



Prostate Cancer

Oncologic Outcome after Extraperitoneal Laparoscopic Radical Prostatectomy: Midterm Follow-up of 1115 Procedures

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Abstract

Background: Although the first laparoscopic radical prostatectomy was performed in 1997, few midterm oncologic data have been published for the extraperitoneal procedure.

Objective: To determine the oncologic outcome of extraperitoneal laparoscopic radical prostatectomy (ELRP).

Design, setting, and participants: From 2000 to 2007, 1115 consecutive patients underwent ELRP for a localized prostate cancer at our department. Follow-up was scheduled and standardized for all patients and recorded into a prospective database. Median postoperative follow-up was 35.6 mo.

Intervention: All ELRP were performed by three surgeons at the Department of Urology, Hospital Henri Mondor, Créteil, France.

Measurements: Biochemical recurrence was defined by prostate-specific antigen level ≥ 0.2 ng/ml.

Results and limitations: In pN0/pNx cancers, postoperative stage was pT2 in 664 patients (59.5%), pT3 in 350 patients (31.4%), and pT4 in 77 patients (6.9%). Positive lymph nodes were reported in 24 patients (2.2%). Margins were positive in 16.1% and 34.6% of pT2 and pT3 cancers, respectively. Final Gleason score was <7 in 288 men (25.8%), $=7$ in 701 men (62.9%), and >7 in 126 men (11.3%). Overall prostate-specific antigen (PSA) recurrence-free survival was 83% at 5 yr. The 5-yr progression-free survival rates were 93.4% for pT2, 74.5% for pT3a, and 55.0% for pT3b tumors, respectively. Multivariate Cox model showed that PSA, Gleason score, pT category, nodal status, and surgical margins were significant independent predictors of biochemical recurrence-free survival.

Conclusions: This assessment of oncologic results demonstrates that ELRP is a safe and effective procedure. On the basis of midterm follow-up data, the prognostic factors of PSA after ELRP failure are the same as those described previously in transperitoneal or open retropubic approaches. The oncologic results of ELRP also are in line with those reported with the use of the retropubic or the transperitoneal laparoscopic approaches.

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1. Introduction

Radical prostatectomy is a standard treatment for localized prostate cancer. The first laparoscopic radical prostatectomy (LRP) was performed in 1997 and was thought not to be feasible because of excessive operative time [1]. However, in the following years, the development of minimally invasive surgery was driven in Europe by some centers able to report considerable experience and to standardize the technique [2–4]. Laparoscopic procedure is a validated treatment modality for localized prostate cancer. Experienced surgeons have described various advantages of laparoscopy [5,6]. Lower blood loss and transfusion rates have been demonstrated to be the main advantages of laparoscopic surgery. Improved cosmesis and shorter convalescence may also be factors in increasing patient acceptance of the surgical procedure and its resultant side effects. Functional results on continence and potency appear comparable to those obtained by open approach [7]. These benefits seem to occur without sacrificing the oncologic standards established by the open approach [8–11]. Globally, laparoscopy has proven to be equivalent to open procedure in radical prostatectomy. However, most published laparoscopy studies fail to address high-volume experience and long-term follow-up. Moreover, larger LRP series reported oncologic results of transperitoneal LRP. Although the first extraperitoneal LRPs (ELRP) were reported in 1997, few midterm oncologic data have been published for the extraperitoneal procedure [12].

Since 2000, ELRP has become the standard surgical technique for localized prostate cancer at our institution. The goal of this study was to evaluate the prostate-specific antigen (PSA) outcomes of ELRP in order to determine the midterm oncologic safety of this procedure, and to assess these oncologic results with respect to the established predictors of biochemical recurrence after radical prostatectomy. To our knowledge, no study of ELRP experience has addressed the biochemical recurrence-free survival according to histoprognostic parameters.

