Age-stratified potency outcomes of bilateral nerve sparing robotic-assisted radical prostatectomy

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Introduction: *This study aims to report age-stratified potency outcomes in men undergoing robot-assisted radical prostatectomy (RARP).*

Materials and methods: *A retrospective review was performed on a database of 1737 patients who underwent RARP for localized prostate cancer between 2007 and 2019. Inclusion criteria consisted of patients undergoing bilateral nerve-sparing RARP. Exclusion criteria were preoperative Sexual Health Inventory for Men (SHIM) score < 17 and postoperative androgen deprivation therapy or radiotherapy. Patients were divided into four cohorts based on age: ≤ 54 years (group 1); 55-59 years (group 2); 60-64 years (group 3) and ≥ 65 years (group 4). Functional outcomes were measured up to 36 months. Kaplan-Meier analysis was performed to compare the time to recovery of potency stratified by age groups using log-rank testing.*

Results: *A total of 542 patients met the selection criteria. Potency rates were significantly different between groups. Groups 1 through 4 demonstrated potency recovery rates of 64.2%, 52.3%, 36.6% and 20.7% at 1-year follow up, respectively. After 3 years, groups 1 through 4 had potency rates of 77.9%, 67.0%, 50.5% and 35.0%, respectively. Recovery of potency was achieved at a median time after surgery of 199, 340 and 853 days for groups 1-3, respectively. The Cox proportional hazard model showed that older age, higher body mass index (BMI), and lower preoperative SHIM score were associated with significantly higher rates of impotence.*

Conclusion: *This study shows that RARP has acceptable potency outcomes, regardless of age. However, patient factors, including older age and preoperative SHIM were significantly associated with poorer functional recovery. This data is valuable in prognostic evaluation and patient counseling.*

Key Words: potency, RARP, prostate cancer, outcomes

Introduction

Erectile dysfunction (ED), also known as impotence, is a common urological complaint affecting around half of men over the age of 40.[1] It has significant impacts on patients' quality of life across all age groups.[2] ED can be secondary to numerous etiologies, including pelvic surgery and radiation therapy.[3] In fact, despite its acceptance as the surgical treatment of choice for localized prostate cancer, impotence remains a common complaint after robot-assisted radical prostatectomy (RARP).[4,5] A recent systematic review shows that the rates of 12-month potency recovery range from 8.2% to 48.8% after open radical prostatectomy (ORP), and from 7.1% to 81.3% after RARP.[6] Therefore, it is

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imperative that urologists take the time to carefully inform and educate patients about their risk of ED after RARP.

Patient age at the time of surgery, among other variables, is a well-established risk factor for postoperative ED.[6-10] However, the evidence focusing on age-stratified potency in patients undergoing RARP is scarce. In this study, we aim to report trends in age-stratified outcomes in Canadian men undergoing bilateral nerve-sparing RARP. We believe that this information would be valuable in preoperative counseling and allow patients to have realistic goals with regards to their potency recovery.

Material and methods

Between January 2007 and November 2019, 1737 patients underwent RARP performed by a single, fellowship-trained surgeon at the Centre Hospitalier de l'Universite de Montreal and Hopital Sacre-Coeur de Montreal. Upon institutional review board approval, a retrospective data review was performed. We included all patients who had at least 1 month of follow up, preoperative Sexual Health Inventory for Men (SHIM) score ≥ 17 with or without phosphodiesterase-5 inhibitors and received strict bilateral nerve sparing surgery. Patients who underwent unilateral or non-nerve sparing RARP and those who had adjuvant androgen deprivation therapy and/or pelvic radiotherapy were excluded as these factors could potentially impact the recovery of potency after RARP and could therefore confound the results of the study. Patients were divided into four cohorts based on age: group 1 (≤ 54 years), group 2 (55-59 years), group 3 (60-64 years), and group 4 (≥ 65 years). Standardized counseling for penile rehabilitation and used phosphodiesterase-5 inhibitors, MUSE, and vacuum devices in the postoperative period as part of their management of patients' recovery of potency.

Baseline and perioperative outcomes

Patient demographic and baseline characteristics were collected, including body mass index (BMI), transrectal ultrasound (TRUS) measurement of prostate volume, biopsy Gleason score, clinical and pathological staging, International Prostate Symptoms Score (IPSS) and SHIM score. Perioperative variables included operative time, surgical pathology, length of hospital stay, catheterization time, and incidence of blood transfusions.

