

Quality of Life Outcomes after Rehabilitation Treatment in Men Undergoing Prostatectomy for Prostate Cancer: A Cohort Study

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Abstract

Objectives: To assess the results of rehabilitation treatment on quality of life of patients undergoing radical prostate surgery.

Methods: We evaluated a cohort of men treated at our Rehabilitation Department after radical prostate surgery between 2007 and 2013. Assessment scales, Expanded Prostate Index Composite (EPIC), Sandvik and International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ), before and after rehabilitation treatment were analyzed.

Results: 33 patients completed the rehabilitation treatment. The mean age of patients was 64.5 years (49-75).

An improvement was observed before and after rehabilitation treatment in the ICIQ and Sandvik scales, and in the urinary and sexual domains of EPIC ($p < 0.005$) and in the hormonal domain of EPIC ($p 0.008$); no significant differences in the intestinal domain of the EPIC ($p 0.068$) were found.

No statistically significant correlation between the assessment scales and the use of protective was obtained.

A statistically significant correlation between the days of bladder catheterization and bowel ($p 0.028$) and sexual ($p 0.004$) EPIC domains was found, but no correlation was found in the other domains of EPIC or the ICIQ and Sandvik scales.

The number of rehabilitation sessions did not correlate with any of the scales evaluated.

Conclusion: Rehabilitation treatment may improve the quality of life of patients undergoing radical prostate surgery.

Introduction

Prostate cancer is the second one in frequency in men. Approximately 900 thousand new cases per year are diagnosed around the world.

In Spain, more than 25 thousand cases are detected every year. It's the most frequent cancer in men (21%), followed by lung cancer.

Prostate cancer is diagnosed mainly between 60 and 80 years of age, with a peak between 70 to 75 years, although there are a significant number of cases beginning from 50 years. Despite this data, we can consider it an advanced age's tumoral disease [1].

Prostate cancer incidence is increasing due to population ageing in developed countries, but also to the generalized use of the Prostate Specific Antigen (PSA), which allows us to detect subclinical tumours. Early detection of the tumoral disease is essential to apply curative treatment, keeping in count that between 60 to 70% of the cases, cancer is organ confined and the elected treatment will be surgery. This fact has special relevance on complications development, because between 25 to 75% of operated patients will present Erectile Dysfunction (ED) and 25% or more will suffer Urinary Incontinence (UI) [2], according to different studies.

Surgical complications can produce a negative impact on Quality of Life (QOL), mainly in relation with UI [3]. Although the majority of the patients recover their continence in the 6 months following the intervention [4], a specific treatment could be initiated to revert or ameliorate this situation. Rehabilitation treatment may improve UI and ED [5,6], optimizing the QOL of these patients [7].

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Several scales have been used to measure UI severity symptoms and their impact on QOL [8-10]. Some of them were originally designed to evaluate female UI, like the Sandvik Severity Index [11], but currently their use is extended to male UI evaluation, not only for epidemiological studies, but also in clinical practice [12,13]. It is remarkable that there is not any specific scale designed to evaluate impact on QOL in male UI. There are mixed scales available that evaluate both severity and impact on QOL, like "International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form" (ICIQ-IU SF) [9]. This scale has a Spanish validated version [14].

Some scales have been developed to evaluate ED but none of them took into account the different therapeutic possibilities for prostate cancer, which are mainly: surgery, external radiotherapy, brachithery and hormonal therapy. All of these therapeutic options, some of them combined during patient's treatment, can produce a negative impact on QOL, due to the development of UI and ED. Wei JT et al. designed the "Expanded Prostate Index Composite" (EPIC) [15]. This scale evaluates iatrogenic effects and their impact on QOL in patients with prostate cancer and involves four clinical domains: urinary domain, bowel domain, sexual domain and the hormonal domain. The hormonal domain is a pioneer one, never before the adverse effects of androgen deprivation had been included in the assessment of the QOL of these patients.

The causes of UI and ED are diverse. Age, receiving radiotherapy treatment, characteristics of the surgical technique and bladder catheterization's duration, are probably the most important aspects to consider [2,16].

Surgical technique is particularly important in preserving continence [17] and erectile function. Therefore, as long as the staging of the cancer disease allows it, there's interest in preserve a number of fundamental anatomical structures such as: the maximum possible length of healthy urethra (smooth sphincter), preserving the bladder neck (detrusor), to avoid aggression in the apex (striated sphincter), perform an urethral anastomosis without support in the pelvic floor muscles, as well as preserve the puboprostatic ligaments and neurovascular bundle (lateral bands) [16,17-19]. Damage on this latter anatomic structure it is more related with postoperative ED, while some authors consider it also involved in urinary continence [17].

