

Общероссийская Общественная Организация Нефрологов "Российское Диализиюе Общество" УЗ ТКБ №52 ДЗ Москвы", ФГБОУ ВО МГМСУ им. А.И. Баркинкова, ГБУЗ ТКБ им. С.П. Боткина"



XII Общероссийская конференция "РДО – 20 лет"

ПРОГРАММА

UCL

Université catholique de Louvain

### Towards an update of the KDIGO Guideline for Glomerulonephritis



Professor Michel Jadoul Cliniques universitaires Saint-Luc Université catholique de Louvain Brussels, Belgium

## KDIGO CONTROVERSIES CONFERENCE ON GLOMERULAR DISEASES 2017 SINGAPORE

Slides: courtesy of Prof. Jürgen Floege (Aachen)



#### KDIGO Controversies Conference on Glomerular Diseases

Jürgen Floege - Conference Co-Chair Brad Rovin - Conference Co-Chair

General Principles, MPGN, C3GN (Swallow Room)			IgAN (Galleria Ballroom)		r <mark>anous GN</mark> con Room)	(Par	D & FSGS adiso Room)		Lupus & ANCA (Cardinal Room)	
				Breakou	t Group Co-Cl	nairs				
Cattran (CA)	Dan	Barbour (CA)	Sean	Nachman (US)	Patrick	Gibson (US)	Keisha	Caster (US)	Dawn	
Hogan (US)	Jonathan	Tang (HK)	Sydney	Wetzels (NL)	Jack	Moeller (DE)	Marcus	Roccatello (IT)	Dario	



# KEY QUESTION: WHICH OF THE 2012 GLOMERULAR DISEASE GUIDELINE RECOMMENDATIONS NEED REVISION?

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## GN GUIDELINE UPDATE UNDERWAY

- Held August 27 29, 2018
- -Sheraton Amsterdam Airport Hotel
- Cochrane Renal & Transplant ERT
- next slides (statements/algorithms) are draft ones (no final recommendations as yet), except for HCV-associated GN



### GN GUIDELINE UPDATE WORK GROUP MEMBERS

KDIGO GN Guideline Update Jürgen Floege - Guideline Co-Chair Brad Rovin - Guideline Co-Chair													
ANCA (Chapters 13 & 14)		General (Chapters 2 & 9)		IgAN (Chapters 10 & 11)		MCD & FSGS (Chapters 3, 4, 5, &						<u>SLE</u> (Chapter 12)	
	Work Group Members												
Sanders (NL)	Jan-Stephan	Adler (US)	Sharon	Barratt (UK)	Jonathan	Gibson (US)	Keisha	Jha (IN)	Vivek	Bridoux (FR)	Frank	Chan (HK)	Daniel T.M.
Tesař (CZ)	Vladimír	Burdge (US)	Kelly	Cook (UK)	Terry	Liew (SG)	Adrian	Ronco (FR)	Pierre	Fervenza (US)	Fernando	Mejía Vilet (MX)	Juan Manuel
		Glassock (US)	Richard	Reich (CA)	Heather	Radhakrishnan (US)	Jai	Wetzels (NL)	Jack	Nester (US)	Carla		
		Rave (US)	Elizabeth	Tang (HK)	Sydney	Vivarelli (IT)	Marina			Sethi (US)	Sanjeev		





### **GN Guideline Update: Timeline**



Feb 2018 Mar 2018 Apr 2018 May 2018 Jun 2018 Jul 2018 Aug 2018 Sep 2018 Oct 2018 Nov 2018 Dec 2018 Jan 2019 Feb 2019 Mar 2019 Apr 2019 May 2019 Jun 2019

Meeting '0' (February 5, 2018): Formalize Scope of Work and PICO with ERT

ERT literature review

WG Meeting (Aug 27-29: Amsterdam) Review evidence, strive for consensus on recommendation wording and grading

- ERT to fine tune evidence review as needed

Next steps:

- Possible WG Meeting 2? Final consensus on recs/rationale
- WG to prepare draft guideline for open review
- Public Review (1 month)
- WG to review public comments
- WG to refine guideline manuscript
- Manuscript submission

## GENERAL MANAGEMENT OF GLOMERULAR DISEASES





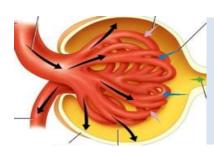
### **GENERAL MANAGEMENT**



- Kidney biopsy remains the cornerstone + likely to expand significantly in the near-term
- need for electron microscopy for every biopsy remains controversial



 ACR and PCR helpful in general clinical management
 not sufficiently accurate for therapeut. decisions when using high-risk medications



 eGFR equations not validated in specific glomerular diseases and patient populations



### **GENERAL MANAGEMENT**



- patient engagement in determining clinical trial eligibility
- patient-related outcomes and measurements rapidly evolving



