A novel intraoperative physician-assigned grading score to predict postoperative return of potency at 1 year after robotic-assisted laparoscopic prostatectomy

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ABSTRACT

Introduction: We examined a novel method of grading nerve sparing in robotic-assisted laparoscopic radical prostatectomy to better predict the potency outcomes of patients at 1-year after surgery. This grading (scale) was based on the surgeon's criteria of intraoperative findings during completion of nerve sparing. This grading was then analyzed statistically to validate its association with potency outcomes.

Methods: We devised a study module based on measurable visual cues intraoperatively where the surgeon risk stratified the surgery into four grades depending on the completeness of nerve sparing, keeping in mind the known parameters influencing potency outcomes. A novel grading scale was then proposed and used in this study for the same. We prospectively collected data and retrospectively analyzed 425 patients undergoing robotic-assisted laparoscopic prostatectomy (RALP) at a high-volume center by a single surgeon.

Results: At 1 year of follow-up, it was found that age, laterality of nerve preservation, weight of prostate, and the surgeon-assigned grading were all statistically significant independent predictors of return of potency in terms of satisfactory penetrative intercourse >50% of times and Sexual Health Inventory for Men \ge 17. However, prostate-specific antigen was found not to be a predictor of the same.

Conclusions: Intraoperative physician-assigned grading was found to be the single most significant predictor of the return of potency at 1-year post-RALP.

INTRODUCTION

Treatment of organ-confined carcinoma of the prostate may result in major adverse effects such as loss of potency and continence besides the risk of inadequate cancer control. Until Walsh's anatomic description and refined surgical techniques were published, radiotherapy was considered a superior modality *vis-a-vis* surgical control. [1] The advent of robots in urology associated with significantly less blood loss and improved visual characteristics along with miniaturized incisions and rapid cancer control led them to become the first-choice modality chosen

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by patients and surgeons. Predicting trifecta (continence, potency, and cancer control) outcomes of organ-confined cancer prostate surgical treatment has been predominantly based on the surgeon's intuition and real-time intraoperative findings. Advances in nerve-sparing technique have resulted in improved potency outcomes, as potency is directly proportional to the quantum and quality of nerves preserved during surgery. [2] Evidence points toward some factors as being associated with better outcomes, such as high-volume centers, bilateral nerve sparing, absence of lateral traction and bleeding, ideal plane of dissection, athermal technique, and a single experienced surgeon. [3-9] However, what is lacking is a standardized measurable intraoperative method

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of scaling and grading the nerve sparing, taking into consideration all these factors simultaneously to enable physicians to preemptively predict the potency outcome postoperatively.

We have tried to create a standardized scoring system to measure the degree of potency for 1-year postrobotic-assisted laparoscopic prostatectomy (RALP). The objective of this retrospective study was to evaluate a novel grading scale which risk-stratified patients intraoperatively, according to the surgeon's categorization of how well nerve sparing was completed. We hypothesized that the surgeon scores would be associated with potency outcomes 1 year after RALP in patients with organ-confined disease.

METHODS

Of the 762 patients who presented to us between March 2013 and March 2016, 425 informed and consented patients were selected after excluding others as per the exclusion criteria defined to undergo RALP by the standard transperitoneal six-port technique using the da Vinci Surgical System Model Si (Intuitive Surgical, Sunnyvale, CA, USA) by a single surgeon at a single high-volume center Exclusion criteria were (Number of patients excluded in parenthesis) - Sexual Health Inventory for Men (SHIM) score <17 preoperatively (54), Charlson Comorbidity Index[10] of >4 and/or history of coronary artery bypass grafting/angioplasty (121), salvage procedures (3), existing penile prosthesis (19) or intracavernosal injections (10), patients refusing penile rehabilitation (8), clinical stage T3 (80), and patients lost to follow-up within 1 year (42).

