

PENECTOMY WITH SIMULTANEOUS COMPARED TO DEFERRED BILATERAL INGUINAL LYMPH NODE DISSECTION FOR SQUAMOUS CELL CARCINOMA OF THE PENIS – EVALUATION OF SURGICAL COMPLICATIONS

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Objective: In men with advanced squamous cell carcinoma of the penis, inguinal lymph node dissection is usually deferred for 6 weeks after primary penectomy. The rationale is that the penile lesion is usually infected and immediate lymphadenectomy may lead to a higher surgical complication rate. However, some patients do not return for deferred node dissection and then present much later with incurable metastatic disease. The aim of this study was to compare the complication rates of simultaneous versus deferred bilateral inguinal lymph node dissection.

Patients and Methods: From October 1999 to September 2006, 29 men with histologically confirmed squamous cell carcinoma of the penis were treated. Penectomy with simultaneous bilateral inguinal lymph node dissection was performed in 18 patients with locally advanced primary lesions (cT2 in 8, cT3 in 10) and palpable inguinal nodes. The complications were compared with a previous study of 34 men who underwent bilateral inguinal lymph node dissection at a mean of 72 days after penectomy at Tygerberg Hospital during the period November 1983 to April 1995.

Results: Post-operative complications occurred in 11 of 18 patients (61.1%); lymphocele formation in 8, lymph leak in 1, wound dehiscence and skin edge necrosis in 5, wound sepsis in 1, lymphedema of the legs in 2, scrotal edema in 1 and cellulitis in 2 patients (more than one complication occurred in some patients). In the previously reported comparison group who had undergone deferred inguinal lymph node dissection at a mean of 72 days after penectomy, complications occurred in 26 of 34 (76.5%) patients: wound sepsis in 12, wound dehiscence in 7, lymphocele in 7, lymph leak in 4, wound abscess in 3, necrosis of wound edges in 2 and hematoma formation in 1.

Conclusions: Penectomy with simultaneous bilateral inguinal lymph node dissection in men with squamous cell carcinoma of the penis does not lead to a higher complication rate compared with primary penectomy and deferred inguinal lymph node dissection performed at a mean of 10 weeks after the primary procedure.

Key Words: penis, cancer, lymph node dissection, complications.

INTRODUCTION

Squamous cell carcinoma (SCC) of the penis metastasizes via the lymphatic system to the inguinal lymph nodes and from there to the pelvic nodes. The inguinal lymph nodes act as a first-stop echelon and it is very rare to have pelvic lymph node metastases without positive inguinal lymph nodes. Because of this predictable pattern

of metastatic spread, an inguinal lymph node dissection (ILND) can detect, stage and possibly cure early metastatic lymph node disease in penile carcinoma¹⁻⁶.

Other modalities to evaluate the inguinal lymph nodes are not yet reliable enough to exclude metastatic lymph node disease^{7,8}. These include clinical examination, computerized

tomography (CT) and magnetic resonance imaging (MRI), lymph node biopsy and ultrasound guided fine needle aspiration (FNA) of the lymph nodes. Dynamic sentinel lymph node biopsy using Technetium⁹⁹ and colloid blue, as well as contrasted MRI with ferumoxtran-10, has improved the sensitivity and specificity significantly, but is expensive and not readily available^{9,10,11}.

However, because of the significant morbidity associated with ILND, there is controversy about the management of the inguinal lymph nodes. Specific issues are the inability to clinically predict the presence of lymph node metastases, the indications for ILND, the timing and the optimal extent of ILND^{2,6,12,13}. Considering the fact that metastatic SCC of the penis can be cured surgically, the morbidity of ILND should be weighed up against the potential for cure¹⁴.

In men with SCC of the penis, the incidence of palpable lymph nodes at presentation is 30%- 60%, depending on the grade and stage of the disease^{13,15}. In cases of palpable inguinal lymphadenopathy, approximately 50% are metastatic and 50% are reactive due to the infected primary tumor. Another conundrum is that 20% of non-palpable inguinal lymph nodes harbor metastatic disease. Given these percentages, the possibility exists that an unnecessary ILND may be done in 50% of patients with palpable lymph nodes and in 80% of patients with non-palpable nodes.

