Extra-corporeal-shock-wave Therapy For Francois De La Peyronies Disease: Initial Experience And A Review Of The Literature

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Abstract

Extra-corporeal-shock-wave therapy for Francois de la Peyronie's disease: Initial experience and a review of the literature
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Abstract:
Background:
Peyronie's disease has been treated with oral medications, extra-corporeal shock wave therapy and by surgical operations. The effectiveness of extra-corporeal shock wave therapy (ESWT) in the management of Peyronie's disease has not been universally confirmed.

Aims and Methods:
To review the notes of all patients with Peyronie's disease who were treated at North Manchester General Hospital between 2003 and 2006 by extra-corporeal lithotripsy in order to establish the effectiveness of the treatment modality.
To review the literature on the treatment modalities of Peyronie's disease in order to establish a consensus opinion regarding the effectiveness of ESWT.

Results:
Five (41.67%) out of 12 patients with pain associated with their Peyronies disease had 50% to 100% improvement in their penile curvature post ESWT
Eight (25%) out of the total of all the 32 patients with Peyronie's disease had 50% to 100% improvement in their penile curvature

Literature review revealed that surgical operations for Peyronie's disease are associated with better outcome than ESWT

Conclusions:
ESWT in our experience is associated with 50% to 100% improvement of penile curvature in 8 (25%) out of 32 patients with peyronie's disease and this outcome is inferior to surgical operations for Peyronie's disease.

Key Words: Peyronie's disease; Extra-corporeal shock wave; lithotripsy; Modulith; Lithotripter; Sex; pain; Curvature.

Introduction

Peyronie's disease refers to acquired penile deformities (curvature, indentation, hourglass deformity or shortening of the penis) which occur during erection. The disease, which is reported to have been described over 250 years ago, was named after Francois de la Peyronie (1).

The disease is more common in men aged greater than 40 years, and has an incidence of 1- 4%. Peyronie's disease is more common in Caucasians. There is some uncertainty about the aetiology of the disease but a number of hypotheses have been postulated including:

• The lesion results from perivascular inflammation (2).
• The genetic predisposition to the disease linked to HLA – DQ5 antigen has been suggested (3).
• The most accepted hypothesis is that the Peyronie’s plaques are caused by aberrant wound healing and scar formation, due to consecutive trauma during intercourse (4; 5; 6; 7).
• Penile deviation in Peyronie’s disease develops as a result of inelastic plaque, limiting extensibility of the penile shaft and thus causing an angled erection (8).

The asymptomatic prevalence is estimated at 0.4% to 1.0% (9). In a study with 100 men who were not
known to have Peyronie’s disease, 22% of them on autopsy were found to have fibrotic lesions of the tunica albuginea compatible with Peyronie’s disease (7; 10; 11; 12). Gerbard and co-workers (7) found that psychological problems associated with Peyronie’s disease were reported by 77% of patients. It has also been stated that the clinical incidence of Peyronie’s disease is increasing (13). It may be that this increase in the incidence of Peyronie’s disease may be associated with the use of erection-enhancing medications. Even though Peyronie’s disease is characterized as a gradual spontaneous resolution process, certain features have been reported to be associated with a lack of spontaneous resolution including more than 2-year duration.

During recent years studies on the use of oral drug therapy including potassium para-aminobenzoate (Potaba), vitamin E, colchicine, tamoxifen, propoleum, acetyl-l-carnitine and propionyl-L-carnitine have been published (14). Verapamil, interferon-α2b, collagenase, cortisone, hyaluronidase, and superoxide dismutase are considered intralesional therapies that have various degrees of success. Other treatments include local gels, iontophoresis, extracorporeal shock wave therapy, and radiation (14). A recent survey regarding drug therapy demonstrated that the majority of patients (76%) are treated with Potaba (46%) or vitamin E (29%) (14), other substances play a minor role.

It has been suggested that Extra-corporeal shock wave therapy (ESWT) is not an appropriate tool to correct penile curvature (14). Surgery is therefore regarded as the gold standard treatment for Peyronie’s disease.

This paper reports a retrospective review of patients with Peyronie’s disease who were treated at North Manchester General Hospital by means of ESWT between 2003 and 2006 with a review of the literature.

Methods

PATIENTS AND METHODS
The clinical notes of all patients with de la Peyronie’s disease who were treated by means of Extracorporeal shock wave therapy between 2003 and April 2006 using Storz Modulith SLK lithotriptor (see Illustration 9) at North Manchester General Hospital were retrospectively reviewed. The patients were also retrospectively interviewed regarding their experience with extra-corporeal therapy for their peyronie’s disease.

