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Low Intensity Extracorporeal Shock Wave Therapy for Female Stress Urinary Incontinence: A Single-Blind, Randomized-Controlled Trial

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Disclosures

- Hikkonu, a member of DirexGroup- study funding and travel support
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- Springer- royalties

Background

Stress urinary incontinence (SUI)

SUI is a prevalent urogynecological problem worldwide, with an estimate as high as 40% in adult women

- *involuntary leakage of urine upon physical activity, such as exercise, exertion, sneezing, coughing, and lifting heavy objects, leading to affect a woman's physical, psychological and social activity, and impact on her quality of life*

Management modalities:

- Lifestyle intervention
- Pelvic floor muscle training
- Electro-stimulation
- Vaginal devices and urethral inserts
- Bulking agents
- Mid-urethral slings and colposuspension

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Background

Clinical LiESWT (2000 to 3000 pulses in 0.20–0.25 mJ/mm2)

- enhances wound healing,
- promotes angiogenesis
- reduces the level of oxidative stress
- induces the releasing of vascular endothelial growth factor (VEGF)
- stimulates proliferation and differentiation of stem cells, with the effect of tissue [illegible]eration.

Therapeutic effects of Low intensity extracorporeal low energy shock wave therapy (LiESWT) on stress urinary incontinence

Cheng-Yu Long[1,2,3,4,11], Kun-Ling Lin[1,4,11], Yung-Chin Lee[5,6,7], Shu-Mien Chuang[5,8], Jian-He Lu[5,7], Bin-Nan Wu[9], Kuang-Shun Chueh[5,10], Chin-Ru Ker[1], Mei-Chen Shen[5] & Yung-Shun Juan[3,5,7,10*]

- single-arm, open- label, multicentre study
- 50 female patients with SUI
- once weekly for 4-weeks (W4) and 8-weeks (W8).
- 8-week of LiESWT treatment meaningfully improved urine leakage (pad test), maximum ow rate, post-voided residual urine, average urine volume, functional bladder capacity, urinary frequency, urgency symptom, and nocturia

Article

Low Intensity Extracorporeal Shock Wave Therapy as a Novel Treatment for Stress Urinary Incontinence: A Randomized-Controlled Clinical Study

Kun-Ling Lin [1,2,3], Kuang-Shun Chueh [1,4,5], Jian-He Lu [6], Shu-Mien Chuang [4,7], Bin-Nan Wu [8], Yung-Chin Lee [4,7,9], Yi-Hsuan Wu [1,4,7], Mei-Chen Shen [4,7], Ting-Wei Sun [4,7], Cheng-Yu Long [2,9,10,*] and Yung-Shun Juan [1,4,5,7,*]

- multicenter, single-blind, RCT
- 60 female patients with SUI randomized to LiSWT vs sham
- once weekly for 4-weeks (W4) and 8-weeks (W8).

Eight weeks of LiESWT attenuated SUI symptoms upon physical activity, reduced urine leakage, and ameliorated overactive bladder symptoms,

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Objective

The objective of the study was to assess safety and efficacy of LiESWT using a novel ***trans-vaginal probe*** for SUI and sexual function (SF).

Methods

- Design: single-blind, randomized-controlled trial
- IRB approval, informed consent
- Women with SUI were randomly assigned to
  - LiESWT with 0.1 mJ/mm^2 intensity, 1600 pulses, twice weekly for 4 weeks
  - Sham treatment, without energy transmission.
  - Treatment:sham ratio- 2:1

Both were administered by a vaginal probe (MoreNova^{FEM}, Hikkonu Medical Systems Ltd, Ramat Hasharon, Israel), designed to deliver the pulses towards the peri-urethral tissue

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Methods

Efficacy at 1 month was evaluated using:

- Patient Global Impression of Improvement (PGI-I)
- Changes from baseline in scores of:
  - International Consultation on Incontinence, Short Form (ICI-Q-SF)
  - Urinary Distress Inventory (UDI-6)
  - Incontinence Impact Questionnaire (IIQ-7)
  - Cough-stress test
  - 1-hour pad test.
- SF was evaluated by the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR).

