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Best Practices in Robot-assisted Radical Prostatectomy: Recommendations of the Pasadena Consensus Panel

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Abstract

Context: Radical retropubic prostatectomy (RRP) has long been the most common surgical technique used to treat clinically localized prostate cancer (PCa). More recently, robot-assisted radical prostatectomy (RARP) has been gaining increasing acceptance among patients and urologists, and it has become the dominant technique in the United States despite a paucity of prospective studies or randomized trials supporting its superiority over RRP.

Objective: A 2-d consensus conference of 17 world leaders in prostate cancer and radical prostatectomy was organized in Pasadena, California, and at the City of Hope Cancer Center, Duarte, California, under the auspices of the European Association of Urology Robotic Urology Section to systematically review the currently available data on RARP, to critically assess current surgical techniques, and to generate best practice recommendations to guide clinicians and related medical personnel. No commercial support was obtained for the conference.

Evidence acquisition: A systematic review of the literature was performed in agreement with the Preferred Reporting Items for Systematic Reviews and Meta-analysis statement.

Evidence synthesis: The results of the systematic literature review were reviewed, discussed, and refined over the 2-d conference. Key recommendations were generated using a Delphi consensus approach. RARP is associated with less blood loss and transfusion rates compared with RRP, and there appear to be minimal differences between the two approaches in terms of overall postoperative complications. Positive surgical margin rates are at least equivalent with RARP, but firm conclusions about biochemical recurrence and other oncologic end points are difficult to draw because the follow-up in existing studies is relatively short and the overall experience with RARP in locally advanced PCa is still limited. RARP may offer advantages in postoperative recovery of urinary continence and erectile function, although there are methodological limitations in most studies to date and a need for well-controlled comparative outcomes studies of radical prostatectomy surgery following best practice guidelines. Surgeon experience and institutional volume of procedures strongly predict better outcomes in all relevant domains.

Conclusions: Available evidence suggests that RARP is a valuable therapeutic option for clinically localized PCa. Further research is needed to clarify the actual role of RARP in patients with locally advanced disease.

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1. Introduction

Radical retropubic prostatectomy (RRP) has long been the most commonly used surgical approach for patients with localized prostate cancer (PCa) and a long life expectancy. In an effort to reduce the morbidity of the procedure, surgeons have developed new surgical techniques such as laparoscopic radical prostatectomy (LRP) and, more recently, robot-assisted radical prostatectomy (RARP) [1–5].

A systematic literature review published in 2009 showed that laparoscopic techniques were associated with advantages in terms of blood loss and transfusion rates compared with RRP [6]. At that time, the limited number of studies comparing RARP with RRP prevented the authors from drawing any conclusions about the superiority of one or the other of these techniques in terms of oncologic and functional outcomes.

In this context, and in the absence of any prospective randomized trial comparing RARP with either RRP or LRP, RARP has become the leading option for treating patients with clinically localized PCa in the United States, and it has been progressively expanding in other countries.

The systematic reviews presented in this issue of *European Urology* suggest that RARP is advantageous in terms of perioperative outcomes and both urinary continence and potency recovery in comparison with RRP [7–10]. However, there are a lack of well-controlled prospective studies of functional outcomes of RARP compared with RRP. The Pasadena Consensus Panel (PCP) recognized that recovery of sexual function and continence following surgery is influenced by multiple factors including surgical experience and institutional volume of surgery, level of pre-morbid function in patients, postsurgical rehabilitation, and outcome assessment methods. These factors have not been sufficiently controlled in most studies. Although the available evidence is still limited, RARP has shown an impact on cancer control equivalent to RRP.

As a complement to the systematic reviews just mentioned, a consensus conference of world leaders in prostate cancer and radical prostatectomy (RP) was convened in Pasadena, California, and at the City of Hope Cancer Center, Duarte, California, in September 2011 under the auspices of the European Association of Urology (EAU) Robotic Urology Section. This paper presents the recommendations of that conference.

2. Evidence acquisition

A systematic review of all published literature related to RARP was performed in August 2011 using the Medline, Embase, and Web of Science databases. The Medline search included only a free-text protocol using the term *radical prostatectomy* across the “Title” and “Abstract” fields of the records. Subsequently, the following limits were used: humans; gender (male); publication date from January 1, 2008, to August 2011; and language (English). The searches of the Embase and Web of Science databases used the same free-text protocol and the same keywords, applying the same publication dates.

Two authors (G.N. and V.F.) separately reviewed the records to select the studies comparing RRP with LRP, RRP with RALP, or LRP with RALP. Other significant studies cited in the reference lists of the selected papers were also evaluated, as well as studies published after the systematic search. All noncomparative studies reporting outcomes of RALP on >100 cases were collected and critically analyzed.

All papers were distinguished according to the 2011 level of evidence for treatment benefit, as currently described by the Centre for Evidence Based Medicine at Oxford University. A total of 44 papers were selected in which RARP was compared with either RRP or LRP. A total of 136 papers were included that evaluated some aspect of RARP. The systematic reviews complied with the recently reported Preferred Reporting Items for Systematic Reviews and Meta-analysis statement [11].

This literature review provided the foundation for the development of individual presentations by conference attendees, most of whom presented ancillary literature reviews and their personal experience on specific subtopics. Over the course of the 2-d conference, systematic review data were presented and considered in three major areas: (1) patient selection and surgical technique, (2) cancer control, and (3) complications and sequelae. Following presentations of currently available evidence, the PCP developed best practice recommendations in each of these areas. A multistage Delphi process was used when needed to rank recommendations or arrive at consensus on individual recommendations [12]. Following the conference, panel members submitted drafts of assigned sections that were incorporated into a draft manuscript for review by all panelists. The manuscript was then revised in light of PCP feedback, and the final version was once again reviewed and approved by all panel members prior to submission for publication.

