

INADEQUACY OF CLINICAL AND IMMUNOLOGIC MONITORING TO IDENTIFY VIROLOGIC FAILURE; THE UGANDA EXPERIENCE

Basenero A¹, Castelnuovo B¹, Birabwa E¹, John L¹, MacAdam K¹, Schlech W², Kambugu A¹

Presenter Dr. Apollo Basenero

¹ Infectious Diseases Institute (IDI), Kampala, Uganda

² Dalhousie University Faculty of medicine Canada

Background

WHO recommends monitoring antiretroviral therapy (ART) by clinical criteria and where feasible by immunologic monitoring since HIV-RNA measurement is costly

Study site



Infectious Diseases Institute (IDI) HIV/AIDS care, Research and Training Centre of Excellence

The IDI clinic

- **Free HIV/AIDS care including laboratory testing, opportunistic infections prophylaxis, and ART provision since September 2004**
- **By June 2007 over 18,000 adult patients were registered at IDI**

ART at the IDI

1st line ART

- **d4t, 3TC, NVP (Multi country Access Program/Global Fund)**
- **AZT, 3TC and EFV (Presidential Emergency Plan For AIDS Relief)**

2nd line

- **d4T or AZT, ddl, LVP/r**

ART monitoring at IDI

- ART is monitored by clinical and immunologic responses
- CD4+ count measurement every 6 months
- VL not routinely performed (50\$)

The “Switch meeting” is a weekly meeting set up in August 2005 to discuss patients that are thought to be failing ART

The switch meeting

- **Attended by doctors, nurses, counselors and pharmacists**
- **A consensus is reached on whether to do a viral load (VL) or employ other interventions**
- **By IDI policy, change from 1st line to 2nd line ART must be approved by this meeting**

Objectives

To evaluate the use of a consensus meeting of care providers in a large urban HIV clinic to determine the need to switch to 2nd line treatment in patients suspected to be failing their 1st line regimen

Methods

Suspected ART failing cases are classified into 3 categories:

- 1) Clearly failing**
- 2) Patients with poor adherence**
- 3) Inconclusive**

Methods

Immunological failure defined according to the WHO guidelines

Adherence measured through self report (visual analog scale) and pill count

Category 1

Clearly failing:

- Proven clinical, immunologic and/or virologic failure
- Counseling sessions revealed good adherence (>95 %)

Switch to 2nd line is recommended, *post hoc* VL done at switching therapy

Category 2

Patients with poor adherence:

- Clinical and/or immunologic failure
- Counseling reveals missing ART doses on several occasions (<95%).

Adherence counseling is emphasized monthly and CD4 count repeated after 3 or 6 months

Category 3

Inconclusive:

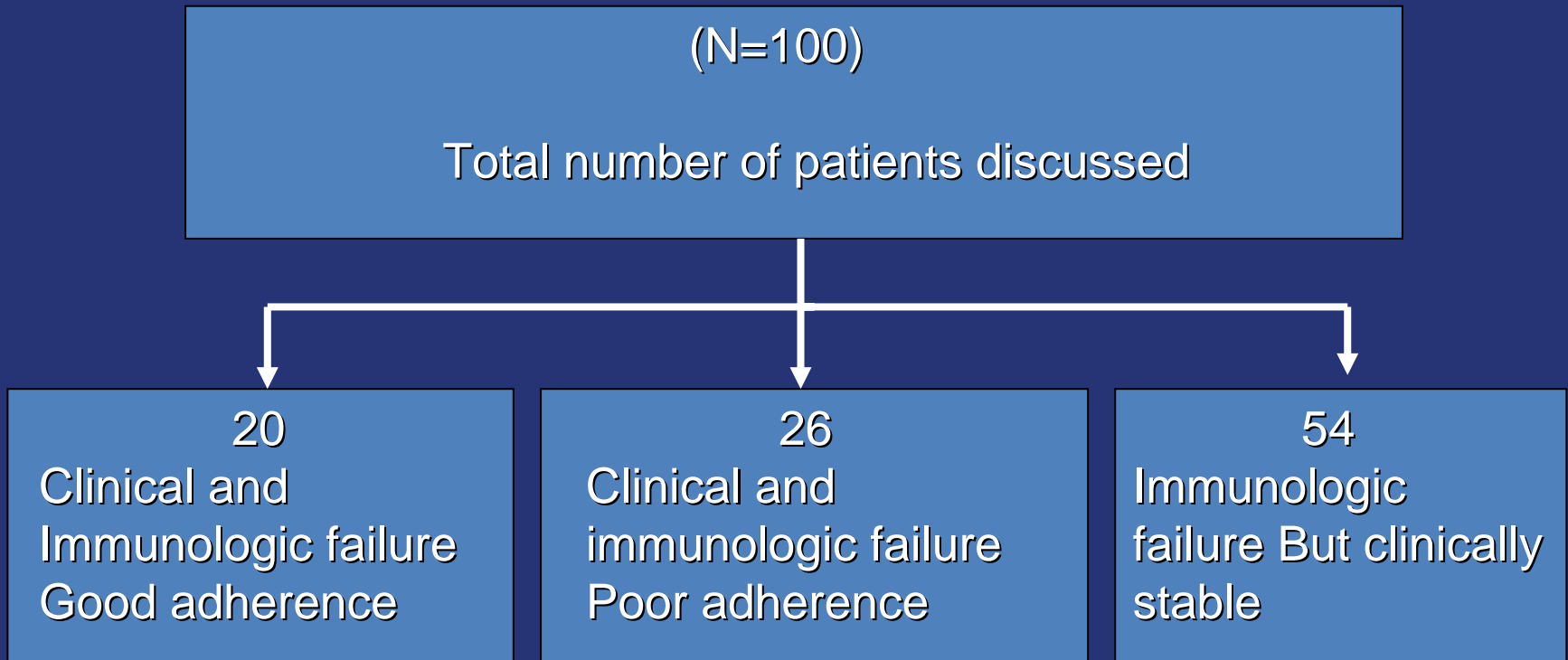
- Immunologic failure BUT clinically stable and with good adherence

