Poster #822

Analysis of Site Performance in Academic and Community-Based Centers in the IDEAL Study

J. H. Jou,[1] M. S. Sulkowski,[2] K. R. Reddy,[3] S. L. Flamm,[4] N. H. Afdhal,[5] J. M. Levin,[6] V. K. Rustgi,[7] R. S. Brown,[8] J. Long,[9] S. Noviello,[9] L. D. Pedicone,[9] J. K. Albrecht,[9] J. G. McHutchison[1]

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Abstract

Background: 76 academic and 42 community-based US centers participated in the IDEAL study, providing an opportunity to evaluate various metrics of quality and site performance in this large multicenter study.

Methods: 3070 treatment-naive, HCV genotype 1 infected patients received peg interferon (PEG) alfa-2b 1.5 or 1 µg/kg/wk plus ribavirin (RBV) 800-1400 mg/d or PEG alfa-2a 180 µg/wk plus RBV 1000-1200 mg/d for up to 48 weeks. We retrospectively evaluated rates of screen failure, completion, and discontinuation of treatment and follow-up, treatment adherence, and virologic response by site type.

Results: Of 4469 subjects screened, 63% and 37% were in academic and community centers, respectively. Screen failure rates were similar (30-32%). Of the 1905 (62%) and 1165 (38%) patients treated in academic and community centers, respectively, baseline characteristics were comparable, except more African Americans (21% vs 15%) were treated at academic centers, and more Hispanics were treated at community centers (10% vs 5%) (Table). End-of-treatment (EOT) response, relapse, and sustained virologic response (SVR) rates in academic and community centers did not differ. 9% of patients in academic and 12% in community centers achieved rapid virologic response (undetectable HCV RNA at week 4); 39% and 42% achieved complete early virologic response (undetectable HCV RNA at week 12). Adherence to ≥80% of PEG and RBV dosing for ≥80% assigned duration was also similar (46% in academic and 47% in community centers). 54% of patients in both academic and community centers completed treatment; there were similar discontinuation rates for treatment failure and adverse events.

Conclusions: No differences in adherence, incidence of adverse events, rates of discontinuation, on-treatment virologic response, and SVR were found when comparing academic and community sites. This large trial further supports that outcomes for patients are largely similar when comparing academic versus community based treatment for chronic hepatitis C.

	Academic Centers	Community Centers
Screen failures	32%	30%
Due to lost to follow-up	2%	2%
Median/mean (SD) treated pts/site	18.5/25.7 (22.8)	21.5/27.7 (25.7)
Male	59%	61%
Mean age, yrs	47.6	47.4
Caucasian/Black/Hispanic	71%/21%/5%	72%/15%/10%
METAVIR F3/4	10%	11%
Treatment phase		
Completed	54%	54%
Discontinued	46%	46%
Due to treatment failure	27%	27%
Due to adverse events	12%	11%
Lost to follow-up	2%	3%
Week 24 follow-up phase		
Completed	79%	78%
Discontinued	9%	9%
Never entered	12%	13%
SVR/EOT/Relapse rate	40%/55%/25% (248/996)	39%/57%/27% (163/614)

Background

- Patients undergoing treatment for hepatitis C at academic centers are thought to have greater access to resources as compared with patients treated at community-based sites
  - In the WIN-R study, treatment at predominantly community-based centers was associated with low retention of patients on treatment and, consequently, higher rates of drop-out[1]
- The extent that differences between community and academic sites may influence treatment outcomes among patients receiving peginterferon (PEG-IFN) alfa plus ribavirin (RBV) for chronic hepatitis C infection in clinical trials is unknown and should be systematically examined

Aim

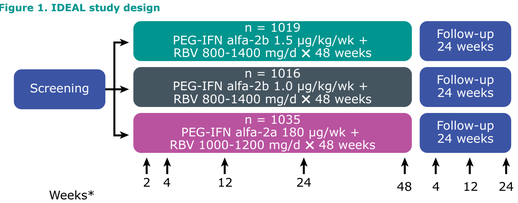
- To evaluate various metrics of quality and site performance in academic and community sites participating in the multicenter IDEAL study[2]

Patients and Methods

Study Design

- This evaluation of study centers is a retrospective analysis based on the IDEAL study database
- IDEAL was a phase 3b, randomized, parallel-arm trial conducted at 118 centers (76 academic and 42 community-based) in the United States (**Figure 1**)
  - PEG-IFN alfa-2b dose was double-blinded, and PEG-IFN alfa-2a and RBV were administered as open-label treatments
  - Patients with a detectable, <2-log decline in HCV-RNA at week 12, or with detectable HCV-RNA at week 24 were discontinued from treatment

Figure 1. IDEAL study design



*HCV-RNA assessments at designated time periods.
PEG-IFN = peginterferon; RBV = ribavirin.

