KDIGO guideline update
HCV and CKD

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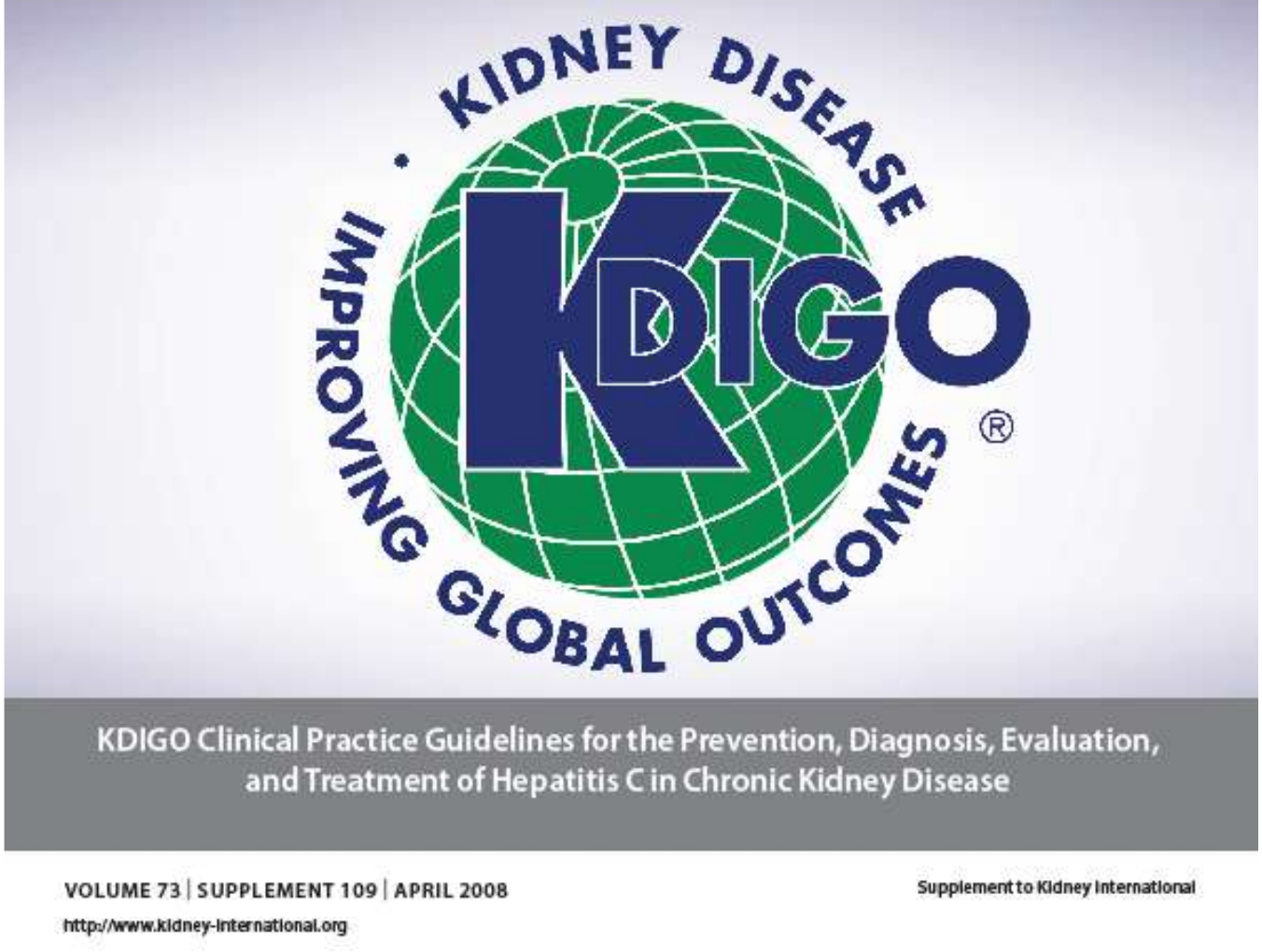
Conflicts of Interest

Research Support: Alexion, Amgen, Janssen-Cilag, MSD, Otsuka, Roche

Lecturing: Abbvie, Amgen, Menarini, MSD

Consulting activities: Astellas, Vifor-FMCRP, MSD

Other : I have cochaired the 2018 update of the HCV in CKD KDIGO Guideline and am KDIGO Co-chair elect



KDIGO clinical practice guidelines for the prevention, diagnosis, evaluation, and treatment of hepatitis C in chronic kidney disease. *Kidney Int Suppl* 2008: S1-99

Hepatitis C

Daniel P Webster, Paul Klenerman, Geoffrey M Dusheiko

PI= protease inhibitors

Direct-Acting Antiviral Agents(DAAs)

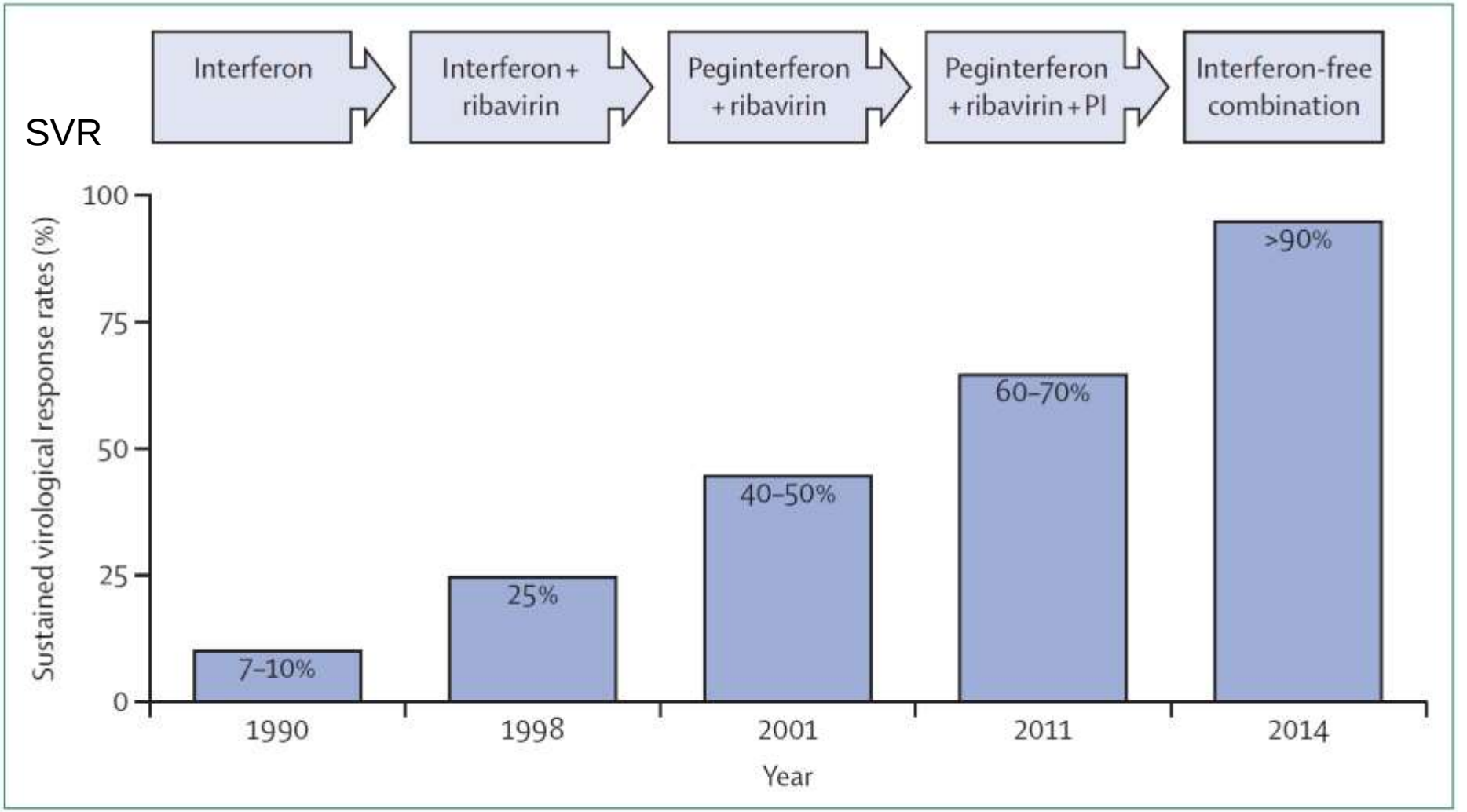


Figure 1: **Changes in standard of care for HCV, and improvements in numbers of sustained virological responses**
Data from references 9–12. PI=protease inhibitor.

