458

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EFFECTS OF THE NEW NEUROMODULATION SYSTEM, SACRAL SURFACE THERAPEUTIC ELECTRICAL STIMULATION, FOR REFRACTORY URINARY INCONTINENCE

Hypothesis / aims of study
The electrical stimulation therapies have been used widely to treat lower urinary tract dysfunction. Many stimulating methods have been reported such as the anal, vaginal, sacral nerve roots and transcutaneus stimulation methods. Transcutaneus electrical stimulation is less invasive and more acceptable to the patients. We investigated the possibility of the new electrical stimulating system,sacral surface therapeutic electrical stimulation (SS-TES) We previously reported that SS-TES might stimulate the pelvic and pudendal nerves directly because surface electrical stimulation to the skin on the posterior sacral foramens of the S2 and S4 was found to change bladder capacity and intra-urethral pressure during stimulation. In this study, we evaluated the efficacy and safty of the SS-TES for refractory urinary incontinence patients.

Study design, materials and methods
This study include 30 patients; 8 are neurogenic bladder, 12 are wet overactive bladder and 10 are nocturnal enuresis. Urodynamic study consisted of filling cystometry before and after the treatment. Electrical stimulation was performed at home with portable electrical stimulator twice daily for one to five months: for a 15-minute duration (10 seconds on 5 seconds off) at 20Hz frequency, biphasic rectangular pulses, 200 μ second width and sub-maximum tolerable intensity to the patient. The surface electrodes (10cm X 6cm) were placed at the level of sacral root from S2 to S4 bilaterally. The patients keep frequency volume chart before the stimulation and for the last one week during stimulation. During the electrical stimulation previous therapies were unchanged and continued. For statistics, the Wilcoxon test and correlation coefficient test were used. Significance level was less than 0.05.

Results
23 patients urodynamically proved detrusor overactivity in filling cystometry before SS-TES. After the SS-TES, maximum cystometric bladder capacity was significantly increased, 208 +/- 94 (mean +/- S.D.) before SS-TES to 282 +/- 67 ml. ($p<0.001$). The amplitude of involuntary detrusor contraction significantry decreased from 40.4 +/- 31.4 before SS-TES to 25.7 +/- 23.9 cmH_2O after SS-TES ($p<0.01$). Bladder compliance increased significantly from 19.4 +/- 4.1 (mean +/- S.D.) before SS-TES to 23.8 +/- 15.5 ml/cmH_2O after SS-TES ($p<0.01$). Frequency of incontinence decreased significantly from 2.3+/-1.4 times/day before treatment to 1.3 +/- 2.0 times/day after treatment ($p<0.01$). Daytime frequency was 8.6 +/- 4.9 times/day before treatment to 7.4 +/- 3.0 times/day after treatment. Among 30 patients, 10 patients (33.3%) showed ‘greatly improved’, 8 patients (26.7%) ‘improved’, 1 patient (3.4%) ‘slightly improved’, 11 patients (36.7%) ‘unchanged’, while no patients were ‘deteriorated’. The percentage of subjects showing more than ‘improved’ was 60% and more than ‘slightly improved’ was 63.4%. There were no side effects on SS-TES.

Interpretation of results
There are many reports on therapeutic effects of electrical stimulation to refractory incontinence. This new stimulating system, SS-TES is almost the same effect for anal or vaginal electrical stimulation. On the other hand, SS-TES is safe and more acceptable than the anal or vaginal electrical stimulation.

Concluding message
Our results suggest that SS-TES is effective for refractory incontinence patients. And the SS-TES is also easy to use, safe and acceptable for patients.

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HUMAN SUBJECTS: This study was approved by the IRB Tohoku University and followed the Declaration of Helsinki Informed consent was obtained from the patients.