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Critical review of 'pentafecta' outcomes after robot-assisted laparoscopic prostatectomy in high-volume centres

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• Historically, the ideal outcome of radical prostatectomy (RP) has been measured by achievement of the so-called 'trifecta', or the concurrent attainment of continence and potency with no evidence of biochemical recurrence. However, in the PSA era, younger and healthier men are more frequently diagnosed with prostate cancer. Such patients have higher expectations from the advanced minimally invasive surgical technologies. Mere trifecta is no longer an ideal outcome measure to meet the demands of such patients.
• Keeping the limitations of trifecta in mind, we have earlier proposed a new method of outcomes analysis, called the 'pentafecta', which adds early complications and positive surgical margins (PSMs) to trifecta.
• We performed a Medline search for articles reporting the complications, PSM rates, continence, potency and biochemical recurrence after robot-assisted RP. Related articles were selected and individual outcomes were reviewed.

What's known on the subject? and What does the study add?
We have earlier proposed 'pentafecta' as an ideal outcome assessment tool after robotic prostatectomy instead of the classically used 'tritecta'. This was done to meet the demands and expectations of the prostate cancer patients from minimally-invasive surgical techniques.

This article reviews each of the five arms of 'pentafecta' outcomes after robotic prostatectomy performed in high volume centres.

KEYWORDS

pentafecta, prostatectomy, outcomes, robot-assisted

INTRODUCTION

In the early 1980s several studies emerged that provided detailed description of the periprostatic anatomy [1]. This played a major role in ameliorating the postoperative morbidity associated with open radical prostatectomy (ORP), as first described by Young in 1905 [2]. This was paralleled with the development of minimally invasive surgery initially by gynaecologists and general surgeons. The first laparoscopic RP (LRP) series was reported by Schuessler *et al.* [3] in 1997. However, the steep learning curve and limitations such as reduction in the range of motion, two-dimensional view, impaired eye–hand coordination, extended learning curve and minimal tactile sensation have prevented the adoption of LRP by most urologists [4–6].

The introduction of the robotic surgical system to the field of urology, with the advantage of three-dimensional binocular magnification, motion scaling, tremor filtration, seven degrees of freedom and preferred surgeon ergonomics has raised new hopes towards a minimally invasive approach to RP. The first robot-assisted RP (RARP) was performed in Germany by Binder and Kramer [7] in 2000 and the procedure has undergone multiple modifications and its growth has been exponential since then.

The 'best case scenario' outcomes for RP have been defined by the 'trifecta' [8], which includes the concurrent achievement of continence and potency while being free from any biochemical evidence of disease. However, trifecta as a measure of outcome assessment has several limitations. For example, a patient with intraoperative rectal injury requiring a colostomy might still achieve trifecta. Similarly, a patient who has psychological distress and even major depression due to a positive surgical margin (PSM) might attain the trifecta as well. For these reasons we earlier proposed a new measure of outcome assessment the 'pentafecta' [9]. The purpose of this article is to review the individual arms of the pentafecta after RARP as reported by high-volume centres.

SEARCH METHOD

We searched the Medline database for articles published since 2006 using medical subject heading search terms 'prostatectomy' and 'outcome assessment

(health care)' and the keywords 'robotic radical prostatectomy', 'robotic-assisted radical prostatectomy' 'robotic', 'continence outcomes', 'potency outcomes', 'PSA recurrence', 'oncological outcomes', 'trifecta' and 'pentafecta', Additionally, a manual search of the references from key review articles was done. Articles with data pertinent to our review and of volume of >100 cases were included. Multiple studies of the same population were identified; the study that is most relevant to our search subject was selected. RARP data from comparative series were recruited as well as non-comparative series.

Outcomes evaluated were:

(I) patient demographics and perioperative outcomes (Table 1 [10–27]).
(II) perioperative complications
(III) PSM rates
(IV) continence outcomes
(V) potency outcomes
(VI) biochemical recurrence (BCR)
(VII) trifecta and pentafecta outcomes.

Weighted means were calculated for each outcome using the patient number in each study as the weighing factor.

PERIOPERATIVE COMPLICATIONS

The limitations that are classically related to complication reporting such as lack of standardized grading system and non-uniform methods of reporting rendered this outcome a difficult one to be assessed and compared among different series. Accordingly, Dindo *et al.* [28] proposed a grading system for surgical complications to overcome part of these limitations (Table 2). As researchers began reporting their complications using standardized grading system, a wide discrepancy in complication rates was observed between studies that did not use this standardized system and those who did, where higher rates of complications were reported in the latter [29].