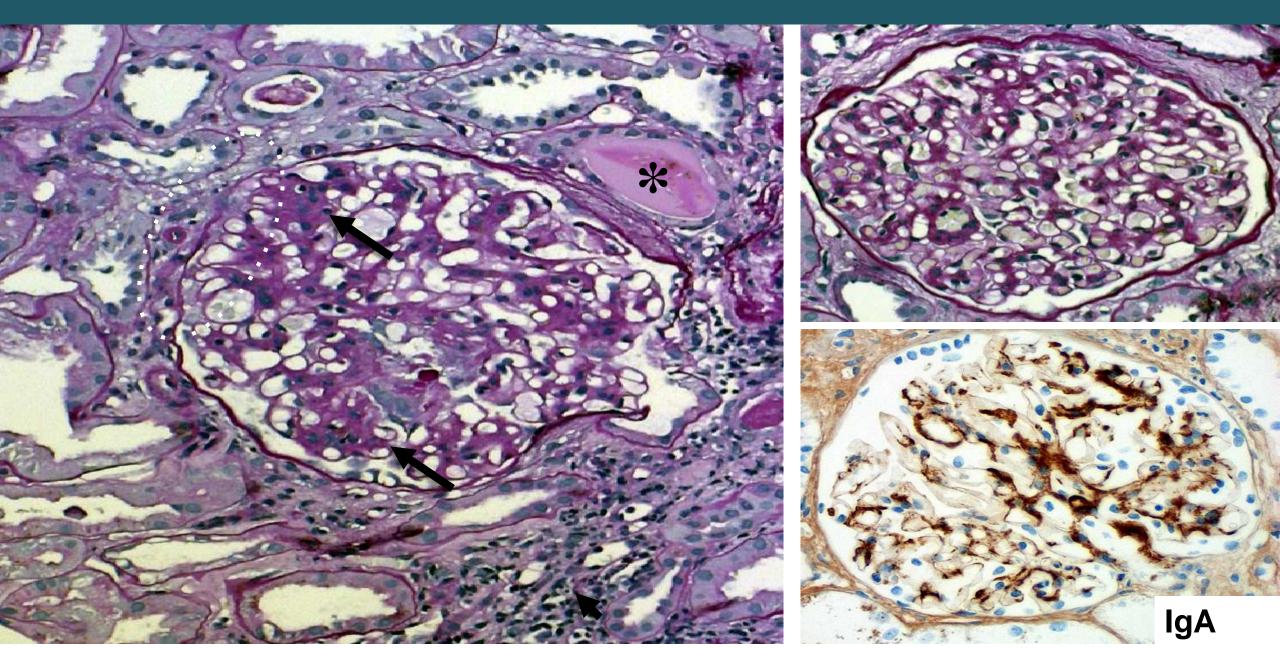
 Newer determinants of progression: pre-maturity, sleep disturbances, obesity, genetics



- Hypertension + proteinuria: no news
- Uncertain: aldosterone or SGLT2 blockers; PCSK9 inhibitors and NOAC in nephrotic pts.
- multidisciplinary support, infection control
- Role of prophylactic anticoagulation discussed



## IGA-NEPHROPATHY



## THE STOP-IGAN TRIAL

The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

### Intensive Supportive Care plus Immunosuppression in IgA Nephropathy

Thomas Rauen, M.D., Frank Eitner, M.D., Christina Fitzner, M.Sc., Claudia Sommerer, M.D., Martin Zeier, M.D., Britta Otte, M.D., Ulf Panzer, M.D., Harm Peters, M.D., Urs Benck, M.D., Peter R. Mertens, M.D., Uwe Kuhlmann, M.D., Oliver Witzke, M.D., Oliver Gross, M.D., Volker Vielhauer, M.D., Johannes F.E. Mann, M.D., Ralf-Dieter Hilgers, Ph.D., and Jürgen Floege, M.D., for the STOP-IgAN Investigators\*

