Key Viral Hepatitis Studies From AASLD 2021

CCO Independent Conference Coverage*

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HBV

TAF for Prevention of HBV Vertical Transmission

- Multicenter, real-world, TDF-controlled study (N = 207)
- **Eligibility**
  - Maternal age >20 yr
  - All pregnancy stages
  - Newly diagnosed with active CHB (treatment naive)
  - Previously diagnosed with active CHB (receiving non-TAF regimen; continue TDF or switch to TAF or TDF from another regimen)
- **Primary endpoints**
  - **Maternal safety:** perinatal adverse events and complications, ALT flare and kidney function at delivery, and postpartum Mo 3 and 6
  - **Infant safety:** structural defects at birth, Apgar scores at 1 min, and abnormal conditions from birth to 7 mo
  - **Infant** anthropometric indexes at birth and 7 mo
- **Secondary endpoints**
  - **Maternal:** rate of undetectable HBV DNA, ALT normalization, and HBeAg and HBsAg loss
  - **Infant:** HBV serologic markers at 7 mo

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TAF for Prevention of HBV Vertical Transmission: Maternal Safety

Safety Result, n (%)	TAF (n = 103)*	TDF (n = 104)*
Perinatal adverse events in ≥10% of women		
▪ Nausea	30 (29.1)	33 (31.7)
▪ Anorexia	23 (22.3)	21 (20.2)
▪ Fatigue	19 (18.4)	20 (19.2)
▪ Vomiting	11 (10.7)	11 (10.6)
Complications in ≥2% of women		
▪ Premature rupture of membranes	13 (12.6)	14 (13.5)
▪ Preterm labor	3 (2.9)	4 (3.8)
▪ Gestational hypertension	3 (2.9)	4 (3.8)
▪ Pneumonia	1 (1.0)	4 (3.8)

*All *P* values >.05 for TAF vs TDF group.

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TAF for Prevention of HBV Vertical Transmission: Infant Safety

Characteristic	TAF (n = 102)*	TDF (n = 104)
Drug exposure duration, wk (SD)	32.4 (9.3)	33.8 (8.3)
Delivery by cesarean section, n (%)	35 (34.3)	39 (37.5)
Apgar score at 1 min (SD)	9.7 (0.5)	9.5 (0.5)
▪ <8, %	0	0
Congenital defects or malformations, %	0*	0
Abnormal conditions, n (%)		
▪ Prolonged neonatal jaundice	13 (12.7)	14 (13.4)
▪ Fever	13 (12.7)	13 (12.5)
▪ Cough	10 (9.8)	9 (8.7)
▪ Vomiting	9 (8.8)	9 (8.7)
▪ Skin rash	6 (5.9)	5 (4.8)
▪ Diarrhea	4 (3.9)	5 (4.8)
▪ Hearing impairment	1 (1.0)†	0
▪ Cutaneous hemangioma	1 (1.0)‡	0

*1 fetus diagnosed with cleft lip and palate by ultrasound aborted at 23 wk and 4 days of gestation. †Secretory otitis media; resolved at 6 mo. ‡Cured at 1 yr.

- No significant different between TAF and TDF groups for each outcome

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TAF for Prevention of HBV Vertical Transmission: Infant Anthropometric Indexes

- No significant differences observed between any anthropometric parameter for children whose mothers received TDF vs TAF at birth or 7 mo

Parameter	TAF (n = 102)		TDF (n = 104)		National Standards	*P Value*		
	Growth Indexes	WHO Z Scores	Growth Indexes	WHO Z Scores		TAF vs TDF	TAF vs Nat'l	TDF vs Nat'l
At birth								
▪ Boys' weight, kg (SD)	3.49 (0.29)	0.33 (0.57)	3.46 (0.31)	0.27 (0.64)	3.38 (0.40)	.671	.010	.079
▪ Boys' height, cm (SD)	50.45 (1.49)	0.58 (0.79)	50.26 (1.53)	0.48 (0.81)	50.40 (1.60)	.529	.825	.540
▪ Boys' head circumference, cm (SD)	34.86 (0.96)	0.24 (0.76)	34.83 (0.79)	0.21 (0.63)	34.0 (1.40)	.864	<.001	<.001
▪ Girls' weight, kg (SD)	3.28 (0.26)	0.16 (0.55)	3.34 (0.37)	0.26 (0.79)	3.26 (0.40)	.337	.595	.146
▪ Girls' height, cm (SD)	49.33 (1.16)	0.39 (0.62)	49.17 (1.14)	0.30 (0.61)	49.80 (1.60)	.478	.006	<.001
▪ Girls' head circumference, cm (SD)	34.11 (0.92)	0.11 (0.78)	34.20 (0.80)	0.19 (0.68)	33.70 (1.30)	.593	.003	<.001
At 7 mo								
▪ Boys' weight, kg (SD)	8.54 (0.40)	0.25 (0.42)	8.65 (0.38)	0.37 (0.40)	8.68 (0.94)	.160	.023	.606
▪ Boys' height, cm (SD)	69.35 (1.57)	0.41 (0.72)	69.24 (1.65)	0.35 (0.75)	69.50 (2.30)	.732	.510	.282
▪ Boys' head circumference, cm (SD)	44.27 (0.76)	0.24 (0.62)	44.40 (0.91)	0.34 (0.74)	43.80 (1.30)	.437	<.001	<.001
▪ Girls' weight, kg (SD)	7.99 (0.31)	0.31 (0.30)	7.98 (0.30)	0.35 (0.30)	8.03 (0.90)	.870	.408	.278
▪ Girls' height, cm (SD)	67.47 (1.62)	0.38 (0.72)	67.57 (1.28)	0.43 (0.55)	67.90 (2.30)	.727	.070	.075
▪ Girls' head circumference, cm (SD)	43.06 (0.61)	0.17 (0.47)	43.10 (0.97)	0.21 (0.74)	42.60 (1.20)	.800	<.001	<.001