All the patients were seen in the out-patients clinic and their histories obtained with regards to symptoms, duration of symptoms as well as treatment received prior to their referral to our unit. Clinical examination details were obtained including presence of palpable plaque in the penis. Details of angulation (curvature) were noted including those obtained by self photography of angulation of penis during erection. All the patients had ultrasound localisation of their de la Peyronie’s plaques prior to their treatment in the Radiology department and/or at the time of their extracorporeal shock wave therapy. Details of any complications emanating out of the shock wave therapy were looked for in the patients’ notes as well as obtained by interviewing the patients as a separate exercise.

For the purpose of analysis the following were recorded:

1. Pain before and/or after Extracorporeal shock wave therapy
2. Curvature/angulation before and/or after extracorporeal shock wave therapy including a record of change in angulation/curvature
3. Sex life before and after extracorporeal shock wave therapy
4. The age of each patient
5. Duration of symptoms before the shock wave therapy
6. Complications of the Extracorporeal shock wave therapy
7. Any treatment given for the de la Peyronie’s disease prior to the extracorporeal shock wave therapy
8. Number of shocks given at each shock wave treatment session and total number of treatment sessions given to each patient
9. Any further treatment given if the Extracorporeal shock wave therapy was not successful as well as outcome of additional treatment
10. Duration of follow up following ESWT

In all 32 patients with a mean age of 54.7 years (range 32 to 67 years) received extracorporeal shock wave therapy for peyronie’s disease between May 2003 and June 2006. These patients were followed up for a period of time ranging from 3 months to 38 months and their mean follow up time was 11.6 months.

Results

Out of a total of 32 patients who were treated by ESWT, 12 (37.5%) had pain associated with curvature of penis during erection (see Illustration 1).
The remaining 20 patients had no pain associated with their erections.

Of the 12 patients who had pain and curvature of penis with their erections, 5 (41.66%) continued to have pain without any improvement following their shock wave therapy, 2 (16.67%) had slight improvement in their pain and 5 (41.66%) had a 50% to 100% improvement in their pain following ESWT (see illustration 2 [table 2]).

All the 20 patients who had no pain associated with their penile curvature during erection continued to experience no pain with their erections after they had had ESWT (see illustration 3 [table 3]).

With regard to penile curvature, out of the 32 patients who had ESWT, 13 (40.6%) experienced no change in their penile curvature (angulation) or the change/improvement was insignificant (less than 10% improvement in curvature), 5 (15.6%) had improvement of between 10% and less than 20% in their penile angulation, 6 (18.8%) had improvement of between 20% and less than 50% in their penile curvature, and 8 (25%) had improvement of between 50% and 100% in their penile curvature (see illustration 4 [table 4]).

The outcome of the penile curvature of the 12 patients whose penile curvature on erection was associated with pain was as follows: 5 (41.67%) had no change in their curvature and the improvement (diminution) in their curvature was less than 10% of the pre-treatment curvature (angulation), 2 (16.67%) had improvement (diminution) in their curvature (angulation) of between 10% and less than 20% of their pre-treatment curvature, 1 (8.33%) had between 20% and less than 50% improvement (diminution) in their pre-treatment curvature and 4 (33.33%) improvement (diminution) in their pre-treatment curvature of between 50% and 100% (see illustration 5 [table 5]).

With regard to coital penetration and sex life, out of the 32 patients who had ESWT, 20 (62.5%), did not experience any improvement in coital penetration or their sex lives, 2 (6.25%) had 1% to less than 20% (slight) improvement in coital penetration and sex post-treatment, 1 (3.125%) had between 20% and less than 50% improvement in coital penetration and sex post treatment, and 9 (28.125%) had 50% to 100% improvement in coital penetration and sex (see illustration 6 [table 6]). Out of the 12 patients who had painful Peyronie’s disease, 9 (75%) did not notice any improvement in coital penetration and sex, 1 (8.33%) had less than 20% improvement in coital penetration and sex, 2 (16.67%) had 50% to 100% improvement in coital penetration and sex (see illustration 7 [table 7]).

Of the 20 patients who did not have pain associated with their curvatures during erection, 11 (55%) did not notice any improvement in coital penetration and sex, 1 (5%) noticed 10 to less than 20% improvement in coital penetration and in sex, 1 (5%) noticed 20 to less than 50% improvement in coital penetration and sex and 7 (35%) noticed 50% to 100% improvement in coital penetration and sex (see illustration 8 [table 8]).

There was no entry of any complication arising following the treatment of the patients. However, after interviewing all the 32 patients, 3 of the patients stated that they noticed very minimal and transient bruising of the penis on the day of treatment but this quickly settled.

