



A Comparative Study of Two Electrostimulation Devices in The Treatment of Overactive Bladder in Women

BLONDELLE Pascal ^{1*}, WOLFF Benoît ², RENARD Olivier ², WALLERAND Hervé ², POULAIN Jean-Eudes ², POUSSOT Dominique ², ALLARD Philippe ², VIGOUROUX Vincent ².

1. Physiotherapist Pelvi-Sphincteric Rehabilitation and Evaluation Unit New Bel Air Clinic, 138 avenue de la République 33073 Bordeaux, France.

2. Urologist Urology Department New Bel Air Clinic, 138 avenue de la République 33073 Bordeaux, France.

Corresponding Author: BLONDELLE Pascal, Physiotherapist Pelvi-Sphincteric Rehabilitation and Evaluation Unit New Bel Air Clinic, 138 avenue de la République 33073 Bordeaux, France.

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Abstract

Overactive bladder (OAB) is defined by the International Continence Society as urinary urgency, with or without frequency and nocturia, with or without urgency urinary incontinence (SUI), in the absence of urinary tract infection or other obvious pathology. SUI is a prevalent condition among women and negatively affects their quality of life (QoL). The aim of this study was assessed the effect of tibial nerve stimulation (TNS) compare with abdominis-perineal stimulation in the treatment of SUI every day for 2 months. QoL was assessed through DITROVIE Questionnaire. Data was collected pre-, post-treatment. These assesments included a OAB USP® score, a perineal-respiratory asynchrony test and a pelvic floor muscles (PFM) measurement.

Course of the treatment with the two medical devices significantly improved QoL (-1 to -2 points) of all women, as well as the USP® score (+60 to +89%). We observe a significant improvement in the correction of abdominal-respiratory asynchrony (-16 to -92%) and in PFM contraction (+3 to +16%) particularly for the Uro-MG group.

Results suggest that Uro stim 2® is effective as a passive neurological stimulation therapy. On the over hand, Uro-MG® is an efficacious therapy for treatment of SUI both as a stimulator and as an expiratory biofeedback creating a Mahony reflex 3 type.

Keywords: *urge – electrostimulation – biofeedback – expiratory – tibial nerve stimulation – perineal muscles – abdominal muscles*

Abbreviations:

SUI: Stress Urinary Incontinence

QoL: Quality of life

DC flow: Direct Current Flow

PFM: Pelvic Floor Muscles

OAB: Overactive Bladder

TNS: Tibial Nerve Stimulation

Introduction

OAB characterizes the bladder immaturity syndrome, the functional symptoms of which are characterized by frequent and urgent needs, sometimes associated with diurnal and nocturnal loss of urine (1). The consequences of these hyper pressures will be repeated urinary tract infections, trabeculations typical of a struggling bladder, and sometimes even small intermittent reflux (2). So-called first-line treatment mainly includes medical treatment, essentially pharmacological, targeting the efferent and afferent side of the voiding reflex, with the use of oral antimuscarinic anticholinergics (oxybutynin) as a reference (3), associated with behavioral measures and lifestyle and dietetics, as well as pelvic-perineal rehabilitation (4). The latter will be proposed on functional instabilities, after elimination of any organic cause creating an irritative bladder spine (5). It is based on the use of electrostimulation, biofeedback and voiding calendar (6, 7, 8, 9). Through this study, we propose to analyze, in the context of the functional rehabilitation of overactive bladder in women, on a cohort of incontinent patients by urge (SIU), the effect of a perineal self-rehabilitation based on the use of either Posterior Tibial Nerve neurostimulation (TNS) or expiratory with abdominis-perineal electrostimulation with a Winner-Flow® tip.

Material and Method

Our study took place over a period of 9 months, from January to September 2021. We opted for self-rehabilitation at home for 2 consecutive months, with assessment and control at the start of self-rehabilitation, at the after four weeks (simple control), then at the end of treatment. Out of a population of 43 women, after an initial assessment consisting of a USP® incontinence score questionnaire (QoL) and a clinical examination, we retained 34 patients (79%), divided into two equal groups of 17 patients, “Uro-MG® Group” (ADTMed, Dijon, France) and “Uro stim 2® Group” (Schwa-Medico, Rouffach, France).

Nine women (21%) who did not present pure urgency incontinence but mixed (SUI + OAB) or who had medical treatment with anticholinergics were discarded.

Age: An average of 62 years (48-71)

Inclusion criteria: SUI. OAB. Menopausal woman or not.

