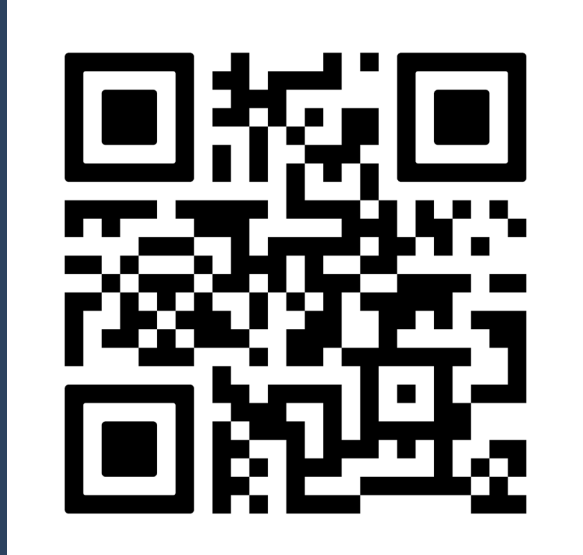


Healthcare Resource Utilization and Costs Associated With Hepatitis B Virus Monoinfection Compared With Hepatitis Delta Virus Prior to Death Among Adults in Italy in the Outpatient Setting

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Conclusions

- Patients with hepatitis delta virus (HDV) had similar outpatient healthcare resource utilization (HCRU) rates before death as the patients with hepatitis B virus (HBV) monoinfection (HBV only)
- Mean per-patient outpatient cost was higher for patients with HDV in their last year of life compared with those with HBV only, highlighting a need for treatments that reduce the personal and economic burden of HDV
- There was a trend toward a higher number of outpatient visits in patients with HDV compared with those with HBV only at both 6 and 12 months prior to death

Plain Language Summary

- Hepatitis delta virus (HDV) infection causes the most severe form of hepatitis and increases the risk of liver disease–related death
- In the outpatient setting in Italy, patients with HDV and those with only hepatitis B virus (HBV) had similar healthcare resource utilization rates
- Patients with HDV had higher per-patient costs in their last year of life compared with patients with HBV
- These findings highlight a need for treatments to reduce the personal and economic burden of HDV

References: 1. Lempp FA, et al. *Nat Rev Gastroenterol Hepatol*. 2016; 13(10):580-9. 2. Huang C, et al. *World J Gastroenterol*. 2014;20(40):14589-97. 3. Da BL, et al. *Gastroenterol Rep*. 2019;7(4):231-45.

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INTRODUCTION

- HDV is a defective RNA virus that completes replication and transmission in the presence of hepatitis B surface antigen^{1,2}
- HDV causes a more severe form of viral hepatitis than does HBV alone^{1,2}
- Chronic HDV infection results in more rapid progression to cirrhosis, and an increased risk for hepatocellular carcinoma and liver disease–related death, compared with HBV only³

OBJECTIVE

- This retrospective study evaluated HCRU and costs in the year prior to death between adults with HDV and those with HBV only in the outpatient setting in Italy

METHODS

- Administrative databases from local health units in Italy, covering 12 million people, were screened for patients with ≥1 HBV or HDV outpatient claim (using exemption codes) between Jan 1, 2009, and Jun 30, 2022 (study period)
- Patients were included if they had their first HBV or HDV diagnosis between Jan 1, 2010, and Jun 30, 2021, and ≥12 months of continuous enrollment before and after diagnosis (identification period)
- Inverse probability of treatment weighting (IPTW) was calculated using propensity scores (probability of having HBV only or HDV, given baseline covariates)
- Mean per-patient all-cause HCRU and costs were compared using the Mann-Whitney U test between HBV only and HDV cohorts following IPTW

