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Platinum Priority – Prostate Cancer

Editorial by James A. Eastham and Peter T. Scardino on pp. 708–709 of this issue

Pentafecta: A New Concept for Reporting Outcomes of Robot-Assisted Laparoscopic Radical Prostatectomy

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Article info

Article history:

Accepted January 14, 2011

Published online ahead of
print on January 25, 2011

Keywords:

Minimally invasive
Robot assisted
Radical prostatectomy
Outcomes
Trifecta
Pentafecta
Counseling tool



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Abstract

Background: Widespread use of prostate-specific antigen screening has resulted in younger and healthier men being diagnosed with prostate cancer. Their demands and expectations of surgical intervention are much higher and cannot be adequately addressed with the classic trifecta outcome measures.

Objective: A new and more comprehensive method for reporting outcomes after radical prostatectomy, the *pentafecta*, is proposed.

Design, setting, and participants: From January 2008 through September 2009, details of 1111 consecutive patients who underwent robot-assisted radical prostatectomy performed by a single surgeon were retrospectively analyzed. Of 626 potent men, 332 who underwent bilateral nerve sparing and who had 1 yr of follow-up were included in the study group.

Measurements: In addition to the traditional trifecta outcomes, two perioperative variables were included in the *pentafecta*: no postoperative complications and negative surgical margins. Patients who attained the trifecta and concurrently the two additional outcomes were considered as having achieved the *pentafecta*. A logistic regression model was created to evaluate independent factors for achieving the *pentafecta*.

Results and limitations: Continence, potency, biochemical recurrence-free survival, and trifecta rates at 12 mo were 96.4%, 89.8%, 96.4%, and 83.1%, respectively. With regard to the perioperative outcomes, 93.4% had no postoperative complication and 90.7% had negative surgical margins. The *pentafecta* rate at 12 mo was 70.8%. On multivariable analysis, patient age ($p = 0.001$) was confirmed as the only factor independently associated with the *pentafecta*.

Conclusions: A more comprehensive approach for reporting prostate surgery outcomes, the *pentafecta*, is being proposed. We believe that *pentafecta* outcomes more accurately represent patients' expectations after minimally invasive surgery for prostate cancer. This approach may be beneficial and may be used when counseling patients with clinically localized disease.

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1. Introduction

Prostate cancer is frequently diagnosed in younger and healthier men who desire to undergo definitive treatment while maintaining their quality of life. Although multiple treatment options are currently available for these patients, radical prostatectomy (RP) remains the standard of care for long-term cancer control [1]. The major outcomes of RP have been classically reported as *trifecta* rates, which denote the likelihood of achieving urinary continence, potency, and cancer control concurrently following surgery [2]. The current demands and expectations of patients who desire surgical treatment for prostate cancer are much higher and cannot be adequately addressed with the classic trifecta outcomes alone [3]. Following minimally invasive approaches, patient satisfaction is highly determined by perioperative complications and also by the presence of positive surgical margin (PSM) rates, which can cause significant long-term psychological distress to patients after surgery [4]. Therefore, patients who have reached the trifecta after RP but who have also experienced postoperative complications and PSMs might not be completely satisfied after surgery.

A new and more comprehensive methodology for reporting outcomes after RP is proposed: the so-called pentafecta. In the pentafecta rate, we included complications and surgical margin status, along with the three major outcomes classically reported in trifecta rates: potency, continence, and biochemical recurrence (BCR)–free survival rates. The purpose of this paper is to report in a single-surgeon experience the rates of achieving the pentafecta in patients who underwent bilateral nerve-sparing surgery. Additionally, a predictive model for discerning the occurrence of the pentafecta was created.

2. Materials and methods

From January 2008 to September 2009, 1111 consecutive patients underwent robot-assisted radical prostatectomy (RARP) by a single surgeon. Following institutional review board approval, the data were prospectively collected in a customized database and retrospectively analyzed. Informed consent was obtained from each patient prior to enrollment in the study.