Strong predictive factors for nodal metastases are the grade of the primary tumor, the depth of tumor infiltration and the presence of lymphovascular invasion (LVI)^{4,6,16-18}. Moderately and poorly differentiated tumors have a 46% and 80-100% risk of lymph node metastases respectively, whereas well-differentiated tumors have a 24% risk. Stage T1 tumors have a 5-11% risk for positive inguinal node metastases, whereas T2 tumors have a 61-75% risk for such metastases

Based on a retrospective analysis of the available data on SCC of the penis, Solsona et al. have updated the EAU Guidelines on the

management of this rare disease²⁰. Tumors are divided into low, intermediate and high risk categories. Low risk penile tumors are Tis, TaG1-2 and T1G1, intermediate risk tumors are T1G2 without LVI, and high risk tumors are T1G3 or any higher stage, regardless of grade. The risk of nodal metastases can be as high as 70% in high risk tumors²⁰.

ILND is usually deferred for 6 weeks after penectomy, during which time the patient is placed on antibiotic treatment, because it is thought that simultaneous penectomy and ILND will result in more complications due to infection of the primary lesion, superimposed on impaired lymphatic drainage after ILND. At Tygerberg Hospital a policy of deferred ILND was followed prior to 1995, but this was reviewed because of unfortunate experiences with patients who did not return for ILND after 6 weeks, only to present at a later stage with fungating and ulcerating inguinal lymph node metastases. This led to a policy of performing ILND at the same time as surgery for the primary penile tumor.

The aim of this study was to evaluate the complications of penectomy and immediate ILND as compared with delayed bilateral ILND performed a few weeks after penectomy.

PATIENTS AND METHODS

Between October 1999 and September 2006, 29 men with histologically confirmed SCC of the penis were treated at Tygerberg Hospital. Penectomy with simultaneous bilateral ILND was performed in 18 patients with palpable inguinal nodes (a total of 36 inguinal block dissections). The indications for bilateral ILND were G2-3 and/or T3-4 primary tumors.

Patients were staged according to the 1998 TNM staging system. Clinical staging included a chest X-ray and abdominal ultrasound. Pus swabs of the primary penile tumors were taken, and patients with a positive culture were treated with an appropriate antibiotic preoperatively. Fine needle aspiration (FNA) cytology of the

clinically suspicious palpable inguinal lymph nodes was done pre-operatively.

Written informed consent was obtained pre-operatively from all patients. Bilateral ILND was performed according to standard techniques. An approximately 10 cm skin incision was made about 1-2 cm inferior the inguinal ligament. Care was taken to preserve the subcutaneous tissue and not to excessively undermine the skin flaps. The borders of the ILND were the adductor longus muscle medially, the sartorius muscle laterally, the apex of the femoral triangle inferiorly and about 2 cm above the inguinal ligament superiorly. The branches of the saphenous vein were ligated at the periphery of the dissection area, and in most cases the saphenous vein itself was ligated and removed to facilitate en bloc nodal clearance. In most cases a sartorius muscle flap was mobilized and brought medially to cover the exposed femoral artery and vein.

A ¼ inch closed suction drain was placed, and the wound was primarily closed with interrupted Nylon 2/0 sutures. A sterile plastic dressing was applied to create an airtight closure for the suction drain to function properly. Perioperative broad-spectrum antibiotic coverage was continued for 5 days after the procedure. Patients were allowed to mobilize on day 2 postoperatively and the wound drains were removed if the drainage was less than 50 ml/day. In cases with persistent lymph drainage the suction mechanism of the suction drain was discontinued and the wound was allowed to drain freely. No patient received peri-operative heparin or compression stockings.

Complications such as lymphocele formation, lymph leak, lymphedema of the legs or scrotum, cellulitis, wound infection, wound dehiscence and skin flap necrosis were carefully documented and managed during the hospitalization period. After discharge the patients were followed up at the Urological Oncology clinic every 6 months for 3 years.

The complication rate in the present study group was compared to a previous study

reported from Tygerberg Hospital, where 34 patients underwent bilateral ILND at a mean period of 72 days after penectomy in the period November 1983 to April 1995²¹.