Results

Table 1- Background data

Variables	Sham (N=9)	Treatment (N=18)	P Value
Age (Y)	46.4±9.8	50.1±8.6	0.3404
BMI	27.3±4.4	25.1±3.7	0.1729
Diabetes	0	2 (11.1)	0.1729
Hypertension	2 (22.2)	2 (11.1)	0.5815
Smoking	0	1 (5.6)	1.0000
Parity	3.0 (2.0–3.0)	3.0 (2.0–3.0)	0.8066
Post-menopausal	4 (44.4)	7 (38.9)	1.0000
HRT	0	1 (5.6)	1.0000
Vaginal Estrogen	0	2 (11.1)	0.5385

Results

Table 2- Urogynecological data in the treatment and sham group before treatment

Variables	Sham (N=9)	Treatment (N=18)	P Value
Urinary incontinence			0.2950
Stress UI	6 (66.7)	16 (88.9)	
Mixed UI	3 (33.3)	2 (11.1)	
Positive cough-stress test	6 (66.7)	13 (81.3)	0.6300
One-hour pad test (Gr)	2.9±6.5	2.4±3.0	0.2642
ICI-Q	10.1±4.7	11.9±3.4	0.4690
UDI-6	39.4±15.2	37.4±14.7	0.8970
IIQ-7	13.7±13.9	28.7±23.4	0.0532
PISQ-IR	3.5±0.3	3.5±0.5	0.4809

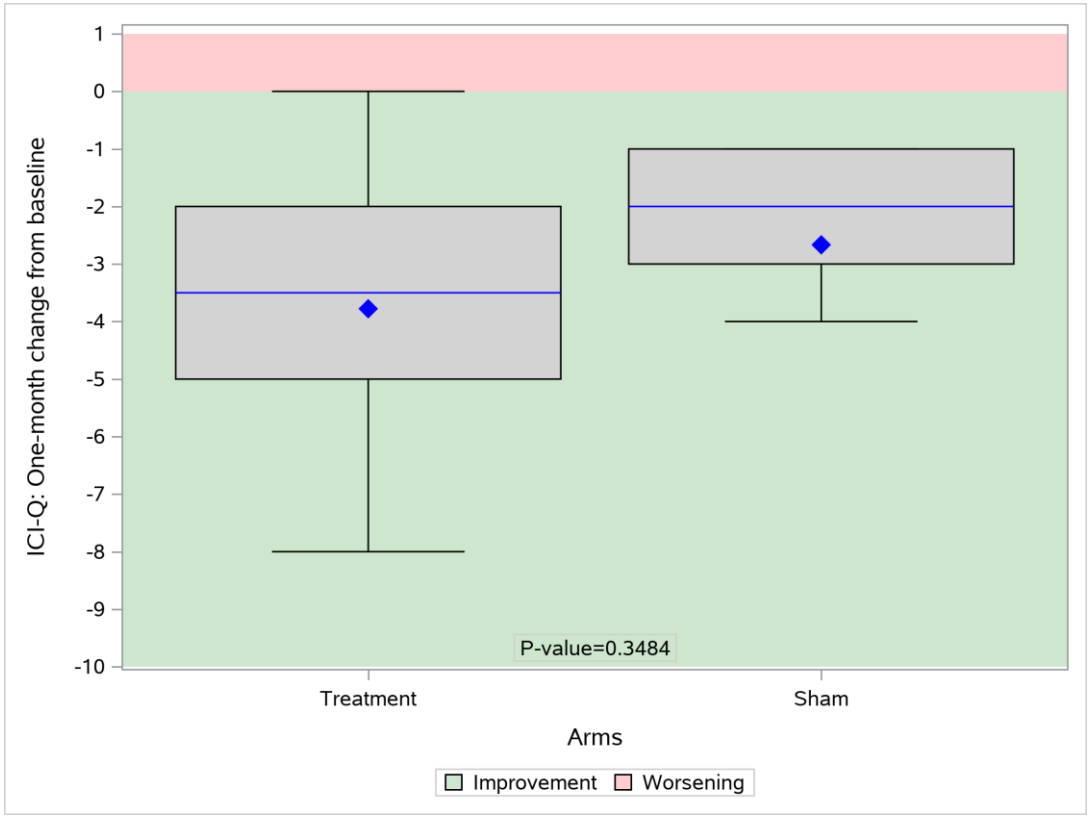
Results

Table 1. Change in urinary incontinence and sexual function at 1-month follow-up between the 2 arms

