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1.

Low intensity shock wave therapy in men with erectile dysfunction and Peyronie's disease: An analysis of predictors of clinical success and patient satisfaction rate based on prospective open-label single arm clinical trial.

Chung E.

International Journal of Urology. Conference: 14th Asian Congress of Urology of the Urological Association of Asia, ACU 2016. Singapore Singapore. Conference Start: 20160720. Conference End: 20160724. Conference Publication: (var.pagings). 23 (pp 7), 2016. Date of Publication: July 2016.

AN: 72344025

Introduction & objectives There is great interest in the use of low intensity extracorporeal shock wave therapy (LiESWT) to treat erectile dysfunction (ED) and Peyronie's disease (PD). This study evaluates factors that predict clinical success and patient satisfaction rate among men with ED and/or PD following LiESWT. **Methods** Men with ED and PD were enrolled in this open-label single arm prospective study. Patient demographics, erectile function including International Index of Erectile Function (IIEF)-5 score, degree of penile curvature and size of Peyronie's plaque, and overall satisfaction score (on a 5-point scale) were reviewed pre and post LiESWT. All patients received standardized treatment protocol. **Results** All patients successfully completed the treatment course and no patient reported any adverse event. Higher patient satisfaction rate was reported in the ED group compared to PD group (rated 4 out of 5 in 70% vs 60%; $P = 0.38$). The overall improvement in IIEF-5 score is moderate in the ED group (improvement >5 points; 70% of men). Factors associated with higher success rate were early disease state, younger men, shorter duration of symptom, smaller penile curvature and plaque size, and moderate IIEF-5 scores ($P < 0.05$). **Conclusion** LiESWT provides a novel and promising therapy for sexual rehabilitation in men with ED and PD. Predictors of success and patient satisfaction rate were early disease state, younger age, shorter duration, smaller penile curvature and plaque size, and moderate IIEF-5 scores.

2.

Low-intensity extracorporeal shockwave therapy, a 6-month follow-up pilot study in patients with organic erectile dysfunction.

Wong M.H.E., Fan C.W.

International Journal of Urology. Conference: 14th Asian Congress of Urology of the Urological Association of Asia, ACU 2016. Singapore Singapore. Conference Start: 20160720. Conference End: 20160724. Conference Publication: (var.pagings). 23 (pp 4), 2016. Date of Publication: July 2016.

AN: 72344012

Introduction Erectile dysfunction affects more than 40% of the male population above the age of 50. Phosphodiesterase 5 inhibitors (PDE5-Is) has become the accepted first line of treatment, however, the effect is limited to sexual act and do not improve spontaneous erection. We

investigate the effect of low-intensity extracorporeal shockwave therapy (Li-ESWT) for men with erectile dysfunction. Method This is a prospective, single-arm pilot study for men with organic erectile dysfunction. Li-ESWT will be administered to patient in a course of 9 weeks, which consist of two 3-week therapy separated by a 3-week rest segment in between. Shockwaves are delivered by a special probe that is attached to a compact electrohydraulic unit with a focused shockwave source (Duolith SD1 Tower, Storz Medical, Germany). IIEF-5 and erectile hardness score (EHS) are documented at baseline and week 13, 26 and 38. Adverse event and side effects are also documented. Results There are a total of 21 men undergone treatments, with an average age of 59.3 (range: 42-69). Average duration of erectile dysfunction is 59 months (18-168). Base line average IIEF-5 is 10 and EHS 2. At week 13, there is a significant increase in IIEF-5 score vs baseline (mean difference 3.89, 95% CI 1.4-6.3, P = 0.0038). The improvement is significant in the subgroup with a baseline IIEF score >7 (95% CI 0.2-5.9, P = 0.034) but not in those with IIEF <7. The improvement persists up to week 26 (mean difference 3.35, 95% CI 0.5-6.1, P = 0.022) but not at week 38. For EHS, there is also a significant improvement vs baseline at week 13 (mean difference 0.83, 95% CI 0.34 -1.33, P = 0.0023). The improvement is maintained at week 26 but not at week 38. There is not a single adverse event or side effect reported. Conclusion Li-ESWT appears to provide significant improvement in erectile function for men with mild to moderate organic erectile dysfunction for a period up to 26 weeks. It can be offer to patients as an adjunct therapy for erectile dysfunction with no adverse event or side effects.

3.

Low intensity extracorporeal shockwave therapy in the treatment of erectile dysfunction: A systematic review and meta-analysis of randomized trials.

Heah N.H., Tan R.B., Leow J.J.

International Journal of Urology. Conference: 14th Asian Congress of Urology of the Urological Association of Asia, ACU 2016. Singapore Singapore. Conference Start: 20160720. Conference End: 20160724. Conference Publication: (var.pagings). 23 (pp 3), 2016. Date of Publication: July 2016.

AN: 72344009

Introduction and Objective Low intensity Shockwave Therapy (LiESWT) has demonstrated promising results in the treatment of erectile dysfunction (ED) refractory to phosphodiesterase-5 inhibitors (PDE5i) therapy. Several centers have conducted randomized controlled trials (RCT) and reported their outcomes. The objective of this study was to review the current literature regarding LiESWT and its efficacy. Methods An electronic systematic review of literature according to Cochrane guidelines was conducted up to October 2015, including all RCTs comparing LiESWT to placebo. Patient demographics including age and number of ED risk factors were compared. The main outcomes compared were change in International Index of Erectile Function - Erectile Function Domain (IIEF-ED) scores, Erection Hardness Score (EHS) grade and complication rates. We performed meta-analyses, comparing continuous and dichotomous variables using weighted mean difference (WMD) and inverse variance pooled risk ratios (RR). All analyses were performed using STATA 12.0 (StataCorp, Texas). Results There were a total of 4 RCTs, comprising of 300 patients (treatment arm: n = 181 vs placebo arm: n = 119). There were no significant differences between the two groups in terms of patient age (P = 0.75) and number of ED risk factors (P = 0.34). Across three studies, the treatment arm had shorter ED duration (WMD: -10.8 months, P < 0.001). There were no significant differences in IIEF-ED scores (WMD: +5.5, 95% CI: -1.3 to +12.3, P = 0.11) and EHS grade (WMD: +0.87, 95% CI: -0.14 to +1.88, P = 0.09) in the treatment group compared to placebo. There were no major

complications reported during all trial periods. Conclusion This meta-analysis of four RCTs showed a favorable response of LiESWT compared to placebo, for the adjunctive treatment of ED refractory to PDE5i, although it did not reach statistical significance. Due to the small overall number of patients, more RCTs need to be conducted to confirm the efficacy and utility of this novel treatment.

4.

Extracorporeal shock wave therapy (ESWT) as a treatment for peyronie's disease.

Broul M., Schraml J., Skala P., Strbavy M.

Journal of Sexual Medicine. Conference: 18th Congress of the European Society for Sexual Medicine. Madrid Spain. Conference Start: 20160204. Conference End: 20160206. Conference Publication: (var.pagings). 13 (5 SUPPL. 2) (pp S221), 2016. Date of Publication: May 2016. AN: 72325627

Objective: Peyronie's disease is an acquired disorder of the tunica albuginea which is characterized by formation of fibrous tissue plaques. It could be associated with erectile dysfunction, painful erection and also with the difficult penetration of erected penis due to its angulation. The aim of our study is to evaluate the efficacy of extracorporeal shock wave therapy as a treatment for patients with Peyronie's disease. Methods: In the period from January 2005 to April 2015, 51 patients with PD were treated with ESWT. The treatment was performed in ten sessions at weekly intervals. We used the Pie-zoLith 3000 device with piezoelectric shockwave source from the Richard Wolf Company. Each session consisted of 500 shockwaves with emission frequency of 90 shockwaves / min. Average age of patients was 57.8 years. Plaques were found on the dorsal side of penis, the average penile deviation angle during erection was 60 degrees and the average size of the plaque was 10.2 mm. Erectile function was assessed with a five question version of International Index of Erectile Function Questionnaire (IIEF-5). The average score in the IIEF-5 was 11.7. Results: The treatment was painless for all the patients. Using visual analogue scale (VAS) patients rated it by grade 1 to 2. In 5 cases (9.8%) there were minor subcutaneous petechiae. Serious complications such as urethral bleeding or extensive hematoma did not occur. We evaluated the effects of the therapy two to three months after the last shock wave session. Both objective and subjective improvements of the condition were found in 37 men (72.6%). The penile deviation was reduced by 47.0% in average to 28.2 degrees , the size of plaque was reduced on average by 19.6% to 8.2 mm and a score in the IIEF-5 questionnaire increased on average by 28.6% to average 16.4 points. All patients were able to have an intercourse after the treatment. Conclusion: ESWT method is effective and safe. It improves sexual health. It has positive effect on reducing pain during erection and improves sexual functions and mental state of patients. Nowadays this method offers routine conservative procedure in the treatment of PD.

5.

Combined treatment of severe erectile function.

Aksonov P.

Journal of Sexual Medicine. Conference: 18th Congress of the European Society for Sexual Medicine. Madrid Spain. Conference Start: 20160204. Conference End: 20160206. Conference Publication: (var.pagings). 13 (5 SUPPL. 2) (pp S173), 2016. Date of Publication: May 2016. AN: 72325541

Objective: Patient H., 65, complained of the weakening of adequate erections and lack of spontaneous erections during past three years. Methods: The examination data: IIEF-6 = 10 points; IIEF-15 = 38 points; penile dopplerography peak systolic rate is 7,8 cm/ sec before and 20.1 cm/sec after stimulation, end diastolic velocity after stimulation is 5,9 cm/sec. The diagnosis is combined severe arteriovenous erectile dysfunction (ED). Results: Performed sessions of low-energy shock wave therapy (LESWT) in combination with PDE-5 inhibitors. Full course included 8 sessions of LESWT, 1 session per week, with simultaneous daily use of 50 mg sildenafil citrate. During treatment till it's end, the patient noted a significant improvement in erectile function (EF). At follow-up examination at 6 months after treatment, improvement of erections was observed, but slightly lower than during the treatment. Spontaneous erections appeared and adequate erections much improved. Conclusion: Combined treatment of severe vascular ED with LESWT plus PDE-5 inhibitors improves the EF and the state of cavernous hemodynamics during treatment as well as long time after it.

6.

Penile low-intensity shock wave therapy for erectile dysfunction: Personal experience.