RESULTS

The 18 patients who underwent penectomy and immediate bilateral ILND had a mean age of 53 (range 34-84) years. None of the patients were HIV positive, but previous human papillomavirus (HPV) infection had been documented in 3 cases. All patients were uncircumcised, and 16 (88.9%) were current or previous smokers. The primary penile lesion had been present for more than a year in 8 (44.4%) and for about 6 months in 5 (27.8%) patients (10 of the 18 patients came from remote areas). Phimosis was present in 6 (33.3%) patients.

The characteristics of the patients in the two groups (current study and historical study) did not differ significantly. In the historical study, the mean age was 54 (range 33-88) years. Phimosis occurred in 22%, and only one patient was circumcised. Two of 18 patients tested positive for HIV²¹. Follow-up in the previous series was available in 78% for a mean of 22 months, whereas 72% in the present study were followed up for a mean of 14.5 months.

The histological grade of the penile biopsies were grade 1 in 7, grade 2 in 10 and grade 3 in 1 patient. The clinical stage of the primary tumor was T2 in 8 and T3 in 10 patients. Bilateral inguinal lymph nodes were palpable in all but one patient, who had unilateral palpable nodes. The decision to perform bilateral ILND in this patient was based on the well known propensity of locally advanced tumors to have bilateral inguinal lymphatic drainage^{9,20}.

Total penectomy with perineal urethrostomy was performed in 6 patients, and partial penectomy was performed in 12. The histological grade of the penectomy specimen was grade 1 in 7, grade 2 in 10 and grade 3 in 1 patient. Pathological stage

of the primary tumor was pT1 in 1, pT2 in 10 and pT3 in 7 patients. The nodal stage was N1 in 2 patients (pT3N1 and pT2N1) and N2 in 2 patients (both pT3N2). In the four node-positive patients metastatic SCC was present unilaterally in 2/10 nodes, 2/13 nodes, 3/10 nodes and 4/9 nodes. None of the dissections had bilateral lymph node involvement. Of the four patients with nodal metastatic disease, two had a positive FNA, in one patient the FNA was not done, and in the other patient the FNA sampling was reported as not representative.

Complications of ILND occurred in 11 patients (61.1%): lymphocele formation in 8, lymph leak in 1, wound dehiscence and skin edge necrosis in 5, wound sepsis in 1, lymphoedema of the legs in 2, scrotal edema in 1 and cellulitis in 2 patients (more than one complication occurred in some patients) (Fig.1, 2). The inguinal complications were bilateral in 9 and unilateral in 2 patients.

A secondary surgical procedure was required in 5 (28%) patients: 3 inguinal wound debridements, 1 secondary wound suturing and 1 split-thickness skin graft. The other patients were managed non-surgically. In cases of wound dehiscence and lymph leak, swabs were sent for microbiological culture and appropriate antibiotics were prescribed. The open wounds were covered with isotonic saline dressings and allowed to heal with granulation. Small lymphoceles were aspirated and large ones were opened with a stab incision and allowed to drain freely. All the draining lymphoceles eventually stopped within 3 weeks. Lymphedema of the legs occurred in 2 patients and resolved after about 3 weeks with elevation of the lower limbs.

Pre-operative medical co-morbidities in the study group included peripheral vascular disease and morbid obesity in 1, previous pulmonary tuberculosis in 1 and emphysema in 1 patient. None of the patients developed major complications such as myocardial infarction, deep vein thrombosis, pulmonary embolism or peri-operative death.

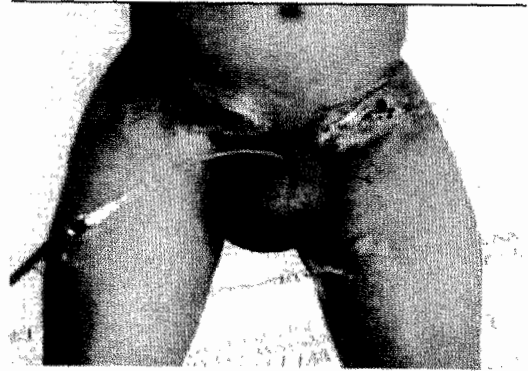


Fig. 1: Bilateral wound sepsis and wound dehiscence with scrotal edema.

