

Is Laparoscopic Radical Prostatectomy Better Than Traditional Retropubic Radical Prostatectomy? An Analysis of Peri-Operative Morbidity in Two Contemporary Series in Italy

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Abstract

Objective: To compare morbidity in two groups of patients who underwent retropubic or laparoscopic radical prostatectomy in the same period.

Patients and Methods: The clinical and pathological data obtained in 50 consecutive patients who underwent retropubic radical prostatectomy (RRP) from January 2001 to December 2001 were compared to those obtained in 71 consecutive patients who were treated in the same year by extraperitoneal laparoscopic radical prostatectomy (LRP). The two groups were comparable in terms of mean pre-operative PSA and biopsy Gleason score. The peri-operative data included operative time, intra-operative and post-operative transfusion rates, complication rates, hospitalization length, and duration of catheterization. The following pathological parameters were considered: Gleason score, pathological stage, and positive surgical margin rate. A comparative evaluation of continence recovery (no pads and any leakage) was made only in patients with follow-up longer than 12 months.

Results: The two groups were comparable in terms of pathological stage and definitive Gleason score. Operating times were significantly shorter in RRP ($p < 0.0001$). LRP patients showed higher autologous ($p < 0.001$) and eterologous transfusion ($p = 0.03$). No significant difference was observed in terms of complication rates ($p = 0.07$). The rectal injury rate was 2.8% in the laparoscopic group. The mean post-operative hospital stay was 10.2 ± 2 days in the surgery group and 7.2 ± 3.4 days in the laparoscopy group ($p < 0.001$). Catheterization time was 8.4 ± 0.9 days in the surgery group and 8 ± 2.8 days in the laparoscopy group ($p = 0.27$). After 12 months, complete continence was achieved in 64% of RRP and 40% of LRP patients, respectively ($p = 0.29$).

Conclusion: The results of our non-randomized study show that up to now laparoscopic radical prostatectomy does not provide significant advantages in terms of peri-operative morbidity compared with the traditional retropubic approach.

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Keywords: Retropubic radical prostatectomy; Laparoscopic radical prostatectomy; Localized prostate cancer; Morbidity

1. Introduction

Radical retropubic prostatectomy (RRP) is currently the “gold standard” of surgical treatment for clinically localized prostate cancer. This surgical technique was first described by Millin in 1945 and has since gained

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widespread application worldwide, particularly in its “anatomic” version, which was described by Walsh et al. in 1983 [1]. Over the years, there has been a significant reduction in the morbidity and mortality associated with this procedure [2]. The oncological efficacy of RRP has been shown by several clinical trials with long-term follow-up [3–5].

The first extraperitoneal laparoscopic radical prostatectomy was reported by Raboy et al. in 1997 [6]. During the same year, Schussler et al. published the results of nine transperitoneal laparoscopic radical prostatectomies [7]. The long operative times and the associated complication rates reported were a limit of the technique until 1999, when technical improvements allowed shorter operating times [8].

Up to now, the published papers have shown the feasibility of laparoscopic radical prostatectomy (LRP) and led to increasing interest in this modern approach to localized prostate cancer treatment. According to those who support laparoscopy, it can reduce treatment morbidity, hospitalization and, because of the optical magnification, it can be a potential advantage in terms of continence and erectile function preservation [9–12]. LRP is currently a reasonable alternative in the treatment of localized prostate cancer. However, whether this new technique is better than traditional RRP is still unclear. In our opinion the answer cannot be given on the basis of clinical studies, which compare modern LRP to historical RRP group [13].

The aim of this paper is to compare morbidity in two groups of patients who underwent retropubic or laparoscopic radical prostatectomy in the same period.

2. Patients and methods

The clinical and pathological data obtained in 50 consecutive patients who underwent retropubic radical prostatectomy (RRP) at the Department of Urology, University of Verona from January 2001 to December 2001 were compared to those obtained in 71 consecutive patients who were treated in the same year by extraperitoneal laparoscopic radical prostatectomy (LRP) at the Unit of Urology, Hospital of Villafranca, Verona.

All RRP procedures were performed by one experienced surgeon (W.A.). All laparoscopies were carried out by one laparoscopist (G.G.), who was out of his learning curve (more than 60 transperitoneal LRPs performed over the previous years).

