HIV AND CHRONIC KIDNEY DISEASE [CKD] PROGRESSION AND END-STAGE RENAL SHORT AND LONG TERM OUTCOMES

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Disclosure of Interests

- Honorariums for Peritoneal dialysis training talks for Adcock Ingram
- Sponsorship for Conferences by Fresenius medical care
Outline: Short and long term outcomes

1. THE SCOPE OF THE HIV PROBLEM
   - Extent of CKD and ESRD in HIV

2. HIVAN and HIVICD

3. HIV and co-infections:
   - Tuberculosis
   - Hep B and C

4. HIV and NCDs
   - Inflammaging
   - Hypertension
   - Diabetes

5. eGFR EQUATIONS AND BIOMARKERS

6. DIALYSIS

7. TRANSPLANTATION

8. CONCLUSIONS AND AREAS WITH GAPS
The extent of HIV worldwide

- **2014** ~ 36.9 million people worldwide were living with HIV
- 2 million (1.9–2.2 million) new infections.
- Sub-Saharan Africa being the **most** affected region, with 25.8 (24–28.7) million people with HIV and ~70% of new infections.  

In 2013, 8 Countries accounted for 57% of the new HIV infections, 5/8where from AFRICA, with all from SSA.
Extent of CKD in HIV worldwide

- The prevalence of CKD in HIV varies geographically & difficult to assess.

- Screening studies utilising proteinuria as an indicator of CKD in HIV revealed prevalence rates of **27% in India**, **12.3% in Iran**, and **5.6% in Brazil**.¹⁻³

  - **Hong Kong:** 16.8%

  - **Africa:** 38% in Nigeria, 33.5% in Zambia, 20% in Uganda, 11.5% in Kenya, and 5.5%–6% in South Africa.⁴⁻⁹

- US: 2038 HIV-infected females: CKD was seen in 7% - 32% & associated with an ↑ rate of death.

- Why the variation?
  - Genetic heterogeneity - likely related to ApoL1, access to health care, initiation of ART, reporting methods, and CKD definition.

References:
8. Han TM et al *Kidney Int.*
How big is the HIV problem in SA?

- SA has reinstated a functional renal registry.
- **9.3%** of 4,571 chronic dialysis patients in the country are HIV-positive.¹

Prognostic factors for CKD & ESRD in HIV

- Black Race [genetic risk APOL-1]
- Low CD4 counts & high viral load.
- Older age
- Hypertension
- Diabetes
- Cardiovascular disease

Jotwani V Am J Kidney Dis 2012

Winston et al Clinical Infectious Diseases 2008

USRDS 2009 – rate of ESRD
The effect of ART on eGFR

- Improvement in renal function has been seen after initiation of ART in patients with HIV-associated CKD. 1, 2, 3, 4


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HIVAN

• HIVAN is caused by direct viral infection of epithelial cells of the glomerulus and the tubular epithelial cells.

• The kidney may also act as an important reservoir for infection despite undetectable viral loads. Can also occur after transplantation.¹

1. Canaud G JASN 2014
PREVALENCE AND RISK OF HIVAN

• 18-fold ↑ risk of developing HIVAN in people of African descent compared with European descent.¹

• There is disparity in its occurrence:
  • US: Reported in 3.5%–10% of HIV-positive individuals.
  • The prevalence in African biopsy series varies greatly ²
    • 5%–27% in Johannesburg
    • 55%–57.3% in Cape Town

Most other biopsy series from Africa have very limited numbers

1 Kopp, et al.. Nat Genet. 2008
2 Diana N , Naiker S Inter Journ of Neph & Renovascular disease 2016
ARE PATTERNS OF HIVAN CHANGING WITH ART?

- With ↑ ART there has been a decline in both the incidence of HIVAN and HIV-associated ESRD.\(^1,2\)
  - 60% reduction in the USRDS\(^3\)

- From biopsy series, there has been a shift from a predominance of HIVAN to an ↑ frequency of non-collapsing FSGS. \(^4\)

- However despite this HIVAN is still the most common renal biopsy finding in HIV positive patients in Cape Town

5. Wearne et al NDT 2012
# Changing renal biopsy and histology in Cape Town

## PRIMARY GNs

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>FSGS</td>
<td>12.8</td>
<td>8.8</td>
<td>11.0</td>
</tr>
<tr>
<td>Crescentic GN</td>
<td>14.9</td>
<td>8.8</td>
<td>10.6</td>
</tr>
<tr>
<td>IgAN</td>
<td>3.7</td>
<td>7.3</td>
<td>6.0</td>
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<td>MCGN</td>
<td>23.4</td>
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<td>MGN</td>
<td>13.3</td>
<td>22.2</td>
<td>9.5</td>
</tr>
<tr>
<td>MCD</td>
<td>5.9</td>
<td>6.1</td>
<td>2.1</td>
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<td>Non-IgA MPGN</td>
<td>16.0</td>
<td>21.5</td>
<td>23.3</td>
</tr>
<tr>
<td>PIGN</td>
<td>10.1</td>
<td>6.9</td>
<td>9.5</td>
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## SECONDARY GNs