Despite the fact that an increasing number of recent series are reporting their complications using this system a great discrepancy is still noted owing to the lack of unified criteria of reporting. Hence, Martin *et al.* [30] proposed 10 criteria for accurate reporting of complications; the information that should be included are: method of accruing data, duration of follow-up, outpatient information, definitions of complications, mortality rate and causes of death, morbidity rate and total complications, procedure-specific complications, severity grading system, length of stay, risk factors in the analysis. For the series included in the present review variable compliance to these criteria is noted. However, the weighted mean was 10.1% for overall complications, 7.7% for minor complications (Clavien 1 + 2) and 2.7% for major complications (Clavien 3 + 4 + 5) as described in Table 3 [10–14,16,17,20,21,23–27,31,32].

Martin criteria were all met for the first time in the RARP literature by Novara *et al.* [24] ($n = 415$) who reported 21.6% of bleeding, 5.3% of lymphorrhoea and 2.4% of pelvic haematoma. On multivariate analysis prostate volume (odds ratio [OR] 0.985; $P < 0.001$) and the number of cases performed ($P = 0.001$) were independent predictors of occurrence of any grade of complication. In grade III and IV only the number of cases performed by the surgeon was significantly associated with major complication in a univariate analysis ($P = 0.001$). A second study meeting all Martin criteria was recently published by Agarwal *et al.* [12]; median follow-up for 24.2 months in 3317 patients showed an overall incidence of 9.8% (7.3% minor, 3.8% major, 2.4% medical, 8.7% surgical, 81.3% ≤30 days, 4.6% within 31–90 days and 14.1% >90 days). The most common early complication was postoperative anaemia/bleeding requiring transfusion (1.7%), the most common delayed was bladder neck contracture (0.7%) and lymphocele (0.8%), on multivariable analysis PSA level and cardiac comorbidity were predictive of medical complication whereas age, gastro-oesophageal reflux and Gleason score were predictive of surgical complications. This discrepancy can possibly be explained by the difference in the sample size of the two series.

We have recently reported our complication rates in a series of 2500 consecutive RARPs [33]. We have met nine criteria and our rates were (5.08% overall, 2.24% grade 1, 1.8% grade 2, 0.56% grade 3, 0.4% grade4). The most common complications were leak in 1.4%, ileus in 0.72% and wound infection in 0.56%, there was significant decrease in the overall complication rates ($P = 0.003$) and in the number of anastomotic leaks ($P < 0.001$) as the surgeon's experience increased.

One of the limitations of the Clavien system is that it does not address adverse intraoperative events like injuries and conversion as a complication. Whether to consider conversion as a complication by itself or as a secondary consequence of an intraoperative complication is still not clear. In the present review many studies specifically mentioned the causes of conversion but none had a systemic classification for these causes. As conversion can be related to robotic malfunction, Lobeau *et al.* [25] suggested a modification of the Clavien system taking intraoperative complications in consideration (adding the suffix **t** to grade I and II if arising from material malfunction) and he added five complications after using his modification. However, we could not identify any series in the present review that have used this modification. The weighted mean of conversion rate for the series included is the present review was 0.27% (Table 1).

Other discrepancies still exist that could not be overcome by Clavien system and Martin criteria. Lack of clear reporting of patients with multiple complications and variability in classifying complications were some of the limitations that we. However, we realise that some manuscripts were not specifically designed to report complications.

PSM RATES

PSM is the one of the most important outcomes to be evaluated after RARP. It is an independent predictor of BCR, local recurrence and distant metastasis [34], and a major source of fear of cancer recurrence and psychological distress for patients after RP [35]. The weighted mean for overall PSM rates in the present review was 15.7% (Table 4 [11,13,14,16,18–24,36–40]).

Several groups studied their learning curve for RARP and showed that it can affect the rates of PSM. In evaluating 500 consecutive cases performed by a single surgeon, Patel *et al.* [41] showed that PSM rate decreased from 13% to 8% in the first and last 100 cases. Similarly, Atug *et al.* [36] reported a statistically significant decrease in PSM rates after comparing three consecutive groups of

