24 – Chronic Hepatitis

Speaker: David Thomas, MD, MPH

2020 INFECTIOUS DISEASE BOARD REVIEW

Chronic Hepatitis

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Disclosures of Financial Relationships with Relevant Commercial Interests

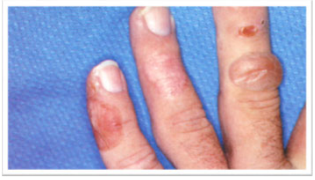
- None

Chronic Hepatitis and Liver Disease

- HCV
- HBV (and delta)
- Other forms
- HIV coinfection
- NB: extra slides are included for updated information

Hepatitis C and a rash

A 44 year old, anti-HCV and HCV RNA positive man feels bad after a recent alcohol binge. He has a chronic rash on arms that is worse and elevated ALT and AST.



OConnor Mayo Clin Proc 1998

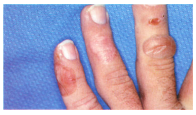
HCV with a rash

The most likely dx is:

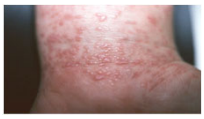
A. Cirrhosis due to HCV and alcohol
B. Vibrio vulnificus
C. Porphyria cutanea tarda
D. Essential mixed cryoglobulinemia
E. Yersinia infection

Compare

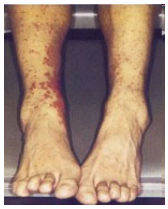
Porphyria cutanea tarda



Lichen planus



Cryoglobulin vasculitis



blogspot.com; OConnor Mayo Clin Proc 1998

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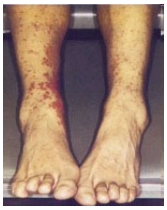
More HCV and rash

55 year old with cirrhosis untreated 1a HCV and



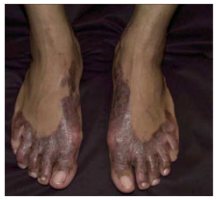
HCV with a rash

What can you counsel:

A. **Rash will likely improve with HCV treatment**
B. **Cryoglobulin blood level closely tracks disease**
C. **Needs a renal biospy**
D. **Needs steroids before HCV treatment**

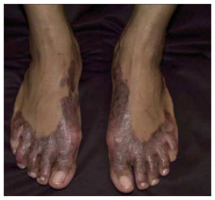
HCV and rash

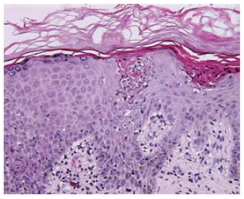
46 year old woman with cirrhosis untreated 1b HCV and



HCV and rash

46 year old woman with cirrhosis untreated 1b HCV and





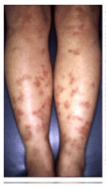
HCV with a rash

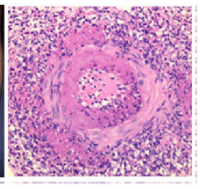
The most likely dx is:

A. **Necrolytic acral erythema**
B. **Porphyria cutanea tarda**
C. **Essential mixed cryoglobulinemia**
D. **Secondary syphilis**
E. **Pemphigus psoriaticus**

HBV and rash

46 year old woman HBsAg pos, anti-HCV neg





Chen Rheum 2014

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HBV with a rash

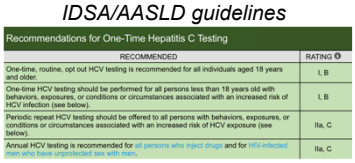
The most likely dx is:

A. Necrolytic acral erythema
B. Porphyria cutanea tarda
C. Essential mixed cryoglobulinemia
D. Polyarteritis nodosa
E. Secondary syphilis vasculitis

Who needs an HCV antibody test?

