

Bilateral vs unilateral laparoscopic intrafascial nerve-sparing radical prostatectomy: evaluation of surgical and functional outcomes in 457 patients

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OBJECTIVE

To evaluate the surgical and functional outcomes in bilateral and unilateral nervesparing laparoscopic radical prostatectomy (nsLRP).

PATIENTS AND METHODS

Between January 2005 and May 2009, 457 nsLRP were performed at our clinic.

In all, 250 patients underwent a bilateral nsLRP and 207 patients underwent an unilateral nsLRP. One surgeon performed all the operations.

All patients presented at biopsy a localized prostate cancer.

Demographic data and perioperative and postoperative measurements and outcomes were compared.

RESULTS

The operative times for bilateral nsLRP and unilateral nsLRP were 165 ± 45 min and 130 ± 25 min, respectively.

The mean intra-operative blood loss was 450 ± 300 mL and 270 ± 160 mL in the bilateral and unilateral nsLRP groups with a transfusion rate of 3% and 1%, respectively (P = 0.013).

Conversion to open surgery was never deemed necessary.

Postoperatively, the mean Gleason Score after nsLRP and distribution of tumour stages was similar in the two groups, and the frequency of positive margins in both groups did not present any statistically significant difference.

At 12 months, a complete continence was reported in 97% of patients who underwent a bilateral nsLRP and in 88% of patients of the unilateral nsLRP group. At that time, 69% in the bilateral nsLRP and 43% in the unilateral nsLRP groups reported the ability to engage in sexual intercourse.

CONCLUSION

The bilateral laparoscopic intrafascial nervesparing technique results in superior functional outcomes with regard to urinary continence and sexual potency, when compared with unilateral nsLRP, reporting similar oncological outcomes.

KEYWORDS

prostate cancer, intrafascial nerve-sparing radical prostatectomy, surgical outcomes, continence recovery, potency

INTRODUCTION

Currently, RP is the only treatment for localized prostate cancer that has shown a cancer-specific survival benefit when compared with conservative management. Actually it is likely that laparoscopic prostatectomies have lower morbidity than the retropubic operation, but studies are as yet unavailable [1].

In the literature we find numerous reports of studies [2–18] that have evaluated the

postoperative outcomes after laparoscopic radical prostatectomy (LRP), regarding operative times, intra-operative complications, mean catheterization time and postoperative hospital stay, oncological outcomes and continence; however, until now data concerning bilateral and unilateral laparoscopic nerve-sparing radical prostatectomy (nsLRP) have been limited.

In the present study, we report our experience with 457 consecutive patients who underwent a bilateral and unilateral nsLRP

with intrafascial technique for clinically localized prostate cancer, in order to evaluate the safety and feasibility of both these techniques.

PATIENTS AND METHODS

Between January 2005 and May 2009, 457 consecutive extraperitoneal nsLRP procedures were performed at our clinic. In all, 250 patients underwent a bilateral nsLRP and 207 patients underwent an unilateral nsLRP.

All patients underwent an intrafascial technique, with the incision of the endopelvic fascia only ventrally and medially to the puboprostatic ligaments, that were spared. Then a careful dissection of the prostate laterally from its periprostatic fascia was performed with preservation of the small nerves and vessels contained in the fascias. Our surgical technique has been described previously [9].

Bilateral nsLRP was performed in patients with a PSA level <10, Gleason ≤7 and only two positive of at least 12 biopsy cores, while unilateral nsLRP was performed in cases of a Gleason Score 4 + 3 or with more than two positive of at least 12 biopsy cores, after frozen section.

Urinary continence and erectile function at the follow-up were evaluated using the International Consultation of Incontinence Questionnaire-Urinary Incontinence (ICIQ-UI) short-form instrument and the IIEF-5, respectively. Questionnaires were self-completed before surgery and at the 1-, 3- and 12-month follow-up. All patients reporting the need of no pad were defined as continent. All the patients with an IIEF-5 of >17 were defined as potent.

Postoperatively, all patients were treated with Vardenafil 20 mg (on demand).

All surgical procedures were performed by one surgeon (F.G.) who had completed at least 90 nsLRPs and at least 150 laparoscopic radical prostatectomies before the beginning of the study, thus reducing the learning-curve effect.

Data were expressed as mean \pm SD and statistical significance was accepted at P < 0.05. Statistical analysis was performed using SigmaPlot® software version 13.0 (SPSS Inc., Chicago, IL, USA) and Graphpad Prism 5 (Graphpad Software Inc., La Jolla, CA, USA).

RESULTS

The final analysis included 457 patients in both groups with similar data for age (mean age 58.5 ± 10.5 years for bilateral nsLRP and 59.7 ± 9.3 years for unilateral nsLRP), mean preoperative PSA level (6.3 ± 3.7 vs 6.8 ± 4.1 ng/mL, respectively) and biopsy Gleason Score (5 ± 2 in both groups) (Table 1).

