

Original Article

Clinical outcomes of inguinal lymph node dissection via the lower abdominal wall approach in patients with penile cancer and risk factors for postoperative lymphatic leakage

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Abstract: Objective: To evaluate the efficacy of the trans-abdominal wall approach for inguinal lymph node dissection (ILND) in patients with penile cancer and to identify independent risk factors for postoperative lymphatic leakage and flap necrosis. Methods: A retrospective cohort study was conducted on 120 patients with penile cancer who underwent trans-abdominal wall approach ILND between January 2018 and December 2019. Based on 3-year follow-up outcomes, patients were divided into a no-complication group (without lymphatic leakage or flap necrosis, n = 84) and a complication group (with lymphatic leakage and/or flap necrosis, n = 36). Demographic, clinical, pathological, and follow-up data were collected. Progression-free survival (PFS) was estimated using the Kaplan-Meier method. Univariate and multivariable logistic regression analyses were performed to identify independent risk factors for postoperative complications. Results: The median follow-up was 36 months. The 3-year PFS rate was 7.5%, and the overall survival rate was 40.0%. In the entire cohort, 40 cases (33.3%) of lymphatic leakage and 4 cases (3.3%) of flap necrosis were observed. Multivariable logistic regression for lymphatic leakage identified older age (OR = 1.115, 95% CI: 1.020-1.219, P = 0.017), prolonged surgery time (OR = 1.072, 95% CI: 1.027-1.118, P = 0.001), positive lymph node count ≥ 2 (OR = 7.200, 95% CI: 1.641-31.588, P = 0.009), and T3 stage (OR = 9.212, 95% CI: 1.234-68.788, P = 0.030) as independent risk factors, while higher preoperative albumin levels were protective (OR = 0.598, 95% CI: 0.479-0.747, P < 0.001). Patients in the complication group had significantly lower EORTC QLQ-C30 scores compared with those in the no-complication group (57.55 ± 11.03 vs. 82.70 ± 6.69 , P < 0.001). Conclusions: Trans-abdominal wall approach ILND provides satisfactory oncological outcomes with acceptable complication rates in patients with penile cancer and inguinal lymph node metastasis. Advanced age, prolonged surgery time, positive lymph node count ≥ 2 , and T3 stage are independent risk factors for lymphatic leakage, whereas higher preoperative albumin levels are protective. Postoperative complications significantly impair patients' quality of life, underscoring the importance of preoperative risk stratification and perioperative optimization.

Keywords: Penile cancer, inguinal lymph node dissection, trans-abdominal wall approach, postoperative complications

Introduction

Penile cancer is a rare malignant tumor of the male reproductive system that originate from penile epithelial cells, with squamous cell carcinoma accounting for over 90% of the cases [1]. The global age-standardized incidence rate of penile cancer is approximately 0.8 per 100,000, but it can reach 3-4 per 100,000 in certain regions, including Africa, South America, and Southeast Asia [2, 3]. Although China is consid-

ered a low-incidence area, recent epidemiological studies have demonstrated a bimodal age distribution of onset, with an increasing proportion of young patients [4, 5]. The development of penile cancer is closely related to multiple factors, including phimosis, redundant prepuce, human papillomavirus infection, smoking, and chronic inflammatory stimulation [6]. Due to atypical early symptoms and delays in seeking medical treatment caused by social embarrassment, about 15%-30% of patients present with

detectable inguinal lymph node metastasis at initial diagnosis [7]. Lymph node metastasis represents the most important prognostic factor for penile cancer, and once inguinal lymph node metastasis occurs, the 5-year survival rate drops from over 80% to approximately 30%-50% [8-10]. Therefore, standardized management of regional lymph nodes is a critical component in improving the prognosis of patients with penile cancer.

Inguinal lymph node dissection (ILND) is the standard treatment for penile cancer with inguinal lymph node metastasis and remains the only potential means to achieve curative treatment [11, 12]. Conventional open ILND requires complete resection of superficial and deep inguinal lymphatic and adipose tissues. Although it provides effective local control, the procedure is associated with a high incidence of postoperative complications. Previous studies have reported that the overall complication rate after open ILND can exceed 50%, with lymph leakage (10% to 40%), flap necrosis (20% to 30%), incision infection (15% to 25%), and lower extremity lymphedema (30% to 50%) being the most frequently observed complications [13-15]. These complications not only prolong hospital stays and increase medical costs, but also substantially impair postoperative quality of life and negatively affect compliance with subsequent treatments. To reduce surgical trauma, several modified surgical approaches have been developed, including modified ILND with preservation of the great saphenous vein, laparoscopic-assisted ILND, and robot-assisted ILND. Among these techniques, robot-assisted ILND via the lower abdominal wall approach offers potential advantages, including magnified visualization, high-definition 3D imaging, and flexible instrumentation, allowing precise dissection of lymph tissues and preservation of flap vascular supply. Theoretically, these advantages may reduce the incidence of flap necrosis and lymphatic leakage [16, 17].

The fundamental principle of the lower abdominal wall approach is to establish an artificial operating space in the inguinal region through balloon dilation, insert trocar ports away from the lesion area, and avoid direct incision of the skin flap. This technique was first reported by Tobias-Machado et al., and subsequent studies have confirmed that it can reduce the risk of flap necrosis and lymphatic leakage compared

to open surgery, while achieving a comparable lymph node yield [18]. However, current evidence is mainly derived from small case series or non-randomized controlled studies, and the complication rates reported by different centers vary greatly. Some studies report a relatively high rate of lymph leakage (15% to 25%) and flap necrosis (8% to 15%) [19]. These discrepancies may be associated with factors such as patient age, nutritional status, surgeon experience, extent of lymph node dissection, and tumor stage [20]. Therefore, identifying independent risk factors for lymphatic leakage and flap necrosis following lower abdominal wall approach ILND is of great significance for preoperative risk stratification, individualized perioperative management, and further optimization of surgical techniques. Currently, most studies investigating risk factors for postoperative complications after ILND in penile cancer patients have focused on conventional open surgeries. Evidence regarding risk factors specific to the minimally invasive approach through the lower abdominal wall remains limited, and most of these studies are based on single-factor analyses without adequate multivariable adjustment [21, 22]. Moreover, limitations such as small sample size, short follow-up time, and inadequate control of confounding factors are common. Therefore, a retrospective study with a relatively large sample size and comprehensive follow-up is warranted to systematically evaluate the clinical efficacy of lower abdominal wall approach ILND and identify risk factors associated with lymphatic leakage and flap necrosis.

