Evaluation of erectile function after laparoscopic radical prostatectomy in a single center

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Introduction: *To evaluate erectile function among men who had undergone laparoscopic radical prostatectomy and received postoperative medical therapy for erectile dysfunction.*

Materials and methods: *We performed a prospective study in men who underwent laparoscopic radical prostatectomy between September 2003 and November 2005 at our center and who received penile rehabilitation after surgery. All patients had antegrade interfascial dissection. They received 10 mg tadalafil on the fifth postoperative day and continued to receive it every other day, regardless of erectile function. Intracavernous injection of alprostadil was initiated at 3 or 6 months depending on response to treatment with tadalafil. Follow up evaluations were done at 3, 6, 12, 18 and 24 months. Oncologic and functional outcomes and compliance were assessed. Patients filled in International Index of Erectile Function-5 (IIEF-5) questionnaires.*

Results: *Of 1078 men who underwent laparoscopic radical prostatectomy during this time, 586 patients met inclusion criteria, complied with the study medication, and had complete data for 24 months. The patients had a median preoperative baseline IIEF-5 score of 22. A total of 150 patients (26%) underwent unilateral nerve-sparing surgery, while 436 patients (74%) had bilateral nerve-sparing surgery. At 24 months, 35% of patients who underwent unilateral nerve-sparing surgery and 68% of patients who underwent bilateral nerve-sparing surgery reported having sufficient erectile function for intercourse without using intracavernous injection of alprostadil. At 24 months after surgery, the median IIEF-5 score was 13 (1-25) for the whole cohort, 5 (1-25) for patients who had undergone unilateral nerve-sparing surgery, and 15 (1-25) for patients who had undergone bilateral nerve-sparing surgery.*

Conclusions: *The findings suggest that adequate patient selection and postoperative medical intervention allows the preservation or recovery of erectile function after laparoscopic radical prostatectomy. Inaccurate selection of patients and postoperative assessment might explain inferior erectile function results following this surgery.*

Key Words: laparoscopy, prostate cancer, erectile dysfunction, PDE-5 inhibitors, penile rehabilitation

Introduction

Due to widespread screening with prostate-specific antigen (PSA) tests, the number of younger men diagnosed with prostate cancer has increased.[1] The standard treatment for localized prostatic cancer remains radical prostatectomy (RP),[2,3] which has a primary goal of achieving cancer control. Secondary goals of RP include preserving continence and potency. Walsh's anatomical description of the prostate's neurovascular bundles led to the development of an anatomical nerve-sparing RP procedure with improved preservation of potency.[4] However, following this surgery, not all patients can achieve an erection that is sufficient for sexual intercourse.

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Recovery of sexual function after RP is influenced by the patient's age and preoperative erectile function, as well as the type of surgery (nerve-sparing or not) and the presence and timing of any complementary treatment.[5] Early medical therapy targeting erectile function may minimize penile structural changes and thus improve the long term response to treatment or recovery of spontaneous erections.[6] Montorsi et al[5] reported that intracavernous injections of alprostadil early after RP improved the recovery of erectile function compared with no treatment. Although this study was completed before the era of phosphodiesterase-5 inhibitors (PDE-5 inhibitors), it provided the rationale for penile rehabilitation given soon after RP. In 1998, the first PDE-5 inhibitor was approved by the US Food and Drug Administration. PDE-5 inhibitors are the most frequently used treatments for erectile dysfunction (ED) following radical prostatectomy; they work by preventing the breakdown of cyclic GMP, and they require the presence of functional nerves and nitric oxide to enhance erection.[7,8] Padma-Nathan et al[7] reported that administration of sildenafil in patients who had undergone bilateral nerve-sparing RP resulted in adequate quality of erections after surgery. Following the introduction of sildenafil citrate into the marketplace, two other PDE-5 inhibitors, tadalafil and vardenafil, have become available.[9] Intracavernous injection of medications for ED is safe and effective for ED after RP.[10] Intracavernous injections with alprostadil produce erections by directly stimulating the production of cyclic AMP in smooth muscle cells, and this is also efficacious for other patients with ED.[11] One study reported that prior to RP, most physicians prescribe PDE-5 inhibitors (95.4%) and intracavernous injections (75.2%); however, there is no consensus on effective penile rehabilitation programs after RP.[12]

More than 10 years ago, our group described the first series of laparoscopic RP[13] and suggested that the laparoscopic approach offered technical advantages and might improve morbidity and penile function outcomes while providing the same treatment efficacy as non-laparoscopic RP.[14] The present study aimed to prospectively evaluate erectile function in patients who had postoperative penile rehabilitation following laparoscopic RP.

