

Clinical Trial on the Use of Biofeedback Prior to Robotic Prostate Surgery (25294)

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Hypothesis / aims of study

Introduction

Prostate carcinoma is the main cancer that affects the male sex.

Due to the improvement in diagnostic techniques that allow us to determine cases in a preclinical phase and the improvement in radiological techniques, the age of affected patients is increasingly younger, and, therefore, problems related to surgery such as sexual functioning and fertility or urinary incontinence, are of increasing interest and concern for this increasingly younger and sexually active population.

The treatment of choice is radical prostatectomy whose main complications are urinary incontinence and erectile dysfunction. Several studies show that performing exercises that work the pelvic floor muscles helps to improve these complications, although sometimes, the execution of these exercises is not done correctly, so the work is not effective.

Many patients have difficulties differentiating the abdominal or gluteal muscles from the perineal muscles, therefore, we consider it necessary to prior training by a specialized professional, to correctly identify the muscles to be worked.

The biofeedback can be an important tool for the identification of this muscle and contribute to decrease rates of urinary incontinence and erectile dysfunction after prostate surgery.

OBJECTIVE OF THE STUDY

To assess whether good training of the pelvic floor muscles, based on the correct performance of perineal exercises guided by biofeedback and supervised by an expert nurse, obtains better results compared to learning without the use of biofeedback.

Study design, materials and methods

Clinical trial of two arms formed with patients with prostate cancer who were going to undergo robotic radical prostatectomy.

Study Group. Two sessions (20 minutes) of pelvic floor training assisted by biofeedback were carried out prior to surgery, where the correct perineal contraction was verified by an expert nurse without the intervention of auxiliary muscles. After this, once admitted to the Urology unit, the usual treatment was applied, consisting of the explanation by the care nurse of the Pelvic Floor Recommendations Guide of the San Carlos Clinical Hospital.

Control Group. Upon admission to the Urology unit, they followed the usual treatment, consisting of the explanation by the care nurse of the Pelvic Floor Rehabilitation Recommendations Guide of the San Carlos Clinical Hospital.



Usual Treatment

Four daily series of:

- Five minutes of strengthening exercises for type I or tonic fibers through prolonged ten-second contractions with a twenty-second rest between them.
- Five minutes of strengthening exercises for type II or phasic fibers, through ten quick contractions lasting one second.

All participants in the study completed the questionnaires at the beginning and four months after surgery.

- ICIQ-sf Urinary Incontinence Questionnaire
- IIEF-5 Erectile Dysfunction Questionnaire
- Quality of life questionnaire (EPIC-CP)

After twelve months, in addition to the previous ones, the following were completed:

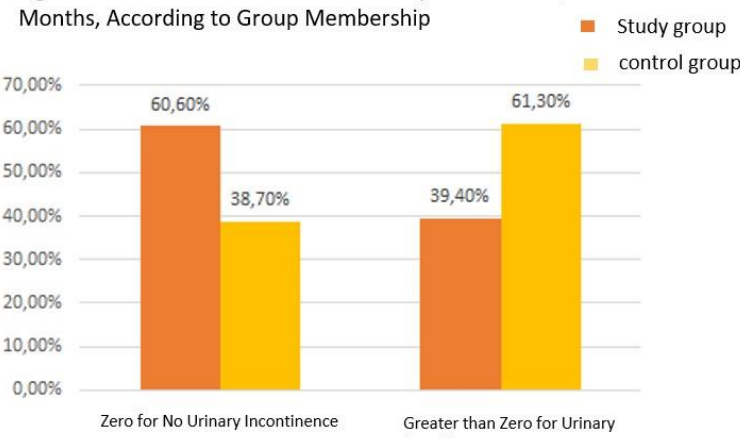
- MMAS-8 Treatment Adherence Questionnaire
- Client Satisfaction Questionnaire (CSQ-8)

Result and interpretation

Figure 1.- IIEF Scale Values for Erectile Dysfunction, at Twelve Months, According to Group Membership.



Figure 2.- ICIQ-SF Scale Values for Urinary Incontinence, at Twelve Months, According to Group Membership



Results and interpretation

Figure 3.- Perceived Quality of Life by Patients at Admission, 4 Months, and 12 Months Post-Surgery; in the Control Group and the Study Group

