Original Article

Radial wave therapy does not improve early recovery of erectile function after nerve-sparing radical prostatectomy: a prospective trial

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Background: Low intensity shockwave therapy is an emerging treatment option for men with vasculogenic erectile dysfunction. Radial wave therapy (rWT), which differs from focused shockwave (fSWT) as it produces lower pressure waves with lower peak energy, is used to treat soft tissue and skin conditions and has some data to support its use in vasculogenic erectile dysfunction. There is limited data for the use of rWT for the treatment of erectile dysfunction after nerve-sparing (NS) radical prostatectomy. We report the first trial of rWT for penile rehabilitation after NS radical prostatectomy.

Methods: We performed a prospective, non-randomized, open-label trial. Men with good pre-operative erectile function who underwent a NS radical prostatectomy at our institution from 2018–2020 were considered for inclusion. We compared post-operative erectile function outcomes between the rWT (6 weekly treatments initiated approximately 2 weeks post-operatively) plus standard of care (phosphodiesterase type 5 inhibitor) arm and the non-sham controlled standard of care arm. The primary end point for our study was the proportion of men who returned to "near normal" erectile function, defined as IIEF-5 score ≥17 and erectile hardness score (EHS) ≥3, by 3 months post-operatively between the intervention and control arm. We also compared mean IIEF-5 scores and median EHSs between the arms.

Results: One hundred and six patients were enrolled, of whom 73 patients had at least one reported survey response between 6 and 12 weeks post-operatively. Five (17%) and 11 (26%) patients recovered erectile function in the control and intervention arms, respectively, which was not a statistically significant difference (P=0.37). However, the intervention arm did have a significantly higher median EHS compared to the control arm (1 *vs.* 2, P=0.03). There were 4 adverse events related to pain during treatment and required only treatment intensity de-escalation.

Conclusions: rWT is safe but did not substantially improve the recovery of early erectile function after NS radical prostatectomy.

Keywords: Erectile dysfunction (ED); penile rehabilitation; prostate cancer; shockwave; radial shockwave therapy

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Introduction

Low intensity shockwave therapy (SWT) is an emerging treatment option for men with vasculogenic erectile dysfunction (ED). The efficacy of SWT in this setting has been evaluated in several meta-analyses of randomized trials suggesting that men with vasculogenic ED experience a significant improvement in erectile function after SWT (1-4). The role of SWT in the post-radical prostatectomy (RP) setting for penile rehabilitation (5), however, is less clear, as the original randomized trials of SWT only enrolled men with vasculogenic ED and excluded men who had undergone RP.

The proposed mechanism of action of SWT—microtrauma that stimulates angiogenesis, stem cell proliferation, and nerve regeneration—suggests some potential for clinical efficacy in the post-RP setting (6,7). Furthermore, studies in rat models of cavernosal nerve injury suggest SWT may restore penile blood flow via revascularization and neuronal regeneration (7,8). There have been 5 studies evaluating SWT in the post-RP setting and 1 post-cystoprostatectomy, 3 of which were randomized controlled trials (9-14); these studies support the safety of low-intensity SWT after prostate surgery, but the clinical outcomes from these studies were underwhelming, noting only small increases in international index of erectile function-5 (IIEF-5) score and erectile hardness score (EHS) (11-13).

The pre-clinical data and clinical trials supporting the utility of SWT in ED uniformly used low-intensity focused shockwaves (fSWT). Radial wave therapy (rWT) is an alternative method of creating acoustic waves that differ from fSWT by having lower pressure waves that produce lower peak energy and thus low tissue penetrance (15-17). rWT is commonly utilized in orthopedics, physical therapy, and dermatology (18-21). The data supporting the use of rWT in ED is limited (22); at our institution the results of rWT treatment for men with vasculogenic ED was equivalent to fSWT (23). However, Sandoval-Salinas *et al.* found no difference between rWT and sham (24). Despite the limited data, rWT is often marketed directly to consumers as evidence-based treatment for ED (25). rWT has not yet been evaluated in the post-RP setting.

Here we report the first trial of rWT for penile rehabilitation after nerve-sparing (NS) RP. We hypothesized that rWT in addition to a phosphodiesterase type 5 inhibitor (PDE5I) would improve early recovery of erectile function following RP compared with a PDE5I alone. We present the following article in accordance with the TREND reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-22-310/rc).

