Peptide Receptor Radionuclide Therapy: Current Status and Future Perspectives

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Selection of Patients
What must be known before PRRT?

- **Histology / immunohistochemistry**
  - grading, proliferation rate (Ki-67), CgA, Synaptophysin, hormone production (e.g. glucagon, gastrin, insulin)

- Receptor density – ideally determined by receptor PET/CT (SUV) or scintigraphy

- Kidney function – MAG3 (TER), Tc-99m DTPA

- Blood profile/chemistry – RBC, WBC, PLT, Crea, BUN
GEP-NETs: > 40 Entities

Considering:
- Localization
- functional activity
- hereditery background

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Molecular Diagnostic Imaging of SMS-R positive tumors

- NET of the intestine (foregut, midgut, hindgut) including bronchus carcinoid, GEP-NET
- Meningioma
- Aesthesioneuroblastoma
- Medullary thyroid cancer (MTC)
- Paraganglioma
- Pheochromocytoma
- Adrenal carcinoma
- Thymus cancer
- Hepatocellular carcinoma
- Merkel cell tumours (and many more…)

Tc-99m SMS Scintigraphy (Te-TOC) for Centers without PET

- Tc-99m Kit: simple, safe, fast, low costs
- Excellent image quality, 4-hr protocol
- Prediction of targeting for tumour therapy
- Commercially available (POLATOM, Poland)

EDDA-HYNIC-TRICINE-TOC
EDDA-HYNIC-TRICINE-TOC
D-Phe1-Tyr3-Octreotide
HYNIC-TOC
TRICINE
EDDA: Ethylenediamine-N-N’-diacetic acid
NHN
D-Phe
NH2
Cys Tyr D-Trp
LysCys ThrThr(ol)
D-Phe1-Tyr3-Octreotide
cyclic octopeptide
hydracino nicotin amide
=complex function for Tc
heterocyclic coligand
coligand

Te-TOC SPECT
CUP (NET proven by liver biopsy), referred for PRRT – bronchus carcinoid
Ga-68 receptor PET/CT – should become standard for all centers with PET

Ga-68 Generator System

Developed in close collaboration between
Radiopharmacy PET/CT Center,
Zentralklinik Bad Berka
and
Institute of Nuclear Chemistry
Johannes Gutenberg-Universität, Mainz,
Germany

Zhernosekov K, Filosofov DV, Baum RP,...
Rösch F
J Nucl Med 2007 (Oct); 48:1741-48

68Ga-elution, purification
and synthesis module
First use July 2004
Radiopharmaceutical synthesis

97±2% $^{68}$Ga @ t = 4 min
chemically and radiochemically pure

eluted directly into labelling vial, containing appropriate amounts of precursor, e.g. DOTA-TOC or DOTA-NOC, and an appropriate volume of water, without (or with) using buffer systems

for syntheses of $^{68}$Ga-labelled tracers within 5 - 10 min
yields: 95 – 98% for $^{68}$Ga-DOTA-NOC

Specific activities:

- 35 MBq / µg DOTA-NOC
  in 5 ml water only
- > 450 MBq / µg DOTA-NOC
  in 0.5 ml water + 1 M HEPES pH4

Radiopharmaceutical purification

Labelling kinetics (min) purified product
1 5 10 after C18
51.4% 85.2% 95%

Quality control:

e.g. on silica gel impregnated glass fibre strips
(TLC alumina sheets SG 60 by MERCK)
Post-processing combined with labelling … … on an automated module

Post-processing of $^{68}$Ge/$^{68}$Ga radionuclide generators using cation exchange resin provides chemically and radiochemically pure $^{68}$Ga 97±2% within 4 min ready for on-line labelling

Highest chemical purity guarantees for high labelling and overall product yields (e.g. $^{68}$Ga-DOTA-conjugated octreotides) of 75±5% decay corrected

Ready for injection – up to 8 patients per day can be studied easy handling in a nuclear medical environment easily to transfer to IAEA and other countries

(in use already in Dehli/India and Santiago de Chile)

Summary $^{68}$Ge/Ga Generator

Significant step towards the routine medical use of the $^{68}$Ge/Ga generator
Gallium-68 will become the Tc-99m for PET/CT!


