

IL-2 and Enfuvirtide in Advanced Virologic Failure
ETOILE (ANRS 123) Study

IL-2 and Enfuvirtide in Advanced Virologic Failure

ETOILE (ANRS 123: Study Design

Study Design: ETOILE (ANRS 123)

- **Background:** Prospective, randomized, open-label trial to evaluate the efficacy of adding subcutaneous interleukin-2 (IL-2) to an optimized antiretroviral regimen in HIV-infected patients with HIV infection who have experienced advanced virologic failure
- **Inclusion Criteria (n = 57)**
 - Age ≥ 18 years of age
 - CD4 < 200 cells/mm³ at screening and in prior 6 months
 - HIV RNA $> 10,000$ copies/mL
 - Genotypic sensitivity score showing ≤ 2 active agents
- **Treatment Arms**
 - Optimized background therapy (OBT)* + IL-2 (8 cycles of 4.5 MIU BID x 5 days every 6 weeks)
 - OBT alone

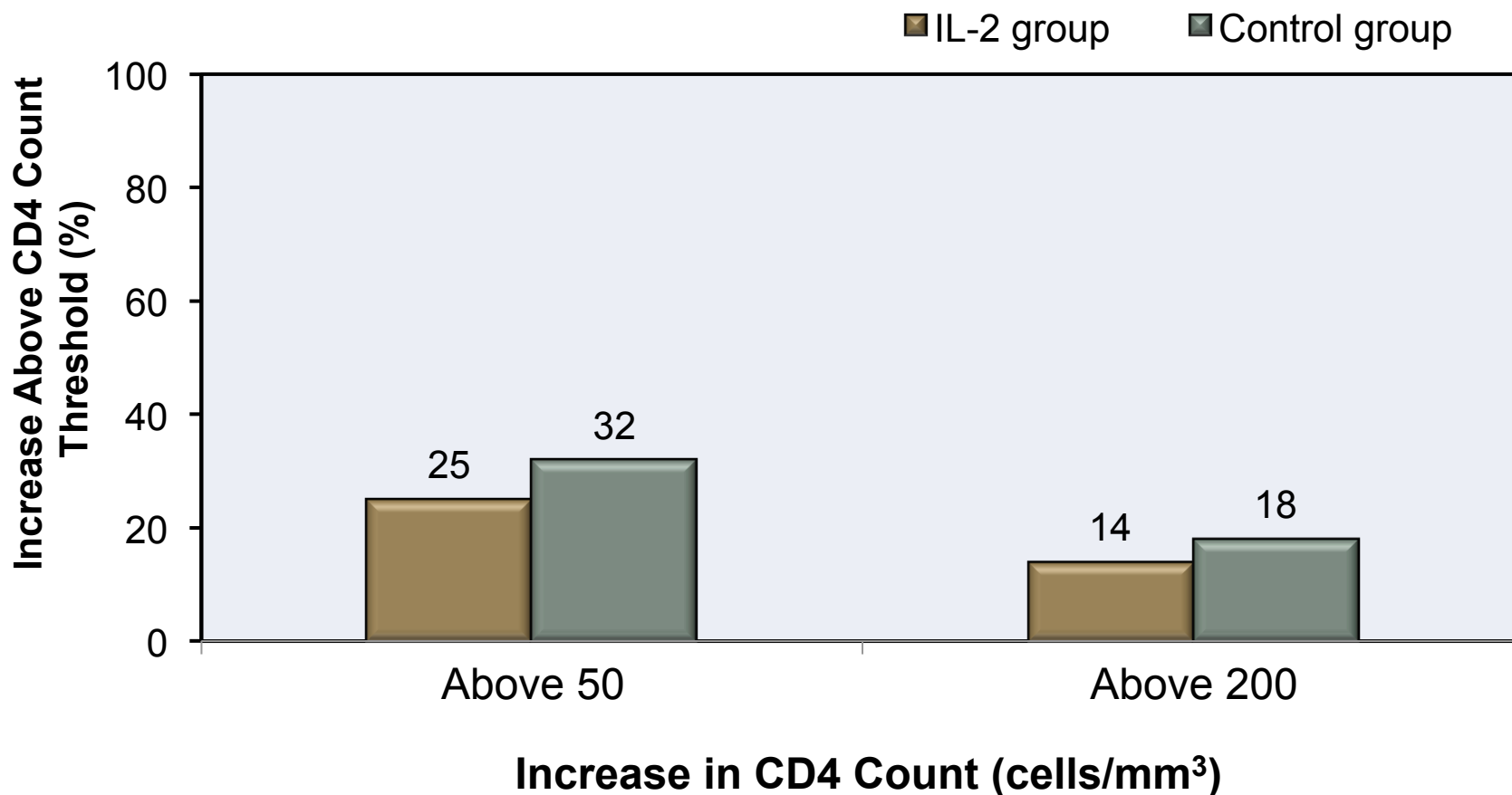
IL-2 Group
OBT + IL-2
(n = 28)

Control Group
OBT alone
(n = 28)

Optimization = use of enfuvirtide for at least 24 weeks from week 0 in enfuvirtide-naïve patients, use of at least one active antiretroviral drug according to GSS, or use of tipranavir plus ritonavir.