Alei G., Letizia P., Rossi A., De Marco F.

Journal of Sexual Medicine. Conference: 18th Congress of the European Society for Sexual Medicine. Madrid Spain. Conference Start: 20160204. Conference End: 20160206. Conference Publication: (var.pagings). 13 (5 SUPPL. 2) (pp S125), 2016. Date of Publication: May 2016.

AN: 72325433

Objective: Penile extracorporeal low-intensity shock wave therapy (LIST) to the penis has recently emerged as a novel and promising modality in the treatment of erectile dysfunction. LIST can improve penile blood flow and endothelial function by stimulating angiogenesis in the penis. We report our personal experience. Methods: We applied LIST to 46 middle- aged men, mean age 54 years, with mild to moderate vasculogenic ED who responded well to the use of PDE5i. Preoperative assessment comprised RigiScan monitoring and administration of the International Index of Erectile Function-5 (IIEF-5) questionnaire. The treatment protocol consisted of one treatment sessions per week for 6 weeks, a 6 -weeks no-treatment interval. Each session comprised the application of 3000 shock waves (energy intensity of 4 mJ/mm³) to each penile shaft and 1000 shock waves for each crura. Results: The results showed that 6 weeks after treatment, erectile function improved in the 85% of the case, good result in 10% and no results in 5% of the patients. The average increase in the IIEF-EF domain score was 8.8 points. Furthermore, erectile function and penile blood flow were measured by using nocturnal penile tumescence (NPT) and color-power Doppler of the penis. All NPT parameters improved as recorded by significant increases in the duration of the erections and penile rigidity. Penile blood flow also improved significantly at the 2-month follow-up examination. Conclusion: The treatment options for ED have greatly expanded and include PDE5i, intracavernosal injections, and penile prostheses. Our experience presented here demonstrate that LIST of the corpora cavernosa is a novel therapeutic option for ED . LIST may have a fundamental effect on penile endothelial function, increasing penile blood flow, and improving erectile function and consequently sexual satisfaction.

7.

Assessment of the treatment efficacy of the low-energy shock wave therapy in patients with vascular erectile dysfunction.

Aksonov P., Gorpynchenko I., Romaniuk M.

Journal of Sexual Medicine. Conference: 18th Congress of the European Society for Sexual Medicine. Madrid Spain. Conference Start: 20160204. Conference End: 20160206. Conference Publication: (var.pagings). 13 (5 SUPPL. 2) (pp S115), 2016. Date of Publication: May 2016. AN: 72325411

Objective: The study evaluated of efficacy and comparative assessment of the effect of low-energy shock wave therapy (LESWT) in 105 patients with vasculogenic erectile dysfunction (ED), depending on the vascularEDtype. The study involved 105men with moderate to severe erectile dysfunction, who were randomized into 2 clinically comparable groups: 52men from the first group underwent monotherapyLESWT sessions. The second group (53 men) underwent LESWT with sildenafil citrate, 50 mg every other day (8 weeks). The patients were differentiated according to the type of ED. In the first group there were 16 patients with arterial ED, 28 with venous ED, 8 had arteriovenous problems. The second group included 17 patients with arterial erectile dysfunction, 25 with venous and 11 with arteriovenous one. The efficacy evaluation was performed according to the IIEF questionnaire before treatment and in 1, 2, 6 and 12 months after treatment. Cavernous hemodynamics was studied using penile Doppler US. Methods: The treatment protocol included one LESWT session/ week during 8 weeks of treatment. Acoustic waves were focused on the corpora cavernosa and on the crura penis. The intensity was 0.09 mJ/mm², a total of 5000 pulses on four segments. Results: Groups with arterial and arteriovenous ED showed the biggest changes of the IIEF and peak systolic velocity when using combination therapy. The group with arterial ED demonstrated a more noticeable treatment effect (at the end of treatment IIEF score improved by 62.58% (p=0.022), after 6 months by 38.61% (p=0.042), after 1 year by 29.96%(p=0.026), peak systolic velocity increased at the end of treatment by 103.27% (p=0.022), after 6 months by 66.35%(p=0.037)). In the monotherapy group, the changes were significant only in patients with arterial and arteriovenous ED only after 6 months of treatment. Conclusion: The results suggest that the most effective and lasting impact of LESWT on vascular ED can be observed in patients with arterial and arteriovenous ED, when used in combination with PDE-5 inhibitors. The effect on patients with venous ED is not significant.

8.

Low intensity shock wave therapy in men with erectile dysfunction and Peyronie's disease in a prospective open-label single arm clinical trial: Analysis of successful predictors in clinical outcomes.

Chung E.

BJU International. Conference: 69th Annual Scientific Meeting of the Urological Society of Australia and New Zealand. Gold Coast, QLD Australia. Conference Start: 20160416. Conference End: 20160419. Conference Publication: (var.pagings). 117 (pp 5), 2016. Date of Publication: April 2016. AN: 72295912

Introduction and Objectives: There is great interest in the use of low intensity extracorporeal shock wave therapy (LiESWT) to treat erectile dysfunction (ED) and Peyronie's disease (PD). This study evaluates factors that predict clinical success and patient satisfaction rate among men with ED and/or PD following LiESWT. Methods: Men with ED and PD were enrolled in this open-label single arm prospective study. Patient demographics, erectile function including

International Index of Erectile Function (IIEF)-5 score, degree of penile curvature and size of Peyronie's plaque, and overall satisfaction score (on a 5-point scale) were reviewed pre and post LiESWT. All patients received standardized treatment protocol. Results: All patients successfully completed the treatment course and no patient reported any adverse event. Higher patient satisfaction rate was reported in the ED group compared to PD group (rated 4 out of 5 in 70% vs. 60%; $p = 0.38$). The overall improvement in IIEF-5 score is moderate in the ED group (improvement greater than 5 points; 70% of men). Factors associated with higher success rate were early disease state, younger men, shorter duration of symptom, smaller penile curvature and plaque size, and moderate IIEF-5 scores ($p < 0.05$). Conclusions: LiESWT provides a novel and promising therapy for sexual rehabilitation in men with ED and PD. Predictors of success and patient satisfaction rate were early disease state, younger age, shorter duration, smaller penile curvature and plaque size, and moderate IIEF-5 scores.

9.

Low-intensity extracorporeal shock wave therapy for severe erectile dysfunction in poor responders to phosphodiesterase type-5 inhibitors: A short-term prospective study.

Zewin T., El-Assmy A., Harraz A., Elsherbini A., Musa Z., Bayoumi A., Al-Kenawy M., Sheir K., Shokeir A.

European Urology, Supplements. Conference: 31st Annual Congress of the European Association of Urology, EAU16. Munich Germany. Conference Start: 20160311. Conference End: 20160315. Conference Publication: (var.pagings). 15 (3) (pp e1115), 2016. Date of Publication: March 2016. AN: 72228728

INTRODUCTION & OBJECTIVES: To evaluate the safety and efficacy of Low-intensity extracorporeal shock wave therapy (LI-SWT) on patients with severe erectile dysfunction (ED) who are poor responders to phosphodiesterase type-5 inhibitors treatment (PR-PDE5I). **MATERIAL & METHODS:** An open label, prospective study was conducted and included 53 consecutive patients with severe vasculogenic ED who are PR-PDE5I (International index of erectile function-erectile function domain <10 and erection hardness score <2). All patients received 12 sessions of penile LI-SWT (2 sessions/week for 3 weeks, then 3 weeks free of treatment, then 2 sessions/week for another 3 weeks). The shock waves were delivered to the distal, mid and proximal penile shaft, and the left and right crura using a specialized focused shock wave probe (Dornier MedTech System, GmbH, Wessling, Germany). The 300 shocks at an energy density of 0.09 mJ/mm^2 and a frequency of 120 shocks per minute were delivered at each of the 5 treatment points with frequency of 4 Hz. Each treatment session was 15 minutes and no local or systemic analgesia was needed. Patients were followed-up after the 1st month of treatment (FU1), 3 months (FU2) and 6 months (FU3) intervals. Effectiveness was assessed by International index of erectile function questionnaire (IIEF) and erection hardness score (EHS). Success was defined as patients who achieved erection hard enough for vaginal penetration (IIEF-EF domain >26 and EHS >3). During the active treatment and till FU1, all patients stopped any regular or on demand intake of PDE5I. After FU1 patients were classified into complete responders to LI-SWT and were followed up at 3 and 6 months, and poor responders (IIEF-EF domain <26 and EHS <2) who received 50 mg daily dose of sildenafil citrate for 2 months, and then reevaluated at 3 months for further subdivision into: responders (PDE5I converter) and non PDE5I converters who will be offered penile prosthesis. **RESULTS:** Mean age was 52 ± 11.4 years and all 53 patients completed the 6 months follow-up program. Hypertension, diabetes mellitus and coronary ischemia were present in 11 (20.8%), 24 (45.3%) and 11 (20.8%) patients, respectively. There were no patients reporting treatment-related adverse events. The mean (SD)

EF-domain and EHS significantly improved after treatment across the follow up period ($p < 0.001$). Pretreatment, all patients had severe ED, At FU1, 16 (30.2%) had normal erectile function, 21 (39.6%) had improvement in IIEF score but still have mild to moderate ED (IIEF-EF domain 11-25 and EHS < 2) and 16 (30.2%) had no response to treatment. During FU2, 7 out of the 16 patients with normal EF at FU1 developed mild ED at FU2 and required oral PDE5i with good response which is maintained at FU3, while patients with no response at FU1 showed also no response to oral PDE5i at FU2 and FU3. Out of the 21 patients with mild to moderate ED at FU1, 10 patients showed good response to oral PDE5i at FU2 till FU3. While 11 patients reported good response to oral PDE5i at FU2 then poor response at FU3. CONCLUSIONS: LI-SWT for men with severe ED and PR-PDE5i is safe and effective. Normal erection was achieved and maintained at 6 months in 9 patients (17%) and restoring PDE5i response was obtained and maintained in 17 patients (32%). A large-scale with longer follow up study is required to determine the value of this treatment for ED.

10.

Initial experience with low intensity extracorporeal shock wave therapy for treatment of erectile dysfunction.

Ngo C.C., Ngai H.Y., To H.C., Au W.H.

BJU International. Conference: Hong Kong Urological Association Annual Scientific Meeting 2014. Kowloon Hong Kong. Conference Start: 20141109. Conference End: 20141109. Conference Publication: (var.pagings). 115 (pp 4), 2015. Date of Publication: February 2015.