TABLE 1 Demographic and perioperative outcomes

References	*N* patients	Median/ mean age, years	Mean BMI, kg/m²	Preop. PSA level, ng/mL	Clinical stage T1c/T2, %	Gleason score <7/7/>7, %	OT, min	Mean EBL, mL	Transfusion rate, % transfused	Conversion rate, %	LOS, days	Catheter duration, days
Hu *et al.* [10]	322	62.1	27.5	–	74.5/24.8	2.5/90.2/7.3	186	250	1.6	0	–	4–7†
Joseph *et al.* [11]	325	60	–	6.6	81/19	6.3 ± 0.6†	130	196	1.3	0	–	7
Agarwal *et al.* [12]	3317	60	27	5	74/24	50.4/39.5/10.1	160	150	2.2	0	1.2	7†§
Mottrie *et al.* [13]	184	62	–	8.7	–	10.5/50/39.5	171	200	0.5	0.54	–	7
Rozet *et al.* [14]	133	62	24.8	7.6	57.1/42.8	76/21.8/2.2	166	609	3	0	5.4	9.2
Borin *et al.* [15]	400	61.2	26.8	6.6	68/26.5	6.4 + 6.5 two groups†	–	103.5	–	–	1	–
Zorn *et al.* [16]	744	59.6	28.1	6.6	74/26	65/29/6	234	222	1.2	1.2	1.2	5.9
Wood *et al.* [17]	117	60.2	–	6.5	–	23/73/4	210	151	–	–	1.2	10
Schroeck *et al.* [18]	362	59.2	27.8	5.4	83.1/16.9	72.2/25.3/2.6	–	150	–	1.6	–	–
Chan *et al.* [19]	660	60	–	6.8	75.3/24.7	81.5/13.6/4.9	207	140	0.8	0.9	1.3	–
Krambeck *et al.* [20]	294	61	–	4.9	72.8/26.9	72.8/23.8/3.4	236	–	5.1	–	–	–
Murphy *et al.* [21]	400	60.2	27.2	7	69.7/30.3	–	186	–	2.5	0.3	3.1	8.2
Rocco *et al.* [22]	120	63	–	6.9	69/31	6(4–9)†	215	200	–	–	3	65/23/12†‡
Ham *et al.* [23]	321	63.5	24.3	29.7	–	–	219	402	–	–	5.3	–
Novara *et al.* [24]	415	62.3	26.2	6.4	–	74/17.3/4.5	184	300	5.5	0.48	6	4–7†
Patel *et al.**	4000	61	28	4.8	76.2/22.9	61.4/30.7/7.9	75	100	1	0.05	1	5
Lebeau *et al.* [25]	240	61.7	25.3	7.8	76.3/23.8	71.6/24.1/4.2	–	–	–	–	–	–
Jeong *et al.* [26]	200	58.8	28.4	6.31	80/20	6.41 (4–9)	212	189	–	1.5	1.13	–
Lasser *et al.* [27]	239	60.6	27.4	5.42	–	6.54 (5–9)†	231.9	–	4.2	0.4	2.37	–
Weighted mean		60.6	27.3	6.17	75.09/23.95	58/33.7/8.15	174.2	185.8	2.19	0.27	1.58	5.7

**Unpublished data, submitted to BJUI; †Not included in calculating the weighted mean; ‡Percentage of patients: <7 days /7 days/>7 days; §Starting at 2008 the authors started to use SPC instead of urethral catheter.*

patients and suggested a learning curve of 30 cases. Others reported longer learning curves: 80 cases were suggested by Weizer *et al.* [42] based on the comparison of the PSM rate in the first 15 and >80 cases (12% vs 2%, $P = 0.05$), with the PSM plateau being reached after 80 cases. However, the continuous improvement in the reported PSM rate with increasing experience reported by others, led some authors to propose longer learning curves; Hong *et al.* [43] proposed an 'oncological experience curve' of 290 cases as a clinically meaningful measure to evaluate learning curve in non-fellowship trained urologists. The learning curve can be even longer as a continued improvement in PSM rate after 700 cases has been reported [16].

For risk factors for PSM after RARP, Liss *et al.* [44] reported that the PSM rate for surgeons in their initial experience can be comparable with that of experienced surgeons, where preoperative PSA level, PSA density, pathological stage and grade are the most important risk factors. The significance of clinical stage as a preoperative independent predictive factor for PSM was shown by Coelho *et al.* [45] (T3 vs T1c, OR 10.7, 95% CI 2.6–43.8 and T2 vs T1c, OR 2.9, 95% CI 1.9–4.6) while in analysing all perioperative variables combined, pathological stage (pT2 vs pT1, OR 2.9, 95% CI 1.9–4.6) and percentage of tumour in the surgical specimen (OR 8.7, 95% CI 2.2–34.5, $P = 0.002$) were independent predictive factors for PSM. In that study higher body mass index (BMI) predicted higher incidence of apical PSM (OR 1.1, 95% CI 1.0–1.3, $P = 0.012$). Similarly, Ficarra *et al.* [46] found that clinical stage was an independent factor for both any and posterolateral PSM (hazard ratio [HR] 2.217, $P = 0.008$, and HR 2.070, $P = 0.025$ respectively), that prostate volume on TRUS (HR 0.420, $P = 0.002$) was a predictor for PSM at any location while biopsy Gleason score ($P = 0.019$) was a predictor for posterolateral PSM. Postoperatively extraprostatic extension of the primary tumour was the only independent predictor of any PSM (HR 11.852, $P < 0.001$) and posterolateral PSM (HR 7.484, $P < 0.001$) Finally, in a multi-institutional study, Patel *et al.* [47] analysed results of 6169 patients from seven institutions and found that the overall PSM rate was 15.7%; the PSM rates for pT2 and pT3 disease were 9.45% and 37.2%, respectively. On multivariate analysis,

pathological stage (pT2 vs pT3, OR 4.588, $P < 0.001$) and preoperative PSA level (PSA level ≤4 vs >10 ng/mL, OR 2.918, $P < 0.001$) were the most important independent predictive factors for PSM. Increasing prostate weight was associated with lower risk of PSM (OR 0.984, $P < 0.001$) and higher BMI was associated with higher risk of PSMs (OR 1.032, $P < 0.001$). For organ-confined disease, preoperative PSA level was the most important factor independently correlated with PSM (PSA level of ≤4 vs >10 ng/mL, OR 3.8, $P < 0.001$)

