



Variation in Xiaflex Practice Patterns: A Survey of International Sexual Society (ISSM) Members (MP65-07)

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Introduction

- Xiaflex (collagenase clostridium histolyticum, CCH) is only FDA approved drug for treatment of Peyronie's Disease (PD)
- Package insert instructions largely based on IMPRESS I and IMPRESS II trials
- Emerging data shows efficacy of CCH in protocols that do not strictly adhere to the package insert (ie use in active phase, ventral plaques, less than 30 degree curvature, different dose schemes with fewer follow-up visits)
- We created an online survey to investigate how practitioners actually use CCH in their own practices, to assess for adherence and evaluate factors that are associated with adherence.

Aims

- To identify variability in practice patterns for CCH among practitioners
- To assess adherence to the package insert instructions
- To evaluate whether provider satisfaction was associated with adherence to instructions

Method

- We created a 30-question online survey on SurveyMonkey
- The survey included demographic questions, examined practice patterns and satisfaction with the CCH product.
- Survey distributed to 1,270 members of the International Society for Sexual Medicine (ISSM) from the European Union, United States, Canada and Australia
- Of the 30 questions, 10 had only one "correct" response that was consistent with the CCH package insert recommendations.
- We calculated an "adherence score" for each survey responder by summing the number of correct responses out of 10
- We assessed what demographic factors were associated with better package insert instruction adherence
- We also evaluated associations between demographic factors and product satisfaction and between adherence scores and product satisfaction
- The mean adherence scores of various groups were compared using the student's t-test
- A chi-squared test was used to determine associations between categorical variables and satisfaction

Results

•132 practitioners reported using CCH out of 1,270 ISSM members from countries where CCH is available (10.4% response rate)

Results

Demographic Information			
Sex	Male	Female	
	95.7%	4.3%	
Age	<35yo	35-55yo	>55yo
	13.6%	60.2%	26.3%
Years in practice	<5y	5-15y	>16y
	31.4%	25.4%	43.2%
Andrology fellowship trained	Yes	No	
	62.7%	37.3%	
Practice	Academic	Private	Mixed
	39.8%	28.8%	31.4%
Country	USA	Outside USA	
	66.1%	33.9%	
Number of CCh administrations	< 10	10-20	>20
	27.9%	16.2%	55.9%

Table 1: Demographic information of survey respondents

- There were no statistically significant differences in adherence scores between the following groups: fellowship vs non-fellowship trained, experienced (>20 uses) vs. less experienced (<10 uses), younger (<35 years old) vs older (>55 years old), those within 5 years of finishing residency vs those 16+ years post-residency, and academic vs private practitioners.
- 66.9% of respondents believed they "followed the protocol outlined in the Xiaflex package insert", but only 10.7% of providers had perfect adherence scores
- Practitioners from the USA had significantly better adherence scores than those outside the USA (average 7.7 vs 5.9, p<0.001).

Xiaflex Package Insert Instructions	% of respondents deviating from recommendation
2 nd injection of cycle 1-3 days after first	52.5
Inject 0.25mL of reconstituted solution	49.2
Inject entire dose at one site	39.3
Maximum number of treatment cycles is 4	36.9
Avoid plaques involving urethra (ie ventral)	32.8
Use Xiaflex for >30-degree curvature	29.5
Define max curvature via artificial erection	27.0
Do not need to hold low-dose aspirin	13.9
Recommend no sex for at least 2 weeks after injection	7.3
Modeling is recommended	6.6

Table 2: Overall adherence to Xiaflex package insert recommendations. Adherence to these 10 package insert instructions were used to determine adherence scores