Lancet 2015; 385: 1124–35

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Outline

- Screening for HCV in CKD
- Treating HCV in CKD
- Preventing HCV transmission in HD
- Managing HCV before /after kidney TP
- Treating HCV-associated GN

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Detection and Evaluation of HCV in CKD

1.1 Screening patients with CKD for HCV infection

1.1.1: We recommend screening all patients for hepatitis C virus (HCV) infection at the time of initial evaluation of chronic kidney disease (CKD) (*1C*).

1.1.1.1:We recommend using an immunoassay followed by nucleic acid testing (NAT) if immunoassay is positive (*1A*).

1.1.2: We recommend screening all patients for HCV infection upon initiation of in-center hemodialysis or upon transfer from another dialysis facility or modality (*1A*).

1.1.2.1: We recommend using NAT alone or an immunoassay followed by NAT if immunoassay is positive (*1A*). Repeat /6months

Kidney Disease: Improving Global Outcomes (KDIGO) Hepatitis C Work Group. KDIGO 2018 Clinical Practice Guideline on the Prevention, Diagnosis, Evaluation, and Treatment of Hepatitis C in CKD. *Kidney Int Suppl.* 2018; in press

Rationale for screening CKD non D patients for HCV

- HCV may cause Membranoprolif. GN
- Greater prevalence of HCV in late CKD stages than in general population
- Consistent association of
  - HCV+ with worse liver, kidney and CV outcomes
  - anti-HCV treatment with better outcomes (liver, kidney, CV)
- Low cost of single EIA for HCV
- Thus testing once for this modifiable risk factor is recommended (1C)

HCV prevalence in prevalent vs. incident (<120 days) patients

DOPPS 1+ Countries: France, Germany, Italy, Japan, Spain, UK, US

	DOPPS Phase				
Region/Country	**1**	**2**	**3**	**4**	**5**
Prevalent patients	14.3 (7894)	12.1 (6682)	9.5 (6245)	9.4 (8617)	8.4 (10042)
Incident patients	5.2 (6186)	5.5 (3018)	5.2 (898)	4.8 (3102)	4.8 (4767)

DOPPS 1 (1996-2001); DOPPS 2 (2002-2004; DOPPS 3 (2005-2008); DOPPS 4 (2009-2012); DOPPS 5 (2012-20015)

M Jadoul et al. submitted

Outcomes for HCV+ versus HCV- patients

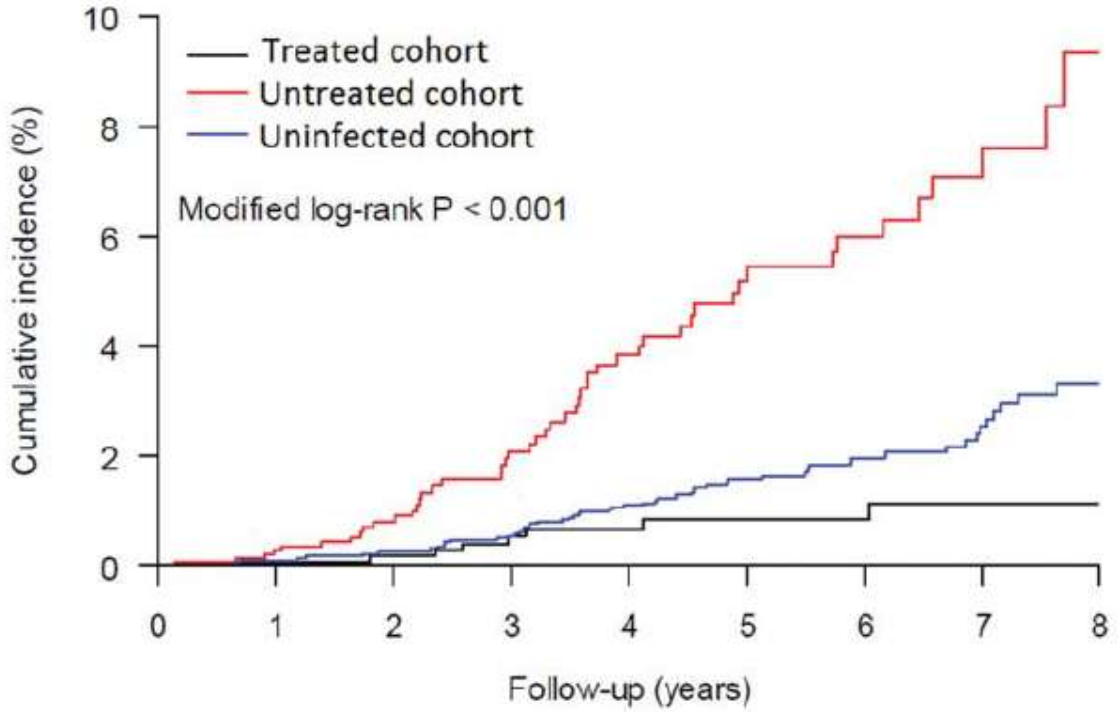
Hemodialysis DOPPS 1-5 (1996-2015)

Event	Unadjusted HR[a] (95% CI)	Adjusted HR[b] (95% CI)
All-cause mortality	1.02(0.95-1.09)	1.12(1.05-1.20)
Cardiovascular	0.97(0.87-1.07)	1.10(0.98-1.22)
Infection	1.05(0.88-1.27)	1.11(0.91-1.34)
Hepatic-related	5.88(3.84-8.99)	5.90(3.67-9.50)

Goodkin D, Bieber B, Jadoul M, *et al*. Mortality, hospitalization, and quality of life among patients with hepatitis c infection on hemodialysis. *Clin J Am Soc Nephrol* 2017; 12: 287-297.

Antiviral treatment for HCV infection is associated with improved outcomes in diabetics

ESRD



Number at risk

Treated	1411	1400	987	755	586	418	303	168	47
Untreated	1411	1388	962	711	530	362	262	152	43
Uninfected	5644	5591	3928	2980	2322	1624	1194	684	201

Hsu YC, *et al. Hepatology* 2014; 59: 1293-1302.

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protease inh. , NS5A inh. , polymerase inh.

- PREVIR , -ASVIR , -BUVIR

Characteristics: variable between molecules

- antiviral activity on some vs all genotypes
- extent of elimination by the kidney
- potential to cause drug-drug interactions (liver)
- barriers to viral resistance (and thus need to add ribavirin)
- ≥ 2 drugs in all regimens (to reduce risk of HCV resistance)

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- ≥ 2 drugs in all regimens (to reduce risk of HCV resistance)

- - Sofosbuvir (SOF) cleared by the kidney
    - eGFR < 30 ml/'= off label use
    - some reports (case series) that SOF -based regimens safe and effective in late CKD
    - optimal dosage of SOF not fully clear
    - worsening of CKD progression by SOF not completely excluded

Grazoprevir plus elbasvir in treatment-naive and treatment-experienced patients with hepatitis C virus genotype 1 infection and stage 4–5 chronic kidney disease (the C-SURFER study): a combination phase 3 study

David Roth, David R Nelson, Annette Bruchfeld, AnnMarie Liapakis, Marcelo Silva, Howard Monsour Jr, Paul Martin, Stanislas Pol, Maria-Carlota Londoño, Tarek Hassanein, Philippe J Zamor, Eli Zuckerman, Shuyan Wan, Beth Jackson, Bach-Yen Nguyen, Michael Robertson, Eliav Barr, Janice Wahl, Wayne Greaves

- First RCT of an oral, interferon-free DAA regimen in CKD stage 4 /5 patients
- <1% of grazoprevir and elbasvir renally excreted: no dose adjustment in CKD
- Single pill: Grazo 100mg/Elbas 50 mg
- primary endpoint = sustained viral response 12 weeks after stopping DAAs (SVR12)