ABSTRACT



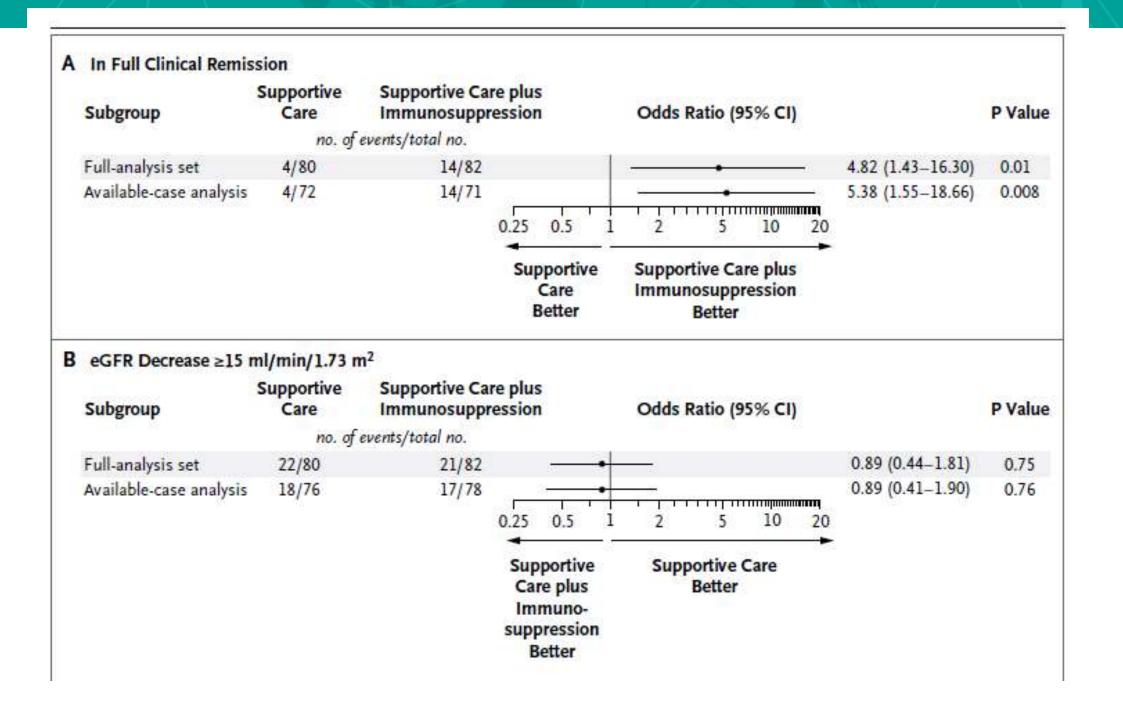




Table 3. Adverse Events during the Trial.					
Variable	Supportive Care (N=80)	Supportive Care plus Immunosuppression (N = 82)	P Value		
Patients with ≥1 serious adverse event — no.	21	29	0.24		
Total no. of serious adverse events	29	33	0.18		
Total no. of events of infection	111	174	0.07		
Total no. of serious adverse events of infection	3	8	0.21		
Diverticulitis or appendicitis	1	3	0.62		
Pneumonia or respiratory tract infection	1	3	0.62		
Viral exanthema	1	1	1.00		
Knee empyema	0	1	1.00		
Death — no.*	1	1	1.00		
Additional adverse events of interest — no. of patients					
≥1 incidence of increase in liver-enzyme level (i.e., alanine amino- transferase >50 IU/ml)	12	13	1.00		
$\geq$ 1 incidence of observed leukopenia (i.e., leukocyte count <4000/ $\mu$ l)	3	2	1.00		
Malignant neoplasm	0	2	0.50		
Impaired glucose tolerance or diabetes mellitus	1	9	0.02		
Gastrointestinal bleeding	0	0	Not determined		
Fracture	0	1	1.00		
Osteonecrosis — no. of patients	0	0	Not determined		
Weight gain (≥5 kg within the first year)	5	14	0.049		





#### JAMA | Original Investigation

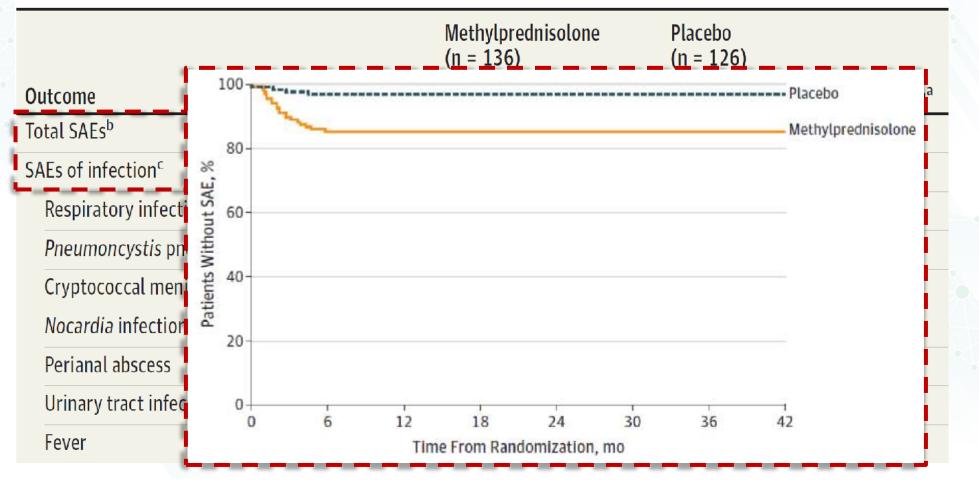
## Effect of Oral Methylprednisolone on Clinical Outcomes in Patients With IgA Nephropathy The TESTING Randomized Clinical Trial

Jicheng Lv, MD; Hong Zhang, PhD; Muh Geot Wong, PhD; Meg J. Jardine, PhD; Michelle Hladunewich, MD; Vivek Jha, MD; Helen Monaghan, PhD; Minghui Zhao, MD; Sean Barbour, MD; Heather Reich, MD; Daniel Cattran, MD; Richard Glassock, MD; Adeera Levin, FRCPC; David Wheeler, FRCP; Mark Woodward, PhD; Laurent Billot, MSc; Tak Mao Chan, MD; Zhi-Hong Liu, MD; David W. Johnson, MD; Alan Cass, FRACP; John Feehally, MD; Jürgen Floege, MD; Giuseppe Remuzzi, MD; Yangfeng Wu, MD; Rajiv Agarwal, MD; Hai-Yan Wang, MD; Vlado Perkovic, PhD; for the TESTING Study Group



### **TESTING:** EARLY TRIAL TERMINATION

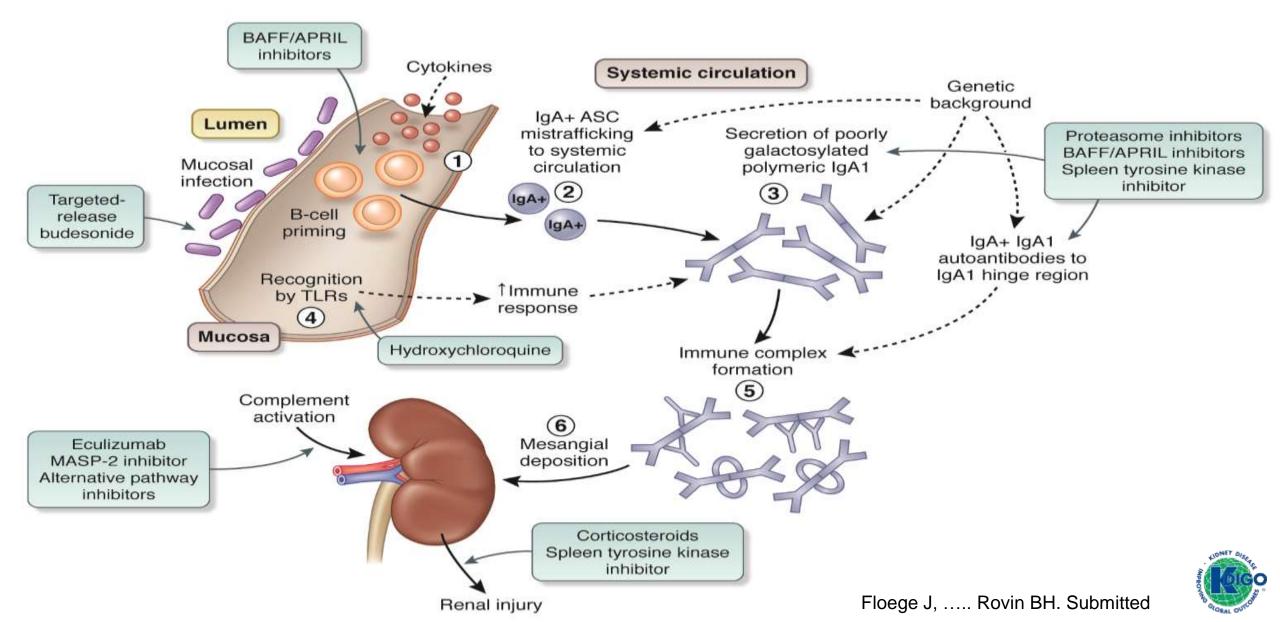
Table 2. Serious Adverse Events and Adverse Events of Special Interest by Treatment Group