Based on this background, this study retrospectively analyzed the clinical data of 120 patients with penile cancer who underwent lower abdominal wall approach ILND at the Department of Urology, Yuncheng Central Hospital, between January 2018 and December 2019. The objectives of this study included: (1) evaluating the short-term and long-term outcomes of this approach, including lymph node yield, postoperative complication profiles, 3-year progression-free survival (PFS) rate and overall survival (OS) rate; (2) identifying independent risk factors for postoperative lymphatic leakage and flap necrosis; and (3) providing evidence for clinical decision-making and guiding preoperative assessment and postoperative management of high-risk patients.

Materials and methods

Study subjects

The clinical data of patients with penile cancer who underwent lower abdominal wall approach ILND at the Department of Urology, Yuncheng Central Hospital, between January 2018 and December 2019 were retrospectively collected. This study was approved by the Ethics Committee of Yuncheng Central Hospital, and all patient information was anonymized. Given the retrospective design, the requirement for written informed consent was waived by the ethics committee.

Inclusion criteria: (1) Age ≥ 18 years; (2) Diagnosis of penile cancer confirmed by histopathological or imaging examination; (3) Patients who underwent lower abdominal wall approach ILND; (4) Availability of complete clinical data, including medical history, physical examination findings, imaging results, pathological findings, and postoperative follow-up records; and (5) Postoperative follow-up duration ≥ 3 years. Exclusion criteria: (1) Presence of other severe comorbidities (e.g., severe cardiovascular or cerebrovascular diseases, renal insufficiency); (2) Patients who did not undergo surgery via the lower abdominal wall approach; (3) Incomplete clinical data or loss to follow-up.

Study design and grouping

A retrospective cohort study design was adopted. According to the occurrence of lymphatic leakage and/or flap necrosis within 30 days after surgery, patients were divided into two groups: the no-complication group and the complication group (with lymphatic leakage and/or flap necrosis). All patients were followed up for 3 years to evaluate survival and recurrence outcomes. The primary outcome measure was the occurrence of postoperative lymphatic leakage or flap necrosis. Secondary outcomes included PFS rate, OS rate, postoperative complications (e.g., infection, ascites, and hernia) and quality of life.

Data collection

The following data were retrospectively collected from the hospital's electronic medical record system:

General demographic characteristics: age, body mass index (BMI), smoking history, alcohol consumption history.

Medical history: hypertension, diabetes, coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD).

Perioperative data: operative time, intraoperative blood loss, total number of dissected lymph nodes, number of positive lymph nodes.

Pathological data: tumor pathological type (squamous cell carcinoma, basal cell carcinoma, adenocarcinoma, and mixed type carcinoma) and T stage.

Postoperative complications: lymph leakage, flap necrosis, incision infection, peritoneal effusion, hernia, and other complications. Lymph leakage was defined as continuous drainage output > 50 mL/day after surgery, with a positive lacteal test. Flap necrosis was defined as postoperative darkening of flap color, tissue necrosis, and the requirement for debridement.

Prognostic data: tumor recurrence, metastasis, or death within 3 years after surgery. PFS time was defined as the interval from the date of surgery to the first recurrence, metastasis or death.

Quality of life: Quality of life was evaluated using the European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire (EORTC QLQ-C30) at 3 months after surgery. Scores ranged from 0 to 100, with higher scores indicating better quality of life.

Two trained researchers independently extracted and cross-checked all data. Any disagreement were resolved through discussion or adjudication by a third researcher.

Surgical method

All patients underwent robot-assisted laparoscopic ILND via the lower abdominal wall approach using the da Vinci surgical system. Patients were placed in a supine position with both lower limbs abducted. A 1.5 cm incision was made 2-3 cm below the apex of the femoral triangle. After blunt dissection through the

subcutaneous tissue, the Scarpa fascia was incised, and a balloon dilator was inserted to create a working space. The dissection space extended superiorly to 2-3 cm above the inguinal ligament, laterally to the anterior superior iliac spine, and medially to the pubic tubercle. A 12-mm optical trocar was inserted for CO₂ insufflation, and the pneumoperitoneum pressure was maintained at 15 mmHg. Subsequently, two 8-mm robotic trocars and one 5-mm assistant trocar were inserted in a triangular configuration, followed by docking of the robotic system.

Dissection was performed within the boundaries of the superficial inguinal lymphatic compartment: superiorly to the spermatic cord, laterally to the sartorius muscle, medially to the adductor longus muscle, and inferiorly to the apex of the femoral triangle. Deep inguinal lymph nodes were dissected along the femoral vessels after opening the femoral sheath. Lymphatic vessels and small blood vessels were sealed using bipolar electrocautery or Hem-o-lock clips. The great saphenous vein was preserved whenever oncologically feasible. All resected specimens were submitted for pathological examination to confirm adequate nodal clearance. After completion of dissection, the surgical field was inspected by an independent urological oncologist, and additional resection was performed if necessary. A closed suction drain was placed in the inguinal region, and the incision was closed in layers. Bilateral ILND was performed sequentially as indicated. Operative time and the total number of dissected lymph nodes were recorded for each side.

Observation outcomes

Primary outcomes: The primary outcome was the occurrence of postoperative lymphatic leakage and/or flap necrosis. The diagnostic criteria were: (1) continuous drainage from the inguinal region for ≥ 5 days with a daily volume > 50 mL, or confirmation of lymphatic fluid by laboratory testing; and (2) postoperative darkening of flap color, blister formation, and necrotic tissue requiring debridement. These events were used as the grouping criterion for the study cohort.

Because lymphatic leakage and flap necrosis have different pathophysiological mechanisms and incidence rates, separate multivariable

logistic regression analyses were performed. The results of these analyses are presented in [Supplementary Tables 1 and 2](#).

Secondary outcomes: Secondary outcomes included postoperative complications (e.g., incision infection or intra-abdominal infection, peritoneal effusion, hernia), PFS time (interval from surgery to the first recurrence, metastasis, or death), OS, and EORTC QLQ-C30 scores.

