Erectile function recovery after roboticassisted radical prostatectomy (RARP): long term exhaustive analysis across all preoperative potency categories

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Introduction: To evaluate erectile function recovery following robotic-assisted radical prostatectomy (RARP) according to preoperative sexual health inventory for men (SHIM) score stratification.

Materials and methods: We prospectively collected data on 250 consecutive patients who underwent RARP by a single surgeon between October 2006 and October 2012. Thirty-six patients were excluded because of lack of preoperative SHIM score. All patients had a minimum follow up of 2 years. Patients were divided into four groups according to their preoperative SHIM score: group 1 with normal potency (SHIM 22-25), group 2 with mild ED (SHIM 17-21), group 3 with mild-moderate ED (SHIM 12-16) and group 4 with moderate-severe ED (SHIM 1-11). Patients were followed at 3, 6, 9, 12, 18, 24 months intervals and twice yearly thereafter. SHIM questionnaire and erection hardness scale (EHS) score were collected at

each visit. Potency was defined as successful penetration during intercourse (EHS score 3-4) with or without phosphodiesterase type 5-inhibitor (PDE5-I).

Results: After exclusion, 214 patients were evaluated. The number of patients in group 1, 2, 3 and 4 were 95, 59, 26 and 34, respectively. At 3, 6, 9, 12, 18, 24 months, SHIM scores and potency rates were statistically different between groups 1 versus 2 versus 3 versus 4 (p < 0.01, at each time point). Patients in each group 1, 2 and 3 showed a statistically significant improvement in potency rates and SHIM scores at consecutive follow up visits up to 24 months (p < 0.01, for each potency group). Potency rates at 24 months for groups 1 to 4 were 83.3%, 54.5%, 50.0%, and 20.7%, respectively (p < 0.001).

Conclusion: For proper patient counseling and better prediction of erectile function recovery after RARP, it is important to stratify patients according to preoperative SHIM scores. Setting realistic expectations may increase patient satisfaction.

Key Words: quality of life, treatment outcome, preoperative potency, prostatic neoplasms, robotic surgical procedures, prostatectomy/adverse effects, erectile dysfunction, erectile function recovery

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Introduction

Erectile dysfunction (ED) exerts a significant impact on patients' quality of life (QoL) following radical prostatectomy (RP).^{1,2} This is of great importance particularly in the most recent years where younger men are being diagnosed with prostate cancer due to increased prostate-specific antigen (PSA) screening.^{3,4} Interestingly, shortly after the introduction of the

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da Vinci robotic system, authors began to report compelling data of improved erectile function and continence recovery post robot-assisted radical prostatectomy (RARP).⁵⁻⁹

A relatively recent meta-analysis showed a 12 and 24 months potency rates following RARP of 54%-90% and 63%-94%, respectively.⁸ Moreover, other reports have shown that the time to potency recovery can vary from 6-24 months.^{10,11} This variability in potency recovery can perhaps be related to differences in surgical techniques, disease factors or perioperative patient factors.

Aside from its negative impact on patient QoL, post-prostatectomy ED also affects patients' partners. ¹² Furthermore, It was also shown that couples have preoperatively been too optimistic about post-prostatectomy erectile function recovery. ¹³

Most radical prostatectomy series, all techniques confounded, report on erectile function recovery in the most optimal patients, namely those with normal preoperative function who underwent bilateral nerve sparing surgery. 14-18 Certain authors have even restricted their inclusion criteria only to the younger aged men in the cohort. 19 The most important prognostic factors for potency recovery after RP are preservation of the neurovascular bundles, age of the patient and sexual function before the operation. 20 The use of postoperative penile rehabilitation has also been correlated to improved outcomes.

Therefore, in order to accurately counsel couples, increase awareness, provide reasonable expectations regarding potency recovery post RARP and help avoid possible decision regrets, we sought to evaluate temporal erectile function recovery post RARP stratified by preoperative sexual health inventory for men (SHIM) score. This study aims to be a real life picture of all patients who underwent RARP by a single surgeon with long term follow up.

