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NEPHROLOGY - REVIEW

# Treatment of prostatitis with low-intensity extracorporeal shockwave therapy (LI-ESWT)

**Datesh Daneshwar**[1] · **Abid Nordin**[2]

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## Abstract

**Background** Prostatitis is known as the inflammation of the prostate. The treatments of prostatitis are either pharmacological or non-pharmacological treatment. However, some of the treatments are not effective and very invasive which can lead to side effects. Thus, low-intensity extracorporeal shockwave therapy (LI-ESWT) is used as an alternative treatment for prostatitis due to its convenient and non-invasive procedure. However, a definite protocol for this treatment is not available due to the variability of the treatment protocols and the lack of research comparing the efficacy of these protocols.

**Objective** To review and compare the efficacy of different LI-ESWT protocols in treating prostatitis.

**Methods** The study was performed by comparing the intensity, duration, frequency and combination with different types of pharmacotherapy drugs of the different LI-ESWT protocols from various studies. The finding from various studies which consist of disease improvement and quality of life (QoL) were also presented in this review.

**Result** From the findings, the protocol can be categorized into three different intensities which are at 3000 pulses, < 3000 pulses and > 3000 pulses. Most studies reported that each protocol is very effective and safe to use and can improve CP symptoms, urinary symptoms, erectile function and QoL. It is also found that no complications or adverse effects occur to the patient.

**Conclusion** Most of the LI-ESWT protocols described are safe and effective in treating CP through the absence of treatment-related adverse effects and maintenance of clinical effects.

**Keywords** LI-ESWT · Prostatitis · Quality of life (QoL) · Review · Treatment

## Introduction

Prostatitis is a common urogenital system disease among male population with a lifetime prevalence of about 9% [1]. According to the classification of US National Institutes of Health (NIH), prostatitis can be divided into four types: Type I (acute bacterial prostatitis), Type II (chronic bacterial prostatitis), Type III (chronic prostatitis/chronic pelvic pain syndrome) and Type IV (asymptomatic inflammatory prostatitis) [2]. Among these, Type III (chronic prostatitis/chronic pelvic pain syndrome) is the most common type, which exists in more than 90–95% of patients with prostatitis [3].

Chronic prostatitis (CP) or chronic pelvic pain syndrome (CPPS) is defined as unspecific poorly localized pelvic inconvenience or tenderness without definite infection or pathology, which lasts for at least three of the prior six months [4]. The prevalence of CP varies from 8.4 to 25% in Europe and Asia. Approximately 35–50% of male population are likely to be affected by CP [5]. Some of the common symptoms of CP include prostatodynia, lower urinary tract symptoms (LUTS) with pollakiuria, nocturia, dysuria, urinary dribbling, weak urinary stream, constipation, rectal pain during and after defecation, genital pain or burning sensation, premature ejaculation, spontaneous sexual stimulation or alteration of orgasms and low back pain that worsened during sitting position. These symptoms may appear simultaneously or progressively and increase the sensation of discomfort, which subsequently affect the patient's quality of life (QoL) [6].

✉ Datesh Daneshwar
datesh.daneshwar@princecourt.com

[1] Urology Clinic, Prince Court Medical Centre, 39, Jalan Kia Peng, 50450 Kuala Lumpur, Malaysia

[2] MedCentral Consulting, International Youth Centre, Jalan Yaacob Latiff, Bandar Tun Razak, Cheras, 56000 Kuala Lumpur, Malaysia

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The exact pathophysiology of CP has not been fully understood. Association of previous infections, pelvic floor hypertension, local chemical alterations and perfusion disturbances are among the causes discussed to have contributed to CP [7]. While the pathophysiology of CP has been suggested to be multifactorial, chronic inflammation is believed to be one of the important causes of CP [2]. In vivo and in vitro studies demonstrate an autoimmune activity against prostate cells induced by inflammation in the prostate [8, 9]. Following the auto-immunological responses, leukocytes including Th1 cells and mast cells are recruited, which trigger the development of CP [10]. Pathogenetic congenital anatomical features show the arterioles responsible for blood supply in the prostate gland do not end in the glandular tissue, instead they end in the connective tissue between the acini. Thus, edema of the prostate, against the background of the inflammatory process, causes compression of these arterioles, resulting in the occurrence of ischemia. As a result of edema of parenchyma, intraprostatic pressure increases with impaired microcirculation. This causes pain in the prostate [11].

There are several treatment options available for CP. Medications such as analgesics, anti-inflammatory agents, antibiotics, alpha receptor blockers, phosphodiesterase type 5 inhibitors and 5α reductase inhibitors are used, either as single therapy or multiple combination therapy, to treat CP. Although these medications are convenient to use, they are not always effective in every patient with CP [12]. For example, a combination therapy of 3-As medication using antibiotics, alpha receptor blockers and anti-inflammatory agents, is often applied as a first-line treatment for CP due to its convenience and effectiveness [13, 14]. However, as much as 46% of CP patients do not respond sufficiently to the 3-As combination therapy [14]. Apart from medication, surgical procedures including intraprostatic injection of botulinum toxin A and invasive neuromodulation are applied when first-line treatments fail to relieve the CP symptoms [2, 15]. However, these procedures are not uniformly successful in treating CP. Besides, they are invasive and the emergence of side effect such as erectile dysfunction hinders the application of these procedures for CP treatment [12].

In view of the disadvantages of medications and surgery, growing research has been conducted in search of another more effective treatment option for CP. Low-intensity extracorporeal shockwave therapy (LI-ESWT) emerges as a popular treatment alternative for CP due to its convenient and non-invasive procedure [16]. LI-ESWT has been shown to be effective in reducing pain in CP patients [17]. The mechanisms involve interrupting nerve impulse flow through hyperstimulation of nociceptors, healing tissue through revascularization process and reducing perineal muscle tone and spasticity [18, 19]. Several studies that investigated the efficacy of LI-ESWT in treating CP have reported favorable outcomes regarding its application [16, 20]. A review analyzing 6 studies involving 317 patients with CP reported that LI-ESWT demonstrated efficacy in CP treatment at 12 weeks (RD = 0.46; 95% CI = 0.28–0.63; $p < 0.00001$). It was observed that the total National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) score, QoL, visual analog scale (VAS) score and urinary symptom scores of the patients improved significantly at 12 weeks following LI-ESWT ($p < 0.05$) [20]. Another review analyzing three randomized controlled trials (RCTs) showed LI-ESWT to be safe and efficacious in treating CP. The study reported significant association between LI-ESWT application with reduced pain domain ($p < 0.001$), improved urinary score ($p < 0.001$), improved QoL ($p < 0.001$) and improved NIH-CPSI score ($p < 0.001$) after 12 weeks of treatment among CP patients [16].

