

## EFFECT OF FUNCTIONAL TRAINING FOR THE PELVIC FLOOR MUSCLES WITH OR WITHOUT ELECTRICAL STIMULATION IN CASES OF URINARY INCONTINENCE FOLLOWING RADICAL PROSTATECTOMY

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### ABSTRACT

**Introduction:** Literature on physical therapy for the pelvic floor muscles to treat urinary incontinence following radical prostatectomy is scarce, with descriptions of differing techniques for physical therapy treatment. **Objective:** To evaluate the effect of physical therapy treatment for recovering urinary continence among patients who had undergone radical prostatectomy, by using functional training of the pelvic floor muscles with or without electrical stimulation. **Method:** Twenty patients with urinary incontinence following radical prostatectomy were selected. The patients were randomly allocated to a control or to an experimental group. The experimental group was composed of ten patients who received physical therapy treatment consisting of functional training of the pelvic floor muscles and electrical stimulation. The control group was composed of ten patients who received physical therapy treatment consisting only of functional training of the pelvic floor. All of the patients were re-evaluated three, six and twelve months after beginning treatment, by using the pad test, visual analog scale (VAS) for incontinence, VAS for the problem and counting the number of diapers (nappies) used. **Results:** There was a statistically significant decrease between the initial and 12<sup>th</sup> month evaluations of the pad test, VAS for incontinence, VAS for the problem and numbers of diapers of the control group and experimental group. However, no statistically significant difference was found when the same variable was compared between the two groups. **Conclusion:** There was no additional improvement from treatment with functional training of the pelvic floor muscles associated with electrical stimulation, in relation to treatment only using functional pelvic floor training. However, there was a significant improvement in urinary incontinence in both groups.

*Key words:* Radical prostatectomy; urinary incontinence; physiotherapeutic techniques; electrical stimulation therapy.

### RESUMO

#### **Efeito do treinamento funcional do assoalho pélvico associado ou não à eletroestimulação na incontinência urinária após prostatectomia radical**

**Introdução:** A literatura sobre fisioterapia do assoalho pélvico no tratamento da incontinência urinária após prostatectomia radical é escassa e relata técnicas diferentes de tratamento fisioterapêutico. **Objetivo:** Avaliar o efeito do tratamento fisioterapêutico na recuperação da continência urinária de pacientes submetidos a prostatectomia radical utilizando treinamento funcional do assoalho pélvico acompanhado ou não da eletroestimulação. **Método:** Foram selecionados 20 pacientes com incontinência urinária pós-prostatectomia radical. Os pacientes foram distribuídos ao acaso em grupos controle e de investigação. O grupo de investigação, composto por 10 pacientes, recebeu como tratamento fisioterapêutico o treinamento funcional do assoalho pélvico e a eletroestimulação. O grupo controle, composto por 10 pacientes, recebeu como tratamento fisioterapêutico o treinamento funcional do assoalho pélvico. Todos os pacientes foram reavaliados 3 meses, 6 meses e 12 meses após o início do tratamento por meio de “pad test”, Escala Visual Análoga (EVA) da incontinência, Escala Visual Análoga (EVA) do problema e número de fraldas utilizadas. **Resultados:** Houve diminuição estatisticamente significativa entre a avaliação inicial e o 12<sup>o</sup> mês do “pad test”, da EVA incontinência, da EVA problema e do número de fraldas no grupo controle e no grupo de investigação. Entretanto, não foi encontrada diferença estatisticamente significativa quando comparadas as mesmas variáveis entre os dois grupos. **Discussão e Conclusão:** Não houve melhora adicional no tratamento com treinamento funcional do assoalho pélvico associado à eletroestimulação quando comparado com o tratamento apenas com treinamento funcional do assoalho pélvico. Entretanto, nos dois grupos, houve melhora significativa da incontinência urinária.

*Palavras-chave:* prostatectomia radical; incontinência urinária; técnicas de fisioterapia; terapia por estimulação elétrica.

## INTRODUCTION

The International Continence Society (ICS) defines urinary incontinence as the complaint of any leakage of urine (involuntary release)<sup>1</sup>. In males, urinary incontinence (UI) is frequent after transurethral resection of the prostate (TRP) and radical prostatectomy, widely used in the treatment of prostate cancer<sup>2</sup>. Urinary incontinence frequency varies according to the type of surgery and the surgical technique, but tends to improve after one or two years<sup>3</sup>. However, some patients continue to have urinary incontinence. A urodynamic study revealed high incontinence frequency (87%) in patients after radical prostatectomy<sup>4</sup>. On the other hand, certain authors relate different frequencies, varying greatly from 0.5 to 87%<sup>5</sup>.