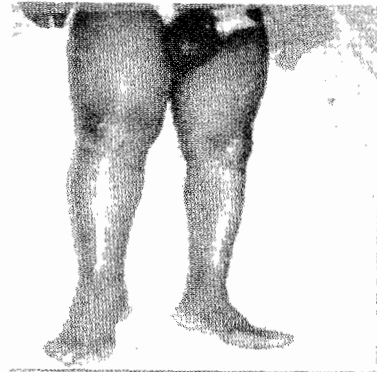


Fig. 2: Lymphedema with cellulitis of the right leg

The mean hospital stay was 30 (range 4-58) days for all patients, 20 (range 4-27) days for patients without complications and 42 (range 27-58) days for patients with complications. Follow-up was available in 13 (72.2%) patients and the average follow-up was 14.5 (range 2-36) months. One of the three remaining patients demised of metastatic disease. He defaulted his three-month follow-up, and presented at 6 months with ulcerating inguinal metastases. One of the four patients with nodal metastases was lost to follow-up.

In the previously reported study group (November 1983 to April 1995), complications of deferred ILND after penectomy occurred in 26 of 34 (76.5%) patients, with wound sepsis in 12, wound dehiscence in 7, lymphocele in 7, lymph leak in 4, wound abscess in 3, necrosis of wound edges in 2 and hematoma formation in 1 (more than one complication occurred in some patients)²¹.

Table: Complications after inguinal lymph node dissection.

	Present Study	Previous Study	Literature	References
Lymphocele	44.4%	20.6%	21%	25
Lymph leak	5.6%	11.8%	23%	2
Lymphedema	11.1%	Not mentioned	55%	25
Wound dehiscence	27.8%	20.6%	41%	25
Wound sepsis	5.6%	35.5%	26%	25
Cellulitis	11.1%	Not mentioned	10%	32
Scrotal edema	5.6%	Not mentioned	4%	8,38
Hematoma	0	2.9%	3%	39
Overall	61.1%	76.5%	50%	25
	n=18	n=34	n=870	
Mean hospital stay (days)	30	17	21	40

The complication rates in the present study group, the previously reported study and the literature are compared in Table 1.

DISCUSSION

SCC of the penis is a rare malignancy, with a reported incidence of 0.1-7.9 per 100,000 per year¹⁵. However, in underdeveloped countries the incidence is significantly higher, with SCC of the penis being the most common male malignancy in Uganda, and constituting 17% of all malignancies in some regions of Brazil^{3,22}. It is more prevalent in uncircumcised males, where phimosis, poor personal hygiene and chronic irritation are contributing factors^{3,20,23,24}.

Untreated metastatic inguinal and pelvic lymph nodes are usually the cause of death in penile cancer due to infection, ulceration and hemorrhage from the femoral vessels^{2,20}. There is considerable controversy about the best way to determine the presence of inguinal lymph node metastases, the indications for, the timing and the extent of ILND^{2,6,12,13}.

ILND has significant postoperative morbidity, with an average rate of 50%²⁵. However, missing the opportunity to surgically

cure a patient of metastatic cancer to the inguinal nodes will have catastrophic results, with patient survival limited to less than 2 years⁹.

There are two approaches to the timing of ILND. Delayed ILND involves active surveillance of men with non-palpable lymph nodes at presentation or after penectomy and antibiotic treatment, where ILND is only performed when palpable lymph nodes are clinically detected on follow-up. Early deferred ILND is performed 6 weeks after initial surgery for the penile tumor, during which time the patient has been on a broad-spectrum antibiotic. The rationale for the 6 weeks delay is that penectomy with simultaneous ILND will result in more complications due to infection of the primary lesion superimposed on impaired lymphatic drainage after ILND. The rationale for the antibiotic treatment is that nodes that are palpable due to infection of the primary tumor will become non-palpable after antibiotic treatment, so that ILND can be avoided. However, as mentioned earlier, the risk of lymph node metastases is dependent on factors that are present at the time of penectomy (grade, stage and LVI of the primary tumor). FNA, with or without ultrasound guidance, can be done on the suspicious inguinal lymph nodes, but the

literature reports false negative rates of about 15%¹³.

