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Carlos Lorenzo García *, Ana Lucía Gúzman Bellodas , Paloma Coronel Rosado

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Article

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

Carlos Lorenzo García [1,†,‡,*], Ana Lucía Gúzman Bellodas [2,‡] and Paloma Coronel Rosado [2]

[1] Hospital Clínico San Carlos 1

[2] Hospital Clínico San Carlos 2

* Correspondence: carloslorenzogarcia@yahoo.es

† Current address: Professor Martín Lago.

‡ These authors contributed equally to this work.

Abstract: Background and Objective: Prostate cancer is the leading cancer affecting males. The treatment is radical prostatectomy, with its main complications being urinary incontinence and erectile dysfunction. Various studies demonstrate that exercises targeting the pelvic floor muscles help improve these complications, although sometimes, these exercises are not performed correctly, rendering the effort ineffective. To avoid this circumstance, a study comparing a group with biofeedback-guided learning led by a nurse expert in the technique against another without this learning method is designed. Methods: Randomized clinical trial with two arms; the study group underwent two biofeedback sessions prior to surgery for the identification of the muscles to work on, compared to another group where no prior learning of the muscles was done. These fifteen-minute sessions involved the placement of electromyography sensors for muscle contraction detection. Both groups followed the same care process where the protocol for reinforcing the perineal muscles after the removal of the urinary catheter was explained. Data were collected through validated questionnaires. Key Findings and Limitations: The results obtained show a clear improvement in the prevalence of urinary incontinence and erectile dysfunction in patients who underwent two biofeedback sessions prior to surgery, as well as a high rate of adherence and satisfaction with the care received in both the control group and the study group, regardless of whether they experienced urinary incontinence and/or erectile dysfunction. Conclusions and Clinical Implications: Biofeedback is a safe method that helps reduce complications after prostatectomy.

Keywords: radical prostatectomy; urinary incontinence; erectile dysfunction; biofeedback

1. Introduction

Prostate cancer ranks first among cancers affecting males 1.

The age of affected patients is becoming younger, thus problems related to surgery such as sexual function, fertility, or urinary incontinence are increasingly of interest and concern for this younger and sexually active population 2.

The surgical treatment of choice is radical prostatectomy (RP), involving the complete removal of the prostate gland 3.

Potential complications of radical prostatectomy include erectile dysfunction (ED) and urinary incontinence (UI)4,5.

Following radical prostatectomy, damage to the internal sphincter can be partially or totally compensated by the activity of the external sphincter, including the complex formed by the rhabdomyosfincter and the levator ani 6.

Greater preoperative strength of the pelvic floor muscles is associated with a lower postoperative incidence of urinary incontinence. Centemero et al. found that patients who began performing pelvic floor muscle strengthening exercises before radical prostatectomy had better rates of urinary incontinence 3 months after the operation (59.3% vs. 37.3%). Therefore, nursing interventions aimed at strengthening the pelvic floor muscles can reduce the incidence of urinary incontinence 7,8.

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Additionally, many patients have difficulty differentiating between abdominal or rectal muscles and the perineal muscles, therefore, we consider prior training by a specialized professional necessary to help them identify the muscles they will subsequently work on.

We believe that the impact of pelvic floor training assisted by biofeedback can be an important tool in improving urinary incontinence after prostatectomy 9,10. In this regard, the conclusions of a meta-analysis conducted in 2016 by Lan-Fang Hsu 10 state that biofeedback can be a complementary treatment to pelvic floor muscle training.

2. Materials and Methods

This is a two-arm Clinical Trial, comprising an experimental group and a control group. Both groups included patients who were to undergo robotic radical prostatectomy.

