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A BLINDED, SHAM-CONTROLLED TRIAL OF POSTPARTUM EXTRACORPOREAL MAGNETIC INNERVATION TO RESTORE PELVIC MUSCLE STRENGTH IN PRIMIPAROUS PATIENTS

Hypothesis / aims of study

To determine the effects of postpartum extracorporeal magnetic innervation (ExMI) on pelvic muscle strength of primiparous patients for the year following childbirth**.**

Study design, materials and methods

Primigravid patients were recruited from our community. Eligible patients were enrolled during their first pregnancy – between 20 and 34 weeks gestation. They were randomized to receive either active or sham ExMI treatments beginning during their 6th postpartum week. Our main outcome measure was pelvic muscle strength as measured by perineometry in cmH_2O. These assessments were made by a single independent observer blinded as to patients' group assignments. Baseline measurements were obtained at the enrollment visits (i.e. while the patients were pregnant), and follow-up measurements were made 6 weeks (prior to ExMI or sham treatment), 14 weeks, 6 months and 12 months postpartum. Between 6 and 14 weeks postpartum, patients completed a course of 16 treatment sessions in either the active or sham ExMI chair (NeoControl®, NeoTonus Inc., Marietta, GA). Our sample size estimate called for 19 patients in each arm to have 80% power of detecting a 40% difference in mean perineometry measures between groups at any point during the study ($\alpha = 0.05$). Mixed randomized-repeated measures analysis of variance was used to analyze the mean perineometry values between the two treatment groups and across all five time periods. Accordingly, group, time and group cross-time interaction effects were tested.

Results

Fifty-one patients enrolled, and 38 patients returned for their postpartum treatment sessions. As expected, there were no demographic differences between the active and sham groups. Likewise, there were no differences between the groups with respect to delivery characteristics (i.e. instrumented or C-section delivery, length of labor stages, damage to the perineum, baby birthweight, or episiotomy use). The analysis of variance procedure indicated no main effect difference between the active or sham ExMI treatments, $F(1,31)=0.02$, $p=0.89$. Also, there was no significant group cross-time interaction, $F(3,88)=2.5$, $p=0.07$, indicating no difference between groups at any given time period. When measures from both groups were combined, an overall time main-effect was found, $F(3,88)=4.4$, $p=0.01$. Namely, mean perineometry measures at baseline were significantly higher (mean = 52.2 cmH_2O) than those at 6 weeks postpartum (mean = 42.3 cmH_2O), $p=0.02$. However, all subsequent perinometry measurements (14 weeks, 6months and 12 months postpartum) were similar to baseline measurements, $p=0.29$, $p=0.53$, $p=0.59$, respectively.

Interpretation of results

We found no differences in pelvic muscle strength among primiparous patients who received active or sham ExMI treatments in the early postpartum period.

Concluding message

Traditional pelvic floor exercises remain the best method for preventing pelvic floor dysfunction following childbirth. ExMI seems to add no muscle strength in this patient population.

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