

A case series of ART-associated gynaecomastia reported to the National HIV & TB Healthcare Workers (HCW) hotline

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MEDICINES
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Introduction

- Gynaecomastia: benign proliferation of glandular breast tissue in males
- Drugs cause 25% of gynaecomastia cases in adults¹
- Other causes- endocrine disorders, HIV, renal disease, aging, puberty and hyperthyroidism
- ART-associated gynaecomastia:
 - Estimated prevalence of 2%^{2,3}
 - Associated with efavirenz, stavudine and didanosine^{2,3}
- Limited data in patients from Sub-Saharan Africa

[1] Carlos et al. Sao Paulo Med J. 2012; 130(3):189-197. [2] Mira et al. Antiviral Therapy .2004; 9:511-514.

[3]Biglia et al. Clin Infect Dis . 2004; 39:1514-1519

Study Objectives

To describe:

- characteristics of patients with suspected gynaecomastia
- clinical management
- patient outcomes
- time to improvement

Methods

- Suspected gynaecomastia cases reported to the National HIV & TB HCW hotline between 1 June 2013 and 31 July 2014 were included
- Initial telephonic follow-up at one month
- Additional follow-up after next visit if no resolution
- Improvement defined as reduction in breast pain and/or breast size

Results

- 51 suspected gynaecomastia cases reported to the HIV & TB HCW hotline
- 11% of 469 ADR queries received by the hotline between June 2013 and July 2014

Results

Table 1: Patient characteristics of suspected gynaecomastia cases

Patient characteristic	N (%) (n=51)
Age, mean \pm sd	34 years \pm 12
Age category	
Adolescents (10-17 years)	7 (14%)
Adult (>18 years)	44 (86%)
Baseline CD4 count (mm ³), mean \pm sd	188 \pm 94
Suppressed viral load (VL<50)	26 (51%)
Type of gynaecomastia	
Unilateral	16 (31%)
Bilateral	29 (57%)
Breast pain present	10 (20%)
Gynaecomastia onset, median months after ART initiation [IQR]	15 months [6-41]

