

# An Open-Label, Single-Center, Evaluator-Blinded, Randomized, Pilot Study on Perceptions of Efficacy, Self-image, and Adherence in the Treatment of Acne Vulgaris in Teenagers

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Acne vulgaris can be a psychologically disturbing disease and many clinicians believe that patients who are bothered by their disease will better adhere to treatment.

In this study, 61 teenagers with moderate to severe acne vulgaris were enrolled in a study to test 3 adherence interventions and assess if their perceptions of disease severity and medication effectiveness impacted adherence to medical therapy. Adherence was monitored using Medication Event Monitoring System (MEMS) caps. At the end of the study, participants were asked: "Do you believe that the treatment was effective at treating your acne?" and "Overall, how do you feel about your appearance?" Participants' responses were matched with their respective adherence rates. Of the 46 participants that completed the study, adherence rates ranged from 8% to 99%. Survey questions on treatment effectiveness and participant perception of appearance yielded mean responses (SD) of 7.6 (2.4) and 7.9 (2.0), respectively. No correlation was found between treatment adherence rates and survey responses. The study concluded that poor correlation between the psychological impact of disease and treatment adherence may be a general phenomenon. Clinicians should not expect patients who are psychologically distressed by their disease to adhere to treatment simply because they are distressed.

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**N**onadherence to medical therapies is a ubiquitous problem across all fields of medicine and is a common cause of apparent treatment failure.<sup>1,2</sup> Many clinicians believe that visually unpleasant or otherwise psychologically disturbing diseases will generate a high motivation for patients to seek medical treatment, and thus will translate into good adherence to therapy. In dermatology, however, adherence to medications is particularly poor.<sup>3,4</sup>

Acne vulgaris has psychologically detrimental effects on patients, and disease severity often correlates with anxiety, depression, and poor self-esteem.<sup>5-7</sup> The psychological impact of the disease could impact the adherence behavior of patients. Many clinicians believe that the more bothersome a disease is for the patient, the more determined that patient will be to seek medical treatment. However, it is not clear if the psychological stress of a disease or motivation to improve the condition translates to better medication adherence. As part of a larger study on treatment interventions to increase adherence rates in the topical treatment of acne vulgaris, we examined participants' perceptions of efficacy and self-image and how they may relate to treatment adherence (Yentzer BA, Gosnell AL, Clark A, et al, unpublished data, February 2010).

## METHODS

After approval by the Wake Forest University School of Medicine Institutional Review Board, 61 participants aged 13 to 18 years with moderate to severe acne vulgaris were enrolled in an open-label, single-center, evaluator-blinded, randomized, pilot study of 3 groups of participants that received treatment adherence interventions and 1 group that received no adherence intervention (ie, no intervention, increased patient visits, parental reminders, or electronic reminders). Participants were included in the study if they had 15 to 50 inflammatory lesions and 30 to 125 total lesions on the face. A negative urine pregnancy test result was required for female participants at the beginning of the study, and participants were required to use contraception during the study.

All participants included in the study were provided with adapalene gel 0.1% (Differin) for once-daily application on the face in the evening for 12 weeks. Participants also were instructed to discontinue use of all personal care agents on the face except a daily facial cleanser (Cetaphil), which also was provided. Participants who experienced facial dryness were allowed to use a facial moisturizer if it did not contain  $\alpha$ -hydroxyl acid. All participants were evaluated at baseline, week 6, and week 12 by a clinician or physician assistant who was not aware of the treatment adherence interventions for the participant being evaluated.

Treatment adherence was monitored by Medication Event Monitoring System (MEMS) caps, which contain microcircuitry that record the date and time of every bottle opening. Additional measures of treatment adherence included participant diaries and self-reports. Although participants were informed that their adherence would be monitored, they were not specifically informed about the use of the MEMS caps until they completed the study, at which time consent was obtained to use the data collected from each participant. Treatment adherence was analyzed only for participants that completed the 12-week trial and had MEMS data available for all 12 weeks.

At their last visit (week 12), participants completed a survey that included the following 2 questions: "Do you believe that the treatment was effective at treating your acne?" and "Overall, how do you feel about your appearance?" Answers were rated on a 10-point scale (1=worst; 10=best). Pearson product moment correlations, non-parametric Kruskal-Wallis tests, and *t* tests were used to compare overall adherence rates with survey answers.