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TAF for Prevention of HBV Vertical Transmission: Infant Efficacy

- Perinatal transmission rate was 0% at 7 mo
  - Positive anti-HBs: 99.0% and 100% of infants in TAF and TDF groups, respectively

Maternal Efficacy Result at Postpartum Mo 18, % (n/N)	TAF (n = 103)*	TDF (n = 104)*
HBV DNA target not detected		
▪ Treatment-naive group	100 (19/19)	100 (22/22)
▪ Switchover or continuation group	100 (11/11)	100 (10/10)
ALT normalization		
▪ Treatment-naive group	94.7 (18/19)	95.5 (21/22)
▪ Switchover or continuation group	100 (11/11)	100 (10/10)
HBeAg seroconversion		
▪ Treatment-naive group	22.0 (13/59)	21.1 (12/57)
▪ Switchover or continuation group	30.4 (7/23)	29.0 (9/31)

*All *P* values >.05 for TAF vs TDF group.

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Key Take-home Points

- There was no perinatal transmission in either the TAF or the TDF group at 7 mo
  - Infants received standard HBV immunoprophylaxis with HBIG and HBV vaccine
- TAF and TDF groups had similar efficacy and safety outcomes between baseline and postpartum Mo 18
- TAF may play a role in pregnant women with active CHB

RETRACT-B: Nucleos(t)ide Analogue Cessation in Patients With CHB

- Retrospective cohort study of 945 patients with CHB who discontinued NA therapy 1 yr prior
  - Patients allowed to have variable levels of HBV DNA and ALT within 1 yr after NA cessation
- Primary outcome: sustained remission 1 yr after NA cessation

Characteristic, %	N = 945
Male	72
Race ▪ Asian ▪ White	 91 9
HBV genotype B	52

Characteristic	N = 945
NA prior to cessation, % ▪ ETV ▪ TDF ▪ Other	 62 29 9
Median NA duration, yr (IQR)	3.0 (3.0-3.6)
HBeAg negative at start, %	84
Cirrhosis prior to NA cessation, %	11
Mean HBsAg at NA cessation, log_{10} IU/mL (SD)	2.6 (0.8)
Median ALT x ULN at NA cessation (IQR)	0.6 (0.4-0.8)
Mean number of visits (IQR)	9 (7-11)
Mean duration between visits, mo (IQR)	4.0 (2.7-6.6)

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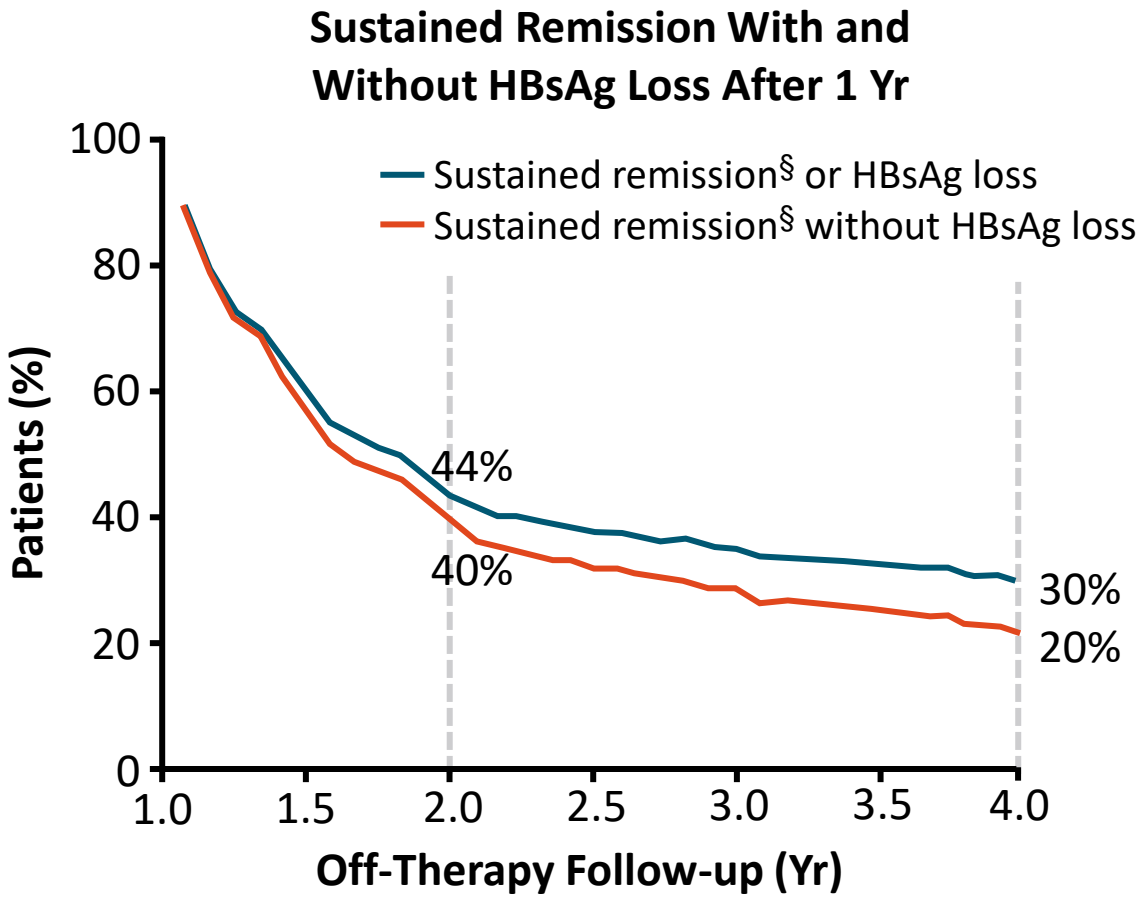
RETRACT-B: Outcomes After Therapy Cessation