### Discussion

Skolarikos and co-workers (15) studied forty patients with previously untreated Peyronie’s disease who underwent ESWT using Dornier Epos overhead-module devices and made the following observations:
1. Of the 40 patients, 7 underwent two sessions and the rest three sessions of treatment.
2. Of the 25 patients with pain on erection, 12 (48%) noticed relief after the first session, while 9 more were pain free at the end of the treatment. (VAS reduction 2.8; p<0.0001, and 2; p < 0.001; respectively)
3. An improvement in penile angulation > 20 degrees was observed, with a mean reduction of 35 degrees (range 20 – 600) p < 0.001)
4. No significant change in plaque size was noted.
5. With regards to erectile dysfunction, 18 (64.2%), had a marked increase in erection quality. (IIEF score change: +4 for 10 patients, +6 for 4 patients and +9 for 2 patients.

They concluded that their results support ESWT as effective and safe first line treatment for Peyronie’s disease.

Hauck and co-workers (16) treated 22 patients with Peyronie’s disease who previously had unsuccessful oral drug therapy with EWST in a prospective design with a follow-up of at least 3 months; For comparison, they used 23 age-matched patients without previous therapy who received oral placebo drug daily for 6 months as control. They reported that their results showed a significant decrease in penile curvature in the patients treated with ESWT. Concerning the decrease in pain, subjective improvement and improvement in the quality of sexual intercourse, they reported that there was no significant difference to the case-control group. They also were of the opinion that
the inhomogeneity of the 2 groups may influence these results due to the questionable varying natural history. They suggested that a prospective controlled multicenter study with standardized parameters (concerning technique and patients) is required to test the effect of ESWT.

Abdel-Salam and colleagues (17), treated 24 patients aged 36 to 67 years with ESWT on the Lithostar overhead-module (Siemens). All their patients had unsuccessful medical treatment before ESWT. They found that: Four patients (17%) showed marked improvement and complete remission of the penile deviation. Six patients, (25%) showed partial remission with painless erections after treatment. Four patients (17%) had painless erections after treatment but still had some penile deviation. In 10 patients (41%), ESWT failed, necessitating subsequent penile surgery. They concluded that their results showed a response rate of 59% with ESWT for Peyronie’s disease including a 17% complete remission rate was encouraging however, further multicenter studies will have to prove if ESWT is a real therapeutic option for this disease.

Mirone and others, (18) entered 481 patients affected with Peyronie’s disease into a prospective trial. Patients with big plaques or with an initial stage of degeneration were excluded. The patients were divided into three groups: a) shock waves alone in 56 patients; b) a combination of shock waves and calcioantagonist (perilesional injection) in 324 patients; c) calcioantagonist alone in 101 patients. The group of 101 patients (group C) treated during the previous 2 years with a medical therapy based on only injection of calcioantagonist, was used as the group. Their ultrasound evaluation of the treated plaques showed a reduction in size in 27/56 patients of the group A, in 159/324 patients of the group B and in 39/101 patients of group C. Painful erection improved in 91.5% of group B, as compared with 45.7% of patients in group C. They concluded that the therapeutic association of shock waves with calcium antagonist injections is an effective non-operative treatment for the stabilization of Peyronie’s disease.

Poulkalis et al., (19) retrospectively studied fifty-three patients with stable Peyronie’s disease who underwent ESWT (group 1). They compared them with fifteen patients, who matched with the base line characteristics of the patients in group 1 and these patients who received no treatment were used as the control group (group 2). The patients’ erectile function (International Index of Erectile Function [IIEF-5] score), pain severity (visual analog scale), plaque size and degree of penile angulation were assessed before and after treatment in group 1 and during the follow up in group 2. The mean follow up time was 32 months (range 6-64 months) in group 1 and 35 months (range 9-48 months) in group 2. Poulkalis et al., (19) observed that considering erectile function and plaque size, there were no significant changes (p > 0.05) in group 1 before and after ESWT. A total of 39 (74%) reported a significant effect in pain relief in group 1 after ESWT. Nevertheless, with regards to improvement in pain, IIEF-5 score and plaque size, no significant differences were observed between the two groups. In 21 patients (40%) of group 1, the deviation angle was decreased more than 10° with a mean reduction in all patients of 11° (range 6 – 20°). No serious complications were noted considering the ESWT procedure. They concluded that ESWT is a minimally invasive and safe procedure for the treatment of Peyronie’s disease. However, the effect of ESWT on penile pain, sexual function and plaque size remains questionable.