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Lupus Nephritis</td>
<td>42.7</td>
<td>36.6</td>
<td>31.2</td>
</tr>
<tr>
<td>HIVAN</td>
<td>14.1</td>
<td>26.7</td>
<td><strong>46.2</strong></td>
</tr>
</tbody>
</table>

(KHRU data unpublished) - Ike Okpechi
Interventions for HIV-associated nephropathy

Ismail Yahaya¹, Olalekan A Uthman², Muhammed Mubashir B Uthman³

- NO Published RCTs or quasi-RCTs were identified
- Various treatment options exist, benefit of each is unknown.
- Include: ART, steroids, angiotensin-converting enzyme inhibitors (ACEI) and cyclosporin [Children] (Ingulli 1991, Khan 2006)
- Observational studies identified steroids and ACEI were beneficial in improving the kidney functions of patients.
THE USE OF CORTICOSTEROIDS TO TREAT HIV-ASSOCIATED NEPHROPATHY IN PATIENTS ON ANTIRETROVIRAL THERAPY: RCT
Wearne et al 2017 * Abstract at WCN - unpublished

- Deaths = 4 patients: sepsis: > 6/12 from completing steroids
- Insignificant improvement in proteinuria. [p=0.3]
- Repeat Renal Bx 21/31
- ↓ fibrosis in the steroid group.
  66.7 % vs 37.5% [p=0.07] & a decline in the number of plasma cells in the interstitium in the steroid group 50% vs 25.2 percent. [p=0.08]
Immune complexes in HIV

• “HIVICK/ HIVICD” is a term used to describe a group of disparate immune-complex related kidney diseases.

• The term includes any GN in a association with HIV.1-3

• Szczech et al: HIVICD occurs predominately in European and Asians 4

• Foy et al5: common in African American and Wearne et al: Black Africans in SA

• ESRD less common than HIVAN6

3. Ross, Ki 2014
The mechanisms by which HIV contributes to immune complex kidney disease are not clear.\(^1\)

Patients with HIV infection exhibit unique immunologic characteristics including immunodeficiency and dysregulation of immunoglobulin synthetic responses and T-Cell function which can result in glomerular IC deposition.\(^2\)

Anti-HIV antibodies may form immune complexes that promote glomerulosclerosis in some patients.\(^2\)

1. Mallipattu et al KI 2014
Optimal treatment of Immune complex GNs in HIV

• Remains unanswered

• ART seems appropriate given the benefits seen in HIV-associated CKD.

• Szczech et al revealed no benefit with cART in patients with HIVICD.¹

• 2 South African studies revealed improved renal function with cART in patients with HIVICD.²,³

• Booth et al reported a significant reduction in proteinuria and improvement in eGFR in patients with HIVICD initiated on cART.⁴

1 Szczech LA, et al Kidney Int. 2004
Heterogeneity of HIVICD makes comparisons between groups and outcomes tricky

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Tuberculosis ...

- TB is a **new** global health emergency [WHO global report 2016]
- \( \sim 10.4 \text{ million} \) new cases annually. **1.8 million** dying annually.
- **73% of adult TB cases are HIV co-infected in SA** (SA DoH)
- TB is the most common opportunistic infection.
- The mean annual risk of an HIV-positive patient to develop TB is 10%. \(^1\)
- In Cape Town the current annual risk in HIV-positive patients with CD4 counts (<250) is **30%**. \(^2\)

2. Lawn et al JID 2011
HIV & TB – coinfection: renal involvement: an entity not to be overlooked.

• Renal involvement can be part of disseminated infection [GIN] or localised genitourinary disease.