Patient Population

- Treatment-naive with chronic hepatitis C, genotype 1 infection
- 18 to 70 years old
- Weight 40 to 125 kg
- Compensated liver disease

Outcomes

- Rates of screen failure, completion and discontinuation of treatment and follow-up, treatment adherence, and virologic response by site type (academic versus community centers) were calculated
- Data from the 3 treatment arms were combined for all analyses

Virologic Response and Adherence Definitions

- Rapid virologic response (RVR): undetectable HCV-RNA at week 4
- Complete early virologic response (cEVR): undetectable HCV-RNA at week 12
- End-of-treatment (EOT) response: undetectable HCV-RNA at the end of treatment
- Sustained virologic response (SVR): undetectable HCV-RNA at the end of the 24-week follow-up period
- Relapse: Detectable HCV-RNA during follow-up in patients with an undetectable HCV-RNA at EOT
- 80:80:80 adherence: ≥80% of PEG and RBV dosing for ≥80% assigned duration
- HCV-RNA levels measured using the COBAS Taqman assay (Roche) with a lower limit of quantitation of 27 IU/mL

Academic and Community Site Regions

- Regions of the United States were defined by the US Census Bureau regions and divisions[3]
- Academic and community sites were located in the following regions:
  - Northeast: Connecticut, Maine, Massachusetts, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont
  - Midwest: Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, Ohio, and Wisconsin
  - South Atlantic: District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, and Virginia
  - South (excluding South Atlantic): Alabama, Kentucky, Louisiana, Tennessee, and Texas
  - West: Arizona, California, Colorado, Oregon, Utah, and Washington

Results

Patients

Screened Patients

- Of 4469 patients screened in the IDEAL study, 2799 (63%) and 1670 (37%) patients were enrolled in academic and community centers, respectively (**Table 1**)
  - Screen failure rates were similar (30%-32%) between the center types

Table 1. Reasons for Screen Failure at Community and Academic Centers

	Academic Centers (n = 2799)	Community Centers (n = 1670)
Overall screen failure rate	32%	30%
Due to protocol ineligibility	24%	23%
Due to patient did not wish to continue	5%	5%
Due to lost to follow-up	2%	2%
Due to noncompliance with protocol	1%	1%
Due to adverse events	0.1%	0.1%

Treated Patients

- Of 3070 patients treated in the IDEAL study, 1905 (62%) and 1165 (38%) patients were treated in academic and community centers, respectively (**Table 2**)
  - Baseline characteristics were comparable
    - More African Americans were treated at academic centers (21% vs 15%)
    - More Hispanics were treated at community centers (10% vs 5%)

Table 2. Demographics and Disease Characteristics of Treated Patients

	Academic Centers (n = 1905)	Community Centers (n = 1165)
Median/mean (SD) treated patients/site	18.5/25.7 (22.8)	21.5/27.7 (25.7)
Male	59%	61%
Age, mean (SD), y	47.6 (8.1)	47.4 (7.8)
Weight, mean (SD), kg	83.4 (16.3)	83.5 (16.3)
Race		
Caucasian	71%	72%
Black	21%	15%
Hispanic	5%	10%
Asian	1%	2%
HCV-RNA >600,000 IU/mL	82%	82%
Steatosis score[a]		
Present	58%	60%
Absent	36%	36%
METAVIR fibrosis score[a]		
F0/1/2	84%	85%
F3/4	10%	11%
Region of the United States		
Northeast	22%	7%
South Atlantic	23%	33%
South[b]	26%	23%
Midwest	21%	16%
West	9%	21%

[a]Data missing for 147 patients (104 in academic centers and 43 in community-based centers).
[b]Excludes South Atlantic states.

