Patient-Reported Validated Functional Outcome After Extraperitoneal Robotic-Assisted Nerve-Sparing Radical Prostatectomy

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ABSTRACT

**Background and Objectives:** Erectile function after prostate surgery is an important criterion for patients when they are choosing a treatment modality for prostate cancer. Improved visualization, dexterity, and precision afforded by the da Vinci robot allow a precise dissection of the neurovascular bundles. We objectively assessed erectile function after robot-assisted extraperitoneal prostatectomy by using the SHIM (IIEF-5) validated questionnaire.

**Methods:** Between July 2003 and September 2004, 150 consecutive men underwent da Vinci robot-assisted extraperitoneal radical prostatectomy for clinically localized prostate cancer. The IIEF-5 questionnaire was used to assess postoperative potency in 67 patients who were at least 6 months postsurgery. Erectile function was classified as impotent (<11), moderate dysfunction (11 to 15), mild dysfunction (16 to 21), and potent (22 to 25). All patients used oral pharmacological assistance postprocedure.

**Results:** Sixty-seven patients were available to complete the IIEF-5 questionnaire 6 months to 1 year postsurgery. Twelve patients were excluded from the study who abstained from all sexual activity after surgery for emotional or social reasons. Of the 55 patients evaluated, 22 (40%) were impotent, 3 (5.5%) had moderate ED, 12 (21.8%) had mild ED, and 18 (32.7%) were fully potent. The table compares IIEF-5 scores with nerve-sparing status. Of patients who had bilateral nerve sparing, 28/45 (62.2%) had mild or no ED within 6 to 12 months postsurgery, and all expressed satisfaction with their current sexual function or rate of improvement after robotic prostatectomy.

**Conclusion:** Robot-assisted extraperitoneal prostatectomy provides comparable outcomes to those of open surgery with regards to erectile function. Assessment of the ultimate maximal erectile function will require continued analysis, as this is likely to further improve beyond 6 to 12 months.

**Key Words:** Robotics, Prostatectomy, Sexual dysfunction, Postoperative complications.

INTRODUCTION

During the last 5 years, advances in laparoscopic equipment and technique, including the addition of the da Vinci surgical system (Intuitive Surgical, Mountain View, California), have resulted in significant progress in the development of minimally invasive surgery for localized prostate cancer. The combination of less postoperative morbidity, improved cosmesis, shorter convalescence, and the possibility of comparable outcomes has lured patient demand away from the conventional open retropubic prostatectomy technique. Robot-assisted prostatectomy has been widely popularized with over 1000 cases already reported in the literature by a single surgeon. At our institution, we developed a total extraperitoneal laparoscopic and robotic approach and found this procedure to be technically feasible and reproducible. Robot-assisted prostatectomy has been performed at multiple centers in both the United States and Europe, with early oncological and functional results still being reported. Objective data using validated questionnaires on postrobot-assisted nerve-sparing radical prostatectomy are sparse. We objectively assessed erectile function after robot-assisted extraperitoneal prostatectomy by using the 5-item version of the International Index of Erectile Function (IIEF-5), also known as the Sexual Health Inventory for Men (SHIM), validated questionnaire.

METHODS

Patients and Data

Analysis of our first 150 patients undergoing extraperitoneal robotic prostatectomy by the same surgeon (JVJ) was
performed. We prospectively collected baseline demographic data, such as race, body mass index, serum PSA, prostate volume, Gleason grade/sum, clinical stage, and associated co-morbidities. Perioperative, intraoperative, and postoperative data along with early functional and short-term oncological results were also prospectively enrolled, recorded, and analyzed. The indications for laparoscopic prostatectomy were identical to those of the conventional open radical retropubic prostatectomy. A nerve-sparing procedure was applied to all patients where oncological control was not jeopardized, regardless of preoperative sexual activity. Bilateral and unilateral nerve-sparing procedures were performed in 93 and 24 patients, respectively. Table 1 reviews the clinical features of the first 150 patients undergoing extraperitoneal robot-assisted nerve-sparing radical prostatectomy at our institution.

Procedure

Our method for development of extraperitoneal pneumoperitoneum and development of the space of Retzius is based on our preliminary experience with laparoscopic radical prostatectomy and has been described elsewhere.

