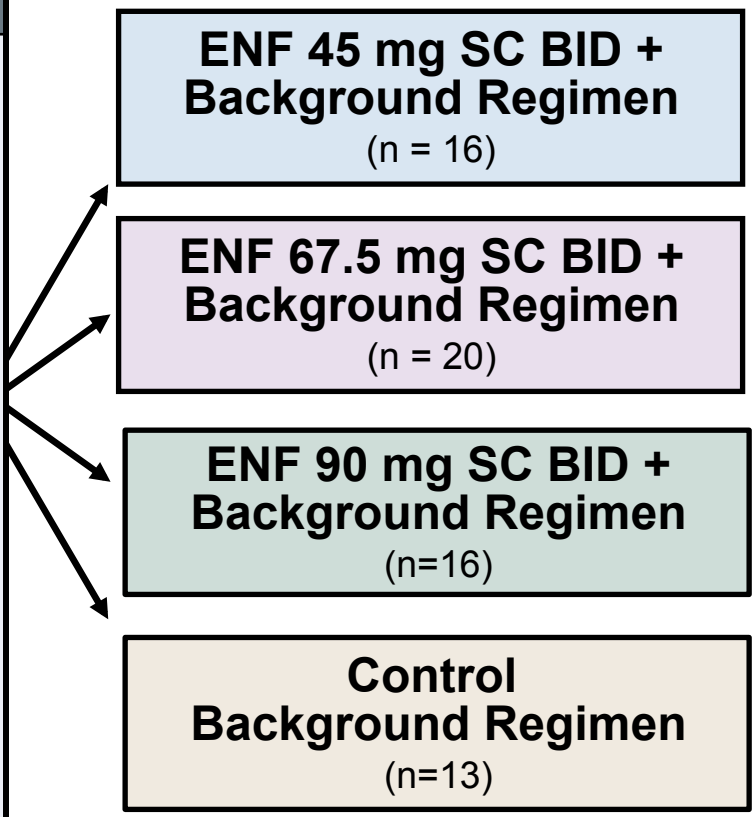
Enfuvirtide Dosing Study in PI-Experienced, NNRTI-Naïve

T20-206 Study

Enfuvirtide Dosing Study in PI-experienced, NNRTI-Naïve
T20-206: Study Design

Study Design: T20-206

- **Background**: Randomized, controlled, phase II, dose-ranging trial to evaluate the safety, efficacy, and pharmacokinetics of 3 doses of enfuvirtide in combination with amprenavir, ritonavir, and efavirenz in PI-experienced, NNRTI-naïve adults
- **Inclusion Criteria (n = 71)**
  - Age ≥18
  - CD4 >200 cells/$mm^{3,}$ HIV RNA ≥1,000copies/mL
  - PI-experienced, NNRTI-naïve
- **Treatment Arms**
  - Background regimen* + ENF 45 mg SC BID
  - Background regimen* + ENF 67.5 mg SC BID
  - Background regime*n + ENF 90 mg SC BID
  - Background regimen* alone