TABLE 1 Preoperative data Bilateral nsLRP Unilateral nsLRP n = 207n = 250P value Mean age 58.5 ± 10.5 59.7 ± 9.3 1.121 Body mass Index (kg/m²) 28 ± 7 29 ± 5 1.119 Preoperative PSA level (ng/mL) 6.3 ± 3.7 6.8 ± 4.1 1.125 5 ± 2 Gleason Score (biopsy) 5 ± 2 1.231 Preoperative clinical stage (patients) 2 T1a 12 0.115 T1b 23 24 1.118 T1c 211 174 0.042 T2a 4 7 0.204

TABLE 2 Intra-operative and postoperative data				
Bilateral nsLRP	Bnilateral nsLRP			
n = 250	n = 207	P value		
165 ± 45	130 ± 25	0.036		
450 ± 300	270 ± 160	0.011		
3	1	0.013		
0.8	0	0.032		
8 ± 1	8 ± 1	1.225		
7 ± 2	7 ± 2	1.225		
nsLRP, nerve-sparing laparoscopic radical prostatectomy.				
	Bilateral nsLRP n = 250 165 ± 45 450 ± 300 3 0.8 8 ± 1 7 ± 2	Bilateral nsLRP Bnilateral nsLRP $n = 250$ $n = 207$ 165 ± 45 130 ± 25 450 ± 300 270 ± 160 3 1 0.8 0 8 ± 1 8 ± 1 7 ± 2 7 ± 2		

The operative time was $165 \pm 45 \text{ min for}$ bilateral nsLRP and 130 ± 25 min for unilateral nsLRP (P = 0.036). The mean intraoperative blood loss was 450 ± 300 ml and 270 ± 160 ml in the bilateral and unilateral nsLRP groups with a transfusion rate of 3% and 1%, respectively (P = 0.013). Two patients in the bilateral nsLRP group presented with a rectal injury, which required intra-operative suturing. However no conversion to open surgery was necessary and no patients developed a post-operative rectal fistula. The mean catheterization time was 8 ± 1 day in both groups (P = 1.225). Each patient underwent a cystography on the 7th postoperative day to evaluate the urethral anastomosis for leakage. The mean hospitalization was 7 ± 2 days (P = 1.225).

nsLRP, nerve-sparing laparoscopic radical prostatectomy.

Perioperative data are summarized in Table 2.

Post-operatively, the mean Gleason Score after nsLRP (6 \pm 1 and 5 \pm 2 for bilateral and unilateral nsLRP, respectively, P = 0.091) and distribution of tumour stages was similar in

the two groups, and the frequency of positive margins in both groups did not present any statistically significant difference. Positive margins were detected in 8.2% and 5.3% of patients with pT2 tumours in the bilateral and unilateral nsLRP groups, respectively (P=0.054) (Table 3).

The overall continence rates are reported in Table 4. Early return to continence at 4 weeks after the operation was achieved by 107 (42.8%) patients in the bilateral nsLRP and 66 (31.8%) in the unilateral nsLRP groups.

Three months postoperatively, in the bilateral nsLRP group 220 patients (88%) were continent, 26 (10.4%) experienced a minimal stress incontinence (1–2 pads per day) and only 4 (1.6%) experienced a moderate stress incontinence (2–4 pads per day). In the unilateral nsLRP group, 153 patients (73.9%) achieved complete continence, 46 (22.2%) had minimal stress incontinence, 8 (3.9%) had moderate incontinence. Three months after

TABLE 3 Post-operative histopathological results Bilateral nsLRP Unilateral nsLRP n = 250n = 207P value Median Gleason Score 6 ± 1 5 ± 2 0.091 Tumour stage (patients): pT2a 165 96 0.014 PT2b 55 33 0.221 pT2c 52 56 0.831 Positive surgical margins (%) pT2 a/b/c 8.2 5.3 0.054 0.044 Mean prostate weight (g) 54 ± 33 45 ± 41

TABLE 4 Postoperative functional outcomes				
	Bilateral nsLRP $n = 250$	Unilateral nsLRP n = 207	<i>P</i> value	
Complete urinary continence (%):				
4 weeks after surgery	42.8	31.8	0.045	
3 months after surgery	88	73.9	0.024	
12 months after surgery	97	88	0.047	
Potency (%):				
1 year after surgery	69	43	0.037	
nsLRP, nerve-sparing laparoscopic raa	lical prostatectomy.			

surgery, no case of complete or severe incontinence was observed. At 12 months, complete continence was reported in 97% of patients who underwent a bilateral nsLRP and in 88% of patients of the unilateral nsLRP group (P = 0.047) (Table 4).

nsLRP, nerve-sparing laparoscopic radical prostatectomy.

Regarding sexual potency, 69% in the bilateral nsLRP and 43% in the unilateral nsLRP groups reported the ability to engage in sexual intercourse 1 year after surgery (P = 0.037) (Table 4). The use of phosphodiesterase type 5 (PED5) inhibitors must be considered when interpreting the potency results (on demand Vardenafil 20 mg).