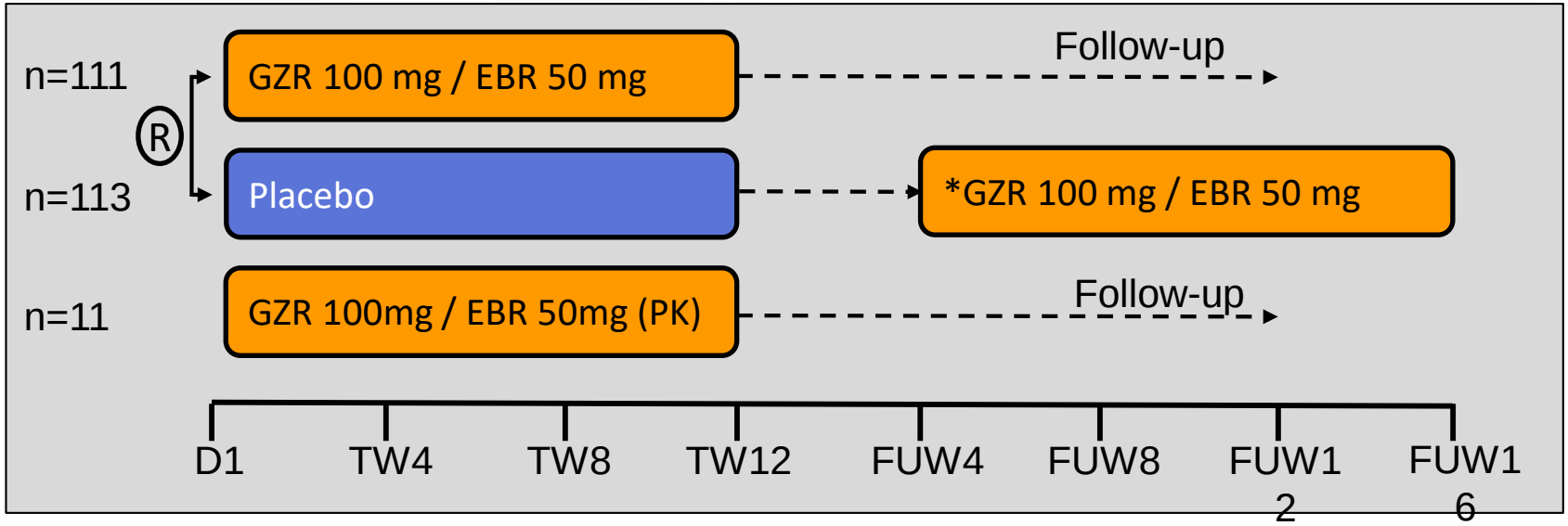
Roth D, et al. *Lancet* 2015; 386: 1537-1545.

PATIENTS CHARACTERISTICS

- HCV Genotype 1 infection (52% 1a, 48% 1b)
- treatment-naive and treatment-experienced patients
- CKD stage 4/5
  - CKD stage 4
  - CKD stage 5 non D, or on hemodialysis (76% of total n)
- Compensated cirrhosis allowed (6 %)
- All HBV and HIV negative

Roth D, et al. *Lancet* 2015; 386: 1537-1545.

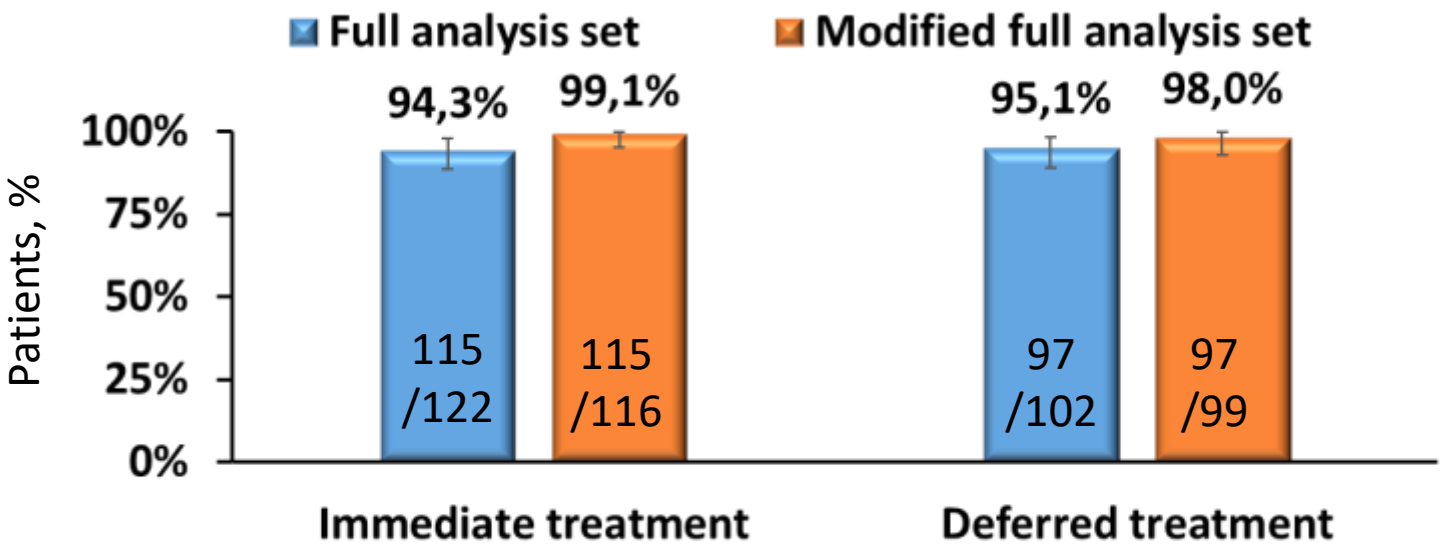
STUDY DESIGN



- Randomized, parallel-group, multi-site, placebo-controlled trial
- 12 weeks of study drug
- 11 patients in open-label GZR/EBR arm underwent intensive pharmacokinetic sampling

Roth D, et al. *Lancet* 2015; 386: 1537-1545.

C-SURFER SVR12 RESULTS
IMMEDIATE AND DEFERRED TREATMENT ARMS



Relapse	1	1	2	2
D/c unrelated to treatment	6	0	3	0

Roth D, et al. *Lancet* 2015; 386: 1537-1545.

Bruchfeld A, et al; *Lancet Gastroenterol Hepatol* 2017; 2: 585-594.

SAFETY SUMMARY

- Tolerance better or similar to placebo
- A single SAE possibly ascribed to study drug, vs one due to placebo
- Clear improvement in ALT/AST with study drug vs placebo
- No difference in bilirubin, or anemia parameters

Roth D, et al. *Lancet* 2015; 386: 1537-1545.
Bruchfeld A, et al; *Lancet Gastroenterol Hepatol* 2017; 2: 585-594.

Glecaprevir and Pibrentasvir in Patients with HCV and Severe Renal Impairment

- Open-label multicenter phase 3 study
- N = 104, 79% males, 25% Black
- HCV Genotype : 1 n= 54
  2 n= 17
  3 n= 11
  4 n=20
  5 n= 1
  6 n= 1
- 88% on HD, 58% treatment naive

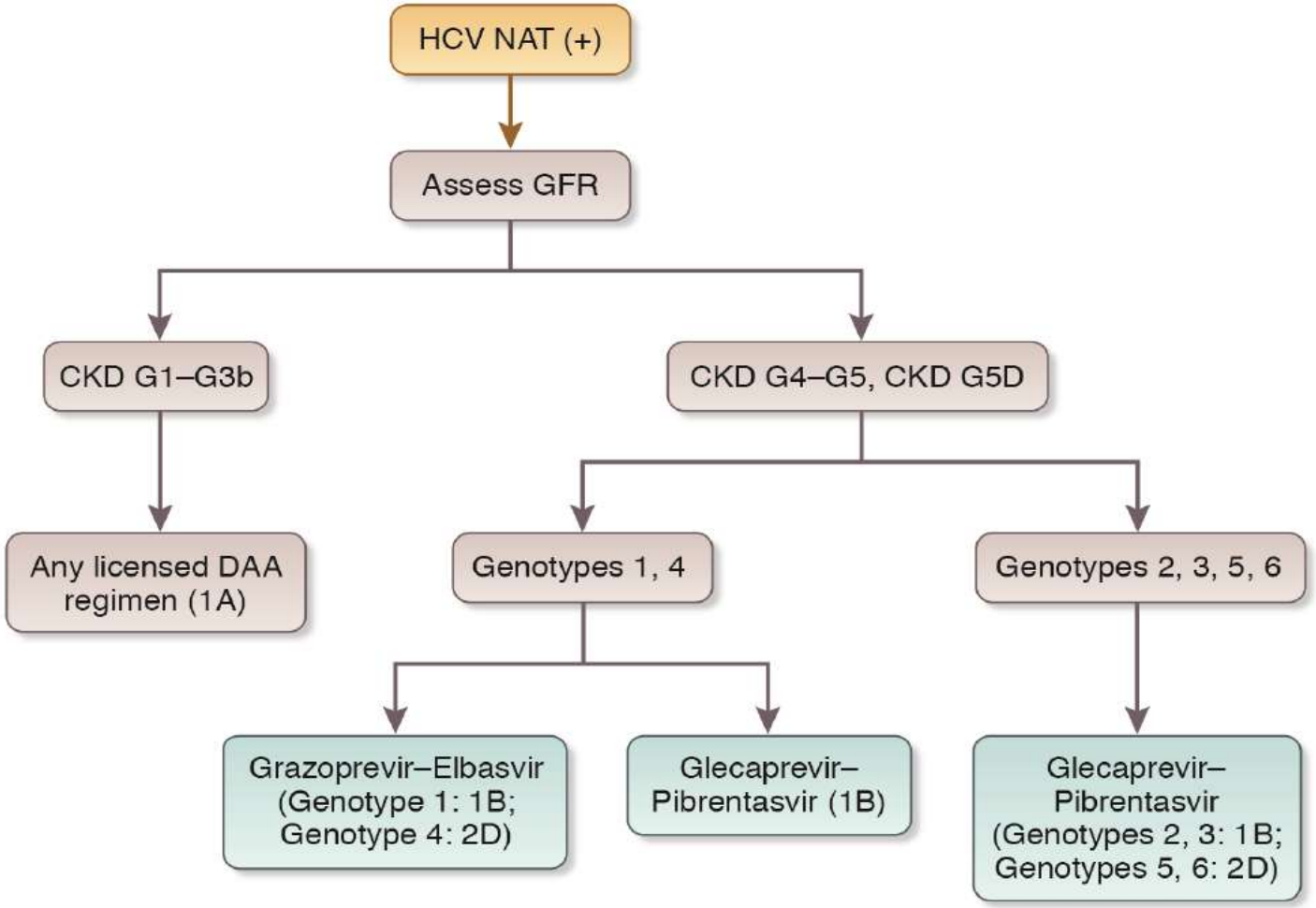
Gane E, *N Engl J Med* 2017; 377: 1448-1455