Exclusion criteria: Pacemaker – Neuromodulation – Mixed urinary incontinence – treatment with anticholinergics.

After the initial assessment, we created two groups:

- 1- Uro-MG® group: 17 patients who were asked to perform two daily abdominis-perineal rehabilitation sessions (9) using a Uro-MG® stimulator (Mode 1. 100 Hz; 831 μ s; DC flow at expiration for the abdomen and Mode 2. 50 Hz; 831 μ s, DC flow at expiration for perineal muscles). (Fig. 1)
- 2- Uro stim 2® group: 17 patients who were asked to perform two daily TNS sessions (10) using a Uro Stim 2® stimulator (Program U3. 10 Hz; 210 μ s; DC flow). (Fig. 2)



Fig. 1 Uro-MG®



Fig. 2 UroStim 2®

The initial assessment included:

- A USP® overactive bladder urinary incontinence and DITROVIE® quality of life questionnaire.
- Cough measurement of the diaphragmatic pressure on the abdominis-perineal compartment (perineal-respiratory asynchrony) by ManoSpiro® sensor (ADTmed, Dijon, France) in supine position. (Fig. 3)
- A measurement of the perineal engagement at expiration induced by a contraction of the expiratory abdominal muscles (Transversus abdominis-Obliquus externus abdominis-Obliquus internus abdominis) over 10" by a 3D Manoscan® Medtronic anal probe (Medtronic France, Bièvres, France) (Fig. 4).



Fig. 3 Testeur ManoSpiro®

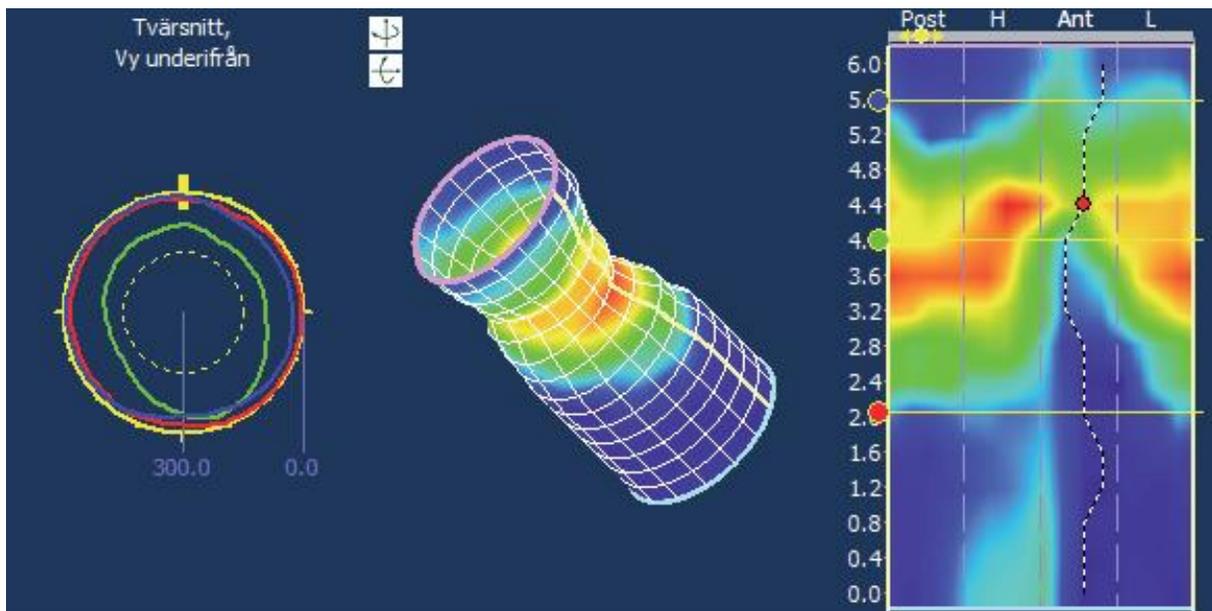


Fig. 4 Manoscan 3D

The final balance sheet included the same items for comparison.

The Uro-MG® group carried out two daily sessions distributed as follows:

- A morning session of abdominal electrostimulation triggered by exhalation in the Winner-Flow® tip and abdominal external bonded electrodes (3 series of 5 exhalations) in standing position (Fig.5).
- -An evening session of perineal electrostimulation always triggered by exhalation into the Winner-Flow® tip and a perineal electrode (3 series of 5 exhalations) in a lying position (Fig.6).