In the present study, only preoperatively continent and potent patients (Sexual Health Inventory for Men [SHIM] score >21) who underwent bilateral, full nerve-sparing surgery and had at least 12 mo follow-up were selected. In all, 626 men had a SHIM score >21 before RARP; of these, 332 patients underwent bilateral, full nerve-sparing surgery and had at least 1 yr follow-up, constituting the final cohort.

Baseline urinary and sexual functions were assessed before RARP with self-administered, validated questionnaires: the Expanded Prostate Cancer Index Composite (EPIC) and the SHIM [5,6]. Patient comorbidity was evaluated using the Charlson comorbidity index score [7].

2.1. Surgical technique and penile rehabilitation

All patients underwent a six-port transperitoneal technique with athermal nerve sparing and early retrograde release of nerve bundles as previously reported [8]. Two technical modifications, aiming to improve the early continence rates, were also performed in all cases:

placement of a periurethral suspension stitch [9] and modified posterior reconstruction of the rhabdosphincter [10].

Penile rehabilitation was recommended for all patients. Patients were advised to use phosphodiesterase type 5 (PDE5) inhibitors at least three times a week until return of sexual function. Rehabilitation using a vacuum erection device (VED) was also recommended once a day, starting 6 wk after surgery.

2.2. Histopathologic evaluation

All surgical specimens were weighed, external surfaces were inked, and specimens were submitted for pathologic evaluation. The apex and bladder-neck cones were amputated and sectioned in the sagittal plane. The remaining specimen was sectioned transversely at 4-mm intervals. PSMs were defined as the presence of tumor on the inked surface of the specimen. Histopathologic staging was performed according to the 2002 TNM system [11].

2.3. Pentafecta rate

Outcomes included in the analysis of the pentafecta rate were complications and PSMs combined with the three outcomes classically reported in the trifecta. Only patients who successfully met all criteria were considered to have reached the pentafecta.

Success in each of the parameters was defined as (1) absence of perioperative complications (grade 0 on Clavien-Dindo grading) [12], (2) negative surgical margins, and (3) achievement of composite trifecta outcomes (continent, potent, and BCR free).

2.4. Definition of complications, continence, potency, and biochemical recurrence-free rates

Complications occurring during the surgical procedure or within 90 d after surgery were documented (early complications) and classified according to the modified Clavien grading system [12]. BCR was defined as two consecutive prostate-specific antigen (PSA) levels of >0.2 ng/ml [13]. Postoperative follow-up comprised a clinical exam and PSA levels at 6 wk; at 3, 6, 9, and 12 mo; and then every 6 mo thereafter for the next 4 yr. In case of recurrence in high-risk patients with PSM or T3 disease, adjuvant therapy was administered based on the decision of a multidisciplinary committee on an individual-patient basis.

Continence rate was assessed with the self-administered EPIC questionnaire at 6 wk and at 3, 6, 12, and 18 mo. The definition of continence was based on the response to the item selected to reflect the range of incontinence severity: “How many pads or adult diapers per day did you usually use to control leakage during the last 4 weeks?” Continence was defined as the use of no pads (score: 0).

Potency rates were evaluated during similar time frames using the SHIM questionnaire. Potency was defined as the ability to achieve and maintain satisfactory erections firm enough for sexual intercourse in >50% of attempts, with or without the use of PDE5 (score ≥ 4 on questions 2, 3, and 5). If patients required VED, penile injections, or transurethral alprostadil for intercourse, they were not considered to be potent.