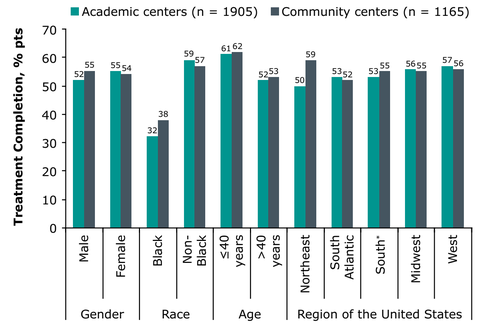
- 54% of patients in both academic and community centers completed treatment (**Table 3**)
  - There were similar discontinuation rates for treatment failure, adverse events, and lost to follow-up at each center type

Table 3. Study Participation

	Academic Centers (n = 1905)	Community Centers (n = 1165)
Treatment phase		
Completed	54%	54%
Discontinued	46%	46%
Due to treatment failure	27%	27%
Due to adverse events	12%	11%
Due to patient did not wish to continue	3%	4%
Due to lost to follow-up	2%	3%
Due to noncompliance with protocol	1%	1%
Due to protocol ineligibility	<1%	<1%
Week-24 follow-up phase		
Completed	79%	78%
Discontinued	9%	9%
Due to lost to follow-up	5%	5%
Due to patient did not wish to continue	3%	3%
Due to noncompliance with protocol	<1%	<1%
Due to adverse events	<1%	<1%
Never entered	12%	13%

  - Treatment completion rates were similar across various demographic characteristics as well as regions in the United States (**Figure 2**)

Figure 2. Treatment completion rates by demographic and regional characteristics

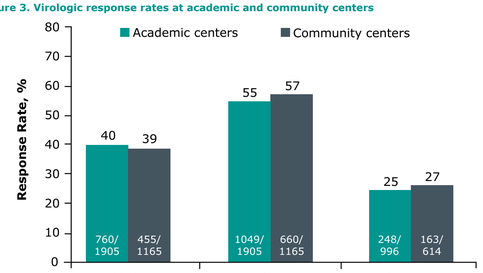


*Excludes South Atlantic states.
P > .05 for all comparisons (nominal *P* values, unadjusted for multiple comparisons).

Virologic Response

- SVR, EOT response, and relapse rates were similar in patients enrolled at academic and community centers (**Figure 3**)

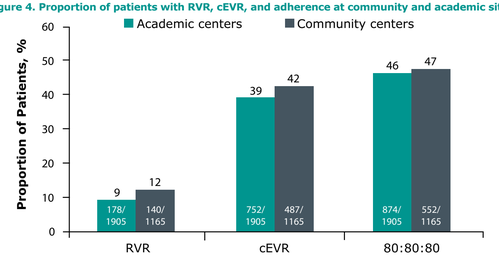
Figure 3. Virologic response rates at academic and community centers



EOT = end of treatment; SVR = sustained virologic response.

- Proportion of patients with RVR, cEVR, and 80:80:80 adherence were also similar at community and academic sites (**Figure 4**)

Figure 4. Proportion of patients with RVR, cEVR, and adherence at community and academic sites



cEVR = complete early virologic response; RVR = rapid virologic response.

- There was no significant difference in SVR rates between community and academic centers within most selected patient subgroups (**Table 4**)
  - However, SVR rates were significantly higher in patients from the Western states when treated at academic centers compared with community centers (49% vs 38%, *P* = .04)

Table 4. SVR Rates by Demographic and Regional Characteristics

	Academic Centers (n = 1905)	Community Centers (n = 1165)
Gender		
Male	38%	40%
Female	43%	38%
Race		
Black	22%	22%
Non-Black	45%	42%
Age		
≤40 years old	54%	48%
>40 years old	37%	37%
Region of the United States		
Northeast	38%	43%
South Atlantic	39%	38%
South[a]	37%	40%
Midwest	42%	39%
West[b]	49%	38%

[a]Excludes South Atlantic states.
[b]*P* = .04; for all other comparisons *P* > .05 (nominal *P* values, unadjusted for multiple comparisons).
SVR = sustained virologic response.

Conclusions

- There were no differences in adherence, incidence of adverse events, rates of discontinuation, on-treatment virologic response, and SVR when comparing academic and community sites
  - SVR rates were higher among patients from the western US states who were treated at academic centers compared with those treated at community centers
- These findings further support that outcomes for patients are largely similar when comparing academic- versus community-based treatment for chronic hepatitis C

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1. Jacobson IM, et al. *Hepatology*. 2007;46(4):971-81.
2. McHutchison JG, et al. *N Engl J Med*. 2009;361(6):580-93.
3. US Census Bureau. http://www.census.gov/geo/www/us_regdiv.pdf.