Follow-up

Follow-up was conducted through outpatient visits or telephone interviews. Patients were followed every 3 months during the first postoperative year and every 6 months thereafter. Follow-up assessments included physical examination, abdominal ultrasonography, pelvic computed tomography (CT) or magnetic resonance imaging (MRI), chest radiography, and other relevant examinations. The last follow-up was conducted in December 2022. Data regarding recurrence, metastasis, survival status, and complications were collected.

Statistical methods

Statistical analyses were performed using SPSS 26.0 and Python 3.13 (with Statsmodels and Lifelines). Continuous variables are presented as mean $\pm$ SD (normally distributed) or median (IQR) (non-normally distributed), and were compared using the independent-sample t-test or Mann-Whitney U test, respectively. Categorical variables are presented as n (%) and compared using the chi-square or Fisher's exact test. PFS curves were generated using the Kaplan-Meier method and compared with the log-rank test. ROC curve analysis assessed the predictive value of operative time for complications, with AUC and optimal cut-off (Youden index) calculated. Univariate logistic regression screened risk factors for the composite outcome (lymphatic leakage and/or flap necrosis); variables with $P < 0.10$ were entered into a multivariable forward stepwise model, which included age, operative time, albumin, positive lymph node count ≥ 2 , and T3 stage. Postoperative infection and pathological subtype were excluded from the multivariable model to avoid reverse causality and model instability, respectively. For complication-specific risk factors, multivariable logistic regression was performed for lymphatic leakage alone

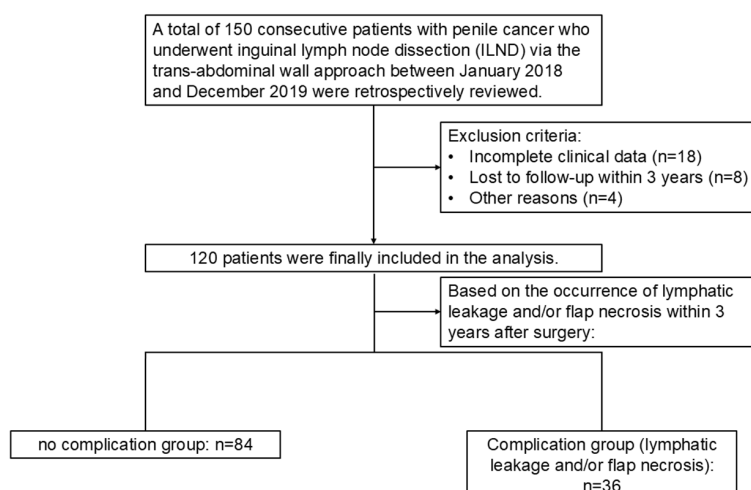


Figure 1. Flow chart of patient selection. A total of 120 patients with penile cancer who underwent trans-abdominal wall approach ILND were included in the final analysis.

(Supplementary Table 1), and univariate logistic regression for flap necrosis alone due to low event count ($n = 4$; Supplementary Table 2). Normality was assessed using the Shapiro Wilk test. Variables with a non normal distribution were summarized as median (IQR) and compared using the Mann Whitney U test. All tests were two-sided, and $P < 0.05$ was considered statistically significant.

Results

Comparison of baseline characteristics between the two groups

A total of 120 patients were included in the final analysis (Figure 1). The mean age the patients was (63.3 ± 8.9) years (range 47-85 years). Based on the occurrence of postoperative complications, patients were divided into the no-complication group ($n = 84$) and the complication group ($n = 36$). Baseline characteristics are summarized in Table 1. Compared with patients in the no-complication group, patients in the complication group were significantly older [median (IQR): 69.00 (60.75-73.25) years vs. 62.00 (56.00-67.00) years, $P = 0.001$], had a longer surgery time [113.03 (100.59-119.61) min vs. 88.81 (74.97-102.69) min, $P < 0.001$], lower preoperative albumin levels [34.77 (32.55-38.03) g/L vs. 40.97 (38.21-43.22) g/L, $P < 0.001$], and higher positive lymph node counts [1.50 (1.00-2.25) vs. 1.00 (0.00-1.00), $P = 0.017$]. The proportion of patients with ≥ 2 positive lymph nodes was

also significantly higher in the complication group (50.0% vs. 23.8%, $P = 0.009$).

Regarding pathological characteristics, squamous cell carcinoma was less common in the complication group than in the no-complication group (66.7% vs. 85.7%, $P = 0.032$), whereas mixed-type carcinoma was more frequent in the complication group (25.0% vs. 9.5%, $P = 0.052$). No significant differences were observed between the two groups in BMI, hypertension, diabetes, smoking status, alcohol consumption, coronary artery disease, COPD, or T stage (all $P > 0.05$). Among the 36 patients

in the complication group, the overlap of lymphatic leakage and flap necrosis is detailed in Table 2. Thirty-two patients (88.9%) developed lymphatic leakage alone, one patient (2.8%) had flap necrosis alone, and 3 patients (8.3%) experienced both complications.

Survival analysis

The 3-year PFS rates at 6, 12, 18, 24, 30, and 36 months were 97.5%, 77.5%, 50.8%, 36.7%, 17.5%, and 7.5%, respectively. The corresponding OS rates were 95.0%, 87.5%, 79.2%, 58.3%, 51.7%, and 40.0%, respectively.

Kaplan-Meier survival curve (Figure 2) showed that PFS in the complication group was significantly worse than that in the no-complication group. The median PFS was 28.68 months in the no-complication group, significantly higher than the 7.28 months in the complication group, although the corresponding 95% CIs were not estimated ($P < 0.001$; Table 3).