Relapse Within 1 Yr of Therapy Cessation	Patients (N = 945)
Virologic relapse,* n (%)	542 (57)
▪ Median max HBV DNA, log_{10} IU/mL (IQR)	4.4 (3.9-5.2)
Biochemical relapse,† n (%)	340 (36)
▪ Median max ALT x ULN (IQR)	2.8 (1.9-5.4)
Clinical relapse,‡ n (%)	222 (24)
≥1 relapse, n (%)	621 (66)

*Virologic relapse: HBV DNA >2000 IU/mL.
†Biochemical relapse: ALT >1.5 x ULN.
‡Clinical relapse: HBV DNA >2000 IU/mL and ALT >1.5x ULN.
§Sustained remission: sustained HBV DNA ≤2000 IU/ml and ALT ≤1.5 x ULN.



- Only 30% had sustained remission or HBsAg loss at 4 yr
- 10% had HBsAg loss after 4 yr and only 20% had sustained remission without HBsAg loss at 4 yr

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RETRACT-B: Predictors of Sustained Remission by HBsAg Loss at 4 Yr

Characteristic, %	Sustained Remission or HBsAg Loss	Sustained Remission Without HBsAg Loss
Age at NA cessation (<50 vs ≥50 yr)	30 vs 30	24 vs 19
Sex (male vs female)	31 vs 27	21 vs 21
NA prior to cessation (TDF vs ETV)	32 vs 29	21 vs 21
Race/ethnicity (White vs Asian)	48 vs 28*	30 vs 20*
Start of therapy HBeAg (positive vs negative)	36 vs 28*	31 vs 19*
HBsAg at NA cessation (<100 vs ≥100 IU/mL)	58 vs 24*	24 vs 20*
Relapse within 1 yr (no relapse vs any relapse)	50 vs 19*	37 vs 13*