For sample size calculation, we used the GRAMNO v7.12 program, which is related to the preceding population of patients undergoing surgery, robotic radical prostatectomy, in the years 2018 and 2019. Considering the two study groups, the sample size was calculated accepting an alpha risk of 0.05 and a beta risk of 0.2 in a bilateral test. It was determined that 29 subjects were needed in the first group and 29 in the second to detect a statistically significant difference between two proportions. We could also calculate the sample size based on the work of Parra et al. 11 and Appoloni et al. 12, related to the incidence of patients developing urinary incontinence or erectile dysfunction after radical prostatectomy. Thus, accepting an alpha risk of 0.05 and a beta risk of 0.2 in a bilateral test, 34 subjects were required in the first group and 34 in the second to detect a statistically significant difference. A follow-up loss rate of 10% was estimated.

Given that the difference in sample sizes is not very large between the two calculation methods, we opted for the larger of the two. Therefore, we will recruit 34 patients in the study group and 34 in the control group.

Study Group: Two pelvic floor training sessions assisted by biofeedback were conducted prior to surgery, where a nurse trained in the technique taught the identification of the muscles to work on, the correct performance of perineal contraction without the involvement of auxiliary muscles, and the two types of exercises for strengthening phasic and tonic fibers. After this, once admitted to the Urology unit, they received standard treatment.

Control Group: Upon admission to the Urology unit, they received standard treatment, consisting of explanation by the attending nurse on how to perform pelvic floor muscle strengthening exercises.

Upon admission to the Urology service for robotic radical prostatectomy, both groups completed the following questionnaires:

- -International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF) 13
- -International Index of Erectile Function-5(IIEF-5) 14.
- -Quality of Life Questionnaire (EPIC-CP) 15.

These are validated questionnaires in the Spanish language that allow determining the impact of urinary incontinence and erectile dysfunction prior to surgery.

After surgery, both groups were instructed to perform exercises, consisting of strengthening exercises for type I or tonic fibers, through prolonged contractions of ten seconds with a twenty-second rest, and strengthening exercises for type II or phasic fibers, through ten rapid contractions of one-second duration.

At 4 months post-hospital discharge, a second telephone call was made to complete the following questionnaires:

- -International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF) 13.
- -International Index of Erectile Function - 5 (IIEF-5) 14.
- -Medication Adherence Report Scale - 8 (MMAS-8) 16.
- -Client Satisfaction Questionnaire (CSQ-8) 17.
- -Quality of Life Questionnaire (EPIC-CP) 15.

At 12 months, a call was made to complete the same questionnaires and thus conclude the study with results 12 months after the intervention.

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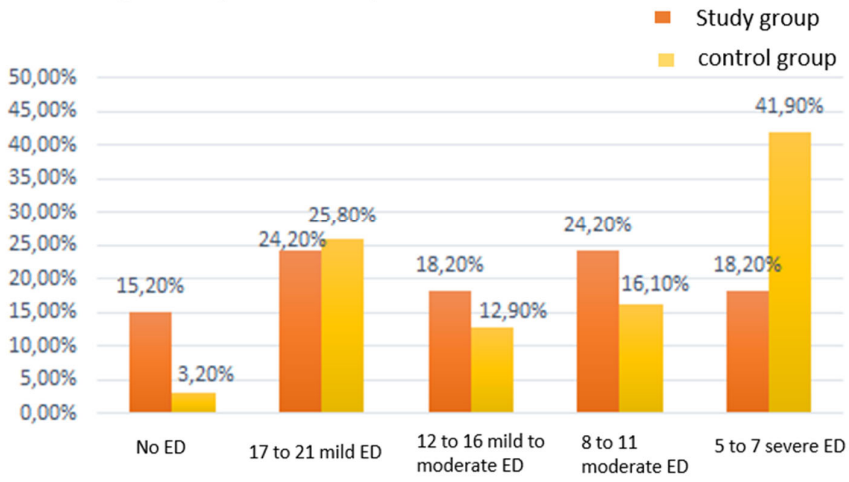
3. Results

The obtained results were as follows: out of the total participants (68), 34 were randomly assigned to the study group, and 34 to the control group. Finally, 4 patients were excluded from the study,(reoperation after surgery 2), (impossibility of follow-up 2). We did not find any adverse effects or complications associated with biofeedback in the patients belonging to the study group. Demographic Variables.