Postoperative complications

During the postoperative follow-up period, 40 patients (33.3%) experienced lymphatic leakage, 4 (3.3%) had flap necrosis, and 29 (24.2%) developed incision infection in the entire cohort. By design, the complication group had a significantly higher proportion of lymphatic leakage (35/36, 97.22%) and flap necrosis (4/36, 11.11%) compared with the no-complication group (5/84, 5.95% and 0/84, 0%, respectively). These differences are inherent to

Table 1. Comparison of baseline characteristics between the two groups

Variables	No complication group (n = 84)	Complication group (n = 36)	Statistic	P value
Age, years, median (IQR)	62.00 (56.00-67.00)	69.00 (60.75-73.25)	955.000†	0.001
BMI, kg/m ² , median (IQR)	22.95 (21.93-24.00)	23.08 (22.07-23.42)	1461.500†	0.775
Surgery time, min, median (IQR)	88.81 (74.97-102.69)	113.03 (100.59-119.61)	630.000†	< 0.001
Albumin, g/L, median (IQR)	40.97 (38.21-43.22)	34.77 (32.55-38.03)	2616.000†	< 0.001
Lymph nodes dissected, median (IQR)	11.00 (10.00-14.25)	12.00 (10.00-14.00)	1497.000†	0.933
Positive lymph nodes, median (IQR)	1.00 (0.00-1.00)	1.50 (1.00-2.25)	1113.500†	0.017
Hypertension, n (%)	21 (25.0)	10 (27.8)	0.008‡	0.927
Diabetes, n (%)	11 (13.1)	7 (19.4)	0.377‡	0.539
Smoking, n (%)	18 (21.4)	9 (25.0)	0.036‡	0.849
Alcohol, n (%)	19 (22.6)	7 (19.4)	0.021‡	0.885
Positive LN ≥ 2, n (%)	20 (23.8)	18 (50.0)	6.824‡	0.009
Pathology type			-\$	0.032
Squamous cell carcinoma	72 (85.7)	24 (66.7)		
Basal cell carcinoma	0 (0.0)	1 (2.8)		
Adenocarcinoma	4 (4.8)	2 (5.6)		
Mixed type	8 (9.5)	9 (25.0)		
Coronary artery disease, n (%)	4 (4.8)	4 (11.1)	-\$	0.239
COPD, n (%)	5 (6.0)	4 (11.1)	-\$	0.450
T stage			0.677	0.713
T1, n (%)	43 (51.2)	16 (44.4)		
T2, n (%)	33 (39.3)	12 (33.3)		
T3, n (%)	8 (9.5)	8 (22.2)		

Note: † Mann-Whitney U test; ‡ Chi-square test; § Fisher exact test. Abbreviations: BMI, Body Mass Index; LN, Lymph Node; COPD, Chronic Obstructive Pulmonary Disease; CAD, Coronary Artery Disease; SCC, Squamous Cell Carcinoma; BCC, Basal Cell Carcinoma.

Table 2. Overlap between lymphatic leakage and flap necrosis in the complication group (n = 36)

	Flap necrosis		Total
	No	Yes	
No lymphatic leak	0	1	1
Lymphatic leak	32	3	35
Total	32	4	36

the grouping definition rather than independent comparative findings. These figures reflect the grouping criterion rather than an independent comparison. In contrast, incision infection, which was not part of the grouping definition, occurred significantly more frequently in the complication group than in the no-complication group (15/36, 41.67% vs. 14/84, 16.67%; $P = 0.007$), suggesting that patients with lymphatic leakage or flap necrosis were also at higher risk for wound infection (**Table 4; Figure 3**).

Postoperative quality of life assessment

Postoperative quality of life assessed using the EORTC QLQ-C30 questionnaire showed that patients in the complication group had significantly lower scores in most domains compared with those in the no-complication group (**Table 5; Figure 4**). The global health status score was 57.55 ± 11.03 in the complication group, significantly lower than the 82.70 ± 6.69 in the no-complication group ($P < 0.001$). Similarly, significant differences were observed between the two groups in the functional subscales, including physical function (66.66 ± 11.48 vs. 87.22 ± 7.19), role function (56.51 ± 10.48 vs. 85.97 ± 7.80), emotional function (54.61 ± 12.15 vs. 83.82 ± 7.42), cognitive function (59.92 ± 10.52 vs. 85.98 ± 7.14), and social function (47.34 ± 12.99 vs. 79.54 ± 9.71) (all $P < 0.001$). These findings suggest that postoperative complications were associated with

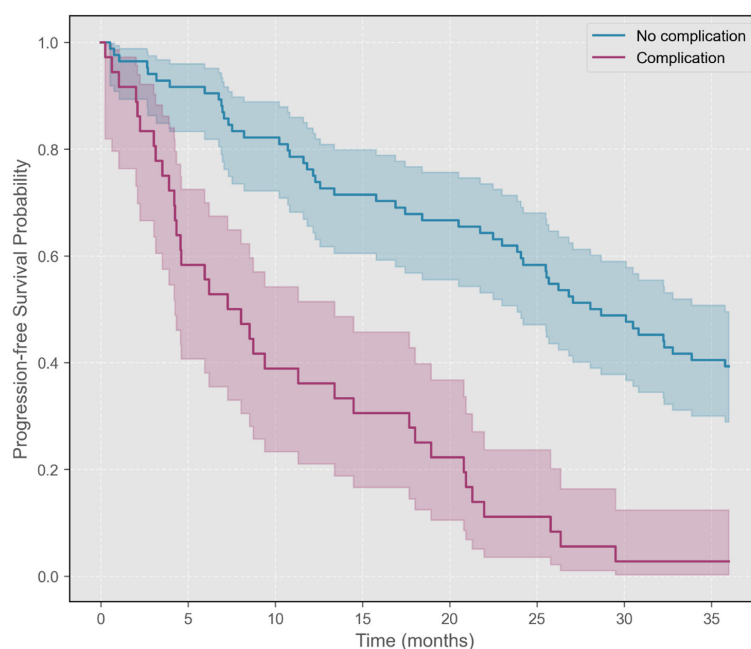


Figure 2. Kaplan-Meier curves of progression-free survival (PFS) between the no complication and complication groups. Abbreviation: PFS, Progression-free Survival.

operative time (OR = 1.072, 95% CI: 1.027-1.118, $P = 0.001$), and positive lymph node count ≥ 2 (OR = 7.200, 95% CI: 1.641-31.588, $P = 0.009$) were independent risk factors for lymphatic leakage, while higher preoperative albumin level was a protective factor (OR = 0.598, 95% CI: 0.479-0.747, $P < 0.001$). T3 stage was also associated with an increased risk of lymphatic leakage; however, the wide confidence interval (OR = 9.212, 95% CI: 1.234-68.788, $P = 0.030$) indicated limited precision, likely due to the small number of T3 cases. The final model included 40 events and 5 covariates, yielding an event per variable (EPV) ratio of 8.0, suggesting acceptable model stability.

