$^{68}$Ga-PSMA PET for staging and re-staging of prostate cancer

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term „PSMA“ in pubmed

68Ga-PSMA
HBED-CC

J591 PSMA targeting
Prostascint (7E11)

publications per year
Agenda

1. Basics on PSMA
2. Recurrent PC and new treatment options
3. Primary PC and Detection
4. Pitfalls
BASICS ON BIOLOGY AND DIFFERENT PSMA-LIGANDS
PSMA

- Prostate-specific membran antigen
- [syn. Glutamate carboxypeptidase II (GCP-II)]
- cell surface protein with overexpression in prostate cancer (750 AS, 84 kDa)
- PSMA expression increases progressively in:
  - Higher grade tumors
  - Under androgen deprivation
  - Metastatic disease
  - Hormone-refractory Prostate cancer
  - also in tumor neovascuclature
- promising target for prostate cancer specific imaging and therapy
- variety of tracers for PET/SPECT-imaging

Maurer T et al, Nat Rev Urol, 2016
PSMA-ligands for PET-imaging

$^{68}$Ga-PSMA DKFZ-617

Benešová et al., JNM 2015

$^{68}$Ga-PSMA HBED-CC (PSMA DKFZ-11)


$^{18}$F-DCFBC

Cho et al, JNM 2012

$^{18}$F-DCFPyL

Szabo et al, Mol Im Biol 2015

$^{68}$Ga-PSMA I&T

Weineisen et al, JNM 2015
68Ga-PSMA HBED-CC

- “Heidelberg Compound”
- Glu-NH-CO-NH-Lys-(Ahx)-[68Ga(HBED-CC)] *
- preliminary studies: high detection rate1 and high lesion-to-background ratio 2

1 Afshar-Oromieh A et al. EJNMMI 2013
2 Afshar-Oromieh A et al. EJNMMI 2014

* Tracer development at DKFZ Heidelberg by Eisenhut M

11C-Cholin

68Ga-PSMA
RECURRENT PROSTATE CANCER
Local recurrence in $^{68}$Ga-PSMA PET/CT

74y/o patient, s/p. RPE 2004 pT2a pN0 Gleason 7, s/p salvage RTx 2010
PSA-value 05/15: 1.76 ng/ml

salvage operation:
soft-tissue including seminal vesicle with a cribriforme, poorly differentiated adenocarcinoma of the prostate (Gleason 7)

Maurer T et al, Nat Rev Uro 2016
75yo patient, s/p RPE 2000, Z.n. RTx 2011, value 1.09 ng/ml

- Secondary LAE confirms LN metastasis
- Postoperative drop of PSA-value <0.07 ng/ml!

Eiber M et al, JNM 2015

Example: single lymph node metastasis
Recurrent prostate cancer: detection efficacy

- 248 patient with BCR after RPE (homoogenous patient group)
- PSA-value: median 1.9 ng/ml (0.2 – 59.4)
- in 89.5% (222/248) of patients at least one suspicious lesion detected
- detection rate dependent on PSA-value, not PSAvel/PSAadt

Histolog. differentiation: (p=0.0190)
- Gleason Score ≤7: 86.7% (111/128)
- Gleason Score ≥8: 96.8% (90/93)

Androgen deprivation tx: (p=0.078)
- + : 97.5.0% (67/70)
- - : 87.1% (155/178)

Eiber M et al JNM 2015
Contribution of CT vs. $^{68}$Ga-PSMA PET within a hybrid PET/CT-examination for lesion detection

248 patients

$^{68}$Ga-PSMA PET/CT negative
26 (10.5%)

$^{68}$Ga-PSMA PET/CT positive
222 (89.5%)

Concordance of pathological findings in PET and CT: 60 (24.1%)

Patients with concordant findings but additional lesions exclusively positive in:

PET: 81 (32.7%)
CT: 3 (1.2%)

Patients with findings exclusively positive in:

PET: 61 (24.6%)
CT: 17 (6.9%)

Eiber M et al JNM 2015

"...molecular imaging has an edge over morphological imaging"

