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Anxiety and depression in patients with erectile dysfunction undergoing Radiofrequency and Shockwave Therapy: preliminary results.

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HYPOTHESIS / AIMS OF STUDY

Erectile dysfunction (ED) can be caused by biological and/or psychogenic factors.[1] Regardless of the cause, it can lead to psychological and emotional distress in the male population, which also results in a decrease in libido and difficulty in discussing this issue with their partner.[1] According to studies, men with ED have symptoms of anxiety and depression which have a direct impact on performance and denial of sexual intercourse.[1] In this context, Radiofrequency (RF) and Shockwave Therapy (SWT) can have an impact on the development of anxiety and depression when erectile dysfunction is improved. [2,3] This study aimed to analyze the repercussions of RF and SWT on ED and on patients' anxiety and depression.

STUDY DESIGN, MATERIALS AND METHODS

This is a randomized clinical trial, started in July 2022, with men aged between 30 and 80 who complained about difficulty in getting or maintaining an erection. Patients were divided into 3 groups: Non-Ablative Radiofrequency (NARF), Shockwave Therapy (SWT) and Combined Therapy (CT). Four scales and questionnaires were used to measure the study's outcomes. The SF-36 (36-Item Short Form Health Survey) questionnaire compared current and the last one-year health status to assess patients' quality of life. The Hospital Anxiety and Depression Scale (HADS) – divided in two subscales for anxiety (HADS A) and depression (HADS D) - was used to assess the main study outcome. Scores ≤7 classify no anxiety and/or no depression, scores of 8-10 classify doubtful cases and scores ≥11 classify definite cases of anxiety and/or depression. The International Index of Erectile Function (IIEF) was used to measure erectile function and treatment's efficacy: 1–7 indicating severe ED, 8–11 moderate ED, 12–16 mild–moderate ED, 17–21 mild ED and 22–25 no erectile dysfunction ED. The Erection Quality Questionnaire (EQQ) assessed erection hardness. A physical assessment was carried out for genital inspection. After the assessment, patients were randomized into one of the three groups and they underwent 12 treatment sessions, once a week. At the end of the treatment, blinded researchers performed the reassessment and analyzed the results. According to the sample size calculation, each group should have 20 patients.

RESULTS AND INTERPRETATION

The preliminary results totalize 23 men: nine on the NARF group, six on the SWT group and eight on the CT group. The mean age of the men from NARF was 61,1±15,8, from the SWT was 71±5,6, and from CT was 60,3±5,8 years old; the main cause of ED was prostatectomy: 66,7% in the NARF group, 83,3% in the SWT group and 100% in the CT group. The three groups were homogeneous on the initial assessment. According to IIEF, patients from NARF and CT had moderate ED (median of 9 and 10 points, respectively) and the SWT group had mild–moderate ED (median of 14). At the end of the treatment, NARF and CT group remained with moderate ED (median of 9 and 11.5) and SWT became also moderate ED (median of 11). No statistical difference was detected in the intra- nor inter-group analysis. According to the HADS A, all the three groups were classified as not having anxiety (median score of NARF 6, SWT 5 and CT 4) nor depression (median score of NARF 5, SWT 7 and CT 5.5). After the treatment, NARF group was classified as having doubtful cases of anxiety with median of 10 points on the scale. No statistical difference was detected in the intra- nor inter-group analysis. According to the EQQ, before the treatment NARF group scored median of 21, SWT scored 48 and CT scored 44. After the treatment, all the groups increased the scores, but no statistical difference was detected, neither intra- nor inter-group. According to the SF-36, before the treatment NARF group scored a mean of 109.7, SWT 110.7 and CT 120.7. After the treatment, NARF and SWT groups had an improvement on the scores (mean of 111.8 and 119.9 respectively) and CT group had a reduction (mean of 115.2). No statistical difference was detected in the intra- nor inter-group analysis. All the results of the scores and questionnaires are in Table 1.

Table 1: Intra- and inter-group comparisons of erection dysfunction, anxiety, depression, and quality of life of the patients.