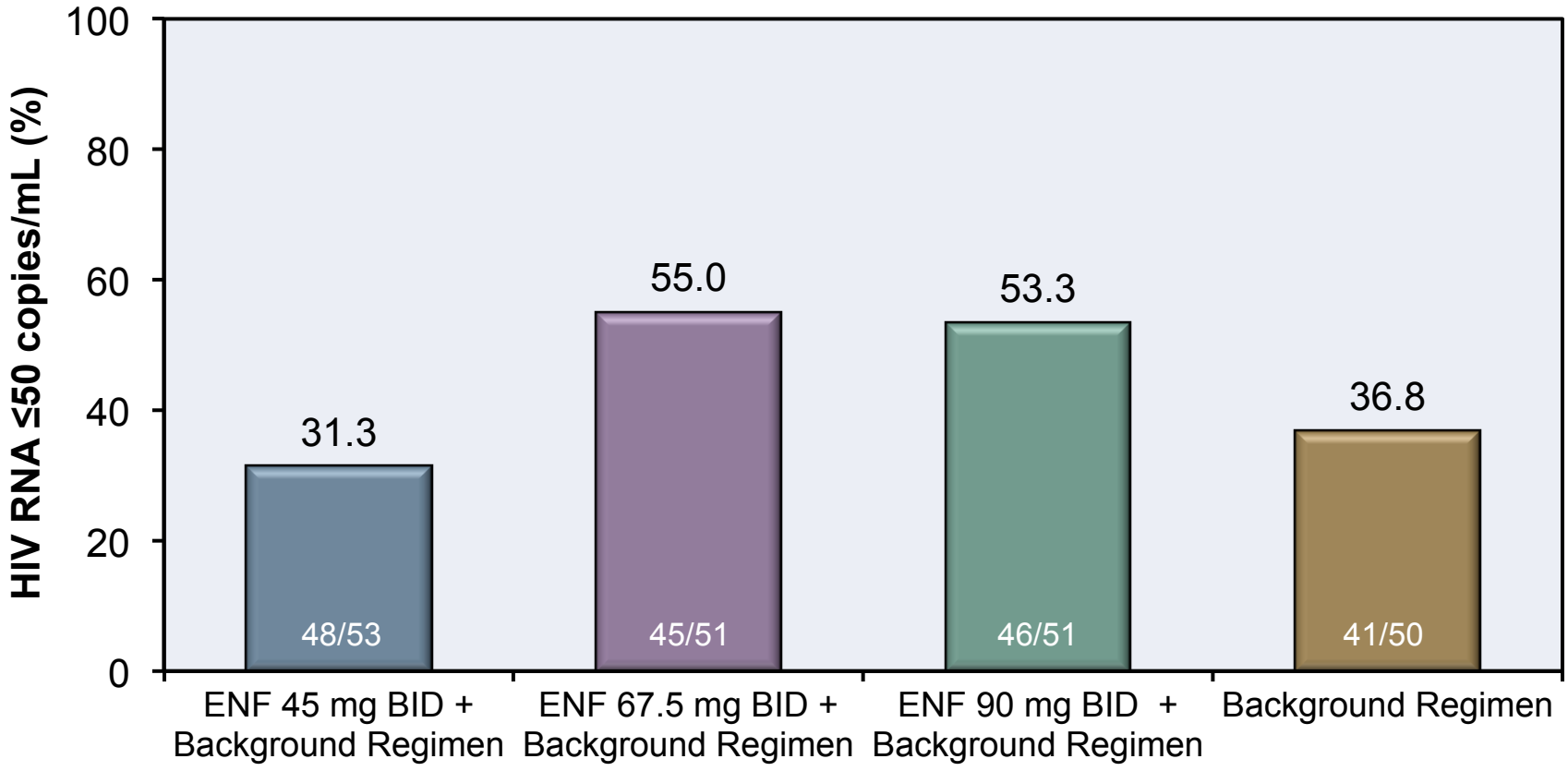


*Background regimen: abacavir 300 mg BID, amprenavir 1200 mg BID, ritonavir 200 mg BID, efavirenz 600 mg QD

Source: Lalezari JP, et al. Antivir Ther. 2003;8:279-87.

Enfuvirtide Dosing Study in PI-experienced, NNRTI-Naïve
T20-206: Result

Week 48: Virologic Response, by Treatment Group (ITT)



Source: Lalezari JP, et al. Antivir Ther. 2003;8:279-87.