Anatomical Nerve-sparing Technique and Considerations

The nerve-sparing operation commences after the seminal vesicles are freed, and the lateral prostatic pedicles are dissected with the reflection of the lateral pelvic fascia off the prostate. The vessels entering the prostate base are selectively coagulated by using bipolar forceps before their transection with da Vinci articulating scissors.

Functional Results

The SHIM validated questionnaire was used to assess potency status at the 6-month and yearly follow-up visit or during a separate phone interview by a third party. All patients receive a prescription for oral pharmacological assistance postprocedure and are instructed on its use. The degree of erectile function was classified into 4 grades: <11 = impotent; 11 to 15 = moderate erectile dysfunction (ED); 16 to 21 = mild erectile dysfunction; 22 to 25 = potent. The patients’ scores were tabulated and entered into an Excel database.

RESULTS

Functional Outcome

A nerve-sparing procedure was performed in 117 of the first 150 patients, 24 unilateral and 93 bilateral. The additional 33 patients had preplanned nonnerve-sparing robotic-assisted prostatectomies to avoid compromising cancer control. The high-risk features used to exclude patients from a nerve-sparing approach were Gleason sum/grade, PSA, number of positive biopsies, and clinical stage. This was discussed in detail with the patients before surgery. The IIEF-5 questionnaire was used to assess postoperative potency in 67 patients who were at least 6 months postsurgery. Erectile function was classified as impotent (<11); moderate dysfunction (11 to 15); mild dysfunction (16 to 21); and potent (22 to 25). All patients used oral pharmacological assistance postprocedure. Twelve patients were excluded who abstained from all sexual activity after surgery for emotional or social reasons. From the remaining 55 patients evaluated, 4 had nonnerve-sparing, 6 had unilateral nerve-sparing, and 45 had bilateral nerve-sparing. Of the 55 patients, 22 (40%) were impotent, 3 (5.5%) had moderate ED, 12 (21.8%) had mild ED, and 18 (32.7%) were fully potent. Table 2 compares IIEF-5 scores with nerve-sparing status. Of patients who had bilateral nerve sparing, 28/45 (62.2%) had mild or no ED within 6 to 12 months postsurgery, and all

| Parameter                      | Mean (Range) |
|-------------------------------|--------------|
| Age                           | 60 (46–76)   |
| Pre-op PSA                    | 6.6 (0.6–26) |
| Clinical Stage                |              |
| T1c                           | 126          |
| T2a                           | 22           |
| T2b                           | 2            |
| Gleason Score                 | 6 (4–8)      |
| Operative time (including docking) | 223 (163–486) minutes |
| Blood Loss                    | 196 mL       |
| Nerve Sparing                 | 117          |
| Unilateral                    | 24           |
| Bilateral                     | 93           |
expressed satisfaction with their current sexual function or rate of improvement after robotic prostatectomy (Table 2). When stratified by age, men under 60 more frequently had an erection sufficient for sexual intercourse than those who were older (mean IIEF-5 scores, 17.6 versus 10.8; \( P < 0.05 \)). At 6-month follow-up, 20/30 patients (67%) who were \( \leq 60 \) years of age reported mild ED or were fully potent, compared with 10/25 (40%) in patients older than 60. Ability to reach an orgasm was asked as a separate question after the set of validated questions. Independent of whether the patients were potent or had erectile dysfunction, greater than 80% of the men remarked that they were able to attain an orgasm or did not have a change in their ability to attain an orgasm.

**DISCUSSION**

The introduction of the anatomical nerve-sparing prostatectomy resulted in improved sexual function without compromising cancer control.\(^{11-13}\) In the PSA era, as patients are being increasingly diagnosed with localized prostate cancer, a main focus of treatment has become prevention of significant nonlife-threatening morbidity (such as incontinence and erectile dysfunction) while maintaining cancer control. The multiple advantages afforded by the robot (increased precision and dexterity with wristed instrumentation, ergonomic manipulation, and 3-dimensional visualization with 10x magnification) have encouraged both laparoscopically naïve and trained surgeons to embrace this technique.\(^{5}\) Current reports have already shown superior return of urinary control when compared with that of open surgery.\(^{1,7-9,14}\) In addition, early series have demonstrated comparable early tumor control and oncological outcomes.\(^{1,6-9,14}\) As opposed to tumor control and incontinence, where there are objective tests that can accurately determine functional and oncological outcomes, preservation of sexual function remains a difficult outcome to assess and quantify. The process of achieving a successful erection for intercourse is dependent on multiple patient parameters including age, co-morbid medical conditions like diabetes and peripheral vascular disease, psychological, behavioral, and social factors. In addition, varying surgical technique and operative modality as well as differences in surgeons’ patient selection has further compromised our understanding of postoperative potency status. Finally, the different definitions of postoperative potency and erectile dysfunction used as well as the multiple validated questionnaires in existence have made it even harder to assess. Therefore, more reports using objective data are needed to better treat patients postoperatively.