2. Patients and methods

2.1. Patient selection

Between January 2000 and December 2007, 1115 consecutive men underwent ELRP for localized prostate cancer at the Department of Urology, Hospital Henri Mondor, Créteil, France. All prostatectomies at our institution were treated by ELRP and were performed by three surgeons (CCA, ADLT, LS). Patients who had received neoadjuvant therapy or adjuvant therapy before PSA relapse were excluded from analyses. A history of previous abdominal surgery, transurethral prostate resection, or hernia repair were not contraindications. All patients were followed at our institution and medical visits were scheduled at 1, 3, and 6 mo and then within a 6-mo interval after ELRP. The hospital's ethics committee approved the study and the good clinical practice criteria were respected.

2.2. Surgical procedure

The surgical technique and the different steps of the surgery were previously described [13]. Lymphadenectomy was performed prior to

the completion of the vesicourethral anastomosis in case of Gleason score >6 and/or PSA level >10 ng/ml. Low-risk patients (primary Gleason grade of 3, clinical T1c stage, PSA level <10 ng/ml) underwent conventional nerve-sparing procedure. Standard lymphadenectomy (external iliac artery area) was performed in 464 patients. A median of 3.5 lymph nodes per side was sampled. In patients who did not undergo lymph node dissection, cancer was classified as pNx. Of the 907 patients who underwent a nerve-sparing surgery, 702 had bilateral preservations and 205 had unilateral preservations.

2.3. Database and statistical analysis

Data were collected prospectively into a database, including preoperative clinical and biological characteristics, patient demographics, surgical data, and postoperative parameters. Pathologic Gleason score, surgical margin (SM) status, presence of extracapsular extension (ECE), seminal vesicle invasion (SVI), and pelvic lymph node positivity were recorded. All pathologic specimens were reviewed by a single senior uropathologist with criteria clearly defined at the beginning of the study. Positive margins were defined as the presence of tumor tissue on the inked surface of the specimen. Pathologic Gleason score was divided as follows: Gleason score <7, =7, or >7. PSA level was considered a qualitative variable as follows: PSA <10 ng/ml, between 10 and 20 ng/ml, and ≥20 ng/ml. Biochemical recurrence was defined as any detectable serum PSA (>0.2 ng/ml) in at least two consecutive measurements. The biochemical recurrence-free survival was estimated using the Kaplan-Meier method. Survival curves were stratified by PSA level and pathologic features, and compared using the log-rank test. The multivariate Cox proportional hazard regression model was used to determine factors influencing PSA-free survival. A double-sided *p* value <0.05 was considered statistically significant. All data were analyzed using SPSS v.16.0 software (SPSS, Chicago, Illinois, USA).

3. Results

Characteristics of patients are listed in Table 1. Mean specimen weight was 53.4 g. Postoperative stage was pT2 in 667 patients (pT2a: 126; pT2b, 30; pT2c, 511), pT3a in 255 patients, pT3b in 110 patients, and pT4 in 83 patients. Among the 83 pT4 tumors, 80 were defined as pT4 by microscopic bladder neck invasion. Final Gleason score was <7 in 288 men (25.8%), =7 in 701 men (62.9%), and >7 in 126 men (11.3%). Positive lymph nodes were noted in 24 patients. Overall positive surgical margin (PSM) rate was 26%. Margins were positive in 16.1% and 34.6% of pT2 and pT3 cancers, respectively (*p* < 0.001). Margins were positive in 5.5% of

Table 1 – Preoperative patient characteristics

No. of patients	1115
Mean age, yr (range)	62.5 (42–81)
Clinical stage (%)	
T1a–b	18 (1.6)
T1c	894 (80.2)
T2	193 (17.3)
T3	10 (0.9)
Mean PSA (ng/ml)	9.8 (0.8–99)
Gleason score (%)	
<7	739 (66)
=7	326 (29)
>7	50 (5)
PSA = prostate-specific antigen.	

