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Invited State-Of-The-Art Review

Regenerative therapies for male sexual dysfunction - a review article

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ABSTRACT

Low-intensity extracorporeal shock wave therapy (Li-ESWT), stem cell therapy and platelet-rich plasma (PRP) injections have emerged as possible treatments for erectile dysfunction (ED) and Peyronie's disease (PD). Li-ESWT appears to work by prompting angiogenesis, yet clinical trials in ED and PD have yielded contradictory results, often compromised by methodological limitations. Similarly, while preliminary studies on stem cell therapy and PRP suggest potential benefits, their clinical efficacy remains uncertain. Standardised research is needed to establish the possible effect of these approaches.

KEY POINTS

- Erectile dysfunction and Peyronie's disease have detrimental effects on quality of life.
- Patients and providers are often unhappy with established treatments and look to regenerative options in the form of low-intensity extracorporeal shock wave therapy, stem cell therapy and platelet-rich plasma injections.
- None of these treatments has an established efficacy profile and should be considered experimental at this stage.

Erectile dysfunction (ED) and Peyronie's disease (PD) are two of the most common male sexual dysfunctions. ED signifies the lack of erections sufficient for satisfactory intercourse and affects approximately 30% of all men over the age of 40, with its prevalence rising as men age [1]. PD is a connective tissue disorder localised to the penis, characterised by the formation of fibrotic plaques within the tunica albuginea [2]. These plaques cause painful erections and progressive penile curvature during the active phase, often resulting in permanent disfigurement. Although it has little public and even medical awareness, PD affects 5-10% of all men, usually debuting after the age of 50 years [3, 4]. Both ED and PD have been shown to significantly impact both intimate relationships and quality of life [5, 6].

Conventional treatments for ED - including phosphodiesterase-5 (PDE5) inhibitors, vacuum devices, as well as injection therapy and intraurethral medications - offer only temporary relief of symptoms, whereas penile implants are an invasive alternative only indicated in severe cases of ED that are refractory to other options [7]. None of these approaches are curative, as they do not address the underlying tissue pathology. The evidence for pelvic floor training for ED remains limited, and it is not recommended in the guidelines of the European Association of Urology [7]. For PD, there is a lack of effective conservative treatment options altogether, frequently making surgical intervention necessary [7]. Considering these therapeutic limitations, interest in regenerative therapies has been growing in recent years. These treatments hold the promise of restoring

damaged tissue and offering a curative solution. For male sexual dysfunction, the focus has been on low-intensity extracorporeal shock wave therapy (Li-ESWT), stem cell therapy and injections of autologous platelet-rich plasma (PRP). Meanwhile, the current evidence is contradictory and limited by small patient cohorts, short follow-up periods and methodological challenges. Nevertheless, private providers are increasingly offering these treatments, often at considerable out-of-pocket costs [8]. The following sections outline the clinical evidence and ongoing controversies surrounding these three treatment approaches.

Low-intensity extracorporeal shock wave therapy (Li-ESWT)

Mechanism of action

Li-ESWT employs acoustic shock waves, generated by electrohydraulic, piezoelectric or electromagnetic technologies, to induce mechanical stress in the target tissues. This stress is believed to trigger a cascade of biological responses - including upregulation of vascular endothelial growth factor and other growth factors - that promote neoangiogenesis and may even facilitate nerve regeneration, both of which are critical for restoring erectile function [9]. Two main forms of ESWT are used: focused shockwave therapy, which delivers energy to precise depths within the tissue, and radial shockwave therapy, which disperses energy over a broader and more superficial area. There is consensus that the latter form is needed for the proposed mechanism of action to be possible, and relevant trials referenced below have employed this method.

Clinical Evidence in ED

In ED, several single-arm studies have shown encouraging improvements in erectile function with focused ESWT. Although some studies incorporate objective measures (e.g., penile duplex ultrasonography or nocturnal penile tumescence assessments), the primary outcomes are predominantly subjective, typically based on the patient-reported questionnaire International Index of Erectile Function (IIEF) (BOX 1) [10, 11]. This reliance on subjective outcomes heightens the potential for placebo effects, emphasising the need for randomised controlled trials. To date, several randomised trials have compared focused Li-ESWT to sham treatments in men with predominantly vascular ED [12-23] (**Table 1**).