There has been a wide range of postnerve-sparing prostatectomy potency rates in the world literature. Walsh reported on 64 patients who underwent conventional open prostatectomy with bilateral neurovascular nerve preservation and found 73% of the patients were potent and sexually active.\(^{15,16}\) In a series by Catalona et al,\(^{17}\) 68% recovery of erections after bilateral, and 41% after unilateral nerve-sparing surgery was reported. When stratified by age, they found a 75% return of erection in patients \( < 60 \) who had bilateral nerve-sparing surgery.\(^{17}\) Gralnek et al\(^{18}\) demonstrated a 39% potency rate in 46 men after unilateral nerve preservation, and in a more recent series, Rabbani et al\(^{19}\) reported on 314 men undergoing open radical prostatectomy and found unilateral nerve preservation to be associated with a 25% rate of erectile function, while bilateral nerve sparing was associated with a 47% rate in patients older than 65 years of age and 76% in patients who were younger. Others have reported a large range of potency rates varying between 11% to 86% (Table 3).\(^{20,21}\)

A large series from Johns Hopkins University demonstrated age to be a predictor of recovery of potency.\(^{22}\) They showed that in patients \( < 50 \) years of age, regardless of the extent of nerve sparing, there was no difference in potency rates. In patients between 50 and 60 years of age, not only was the overall potency rate decreased, but recovery of erectile function was strongly dependent on whether one or both neurovascular bundles were preserved. Reports by Catalona et al\(^{17}\) and Rabbani et al\(^{19}\) also demonstrated that age and extent of nerve preservation were strong predictors of the return of erectile function.

Reports on erectile function after laparoscopic and robotic nerve-sparing radical prostatectomy have been scant. Moreover, the initial data were subjective without the use of validated questionnaires. Turk et al\(^{23}\) reported on 125

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**Table 2.** Erectile Function by Nerve-Sparing Status

| IIEF-5 Score | Class of Erectile Dysfunction | Nonnerve Sparing | Unilateral Nerve Sparing | Bilateral Nerve Sparing |
|-------------|-------------------------------|-----------------|-------------------------|------------------------|
| \( < 11 \)   | Impotent                      | 4               | 3                       | 15                     |
| 11–15       | Moderate                      | –               | 1                       | 2                      |
| 16–21       | Mild                          | –               | –                       | 12                     |
| 22–25       | Potent                        | –               | 2                       | 16                     |
| Total Patients |                           | –               | 6                       | 45                     |
patients who underwent laparoscopic prostatectomy. Of 44 patients having either unilateral or bilateral nerve preservation, they found 18 patients having spontaneous intercourse and 8 needing pharmacological assistance. Rassweiler et al. reported on 100 patients undergoing laparoscopic radical prostatectomy, whereby 10 patients underwent unilateral nerve-sparing surgery with only 4 of these men having intercourse with the aid of pharmacotherapy. Six of 10 patients undergoing laparoscopic bilateral nerve-sparing prostatectomy had successful intercourse in a series by Bollens et al., and 9 of 20 (preoperative potent patients) undergoing laparoscopic bilateral nerve-sparing prostatectomy had successful intercourse in Guillonneau and Vallancien’s early series. Subsequently, both teams reported potency rates of 65% and 60%, respectively, in their larger series. Using sexual function questionnaires, Katz et al. reported on 143 patients undergoing laparoscopic nerve-sparing radical prostatectomy. Fifty-eight percent of patients who had erections preoperatively maintained their erections after surgery. There have been even fewer reports of potency outcome after robotic-assisted nerve-sparing surgery compared to laparoscopic techniques. There are several reasons for this, including the relatively recent adoption of robotic surgery and the fact that nerve-sparing techniques are more difficult to perform robotically. However, recent data suggest that robotic-assisted nerve-sparing prostatectomy is a feasible and effective approach for preserving erectile function. A recent study by Menon et al. reported on 251 patients undergoing robotic-assisted nerve-sparing prostatectomy, with 72% of patients achieving satisfactory potency outcomes. These results are similar to those seen with laparoscopic nerve-sparing prostatectomy, suggesting that robotic surgery may be a viable option for preserving erectile function in men undergoing prostatectomy. Overall, the data suggest that nerve-sparing prostatectomy is an effective approach for preserving erectile function in men undergoing prostatectomy, and that both laparoscopic and robotic techniques can achieve similar outcomes. However, further research is needed to determine the best approach for preserving erectile function in men undergoing nerve-sparing prostatectomy.
with laparoscopic and open surgery. Menon et al reported 82% of preoperatively potent patients younger than 60 having a return of some sexual activity using the expanded prostate cancer index composite, and 64% having sexual intercourse at 6-month follow-up.\textsuperscript{2,3} Of patients over 60 years of age, 75% had sexual activity and 38% had sexual intercourse. Using SHIM, Ahlering et al\textsuperscript{3} reported a lower 43% potency rate after cautery-free robotic-assisted prostatectomy when including patients up to the age of 65. Recent reports by Menon et al\textsuperscript{30,31} describe the outcomes after robotic-assisted prostatectomy using both conventional and prostatic fascia-sparing techniques. At 12-month follow-up, 74% of patients having undergone conventional nerve-sparing robotic-assisted prostatectomy, and 97% of those having undergone the fascia-sparing procedure achieved erections sufficient for intercourse. In patients who did not use medications, however, SHIM scores demonstrated that the percentage achieving normal erections in the conventional and fascia-sparing groups was only 17% and 51%, respectively.\textsuperscript{30–33}