Mottaghy F et al EJNMI 2015, editorial commentary
Value of $^{68}$Ga-PSMA PET for the detection of lymph node metastases in recurrent PC: results confirmed by secondary lymphadenectomy

**Histopathology:**
correctly classified as lymph node metastases

**Histopathology:**
false negative

Rauscher I et al., JNM 2016
Aim- Methods- Results

Aim: to evaluate the accuracy of $^{68}$Ga-PSMA HBED-CC PET compared to morphological imaging for assessment of lymph node metastases (LNM) in patients with recurrent prostate cancer (PC)

Methods:
- retrospective inclusion of 48 patients with biochemical recurrence (median PSA level of 1.31 ng/ml; IQR 0.75-2.55 ng/ml) and suspicious LN in PET and/or morphological imaging
- $^{68}$Ga-PSMA HBED-CC PET/CT (n= 31) or PET/MR (n= 17) performed before salvage lymphadenectomy
- Reference standard: histopathology

Results:
- histopathology: LNM in 68/179 resected anatomical LN fields (38.0%)
- LNM detection: 53/68 LN fields (78%) for $^{68}$Ga-PSMA HBED-CC PET, 18/67 LN fields (27%) for morphological imaging
- Specificity: 97% for $^{68}$Ga-PSMA HBED-CC PET, 99% for morphological imaging
- mean size of suspicious LN: 8.3 ± 4.3 mm (range 4–25 mm) in $^{68}$Ga-PSMA HBED-CC PET, 13.0 ± 4.9 mm (range 8-25 mm) in morphological imaging
Conclusion

\( ^{68} \text{Ga-PSMA HBED-CC PET is} \)

- significantly superior than morphological imaging, esp. in detection of small LNM
- promising method for early detection of LNM in patients with biochemical recurrent PC, even at very low PSA-values
- might represent a valuable tool for guiding secondary lymphadenectomy

\[ \rightarrow \] one single PSMA positive LN left obturator, histology: negative
New treatment options with PSMA: Radioguided surgery in localised recurrent PC

$^{111}$In-labeled or $^{99}$mTc PSMA-based radioguided surgery
Clinical value of PSMA-RGS

\(^{111}\text{In-PSMA-RGS vs. Histopathology:}\)
- lesions were identified intraoperatively using a \(\gamma\)-probe in 30/31 patients
- Ex vivo measurements correlated well with histology:
  Sensitivity 92.3\%, specificity 93.5\% and accuracy 93.1\%

\(^{111}\text{In-PSMA-RGS vs. postoperative PSA:}\)
- PSA decline >50\% observed in 23/31 patients and >90\% in 16/31 patients
- PSA decline <0.2ng/ml could observed in 18/31 patients

\(^{111}\text{In-PSMA-RGS: outcome}\)
- 10 patients presented with surgery-related complications

Summary:
- high value for intraoperative detection of even small metastatic lesions in PC patients scheduled for salvage lymphadenectomy
- might have a beneficial influence on further disease progression
- patient identification on the basis of PSMA-PET and clinical parameters crucial to obtain satisfactory results

Rauscher et al.-under revision (BJUI)
$^{68}$Ga-PSMA HBED-CC PET for radiotherapeutic management of prostate cancer

- 57 patients (15 primary diagnosis, 42 recurrent PC)
- Treatment plan for radiotherapy was changed in 52% pts

![Change in RX](image_url)

**Fig. 1** Overview of the impact of PSMA staging results on radiotherapy (RX). In light grey cases treatment was carried out as initially planned based on conventional staging information, and in dark grey cases radiotherapeutic management was changed in dose or target volume.

**Fig. 2** Example of the impact of PSMA imaging on radiotherapeutic management at initial diagnosis of intermediate-risk prostate cancer. A PSMA PET/CT with tracer uptake in a paraaortic lymph node (SUV$_{max}$ 3.1; arrow) which was not clearly pathological in conventional CT (b). Accordingly the irradiation plan was changed with coverage of perirectal space and a simultaneous boost to the lymph node (c: IMRT in 34 fractions with 51 Gy to lymphatic pathways, 76.5 Gy to the prostate and 61.2 Gy to the pathological lymph node). d IMRT plan prior to PSMA PET information without sufficient coverage of the pathological lymph node.

