

DIAGNOSTIC EVALUATION II:

Diagnostic evaluation II

IMAGING:

MAGNETIC RESONANCE IMAGING (MRI):

Targeted biopsy improves the detection of ISUP grade > 2 cancer and reduces the detection of ISUP grade 1 cancer as compared to systematic biopsy.

Recommendations for all patients	Strength rating
Do not use magnetic resonance imaging (MRI) as an initial screening tool.	Strong
Adhere to PI-RADS guidelines for MRI acquisition and interpretation and evaluate MRI results in multidisciplinary meetings with pathological feedback.	Strong

Recommendations for biopsy-naïve patients	Strength rating
Perform MRI before prostate biopsy.	Strong
When MRI is positive (i.e. PI-RADS ≥ 3), combine targeted and systematic biopsy.	Strong
When MRI is negative (i.e., PI-RADS ≤ 2), and clinical suspicion of PCa is low (e.g. PSA density < 0.15 ng/mL), omit biopsy based on shared decision-making with the patient.	Weak

TRANSRECTAL ULTRASOUND AND ULTRASOUND-BASED TECHNIQUES:

Standard TRUS is not reliable at detecting prostate cancer (PCa).

PROSTATE BIOPSY:

The need for prostate biopsy is based on PSA level, other biomarkers and/or suspicious digital rectal exam (DRE) and/or imaging.

Recommendations	Strength rating*
At least 8 systematic biopsies are recommended in prostates with a size of about 30 cc and 10 to 12 core biopsies are recommended in larger prostates, with > 12 cores not being significantly more conclusive.	Strong
Transperineal biopsies are preferred over transrectal biopsies.	Strong
Where MRI has shown a suspicious lesion MR-targeted biopsy can be obtained through cognitive guidance, US/MR fusion software or direct in-bore guidance.	Weak
Use a single oral dose of either cefuroxime or cephalexin or cephalosporin as antibiotic prophylaxis for transperineal biopsy. Patients with severe penicillin allergy may be given sulphamethoxazole.	Weak
Ensure that prostate core biopsies from different sites are submitted separately for processing and pathology reporting.	Strong

Repeat biopsy after previously negative biopsy:

Recommendations for patients with prior negative biopsy	Strength rating
Perform MRI before prostate biopsy.	Strong
When MRI is positive (i.e. PI-RADS ≥ 3), perform targeted biopsy only.	Weak
When MRI is negative (i.e., PI-RADS ≤ 2), and clinical suspicion of PCa is high, perform systematic biopsy based on shared decision-making with the patient.	Strong

Other indications for repeat biopsy are rising and/or persistently elevated PSA, suspicious DRE and intraductal carcinoma as a solitary finding.

Recommended terminology for reporting prostate biopsies:

Recommendations	Strength rating
Benign/negative for malignancy; if appropriate, include a description.	Strong
Active inflammation.	
Granulomatous inflammation.	
High-grade prostatic intraepithelial neoplasia (PIN).	
High-grade PIN with atypical glands, suspicious for adenocarcinoma (PINATYP).	
Focus of atypical glands/lesion suspicious for adenocarcinoma/atypical small acinar proliferation, suspicious for cancer.	
Adenocarcinoma, provide type and subtype, and presence or absence of cribriform pattern.	
Intraductal carcinoma.	

CLINICAL STAGING:

T-STAGING:

So far, only DRE findings is part of the risk category stratification for cT category.

Magnetic resonance imaging findings can improve the prediction of the pathological stage when combined with clinical and biopsy data. T2-weighted imaging remains the most useful method for local staging on MRI.

N-STAGING:

Abdominal CT and T1-T2-weighted MRI indirectly assess lymph nodes (LNs) invasion by using LN diameter (8 mm short axis in the pelvis) and morphology. The size of non-metastatic LNs varies widely and may overlap the size of LN metastases. Nomograms combining clinical and biopsy findings have been used to estimate the risk of patients harbouring positive LNs.

PSMA PET/CT is more accurate in N-staging as compared to MRI, CT or choline PET/CT; however, small LN metastases, under the spatial resolution of PET (~5 mm), may still be missed. For patients at risk for pN+, an ePLND should be performed regardless of the results of the PSMA PET.

M-STAGING:

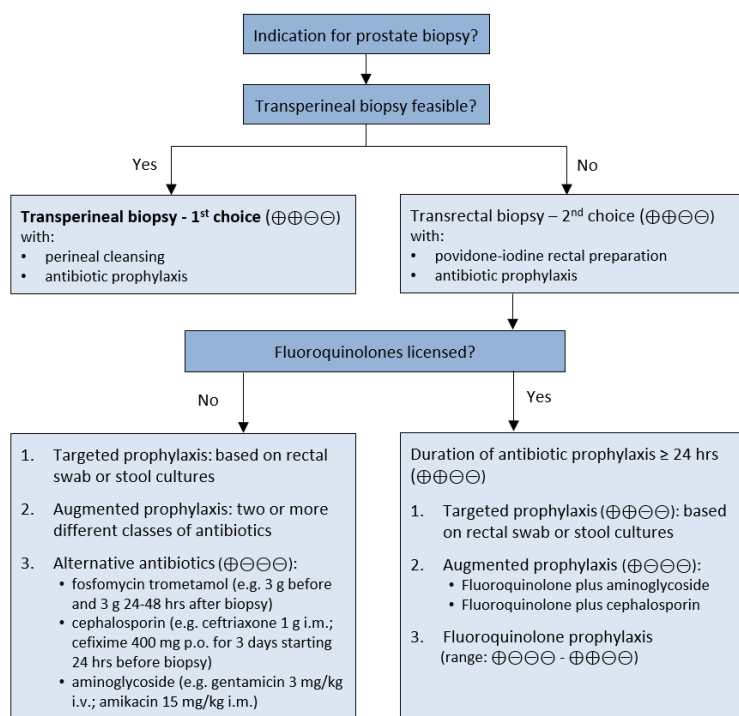
Evidence shows that choline PET/CT, PSMA PET/CT and whole-body MRI provide a more sensitive detection of LNs and bone metastases than the classical work-up with bone scan and abdominopelvic CT.

Replacing bone scan and abdominopelvic CT by more sensitive imaging modalities may be a consideration in patients with high-risk PCa undergoing initial staging.

However, in absence of prospective studies demonstrating survival benefit, caution must be used when taking therapeutic decisions.

Results from RCTs evaluating the management and outcome of patients with (and without) metastases only detected by choline PET/CT, PSMA PET/CT and MRI are awaited before a decision can be made to treat patients based on the results of these tests.

Introductory statement	LE
Systematic biopsy is an acceptable approach in case MRI is unavailable.	3



Summary of evidence	LE
PSMA PET/CT is more accurate for staging than CT and bone scan for high-risk disease but to date no outcome data exist to inform subsequent management.	1b

Recommendations	Strength rating
Any risk group staging	
Use pre-biopsy MRI for local staging information.	Weak
Low-risk localised disease	
Do not use additional imaging for staging purposes.	Strong
Intermediate-risk disease	
In ISUP grade 3, include at least cross-sectional abdominopelvic imaging and a bone-scan for metastatic screening.	Weak
High-risk localised disease/locally advanced disease	
Perform metastatic screening including at least cross-sectional abdominopelvic imaging and a bone-scan.	Strong
When using PSMA PET or whole body MRI to increase sensitivity, be aware of the lack of outcome data of subsequent treatment changes.	Strong