

Proficiency score as a predictor of early trifecta achievement during the learning curve of robot-assisted radical prostatectomy for high-risk prostate cancer: Results of a multicentric series

Umberto Anceschi^a, Rocco Simone Flammia^b, Antonio Tufano^{b,*}, Michele Morelli^c, Antonio Galfano^c, Lorenzo Giuseppe Luciani^d, Leonardo Misuraca^a, Paolo Dell'Oglio^c, Gabriele Tuderti^a, Aldo Brassetti^a, Maria Consiglia Ferriero^a, Alfredo Maria Bove^a, Riccardo Mastroianni^a, Francesco Prata^a, Isabella Sperduti^e, Giovanni Petralia^c, Silvia Secco^c, Ettore Di Trapani^c, Daniele Mattevi^d, Tommaso Cai^d, Aldo Massimo Bocciardi^c, Giuseppe Simone^a

^aDepartment of Urology, IRCCS "Regina Elena" National Cancer Institute, Rome, Italy; ^bUrologic Clinic, Department of Maternal-Child and Urologic Sciences, Sapienza University of Rome, Italy; ^cOspedale Niguarda Ca' Granda, Department of Urology, Milan, Italy; ^dDepartment of Urology, APSS Santa Chiara Regional Hospital, Trento, Italy; ^eDepartment of Biostatistical Unit, IRCCS Regina Elena National Cancer Institute, Rome, Italy

Abstract

Background: Recently, an innovative tool called "proficiency score" was introduced to assess the learning curve for robot-assisted radical prostatectomy (RARP). However, the initial study only focused on patients with low-risk prostate cancer for whom pelvic lymph node dissection (PLND) was not required. To address this issue, we aimed to validate proficiency scores of a contemporary multicenter cohort of patients with high-risk prostate cancer treated with RARP plus extended PLND by trainee surgeons.

Material and methods: Between 2010 and 2020, 4 Italian institutional prostate-cancer datasets were merged and queried for "RARP" and "high-risk prostate cancer." High-risk prostate cancer was defined according to the most recent European Association of Urology guidelines as follows: prostate-specific antigen >20 ng/mL, International Society of Urological Pathology ≥ 4 , and/or clinical stage (cT) $\geq 2c$ on preoperative imaging. The selected cohort (n = 144) included clinical cases performed by trainee surgeons (n = 4) after completing their RARP learning curve (50 procedures for low-risk prostate cancer). The outcome of interest, the proficiency score, was defined as the coexistence of all the following criteria: a comparable operation time to the interquartile range of the mentor surgeon at each center, absence of any significant perioperative complications Clavien-Dindo Grade 3–5, no perioperative blood transfusions, and negative surgical margins. A logistic binary regression model was built to identify the predictors of 1-year trifecta achievement in the trainee cohort. For all statistical analyses, a 2-sided $p < 0.05$ was considered significant.

Results: A proficiency score was achieved in 42.3% patients. At univariable level, proficiency score was associated with 1-year trifecta achievement (odds ratio, 8.77; 95% confidence interval, 2.42–31.7; $p = 0.001$). After multivariable adjustments for age, nerve-sparing, and surgical technique, the proficiency score independently predicted 1-year trifecta achievement (odds ratio, 9.58; 95% confidence interval, 1.83–50.1; $p = 0.007$).

Conclusions: Our findings support the use of proficiency scores in patients and require extended PLND in addition to RARP.

Keywords: Trifecta; Learning curve; Robot-assisted radical prostatectomy; High-risk prostate cancer

1. Introduction

The removal of pelvic lymph nodes, termed pelvic lymph node dissection (PLND), has become an integral part of radical prostatectomy (RP) for prostate cancer (PCa) since the procedure was popularized by Walsh et al. in the 1980s. The current European Association of Urology (EAU) PCa guidelines recommend extended pelvic lymph node dissection (ePLND) in all high-risk PCa (HRPCa) patients.^[1] Notably, the addition of ePLND to RP increases the risk of perioperative complications.^[2,3] Consequently, young surgeons usually begin performing RP with ePLND after completing the learning curve (LC) for RP alone. In this regard, we recently introduced an innovative tool, namely, "Proficiency score" to provide an early assessment of surgical quality among trainee surgeons performing robot-assisted radical prostatectomy (RARP).^[4] However, this novel composite outcome was conceived on RARP patients not requiring ePLND.^[4] This study aimed to validate proficiency

*Corresponding Author: Antonio Tufano, Urologic Clinic, Department of Maternal-Child and Urologic Sciences, Sapienza University of Rome, Policlinico Umberto I, Viale del Policlinico 155, IT-00161 Rome, Italy. E-mail address: antonio.tufano91@gmail.com (A. Tufano).

