

Peniscarcinoom

epidemiologie, pathologie, diagnostiek en behandeling



Dr. O.R. Brouwer, MD, PhD, FEBU
AIOS Onderwijs 2023

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Dr. Oscar Brouwer, MD, PhD, FEBU

2023: Intercontinentale richtlijn peniscarcinoom

EAU-ASCO Collaborative Guidelines on Penile Cancer

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B. Ayres, J. Crook, M.S. van der Heijden, P.A.S. Johnstone,
A. Necchi, P. Oliveira, L.C. Pagliaro, A. Parnham, C.A. Pettaway,
C. Protzel, R.B. Rumble, D. Sánchez Martínez, P.E. Spiess
Patient Advocates: K. Manzie, J-D. Marcus, J. Osborne
Panel Associates: T. Antunes-Lopes, L. Barreto, R. Campi,
S. Fernandez Pello, H.A. Garcia Perdomo, I. Greco,
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Inhoud

- Incidentie
- Etiologie en pathologie
- Stadiëring
- Diagnostiek primaire tumor
- Behandeling primaire tumor
- Diagnostiek lymfeklieren
- Behandeling lymfeklieren
- Gevorderde ziekte
- Follow-up
- Take home messages

EAU-ASCO Collaborative Guidelines on **Penile Cancer**

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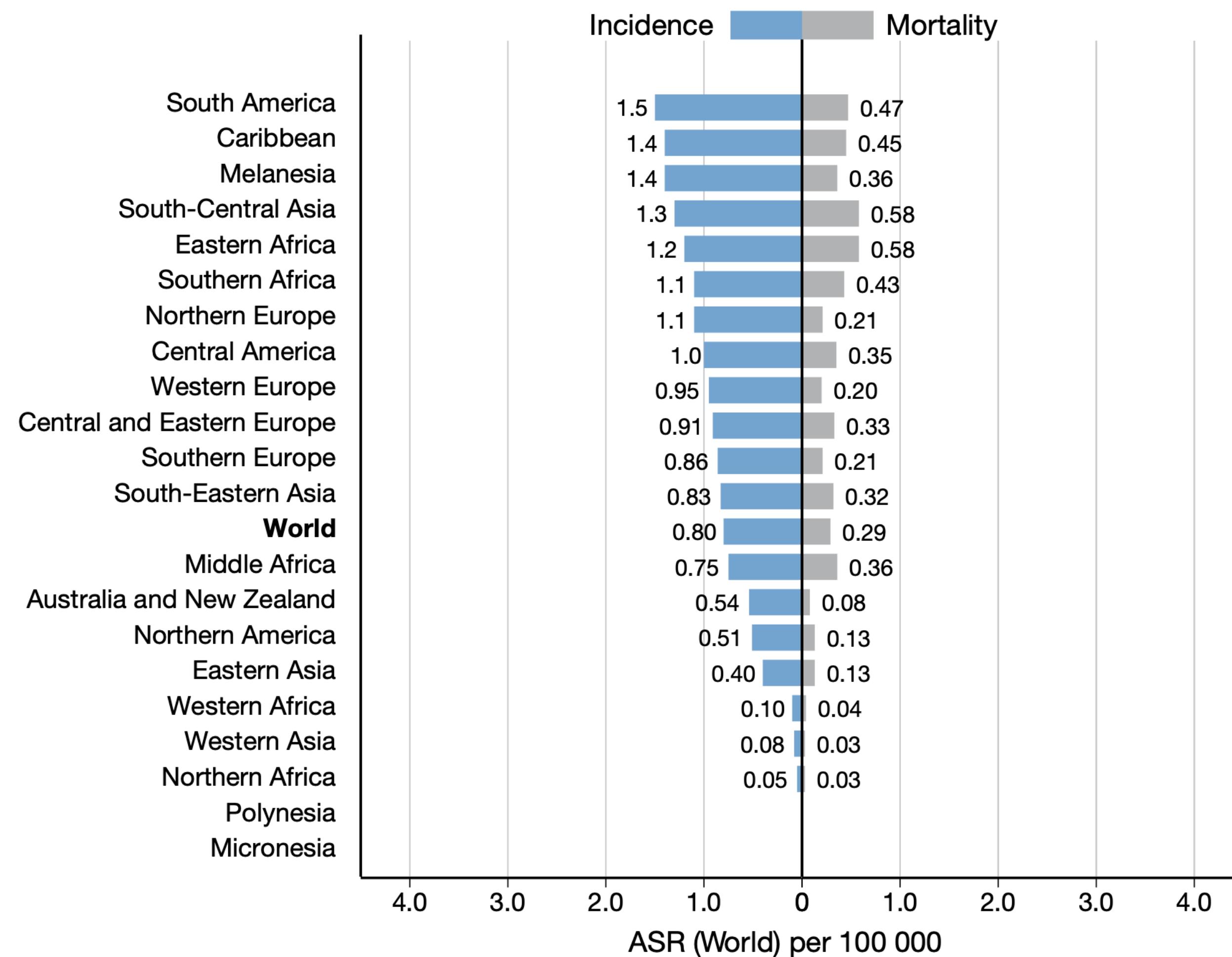
eau European
Association
of Urology

Incidentie

Nederland:

- Zeldzaam: circa 1 per 100.000
- 0,6% van alle mannelijke kankers

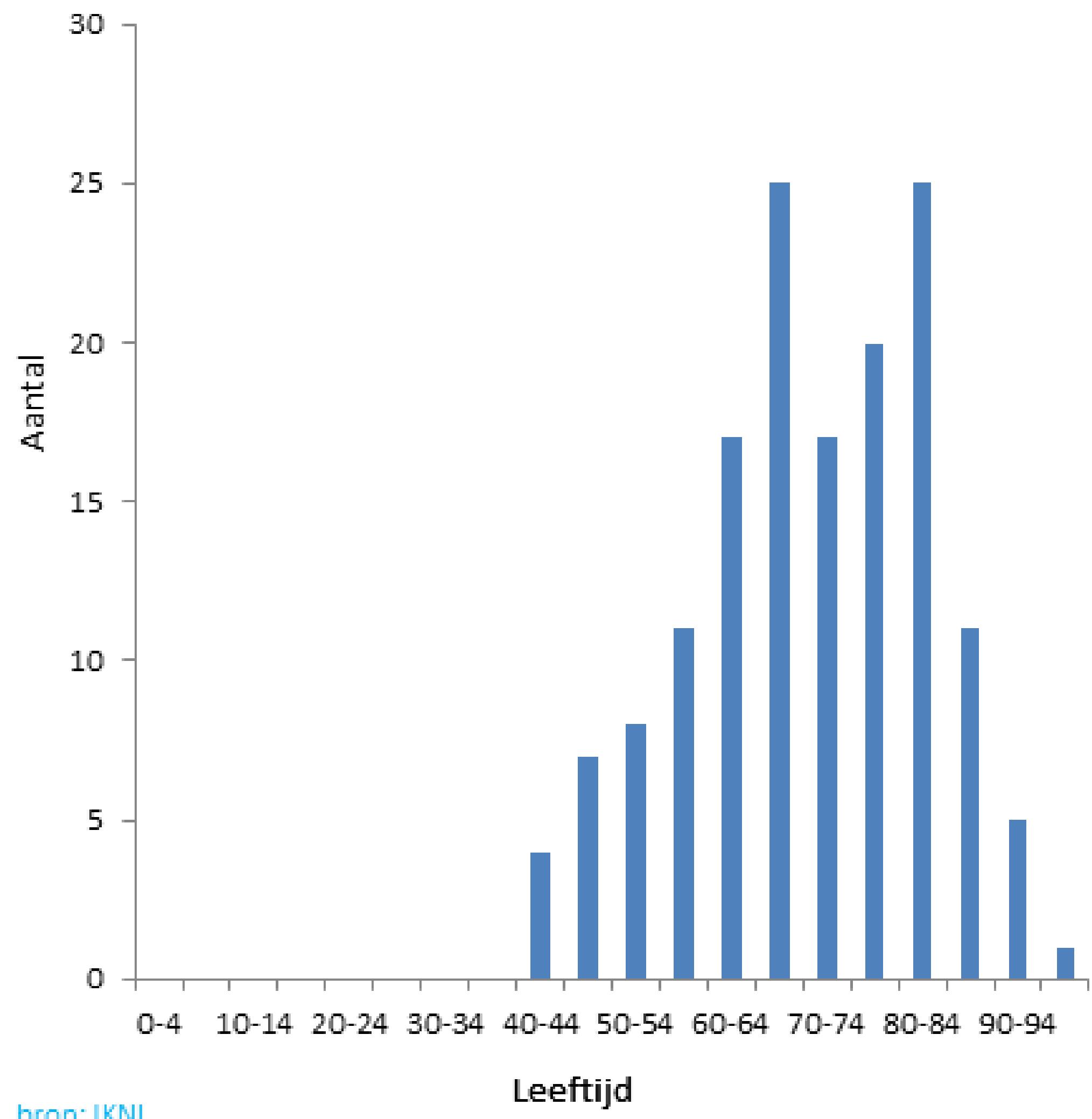
Age standardized (World) incidence and mortality rates, penis



Oude mannenziekte?

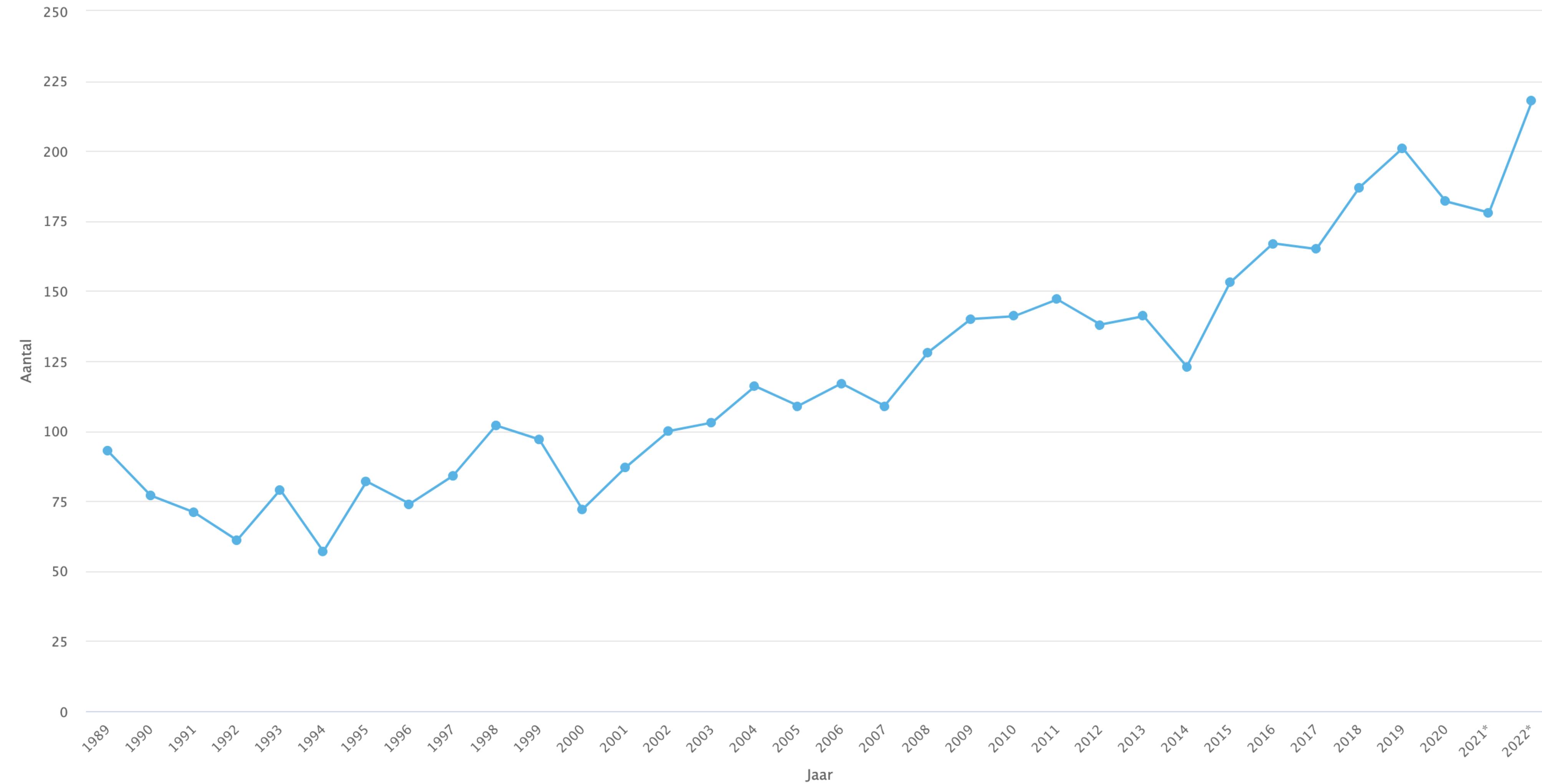
- Mediane leeftijd: 60-65 jaar
- 5% <40jr

dus niet alleen 'oude mannen' !



bron: IKNL

Incidentie neemt toe!



NKR

Niet alleen in NL....

Trends in incidence, mortality and survival of penile squamous cell carcinoma in Norway 1956–2015

Bo T. Hansen ¹, Madleen Orumaa¹, A. Kathrine Lie², Bjørn Brennhovd³ and Mari Nygård ¹

- *The incidence of SCC increased during 1956–2015, with an average annual percentage change of 0.80%*
- *The increase was strongest among men diagnosed at a relatively early age (age<64 years).*
- *Since a substantial proportion of penile SCC is caused by human papillomavirus (HPV), the incidence increase may in part be attributed to increased exposure to HPV in the population.*

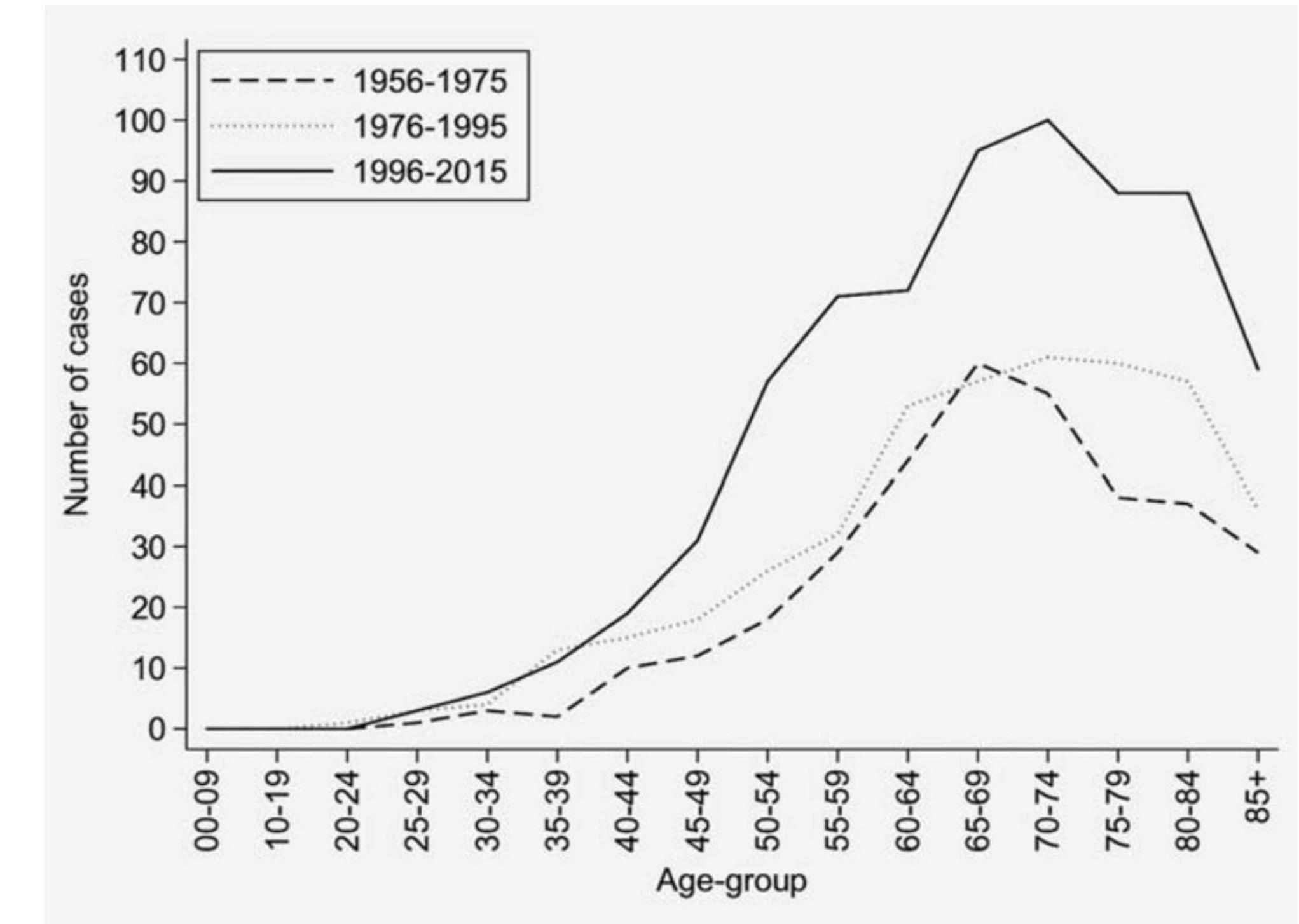


Figure 1. Age-specific number of cases of penile SCC in Norway by calendar period.

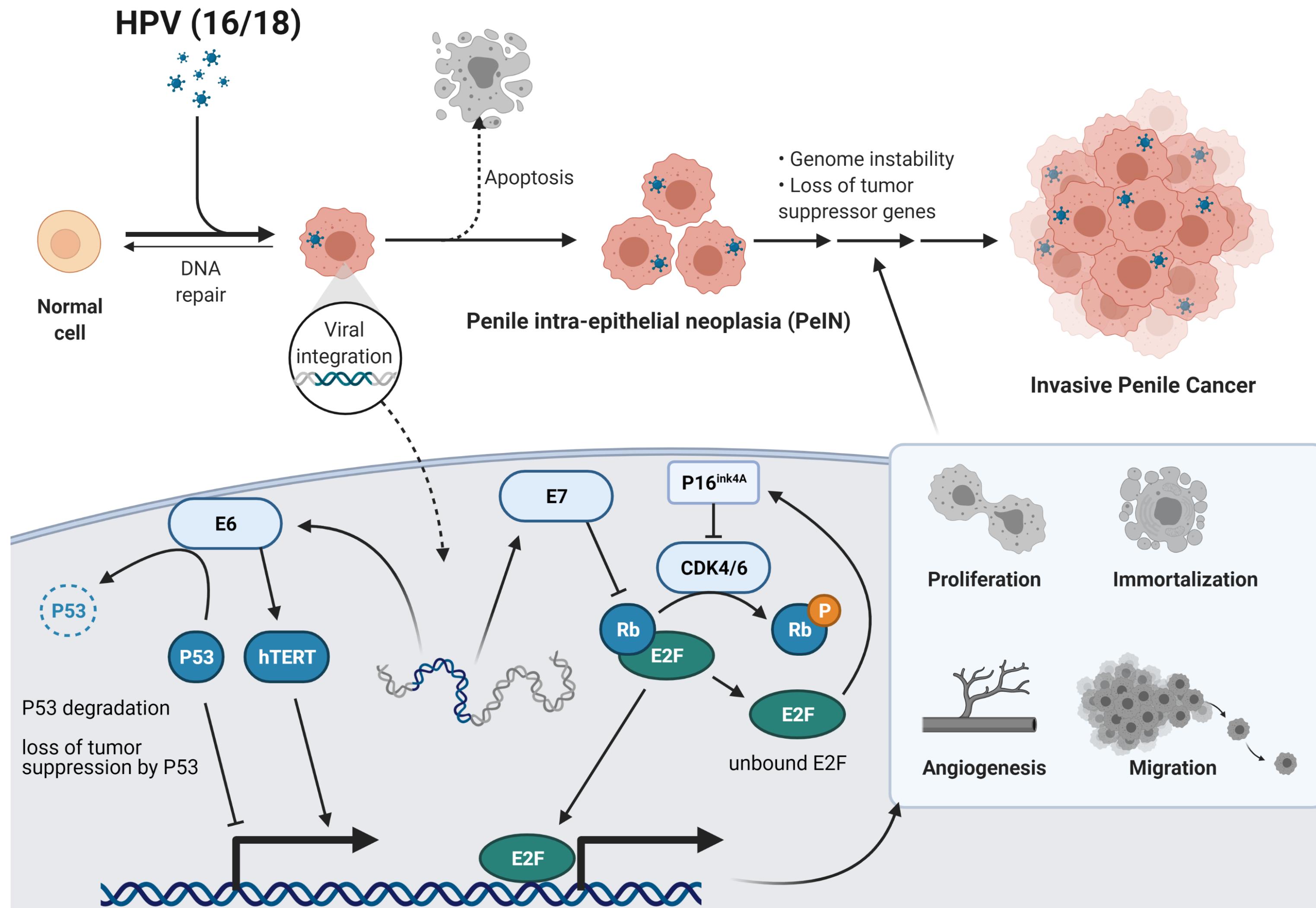
Etiologie / Risicofactoren

- HPV (HPV-16): *circa 30-50% vd invasieve peniscarcinomen is HPV gerelateerd*
- Phimosis: 25-75% hebben phimosis (OR 11-16 vs. geen phimosis)
- Slechte hygiëne (laag economische status)
- Chronische inflammatie (*45% in PeCa pt vs. 8% control*)
- Lichen Sclerosus
- Ultraviolet A phototherapie
- Roken (*5x meer risico vs. niet rokers*)
- Promiscuïteit / multiple partners
- Immuungecompromiteerden



Thomas et al. Curr opin Urol 2019, Olesen et al. Lancet Oncology 2019

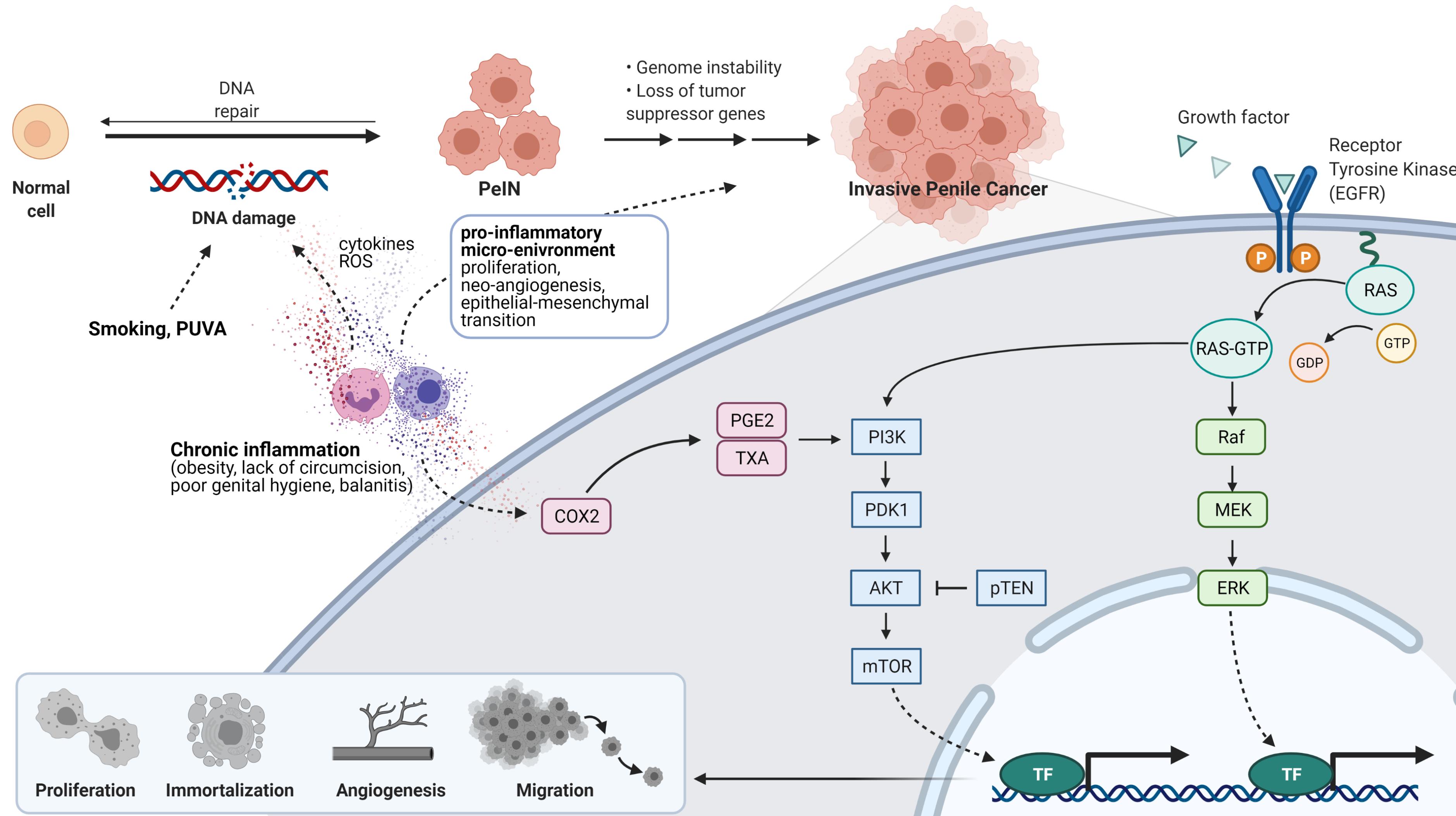
Pathogenese: HPV gerelateerd



HPV + peniscarcinoom mogelijk
geassocieerd met betere overleving
vergeleken met HPV-

Meer data nodig:
Testen!

Pathogenese: niet-HPV gerelateerd



Peniele Intra-epitheliale Neoplasie : PeIN

Vroegere benaming: CIS, M. Queyrat, M. Bowen, Tis, dysplasie

WHO 2022:

- **HPV-independent**
 - Differentiated PeIN
- **HPV-associated PeIN**
 - Common patterns: basaloid (undifferentiated), warty (condylomatous), and mixed
 - Other (less frequent) patterns: pagetoid, clear cell, and spindle cell histology

- Voorstadium van peniscarcinoom (*premaligne*)
- Komt meestal voor op glans / penisschacht
- Progressiekans tot 15% (*ondanks behandeling*)
- Recidiefkans hoog

Histologische subtypes peniscarcinoom

- Verreweg in de meeste gevallen plaveiselcelcarcinoom (SCC, 95%)
- Echter cave: histologische varianten met slechtere prognose

Subtype	Freq (%)	Prognosis / management
Usual SCC	48-65	Depends on location, stage and grade
<i>Warty</i>	7-10	Good prognosis, metastasis rare
<i>Basaloid</i>	4-10	Poor prognosis, frequently early inguinal nodal metastasis
<i>Warty-basaloid</i>	9-14	Poor prognosis, high metastatic potential
<i>Papillary</i>	5-15	Good prognosis, metastasis rare
<i>Verrucous</i>	3-8	Good prognosis, no metastasis
Sarcomatoid	1-3	Very poor prognosis, early vascular metastasis (skip metastasis)
Clear Cell	1-2	Exceedingly rare, associated with HPV, aggressive
Mixed	9-10	Heterogeneous group
Melanoma	<1	Melanoma guidelines (mucosal)
Super rare	<1	<i>pseudohyperplastic, carcinoma cuniculatum, pseudoglandulair, adenosquamous, mucoepidermoid</i>
Metastasis (other malignancy)	<1	M+ disease

Pathologie: summary of evidence & recommendations

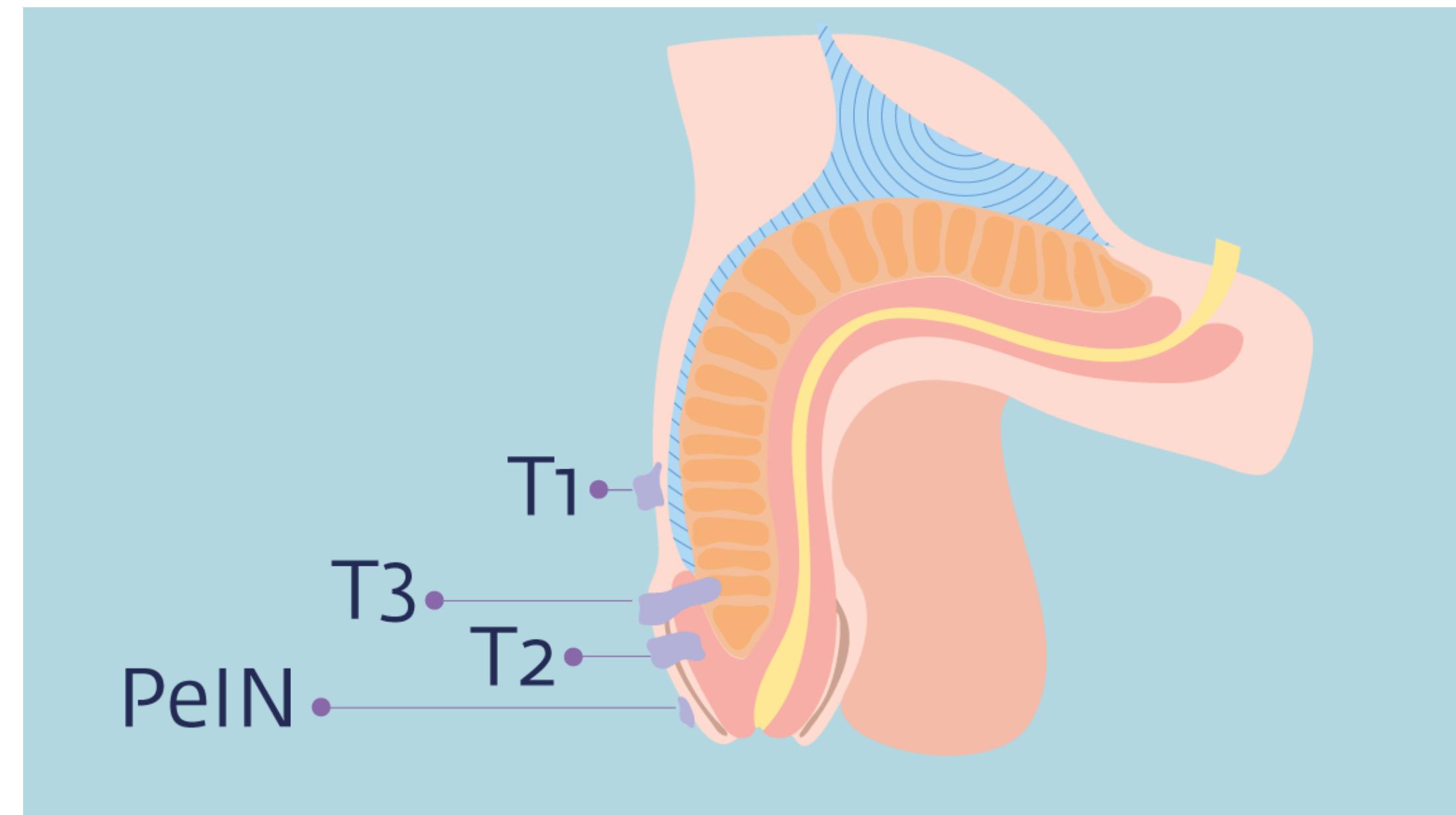
Summary of evidence	LE
Incidence of penile cancer varies according to geographical location, race and ethnicity.	2a
Western developed countries have seen a slight increase in incidence, which may be caused by higher HPV infection rates.	2a
In analogy to other HPV-associated cancers, HPV status may influence DSS of penile cancer, but more data is needed, underlining the importance of routine assessment of HPV status in all penile cancer patients.	2b

Recommendations	Strength rating
The pathological evaluation of penile carcinoma specimens must include the pTNM (see Chapter 4) 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

ICCR = International Collaboration on Cancer Reporting.

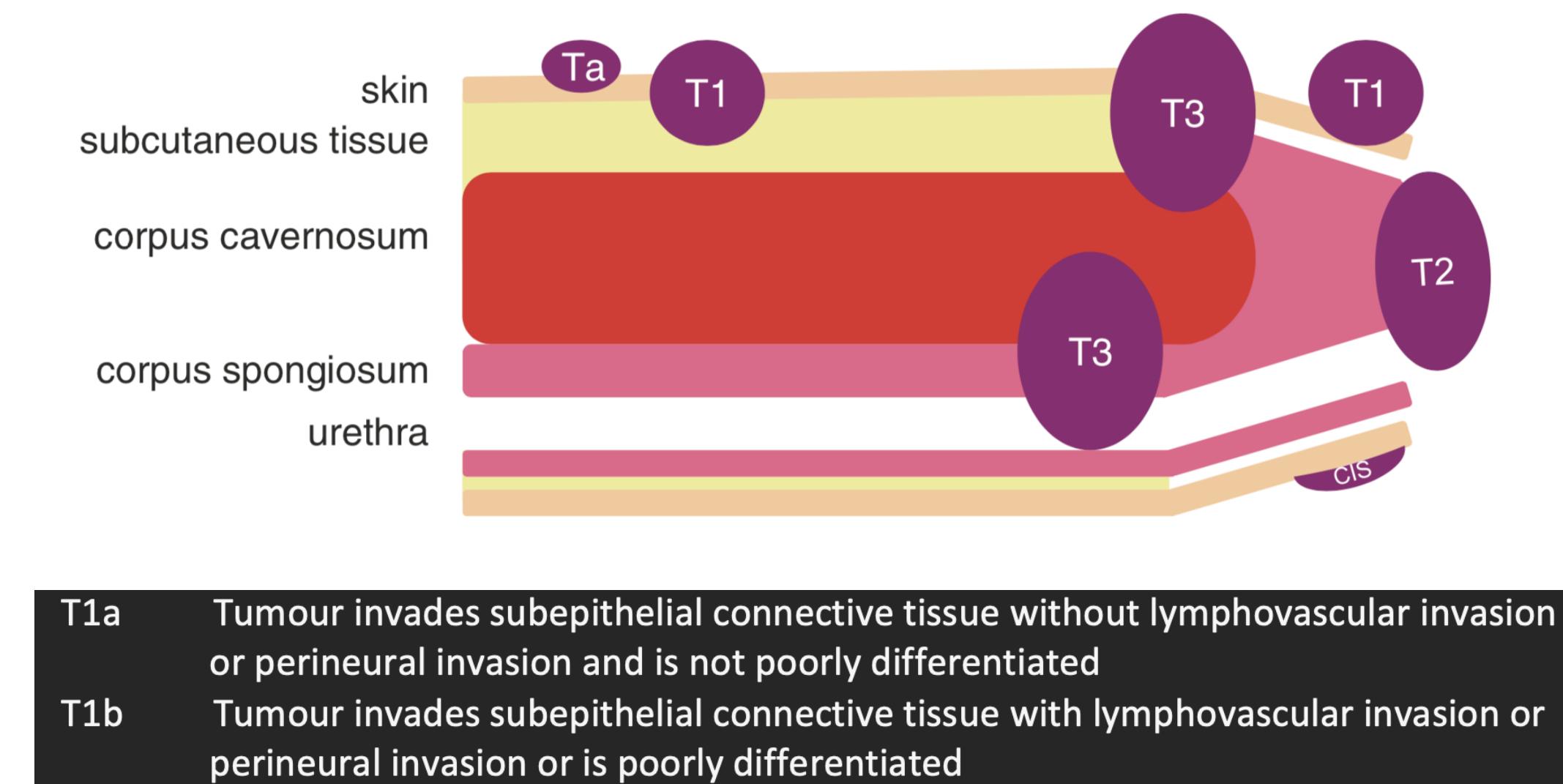
Stadiëring: TNM (8th ed.): Primary Tumor (T), Grade (G)

T:



G:

- GX: Graad niet te bepalen in beschikbare weefsel
- G1: Goed gedifferentieerd
- G2: Matig gedifferentieerd
- G3: Slecht gedifferentieerd
- G4: Ongedifferentieerd



Feature	Grade 1	Grade 2	Grade 3
Cytological atypia	Mild	Moderate	Anaplasia
Keratinisation	Usually abundant	Less prominent	May be present
Intercellular bridges	Prominent	Occasional	Few
Mitotic activity	Rare	Increased	Abundant
Tumour margin	Pushing/well	Infiltrative/ill defined	Infiltrative/ill defined

Stadiëring: TNM (8th ed.): Lymph Nodes (N)

Clinical N stage (cN)

N - Regional Lymph Nodes

- NX Regional lymph nodes cannot be assessed
- N0 No palpable or visibly enlarged inguinal lymph nodes
- N1 Palpable mobile unilateral inguinal lymph node
- N2 Palpable mobile multiple or bilateral inguinal lymph nodes
- N3 Fixed inguinal nodal mass *or* pelvic lymphadenopathy, unilateral or bilateral

Pathological N stage (pN)

pN - Regional Lymph Nodes

- pNX Regional lymph nodes cannot be assessed
- pN0 No regional lymph node metastasis
- pN1 Metastasis in one or two inguinal lymph nodes
- pN2 Metastasis in more than two unilateral inguinal nodes or bilateral inguinal lymph nodes
- pN3 Metastasis in pelvic lymph node(s), unilateral *or* bilateral extranodal or extension of regional lymph node metastasis

Stadiëring: TNM (8th ed.): Distant metastasis (M)

Clinical M stage (c)M

M - Distant Metastasis

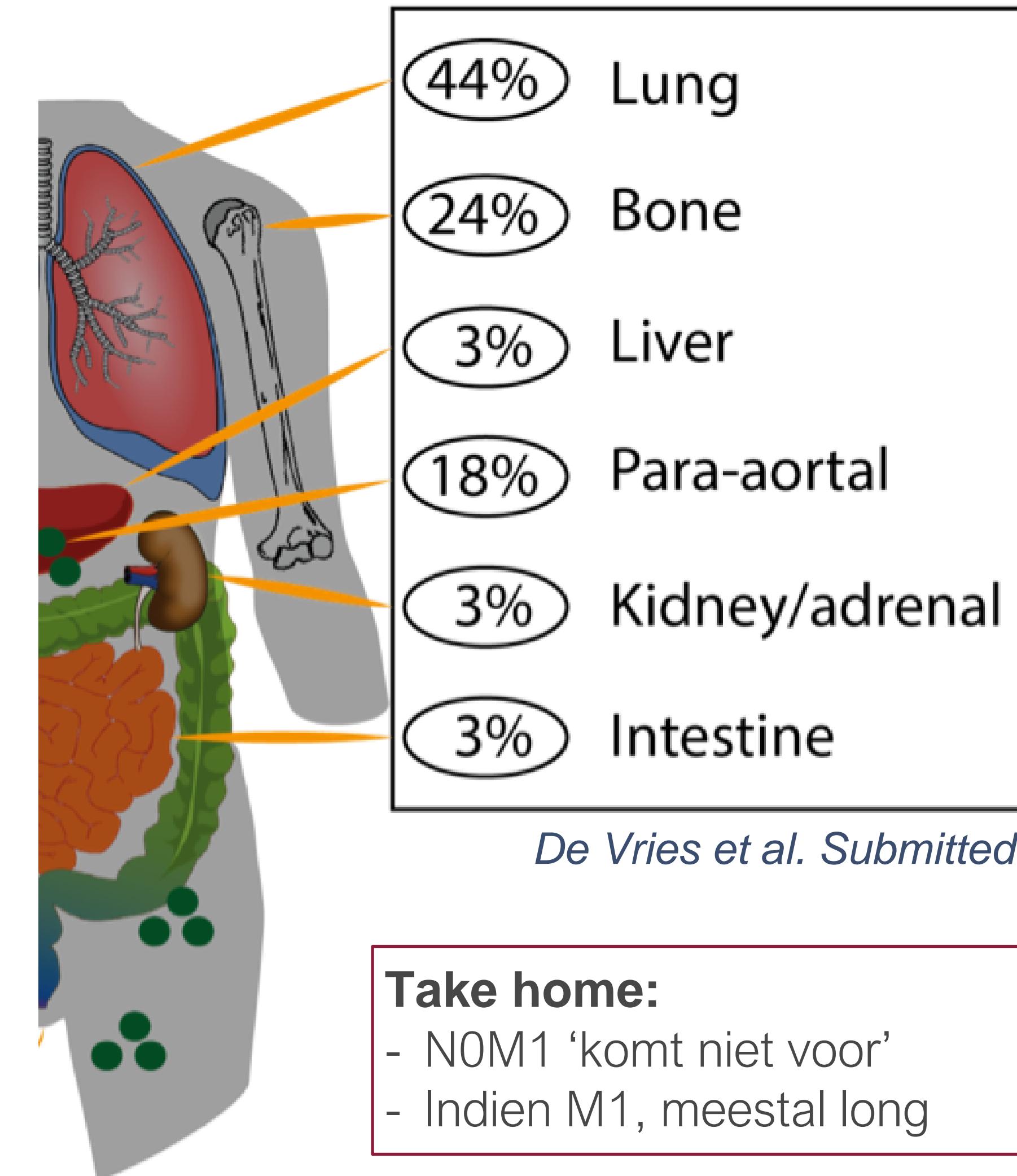
M0 No distant metastasis

M1 Distant metastasis

Pathological M stage (p)M

pM - Distant Metastasis

pM1 Distant metastasis microscopically confirmed



Take home:

- NOM1 'komt niet voor'
- Indien M1, meestal long

Overleving:

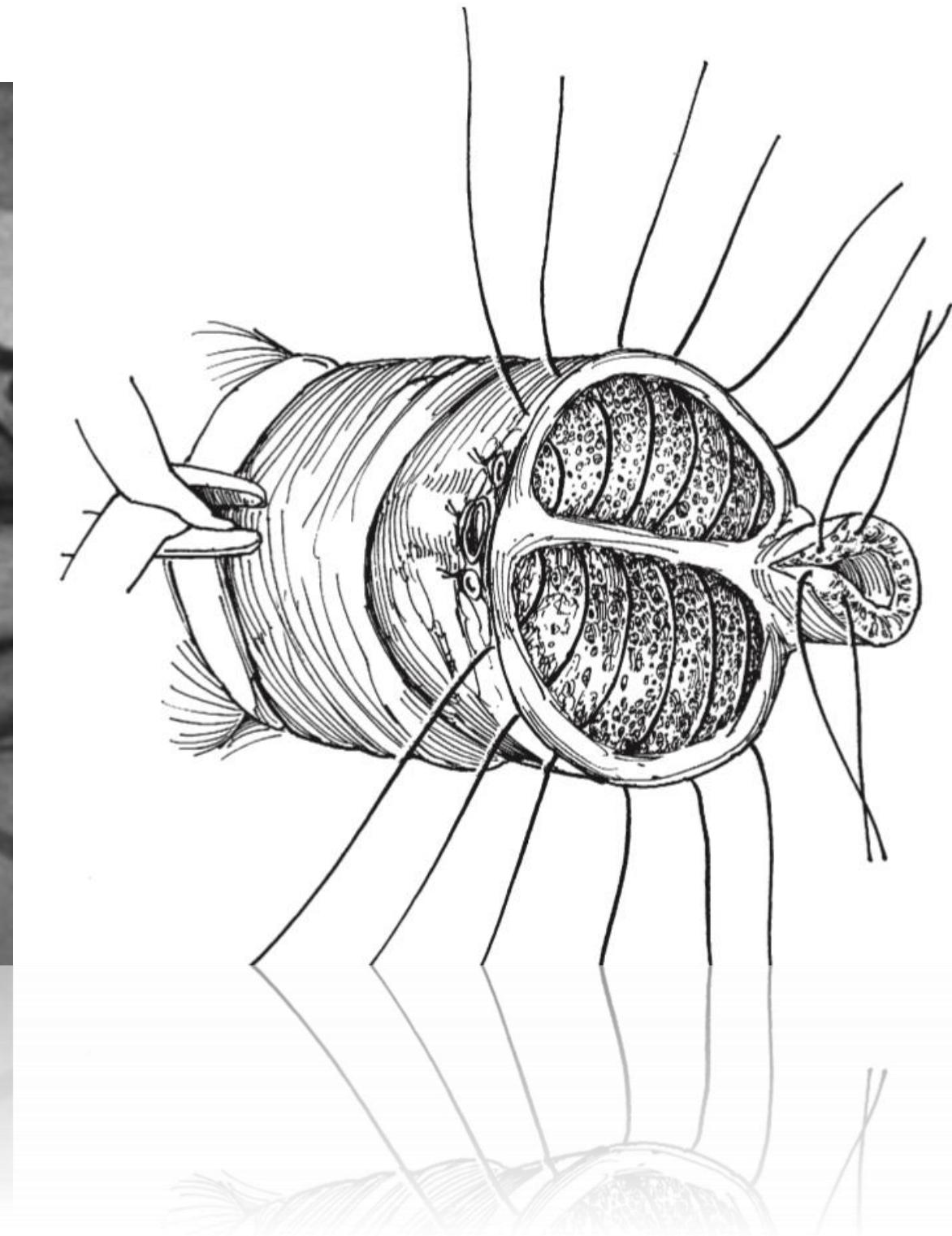
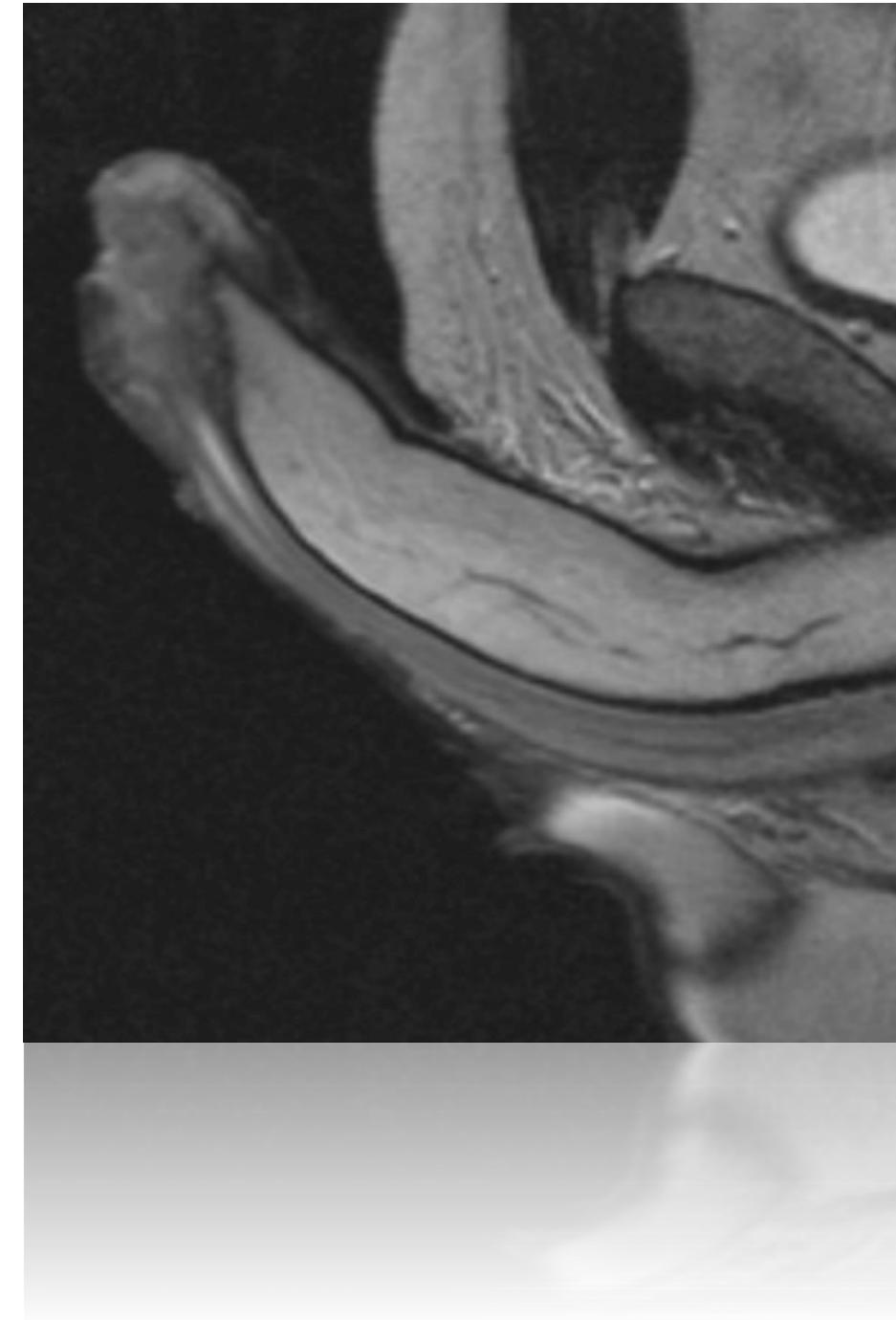
Stage	5yr Survival
Localized (T1, T2, N0 M0)	81% - >90%
Lymph node metastases (N1 / N2 / N3)	75% / 60% / 35%
Recurrent lymph node metastases	16%
Distant metastases (M1)	0% - 11%