Disclosures

J. H. Jou has nothing to disclose. M. S. Sulkowski serves as advisor for Roche, Schering-Plough, Merck, Human Genome Sciences, BIPI, Gilead, Vertex, Tibotec, Bristol-Myers Squibb, and Pfizer and receives grant/research support from Mederax, Peregrine, Debiopharm, and Abbott. K. R. Reddy has served as advisor to Bayer, Genentech/Roche, Gilead, Merck, Salix, Tibotec, and Vertex and as investigator for Bristol-Myers Squibb, Genentech/Roche, Gilead, Merck, Tibotec, and Vertex. S. L. Flamm serves as speaker for Gilead and Merck, consultant for Gilead, Merck, and Vertex, and receives research support from Abbott, Gilead, Merck, Pfizer, and Vertex. N. H. Afdhal has nothing to disclose. J. M. Levin serves as advisor to Gilead, Merck, Roche, and Schering-Plough Corporation, now Merck & Co., Inc., and as speaker for Cubist, Gilead, Merck, and Schering-Plough Corporation, now Merck & Co., Inc. V. K. Rustgi has served as a speaker for Bristol-Myers Squibb, Gilead, Roche, and Schering-Plough Corporation, now Merck & Co., Inc., and has received research funding from Bristol-Myers Squibb, Gilead Sciences, Roche, Schering-Plough Corporation, now Merck & Co., Inc., and Vertex Pharmaceuticals. R. S. Brown has served as a speaker for Schering-Plough Corporation, now Merck & Co., Inc., and received research funding from Schering-Plough Corporation, now Merck & Co., Inc. S. Noviello is a former employee and now consultant of Schering-Plough Research Institute, now Merck & Co., Inc. J. Long, L. D. Pedicone, and J. K. Albrecht are employees of Schering-Plough Research Institute, now Merck & Co., Inc., and S. Noviello, L. D. Pedicone, and J. K. Albrecht are stockholders of Schering-Plough Corporation, now Merck & Co., Inc. J. G. McHutchison has received research support from and served as advisor to Schering-Plough Corporation, now Merck & Co., Inc.

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Analysis of Site Per

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Abstract

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Methods: 3070 treatment-naive, HCV genotype 1 infected patients received peg interferon (PEG) alfa-2b 1.5 or 1 µg/kg/wk plus ribavirin (RBV) 800-1400 mg/d or PEG alfa-2a 180 µg/wk plus RBV 1000-1200 mg/d for up to 48 weeks. We retrospectively evaluated rates of screen failure, completion, and discontinuation of treatment and follow-up, treatment adherence, and virologic response by site type.

Results: Of 4469 subjects screened, 63% and 37% were in academic and community centers, respectively. Screen failure rates were similar (30-32%). Of the 1905 (62%) and 1165 (38%) patients treated in academic and community centers, respectively, baseline characteristics were comparable, except more African Americans (21% vs 15%) were treated at academic centers, and more Hispanics were treated at community centers (10% vs 5%) (Table). End-of-treatment (EOT) response, relapse, and sustained virologic response (SVR) rates in academic and community centers did not differ. 9% of patients in academic and 12% in community centers achieved rapid virologic response (undetectable HCV RNA at week 4); 39% and 42% achieved complete early virologic response (undetectable HCV RNA at week 12). Adherence to ≥80% of PEG and RBV dosing for ≥80% assigned duration was also similar (46% in academic and 47% in community centers). 54% of patients in both academic and community centers completed treatment; there were similar discontinuation rates for treatment failure and adverse events.