Table 2. Sustained Virologic Response Rate.

Time of measurement	Value
On-treatment response — no./total no. (%)*	
Week 1	37/101 (37)
Week 2	77/100 (77)
Week 4	98/103 (95)
Week 8	103/103 (100)
Final treatment	104/104 (100)
Posttreatment response — no./total no. (%)†	
Sustained virologic response at posttreatment week 4	103/104 (99)
Sustained virologic response at posttreatment week 12	102/104 (98)
Sustained virologic response at posttreatment week 24	100/104 (96)‡

Tolerance OK (pruritus 20%, fatigue 14%, nausea 12%)
No safety signal

Gane E et al. *N Engl J Med* 2017; 377: 1448-1455



Algorithm 1. Treatment scheme for CKD G1-G5D

Recommendation grading is provided for each specific treatment regimen and HCV genotype.

CKD G, chronic kidney disease, GFR category; DAA, direct-acting antiviral; GFR, glomerular filtration rate; GT, genotype; HCV, hepatitis C virus; NAT, nucleic acid testing.

Kidney function	HCV genotype	Recommended regimen(s)	Strength of evidence	Alternate regimen(s)	Strength of evidence
CKD G4–G5 (GFR < 30 ml/min/ 1.73 m²) including HD, KTR[b]	1a	Grazoprevir/elbasvir	1B	Ritonavir-boosted paritaprevir, ombitasvir, and dasabuvir (also known as PrOD or 3D regimen) with ribavirin	2D
		Glecaprevir/pibrentasvir	1B	Daclatasvir/asunaprevir	2C
	1b	Grazoprevir/elbasvir	1B	Ritonavir-boosted paritaprevir, ombitasvir, and dasabuvir (also known as ProD or 3D regimen)	2D
		Glecaprevir/pibrentasvir	1B	Daclatasvir/asunaprevir	2C
	2,3	Glecaprevir/pibrentasvir	1B		
	4	Grazoprevir/elbasvir	2D		
		Glecaprevir/pibrentasvir	1B		
	5,6	Glecaprevir/pibrentasvir	2D		
CKD G5 PD	n/a (reasonable to follow proposed regimens for HD)				
KTR (GFR ≥ 30 ml/min/ 1.73 m²)	1a	Sofosbuvir with ledipasvir, daclatasvir or simeprevir	1B	Sofosbuvir/ribavirin	2D
		Glecaprevir/pibrentasvir[c]	1C		
	1b	Sofosbuvir with ledipasvir, daclatasvir or simeprevir	1B		
		Glecaprevir/pibrentasvir[c]	1C		
	2, 3, 5, 6	Glecaprevir/pibrentasvir[c]	1D	Sofosbuvir/daclatasvir/ribavirin[d]	2D
	4	Sofosbuvir with ledipasvir, daclatasvir or simeprevir	1D		
		Glecaprevir/pibrentasvir[c]	1D		

Drug-drug interactions with DAAs

- 12 weeks treatment with DAAs
- Important to review the potential interactions, and available alternative drugs or need to adapt dosages of drugs coprescribed with DAAs

https://www.hep-druginteractions.org/checker##table-view-wrap

Accessed on May 22, 2018

	Elbasvir/Grazoprevir	Glecaprevir/Pibrentasvir	Ledipasvir/Sofosbuvir	OBV/PTV/r + DSV	Sofosbuvir/Velpatasvir	Sofosbuvir/Velpatasvir/ Voxilaprevir
Atorvastatin	■	●	■	●	■	●
Escitalopram	◆	◆	◆	◆	◆	◆
Levetiracetam	◆	◆	◆	◆	◆	◆
Moxonidine	◆	◆	◆	◆	◆	◆
Pantoprazole	◆	▲	■	▲	■	■

● Do Not Coadminister ■ Potential Interaction ▲ Potential Weak Interaction ◆ No Interaction Expected ◆ No Clear Data

○ Do Not Coadminister □ Potential Interaction △ Potential Weak Interaction ◇ No Interaction Expected ◇ No Clear Data

CHAPTER 2
TREATMENT OF HCV INFECTION IN PATIENTS WITH CKD

2.5: As hepatitis B reactivation has been described with DAA therapy, all treatment candidates should undergo testing for HBV infection prior to therapy. If hepatitis B surface antigen [HBsAg] is present, the patient should undergo assessment for HBV therapy. If HBsAg is absent but markers of prior HBV infection (HBcAb positive with or without HBsAb) are detected, monitor for HBV reactivation with serial HBV DNA and liver function tests during DAA therapy (*Not Graded*)

Bersoff-Matcha SJ, *et al.* HBV Reactivation Associated With Direct-Acting Antiviral Therapy for Chronic Hepatitis C Virus: A Review of Cases Reported to the U.S. Food and Drug Administration Adverse Event Reporting System. *Ann Intern Med* 2017; 166: 792-798.

Impact of HCV treatment on kidney TP timing

- Renewed interest for the use of HCV+ grafts , especially in the USA.
- Waiting time for deceased donor frequently > 5 years, whereas HCV+ graft may be available very rapidly (local epidemiology!)
- Good long-term results in Spain of HCV+ kidneys to HCV+ recipients (Morales JM, *et al.* Long-term experience with kidney transplantation from hepatitis C-positive donors into hepatitis C-positive recipients. *Am J Transplant* 2010; **10:** 2453-2462.)

- **2.1.3:Treat kidney transplant candidates in collaboration with the transplant center to optimize timing of therapy. (*Not Graded*)**

Treatment With Ledipasvir–Sofosbuvir for 12 or 24 Weeks in Kidney Transplant Recipients With Chronic Hepatitis C Virus Genotype 1 or 4 Infection

A Randomized Trial

Massimo Colombo, MD; Alessio Aghemo, MD; Hong Liu, PhD; Jie Zhang, PhD; Hadas Dvory-Sobol, PhD; Robert Hyland, DPhil; Chohee Yun, MD; Benedetta Massetto, MD; Diana M. Brainard, MD; John G. McHutchison, MD; Marc Bourlière, MD; Markus Peck-Radosavljevic, MD; Michael Manns, MD; and Stanislas Pol, MD

Median of 10 years after kidney TP
Cockroft : median 56 ml/min
Tacrolimus 47%, Cyclosporin 39%, MMF 61%, Steroids 98%
Cirrhosis : 15%

Table 2. Response During and After Treatment

Variable	Ledipasvir-Sofosbuvir		Total (n = 114)
	12 wk (n = 57)	24 wk (n = 57)	
HCV RNA level less than the LLOQ during treatment, *n/N (%)*			
Baseline	0/57 (0)	0/57 (0)	0/114 (0)
Week 1	9/57 (16)	7/57 (12)	16/114 (14)
Week 2	31/57 (54)	33/57 (58)	64/114 (56)
Week 4	50/57 (88)	52/57 (91)	102/114 (89)
Week 8	56/56 (100)*	57/57 (100)	113/113 (100)
Week 12	56/56 (100)*	57/57 (100)	113/113 (100)
Week 16	NA	57/57 (100)	57/57 (100)
Week 20	NA	57/57 (100)	57/57 (100)
Week 24	NA	57/57 (100)	57/57 (100)
HCV RNA level less than the LLOQ after end of treatment, *n/N (% [95% CI])*			
SVR4	57/57 (100 [94–100])	57/57 (100 [94–100])	114/114 (100 [97–100])
SVR12	57/57 (100 [94–100])	57/57 (100 [94–100])	114/114 (100 [97–100])
Overall virologic failure (relapse), *n/N (%)*	0/0 (0)	0/0 (0)	0/0 (0)

Tolerance of DAA regimen OK

Colombo M, *et al*. *Ann Intern Med* 2017; 166: 109-117.