Take home:

- N-status belangrijkste prognostische factor
- Recidieven doen het slechter (vooral N-recurrence)
- M1 = infauste prognose
- Vroege diagnose van klieren dus van cruciaal belang
- Meer onderzoek nodig voor advanced stages

Primaire tumor

diagnostiek en behandeling



Presentatie

- Glans 48%
 - Preputium 21%
 - Glans + preputium 9%
 - Corona 6%
 - Schacht <2%
- **25-50% >1 jaar patient delay**



Diagnostiek primaire tumor: *Lichamelijk Onderzoek / Biopt*

Recommendations	Strength rating
Primary tumour	
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
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

Advies AVL:

- Lichamelijk onderzoek: cT, cN status

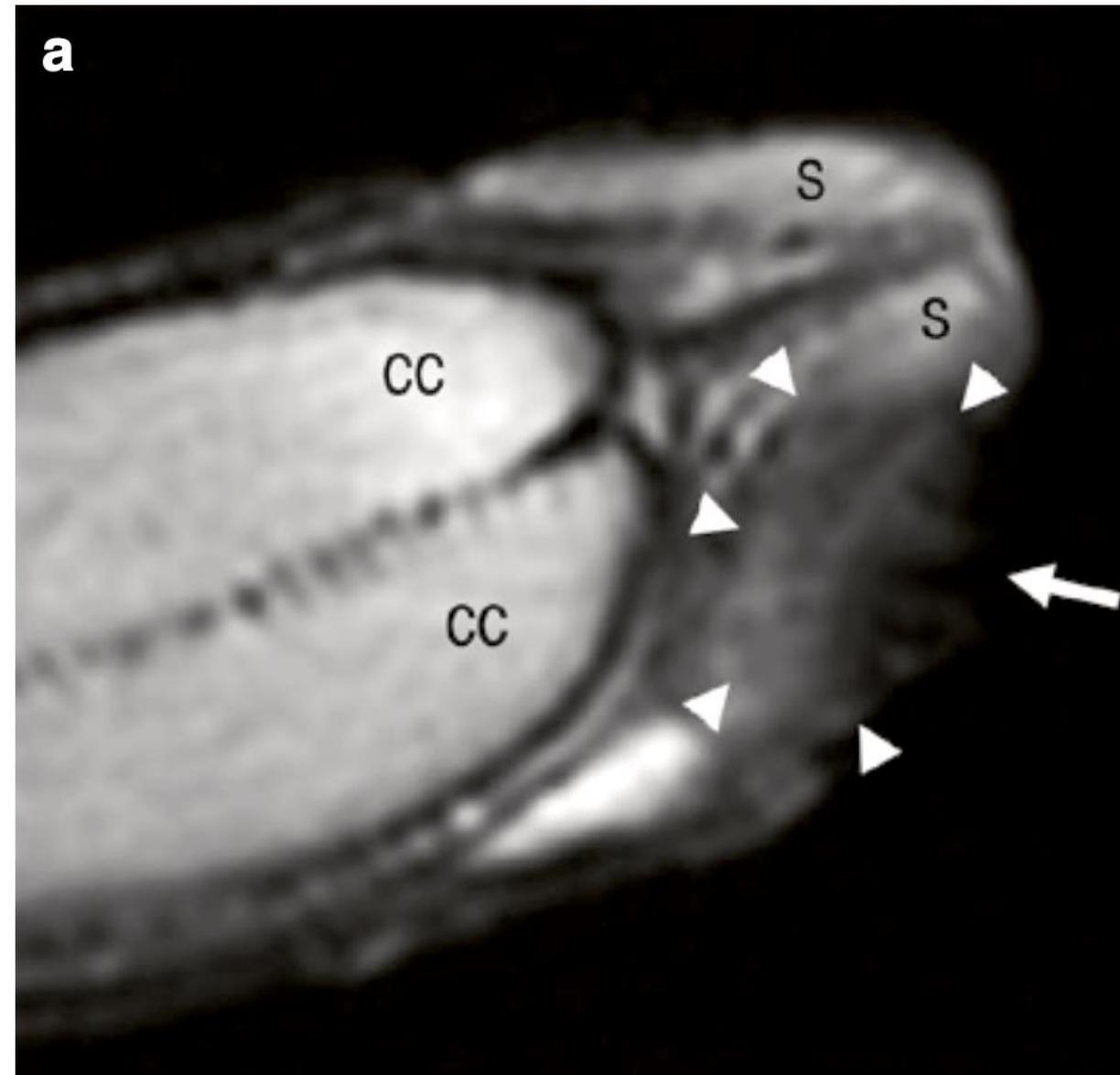
Biopt:

- Bij twijfel aan diagnose (stans 3mm)
- Om PeIN te bevestigen voor start topicale/laser therapie
- NB: Bij PA aanvraag: subtype, gradering, LVI, PNI, HPV

Diagnostiek primaire tumor: *Beeldvorming*

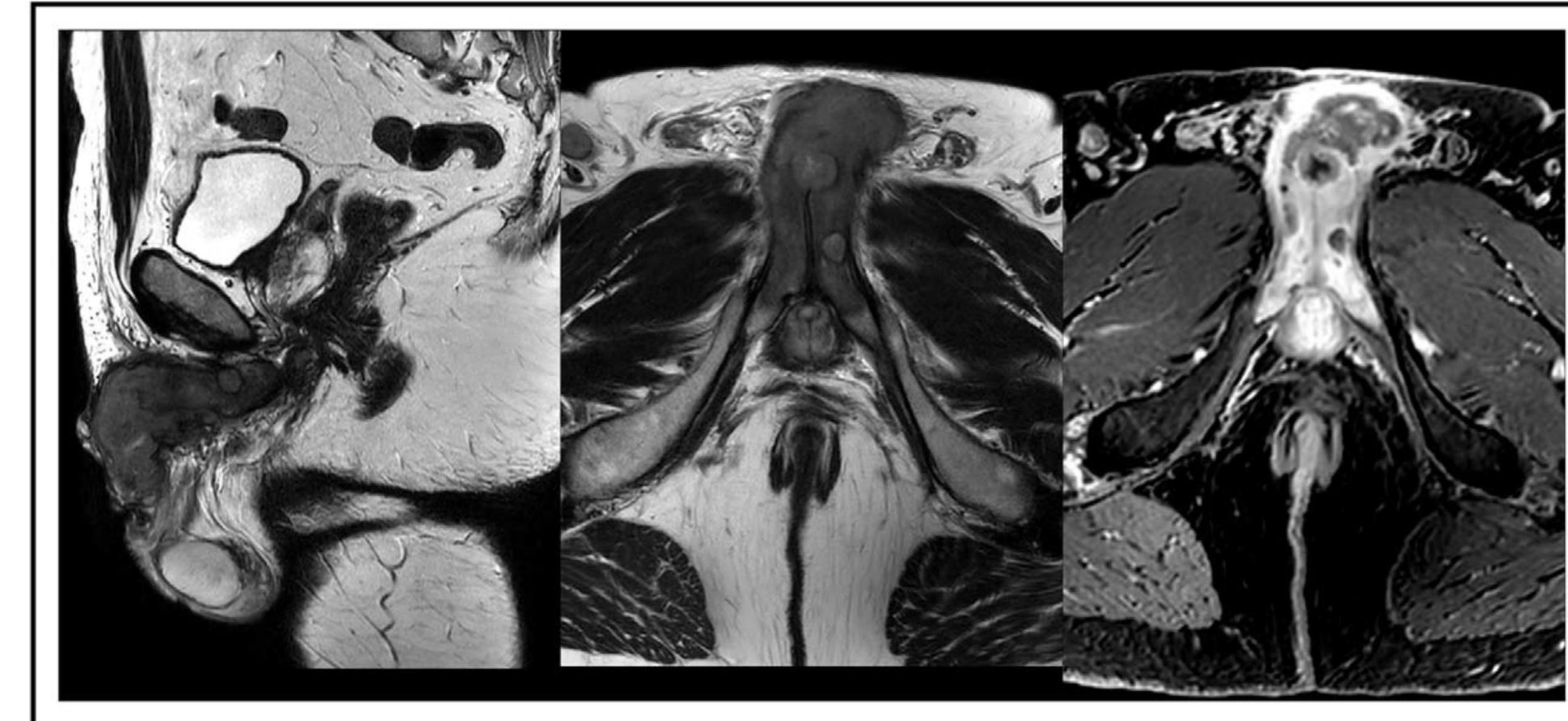
Perform magnetic resonance imaging (MRI) of the penis/primary tumour (artificial erection not mandatory) when there is uncertainty regarding corporal invasion and/or the feasibility of (organ-sparing) surgery. If MRI is not available, offer ultrasound (US) as alternative option.

Weak



Onderscheid T2/T3

indien glansectomie (cavernosa-sparend)
overwogen wordt*



Indien twijfel resectabiliteit (T3/T4)

*The sensitivity and specificity of MRI in predicting corporal invasion was reported as 82.1% and 73.6%

Behandeling primaire tumor: *PeIN*

Topicale therapie (creme):

- Imiquimod / 5-FU
- In combinatie met circumcisie beter (CR tot 73%)
- voordeel: zelf aan te brengen, mogelijk lang effect
- nadeel: 6-12wk, recidiefkans, irritatie/blaren



Guideline update: PenN Treatment

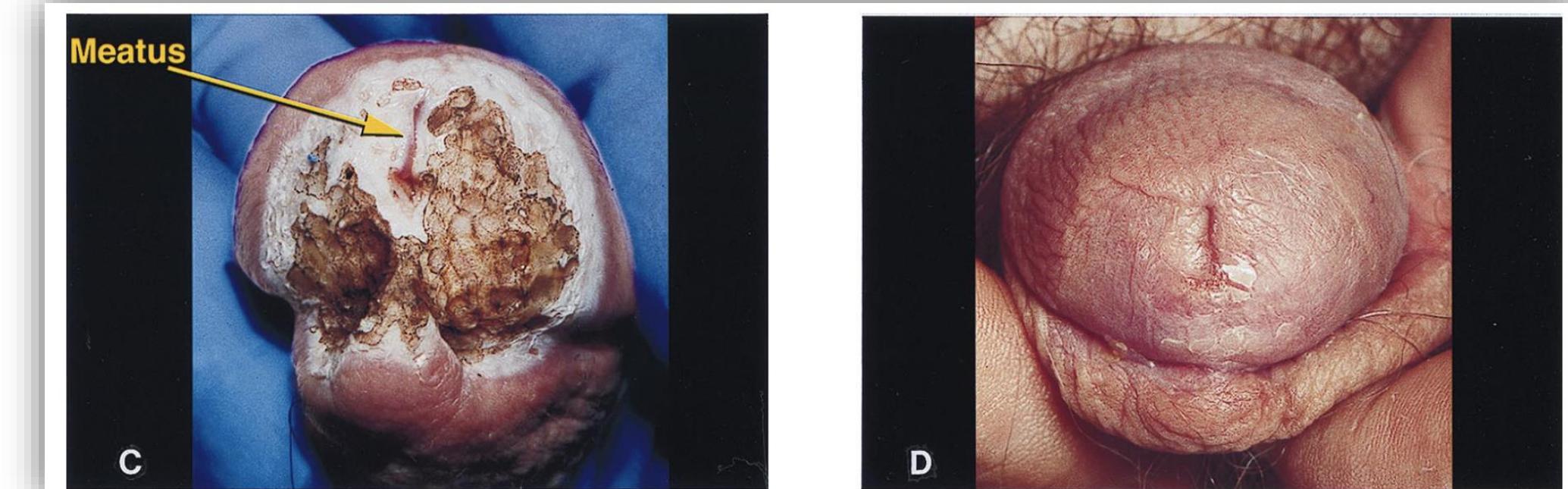
- First line: Topical treatment (after circumcision)
 - **Imiquimod (Aldara): activation of immune cells via toll-like receptor 7**
 - *3 times per week for 12 weeks*
 - **5-fluorouracil (Efudex): inhibition of thymidylate synthase**
 - *12-hours every 48 hours during a 4 to 6 week treatment course*

Behandeling primaire tumor: *PeIN, T1a*



Laserbehandeling:

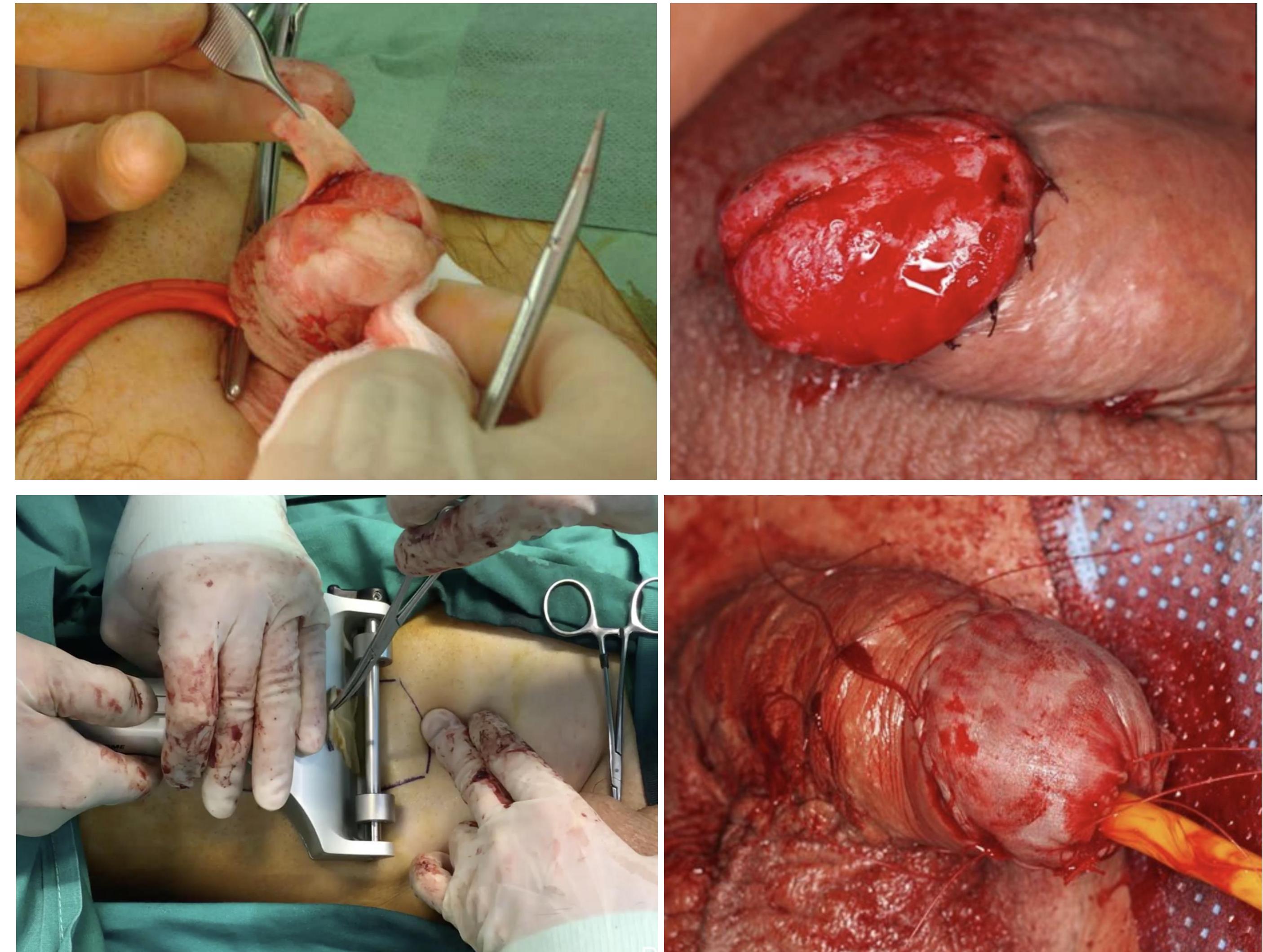
- CO2 / YAG: recidiefkans tot 48%
- voordeel: snel (poliklinisch)
- nadeel: bij grote gebieden, meatus



Behandeling primaire tumor: *PeIN, T1a*

Glansresurfacing (+ split skin grafting):

- recidiefkans 4%
- altijd in combinatie met circumcisie
- voordeel: recidiefkans laag
- nadeel:
 - positieve marges 20%,
 - graft loss 5-10%
 - 5-dg CAD



Behandeling primaire tumor: *PeIN-casus AVL: resurfacing*



Presentation



Biopsy: PeIN



3 months after resurfacing



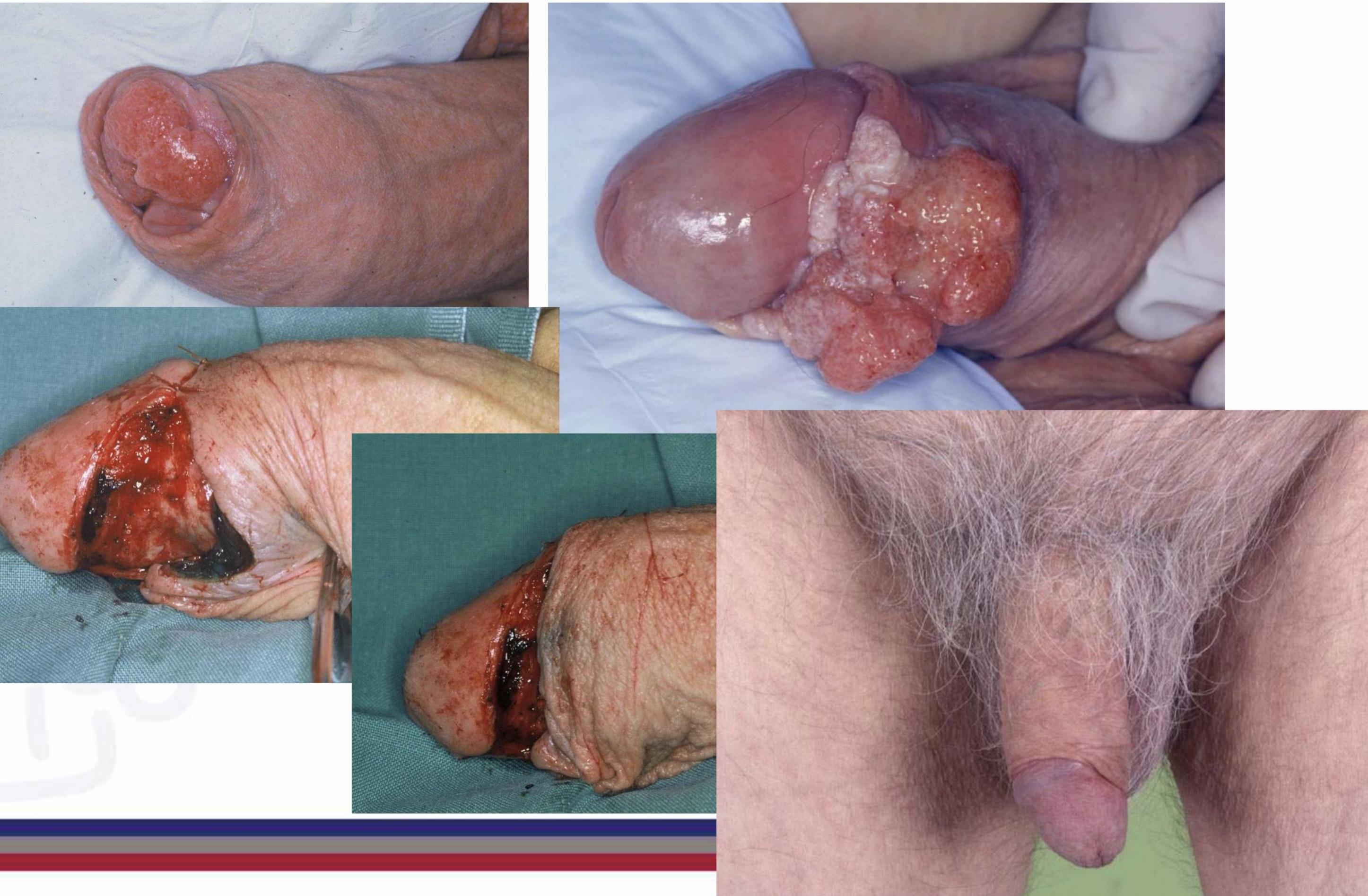
6 months

Behandeling primaire tumor: **T1-T2**

- When feasible, T1-T2 lesions should receive organ-sparing treatment:
 - wide local-excision, *1-3mm marge bij PA is voldoende*
 - Radiotherapie/Brachytherapie (*wordt in NL niet meer gedaan*)
 - Oncologisch mogelijk equivalent
 - Functionele uitkomsten vallen tegen (cave meatusstenose)
 - Glansectomie (=cavernosa-sparend, +/- split skin grafting)
- Partiële penectomie (*strikt genomen: overbehandeling tenzij T3*)

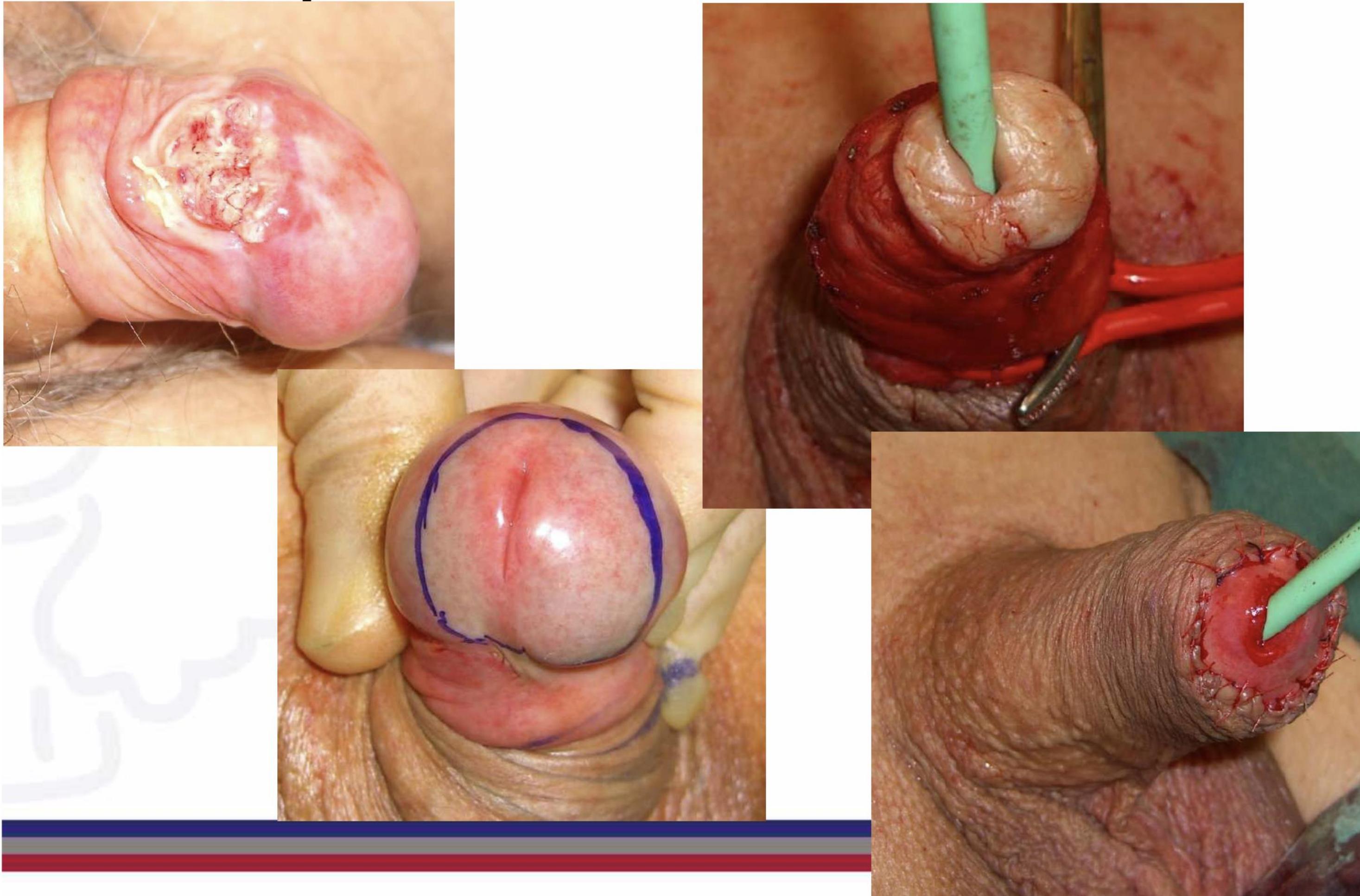
Behandeling primaire tumor: **T1-T2**

Surgery: Local Excision



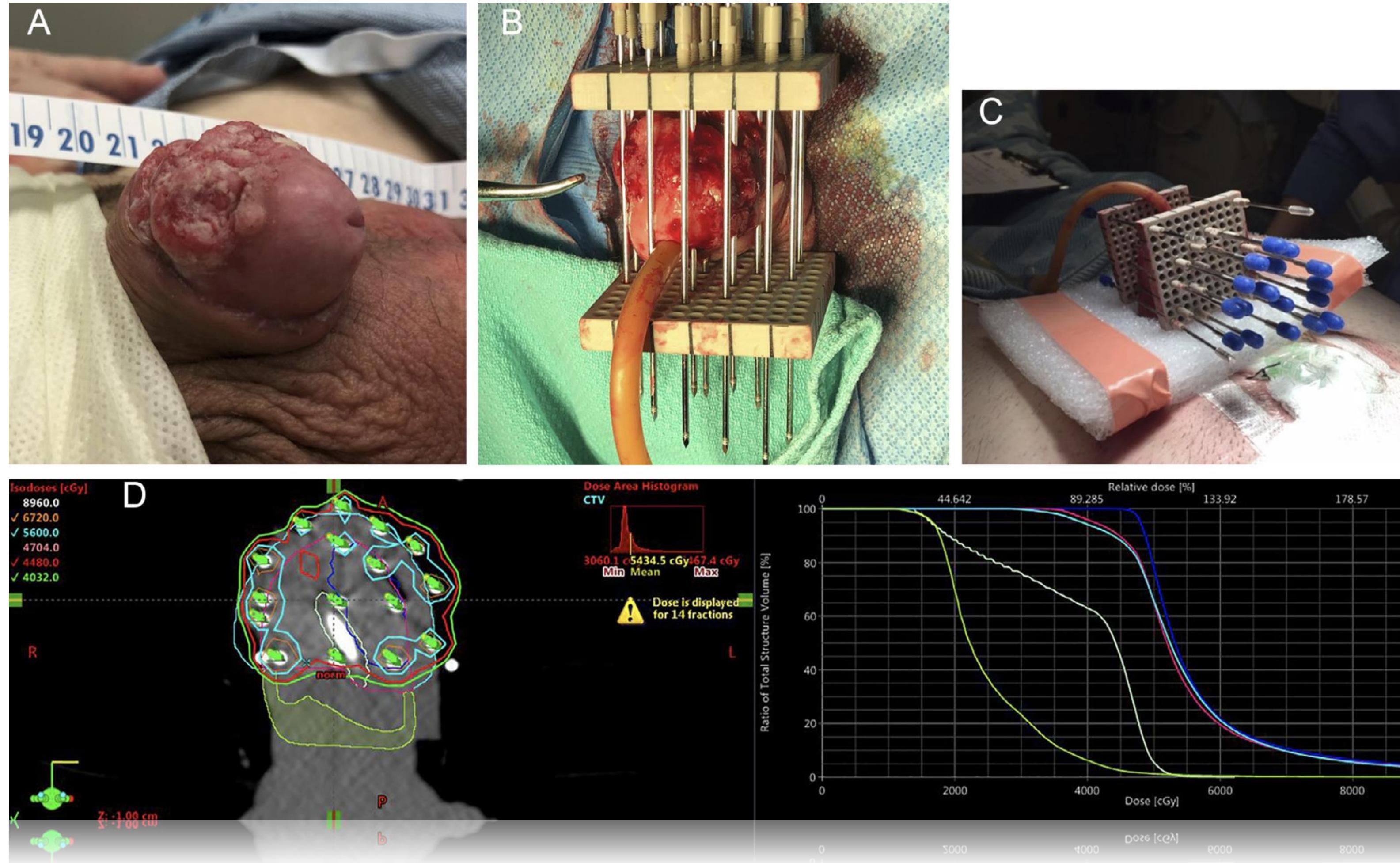
Behandeling primaire tumor: **T1-T2**

T1-T2 penile cancer: Local excision



Behandeling primaire tumor: T1-T2

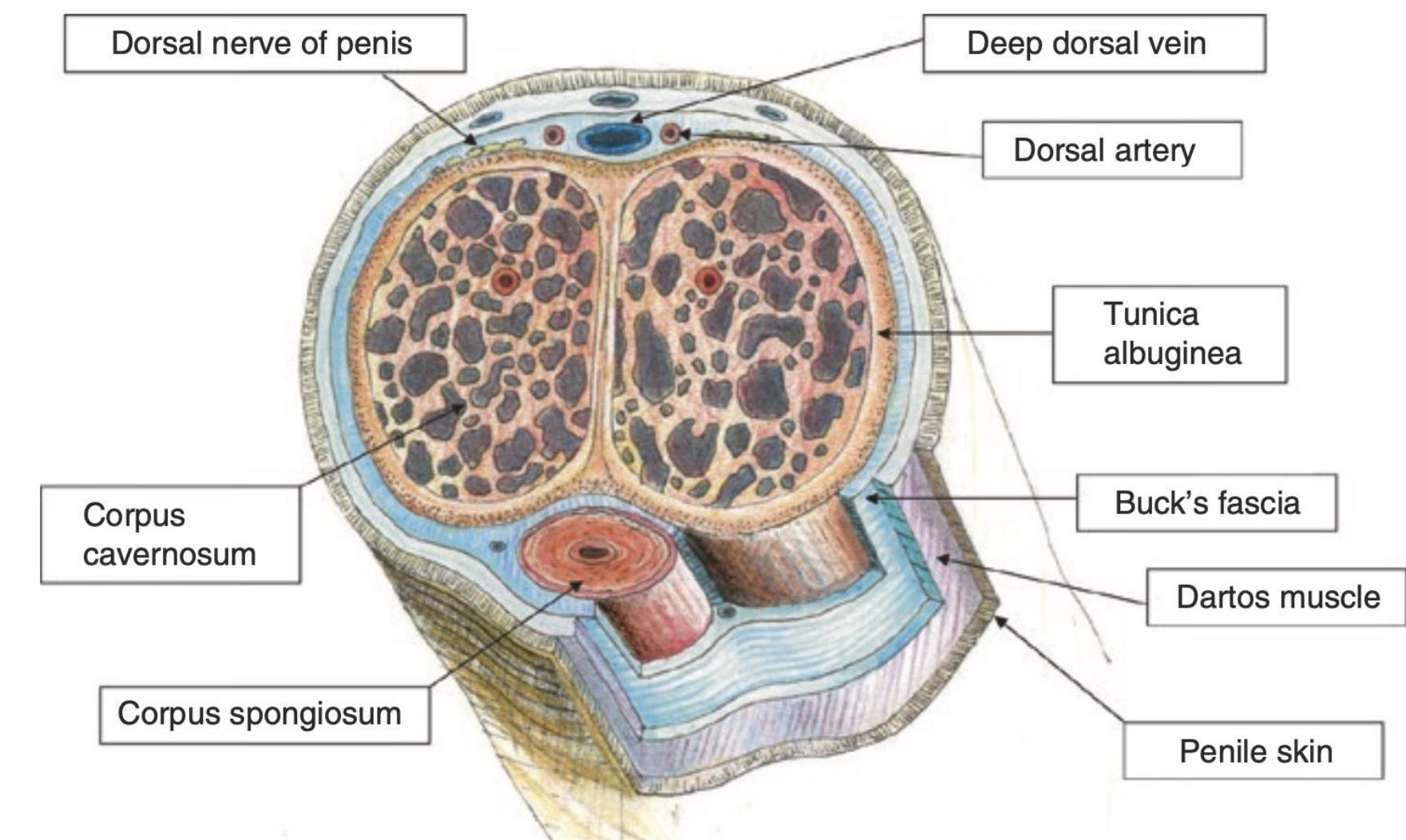
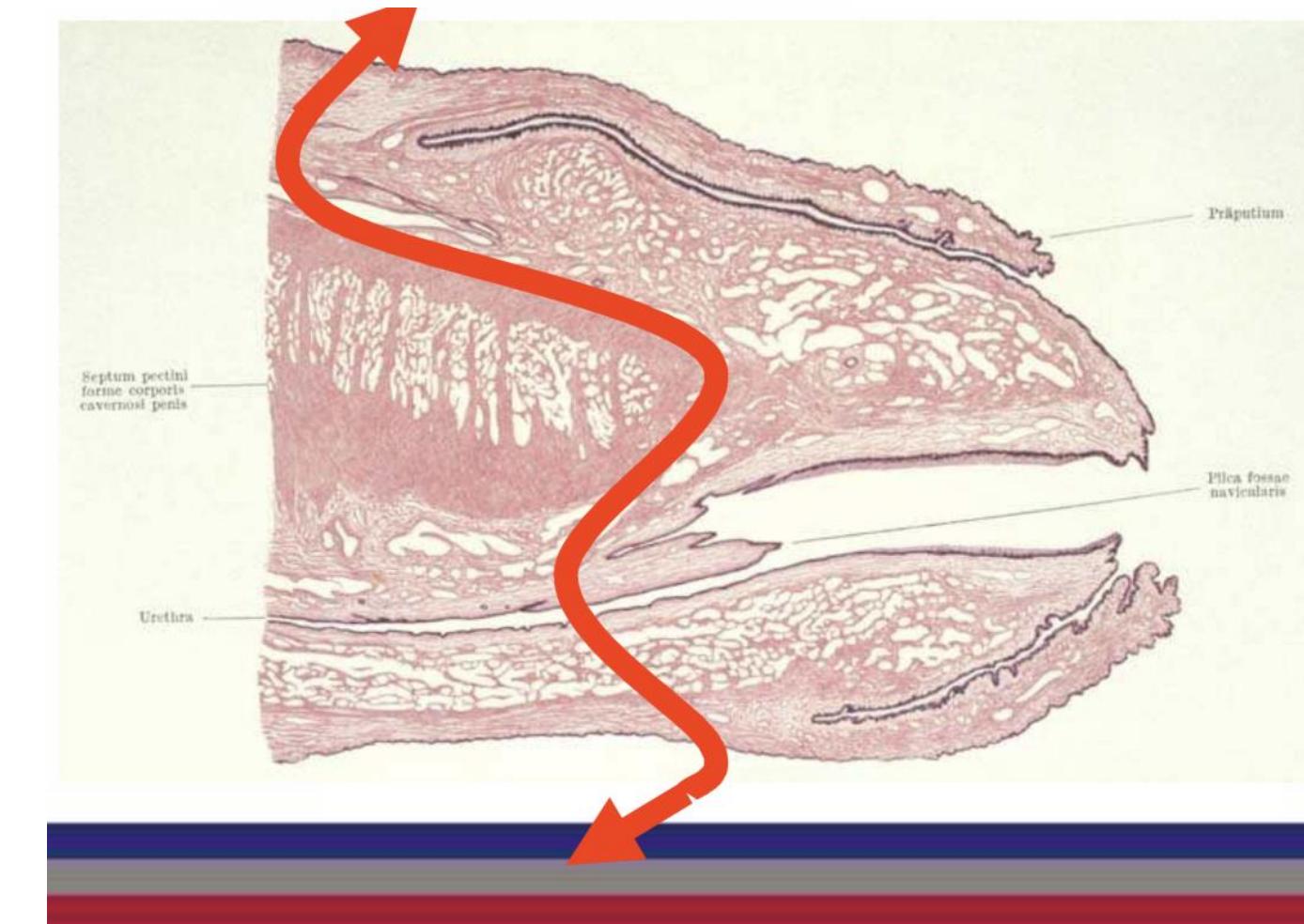
Brachytherapie



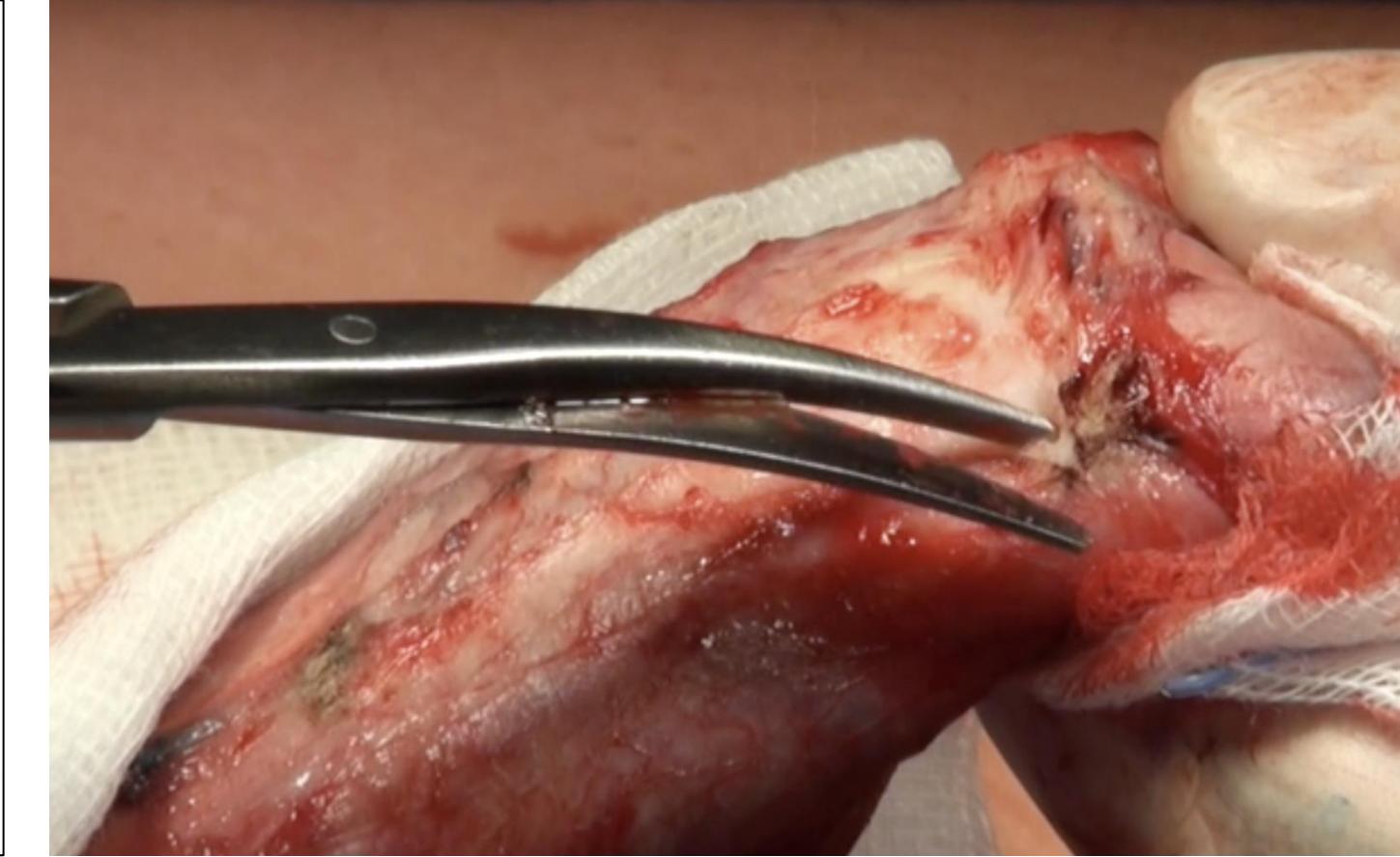
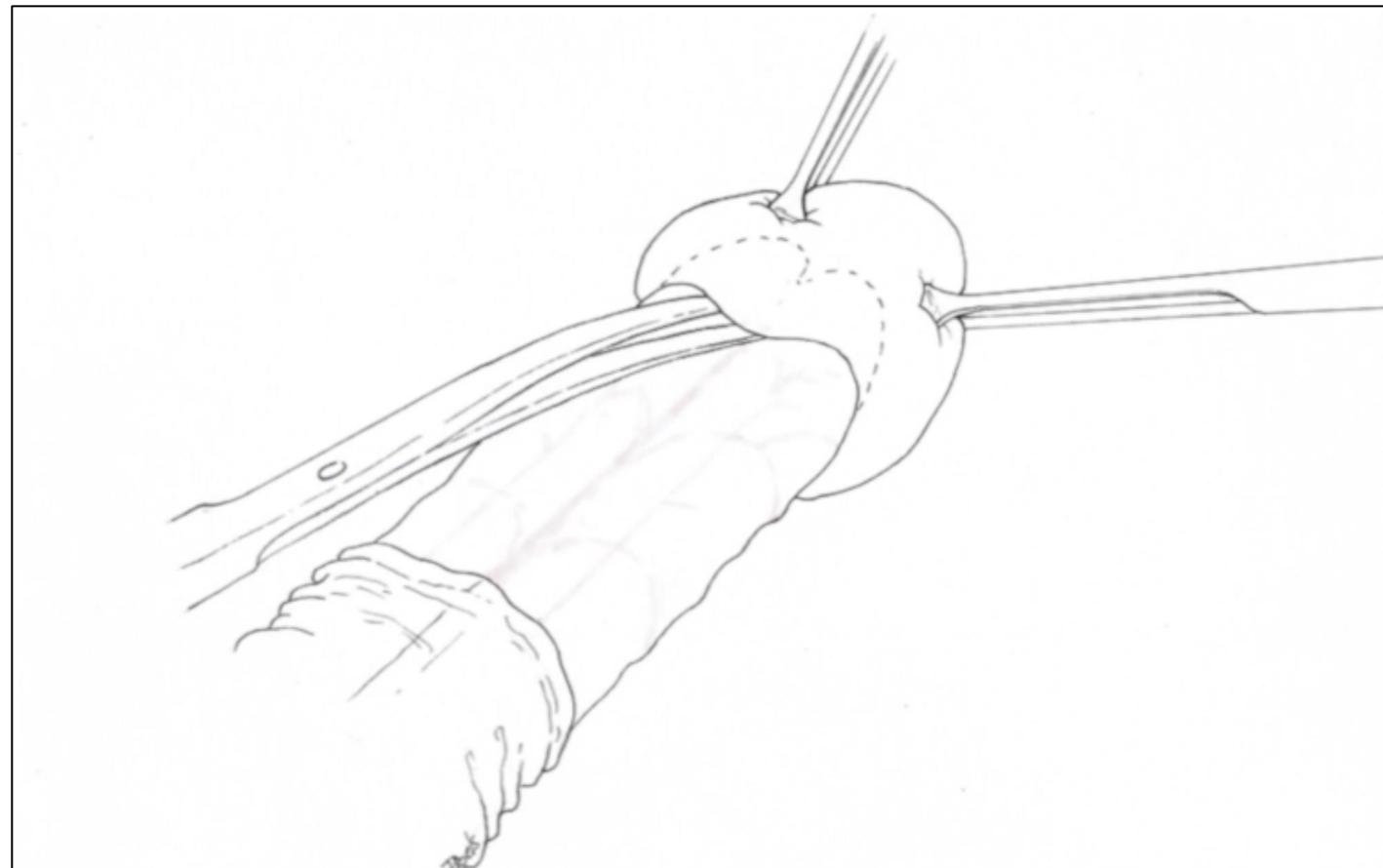
Behandeling primaire tumor: **T1-T2**