A. 33 year old woman with normal ALT and negative test during pregnancy at 28
B. 55 year old man s/p HCV treatment
C. 24 year old pregnant woman with no risk factors
D. Former PWID who was HCV negative 1 yr ago
E. HIV positive MSM with negative HCV antibody test 5 years ago and no risk factors

IDSA/AASLD guidelines



Recommendations for One-Time Hepatitis C Testing	
RECOMMENDED	RATING
One-time, routine, opt out HCV testing is recommended for all individuals aged 18 years and older.	I, B
One-time HCV testing should be performed for all persons less than 18 years old with behaviors, exposures, or conditions or circumstances associated with an increased risk of HCV infection (see below).	I, B
Periodic repeat HCV testing should be offered to all persons with behaviors, exposures, or conditions or circumstances associated with an increased risk of HCV exposure (see below).	IIa, C
Annual HCV testing is recommended for all persons who inject drugs and for HIV-infected men who have unprotected sex with men.	IIa, C

USPSTF 2020

RECOMMENDATION The USPSTF recommends screening for HCV infection in adults aged 18 to 79 years. (B recommendation)

JAMA. doi:10.1001/jama.2020.1123
Published online March 2, 2020.

54 y/o with HCV antibodies and RNA

54 year old Caucasian man was anti-HCV pos after elevated ALT noted by primary. Brief IDU when 20-21; moderate ETOH; otherwise well.

HCV RNA 4 million IU/L; Genotype 1a; ALT 42 IU/ml; AST 65 IU/ml; TB 1.6 mg/dl; Alb 3.9 mg/dl; Hb – 13.4 mg/dl; PLT 110,000; creatinine 1.2 mg/dl; HBsAg pos; anti-HBc pos. HIV neg

54 y/o with HCV antibodies and RNA

Which of the following is the next appropriate step:

A. Treat with oral regimen for 12 weeks
B. Check HCV 1a resistance test
C. Elastography
D. Confirm HCV antibody test
E. Repeat skin exam looking for acral necrolysis

HCV NS5 RAS testing is uncommonly recommended

Treatment naive	*Treatment experienced*
• Genotype 1a and elbasvir/grazoprevir	• 1a and ledipasvir/sofosbuvir 'considered'
• Genotype 3 AND cirrhosis for sofosbuvir/velpatasvir	• Genotype 3 and sofosbuvir/velpatasvir

NB: no PI resistance testing
Clinically sig is >100-fold in vitro

Wyles, HCVguidelines.org

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Staging is needed for chronic HCV

1. Drug approvals
2. Rule out cirrhosis
   - Treatment duration and safety
   - Screen for HCC and/or varices

Hcvguidelines.org

Staging is needed for chronic HCV

Accepted staging methods	Not for routine staging
1. Liver biopsy	1. Viral load
2. Blood markers	2. HCV genotype
3. Elastography	3. Ultrasound
4. Combinations of 1-3	4. CT scan or MRI

Hcvguidelines.org

Liver staging pearls

- FIB4 is great value

Liver staging pearls

$$\text{FIB 4} = \frac{\text{Age (yrs) x AST (U/L)}}{\text{Platelet count } (10^9/\text{L}) \text{ x ALT (U/L)}^{1/2}}$$

847 liver biopsies with chronic HCV

	Liver Biopsy (METAVIR)		
FIB4 Index	F0-F1-F2	F3-F4	Total
<1.45	94.7% (n = 521)	5.3% (n = 29)	550
1.45-3.25	73.0% (n = 168)	27.0% (n = 62)	230
>3.25	17.9% (n = 12)	82.1% (n = 55)	67
Total	82.8% (n = 701)	17.2% (n = 146)	847

Sterling Hepatology 2006; Vallet-Pichard Hepatology 2007

Liver staging pearls

- Fib -4 is great value
  - –(but doesn't work for insurance approval)
- Transient elastography balances sensitivity and specificity

Validity of Noninvasive Tests for Cirrhosis*

Test	% Sens	% Spec	AUROC
Fibrotest[1] >.56	85	74	.86
Fibrotest > .73	56	81	-
FIB4[2], >1.45	87	61	.87
APRI[3], >1.0	51	91	0.73
Elastography 12.5 kPa	89	91	0.95

Singh Gastro 2017; Chou Ann Intern Med 2013; Castera Gastro 2012

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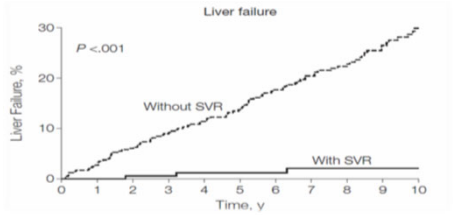
54 year old with HCV

Elastography (17.3 kPa) and Fib-4 (5.5) consistent with cirrhosis. Ultrasound and UGI are ok and you recommend treatment but he wants to know why. Which is NOT true of successful treatment?