Materials and methods

We performed a prospective study of patients who were treated at a single center (where a high volume of laparoscopic RP is performed) and who met the study's inclusion and exclusion criteria. To be included in the study, patients had to have bilateral or unilateral nerve-sparing laparoscopic RP and penile rehabilitation with pharmacological prophylaxis soon after surgery. The patients' potency — defined as their ability to have intercourse with penetration — was evaluated using the International Index of Erectile Function (IIEF-5) questionnaire.[15]

Between September 2003 and November 2005, 1078 men underwent extraperitoneal laparoscopic RP for prostate cancer at our center. Four urologists performed the surgeries. The technique, which was previously described,[16] involved ante grade and interfascial dissection in all cases. At the end of each procedure, the surgical team stated the grade of nerve preservation. All tumors were staged according to table 1 of the 2002 TNM classification. Biochemical cancer recurrence was defined as having a single PSA level ≥ 0.2 ng/L. The patients evaluated their postoperative sexual function using the IIEF-5 questionnaire. Patients were followed for 24 months, which was based on the reported maximum time for recovery of erectile function after surgery.[17]

Patients were required to be sexually active prior to laparoscopic RP to be eligible for study inclusion. Of the 1078 men who underwent extraperitoneal laparoscopic RP for prostate cancer, 102 patients were foreigners or could not comply with the study follow up, 94 patients underwent non nerve-sparing laparoscopic RP, and 162 patients did not want to receive ED therapy, which left 720 patients who met study eligibility criteria.

Regardless of their erectile function, all patients received 10 mg tadalafil starting on the fifth day after surgery, and they were instructed to take it every other day from then on. At 3 months, if patients had a poor response to oral therapy for ED (that is, they were unable to achieve sexual penetration), they were switched to intracavernous injections with 5 mg alprostadil, to be taken twice a week or as needed.

Patients had medical evaluations at 3, 6, 12, 18, and 24 months. At each medical evaluation, if a patient had recovered satisfactory sexual function, he was given the option of stopping tadalafil and starting on-demand treatment with alprostadil injection. The study did not include the use of Doppler to guide alternative penile rehabilitation. At each physician visit, a patient brought an IIEF-5 questionnaire that he had filled in at home, and the physician evaluated the patient's ability to obtain and/or maintain an erection sufficient for penetration. Patients also provided information regarding orgasms. Successful penile rehabilitation was defined as being able to achieve sexual intercourse without the use of an intracavernous injection. Treatment tolerance and compliance were monitored.

TABLE 1. **Baseline patient demographics**

Characteristic	Number of patients (%)*
Number of patients	586
Median patient age (range), years	60 (44-74)
Median overall preoperative IIEF-5 score	22
Unilateral NS procedure	
Number of patients (%)	150 (26)
IIEF-5 score > 20, % of patients	68
Bilateral NS procedure	
Number of patients (%)	436 (74)
IIEF-5 score > 20, % of patients	68
pT2	490 (83.6)
Positive margins	53 (11)
pT3	96 (16.3)
Positive margins	13 (14)

*Except when otherwise indicated.
IIEF-5 = 5-item International Index of Erectile Function.
NS = nerve–sparing

TABLE 2. **Percent of patients using intracavernous injections at 6 and 12 months after laparoscopic radical prostatectomy**

Type of surgery	Use of ICI of ED therapy (% of patients)	
	6 months postoperative	12 months postoperative
Unilateral NS	68	60
Unilateral NS and baseline IIEF-5 > 20	71	64
Bilateral NS	63	52
Bilateral NS and baseline IIEF-5 > 20	62	50
All types	65.5	56

ICI = intracavernous injection; ED = erectile dysfunction; IIEF-5 = 5-item International Index of Erectile Function; NS = nerve-sparing.