Multiple modifications have been adopted to decrease PSM after RARP. A more aggressive apical resection (3–6 mm distal to the prostatourethral junction) was described by Borin *et al.* [15] and an improvement in the overall and apical PSM rates was reported (17.6% vs 7.5%, $P = 0.003$; and 13% vs 5.5%, $P = 0.01$, respectively) yet, no difference in percentage and time of continence between the two group was found. Subsequently, Tewari *et al.* [48]

TABLE 2 Clavien grading system

Grade*	Definition
1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.
2	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
3	Requiring surgical, endoscopic or radiological intervention. IIIa – Intervention not under general anaesthesia. IIIb – Intervention under general anaesthesia.
4	Life-threatening complication requiring IC/ICU management. Grade IVa – Single organ dysfunction. Grade IVb – Multi-organ dysfunction.
5	Death of a patient.
	If the patient suffers from a complication at the time of discharge, the suffix 'd' for 'disability' is added to the respective grade of complication.

- *Minor complications include grade 1 and 2.*
- *Major complications include grade 3, 4 and 5.*

TABLE 3 Complications

Reference	*N* patients	Overall complication rate, %	Clavien grading	Minor 1 and 2, %	Major 3,4 and 5, %	Martin criteria N/10	Most common complication reported
Hu *et al.* [10]	322	14.6	Yes	12.8	1.8	6	Urine leak
Rozet *et al.* [14]	133	19.4	Yes	12.6	6.8	6	Urinary infection and postoperative bleeding
Novara *et al.* [24]	415	21.6	Yes	19	3.2	10	Blood transfusion
Lasser *et al.* [27]	239	19.6	Yes	14.6	5	8	Prolonged hospitalization and leak
Agarwal *et al.* [12]	3317	11.1	Yes	7.3	3.8	10	Postoperative bleeding
Patel*	4000	6.1	Yes	5.1	1	9	Urine leak
Lebeau *et al.* [25]	240	8.8	Yes	4.6	2.1	7	Ileus, lymphorrhoea, retention, transfusion and urosepsis (2 each)
Joseph *et al.* [11]	325	8.6	No	–	–	6	Bladder neck contracture
Mottrie *et al.* [13]	184	11.9	No	–	–	4	postoperative haematoma
Wood *et al.* [17]	117	21.3	No	–	–	6	Urinary retention
Krambeck *et al.* [20]	248	8	No	–	–	7	Blood transfusion
Zorn *et al.* [16]	700	8.5	No	–	–	6	Wound infection/hernia
Ham *et al.* [23]	321	5.3	No	–	–	4	Ileus
Murphy *et al.* [21]	400	15.7	Yes	10.5	5.25	6	Anastomotic stricture specific complications in grade 1 and 2 not clearly reported
Fisher *et al.* [31]	210	26	Yes	17.6	8.5	4	Bleeding
Ou *et al.* [32]	200	12	Yes	9.5	2.5	9	Blood transfusion
Jeong *et al.* [26]	200	12	Yes	9	3	7	Urinary retention
Weighted mean		10.19		7.69	2.69		

**unpublished data submitted to BJUI.*

TABLE 4 PSMs

Reference	*N* patients	Pathological stage, %			PSM, %		
		pT2	pT3	pT4	pT2	pT3	Overall
Joseph *et al.* [11]	325	81	19	0	–	–	13
Atug *et al.* [36]	140	87.9	9.3	2.8	18	53.8	18.5
Badani *et al.* [37]	2766	77.7	22	0.3	13	35	12.3
Mottrie *et al.* [13]	184	62.5	37.5	0	2.5	37.1	15.7
Rozet *et al.* [14]	133	88.5	11.5	0	13	20.9	19.5
Yee *et al.* [38]	500	71	26	2	3.1	15.9	7.4
Tewari *et al.* [39]	700	83.5	13.6	2.9	5.4	–	–
Zorn *et al.* [16]	744	–	–	–	12.9	44.8	18.8
Schroeck *et al.* [18]	362	79.3	20.7	0	–	–	29.3
Chan *et al.* [19]	660	80.6	19.4	0	11.3	45	17.9
Krambeck *et al.* [20]	294	90.1	9.9 Both T3&T4	–	–	–	15.6
Murphy *et al.* [21]	400	70	29.8	0.2	9.6	42.3	19.2
Rocco *et al.* [22]	120	73	24	3	17	34	22
Ham *et al.* [23]	321	55.1	43.7	1.2	–	–	33.3
Novara *et al.* [24]	273	63	36.7	3	–	–	29
Patel*	4000	76.2	22.9	0.8	5.8	26.1	10.8
Magheli *et al.* [40]	522	–	–	–	9.3	48.5	19.5
Weighted mean		76.54	22.62	0.83	8.92	33	14.75