Methods

Study design and population

We performed a prospective, non-randomized, open-label trial. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Cleveland Clinic institutional review board (No. 18-919) and informed consent was obtained from all individual participants. All men who underwent either open or robot-assisted RP with any surgeon (8 surgeons were included) at our institution from 2018 to 2020 were considered for inclusion. Men were identified for inclusion if their pre-operative IIEF-5 score was ≥17 (with or without a PDE5I) and they underwent a bilateral NS RP, as dictated on their operative report. Exclusion criteria included pre-operative moderate or severe ED (IIEF-5 score <17), non-NS surgery, adjuvant radiation therapy within the observation period (3 months post-operatively), Grade Group ≥4 prostate cancer (as these patients are at higher risk of requiring adjuvant radiation and we presumed that the NS may not be as thorough), or pre-operative vacuum erectile device or intracavernosal injection use. All eligible men were approached in the early post-operative period (<2 weeks post-operatively) and offered enrollment in the rWT arm. As a referral center with patients traveling from great distances for care, many patients would not be able to travel for the weekly rWT treatments. Those unable to participate in the rWT arm were invited to continue our standard care and allow us to monitor their outcomes in the control arm. A time diagram from day of NS RP through outcome assessments can be seen in *Figure 1*.

Intervention

At our institution, all post-NS RP patients are offered a PDE5I as part of their baseline penile rehabilitation. Selection of specific PDE5I drug, dosing, and frequency was left to the discretion of the treating surgeon, but most commonly entailed a daily low dose of either sildenafil or tadalafil. Men enrolled in the rWT arm were treated with 6 consecutive weekly sessions beginning approximately 2 weeks post-operatively. The Zimmer enPuls Pro (Zimmer MedizinSysteme GmbH, Neu-Ulm, Germany) rWT device was used to deliver 10,000 "shocks" per treatment

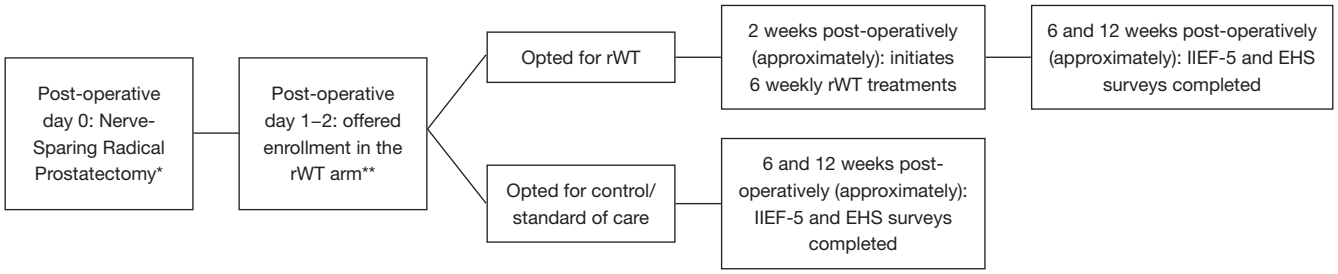

Figure 1 Time diagram of nerve sparing radical prostatectomy through outcome assessments. *, must meet all inclusion criteria: pre-operative IIEF-5 score ≥17 (with or without a phosphodiesterase type 5 inhibitor), underwent a bilateral nerve-sparing radical prostatectomy, as dictated on their operative report. Exclusion criteria included pre-operative moderate to severe erectile dysfunction (IIEF-5 score <17), non-nerve-sparing radical prostatectomy, adjuvant radiation therapy within the observation period (3 months post-operatively), Grade Group ≥4 prostate cancer or pre-operative vacuum erectile device or intracavernosal injection use. **, in addition to standard of care penile rehabilitation with a phosphodiesterase type 5 inhibitor. rWT, radial wave therapy; IIEF-5, international index of erectile function-5; EHS, erectile hardness score.

at a power of 90 mJ and frequency of 15 Hz. Treatment sites included the distal, mid, and proximal corporal shaft bilaterally as well as the cavernosal neurovascular bundles at the dorsal penopubic junction bilaterally for a total of 8 treatment sites.