Oeynhausen et al., (20) reported on their results of ESWT in their 30 patients with Peyronie’s disease who were treated between March 1999 and September 2000. The patients were interviewed on a regular basis about pain and problems with sexual intercourse. The plaques were examined at regular intervals by palpation and with ultrasound. Before and after therapy the patients took Polaroid pictures of penile curvature. On average 4.5 sessions of ESWT were delivered using 2000 – 4000 shock waves per plaque at four-week intervals. They found that 13 out of 16 patients had a decrease of pain score. Bending of the erect penis improved in 17 out of 29 cases, rigidity during erection improved in 13 out of 24 cases. 17 out of 30 patients had more satisfactory intercourse after treatment. They concluded that ESWT seems to be a promising new option for therapy in a case of Peyronie’s disease without any serious side-effects and should be tried before a penile operation.

Husain and co-workers (21) treated 37 patients with Peyronie’s disease using ESWT. Before the treatment the degree of angulation was assessed by artificially inducing an erection with a vacuum device. The severity of pain was assessed using visual analogue scale (0-5). Each patient was treated with a minimum of three sessions of ESWT (3000 shock waves at an energy level density of 0.11-0.17 mJ/mm²) at 3-week intervals. They analysed the results using Wilcoxon signed-rank test. 34 of the 37 patients completed the protocol; the mean (range) duration of the disease was 19.43 (4-60) months and the mean (range of) follow-up 7.5 (5 – 11) months. Almost half (47%) of the patients reported an improvement in angulation, with a
mean reduction of 29.3° (range 10° – 60°) (P < 0.001); 12 of the 20 (60%) patients with pain on erection reported immediate relief, the mean reduction being 2.3 (1-4) on the visual analogue scale (P< 0.001). They observed only minimal bruising at the site of treatment and no major side-effects were reported.

Lebret et al., (22) carried out a prospective study in 54 patients to assess whether extracorporeal shock wave therapy (ESWT) using a standard radioscopic location lithotripter is effective in the treatment of Peyronie’s disease. Before and after treatment, the angulation was calculated by auto-photography. Pain severity was assessed by visual analog pain scale. A self-evaluation questionnaire (International Index of Erectile Function) was utilised. All the patients had symptoms (35 patients had pain on erection and 51 had angulation greater than 20 degrees). The mean duration of the disease was 16 months. The mean angulation prior to treatment was 48 degrees (range 10° -100°). Twenty-four patients had erectile dysfunction (questionnaire score was less than 18). Multiline Siemens lithotripter was used. The plaque was identified by palpation, and 1 mL of contrast agent was injected. Scopic visualization was used. Each patient received a minimum of one session of ESWT (3000 shock waves, 7 kJ) applied to a flaccid penis. Lebret and co-workers reported that all the patients completed the protocol and that tolerance and safety were excellent. Out of the 35 patients with pain on erection 31 (91%) noticed relief immediately after ESWT (mean reduction 2.9 on the visual analog pain scale) (P < 0.00001). An improvement in angulation (greater than 10 degrees) was observed in 29 (53.7%) patients with a mean reduction of 31 degrees (P < 0.001). With regards to patients erectile dysfunction, only 6 (25%) had increased questionnaire score (greater than 4). Twenty-five patients felt that their plaques were smoother after the treatment.

Hamm and co-workers (23) studied 28 patients (mean age 57 years, range 34 – 72) with stable Peyronie’s disease who were treated with 3.9 (3 – 5) sessions of ESWT to their Peyronie’s plaques. The patients’ erectile function, pain and penile angle were assessed before and after treatment with ESWT. Hamm and colleagues, reported that 20 felt that their erection improved after the procedure; 11 patients were able to recommence sexual intercourse and the index of erectile function increased in all except one patient.hey concluded that ESWT produces a significant improvement in pain and penile angle, with no serious complications.

Colombo and Nicola (24) published a study of 82 patients with Peyronie’s disease, aged between 44 and 74 years old (average age 53.8 years) who were treated by means of ESWT, every other day; energy density value; at least level “4” (0.11 mj/sqmm). A case history was drafted for each patient and they all underwent an objective examination, a dynamic ultrasound scan of the penis after a drug induced erection. The complaint had lasted for a period of time varying from a minimum of 3 to a maximum of 120 months (average time 23.3 months). 44 patients reported painful erection and 78 exhibited bending of the penis during erection. The pre-treatment dynamic ultrasound scan of the penis showed plaques of calcific features in 36 patients and in 46 cases the ultrasound scan images were compatible with fibrotic thickening. After completion of the 4th treatment session, the patients were given a questionnaire to fill in to enable a subjective evaluation of the results to be assessed. All the patients had photographs and dynamic ultrasound scan of the penis after drug-induced erection, pre and post treatment. Often a slight alteration appeared on the skin of the penis (petechiae), which disappeared spontaneously within 48 hours. After completion of the 4th treatment session, 37 patients out of the 82 (45%) reported subjective improvement described as “stoppage” in the progression and / or partial regression of the disease with a feeling of a smaller size of the plaque on self examination. Pain was reported to have disappeared in 31 (70.4%) out of the 44 patients concerned. At the clinical check, based upon the ultrasound scans which were carried out after ESWT, in 34 cases (41%), the authors noted reduction in the echogenicity or in the size of the treated plaque. An unchanged plaque was observed in 32 patients (39%), and in 16 cases (19.5%) a larger plaque or a calcific evolution was established. A comparison of the photographs revealed a reduction of the curvature in 24 patients out of 78 (30.7%). Of the 46 patients in whom the disease had non-calcific characteristics, according to the ultrasound scans, 21 (46%) showed evidence of improved disease and 25 (54%) of the treated plaque had stabilised or worsened. With regard to the group of 36 patients with calcific plaques, 13 (36%) improved whilst 23 (64%) the calcific plaques were unchanged or worsened.