Sexual outcomes

Sexual function was evaluated using the self-administered SHIM questionnaire during clinic visits. Potency was more specifically assessed using the erection hardness score (EHS) and was defined as an erection hard enough for penetration, corresponding to an EHS score of 3 or 4.[11,12] Given our lack of preoperative EHS data, a preoperative SHIM score ≥ 17 (mild ED) was used as the cut off for preoperative potency similarly to a previous study by Mandel et al.[13] All patients were put on postoperative phosphodiesterase-5 inhibitors as of postoperative day 10 up to at least 1-year after the operation. We recorded patients' data at each follow up visit (i.e. at 3, 6, 9, 12, 18, 24, 30, and 36 months postoperatively).

Surgical technique

Our RARP surgical technique has been described in prior reports from our group.[14-16]

Statistical analysis

Descriptive statistics were used to summarize our study population's baseline characteristics. Continuous variables were reported as median followed by the range as a measure of central tendency. All categorical variables were reported as proportions. Means of continuous variables were compared using an analysis of variance (ANOVA), while categorical variables were analyzed using the Chi-square test. Kaplan-Meier analysis was performed to compare the time to recovery of potency and differences between elderly age groups using log-rank testing. Cox proportional hazards regression models were constructed to evaluate the impact of time on potency by age group. Multivariable models were evaluated adjusting for age, BMI, PSA, preoperative IPSS and QoL score, TRUS, and pathology measurement of prostate volume. A p value < 0.05 was considered statistically significant in all two-tailed tests. All statistical analyses were performed using RStudio Statistical package (Version 1.2.5033).

Results

Preoperative characteristics

A total of 542 patients were included in this study. There were 145 patients in group 1, 137 patients in group 2, 148 patients in group 3, and 112 patients in group 4. Table 1 describes the baseline patient characteristics. BMI was similar across all age groups ($p = 0.718$). At baseline, there were significant differences in preoperative PSA ($p < 0.01$), TRUS-measured prostate volume ($p < 0.01$), D'Amico risk group ($p < 0.01$), and clinical stage ($p < 0.01$). Baseline SHIM score varied significantly between the groups ($p < 0.01$), the highest being in Group 1 (23.5) and the lowest in being in Group 4 (21.31).

