



Post Marketing Safety Determination for Subcutaneous C1-Inhibitor Prophylactic Treatment in Hereditary Angioedema

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Background

- Hereditary Angioedema (HAE) is a disorder with recurrent episodes of angioedema due to excessive bradykinin production.
- Angioedema most often presents in the gastrointestinal or cutaneous tissue. Laryngeal angioedema is less common but can be life-threatening.
- There are various treatments available for acute episodes of angioedema and for prophylaxis.
- In some patients, especially in those with frequent episodes of angioedema, prophylaxis is started.
- Subcutaneous C1-inhibitor ([C1-INH(SC)] Haegarda®) is a newly approved prophylactic medication. It is self-administered twice weekly.
- Initial randomized multicenter trials showed that patients on this medication had 3.51 fewer attacks per month compared with placebo.
- Most commonly reported adverse effects included injection site reactions, hypersensitivity, nasopharyngitis, and dizziness.

Objective

- The aim of this quality assessment was to evaluate compliance, tolerability and safety of C1-INH(SC) in our HAE patients.

Methods

- We identified thirteen of our HAE patients, who are on C1-INH(SC) prophylaxis.
- We conducted an 11-question telephone survey.
- The goal was to determine if our patients use this medication correctly, experience adverse effects and how much they benefit from this medication.

Results

C1-INH(SC)	
Used as directed	9 patients (82%)
Average tolerability (range: 1 to 5)	4.6
Ease of injection (range: 1 to 5)	4.2
Experienced local side effects*	8 patients (73%)
Other adverse effects	0
Average time to inject the medication	5.9 minutes
Decreased frequency of attacks	11 patients (100%)
Average attack rate prior to start of medication	2.3 attacks per month
Average attack rate after the start of medication	0.3 attacks per month
Improved quality of life	11 patients (100%)
Decreased anxiety	10 patients (91%)

*local side effects reported included swelling, bruising or redness at injection site

Conclusion

- Most of our patients used this medication correctly and tolerated it very well.
- It was thought to be easy to inject. Even though side effects were common, compliance was not affected. Side effects were only local.
- All patients benefited from this medication and had decreased rate of attacks by an average of 2 attacks per month.

References

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