ORIGINAL PAPER

Does the placement of a collagen-fibrin sealant reduce complications of radical inguinal lymph node dissection – Comparative study in patients with penile cancer

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__Summary__ *Objective: Management of patients with penile cancer (PeC) with palpable inguinal lymph nodes (ILNs) relies on radical ILN dissection (RILND). Low burden of nodal metastatic disease may lead to long-lasting survival with surgical management. Nevertheless, RILND involves significant postoperative morbidity. We compared the complications of patients undergoing RILND with (RILND-T) and without (RILND-0T) placement of a collagen-fibrin sealant patch on the resection bed.*
Materials and methods: We conducted an observational retrospective study. Data from men submitted to RILND-T and RILND-0T from Jan/2001 to Feb/2022, in a tertiary care centre were compared. The primary endpoint was the overall incidence of complications until 1 month after the procedure and their respective severity in both cohorts (Clavien-Dindo classification system). Secondarily, length of hospital stay (LOHS) was analysed. The placement of a collagen-fibrin sealant patch was left at the surgeon's discretion.
Results: Seven patients underwent RILND-T and 20 underwent RILND-0T, respectively. There were no differences in pathologic TNM stage nor in the total number of ILNs removed (17 ± 4 vs. 20 ± 8, p = 0.37). Overall, 23 (85.2%) patients had complications. The complication rate was similar in both cohorts (85.7% vs 85%, p = 0.73). Surgical wound infection (3/7 vs. 11/20) and lymphocele (4/7 vs. 11/20) were the most reported complications. Patients undergoing RILND-T were discharged faster (mean length of hospital stay 9 ± 3 vs 19 ± 20 days, p = 0.22).
Conclusions: The application of a collagen-fibrin sealant patch on the resection bed does not seem to reduce the postoperative complication rate in patients undergoing RILND. Nevertheless, a trend towards a shorter LOHS in patients with RILND-T cannot be excluded and should be validated by further studies with a higher number of patients.

KEY WORDS: *Penile Cancer; Radical Inguinal Lymph Node Disssection; Radical Inguinal Lymphadenectomy; Complications of Radical Inguinal Lymph Node Dissection.*

INTRODUCTION

Penile cancer (PeC) is a rare neoplasm representing the 32nd most common cancer worldwide (1). It displays an overall incidence of around 1/100.000 males in Europe and the USA (2). In 2020, 36 068 new cases were diagnosed, and 13 211 men died due to PeC (1). The incidence increases with age with a peak in the sixth decade (3).
In *Portugal*, PeC represents the 30th most common cancer with 119 new cases diagnosed in 2020 (4).
PeC metastatic spread complies with the route of anatomical drainage, beginning with the inguinal lymph nodes (superior medial zone of the inguinal region and, afterwards, central inguinal nodes) followed by the pelvic lymph nodes. Whenever inguinal lymph nodes are palpably enlarged, *radical inguinal lymph node dissection* (RILND) should be the diagnostic and therapeutic approach (2). Other diagnostic tools have already been evaluated. *Positron-Emission Tomography* (PET) *computed tomography* (CT) using 18-F-fluorodeoxyglucose (18F-FDG-PET-CT) has shown good accuracy confirming inguinal metastasis and detecting systemic disease (82-99% sensitivity for ILN metastasis in patients with clinically evident disease) whereas *magnetic resonance imaging* (MRI) with lymphotrophic nanoparticles (ferumoxtran-10, ferucarbotran, ultrasmall superparamagnetic iron oxides) might be an adequate choice for the evaluation patients with a limited physical and/or clinical exam (100% sensitivity and 97% specificity). Even though ultrasound-guided biopsy may allow for the pathological diagnosis of disease in clinically positive patients, they will ultimately require radical inguinal lymph node dissection as for local staging. The risk of distant metastasis whenever inguinal lymph nodes are palpable is high deeming radiographical evaluation with CT or MRI necessary (5).
The involvement of locoregional lymph nodes represents the most clinically significant prognostic factor for patients with PeC (6). The recurrence free and overall survival are largely dependent on ILN disease burden with a significant decrease in the 5-year survival in patients with positive deep pelvic lymph nodes (0-12%) versus patients with a single involved inguinal node (80%) (7).
The surgical excision of clinically positive lymph nodes is decisive for patient survival as it may result in cure. Nevertheless, RILND might be delayed by physicians and patients due to its anticipated postoperative morbidity leading to worsened overall survival (8). The complica-