TABLE 1. **Patient baseline characteristics by age group**

	Group 1	Group 2	Group 3	Group 4	p value
Age group, years (n)	< 55 (145)	55-59 (137)	60-64 (148)	≥ 65 (112)	
Mean age, years (SD)	51.0 (3.2)	57.0 (1.4)	61.8 (1.4)	67.4 (2.2)	
Mean body mass index, kg/m^2 (SD)	27.1 (3.6)	26.9 (4.1)	26.5 (3.9)	26.9 (4.7)	0.72
Body mass index groups % (n)					
< 30	80.9 (110)	85.3 (110)	86.8 (112)	82.8 (82)	0.45
≥ 30	19.1 (26)	14.7 (19)	13.2 (17)	17.2 (17)	0.18
Mean preoperative PSA, ng/dL (SD)	6.1 (4.4)	5.5 (2.7)	6.2 (3.1)	7.5 (6.8)	< 0.01
Mean TRUS prostate size, g (SD)	33.4 (13.2)	35.4 (12.3)	41.0 (16.4)	42.0 (20.5)	< 0.01
Mean specimen prostate size, g (SD)	44.4 (13.2)	46.2 (13.3)	50.3 (16.3)	54.4 (47.9)	< 0.01
D'Amico risk group, % (n)					< 0.01
Low	51.1 (72)	37.8 (51)	35.2 (51)	24.3 (26)	
Intermediate	46.1 (65)	60.0 (81)	59.3 (86)	59.8 (64)	
High	2.8 (4)	2.2 (3)	5.5 (8)	15.9 (17)	
Biopsy Gleason score, % (n)					0.01
6	55.2 (80)	40.9 (56)	38.5 (57)	29.5 (33)	
7	42.8 (62)	57.7 (79)	56.1 (83)	58.0 (65)	
≥ 8	2.1 (3)	1.5 (2)	5.4 (8)	12.5 (14)	
Specimen Gleason score, % (n)					< 0.01
6	29.2 (42)	19.7 (27)	19.6 (29)	12.5 (14)	
7	68.1 (98)	77.4 (106)	76.4 (113)	73.2 (82)	
≥ 8	2.8 (4)	2.9 (4)	4.1 (6)	14.3 (16)	
Clinical stage, % (n)					0.65
≤ T1c	86.2 (125)	80.9 (110)	79.7 (118)	75.0 (84)	
T2a	10.3 (15)	16.2 (22)	16.9 (25)	19.6 (22)	
T2b	2.8 (4)	2.2 (3)	3.4 (5)	3.6 (4)	
T2c	0.7 (1)	0.7 (1)	0	0.9 (1)	
T3	0	0	0	0.9 (1)	
Pathologic stage, % (n)					0.42
T2a	9.9 (15)	10.2 (14)	10.1 (15)	4.5 (5)	
T2b	12.5 (19)	8.0 (11)	7.4 (11)	10.0 (11)	
T2c	57.2 (87)	58.4 (80)	56.1 (83)	56.4 (62)	
T3a	19.1 (29)	20.4 (28)	21.6 (32)	26.4 (29)	
T3b	1.3 (2)	2.9 (4)	4.7 (7)	2.7 (3)	
Mean preoperative IPSS (SD)	6.2 (5.2)	6.6 (5.4)	7.1 (6.4)	7.9 (6.1)	0.11
Preoperative IPSS groups, % (n)					
0-7	67.6 (98)	63.2 (86)	67.6 (100)	55.9 (62)	0.59
8-19	30.3 (44)	33.8 (46)	27.0 (40)	37.8 (42)	0.40
20-35	2.1 (3)	2.9 (4)	5.4 (8)	6.3 (7)	0.40
Meanpreoperative SHIM (SD)	23.5 (2.0)	22.7 (2.5)	22.2 (2.5)	21.3 (2.5)	< 0.01
Preoperative SHIM, % (n)					< 0.01
SHIM 17-21	25	47	54	57	
SHIM 22-25	120	90	94	55	
Preoperative QoL, mean (SD)	1.3 (1.4)	1.5 (1.4)	1.4 (1.3)	1.6 (1.3)	0.22
Preoperative QoL groups % (n)					
0-2	95.8 (113)	98 (98)	97.4 (114)	96.4 (80)	0.15
3-4	0	0	0	0	0.95
5-6	4.2 (5)	2 (2)	2.6 (3)	3.6 (3)	0.91

TABLE 2. **Perioperative outcomes by age group**

	Group 1	Group 2	Group 3	Group 4	p value
Age group, years (n)	< 55 (145)	55-59 (137)	60-64 (148)	≥ 65 (112)	
Mean estimated blood loss, mL3 (SD)	214.7 (126.3)	235.9 (135.3)	241.8 (151.5)	265.5 (152.6)	0.04
Mean foley removal day, days (SD)	5.5 (1.5)	5.8 (1.5)	6.0 (1.7)	6.3 (1.3)	< 0.01
Mean operative time, minutes (SD)	167.9 (40.5)	174.7 (51.3)	178.0 (43.1)	186.5 (47.9)	0.01
Hospital stay, days (SD)	1.1 (0.4)	1.1 (0.4)	1.1 (0.4)	1.2 (0.6)	0.39
Surgical margin, % (n)					0.60
Negative	108	112	112	86	
Positive	35	25	35	25	
Clavien-Dindo complication rate, n					
No complications	107	140	169	188	52
1	74	109	129	142	41
2	24	20	35	33	8
3a	6	6	3	5	2
3b	3	4	1	5	0
4a	0	0	1	3	1
4b	0	1	0	0	0

Perioperative outcomes

Table 2 shows all perioperative outcomes. There were significant variations in operative time across the age groups (p = 0.01), with group 1 having the shortest (167.9 minutes, SD = 40.46) and group 4 having the longest (186.5 minutes, SD = 47.86) mean operative time. Mean estimated blood loss and mean foley catheter removal day were also statistically different across groups (p = 0.04 and p < 0.01, respectively), and seemed to increase with age. There were no differences between age groups in terms of length of hospital stay (p = 0.39) and positive margin rate.

