

Background: Adherence is a known predictor of treatment outcome with HAART, but has not been evaluated in patients with acute or early HIV infection, where better immune function may affect therapeutic response.

Methods: The predictive value of adherence scores at 2 and 4 months after HAART initiation were assessed with Medication Event Monitoring System (MEMS) caps on all antiretroviral medications used by 22 participants in a study (AIEDRP) of early treatment of HIV infection (within 1 year from seroconversion). Inclusion criteria were: 1) continuous HAART for the first 4 months of therapy. 2) MEMS caps used continuously for at least 2 months within this time. Adherence scores were calculated as the total number of recorded openings divided by the total number of prescribed openings, X 100. A successful response was defined as a viral load of < 50 copies/ml at 4 months. Adherence at 2 months was also evaluated as a predictor because current DHHS guidelines include a ≥ 1 log₁₀ decline in viral load at 2 months after HAART initiation in the definition of therapeutic success. 22 patients provided data at 2 months and 18 at 4 months.

Results: Patients who did (n=14) or did not (n=8) respond successfully were similar in initial viral load, age, sex, race or risk factor (Wilcoxon rank sum test, Fisher's exact test). However, those who responded successfully had significantly higher adherence scores at 2 months (median=98.9, range 58.3-108.6), than those who did not (median=83.3, range 29.7-101.5; p=0.03, Wilcoxon rank sum test). Modeling adherence as a continuous variable, a 10 % increase in adherence score at either 2 or 4 months was associated with a successful response (OR= 1.71, p=0.063; OR=2.37, p=0.081, respectively. Logistic regression [LR]). As a dichotomous variable with a cut-off score of 90%, adherence > 90% at 2 months had an OR of 10 (p=0.029, LR) for a successful response and at 4 months was associated with an OR of 11 (p=0.07, LR).

Conclusions: In patients with acute or early HIV infection, adherence scores two months after HAART initiation significantly predicted successful suppression of viral load (< 50 copies/ml) at 4 months.

Background

- Adherence is a major determinant of treatment outcomes with HAART.
- Poor adherence can contribute to sub-optimal drug levels and therefore the potential for HIV replication and resistance.
- Quantitative measures in people with chronic HIV infection have suggested that 95% adherence to HAART is needed to obtain maximal viral suppression. However, similar data are not available for people with recent HIV infection.

Objectives

- To evaluate adherence to HAART in people with recent HIV infection
- To determine if adherence is associated with, or can predict, viral suppression in early HIV infection

Methods

- Subjects

- Participants in the Baltimore site of the Acute HIV Infection and Early Disease Research Program (AIEDRP). AIEDRP participants have proven recent HIV infection (< 1 year).
- On HAART continuously for at least 4 months after starting therapy
- Used MEMS caps continuously for at least 2 months within the first 4 months of therapy

- Adherence Assessment

- Medication Event Monitoring System (MEMS®) which records times and dates of bottle openings.
- Each antiretroviral medication was monitored

- Overall Adherence Scores calculated as:

$$\frac{\text{Total \# recorded cap openings}}{\text{Total \# prescribed cap openings}} \times 100$$

using combined data for all medications.

- Adherence Score at 2 months included all data from 0 – 2 months of therapy.
- Adherence Score at 4 months included all data from 0 - 4 months of therapy.
- Assessment of Response to HAART
 - HAART defined according to DHHS guidelines.
 - Successful response defined as plasma HIV RNA (Roche PCR) < 50 copies/ml at 4 months of treatment.
 - Plasma HIV RNA was measured at least monthly.

Table 1. Study population characteristics

Characteristic	Treatment Outcome at 4 months		P-value*
	Success (n=14)	Failure (n=8)	
Age (median)	42.5	46.5	0.31
Initial HIV RNA (median log ₁₀)	5.06	5.03	0.56
Sex			
Male	11	4	0.34
Female	3	4	
Race			
White	8	3	0.66
African-American	6	5	
HIV Risk Factor			
MSM	5	1	0.74
IDU	3	2	
Heterosexual	3	2	
Other	3	3	
Duration of Infection at baseline**			
< 2 months	6	2	0.65
2 – 12 months	8	6	

* Wilcoxon rank sum test for continuous variables, Fisher's exact test for categorical variables

**Baseline = start of HAART

Table 2 - Adherence scores at 2 and 4 months of therapy were significantly associated with outcome of treatment

		Treatment Outcome		P-value ¹
		Failure	Success	
Adherence Score at 2 months		N=8	N=14	
	Mean (SD)	74.7 (26.8)	94.5 (13.2)	
	Median (IQR) ¹	83.3 (52.9 – 96.8)	98.9 (91.1 – 100.4)	0.03
Adherence Score at 4 months		N=6	N=12	
	Mean (SD)	77 (26.3)	97.3 (6.4)	
	Median (IQR)	83.8 (59 – 99.2)	99.3 (95.5 – 100.3)	0.06

¹ P-value by the Wilcoxon rank-sum test

* Data for this table are displayed in Figures 1 and 2.