Results

Table 2: ART regimens and additional drug suspects

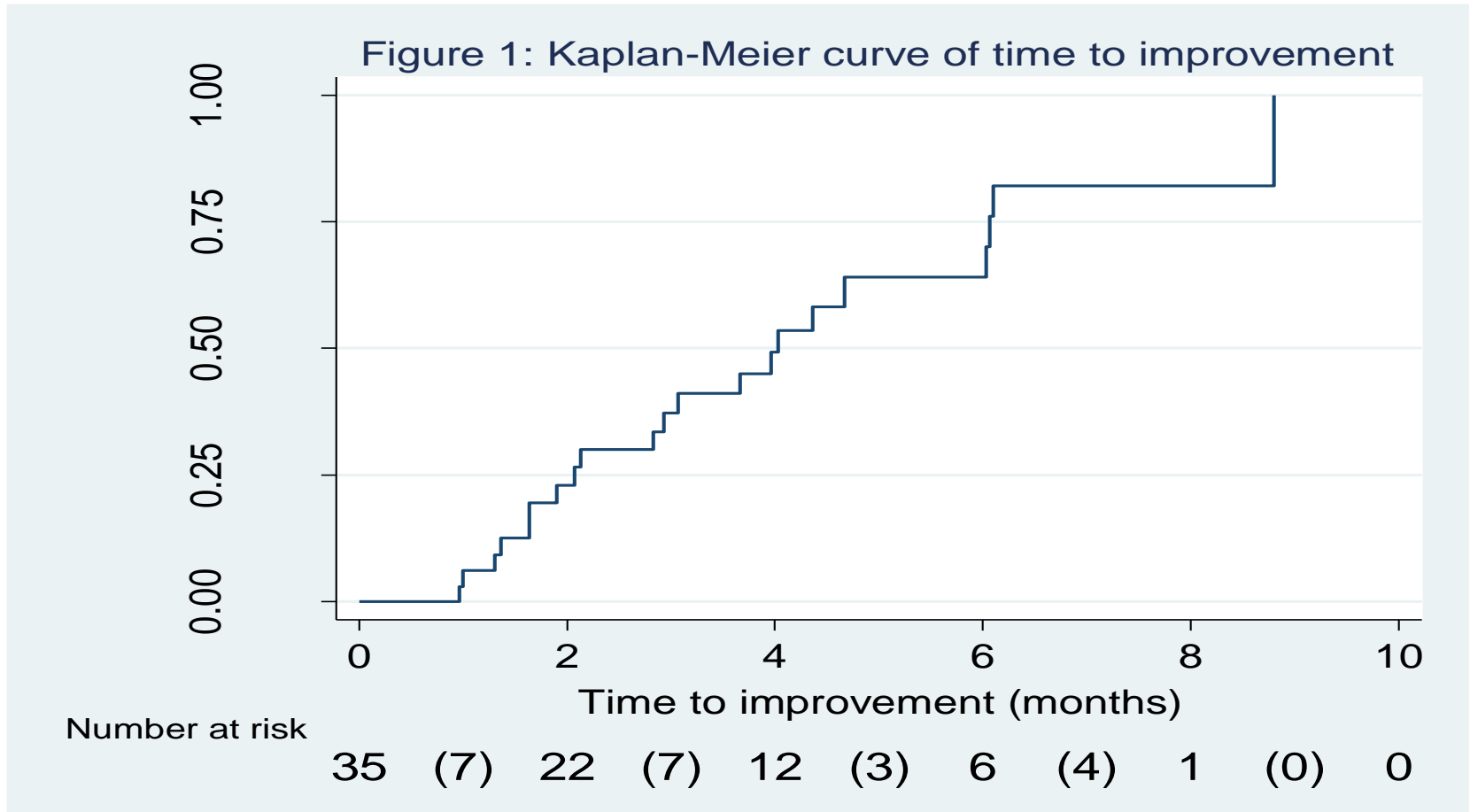
ART regimen	N (%) (n=51)
TDF + 3TC/FTC + EFV	40 (78%)
D4T + 3TC + EFV	5 (10%)
ABC + 3TC + EFV	4 (8%)
AZT + 3TC + EFV	1 (2%)
Additional drug suspects	
Yes	16 (31%)
Drug suspects*	INH (12), D4T (5), amlodipine (1)

*Some had > 1 suspect drug

Results

- 35/51 (68%) followed up, median 4 months , IQR[1-6]
- At follow-up, testosterone measured in 25/35 (71%):
 - 19 (76%) - normal
 - 2 (8%) - low
- Efavirenz switched in 29 (82%) cases of which:
 - 16 cases had normal testosterone levels
 - 27 switched to nevirapine and 2 cases to lopinavir/ritonavir
- Overall patient outcomes in 35 patients with follow-up:
 - Resolution- 7 (20%)
 - Improvement- 14 (40%)
 - Unchanged- 3 (8%)
 - Unknown- 11 (31%)

Results



Median time to improvement- 3 months, IQR [2-4] , range (1-8 months)

Discussion and Conclusion

- Efavirenz-associated gynaecomastia was frequently reported
- Most cases had prolonged efavirenz exposure and normal testosterone⁴
- 7 adolescents cases of suspected gynaecomastia- scarce data
- Overall patient outcomes were favourable
- Prospective studies are needed to determine:
 - Incidence and risk factors
 - Proportion associated with hypogonadism
 - usefulness of testosterone quantification
 - Optimal management- continue/stop efavirenz?
 - Incidence and optimal management of efavirenz-associated gynaecomastia in puberty

Acknowledgements

- The National HIV & TB HCW hotline pharmacists at the Medicines Information Centre
- This research has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC) under terms of Cooperative Agreement Number GGH000371. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the CDC