Although LI-ESWT is a safe and effective treatment option for CP, there is no definite treatment protocol available for this procedure. Some studies recorded LI-ESWT deliverance over the course of 4 weeks (four sessions) whereas some over 8 weeks (eight sessions) [21–23]. In terms of shock parameters, some reported 3000 pulses at 0.25 mJ/mm$^2$ energy flux density (EFD) and 5 Hz frequency [24], some reported 2500 pulses at 0.25 mJ/mm$^2$ and frequency 3 Hz [22], while some reported 5000 pulses at 0.096 mJ/ mm$^2$ EFD and 5 Hz frequency [25]. Due to the variability of the treatment protocols and lack of research in comparing efficacy of these protocols, it is difficult to determine which protocol is more superior in treating CP. To fill this gap, this review aims to review and compare the efficacy of different LI-ESWT protocols in treating CP.

## LI-ESWT delivered at 3000 pulses

The most commonly recorded protocol involves deliverance of 3000 pulses at EFD of 0.25 mJ/mm$^2$ and frequency of 3 Hz to the perineum at 6 different anatomical sites over the course of four sessions (once a week for 4 weeks). The location of the shockwave transducer changed after every 500 pulses to cover the entire area of the prostate and pelvic floor. The entire duration of treatment for each patient is about 18 min per session [21]. Table 1 summarizes the studies utilizing this protocol in the literature review.

Following treatment with the protocol on 34 male patients with CP over three months, a study reported significant improvements in pain ($p < 0.05$) and QoL ($p < 0.05$) of the patients at 1, 4, and 12 weeks follow-up after treatment. The patients' voiding conditions were also improved temporarily without statistical significance ($p > 0.05$) [17]. When comparing between a group of 30 CP patients who were treated with the LI-ESWT protocol to a group of 30 CP patients receiving sham procedure, the LI-ESWT group

**Table 1** Summary of studies using 3000 pulses LI-ESWT protocol

| Studies | Study design | Sample size | Treatment protocol | Treatment Duration | Follow-up | Outcomes | References |
|---|---|---|---|---|---|---|---|
| Zimmermann et al. (2008) | Clinical trial | 34 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 3 Hz | Once a week for 4 weeks (4 sessions) | 1, 4 and 12 weeks | Improvement in pain and QoL; no adverse effect | [17] |
| Zimmermann et al. (2009) | Randomized, double-blind, placebo-controlled study | 60 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 3 Hz | Once a week for 4 weeks (4 sessions) | 1, 4 and 12 weeks | Improvement in NIH-CPSI, IPSS, VAS, IIEF, QoL; no adverse effect | [26] |
| Li and Man (2020) | Open-label clinical trial | 32 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 3 Hz | Once a week for 4 weeks (4 sessions) | 1, 2, 4 and 12 weeks | Significant improvement in NIH-CPSI and VAS ($p < 0.05$) | [21] |
| Skaudickas et al. (2020) | Clinical trial | 40 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 3 Hz | Once a week for 4 weeks (4 sessions) | 4 and 12 weeks | Significant improvement in NIH-CPSI (38%, $p < 0.001$), IPSS (39%, $p < 0.001$), VAS (24%, $p < 0.001$) and IIEF (8%, $p < 0.001$) | [27] |
| Jin et al. (2022) | Open-label, single-arm trial | 91 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 3 Hz | Once a week for 4 weeks (4 sessions) | 1, 2, 3, 4, 5, 8 and 16 weeks | Significant improvement in NIH-CPSI, IPSS and VAS ($p < 0.05$), except IIEF-5; treatment effective rates were 28.57% (1 week), 38.46% (2 weeks), 47.25% (3 weeks), 51.65% (4 weeks), 57.30% (5 weeks), 68.18% (8 weeks) and 69.44% (16 weeks); no adverse effect | [28] |
| Sakr et al. (2021) | Prospective randomized double-blind placebo-controlled clinical trial | 155 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 3 Hz | Once a week for 4 weeks (4 sessions) | 1, 3, 6 and 12 months | Improvement in NIH-CPSI, IPSS, VAS and IIEF-5; 82.8% had $\geq 6$ score reduction in NIH-CPSI total score; efficacy remained throughout long-term follow-up | [29] |
| Guu et al. (2018) | Open-label, single-arm prospective study | 33 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 240 pulses/min | Once a week for 4 weeks (4 sessions) | 1, 4 and 12 weeks | Significant improvement in NIH-CPSI (81.82%, $p < 0.001$), VAS (2.18%, $p < 0.001$), IPSS (6.59%, $p < 0.001$) and IIEF-5 (4.12%, $p = 0.002$); no adverse effect | [30] |

**Table 1** (continued)

| Studies | Study design | Sample size | Treatment protocol | Treatment Duration | Follow-up | Outcomes | References |
|---|---|---|---|---|---|---|---|
| Vahdatpour et al. (2013) | Randomized controlled trial | 40 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 3 Hz, 0.05 mJ/mm$^2$ added each week (0.3 mJ/mm$^2$ in week 2, 0.35 mJ/mm$^2$ in week 3, 0.4 mJ/mm$^2$ in week 4) | Once a week for 4 weeks (4 sessions) | 1, 2, 3 and 12 weeks | Significant mean difference in NIH-CPSI ($p<0.0001$), VAS ($p<0.0001$), urinary score ($p=0.001$) and QOL score ($p<0.0001$) between LI-ESWT and sham groups; no adverse effect | [31] |
| Moayednia et al. (2014) | Clinical trial | 37 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 3 Hz, 0.05 mJ/mm$^2$ increment for each week | Once a week for 4 weeks (4 sessions) | 16, 20 and 24 weeks | No significant mean difference in NIH-CPSI, VAS, urinary score and QOL score between LI-ESWT and sham groups at 24 weeks follow-up (treatment effect not maintained at 6 months) | [32] |
| Pajovic et al. (2016) | Randomized controlled trial | 30 patients | Treatment group: 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 3 Hz + alpha blocker + anti-inflammatory + muscle relaxant<br>Control group: alpha blocker + anti-inflammatory + muscle relaxant | Once a week for 4 weeks (4 sessions) | 12, 24 and 36 weeks | Improvement in post void residual urine and maximum flow rate in treatment group but not in control group; better improvement in NIH-CPSI for treatment group than control group | [33] |
| Wu et al. (2021) | Single-center, prospective, single-arm cohort study | 215 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 4 Hz | Once a week for 6 weeks (6 sessions) | 1, 2, 6 and 12 months | Improvement in NIH-CPSI (reduction of 31.3–53.6%), IIEF-5, EHS, IPSS and AUA QoL_US | [34] |
| Kim et al. (2021) | Prospective, randomized, double-blind, placebo-controlled | 30 patients | 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 3 Hz | Once a week for 8 weeks (8 sessions) | 4 weeks | Significant improvement in NIH-CPSI ($p=0.002$), pain ($p=0.02$) and QoL ($p=0.001$) for LI-ESWT group compared to placebo group; significant improvement in VAS score ($p=0.002$) for LI-ESWT group; no adverse effects | [4] |