**unpublished data, submitted to BJUI; In Krambeck et al. the 9.9 value was calculated in pT2 only.*

TABLE 5 Continence outcomes

Reference	*N* patients	Ages, years	Follow-up, months	Continence % at *n* months				
				Immediate	1	3	6	12
Joseph *et al.* [11]	325	60	6	24	56	93	96	–
Borin *et al.* [15]	400	61.2	6	–	70.5	89	97	–
Zorn *et al.* [54]	300	59.4	24	–	23	47	68	90
Krambeck *et al.* [20]	294	61	12	–	–	–	–	91.8
Murphy *et al.* [21]	400	60.2	>18	–	–	–	–	91.4
Rocco *et al.* [22]	120	63	12	–	–	70	93	97
Novara *et al.* [52]	304	61.6	12	–	–	–	–	90
Mottrie *et al.* [13]	184	60	6	–	43	–	95	–
Patel *et al.* [50]	1100	58	18	–	6 weeks 67.7	85.4	95.7	97.4
Tewri *et al.* [39]	N* 214	64.3	13	13.1	35.2	50.2	61.9	82.1
	P* 304	62.8	13	27	59	76.6	85.6	91.2
	T* 182	61.2	6	38.4	82.5	91.3	97.1	–
Menon *et al.* [51]	1142	60.2	12	–	–	–	–	92
van der Poel *et al.* [53]	151	60	12	–	–	–	54	70
Weighted mean		60.35		25.17	58.54	79.08	87.89	91.85

**N, no reconstruction; P*, posterior reconstruction; T*, total reconstruction.*

described the synchronous apical dissection technique with circumferential visualization of the apex and the urethra to decrease the rate of apical PSM. This resulted in significantly lower apical PSM rates in the treatment group (1.4% vs 4.4%, $P = 0.04$) despite a significantly higher incidence of aggressive cancer (≥ pT3a) documented on final specimen pathology (16% vs 10%, $P = 0.027$).

CONTINENCE OUTCOMES

Incontinence is a feared complication of RP and has a heavy impact on quality of life [49]. Although evaluated in multiple studies, comparison among them is hampered by the lack of standard definition, multiple assessment methodology and variability in follow-up duration among different series. Methods of assessment in the present review varied from subjective evaluation by surgeon interview [11,13,15,16,20–22,39,50,51] to self-administered questionnaires, e.g. the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UISF) [52] and the Expanded Prostate Cancer Index Composite (EPIC) [51]. Definitions found in the present review varied from zero or 1 pad [11,13,15,16,20–22,39,50,51], any involuntary urine loss [53], and ICIQ-UISF (no leak answer to 'how often do you leak urine'?) [52]. This variation was reflected in the wide range of continence in different reviews including our review (Table 5 [11,13,15,20–22,39,50,51–54]). The weighted means (range) for continence in the present review were 87.8 (54–97.1)% at 6 months and 91.8 (70–97)% at 12 months.

For predictors of recovery of continence after RARP, Shikanov *et al.* [55] reported that age (OR 0.97, $P = 0.002$), baseline IPSS (OR 0.98, $P = 0.02$) and the Sexual Health Inventory for Men (SHIM) scores (OR 1.02, $P = 0.005$) were independently associated with being pad free, while Novara *et al.* [52] found on multivariable analysis that age (OR 1.076, $P = 0.027$) and Charlson comorbidity index (OR 1.635, $P = 0.009$) were independent predictors of continence. Conversely, van der Poel *et al.* [53] reported that the extent of fascia preservation at the lateral aspects of the prostate was the best predictor of continence. Recently, Ko *et al.* [56] studied the predictive factors of early return of continence and found that only age (OR 0.982, 95% CI 0.973–0.990, $P < 0.001$) and performance of the nerve-sparing (NS) procedure [partial NS (OR 1.603, 95% CI 1.222–2.101, $P = 0.002$), bilateral NS (OR 1.419, 95% CI 1.079–1.888, $P = 0.012$) relative to the no NS group] were independent predictors and the median time to recovery of continence was longer in older patients and in no NS group (both $P < 0.001$). Notably each one of these studies used a different methodology to assess continence.

