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Penile Cancer

EAU-ASCO Collaborative Guidelines

Brouwer, O et al.

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1 Background & Methodology

Introduction

- Penile cancer is a rare disease, but it has a significant impact on QoL in many ways.
- Patients not only suffer the psychological and emotional stress of a cancer diagnosis and what that means for the rest of their lives, but also the psychological impact and stigma of cancer on an intimate part of the body.
- The Guideline Panel strongly recommends that these emotional, social, and physical needs are discussed and addressed early in the patient pathway, through a holistic and multi-disciplinary approach.
- This guideline is the result of a collaboration between the EAU and the ASCO, presenting a complete revision of the prior version(s), with the aim to offer worldwide physician and patient guidance in the management of this rare disease.

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Guideline Development Methodology

- The guideline development process includes:
  - a systematic literature review by guidelines staff
  - an expert panel provides critical review and evidence interpretation to inform guideline recommendations
  - final guideline approval by EAU Guidelines Office Board and ASCO EBMC
- The EAU Guidelines Development Handbook can be found at: https://uroweb.org/eau-guidelines/methodology-policies
- The ASCO Guideline Methodology Manual can be found at: www.asco.org/guideline-methodology

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2 Summary of Recommendations

Summary of Recommendations

Pathological Assessment of Tumour Specimens

Recommendation	Strength of Recommendation
The pathological evaluation of penile carcinoma specimens must include the pTNM stage and an assessment of tumour grade.	Strong
The pathological evaluation of penile carcinoma specimens must include an assessment of p16 by immunohistochemistry.	Strong
The pathological evaluation of penile carcinoma specimens should follow the ICCR dataset synoptic report.	Strong

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Summary of Recommendations

Diagnostic Evaluation and Staging Recommendations: Primary Tumor

Recommendation	Strength of Recommendation
Perform a detailed physical examination of the penis and external genitalia, recording morphology, size and location of the penile lesion, including extent and invasion of penile (adjacent) structures.	Strong
Perform MRI of the penis/primary tumour (artificial erection not mandatory) when there is uncertainty regarding corporal invasion and/or the feasibility of (organ-sparing) surgery. If MRI is not available, offer US as alternative option.	Weak
Obtain a pre-treatment biopsy of the primary lesion when malignancy is not clinically obvious, or when non-surgical treatment of the primary lesion is planned (e.g., topical agents, laser, radiotherapy).	Strong

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Summary of Recommendations

Diagnostic Evaluation and Staging Recommendations: Inguinal Lymph Nodes

	Strength of Recommendation
• Perform a physical examination of both groins. Record the number, laterality and characteristics of any palpable/suspicious inguinal nodes.	Strong

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Summary of Recommendations

Diagnostic Evaluation and Staging Recommendations: Clinically Node-Negative (cN0)

Recommendation	Strength of Recommendation
If there are no palpable/suspicious nodes (cN0) at physical examination, offer surgical LN staging to all patients at high risk of having micro-metastatic disease (T1b or higher).	Strong
In case of T1a G2 disease, also discuss surveillance as an alternative to surgical staging with patients willing to comply with strict follow-up.	Weak
When surgical staging is indicated, offer DSNB. If DSNB is not available and referral is not feasible, or if preferred by the patient after being well informed, offer ILND (open or video-endoscopic).	Strong
If DSNB is planned, perform inguinal US first, with FNAC of sonographically abnormal LNs.	Strong

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Summary of Recommendations

Diagnostic Evaluation and Staging Recommendations: Clinically Node-Positive (cN+)

Recommendation	Strength of Recommendation
If there is a palpable/suspicious node at physical examination (cN+), obtain (image-guided) biopsy to confirm nodal metastasis before initiating treatment.	Strong
In cN+ patients, stage the pelvis and exclude distant metastases with ^{18}FDG-PET CT or CT of the chest and abdomen before initiating treatment.	Strong

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Summary of Recommendations

Local Treatment of Penile Carcinoma

Recommendation	Strength of Recommendation
Offer a balanced and individualised discussion on benefits and harms of possible treatments options with the goal of shared decision making.	Strong
Inform patients of the higher risk of local recurrence when using organ-sparing treatments compared to amputative surgery.	Strong

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Summary of Recommendations

Local Treatment of Penile Carcinoma: Topical Therapy

Recommendation	Strength of Recommendation
Offer topical therapy with 5-fluorouracil or imiquimod to patients with biopsy-confirmed PeIN.	Weak
Clinically assess treatment effects after a treatment-free interval and in cases of doubt perform a biopsy. If topical treatment fails, it should not be repeated.	Weak

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Summary of Recommendations

Local Treatment of Penile Carcinoma: Laser Ablation

- Offer laser ablation using CO_2 or Nd:YAG laser to patients with biopsy-confirmed PeIN, Ta or T1 lesions.