Table 3. Progression-free survival rates at each time point

Time (months)	No complication PFS (%)	Complication PFS (%)
0	100.0	100.0
6	90.5	55.6
12	76.2	36.1
18	67.9	27.8
24	60.7	11.1
30	48.8	2.8
36	39.3	2.8

Note: Median PFS: 28.68 months in no-complication group; 7.28 months in complication group. Log-rank $P < 0.001$. Abbreviation: PFS, Progression-free Survival.

substantial impairment in patients' physical functioning and psychosocial well-being.

Risk factors for lymphatic leakage

To identify independent risk factors for postoperative lymphatic leakage, multivariable logistic regression analysis was performed (**Table 6**; **Figure 5**). The model included age, operative time, preoperative albumin level, positive lymph node count ≥ 2 , and T3 stage as covariates. The results showed that older age (OR = 1.115, 95% CI: 1.020-1.219, $P = 0.017$), prolonged

ROC analysis of operative time for predicting complications

Among the independent risk factors identified in the multivariable model, operative time is the only modifiable intraoperative parameter. Age, albumin, T stage, and lymph node status are baseline or pathological characteristics that cannot be altered during surgery. Therefore, ROC curve analysis was specifically performed for operative time to provide a clinically actionable cut-off value for intraoperative decision-making (**Figure 6**). The analysis demonstrated an AUC of 0.792 (95% CI: 0.696-0.887). The optimal cut-off value for operative time was 98.2 min, with a sensitivity of 83.3% and a specificity of 66.7%. This cut-off value is exploratory and requires external validation before clinical application.

Supplementary analyses for each complication

As a sensitivity analysis, an additional multivariable logistic regression analysis was performed for the composite endpoint of lymphatic leakage and/or flap necrosis (**Supplementary Table 1**). In this model, age (OR = 1.087, 95% CI: 1.006-1.175, $P = 0.034$), operative time (OR = 1.068, 95% CI: 1.028-1.109, $P < 0.001$),

Table 4. Comparison of postoperative complication rates between the two groups

Complication	No complication (n = 84)	Complication (n = 36)
Lymphatic leakage, n (%)	5 (5.95)	35 (97.22)
Flap necrosis, n (%)	0 (0.00)	4 (11.11)
Infection, n (%)	14 (16.67)	15 (41.67)

Note: Lymphatic leakage and flap necrosis were the grouping criteria; their between-group differences reflect study design rather than independent comparative findings. For infection (not a grouping criterion), $P = 0.007$.

albumin level (OR = 0.682, 95% CI: 0.572-0.813, $P < 0.001$), and T3 stage (OR = 7.732, 95% CI: 1.223-48.858, $P = 0.030$) were significantly associated with the composite endpoint, whereas positive lymph node count ≥ 2 was not (OR = 2.368, 95% CI: 0.690-8.126, $P = 0.171$). For flap necrosis, due to the small number of events ($n = 4$), only univariate logistic regression analysis were performed ([Supplementary Table 2](#)). None of the examined variables reached statistical significance, although a potential trend toward a protective effect was observed for albumin (OR = 0.945, 95% CI: 0.762-1.172, $P = 0.607$), and this association did not reach statistical significance.

Discussion

Given the single-arm design, direct comparisons with open surgery were not feasible. Therefore, our findings should be interpreted as a descriptive evaluation of this minimally invasive technique. In this retrospective study, the clinical data of 120 patients with penile cancer who underwent ILND via the lower abdominal wall approach were analyzed, with a median follow-up duration of 36 months. This approach achieved effective inguinal lymph node clearance (mean lymph node yield of 13.0). The 3-year PFS rate and OS rate were 7.5% and 40.0%, respectively, which were comparable with previously reported outcomes for open surgery [23, 24]. The overall incidence rate was 33.3% for lymphatic leakage and 3.3% for flap necrosis, which were comparable with the lower range of historically reported data for open surgery (20%-40% for lymphatic leakage and 20%-30% for flap necrosis) [25, 26]. Multivariable logistic regression analysis identified age, prolonged surgery time, and positive lymph node count ≥ 2 as independent risk fac-

tors for lymphatic leakage, whereas higher preoperative albumin levels were associated with a protective effect. T3 stage was also significantly associated with increased risk of lymphatic leakage. Furthermore, patients with postoperative complications had significantly lower EORTC QLQ-C30 scores than those without complications (57.55 ± 11.03 vs. 82.70 ± 6.69), suggesting that complications may substantially impair patients' physical and psychological well-being.

Robotic-assisted ILND via the lower abdominal wall approach is a relatively novel minimally invasive technique. Compared with conventional open surgery, this surgical method establishes an operative space through small incisions distant from the lesion, thereby avoiding extensive flap dissection and theoretically preserving flap vascularity and lymphatic drainage [27]. In this study, the average lymph node yield was 13.0, comparable to the 12-15 nodes typically achieved with open surgery. In addition, the 3-year PFS and OS rates after surgery were generally consistent with the results of open surgery [27, 28], indicating that the lower abdominal wall approach may provide adequate oncological control. In this cohort, the incidence of lymphatic leakage (33.3%) and flap necrosis (3.3%), which were comparable with the lower range of historically reported data for open surgery (10%-40% for lymphatic leakage and 20%-30% for flap necrosis) [28, 29], suggesting that this surgical method may offer potential advantages in reducing postoperative complications.