Lebret and colleagues (25) noted that 19 patients (73%) out of 26 patients who were treated by ESWT reported a very marked reduction of pain on erection and 8 (31%) reported a reduction of curvature on erection, this reduction was demonstrated objectively (by tracing or photographs) for only 3 patients (11%). Six (37%) of the patients suffering from erectile dysfunction, reported improvement of the quality of erection, as was reflected by their HEF score.
Warner (26) reported on the results of a study of extracorporeal shock wave treatment for Peyronie’s disease conducted at the Hôpital Foch in Suresne in France. In this study 54 men with Peyronie’s disease were treated by ESWT. Of the 35 patients that had pain on erection, 91% noticed relief immediately after ESWT. Twenty-nine patients (54%) noticed an improvement in penile angle, and 25 thought that their plaques had been smoothened by the procedure. Overall 61% of the patients thought that their condition had improved after therapy. Only 9 (16%) thought that they had had inadequate treatment and went on to have surgery.

Neimark and colleagues (27) analysed the results of 28 patients, with Peyronie’s disease, who were treated by ESWT. They concluded that ESWT is an effective, safe method of treatment for Peyronie’s disease but they recommended that further study and accumulation of clinical experience is required.

Michel and colleagues (28) enrolled 65 patients (age 58.4 ± 8.7 years) with Peyronie’s disease in a therapeutic pilot study. The duration of the disease was 33.7 ± 42.9 months. The inclusion criteria for the study palpable plaque together with deviation, pain (visual pain scale), or loss of distal rigidity. Clinical examination was performed prior to the first therapy and 1, 6, and 18 months after delivery of the last shock wave treatment. The examination included palpation and ultrasound scan of the plaque (mean surface size 2.2 ± 1.1 cm²), measurement of deviation, assessment of pain and distal loss of rigidity (artificial erection was induced by intracavernosal injection of 5 µg of alprostadil [caverject]). Shockwaves (1000 impulses at 12 kV per square centimetre of plaque) were delivered to the non erect penis once a week for a period of x5 weeks with Minilith; Storz Medical lithotripter. Eighteen months (N = 35) after the last shockwave session, the deviation angle had decreased from 59.3° ± 38.1° to 49.3° ± 32.5°. (N = 24; P = 0.1496). Pain during erection disappeared in 15 of 17 patients and was reduced in 1 other patient (P < 0.0001). There was no observed effect on distal rigidity in any patient. Six patients achieved satisfactory sexual intercourse (vaginal penetration) before and 15 patients after shockwave therapy. The adverse effects were small skin hematomas in 90% of patients and initial macrohaematuria in 30%.

Claro and co-workers (29) treated 25 patients aged 42 to 68 years, (mean age = 54) who presented with penile deviation and sexual distress caused by Peyronie’s disease in a non-invasive manner. The time of penile deviation ranged from 16 to 52 months (mean = 30). All the patients had previous unsuccessful treatment for Peyronie’s disease. The angulation’s deformity was assessed by photography at home. The patients received vitamin E (1,200 mg daily) during 3 months and underwent 3 to 6 sessions (mean – 3) of ESWT (3,000 to 4,000 shockwaves) at a power level 1 to 2 at 1 – week intervals. Out of the 25 patients treated, 16 (64%) reported an improvement in penile angulation, with a mean reduction of 21 degrees (10 to 40). Eight patients reported that their spontaneous erections had improved. On the whole, the patients developed only minimal bruising at the site of treatment and skin haematoma. Four patients had urethral bleeding. The mean angulation after treatment in the control group was 48.67 degrees (30 – 70) and in the study group was 24.42 degrees (0 – 70), and this was considered statistically significant.