Results

Patient characteristics and overall results

Of the 720 patients eligible for study inclusion, 31 patients (4%) were lost to follow up, 43 patients (6%) were noncompliant with medication (due to sides effects or cost), and 60 patients (8%) had elevated PSA levels and required additional hormonal or radiation treatment. Data from these 134 patients (18%) were excluded, which left 586 patients for whom data was analyzed.

Table 1 shows the baseline demographics of the 586 patients. They had a median age of 60 years (range, 44 to 74 years). About one-quarter of them, 150 patients (26%) underwent unilateral laparoscopic RP and the rest, 436 patients (74%), underwent bilateral laparoscopic RP. Table 2 shows the use of intracavernous injection of alprostadil at 6 and 12 months for patients who underwent bilateral or unilateral nerve-sparing laparoscopic RP. Table 3

TABLE 3. **Erectile function outcomes at 24 months after laparoscopic radical prostatectomy**

Surgery type and median preoperative IIEF-5 score	Median IIEF-5 at 24 months	ICI-free intercourse at 24 months* (% of patients)	ICI-free and oral treatment-free intercourse at 24 months** (% of patients)
Unilateral NS (n = 150)	5	35	22
IIEF-5 < 20 (n = 58)	2	21	11
IIEF-5 > 20 (n = 92)	7.5	43	29
Bilateral NS (n = 436)	15	68	47
IIEF-5 < 20 (n = 138)	10	51	31
IIEF-5 > 20 (n = 298)	17	76	54
Both types (n = 586)	13	59	40

*Erectile function sufficient for intercourse, without ICI of ED therapy.
**Erectile function sufficient for intercourse, without ICI of ED therapy and without oral ED therapy.
ICI = intracavernous injection; ED = erectile dysfunction; IIEF-5 = 5-item International Index of Erectile Function; NS = nerve-sparing.

summarizes the end-of-study, 24 month results for ability to achieve erectile function (sufficient to attain penetration) without intracavernous injection of ED therapy, or without oral or intracavernous injection of ED therapy.

Preoperative and postoperative IIEF-5 scores, type of neurovascular dissection

The possible IIEF-5 scores are 5 for lowest erectile function and 25 for highest erectile function. However, some patients only answered one part of one of the five questions, giving them a score of "1". Prior to surgery, the median IIEF-5 score was 22 (1-25) for the entire study group, 21 (1-25) for patients who went on to have a unilateral nerve-sparing procedure, and 23 (1-25) for patients who went on to have a bilateral nerve sparing procedure, Figure 1. The preoperative IIEF score was above 20 for 67% of patients; 10 to 20 for 30% of patients; and below 10 for 3% of patients. At 24 months after laparoscopic RP, the median IIEF-5 score was 13 (1-25) for the entire cohort; 5 (1-25) for patients who had undergone unilateral nerve-sparing surgery, and 15 (1-25) for patients who had undergone bilateral nerve-sparing surgery ($p < 0.001$).

Figure 2 shows the postoperative IIEF-5 scores for patients who had preoperative IIEF-5 scores from 5 to 20 or above 20, and who underwent unilateral or bilateral nerve-sparing procedures. The best overall recovery of IIEF-5 back to baseline occurred in the bilateral nerve-sparing group, among patients with an initial IIEF-5 above 20 ($p < 0.001$). Patients who underwent a unilateral nerve-sparing procedure had the lowest overall recovery of potency.

Intercourse achievement, IIEF-5 scores, and type of neurovascular dissection

Figures 3 and 4 show the percentage of patients who had regained erections sufficient for intercourse, without intracavernous injection of therapy for ED, by 3 to 24 months after undergoing laparoscopic RP. The percentage of patients achieving intercourse increased over time. At 24 months, in the entire cohort, 35% of patients who had undergone unilateral nerve-sparing RP and 68% of patients who had undergone bilateral nerve-sparing RP had regained erections sufficient for intercourse ($p < 0.001$), Figure 3. Among patients with no ED prior to surgery (IIEF-5 above 20), at 24 months, 43% of those who had undergone unilateral nerve sparing RP and 76% of those who had undergone bilateral nerve sparing RP had regained erections sufficient for intercourse, Figure 4.