Glansectomie (cavernosa-sparedend)

- recidiefkans 5-10%
- voordeel: penislengte, sexuele functie
- nadeel:
 - positieve marges indien toch T3 (MRI!)
 - indien SSG: graft loss 10-15%

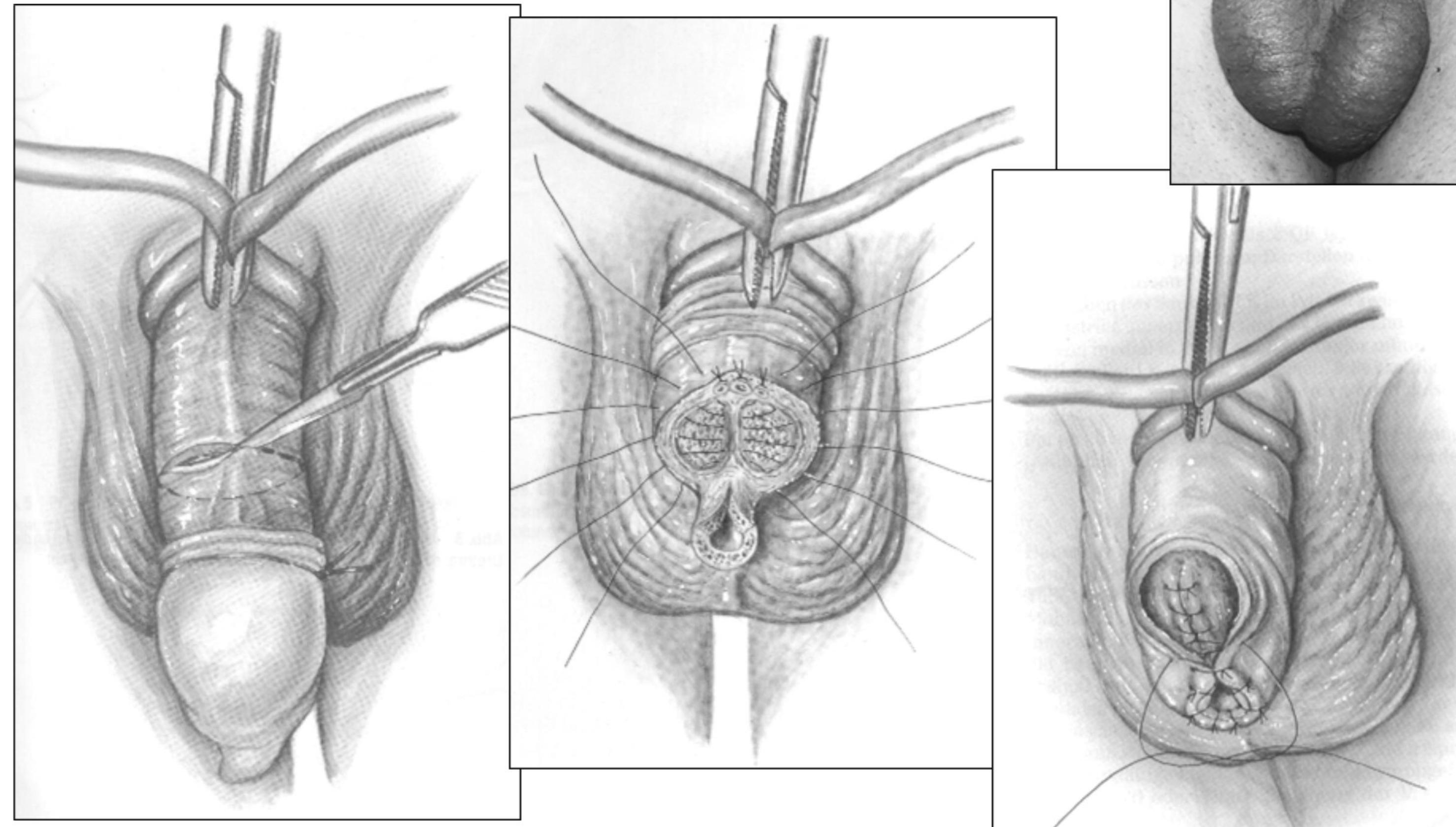


Behandeling primaire tumor: **Glansectomie**

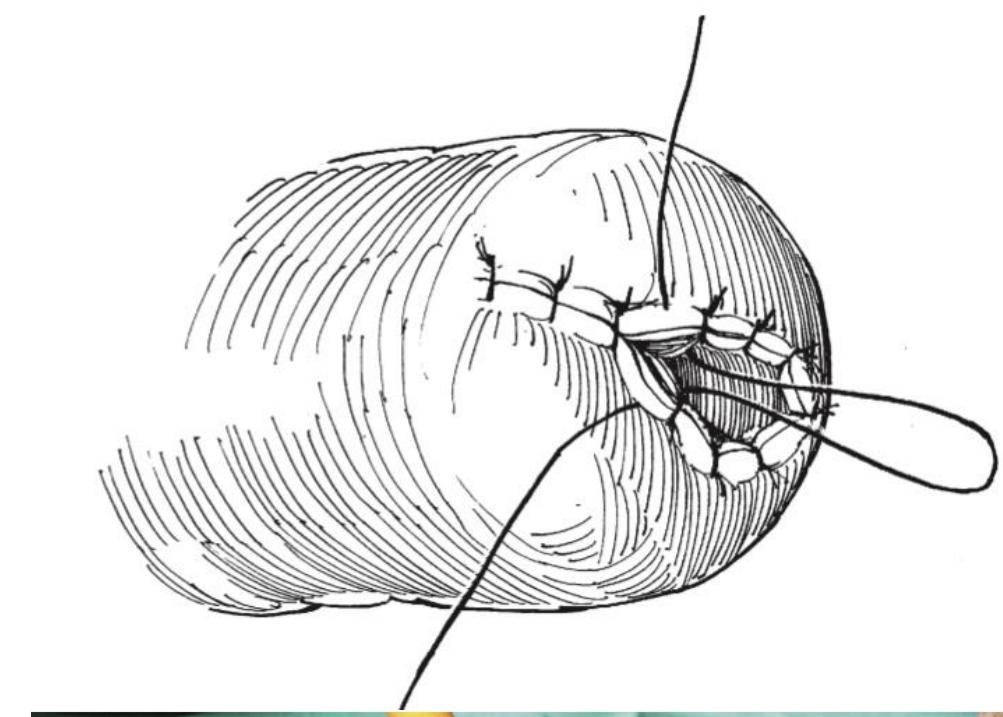
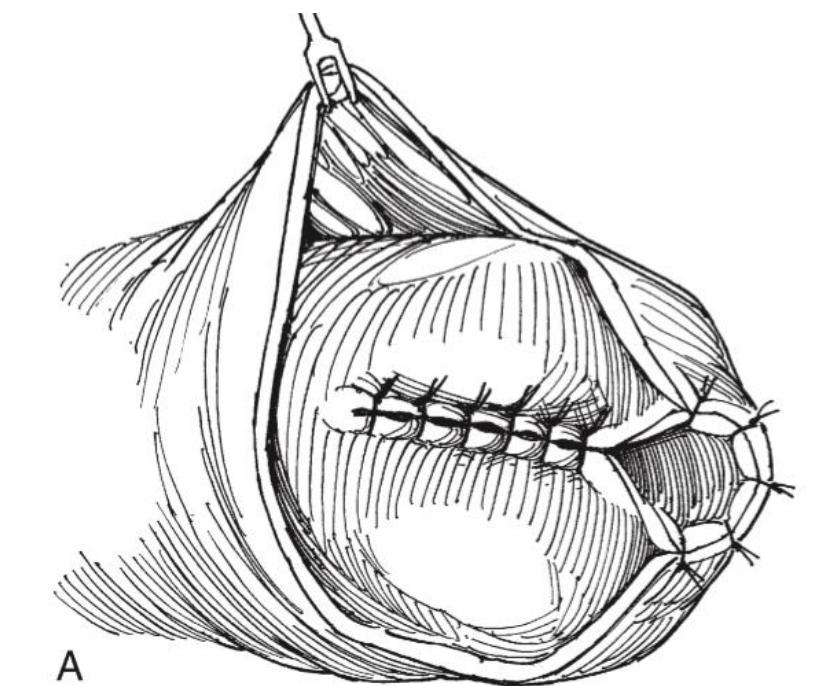
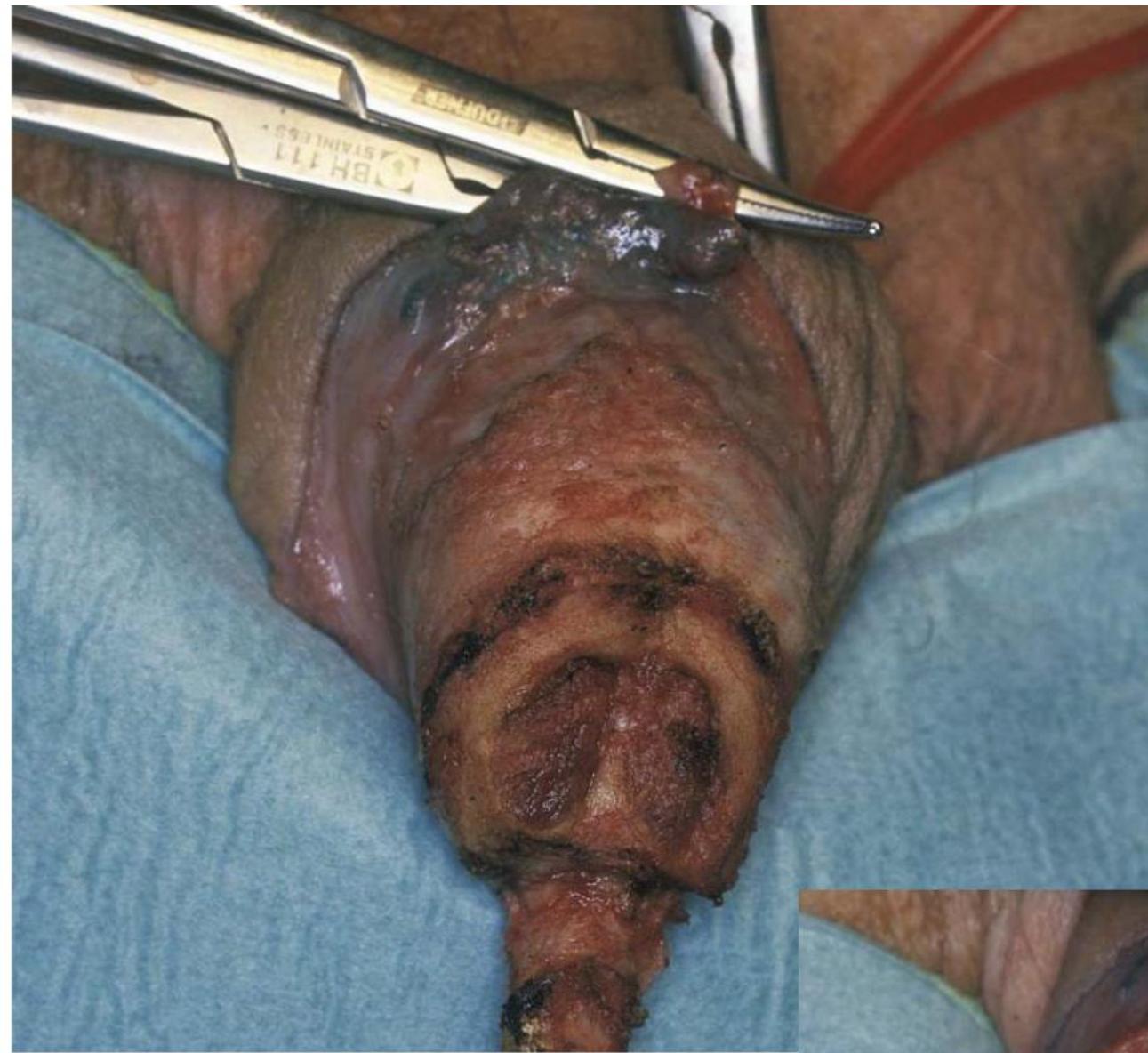


Behandeling primaire tumor: **T3**

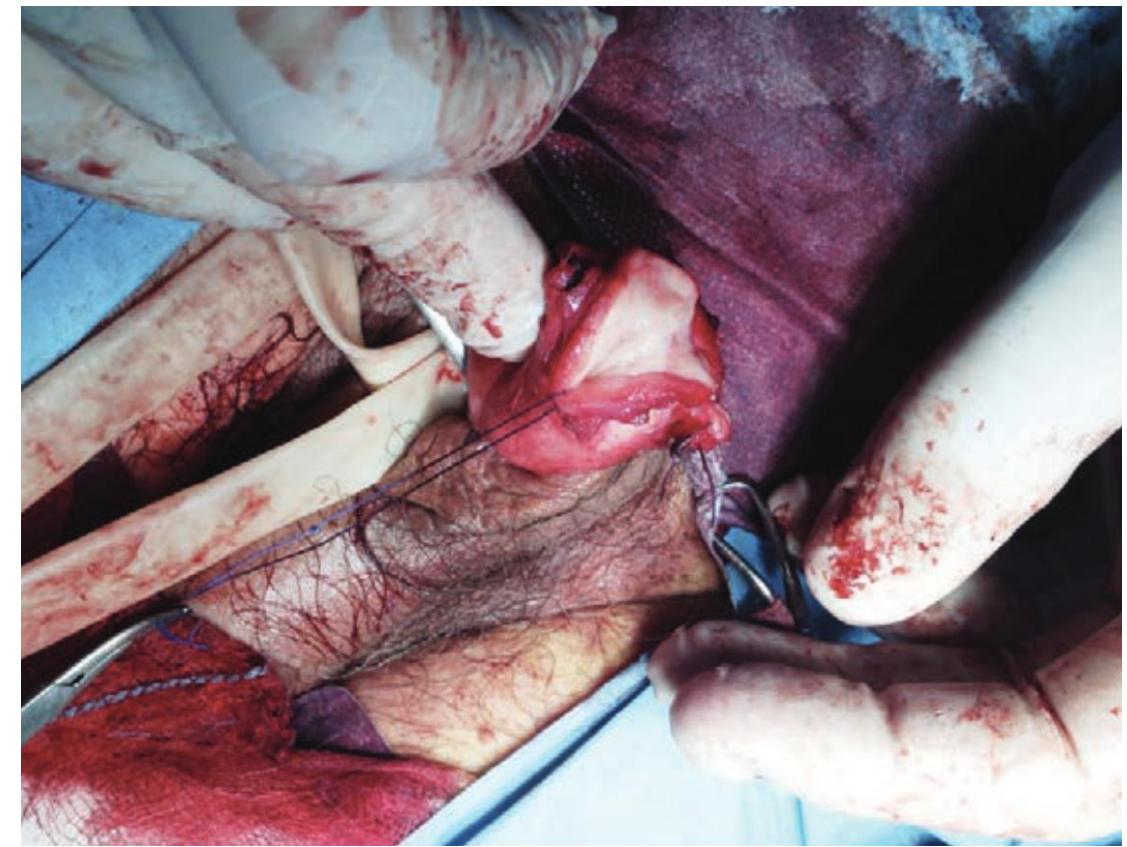
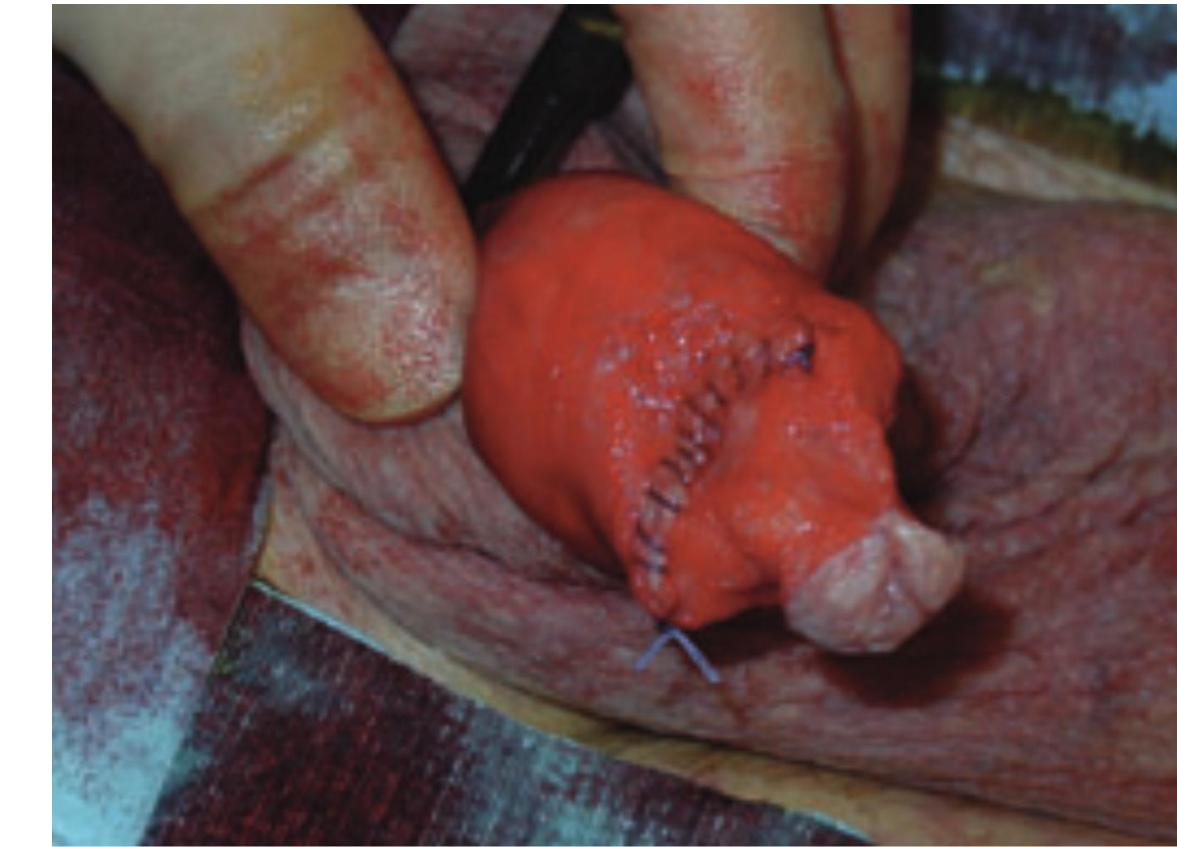
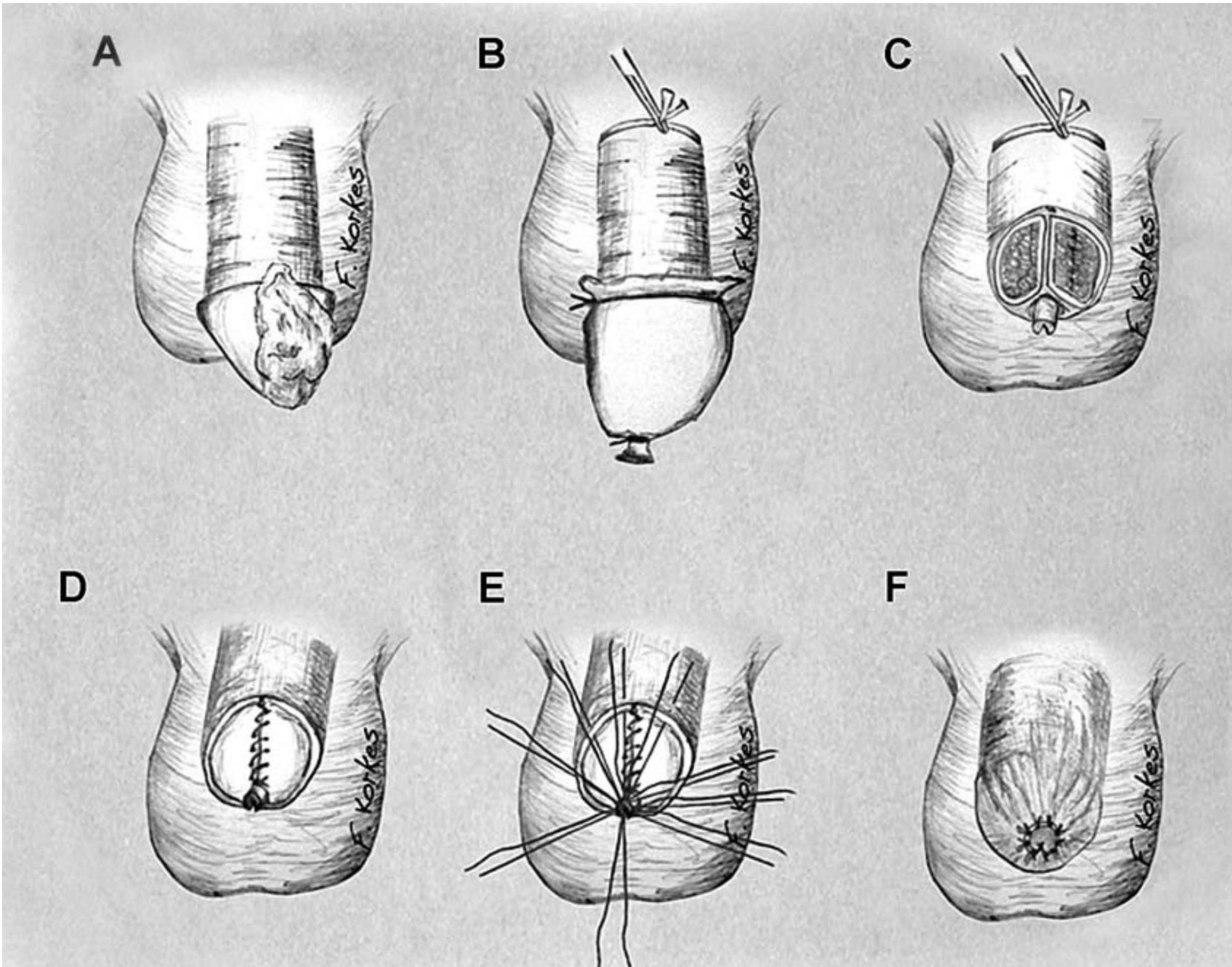
Partial penectomy T3



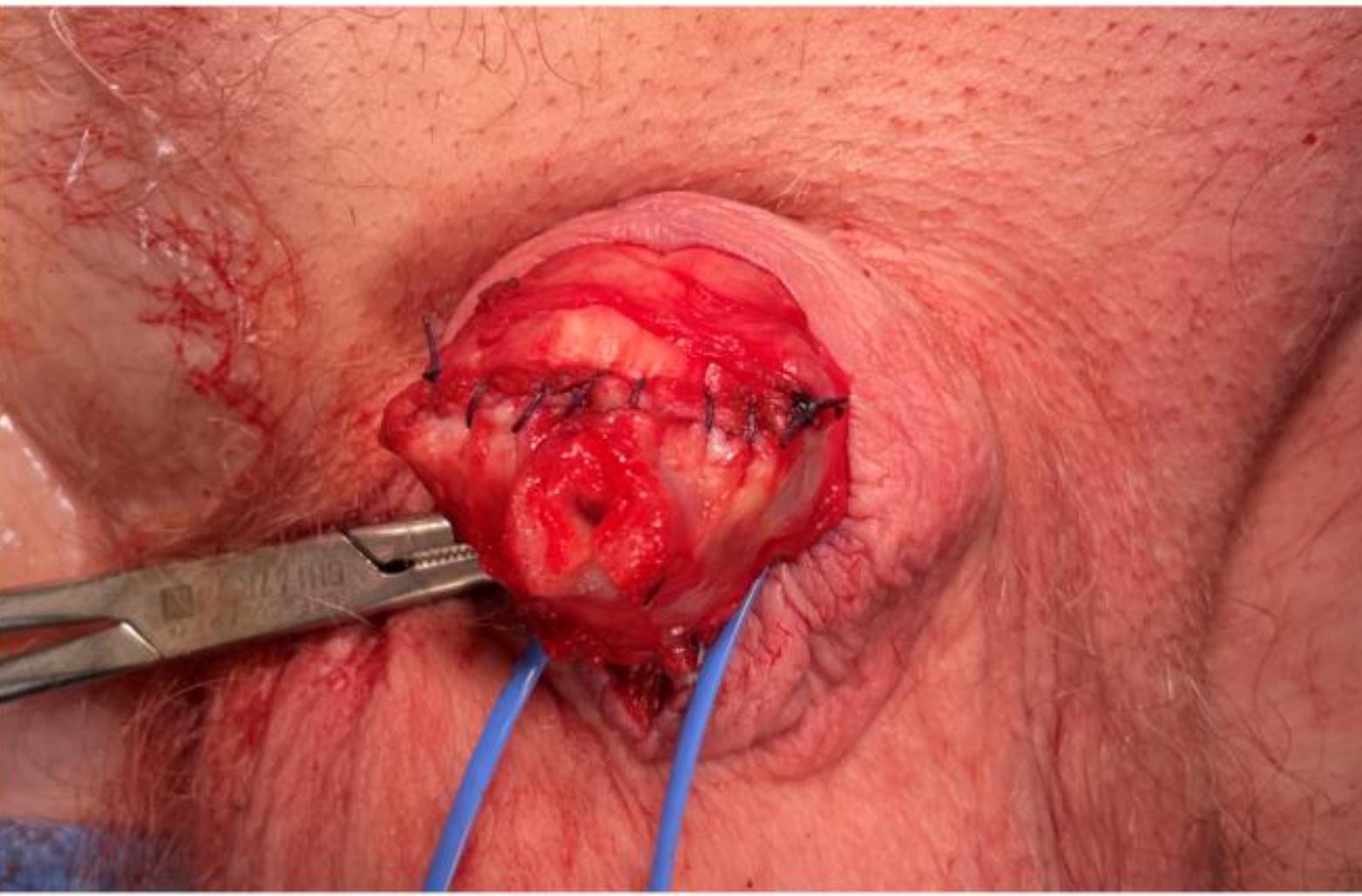
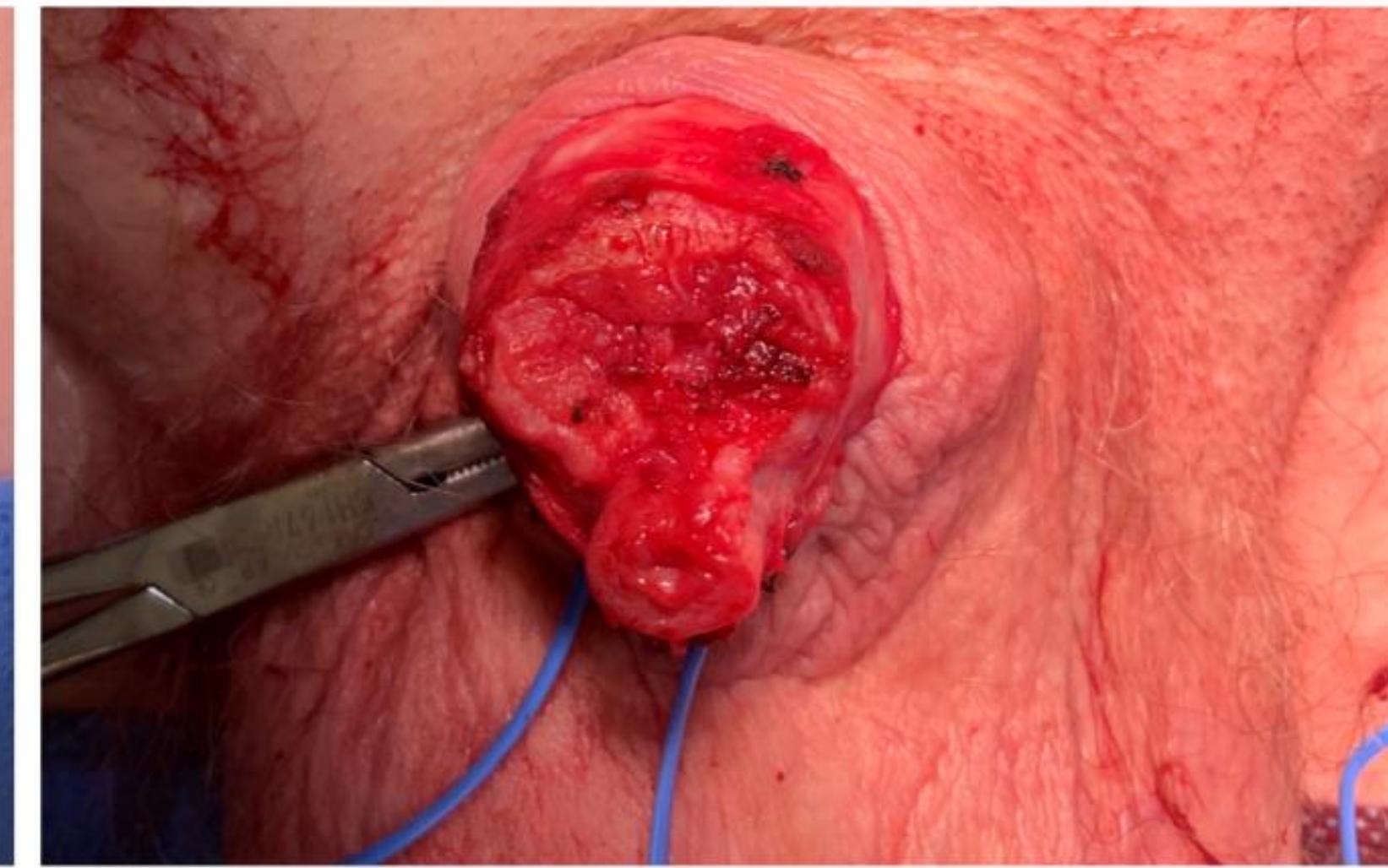
Behandeling primaire tumor: *Partiele penectomie*



Behandeling primaire tumor: *Partiele penectomie*



Behandeling primaire tumor: *Partiele penectomie*



Penile Sparing Surgery for Penile Cancer—Does it Affect Survival?

Rosa S. Djajadiningrat, Erik van Werkhoven, Wim Meinhardt, Bas W. G. van Rhijn,
Axel Bex, Henk G. van der Poel and Simon Horenblas*

From the Departments of Urology and Biometrics (EvW), The Netherlands Cancer Institute Amsterdam, Amsterdam, The Netherlands

- 859 patienten (451 penile sparing, 408 partial penectomy)
- 5-yr recurrence penile sparing: 27%
- 5-yr recurrence partial penectomy: 3,8%
- Echter geen invloed op 5 yr CSS
- Wel van invloed: pT-stage, N-stage, LVI

Conclusions: Significantly more penile preservation therapies were performed in more recent years. Although patients treated with penile preservation experienced more local recurrences, 5-year cancer specific survival was not jeopardized.

MINI REVIEW | ARTICLES IN PRESS

Challenges in Organ-sparing Surgery for Penile Cancer: What Are the Limits?

Laura Elst [†] • Manon Vreeburg [†] • Oscar Brouwer [‡] • Maarten Albersen [§]   • Show footnotes

Published: January 16, 2023 • DOI: <https://doi.org/10.1016/j.euf.2023.01.005>

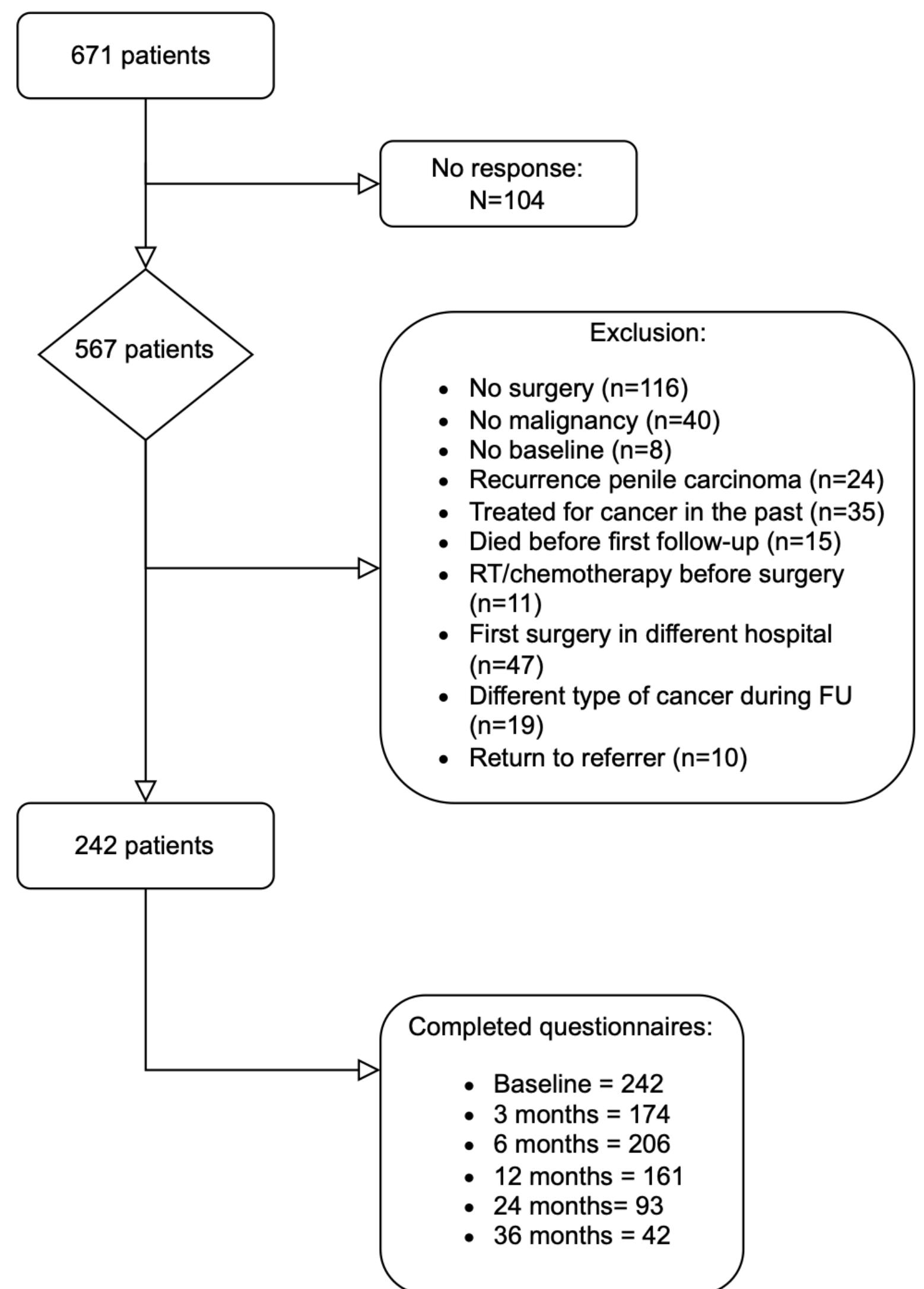
- Cave: bulky, high grade tumours (G3, LVI)
- *for bulky or higher-grade lesions where local recurrence may have an impact on survival, adoption of a wider margin or partial penectomy may be prudent and should be discussed with the patient*

Behandeling primaire tumor: *Quality of Life*

Sexual life following resurfacing, glandectomy and partial amputation

- Resurfacing
 - Chance for restoration of sensoric perception
- Glandectomy and partial amputation
 - Preservation of sexual function and activity, but reduced sensitivity
 - Sufficient erection 66,7%
 - Orgasms 72,2%
 - 55,6% restoration of regular sexual intercourse
 - 72,2% ejaculation and orgasms by sexual intercourse/stimulation
 - Without sexual intercourse
 - 50% dissatisfied due to small penis/absence of glans

QoL (AVL)



- EORTC-qlq-C30
- IIEF-15
- MSES
- CWS
- Custom section on micturition

QoL (AVL)

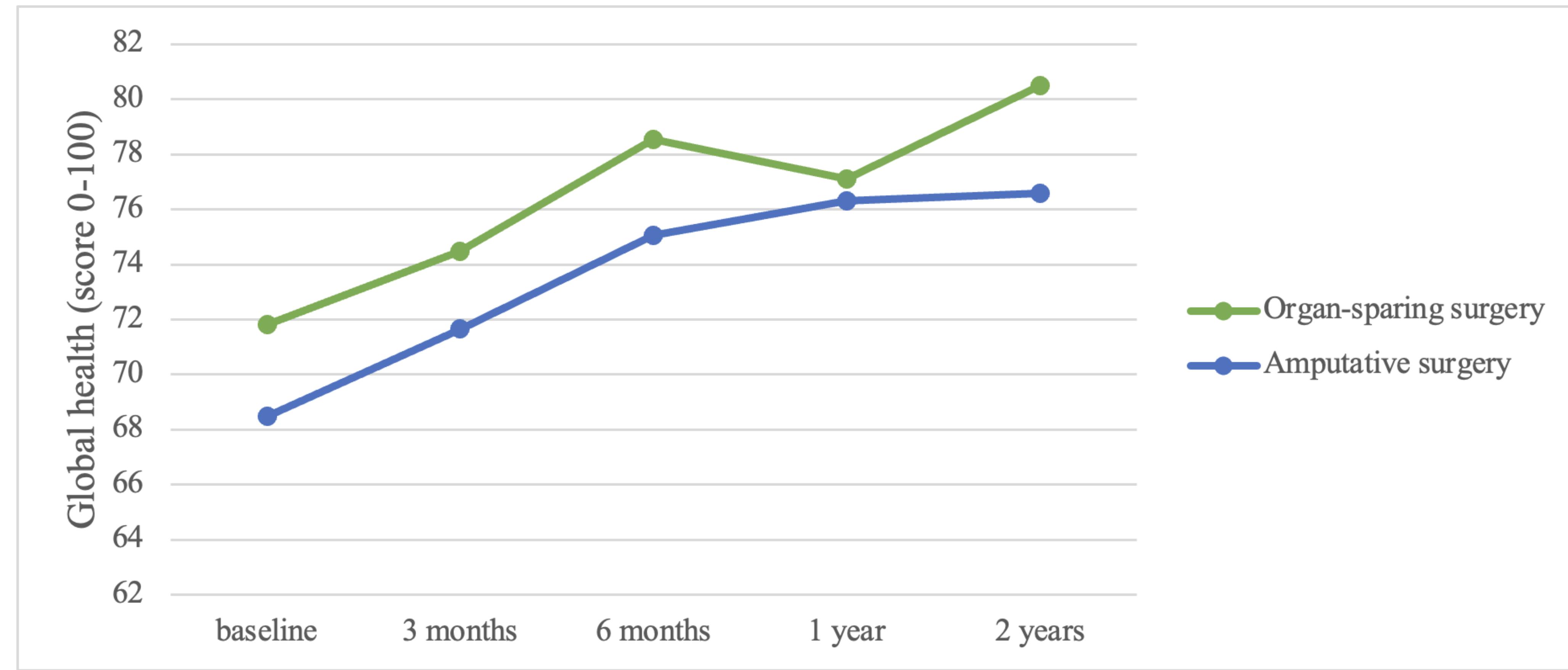


Figure 2. Mean global health scores divided by surgical groups over a 2-year period. A higher score means better functioning, with 76 being average for healthy men aged 70-94.

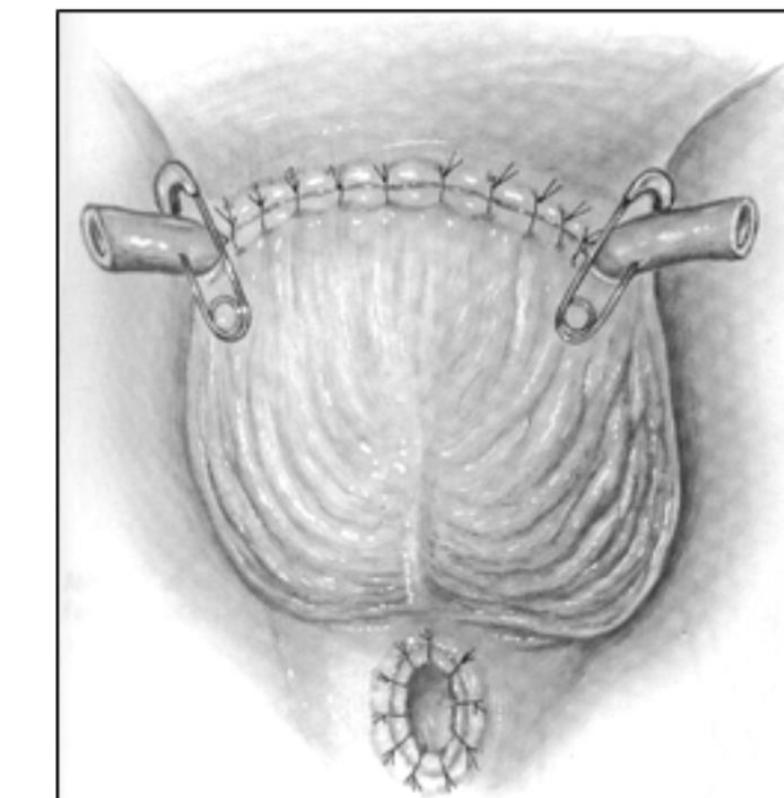
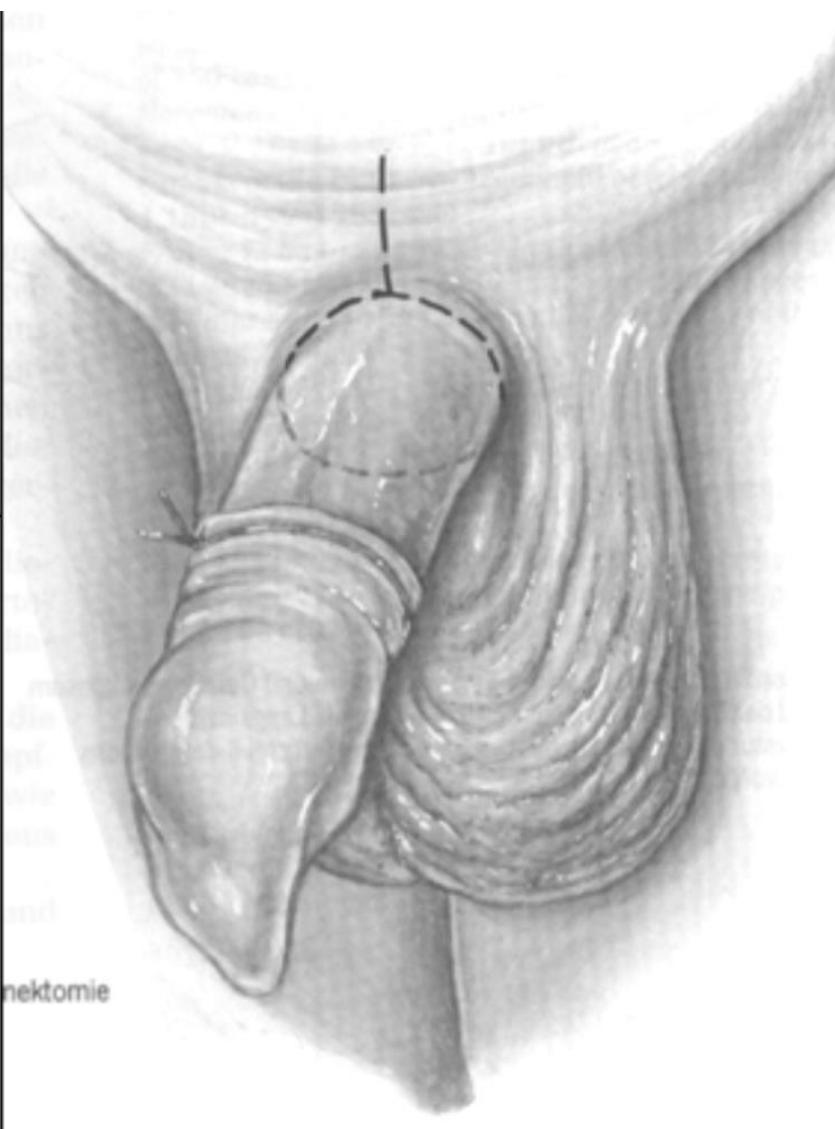
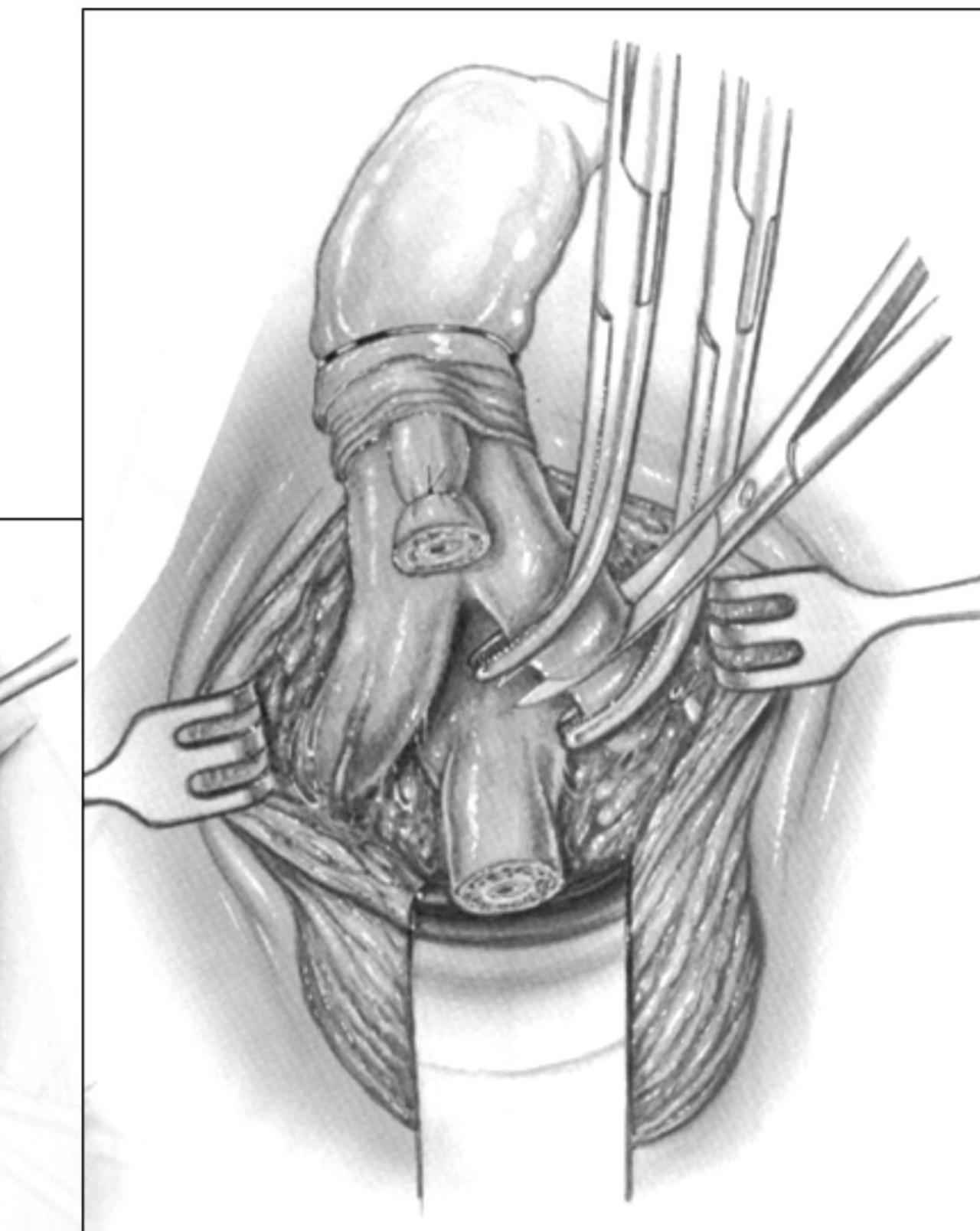
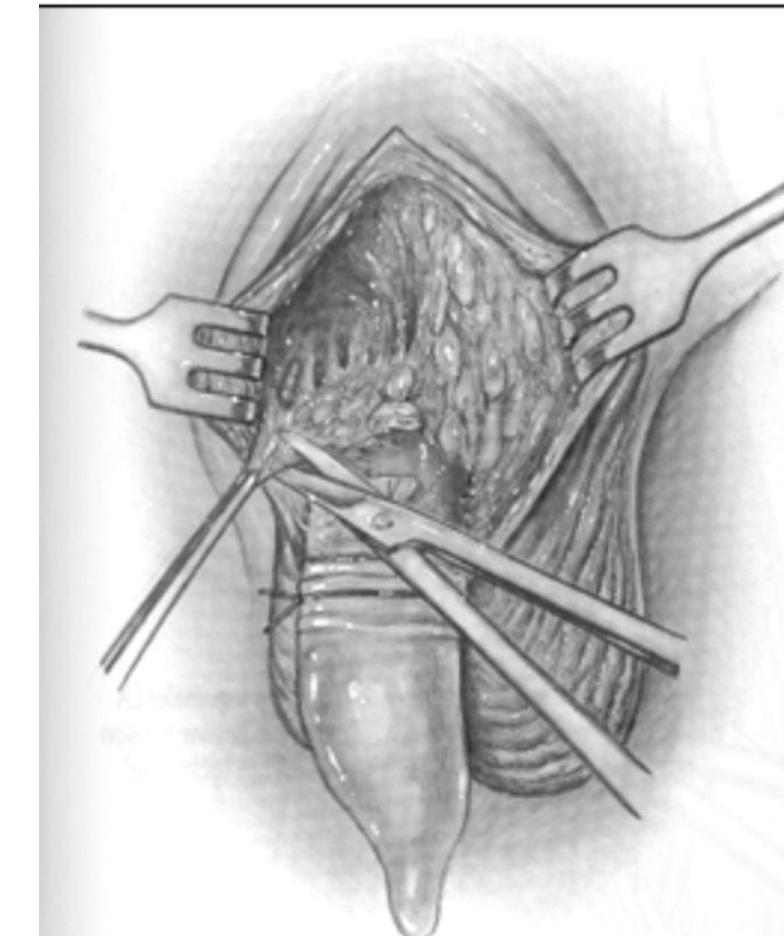
Evaluation ongoing: van Harten et al.

