

# 415 – ULTRASOUND ASSESSMENT IN WOMEN WITH VAGINAL LAXITY TREATED BY PELVIC FLOOR MUSCLE TRAINING OR RADIOFREQUENCY: A SECONDARY ANALYSIS OF A RANDOMIZED CLINICAL TRIAL



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## Hypothesis / aims of study

Vaginal laxity (VL) has gained visibility in the last decade with the advent of energy-based therapies and it is defined as a complaint of excessive vaginal flaccidity, with a prevalence that varies between 24-38%.

**Aim of study:** To compare the vaginal wall thickness (VWT) measurement by two-dimensional ultrasound (2D-US) and pelvic floor muscle morphometry by four-dimensional translabial ultrasound (4D-TLUS) in women with vaginal laxity (VL) who underwent treatment with radiofrequency (RF) or pelvic floor muscle training (PFMT) after 30 days and six months.

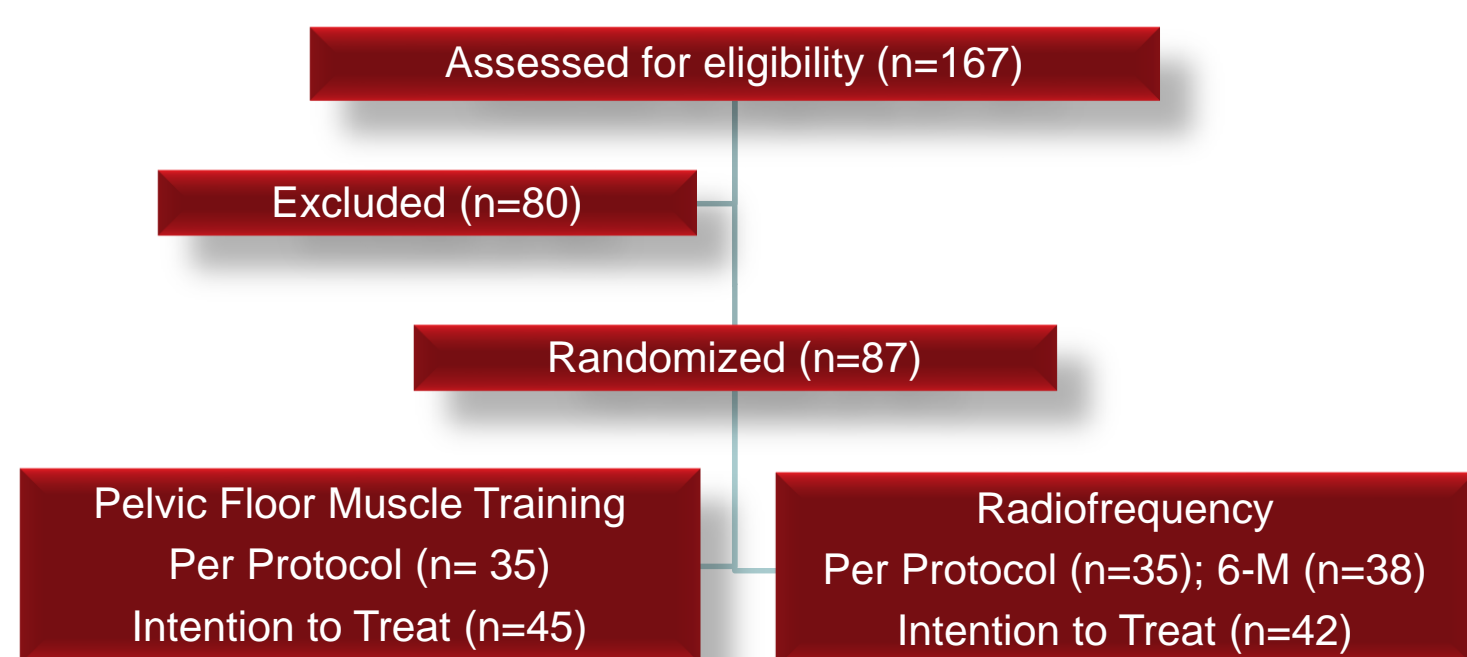
## Study design, materials and methods

A secondary analysis of a randomized clinical trial that occurred between February 2020 and December 2021 was performed. Women with VL were enrolled and treated with RF or PFMT for 12 weeks. Ultrasound examiners were blinded for the groups. Transabdominal (TAUS) and transvaginal (TVUS) ultrasound were performed with 2D-US analysis. The 4D-TLUS was used for PFM morphometry assessment. We performed per-protocol and intention-to-treat analysis (5% significance).

## Results

One hundred and sixty-seven women were recruited. Of these, 87 were randomized into two groups (PFMT n=45 vs Radiofrequency n=42) (Figure 1).

