The Effect of Duration of Penile Traction Therapy in Patients Undergoing Intralesional Injection Therapy for Peyronie's Disease

Faysal A. Yafi, Michael R. Pinsky, Carrie Stewart, Premsant Sangkum, Erhan Ates, Landon W. Trost, Suresh C. Sikka and Wayne J. G. Hellstrom*,†

From the Department of Urology, Tulane University School of Medicine, New Orleans, Louisiana (FAY, MRP, CS, PS, SCS, WJGH), Akdeniz University School of Medicine, Antalya, Turkey (EA), and Mayo Clinic, Rochester, Minnesota (LWT)

Abbreviations and Acronyms

CCH = collagenase clostridium histolyticum

EDV = end diastolic vascular velocity

IFN = interferon α-2b

ILI = intralesional injection

PD = Peyronie's disease

PSV = peak systolic velocity

PTT = penile traction therapy

SPL = stretched penile length

Accepted for publication March 11, 2015.

* Correspondence: Department of Urology, Tulane University Health Sciences Center, 1430 Tulane Ave. SL-42, New Orleans, Louisiana 70112 (telephone: 504-988-3361; FAX: 504-988-5059; e-mail: whellst@tulane.edu).

† Financial interest and/or other relationship with Abbvie, Allergan, American Medical Systems, Antares, Apricus, Astellas, Auxilium, Coloplast, Endo, Lilly USA, New England Research Institutes Inc., National Institutes of Health, Pfizer, Promescent, Repros Therapeutics and Theralogix.

Purpose: The concomitant use of penile traction therapy with interferon α-2b has been previously described. We present an update on our clinical experience to assess the benefit and duration of daily traction.

Materials and Methods: A retrospective review of patients who underwent interferon α-2b therapy between 2001 and 2012 was performed. Charts were reviewed and data collected regarding various patient demographics, vascular parameters, objective length and curvature measurements, and use of penile traction therapy. Penile traction therapy was further stratified according to duration of daily use.

Results: A total of 112 patients underwent a median of 12 interferon α-2b injections (range 6 to 24). Daily use of penile traction therapy was reported by 31% of patients. There were no differences in patient demographics, initial vascular status, pretreatment stretched penile length, erect circumference and curvature between patients who followed a penile traction therapy regimen and those who did not. Overall, the use of penile traction therapy did not effect change in penile circumference (with therapy +3.2 mm [SD 6.5] vs no therapy +2.1 mm [SD 7.4], p=0.45), change in curvature (with therapy −8.1 degrees [SD 16.0] vs no therapy −9.9 degrees [SD 11.8], p=0.49) or change in stretched penile length (with therapy +2.4 mm [SD 0.9] vs no therapy +1.3 mm [SD 0.8], p=0.56). Men who used penile traction therapy 3 or more hours per day gained significantly greater stretched penile length compared to those who did not use penile traction therapy (4.4 mm [SD 0.5] vs 1.3 mm [SD 0.8], p=0.04).

Conclusions: Routine penile traction therapy during intralesional injection with interferon α-2b for Peyronie's disease may result in a small but subjectively meaningful improvement in stretched penile length, without affecting curvature, if used for at least 3 hours a day.

Key Words: penile induration; traction; injections, intralesional; interferon alfa-2b

PEYRONIE'S disease is characterized by the abnormal deposition of fibrous plaque(s) in the tunica albuginea, resulting in penile curvature, pain and deformity. PD prevalence rates range from 3.2% to 8.9% in the general population and up to 20.3% in specific subgroups.[1–3] As a nonsurgical option for the treatment of PD, intralesional injection therapy has been well-defined, although the role of concomitant or adjunct penile traction therapy remains uncertain.

As monotherapy for patients after prostatectomy, PTT has demonstrated preservation of penile length.[4]

0022-5347/15/1943-0754/0
THE JOURNAL OF UROLOGY®

http://dx.doi.org/10.1016/j.juro.2015.03.092
Vol. 194, 754-758, September 2015
Printed in U.S.A.

However, PTT has failed to demonstrate significant improvements in penile curvature with extended use as monotherapy in the patient with PD.[5] After surgical correction of curvature for PD, the use of PTT is associated with increased penile length and perception of length preservation.[6] The same claims cannot yet be made for the use of PTT with nonsurgical methods of PD treatment. While the concomitant use of PTT with verapamil or interferon α-2b has been described previously, there is a paucity of available literature and some discrepancy among the results.[7,8] We present an update on our clinical experience with men undergoing ILI therapy with IFN to assess the benefit of the duration of daily PTT use in this patient population.