Sexual and functional outcomes

Figure 1 shows postoperative functional and sexual outcomes. There was a significant difference in mean SHIM scores at every time point recorded. Mean SHIM score changes from baseline were statistically different across groups as of the 3-month follow up (p < 0.01). At 36 months, group 1 had the smallest mean SHIM change from baseline (-6.38, SD = 5.34) while group 4 demonstrated the largest decrease in SHIM score (-11.22, SD = 7.66). Additionally, there was a significant difference in EHS score over time, with group 1 showing the highest EHS at all time points (score of 2.39 [SD 1.09] and 3.36 [SD 0.71] at 1- and 36-month follow up, respectively). Group 4, on the other hand, demonstrated the lowest EHS scores at all time points (score of 1.46 [SD 0.75] and 2.50 [SD 1.10] at 1- and 36-month follow up, respectively). Groups were similar in both IPSS and QoL score changes from baseline through the follow up period.

Recovery of potency outcomes

Over the 3-year follow up, older patients consistently demonstrated less favorable potency outcomes. Incidence plot estimates, Figure 2, demonstrated potency rates with respect to time after surgery. There were significant differences across groups in their potency recovery curve (p < 0.01). At 1-year follow up, group 1, 2, 3 and 4 demonstrated potency recovery rates of 64.2%, 52.3%, 36.6% and 20.7%, respectively. At 2 years post operation, they demonstrated potency recovery rates of 75.0%, 65.3%, 47.5% and 30.0%, respectively. Finally, at 3 years, they demonstrated potency recovery rates of 77.9%, 67.0%, 50.5% and 35.0%, respectively. Time of median recovery of potency was 199, 340 and 853 days for groups 1-3, respectively.

Cox-proportional hazards regression

On Cox-proportional hazards regression models, younger patients aged ≤ 54 were respectively 43% and 56% more likely to return to potency per unit of time following RARP compared to group 3 [HR 0.57; 95% CI 0.43-0.74; p < 0.01] and 4 [HR 0.44; 95% CI 0.32-0.60; p < 0.01], respectively. There was no statistically significant difference in potency recovery in group 2 [HR 0.80; 95% CI 0.62-1.01; p = 0.06] compared to