Hauck and associates (30) did an exploratory meta-analysis of published studies in the international literature to investigate the therapeutic effects of extracorporeal shock wave therapy for Peyronie’s disease. They compared the treatment outcomes from 17 study groups which were identified by a computerised literature search with the natural history outcomes and data from control groups from 2 controlled ESWT studies. An exploratory meta-analysis was performed due to the fact that a methodologically sound meta-analysis lege artis did not appear appropriate, since treated groups differed considerably in structure, the selection of outcome measures were inconsistent and measurements were not standardized. The results indicated that ESWT seems to have an effect on penile pain during erection and on the improvement of sexual function. Pain seemed to resolve faster after ESWT than during the course of the natural history. The effect on plaque size was less impressive. They concluded that ESWT in Peyronie’s disease at least seemed to be effective with regard to penile pain and sexual function as compared with the natural history. Deducing from the data the effect on plaque size and curvature remains questionable. However, ESWT is not an evidence based therapy at present. They recommended that a controlled (preferably pairwise matched), single blind, multicenter study with careful, detailed documentation of disease symptoms before intervention and of outcomes is required to evaluate the real effect of ESWT.

Taylor and co-workers (31) reported their study in which a series of 36 patients with Peyronie’s disease received ESWT as a primary treatment. Subjective response rates were compared on the basis of patient age, degree of pre-treatment penile curvature, predisposing medical factors, duration of disease, and
extent of plaque calcification. Taylor et al reported that 10 men (27.8%) reported subjective improvement in curvature after ESWT. Of the factors considered, only age and pre-treatment curvature influenced outcomes: 50% of the men below the mean age reported improvement in comparison with 5.6% of older men and 62.5% of men with mild curvature reported improvement in comparison with 8.3% of those with severe curvature. They concluded that the response to ESWT is not the same for all men with Peyronie’s disease. Younger men and those with milder curvature have the best options.

Hauck and colleagues (32) evaluated the effects of ESWT in a large series of patients with Peyronie’s disease via a prospective study. In this prospective study, 114 patients with Peyronie’s disease were treated with ESWT. The baseline and follow-up examinations included ultrasound, as well as measurement of plaque size and curvature. The symptoms were evaluated based upon a standardized interview. A minilith SL 1 (Storz Medical A G, Kreuzlingen, Switzerland) lithotriptor was used with 4,000 shock waves at a maximum energy level of 0.17 mJ/mm² applied per session. With regard to the results, 96 patients were available for follow-up. Considering the total study group no significant changes were observed in penile curvature, plaque size or sexual function despite significant improvements in patients with a curvature of 31 to 60 degrees. Penile pain ceased in 76% of the affected patients. They concluded based upon their data that ESWT does not appear to be significantly effective for decreasing penile curvature and plaque size or improving sexual function in the total population of patients with Peyronie’s disease improvements in individuals. Penile pain seems to resolve earlier than during the natural course. With regard to the results of this study and previous reports with exact documentation of the clinical findings it can be concluded that ESWT cannot be recommended as a standard procedure for Peyronie’s disease. To evaluate the exact efficacy of ESWT a controlled, single-blind, multicenter study with exact documentation of symptoms is urgently required.

Strebel and co-workers (33) did a study to evaluate whether extracorporeal shockwave therapy (ESWT) offers an effective treatment for the main complications of Peyronie’s disease (PD), namely, penile deformity and angulation, painful erection and unsatisfied sexual intercourse. From September 1999 to January 2001, 52 patients with PD were treated with ESWT. Pain during erection was assessed with visual analogue scale. Penile deviation was determined by photographs with goniometer. Five treatment sessions were given at weekly intervals. Each treatment consisted of 3000 shockwaves with an emission frequency of 120 shockwaves per minute and a mean intensity of 0.17 mJ/mm². A storz Minilith SL 1 with intergrated inline ultrasound probe was used. All 52 patients were evaluated 6 weeks after ESWT for early follow-up. Prior to ESWT intercourse was impossible or difficult for 40 men; 29 patients suffered mainly from penile deformity, 14 from painful erection and 8 mainly from loss of distal rigidity. A total of 30 patients referred to painful erection prior to treatment. Pain reduction was achieved in 28 (93%) of patients. 19 patients (63%) reported total relief of pain following ESWT. Mean pain score dropped from 4.2 to 1.3 in patients who suffered predominantly from painful erections. Coital satisfaction improved in 11 patients after therapy. Mean angulation before (40%) and after (37%) ESWT did not change significantly. Late follow-up after a 11.1 months (mean), (range 4 – 17 months), was completed in 36 patients. In total, 19 men reported that ESWT improved their Peyronie’s disease. Of these 16 noted no change. Only one of the patients noticed a worsening of his disease during or after therapy. The complication rate was low with only minor side effects such as minimal skin bruising and one urethral bleeding occurred. They concluded that ESWT did reduce pain during erection in patients suffering mainly from painful erection due to PD. However, penile angulation did not improve significantly in their setup and thus intercourse difficulties did improve only in 28% of the patients. In view of these findings Strebel and co-workers did not recommend ESWT as a primary treatment for PD.

