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Feasibility, complications and oncologic results of a limited inguinal lymph node dissection in the management of penile cancer

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ABSTRACT

Purpose: In patients with penile cancer (PeCa) and increased risk of inguinal lymphatic dissemination, inguinal lymphadenectomy offers a direct histological staging as the most reliable tool for assessment of the nodal metastasic status and a definitive oncologic treatment simultaneously. However, peri- and/or postoperative mutilating sequalae often occurn. We report on clinical outcome and complications of a limited inguinal lymph node (LN) dissection.

Materials and Methods: Clinical and histopathological data of all patients with PeCa who underwent limited inguinal lymphadenectomy (LIL) at our institution between 1986 and 2012 were comprehensively analyzed. Perioperative results were presented in relation to one-sided procedures, if appropriate, which were assessed without cross comparison with contralateral LILs.

Results: 29 consecutive patients with PeCa aged 60±10.3 years were included in the current study with 57 one-sided LIL performed. Mean operative time for one-sided LIL was 89.0±37.3 minutes with 8.1±3.7 LNs removed. A complication rate of 54.4% (n=31), including 16 minor and 15 major complications was found in a total of 57 procedures with leg oedema being the most prevalent morbidity (15.8%). 4 patients with clinically positive LNs developed inguinal lymphatic recurrence within 9 months after surgery.

Conclusions: Our technique of limited inguinal LN dissection provided an acceptable complication rate without aggravating morbidity. We experienced no recurrences in clinically LN negative patients, so that the approach might be a reasonable option in this scenario. In patients with enlarged LNs, radical inguinal lymphadenectomy still appears to represent the gold standard.

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INTRODUCTION

Inguinal lymphadenectomy (iLAD) is essential within the treatment algorithm of penile squamous cell carcinoma (PeCa). The inability of conventional imaging techniques to reliably detect the presence of micrometastases and the fact that lymph node (LN) involvement is the most crucial variable predicting patient survival (1), iLAD offers a direct histological LN staging (2) and a definitive oncological treatment at the same time. However, since the surgical management of inguinal LNs in patients with PeCa is associated with a high risk of perioperative and long-term sequelae, reluctance

emerges considering whether to perform this procedure in an individual patient. Being standard of care for patients with nodal invasion, iLAD is not justified for every patient with clinically negative nodes and may represent in up to 75% an overtreatment with risk of aggravating complications (1, 3, 4). Conversely, keeping a potentially curative approach of an iLAD in mind, around 75% of patients with up to 2 positive inguinal LNs present a long term survival (1), while a significant proportion of patients submitted to surveillance will have a consecutive LN relapse and will face survival disadvantages, not having undergone surgery in first place (5, 6).

Identifying appropriate candidates with non-palpable nodes who are at high risk for occult regional lymphatic involvement and might benefit most likely from surgery is challenging but crucial for long-term survival (2). Moreover, taking into account that experience with dynamic sentinel LN biopsy (DSNB) as diagnostic procedure with favorable complications rate is still limited to several centers (7), reduction of morbidity of iLAD is an important prerequisite for changing physician`s cautious attitude to indicate surgical approach.

In the current study, we present our experience with limited open iLAD (LIL) in PeCa patients treated at our institution with particular emphasis to assessment of morbidity as well oncologic parameters.

MATERIALS AND METHODS

Clinical Characteristics

The study was conducted after receiving approval of the study protocol by the Ethics Committee of the Goethe University (no. 162/13). Epidemiological, clinical and histopathological data of all patients with PeCa consecutively treated with LIL at our institution between 1986 and 2012 were retrospectively collected from the patient charts and analyzed comparatively. Charlson comorbidity index was calculated as proposed by Charlson et al. (8). Patients were generally assessed for inguinal and visceral metastases by physical examination and ultrasound of the inguinal region and computed tomography of the abdomen and pelvis as well as chest X-ray. Tumor stage and grade was determined according to the current TNM classification, which remained unchanged for PeCa from fourth to sixth edition between 1987 and 2009.