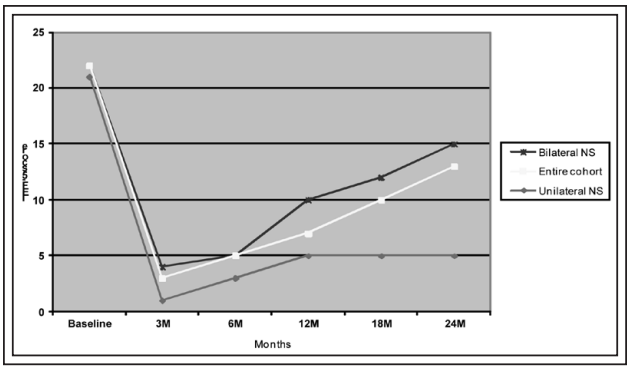

Figure 1. IIEF-5 scores following laparoscopic radical prostatectomy.
IIEF-5 = 5-item International Index of Erectile Function
NS = nerve-sparing

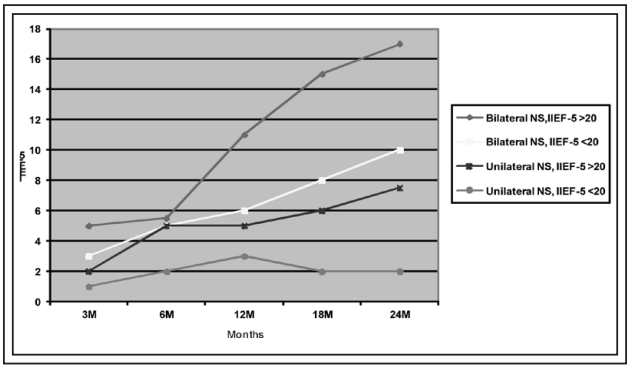

Figure 2. IIEF-5 scores following laparoscopic radical prostatectomy: sub-analysis based on preoperative IIEF-5 scores and surgery type.
IIEF-5 = 5-item International Index of Erectile Function;
NS = nerve-sparing.

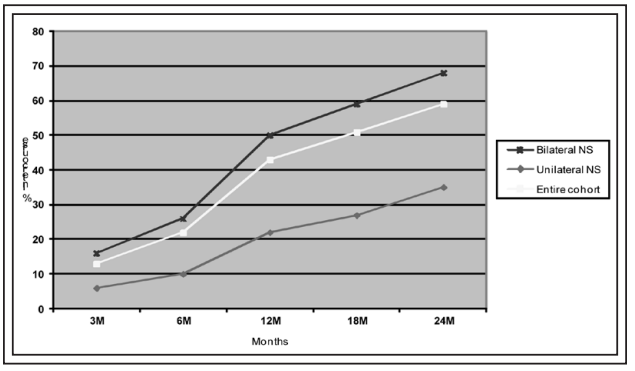

Figure 3. Percent of patients who were able to achieve intercourse following laparoscopic radical prostatectomy.
NS = nerve sparing.

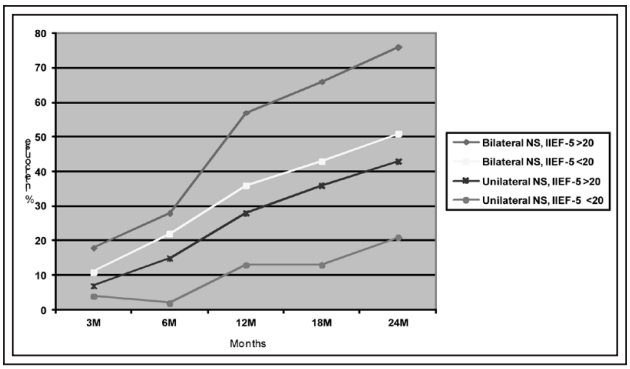

Figure 4. Percent of patients who were able to achieve intercourse following laparoscopic radical prostatectomy: sub-analysis based on preoperative IIEF-5 scores and surgery type.
IIEF-5 = 5-item International Index of Erectile Function; NS = nerve-sparing.