Umberto Anceschi and Rocco Simone Flammia equally contributed to the current study.

Supplemental Digital Content is available for this article.

Current Urology, (2024) 18, 2, 110–114

Received January 4, 2023; Accepted May 4, 2023.

<http://dx.doi.org/10.1097/CU9.0000000000000213>

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scores of a contemporary multicenter cohort of HRPcCa patients treated with RARP plus ePLND by trainee surgeons. We hypothesized that “Proficiency score” could predict 1-year trifecta achievement in high-risk setting, when ePLND in addition to RARP is required.

2. Material and methods

2.1. Study design and study population

We relied on a retrospective multi-institutional cohort study spanning 2010–2020. We included patients with HRPcCa, according to the EAU guidelines,^[5] treated with RARP plus ePLND at any of the participating institutions. The EAU guidelines define HRPcCa as follows: International Society of Urological Pathology grade group ≥ 4 or clinical T stage $\geq 2c$ or prostate-specific antigen > 20 ng/mL. All patients underwent conventional preoperative imaging (computed tomography, bone scan, and/or magnetic resonance imaging). We excluded patients with metastasis and those who received radiotherapy as an upfront local treatment for PCa. Moreover, patients operated on by mentors were necessary only to calculate the proficiency score and were subsequently excluded (Supplementary Table 1, <http://links.lww.com/CURRUROL/A36>). In addition, based on previous literature, only the first 50 consecutive RARP plus ePLND procedures performed by trainee surgeons are considered part of the LC.^[6,7] Thus, the final cohort relied exclusively on RARP plus ePLND performed by a trainee surgeon during LC.

2.2. Variable’s definition

The following data were available: age (in years), body mass index (in kilograms per meter square), hypertension, diabetes, American Society of Anesthesiologists score (1–2 vs. 3–4), prostate weight (in milliliters), operation duration (in minutes), technique (Retzius sparing vs. standard approach), number of consecutive procedures, time from LC starting for HRPcCa cases (in months), nerve-sparing approach (yes vs. no), perioperative transfusion, 30-day perioperative complication (highest Clavien-Dindo), pathologic T stage (pT2 vs. pT3 vs. pT4), lymph node yield, surgical margin status, 1-year continence status (no/safety vs. multiple pads), 1-year sexual function (spontaneous erection sufficient for intercourse \pm phosphodiesterase-5 inhibitors), 1-year biochemical recurrence (BCR) and 1-year trifecta, adjuvant treatment (radiotherapy vs. androgen deprivation therapy vs. combined radiotherapy and androgen deprivation therapy). Trifecta was defined as follows: (1) prostate-specific antigen < 0.2 ng/mL with confirmatory value; (2) attainment of erections sufficient for intercourse with or without oral pharmacological agents; and (3) wearing zero/safety pads.^[8] The outcome of interest, the proficiency score, was defined as the coexistence of all the following criteria: a comparable operation time to the interquartile range of the mentor surgeon at each center (Table 1), absence of any significant perioperative complications Clavien-Dindo Grade 3–5, no perioperative blood transfusions, and negative surgical margins.

2.3. Statistical analysis

First, a proficiency score was calculated for the trainee surgeons based on a previously published definition for each patient. Frequencies and proportions were reported for categorical variables, whereas medians and interquartile ranges were reported for continuously coded variables. Descriptive analyses were performed. Second, to test the association between proficiency score and 1-year trifecta achievement in patients with HRPcCa, we fitted univariate and multivariate logistic regression models. All available

covariates were tested in a stepwise fashion according to a previous methodology.^[9] All tests were 2-sided, with the significance level set at $p < 0.05$. Statistical analysis was performed using the Statistical Package for Social Sciences software (SPSS) software v.27.0 (IBM Corp, Armonk, NY).