Figure 1 – Flowchart of the Randomized Studies



Women with ballooning presented significantly worse scoring in sexual function (p=0.037) and vaginal symptoms (p=0.007) than women without ballooning. The correlation between baseline questionnaire scores and ultrasound measurements are displayed in Tables 1, 2 and 3. Figure 2 shows the assessment of levator hiatus.

Table 1 - Correlation between baseline questionnaire scores and measurements of the vaginal wall thickness by transabdominal ultrasound (n=87).

Questionnaire Scores	TAUS Proximal		TAUS Middle-third		TAUS Distal	
	r	p-value	r	p-value	r	p-value
VLQ	0.227	0.034	0.194	0.071	0.188	0.081
FSFI Total Score	-0.125	0.247	-0.100	0.354	-0.022	0.835
ICIQ-VS						
Vaginal Symptoms	0.119	0.268	0.136	0.206	0.007	0.945
Sexual Matters	-0.064	0.554	-0.024	0.818	-0.056	0.601
QoL	-0.113	0.294	0.044	0.681	-0.107	0.320
Question 4	-0.016	0.878	0.016	0.882	-0.120	0.264
FSDS-R	0.011	0.914	0.086	0.424	-0.059	0.584
ICIQ-SF	-0.087	0.422	0.054	0.614	-0.064	0.550

Table 2 - Correlation between baseline questionnaire scores and measurements of the vaginal wall thickness by transvaginal ultrasound (n=87).

Questionnaire Scores	TVUS Proximal		TVUS Middle-third		TVUS Distal	
	r	p-value	r	p-value	r	p-value
VLQ	0.239	0.025	0.057	0.598	0.113	0.293
FSFI Total Score	0.120	0.268	0.170	0.113	0.222	0.038
ICIQ-VS						
Vaginal Symptoms	-0.154	0.153	-0.063	0.556	-0.165	0.124
Sexual Matters	-0.200	0.062	-0.059	0.583	-0.022	0.839
QoL	-0.156	0.148	-0.226	0.035	-0.160	0.137
Question 4	-0.295	0.005	-0.076	0.479	-0.179	0.095
FSDS-R	-0.189	0.079	-0.152	0.158	-0.161	0.134
ICIQ-SF	-0.125	0.248	-0.113	0.295	-0.102	0.346

TAUS: Transabdominal Ultrasound; TVUS: Transvaginal Ultrasound; VLQ: Vaginal Laxity Questionnaire; FSFI: Female Sexual Function Index; QoL: Quality of Life; FSDS-R: Female Sexual Distress Scale – Revised; ICIQ-VS: International Consultation on Incontinence Questionnaire – Short Form; ICIQ-SF: International Consultation on Incontinence Questionnaire – Vaginal Symptoms; r = Spearman correlation coefficient; Dancy & Reidy interpretation (0.1-0.39: Weak; 0.4-0.69: Moderate; 0.7-0.9: Strong);

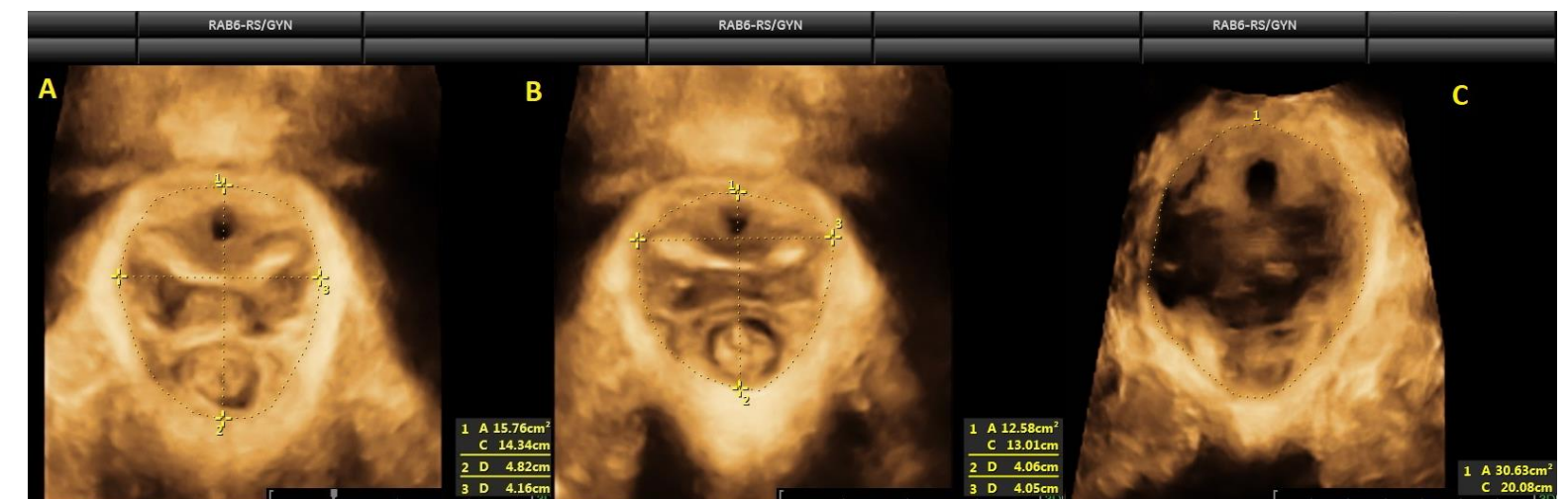
Analysis of variance among 2D-US, intervention groups and assessment periods has shown that measurements of the TAUS proximal vagina increased in the PFMT group after 6 months (from 9.90 ± 3.14 mm to 10.53 ± 2.71 mm; p=0.006). TAUS/TVUS distal vagina measurements were reduced after 6 months of RF (TAUS from 11.79 ± 3.67 mm to 10.51 ± 2.51 mm; p=0.018/TVUS from 7.94 ± 1.83 mm to 7.32 ± 2.10 mm; p=0.037). On the other hand, 4D-TLUS measurements did not present differences according to the intervention and/or groups.

