

Background:

- Immune checkpoint-inhibitors (ICIs) improve the survival in certain cancers.
- Little is known about their biliary toxicity.
- We investigated the epidemiology of ICI-induced cholangitis and describe underlying associations.

Methods:

- Commercial database (Explorys Inc, Cleveland, OH) with 26 major integrated US healthcare systems.
- A cohort of patients who were on ICIs (nivolumab, pembrolizumab, ipilimumab and atezolizumab)
- Conducted between 2011 and 2022
- Patients who developed new diagnosis of cholangitis after taking ICIs were selected.

Variable	Patients who received ICI		Patients with Cholangitis who did not receive ICI
	ICI without Cholangitis	ICI-Induced Cholangitis	
Age			
18 -65	7190 (37%)	90 (35%)	417,140 (59%)
>65	12,250 (63%)	160 (62%)	288,960 (41%)
Female	8,130 (42%)	130 (50%)	475,350 (67%)
Race			
Caucasian	16,150 (84%)	220 (85%)	539,340 (76%)
Others	3180 (16%)	40 (15%)	171,010 (24%)
Co-morbidities			
Hypertension	19,330 (71%)	200 (77%)	382,890 (54%)
T2DM	5,560 (29%)	90 (35%)	176,910 (25%)
Hyperlipidemia	11,830 (62%)	160 (62%)	329,520 (47%)
Obesity	4,510 (23%)	90 (35%)	236,120 (33%)
CAD	5,720 (30%)	90 (35%)	130,060 (18%)
Cholelithiasis	1,570 (8%)	170 (65%)	532,590 (75%)

Table 1: Baseline Characteristics of Patients Receiving ICIs

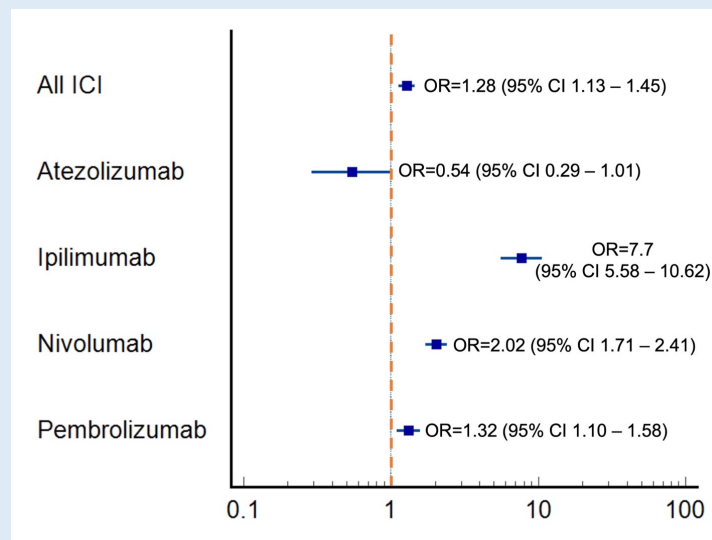


Figure 1: Odds Ratio with 95% Confidence Interval of Immune Checkpoint Inhibitor-Induced Cholangitis

Results:

- 417,390 patients had a diagnosis of cholangitis
- 260 patients had a prior history of ICI use.
- Patients with ICI use and cholangitis were more likely to be female [OR: 1.38; 95% CI 1.08–1.76].
- No statistically significant age or race-based differences.
- Patients who received any ICI had a significantly higher risk of cholangitis [OR: 1.28; 95% CI 1.13–1.45].
- Patients who received Ipilimumab had the highest odds of developing ICI-induced cholangitis (Figure 1).

Discussion:

- Patients taking ICI have a higher risk of cholangitis
- Ipilimumab poses the greatest risk for ICI-induced for cholangitis.
- The risk of cholangitis should be discussed with all patients prior to initiating an ICI