Sterzinger F et al EJNMMI 2015
PRIMARY PROSTATE CANCER AND DETECTION
**68Ga-PSMA PET for primary LN staging**

- 130 interm./high risk primary PCa
- 35 PET/CT, 95 PET/MR using $^{68}$Ga PSMA-HBED-CC
- Standardized ePLND with separated field histopathology
- Exclusion of 11 pts. (8.4%) with no/faint PSMA-expression in primary tumor

- LN metastases in 36 of 119 pts. (108 of 678 dissected LN fields)
### 68Ga-PSMA PET for primary LN staging

<table>
<thead>
<tr>
<th></th>
<th>Sens (%)</th>
<th>Spec (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>Acc. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient-based</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT/MRI</td>
<td>41.7</td>
<td>85.5</td>
<td>55.6</td>
<td>77.2</td>
<td>72.3</td>
</tr>
<tr>
<td>PSMA-PET</td>
<td>75.0</td>
<td>98.8</td>
<td>96.4</td>
<td>90.1</td>
<td>91.6</td>
</tr>
<tr>
<td><strong>Field-based</strong>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT/MRI</td>
<td>28.3</td>
<td>97.1</td>
<td>59.6</td>
<td>88.7</td>
<td>87.3</td>
</tr>
<tr>
<td>PSMA-PET</td>
<td>76.2</td>
<td>99.1</td>
<td>94.2</td>
<td>95.5</td>
<td>95.7</td>
</tr>
</tbody>
</table>

*GEE-model to account for multiple measurements in same pts.

- 9 false negative patients:
  - mean max. size of LN in false negative fields: 3 ± 1mm (range: 1 – 5mm)
  - 3 patients with only micrometastases
  - 6 patients (one template), 3 patients (two templates) pN+

Maurer et al., J Urol 2015
Brief Correspondence

$^{68}$Ga-PSMA Positron Emission Tomography/Computed Tomography Provides Accurate Staging of Lymph Node Regions Prior to Lymph Node Dissection in Patients with Prostate Cancer

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Abstract

We evaluated the accuracy of $^{68}$Ga-prostate-specific membrane antigen-HBED-CC ($^{68}$Ga-PSMA) positron emission tomography/computed tomography (PET/CT) for nodal staging prior to lymph node dissection (LND) in patients with prostate cancer (PCa). Thirty-four patients with histologically proven PCa underwent $^{68}$Ga-PSMA-HBED-CC PET/CT prior to radical prostatectomy with primary LND (pLND; n = 20) and PET/CT prior to secondary LND (sLND; n = 14). Accuracy of PET and CT were analysed separately for staging of the following 71 lymph node (LN) regions: pelvic left (n = 30), pelvic right (n = 31), presacral (n = 3), and para-aortic (n = 7). Postoperative histopathology was taken as a reference standard. Thirty-seven of 71 (52%) regions showed LN metastases on histopathology. Sensitivity, specificity, positive predictive value, and negative predictive value for detection of LN metastases were 84%, 82%, 84%, and 82% for PET criteria and 65%, 76%, 75%, and 67% for CT criteria. PET was more accurate for nodal staging compared with CT both at pLND (88% vs 75%) and sLND (77% vs 65%). Overall, $^{68}$Ga-PSMA PET/CT provides accurate nodal staging prior to pLND and sLND for PCa. Patient summary: $^{68}$Ga-PSMA positron emission tomography/computed tomography is accurate in detecting tumour spread to lymph nodes before patients undergo surgery for prostate cancer.

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Simultaneous $^{68}$Ga-PSMA HBED-CC PET/MRI improves the localization of primary prostate cancer

Hybrid PET/MR allows direct comparison between mpMR, PET and combined PET/MR!