In this study, age was identified as an independent risk factor for lymphatic leakage (OR = 1.115, 95% CI: 1.020-1.219, $P = 0.017$). The association remained significant after adjusting for other covariates. The relatively advanced mean age in our cohort (median: 62.0 years) may partly explain the observed complication rate. Elderly patients have diminished dermal vascularity, impaired wound healing capacity, and reduced tolerance to surgical stress, which may increase the risk of post-operative flap ischemia, necrosis, and lymphatic leakage [30, 31]. In addition, age-related comorbidities, including hypertension and diabetes, may further prolong the wound healing time. These findings are consistent with previous studies by Tan et al. [32] and Liu et al. [33]. Therefore, for

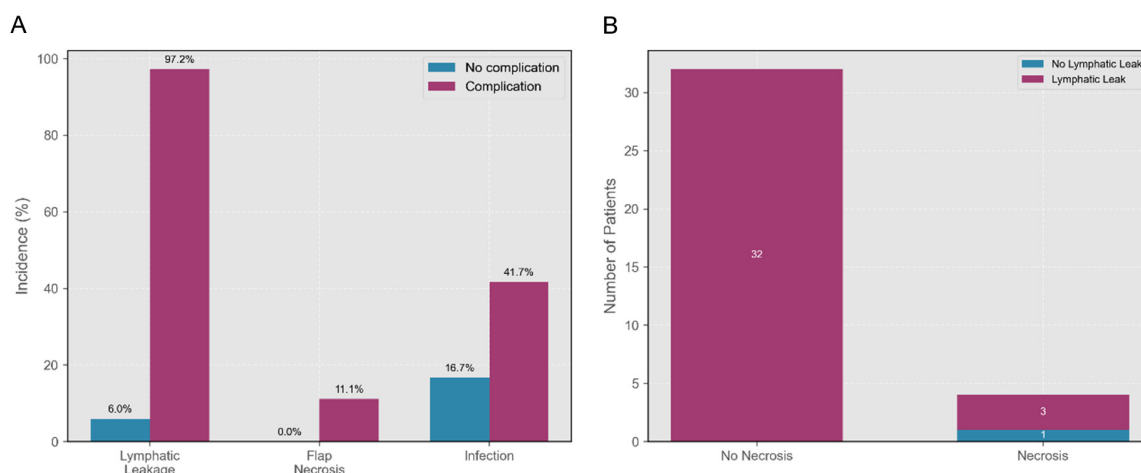


Figure 3. Comparison of postoperative complications between the no-complication and complication groups. A. Comparison of complication rates between the two groups. Lymphatic leakage and flap necrosis were the grouping criteria; group differences for these two complications reflect study design rather than independent comparative findings. Infection was not part of the grouping definition and showed a significant between-group difference ($P = 0.007$). Data are presented as percentages. B. Overlap of lymphatic leakage and flap necrosis in the complication group ($n = 36$). Among the 36 patients, 32 (88.9%) developed lymphatic leakage alone, 1 (2.8%) had flap necrosis alone, and 3 (8.3%) experienced both complications.

Table 5. Comparison of postoperative quality of life scores (EORTC QLQ-C30) between the two groups

QoL Dimension	No complication (n = 84)	Complication (n = 36)	P value
Global health status	82.70 ± 6.69	57.55 ± 11.03	< 0.001
Physical function	87.22 ± 7.19	66.66 ± 11.48	< 0.001
Role function	85.97 ± 7.80	56.51 ± 10.48	< 0.001
Emotional function	83.82 ± 7.42	54.61 ± 12.15	< 0.001
Cognitive function	85.98 ± 7.14	59.92 ± 10.52	< 0.001
Social function	79.54 ± 9.71	47.34 ± 12.99	< 0.001

Note: Abbreviation: QoL, Quality of Life; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30.

elderly patients with penile cancer, comprehensive preoperative assessment of nutritional status and comorbidities is particularly important. Intraoperatively, careful preservation of flap blood supply and enhanced postoperative wound management may help reduce the incidence of complications.

Operative time was another significant risk factor for lymphatic leakage (OR = 1.072, 95% CI: 1.027-1.118, $P = 0.001$). Each additional minute of operative time was associated with a 7.2% increase in the risk of lymphatic leakage. Prolonged operative time may reflect more extensive lymph node dissection, challenging anatomical conditions, or increased surgical

complexity, thereby increasing the likelihood of lymphatic vessel injury and flap ischemia [34]. Additionally, prolonged pneumoperitoneum and the use of electrocautery may contribute to thermal tissue injury [35]. In this study, the mean operative time in the complication group was significantly longer than that in the no-complication group (111.89 ± 20.04 vs. 88.55 ± 20.21 , $P < 0.001$), consistent with previous reports [23, 24]. Therefore, improving surgical efficiency while maintaining adequate lymph nodal dis-

section quality may help reduce the risk of postoperative complications, especially in complex cases, where advance planning is essential [29, 36].

Preoperative hypoalbuminemia was identified as an independent risk factor for lymphatic leakage. Higher albumin levels significantly reduced the risk of lymphatic leakage (OR = 0.598, 95% CI: 0.479-0.747, $P < 0.001$). Albumin is an important indicator of nutritional status and systemic physiological reserve [17]. Hypoalbuminemia indicates malnutrition or chronic disease-related depletion and is associated with impaired tissue repair capacity, compromised immune function, and increased

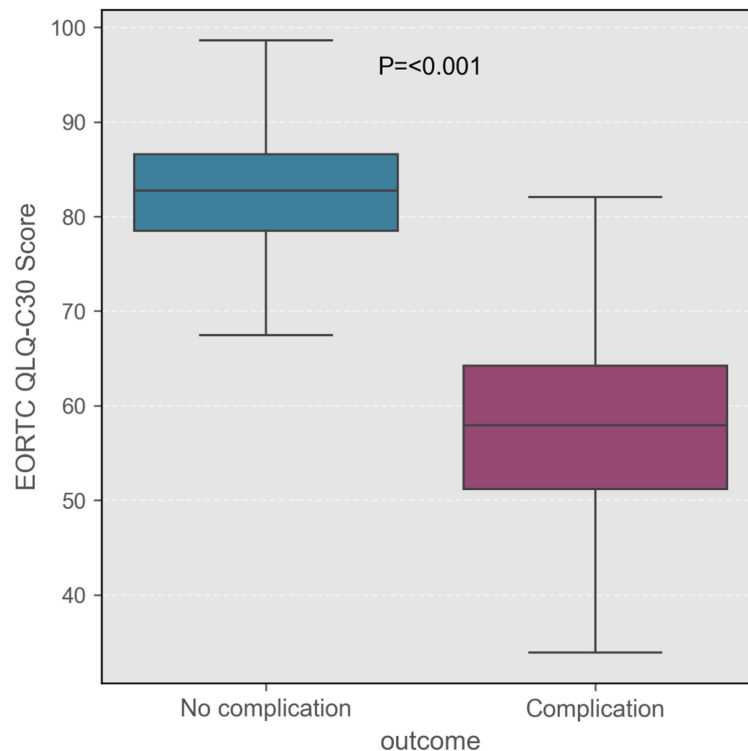


Figure 4. Comparison of postoperative EORTC QLQ-C30 scores between the no complication group and complication group. Abbreviation: EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30.