2.5. Statistical analysis

Continuous parametric variables were reported as the mean plus or minus standard deviation (SD) or as the median values and interquartile range (IQR). Mann-Whitney and chi-square tests were used to compare continuous and categorical variables as appropriate. A stepwise logistic regression was used to identify independent predictors for achieving the pentafecta. The six variables entered into the model were age, body mass

Table 1 – Patients' characteristics (n = 332 patients)

Variable		
Age, yr, mean $\pm$ SD		58.57 $\pm$ 7.532
BMI, mean $\pm$ SD		28.07 $\pm$ 3.818
SHIM score, median (IQR)		24 (23–25)
Charlson comorbidity index, median (IQR)		2 (1–2)
PSA, median (IQR)		4.4 (3.4–5.9)
		No. (%)
Clinical stage	T1c	308 (92.7)
	$\geq$ T2	24 (7.3)
Biopsy Gleason score	$\leq$ 6	243 (73.2)
	7	83 (25.0)
	$\geq$ 8	6 (1.8)
D'Amico risk classification	Low risk	223 (67.2)
	Intermediate risk	96 (28.9)
	High risk	13 (3.9)
Pathologic stage	pT2	309 (93.0)
	$\geq$ pT3, pT4	23 (6.9)
Specimen Gleason score	$\leq$ 6	152 (45.8)
	7	169 (50.9)
	$\geq$ 8	11 (3.3)
Prostate weight range, g	20–40	94 (28.3)
	41–60	171 (51.5)
	$>$ 60	67 (20.2)

SD = standard deviation; BMI = body mass index; SHIM = Sexual Health Inventory for Men; IQR = interquartile range; PSA = prostate-specific antigen.

index (BMI), PSA level, clinical stage, biopsy Gleason grade, and Charlson comorbidity index. A two-tailed test with $p < 0.05$ was considered statistically significant. All statistical analyses were performed using SPSS v.16.0 (SPSS Inc, Chicago, IL, USA).

3. Results

Patient characteristics are described in Table 1. The median follow-up was 22 (IQR: 17.3–26.3) mo. Hypertension (35.8%) and dyslipidemia (24.3%) were the two most common comorbidities reported. According to the d'Amico Risk stratification [14], 67.0% of patients were classified as low risk, 28.9% as intermediate risk, and 3.9% as high risk.

3.1. Perioperative outcomes

Twenty-two of 332 patients (6.6%) experienced 22 complications. There were no cases of multiple organ failure or

Table 2 – Complications

Complications	Occurrences (n = 22)	Clavien grade	Incidence, %
Perioperative (before hospital discharge)			
Myocardial infarction	1	4a	4.54
Ileus	4	2	18.18
Hepatitis	2	2	9.09
Blood transfusion	1	2	4.54
Postoperative (after hospital discharge)			
Anastomotic leakage	7	1d	31.82
Urinary retention	2	1d	9.09
Wound infection	2	2	9.09
Incisional hernia	1	3b	4.54
Bladder neck contracture	2	3b	9.09
Total	22	–	6.6

Table 3 – Variables comprising the pentapecta success rates

Variable	Proportion of patients	%
Complication	310/332	93.4
PSM	301/332	90.7
Potency	298/332	89.8
Continence	320/332	96.4
BCR-free rate	320/332	96.4
Trifecta	276/332	83.1
Failure to achieve trifecta	56/332	16.9
Pentapecta	235/332	70.8
Failure to achieve pentapecta	97/235	29.2

PSM = positive surgical margin; BCR = biochemical recurrence.

death (Gleason grade 4b and 5). Minor complications (grade 1 and 2) constituted 77.3% of all those reported. The incidence of major complications (grade $\geq$ 3) was $<$ 1.5%. Complications are depicted in Table 2.

3.2. Oncologic outcomes: biochemical recurrence and positive surgical margins

The overall PSM rate was 9.3%. Stage-specific PSM rates were 6.9% (21 of 302) and 33.3% (10 of 30) for pT2 and pT3 tumors, respectively. The overall BCR-free rate at 12 mo was 96.4%; 12 patients underwent further salvage therapy with either radiation and/or hormonal treatment. Of the patients who experienced BCR, 25.0% had PSMs.