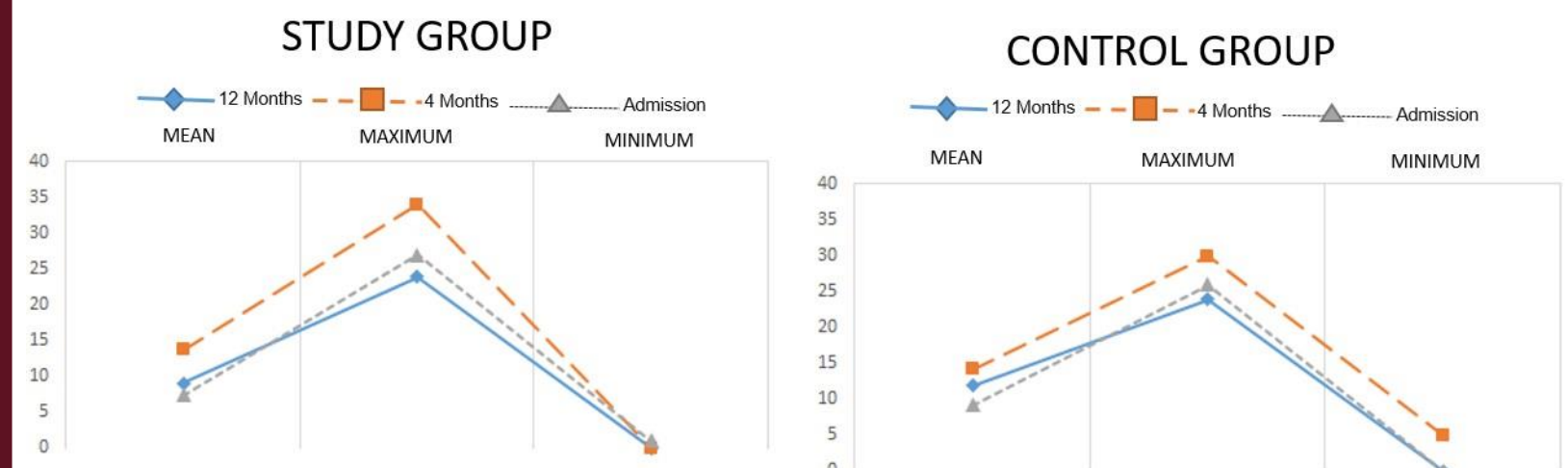


Figure 4.- Quality of Life in Patients with Erectile Dysfunction or Urinary Incontinence



Figure 5.- Adherence to pharmacological treatment (MMAS-8), At 12 months, according to group distribution.

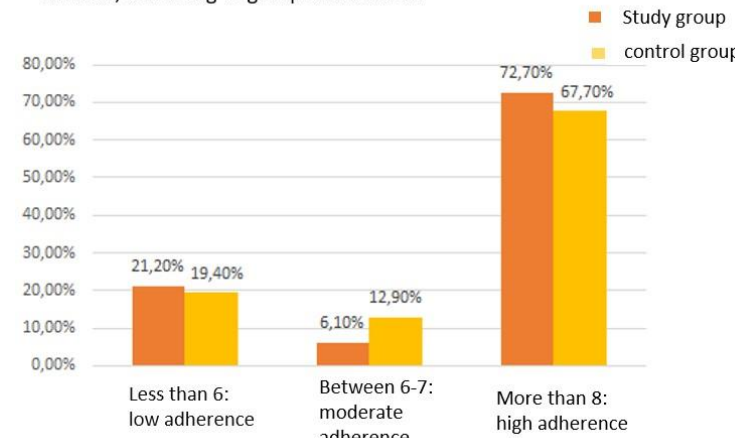


Figure 6.- Adherence to treatment in the presence or absence of urinary incontinence (UI).

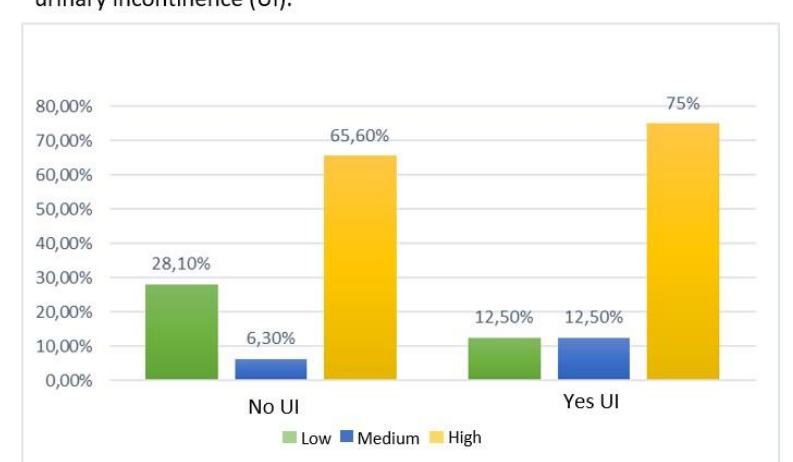


Figure 7.- The level of satisfaction measured by the CSQ-8 scale, compared between the control and study groups.

