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Extracorporeal shock wave therapy in the management of Peyronie's disease: initial experience

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Objective To evaluate prospectively the efficacy of extracorporeal shock wave therapy (ESWT) as a conservative treatment for Peyronie's disease.

Patients and methods After obtaining ethical committee approval, 37 patients with Peyronie's disease were treated using ESWT. Before treatment the degree of angulation was assessed by artificially inducing an erection with a vacuum device. The severity of pain on erection was assessed using a visual analogue scale (0–5). Each patient was treated with a minimum of three sessions of ESWT (3000 shock waves at an energy density of 0.11–0.17 mJ/mm^2) at 3-week intervals. The results were analysed using the Wilcoxon signed-rank test.

Results Of the 37 patients, 34 completed the protocol; the mean (range) duration of the disease was 19.43 (4–60) months and the mean 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°(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 ($P < 0.001$). There was only minimal bruising at the site of treatment and no major side-effects were reported.

Conclusion ESWT is an effective and safe treatment for Peyronie's disease; the long-term follow-up and results are awaited.

Keywords Extracorporeal shock wave therapy, Peyronie's disease, efficacy, pain

Introduction

Although Peyronie's disease is named after Francois De La Peyronie, it was first described in the medical literature in 1561, in correspondence between Fallopius and Vesalius [1]. In 1267, Theodoric wrote a chapter on penile tubercles, which were distinct from the more common 'penile warts'. Therefore, over the centuries this ailment has caused significant distress; Peyronie's disease affects the quality of life of the patient.

Various surgical and conservative treatments have been described [2,3]; recently, targeting the plaque with extracorporeal shock waves has been tried, with encouraging results. This method of treatment is not invasive and appears to be effective. Thus we prospectively evaluated extracorporeal shock wave therapy (ESWT) in patients with Peyronie's disease.

Patients and methods

Patients were recruited from the general urology clinic and the erectile dysfunction clinic. Approval was obtained from the local ethical committee. After obtaining informed consent, 37 patients agreed to take part in the study. Before ESWT a detailed medical and sexual history was obtained. Questions about the quality of erections elicited the frequency and turgidity of erections, pain on tumescence, and the ability for successful penetration and completion of intercourse. The degree of erection was recorded by inducing an erection with a vacuum device and measuring the angulation with a goniometer [4]. These variables were measured before and after completing ESWT. The degree of pain on erection was recorded on a visual analogue scale (VAS) with zero being no pain and 5 being severe pain. A 7.5-MHz linear ultrasound transducer was used to localize the plaque; this was also used to record the plaque size before and after ESWT and to determine the presence or absence of calcification in the plaque. ESWT was administered using a Storz Minilith SL 1 (Storz Medical AG, Switzerland) with its cylindrical coil source used to deliver the shock waves. The accuracy of the delivery of shock waves to the target was monitored by an in-line ultrasound transducer. A total of 3000 shock waves were delivered at an energy density of 0.11–0.17 mJ/mm^2 at each treatment session. Each patient completed a minimum of three sessions carried out in the outpatient clinic, with the patient seated and a shock-absorbing pad placed under the penis to prevent transmission of shock waves to the testicles.

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On completing each treatment session the discomfort and pain felt by the patients were recorded, with the incidence of any bruising/haemorrhage at the site of treatment. The results were analysed using the Wilcoxon signed-rank test. The difference in the reduction of pain and angulation between patients with a disease duration of more or less than 12 months was analysed using the Mann–Whitney *U*-test.

Results

Of the 37 patients, 34 completed the protocol of three treatment sessions. Five patients had a history of trauma during intercourse and 10 had a disease duration of <12 months. The descriptive statistics of age and duration of disease are shown in Table 1. Of the 34 men completing ESWT, 32 (94%) had an angulation on erection; 20 patients (59%) had pain on erection and of these only eight had had the disease for <12 months. The mean and range for pain and angulation before and after ESWT are also shown in Table 1. Twelve of 20 men (60%) reported a reduction in pain on erection; the mean (range) reduction on the VAS was 1.9 (0–4) and the difference was statistically significant ($P<0.001$). Fifteen (47%) of the patients reported an improvement in angulation; the mean reduction was $12.8°(0°-60°)$ and the difference was statistically significant ($P<0.001$). The difference in angulation and pain on erection between patients with a disease duration of more or less than 12 months is shown in Table 2. Although there was a statistically significant reduction in pain and angulation within both groups, the difference between the groups was not statistically significant for either pain or angulation.

All the patients tolerated ESWT and required no analgesia; the mean (range) VAS for pain during ESWT was 0.84 (0–3). Only one patient recorded a score of 3 on the VAS and in this patient the plaque was near the glans; there was minor bruising at the site of treatment. None of the patients had bruising for >24 h. Nineteen patients had surface bleeding at the point of entry of the shock waves, but this did not continue for more than a few minutes after ESWT. There were no other complications.