Table 6. Multivariable logistic regression analysis of risk factors for lymphatic leakage

Variable	OR	95% CI	P value
Age (per year)	1.115	1.020-1.219	0.017
Surgery time (per min)	1.072	1.027-1.118	0.001
Albumin (per g/L)	0.598	0.479-0.747	< 0.001
Positive LN ≥ 2	7.200	1.641-31.588	0.009
T3 stage (vs. T1/T2)	9.212	1.234-68.788	0.030

Note: The model included age, surgery time, albumin, positive lymph node count ≥ 2 , and T3 stage as covariates. The dependent variable was lymphatic leakage (n = 40 events). Event per variable (EPV) ratio = 8.0. Abbreviation: OR, Odds Ratio; CI, Confidence Interval; LN, Lymph Node; EPV, Event Per Variable.

risk of infection and wound-healing complications [23, 25]. In this study, the average albumin level in the complication group was significantly lower than that in the no-complication group (35.80 ± 3.15 g/L vs. 42.03 ± 3.58 g/L, $P < 0.001$). Therefore, routine preoperative assessment of albumin levels and timely nutritional support for patients with hypoalbuminemia may help reduce postoperative complications [18].

T3 stage was also significantly associated with an increased risk of lymphatic leakage (OR = 9.212, 95% CI: 1.234-68.788, $P = 0.030$). However, the wide confidence interval indicates limited precision, which may be attributable to the relatively small number of T3 cases (n = 16). T3 stage tumors involving the urethra or corpus cavernosum generally represent a higher local tumor burden and require more extensive dissection, thereby increasing surgical trauma and the risk of lymphatic leakage [15]. These findings should therefore be interpreted cautiously and require validation in larger cohorts.

The potential mechanisms underlying these associations are supported by previous basic and translational studies. Aging has been shown to impair lymphatic endothelial glycocalyx integrity and barrier function, potentially increasing lymphatic vessel permeability [37]. Preoperative hypoalbuminemia reflects reduced availability of amino acid required for collagen synthesis and fibroblast activity, consistent with evidence that protein-based scaffolds can promote fibroblast migration and tissue repair [38, 39]. Furthermore, prolonged surgical time exacerbates ischemia-reperfusion injury in lymphatic tissues; experimental

studies have demonstrated increased cellular apoptosis and fibrosis following prolonged ischemia exposure in rodent models [40]. These mechanistic findings support the clinical associations observed in our study, although further experimental and clinical studies are required for confirmation.

This study demonstrated that patients with postoperative complications had significantly lower EORTC QLQ-C30 scores than those with-

Trans-abdominal ILND for penile cancer: complications and risk factors

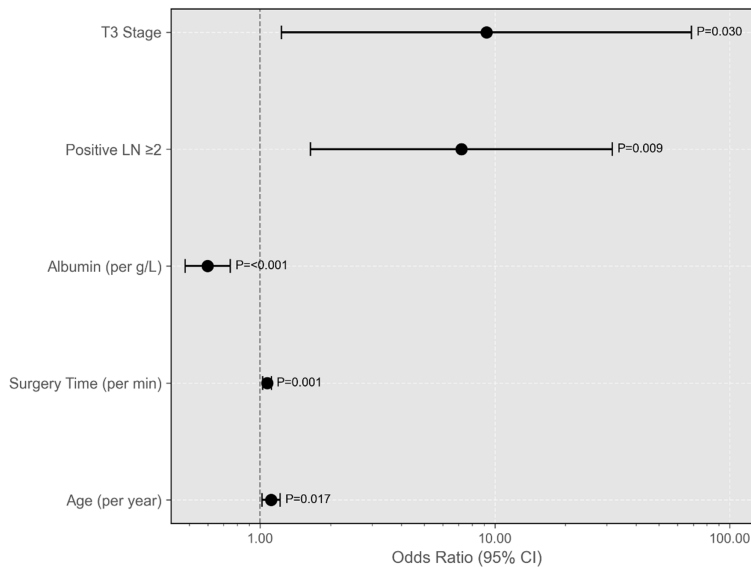


Figure 5. Forest plot of multivariable logistic regression analysis for risk factors of postoperative lymphatic leakage. Abbreviation: OR, Odds Ratio; CI, Confidence Interval; LN, Lymph Node.

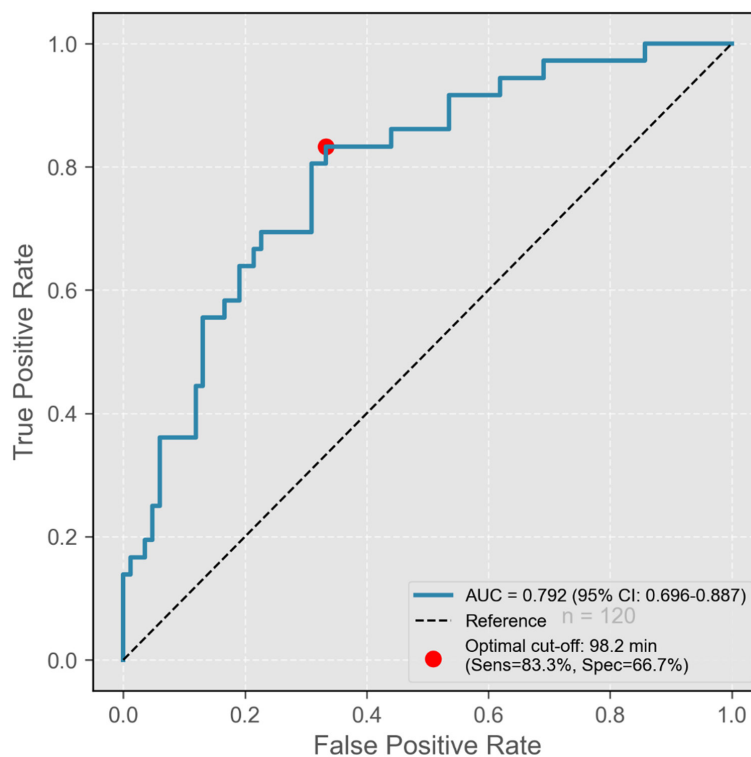


Figure 6. Receiver operating characteristic (ROC) curve of surgery time for predicting postoperative complications. Abbreviation: ROC, Receiver Operating Characteristic; AUC, Area Under the Curve; CI, Confidence Interval.