Surgical procedure and scale development – All continent patients (no pad usages) having a minimum SHIM score of 17 and able to have satisfactory penetrative intercourse >50% of the time were included in the study. Patients in the study were comparable with no significant differences demographically or clinically. Table 1 shows all the comparable features pre, peri, and postoperatively. The data here are shown in accordance with the subsequent groups classified as per the surgeon's evaluation and intraoperative physician-assigned grading (IOPAG). Table 2 shows the Charlson index of all the patients. All patients underwent surgery with the intent of athermal intrafascial clipless complete nerve-sparing RALP in accordance with the types of nerve dissection advocated by Schatloff et al.[11] Whenever there was a peripheral lesion and the area was visually suspicious of extracapsular disease, the nerve was sacrificed. Quantum of nerve sparing (unilateral or bilateral), presence of periprostatic adhesions, lateral traction on the nerves, cautery usage with bleeding, and trauma to the nerves were taken as defining parameters in IOPAG because prior literature shows these factors as possibly affecting potency outcomes.[3-8] Six yes or no questions were answered

and scored as per Table 3. Based on their scores, patients were risk stratified into Grades 1 to 4. The patients were discharged on the 1st postoperative day and were on regular follow-up visits every 3 months. Each patient was initiated on a penile rehabilitation program, wherein they received a phosphodiesterase-5 inhibitor (PED5) every day (tadalafil 5 mg) starting 3 weeks after surgery and a vacuum erection device (VED) twice a week starting 4 weeks after surgery. Compliance to this regimen was confirmed during each 3-monthly visit and telephonically monthly by the office technicians for 1 year. Potency was recorded, as defined by the ability to have satisfactory penetrative intercourse at least 50% of the time with or without the use of PED5 inhibitors and SHIM score of \geq 17. Some (n = 87) out of state/country patients were interviewed telephonically by the investigators for determination of their potency levels. All the data were prospectively collected in a customized database and then retrospectively analyzed at 1 year of follow-up.

Statistical analysis

Hierarchical multiple regression (HMR) analysis was performed by the hospital's biostatistician to measure the unique and independent relationship between age, laterality of nerve sparing, prostate weight, prostate-specific antigen (PSA), and the IOPAG. For the HMR analysis, five models were created that helped to show the incremental predictive value of postoperative potency for 1 year, from variables within each model. Model 1 contained age (>60 years), Model 2 included the laterality of nerve sparing, Model 3 included prostate weight, Model 4 had the PSA, and Model 5 included the IOPAG. A one-way ANOVA was used to compare the differences between the change in SHIM score and the grades of IOPAG. A post hoc test with Bonferroni's alpha adjustment was used when appropriate. Statistical comparison between categorical variables was performed using Chi-square test. A priori α level of P < 0.05 was considered statistically significant. All statistical analyzes were performed using SPSS Version 22.0 software (IBM, Chicago IL, USA).

RESULTS

There were 425 patients included in this study. Average age (mean \pm standard deviation) was 60.8 ± 3.5 years. Out of these patients, 386 underwent full bilateral nerve sparing, 24 had unilateral nerve sparing, and 15 had nonnerve sparing surgery.

Results of HMR analysis indicated that Model 1 (age) was a significant independent predictor for reported SHIM scores F (1426) = 5.57, P = 0.019. The addition of Model 2 (laterality of resection) accounted for additional variance in SHIM scores, Δ F (1426) = 3.83, P = 0.051 which was not statistically significant. The addition of prostate weight in Model 3 accounted for an additional variance, Δ F (1426) = 6.84,