Study Group: 33 Patients (1 loss)
Mean age: 62.85
Smokers: 2
Diabetics: 3
Previous medication for erectile dysfunction (ED): 1
Previous medication for urinary incontinence (UI): 0
Control Group: 31 Patients (3 losses)
Mean age: 62.00
Smokers: 3
Diabetics: 5
Previous medication for ED: 3
Previous medication for UI: 1
Primary Variables.

Erectile Dysfunction Questionnaire (IIEF): After applying statistics such as Chi-Square ($p=0.159$), we can observe a difference of almost 5 times more patients without ED in the study group compared to the control group. Furthermore, we observe a significant difference in the severity of ED between both groups, noting that the control group has almost double the number of patients with severe ED compared to the study group. (Figure 1).

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



Urinary Incontinence Questionnaire (ICIQ-SF): Applying again, as these are two descriptive variables, the Chi-Square test, we obtained a result with a significance level of 0.080, concluding that there is a relationship between the two variables. We observed clearly that almost double the number of patients in the study group do not have UI compared to the control group. Despite these data, there is a decrease in the number of UI cases between 4 and 12 months in both groups; from 66.7% of incontinent patients at 4 months to 39.4% at 12 months in the study group, and from 74.2% to 61.3% in the control group (Figure 2).

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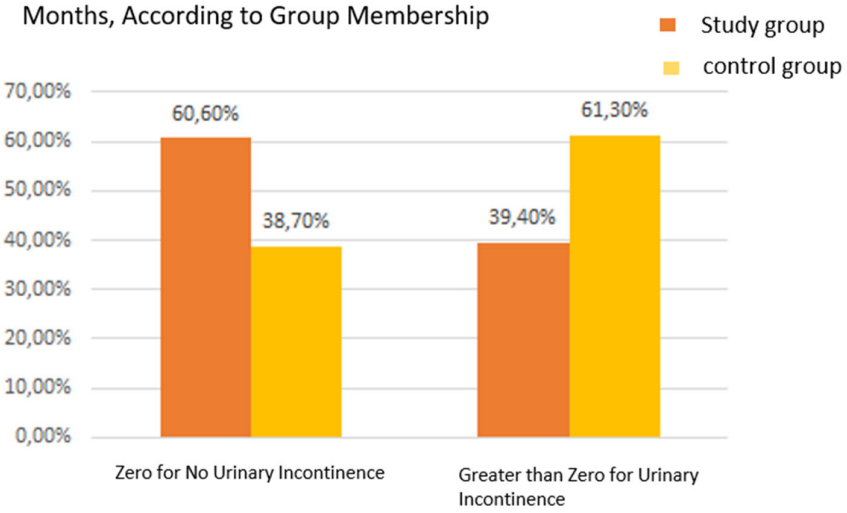
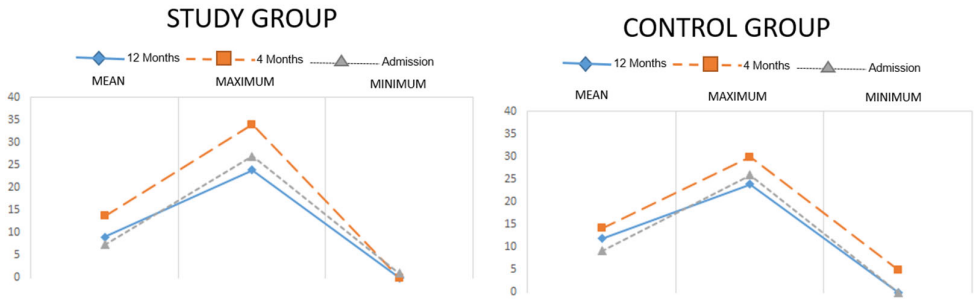
Figure 2.- ICIQ-SF Scale Values for Urinary Incontinence, at Twelve Months, According to Group Membership