Figure 1. Patient Identification

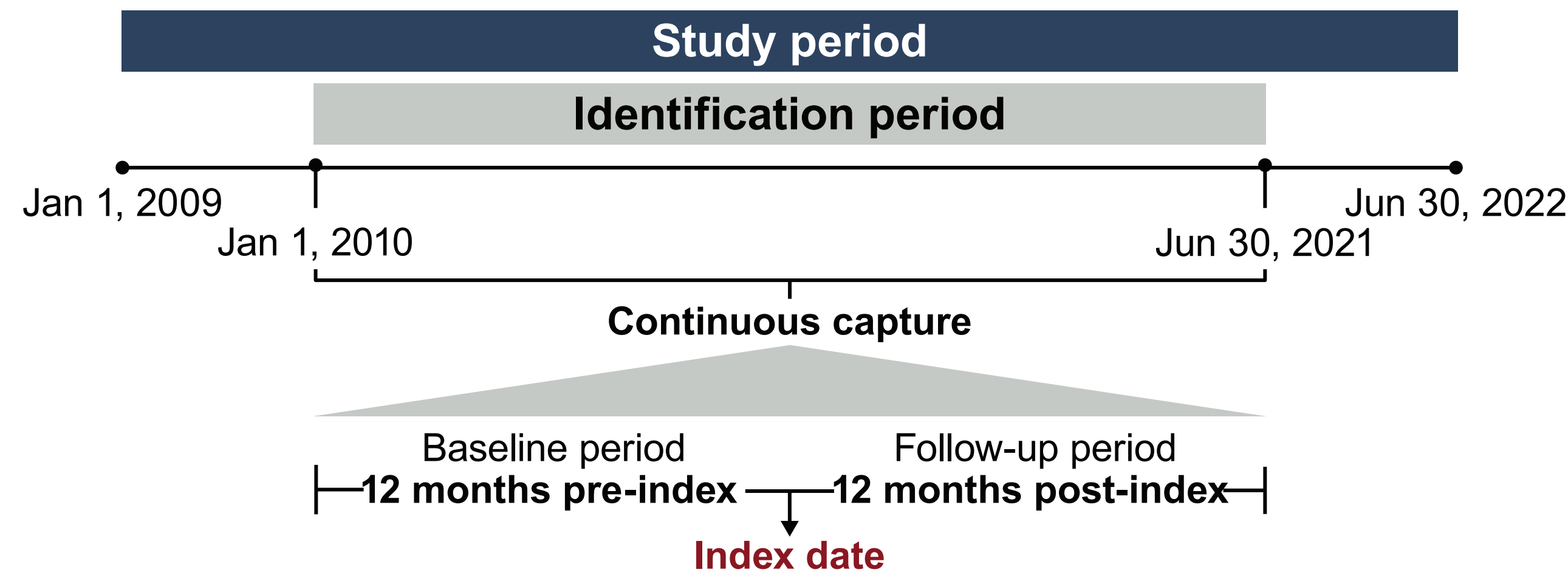