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CHAPTER 3: PREVENTING HCV TRANSMISSION IN HEMODIALYSIS UNITS

3.1: We recommend that hemodialysis facilities adhere to standard infection control procedures including hygienic precautions that effectively prevent transfer of blood and blood-contaminated fluids between patients to prevent transmission of blood-borne pathogens (see Table 2) (*1A*).

3.1.1: We recommend regular observational audits of infection control procedures in hemodialysis units (*1C*).

3.1.2: We recommend *not* using dedicated dialysis machines for HCV-infected patients (*1D*).

3.1.3: We suggest *not* isolating HCV-infected hemodialysis patients (*2C*).

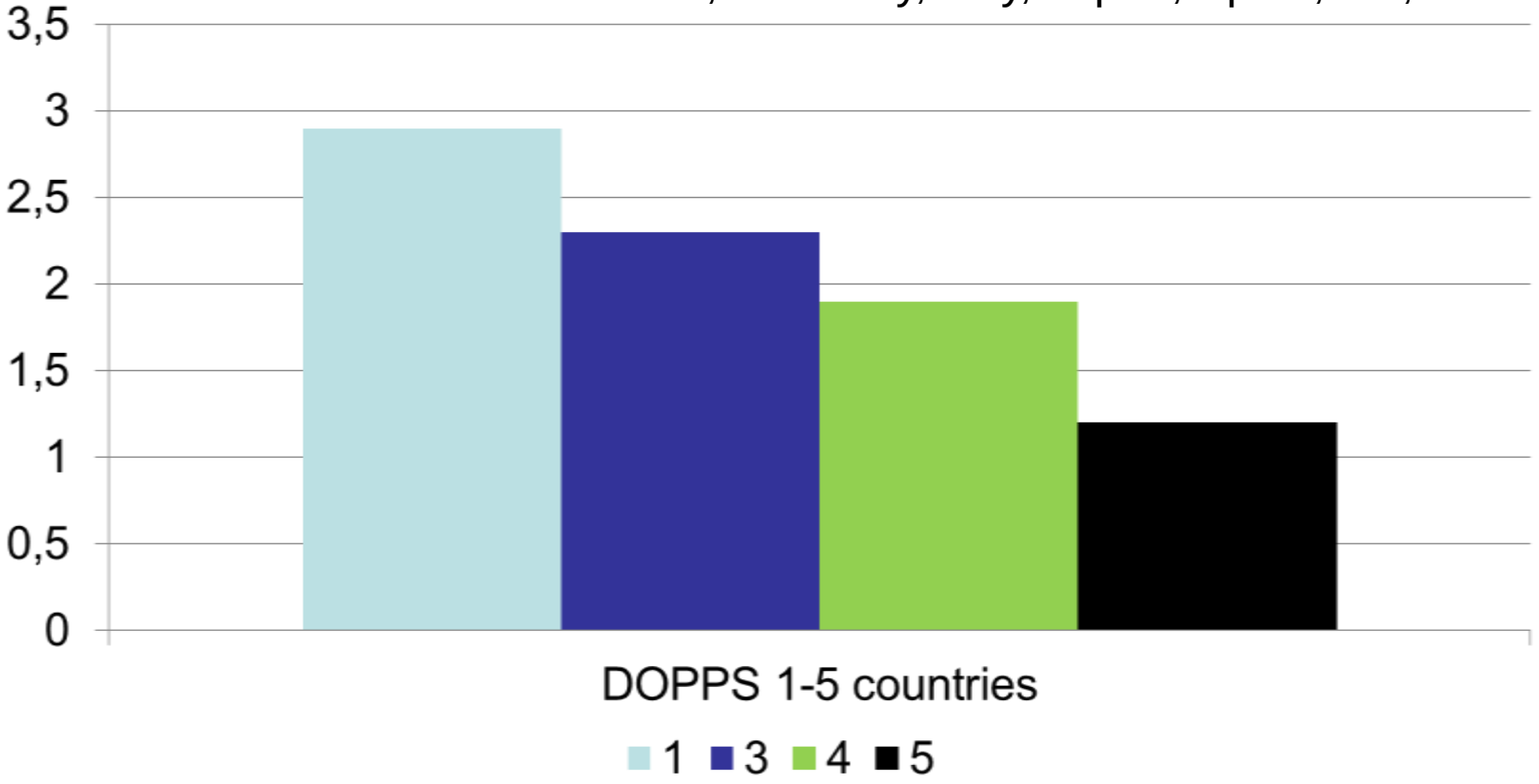
3.1.4: We suggest that the dialyzers of HCV-infected patients can be reused if there is adherence to standard infection control procedures (*2D*).

Table 1. Infection control practices (“hygienic precautions”) particularly relevant in preventing HCV transmission

- **Proper hand hygiene and glove changes, especially between patient contacts, before invasive procedures, and after contact with blood and potentially blood-contaminated surfaces/supplies**
- **Proper injectable medication preparation practices following aseptic technique and in an appropriate clean area, and proper injectable medication administration practice**
- **Thorough cleaning and disinfection of surfaces at the dialysis station, especially high-touch surfaces**
- **Adequate separation of clean supplies from contaminated materials and equipment**

HCV incidence per 100 patients years, by DOPPS region/country and phase

DOPPS 1-5 Countries : France, Germany, Italy, Japan, Spain, UK, US



DOPPS 1	DOPPS 3	DOPPS 4	DOPPS 5
1996-2001	2005-08	2009-11	2012-15

M Jadoul et al. submitted

Arguments for Nosocomial transmission

- DOPPS HCV incidence rates, by facility practice:
  - Do not accept HCV+ patients: 0.6 (0.3,1.3)
  - HCV+ pts treated at a general station: 2.3 (2.1,2.5)

- Clustering of HCV seroconversions in some facilities (mini-outbreaks)
  - 60% of facilities had 0 cases over ~3 years follow-up
  - 3% of facilities had 5+ cases

- Transfusional HCV transmission: currently < 1 case per per million transfusions in high income countries

- IV drug users generally much younger than the HD DOPPS patients with HCV seroconversion

