EVALUATION OF DIFFERENT ADVERSE DRUG REACTIONS (ADR's) AND THEIR GRADE AMONG HIV PATIENTS NEWLY STARTED/SUBSTITUTED ON COMBINED TENOFOVIR/LAMIVUDINE/DOLUTEGRAVIR (TDF/3TC/DTG) IN THE TWO MAJOR HOSPITALS IN ONITSHA METROPOLIS, ANAMBRA STATE, NIGERIA.

Okoro K[1], Okoro T[2]

- [1]Nnamdi Azikiwe University Teaching Hospital, (NAUTH) Nnewi, Anambra State, Nigeria. (kenpx4u@gmail.com, +2348067301138, +2348166346083)
- [2] Federal Medical Centre (FMC) Owerri, Imo State, Nigeria.

BACKGROUND

- Overtime there has been modifications in the WHO guideline for the management of HIV infection especially since the introduction of HAART (Highly Active Anti-Retroviral Therapy).
- In Nigeria, more than 70% of HIV patients deemed clinically qualified have been transitioned to the dolutegravir regimen in combination with tenofovir and lamivudine from the second half of 2018 till date.
- Newly diagnosed HIV patients prequalified after all the recommended test and screenings are being started on dolutegravir based regimen in combination with tenofovir and lamivudine.

OBJECTIVE

- This study comparatively aim to evaluate the different Adverse Drug Reactions (ADR's) and their severity among adult HIV patients on dolutegravir in combination with tenofovir and lamivudine as (TDF/3TC/DTG).

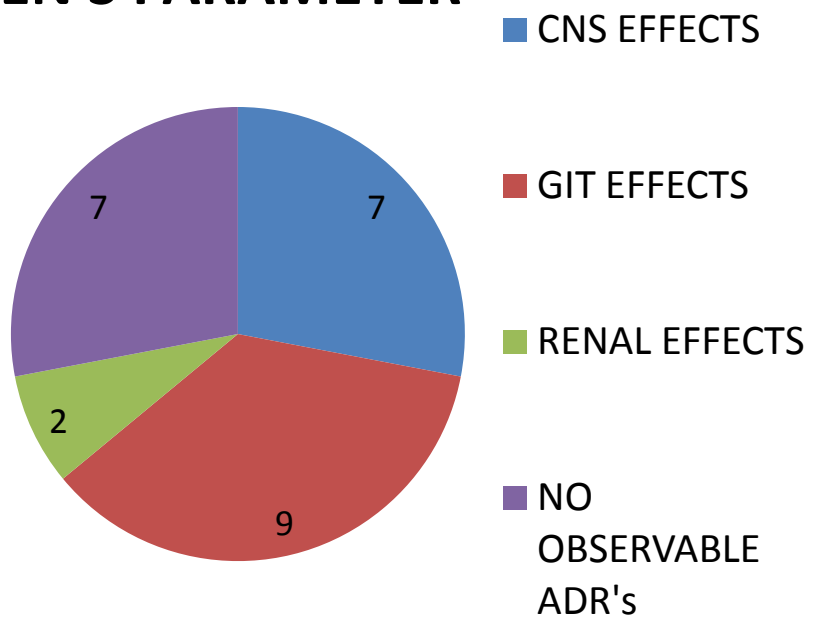
METHODS

- Randomization Selection Study(RSS), giving adult patients transitioned/substituted and newly started on 50mg dolutegravir based regimen in combination with tenofovir and lamivudine as (TDF/3TC/DTG) were conducted.
- 50 adult patients comprising 25 men and 25 menopausal women from two major hospitals (ST. CHARLES BORROMEO HOSPITAL, ONITSHA AND HOLY ROSARY HOSPITAL, ONITSHA) both in Anambra State of Nigeria) were sampled and used.

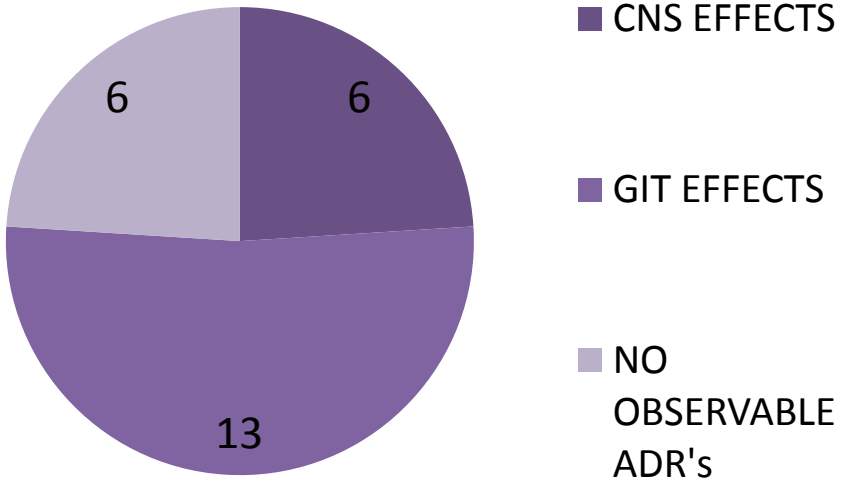
Data Source
Data were drawn from the two major hospitals at Onitsha metropolis of Nigeria with informed consent.