**Table 1** (continued)

| Studies | Study design | Sample size | Treatment protocol | Treatment Duration | Follow-up | Outcomes | References |
|---|---|---|---|---|---|---|---|
| Zhang et al. (2019) | Prospective, non-randomized, controlled study | 45 patients | Treatment group: LI-ESWT; 3000 pulses at frequency 10 Hz and pressure 1.8–2.0 bar (started at 1.8 with 0.1 bar increment per week until 2.0 bar)<br>Control group: alpha blocker (tamsulosin 0.2 mg/day) and anti-inflammatory (celecoxib 200 mg/day) for 8 weeks | Once a week for 8 weeks (8 sessions) | 3 months | Significant improvement in NIH-CPSI, QoL, VAS, IPSS and IIEF-5 ($p < 0.001$); recurrence rate of symptoms in treatment group (4%) at 3 months was significantly lower than in control group (50%, $p < 0.001$); no adverse effect | [23] |
| Trishch et al. (2021) | Clinical trial | 63 patients | LI-ESWT treatment group: 3000 pulses at EFD 90–120 mJ, frequency 10 Hz, pressure 1.5–2 bar<br>Control group: antibiotics, non-steroidal anti-inflammatory drugs, alpha blockers, muscle relaxants for 1 month | Twice a week for 4 weeks (8 sessions) | 3 and 6 months | Improvement in NIH-CPSI (51.5% reduction than before treatment) and prostate vascularization, but not urination disorders | [11] |
| Salama and Abouelnaga (2018) | Randomized, single-blinded study | 40 patients | 3000 pulses at pressure 3–5 bar (pressure increased until patient's tolerance) and frequency 12 Hz | Twice a week for 4 weeks (8 sessions) | 8 weeks | Significant improvement in NIH-CPSI total score, pain domain, urinary score and QoL within radial LI-ESWT group ($p < 0.05$); mean differences in NIH-CPSI total score, pain domain, urinary score and QoL between radial LI-ESWT and control groups were significant | [35] |
| Daneshwar and Nordin (2022) | Prospective interventional study | 50 patients | Medication prior LI-ESWT treatment: 500 mg levofloxacin once daily/500 mg ciprofloxacin twice a day for 1/12 + alpha blockers/5 mg Cialis once daily for 1 month; LI-ESWT treatment: 3000 pulses at EFD 0.25 mJ/mm$^2$ and frequency 5 Hz | Twice a week for 5 weeks (10 sessions) | 1/12 post-treatment | Significant improvement in NIH-CPSI ($p < 0.001$), IIEF ($p < 0.001$) and IPSS ($p < 0.001$), but not SHIM ($p = 0.130$) and uroflometry parameters; no adverse effect | [24] |

exhibited statistically significant improvements in NIH-CPSI ($p < 0.05$), VAS for pain evaluation ($p < 0.05$), International Prostate Symptom Score (IPSS) ($p < 0.05$), International Index of Erectile Function (IIEF) ($p < 0.05$) and voiding conditions ($p < 0.05$) compared to the other group at 1, 4, and 12 weeks follow-up [26].

Another study involving 32 patients suffered from CP for over three months were also treated with the same LI-ESWT protocol. It was observed that at 12 weeks of follow-up, there were statistically significant improvements in NIH-CPSI score ($19.57 \pm 7.31$; $p < 0.05$) and VAS pain score ($4.00 \pm 1.66$; $p < 0.05$) from baseline NIH-CPSI score ($26.14 \pm 9.26$) and VAS pain score ($6.14 \pm 2.86$). Although the differences were not statistically significant, there were slight improvements in the urinary score (baseline $= 4.57 \pm 3.76$; week $12 = 3.43 \pm 3.13$; $p > 0.05$) and QoL (baseline $= 9.14 \pm 2.38$; week $12 = 8.71 \pm 3.17$; $p > 0.05$) at 12 weeks follow-up compared to their baseline values respectively [21].

Similarly, Skaudickas et al. applied the same treatment protocol on 40 patients diagnosed with CP in Lithuania. The effects of LI-ESWT on pain QoL, erectile function and urination were evaluated at 4 and 12 weeks follow-up based on NIH-CPSI, IPSS, IIEF and VAS. According to the study results, statistically significant improvements were observed in all the parameters of NIH-CPSI (43%; $p < 0.001$), IPSS (37%; $p < 0.001$), IIEF (6%; $p < 0.001$) and VAS (24%; $p < 0.001$) at week 4, with the greatest improvement recorded for NIH-CPSI. The treatment effect remained throughout the entire 12 weeks of follow-up period. At 12 weeks follow-up, significant improvements were still observed in NIH-CPSI (38%; $p < 0.001$), IPSS (39%; $p < 0.001$), IIEF (8%; $p < 0.001$) and VAS (52%; $p < 0.001$), with the greatest improvement recorded for VAS [27]. When the same protocol was applied on a group of 91 patients with prostatitis-like symptoms and treatment effects were evaluated at 1, 2, 3, 4, 5, 8 and 16 weeks follow-up, significant improvements in NIH-CPSI, IPSS and VAS were observed at week 4 when compared to baseline values ($p < 0.05$), except for IIEF-5. The treatment effective rates at week 1, week 2, week 3, week 4, week 5, week 8 and week 16 were 28.57%, 38.46%, 47.25%, 51.65%, 57.30%, 68.18% and 69.44% respectively. This suggested that the efficacy of LI-ESWT could be maintained within four months [28].