Table 2 – Postoperative patients characteristics

Stage		Total no. (%)	Positive margin (%)	Gleason score (%)		
pT	pN			<7	=7	>7
pT2a	pN0/pNx	126 (11.2)	7 (5.5)	76 (6.7)	47 (4.2)	3 (0.3)
pT2b	pN0/pNx	30 (2.7)	3 (10)	10 (1)	19 (1.6)	1 (0.1)
pT2c	pN0/pNx	508 (45.6)	97 (19.1)	175 (15.6)	323 (29)	10 (1)
pT2c	pN1	3 (0.2)	0	0	3 (0.2)	0
pT3a	pN0/pNx	250 (22.4)	82 (32.8)	20 (2)	197 (17.6)	33 (2.8)
pT3a	pN1	5 (0.5)	2 (40)	0	2 (0.2)	3 (0.3)
pT3b	pN0/pNx	100 (9)	41 (41)	3 (0.3)	56 (5)	41 (3.7)
pT3b	pN1	10 (1)	3 (30)	0	7 (0.7)	3 (0.3)
pT4	pN0/pNx	77 (6.9)	57 (74)	4 (0.3)	45 (4)	18 (2.6)
pT4	pN1	6 (0.5)	4 (66.6)	0	2 (0.2)	4 (0.3)

pT2a, 10.0% of pT2b, and 19.1% of pT2c tumors ($p < 0.001$) (Table 2).

Mean and median follow-up after ELRP in our cohort was 35.3 mo (± 19.8) and 35.6 mo (range: 1–92). Two hundred eighteen patients have been lost during follow-up. PSA recurrence occurred in 146 patients (13.1%) in a mean of 7.9 mo after ELRP (median 3.1 mo; range: 1–42). The overall PSA recurrence-free survival rates were 84% at 3 yr and 83% at 5 yr. Patients with biochemical recurrence were treated as follows: 41 men received external radiation, 67 received hormone therapy, and 12 received a combination of radiotherapy and androgen deprivation therapy. The 3- and 5-yr recurrence-free survival rates were 86.7% (95% confidence interval [CI]: 83.3–90.1) for PSA < 10 ng/ml, 74.1% (95% CI: 66.1–82.1), and 69.8% (95% CI: 61.0–78.6) for a PSA level ranging from 10 to 20 ng/ml, and 47.5% (95% CI: 32.3–62.7) for PSA ≥ 20 ng/ml (Fig. 1). Curves were statistically different ($p < 0.0001$).

According to the Gleason score, difference between survival curves also reached significance ($p < 0.0001$) (Fig. 2). Patients with a Gleason score >7 had a 5-yr progression-free survival rate of 36.1% (95% CI: 25.3–46.9) compared with 82.8% (95% CI: 78.2–87.4) for those with a Gleason score =7 and with 93.5% (95% CI: 89.1–97.9) for those with a Gleason score <7 ($p < 0.0001$) (Fig. 2).

Patients with PSM had a progression-free survival rate of 56.6% (95% CI: 48.2–65.0) at 5 yr compared with 89.0% (95% CI: 85.6–92.4) for those with negative surgical margins (NSM). Surgical margin status was a predictor of PSA recurrence by the log-rank test ($p < 0.0001$) (Fig. 3).

According to the pathologic stage, 5-yr progression-free survival rate was 93.4% (95% CI: 90.6–96.2) for pT2 cancers,

70.2% (95% CI: 63.8–76.6) for pT3 cancers, and 42.7% (95% CI: 27.9–57.5) for pT4 cancers ($p < 0.0001$) (Fig. 4). The 5-yr progression-free survival rate was 98.3% in pT2a tumors, compared with 88.9% and 92.5% in pT2b and pT2c tumors, respectively ($p = 0.062$).

When analysis was stratified by pathologic stage and margin status, the 5-yr progression-free survival rate was 96.9% for pT2 with NSM. Similar 5-yr progression-free survival rates were noted in pT2 with PSM and pT3a with NSM (76.6% and 81.6%, respectively, $p = 0.26$) (Fig. 5).

When analysis was stratified by pathologic stage and Gleason score, the 5-yr progression-free survival rates were 93.5% for pT2 with Gleason score <7, 93.1% for pT2 with Gleason score =7, 77.5% for pT3a with Gleason score =7, and 66.6% for pT3b with Gleason score =7.

