

FIGURE 1

Table. 1 Comparison of baseline characteristics between intervention group and control group.

Variable	IG (n#%)	CG (n#%)	p-value
Age (y/o), mean (SD)	64.58 (9.32)	62.78 (8.87)	0.681 *
Height (m), mean (SD)	1.58 (0.06)	1.57 (0.07)	0.849 *
Weight (kg), mean (SD)	63.33 (13.50)	63.78 (13.57)	0.945 *
BMI (kg/m ²), mean (SD)	25.64 (6.12)	25.90 (5.25)	0.925 *
Waist circumference (cm), mean (SD)	92.05 (14.27)	95.67 (12.97)	0.582 *
Parity, mean (SD)	1.89 (1.45)	1.89 (1.27)	1.000 *
Vaginal delivery	1.56 (1.51)	1.67 (1.41)	0.874 *
Cesarean section	0.33 (1.00)	0.22 (0.67)	0.785 *
Marital, n (%)			0.471 *
Single	0 (0%)	2 (22%)	
Married	7 (78%)	7 (78%)	
Divorced/separated	1 (11%)	0 (0%)	
Widowed	1 (11%)	0 (0%)	
Living, n (%)			0.282 *
Living with spouse	4 (44%)	3 (33%)	
Living with children	3 (33%)	4 (44%)	
Living alone	0 (0%)	2 (22%)	
Others	2 (22%)	0 (0%)	
Education, n (%)			1.000 *
Bachelor degree or above	4 (44%)	4 (44%)	
Junior college	1 (11%)	0 (0%)	
Senior/vocational high school	2 (22%)	2 (22%)	
Primary school or below	2 (22%)	3 (33%)	
Employment, n (%)			0.430 *
Full time	4 (44%)	4 (44%)	
Part time	3 (33%)	1 (11%)	
No	2 (22%)	4 (44%)	
Smoking, n (%)			1.000 *
Current smoker	0 (0%)	0 (0%)	
Ex-smoker	0 (0%)	1 (11%)	
Never smoker	9 (100%)	8 (89%)	
Drinking, n (%)			1.000 *
Usually (>once/week)	1 (11%)	0 (0%)	
Often (1-5 times/month)	0 (0%)	0 (0%)	
Seldom (1-5 times/half year)	4 (44%)	5 (56%)	
Never	4 (44%)	4 (44%)	

* tested by Independent t test

† tested by Chi-square test

N: number; %: percentages; SD: standard deviation; IG: Intervention group; CG: control group; y/o: years old; m: meter; kg: kilogram; kg/m²: kilogram per meter square; cm: centimeter.

Table. 1 Comparison of baseline characteristics between intervention group and control group.

FIGURE 2

Table.2 Comparison of outcomes between baseline and post-intervention in the intervention group and control group.

Variables	IG (n#%)		Mean difference (95%CI)	Intragroup p-value [†]	CG (n#%)		Mean difference (95%CI)	Intragroup p-value [†]	Intergroup p-value [‡]
	Pre-intervention mean (SD)	Post-intervention mean (SD)			Pre-intervention mean (SD)	Post-intervention mean (SD)			
Signal indicator*	Strength	2.50 (1.07)	3.39 (0.93)	0.89 (0.16, 1.57)	0.02*	3.52 (1.25)	3.02 (1.30)	-0.50 (-0.27, 1.27)	0.170
	Holding length (sec)	14.90 (14.77)	28.75 (13.88)	14.25 (0.55, 27.95)	0.003*	5.38 (2.72)	11.38 (14.23)	6.00 (-3.68, 15.68)	0.140
	Number of MVC	5.50 (6.21)	22.00 (16.75)	16.5 (3.95, 29.41)	0.000*	9.58 (9.44)	10.00 (9.90)	0.42 (-1.76, 9.90)	0.920*
Measometry*	Strength	9.36 (7.90)	11.80 (8.04)	2.43 (-1.25, 6.19)	0.153	10.81 (12.28)	10.45 (15.07)	-0.36 (-4.26, 3.17)	0.730
	Endurance	17.31 (25.57)	10.68 (14.40)	-6.63 (-26.30, 15.25)	0.315	2.88 (1.53)	4.02 (2.21)	1.15 (-1.05, 4.30)	0.313
	ICIQ	7.89 (5.21)	5.00 (3.06)	-2.89 (-4.87, -0.91)	0.000*	9.88 (4.20)	8.44 (4.50)	-1.44 (-3.55, 0.66)	0.153
ICIQ	32.00 (19.70)	27.22 (8.00)	-4.78 (-10.84, 1.30)	0.087	35.80 (7.33)	31.22 (9.30)	-4.58 (-7.37, 0.30)	0.484	

* t-test

† tested by paired-t test

‡ tested by repeated-measure analysis of variance test

§ p-value<0.05

IG: Intervention group; CG: control group; SD: standard deviation; 95%CI: 95 percent confidence interval; sec: second; MVC: maximal voluntary contraction; cmH₂O: centimeter of water; ICIQ: ICIQ-8/BP: International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form; ICIQ-LUTSqol: International Consultation on Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life Module.

Table.2 Comparison of outcomes between baseline and post-intervention in the intervention group and control group.