M Jadoul et al. submitted

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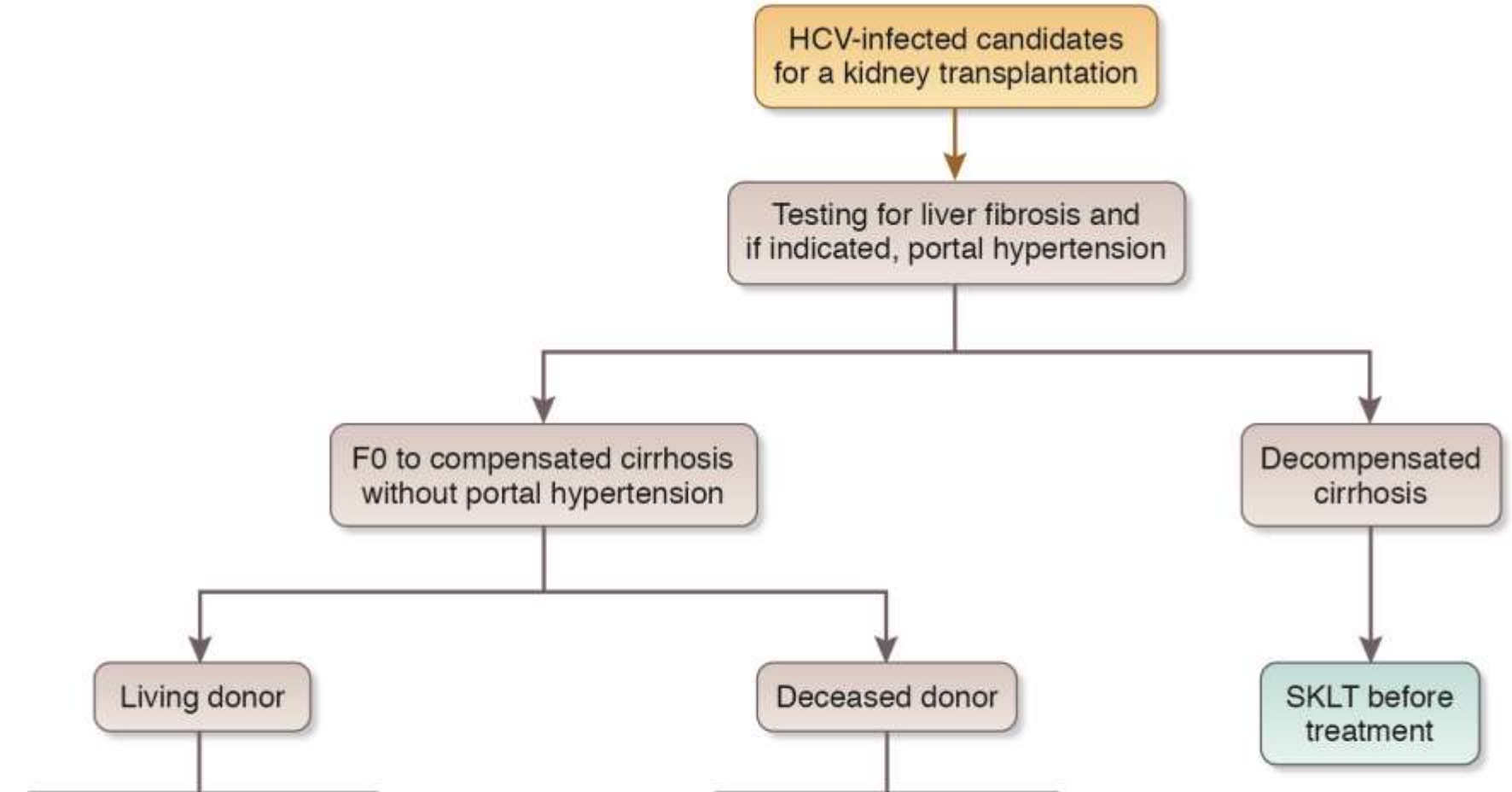
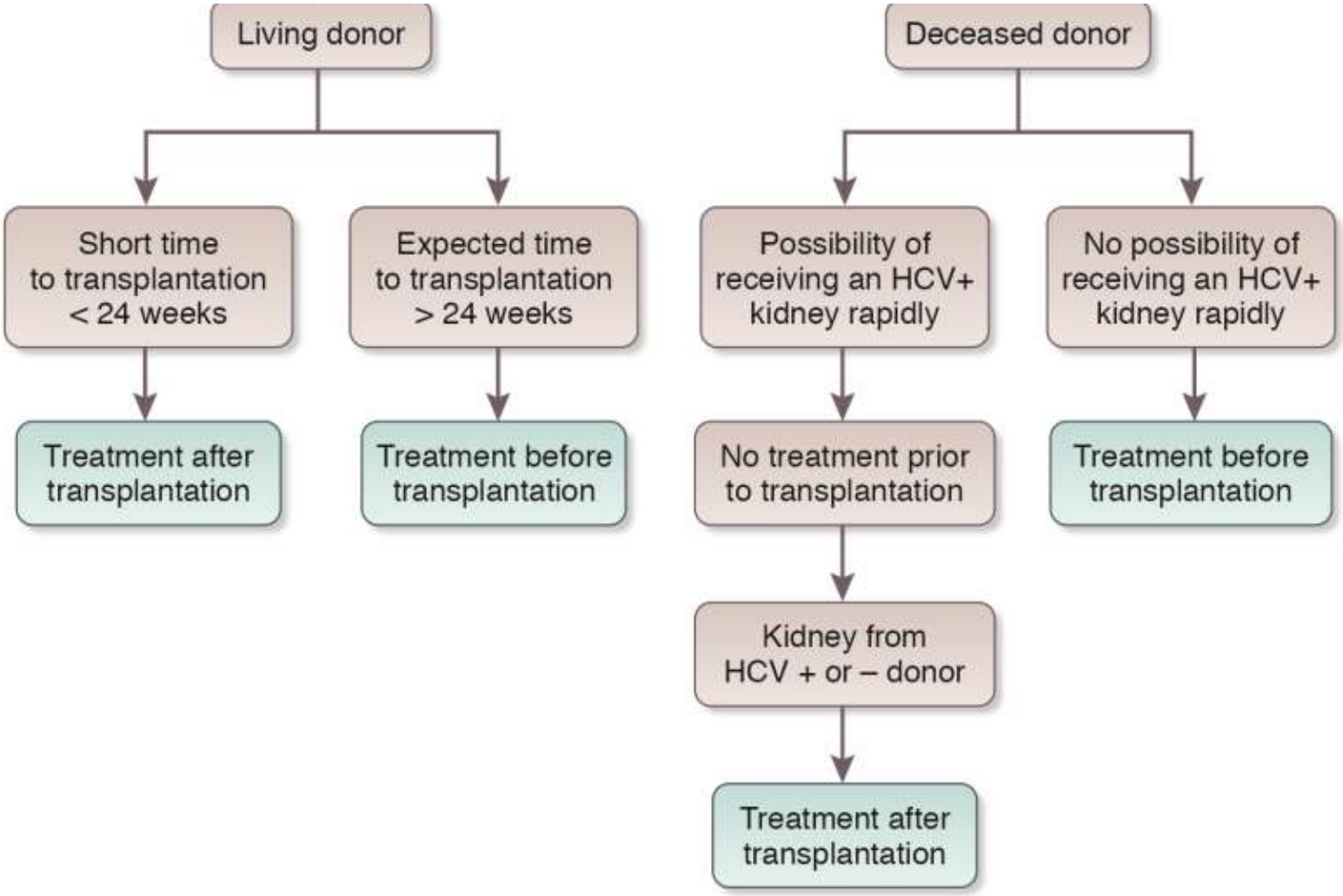
CHAPTER 4: MANAGEMENT OF HCV-INFECTED PATIENTS BEFORE AND AFTER KIDNEY TRANSPLANTATION



CHAPTER 4: MANAGEMENT OF HCV-INFECTED PATIENTS BEFORE AND AFTER KIDNEY TRANSPLANTATION



Use of kidneys from HCV-infected donors

4.4.1: We recommend all kidney donors be screened for HCV infection with both immunoassay and NAT (if NAT is available). (1A)

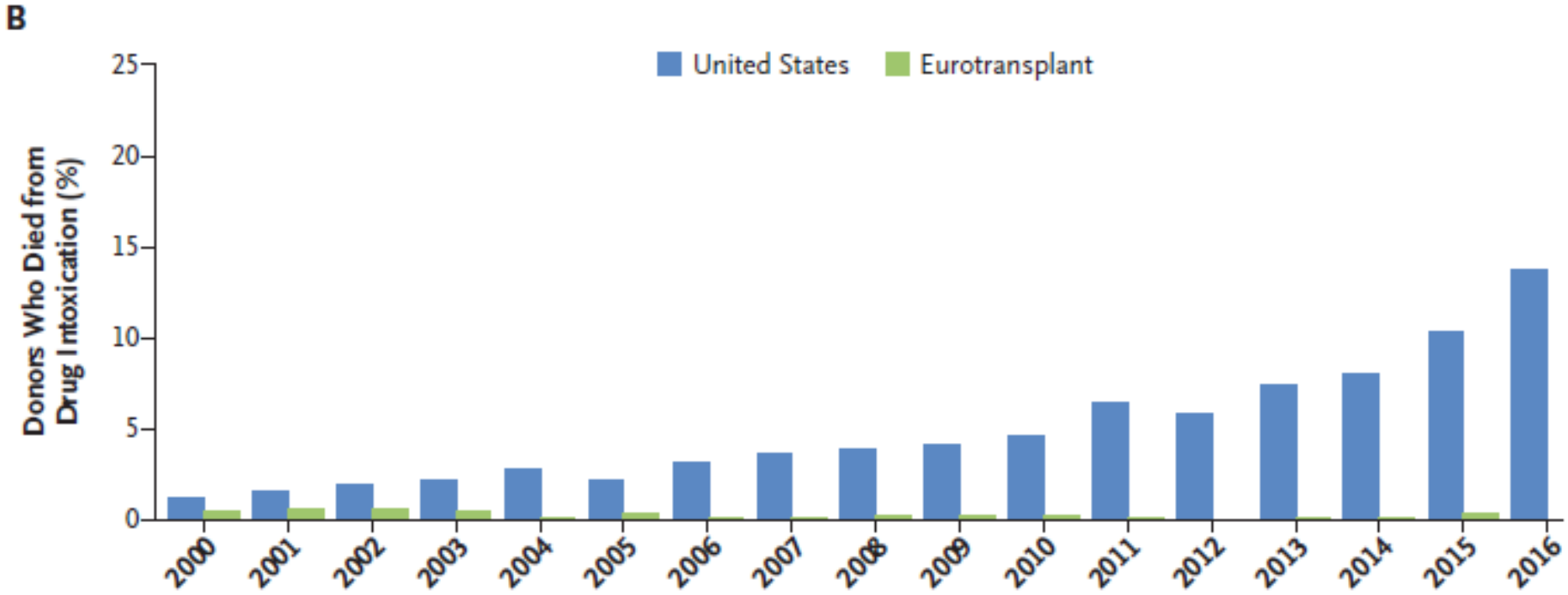
4.4.2: We recommend that transplantation of kidneys from HCV RNA-positive donors be directed to recipients with positive NAT. (1A)

