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Inguinal lymphadenectomy in penile cancer patients: a comparison between open and video endoscopic approach in a multicenter setting

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Abstract

Objectives: To compare differences of operative outcomes, post-operative complications and survival outcomes between open and laparoscopic cases in a multicenter study.

Methods: This was a retrospective cohort study performed at three European centers from September 2011 to January 2019. The surgeon decision to perform open inguinal lymphadenectomy (OIL) or video endoscopic inguinal lymphadenectomy (VEIL) was done in each hospital after patient counselling. Inclusion criteria regarded a minimum follow-up of 9 months since the inguinal lymphadenectomy.

Results: A total of 55 patients with proven squamous cell penile cancer underwent inguinal lymphadenectomy. 26 of them underwent OIL, while 29 patients underwent VEIL. For the OIL and VEIL groups, the mean operative time was 2.5 vs. 3.4 h ($p=0.129$), respectively. Hospital stays were lower in the VEIL group with 4 vs. 8 days in OIL patients ($p=0.053$) while number of days requiring drains to remain *in situ* was 3 vs.

6 days ($p=0.024$). The VEIL group reported a lower incidence of major complications compared to the OIL group (2 vs. 17%, $p=0.0067$) while minor complications were comparable in both groups. In a median follow-up period of 60 months, the overall survival was 65.5 and 84.6% in OIL and VEIL groups, respectively ($p=0.105$).

Conclusions: VEIL is comparable to OIL regarding safety, overall survival and post-operative outcomes.

Keywords: complications; inguinal lymphadenectomy; laparoscopic approach; penile cancer.

Introduction

Penile cancer (PC) is a rare malignant disease with an overall incidence of $<1/100,000$ in Western countries while constitutes up to 10% of malignancies in men in African, Asian and South American regions. Squamous cell carcinoma (SCC) accounts for more than 95% of PC cases [1–3]. Albeit several risk factors are associated with this malignancy, such as the presence of phimosis, smoking and low social economic status, the incidence of PC is mostly related to the prevalence of human papilloma virus (HPV) in the population with at least one-third of cases that could be attributed to HPV-related carcinogenesis [4, 5]. The presence and the extent of metastasis to the inguinal region, which occurs in 20–40% of PC patients, are the most important prognostic factors for survival in PC patients with SCC, representing one of the strongest predictors of mortality [6]. Inguinal lymphadenectomy (IL) alone can be curative and is therefore recommended [7, 8]. Unlike many other genitourinary tumors, which require systemic therapeutic strategies once metastasis has occurred, the characteristics of penile SCC, exhibiting a prolonged loco regional phase before distant dissemination, provide a rationale for the therapeutic value of IL [9].

The European Association of Urology (EAU) guidelines recommended IL in stages more than T1b G2 and in cases of palpable inguinal lymph nodes [10]. Nevertheless, there are two important issues: first, the risk of micrometastasis, which could be up to 25%, especially among patients with

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clinically negative groins; second, the risk associated with IL which may result in postoperative complications [11]. Albeit the introduction of sentinel lymph node dissection has prevented IL in 76% of patients, the procedure is still needed in order to assess lymph nodes status [12]. The open approach during IL (OIL) has been the gold standard management and, due to the improvement of surgical techniques in the last 10 years, the morbidity has been reduced to 30% for diagnostic IL (in the absence of nodal metastasis) and to 24–29% for therapeutic IL (in the presence of nodal metastasis) [13]. In the age of the minimally invasive approach, the video endoscopic IL (VEIL) emerged as a valid and feasible option that includes all the benefits of minimally invasive surgery in reducing the morbidity related to IL [14]. The aim of our study is to compare the differences in operative outcomes, postoperative complications and survival outcomes between OIL and VEIL in a multicenter series.

Materials and methods

Study design

This was a retrospective cohort study performed at three European centers from September 2011 to January 2019. Local Institutional Review Board approved the study at each participating center, which was: Hospital San Bassiano, Bassano del Grappa, Italy; Semmelweis University, Budapest, Hungary; University of Naples “Federico II”, Naples, Italy. Inclusion criteria were staging and treatment of primary tumor with partial or total penectomy 4 weeks before IL and minimum follow-up of 9 months since the IL. Exclusion criteria were: distant metastatic disease, skin involvement and prior history of surgery or radiotherapy in the inguinal or thigh region. The decision to perform OIL or VEIL was done in each hospital by the surgeon with the patient after explaining the costs, technique and complications of each approach. We collected data about patients’ characteristics in addition to pre-operative and operative data, which included complications rate, number of lymph nodes removed and survival outcomes. In each center, the surgical team performing both surgical approaches remained constant during the study period, with an experienced laparoscopic surgeon (>100 OIL and >150 VEIL) for the surgical team.