2.1. Radical retropubic prostatectomy

We performed a median 12-cm long infraumbilical prepubic incision. Vasa deferentia were ligated and sectioned in their pelvic tract, after inguinal ring emergence. Pelvic lymphadenectomy was performed in all patients and it always included external iliac and obturator lymph nodes. The prostate was mobilized by lateral incision of the endopelvic fascia on its line of reflection, along the levator ani muscle. The dorsal venous complex was ligated and

sectioned using the “bunching technique” [14]. Pubo-prostatic ligaments were spared. The urethral wall was then incised just under the prostate apex with a cold knife under visual control. Once the rectourethralis was sectioned, the plane between Denonvilliers fascia and the anterior rectal wall was developed. This was followed by ligation and section of the prostatic pedicles, release of seminal vesicles, and section of vasa deferentia. The intentional preservation of the neurovascular bundles was not performed in any case.

The bladder neck was dissected and a racket handle reconstruction was performed. Using a 3-0 suture, the bladder mucosa was everted with interrupted sutures. A urethro-vesical anastomosis was made with 6 interrupted 2-0 Vycril sutures. A further suture was placed between the posterior urethral wall and the external bladder neck to reduce anastomosis tension. To preserve the anastomosis a 22 Ch catheter was placed.

2.2. Extraperitoneal laparoscopic radical prostatectomy

Pelvic lymphadenectomy was not routinely performed in patients with PSA <10 ng/ml and biopsy Gleason score <7. The patient was in a dorsal supine position. A small pillow was placed under the pelvis. A 1-cm lower umbilical incision was made, thus introducing a finger in the pre-peritoneal space. The working space was enlarged using a balloon. Four trocars were usually put in place. The first 10-mm trocar was put in the incision following the Hasson technique; and left for the laparoscope. A second 12-mm trocar was placed along the umbilical-iliac line, medially to the right upper anterior iliac crest, and a third 5-mm trocar was placed symmetrically in the left iliac fossa. The fourth 5-mm trocar was introduced in the right pararectal fossa along the transverse umbilical line, near the right margin of the rectal line. The endopelvic fascia was exposed and incised bilaterally. The deep venous complex was ligated with a 2-0 Monocryl suture. A vesico-prostatic plane was then developed and the bladder neck was dissected following the neck sparing technique. The postero-upper prostatic pedicles were incised, the vasa deferentia were ligated and sectioned, and the seminal vesicles were freed. The Denonvilliers fascia was then opened and the posterior surface of the prostate was isolated descending from the rectal wall. The neurovascular bundles were spared bilaterally in 9 cases and monilaterally in 9 cases. The pubo-prostatic ligaments and deep venous complex were sectioned. The urethra was sectioned under the prostatic apex and a Benique catheter was introduced to facilitate the uretrovesical anastomosis. The anastomosis was performed using 3 running sutures. An in-dwelling catheter was placed just before completing the anterior suture. The specimen was extracted using a laparoscopic bag through an enlargement of the infra umbilical incision. The incisions were closed in the usual fashion.

2.3. Evaluated parameters

The peri-operative data included operative time, intra-operative and post-operative transfusion rates, complication rates, hospitalization length, and duration of catheterization. The following pathological parameters were considered: Gleason score, pathological stage, and positive surgical margin rate.

The specimens obtained during RRP were processed according to the Stanford procedure [15]. After fixation in 10% formalin, the surface was inked and the whole specimen was cut into 2 to 3-mm-thick sections. The apical area was amputated and cut in perpendicular sections. The bladder neck was sectioned along the sagittal plane and the remaining specimen was sectioned transversally. A single pathologist reviewed all the slides.

The specimen after LRP was cut into 4 to 6-mm thick sections according to a different protocol. The slides were reviewed by one other pathologist.

During follow-up, PSA was sampled every 3 months. Biochemical progression was defined by PSA values >0.3 ng/ml. All the patients who underwent adjuvant therapy because of unfavourable prognostic factors were excluded by the biochemical progression analysis.

A cross-sectional comparative evaluation of continence recovery was made only in patients with follow-up longer than 12 months [16]. All the patients who needed no protection system were considered as continent. Data on continence recovery were reported also in terms of complete continence, defined as the absence of urinary leakage. These data were collected by a specific non-validated questionnaire. Erectile function recovery was defined as the ability to have sexual intercourse spontaneously or Sildenafil-assisted.

2.4. Statistical analysis

The Pearson χ^2 and the Fisher exact test were used to compare categorical variables. The Student's *t*-test was used to compare continuous variables. All the analyses showed minimal statistical significance having $p < 0.05$. All the clinical and pathological data of the patients were collected in one database and were analyzed using 10.1 SPSS software by one of the authors (V.F.)