3. Results

3.1. Baseline characteristics

We identified 144 patients who were treated by 4 trainee surgeons during LC (Table 2). The median patient age was 68 (63–72) years, with most patients exhibiting American Society of Anesthesiologists 1–2 (92.9%) and low rates of hypertension (25.3%) and diabetes (8.8%). The median operative time was 195 minutes (132–242) with a median lymph node yield of 20 (16–26) nodes removed. Of these patients, 60.5% were treated using the Retzius-sparing approach, and 27.4% received nerve sparing. At the final pathological examination, the majority of patients harbored pT3 stage disease (55.7%). Moreover, 38.8% of patients had a positive surgical margin (PSM). Overall, we recorded 1 Clavien-Dindo I complication (0.7%, lymphocele treated conservatively), 3 (2.1%) Clavien-Dindo II complications (anemia requiring blood transfusion), and 6 (4.1%) Clavien-Dindo IIIa complications (lymphocele requiring percutaneous drainage). At 1-year follow-up, the BCR-free, continence, potency, and trifecta rates were 86.9%, 73.6%, 19.7%, and 13.1%, respectively.

3.2. Predictors of “Proficiency score” achievement

Overall, 61 patients (42.3%) achieved proficiency scores. In the univariate logistic regression analysis, the proficiency score was associated with 1-year trifecta achievement (odds ratio [OR], 8.77; 95% confidence interval [CI]: 2.4–31.7, $p = 0.001$). Among the potential confounders, only age, surgical approach, and nerve-sparing technique were significantly associated with 1-year trifecta achievement at the univariate level (each $p < 0.05$). After multivariable adjustments for age, surgical approach, and nerve sparing, proficiency score achievement was still associated with 1-year trifecta achievement (OR, 9.58; 95% CI, 1.83–50.1; $p < 0.001$) (Table 3).

4. Discussion

Over the last few decades, an inverse stage migration phenomenon in RP-treated patients has been observed worldwide.^[10,11] This phenomenon is described as a relative increase in the number of PCa patients with high-risk features. Notably, current guidelines recommend the adoption of ePLND in addition to RP in patients with HRPcCa based on staging and prognostic ability, which

Table 1
Distribution of trainee involved, median operative times of experienced surgeons for RARP plus ePLND in the high-risk setting, serving as proxy for calculating proficiency score.

Center	LC period	Median operative time	IQR	Number of trainee on LC
Niguarda	2014–2021	210	128–250	2
Trento	2015–2021	203	150–255	1
“Regina Elena” National Cancer Institute	2019–2021	205	188–238	1

ePLND = extended pelvic lymph node dissection; IQR = interquartile range; LC = learning curve; RARP = robot-assisted radical prostatectomy.

Table 2
Baseline, perioperative, pathologic, and functional outcomes of trainees cohort performing RARP plus ePLND for HRPCa.

Variable	Trainee surgeons (n = 144)
Age at surgery, yr, median (IQR)	68 (63–72)
No. consecutive procedures, n, median (IQR)	10 (4–25)
Time from starting HRPCa cases, mo, median (IQR)	7.2 (2–12)
Surgical technique, n (%)	
Retzius sparing	86 (60.5)
Transperitoneal	58 (39.5)
Operative time, min, median (IQR)	195 (132–242)
ASA score, n (%)	
1–2	132 (92.9)
3–4	12 (7.1)
Diabetes, n (%)	7 (8.8)
Hypertension, n (%)	20 (25.3)
BMI, kg/m ² , median (IQR)	26 (24–29)
Nerve-sparing intent, n (%)	39 (27.4)
pT stages, n (%)	
pT1–pT2	63 (44.3)
pT3	81 (55.7)
pT4	-
Lymphadenectomy template type, n (%)	
Extended	133 (94.4)
Super extended	8 (5.6)
Lymph-node yield, median (IQR)	20 (16–26)
PSM, n (%)	56 (38.8)
30-days—Clavien-Dindo complications, n (%)	
I	1 (0.7)
II	3 (2.1)
IIIa	6 (4.1)
IIIb	0 (0)
IV	0 (0)
V	0 (0)
Perioperative transfusions, n (%)	3 (2.1)
Prostate weight, mL, median (IQR)	40 (30–58.2)
1-Year BCR, n (%)	19 (13.1)
Adjuvant therapy type, n (%)	
RXT	10 (7)
ADT	9 (6.3)
ADT + RXT	22 (15.4)
Continence (0–1 safety/pad)	106 (73.6)
Sexual functions (spontaneous and/or with PDE5-I use)	28 (19.7)
Trifecta (1-yr), n (%)	19 (13.1)
Proficiency score, n (%)	61 (42.3)

ADT = androgen deprivation therapy; ASA = American Society of Anesthesiologists; BCR = biochemical recurrence; BMI = body mass index; ePLND = extended pelvic lymph node dissection; HRPCa = high-risk prostate cancer; IQR = interquartile range; PDE5-I = phosphodiesterase-5 inhibitor; PSM = positive surgical margin; RARP = robot-assisted radical prostatectomy; RXT = radiotherapy.