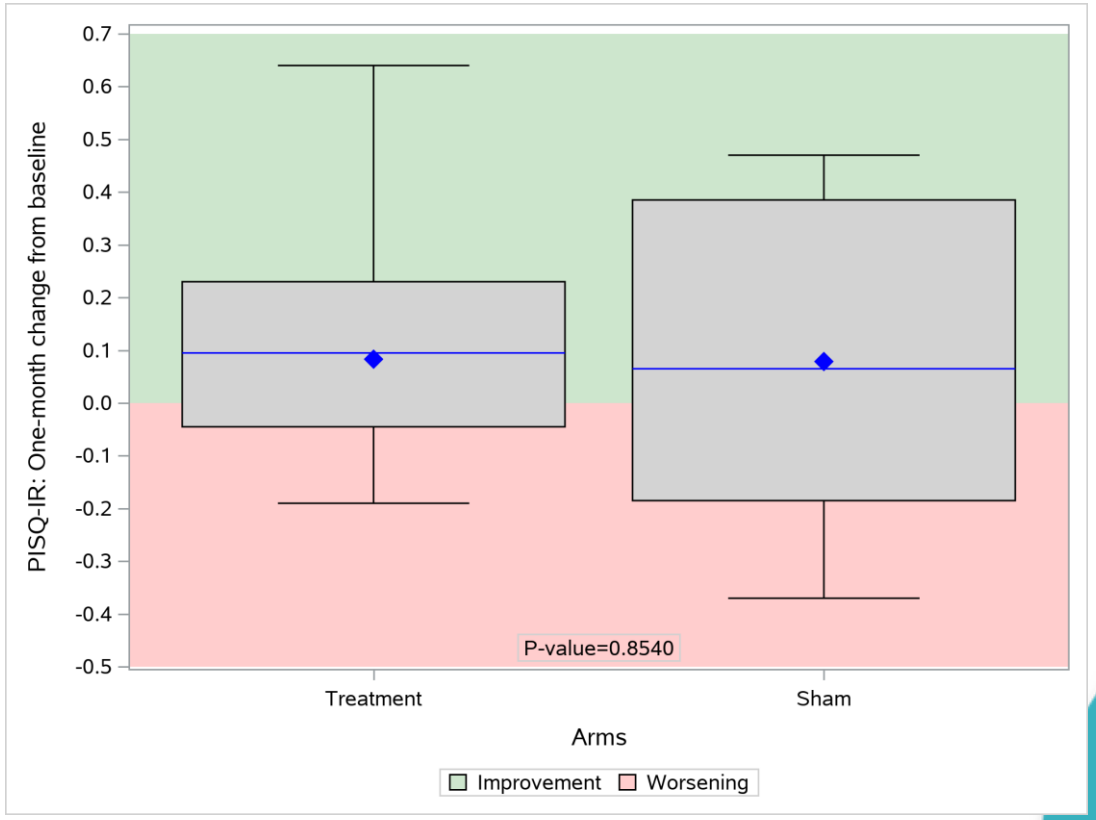
Variables	Sham (N=9)	Treatment (N=18)	P Value
Change in cough-stress test			
Positive pre-Tx, negative at 1 month	3 (33.3)	5 (33.3)	1.0000
Change in one-hour pad test (Gr)	-1.4±4.4	-0.3±3.4	0.8505
Change in ICI-Q	-2.7±1.9	-3.8±3.0	0.3484
Change in UDI-6	-11.9±15.6	-11.2±14.3	0.9794
Change in IIQ-7	-1.0±7.3	-15.9±25.8	**0.0239**
Change in PISQ-IR	0.1±0.3	0.1±0.3	0.8540
VAS for pain level (0-10)	0.1±0.3	0.6±1.0	0.2146