DISCUSSION

In recent years, LRP has been established as a safe and effective treatment for prostate cancer in specialized centres [2–18]. With better visualization of the anatomy and a relatively bloodless field, nsLRP has the potential to provide good functional outcomes with equal oncological

effectiveness [18]. Recent anatomical studies [19,20] have illustrated, in detail, the prostatic neuroanatomy, detecting additional neural tissue to the nerve-bundles on the anterior mid-part and posterior surface of the prostate. The influence of anterior periprostatic nerve tissue has suggested the use of a more anterior incision of the levator fascia for the surgical technique. In the uniand bilaterial nerve-sparing procedure, it must be further recommended that in order to spare these anterior nerve fibres, the surgeon should choose a more ventral incision in the mid-part, while continuing towards the base. Towards the prostate apex, 84.37% of the combined nerves have been identified to be located in the posterolateral and posterior section of the circumference. The origin and function (innervation) of the posterior lateral and posterior nerve tissue at the apex currently remains unclear; therefore, a close preparation at the apex to preserve the nerve concourse has to be performed. Moreover, frozen sections might be helpful to secure complete gland and cancer removal [19].

It has been postulated that nsLRP resulted in a higher rate of positive margins. For an objective evaluation of the positive margin rate, three aspects have to be considered. The first is the technique of histopathological examination, because pathological evaluation of the prostate can influence the detection of positive margins. The second aspect is the stratification of positive margin rates according to pathological stage (pT2 or pT3). The third aspect is the case selection (with or without adjuvant therapy) [18]. There is an outstanding question regarding the impact of the intrafascial nerve-sparing technique in the oncological outcome. Some investigators suggest that the extended preservation of the periprostatic fascias may prevent the postoperative pathological evaluation from detecting positive surgical margins [21]. Other investigators propose that the increased fascia preservation does not influence the oncological outcome of the procedure [13,14].

Evaluating the oncological outcomes after bilateral and unilateral nsLRP, we noted that positive margins were detected in 8.2% and 5.3% of patients with pT2 tumours in the bilateral and unilateral nsLRP groups, respectively. Nevertheless the incidence of positive margins after bilateral nsLRP was correlated with pT2 tumours and this has to be interpreted considering that our pathologists usually perform a very thin cut of the prostate, resulting in a higher possibility of finding a positive margin. Moreover, we considered as positive margins also the patients where the pathologist reported a suspicious but not absolute certainty of histopathological positive margins.

These results are similar to the outcomes associated with other techniques of nervesparing prostatectomy (i.e. extrafascial and interfascial), confirming that intrafascial nsLRP is an oncological safe procedure in the therapy of low-risk organ-confined prostate cancer.

The quality of life is strongly affected by urinary incontinence. It had been shown that the incidence of postoperative incontinence depends on the urologist's experience, patient's age (increased frequency after 70 years) and operative technique (i.e. nervesparing or not) [5,6]. Laparoscopic surgery may offer an improved identification of anatomic landmarks such as striated muscles and neurovascular bundles, resulting in less

damage to the striated sphincter. Moreover, Stolzenburg et al. [12] proved better results on early continence by preserving the puboprostatic ligament during nsLRP. In the present study, we observed an earlier return to continence in patients who underwent a bilateral nsLRP in comparison with patients who underwent an unilateral nsLRP. A marked difference was noted at 3 months after surgery, with complete continence in 88% of the bilateral nsLRP and in 73.9% in the the unilateral nsLRP groups. At 12 months, complete continence was reported in 97% of patients who underwent a bilateral nsLRP and in 88% of patients of the unilateral nsLRP aroup.

When postoperative potency is defined as the patient's reported ability to achieve sexual intercourse with or without the use of PDE-inhibitors, the potency rates after bilateral nerve- sparing LRP are 33% to 67% in series worldwide [2–17]. One year after bilateral nerve-sparing radical prostatectomy, 69% of patients in the bilateral nsLRP group and 43% in the unilateral nsLRP group had recovered sexual potency. Moreover, younger patients (<55 years old) presented better postoperative potency in comparison with older patients (>55 years old).

In conclusion, the bilateral laparoscopic intrafascial nerve-sparing technique results in superior functional outcomes with regard to urinary continence and sexual potency, when compared with unilateral nsLRP, reporting similar oncological outcomes. A bilateral nerve-sparing technique has to be the preferred option in younger patients with low-risk, organ-confined prostate cancer.

CONFLICT OF INTEREST

None declared.

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Abbreviations: nsLRP, nerve-sparing laparoscopic radical prostatectomy; LRP, laparoscopic radical prostatectomy; ICIQ-UI, International Consultation of Incontinence Questionnaire-Urinary Incontinence; PED5, phosphodiesterase type 5.