Materials and methods

Study population

After institutional review board approval, we reviewed data of 250 consecutive patients who underwent RARP at our institution between October 2006 and October 2012 by a fellowship-trained robotic surgeon. None of the patients had previous pelvic radiation or neoadjuvant hormonal therapy. The perioperative details of this cohort have been published elsewhere.²¹ At the current analysis, all patients had more than 24 months follow up. Data were collected prospectively and analyzed retrospectively. Perioperative patients' characteristics included age, body mass index (BMI), SHIM score,

international prostate symptom score (IPSS), serum PSA, pathological tumor stage, trans-rectal ultrasound (TRUS) prostate size, nerve sparing status and estimated blood loss (EBL). We excluded 36 patients due to lack of preoperative SHIM score. Patients were divided into four groups according to preoperative SHIM score: group 1 with normal potency (SHIM 22-25), group 2 with mild ED (SHIM 17-21), group 3 with mild-moderate ED (SHIM 12-16) and group 4 with moderate-severe ED (SHIM 1-11). Patients were followed at 3, 6, 9, 12, 18, and 24 months intervals, and twice yearly thereafter.

Outcomes

The main outcome of our study was erectile function recovery post RARP. SHIM questionnaire and erection hardness score (EHS) were obtained preoperatively as well as at each follow up visit. Potency was defined as successful penetration during intercourse (EHS score 3-4) with or without phosphodiesterase type 5-inhibitor (PDE5-I).

Statistical analysis

All tests were two-sided and considered a p value ≤ 0.05 to determine statistical significance. The IBM SPSS Statistics package (IBM Corporation, version 21, Armonk, NY, USA) was used for analysis. Data were summarized using descriptive statistics, and central tendency was measured with the median followed by the first and third quartiles (25%-75%). Group differences were determined using the chi-square test statistic or the Fisher's exact test for categorical variables. The Mann Whitney U test was used for continuous not-normally distributed variables. A Kruskal-Wallis one-way analysis of variance was used to compare multiple independent groups.

Results

After exclusions, 214 patients were evaluated. Baseline demographics, clinical and pathologic data for each group are summarized in Table 1. The number of patients in group 1, 2, 3 and 4 were 95 (44.4%), 59 (27.6%), 26 (12.4%) and 34 (15.9%), respectively. IPSS, PSA, tumor pathological stage, prostate volume and EBL were not statistically different between groups (p = NS). Age and BMI were statistically lower in patients with higher preoperative SHIM scores (p = 0.024 and p = 0.048, respectively). In addition, nerve preservation was statistically higher in higher SHIM groups (p < 0.001). None of the patients had previous pelvic radiation or neoadjuvant hormonal therapy.

Potency rates are summarized in Table 2. Men in groups 1, 2 and 3 showed a statistically significant improvement in potency rates at consecutive follow up

TABLE 1. Baseline characteristics

	Group 1 (n = 95) (SHIM 22-25)	Group 2 (n = 59) (SHIM 17-21)	Group 3 (n = 26) (SHIM 12-16)	Group 4 (n = 34) (SHIM 1-11)	p value
Age (years) [median (Q_1 - Q_3)]	59 [55-63]	62 [56-67]	61 [59-66]	63 [58-69]	0.024*
BMI (kg/m^2) [median (Q_1 - Q_3)]	26 [24-30]	27 [25-29]	28 [26-30]	28 [26-32]	0.048*
Preoperative SHIM [median (Q ₁ -Q ₃)]	24 [23-25]	19 [18-21]	15 [14-15]	5 [2-7]	< 0.001*
IPSS [median (Q_1-Q_3)]	5 [2-9]	5 [2-10]	9 [2-18]	8 [2-13]	0.176
PSA (ng/mL) [median (Q ₁ -Q ₃)]	5.7 [4.6-8.0]	5.6 [4.7-7.6]	6.3 [4.8-7.5]	5.5 [4.5-8.6]	0.931
Tumor p stage[n, (%)]					0.097
T2	65/89 (73)	46/55 (84)	15/26 (58)	23/32 (72)	
T3	24/89 (27)	9/55 (16)	11/26 (42)	9/32 (28)	
Prostate volume [median (Q_1-Q_3)]	33 [25-42]	31 [25-42]	33 [26-53]	31 [25-40]	0.768
Nerve sparing [n, (%)]					0.001*
Bilateral	74/94 (79)	41/57 (72)	18/25 (72)	19/34 (60)	
Unilateral	16/94 (17)	14/57 (25)	4/25 (16)	5/34 (15)	
Wide excision	4/94 (4)	2/57 (4)	3/25 (12)	10/34 (29)	
EBL (mL) [median (Q ₁ -Q ₃)]	300 [200-400]	300 [200-400]	200 [150-350]	300 [200-425]	0.074

SHIM = sexual health inventory for men; BMI = body mass index; IPSS = international prostate symptom score; PSA = prostate-specific antigen; EBL = estimated blood loss

visits (p < 0.001, p < 0.001 and p = 0.05, respectively). However, group 4 patients did not show any statistically significant improvement. At 3, 6, 9, 12, 18 and 24 months, potency rates were significantly higher for better SHIM groups compared to lower SHIM groups (p \leq 0.002 at each time point). At 12 months,

potency rates for groups 1-4 were 72.9%, 48.1%, 33.3% and 13.9% respectively (p < 0.001), with an overall potency rate of 42.5% for the entire cohort. At 24 months, the same rates were respectively 83.3%, 54.5%, 50% and 20.7% (p < 0.001), which represents an overall potency rate of 49.1%, irrespective of nerve sparing.

