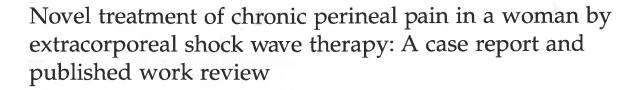
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#### **Abstract**

In published work review, extracorporeal shock wave therapy (ESWT) has been showed to be effective in treating chronic perineal/pelvic pain in men, but there was no published report on its use in women. We report a case of female chronic perineal pain successfully treated by ESWT. A 51-year-old woman presented with persistent perineal scar pain after excision of a vulval-vaginal nodule despite oral analgesics and gabapentin. After 11 cycles of ESWT, she reported termination of analgesics consumption and decreased perineal pain score from 8 to 2. The Short Form 36 Questionnaire demonstrated improvement in physical and mental health conditions. There was no complication encountered. We postulate that the effect of ESWT in this patient was based on reduction of muscle tone and alternating the threshold of pain memory, similar to the mechanisms in male patients. Further study is required to determine the use of ESWT in treating female chronic perineal pain.

**Key words:** irritative condition of pelvic floor, neuromodulation, pelvic pain.

# Introduction

Perineal pain is one of the most problematic clinical conditions to female patients as it causes discomfort and is associated with disturbance in sexual function, voiding and bowel movement. This symptom is part of the commonly presenting pelvic pain syndrome which was defined as persistent or recurrent episodic pelvic pain associated with symptoms suggesting lower urinary tract, sexual, bowel or gynecological dysfunction in the absence of proven infection or other obvious pathology.1

Commonly employed treatment for chronic pelvic pain includes various analgesics such as non-steroidal anti-inflammatory drugs, opioids and gabapentin. However, most patients found themselves having suboptimal pain control. This can be explained by treatment failure in targeting the underlying pathophysiology. In some published work reports, acupuncture and traditional Chinese medicine has been used for this intractable condition.2 To our knowledge, extracorporeal shock wave treatment (ESWT) has been used in male chronic pelvic pain and various neuromuscular pains for years.3 However, it has not been applied in women for similar conditions. We postulate that ESWT, through similar anatomical and physiology effects, may offer a new choice of treatment for female patients with chronic perineal pain.

### Case Report

A 51-year-old Chinese woman with two previous normal vaginal deliveries without any genital tract trauma and good past health, was first referred to us for urinary frequency, urgency and incontinence in 2008. Physical and pelvic examination was unremarkable with no pelvic floor abnormality detected. Overactive bladder syndrome was diagnosed after an urodynamic

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investigation, and her symptoms improved after bladder training and appropriate drinking advice.

In 2009, this patient had an excision of a right vulvalvaginal nodule by a gynecologist in another hospital. The pathology report confirmed it was a benign inclusion cyst. She revisited our unit 4 months after the surgery and complained of right vulval pain near the wound site at the 7-8 o'clock position of the right vulva. She also complained of dyspareunia during sexual intercourse at a similar anatomical position. On physical examination, there was no local lesion seen in the vulva and vaginal area except a small piece of scar tissue approximately 1 cm in length at a wound site. Local tenderness was elicited during palpation but there was no sign of local inflammation or infection observed. Oral paracetamol was prescribed for treatment. Subsequent magnetic resonance imaging of the pelvis showed no anatomical pathology at the tender site. Treatment was switched to etoricoxib 120 mg daily for persistent pain. She was also referred to the specialist pain clinic and medical record showed similar physical examination findings. Gabapentin was prescribed in addition to oral analgesics for optimizing pain control. The patient demanded continuous analgesics treatment as the pain recurred shortly upon termination of analgesics.

In view of persistent symptoms, the option of scar excision was discussed but the patient strongly refused further surgical intervention. The option of ESWT was discussed for possible effect of pain control. A detailed explanation of this new form of non-invasive treatment and uncertainty in outcome were explained to her. The patient agreed and signed the informed consent form before ESWT.

