Radiologic perspective on oligometastatic and oligo-recurrence detection

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Executive chair, International Cancer Imaging Society
Trustee, International Society of Magnetic Resonance in Medicine
## Disclosures: active 2017

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<th>Category</th>
<th>Details</th>
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<tr>
<td>Research Support/Agreement</td>
<td>Siemens Healthineers</td>
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<tr>
<td>Employee</td>
<td>None</td>
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<tr>
<td>Consultant</td>
<td>None</td>
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<tr>
<td>Major Stockholder</td>
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<td>Speakers Bureau</td>
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<td>Siemens Healthineers</td>
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</table>

*Presentation may include discussions of the off-label use of drugs, equipment and software*
Testing for BCR

Likely systemic recurrence*

Likely pelvic recurrence*

Pelvis/prostate recurrence mpMRI

Option

NextGen imaging restaging = WB-MRI or PET/CT^ (tracer of choice)

Pelvic recurrence unlikely*

Pelvic recurrence likely*

Consider

M0/M+

\pm PET/CT**

M0

M+

M++

Local recurrence

Salvage Rx options

Systemic restaging WB-MRI or PET/CT

No local recurrence

No salvage options

No image detected disease

SACT

^depending on cost/availability/expertise; **PET/CT maybe needed if WB-MRI used as the 1st step; BCR biochemical relapse; M0 = no detected metastases; M+ oligo-metastases; M++ poly-metastases; SACT systemic anticancer therapy

*Recurrence site: multiple factors
- Primary therapy (unimodality or multimodality)
- Pathological status – Gleason score/prognostic group; margins; nodal status
- PSA level; PSA-DT
- Nomograms; genomic analysis