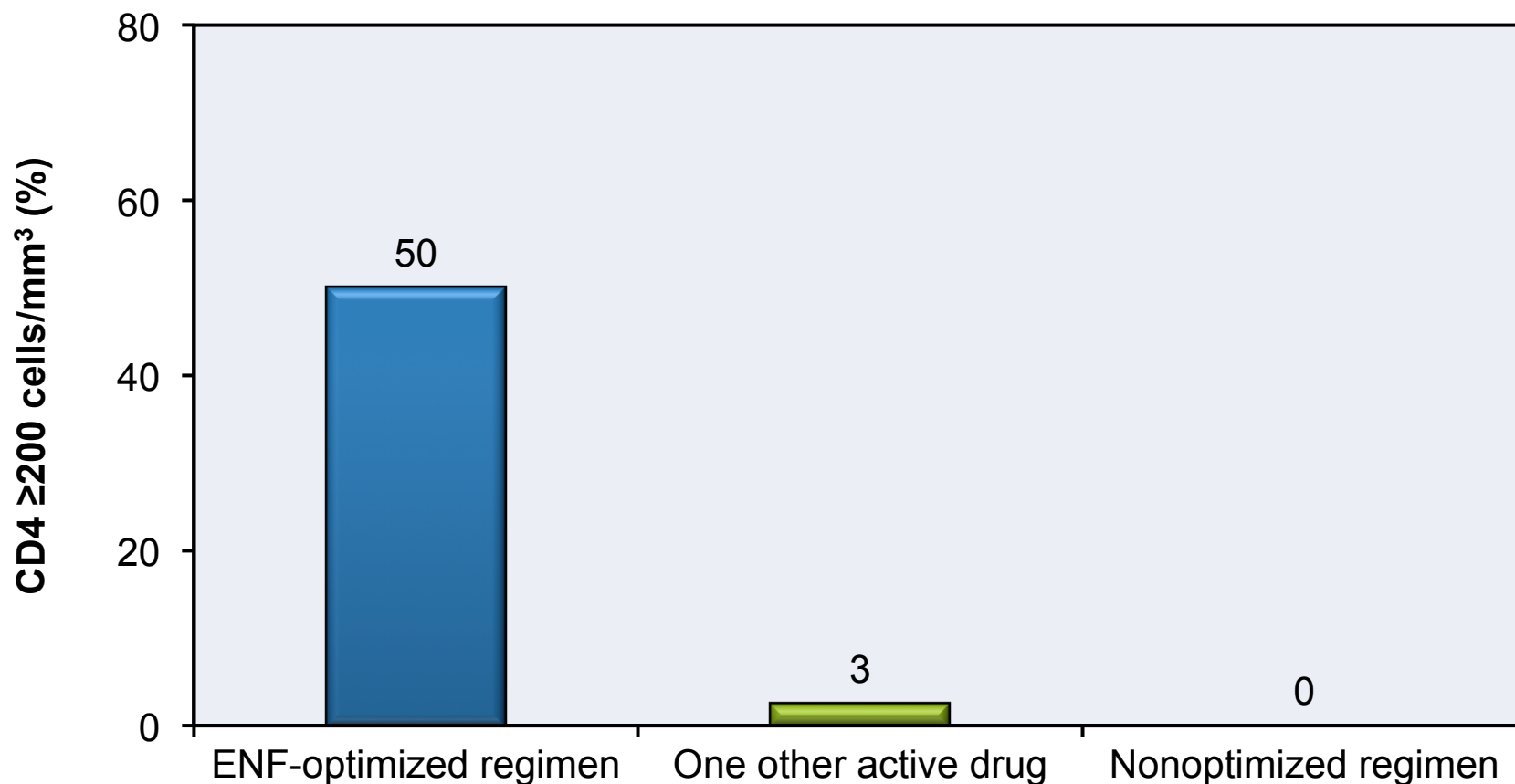
IL-2 and Enfuvirtide in Advanced Virologic Failure ETOILE (ANRS 123): Result