Preoperative and perioperative workup

The EAU Guidelines were used in order to follow a unique management pre- and post-operative in each center. Before the surgery, all patients of both groups followed the same pre-operative workup with a single dose of cefazolin 30 min before surgery and heparin prophylaxis. On post-operative day 1, all patients were given low molecular weight heparin and lower limb stockings. Drains were left *in situ* up to patient discharge and removed after output was less than 50 mL per day. The Clavien Dindo classification was used to assess complications, divided into minor (grades 1 and 2) and major (> grade 3a) [15].

Surgical technique

General anaesthesia was administered to the patients. Patients were in the supine position with the head 15° lower compared to the hip. Both lower extremities were straightened and abducted by about 45° (scissor position). Both knee joints were slightly flexed and rotated externally, with the catheter indwelled. The OIL was performed via the (inverse) S-shaped inguinal incision. In the VEIL approach, a 10-mm optical trocar and two 5-mm operating trocars were placed. The optical trocar was placed in the apex of Scarpa’s triangle after the skin incision and the creation of a subcutaneous space by blunt finger dissection. The pCO₂ was 8–10 mmHg. The surgical technique is the same in both techniques, and it involved the removal of superficial and deep lymph nodes according to the scheme described by Deshler, sparing main venous structures [16]. All lymphadenectomies were performed unilaterally.

Follow up

Patients were followed according to the EAU guidelines, including a physical examination of penis and groins for local and/or regional recurrence. Radiological assessment was performed at three months intervals for the first two years [10, 17].

Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) v. 19.0 (IBM Inc., Armonk, NY, USA). Data are shown as means ± standard deviation (SD), as medians (range), or as numbers (percentage). The normality of data was assessed via the Kolmogorov–Smirnov test. Univariate comparisons of dichotomous data were performed with the use of the chi-square with continuity correction. Comparisons between groups were performed with the use of the *t*-test to test group means with SD by assuming equal within-group variances. Kaplan–Meyer curves were analyzed to characterise survival outcomes. We calculated two-sided *p*-values. A *p*-value <0.05 was considered to indicate statistical significance.

Results

A total of 55 patients underwent IL for PC diagnosis. In particular, 26 and 29 patients underwent OIL and VEIL, respectively. Descriptive characteristics of patients involved, including clinical, demographic and lymph nodal data are reported in Table 1. The median age at diagnosis was older in the VEIL group with 62.17 vs. 59.31 years of the OIL group. The OIL group showed, in addition, a higher prevalence of circumcised patients (61.5%) compared to the VEIL group (34.5 and 24.1%, respectively). However, the two groups were otherwise comparable in terms of diabetes, smoking status, body mass index and cardiovascular disease. The primary lesion was more frequently localized on the glans plus foreskin in both groups, with 46.2 and 44.8% in the OIL and VEIL groups, respectively. Palpable lymph

nodes and positive pre-operative PET-CT concerning inguinal lymph nodes were reported in over 50% of patients in both groups. All specimens were SCC and the groups were comparable for the type of surgery, pathological T status, grading, lymph and vascular invasion of the primary lesion. Positive surgical margins were found in 7.79 and 10.3% of patients of OIL and VEIL group, respectively. Table 2 described lymph nodes management and pathological status. The average superficial lymph nodes yield per groin exceeded 10 and was similar in both treatment groups. In 7 cases, pelvic and inguinal lymph nodes were removed in the same operative session. Regarding nodal status, 46.2% of patients of OIL group and 31% of VEIL group were pN0. None of the patients treated with VEIL experienced any intraoperative event requiring deviation from the planned surgical technique or conversion to open surgery. Recurrence rates were comparable between both groups with 53.8% of OIL and 34.5% of VEIL ($p=0.148$). In particular, local recurrence was most frequent in the OIL group compared to the VEIL group (38.5 vs. 10.3%), while pelvic lymph nodal recurrence was higher in the VEIL group, with 17.2 vs. 3.8% of the OIL group. Operative and postoperative data were described in Figure 1. As concerning operative time, it was significantly higher in VEIL compared to OIL, with 3.4 vs. 2.5 h, respectively ($p=0.129$). Conversely, patients who underwent VEIL had a significantly shorter median hospital stay (4 vs. 8 days, $p=0.053$) and number of days requiring drains to remain *in situ* (3 vs. 6 days, $p=0.024$). Regarding postoperative complications, more than 75% of patients in both groups experienced some degree of complications, although major complications rates were overall low. In particular, patients treated with VEIL experienced a significantly lower incidence of major complications, reported as Clavien–Dindo grade 3, (2 vs. 17%, $p=0.0067$), which included edge necrosis (9.8 vs. 23%, $p=0.048$), flap necrosis (2 vs. 13%, $p=0.035$) and severe limb edema (0 vs. 9%, $p=0.029$). Minor complications reported as Clavien–Dindo grade 1–2 were comparable in both groups, including lymphocele, surgical site infection, cellulitis and early/late limb edema. In the VEIL group indeed 30% of patients reported minor complications, which included local wound complications, minor leg edema or lymphocele non-interfering with ambulation and cellulitis. In the OIL group, 27.5% of patients had similar minor postoperative complications, including leg lymphedemas, local wound complications and minor flap necrosis. Finally, Figure 2 shows the Kaplan–Mayer related to penile cancer recurrence, reporting, in a median follow-up period of 60 months, an overall survival of 65.5% for OIL and 84.6% for VEIL ($p=0.105$).

