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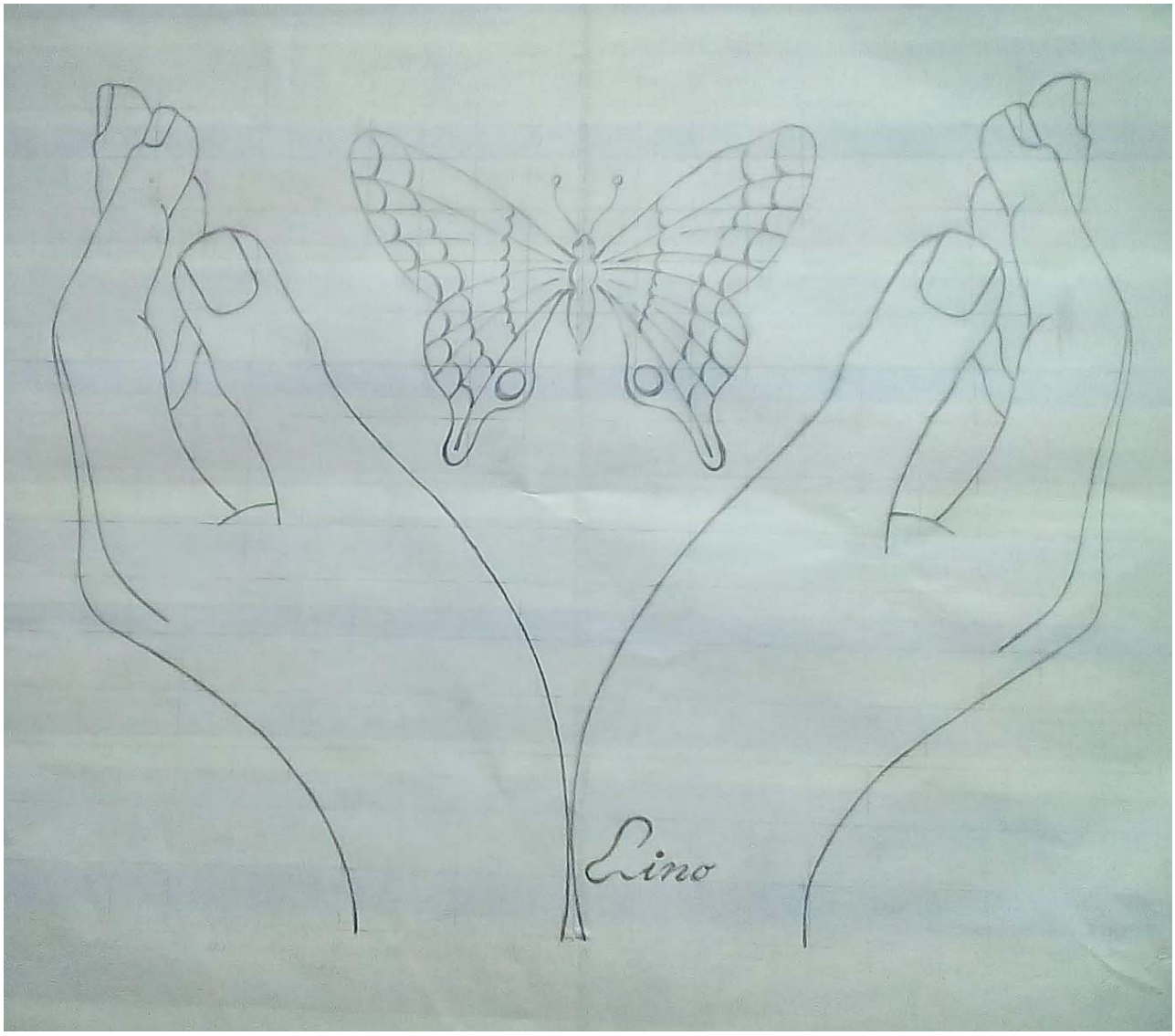

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The treatment of urinary incontinence: a valid non-pharmacological alternative.

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KEY-WORDS: non-pharmacological treatment, urinary incontinence, urge incontinence, stress incontinence, situational incontinence.