TABLE 1. Randomised controlled trials comparing focused low-intensity extracorporeal shock wave therapy to sham

Reference	Included patients, n	Patients	FU, mos.	IIEF-EF/5 change ESWT versus sham	Significance
Vardi et al. 2012 [20]	33	Vasculogenic	1	+3	p =0.0322
Olsen et al. 2015 [21]	105	Vasculogenic	6	?	NS
Yee et al. 2014 [22]	58	Vasculogenic	1	1.5	p = 0.243
Srini et al. 2015 [23]	92	Vasculogenic	12	+11.4	p < 0.05
Kitrey et al. 2016 [13]	55	PDE5i-nonresponders	1	+4.5	p < 0.005
Fojecki et al. 2017 [14]	126	Vasculogenic	1.75	+0.7	p = 0.9
Kalyvianakis & Hatzichristou 2017 [15]	46	Vasculogenic	12	+3.9	p < 0.01
Yamaçake et al. 2019 [12]	20	Kidney transplanted	3	+4.7	p = 0.018
Shendy et al. 2021 [18]	42	Diabetics	1.25	+4.1	p < 0.001
Sramkova et al. 2020 [16]	60	Vasculogenic	3	+5.6	p < 0.001
Vinay et al. 2021 [17]	76	PDE5i-nonresponders	6	+4	p < 0.001
Ortac et al. 2021 [19]	66	Vasculogenic	3	+1.5	p = ?

ESWT = extracorporeal shock wave therapy; FU= follow-up; IIEF = International Index of Erectile Function; PDE5i = phosphodiesterase type 5 inhibitor.

Notably, the results of the trials are contradictory, with four trials (combined number of patients 355) showing no benefit over sham for their primary outcome (n=355) and seven trials (combined number of patients 332) showing a statistically significant improvement. In meta-analyses, this has translated into a small, combined benefit bordering on clinical significance [24, 25]. Notably, several of the individual trials have important drawbacks. For example, in the trial by Srini et al. [23] that reported the largest improvement in erectile function, dropout rates were 58% in the placebo group and 42% in the active group, with no explanation or statistical adjustments provided. These figures clearly compromise the study's validity; yet, the trial has been uncritically included in all published meta-analyses. Another important criticism is that most positive trials report either no or only a very small placebo effect in the sham groups - a finding that is uncommon in ED studies. This suggests a potential issue with blinding, which is unsurprising given that Li-ESWT is a mechanical treatment that, while painless, is still perceptible. In addition to trials in vasculogenic ED, Li-ESWT has been evaluated in men following prostate cancer surgery; most recently in a randomised trial by Pedersen et al [26]. These studies have not demonstrated a significant benefit over sham treatment. Beyond debates about its efficacy, treatment protocols vary considerably in energy delivery, treatment frequency and overall duration, with no consensus on the optimal approach.

Clinical evidence in PD

Similar to its application in ED, early uncontrolled case series of Li-ESWT in PD demonstrated potential benefits, notably in reducing pain and improving penile curvature [27]. Subsequent randomised trials of focused ESWT have confirmed an effect on pain but have been less encouraging regarding changes in curvature. In 2009, Palmieri and colleagues randomised 100 men with active-phase PD to receive either four weekly sessions of Li-ESWT or a sham treatment [28]. The Li-ESWT group achieved statistically significant reductions in pain and deformity compared to placebo, but the improvement in penile curvature was modest as the mean curvature

decreased by 1.43 degrees in the Li-ESWT group but increased by 1.8 degree in the placebo group. In another trial, 36 men with stable-phase PD were randomised to six sessions of either Li-ESWT or a sham treatment, with no significant differences being observed between the groups in either subjective or objective outcomes [29]. Similarly, another randomised placebo-controlled trial involving 102 men with stable-phase PD compared six weekly sessions of Li-ESWT to a sham treatment [30] . Although this study demonstrated a significant reduction in pain at four weeks in the Li-ESWT group, no improvement in penile curvature was observed; in fact, both of the latter two trials reported a non-significant numerical worsening in curvature among Li-ESWT–treated patients compared to sham. These findings align with a 2016 meta-analysis of six comparative studies, which concluded that while Li-ESWT reduces pain, it does not lead to improvements in penile curvature [31].

Stem cell therapy

Mechanism of action

Stem cell therapy for male sexual dysfunction aims to repair damaged erectile tissue through intrinsic regenerative capabilities, including differentiation into various cell types and secretion of growth factors that promote tissue repair [32].

