



European Association of Urology



Review – Prostate Cancer

Laparoscopic Radical Prostatectomy: A Critical Analysis of Surgical Quality

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Article info

Article history:

Accepted January 11, 2006

Published online ahead of
 print on January 31, 2006

Keywords:

Prostate
 Neoplasms
 Laparoscopy

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Abstract

Objective: To review the literature and answer the question of whether the laparoscopic approach meets the quality standards.

Methods: We conducted an extensive Medline literature search. The articles obtained and the experience at Memorial Sloan-Kettering Cancer Center were used for interpretation and critical analysis of results. Long-term quality indicators are oncologic efficacy, potency rate, and continence rate. Short-term quality indicators are blood loss and transfusion rate, hospital stay, postoperative recovery, and rate and severity of complications.

Results: Long-term quality indicators. Oncologic efficacy. Despite recent evidence that pelvic lymph node dissection (PLND) at radical prostatectomy may be necessary to detect occult positive lymph nodes, and that extended node dissection may also have a positive impact on disease-free survival, PLND is rarely performed during laparoscopic radical prostatectomy (LRP), which may have a negative impact on the long-term recurrence-free probability. Positive margins rates range from 11% to 26%, ranging from 6% to 8% for organ-confined disease and from 35% to 60% in those with extraprostatic extension. Most of these data include the first patients operated on when the technique of LRP was in early development. These rates seem high as compared to the contemporary data achieved in retropubic radical prostatectomy.

Short-term biochemical recurrence rate have been published by only two centers and generalization to the whole laparoscopic patients and to long-term results are at present time hazardous. **Functional outcome.** Given the complexity of measuring, interpreting, and reporting continence and erectile dysfunction, the available results after LRP do not allow drawing any conclusion. Furthermore, the number of patients on whom results are reported is disproportionately low in relation to the large LRP experience accumulated so far.

Short-term quality indicators. Assessment of LRP equanimity includes factors such as blood loss, transfusion rates, hospital stay, duration of catheterization, and complication profile. All the reports are concordant and demonstrate a benefit for the laparoscopic approach. However, no prospective and parallel studies compare the respective advantages of LRP and radical retropubic prostatectomy in reference centers.

Conclusions: In a review of the published literature results of LRP, there is not enough evidence to answer the question of whether the laparoscopic approach meets the quality standards. The available biochemical recurrence information is promising but limited to the short-term and the experience of two centers only. The question of omitting the PLND or performing a limited one in high-risk patients needs to be answered. The functional results analyses suffer from a lack of uniformity in methodology, a limited follow-up, and a disproportionately small number of patients in relation to the accumulated experience. Future reports of the post-learning phase era are dramatically needed.

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1. Introduction

The feasibility, reproducibility, and teachability of laparoscopic radical prostatectomy (LRP) are proven through its worldwide use [1-9]. The technique is well established and is beyond the transition period from the initial experience of the pioneer laparoscopic surgeons. The questions remain now that the technique is reaching maturity: How is it performing and how do we measure the quality of an LRP?

The goal of modern radical prostatectomy is to excise all cancer with the least morbidity and chance for a full recovery of continence and potency. This aim is a formidable and challenging task and has resulted in a number of technical innovations contributing to the great strides realized in the surgical treatment of clinically localized prostate cancer [1,10-12]. Such an innovation is the use of the laparoscopic approach in performing radical prostatectomy [1,12] with the aspiration that LRP will equal other approaches in terms of oncologic efficacy and functional outcome but yet surpass them in regard to convalescence and short-term morbidity.

For this review, we propose a set of short- and long-term or principal quality indicators to measure the performance of LRP. The long-term quality indicators are oncologic efficacy (biochemical recurrence rate and disease-specific survival, but by default the predicting factors of biochemical recurrence influenced by the surgical technique: positive surgical margin status and lymph node status), potency rate, and continence rate. The short-term quality indicators are blood loss and transfusion rate, hospital stay, postoperative recovery, and rate and severity of complications. The three principal quality indicators are inextricably linked and in our opinion should always be reported together. The short-term parameters, on the other hand, will only gain importance when the long-term parameters have been successfully achieved.

2. Methods

We conducted an extensive Medline literature search (search terms "laparoscopic radical prostatectomy" and "radical prostatectomy") from 1990 through 2005; only full-length English and French language articles identified during this search were considered for this analysis. The articles obtained under the search term "laparoscopic radical prostatectomy" and our experience (January 2003 until present) at Memorial Sloan-Kettering Cancer Center (MSKCC) were used for interpretation and critical analysis of results. A preference was given to the articles with larger series (>100 patients). The laparoscopic results were interpreted as whole regardless of the technical differences (transperitoneal versus extraperito-

neal, antegrade versus retrograde dissection, number, disposition or size of the surgical ports, etc).