AN: 72297061

Objective: To report our initial experience with use of low intensity extracorporeal shock wave therapy (LI-ESWT) for treatment of erectile dysfunction (ED) Patients & Methods: A total of 7 men with ED who had responded to phosphodiesterase type-5 inhibitors (PDE5i) underwent 6 sessions of LI-ESWT. Visual Analog Scale (VAS) after each session, changes in International Index of Erectile Function EF (IIEF-EF) domain scores, Erection Hardness scores (EHS) and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) scores and record of spontaneous erection without PDE5i and morning erections were analysed at 1, 3 and 6 months post-treatment. Results: At 1, 3 and 6 months post-treatment, mean IIEF-EF was 13.8, 15.3 and 15.0 respectively vs 13.1 before treatment; mean EHS was 2.7, 2.6 and 2.6 respectively vs 2.1 before treatment; mean EDITS was 53.9, 50.3 and 51.6 respectively vs 43.8 before treatment. Mean VAS score for each session was 1.2. Spontaneous or morning erection was reported by 28% of patients while this was absent in all men before LI-ESWT. Conclusion: LI-ESWT is a safe, noninvasive and tolerable treatment for patients with ED. There is tendency of improvement of IIEF; EHS; EDITS scores and spontaneous erection without PDE5i and morning erection in this study.

11.

The safety and efficacy of Li-ESWT in 604 patients for erectile dysfunction: Summary of current and evolving evidence.

Feldman R., Denes B., Appel B., Srinivasan S., Shultz T., Burnett A.

Journal of Urology. Conference: 2015 Annual Meeting of the American Urological Association, AUA. New Orleans, LA United States. Conference Start: 20150515. Conference End: 20150519. Conference Publication: (var.pagings). 193 (4 SUPPL. 1) (pp e905-e906), 2015. Date of Publication: April 2015.

AN: 71859905

INTRODUCTION AND OBJECTIVES: Low intensity shock wave therapy (Li-ESWT) is currently approved in over 20 countries and available at over 200 clinics worldwide. A US multicenter study has been completed and the data are currently under FDA review. Herein we provide an overview of the clinical experience to date on the safety and efficacy of Li-ESWT for the treatment of erectile dysfunction. Studies were conducted in men with ED considered responders and in men considered poor responders to PDE5i. We report pooled data from 5 randomized, placebo-controlled studies (USA, Israel, Greece and India) and 3 single-arm open label studies (Israel, Japan). Li-ESWT for ED has been recently included in the European Association of Urology guideline 2013 for male sexual dysfunction **METHODS:** The database included men (N=604) using the same treatment protocol with Li-ESWT (ED1000 Medispec applicator; Active Rx N=440; Sham Rx N=164).; Li-ESWT was applied to the corpora 2X weekly for 3 weeks and repeated after a 3 week rest period for a total of 12 Rx sessions. Changes in IIEF-EF domain were assessed at baseline and at mid-treatment; 1 month (FU1), 3 months (3M), 6 months (FU2) 12 (FU3) and 24 months (FU4) post treatment. Objective measurements of efficacy were assessed by various measures including penile US Doppler (Greece, penile triplex), Flow Mediated Dilation (FMD, Israel) and nocturnal penile tumescence (NPT, USA). Incidence and severity of adverse events were recorded. **RESULTS:** Results of pooled data revealed that 55%, 61%, 65% and 71% of the subjects achieved a minimally clinical important difference (MCID) in their IIEF-EF score from baseline at midterm, FU1, FU2 and FU3 and FU4 respectively. The mean change in IIEF-EF from baseline was 5, 6.8, 6.2 and 7 points at midterm, FU1, FU2 and FU3 and FU4 respectively. Li-ESWT applied via the ED-1000 was well tolerated; reported AEs were mild and resolved spontaneously. Results from selected studies in which objective measures were assessed are presented in table 1. **CONCLUSIONS:** In these pooled data analyses, Li-ESWT was demonstrated to be safe and effective for the treatment of ED in men considered responders as well as non-responders to PDE5i therapy. Li-ESWT was well tolerated, adverse events were mild, self-limited and resolved spontaneously. These results support the role of Li-ESWT in the management of men with ED. (Table Presented).

12.

Erectile dysfunction shock wave therapy (EDSWT) improves hemodynamic parameters in patients with vasculogenic erectile dysfunction (ED): A triplex-based sham-controlled trial.

Hatzichristou D.G., Kalyvianakis D.E.

European Urology, Supplements. Conference: 30th Annual Congress of the European Association of Urology, EAU15. Madrid Spain. Conference Start: 20150320. Conference End: 20150324. Conference Publication: (var.pagings). 14 (2) (pp e124-e124a), 2015. Date of Publication: April 2015.

AN: 71831093

INTRODUCTION & OBJECTIVES: Several reports have documented the subjective improvement of erectile function after EDSWT in patients with vasculogenic ED. Data of objective assessment of penile hemodynamics are lacking. The purpose of the study was to assess penile hemodynamics before and after ESWT. **MATERIAL & METHODS:** This is a double-blind, randomized and controlled trial. 46 ED patients were randomized; 30 of them underwent EDSWT, while 16 had sham procedure in a double blind fashion. All patients had penile triplex by the same investigator right before and 3 months post-treatment. Patient demographics, as well as IIEF was assessed before, at 1,3 and 6 months post-treatment. **RESULTS:** Mean IIEF improved by 4.3 and 4.6 points at 1 and 3 months follow-up, while at the sham group the improvement

was 1.8 and 1.4 respectively ($p < 0.001$). Mean peak systolic velocity increased by 4.5 and 0.6 cm/sec for the EDSWT and the sham groups respectively ($p < 0.001$). (Figure Presented)
CONCLUSIONS: The present study confirms the beneficial effect of EDSWT in penile hemodynamics. Such results offers objective documentation of the value of this relatively new treatment modality, which is the only available offering cure in several ED patients.

13.

Evaluation of extra corporeal shock wave therapy in cases of peyronie's disease with erectile dysfunction: A preliminary report.

Jain R.J., Shimpi R.K.

Indian Journal of Urology. Conference: 48th Annual Conference of Urological Society of India, USICON 2015. Ranchi India. Conference Start: 20150205. Conference End: 20150208.

Conference Publication: (var.pagings). 31 (pp S74), 2015. Date of Publication: January 2015.

AN: 71815140

INTRODUCTION AND OBJECTIVE: The noninvasive treatment options for Peyronie's Disease(PD) are oral Potassium AminoBenzoate(POTABA), Intralesional steroids, Verapamil ointment etc, if there is no gross penile deformity. Apart from surgical treatment, there is no specific treatment for the plaques. In this preliminary report, I tried to evaluate the use of EXTRA CORPOREAL SHOCK WAVE THERAPY (ESWT) for painful erections and erectile dysfunction(ED). **METHODS:** 12 men aged 24-37 years treated between Jan 2011-July 2014 are included. 10 patients had a single plaque while 2 had 2 or more plaques. Those patients who had failed conservative treatment were included. Evaluation consisted of routine and specific investigations such as Color Penile Doppler and soft tissue xray of the penis. ESWT consists of 8 weekly treatment of 20 minutes duration at the intensity of 1 on OPD basis. The results were evaluated at baseline, 8, 12 and 24 weeks after the therapy. All patients continued Verapamil ointment thereafter. For evaluation, I employed International Index of Erectile Function(IIEFS), Visual Analogue Score(VAS). The treatment was well tolerated. **RESULTS:** 14 patients reported significant improvement of mean VAS score, mean IIEFS score at 12 weeks and 24 weeks. The mean plaque size reduced by 1.2-1.8 cm but the curvature degree did not improve significantly. 17 patients reported that the pain had significantly reduced after the therapy. **CONCLUSION:** ESWT can significant improve the painful erections and to some extent ED in these patients.

14.

The prognostic factors for the efficacy of low-intensity shock wave therapy for erectile dysfunction.

Hisasue S., China T., Ide H., Shirai M., Abdelhamed A., Matsushita K., Yamaguchi R., Muto S., Wakumoto Y., Tsujimura A., Horie S.

Journal of Sexual Medicine. Conference: 16th World Meeting on Sexual Medicine. Sao Paulo Brazil. Conference Start: 20141008. Conference End: 20141012. Conference Publication:

(var.pagings). 12 (pp 30), 2015. Date of Publication: January 2015.

AN: 71788766

Objective: Phosphodiesterase type 5 inhibitors (PDE5i) revolutionized the treatment of erectile dysfunction (ED). However, even in vasculogenic ED patients, one fifth of them showed poor response to PDE5i. Recently low-intensity shock wave therapy (LI-SWT) has been reported to be effective in 60% of patients. The goal of this study is to evaluate the efficacy of LI-SWT and the prognostic factors for its efficacy for ED patients in Japan. **Material and Method:** This study included 58 patients with ED history for more than 6 months, sexual health inventory for men

(SHIM) score of <12 without PDE5i, erection hardness score (EHS) grade 1 or 2, mean penile circumferential change (MPCC) by erectometer assessing sleep related erection of <25 mm, and nonneurological pathology. Patients were treated by a low energy shockwaves generator (ED1000, MEDISPEC, MD, USA); 3-minute application of 300 shock waves (intensity of 0.09 mJ/mm²) in 5 different anatomical sites of penis. After the baseline assessment, treatment was done twice a week for 3 weeks (6 times), no treatment for 3 weeks, and twice a week for 3 weeks (6 times) again. Total of 12 shock wave treatments were applied. SHIM score and EHS with or without PDE5i, MPCC were assessed at baseline, 1, 3, and 6 months following the termination of LI-SWT. Student's t-test was used to assess the improvement of erectile function. Logistic regression analysis was done for the multivariate analysis for the efficacy of LI-SWT using the parameters of age, free testosterone level, body mass index, ED history, baseline MPCC, and comorbidities. Result(s): Of 57 patients who assigned for LI-SWT trial, 56 patients were analyzed. Median age was 64 years and median ED duration was 3 years. One, 3 and 6 months after LI-SWT, each of SHIM and EHS with and without PDE5i were significantly increased ($p < 0.001$). MPCC was also improved increased from 13.1 mm to 20.2 mm after LI-SWT ($p < 0.001$). In the multivariate analysis, age and concomitant comorbidities number were the statistically significant predictors for the efficacy of LI-SWT. Conclusion: The current study showed the efficacy and feasibility of LI-SWT for ED patients in Japan. The multivariate analysis for the efficacy of LI-SWT showed that age and concurrent comorbidities were significant predictors. Older ED patients with several comorbidities should be informed about the less responsiveness to LI-SWT before the treatment.

