Evidence Update

HIV/AIDS Series

Should HIV-infected adults with chronic unsuppressed viraemia have a treatment break before starting a new HIV regimen?

Patients changing HIV treatment due to drug resistant HIV should not have a treatment break before starting the new regimen.

Inclusion criteria

Studies:

Randomized controlled trials (RCTs) and non-randomized trials with or without a control group.

Participants:

Adults with chronic HIV infection unsuppressed by anti-retroviral therapy (ART) .

Intervention:

Intervention: structured ART treatment interruption.

Control: usual care, without interruption of ART.

Outcomes:

Primary: change in CD4 count, CD8 count, or CD8 specific response, plasma HIV viral load, or HIV genotypic patterns; AIDS-defining disease events, death, antiretroviral drug levels, quality of life.

Adverse events: adverse drug effects and toxicities.

Results

- Eight RCTs were included in the review; four were adequately concealed.
- One trial compared 16 weeks structured treatment interruption with no interruption. With interruption, clinical disease progression was more common (hazard ratio 2.57, 95% confidence interval 1.2 to 5.5; 270 participants) and CD4 counts lower.
- One trial compared 12 weeks interruption followed by salvage therapy with no interruption. With interruption, 55% of participants achieved a viral load < 50 copies/mL after 3 months on salvage therapy, compared with 69% of participants with no interruption (134 participants).
- The results of three smaller trials (30, 41, and 46 participants) all suggested that interruption was less effective or no different to an immediate switch of ART regimen.
- One trial in 68 patients with advanced HIV moved patients to GigHAART (a regimen of 8-9 drugs) and compared 8-week structured interruption with no interruption. Viral suppression results were better in the interruption group.

Adapted from Pai NP, Lawrence J, Reingold AL, Tulsky JP. Structured treatment interruptions (STI) in chronic unsuppressed HIV infection in adults. *Cochrane Database of Systematic Reviews* 2006, Issue 3. Art. No.: CD006148. DOI: 10.1002/14651858.CD006148. *Evidence Update* published in March 2007.

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Authors' conclusions

Implications for practice:

For people with ART treatment failure due to drug-resistant HIV, there is no evidence that planned breaks in ART before switching to an optimized treatment regimen increases treatment success, and some evidence that the practice may be harmful. Results from the largest RCT in this area, the OPTIMA (Options in Management of Anti-retrovirals) trial, are awaited.

Implications for research:

Future trials should be designed with adequate power to determine differences in clinical endpoints, adopt standardized outcomes, and use longer follow up.