

Comparing Outcomes of Robotic and Open Inguinal Lymph Node Dissection in Patients with Carcinoma of the Penis



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Abbreviations and Acronyms

DAPLE = approximate Bayesian logistic regression via penalized likelihood estimation with data augmentation

ENR = elastic net regression

NCCN® = National Comprehensive Cancer Network®

OILND = open inguinal lymph node dissection

RA-VEIL = robot-assisted VEIL

SLNB = sentinel lymph node biopsy

VEIL = video endoscopic inguinal lymph node dissection

Purpose: We compared outcomes between robot-assisted video endoscopic inguinal lymphadenectomy and open inguinal lymph node dissection in patients without bulky nodal metastasis in a tandem contemporary cohort.

Materials and Methods: We retrospectively analyzed a prospectively maintained hospital registry of 51 patients who underwent robot-assisted video endoscopic inguinal lymphadenectomy and 100 treated with open inguinal lymph node dissection from 2012 to 2016 for groins without bulky nodal metastasis and who had a minimum 9-month followup. Complications were graded by the Clavien-Dindo classification, and nodal yield and disease recurrence during followup were assessed. Elastic net regression was used to select variables associated with major complications (Clavien 3a or greater) for multivariable analysis of plausible factors, including patient age, diabetes, body mass index, smoking, nodal stage, surgery type, sartorius transposition, saphenous vein transection and adjuvant radiotherapy. Penalized likelihood logistic regression methods were used for multivariate analysis to ascertain final effect sizes while accounting for sparse data bias.

Results: Robot-assisted video endoscopic inguinal lymphadenectomy and open inguinal lymph node dissection had comparable median lymph node yields (13 vs 12.5). No patient experienced recurrence during the median followup of 40 months. Robot-assisted video endoscopic inguinal lymphadenectomy was associated with significantly lower hospital stay, days needing a drain in situ, incidence of major complications, edge necrosis, flap necrosis and severe limb edema. On multivariable analysis pathological nodal stage (OR 2.8, 95% CI 1.1–6.8, $p = 0.027$) and open inguinal lymph node dissection (OR 7.5, 95% CI 1.3–43, $p = 0.024$) emerged as independent risk factors associated with an increased risk of major complications.

Conclusions: Robot-assisted video endoscopic inguinal lymphadenectomy is a feasible technique which allows for a similar nodal yield while being associated with lower morbidity than open inguinal lymph node dissection in patients without bulky groin adenopathy.

Key Words: penile neoplasms, lymph node excision, robotic surgical procedures, postoperative complications, regression analysis

THE incidence of penile cancer varies from 0.4% to 0.6% of all malignant neoplasms in men in the United States and Europe to up to 10% of

men in the developing nations of Asia, Africa and South America.¹ Lymph nodal status primarily determines not only survival but also

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morbidity because of the sequelae of groin dissection.²

OILND has been the gold standard surgical management of the groin but older series describe morbidity rates up to 100% with the historical technique.³ Modifications such as thicker skin flaps and a reduced field of dissection have successfully decreased morbidity and yet a 27% major morbidity rate has been described in contemporary series.³ While SLNB has lower morbidity, its scope is restricted to patients with a clinically negative groin.⁴ VEIL emerged as an attractive option with the promise of decreased morbidity which is inherent to minimal access techniques.⁵ However, problematic ergonomics and the lengthy learning curve prevented it from being widely adopted.

This led to the introduction of robotic surgery. The 3-dimensional view, magnification, tremor filtration, motion scaling and 7 degrees of wrist movements in RA-VEIL overcome most limitations of VEIL.⁶ With feasibility and acceptable perioperative complications in clinically impalpable groins RA-VEIL is gaining momentum the world over. However, to our knowledge there are no studies directly comparing its outcomes with those of OILND or showing its feasibility in clinically palpable groins. Thus, in a tandem contemporary cohort we analyzed the records of patients without bulky nodal metastasis who were surgically treated at a single tertiary cancer care center with the aim of comparing RA-VEIL and OILND in terms of clinical outcomes.

PATIENTS AND METHODS

Our large volume, regional cancer center provides outpatient uro-oncologic care to more than 5,000 patients annually and maintains a prospective registry of all surgical patients. Traditionally OILND was performed but with the introduction of robotic surgery in 2011 RA-VEIL has been offered as an equal option to all patients at high risk and patients at intermediate risk with positive lymphovascular invasion, further satisfying the criteria of inguinal node size less than 3 cm clinically and no gross nodal fixation to skin or underlying structures.² The decision to perform RA-VEIL or OILND was left to the patient after explaining the cost, technique and complications of each procedure.

With institutional ethical committee approval we retrospectively analyzed the prospectively maintained penile carcinoma surgical registry from May 1, 2012 to May 31, 2016 for all patients who were equally eligible to undergo RA-VEIL or OILND and who had completed a minimum 9 months of followup. We assessed preoperative clinical and demographic characteristics, and perioperative and postoperative outcomes, including complications, pathological parameters on the final histopathological report and disease recurrence at followup. The surgical

team treating the 2 groups remained constant during the study period.

Preoperative Workup and Perioperative Management

NCCN Guidelines® were followed for the preoperative workup and patients underwent definitive management of the primary and associated lymph nodes at the same setting.² Intraoperative blood loss was determined by the external estimation method by estimating losses in surgical gauze and suction apparatus. On postoperative day 1 low molecular weight heparin and lower limb stockings were given to all patients and ambulation started. They were discharged from the hospital with drains in situ, which were removed after output was less than 50 ml per day at subsequent outpatient department visits.

Complications were graded by the Clavien-Dindo classification and further divided into minor—Clavien grades 1 and 2, major—Clavien grade 3a or greater, early—30 days or less postoperatively and late—greater than 30 days.⁷ Minor complications included leg edema not interfering with ambulation, lymphocele managed by needle aspiration, focal skin necrosis requiring no reconstructive surgery and cellulitis managed by oral antibiotics. Major complications included infection needing intravenous antibiotics, severe leg edema interfering with ambulation, lymphocele needing drain placement, skin flap necrosis requiring surgical reconstruction, venous thromboembolism and death of any direct cause. Lymphedema severity was reported according to the ISL (International Society of Lymphology) classification, which combines clinical parameters of limb softness or firmness with the outcome after limb elevation to classify lymphedema into 3 stages.⁸ Preclinical stage was not assessed due to a lack of the sophisticated equipment needed to identify it.

Patients were followed with clinical evaluation of the primary and the groin every 3 months for the first 2 years with individualized radiological assessment in those with node positive findings according to NCCN Guidelines.²

Our surgical technique of RA-VEIL and OILND (superficial followed by complete inguinal lymph node dissection with or without pelvic node dissection if superficial nodes are reported as positive on frozen section biopsy) was previously well described.⁹ The da Vinci® Si HD was used in all RA-VEIL cases. Figure 1 shows dissection boundaries and figure 2 shows port positioning. The surgical boundary of RA-VEIL was similar to that of OILND. The robot was docked from the right side of the patient at a 45-degree angle and used to operate on each thigh. Figure 3 shows the inside view and figure 4 shows the appearance of the thigh after RA-VEIL. Pelvic lymph node dissection was done, including robotically in the RA-VEIL group, if frozen section showed positivity in more than 1 node or in bilateral inguinal nodes. Patients with more than 2 positive nodes or bilateral metastasis, extranodal cancer extension or positive pelvic nodes were referred for further concurrent chemoradiotherapy.

Statistical Analysis

Continuous data are presented as the median and IQR, and categorical variables are presented as the number

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