3. Evidence synthesis

3.1. Patient selection and surgical techniques

3.1.1. Patient selection

The indications for RARP, identical to those accepted for RRP and LRP, are summarized in Table 1 [13–15]. The PCP noted that certain cases because of their complexity should be best performed by experienced or very experienced surgeons (Table 2) [16]. For example, patients who have undergone prior transurethral resection of the prostate (TURP) surgery may present surgical challenges for the novice RARP surgeon.

3.1.1.1. Indications and technique for nerve-sparing robot-assisted radical prostatectomy. Deeper insights into the distribution and course of the cavernous nerves in recent years have allowed clinicians to increase their knowledge about prostate anatomy and specifically about the network of nerves surrounding the prostate, seminal vesicles, and urethral sphincter [17]. These new anatomic concepts have suggested a role for high incision of the levator ani fascia

Table 1 – Indications for radical prostatectomy according to international guidelines

American Urological Association, 2007 [20]	European Association of Urology, 2011 [34]	National Comprehensive Cancer Network, 2011 [15]
Low-risk localized PCa Intermediate-risk localized PCa High-risk localized PCa	Low- and intermediate-risk localized PCa and a life expectancy >10 yr Patients with stage T1a disease and a life expectancy >15 yr or GS 7 Selected patients with low-volume high-risk localized PCa Highly selected patients with very high-risk localized PCa (cT3b–T4 N0 or any T N1) in the context of multimodal treatment	Very low-risk cancer (T1c, GS ≤6, PSA <10, <3 positive prostate biopsy cores, ≤50% cancer in any core) and life expectancy >20 yr Low- and intermediate-risk patients with life expectancy survival >10 yr High-risk and very high-risk (T3b–4) patients
PCa = prostate cancer; GS = Gleason score; PSA = prostate-specific antigen.		

Table 2 – Challenging cases and level of surgeon experience

Level of surgeon experience	Challenging cases
Experienced [†]	Obese patients (BMI >30) Large prostate (prostate volume >70 g) Previous TURP or other procedure for BPH Large median lobe High-risk patients requiring extended pelvic lymph node dissection Patients with previous pelvic surgery
Very experienced*	Salvage robot-assisted radical prostatectomy after radiation therapies, cryotherapy, or high-intensity focused ultrasound
BMI = body mass index; TURP = transurethral resection of the prostate; BPH = benign prostatic hyperplasia. * The Pasadena Consensus Panel did not reach any consensus about the definition of experienced surgeon (number of procedures needed in an acceptable period of time). Data from the literature classifies surgeons as high volume (≥40 procedures per year) or low volume (<40 procedures per year) [4].	

that allows preservation not only of the cavernous nerves at the posterolateral surface of the prostate but also nerve fibers located along the lateroanterior part of the gland [18,19]. According to the personal experience of the experts involved in the Pasadena conference, the better tridimensional magnification, scaling of movements, and 7 degrees of freedom associated with the robotic techniques allows the extension of the nerve-sparing procedure to be modulated according to cancer risk stratification, patients' preoperative characteristics, and patients' desire to preserve erectile function.

A maximum preservation of cavernous nerves (full nerve sparing), obtained by following the plane between the prostatic capsule and the multilayer tissue of the prostatic fascia, is recommended in sexually active and functional men without comorbidities and with limited-risk disease. A less extended nerve-sparing technique (partial nerve sparing) within the multilayer tissue of prostatic fascia might be considered for patients who are at risk of extracapsular extension but who would still benefit from an anatomic procedure. In patients with preoperative

erectile dysfunction and/or relevant comorbidities as well as in those not interested in postoperative sexual activity, preservation of the cavernous nerves should be considered to facilitate the precise dissection of the external urethral sphincter and to minimize the potential to exacerbate postoperative urinary incontinence (Table 3).

The PCP recognized that certain PCa patients should undergo a non-nerve-sparing operation (ie, when the presenting disease is clearly extraprostatic). Although few data are available in the literature regarding RARP for unilateral nerve-sparing techniques, participants at the PCP believed these techniques can be considered in patients with monolateral extraprostatic disease. In such cases, partial preservation of the neurovascular bundles limited to the side with organ-confined disease or no disease may be indicated.

3.1.1.2. *Indications for concomitant pelvic lymph node dissection.* As in the case with RRP, bilateral pelvic lymph node dissection (PLND) during RARP should be considered for patients with intermediate-risk PCa (cT2a and/or prostate-specific antigen

Table 3 – Indications for nerve-sparing robot-assisted radical prostatectomy

Nerve-sparing extension	Anatomic planes	Categories
Full	Plane between the prostatic capsule and the multilayer tissue of the prostatic fascia	Preoperative potent men without comorbidities Low-risk localized disease
Partial	Planes within the multilayer tissue of prostatic fascia	Preoperative potent men without comorbidities Intermediate- or high-risk localized disease
Minimal	Preservation of cavernous nerves running at the posterolateral surface of the prostate	Preoperative patients with erectile dysfunction and/or with comorbidities Patients not interested in sexual activity

Table 4 – Currently available guidelines on pelvic lymph node dissection in prostate cancer

Guidelines	Indication for PLND	Extent of PLND
American Urological Association, 2007 [20] European Association of Urology, 2011 [34]	PLND generally reserved for patients with higher risk of nodal involvement Men with intermediate PCa (cT2a, PSA 10–20 ng/ml, biopsy Gleason score 7) or high risk (>cT2b, PSA >20 ng/ml, Gleason score 8)	Not indicated Extended
National Comprehensive Cancer Network, 2011 [15]	PLND can be excluded in patients with <7% predicted probability of lymph node metastases by nomograms, although some patients with nodal metastases will be missed. An extended PLND is preferred when PLND is performed.	Extended
PLND = pelvic lymph node dissection; PCa = prostate cancer; PSA = prostate-specific antigen.		