out complications (57.55 ± 11.03 vs. 82.70 ± 6.69 , $P < 0.001$). Patients with complications

factors for lymphatic leakage, these findings remain exploratory and do not yet represent a

may suffer from prolonged wound drainage, persistent pain, repeated dressing changes, and in some cases, secondary surgical interventions, which can impose substantial psychological burden and social limitations, thereby negatively affecting overall quality of life [7]. These findings highlight that, in addition to oncological outcomes, clinicians should also pay attention to functional recovery and patient-reported outcomes. Prevention and effective management of postoperative complications should be regarded as important components of treatment quality assessment.

Based on these findings, several clinical considerations are proposed: (1) preoperative nutritional assessment and optimization are essential for elderly patients and those with low albumin levels; (2) meticulous surgical techniques should be adopted, including avoidance of unnecessary electrocautery, and reduction of operative time while ensuring adequate lymph node clearance; (3) postoperative wound management should be strengthened; (4) postoperative nutritional status should be monitored, and albumin supplementation may be considered for selected patients when necessary; (5) multidisciplinary collaboration involving nutrition specialists, wound care teams, and surgical departments may facilitate the prevention and management of complications.

Although our study identified several independent risk factors

validated clinical prediction tool. The development of a reliable preoperative risk stratification nomogram or scoring system requires larger sample sizes and prospective external validation, which were beyond the scope of this retrospective study. Nevertheless, the ROC-derived cut-off value for surgery time (98.2 min) provides a preliminary reference for intraoperative risk assessment, but it was derived and evaluated in the same cohort and thus requires independent external validation. Future studies integrating these risk factors into formal prediction model and evaluating their clinical utility in guiding perioperative interventions are warranted.

This study has several limitations. First, the retrospective design inevitably introduces selection bias and information bias. Some variables, such as smoking and alcohol consumption history, were obtained from medical records and may be incomplete. Second, this was a single-center study, with a relatively limited sample size ($n = 120$). Although multivariable regression analysis was performed to adjust for potential confounding factors, the number of outcome events was relatively small, and the possibility of model overfitting cannot be completely excluded. Third, the absence of a control group of open surgery precluded direct comparisons between different surgical approaches, and the potential advantages of the lower abdominal wall approach require further validation. Fourth, some postoperative quality-of-life questionnaires were incompletely collected during follow-up, which may have introduced response bias and affected the representativeness of the results. Fifth, the influence of the surgeon learning curve was not analyzed. Differences in surgical experience among operators may have influenced postoperative outcomes. Sixth, the primary endpoint was defined as a composite outcome of lymphatic leakage and flap necrosis, which are complications with distinct underlying mechanisms. Seventh, the ROC-derived cut-off value for operative time was both identified and evaluated in the same cohort, which may introduce overfitting bias. The performance of this cut-off should be validated in independent external cohorts before it can be recommended for routine clinical decision-making. Therefore, our findings should be considered exploratory and hypothesis-generating rather than confirmatory. Although additional analyses were performed separately for

each complication, the low incidence of flap necrosis limited the statistical power to identify independent risk factors. Additionally, while we identified independent risk factors for lymphatic leakage, a formal preoperative risk prediction model or validated perioperative management algorithm was not developed. The development and external validation of such tools require prospective cohort studies with larger sample sizes, which remain as important directions for future research.

Separate analyses ([Supplementary Tables 1 and 2](#)) suggested that age and hypoalbuminemia were associated with lymphatic leakage, whereas no independent predictors of flap necrosis were identified, likely due to the limited number of events ($n = 4$). Larger multi-center, prospective studies are warranted to validate these findings and explore novel complication-reduction strategies, including indocyanine green lymphography and negative-pressure wound therapy.

Conclusion

The lower abdominal wall approach ILND in penile cancer patients with inguinal lymph node metastasis demonstrated acceptable oncological outcomes and a relatively favorable postoperative complication profile in this cohort. Advanced age, prolonged operative time, and positive lymph node count ≥ 2 were identified as independent risk factors for lymphatic leakage, whereas higher preoperative albumin was a protective factor. Postoperative complications significantly impaired patients' quality of life. These findings highlight the importance of preoperative risk assessment, nutritional optimization, and meticulous perioperative management in reducing postoperative complications.

Disclosure of conflict of interest

None.

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Trans-abdominal ILND for penile cancer: complications and risk factors

Supplementary Table 1. Multivariable logistic regression analysis for composite outcome (sensitivity analysis)

Variable	OR	95% CI	P value
Age (per year)	1.087	1.006-1.175	0.034
Surgery time (per min)	1.068	1.028-1.109	< 0.001
Albumin (per g/L)	0.682	0.572-0.813	< 0.001
Positive LN $\geq$ 2	2.368	0.690-8.126	0.171
T3 stage (vs. T1/T2)	7.732	1.223-48.858	0.030

Note: This is a sensitivity analysis combining lymphatic leakage and flap necrosis as a composite endpoint (outcome). Abbreviation: OR, Odds Ratio; CI, Confidence Interval; LN, Lymph Node.

Supplementary Table 2. Univariate logistic regression analysis for risk factors of flap necrosis (due to low event count, n = 4)

Variable	OR	95% CI	P value
Age (per year)	1.040	0.922-1.172	0.523
Surgery time (per min)	1.018	0.975-1.063	0.414
Albumin (per g/L)	0.945	0.762-1.172	0.607
Positive LN $\geq$ 2	0.712	0.072-7.075	0.772
T3 stage (vs. T1/T2)	0.000	0.000-inf	0.997

Note: Abbreviation: OR, Odds Ratio; CI, Confidence Interval; LN, Lymph Node.