tions of RILND can be as high as 50% (9), ranging from seroma and hematoma formation to wound infection and even more severe complications such as difficulty in ambulating, deep venous thrombosis (DVT) and chronic lymphoedema. More recent studies have reported a lower morbidity in about 25% of cases (10).

Meticulous surgical technique with careful tissue handling along with avoidance of electrocauterization, modified incision lines, suction drainage devices, videoendoscopic surgery, omentoplasty and placement of a collagen-fibrin sealant patch have already demonstrated efficacy in achieving hemostasis after liver and kidney surgery (11), in preventing leakage after lung surgery (12), and in reducing lymphatic fluid production after mediastinal (13) and axillary (14) lymph-node dissection and, therefore, minimise postoperative morbidity (15).

Additionally, there is evidence that the placement of a fibrin glue sealant is beneficial towards reducing the complication rates in RILND, namely seroma (16).

On the other hand, evidence of benefit due to vacuum suction in RILND for PeC (17), sealants in RILND for melanoma (18), or collagen-fibrin sealant patch in ILND in vulvar cancer (19) is still lacking.

To our knowledge, this is the first observational study reporting the efficacy of placing a collagen-fibrin sealant patch (*TachoSil*®) in the resection bed of patients with PeC submitted to RILND.

MATERIALS AND METHODS

Our study complies with the STROBE (*Strengthening the Reporting of Observational studies in Epidemiology*) guidelines for observational original research studies.

A retrospective observational study was conducted at a tertiary oncological care centre. Consecutive patients with PeC who underwent any kind of *inguinal lymph node dissection* (ILND) between January of 2000 and February of 2022 were identified. From the 214 patients with PeC initially retrieved, 110 did not undergo ILND and were excluded from the study. Patients who underwent ILND other than RILND, namely modified ILND (n = 54) or dynamic sentinel ILND (n = 23) were excluded.

RILND technique was the same in all patients included. It involved an incision parallel and 1-2 cm inferior to the inguinal ligament. Skin flaps were created preserving the Scarpa's fascia to avoid necrosis. RILND comprised the traditional boundaries margin of the external inguinal ring until the *anterior superior iliac spine* (ASIS), superiorly, the ASIS and a line drawn 20cm inferiorly, laterally, the pubic tubercle and a line drawn 15 cm inferiorly from it, medially, and a line connecting both lateral and medial limits. A long saphenous vein ligation was usually performed at the apex of the femoral triangle. Sartorius muscle transposition might be done to cover the femoral vessels. Placement of *TachoSil*® on the resection bed was left at the surgeon's discretion. Cohorts were compared based on the placement of *TachoSil*® during the RILND. A single patch of *TachoSil*® was applied, with the yellow active side onto the resection bed, after blood and other fluids were cleaned. The patch had to extend around the inguinal lymphadenectomy area and maintained in place for at least 3 min.

Data was obtained through the available consultation records. Data concerning clinical history (including risk factors for PeC), physical examination and pathological results were collected. Patients' comorbidities were documented and assessed with *Charlson Comorbidity Score* (CCI). Pertaining to the surgical procedure, surgical reports were examined and data on the surgical technique and amount of blood loss were gathered.

Postoperative complications after RILND were defined as those that occurred immediately after surgery, whether during the initial hospital stay or within 30 days of RILND. RILND postoperative complications were quantified using the *Clavien-Dindo* classification system for surgical complications (20).

Hospitalization records were available. Amount of drainage volume, duration of drain placement and deambulation start were assessed.

All complications were followed until resolution and hospital discharge and, when applicable, surgical interventions of major complications were recorded by their specific date and type of procedure required. Readmissions during the first 30 postoperative days were determined as well as the hospitalization reason and duration.