The use of ESWT for the treatment of Peyronie’s disease has been on the rise over the last decade. More than 20 original papers, one meta-analysis, and two review articles have been published so far (34; 35; 36). Majority of uncontrolled studies in which ESWT has been used to treat Peyronie’s disease have described positive effects on nearly all symptoms associated with Peyronie’s disease. Nevertheless, studies published recently with exact documentation of the symptoms before and after treatment do not appear to reveal significant effects on important symptoms of penile curvature and plaque size (28; 32; 33).

The exploratory meta-analysis of the studies published by Hauck and co-workers (14; 30) did not demonstrate a significant effect of ESWT on penile curvature or plaque size. ESWT appears to have an effect on penile pain during erection and consequently, on the improvement of sexual function. Pain appears to resolve faster after ESWT than during the natural course.
course of the disease (14). It has been suggested that the only single-blinded approach confirm this tendency (14; 37). However, ESWT is not an appropriate tool to correct penile curvature (37).

Hauck and co-workers (37) have suggested that despite the lack of severe side-effects, data published so far do not justify considering ESWT as an evidence-based standard procedure for the treatment of Peyronie’s disease. They also suggested that ESWT may be beneficial only to achieve freedom from pain within a short time. However, the question arises whether a symptom such as pain that resolves spontaneously with time should be treated by an expensive method such as ESWT (14; 37).

Nesbit operation was first performed as treatment for Peyronie’s disease in 1977 but it was first reported by Pryor two years later (38). It has been reported that with the use of Nesbit procedure, penile straightening should be achieved in 70 – 100% of patients with satisfaction rates of 67 – 100% (39). Plaque excision and grafting is considered to be an obsolete operation. This statement has been confirmed in a large series of 418 men treated by plaque excision and a dermal graft. It was found that 17% of patients required further surgery for curvature and that 20% of patients had significant impairment of erection (40). With the knowledge that excision of plaques results in an impaired erection, Lue devised the operation of plaque incision only, with the insertion of a venous patch to lengthen the diseased side and thus minimise any shortening (41). The results have been encouraging with straightening of the penis in 75 – 90% of cases with few complications (39). Nevertheless, postoperative erectile dysfunction may occur in up to 15% of patients and penile shortening may still occur, 40% in one series, even though to a lesser degree than with a Nesbit procedure (39). However, at 5 years the results decrease to satisfaction rates of 60% and this is thought to be likely due to worsening erectile dysfunction in patients who are inherently at risk of this preoperatively (39).

The results of our study would indicate that Extra-corporeal shock wave therapy should not be the gold standard treatment in view of the fact Nesbit’s procedure has been reported to give a better outcome. One session of ESWT costs about £250 and three sessions cost about £450. In view of the fact that less than half of the patients who have received ESWT for Peyronie’s disease have had satisfactory outcome it would be said that the treatment of Peyronie’s disease by ESWT is not cost effective.

Conclusion

Results of our study indicate that the outcome of ESWT as treatment modality for Peyronie’s disease in our experience is inferior to surgical operation for Peyronie’s disease in view of the fact that only a small percentage of patients have experienced improvement in their penile curvature as well as coital satisfaction.

Abbreviation(s)

ESWT

Authors Contribution(s)

A K Venyo designed the study, A k Venyo and S Imran collected and analysed the data. A K Venyo wrote the manuscript which was read and agreed upon by both authors.

References

1. de la Peyronie F. Sur quelques obstacles qui s’opposent à l’ejaculation maturelle de la semence. Memoire de l’Academie de Chirugie 1743; 1: 318


26. Warner J Shock Treatment Helps Peyronie’s Disease WebMD Medical News 2002; can be found at: http://www.webmd.com/content/Article/16/2952_1529.htm


34. Hauck E W, Mueller U O, Bschleipfer T, Schmelz
Illustrations

Illustration 1

TABLE 1
SYMPTOMS OF PAIN OR NO PAIN PRE-ESWT

| Number of patients with penile curvature on erection before ESWT | 12 |
| Number of patients with curvature on erection but no pain before ESWT | 20 |
| Total | 32 |
Illustration 2

TABLE 2
OUTCOME OF PAIN POST ESWT OF GROUP OF PATIENTS WITH PAIN PRE ESWT (Patients with pain pre-ESWT)