Another study also applied the same protocol on a group of 155 patients with CP, but the treatment effects on NIH-CPSI, IPSS, VAS and IIEF-5 were observed over a longer period of 12 months follow-up. Significant improvements were observed for NIH-CPSI ($p < 0.05$), IPSS ($p < 0.05$), VAS ($p < 0.05$) and IIEF-5 ($p < 0.05$) among the patients throughout the whole follow-up period, indicating the long-lasting treatment effect of LI-ESWT. At first month follow-up after the treatment, 82.8% patients ($n = 63$) had $\geq 6$ points decrease in NIH-CPSI total score. It was also observed that patients with history of psychological disorders and had higher baseline NIH-CPSI score demonstrated significantly lower response rate to LI-ESWT ($p = 0.005$, 0.02 & $p = 0.002$, 0.004 respectively), as compared to patients without psychological disorders and lower baseline NIH-CPSI score [29]. None of the above studies reported any adverse effect following the treatment protocol of 3000 pulses delivered at EFD of 0.25 mJ/mm$^2$ and frequency of 3 Hz over four sessions.

Next, a study modified the treatment protocol stated above by adjusting its frequency to 240 pulses per min. This 4-session protocol (once a week for 4 weeks) was then tested on 33 male patients with CP refractory to the conventional 3-As therapy. The patients recruited were those who did not achieve 6-point decrease in NIH-CPSI total score after taking a full course maximal dose of 3-As therapy for at least three of the preceding 6 months. The 3-As therapy included fluoroquinolone (500 mg once daily), alpha blocker (recommended dose once daily) and acetaminophen / non-steroidal anti-inflammatory drug (recommended dose twice or three times daily). Clinical symptoms of patients were assessed at 1, 4 and 12 weeks follow-up after LI-ESWT based on NIH-CPSI score, VAS score, IIEF-5 and IPSS. It was observed that the mean value of NIH-CPSI total score decreased from baseline $28.03 \pm 6.18$ to $18.97 \pm 8.35$ and $15.06 \pm 7.67$, with differences of 9.06 and 12.97 ($p < 0.001$) at 4 and 12 weeks follow-up respectively. 81.82% patients ($n = 27$) had $\geq 6$-point decrease in NIH-CPSI total score with a 3.29 decrease ($p < 0.001$) and 5.97 decrease ($p < 0.001$) in VAS score and IPSS total score respectively at 12 weeks follow-up after LI-ESWT. Significant increase in mean value of IIEF from baseline $17.52 \pm 4.71$ to $19.42 \pm 4.12$ was also recorded at 12 weeks follow-up, with a difference of 1.9 ($p = 0.002$). No adverse effect was reported following the protocol adjustment of frequency to 240 pulses per min [30].

Meanwhile, in 2013, another study applied the usual protocol of 3000 pulses delivered at EFD of 0.25 mJ/mm$^2$ and frequency of 3 Hz over the course of 4 sessions (once a week for 4 weeks), but with slight modification to the EFD. An EFD of 0.05 mJ/mm$^2$ was added for each week (0.3 mJ/mm$^2$ in week 2, 0.35 mJ/mm$^2$ in week 3 and 0.4 mJ/mm$^2$ in week 4). The effects of LI-ESWT were then observed at 1, 2, 3 and 12 weeks follow-up based on NIH-CPSI score, pain domain, urinary score and QoL. At 12 weeks follow-up, significant differences in NIH-CPSI score ($19.4 \pm 1.4$ vs $26.9 \pm 3.0$; $p < 0.0001$), pain domain ($9.5 \pm 0.9$ vs $13.7 \pm 1.6$; $p < 0.0001$), urinary score ($3.7 \pm 1.5$ vs $5.4 \pm 1.3$; $p = 0.001$) and QoL ($6.1 \pm 0.8$ vs $7.8 \pm 0.9$; $p < 0.0001$) were observed between the group who received LI-ESWT treatment and those in the sham group, respectively. The results revealed that the NIH-CPSI total score ($26.5 \pm 3.4$ vs $16.3 \pm 2.1$), pain domain ($13.8 \pm 2.6$ vs $8.7 \pm 1.5$), urinary score ($4.6 \pm 2.8$ vs

2.9 ± 1.5) and QoL (8.1 ± 1.7 vs 4.6 ± 1.3) in the LI-ESWT group were improved at 3 weeks follow-up. However, the improvements showed slight deterioration at 12 weeks follow-up but remained lower than baseline scores (19.4 ± 1.4; 9.5 ± 0.9; 3.7 ± 1.5; 6.1 ± 0.8), indicating lasting LI-ESWT effects until 12 weeks follow-up period. In the sham group, mild decrease in all the parameters were observed at 3 weeks follow-up (27.1 ± 3.1 vs 22.4 ± 1.1; 13.6 ± 2.0 vs 11.0 ± 0.7; 5.2 ± 2.0 vs 4.3 ± 0.9; 8.3 ± 1.9 vs 7.0 ± 0.7). By 12 weeks follow-up, however, the values for all parameters returned to baseline (26.9 ± 3.0; 13.7 ± 1.6; 5.4 ± 1.3; 7.8 ± 0.9) [31].

In the subsequent year, the same group of researchers conducted another study investigating treatment effects of the modified protocol with 0.05 mJ/mm$^2$ EFD increment for each session over a long-term follow-up period of 16, 20 and 24 weeks. This study, which involved the same batch of CP patients in 2013, reported no significant differences in NIH-CPSI total score (26.41 ± 1.53 vs 27.00 ± 1.01; $p = 0.184$), pain domain (13.58 ± 2.12 vs 13.59 ± 1.76; $p = 0.982$), urinary score (4.83 ± 1.84 vs 5.18 ± 1.72; $p = 0.550$) and QoL (8.00 ± 1.18 vs 8.16 ± 1.35; $p = 0.701$) between the treatment group and sham group at week 24. For both treatment (26.03 ± 3.72 vs 26.41 ± 1.53; 13.05 ± 2.60 vs 13.58 ± 2.12; 4.71 ± 2.69 vs 4.83 ± 1.84; 8.18 ± 1.71 vs 8.00 ± 1.18) and sham groups (27.18 ± 2.51 vs 27.00 ± 1.01; 13.77 ± 1.90 vs 13.59 ± 1.76; 5.19 ± 1.77 vs 5.18 ± 1.72; 8.22 ± 2.20 vs 8.16 ± 1.35), scores for all four parameters were not statistically significant from baseline at week 24. On the contrary, the values at week 24 showed deterioration when compared to baseline. The results indicated that although LI-ESWT protocol with EFD increment for each session is a safe and effective treatment method when evaluated over short-term follow-up period, its treatment effect does not last over long-term follow-up period [32].