Behandeling primaire tumor: (groot T3)-T4

Indien (initieel) irresectabel:

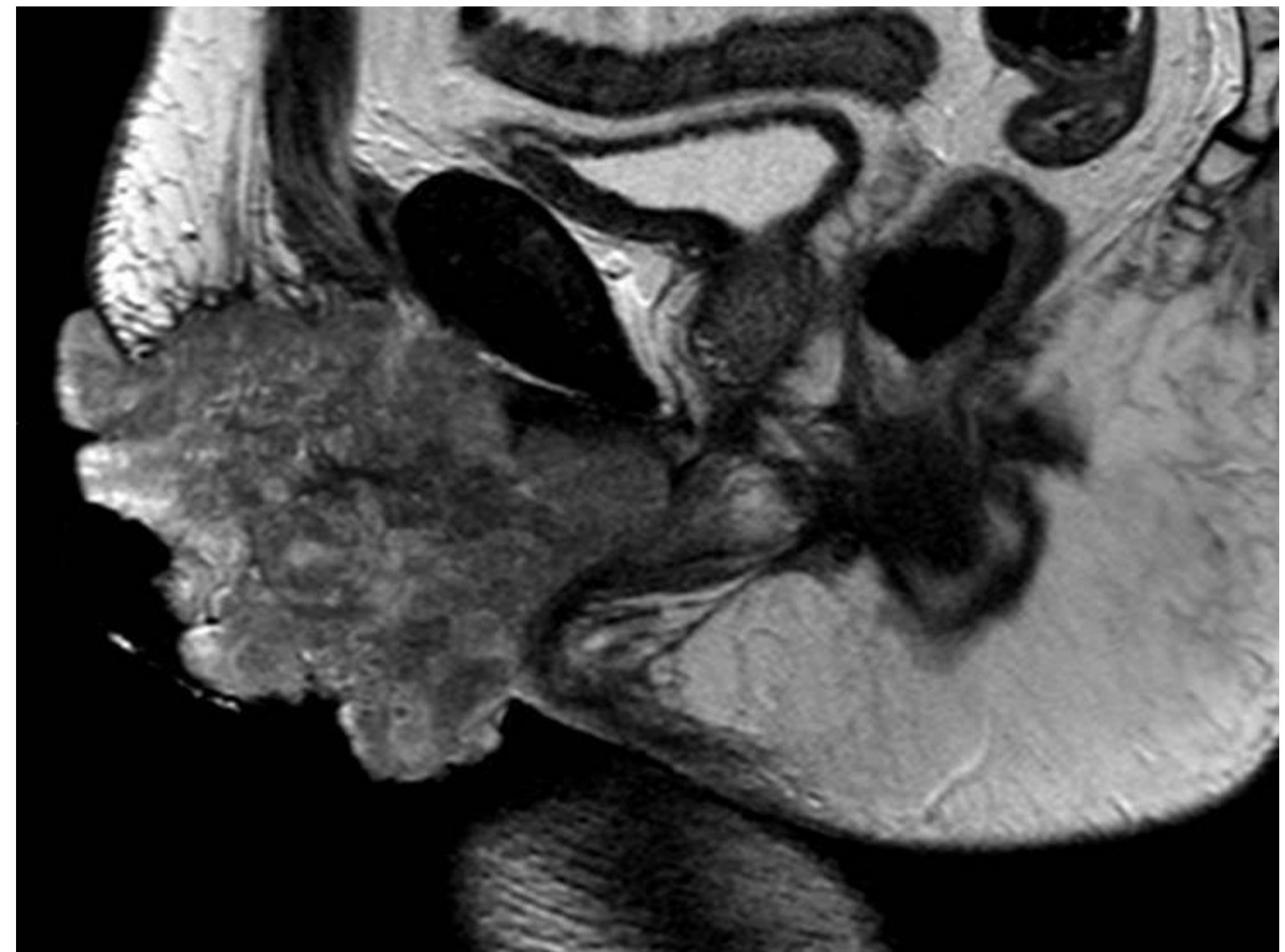
- Neoadjuvante chemotherapie
- Chemoradiatie (AVL)

Total penectomy (amputation of penis) with perineal urethrostomy
T (3), 4

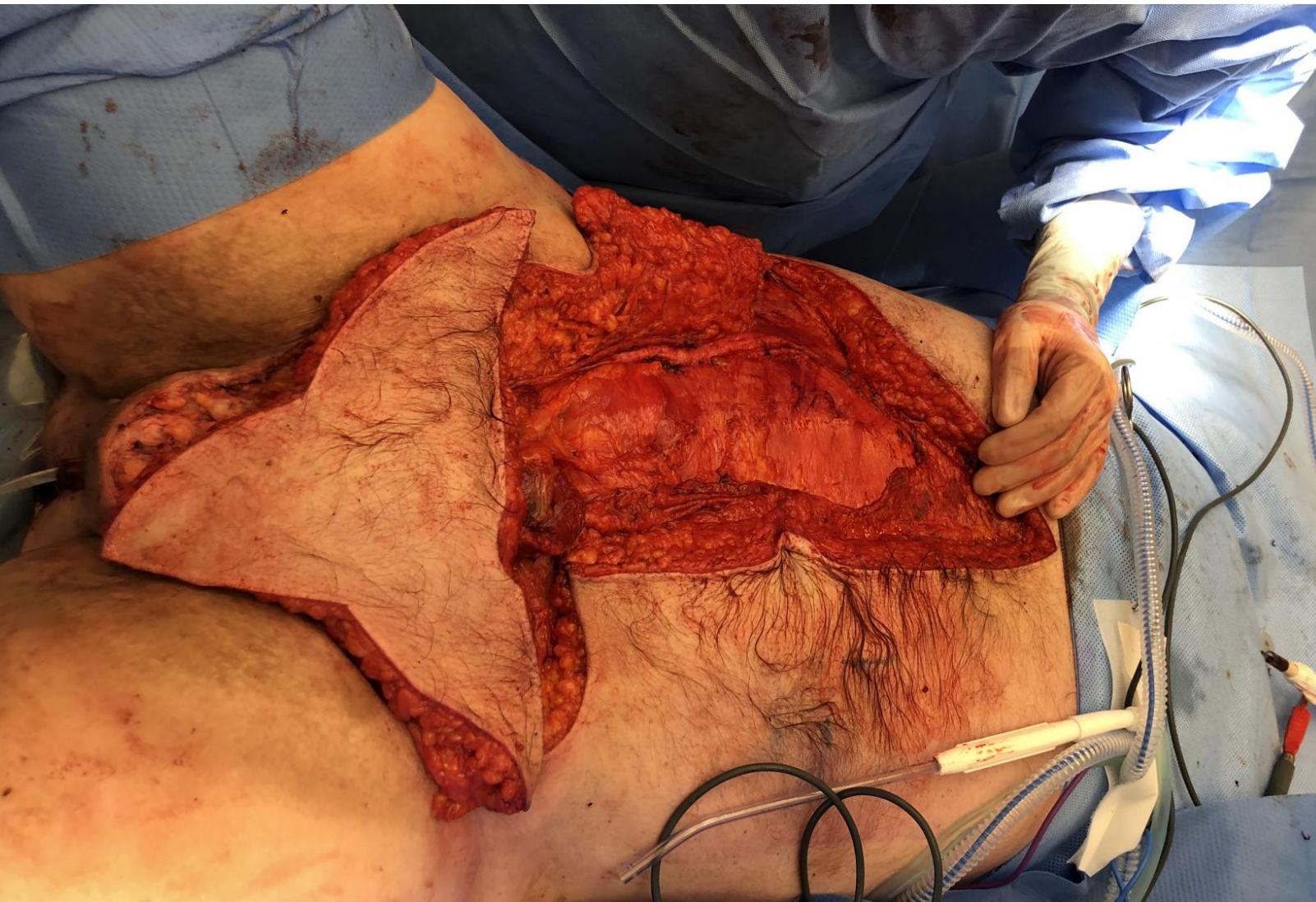
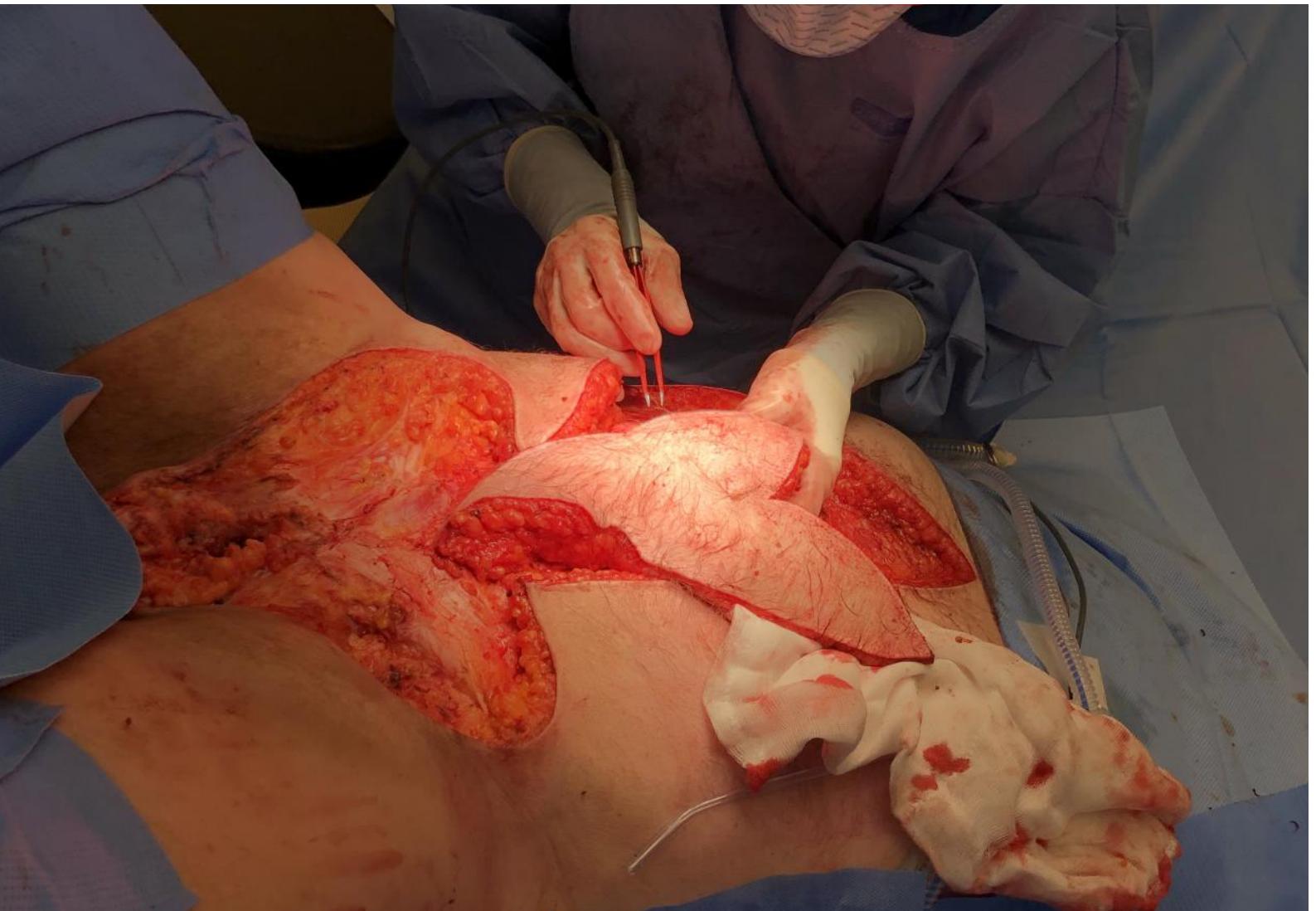
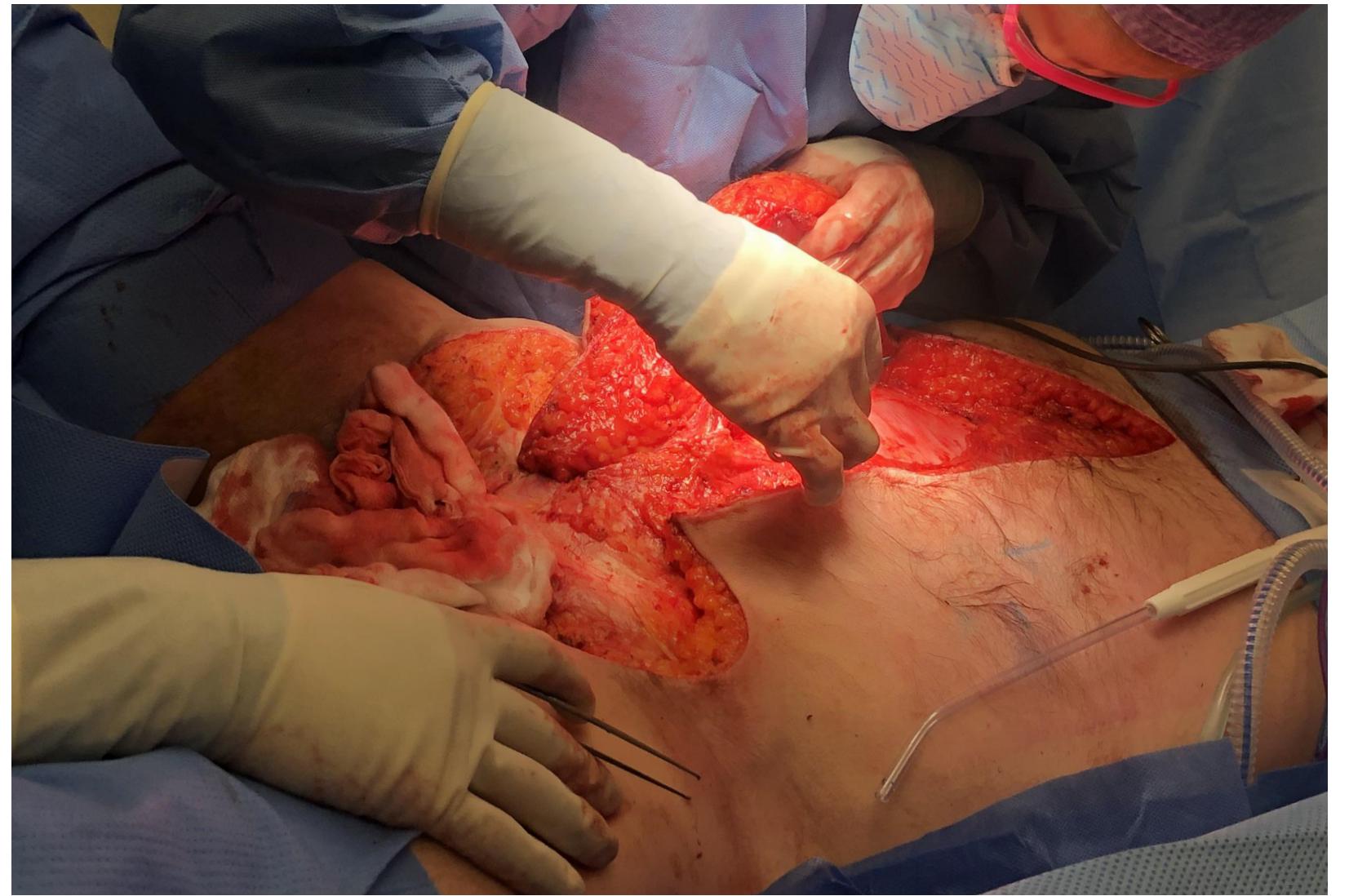
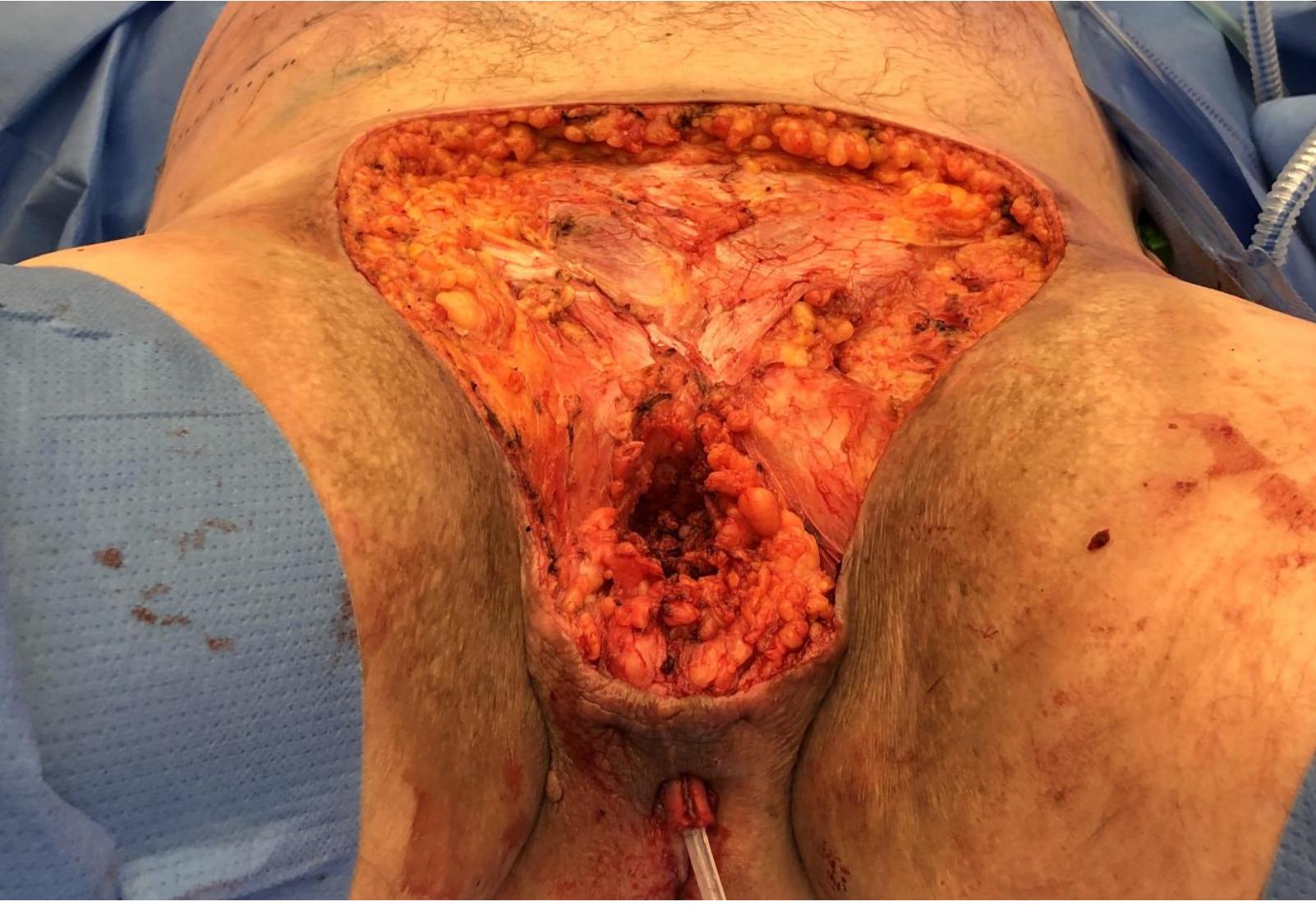
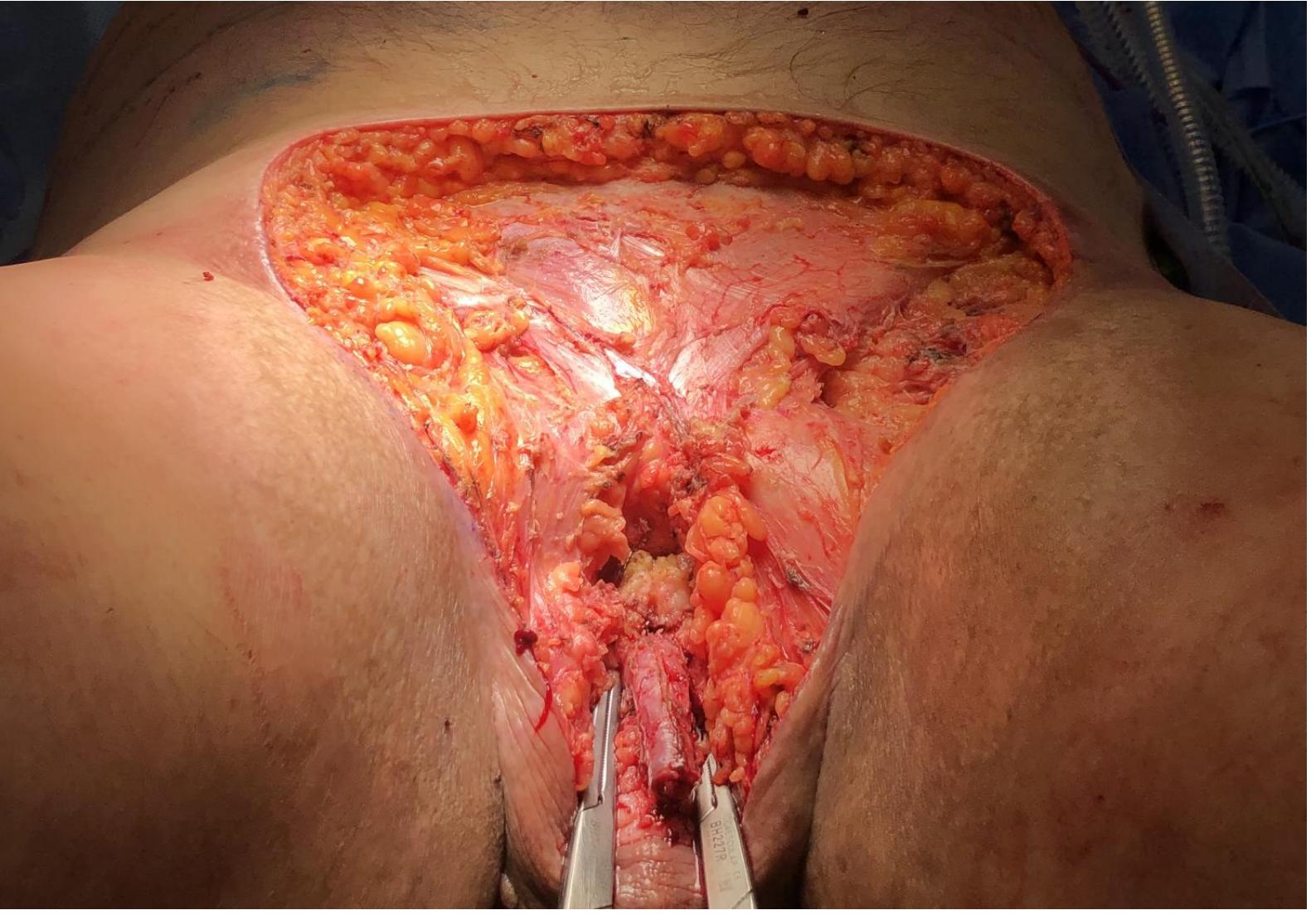


Behandeling primaire tumor: **T4**

- 58 jaar oud
- Irresectabele T4 tumor
- Neoadjuvante chemotherapie
- Neoadjuvante radiotherapie
- Totale penectomie, perineostoma, VRAM reconstructie



Behandeling primaire tumor: T4



Behandeling primaire tumor: T4



3 months after

Behandeling primaire tumor: *EAU recommendations*

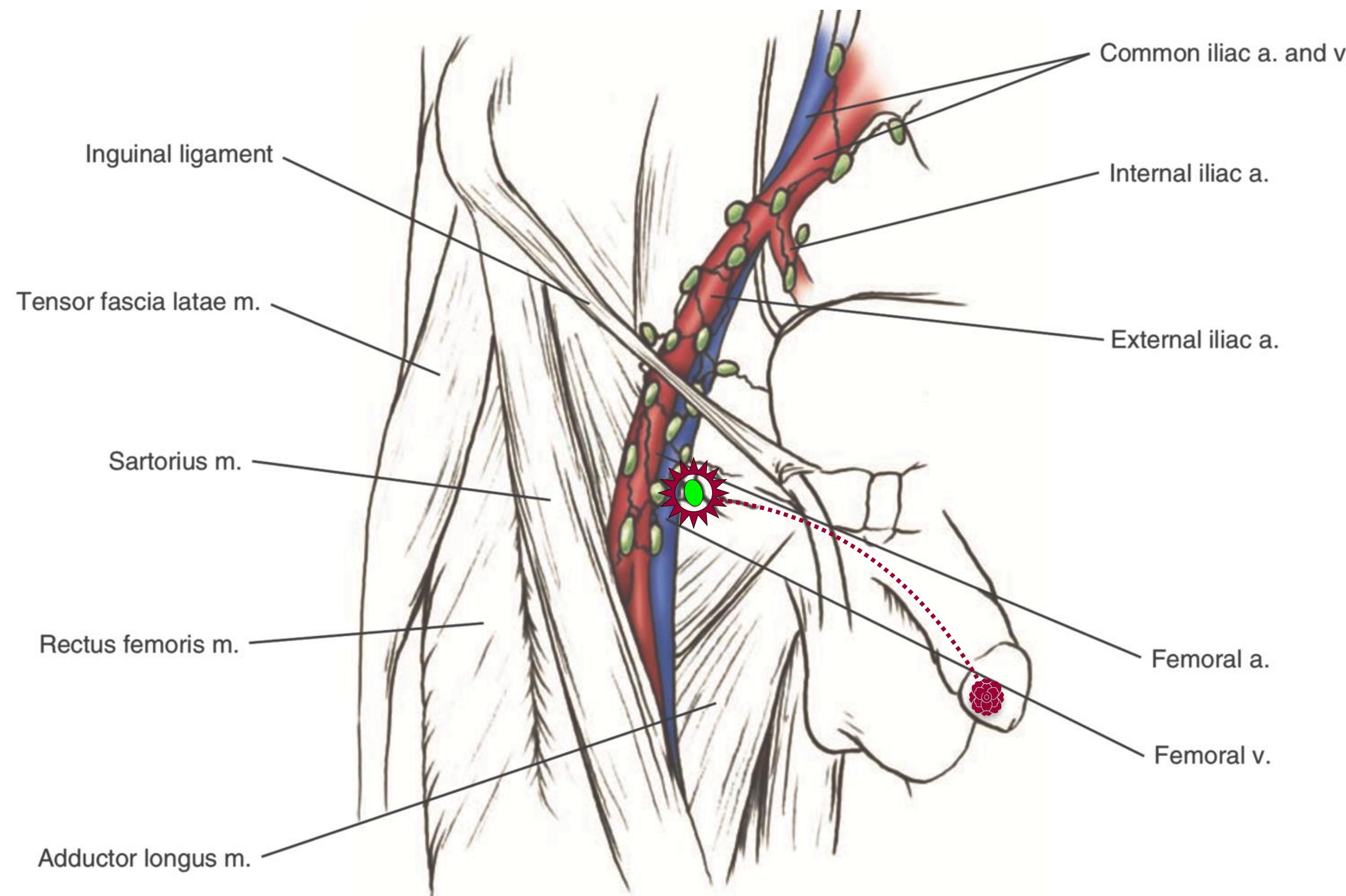
Recommendations	Strength rating
Offer a balanced and individualised discussion on benefits and harms of possible treatments options with the goal of shared decision making.	Strong
Inform patients of the higher risk of local recurrence when using organ-sparing treatments compared to amputative surgery.	Strong
<i>Topical therapy</i>	
Offer topical therapy with 5-fluorouracil or imiquimod to patients with biopsy-confirmed penile intra-epithelial neoplasia (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
<i>Laser ablation</i>	
Offer laser ablation using CO ₂ or Nd:YAG laser to patients with biopsy-confirmed PeIN, Ta or T1 lesions.	Weak

Behandeling primaire tumor: *EAU recommendations*

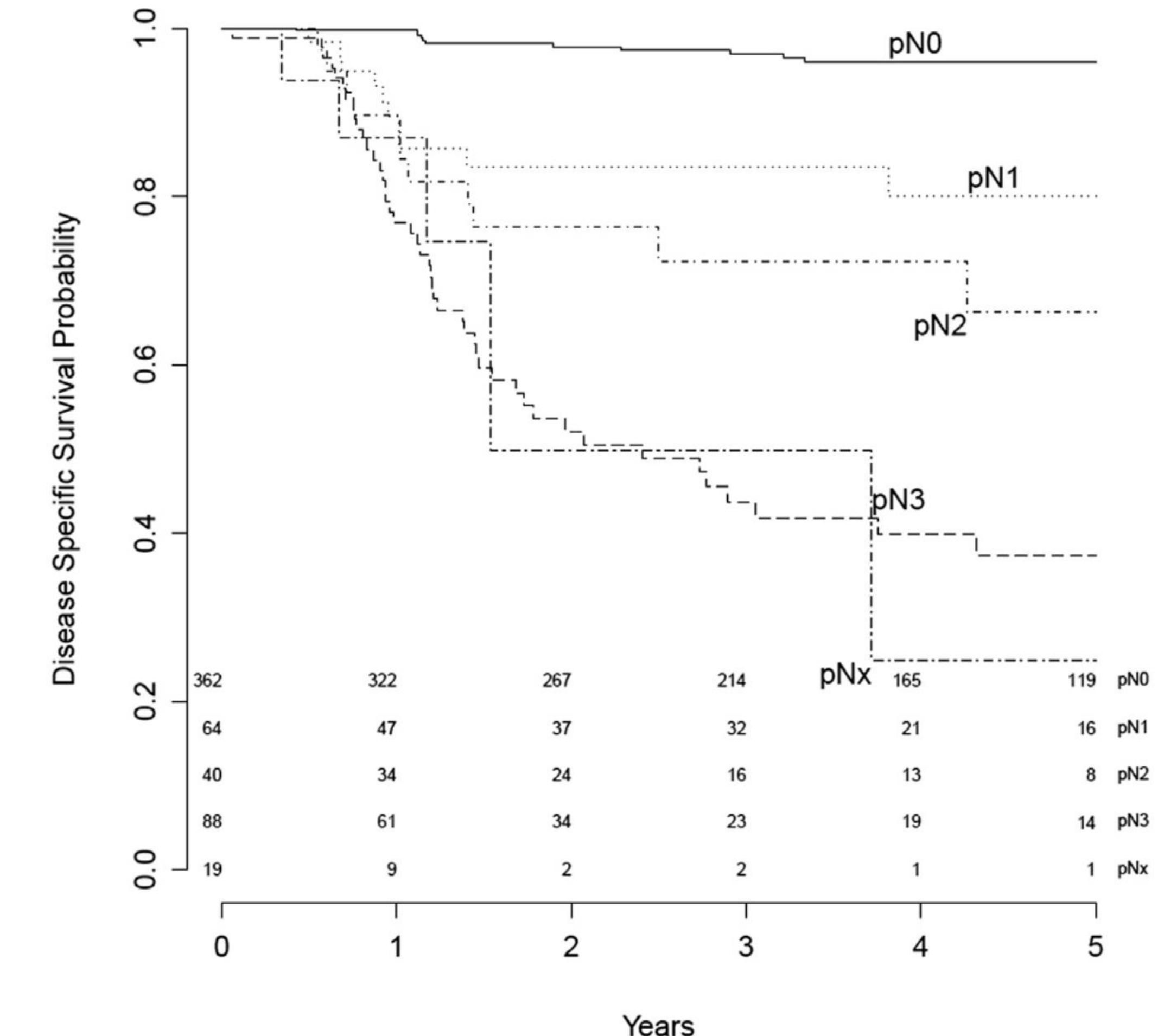
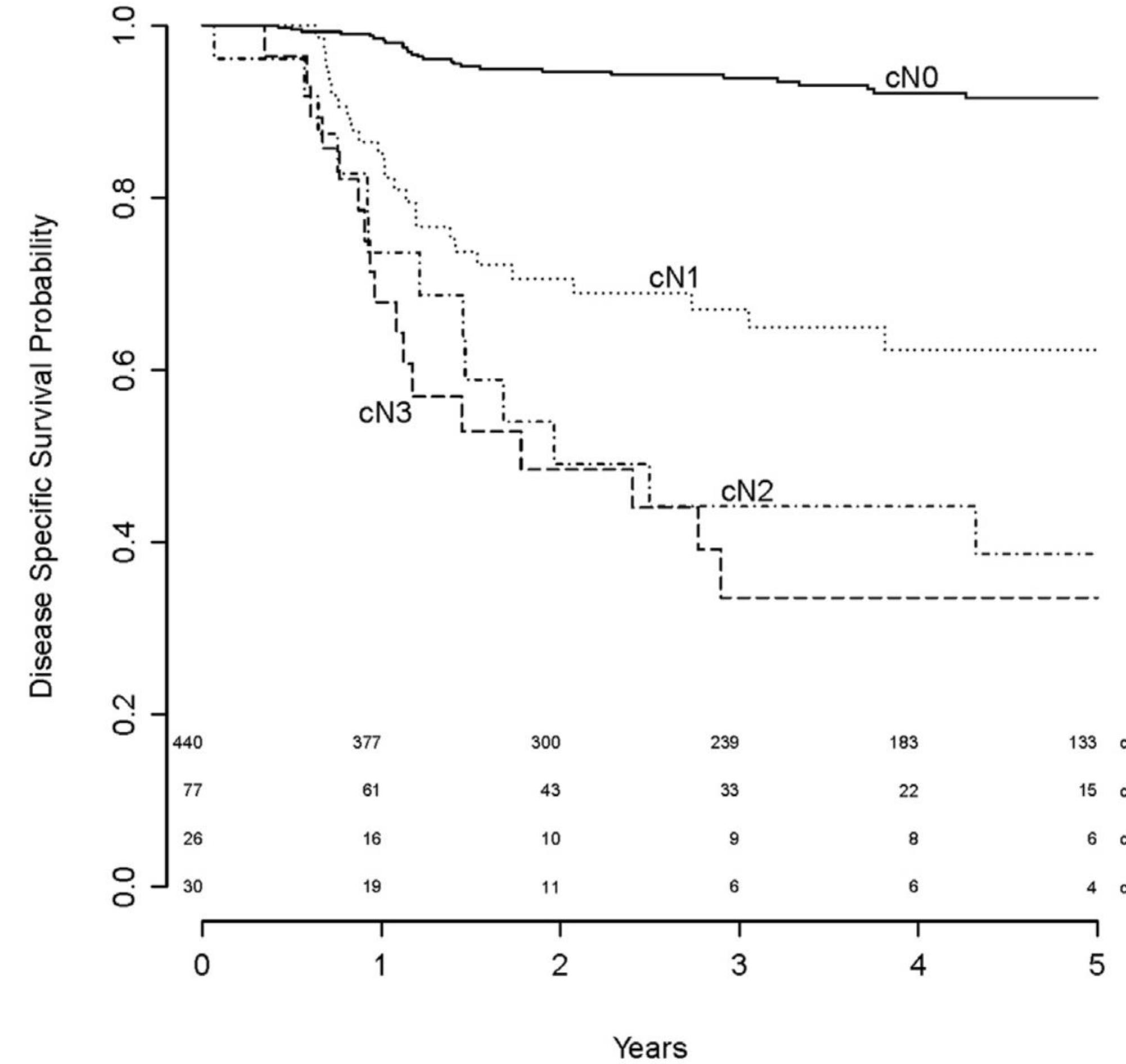
<i>Organ-sparing treatment: surgery (circumcision, wide local excision, glansectomy and glans resurfacing)</i>	
Offer organ-sparing surgery and reconstructive techniques to patients with lesions confined to the glans and prepuce (pT1N, Ta, T1-T2) and who are willing to comply with strict follow-up.	Strong
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
<i>Organ-sparing treatment: radiotherapy (EBRT and brachytherapy)</i>	
Offer radiotherapy to selected patients with biopsy-confirmed T1 or T2 lesions.	Strong
<i>Amputative surgery (partial- and total penectomy)</i>	
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
<i>Multimodal therapy</i>	
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.	Weak

Lymfeklieren bij peniscarcinoom

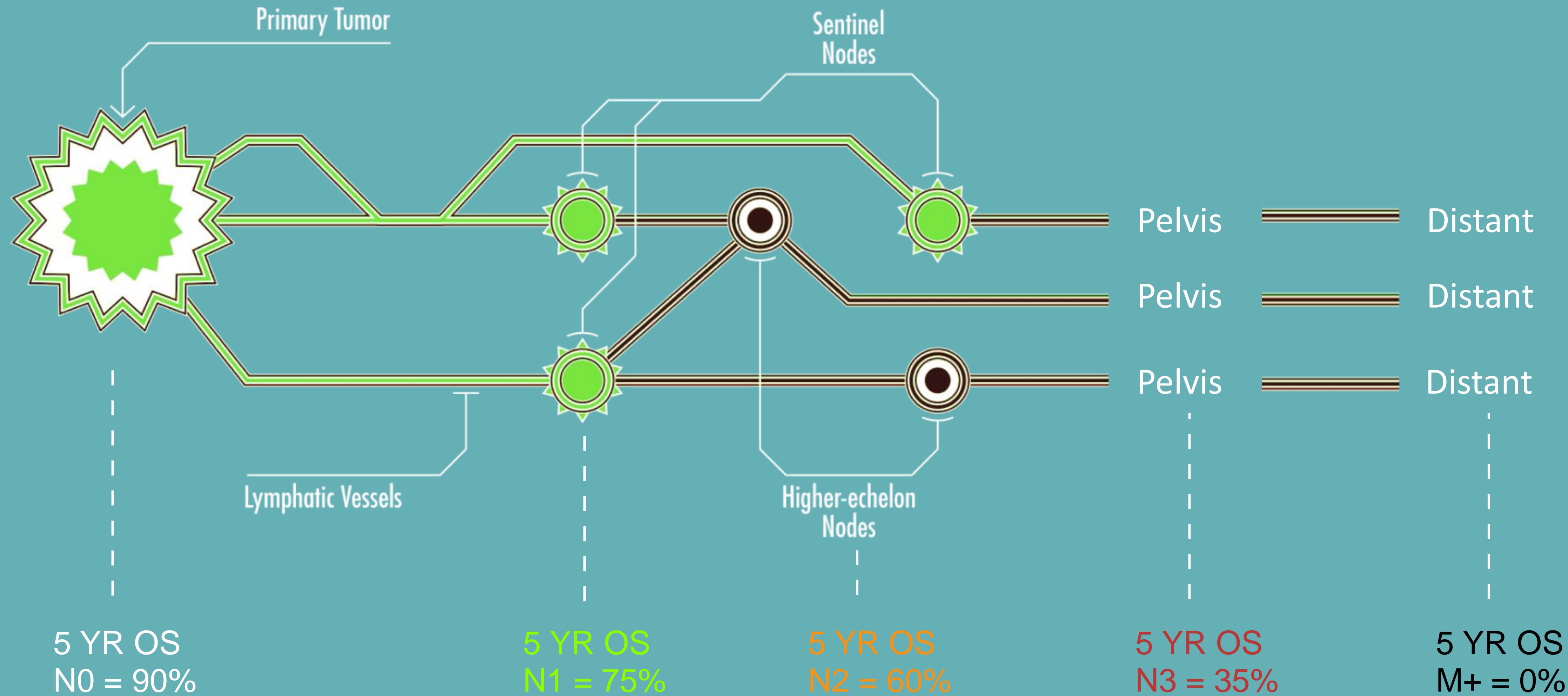
diagnostiek en behandeling



Overleving: N-status (AVL)

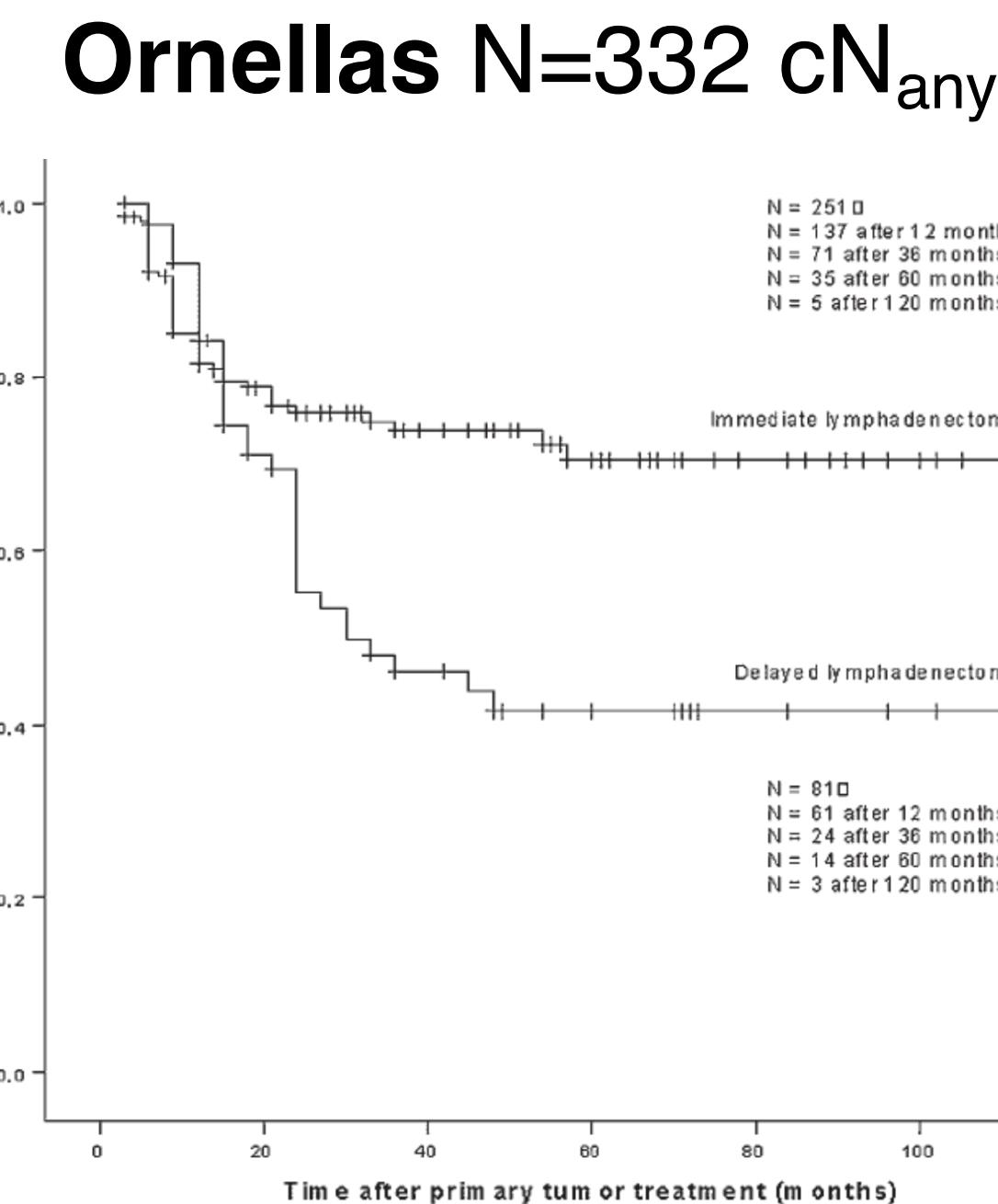
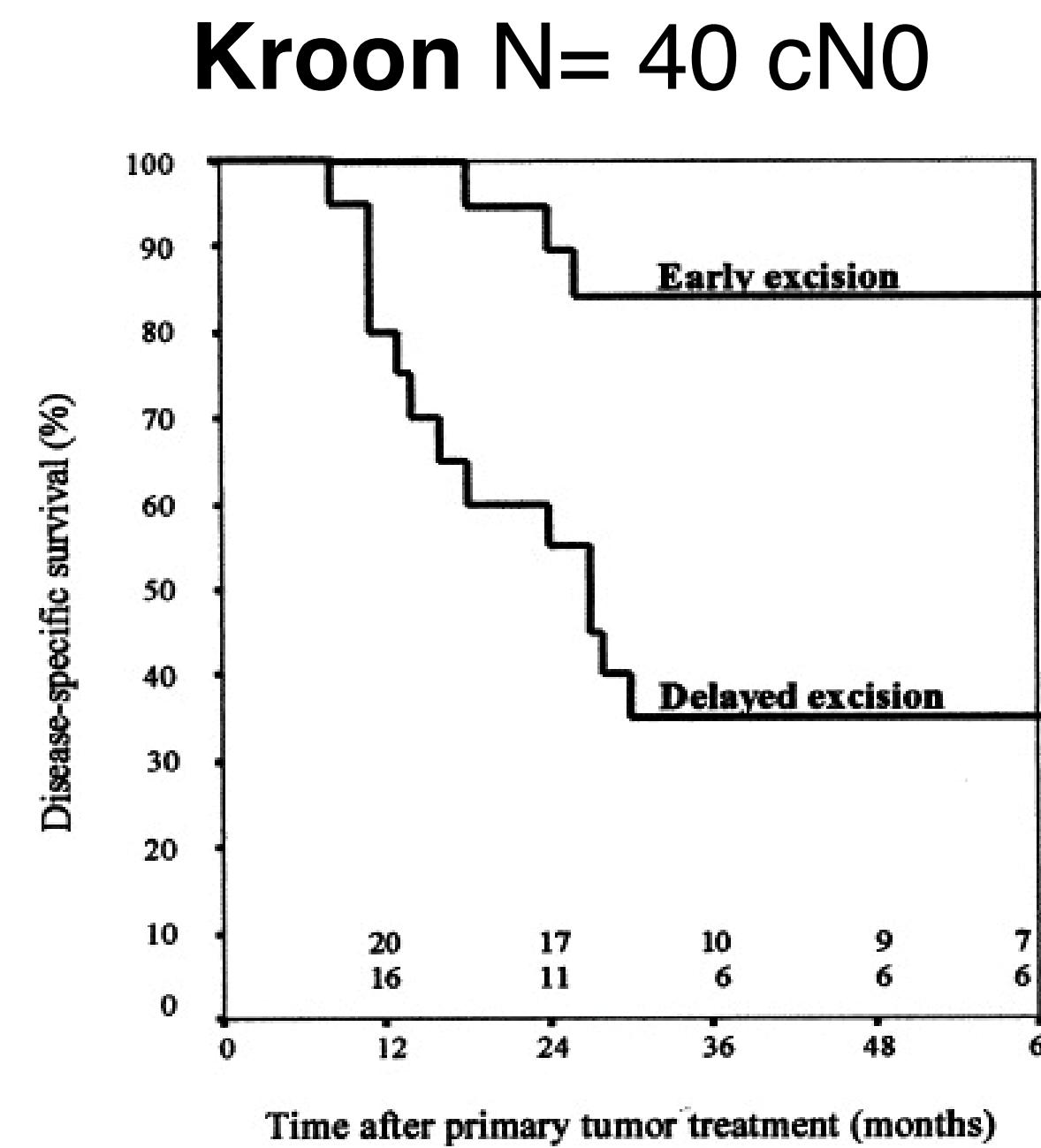


Penile cancer: metastatic pathway



Early detection LN disease is crucial

- Early resection occult metastasis vs. resection when palpable at surveillance (CSS 84% vs 35% at 3 years)



Kroon et al, J Urol 2005.
Ornellas J Surg Oncol 2008

Most patients present with non palpable nodes

- 80% are clinically node negative (cN0) at time of diagnosis
- However:

EAU risk category	Occult LN-metastasis
Good (T1G1)	0-1%
Intermediate (T1aG2)	5-10%
High (\geq T1b, T2-4)	20-25%

Approximately 10-20% still harbour occult metastases (intermediate / high risk)

No useful/validated nomograms to predict N-status

Imaging options?