15.

Early experiences with single session low-intensity shock wave therapy for erectile dysfunction: Multi-center study.

Jung G., Ha S., Seo J., Park S., Seo K., Eom M., Rhee H.

Urology. Conference: 34th Congress of the Societe Internationale d'Urologie, SIU 2014. Glasgow United Kingdom. Conference Start: 20141012. Conference End: 20141015. Conference Publication: (var.pagings). 84 (4 SUPPL. 1) (pp S67-S68), 2014. Date of Publication: October 2014.

AN: 71653964

Introduction and Objectives: Shock wave therapy is a novel treatment option for erectile dysfunction (ED), and has been proved to be effective in some studies. But the treatment methods were empirical and there is no established shock wave treatment method for ED yet. We analyzed our experiences with shortcourse single session Low-intensity shock wave therapy (LSWT) for ED. Materials and Methods: Forty eight consecutive ED patients without any history of pelvic surgery, trauma and/or irradiation who underwent single session LSWT from December 2012 to July 2013 at the 3 centers were included in this study. We applied LSWT to the patients using ED-1000TM (Medispec Ltd.). Single session treatment consisted with 8-time treatment: twice a week, for 4 weeks. Erectile function was assessed with self-administrated International Index of Erectile Function- Erectile Function Domain (IIEF-EFD) score and Erection Hardness Score (EHS) before and 1 month after treatment. The patients' satisfaction to the treatment was assessed by Global Assessment Questionnaire (GAQ) 1 month after the treatment. Results: Mean IIEF-EFD score increased from 12.6 points to 17.6 points after treatment ($p < 0.001$). There were 22 patients (45.8%) who had a 5-point or greater increase in IIEF-EFD score and 34 patients (70.8%) who answered positively to GAQ after treatment. Among 28 patients who couldn't achieve erection hard enough to penetrate initially (EHS < 2), 39.3% (11/28) could achieve

penetration after the treatment (EHS > 3). No adverse events were reported from the treatment. Conclusion: Single session LSWT improved erectile function of ED patients without any adverse events.

16.

Evaluation of extra-corporeal shock wave therapy for the patients of peyronie's disease: A preliminary report.

Shimpi R.

Urology. Conference: 34th Congress of the Societe Internationale d'Urologie, SIU 2014. Glasgow United Kingdom. Conference Start: 20141012. Conference End: 20141015. Conference Publication: (var.pagings). 84 (4 SUPPL. 1) (pp S34), 2014. Date of Publication: October 2014. AN: 71653876

Introduction and Objectives: The noninvasive treatment options available for P.D are oral POTABA, Intra-lesional Steroids, Verapamil ointment, etc., if there is no gross penile deformity. Apart from surgical treatment, there is no specific treatment for the plaques. In this preliminary report, I tried to evaluate the use of ESWT for the painful erections and erectile dysfunction. Materials and Methods: Twenty two men in the age group of 24-37 years (mean 28 years) treated between January 2009 and July 2011 are included in the present study. Seventeen patients had a single plaque while 5 patients had 2 or more plaques. Those patients who have tried conservative treatment, but were nonresponders, are included in the present study. Evaluation consisted of routine and specific investigations such as Colour Penile Doppler and soft tissue X-ray of the penis. ESWT consists of 8 weekly treatment of 20 min duration at the intensity of 1. The results are evaluated at baseline, 8 weeks, 12 weeks and 24 weeks after the therapy. All the patients continued Verapamil ointment thereafter. For evaluation, I have employed the International Index of Erectile Function (IIEFS) questionnaire, VAS (Visual Analogue Scale). The treatment was performed on an out-patient basis and was well tolerated. Results: Fourteen patients reported significant improvement of mean VAS score, mean IIEFS score at 12 weeks and 24 weeks. The mean plaque size reduced by 1.2-1.8 cm but the curvature degree did not improve significantly. Seventeen patients reported that the pain had significantly reduced after the therapy. Conclusions: ESWT can significantly improve the painful erections and to some extent, E.D. in the patients with Peronie's Disease. The ESWT can also stabilize the plaque size and may reduce the progression of the disease and needs long-term follow-up.

17.

Efficacy of low intensity extracorporeal shockwave therapy (LI-ESWT) in Indian men with organic ED.

Joshi P.B., Reddy R., Vasan S.S.

Indian Journal of Urology. Conference: 47th Annual Conference of Urological Society of India, USICON 2014. New Delhi India. Conference Start: 20140130. Conference End: 20140202. Conference Publication: (var.pagings). 30 (pp S99), 2014. Date of Publication: January 2014. AN: 71491121

Introduction: Erectile dysfunction is known to be associated with a number of physical conditions. Currently PDE5 inhibitors are preferred first line treatment. Low Intensity Shock Wave Therapy (LISWT) has been shown to significantly improve erectile function in men previously PDE5(i) dependent. We share our experience and results with this therapy in an Indian population of men with ED. Aim: This study analyzed the efficacy of LI-ESWT in Indian

men with organic ED who had previously responded to PDE5(i). Materials and Methods: Prior to enrollment, all the patients underwent a one month PDE5i washout period. Erectile function and penile hemodynamics were assessed to substantiate a vascular etiology. They were randomized to receive either 12 sessions of LI-ESWT (N = 95) or placebo/sham therapy (N = 40). Outcomes were assessed using erection hardness score, International Index of Erectile Function-Erectile Function domain and Clinical Global Impression of Change scores at 1, 3, 6, 9 and 12 months post-treatment. Results: We found a significant increase in the EHS and IIEF EF DOMAIN from visit 1 to 5 in the treated group. The differences in outcome between the two groups was significant ($P < 0.0001$). Out of 60 men in the LI-ESWT group who completed the study, 47 (78%) men at FU1 and 43 (71%) at FU5 were able to achieve spontaneous erections hard enough for penetration. Conclusions: LI-ESWT had a positive long-term clinical impact with improvement of erectile function. The efficacy and tolerability, coupled with its potential rehabilitative characteristics, make it an attractive new therapeutic option.

18.

Additional shockwave treatment improves erectile function in patients with poor response to the standard shockwave protocol.

Vardi Y., Appel B., Kitrey N.D., Massarwa O., Gruenwald I.

European Urology, Supplements. Conference: 29th Annual Congress of the European Association of Urology, EAU. Stockholm Sweden. Conference Start: 20140411. Conference End: 20140415. Conference Publication: (var.pagings). 13 (1) (pp e604), 2014. Date of Publication: April 2014.

AN: 71485604

INTRODUCTION & OBJECTIVES: The effect of low-intensity shockwave as a treatment option for erectile dysfunction has been previously described. The current protocol consists of 12 treatment sessions. The aim of this study was to assess the efficacy of a second treatment course of shockwave therapy, identical to the first, in patients who have not satisfactorily responded to the first round. **MATERIAL & METHODS:** All the men that were treated by shockwave therapy, and did not meet our criteria for success and showed partial or no response during the six months after the end of the protocol, were offered to repeat an identical treatment protocol for the second time. The initial failure and the response to the second treatment protocol were evaluated one month after the end of treatment and were defined according to the change in the IIEF-EF domain questionnaire (Rosen minimal change clinical improvement) and/or by CGIC (Clinical Global Impression of Change). **RESULTS:** Thirty patients were included in this study. Their median age was 58 (28-76), 13 (43.3%) had diabetes mellitus, and 25 (83.3%) had cardiovascular disease or significant cardiovascular risk factors. 22 patients (73.3%) had severe ED. Their median baseline IIEF-EF score before treatment was 8 (range 6-19), and after the first treatment protocol it improved to a median of 10 points. Twelve patients (40%) responded successfully to the additional treatment protocol according to the Rosen criteria, and 17 (56.6%) by the CGIC. The median IIEF-EF score on follow-up after the second course increased from 8 to 13.5 points. **CONCLUSIONS:** Recently there have been reports from other sources on evaluating shorter protocols by lowering the number of sessions. Our study shows the opposite, and demonstrates that there are patients who need additional exposure to this energy in order to respond. A "Second round" protocol was effective in approximately half the patients who responded poorly to the standard one. Further research is needed to develop optional treatment protocols that could maximize the positive effect of shockwave treatment.

19.

Low intensity extracorporeal shock wave therapy for the treatment of medically refractory erectile dysfunction: First initial Australian experience on clinical outcomes and patient satisfaction rate.

Navaratnam A., Chung E.

BJU International. Conference: 67th Annual Scientific Meeting of the Urological Society of Australia and New Zealand. Brisbane, QLD Australia. Conference Start: 20140316. Conference End: 20140319. Conference Publication: (var.pagings). 113 (pp 7-8), 2014. Date of Publication: March 2014.

AN: 71408519

Introduction: Low intensity extracorporeal shock wave therapy (Li-ESWT) has been shown to induce neovascularization in the animal models and enhances penile perfusion and improves erectile function in clinical trials. This first Australian study evaluates the effect of Li-ESWT in men with medically refractory erectile dysfunction (ED). Patients and Methods: Open-label single arm prospective study on ED patients with International Index of Erectile Function (IIEF)-5 score > 17 at baseline were enrolled after informed consent. Patient demographics, change in IIEF-5 and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) scores, and overall satisfaction score (on a 5-point scale) were recorded. This study utilises a treatment template consisting of 3000 shock waves (1000 shock waves each to proximal 1/3 penis, distal 1/3 penis and corporal bodies at perineum) twice weekly for 6 weeks period. Results: All patients have tried and failed oral phosphodiesterase type 5 inhibitors and the majority of patients have ED longer than 18 months (mean 21.8; 6to 60 months). There was no reported adverse event. The majority of patients reported an improvement in IIEF-5 score by 5 points (70%) and EDITS Index score > 50% (65%). Most patients were satisfied (4 out of 5; 60%) and would recommend Li-ESWT to their friends (80%). Conclusion: Li-ESWT appears to improve erectile function and potential play an important role in penile rehabilitation in men with medical refractory ED.

20.

Extra corporal shockwave therapy in the treatment of post-prostatectomy erectile dysfunction.

Fode M., Frey A., Sonksen J.