Number of Ga-68 PET/CT Studies

2004 2005 2006 2007

Ga-68 Receptor PET/CT

The Bad Berka Experience (>2,300 studies)

Receptor PET/CT using the Ga-68-labeled somatostatin analogue DOTA-NOC enables the molecular imaging of neuroendocrine tumours and their metastases with very high diagnostic sensitivity and specificity.

Advantages:
- Semiquantitative, reproducible data (SUV) which can be used for selecting patients for PRRT and evaluation of therapy response
- fast protocol (60-90 min.), patient friendly, low radiation burden
- flexibility, daily use, lower (!) cost than Octreotide scintigraphy
- a new goldstandard for in vivo SMS receptor imaging

Comparative studies will probably allow to determine tumor and kidney dosimetry prior to subsequent PRRT using Y-90 or Lu-177-labeled somatostatin analogues.
Ga-68 DOTA-NOC receptor PET/CT: SUV of primary tumors and metastases

<table>
<thead>
<tr>
<th>SUV primary tumors (n = 400 patients)</th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary tumours</td>
<td>19.2</td>
<td>8.2 – 109</td>
</tr>
<tr>
<td>Liver mets</td>
<td>20.9</td>
<td>3.3 – 105</td>
</tr>
<tr>
<td>Lymph node mets</td>
<td>9.5</td>
<td>4.2 – 152</td>
</tr>
<tr>
<td>Bone mets</td>
<td>13.6</td>
<td>3.0 – 20.4</td>
</tr>
<tr>
<td>Brain mets</td>
<td>12.3</td>
<td>4.6 – 17.2</td>
</tr>
<tr>
<td>Lung mets</td>
<td>2.3</td>
<td>1.6 – 5.6</td>
</tr>
<tr>
<td>Abdominal mets</td>
<td>14.8</td>
<td>5.8 – 34.1</td>
</tr>
</tbody>
</table>

Selection of Patients
What must be known before PRRT?

- **Histology / immunohistochemistry**
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- **Receptor density** – ideally determined by receptor PET/CT (SUV) or scintigraphy

- **Kidney function** – MAG3 (TER), Tc-99m DTPA (GFR)

- **Blood profile/chemistry** – e.g. RBC, WBC, PLT, Crea, BUN
Kidney Toxicity - Summary

Effect of Y-90 on renal function is much more pronounced (detrimental) as compared to Lu-177.

The number of courses given to the patient is a very important parameter to be taken into consideration for assessing the affect of PRRT on kidney function.

Lower quantity of radioactivity for each therapy course can be administered while increasing the number of courses and the time interval between courses with almost similar (better?) results on the tumor but with
Selection of Patients

What must be known before PRRT?

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Increased Hematological Toxicity

➢ Previous chemotherapy (e.g. cisplatinum, etoposide, streptotozin etc.)
➢ Previous external radiation therapy (large fields)
➢ Previous high-dose PRRT with Y-90
➢ Disseminated bone (marrow) involvement
➢ Decreased renal function
Peptide Receptor Radionuclide Therapy

How is it performed?

• Choice of peptide (DOTA-TATE or DOTA-TOC)
• Choice of radionuclide (Lu-177, Y-90)
• Kidney protection (lysine, arginine, Rotterdam protocol)
• Tumor and organ dosimetry (posttreatment scan)
• Monitoring of toxicity (follow-up)
Physical Properties of Radionuclides used for PRRT

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>$t_{1/2}$ (d)</th>
<th>Energy (keV)</th>
<th>Path length (mm)</th>
<th>Gamma (keV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{177}$LuTetium</td>
<td>6.7</td>
<td>133</td>
<td>2</td>
<td>113 (6.6%) 208 (11%)</td>
</tr>
<tr>
<td>$^{90}$Yttrium</td>
<td>2.7</td>
<td>935</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>$^{111}$Indium*</td>
<td>2.8</td>
<td>14.7</td>
<td>&lt;0.01</td>
<td>172 (90%) 247 (94%)</td>
</tr>
</tbody>
</table>