3. Results

3.1. Pre-operative data

Those patients undergoing RRP had a mean age of 64.28 ± 6.6 years (median value 66 years; range 49–74). Mean pre-operative PSA value was 11 ± 9 ng/ml (median value 9.3 ng/ml; range 2–35). Rectal examination showed the following clinical stages (TNM, 1997): T1b in 4 patients (8%); T1c in 26 (52%); T2a in 15 (30%); T2b in 4 (8%), and T3 in one patient (2%). The mean biopsy Gleason score was 5.7 ± 1.2 (median value 6; range 4–7).

Those patients undergoing LRP had a mean age of 63.14 ± 5.8 years (median value 64 years; range 49–73). The mean pre-operative PSA value was 15.7 ± 17.5 ng/ml (median value 10 ng/ml; range 2–100). The clinical stages were as follows: T1b in 1 patient (1.5%), T1c in 20 patients (28%), T2a in 34 (48%), T2b in 10 (14%), and T3 in 6 (8.5%). The mean biopsy Gleason score was 5.8 ± 1.3 (median value 6; range 4–9). Table 1 summarizes the pre-operative characteristics of the two groups (Table 1).

3.2. Peri-operative data

The mean operating time was 105 ± 17 minutes (range 50–157) for RRP without lymphadenectomy and 180 ± 20 minutes (range 120–240) for LRP without lymphadenectomy, respectively. The difference between the mean operative times was statistically significant ($p < 0.0001$).

Seventeen patients (34%) undergoing RRP and 45 patients (63%) in the laparoscopy group received blood

Table 1

Pre-operative characteristics of the 121 studied patients

	RRP (50 patients)	LRP (71 patients)	<i>p</i> value
Mean age	64.28 ± 6.6	63.14 ± 5.8	0.32
Pre-operative PSA (ng/ml)	11 ± 9	15.7 ± 17	0.09
Clinical stage (%)			0.01
T1b	4 (8%)	1 (1.5%)	
T1c	26 (52%)	20 (28%)	
T2a	15 (30%)	34 (48%)	
T2b	4 (8%)	10 (14%)	
T3	1 (2%)	6 (8.5%)	
Biopsy (Gleason score)	5.7 ± 1.2	5.8 ± 1.3	0.76

transfusions ($p < 0.001$). None of the patients in the surgery group and 8 patients (11%) in the laparoscopy group were submitted to eterologous blood transfusions ($p = 0.03$).

In the surgery group the following complications were observed: fever (≥ 38 °C, longer than 2 days) was seen in 7 patients (14%); wound infection was observed in one patient (2%), and acute urinary retention was seen in two patients (4%), which was managed by in-dwelling catheter for 24 hours.

In the laparoscopic group, 2 rectal injuries (2.8%) were observed and treated intra-operatively by rectal sutures. In one patient (1.4%), pelvic haematoma was surgically drained. One patient had port site infection (1.4%); another patient had acute urinary retention, which was treated by temporary catheterization (1.4%). In the laparoscopy group the clinical complications included persistent (longer than 2 days) fever (≥ 38 °C) in 15 patients (21%); cardiovascular complications in 3 (4.2%); transient peripheral nerve impairment in 2 (2.8%) (sciatic nerve in one case and brachial nerve in another), and ileus in one (1.4%). Table 2 summarizes a comparative analysis of the complications observed (Table 2).

Table 2

Peri-operative complications

	RRP (50 patients)	LRP (71 patients)
Surgical complications		
Rectal injury	0	2 (2.8%)
Haematoma drain	0	1 (1.4%)
Peripheral nervous system	0	2 (2.8%)
Wound/port site infection	1 (2%)	1 (1.4%)
Medical complications		
Infections (fever)	7 (14%)	15 (21%)
Cardiovascular	0	3 (4.2%)
Ileus	0	1 (1.4%)
Urinary retention	2 (4%)	1 (1.4%)
Overall	10 (20%)	26 (37%)
Comparative analysis (χ^2 , $p = 0.07$).		

The mean post-operative hospital stay was 10.2 ± 2 days (median value 10 days; range 7–15) in the surgery group and 7.2 ± 3.4 days in the laparoscopy group (median value 7 days; range 2–19). The difference in hospitalization stay was statistically significant ($p < 0.001$). Catheterization time was 8.4 ± 0.9 days (median value 8 days; range 7–12) in the surgery group and 8 ± 2.8 days (median value 7 days; range 4–18 days) in the laparoscopy group ($p = 0.27$). Cystogram was routinely performed in both groups before catheter removal.