The multivariate Cox proportional hazard model showed preoperative PSA, Gleason score, tumor stage, nodal status,

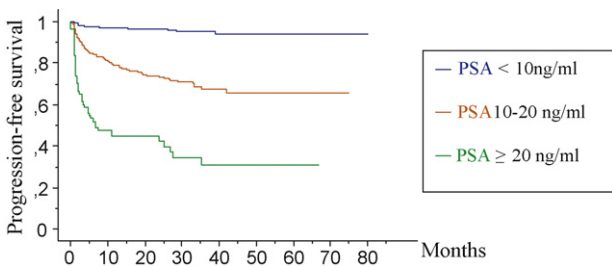


Fig. 1 – Biochemical progression-free survival stratified by preoperative prostate-specific antigen. PSA = prostate-specific antigen.

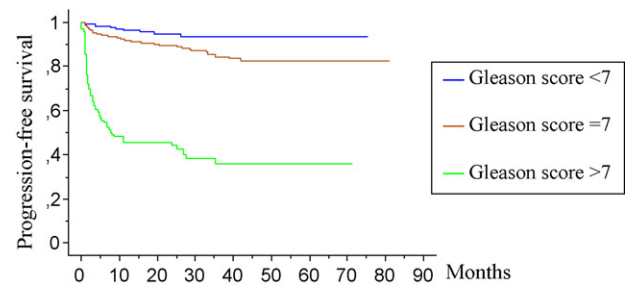


Fig. 2 – Biochemical progression-free survival stratified by Gleason score.

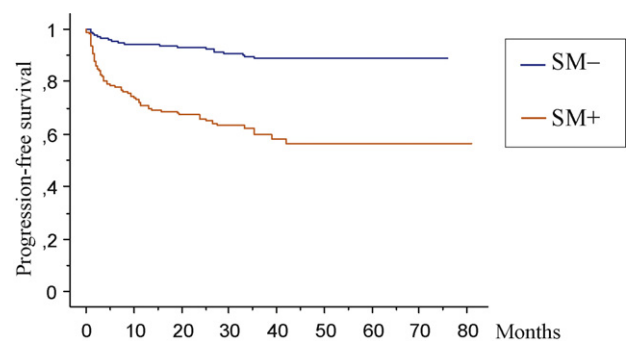


Fig. 3 – Biochemical progression-free survival stratified by surgical margins. SM- = negative surgical margins; SM+ = positive surgical margins.

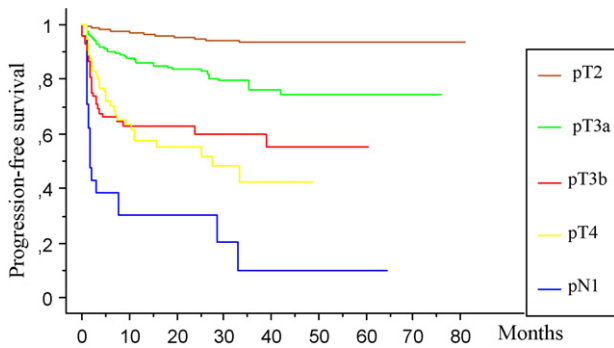


Fig. 4 – Biochemical progression-free survival stratified by pathologic stage.

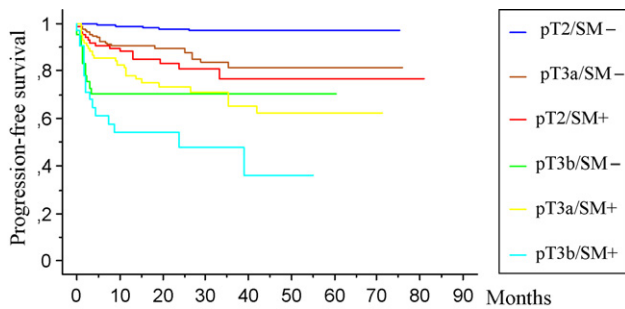


Fig. 5 – Biochemical progression-free survival stratified by pathological stage and surgical margins. SM– = negative surgical margins; SM+ = positive surgical margins.

and surgical margins were significant independent predictors of biochemical recurrence-free survival. Hazards ratios and *p* values are listed in Table 3.

4. Discussion

Radical prostatectomy is a standard treatment for localized cancer prostate. The open approach has proven oncologic safety with extraperitoneal access as standard of care.