M0 = no detected metastases; M+ oligo-metastases; M++ poly-metastases; SACT systemic anticancer therapy
<table>
<thead>
<tr>
<th>Study</th>
<th>Modality</th>
<th>Patients</th>
<th>Main study findings</th>
<th>Authors’ conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sciarra et al. 2008</td>
<td>MRI (MRS, DCE)</td>
<td>50</td>
<td>For identification of local recurrent PCa after RP (biopsy confirmed), MRS and DCE showed an AUC at ROC analysis of 0.942 and 0.931. Combination of DWI and MRS increased diagnostic accuracy (AUC: 0.964)</td>
<td>MRI with combined DWI and MRS accurately identifies local recurrent PCa after RP</td>
</tr>
<tr>
<td>Cirillo et al. 2009</td>
<td>MRI (T2w, DCE)</td>
<td>72</td>
<td>DWI showed a sensitivity, specificity, and accuracy of 84.1%, 89.3%, and 86.1% compared with 61.4%, 82.1%, and 69.4% for sole T2w for identification of local recurrent PCa after RP</td>
<td>DWE improves the diagnostic performance compared with sole T2w</td>
</tr>
<tr>
<td>Panebianco et al. 2013</td>
<td>MRI (T2w, DWI, DCE)</td>
<td>242</td>
<td>For identification of local recurrent PCa after RP (biopsy confirmed), T2w and DWI showed a sensitivity, specificity, and accuracy of 100%, 97%, and 91% compared with 98%, 96%, and 89% for T2w and DWI. In a cohort confirmed by PSA follow-up after RT, these values were 98%, 94%, and 93% for T2w and DCE compared with 97%, 95%, and 93% for T2w and DWI.</td>
<td>DCE is the most reliable technique in detecting local PCa recurrence after RP, although DWI can be proposed as a reliable alternative</td>
</tr>
<tr>
<td>Donati et al. 2013</td>
<td>MRI (T2w, DWI, DCE)</td>
<td>53</td>
<td>For identification of local recurrent PCa after RT (biopsy confirmed), T2w and DWI performed significantly better than sole T2w (p ≤ 0.014). DCE sequences did not contribute significant incremental value to T2w and DWI.</td>
<td>Addition of DWI or DCE to T2w significantly increases accuracy for detection of recurrent PCa after RT</td>
</tr>
<tr>
<td>Panebianco et al. 2014</td>
<td>MRI (MRS)</td>
<td>50</td>
<td>MRS during follow-up after RT correctly identified 43 patients who responded to RT, 5 patients who recurred, and 2 patients who had persistent disease preceding the diagnosis of biochemical relapse</td>
<td>MRS has greater potential than PSA level in monitoring patients after RT because it anticipates PSA nadir and biochemical relapse</td>
</tr>
<tr>
<td>Cimitan et al. 2006</td>
<td>18F-FCH PET/CT</td>
<td>100</td>
<td>46/100 patients (PSA: 0.12–14.3 ng/ml) without lesions on PET/CT (89% of patients with PSA &lt; 4 ng/ml and 87% of patients with Gleason score &lt; 8)</td>
<td>No significant impact in patients with BCR of PCa if PSA &lt; 4 ng/ml but may be helpful to rule out systemic disease in selected cases</td>
</tr>
<tr>
<td>Krause et al. 2008</td>
<td>11C-Cho PET/CT</td>
<td>63</td>
<td>DR of lesions on PET/CT was 36% for PSA &lt; 1 ng/ml, 43% for PSA 1 to &lt;2 ng/ml, 62% for PSA 2 to &lt; 3 ng/ml, and 73% for PSA 3 ng/ml.</td>
<td>DR of PET/CT shows a positive relationship with PSA levels in patients with BCR of PCa</td>
</tr>
<tr>
<td>Giovacchini et al. 2010</td>
<td>11C-Cho PET/CT</td>
<td>109</td>
<td>In patients with BCR of PCa and uneventful conventional imaging, DR of PET/CT was 11%. PSA was the only predictor of positive PET/CT.</td>
<td>PET/CT may be useful for restaging but cannot be used to guide therapy</td>
</tr>
<tr>
<td>Mitchell et al. 2013</td>
<td>11C-Cho PET/CT</td>
<td>176</td>
<td>In 32% of patients with BCR of PCa, PET/CT identified lesions not detected by conventional imaging. Trigger PSA (HR: 1.37; p = 0.04) and initial clinical stage (HR: 5.19; p = 0.0035) were significant predictors of positive PET/CT.</td>
<td>The optimal PSA value for DR is approximately 2.0 ng/ml. PET/CT substantially enhances DR compared with conventional imaging at lower PSA</td>
</tr>
<tr>
<td>Marzola et al. 2013</td>
<td>18F-Cho PET/CT</td>
<td>233</td>
<td>DR of lesions on PET/CT increases significantly with higher PSA. PET-positive patients presented with accelerated PSA kinetics (mean PSA DT = 6 mo vs 15.4 mo; mean PSA velocity = 9.3 ng/ml per year vs 0.9 ng/ml per year).</td>
<td>In about 20% of patients, detection of lesions by PET/CT enabled locoregional radiation therapy</td>
</tr>
<tr>
<td>Afshar-Oromieh et al. 2015</td>
<td>68Ga-PSMA</td>
<td>319</td>
<td>DR of PET/CT was positively associated with PSA level and ADT, but not with Gleason score and PSA DT. Histologic confirmation in 42 patients showed a sensitivity, specificity, NPV, and PPV of 76.6%, 100%, 91.4%, and 100% on a lesion-based analysis.</td>
<td>PET/CT detects recurrent PCa in a high number of patients. Radiotracer is highly specific for PCa</td>
</tr>
<tr>
<td>Eiber et al. 2015</td>
<td>68Ga-PSMA</td>
<td>248</td>
<td>DR of lesions on PET/CT was 57.9% for PSA 0.2 to &lt;0.5 ng/ml, 72.7% for PSA 0.5 to &lt;1 ng/ml, 93.0% for PSA 1 to &lt;2 ng/ml, 96.8% for PSA ≥2 ng/ml. Compared with conventional imaging, PET showed exclusively pathologic findings in 32.7% and additional involved regions in 24.6% of patients.</td>
<td>PET/CT shows substantially higher DR than reported for other imaging modalities especially at low PSA (&lt;0.5 ng/ml)</td>
</tr>
</tbody>
</table>

Imaging for Prostate Cancer Recurrence. T Maurera, M Eiberb, S Fanti, L Budäusd, V Panebianco. EU Focus, Volume 2 Issue 2, June 2016, Pages 139-150
Pelvic recurrence – which imaging modality?