MATERIALS AND METHODS

Retrospective data were collected from 127 patients who underwent intralesional IFN injections for the treatment of PD at a single institution between 2001 and 2012. Charts were reviewed, and data regarding various patient demographics, vascular parameters from penile duplex Doppler ultrasound, and length and curvature measurements were collected before and after treatment. Furthermore, information regarding the use and frequency of use of PTT (Andropenis®) was collected. Data regarding PTT were available for 112 patients.

All patients underwent baseline penile duplex Doppler ultrasound after intracavernosal injection of a vasodilator agent (prostaglandin E1) 2 to 4 weeks before and 6 to 8 weeks after final ILI. Peak systolic velocity, end diastolic vascular velocity and resistive index (defined as PSV minus EDV divided by PSV) were recorded, and used to determine the etiology of erectile dysfunction. Arterial insufficiency was defined as PSV less than 30 cm per second and EDV as 5 cm per second or less, veno-occlusive dysfunction as EDV greater than 5 cm per second and PSV 30 cm per second or greater, mixed vascular disorder as PSV less than 25 cm per second and EDV greater than 5 cm per second, and finally nonvascular etiology as PSV greater than 30 cm per second, EDV 5 cm per second or less and resistive index greater than 0.8.[9]

The circumferential penile diameter was measured at mid shaft. Before intracavernosal injection phallus length was measured after maximal manual stretch from the base of the penis at the pubopenile junction to the tip of glans. This measurement strategy was considered the easiest, most reproducible and most accurate technique. It allows accounting for anatomical discrepancies, excess fat in the infrapubic area as well as glans expansion at erection. Post-injection measurements were made at peak erection. The degree of penile curvature, its direction and the presence of any hourglass deformity or indentation were also recorded.

Treatment with interferon consisted of biweekly injections of 2,000,000 U IFN suspended in 10 cc normal saline. Beginning in 2008 patients were routinely counseled to use PTT a minimum of 2 hours daily but more if possible. PTT use was identified in the medical records based on patient self-reporting of compliance with 2 hours of therapy on a regular basis. Patients were divided into 2 groups based on whether they followed (group 1) or did not follow (group 2) a regular PTT regimen. Duration (hours per day) of use was also collected by personal interview.

Statistical analysis was performed using SAS® 9.2 for Windows®. Continuous variables were expressed as means ± SD. The Student t-test was used to determine differences between continuous variables. Categorical variables were presented as percentages. The Pearson chi-square test or Fisher exact test, as appropriate, was used to determine differences in categorical variables and $p < 0.05$ was considered statistically significant.

RESULTS

Overall, 127 patients underwent a median of 12 IFN injections (range 6 to 24). Mean age of the cohort was 54.5 years (SD 9.5) and 88% of the patients were in a sexual relationship. Mean duration from onset to presentation with PD was 2.9 years and 48% of patients reported receiving previous oral therapy. Mean baseline SPL and circumference at peak erection were 13.2 and 11.4 cm, respectively. The remaining demographic, clinical and disease specific information is presented in table 1. A total of 34 patients (31%) reported regular use of PTT. There were no differences between the 2 groups in terms of age, body mass index, IIEF-5 (International Index of Erectile Function) score, years with PD, previous oral therapy, degree or duration of curvature, and pretreatment SPL and erect circumference. Patients who did not undergo PTT were more frequently in a relationship (93.4% vs 76.5%, p=0.0109), and had less hourglass deformity (19.2% vs 47.1%, p=0.0025) and less vascular erectile dysfunction etiology (64.1% vs 82.4%, p=0.03).

When comparing the before and after IFN therapy data there was no significant difference in change in mean SPL (+2.4 vs +1.3 mm, p=0.56), mean erect circumference (+3.2 vs +2.1 mm, p=0.45) or mean degree of curvature (−8.1 vs −9.9 degrees, p=0.49) between patients who routinely underwent PTT for any duration and those who did not (table 1). Detailed information by personal inquiry regarding daily stretching frequency was available for 18 patients who were following a PTT regimen. When these patients were stratified according to frequency of stretching (less than 3 hours daily [8 patients] vs 3 or more hours daily [10 patients]), there were no significant differences between the 2 groups with regard to demographic, clinical and disease specific characteristics. Furthermore, no differences were observed between the 2 groups in terms of change in SPL, erect circumference or degree of curvature (table 2). However, the use of PTT for 3 or more hours daily resulted in a significant increase in SPL