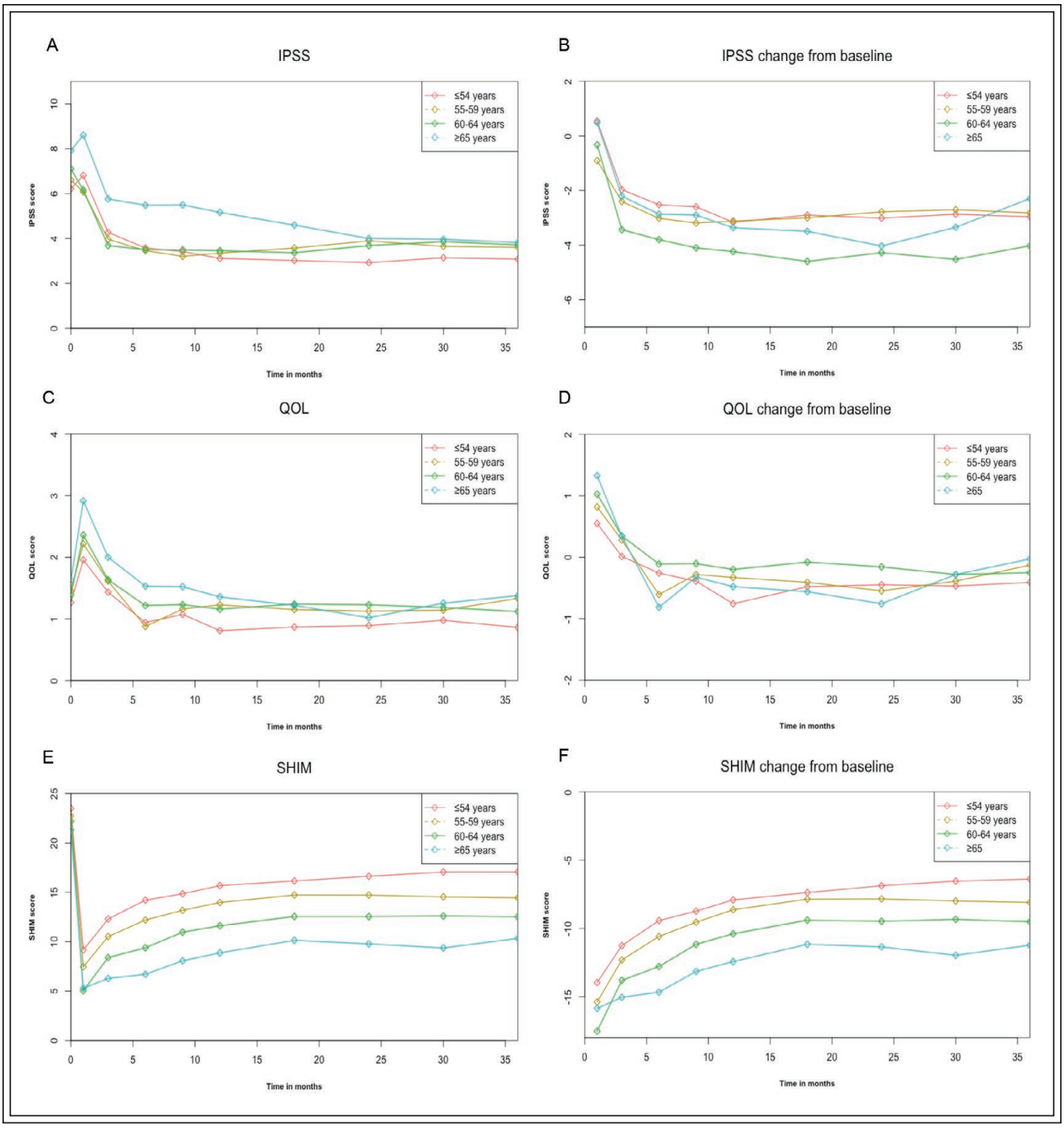

Figure 1. Age-specific outcomes over time. **(A)** Mean IPSS score over time **(B)** Mean IPSS change from baseline over time **(C)** Mean QOL score over time **(D)** Mean QOL score change from baseline over time **(E)** Mean SHIM score over time **(F)** Mean SHIM score change from baseline over time.

group 1. Higher preoperative SHIM scores significantly increased the likelihood of potency recovery for all age groups [(group 1: HR 1.07; CI 1.03-1.10; $p < 0.01$); (group 2: HR 1.09; CI 1.05-1.12; $p < 0.01$); (group 3: 1.09; CI 1.06-1.10; $p < 0.01$); group 4: HR 1.09; CI 1.06-1.10; $p < 0.01$]. BMI was a significant risk factor for worse potency outcomes in group 2 and 3. TRUS-calculated prostate size, preoperative QoL, preoperative IPSS,