ABSTRACT

BACKGROUND: Urinary incontinence is a very frequent clinical condition in the adult and elderly population. some cases of incontinence become manifest after childbirth. These clinical conditions linked with minimal o severe urinary incontinence can be either transient or chronic conditions that affect the patient's quality of life for many years. **AIM:** the aim of the present study is to evaluate the efficacy of non-pharmacological treatment of urinary incontinence through the use of percutaneous electrostimulation. **MATERIALS and METHODS**: In order to evaluate the efficacy of electro-stimulation as a non-pharmacological treatment of urinary incontinence we currently enrolled 12 patients in our study (5 men and 7 women with an average age of 70 years old and a standard deviation of 11,2 years old). All enrolled patients accepted the enrolment criteria and provided informed consent for the treatment of health data. In accordance with the 2020 guidelines for urinary incontinence, all enrolled subjects underwent anamnestic and clinical evaluation. After the initial clinical evaluation, the ICIQ-SF (International Consultation on Incontinence Questionnaire-Short Form) was proposed to the evaluation of urinary incontinence. All enrolled subjects in the present study underwent 7 days of treatment with electro-stimulation as reported in the scheme attached to the table. At the end of the treatment a second administration of the ICIQ-SF test was performed. **RESULTS:** the results of the treatment, evaluated using ICIQ-SF scale, appear to be statistically significant ($P < 0,001$) in all the items (Tab. 2). The outpatient follow-up allows us to establish the times and methods for any new treatment cycles in order to individualize the non-pharmacological therapy of subjects suffering from urinary incontinence, highlighting unnecessary excesses of treatment which, even if without side effects, would still go to impact on the quality of life of the subjects who have to go to the clinic and the care-givers who have to accompany them. **DISCUSSION:** Based on the data relating to the ICIQ-SF questionnaire and the

experiences reported by patients, the treatment of urinary incontinence represents a valid alternative to reduce or eliminate the discomfort due to urinary incontinence, especially in the older age group which often presents, significant psycho-physical limitations such as to make impossible a rehabilitation treatment that requires the direct participation of the subject in the execution of rehabilitation exercises. **CONCLUSION**: Our experience has allowed us to treat all age groups of the sample of subjects belonging to our Geriatrics clinic. the only reason for exclusion from the study was the presence of contraindications to the use of the electrostimulator as shown in the table.

LIMITS of the study: The only limitations of the study are related to the presence of contraindications to the use of the electro-stimulator (Table 2).

Background: Urinary incontinence is a very frequent clinical condition in the adult and elderly population. Some cases of incontinence become manifest after childbirth. These clinical conditions linked with minimal o severe urinary incontinence can be either transient or chronic conditions that affect the patient's quality of life for many years. Urinary incontinence can be classified as follow:

1) Urge incontinence: if the condition is due to an overactive bladder;
2) Stress incontinence: if the condition is due to intrinsic sphincter deficiency for a poorly functioning urethral sphincter muscle or to hypermobility of the bladder neck / urethra;
3) Overflow incontinence: if the condition is due to either poor bladder contraction or blockage of the urethra;
4) Mixed incontinence: if the condition presents combined features of the various types.

The possible treatments include pelvic floor muscle training, bladder training, surgery, and electrical stimulation. Behavioural therapy generally works better than medication for stress and urge incontinence. The benefit of medications is small and long term safety is unclear. Urinary incontinence is more common in older women.

Aim: the aim of the present study is to evaluate the efficacy of non-pharmacological treatment of urinary incontinence through the use of percutaneous electrostimulation. The study began in September 2021.

Materials and Methods: In order to evaluate the efficacy of electro-stimulation as a non-pharmacological treatment of urinary incontinence, at this moment, we enrolled 12 patients in our study (5 men and 7 women with an average age of 70 years old and a standard deviation of 11,2 years old).

Study design: All enrolled patients accepted the enrolment criteria and provided informed consent for the treatment of health data.

Study patients: The exclusion criteria were: 1) pacemakers or defibrillators, 2) subjects suffering from neuro-muscular diseases; 3) subjects suffering from oncological pathology in

the pelvic area; 4) subjects suffering from epilepsy; 5) subjects suffering from urinary infections in the absence of antibiotic treatment. All enrolled subjects in the present study underwent 7 days of treatment with electro-stimulation as reported in the scheme attached to the table. At the end of the treatment a second administration of the ICIQ-SF test was performed.

Study procedures: In accordance with the 2020 guidelines for urinary incontinence, all enrolled subjects underwent anamnestic and clinical evaluation. After the initial clinical evaluation, the ICIQ-SF (International Consultation on Incontinence Questionnaire-Short Form) was proposed to the evaluation of urinary incontinence. According to the indications of the user manual of the electrostimulator, the subjects enrolled were treated with the P1 electrostimulation program in case of prevalence of urge incontinence (Tab. 1) and with the P3 electrostimulation program in case of prevalence of stress incontinence (Tab. 1). Patients who had no unacceptable side effects of the target dose of the electrostimulation (2-8 mA) were assigned to the study group. Patients were evaluated during the first day and after 7 days.