*P <.05

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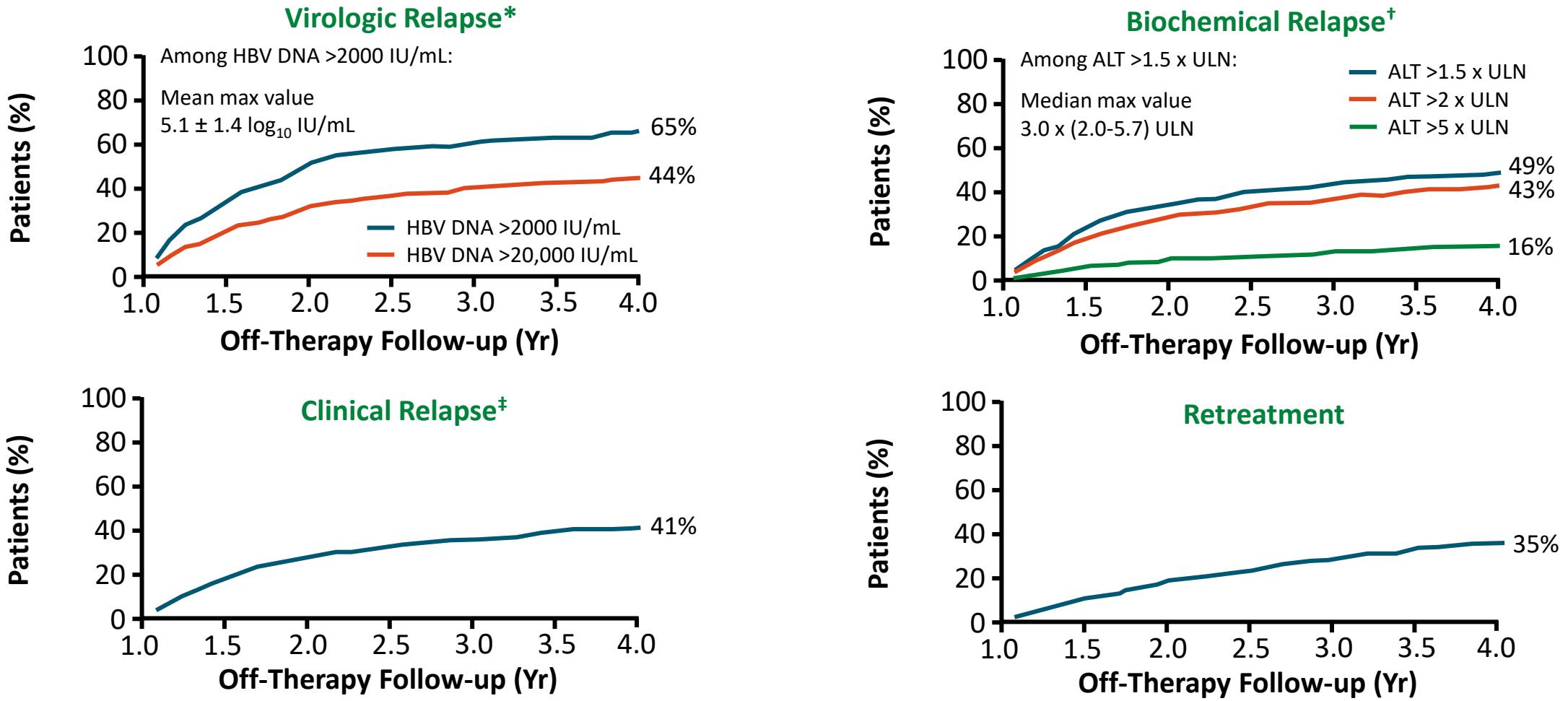
RETRACT-B: Relapse and Retreatment Over 4 Yr



*Virologic relapse: HBV DNA >2000 IU/mL. †Biochemical relapse: ALT >1.5 x ULN. ‡Clinical relapse: HBV DNA >2000 IU/mL and ALT >1.5 x ULN.

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Key Take-home Points

- Sustained remission and HBsAg loss were uncommon after stopping NA therapy even in well-suppressed patients, with 66% experiencing virologic relapse by Yr 4
- No relapse within the first yr of treatment discontinuation, White race, HBeAg positive at treatment start, and low HBsAg titers were each associated with sustained response

Selected Novel Therapies Being Investigated for HBV

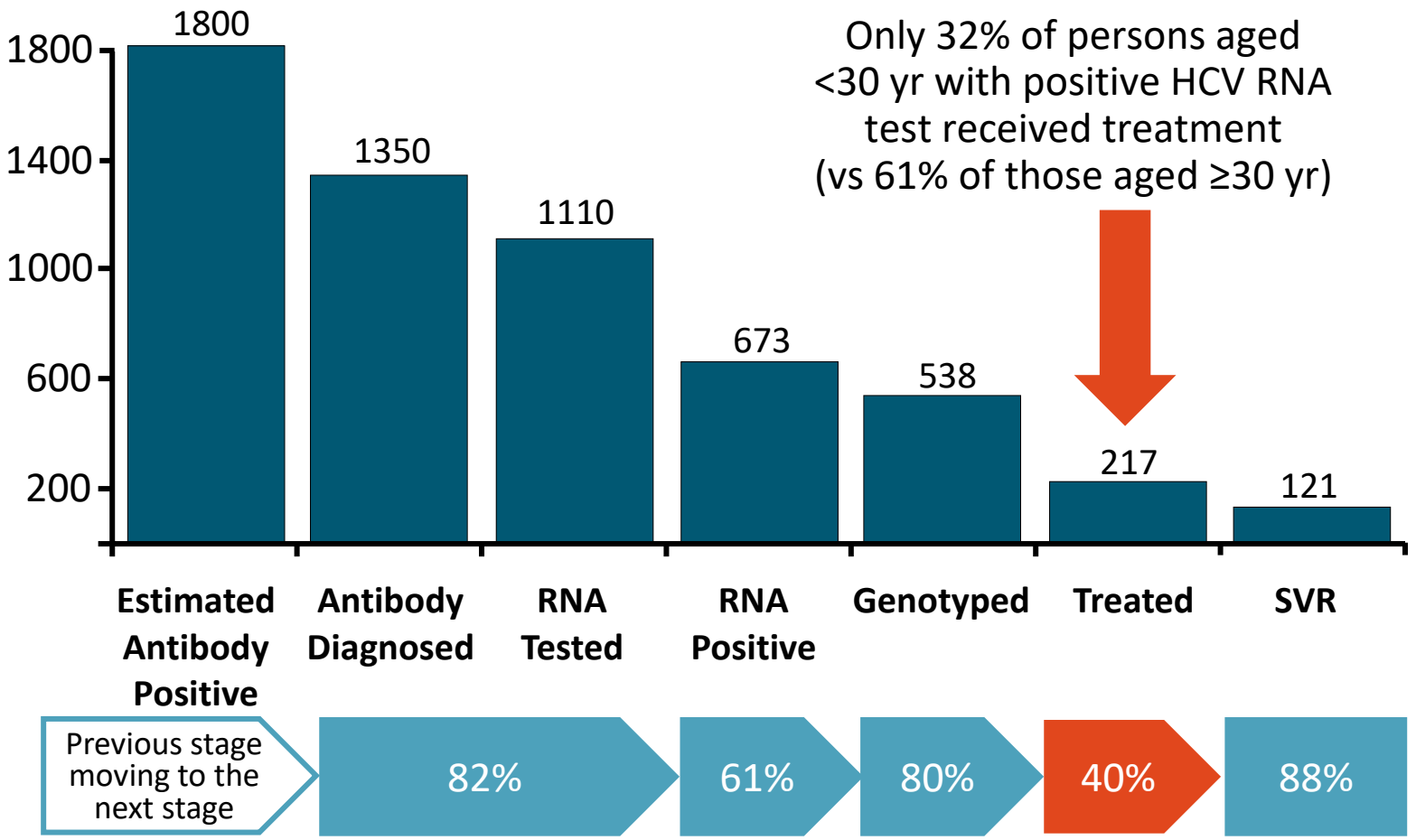
Compound	Class	Mode of Action
EDP-514[1] **ABI-4334**[2]	HBV core inhibitors	Inhibits HBV replication by preventing de novo formation of new HBV cccDNA and blocks the assembly and release of new viral particles containing pregenomic RNA or HBV DNA
JNJ-3989/JNJ-6379[3]	siRNA/capsid assembly modulator	Prevents transcription of mRNAs involved in the production of viral proteins, including HBV polymerase and HBsAg/inhibits viral replication by producing viral capsids without genomic material
REP 2139-Mg and REP 2165-Mg[4]	Nucleic acid polymers	Inhibit assembly and secretion of HBV subviral particles
ZM-H1505R[5]	Capsid assembly modulator	Inhibits viral replication by producing viral capsids without genomic material; active against variants resistant to other HBV capsid assembly modulators
AB-729[6]	GalNAc-conjugated single-trigger RNA interference agent	Blocks all HBV RNA transcripts, resulting in suppression of viral replication and all viral antigens
3A-HBV[7]	Vaccine	Induces production of neutralizing antibodies against all 3 surface antigens: pre-S1, pre-S2, and S