- 53 interm./high risk primary PC
- $^{68}$Ga-PSMA HBED-CC multiparametric PET/MR study
- radical prostatectomy within 4 weeks
- histopathological assessment of tumor infiltration on sextant base

- MR assessment: PIRADS v1
  (Prostate Imaging-Reporting and Data System)
- PET and PET/MR assessment: 5-point-scale

Table 1 – Patient characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>53</td>
</tr>
<tr>
<td>Intermediate risk (%)</td>
<td>25 (47)</td>
</tr>
<tr>
<td>High risk (%)</td>
<td>28 (53)</td>
</tr>
<tr>
<td>Neoadjuvant hormonal treatment</td>
<td>None</td>
</tr>
<tr>
<td>Clinical demographics (IQR)</td>
<td></td>
</tr>
<tr>
<td>Median PSA value, ng/ml</td>
<td>12.0 (6.9–18.8)</td>
</tr>
<tr>
<td>Median age, yr</td>
<td>66 (62–72)</td>
</tr>
<tr>
<td>Pathologic demographics</td>
<td></td>
</tr>
<tr>
<td>Gleason score (%)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>3 (5.7)</td>
</tr>
<tr>
<td>7</td>
<td>35 (66)</td>
</tr>
<tr>
<td>8</td>
<td>10 (19)</td>
</tr>
<tr>
<td>9</td>
<td>4 (7.5)</td>
</tr>
<tr>
<td>10</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>Stage (%)</td>
<td></td>
</tr>
<tr>
<td>pT2a</td>
<td>4 (7.5)</td>
</tr>
<tr>
<td>pT2b</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>pT2c</td>
<td>18 (34)</td>
</tr>
<tr>
<td>pT3a</td>
<td>18 (34)</td>
</tr>
<tr>
<td>pT3b</td>
<td>11 (21)</td>
</tr>
<tr>
<td>pT4</td>
<td>1 (1.9)</td>
</tr>
</tbody>
</table>

IQR = interquartile range; PSA = prostate-specific antigen.

Eiber M, Eur Urol 2016
Simultaneous $^{68}$Ga-PSMA HBED-CC PET/MRI improves the localization of primary prostate cancer

Patient-based detection rate:

mpMRI: 66%

PET: 92% $p<0.001$ (to mpMRI)

PET/mpMRI: 98% $p<0.001$ (to mpMRI)

prospective studies are warranted to evaluate the potential value eg. for biopsy guidance, RTX planning

Table 3 – Diagnostic accuracies for tumor localization using multiparametric magnetic resonance imaging (MRI), positron emission tomography (PET), and gallium 68 prostate-specific membrane antigen HBED-CC PET/MRI for Youden-selected thresholds: negative versus positive sextants

<table>
<thead>
<tr>
<th></th>
<th>AUC (95% CI)</th>
<th>Youden-selected threshold</th>
<th>Sensitivity, %, at threshold (95% CI)</th>
<th>Specificity, %, at threshold (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mpMRI</td>
<td>0.73 $^{*}$ $^{†}$ (0.66–0.80)</td>
<td>4 $^{§}$</td>
<td>43 (33–53)</td>
<td>98 (94–100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>58 (49–66)</td>
<td></td>
</tr>
<tr>
<td>PET</td>
<td>0.83 $^{*}$ $^{#}$ (0.78–0.87)</td>
<td>4</td>
<td>64 (56–72)</td>
<td></td>
</tr>
<tr>
<td>PET/MRI</td>
<td>0.88 $^{*}$ $^{†}$ (0.84–0.92)</td>
<td>4</td>
<td>76 (68–82)</td>
<td></td>
</tr>
</tbody>
</table>

$^{*}$: mpMR vs. PET $p = 0.003$; $^{#}$: PET vs. PET/MRI $p = 0.002$; $^{†}$: mpMR vs. PET/MRI $p < 0.001$

Eiber M, Eur Urol 2016
# Summary: Potential indications for $^{68}$Ga-PSMA PET/CT

