

Radical Open Inguinal Lymphadenectomy for Penile Carcinoma: Surgical Technique, Early Complications and Late Outcomes

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Abbreviations and Acronyms

DVT = deep vein thrombosis
RIL = radical inguinal lymphadenectomy

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Purpose: We reviewed our recent experience with inguinal lymph node dissection in patients with penile cancer to assess the incidence and magnitude of complications caused by this procedure.

Materials and Methods: Radical bilateral inguinal lymphadenectomy was performed in 170 patients (340 procedures). Prophylactic and therapeutic radical inguinal lymphadenectomy was done in 67 (39.4%) and 103 patients (60.6%), respectively. Operative time and length of hospital stay were examined. Complications were divided into minor and major, and early (30 days or less after surgery) and late (greater than 30 days), and analyzed.

Results: A total of 35 complications (10.3%) were observed, of which 25 (71.4%) were minor and 10 (28.6%) were major. We noted lymphedema in 14 patients (4.1%), seroma in 4 (1.2%), scrotal edema in 3 (0.9%), skin edge necrosis in 3 (0.9%), lymphocele in 3 (0.9%), wound infection in 2 (0.6%), flap necrosis in 2 (0.6%), wound abscess in 2 (0.6%) and deep venous thrombosis in 2 (0.6%). There was no significant difference in complication rates between patients treated with prophylactic vs therapeutic dissection. Mean hospital stay was 6.4 days (range 4 to 27). Average operative time for radical unilateral inguinal lymphadenectomy was 94 minutes.

Conclusions: Our contemporary series includes a lower incidence of complications, such as wound infection, skin flap necrosis, lymphocele and lymphedema. To our knowledge this series represents the lowest incidence rate of complications described in the international literature.

Key Words: penis, carcinoma, lymph node dissection, postoperative complications, outcome assessment (health care)

ALTHOUGH penile squamous cell carcinoma is one of the few urological cancers that is potentially curable by lymphadenectomy, the procedure is associated with a significant incidence of morbidity. Thus, a significant number of patients with penile cancer at risk for metastasis have not undergone potentially curative inguinal lymphadenectomy.¹ Should we perform lymphadenectomy in all

patients and expose them to the morbidity risk of inguinal dissection? This is one of the most controversial points in urological literature. At initial presentation 50% of patients with penile squamous cell carcinoma have inguinal lymphadenopathy but only half of them have metastatic lymph node involvement.² Furthermore, 20% of patients with clinically negative inguinal lymph nodes have

micrometastasis, which is only diagnosed by histopathological examination of surgical specimens obtained at lymphadenectomy.²

Recent reports demonstrated that the conventional lymphadenectomy complication rate can be decreased to 50% in experienced hands, and with adequate intraoperative and postoperative care.^{3–5} Because of the discrepancy between clinical staging and pathological findings, and based on the results obtained by our group with the surgical approach to the inguinal region we recommend RIL in patients with clinically negative nodes at high risk for inguinal dissemination and in those with clinically positive inguinal nodes.

Several years ago we reported a study of lymphadenectomy complications using several types of incisions. We subsequently chose to use the Gibson incision for all lymphadenectomies in patients with penile tumors. A contemporary technique such as laparoscopic lymphadenectomy aims to minimize the morbidity of lymph node dissection. Moreover, intensive preoperative and postoperative care as well as antibiotics has decreased the incidence of wound complications. With these considerations in mind we analyzed our current experience with the open procedure to assess the incidence of complications associated with this surgical technique.

PATIENTS AND METHODS

Patient Characteristics

Between January 2002 and December 2011 at our hospitals 255 men with squamous cell carcinoma of the penis were evaluated, including 170 who underwent bilateral RIL (340 procedures). Patients with ulcerated inguinal metastasis who received chemotherapy and/or underwent palliative surgery and myocutaneous flap reconstruction were excluded from study. Clinical and pathological staging was done according to the 2002 TNM classification system. Patients were clinically evaluated for inguinal and visceral metastasis by physical examination of the inguinal region and computerized tomography of the abdomen, pelvis and chest. Pathological material was reviewed and all tumors were histologically classified based on the Broders system. Mean patient age was 58.2 years (range 25 to 91) and mean lesion size was 4 cm (range 0.3 to 15). Only 2 pathologists reviewed the penile lesion and lymphadenectomy specimens.