Table 1: Demographic, clinical and tumor characteristics.

	OIL	VEIL	p-Value
Number of patients	26	29	
Age at diagnosis mean (median – Std)	59.31 (59–9.895)	62.17 (60–11.769)	0.357
No of circumcision, %	16 (61.5)	7 (24.1)	0.005
Smokers, %	16 (61.5)	10 (34.5)	0.45
Diabetes, %	3 (11.5)	7 (24.1)	0.226
Cardiovascular disease, %	3 (11.5)	5 (17.2)	0.549
Body mass index, kg/m² (median, IQR)	26 (23.3–30.6)	25.7 (23.1–29.1)	0.68
Site of neoplasm, %			0.172
Glans	12 (46.2)	10 (34.5)	
Foreskin	1 (3.8)	6 (20.7)	
Glans+Foreskin	12 (46.2)	13 (44.8)	
Palpable lymphnodes, %	14 (53.8)	13 (46.4)	0.586
Positive PET-TC, %	17 (65.4)	16 (55.2)	0.440
Type of surgery, %			0.227
Circumcision	1 (3.8)	6 (20.7)	
Local excision	6 (23.1)	6 (20.7)	
Glansectomy	9 (34.6)	7 (24.1)	
Partial penectomy	8 (30.8)	5 (17.2)	
Total penectomy	2 (7.7)	5 (17.2)	
Pathological status T, %			0.556
Tis	0 (0)	2 (6.9)	
pT1A	10 (38.5)	9 (31)	
pT1B	6 (23.1)	4 (13.8)	
pT2	6 (23.1)	9 (31.8)	
pT3	4 (15.4)	5 (17.2)	
Grading, %			0.803
G1	4 (15.4)	4 (13.8)	
G2	16 (61.5)	16 (55.2)	
G3	6 (23.1)	9 (31)	
Vascular invasion +, %	12 (46.2)	10 (34.5)	0.378
Lymphovascular invasion +, %	5 (19.2)	10 (34.59)	0.361
Surgical margins +, %	2 (7.79)	3 (10.3)	0.733

Statistically significant values ($p<0.05$) are reported in bold.

Discussion

In the recent years, in order to reduce the morbidity associated to surgical complications after IL, a minimally invasive approach has been used in several centers. Since the first technique description by Tobias–Machado et al., the VEIL approach has decreased the morbidity of open conventional technique, maintaining oncological radicality [18, 19]. In further studies published, Sotelo et al. have described VEIL like a safe and feasible technique that appears to diminish the wound-related complications associated with the standard OIL [20]. Nevertheless, VEIL technique was

Table 2: Lymph nodes management and pathological status.

	OIL	VEIL	P-Value
Number of superficial LN mean (median – SD)	12.08 (12–3.428)	12.28 (12–5.021)	0.097
Number of deep LN mean (median – SD)	3.12 (4–2.673)	4.52 (3–4.904)	0.008
Positive superficial LN, %	16 (61.5)	19 (65.5)	0.759
Positive deep LN, %	5 (19.2)	2 (6.9)	0.64
Positive pelvic lymphnodes, %	8 (30.8)	8 (27.6)	0.795
Removed in the same session, %	7 (26.9)	7 (24.1)	0.813
Nodal status, %			0.142
pN0	12 (46.2)	9 (31)	
pN1	5 (19.2)	13 (44.8)	
pN2	9 (34.6)	7 (24.1)	
Metastasis, %			0.560
M0	23 (88.5)	27 (93.1)	
M1	2 (7.7)	2 (6.9)	
M2	1 (3.8)	0 (0)	
Recurrence, %	14 (53.8)	10 (34.5)	0.148
Type of recurrence, %			0.131
Local	10 (38.5)	3 (10.3)	
Pelvic lymph nodes	1 (3.8)	5 (17.2)	
Systemic disease	3 (11.5)	2 (6.9)	
Chemotherapy, %	9 (34.6)	6 (20.7)	0.008
Radiotherapy, %	0 (0)	1 (3.4)	0.431