1. Feld. AASLD 2021. Abstr 822. 2. Xu. AASLD 2021. Abstr LP4. 3. Yuen. AASLD 2021. Abstr LO10. 4. Hershkovich. AASLD 2021. Abstr 840.
5. Jiang. AASLD 2021. Abstr LP7. 6. Yuen. AASLD 2021. Abstr LP18. 7. Diaz-Mitoma. AASLD 2021. Abstr 706.

HCV

2019 HCV Care Cascade for Children and Youth in British Columbia, Canada

- Analysis of HCV diagnoses and progress along the care cascade among BC residents aged <30 yr in 2019 who were diagnosed with HCV and in the BC Hepatitis Testers Cohort



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2019 HCV Care Cascade for Children and Youth in British Columbia, Canada: Demographics

Parameter, n (%)	HCV Ab Diagnosed (n = 1350)	HCV RNA Positive (n = 673)	Treatment Initiated (n = 217)	SVR Confirmed (n = 121)	SVR Unknown or Missing (n = 58)
Female	763 (56.5)	360 (53.5)	110 (50.7)	67 (55.4)	25 (43.1)
Location					
▪ Urban	1208 (89.5)	603 (89.6)	194 (89.4)	108 (89.3)	>50 (>90)
▪ Rural	106 (7.9)	57 (8.5)	23 (10.6)	13 (10.7)	<5
Age range					
▪ 4-13	71 (5.3)	26 (3.9)	<5	<5	<5
▪ 14-19	89 (6.6)	35 (5.2)	6 (2.8)	<5	<5
▪ 20-24	300 (22.2)	131 (19.5)	45 (20.7)	29 (24.0)	10 (17.2)
▪ 25-29	890 (65.9)	481 (71.5)	164 (75.6)	91 (75.2)	42 (72.4)

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2019 HCV Care Cascade for Children and Youth in British Columbia, Canada: Demographics

Parameter, n (%)	HCV Ab Diagnosed (n = 1350)	HCV RNA Positive (n = 673)	Treatment Initiated (n = 217)	SVR Confirmed (n = 121)	SVR Unknown or Missing (n = 58)
Material deprivation quintile					
▪ Q1 (most privileged)	183 (13.6)	94 (14.0)	36 (16.6)	22 (18.2)	8 (13.8)
▪ Q5 (most deprived)	385 (28.5)	209 (31.1)	52 (24.0)	31 (25.6)	11 (19.0)
Social deprivation quintile					
▪ Q1 (most privileged)	155 (11.5)	67 (10.0)	25 (11.5)	16 (13.2)	7 (12.1)
▪ Q5 (most deprived)	488 (36.2)	266 (39.5)	82 (37.8)	46 (38.0)	20 (34.5)
Elixhauser comorbidity index ≥1	570 (42.2)	318 (47.3)	110 (50.7)	59 (48.8)	27 (46.6)
Mood and anxiety disorder	754 (55.9)	409 (60.8)	141 (65.0)	80 (66.1)	35 (60.3)
Opioid agonist therapy	746 (55.3)	440 (65.4)	134 (61.8)	66 (54.6)	44 (75.9)
Treatment type					
▪ DAA			189 (87.1)	109 (90.1)	47 (81.0)
▪ IFN			28 (12.9)	12 (9.9)	11 (19.0)