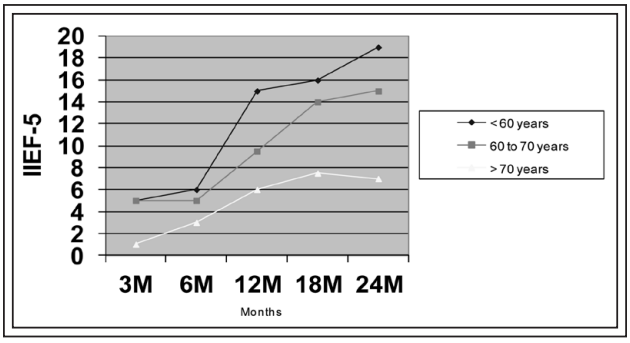

Figure 5. IIEF-5 scores following laparoscopic radical prostatectomy in patients with preoperative IIEF-5 scores above 20: sub-analysis based on age
IIEF-5 = 5-item International Index of Erectile Function; NS = nerve sparing.

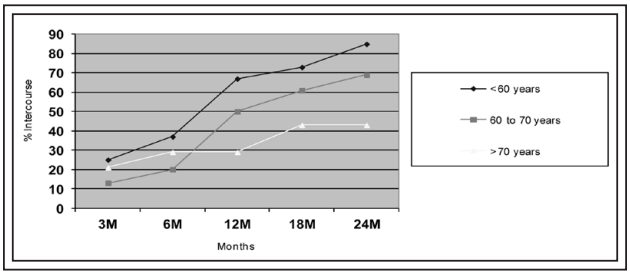

Figure 6. Percent of patients who were able to achieve intercourse following laparoscopic radical prostatectomy: sub-analysis based on age.

Age, postoperative IIEF-5 scores, and attainment of intercourse

Patients younger than 60 years old who had a preoperative IIEF-5 score above 20 had the highest postoperative IIEF-5 scores and were most likely to achieve sexual intercourse during follow up; at 24 months, patients in this subgroup had a median postoperative IIEF-5 score of 17 and 85% had regained erections sufficient to achieve intercourse ($p < 0.001$), Figures 5 and 6. Patients between 60 and 70 years of age also obtained considerable erectile function by 24 months. Among all patients, recovery of erectile function became more evident starting from 6 months after surgery. Improvement was observed in all patients in the study. However, patients older than 70 years had poorer results. In the three age groups, recovery of erectile function continued to increase from 12 months to 24 months after surgery.

Orgasm

In the total cohort, 9% of patients did not report any information about orgasms. Another 16% of patients reported the absence of orgasms. Among the 75% of patients who reported the presence of orgasms, 54%, 20% ,and 1% of patients, respectively, reported experiencing worse, comparable, and better orgasms than those experienced at baseline ($p < 0.001$).

Treatment compliance

Forty-three patients (6%) did not comply with medication. The most frequent side effects reported by patients were stomach pain in 18 patients (42%), headache in 7 patients (16%), and myalgia in 8 patients (19%). A total of 10 patients (23%) reported that they did not comply with treatment due to the cost of the drug.

Discussion

We undertook a study of postoperative sexual function among patients who underwent laparoscopic RP. The primary goal of RP is to give the patient the best result to treat prostate cancer. Secondary goals are to maintain preoperative potency and continence status. Potency after a radical prostatectomy is reported to range from 22% to 80%.[18] Despite careful nerve-sparing surgery, ED remains an issue.[19] Findings from recent studies that looked at recovery of erectile function following different types of RP are summarized in Table 4. Responsiveness to PDE-5 inhibitors after RP clearly depends on the time from surgery, with the maximum recovery occurring at 18 to 24 months after surgery.[17] As corpus cavernosal atrophy and fibrotic changes happen in the first 3 months after RP,[20] early postoperative intervention is crucial.

TABLE 4. **Erectile function recovery after radical prostatectomy: recent study reports**

Study	Technique	Endpoint (months)	Number of patients	Erectile function recovery (% of patients)
Anastasiadis et al, *Urology* 2003	LRP	12	32	42†
Curto et al, *Eur Urol* 2006	LRP	12	137	59†
Salomon et al, *Eur Urol* 2002	LRP	12	43	51†
Rogers et al, *J Urol* 2006	LRP	12	127	60*
Wagner et al, *Int J Impot Res* 2006	LRP	12	53	60**
Deliveliotis et al, *BJU Int* 2005	ORP	24	105	25‡
Rocco et al, *J Urol* 2006	ORP	18	43	44‡
Michl et al, *J Urol* 2006	ORP	12	302	74‡
Kaul et al, *BJU Int* 2006	ORP	12	102	69§§
Dalkin et al, *Urol Oncol* 2006	ORP	24	56	35‡‡
Descazeaud et al, *J Urol* 2006	ORP	12	189	43†
Martis et al, *Surg Oncol* 2007	ORP	24	100	60†
Zorn et al, *Eur Urol* 2007	RALRP	24	227	76††
Berry et al, *J Endourol* 2009	RALRP	12	237	83†
van der Poel et al, *Urology* 2009	RALRP	6	107	53‡
Krambeck et al, *BJU Int* 2009	RALRP	12	286	70†
Finley et al, *BJU Int* 2009	RALRP	24	58	89.7†