Strength of Recommendation
Weak

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Summary of Recommendations

Local Treatment of Penile Carcinoma

Organ-Sparing Treatment: Surgery (Circumcision, Wide Local Excision, Glansectomy and Glans Resurfacing)

Recommendation	Strength of Recommendation
Offer organ-sparing surgery and reconstructive techniques to patients with lesions confined to the glans and prepuce (PeIN, Ta, T1–T2) and who are willing to comply with strict follow-up.	Strong
Perform intra-operative frozen section analysis of resection margins in cases of doubt on the completeness of resection.	Weak
Offer salvage organ-sparing surgery to patients with small recurrences not involving the corpora cavernosa.	Weak

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Summary of Recommendations

Local Treatment of Penile Carcinoma

Organ-Sparing Treatment: Radiotherapy (EBRT and Brachytherapy)

Recommendation	Strength of Recommendation
Offer radiotherapy to selected patients with biopsy-confirmed T1 or T2 lesions.	Strong

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Summary of Recommendations

Local Treatment of Penile Carcinoma

Amputative Surgery (Partial- and Total Penectomy

Recommendation	Strength of Recommendation
Offer partial penectomy, with or without reconstruction, to patients with invasion of the corpora cavernosa (T3) and those not willing to undergo organ-sparing surgery or not willing to comply with strict follow-up.	Strong
Offer total penectomy with perineal urethrostomy to patients with large invasive tumours not amenable to partial amputation.	Strong
Offer amputative surgery to patients with large local recurrences or corpora cavernosa involvement.	Weak

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Summary of Recommendations

Local Treatment of Penile Carcinoma: Multimodal Therapy

- Offer induction chemotherapy followed by surgery to responders, or chemo-radiotherapy to patients with non-resectable advanced primary lesions, or to patients with locally advanced-disease who refuse surgical management.

Strength of Recommendation
Weak

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Summary of Recommendations

Radical Inguinal Lymph Node Dissection in cN1-2 Disease

Recommendation	Strength of Recommendation
In patients with cN1 disease offer either ipsilateral: ▪ fascial-sparing inguinal lymph node dissection ▪ open radical ILND; sparing the saphenous vein, if possible	Strong
In patients with cN2 disease offer ipsilateral open radical ILND; sparing the saphenous vein, if possible.	Strong
Offer minimally-invasive inguinal LN dissection to patients with cN1–2 disease only as part of a clinical trial.	Strong
Offer chemotherapy as an alternative approach to upfront surgery in selected patients with bulky mobile inguinal nodes or bilateral disease (cN2) who are candidates for cisplatin and taxane-based chemotherapy.	Weak

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Summary of Recommendations

Radical Inguinal Lymph Node Dissection in cN1-2 Disease (continued)

- Complete surgical inguinal and pelvic nodal management within 3 months of diagnosis (unless the patient has undergone prior neoadjuvant chemotherapy).

Strength of Recommendation
Weak

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Summary of Recommendations

Prophylactic Pelvic Lymph Node Dissection

Recommendation	Strength of Recommendation
Offer open or minimally-invasive prophylactic ipsilateral pelvic lymphadenectomy to patients if: three or more inguinal nodes are involved on one side on pathological examination; extranodal extension is reported on pathological examination	Weak
Complete surgical inguinal and pelvic nodal management within 3 months of diagnosis (unless the patient has undergone neoadjuvant chemotherapy).	Weak

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Summary of Recommendations

Surgical Management of cN3 Disease

Recommendation	Strength of Recommendation
Offer neoadjuvant chemotherapy (NAC) using a cisplatin- and taxane-based combination to chemotherapy-fit patients with pelvic lymph node involvement or those with extensive inguinal involvement (cN3), in preference to up front surgery.	Weak
Offer surgery to patients responding to NAC in whom resection is feasible.	Strong
Offer surgery to patients who have not progressed during NAC, but resection is feasible. See also (chemo)radiation.	Weak
Do not offer Video Endoscopic Inguinal lymphadenectomy.	Strong