Parameter (405)	Group 1 (<i>n</i> =258)	Group 2 (<i>n</i> =111)	Group 3 (n=41)	Group 4 (n=15)	Р
Total patients (425)					
Age					
Mean±SD	59.9±0.5	62.1±3.5	62.6±3	60.0±4	0.01
Median	60.5	64.5	57.5	64	
BMI					
Mean±SD	24.5±3	23.3±3	23.9±2.8	25.9±2.9	< 0.001
Median	24.6	24.8	25.4	24.6	
Preoperative SHIM					
Mean±SD	21±0.0	16±0.5	20±1	20±0.5	0.03
Median	21	15	20	21	
PSA					
Mean±SD	7.9±0.2	7.2±0.9	9.2±0.0	10.3±4.4	0.6
Median	4.1	6.5	5.6	9.6	
AUA score					
Mean±SD	10.5±3.6	10.6±3.5	9.5±3.6	9.4±3.5	0.288
Median	10	10	10	10	
Preoperative Gleason					
≤6 (185)	114	48	16	7	0.016
7 (189)	119	52	15	3	
≥8 (51)	25	11	10	5	
Clinical stage (T)					
Stage T1-T2	258	111	41	15	0.002
Stage T3-T4	00	00	00	00	
D'Amico risk prediction					
Low	101	40	14	5	0.002
Intermediate	128	60	15	4	
High	29	11	12	6	
Postoperative SHIM					
Mean±SD	18±1	16±0.5	9±1.5	11±2	0.001
Median	18	15	9	11	
Prostate weight					
Mean±SD	43±33	49±23	51±00	57±17	0.001
Median	66	53	76	61	
Console time (min)					
Mean±SD	67.2±3	67±5	66±11	62.7±1	0.28
Median	57	67	73	64	
Estimated blood loss (ml)					
Mean±SD	61±1.4	71.5±3.9	83.6±0	85±7	< 0.001
Median	61	71.5	73	85	
Postoperative Gleason					
≤6	85	36	17	4	0.32
7	140	58	17	6	
≥8	33	17	7	5	
Tumor volume (cc)					
Mean±SD	1.35±0.7	1.5±0.7	1.5±0.7	1.6±0.7	0.21
Median	1.2	0.7	1.3	1.5	
Positive margins (%)	38 (14.7)	15 (13.5)	8 (19.5)	4 (26.6)	0.49
Extracapsular spread (%)	52 (20.1)	14 (12.6)	5 (12.1)	2 (13.3)	0.25
Seminal vesicle invasion (%)	4 (1.5)	3 (2.7)	2 (4.8)	3 (20)	< 0.001
Lymphovascular invasion (%)	8 (3.1)	6 (5.4)	5 (12)	3 (20)	0.08
Perineural invasion (%)	98 (37.9)	45 (40.5)	16 (39)	6 (40)	0.703
Potency rate at 1 year (%)	209 (81)	62 (55.8)	8 (19.5)	2 (13.3)	0.001
PSA ≥0.01 ng/ml at 1 year (%)	1 (0.39)	3 (3.6)	5 (12.1)	2 (13.3)	

 $SD = Standard\ deviation,\ SHIM = Sexual\ Health\ Inventory\ for\ Men,\ BMI = Body\ mass\ index,\ PSA = Prostate-specific\ antigen,\ AUA = American\ Urological\ Association$

P = 0.009. PSA was not a statistically significant (P > 0.05) predictor in Model 4. IOPAG had a relationship with SHIM scores and was the only significant (F = 28.42, P < 0.001) predictor in the full model accounting for 20% of variance in SHIM scores [Table 4]. One-way ANOVA revealed a significant (P < 0.001) main effect of the changes in SHIM scores between the grades of IOPAG. Moreover, *post hoc* test with Bonferroni's alpha adjustment demonstrated that

Grade 1 had a significantly (P < 0.0001) lower decrease in SHIM scores from the other groups, while Grade 2 had a significantly lower decrease in SHIM scores when compared to Grades 3 and 4 [Figure 1]. We did not find statistically significant differences between Grades 3 and 4 with regard to the change in SHIM scores. Chi-square analysis showed significant (P < 0.001) differences in the percentage of potent patients, which declined as the IOPAG grade increased.

DISCUSSION

Organ-confined carcinoma prostate and its treatment options will always have postoperative potency as a major concern in the discussion with patients. The goal of this study was to develop a scale to predict the postoperative potency outcomes as measured by the satisfactory penetrative ability and the SHIM score ≥17 post-RALP. The data of this study has revealed that there is a strong association between IOPAG and postoperative potency, with IOPAG being an independent predictor ofpotency. These findings suggest that the IOPAG may have significant implications in training resident physicians, besides being useful in counseling the patient

Table 2: Age distribution of Charlson index in all patients							
Age							
(years)	0	1	2	3	4		
40-49	n=30	n=1					
50-59		<i>n</i> = 140	<i>n</i> =5				
60-69			n=184	n=17			
70-79				n=42	n=5		
80					n=1		

Table 3: Criteria for intraoperative physician-assigned grading score Unilateral sparing (yes/no) Lateral traction on neurovascular bundles (yes/no) Periprostatic adhesions (yes/no) Nonathermal hemostasis (yes/no) Trauma to the neurovascular bundles (yes/no) Bleeding > 100 ml (yes/no) Grade 3 Grade 1 Grade 2 Grade 4 0 yes ≤3 yes ≥4 yes No nerve sparing

immediately after surgery and to schedule appropriate and timely secondary interventions if necessary, for example, insertion of a penile prosthesis.