Classically, lateral bands preservation has been considered a priority to preserve erectile function. Unfortunately, their preservation is not always possible if they are affected by oncologic disease. Another determinant fact, especially from age of 65 years, is the presence of ED before surgery. It can be assumed that above age 65, if there is preexisting ED, the erectile function will be very difficult to recover despite any of lateral bands preservation. Instead, in younger patients, with preserved erectile function previously to the surgery, it is possible to achieve a good postoperative function; even in cases that surgical resection of neurovascular bundle is performed. In this matter, most authors agree that the innervations of all these anatomical structures are complex and there is a wide inter patient variability [19,20].

Erectile function is not systematically assessed in a rehabilitation medical consultation, because it is considered a disorder related to specialties such as Urology or Andrology. Nonetheless, some patients

can expose this problem in our consultation. Insofar as treatment techniques used in rehabilitation for UI affects neuromuscular structures associated with erectile function, and it is also involved in the quality of life of the individual, pelvic floor rehabilitation treatment could be useful to improve ED.

Likewise, the postoperative catheterization time should be as short as possible, taking into account the urethral postsurgical edema, which may influence the development of acute urinary retention if bladder catheter is removed too soon [21].

Objectives

This study evaluates the results following rehabilitation in QOL of patients undergoing radical prostatectomy, measured in severity and impact of UI and also in relation to the ED.

Patients and Methods

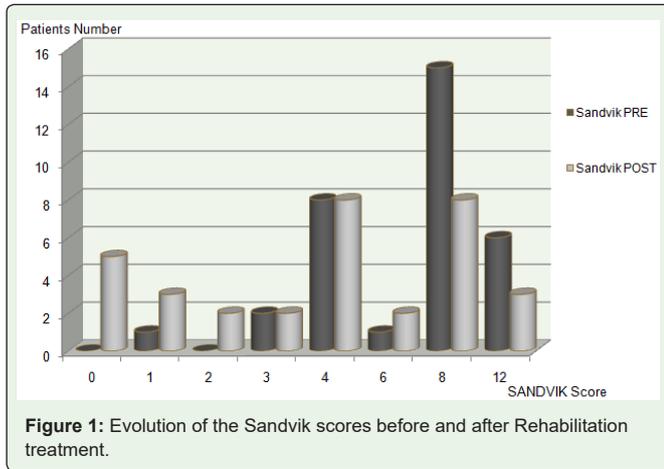
A cohort of 33 patients was evaluated. All of them suffered UI after having undergone radical prostate surgery due to prostate cancer, in the period between December 2007 and April 2013. Surgical technique was laparoscopic, except in one case which required open surgery (retropubic prostatectomy).

In 11 patients surgery was done with neurovascular bundle preservation, at least partially.

Rehabilitation proceeding in our Service includes: hygienic-dietary recommendations; biofeedback; postural control exercises and control muscle synergies (abdominal muscles, gluteal muscles and adductors), as well as Pelvic Floor Muscle Strengthening (PFMS) exercises, performed individually and in group therapy. PFMS exercises are mainly based on superficial transverse muscle, puborectalis, bulbospongiosus and sphincters training. Patients perform 10 repetitions of each exercise, maintaining contraction 5 seconds followed by 10 seconds of rest after each exercise. Also hipopressive exercises in standing position are included in non-hypertensive patients.

Patients performed 2 rehabilitation sessions per week, spread over two consecutive phases: first an individual phase followed by group therapy, both conducted and supervised by the physiotherapists of our Service. Patients performed between 4 and 6 individual sessions. In this phase of the treatment, hygienic-dietary recommendations were indicated and patients were instructed in postural and in PFMS exercises, with the support of biofeedback. Group therapy was developed across 8 therapy sessions, where patients kept doing the exercises regimen initiated in the individual phase. They were subsequently advised to continue at home the exercises learned in our Service

Eight cases received intracavitary electrostimulation, during the individual phase. A high frequency biphasic alternating electric current was used (minimum 50Hz) at 300 μ s of amplitude. The dosage of the intensity depends on the tolerance of each patient. Electrostimulation was used in those patients who had difficulties to perform a physiologic pattern of pelvic floor muscular contraction and who perform this contraction with abdominal, gluteal and/or adductors muscles synergies, or even with inversion of the physiologic contraction pattern, as an adjuvant technique to biofeedback, and to improve patient proprioception.