[PSA] 10–20 ng/ml and/or biopsy Gleason score of 7), high-risk PCa (>cT2b and/or PSA >20 ng/ml and/or Gleason score \geq 8), or patients with \geq 7% likelihood of having node metastases according to available nomograms (Table 4) [14,15,20]. Current National Comprehensive Cancer Network guidelines [15] recommend a PLND for all risk categories of PCa if prediction models indicate a 2% risk of lymph node invasion or higher (current American Urological Association guidelines [20] recommend that PLND generally be reserved for patients with a higher risk of nodal involvement).

The lymph node drainage of the prostate appears to be wide and bilateral [21]. The primary drainage of the prostate appears to be in the following order: external and obturator (38%), internal iliac (25%), common iliac (16%), para-aortic/caval (12%), presacral (8%), and inguinal (1%) [21].

An appropriate PLND includes removal of all node-bearing tissue from an area bounded by the external iliac artery anteriorly, the pelvic sidewall laterally, the bladder wall medially, the floor of the pelvis posteriorly, Cooper ligament distally, and the common iliac artery/ureter crossing proximally [14,15]. When these anatomic boundaries are respected, PLND usually retrieves \geq 10 lymph nodes [22,23].

Multiple retrospective case series indicate that if the limits of the node dissection are expanded during RP, an increased number of lymph nodes are removed and the incidence of positive lymph nodes rises [24,25]. This comes at the price of increased operative time and slightly increased complication rates [24] including lymphocele.

Bader et al. [26] and Briganti et al. [27] showed that men with a limited number of positive lymph nodes following RP can have prolonged cancer-specific survival, although most of these men were treated with adjuvant androgen ablation with or without external-beam radiation therapy. These data imply that RP is not contraindicated in men thought to be at significant risk for positive lymph nodes and that an appropriately performed PLND could, in fact, offer a survival advantage.

The publications available on RARP (primarily retrospective cases series) show that an extended PLND can be safely accomplished at the time of RARP, although in most of the reported series the number of removed lymph nodes was small [28]. The PCP agreed that a bilateral extended PLND is indicated for intermediate- and high-risk patients. A PLND should be considered optional in low-risk patients (D'Amico criteria [29] or N+ risk <3% according to available nomograms).

3.1.2. Patient preparation and anesthesia

There is no medical standard for an optimal time span between biopsy diagnosis and surgery. Many advise an interval \geq 4–6 wk [30]. There is no standard practice for bowel preparation; clinicians should follow their institutional guidelines.

It is standard procedure to advise patients to stop taking all anticoagulants a week before surgery, although some emerging evidence suggests that allowing continued low-dose nonsteroidal anti-inflammatory drugs or aspirin is not associated with the occurrence of bleeding events and could be beneficial in preventing serious adverse cardiac thrombotic events [31].

Concerning medical deep vein thrombosis (DVT) prophylaxis, the incidence of thromboembolic events after laparoscopic procedures is very low, and data from the most relevant multi-institutional observational study do not support the routine use of low molecular weight heparin (LMWH) prophylaxis in patients without risk factors [32]. In this last category, early mobilization and mechanical venous thromboembolism (VTE) prophylaxis is advised until mobility is no longer significantly reduced. However, according to the National Institute for Health and Clinical Excellence (NICE) guidelines, patients with an increased risk of VTE (Table 5) must be considered for pharmacologic VTE prophylaxis. The administration of LMWH could be continued until the patient is no longer at increased risk of VTE (generally 5–7 d) or prolonged for a longer period (28 d after surgery), especially for very high-risk patients (eg, previous VTE) [33].

RARP is a laparoscopic urologic procedure with an open urinary tract (clean contaminated). Therefore, antibiotic prophylaxis (a single perioperative course) using second- or third-generation cephalosporin is recommended [34]. RARP is performed using the Trendelenburg position to facilitate exposure of the pelvic area. The degree of Trendelenburg inclination is not standardized, and a wide range (between 10° and 40°) is reported in the literature. Patients receiving RARP in a steep Trendelenburg position for 3–4 h do not present significant cerebrovascular, respiratory, or hemodynamic problems [35,36]. More caution should be recommended for procedures with a longer operative time, for patients with a American Society of Anesthesiologists score \geq 3, or patients who are obese. A prolonged steep Trendelenburg position can increase intraocular pressure but has not been correlated with relevant clinical sequelae [37]. For patients with glaucoma, however, particular caution should be exercised, and it is recommended that

Table 5 – Venous thromboembolism risk factors in candidates for robot-assisted radical prostatectomy

Patient-related factors	Surgery-related factors
Active cancer or cancer treatment	Surgical procedure with a total anaesthetic and surgical time >90 min or >60 min if the surgery involved the pelvis or lower limb
Age >60 yr	Expected substantial reduction in mobility
Known thrombophilia	
Obesity	
Significant comorbidities (eg, heart disease, metabolic, endocrine, or respiratory pathologies, acute infection diseases)	
Personal history or first-degree relative with history of venous thromboembolism	
Use of hormone replacement therapy	
Varicose veins with phlebitis	

ophthalmologic clearance be obtained for such patients before RARP.

3.1.3. Surgical techniques

RARP is performed using the three- or four-arm da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA). Some surgeons may prefer the four-arm system because it provides additional stability and dexterity. However, a three-arm robot is an option, and an additional assistant port site can provide additional dexterity.

RARP can be performed using a transperitoneal or extraperitoneal approach. The former is the most commonly used and may have advantages in those patients requiring PLND.

Primary access for pneumoperitoneum can be performed using the Veress needle or direct open access via the Hasson technique. The camera port should be placed above the umbilicus except when the distance from the pubis exceeds 26 cm. A transverse camera port incision may be considered an alternative to the standard vertical incision to reduce the risk of camera port site hernia due to specimen extraction, particularly in obese patients and/or patients with large prostates [38]. Port placement and number of trocars for the assistant can vary according to surgeon preference, but it must provide sufficient distance between the camera and working ports to prevent internal or external collision of instruments [39].