Table 3 – Multivariate Cox proportional hazard model for different variables for prediction of biochemical recurrence risk

	Risk ratio	95% CI	<i>p</i> value
PSA <10 ng/ml	1	–	–
PSA 10–20 ng/ml	1.243	0.795–1.943	0.339
PSA ≥20 ng/ml	2.920	1.743–4.894	<0.0001
Gleason score <7	1	–	–
Gleason score =7	1.280	0.583–2.809	0.538
Gleason score >7	4.447	1.868–10.584	0.001
pT2	1	–	–
pT3a	2.759	1.640–4.643	<0.0001
pT3b	3.682	1.928–7.032	<0.0001
Negative lymph nodes	1	–	–
Positive lymph nodes	5.606	2.904–10.825	<0.0001
Negative surgical margin	1	–	–
Positive surgical margin	2.717	1.817–4.063	<0.0001

CI = confidence interval; PSA = prostate-specific antigen.

LRP was introduced to combine the advantages of laparoscopy without compromising the oncologic results of open surgery. Thus, the development of minimally invasive surgery was driven in Europe by some centers able to report considerable experience and to standardize the technique. In terms of oncologic follow-up, LRP is now approaching 10 yr. Some laparoscopy centers have published 3- and 5-yr outcomes; however, most of these series reported midterm oncologic experience of the transperitoneal approach. Concerning the ELRP, Rozet et al showed equivalent operative, postoperative, and pathologic results when comparing the extraperitoneal and the transperitoneal approach [14]. Stolzenburg and coworkers also reported interesting results of ELRP in terms of operative parameters and surgical margin rate [15]; however, these studies failed to address PSA failures and the impact of classic histoprognostic parameters.

The ELRP has routinely been performed in our department since 2000 [3,13]. The extraperitoneal approach has been demonstrated to be a safe and reproducible procedure, with a fast recovery after surgery. To our knowledge, no study has addressed the midterm oncologic results of ELRP and the impact of the histoprognostic parameters on the biochemical recurrence-free in extraperitoneal approach. The focus of this paper is on assessment of this oncologic outcome.

Transperitoneal LRP studies demonstrated that laparoscopy had the potential to give good functional results with equal oncologic effectiveness [9,10]. Guillonnet et al reported the oncologic outcome of 1000 patients after transperitoneal LRP with an overall actuarial, biochemical, PSA-free survival between 88% and 92% for pT2 and between 44% and 77% for pT3 at 3 yr [9]. Recently this series has been updated [16]. Rassweiler et al reported a PSA-free survival at 89.5% for pT2 and 68.2% for pT3 at 5 yr [10]. These cancer control rates by pathologic stage are within the confidence ranges reported by other centers (Table 4). Comparatively, the progression-free survival rate was 85% at 5 yr in our series (98% and 77% for pT2 and pT3, respectively).

Our findings support evidence of the impact of preoperative PSA level on the risk of postoperative biochemical recurrence after ELRP. Our results are in line with the well-known results of open and transperitoneal laparoscopic approaches. Han et al reported 5-yr progression-free survival rates of 94% for PSA level of 0–4 ng/ml, 89% for PSA 4.1–10 ng/ml, 73% for PSA 10–20 ng/ml, and 60% for PSA >20 ng/ml [17]. For Pavlovich et al, preoperative PSA was associated with 3-yr biochemical recurrence-free survival (PSA ≥10 ng/ml vs >10 ng/ml) [18].

The Gleason score also had a significant impact on progression-free survival. In the series of Catalona and Smith, the progression-free survival rates at 3 yr were 92%, 85%, and 62% of Gleason 2–4, 5–7, and 8–10, respectively [19]. The extraperitoneal procedure did not change this value. We found that a high Gleason score was significantly associated with a worse prognosis.