Quality of Life Questionnaire (EPIC-CP): This questionnaire contains 16 items divided into 4 domains; each domain contains 3 questions with Likert scale response options ranging from 0 to 4 points. Scores range from 48 points to 0 points, with lower scores indicating better perceived quality of life. Comparing the scores of both groups, we see a slight difference in the perceived quality of life at 12 months for patients in the study group (average score of 9.09) compared to the control group (average score of 11.97). Although their minimum and maximum values are the same (0-24), we can conclude that the perception of quality of life in patients in the study group is slightly higher than that perceived by the control group (Figure 3).

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



Similarly, comparing these results with those obtained in the two main questionnaires, we can draw certain conclusions.

Quality of Life and Erectile Dysfunction:

Patients without ED have an average score of 2.33.

With ED, the difference from patients without ED also varies, and among the ED subgroups, the average score increases as the severity of ED increases. Thus, the correlation between the perception of quality of life and erectile dysfunction is clearly observed.

Quality of Life and Urinary Incontinence:

Patients without urinary incontinence have a lower average score (8.47) than those with urinary incontinence (12.50). Therefore, the perceived quality of life by patients without urinary incontinence is higher than that perceived by patients with incontinence. (Figure 4)

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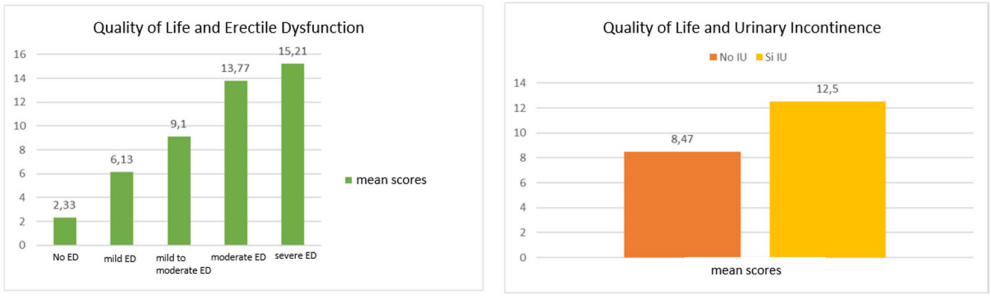
Figure 4.- Quality of Life in Patients with Erectile Dysfunction or Urinary Incontinence



Medication Adherence Questionnaire (MMAS-8): This questionnaire, validated by Morisky (2008) (18), consists of several questions with YES/NO responses (scored as YES=0 points/NO=1 point), and one question scored on a Likert scale (0-4). Scores thus range across various ranges:

Low Adherence <6

Moderate Adherence 6 or 7

High Adherence 8

The results obtained in our study show an overall high adherence (70.3%). By cross-referencing the data obtained in the MMAS-8 test with those of the urinary incontinence questionnaire, we obtain the following results, where there is a high adherence to treatment in both patient groups. There are almost 10% more patients with UI who adhere strictly to treatment, (Figure 5), (Figure 6)

