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## A CROSS-OVER STUDY FOR EVALUATION OF FUNCTIONAL CONTINUOUS MAGNETIC STIMULATION (FCMS) IN PATIENTS WITH URINARY INCONTINENCE ON PELVIC FLOOR MUSCLE EXERCISE (PFME)

### Hypothesis / aims of study

To evaluate therapeutic effect of functional continuous magnetic stimulation (FCMS) on urinary incontinence in cross-over manner in patients on pelvic floor muscle exercise (PFME).

### Study design, materials and methods

A total of 61 patients complaining of urinary incontinence were instructed to practice PFME for 4 weeks before initiation of treatment and self-administered in an incontinence questionnaire and in a QoL questionnaire (International Consultation on Incontinence- Questionnaire: Short Form (ICIQ-SF)). The study included 56 patients, from whom informed consent could be obtained in written form. They had urinary incontinence once or more a week and underwent urodynamic study (UDS): 38 having urge incontinence and detrusor overactivity (DO) (urge incontinence group) and 18 having stress incontinence but not DO (stress incontinence group). The patients of the respective groups were randomly assigned either to active-sham(A-S) treatment or to sham-active (S-A) treatment. Both active treatment and sham treatment were performed once a week for 10 weeks. The study period had a 4-week wash-out interval between the two treatment schedules. The patients were instructed to practise PFME everyday in the same way as they did in the pre-treatment period.
UDS was performed at the ends of active treatment and sham treatment. Patients self-administered in the (ICIQ-SF). The incontinence questionnaire consisted of 8 items including the frequency of incontinence, urinary frequency, urge incontinence, etc. Each item was graded on a 5-rank scale.

### Results

Bladder capacity was significantly improved after the active treatment in the A-S group ($p=0.0004$) and in the S-A group ($p=0.0358$) as compared with the initial bladder capacity (Table 1). In the former group, there were 6 patients who were well improved on the active treatment and did not undergo the sham treatment and 4 patients who discontinued the sham treatment. In the latter group, there were 2 patients who were improved after the sham treatment and discontinued the study before entry in the active treatment schedule.
Leak point pressure (LPP) was significantly improved on the active treatment in the A-S group ($p=0.0079$) and it trended to be improved on the active treatment in the S-A group (Table 2). In the A-S group, there were 5 patients who were symptomatically improved on the active treatment and discontinued the study before entry in the sham treatment schedule and 2 patients who dropped out after the active treatment. In the S-A group, there was 1 patient who was symptomatically improved on the sham treatment and discontinued the study before entry in the active treatment schedule.
In the interim evaluation (after the first half of the treatment schedule), urinary incontinence was evaluated in 23 patients of the urge incontinence group including 4 patients who were symptomatically improved on the active treatment and did not undergo the sham treatment and 2 patients who were improved on the sham treatment and discontinued the study before entry in the active treatment, and in 15 patients of the stress incontinence group including 1 patient who was improved on the active treatment and discontinued the study before entry in the sham treatment and 1 patient who was improved on the sham treatment and discontinued the study before entry in the active treatment.
In the interim evaluation after the first half of treatment schedule, the UDS parameters were remarkably improved in the A-S group, but the improvement rate of incontinence was not remarkable. It trended to be greater in the A-S group and in the S-A group at the completion of the whole treatment than at the end of the first half of treatment.

Table 1. Changes in bladder capacity at strong desire to void (SD)

(urge incontinence group)

| | Pre-treatment | Interim (10 weeks) | Post-treatment |
|---|---|---|---|
| A-S treatment | 210.6±102.2 n=20 | 257.0±110.8 n=19<br>p=0.0004 | 287.0±125.6 n=9<br>p=.0.0707 |
| S-A Treatment | 206.8±54.0 n=18 | 236.8±112.0 n=18<br>p=0.3010 | 254.4±97.1 n=16<br>p=0.0358 |

Wilcoxon's signed rank test (Mean±SD)(ml)

Table 2. Changes in LPP (Stress incontinence group)

| | Pre-treatment | Interim ( 10 weeks) | Post-treatment |
|---|---|---|---|
| A-S treatment | 104.4±29.8 n=10 | 131.6±22.2 n=10<br>p=0.0079 | 119±12.5 n=3<br>p=0.4446 |
| S-A Treatment | 99.0±30.2 n=8 | 110.8±26.1 n=8<br>p=0.5231 | 118.5±26.6 n=7<br>p=0.1657 |

Wilcoxon's signed rank test (Mean±SD)($cmH_2O$)

Table 3. Improvement rates of urinary incontinence and QoL in the urge incontinence group

| | | Interim (n=14) | | Post-treatment (n=8) | |
|---|---|---|---|---|---|
| | | incontinence | QoL | incontinence | QoL |
| A-S treatment | Improved<br>Not improved | 57.1%<br>42.9% | 28.6%<br>71.4% | 62.5%<br>37.5% | 50.0%<br>50.0% |
| | | n=9 | | n=6 | |
| S-A Treatment | Improved<br>Not improved | 55.6%<br>44.4% | 33.4%<br>66.6% | 100%<br>0% | 66.6%<br>33.4% |

Incontinence Interim vs. Post- treatment p=0.1730

A-S treatment group vs. S-A treatment group p=0.0906 Fisher's exact test

Table 4. Improvement rates of urinary incontinence and QoL in the stress incontinence group

| | | Interim evaluation n=7 | | Post-treatment n=6 | |
|---|---|---|---|---|---|
| | | incontinence | QoL | incontinence | QoL |
| A-S treatment | Improved<br>Not improved | 42.9%<br>57.1% | 14.3%<br>85.7% | 83.3%<br>16.7% | 50.0%<br>50.0% |
| | | n=8 | | n=5 | |
| S-A Treatment | Improved<br>Not improved | 50.0%<br>50.0% | 25.0%<br>75.0% | 80.0%<br>20.0% | 40.0%<br>60.0% |

Incontinence Interim vs. Post- treatment p=0.0687

A-S treatment group vs. S-A treatment group p=0.8865 Fisher's exact test

**Interpretation of results**

Therapeutic effect of FCMS was evidenced by remarkable improvement in UDS parameters (bladder capacity and leak point pressure) in the A-S group after the active treatment. The improvement rate of incontinence trended to be greater after the whole treatment period than after the first half of treatment in the A-S group and in the S-A group, suggesting that the improvement in incontinence is delayed in comparison with the improvement in UDS parameter. It seemed that, at the first 10 weeks, there were many patients who were not aware of improvement in incontinence and that the number of patients realizing symptomatic improvement increased only at the end of the whole treatment period of 24 weeks.

**Concluding message**

FCMS and PFME are effective for urinary incontinence. FCMS treatment results in remarkable improvement in UDS parameter in short term (two to three months). However, it seems that it takes five to six months or longer until the percentage of patients realizing the improvement in incontinence or in QoL clearly increases.