In addition to the conventional LI-ESWT protocol of 3000 pulses at EFD of 0.25 mJ/mm$^2$ and frequency of 3 Hz performed over the course of 4 weeks (once per week in a total of four sessions), Pajovic et al. treated their group of 30 CP patients with an additional medication of alpha blocker, anti-inflammatory agent and muscle relaxant. Effects on NIH-CPSI score, post void residual urine (PVR) and maximum flow rate ($Q_{MAX}$) were assessed at 12, 24 and 36 weeks follow-up. Following combined LI-ESWT treatment with medication, significant improvements were observed in NIH-CPSI score ($p < 0.05$), PVR ($p < 0.05$) and $Q_{MAX}$ ($p < 0.05$). When compared to patients who only treated with triple medication, patients treated with combined LI-ESWT and medication achieved better improvements in all the parameters measured ($p < 0.05$) [33].

While maintaining the number of electric pulses at 3000 and EFD at 0.25 mJ/mm$^2$, Wu et al. modified the LI-ESWT protocol by increasing the frequency to 4 Hz and number of sessions to a total of six sessions (once a week for 6 weeks). The modified protocol was performed on a group of 215 patients with CP and its efficacy was assessed at 1, 2, 6 and 12 months follow-up, using NIH-CPSI, IPSS and American Urological Association Quality of Life (AUA QoL_US) (for urinary symptoms evaluation), as well as IIEF-5 and Erection Hardness Score (EHS) (for sexual function evaluation). For CP symptoms evaluation, when comparing to the mean baseline NIH-CPSI total score of 27.10 ± 6.81, the mean NIH-CPSI total scores decreased by 31.3%, 37.3%, 35.7% and 53.6% at 1, 2, 6 and 12 months follow-up, respectively. For LUTS evaluation, when comparing to the baseline IPSS value of 13.9 ± 8.41, a 27.1%, 38.0%, 42.0% and 50.9% time-dependent improvements were observed for urinary symptom severity at 1, 2, 6 and 12 months. In terms of QoL, significant improvements in mean AUA QoL_US score compared to baseline (4.29 ± 1.54) were observed at 2 (3.45 ± 2.34; $p = 0.0339$), 6 (3.25 ± 1.69; $p = 0.0001$) and 12 months (2.60 ± 1.56; $p < 0.0001$). For sexual function, IIEF-5 scores improved significantly at 1 (18.43 ± 6.43; 1.1 fold; $p = 0.0019$), 2 (20.42 ± 5.59; 1.3 fold; $p = 0.0046$), 6 (20.25 ± 5.94; 1.3 fold; $p = 0.0348$) and 12 months (18.65 ± 6.85; 1.2 fold; $p = 0.0002$), compared to mean baseline score of 15.82 ± 7.70. Such improvements were consistent with improved EHS recorded at 3.37 ± 0.65, 3.42 ± 0.58, 3.75 ± 0.45 and 3.32 ± 0.85 for 1, 2, 6 and 12 months follow-up, compared to baseline (3.11 ± 0.99). This findings proved the effectiveness of the modified six-session LI-ESWT to be maintainable for at least one year [34].

Meanwhile, Kim et al. extended the number of sessions for the LI-ESWT protocol of 3000 pulses at EFD of 0.25 mJ/mm$^2$ and frequency of 3 Hz to a total of 8 sessions performed once a week for 8 weeks. They assessed the efficacy of the modified treatment protocol by comparing between groups who received LI-ESWT ($n = 15$) and those who received placebo treatment ($n = 15$). At week 4 follow-up, significant improvements in NIH-CPSI total score (16.1 ± 4.2 vs 27.1 ± 4.8; $p < 0.05$), IIEF-EF (14.0 ± 11.4 vs 11.3 ± 10.7; $p < 0.05$), VAS (2.7 ± 1.9 vs 6.5 ± 2.5; $p < 0.05$) and QoL (5.7 ± 2.3 vs 9.1 ± 2.2; $p < 0.05$) compared to baseline were observed for the LI-ESWT group, but not for the placebo group. In comparison between the two experimental groups, significant differences were observed for all the parameters of NIH-CPSI total score ($p = 0.002$), IIEF-EF ($p = 0.019$), VAS ($p = 0.002$) and QoL ($p = 0.001$) at week 4 follow-up. This indicated the efficacy of the increased number of LI-ESWT sessions to eight to be maintainable up to 4 weeks after treatment [4].

Similarly, another study also employed the 8 sessions (performing once a week for 8 weeks) LI-ESWT regimen involving deliverance of 3000 pulses, but with slight modification to the frequency (10 Hz) and pressure (1.8–2.0 bar). Started at 1.8 bar, the pressure was increased by 0.1 bar per week until 2.0 bar. Efficacy of LI-ESWT in

treating CP was evaluated based on comparison between LI-ESWT group ($n = 25$) and control group treated with conventional drugs ($n = 20$). The combination of drugs prescribed were alpha blocker (tamsulosin 0.2 mg/day) and anti-inflammatory (celecoxib 200 mg/day). The results showed that 100% of patients in LI-ESWT group scored ≤ 2 on NIH-CPSI QoL whereas 90% (18 out of 20) patients in the control group scored ≤ 2 on NIH-CPSI QoL after treatment. As high as 96% (24 out of 25) patients in LI-ESWT group achieved > 50% reduction in NIH-CPSI total score, while only 75% (15 out of 20) patients in the control group had the same achievement. Both LI-ESWT and control groups exhibited significant improvements in NIH-CPSI ($p < 0.001$), IPSS ($p < 0.001$), VAS ($p < 0.001$), IIEF-5 ($p < 0.001$) and QoL ($p < 0.001$) at 3 months follow-up when compared to baseline values. For between-group comparisons, significant differences between the two groups were observed for NIH-CPSI ($p = 0.006$) and IIEF-5 ($p = 0.002$) immediately after treatment at week 8. At 3 months follow-up period, the CP recurrence rates for LI-ESWT group and control group were 4% (1 out of 25) and 50% (10 out of 20), respectively. The difference was statistically significant ($p < 0.001$). Low recurrence rate among the LI-ESWT group indicated the shockwave protocol with modified frequency and pressure could maintain the treatment effect for as long as 3 months for most CP patients [23].

