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Siyou W[1], Juanjuan Y[1], Guomei C[1], Mingyi X[1]
1. *Shanghai Research Institute of Acupuncture and Meridian*

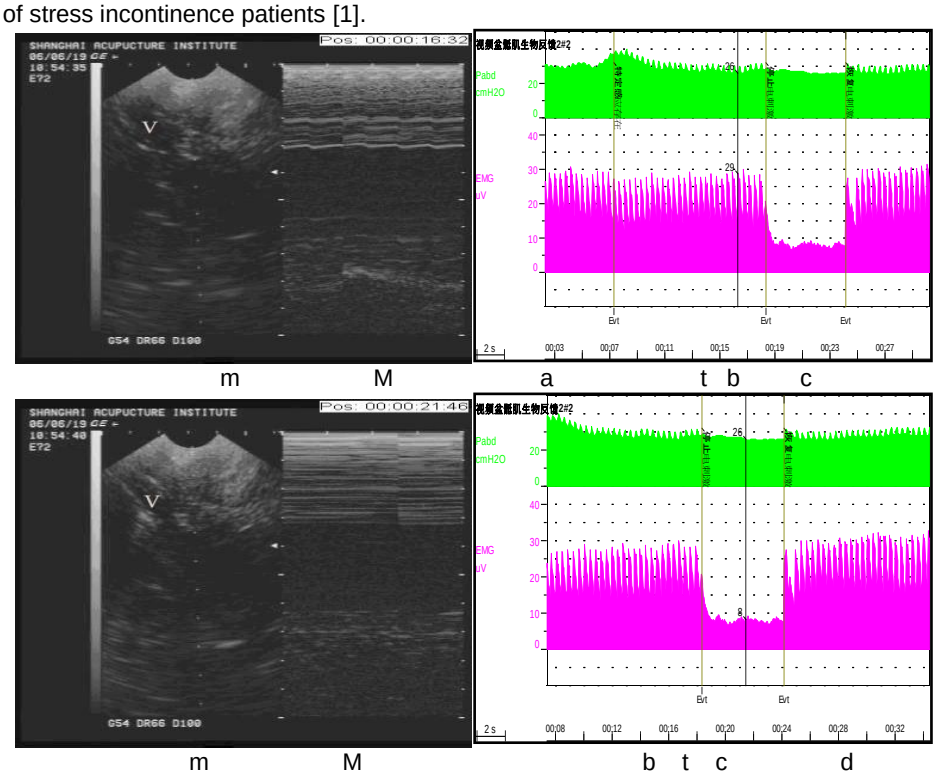
SIMULTANEOUS PERINEAL ULTRASOUND AND VAGINAL PRESSURE MEASUREMENT PROVES THE EFFICACY OF ELECTRICAL PUDENDAL NERVE STIMULATION IN TREATING FEMALE STRESS INCONTINENCE

Hypothesis / aims of study

By combining the advantages of pelvic floor muscle training (PFMT) and transvaginal electrical stimulation (TES) and incorporating the technique of deep insertion of long needles, we developed electrical pudendal nerve stimulation (EPNS).The aim of this study was to prove that EPNS can contract the pelvic floor muscles (PFM), replace PFMT and effectively treat female stress urinary incontinence (SUI).

Study design, materials and methods

EPNS was performed as follows. The patient was placed in a prone position. Four sacral points were selected. The two upper points are located by the two edges of the sacrum on a level with the fourth sacral foramina. The locations of the two lower points are about 1 cm bilateral to the tip of the coccyx. Two needles of 0.40×100 mm (acupuncture needles) were perpendicularly inserted into the two upper points deeply to reach the root of the pudendal nerve. Two needles 0.40×100 or 125 mm were inserted obliquely towards the ischiorectal fossa into the two lower points deeply to reach the perineal nerve. When the four needles were electrified to stimulate the pudendal nerves using a Multi-Purpose Health Device (biphasic, 2 ms pulse duration, 45-55 mA, 2.5 Hz), perineal ultrasound images of PFM contractions, vaginal pressure (green in the picture) and pelvic floor surface myoelectricity (red in the picture) were recorded simultaneously by use of a urodynamic instrument with video suite (Medtronic Duet Encompass). Simultaneous records were also obtained under three conditions in the process of EPNS: 1) stopping electric stimulation; 2) reducing the current intensity; 3) drawing back the two lower needles. The therapeutic effect was evaluated after treatment according to objective criteria: stress test and pad test, and subjective criteria: a questionnaire to measure the severity of symptoms and the quality of life of stress incontinence patients [1].



