



Original article

Evaluating the accuracy of intraoperative frozen section during inguinal lymph node dissection in penile cancer

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Abstract

Introduction: Inguinal lymph node dissection is an integral part in the management of invasive penile tumors with intraoperative assessment often aiding decision-making during dissection. In this study, we evaluate the diagnostic value of intraoperative frozen section (FS) and analyze clinicopathologic factors that affect its accuracy.

Material and methods: We, retrospectively, reviewed 84 patients with squamous cell carcinoma of the penis who underwent inguinal lymph node dissection at our institution. Intraoperative FS from the superficial inguinal nodes was available in 65 patients and compared with correspondent permanent sections (pathologic node staging [pN]). Sensitivity and specificity were calculated and factors associated with a false negative event were analyzed using logistic regression.

Results: The total positive node rate was 60% (39/65). Of 39 pN+ cases, 10 (25.6%) had false-negative FS, whereas the remaining 29 were concordant intraoperatively. Sensitivity and specificity were 0.74 and 1, respectively. On univariable analysis, higher body mass index was associated with a false negative event although there was no association with age, receipt of neoadjuvant therapy, or clinical node stage.

Conclusion: Intraoperative FS is highly specific and moderately sensitive for the detection of positive superficial inguinal lymph nodes in penile cancer. Its use can help guide intraoperative surgical planning while limiting its reliance for patients with higher body mass index.

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Keywords: Penile cancer; Frozen section; Lymphadenectomy

1. Introduction

Penile cancer is a rare disease in Europe and North America with an incidence of approximately 1 per 100,000 males [1]. A thorough physical examination with palpation of both groins is an essential component in staging for these patients [2]. Even those with negative palpable groins clinical node staging (cN0), the likelihood of micrometastatic disease approaches 25% [3]. Therefore, invasive surgical staging of the lymph nodes is recommended for those with high-risk

primary tumor features regardless of clinical groin status [2,4].

Frozen section (FS) histologic examination is currently recommended during the intraoperative evaluation of the lymph nodes, with a positive result dictating complete lymphadenectomy during sentinel lymph node biopsy or modified inguinal lymph node dissection (ILND) procedures [4,5]. In addition, results of intraoperative FSs can be used in deciding if contralateral assessment of the nodes is necessary [6]. Therefore, FS is an important tool during surgical planning and plays a major role in the lymphatic assessment of patients with penile cancer.

Although an accurate FS is central to the performance of a thorough lymphadenectomy, there are no studies reporting on the diagnostic value of FS in the penile cancer literature.

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In this study, we report on the accuracy of FS during intraoperative assessment of the superficial inguinal nodes, and evaluate clinicopathologic factors that may affect accuracy from our single institution experience.

2. Material methods

2.1. Data source

Study was performed after approval from Institutional Review Board. We, retrospectively, reviewed medical records of 84 consecutive patients who presented between March 1994 and May 2014 with clinically nonmetastatic squamous cell carcinoma (SCC) of the penis and available nodal pathology. FS intraoperative evaluation was available in 65 of these patients and compared to final pathology on permanent paraffin section of the superficial inguinal nodes. Collected variables included age, body mass index (BMI), cN and pathologic node (pN) staging, and presence of extranodal extension (ENE). Patients with final positive node status that were initially reported as negative during intraoperative assessment were considered false-negative (FN) events.

2.2. Treatment information

Lymphadenectomy started with a modified superficial lymph node dissection as described by Catalona [7]. Intact package of lymph nodes were dissected sharply and sent to pathology for evaluation. If any lymph node was found to contain cancer, then a radical ILND was performed. Many biopsies were reviewed for FS and all as permanent final pathology. Fresh specimens were macroscopically measured with the 3 largest dimensions recorded and subsequently cut at 2 mm intervals for inspection and fixation. All intraoperative and permanent sections were evaluated by a team of dedicated genitourinary pathologists, and staging was assigned according to the seventh edition of the American Joint Committee on Cancer tumor-node-metastasis cancer staging system. Cases before 2010 were reclassified according to this same edition [8].

2.3. Statistical analysis

Statistical analysis was performed using SPSS software package version 24 (IBM Corporation, Armonk, NY). Data were expressed as median and interquartile range for continuous variables, and binary variables were reported as counts and percentages. Sensitivity, specificity, positive predictive value, and negative predictive value of FS were assessed. Univariable logistic regression analysis was performed to determine the association of demographic and histologic characteristics with an FN event. A $P < 0.05$ was considered statistically significant.

Table 1
Baseline clinical and demographic characteristics

Factor	Level	n	%
Age, y (median)	64.5 (IQR: 54.3–71)	65	100
Body mass index, kg/m ² (median)	29.2 (IQR: 26.2–34)	63	96.9
1 Neoadjuvant treatment before ILND			
	None	56	86.2
	Chemotherapy	6	9.2
	Radiation	2	3.1
	Chemoradiation	1	1.5
2 Clinical node stage			
	cN0	38	58.5
	cN1	8	12.3
	cN2	14	21.5
	cN3	5	21.5
3 Extranodal extension			
	No	47	72.3
	Yes	18	27.7

IQR = interquartile range.

3. Results

3.1. Patient characteristics

Demographic and clinical characteristics are provided in Table 1. Median age was 64.5 years and median follow-up was 18.2 months. The median BMI was 29.2 kg/m². A total of 27 patients (41.5%) presented with palpable adenopathy (cN+), whereas 38 (58.5%) had no inguinal disease present (cN0) at the time of surgery. A total of 9 patients had received systemic therapy in the neoadjuvant setting with chemotherapy (9.2%), external beam radiation (3.1%), or chemoradiation (1.5%).

3.2. Pathologic characteristics and accuracy of FS

The positive node rate was 60% (39/65) with 27% having ENE on final pathology. The median number of nodes was 11 (8.75–16) and 13 (10–19) for cN0 and cN+ patients, respectively. Of 39 pN+ cases, 10 (25.6%) had FN FS, whereas the remaining 29 were concordant intraoperatively. Sensitivity and specificity of FS were 0.74 and 1, respectively (Table 2). Accuracy stratified as cN+ vs. cN0 status was not significantly different (Supplementary Table 1).

There were no false-positive intraoperative sections.

3.3. Factors associated with FN event

Of the 10 FN sections, 6 were in cN0 patients, whereas 4 were in cN+ patients (Supplementary Table 2). Furthermore, 6 of these patients died of disease and 4 were alive at the time of analysis. On univariable analysis, only BMI was associated with a FN event while there was no association with age, neoadjuvant treatment, ENE, clinical stage, or nodal yield. BMI remained significant after adjusting for ENE ($P = 0.026$) (Table 3), and after adjusting for other covariates independently (not shown).

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