Selective versus Standard Ligature of the Deep Venous Complex during Laparoscopic Radical Prostatectomy: Effects on Continence, Blood Loss, and Margin Status

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Abstract

Background

Continence after laparoscopic radical prostatectomy is critical to patients and to surgeons. In this setting, the management of deep venous complex (DVC) without involvement of the sphincter fibres could be an important step of the procedure.

Objective

To evaluate the effects of a personal selective suture of the plexus (selective ligature of the deep venous complex [SLDVC]) on continence, blood loss, and surgical margin status during laparoscopic radical prostatectomy (LRP).

Design, setting, and participants

We planned a prospective randomised study. Sixty consecutive patients with clinically localised prostate cancer were involved in the study and were divided into two groups: group A (30 patients) underwent LRP with extraperitoneoscopic approach with standard management of DVC; group B (30 patients) underwent LRP with SLDVC.

Intervention

In group A, a standard ligature of DVC was performed (ligature and subsequent section); in group B, a selective ligature of DVC after its section was performed.

Measurements

Continence was evaluated during follow-up visits at catheter removal, and after 1, 3, 6, and 12 mo, perioperative variables and pathologic features of specimens were recorded.

Results and limitations

The two groups were comparable in terms of age, body mass index (BMI), prostate-specific antigen (PSA) values, and Gleason score at biopsy. No differences were found between the two groups in terms of operative times, blood loss, catheterisation time, and postoperative stay or histologic status. As far as continence rate is concerned, a significant difference was recorded between the groups (53% in group A vs 80% in group B) after 3 mo.

Conclusions

This selective ligature of the DVC after its section can contribute to early recovery of continence. Our data suggest that SLDVC compromises neither the safety of the procedure nor its oncologic effectiveness.

Keywords

- Laparoscopic prostatectomy;
- Deep venous complex;
- Selective ligature;
- Urinary incontinence

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1. Introduction

With the continuous refinements of operative techniques, laparoscopic radical prostatectomy (LRP) has had a worldwide diffusion with a complication rate continuously and significantly decreasing in recent years [1], [2], [3], [4], [5], [6] and [7]. Nevertheless, postoperative urinary incontinence (PUI) remains an important issue, with an incidence ranging from 1% to 50% [3] and [8]. Moreover, nowadays, not only continence but also its early recovery are increasing in importance to both patients and surgeons [9], [10], [11] and [12].

Many techniques have been proposed to preserve continence after radical prostatectomy (RP), and surgeons have different opinions about them. The preservation of the urethral sphincter (US), however, seems to be an important point during RP, and a selective suture of the deep venous complex (DVC) could be a crucial step in this setting [13], [14] and [15].

Placing a selective suture as described by Walsh for radical retropubic prostatectomy (RRP) [13] and [14] is not always possible during LRP, and surgeons can place the suture deeply to avoid bleeding with the risk of involvement of some fibres of the US in the suture [4] and [16].

We used a selective suture of the plexus during LRP, and we planned a prospective randomised study to evaluate the effects of this technique on continence.

2. Patients and methods

After institutional approval, 60 consecutive patients with clinically localised prostate cancer (T1–T2) to whom we proposed LRP were involved in the study. Randomisation of patients lasted from February 2006 to July 2007; the entire study lasted until July 2008. For patients with serum PSA > 10 ng/ml and/or Gleason score at biopsy ≥7, a pelvic lymph node dissection (LND) was planned. After obtaining a complete informed consent, the patients were randomised using a plan generated with http://www.randomization.com. Patients and were divided into two groups: group A (30 patients) underwent LRP with standard management of the DVC (or Santorini's plexus), whereas group B (30 patients) underwent LRP with selective ligature of the DVC (SLDVC) after its section. For each patient, the following preoperative variables were recorded: age, body mass index (BMI), prostate-specific antigen (PSA) serum values at diagnosis, and Gleason score (GS) at prostate biopsy.

2.1. Surgical technique

All patients underwent LRP with an extraperitoneoscopic approach, as previously described [17], and all procedures were performed by the same surgeon (FP). The DVC treatment was the only difference between the groups. In the interest of clarity, we have followed the anatomic nomenclature described by Walsh [13] and [14].