Urinary incontinence after radical prostatectomy is the consequence of sphincter lesions which make the geometry of the urethrovesical junction less favorable to maintaining urinary continence, resulting in greater demand from the external urethral sphincter<sup>6</sup>. With the removal of the prostatic urethra after surgery, the structure that maintains continence is the external sphincter<sup>7</sup>.

Urinary continence depends on the integrity of the internal sphincter in the vesical neck, on the passive urethral mechanism formed by the prostatic and the membranous segments, and on the external sphincter of the pelvic floors, which in turn depends on the integrity of striated muscle fibers, capable of rapid contractions, voluntary in nature and easily fatigued. The external sphincter is important in continence during sudden increases in intra-abdominal pressure<sup>2,8</sup>.

Incontinence after prostatectomy is a complication that is difficult to treat and causes a profound negative impact in the individual's quality of life, creating psychological problems such as anxiety, insomnia and depression, as well as complications like urinary tract infection, dermatitis, embarrassment, and it deeply affects the individual's self-esteem<sup>9,10,11</sup>. The recommended treatment for urinary incontinence after prostatectomy is physical therapy and includes training of pelvic floor muscles, the use of "biofeedback", functional electro-stimulation of the pelvic floor with endo-anal electrodes, transcutaneous electrical stimulation or a combination of these methods. The conservative treatment must be combined with lifestyle changes, such as reduction or elimination of caffeine and smoking, physical exercise and bladder muscle training. However, the efficacy of the various modalities of conservative treatment of urinary incontinence after prostatectomy is still controversial<sup>12</sup>.

Functional pelvic floor training is a specific pelvic floor contraction method aimed at improving urethral sphincter efficacy during periods of increase in intra-abdominal pressure<sup>12</sup>. Electro-stimulation, on the other

hand, aids periurethral striated muscle contraction by activating the sphincter and inhibiting the detrusor muscle<sup>13</sup>. Studies have shown the positive effect of functional pelvic floor training in patients with urinary incontinence after prostate surgery<sup>5,14</sup>. Electro-stimulation, on the other hand, can be used as the only therapy or a second treatment option, when other methods fail<sup>15,16</sup>.

A systematic review of the conservative treatment for urinary incontinence after prostatectomy analyzed 10 prospective, randomized controlled studies with 667 patients. The types of treatment consisted of functional pelvic floor training, "biofeedback" and electro-stimulation, either isolated or combined. The authors concluded that the various physical therapy treatments for urinary incontinence after prostatectomy seem controversial<sup>15</sup>.

The objective of the present study was to evaluate the effect of physical therapy treatment on patients with urinary incontinence after radical prostatectomy using functional pelvic floor training with or without electro-stimulation.

## METHODS

### Subjects

We assessed twenty patients with post-radical prostatectomy urinary incontinence that were attended at the Urology Clinic of Universidade Estadual de Campinas, between May 2003 and September 2004. The inclusion criteria were: adult patients submitted to radical prostatectomy who displayed urinary incontinence, with a minimum post-surgery period of six months and who had undergone a urodynamic test. Exclusion criteria were: current urinary infection, patients already submitted to incontinence correction surgery and patients fitted with a pacemaker of any kind.

The patients included in the study were randomly divided between control group and investigation group and were prospectively assessed. Two patients were excluded from the study because of urinary infection and one because he had already undergone urinary incontinence surgery. The investigation group (n= 10) received, as physical therapy treatment, the functional pelvic floor muscle training together with electro-stimulation. Four patients had urge urinary incontinence and 6 had stress urinary incontinence. The control group (n= 10) received, as physical therapy treatment, the functional pelvic floor muscle training. In this group, 5 patients had urge urinary incontinence and 5 had stress urinary incontinence. The study was approved by the Ethics in Research Committee of the Medical Sciences Faculty of UNICAMP under nº 077/03, and the patients signed a consent form after receiving information.

## Procedure

Patients were assessed during the first appointment according to the patient's description of the items in the urinary incontinence physical therapy assessment. During the second appointment, the following were performed: a one-hour "pad test", an incontinence Visual Analog Scale, a Visual Analog Scale of the problem and questioning on the number of diapers used each day. These procedures were followed on the third, sixth and twelfth month after the beginning of the study.