Figure 1 – Adherence scores at 2 months and response to HAART (n=22)

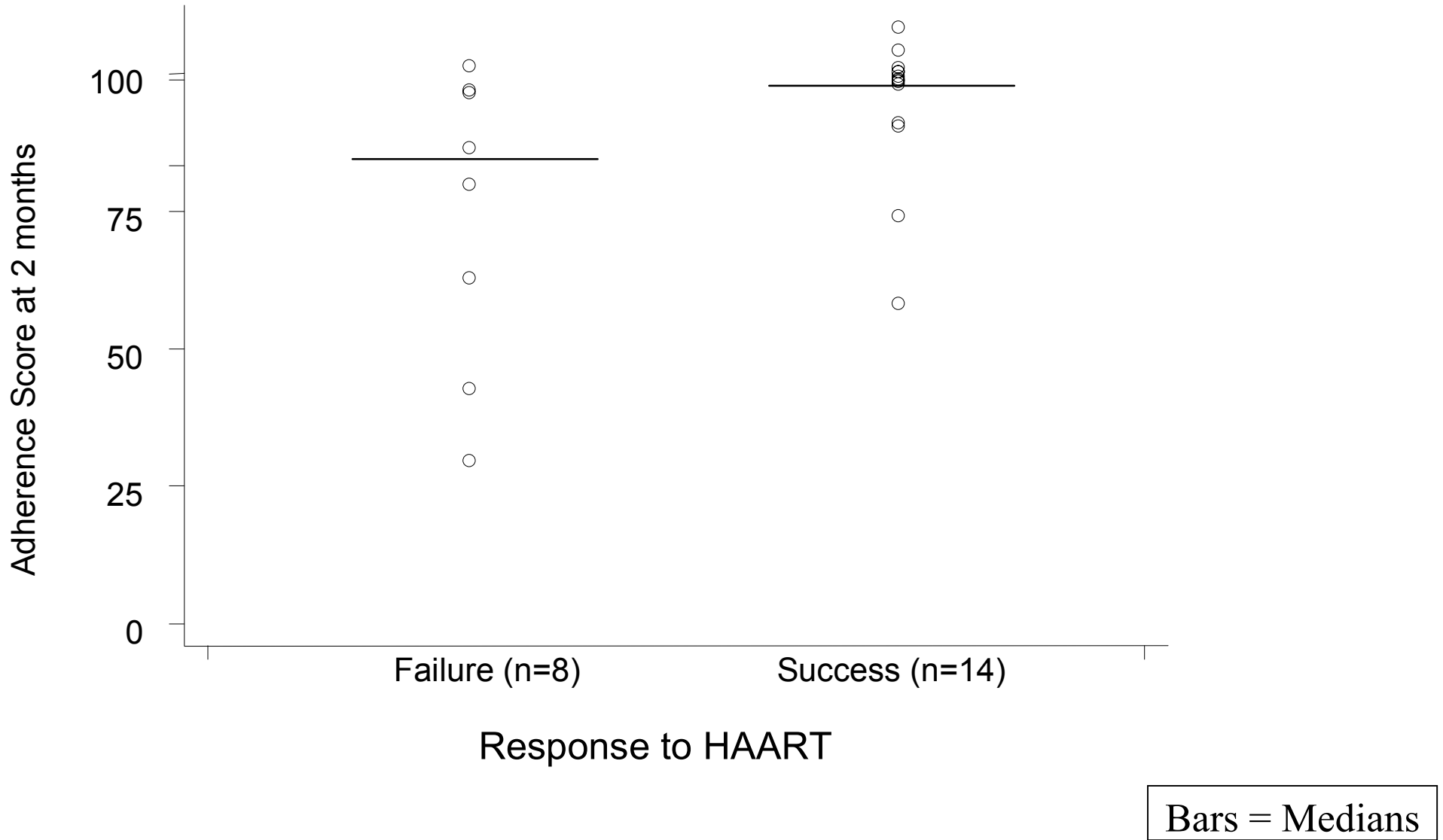


Figure 2 - Adherence scores at 4 months and response to HAART (n=18)

