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Oncologic outcome after extraperitoneal laparoscopic radical prostatectomy:
mid-term follow-up of 1115 procedures

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26 Word count text: 299

27 Word count text: 2460

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29 Keywords : Prostate neoplasm; Laparoscopy; Prostatectomy; Retroperitoneal; Recurrence-

30 free survival

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33 **Abstract**

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36 *Background :*

37 Although the first laparoscopic radical prostatectomy was performed in 1997, few mid-term
38 oncologic data have been published for the extraperitoneal procedure.

39

40 *Objective :*

41 To determine the oncologic outcome of extraperitoneal laparoscopic radical prostatectomy
42 (ELRP).

43

44 *Design, setting, and participants :*

45 From 2000 to 2007, 1115 consecutive patients underwent ELRP at our department for a
46 localized prostate cancer. Follow-up was scheduled and standardized for all patients and
47 recorded into a prospective database. Median postoperative follow up was 35.6 months.

48

49 *Intervention :*

50 All ELRP were performed by 3 surgeons at the Department of Urology, Hospital Henri
51 Mondor, Créteil, France.

52

53 *Measurements :*

54 Biochemical recurrence was defined by PSA greater than or equal to 0.2ng/ml.

55

56 *Results and limitations :*

57 In pN0/pNx cancers, postoperative stage was pT2 in 664 patients (59.5%), pT3 in 350
58 patients (31.4%), pT4 in 77 patients (6.9%). Positive lymph nodes were reported in 24
59 patients (2.2%). Margins were positive in 16.1% and 34.6% of p T2 and pT3 cancers,
60 respectively. Final Gleason score was <7 in 288 men (25.8%), =7 in 701 men (62.9%) and >7
61 in 126 men (11.3%). Overall PSA recurrence free survival was 83 % at 5 years. The 5-year
62 progression free survival rates were 93.4% for pT2, 74.5% for pT3a and 55.0% for pT3b
63 tumors, respectively. Multivariate Cox model showed that PSA, Gleason score, pT, nodal
64 status and surgical margins were significant independent predictors of biochemical recurrence
65 free survival.

66

67 *Conclusions :*

68 This assessment of oncologic results demonstrates that ELRP is a safe and effective
69 procedure. On the basis of mid-term follow-up data, the prognostic factors of PSA after ELRP
70 failure are the same than those described previously in transperitoneal or open retropubic
71 approaches. The oncologic results of the ELRP are in line with those reported with the use of
72 the retropubic or the transperitoneal laparoscopic approaches.

73

1. Introduction

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77 Radical prostatectomy is a standard treatment for localized prostate cancer. The first
78 laparoscopic radical prostatectomy (LRP) was performed in 1997 and was thought not to be
79 feasible because of excessive operative time [1]. However, in the following years, the
80 development of minimally invasive surgery was driven in Europe in some centres able to
81 report considerable experience and to standardize the technique [2-4]. Laparoscopic procedure
82 is actually a validated treatment modality for localized prostate cancer. Experienced surgeons
83 described various advantages of the laparoscopy [5-6]. Lower blood loss and transfusion rate
84 have been demonstrated to be the main advantages of laparoscopic surgery. Improved
85 cosmesis and shorter convalescence may also participate to increase patient acceptance of
86 surgical procedures and its resultant side effects. Functional results on continence and potency
87 appeared comparable than those obtained by open approach [7]. These benefits seem to occur
88 without sacrificing the oncologic standards established by the open approach [8-11]. Globally,
89 laparoscopy has proven to be equivalent to open procedure in radical prostatectomy.

90 However, most of published laparoscopy studies failed to address high volume experience
91 and long-term follow-up. Moreover, larger LRP series reported oncologic results of
92 transperitoneal LRP. Although the first extraperitoneal LRP (ELRP) were reported since
93 1997, few mid-term oncologic data have been published for the extraperitoneal procedure
94 [12].

95 Since 2000, ELRP is the standard surgical technique for localized prostate cancer at our
96 institution. The goal of this study was to evaluate the PSA outcomes of ELRP in order to
97 determine the mid-term oncologic safety of this procedure, and to assess these oncologic

98 results in respect to the established predictors of biochemical recurrence after radical
99 prostatectomy. To our knowledge, no study of ELRP experience has addressed the
100 biochemical recurrence-free survival according to the histoprognostic parameters.

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102

103 **2. Patients and Methods**

104

105 2.1 Patient selection.

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

115

116 2.2 Surgical procedure.

117 The surgical technique and the different steps of the surgery were previously described [13].
118 Lymphadenectomy was performed prior to the completion of the vesicourethral anastomosis
119 in case of Gleason score greater than 6 and/or PSA level greater than 10 ng/ml. Low-risk
120 patients (primary Gleason grade of 3, clinical T1c stage, PSA level <10 ng/ml) underwent
121 conventional nerve-sparing procedure. Standard lymphadenectomy (external iliac artery area)
122 was performed in 464 patients. A median of 3.5 lymph nodes per side was sampled. In
123 patients who did not undergo lymph node dissection, cancer was classified as pNx. 907
124 patients underwent a nerve sparing surgery as follows: 702 bilateral preservations and 205
125 unilateral.