Substantial evidence exists that early deferred ILND is better than delayed ILND (the wait and see approach) even with strict follow-up and good patient compliance^{3,17,26}. It seems that delayed ILND is most often too late. In spite of using the early deferred approach, the experience at Tygerberg Hospital showed that some patients do not return for ILND after 6 weeks and present later with fungating and ulcerating inguinal lymph nodes.

Penile carcinoma patients are notorious for their poor compliance to follow-up^{6,23,27-29}. The poor socio-economic status of many of these patients is an important factor²⁰. Despite counseling that their prognosis depends on the status of their inguinal lymph nodes, many patients think that the radical, mutilating and emasculating penile surgery was their definitive treatment. Because early metastatic inguinal lymph nodes are not symptomatic or bothersome, patients do not see the need for regular follow-up. The patient referral area of Tygerberg Hospital extends to more than 400 km, with 50% of the patients residing outside the metropolitan area. All our patients were dependent on public transport, which is expensive for indigent patients and not readily accessible. Regardless of these logistical, financial and intellectual obstacles, an effort should be made to stress the importance of follow up, since this is an integral part of the management of this disease. After a recurrence-free period of 2 to 3 years, the patient can be considered cured and may be discharged^{3,11,21,30}.

Since the value of an ILND is undisputed, various improvements in intra- and postoperative care have led to a decrease in the complication rate. The original radical ILND as described by Daseler in 1948 was deemed excessive, and subsequent alterations to the technique have led to the modified ILND, the main principle of which is a limited dissection^{27,31}. The nodal packet around the saphenous vein and fossa ovalis

is removed, sparing the vein itself. The lateral border is the femoral artery, medially it is the adductor muscle, superiorly the inguinal ligament and inferiorly the inferior edge of the fossa ovalis^{27,28}.

A sartorius muscle flap can be used to cover the exposed femoral vessels. This muscle is conveniently situated next to the area of groin dissection and no functional deficit is encountered when it is mobilized from its origin at the anterior superior iliac spine. Care should be taken not to compromise the proximal vascular pedicle entering the sartorius muscle medially. This can be ensured by limiting the proximal muscle mobilization to 6,5 cm distally and rotating the muscle head medially, rather than shifting it medially over the femoral vasculature^{32,33}. Other principles and techniques include conservative skin incisions, leaving adequate subcutaneous tissue on mobilized skin flaps, trimming the skin edges before closing and the use of a broad-spectrum peri-operative antibiotic^{1,8,20,32,34}.

Extensive ILND with difficult primary wound closure can be expected if the nodal mass is large or involves the skin^{35,36}. Myocutaneous flaps are proven solutions to aid in wound closure and filling of the dead space. Options include the tensor fascia lata, the gracilis and the rectus abdominis myocutaneous flaps^{3,12,36,37}. Although it adds time and cost to the procedure, there should be a low threshold to use a myocutaneous flap, since it dramatically improves wound healing and limits the post-operative complications^{36,37}. Co-morbid factors related to a higher incidence of complications after ILND are patients with an ASA score \geq III, specifically diabetes mellitus, obesity, old age, smoking, poor nutritional status and immunosuppressive medication^{1,34,35}.

Post-operative lymphedema of the legs can be limited by peri- and post-operative use of elastic or pneumatic compression stockings for up to 6 months^{27,32,34,37,38}. Elevation of the legs to 30° at night, and the use of diuretics have also been proven to be beneficial³². Early

postoperative mobilization will help to prevent deep vein thrombosis (DVT), although it may potentially worsen early lymphedema of the lower limbs^{35,38}. Prevention of DVT should take preference over the lymphedema, which can be managed by the aforementioned methods.

Lymphocele formation occurs secondary to the sequestration of lymph from the disrupted lymphatic ducts into the potential space where the lymph nodes were removed. There is controversy about the use of prophylactic heparin, as this may increase lymphocele formation³⁸. Lymph leakage can be limited by meticulous identification and ligation of lymphatic ducts during the ILND. Obliteration of the potential space in the post-dissection groin will also help to prevent lymphocele formation. A closed suction drain and compression dressings as well as the mobilization of muscular flaps may achieve this. The wound should be closed in an airtight manner to allow the closed suction drain to perform properly. However, care should be taken not to strangulate the skin edges with continuous running sutures, as this may lead to skin edge necrosis and wound breakdown. Occlusion of the dead space can also be done by the placement of deep absorbable sutures and the use of tissue glue³⁴.