We also evaluated time between treatment of the primary lesion and inguinal dissection. We considered lymphadenectomy to be prophylactic when performed in patients with clinically negative lymph nodes at high risk for inguinal dissemination (pT2, lymphovascular invasion, and/or Broders histological classification II or greater). We considered it therapeutic when performed in men with clinically positive inguinal lymph nodes. We also evaluated the operative time required for each procedure and the length of hospital stay. Patients were followed at outpatient visits monthly for 3 months after

hospital discharge, every 3 months during followup year 1 and every 6 months thereafter.

All patients were evaluated prospectively and provided informed consent to participate in the study. Our institutional review board also approved the study. Data collection was done by medical assistants during perioperative and outpatient followup based on a checklist of the major complications associated with this type of procedure.

Surgical Procedure

Standard inguinal lymphadenectomy was performed with inclusion of the superficial and deep inguinal nodes. Figure 1 shows the complete procedure. It is not necessary to transpose the sartorius muscle for femoral vessel coverage. A 0.5 to 1.0 cm narrow strip of skin is removed from the edge of the lower skin flap and the wound is closed. The skin strip is removed from the lower flap since this area is more susceptible to ischemia due to tension during surgical lymph node dissection. After tissue removal bleeding at the skin edges is examined to determine whether the flap is viable. Suction drains are inserted lateral to the incision near the anterosuperior iliac spine. This technique is the same as that first reported in 1991 by Ornellas et al⁶ and similar to that described by Fraley and Hutchens⁷ without a complementary distal incision procedure.

Postoperative Care

All patients received antibiotic therapy, which was initiated at anesthetic induction and maintained during hospital stay. We used first-generation cephalosporins in most cases according to our committee to control hospital infection. In specific cases cultures were made of the primary tumor and patients were treated in accord with the result. All patients were restricted to bed rest for 3 days with ambulation starting on postoperative day 4.

Acquired and hereditary factors have essential roles in DVT. Hip or leg fracture, hip or knee replacement, major general surgery or trauma and spinal cord injury are considered strong risk factors. Low molecular weight heparin was prescribed in patients at high risk for DVT and discontinued after the onset of ambulation. Local dressings were performed without fixing with adhesive tape. Oily lotion with essential fatty acids, and vitamins A and E (Dersani, Saniplan, Rio de Janeiro, Brazil) was applied daily in the groin area of the inguinal dissection to maintain the moisture balance of the skin, improve its elasticity and prevent wounds. No compression device was used to avoid lymphedema. Suction drains were removed after the output was less than 50 ml in 24 hours. Patients were discharged from the hospital 24 hours after inguinal drain removal.

Complications

We divided patients into 2 groups according to time to complication onset. Early complications were defined as those that emerged within 30 days of surgery. Late complications were categorized as those that emerged after this period. Complications were stratified as minor or major based on the definitions of Bevan-Thomas et al.³

