

WHAT DOES A WOMAN FEEL DURING PELVIC MAGNETIC STIMULATION?

Hypothesis / aims of study

Pelvic floor muscle training is the first-line conservative treatment for female urinary stress incontinence. Other active treatments include : behavioral tips; electrical or magnetic stimulation; pads; drug therapies and surgery including sling procedures and colposuspension. Up to date there is currently lack of randomized, adequately powered sham-controlled trials with validated outcomes, that allow recommendations on the use of magnetic stimulation for female stress urinary incontinence. Someone states that it doesn't give any sensation. The goal of this study is to assess the feelings in healthy women by an exposure to magnetic stimulation under the pelvic floor for 20 minutes. We also want to evaluate if there is a significant correlation between the age or BMI (Body Mass Index) and the intensity of the sensations.

Study design, materials and methods

A total of 20 healthy women were evaluated with age, weight and height in order to calculate the BMI and then through an accurate medical history. Women were between 36-59 years old, with an average age of 50.4 years.

Only subjects without urinary symptoms entered the study. Women seated with the perineum in the middle of a seat to allow for the greatest effect of the pulsating magnetic field on the pelvic floor and sphincter muscles. The treatment lasted 20 minutes divided in 2 periods of 10 minutes each with a different frequency of stimulation; first period: frequency 5 Hz, 5 seconds of activity and 5 seconds of pause; second period: frequency of 50 Hz, 5 seconds of activity and 5 seconds of pause. The intensity of stimulation could be gradually increased to a maximum tolerable value from 0 to 100.

At the end of the session women were submitted to the following questions: What did you feel? Pain: yes/no, Where? anus/vagina/other, Did you feel pelvic floor contraction, vibration, heat? yes/no/other. A visual analogue scale (VAS) and a verbal rating scale (VRS) were submitted to the women.

The results were loaded into a database and analyzed by the statistical software STATA. The variables (intensity of stimulation, BMI, age, first and second period) were classified in contingency tables and the relative confident intervals at 95% were calculated. A p-value of <0.05 was considered significant for all the tests. For the analysis of the data we used the following definitions: low intensity < 60, high intensity: ≥ 60. Normal weight (BMI <25,5), over weight (BMI 25,5 - 30), obesity (BMI > 30).

Results

12 (60%) women had normal weight, 7 (35%) were overweight and one obese (5%).

The average BMI was 24,2. Women experienced the magnetic stimulation as vibration (55%) (IC:31,5-76,9%), pelvic floor contraction (55%) (IC 31,5%-76,9%), heat (15%)(IC 3,2%-37,9%). Most of the women registered at least one feeling sensation, while 35% referred 2 kinds of feelings at the same time. No one registered simultaneously more than 2 sensations. Sensations were felt into the vagina (47,2%) (IC 95%: 29,8%-64,9%), perineum (23,5%) (IC 95%:10,7-41,2%), anus (17,6%)(IC 95%:6,8-34,5%), gluteus (8,8%) (IC 95%:1,9-23,7%). A woman reported calves contraction (2,9%) (IC 95%: 0,1-15,3%). 40% reported feeling simultaneously in 2 places, others (15%) in 3 places simultaneously and the remaining 45% in a unique place.

11 women (55%) (IC 95%: 31,5%-76,9%) didn't feel pain with a VRS score under 0, while 1 (5%) (IC 95%: 0,1%-24,9%) woman referred soft painful sensation with a VRS 1; 7 (35%) women felt moderate pain with a VRS score 2, 4 women (20%) (IC 95%: 5,7%-43,7%) with a VRS score 3, 3 women (15%) (IC 95%: 3,2%- 37,9%) with a VRS score 4; 1 (5%)(IC 95%: 0,1%-24,9%) woman referred a strong painful sensation into the vagina with VRS 5 but not enough to stop the stimulation while VRS score over 6 was never reported. VRS scale is similar to VAS.

First period: women feeling stimulation with intensity < 60 were 83% normal weight and 17% overweight; while those feeling stimulation with intensity ≥ 60 were 50% with normal weight and 50% overweight or obese,

Second period: women feeling stimulation with intensity < 60 were 78% normal weight and 22 % overweight; while those feeling the stimulation with intensity ≥ 60 were 45,5% normal weight and 54,5% overweight or obese

First period: women feeling stimulation with intensity < 60 were 33% less than 50 years old and 67% more than 50 years; while those feeling the stimulation with intensity ≥ 60 were 43% less than 50 years old and 57% more than 50 years.