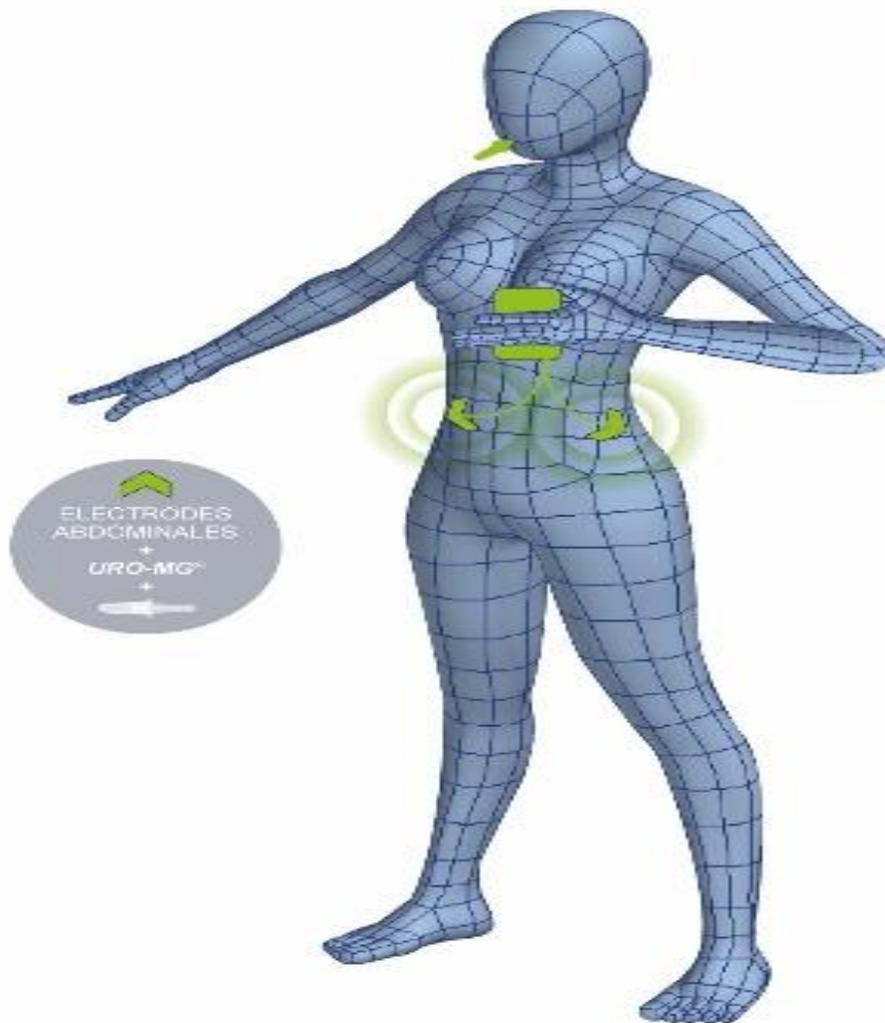


Fig. 5 Abdominal électrodes

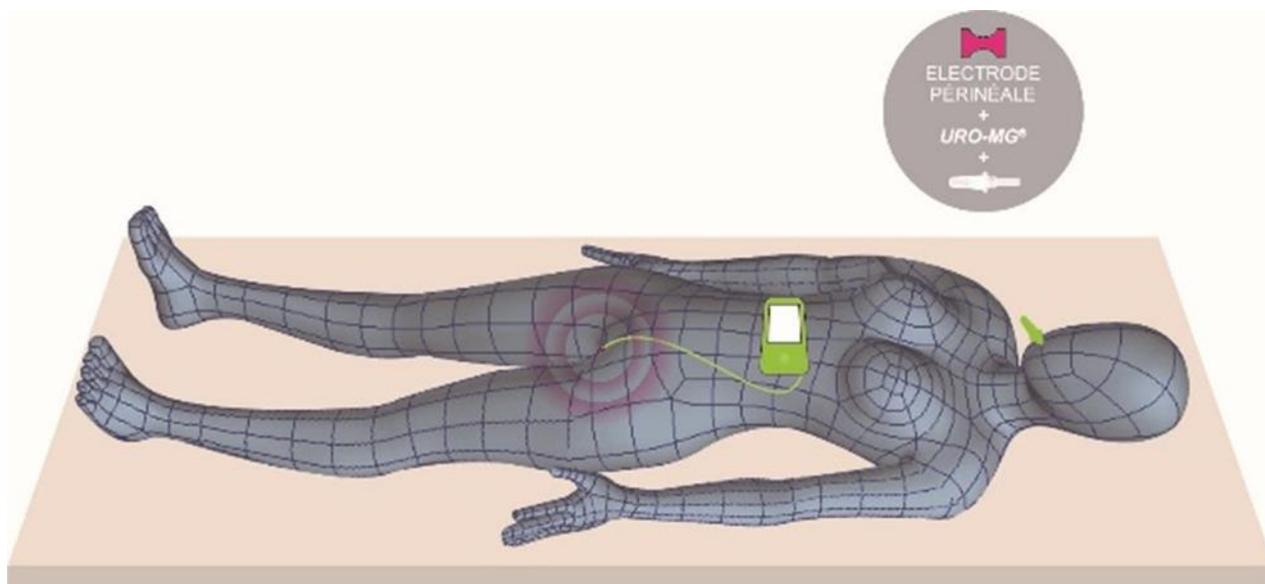


Fig. 6 Perineal electrodes

The Uro stim 2® group carried out two daily electrostimulation sessions lasting 20 minutes each, in morning and evening, at the level of the NTP by external bonded electrodes (Fig.7).



Fig. 7: NTP electrodes position

Explanations on the rehabilitation to be carried out and the methods of use, depending on the equipment, were given during the initial assessment.

The two devices used had the following characteristics:

- -Uro-MG®: electro stimulator delivering rectangular biphasic currents with zero average from 10 to 100 Hz for a single width of 831 μ s, at intensity between 0 and 80 mA. The chosen current is triggered at the abdominal or perineal level by the frequency of expiration, via a tip called Winner-Flow® (presenting resistance gauges allowing physiological regulated expiration) recorded by a microphone at the level of the electrostimulation unit. This device complies with European Class IIa “medical device” directives.
- -Uro Stim 2®: electro stimulator delivering continuous and intermittent frequencies between 1 and 120 Hz with pulse widths of 50 to 600 μ s, intensity ranging from 0 to 80 mA. Complies with Class IIa European “medical device” directives.

Results

At the initial assessment, we found:

1. Uro-MG® group:

- USP® score Overactive bladder of 15 (11-20)
- DITROVIE score of 4 (3-5)