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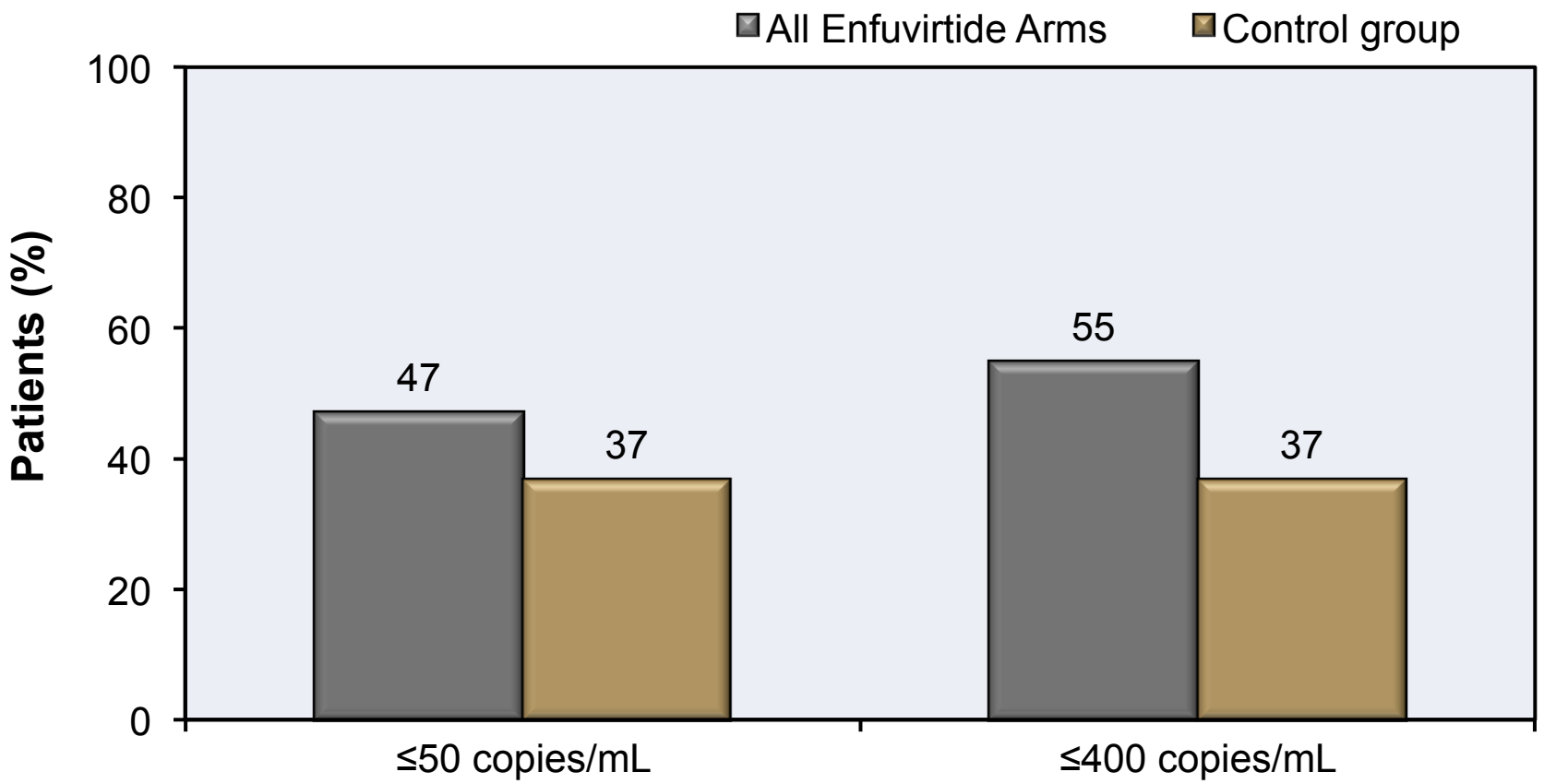
Enfuvirtide Dosing Study in PI-experienced, NNRTI-Naïve
T20-206: Result

48 Week: Overall Virologic Response (ITT)



Source: Lalezari JP, et al. Antivir Ther. 2003;8:279-87.

Enfuvirtide Dosing Study in PI-experienced, NNRTI-Naïve
T20-206: Result

Most Frequent Treatment-Emergent Adverse Events	ENF 45 mg	ENF 67.5 mg	ENF 90 mg	All ENF	Control
Nausea	6 (37.5%)	10 (50.0%)	8 (50.0%)	24 (46.2%)	8 (42.1%)
Diarrhea	6 (37.5%)	10 (50.0%)	6 (37.5%)	22 (42.3%)	7 (36.8%)
Dizziness (excluding vertigo)	8 (50.0%)	2 (10.0%)	6 (37.5%)	16 (30.8%)	4 (21.1%)
Fatigue	3 (18.8%)	5 (25.0%)	7 (43.8%)	15 (28.8%)	7 (36.8%)
Abnormal dreams	3 (18.8%)	4 (20.0%)	6 (37.5)	13 (25.0%)	5 (26.3%)
Headache	5 (31.5%)	1 (50.0%)	5 (31.3%)	11 (21.1%)	1 (5.3%)
Blood TG increase / hyperTG	4 (25.0%)	5 (25.0%)	1 (6.3%)	10 (19.2%)	6 (31.5%)
Neutropenia	5 (31.1%)	3 (15.0%)	1 (6.3%)	9 (17.3%)	3 (15.8%)
Hypoesthesia	2 (12.5%)	3 (15.0%)	2 (12.5%)	7 (13.5%)	3 (15.8%)
Nasopharyngitis	2 (12.5%)	3 (15.0%)	2 (12%%)	7 (13.5%)	2 (10.5%)
Vomiting	1 (6.3%)	2 (10.0%)	4 (25.0%)	7 (13.5%)	4 (21.1%)
Dermatitis NOS	2 (12.5%)	2 (10.0%)	2 (12.5%)	6 (11.5%)	3 (15.8%)
Insomnia NEC	2 (12.5%)	2 (10.0%)	2 (12.5%)	6 (11.5%)	4 (21.1%)

Source: Lalezari JP, et al. Antivir Ther. 2003;8:279-87.

Enfuvirtide Dosing Study in PI-experienced, NNRTI-Naïve
T20-206: Conclusion

Conclusion: “These results indicate that enfuvirtide has a favourable safety profile and is a promising new antiviral agent for HIV-infected patients who have been on previously failing ARV regimens.”

Source: Lalezari JP, et al. Antivir Ther. 2003;8:279-87.

Acknowledgment

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