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A randomized, double-blinded, sham-controlled trial of postpartum extracorporeal magnetic innervation to restore pelvic muscle strength in primiparous patients

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KEY WORDS

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Objective: The purpose of this study was to determine the effects of extracorporeal magnetic innervation (ExMI) on pelvic muscle strength of primiparous patients.

Study design: Primigravid patients were randomized to receive either active or sham ExMI postpartum treatments for 8 weeks. The main outcome measure was pelvic muscle strength measured by perineometry at baseline (midtrimester), 6 weeks (before treatments), 14 weeks, 6 months, and 12 months postpartum. Mixed randomized-repeated measures ANOVA was used to analyze the mean perineometry values between the 2 groups and across all 5 time periods.

Results: Fifty-one patients enrolled, and 18 were lost to attrition. There were no differences in demographics or delivery characteristics between the active and sham groups. There was an overall time effect, $F(3,85) = 3.1$, $P = .049$, but no group, $F(1,31) = 0.007$, $P = .94$, or (group)(time) interaction, $F(3,85) = 1.8$, $P = .15$.

Conclusion: We found no differences in pelvic muscle strength between patients receiving active or sham ExMI treatments in the early postpartum period.

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Damage to the muscles, nerves, and connective tissue of the pelvic floor as a result of pregnancy and childbirth is believed to play a major role in the development of

common disorders such as urinary incontinence, fecal incontinence, and pelvic organ prolapse.^{1,2,3}

Targeted exercise programs can strengthen the pelvic floor muscles, and may even reduce the incidence of pelvic floor dysfunction after childbirth.^{4,5} As for any exercise regimen, the intensity, frequency, and duration of pelvic floor training will greatly affect results.⁶ Therefore, any way of reducing the voluntary aspects of a pelvic floor training program (eg, providing 'passive exercise') should improve patient compliance. In recent years, extracorporeal magnetic innervation (ExMI) has been promoted as a way to do just that—passively

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exercise the pelvic floor muscles while a patient sits fully clothed in an ExMI chair (Neocontrol, Neotonus, Inc, Marietta, Ga).⁷

Thus, our objective for this study was to determine the effects of postpartum pelvic floor ExMI therapy on pelvic muscle strength of primiparous patients.

Material and methods

This study was approved by the University of Louisville Human Studies Committee (HSC #502.00), and was conducted between February 2001 and July 2003.

Any nulliparous patient between 20 and 34 weeks' gestation was eligible for the study. Participants were recruited from the Louisville, Kentucky community via print and radio ads, presentations at prenatal classes, and displays set up in the waiting areas of various local private practice groups. All potential participants were screened by a single study coordinator (LB) via telephone interviews. After initial screening, all participants underwent a standardized informed consent process by the same study coordinator.

After obtaining informed consent, the study coordinator randomized each patient to either the active or sham group and collected baseline demographic information, as well as subjective assessments of pelvic floor dysfunction.⁸ Group allocation was determined by a computer-generated blocked randomization scheme, and allocation concealment was maintained via sequentially numbered opaque sealed envelopes.

During the initial visit, each patient also underwent a physical examination including urine stop test,⁹ digital assessment of pelvic muscle strength,¹⁰ and strength assessment via a perineometer (Contimed[®] II, Hollister, Inc, Libertyville, Ill). Throughout the entire study period, each of these tests was performed by a single technician (not LB) who was blinded as to patients' group assignments. Regardless of group assignment, the technician taught each patient how to perform pelvic muscle contractions, and advised them to initiate a program of pelvic muscle training. Compliance with this exercise program was tracked at each subsequent visit with the assumption that the randomization would "wash out" any differential effects of pelvic floor exercises between groups.

The main outcome measure was pelvic muscle strength as measured by perineometry in cmH₂O. These measures were obtained at baseline, (ie, while the patients were pregnant), and follow-up measurements were made 6 weeks (before active or sham ExMI treatment), 14 weeks, 6 months', and 12 months' postpartum.

Based on work by Morkved and Bo,¹¹ we estimated that an effect size of greater than or equal to 30% for the active vs sham group in terms of perineometry measures would be clinically significant. Therefore, the sample size estimate called for 19 patients in each arm of the study to have an 80% power to detect this difference ($\alpha = 0.05$).