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Summary of Recommendations

Neoadjuvant and Adjuvant Chemotherapy

Recommendation	Strength of Recommendation
Offer neoadjuvant chemotherapy using a cisplatin- and taxane-based combination to chemotherapy-fit patients with pelvic lymph node involvement or those with extensive inguinal involvement (cN3), in preference to up front surgery.	Weak
Offer chemotherapy as an alternative approach to upfront surgery to selected patients with bulky mobile inguinal nodes or bilateral disease (cN2) who are candidates for cisplatin and taxane-based chemotherapy.	Weak
Have a balanced discussion of risks and benefits of adjuvant chemotherapy with high-risk patients with surgically resected disease, in particular with those with pathological pelvic LN involvement (pN3). See also section on post-operative radiotherapy.	Weak

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Pre- and Post-Operative Radiotherapy

Recommendation	Strength of Recommendation
• Offer adjuvant radiotherapy (with or without chemo sensitisation) to patients with pN2/N3 disease, including those who received prior neoadjuvant chemotherapy.	Weak
• Offer definitive radiotherapy (with or without chemo sensitisation) to patients unwilling or unable to undergo surgery for lymph node dissection.	Weak
• Offer radiotherapy (with or without chemo sensitisation) to cN3 patients who are not candidates for multi-agent chemotherapy.	Weak

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Summary of Recommendations

Systemic and Palliative Therapies for Advanced Penile Cancer

Systemic Therapies

Recommendation	Strength of Recommendation
Offer patients with distant metastatic disease, platinum-based chemotherapy as the preferred approach to first-line palliative systemic therapy.	Weak
Do not offer bleomycin because of the pulmonary toxicity risk.	Strong
Offer patients with progressive disease under platinum chemotherapy the opportunity to enroll in clinical trials, including experimental therapies within phase I or basket trials.	Strong

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Summary of Recommendations

Systemic and Palliative Therapies for Advanced Penile Cancer

Radiotherapy

Recommendation	Strength of Recommendation
• Offer radiotherapy for symptom control (palliation) in advanced disease.	Strong

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Summary of Recommendations

Follow-Up and Quality of Life

Recommendation	Strength of Recommendation
Deliver penile cancer care as part of an extended multi-disciplinary team comprising of urologists specialising in penile cancer, specialist nurses, pathologists, uro-radiologists, nuclear medicine specialists, medical and radiation oncologists, lymphoedema therapists, psychologists, counsellors, palliative care teams for early symptom control, reconstructive surgeons, vascular surgeons, sex therapists.	Strong
Follow-up men after penile cancer treatment, initially three-monthly for 2 years then less frequently to assess for recurrent disease and to offer patient support services through the extended multi-disciplinary team. At discharge, recommend self-examination with easy access back to the clinic as local recurrence can occur late.	Strong

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Summary of Recommendations

Follow-Up and Quality of Life (continued)

Recommendation	Strength of Recommendation
Discuss the psychological impact of penile cancer and its treatments with the patient and offer psychological support and counselling services.	Strong
Discuss the negative impact of treatments for the primary tumour on penile appearance, sensation, urinary and sexual function so that the patient is better prepared for the challenges he may face.	Strong
Discuss the potential impact of lymphoedema as a consequence of inguinal and pelvic lymph node treatment with the patient and assess patients for it at follow-up and refer to lymphoedema therapists early.	Strong

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3 Additional Resources

Additional Resources

- Additional information is available at https://uroweb.org/guidelines/penile-cancer and www.asco.org/genitourinary-cancer-guidelines.

- Patient information is available at www.cancer.net.

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Abbreviations

- ^{18}FDG-PET, ^{18}F-fluoro-2-deoxy-D-glucose positron emission tomography
- ASCO, American Society of Clinical Oncology
- cN+, clinically-node positive
- cN0, clinically-node negative
- cN1, clinical N1 disease
- cN2, clinical N2 disease
- cN3, clinical N3 disease
- CT, computed tomography
- DSNB, dynamic sentinel node biopsy
- EAU, European Association of Oncology
- EBMC, Evidence Based Medicine Committee
- EBRT, external beam radiotherapy
- FNAC, fine needle aspiration cytology
- ICCR, International Collaboration on Cancer Reporting
- ILND, inguinal lymph node dissection
- LN, lymph node
- MRI, magnetic resonance imaging
- NAC, neoadjuvant chemotherapy
- PeIN, penile intra-epithelial neoplasia
- QoL, quality of life
- US, ultrasound

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