Our data are based on the 55 eligible patients able to fulfill the abovementioned criteria and undergo objective questioning using the IIEF-5 validated questionnaire. Currently, the IIEF questionnaire published by Rosen et al\textsuperscript{10} in 1997 is a worldwide accepted and validated tool in assessing all aspects of sexual function and dysfunction. Of the 55 patients we evaluated, 22 (40%) were impotent, 3 (5.5%) had moderate ED, 12 (21.8%) had mild ED, and 18 (32.7%) were fully potent. Of patients who had bilateral nerve sparing, 28/45 (62.2%) had mild or no ED within 6 to 12 months postsurgery, and all expressed satisfaction with their current sexual function or rate of improvement after robotic prostatectomy. The overall rate of sexual function at 1 year of 62.2% is comparable to the results in open and early laparoscopic and robotic surgery. As can be expected, the majority of these patients had undergone bilateral nerve-sparing techniques. All of our patients receive a prescription for oral pharmacologic assistance and take the medication routinely after surgery and discontinue it when they feel they can do without it. When the patients are stratified to younger or older than 60, men under 60 years of age had a statistically significant increase in the rate of erection sufficient for sexual intercourse; however, those who were older did not (Mean IIEF-5 scores of 17 versus 10; P<0.05). At 6-month follow-up, 20/30 patients (67%) who were ≥60 reported mild ED or were fully potent, compared with 10/25 (40%) in those patients >60. This reinforces the multiple interactions relating to potency, age being one of them. Our finding is consistent with findings in the current literature. Table 3 reviews the varying literature on potency rates and method of prostatectomy. One limitation of our study is that preoperative potency scores were not attained, which alters the interpretation of our postoperative results, as a patient who was impotent preoperatively will not become potent after surgery thereby lowering our results. This would render our potency rate to be artificially low due to inclusion of impotent patients or patients with poor baseline erectile status. Despite this, our results are encouraging, which also adds a functional outcome to the benefit of robotic-assisted radical prostatectomy.

The time to recovery of sexual function has also been a matter of debate. Follow-up times after surgery have been variable with many studies showing that recovery of erection is a function of time and may occur more than 1 year after surgery. Walsh et al\textsuperscript{15,16} reported an improvement in potency of 72% to 86% between 12 and 18 months postoperatively. In the series by Rabbani et al,\textsuperscript{19} 75% of the men who were potent regained potency after 11.8 months.

CONCLUSION

Robotic-assisted nerve-sparing surgery is currently an established and reproducible technique. The benefits of the robot allow for better visualization and subsequent meticulous dissection and preservation of the neurovascular bundles. Our preliminary results provide comparable objective outcomes to open surgery with regards to erectile function. Assessment of the ultimate maximal erectile function will require continued analysis, as this is likely to further improve beyond 6 to 12 months.

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