Statistical analysis

The primary outcome was the overall complication rate in both cohorts. Secondary endpoint measures were the incidence of each complication in RILND-T and RILND-0T groups.

To determine whether the data had a Gaussian distribution, Gaussian curve and Kolmogorov-Smirnov test were used. Comparisons of the continuous variables between groups were made using the Student's T-test for normally distributed and Mann-Whitney U for not normally distributed variables. The chi-squared and Fisher's exact tests were used to compare categorical variables. Statistical analyses were performed using SPSS 25.0 (*IBM Software division, Somers, NY, USA*). All reported p values are two-sided, and p values < 0.05 were considered to indicate statistical significance.

RESULTS

A total of 27 patients with PeC submitted to RILND were collected for the present study. While 7 patients underwent RILND-T, 20 patients underwent RILND-0T.

Table 1 displays patient demographics, surgical outcomes and lymph node counts.

The mean age (70 ± 7 *vs* 64 ± 14 years, p = 0.32), CCI (6 ± 2 *vs* 5 ± 2, p = 0.35) and body mass index (BMI - 25 ± 4 *vs* 27 ± 4 kg/m^2, p = 0.27) were comparable in both cohorts.

The majority of patients (n = 26) had confirmed conventional *squamous cell carcinoma of the penis* (SCCP), with only one patient having a mixed warty-basaloid subtype. The primary penile tumour grade (Table 2) was similar in both cohorts (p = 0.42) as well as lymphovascular invasion (14.8% *vs* 29.6%, p = 0.85).

Patients had a mean 17 ± 4 and 20 ± 8 lymph nodes harvested in the RILND-T and in the RILND-0T group (p = 0.37), respectively. The median largest diameter lymph node with tumour present was 2.7 (range 0.5-5-3) and 3.7 (range 0.4-6.5) cm (p = 0.65).

The mean length of hospital stay after RILND was longer in the cohort without placement of collagen-fibrin sealant patch (9 ± 3 *vs* 19 ± 20 days, p = 0.22). The mean time to ambulation was 2 ± 1 in both cohorts (p = 0.16). Inguinal suction drains were kept in place for a mean of 5 ± 3 and 5 ± 1 days (p = 0.55).

A detailed summary of clinical nodal staging and pathological staging can be found in Tables 3 and 4, respectively.

Overall, of the 27 patients with PeC included in the present study, 23 (85.2%) had at least one postoperative complication and 20 patients having more than a single complication (88 instances of complications overall). The complication rate was similar in both cohorts (85.7% *vs* 85%, p = 0.73) and when analysing the complications on a per patient basis, there was a comparable mean number of 3 complications per patient in both groups (p = 0.88). The most commonly encountered complications were lymphocele (57.1% *vs* 55%, p = 0.4) and wound infection (42.9% *vs* 55%, p = 1). Vascular and neural injuries were

Table 1.
Patient demographic characteristics, surgical outcomes and lymph node counts.

Characteristics	RILND-T	RILND-0T	p
Age, in years (mean ± standard deviation)	70 ± 7	64 ± 14	0.32
BMI, in kg/m^2 (mean ± standard deviation)	25 ± 4	27 ± 4	0.27
Length of hospital stay, in days (median, range)	9 ± 3	19 ± 20	0.20
Post-surgical walk day (mean ± standard deviation)	2 ± 1	2 ± 1	0.16
Post-surgical drain removal (mean ± standard deviation)	5 ± 3	5 ± 1	0.55
Total number of lymph nodes taken (mean ± standard deviation)	17 ± 4	20 ± 8	0.37
Total number of positive lymph nodes (mean ± standard deviation)	1 ± 1	4 ± 4	0.13
Largest lymph node size, in cm (median, range)	2.7, 0.5-5.3	3.7, 0.4-6.5	0.65

RILND-T: Radical inguinal lymph node dissection with TachoSil® placement; RILND-0T: Radical inguinal lymph node dissection without TachoSil® placement; BMI: Body mass index.

Table 2.
Penile tumour grade.