Study Population and duration
Nigerian patients comprising 25 adult men of 30 years + and 25 menopausal adult women of 50 years + between January to April 2019.

MEN'S PARAMETER



WOMEN'S PARAMETER



Statistical Analysis

1. Analysis of ADR's and classified grades among adult male patients.
2. Analysis of ADR's and classified grades among menopausal adult female patients.

RESULTS

TABLE 1.0

MEN'S PARAMETERS

Observable ADR's/Non-observable ADR's

DIFFERENT ADR's AT DIFFERENT BODY SITES	NUMBER OF ADULT MALE PATIENTS	PERCENTAGE REPRESENTATION (%)
CNS EFFECTS (Insomnia, Headache, fatique, dizziness)	7	28
GIT EFFECTS (increased appetite, diarrhea, nausea and vomiting)	9	36
RENAL EFFECTS (frequent urination – dysuria)	2	8
NO OBSERVABLE ADR'S	7	28

TABLE 1.1

WOMEN'S PARAMETERS

Observable ADR's/Non-observable ADR's

A BAR-CHART OF PERCENTAGE DISTRIBUTION OF ADR's AMONG MEN AND WOMEN (PPP – PERCENTAGE PATIENTS POPULATION)

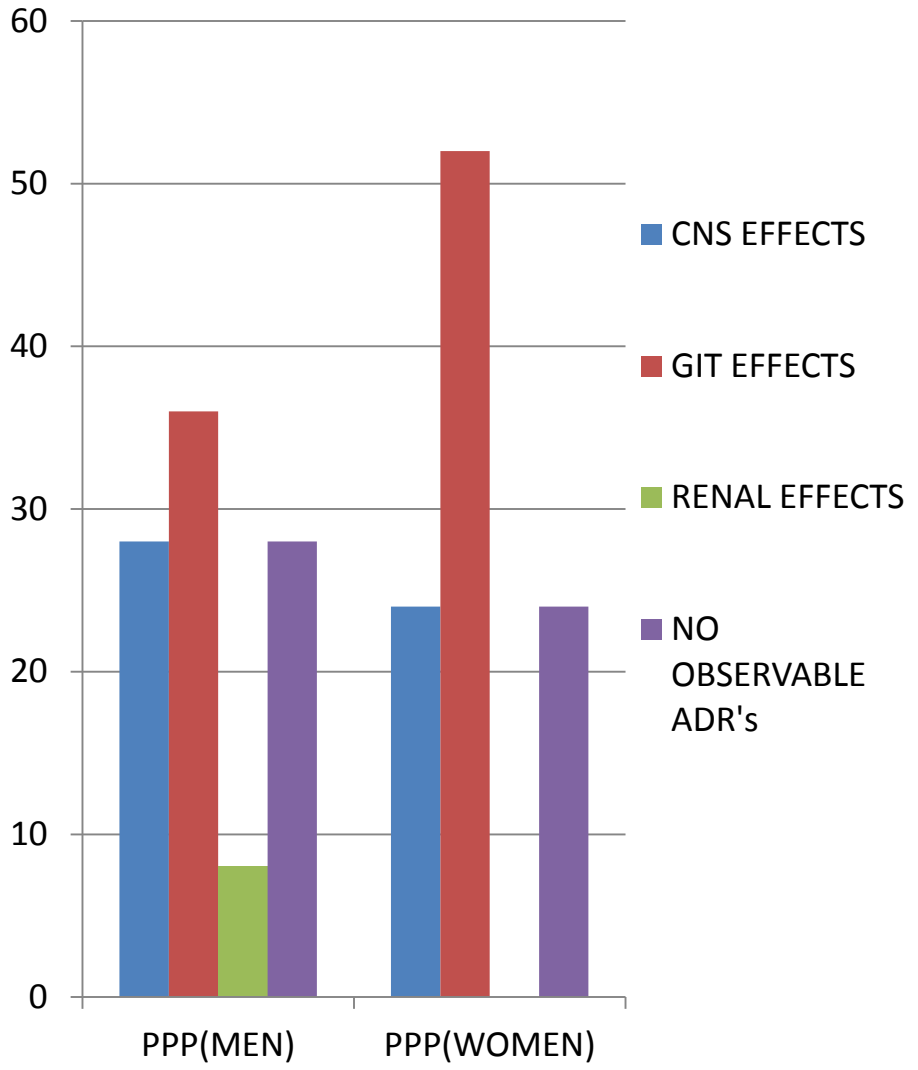


TABLE 1.1
WOMEN'S PARAMETERS
Observable ADR's/Non-observable ADR's

DIFFERENT ADR's AT DIFFERENT BODY SITES	NUMBER OF ADULT MALE PATIENTS	PERCENTAGE REPRESENTATION (%)
CNS EFFECTS (Insomnia, Headache, fatique, dizziness)	6	24
GIT EFFECTS (increased appetite, diarrhea, nausea and vomiting)	13	52
NO OBSERVABLE ADR'S	7	28