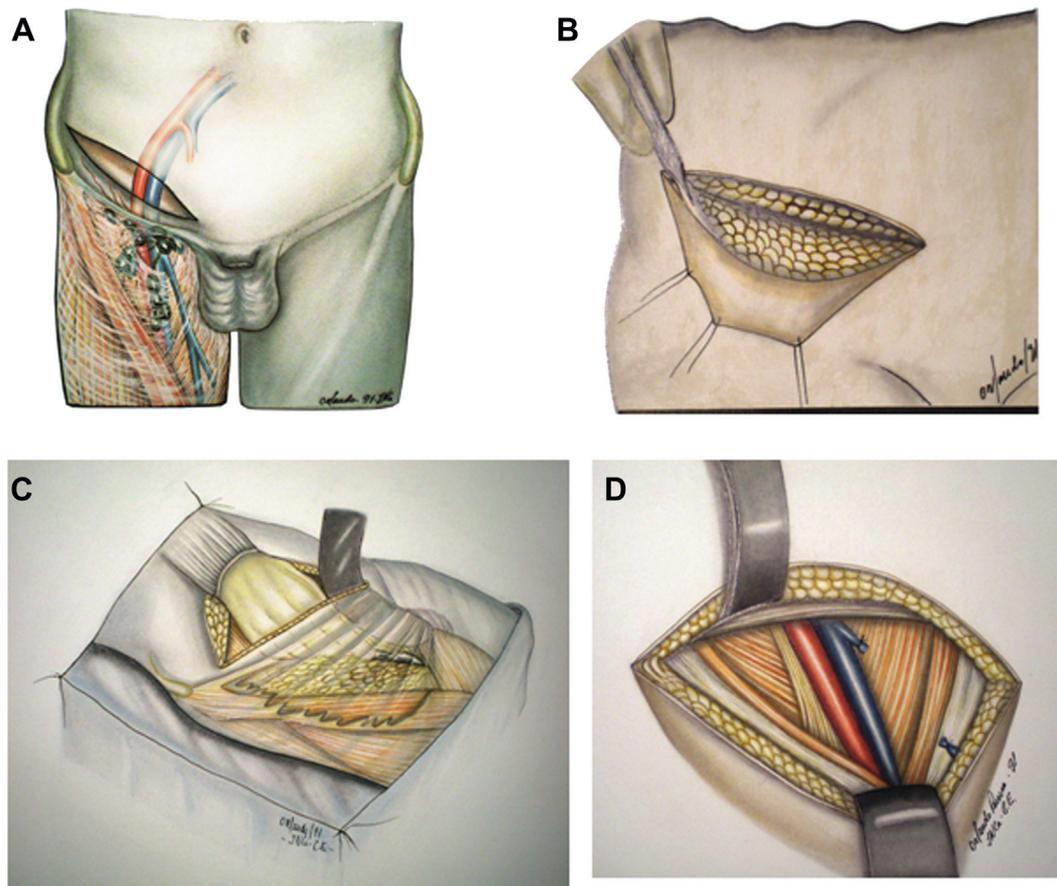


Figure 1. Patient is placed supine with legs fixed in moderate external rotation. Ten cm horizontal skin incision is made 2 cm above inguinal crease with pubic symphysis and anterior superior iliac spine as anatomical reference points. *A*, incision ends are bent up to allow for maximum lower flap vascularization. At inguinal dissection upper end Scarpa fascia fibrofatty tissue is incised, exposing external oblique muscle aponeurosis and continuing up toward inguinal ligament. *B*, subcutaneous tissue superficial to Scarpa fascia is preserved by dissecting lower skin flap at Scarpa fascia level until approximately 12 cm below incision, where femoral triangle apex is reached. At inferior dissection distal limit greater saphenous vein is isolated and severed between ligatures. Dissection continues with identification, ligation and section of greater saphenous vein, and its branches at its insertion into femoral vein. *C* and *D*, surgical specimen is removed close to femoral vessels, which are left clean to femoral triangle apex. Resection includes lymphatic tissue between sartorius and adductor longus muscles, and fascia covering these muscles. All subcutaneous tissue along proximal, distal, medial and lateral margins is sutured to avoid lymph drainage.

RESULTS

Five patients (2.9%) were treated with topical 5-fluorouracil cream 5% due to carcinoma in situ, 4 (2.4%) underwent circumcision due to lesions limited to the foreskin and 4 (2.4%) underwent primary lesion resection of superficial tumors smaller than 4 cm. The penis was partially amputated in 118 patients (69.4%) with tumors larger than 4 cm and/or signs of invasive disease. Total penile amputation was performed in 32 patients (18.8%) with extensive lesions and/or invasive disease affecting the penile shaft. Only 7 men (4.1%) underwent emasculation due to large tumors with extensive involvement of the penile shaft and scrotum. Table 1 lists primary tumor pathological characteristics and clinical lymph node status of the inguinal region.