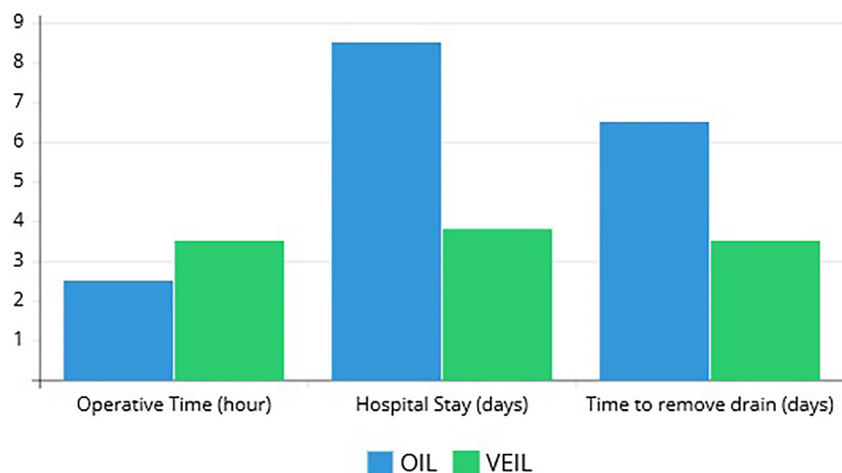
LN, lymph nodes; SD, standard deviation.

accompanied by report of inguinal recurrence at follow up [21, 22]. However, in a study by Tobias–Machado et al. that described patients who underwent OIL on one side and VEIL on the other side, the number of lymph nodes removed were similar on both sides and no differences in progression or disease relapse was found after 18 months of follow up [23]. In a recent meta-analysis published by Hu et al. which included seven studies, the pooled OR for recurrence rate showed no difference between OIL and VEIL groups (OR=1.54, 95% CI [0.41, 5.84], $p=0.530$) [24]. In our multicenter experience, recurrence rate and patients' overall survival

were comparable in both groups, after a median follow of 5 years while local recurrence was most frequent in OIL group. Nevertheless, pelvic lymph nodes recurrence was more common in VEIL group, although not statistically significant.

As concerning the operative time, as reported in the literature, VEIL technique prolonged the duration of surgery procedure compared to OIL (134.82 vs. 116.53 min) [25]. The main reason is related to the learning curve of VEIL procedure, complicated by the rarity of PC [26]. Regarding the robotic approach experience in IL, operative time was similarly higher than OIL (75 vs. 60 min) but lower than VEIL (91 vs. 165 min); indicating quicker ability to dissect after the robot is docked in place [6]. In our case series, we reported an average difference in the two groups of about 50 min, slightly higher than that reported in the literature. The main reason for this increased operative time could be related to the multicenter design of our study and the different learning curve of the surgeons involved. Several studies reported that the length of hospital stay was reduced in the VEIL group. In particular, these values ranged from 4 to 24.3 days and from 2.5 to 15.8 days in OIL and VEIL groups, respectively [24]. This is confirmed by a recent study published by Yadav et al. and, similarly, by our series which reported a halved hospital stay of VEIL patients compared to OIL patients [27].

After the IL procedures, the drain tube represents an important way to control the quantity and quality of the output. Yadav et al. removed the drain tube when the daily output was less than 20 mL [27]. Nevertheless, Wang et al. removed the drainage tube when the daily output was less than 50 mL for 2 days [28]. In both published series, the drain was removed early in the VEIL group. According to Wang et al., we removed the drain after output was less than 50 mL per day, reporting an early removal of the drain tube (three days before, on average) in VEIL patients compared to OIL [26].