Characteristics	RILND-T	RILND-0T	p
Tumour grade, in percentage			0.42
- Well-differentiated (G1)	26.7	0	
- Moderately differentiated (G2)	40	80	
- Poorly differentiated (G3)	33.3	20	
- Undifferentiated (G4)	0	0	

RILND-T: Radical inguinal lymph node dissection with TachoSil® placement; RILND-0T: Radical inguinal lymph node dissection without TachoSil® placement.

Table 3.
Clinical node staging.

Characteristics	RILND-T	RILND-0T	p
Nodal stage, in percentage			0.21
- cN0	57.1	15	
- cN1	0	15	
- cN2	28.6	35	
- cN3	14.3	35	

RILND-T: Radical inguinal lymph node dissection with TachoSil® placement; RILND-0T: Radical inguinal lymph node dissection without TachoSil® placement.

Table 4.
Pathological staging, PeC and nodes.

Characteristics	RILND-T	RILND-0T	p
Tumour stage, in percentage			0.81
- CIS	0	0	
- pT1	21.1	14.3	
- pT2	42.1	42.9	
- pT3	36.8	42.9	
- pT4	0	0	
Nodal stage, in percentage			0.35
- pN0	20	42.9	
- pN1	5	14.3	
- pN2	20	0	
- pN3	55	42.9	

RILND-T: Radical inguinal lymph node dissection with TachoSil® placement; RILND-0T: Radical inguinal lymph node dissection without TachoSil® placement; CIS: Carcinoma in situ.

Table 5.
Complication incidence rates according to Clavien-Dindo classification.

Characteristics	RILND-T	RILND-0T	p
Chronic lymphoedema, n (percentage)	1 (14.3)	1 (5)	0.46
- Clavien-Dindo grade I, in percentage	14.3	5	
Deep venous thrombosis, n (percentage)	1 (5)	0 (0)	-
- Clavien-Dindo grade II, in percentage	5	0	
Lymphocele, n (percentage)	4 (57.1)	11 (55)	0.4
- Clavien-Dindo grade I, in percentage	42.9	55	
- Clavien-Dindo grade II, in percentage	14.3	0	
Lymphorrhea, n (percentage)	3 (42.9)	9 (45)	-
- Clavien-Dindo grade I, in percentage	42.9	45	
Neural injury, n (percentage)	0 (0)	0 (0)	-
Skin necrosis, n (percentage)	2 (28.6)	6 (30)	0.75
- Clavien-Dindo grade I, in percentage	2	20	
- Clavien-Dindo grade II, in percentage	0	10	
Vascular injury, n (percentage)	0 (0)	0 (0)	-
Wound dehiscence, n (percentage)	3 (42.9)	4 (20)	0.48
- Clavien-Dindo grade I, in percentage	15	42.9	
- Clavien-Dindo grade II, in percentage	5	0	
Wound infection, n (percentage)	3 (42.9)	11 (55)	-
- Clavien-Dindo grade II, in percentage	42.9	55	

not noted. All of the complications recorded were *Clavien-Dindo* II grade or less.

A total of 3 patients were readmitted due to complications, 1 from the RILND-T (1/7) and 2 (2/20) from the RILND-0T cohort. The hospital readmission time was similar in both groups (11 and 10 days, respectively). None of the patients were submitted to surgical exploration nor surgical management of major complications. Table 5 shows complication rates and type as categorised by the *Clavien-Dindo* classification.

DISCUSSION

The present study reports the experience from a Portuguese high-volume oncological care centre. It details the postoperative complication rates from RILND, as categorised by the *Clavien-Dindo* classification system, from January of 2001 until February of 2022 with and without placement of collagen-fibrin sealant patch on the resec-

tion bed. To our knowledge, this is the first observational study reporting the efficacy of placing a collagen-fibrin sealant patch in the resection bed of patients with PeC submitted to RILND.

Previous series on complication rates state results averaging 40-70% (21). Although we report a higher overall complication rate, all of the patients had minor complications (*Clavien-Dindo* I and II) which translated into a regular postoperative management in most cases.

Lymphocele and wound infection were the most common complications (57.1% *vs* 55% and 42.9% *vs* 55%, respectively).

