

Once-Daily vs. Twice-Daily Enfuvirtide in Treatment-Experienced

T20-401 Study

Once-Daily vs. Twice-Daily Enfuvirtide in Treatment-Experienced T20-401: Study Design

Study Design: T20-401

- **Background:** Randomized, active-controlled, open-label phase II trial to evaluate the feasibility of once-daily dosing of enfuvirtide and to compare the safety, tolerability, and adherence of once-daily versus twice daily enfuvirtide dosing in HIV-infected treatment-experienced adults
- **Inclusion Criteria (n = 61)**
 - Enfuvirtide naïve
 - HIV RNA $\geq 5,000$ copies/mL on unchanged prestudy regimen for ≥ 28 days
 - Prior experience or resistance to PIs, NRTIs, and NNRTIs
- **Treatment Arms**
 - Optimized background (OB) + enfuvirtide 180 mg QD*
 - Optimized background + enfuvirtide 90 mg BID

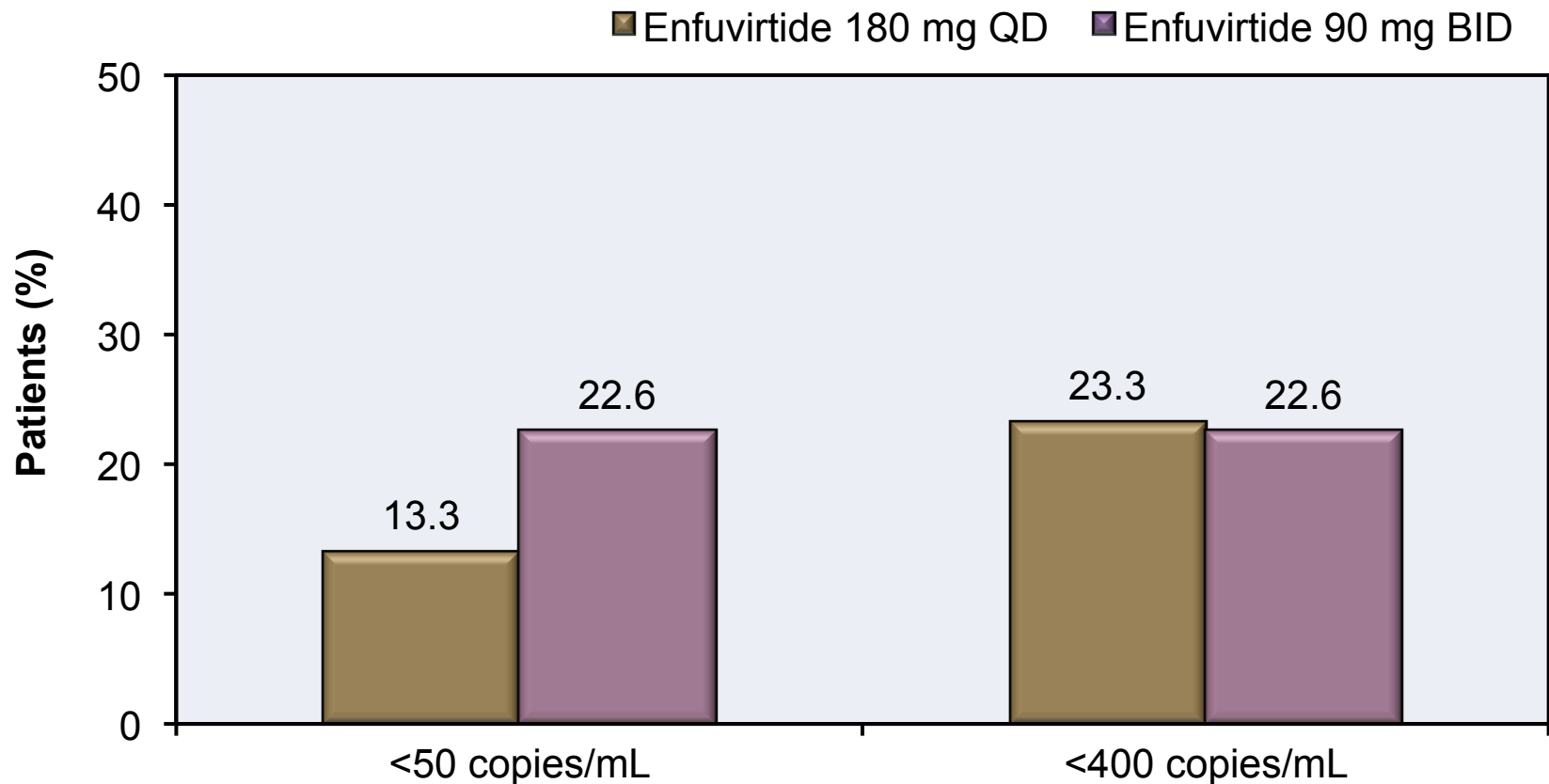
**Optimized background
+ Enfuvirtide 180 mg QD**
(n= 30)