4.4.3: After the assessment of liver fibrosis, potential HCV-positive living kidney donors who do not have cirrhosis should undergo HCV treatment before donation; they can be accepted for donation if they achieve sustained virologic response (SVR) and remain otherwise eligible to be a donor. (Not Graded)

Transplanting HCV-RNA(+) kidneys into HCV(-) recipients ?

- Preliminary exciting results from 2 US TP Centers (Philadelphia and Hopkins)
- total : around 30 patients
- Very short waiting time for TP (weeks)
- DAAs immediately before or after TP, for 12 weeks, with SVR12 in all pts
- No safety signal
- Strategy as yet investigational according to KDIGO WG

Durand C et al. *Ann Intern Med.* 2018; doi:10.7326/M17-2871
Reese P et al. *Ann Intern Med. 2018;* doi:10.7326/M18-0749



Mehra M et al The drug intoxication epidemic and solid organ transplantation NEJM 2018; 378;1943-1945

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CHAPTER 5: DIAGNOSIS AND MANAGEMENT OF KIDNEY DISEASES ASSOCIATED WITH HCV INFECTION

5.1: We recommend that a kidney biopsy be performed in HCV-infected patients with clinical evidence of glomerular disease (*Not Graded*).

5.2: We recommend that patients with HCV-associated glomerular disease be treated for HCV (*1A*).

Mild (kidney) disease : DAAs first (1C)
Severe (kidney) disease : DAAs and IS agents (+ plasma exchange?) (1C)
We recommend rituximab as the first-line immunosuppressive treatment (*1C*).

active HCV-associated glomerular disease who do not respond to antiviral therapy, particularly those with cryoglobulinemic kidney disease (*1B*).

5.2.3.1: We recommend rituximab as the first-line immunosuppressive treatment (*1C*).

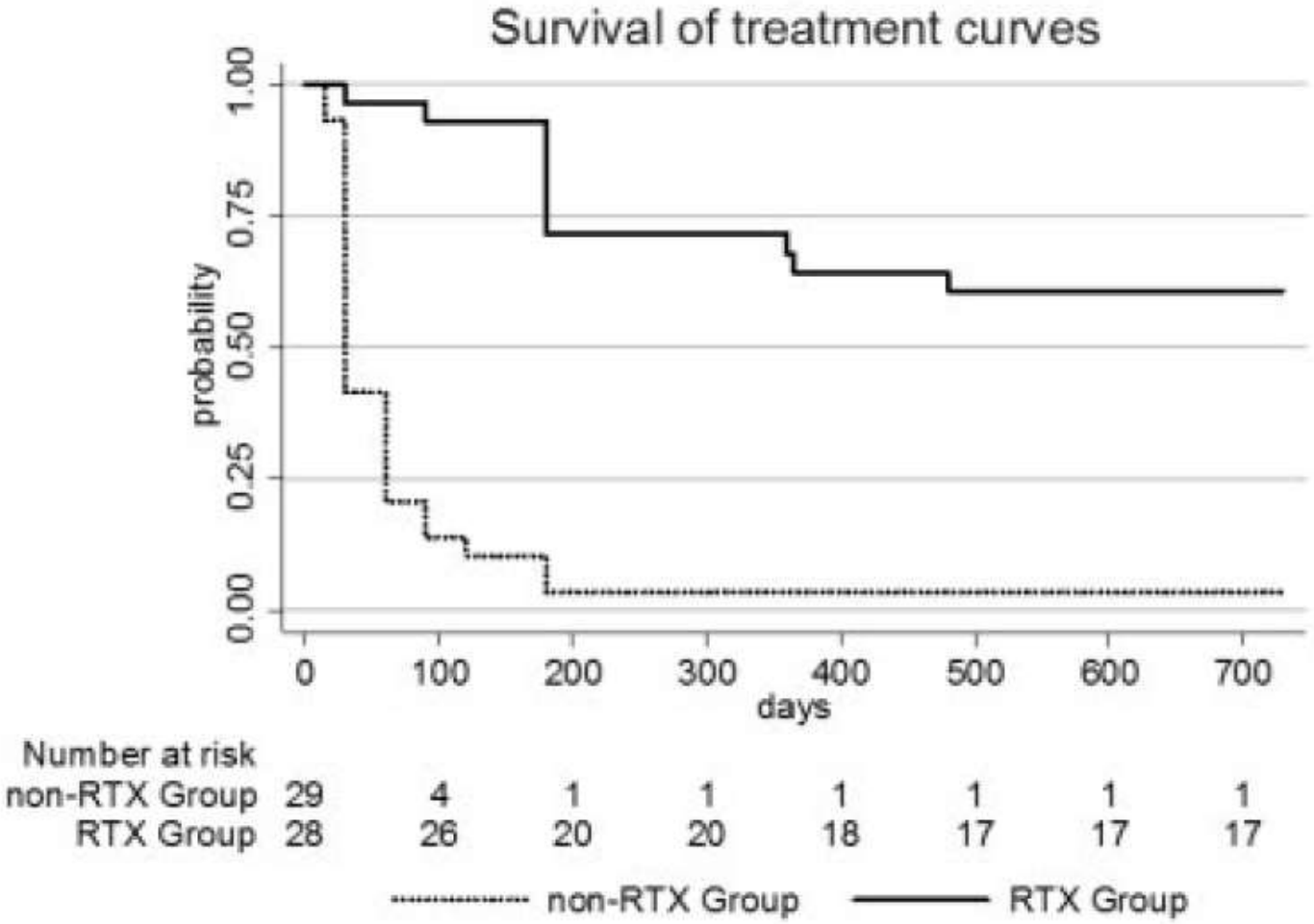

Figure 2. Survival curves in patients randomized to receive rituximab (RTX) therapy or conventional therapy (non-rituximab [non-RTX]), consisting of glucocorticoids, azathioprine, cyclophosphamide, or plasmapheresis.

De Vita S, *et al.* A randomized controlled trial of rituximab for the treatment of severe cryoglobulinemic vasculitis. *Arthritis Rheum* 2012; 64: 843-853.