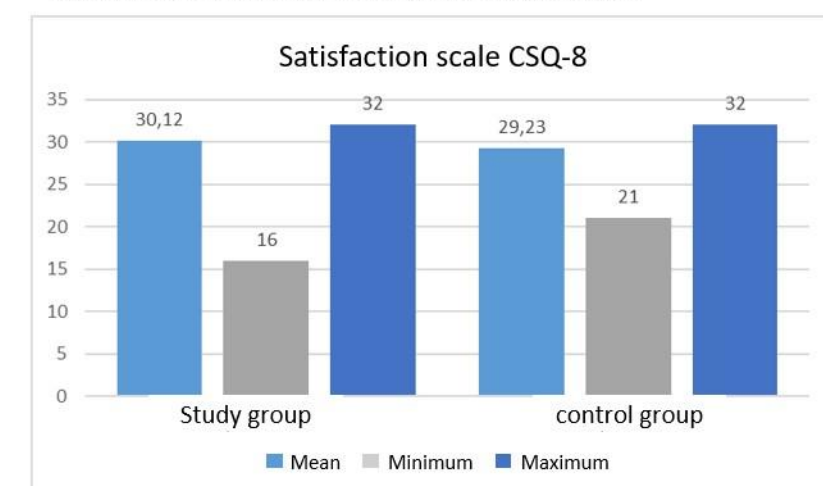
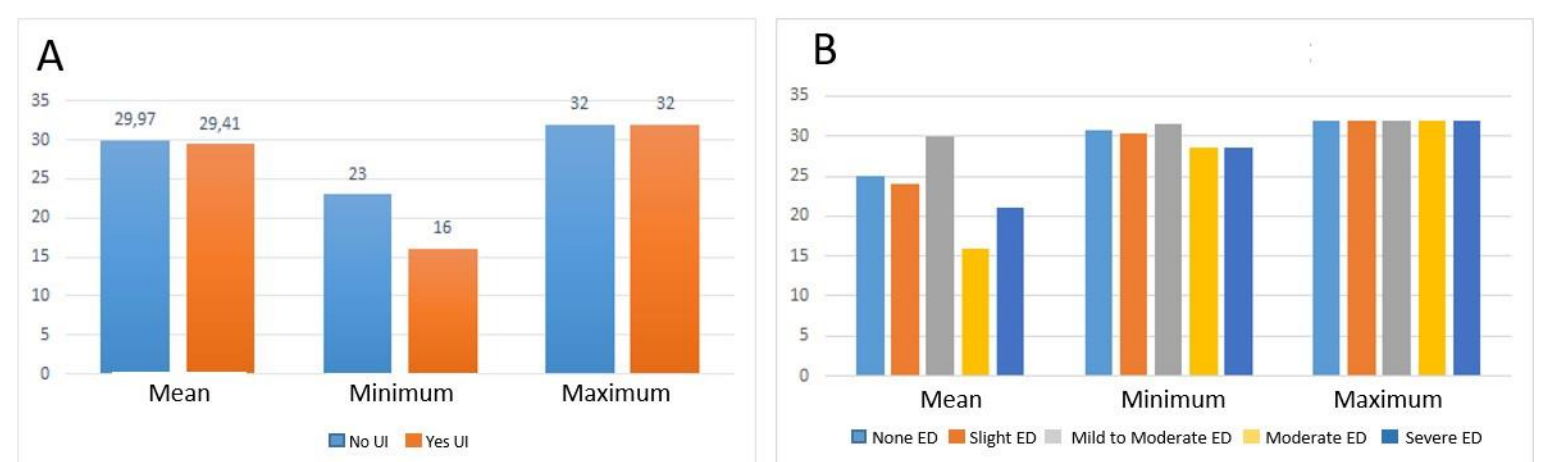


Figure 8.- In figure A, the satisfaction level of patients based on the presence or absence of urinary incontinence (UI). In figure B, the satisfaction level of patients based on the presence and severity, or absence of erectile dysfunction (ED).



Conclusions

1. The use of biofeedback as a support element in the prevention of urinary incontinence and erectile dysfunction in patients who are going to undergo robotic radical prostatectomy is a safe technique that can provide advantages in strengthening the perineal muscles.

2. With the use of biofeedback we have improved by 50% the incidence of urinary incontinence and erectile dysfunction in patients undergoing robotic radical prostatectomy at the San Carlos Clinical Hospital.

3. Although the distribution of the sample is very homogeneous and observing an evident improvement in the incidence of urinary incontinence and erectile dysfunction of the control group, a statistically significant relationship is not achieved between its use and the improvement of the variables under Study (Chi-Cuadrado $p=0,159$; $p=0,080$)

We can attribute the possible cause to an insufficient sample.

References

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