Of the three patients who did not complete the protocol, one reported marked pain during ESWT and only underwent one session. In this patient the plaque was also close to the glans. After two sessions of ESWT another patient (with a 2.5 cm plaque) reported that the results were not as he desired and he has since had the plaque excised, with vein grafting. The third patient did not continue after two sessions and could not be contacted.

Table 1 Descriptive statistics of the whole study population, and for pain (20 patients) and angulation (32 patients) before and after treatment with ESWT

Variable	*Mean (range)*
Age (years)	56.14 (24.0–69.0)
Duration of disease (months)	19.43 (4.0–60.0)
Duration of follow-up (months)	7.5 (5.0–11.00)
Pain (VAS score)	
Before treatment	2.5 (1.0–4.0)
After treatment	0.6 (0–3.0)
Angulation (°)	
Before treatment	50.5 (20–90)
After treatment	37.7 (10–80)

Table 2 The mean reduction in pain and angulation in patients with different duration of disease. The reductions in both groups were significant ($P<0.05$) but the difference between groups was not

Duration of disease (months)	*Mean reduction in*	
	Pain (VAS)	*Angulation (°)*
>12	1.2	32.5
<12	1.2	16.5

Discussion

Peyronie's disease affects the quality of life of both the patient and his partner. The exact cause of the disease is unknown, with most cases being idiopathic [5]. However, there is evidence that associated trauma during intercourse is a causal factor [6,7]. Lowsley and Kirwin [8] stated that the frequency of dorsal cavernosal involvement is associated with this part of penis being subjected to the greatest mechanical strain during intercourse. More recently, Somers and Dawn [9] suggested microvascular trauma as an aetiological factor in the origin of Peyronie's disease. Whatever the cause, the final outcome is the deposition of connective tissue in the tunica albuginea of the corpora cavernosum. There is initial perivascular inflammatory cell infiltrate in the tunica albuginea, followed by the deposition of collagen and fibrin, which is characteristic of the penile plaques found in patients with Peyronie's disease [9]. It is this plaque which causes the angulation deformity of the erect penis, and before formation the inflammatory cellular exudates account for the pain during tumescence. The patient then has sexual dysfunction and difficulty in penetrative sexual activity, and it usually for this that he consults a physician.

Surgical correction of the deformity and/or plaque is considered the 'gold standard' for treating Peyronie's disease, but it has some disadvantages [10]. Some reduction in penile length and *de novo* impotence are

not uncommon after surgery, and can therefore produce an unsatisfactory outcome [11]. As a result, several conservative or minimally invasive treatments have been tried, i.e. oral agents like colchicine, tamoxifen, potassium *p*-amino benzoate and vitamin E, or intralesional injections of mercury and iodide, steroids, verapamil and clostridial collagenase.

The exact mechanism of action of ESWT is unknown but there are two theories; one is that there is direct damage to the plaque [12] and the other is that ESWT causes increasing vascularity of the area by generating heat, which leads to the induction of an inflammatory reaction, resulting in lysis of the plaque and removal by macrophages.

The natural history of Peyronie's disease is variable. Gelbard *et al.* [13], in a questionnaire follow-up of 97 men with Peyronie's disease of 3 months' to 8 years' duration, found that 13% had gradual resolution, 47% believed there was little or no change and 40% reported gradual progression. There was no statistically significant association between disease duration and spontaneous improvement in penile bending.

The present study included patients with a duration of disease of <12 months to determine whether ESWT interrupted the natural history of Peyronie's disease. Although the reductions in pain on erection and angulation were statistically significant (within group comparison), ESWT seemed to produce more benefit in reducing the angulation in patients with a disease duration of >12 months. There was no statistically significant reduction in pain and angulation between the groups.

Two patients had no angulation but had palpable plaques and pain on erection which failed to disappear with time (disease duration >12 months). Although it is well documented that pain in Peyronie's disease diminishes with time, the present patients noticed a reduction in pain immediately after ESWT; this has also been reported by others [14]. Only two of the present patients had definite calcification, too few to draw any conclusions about the response to ESWT and the presence or absence of calcification.

None of the present patients reported urethral bleeding [15]. It was presumed that plaques on the ventral surface of the penis would account for urethral bleeding after ESWT. Other than bruising, which disappeared after 24 h, and a few haemorrhagic blisters, there were no significant complications.

In conclusion, this initial experience suggests that ESWT is an effective conservative treatment for Peyronie's disease. However, long-term results are needed to determine the true efficacy of the procedure, and in more patients, to provide the appropriate power and to allow an analysis of the subgroup of patients who would best benefit from this treatment.

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