VL is requested

Results

- **4200 started ART at IDI since September 2004**
- **73% on NVP, 3TC and d4t (MAP)**
- **27% on AZT, 3TC and EFV (PEPFAR)**
- **67% female**
- **Median age 37.5 yrs**
- **Median baseline CD4+ count 104 cell/ μ L (1-516)**

Results



Category 1

Clinical and immunologic failure with good adherence (20)

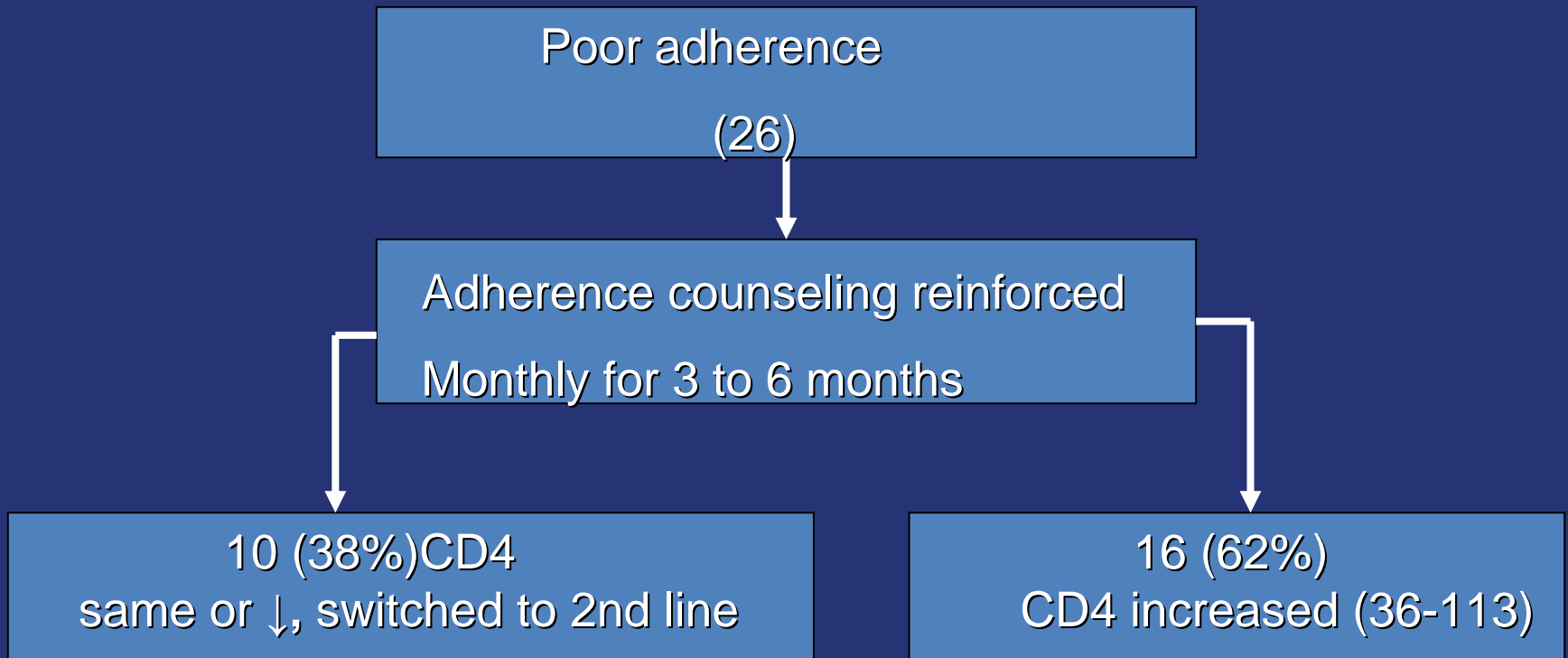


All switched to 2nd line

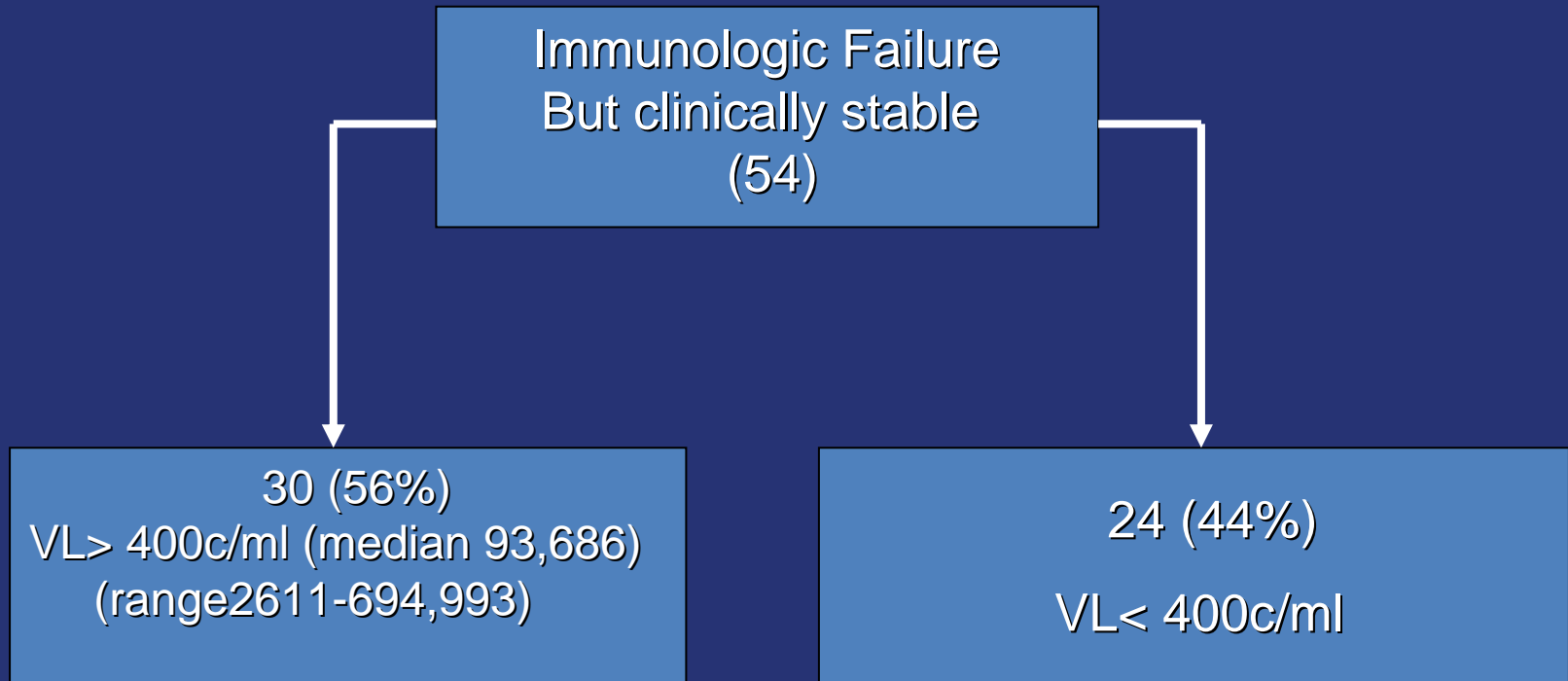


15/15 who had post hoc VL > 400 c/ml (detectable)

Category 2



Category 3



Conclusions

- **Virological failure can be detected in presence of immunological and clinical failure by a consensus of trained clinicians**
- **In patients with poor adherence, interventions such as intensive counseling are recommended before switching to 2nd line therapy or performing VL measurement**

Conclusions

- Immunological failure alone predicted virological failure in only 56% and may lead to unnecessary ART change in up to 44% of patients
- This suggests that VL testing should be an essential part of monitoring in RLS and resources should be made available to make this possible.

Acknowledgements

- **Our Friends, the patients at IDI**
- **Switch meeting team**
- **IDI staff**
- **Mulago Hospital and Complex**