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Key Take-home Points

- Findings revealed a significant gap in receipt of HCV treatment for young people in British Columbia living with HCV infection
  - Barriers to accessing HCV treatment and other services must be identified and addressed
- Many young people in British Columbia with HCV are socioeconomically marginalized and disproportionately affected by mood disorders and anxiety
  - Important to have HCV services grouped with other healthcare and social services

HCV Global Status Update: Prevalence and Cascade of Care in 2020

- Global HCV prevalence declined from 63.7 million in beginning of 2015 to 56.9 million in beginning of 2020
  - In 2020, prevalence was highest in Eastern Europe and Central Asia
  - >50% of infections were in China, Pakistan, India, Russia, and the US
- >10 million people initiated a DAA between 2015 and the end of 2020
  - More than one third of people initiating treatment were in Egypt
- In 2020, <25% of viremic infections were diagnosed and <10% initiated treatment

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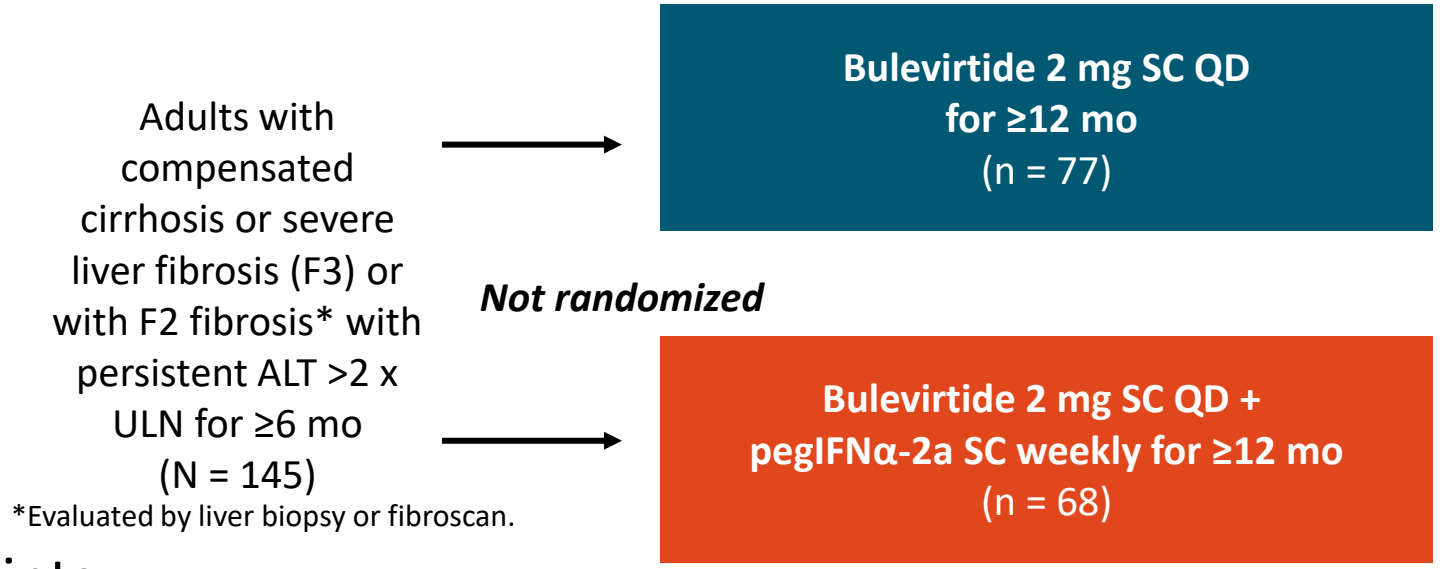
Key Take-home Points

- Global prevalence of HCV has declined since 2020, but 57 million viremic infections still exist
- Lack of screening (and subsequent diagnosis) remain a large barrier to HCV elimination worldwide

HDV

Beyond cATU: Bulevirtide ± PegIFNα-2a for Chronic HDV Infection

- Multicenter, prospective, retrospective, observational study in patients with chronic HDV from French cATU program



Efficacy endpoints:

- **Virologic efficacy** defined as HDV RNA undetectable or decrease by ≥2 $\log_{10}$ from baseline or undetectable HDV RNA
- **Biochemical efficacy** defined as normal ALT levels (ALT <40 IU/L)

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Beyond cATU: Bulevirtide ± PegIFNα-2a for Chronic HDV Infection: Virologic Efficacy

Time	HDV RNA Undetectable or Decrease by ≥2 log_{10} From Baseline,*† % (n/N)	
	Bulevirtide (n = 77)	Bulevirtide + PegIFNα-2a (n = 68)
Day 0	0	0
Mo 1	1.5 (1/66)	22.0 (11/50)
Mo 2	14.8 (8/54)	48.8 (20/41)
Mo 3	28.2 (20/71)	68.6 (35/51)
Mo 6	52.3 (34/65)	84.4 (38.45)
Mo 9	59.2 (29/49)	89.5 (34/38)
Mo 12	68.3 (28/41)	93.9 (31/33)

*Missing does not equal failure. †Study not powered to compare bulevirtide vs bulevirtide + pegIFNα-2a.