Second period: women feeling stimulation with intensity < 60 were 44 % less than 50 years old and 56% more than 50 years; while those feeling stimulation with intensity ≥ 60 were 36% more than 50 years old and 64% more than 50 years.

Interpretation of results

All women felt a sensation. The human specimen was not homogeneous for the BMI as the obese number is not representative.

The most frequently felt sensations were vibration and contraction while the most involved area was the vagina.

Overweight women felt the sensation both during the first and second period with a higher stimulation intensity compared to normal weight with $p \leq 0,05$. The age wasn't discriminating for feeling perception.

Concluding message

Magnetic stimulation is a non-invasive and painless treatment option. Stimulation is correctly felt at pelvic floor level from all women with the necessity to increase the intensity in overweight/ obese women independently from the age

First Period Stimulation			
Intensity stimulation	N	%	IC:95%
<60	6	30,0%	11,9% 54,3%
≥60	14	70,0%	45,7% 88,1%
Totale	20	100,0%	

First Period Stimulation			
Intensity stimulation	N	%	IC: 95%

45	1	5,0%	0,1-24,9%
60	5	25,0%	8,7-49,1%
65	4	20,0%	5,7-43,7%
70	2	10,0%	1,2-31,7%
75	1	5,0%	0,1-24,8%
80	1	5,0%	0,1-24,8%
90	2	10,0%	1,2-31,7%
100	4	20,0%	5,7-43,7%
Total	20	100,0%	

Sensations felt in patients stratified for BMI-1st period int <60	
BMI	SENSATIONS
Normal weight %	5 83,3
Overeigh/Obose %	1 16,7
TOTAL %	6 100,0

Sensations felt in patients stratified for BMI- 1st period int ≥60	
BMI	SENSATIONS
Normal weight %	7 50
Overeigh/Obose %	7 50
TOTAL %	14 100,0

Sensations felt in patients stratified for AGE-1st period int <60	
AGE	SENSATIONS
<50 %	2 33,3
>50 %	4 66,7
TOTAL %	6 100,0

Sensations felt in patients stratified for AGE- 1st period int ≥60	
AGE	SENSATIONS
<50 %	6 42,9
>50 %	8 57,1
TOTAL %	14 100,0

Second period Stimulation			
Int Stimulation	N	%	IC: 95%
40	1	5,0%	0,1-24,9%
55	4	20,0%	5,7-43,7%
60	4	20,0%	5,7-43,7%
65	2	10,0%	1,2-31,7%
70	2	10,0%	1,2-31,7%
75	1	5,0%	0,1-24,8%
80	2	10,0%	1,2-31,7%
90	2	10,0%	1,2-31,7%
100	2	10,0%	1,2-31,7%
Totale	20	100,0%	

Second period Stimulation			
Int Stimulation	N	%	IC: 95%
<60	9	45,0%	23,1% 68,5%
>60	11	55,0%	31,5% 76,9%
Totale	20	100,0%	

Sensations felt in patients stratified for AGE- 2nd period int < 60	
AGE	SENSATIONS
<50 %	4 44,4
>50 %	5 54,6
TOTAL %	9 100,0

Sensations felt in patients stratified for AGE- 2nd period int ≥60	
AGE	SENSATIONS
<50 %	4 36,4
>50 %	7 63,6
TOTAL %	11 100,0

Sensations felt in patients stratified for BMI- 2nd period int <60	
BMI	SENSATIONS
Normal weight %	7 77,8
Overeigh/Obese %	2 22,2
TOTAL %	9 100,0

Sensations felt in patients stratified for BMI- 2nd period int ≥60	
BMI	SENSATIONS
Normal weight %	5 45,5
Overeigh/Obese %	6 54,5
TOTAL %	11 100,0

References

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Disclosures

Funding: Nobody **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** The goal of this study is to assess the feelings in healthy women by an exposure to magnetic stimulation under the pelvic floor for 20 minutes **Helsinki:** Yes **Informed Consent:** Yes