Table 1 Demographic information for the original active (n = 25) and sham (n = 26) groups

| | Type of treatment | | P value |
|---|-------------------|----------------|---------|
| | Sham(n = 26) | Active(n = 25) | |
| | Mean (SD) | Mean (SD) | |
| Age [§] | 29.2 (5.3) | 28.9 (4.7) | .83 |
| Total IIQ score* | 2.8 (4.4) | 1.0 (1.9) | .14 |
| Total UDI score [†] | 5.2 (3.8) | 3.4 (2.2) | .13 |
| DMS score | 3.2 (2.4) | 2.5 (1.7) | .31 |
| Urine stop time(in sec) | 2.6 (1.1) | 3.2 (1.8) | .38 |
| Average perineometry value (in cmH ₂ O) [§] | 56.8 (25.9) | 45.7 (25) | .14 |
| | % | % | |
| Caucasian [‡] | 88 | 84 | .87 |
| African American [‡] | 8 | 12 | |
| Hispanic [‡] | 4 | 4 | |

* Incontinence impact questionnaire.

[†] Urogenital distress inventory.⁸

[‡] Pearson's chi-square test.

[§] Independent samples t test.

^{||} Mann-Whitney U.

Patients contacted our study coordinator upon delivering their babies. The coordinator then performed a chart review to obtain information regarding their delivery characteristics, including delivery mode, length of labor stages, baby birth weight, and episiotomy use/perineal damage.

Six weeks after delivery, each patient underwent a postpartum muscle strength assessment, as described above. Immediately thereafter, they each underwent the first treatment in the ExMI chair. These treatments (either active or sham) were performed twice weekly for 8 weeks—between 6 and 14 weeks' postpartum for each patient. All patients were asked to sit comfortably in the center of the ExMI chair and remain still. For the active group, the ExMI chair was set to deliver a treatment of 50 Hz intermittently (5 seconds on, 5 seconds off) for 20 minutes. At each visit, the stimulating amplitude was gradually increased up to each patient's tolerable level. In an effort to further conceal the randomization scheme, all patients were informed that they may or may not appreciate the muscle stimulation regardless of their group assignments.

The sham treatments were identical in terms of duration and overall patient experience. In fact, the same chair was used for both groups. In order to deliver sham treatments, the study coordinator simply placed a lead-lined seat over the magnetic coil instead of the usual seat. The active and sham seats were indistinguishable to the study participants, and the chair made the same noises during the active and sham treatment sessions. In order to further conceal group assignments, care was taken to schedule treatment sessions such that no two patients were in the office at the same time (thus, limiting their chances of "comparing notes"). Patients were paid \$10

Table II Delivery characteristics of the original active (n = 25) and sham (n = 26) groups

| | | Type of treatment | | P value |
|----------------|--|---------------------------|-----------------------------|---------|
| | | Sham(n = 26) Mean (SD) | Active(n = 25) Mean (SD) | |
| | Latent phase of labor (in min) [‡] | 542.5 (226.7) | 729.5 (411.7) | .1 |
| | Second stage of labor (in min) [‡] | 72.4 (54.2) | 93.2 (72.1) | .4 |
| | Baby birth weight (in g) [†] | 3295.1 (488.1) | 3289.2 (396.7) | .97 |
| | Perineometry values (in cmH ₂ O) [†] | 38.7 (20.2) | 47.4 (22.1) | .21 |
| Delivery type* | Vaginal | 73.1% | 68% | |
| | Cesarean section | 26.9% | 32% | .76 |
| Forceps used?* | Yes | 18.2% | 9.5% | |
| | No | 81.8% | 90.5% | .66 |
| Vacuum used?* | Yes | 13.6% | 9.5% | |
| | No | 86.4% | 90.5% | .67 |
| Episiotomy?* | Yes | 27.3% | 38.1% | |
| | No | 72.7% | 61.9% | .53 |

* Pearson's chi-square test.

† Independent samples *t* test.

‡ Mann-Whitney *U*.

per visit; therefore, total patient compensation was \$200 if they completed all 20 of the study visits.