The articles obtained under the search term "radical prostatectomy" were used for argumentation purposes.

3. Results

3.1. Long-term quality indicators

3.1.1. Oncologic efficacy

Oncologic efficacy is best measured by disease-specific survival; however, given the fact that LRP has only been regularly performed since 1998, information about long-term follow-up is unavailable. The surrogate to disease-specific survival is the biochemical recurrence rate. The latter is certainly affected by two parameters that are also directly affected by the surgeon and the surgical technique: positive surgical margin rate and nodal status. The nodal status as a quality indicator is worth discussing because the indication and anatomic limits of the pelvic lymphadenectomy performed concomitantly with LRP can be highly variable among surgeons or institutions.

3.1.2. Nodal status

The presence of lymph node metastasis portends a poor prognosis. Accurate identification of men with nodal metastasis allows a better prognostication and helps with initiation of adjuvant therapy. The advent of prostate-specific antigen (PSA) and aggressive screening has led to a downward stage migration of prostate cancer with a significant decrease in the incidence of nodal metastasis at the time of initial therapy. These findings led a number of surgeons to forego pelvic lymphadenectomy during radical prostatectomy and only select men with high-risk features to undergo a lymph node dissection (LND). However, recent data suggest that extended LND at radical prostatectomy may be necessary to detect occult positive lymph nodes and that extended node dissection may also have a positive impact on disease-free survival [13-17]. Moreover, immunohistochemical analyses using reverse transcription-polymerase chain reaction (RT-PCR)-based assay for PSA mRNA and prostate-specific membrane antigen detect more lymph node micrometastases that were undetectable by conventional pathologic methods [18-21]. Instead of omitting pelvic lymphadenectomy, in our opinion, the field should probably place emphasis on performing an extended node dissection in order to:

1. Give a therapeutic benefit and a chance for cure to those men with nodal micrometastasis involving

one lymph node only without extracapsular involvement.

2. Help in reducing the number of patients with pathologically organ-confined disease with unknown nodal status who go on to develop biochemical recurrence.

A review of the laparoscopic literature shows variability in the indications and rate of pelvic lymphadenectomy. The Montsouris group selected for lymphadenectomy patients with cT2b, PSA level >10, predominant Gleason 4, and more than three of six positive biopsy cores. In their experience with 1000 patients, 216 patients underwent lymphadenectomy (21.6%) and 6 had nodal metastases (0.6%) [22]. Stolzenburg et al., in a multi-institutional study from Germany, performed LND on patients with PSA level >10 ng/ml or Gleason sum >6. This selection resulted in 266 pelvic LNDs (38%) with metastases detected in 14 patients (2%) [23]. The Heilbronn group performed a lymphadenectomy limited to the obturator fossa in 417 of 500 patients (83.4%) yielding a median nodal count of six with a 1.2% positivity rate [24].

We recently compared our experience of limited versus extended (external iliac, obturator, and hypogastric nodal groups) LND during LRP and found that on multivariate logistic regression analysis, controlling for PSA, biopsy Gleason, clinical stage, pathologic Gleason, pathologic stage, and seminal vesicle invasion, the extended LND independently affected the rate of node positivity with a relative risk (RR) of 21.2 (95% confidence interval [CI], 3.4–133, $p = 0.001$). Other independent predictors of node positivity were seminal vesicle invasion (RR, 42.6; 95%CI, 3.9–462; $p = 0.002$) and clinical stage T3 versus T1c (RR, 14.7; 95%CI, 2–109; $p = 0.008$). The median (mean) number of nodes retrieved was 9 (10) and 14 (15) after limited and extended LND, respectively ($p < 0.001$). We concluded that an LND including the external iliac, obturator, and hypogastric lymph node groups yields positive nodes more frequently and retrieves a higher total nodal count than the often-performed LND limited to the external iliac nodes. Others using open radical prostatectomy had similar findings [13–16].

3.1.3. Positive surgical margin rate

A positive surgical margin is defined as presence of cancer at the inked margin of resection on the prostatectomy specimen [25]. The prognostic significance of a positive surgical margin is a higher risk of biochemical, local, and systemic progression [26–29].