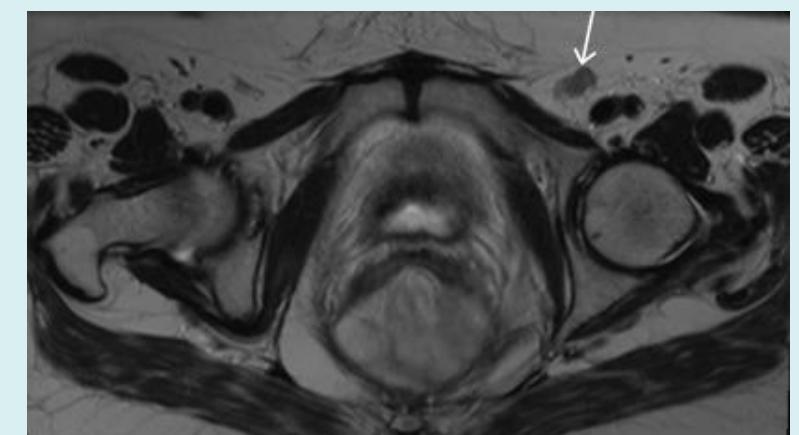
cN0: Non-invasive inguinal staging techniques remain inaccurate

Inguinal ultrasound:

- low sensitivity in cN0 (39%)
- relatively high specificity (+ FNAC) -> if N+ then radical ILND
- can reduce number of groins needing invasive staging (by 11%)

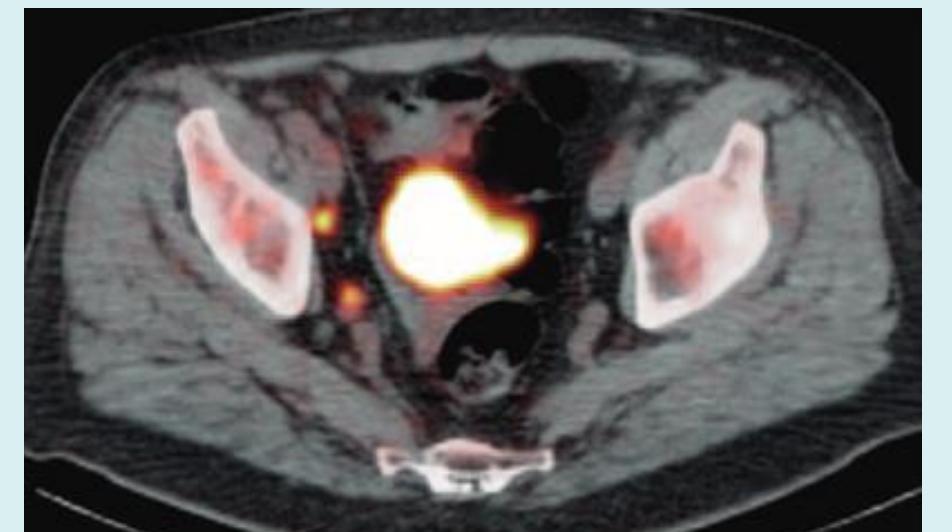


CT or MRI cannot detect micro-metastases reliably (sensitivity approx. 20-40%)



PET/CT does not detect micro-metastases reliably

- sensitivity 57% in cN0 patients (vs 91% if FNAC+)
- specificity 88-92% in cN0 patients (vs 100% if FNAC+)



Therefore, surgical staging remains indispensable for cN0 patients

Surgical staging options

Radical Inguinal Lymph Node Dissection (ILND)

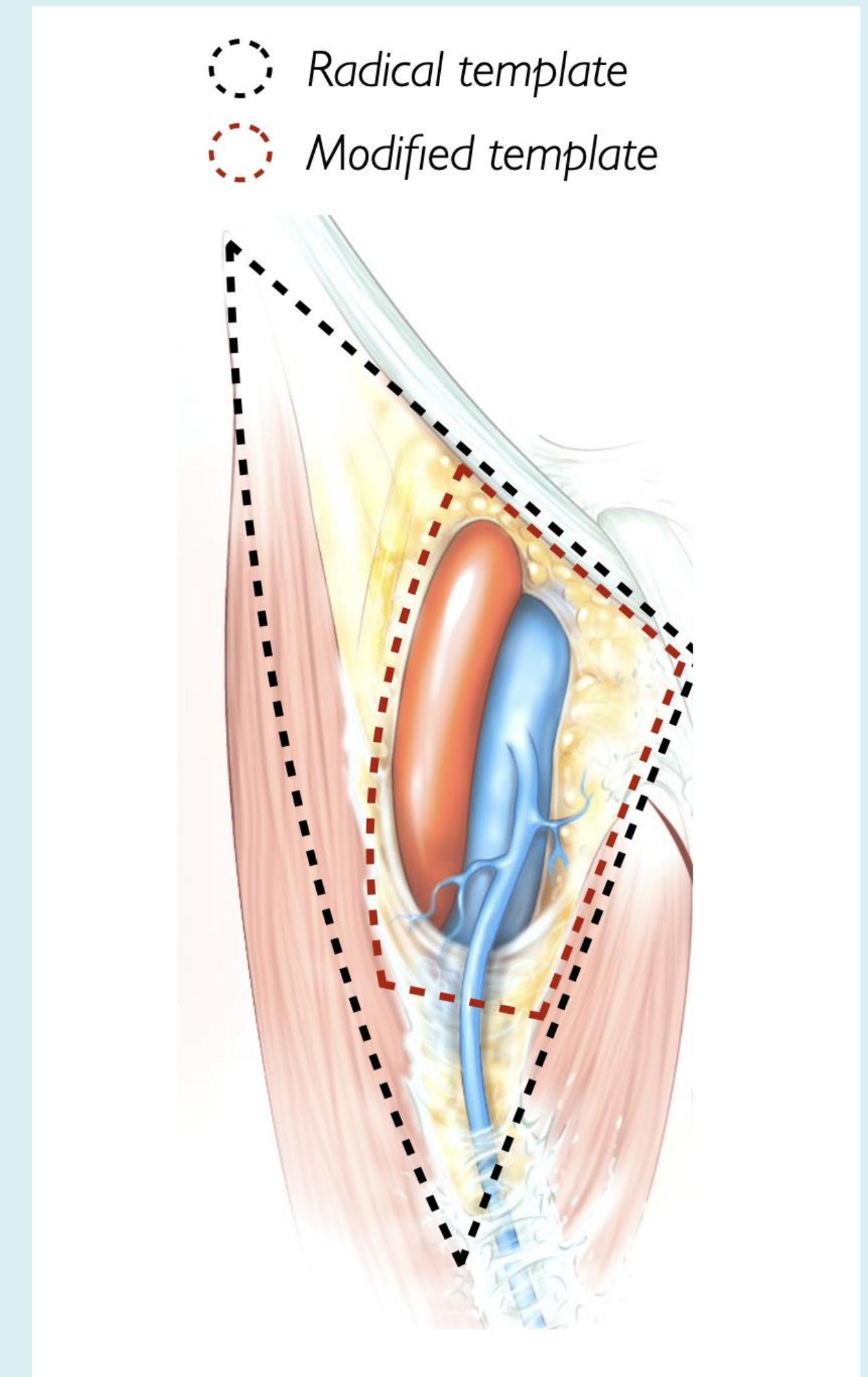
- Highest sensitivity by definition
- Highest morbidity: **50-88% complications**
- (RA)-VEIL: little data, average 35-40%

Modified Inguinal Lymph Node Dissection: (MILND)

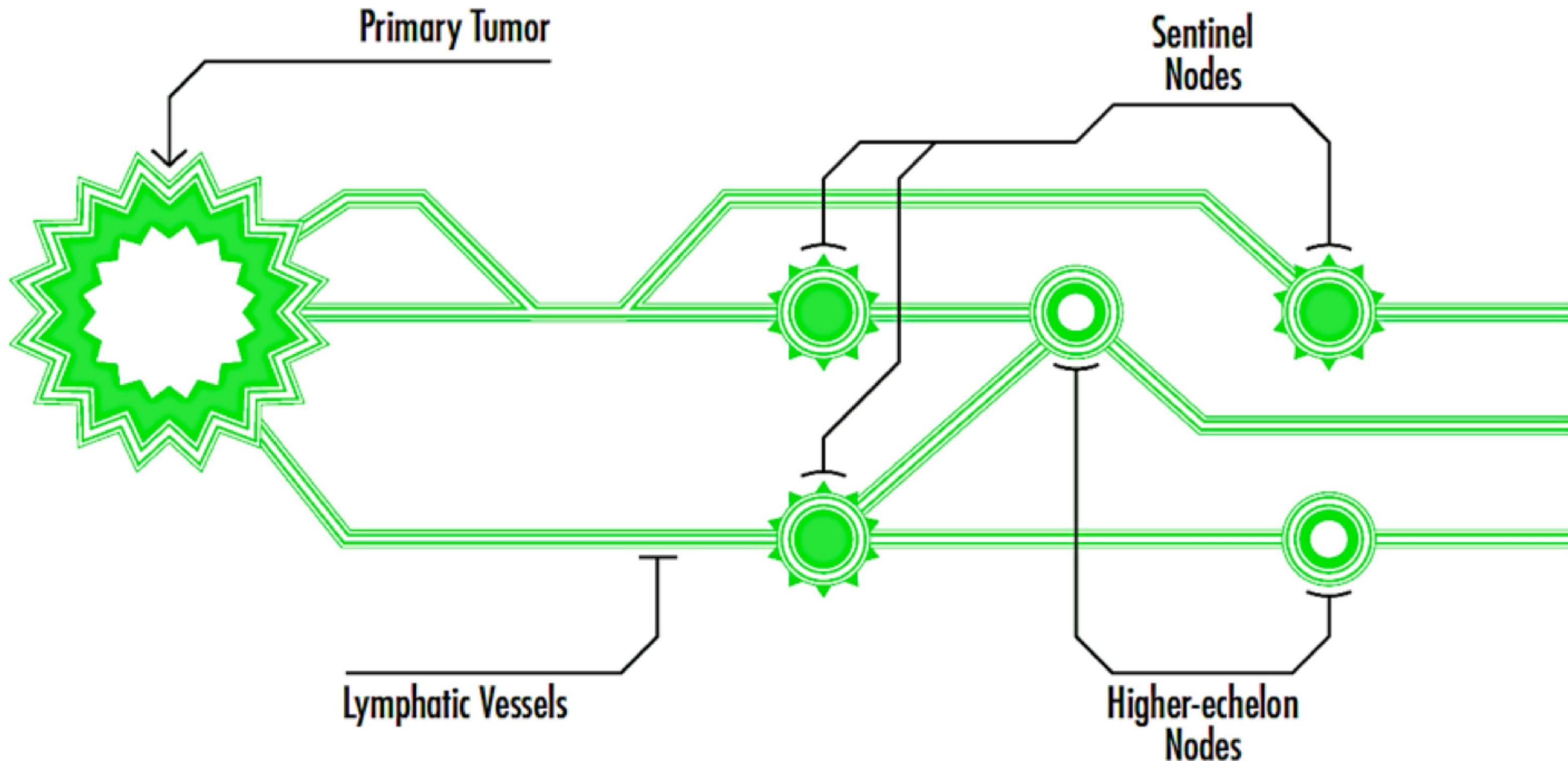
- Good sensitivity (FN rate still 7-15%)
- Still substantial morbidity: **38-58% complications**

Dynamic Sentinel Node Biopsy

- Good sensitivity (FN rate 5-15%, lowest in high volume centers)
- Can be performed in same session primary treatment, or secondary/delayed
- Lower morbidity: **6-14% complications (high volume centers)**



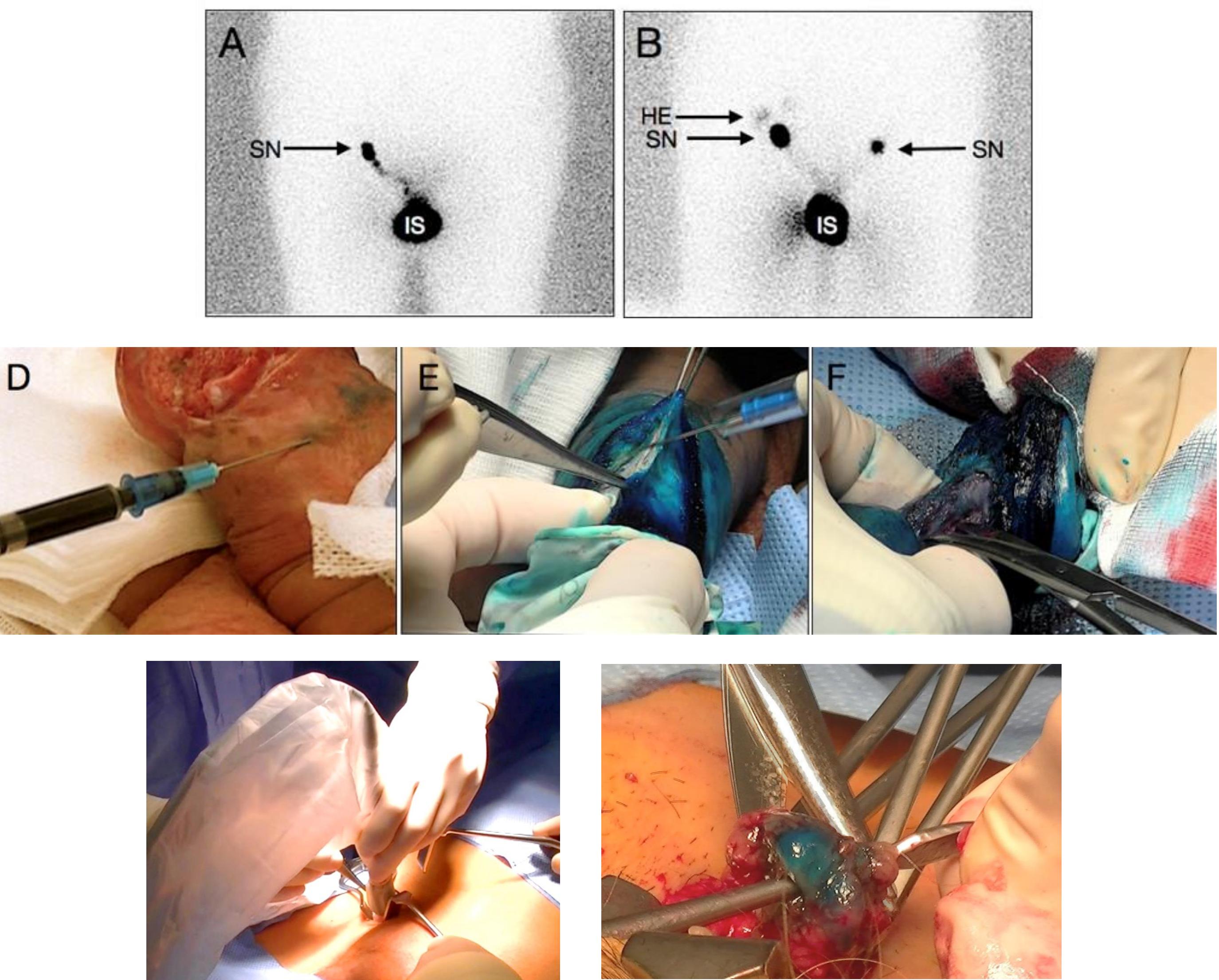
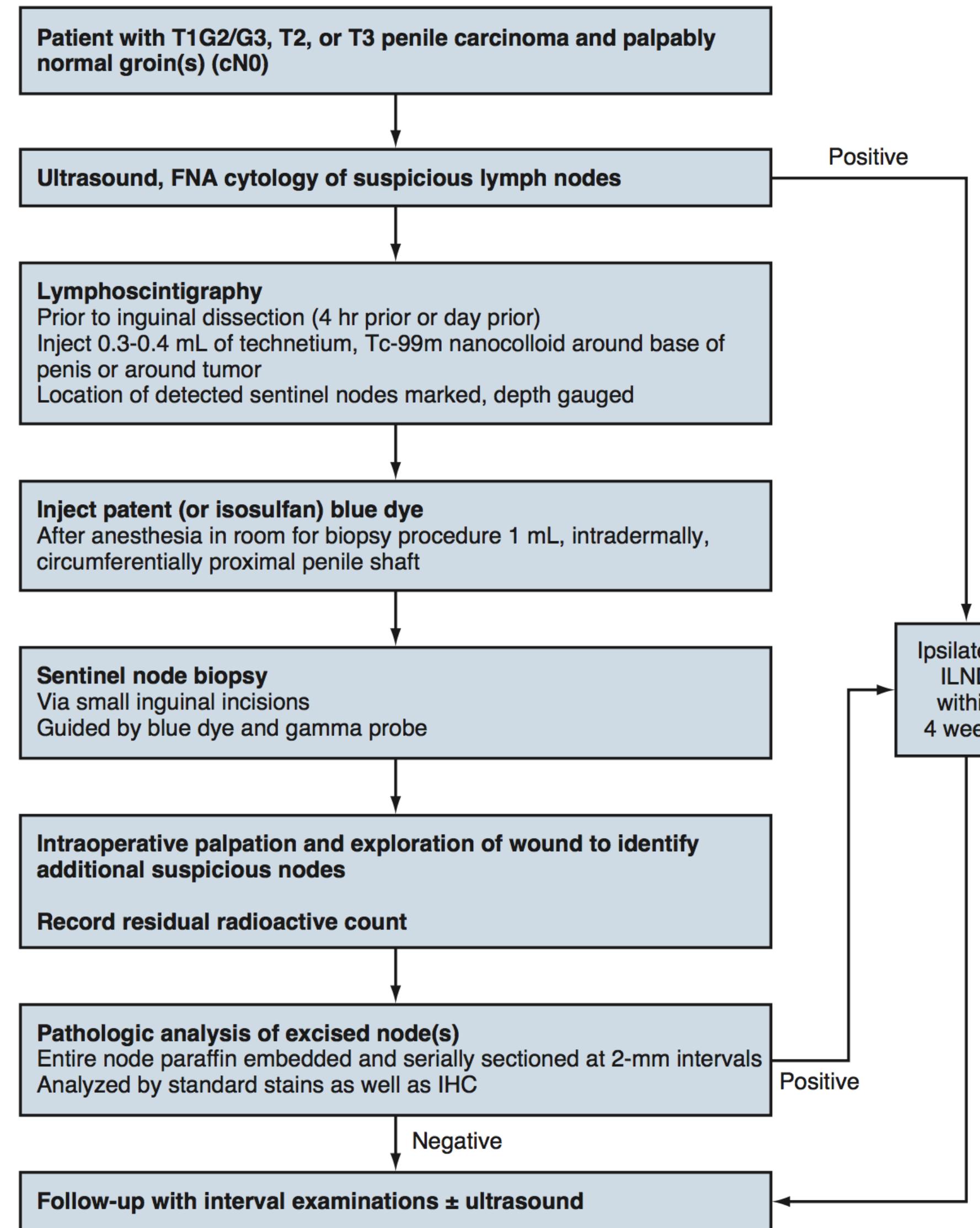
Sentinel node concept (SN)



- SN first site of nodal metastasis
- pN0 at SN = pN0 in ipsilateral lymph node basin
- SN biopsy less morbid than LND
- pN0 at SN biopsy spares patients unnecessary LND
- If SN positive: indication LND

Figure: Brouwer et al. 2013

Traditional approach LN staging: cN0 (Europe)



Hybrid DSNB: 10 year experience

available at www.sciencedirect.com
journal homepage: www.europeanurology.com



Platinum Priority – Penile Cancer

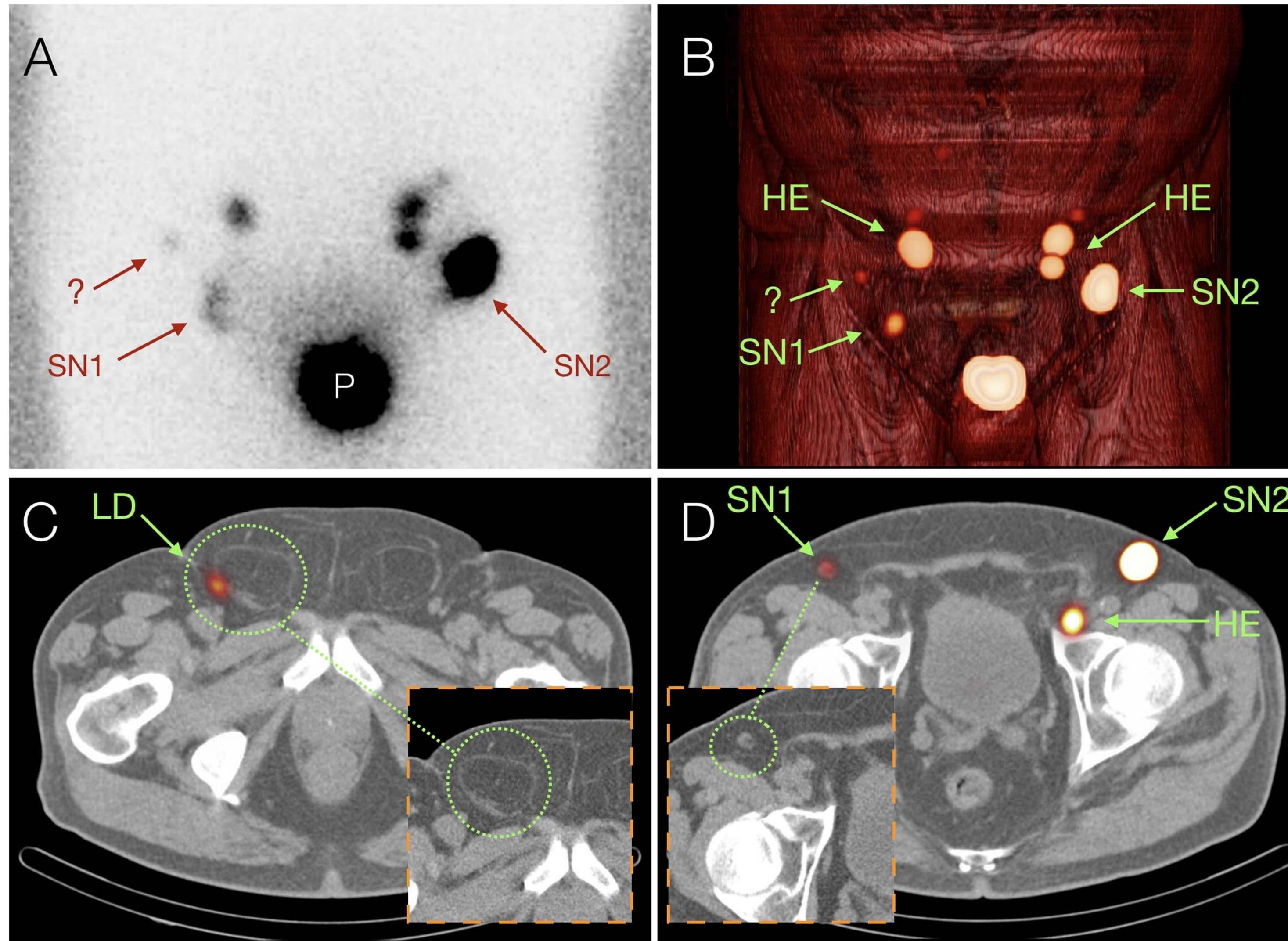
Editorial by Ahmet Murat Aydin, Nicholas H. Chakiryan and Philippe E. Spiess on pp. 873–874 of this issue

Hybrid Indocyanine Green-^{99m}Tc-nanocolloid for Single-photon Emission Computed Tomography and Combined Radio- and Fluorescence-guided Sentinel Node Biopsy in Penile Cancer: Results of 740 Inguinal Basins Assessed at a Single Institution

Paolo Dell'Oglio ^{a,b,c,1}, Hielke M. de Vries ^{b,c,1}, Elio Mazzone ^d, Gijs H. KleinJan ^{c,e}, Maarten L. Donswijk ^f, Henk G. van der Poel ^b, Simon Horenblas ^b, Fijt W.B. van Leeuwen ^{b,c}, Oscar R. Brouwer ^{b,c,*}

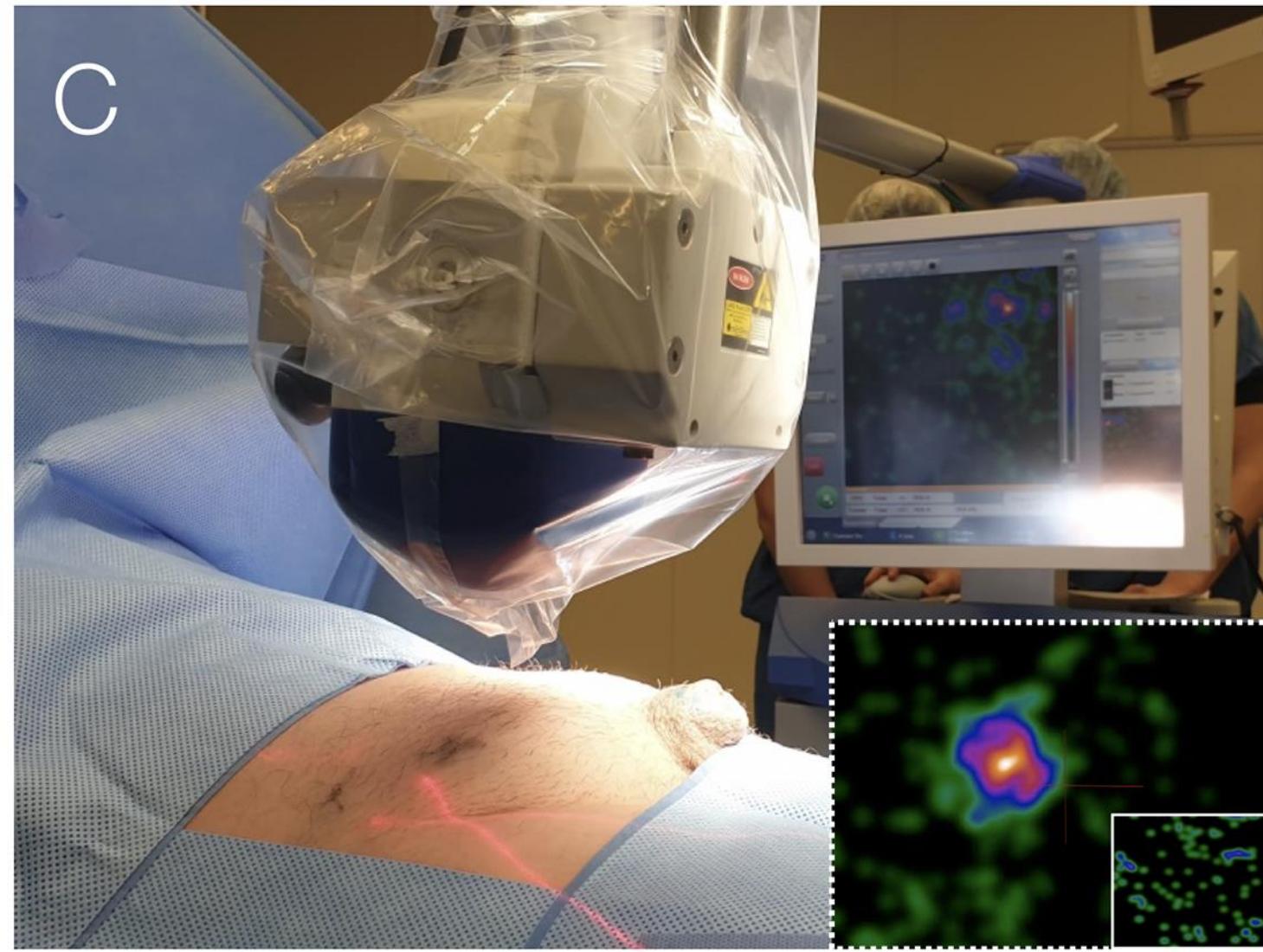
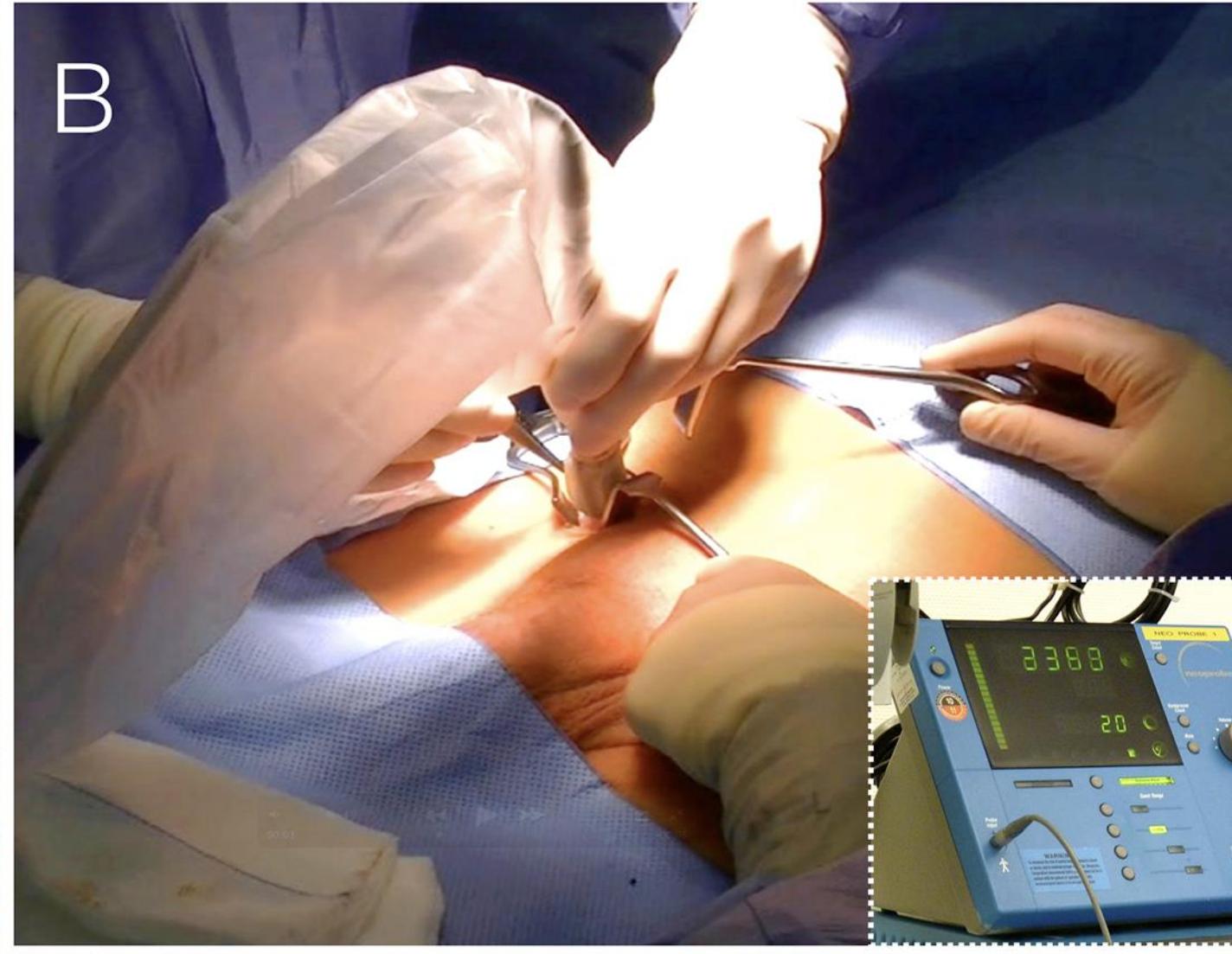
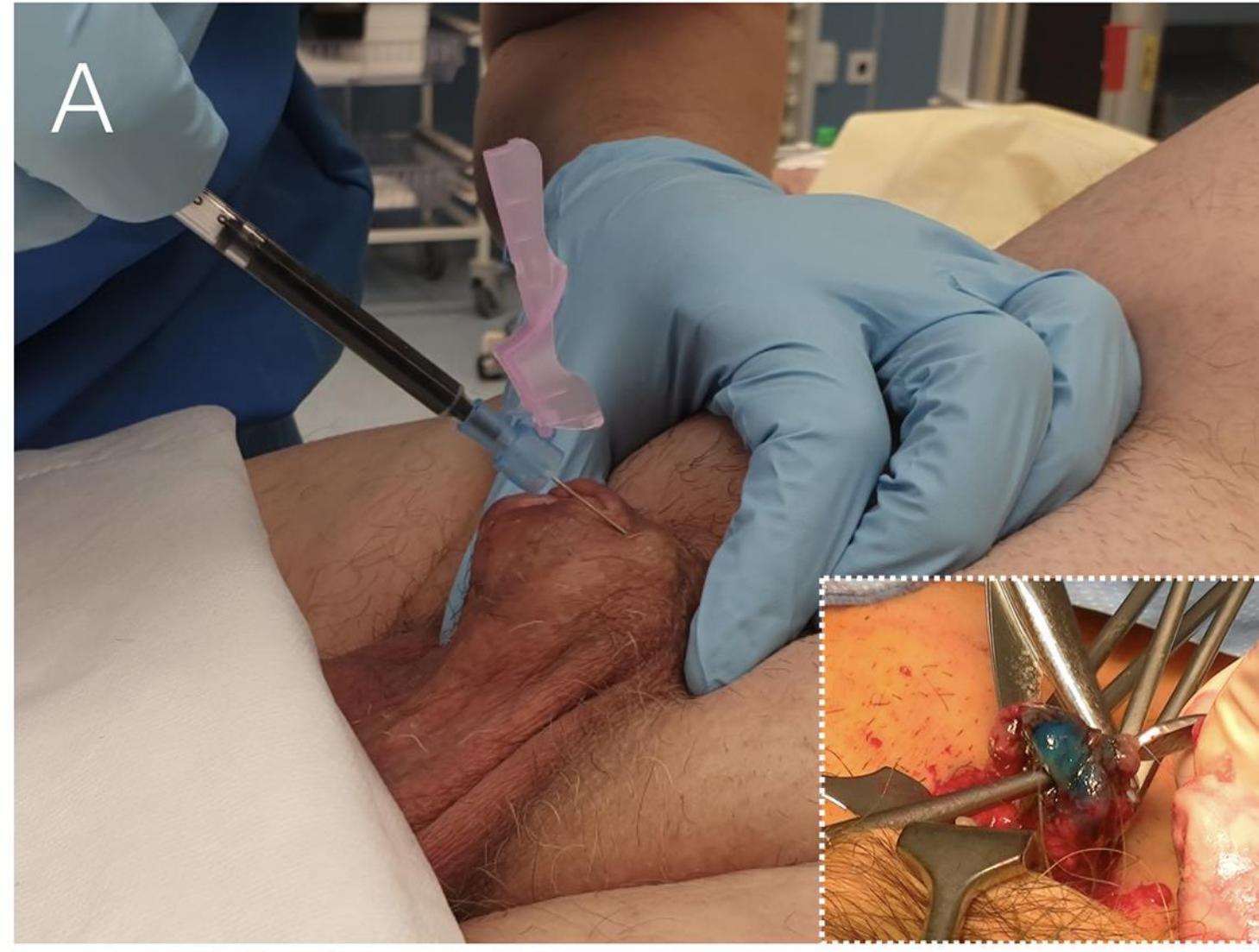
^aDepartment of Urology, ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy; ^bDepartment of Urology, Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands; ^cInterventional Molecular Imaging Laboratory, Department of Radiology, Leiden University Medical Center, Leiden, The Netherlands; ^dDepartment of Urology and Division of Experimental Oncology, URI, Urological Research Institute, IRCCS San Raffaele Scientific Institute, Milan, Italy; ^eDepartment of Urology, Leiden University Medical Center, Leiden, The Netherlands; ^fDepartment of Nuclear Medicine, Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands

