months.

100% had AEs of any grade

The most frequent AEs were hematologic 15.4% and digestive 23.1%.

There were no immune-mediated effects.

Discontinuations were 44%.

TOPAZ-1

Median age 64(20-84) years, 49.6% men, ECOG0: 50.7% and 55.7% intrahepatic.

Median OS was 12.8(11.1-14) months.

Median PFS 7.2(6.7-7.4) months.

99,4% had AEs of any grade

The most frequent AEs were hematologic 48.2%, 40.2% digestive and 12.7% immune-mediated.

Discontinuations occurred in 13%.

CONCLUSION AND RELEVANCE

In our study, the current cohort sample is small, so results obtained need to mature to confirm the benefits in OS.

The PFS results are similar to and slightly superior to those of TOPAZ-1.

In terms of safety, AEs were similar in both cohorts and with respect to the TOPAZ-1.

No immune-mediated effects were observed in our populations.

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