Editorial

Serious complications of collagenase clostridium histiolyticum injection for Peyronie's disease: more than meets the eye!

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Provenance: This is a Guest Editorial commissioned by Section Editor Yongde Xu, PhD (Department of Urology, First Hospital Affiliated to Chinese PLA General Hospital, Beijing, China).

Comment on: Yafi FA, Anaissie J, Zurawin J, *et al.* Results of SMSNA Survey Regarding Complications Following Intralesional Injection Therapy With Collagenase Clostridium Histolyticum for Peyronie's Disease. J Sex Med 2016;13:684-9.

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The serious adverse effects of collagenase clostridium histiolyticum (CCH) injection for the treatment of Peyronie's disease include penile hematoma and fracture, yet the broad prevalence of these complications was incompletely understood until recently. Yafi *et al.* examined the prevalence of these serious complications across members of the Sexual Medicine Society of North America (SMSNA), and their survey results shed important light on practice patterns and complication rates observed by CCH prescribers. Survey results were obtained from 100 members of the SMSNA who prescribe CCH and revealed significant variation in post-injection management and treatment of procedural complications of post-injection hematoma and corporal fracture. Of the 100 survey respondents, only 37% utilized a dressing or wrap after injection, and only 54% stopped anticoagulants or antiplatelet agents prior to injection. A large fraction (27%) of respondents reported severe hematomas in >10% of patients, and even more (34%) reported corporal fracture among their patients. Of the providers who had treated corporal fractures after CCH injection, 6 had encountered two fractures and 1 provider had encountered three fractures (1). These numbers are significantly higher than those previously reported in the peer reviewed literature. In the IMPRESS I & II trials, only 6 of 551 (1.1%) patients treated with CCH reported severe adverse events (3 severe hematomas, 3 corporal fractures) (2). Yang and Bennett reported 4 hematomas (8%) and 1 corporal fracture (2%) out of 49 CCH-treated subjects (3). In contrast to the above, Levine *et al.*'s phase 3 study of 347 CCH treated patients reported an even lower rate of severe adverse events, with a total of 3 (0.8%) (2 hematomas, 1 corporal fracture) (4).

Although Yafi *et al.*'s survey data cannot assess the overall frequency of severe adverse events following CCH injection and are limited by an overall small number of respondents, the data do imply that the rate of significant complications after CCH injection may be higher than previously reported. However, this should be taken in the context that complication rates may vary in light of a lack of standardized definitions of these complications, limiting direct comparisons. While the management of corporal rupture generally involves surgical intervention, only 67% of survey respondents proceeded with surgical intervention, and of these, 62% qualitatively reported that the tissue quality after CCH associated fracture was worse than what is typically expected after a fracture not associated with CCH. While 33% of providers proceeded with non-surgical management of corporal ruptures, comparisons of outcomes between the two groups are challenging given the lack of a standard definition of post-CCH corporal rupture and the inability to objectively assess the severity of corporal ruptures.

Current CCH prescriber information recommends waiting "at least 2 weeks" after completion of a CCH injection treatment cycle before resuming sexual activity.

Interestingly, 44% of providers reported corporal ruptures after the 2-week period; no ruptures were reported beyond 30 days after injection (1). Yafi *et al.* suggest that providers could consider extending sexual activity restrictions to 30 days post-injection, as vigorous sexual intercourse could play a role in CCH associated corporal ruptures between 14 and 30 days after injection.

This study provides valuable data regarding the practice patterns and complications of a relatively large cohort of CCH prescribers for the management of Peyronie's disease. Although the study design does not allow for a robust analysis of complication rates following CCH injection, it brings to light the possibility that significant complications from CCH treatment may be under reported. This highlights the need for further investigation to better understand the risks of adverse events following CCH injection as well as measures that can be taken in order to maximize patient safety and treatment efficacy across the spectrum of providers who treat the condition.

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Footnote

Conflicts of Interest: Dr. AW Pastuszak is an advisory board member and consultant for Endo Pharmaceuticals. Dr. C Hobaugh has no conflicts of interest to declare.

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