*not suitable for therapy

Kwekkeboom et al., J Clin Oncol 2005;23:2754-2762

$[^{177}$Lu-DOTA$^0$,Tyr$^3$]Octreotate Therapy: Relation to Chemotherapy

Table 3. Results and Side Effects of Chemotherapy in Patients With Neuroendocrine Tumors Compared With the Present Study

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Tumor Type</th>
<th>No. of Patients</th>
<th>PR and CR (%)</th>
<th>Hematologic Toxicity Grade 3 and 4 (%)</th>
<th>Nausea and Vomiting (%)</th>
<th>Other Major Side Effects</th>
<th>Study</th>
</tr>
</thead>
</table>
| Carci | Carci | 24 | 21 | 4 | Na | Na | — | Morrow et al
| FU   | Carci | 19 | 20 | 3 | Na | Na | — | Morrow et al
| STZ + FU | Carci | 43 | 33 | 7 | Na | Na | — | Morrow et al
| NTZ + FU | NIP | 42 | 36 | 17 | 0 | 83 | Renal toxicity, 2%; liver failure, 2% | Morrow et al
| STZ + FU | NIP | 42 | 36 | 17 | 29 | 82 | Renal toxicity, 5%; liver failure, 1% | Morrow et al
| STZ + doxorubicin | NIP | 32 | 40 | 7 | 25 | 81 | Danesia, 3%; renal insufficiency, 7% | Morrow et al
| STZ + doxorubicin | NIP | 32 | 40 | 7 | 25 | 81 | Danesia, 3%; renal insufficiency, 7% | Morrow et al
| STZ + doxorubicin | NIP | 32 | 40 | 7 | 25 | 81 | Danesia, 3%; renal insufficiency, 7% | Morrow et al
| STZ + doxorubicin | NIP | 32 | 40 | 7 | 25 | 81 | Danesia, 3%; renal insufficiency, 7% | Morrow et al
| DRC | Carci | 12 | 13 | 3 | Na | Na | — | Vuk Vildz et al
| DRC | Carci | 12 | 13 | 3 | Na | Na | — | Vuk Vildz et al
| DRC | Carci | 12 | 13 | 3 | Na | Na | — | Vuk Vildz et al
| F1 + F1 | Carci | 24 | 33 | 7 | 25 | 81 | Danesia, 3%; renal insufficiency, 7% | Morrow et al
| Mitomycin | Carci | 35 | 14 | 32 | 26 | — | — | Morrow et al
| Paclitaxel | Carci | 30 | 4 | 7 | 25 | 81 | Danesia, 3%; renal insufficiency, 7% | Morrow et al
| Paclitaxel | Carci | 30 | 4 | 7 | 25 | 81 | Danesia, 3%; renal insufficiency, 7% | Morrow et al

Abbreviations: PR, partial remission; CR, complete remission; DRC, dimethylaminoethyl carbamate; FU, fluorouracil; STZ, streptozocin; Carci, carcinoid; NIP, neuroendocrine pancreatic tumor; NA, not available; F1, interferon alpha; $[^{177}$Lu-octreotate; $[^{177}$Lu-DOTA$^0$,Tyr$^3$]octreotate.

*Response evaluation including biochemical responses and physical examination for evaluation of hepatomegaly.

Erasmus MC

Kwekkeboom et al, J Clin Oncol 2005;23:2754-2762
Tumor Response and Clinical Benefit in Neuroendocrine Tumors After 7.4 GBq $^{90}$Y-DOTATOC

Christian Waldherr, MD; Miklos Pleso, MD; Helmut R. Machele, PhD; Tilman Schumacher, MD; Armin Crnzdara, MD; Egbert U. Nitzsche, MD; Andreas Hallmman, MD, and Jan Moeller-Bened, MD

PRRT - SEQUENTIAL USE OF Y-90 & LU-177

Y-90 DOTA-TOC has been most frequently used for the treatment of metastatic neuroendocrine tumors (Waldherr et al., Paganelli et al.).

Lu-177 DOTA-TATE has shown very promising results in somatostatin receptor (SSTR) positive GEP tumors (Kwekkeboom et al.).

Few data exist on the use of Y-90 DOTA-TATE for PRRT of NET, none on the sequential use of Y-90 and Lu-177 DOTA-TATE.