SPECT/CT



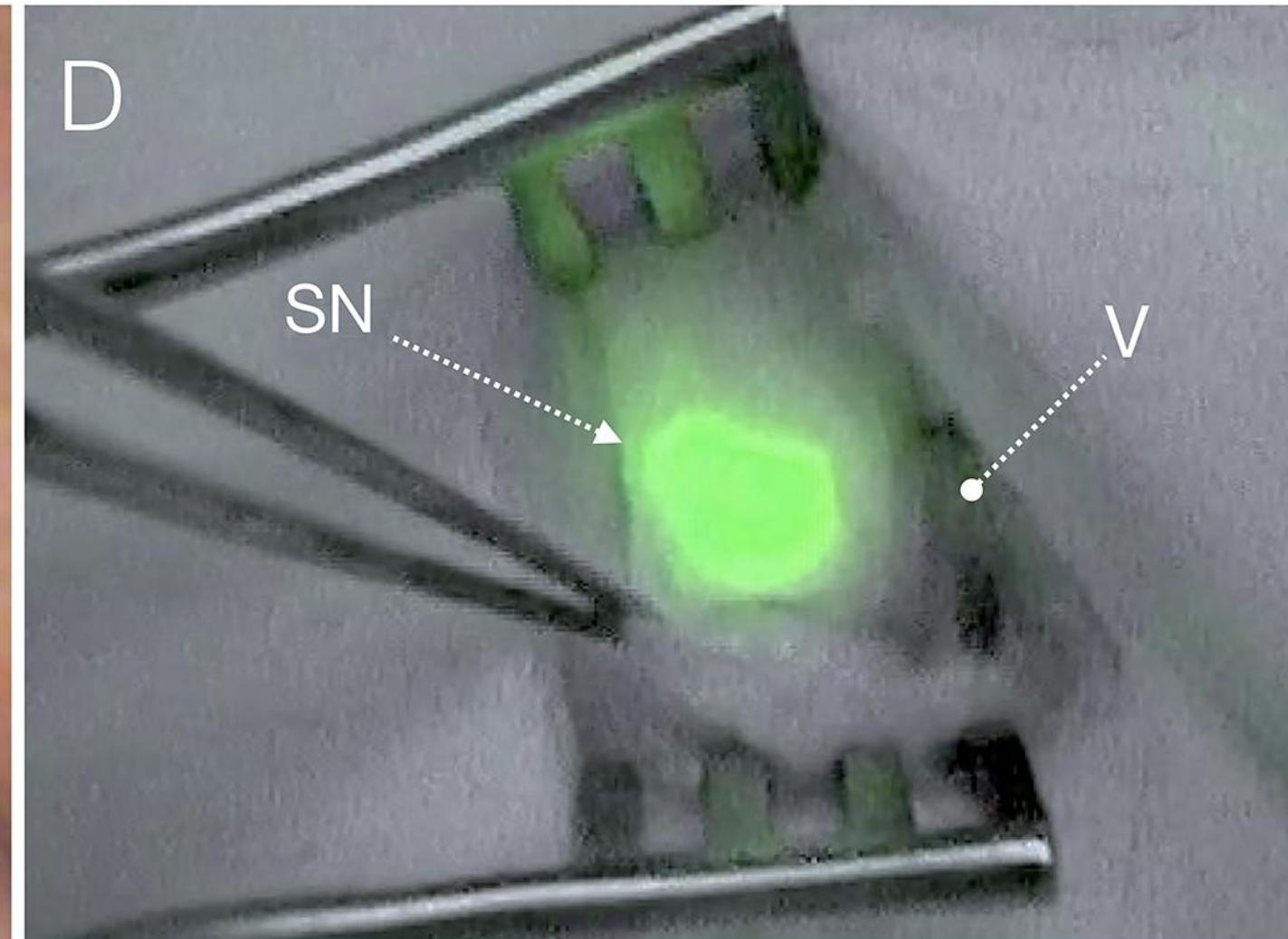
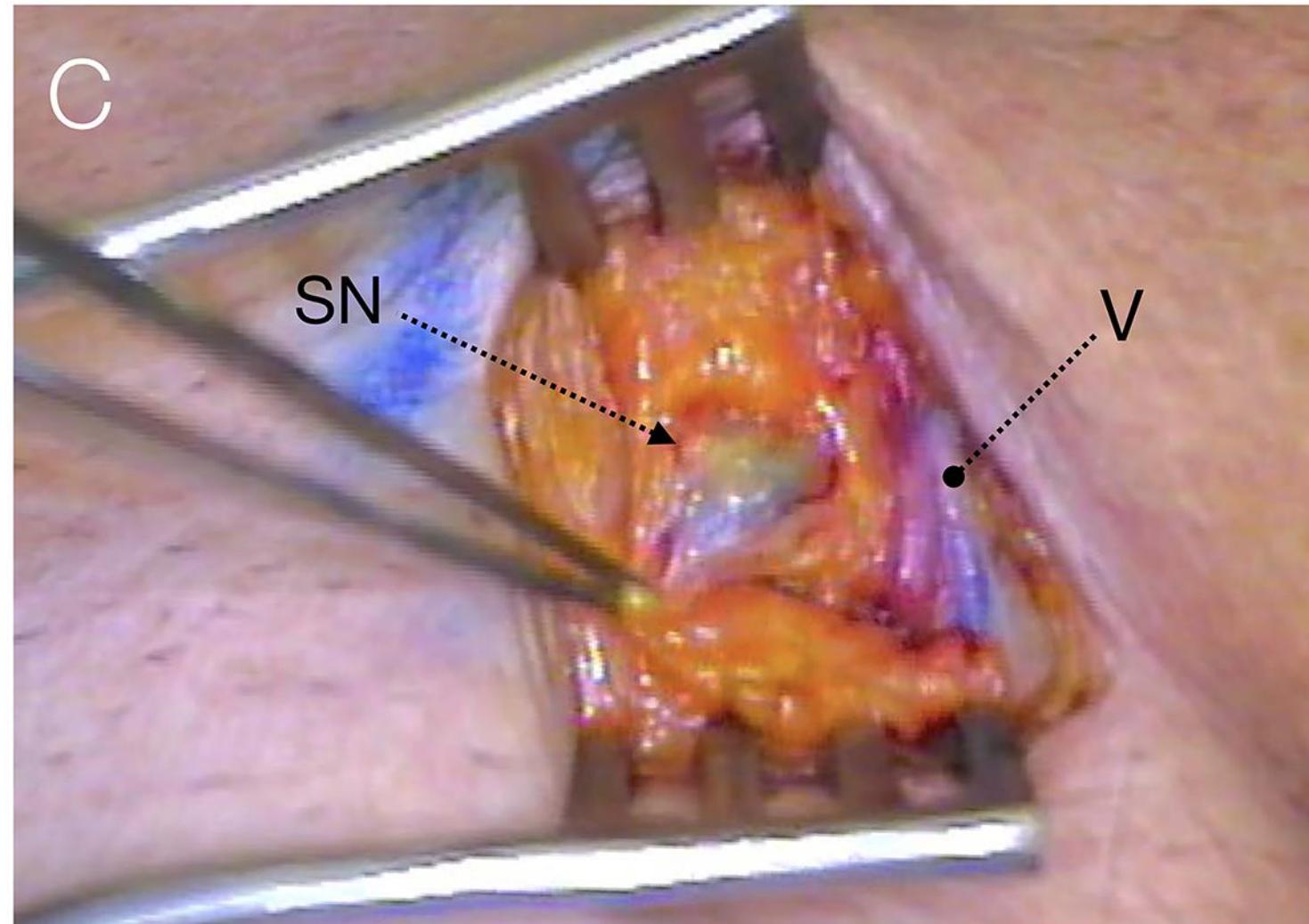
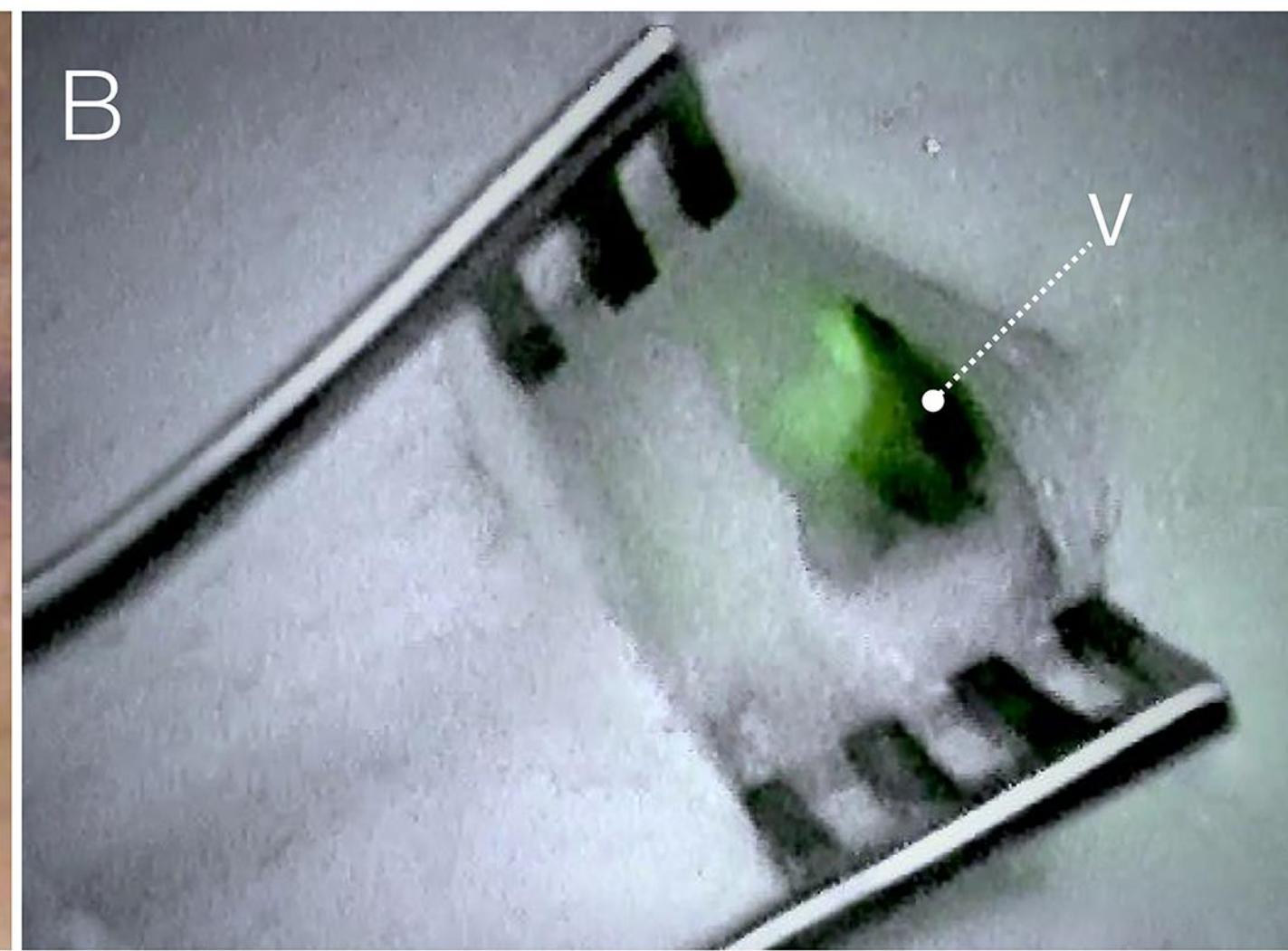
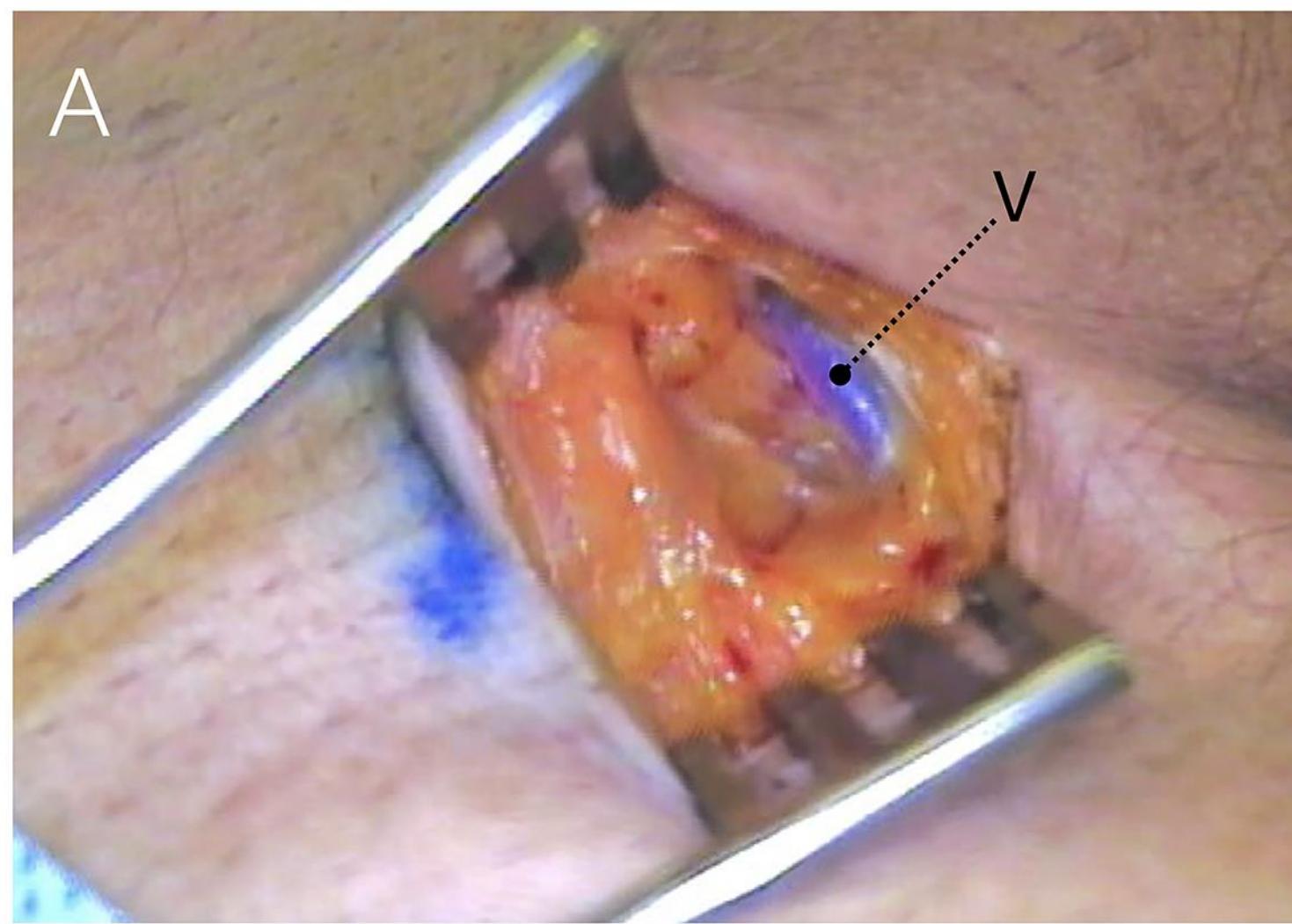
- Increased sensitivity: detection of more SNs
- 3D surgical 'roadmap'
- Differentiation of SNs and higher echelon (pelvic) nodes
- Corresponding node on CT
- Can identify pathologic node that did not pick up tracer

Comparison of blue dye vs. fluorescence guided SN biopsy



- $\geq T1G2N0$ PeCa patients
- n=400, 740 groins
- ICG- 99m Tc-nanocolloid
- SPECT/CT
- Radio/Flu guided SN biopsy

Blue dye vs. ICG



Comparison with blue dye:

- n=266, 492 groins, 900 SNs
- **ICG vs Blue: 95 vs 56% ($p<0.001$)**
- **16% of positive SNs not blue**

- Median F/U 400 pts (740 groins): 36 mo
- False neg. rate per groin 8.7% (FN)
- Probability of a neg procedure to become FN at 2-years of 1.4%
- **(8 FN-groins / 740 groins)**
- **Diagnostic accuracy 99%**

Hybrid ICG-^{99m}Tc-nanocolloid for SPECT/CT and combined radio-and fluorescence-guided sentinel node biopsy in penile cancer: results of 740 inguinal basins assessed at a single institution

Paolo Dell'Oglio, Hielke M. de Vries, Elio Mazzone, Gijs H. KleinJan, Maarten L. Donswijk, Henk G. van der Poel, Simon Horenblas, Fijs W.B. van Leeuwen, Oscar R. Brouwer

**Netherlands Cancer Institute, Antoni van Leeuwenhoek Hospital, Amsterdam
Leiden University Medical Center, Leiden, the Netherlands**

SUPPLEMENTARY VIDEO: HYBRID SENTINEL NODE PROCEDURE

Learning curve?

- Breast Cancer: 20-40 procedures
- *Recommendation consensus: 20 per year*
- Gynecological: 27-40 procedures
- Penile Cancer (meta-analysis, 17 studies*):
 - Pooled sensitivity: 88%
 - Subgroup high volume centers (>30): 92-97%
 - *Amsterdam : 80 SN procedures per year*

The Learning Curve in Sentinel Node Biopsy:
The ALMANAC Experience

The learning curve and sentinel node biopsy

**Learning curve for sentinel lymph node mapping
in gynecologic malignancies**

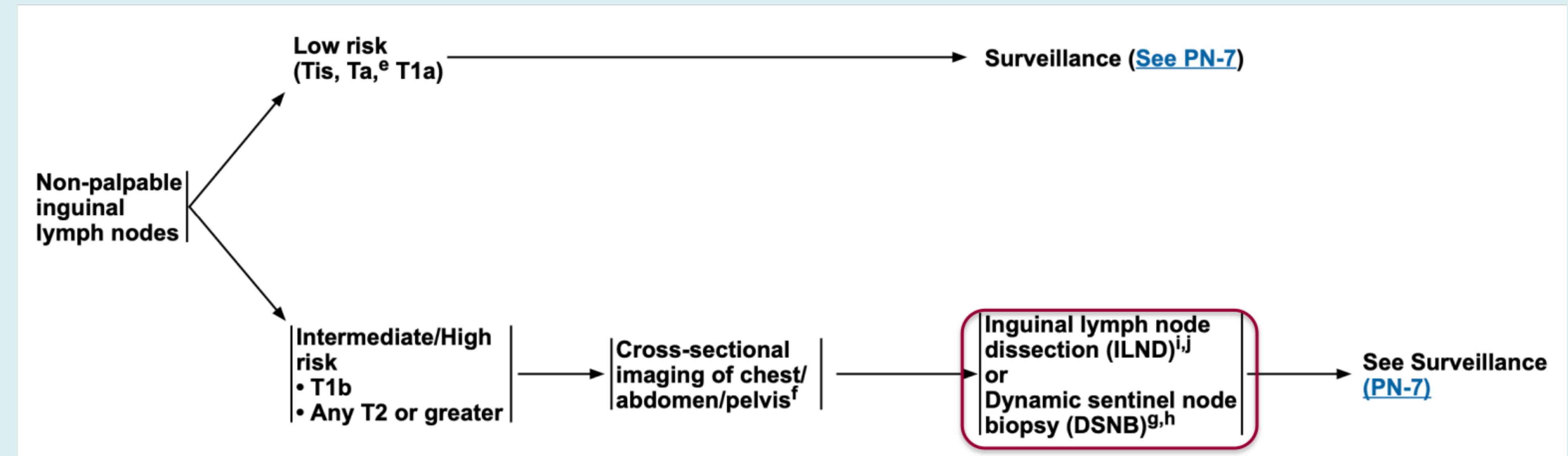


European
Association
of Urology

Regional lymph nodes	Management of regional lymph nodes is fundamental in the treatment of penile cancer	Strength rating
No palpable inguinal nodes (cN0)	Tis, Ta G1, T1G1: surveillance. > T1G2: invasive lymph node staging by either bilateral modified inguinal lymphadenectomy or dynamic sentinel node biopsy.	Strong Strong



National
Comprehensive
Cancer
Network®



Previous guideline: Intermediate risk: **T1aG2 or higher = indication surgical staging**

Lymphovascular and perineural invasion are risk factors for inguinal lymph node metastases in men with T1G2 penile cancer

Christian D. Fankhauser^{1,2,3,15}  · Hielke M. de Vries^{4,5} · Eduard Roussel⁶ · Jakob Kristian Jakobsen⁷ · Allaудин Issa¹ · Esther W. C. Lee¹ · Nicolo Schifano^{8,9,10} · Hussain Alnajjar^{8,9,10} · Fabio Castiglione^{8,9,10} · Luca Antonelli^{2,11} · Pedro Oliveira¹² · Maurice Lau¹ · Arie Parnham¹ · Maarten Albersen⁶ · Nicholas A. Watkin¹³ · Asif Muneer^{8,9,10} · Ben E. Ayres¹³ · Oscar R. Brouwer^{4,5} · Vijay Sangar^{1,14}

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- Multicenter analysis 544 patients with T1G2
- T1aG2: 6% N+
- T1bG2: 22-30% N+

Recommendations cN0: 2023

<i>Clinically node negative (cN0)</i>	
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 T1aG2 disease, also discuss surveillance as an alternative to surgical staging for 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 fine needle aspiration cytology (FNAC) of sonographically abnormal LNs.	Strong

Recommendations cN+: 2023

Clinically node positive (cN+)

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 positron emission tomography (PET/CT) or CT of the chest+abdomen before initiating treatment.

Strong

Lymph node imaging penile cancer (cN+)

If palpable abnormalities in groin:

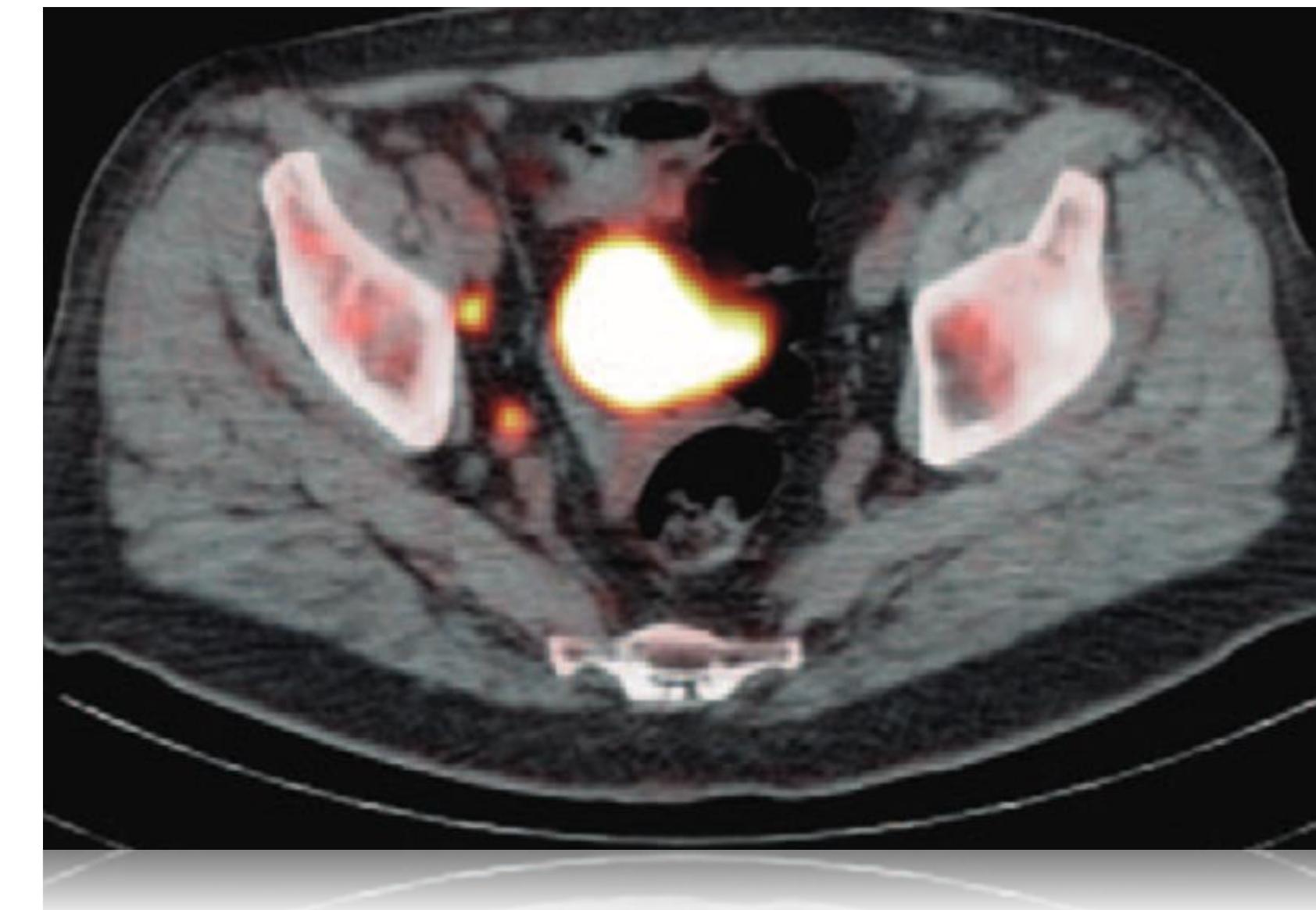
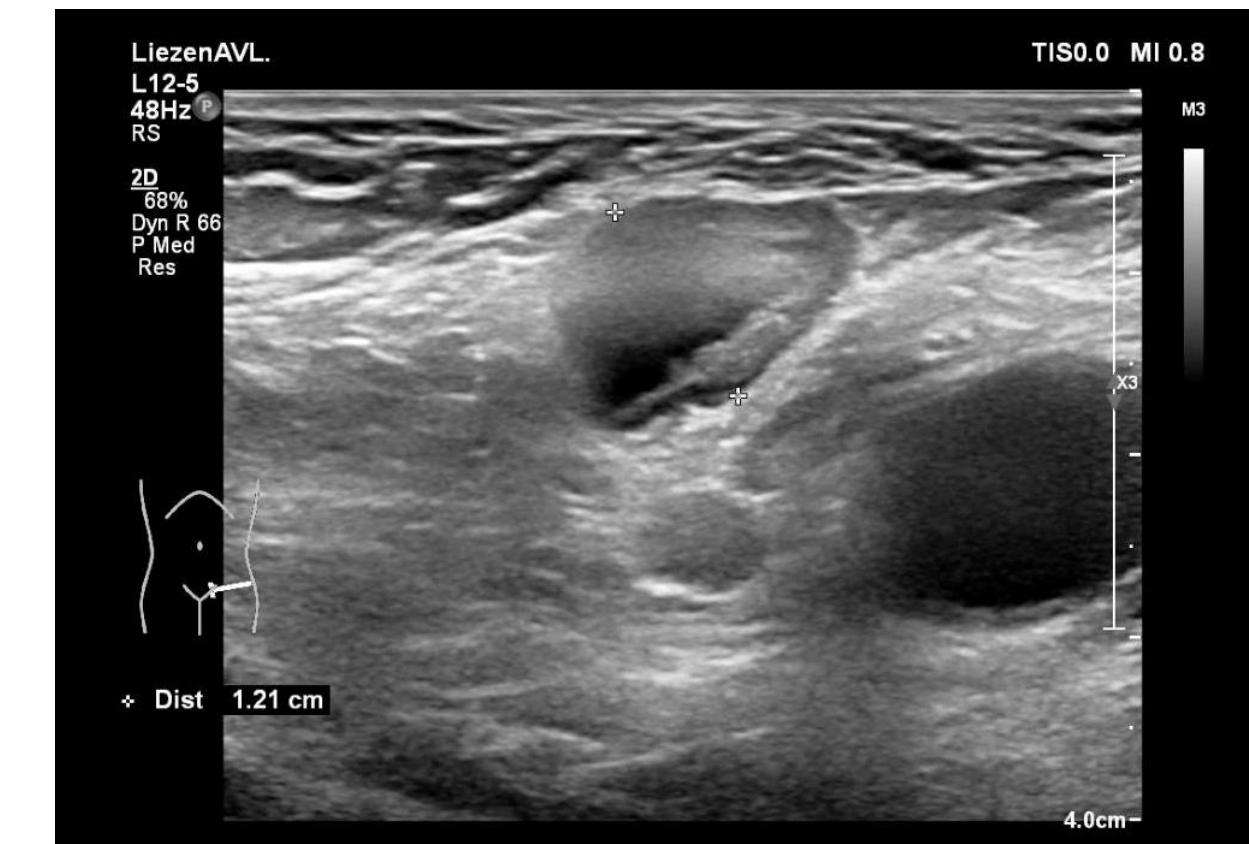
- No place for (6 weeks) antibiotics
- Ultrasound + FNAC
- If metastasis proven:
 - ❖ Additional imaging useful
 - PET/CT
 - *sensitivity* 91%
 - *specificity* 100%

N1 PET/CT:

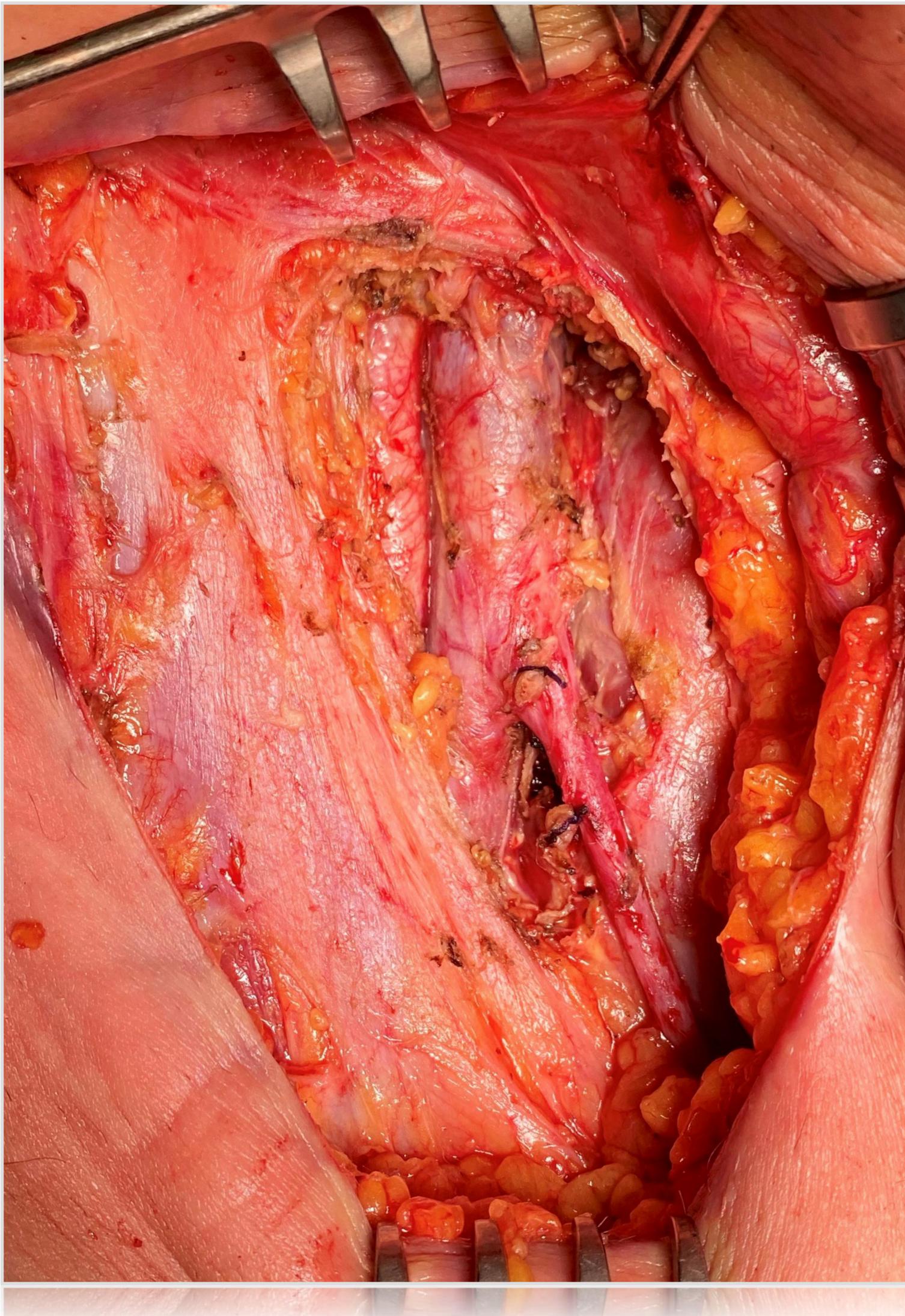
-> Inguinal Lymphadenectomy

N2-3 PET/CT:

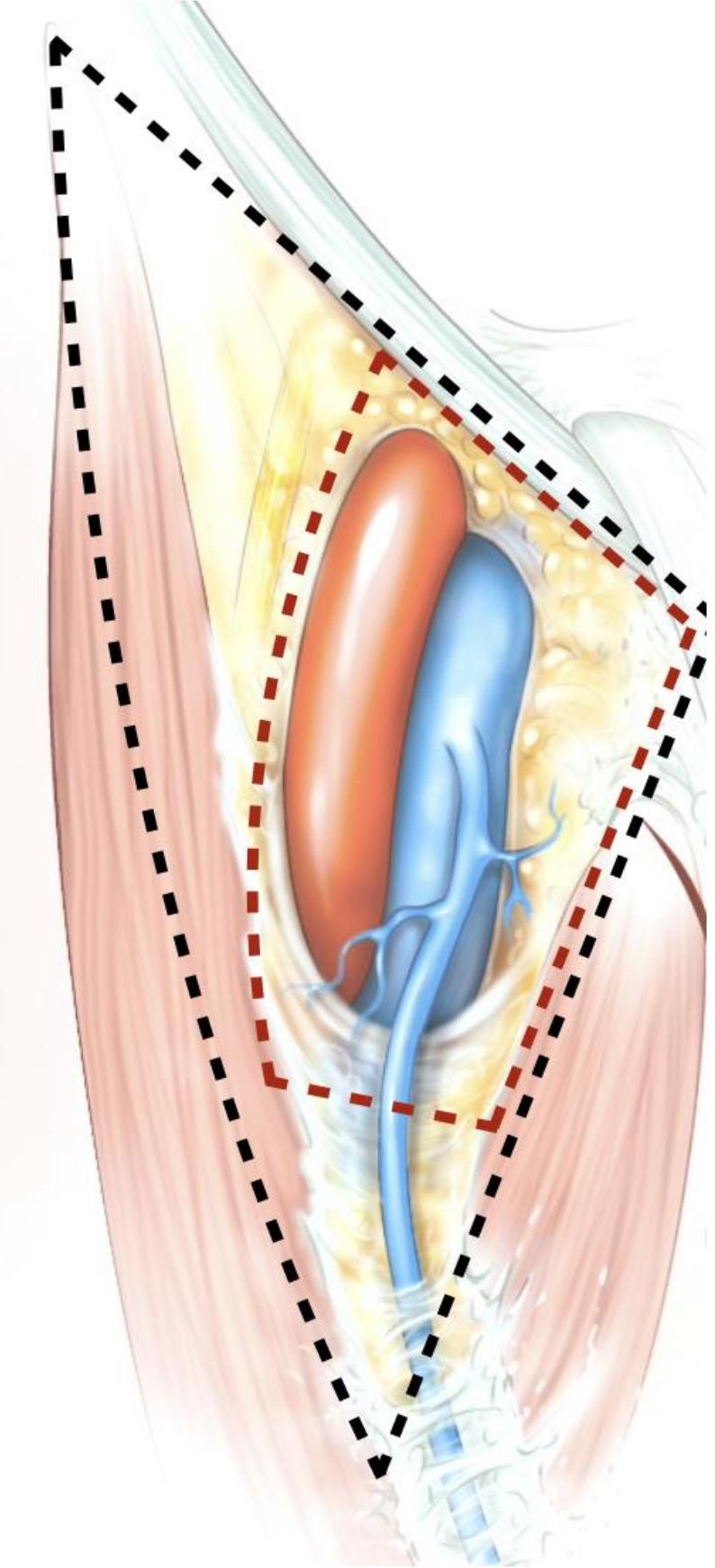
-> consider multimodal treatment



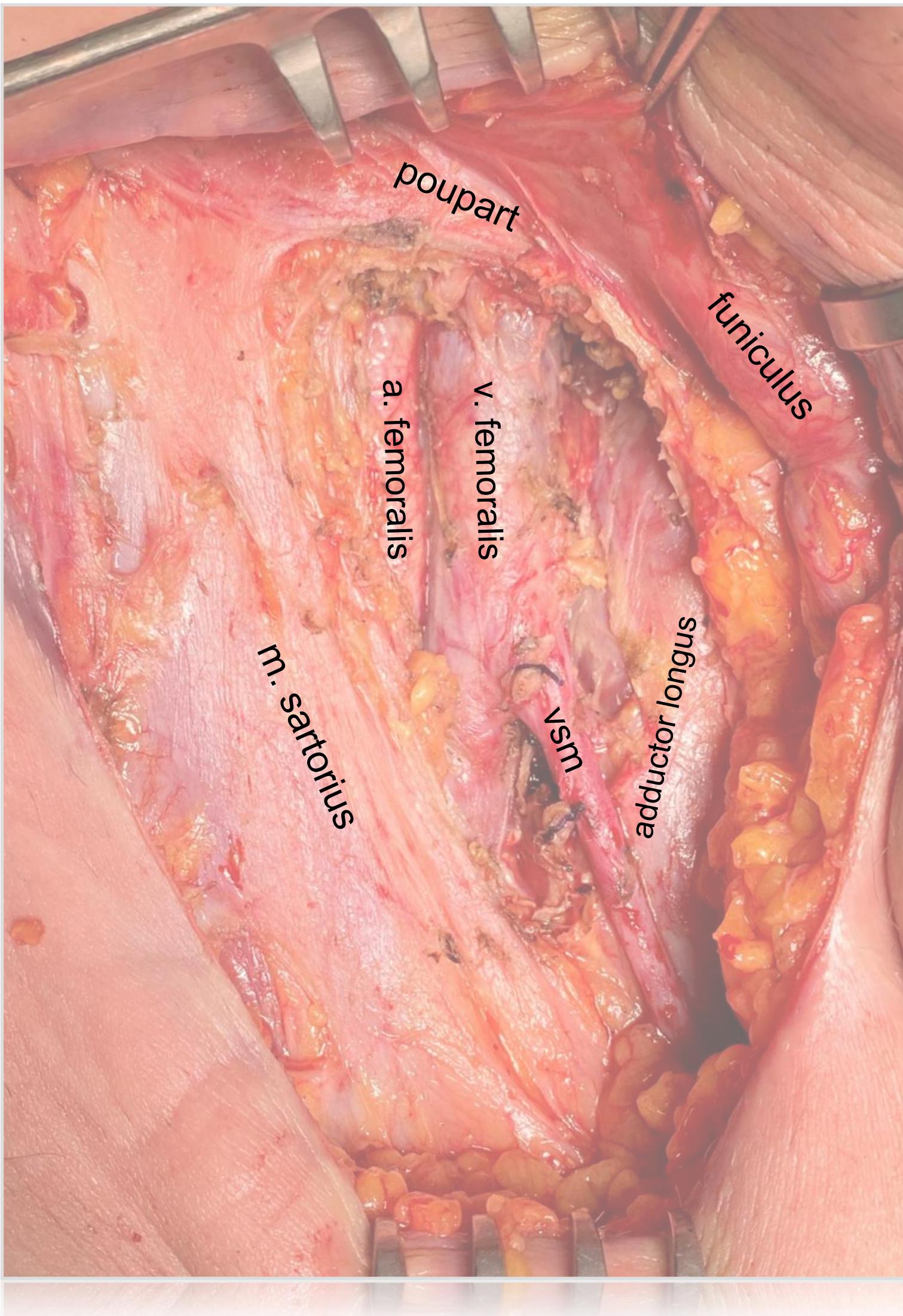
Radical Inguinal Lymphadenectomy (ILND)



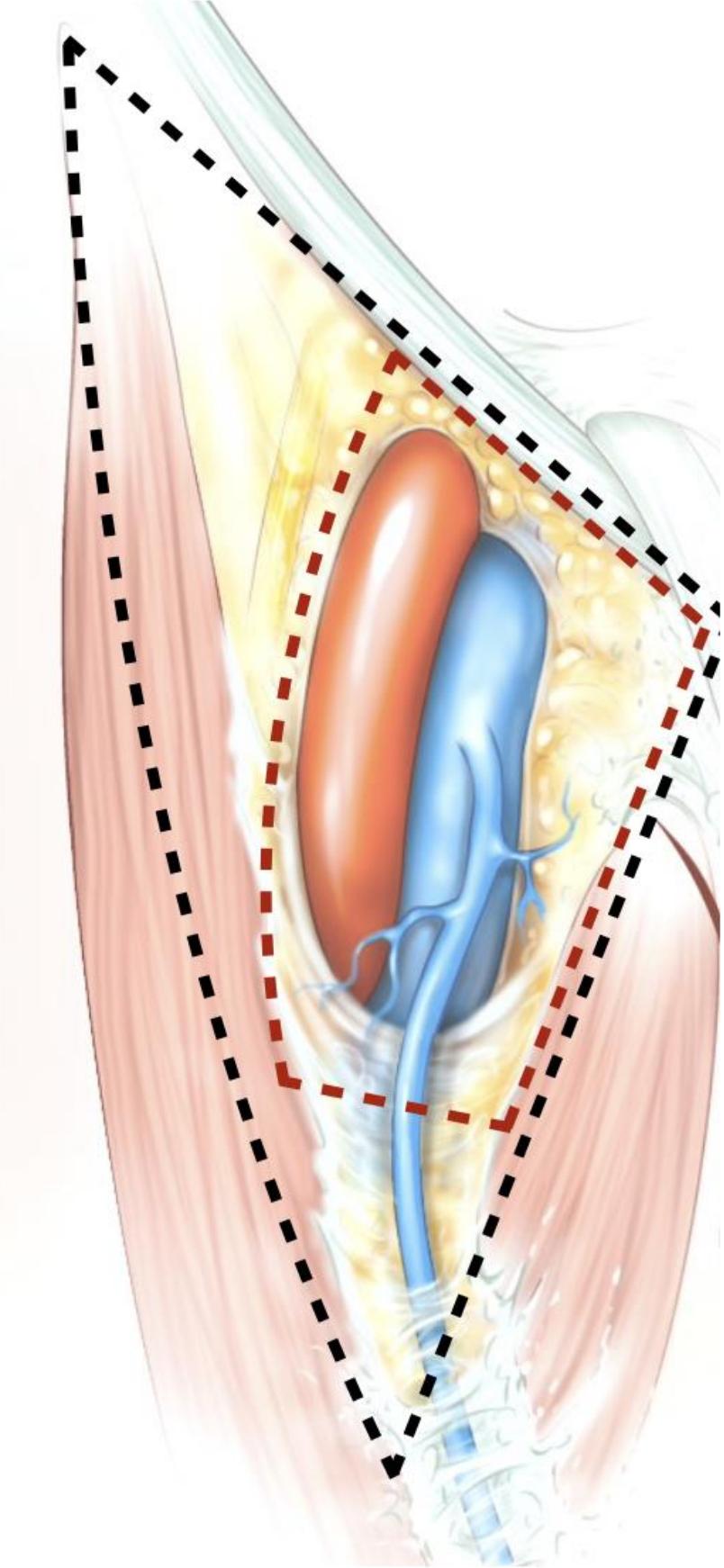
- Radical template
- Modified template



Radical Inguinal Lymphadenectomy (ILND)

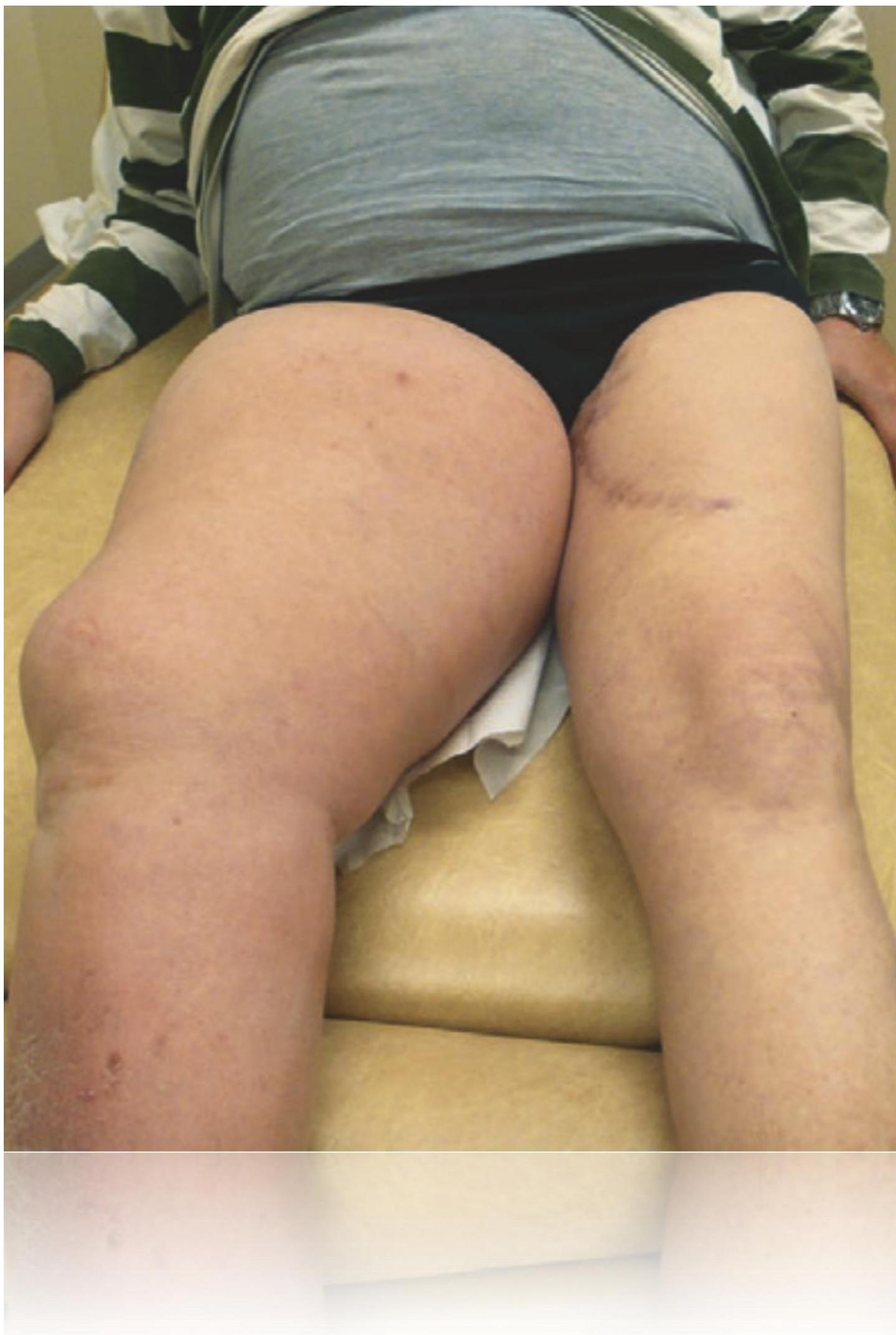


- (dashed line) Radical template
- (dotted line) Modified template



Complicaties ILND

- AVL 2003-2010, n=273
 - Wondcomplicaties totaal: 50-65%
 - Wondinfectie: 44%
 - Seroom: 30%
 - Huidnecrose/problemen: 16-26%
 - Lymphoedeem 20-30%
 - Lymphoedeem graad III: 10%
- ❖ Multidisciplinaire nazorg!



Anderson classificatie

- Graad
- I pitting oedeem met geringe fibrose
- II non pitting oedeem met matige fibrose
- III huidhypertrofie met insnoeringen van huid
- IV als III met papillomatuze woekering
- V klassieke elefantiasis

2022 analyse: Peniscarcinoom, Vulvacarcinoom, Melanoom ILND

	PeCa	VC	MM	Total
Patients	114 (35,2)	48 (14,8)	162 (50)	324
Operations	128 (37,4)	50 (14,6)	164 (48)	342
Groins	143 (37,5)	74 (19,4)	164 (43)	381
Gender (m/f)	114/0	0/48	65/97	179/145
Age (yrs)	69	61	63	66
BMI (kg/m ²)	27,9	27,6	26,5	27,3
Diabetes	32 (28,1%)	9 (18,8%)	15 (9,3%)	56
Smoker	18 (15,8%)	8 (16,7%)	12 (7,4%)	38

Complication rates

88,4% of the groins had early complications (n=565)

85,3%

Penile cancer

85,1%

Vulvar cancer

92,6%

Malignant melanoma



50,4% of the groins had late complications (n=194)

52,1%

Penile cancer

58,1%

Vulvar cancer

45,3%

Malignant melanoma



Most occurring complications

837 complications in total, 54% was graded CD1

Wound infection



1

Seroma/lymphocele



2

Lymphedema



3

High volume per surgeon better?