Week 52: Immunovirologic Response



IL-2 and Enfuvirtide in Advanced Virologic Failure ETOILE (ANRS 123): Result

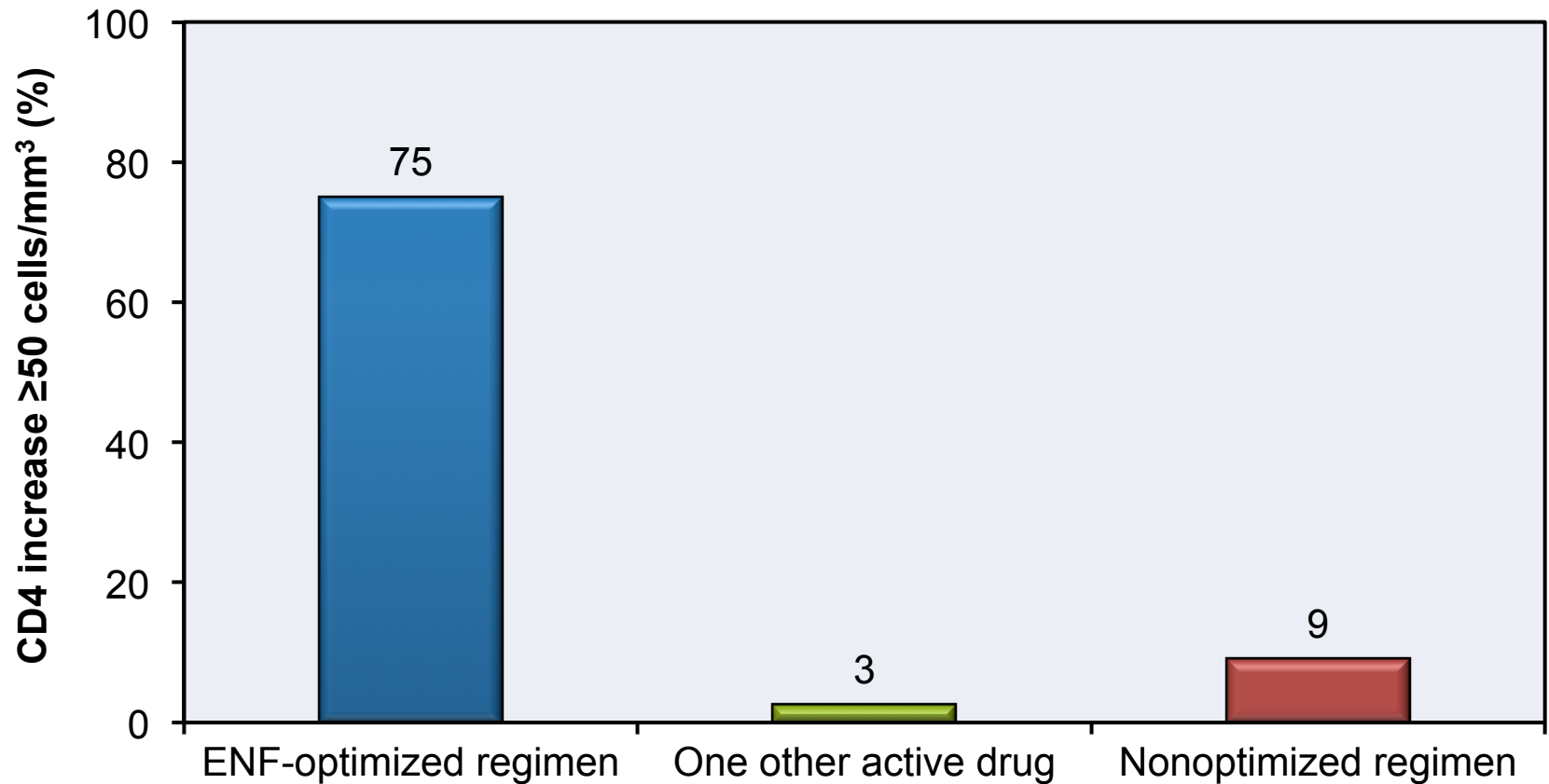
Week 52: Immunovirologic Response



Source: Viard B, et al. *AIDS*. 2009;23:1383-8.

IL-2 and Enfuvirtide in Advanced Virologic Failure ETOILE (ANRS 123): Result

Week 52: Immunovirologic Response



IL-2 and Enfuvirtide in Advanced Virologic Failure ETOILE (ANRS 123): Conclusions

Conclusions: “IL-2 failed to increase CD4 cell count in immunocompromised patients with multiple therapeutic failures. Enfuvirtide use was highly associated with success.”

Acknowledgment

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