Clinical evidence in ED

Despite a multitude of promising animal studies, the clinical evidence regarding stem cells is very limited. Thus, penile stem cell injections as a treatment for ED have mainly been explored in a series of small pilot studies with stem cells derived from several different sources (both autologous and allogeneic) and varying quality in their reporting of erectile function outcomes. Overall, autologous adipose-derived stem cells seem to be the most attractive option owing to their ease of harvest and immunological advantages. Such cells have been examined in two Danish trials, including 17 men with ED after prostate cancer surgery [33] and ten men with presumed vasculogenic ED, respectively [34] . In the prostatectomy study, 8/17 men achieved erections sufficient for sexual intercourse over the study period. However, the overall increase in erectile function score as measured by the International Index of Erectile Function Questionnaire was not statistically significant. In the second study, a modest statistically significant increase was observed in overall erectile function score. Still, on an individual level, only 3/10 men experienced clinically meaningful functional improvements. At the time of writing, only one – clearly underpowered – randomised trial on the subject has been published [35]. Here, 20 diabetic men were randomised to receive penile injections with autologous mesenchymal stem cells or saline. The study reported a significant increase in erectile function in the treatment group, bordering on a clinically meaningful improvement, and no significant changes in the placebo group.

Clinical evidence in Peyronie's disease

In PD, three investigations have explored the effects of intralesional stem cell injections into penile plaques. One study utilised allogeneic placental-derived mesenchymal stem cells , another employed autologous mesenchymal stem cells derived from the stromal vascular fraction , and the last study used autologous adipose-derived stem cells [36], another employed autologous mesenchymal stem cells derived from the stromal vascular fraction [37], and the last study used autologous adipose-derived stem cells [38]. Two studies observed improvements in penile curvature among patients in the chronic phase of PD, with one study reporting objective curvature improvements ranging from 10° to 120° (15-100% improvement) [36, 37]. The last study found no significant difference in curvature after treatment [38]. These preliminary findings are contradictory, and larger randomised controlled trials are necessary to examine the efficacy of stem cell therapy in PD.

Platelet-Rich Plasma Therapy

Mechanism of action

Platelet-rich plasma (PRP) therapy utilises a concentrated preparation of platelets derived from the patient's own blood. These platelets release growth factors that are believed to stimulate tissue repair and angiogenesis, thereby enhancing local regenerative processes [39]. However, the three randomised placebo-controlled trials have shown diverging results, with two positive and one negative trial.

Clinical evidence in erectile dysfunction

Like for the other regenerative treatment options, PRP has demonstrated promise in early uncontrolled case series, with most studies reporting modest improvements in erectile function [40]. However, results from three randomised, placebo-controlled trials remain mixed. In the first trial, Poulios et al. randomised 60 men with vasculogenic ED to receive either PRP or placebo [41]. At six months, 69% of the PRP group achieved a clinically meaningful improvement in erectile function, compared to 27% in the placebo group; a difference that reached statistical significance. Similarly, in a second randomised controlled trial by Shaher et al. (n=100), 70% of men in the PRP group showed improvement at 12 months versus 16% in the placebo group, also achieving statistical significance [42]. However, the overall IIEF erectile function score in the second study did not reach statistical significance. The third randomised trial by Masterson et al., which involved 28 men receiving intracavernosal PRP injections and 33 receiving placebo, found no significant differences at any follow-up point [43]. All studies utilised two PRP injections with penile constriction, and the reasons for these varied outcomes remain unclear. The two positive trials predominantly included men with mild ED, whereas the negative trial had a larger proportion of patients with moderate ED. Moreover, similar to findings in Li-ESWT studies, the positive trials exhibited an absence of placebo responses. In conclusion, further research is needed before PRP can be incorporated into the ED treatment armamentarium.

Clinical evidence in Peyronie's disease

For PD, research on PRP is even more limited. In one prospective cohort study, Virag et al. [44] evaluated a combined injection of PRP and hyaluronic acid in 90 patients with established penile plaques and deformity, reporting an average curvature reduction of approximately 16.54° - roughly a 40% improvement. In a retrospective case series, Matz et al. [45] noted that four out of five patients with available follow-up data experienced subjective improvements in curvature. Conversely, preliminary results from a randomised, placebo-controlled crossover trial [46] showed no significant changes in penile curvature, underscoring the variability in outcomes.

Conclusion

Regenerative treatments represent an attractive frontier in managing male sexual dysfunction because they are designed to repair the underlying tissue damage that conventional therapies do not address. However, despite encouraging preliminary data, current evidence remains limited and contradictory across all available options. None of these modalities has yet demonstrated robust, reproducible outcomes sufficient to establish them as curative treatments for ED or effective conservative alternatives for curvature correction PD. Consequently, large-scale, high-quality randomised controlled trials with standardised protocols are needed to determine their long-term efficacy and safety. Until such studies are available, the clinical use of these treatments remains controversial and questionable.

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