<table>
<thead>
<tr>
<th>Benefit using $^{68}$Ga-PSMA ligand PET/CT</th>
<th>Patient group</th>
</tr>
</thead>
</table>
| **High estimated benefit / diagnostic gain** | • Primary staging in high-risk disease according to D'Amico classification  
• Biochemical recurrence with low PSA-values (0.2 ng/ml to 10 ng/ml)¹ |
| **Low estimated benefit / diagnostic gain** | • Primary staging in low-risk (and intermediate-risk) disease according to D'Amico classification |
| **Potential application with promising preliminary data** | • Biopsy targeting after previous negative biopsy, but high suspicion of PC (esp. in combination with multiparametric MRI using PET/MRI) |
| **Potential application with current lack of published data** | • Monitoring of systemic treatment in metastatic CRPC ²  
• Monitoring of systemic treatment in metastatic castration-sensitive PC ²  
• Active surveillance (esp. in combination with multiparametric MRI using PET/MRI)  
• Treatment monitoring in metastatic castration-resistant PC undergoing radioligand therapy targeting PSMA (e.g. $^{177}$Lu-PSMA-ligand) |

Table from “$^{68}$Ga-PSMA ligand PET/CT in patients with prostate cancer: How we review and report.” Rauscher I et al., Cancer Imaging 2016
PITFALLS
### PSMA expression in normal tissues

<table>
<thead>
<tr>
<th>Tissue</th>
<th>PSMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genitourinary organs</td>
<td></td>
</tr>
<tr>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td>Glomeruli</td>
<td>–</td>
</tr>
<tr>
<td>Tubules</td>
<td>+</td>
</tr>
<tr>
<td>Bladder</td>
<td></td>
</tr>
<tr>
<td>Transitional epithelium</td>
<td>–</td>
</tr>
<tr>
<td>Smooth muscle</td>
<td>–</td>
</tr>
<tr>
<td>Prostate</td>
<td></td>
</tr>
<tr>
<td>Epithelium</td>
<td>+</td>
</tr>
<tr>
<td>Stroma</td>
<td>–</td>
</tr>
<tr>
<td>Testis</td>
<td>–</td>
</tr>
<tr>
<td>Cervix</td>
<td>–</td>
</tr>
<tr>
<td>Breast</td>
<td>–</td>
</tr>
<tr>
<td>Digestive system</td>
<td></td>
</tr>
<tr>
<td>Parotid</td>
<td>–</td>
</tr>
<tr>
<td>Stomach</td>
<td>–</td>
</tr>
<tr>
<td><strong>Duodenum</strong></td>
<td>+</td>
</tr>
<tr>
<td>Ileum</td>
<td>–</td>
</tr>
<tr>
<td>Colon</td>
<td>+</td>
</tr>
<tr>
<td>Liver</td>
<td>–</td>
</tr>
<tr>
<td>Pancreas</td>
<td>–</td>
</tr>
<tr>
<td>Hematological system</td>
<td></td>
</tr>
<tr>
<td>Lymph node</td>
<td>–</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>–</td>
</tr>
<tr>
<td>Skin</td>
<td>–</td>
</tr>
<tr>
<td>Skeletal muscle</td>
<td>–</td>
</tr>
<tr>
<td>Endocrine organs</td>
<td></td>
</tr>
<tr>
<td>Thyroid</td>
<td>–</td>
</tr>
<tr>
<td>Adrenal</td>
<td>–</td>
</tr>
<tr>
<td>Cortex</td>
<td>–</td>
</tr>
<tr>
<td>Medulla</td>
<td>–</td>
</tr>
<tr>
<td>Pancreatic islets</td>
<td>–</td>
</tr>
<tr>
<td>Nervous system</td>
<td></td>
</tr>
<tr>
<td>Frontal cortex</td>
<td>–</td>
</tr>
<tr>
<td>Cerebellum</td>
<td>–</td>
</tr>
<tr>
<td>Eye</td>
<td>–</td>
</tr>
<tr>
<td>Peripheral ganglion</td>
<td>–</td>
</tr>
</tbody>
</table>