- Locally recurrence is best detected by mpMRI: T2W (morphology), diffusion (cellularity) and dynamic contrast enhancement (vascularity)
  - Can differentiate between residual prostate tissue and scar with high accuracy
  - Performance of mpMRI is superior to choline PET/CT
  - Detection by PET/CT is impaired by tracer accumulation in bladder

- Pelvic nodal disease is best detected by PET/CT techniques
  - MRI/CT use size criteria – both are markedly limiting
  - USPIO’s likely to dramatically improve MRI performance but lack commercial availability (on-going phase 3 studies)
  - Sensitivity: PSMA >> Choline PET/CT; availability Choline PET/CT >> PSMA
Local recurrence of prostate cancer after radical prostatectomy is at risk to be missed in $^{68}$Ga-PSMA-11-PET of PET/CT and PET/MRI: comparison with mpMRI integrated in simultaneous PET/MRI.
Pelvic recurrence – no single imaging modality

- Locally recurrence is best detected by mpMRI: T2W (morphology), diffusion (cellularity) and dynamic contrast enhancement (vasularity)
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- Pelvic nodal disease is best detected by PET/CT techniques
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  - Sensitivity: PSMA >> Choline PET/CT; availability Choline PET/CT >> PSMA
    - Neither PET test is perfect when PSA levels are < 0.2ng/ml
**Testing for BCR**

*Suitable for salvage*

- **Likely systemic recurrence***
  - Systematic staging
    - WB-MRI or PET/CT* (tracer of choice)
    - M0/M+
    - **M++**
      - SACT
    - **M+**
      - Salvage Rx options
      - Recurrence site: multiple factors
        - - Primary therapy (unimodality or multimodality)
        - - Pathological status – Gleason score/prognostic group; margins; nodal status
        - - PSA level; PSA-DT
        - - Nomograms; genomic analysis
  - Pelvic recurrence unlikely***
  - +PET/CT**
  - **M0**
  - Pelvic recurrence likely***
  - Pelvis/prostate recurrence mpMRI
    - Consider

- **Likely pelvic recurrence***
  - Systemic restaging
    - WB-MRI or PET/CT*
    - M0/M+
      - M0/M0
      - M++
    - No salvage options
  - No local recurrence

* depending on cost/availability/expertise; **PET/CT maybe needed if WB-MRI used as the 1st step; BCR biochemical relapse; M0 = no detected metastases; M+ oligo-metastases; M++ poly-metastases; SACT systemic anticancer therapy
Testing for BCR Suitable for salvage

- Likely systemic recurrence*
- Likely pelvic recurrence*

Systematic staging
WB-MRI or PET/CT* (tracer of choice)

±PET/CT**

- M0/M+
- M++
- SACT

Pelvis/prostate recurrence mpMRI

- M0
- M+
- M++

No image detected disease

Salvage Rx options

Systemic restaging
WB-MRI or PET/CT

- M+/M0
- M++

No local recurrence

No salvage options

*Recurrence site: multiple factors
- Primary therapy (unimodality or multimodality)
- Pathological status – Gleason score/prognostic group; margins; nodal status
- PSA level; PSA-DT
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Imaging for (early) detection of metastases

(Guidelines emphasis is still on CT/BS)

New diagnosis*

• Various guidelines – Euro/USA differences*
• High risk, unfavourable subgroup of intermediate risk, symptomatic

BCR post-RT**

• PSA between 5-10 ng/mL
• Repeat imaging if prior negative, every PSA doubling

BCR-post prostatectomy

• PSA ≥2 ng/mL**
• Repeat imaging if prior negative, every PSA doubling**
• PSADT < 6 months***

M0-CRPC

• New diagnosis*
• PSA ≥2 ng/mL**
• Repeat imaging if prior negative, every PSA doubling**
• PSADT < 6 months***


**Imaging for (early) detection of metastases**

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**BCR-post prostatectomy**
- PSA ≥2 ng/mL**
- Repeat imaging if prior negative, every PSA doubling**
- PSADT < 6 months**