Results

ICI-Q at 1 month



PISQ-IR at 1 month



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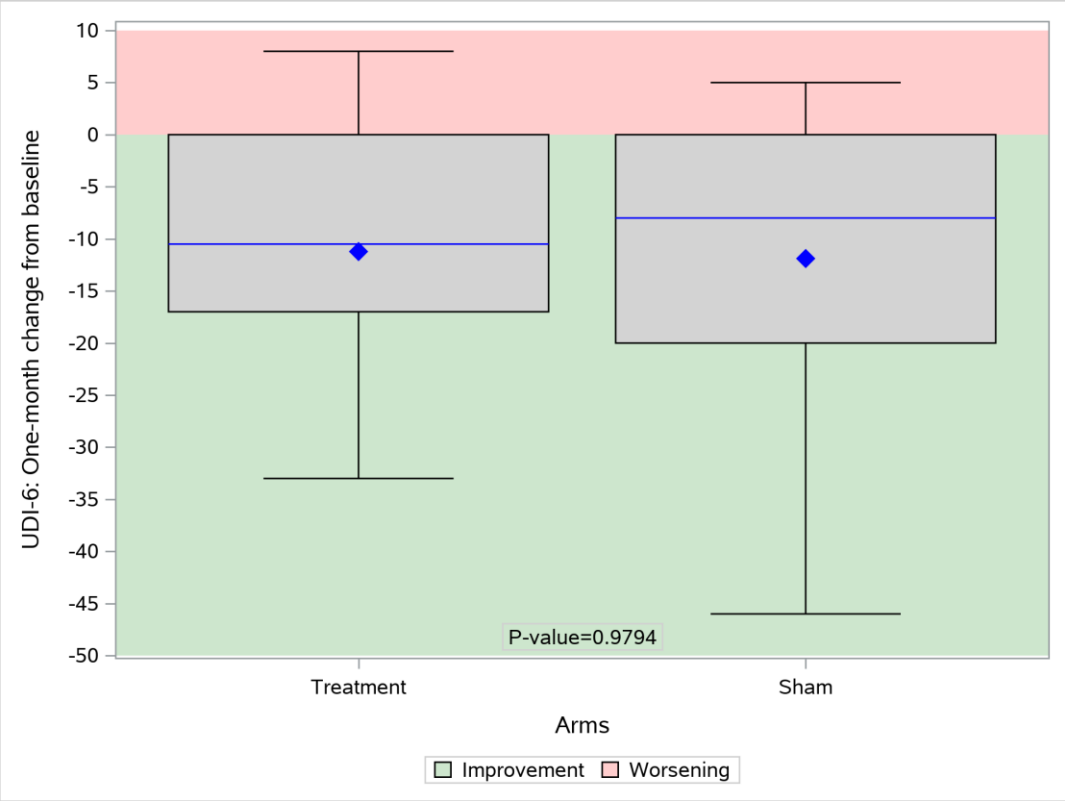
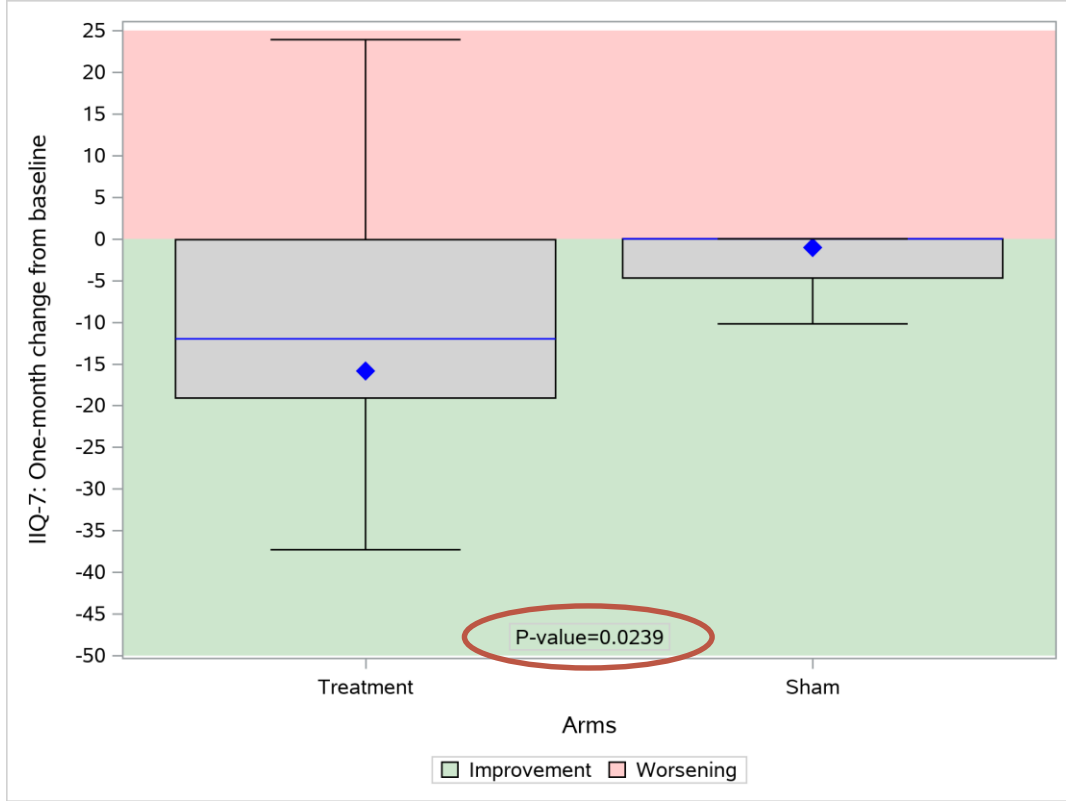
Results

UDI-6 at 1 month



IIQ-7 at 1 month



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Results

Possible procedure-related adverse events were mild and patients fully recovered:

- spotting (2 women, study group)
- UTI (1- study group, 1- sham)
- bacterial vaginosis (1- study group).

Conclusion

- LiESWT for SUI by a vaginal probe is well-tolerated and safe.
- Upon short-term follow-up, we observed significantly greater improvement in the impact of urinary incontinence in the study group, indicating LiESWT is a promising, energy-based alternative for SUI.


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