

496 Abstracts

event. This concept that prop. only induces an increase of residual urine in infravesical obstruction, e.g. in BPH or reflex incontinence associated with DSD, or in reduced detrusor contractility must be investigated further.

- [1] Madersbacher et al. BJU 1999; 84: 646-651
- [2] Saito et al. Jap J Urol Surg 1999; 12: 525-536
- [3] Stöhrer et al. Spinal Cord 1999; 37: 196-200
- [4] Tsuchida et al. Acta urol jap 1990; 36: 915-919

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92

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Title (type in CAPITAL LETTERS, leave one blank line before the text):

EFFICACY OF EXTRAMURAL PHYSICAL THERAPY MODALITIES IN WOMEN WITH PROVEN BLADDER OVERACTIVITY: A RANDOMIZED CLINICAL TRIAL

Aims of Study

The symptoms of bladder overactivity consist of urgency, frequency, nocturia and/or urge incontinence. The underlying etiology is still only partially understood. In this study bladder overactivity is perceived as a dysfunction of the bladder in which a subject has no or decreased control over sudden contractions of the detrusor muscle, so that this leads to premature passage of urine [1]. To guarantee homogeneity of the study population a tool was found in the application of ambulatory urodynamics. The Detrusor Activity Index (DAI), based on ambulatory urodynamics, uses results of extramural ambulatory cystometry to quantify detrusor activity during several consecutive filling phases [2]. The aim of this study is to assess the efficacy of lower urinary tract exercises (LUTE) and functional electrostimulation (FES) in women with proven bladder overactivity ($DAI \geq 0.5$).

Methods

In a single blind randomized clinical trial with four arms we studied the efficacy of three treatment modalities, i.e. LUTE (group 1), office and home based FES (group 2) and office based FES and LUTE (group 3) versus a no-treatment group (group 4). During a 2-week qualification period inclusion and exclusion criteria were checked, medical history was taken, a micturition diary combined with pad test was obtained and, finally, ambulatory urodynamics according to ICS standards [3] were performed. The data at the end of this period established baseline values. After the qualification period each patient of groups 1-3 received 9 treatment sessions, once a week. LUTE consisted of patient information, bladder training, specific pelvic floor muscle exercises (PFME) and toilet behavior. FES was applied vaginally with a stochastic electrical current between 4 and 10 Hz, at maximal tolerable level. A portable microprocessor controlled system, the ProUrge system (Innocept Medizintechnik Inc, Gladbeck, Germany) was used. In this study the DAI was the principal effect parameter. The ambulatory urodynamics were taken before randomization and at the end of the study period (within 14 days). Subjective outcome was measured by the Incontinence Impact Questionnaire (IIQ-7) [4]. This was done twice identically, after the first ambulatory investigation and at the end of the study period (within 14 days).

Results

Out of a total of 83 patients with symptoms of urgency and frequency, indicative for an overactive bladder, 71 patients had pre and post-treatment DAI values; from these, a subgroup of 57 randomized patients, mean age 55.2 (sd. 13.5) with $DAI \geq 0.5$, were considered as having *proven* bladder overactivity and were evaluated. Baseline characteristics (see Table 1), based on standardized medical history and baseline values of outcome parameters showed no statistical differences between groups. In repeated measures ANCOVA of DAI-score differences between pre- and post-treatment conditions overall differences over therapy groups were not statistically significant ($F=2.28$ by 3 and 52 df; $p=0.090$) (see Table 2). ANOVA of IIQ-7-score differences between pre- and post treatment conditions showed no statistical overall differences over therapy groups ($F=1.10$ by 3 and 48 df; $p=0.358$).

Conclusions

Our results do not show overall significance. A plausible explanation for this result appears to be a power problem. Since $p_{\text{overall}} = 0.090$ is not significant we performed a sensitivity analysis (see Figure) and we inspected the specific differences between groups. Ensuing power analysis, in a design with only two arms (control vs. FES) showed that with 20 patients in each arm we might have reached statistical significance and that a strong treatment effect (standardized effect = 0.80, power=0.80) on bladder overactivity in group 2 (FES) would have been reached. This is the first study in which a homogeneous study population was established and efficacy was measured quantitatively, indicating a large effect of intravaginal FES in women with proven bladder overactivity.

Table 1: Comparison of Baseline Characteristics (T=0, N=57)

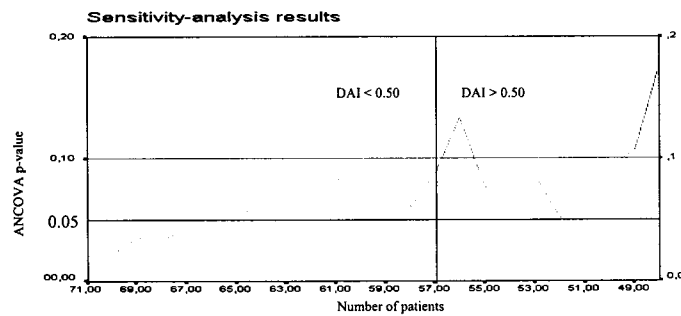
	Controls	LUTE	FES	Combination
Padtest MUDO in ml. mean (sd) N	65 (87) 14	62 (93) 13	120 (225) 14	113 (170) 16
Frequency voidings / hrs mean (sd) N	1.28 (0.52) 14	1.33 (0.57) 13	1.19 (0.56) 14	1.06 (0.46) 16
Volume / voiding (ml) mean (sd) N	144 (74) 14	143 (59) 13	131 (66) 14	105 (52) 16
Dai-1 mean (sd) N	0.853 (0.145) 14	0.843 (0.164) 13	0.841 (0.180) 14	0.865 (0.165) 16
IIQ-7 mean (sd) N	0.77 (0.74) 14	0.99 (0.75) 13	0.91 (0.69) 13	0.61 (0.58) 14

No significant differences between groups on baseline characteristics were found

Table 2: Statistical characteristics / results dai and difference of dai (N = 57/ dai pre \geq 0.50)

Egroup	DAI pre-means	Sd	DAI post-means	Sd	diff.dai	sd
Control	0,853	0,145	0,795	0,255	0.058	0.188
LUTE	0,843	0,164	0,622	0,389	0.221	0.370
FES	0,841	0,180	0,567	0,370	0.274	0.354
Combination	0,865	0,165	0,830	0,292	0.035	0.261
Total:	0,851	0,160	0,709	0,339	0.142	0.310

Figure:



References:

1. BJU, vol. 83, Suppl. 2., 1999: p. 16-21
2. Neurorol Urodyn, vol. 19, 2000: p. 113-125
3. J Urol, vol. 157, 1997: p. 596-599
4. Neurorol Urodyn, vol. 14, 1995: p. 131-139