The "pad test" consisted of measuring the initial weight of the diaper worn after the patient urinated. After that, the patient drank 500 ml of water and remained seated for an hour. Then, the "pad test" items were performed: a 30-minute walk; a 20-step climb; a 20-step descent; sudden changes in position such as sitting and getting up 10 times; 10 simulations of repeated coughs; running for 1 minute; lifting objects from the floor to the chest and putting them back on the floor 5 times, and washing their hands in running water for 1 minute. Finally, the weight of the diaper was measured again, and urinary incontinence was ranked as: light (2g to 10g); moderate (11g to 50g); serious (51g to 100g) or very serious (more than 100g)<sup>17,18</sup>.

In the incontinence Visual Analog Scale, the patient would choose a score between 0 and 10, with 0 representing no incontinence and 10 representing complete incontinence observed during the period of time before each assessment<sup>19</sup>. In the Visual Analog Scale of the problem, the patient would choose a score between 0 and 10, with 0 representing no problem and 10 representing a great problem observed during the period of time prior to each assessment<sup>19</sup>. The patient would report the number of diapers used daily<sup>17</sup>.

Patients were initially trained to contract the elevator muscle of the anus in supine, lateral decubitus, sitting and standing positions. Exercises started with 2-second contractions, followed by 4-second relaxation. The following day, contractions lasted 3 seconds and relaxation lasted 6 seconds; and the contraction and relaxation time increased daily until contractions lasted the maximum of 10 seconds and relaxation, 20 seconds. Afterwards, the patient would start again with 2-second contractions and 4-second relaxation<sup>20</sup>. Patients had to perform 90 contractions a day, divided equally: 30 in the morning, 30 in the afternoon and 30 in the evening<sup>19</sup>. Patients were told to do these exercises at home.

Only the patients in the investigation group were submitted to electro-stimulation with endo-anal electrode (Dualpex 961 Uro<sup>®</sup>) once a week for 20 minutes<sup>19</sup>. For the first 3 months, the frequency used for patients with detrusor instability and urge urinary incontinence was 8Hz, and 35Hz for patients with sphincter deficiency and stress urinary incontinence. After 3 months, 10 Hz was the frequency used for patients with urge urinary incontinence and 50Hz for those with stress urinary incontinence<sup>21</sup>. Patients were reassessed after 3, 6 and 12 months from the beginning of the physical therapy treatment.

## Statistical analysis

The non-parametric Friedman test was used to assess possible differences over time: 1st (assessment), 2<sup>nd</sup> (3 months), 3<sup>rd</sup> (6 months) and 4<sup>th</sup> (12 months) in each group of patients for the "pad test", incontinence VAS, problem VAS and number of diapers.

The Mann-Whitney test was used to compare continuous variables and differences between groups, with the relative variation (delta %) defined as:

$$\Delta\% = \frac{\text{initial value} - \text{final value (12 months)}}{\text{Initial value}} \times 100$$

Results were presented as mean  $\pm$  SD.

The software SPSS 13.0 for Windows was used for statistical analysis, and the level of significance was set as 0.05.

## RESULTS

Male patients with urinary incontinence selected for the study were aged  $64.3 \pm 5.2$  years (variation of 56 to 72 years of age). The time of commencement of physical therapy after surgery was similar in both control and investigation groups ( $16.8 \pm 13.5$  months versus  $12.3 \pm 10.3$  months, respectively;  $p = 0.393$ ).

In the initial assessment, there was no significant difference between control and investigation groups as to the 1<sup>st</sup> "Pad test" which was  $9.0 \pm 8.1$  g versus  $28.0 \pm 33.8$  g respectively,  $p = 0.190$ ; 1<sup>st</sup> Analog Visual Scale for incontinence  $4.6 \pm 0.7$  versus  $5.7 \pm 2.4$  respectively,  $p = 0.481$ ; 1<sup>st</sup> Analog Visual Scale for the problem  $5.7 \pm 2.4$  versus  $5.9 \pm 1.8$  respectively,  $p = 0.48$  and 1<sup>st</sup> number of diapers  $1.7 \pm 0.9$  versus  $2.5 \pm 1.3$  respectively,  $p = 0.416$ .

Although assessments were made initially and after 3, 6 and 12 months, the results compare the initial assessment to the final assessment on the twelfth month.

The analysis of the initial and final (12<sup>th</sup> month) "pad test" assessments revealed a significant decrease over time in both groups of patients. In the control group, it was  $9.0 \pm 8.1$  g (5 to 30) in the initial assessment and  $3.5 \pm 2.4$  g (0 to 5) in the 12<sup>th</sup> month,  $p = 0.01$ . In the investigation group, it was  $28.0 \pm 33.8$  g (5 to 100) in the initial assessment and  $9.4 \pm 12.7$  g (0 to 40) in the 12<sup>th</sup> month,  $p < 0.001$ .

