







Do Antiplatelet Drugs Use Contribute to Clinical Outcomes in Patients Receiving Penile Low-Intensity Shock Wave Therapy for Erectile Dysfunction?

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Abstract

Aim: Low-intensity extracorporeal shock wave therapy (Li-SWT) is one of the recommended treatment options in patients with erectile dysfunction (ED). Li-SWT is safe in patients using antiplatelet drugs (APs), however, there are no specific studies on the contribution of APs use to clinical improvement in erectile function. We aimed to evaluate the early clinical results of Li-SWT administration and whether the use of APs had an additional positive contribution to clinical improvement and safe in ED patients.

Methods: Patients with ED for more than 6 months despite using (5 mg/day) PDE5i were included in our study. Patients treated with Li-SWT and using PDE5i were classified as Group 1, patients treated with Li-SWT and using APs and using PDE5i were considered Group 2. The evaluation results of the International Index of Erectile Function-Erectile Function Area (IIEF-EF) in all patients baseline and after treatment were examined.

Results: There are 25 patients in each group. Analysis of IIEF-EF scores showed significant increases in both groups after treatment [group 1 (p=0.001); group 2 (p=0.001)]. When the IIEF-EF scores of the groups before and after the treatment were compared with each other; it was shown that baseline scores were similar (p=0.746) and that APs use had no statistically significant effect on post-treatment scores (p=0.613) No side effects were seen in APs.

Conclusions: This study showed that penile Li-SWT significantly increases the IIEF-EF scores and response of (5 mg/day) PDE5i in ED patients and safe, also in AP users. However, Using AP in Li-SWT does not contribute positively to clinical results.

Keywords: Erectile dysfunction (ED), Antiplatelet (AP), Endothelial dysfunction, Low intensity extracorporeal shockwave therapy (Li-SWT), Phosphodiesterase type 5 inhibitor (PDE5i).

1. Introduction

Erectile dysfunction (ED) affects men of all ages. Its incidence is in the range of 30-65% in men over 40 years of age with vascular risk factors (VRF) such as metabolic syndrome, diabetes mellitus (DM) and hypertension (HT)^{1,2}.

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Oral Phosphodiesterase type 5 inhibitors (PDE5i), hormone replacement, also in severe patients intracavernosal injections or penile prosthesis implants are used in current medical treatment (MT)^{3,4}. Due to MTs does not change the underlying pathophysiology, researches has focused on the concept of "regenerative therapies (RT)". RT is based on the idea of applying low-intensity extracorporeal shock wave therapy (Li-SWT) for the restoration of the erectile mechanism⁵. Mechanical stress and micro-trauma caused by Li-SWT in the tissue provide non-enzymatic nitric oxide production, activate vascular endothelial growth factor, and cause angiogenesis^{6,7}. Li-SWT is effective and safe, especially in patients with vascular-derived ED² and is weakly recommended in the EUA ED guideline for the treatment of mild organic ED⁸.

The relationship between ED and microvascular circulation disorder, also the restorative effects of antiplatelet drugs (APs) therapy in endothelial dysfunction, as well the role of activated platelets in the pathogenesis of ischemia/reperfusion injury are known^{9,10}. Studies

have shown that Li-SWT therapy is safe in patients using APs¹¹, however, there are no specific studies on the contribution of APs use to clinical improvement in erectile function.

In this study, we aimed to evaluate the early clinical results of Li-SWT administration and whether the use of APs had an additional positive contribution to clinical improvement and safe in sexually active 5 mg/day PDE5i refractory ED patients.

2. Materials and methods

Patients who applied to our clinic with the complaint of erectile dysfunction for more than 6 months despite using 5 mg/day PDE5i (Tadalafil) between January 2015 and January 2021 and received penile Li-SWT were included in our study. Diabetic Patients with HbA1C levels > 7 ng/ml and patients with a history of pelvic surgery (radical prostatectomy) and neurologic mediated disease (such as Multiple Sclerosis) and patients with the International Index of Erectile Function-Erectile Function (IIEF-EF) > 26 and testosterone levels < 4 ng/ml, patients using Thiazide Diuretics and Beta Blockers (except Nebivolol) were excluded from the study.

Patient data were collected retrospectively. First examination findings, laboratory results, and 6-month follow-up results after treatment were examined. We prescribed 5 mg/day PDE5i to all patients undergoing Li-SWT during treatment and for at least the first 3 months after treatment. Patients treated with one course of Li-SWT and using PDE5i were classified as Group 1, patients treated with one course of Li-SWT and using APs (100 mg/day acetylsalicylic acid or 75 mg/day dipyridamole/clopidogrel) for other diseases and using PDE5i were considered Group 2.