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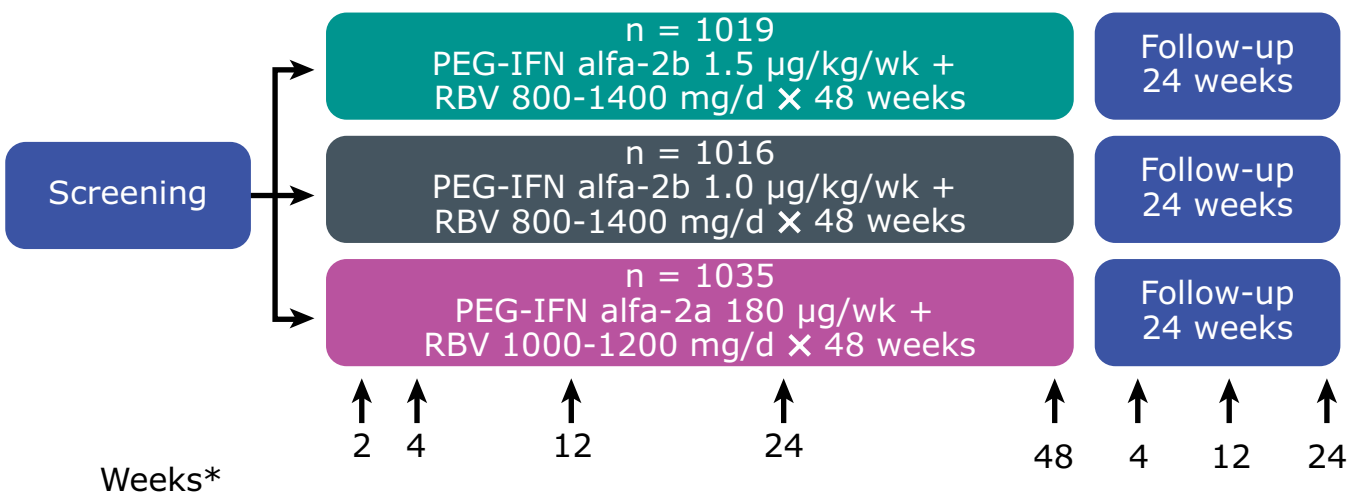

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Table 2. Demographics and Disease Characteristics of Treated Patients

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Community-Based Centers

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Table 3. Study Participation

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Due to patient did not wish to continue	3%	4%
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Week-24 follow-up phase		
Completed	79%	78%
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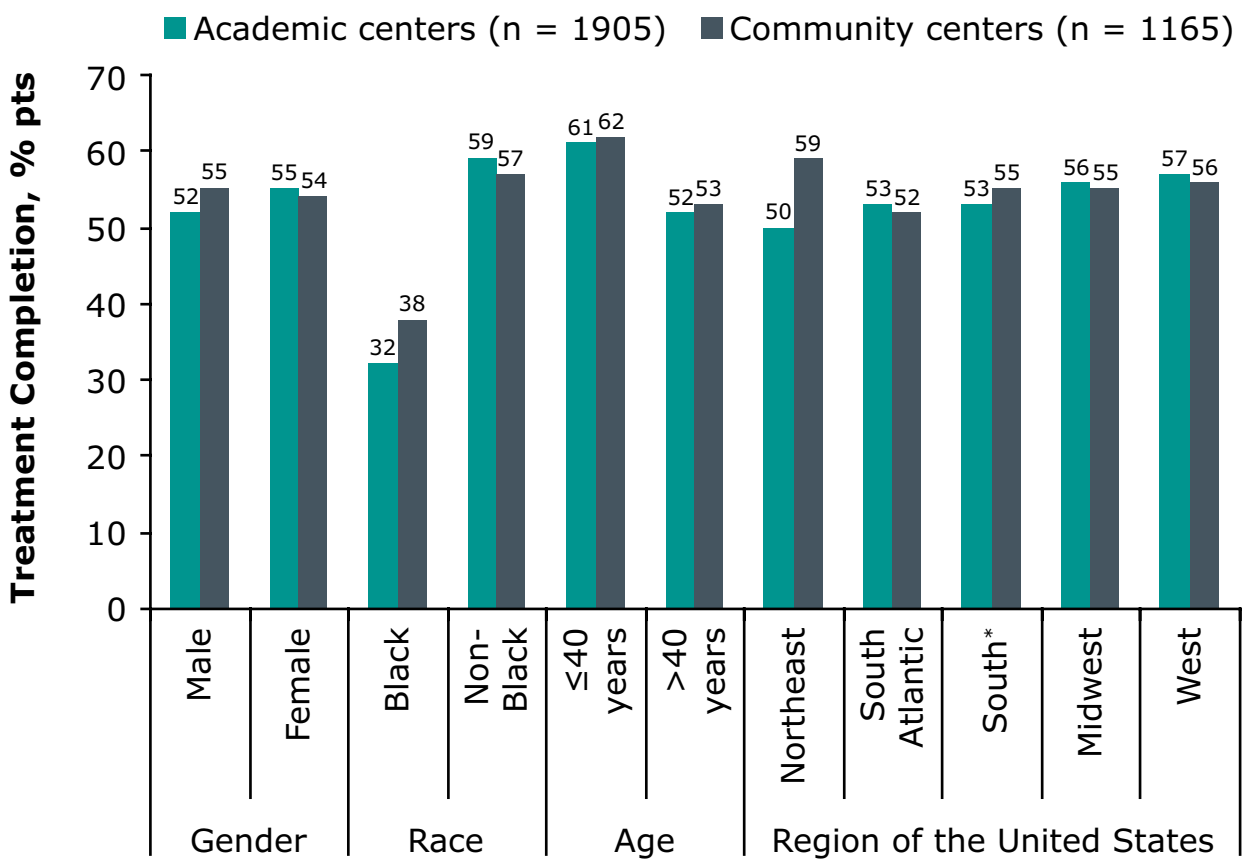
Due to adverse events	<1%	<1%
Never entered	12%	13%