• The incidence of renal involvement was high in 2 autopsy studies
  • India: 17 of 35 kidneys from patients who died of AIDS had renal TB [1]
  • Mexico: M. tuberculosis was identified in 19 of 44/370[2] [12%] of all HIV positive renal biopsies had granulomatous interstitial nephritis.[3]
  ❑ Associated with low CD4 counts
  ❑ Poorly formed granulomas
  ❑ TB GIN - IRIS was likely in 6 cases

• ? Role for corticosteroids in selected cases

↑ morbidity and mortality with HIV/HBV Co-infection

- Similar transmission factors
- Less chance to clear acute HBV
- ↑ HBV replication & rates of reactivation
- Progression to fibrosis and cirrhosis is 5x faster with higher liver related deaths
- HCC - occurs at a younger age and is more aggressive.
- ART- related immune reconstitution hepatitis

6 million HIV/HBV co-infected infected individuals

36 million HIV

350 - 400 million HBV

Hepatitis B status


No. of patients with data = 5126
Therapeutic Options for Hepatitis B – HIV Coinfection

- The management of HBV- HIV coinfection remains a challenge especially when there is renal impairment:

  - **HIV/HBV Co-infection**: Dual viral suppression

  - Tenofovir plus lamivudine or emtricitabine with a third agent should be first line therapy for almost all HIV-infected HBs-Ag patients.

  - Entecavir

  - **Tenofovir Alafenamide**: TAF registered by FDA in November 2016

  - Standard Interferon & Pegylated Interferon
Renal Laboratory Parameters in CHB Patients Treated with TAF vs TDF

- Smaller eGFR declines with TAF vs TDF in patients with older age and those with comorbid conditions (HTN/DM/CVD)

**Age**

<table>
<thead>
<tr>
<th>Age &lt;50 y</th>
<th>Age ≥50 y</th>
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<tbody>
<tr>
<td>n=642</td>
<td>n=294</td>
</tr>
<tr>
<td>-0.4</td>
<td>-3.4</td>
</tr>
<tr>
<td>*P&lt;0.001</td>
<td>*P=0.01</td>
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</table>

**Comorbid Conditions**

<table>
<thead>
<tr>
<th>No HTN/DM/CVD</th>
<th>HTN/DM/CVD</th>
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<tbody>
<tr>
<td>n=691</td>
<td>n=136</td>
</tr>
<tr>
<td>-0.6</td>
<td>-4.8</td>
</tr>
<tr>
<td>*P&lt;0.001</td>
<td>*P=0.003</td>
</tr>
</tbody>
</table>

TAF treatment resulted in smaller declines in eGFR\textsubscript{CG} and fewer patients showed CKD stage worsening compared with TDF treatment

*p-values from Wilcoxon 2-sample test; \(^1\)Hypertension (HTN), diabetes mellitus (DM), and cardiovascular disease (CVD) determined by medical history or concomitant medication.

Agarwal, AASLD 2016, Poster 1844
Prevention: HBV Vaccination

• Ideally all individuals should be vaccinated
• **High risk groups must be vaccinated**
  - Health-care workers
  - All laboratory staff working with clinical specimens
  - Policemen, firemen and members of the armed forces
  - Persons with endstage renal disease requiring dialysis

**Dependent on ability to:**

• Screen high risk individuals: HBsAg and anti-HBs
• Administer HBV Vaccine

**At all levels of care**

- Persons with chronic liver disease
- Residents and staff of facilities for the developmentally disabled
- Patients receiving frequent transfusions of blood or blood components
- Transplant candidates before transplantation
Hepatitis C status

No. of patients with data = 4702


No. of patients with data = 4702
Rx of Hepatitis C is challenging in CKD

**Genotype 1 and 4**

- Requires a **Ribaviron based regimen**:
  - Causes haemolytic anaemia in CKD

**RUBY-1**: used a ↓ dose of Ribaviron

- Good viral response without significant haemolytic anaemia.

**C-SURFER** = Ribaviron free

CKD stage 4 & 5

- Grazoprevir GZR + EBR Elbasvir [HCV G1]: good outcomes “CURE”

- However not widely available nor affordable: **limited to G1 and G4**

**Genotype 2,3,5,6**

- Need a Sofosbuvir based regimen:
  - Sofosbuvir and its metabolite are renal
  - Ly eliminated & ↑ in renal impairment: & associated with worsening of renal function

- Can use in mild to moderate renal impairment (eGFR >30 ml/min),
  - CI < 30ml/min

- Recent study of 50 patients with eGFR<30ml/min and sofosbuvir 400mg dosed every alternate day, yielded an SVR of 86%¹

1. Pockros PJ, et al. AASLD 2015, San Francisco. #1039
2. Roth D, et al (the C-SURFER study):. *Lancet* 2015;
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↓ HIVAN

CKD: as living longer and ↑ risk of developing diabetes and hypertension

Compounded by accelerated aging in HIV

↑ “Inflammaging”
• ART does not fully restore health.

• Inflammation and immunosenescence have been implicated in premature aging despite viral suppression.