Lv J et al, JAMA. 2017;318(5):432-442

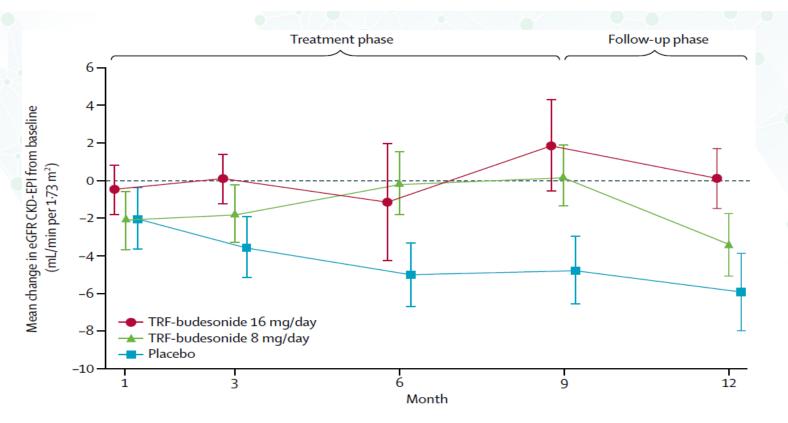
### IGA NEPHROPATHY - NEW OPTIONS FOR THERAPY



Lancet 2017; 389: 2117-27

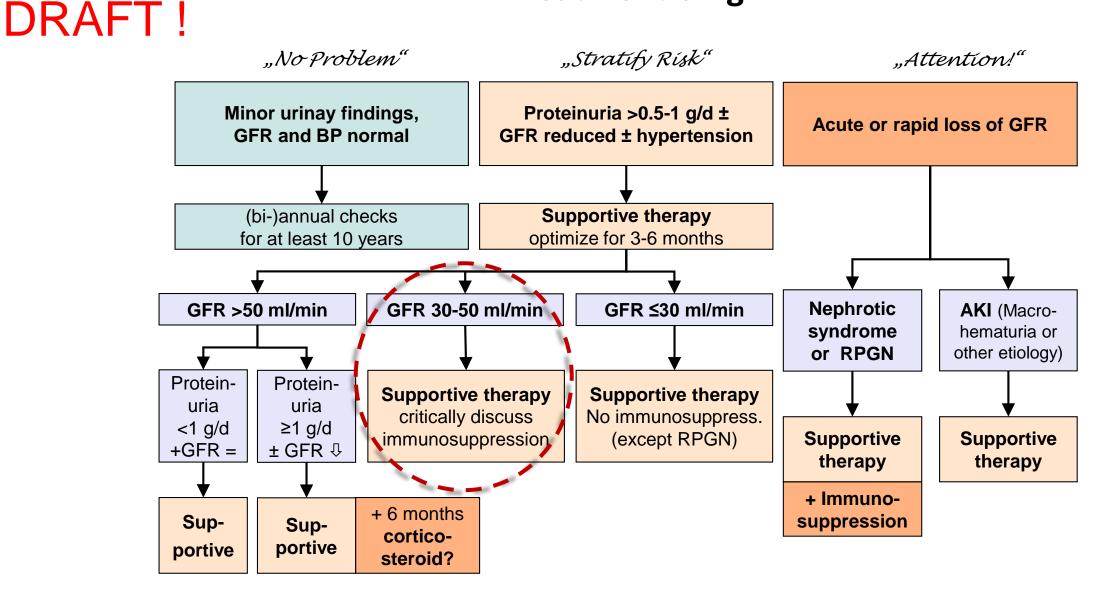
#### Targeted-release budesonide versus placebo in patients with *W* is IgA nephropathy (NEFIGAN): a double-blind, randomised, placebo-controlled phase 2b trial

Bengt C Fellström, Jonathan Barratt, Heather Cook, Rosanna Coppo, John Feehally, Johan W de Fijter, Jürgen Floege, Gerd Hetzel, Alan G Jardine, Francesco Locatelli, Bart D Maes, Alex Mercer, Fernanda Ortiz, Manuel Praga, Søren S Sørensen, Vladimir Tesar, Lucia Del Vecchio, for the NEFIGAN Trial Investigators