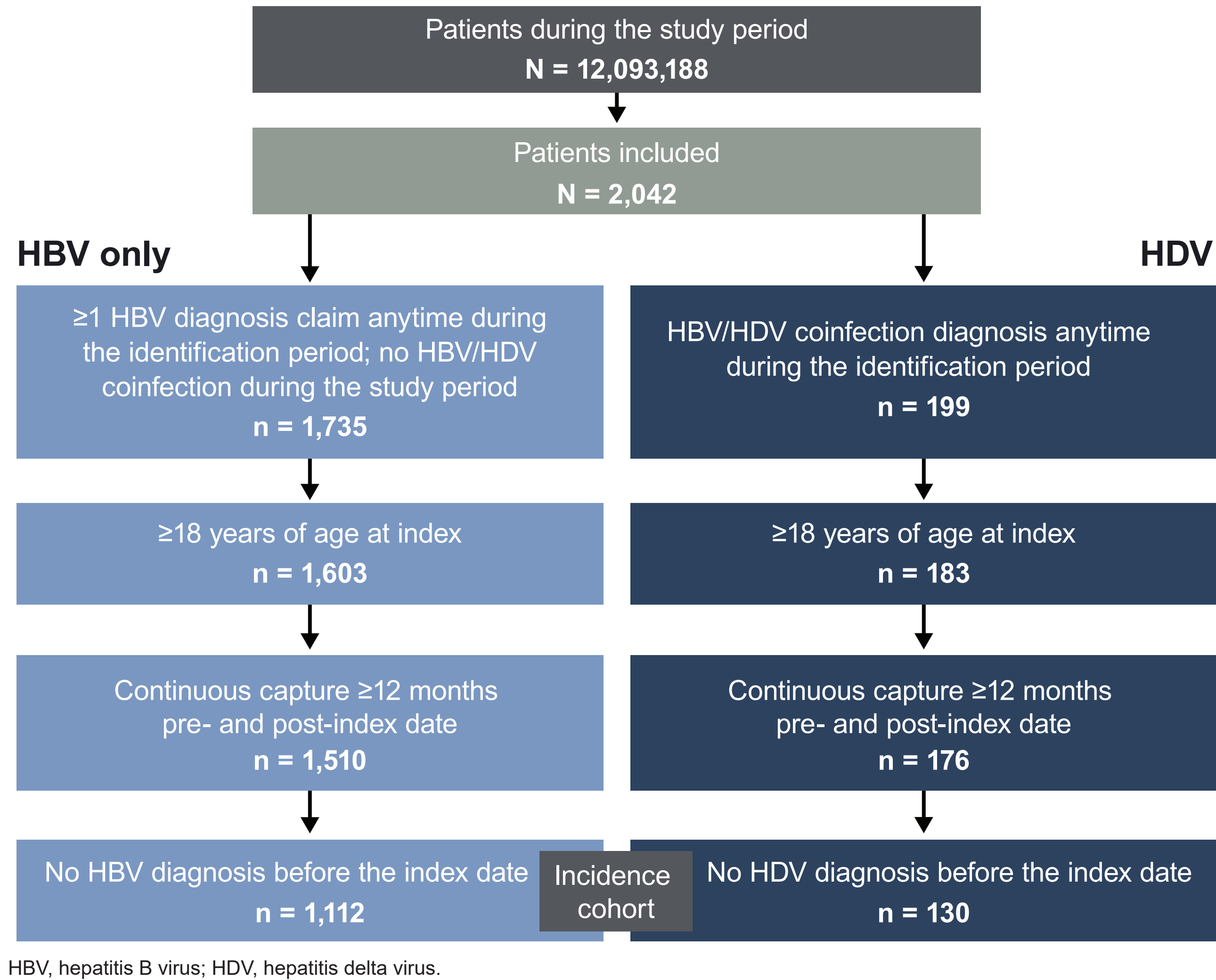