Table 1 shows the comparison between groups in regard to the "pad test". Groups were compared using the relative variation (delta %). There was no statistically significant difference between groups in relation to the "pad test". In the initial assessment of the investigation group (1<sup>st</sup> "pad test"), 10 patients were observed and, at the end of the 12-month period, 8 patients in this group were assessed because 2 had been discharged in the 3<sup>rd</sup> and 6<sup>th</sup> month and were excluded from the final analysis.

The analysis of the incontinence VAS data from the initial assessment and the end of the 12<sup>th</sup> month revealed

**Table 1.** Mean value comparison of relative variation (delta %) of the pad test between investigation and control groups in the initial and final (12<sup>th</sup> month) assessments.

Groups	Patients	Mean $\pm$ SD $\Delta\%$	Minimum $\Delta\%$	Maximum $\Delta\%$	p
<b>Control</b>	10	41.7 $\pm$ 46.6	0	100	0.466
<b>Investigation</b>	8	62.1 $\pm$ 32.5	0	100	

\* Mann-Whitney Test. In the investigation group, 8 patients were assessed because by the end of the study 2 patients had been discharged: one patient in the 3<sup>rd</sup> month and one in the 6<sup>th</sup>.

**Table 2.** Mean value comparison of the relative variation (delta %) of the incontinence Visual Analog Scale (incVAS) and of the problem Visual Analog Scale (probVAS) between investigation and control groups, in the initial and final (12<sup>th</sup> month) assessments.

Groups	Patients	Mean $\pm$ SD $\Delta\%$	Minimum $\Delta\%$	Maximum $\Delta\%$	p
<b>(incVAS) Control</b>	10	37.5 $\pm$ 24.6	0	60	0.893
<b>Investigation</b>	8	42.7 $\pm$ 40.2	0	100	
<b>(probVas) Control</b>	10	48.5 $\pm$ 30.2	0	80	0.529
<b>Investigation</b>	8	43.0 $\pm$ 39.6	0	100	

\* Mann-Whitney Test. Concerning the incVAS and probVAS assessments in the investigation group, 8 patients were assessed because by the end of the study 2 patients had been discharged, one in the 3<sup>rd</sup> month and one in the 6<sup>th</sup>.

**Table 3.** Mean value comparison of the relative variation (delta %) of the number of diapers in the control and investigation groups in the initial and final (12<sup>th</sup> month) assessments.

Groups	Patients	Mean $\pm$ SD $\Delta\%$	Minimum $\Delta\%$	Maximum $\Delta\%$	p
<b>Control</b>	7	54.8 $\pm$ 35.6	0	100	0.680
<b>Investigation</b>	8	57.9 $\pm$ 30.5	0	100	

\* Mann-Whitney Test. Initially in the control group, 2 patients used external male catheters and 1 patient did not use diapers. Therefore, the number of the patients in the control group was 7. In the investigation group, 2 patients had already been discharged (3<sup>rd</sup> and 6<sup>th</sup> months) by the end of the study. Thus, the number of patients was 8.

a significant decrease in both groups of patients over the 12-month period. In the control group, it was  $4.6 \pm 0.7$  (3 to 5) in the initial assessment and  $2.8 \pm 1.0$  (2 to 5) in the 12<sup>th</sup> month,  $p < 0.001$ . In the investigation group, it was  $5.7 \pm 2.4$  (3 to 10) in the initial assessment and  $3.4 \pm 2.2$  (0 to 5) in the 12<sup>th</sup> month,  $p = 0.005$ . As for the problem VAS, there was also a significant decrease in both groups of patients over the 12-month period. In the control group, it was  $5.7 \pm 2.4$  (3 to 10) in the initial assessment and  $2.6 \pm 1.2$  (1 to 5) in the 12<sup>th</sup> month,  $p < 0.001$ . In the investigation group, it was  $5.9 \pm 1.8$  (4 to 10) in the initial assessment and  $3.5 \pm 2.3$  (0 to 5) in the 12<sup>th</sup> month,  $p = 0.002$ .