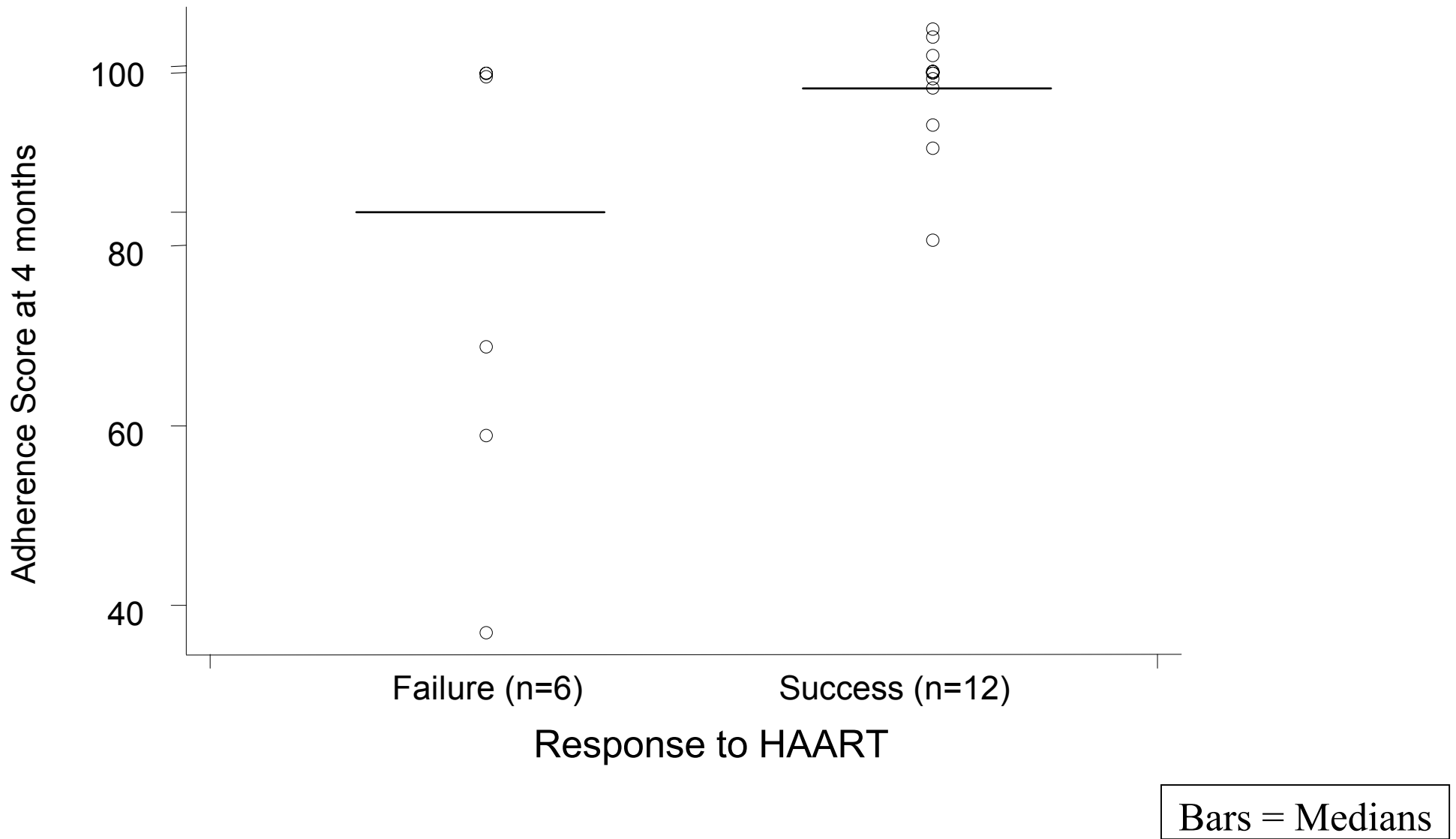


Table 3 - Adherence scores (continuous and categorical) were significantly associated with treatment outcome (logistic regression).

Time of Assessment of Adherence Score	Adherence Score Analyzed as Continuous Variable *		Adherence Score Analyzed as Categorical Variable**	
	OR	P-value	OR	P-value
2 months	1.7	0.063	10	0.029
4 months	2.4	0.081	11	0.07

* OR is for likelihood of achieving < 50 copies/ml per 10% increase in adherence score

** OR is for likelihood of achieving < 50 copies/ml for adherence score > 90% as compared to < 90%

Conclusions

- Higher adherence at 2 months after HAART initiation in patients with early HIV infection was significantly associated with treatment success (defined as a plasma HIV RNA <50 copies/mL at 4 months).
- At either 2 or 4 months after initiation of HAART, increases in adherence levels were associated with a greater probability of success in suppressing plasma HIV RNA at 4 months.

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