— Treatment completion rates were similar across various demographic characteristics as well as regions in the United States (**Figure 2**)

Figure 2. Treatment completion rates by demographic and regional characteristics

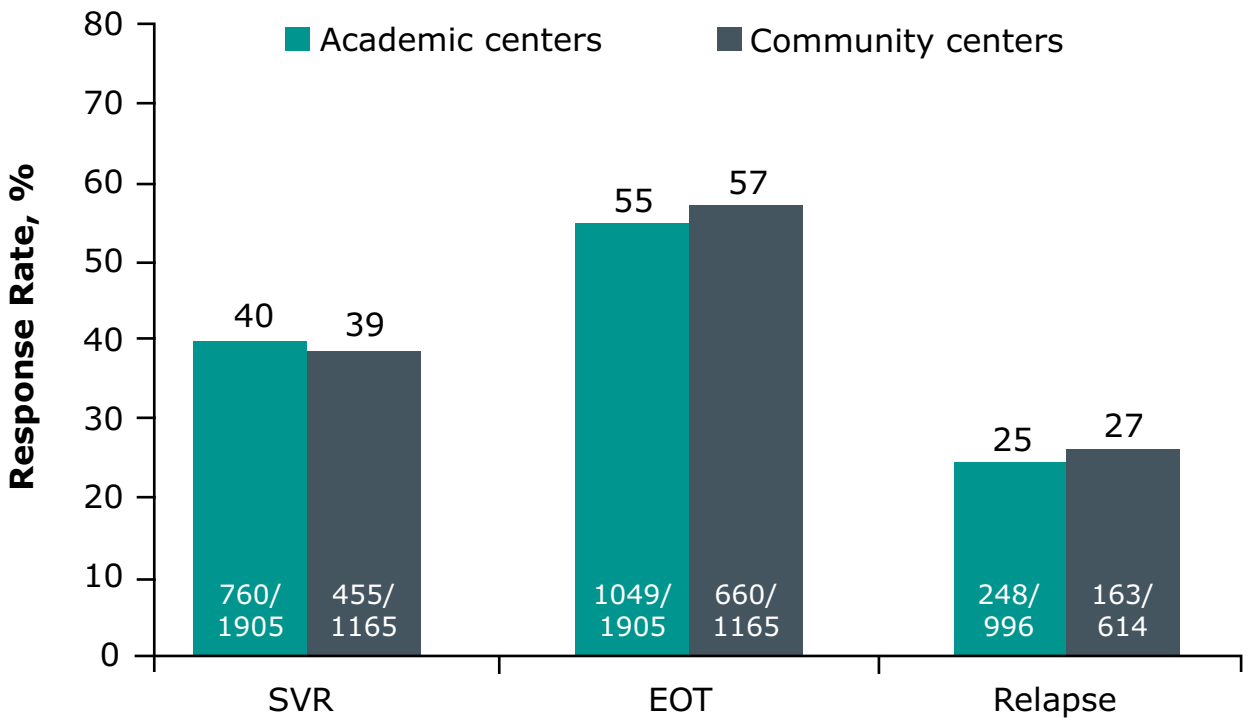


*Excludes South Atlantic states.
P > .05 for all comparisons (nominal *P* values, unadjusted for multiple comparisons).

Virologic Response

- SVR, EOT response, and relapse rates were similar in patients enrolled at academic and community centers (**Figure 3**)

Figure 3. Virologic response rates at academic and community centers



EOT = end of treatment; SVR = sustained virologic response.