Figure 2. Patient Attrition Flow Chart



- Of 1,242 outpatients meeting inclusion criteria (HBV only, n = 1,112; HDV, n = 130), 55 died

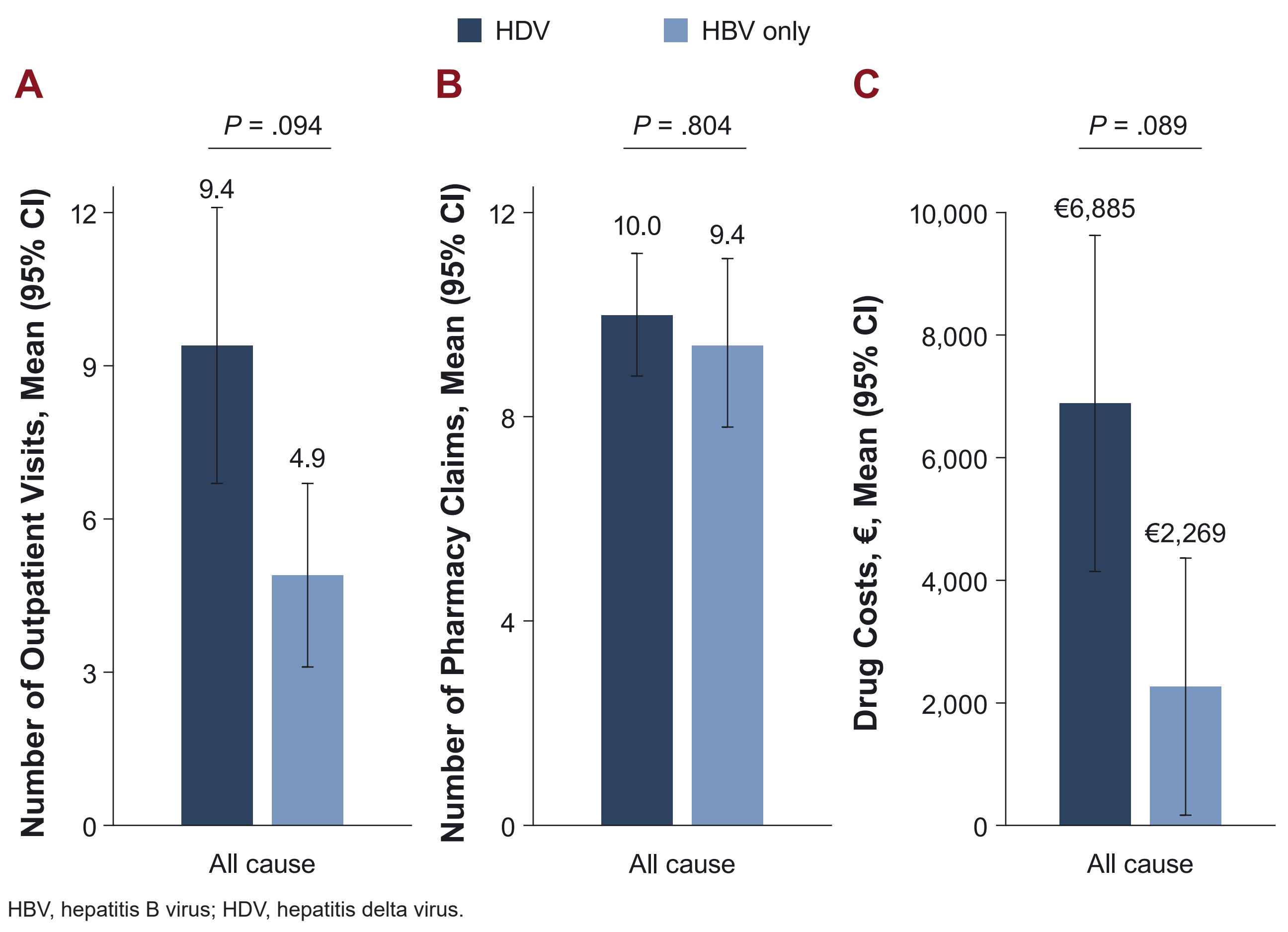
RESULTS

Table 1. Baseline Demographics and Disease Characteristics

Baseline Variables	Before IPTW			After IPTW		
	HBV Only n = 1,112	HDV n = 130	P-Value	HBV Only n = 1,242	HDV n = 1,270	P-Value
Age, years, mean (SD)	49 (14.1)	51 (11.9)	.121	49 (13.9)	50 (14.1)	.671
Age range, years						
18–34	227 (20.4)	11 (8.5)	.001	238 (19.2)	222 (17.5)	.276
35–44	185 (16.6)	28 (21.5)	.161	213 (17.1)	213 (16.8)	.801
45–54	296 (26.6)	46 (35.4)	.034	342 (27.5)	344 (27.1)	.800
55–64	275 (24.7)	31 (23.8)	.825	306 (24.6)	332 (26.1)	.387
65–74	95 (8.5)	12 (9.2)	.791	107 (8.6)	124 (9.8)	.319
≥75	34 (3.1)	<4 (NC)	NC	36 (2.9)	35 (2.8)	.829
Sex, male	618 (55.6)	79 (60.8)	.259	695 (56.0)	615 (48.4)	<.001
CCI, mean (SD)	0.2 (0.5)	0.3 (0.8)	.099	0.2 (0.5)	0.2 (0.7)	.801
CCI score						
0	930 (83.6)	102 (78.5)	.137	1,033 (83.2)	1,069 (84.2)	.497
1	152 (13.7)	24 (18.5)	.138	175 (14.1)	150 (11.8)	.089
2	20 (1.8)	<4 (NC)	NC	23 (1.9)	45 (3.5)	.009
3	8 (0.7)	0 (0.0)	.332	9 (0.7)	0 (0.0)	.002
4+	<4 (NC)	<4 (NC)	NC	<4 (NC)	6 (0.5)	NC

