449

Wang A C[1], Chih S Y [1], Chen M C[2]
1. Chang Gung University Hospital, 2. Chang Gung University

COMPARISON OF ELECTRIC STIMULATION AND OXYBUTYNIN CHLORIDE IN THE MANAGEMENT OF OVERACTIVE BLADDER WITH SPECIAL REFERENCE TO URINARY URGENCY: A RANDOMIZED PLACEBO-CONTROLLED TRIAL

Hypothesis / aims of study
Our aims were to compare the efficacy of electric stimulation (ES), oxybutynin and placebo in managing the symptom complex of overactive bladder (OAB), particularly urgency.

Study design, materials and methods
A randomized placebo-controlled trial was conducted for 68 patients with OAB laying emphasis on urinary urgency.
The interventions for the 12-week treatment period, conducted by the physiotherapist who was unaware of the progress and outcome, included (a) an vaginal ES program using biphasic symmetric, pulsed current with 10-Hz frequency, 400-μs pulse width, 10/5 duty cycle, and varying intensity, and (b) oxybutynin (2.5mg) or placebo tds. Identical preintervention and postintervention assessment including the measurement of warning time (WT), urodynamics, voiding diaries and King's Health Questionnaire (KHQ). Reduction rate of OAB was defined as the number of patients with subjective improvement/cure of urgency divided by the total number of patients in each group.

Results
Of the 68 women who completed this study, 24 were in the ES, 23 in the oxybutynin, and 21 in the placebo group.
Between-group comparison showed that significant improvements in pad count, episodes of urgency, nocturia, domain 2 and total score of KHQ existed between ES and the other groups (all $p \leq 0.029$). The changes in WT, maximal voided volume, episodes of urgency, and frequency were significantly improved between oxybutynin and placebo (all $p<0.013$). Additionally, a comparison of the voided volume in uroflowmetry between ES and placebo revealed greater difference after treatment (p=0.013). The reduction rate of OAB was 58.4% for ES, 39.1% for oxybutynin, and 9.5% for the placebo group (P=0.036).

Table. Comparison of changes* in objective and subjective outcome measures

Variable	ES (n=24)	Oxybutynin (n=23)	Placebo (n=21)	P value (among 3 groups)	Pairwise comparison		
	Median (Min,Max)	Median (Min,Max)	Median (Min,Max)		P value (ES* vs. Oxy†)	P value (Oxy† vs. Pl†)	P value (ES* vs. Pl†)
Objective							
Warning Time (second)	30(-27,573)	9(-5,703)	-1.5(-46,17)	<.001	0.105	<0.001	0.002
Maximal voided volume (ml/ micturition)	27 (-50,100)	35 (-60,151)	0 (-100,90)	0.035	0.274	0.011	0.116
Pad count (number/24h)	-0.9(-2.1,2)	0(-1,2)	0(-4,3)	0.012	0.018	0.253	0.012
Subjective (episode/24h)							
Urgency	-10.15 (-16.0)	-3 (-12,-0.1)	-1.3 (-10.5,2)	<0.001	0.003	0.013	<0.001
Frequency	-3.0(-14,0.5)	-2.15(-12.8,2.3)	-0.75(-6.5,2.3)	.002	0.295	0.010	0.001
Nocturia	-0.8 (-6.5, 0.4)	0 (-2,1)	0 (-1.5,2)	0.002	0.015	0.144	0.001
Urinary incontinence	0 (-2,2)	0 (-1,1)	0 (-2,1)	0.413			

The Kruskal-Wallis test and the Mann-Whitney test were used for comparison among 3 groups and pairwise comparison, respectively. ES: electric stimulation, †: oxybutynin, ‡: placebo.
*: The change denotes the measurement after treatment minus that before treatment.

Interpretation of results
Urinary urgency can cause a decrease in voided volume (VV) through increased urinary frequency. Hence, treatments such as ES or oxybutynin which can alleviate the severity of urgency may improve VV. Our data indicates that the maximal voided volume (MVV) recorded in the voiding diary for both active treatment groups was significantly increased after treatment. However, the difference between ES and oxybutynin was not significant. The greater difference of MVV (in voiding diary) was noted between oxybutynin and placebo (p=0.011, Table). For volume voided (in uroflowmetry) the greater difference was seen between ES and placebo (p=0.013, Mann-Whitney test).

Concluding message

ES had the greatest subjective outcome for OAB and was the most effective of the three treatments. Oxybutynin was more effective than placebo.

FUNDING: **National Science Council, Taiwan**
DISCLOSURES: **NONE**
CLINICAL TRIAL REGISTRATION: **Chang Gung Memorial Hospital IRB No.92-607**
HUMAN SUBJECTS: **This study was approved by the Chang Gung Memorial Hospital IRB No.92-607 and followed the Declaration of Helsinki Informed consent was obtained from the patients.**