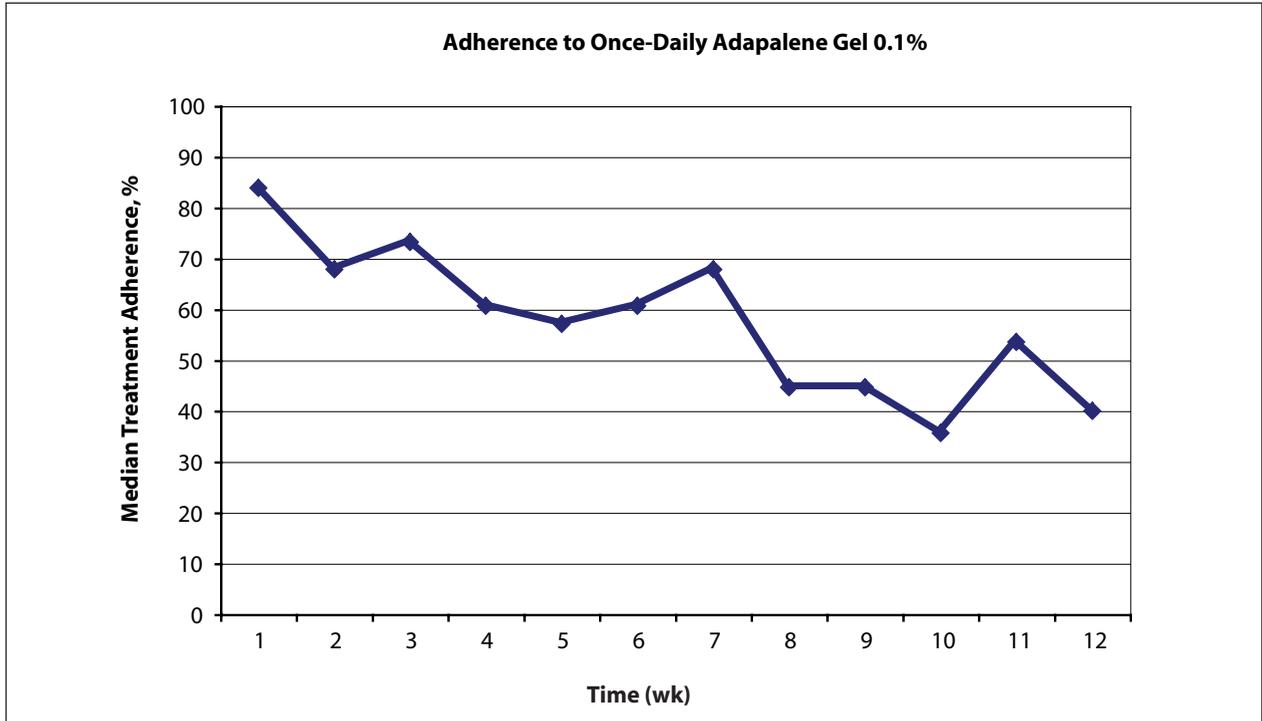
## RESULTS

Of the 61 participants, 46 participants completed the 12-week study and had usable treatment adherence data. Overall adherence to once-daily application of adapalene gel 0.1% ranged from 8% to 99% for the 12-week study period. Adherence to topical therapy declined over time from a group median of 84% for week 1 to 40% by week 12 (Figure 1).