We perform penile Li-SWT treatment mainly on patients with organic erectile dysfunction who do not benefit or partially benefit from 5mg/day Tadalafil treatment. To all patients Li-SWT was applied for one course which was consisted of 5 implementations 7±2 days apart. In each implementation; 1,800 shock-waves(SW)(0.09 mJ/mm²) were applied to the distal penile shaft and 1,800 SWs to the perineal corpus cavernosum. A total of 18,000 SWs was applied to each patient at the end of one session. The treatment was administered in an outpatient setting without anesthesia, the application areas were the same, and each imple-

mentation lasted approximately 20 minutes¹².

Linear SW were applied with Renova(Initia Ltd. Petah Tikva Israel), a second generation electromagnetic energy source Li-SWT device. All sessions were conducted by the same urologist. The probe was manually supported to provide an effective tissue contact without using any stabilizers or additional accessories.

Evaluations were made baseline and after treatment with the IIEF-EF¹³. In the evaluation; the short-term clinical results of Li-SWT application were evaluated separately for both groups and whether the use of AP made a positive contribution to clinical improvement or not was evaluated by comparing the groups. Also, the safe of APs uses is evaluated with physical examination and anamnesis for each pre/post- implementation.

2.1. Statistical analyses

The SPSS 22.0(SPSS Inc. Chicago, IL, United States) software was used for statistical analysis. Continuous variables were given as mean ± standard deviation. Independent t tests were performed on these variables. P value <0.05 was considered significant. The study which was approved by Çukurova University Clinical Research Ethics Committee with the number 120 and date 05/13/2022.

3. Results

Data of 87 patients were reviewed retrospectively and 37 patients were excluded from the study; 3 patients lacked hormonal evaluations, 4 patients had recurrent testosterone insufficiency, 7 patients had ongoing diuretics and 2 patients beta-blockers medications, 1 patient had multiple sclerosis and 4 patients had previous radical prostatectomy history, 16 patients had high HbA1C levels. 50 patients were included in the study.

There are 25 patients in each group. The mean age of Group1 was 46.7±13.2 years, and the mean age of Group 2 was 54.2±10.5 years. Mean age of group 2 was significantly higher (p=0.03). There was no statistically significant difference in terms of the demographic characteristics of the groups, except for the mean age of the patients (Table 1).

Table 1

Comparison of demographic data

	Group 1	Group 2	p value
Age (year)	46.7±13.2	54.2±10.5	0.03
Duration of ED (year)	4.64±3.58	3.84±2.56	0.368
Hypertension (n)	4	10	0.114
Diabetes mellitus (n)	8	15	0.088
Cardiovascular diseases (n)	8	15	0.088
Benign prostatic hyperplasia (n)	6	11	0.232
Benign prostatic hyperplasia surgery history (n)	0	1	1.00
Chronic kidney disease (n)	0	1	1.00
Usage of antidepressants (n)	11	4	0.062

(ED: Erectile dysfunction)

Table 2
IIEF-EF score changes of Groups

	Group 1	Group 2	p
Baseline	11.68±4.22	11.32±3.57	0.746
IIEF-EF score changes in pre&post Li-ESWT			
6th month	22.56±4.67*	21.88±4.76*	0.613

(IIEF-EF: International Index of Erectile Function-Erectile Function, Li-ESWT: Low-intensity extracorporeal shock wave therapy)

Table 3
IIEF-EF scores of patients in pre-post Li-SWT

		Group 1 Pre / post Li- SWT	Group 2 Pre / post Li- SWT	p
IIEF-EF ≥26 patients in post Li-SWT	EF 6th month (n,%)	8 / 25 (32)	6 / 25 (24)	0.754
IIEF-EF ≥26 patients in post Li-SWT (according to baseline ED grades)	Mild to moderate (n, %)	2 / 3 (66.7)	2 / 3 (66.7)	1.0
	Moderate (n, %)	5 / 15 (33.3)	3 / 13 (23.1)	0.686
	Severe (n, %)	1 / 7 (14.3)	1 / 9 (11.1)	1.0

(ED: Erectile dysfunction, EF: Erectile function, IIEF-EF: International Index of Erectile Function-Erectile Function, Li- ESWT: Low-intensity extracorporeal shock wave therapy)