126

127 2.3 Database and statistical analysis.

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

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146

147 **3. Results**

148

149 Characteristics of patients are listed in Table 1.

150

151 Mean specimen weight was 53.4 g. Postoperative stage was pT2 in 667 patients (126 pT2a, 30
152 pT2b and 511 pT2c), pT3a in 255 patients, pT3b in 110 patients, and pT4 in 83 patients.

153 Among the 83 pT4 tumors, 80 were defined as pT4 by microscopic bladder neck invasion.

154 Final Gleason score was <7 in 288 men (25.8%), =7 in 701 men (62.9%) and >7 in 126 men
155 (11.3%). Positive lymph nodes were noted in 24 patients. Overall positive surgical margin

156 rate was 26%. Margins were positive in 16.1% and 34.6% of p T2 and pT3 cancers,

157 respectively ($p < 0.001$). Margins were positive in 5.5% of pT2a, 10.0% of pT2b and 19.1% of

158 pT2c tumors ($p < 0.001$). Data are given in Table 2.

159

160 Mean and median follow-up after ELRP in our cohort was 35.3 months (± 19.8) and 35.6

161 months (range 1 to 92). 218 patients have been lost during follow-up. PSA recurrence

162 occurred in 146 patients (13.1%) with a mean of 7.9 months after ELRP (median 3.1 months;

163 range 1 to 42). The overall PSA recurrence free survival rates were 84% at 3 years and 83% at

164 5 years. Patients with biochemical recurrence were treated as follows: 41 men received

165 external radiation, 67 hormone therapy and 12 a combination of radiotherapy and androgen

166 deprivation therapy.

167

168 The 3- and 5-year recurrence free survival rates were 86.7% (95% CI: 83.3-90.1) for

169 PSA<10ng/ml, 74.1% (95% CI: 66.1-82.1) and 69.8% (95% CI: 61.0-78.6) for a PSA level

170 ranging from 10 to 20 ng/ml, and 47.5% (95% CI: 32.3-62.7) for PSA \geq 20ng/ml (Figure1).

171 Curves were statistically different ($P < 0.0001$).

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

177 Patients with positive surgical margins had a progression free survival rate of 56.6% (95% CI:
178 48.2-65.0) at 5 years compared to 89.0% (95% CI: 85.6-92.4) for those with negative surgical
179 margins. Surgical margin status was predictor of PSA recurrence with the log-rank test ($P <$
180 0.0001) (Figure 3).

181 According to the pathological stage, 5-year progression free survival rate was 93.4% (95%
182 CI: 90.6-96.2) for pT2 cancers, 70.2% (95% CI: 63.8-76.6) for pT3 cancers and 42.7% (95%
183 CI: 27.9-57.5) for pT4 cancers ($P < 0.0001$) (Figure 4). The 5-year progression free survival
184 rate was 98.3% in pT2a tumors, compared with 88.9% and 92.5% in pT2b and pT2c tumors,
185 respectively ($p=0.062$).

186 When analysis was stratified by pathological stage and margin status, the 5-year progression
187 free survival rate was 96.9% for pT2 with negative surgical margins. Similar 5-year
188 progression free survival rates were noted in pT2 with positive surgical margins and pT3a
189 with negative surgical margins (76.6% and 81.6%, respectively, $P=0.26$; figure 5).

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

193 The multivariate Cox proportional hazard model showed preoperative PSA, Gleason score,
194 tumour stage, nodal status and surgical margins were significant independent predictors of
195 biochemical recurrence free survival. Hazards ratios and p values are listed in Table 3.

196

197

198 **4. Discussion**

199

200

201 Radical prostatectomy is a standard treatment for localized cancer prostate. Open approach
202 has proven oncologic safety with extraperitoneal access as standard of care. Laparoscopy
203 radical prostatectomy was introduced to combine the advantages of laparoscopy without
204 compromising the oncologic results of open surgery. Thus, the development of minimally
205 invasive surgery was driven in Europe in some centres able to report considerable experience
206 and to standardize the technique. In terms of oncologic follow up, laparoscopic radical
207 prostatectomy is now approaching 10 years. Some laparoscopy centres have yet published 3-
208 year and 5-year outcomes. However, most of these series reported mid-term oncologic
209 experience of the transperitoneal approach. Concerning the ELRP, Rozet et al. showed
210 equivalent operative, postoperative and pathological results when comparing the
211 extraperitoneal and the transperitoneal approach [14]. Stolzenburg and coworkers also
212 reported interesting results of ELRP in terms of operative parameters and surgical margin rate
213 [15]. However, these studies failed to address PSA failures and the impact of classical
214 histoprognostic parameters.