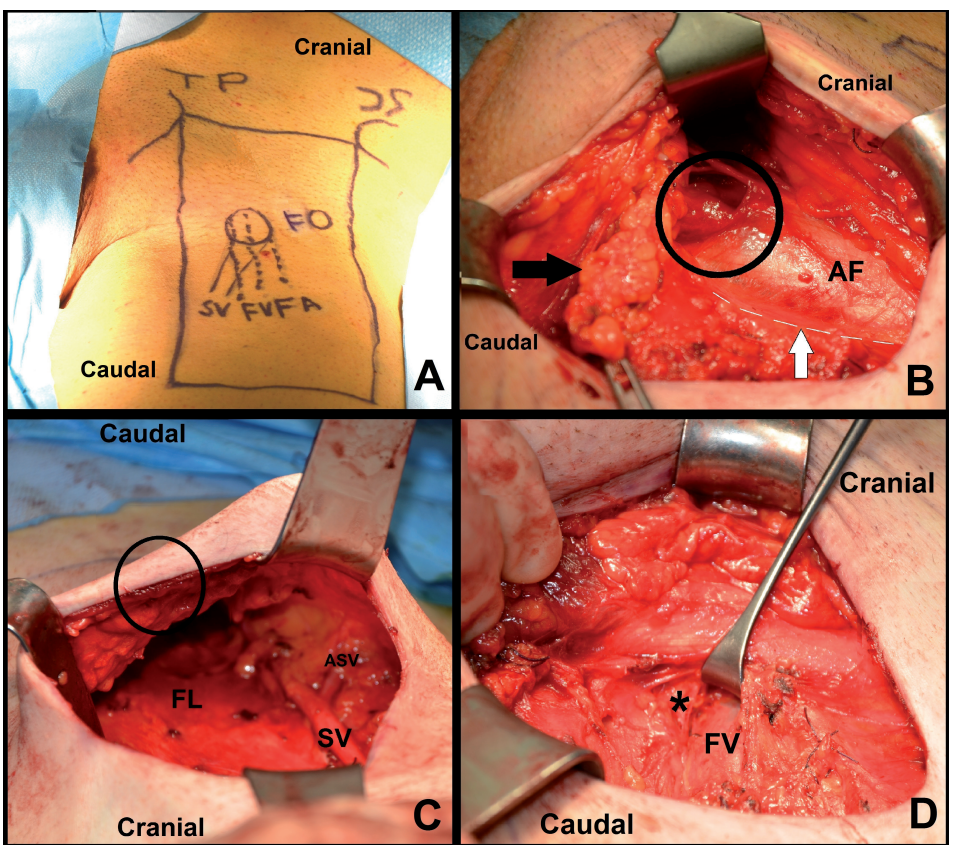
Risk groups for occult metastasis were defined according to pathologic stage of the primary tumor: stages ≤pT1 G1 being low risk group, stage pT1 G2 – intermediate risk and stages ≥pT1 G3 being high risk group. In cases of intermediate or high risk for occult metastases without clinical evidence for inguinal LN dissemination, LILs were defined to be performed with prophylactic intent. If clinical or radiological signs for inguinal LN involvement were present, LILs were considered therapeutic. Surgical procedures for recurrent inguinal dissemination after primary resection or significantly ulcerated inguinal LN metastases were excluded from the study. Neoadjuvant chemotherapy or radiation was not performed in any case.

After hospital discharge, patients were followed in our outpatient clinic or cooperating outpatient units every three months for two years and biannually thereafter until five years after diagnosis. Subsequent follow-up controls took place annually.

Surgical procedure

LILs were all performed under general anesthesia. Patients were placed in supine position with the leg of the appropriate side being externally rotated and abducted in the hip joint and flexed in the knee joint, so that the sole of the foot abutted on the opposite knee and was fastened with a strap. The dissection field was marked as following: cranial border – line connecting anterior superior iliac spine and tuberculum pubicum, medial border – 18 cm perpendicular from tuberculum pubicum downwards, lateral border – 20 cm perpendicular from anterior superior iliac spine downwards, caudal border – connection line between both perpendicular ends (dissection field and selected surgical steps are illustrated in Figure-1). After proper disinfection, a 10 cm skin transverse incision was performed 2 fingerbreadths below the inguinal crease. Camper fascia was incised until Scarpa fascia could be identified. Fibrofatty tissue between Scarpa fascia and fascia lata was then diligently dissected with meticulous ligation of lymphatic vessels. Particular attention was paid to preservation of at least 4-5 mm skin

Figure 1 - (A) Preoperative view of the left groin with dissection borders and selected anatomic structures marked on the skin. (B) Cranial extension of the dissection field. Circle - external inguinal ring, arrow - lymphatic tissue being removed, white dotted line with white arrow - inguinal ligament. (C) Caudal dissection area with thick skin flaps preserved (circle). (D) Deep inguinal nodes (asterisk) are being dissected in the femoral canal.