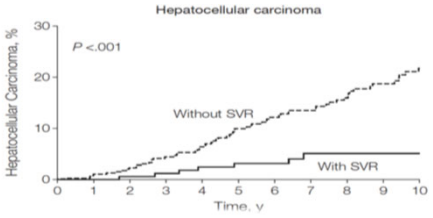
A. reduces risk of reinfection
B. reduces risk of death
C. reduces risk of HCC
D. reduces risk of liver failure

SVR reduces clinical outcomes



Van der Meer, *JAMA* 2012. Backus, *Clin Gastro* 2011. Imazeki, *Hepatology* 2003. Shiratori, *Ann Intern Med* 2005. Veldt, *Ann Intern Med* 2007. Berenguer, *Hepatology* 2009.

SVR reduces clinical outcomes



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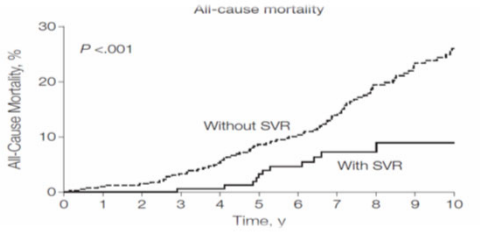
SVR reduces clinical outcomes



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AASLD — HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C — IDSA Infectious Diseases Society of America

Home | Test, Evaluate, Monitor | Treatment-Naive | Treatment-Experienced | Unique & Key Populations | About

RECOMMENDED	DURATION	RATING
Daily fixed-dose combination of elbasvir (50 mg)/grazoprevir (100 mg) for patients without baseline NS5A RASs[b] for elbasvir	12 weeks	I, A
Daily fixed-dose combination of glecaprevir (300 mg)/pibrentasvir (120 mg)[c]	12 weeks	I, A
Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg)	12 weeks	I, A
Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg)	12 weeks	I, A

54 y/o with HCV antibodies, RNA, and cirrhosis

Treatment is given with glecaprevir and pibrentasvir

Treatment week 8: HCV RNA undet; ALT 1279 IU/L; AST 987 IU/L; TB 3.2 mg/dl.

Which test is likely to be most helpful?

A. Glecaprevir level
B. HCV resistance test
C. GGT
D. HBV DNA
E. Liver biopsy with EM

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U.S. Food and Drug Administration
Protecting and Promoting Your Health

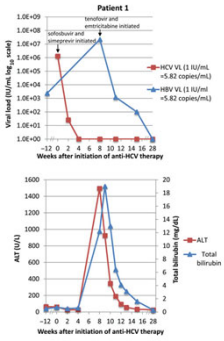
Drug Safety Communications

FDA Drug Safety Communication: FDA warns about the risk of hepatitis B reactivating in some patients treated with direct-acting antivirals for hepatitis C

Safety Announcement

[10-04-2016] The U.S. Food and Drug Administration (FDA) is warning about the risk of hepatitis B virus (HBV) becoming an active infection again in any patient who has a current or previous infection with HBV and is treated with certain direct-acting antiviral (DAA) medicines for hepatitis C virus. In a few cases, HBV reactivation in patients treated with DAA medicines resulted in serious liver problems or death.

Bersoff-Macha Ann Intern Med 2017; Thio and Balagopal CID 2015



Drug Safety Communications

n: FDA warns about the risk of hepatitis B reactivating in d with direct-acting antivirals for hepatitis C

rug Administration (FDA) is warning about the risk of n active infection again in any patient who has a current or treated with certain direct-acting antiviral (DAA) medicines , HBV reactivation in patients treated with DAA medicines death.

soff-Macha Ann Intern Med 2017; Thio and Balagopal CID 2015

Flare of HBV with DAA treatment of HCV

- All are tested for HBV
  - HBsAg pos: treat per HBV guidelines
  - Anti-HBc pos: monitor