2.1.1. Group A

After the incision of the levator fascia, puboprostatic ligaments are sectioned in the middle part. DVC is ligated at the level of the prostate apex with a single stitch in a figure-8 fashion (0 Polysorb with a semicircular CV-17 needle), trying to avoid involvement of the surrounding tissue, particularly muscle fibres of the US. Then the prostate is dissected with the anterograde technique, and the DVC is sectioned just before the section of the urethra (Fig. 1a and b).

2.1.2. Group B

After the incision of the levator fascia, puboprostatic ligaments are sectioned in the middle part. The prostatectomy is performed with the standard technique. When the DVC has to be managed, just before the urethra section, the insufflation pressure is increased up to 16–18 mm Hg and the DVC is sectioned. In the case of a wide plexus, the lateral part is coagulated with bipolar forceps (Microfrance CV 136), while the middle portion is sectioned with scissors. The urethra is then sectioned and the prostate removed. When present, one or two arteries that run in the DVC are coagulated with bipolar forceps. If plentiful bleeding is observed, the DVC is gently pressed with the tip of the suction probe to reduce the blood loss. Then a selective suture of the plexus is performed with one or two stitches in a figure-8 fashion (2/0 Polysorb V-30 with a 3/8 circular needle), trying to avoid involvement of the surrounding tissue (Fig. 2a and b). After the suture, the insufflation pressure is reduced to 13 mm Hg and haemostasis is verified. To avoid the risk of reduction of CO_2 pressure, suction probe activation is kept to the minimum during cold transaction.

Subsequent steps of the procedure are the same for the two groups. The bladder-neck preservation technique is utilised when possible, and the vesicourethral anastomosis is carried out with five or six interrupted sutures of 2-0 Polysorb and 5/8 circular GU-46 needle.

When indicated, a nerve-sparing procedure was performed with an intrafascial technique without changing management of the DVC.

2.2. Pathologic analyses

The surgical specimen was fixed in formalin and the prostate surface inked. The specimen was sectioned at 4-mm intervals perpendicularly on the inked base. Margins were classified as positive (cancer reaches the inked margin) or negative (normal tissue between inked margin and cancer). Moreover, extracapsular extension, seminal vesicle invasion, Gleason score, prostate volume, and cancer volume were recorded, and lymph node metastases in patients underwent LND. Postoperative pathologic classification was performed according to the 2002 TNM classification.

2.3. Perioperative variables

The following variables were considered: operative times, estimated blood loss, number of patients who required blood transfusion and number of transfusions, complications, and conversion to open surgery. Moreover, Foley catheter duration and postoperative stay were recorded.

2.4. Continence

Continence was evaluated during follow-up visits at catheter removal and after 1, 3, 6, and 12 mo. During these visits, a physical examination was performed and each patient was required to fill out a standardised questionnaire (International Continence Society [ICS] male short form [SF], questions I1–I6, with scores ranging from 0–24), validated by the Italian Flow Study Group [18]. Patients were then interviewed by a urologist on the staff who did not participate in the randomisation of patients to evaluate the degree of incontinence on the basis of pads used during the last 24 h before the visit. After 6 and 12 mo, a uroflowmetry was performed during the visit to exclude urethral strictures.

Continence was defined as zero pads. According to the Rocco definition [19], if some patients used one diaper per 24 h for safety, for fear of incontinence, or because of the leakage of a few drops of urine on exertion, they were also considered continent. Moderate incontinence was defined as two pads per 24 h and severe incontinence was defined as more than two pads per 24 h.

2.5. Statistical analyses

The sample size was calculated with the SS PLUS v.1.0 programme. Data from each patient were recorded and analysed statistically using student *t* test, χ^2 test, and the Fisher exact test. The variables of both groups were compared to identify significant differences. Multiple logistic regression analysis was performed to investigate the association between urinary continence and patient age, BMI, prostate volume, preoperative PSA value, LND, and intrafascial nerve-sparing procedure in the two groups. A further analysis was performed in subgroups of patients who underwent the nerve-sparing procedure to evaluate whether this technique modified the continence rate in the two groups.