Study outcome: The primary outcome of the study is the evaluation of the variation from the baseline to 7 days of the score of the ICIQ-SF questionnaire for urinary incontinence evaluation in patients treated with percutaneous electrostimulation (in a scale from 0 to 19, with lower scores indicating fewer symptoms and physical limitations associated with urinary incontinence).

Statistical analysis: We used Paired T-test to compare the data before and after treatment in small groups (12 patients).

Results: the results after the treatment with percutaneous electrostimulation appear to be statistically significant. The outpatient follow-up allows us not only to establish the times and methods for any new treatment cycles - in order to individualize the non-pharmacological therapy of subjects suffering from urinary incontinence - but also highlight unnecessary excesses of treatment which, even if without side effects, could still impact the quality of life of those subjects who require periodical medical check-ups and their care-givers.

Study patients: All enrolled subjects in the present study underwent 7 days of treatment with electro-stimulation as reported in the scheme attached to the table. At the end of the treatment a second administration of the ICIQ-SF test was performed. None side effects are declared after treatment.

Study drug administration and follow-up: Except for discontinuations owing to death, the study drugs was discontinued in 2 patients due to low compliance to the treatment for dementia and 1 patient for prostatic cancer. The median duration of follow-up was 7 $\pm$ 1 days. This value was related to the clinical conditions and the presence of the criteria for treatment of the urinary incontinence using percutaneous electrostimulation protocols.

Study outcome: The mean change from baseline in the ICIQ-SF score was a statistically significative reduction after the treatment (Fig. 1-4).

Safety: The treatment is effective and well-tolerated when used in routine clinical practice. 4 patients did not start the study medication and were excluded from the safety analyses because during the run-in period they showed low compliance (2 patients), or they were affected by dementia (1 patients) or prostatic cancer (1 patient).

Discussion: Based on the data relating to the ICIQ-SF questionnaire and the experiences reported by patients, the treatment of urinary incontinence represents a valid alternative to reduce or eliminate the discomfort caused by the condition, especially in the older age group which often presents significant psycho-physical limitations so as to prevent any rehabilitation treatment that requires the cooperation and the direct participation of the subject.

Conclusion: Our experience has allowed us to treat all age groups of the sample of subjects belonging to our Geriatrics clinic. The only reason for exclusion from the study was the presence of contraindications to the use of the electrostimulator as: 1) pacemakers or defibrillators, 2) subjects suffering from neuro-muscular diseases; 3) subjects suffering from oncological pathology in the pelvic area; 4) subjects suffering from epilepsy; 5) subjects suffering from urinary infections in the absence of antibiotic treatment. Our study was designed to provide evidence to support the efficacy of the percutaneous electrostimulatio as non-pharmacological treatment in the management of patients with urinary incontinence. Data show that the treatment with electrostimulation improves the quality of life by reducing the degree of urinary incontinence. Therefore, the percutaneous electrostimulation can be a valid treatment, especially in elderly people with comorbidity for rehabilitation programs (Fig. 1-4). This experience led us to use percutanoeus electrostimulation in older patients with urinary incontinence respecting the exclusion criteria for the treatment as reported. Other studies are in progress to evaluate the neurovegetative effects of percutaneous electrostimulation as treatment for urinary incontinence. The treatment is efficacy and well-tolerated when used in routine clinical or home rehabilitation programs. Our data give comfortable results but further evaluations are needed to extend the data gathered in a small group of Italian patients to the general population and give a conclusive results.

LIMITATIONS OF THE STUDY: The only limitations of the study are related to the presence of contraindications to the use of the electro-stimulator as: (1) pacemakers or defibrillators, 2) subjects suffering from neuro-muscular diseases; 3) subjects suffering from oncological pathology in the pelvic area; 4) subjects suffering from epilepsy; 5) subjects

suffering from urinary infections in the absence of antibiotic treatment.