Surgeon with most ILNDs per year (total 56)

ODDS RATIO / CHANCE OF COMPLICATIONS

OR 0,455 (0,216-0,955)

p=0,037

Recent advances: RA-VEIL

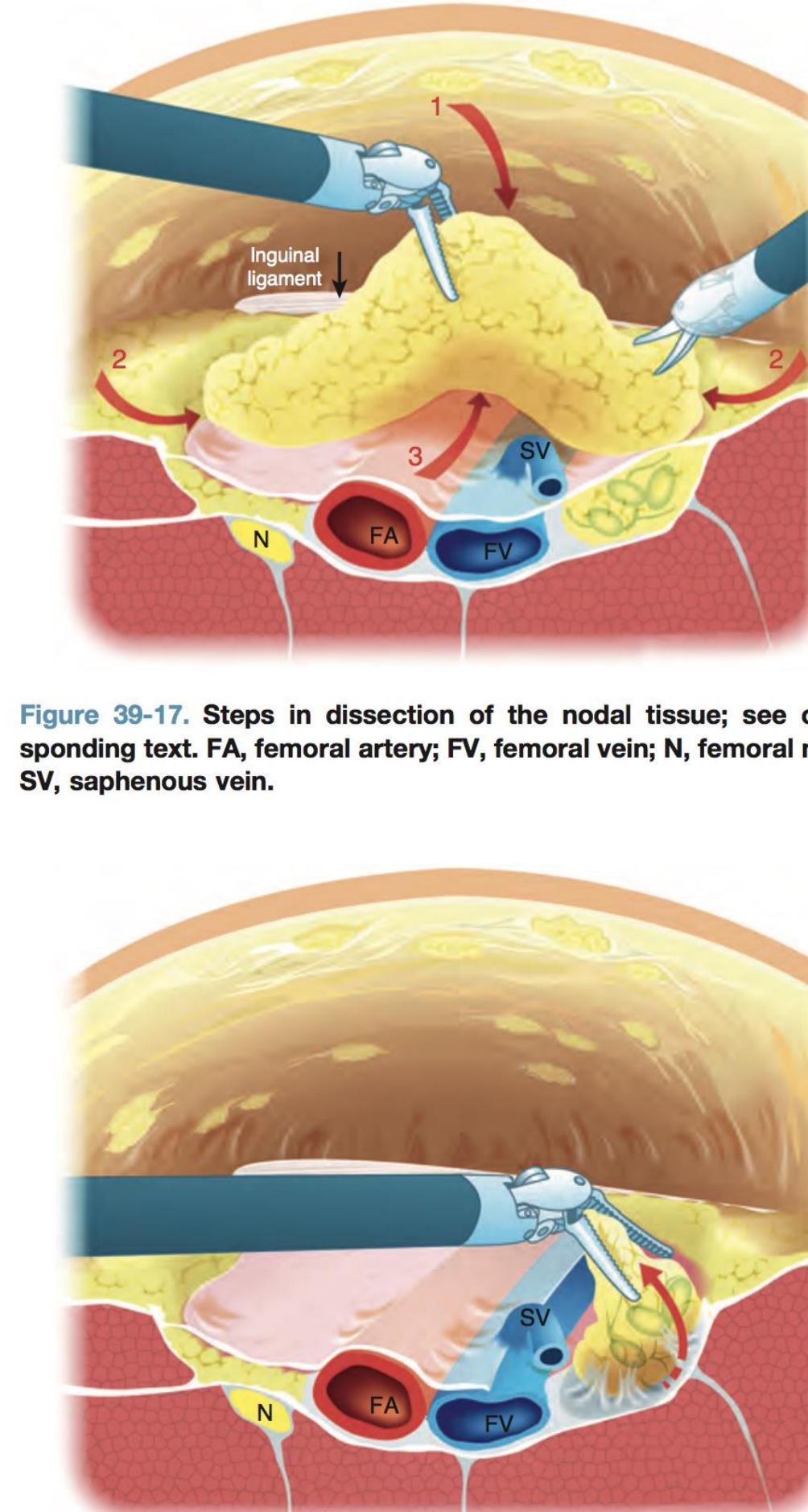
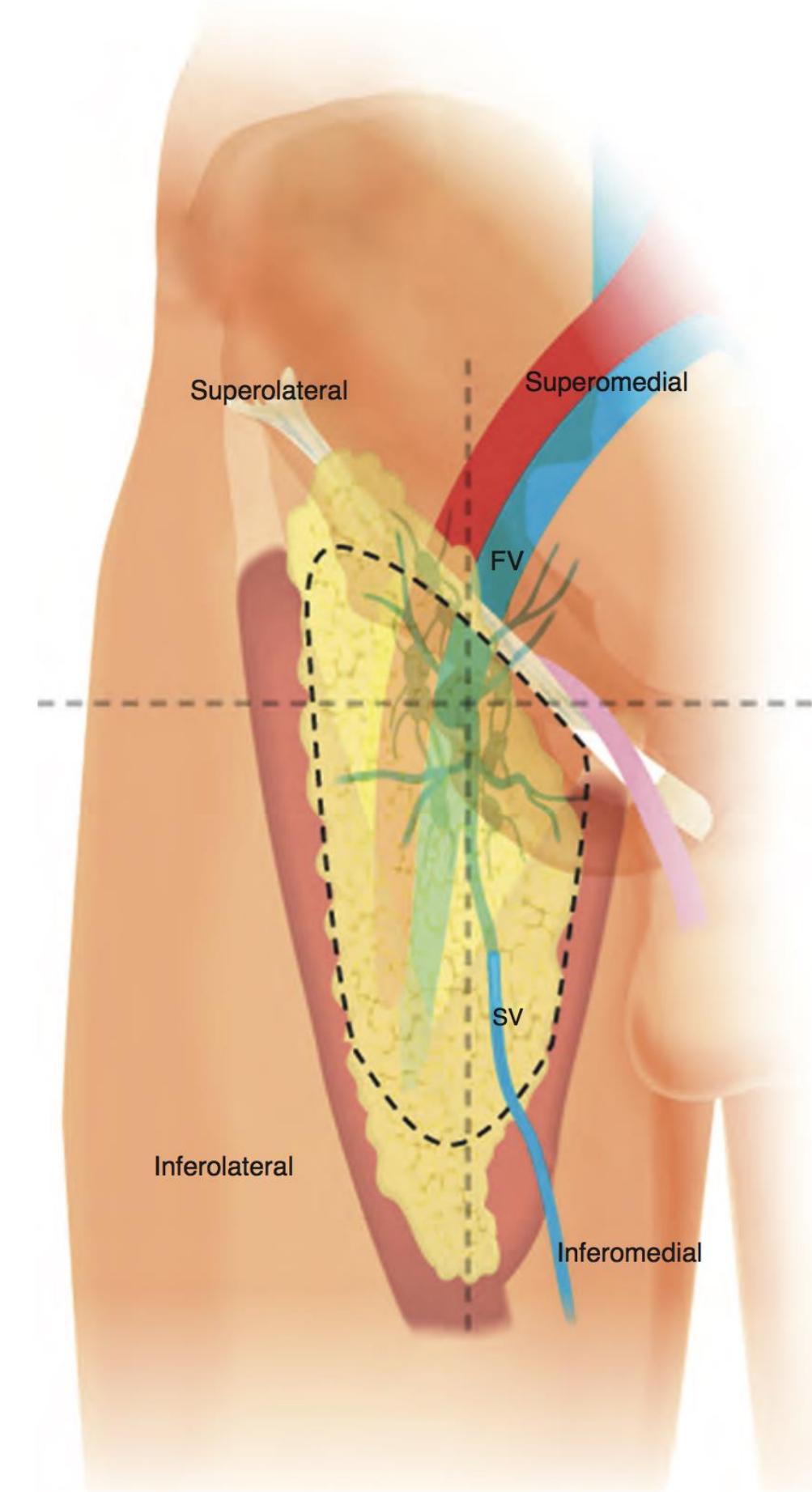
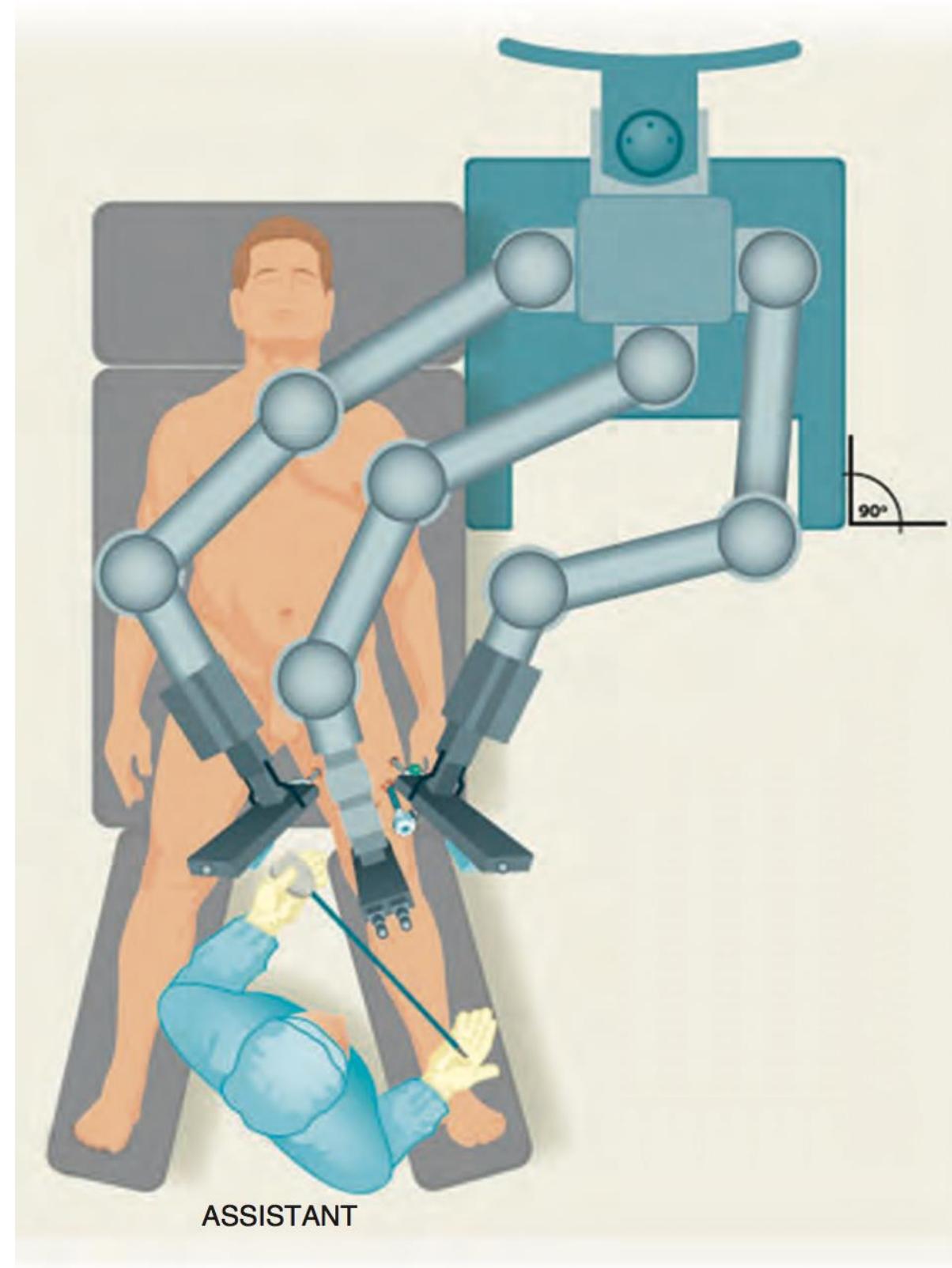
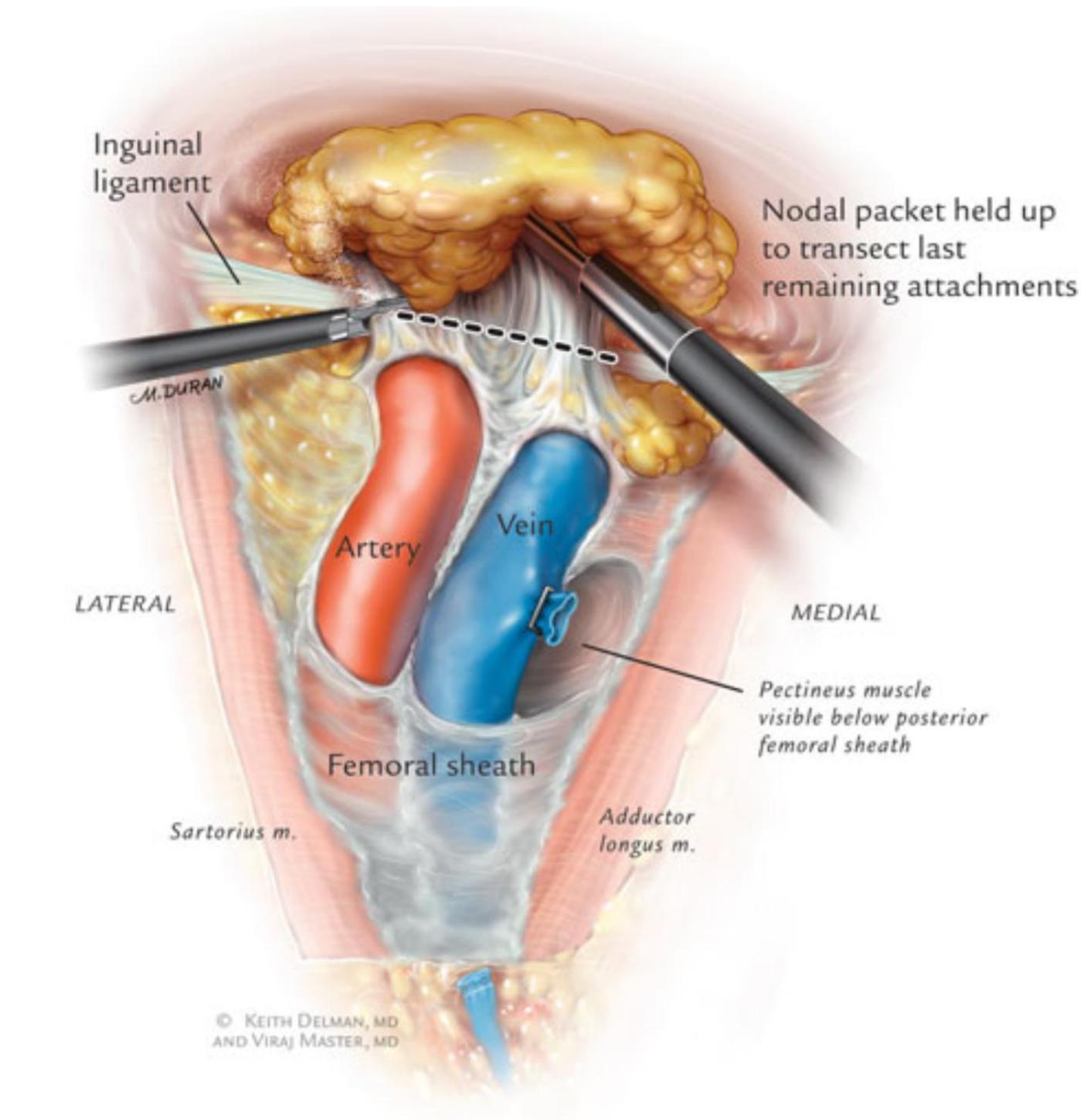


Figure 39-17. Steps in dissection of the nodal tissue; see corresponding text. FA, femoral artery; FV, femoral vein; N, femoral nerve; SV, saphenous vein.



Endoscopic / Robot?

Series	Techn	N (MI)	Design	LN	COMP
Singh 2017	RAVEIL	51	Prospective single arm vs historic cohort OILND	13	75%
Russel 2017	RAVEIL + VEIL	18	Single arm	8-10	33%
Romanelli 2017	VEIL	20	Single arm	8	33%
Kumar 2017	VEIL	17	Prospective single arm vs historic cohort OILND	9,36 (vs 7,11)	36%
Cui 2016	VEIL	23	Nonrandomized saphenous vein ligation vs preservation	8,5	34%
Yuan 2015	VEIL	12	Prospective single port VEIL vs contralateral VEIL	10,5	25%
Matin 2013	RAVEIL	10	Single arm phase 1	9	N/A
Zhou 2013	VEIL	7	Single arm	12,3	42%
Master 2009	VEIL	29	Single arm	10	42 %
T Machado 2007	VEIL	10	Prospective vs OILND contralateral	10	20%
Sotelo 2007	VEIL	8	Single arm	9	23%

- Small series
- Mostly retrospective
- Mostly single arm

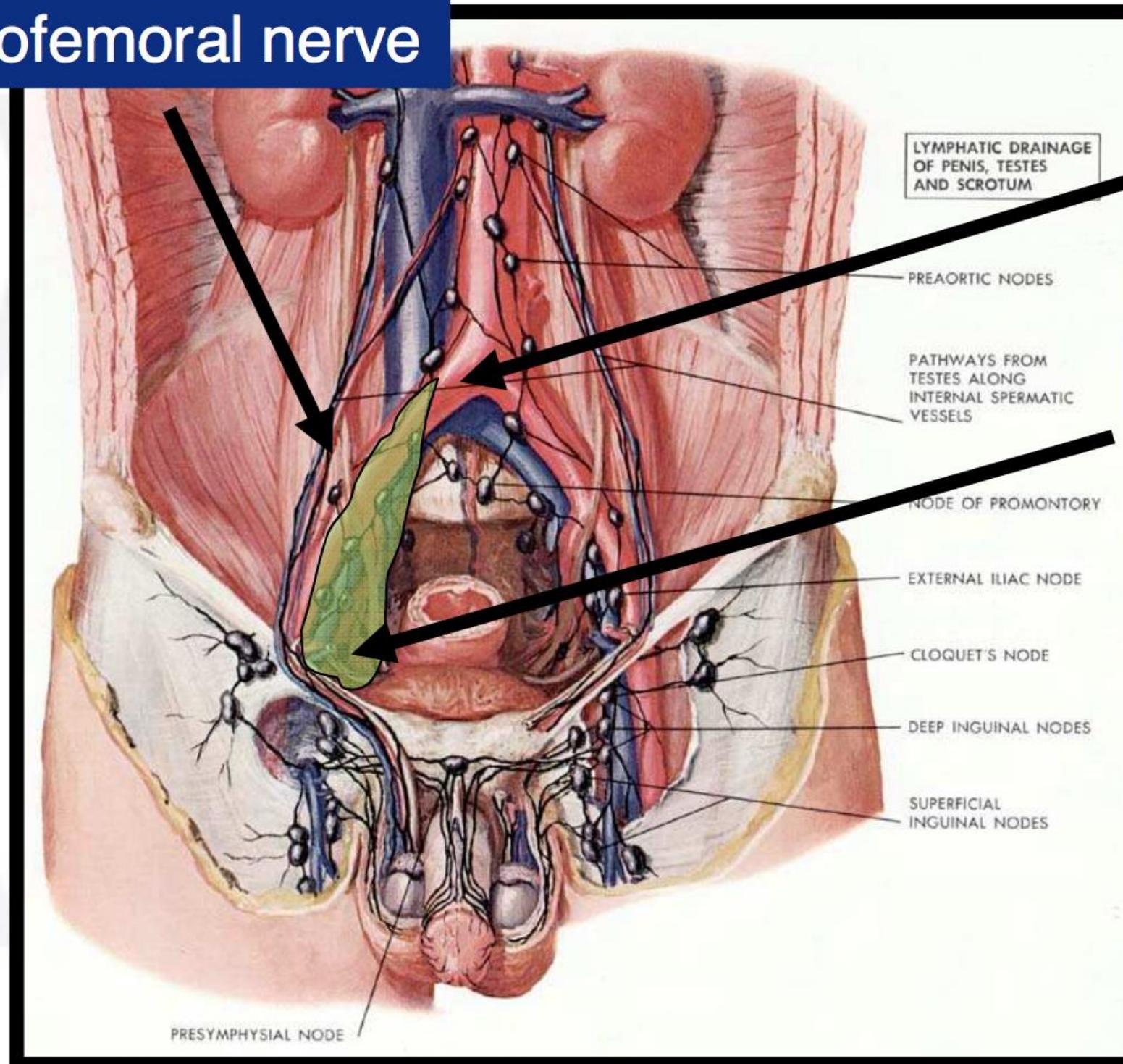
- Lower morbidity (vs. open ILND)
- However, still substantial
- Lymphedema remains a problem
- Not widely adopted

most experience in cN0
oncologically safe in cN+?

Pelvic Lymph Node Dissection (PLND)

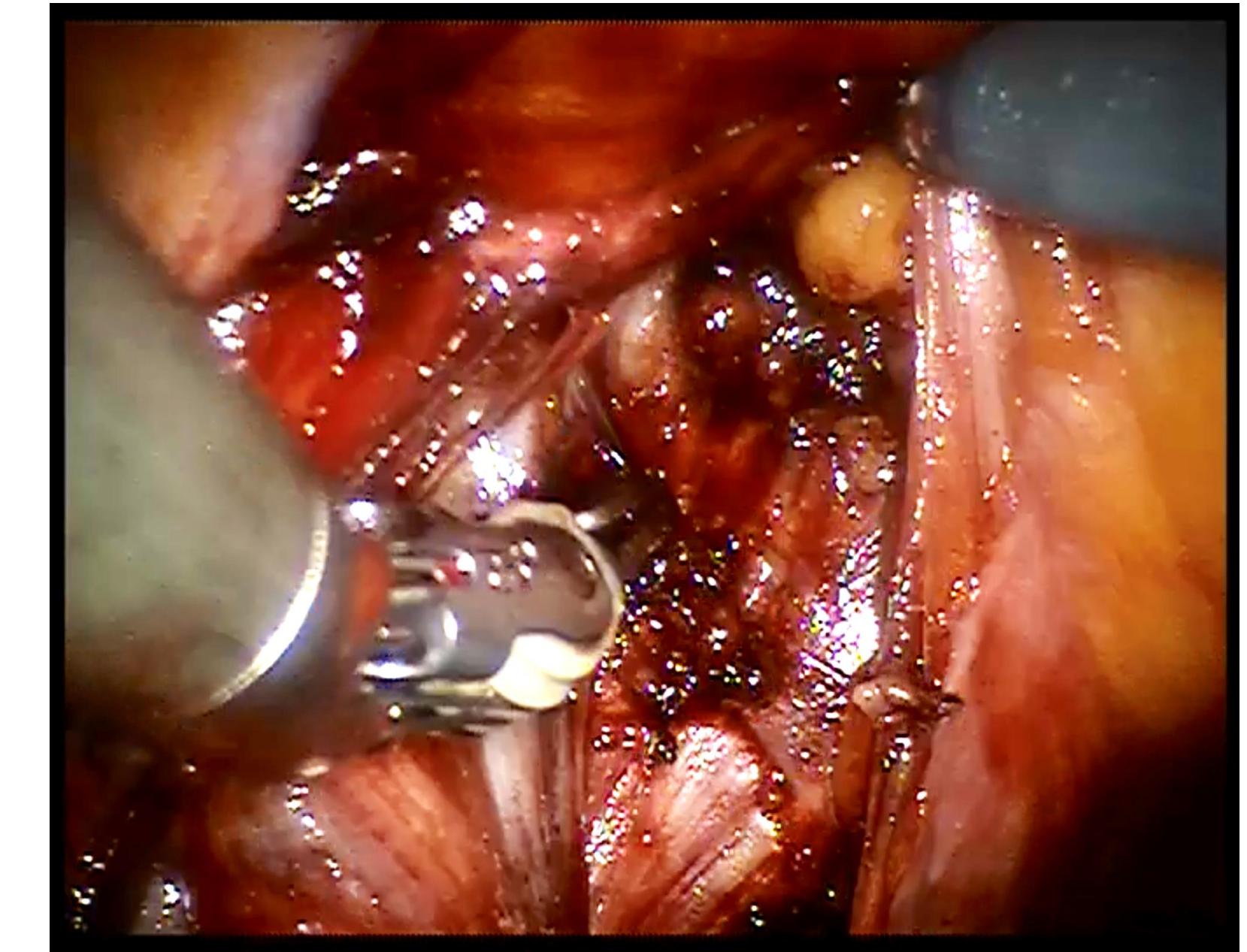
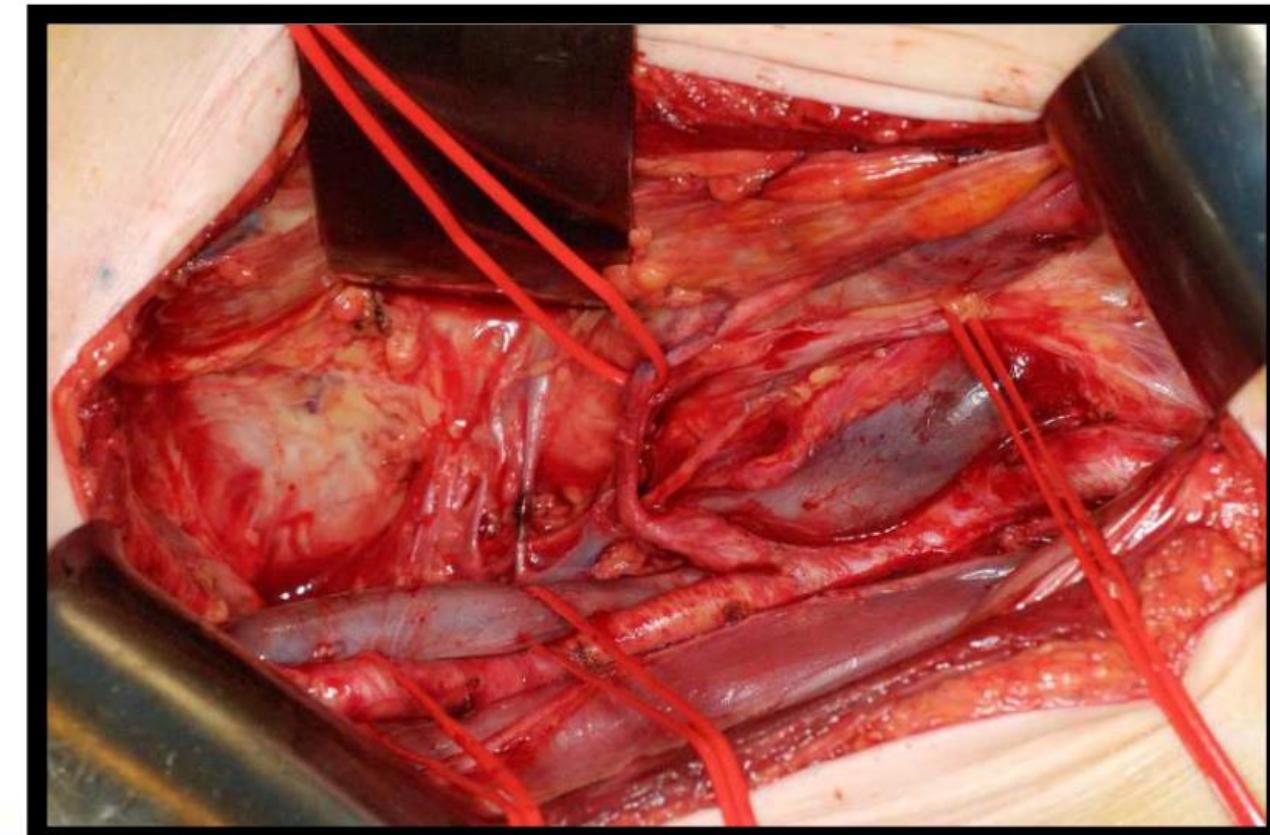
- 20-30% van de patienten met pos. liesklieren heeft ook positieve bekkenklieren
- Indicaties PLND EAU 2023: **≥ 3 pos. inguinale klieren + of extranodale extensie (ENE)**

Genitofemoral nerve



Aortic bifurcation

Node of Cloquet/Rosenmuller



Lymph node management: ***N1-N2***

Recommendations	Strength rating
<p>In patients with cN1 disease offer either ipsilateral:</p> <ul style="list-style-type: none">• fascial-sparing inguinal lymph node dissection• open radical ILND; sparing the saphenous vein, if possible	Strong
<p>In patients with cN2 disease offer ipsilateral open radical ILND; sparing the saphenous vein, if possible.</p>	Strong
<p>Offer minimally-invasive ILND to patients with cN1–2 disease only as part of a clinical trial.</p>	Strong
<p>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 (see Section 6.4.1).</p>	Weak
<p>Complete surgical inguinal and pelvic nodal management within 3 months of diagnosis (unless the patient has undergone prior neoadjuvant chemotherapy).</p>	Weak

Lymph node management: N3

Summary of evidence	LE
Surgery alone will rarely cure patients with cN3 disease.	3
Even when technically feasible, upfront surgery is associated with significant complications which may delay or prevent delivery of adjuvant therapy.	3
About half of the patients with advanced (cN2–cN3) penile cancer respond to combination chemotherapy. Responders that subsequently undergo consolidative inguinal/pelvic LND have an OS chance of about 50% at 5 years.	2a

Recommendations	Strength rating
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. (see Section 6.4.1).	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

Management of the penile squamous cell carcinoma patient after node positive radical inguinal lymph node dissection: current evidence and future prospects

Hielke M. de Vries^a, Sarah R. Ottenhof^a, Michiel S. van der Heijden^b,
Floris J. Pos^c, Simon Horenblas^a, and Oscar R. Brouwer^a

KEY POINTS

- Adjuvant treatment for patients with pN1 after ILND does not seem to influence survival.
- Extranodal extension or at least two inguinal tumor positive nodes at ILND places a patient at high risk of ipsilateral pelvic nodal involvement and prophylactic PLND is still the current standard.
- Adjuvant radiotherapy might be of benefit for patients with pN2 and/or pN3 but prospective evidence is lacking.
- Because of the high toxicity of adjuvant chemotherapy regimens, conflicting retrospective data, and the lack of prospective evidence, current guideline recommendations should be interpreted with caution.
- The role of (adjuvant) chemoradiotherapy is currently being investigated in prospective studies such as the InPACT trial and results are highly anticipated.

Recommendations: previous

Adjuvant chemotherapy

In pN2/pN3 patients after radical lymphadenectomy.

Strong

Recommendations: 2023

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

Recommendations: previous

Radiotherapy

Not recommended for nodal disease except as a palliative option.

Strong

Recommendations: 2023

Recommendation	Strength rating
Offer adjuvant radiotherapy (with or without chemo sensitisation) to patients with pN2/N3, including those with 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

M+ / Palliatieve zorg

Recommendations	Strength rating
<i>Systemic therapies</i>	
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 enrol in clinical trials, including experimental therapies within phase I or basket trials.	Strong
<i>Radiotherapy</i>	
Offer radiotherapy for symptom control (palliation) in advanced disease.	Strong

Follow up: EAU 2023

	Interval of surveillance		Examinations and investigations	Minimum duration of follow-up
	Years 1–2	Years 3–5		
Recommendations for follow-up of the primary tumour				
Penile-preserving treatment	3-monthly	6-monthly	Regular physician or self-examination. Repeat biopsy after topical or laser treatment for PeIN (optional).	5 years
Amputation	3-monthly	Annually	Regular physician or self-examination.	5 years
Recommendations for follow-up of the inguinal lymph nodes				
Surveillance	3-monthly	6-monthly	Regular physician or self-examination. US ± FNAC optional.	5 years
pN0	3-monthly	Annually	Regular physician or self-examination. US ± FNAC optional.	5 years
pN+	3-monthly	6-monthly	Regular physician or self-examination. US ± FNAC, CT chest/abdomen/pelvis or ¹⁸ FDG-PET/CT optional.	5 years

AVL:

Jaar 1-2: elke 3mnd

Jaar 3-5: elke 6mnd

- altijd: LO + echo liezen
- Indien pN+ dan ook PET/CT



Updates on penile cancer management: where do we stand, and how to move forward?

Oscar R. Brouwer and Daher Chade

- Rol van chemoradiatie
- Rol van immunotherapie
- Tumor micro-environment
- Transcriptomics
- Europese samenwerkingen
- Nieuwe EAU-ASCO guidelines

N15PEN: Chemo-RT

- 33 patienten
- 79% stage IV disease
- Response in 24 (72%) patients
- 13 (39%) complete response

Table 3. PET/CT based response (n=33)

Initial metabolic response	N (%)	Best metabolic response	N (%)	Failure location	Status at the end of follow-up		
					N	NED	AWD
Complete	10 (30)	Complete	10 (30)	None	4	4	
				In-field	3	1	2
				Out-field	2		2
				Both	1		1
Partial	14 (42)	Complete	3 (9)	None	3	3	
		Partial	11 (33)	None	2	2	
				In-field	4	1	3
				Out-field	2		2
				Both	3		3
Progression	5 (15)	Progression	5 (15)	In-field	2	1	
				Out-field	3		3
Stable	1 (3)	Stable	1 (3)	In-field	1		1
Not evaluable	3 (9)	Not evaluable	3 (9)	None	1	1	
				Both	1		1
				Not evaluable	1		1

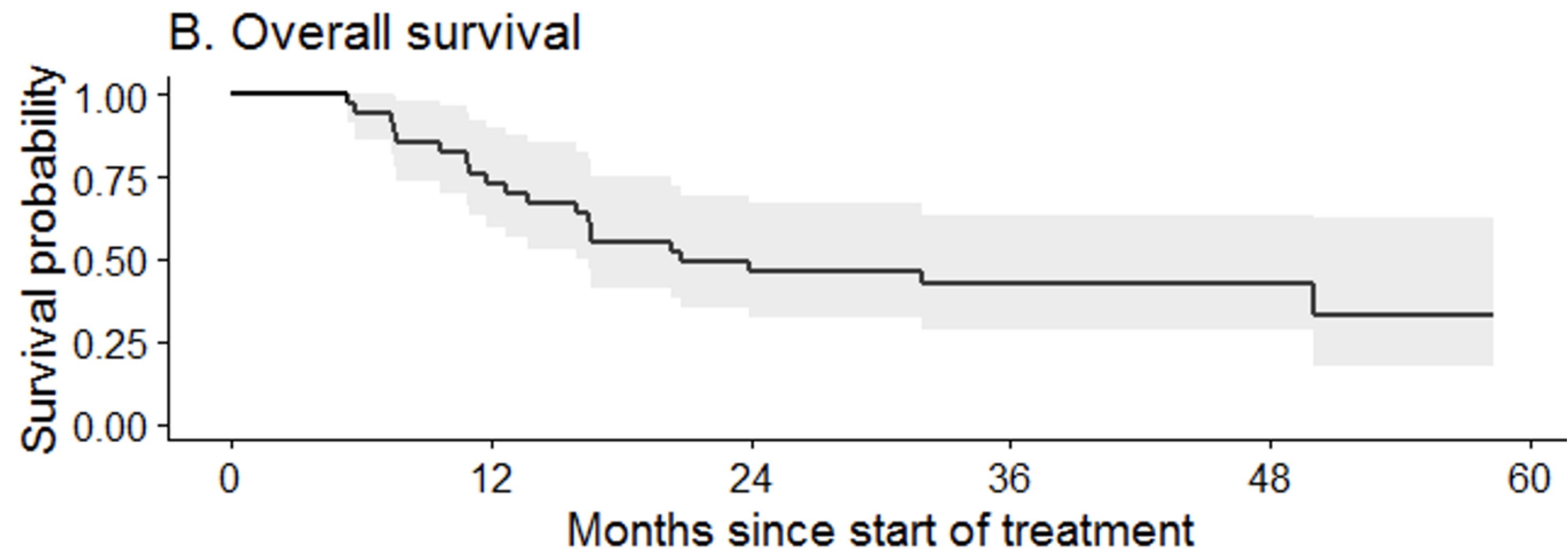
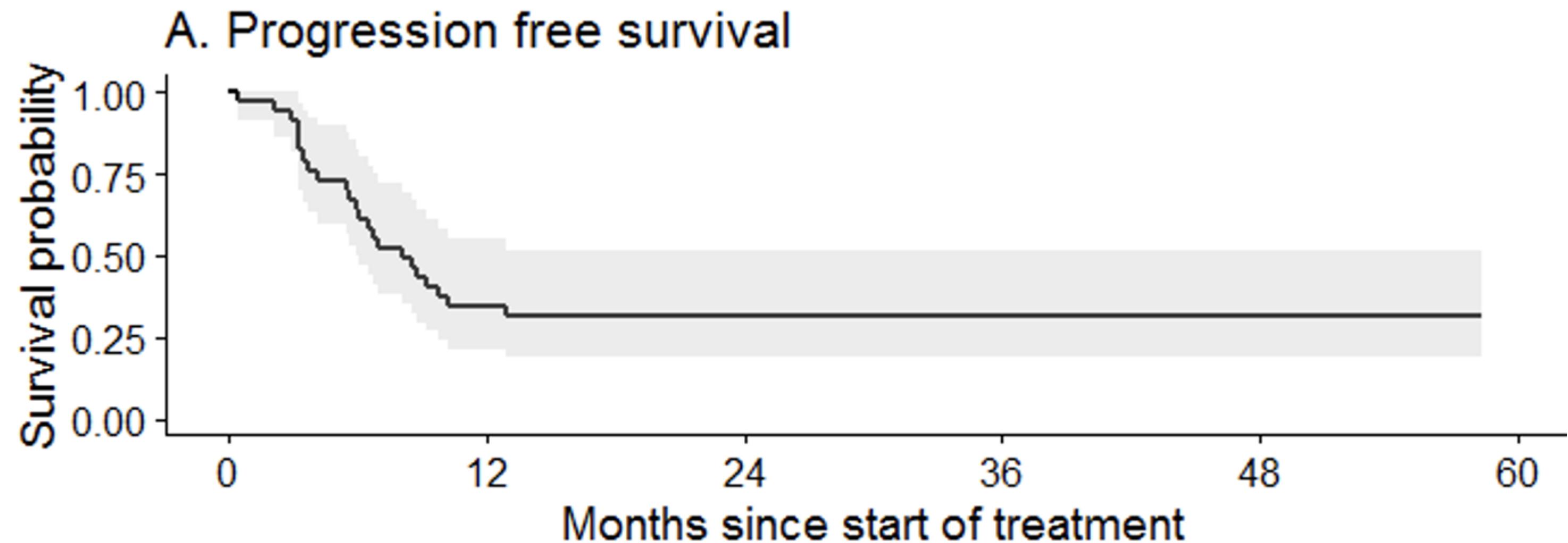
NED = no evidence of disease; AWD = alive with disease; DD = death of disease

N15PEN: Survival

- Median F/U 40 months
- All deaths penile cancer related
- 1yr PFS 34%, 2yr 31%
- 1yr OS 73%, 2yr 46%
- HPV status: no difference
($p=0.67$)

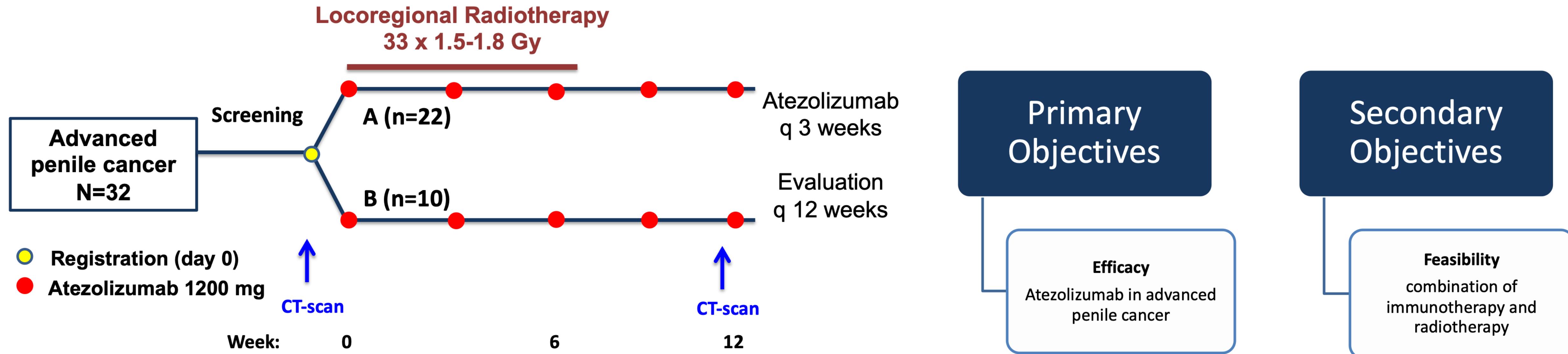
Neoadj Chemo + surgery study:

- 1yr PFS 31%, 2yr PFS 12%
- 1yr DSS 49%, 2yr DSS 28%



PERICLES (submitted): Immune therapy in advanced penile cancer

Studie schema: PERICLES

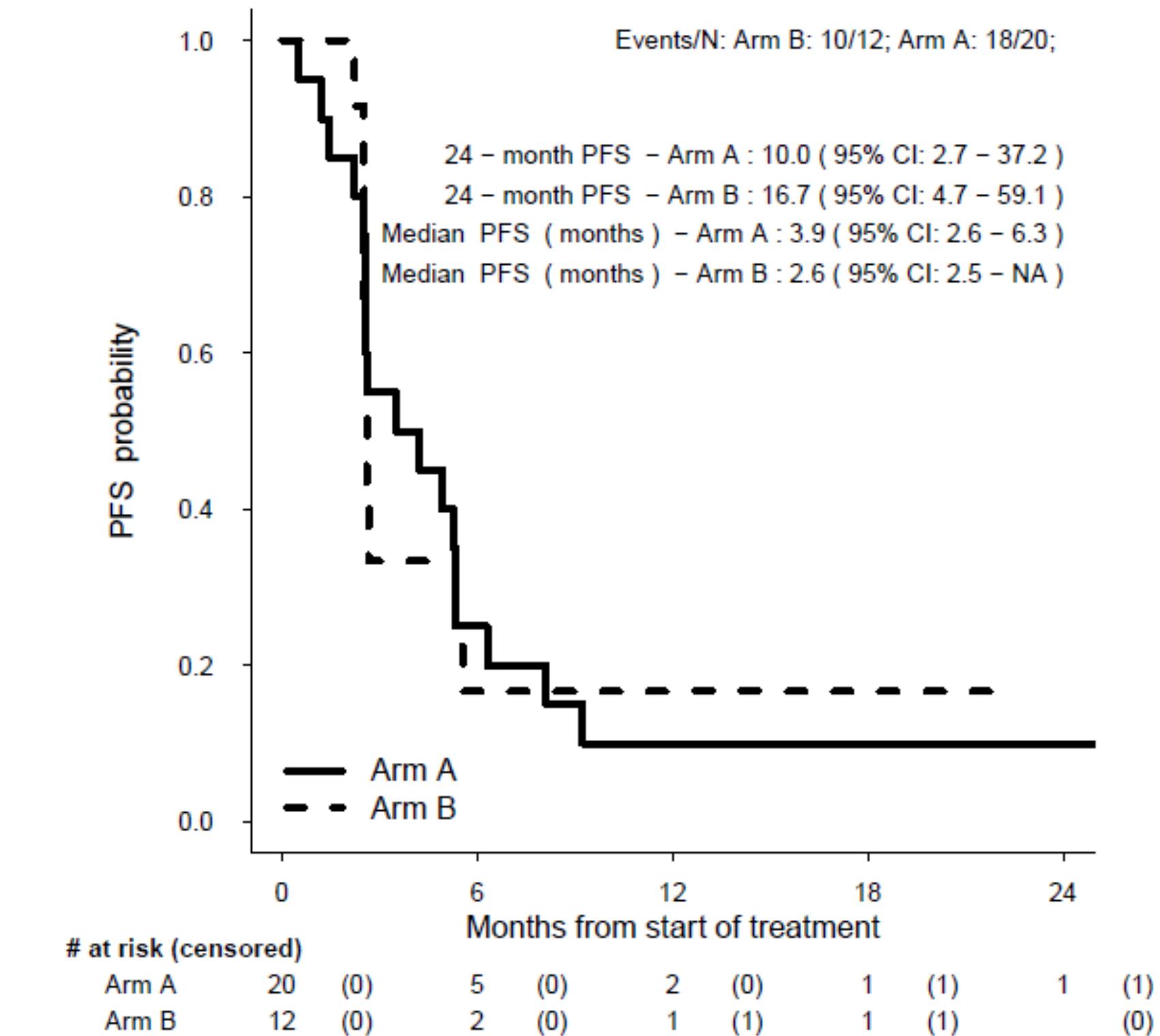
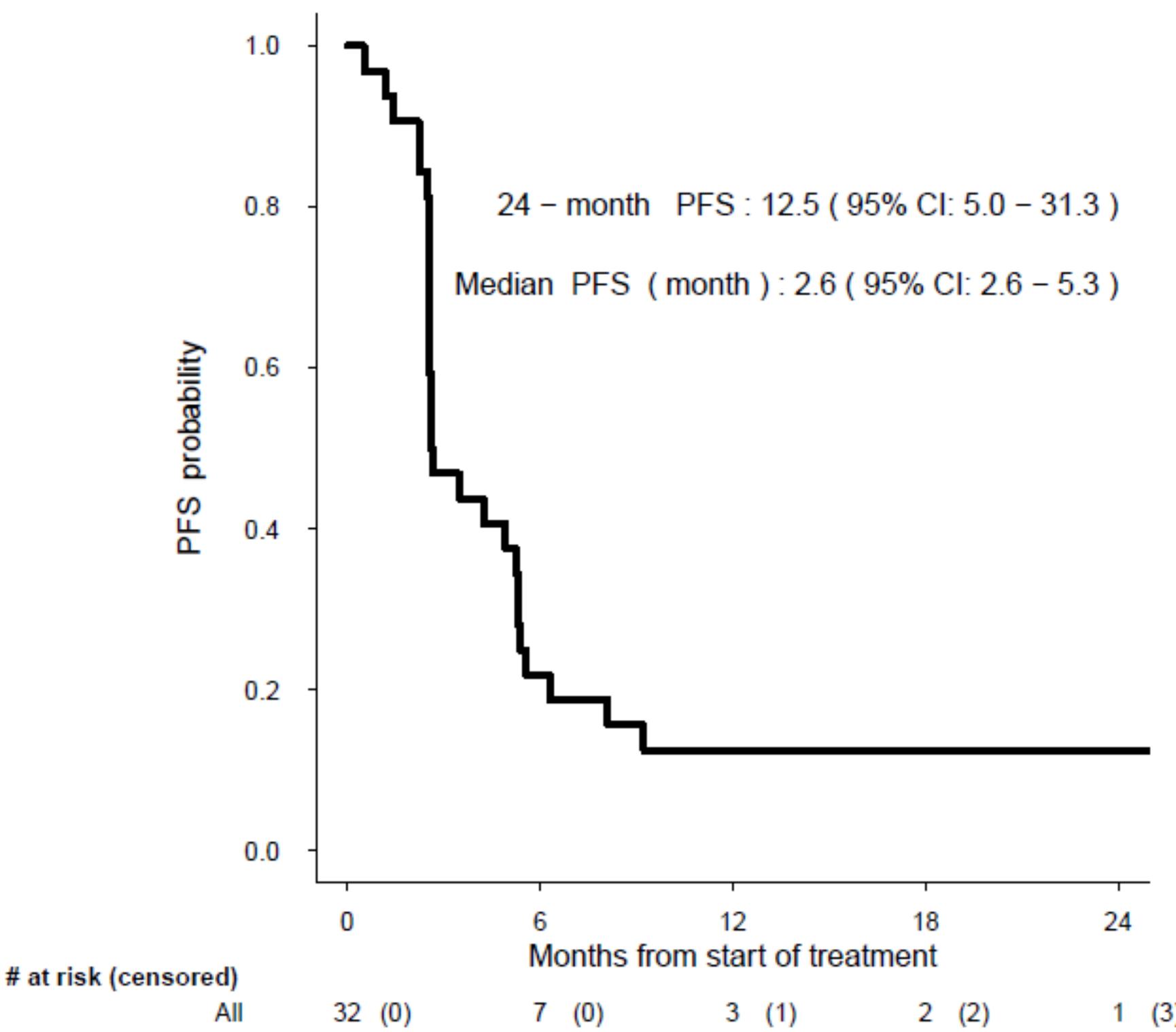