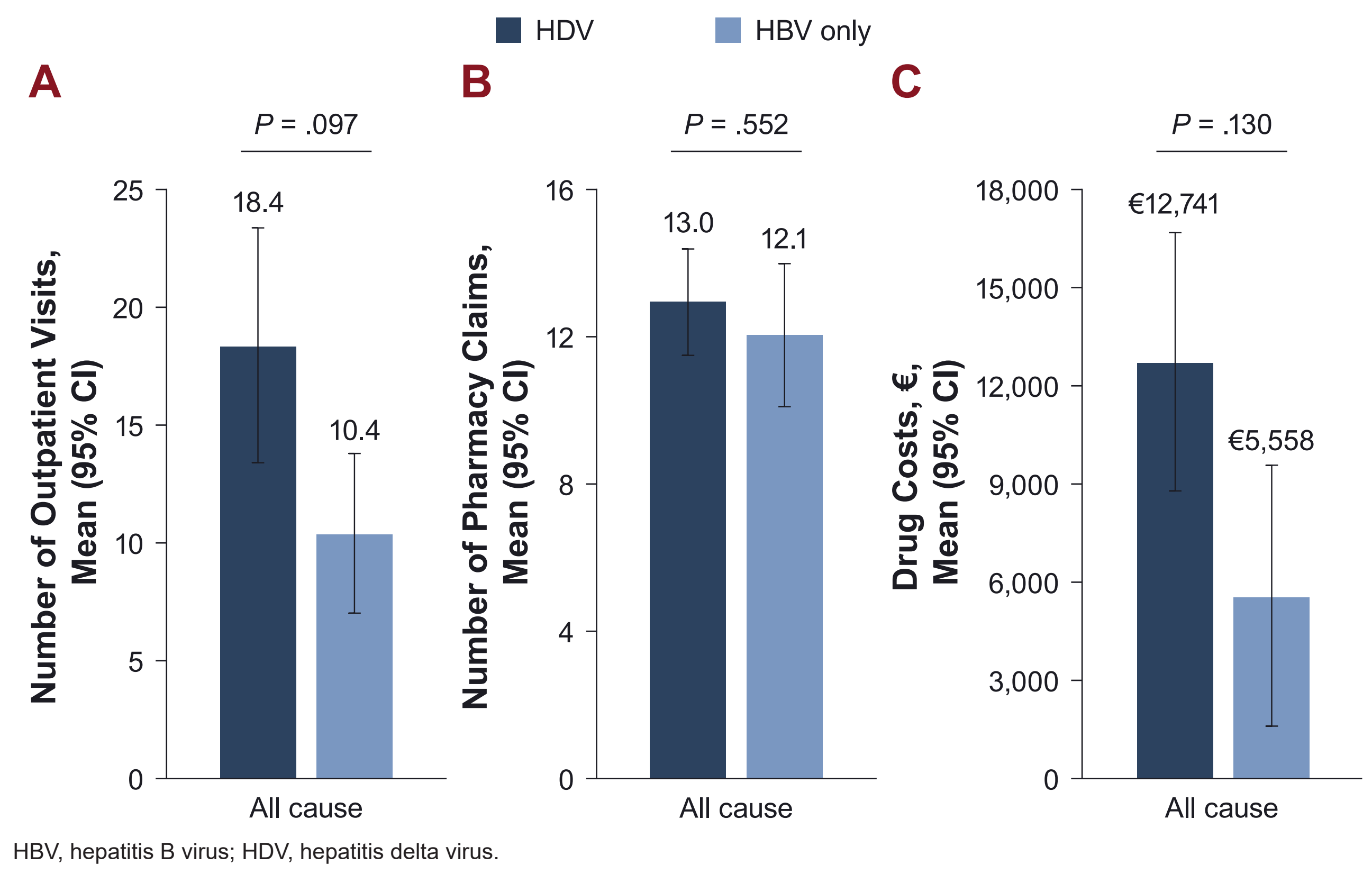
Data are reported as n (%) unless otherwise noted. **Bold** P-values indicate significance for HDV vs HBV only. CCI, Charlson Comorbidity Index; HBV, hepatitis B virus; HDV, hepatitis delta virus; IPTW, inverse probability of treatment weighting; NC, not calculated.

Figure 3. Total All-Cause Outpatient Visits (A), Pharmacy Claims (B), and Drug Costs (C) 6 Months Prior to Death