3.3. Pathological data

In the RRP group, the pathological stage was pT2 in 33 patients (66%); pT3a in 8 (16%); pT3b in 5 (10%); pT4 in 2 (4%), and pN+ in 2 (4%). In the laparoscopy group, the pathological stage was pT2 in 42 patients (60%); pT3a in 18 (26%); pT3b in 5 (7%); pT4 in 4 (6%), and pN+ in one patient (1%). In the surgery group, the mean Gleason score was 6.30 ± 0.95 (median value 6; range 5–9) and was 6.46 ± 1.31 (median value 7; range 4–9) in the laparoscopy group. The two groups were comparable in terms of pathological stage ($p = 0.61$) and Gleason score ($p = 0.45$) (Table 3).

The positive surgical margin rate was 24% in the surgery group and 30% in the laparoscopy group ($p = 0.46$). Table 4 summarizes the positive surgical margin rates, stratifying pathological stages (Table 4).

3.4. Follow-up data

The mean follow-up was 10.16 ± 3.51 months (median value 10 months; range 4–18) in the RRP group

and 10.28 ± 3.64 months (median value 10 months; range 4–16) in the LRP one ($p = 0.94$). Six patients (12%) in the RRP group and 8 patients (11%) in the LRP group underwent adjuvant therapies and were excluded based on an analysis of biochemical disease-free survival (DFS). At mean follow-up, a post-operative PSA value >0.3 ng/ml was seen in 5/44 (11%) RRP patients and in 12/63 (19%) laparoscopic patients ($p = 0.28$).

Only 34 patients had a follow-up >12 months (20 in the LRP group and 14 in the RRP group). According to the complete continence criteria, 9 patients (64%) in the surgery group and 8 (40%) in the laparoscopy group were considered as continent. Moreover, 11/14 R.R.P. patients (78.5%) and 12/20 LRP patients (60%) required no urinary protection system ($p = 0.29$). Sildenafil-assisted sexual function recovery occurred in 4/40 (10%) of RRP patients and in 5/57 (8.8%) of LRP patients with a >6 -month follow-up.

4. Discussion

This paper is a comparative non-randomized study, analyzing the morbidity data in two groups of patients who were submitted to radical retropubic or extraperitoneal laparoscopic prostatectomy during 2001 at two different centres in the same geographical area. The two groups were comparable in terms of mean pre-operative PSA and biopsy Gleason score. A statistically significant difference was observed in the clinical stage based on rectal examination ($p = 0.01$). However, the two groups were comparable in terms of pathological stage and definitive Gleason score.

Laparoscopy is a modern, mini-invasive approach, which presupposes to duplicate traditional open techniques. Extraperitoneal laparoscopy seems more suitable to meet these criteria than the transperitoneal approach. The potential advantages of the extraperitoneal approach consist in a lower risk of iatrogenic injuries to intra-peritoneal organ, cancer cell spillage, or urinary leakage in the peritoneal cavity. The possible disadvantages include reduced working-space and potential increased traction on the anastomosis due to more limited bladder mobilization [12]. We hope that over the next few years, multi-center randomized trials will identify the best laparoscopic approach to be performed for radical prostatectomy.

Over the last few years, the operating time for laparoscopic radical prostatectomy has been reduced. Whilst the preliminary experiences of Schussler et al. showed a mean operating times of 9.4 hours, these are now 3 to 4 hours [17,18]. These are substantially longer than the surgical times, which are approximately 2 hours [19].

Table 3

Pathological characteristics of the 121 studied patients

	RRP (50 patients)	LRP (71 patients)	<i>p</i> value
Pathological stage (%)			0.61
T2	33 (66%)	42 (60%)	
T3a	8 (16%)	18 (26%)	
T3b	5 (10%)	5 (7%)	
T4	2 (4%)	4 (6%)	
N+	2 (4%)	1 (1%)	
Pathological Gleason score	6.3 ± 0.9	6.4 ± 1.3	0.45
Positive surgical margins	12 (24%)	21 (30%)	0.46

Table 4

Positive surgical margin rates in relation to pathological stage ($p = \text{NS}$ in all analyses)

Groups	pT2 (75 patients)	pT3a (26 patients)	pT3b (10 patients)	pT4/N+ (9 patients)
RRP (50 patients)	2/33 (6%)	3/8 (37.5%)	3/5 (60%)	4/4 (100%)
LRP (71 patients)	6/42 (14%)	7/18 (39%)	3/5 (60%)	5/5 (100%)

Our data confirmed that operating times are significantly shorter in retropubic radical prostatectomy.