In all analyses, the differences were considered statistically significant at $p < 0.05$. When no statistically significant results were found, "$p > 0.05$" is clearly indicated.

2.6. Study end points

The primary end point was to evaluate the effects of SLDVC on immediate (at catheter removal) and early (at 1 and 3 mo) continence and to determine whether continence is higher for patients treated with this technique. Secondary end points were to evaluate the effects of SLDVC on long-term continence (6 mo and 1 yr), blood loss, and surgical margin status and to determine whether blood loss and positive surgical margins are higher in the patients treated with SLDVC.

3. Results

No patients dropped out of this study, and complete data were obtained for each patient.

Patient characteristics of both groups are summarised in Table 1. One patient in group A was previously treated with transurethral prostatectomy (TURP). No differences were found between groups A and B in terms of age, BMI, serum PSA values at diagnosis, and Gleason score at biopsy ($p > 0.05$), so the two groups were comparable.

3.1. Perioperative variables

Operative times were 140 min (range: 85–195) in group A and 151 min (range: 110–210) in group B. LND was performed in 14 (46%) patients in group A and in 12 (40%) patients in group B ($p > 0.05$). Bladder-neck preservation was completed in all but one patient (the patient previously treated with TURP). The nerve-sparing procedure was performed in 12 of 30 (40%) patients in group A and in 13 of 30 (43%) patients in group B ($p > 0.05$), and all patients underwent an intrafascial bilateral procedure.

In 16 of 30 (53%) patients in group B, the DVC was sectioned, whereas in 14 of 30 (47%) patients in group A, the DVC was cauterised with bipolar forceps in the lateral parts and sectioned in the middle part.

Mean estimated blood losses were 350 ml (range: 150–700) in group A and 450 ml (200–1000) in group B. Blood transfusions were required in 1 of 30 (3.3%) group A patients and in 1 of 30 (3.3%) group B patients; the number of transfusions was two for both patients.

No complications or conversion to open surgery were recorded in the groups.

The χ^2 test and the Fisher exact test did not reveal statistical significant differences for any of the evaluated parameters ($p > 0.05$).

Mean catheterisation time was 8.2 d versus 8.6 d and mean postoperative stay was 8.9 d versus 7.5 d for groups A and B, respectively ($p > 0.05$).

3.2. Pathology

Oncologic results are summarised in Table 2. Groups A and B did not exhibit significant differences regarding their histologic status ($p > 0.05$). All R1 pT3 patients (three of group A and two of group B, $p > 0.05$) underwent external beam radiotherapy 3 mo after the procedure.

3.3. Continence

Fig. 3 shows continence results at catheter removal and after 1, 3, 6, and 12 mo. At 3 mo, the rate of continent patients was higher in group B than in A, and the difference was significant ($p = 0.02$).

Five of 30 patients in group A (16%) and 3 of 30 patients of group B (10%) reported incontinence even after 12 mo of follow-up. Three of the five incontinent patients in group A versus none of the three incontinent patients in group B presented moderate incontinence, while two of the five incontinent patients in group A versus all three incontinent patients in group B presented severe incontinence ($p > 0.05$).

As far as the ICS male SF questionnaire is concerned, a statistically significant difference between the two groups was recorded only at 3 mo (10.7 in group A vs 6.0 in group B; $p = 0.03$). No urethral strictures were recorded, and flowmetry was normal in all cases.

Multiple linear regression analysis revealed no relationships linking continence to age, BMI, Gleason score, PSA value, LND, or intrafascial procedure in either group ($p > 0.05$).

In the subgroups of patients treated with the nerve-sparing procedure (12 of group A vs 13 of group B), no differences were recorded in terms of blood loss, surgical margin status, and continence between the two groups ($p > 0.05$).

Furthermore, in group B, no differences were recorded in terms of blood loss, surgical margin status, and continence between the subgroups of patients treated with pure cold section of the DVC (16 patients) and those treated in combination with bipolar coagulation (14 patients; $p > 0.05$).

4. Discussion

With LRP, the rate of continent patients after 1 yr varies from 50% to 91.7% according to a recent review by Rassweiler [3] and from 83% to 100% according to a review by Guilloneau [2].