TABLE 2. Postoperative potency rates according to preoperative SHIM score

Potency group (SHIM)	Post	operative 1	otency rat	es (EHS ≥ 3	3) with or v	vithout PD	E5i	p value
	1 m	3 m	6 m	9 m	12 m	18 m	24 m	_
Normal (22-25)	25.6%	42%	48.7%	60.3%	72.9%	82.1%	83.3%	< 0.001
n = 95	(21/82)	(29/69)	(38/78)	(47/78)	(54/74)	(55/67)	(60/72)	
Mild ED (17-21)	15.7%	27.3%	30.7%	41.5%	48.1%	51.9%	54.5%	< 0.001
n = 59	(9/57)	(15/55)	(16/52)	(22/53)	(26/54)	(28/54)	(30/55)	
Mild-Mod ED (12-16)	12%	20.8%	29.2%	30.4%	33.3%	40%	50%	0.05
n = 26	(3/25)	(5/24)	(7/24)	(7/23)	(7/21)	(8/20)	(9/18)	
Mod-Severe ED (1-11) n = 34 p value	6.1% (2/33) 0.064	6.5% (2/31) 0.002	6.5% (2/31) < 0.001	14.8% (4/27) < 0.001	13.9% (4/29) < 0.001	14.8% (4/27) < 0.001	20.7% (6/29) < 0.001	0.056

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TABLE 3. Postoperative SHIM scores for all groups at each visit

Potency group	Preop SHIM		Postop	SHIM (me	dian [Q1-Q	3])		p value
(SHIM)	(median)	3 m	6 m	9 m	12 m	18 m	24 m	
Normal (22-25) n = 95	24 [23-25]	8.0 [3.0-15.0]	11.0 [5.0-17.0]	14.5 [8.0-19.0]	15.0 [8.8-22.0]	18.0 [14.0-22.0]	20.0 [16.0-22.0]	0.001
Mild ED (17-21) n = 59	19 [18-21]	5.0 [1.0-12.0]	5.5 [2.3-13.8]	9.0 [4.0-16.0]	9.5 [5.0-17.0]	11 [5.0-19.3]	11.5 [5.0-20.0]	< 0.001
Mild-Mod ED (12-16) n = 26	15 [14-15]	2.0 [1.0-6.0]	4.5 [1.0-6.0]	5.0 [1.0-8.5]	4.0 [1.0-7.0]	7.0 [1.0-12.0]	8.5 [2.0-17.0]	< 0.001
Mod-Severe ED (1-11)	4.5 [2.0-7.3]	1.0 [1.0-2.0]	1.0 [1.0-3.0]	1.0 [1.0-3.5]	1.0 [1.0-2.5]	1.0 [1.0-2.5]	1.5 [1.0-5.0]	0.018
p value		< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	

Postoperative SHIM scores of all groups are summarized in Table 3. Patients of all four groups experienced a statistically significant improvement of their SHIM score up to 24 months (p < 0.001 for groups 1-3, and p < 0.05 for group 4). Moreover, patients with higher preoperative SHIM scores had a statistically higher improvement of their SHIM scores compared to those with lower SHIM (p < 0.001 at each time point). At 24 months, median SHIM scores for group 1-4 were

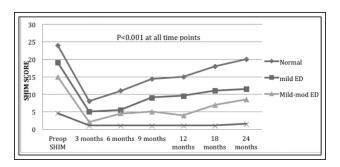


Figure 1. SHIM score's changes.

TABLE 4. Return to baseline SHIM score at 12 months

Potency group (SHIM)	Return to baseline SHIM (%, fraction)
Normal (22-25) n = 95	27.4% (17/62)
Mild ED (17-21) n = 59	21.2% (11/52)
Mild-Mod ED (12-16) n = 26	5.3% (1/19)
Mod-Severe ED (1-11) n = 34	85.7% (24/28)

respectively 20, 11.5, 8.5 and 1.5 (p < 0.001). Figure 1 illustrates recovery pattern for each group over time. Moreover, at 12 months, 27.4%, 21.2%, 5.3% and 85.7% of men in groups 1, 2, 3 and 4 respectively, returned to their baseline SHIM, Table 4.