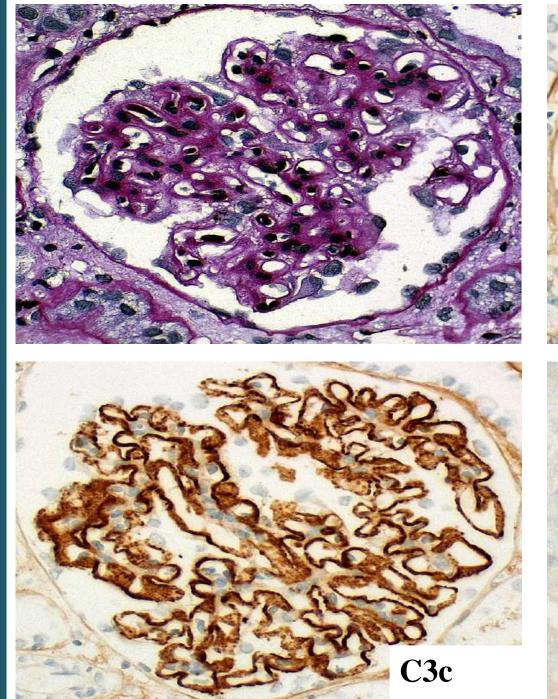


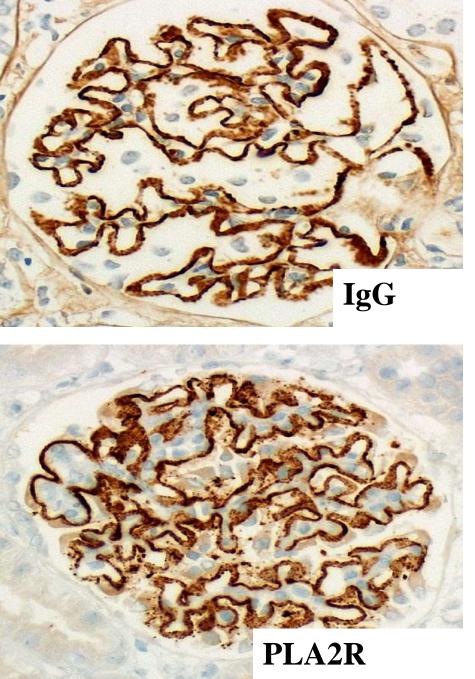


#### **Treatment of IgAN**

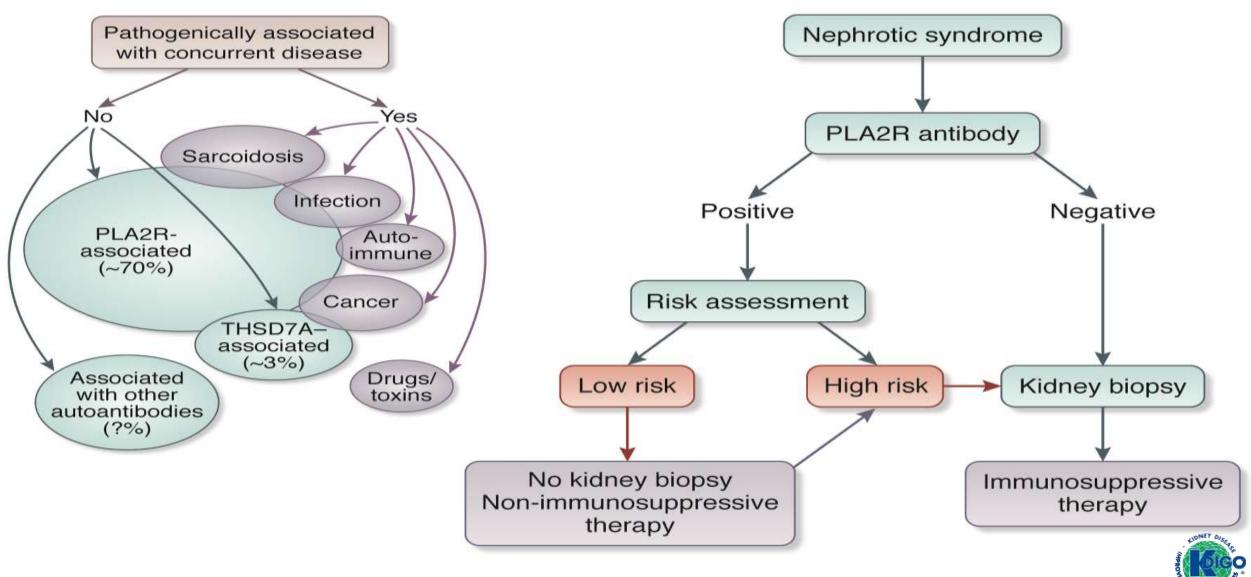


### Membranous GN



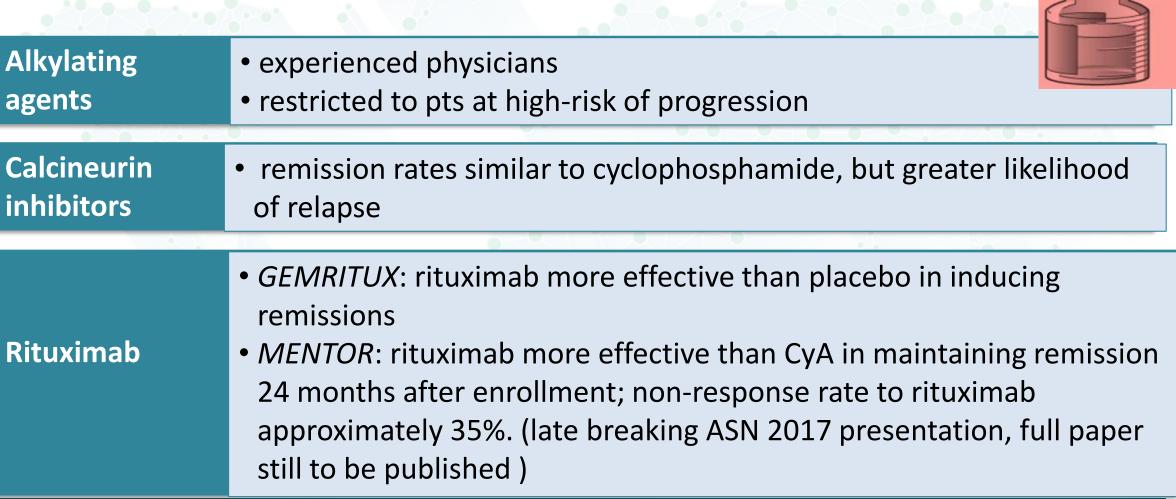


### MEMBRANOUS GN – WORK-UP + THERAPY



Floege J, ..... Rovin BH. Submitted

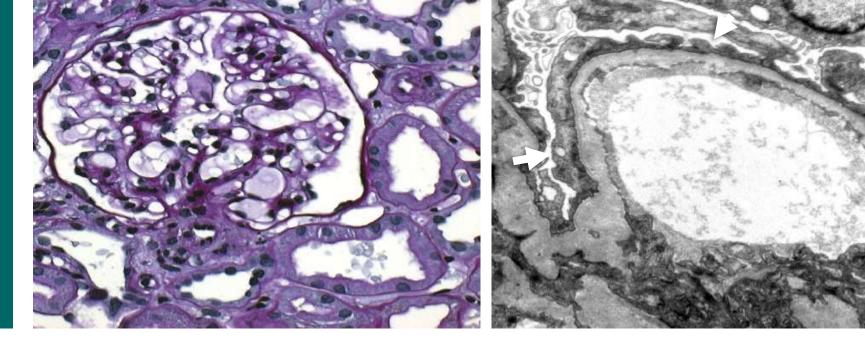
## MEMBRANOUS GN – IMMUNOSUPPRESSION



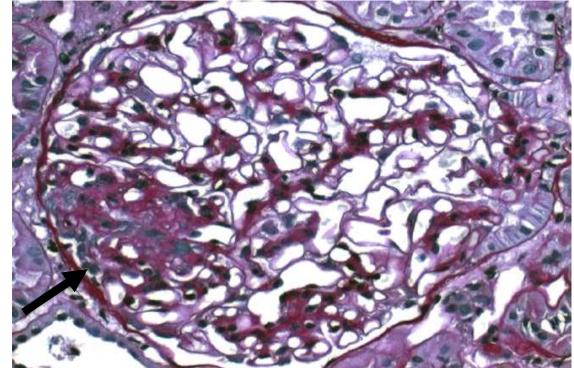
...It is likely that the choice of therapy may be determined by improved risk-stratification models incl. autoantibody levels ...

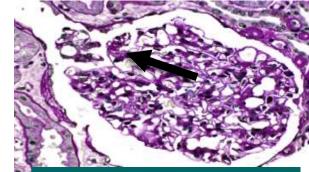


### MINIMAL CHANGE NEPHROPATHY

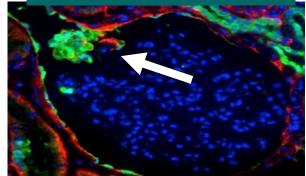


### FOCAL SEGMENTAL GLOMERULO-SCLEROSIS





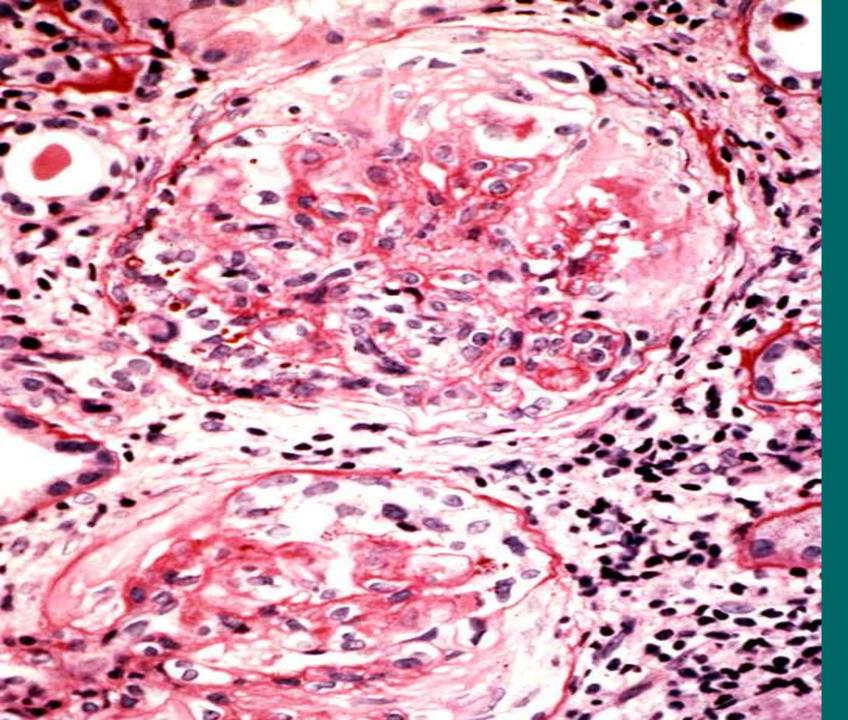
Parietal cell activation



## MINIMAL CHANGE GN & FSGS

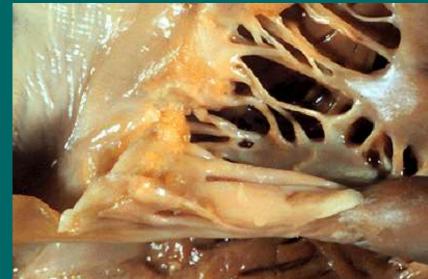
- "Steroid sensitive" and "steroid-resistant NS" should remain
- Term "primary/idiopathic FSGS" may require revision.
- Genetic testing: patients with congenital/infantile forms of nephrotic syndrome, syndromic features, familial forms
- *Children*: Steroids first in all nephrotic pts; need for a global definition of "steroid resistance," precise order of CYC, MMF, CNI and rituximab not well determined.
- Adults: minimum 16 weeks of high-dose steroids as first-line therapy for FSGS or MCD controversial. Several studies indicate that > 8-12 weeks steroids does not reduce relapse. CNIs or CYC second-line agents in adults with MCD. RTX emerging second-line therapy in MCD. CNIs and MMF second- and third-line treatments, resp., for FSGS.