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

220

221 Transperitoneal LRP studies have demonstrated that laparoscopy had the potential to give
222 good functional results with equal oncologic effectiveness [9-10]. Guillonnet et al. reported

223 the oncologic outcome of 1000 patients after transperitoneal laparoscopic radical
224 prostatectomy with an overall actuarial biochemical PSA-free survival between 88% and 92%
225 for pT2, and between 44% and 77% for pT3 at 3 years [9]. Recently, this series has been
226 updated [16]. Rassweiler et al reported a PSA-free survival at 89.5% for pT2 and 68.2% for
227 pT3 at 5 years [10]. These cancer control rates by pathologic stage are within the confidence
228 ranges reported by other centres (table 4). Comparatively, the progression free survival was
229 85% at 5 years in our series (98% and 77% for pT2 and pT3 respectively).

230 Our findings supported evidence of the impact of preoperative PSA level on the risk of
231 postoperative biochemical recurrence after ELRP. Our results were in line with the well-
232 known results of open and transperitoneal laparoscopic approaches. Han et al reported 5-year
233 progression-free survival rates of 94% for PSA 0 to 4 ng/ml, 89% for PSA 4.1 to 10 ng/ml,
234 73% for PSA 10 to 20 ng/ml and 60% for PSA greater than 20 ng/ml [17]. For Pavlovich et
235 al, preoperative PSA were associated with the 3-year biochemical recurrence-free survival
236 (PSA 10ng/ml or greater versus greater than 10 ng/ml) [18].

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

242 It has been postulated that LRP resulted in a higher rate of positive surgical margins. Recent
243 studies could not detect any specific oncologic risk when comparing the rate of positive
244 margins after open or laparoscopic radical prostatectomy [9-11,20-23]. Interestingly, the rate
245 of PSM was the most ranging variable reported in the literature (Table 4), especially in pT2
246 tumors (ranges from 6.2% to 27.5% in oncologic series). These discrepancies can be
247 explained by surgical experience, patient selection or the different surgical procedures [21].

248 We previously found that overall PSM rates were similar between ELRP and open procedures
249 although the locations for PSM were specific [23]. In our series, the surgical technique has
250 evolved across time, especially in terms of bladder neck preservation, nerve sparing technique
251 and apical dissection. Our study also included a consecutive experience starting with the first
252 patients and so, reflecting the evolution of surgical technique and including the learning curve
253 of each surgeon. This particularity might contribute to explain the relatively high rate of PSM
254 in pT2 cancers (16%). In the largest ELRP series, Stolzenburg et al emphasized that the low
255 PSM rates in their study (9.7% in pT2 tumors) might be partially explained by a relatively
256 low number of patients who had undergone nerve sparing procedures [22]. A study also
257 showed a higher positive margin rate after laparoscopic radical prostatectomy for junior
258 versus experienced surgeons [24]. In our series, margins were positive in 26% of cases,
259 including 16% and 34% of pT2 and pT3 tumors, respectively. The rate also increased within
260 the pT2 stage (5.5% in pT2a, 10.0% in pT2b and 19.1% in pT2c; $p < 0.001$). Rozet et al, with
261 the use of ELRP, reported a positive margin rate of 14.6% and 25.6% for pT2 and pT3
262 tumors, respectively and found no significant differences when comparing with the
263 transperitoneal approach [14]. The presence of positive surgical margin was a significant and
264 independent predictor of PSA failure in our series. These findings were consistent with data
265 from open and transperitoneal LRP studies [10,25-26].

266 Extracapsular extension, seminal vesicle invasion and the TNM classification were strong
267 predictors of biochemical recurrence. In pT2 cancers, recurrences were noted in 0.8% of
268 pT2a, 6.7% of pT2b and 4.3% of pT2c tumors with no significant differences in terms of
269 progression free survival ($p = 0.062$). Multivariate analysis confirmed the independent value of
270 each factor. These findings were hypothesized in ELRP but no published data have confirmed
271 it. The cancer control rates by pathological stage were within the confidence ranges reported
272 by centres using open procedure and transperitoneal LRP (Table 4). Patients with neoadjuvant

273 and adjuvant therapy before relapse were excluded from the analysis because PSA failure was
274 defined as the study endpoint. This selection criterion introduced a bias by excluding poor
275 risk men. However, as adjuvant radiotherapy was not currently used at our institution, only 47
276 patients were excluded from the analysis due to neoadjuvant or adjuvant therapy.

277 We'd like to emphasize that the present study included the very first patients who had
278 undergone ELRP, and reflected the complete surgical experience of ELRP.

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

285

286 **5. Conclusions**

287

288 Extraperitoneal radical laparoscopic prostatectomy is actually a well-known and standardized
289 procedure, combining the advantages of laparoscopy and extraperitoneal approaches. On the
290 basis of mid-term follow-up data, our assessment confirms that the prognostic factors of PSA
291 failure after ELRP are the same than those described previously in transperitoneal or open
292 retropubic approaches. The oncologic results of the ELRP are in line with those reported with
293 the use of the retropubic or the transperitoneal laparoscopic approaches.

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