Analysis of IIEF-EF scores showed significant increases in both groups after treatment [group 1, from baseline 11.68±4.22 to 22.56±4.67 at 6th month(p=0.001); group 2 from baseline 11.32±3.57 to 21.88±4.76 at 6th month(p=0.001)]. When the IIEF-EF scores of the groups before and after the treatment were compared with each other; it was shown that baseline scores were similar(p=0.746) and that APs use had no statistically significant effect on post-treatment scores(p=0.613)(Table2). Post-treatment IIEF-EF ≥26 ratios; in group 1 was %32, in group2 was %24 and in all patients was %28. The ED grades of the patients were determined according to the pre-treatment IIEF-EF score. Initially, there were 16 patients with severe ED, 28 with moderate ED, and 6 with mild-moderate ED. According to baseline ED grades post-treatment IIEF-EF ≥26 ratios; 12.5% in severe, 28.6% in moderate, and 66.7% in mild to moderate ED patients were (Table 3).

No patient during treatment and follow-up reported penile pain, skin reactions or hematuria.

4. Discussion

Current medical treatment of ED focuses on symptomatic improvement. Based on our knowledge of ED pathophysiology, the

concept of regenerative therapies and Li-SWT applications have gained popularity after 2010. Recent studies have once again demonstrated that focused or linear alternatives in shockwave delivery are not superior to each other in terms of safety and effectiveness¹⁴.

ED guideline of EUA states that Li-SWT can be used in patients with mild organic ED or in poor responders to PDE5i with a weak recommendation level. In contrast the ED guideline of AUA, is still classified as investigational⁸.

First, in 2010, Vardi et al. reported the use of Li-SWT in the treatment of ED in a retrospective clinical study. As a result, after 6 months, with oral PDE5i therapy 10 out of 20 patients was reported better EF¹⁵. Also two years later, with a randomized, double-blind, placebo-controlled study on the same patients; it was demonstrated that Li-SWT had a physiological effect on EF and that spontaneous erection was satisfactory for penetration and sexual intercourse in 50% of patients¹⁶. Similarly, all patients of us who were initially refractory to 5 mg/day PDE5i reported that they became responsive approximately at 3th-4th weeks of the treatment with better hardness. None of them suffered from the side-effects to PDE5i because they were using at past also. The recommendation of PDE5i use to maximize the improvement in erectile function has almost standard

in Li-SWT applications¹⁷. Subsequent studies have shown that Li-SWT, which promotes angiogenesis, can restore natural and spontaneous EF by repairing penile hemodynamics and underlying pathologies, particularly in vasculogenic ED¹⁸.

In the literature, there was a recent experimental study showing that Li-SWT reversed age-related physiological changes in old rat erectile tissues partially¹⁹. The results are exciting for the hope that ED may be cured with Li-SWT for sure.

In aging and metabolic diseases (DM, HT, hyperlipidemia, etc.), the prevalence of cardiovascular disease increases with the emerging atherosclerosis and microvascular circulation disorders. Studies show a correlation between cardiovascular disease and the prevalence of ED [1]. APs, that are used in both peripheral and coronary artery diseases have restorative effects in endothelial dysfunction, as well the role of activated platelets in the pathogenesis of ischemia / reperfusion injury^{9,10}. One of the mechanisms of action of Li-SWT is the increase in tissue blood supply through neoangiogenesis⁷. Since the tissue blood supply increased with the use of AP, we sought an answer to the question "Did the use of AP together with the SWs contribute positively to the clinical results?". For this purpose, we retrospectively evaluated the data of our one session Li-SWT applied patients into two groups; without AP (group 1) and while using AP (group 2). Srini et al. reported that more than 70% of patients with vasculogenic ED in the active treatment group could experience spontaneous erections with Erectile Hardness Scale (EHS) scores of 3 after treatment with focused Li-SWT²⁰. Similarly, in our study, we observed that 66.67% of patients with mild-moderate ED in groups 1 and 2 reached IIEF-EF \geq 26 score at the end of 6 months and achieved a satisfactory sexual life. Although, it was safe, we could not observe the use of AP have any positive contribution on clinical results. In a meta-analysis, Lu et al., demonstrated that the therapeutic efficacy was higher in patients with mild to moderate ED than those with severe ED or severe comorbidities. They concluded that the duration of Li-SWT were closely related to the improvement of clinical outcomes and IIEF scores, and that Li-SWT and PDE5i combination therapy was more effective²¹. Similarly, in our clinic, we prescribe the PDE5i 5mg/day for during and after treatment at least 3 months in order to increase blood supply in the tissue restoration process and to improve the IIEF-EF scores and also to build of sexual life self-confidence. Our clinical experience showed that, patients who tolerate and responsive to PDE5i continue using the drug voluntarily, for a more satisfactory sexual life, without a doctor's prescription.