### LUPUS ERYTHEMATOSUS





### LUPUS NEPHRITIS

ISN/RPS	<ul> <li>does not consider tubulointerstitial injury, vascular lesions, or</li></ul>		
classification	podocytopathies		
Genetic testing	<ul> <li>no clear clinical benefit from testing</li> <li>risks &amp; benefits of APOL1 testing to be clarified</li> </ul>		
Repeat	<ul> <li>patients with clinical remission can still have histologic activity and</li></ul>		
renal biopsy	vice versa		
Prediction & Monitoring	<ul> <li>proteinuria at one year best predictor of long term renal outcome</li> <li>biomarker panels will be required to accurately stratify risk, predict flare, determine + monitor treatment, and predict prognosis</li> </ul>		



### LUPUS NEPHRITIS



Antimalarials	recommended for all patients with LN
Contino	e use et levrest pessible dese during maintenance
Cortico- steroids	<ul> <li>use at lowest possible dose during maintenance</li> <li>Low/zero-steroids protocols under investigation</li> </ul>
CYC-/MMF- regimens	<ul> <li>remain the gold standard therapy for remission induction</li> </ul>
Calcineurin- inhibitors	<ul> <li>Ongoing studies address role and toxicity in ethnically diverse populations</li> </ul>
Maintenance Therapy	<ul> <li>minimum of 3 years, prolonged B-cell depletion with a RTX plus CYC may reduce the duration</li> <li>A repeat kidney biopsy may be helpful</li> </ul>



### **REFRACTORY LUPUS NEPHRITIS**

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- Verify adherence (check mycophenolic level if on MMF/check infusion records if on CYC)
- Repeat biopsy if concern for chronicity or other diagnosis (?TMA, etc.)

- · Switch from MMF to CYC or vice versa
- Consider regimen with combined MMF/CNI 'multi-target' therapy or
- Addition of Rituximab or
- Consider prolonged course of IV pulse CYC
- Consider intravenous IgG *or* plasmapheresis (especially in setting of concomitant TMA or refractory APS). *Minimal evidence outside of case reports*



## ANCA VASCULITIS





## **ANCA** VASCULITIDES

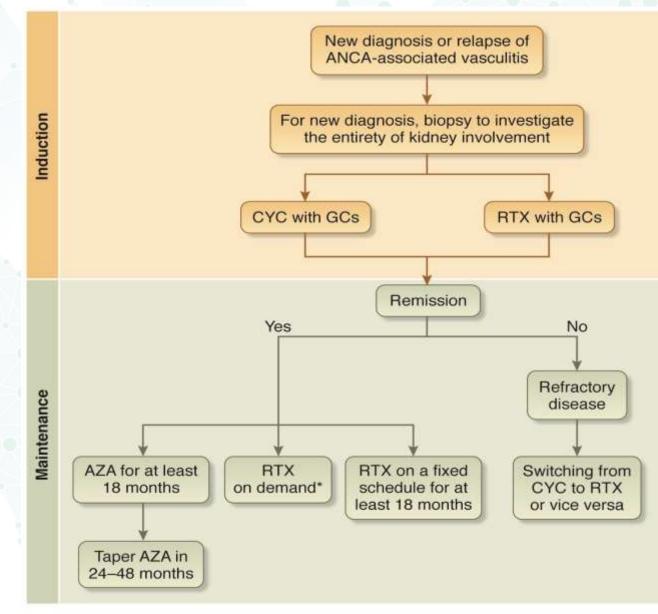
**ANCA** serology and **Biomarkers** 

- MPO vs. PR3 ANCA has predictive value with respect to outcomes and risk of relapse
- New biomarkers: Serum - CXCL 13, MMP-3, TIMP-1
  - Urine soluble CD163





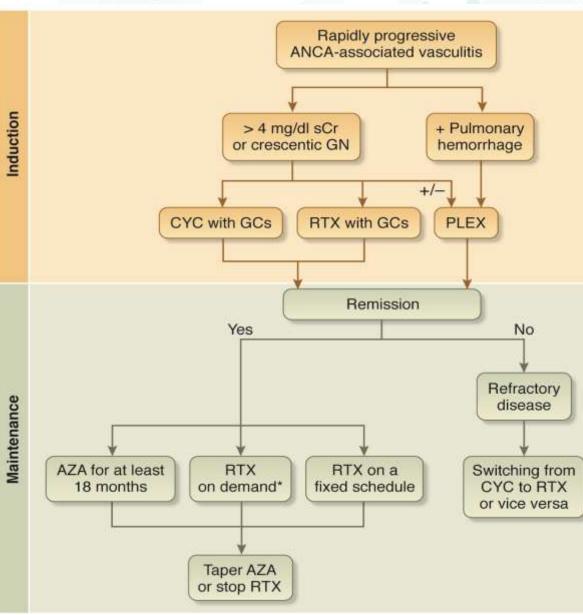
### ANCA VASCULITIDES



Rovin BH, ..... Floege J. Submitted



## SEVERE ANCA VASCULITIDES



Rovin BH, ..... Floege J. Submitted

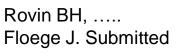
## **REFRACTORY ANCA** VASCULITIDES

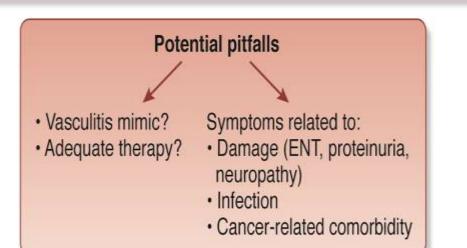
#### Refractory disease:

- No improvement in 4 weeks
- Improvement of less than 50% in 6 weeks of treatment (as measured by BVAS/WG)
- Chronic persistent disease after more than 12 weeks

#### Change in therapy:

- Switch to RTX if previously treated with CYC (especially in PR3-ANCA patients) or vice versa
- Oral CYC if previous IV CYC failure (and RTX unavailable)
- IVIg 0.4 gr/kg for 5 days especially if persistent low disease activity







## ANCA VASCULITIDES – RITUXIMAB REGIMENS

#### Induction

- Four weekly intravenous doses of 375 mg/m<sup>2</sup>
- Four weekly intravenous doses of 375 mg/m<sup>2</sup> and 1 monthly infusion one and 2 months apart