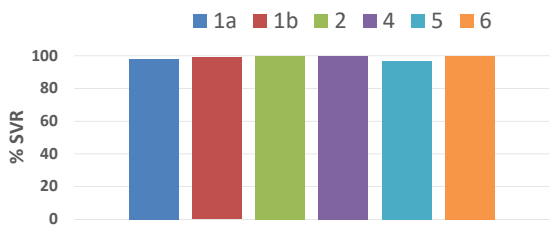
Bersoff-Macha Ann Intern Med 2017; Thio and Balagopal CID 2015

A. Glecaprevir and pibrentasvir
B. Sofosbuvir and velpatasvir
C. Sofosbuvir and ledipasvir
D. Elbasvir and grazoprevir

Which 2 regimens are pangenotypic?

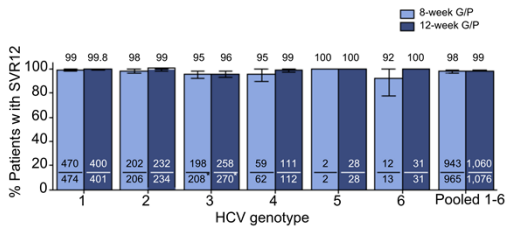
1. **A and B**
2. **A and C**
3. **B and C**
4. **C and D**

Sofosbuvir and velpatasvir for 12 weeks among 624 patients with chronic hepatitis C



Feld NEJM 2015

Glecaprevir and pibrentasvir for chronic hepatitis C



Puoti J Hepatol 2018

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A. Glecaprevir and pibrentasvir
B. Sofosbuvir and velpatasvir
C. Sofosbuvir and ledipasvir
D. Elbasvir and grazoprevir

Which regimens are approved for ESRD?

1. A and B
2. A and C
3. A, B and C
4. A, B, C and D

A. Glecaprevir and pibrentasvir
B. Sofosbuvir and velpatasvir
C. Sofosbuvir and ledipasvir
D. Elbasvir and grazoprevir

Which regimens have concerns with TDF?

1. A and B
2. B and C
3. A, B and C
4. A, B, C and D

A. Glecaprevir and pibrentasvir
B. Sofosbuvir and velpatasvir
C. Sofosbuvir and ledipasvir
D. Elbasvir and grazoprevir

Which regimen is recommended with etravirine?

1. A
2. B
3. C
4. D

		Ledipasvir/ Sofosbuvir (LDV/SOF)	Sofosbuvir/ Velpatasvir (SOF/VEL)	Elbasvir/ Grazoprevir (ELB/GRZ)	Glecaprevir/ Pibrentasvir (GLE/PIB)	Sofosbuvir/ Velpatasvir/ Voxilaprevir (SOF/VEL/VOX)
Protease Inhibitors	Boosted Atazanavir	A	A			
	Boosted Darunavir	A	A			
	Boosted Lopinavir	ND, A	A			ND
NNRTIs	Doravirine		ND		ND	ND
	Efavirenz				ND	ND
	Rilpivirine					
	Etravirine	ND	ND	ND	ND	ND
Integrase Inhibitors	Bictegravir		ND	ND	ND	
	Cobicistat-boosted elvitegravir	C	C			C
	Dolutegravir					ND
	Raltegravir					ND
	Maraviroc	ND	ND	ND	ND	ND
NRTIs	Abacavir		ND	ND		ND
	Emtricitabine					
	Lamivudine		ND	ND		ND
	Tenofovir disoproxil fumarate	B, C	B, C			C, D
	Tenofovir alafenamide	D	D	ND		D

green indicates coadministration is safe; yellow indicates a dose change or additional monitoring is warranted; and red indicates the combination should be avoided.

ND: No data

Slide 40 of 44

HCV treatment summary 2020

- Two pangenotypic regimens: SOF VEL and GP
- No change for HIV (avoid drug interactions)
- Watch for HBV relapse at week 8
- No change for acute
- No change for renal insufficiency
- Test, don't treat during pregnancy

Chronic hepatitis B

31 yr old Asian woman is referred to see you because she had a positive HBsAg test. She is otherwise feeling fine.

HBsAg pos, HBeAg neg, anti-HBe pos, ALT 78 IU/ml, AST 86 IU/ml, TB 0.8, albumin 4.2 g/dl, INR 1.