- Abdominis-respiratory asynchrony of +854 mN (from + 638 to + 1029 mN for a physiological value \leq 0 min)
- Anoperineal contraction of 123 mmHg (90-175) (Table 1)

2. Uro Stim 2® group:

- USP® of 16 (12-20)
- DITROVIE score of 4 (2-5)
- Abdominis-respiratory asynchrony of +789 mN (from + 451 to + 1103 mN for a physiological value \leq 0 min)
- Anoperineal contraction of 127 mmHg (97-169) (Table 2)

At the final assessment, we found the following values:

1. Uro-MG® group:

- USP® score of 3 (0 -5)
- DITROVIE score of 2 (1-4)
- Abdominis-respiratory asynchrony of +61 mN (from - 12 to + 159 mN for a physiological value ≤ 0 min)
- Anoperineal contraction of 143mmHg (105-18) (Table 1)

2. Uro Stim 2® group:

- USP® Overactive Bladder score of 5 (4-13)
- DITROVIE score of 3 (1-5)
- Abdominis-respiratory asynchrony of +657 mN (from + 409 to + 913 mN for a physiological value ≤ 0 min)
- Anoperineal contraction of 131 mmHg (92-177) (Table 2)
-

We observed between the two assessments:

- A significant improvement in the USP® scores according to the two groups concerned, namely:
- Uro-MG® group down 12 points (80%) in the USP® score.
- Uro Stim 2® group down 11 points (69%) in the USP® score.
- A significant improvement in the DITROVIE score in both groups, respectively -2 and -1 points.
- A significant improvement in the correction of abdominal-respiratory asynchrony in the Uro-MG® group (-92%). This improvement is in the Uro Stim 2® group of -16%.
- An improvement in anoperineal contraction of +16% for the Uro-MG® group and +3% for the Uro Stim 2® group.