It has been postulated that LRP results in a higher rate of PSM. Recent studies could not detect any specific oncologic

Table 4 – Oncologic results of open prostatectomy, transperitoneal laparoscopic radical prostatectomy (TLRP), and extraperitoneal laparoscopic radical prostatectomy (ELRP)

References	No. of patients	% Surgical margins		Progression-free survival (%)			
		pT2	pT3	3-yr		5-yr	
				pT2	pT3	pT2	pT3
Open prostatectomy							
Catalona and Smith [19]	1778	20.9		92.5	78.7	90	68.7
Han et al [17]	2494	–	26.4	85	75	75	60
Hull [25]	1000	12.8		95.6	85.3	94.9	75.3
TLRP							
Guilonneau et al [9]	1000	15.5	31.1	89	67	–	–
Rassweiler et al [10]	500	7.4	31.8	95.2	71.6	89.5	68.2
Lein et al [27]	1000	13.6	51.5	95.4	78.6	–	–
Hara et al [28]	136	27.5	68	91.8	51	–	–
Pavlovich et al [18]	528	6.2	39.3	98.2	78.5	–	–
Touijer et al [16]	1564	–	–	–	–	83	69
ELRP							
Rozet et al [14]	600	14.6	25.6	–	–	–	–
Stolzenburg et al [15]	1300	9.8	34.3	–	–	–	–
Present series	1115	16	34.8	93.4	72.5	93.4	70.2

risk when comparing the rate of positive margins after open or LRP [9–11,20–23]. Interestingly, the rate of PSM was the most ranging variable reported in the literature (Table 4), especially in pT2 tumors (range: 6.2–27.5% in oncologic series). These discrepancies can be explained by surgical experience, patient selection, or the different surgical procedures [21]. We previously found that overall PSM rates were similar between ELRP and open procedures, although the locations for PSM were specific [23]. In our series, the surgical technique has evolved over time, especially in terms of bladder neck preservation, nerve sparing technique, and apical dissection. Our study also included a consecutive experience, starting with the first patients, and so reflects the evolution of surgical technique and includes the learning curve of each surgeon. This may help explain the relatively high rate of PSM in pT2 cancers (16%). In the largest ELRP series, Stolzenburg et al emphasized that the low PSM rates in their study (9.7% in pT2 tumors) might be partially explained by a relatively low number of patients who had undergone nerve-sparing procedures [22]. A study also showed a higher positive margin rate after LRP for junior versus experienced surgeons [24]. In our series, margins were positive in 26% of cases, including 16% and 34% of pT2 and pT3 tumors, respectively. The rate also increased within the pT2 stage (5.5% in pT2a, 10.0% in pT2b, and 19.1% in pT2c; $p < 0.001$). Rozet et al, using ELRP, reported a positive margin rate of 14.6% and 25.6% for pT2 and pT3 tumors, respectively, and found no significant differences when comparing these data with the transperitoneal approach [14]. The presence of PSM was a significant and independent predictor of PSA failure in our series. These findings were consistent with data from open and transperitoneal LRP studies [10,25,26].

ECE, SVI, and the TNM classification were strong predictors of biochemical recurrence. In pT2 cancers, recurrences were noted in 0.8% of pT2a, 6.7% of pT2b, and 4.3% of pT2c tumors with no significant differences in

terms of progression-free survival ($p = 0.062$). Multivariate analysis confirmed the independent value of each factor. These findings were hypothesized for ELRP, but no published data have confirmed them. The cancer control rates by pathologic stage were within the confidence ranges reported by centers using open procedure and transperitoneal LRP (Table 4). Patients with neoadjuvant and adjuvant therapy before relapse were excluded from the analysis because PSA failure was defined as the study end point. This selection criterion introduced a bias by excluding poor-risk men. However, as adjuvant radiotherapy was not currently used at our institution, only 47 patients were excluded from the analysis due to neoadjuvant or adjuvant therapy.

We would like to emphasize that the present study included the very first patients who had undergone ELRP and reflected the complete surgical experience of ELRP.

Prostate cancer surgery has evolved during the last 15 yr. Laparoscopy has proven safety and reproducibility in terms of oncologic and functional results. The transperitoneal technique remains the most frequent procedure for LRP. Thus, published studies have confirmed satisfactory oncologic results of the transperitoneal technique with a 3- and 5-yr follow-up [9,10,18,27,28]. To our knowledge, equal results for ELRP were assumed but had not been reported. Our findings confirmed it.