Journal of Sexual Medicine. Conference: 16th Annual Congress of the European Society for Sexual Medicine and the 12th Congress of the European Sexology Federation. Istanbul Turkey. Conference Start: 20140129. Conference End: 20140201. Conference Publication: (var.pagings). 11 (pp 42), 2014. Date of Publication: January 2014.

AN: 71355525

Objective: Extra corporal shockwave therapy (ESWT) has shown promise in the treatment of erectile dysfunction (ED). However, published trials have excluded patients who have undergone radical prostatectomy (RP). Our pilot study explores ESWT in the treatment of post-prostatectomy ED. Methods: Men with a preoperative IIEF-5 score of at least 22 who suffered from ED at least 1 year after a bilateral nerve sparing RP were invited to participate. Use of erectile aids was documented and patients were asked to maintain the treatment regime they used at inclusion. ESWT was performed with the Duolith SD1 T-Top. The therapy consisted of 2 sessions every other week for 6 weeks. At each session 500 shockwaves were given at 6 points on the penis with a frequency of 5 hz, and an intensity of 0.12-0.20 mJ/mm². The IIEF-5 questionnaire was administered at baseline and after the last treatment session. The Wilcoxon signed rank test was used for paired analysis before and after treatment. The perception of

ESWT was assessed by a global satisfaction question. Results: Data were available for 17 patients. Two patients were excluded because they started PDE5-inhibitor treatment during the study. For the remaining 15 patients, the median age was 61 years (range 51-70) and the median time since RP was 23 months (range 12-54). The median baseline IIEF-5 score was 9 (range 5-20). At follow-up, there was an overall median IIEF-5 improvement of 3 (range-1 to 8; $p = 0.0068$). 7/15 patients improved in ED category according to Rosen et al (Int J Impot Res. 1999 Dec;11(6): 319-26.) and 11/15 reported to be satisfied with ESWT. Aside from mild selflimiting discomfort no patients experienced adverse events. Conclusion: ESWT may have a beneficial effect on post prostatectomy ED. Placebo controlled trials are needed to explore this effect further.

21.

Treatment of erectile dysfunction with extracorporeal shockwave therapy (ESWT). A prospective, randomised, double-blind, placebo-controlled study.

Olsen A., Persiani M., Andersen S., Hanna M., Lund L.

Journal of Sexual Medicine. Conference: 16th Annual Congress of the European Society for Sexual Medicine and the 12th Congress of the European Sexology Federation. Istanbul Turkey. Conference Start: 20140129. Conference End: 20140201. Conference Publication: (var.pagings). 11 (pp 24-25), 2014. Date of Publication: January 2014.

AN: 71355475

Objective: The aim is to demonstrate that penile shockwave application in patients with erectile dysfunction (ED) of vascular origin leads to a greater increase in potency than in the control group. Methods: A prospective, randomised, blinded, placebo-controlled study conducted from 2012-2013. The study enrolled 112 male participants unable to fulfil an intercourse either with or without medication. All participants had ED >six months. Seven of the patients were excluded due to the protocol. Each patient provided their full medical and sexual history. After the initial interview they were randomly assigned either Extracorporeal Shockwave Treatment (ESWT) ($n = 51$) or placebo ($n = 54$). Patient's received five treatments over a five week period, blinded for the patients and physicians. Assessment of ED was performed at screening, 5, 12 and 24 weeks after treatment by interview and validated sexual function questionnaires: Erection Hardness Score (EHS) and International Index of Erectile Function (IIEF). The chi-squared test #2 was used to analyse differences between patient groups. Results: All enrolled patients but two completed the study. The median age was 60 years (range 37-80 years). Both groups showed similar characteristics in co-morbidities and use of PDE-5 inhibitors. Over the five week treatment period a significant amount of patients from the ESWT group improved their EHS. Twenty-nine patients (56.9 %) had an EHS of 3-4, allowing full sexual intercourse without medication compared to the placebo group, where only five (9%) showed similar results ($p = 0.0001$). Conclusion: This study has shown that 59 % of patients with ED of organic origin be treated alone by ESWT compared to the placebo group. At 24 week follow-up 12 patients (28.2%) still belonged to category 3-4. The study showed the same response in the placebo group when it was treated with active ESWT. Treatment is patientfriendly and has no side effects.

22.

Low intensity shock wave (Lisw) treatment (Renova) in order to improve male sexual function: A preliminary data on 42 patients.

Iacono F., Ruffo A., Prezioso D., Romeo G., Illiano E., Romis L., Di Lauro G.

Journal of Sexual Medicine. Conference: 16th Annual Congress of the European Society for Sexual Medicine and the 12th Congress of the European Sexology Federation. Istanbul Turkey. Conference Start: 20140129. Conference End: 20140201. Conference Publication: (var.pagings). 11 (pp 24), 2014. Date of Publication: January 2014.

AN: 71355474

Objective: The aim of our study is to investigate the safety and efficacy of Low intensity Extracorporeal shock wave therapy LI-ESWT (Renova) in the treatment of erectile dysfunction. **Methods:** We enrolled 47 patients with erectile dysfunction (ED). They underwent to four weekly session using a dedicated device (Renova) for the management of erectile dysfunction. The treatment included four weekly sessions. During each treatment session, a LI-ESWT was applied at four different anatomical area, right and left corpus cavernosum and right and left crus penis (900 shocks, 0.09 mJ/mm² intensity at 240 shocks/min at each site for a total of 3600 shocks). Patient were followed at one month after treatment. Three self-administered questionnaire: International Index of Erectile Function-Erectile Function (IIEF-ED), Sexual Encounter Profile (SEP-Questions 2 and 3) were given to patients to assess their sexual function pre and post treatment. **Results:** Five patients dropt out of treatment, so forty-two patients (mean age was 59.2 years) were evaluable. At one month follow-up, we noticed a statistically significant improvement in IIEF-ED domain scores in treated patients (from a mean of 12+/-4.8 at baseline to 23.5+/-5.3, $p < 0.05$). SEP-Q2 and SEP-Q3 success rates improved from 57% to 84% and from 24% to 76% respectively. No side effects were reported. **Conclusion:** (LI) ESWT improves male sexual function inducing neovascularization in the treated tissues by stimulating the expression of angiogenesis-related growth factors, such as endothelial nitric oxide synthase, vascular endothelial growth factor, and endothelial cell proliferation factors, such as proliferating cell nuclear antigen. This therapy shows a statistically significant clinical improvement of erectile function without any side effect or contraindication. In our opinion further studies are needed even to assess the possibility to repeat the treatment cyclically or in association with PDE5-i or with nutraceutical composite.

23.

Mid-term follow-up on the effect of low intensity shock waves for the treatment of erectile dysfunction.

Gruenwald I., Appel B., Massarwi O., Vardi Y.

Journal of Urology. Conference: 2013 Annual Meeting of the American Urological Association, AUA. San Diego, CA United States. Conference Start: 20130504. Conference End: 20130508. Conference Publication: (var.pagings). 189 (4 SUPPL. 1) (pp e619), 2013. Date of Publication: April 2013.

AN: 71032452

INTRODUCTION AND OBJECTIVES: Our aim was to evaluate the overall mid-term efficacy (6 months) of penile Low Intensity Shock Wave therapy (LI-ESWT) in patients who participated in different studies regardless of ED severity, response to PDE5i, and etiology of ED. **METHODS:** During the past 30 months we have followed up and evaluated the efficacy of LI-ESWT on 191 ED patients (155 treated and 36 Sham). These subjects represent various degrees of ED severity and response to PDE5i therapy. All received the same treatment protocol but participated in different trials. Follow-up data were collected at the 6 month period after end of treatment and were compared to the patients' baseline scores before treatment. **RESULTS:** Mean age was 59+/- 10.3 and Mean ED Duration was 65.1 months. 86.4% were cardiovascular patients, 61 (40%) were diabetic of which 50.81% had a significant clinical improvement. The mean baseline

IIEF-EF domain scores were 11.0 (and mean baseline total IIEF score was 34.48). Based on changes in IIEF-EF Domain scores, 57.4% of all males had a significant clinical improvement 6 months after therapy. Categorizing them to severe, moderate and mild ED groups showed that 52%, 65% and 79% improved respectively according to the newly defined minimal clinical improvement criteria. Thirty two percent of the mild group reached normalization, while 24% and 15% of the moderate and severe group reached normalization respectively. **CONCLUSIONS:** In this study we have demonstrated that applying LI-ESWT directly to the penis has a significant clinical effect for all ED severities, for cardiovascular and diabetic patients as well as for either responders or non-responders to PDE5i therapy. This study also showed that the clinical effect is maintained at least for a 6 month period. Further follow up on a larger scale of ED populations is necessary in order to fully evaluate the long term or permanent effect of this treatment modality.

24.

Patient and partner satisfaction from extracorporeal shockwave therapy (ESWT) for ED treatment.

Hattat H., Hattat E., Hattat I.

Journal of Sexual Medicine. Conference: 15th Congress of the European Society for Sexual Medicine. Amsterdam Netherlands. Conference Start: 20121206. Conference End: 20121208. Conference Publication: (var.pagings). 9 (pp 316), 2012. Date of Publication: December 2012. AN: 70954104

Objective: ESWT is a new therapy option for ED. The aim of this study was to assess the effect of the treatment on erectile quality and on the sexual satisfaction of couples. **Methods:** 40 men with vasculogenic ED were chosen as treatment (n:23) and placebo groups (n: 17) Treatment included 2 sessions/week for 3 weeks, repeated after a 3 week no-treatment interval. At each session ESWT was applied on the penile shaft and crura in 10 different anatomical sites, 300 shock waves per site (frequency 3.5 Hz, energy density 0.25 mJ/mm²). No other ED treatment were included. IIEF ED, intercourse satisfaction and general satisfaction domain scores pre and 1 month post treatment as well as post treatment EDITS (Erectile dysfunction inventory of treatment satisfaction) scores for the patients and their partners were assessed. **Results:** Treatment and placebo groups were not statistically different regarding age, IIEF ED, intercourse satisfaction and general satisfaction scores ($p = 0,458$; $p = 0,761$; $p = 0,399$; $p = 0,063$). At posttreatment, IIEF ED, intercourse satisfaction and general satisfaction scores were significantly higher for the treatment group compared with placebo ($p = 0,043$; $p = 0,0001$; $p = 0,0001$). Both the patient and the partner EDITS scores were significantly higher than the placebo group ($p = 0,0001$; $p = 0,0001$). EDITS patient and partner scores were positively correlated with IIEF ED scores ($r = 0,951$ $p = 0,0001$; $r = 0,923$ $p = 0,0001$). Age was positively related to EDITS patient score averages ($r = 0,317$ $p = 0,012$). On the other hand, age is negatively related to IIEF ED, intercourse satisfaction and general satisfaction sub-scores ($r = -0,908$ $p = 0,0001$; $r = -0,357$ $p = 0,024$; $r = -0,385$ $p = 0,015$). **Conclusion:** ESWT has the potential to improve erectile function with high treatment satisfaction rates for both the patients and the partners. The treatment satisfaction is higher for older age groups.