TABLE 1	InitialAssessment	Final Assessment	Gain
Uro-MG® Group			
USP Score	15 (11-20)	3 (0-5)	80%
DITROVIE	4 (3-5)	2 (1-4)	2 points
Abdomino-Respiratory Asynchrony	854 mN (de 638 à 1029)	61mN (de -12 à 159)	92%
Ano-périneal Contraction	123 mmHg (90 à 175)	143 mmHg (105 à 18)	1,16%

TABLE 2	Initial Assessment	Final Assessment	Gain
Uro Stim 2® Group			
USP Score	16 (12-20)	5 (4-13)	68%
DITROVIE	4 (2-5)	3 (1-5)	1 point
Abdomino-Respiratory Asynchrony	789 mmHg (451 à 1103)	657 mmHg (409-913)	16,00%
Ano-périneal Contraction	127 mmHg (97-169)	131 mmHg (97-177)	1,03%

Discussion

The purpose of our study was to highlight the electrostimulation well founded in urinary disorders such as an overactive bladder by using two proven electrical techniques, one by neurostimulation of the NTP and the other by abdominis-perineal electrostimulation with expiratory trigger.

We found that the two groups each presented significantly improved USP® scores for the pathology treated with significant differences of 80 and 69%, significantly greater in the Uro-MG® group.

The same was true for the DITROVIE score, which is a scale for assessing disruption of quality of life during voiding disorders, with an improvement difference of 2 and 1 point respectively.

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Abdominis-respiratory asynchrony is almost completely corrected in patients using the Uro-MG® device (-92%), compared to the group performing tibial neurostimulation (-16%). This very significant difference in the correction of abdominis-respiratory asynchrony between the two techniques is explained by the fact that:

- The Uro Stim 2® is an excito-motor and electrical analgesic stimulator with 2 separate galvanic channels of the constant current type whether or not delivering a current depending on whether it is switched on or off by the user. It is used as a neurostimulator at the level of the ankle on the posterior tibial afferent sciatic nerve. Its action is purely passive for the patient.
- The Uro-MG® is an electro stimulator whose currents are biphasic, symmetrical with zero average. It is distinguished by the fact that it delivers its currents to the stimulation block, using the patient's expiratory frequency, via the Winner-Flow® tip, as a trigger. The positioning of the cutaneous electrodes at the abdominal then perineal level, beyond the impact on urinary incontinence, has an impact on the perineum-abdominal-pharynx-buccinator expiratory chain, making it possible to correct the deleterious piston engagement of the diaphragm on the viscera and pelvic organs. This device is defined as an electrical cutaneous Biofeedback. The patient performs active-assisted biofeedback of the abdominis-perineo-pharyngeal plane. We see an interest in it in the treatment of overactive bladder. The user of the Uro-MG®, at the same time as she corrects the control's inversion of the abdominis-perineal physiology, engages in active work of the abdominal muscles (Transversus abdominis-Obliquus externus abdominis-Obliquus internus abdominis) versus the inspiratory muscles (diaphragm). It seems important to ventilate these patients in voluntary expiration and activation of the abdominal muscles, to obtain a synergistic contraction of their pelvic floor, allowing a detrusor's contraction inhibition of the Mahony reflex 3 type, reflex implemented in rehabilitation session and especially in self-rehabilitation, to allow patients to no longer be dependent on bladder volume.

It should be noted that no intolerance to currents has been reported, proving the harmlessness of the electrical stimulation delivered by both medical devices.

Conclusion

Our study is limited by the low recruitment of cases, the difficulty of the patients to talk about it spontaneously, the lack of medical history and the inclusion of a single practitioner specialized in perineal rehabilitation.

It shows all the same the interest of information on secondary pelvic-perineal affections in women but also very certainly in men. Despite this low level of recruitment, we have demonstrated that the simple and daily use of well-targeted electrostimulation in relation to the urinary pathology detected, improves

the daily life and the comfort of patients benefiting from self-rehabilitation. We noted the harmlessness of the two electro stimulators used for this study at the cutaneous level, in accordance with the European directives "medical devices" class IIa, making it possible to consider a self-rehabilitation treatment at home easily reproducible by the patient suffering from urinary disorders.

The clear advantage of the expiratory biofeedback type stimulation creating a Mahony reflex 3 type, suggests that we could design a study with a stimulator bringing together on two separate channels the characteristics of both a cutaneous biofeedback of the Uro-MG® and neurostimulation of the afferent nerve of the Uro Stim 2® type.

Declaration of conflicts of interest

The authors, during the last 5 years, has had no conflict of interest with the companies ADTMed and Schwa Medico.

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