A high rate of complications was seen in both groups (more than 85% of the patients had some sort of complication). Nevertheless, none of the complications were graded higher than II, as assessed by the *Clavien-Dindo* classification.

Measures to avoid complications during RILND

Several studies have been conducted in order to find validated measures to reduce morbidity. Careful tissue handling and avoiding electrocautery as well as preserving the saphenous vein and postoperative measures to improve drainage (stocking, bandaging, inguinal pressure dressings or vacuum suction) minimise postoperative morbidity (10, 22, 23). A systematic review and meta-analysis (24) on surgical techniques to reduce postoperative lymphoedema reported that sparing the long saphenous vein, fascia preserving dissection, pedicled omental flap and microsurgery are efficient. When available, minimally-invasive surgical approaches (laparoscopic, robot-assisted) for inguinal lymphadenectomy, in small series, have been reported to significantly reduce post-operative morbidity except for the rate of lymphoceles (10, 17, 25-27).

Collagen-fibrin sealant patch as an adjuvant to reduce RILND complications

As previously stated, collagen-fibrin sealant patch and other similar fibrin-based sealants have already been studied in different fields as surgical adjuvants to reduce lymphadenectomy-related morbidity, namely, lymphorrhea, lymphoceles, and lymphoedema.

The reported results are conflicting. In breast cancer patients undergoing axillary lymph node dissection, the fibrin-based sealant reduced the overall lymphatic drainage amount, which allowed an earlier removal of closed suction drains; on the other hand, other studies noted no significant differences regarding the incidence and severity of the above-mentioned complications (28, 29). It was also investigated in patients with endometrial cancer: even though the placement of *TachoSil®* in laparoscopic pelvic lymphadenectomy translated into a significantly lower prevalence of lymphocele, there was no significant difference regarding the symptomatic forms of lymphocele (30). The outcomes after collagen-fibrin sealant patch placement on the resection bed are inconsistent. Accordingly, a meta-analysis from 2014 (25) concluded that the available evidence is not robust enough to recommend the use of fibrin-based sealants in inguinofemoral lymphadenectomy for malignant conditions, especially considering the additional cost for these products.

Overall, our results suggest that collagen-fibrin sealant patch did not seem to be effective in improving postoperative complications both in quantity and in severity as assessed by the *Clavien-Dindo* classification.

Additionally, in our study, the inguinal drains were not removed earlier in the cohort submitted to RILND-T (on average, on the fifth postoperative day in both groups). Nevertheless, there is a trend towards a shorter length of hospital stay in patients who underwent placement of the collagen-fibrin sealant agent.

Pitfalls

Because of the relative rarity of penile cancer, there was a paucity of patients undergoing RILND with and without placement of collagen-fibrin sealant patch on the resection bed. Future studies, grouping together multiple patient series from different centres, might help overcome this by providing a greater database of patients, which is required to achieve statistical significance. Furthermore, by combining patient data from multiple centres, variability of patient demographics and surgical technique could be unbiased and therefore externally validated for the general patient experience.

Furthermore, because of the retrospective nature of the present study, data collection was limited to what was reported initially at the time of patient care and during the follow-up. This is largely the reason why complication reporting was limited to 30 days postoperatively; there were difficulties in collecting long-term follow-up data.

Accordingly, the small dimension of the study does not allow to exclude completely a potential effect of collagen-fibrin sealant patch for all complications, although results of our study refute its utility and data previously gathered in other studies suggest that it is improbable.

CONCLUSIONS

The significant morbidity associated with RILND for penile cancer treatment highlights the relevance of adopting techniques that minimise and avoid complications. With better understanding of the possible complications after RILND and its rate, attitudes towards diminishing their incidence may be implemented. By tailoring peri- and postoperative care accordingly, outcomes may be improved.

There seems to exist a clear trend towards a lower length of hospital stay in patients in whom the collagen-fibrin sealant patch was placed surgically on the resection bed. Even though we did not prove collagen-fibrin sealant patch placement on the resection bed of patients undergoing RILND to improve the outcomes, we cannot completely exclude a potential beneficial effect of this approach without having conducted a prospective randomised trial.

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