A Randomized Controlled Trial of Rituximab Following Failure of Antiviral Therapy for Hepatitis C-Associated Cryoglobulinemic Vasculitis

Michael C. Sneller, M.D., **Zonghui Hu, Ph.D.**, and **Carol A. Langford, M.D., M.H.S.**
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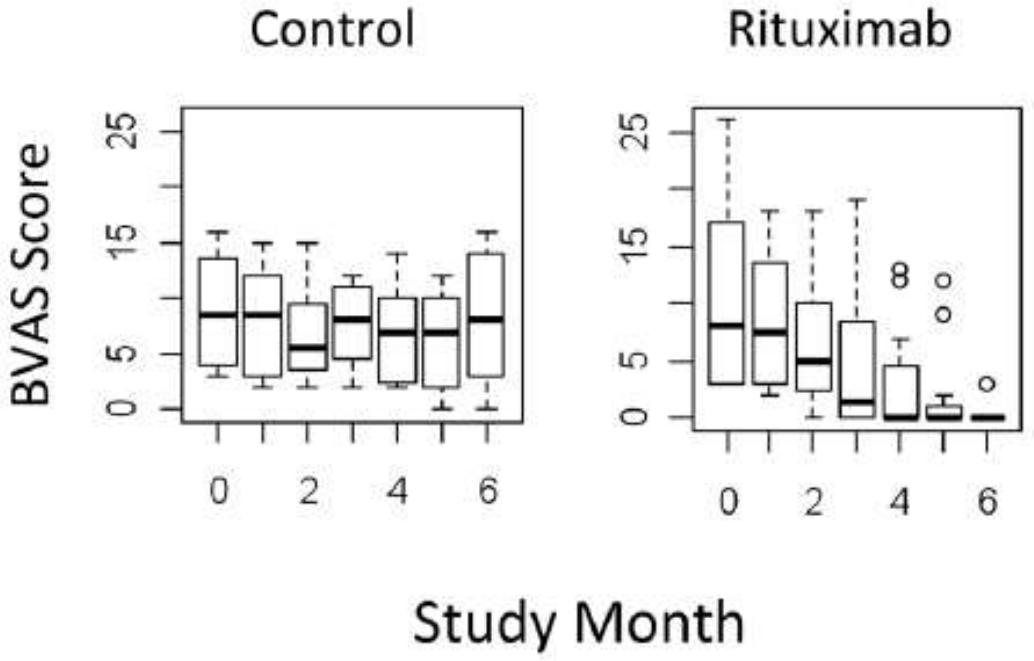
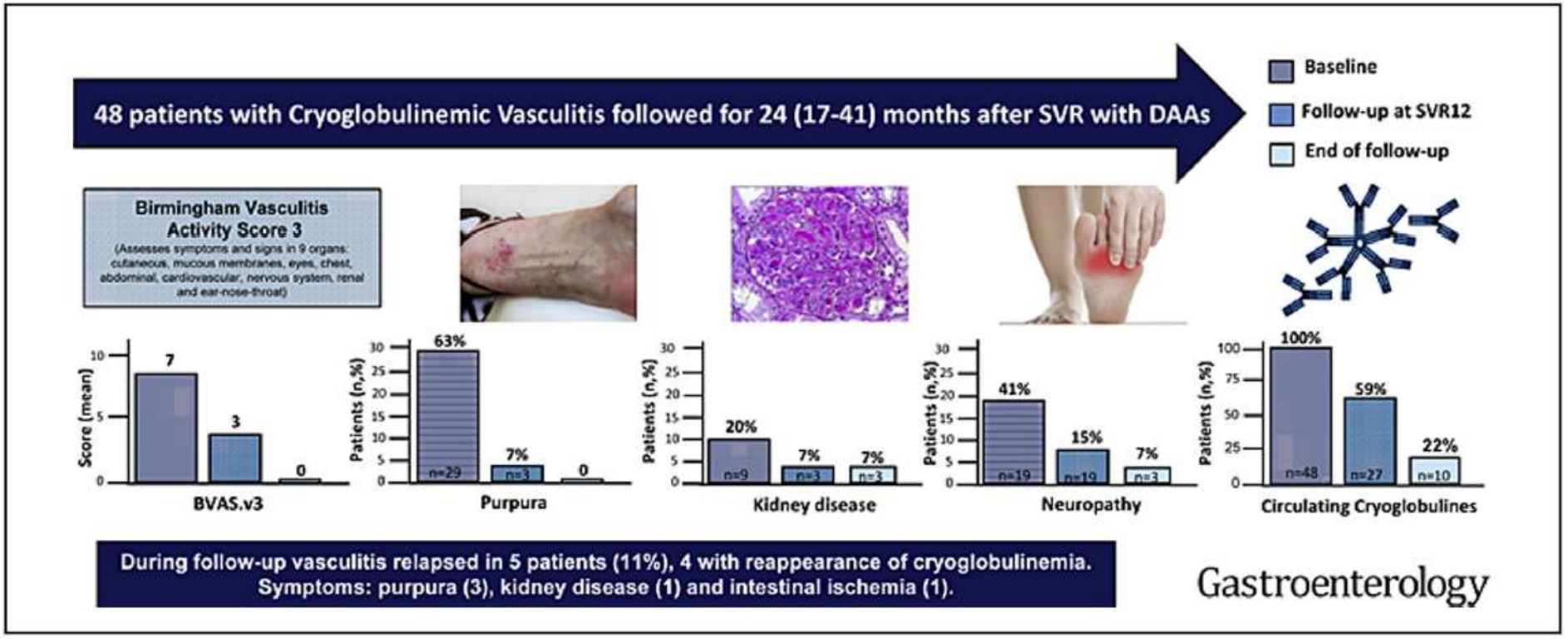


Sneller MC et al. *Arthritis Rheum* 2012; 64: 835-842.

Long-Term Outcomes of Patients With HCV-Associated Cryoglobulinemic Vasculitis After Virologic Cure

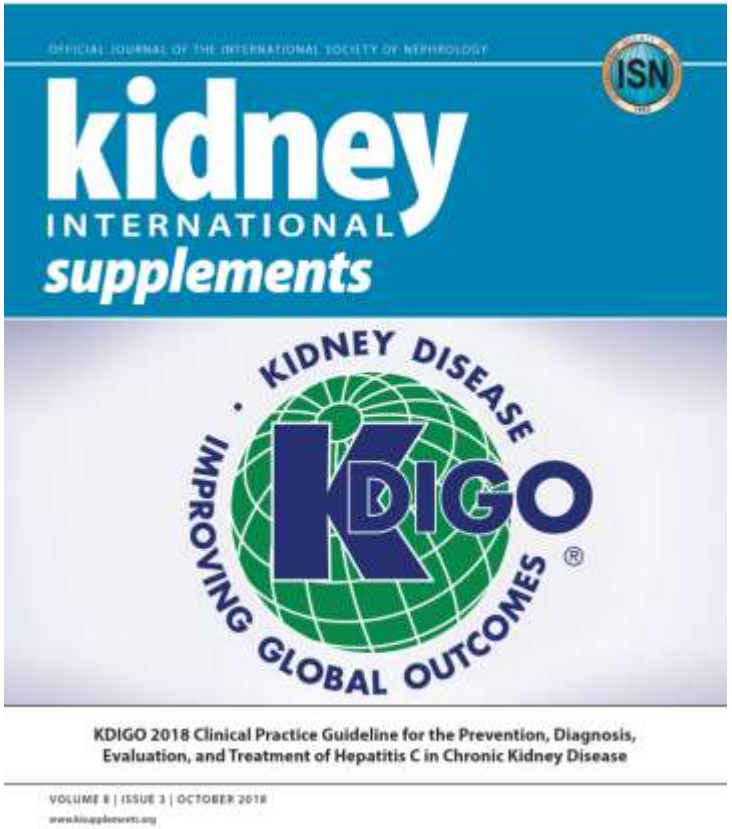
Martín Bonacci,[1] Sabela Lens,[1] Zoe Mariño,[1] María-Carlota Londoño,[1] Sergio Rodriguez-Tajes,[1] José M. Sánchez-Tapias,[1] Manel Ramos-Casals,[2] José Hernández-Rodríguez,[3] and Xavier Forns[1]



Gastroenterology 2018;155:311–315

Take-Home Messages

- Exciting time for those involved in the battle against HCV in CKD/dialysis/ kidney TP
- Major progress in the treatment of HCV in CKD patients: impressive new evidence
- No complacency anymore: right time to get rid of HCV from nephrology field , in line with WHO commitment to eliminate viral hepatitis as a public health problem by 2030
- Combining treatment and prevention (HD !)



www.kidney-international.org

guideline summary

Executive summary of the 2018 KDIGO Hepatitis C in CKD Guideline: welcoming advances in evaluation and management

Check for updates

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Michel Jadoul[1], Marina C. Berenguer[2,3,4], Wahid Doss[5], Fabrizio Fabrizi[6], Jacques Izopet[7,8], Vivekanand Jha[9,10], Nassim Kamar[11,12,13], Bertram L. Kasiske[14,15], Ching-Lung Lai[16,17], José M. Morales[18], Priti R. Patel[19], Stanislas Pol[20], Marcelo O. Silva[21,22], Ethan M. Balk[23], Craig E. Gordon[24], Amy Earley[25], Mengyang Di[23,26] and Paul Martin[27]

Kidney International (2018) **94,** 663–673