• Premature “aging.” reflects a complex condition reflecting ↑ burden of comorbid diseases, higher prevalence of traditional behavioral risk factors (e.g., substance abuse), ART toxicity, and chronic inflammation.
Background Factors
- Lifestyle factors
- Aging
- Urbanization
- Social and economic determinants
- Genetics and Epigenetics

Kidney Disease

HIV-AIDS

Drugs for OIs

ART

Complications
- Neurologic
- Metabolic
- Cardiovascular
- Others

Other NCDS
- DM, HTN and CVD

Abbreviations: ART-Antiretroviral Therapy; CVD-Cardiovascular Disease; DM-Diabetes Mellitus; HTN-Hypertension; OIs – Opportunistic Infections
Patients with both HIV and DM were at increased risk of progressive CKD even after adjusting for traditional CKD risk factors.

Raj Medapalli, et al J Acquired Imm Defic Syndrome 2012
PREVALENCE OF DIABETES IN CAPE TOWN
2009

Average Age = 32 years

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>NGT (%)</th>
<th>Pre-DM (%)</th>
<th>DM (%)</th>
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<tr>
<td>Naïve</td>
<td>406</td>
<td>317(78.1)</td>
<td>75(18.5)</td>
<td>14(3.4)</td>
</tr>
<tr>
<td>ART</td>
<td>443</td>
<td>329(74.3)</td>
<td>104(23.5)</td>
<td>10(2.2)</td>
</tr>
</tbody>
</table>

p = 0.173

Dave et al, J Acquir Immune Defic Syndr 2011;57:284–289
Hypertension in HIV

- Chronic HIV and ART are associated with increased risk of developing hypertension.\(^1\)

- In studies of HIV-positive patients from high-income countries, hypertension prevalence ranges from 13 to 34%.\(^2,3\)

- However, data from low- and middle-income countries remain sparse.

62% were non-dippers

68% had hsCRP >3mg/L

Central aortic BP higher in HIV cohort vs. normal population
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   RISK SCORES AND AKI

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eGFR prediction formulas in HIV

- CKD-EPI equation reported to be more accurate than the MDRD equation overall and across most subgroups
- No eGFR prediction formula has been specifically validated in the HIV-infected population.
- Cystatin C as an alternative marker of kidney function in HIV\(^1,2\):
  - Infected Individuals: detection of worse kidney function when measured by cystatin C compared with HIV-negative controls

Development and Validation of Risk Scores for CKD in HIV infection

Mocroft et al: PLOS - 2015

NNH among those at low (risk score < 0), medium (risk score 0–4), or high risk (risk score 5) of CKD.

Conclusions: The risk score for CKD has direct clinical relevance to weigh the benefits of certain ART against the risk of CKD and to identify those at greatest risk of CKD.
Long-term clinical consequences of acute kidney injury in the HIV-infected

Andy L. Choi¹ ², Yongmei Li¹, Chirag Parikh³, Paul A. Volberding¹ and Michael G. Shlipak¹ ²

Figure 1 | Age-standardized event rates 90 days after discharge by stage of in-hospital acute kidney injury. Note that y axis is on log₂ scale.
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Dialysis and HIV

• No evidence to suggest superiority of one dialysis modality over another.¹

• Survival rates on dialysis are comparable to HIV-negative patients.

• HIV-positive patients do not require isolation or dedicated machines.²

• Factors associated with improved survival of HIV-positive patients on dialysis: younger age, higher CD4 counts, ART, and initiation of RRT at an earlier stage of HIV infection.¹³⁴

• Retrospective data demonstrate significant ↑ in graft thrombosis and infections, which is not seen in patients with native AVF
  — Thus, AVF are the access of choice, and early creation of AVF is recommended ⁵⁶

Morbidity and mortality of black HIV-positive patients with end-stage kidney disease receiving chronic haemodialysis in South Africa

J Fabian,1,2 MD, MMed; H A Maher,1 Registered Nurse; C Clark,3 M Tech Clinical Technology, BSc, PhD; S Naicker,4 MD, PhD; P Becker,4 PhD; W D F Venter,5 MD, MMed

- Retrospective study: compared the incidences of vascular and infectious morbidity and mortality in black HIV-positive patients receiving HD cw HIV-negative patients

- HIV POSITIVE GROUP
  - ↑ Incidence of TB
  - ↑ Hospital admissions for vascular access related infections
  - Significantly lower albumin (p<0.05) and Hb (p<0.01), w/out impacting on mortality.