A 2 × 5 mixed randomized-repeated measures analysis of variance was used to analyze the perineometry data between the 2 treatment groups and across all 5 time periods. Accordingly, group, time, and group × time interaction effects were tested. An alpha level less than 0.05 was deemed statistically significant, and $P < .05$. Assumptions of normality of sampling distribution and homogeneity of variance were assessed. Mauchly's test of sphericity was performed, and the test signified that the assumption of sphericity was violated; thus, the Huynh-Feldt epsilon was used to adjust the degrees of freedom for the *F* statistic. We also used an independent *t* test to evaluate the differences between baseline and 6-week postpartum perineometry measurements among women who delivered vaginally and via cesarean section. Demographics and delivery characteristics were compared for the overall groups (n = 51), as well as the final sample size (n = 33). Comparisons were made to assess whether any differential or predictable loss to follow-up had occurred over the course of the study. Demographic comparisons were made using independent samples *t* test for parametric data; the Mann-Whitney *U* test for non-parametric data; and the Pearson chi-square test for proportions. SAS/STAT software, version 8.02 (SAS Institute, Inc, Cary, NC) was used for the analysis.

Results

No protocol deviations or adverse events occurred during the study period. Fifty-one patients enrolled in the study and were randomized to the active (n = 25) and sham (n = 26) groups. Table I provides the de-

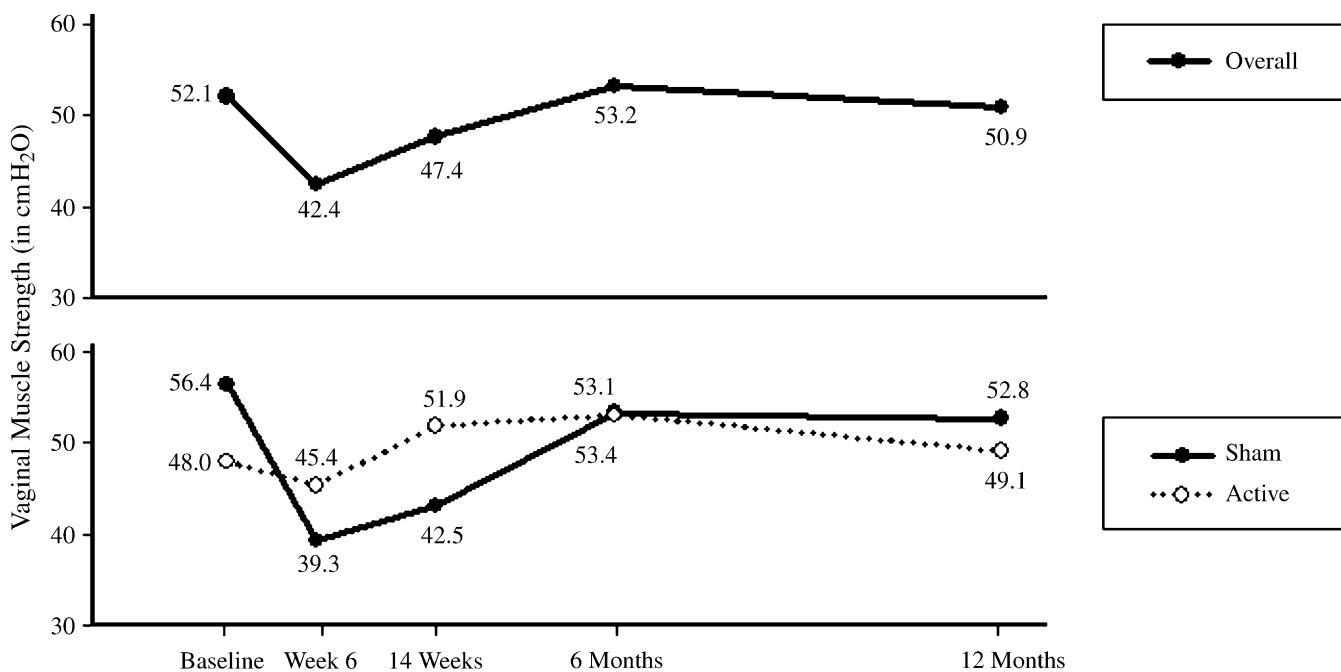
Table III ANOVA for the group, time, and time × group interaction between the active (n = 18) and sham (n = 17) groups