Several studies have shown that bilateral neurovascular bundle preservation is a positive indicator for return of potency. However, ancillary factors such as thermal injury, inflammatory response, lateral traction injury, and scar tissue formation have a contributory effect on the same.^[3] Minimizing these adverse effects on nerve preservation and regeneration is one of the prime goals of a well-done RALP; therefore, it is of utmost importance to have some definitive predictive criteria incorporating these factors, to be able to foresee such side effects, especially potency levels postoperatively.

Whelan *et al.* demonstrated that RALP provides better potency outcomes than an open radical prostatectomy but only in high-volume centers with experienced surgeons.^[9] Consequently, our patient pool was chosen from a single

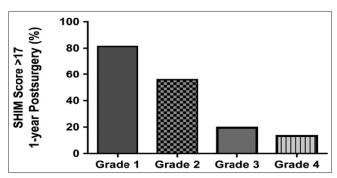


Figure 1: Intraoperative physician-assigned grading based change in the percentages of Sexual Health Inventory for Men score, in potent men at 1 year after robotic-assisted laparoscopic prostatectomy

Table 4: Hierarchical multiple regression models examining relationships between intraoperative physician-assigned grading, clinical, laboratory, intraoperative parameters, and the change in Sexual Health Inventory for Men score

Predictor	β	sr	P	R ²	ΔR^2	F	∆ F	Р
Model 1								
Age ≥60	-0.806	-0.115	0.019	0.013	-	5.691	-	0.017
Model 2								
Age ≥60 years	-0.849	-0.122	0.012	0.022	0.009	4.817	3.903	0.049
Laterality of sparing	1.118	0.095	0.051					
Model 3								
Age ≥60 years	-0.749	-0.107	0.028	0.037	0.015	5.377	6.374	0.012
Laterality of sparing	1.009	0.086	0.077					
Prostate weight	-0.022	-0.127	0.009					
Model 4								
Age ≥60	-0.745	-0.107	0.029	0.041	0.004	4.453	1.658	0.199
Laterality of sparing	0.992	0.085	0.082					
Prostate weight	-0.022	-0.127	0.009					
PSA	-0.018	-0.058	0.232					
Model 5								
Age ≥60	-0.517	-0.074	0.085	0.241	0.200	26.580	110.443	< 0.0001
Laterality of sparing	0.079	0.007	0.876					
Prostate weight	-0.008	-0.048	0.269					
PSA	-0.014	-0.043	0.312					
IOPAG	-2.082	-0.480	0.000					

Dependent variable: DSHIM. DSHIM= Δ SHIM=Change in Sexual health inventory of men score, IOPAG=Intraoperative physician-assigned grading, PSA=Prostate-specific antigen

high-volume center, operated by the same surgeon who has done >250 RALP's per year for the last 10 years. In a larger reported series, Ficarra *et al.* summarized that the incidence of erectile function recovery after RALP at 1 year was 70% (54%–90%).^[12] However, in this current study, potency rates were categorized as per the grade of nerve dissection and at 1 year were found to be 81%, 55.8%, 19.5%, and 13.3% for Grades 1 to 4, respectively. The overall potency rate disregarding the IOPAG was 66.5%. This agrees with the earlier reported value of 70%. When the IOPAG is incorporated, it is seen that in the lower grades, the potency rates are much higher with a tendency to fall with increase in the IOPAG.