One should note that patients expect not only to be continent but also to have an early return to continence, and these expectations have driven surgeons to various anatomic studies and technical modifications to ameliorate these variables [9], [11], [19], [20], [21] and [22].

As far as early continence is concerned, one should note that the preservation of the US is probably one of the crucial points. In light of this, avoiding damage to the muscle fibres during management of the DVC is fundamental, so the suture of the plexus should be performed in a selective fashion, as suggested by some authors during open procedures [10], [13], [15] and [20].

During LRP, the suture is usually placed superficially in the DVC before severing the plexus, but sometimes it happens that the surgeon places the suture more deeply to avoid bleeding, causing a risk of involvement of the US in the suture. In our opinion, this could be one of the reasons for the wide variability in early continence results.

With SLDVC, the surgeon can exactly identify the bleeding veins and can selectively suture only where it is required. We planned this study to understand the real effect of this technique on urinary continence, and, to our knowledge, this is the first report that analyses a technical modification of DVC management in prospective and randomised fashion.

We introduced SLDVC after an adequate learning curve (about 300 procedures) and the same surgeon (FP) performed all the procedures, avoiding bias due to different operators.

The two groups are comparable in terms of age, BMI, prostate volume, and preoperative pathologic features.

No differences were recorded between the two groups in terms of perioperative variables and complications, making SLDVC as safe as standard management of DVC.

As far continence is concerned, we recorded a significant advantage for group B at 3 mo, both in terms of ICS male SF score and in terms of pads used in 24 h, demonstrating that SLDVC allows a quicker recovery of continence. Nevertheless, we also expected a significant difference at catheter removal and at 1 mo, as reported by some authors with other techniques [9] and [11]. In our opinion, this probably means that the preservation of the integrity of the US is important but it is not the earliest variable involved in recovery of continence. One should also note, however, that this could be related to the number of patients involved in the study. After 6 and 12 mo of follow-up, the continence rate and degree of continence are similar in the two groups, and this confirms data from other studies [9] and [11]. The long-term continence rate was comparable to other results in the literature [2], [3], [9], [11] and [16].

When SLDVC is performed, a potential risk of bleeding exists, representing the most important drawback of this procedure. To reduce it, we increase the pneumoperitoneum pressure of CO_2, we selectively coagulate the small arteries running inside the plexus that contribute to the bleeding, and we gently apply pressure with the tip of suction probe. In the case of a wide DVC, we prefer to coagulate the lateral parts of the venous complex using bipolar forceps and then sever the middle part of the plexus. There is a potential risk of thermal injury of the US using coagulation of the DVC; to prevent US damage, the use of bipolar forceps is basic and the surgeon has to coagulate only the superficial and lateral branches of the DVC. With these techniques, we have prevented massive bleeding and consequently managed the prostate apex without compromising the oncologic radicality. Actually, our results showed a slight increase in bleeding in group B, although it was not significant ($p > 0.05$), and there was no difference between the groups in terms of surgical margin status, particularly at the apex ($p > 0.05$).

Multiple linear regression analysis revealed no relationships linking continence to age, BMI, prostate size, or Gleason Score, so these variables could not predict the postoperative outcome in terms of continence. Our results confirm the experience of other authors [5] and [23].

As far as the nerve-sparing technique is concerned, one should note that the number of procedures in the two groups is similar ($p > 0.05$), and the two groups are comparable. Moreover, between the subgroups of patients treated with this procedure, no difference in terms of continence was recorded in comparison to patients treated with the extrafascial technique at catheter removal and at 1, 3, 6, and 12 mo after the procedure ($p > 0.05$); nevertheless, due to the small size of the sample, we cannot draw definite conclusions.

Another interesting point is the reproducibility of this technique during robot-assisted LRP: Our initial experience, not reported yet, suggests that in some cases, this technique could be even easier with the help of a robot, as reported by Gaston et al [24].