cannot be matched by any other currently available procedure, and the potential oncologic benefit.^[1,12] Nonetheless, ePLND is a complex surgical procedure with a higher complication rate than either RP alone or RP with limited PLND.^[13,14] Under these premises, young urologists should be adequately trained to perform ePLND in addition to RARP, as it is required more frequently among surgically treated PCa patients. To address this need, we recently introduced an innovative tool, namely, “proficiency score” to provide an early assessment of surgical quality among trainee surgeons performing RARP.^[4] In the current study, we validated this tool in patients with HRPCa treated with RARP plus ePLND performed by trainee surgeons. Our study made several noteworthy observations.

First, we identified a unique cohort of 144 patients treated by 4 trainee surgeons using either the standard anterior or Retzius-sparing approach. The median operative time was 195 minutes, which was slightly longer than the 168 minutes reported by Yuh et al.^[15] in the largest meta-analysis of RARP for HRPCa. Similarly, the PSM rate was 38.8%, which was higher than the pooled rate of 15% (range, 6.5%–32%) reported by Yossepowitch et al.^[16] in their systematic review and meta-analysis. These differences may reflect the fact that RARPs in the current cohort were performed by trainee surgeons during LCs. In contrast, the median number of lymph nodes removed (n = 20) was comparable with the data reported in the most recent randomized controlled trial testing the survival benefit of extended versus limited PLND (17 vs. 3).^[17] In summary, trainee surgeons performed RARP plus ePLND satisfactorily according to the number of lymph nodes removed, despite the longer median operative time and higher rate of PSM results.

Second, we recorded 1-year BCR-free rate and continence rates of 86.9% and 73.6%, respectively. These results are in agreement with data from previously published series.^[18,19] Conversely, we reported an unexpectedly lower potency rate (19.7%) than that reported in the current literature (52%–60%).^[15] These conflicting results may be attributable to the heterogeneous definitions of sexual success. Alternatively, it can be postulated that patients, for whom sexual outcomes were not a priority based on preoperative planning were preferred for training. This scenario was further supported by the low rate of nerve-sparing techniques (15.7%). Unfortunately, the retrospective design of our study does not provide a definitive explanation. In summary, the oncological and functional outcomes in the current cohort reflect data from the contemporary literature, with the exception of potency rates.

Third, according to the proficiency score definition, 42.3% of patients received adequate treatment. After multivariable adjustments for important confounders, the proficiency score was an independent predictor status of 1-year trifecta achievement (OR, 9.58; *p* < 0.001). These findings are in agreement with previous results in patients with low-/intermediate-risk PCa treated with RARP without ePLND.^[4] Consequently, the proficiency score may represent a reliable tool for the early evaluation of RARP with or without ePLND performed by trainee surgeons, not only for low/intermediate but also for HRPCa. It is important that proficiency scores can be extended to patients requiring ePLND. Indeed, both the increasing trend of active surveillance for low-risk PCa patients^[20–22] and contemporary attempts to expand its indications to favorable intermediate-risk PCa patients^[23–27] further support inverse stage migration among RARP-treated patients. Consequently, in the next few years, most candidates for surgical treatment will require ePLND in addition to RARP, because PCa exhibits a more aggressive phenotype. Therefore, it is necessary to provide young urologists with adequate training in RARP and ePLND. In this regard, the proficiency score may represent a unique tool for a standardized early evaluation of the quality of surgery based on PSM status, intraoperative transfusions, significant perioperative complications, and operative time, which is considered relative to the interquartile range of the mentor’s operative time. Notably, proficiency scores provide mentors and trainees with an immediate training assessment without waiting for oncological and functional outcomes, as all criteria are expected to be screened within a couple of weeks after surgery. This finding has several important implications in clinical practice. First, the length of surgical training can be personalized once a satisfactory success rate threshold is established and validated relative to the minimum number of procedures required (i.e., a 75% success rate out of 50 minimum procedures required). Second, proficiency scores may help mentors decide on techniques that can be taught more effectively according to training length and patient safety. Third, different

Table 3
Univariable and multivariable logistic regression analysis to identifying predictors of 1-year trifecta achievement after RARP plus ePLND in the high-risk setting for trainees.