This is our usual clinical UI management in our Rehabilitation Service.

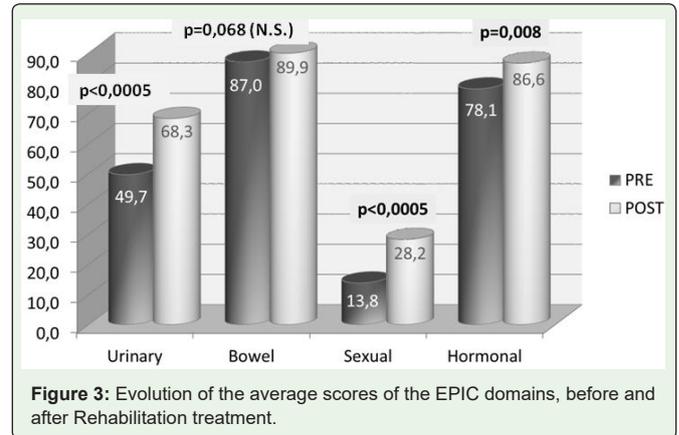
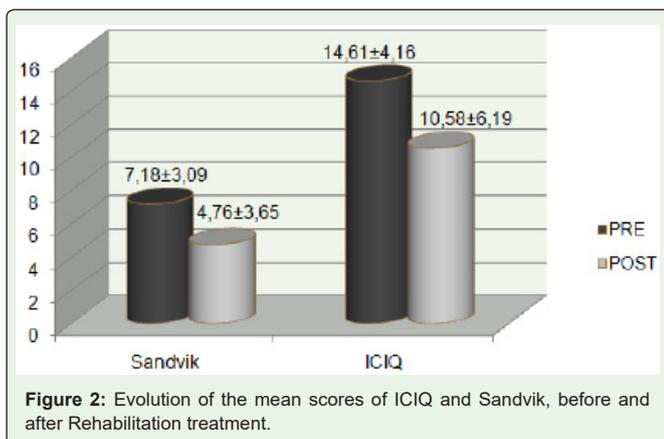
Patients were evaluated using validated Spanish versions of Sandvik Severity Index (modified version), International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF), and the Expanded Prostate Index Composite (EPIC), as well as the number of pads used before starting treatment and also at 3 and 6 months after finishing therapy sessions [10,11,15,18,22,23]. No long term follow-up was performed.

Statistical Analysis

Differences between data obtained in the three scales and pads used before and after rehabilitation treatment were analyzed. Data were analyzed with the statistical program IBM SPSS. After an initial descriptive analysis, Kolmogorov normality test was applied to the different quantitative variables. For pre and post intervention comparison Wilcoxon non parametric test was used. Comparisons of quantitative variables among different subgroups of patients (protectors, bladder catheterization, number of rehabilitation sessions, DE) were performed using the U test of Mann-Whitney. The correlation between quantitative variables was studied using the Spearman coefficient.

Results

All the 33 studied patients completed the rehabilitation treatment



and answered the questionnaires. The mean age of the patients was 64.5 ± 5, 6 yr (between 49 and 75 yr). The average postoperative catheterization time length was 21 days (between 8-40 days) and patients performed an average of 12.42 (6-27) sessions. Patients were assessed in our department about a week after the removal of the bladder catheter.

An improvement in the results of rating scales before and after rehabilitation treatment was observed in ICIQ and Sandvick scales, in urinary and sexual domains of EPIC (p<0,005), and in the Hormonal domain of EPIC (p 0.008). No significant differences were observed in the Intestinal domain of EPIC (p 0.068) (Figures1-3).

Median Use of pads before treatment was 3 (0-8) and after treatment 1.5 (0-6).

The percentage of change in scores obtained in rating scales, before and after rehabilitation treatment, showed a correlation with varying statistical significance in some cases (Table 1).

No statistically significant correlation between the change in score rating scales and the use of pads was observed.

A significant correlation between the days of bladder catheterization and the bowel domain (-0.382; p 0.028) and sexual domain (0.545; p 0.004) of EPIC scale was observed, but no correlation was observed in the other domains of EPIC neither ICIQ nor Sandvik scales.

Referring to the number of rehabilitation sessions no correlation was observed with any of the scales evaluated, it only came close to statistical significance in sexual domain of EPIC (p=0.75).

No significant differences were observed in the evaluated scales between the subgroup of patients who had pre-prostatectomy ED, and patients who had a normal preoperative erectile function.

