Effect of Phenylephrine on Injection Site Reactions in Multiple Sclerosis Patients Treated with Plegridy (peginterferon beta-1a)

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Objective

- The primary objective was to assess whether phenylephrine cream can reduce injection site reactions (ISRs) appearing after peg-interferon sub-cutaneous injection.
- The secondary objective was to assess whether the phenylephrine cream can reduce the burden of ISRs on quality of life.

Background

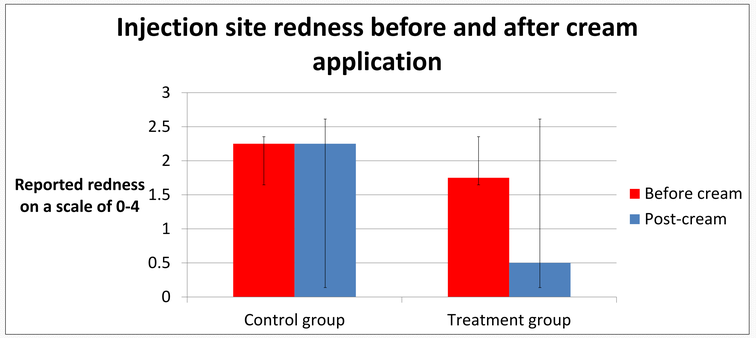
- Injection site reactions (ISRs) which may include pain, swelling, and redness at the injection site are common side effects of the sub-cutaneous (SC) interferon medications including peginterferon beta-1a (Plegridy), an SC disease-modifying therapy for relapsing Multiple Sclerosis (RMS). There is currently no standard protocol for managing ISRs for interferon-beta medications, despite the burden ISRs may place on patients.
- We believe Maximum Strength Preparation H Cream may decrease post injection pain and phenylephrine may decrease post injection erythema. Adherence to therapy is widely recognized as a barrier to optimal disease management and while reducing dosing frequency may improve adherence, medication tolerability still remains a barrier to adherence.

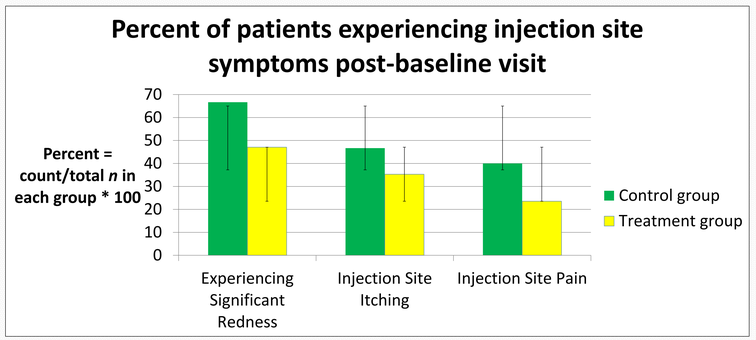
Methods

- 32 persons with relapsing-remitting MS (RRMS) who were Plegridy treatment-naïve or on treatment (≤12 months) were enrolled and randomized to one of two groups: 1) Topical Preparation H arm and 2) Non-treatment arm. The Preparation H arm applied the phenylephrine cream at the first sign of erythema at least 2 hours after the first *titration* dose of Plegridy. The non-treatment arm did not apply phenylephrine cream at first incidence of erythema, but at least 2 hours after the first *full* dose of Plegridy.
- Patients completed diaries on a portable device for up to10 days post-injection. Injection location, duration, and pain were recorded in the Injection Diary. Frequency of redness, itching, and swelling after an injection, as well as degree of burden on daily activities, were recorded in the Multiple Sclerosis Treatment Concerns Questionnaire (MSTCQ) diary. Degree of redness was recorded in the Site Reaction Diary 6-8 hours after post-cream application.
- Descriptive stats were provided; t-tests were performed to compare the endpoints between the two treatment arms.

Table 1: Demographic Characteristics

	Treatment (n=17)	Control (n=15)
Age (mean±SD)	48.5±10.9	43.1±15.5
Naïve to Plegridy (%)	29.4	33.3
Previous Interferon (%)	41.2	66.7
Gender (%Female)	82.4	80.0
Ethnicity (%Hispanic)	6.7	0.0
Race (total #)	-	-
Caucasian:	10	14
African American:	6	1
Asian:	0	0
Mixed/Other:	1	0
Unknown/Unreported:	0	0





Results

- Change scores in average ISR redness were used to calculate improvement in redness from baseline to post-cream. Patients rated their redness in the Site Reaction Diary, which utilized a 4-point Likert scale (0 indicating no redness and 4 indicating completely unacceptable redness). While the reported redness for the treatment group decreased after cream application (*M*=-0.50, *SD*=0.71) compared to no change in the control group *(M*=0.00, *SD*=0.00), this group difference was not statistically significant (*p*=0.34).
- Change in MSTCQ scores was the secondary endpoint, with higher scores indicating a more bothersome ISR measured by reaction duration, frequency, and interference in daily activities. MSTCQ scores for the specific question, “How bothersome is the site reaction?” from Baseline to Day 29 decreased in the treatment group (*M*=-0.33, *SD*=0.61) and increased in the control group (*M*=0.38, *SD*=0.75). This change, however, was not statistically significant (*p*=0.24).
- Of note, the study was not powered to detect statistical significance, so lack of significance may not necessarily be indicative of lack of effectiveness.

Conclusions

- Topical treatment with phenylephrine for the management of ISRs showed trends towards efficacy, specifically reducing injection site redness, in this pilot study. More studies with larger sample sizes are needed to verify the safety and efficacy of this intervention.

References

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