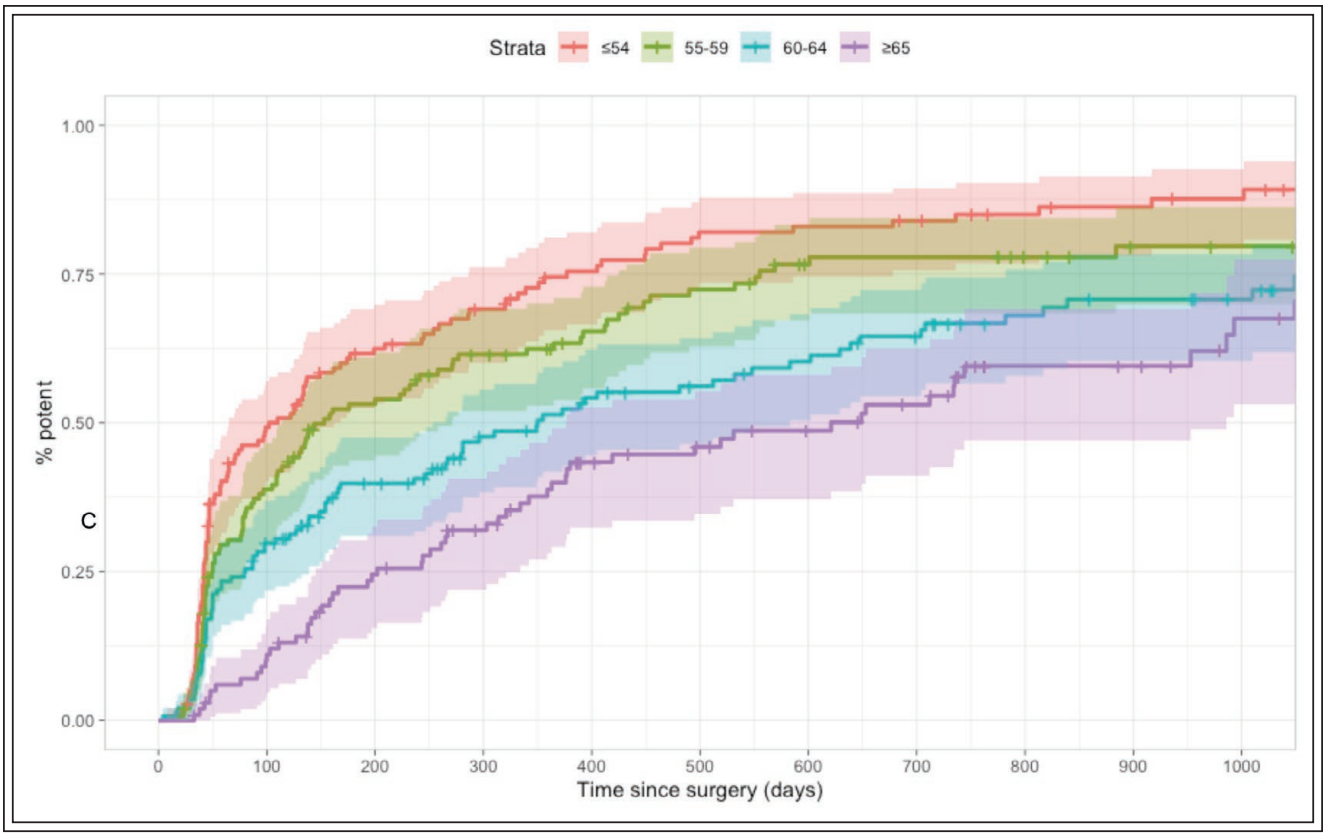

Figure 2. Age-specific potency recovery after the surgery. Potency defined as erection hardness score 3-4.

duration of hospitalization, length of operation, and estimated blood loss did not significantly impact the likelihood of potency recovery across all age groups.

Discussion

ED can severely affect a patient's postoperative quality of life[4,5] and remains an important consideration for the majority of men requiring radical prostatectomy, regardless of age group.[17] Although advancements in technology have led to better surgical outcomes, ED remains a well-known side-effect of RARP with studies showing 12- and 24-month rates of potency recovery rates after bilateral nerve sparing RARP ranging from 50% to 86% and from 62% to 90%, respectively.[18] Despite age being a well-known predictor for impotence after RARP,[18] only a handful of studies have investigated the potency outcomes of RARP in tan elderly population, and very few studies have quantified the changes in potency outcomes in an age-stratified manner. In this study, we established and quantified the stepwise age-related decline in potency recovery in patients undergoing bilateral nerve-sparing RARP. We showed that, with each subsequent increase in the 5-year age group, there was a significant drop in postoperative potency recovery. Additionally, we quantified the time of median recovery of potency in each age group. This granularity of data will be of great benefit to physicians during patient counseling.

In our sample, over 77.9% of men aged 54 and younger, and 67% of men aged 55-59 years retained potency after 36 months. In comparison, only half of men between 60-65 years of age and 35% of men over 65 retained potency after the operation in the same time period. The rates of potency of the oldest age group remained consistently lower than groups 1-3 across all time points. Furthermore, older patients regained potency after surgery significantly slower than their younger counterparts. A meta-analysis by Ficarra et al assessed potency recovery after RARP, showing rates of 12- and 24-month potency recovery after bilateral nerve sparing surgery of 74% (62-90%) and 82% (69-94%), respectively.[19] Our findings were inferior to those found by Patel et al. In their retrospective analysis, at 1-year follow

up, there was a significant difference in potency recover rates in patients aged <= 55 [57/60 (95%)], 56-65 [74/78 (94.8%)] and > 65 years of age [31/39 (79.5%)]. Although, their study excluded patients with SHIM score < 22 and their study was limited by a relatively small sample size.[18] Mendiola et al showed similar 1-year potency outcomes between men of different age groups (< 50, 50-59 and >= 60 years of age) undergoing bilateral nerve sparing RARP.[17] Supporting the results of our study, they demonstrated that younger men achieved subjective potency significantly earlier than older patients. Our findings were also similar to those of Kumar et al who found a 24-month follow up potency rate for patients under and over 70 years of age of 52.3% and 33.5%, respectively ($p < 0.001$).[20]