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Which of the following tests is not recommended?

A. HIV test
B. HBV resistance
C. HBV genotype
D. Hepatitis Delta testing
E. Quantitative HBV DNA level

The work up of CHB may include ultrasound

US starts at 50 for Asian women

Surveillance recommended		
Population group	**Threshold incidence for efficacy of surveillance (> .25 LYG)(%/year)**	**Incidence of HCC**
Asian male hepatitis B carriers over age 40	0.2	0.4-0.6%/year
Asian female hepatitis B carriers over age 50	0.2	0.3-0.6%/year
Hepatitis B carrier with family history of HCC	0.2	Incidence higher than without family history
African/North American Blacks with hepatitis B	0.2	HCC occurs at a younger age
Cirrhotic hepatitis B carriers	0.2-1.5	3-8%/yr
Hepatitis C cirrhosis	1.5	3-5%/yr
Stage 4 primary biliary cirrhosis	1.5	3-5%/yr
Genetic hemachromatosis and cirrhosis	1.5	Unknown, but probably > 1.5%/year
Alpha 1-antitrypsin deficiency and cirrhosis	1.5	Unknown, but probably > 1.5%/year
Other cirrhosis	1.5	Unknown
Surveillance benefit uncertain		
Hepatitis B carriers younger than 40 (males) or 50 (females)	0.2	< 0.2%/yr
Hepatitis C and stage 3 fibrosis	1.5	< 1.5%/yr
Non-cirrhotic NAFLD	1.5	< 1.5%/yr

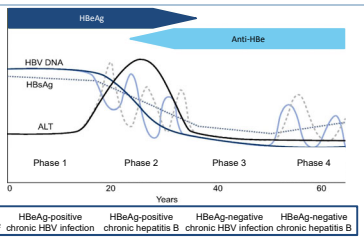
Use testing to define disease phase

- The natural history of chronic HBV infection has been schematically divided into five phases

Chronic hepatitis B / Chronic HBV infection	HBeAg positive		HBeAg negative		
	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
	Chronic HBV infection	Chronic hepatitis B	Chronic HBV infection	Chronic hepatitis B	Resolved HBV infection
HBsAg	High	High/ intermediate	Low	Intermediate	Negative
HBeAg	Positive	Positive	Negative	Negative	Negative
HBV DNA	>10^7 IU/mL	10^4–10^7 IU/mL	<2,000 IU/mL*	>2,000 IU/mL	<10 IU/mL‡
ALT	Normal	Elevated	Normal	Elevated†	Normal
Liver disease	None/minimal	Moderate/ severe	None	Moderate/ severe	None§
Old terminology	Immune tolerant	Immune reactive HBeAg positive	Inactive carrier	HBeAg negative chronic hepatitis	HBsAg negative /anti-HBc positive

*HBV DNA levels can be between 2,000 and 20,000 IU/mL in some patients without signs of chronic hepatitis; †Persistently or intermittently, based on traditional ULN (~40 IU/L). ‡cccDNA can frequently be detected in the liver; §Residual HCC risk only if cirrhosis has developed before HBsAg loss.
EASL CPG HBV. J Hepatol 2017;67:370–98

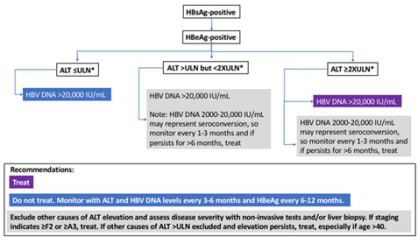
Use testing to define disease phase[1]



New nomenclature[2]	HBeAg-positive chronic HBV infection	HBeAg-positive chronic hepatitis B	HBeAg-negative chronic HBV infection	HBeAg-negative chronic hepatitis B

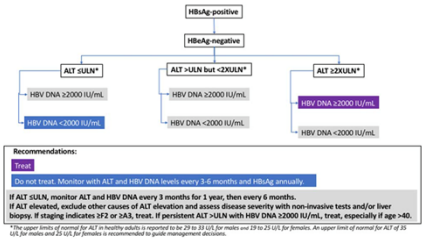
1. Lok A, et al. J Hepatol 2017;67:847–61;
2. EASL CPG HBV. J Hepatol 2017;67:370–98

