

Baseline Characteristics from an Ongoing Phase 3 Study of Collagenase Clostridium Histolyticum in Patients with Peyronie's Disease

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ABSTRACT

Introduction. Peyronie's disease (PD) is a localized penile collagen disorder of the tunica albuginea associated with significant physical deformity and psychological impairment. Current understanding of pretreatment characteristics in patients with chronic PD is limited by small samples, varied quality of assessments, and the lack of a PD-specific, validated measure of the psychosexual impact of PD.

Aims. Reporting baseline demographic and disease characteristics of the large multinational cohort of subjects with chronic PD who participated in the collagenase clostridium histolyticum (CCH, an investigational intralesional injection and minimally invasive intervention) phase 3 clinical study program. Findings from well-defined assessments, including the Peyronie's Disease Questionnaire (PDQ), the first validated PD-specific patient-reported measure of psychosexual impact, are reported.

Methods. Subjects included men ≥ 18 years old with PD symptoms ≥ 12 months and penile deformity between 30° and 90° . Analysis data included demographics, disease history, and psychosexual impact.

Main Outcome Measures. Penile deformity, disease symptoms, the International Index of Erectile Function, and the PDQ were assessed.

Results. Eight hundred thirty-two subjects were enrolled from 64 sites across the United States and Australia. The mean age was 57.7 years; mean PD duration was 4.1 years. The majority of subjects had penile deformity $\leq 60^\circ$ (77.3%); mean penile deformity was 50.5° . Subjects reported having intercourse a mean of 10.2 times in the previous 3 months, 70.8% reported difficulty in performing vaginal intercourse, and 80.4% reported less frequent vaginal intercourse. Approximately 71.5% of subjects with severe ($>60^\circ$) and 58.1% of subjects with mild/moderate ($\leq 60^\circ$) penile deformity were "very bothered" or "extremely bothered" upon last look at their erect penis ($P = 0.0041$), as measured by the PDQ.

Conclusions. These data add to the body of knowledge regarding the clinical impact of chronic phase PD, including the PD-specific patient-reported psychosexual symptoms, using a large multinational chronic PD cohort in the CCH phase 3 clinical program. **Gelbard M, Hellstrom WJG, McMahon CG, Levine LA, Smith T, Tursi J, Kaufman G, and Goldstein I. Baseline characteristics from an ongoing phase 3 study of collagenase clostridium histolyticum in patients with Peyronie's disease. J Sex Med 2013;10:2822–2831.**

Key Words. Peyronie's Disease; Penile Induration; Clostridium Histolyticum; Questionnaires

Introduction

Peyronie's disease (PD) is an inflammatory disorder that is characterized by the formation of nondistensible collagen plaques in the tunica albu-

ginea of the penis [1–5]. These plaques lead to alterations in the ability of the tunica to expand uniformly, which causes varying degrees of penile deformity, including curvature and other deformities such as notching or hourglass defects, during

erection [1,6]. Within the general population, the reported prevalence of PD ranges from 0.39% to 7.1% [7–9], whereas varied results are observed in other studies according to study design and the patient population included. For example, in men undergoing prostate exams, the prevalence of PD ranges from 3.67% to 8.9% [10,11], whereas patients with comorbidities, such as erectile dysfunction (ED) and/or diabetes mellitus, have had prevalence ranges reported as high as 7.9% to 20.3% [12–14].

Patient demographics and disease characteristics, such as history of trauma to the erect penis, the presence of Dupuytren's disease or family history of PD, degree of penile deformity, plaque location and calcification, and presence of ED, are important in the diagnosis of PD and/or may contribute to understanding the pathogenesis of PD and patient response to treatment [3–6,15]. Shortcomings in the existing literature characterizing patients with PD include small sample sizes and variation in the type and quality of measures used [16–18].

The genitourinary evaluation in the flaccid state should include stretched penile length, as well as identification of plaque characteristics and the presence of pain on palpation [3]. Penile erection should be initiated by intracavernosal injection of vasoactive agents with or without concomitant visual sexual stimulation. The genitourinary evaluation in the erect state should assess the severity of the deformity, including degree of penile deformity as determined by goniometry with or without photography. The use of imaging by penile duplex Doppler ultrasonography in the flaccid or erect state allows detection of plaque location and calcification and assessment of penile vasculature in the presence of ED [3,4,6,19].

PD can be associated with significant distress and sexual dysfunction [20]. In addition to the physical impairment, the psychological impact of the disease can be profound and should be included as part of the disease assessment [3,21]. Forty-eight percent of PD patients have clinically relevant depression [22]. High levels of emotional distress, self-esteem issues, and relationship difficulties have also been reported [20,21]. ED, which may result from an underlying vascular disease or be related to the psychological and/or physiological components of the disease [19,23], is another common complaint among patients with PD [1,3,24]. The International Index of Erectile Function (IIEF) has been used to assess sexual function and treatment-related changes among

PD patients, although it was not targeted to and has never been validated in the PD population [16].

A significant barrier to understanding the psychosexual impairment associated with PD has been the lack of a validated PD-specific measure. A validated measure specific to PD that takes into account the psychosexual impact of the disease severity and evaluating treatment efficacy over time. A novel PD-specific questionnaire, the Peyronie's Disease Questionnaire (PDQ), was developed with the guidance of the Food and Drug Administration's Study Endpoints and Labeling Development group and in accordance with established scientific standards [25]. The validated PDQ measure, included in the phase 3 clinical program for collagenase clostridium histolyticum (CCH, an investigational, intralesional, minimally invasive intervention), assesses the impact and severity of PD symptoms in three domains: Symptom Bother, Psychological and Physical Symptoms, and Penile Pain [26]. The current study examines baseline data from the CCH phase 3 clinical program and provides the first opportunity to characterize PD-specific psychosexual symptoms using the PDQ in a large, multinational cohort of men with chronic PD.

Aims

The objectives of the current analysis were to analyze baseline demographics and disease characteristics in the large multinational and multi-institutional cohort of subjects with chronic (>1 year) PD who participated in the CCH phase 3 clinical study program. Patients were studied according to uniform criteria using well-defined procedures. Novel findings using the newly developed PDQ, the first validated PD-specific patient-reported measure of the psychosexual impact of PD, are reported.

Methods

Overview of Study Design

Two identical, randomized, prospective, double-blind, placebo-controlled phase 3 studies were carried out at study sites in the United States and Australia and analyzed together in this report (The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies [IMPRESS] I and II). The study protocols were approved by an

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