The extraperitoneal space is usually entered by making an incision on the anterior peritoneum superior to the dome of the bladder and lateral to the medial umbilical ligaments. Access to the extraperitoneal space can also be obtained using the Montsouris approach to the seminal vesicles [40]. Care must be taken to identify and preserve accessory pudendal arteries to reduce potential vascular damage to erectile tissue.

The PCP supported the incision of endopelvic fascia on its line of reflexion to gain access to the lateral surface of the prostate in close contact with the fibers of the levator ani muscles. It was recognized, however, that the dissection of the prostate can be completed while leaving the levator ani fascia intact.

The dissection of the prostate can be done using an antegrade (from bladder neck to the apex) or retrograde (from apex to bladder neck) approach. The former is most popular and recommended for minimizing bleeding and traction and optimizing nerve-sparing dissection.

A wide bladder neck dissection is not usually recommended with the exception of patients with a large median lobe. When the bladder neck is widely opened, there is a need to reconfigure it, and various techniques are available and deemed equally effective. Similarly, the PCP did not recommend preservation of the intraprostatic urethra due to the higher risk of positive surgical margins and no evidence of improvement in the recovery of continence.

During RARP the seminal vesicles can be safely and precisely removed either entirely or partially according to the patient's oncologic status. To avoid injury to cavernous nerves, the minimal use of cautery and traction in the area of the seminal vesicles is recommended [41].

Meticulous retroprostatic dissection is essential. In patients where nerve preservation is advisable, the posterior layer of Denonvilliers' fascia (which contains communicating nerve fibers) can be left on the rectum; in high-risk patients it should be included with the specimen [42].

In the last decade, some robotic surgical techniques were developed with the aim of maximizing the preservation of the fibers located within the periprostatic tissue that covers the lateral and anterior surface of the prostate [19]. Anatomic studies showed that multiple compartments could be developed from the levator fascia to prostate capsule by entering different fascial planes during surgery [43]. However, the PCP found wide variability and subjectivity among surgeons regarding these facets of the procedure; hence no recommendation of a standard or preferred fascia approach and related surgical techniques was made. It is suggested that intrafascial and interfascial definitions be replaced with the newer concept of "incremental" nerve-sparing procedures previously described [44].

During RARP, the cavernous nerves can be damaged by direct mechanical trauma, traction, or thermal energy. Robotic technology may improve the precision of movements in small and deep spaces, potentially reducing mechanical, thermal, or traction injury to nerve tissue. Cautery-free dissection is recommended to avoid thermal injury of cavernous nerves. However, the judicious use of thermal energy including pinpoint coagulation at low cautery levels (ie, <30 W) applied briefly (ie, <1 s) is a valid alternative that has been reported in the literature. More significant use of thermal energy and/or higher cautery levels is not advised during nerve-sparing procedures.

The puboprostatic ligaments are usually exposed and divided sharply as they attach to the prostate to gain access

to the dorsal vascular complex (DVC). The DVC is usually ligated with either one or two interrupted sutures and then divided using scissors, monopolar electrocautery, or stapler devices. As an alternative, the DVC can be first divided and then selectively ligated with a running suture. After exposure of the prostatic apex, the urethra must be carefully transected beyond the apex of the prostate. The urethra is divided with care taken to avoid injury to the neurovascular bundles and the sphincter. Retroapical transection of the urethra can be considered an option [45].

Posterior musculofascial plate reconstruction (Rocco stitch) has been proposed to improve the recovery of urinary continence [46–49]. Although no prospective randomized trials have proven this hypothesis, there was unanimous agreement among the PCP that posterior reconstruction may facilitate performing the urethrovesical anastomosis and reduce bleeding. This step of the procedure should be considered optional. The posterior reconstruction may be performed either with interrupted sutures or with a running suture, and there is no substantial difference between the two techniques. Better results were reported when a periurethral suspension stitch [50] or an anterior reconstruction [51] was added to the Rocco stitch [52]. The running suture as described by van Velthoven et al. [53] is the most frequently used technique to perform the urethrovesical anastomosis. A monofilament suture is typically used for the anastomosis. Barbed sutures have been proposed to facilitate the configuration of both the posterior reconstruction and the anastomosis and to reduce the time needed to complete this step of the procedure [54].

A catheter is placed into the bladder during the completion of the urethrovesical anastomosis. The anastomosis should be tested intraoperatively by filling the bladder with fluid and checking for leaks. Positioning a percutaneous suprapubic tube drain instead of a transurethral catheter is an option to reduce patient discomfort [55], but most surgeons select the catheter option.

Concomitant inguinal hernia repair may be considered in all symptomatic cases [56]. A drain should be positioned and removed early during the postoperative course in some cases, but it is optional in those cases where there is a very low risk of postoperative hemorrhage or urinary extravasation. Trocars should be removed under direct vision to detect bleeding.

A cystogram is recommended before removal of the urethral catheter in patients at high risk for leakage (ie, previous TURP, salvage RARP), and it should be considered optional in all patients except those at high risk for leakage. Early catheter removal, that is, on postoperative day 4 or 5, should be considered in those with a low risk of extravasation.

3.1.4. Key consensus recommendations

The following recommendations are made with regard to patient selection and surgical technique;

- There are no absolute contraindications to RARP.
- Obesity, previous abdominal surgery, larger prostate size, and previous radiation are not absolute contraindications

for RARP, although such patients may be best operated on by only experienced clinicians.