TABLE 6 Potency outcomes

Reference	*N*	Age, years	Type of NS, %			Follow-up, months	Potency, %		Overall potency at n months			
			Uni.	Bi.	None		Uni.	Bi.	3	6	12	18
Joseph *et al.* [11]	325	60	23.6	70	6.4	12	58	80.6	–	77.1	–	–
Zorn *et al.* [54]	300	59.4	26.4	59.6	14	24	62	83	47	58	74	76.5
Krambeck *et al.* [20]	294	61	91	9	12	–	–	–	–	70	–	–
Murphy *et al.* [21]	394	60.2	28.2	65.3	–	12	–	–	–	–	62	–
Rocco *et al.* [22]	120	63	–	–	–	12	–	–	31	43	61	–
Novara *et al.* [52]	304	61.6	7	66	27	12	–	–	–	–	49	–
Mottrie *et al.* [13]	184	62	13	64.5	18.1	6	47	70	–	66.6	–	–
Patel *et al.* [50]	1100	58	–	–	–	18	–	–	–	68.8	91.5	96.6
Tewari *et al.* [67]	215	60	11	85	4	12	–	87	–	–	–	–
Menon *et al.* [51]	1142	60.2	25	33	>18	–	100	–	–	–	70	100
van der Poel and de Block [68]	107	59.6	45.8	54.2	–	6	40.8	63.8	–	53	–	–
Finley *et al.* [69] with cautery	42	56.5	26	74	–	>18	50	67.8	8.3	14.7	43.2	63.1
Finley *et al.* [69] without cautery	62	57	26	74	–	>18	80	93	32.1	57.1	76.6	89.6
Weighted mean		59.75	28.64	43.89	15.47		79.42	79.45	38.85	65.49	73.90	95.09

Uni., unilateral; Bi, bilateral.

Multiple modifications have been proposed to improve continence outcomes in RARP. The total reconstruction technique was described by Tewari *et al.* [39], who compared it with no reconstruction (control) and anterior reconstruction only. At 52 weeks of follow-up the continence rate was significantly lower in the control group than in the anterior and total reconstruction groups ($P < 0.01$). A modified posterior reconstruction reported by Coelho *et al.* [57] resulted in increased continence rates at 1 and 4 weeks, and less incidence of leak compared with no reconstruction. Conversely, Menon *et al.* [58] in a randomized controlled trial showed no improvement in continence rates after reconstruction of the posterior rhabdosphincter and puboprostatic collar and the follow-up results [59] at 2 years showed that long-term urinary outcomes were excellent for patients undergoing RP with either single or double layer anastomosis. Although patients with single-layer anastomoses were more likely to leak at 1 week and had longer duration of catheterization, this did not lead directly to bladder neck contracture or incontinence. Similar results were reproduced in smaller series by Sutherland *et al.* [60] who randomized 94 patients and Joshi *et al.* [61] who alternatively assigned 107 patients into treatment and control groups.

The periurethral suspension suture described by Patel *et al.* [62] showed higher early continence rates (at 3 months 92.8% vs 83%; $P = 0.013$) and shorter interval to recovery of continence in the suspension group [median (mean) 6 (7.338) weeks, 95% CI 6.387–8.288) than in the no-suspension group [median (mean) 7 (9.585) weeks, 95% CI 7.558–11.612, log-rank test, $P = 0.002$). The same authors described a modified transverse plication for bladder neck reconstruction and reported favourable outcomes in term of decrease in urine leakage and bladder neck contracture [63].

Other modifications include the anterior urethropexy technique described by Johnson *et al.* [64], which consisted in 'placing a 2-0 braided absorbable suture through the anterior urethra and tied after dorsal vein occlusion, then brought through the periosteum of the posterior pubis and secured with an absorbable clip'. They compared groups with and without anterior urthropexy using the EPIC questionnaire and there were significant differences in the incontinence ($P = 0.015$) and sexual ($P = 0.002$) domains at 3 months in favour of the urethorpexy group. Recently, Asimakopoulos *et al.* [65] described a pubovesical complex-sparing technique, which involved 'developing a ventral plane of dissection between the detrusor apron and the prostate. The soft connective tissue between the Santorini's plexus and the prostate is bluntly dissected, leaving the plexus intact and in place'. Their preliminary results included encouraging continence and potency outcomes; however, the study was limited by small sample size (30 patients), low mean age (52 years) and low co-morbidity profile. Using intraoperative cooling balloon in 109 patients, hypothermia was proposed by Finley *et al.* [66] to improve continence and sexual outcomes. The median time to zero pad use was (39 vs 62 days, $P < 0.001$) and overall pad-free rate at 1 year was (96.3% vs 86.6%, $P < 0.001$) in treatment and controls respectively, while potency rates at 3 months were unchanged and at 15 months were significantly better for the hypothermic group (83% vs 66%, $P = 0.045$).

POTENCY OUTCOMES

Recovery of erectile function after RP is a difficult outcome to compare. Series in the present review (Table 6 [11,13,20–22,50,51,52,54,67–69]) used multiple methods of assessment including subjective evaluations [13,20,22,54], SHIM [21,50,51] and the International Index of Erectile Function 6 (IIEF-6) [52]. Weighted means (range) for these series in preoperative potent patients at 3, 6, 12, 18 months were 38.8 (8.3–47)%, 65.4 (14.7–77.1)%, 73.9 (43.2–91.5)%, 95 (63.1–100)%.