A: Patients who may benefit from locoregional RT for local control

B: Patients without expected benefit of l.r. RT (e.g. pts with distant metastases)

Primary objective: 1 year PFS $\geq 35\%$

Median follow-up 22 months (IQR 4.4-14 months)

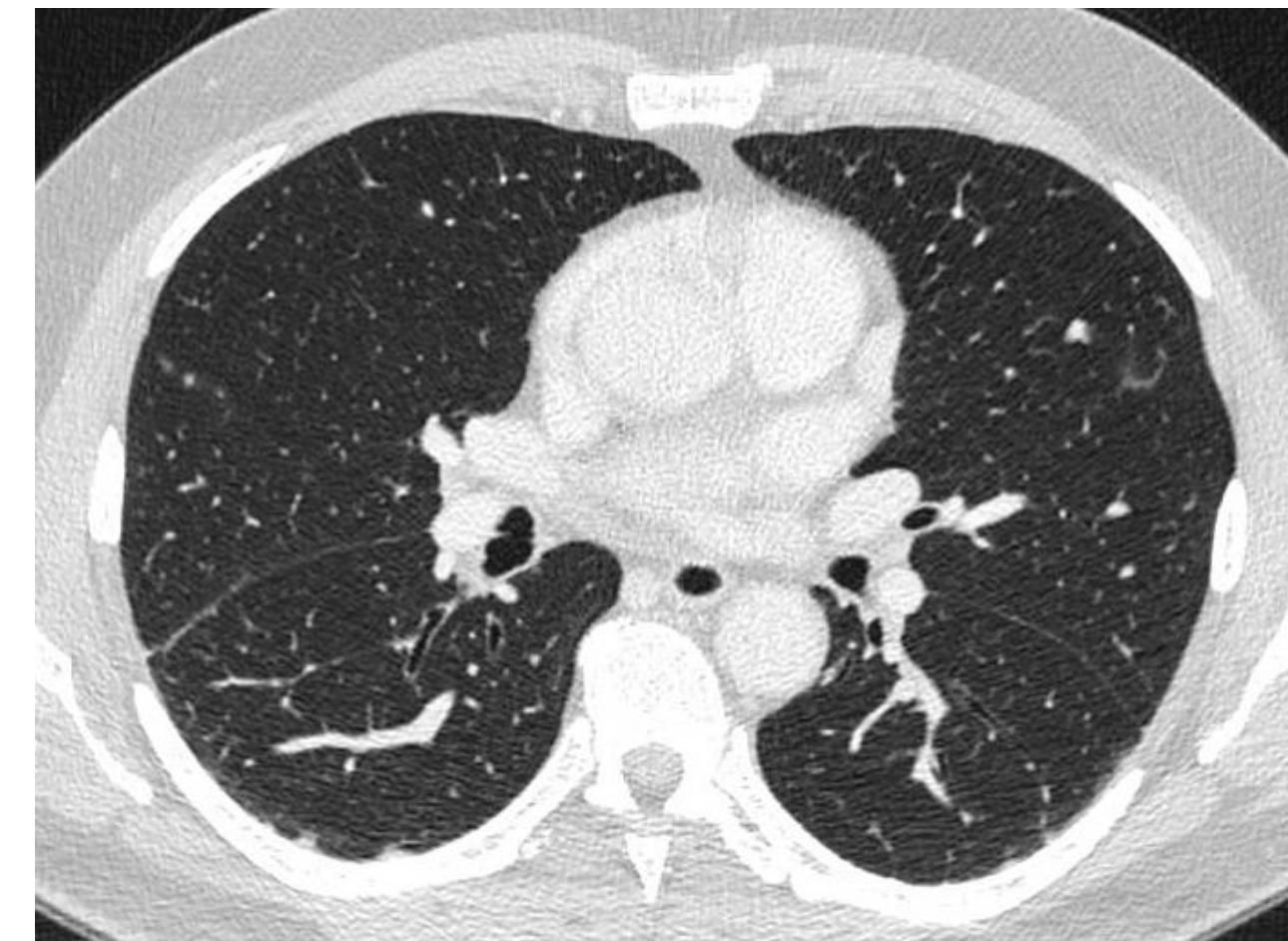
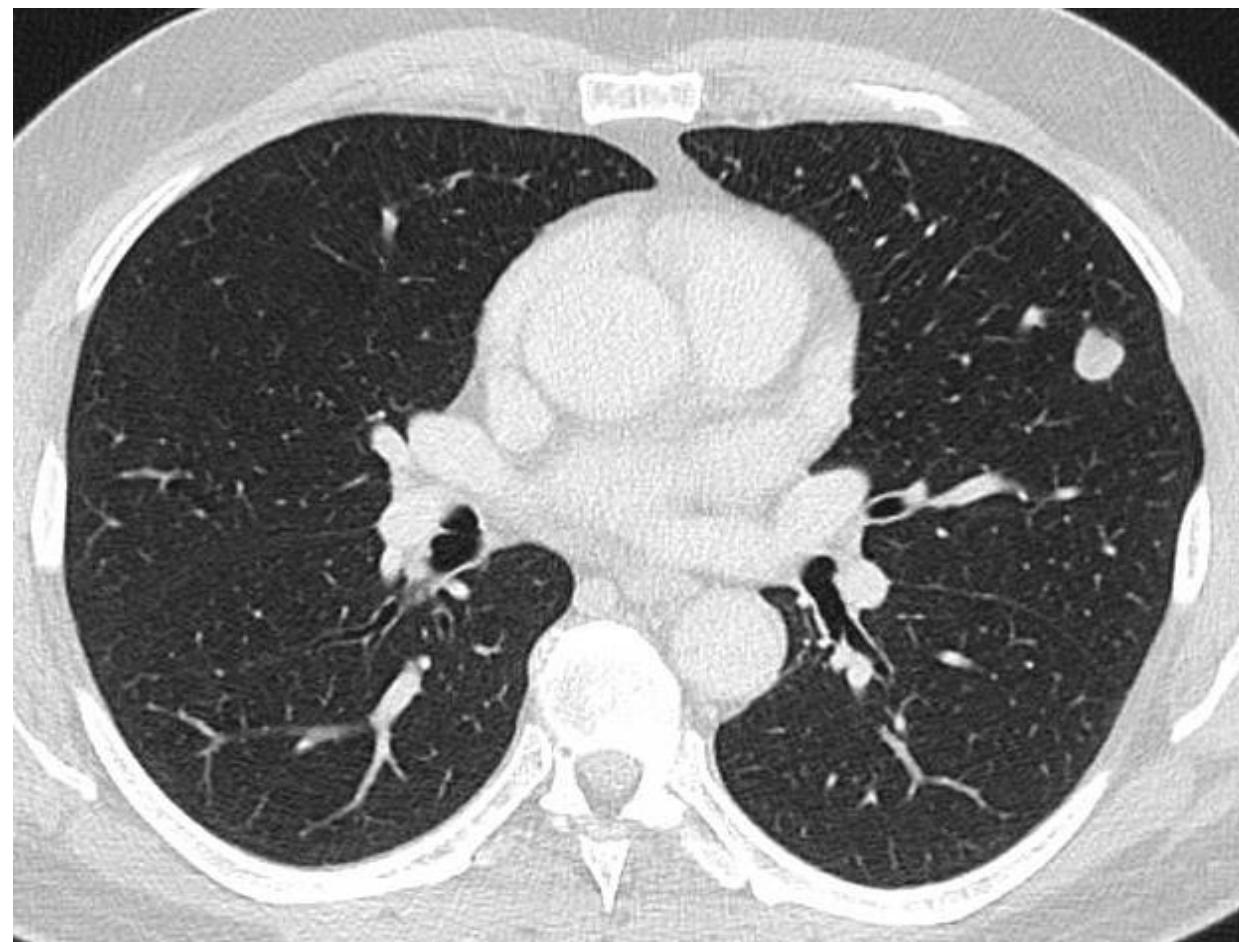


Pt #31
Arm B (Atezo only)

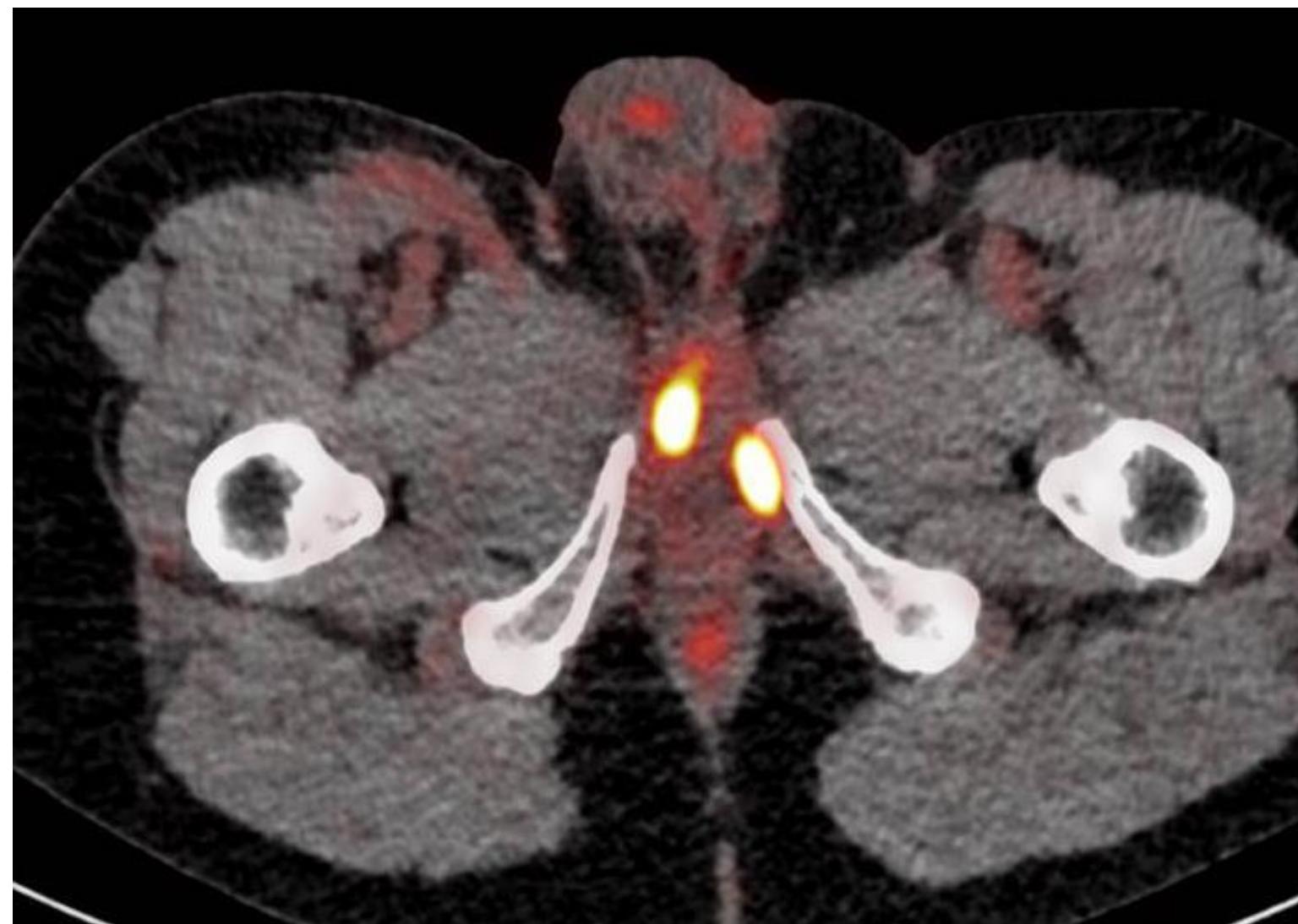
Baseline

9 months Atezolizumab

Chest CT
Pulm Metastasis
(target lesion)

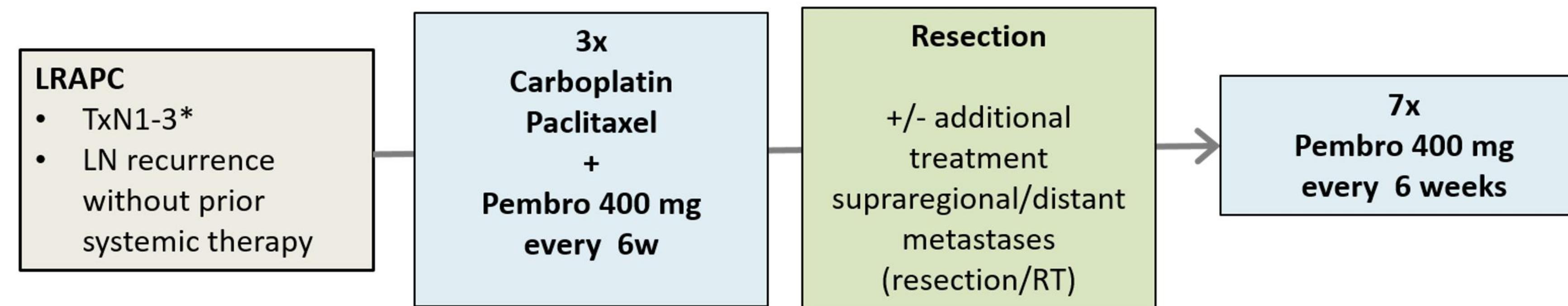


FDG PET-CT
Local recurrence



2023: ALPACA

ALPACA: anti-PD1 + chemotherapy induction treatment for locoregionally advanced penile cancer



*cN1 only in case of central nodal necrosis and/or an irregular nodal border, or node >3cm
Supraregional/distant metastases (max 2) allowed if local treatment feasible



Primary Objective:

- The pathological complete response (pCR) rate of CP+P excludes the expected historical pCR rate of 7%, aiming for a pCR rate of 25%.
- One-sided 5% significance level, sample size of 28 subjects
- 80% power to demonstrate a pCR \geq 7%.

Should the Care of Penile Cancer be Confined to Centralized Centers of Excellence?

Mohamed H. Kamel *

Making surgery safer by centralization of care: impact of case load in penile cancer

Joren Vanthoor¹ · Anita Thomas² · Igor Tsaur² · Maarten Albersen¹  · and in collaboration with the European Reference Network for rare urogenital diseases and complex conditions (eUROGEN)



Volume outcome relationship in penile cancer: a systematic review

Fahad Quhal^{a,b}, Benjamin Pradere^c,
Keiichiro Mori^{a,d}, and Shahrokh F. Shariat^{a,e,f,g,h,i,j,k}

Summary

The optimal management of penile cancer remains a major therapeutic challenge. Patients with invasive tumors are less adequately managed in lower volume nonspecialized centers. The data convincingly support efforts to centralize penile cancer care and to promote the development of centers of expertise in order to achieve the best possible outcomes for each patient.

- More penile sparing surgery
- Better histopathological diagnosis
- Greater use of DSNB/ ILND
- Multidisciplinary teams
- More research
- New treatments
- Guidelines

Survival?

UK: Improving Outcomes Guidance 2002

- Centralisation of penile cancer services in UK
 - Population at least 4 million
 - Minimum 25 new cases / year
 - Supranetwork Centres established
 - 9 in England
 - 1 Wales
 - 2 Scotland



UK data: Improvement in survival after centralisation

- Pre-centralisation (1996-2000)
- n = 294
- 5-year CSS 72.7% (66.9-77.7%)

- Post centralisation (2001-2011)
- n = 433
- 5-year CSS 84.9% (81.2-88.5%)

AVL : landelijk en internationaal erkend expertisecentrum



NEDERLANDSE FEDERATIE VAN
UNIVERSITAIR MEDISCHE CENTRA

Patiëntenplatform

zeldzame kankers



Nederlandse
Federatie van
Kankerpatiënten
organisaties

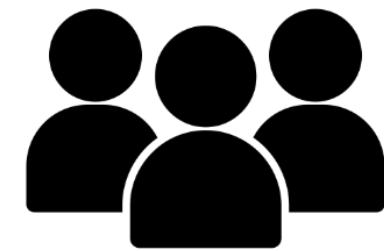
EUROPEAN REFERENCE NETWORKS
FOR RARE, LOW-PREVALENCE AND COMPLEX DISEASES

Share. Care. Cure.



European
Reference
Network

eUROGEN
Urogenital Diseases



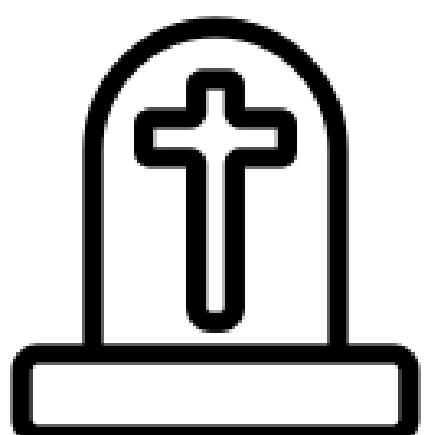
All newly diagnosed penile cancer patients from 1990 – 2020



Data from The Netherlands Cancer registry, population based with nationwide coverage

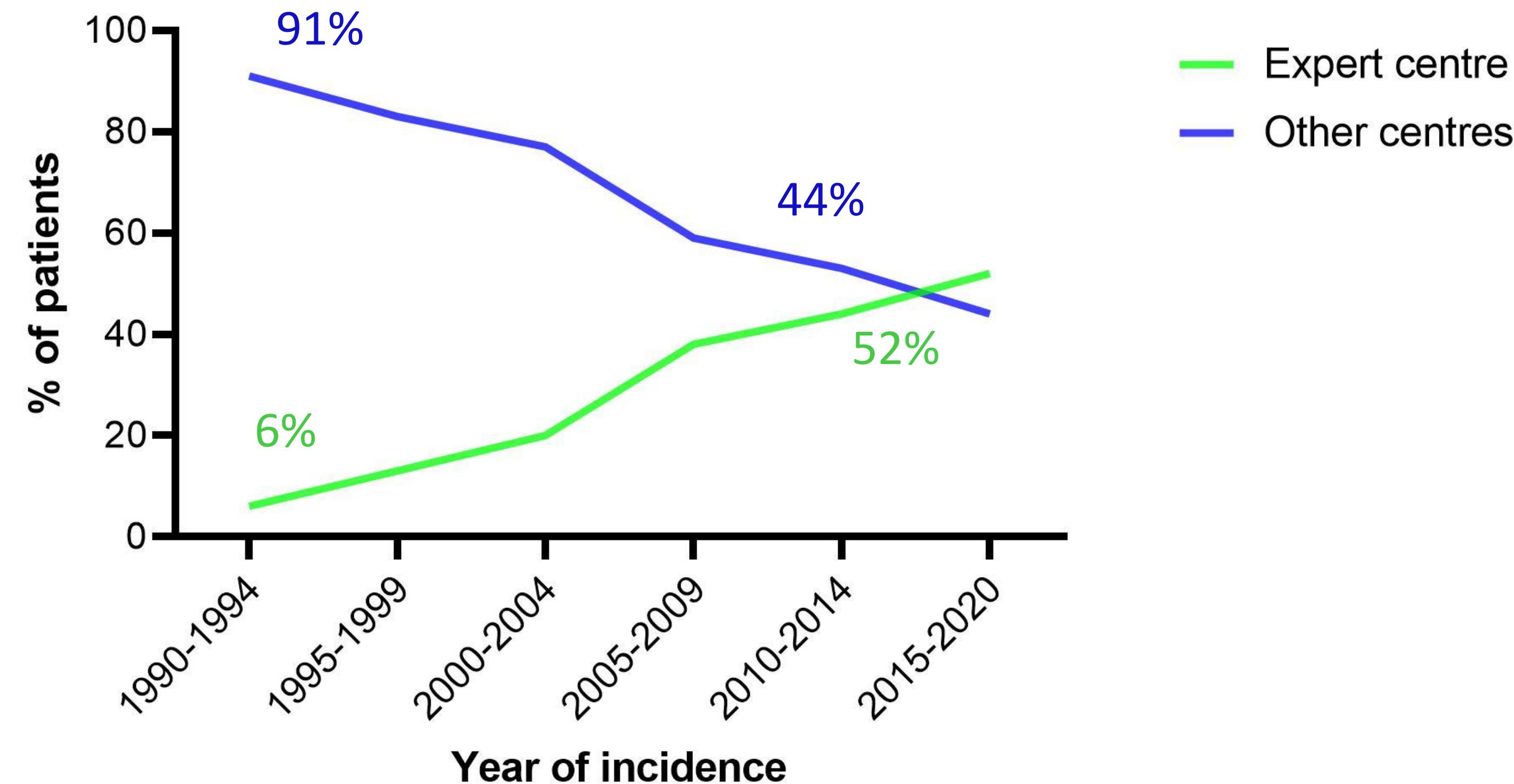


Diagnosis by histological biopsy

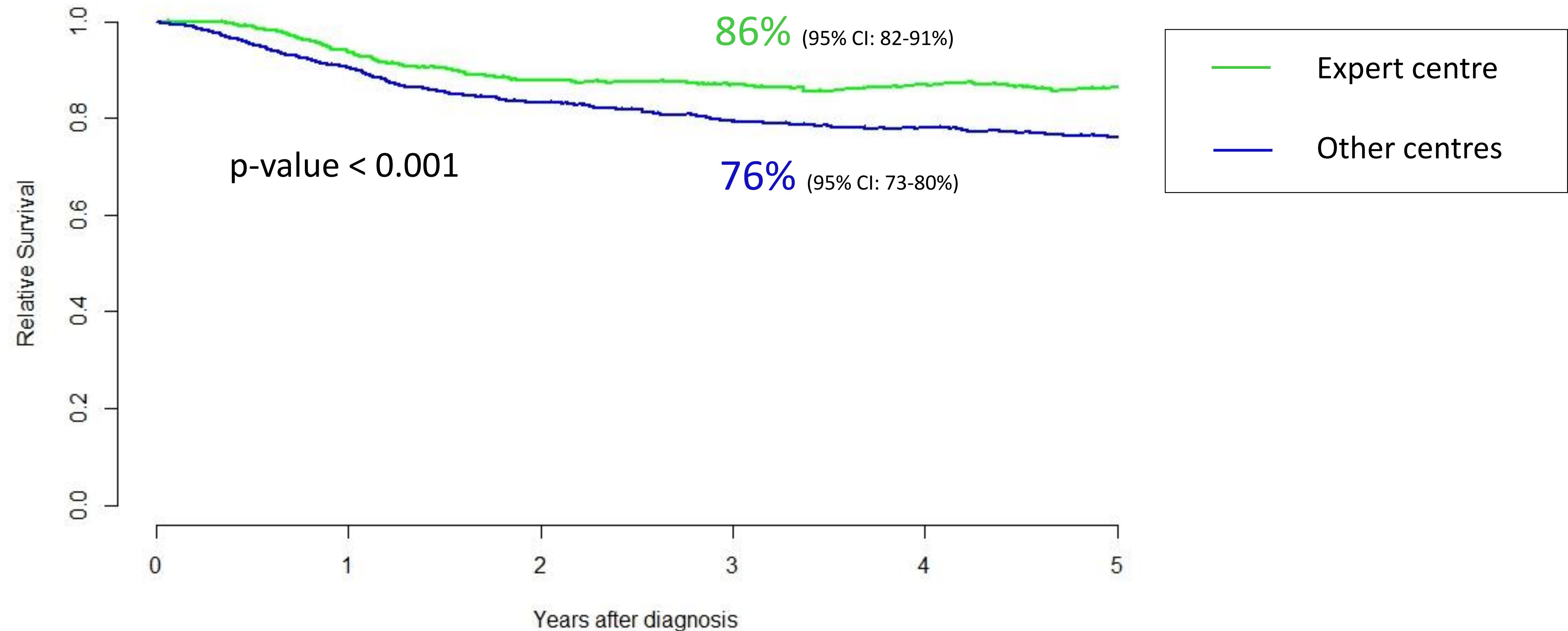


Probability of death due to penile cancer is estimated with relative survival ratio
→ Cause of death is not provided

Incidence increase 0.92 per 100,000 men to 1.83 per 100,000 men in 30 years

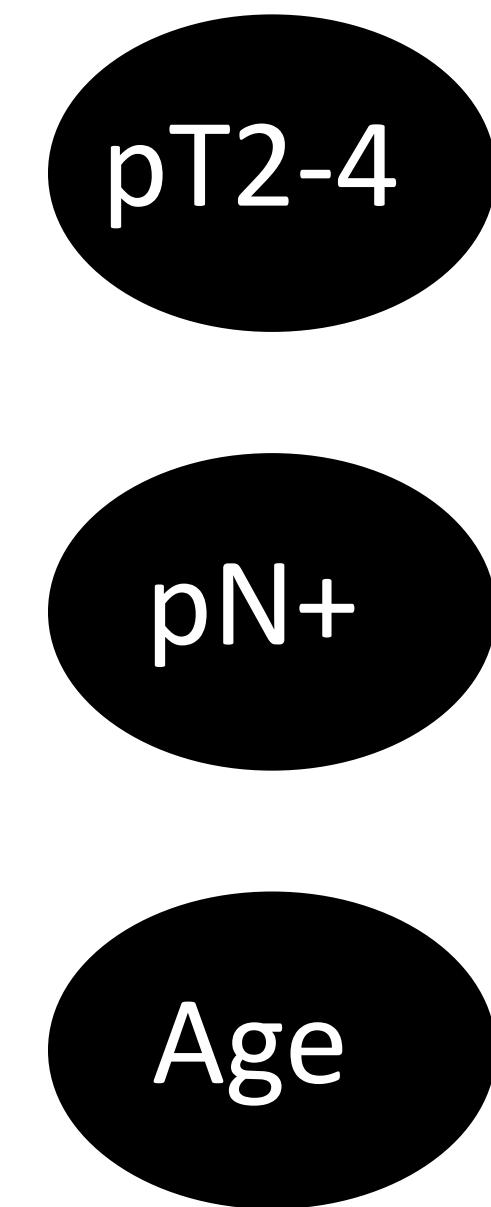
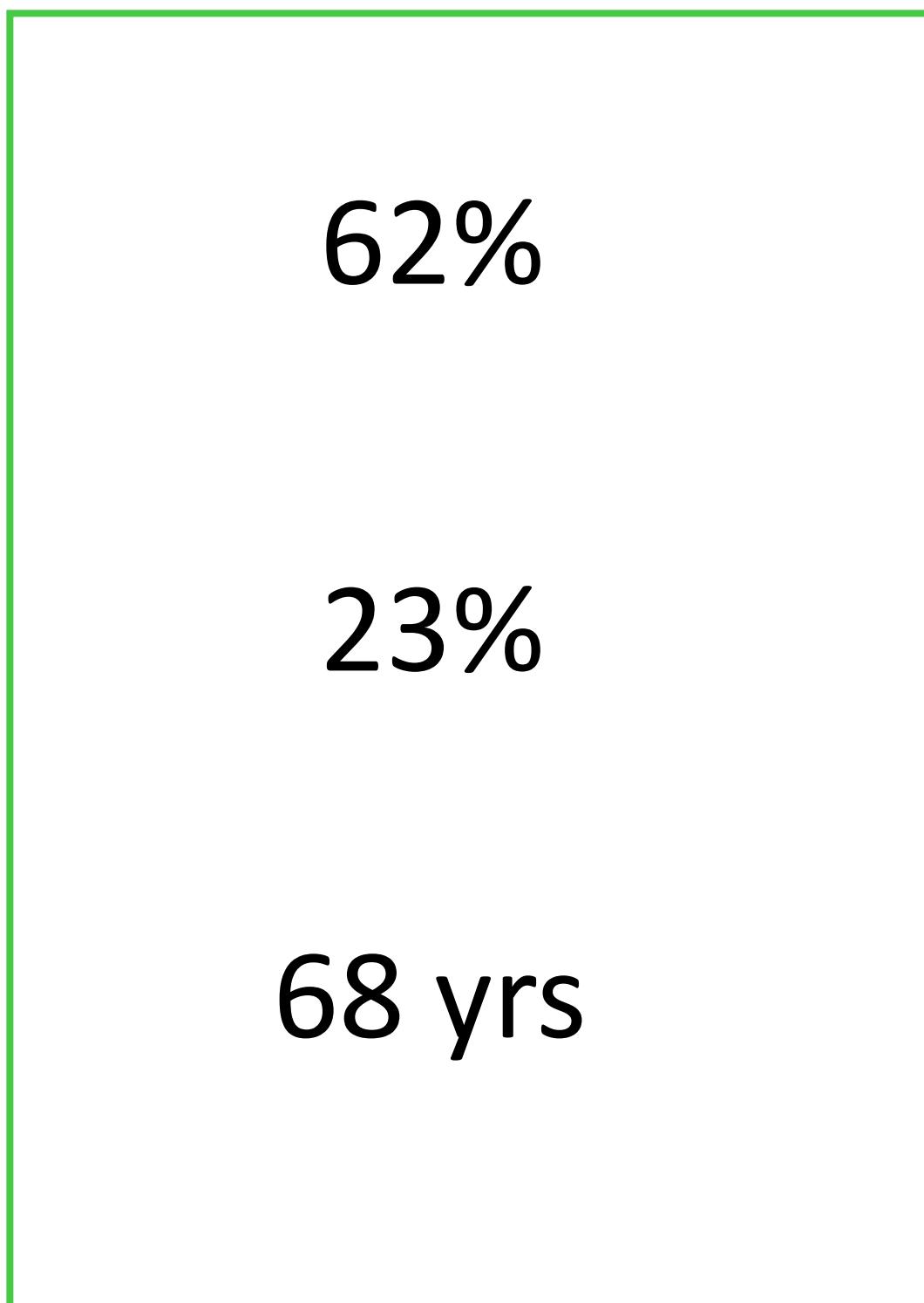


5-year relative survival

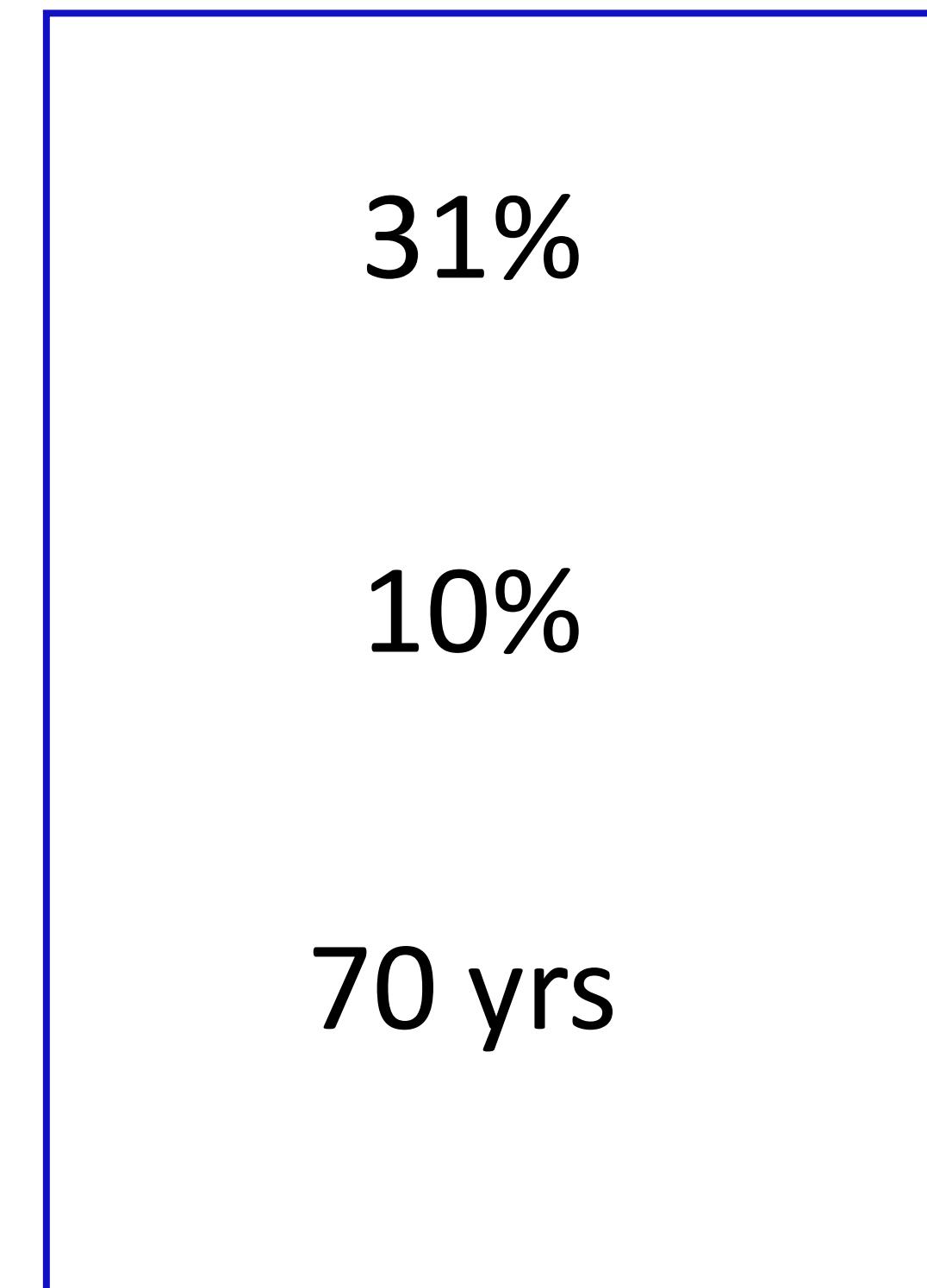


Patient characteristics

Expert centre



Other centres



Multivariate cox regression

Correction for age, pT, pN and histological grade

Treatment in **other centres** remains a **predictor for worse survival**

HR 1.16 (95% CI: 1.02 – 1.32)

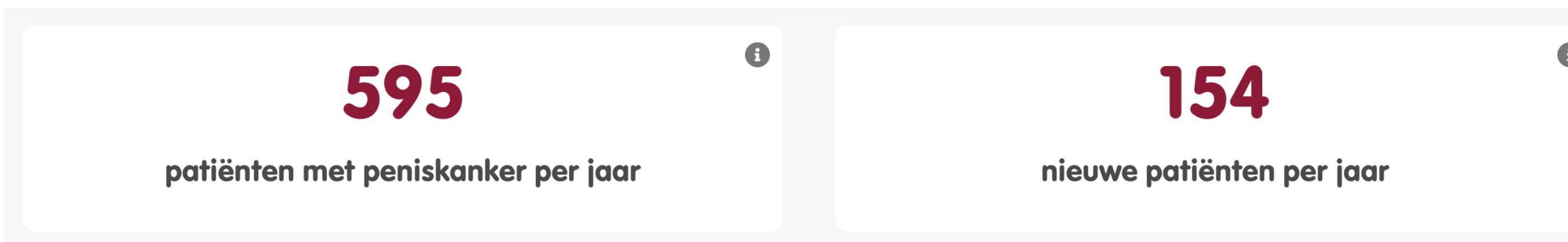
p-value = 0.026

Sneldiagnostiek zorgpad peniscarcinoom AVL

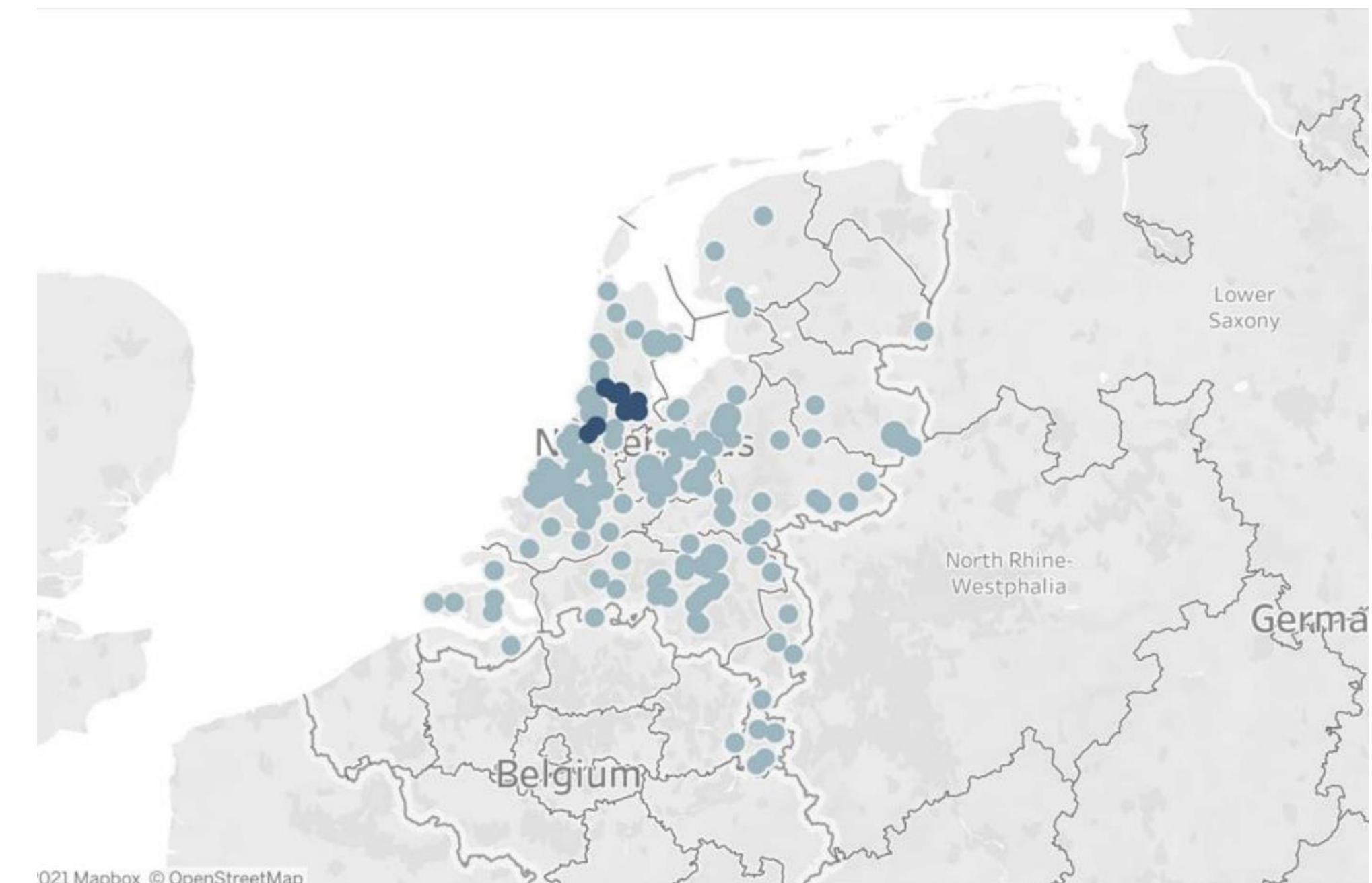
Sneldiagnostiek

U kunt doorgaans binnen 12 dagen terecht voor sneldiagnostiek. U krijgt dan op één dag een afspraak bij de uroloog en verpleegkundig specialist. Zo nodig krijgt u ook een echografisch onderzoek van de liezen, bipt, en een afspraak bij de anesthesiologie.

sneldiagnostiek →



12
dagen



- SD penis zorgpad: echo liezen, uroloog, VS, zo nodig bipt / laserbehandeling op dag van eerste bezoek
- Zelfde middag MDO (*urologie, radiotherapie, oncologie, pathologie, radiologie, nucgen*) en beliefspraak
- Sinds 2020: standaard 5 SD penis plekken per week (samen met AIOS/fellow, op dinsdag)

Verwijzing sneldiagnostiek poli

- Verwijzing SD peniscarcinoom-poli AVL:
 - www.avl.nl/verwijzers
 - Wachttijd 1-2wk
 - Alle afspraken op 1 dag (*inclusief echo liezen*)
 - Ook PeIN (*laser/resurfacing bij falen topicale therapie*)
 - Biopt: bij twijfel of alleen PeIN (*stansbiopt $\geq 3mm$*)
 - Liever geen irradicale circumcisie (*ivm reconstructie*)
 - Let op PA aanvraag: *HPV-16 IHC, LVI, PNI, Gradering*

Aanmeldformulier nieuwe patienten

Dit formulier is bedoeld voor verwijzende specialisten en huisartsen. Wij vragen u dit formulier zo volledig mogelijk in te vullen en alle relevante documentatie mee te sturen. Na versturen van dit formulier verwerkt onze afdeling planning de gegevens en wordt de patiënt uitgenodigd op de meest adequate polikliniek voor deze problematiek. Bij vragen kunt u bellen met het volgende telefoonnummer:

- 020 512 9111

Velden met een * zijn verplicht

Patientgegevens

Patient doorverwijzen naar

Achternaam
Initialen
Geslacht
Geboortedatum
Adres
Huisnr. / Toevoeging
Postcode
Plaats
Telefoonnummer
Emailadres
BSN
Reeds in het AVL geweest?
 Diagnose/verdenking
 Selecteer

Afspraakbevestiging

Afspraakbevestiging sturen aan
 Patient
 Familie
 Verwijzer

Verwijsmateriaal

Verwijsbrief
Indien de verwijsbrief (nog) niet beschikbaar is, hier vraagstelling en eerder uitgevoerde onderzoeken beschrijven
 Choose file No file chosen

Verslagen (Beeldvorming, Pathologie en OK)
 Choose file No file chosen
 Choose file No file chosen

Peniskankerzorg NL in ontwikkeling

- AVL = referentie/expertisecentrum
- Samenwerking met 3 regionale centra
- *'zorg in eigen regio als het kan'*
- Landelijk MDO
- Toekomst: Landelijke database



Take home messages

- Peniscarcinoom is zeldzaam, incidentie neemt (licht) toe
- HPV: belangrijkste risicofactor: vaccinatie!
- Overleving wordt met name bepaald door lymfeklierstatus, N2-N3 ziekte: poor survival
- Vroegtijdig opsporen en behandelen van lymfeklieruitzaaiingen cruciaal
- Chirurgie blijft gouden standaard: complicatiegevoelig, leercurve, multidisciplinair team
- Onderzoek naar nieuwe multimodale behandelstrategiën voor N2-N3 ziekte noodzakelijk
- Concentratie van zorg:
 - *Meer penissparende chirurgie*
 - *Betere (relatieve) overleving*
 - *SN procedure: balans tussen minimaliseren morbiditeit, maximaliseren sensitiviteit*
 - *Studies naar chemoradiatie, immunotherapie (+/- radiotherapie) ongoing*

Urologische Oncologie AVL

Prof. H.G. van der Poel (*hoofd*)

Prof. Dr. A. Bex

Dr. K. Barwari

Dr. O.R. Brouwer

Dr. N.M. Graafland

Dr. K. HendrickSEN

Drs. M.W. van de Kamp

Dr. P.J. van Leeuwen

Dr. M. Nicolai

Dr. B.W.G. van Rhijn

Drs. E.M.K. Wit

Fellows Urologie 2023

Dr. A. Postema

Dr. L. Mertens

AIOS Urologie Q1-2 2023

Drs. M. Nijenhuis

Dr. W. Beukers

Drs. P. Polm

Verpleegkundig specialisten

Mw. J. Bloos

Mw. N. van Galen

Mw. J. van Kesteren

Dhr. H.A.M. van Muilekom

Mw. M. Oosterveer

Mw. C.N. Tillier

Dhr. J. Visser



Dank voor de aandacht!