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

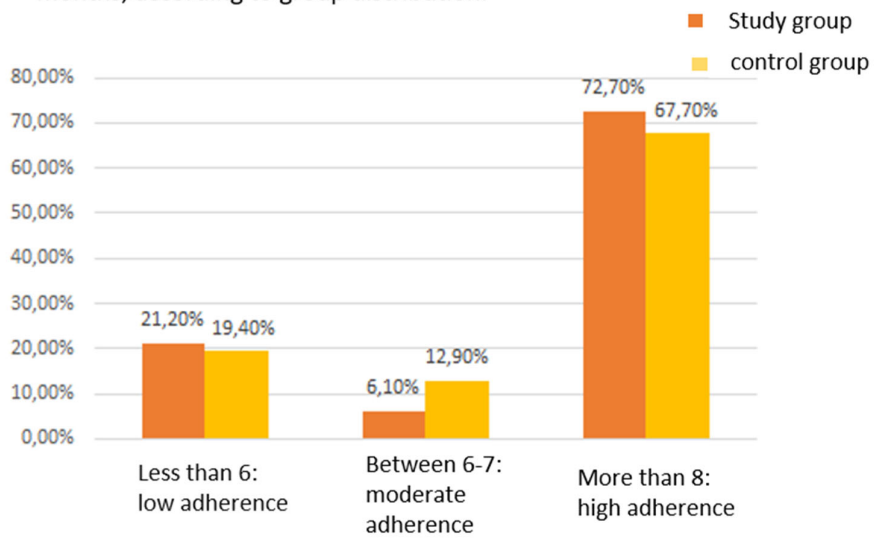


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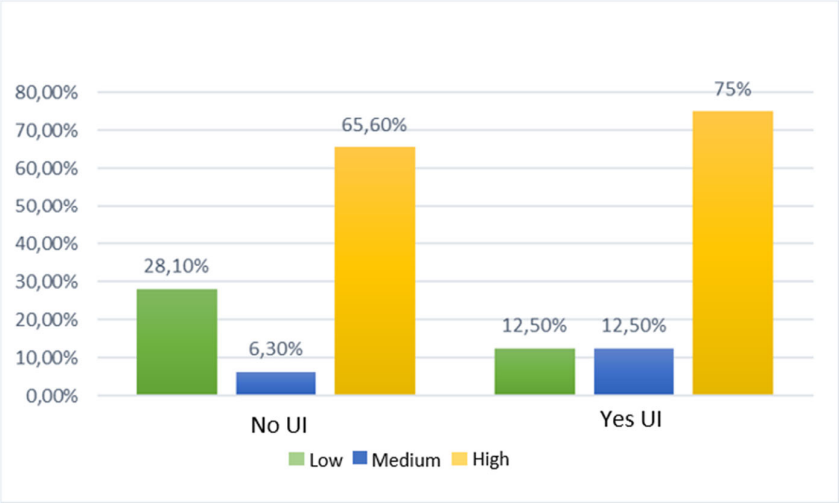
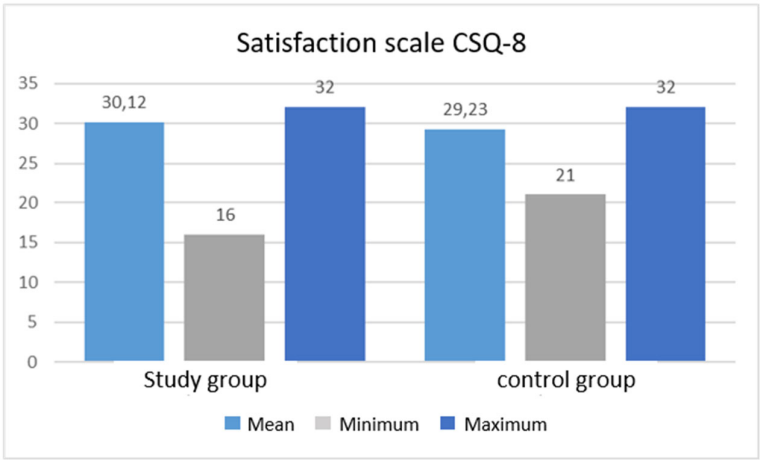
Figure 6.- Adherence to treatment in the presence or absence of urinary incontinence (UI).