Of the 170 patients evaluated 67 (39.4%) underwent bilateral prophylactic RIL and 103 (60.6%) underwent bilateral therapeutic RIL (340 procedures). Time from primary tumor treatment to inguinal lymphadenectomy was 2 to 6 weeks in 110 men (71%) while in 45 (29%) the 2 procedures were performed simultaneously. Average hospital stay was 6.4 days (range 4 to 27). Average operative time for unilateral RIL was 94 minutes. A mean of 10.9 lymph nodes (range 6 to 19) was removed at each unilateral RIL. Chest, abdomen and pelvis computerized tomography done systematically to stage all bilateral RIL cases revealed no visceral metastasis or pelvic lymphadenopathy suggesting tumor spread.

A total of 35 complications were associated with the 340 procedures (10.3%), of which 25 (71.4%) were minor and 10 (28.6%) were major. Table 2

Table 1. Clinical and pathological characteristics of primary penile tumor and lymph node status in 170 patients undergoing bilateral RIL

	No. pTis (%)	No. pT1 (%)	No. pT2 (%)	No. pT3 (%)	No. pT4 (%)
Grade:	—	8 (4.7)	110 (64.8)	40 (23.5)	7 (4.1)
1	Not applicable	4 (2.35)	32 (18.9)	15 (8.8)	2 (1.2)
2	Not applicable	4 (2.35)	70 (41.2)	23 (13.5)	5 (2.9)
3	Not applicable	0 (0)	8 (4.7)	2 (1.2)	0 (0)
Lymphovascular invasion:	—	8 (4.7)	110 (64.8)	40 (23.5)	7 (4.1)
Present	Not applicable	4 (2.35)	36 (21.2)	14 (8.2)	4 (2.35)
Absent	Not applicable	4 (2.35)	74 (43.6)	26 (15.3)	3 (1.75)
Clinical lymph node status:	5 (2.9)	8 (4.7)	110 (64.8)	40 (23.5)	7 (4.1)
cN0	0	5 (2.9)	54 (31.8)	8 (4.7)	0
cN1	2 (1.2)	2 (1.2)	15 (8.9)	8 (4.7)	0
cN2	3 (1.75)	1 (0.6)	29 (17.1)	24 (14.1)	2 (1.2)
cN3	0	0	12 (7)	0	5 (2.9)

shows complication rates and types in patients treated with prophylactic vs therapeutic RIL. Of the 35 complications evaluated 23 (65.7%) were early and 12 (34.3%) were late (table 2). Only 1 patient (0.3%) presented with an intraoperative complication (femoral vein injury). Average followup was 37.2 months. Figure 2 shows flap necrosis and an example of lymphedema.

DISCUSSION

In recent years efforts to decrease the morbidity of lymphadenectomy have been based on surgical procedures to reduce the area of lymph node dissection. However, these techniques were accompanied by reports of inguinal recurrence at followup.^{8,9} In patients with clinically negative lymph node or palpable adenopathy a viable option would be selective lymphadenectomy, as proposed by Catalona.¹⁰ However, due to the possible metastatic involvement of lymph nodes located outside the limited dissection area, caution is recommended when using these approaches.¹¹

As described by Bishoff et al¹² and standardized by Tobias-Machado et al,¹³ video endoscopic access to decrease the morbidity of conventional technique has proved feasible and may reduce postoperative morbidity.¹⁴ In another study in which patients underwent open RIL on one side and video endoscopic lymphadenectomy on the other Tobias-Machado et al removed a similar number of nodes on the 2 sides and there was no disease relapse or progression at an average followup of 18 months.¹⁵ The laparoscopic technique using a single portal¹⁶ is the next step in the scenario of minimally invasive surgery. Studies in larger samples with longer followup may show whether these approaches are really advantageous. In the literature there are already reports of using the robotic platform for inguinal lymphadenectomy in penile cancer cases.¹⁷ However, to our knowledge there are no comparative studies.