Obviously, we do not intend to claim that SLDVC is the best way to manage the venous complex, but we offer a contribution on this topic and, in particular, we highlight the fact that a more selective treatment of the DVC allows more appealing functional results. We also believe other techniques, such as the use of different coagulation systems (ie, pulsed radiofrequency [RF] energy), robot-assisted LRP, and other devices [25], could further simplify the management of the plexus and enable this.

5. Conclusions

The prevention of US damage during DVC treatment is an important step during RRP. We used a selective ligature of the DVC after its section during an LRP procedure, and our results demonstrate that this technique, in skilled hands, can contribute to early recovery of continence. Moreover, our study suggests that SLDVC does not compromise either the safety of the procedure or its oncologic effectiveness.

Author contributions: Francesco Porpiglia 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: Porpiglia, Fiori.

Acquisition of data: Grande, Morra.

Analysis and interpretation of data: Grande, Porpiglia.

Drafting of the manuscript: Porpiglia, Fiori.

Critical revision of the manuscript for important intellectual content: Porpiglia, Scarpa.

Statistical analysis: Grande.

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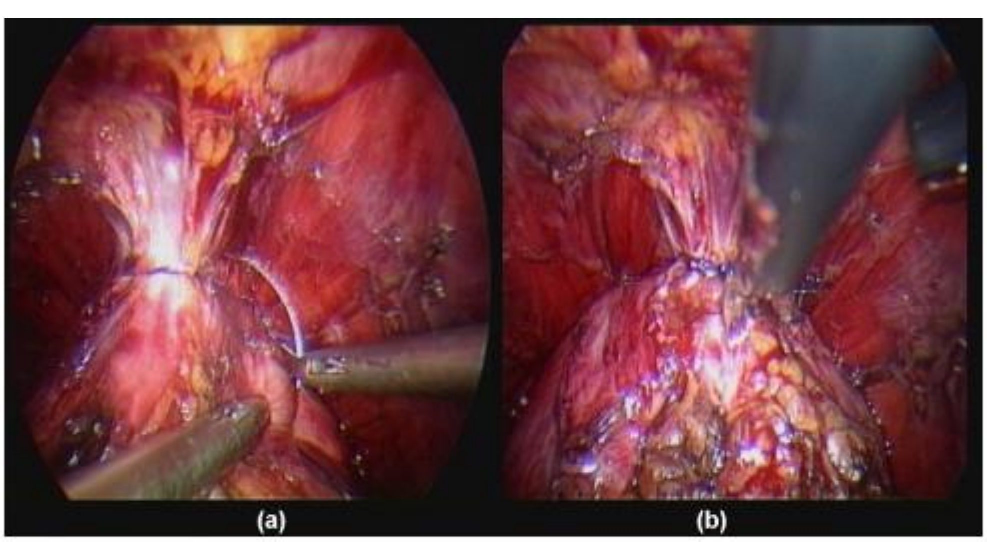

Fig. 1.

(a) The deep venous complex (DVC) is ligated at the level of the prostate apex with a single stitch; (b) the DVC is sectioned.

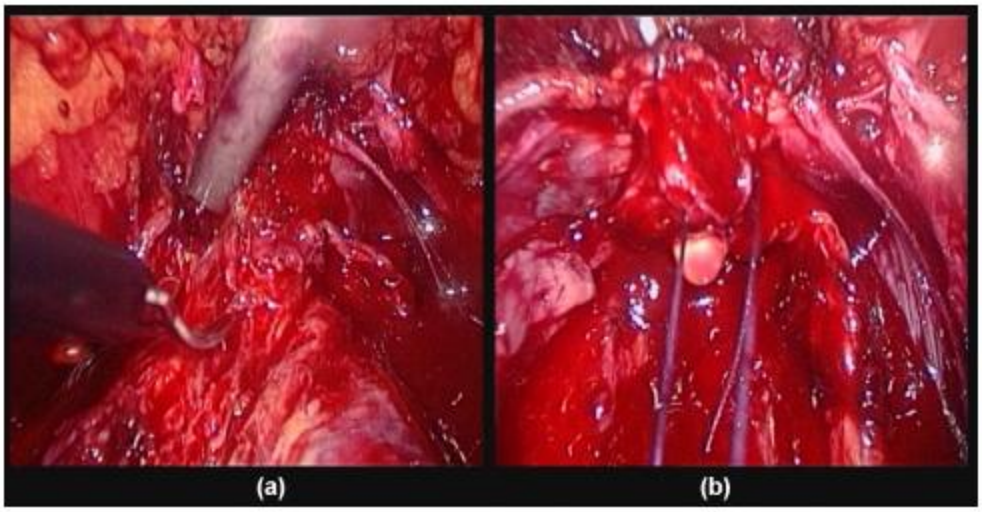

Fig. 2.