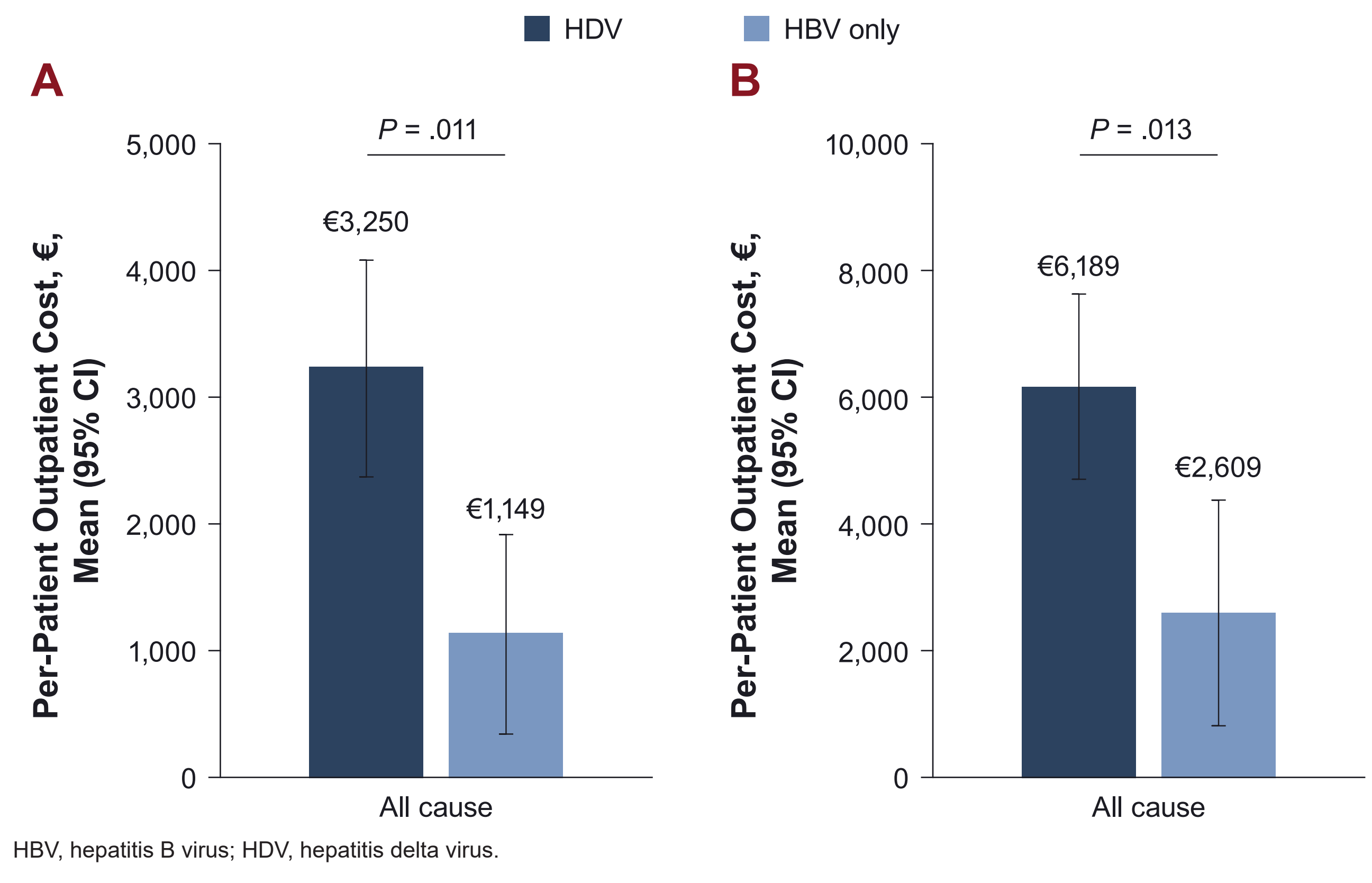
- In the 6 months before death, there were no significant differences in mean per-patient all-cause pharmacy claims or drug costs between patients with HBV only and those with HDV
- There was a trend toward a higher number of outpatient visits in patients with HDV vs those with HBV only

Figure 4. Total All-Cause Outpatient Visits (A), Pharmacy Claims (B), and Drug Costs (C) 12 Months Prior to Death



- In the 12 months before death, there were no significant differences in mean per-patient all-cause pharmacy claims or drug costs between patients with HBV only and those with HDV
- There was a trend toward a higher number of outpatient visits in patients with HDV vs those with HBV only

Figure 5. Total Per-Patient All-Cause Outpatient Costs 6 Months (A) and 12 Months (B) Prior to Death



- In both the 6 months and 12 months before death, mean per-patient all-cause outpatient costs were lower for patients with HBV only than for patients with HDV

LIMITATIONS

- Time of diagnosis may not correspond to the time of infection; therefore, results may reflect delayed HCRU and costs
- Data presented here were measured for other purposes, and confounding factors may not have been measured; therefore, the results should be interpreted with caution
- Although IPTW was performed to account for confounding factors, the study populations may have been underestimated due to the lack of approved diagnostic assays and suboptimal screening practices to determine HDV and HBV status
- The small sample size of patients with HDV and the inherent heterogeneity in HCRU data may limit the ability to determine statistically significant differences between the 2 populations