Outcome measurements

IIEF-5 scores were collected pre-operatively on all patients undergoing RP in clinic. IIEF-5 and EHS surveys were mailed to participants in both arms to be returned at approximately 6 and 12 weeks post-operatively. The abridged five-item version of the IIEF (also known as the Sexual Health Inventory for Men) is a validated questionnaire that objectively measures erectile function in both clinical and research settings (26,27). The EHS is a validated, single-item 5-point survey to assess erectile hardness; scores 0 through 4 indicate subjective measurement of progressive erection hardness with 3 and 4 indicative of the ability to achieve penetrative intercourse (28). Additionally, patients were asked whether they were taking their PDE5I as prescribed.

The primary endpoint for this study was a comparison of the proportion of men who returned to "near normal" erectile function, defined as IIEF-5 score ≥17 and EHS ≥3, by 3 months post-operatively between the intervention and control arm. Secondary outcomes included comparisons of mean IIEF-5 scores and median EHS between the arms at 6–12 weeks post-operatively.

Statistical analysis

We assumed the baseline recovery of "near normal" erectile function by 12 weeks post-NS RP to be 20% and an absolute benefit of rWT of 25%. Using a power of 0.8 and alpha 0.05, we needed to recruit 54 patients per arm to adequately power our study.

Endpoints with binary outcomes were evaluated using the chi-squared test, while the independent samples *t*-test was used for continuous outcomes and the Mann-Whitney-Wilcoxon test for ordinal outcomes. P values <0.05 were considered statistically significant. Statistical analyses were performed using Jamovi Version 1.6.23

Results

One hundred and six patients were enrolled (62 in the control arm and 44 in the intervention arm) of whom 73 patients had at least one reported survey response between 6 and 12 weeks post-operatively (30 in the control arm and 43 in the intervention arm); for patients with two survey responses, the latter was used for analysis. Baseline patient characteristics are demonstrated in *Table 1*. No statistically significant differences were noted between the arms. The mean pre-operative IIEF-5 scores in the control and intervention arms were 22.8 (+/– 2.3) and 22.2 (+/– 2.5), respectively, which were not significantly different.

Erectile function outcomes are displayed in *Table 2*. For our primary outcome, 5 (17%) and 11 (26%) patients recovered early erectile function in the control and

Table 1 Patient characteristics

Characteristic	Control (n=30)	Intervention (n=43)	P value
Mean age (SD), years	62.5 (7.6)	59.5 (6.9)	0.11
Mean pre-operative IIEF-5 (SD)	22.8 (2.3)	22.2 (2.5)	0.34
Diabetes	1 (3%)	3 (7%)	0.49
Hypertension	10 (32%)	16 (37%)	0.48
Coronary artery disease	0	2 (5%)	0.23
Peripheral artery disease	0	0	–
Any smoking history	15 (50%)	16 (37%)	0.32
Any post-operative PDE5I use	20 (63%)	31 (72%)	0.28
Mean Charlson Comorbidity index (SD)	2.1 (1.2)	2.0 (1.1)	0.60

SD, standard deviation; IIEF-5, international index of erectile function-5; PDE5I, phosphodiesterase type 5 inhibitor.

Table 2 Erectile function outcomes between 6–12 weeks

Outcome	Control	Intervention	P value	95% CI
Return to IIEF-5 ≥17 and EHS ≥3	5 (17%)	11 (26%)	0.37	–
Median EHS [IQR]	1 [1–2]	2 [1–3]	0.03	–1.03 to –0.06
Mean IIEF-5 score (SD)	9.4 (6.6)	10.9 (6.7)	0.33	–0.70 to 0.24

IIEF-5, international index of erectile function-5; EHS, erectile hardness score; CI, confidence interval; IQR, interquartile range; SD, standard deviation.

Table 3 Categorical EHS

Study arm	EHS <3	EHS ≥3	P value
Intervention	28	15	0.46
Control	22	8	

EHS, erectile hardness score.

intervention arms, respectively, which was not a statistically significant difference (P=0.37). A statistically significant difference was noted in the post-operative median EHS between the control and intervention arms with scores of 1 (interquartile range, 1–2) and 2 (interquartile range, 1–3), respectively (P=0.03). *Table 3* lists the categorical post-operative EHS scores for both arms using an EHS of 3 as the cut off; there was no significant difference between the arms (P=0.46). The mean post-operative IIEF-5 scores in the control and intervention arms were 9.4 (+/– 6.6) and 10.9 (+/– 6.7), respectively (P=0.33).

