

ACHIEVING AN ENDPOINT OF COMPLETELY CLEAR OF INFLAMMATORY LESIONS AND ERYTHEMA AFTER TREATMENT OF ROSACEA PROVIDES MULTIPLE POSITIVE PATIENT OUTCOMES: A POOLED ANALYSIS

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INTRODUCTION

- Rosacea treatment "Success" is defined on the Investigator Global Assessment (IGA) scale (0 [clear] through 4 [Severe]) as 0 or 1 ("clear" or "almost clear")
- This definition is used in clinical trials, by regulatory bodies, and by payers and physicians
- Is it clinically meaningful to be "clear" vs "almost clear"?
 - What impact is there (if any) on the health related quality of life of rosacea patients?
 - What impact is there (if any) on the time to relapse?

Figure 1. Better Improvement of Rosacea

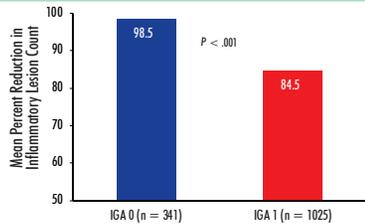
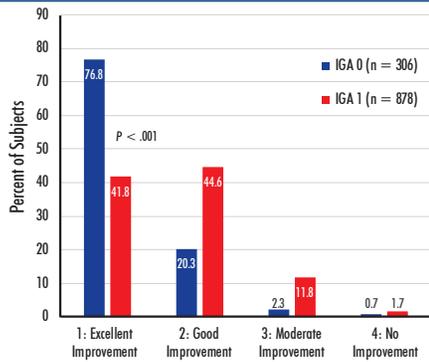


Figure 2. Better Patient Appreciation

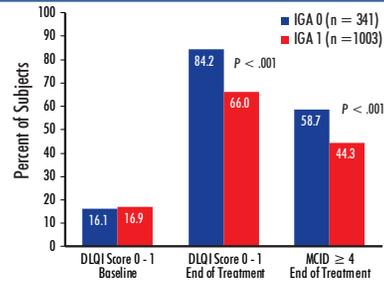


METHODS

Study Design

- Objectives
 - To evaluate whether, after successful treatment, "clear" subjects had better outcomes than "almost clear" subjects
- Methods
 - Pooled analysis of 1366 rosacea subjects from 4 randomized controlled trials with IGA assessments before and after treatment (ivermectin, metronidazole, or vehicle)
- Assessments
 - Dermatology Life Quality Index (DLQI) questionnaire
 - Subject assessment of rosacea improvement
 - Time to relapse
 - Relapse defined as an IGA score of 2 ('mild') after a successful 16-week treatment period (IGA 0/1)

Figure 3. Better Improvement in QoL



DLQI Scores:

- 0 - 1 = No effect at all on the patient's life
- 2 - 5 = A small effect on the patient's life
- 6 - 10 = A moderate effect on the patient's life
- 11 - 20 = A very large effect on the patient's life
- 21 - 30 = An extremely large effect on the patient's life

REFERENCES

- Webster G, Schaller M, Tan J, et al. Defining treatment success in rosacea as 'clear' may provide multiple patient benefits: results of a pooled analysis. *J Dermatol Treat.* 2017;28(5):469-474.

RESULTS

- Mean percent reduction in inflammatory lesions between baseline and end of treatment was 14% better in "clear" subjects than "almost clear" subjects, with a reduction of 98.5% lesions vs. 84.5% (P < .001; Figure 1).¹
- Between baseline and the end of treatment more "clear" subjects reported "excellent" improvement than "almost clear" subjects (76.8% vs. 41.8%; P < .001; Figure 2).¹
- Better mean improvements were observed for the "clear" subjects in all 6 of the domains of the DLQI (Figure 3).
- More "clear" subjects than "almost clear" subjects had a final DLQI score of 0-1 (84% vs. 66%; P < .001).
- More "clear" subjects than "almost clear" subjects had (minimal clinically important difference) MCID (≥ 4 points change) in DLQI score (59% vs. 44%; P < .001).
- Median time to relapse was:
 - 85 days (3 months) for "almost clear" subjects
 - More than 252 days (8 months) for "clear" subjects (Figure 4)
- Relapse was delayed by more than 5 months for "clear" subjects compared to "almost clear" subjects (P < .001; Figure 5).

Figure 4. Median Time to Relapse (Months)

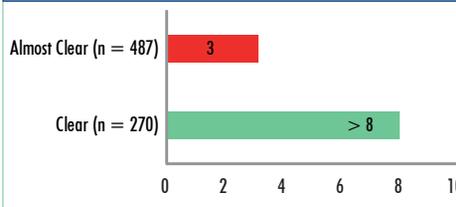


Figure 5. Representative Photographs (10355-108-028)



Figure 5. Median Time to Relapse (Months)

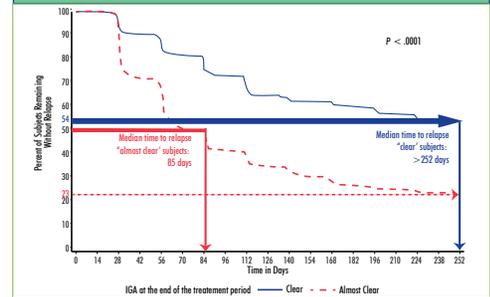


Table 1. Data From 4 Previous Randomized Controlled Trials Were Included in This Analysis

Study	Interventions	DLQI	Subject assessment of rosacea improvement	Time to relapse
SPR.40027	Dose range study IVM 0.1% QD, 0.3% QD, 1% QD, 1% BID and vehicle 12-Week treatment	X	-	-
SPR.18170	IVM 1% vs. Vehicle 12 weeks	X	X	-
SPR.18171	IVM 1% vs. Vehicle 12 weeks	X	X	-
SPR.40173	IVM 1% vs. Metro 0.75% 16 weeks (36-week follow-up)	X	X	X

SUMMARY

- These results emphasize that achieving an endpoint of IGA 0 ("clear") in rosacea may provide multiple patient benefits and a significantly prolonged time before relapse
- Achieving a treatment outcome of "clear" provides
 - Better patient appreciation of rosacea improvement
 - 35% more subjects reported 'excellent improvement'
 - Better improvement in quality of life, as measured by DLQI
 - A longer time to relapse
 - ≥ 5 months relapse-free time