V=vagina, m=M-mode line, M=M-mode image, t=the time corresponding to the left image

Results

Thirty-five female patients (aged 54.9±9.7) with urodynamically proven SUI were enrolled. There were no dropouts. A sensation referred to the urethra or the anus was produced when the two upper needles were inserted perpendicularly to a depth of 80 to 90 mm. A sensation referred to the urethra was produced when the two lower needles were inserted laterally to a depth of 90 to 110 mm. When EPNS was performed correctly, the patient felt strong rhythmic and cephalad PFM contractions with the urethra as the center and without discomfort. Simultaneous records showed the following: 1) cranio-caudal PFM contractions on the B-mode image; 2) the M-mode curves indicating the PFM contractions (upper image, amplitude: about 1 mm, n=31, 14 cases ≥1 mm and 17 cases <1 mm); 3) a sawtooth curve of changes in vaginal pressure (a-b and c-d periods in the pictures, amplitude: 2.61±1.69 cmH2O, n=34); 4) pelvic floor myoelectric waves (a-b and c-d periods; amplitude: 23.9±25.3 μV, n=34). The vaginal pressure amplitude was significantly larger in the patients with ≥1 mm PFM contraction amplitude (3.34±1.44 cmH2O) than in the patients with <1 mm (2.11±0.92 cmH2O) (t-test, P<0.05). If during the process of EPNS the electric current was stopped (b-c period in the picture) or its intensity was reduced to 7-12 mA or the two lower needles were gradually drawn back until the tips were 1~2 cm away from the original positions, then B-mode PFM contractions, M-mode curves (lower image)and sawtooth changes in vaginal pressure (b-c period) disappeared.

In the 35 patients, SUI severity and quality of life score was 16.5±4.0 (full score 28) before treatment (baseline) and decreased to 4.2±4.0 after 28.5±13.0 sessions of treatment (1 hr each session). A t-test showed a significant pre-/post-treatment difference in the score ($p<0.05$). At the end of treatment, 100% improvement (stress test and pad test: negative; post-treatment score: 0) occurred in

16 cases (45.7%), 75%~<100% improvement in 4 cases (11.4%) and 50%~<75% improvement in 10 cases (28.6%).

Interpretation of results

The site beside the sacral edge on a level with the fourth foramen is where the root of the pudendal nerve passes, so the body surface over it (the upper point) was selected for deep perpendicular insertion of a long needle. Because the pudendal nerve contains sensory fibers innervating the external genitalia and anus, the needling sensation is referred to the urethra or anus. The pudendal nerve gives off the perineal nerve, which innervates the PFM and the skin of the external genitalia, at the posterior margin of the urogenital diaphragm on the lateral wall of the ischiorectal fossa, so a long needle is inserted beside the tip of the coccyx laterally towards the ischiorectal fossa to make the needle tip reach the perineal nerve, and the needling sensation is only referred to the urethra. When the four needles were electrified, therefore, the patient felt strong rhythmic and cephalad PFM contractions with the urethra as the center and the ultrasonic image showed cranio-caudal PFM contractions with an amplitude of 1 mm or so (>0 but <2 mm), indicating that EPNS can exactly excite the pudendal nerve and contract the PFM. The vagina is surrounded by the PFM and PFM contraction will compress it. Therefore, vaginal pressure changed with rhythmic PFM contractions and a sawtooth curve of its changes was visible. The disappearance of B-mode PFM contractions, M-mode curves and the sawtooth curve of vaginal pressure during a discontinuity or reduction in the electric current, or a change in the position of the needle tip indicates that strong electrical stimulation and correct localization of the needle tip are needed for effective PFM contractions. The good therapeutic effect shows that EPNS can replace PFMT and effectively treat female SUI.

Concluding message

In this study, the simultaneous measurements have shown the mode of therapeutic action of EPNS on SUI. They also have shown that EPNS combines the advantages of PFMT (direct PFM contraction) and TES (passive PFM contraction and good compliance), The therapeutic effect in these 35 patients where ≥50% improvement rate reaches 85.7% is similar to our previous research results where ≥50% improvement rate reached 87.1% [2], This shows again that EPNS has an exact and reproducible therapeutic effect and is tolerated well by patients. It deserves further clinical study.

References

1. BJOG (2003)110;983–988
2. J Acupunct Tuina Sci (2006)4;170–173

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee of Shanghai Yueyang Hospital of Integrated Traditional and Western Medicine**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**