Table 2 compares groups as to incontinence and problem VAS using relative variation (delta %). There was no statistically significant difference between groups. The analysis of the data on the number of diapers in the initial assessment and at the end of the 12<sup>th</sup> month revealed a significant fall in both groups of patients over the 12-month period. In the control group, it was  $1.7 \pm$

$0.9$  (0 to 3) diapers in the initial assessment and  $0.7 \pm 0.7$  (0 to 2) diapers in the 12<sup>th</sup> month,  $p = 0.002$ . In the investigation group, it was  $2.5 \pm 1.3$  (0 to 5) diapers in the initial assessment and  $1.1 \pm 0.6$  (0 to 2) in the 12<sup>th</sup> month,  $p < 0.001$ . In the control group, two patients initially used an external male catheter and a patient did not use diapers; therefore, with regard to the number of diapers, 7 patients were assessed. In the investigation group, 10 patients were initially assessed; but at the end of the study, 2 of them had been discharged due to continence and were excluded from the final analysis.

Table 3 shows the comparison between groups as to the number of diapers. The comparison of the differences between groups using relative variation (delta %) did not reveal a statistically significant difference. Over the period of the study, three patients of the investigation group were discharged (on the 3<sup>rd</sup> month, 6<sup>th</sup> month and at the end of the 12<sup>th</sup> month) because they regained urinary continence diagnosed by the physical therapy methods used in this study.



## DISCUSSION

There is no consensus in literature regarding the best physical therapy treatment option among the various conservative treatments for urinary incontinence after radical prostatectomy<sup>15</sup>. The most frequently used conservative treatment is functional pelvic floor muscle training<sup>15,16,22-24</sup>. Electro-stimulation is also used to treat patients with both stress urinary incontinence and urge urinary incontinence<sup>25,26</sup>. Some authors suggest that urinary incontinence is cured more rapidly when functional pelvic floor training is combined with electro-stimulation<sup>27,28</sup>. However, in the present prospective study, the combination of electro-stimulation did not increase the effect of functional pelvic floor training. In patients submitted to both types of treatment, there was a reduction in the "pad test" values both in the control group and the investigation group. Also, when compared to the final results between the two groups of patients, there was no significant difference, as other authors have observed<sup>16,20,29</sup>. Galeri and Sottini<sup>30</sup> compared patients who had functional pelvic floor muscle training and electro-stimulation with patients who only had functional pelvic floor muscle training. The authors found a gradual improvement in the first 3 months of rehabilitation in all patients and concluded that, regardless of the type of treatment, there is a rapid initial recovery from urinary incontinence and, after 12 months, only 15% to 20% of patients were still incontinent<sup>30</sup>. Another study, that evaluated the efficacy of conservative treatment in prostatectomy patients with urinary incontinence eight weeks or more after surgery, compared patients who had only instructions on how to train the pelvic floor muscles at home with patients who had functional pelvic floor training under the supervision of a physical therapist or functional pelvic floor training and electro-stimulation. The study revealed that incontinence improved quickly in all groups in the first 12 weeks, regardless of the type of physical therapy treatment<sup>31</sup>.

Urinary incontinence is often assessed with the use of the "pad test" because it is considered simple and objective<sup>16,17,20</sup>. Assessments of incontinence and problem VAS and number of diapers, although subjective, were methods used in this present study in an attempt to obtain greater sensitivity in the assessment of the response to physical therapy treatment for urinary incontinence. The results obtained were in agreement with the "pad test".

Most similar studies assess the effect of premature functional pelvic floor training and/or electro-stimulation because most authors believe that the best response is obtained when pelvic floor exercises begin immediately after the vesical catheter is removed<sup>5,14,19</sup>. In the present study however functional pelvic floor training, combined or not with electro-stimulation, began late (at least 6

months after surgery), and the results showed an improvement in urinary incontinence in both study groups. In addition to that, although patients with stress and urge urinary incontinence were analyzed, they were randomly and equally divided into two groups, and the result was beneficial with physical therapy treatment in both types of urinary incontinence. Literature recommends that urinary incontinence due to the detrusor instability be treated with physical therapy and anticholinergic medication before any surgical treatment is considered, while stress urinary incontinence does not respond to physical therapy and treatment is based on surgery<sup>32</sup>.

Although the present study included a small number of patients with different etiologies of urinary incontinence (sphincter insufficiency or detrusor hyperactivity), it revealed a reduction in urinary incontinence in all patients. Considering that there are few studies in literature that assess physical therapy treatment of male urinary incontinence after prostatectomy, this can be considered a pilot study. Results suggest that physical therapy contributed to the reduction in urinary incontinence, regardless of the technique (functional pelvic floor training, combined or not with electro-stimulation) without adverse effects.

We concluded that, in the studied population of males with post-radical prostatectomy urinary incontinence, there was no additional improvement in the treatment with functional pelvic floor training combined with electro-stimulation when compared to only functional pelvic floor treatment. New studies and techniques are needed to investigate and obtain better results in the treatment of male urinary incontinence.

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