### Results of PSMA immunohistochemistry in tumor cells and tumor-associated neovascularity

<table>
<thead>
<tr>
<th>Tumor</th>
<th>Tumor cells</th>
<th>Neovasculature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional renal cell carcinoma</td>
<td>0/11</td>
<td>11/11</td>
</tr>
<tr>
<td>Transitional cell carcinoma</td>
<td>0/6</td>
<td>6/6</td>
</tr>
<tr>
<td>Testicular embryonal carcinoma</td>
<td>0/1</td>
<td>1/1</td>
</tr>
<tr>
<td>Colonic adenocarcinoma</td>
<td>0/5</td>
<td>5/5</td>
</tr>
<tr>
<td>Neuroendocrine carcinoma</td>
<td>0/5</td>
<td>5/5</td>
</tr>
<tr>
<td>Glioblastoma multiforme</td>
<td>0/1</td>
<td>1/1</td>
</tr>
<tr>
<td>Malignant melanoma</td>
<td>0/5</td>
<td>5/5</td>
</tr>
<tr>
<td>Pancreatic duct carcinoma</td>
<td>0/4</td>
<td>4/4</td>
</tr>
<tr>
<td>Non-small cell lung carcinoma</td>
<td>0/5</td>
<td>5/5</td>
</tr>
<tr>
<td>Soft tissue sarcoma</td>
<td>0/6</td>
<td>5/6</td>
</tr>
<tr>
<td>Breast carcinoma</td>
<td>0/6</td>
<td>5/6</td>
</tr>
<tr>
<td>Hemangiomatosis</td>
<td>0/3</td>
<td>0/3</td>
</tr>
<tr>
<td>Hemangioma</td>
<td>0/1</td>
<td>0/1</td>
</tr>
<tr>
<td>Angiosarcoma</td>
<td>0/1</td>
<td>0/1</td>
</tr>
<tr>
<td>Angiolipoma</td>
<td>0/1</td>
<td>0/1</td>
</tr>
<tr>
<td>Angiomyolipoma</td>
<td>0/2</td>
<td>0/2</td>
</tr>
<tr>
<td>Prostatic adenocarcinoma</td>
<td>12/12</td>
<td>2/12</td>
</tr>
</tbody>
</table>

Chang et al, Cancer Res 1999

Silver et al, Clin Cancer Res 1997
PSMA-PET is not completely specific for PCa!

- Renal Cell Cancer in a patient with PCa

PSA drop 1.25 to 0.25 ng/ml under AHT
=> Bx mediastinal/retroperitoneal LN revealed: LNM were from recurrent RCC

- Initial experience using $^{68}$Ga-PSMA PET for staging of RCC

Six patients with different subtypes of RCC
-> potential value for detecting metastases
-> no additional value for primary tumor

Einspieler I et al., Clin Nuc Med 2016

Sawicki et al, EJNMMI 2016
• Celiac ganglia

in 89.4% (76/85) of patients celiac ganglia were PSMA PET positive!

• Cervical/ celiac/ sacral ganglia
• neurogenic tumors (schwannoma)
PSMA-PET is not completely specific for PCa!

- PSMA PET in differentiated thyroid cancer

Verburg F et al., EJNM 2015
PSMA-PET is not completely specific for PC!

Patient presenting with recurrent PC:
PSA 0.38 ng/ml

Pathology: non-specific reparative changes
-> false positive bone lesion
• PSMA PET cannot discriminate between LC and PCa lung mets

Histologically proven PCa metastasis

Histologically proven primary LC with LNM

Pyka T et al., JNM 2015
Conclusion

- **recurrent PC:**
  - significantly superior than morphological imaging especially in detection of small LNM
  - promising method for early detection of LNM in patients with biochemical recurrent PC, even at very low PSA-values
  - might represent a valuable tool for guiding salvage lymphadenectomy

- **primary PC**
  - encouraging results, but limited experience, evidence still missing
  - potential for "image guided"- biopsy (preferably using PET/MR)

- **pitfalls:**
  - PSMA not completely specific for PC (e.g. neovasculature of other tumors)

- **are ¹⁸F-labelled compounds the future?**
  - potential higher patient throughput with smaller logistical issues (availability, production amount, image resolution)

- Prospective multicenter trials mandatory for high level of evidence for incorporation into guidelines
Acknowledgment

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Gitti Dzewas
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Petra Watzlowik
Jürgen Gschwend
Tobias Maurer
Thank you very much for your attention