Of 106 enrolled patients, four adverse events were noted. All four events were related to genital pain during the treatment and required treatment intensity (energy or duration) de-escalation or no treatment changes. One patient un-enrolled from the intervention arm due to concerns of the procedural pain; the plan was to maintain his data in the intervention arm as an intent-to-treat analysis, however, he was subsequently lost to follow-up.

Discussion

In this study, we aimed to determine if rWT had an effect on early recovery of erectile function after NS RP. Though our study was underpowered, we did not find a statistically significant difference in our primary outcome of "near normal" erectile function, defined as a post-operative IIEF-5 score ≥17 and EHS ≥3 within 3 months of NS RP, in the men who selected treatment with rWT compared to non-placebo control. If the true benefit of rWT in our study was 26% recovery in the intervention arm compared to 17% in the control arm, then a trial with 326 subjects per arm would be required. While men in the intervention arm did have significantly higher EHS than did men in the

control arm, the reported erectile hardness would not be categorized as suitable for penetrative intercourse.

ED after NS RP is multifactorial and can be a result of neural damage (traction on the cavernous nerves), insufficient arterial inflow (related to ligation of pudendal arterial branches), absence of cavernosal oxygenation and neuropraxia-associated damage to erectile tissue resulting in veno-occlusive dysfunction (5,29). Ischemic hypoxia of the corpus cavernosum can then cause fibrosis, further exacerbating the ED (29). Fibrotic changes of the corpus cavernosum can be present at just 2 months after RP (29). Furthermore, initiation of penile rehabilitation more than 6 months after RP predicts for failure of erection recovery, whereas early penile rehabilitation may improve cavernosal oxygenation and prevent hypoxia-induced fibrosis (5). For this reason, we initiated our intervention soon after Foley catheter removal after RP. Indeed, Porst, in a review of fSWT for treatment of vasculogenic ED, Peyronie's Disease and post-RP and a description of the author's own experiences using fSWT, reported treating 12 consecutive post-RP patients with fSWT starting after indwelling catheter removal (at 8–14 days post-RP) (10); ten of these men had return to baseline potency with aid of a PDE5I after fSWT treatment (10). Similarly, Baccaglini *et al.* performed a randomized controlled trial of post-RP men with the fSWT intervention initiated at 6 weeks post-RP (11). In their study, both arms received daily PDE5I starting at time of indwelling catheter removal with a 2-week PDE5I washout period prior to the 4-month post-op visit; at this time point, there was a significantly improved median IIEF-5 score for the intervention arm compared to control (12.0 versus 10.0, respectively, P=0.006), however, the primary clinical outcome of their study, IIEF-5 difference ≥4 between arms, was not met (11). Furthermore, the percent of men with an IIEF-5 score ≥17 after treatment was not significantly different between groups (11). Jang *et al.*, in a non-sham controlled non-randomized prospective study evaluated fSWT in post-NS RP men initiated on the fourth day after surgery (14). Only post-operative EHS scores were reported, with no statistically significant difference between the treatment and control arms; still, the proportion of men with EHS ≥3 favored the treatment arm. Of note, a pre-operative IIEF-5 score ≥15 was acceptable for inclusion in this study; further, there were no reports of post-operative IIEF-5 scores for either arm (14).

Erectile function after NS RP has been shown to recover in about 60–74% of men at >12 months post-operatively (30,31). Both Frey *et al.*, in a small non-controlled pilot study, and Ladegaard *et al.*, in a randomized placebo-controlled prospective study, performed their trials of fSWT on men with severe ED who were greater than 6 months removed from RP (9,12). Both studies reported statistically significant increases in erectile function outcomes but noted that these improvements were unlikely to have an effect on successful sexual intercourse (9,12). While measuring short term erectile function outcomes could limit the typically expected progressive recovery in function, we sought to determine if a restorative therapy such as rWT could hasten this progression; thus, our primary endpoint was early recovery in erectile function. Furthermore, the strict criteria for our primary endpoint—IIEF-5 score ≥17 and EHS ≥3—was chosen to assess for clinically significant early recovery in erectile function. This timing for our primary outcome was similar to Baccaglini *et al.*'s outcome measurement (11).