3.3. Functional outcomes

The overall continence rates were 65.9%, 85.8%, 94.2%, and 96.3% at 6 wk, and 3, 6, and 12 mo, respectively. A total of 298 (89.7%) of the 332 patients were potent at 12 mo. The overall potency rates were 53.9%, 68.0%, and 86.1% at 6 wk, and at 3 and 6 mo, respectively (Table 3).

3.4. Trifecta and pentapecta outcomes

The overall trifecta rates were 43.1%, 64.1%, 79.2%, and 83.1% at 6 wk, and 3, 6, and 12 mo, respectively. The pentapecta rates at 3 and 6 mo were 51.8% and 66.9%, respectively. The pentapecta rate at 12 mo was 70.8% (235 of 332 patients). When stratifying outcomes by patient age, the pentapecta rates were 75.9%, 68.9%, and 62.1% for patients $\leq$ 55 yr, 56–65 yr, and $>$ 65 yr, respectively.

The most common reasons for not achieving the trifecta were erectile dysfunction (57.1% of patients not achieving trifecta), followed by BCR (19.6%) and urinary incontinence (19.6%). The most common reasons for not reaching the pentapecta were erectile dysfunction (35.0%) and PSM (31.9%).

On univariable analysis, patient age (pentapecta vs no pentapecta, 57.8 ± 7.2 vs 60.2 ± 8.0 yr, respectively; $p < 0.013$) and pathologic stage (pentapecta vs no pentapecta, $\geq$ pT3 = 5.5% vs 18.5%; $p = 0.002$) were significantly correlated with pentapecta rates (Table 4). In the multivariable analysis, patient age (odds ratio [OR]: 0.957; $p = 0.009$) was confirmed as the only

Table 4 – Univariable analysis of factors correlated with the pentafecta

Variable		Outcomes after 12 mo (n = 332)		p value
		Pentafecta achieved (n = 235)	Pentafecta not achieved (n = 97)	
Age, mean ± SD		57.8 ± 7.2	60.2 ± 8.0	0.013
BMI, mean ± SD		28.3 ± 4.0	27.6 ± 3.2	0.6
Charlson comorbidity index, median (IQR)		2 (1–2)	2 (1–2)	0.805
SHIM score, median (IQR)		24 (23–25)	24 (23–25)	0.066
Biopsy Gleason score, No. (%)	≤6	176 (74.8)	67 (69.0)	0.617
	7	54 (22.9)	29 (29.8)	
	≥8	5 (2.1)	1 (1.0)	
Median PSA (IQR)		4.4 (3.3–6.0)	4.45 (3.6–5.8)	0.739
Clinical stage		No. (%)	No. (%)	0.805
	T1	218 (92.8)	90 (92.8)	
D'Amico risk stratification	≥T2, T3	17 (7.2)	7 (7.2)	0.106
	Low risk	158 (67.2)	62 (63.9)	
	Intermediate risk	62 (26.4)	34 (35.1)	
Nerve-sparing approach	High risk	12 (5.1)	1 (1.0)	0.084
	Antegrade	91 (38.7)	48 (49.4)	
Specimen Gleason score	Retrograde	144 (61.3)	49 (50.5)	0.713
	≤6	113 (48.1)	39 (42.3)	
	7	115 (48.9)	54 (55.7)	
Pathologic stage	≥8	7 (3.0)	4 (4.1)	0.006
	pT2	222 (94.5)	80 (82.5)	
	≥pT3, pT4	13 (5.5)	17 (18.5)	
Tumor volume, %	0–10	130 (55.3)	42 (43.3)	0.135
	11–20	67 (28.5)	33 (34.0)	
	20–100	36 (15.3)	24 (24.7)	
Prostate weight range, g	20–40	62 (26.4)	32 (33.0)	0.495
	41–60	122 (51.9)	49 (50.5)	
	>60	43 (18.3)		
Operative time, min, mean ± SD		76.1 ± 10.5	77.3 ± 11.7	0.521
EBL, ml, mean ± SD		114.4 ± 33.5	121.1 ± 34.5	0.075
Lymph-node dissection, No. (%)		45 (19.3)	19 (19.0)	0.933
Lymph-node yield, No. (IQR)		2 (1–2)	2 (1–2)	0.978
Positive lymph nodes, No.		0	0	–

SD = standard deviation; BMI = body mass index; IQR = interquartile range; SHIM = Sexual Health Inventory for Men; PSA = prostate-specific antigen; EBL = estimated blood loss.

factor independently associated with pentafecta rates, with older age predicting lower pentafecta rates (Table 5).