While maintaining the total course of 8 sessions for LI-ESWT similar to Kim et al. and Zhang et al., Trishch et al. conducted the shockwave therapy twice a week for 4 weeks, applying 3000 pulses at energy of 90–120 mJ, frequency of 10 Hz and pressure of 1.5–2.0 bar on the perineum. Results showed significant improvements in NIH-CPSI total score ($12.85 \pm 1.36$ vs $26.85 \pm 4.41$; $p = 0.015$), pain or discomfort ($6.45 \pm 0.94$ vs $14.48 \pm 1.93$; $p = 0.018$), and QoL ($1.64 \pm 0.17$ vs $4.33 \pm 0.96$; $p = 0.009$) at 6 months follow-up compared to baseline. The CP symptom dynamics parameter, violations of urination showed slight improvement at 6 months follow-up ($3.21 \pm 0.11$) from baseline ($3.97 \pm 0.83$), but the changes were not significant ($p = 0.132$). For parameters concerning prostate hemodynamics, significant improvements were observed at 6 months follow-up for peak systolic velocity ($p = 0.010$), diastolic velocity ($p = 0.024$), average linear velocity ($p = 0.020$), pulsation index ($p = 0.007$), index of resistance ($p = 0.004$), diameter of vessels ($p = 0.004$), density of vascular plexus ($p = 0.008$) and volumetric blood flow ($p = 0.004$). The total relative improvement in the prostate hemodynamics for the patients treated with LI-ESWT were 39.2% at 6 months follow-up. This findings showed that the application of LI-ESWT provides stimulation of microcirculation in the prostate gland, thus contributing to a stable and long-lasting clinical effect [11].

Similar to Trishch et al., Salama and Abouelnaga also conducted the LI-ESWT twice per week for 4 weeks (8 sessions). They delivered 3000 pulses per session, at a frequency of 12 Hz and pressure of 3–5 bar, with the pressure increased gradually until reaching the tolerable level of pain. At 8 weeks follow-up evaluation time, significant improvements were observed for NIH-CPSI total score ($5.70 \pm 3.81$ vs $26.15 \pm 2.94$), pain domain ($2.45 \pm 1.73$ vs $12.00 \pm 1.58$), urinary score ($1.4 \pm 1.09$ vs $5.8 \pm 1.5$) and QoL ($1.85 \pm 2.03$ vs $8.35 \pm 1.18$) when compared to baseline ($p < 0.05$), within the group of patients receiving LI-ESWT. For comparison in between the treatment group and control group, significant differences were observed for all four parameters at 8 weeks follow-up ($p < 0.05$). Improvements observed in the treatment for the four parameters were significantly better than that of the control group ($p < 0.05$) [35].

While maintaining the number of pulses at 3000 and EFD at 0.25 mJ/mm$^2$, Daneshwar et al. modified the frequency to 5 Hz and increased the number of LI-ESWT sessions to 10 sessions (twice a week for 5 weeks). They assessed the efficacy of this protocol on a group of 50 patients with recurred CP symptoms. Their symptoms recurred after being prescribed with either 500 mg of levofloxacin once daily or 500 mg of ciprofloxacin twice daily along with alpha blockers, harnal or tamsulosin. So, in addition to the modified LI-ESWT treatment, 5 mg of Cialis once daily was also prescribed in combination with the LI-ESWT treatment. Effectiveness of the combined regimen of LI-ESWT and medication was evaluated at a follow-up period of 1/12 post-treatment based on NIH-CPSI, pain domain, QoL, IPSS, IIEF and Sexual Health Inventory for Men (SHIM) scores as well as changes in uroflowmetry. Following the completion of 10 sessions of LI-ESWT, significant improvements were observed in NIH-CPSI ($0.74 \pm 1.03$ vs $5.14 \pm 14.5$; $p < 0.001$), pain domain ($0.9 \pm 1.37$ vs $9.92 \pm 5.72$; $p < 0.001$), IPSS ($9.04 \pm 7.01$ vs $24.68 \pm 9.28$; $p < 0.001$), IIEF ($49.48 \pm 28.30$ vs $45.42 \pm 16.24$; $p = 0.036$) and QoL ($1.16 \pm 1.78$ vs $8.02 \pm 3.17$; $p < 0.001$), except SHIM ($16.02 \pm 9.85$ vs $14.28 \pm 6.02$; $p = 0.130$), when compared to baseline. For improvements in uroflowmetry, no significant changes were recorded in terms of peak flow rate ($20.58 \pm 7.84$ vs $21.21 \pm 10.77$; $p = 0.336$), void volume ($472.85 \pm 169.95$ vs $436.17 \pm 185.35$; $p = 0.057$) and voiding time ($48.34 \pm 22.36$ vs $44.41 \pm 25.26$; $p = 0.757$), in comparison to baseline values. Despite some parameters like SHIM and uroflowmetry which showed no significant changes post LI-ESWT treatment, the significant improvements demonstrated by other parameters such as NIH-CPSI, pain domain, IPSS, IIEF and QoL indicated an overall success of the treatment in improving the CP symptoms among the patients [24].

In general, LI-ESWT protocol, which involves deliverance of 3000 pulses at EFD 0.25 mJ/mm$^2$ with frequency

varies from 3 to 12 Hz and pressure varies from 1.5 bar to 5 bar, performing over the course of 4–10 sessions, or conducted in combination with additional medication, is a safe and effective procedure that can be used to treat CP. No serious adverse effects like hematuria, hemospermia, perineal pain or ecchymosis emerge following the LI-ESWT treatment as reported from all the studies stated above. With the exception of protocol involving gradual weekly increment of EFD described by Vahdatpour et al. [31] and Moayednia et al. [32] that reported failure of the protocol in maintaining treatment effect on a long-term basis, the rest of the protocols show great improvements in CP symptoms, urinary symptoms, erectile function and QoL with the treatment effect successfully maintained for as long as one year post-treatment.