Ours is the first study to evaluate rWT in the post-RP setting. While there is doubt regarding the beneficial effects of rWT as a treatment for ED given the lower intensity acoustic waves and the lack of clinical data, rWT devices are designated as class 1 devices that do not require regulatory approval (15-17). Thus, these devices can be marketed as efficacious ED treatment despite limited supporting data (25). There are two recent studies that reported beneficial effects of rWT on ED (22,23). Wu *et al.* retrospectively compared fSWT and rWT for treatment of men with vasculogenic ED; at 6 weeks after treatment, there were similar statistically and clinically significant improvements in IIEF-5 scores (23). Yamaçake *et al.* performed a randomized double-blinded placebo-controlled trial using rWT on renal transplant patients with ED (22). In this trial, with 10 patients per arm, rWT significantly improved IIEF-5 scores at 3 months after treatment compared to sham. Sandoval-Salinas *et al.*, reported a randomized controlled trial of men with mild or moderate ED treated with rWT or sham therapy (40 men per arm) and found no differences in IIEF-5 score and EHS (24). While our primary endpoint also had no difference in IIEF-5 scores between the arms, we did find a significant difference in EHS. IIEF-5 is validated to assess erectile function, but a limitation of this questionnaire is that it focuses on current sexual behavior (32); with our goal of assessing early erectile function recovery, it is likely that study participants were not yet able to achieve an erection sufficient for intercourse. For this reason, we also used the EHS, which simply assesses the hardness of a subject's erection. While the median EHS after rWT was significantly higher than that of the control arm (2 *vs.* 1),

this may not be clinically significant since an EHS ≥3 correlates with successful penetrative intercourse (33). Thus, we felt that including both assessment scores would be best to evaluate for early return of erectile functions. Another noteworthy outcome of our study is that 42/43 (97.7%) of the patients in the intervention arm completed all 6 treatments with rare limited and no severe adverse effects. Thus, our study supports the safety of rWT in this setting.

Our study has several notable limitations. First, the study is not randomized, blinded or sham-controlled, thus leading to a selection bias of patients who opted for the intervention arm. Given our patients are often from locations that preclude weekly visits to our facility, randomizing only patients who lived within driving distance would have caused prohibitive barriers to enrollment. If the current study design showed a significant signal of erectile improvement with rWT it would have justified the implementation of a larger truly sham controlled study. The lack of a sham control also introduces the potential for a placebo benefit in the treatment group compared to the control arm. Further, we believe that those who chose the intervention arm may self-select for being highly motivated to achieve early erectile function recovery. With the lack of difference between arms in our primary outcome, this selection bias provides further support for the lack of efficacy of rWT on early erectile function recovery after NS RP. Our study is also underpowered based on the pre-study power analysis we performed. This is likely a result of unreturned surveys, as 106 men were enrolled in the study, but only 73 filled out surveys; the vast majority of those who did not return surveys were from the control arm. Last, given that we have multiple surgeons across several hospitals performing RPs at our institution, we were unable to enforce a standard for PDE5I use; still, there was no significant difference in percentage of men who used PDE5I between arms and there is no evidence that one PDE5i regimen for penile rehabilitation is significantly more effective than another.

Conclusions

ED post-NS RP is an important quality of life issue that both patients and providers struggle to manage. In this prospective, non-randomized, open-label trial, rWT did not substantially improve the recovery of early erectile function after NS RP. rWT may contribute to improvement in erectile hardness, but the clinical effect is likely marginal. While rWT is safe, we cannot conclude that it has a positive effect on early recovery of erectile function after post-NS RP. Future studies may consider focusing on longer-term outcomes with a larger sample size.

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Footnote

Reporting Checklist: The authors have completed the TREND reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-22-310/rc

Data Sharing Statement: Available at https://tau.amegroups.com/article/view/10.21037/tau-22-310/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-22-310/coif). DAS serves as an unpaid editorial board member of *Translational Andrology and Urology* from August 2022 to July 2024. DAS is a full-time employee of Exact Sciences whose products are unrelated to this manuscript. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Cleveland Clinic institutional review board (No. 18-919) and informed consent was obtained from all individual participants.

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