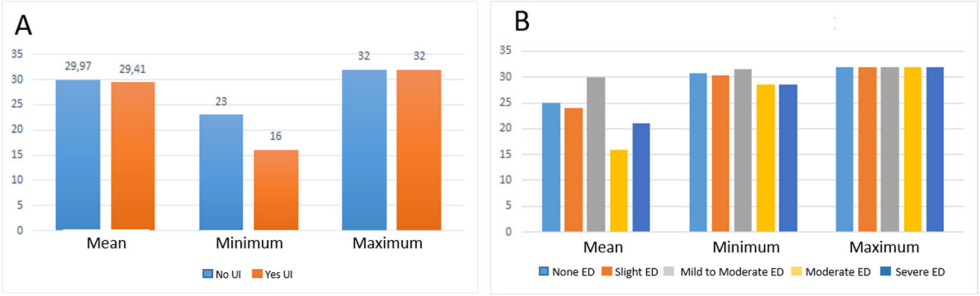
Level of Satisfaction with the Service (CSQ-8): This questionnaire is based on 8 questions with evaluations ranging from 1 to 4 points, and satisfaction is directly related to the number of points. Differentiating by groups, the results obtained are as follows (Figure 7):

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



Study Group: 30.12 points; (Figure 8)

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).



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Control Group: 29.23 points; . The significance level after performing Mann-Whitney T-tests is 0.199, concluding that there are no differences between both groups. Analyzing the results together with the results obtained in the UI and ED questionnaires, we obtain the following results: Based on this data, we can conclude that both groups present a high level of satisfaction regardless of the group they belonged to and regardless of whether they currently have UI and/or ED

1. Discussion

After surgery and immediate postoperative period, other problems arise that have not been previously described in most cases, and once the fear of tumor consequences is overcome, it jeopardizes their new daily life. Erectile dysfunction and urinary incontinence are aspects that determine the quality of life of the patient.

Hence the importance of preoperative health education, not only to recover the perineal musculature as soon as possible or for the patient to perform the exercises correctly, but also for the patient to know from the very beginning the real possibility of experiencing incontinence and/or erectile dysfunction.

We cannot attribute the lack of statistical significance in the study of variables to the diversity of personnel in the performance of the biofeedback technique, as the same professional was responsible for carrying out the training with this technique.

The degree of adherence obtained in our series is relevant, if we take as a reference the work of Morris et al. 18, where they estimate between 30% to 50% the lack of adherence to a treatment regardless of the disease, prognosis, or treatment, in our series we achieved an adherence of 70% in performing perineal rehabilitation at one year.

As Girotti et al. 20, in a prospective cohort study of 60 patients performing intermittent catheterization where the adherence rate at 6 months (61.7%) was similar to that at one year (58%), in our series, there are also no significant differences in adherence at 4 months and at one year.

The erectile dysfunction rates vary for robotic surgery between 3-51% in the literature. Other authors speak of erectile dysfunction rates of 30%, while others speak of recovery to pre-surgery states in only 33%.

In our series, we observed moderate/severe dysfunction rates of 42% for the study group compared to 58% for the control group, indicating an improvement in rates in the study group. This improvement is observed in all subdivisions, including patients who do not have erectile dysfunction, who are up to 5 times more numerous in the study group. Severe dysfunction is present in double the number of patients in the control group compared to the study group.

Regarding urinary incontinence, the literature speaks of rates of up to 80%. In our work, we observed rates of incontinence that double in the case of the control group, maintaining a rate of incontinence in the study group of 39%.

Our work coincides with other studies such as LF Hsu et al. 10, where time is crucial for continence recovery. In our series, for the study group, we went from incontinence rates of 66% at 4 months to incontinence rates of 39% one year after surgery. This improvement is not reflected in the control group to the same extent.

These long-term incontinence results are similar to those obtained by Dijkstra-Eshuis et al. 21, who, after randomizing 122 patients into two groups, one with prior biofeedback technique and the control group, obtained an incontinence rate at one year of 32.8% (in our work 38.7% in the study group; 61.3% in the control group), without a clear improvement in the study group. However, Grabbert et al. (26), who, on a sample of more than 4000 patients and a median follow-up of 42 months, obtained incontinence rates of 77% (ICIQ = 0), in our work the study group ICIQ = 0 is obtained by 60.6% of the patients and in the control group only 38.7%.