## LI-ESWT delivered at < 3000 pulses

As illustrated in Table 2, some studies recorded the application of LI-ESWT protocol that delivered pulses less than 3000 pulses. For example, in 2016, a study documented the deliverance of 2500 pulses at EFD 0.25 mJ/mm$^2$ with, frequency of 3 Hz and pressure of 1 bar, performed once a week for 4 weeks (4 sessions). The duration for each session was approximately 13 min. When the protocol was assessed on 25 CP patients who failed at least previously three modalities of treatment including lipophilic antibiotic, simple analgesic and alpha blockers, it was found out that the NIH-CPSI total score ($15.4 \pm 6.6$ vs $27.5 \pm 8.7$; $p = 0.000$), IPSS ($11.0 \pm 7.4$ vs $18.8 \pm 8.9$; $p = 0.000$), IIEF ($19.6 \pm 4.6$ vs $15.8 \pm 6.2$; $p = 0.001$) and AUA QoL_US ($2.3 \pm 1.1$ vs $4.6 \pm 1.4$; $p = 0.000$) showed significant improvements at 2 weeks follow-up post-treatment from baseline [22]. In 2017, another study was conducted to investigate the long-term effect of the LI-ESWT protocol over a follow-up period of 6 and 12 months. Similar to previous 2016 study, this study was also conducted on a larger group of 41 CP patients who failed to respond to at least previously three modalities of treatment other than LI-ESWT. The results reported 30% improvements in NIH-CPSI total score ($p = 0.000$), 38% in IPSS ($p = 0.000$), 18% in IIEF ($p = 0.002$) and 33% in AUA QoL_US ($p = 0.000$) at 12 months follow-up compared to baseline. The differences in all parameters were statistically significant [36]. This showed that the LI-ESWT protocol with reduced electric pulses to 2500 pulses is effective and its treatment effect could be maintained both short-term and long-term for as long as a year after the therapy.

Meanwhile, another study documented a LI-ESWT protocol with further reduced pulses to 2000 delivered at a lower EFD of 0.06 mJ/mm$^2$ and lower frequency of 2 Hz, but with increased number of sessions to 10 sessions performing 5 times a week for 2 weeks. The EFD was started at 0.06 mJ/

**Table 2** Summary of studies using 2000–2500 pulses LI-ESWT protocol

| Studies | Study design | Sample size | Treatment protocol | Treatment duration | Follow-up | Outcomes | References |
|---|---|---|---|---|---|---|---|
| Al Edwan et al. (2016) | Open-label uncontrolled clinical trial | 25 patients | 2500 pulses at EFD 0.25 mJ/mm$^2$, frequency 3 Hz and pressure 1 bar | Once a week for 4 weeks (4 sessions) | 2 weeks | Significant improvement in NIH-CPSI ($p = 0.000$), IPSS ($p = 0.000$), AUA QOL_US ($p = 0.000$) and IIEF ($p = 0.001$); no adverse effect | [22] |
| Al Edwan et al. (2017) | Open-label uncontrolled clinical trial | 41 patients | 2500 pulses at EFD 0.25 mJ/mm$^2$, frequency 3 Hz and pressure 1.0 bar | Once a week for 4 weeks (4 sessions) | 6 and 12 months | Significant improvement in NIH-CPSI (30%, $p = 0.000$), IPSS (38%, $p = 0.000$), AUA QOL_US (33%, $p = 0.000$) and IIEF (18%, $p = 0.002$); no adverse effect | [36] |
| Zeng et al. (2012) | Prospective, randomized and sham-controlled study | 80 patients | 2000 pulses at EFD 0.06 mJ/mm$^2$ (intensity increased until maximum tolerable pain level) and frequency 2 Hz | 5 times a week for 2 weeks (10 sessions) | 4 and 12 weeks | Significant improvement in NIH-CPSI, pain domain and QoL ($p < 0.01$); no adverse effect | [37] |

$mm^2$ and was then gradually increased to the maximum level of tolerable pain reported by the patient. This EFD was recorded to be used as the EFD for subsequent sessions. The efficacy of the modified protocol was assessed by comparing between a group of patients treated with actual LI-ESWT ($n=40$) and another group receiving sham treatment ($n=40$). Assessment was conducted at 4 and 12 weeks follow-up after treatment based on NIH-CPSI, pain domain and QoL. For within group comparison, significant improvements in NIH-CPSI score ($p<0.01$), pain domain ($p<0.01$) and QoL ($p<0.01$) were observed among LI-ESWT group at 12 weeks follow-up compared to baseline. While no significant improvements were observed among the sham group for all parameters ($p>0.05$) at 12 weeks follow-up. For between-group comparison, significant differences were observed for NIH-CPSI score ($p<0.05$), pain domain ($p<0.05$) and QoL ($p<0.05$) between the two groups, with better improvements in all the parameters for LI-ESWT group at 12 weeks follow-up. Specifically, 71.1% of patients in LI-ESWT group exhibited perceptible improvement in NIH-CPSI score compared to 27.0% of patients in the sham group at end-point follow-up ($p<0.001$). 28.9% of patients in LI-ESWT group exhibited clinically significant improvement in pain compared to 10.8% in sham group ($p<0.01$). Also, greater number of patients in LI-ESWT group were rated as responders (perceptible and clinically significant responses) at 4 and 12 weeks follow-up compared to patients in sham group [37].

Overall, LI-ESWT protocol with varying electric pulses (2000–2500 pulses), EFD (0.06–0.25 $mJ/mm^2$, frequency (2–3 Hz) and number of sessions (4 sessions–10 sessions) proved to be a safe procedure without any reported adverse effect. Moreover, these protocols are suggested to be effective since the clinical improvements in terms of urinary symptoms, pain, erectile function and QoL could be maintained throughout short-term and long-term follow-up period.

## LI-ESWT delivered at > 3000 pulses

Several studies employed a LI-ESWT protocol with increased pulses of 5000 administered over a total course of 6 sessions (Table 3). A study performed the 5000 pulses LI-ESWT at an EFD of 0.096 $mJ/mm^2$ and frequency of 5 Hz on a cohort of 50 patients with CP. By randomizing the patients into two groups, 25 patients in each group, the study aimed to investigate whether there was any difference in treatment efficacy when the designated LI-ESWT procedure was administered once (extended over 6 weeks) or twice a

**Table 3** Summary of studies using 5000 pulses LI-ESWT protocol

| Studies | Study design | Sample size | Treatment protocol | Treatment duration | Follow-up | Outcomes | References |
|---|---|---|---|---|---|---|---|
| Mykoniatis et al. (2021) | Two-arm, parallel-group, randomized controlled trial | 50 patients | 5000 pulses at EFD 0.096 $mJ/mm^2$ and frequency 5 Hz | Once a week for 6 weeks vs twice a week for 3 weeks (6 sessions) | 1 and 3 months | Significant improvement in NIH-CPSI, pain, QoL, IPSS and IIEF-ED ($p<0.001$) for both groups; no significant differences in NIH-CPSI, pain, urinary, QoL, IPSS and IIEF-ED between both groups; no adverse effects | [25] |
| Mykoniatis et al. (2021) | Prospective, sham-controlled, double-blind study | 45 patients | 5000 pulses at EFD 0.1 $mJ/mm^2$ and frequency 5 Hz | Once a week for 6 weeks (6 sessions) | 4, 12 and 24 weeks | Significant improvement in NIH-CPSI, pain and QoL subdomains, but not NIH-CPSI urinary subdomain, IPSS, PSA and mpMRI-PIRADS, when compared to sham group | [38] |

week (extended over 3 weeks). At 1- and 3-months follow-up evaluations, the NIH-CPSI total, pain, QoL, IPSS and IIEF-ED scores were significantly improved in both groups ($p < 0.001$ for all parameters). When comparing between the two groups, however, no significant differences were observed in all the parameters at both follow-up evaluations. No adverse events or dropouts recorded for both experimental groups. This indicated that applying the LI-ESWT protocol either once weekly for 6 weeks or twice weekly for 3 weeks were equally safe and effective in treating CP [25].

