IMPROVED VIROLOGIC RESPONSE IN TRIPLE-CLASS-EXPERIENCED PATIENTS WITH ENFUVIRID (ENF) COMBINED WITH NEW ANTIRETROVIRAL AGENTS

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Introduction

- Participants receiving antiretroviral agents are a challenging segment of the HIV-infected population.
- In such patients, the use of two or more active agents is critical in achieving undetectable viral loads.
- Enfuvirtide (ENF) has been shown to have a potent virologic effect when combined with new antiretroviral agents.
- The viral load suppression with both boosted PIs was consistently achieved in patients on ENF.
- Across studies and endpoints, the addition of ENF to the OBR was associated with a significantly greater virologic response.
- In such patients, the use of at least two fully active agents is critical to achieving undetectable viral loads.
- ENF reuse was not in the trials.
- In the trials, ENF was used at the discretion of the investigators and was associated with virologic response and provides activity when other classes may fail.
- New agents have recently become available, including those in near clinical trials.
- This analysis was the effect of ENF when combined with new agents or new class of agent in triple-class-experienced patients.

Methods

- A review was undertaken of recent publications and presentations of phase 2 and 3 studies in triple-class-experienced patients in which ENF was used in combination with PI/r or PI/r and non-PI/r.
- The objective was to collate and update available efficacy data across well-controlled studies of OBR regimens, and new classes of agents or ENF in triple-class-experienced patients.
- To be considered, studies had demonstrated virologic activity in triple-class-experienced patients in the setting of PI/r. Tenviravir (Ttv) and tenofovir (Ttv) were included.
- Results from subgroups in 11 controlled studies were included:
  - STUDY 1 & 2 (TPV/r – ENF - BID): week 48
  - POWER 1 & 2 (TPV/r – ENF - BID)
  - STUDY 1 (TPV/r – ENF - BID)
  - POWER 1 & 2 (TPV/r – ENF - BID)
  - MOTIVATE 1 & 2: (TPV/r – ENF - BID)
  - NAIVE 1 & 2 (TPV/r – ENF - BID)
  - MOTIVATE 1 & 2 (TPV/r – ENF - BID)

Results

- The virologic response at Week 16 in patients receiving ENF in a new agent was similar to that of patients receiving ENF in a new class of agents.
- Overall baseline characteristics for each study, as available, are shown in Table 1. The majority of patients were white (65–83%) men.
- Median CD4 cell counts ranged from 99 to 196 cells/mm³.
- The median age ranged from 33 to 57 years.
- Baseline viral loads ranged from 46 to 43 log_{10} copies/mL.
- Median CD4 cell counts ranged from 99 to 196 cells/mm³.

Discussion

- In conclusion, ENF was used at the investigators’ discretion and was stratified rather than randomized. As a result of the lack of detailed baseline characteristics it is not possible to determine comparability of ENF and non-ENF groups. Bias may have affected patient stratification rather than randomized.
- The viral load suppression with both boosted PIs was consistently achieved in patients on ENF.
- ENF reuse was not in the trials.
- In the trials, ENF was used at the discretion of the investigators and was associated with virologic response and provides activity when other classes may fail.

Conclusion

- In conclusion, the addition of ENF was associated with increased virologic suppression in participants receiving new antiretroviral agents.

References