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RADIOFREQUENCY AND SHOCK WAVES IN PEYRONIE'S DISEASE: SYSTEMATIC REVIEW AND PRELIMINARY RESULTS OF A PILOT STUDY

Lenzi J¹, Mamede C¹, Almeida R¹, Araújo E¹, Lemos A¹, Brasil C¹, Jorge D¹, Sodr e D¹, Quiberville A¹, Sodr e P¹, Gomes T¹, Cerqueira M¹, Cantharino C¹, Marianno A¹, Teles A¹, Balthazar C¹, Araujo R¹, Canario A¹, Pereira I¹, Santos J¹, Oliveira M¹, Rezende L², Freire P¹, Lord elo P¹

1. *Patricia Lord elo's Institute (IPL) - Pelvic Floor Care Center (CAAP) - Bahiana School of Medicine and Public Health, 2. UNIFAE*

HYPOTHESIS / AIMS OF STUDY

Peyronie's disease (PD) is characterized by the presence of fibrotic plaques in the tunica albuginea, compromising the penis size with effects on sexual function like pain and the penetration incapacity. The most effective treatment so far is the plaque removal through a surgical procedure, however post-surgical impotency rate ranges from 60 to 80%. The searches for non-surgical treatment procedures with low cost and risk are constant. Shock Waves (SW) is an acoustic wave which carries high energy and low frequency, but its effectiveness on PD treatment is still controversial. Radiofrequency (RF) is a diathermy technique with action on the collagen and elastin molecules, relieving the tissue. Therefore, since the publication of a systematic review, there is the hypothesis of the association of both techniques.

Aim of the study: Verify the results of the Shockwaves usage on PD treatment through a systematic review and describe the effect of Shockwaves Plus Radiofrequency (SW + RF) on patients with Peyronie's disease.

STUDY DESIGN, MATERIALS AND METHODS

We conducted a systematic review according to Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA)¹. The search was carried out in electronic databases: PubMed and EMBASE and it used both Medical Subject Headings (MeSH), as well as Boolean operators "AND" and "OR". The keywords were: Peyronie's Disease; Shockwave Therapy; Erectile Dysfunction. The inclusion criteria were studies published until December 2020, that evaluated the outcome of curvature of the penis.

The search was carried out by two authors independently and after selecting the inclusion criteria, the findings were

compared. When there was a discrepancy, a third appraiser was consulted, and this was resolved by consensus.

The pilot study was conducted with 10 patients with PD symptoms that were forwarded to a reference center in Salvador-BA. The diagnosis was confirmed by a radiologist that performed ultrasonographic images of the plaque after the erection induction through the application of 0,5 ml of Qa-udrimix R9 of FLUKKA PHARMA, containing prostaglandin, papaverine, phentolamine and atropine. The USG exam was responsible for the penis study, through the ventral face scan, evaluated in the transversal and in the longitudinal, from the glans to the base of the penis, searching for hyper-echoic focal thickening of the tunica albuginea and evaluating its dimensions. Still with the erection induction, it was performed a photographic documentation to measure the penis angulation with the patient in orthostasis. It was investigated the capacity of penetration and classified in: 1 = absent, 2 = present and painful, 3 = present and not painful.

The RF + SW technique was performed by physiotherapists using IBRAMED's devices like Thork model (SW) and Nartek model (RF) having the respective parameters: 120 mj, 10 Hz and 2000 pulses, with 15 mm stainless steels radial electrode and 38°C (100,4°F), monopolar and with 20 mm resistive electrode. Before it was performed, the plaque was palpated to identify the application spot.

At the end of the treatment, the evaluation protocol was repeated, and the patient was questioned about the treatment satisfaction on a scale of 0 to 10. The higher the number the greater the satisfaction.

RESULTS

We founded 205 articles. After the analysis 13 publications were included in this review.

Hauck et al. showed the average plaque size in the ESWT group increased after treatment but decreased in the control group. This result corroborates with Hatzichristodoulou et al. who demonstrated assigned 102 men with stable Peyronie's disease for at least 3 months to 6 ESWT sessions with 2,000 shockwave shots per session. Palmieri et al showed that, with the four weekly treatment sections, the average plaque size and average degree of curvature remained unchanged in the ESWT group. In a report of 25 cases, Claro et al showed an improvement in curvature. However, there was no comparison with the control group and ESWT was associated with another therapy.

So far, there have been five patients with an average age of 56,3 years with Peyronie's disease diagnosed for at least one year. The results of the measurement plaque in the ultrasound, angulation through photography, satisfaction and penetration capacity are on table 1. No adverse effects were reported by the five participants.

INTERPRETATION OF RESULTS

ESWT is a non-invasive therapy, safe to apply in clinical practice and has been used in different disorders in urology. We conducted an extensive literature search and the compiled data of 654 patients on the use of ESWT in relation to Peyronie's disease demonstrates that there is no clear biological theory for the effects of OCD and does not point to benefits in relation to curvature.

For these reasons, it seems reasonable to test the application associated to another technique. There was a reduction in the plaque length measures and in the angulation through the photographic documentation. However, it is important to say that the plaque thickness and/or the histological tissue evaluation better represent the changes through the treatment of SW + RF.

The satisfaction with the treatment was related to the penetration capacity, but as the satisfaction was not maximum, it is supposed that the penis apparency influence aesthetics, decreasing satisfaction.

Besides, another hypothesis is related to the technique parameters, like application frequency and number of sections. In this systematic review was not found the pattern of these variables.

CONCLUDING MESSAGE

The results of our systematic review revealed that the ESWT doesn't seem to be an effective choice for PD patients when related to the curvature outcome. That said, more high-quality studies are necessary to overcome the limitations of the current data. For now, in the pilot study, there were no reports of adverse effects. Besides, there was a change in all patient satisfaction, in the USG measure, in the angulation measure and in the penetration capacity, in the majority the SW+RF appears to be a promising therapeutic option for PD, requiring more randomize clinical trials.