<table>
<thead>
<tr>
<th>RESULTS OF ESWT</th>
<th>NUMBER</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>No improvement in pain</td>
<td>5</td>
<td>41.67%</td>
</tr>
<tr>
<td>Slight improvement in pain (1-20%)</td>
<td>2</td>
<td>16.66%</td>
</tr>
<tr>
<td>21% to &lt; 50% improvement in pain</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>50% to 100% improvement in pain</td>
<td>5</td>
<td>41.67%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>12</strong></td>
<td></td>
</tr>
</tbody>
</table>
Illustration 3

TABLE 3 OUTCOME OF PATIENTS WITHOUT PAIN PRE ESWT FOLLOWING ESWT

<table>
<thead>
<tr>
<th>Number of patients with no pain</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>pre-treatment</td>
<td></td>
</tr>
<tr>
<td>Number of patients with no pain</td>
<td>20</td>
</tr>
<tr>
<td>post-treatment</td>
<td></td>
</tr>
</tbody>
</table>
### TABLE 4 OUTCOME OF PENILE CURVATURE POST ESWT (ALL PATIENTS INCLUDED)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change in angulation of penis or up to less than 10% improvement</td>
<td>10</td>
<td>40.6%</td>
</tr>
<tr>
<td>10 to less than 20% improvement in penile angulation</td>
<td>5</td>
<td>15.6%</td>
</tr>
<tr>
<td>20 to less than 50% improvement in angulation of penis</td>
<td>6</td>
<td>18.8%</td>
</tr>
<tr>
<td>50 to 100% improvement in bend (angulation)</td>
<td>8</td>
<td>25%</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td></td>
</tr>
</tbody>
</table>
Illustration 5

TABLE 5 OUTCOME OF PENILE CURVATURE POST ESWT OF PATIENTS WITH PAINFUL PEYRONIES DISEASE POST ESWT

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change to less than 10% improvement in curvature</td>
<td>5</td>
<td>41.67%</td>
</tr>
<tr>
<td>10% to less than 20% improvement in curvature</td>
<td>2</td>
<td>16.67%</td>
</tr>
<tr>
<td>20% to less than 50% improvement in curvature</td>
<td>1</td>
<td>8.33%</td>
</tr>
<tr>
<td>50% to 100% improvement in curvature (no bend)</td>
<td>4</td>
<td>33.33%</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td></td>
</tr>
</tbody>
</table>
### Illustration 6

**TABLE 6 OUTCOME OF SEX LIFE POST ESWT (ALL PATIENTS INCLUDED)**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coital penetration and sex not improved</td>
<td>20</td>
<td>62.5%</td>
</tr>
<tr>
<td>1% to less than 20% (slight) improvement in coital penetration and sex</td>
<td>2</td>
<td>6.25%</td>
</tr>
<tr>
<td>20% to less than 50% improvement in coital penetration and sex</td>
<td>1</td>
<td>3.125%</td>
</tr>
<tr>
<td>50% to 100% improvement in coital penetration and sex</td>
<td>9</td>
<td>28.125%</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td></td>
</tr>
</tbody>
</table>
Illustration 7

TABLE 7 OUTCOME OF SEX LIFE POST ESWT OF PATIENTS WHO HAD PAINFUL PEYRONIES' DISEASE PRIOR TO ESWT

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coital penetration and sex not improved</td>
<td>9</td>
<td>75%</td>
</tr>
<tr>
<td>1% to less than 20% (slight) improvement in coital penetration</td>
<td>1</td>
<td>8.33%</td>
</tr>
<tr>
<td>and sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20% to less than 50% improvement in coital penetration and sex</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>50% to less than 100% improvement in coital penetration and sex</td>
<td>2</td>
<td>16.67%</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td></td>
</tr>
</tbody>
</table>
**Illustration 8**

**TABLE 8 OUTCOME OF SEX LIFE POST ESWT OF PATIENTS WHO HAD NO PAIN ASSOCIATED WITH THEIR PEYRONIES' DISEASE AT THE TIME OF ESWT**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coital penetration and sex not improved</td>
<td>11</td>
<td>55%</td>
</tr>
<tr>
<td>1% to less than 20% (slight) improvement in coital penetration and sex</td>
<td>1</td>
<td>5%</td>
</tr>
<tr>
<td>20% to less than 50% improvement in coital penetration and sex</td>
<td>1</td>
<td>5%</td>
</tr>
<tr>
<td>50% to 100% improvement in coital penetration and sex</td>
<td>7</td>
<td>35%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>20</strong></td>
<td><strong>-</strong></td>
</tr>
</tbody>
</table>
Illustration 9

Figure 1 Modulith SLK Lithotriptor
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