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SIDE EFFECTS, FEASIBILITY AND ADHERENCE TO TREATMENT DURING HOME-MANAGED ELECTRICAL STIMULATION FOR URINARY INCONTINENCE. A NORWEGIAN NATIONAL COHORT OF 3198 WOMEN.

Aims of Study
Our objective was to analyse side effects, feasibility and adherence to treatment during home-managed electrical stimulation for urinary incontinence in women.

Methods
This was a prospective cohort study of all women treated with home-managed electrical stimulation in Norway 1992-1994. Data were collected from both patients and physicians by questionnaires before and after treatment. Of the 3198 women, 151 did not have incontinence of urge, stress, or mixed type. These were not included in the analyses. In addition, 15 women did not start treatment because of severe illness or death, and 24 did not complete the treatment because of pregnancy or cancer. After exclusions of these patients, 3008 women with urinary incontinence remained in the study. The median age was 51 years (mean 53,SD 14), and the range was 14 to 95 years.

We have complete baseline informations for all the women (100%), 2720 patients (90%) returned the first questionnaire, and 2164 (72%) the second; 2092 (70%) answered both questionnaires. The physicians returned questionnaires after treatment for 2191 patients (73%). Physicians or patients returned questionnaires for 2602 (87%).The patients were treated for stress incontinence (45%), urge incontinence (16%) and mixed incontinence (39%). Of the 3008 patients, 47% were treated by short-term maximal (low-frequency) and 53% by long-term (high frequency) electrical stimulation. Two patients were treated with both short and long-term stimulation.

Results
The majority of the patients (89%) found the stimulator easy or acceptable to use. Severe practical problems were infrequent regardless type of stimulator, but users of maximal stimulators reported fewer practical problems than users of long-term stimulators ($p< 0.001$).

Half of the patients (50%) had no or little discomfort from stimulator use, whereas 9% found the stimulator very unpleasant, difficult or impossible to use.

Patients with good treatment effects (cured/ much better) had fewer practical problems (96% versus 82% easy or acceptable to use, $p<0.001$), and less discomfort than the rest (66% versus 41% no or little discomfort, $p<0.001$).

Half of the patients (51%) claimed to have had one or more side effects related to the treatment, most of them mild. A wide range of side effects were reported, the majority related to local discomfort (table I).

Twenty-four patients did not start treatment because they changed their mind, had other diseases, or for unknown reasons. Altogether 306 patients (12%) discontinued treatment (before 1 month for the maximal stimulator and before 3 months for the long-term stimulator). Users of long-term stimulator discontinued the treatment more often than maximal stimulator users (17% versus 6%, $p< 0.001$).

A total of 79% of the patients recommended the treatment to other women with similar problems.

TABLE I. Side effects of treatment with electrical stimulation.

	Total n=2164		Long-term-stimulator n=1105#		Maximal stimulator n=1061#		
	n	%	n	%	n	%	
Soreness/local irritation	565	26	294	27	271	26	
Pain	432	20	166	15	266	25	***
Psychological distress ##	155	7	88	8	67	6	
Side effects specified in open ended question:							
Uncomfortable stimulator- introduction and removal	89	4	77	7	12	1	
Electrically induced discomfort	83	4	52	5	31	3	
Sleep disturbance	57	3	57	5	0	0	
General symptoms	23	1	13	1	10	1	
Intestinal symptoms	22	1	12	1	10	1	
Sexual impairment	8	<1	8	1	0	0	
Other	10	<1	6	1	4	<1	
Patients with one or more side effects	1108	51	561	51	547	52	

Two patients used both maximal and long-term stimulator.
These 155 (7%) patients stated that the treatment induced some psychological distress, anxiety for electrical effects, low motivation for stimulation or other psychological effects
*** Statistical significance between stimulator types, P<0.001 (chi-square tests)

Conclusions

Home-managed electrical stimulation was practicable and well accepted. Half of the patients reported various degrees of side effects with treatment, but no serious events were reported.