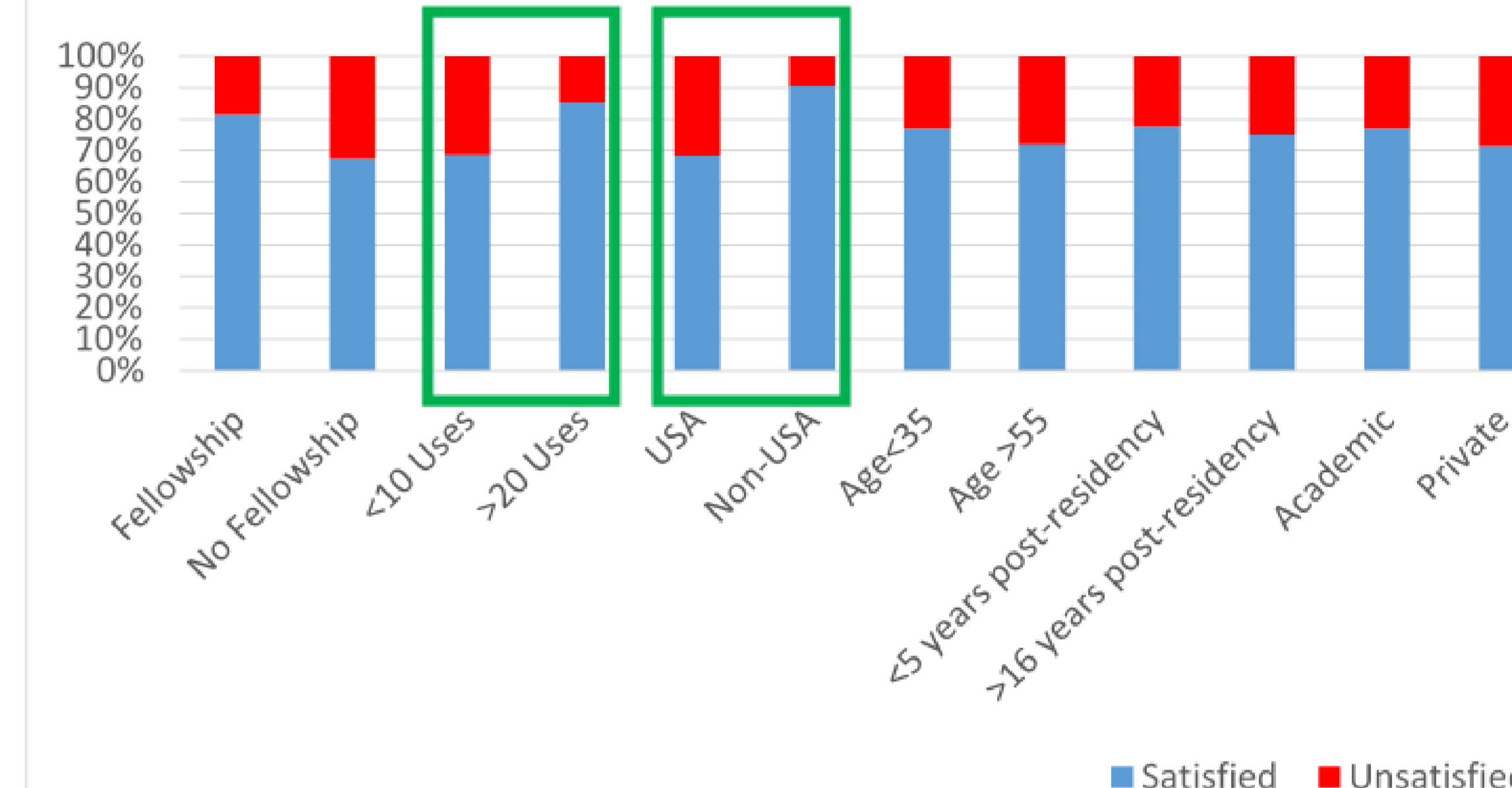


Figure 1: Percentage of each demographic group that answered "yes" to the question "Are you, as a provider, satisfied with the product CCH?" (Answer choices were "yes" or "no"). Statistically significant differences outlined in GREEN

- Overall 76.2% of responders were satisfied with CCH
- Satisfied users of CCH did not have significantly different adherence scores than non-satisfied users
- The most common reasons for dissatisfaction were perceived poor treatment response (85.7%) and difficulty with insurance coverage for treatment (54.1%).

Conclusions

- CCH practice patterns are non-uniform
- Users of CCH commonly deviate from the package insert guidelines
- Overall, adherence to CCH package insert instructions is not associated with greater satisfaction of the product by binary assessment of satisfaction
- Practitioners from the USA tended to adhere better to the package insert guidelines, but were less satisfied with CCH
- Study limitations included: Incomplete answering of survey by some participants, recall bias, low response rate, satisfaction data not granular.

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