Novara *et al.*'s data published that independent predictors of potency after 12 months were age, Charlson Comorbidity Index, and baseline SHIM score.^[13] Shikanov *et al.* have shown that age, baseline SHIM score, erection suitable for intercourse at baseline, and bilateral nerve sparing were independently associated with recovering erectile function.^[14] The present study results agree with these findings, though it adds another parameter in terms of surgeon-assigned grading as an independent predictor of postsurgery erectile function.

With regard to the type of periprostatic fascial dissection, Shikanov *et al.* reported that interfascial versus extrafascial nerve dissection produced potency rates of 64% and 40% at 1 year. [15] Hong Weng *et al.* suggested intrafacial to be superior to interfascial nerve sparing in terms of subsequent potency. [16] In the present study, we exclusively included intrafascial nerve dissection patients, keeping in mind its documented superiority over other methods. Comparing cautery and noncautery techniques has produced conflicting results, with Ahlering *et al.* showing a benefit with the cautery-free technique, [17] but Samadi *et al.* not demonstrating any benefit with the athermal technique in a larger study. [18] Interestingly, traction-free techniques also have conflicting reports. In this study, we have included athermal technique and no lateral traction on nerves as proposed criteria for IOPAG.

An intraoperative classification of the degree of nerve sparing has been proposed by Schatloff *et al.*, wherein four grades of nerve sparing were described on the visual cues by the operating surgeon. [11] Reported potency rates for men in this series at 1-year follow-up was 90.6%, 76.2%, 60.5%, and 57.1% for nerve-sparing Grades 1, 2, 3, and 4, respectively. They defined potency as SHIM \geq 21. However, we chose to incorporate more measurable visual cues into our proposed criteria for IOPAG, to better define and stratify the nerve sparing. Besides, we chose to select patients with SHIM \geq 17 for this study because at this functional level of potency patients had satisfactory penetrative intercourse most of the times. Engel in a randomized study reported a higher ability for penetrative intercourse in patients, post-RALP, who were concomitantly treated with PDE5 inhibitor and VED versus

tadalafil alone. [19] We provided our patients with a PDE5 inhibitor combined with VED for penile rehabilitation. Stern *et al.* concluded that surgeon perception of intraoperative performance during RALP lacks predictive power with respect to continence. [20] They did not study the impact on potency outcomes though. This lacuna has been fulfilled by the current study. The findings of Shaun Kilminster *et al.* concluded that men <60 years have a significant likelihood of regaining adequate potency after RALP. [21] In the current study, the overall potency rates for age <60 years and age >60 years were 71.5% and 62.5%, respectively.

The present study reports that the IOPAG is a strong measurable predictor of potency outcomes at 1 year after RALP.

Limitations

One of the limitations of this study is the dependency on a single experienced surgeon's evaluation. While this may seem to limit the generalizability of the IOPAG, it has an advantage of eliminating the bias arising out of intersurgeon variation in interpretation of intraoperative visual cues. Another limitation is the retrospective study design of 425 patients. A larger, longer duration, multicentric, prospective study with different surgeons evaluating the same RALP individually and concurrently could be more enlightening and is a possible future direction. IOPAG being an intraoperative score needs to be compared with the standard universally accepted preoperative predicting scores to check for its potency predictive validity. Some of the potency data were obtained over telephone and not by clinical interview, so it has the potential to vitiate the interpretations of this study due to recall bias. In addition, this study had a limited follow-up of 1 year; a longer period of evaluation may have shown some previously impotent men eventually qualify as potent because potency is known to keep recovering up to 2 years after RALP.

CONCLUSIONS

This study found a strong association between the IOPAG of risk stratification of the nerve sparing and subsequent functional potency outcomes at the end of 1 year, with IOPAG being an independent and the strongest predictor in our model when performed by an experienced surgeon. This experienced surgeon's perception of quality of nerve sparing correlates well with the potency outcomes at 1-year postsurgery. Patients with lower IOPAG of nerve sparing had a higher grade of potency. Besides, the lower the IOPAG, the lesser the decline in change of SHIM value along with a higher percentage of respective patients regaining acceptable potency. This proposed IOPAG system has a potential to predict the postoperative return of erectile function post-RALP and can be used for patient counseling and arranging appropriate early interventions such as a penile prosthesis placement in the future as needed.

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