5. Conclusions

ELRP is a well-known and standardized procedure combining the advantages of laparoscopy and extraperitoneal approaches. On the basis of midterm follow-up data, our assessment confirms that the prognostic factors of PSA failure after ELRP are the same as those described previously in transperitoneal or open retroperitoneal approaches. The oncologic results of the ELRP are in line with those reported with the use of the retroperitoneal or the transperitoneal laparoscopic approaches.

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

Study concept and design: Salomon, Abbou, de la Taille.

Acquisition of data: Salomon, Hoznek, Vordos, Yiou, Ploussard, Xylinas, Paul, Gillion.

Analysis and interpretation of data: Paul, Ploussard, Nicolaiew, Salomon.

Drafting of the manuscript: Salomon, de la Taille.

Critical revision of the manuscript for important intellectual content: Salomon, Abbou, de la Taille, Ploussard.

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Editorial Comment on: Oncologic Outcome After Extraperitoneal Laparoscopic Radical Prostatectomy: Midterm Follow-up of 1115 Procedures

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Laparoscopic radical prostatectomy is coming of age, as the hopes, beliefs, and hard work of the first generation finally come to fruition. Indeed, much enthusiasm accompanied the innovative period when laparoscopic surgeons felt that the vision of and full access to the depths of the male pelvis might allow for a better radical prostatectomy both in terms of oncologic and functional outcome. Ten years later, the hypothesis is tested and the data for both transperitoneal [1] and extraperitoneal [2] laparoscopic radical prostatectomy have shown that the overall freedom from progression rates are within the same range as those obtained after open radical prostatectomy. In-depth comparisons are precluded by the methodological biases inherent in a disease known to span a wide prognostic spectrum, with the overlapping of the different risk stratification schemes used and the heterogeneity of the various definitions of treatment failure.

In this paper, Paul and coworkers reported the midterm oncologic outcome of laparoscopic radical prostatectomy performed via extraperitoneal approach. The authors used a prostate-specific antigen (PSA) cut-off of 0.2 ng/ml as treatment failure after excluding patients who received adjuvant therapy [2]. Oncologic outcome is best defined by cancer-specific survival; however, meeting such an end point in prostate cancer requires long follow-up. Accepted surrogate end points to measure treatment success have included freedom from progression defined as biochemical recurrence and/or administration of adjuvant therapy. Defining the oncologic outcome solely by PSA relapse and by excluding those who, based on aggressive pathologic features, received adjuvant therapy to help reduce an already high risk of failure introduces a selection bias and further muddies the water.

The analysis by Paul and coworkers shows that the prognosis is dictated by preoperative PSA levels, pathologic stage, Gleason grade, positive surgical margins, and lymph node status [2]. The first three factors are *immutable* and are manifestations of the biology of the disease; the last two are partially influenced by the surgical technique and represent some of the areas in which a surgeon's performance can improve and certainly can affect the

prognosis. The role of the surgeon as an independent predictor of outcome is well established [3,4]. Apart from better local control (lower positive surgical margins) and pelvic lymph node dissection, it is unclear what some surgeons do and others don't that explains the wide variation in results seen among surgeons. Perhaps it is the immeasurable individualization of care through careful matching of the surgical strategy to the requirements of the cancer.

As shown in the manuscript, the team at Henri Mondor Hospital has acquired a great deal of experience with extraperitoneal laparoscopic radical prostatectomy, but could those results be used to counsel a patient seen today at that institution? Certainly not. This data retrospectively represents the last 8 yr (2000–2007) and encompasses the effects of periods of experimentation with the technique, of transfer of knowledge among team members, and, finally, of maturation. One would expect, for example, that for the individual patient, the risk of positive surgical margin rate is perhaps much lower today at that institution than the reported rate of 26%. Yet, it is not inaccurate to assume that the low incidence of nodal metastases is underestimated and that the extraperitoneal approach is a limiting factor to performing an extended pelvic lymphadenectomy. The latter is proven to be a better staging operation [5].

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