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Initial clinical experience of Linear Focused, Low Intensity Shockwave for treatment of ED patients with different severity symptoms.

Cruz-Navarro, Natalio 1 Martin-Morales Antonio2

1: ANDROMEDI Sevilla (Spain) 2: Instituto Urología Málaga (Spain)

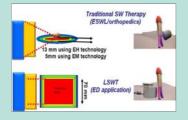
Introduction

Low Intensity Shockwaves (LISW) are known to produce revascularization and have been used to treat Erectile Dysfunction.

LISW use very low energy (0.09 mJ/mm2), equivalent to 10% of the energy used by conventional kidney stone lithotripters in the treatment of urinary tract stones.

The present study uses a specific device ('Renova') that uses a Line Focused Shockwave, differing from previous models in that it achieves substantially superior organ coverage. The Renova is a device that generates a low intensity shockwave focused along a line of 60 mm and hence is able to apply shockwaves to the Corpuses and Crura effectively.

Low-intensity shock wave therapy to the penis and crura may help men with mild to severe erectile dysfunction (ED), both for patients that are responsive and unresponsive to conventional Phosphodiesterase type 5 inhibitor treatment (PDE5-i).



Δim

The aim of this clinical experience was to assess the feasibility of the application of Linear-Focused Low Intensity Shockwaves (Renova Direx Group) as an alternative or complementary treatment for Vascular ED patients with different degrees of symptom severity.

Method

The treatment was offered in a routine natural way in 2 medical centers: 46 patients in Malaga (Serie A), and 35 in Seville (Serie B). The treatment is composed of 4 weekly sessions (20 minutes each), in which shockwaves were applied, into 4 areas; right and left crura, and right and left corpus cavernosum, with 900 shockwaves in each site (Total 14400). No need for anesthesia, sedation or painkillers. The evaluation was done using the IIEF-EF, SEP and GAQ at baseline visit and 1and 3 months post treatment...

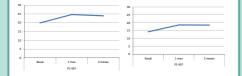


Results

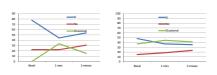
1 mm 21,54 04,99% 65,31%	80 60 -
1 mms 21,54 04,98% 65,31%	
	20 -
Summ 21,22 69,39% 64,32%	Baseline 1 3

Average IIEF-EF increased significantly from 19.94 and 14,03 at baseline to 23.92 and 18.53 at 3 months post treatment.

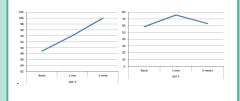
SE	RIE (IIEF)	BASELINE	1 MONTH	3 MONTHS
Α	(Malaga)	19,95	24,67	23,92
В	(Sevilla)	14,03	18,62	18,53



A number of patients stopped using PDE-i: 30,77 % and 23,53 % respectively.

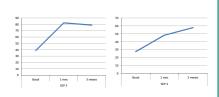


SEP 2 increased from 88,89 % and 43,48% to 100% and 66,67%.



Results

SEP 3 increased from 38,89 % and 27,59 % to 78,75% and 57,89%.



Use of PDE5-I for sexual intercourse was reduced from 77,78 % and 85,19 % to 53,85 and 35,29 % at 3 months post-treatment.

No side effects were recorded.

Discussion

In previous publications, Vardi et al. (1) showed an overall increase of 7.4 points in IIEF-EF score (13.5-20.9, p = 0.001) in patients with mild to moderate ED. Gruenwald et al., in 2012, analysed the results in a group of 29 patients with more severe ED (IIEF 8.8), non-responders to PDE5-i and with multiple cardiovascular risk factors (2). At 3 months of treatment the mean IIEF-EF score rose from 10 points to 18.8 \pm 1, p <0.0001. Vardi et al. in 2012, published the results of a prospective, randomized, double-blind, placebo-controlled study in a group of 60 patients with DE (3) with similar results.

Comparing our results with published data, we emphasize that this is a group of unselected patients, since the study was performed to check whether the L-LSWT can be considered a real therapeutic alternative in patients with ED.

Conclusion

The results of both series at 3 months show a consistent and global improvement in IIEF-EF, SEP 2 and SEP 3 parameters.

The outcome of the treatment is related to the baseline symptoms severity, meaning that on average, patients with more severe ED symptoms will improve, but will not reach the final level of improvement that can be obtained in mild to moderate patients.

In our experience Linear-Focused Low Intensity Shockwave treatment is a valid alternative or complement to current available treatments.

References

- 1.- European Urology 58 (2010) 243-248.
- 2.- J Sex Med 2012;9:259-264.
- 3.- J Urol. 2012 May;187(5):1769-75.