- A transperitoneal antegrade surgical approach is the most commonly used.
- Robotic techniques have changed the understanding of prostate anatomy, thus making obsolete some commonly used terms use as *interfascial* or *intrafascial dissections*. The newer concept of incremental nerve-sparing procedures (full, partial, and minimal) should be adopted.
- Thermal energy should be used judiciously and with low cautery levels. Traction of tissues should also be minimized.
- Seminal vesicles can be removed either partially or completely during RARP according to the patient's oncologic status.
- RARP and RRP have equivalent efficacy for performing prostatectomy-related extended PLND.
- Single running suture is the most frequently used technique to perform the urethrovesical anastomosis. Monofilament is the standard suture. Barbed suture is an acceptable option.
- The use of medical DVT prophylaxis is optional. If used, clinicians should follow NICE or other national guidelines.

3.2. Cancer control

This section reviews the following critical issues related to cancer control and RARP: the suitability of RARP for patients with high-risk PCa, the prevalence of positive surgical margins (PSMs) in RARP, the use of adjuvant therapies following RARP, and the long-term oncologic efficacy of RARP.

3.2.1. Biochemical recurrence rates

Long-term data regarding biochemical recurrence of PCa after RARP are sparse because few centers have been performing this procedure >5 yr. Available nonrandomized comparative studies failed to demonstrate any differences in the biochemical recurrence-free survival among open RP (ORP), LRP, and RARP. However, they are all hampered by relatively short follow-up. The most detailed RARP series that is available reports biochemical recurrence-free survival estimates of 95.1%, 90.6%, 86.6%, and 81.0% at follow-up durations of 1, 3, 5, and 7 yr, respectively (median follow-up: 5 yr) [57,58]. The PCP agreed that current evidence shows that RARP is equivalent to RRP in terms of biochemical disease-free survival.

3.2.2. Robot-assisted radical prostatectomy for high-grade prostate cancer

Despite a trend in recent years toward performing prostatectomies for more clinically localized, lower grade disease (driven, in part, by the widespread use of PSA screening) [59], 20–30% of patients with PCa still present with high-risk disease as defined by serum PSA, T stage, and/or cancer grade [60]. Such patients are candidates for a variety of options, most notably neoadjuvant and adjuvant androgen deprivation combined with well-targeted high-dose radiotherapy or surgery followed selectively by

adjuvant therapy. The trend toward more surgical management of men with such cancers is supported by contemporary studies that have shown favorable results in treating high-risk disease with RP [61–63]. A recent comparative effectiveness study assessing >7000 men in the Cancer of the Prostate Strategic Urologic Research Endeavor database found that men with high-risk PCa had a lower mortality if they were treated with surgery compared with radiation or androgen-deprivation therapy alone [61].

This trend for surgical management of high-risk tumors overlaps with the increasing use of minimally invasive RARP surgery. The role of RARP in the context of high-risk disease, however, has not been well described to date. The current literature on RARP in men with high-risk PCa is sparse but improving as more centers publish their experience.

On the whole, the available studies suggest that RARP is a feasible option for men with high-risk PCa and can achieve equivalent oncologic and functional outcomes compared with ORP [64]. Several studies have challenged the use of RARP in high-risk patients, however, suggesting that complication and positive margin rates are too high [65]. After a thorough discussion, the PCP agreed that the findings could reflect early experience with robotic technology and surgeons who are still on their learning curve. Studies have shown that surgical volume and experience generally lead to better outcomes [66], and robotic surgery is no exception to this rule. Therefore, as more men with high-risk PCa move toward surgery, the choice to use an open versus robotic approach should depend on the surgeon and his or her level of comfort and experience with either approach.

3.2.3. Robot-assisted radical prostatectomy and positive surgical margins

PSMs are defined as tumor at the inked margin of the prostatectomy specimen. The impact of PSMs on cancer-related outcome has been studied extensively. A clear association between PSMs and cancer-specific mortality was shown in only a single large population-based study, indicating that patients with PSM had a 1.7-fold higher risk of death compared with those without [67]. Several other studies demonstrated that PSMs are a risk factor for disease progression after surgery [68].

The PCP agreed that PSMs should be stratified for pathologic stage (pT2 vs non-organ confined), location, number and extent, and Gleason score at the positive margin. Much evidence suggests that PSMs in pT2 disease are, for the most part, iatrogenic and hence potentially avoidable [68]. In pathologic pT3 cancers, PSMs are much more frequently associated with the extent of disease.

Most PSMs are reported to occur at the apex (6%), posterolaterally adjacent to the neurovascular bundle (NVB) (5%), anteriorly (1–2%), or at the bladder neck (2%) [69]. In organ-confined disease, the risk of PSMs at the level of the prostatic apex is thought to be increased by the absence of a visual or pathologic prostatic capsule to serve as a guide. A positive margin there should not necessarily be considered as “surgical failure,” as could be the case in T2 elsewhere. Similarly, PSMs adjacent to the NVB may occur when

surgeons attempt to preserve maximum potential sexual function. The bladder neck is a relatively unusual site for PSMs because this region is only rarely involved in significant disease, although when there is extensive disease at the base/bladder neck, it tends to be higher grade with higher stage (pT4) and with average PSM rates of 50% [68].

The results of the systematic review of oncologic outcomes in this issue indicate that the average rate of PSMs in pT2 disease is 8–10% and in pT3 disease is about 37% [10]. As with ORP, surgeon experience has been closely linked to reductions in PSM rates. As surgeons gain experience, PSMs generally are reduced, which suggests an iatrogenic role in PSMs. Detailed knowledge of critical anatomy and techniques was demonstrated to reduce apical, lateral, or bladder neck PSMs in organ-confined disease [68]. For non-organ-confined disease, it was also shown that as surgeons gain experience they become better able to discern which cases need wider excision and also to perform these wider excisions more accurately, both of which tend to reduce the rates of PSMs.