- Proportion of patients with RVR, cEVR, and 80:80:80 adherence were also similar at community and academic sites (**Figure 4**)

s in the IDEAL Study

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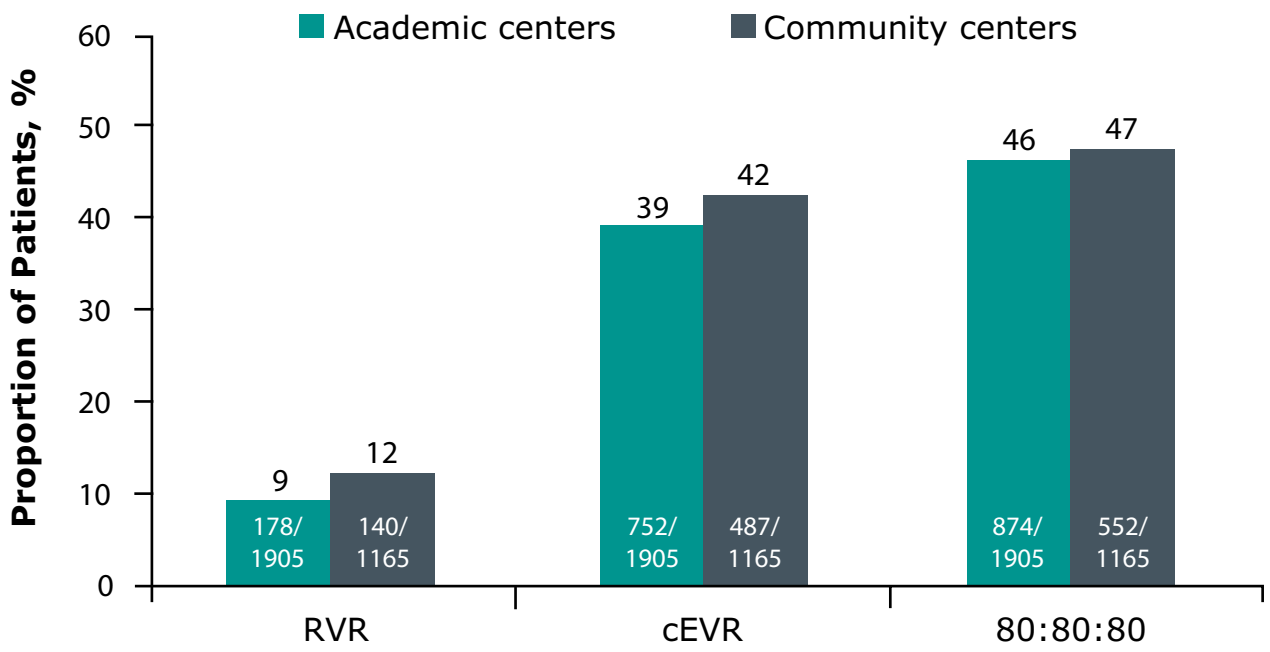
Figure 4. Proportion of patients with RVR, cEVR, and adherence at community and academic sites



cEVR = complete early virologic response; RVR = rapid virologic response.

- There was no significant difference in SVR rates between community and academic centers within most selected patient subgroups (**Table 4**)
  - — However, SVR rates were significantly higher in patients from the Western states when treated at academic centers compared with community centers (49% vs 38%, *P* = .04)

Table 4. SVR Rates by Demographic and Regional Characteristics

	Academic Centers (n = 1905)	Community Centers (n = 1165)
Gender		
Male	38%	40%
Female	43%	38%
Race		
Black	22%	22%
Non-Black	45%	42%
Age		
≤40 years old	54%	48%
>40 years old	37%	37%
Region of the United States		
Northeast	38%	43%
South Atlantic	39%	38%
South[a]	37%	40%
Midwest	42%	39%
West[b]	49%	38%

[a]Excludes South Atlantic states.
[b]*P* = .04; for all other comparisons *P* > .05 (nominal *P* values, unadjusted for multiple comparisons).
SVR = sustained virologic response.

Conclusions

- There were no differences in adherence, incidence of adverse events, rates of discontinuation, on-treatment virologic response, and SVR when comparing academic and community sites
  - — SVR rates were higher among patients from the western US states who were treated at academic centers compared with those treated at community centers
- These findings further support that outcomes for patients are largely similar when comparing academic- versus community-based treatment for chronic hepatitis C

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