**Optimized background
+ Enfuvirtide 90 mg BID**
(n =31)

*Enfuvirtide given SC; the 180 mg QD dose delivered as two 90 mg SC injections

Once-Daily vs. Twice-Daily Enfuvirtide in Treatment-Experienced T20-401: Result

Week 48: Virologic Response (ITT)

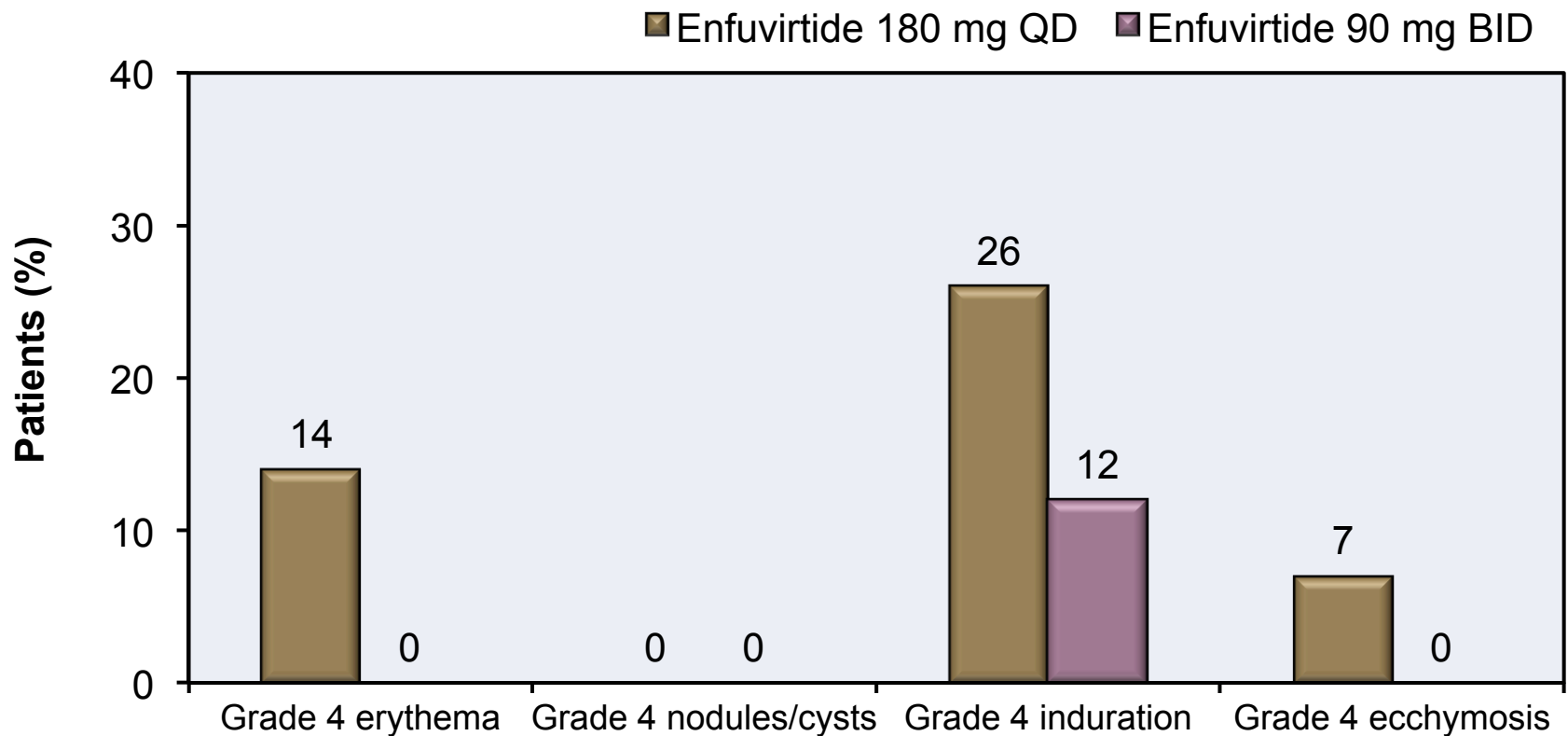


Enfuvirtide in both arms given with optimized background antiretroviral therapy

Source: Wright D, et al. HIV Clin Trials. 2008;9:73-82.