**M0-CRPC**

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Advantages and limitations of available whole-body imaging methods for advanced prostate cancer

Padhani AR, et al. Rationale for Modernising Imaging in Advanced Prostate Cancer, European Urology Focus, Available online 15 July 2016, ISSN 2405-4569,

Table 1 - Summary of the advantages and limitations of whole-body imaging methods suited for advanced prostate cancer evaluations

<table>
<thead>
<tr>
<th>Method</th>
<th>Strengths</th>
<th>Weaknesses</th>
<th>Opportunities</th>
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</thead>
<tbody>
<tr>
<td>CT scan</td>
<td>Widely available</td>
<td>Does not directly evaluate malignant bone disease when soft tissue is about</td>
<td>Complementary to PET or whole-body MRI information</td>
</tr>
<tr>
<td></td>
<td>Easily standardised</td>
<td>Radiation exposure</td>
<td>Scintigraphic change in nonmetastatic lesions as potential response parameter</td>
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<td></td>
<td>Low cost</td>
<td>Limited local disease evaluations</td>
<td>Long metastases detection</td>
</tr>
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<td></td>
<td>Fast acquisition</td>
<td>Subcartilaginous nodal characterisation</td>
<td>Lytic vs nonlytic bone metastases subclassification</td>
</tr>
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<td></td>
<td>Quantitative assessment</td>
<td>Cannot visualise infiltrative (nonosteolytic) bone disease</td>
<td></td>
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<tr>
<td></td>
<td>(Steinberg unit)</td>
<td>CT imaging response</td>
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<tr>
<td></td>
<td>Ability to characterise bone disease into the severity between sclerotic</td>
<td>Inability to diagnose response/progression in sclerotic bone metastases</td>
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<tr>
<td></td>
<td>and lytic</td>
<td></td>
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<tr>
<td></td>
<td>Soft tissue and lytic bone metastasis detection and response assessments</td>
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<tr>
<td></td>
<td>Incorporated into clinical practice and trial guidelines</td>
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<tr>
<td>Bone scan</td>
<td>SBEM available</td>
<td>Does not directly evaluate malignant bone disease; reactive osteoblastic</td>
<td>Improved test performance by addition of SPET/CT capability</td>
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<tr>
<td></td>
<td>Easily standardised</td>
<td>uptake only</td>
<td>Development of bone scan index as prognostic biomarker</td>
</tr>
<tr>
<td></td>
<td>Low cost</td>
<td>Largest examination times</td>
<td></td>
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<td></td>
<td>Incorporated into clinical practice and trial guidelines</td>
<td>Pre- and post-examination care precautions</td>
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<td></td>
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<td>Radiation exposure to patient and public due to longer half-life of</td>
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<td>Technetium 99m Tc99m</td>
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<td></td>
<td></td>
<td>No ability to assess soft tissue disease</td>
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<td></td>
<td></td>
<td>Lower sensitivity and specificity than CT/IRM</td>
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<td></td>
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<td>Bone scan image response</td>
<td></td>
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<td></td>
<td></td>
<td>No positive benefit criteria (progression only)</td>
<td></td>
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<tr>
<td>Sodium</td>
<td>High sensitivity and reliability good specificity for bone metastases</td>
<td>Does not directly evaluate malignant bone disease; reactive osteoblastic</td>
<td>Development of NaT tumour volume index as prognostic biomarker</td>
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<tr>
<td>fluoride</td>
<td>(CT component adds specificity) Medium-length examination times</td>
<td>uptake only</td>
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<tr>
<td>PET/CT</td>
<td></td>
<td>Limited tracer availability</td>
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<td></td>
<td></td>
<td>Expensive</td>
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<td></td>
<td>Multiple sources of radiation exposure (CT scans and radiocurium)</td>
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<td></td>
<td></td>
<td>Coregistration/alignment problems (not blemishlike)</td>
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<td></td>
<td></td>
<td>Limited ability to assess soft tissue disease related to the lower</td>
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<td></td>
<td></td>
<td>quality of the CT component used for attenuation correction</td>
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<td></td>
<td></td>
<td>Flare response phenomenon</td>
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<td></td>
<td></td>
<td>No positive benefit criteria (progression only)</td>
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<tr>
<td>Chlorine</td>
<td>Directly evaluates malignant bone marrow disease</td>
<td>Limited tracer availability</td>
<td>Development of SSTR as a potential response biomarker</td>
</tr>
<tr>
<td>PET/CT</td>
<td>High sensitivity and reliability good specificity for detection of bone</td>
<td>Expensive</td>
<td>Development of tumour load as a prognostic biomarker</td>
</tr>
<tr>
<td></td>
<td>and soft tissue metastases</td>
<td>Multiple sources of radiation exposure (CT scans and R-18F)</td>
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<tr>
<td></td>
<td>Objective response parameters (SUV) Medium-length examination times</td>
<td>(SUV)</td>
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<tr>
<td></td>
<td></td>
<td>Some post-examination care precautions (not blemishlike)</td>
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<td></td>
<td></td>
<td>Potential to be influenced by bone marrow-stimulating factors</td>
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<td></td>
<td></td>
<td>Inability to accurately assess liver and systemic lesions</td>
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<tr>
<td>Whole-body</td>
<td>Directly evaluates malignant bone marrow disease</td>
<td>Radiation-free long-term follow-up</td>
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<tr>
<td>MRI</td>
<td>Limited availability</td>
<td>Surgical planning</td>
<td></td>
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<tr>
<td></td>
<td>Lack of radiation</td>
<td>Event-related imaging (spinal cord compression, critical fractures)</td>
<td></td>
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<tr>
<td></td>
<td>Flexible, adaptable imaging (possible to tailor examinations according to disease location)</td>
<td>“One-stop-shop” - bone and soft tissue disease detection and response assessments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ability to detect and assess response of bone and soft tissue disease</td>
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<tr>
<td></td>
<td>Including the prostate, nodes, and uterus</td>
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<tr>
<td></td>
<td>Objective response parameters (size, volume, and ADC measurements)</td>
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</tbody>
</table>