TP = tuberculum pubicum, **IS =** (anterior superior) iliac spine, **FO =** fossa ovalis, **SV =** (great) saphenous vein, **ASV =** (medial) accessory saphenous vein, **FV =** femoral vein, **FA =** femoral artery, **AF =** abdominal fascia, **FL =** fascia lata.

flap. While fascia lata and great saphenous vein were preserved, vena circumflexa, ilium superficialis, vena epigastrica superficialis and venae pudendae externae were dissected. Afterwards, fibrofatty tissue with superficial LNs was removed en bloc. Finally, deep LNs were dissected in fossa ovalis and femoral canal after exposing femoral vessels. Wound drains without suction were placed in the cranial and caudal part of the dissected field. Camper fascia was adapted at fascia lata and the wound closed. The leg was immediately winded with short-stretch bandage from the sole of the foot till the inguinal crease.

Postoperative care

All patients received antibiotic therapy initiated at the latest before skin incision and maintained at least until removal of drains. Generally, β-lactam antibiotics were used unless cultures from the primary tumor or urine yielded results necessitating application of other antibiotics. Patients were mobilized starting on postoperative day 1. Prior to discharge, short-stretch bandage was replaced by individually matched elastic compression stockings. Unfractionated or low molecular weight heparin was prescribed after surgery and discontinued on postoperative day 6 at the

earliest unless clinical signs of a significant leg oedema were present. Drains were removed after the daily secretion amount was below 30 mL.

Complications

Complications occurring during a 30-day period after surgery were defined as early and thereafter as late complications. Classification of the complication type and severity was performed according to Bevan-Thomas et al. (9) and the modified Clavien system (10).

Statistics

Clinical variables are presented as absolute numbers, mean ± standard deviation or percentage. Fisher's exact test was used for comparative assessment of the complication rate between prophylactic and therapeutic LIL.

RESULTS

Twenty-nine consecutive patients with PeCa aged 59.5±10.3 years were included in the current study with 57 one-sided LILs performed (Table-1). Body-Mass-Index (BMI) of the study cohort was 28.6±3.6.

Radical circumcision was the definitive treatment of the primary lesion limited to the foreskin in 1 (3.4%) patient. Circumcision combined with local tumor excision was performed in 7 (24.1%) men with superficial tumors below 4 cm dimension. In 17 (58.6%) patients with tumors larger than 4 cm and/or invasive disease, partial penectomy was carried out. Total penectomy was the treatment of choice in 4 men (13.8%) with large tumors and/or extensive proximal involvement of the penile shaft or scrotum. Clinical and histopathological characteristics of primary PeCa and LN status are presented in Table-2. At our institution, no patients with PeCa staged pTis or pTa underwent LIL due to low risk of lymphatic metastases and clinically negative inguinal LNs. On the other hand, all patients with pT4 tumors presented systemic metastases so that they have not received inguinal lymphadenectomy but palliative chemotherapy.

28 patients underwent bilateral LIL, while one patient rejected further surgical treatment

Table 1 - Demographic and clinical characteristics of the study cohort. Nr - patient number, age in years at cancer diagnosis, CCI - Charlson Comorbidity Index, Y/N - circumcision in the past before cancer diagnosis yes/no.

Nr	Age	Circumcision	CCI
1	33	Y	2
2	71	N	3
3	58	N	4
4	41	Y	2
5	64	N	2
6	46	N	2
7	63	N	3
8	72	N	5
9	66	N	2
10	56	N	2
11	53	N	4
12	67	N	4
13	69	N	6
14	61	N	2
15	67	N	2
16	71	N	4
17	58	N	3
18	67	N	4
19	56	N	2
20	66	N	6
21	61	N	2
22	61	N	7
23	41	N	6
24	54	N	6
25	53	N	7
26	50	N	6
27	62	Y	2
28	60	N	7
29	79	N	6

Table 2 - Clinical and pathological characteristics of primary tumour and clinical LN status of 29 patients diagnosed with penile cancer undergoing LIL.