Variables	NARF (n=9)		SWT (n=6)		CT (n=8)		Intergroup p-value
	Baseline	Final	Baseline	Final	Baseline	Final	
IIEF M(IQR)	9(5-11)	9 (6-16.5)	14 (8-19.5)	11 (8-16.5)	10 (7.3-15.5)	11.5 (6.5-14)	0.585**
p-value	0.293*		0.916*		0.610*		
HADS A M(IQR)	6 (2-12)	10 (3-13.5)	5 (3-7.75)	4 (2.75- 4)	4 (3.3-6.3)	4 (3.3-5)	0.366**
p-value	0.310*		0.216*		0.916*		
HADS D M(IQR)	5 (2.5-8)	5 (4-13.5)	7 (4-10.5)	3.5 (1.8-8.5)	5.5 (1.5-7.0)	3 (2 -4.75)	0.460**
p-value	0.213*		0.340*		0.325*		
EQQ M(IQR)	21 (8-44)	29 (2-48)	48 (9-64)	52 (21-69)	44 (22-72)	46 (18-58)	0.565**
p-value	0.362*		0.466*		0.610*		
SF-36 m±SD	109.7 ±19.2	111.8 ±24.5	110,7 ±17,1	119.9 ±15.5	120.7 ±22.3	115.2 ±25.7	0.368**
p-value	0.671***		0.512***		0.111***		

IIEF: International Index of Erectile Function; HADS A: Hospital Anxiety and Depression Scale Anxiety; HADS D: Hospital Anxiety and Depression Scale Depression; EQQ: Erectile Quality Questionnaire; SF-36: 36-Item Short Form Health Survey; M: median; IQR: Interquartile Range; m: mean; SD: standard deviation; *Wilcoxon test; **Anova test; ***Pairwise t-test.

The patients from the study weren't classified as having anxiety nor depression, according to the HADS, neither at the beginning nor at the end of the treatment. Regarding depression, the median score of the groups after the treatment stayed the same or became lower, which is a positive result. Regarding the anxiety, NARF was the only group that increased the score, changing from not having anxiety to doubtful case, which is a negative result. The NARF group also had the highest score for anxiety at the beginning of the study, the lowest score for erectile function for both the IIEF and EQQ (showing worse ED) and lowest quality of life according to the SF-36. This fact could be explained because the anxiety can negatively influence the erectile function, as the ED can generate anxiety on the patient. That happens because noradrenaline (liberated with the anxiety feeling) leads to the contraction of the cavernous artery which impacts negatively on the quality of the penile erection.[1] The only questionnaire that changed positively in all the groups was the EQQ, showing a possible positive result on the rigidity of the erection. But it is necessary to emphasize that the IIEF is the most used questionnaire to assess ED and it presents a broader approach than EQQ. For now, EQQ should be used as an additional questionnaire to assess erectile function, so this result should be carefully interpreted. It is believed that SWT generates microlesions in the tissue that stimulate a series of reactions that result in the release of angiogenic factors such as the synthesis of endothelial nitric oxide, endothelial growth factor and proliferation of nuclear cell antigen. And in relation to NARF, it is believed that the deep heating generated in the tissue, the remodeling of collagen fibers and the stimulation of fibroblasts to produce new collagen and elastin fibers would have the potential to improve penile erection.It is important to emphasize that there were no statistical differences in neither the intergroup nor intragroup analysis, which may have occurred due to the small sample size of the study, which has not yet reached even half of what was predicted in the sample size calculation.

CONCLUSIONS

The study showed no statistical difference in neither the inter- nor the intra-group analyses for any of the outcomes assessed: anxiety, depression, erectile dysfunction, and quality of life. No median score classified the patients of the groups as having anxiety nor depression, after the treatment patients reached even lower scores for almost all the groups. There is a tendency of improvement of the quality of erection with a simpler questionnaire as EQQ. It is necessary to continue the study to reach the predicted simple size to have a final analysis.

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