Variable	Univariable analysis				Multivariable analysis			
	OR	95% CI		p	OR	95% CI		p
		Lower	Higher			Lower	Higher	
Age at surgery, yr	0.87	10.80	0.94	0.01	0.87	0.79	0.97	0.01
ASA score 3–4 vs. 1–2	21.35	0.14	12.2	0.788	-	-	-	-
Diabetes	0.58	0.12	2.80	0.503	-	-	-	-
Hypertension	1.31	0.48	3.59	0.594	-	-	-	-
BMI, kg/m ²	1.01	0.70	1.46	0.931	-	-	-	-
Consecutive HRPcA procedures, n	0.98	0.95	1.02	0.504	-	-	-	-
Time from starting to perform HRPcA cases, mo	0.82	0.59	1.14	0.253	-	-	-	-
Surgical technique, RS vs. STD	0.23	0.06	0.86	0.029	1.03	0.19	5.56	0.970
Proficiency score (MOT, no PSM, no Clavien 3–5, no transfusions)	8.77	2.42	31.7	0.001	9.58	1.83	50.1	0.007
Nerve-sparing intent	15.6	4.75	51.3	0.001	13.3	3.52	50.6	0.001
Prostate volume, mL	0.99	0.97	1.01	0.481	-	-	-	-
Lymph node yield, n	0.99	0.94	1.05	0.978	-	-	-	-
Lymphadenectomy template (extended vs. super extended)	0.58	0.09	3.72	0.583	-	-	-	-
Adjuvant treatment (including RXT, ADT alone or combined)	0.21	0.02	1.71	0.146	-	-	-	-

Boldface represents that the *p* value (< 0.05) was statistically significant for those variables.
 ADT = androgen deprivation therapy; ASA = American Society of Anesthesiologists; BMI = body mass index; CI = confidence interval; ePLND = extended pelvic lymph node dissection; HRPcA = high-risk prostate cancer; MOT = median operative time; OR = odds ratio; PSM = positive surgical margin; RARP = robot-assisted radical prostatectomy; RS = Retzius sparing; RXT = radiotherapy; STD = standard approach.

training programs can be easily compared prospectively without the need for follow-up data. In summary, our findings support the use of proficiency scores in patients and require ePLND in addition to RARP. The implementation of this versatile comprehensive tool in contemporary training programs will provide mentors and trainees with standardized and time-saving surgical quality assessments.

Our study had some limitations. The first and foremost limitation is the retrospective study design. Consequently, standardized training protocols were not adopted in this study. Moreover, we did not have data on the previous surgical experience of trainees or information on how and to what extent mentors supported trainees during RARP. However, these data may only be available if a prospective study is conducted. Second, we relied on a limited sample size and low event rate. Ideally, similar analyses should be repeated using a larger sample size. These results cannot be generalized to tertiary referral high-volume robotic centers where trainees are routinely exposed to multiple robotic surgical procedures as observers or assistants. Consequently, the LC at this center extends well beyond the first RARP performed as the main operator.

5. Conclusions

Our findings support the use of proficiency scores in patients and require ePLND in addition to RARP. The implementation of this versatile comprehensive tool in contemporary training programs will provide mentors and trainees with standardized and time-saving surgical quality assessments.

Acknowledgments

None.

Statement of ethics

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki and was approved by the Institutional

Review Board of IRCCS “Regina Elena” National Cancer Institute. A waiver of informed consent was obtained, given the retrospective nature of the study.

Conflict of interest statement

The authors declare that they have no conflicts of interest.

Funding source

None.

Author contributions

All authors listed gave a substantive contribution to this study and to this original article.
 UA, RSF: Conceptualization, writing—original draft preparation;
 RSF, AT, MM: conceptualization, formal analysis and investigation;
 IS: Statistical analysis;
 AG, LGL, LM, PD, GT, AB, MCF, AMB, RM, GP, DM, TC, SS: Methodology;
 UA, RSF: Conceptualization;
 UA, AT, FP, EDT: Writing—review and editing;
 AMB, GS: Project development.

Data availability

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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How to cite this article: Anceschi U, Flammia RS, Tufano A, Morelli M, Galfano A, Luciani LG, Misuraca L, Dell'Oglio P, Tuderti G, Brassetti A, Ferriero MC, Bove AM, Mastroianni R, Prata F, Sperduti I, Petralia G, Secco S, Di Trapani E, Mattevi D, Cai T, Bocciardi AM, Simone G. Proficiency score as a predictor of early trifecta achievement during the learning curve of robot-assisted radical prostatectomy for high-risk prostate cancer: Results of a multicentric series. *Curr Urol* 2024;18(2):110–114. doi: 10.1097/CU9.0000000000000213