In this study the average hospital stay of the patients with complications was more than double that of the uncomplicated cases (42 vs 20 days). However, we followed a conservative approach regarding patient discharge, and did not transfer patients if satisfactory wound management was not available at the referring secondary hospital.

The fact that only 4/18 (22.2%) of the palpable inguinal lymph nodes contained metastatic SCC, and not about 50% as reported in the literature, may be attributed to the small number of patients in this study. Another factor may be that almost all the patients presented with infected, fungating penile lesions, possibly explaining the reactive lymph nodes. In the historical study metastases were present in 49% of the patients who underwent ILND²¹.

The shortcomings of this study are the limited number of patients and the use of a historical control group, making valid statistical analysis impossible. However, because of the rarity of SCC of the penis, the publication of all data should be encouraged, so that future meta-analyses can be performed in order to determine the optimal management of this disease.

In conclusion, in this study surgical complications occurred in 11 of 18 (61.1%) men with SCC of the penis who had undergone penectomy and simultaneous bilateral ILND in the period 1999 to 2006. In comparison, complications occurred in 26 of 34 (76.5%) men who had undergone bilateral ILND at a mean of 72 days after penectomy in the period 1983 to 1995, indicating that penectomy and immediate bilateral ILND does not lead to a clinically significant increase in the risk of postoperative complications.

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RESUME

Pénectomie avec dissection inguinale bilatérale des chaînes lymphatiques simultanée comparée à la différée pour le carcinome squameux du pénis. L'évaluation des complications chirurgicales

Objectif: Chez les hommes avec carcinome squameux avancé du pénis, la dissection inguinale des ganglions lymphatiques est habituellement reportée pendant 6 semaines après pénectomie primaire. Le raisonnement est que la lésion pénienne est habituellement infectée et la lymphadénéctomie immédiate peut mener à une fréquence plus élevée de complications chirurgicales. Cependant, quelques patients ne retournent pas pour la lymphadénéctomie et consultent beaucoup plus tard avec une maladie métastatique incurable. Le but de cette étude est de comparer la fréquence des complications de la lymphadénéctomie simultanée contre la différée.

Patients et méthodes: D'octobre 1999 à septembre 2006, 29 hommes avec carcinome squameux du pénis histologiquement confirmé ont été traités. Une pénectomie avec dissection inguinale bilatérale simultanée des ganglions lymphatiques a été réalisée chez 18 patients avec des lésions primaires localement avancées (cT2 dans 8 cas, cT3 dans 10) et des ganglions inguinaux palpables. Les complications ont été comparées à une étude précédente de 34 hommes qui ont subi la dissection inguinale bilatérale de ganglions lymphatiques à en moyenne 72 jours après pénectomie à l'hôpital de Tygerberg pendant la période le novembre 1983 à avril 1995.

Résultats: Les complications postopératoires se sont produites chez 11 des 18 patients (61.1%) : formation de lymphocèle chez 8, fuite de lymphes chez 1, nécrose et déhiscence des berges chez 5, sepsis chez 1, lymphoedème des jambes chez 2, oedème scrotal chez 1 et cellulite chez 2 patients (plus d'une complication s'est produite chez quelques patients). Dans le groupe de comparaison précédemment enregistré qui avait subi la dissection inguinale reportée de ganglions lymphatiques à en moyenne 72 jours après la pénectomie, les complications se sont produites chez 26 des 34 patients (de 76.5%) : sepsis chez 12, la déhiscence chez 7, le lymphocèle chez 7, la fuite de lymphes chez 4, l'abcès de paroi chez 3, la nécrose des bords chez 2, formation de hématome chez 1.

Conclusion: La pénectomie avec dissection inguinale bilatérale simultanée de ganglions lymphatiques chez les hommes avec carcinome squameux du pénis ne présente pas une fréquence plus élevée de complications comparée à la dissection inguinale différée de ganglions lymphatiques réalisée à en moyenne 10 semaines de la pénectomie primaire.

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