Randomized controlled trials comparing the prevalence of PSMs following ORP, LRP, and RARP are lacking. However, the available evidence from nonrandomized comparative studies suggests that PSMs rates are likely to be similar regardless of the different possible surgical approaches [10]. Specifically, PSM rates ranging from 11% to 38% were reported following RRP, from 12% to 31% following LRP, and from 9% to 29% following RARP [68].

3.2.4. Adjuvant and salvage therapies after robot-assisted radical prostatectomy

Data concerning the use of adjuvant therapies following RARP are limited. However, some initial population-based studies evaluating US patient data from 2003 to 2005 suggested that patients treated with minimally invasive RP (ie, mainly RARP, due to the limited use of LRP in the United States) were at increased risk of receiving adjuvant therapies compared with those treated with RRP [70]. Following the publications of these data, some concerns arose that RARP patients may be receiving suboptimal oncologic treatment. However, subsequent Surveillance, Epidemiology and End Results analyses failed to confirm these earlier data [65,71], demonstrating that surgical approach was not associated with any differences in the risk of adjuvant therapies following RP. In addition, the author of the original paper published a letter acknowledging the limitations of his study [72].

Conversely, D'Amico risk group, presence of nodal metastases, PSMs, and surgeon volume were all independent predictors of receiving additional cancer therapies [71]. The PCP agreed that RARP does not expose patients to an increased risk of adjuvant therapies compared with the other surgical approaches to RP, provided the standard criteria for patient selection, surgical technique, and lymph node dissection are used.

3.2.5. Key consensus recommendations

The following recommendations are made with regarding to cancer control:

- Available data suggest that RARP may also be used in patients with D'Amico high-risk cancers, provided that standard criteria for patient selection, lymph node dissection, and nerve preservation are fulfilled.
- Positive surgical margin rates after RARP are equivalent to those reported after RRP and LRP.
- When appropriately performed, RARP is not associated with an increased risk of patients needing adjuvant therapies.
- Biochemical disease-free survival after RARP seems to be equivalent to other approaches, although existing data are limited.
- RARP is appropriate for those with high-risk disease; the surgical approach should be determined by the surgeon's experience and expertise.

3.3. Functional outcomes and complications of robot-assisted radical prostatectomy surgery

As with many of the issues discussed thus far in this paper, high-quality comparative data on surgical complications and sequelae between RARP and RRP are limited, and what data exist are difficult to interpret because of the lack of standardized terms and reporting procedures. The risk of experiencing complications is, of course, related to a range of risk factors including age, body mass index, comorbidity, experience of the surgeon, previous lower abdominal surgery, previous TURP, and previous radiation and/or hormone therapy as well as intraoperative risk factors (prostate volume, median lobe). This section examines the nature of complications and how they are reported, reviews the evidence related to the two most pressing functional outcomes of RARP (urinary continence and potency), and makes numerous recommendations for clinical practice and future research.

3.3.1. Complications

The PCP agreed that a standardized method to accrue, define, and report complications following RARP is required. Accurate reporting allows physicians to counsel patients adequately on expected outcomes, and it permits valid comparisons between series and earlier recognition of patterns of complications that should prompt changes in care. The differences currently being reported between series may simply reflect the diligence of an institution at collecting and reporting outcomes.

An ad hoc panel of the EAU guidelines office recently addressed the issue of reporting complications [73]. The panel reviewed all the available classification systems for the reporting of complications and proposed a modification of the Martin criteria for accurate and comprehensive reporting of surgical outcomes [73]. The PCP recommends that surgeons be aware of these different instruments and use whichever one is most relevant to their practice and needs.

The PCP noted that the definition of *surgical complication* is still not standardized, although it noted the existence of the Accordion system, which may serve as a model for a more widely adopted definition (Table 6). The PCP recognized the clear distinction, made also by Clavien-Dindo, between

complications and sequelae, which are phenomena such as anejaculation that are inherent to the procedure. Likewise, specific postoperative complications of RARP, such as lymphorrhea, lymphocele, bleeding, pelvic hematoma, urine leakage, disrupted anastomosis, and penile shortening, need to be defined in a standardized fashion. Nonetheless, the PCP recommends that complications should be assessed not only during the intraoperative and early postoperative period but also within 3 mo postsurgery. Results should be available for most patients to be meaningful. For studies of complication rates following RP surgery, the PCP believes it is critically important that patients selected for follow-up be representative of all patients receiving treatment at that center and not a subsample that could be influenced by selection factors. Prospective disease registries should be developed using physician-, patient-, and hospital-reported outcomes. These would be of optimal benefit in assessing the costs and outcomes of surgery.

It was suggested that a comprehensive report of post-prostatectomy outcomes may be best represented by the *trifecta* concept, that is, measuring the rate of patients who simultaneously have an undetectable PSA and complete recovery of both urinary continence and erectile function [74]. A newer, more comprehensive *pentafecta* approach was suggested that includes perioperative complications and PSM rates, a concept the PCP endorsed as more accurately reflecting the real conditions facing postoperative patients, although it has not yet been validated [75].

A potential complication of RARP specific to this procedure is device failure, although such failures appear to be quite rare, occurring in only 34 of 8240 reported cases (0.4%) in a multi-institutional study [76]. Of these, 24 events were identified preoperatively, leading to cancellation of the procedure. Of the 10 device failures that developed intraoperatively, 8 cases were converted to open surgery, with 2 converted to a conventional laparoscopic approach. Smaller studies reported similarly low rates of device failure [77–79]. Most of the adverse events relate either to broken instrument tips or to failure of electrocautery elements.