ORP = open radical prostatectomy; LRP = laparoscopic radical prostatectomy; RALRP = robot assisted laparoscopic radical prostatectomy. †Sufficient erection for intercourse; ‡International Index of Erectile Function-5 (IIEF-5); *Expanded Prostate Cancer Index Composite (EPIC); ‡‡SF36TM; §§Sufficient erection for intercourse and Sexual Health Inventory for Men (SHIM); **Sexual Function Subscale Score (SFSS) and EPIC; ††UCLA Prostate Cancer Index Score (UCLA-PCI), SF36TM, and Sufficient erection for intercourse.

Therefore, we decided to prescribe tadalafil 10 mg every other day and to prescribe intracavernous injection of alprostadil when there was no effective response to the oral agent. Tadalafil is a long-acting PDE-5 inhibitor. Recently, in an experimental setting, it was shown to be an apoptosis inhibitor in cavernous endothelial and smooth muscle cells with activation of kinases associated with cellular survival.[19] Intracavernous injection of alprostadil has been reported to be an effective alternative treatment for ED among patients who do not respond to PDE-5 inhibitors.[20] Since patients who have ED after undergoing RP are one of the patients groups that is most refractory to treatment with PDE-5 inhibitors, we decided to offer intracavernous injection of alprostadil to patients who did not respond to tadalafil at 3 or 6 months. Our rationale was to offer a therapy that had a different mechanism of action on cyclic GMP (acting on direct production versus breakdown).[21] This strategy was originally presented by Nandipati and colleagues;[22] they reported that in a non-placebo-controlled trial of 22 men who received intracavernous injection of ED therapy and sildenafil, 96% of patients achieved sexual activity with intracavernous injection of ED therapy or combined therapy.

Surgical technique, neurovascular bundle sparing

The interfascial plane was selected for comprehensive nerve-sparing, in order to safely remove the cancer while preserving erectile function. The decision to perform unilateral or bilateral nerve sparing PR was based on pre and intraoperative findings.[23]

Sexual activity, baseline IIEF-5 scores

Sexual function, particularly erectile capacity, declines with age in men. There are significant age-related decreases in self-reported frequency of sexual activity and in erectile response to sexual stimuli.[24] In one study, a comprehensive assessment revealed that 50% of candidates for radical prostatectomy presented with abnormal erectile function,[25] so baseline evaluation is of the utmost importance, and it is even more important when a great deal of variation exists in surgical techniques and methods of erectile assessment. We observed that 67%, 30%, and 3% of the patients had

preoperative IIEF-5 scores above 20, between 10 and 20, and below 20, respectively, and the best return of IIEF-5 scores to baseline levels occurred in patients who had bilateral nerve-sparing surgery and had initial IIEF-5 scores above 20 ($p < 0.001$). Postoperative erectile function outcomes are better among patients who have good baseline erectile function. This subgroup of patients probably represents the most important group of patients who would benefit from penile rehabilitation after laparoscopic RP. We found that 43% to 76% of patients with an IIEF-5 score greater than 20 were able to attain erectile function sufficient for intercourse without using intracavernous-injections of ED therapy, at 24 months, Table 3.