The ESWT treatment cycle was started in June 2012. The machine used in this case was a Duolith tower SD1 with 4-cm<sup>2</sup> probe delivering energy ranging 0.01-0.55 mJ/mm<sup>2</sup> manufactured by Storz Medical (Tägerwilen, Switzerland) (Fig. 1). Each treatment composed of 3000 focused shock waves with 750 pulsation each at the bilateral upper thigh (4 cm from clitoris) and bilateral lower thigh (4 cm below the upper treatment region) regions. The energy level was set at 0.25 mJ/mm<sup>2</sup> and the frequency was set at 3 Hz. This treatment modality was used according to the usual recommended dose and frequency in treatment of male chronic pelvic pain syndrome.4 The overall treatment duration for each cycle lasted for approximately 20 min and was repeated at monthly intervals. The treatment was performed without any anesthesia or analgesia.

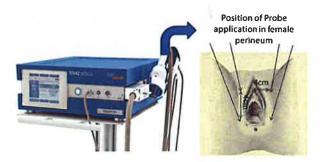


Figure 1 The Duolift SD 1 machine manufactured by Storz Medical used in this case for extracorporeal shock wave therapy and its site of application in female perineum.

The response was measured clinically by using a visual analog scale (VAS) ranging 1-10 (1 = least pain and 10 = most severe pain). During the pretreatment period, the patient gave a score of 8 on the VAS. After the first cycle of treatment, the pain score was reduced to 6. The treatment cycle was continued for 11 months from June 2012 to May 2013. The clinical VAS response was given at a range of 6–7 during the first 6 months by the patient. However, she had reduced by 50% her consumption of oral analgesics compared with the pretreatment period. The VAS was further reduced to 3 at the seventh to 11th cycles of treatment. During the latest follow-up assessment on December 2013, she reported the termination of analgesics consumption and graded score 2 on the VAS pain score. The Short Form 36 Health Survey (SF-36) is used retrospectively to assess the overall health implications for this patient before and after ESWT (Table 1). Overall, we found that she had the best percentage of improvement in bodily pain (30%), mental health (32%) and social functioning (30%) scales. There was no complication of discomfort encountered during the whole treatment period.

## Discussion

A woman with chronic perineal pain despite oral analgesics and gabapentin had suffered significantly and compromised much of her quality of life. On reviewing published works on successful outcome of using ESWT for male chronic pelvic pain syndrome (Table 2),<sup>4-7</sup> we decided to use the same modality of treatment of female patients with chronic perineal pain. Our patient was successfully treated with 11 cycles of ESWT without any complications. According to our

Table 1 Percentage of improvement of the patient before and after extracorporeal shock wave therapy for chronic perineal pain by using the Short Form 36 Health Survey

| Scale                | Pretreatment score (n/100) | Post-treatment score (n/100) | Improvement<br>(%) |
|----------------------|----------------------------|------------------------------|--------------------|
| Physical functioning | 73.3                       | 92                           | 18.7               |
| Role – physical      | 50                         | 75                           | 25                 |
| Bodily pain          | 60                         | 90                           | 30                 |
| General health       | 50                         | 76.7                         | 26.7               |
| Vitality             | 50                         | 75                           | 25                 |
| Social functioning   | 60                         | 90                           | 30                 |
| Role – emotional     | 66.7                       | 80                           | 13.3               |
| Mental health        | 52                         | 84                           | 32                 |

Table 2 List of published work evaluating effects of ESWT on chronic pelvic pain

| Author                            | Subject characteristics                                   | Details of ESWT used  | Results (12 weeks after treatment)  |
|-----------------------------------|---|---|---|
| Zimmermann<br>et al. <sup>4</sup> | 34 male subjects with<br>CPPS                             | Duolith SD1 (Storz Medical),<br>0.11 mJ/mm², 3 Hz, 2000 impulses              | Statistically significant improvements in pain and quality of life but not in voiding conditions                            |
| Zimmermann et al. <sup>5</sup>    | 60 male subjects with CPPS                                | Duolith SD1 (Storz Medical),<br>0.25 mJ/mm <sup>2</sup> , 3 Hz, 3000 impulses | Statistically significant improvement of pain, QoL and voiding conditions   |
| Alessandro<br>et al. <sup>6</sup> | 100 male subjects with<br>Peyronie's disease              | Duoift (Storz Medical), 0.25 mJ/mm²,<br>4 Hz, 2000 impulses                   | Statistically improvement of mean VAS, IIEF and QoL score.  |
|                                   |   |   | No change in mean plaque size and mean curvature degree.  |
| Zeng et al. <sup>7</sup>          | 80 male subjects with<br>IIIB CPPS/chronic<br>Prostatitis | Haibin Medical Equipment<br>HB-ESWT-01, 0.06 mJ/mm², 2 Hz,<br>2000 impulses   | Statistical significant improvement of National Institute of Health Chronic Prostatitis Symptom Index, pain and QoL scores. |