To predict erectile function after RARP, Novara *et al.* [70] identified age (HR 2.8, $P < 0.001$), Charlson score (HR 2.9, $P = 0.007$), and baseline IIEF-6 score (HR 0.8, $P < 0.001$)

as independent factors in patients who had bilateral NS. Similarly Shikanov *et al.* [55] reported that age (OR 0.92, $P < 0.001$), baseline SHIM score (OR 1.1, $P < 0.001$) and performance of a NS procedure (OR 2.92, $P < 0.001$) were independently associated with recovery of erectile function. However, van der Poel and de Block [68] reported that extent of fascial preservation was a stronger predictor of potency recovery than its laterality (bilateral or unilateral) or depth (interfascial or intrafascial). More ventral fascial preservation significantly contributed to postoperative erectile function recovery and age was an independent factor as well.

Several modifications of the NS technique were described within the focus period of the present review. The adverse effect of cautery on erectile function was established by Ahlering *et al.* [71]). They found that a cautery-free NS improved early return of sexual function 4.7-fold over cautery. Subsequently, they reported the results of their 'clip-less athermal NS technique', where 80% and 93% of patients recovered erectile function at 2 years for unilateral and bilateral NS, respectively [72]. On the other hand Patel *et al.* [73] described the athermal early retrograde technique of NS whereby lateral pelvic fascia is incised at the level of the apex and the mid portion of prostate and an avascular plane is developed between the neurovascular bundles (NVBs) and the prostatic fascia. This plane is extended posteriorly until it meets the interfascial plane developed initially between the prostate and the rectum. The entire dissection is conducted athermally. The vascular pedicle is clipped. Releasing the bundle early and delineating its path to avoid inadvertent damage at his point. It is then released distally to the level of pelvic floor to avoid damaging it during the apical dissection or vesico-urethral anastomosis. The reported potency rate (ability to achieve vaginal penetration with or without a phosphodiesterase type 5 inhibitor [PDE5I]) was 87.7%. The 'superveil' modification of the formerly described 'veil of Aphrodite' was described by Menon *et al.* [74]. In the original technique the interfascial plane is extended as distally as possible towards the apex, and laterally to expose pedicles. The pedicles are divided by clipping or bipolar cauterization and the prostatic fascia is incised anteriorly to enter the intrafascial plane. Sharp and blunt dissection on the fascia is performed athermally until the entire peri-prostatic fascia is released including from the 11 o'clock to 1 o'clock positions by extending the interfascial dissection anteriorly. The reported postoperative potency rate at 18 months was 94%.

Based on the current understanding of the anatomical variations of periprostatic fascial anatomy and its relation to NVBs [75–77] different NS techniques exist depending upon the depth of fascial dissection. Techniques are either extrafascial, intrafascial or interfascial. Comparing extrafascial and interfascial approaches Shikanov *et al.* [78] found that the interfascial-NS group achieved statistically significant better sexual function ($P = 0.02$) and potency rates ($P = 0.03$) at 12 months after RARP without a statistically significant difference in PSM. Whereas Zorn *et al.* [79] noticed that the interfascial approach resulted in improved potency outcomes but with higher posterolateral PSMs. Conversely, comparison between the interfascial and athermal intrafascial robotic approach by Potdevin *et al.* [80] showed higher potency rates and the time to continence recovery in the intrafascial group. Potency rates at 3, 6, and 9 months were 16.7%, 43.8%, and 66.7% in the interfascial group and 24.2%, 81.8%, and 90.9% in the intrafascial group. Stolzinberg *et al.* [81] randomized 400 patients into either intrafascial or interfascial NS and by categorizing both groups by age they reported potency results at 12 months as 93.5% vs 77.1% (aged <55 years), 83.3% vs 50% (aged 55–65 years), and 60% vs 40% (aged >65 years) in favour of the intrafascial approach, while the PSM rate was 9% in the interfascial group and 9.5% in intrafascial group.

BCR

Few studies have reported the long-term BCR rates after RARP. Recently, Menon *et al.* [82] reported that biochemical-free survival (BFS) in 1384 consecutive patients at a median (interquartile range) follow-up of 60.2 (37.2–69.7) months were 95.1%, 90.6%, 86.6%, and 81.0% at 1, 3, 5, and 7 years, respectively. The median time to BCR was 20.4 months; 65% of BCR incidences occurred ≤3 years and 86.2% ≤5 years. On multivariable analysis, the strongest predictors of BCR were pathological Gleason grade 8–10 (HR 5.37, 95% CI 2.99–9.65, $P < 0.001$) and pathological stage T3b/T4 (HR 2.71, 95% CI 1.67–4.40, $P < 0.001$).

Murphy *et al.* [21] reported 13.4% BCR in 395 patients after a median follow-up of 22 months. Shikanov *et al.* [83] reported BFS rates were 99%, 97%, 96%, and 91% at 3, 6, 12, and 24 months, respectively. Subsequently, Patel *et al.* [50] reported BFS rates of 98.7%, 97.5%, 96.7% 95% and 91.4% at 6 weeks, 3, 6, 12, and 18 months after RARP, respectively. Lastly, Novara *et al.* [84] reported that 2% of patients had relapsed after a median follow-up of 14 months.