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Beyond cATU: Bulevirtide ± PegIFNα-2a for Chronic HDV Infection: Biochemical Efficacy

Time	ALT <40 IU/L,* % (n/N)	
	Bulevirtide (n = 77)	Bulevirtide + PegIFNα-2a (n = 68)
Day 0	11.7 (9/77)	10.7 (6/56)
Mo 1	21.9 (16/73)	5.7 (3/53)
Mo 2	32.8 (20/61)	18.2 (8/44)
Mo 3	39.7 (29/73)	27.5 (14/51)
Mo 6	45.3 (29/64)	35.6 (16/45)
Mo 9	51.0 (25/49)	41.0 (16/39)
Mo 12	48.8 (20/41)	36.4 (12/33)

*Study not powered to compare bulevirtide vs bulevirtide + pegIFNα-2a.

Beyond cATU: Bulevirtide ± PegIFNα-2a for Chronic HDV Infection: Safety

Parameter,* n	Bulevirtide (n = 77)	Bulevirtide + PegIFNα-2a (n = 68)
Any adverse event	29	43
Grade 3/4 adverse event	7	6
Discontinuations due to adverse events	2	3
Liver-related adverse events	4	2
Injection site reactions	2	2
Elevated bile acid	76	68
Death	0	0

*Study not powered to compare bulevirtide vs bulevirtide + pegIFNα-2a.

De Ledinghen. AASLD 2021. Abstr OA21.

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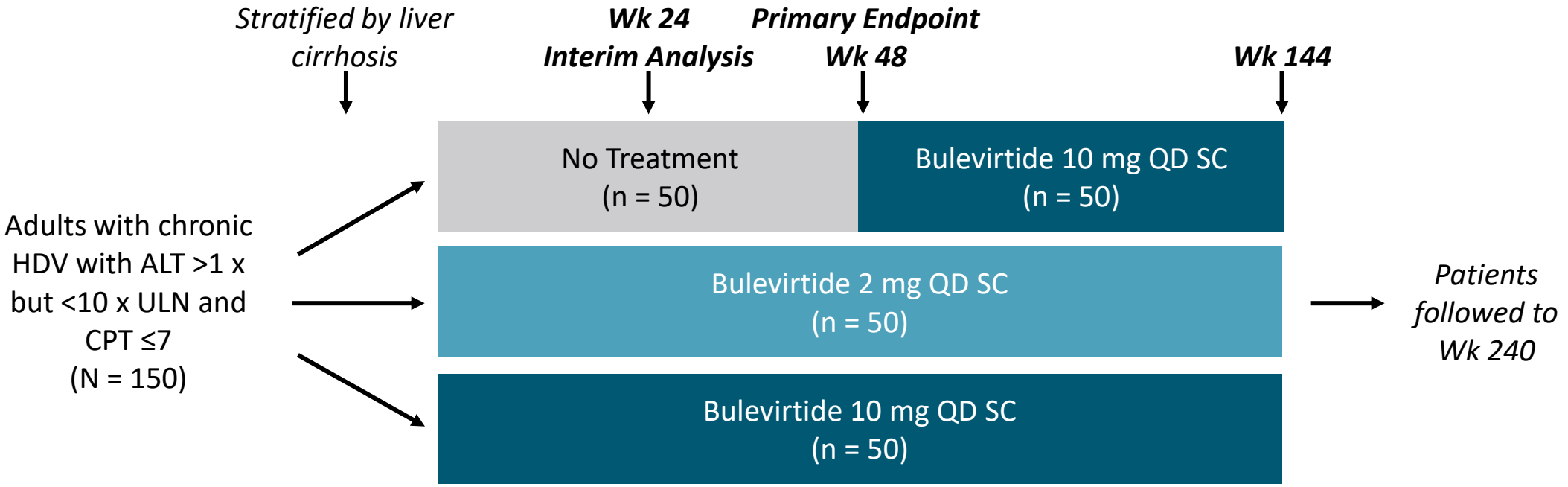
Key Take-home Points

- Bulevirtide ± pegIFNα-2a was safe and effective at achieving HDV viral suppression
- Virologic suppression was more common in the bulevirtide + pegIFNα-2a group

MYR301: High- vs Low-Dose Bulevirtide in Patients With Chronic HDV Infection: Wk 48 Analysis