The increased prevalence of comorbidities such as cardiovascular disease and diabetes associated with aging can also contribute to these findings due to gradual accumulation of microvascular damage known to affect potency over time.[1] The difference in potency across the groups could be explained by multiple different factors. First, preoperative factors such as mean preoperative SHIM were significantly different across groups, decreasing with older age. Known intraoperative risk factors contributing to ED post-RARP include thermal nerve injury, traction and distraction.[21-23] These risk factors might not be significantly impacted by varying age, although the current evidence is limited. Mean prostate pathology specimen weight was significantly different across groups and increased with age, suggesting that older patients required a wider dissection, potentially increasing the likelihood of damage to the nerve plexus. Postoperative risk factors such as inflammation a wound healing might be contributory in the postoperative ED status of the patient.[24] Wound healing and inflammatory response are impaired at older ages, due to various factors, including microvascular damage and atherosclerosis, leading to decreased blood flow to wounds. Additionally, an age-related decrease in neuronal plasticity can hinder the ability of pelvic floor muscle adaptation after surgery in older men.[25]

Our Cox-proportional regression analysis demonstrated that preoperative SHIM score and age and BMI were all risk factors affecting potency recovery. Similarly, Shikanov et al reported that age (OR: 0.92; $p < 0.0001$), SHIM score (OR: 1.1; $p < 0.0001$), and bilateral nerve sparing (OR: 2.92; $p < 0.0001$) were independently associated with greater capacity to achieve potency.[26] However, conflicting results have been reported regarding the role of BMI in postoperative potency. Wiltz et al reported potency outcomes significantly lower for obese men at both 12 and 24 months after radical prostatectomy[27] while Muskovic et al and Uffort et al failed to demonstrate significant differences in 1-year potency rates after stratification by BMI.[28,29] Novara et al reported age > 60 years (OR: 2.828; 95% CI, 1.591-5.027), Charlson score >= 1 (OR: 2.992; 95% CI, 1.358-6.588), and baseline SHIM score used as a continuous variable (OR: 0.843; 95% CI, 0.799-0.889) to be independent predictors of postoperative impotence.[30] Using the Briganti risk stratification, the authors reported a 12-month potency recovery of 81.9% in the low-risk group (age ≤ 60 year, baseline IIEF-6 > 21, Charlson score ≤ 1), 56.7% in the intermediate-risk group (age 66–69 years, baseline IIEF-6 11-21, Charlson score <= 1), and 28.6% in the high-risk group (age ≥ 70, baseline IIEF-6 ≤ 10, Charlson score ≤ 2) ($p < 0.001$).[30]

The limitations of this study include its retrospective design. Older patients in our study also represent a highly selected cohort who were likely healthier and motivated to undergo surgery. Data from our study represent the outcomes of RARP performed by a surgeon in a high-volume center and may therefore not be generalizable to all surgeons or centers. Preoperative erectile hardness score of patients was not available. Therefore, to minimize the rate of preoperative impotency in our cohort, patients with a SHIM < 17 were excluded from the study. Furthermore, our study collection did not account for evaluation of penile rehabilitation prior and after the procedure. The study also did not collect data on the degree of nerve-sparing. Other confounding variables include the costs of erectile dysfunction medication limiting their use in patients, as well as other factors such as the patient's sexual activity. Our data cannot be generalized to patients who received unilateral- or non-nerve sparing surgery. Despite these limitations, the strengths of our study include a long follow up time, a large sample size, the use of a strict definition of potency and inclusion of strict bilateral nerve sparing patients. Additionally, this is the first Canadian study to assess RARP potency outcomes according to age.

Conclusion

This study demonstrates that RARP is associated with acceptable sexual function outcomes, regardless of age. However, we identified differences in outcomes across age groups in all functional measurements, as older patients had significantly inferior potency recovery rates and longer time to recovery of potency post-operatively compared to younger patients. This data is valuable in prognostic evaluation and patient counseling. □

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