3.3.2. Urinary incontinence

Urinary incontinence (UI) has been repeatedly shown to be one of the most important factors affecting patient quality of life (QoL) following RP—more important, in fact, than sexual functioning [80]. Determining whether a patient is continent, however, is not straightforward. Traditionally, a patient was considered continent if he did not use any security pads [81]. Others used a broader definition of up to

Table 6 – Accordion Severity Grading System

A complication is a combination of the following items:

- An event unrelated to the purposes of the procedure
- An unintended result of the procedure
- An event occurring in temporal proximity to the procedure
- Something causing a deviation from the ideal postoperative course
- An event that induces a change in management
- Something that is morbid (ie, causes suffering directly by causing pain or indirectly by subjecting the patient to additional interventions)

one pad per day [82]. It has been shown, however, that patient QoL is significantly better in patients who are pad free as compared with those who wear one security pad [83]. Other studies suggest that significant numbers of patients who tell their doctor they do not use any pads still experience leakage of a small or moderate amount of urine at least once a day [84]. The lack of standardization in the reported literature on UI hampers an accurate assessment of the prevalence of this common outcome and makes it harder for physicians to help patients set realistic expectations for their postsurgical experience. The PCP recommended that the definitions for UI be standardized and that a definition of no pads is better correlated with overall QoL than either zero to one or one pad.

Regardless of the definition, however, it is clear that UI is a significant consequence of RP. Parker et al. report that at the 5-yr postoperative mark, only 38% of men returned to their preoperative continence level [85]. Another study found that up to 47% of men had worse continence at 1 yr than they expected preoperatively [86].

An increased age at RARP is the best predictor of UI, although a number of other significant risk factors have been reported (Table 7).

Evidence from the systematic reviews published in this issue of *European Urology* suggests that the recovery of urinary continence following RARP is usually better than after RRP [7,87]. Ficarra et al. found better urinary continence results after 12 mo for RARP patients (97%) compared with RRP patients (88%) [87]. Patients were categorized as continent if they reported no leak or leaks about once a week or less. The mean time to continence recovery for RARP patients was 25 d compared with 75 d for RRP patients ($p < 0.001$). Tewari et al. also showed a more rapid return of urinary continence for RARP patients, with a median time to return of continence for the RARP group of 44 d compared with 160 d for the RRP group [88].

A single-surgeon study in which continence was defined as requiring no pads reported similar continence rates for RARP and ORP (75% vs 76%) [89]. Likewise, Krambeck et al. found no statistically significant difference in urinary continence outcomes between surgical approaches [90]. Using a nonvalidated questionnaire, patients were considered continent if they reported no urinary leakage or required only a security pad. Urinary continence at 1 yr was 92% for RARP and 94% for RRP ($p = 0.34$) [91]. The PCP recognizes that postoperative recovery of urinary continence may also be influenced by the patient's preoperative

condition and that available studies do not provide an adequate comparison of postoperative continence rates in patients treated by RARP versus RRP.

Many different surgical procedures have been identified that may help maximize the chances for postsurgical continence, and surgeons are encouraged to review these techniques [92]. In addition, the PCP recommends that clinicians counsel patients preoperatively about the potential for UI and the options available for correcting and/or minimizing this potential outcome, such as pelvic floor exercises, medications, or lifestyle modifications [93].

3.3.3. Sexual dysfunction

As is the case with UI, data comparing outcomes related to erectile function and other aspects of sexual function after RARP and RRP are limited by short follow-up times and reports from only a few centers. For example, Krambeck et al. reported no significant difference in 1-yr potency rates between RRP and RARP (63% vs 70%; $p = 0.08$), with potency defined as erections satisfactory for intercourse with or without phosphodiesterase type 5 inhibitors [90]. Tewari et al. reported a shorter median time to potency recovery with RARP than with RRP (180 vs 440 d; $p < 0.05$) [88].

A significant advantage for RARP in terms of preserving erectile function was found by Ficarra et al. in a study that measured erectile function with the International Index of Erectile Function-5. With analysis limited to patients receiving bilateral nerve-sparing RP with at least 1 yr of follow-up, 49% of ORP versus 81% of RALP patients were potent ($p < 0.001$) [6]. (The analysis adjusted for the effects of age, preoperative erectile function, and comorbidities.)

The systematic reviews presented in this issue of *European Urology* suggest that RARP is advantageous in potency recovery in comparison with RRP [9]. However, there are a lack of well-controlled prospective studies of functional outcomes of RARP compared with RRP, and the level of surgeon experience, institutional volume of surgery, postoperative rehabilitation, and means of outcome assessment have varied considerably between studies. The PCP recognizes that, similar to urinary continence, the postoperative recovery of erectile function may be influenced by the patient's preoperative condition and postoperative rehabilitation. The PCP suggested that the goal should be a return to a patient's presurgical level of erectile functioning, which requires a careful assessment of patient sexual function before surgery. The PCP also suggested that sexual functioning is different from, and may be independent of, erectile functioning. Clinicians need to inquire about, and record, information from patients about orgasmic function, libido, and overall sexual satisfaction. In addition, postoperative anejaculation should be discussed with patients, as well as fertility preservation strategies if those are desired [94].

The PCP recommended specific steps that surgeons can take to minimize erectile difficulties and other forms of sexual dysfunction following RARP surgery:

- Avoid any use of thermal energy within 5–10 mm of the neurovascular bundle, especially after the prostatic pedicle has been released.

Table 7 – Risk factors for urinary incontinence following robot-assisted radical prostatectomy

Increased age
Obesity [81]
Short membranous urethral length on both preoperative and postoperative endorectal magnetic resonance imaging [97]
Postprostatectomy anastomotic strictures [98]
Low institutional and/or surgeon caseload [99]
Neurovascular bundles not preserved [100]
Bladder neck injured or not preserved [101]
Large prostate [102]

- Minimize traction during surgery.
- Counsel patients regarding the potential sexual complications of surgery and available options for postsurgical management.