	Total	Grade 1	Grade 2	Grade 3	Tumour size (cm)	cN-/cN+
pT1 (N (%))	16 (55.2)	3 (10.3)	9 (31.0)	4 (13.8)	2.1±2.5	10/6
pT2 (N (%))	11 (37.9)	2 (6.9)	8 (27.6)	1 (3.4)	2.5±1.4	7/4
pT3 (N (%))	2 (6.9)	0 (0)	1 (3.4)	1 (3.4)	7.0±2.8	0/2

after undergone a one-sided LIL. 33 LILs (57.9%) were conducted with prophylactic intention and 24 (42.1%) therapeutic. 42 bilateral LILs (75.0%) were performed simultaneously, whereas 14 bilateral LILs (25.0%) were carried in a two step procedure, starting with the clinically positive side, if present, and performing the contralateral LIL 4 to 13 weeks after surgical convalescence using the same dissection technique. Time from definitive primary tumor therapy to LIL was 1 to 53 weeks, while in 6 patients (20.7%) these interventions occurred simultaneously. Time of hospital stay was 14.2±6.1 days. Operative time for one-sided LIL was 89.0±37.3 minutes. 8.1±3.7 LNs were removed during unilateral LIL. From 242 LNs removed during prophylactic LIL, histopathological examination revealed one LN metastasis. In contrast, 27 nodes were found to be metastatic out of 202 extirpated during therapeutic LIL. None of the low risk patients presented histologically positive LN, while LN metastases were found in 3 intermediate risk patients (33.3%) and in 7 patients (41.2%) of the high risk group.

A total of 31 complications (54.4%) including 16 minor (28.1%) and 15 major (26.3%) were observed in 57 performed LILs. 9 patients (31.0%) experienced no postoperative complications. Separate complication types and rates stratified to prophylactic and therapeutic LIL as well as early and late onset are described in Table-3 according to Bevan-Thomas (9). Classification of the complications according to Clavien (10) is depicted in Suppl. Table-1. Complication rates of prophylactic LIL (n=16, 48.5%) were decreased compared to therapeutic LIL (n=15, 62.5%) without reaching statistical significance ($p>0.05$). There were no relevant intraoperative complications or mortality associated with LIL. 4 patients (13.8%) who received a therapeutic LIL and revealed LN metastases developed histologically proven inguinal lymphatic recurrence 3 to 9 months after LIL. Follow-up period of the study cohort was 49.5±42.6 months with 5 patients lost in the course of postoperative surveillance.

DISCUSSION

Penile cancer is a rare entity in Europe and North America with an incidence rate of less than 1 per 100,000 males (11). In many central European countries, particularly in Germany, therapeutic management of this cancer entity is not limited to high-volume referral centres but rather distributed to a large number of hospitals resulting in relatively small case numbers per institution. Strategies concerning the indication to iLAD as well as surgical technique vary significantly. Thus, different template extension and perioperative management on one hand and inconsistent methodology of complication definition, grading, reporting and way of data acquisition (prospectively/retrospectively) on the other (12) contribute to a great variability of iLAD complication rates reported in literature. We comprehensively analyzed the outcome of our technique with horizontal skin incision, limited dissection field including thick skin flaps, preservation of fascia lata and great saphenous vein without transposition of the sartorius muscle and compared our results with those of other institutions.

Historically, classic radical iLAD (RIL) for PeCa (13-15) with a skin incision of 10 cm length, an extensive dissection field with a complete exposition of the femoral vessels, division of the great saphenous vein and transposition of the sartorius muscle was accompanied by considerable

Table 3 - 31 clinically relevant complications associated with 57 LILs. In brackets - complication rates. Complication rates of prophylactic and therapeutic LIL presented in relation to respectively performed LILs, early and late complication rates related to all LILs.

Complication	Prophylactic LIL N (%)	Therapeutic LIL N (%)	Early complication N (%)	Late complication N (%)
Minor:	**9 (27.3)**	**7 (29.1)**	**16 (28.1)**	**0 (0)**
Leg oedema mild + moderate	4 (12.1)	5 (20.8)	9 (15.8)	0 (0)
Wound infection	2 (6.1)	2 (8.3)	4 (7.0)	0 (0)
Seroma	2 (6.1)	0 (0)	2 (3.5)	0 (0)
Paresthesia	1 (3.0)	0 (0)	1 (1.8)	0 (0)
Major:	**7 (21.2)**	**8 (33.3)**	**10 (17.5)**	**5 (8.8)**
Wound infection + intravenous antibiotics	1 (3.0)	0 (0)	0 (0)	1 (1.8)
Lymphocele + intervention	3 (9.1)	1 (4.2)	2 (3.5)	2 (3.5)
Wound reexploration for abscess, hematoma, infected lymphocele, wound healing deficit	3 (9.1)	6 (25.0)	7 (12.3)	2 (3.5)
DVT	0 (0)	1 (4.2)	1 (1.8)	0 (0)
Total	16 (48.5)	15 (62.5)	26 (45.6)	5 (8.8)

DVT = deep venous thrombosis.