As for the ED, we must mention that besides rehabilitation treatment, most of the patients received drug treatment at some point in the evolution of the process, but almost always the prescription was late (more than 3 months after prostatectomy) and usually did not coincide with the implementation of rehabilitation treatment. In fact, only 2 of 33 patients recovered erectile function after surgery. In relation to patients with ED, 11 did not follow specific treatment; 15 patients needed intracavernous alprostadil with acceptable results in most cases (in one case it was not effective and in 2 cases the effects

Table 1: Correlation between assessment scales, pre and post rehabilitation treatment. (Significant results are specified in bold font; N.S: non significative result).

Pre-RHB	SANDVICK	ICIQ	EPIC Urinary	EPIC Bowel	EPIC Sexual	EPIC Hormonal
SANDVICK	1	0.730 (P<0.0005)	-0.223 (N.S.)	0.064 (N.S.)	-0.069 (N.S.)	0.046 (N.S.)
ICIQ		1	-0.522 (P=0.002)	0.033 (N.S.)	-0.133 (N.S.)	-0.201 (N.S.)
EPIC Urinary			1	0.326 (P=0.064)	0.368 (P=0.035)	0.449 (P=0.009)
EPIC Bowel				1	-0.043 (N.S.)	0.354 (P=0.044)
EPIC Sexual					1	0.359 (P=0.040)
EPIC Hormonal						1

Post-RHB	SANDVICK	ICIQ	EPIC Urinary	EPIC Bowel	EPIC Sexual	EPIC Hormonal
SANDVICK	1	0.896 (P<0.0005)	-0.755 (P<0.0005)	-0.240 (N.S.)	-0.203 (N.S.)	-0.291 (N.S.)
ICIQ		1	-0.795 (P<0.0005)	-0.311(P=0.078)	-0.384 (P=0.027)	-0.253 (N.S.)
EPIC Urinary			1	0.319 (P=0.070)	0.409 (P=0.018)	0.454 (P=0.008)
EPIC Bowel				1	0.162 (N.S.)	0.454 (P=0.008)
EPIC Sexual					1	0.119 (N.S.)
EPIC Hormonal						1

were partial) and 4 cases preferred oral treatment of various types with mixed results. In one case no data were obtained in this regard.

Discussion

Early diagnosis of cancer disease is essential to try to improve survival and also in order to obtain good functional results, as it will allow the use of minimally invasive surgical techniques, if the tumor is located and whether surgery is indicated.

Bladder catheterization length time influences the results of continence. Laparoscopic surgery has meant an evolutionary progress that has positively influenced this aspect because the standards published today show a time of catheterization of 5-7 days [21], pretty much below the data obtained in the studied sample (21 days). Most patients' subject of this study required a less conservative surgery and perhaps this fact conditioned, at least in part, the duration of catheterization.

The functional results depend to a great extent on the surgical technique, but specifically in terms of neuromuscular preservation since, in terms of preservation of continence and erectile function, as of today it is not demonstrated that none surgical technique is superior to another, whether open, laparoscopic or robotic.

New techniques of robotic surgery may have a role in the preservation of some structures such as the neurovascular bundle.

PFMS exercises remain the treatment of choice in the rehabilitation of incontinence in general, including incontinence associated to radical prostatectomy [3,7], both applied in isolation, as associated with Biofeedback and / or electrostimulation.

This paper described the use of intracavitary electrostimulation in 8 patients; it was a subgroup of patients with a mean age generally higher than the age group (69 versus 64.5 years). Electrostimulation has been used traditionally in the rehabilitation of neuromuscular injury with the intent to improve muscle trophism and reinnervation. Due to the small number of patients who received electrotherapy, this parameter has not been assessed in this study.

Anyway it should be noted that currently there is no clear evidence that adding biofeedback, electrostimulation, or supervised training is more effective than PFMS exercises only [24,25]. Nevertheless, if we compare the evolution of the levels of scientific evidence that has been published over the last few years, we can see that there has been a progressive increase in such evidence in favor of the usefulness of rehabilitation treatment to improve quality of life of patients undergoing radical prostatectomy. This fact can be seen in the "Urinary Incontinence Guidelines of the European Association of Urology" 2013 updated version, compared to the 2009 version [24,26].

Despite the controversial evidence, current literature supports that rehabilitation treatment is at least useful to contribute to the rapid recovery of urinary continence [27].

The severity of urinary incontinence will undoubtedly influence functional outcomes. Patients with a higher degree of urinary incontinence at 2-3 months postoperatively are likely to have worse outcomes in the longer term.