The factors shown to influence the positive surgical margin rate are the preoperative serum PSA level, Gleason grade, clinical stage, the surgeon and surgical technique, and patient selection [29,30]. There are only three large series of LRP that report the pathologic and oncologic results on 500 patients or more. First, the Montsouris group reported on the first 1000 patients with an overall positive surgical margin rate of 19.2%, 15.5% for pT2 and 31% for pT3 disease [22]. The Heilbronn clinic experience with 500 patients reported an overall positive surgical margin rate of 19%, 7.4% for pT2 and 31.8% for pT3 disease [24]. Both of these series report the results of high-volume institutions; however, the report includes the first patients operated on during the trial and tribulation period, when the technique of LRP was in early development and the surgeons were either developing the technique or learning its application. In a third large series of 700 extraperitoneal LRPs performed between December 2001 and November 2004, the reported positive margin rate for pT2 was 10.8%, 31.2% for pT3 tumors with an overall rate of 19.8% [23].

As the technique matures, the positive surgical margin rate is expected to decrease. Similar to what was seen with the open approach, the positive surgical margin rate was decreasing gradually as improvement and surgeons' expertise with the technique along with a downward stage migration took place, setting the standard for acceptable positive surgical margin rate at around 10%. The most recent experience of nearly 500 LRPs performed at MSKCC between January 2003 and June 2005 shows an overall positive surgical margin rate of 11%, 8.2% for pT2 and 17.2% for pT3 disease. In this contemporary series, there was a statistically significant decreasing rate of positive surgical margins over time without any evidence of downward stage migration. This decrease in positive surgical margins was seen in both organ-confined and non-organ-confined disease and was attributed to an institutional multidisciplinary continuous quality improvement program [31]. Others have, with smaller experiences, reported overall positive surgical margin rates ranging from 11% to 26%; this rate ranged from 6% to 8% for organ-confined disease and from 35% to 60% in those with extraprostatic extension [5,32–35].

3.1.4. Biochemical progression-free rate

PSA recurrence is used to assess cancer control. Interpretation of results needs to consider the PSA cut-off used to define failure or recurrence. Different experiences of radical prostatectomy reported biochemical-free results with a PSA cut-off ranging from 0.1 to 0.4 ng/ml and rising [22,24,29,36].

Table 1 – Oncologic results

Year	Institution [reference]	No. of patients	Overall PSM	PLND	Positive lymph nodes/type	Median nodal count	Freedom from progression
2003	Montsouris [22]	1000	19.2%	21.6%	0.6%	–	90.5% at 3 yr
2005	Heilbronn [24]	500	19%	83.4%	1.2% limited	6	83% at 3 yr 73.1% at 5 yr
2005	Multicentric German study [23]	700	19.8%	38%	2%	–	–
2005	MSKCC [31]	485	11%	62%	1.6% limited 7% extended	9 limited 14 extended	–

PSM = positive surgical margins; PLND = pelvic lymph node dissection.

Although the data continue to mature for LRP series, the short-term biochemical-free recurrence results appear similar to those reported in the open radical prostatectomy experience. The cancer control outcomes reported by the team from Montsouris on 1000 men showed a 3-yr actuarial biochemical recurrence-free probability of 90.5%; progression was defined as a PSA level >0.1 ng/ml and confirmed by a second increase, even between 0.1 and 0.19 ng/ml. The freedom from progression by stage was 91.8% for pT2aN0/Nx, 88% for pT2bN0/Nx, 77% for pT3aN0/Nx, 44% for pT3bN0/Nx, and 50% for patients with nodal metastases [22]. Recently, the Heilbronn group reported an overall freedom from biochemical progression of 83% at 3 yr and 73.1% at 5 yr. In their series, progression was defined as two PSA values >0.2 ng/ml [24] (Table 1).

These results merely represent the short-term biochemical recurrence rate of just two centers. Generalizing these findings and concluding that LRP meets the quality standards in regard to oncologic results will be pure extrapolation given the worldwide use of LRP. Without a way of critically appraising all the evidence for lack of availability, more time is perhaps needed to allow other teams to review their experience of long-term survival and freedom from biochemical and clinical progression after LRP.

3.1.5. Functional outcome

The lack of uniformity in defining, assessing, and reporting functional results following radical prostatectomy in general leads to a disparity of results among different series. The definition used, the methodology by which the data are gathered and analyzed, and the time of assessment need to be considered while the results of potency and continence postoperatively are interpreted. This may preclude any comparative analyses among series.

3.1.6. Continence

Using the validated International Continence Society questionnaire, the Montsouris group reported on a

series of 255 patients with 12-mo follow-up after LRP; 209 patients (82.3%) were pad free, 31 (12%) needed one pad a day, and 15 patients (5.9%) had urinary incontinence requiring more than two pads a day [37]. Stolzenburg et al., using the same validated questionnaire, reported the results on 700 extraperitoneal LRPs performed between December 2001 and November 2004. Among 500 patients who had 6 mo follow-up, 419 patients (83.8%) were pad free, 52 (10.4%) needed one to two pads a day, and 29 patients (5.8%) had urinary incontinence requiring more than two pads a day [23].