Johansson E et al. 22, in a sample of 182 patients undergoing radical prostatectomy with a median follow-up of 12.2 years, obtained urinary incontinence rates of 41%, similar to the control group in our series.

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Erectile dysfunction results also improve in the long term, coinciding with the work of Grabbert, M et al. 23, who obtained erectile dysfunction rates of 39% with an IIEF-5 score greater than 20 points. In our study, this score is only obtained by the study group (39.4% IIEF-5 >17 points) and not by the control group (29.0% IIEF-5 >17 points). This author identifies time as a risk factor in quality of life.

Johansson E et al. 22 obtained erectile dysfunction rates of 84%, very similar to the rates obtained in the study group (84.8%) of the present work and differing from the control group, which obtained much higher rates (96.8%).

2. Conclusions

The use of biofeedback as a supportive element in preventing urinary incontinence and erectile dysfunction in patients undergoing robotic radical prostatectomy is a safe technique that can provide advantages in helping patients learn pelvic floor muscle strengthening exercises more easily and rigorously.

With the use of biofeedback, we have improved the incidence of urinary incontinence and erectile dysfunction in patients undergoing robotic prostatectomy at the Hospital Clínico San Carlos in Madrid, with a 50% improvement in the rates of urinary incontinence and severe erectile dysfunction.

Although the sample distribution is very homogeneous between the two groups, and there is an evident improvement in the incidence of urinary incontinence and erectile dysfunction in patients who have undergone biofeedback sessions, a significant proportion between its use and the improvement of the study variables is not achieved. We can attribute this to an insufficient sample size as a possible cause, despite observing a favorable trend, we do not obtain a statistically significant relationship.

In conclusion, we would like to emphasize the importance of continuing studies related to the role of nursing in radical prostatectomy, where it can be seen that helps to improve UI and ED, as well as the quality of life of patients undergoing these types of interventions.

This clinical trial highlights the need for more studies in this area, where nursing can develop an important and decisive role in the perioperative care of these patients, directly influencing an improvement in their quality of life.

Author Contributions: Carlos Lorenzo García: Conceptualization, methodology, software, Validation, Formal analysis, Research, Resources, Data curation, Original draft writing, Review and editing writing, Visualization, Supervision, Project administration, Financing acquisition Paloma Coronel Rosado: Conceptualization, methodology, software, Validation, Formal analysis, Research, Resources, Data curation, Original draft writing, Review and editing writing, Visualization, Supervision, Project administration, Financing acquisition Ana Lucía Guzmán Bellodas: Conceptualization, methodology, software, Validation, Formal analysis, Research, Resources, Data curation, Original draft writing, Review and editing writing, Visualization, Supervision, Project administration, Financing acquisition. All authors have read and agreed to the published version of the manuscript

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Institutional Review Board Statement: "The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board (or Ethics Committee) of NAME OF CEim Hospital Clínico San Carlos Código 21/493-E 29/07/2021

Informed Consent Statement: "Informed consent was obtained from all subjects involved in study." "Written informed consent has been obtained from the patient(s) to publish this paper"

Data Availability Statement: The data sets presented in this article are not available because they are part of an ongoing study. Requests to access the data sets should be directed to carlos.lorenzo@salud.madrid.org

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Conflicts of Interest: The authors declare no conflicts of interest.

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Abbreviations

The following abbreviations are used in this manuscript:

(ICIQ-SF)	International Consultation on Incontinence SF
(IIEF-5)	International Index of Erectile Function -5
(MMAS-8)	Medication Adherence Report Scale - 8
(CSQ-8)	Client Satisfaction Questionnaire
(EPIC-CP)	Quality of Life Questionnaire
ED	Erectile dysfunction
UI	Urinary Incontinence
RP	Radical prostatectomy

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