3.3.4. Key consensus recommendations

The following recommendations are made with regard to functional outcomes and complications of RARP:

- The definition of surgical complications should be standardized, complications should be assessed in detail from the intraoperative period until at least 3 mo postoperatively, and results should be available in most patients.
- Systematic reviews indicate the potential superiority of RARP for preservation of continence and potency following RP surgery; however, methodological limitations in most studies and the lack of prospective randomized trials need to be considered. Other factors, such as the level of surgeon experience, means of outcome assessment, pre-morbid function, and postsurgical rehabilitation of the patient, can have a significant impact on functional outcomes.
- Comparative studies of functional outcomes following RP surgery performed according to best practice guidelines are needed.
- Postoperative anejaculation and fertility preservation strategies should be discussed with patients, and realistic expectations should be set regarding a return to continence and baseline potency.
- Although the most appropriate way to report composite outcomes following RP has yet to be standardized, such reporting should take into account baseline patient characteristics, type of surgery, use of adjuvant therapies, and peri- and postoperative complications and sequelae.

3.4. Research needs and priorities

3.4.1. Patient selection and surgical techniques

A number of areas related to patient preparation and surgical procedures were identified by the PCP as needing further research. For example, observational studies are needed to evaluate the real incidence of VTE in RARP series and to identify specific risk factors. Prospective studies are needed to verify the potential benefit of pharmacologic prophylaxis for VTE. Anesthesiology procedures are not

currently standardized and vary widely between hospitals. The PCP supports the need to define a RARP anesthesiology standard with particular attention given to aspects that influence the postoperative course as well as the need for a central venous catheter and pain management.

The systematic review of the literature revealed that numerous steps of the surgical procedure are not reported [7–10,95]. This critical aspect can negatively influence the correct interpretation of reported functional and oncologic outcomes [96]. It is imperative, therefore, that the main aspects of surgical procedure be divulged in high-quality reports of RARP surgery. Table 8 summarizes the proposed Pasadena criteria for such reporting.

The PCP supported the creation of a survey and resulting database of surgical techniques currently being used by RARP surgeons. This could be the first step in creating an evidence-based classification of surgical variants in four different categories: *recommended*, *optional*, *investigational*, and *not recommended*.

Few data are available about the most challenging cases (obese patients, median lobe, large prostate, previous TURP, and salvage RARP). Clinical research should be encouraged to confirm the safety and effectiveness of RARP for these particular cases. Comparative studies should be performed to evaluate if robotic technology is able to improve the perioperative, functional, and oncologic outcomes in comparison with the traditional RRP.

3.4.2. Cancer control

The PCP identified a number of issues related to RP and cancer control that would benefit from further research. First would be the need to study the impact of RARP in large populations of high-risk PCa patients where the role of PLND should be more important. It is not known whether a type of “positive” margin exists that is, in fact, benign, and, if so, what the pathologic hallmarks of such margins are. It would also be desirable if the definitions of *high-risk*, *intermediate-risk*, and *low-risk* prostatectomy patients could be standardized to allow for more accurate cross-study comparisons. It was noted that no studies have yet been conducted on the long-term cost effectiveness of active surveillance versus RRP versus RARP. Also unknown is whether imaging techniques such as magnetic resonance imaging, computed tomography,

Table 8 – Essential surgical steps that must be described in the scientific publication (Pasadena criteria)

Initial steps	Demolitive steps	Reconstructive steps
Robotic arms, no.	Retzius access	Posterior reconstruction
Primary access for pneumoperitoneum	Opening the endopelvic fascia	Anterior suspension
Camera port placement	Puboprostatic ligaments management	Urethrosesal anastomosis
Trocars placement	Bladder neck dissection	
	Dissection of seminal vesicles	
	Retroprostatic dissection	
	Release of NV bundles	
	Control of prostate vascular pedicles	
	Preservation of NV bundles	
	Division of DVC	
	Apical and urethral dissection	

NV = neurovascular; DVC = dorsal vascular complex.

infrared light-guided utilities, or other types of imaging facilitate treatment decision making in patients with PCa, regardless of the selected treatment approach. What types and timing of RP are best for patients requiring multimodal therapy? And, finally, will new forms of systemic therapy (ie, vaccines, abiraterone, MDV3100, cabazitaxel) improve outcomes? All these issues should be given research priority in the coming years.

3.4.3. Surgical complications and sequelae

Definitions of erectile function and how to measure it following RP need to be standardized, with the PCP recommending that researchers report on erectile function at 1, 3, 6, 9, and 12 mo postoperatively and yearly thereafter using well-validated instruments. Results should be available for most, if not all, patients in the practice. Data on sexual function and continence should be routine data points in every case.

Most studies of preserving erectile function in men undergoing prostatectomy have studied younger men with normal sexual function. Additional research is needed to explore postoperative outcomes among older men and those with less than perfect preoperative erectile function. The role of penile rehabilitation in the RARP setting should be assessed.

Finally, the effect of RP on the natural history of lower urinary tract symptoms (LUTS) has not been widely studied; there is paucity of data assessing LUTS pre- and postoperatively and on the effect of RP on the natural history of LUTS. This could be addressed by studies evaluating LUTS in these groups using similar reporting criteria, rather than different questionnaires, as was the case in most studies to date.

4. Conclusions

RARP has been widely adopted despite an absence of high-quality randomized controlled clinical trials comparing it with traditional RRP. A systematic review of the available evidence suggests that in patients with clinically localized PCa, RARP is equivalent to RRP in cancer control. Although the accompanying systematic review indicates that RARP is advantageous in preservation of continence and potency recovery, there are a lack of well-controlled prospective studies of functional outcomes of RARP compared with RRP. Future comparisons ideally should be conducted of surgical outcomes following RP surgery performed according to best practice guidelines, as described in the current paper. Available data suggest that RARP offers advantages in reduced blood loss, lower transfusion rates, and shorter length of hospital stay than RRP. Likewise, the best available data suggest there are minimal differences between the surgical approaches in terms of overall postoperative complications. As with RRP, surgeon experience and institutional volume of procedures strongly predict better outcomes at all levels.

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