Once-Daily vs. Twice-Daily Enfuvirtide in Treatment-Experienced T20-401: Result

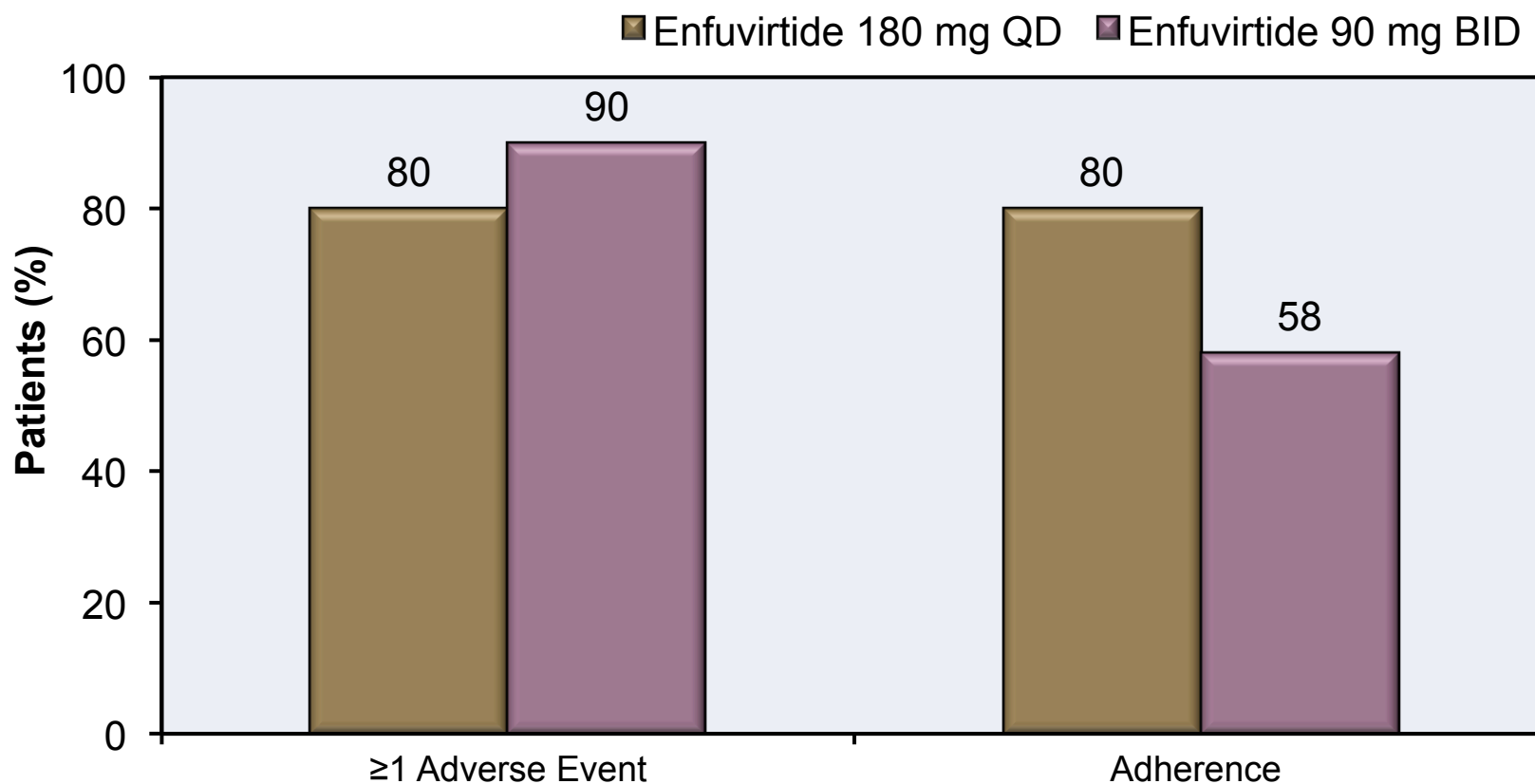
Week 48: Injection Site Reactions (Grade 4)



Enfuvirtide in both arms given with optimized background antiretroviral therapy

Once-Daily vs. Twice-Daily Enfuvirtide in Treatment-Experienced T20-401: Result

Week 48: Adverse Events and Adherence



Enfuvirtide in both arms given with optimized background antiretroviral therapy

Once-Daily vs. Twice-Daily Enfuvirtide in Treatment-Experienced T20-401: Conclusion

Conclusion: “The antiviral efficacy, safety, and tolerability of 180 mg enfuvirtide once daily appeared comparable with that of 90 mg enfuvirtide twice daily at Week 48, although the study was not powered to demonstrate the noninferiority of once daily versus twice daily.”

Acknowledgment

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