25.

Erectile dysfunction shock wave therapy- A new treatment modality in the management of erectile dysfunction: Patient selection and optimizing strategies.

Srini V.S., Srinivas B.V.

Journal of Sexual Medicine. Conference: 13th Biennial Meeting of the Asia-Pacific Society for Sexual Medicine. Kaohsiung Taiwan (Republic of China). Conference Start: 20111116.

Conference End: 20111120. Conference Publication: (var.pagings). 9 (pp 120), 2012. Date of Publication: March 2012.

AN: 70683597

Purpose: Erectile Dysfunction Shockwave Therapy (EDSWT) has brought new hope in the management of Erectile Dysfunction. Its role in treatment of ED has not been established to date, however its application in different medical disciplines to treat various organ dysfunction owing to its property of neovascularization has proved its worth. Our objective was to evaluate the efficacy of EDSWT on men with erectile dysfunction (ED), to analyze its effect on various subgroups and predict the indications of the usage of EDSWT. Materials and Methods: We conducted a double-blind randomized placebo controlled study at a single tertiary andrology hospital setting. A total of 112 patients diagnosed to have arteriogenic erectile dysfunction who had International Index of Erectile Function ED (IIEF-ED) domain scores between 3 and 18 (average: 8.25) and abnormal nocturnal penile tumescence (NPT) parameters were enrolled for the study after obtaining written consent. 29 patients were lost for follow up. 83 patients completed the study with a follow up period of 12 months. The study group were divided into 3 groups, the first group comprised of 26 patients who had responded to oral phosphodiesterase type 5 inhibitors (PDE5-I) prior to the study, the second group comprised 32 patients of non responders to PDE5-I and rest 25 formed patients who had not been on any therapy for ED before. Shockwave therapy comprised two treatment sessions per week for 3 weeks, which were repeated after a 3 week no-treatment interval. Assessment of erectile function was performed objectively by Doppler ultrasound examination. Follow up assessments with IIEF- ED questionnaire and doppler ultrasound examinations were done at 6 and 12 months periods. Results: We evaluated 83 middle-aged men (average age: 39.5 year) with arteriogenic ED (mean duration: 2.08 years). Among the 83 patients, 51 of them had co-morbidities. 27 had Diabetes mellitus, 26 had hypertension and 12 had hypercholesterolemia. At 6 months of follow-up period, significant increases in IIEF-ED domain scores were recorded in all men (23.30 ± 3.37 vs 7.85 ± 2.68 , $p < 0.001$); these remained unchanged after 12 months. Significant increases in the duration of erection and penile rigidity were also recorded. Doppler ultrasound study objectively recorded the improvement in penile blood flow parameters in terms of peak systolic velocity, end diastolic velocity, vessel wall circumference, vessel wall thickness, pulsatility index, resistivity index. 14 out of 26 (53.85%) patients belonging to PDE5-I responders group required no more therapy. 22 out of 32 (68.75%) patients belonging to PDE5-I nonresponders group improved among which 9 (28.12%) required no more therapy and rest (71.88%) required phosphodiesterase type 5 inhibitors during follow up. No adverse events were noted during procedure and in follow-up. Conclusion: This is the first study in literature that assessed the efficacy of EDSWT for ED based on both subjective and objective evidence. The treatment has shown promising results in its efficacy of improvement of erectile function and the fact that the effects were natural, long lasting and measurable improvement gives a hope in attainment of a possible cure to Erectile dysfunction which no other therapy has been able to provide to date. Similar studies with larger number and longer follow-up needs to be evaluated to establish the definite role of EDSWT in the management of ED.

26.

The effect of low intensity shock waves for the treatment of various degrees of erectile dysfunction severity: 6-month follow up.

Vardi Y., Appel B., Massarwi O., Gruenwald I.

Journal of Sexual Medicine. Conference: World Meeting on Sexual Medicine 2012. Chicago, IL United States. Conference Start: 20120826. Conference End: 20120830. Conference Publication: (var.pagings). 9 (pp 246-247), 2012. Date of Publication: August 2012.

AN: 70928522

Objective: Our aim was to evaluate the overall mid-term efficacy (6 months) of penile Low Intensity Shock Wave therapy (LI-ESWT) in patients who participated in different studies regardless of ED severity, response to PDE5i, and etiology of ED. Methods: During the past 30 months we have followed and evaluated the efficacy of LI-ESWT on 124 ED patients who at baseline were either responders or non- responders to PDE5i therapy. For responders evaluation at baseline and at followup was done without PDE5i therapy while for the non-responders evaluation was done under PDE5i therapy. These subjects were mainly cardiovascular and diabetic ED patients and represent various degrees of ED severity. They participated in different trials but all received the same treatment protocol. Follow-up data was collected at 6 months and their follow-up IIEF-ED scores were compared to their baseline scores. Results: Mean age was 54.6y +/- 10 years. Based on changes in IIEF-ED Domain scoring, 61% of all males had a significant clinical improvement 6 months after therapy. When sub-dividing them to severe, moderate and mild ED groups, we found that 52, 65 and 79 percent improved respectively according to the newly defined minimal clinical improvement criteria (Rosen et al. . .). Thirty two percent of the mild group reached normalization, while 24% and 15% of the moderate and severe group reached normalization respectively. Of these cardiovascular patients, 50 (40%) were diabetic of which 56% had a significant clinical improvement. Of these- 48%, 56% and 78% improved for severe, moderate and mild ED respectively. Conclusions: In this study we have demonstrated that applying LI-ESWT directly to the penis has a significant clinical effect for all ED severities, for cardiovascular and diabetic patients as well as for either responders or non- responders to PDE5i therapy. This study requires further follow up in a larger scale of ED population in order to fully evaluate the long term or permanent effect of this treatment modality.

27.

Initial experience of low-intensity shock wave therapy for the ED patients in Japan.

Hisasue S., China T., Ide H., Yosii T., Saito K., Isotani S., Muto S., Yamaguchi R., Horie S.

Journal of Sexual Medicine. Conference: World Meeting on Sexual Medicine 2012. Chicago, IL United States. Conference Start: 20120826. Conference End: 20120830. Conference Publication: (var.pagings). 9 (pp 195), 2012. Date of Publication: August 2012.

AN: 70928381

Objective: Phosphodiesterase type 5 inhibitors (PDE5i) revolutionized the treatment of erectile dysfunction (ED). However, even in vasculogenic ED patients, one fifth of them showed poor response to PDE5i. Vardi et al. recently reported the beneficial effects of low-intensity shock wave therapy (LI-ESWT) on mild and moderate ED. We report our initial experience of LI-ESWT (ED1000TM) for ED patients in Japan. Methods: This study included patients with ED history for more than 6 months, sexual health inventory for men (SHIM) score of <12 without PDE5 inhibitor, EHS grade 1 or 2, mean penile circumferential change (MPCC) by erectometer of <25 mm, and non-neurological pathology. Patients were treated by a low energy shockwaves generator (ED1000, MEDISPEC, MD, USA); 3-minute application of 300 shock waves (intensity of

0.09 mJ/mm²) in 5 different anatomical sites of penis. After the baseline assessment, treatment was done twice a week for 3 weeks (6 times), no treatment for 3 weeks, and twice a week for 3 weeks (6 times) again. Total of 12 shock wave treatments were applied. Results: Of 35 patients who assigned for the LI-ESWT trial, we analyzed the 14 patients whose data were available at 4 weeks after treatment. Median age was 61 years (range; 39-83). Median duration of ED was 3 years (range; 0.5-18). Median SHIM score was 5 (range; 1-12). Median MPCC was 14 mm (range; 6.7-28.3). One experienced mild pain on the penis during the procedure. SHIM after treatment was significantly increased from 5 to 10 ($p = 0.041$, Wilcoxon signedrank test). Baseline EHS was 0 in 4, 1 in 2, and 2 in 3 patients, and EHS after LI-ESWT was 2 in 4 and 3 in 5 patients. Mean MPCC was increased from 12.83 mm to 24.17 mm after LI-ESWT ($p = 0.029$). Conclusions: We reported the pilot study of LI-ESWT for ED in Japan. This study showed the safety and feasibility of the low energy shockwaves treatment for Japanese ED patients.

28.

The efficacy of low intensity shock wave therapy to the penis for vasculogenic erectile dysfunction-a randomized shamcontrolled double blind study.

Vardi Y., Appel B., Shechter A., Gruenwald I.

Journal of Sexual Medicine. Conference: World Meeting on Sexual Medicine 2012. Chicago, IL United States. Conference Start: 20120826. Conference End: 20120830. Conference Publication: (var.pagings). 9 (pp 193), 2012. Date of Publication: August 2012.

