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REHABILITATION VS DRUG THERAPY FOR URGE URINARY INCONTINENCE, THE SHORT AND THE LONG TERM OUTCOME.

Hypothesis / aims of study

Urge Urinary Incontinence (UUI) is the complaint of involuntary urine leakage accompanied by or immediately preceded by urgency. Clinical experience has shown that an overactive bladder (OAB) with associated UUI is not amenable to surgical correction. Pharmaceutical agents and conservative therapy remain the main management, but there is little evidence available about long-term outcome with these treatments, including its effect on Quality of Life (QoL).
In the report from the Pelvic Floor Clinical Assessment Group of the International Continence Society (ICS), urgency, frequency and UUI are symptoms that are associated with pelvic floor muscle dysfunction. According to ICS standards, lower urinary tract rehabilitation includes pelvic floor muscle training (PFMT), biofeedback and behavioral modification to treat maladaptive voiding patterns. PFMT is the most commonly used physical therapy treatment for women with Stress UI. It is sometimes recommended for mixed UI but less commonly than in UUI.
The aim of the study was to compare the short and long term effectiveness of pelvic floor rehabilitation treatment, with a standard drug treatment for UUI.

Study design, materials and methods

Parallel clinical trial was maid between 2004-2006, to compeer Pelvic Floor Rehabilitation (REH) treatment with Medication (MED) treatment. Forty four female patients who suffered from UUI and idiopathic Detrusor overactivity, were assigned to either a REH group (REH) (N=24, age 54.5±9.7) or a MED group (N=20, age 56.8±8). The REH group included five meetings, for patient's education of skills and strategies for preventing incontinence and provided with instructions for daily home practice, including pelvic floor muscles training. The MED group received an anticholinergic agent 5mg/day (oxybutynin ER). The study included four measurement phases, including study entry, treatment discharge at 3 months (REH or MED) and follow up at 3 months and 18 months after completion of treatment (period 6 and 21 months).
Patients were asked to complete a voiding questionnaire including the number of incontinence episodes experienced in a week (Inco/week), frequency of voiding per day (Freq/day), and frequency of voiding per night (Freq/ night). Patients were asked about adverse events throughout the program. Quality of life (QoL) was assessed using the Incontinence QoL Instrument (I-QoL).
Treatment effect on outcome measurements was analyzed using a repeated measure ANOVA model with a between subjects factor of group (REH vs MED), and a within subject factor of time (entry, 3, 6 and 21 months).

Results

At baseline, subjects had a mean of 10±3.5 Freq/day, 2.5±1.2 Freq/night and 10±13.5 episodes of Inco/week. The most common adverse event at entry time was dry mouth (86.3%) and fatigue (54.5%),
In the within group comparison, both groups had improved significantly over time, for both urinary symptoms and I-QoL ($p<0.01$). There was a significant group-time interaction effect on Freq/day. While REH improved during the 6 months period, the MED deteriorated to mean baseline value ($p<0.01$), the situation was left over 21 months. The number of adverse events was significantly fewer in the REH compared to MED at 6 and 21 months ($p=0.05$).
A significant negative association was found between the urinary symptoms and the I-QoL at 6 months and at the 21 month follow-up. (r_p=-0.45 to-0.57, $p<0.05$, -0.35 to-0.62, $p<0.05$, respectively).

Interpretation of results

This study presents several important findings. Most significantly, we found that women who were treated with a relatively brief rehabilitation intervention were able to continue to benefit from the skills they acquired. They either maintained their gains or further improved upon them, with decreasing urinary frequency during the day and night. In contrast, the medically treated group returned to baseline status, while showing more side effects than the rehabilitation group. The urinary frequency impacted the subjects' quality of life, particularly in relation to nocturnal urinary frequency
The mechanism by which rehabilitation training produced long-term improvement is unclear. One explanation is that PFMT increases muscle strength and tolerance. It is also possible that the improvements seen in the rehabilitation programs can be attributable to as of yet unmeasurable physiologic effects. Possible psychological effects associated with peer support within the program may induce patient empowerment, or improve coping skills.
The higher rates of adverse events in both groups at study entry may occur when incontinent women restricted fluid intake. The higher rates of adverse events in the MED group during the follow-up period may occur when restricting fluid intake even without the drug, often implemented in order to prevent incontinence episodes.
A significant negative relationship was found between urinary Freq/ night, and QoL at each stage of the program, while a moderate negative correlation between Inco/week and QoL at the end of intervention and during the follow-up period. Most researchers investigate treatment for UUI in terms of incontinence episodes and micturitions in 24 hours, but in our opinion, nocturnal awaking is of greater importance, especially in the elderly population.

Concluding message

This study shows that UUI patients, who were provided specific rehabilitative therapy, were maintained and even improved symptomatically, 21 months beyond the intervention period. We support the findings of other studies that pelvic floor rehabilitation,

provided by knowledgeable physiotherapists, can teach and motivate patients to change their behavior to reduce their symptoms and improve their QoL.

References
1. Int Urogynecol J (2007) 18:407-411
2. Int Urogynecol J (2008) 19:47-52

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**This study was approved by the Ethics committee of the Assaf Harofeh Medical Center, 54/03 (22/7/03)**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**This study was approved by the Ethics committee of the Assaf Harofeh Medical Center and followed the Declaration of Helsinki informed consent was obtained from the patients.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**