Inguinal lymphadenectomy is historically associated with a high complication rate.^{3,18} More contemporary surgical series show an overall complication rate of between 45% and 57% in patients undergoing this procedure as part of penile

Table 2. Minor and major complications related to 134 prophylactic and 206 therapeutic RILs, and 35 early and late complications related to all 340 RILs

Complication	No. Complications (%)			
	Prophylactic RIL*	Therapeutic RIL†	Early	Late
Minor:	13 (9.6)	12 (6)	15 (42.9)	10 (28.6)
Wound infection	0	1 (0.5)	1 (2.85)	0
Seroma	2 (1.5)	2 (1)	4 (11.5)	0
Leg edema (trace/+ 1/+ 2)	4 (2.9)/1 (0.75)/3 (2.2)	3 (1.5)/2 (1)/1 (0.5)	5 (14.35)/1 (2.85)/0	2 (5.7)/2 (5.7)/4 (11.5)
Skin edge necrosis	1 (0.75)	2 (1)	3 (8.5)	0
Scrotal edema	2 (1.5)	1 (0.5)	1 (2.85)	2 (5.7)
Major:	6 (4.5)	4 (2)	8 (22.8)	2 (5.7)
Wound infection + intravenous antibiotics	0	1 (0.5)	1 (2.85)	0
Lymphocele + intervention	2 (1.5)	1 (0.5)	2 (5.7)	1 (2.85)
Flap necrosis/treatment	1 (0.75)	1 (0.5)	2 (5.7)	0
Wound abscess/cellulitis	2 (1.5)	0	2 (5.7)	0
DVT	1 (0.75)	1 (0.5)	1 (2.85)	1 (2.85)
No./total No. (%)	19	16	23/35 (65.7)	12/35 (34.3)

* No lymphocele not requiring intervention as minor complication, or wound seroma requiring operating room drainage, debilitating leg edema, hematoma, sepsis or death as major complication.

† No lymphocele not requiring intervention as minor complication, or seroma requiring operating room drainage, debilitating leg edema, hematoma, sepsis or death as major complication.



Figure 2. A, after bilateral lymphadenectomy using Gibson incision right skin necrosis developed in mid inferior flap as early complication. This area is most susceptible to skin necrosis due to poor blood supply. B, final appearance of inguinal region after necrotic area healed. Another surgery was not needed to correct defect in affected area. C, moderate lymphedema of left leg was late complication that developed 18 months after bilateral lymphadenectomy using Gibson incision.

cancer management (table 3).^{3–6,18–24} In our most recent 170 patients treated with inguinal lymphadenectomy the overall complication rate was 10.3%, including 25 minor (71.4%) and 10 major complications (28.6%). To our knowledge this is the lowest complication rate in the international literature (table 3). A limitation when analyzing these results is the lack of patient randomization to compare the Gibson incision on one side to laparoscopic lymphadenectomy on the other.

Baronofsky reported that inguinal skin vascularization at the level of the subcutaneous adipose tissue is horizontal.²⁵ This explains the high percentage of skin edge necrosis observed with vertical incisions that mostly interrupt the skin blood supply of the inguinal region. With the Gibson incision the incidence of flap necrosis is low, probably because the incision is horizontal and made in the superior margin of dissection above the inguinal ligament. The superior flap is always viable because dissection is carried below the incision. Due to the small percent of necrosis in our series we believe that it is

not necessary to transpose the sartorius muscle for femoral vessel coverage. Transposing the sartorius muscle is one of the factors most strongly associated with moderate to severe wound complications.²⁶ In our previous series the Gibson incision was used in 85 inguinal lymphadenectomies and skin flap necrosis developed in 4 cases.⁶ Reoperation with skin grafting was necessary in only 1 patient. In the current series of 340 surgical procedures there were 2 cases of flap necrosis and 3 of skin edge necrosis, of which neither required skin grafting. In the 2 cases of skin flap necrosis conservative treatment was performed with tissue débridement and daily dressings. Patients remained hospitalized until granulation tissue appeared. After hospital discharge they were followed weekly to assess the progress of healing.