In patients refractory to conservative treatment, implantation of an artificial urinary sphincter is considered the standard treatment, with levels of recovery of continence of up to 80-90% of cases (being worse in individuals undergoing radiotherapy) [2,24]. Currently, there are other technical options such as the male sling, whose effectiveness is disputed, but could be useful in certain circumstances.

Referring to erectile function, the patient must be informed of the several options currently available.

Some patients prefer to try non-invasive measures as first choice: oral agents such as inhibitors of phosphodiesterase type 5 (PDE5, of which there are currently three: sildenafil, tadalafil and vardenafil) or the intraurethral α -1 adrenergic inhibitor (alprostadil, which can be combined with those described above); and physical measures such as the implementation of a ring at the base of the penis or the use of a vacuum device. If conservative measures are not sufficient, intracavernous alprostadil injections remain today the treatment of choice, although the patient may be reluctant to be treated, at least initially.

If this option is not effective, other options should be considered, such as penile prosthesis.

In the literature there are numerous references that address the management of ED, both generally and specifically as a complication after prostatectomy. Since Montorsi described the concept of “penile rehabilitation” [28], in relation to tissue oxygenation of the corpora cavernosa and the prevention of fibrosis that occurs after the onset of erectile dysfunction, there have published numerous papers that follow these principles. While in our opinion, as rehabilitation specialists, we miss the inclusion in the concept of a more specific for neuromuscular reeducation guidelines, because in the original description only the pharmacological treatment of ED is included, with support of some physical measures, such as vacuum devices. In parallel to this work, there are others that do include the rehabilitation of a more according to how we understand it that is way: with neuromuscular techniques, such as biofeedback, pelvic floor exercises and even electrostimulation reeducation. In this sense, Dorey has published some works that are described more specifically these therapeutic options [29,30]. In fact, Dorey’s slogan: “use it or lose it” is probably the best description of the objective of neuromuscular rehabilitation. If we want to maintain a certain level of muscle performance, we have to perform exercises “for life” [30,31].

Some studies have reported an ED recovery of up to 40% of patients after making a 3 month PFMS program [32].

We therefore consider that the concept of “penile rehabilitation” should be approached from a broader perspective and taking into account the neuromuscular component. We want to state that we believe that no treatment is exclusive; in fact we believe that all therapeutic options may complement each other.

The approach of ED is complex and multidisciplinary and should assess each case individually. The patient should be cognizant of the possible consequences of the intervention and should actively participate in their treatment program. In some cases, it has been recommended the involvement of the patient’s partner [33].

Despite the large literature available, there are no guidelines with a high level of scientific evidence to indicate what the best management options for ED are. However, most authors agree at least in the treatment of ED should be as early as possible to try to prevent the retractable fibrosis of the corpora cavernosa and consider it appropriate to start treatment at the time of removal of the bladder catheterization.

In our sample, the results of ED recovery are very poor, although we must bear in mind that the sample is small. Probably these results have been conditioned by factors such as age and previous ED. The improvement results obtained Sexual domain of the EPIC scale may be due to a phenomenon of adaptation by patients.

The other areas covered by the EPIC scale (intestinal and hormonal) probably would be relegated to a background in rehabilitation management, or in any case in highly selected patients, as they refer possible complications due primarily to treatment with radiotherapy and hormone therapy. Anyway we must not forget that secondary intestinal neuropathic alterations due to radiotherapy could benefit from most techniques described in the urinary and sexual domains. In our study, only two patients had been treated with radiotherapy. The adjuvant hormonal treatment can produce an

androgen deprivation and therefore also affect erectile function. In this study no patient had received this treatment modality.

Conclusion

Rehabilitation treatment applied in our department has managed to improve the quality of life of patients undergoing radical prostate surgery.

PFMS exercises are useful in rehabilitation treatment of incontinence associated to radical prostatectomy. Referring to erectile dysfunction, despite the lack of scientific evidence, there are some promising studies that support both the drug treatment and rehabilitation, along with some physical measurements, may improve erectile dysfunction secondary to prostatectomy.

We consider this study supports the evidence that rehabilitation treatment can be helpful in order to improve urinary incontinence and erectile dysfunction in patients undergoing prostatectomy.

Limitations

The authors are aware of the limitations of this study, such as the small sample size; prolonged length time bladder catheterization in the cohort analyzed, above the averages currently published; the absence of control group; short-term monitoring and the lack of specific assessment scales for ED in our work.

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