Discussion

ED is one of the most bothersome complications of radical prostatectomy, as it negatively impacts patients' sexuality and QoL.^{2,22} Several factors have been reported to affect potency recovery post radical prostatectomy, including age, preoperative potency, comorbidities and surgical technique.^{8,15,16,23} Despite advances in surgical techniques and decision-making tools, erectile function recovery remains hard to predict, particularly when counseling patients preoperatively about their specific odds of recovery.

Several sexual health questionnaires to assess erectile function have been reported (IIEF, SHIM, UCLA-PCI, EPIC).²⁴⁻²⁷ However, there has not been a general consensus on a standard one so far. Given its high sensitivity and specificity,^{28,29} its widespread use³⁰⁻³³ and its ease to be collected, we selected SHIM score as a tool to stratify patients according to their preoperative erectile function and also as a follow up tool postoperatively. In this study, patients were divided according to their preoperative SHIM score into four groups; group 1 (SHIM 22-25), group 2 (SHIM 17-21), group 3 (SHIM 12-16) and group 4 (SHIM 1-11). As expected, patients with higher preoperative SHIM scores were statistically younger and had lower BMI scores, which is comparable to other published data. 34-36 Similarly, nerve preservation was statistically higher in higher SHIM groups. This finding indicated that our choice of nerve sparing technique was tailored according to patients' preoperative erectile function. This is an inherent bias

that is caused by non-blinding of the surgeon and the high patients' demand for nerve sparing.

We evaluated potency recovery using the widely used definition of successful penetration during intercourse (EHS of 3-4/4) with or without PDE5-I, which was initially described in 1998³⁷ and formally validated in 2007.³⁸ Overall, 83.3%, 54.5%, 50%, and 20.7% of patients with respectively normal erectile function, mild ED, mild-moderate ED, and moderate-severe ED, were potent 24 months postoperatively, including all comers. This matches what has been reported by other groups regarding preoperative potency as an independent predictor of potency recovery post radical prostatectomy.³⁹⁻⁴¹

Furthermore, it has been shown that most men continue to improve their erectile recovery even beyond 1 year.⁴² Therefore, we evaluated erectile function up to 24 months. We found that all groups experienced a statistically significant improvement of SHIM scores and potency rates at 18 and 24 months. This finding underscores the fact that for all preoperative SHIM categories, potency recovery may continue to improve between 12 and 24 months. In fact, the trend of the curves may also suggest continued recovery beyond 24 months.

To the best of our knowledge, only few studies correlated potency recovery post RP to preoperative SHIM scores. Woo and colleagues recently reported on potency recovery post RARP.⁴³ Potency rate at 12 months was 79.7% for those with normal SHIM (22-25), and only 21.4% of men returned to their baseline erectile function. In our study, potency rate of the same SHIM subgroup was comparable with 72.9%, at 12 months, and 27.4% of men returned to their baseline SHIM (22-25). This finding supports what has been concluded in the aforementioned study that the majority of men with normal preoperative SHIM are at risk of developing a significant erectile function deficit after surgery.

All our patients were encouraged to follow a sexual rehabilitation protocol with daily or on demand PDE5-I use, however data on PDE5-I compliance were not available in this study. Another recent study evaluating the return to baseline erectile function using the extended prostate cancer index composite (EPIC),⁴⁴ has shown that post nerve sparing RP, 85% of preoperatively potent men were potent at 24 months. On the other hand, only 27% returned to baseline erectile function. These findings are again similar to ours and confirm them.

Given the rarity of data assessing post RARP potency recovery and the trend of SHIM score improvement based on preoperative potency, we believe that our study presents important data that can help counsel men about post RARP erectile function recovery in a real life scenario. However, our study is not devoid of limitations. These include its retrospective nature, single center and single surgeon's experience, lack of blinding for nerve sparing technique and lack of knowledge about use or consistency of penile rehabilitation. In addition, comorbidities were not accounted for in this study.

Conclusion

For proper patient counseling regarding potency recovery post RARP, it is important to stratify patients according to preoperative SHIM score. The higher the preoperative SHIM, the faster the recovery of potency and the higher the improvement of SHIM scores that occur. Whereas erectile function recovery continues to improve after the first year, the vast majority of men still experience an incomplete return to baseline potency after RARP. \square

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