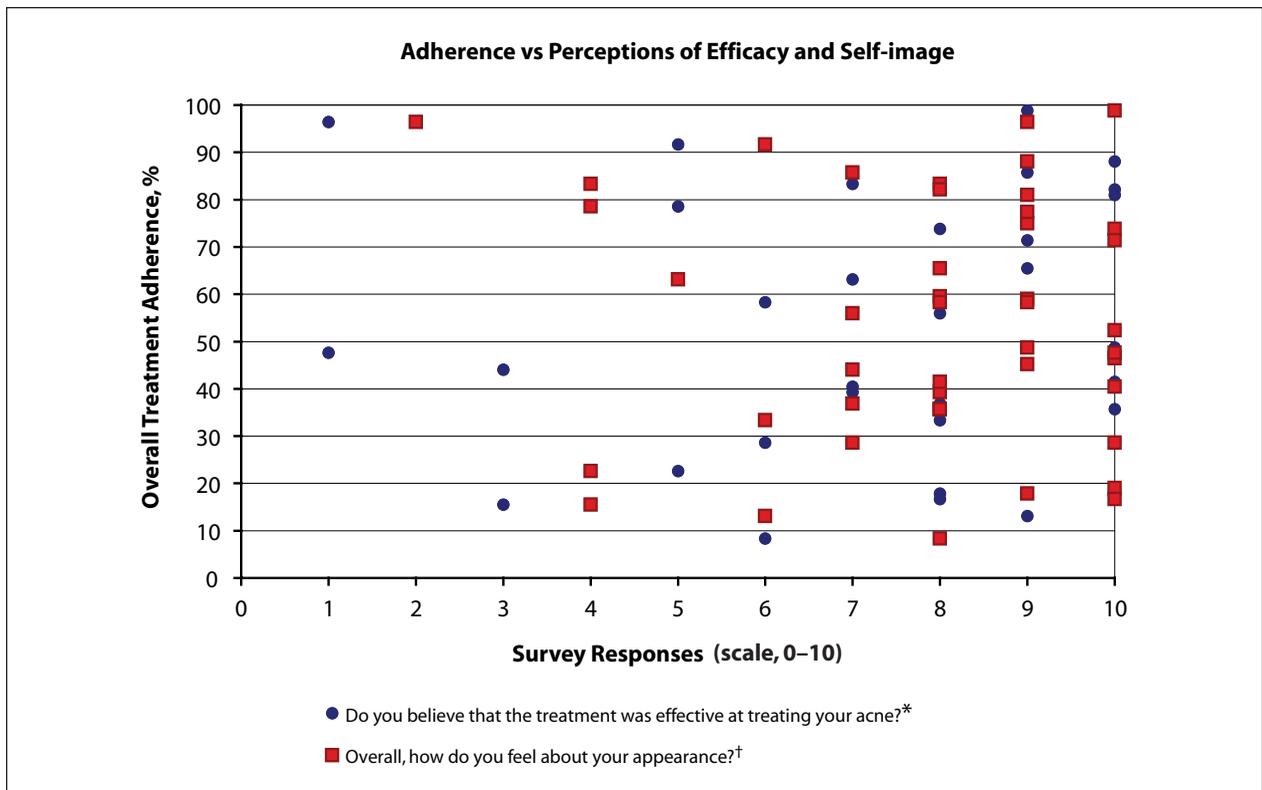
Only 1 of the 46 participants did not respond to the survey. Responses to the survey question: "Do you believe that the treatment was effective at treating your acne?" ranged from 1 to 10 (1=worst; 10=best), with a mean score (SD) of 7.6 (2.4). Participant responses to the survey question: "Overall, how do you feel about your appearance?" ranged from 2 to 10 (1=worst; 10=best), with a mean score (SD) of 7.9 (2.0). There was no association between overall adherence and perception of efficacy or self-image (Figure 2) (Pearson product moment correlations,  $-0.06$  and  $0.01$ , respectively;  $P=.70$  and  $P=.96$ , respectively). Furthermore, there were no statistical differences in overall mean treatment adherence and rating of perceptions of efficacy or self-image when using categorical analysis of low ( $<7$ ) and high ( $\geq 7$ ) responses (nonparametric Kruskal-Wallis test,  $P>.05$ ) (Figure 3).