#### Maintenance

- 1000 mg every 6 months
- 1000 mg every 4 months
- 1000 mg every 6 months for 24 months
- 4 weekly doses of 375 mg/m<sup>2</sup> or two biweekly doses of 1000 mg, given on the basis of laboratory parameters
- 375 mg/m<sup>2</sup> every 6 months
- 1000 mg every 6 months
- 1000 mg every 12 months
- 500 mg on days 1 and 15, again every 6 mon for a total of 5 doses





### Randomized Trial of C5a Receptor Inhibitor Avacopan in ANCA-Associated Vasculitis

David R.W. Jayne,\* Annette N. Bruchfeld,<sup>†</sup> Lorraine Harper,<sup>‡</sup> Matthias Schaier,<sup>§</sup> Michael C. Venning,<sup>||</sup> Patrick Hamilton,<sup>||</sup> Volker Burst,<sup>¶</sup> Franziska Grundmann,<sup>¶</sup> Michel Jadoul,\*\* István Szombati,<sup>††</sup> Vladimír Tesař,<sup>‡‡</sup> Mårten Segelmark,<sup>§§</sup> Antonia Potarca,<sup>|||</sup> Thomas J. Schall,<sup>|||</sup> and Pirow Bekker,<sup>|||</sup> for the CLEAR Study Group

> Double –blind double-placebo RCT Avacopan : oral drug, C5a receptor inhibitor

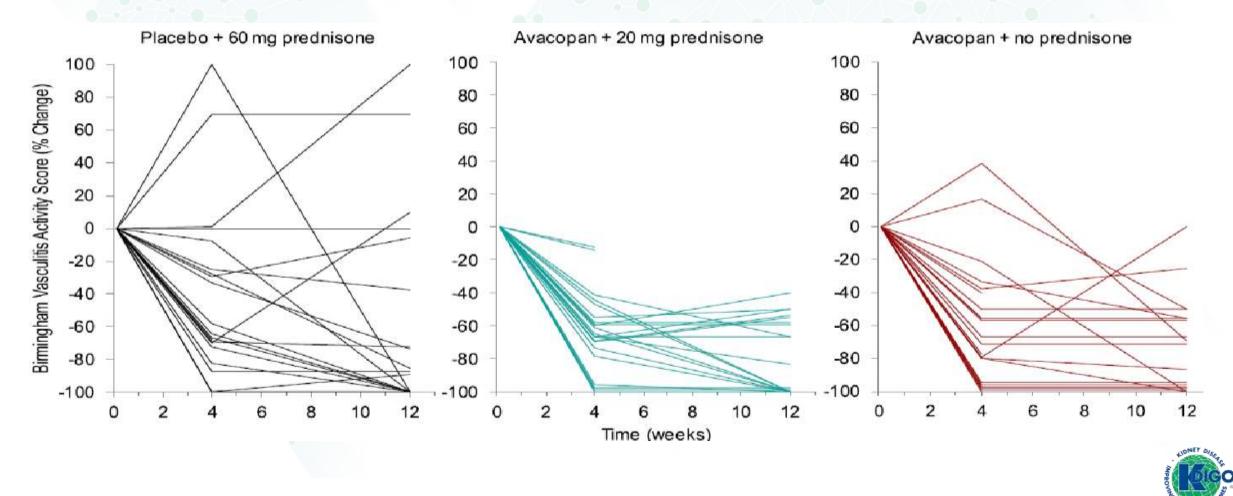
www.jasn.org

CLINICAL RESEARCH



### AVACOPAN FOR ANCA VASCULITIS

- > 67 pts with newly diagnosed or relapsing ANCA vasculitis
- > All treated with cyclophosphamide or rituximab.



### MPGN need for a new nomenclature based on pathogenesis and injury pattern

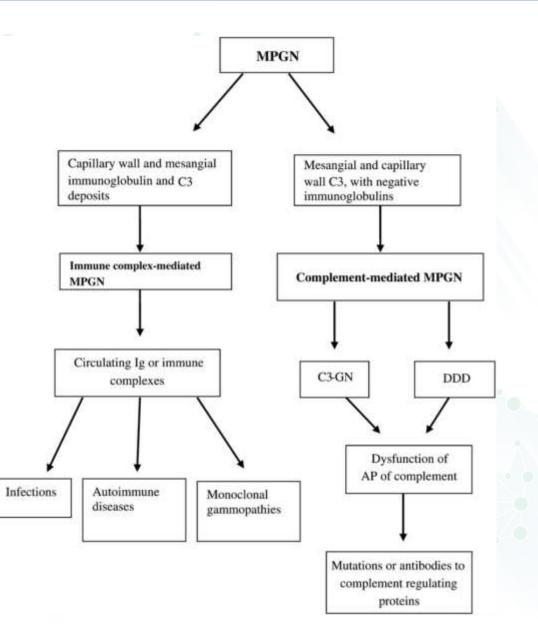
Nephrol Dial Transplant (2012) 27: 4288-4294 doi: 10.1093/ndt/gfs288 Advance Access publication 13 July 2012 NEPhrelogy Dialysis Transplantation

Full Review

Idiopathic membranoproliferative glomerulonephritis: does it exist?

Fernando C. Fervenza<sup>1</sup>, Sanjeev Sethi<sup>1,2</sup> and Richard J. Glassock<sup>2,3</sup>







## Infectious GN

- No RCT in HBV or HIV- associated GN
- Still, arguments supporting the impact of HAART and RAAS Blockade in HIV-associated GN
- HCV- associated GN covered by update of GL on HCV in CKD (publication KI supplement + exec summary in KI on sept 19, 2018)



## Conclusion

- Update of KDIGO GN Guideline underway
- Full update : many new important studies , moving field
- Publication may be expected in late 2019
- Public review : spring /summer 2019 ; register at www.kdigo.org