Table 3 - Correlation between baseline questionnaire scores/POP-Q and measurements of the 4D translabial ultrasound (n=87)

Variables	Hiatal Area Narrowing		Puborectalis Retraction		A-P Diameter Difference		R-L Diameter Difference	
	r	p-value	r	p-value	r	p-value	r	p-value
VLQ	0.135	0.286	-0.159	0.206	0.280	0.025	0.066	0.599
FSFI Total Score	-0.077	0.540	0.081	0.948	0.129	0.307	-0.293	0.018
ICIQ-VS								
Vaginal Symptoms	0.085	0.503	0.172	0.171	-0.295	0.017	0.062	0.960
Sexual Matters	-0.036	0.775	-0.048	0.704	-0.183	0.145	0.063	0.620
QoL	0.079	0.530	-0.059	0.642	-0.055	0.663	0.144	0.255
Question 4	0.090	0.943	0.023	0.853	-0.244	0.051	0.051	0.687
FSDS-R	0.130	0.302	-0.112	0.377	-0.029	0.819	0.245	0.050
ICIQ-SF	-0.014	0.909	0.103	0.417	-0.145	0.249	0.051	0.684

4D: four-dimensional; A-P: Anterior-Posterior; R-L: Right-Left; VLQ: Vaginal Laxity Questionnaire; FSFI: Female Sexual Function Index; QoL: Quality of Life; FSDS-R: Female Sexual Distress Scale – Revised; ICIQ-VS: International Consultation on Incontinence Questionnaire – Short Form; ICIQ-SF: International Consultation on Incontinence Questionnaire – Vaginal Symptoms; r = Spearman correlation coefficient; Dancy & Reidy interpretation (0.1-0.39: Weak; 0.4-0.69: Moderate; 0.7-0.9: Strong);

Figure 2 – Levator hiatus dimensions at rest, during voluntary contraction and hiatal ballooning in a participant with vaginal laxity.



Levator hiatus dimensions at rest (A) and during voluntary contraction (B) in a participant with vaginal laxity. Hiatal ballooning (C) on Valsalva maneuver in another participant with vaginal laxity (axial plane).

## Interpretation

- To our knowledge, this is the first comparative study of US assessment of VWT and pelvic floor muscle morphometry and function in women with VL.
- This makes this section even harder to compare the literature with our findings, as there is scant data on this subject.
- An increase in VWT was found in all measurement techniques (TAUS and TVUS) and during follow-ups in participants treated with PFMT.
- Our findings showed the Hiatal Area Narrowing and A-P Diameter Difference measurements were significantly higher in the PFMT group 30 days post-treatment. A significant increase was also observed in these two variables and the R-L Diameter Difference, in the follow-up periods in the PFMT group.
- The use of ultrasound for the objective assessment of VWT and the morphometry and contractile function of the pelvic floor muscles has contributed to the understanding of VL and raised questions for future studies.

## Conclusions

Women with ballooning on 4D-TLUS presented significantly worse scoring in sexual function and vaginal symptoms. 2D-US found that RF reduced the VWT of the distal vagina after six months and PFMT increased the VWT of the proximal vagina after six months.

## References

- Pereira GMV, Juliato CRT, de Almeida CM, et al. Effect of radiofrequency and pelvic floor muscle training in the treatment of women with vaginal laxity: A study protocol. *PLoS One*. 2021;16(11):e0259650.
- Pereira GMV, Almeida CM, Martinho N, de Andrade KC, Juliato CRT, Brito LGO. Pelvic floor muscle training vs radiofrequency for women with vaginal laxity: randomized clinical trial. *J Sex Med*. 2024 Aug 1;21(8):700-708.