4. Discussion

The demands and expectations of patients who desire surgical treatment for prostate cancer are high and cannot be adequately addressed by trifecta outcomes alone. Patients' expectations for postoperative health-related quality of life (HRQoL) are higher for innovative, less invasive surgical approaches (eg, RARP) than they are for the traditional open

approach [3]. Schroeck et al. [3] recently compared patient satisfaction and regret after 966 open RP and 361 RARP performed in a single institution. Although the function and bother scores were similar between the groups, patients undergoing RARP were approximately three to four times as likely to be dissatisfied and regretful as patients undergoing open RP after adjusting for sociodemographic variables and EPIC domain scores. The authors concluded that patients who underwent RARP were more likely to be regretful and dissatisfied probably because of a higher expectation for an innovative procedure. They went further and suggested that urologists should carefully portray the risks and benefits of new technologies during preoperative counseling in an effort to minimize regret and maximize postoperative satisfaction.

Based on these observations, we propose a more comprehensive method of reporting outcomes following RP, the pentafecta, which adds perioperative complications and PSM rates to the major outcomes currently reported as the trifecta rates. Patients ultimately want to know if the treatment option will render them cancer free with a minimum of complications and the shortest possible convalescence time while preserving normal urinary and sexual function. Therefore, pentafecta rates can portray

Table 5 – Multivariable analysis: independent predictors of the pentafecta

	p value	Odds ratio	95% confidence interval
Age	0.009	0.957	0.926–0.989
Body mass index	0.126	1.052	0.986–1.122
Charlson comorbidity index	0.279	1.149	0.894–1.477
Prostate-specific antigen	0.924	0.996	0.923–1.075
Biopsy Gleason score	0.264	1.360	0.793–2.332
Clinical stage	0.938	0.963	0.377–2.464

postoperative patient satisfaction more accurately, thus constituting a valuable tool for counseling patients with clinically localized prostate cancer.

One of the initial studies reporting trifecta outcomes, published by Shikanov et al. [15], showed overall trifecta rates of 71.0% at 12 mo after surgery when applying subjective continence and potency definitions. Nevertheless, overall PSM rates as high as 19.5% were reported. The trifecta rate after such a short postoperative follow-up clearly does not reflect actual cancer control, as the risk of BCR clearly persists even beyond 5 yr after RP [16] and therefore does not represent patient satisfaction or regret rates.

Another caveat in trifecta outcomes regards postoperative complications. Patients who experience surgical complications, which can potentially affect postoperative HRQoL and satisfaction (such as a rectal injury and diverting colostomy), may still achieve trifecta. Novara et al. [17] recently published their trifecta rates in 242 consecutive RARPs with a minimum 12-mo follow-up. A trifecta outcome was achieved by 137 of 242 patients (57%). However, in a different study evaluating a similar cohort of patients, the same authors [18] reported postoperative complication rates of 21.6% (90 of 415 patients). Three percent (12 of 405) of the patients had a major complication (Clavien III and IV), including 11 patients who required reoperation (eg, nephrostomy, surgical reexploration for pelvic hematoma, and bowel perforation). Therefore, although encouraging trifecta rates were reported, these results may not reflect true patient-satisfaction rates.