Treat when high replication *and* disease
HBeAg positive



AASLD guidelines, Terrault Hepatology 2018

HBeAg negative is 2,000 IU vs 20,000 IU



AASLD guidelines, Terrault Hepatology 2018

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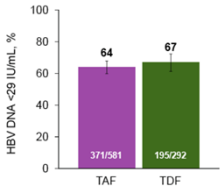
Four preferred treatments for chronic hepatitis B

HBeAg Positive	Peg-IFN*	Entecavir†	Tenofovir Disoproxil Fumarate†	Tenofovir Alafenamide‡
% HBV-DNA suppression (cutoff to define HBV-DNA suppression)§	30-42 (<2,000-40,000 IU/mL) 8-14 (<80 IU/mL)	61 (<50-60 IU/mL)	76 (<60 IU/mL)	73 (<29 IU/mL)
% HBeAg loss	32-36	22-25	—	22
% HBeAg seroconversion	29-36	21-22	21	18
% Normalization ALT	34-52	68-81	68	—
% HBsAg loss	2-7 11 (at 3 years posttreatment)	4-5	8	1
HBeAg Negative	**Peg-IFN**	**Entecavir**	**Tenofovir Disoproxil Fumarate†**	**Tenofovir Alafenamide‡**
% HBV-DNA suppression (cutoff to define HBV-DNA suppression)‖	43 (<4,000 IU/mL) 19 (<80 IU/mL)	90-91 (<50-60 IU/mL)	93 (<60 IU/mL)	90 (<29 IU/mL)
% Normalization ALT¶	59	78-88	76	81
% HBsAg loss	4 6 (at 3 years posttreatment)	0-1	0	<1

TAF 25 mg with or without FTC

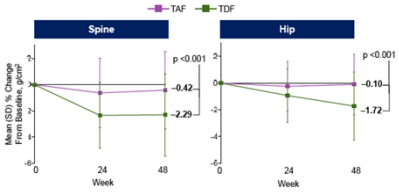
AASLD guidelines, Terrault Hepatology 2018

TAF is as effective and safer than tenofovir DF for chronic hepatitis B



Chan Lancet Gastro 2016

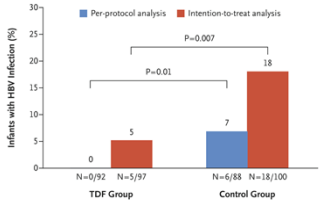
TAF is as effective and safer than tenofovir DF for chronic hepatitis B



Chan Lancet Gastro 2016

Treat HBV in pregnant women if HBV DNA level above 200,000 IU/ml

Rec for all pregnant women to have quantitative HBV DNA TEST



Terrault Hepatology 2015; Pan NEJM 2016

Treatment of HBV changes with renal insufficiency

- **GFR 30-60** mL/min/1.73 m^2 **: TAF preferred**
- **GFR <30-10: TAF OR entecavir 0.5 q 3d**
- **GFR <10 no dialysis: entecavir 0.5**
- **Dialysis: TDF 300/wk PD or entecavir 0.5mg/wk or TAF 25mg PD**

It is hard to stop HBV treatment

- **If HBeAg conversion noted and no cirrhosis *consider* stopping after 6 months**
- **HBeAg neg when treatment started and all with cirrhosis stay on indefinitely**

HIV/HBV coinfected need treatment for both

- All are treated and tested for both
- HBV-active ART
- Entecavir less effective if LAM exposure
- Watch switch from TAF/TDF containing regimen

What if HBV levels stay detectable?

- Continue monotherapy, ideally with TAF or TDF
- Rising levels (breakthrough)
  - Add second drug or switch esp if initial Rx with ETV

Hepatitis serology in the oncology suite

You are called about 62 year old Vietnamese scientist who is in oncology suite where he is about to get R-CHOP for Non Hodgkins lymphoma. Baseline labs: normal AST, ALT, and TBili. Total HAV detectable; anti-HBc pos; HBsAg neg; anti-HCV neg.

What do you recommend?