Link et al. reported their results of health-related quality of life after LRP using the Expanded Prostate Cancer Index Composite (EPIC), a reliable and validated instrument with prostate targeted items. Of the 122 men included in the analysis, 45 had a 12-mo follow-up. The urinary domain score at 12 mo was 94% of baseline. When the authors used a single-method question and defined continence as no pads required, 66.7% of their patients were considered continent at 12 mo [38].

Rassweiler et al. reported an experience of 450 LRPs; among the 300 men with 12-mo follow-up, the continence rate was 91%. However, the authors did not state the definition of continence or the methodology of measurement used in their analysis [39]. Similarly, others reported 90% and 91% continence rates [5,40].

The wide variability of continence rate at 12 mo after LRP (66.7–91%) demonstrates, in part, the impact of the heterogeneity of methodology on the results, with lower rates in the series using validated instruments to measure continence. This discrepancy has been shown before in the open radical prostatectomy literature as well. Stanford et al. measured changes in urinary function in 1291 men who have undergone radical prostatectomy for clinically localized prostate cancer as part of the Prostate Cancer Outcomes Study (PCOS), a population-based longitudinal cohort study with up to 24 mo of follow-up, and found that at 12 mo postoperatively, only 31% reported having total urinary

control and 60.5% were pad free and 14.3% estimated that their urinary incontinence represents a moderate to big problem [41]. These results are also far worse than the one assessed by other methodologies. Laparoscopy as an approach to performing radical prostatectomy may not be responsible for different continence rates than the one seen with other approaches; however, the surgical technique will matter, and technical refinement has been shown to result in better continence rates [42].

In summary, given the complexity of measuring, interpreting, and reporting continence, the available results after LRP are not better or worse and suffer from the same biases as prior experiences. However, the number of patients on whom results are reported is disproportionately low in relation to the large LRP experience accumulated so far.

3.1.7. Potency

Preoperative potency, extent of neurovascular bundle preservation, and patient age were significant predictors of potency after radical prostatectomy and along with the use of phosphodiesterase type 5 (PDE5) inhibitors need to be considered when interpreting the potency results.

Most series of LRP include potency data only on a small subset of patients, usually treated after the techniques of LRP and neurovascular bundle preservation were mastered. Stolzenburg et al., using the International Index of Erectile Dysfunction (IIEF) to measure post-LRP potency, reported their experience with 700 extraperitoneal LRPs. The follow-up was 6 mo and nerve sparing was performed in 185 preoperatively potent patients (26.4%), unilaterally in 114 patients (16.2%) and bilaterally in 71 (10.1%). At 6 mo, 8 of 66 men with unilateral (12.1%) and 16 of 34 with bilateral nerve preservation (47.1%) had erections sufficient for intercourse with or without the help of PDE5. Baseline and postoperative IIEF scores were not reported [23]. Using question 3 (“How often were you able to obtain an erection to be able to penetrate your partner?”) and question 4 (“How often were able to maintain your erection after you had penetrated your partner?”) of the IIEF to determine potency, Roumeguere et al. reported a 65.3% 1-yr potency rate in 26 preoperatively potent men who underwent bilateral nerve sparing [43]. Evaluating potency with the EPIC questionnaire, Link et al. reported a decrease to 64% of baseline at 12 mo for both the sexual function and bother subdomains. In the same experience, using a single question to determine potency (“During the last 4 weeks, how often did you have sexual intercourse?”), the potency rate was 78.9% at 12 mo in a subgroup of 50 preoperatively potent men who

underwent bilateral nerve sparing. Of note, most patients used PDE5 and 10.7% were using vacuum erection devices, pharmacologic injection therapy, or transurethral alprostadil postoperatively. The latter group of patients was asked to assess sexual function without such therapy [38].

Of their initial 550 patients, the Montsouris group reported data on a subset of 47 consecutive patients younger than 70 years of age. Of those patients who were preoperatively potent and who had bilateral nerve sparing LRP, 31 (66%) were able to have intercourse with or without PDE5 [37]. Rassweiler et al. reported in their first 180 LRP series, 10 patients with nerve sparing (2 bilateral and 8 unilateral). Four patients had “sufficient erections with sildenafil” [39]. Katz et al. reported on 143 preoperatively potent patients; 26 responded to the questionnaire at 12 mo and 23% had had sexual intercourse with any erectogenic therapy. The questionnaire used was a nonvalidated set of 3 questions with “yes” and “no” answers [44].