The overall trifecta rate in our series, at 12 mo, was 83.1%. However, when combining the trifecta outcomes with complications and PSMs, a successful outcome was achieved in 70.8% of the patients (pentafecta rate). The most common reasons for failure to reach the pentafecta in an individual outcome were erectile dysfunction (35.0%) and PSM (31.9%). We therefore hypothesize that the 13.2% difference between the trifecta and pentafecta rates in our series represents patients who had a suboptimal outcome and potentially are not fully satisfied with the surgical treatment.

Patient age and pathologic stage were the only factors associated with pentafecta outcomes on univariable analysis. These results are not surprising because pathologic stage is one the most important predictors for PSMs and BCR after RP, whereas patient age is clearly correlated with functional outcomes after surgery. Menon et al. [19] recently analyzed long-term oncologic outcomes in a series of 1384 consecutive RARPs. The actuarial BCR-free rates were 95.1%, 90.6%, 86.6%, and 81.0% at 1, 3, 5, and 7 yr, respectively; on multivariable analysis, the strongest predictors of BCR were pathologic stage T3b of T4 (OR: 2.71; 95% confidence interval [CI], 1.67–4.40; $p < 0.0001$), and pathologic and Gleason grade 8–10 (OR: 5.37; 95% CI, 2.99–9.65; $p < 0.0001$). With reference to the correlation between patient age and functional outcomes after RP, Mendiola et al. [20] recently evaluated age-stratified functional outcomes in 338 consecutive RARPs and showed that younger men achieved subjective continence and

potency significantly earlier than older men. Similarly, Rogers et al. [21] evaluated potency and continence rates in 369 patients who underwent laparoscopic RP (LRP) performed by two surgeons. The patients were stratified into three age groups: group 1, <50 yr; group 2, 50–59 yr; and group 3, ≥60 yr. Outcomes were assessed with self-administered questionnaires. Younger men had higher continence (100%, 91%, and 81%, for groups 1, 2, and 3, respectively, $p < 0.01$) and potency rates (70%, 67%, and 46%, respectively, $p < 0.01$) at 1 yr after LRP when compared with older men.

The present study has some limitations. Our outcomes are based on a single surgeon who has performed >4000 RARPs. Therefore, the extensive experience of the surgeon may have influenced the results and complication rates of our study and, as a result, the outcomes cannot be generalized. Furthermore, we analyzed a selective population of preoperatively potent patients with SHIM scores ≥21 who underwent bilateral nerve-sparing RARP. Previous studies on trifecta outcomes have also included partial and non-nerve-sparing procedures, which may have also affected the overall results. Finally, the study is limited by the short follow-up, which can affect BCR-free and functional outcomes. Another limitation is that we have not been able to strictly adhere to guidelines set forth by Mulhall [22] and Martin [23] whilst reporting erectile function and complications. As strengths, our study used validated, self-administered questionnaires to evaluate continence and potency rates serially.

5. Conclusions

We propose a more comprehensive approach for determining outcomes following RP, which combines perioperative complications and PSM rates to the major outcomes currently reported in the trifecta rates. We believe that pentafecta outcomes more accurately reflect patient expectations following surgery for prostate cancer. This approach may be beneficial and should be used when counseling patients with clinically localized disease. In our single-surgeon experience, patient age was independently found to be associated with pentafecta rates. Further studies applying the proposed pentafecta algorithm in different series are necessary to validate the current observations using postoperative HRQoL and satisfaction instruments.

Author contributions: Vipul R. Patel had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Patel, Sivaraman, Coelho.

Acquisition of data: Chauhan, Sivaraman, Palmer, Orvieto, Coughlin, Coelho, Rocco.

Analysis and interpretation of data: Sivaraman, Coelho, Patel.

Drafting of the manuscript: Sivaraman, Coelho, Patel.

Critical revision of the manuscript for important intellectual content: Patel.

Statistical analysis: Sivaraman, Coelho.

Obtaining funding: None.

Administrative, technical, or material support: Camacho.

Supervision: Patel.

Other (specify): None.

Financial disclosures: I certify that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: None.

Funding/Support and role of the sponsor: None.

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