Suppl. Table 1 - Type, rate per procedure (in brackets) and severity of 31 complications related to 57 LILs.

Complication	Grade 1 N(%)	Grade 2 N(%)	Grade 3a (N%)	Grade 3b (N%)	Total (N%)
Wound infection	0 (0)	5 (8.8)	0 (0)	8 (14)	13 (22.8)
Leg oedema	9 (15.8)	0 (0)	0 (0)	0 (0)	9 (15.8)
Seroma/lymphocele	2 (3.5)	0 (0)	4 (7)	0 (0)	6 (10.5)
Hematoma	0 (0)	0 (0)	0 (0)	1 (1.8)	1 (1.8)
Paresthesia	1 (1.8)	0 (0)	0 (0)	0 (0)	1 (1.8)
DVT	0 (0)	1 (1.8)	0 (0)	0 (0)	1 (1.8)
Total	12 (21.1)	6 (10.5)	4 (7.0)	9 (15.8)	31 (54.4)

DVT = deep venous thrombosis.

morbidity rates. The most common cited complications included wound infection (10-20%), lymphocele/seroma (19-45%), particularly mutilating skin edge necrosis (14-65%), and lymphoedema (2-100%) (1). Johnson et al. (16) reported that only 18% of patients experienced no postoperative complications during 101 groin dissections in 67 patients. Similarly, Kamat et al. (17) observed an overall complication rate of 87% in 31 patients and Horenblas et al. (18) described a complication

rate of 53% in 32 patients with RIL. A recently published large series from the Netherlands by Stuiver et al. (19) including 237 RILs reported 195 complications (82.3%). In contrast, Koifman et al. (20) observed in a large series of 170 patients with 340 RILs without muscle transposition an overall complication rate of only 10.3%. To our knowledge this is the currently lowest reported complication rate for this technique. The high incidence of PeCa in Brazil with nearly 300 newly diagnosed patients per year (15), leading to the high number of patients within a 10 years study period and a consequently expanded expertise of the group in RIL surgical techniques as well as an optimized postoperative patient management contributed to these outstanding results. However, only a few centres experience such a high volume of patients with PeCa resulting conceivably in a higher perioperative complication rate.

Hence, several modifications of this radical technique mainly aiming to reduce the dissection area have been proposed to alleviate immediate and long-term sequelae and to improve the quality of life, while maintaining the oncologic benefit of the procedure. The most commonly used technique is the modified inguinal lymphadenectomy (MIL) proposed by Catalona (21). This technique is mainly characterized by a shorter skin incision of 6-7 cm, reduced dissection field which is predominantly focusing on deep inguinal nodes in fossa ovalis with omitting of the regions lateral to femoral artery and caudal to fossa ovalis, as well as maintenance of the saphenous vein and no transposition of sartorius muscle (1). In case of histologically proven metastases during this procedure, RIL is recommended to be performed (1). In a series with 6 patients with clinically negative LNs, Catalona reported one lymphocele and mild lymphoedema in most cases (21). In a small cohort of 12 patients, Parra et al. (22) observed no major complications, skin flaps necrosis or leg oedema. Similarly, no significant sequelae were indicated by Jacobellis et al. (23) in bilateral MILs of 8 patients with PeCa and 2 with penile leiomyosarcoma. In concert with these results, Bouchot et al. (4) describes only 12 minor complications in 118 MILs (10.2%).

Our approach with a limited extent of dissection compared to the standard RIL was conducted aiming the reduction of perioperative sequalae and simultaneously preserving the oncologic safety. Particularly, the dissection of the great saphenous vein, fascia lata, wide exposure of the femoral vessels and consequent transposition of the sartorius muscle was avoided in order to limit the dissection of the deep lymphatic vessels and deterioration of lymph flow. With this technique, we experienced an overall complication rate of 54.4%, which ranges expectably between that of the most series with RIL and MIL as proposed by Catalona (21) Thereby, leg oedema represented the most prevalent morbidity (overall 15.8%). Surgical re-exploration was required in 9 patients (15.8%). The spectrum of complications was comparable to other publications on RIL, except that relevant skin edge necrosis was not observed in our cohort using a horizontal skin incision, most likely based on the fact that skin vascularisation is horizontal at the level of the subcutaneous adipose tissue (14), resulting in a high incidence of skin flap necrosis if a vertical dissection is used, interrupting the blood supply.