Among the comparative studies reporting BCR between ORP and RARP, Schroeck *et al.* [18] found no significant difference in BFS after adjusting for clinical (HR 0.82, 95% CI 0.48–1.38, $P = 0.448$) and pathological stage (HR 0.94, 95% CI 0.55–1.61, $P = 0.824$). Similarly, Krambeck *et al.* [20] reported that the 3-year BFS rate was not significantly different between the two groups (RARP 92.4% vs ORP 92.2%, $P = 0.69$). Subsequently, Barocas *et al.* [85] compared the 3-year BFS after RARP and ORP and found no significant difference. On multivariate analysis extracapsular extension, PSM and pathological Gleaseon score ≥7 were independent predictors of BCR while surgical approach was not.

TRIFECTA AND PENTAFECTA OUTCOMES

The concept of reporting the likelihood of concurrent achievement of oncological and functional outcomes after RP was first proposed by Salomon *et al.* [8] in 2003. Although each specific outcome of RP has been extensively described, few series analysing the trifecta rates after RP have been previously reported [8,86–88] and only three series reported trifecta after RARP [50,83,84]

Trifecta rates after RARP were first reported by Shikanov *et al.* [83] who evaluated 380 patients after bilateral NS RARP. Continence and potency were evaluated by surgeon interview (subjective) and using UCLA-PCI self-administered questionnaire (objective). BCR was defined as a detectable (>0.05 ng/mL) increasing PSA level on two consecutive tests. Trifecta rates applying subjective continence and potency definitions were 34%, 52%, 71%, and 76% at 3, 6, 12, and 24 months, respectively. Whereas using

objective continence and potency definitions rates were 16%, 31%, 44%, and 44%. The difference was statistically significant at each time point ($P < 0.001$). Subsequently, Patel *et al.* [50] evaluated 404 RARPs performed by one surgeon. Using self-administered validated questionnaires (EPIC and SHIM). Postoperative continence was defined as the use of no pads; potency was defined as the ability to achieve and maintain satisfactory erections for sexual intercourse >50% of times, with or without the use of oral PDE5Is; BCR was defined as two consecutive PSA levels of >0.2 ng/mL. The trifecta rates at 6 weeks, 3, 6, 12, and 18 months after were 42.8%, 65.3%, 80.3%, 86% and 91%, respectively. Age-stratified analysis showed that younger men had a shorter time to achieve the trifecta and had higher trifecta rates at 6 weeks, 3 and 6 months after RARP compared with older men ($P < 0.01$ at all time-points).

Subsequently, Novara *et al.* [84] evaluated 242 consecutive patients. The ICIQ-UISF and IIEF-6 were used. BCR was defined as a PSA level of >0.2 ng/mL. A trifecta outcome was achieved by 137 patients (57%) at 12 months. On univariable regression analysis, age at surgery ($P < 0.001$), BMI ($P = 0.028$), preoperative IIEF-6 score ($P < 0.001$) and prostate volume ($P = 0.036$) were significantly associated with trifecta rates. On multivariable analysis, only age at surgery (OR 1.095; $P = 0.005$) and preoperative IIEF-5 score (OR 0.803; $P < 0.001$) were independent predictors of trifecta.

We have earlier proposed a new criterion to report outcomes after RP. The 'pentafecta' is the combination of the trifecta outcomes plus PSM and complications [9]. We evaluated 1111 consecutive patients, 332 were preoperatively potent, continent, underwent bilateral NS and had 1 year of follow-up. Using the same definitions as in our trifecta study [50], 70.8% achieved the pentafecta at 12 months. On multivariable analysis, patient age ($P = 0.001$) was the only factor independently associated with the pentafecta. The most common reasons for not reaching the pentafecta were erectile dysfunction (35.0%) and PSM (31.9%).

CONCLUSIONS

RARP is a safe and effective method for the treatment of clinically localized prostate cancer. The long-term outcomes of the procedure are not completely known. However, the perioperative, functional and early oncological outcomes of the procedure are encouraging.

CONFLICT OF INTEREST

None declared.

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Abbreviations: **(O)(L)(RA)RP**, (open) (laparoscopic) (robot-assisted) radical prostatectomy; **PSM**, positive surgical margin; **BCR**, biochemical recurrence; **OR**, odds ratio; **BMI**, body mass index; **HR**, hazard ratio; **ICIQ-UISF**, International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form; **EPIC**, the Expanded Prostate Cancer Index Composite; **SHIM**, the Sexual Health Inventory for Men; **IIEF-6**, the International Index of Erectile Function 6; **BFS**, biochemical-free survival; **NS**, nerve-sparing; **NVB**, neurovascular bundle; **PDE5I**, phosphodiesterase type 5 inhibitor

SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Video S1.

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