Anatomy reports of the inguinal region applied to lymphadenectomy are sparse. The number of superficial and deep inguinal nodes varies from 10 to 15 and 0 to 5, respectively.^{27–29} In the current series the average number of lymph nodes removed

Table 3. Postoperative complications associated with inguinal lymphadenectomy in surgical series

References	No. Pts	% Overall Complications	No. Wound Infection (%)	No. Wound Dehiscence + Necrosis (%)	No. Lymphocele (%)	No. Lymphedema (%)
Johnson and Lo ¹⁸	67	82	14	50	9	50
Ornellas et al ^{6*}	44	—	15	5	9	16
Ravi ¹⁹	112	—	—	25	9	16
Kamat et al ²⁰	31	87	—	—	—	—
Lopes et al ²¹	145	—	—	18	—	30
Darai et al ²²	85	—	12	14	3	32 (severe)
Ayyappan et al ²³	78	—	70	36	87	57 (severe)
Coblentz and Theodorescu ²⁴	22	45	9	9	27.2	0
Bevan-Thomas et al ³	53	57	10	8 (necrosis)	—	23
Nelson et al ⁴	22	—	7.5 (minor)	2.5 (necrosis)	15	15
Spiess et al ⁵	43	49	9	11	2	17
Present series	170	10.3	0.9	1.5 (necrosis)	2	4.1

* Gibson incision.

was 10.9 for each unilateral RIL, supporting the extension of lymphadenectomy despite the low morbidity of the Gibson incision.

Mean hospital stay was also lower compared to our historical series.⁶ Length of stay was 6.4 days for our current series and 16 days for our historical series. Operative time also decreased when we compared the 2 series. In the current series bilateral RIL required an average of 3 hours 13 minutes vs 4 hours 50 minutes in the historical series.

The percent of minor and major complications decreased compared to our previous series.⁶ The incidence of lymphedema was markedly reduced from 16% to 4.1%. Differences according to the incidence and severity of lymphedema may be related in part to the type of surgery. In our previous series 28 ilio-inguinal lymphadenectomies were done compared to the current series, in which only inguinal dissection was done.

Apart from these differences we believe that the best results of contemporary series may be related to various factors, including surgical technique and measures to prevent lymphedema. Nevertheless, lymphedema measurement is partly subjective, leading to different interpretations. Wound infection and seroma rates also appear remarkably decreased when comparing our current and former⁶ studies. Perhaps a more careful approach with meticulous control of lymphatics and blood vessels along the subcutaneous tissue margins avoided lymph drainage, decreasing the risk of lymphocele

and/or hematoma, which could lead to infection. Similarly, the best postoperative care could prevent wound infection. DVT and sepsis are serious complications that should be promptly prevented when possible. Two of our patients presented with DVT. In 1 case it was related to an intraoperative femoral vein lesion, which was promptly corrected. The other case presented during outpatient clinic followup. After treatment each patient progressed without sequelae. In patients with a remote history of DVT/pulmonary embolism low dose, low molecular weight heparin must be administered perioperatively until postoperative day 28, in accordance with the results of a recent randomized trial.³⁰

CONCLUSIONS

Prophylactic RIL became justified in select patients after surgical morbidity decreased due to modification of the inguinal approach. Associated morbidity is reasonable in relation to therapeutic RIL, considering the potential therapeutic benefit. Conventional open RIL should remain the gold standard for penile cancer until studies in larger samples with longer followup show that minimally invasive approaches are advantageous. In this contemporary series we noted a markedly lower incidence of wound infection, skin flap necrosis, lymphocele and lymphedema. To our knowledge this series presents the lowest complication rates in the international literature.

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