If bilateral surgery should be accomplished simultaneously or as a two step procedure still remains to be investigated. The pros for one step approach might include one anesthesia with the respective risks, one postoperative hospital stay and only one surgical recovery process implicating in postoperative pain, impaired mobilization, prolonged use of compression stockings, venous thromboembolism prophylaxis, analgesic and antibiotic therapy. However, as evidence on this issue is limited, concerns exist that simultaneous approach might lead to a higher overall wound size at the same time with an eventually augmented risk for wound infection, furthermore impaired mobilization and quality of life, as e.g. lymphorrhoea or lymphoceles that are often rather bothersome. Moreover, a deep venous thrombosis on both sides as the worst case might represent a precarious condition. In our study, 25% of patients with a bilateral LIL underwent a two step procedure. Even a higher rate of patients with a bilateral surgery (28 out of 73 patients, 38.4%) was exposed to a two step procedure in the large contemporary series of Stuiver et al. (19). Of note, bilateral dissection in a single procedure was one

of the factors most strongly associated with the occurrence of moderate to severe wound complications in a multivariate analysis in this study. The selection of the one vs. two step surgery still seems to be on the discretion of the surgeon. Obviously, prospective randomized trials are required to comparatively assess both strategies in terms of general health cost, complication rates as well as if clinical variables as Charlson comorbidity index or BMI might assist individually the selection of the most appropriate approach. Further research is also needed to shed more light on the influence of the histopathologic result of the one-side surgery on extension of the contralateral dissection.

Local inguinal tumour recurrence is the main concern of surgical approaches with a limited dissection field. Surprisingly, only a few studies reported about this critical issue (2). Thus, Lopes et al. (24) criticized Catalona´s procedure with avoiding the dissection of the LNs lateral to the femoral artery as unreliable due to local recurrence in 2 out of 13 patients and the fact that no patient presented metastases in the medial quadrant LNs. In concert with these results, 2 out of 18 patients experienced local recurrence within two years after MIL published by D´Ancona et al. (25). In contrast, Colberg et al. (26) observed no local recurrence in nine patients despite the histological finding of metastases in three of them. Nevertheless, omitting of the dissection laterally to the femoral artery as well as superior zones has to be critically reviewed. A recently published study by Leijte et al. on the penile lymphatic drainage (27) provided evidence for location of sentinel and higher-tier nodes in superior and central inguinal zones. Furthermore, the number of removed nodes should be taken into account as tenuous data on the groin lymphatic anatomy suggest the presence of 10-15 superficial and 0-5 deep inguinal nodes (20, 28, 29).

The average number of removed LNs per side in our study was 8.1, which is slightly lower compared to most recent studies (19, 20) using RIL with 9 (median) and 10.9 (mean) nodes, respectively. Unfortunately, 4 patients with therapeutic LIL in our study experienced local inguinal recurrence within 9 months after surgery despite our approach with dissection of all five anatomical sectors of the inguinal LNs as described by Daseler et al. (30). Local recurrence might be based on insufficient dissection of the deep lymphatics on the femoral vessels due to their reduced exposure and preservation of fascia lata using our approach of LIL.

Recently, video-endoscopy (31) with further advancement of a single-port access (32) and even robotic-assisted techniques (33) have been proposed for iLAD aiming to further decrease perioperative sequalae. These series yielded promising preliminary results. However, until a definitive assessment of the reliability and oncologic safety of these approaches will be possible after presentation of studies with larger sample size and longer follow-up in the future, open iLAD still remains a state-of-the-art procedure if surgical approach is indicated. Also, the role of DSNB, currently applied only in a few centres worldwide, should be further elucidated.

The current study is limited by its restricted sample size and retrospective nature, which might have contributed to underestimated complication rates (12). Taking into account a low incidence of PeCa in Europe, cooperative research in this area might be crucial to achieve more robust evidence with higher patient numbers and a shorter recruitment period. Nevertheless, we believe that our results reflect the “real life” in central Europe, where procedures are performed out of high-volume referral centres and in regions with a low incidence of the disease.

In conclusion, our technique of a limited inguinal dissection provided an acceptable complication rate without aggravating morbidity. We experienced no recurrences in clinically negative patients, so that LIL might be a reasonable option for this cohort and incorporation of frozen section analysis into this approach with extending the dissection field to radical template in case of positivity might further reduce the risk of local recurrence. In patients with clinically enlarged LNs, more extended resection is required and RIL still is the gold standard.

CONFLICT OF INTEREST

None declared.

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