AN: 70928376

Objective: In two previous studies we have shown that Low Intensity Shock Wave Therapy (LI-ESWT) is effective for treating ED. The aim of this study was to re-establish and validate these results on a larger group of ED patients responding to PDE5i's in a randomized double-blind sham-controlled fasion. Methods: Sixty vasculogenic ED patients were eligible for final evaluation. Their mean age was 56.5 y +/- 10 and at screening had an IIEF-ED Domain < 19 (without PDE5i treatment). After a one-month washout, they underwent a baseline assessment of erectile function using validated questionnaires and objective local endothelial function testing using the penile flow mediated dilatation technique (FMD). At this visit a blinded randomization to treatment (2/3) and sham (1/3) was performed. The average IIEF-ED at baseline was 12.3 +/- 4.1 (SEM) with no statistical significant difference between the placebo and teatment groups. The treatment protocol included 12 sessions of LI-ESWT, twice a week for 3 weeks, repeated after a 3-week notreatment interval. During the whole study period no PDE5i was allowed and re-evaluation of erectile function was performed onemonth post treatment. For those who did not sufficiently respond to the treatment (IIEF-ED an increase of less than 5 points) an additional 12 session shock wave treatment was offered. Results: The average increase in IIEF-ED score between baseline and one month post treatment follow up was 6.7 +/- 0.8 for the treatment group vs. 2.9 +/- 1.43 for the sham ($P = 0.0098$). Sixty five percent of the treated group had an increase of >5 points compared to 25% of the sham, $P = 0.0003$. All the penile hemodynamic parameters signifi- cantly increased only in the treatment group ($P = 0.0009$). No adverse events were reported. All other evaluated parameters showed similar results. Twenty three subjects underwent a second shock wave treatment, 16 were from the placebo group (80%). One Month after the end of the second treatment session , the IIEF - ED score of these 16 patients increased from an average of 11.8 +/- 1.9 to 16.6 +/- 1.2, $p = 0.007$. Conclusions: This first randomized sham controlled double blind study we demonstrated that LI-ESWT applied directly to the penis has a clinical significant effect on the erectile mechanism and

hemodynamics. This study requires further investigation in a larger scale of ED population and needs more basic science research in order to fully understand its mechanism of action.

29.

Initial experience of low-intensity shock wave therapy for the treatment of erectile dysfunction in teikyo University Hospital, Japan.

Hisasue S., China T., Ide H., Inoue M., Yosii T., Saito K., Isotani S., Muto S., Yamaguchi R., Horie S. Urology. Conference: 32nd Congress of the Societe Internationale d'Urologie. Fukuoka Japan. Conference Start: 20120930. Conference End: 20121004. Conference Publication: (var.pagings). 80 (3 SUPPL. 1) (pp S313-S314), 2012. Date of Publication: September 2012.

AN: 70900086

Introduction and Objective: Phosphodiesterase type 5 inhibitors (PDE5i) revolutionized the treatment of erectile dysfunction (ED). However, even in vasculogenic ED patients, one fifth of them showed poor response to PDE5i. Recently the beneficial effects of lowintensity shock wave therapy (LI-ESWT) have been reported in the angiogenesis of post-ischemic heart. We report our initial experience of LI-ESWT (ED1000TM) in the treatment of ED. Materials and Methods: This study included patients with ED of more than 6 months sexual health inventory for men (SHIM) score of < 12 without PDE5 inhibitor, EHS grade 1 or 2, mean penile circumferential change (MPCC) by erectometer of <25mm, and non-neurological pathology. Patients were treated by a low energy shockwaves generator (ED1000, MEDISPEC, MD, USA); 3-minute application of 300 shock waves (intensity of 0.09 mJ/mm²) in 5 different anatomical sites of penis. After the baseline assessment, treatment was done twice a week for 3 weeks (6 times), no treatment for 3 weeks, and twice a week for 3 weeks (6 times) again. Total of 12 shock wave treatment was applied. Results: Of 30 patients who assigned for the LI-ESWT trial, we analyzed the 12 patients whose data were available at 4 weeks after treatment. Median age was 61 years (range; 39-83). Median duration of ED was 3 years (range; 0.5-18). Median SHIM score was 5 (range; 1-12). Median MPCC was 14 mm (range; 6.7-28.3). One experienced mild pain on the penis during the procedure. SHIM after treatment was significantly increased from 5 to 10 (p=0.041, Wilcoxon signed-rank test). Baseline EHS was 0 in 4, 1 in 2, and 2 in 3 patients, and EHS after LI-ESWT was 2 in 4 and 3 in 5 patients. Mean MPCC was increased from 12.83 mm to 24.17 mm after LI-ESWT (p=0.029). Conclusions: We reported the pilot study of LI-ESWT for ED in Japan. This study showed the safety and feasibility of the low energy shockwaves treatment.

30.

Extracorporeal shockwave therapy improves erectile dysfunction - A pilot study.

Lund L., Pedersen D.V., Zimmermann R., Hanna M.

Journal of Endourology. Conference: 30th World Congress of Endourology and SWL, WCE 2012. Istanbul Turkey. Conference Start: 20120904. Conference End: 20120908. Conference Publication: (var.pagings). 26 (pp A436), 2012. Date of Publication: September 2012.

AN: 70876768

OBJECTIVE: We want to investigate whether ESWT can be used as a treatment for men with erectile dysfunction (ED). METHODS: 15 men with ED were included in this pilot study. All the men apart from one have tried treatment with PDE-5 inhibitors or injection therapy. Treatment was performed without local anesthesia with 0.13 mJ/mm², frequency of 5 Hz with a total of 3000 shock waves. The men received 1 ESWT treatment each week for 5 weeks. Assessment of erectile function was performed at screening, 1, 2 and 6 months after treatment using validated

sexual function questionnaires. RESULTS: Mean age was 58 years (range 42-67). 10 men (67%) had comorbidity. BMI 25 (range 18-33). One had not received medical treatment. BMI 25 (range 18-33). All completed the treatments and no side effects or pain during / after treatment were observed. All 15 men had effect of treatment with increased swelling of the penis and 11 men (73%) could now have an erection without medication and were able to have sexual intercourse. Questionnaire 1 baseline score was 7.4 and after treatment fall to 3.7 (1 month), 4.3 (2 month) ($p < 0.01$) and 4.5 (6 month). Questionnaire 2 baseline score was 10.3 and after treatment rose to 17.8 (1month) and 16.3 (2month) ($p < 0.01$) and 15.9 (6 month). CONCLUSIONS: 11 men (73%) had an immediate and up to 6 month effect of ESWT treatment for ED. The treatment is patientfriendly, has no side effect and can be used for all patients even those on anticoagulants.

31.

The efficacy of low-intensity extracorporeal shock waves for ED patients who respond to oral therapy: A randomized, doubleblind, placebo-controlled study.

Gruenwald I., Appel B., Kilchevski A., Vardi Y.

European Urology, Supplements. Conference: 27th Annual Congress of the European Association of Urology, EAU. Paris France. Conference Start: 20120224. Conference End: 20120228. Conference Publication: (var.pagings). 11 (1) (pp e597-e597a), 2012. Date of Publication: February 2012.

AN: 70863373

INTRODUCTION & OBJECTIVES: Our aim was to evaluate the efficacy of Low Intensity Extracorporeal Shockwave Therapy (LIESWT) in men with erectile dysfunction (ED) of vasculogenic etiology in a prospective randomized controlled trial (PRCT). MATERIAL & METHODS: Sixty men with vasculogenic ED completed the study. They had a mean International Index of Erectile Function ED domain score (IIEF-ED) of 12.2 (range 1-19) (when not on PDE5i therapy). These men had previously responded to PDE5i's (mean IIEFED domain: 22.7). All subjects were randomized to 12 sessions of LIESWT or sham treatment. LI-ESWT was applied to the penile shaft and crura at five different sites. Assessment of erectile function was performed prior to the first treatment (V1) and at 1 month after the final treatment session (FU1) using validated sexual function questionnaires (IIEF, Erection Hardness Scale-EHS) and penile hemodynamics and endothelial function testing (Flow mediated dilatation technique- FMD). A change in the IIEF-ED Domain score of more than 5 points was used as the main outcome measure of treatment success. RESULTS: The LI-ESWT treated group (treatment) evidenced a greater increase in Total IIEF and IIEF-ED from V1 to FU1 versus the sham group. Total IIEF: 12.2+/-2.0 (change score mean+/-sem) vs. 3.2+/-3.1, $P=0.0196$. IIEF-ED: 6.7+/-0.9 vs. 3.0+/-1.4, $P=0.0322$. Similar improvements were observed in the penile endothelial function, expressed by FMD maximum (FMDm). FMDm of the treated group improved by median 8.2 ml/min per deciliter (range -17.0 to 124.8) vs. - 0.1 (range -9.2 to 18.5) for the sham-treated group, $P<0.0001$. Combining the objective and subjective parameters for each individual, we found that 22 patients in the active group (56%) showed significant improvement in both IIEF and FMD whereas only 1 patient in the placebo group (5%) showed an improvement in both, $P<0.0001$. Of the treated group, 13 patients had an EHS>3 before treatment vs.31 ($p=0.0013$) after LI-ESWT. in the sham group, no significant difference in number of patients with an EHS>3 was found(8 before vs. 7 after sham treatment). In addition, the treated group experienced a significantly greater increase in the IIEF Total Satisfaction category from from V1 to FU1, 1.9+/-0.5, vs. the sham-treated group, 0.1+/-0.4, $P=0.0054$. None of the patients experienced adverse effects from the treatment. CONCLUSIONS: In this specifically designed PRCT we have been able to

prove that LI-ESWT is an effective therapeutic option for men with erectile dysfunction of vasculogenic origin.

32.

Does low-intensity extracorporeal shock wave therapy have a physiologic effect on erectile function? Short-term results of a randomized, double-blind, sham-controlled study.

Vardi Y., Appel B., Kilchevsky A., Gruenwald I.

Journal of Urology. Conference: 2012 Annual Meeting of the American Urological Association, AUA. Atlanta, GA United States. Conference Start: 20120519. Conference End: 20120523. Conference Publication: (var.pagings). 187 (4 SUPPL. 1) (pp e606), 2012. Date of Publication: April 2012.

AN: 70721562

INTRODUCTION AND OBJECTIVES: Low-intensity extracorporeal shockwave therapy (LI-ESWT) is currently under investigation regarding its ability to promote neovascularization in different organs. Our aim is to study the clinical and physiologic effect of LI-ESWT on the erectile function of men with erectile dysfunction (ED) and cardiovascular risk factors who are phosphodiesterase-5 inhibitor (PDE5i) responders. **METHODS:** After a 1-month PDE5i washout period, 67 men were randomized in a 2:1 ratio to receive either 12 sessions of LI-ESWT (treated) or sham therapy (sham-treated). Erectile function and penile hemodynamics were assessed prior to the first treatment (V1) and one month after the final treatment (FU1) using validated sexual function questionnaires and veno-occlusive strain gauge plethysmography. **RESULTS:** Clinically, we found a significantly greater increase in the International Index of Erectile Function-ED (IIEF-ED) domain score from V1 to FU1 in the treated group versus the sham-treated group (6.7+/-0.9 vs. 3.0+/-1.4 [mean +/- SEM], P=0.0322). Nineteen men in the treated group who were unable to achieve erections hard enough for penetration initially (Erection Hardness Score (EHS) < 2) were subsequently able to achieve erections firm enough for penetration (EHS > 3) following treatment, compared to none in the sham-treated group. Physiologically, penile blood flow significantly improved in the treated group versus the sham-treated group (maximal post-ischemic penile blood flow: 8.2 ml/min/dL vs 0.1 ml/min/dl, p<0.0001). None of the men experienced discomfort or reported any adverse effects due to the treatment. **CONCLUSIONS:** This is the first randomized, double-blind, sham-controlled study showing that LI-ESWT has a positive short-term clinical and physiologic effect on the erectile function of men who respond to oral PDE5i therapy. The feasibility and tolerability of this treatment, coupled with its potential rehabilitative characteristics, make it an attractive new therapeutic option for men with ED.