**Figure 1:** Operative and postoperative data.

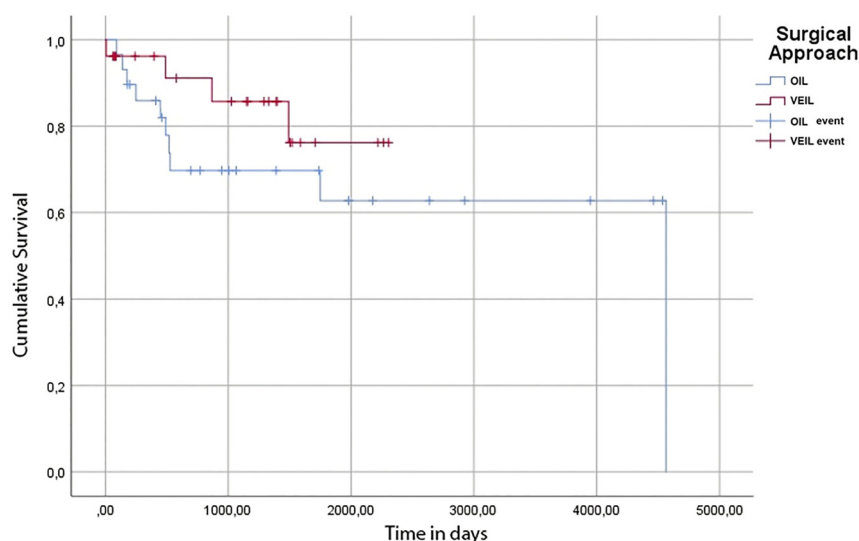


Figure 2: Kaplan–Mayer associated with penile cancer recurrence in OIL and VEIL ($p=0.105$).

IL is historically associated with a high complication rate between 45 and 57% in patients undergoing this procedure as part of penile cancer management [29]. In particular, wound infection, skin necrosis (16.7–36% in OIL and 0–11.8% in VEIL groups) and lymphedema were the most common postoperative complications [24]. Nevertheless, the possibility of major complications such as deep vein thrombosis, led surgeons to search for less invasive methods [30, 31]. To our knowledge, we are the first to report a series of patients when directly comparing OIL and VEIL in a multicenter cohort. This establishes the feasibility of both techniques in routine clinical practice, particularly concerning the complications rate. Major complication rate was lower in VEIL while those of OIL were similar to rates in contemporary cohorts, although the patients treated with OIL were significantly older [32]. With a laparoscopic approach, better preservation of skin lymphatics and vasculature due to smaller port incisions and atraumatic retraction by gas instead of by mechanical retractors and avoiding the need for sartorius muscle rotation due to incision placement at a distance from the great vessels may explain the significant lower observed incidence of lymphedema and skin related morbidity with VEIL [33]. In our clinical series we do not have lymphedema and one skin necrosis in the VEIL group, but in the OIL group we had four lymphedemas and one necrosis that required surgical intervention. Wang series is according to our experience and reported these complications in half cases in the VEIL group [28]. Schwenter et al. published the major complications in the OIL series compared with one only major complication in the VEIL group [34]. Since Catalona et al. described the preservation of the internal saphenous vein during IL suggesting a reduction

in morbidity, without oncological risks [35]. Transposing the sartorius muscle is one of the factors most strongly associated with moderate to severe wound complications with fascia lata preservation [36]. The number of dissected lymph nodes of the two groups in all included studies was greater than 7, which demonstrated that both groups achieved effective cancer control. Therefore, regarding the number of dissected lymph nodes, we can only conclude that there was no significant difference between the two groups according to current evidence [24]. The number of superficial and deep inguinal nodes varies from 10 to 15 and 0 to five in VEIL and OIL, respectively [36]. Lastly, despite a reduced hospital stay as well as complications rates, the use of VEIL and other similar video endoscopic techniques for inguinal lymphadenectomy must consider also the cost associated with these procedures. It is well known that a robotic assisted surgery has greater costs compared to the open approach being therefore an important limitation for small centers. On the other side, however, the possibility to reduce hospital stay and major complications could reduce, partly, this cost. Further studies are required in order to assess also the economical aspects of robotic surgery in the pattern of penile cancer management and inguinal lymphadenectomy [37, 38].

There are different limitations in our study which included the retrospective nature of our study, which could have led to possible information detection bias and missing data, and the relatively small sample size which could not permit further sub-analyses. In addition, the multicenter design, albeit permitted to enroll more cases, has the limitation of having different surgeons despite a similar surgical experience.

Conclusions

VEIL can reduce hospital stay and drainage time and is generally superior in terms of postoperative complications compared to OIL, reporting similar oncological outcomes in a multicenter real-life context. Further studies are required to assess the feasibility of the procedure according to risks and costs.

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Competing interests: Authors state no conflict of interest.

Informed consent: Informed consent was obtained from all individuals included in this study.

Ethical approval: This retrospective study was approved by the institutional research ethics committee of institutions involved and performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments.

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