ADC = advanced prostate cancer; OB = osteoblastic; CT = computed tomography; MRI = magnetic resonance imaging; PET = positron emission tomography; SPET/CT = single-photon emission computed tomography; SUV = specific uptake value.
Prospective evaluations of planar bone scan, SPECT, SPECT/CT, NaF PET/CT and WB-MRI for the detection of bone metastases in high risk breast and prostate cancer patients: SKELETA clinical trial.

- Twenty-six breast and 27 prostate cancer patients at high risk of bone metastases
- Five independent modality specific reviewers interpreted each modality without the knowledge of other imaging findings
- The final metastatic status (best value comparator) based on reading of all scans, clinical and imaging follow-up (minimal and maximal follow-up time was 6, and 32 months, respectively)
- Regional level analyses
- WB-MRI (with DWI) showed similar diagnostic accuracy to 18F-NaF PET/CT and outperformed SPECT/CT, and planar B one scans

<table>
<thead>
<tr>
<th>Modality</th>
<th>sensitivity</th>
<th>Equivocal findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone scan - planar</td>
<td>62%</td>
<td>50</td>
</tr>
<tr>
<td>SPECT</td>
<td>74%</td>
<td>44</td>
</tr>
<tr>
<td>SPECT/CT</td>
<td>85%</td>
<td>5</td>
</tr>
<tr>
<td>NaF PET/CT</td>
<td>93%</td>
<td>6</td>
</tr>
<tr>
<td>WB-MRI inc DWI</td>
<td>91%</td>
<td>4</td>
</tr>
</tbody>
</table>

Jambor I, et al. Prospective evaluation of planar bone scintigraphy, SPECT, SPECT/CT, 18F-NaF PET/CT and whole body 1.5T MRI, including DWI, for the detection of bone metastases in high risk breast and prostate cancer patients: SKELETA clinical trial. Acta Oncologica 2016; Vol. 55(1) [epub]
Next generation imaging (Choline-PET, WB-MRI) better than bone scan for bone metastasis detection in prostate cancer