Two points become obviously clear when reviewing the published potency results after LRP. First, neurovascular bundle preservation, rather than predominating, constitutes a minority in each reported experience. Subsequently, potency data comprise only a small number of patients in each series. Second, the available results, although interesting, do not represent the current status of LRP. Now that the technique is beyond the learning phase, the LRP literature is due for more substantial functional results.

3.2. Short-term quality indicators

3.2.1. Equanimity

Assessment of LRP equanimity includes factors such as blood loss, transfusion rates, hospital stay, duration of catheterization, and complication profile.

One of the greatest advantages of LRP is its lower intraoperative blood loss and intraoperative and postoperative transfusion rate. The Montsouris group reported a mean blood loss of 380 ml and an allogeneic transfusion rate of 4.9% with no autologous blood transfusion for all 550 patients. In the last 350 patients, the mean blood loss and transfusion rate declined to 290 ml and 2.6%, respectively [37]. Eden et al. reported a mean blood loss of 313 ml and an allogeneic transfusion rate of 3% [5]. The average reported blood loss after LRP is 430 ml (103–1110 ml). The wide range may be explained by variability in the technique. Rassweiler et al. reported the highest mean blood loss with an average of 1110 ml and a transfusion rate of 30% for

their initial 219 patients and 800 ml with a 9.6% transfusion rate for the last 219 patients [45]. The authors attributed the relatively higher blood loss and transfusion rate in their series to difficulties encountered with the ascending technique, which includes early dissection and ligation of the dorsal vascular complex, followed by a transection of the urethra, a step that is performed last in the retrograde approach [12].

Data regarding the length of hospital stay and postoperative hospital readmission, which could reflect the immediate postoperative convalescence, needs to be interpreted within the specific health care standards of each country. The expected duration of hospitalization varies greatly between Europe and the United States and the rate of readmissions is unknown.

Various durations of catheterization after LRP have been tried, ranging from 2 to 10 d. Early removal of the catheter may subject the patients to urinary retention. Nadu et al. reported a 10.4% urinary retention when the catheter was removed between 2 to 4 d postoperatively [46], but a catheterization time as long as 10 to 14 d may be unnecessary. It seems that the average duration of catheterization after LRP is around 7 d.

The true incidence of anastomotic leaks after LRP is uncertain because most small leaks remain undiagnosed and resolve spontaneously with bladder drainage. After transperitoneal LRP a leak is usually manifested by back pain, uroperitoneum, and ileus with laboratory signs of urine reabsorption. The reported incidence after LRP ranges from 1% to 10% [4,47]. On the other hand, anastomotic strictures are a rare event after LRP (0–3.3%) [47–49]. This low incidence may be attributed to a tension-free anastomosis and a good mucosa-to-mucosa approximation between the bladder and the urethra.

Complication rates after LRP have varied significantly from 3.6% to 34% [4,6,37,45,48,50,51]. Unclear and nonstandardized reporting makes interpretation of the reported data difficult and the effect of the learning phase skews the results strongly. In a comprehensive description of the incidence and types of complications after 567 LRPs performed over a 3-yr period at Montsouris, the total, major, and minor complication rates were 17.1%, 3.7%, and 14.6%, respectively. Major complications requiring reoperation were bowel or rectal injury in 1% of cases, hemorrhage in 1%, and ureteral injuries in 0.3% [47].

Rectal injury is a potential severe complication of radical prostatectomy, occurring between 1% and 2% of LRP cases, often during the apical dissection

during a wide excision of the prostate. When recognized intraoperatively and adequately repaired, a rectal injury is of no consequence; however, a missed rectal injury can result in fistulae, peritonitis requiring reoperation, and temporary colostomy [45,49,52,53].

4. Conclusion

In review of the published literature results of LRP, evidence is insufficient to answer the question of whether the laparoscopic approach meets quality standards.

The available biochemical recurrence information is promising; however, it is limited to the short-term and the experience of two European centers only. The question of omitting the pelvic LND or performing a limited one in high-risk patients needs to be revisited as data from the open radical prostatectomy literature shows a clear staging and therapeutic advantage in favor of the extended LND. Avoiding a pelvic lymphadenectomy may and most likely will affect the oncologic efficacy of radical prostatectomy.

The functional results analyses, on the other hand, suffer from a lack of uniformity in methodology, a limited follow-up, and a disproportionately small number of patients in relation to the accumulated experience, thus precluding any sound assessment of how LRP prostatectomy is performing in terms of quality of life outcomes. Future reports of the post-learning phase era are dramatically needed.

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