## COMMENT

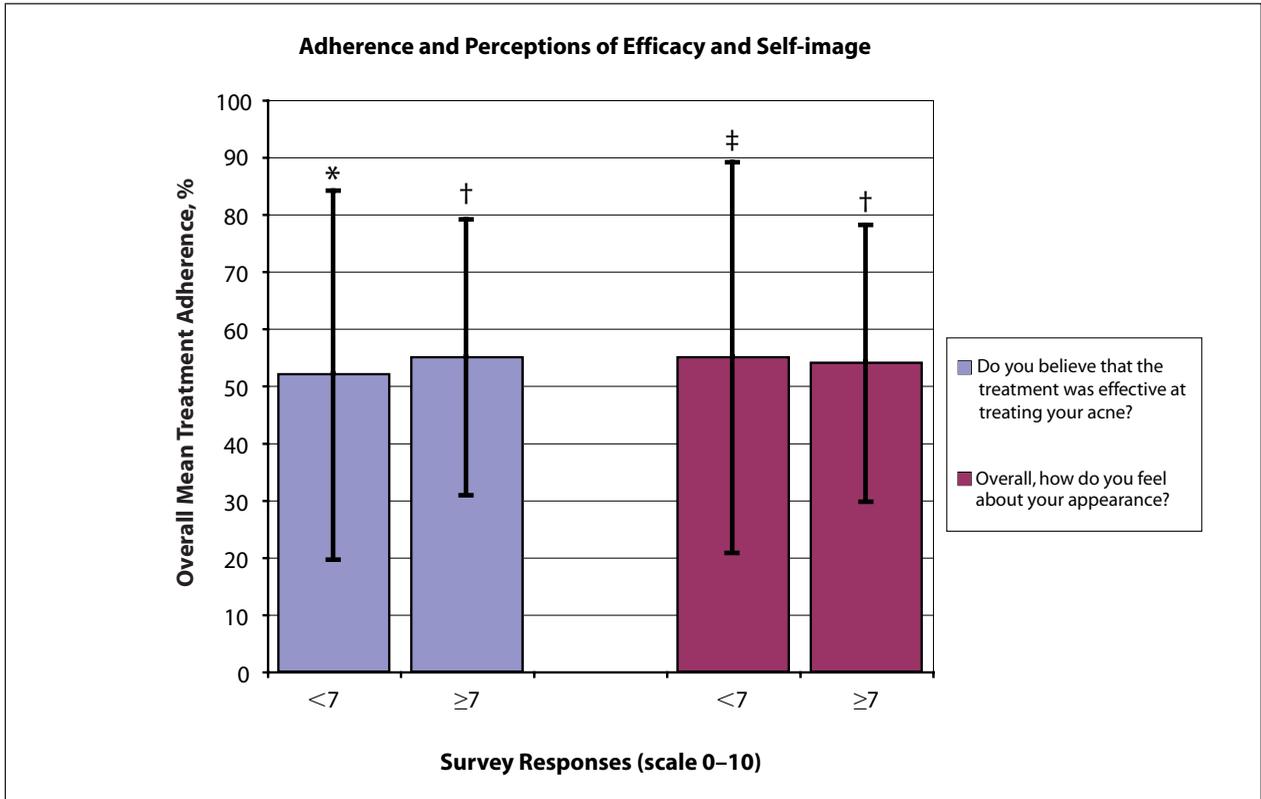
Acne vulgaris is a chronic, potentially disfiguring condition associated with poor self-esteem and depression.<sup>7</sup> Prolonged treatment often is required for improvement and, as with many chronic diseases, adherence to medical therapy is difficult to sustain.<sup>8</sup> The participants in



**Figure 1.** Weekly treatment adherence to once-daily adapalene gel 0.1%, monitored by Medication Event Monitoring System (MEMS) caps, declined over time from a group median of 84% for week 1 to 40% by week 12.



**Figure 2.** There was no association between overall treatment adherence and perceptions of efficacy or self-image (Pearson product moment correlations,  $-0.06$  and  $0.01$ , respectively;  $P=.70$  and  $P=.96$ , respectively). Asterisk indicates mean survey response (SD),  $7.6$  ( $2.4$ ); dagger, mean survey response (SD),  $7.9$  ( $2.0$ ).



**Figure 3.** Differences in overall mean treatment adherence and rating categories on perceptions of efficacy or self-image were not statistically significant when using categorical analysis of low (<7) and high (≥7) responses (nonparametric Kruskal-Wallis test;  $P > .05$ ). Rating was on a scale of 1 to 10 (1 = worst; 10 = best). Error bars indicate SD. Asterisk indicates SD = 32%; dagger, SD = 24%; double dagger, SD = 34%.

our study experienced moderate to severe acne vulgaris, and it may be expected that individuals with distressing disease will adhere to treatment. Although a larger trial may provide better insight into the motivating effects of patient perceptions of efficacy and self-image on treatment adherence rates, it is likely that if such a difference in treatment adherence rates exists, it is too small to be clinically significant. Clinicians should not expect patients who are psychologically distressed by their disease to adhere to treatment simply because they are distressed.

Poor correlation between the impact of disease and treatment adherence may be a general phenomenon. Subjectively worse disease in patients with psoriasis also has not been associated with better adherence.<sup>9</sup> Patients with actinic keratoses, on the other hand, have high rates of adherence to topical therapy.<sup>10</sup> This may be secondary to fear of death related to the premalignant nature of actinic keratoses. However, it also may be that better medical adherence is inherent to this population of older patients.

Adherence to treatment is especially challenging to achieve with teenaged patients.<sup>11</sup> Teenagers may have oppositional defiant relationships with their parents and purposefully fail treatment out of spite. Additionally,

nonadherence in patients with acne vulgaris may result from inadequate education about the disease and its treatment.<sup>12</sup> Patients with acne vulgaris may give up on treatment before the 2 to 3 months that may be required to achieve optimal efficacy.<sup>13-16</sup> Educating patients about the disease and its treatment, simplifying treatment regimens, and using office visits judiciously all may help to improve adherence to acne therapy in teenagers.<sup>12,15,17</sup> Development and validation of interventions to improve adherence to therapy for acne vulgaris is needed.

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