| Source | Sum of squares | Df | Mean square | F | Sig. |
|--------------|----------------|------|-------------|------|------|
| Group | 16.6 | 1 | 16.6 | .007 | .935 |
| Error | 77128.7 | 31 | 2488.0 | | |
| Time | 2624.5 | 2.7 | 958.7 | 2.8 | .049 |
| Time × group | 1717.8 | 2.7 | 627.5 | 1.8 | .152 |
| Error (time) | 29077.2 | 84.9 | 342.6 | | |

mographic information, and Table II provides delivery characteristics for the 2 groups. As expected, there were no baseline differences between the 2 groups. Only 2 patients in each group actually adhered to the recommended pelvic muscle exercise program during the study protocol.

Of the 38 patients that returned for their first postpartum study visit, 5 failed to return for post-treatment muscle strength assessment, reducing the sample size to 33. Out of the 33 subjects, 7 had at least 1 missing data point. These subjects' missing data points were dealt with by employing the "last observation carried forward" (LOCF) principle, which imputes a missing value based on the last time period where that subject had a measured value.¹² No statistical differences were found between the final study group (n = 33), and those patients lost to attrition.

Table III provides the ANOVA for the group, time, and time × group interaction, and Figure depicts the mean vaginal muscle strength in cmH₂O between groups across time and the overall mean vaginal muscle strength scores across time. The results show an overall time effect, $F(3,85) = 3.1$, $P = .049$, but no group,



Figure

$F(1,31) = 0.007, P = .94$, or group \times time interaction, $F(3,85) = 1.8, P = .15$, indicating that at no time period was there a difference between groups in terms of vaginal muscle strength as it changed over time. When the other strength assessment measures (ie, urine stop test and digital exam) were compared between groups over time, again no differences were found.

The difference between perineometry measurements at baseline and 6 weeks between the active and sham groups (mean change score decrease = 17.1 and 2.6, respectively) was analyzed using independent sample *t* test. This difference did not achieve significance ($P = .08$). The same analysis was performed comparing the 6 week and 14 week perineometry measurements, and again the difference did not achieve significance ($P = .54$). The results of these analyses corroborated the nonsignificant group \times time interaction effect mentioned above.

Because an overall time effect was found, contrasts were performed comparing the baseline measurement to all other time points. As expected, the analysis showed a sharp statistical drop in the combined mean vaginal muscle strength between baseline (mean = 52.1) and follow-up at 6 weeks (mean = 42.4), $P = .02$. However, by the 14-week, 6- and 12-month postpartum time periods, the mean perineometry measurements were not statistically different from the baseline measurement ($P = .25, P = .84, P = .80$, respectively), shown in Figure.

Table IV demonstrates the differences between baseline and 6-week postpartum perineometry measurements

Table IV Mean and standard deviations of perineometry measurements at baseline and 6 weeks for patients who delivered vaginally and via cesarean section (regardless of group assignment)

| | Baseline | 6 weeks | Change score |
|---------------------------|-------------|-------------|---------------|
| | Mean (SD) | Mean (SD) | Mean (SD) |
| Type of delivery | | | ($P = .14$) |
| Vaginal (n = 28) | 54.1 (26.6) | 39.2 (19.8) | 14.9 (25.2) |
| Cesarean section (n = 10) | 53.8 (30.4) | 53.1 (23.1) | 0.7 (26.6) |

among those women who delivered vaginally and via cesarean section (regardless of group assignment).

Comment

The obvious strength of this study is the design—a randomized, double-blinded, sham-controlled trial, and its obvious shortcoming was the small number of patients. Although the initial recruitment goals were met, the attrition rate was greater than expected. Therefore, the final study group of 33 was smaller than the 38 patients called for in the power calculation.

As with any RCT, the external validity of the results may be questioned. That is especially true for this study population, who may have been healthier and generally more interested in their own health than the remainder of community. There is no way to determine whether such a difference actually exists.