Jeffrey D et al. published a meta-analysis evaluating 7 randomized controlled studies with a total of 607 patients from November 2005 to July 2018)². As we determined in our study, good tolerability was stated, on the other hand, it was emphasized that a specific treatment protocol and long-term follow-up results were needed.

In the evaluation, mean change in IIEF-EF scores before and after 1 month was statistically significant². Similarly, our IIEF-EF scores were significantly increase at 6th month after the treatment for both groups. The mean pre-treatment IIEF-EF scores of groups were similar. However, when the additional positive contribution of the AP drugs used by the group 2 patients to the improvement of IIEF-EF was evaluated, no statistically significant difference was found in contrast our expectation.

Dimitrios Kalyvianakis et al. published the 3-month follow-up results of 35 patients with vasculogenic ED who received anti-coagulant/antiplatelet drugs during Li-SWT treatment and during the follow-up period. After each implementation and 1-3 months after treatment, all patients were evaluated by penile physical examination and ultrasound. As a result, no side effects, skin reactions or bleeding were reported¹¹. Similarly, we did not observe any side effects in group 2 and this result is a second "yes" to safe of Li-SWT

therapy is in patients receiving anti-coagulant/antiplatelet. We found that a single session was insufficient in patients with severe and moderate ED. These results are in line with the ED treatment guideline of EUA⁸.

Hüseyin M Adeldaeim et al. reported "Prognostic Indicators for Successful Low Intensity Extracorporeal Shock Wave Therapy in Erectile Dysfunction" study, involving 425 patients with 30 months of follow-up period. As result, affecting the success in Li-SWT important factors were age, diabetes, hypertension, smoking, obesity, hyperlipidemia, pre-treatment Sexual Health Inventory for Men (SHIM) score, ED duration. At follow-up, 168(76.3%) of the Li-SWT responders reported satisfactory sexual intercourse with a SHIM score of 22-25 without using PDE5i. They reported safe and effective ED treatment during follow-up, in 39.5% successfully treated of all patients²². In contrast, our successful treatment rate was %28 and lower than this study, because our baseline severe grade ED patients rate were %32 and our success criteria was IIEF-EF score \geq 26. Almost all studies have focused on improving EF after Li-SWT.

Olsen et al. published in 2015 a double-blind randomized prospective controlled study of Li-SWT application to patients with ED with comorbidities such as hypertension, diabetes, hyperlipidemia and coronary artery disease without giving treatment for these diseases. As a result, they reported that there was no clear information about the relationship between the clinical outcomes of Li-SWT and these comorbidities²³. More randomized controlled prospective studies are needed to evaluate the relationship of ED with idiopathic or comorbid factors.

Under 7% HbA1C has been shown to reduce microvascular and neuropathic complications of diabetes²⁴. Also antihypertensive drugs are involved in the development of erectile dysfunction. The thiazide type diuretics, the aldosterone receptor blockers, and the β -adrenergic receptor blockers are the most prominent of these²⁵. Due to this point of view before applying Li-SWT in our clinic; we make treatment arrangements for ED patients with comorbidities (DM, HT, cardiovascular diseases, etc.) via the consultations of the relevant specialists. With this approach, we believe that existing comorbid factors will have a minimal negative impact on the success of Li-SWT treatment.

The strengths of our study are that it is the second study on the safety of APs use in Li-SWT patients and that it is the first study to suggest that APs can contribute to tissue restoration by improving tissue perfusion and endothelial dysfunction. The limitations and weaknesses of the study are that it evaluates a small group of patients retrospectively and the lack of a penile Doppler USG control.

5. Conclusions

Our results showed that the use of APs drugs with the application of Li-SWT was safe, but might not positively contribute to clinical results. The possible contribution of APs to tissue restoration and perfusion in Li-SWT may be the subject of future experimental animal studies. In our study, we concluded that 5 mg/day PDE5i refractory ED patients will be responsive to PDE5i treatment with Li-SWT application, additionally that the treatment was most effective in patients with mild and mild-moderate ED.

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Statement of ethics

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki and was approved by Çukurova University Hospital Medical Ethics Committee with the decision no. 122 dated 13.05.2022.

Conflict of interest statement

The authors declare that they have no financial conflict of interest with regard to the content of this report.

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Author contributions

The authors confirm contribution to the paper as follows: study conception and design: SG, MD; data collection: SG; analysis and interpretation of results: NAK, NA, IOY; draft manuscript preparation: SG. All authors reviewed the results and approved the final version of the manuscript.

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