- Multicenter, open-label, randomized phase III trial



- Primary endpoint: combined response defined by undetectable HDV RNA or decrease by ≥2 $\log_{10}$ IU/mL from baseline + normalized ALT at Wk 48
- Core liver biopsies obtained in a subgroup of patients at baseline and Wk 48 to assess antiviral efficacy: 79 paired biopsies for IHC, 66 paired biopsies for qPCR

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MYR301: High- vs Low-Dose Bulevirtide in Patients With Chronic HDV Infection: Intrahepatic HDAg, HDV RNA Levels

Parameter	No Treatment	Bulevirtide 2 mg	Bulevirtide 10 mg
Patients with HDAg assessment, n	27	21	31
Median change in HDAg from Wk 0-48, log_{10}	+0.01	-2.05	-2.04
▪ Undetectable HDAg, n (%)	1 (3.7)	11 (52.4)	14 (45.2)
Patients with HDV RNA assessment, n	18	21	27
Median change in HDV RNA from Wk 0-48, log_{10}	+0.09	-2.23	-2.49
▪ Undetectable HDV RNA, n (%)	2 (11.1)	7 (33.3)	14 (51.9)

- Intrahepatic HDV RNA levels correlated strongly with number of HDAg-positive cells and HDV RNA (r = 0.94)

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MYR301: High- vs Low-Dose Bulevirtide in Patients With Chronic HDV Infection: Changes in Gene Expression

Parameter	No Treatment	Bulevirtide 2 mg	Bulevirtide 10 mg
Patients with CXCL10 assessments, n	18	16	23
Median change in CXCL10 from Wk 0-48, log_{10}	-0.07	-0.89	-0.80

- Reduction in expression of CXCL10 correlated with reduction in HDV RNA levels (r = 0.80)
- Bulevirtide also associated with reduced expression of interferon-stimulated genes and inflammatory chemokines and cytokines

Allweiss. AASLD 2021. Abstr 223.

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Key Take-home Points

- Intrahepatic HDV RNA levels significantly declined by Wk 48 with bulevirtide treatment vs none
  - More than 33% of bulevirtide-treated patients achieved undetectable HDV RNA
- Number of HDAg-positive hepatocytes significantly declined by Wk 48 with bulevirtide treatment vs none
  - Approximately 50% of bulevirtide-treated patients achieved undetectable HDAg levels
- Reduction in liver inflammation due to reduction in HDV infection

US Claims Database Analysis: Prevalence and Characteristics of HDV Infection in US

- US claims database analysis of adults diagnosed with HDV infection among those with ≥1 HBV or HDV infection diagnoses from 2014-2020
- HDV infection prevalence among diagnosed HBV-infected patients: 11.2%

Baseline Characteristic	HDV Infection (n = 23,456)
Mean age, yr (SD)	51.5 (15.9)
Age category by yr, %	
▪ 18-34	18
▪ 35-44	15
▪ 45-54	21
▪ 55-64	25
▪ 65-74	15
▪ ≥75	7
Geographic region, %	
▪ North central	35
▪ Northeast	31
▪ South	20
▪ West	13
▪ Other/unknown	1

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US Claims Database Analysis of Patients With HDV Infection vs HBV Monoinfection: Baseline Characteristics

- National US claims database analysis of adults diagnosed with HDV infection (n = 23,456) or HBV monoinfection (n = 201,388) from 2014-2020

Characteristic	HDV Infection (n = 23,456)	HBV Monoinfection (n = 201,388)	*P* Value
Mean age, yr (SD)	51.5 (15.9)	53.5 (14.7)	<.001
Mean CCI score* (SD)	1.5 (2.26)	1.3 (2.02)	<.001
Female, %	53	47	<.001
Insurance type ▪ Commercial ▪ Medicaid ▪ Medicare	 49 23 23	 53 16 26	<.001

*CCI weighs 15 comorbidities to determine 1-yr mortality risk; estimated during a 12-mo period prior to index date.

Jacobson. AASLD 2021. Abstr 695.

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US Claims Database Analysis of Patients With HDV Infection vs HBV Monoinfection: Comorbidities and Liver Disease Severity

Parameter, %	HDV Infection (n = 23,456)	HBV Monoinfection (n = 201,388)	*P* Value
Hypertension	50.9	42.7	<.05
History of smoking	26.4	22.6	<.05
Substance abuse	17.2	10.3	<.05
Alcohol abuse	9.3	7.2	<.05
Mental health disorders	15.7	12.5	<.05
HCV infection	13.2	12.1	<.05
HIV infection	24.0	8.7	<.05
Decompensated cirrhosis	9.2	8.4	<.05
Compensated cirrhosis	13.9	13.9	NS
Hepatocellular carcinoma	2.4	2.0	<.05
Liver transplant	1.3	0.8	<.05

Jacobson. AASLD 2021. Abstr 695.

Slide credit: clinicaloptions.com

Key Take-home Points

- Patients with HDV have a significantly higher risk of liver disease and increased rates of comorbidities compared with patients with HBV monoinfection
- Characterization of the population with HDV highlights the importance of early linkage to care to mitigate disease progression

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New data in **HBV**, **HCV**, and **HDV**, including:

- **ClinicalThought commentaries** featuring expert interpretation of the data
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