Aging and outcomes after laparoscopic RP

Independent of the surgical approach (open surgery versus laparoscopic surgery), younger men who undergo RP regain continence and potency faster than older men who undergo this surgery.[26] However, analyses of validated questionnaire subscales demonstrated that by the end of the first postoperative year, the return to preoperative baseline urinary continence and sexual function is similar in all age groups.[26] In the present study, patients younger than 70 years old showed continuous improvement of intercourse up to 24 months postoperative, and patients younger than 60 years had the best outcomes ($p < 0.001$), Figure 6. Improvement was more evident beyond 6 months after surgery in all groups and continued up to 24 months. Our results are similar to those reported in other laparoscopic RP series in which 53.8% to 79.5% of patients and 55.6% to 58.8% of patients who underwent bilateral and unilateral nerve-sparing surgery, respectively, had erectile function at up to 18 months after surgery.[14] Raina et al[27] reported that 76% and 53.5% of men who underwent bilateral and unilateral nerve-sparing retropubic radical prostatectomy, respectively, maintained their potency with the assistance of sildenafil at 1 year after surgery.[27]

It has also been demonstrated that the efficacy of PDE-5 inhibitors is related to the degree of neurovascular preservation, preoperative erectile status, patient age, and the interval before starting the sildenafil.[27] Our data further supports these observations. The best return to baseline IIEF-5 scores occurred in patients who had bilateral nerve-sparing surgery and a preoperative IIEF-5 score above 20. Conversely, patients who underwent unilateral nerve sparing-surgery had a more modest return to baseline IIEF-5 scores, especially if they had preoperative IIEF- 5 scores below 20. In the current study, tadalafil was given as a primary preventive medication for penile rehabilitation. Padma-Nathan[28] suggested that post-prostatectomy ED is initiated by neuropraxia and perpetuated by cavernosal smooth muscle apoptosis.[28] In that study, a 7-fold improvement in the return of spontaneous erections was observed in men using sildenafil nightly as primary preventative medication after a bilateral nerve-sparing RP. This improvement and mechanism for primary prevention is thought to be due to the PDE-5 inhibitor's role in improved endothelial function, neuronal regeneration, and neuroprotection.[28] In the current study, the potency rates of 43% and 76% in patients who underwent a unilateral and bilateral nerve-sparing laparoscopic RP, respectively, may be due to the elective dissection of the neurovascular bundle with laparoscopy, the effects of tadalafil and/or intracavernous injection of ED therapy, and a detailed postoperative management. Some authors have suggested that PDE-5 inhibitors likely have a limited effect in the early postoperative period following RP.[5] They suggested alternative treatments — such as intracavernous injection of ED therapy, the use of vacuum devices, or a medicated urethral system — during the temporary neuropraxia, which is reported to last at least 6 to 12 months.[5,28,29] In the current study, patients who did not have satisfactory results with tadalafil at 3 or 6 months were offered a trial of intracavernous injection of ED therapy. At 6 and 13 months, 65.5% and 56% of patients, respectively, were using intracavernous injection of ED therapy.

A shortcoming of the present study is it was not a double-blind, placebo-controlled study, and results were compared to historical data in the literature. Results from a recent randomized, double-blind, placebo-controlled study reported a return of normal spontaneous erections in 24% to 33% of patients (depending on the dose of sildenafil) in a cohort of 76 patients treated with postoperative nightly sildenafil after bilateral nerve sparing RP, with an initial follow up of 9 months.[30] It would be beneficial to perform longer series of double-blind, placebo-controlled studies with long term follow up to evaluate the effects of penile rehabilitation in control patients. It would also be useful to systematically assess treatment response and treatment satisfaction in terms of patient and partner satisfaction, since ED affects family life. Despite these study limitations, our results provide insights from a prospective evaluation of patients from a high-volume center, where a validated self-reported assessment tool (the IIEF-5) was used and patients were followed for 24 months.

Conclusion

In the current study, preoperative sexual function predicted postoperative erectile function following RP, and age strongly correlated with postoperative sexual

function. IIEF-5 scores at 1 year following RP were about 50% of the preoperative IIEF-5 scores, and improvement continued up to 2 years after the procedure. PDE-5 inhibitors were largely ineffective in the first 6 months after RP. Bilateral nerve-sparing surgery resulted in the best postoperative erectile function. Orgasms attained after surgery were less satisfactory than those attained prior to the surgery, according to patients' reports. Erections that were adequate for intercourse did not always correlate with successful intercourse.

These findings suggest that adequate patient selection and postoperative medical intervention allows the preservation or recovery of erectile function after laparoscopic RP. Inaccurate selection of patients and postoperative assessment might explain inferior erectile function results following this surgery. □

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