(a) The deep venous complex (DVC) is sectioned. The plexus is gently pressed with the tip of the suction probe to reduce blood loss; (b) selective ligature of the DVC with a single stitch in a figure-8 fashion.

Table 1.

Patient characteristics and preoperative pathologic data

	Group A (30 patients; standard technique)	Group B (30 patients; SLDVC)	*p* values
Age, mean ± SD	63.4 ± 5.06	64.0 ± 6.1	NS
BMI, mean ± SD	28.1 ± 2.6	27.1 ± 1.7	NS
PSA, ng/ml, mean ± SD	9.8 ± 7.15	8.27 ± 4.05	NS
US prostate volume, cm^3, mean ± SD	60.14 ± 20	58 ± 18	NS
GS at biopsy, mean ± SD	6.03 ± 0.59	6.01 ± 1.2	NS
T stage, No. (%)	T1 27 (90)	T1 24 (80)	NS
	T2 3 (10)	T2 6 (20)	

SLDVC = selective ligature of the deep venous complex; NS = not significant; BMI = body mass index; PSA = prostate-specific antigen; US = urethral sphincter; GS = Gleason score.

Table 2.

Pathologic data*

	Group A (n = 30)	Group B (n = 30)	p values	Group A (n = 30) Positive margins (R1)	Group B (n = 30) Positive margins (R1)	p values
pT2, No. (%)	23 (76)	21 (70)	NS	3 (apex: 1 patient)	3 (apex: 1 patient)	NS
pT3, No. (%)	7 (24)	9 (30)	NS	3 (apex: 1 patient)	2 (apex: 1 patient)	NS
N0, No. (%)	13 (43)	12 (40)	NS	–	–	–
N1, No. (%)	1 (3)	1 (3)	NS	–	–	–
Nx, No. (%)	14 (54)	17 (57)	NS	–	–	–
Pathologic GS, mean ± SD	6.42 ± 0.9	6.64 ± 0.7	NS	–	–	–
Prostate size, cm^3, mean ± SD	48.14 ± 21.5	46.57 ± 16.9	NS	–	–	–
Tumor volume, cm^3, mean ± SD	2.2 ± 1.53	2.3 ± 1.74	NS	–	–	–

NS = not significant; GS = Gleason score.

* Group A underwent the standard technique and Group B underwent selective ligature of the deep venous complex (SLDVC).

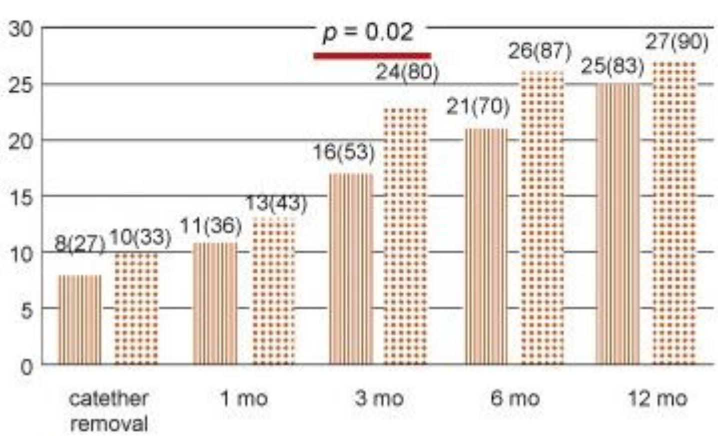

Fig. 3.

Number of continent patients (continence rate in parentheses) at catheter removal and at 1, 3, 6, and 12 mo; p value at 3 mo was statistically significant. Group A = striped; Group B = dotted.