Maintaining the frequency at 5 Hz, another study used a 5000 pulses LI-ESWT protocol with slight modification to the EFD (0.1 mJ/mm$^2$), administered once a week for 6 weeks (6 sessions). When comparing to a group of 15 CP patients receiving sham treatment, 30 patients in the LI-ESWT group showed clear and persistent improvements in NIH-CPSI total score, pain and QoL subdomains at 4, 12 and 24 weeks follow-up after the treatment. On the other hand, NIH-CPSI urinary subdomain, IPSS, PSA and mpMRI-PIRADS scores did not show significant difference between the two groups for all follow-up timepoints. Adverse effect was not reported from the patients following the LI-ESWT [38].

In general, application of 5000 pulses at either 0.096 mJ/mm$^2$ or 0.1 mJ/mm$^2$ over the course of 6 sessions is shown to be safe since no adverse effect is reported from the studies. In terms of improvements in CP symptoms, erectile function and QoL, the treatment effect of 5000 pulses LI-ESWT can be maintained over both short- and long-term period of time, extending from 1 to 6 months.

## Future perspective

Although many research have been conducted on the efficacy of 3000 pulses LI-ESWT protocol, research on its efficacy over a long-term basis is still lacking. Since there are variation in the outcomes reported for long-term maintenance of treatment effect, further research should be conducted to investigate this variation. Hopefully, factors that contribute to this variation would be defined and eliminated to provide an effective treatment option for CP with more stable long-term clinical effect. Moreover, extensive research should be conducted to examine the efficacy of LI-ESWT being applied in combination with other treatment like medication to improve the efficiency in treating CP. Although research has shown the feasibility of this treatment regimen in mitigating CP, its short-term and long-term effect are still largely unknown. Therefore, more clinical trials should be conducted to fill-in this gap. Lastly, research concerning the difference in treatment efficacy between focused and radial LI-ESWT is still preliminary. Most of the research conducted focus on protocol utilizing focused LI-ESWT. Even though radial LI-ESWT has also been proven to be effective in improving the symptoms of CP, the difference in its treatment effect from that of focused LI-ESWT remains unclear. Hence, this knowledge gap should be filled by comparing the efficacy between these two types of shockwave therapy.

## Concluding section

In conclusion, most of the LI-ESWT protocols described above are safe and effective in treating CP, as demonstrated by the absence of treatment-related adverse effects and

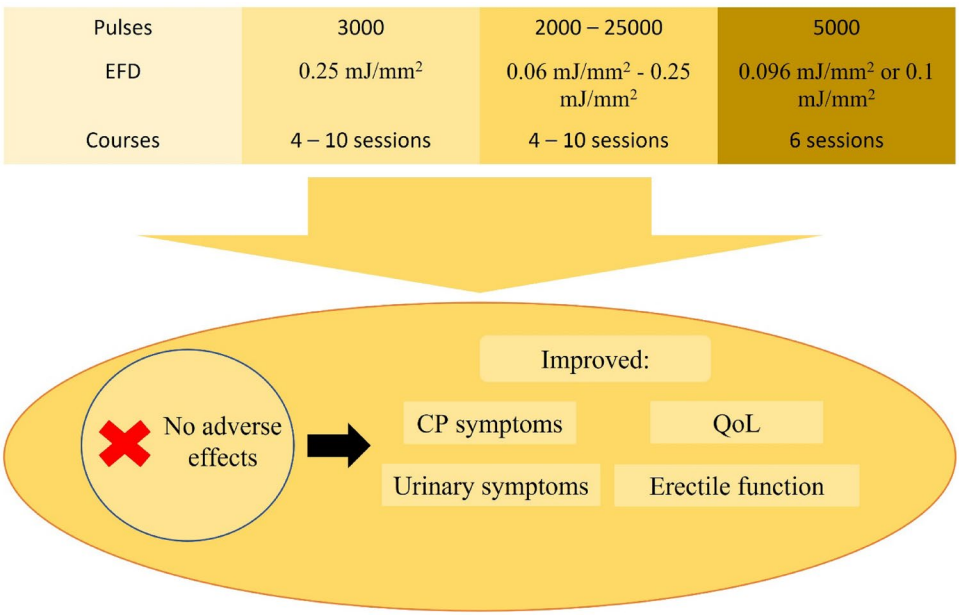


**Fig. 1** Summary of LI-SWT protocols

maintenance of clinical effects over both short- (2 weeks) and long-term period of time (one year) (Fig. 1). For the aspects of clinical effects, great improvements in CP symptoms, urinary symptoms, erectile function and QoL are widely reported from the studies. With the exception of a protocol that involves deliverance of 3000 pulses at gradually increased EFD for each week (which reported slight deterioration in the improvements of urinary symptoms, pain and QoL at week 24), the remaining protocols that involve deliverance of various number of pulses at a stable EFD exhibit great maintenance of clinical effects in the patients extended over a period of time post-treatment. Hence, it can be deduced that regardless of the changes in number of pulses, frequency, pressure, total number of sessions and number of sessions performed in each week, the desired clinical effects can be maintained effectively with the application of a stable EFD (at any intensity) for each LI-ESWT session. In view of the large number of studies supporting the application of protocol involving deliverance of 3000 pulses at EFD 0.25 $mJ/mm^2$ and frequency of 3 Hz over a total course of 4 sessions (once a week for 4 weeks) through multiple reported favorable outcomes, it is recommended for this protocol to be an alternative treatment option for CP.

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**Data availability** The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request. Data are located in controlled access data storage at Prince Court Medical Centre.

## Declarations

**Conflict of interest** The authors declared no competing interests.

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