A. Hold rituximab
B. Hold prednisone
C. Entecavir 0.5 mg
D. HCV PCR
E. HBV DNA

Rituximab, high-dose prednisone, and BM transplant high risk for HBV reactivation

- If HBsAg pos, prophylaxis always recommended
- If anti-HBc pos but HBsAg neg, prophylaxis still recommended with high risk exposures
- Use TAF or ETV

AASLD Terrault Hepatology 2018

Isolated anti-core antibodies usually reflect occult hepatitis B in high risk groups

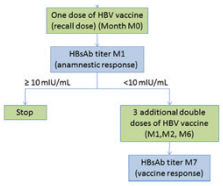
- Most often true positive test in HIV pos or with HBV risk
- Primary responses to vaccination
- 29 anti-HBc and 40 negative for anti-HBc
  - anamnestic response in anti-HBc pos (24%) vs anti-HBc neg (10%)
  - 50% anti-HBc pos also tested positive for anti-Hbe
  - Anti-HBs seroconversion in ~60% both groups

Gandhi JID 2005; Terrault Hepatology 2018; Piroth CID 2018

24 – Chronic Hepatitis

Speaker: David Thomas, MD, MPH

HBV vaccination recommended in persons with isolated anti-HBc



Gandhi JID 2005; Terrault Hepatology 2018; Piroth CID 2018

HBV Prevention is with vaccine and sometimes HBIG

Pre-exposure:

- vaccinate and get post vaccination titers (<2 months) if exposure likely

Post Exposure:

- vaccinate if not already done or not known to respond
- add HBIG when infection likely
- infants of HBsAg pos mothers get immediate vaccination and HBIG

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How do we prevent HBV?

Vaccine	Formulations	Dose	Schedule	Cost[a]
Hepatitis B				
Heplisav-B (Dynavax)	0.5 mL solution in single-dose vials	≥18 yrs[b]: 0.5 mL IM	2 doses (0 and 1 mo)	$230.00
Engerix-B (GSK)	0.5, 1 mL suspension in single-dose vials, prefilled syringes	Birth-19 yrs: 0.5 mL IM[c] ≥20 yrs: 1 mL IM[c]	3 doses (0, 1, and 6 mos)[d]	66.90 169.50
Recombivax HB (Merck)	0.5, 1 mL suspension in single-dose vials, prefilled syringes	Birth-19 yrs: 0.5 mL IM[c] ≥20 yrs: 1 mL IM[c]	3 doses (0, 1, and 6 mos)[d,e]	69.60 181.40
Hepatitis A/B				
Twinrix (GSK)	1 mL suspension in single-dose vials, prefilled syringes	≥18 yrs: 1 mL IM	3 doses (0, 1, and 6 mos)[f]	298.50

MMWR / January 12, 2018 / Vol. 67 / No. 1; Medical Letter JAMA 2018

A final case of chronic hepatitis in transplant recipient

51 y/o HTN, and ankylosing spondylitis s/p renal transplant presents with elevated liver enzymes. Pred 20/d; MMF 1g bid; etanercept 25mg twice/wk; tacro 4mg bid.

HBsAg neg, anti-HBs pos, anti-HBc neg; anti-HCV neg; HCV RNA neg; CMV IgG neg; EBV neg; VZV neg. ALT 132 IU/ml, AST 65 IU/ml; INR 1. ALT and AST remained elevated; HBV, HCV, HAV, CMV, EBV serologies remain neg.

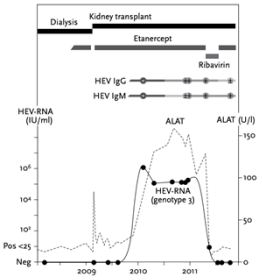
Barrague Medicine 2017

Which test is most likely abnormal

1. HEV PCR
2. HCV IgM
3. Tacrolimus level
4. Adenovirus PCR
5. Delta RNA PCR

Chronic HEV in transplant recipient

- Europe (boar)
- Can cause cirrhosis
- Tacrolimus associated
- Ribavirin may be effective



Barrague Medicine 2017

24 – Chronic Hepatitis

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Chronic Hepatitis for the Boards Summary

- **HCV-associated conditions: PCT or cryoglobulinemia**
- **HBV-associated: PAN**
- **HCV: staging or treatment outcome**
- **HBV: relapse post rituximab**
- **Guess b and good luck**