S Afr Med J 2015
PD program in Africa: challenges
Peritoneal Dialysis and HIV

- Variable rates of peritonitis reported. Some studies: increased incidence of pseudomonas and fungal peritonitis in HIV-positive PD patients.\(^1,2\)

- Other studies show comparable rates with HIV-negative PD patients.\(^3,4\)

- HIV survives in peritoneal dialysis drainage fluid and dry tubing and thus should be disposed of correctly.\(^5,6\)

South African PD study

Ndlovu et al evaluated the effects of HIV on ART on peritonitis rates & technique failure

- HIV: significantly ↑ rate of peritonitis
  - 1.86 vs. 0.76 episodes/person-years; HR: 2.41; 1.69–3.45, P < 0.001).

- ↑ peritonitis rate when CD4 count < 200

- HIV associated with increased peritonitis relapse

- No difference in Catheter failure rates between the groups

Ndlovu et al BMC Nephrology 2017
RestricUon of dialysis in state sector in SSA

• Chronic dialysis programs are not publicly funded in most SSA countries.

• In South Africa, there is government funding, but only a limited number of patients are accepted/eligible.¹

• HIV-infected patients only eligible if CD4 count <200, with a suppressed viral load, and if space is available in the dialysis center.

• Peritoneal dialysis has largely been underutilized in most resource-limited settings.

1. Swanepeol CS et al Nature’s review Neph 2013
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RENAL TRANSPLANTATION IN HIV

Patient and Graft survival in the NIH Multicentre Trial

Stock et al:

150 HIV positive recipients from negative donors

Renal transplantation in HIV

- Muller et al\textsuperscript{2} : Outcomes of 27 HIV-positive to HIV-positive kidney transplants

- Pharmacological interactions occur between antiretroviral agents and transplant medications.

- Increased risk of rejection


1 Year Graft survival: 93%
5 Year Graft survival: 84%

1 Year Patient survival: 84%
5 Year Patient survival: 74%
Where are we?

- 43 Recipients
  - 4 new patients transplanted 2016
  - 2 new patients transplanted 2017

- 24 Deceased Donors

Muller E, et al  *Unpublished data*
2017
Patient outcomes

Muller E, et al. Unpublished data 2017

- Alive and well: 29
- Alive and on dialysis: 6
- Died: 8
**No** allograft showed HIVAN at the time of donor transplantation.

Features of HIVAN were seen in 7/27 patients [26%]

Histological findings included:
- Podocyte hypertrophy
- Collapsing FSGS
- Fetal glomeruli
- Microcyst formation

Mean time to HIVAN = 2 yrs 7 months  
Minimum = 9 months  
Maximum = 5.6 years
HIV DIALYSIS VS TRANSPLANTATION

- 32 HIV positive patients: 65 transplanted, 67 remained on dialysis

1 Mysore S et al. Plenary session American Transplantation Congress
HIV is currently the most common cause of mortality in SA.

The high rate of HIV infection adds complexity to a health system already overwhelmed by chronic kidney disease [CKD].
Screening and early diagnosis of HIV CKD

- HIV-positive individuals present with advanced stages of CKD in clinical practice in Africa.

- Screening for early diagnosis of kidney disease is critical at HIV detection as well as concurrent screening for diabetes and hypertension with ongoing surveillance. 1,2

  - Those at high risk for kidney disease should be identified (i.e., black race, CD4+ count < 200 cells/mm3, HIV RNA levels 14000 copies/mL, diabetes, hypertension, or coinfection)

- Screening strategies: blood pressure, kidney function (serum creatinine; eGFR), and (proteinuria via spot urine protein: creatinine ratios; hematuria).

- Timely referral to nephrology services where possible.

So.... There are challenges
Challenges

• With the massive scale-up of access to antiretroviral therapy (ART), HIV has become a chronic disease with new challenges – Particularly in resource-limited countries

• There is collision of the epidemics of hypertension, DM, and an aging HIV-infected population living longer on ART

• Substantial impact on the mortality and morbidity from CKD is inevitable unless preventive and early detection efforts are implemented
Where are the gaps

- Renal registries to guide us for true prevalence
- Steroids in HIVAN; still not answered
- ICGN – best treatment strategies
- Renal TB...another epidemic...management strategies to prevent progression to CKD
- eGFR formula validation in HIV & biomarkers
- Validation of Risk scores; for ART initiation and CKD
- Old studies for Dialysis and HIV
- Renal transplants & risk of HIVAN recurrence & rejection
- Incorporating screening for hypertension, DM, and renal function
- Managing point-of-care urea and creatinine tests to screen for kidney injury in primary care settings
Special Thanks
Charles Swanepoel
Ike Okpechi

ASSISTANCE WITH SLIDES

Mark Sonderup
Wendy Spearman
Phindile Gina
Razeen Davids