



Original Article

The video endoscopy inguinal lymphadenectomy for vulvar cancer: A pilot study



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ABSTRACT

Objective: This prospective pilot study aims to validate feasibility, efficacy and safeness of the innovative technique of video endoscopy inguinal lymphadenectomy (VEIL) and compare it to open inguinal lymphadenectomy (OIL) in the staging and treatment of vulvar cancer (VC).

Material and methods: All patients affected by VC suitable for bilateral inguinal-femoral lymphadenectomy were prospectively enrolled and submitted to VEIL on one side and OIL contralaterally, sparing the saphenous vein.

The surgical and post-surgical data were collected. Univariate analysis included chi square analysis or Fisher's exact test, when appropriate for categorical variables, and the Student t test and Mann–Whitney test when appropriate for continuous variables.

Results: Between October 2014 and June 2015 fifteen patients were valuable for the study. Although nodal retrieval was comparable for both procedures, operative time was higher after VEIL. No intra-operative complications were observed in both techniques. Postoperative complications were observed in 3 and 2 cases for OIL and VEIL respectively. One patient needed reoperation after OIL for wound necrosis and infection. According to Campisi's stage, lymphedema resulted significantly to be lower after VEIL ($p = 0.024$).

Conclusions: Waiting for larger series and longer follow-up data, the VEIL seems to be feasible allowing a radical removal of inguinal lymph nodes as well as OIL with lower morbidity.

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Introduction

Vulvar carcinoma (VC) is an uncommon cancer that has a bimodal age distribution and it is seen both in young and older women with risk factors including human papilloma virus (HPV) infection, smoking, and vulvar skin disease [1,2]. The surgical treatment for VC have greatly improved over the last three decades with more conservative surgery that carries decreased risk morbidity (e.g. leg lymphedema, disfigurement, sexual dysfunction). Surgical management of VC must be individualized and tailored to the extent of disease [3]. The efforts in optimizing care to the individual patient, have minimizing the physical, psychological

and sexual morbidity [3–7]. Groin lymphadenectomy is an integral part of the surgical management of invasive VC, and the evaluation of nodes still remain the most important prognostic factor [8,9]. However, groin lymphadenectomy can be omitted for early stage due to the negligible risk of node metastasis. More in depth for unifocal lesion <4 cm with no clinical or radiological evidence of node metastasis, the sentinel lymph node biopsy (SNB) is a valid and safe technique with negligible postoperative morbidity [10,11]. However, for all the other stages, unilateral or bilateral inguino-femoral lymphadenectomy is mandatory and, despite the care' improvements, post-operative wound dehiscence, lymphocele, lymphedema, infections and psychosexual impairment, are still early and long-term complicated [12]. To reduce the post-operative morbidity, some authors have described alternative surgical approach to inguinal lymph node dissection with unclear oncological outcomes. In this context an endoscopic procedure, with a small incision away from the dissecting area, seems to be a new and

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attracting approach, duplicating the standard procedure with less morbidity and our group firstly described in the last year the video endoscopic inguinal lymphadenectomy for VC (VEIL) [13–18].

Here following a pilot study comparing perioperative outcome between open inguinal lymphadenectomy (OIL) and VEIL in patients with VC is described.

Materials and methods

The study was approved by the local ethics committee and patients involved in the study signed a written informed consent to participate before recruitment. This is a Single-Institutional pilot study aimed to evaluate the feasibility, complications and efficacy of video endoscopic inguinal lymphadenectomy (VEIL) comparing to standard open inguinal lymphadenectomy (OIL) in the staging and treatment of VC. All patients with VC suitable for bilateral inguinal-femoral lymphadenectomy were prospectively enrolled and submitted to VEIL on one pelvic side (*Cases*) and OIL contralaterally (*Controls*). Moreover, with the aim to render the surgical technique as homogeneous as possible, all the VEILs were performed on the left side.

Inclusion criteria were: 1) histological diagnosis of VC; 2) Age <90 years; 3) patients with VC with or without nodal involvement, suitable for bilateral inguinal-femoral lymphadenectomy; 4) performance Status ≤ 2 ; 5) written informed consent to participate before recruitment.

Exclusion criteria were: 1) Bulky nodes fixed to overlying skin; 2) patient submitted to pelvic lymphadenectomy for other gynecological cancer; 3) previous chemotherapy or radiotherapy; 4) concomitant hematologic or lymphatic disease; 5) patient suitable for bilateral sentinel lymph node biopsy; 6) cardiovascular, liver, renal, lung diseases.