Another possible limitation of the study was the reproducibility of the main outcome measure, perineometry. That possible limitation was mitigated by the employment of a single blinded technician to perform all study measurements in a standardized fashion. Further, results of 2 other muscle strength assessments (ie, the urine stop test and digital exam) jived with the perineometry results.

One could argue that the baseline perineometry measures were inherently flawed because of the pelvic floor changes that occur during the midtrimester. However, the change in perineometry values over time (not the absolute values) was our main outcome measure.

The characteristics of the ExMI treatments themselves represent 2 other possible study limitations. The frequency or “dose” of 50 Hz chosen for this study could have been suboptimal for strengthening pelvic floor muscles via the ExMI approach. However, when incorporated via direct electrical stimulation (ie, with vaginal probes), that frequency is known to cause forceful contractions of skeletal muscle¹³ and, as such, has been widely used in the treatment of stress urinary incontinence.¹⁴

It is also possible that 16 treatment sessions over a 2-month period represents an overall “dose” that is simply too small to strengthen the pelvic floor muscles in any meaningful way. Perhaps home-based treatments performed daily would have had a greater effect. Testing that theory, of course, would require another study.

Finally, it is possible that starting the treatment sessions earlier in the postpartum period would have been more beneficial. However, given the physiologic, emotional, and logistic difficulties that can be associated with the early postpartum period, starting treatments any sooner would have been infeasible.

In conclusion, notwithstanding the above-mentioned limitations, use of ExMI to restore pelvic floor muscle strength after childbirth appears to be ineffective.

References

1. Handa VL, Harris TA, Ostergard DR. Protecting the pelvic floor: obstetric management to prevent incontinence and pelvic prolapse. *Obstet Gynecol* 1996;88:470-8.
2. Brubaker L. Vaginal delivery and the pelvic floor. *Int Urogynecol J* 1998;9:363-4.
3. DeLancey JOL. Childbirth, continence, and the pelvic floor. *N Engl J Med* 1993;329:1956-7.
4. Morkved S, Bo K, Schei B, Salvesen KA. Pelvic floor muscle training during pregnancy to prevent urinary incontinence: a single blind randomized controlled trial. *Obstet Gynecol* 2003;101:313-9.
5. Sampsel CM, Miller JM, Mims BL, DeLancey JOL, Ashton-Miller JA, Antonakos CL. Effect of pelvic muscle exercise on transient during pregnancy and after birth. *Obstet Gynecol* 1998;91:406-12.
6. Bouchard C. Physical activity and health: introduction to the dose-response symposium. *Med Sci Sports Exerc* 2001;33:347-50.
7. Galloway NT, Risk E, El-Galley S, Sand PK, Appell RA, Russell HW, et al. Extracorporeal magnetic innervation therapy for stress urinary incontinence. *Urology* 1999;53:1108-11.
8. Ubersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: the incontinence impact questionnaire and the urogenital distress inventory. *Neurourol Urodyn* 1995; 14:131-9.
9. Kerschman-Schindl K, Uher E, Wiesinger G, Kaider A, Ebenbichler G, Nicolas P, et al. Reliability of pelvic floor muscle strength measurement in elderly incontinent women. *Neurourol Urodyn* 2002;21:42-7.
10. Brink CA, Wells TJ, Sampsel CM, Taillie ER, Mayer R. A digital test for pelvic muscle strength in women with urinary incontinence. *Nurs Res* 1994;43:352-6.
11. Morkved S, Bo K. The effect of postpartum pelvic floor muscle exercise in the prevention and treatment of urinary incontinence. *Int Urogynecol J* 1997;8:217-22.
12. Meinert CL, Tonascia S. *Clinical trials: Design, conduct and analysis*. New York, NY: Oxford University Press; 1986.
13. Laycock J, Vodusek DB. Electrical stimulation in therapeutic management of incontinence and pelvic pain. In: Laycock J, Haslam J, editors. London: Springer-Verlag; 2002. p. 85-9.
14. Sand PK, Richardson DA, Staskin DR, Swift SE, Appell RA, Whitmore KE, et al. Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: a multicenter, placebo-controlled trial. *Am J Obstet Gynecol* 1995;173:72-9.