<table>
<thead>
<tr>
<th>Study</th>
<th>Sensitivity % (95% CI)</th>
<th>Specificity % (95% CI)</th>
<th>DOR</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per patient analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FCH-PET/CT</td>
<td>587 (87-93)</td>
<td>97 (93-99)</td>
<td>150.7</td>
<td>0.95</td>
</tr>
<tr>
<td>MRI</td>
<td>695 (90-98)</td>
<td>96 (92-98)</td>
<td>343.2</td>
<td>0.98</td>
</tr>
<tr>
<td>Bone scan - planar</td>
<td>11</td>
<td>82 (78-85)</td>
<td>20.3</td>
<td>0.89</td>
</tr>
<tr>
<td>Bone scan (prospective)</td>
<td>6</td>
<td>76 (69-82)</td>
<td>12.7</td>
<td>0.85</td>
</tr>
<tr>
<td>Bone scan (retrospective)</td>
<td>5</td>
<td>86 (76-92)</td>
<td>35.3</td>
<td>0.92</td>
</tr>
</tbody>
</table>

MET-RADS-P: standard for WB-MRI in metastatic cancer

• Establish minimum technical parameters for data acquisition
• Establish standardized data collections that enables detailed reporting of the disease phenotype based on anatomic patterns of metastatic spread
• Develop criteria to assess response of metastatic bone disease
• Summarize likelihood of response in bone (MET-RADS criteria) and soft tissues (RECIST v1.1 & PCWG3 guidance)
• Suggest methods to record presence, location & extent of discordant responses
• Enable data collection for outcomes monitoring in clinical trials
• Allow the education of radiologists, to reduce variability in interpretations
• Enhance communication with referring clinicians
Testing for BCR Suitable for salvage

Likely pelvic recurrence*

Likely systemic recurrence*

NextGen imaging restaging = WB-MRI or PET/CT^ (tracer of choice)

Pelvis/prostate recurrence mpMRI

Systemic restaging WB-MRI or PET/CT

No local recurrence

Local recurrence

Salvage Rx options

No detected disease: prostate bed RT

M0/M+ option

Pelvic recurrence likely*

No salvage options

M++

M+/M0

SACT

M0

Pelvic recurrence unlikely*

\^depending on cost/availability/expertise; **PET/CT maybe needed if WB-MRI used as the 1\textsuperscript{st} step; BCR biochemical relapse; M0 = no detected metastases; M+ oligo-metastases; M++ poly-metastases; SACT systemic anticaner therapy

- Recurrence site: multiple factors
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M+/M0

Likely systemic recurrence*

No detected disease: prostate bed RT

*Recurrence site: multiple factors
- Primary therapy (unimodality or multimodality)
- Pathological status – Gleason score/prognostic group; margins; nodal status
- PSA level; PSA-DT
- Nomograms; genomic analysis

^depending on cost/availability/expertise; **PET/CT maybe needed if WB-MRI used as the 1st step; BCR biochemical relapse; M0 = no detected metastases; M+ oligo-metastases; M++ poly-metastases; SACT systemic anticancer therapy
Post prostatectomy recurrence
(pT3, N1, G1 4+4; RT to resection bed) Response to SBRT

10Dec12
PSA 6.1 ng/ml

14Mar13
PSA 0.7 ng/ml
Post prostatectomy recurrence

(*pT3, N1, G1 4+4; RT to resection bed*) Response to SBRT


Post prostatectomy recurrence

(*pT3, N1, G1 4+4; RT to resection bed*) Response to SBRT
Detecting oligometastatic and oligorecurrence in BCR — imagers viewpoint (nuclear medicine & radiology)

• No available, single imaging modality can detect everything required for clinical decision making
  – Use a step-wise algorithmic, multimodality imaging approach
Detecting oligometastatic and oligorecurrence in BCR – imagers viewpoint (nuclear medicine & radiology)

• No available, single imaging modality can detect everything required for clinical decision making
  – Use a step-wise algorithmic, multimodality imaging approach
• Stop using BS/CT scans when expensive salvage therapy is being considered for BCR
• Next generation imaging (WB-MRI (incl DWI) and/or PET/CT (tracer of choice) shows superior sensitivity for recurrence detection
• Do systemic restaging before local recurrence staging for M0/M+ if salvage Rx is an option