Background

Dolutegravir (DTG) based regimen was recommended as an alternative in the Nigeria National Guideline for HIV Prevention, Treatment and Care (2016). In July 2017 a 12-month follow up study on early adopter acceptability commenced at 3 high volume Centers of Excellence. Subjects were surveyed on questions regarding DTG acceptability, including side effects at 2 months, 6 months, 12 months, and 18 months post DTG initiation. All survey time points study subjects frequently self-reported an ‘increase in appetite’ at a rate higher than any other listed side effect: 2 months – 20%, 6 months – 19%, 12 months – 15%.

We extracted weight and height information on the study patients to analyze weight and body mass index (BMI) changes that occurred after DTG initiation up to 24 months post DTG initiation. The objectives were to: 1. Describe changes in study subject weight and BMI from baseline time of switch (T0) to 6 months (6m), 12 months (12m), 18m and 24 months (24m). 2. Determine if weight change trends were changing over time, 3. Look at proportion of patients gaining more than 10% of baseline weight, and 4. Changes in BMI category

Methods

• Study population: There were 271 subjects in the acceptability study, only treatment experienced patients at switch were included in the analysis, 235 (87%) were included in the analysis, 235 (87%) had a baseline weight at T0 and 24m, 149 (55%) had a BMI at T0 and 24m.

• Age, sex, facility, weight, height, viral load and CD4 data were extracted in Descriptive Statistics:

<table>
<thead>
<tr>
<th></th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
</tr>
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<tbody>
<tr>
<td>BMI Category</td>
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<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
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<tr>
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<td>62</td>
<td>50</td>
<td>18</td>
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<td>Underweight</td>
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<td>9</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Overweight</td>
<td>26</td>
<td>10</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Obese</td>
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<td>6</td>
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<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>213</td>
<td>86</td>
<td>48</td>
<td>18</td>
<td>0</td>
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</tr>
</tbody>
</table>

Baseline BMI distribution (n=167)

- For most of the BMI categories the proportion of patients gaining 10% or has increased, however for those with a normal baseline BMI, there shows signs of plateauing

3. Look at proportion of patients gaining more than 10% weight from their baseline weight over time

4. Trends in proportion of patients by BMI category over time

- Study participants were enrolled from a population of PLHIV experiencing side effects so some weight gain may be non-specific on time of day or clothing during weight measurements.
- Not all subjects in the cohort have discontinued DTG due to weight or appetite concerns.
- Further analysis should be considered to determine if there is a consistent plateauing after 18 months.

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Results: Weight changes at 6m, 12m, 18m, and 24m

- All BMI – Overall there is an increase in the percent of weight gained at all follow up times compared to baseline, but there is a plateauing at 24m (all p-values <0.01)
- Normal BMI – there is a statistically significant increase in percent of weight at all 6m, 12m, and 18m, with a decrease from 18m to 24m (all p-values < 0.01)
- Overweight/ obese – there is no statistical increase until 18m then percent of weight gain starts to increase

Conclusions and Limitations

- There was weight gain among patients that switch to DTG and the weight gain may continue for up to 18 months with signs of plateauing. This was found particularly in subjects with normal baseline BMIs at time of switch.
- We did not find weight gains amongst the overweight and obese population for the first year after switch, that increased at 18m and 24m. Although this is a small sample size.
- No subjects in the cohort have discontinued DTG due to weight or appetite concerns.
- Further analysis should be considered to determine if there is a consistent plateauing after 18 months.

Limitations:
- The study was not a controlled trial and was not initially designed to assess changes in weight. It was not powered to look at weight changes so conclusions could not be drawn in all circumstance.
- Not all subjects had weights consistently recorded. Additionally, scales were not calibrated and there were no specifics on time of day or clothing during weight measurements.
- Not all subjects in the study had recorded weights (82%) - there is a potential for bias with subjects that have recorded weights more likely to have experienced weight change and had this data purposefully collected.
- There are natural weight gains that occur over time and the analysis does not include a control group to compare if the weight gains found would be unique to DTG patients and would not occur on other regimens.
- Study participants were enrolled from a population of PLHIV experiencing side effects so some weight gain may be expected for patients switching to a more tolerable regimen with a ‘return to health effect’.