We decided to perform the comparison of these two surgical approaches in the same patient to have identical clinical and body characteristics and consequently to minimize the influence of non-treatment factors.

All patients were submitted to ultrasound examination and/or TC and/or PET/TC as preoperative assessment. In case of bulky and/or suspicious inguinal-femoral lymph nodes, women were underwent to fine needle aspiration cytology (FNAC).

Moreover, if preoperative imaging did not report bilateral inguinal lymph-node metastases, a bilateral groin lymphadenectomy was performed when FNAC showed metastatic disease on inguinal nodes and/or when it did not fulfill all the criteria to perform a SNB (i.e. tumor diameter >4 cm, previous vulvar surgery, multifocal lesion, midline tumor in which the lymphoscintigraphy didn't identify the sentinel nodes).

Surgical technique

The same surgical team performed all surgical procedures. At the beginning of the operation, patients received a single shot antibiotic treatment. All patients underwent standard inguinal lymph node dissection, sparing the saphenous vein bilaterally. However, at one side it was performed endoscopic inguinal lymphadenectomy as previously published [18], whereas on the other side a standard inguinal lymphadenectomy surgery (OIL) was performed. In no cases it was performed a sentinel node biopsy.

For the *Controls* we used the standard technique for inguinal lymph node dissection [19]. On the other hand, for the *Cases* the endoscopic technique was described by Tobias-Machado et al. [15,20]. In detail the surgeon stood on the outside of operative limb and the assistant between the patient's legs. We practice the first 12 mm skin incision about 2 cm distal to the apex of femoral triangle. We proceeded with a finger dissection deep to the Scarpa's

fascia. Once enough space was created, we placed a 12 mm port with a pressure of 10 mmHg. Then two short bladeless trocars were placed 3 cm outside of boundaries of the femoral triangle, respectively.

After additional dissection, we proceeded with the development of the anterior space between the fibro fatty packet containing the lymph nodes and the subcutaneous fat. The main landmarks of dissection were medially the adductor longus muscle, laterally the sartorius muscle, superiorly the inguinal ligament and the inferior margin was the apex of the femoral triangle.

Saphenous vein along with the femoral vein and artery were visualized and spared after a care dissection. An exposure of the sapheno-femoral junction was practiced, as previously described by Ames, an infero-medial dissection around the femoral vein to obtain a complete deep inguino-femoral nodes resection [18]. All the surgical dissection was performed by using ultrasonic dissecting scalpel.

Postoperative care

All clinical, surgical and post-surgical data were recorded in an electronic database. During the postoperative course the patient was routinely examined. Criteria for discharging patients were as follows: no fever, no pelvic inflammation, no lymphedema (swelling of the lower extremities), and good clinical conditions. All patients received a daily dose of subcutaneous low-molecular weight heparin starting from the day after surgery and continuing at least for 4 weeks postoperatively.

The lower extremity lymphedema (LEL) was described according to Yamamoto and Campisi clinical classification [21,22]. The Yamamoto's index and the conventional Campisi's clinical stages [22] are both potentially useful in determining the severity of postoperative lymphedema thus assessing potentially differences between the two surgical approach [21].

Moreover, according to our protocol, a post-operative ultrasound (US) examination was performed beyond 6 weeks after the surgery by the same physician to evaluate inguinal lymph cyst or lymphedema at the follow-up.

Statistical analysis

Univariate analysis included chi square analysis or Fisher's exact test, when appropriate for categorical variables, and the Student t test and Mann–Whitney test when appropriate for continuous variables. All p values are considered significant if the p value < 0.05. The SPSS statistical software program (SPSS Inc., Chicago, IL) was used.

Results

Between October 2014 and June 2015 fifteen consecutive patients affected by VC suitable for bilateral inguino-femoral lymphadenectomy were enrolled. Patient's characteristic and histological features are summarized in Table 1, whereas the surgical-pathological details were showed in Table 2 Median age was 70.5 years (range, 63–86 years), and median body mass index (BMI) was 27.3 kg/m² (range, 22.2–35.1). Intra-operative time was significantly higher at VEIL with respect to OIL procedure (110 min vs. 45 min, respectively, p < 0.01), although a time-trend improvement was observed (Fig. 1).

The median number of lymph nodes removed was 10 (range, 3–17), with no statistically significant differences between the two "hemigroin". Eight women (54%) had positive lymph-nodes: among them four had bilateral metastases, whereas one and three patients had unilateral metastases detected by VEIL and OIL,

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