Efficacy on Interferential Low Frequency Therapy for Overactive Bladder Syndrome

Hypothesis / aims of study
Examining the clinical efficacy on the interferential low frequency therapy for elderly patients with overactive bladder syndrome, for whom anticholinergics were not effective.

Study design, materials and methods
Subjects are 80 patients over 65 years with urinary incontinence, who are clinically diagnosed with overactive bladder (OAB) syndrome (40 men and 40 women; median age 72.0 years). They have agreed to participate in the clinical trials. All the subjects are without serious complications. For over three months, they were administered anticholinergics (20mg/day propiverine hydrochloride), but in an interview after the administration period they responded that their QOL scores were 4 or over (mostly dissatisfied to terrible). After the anticholinergics had been washed out for over one week, the patients were provided with functional electrical stimulation therapy (or interferential low frequency therapy (IF)) alone for three months through four surface electrodes (20Hz, 20mA) attached to the lower belly and buttocks. Using the Uromaster® (made by Nihon Medix Co.), the patients had a 20-minute treatment twice a week for the first three weeks, and then once every two weeks after that. Before and after IF, the following items were examined.
1) Average incontinence frequency in a week
2) PAD test for 60 minutes
3) Frequency and voided volume in the daytime and nighttime
4) Fluid intake volume
5) IPSS, QOL score
6) UFM (voiding time, voided volume, maximum flow rate (Qmax), average flow rate (Qave))
7) PVR (postvoid residual urine)
8) Specific gravity of urine
9) Hours spent outside per day
10) Radius of action
11) Frequency of IF treatment required to show effects
12) Blood pressure and pulse in the standing position
13) Values of clinical examination
14) Adverse events of IF
During the trial, no behavioral advice, including fluid intake advice, was provided to the patients. The voiding diary was kept for five days. As for the UFM, PVR and blood pressure, median values of three measurements were used.

Results
After an median of eight treatments of IF, the patients showed significant improvements and this effect continued. Improvement was seen in the following symptoms.
1) Average incontinence frequency 13.3 → 3.6 times/week, p=0.0001
2) 60-minute PAD test 17.5 → 3.1g, p=0.0157
3) Voiding frequency in the daytime 8.3 → 7.0 times, p=0.0003
   Voiding frequency in the nighttime 1.8 → 1.4 times, p=0.0004
4) IPSS (median value) 13 → 6.5, p<0.0001
   QOL score (median value) 5 → 2, p<0.0001
5) Average voided volume 170.2 → 254.2ml, p<0.0001
   Average Qmax 18.1 → 25.7ml/sec, p<0.0001
   Average Qave 8.9 → 12.1ml/sec, p<0.0001
6) Average hours spent outside per day 1.5 → 3hrs, p<0.0001
7) Average radius of action 400 → 1200m, p<0.0001

Although the volume of fluid intake and voided volume tend to increase and the specific gravity of urine (urinary osmotic pressure) tends to decrease, their improvements were not significant. Blood pressure and pulse in the standing position as well as the values of clinical
examination did not change much, while the adverse events of IF were not recognized. When comparing the average plasma osmotic pressure (295.1 mOsm/l) and average BNP (41.3 pg/ml) before and after the treatment, there were no marked changes.

**Interpretation of results**

The results raise the possibility that IF has better effects than anticholinergics on the OAB syndrome with urinary incontinence. It is clear that the OAB can significantly impair the QOL and reduce the ADL. By improving the urgent incontinence, the ADL will be improved and the physical activity and fluid intake volume will increase. In this examination, medication was not used in order to observe the effects of IF alone. However, if IF treatment is provided in combination with anticholinergic medication and behavioral therapy, it will have a better effect on OAB symptoms. It takes a relatively short time (about 1.5 months) for IF to have a noticeable effect, enabling patients to experience improvements in urinary urgency. Thus, even if no advice is given by urologists, the patients’ ADL will improve and physical activity will increase. These improvements will enable the patients to have more positive muscle training, including pelvic floor physical training. In addition, because no side effects are evident, IF can be provided to those patients who cannot take medication due to various reasons. IF is safe and can be provided at home for patients who are unable to attend hospital. In the meantime, this examination has also revealed that many patients showed high values of plasma osmotic pressure and BNP. However, urinary osmotic pressure was often low (300-400mOsm/l) at the same time. It is the urologists’ responsibility to provide patients, especially elderly ones, with advice on fluid intake and management, with a comprehensive consideration of not only the specific gravity of urine and urinary osmotic pressure but also plasma osmotic pressure and BNP, as indicators of ventricular function.

**Concluding message**

IF is safe and effective for wet OAB. IF combined with medication and behavioral therapy may result in noticeable effect for OAB patients.