ADR's Grading

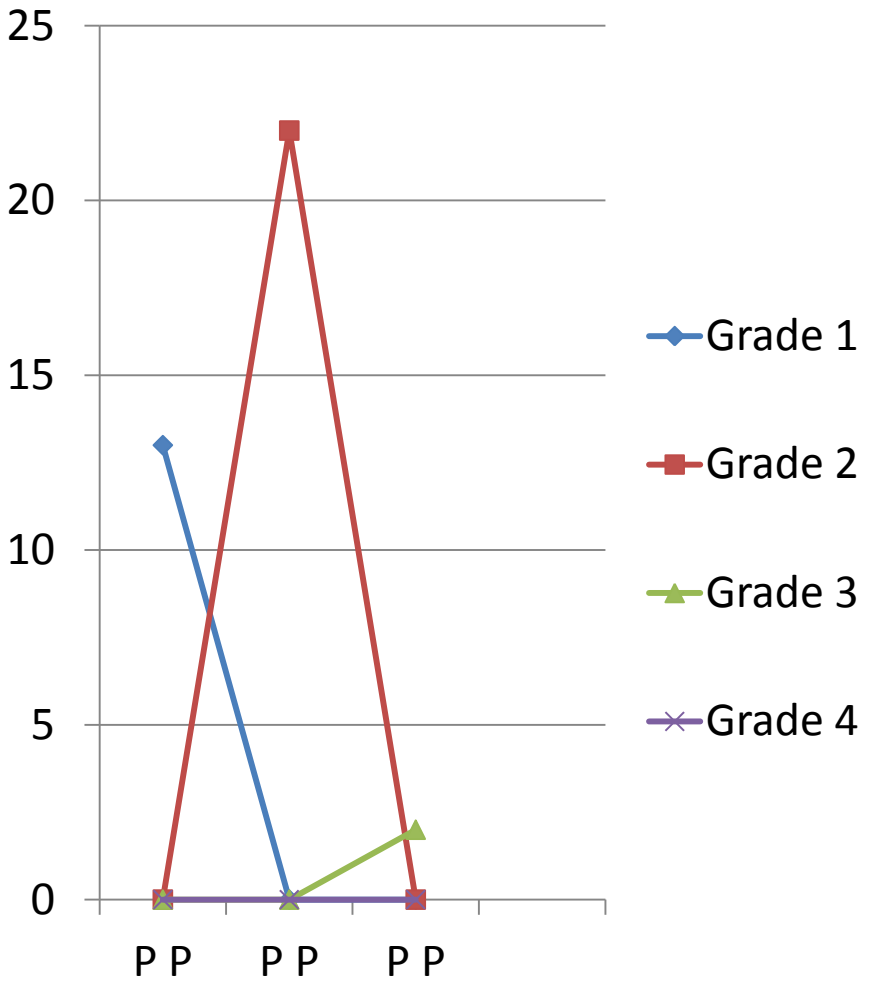
Grade 1 – Mild Effect
Grade 2 – Moderate Effect
Grade 3 – Severe Effect
Grade 4 – Life threatening

Total Number Distribution of ADR's grades for both randomized selected adult males and females.

Table 1.2

Different ADR's at different body sites	Number of patients on grade 1	Number of patients on grade 2	Number of patients on grade 3	Number of patients on grade 4

GRAPHICAL REPRESENTATION OF ADR's GRADES AGAINST PATIENTS POPULATION. (PP - PATIENTS POPULATION)



CNS EFFECTS	13	_	_	_
GIT EFFECTS	_	22	_	_
RENALEFFECTS (FREQUENT URINATION)	_	_	2	_

Table 1.3
Total Percentage Distribution of ADR's grades for both randomized selected adult men and women.

DIFFERENT ADR's AT DIFFERENT BODY SITES	PERCENTAGE OF PATIENT ON GRADE 1 (%)	PERCENTAGE OF PATIENT ON GRADE 2 (%)	PERCENTAGE OF PATIENT ON GRADE 3 (%)	PERCENTAGE OF PATIENT ON GRADE 4 (%)
CNS EFFECTS	**26**	-	-	-
GIT EFFECTS	-	**44**	-	-
RENAL EFFECTS	-	-	**4**	-

CONCLUSION

- Dolutegravir on a combination regimen of TDF/3TC/DTG has more tolerable and highly specific ADR's.
- The general ADR's observed with dolutegravir in TDF/3TC/DTG is minimal (with proportionate increase in GIT effects) and well separated.
- ADR's in Dolutegravir as TDF/3TC/DTG is better managed with positive outcomes, hence high sensitivity, efficacy and safety as a first line regimen, thereby ensuring improved quality of life.

REFERENCES

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