Conflict of Interest: none declared

TABLES

Programme	Programme mode	Wave form	Treatment time mode (min)	Frequency (Hz	Pulse width (μs)	Total treatment time (min)	Applies in the following incontinence type
P1	1	Synchronous (SY)	8	35	220	28	Urge incontinence
	2		20	10	240		
P2	1	Alternating(AL)	5	3	250	27	Mixed /faecal incontinence
	2		6	10	220		
	3		6	20	220		
	4		5	35	200		
	5		5	10	220		
P3	1	Pulse width modulation	5	20	300-450	15	Stress incontinence
	2	Modulation	5	3-35	175-275		
	3	Continuous	5	50	220		
P4	1	Continuous	8	10	240	25	Mixed /faecal incontinence
	2	Synchronous (SY)	12	20	275		
	3		5	35	200		
P5	1	Synchronous (SY)	20	10	240	38	Urge incontinence
	2		10	20	275		
	3		8	35	220		

Tab. 1: technical characteristics of the percutaneous electrostimulation protocols used in the study.

	Control ± DS	Effect ± DS	Probability (P)
ICIQ- SF (tot)	15,900 ± 2,807	1 ± 0	< 0,001
ICIQ- SF (sez. 1)	1,900 ± 0,876	0 ± 0	< 0,001
ICIQ-SF (sez. 2)	5,000 ± 1,054	0 ± 0	< 0,001
ICIQ-SF (sez. 3)	9,000 ± 1,700	1 ± 0	< 0,001

Tab. 2 Descriptive statistics about the ICIQ-SF score in patients with urinary incontinence treated with percutaneous electrostimulation. Data are expressed as mean ± Standard Deviation.

FIGURES

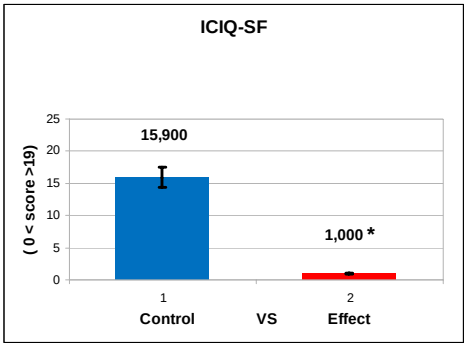

Fig 1. Graphical representation of the main value of the ICIQ-SF score in patients with urinary incontinence treated with percutaneous electrostimulation. Data are expressed as mean ± Standard Deviation.

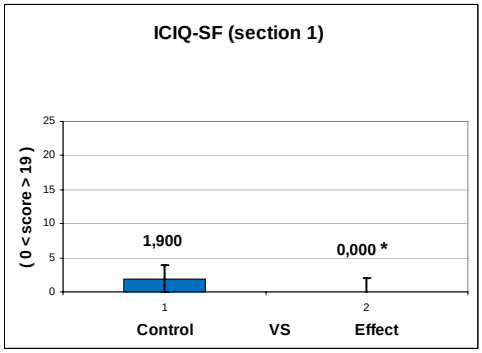

Fig. 2 Graphical representation of the main value of the ICIQ-SF score (section 1) in patients with urinary incontinence treated with percutaneous electrostimulation. Data are expressed as mean ± Standard Deviation.

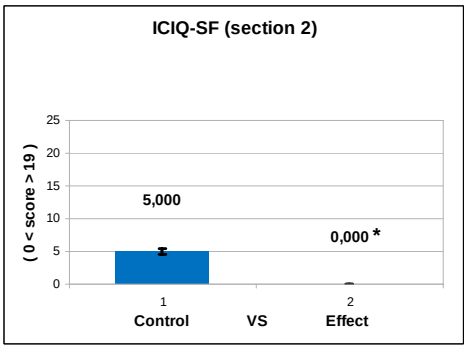

Fig 3. Graphical representation of the main value of the ICIQ-SF score (section 2) in patients with urinary incontinence treated with percutaneous electrostimulation. Data are expressed as mean ± Standard Deviation.

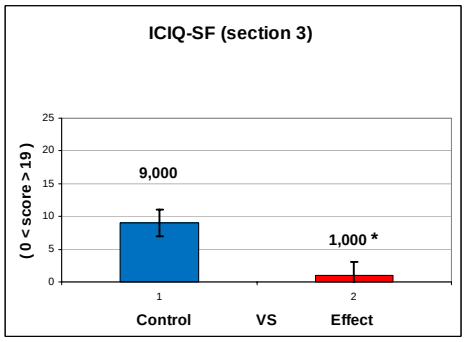

Fig. 4 Graphical representation of the main value of the ICIQ-SF score (section 3) in patients with urinary incontinence treated with percutaneous electrostimulation. Data are expressed as mean ± Standard Deviation.

Reference:

1) Cacciari LP, Dumoulin C, Hay-Smith EJ. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women: a cochrane systematic review abridged republication. Braz J Phys Ther. 2019 Mar-Apr;23(2):93-107.

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