CPPS, chronic pelvic pain syndrome; ESWT, extracorporeal shock wave therapy; IIIB, International Index of Erectile Function; QoL, quality of life; VAS, visual analog scale.

knowledge, this is the first reported case of successful treatment of ESWT in chronic perineal pain in female.

In contrast to shock wave therapy for lithotripsy that uses a high energy level, shock wave therapy in treatment of pain involves a low energy density (0.25 mJ/ mm<sup>2</sup>). This explains why patients can tolerate the whole treatment process without analgesia. The energy level was set at 0.25 mJ/mm<sup>2</sup> and frequency at 3 Hz with 3000 pulses per treatment cycle that was recommended by the manufacturer and has been used in male patients with chronic pelvic pain syndrome without any complications.3,4 According to the data from manufacturers, the probe used in this case can deliver energy up to 4 cm<sup>2</sup> horizontally and 15-45 mm in depth. This explains why we put the probe 4 cm lateral to midline horizontally in order to maximize coverage in the horizontal plane. Similarly, the length of the perineum is approximately 6 cm measured from clitoris to perineal body, the placement of the probe 4 cm lateral to the clitoris and 4 cm below can maximize the range of cover in the vertical perineal plane. For the depth of penetration, the shock wave can be targeted to the whole pelvic floor muscles, particularly levator ani (Iliococcygeus muscle, Pubococcygeus muscle and Puborectalis muscle) stretching from its insertion at the pubis to the sacrum.

Extracorporeal shock wave therapy was first introduced by Butz and Trichart in 1996. There are two possible mechanisms to explain its efficacy in managing perineal pain. The first mechanism is the effect on transformation of molecular–biologic signals and hence modifies the mechano-transduction within cells. This action will improve the microvasculature and reduce the muscle tone and spasticity. This effect has been demonstrated in reperfusion of the ischemic myocardial area by local application of ESWT.<sup>8</sup> Also, improvement of microvasculature will enhance the transposition of cells for modification and resolution of

scar tissue in the treatment area as demonstrated in treatment of Peyronie's disease. ESWT effect also has been demonstrated on muscle tone reduction and subsequent improvement on range of movement in patients with stroke and upper arm contracture. In the same fashion, the effect of ESWT in reducing the muscle tone and spasm in the levator ani muscle of female patients may reduce the nociception in the local area. Thus, it treats the condition by targeting the underlying cause rather than simple analgesic effect.

The second mechanism involves the effect on neuroplasticity of the human pain memory and hence alternating the threshold of the pain memory and resetting the tolerance level as described by Wess.<sup>10</sup> In a human neurological hologram, chronic pelvic pain may be represented by a reflex pattern between pain sensation and muscle contraction. The use of hyperstimulation shock wave may modulate the reflex cycle by introducing strong sensor input but weak motor output, thus erasing the old reflex pattern in chronic pelvic pain. As these two mechanisms can work anatomically in the same way in both males and females, we postulate that ESWT also may be effective for pelvic pain in female patients. However, we could not exclude a placebo effect as highlighted by a recent meta-analysis on the treatment of chronic pelvic pain syndrome.11

The advantages of using ESWT include non-invasiveness and easy application of the probe to the local pain area without analgesia. It can be performed in an outpatient setting at relatively low cost. However, the successful outcome of this case is isolated and it may be caused by placebo effect. Furthermore, the retrospective use of the SF-36 in assessment of overall health impact may introduce recall bias. For further clinical evidence and guidance in this area, it is suggested that a prospective study with outcome measure by validated standard questionnaire such as the SF-36 should be performed in the near future.

### Disclosure

No conflict of interest were declared by the authors.

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