The pressure of the pneumoperitoneum on small venous vessels and the meticulous haemostasis needed for optimal laparoscopic visualization are usually indicated as the main factors involved in the reduced bleeding during laparoscopic surgery [19]. Transfusion rates in the main laparoscopy group ranged between 2 and 31% [10,17]. Rassweiler et al. identified a possible correlation between transfusion rate and specimen weight. In their series, 17% of the patients with a specimen smaller than 25 g and 47% of those with a prostate volume greater than 45 g received blood transfusions [17].

An improved surgical technique, particularly in the control of the deep venous plexus, and the experience gained have led to a significant reduction in intra-operative blood loss and transfusion rates in patients undergoing RRP. The percentage of heterologous blood transfusions now range between 1 and 11% in the RRP group [4,20]. These data suggest that autologous blood should not be taken routinely before RRP in many centers [20]. In our experience, LRP patients showed higher autologous and heterologous transfusion rates.

Surgical series now show that rectal injuries occur in less than 0.5% of cases [4,21]. In the laparoscopic series, this complication is reported in 1 to 3% of cases [10,18]. Our experience confirmed the higher risk of rectal injury. While open surgery develops, this difference seems likely to disappear as the experience in laparoscopic procedures improves.

Length of hospitalization and catheterization times are important criteria to assess radical prostatectomy morbidity. Hospital stay is a difficult parameter to evaluate because it is affected by economic and social pressure in different geographic areas. In recent years, in the US the systematic application of specific clinical pathways has led to shorter hospitalization after radical prostatectomy up to less than 3 days [22]. The average hospital stay for laparoscopy in European hospitals ranges between 6 and 10 days [9,17]. Data comparison is not possible because of the different health care systems. Our study showed a significantly shorter hospitalization in those patients undergoing laparoscopic treatment. This result was partially due to different attitudes in patients discharge in the two Centres. While in the surgery group, patients were always discharged after drains and in-dwelling catheter had been removed; in the laparoscopy group, patients were often dismissed with the in-dwelling catheter. This statement is supported by the average catheterization time, which was overlapping in the two series. The presence of positive surgical margins could

be predictive of an higher risk of biochemical and clinical disease progression. This condition could be related to the extracapsular extension of the neoplasm or could be due to a lack of surgical efficacy. The laparoscopic approach does not seem to increase the risk of positive surgical margins in relation to radical retropubic prostatectomy [23]. Our paper showed no significant difference in positive surgical margin rates between the two groups. However, the different method of specimen analysis could have influenced the positive surgical margin detection. It has been shown that 4 to 6-mm sections missed up to 12% of positive surgical margins compared with 2 to 3-mm sections [23,24].

Urinary continence rates after radical prostatectomy can vary significantly in relation to the different continence criteria applied and to the modality of data collection. In recent papers, the use of specific continence questionnaires showed that the percentage of patients requiring protection systems at least 12 months after RRP ranged between 7 and 20% [25,26]. In a US Medicare population of 25,651 patients who had undergone radical prostatectomy in 1991, 8% of patients had urinary incontinence one year after surgery [27]. The percentage of patients using protection systems one year after laparoscopic radical prostatectomy ranged between 3 and 15% [10,12,17,28,29]. However, these data refer to less than 400 patients who were treated in a few centres of excellence (Table 5).

Our data on urinary continence must be considered as preliminary. They cannot be compared to those reported in the literature because of the limited number of patients with adequate follow-ups. However, similarly to the data published in the literature, we found no real advantage for laparoscopic surgery.

Although reported in the paper, the data on sexual function were not adequately evaluable because of the little number of operations performed using the nerve-sparing technique and because of the insufficient follow-up.

Table 5

Urinary continence rate after laparoscopic radical prostatectomy (Literature review)

Author	Whole group cases	Follow-up cases	Continence rate (%)	Follow-up (months)
Guilhonau, 2001 [28]	350	133	85.5	12
Rassweiler, 2001 [17]	180	88	97	12
Bollens, 2001 [12]	50	14	85	6
Turk, 2001 [10]	125	n.a.	92	9
Salomon, 2002 [29]	235	100	90	12
Overall	940	335	85–97	6–12

n.a.: not available.

5. Conclusion

In the recent years laparoscopic surgery has been suggested by an increasing number of authors as the main alternative to open surgery for radical prostatectomy. The results of our non-randomized study show that up to now laparoscopic radical prostatectomy does not provide significant advantages in terms of peri-operative

morbidity compared with the traditional retropubic approach.

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