33.

Low-intensity extracorporeal shock wave therapy for erectile dysfunction in phosphodiesterase type 5 inhibitor responders: A randomized, double-blind, placebocontrolled study.

Massarwi O., Vardi Y., Appel B., Gerber E., Sprecher E., Kilchevsky A., Gruenwald I.

Journal of Sexual Medicine. Conference: 14th Annual Congress of the European Society for Sexual Medicine. Milan Italy. Conference Start: 20111201. Conference End: 20111204. Conference Publication: (var.pagings). 8 (pp 397), 2011. Date of Publication: December 2011.

AN: 70612150

Objective: To evaluate the impact of Low Intensity Extracorporeal Shockwave Therapy (ESWT) on men with ED in a prospective randomized controlled trial. **Methods:** We enrolled 60 men with vasculogenic ED who were responders to PDE5is. Their mean baseline International Index of Erectile Function ED domain score (IIEF-ED) was 12.2 after a 1-month PDE5i washout period. The men were then randomized to 12 sessions of ESWT or sham treatment. ESWT was applied to the penile shaft and crura at five sites. Assessment of erectile function was performed prior to the first treatment (V1) and 1 month after the final treatment (FU1) using validated sexual function questionnaires and flow-mediated dilatation (FMD) testing. **Results:** The ESWT group (treatment) evidenced a greater increase in IIEF-ED from V1 to FU1 vs. the sham group: 6.7 +/- 0.9 (mean (Figure presented) change score +/- SEM) vs. 3.0 +/- 1.4, P = 0.0322. Similar improvements were observed in penile endothelial function, expressed by FMD maximum (FMD): mean change 8.2 mL/minute/dL for the treatment group vs. -0.1 mL/minute/dL for the sham group, P < 0.0001. Combining the objective and subjective parameters, we found that 22 patients in the treatment group (56%) showed significant improvement in both IIEF and FMD whereas only 1 patient in the sham group (5%) showed an improvement in both. Importantly, the treatment group experienced a greater increase in the IIEF Overall Satisfaction category, 1.9 +/- 0.5, vs. sham, 0.1 +/- 0.4, P = 0.0054. None of the patients experienced adverse effects from the treatment. **Conclusion:** This is the first randomized, double-blind, placebocontrolled study demonstrating that ESWT has a positive physiologic effect on cavernosal hemodynamics. As such, ESWT represents a new, effective, and well tolerated treatment for men with erectile dysfunction who previously responded to pharmacotherapy.

34.

Low intensity extracorporeal shock wave therapy for erectile dysfunction in ed patients: Initial experience in Japan.

Inoue S., Kurimura Y., Sadahide K., Ueno T., Ikeda K., Hieda K., Shoji K., Miyamoto K., Ohara S., Kobayashi K., Kajiwara M., Teishima J., Matsubara A.

Journal of Sexual Medicine. Conference: 14th Biennial Meeting of the Asia-Pacific Society for Sexual Medicine. Kanazawa Japan. Conference Start: 20130531. Conference End: 20130602. Conference Publication: (var.pagings). 10 (pp 224)

AN: 71095928

Objective: Low-intensity extracorporeal shockwave therapy (LIESWT) is currently under investigation regarding its ability to promote neovascularization in different organs. We evaluate the effect of LI-ESWT on men with erectile dysfunction (ED). **Patients and Methods:** This was an open-label single-arm prospective study on ED patients with erection hardness score (EHS) <2 at baseline. We treated 5 middle-aged men (average age: 63.2 year) with ED. Three were performed non-nerve sparing laparoscopic radical prostatectomy (operation group), and other two had many ED risk factors (non-operation group). LI-ESWT comprised two treatment sessions per week for 3 week, which were repeated after a 3-week no-treatment interval. LI-ESWT was applied to the penile shaft and crura at five different sites. Assessment of erectile function was performed at screening (pre) and at 1 month after the end of the two treatment sessions (post) using validated sexual function questionnaires; the sexual health inventory for men (SHIM) scores, nocturnal penile tumescence (NPT) parameters and EHS. **Results:** At 1 month follow-up, there mean were almost no changes in mean SHIM scores were recorded in all men (pre 6.4, post 7.0). There were slightly increase NPT (pre 0.7, post 1.8) and EHS (pre 0.8, post 2.2). All men in the non-operation group were improved (EHS 3 or greater), but all men in the operation group were not improved (EHS 2 or less). No pain was reported from the treatment and no

adverse events were noted during follow-up. Conclusions: Penile LI-ESWT is a new modality that has the potential to treat ED patients. Its main advantages are the potential to improve erectile function and to contribute to penile rehabilitation without pharmacotherapy. Penile LI-ESWT has an effect to the patients in non-operation group, but may be ineffective in the operation group especially in non-nerve sparing procedures.

35.

The impact of age on the efficacy of low-intensity shock wave therapy for the erectile dysfunction in Japanese patients.

Hisasue S.-I., China T., Koja M., Yamaguchi R., Ide H., Muto S., Horie S.

Journal of Sexual Medicine. Conference: 14th Biennial Meeting of the Asia-Pacific Society for Sexual Medicine. Kanazawa Japan. Conference Start: 20130531. Conference End: 20130602. Conference Publication: (var.pagings). 10 (pp 224)

AN: 71095927

Objective; Low-intensity shock wave therapy (LI-ESWT) is a novel and promising modality for the patients with mild to moderate erectile dysfunction (ED). Vardi et al. reported that the pretreatment severity of ED influenced the efficacy of LI-ESWT. In this study, we assessed the efficacy and the predictors for the recovery after LI-ESWT in Japanese patients. Methods: This study included patients with ED whose history lasted more than 6 months, sexual health inventory for men (SHIM) score of <12 without PDE5 inhibitor, EHS grade 1 or 2, mean penile circumferential change (MPCC) by erectometer for sleep related erection (SRE) of <25 mm. Patients were treated by a low energy shockwaves generator (ED1000, MEDISPEC, MD, USA). We examined the predictors for the functional recovery by multivariate analysis with logistic regression using parameters of age, body mass index, free testosterone level, baseline MPCC and concomitant 3 risk factors in smoking, hypertension, diabetes, or ischemic heart disease. Results: Of 52 patients treated by LI-ESWT, we analyzed the 41 patients whose data were available at 4 weeks after treatment. Median age was 64 years (range; 37-83). Median duration of ED was 3 years (range; 0.5-18). SHIM after the treatment was significantly increased from 5 to 9 ($p < 0.001$, Wilcoxon signed-rank test). Baseline EHS was 1 in 22, and 2 in 19 patients, and EHS after LI-ESWT was 1 in 8, 2 in 10, 3 in 20 and 4 in 3 patients. Median MPCC was increased from 11.7 mm to 19.0 mm after LI-ESWT ($p < 0.001$). The multivariate analysis was done to determine the predictors of the sufficient erection for the penetration (EHS>3) after LI-ESWT. It revealed that the age and the baseline MPCC were the significant predictors for the recovery after LI-ESWT. The improvement of SRE was statistically significant in the patients younger than 65 years (figure). Conclusions: LI-ESWT is effective for Japanese ED patients. In this study, patients' age and baseline erectile function are the independent predictors for the effectiveness of LI-ESWT. We should thoroughly discuss with the older patients with severe ED before LI-ESWT.

36.

The efficacy and feasibility of low-intensity shock wave therapy for erectile dysfunction in Japanese patients.

Hisasue S.-I., Horie S.

Journal of Sexual Medicine. Conference: 14th Biennial Meeting of the Asia-Pacific Society for Sexual Medicine. Kanazawa Japan. Conference Start: 20130531. Conference End: 20130602. Conference Publication: (var.pagings). 10 (pp 208)

AN: 71095877

Low-intensity shock wave therapy (LI-ESWT) is a novel and promising modality for the patients with mild to moderate erectile dysfunction (ED). Vardi et al. reported that the pretreatment severity of ED influenced the efficacy of LI-ESWT. In this study, we assessed the efficacy and the predictors for the recovery after LI-ESWT in Japanese patients. This study included patients with ED whose history lasted more than 6 months, sexual health inventory for men (SHIM) score of 12 without PDE5 inhibitor, EHS grade 1 or 2, mean penile circumferential change (MPCC) by erectometer for sleep related erection (SRE) of 25mm. Patients were treated by a low energy shockwaves generator (ED1000, MEDISPEC, MD, USA). We examined the predictors for the functional recovery by multivariate analysis with logistic regression using parameters of age, body mass index, free testosterone level, baseline MPCC and concomitant 3 risk factors in smoking, hypertension, diabetes, or ischemic heart disease. Of 52 patients treated by LI-ESWT, we analyzed the 41 patients whose data were available at 4 weeks after treatment. Median age was 64 years (range; 37-83). Median duration of ED was 3 years (range; 0.5-18). SHIM after the treatment was significantly increased from 5 to 9 ($p < 0.001$, Wilcoxon signed-rank test). Baseline EHS was 1 in 22, and 2 in 19 patients, and EHS after LI-ESWT was 1 in 8, 2 in 10, 3 in 20 and 4 in 3 patients. Median MPCC was increased from 11.7 mm to 19.0 mm after LI-ESWT ($p < 0.001$). The multivariate analysis was done to determine the predictors of the sufficient erection for the penetration (EHS3) after LI-ESWT. It revealed that the age and the baseline MPCC were the significant predictors for the recovery after LI-ESWT. The improvement of SRE was statistically significant in the patients younger than 65 years (figure). LI-ESWT is effective for Japanese ED patients. In this study, patients' age and baseline erectile function are the independent predictors for the effectiveness of LI-ESWT. We should thoroughly discuss with the older patients with severe ED before LI-ESWT.