Our strategy is to study
- the therapeutic efficacy and
- to evaluate the short and longterm adverse effects

of PRRT using the somatostatin analogue octreotate labeled with Y-90 or Lu-177 in patients with progressive, metastasized neuroendocrine tumors (mostly with large tumor burden).

<table>
<thead>
<tr>
<th>Tumor type</th>
<th>Progression before treatment</th>
<th>CR</th>
<th>PR</th>
<th>SD</th>
<th>Progressive disease within or after treatment</th>
<th>Overall tumor response</th>
<th>CR, PR, SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPT (p = 13)</td>
<td>13 (100%)</td>
<td>1</td>
<td>4</td>
<td>6</td>
<td>2</td>
<td>38% (11/30)</td>
<td>11 (85%)</td>
</tr>
<tr>
<td>Intestinal NET (p = 12)</td>
<td>12 (100%)</td>
<td>—</td>
<td>1</td>
<td>11</td>
<td>—</td>
<td>8% (2/25)</td>
<td>2 (100%)</td>
</tr>
<tr>
<td>Bronchial NET (p = 3)</td>
<td>3 (100%)</td>
<td>—</td>
<td>—</td>
<td>3</td>
<td>—</td>
<td>0% (0/20)</td>
<td>0 (00%)</td>
</tr>
<tr>
<td>NET of unknown origin (n = 9)</td>
<td>9 (100%)</td>
<td>—</td>
<td>2</td>
<td>6</td>
<td>1</td>
<td>32% (3/9)</td>
<td>2 (89%)</td>
</tr>
<tr>
<td>Others (p = 2)</td>
<td>2 (100%)</td>
<td>1</td>
<td>—</td>
<td>1</td>
<td>—</td>
<td>50% (2/4)</td>
<td>2 (100%)</td>
</tr>
<tr>
<td>All (p = 39)</td>
<td>39 (100%)</td>
<td>2</td>
<td>7</td>
<td>27</td>
<td>3</td>
<td>23% (9/39)</td>
<td>36 (92%)</td>
</tr>
</tbody>
</table>

CR = complete remission; PR = partial remission; SD = stable disease; EPT = endocrine pancreatic tumor; NET = neuroendocrine tumor
Total number of patients treated \( n = 475 \)
Total number of treatment sessions \( n = 1400 \)
(as of January 31, 2008)

RADIOPEPTIDE THERAPY (ZKL BAD BERKA)

Yttrium-90 \( n = 816 \)
Lutetium-177 \( n = 587 \)

Age: 4 – 81 years
mean 59 years

RESPONSE TO PRRT – DIFFERENT TREATMENT REGIMENS BAD BERKA

Highest response rate was observed with Y-90 followed by Lu-177 + Y-90 and Lu-177 DOTA-TATE alone
Peptide Receptor Radionuclide Therapy

How is it performed?

• Choice of peptide (DOTA-TATE or DOTA-TOC)
• Choice of radionuclide (Lu-177, Y-90)
• **Kidney protection** (lysine, arginine, Rotterdam protocol)
• Tumor and organ dosimetry (posttreatment scan)
• Monitoring of toxicity (follow-up)

Studies before therapy

- Renal scintigraphy \([99mTc-MAG3]\)
- GFR measurement \([99Tc-DTPA]\)
- Receptor PET/CT* \([68Ga-DOTA-NOC]\)

Infusion (15 min.) of 90Y / 177Lu-DOTA-TATE

Infusion of aminoacid solution (- 0.5 till 4 hrs)

BAD BERKA PROCEDURE FOR PRRT

- 2 days
- 3 days

**Studies under therapy**

177Lu-DOTA-TATE WB scan [planar scans for dosimetry]
177Lu-DOTA-TATE- SPECT of the tumor region
Blood sampling
Urine sampling

* Since July 2004. Previously, Tc-99m EDDA Hynic TOC (planar & SPECT) was performed. In selected patients, also F-18 FDG and / or F-18 fluoride PET/CT is performed as well as MRI of the liver / bones
LONG TERM FOLLOW-UP AFTER 5 CYCLES OF PRRT

The results in 35 patients having received more than 5 cycles of PRRT show a mean fall in TER / GFR of 18% / 16%, respectively. None of the patients developed significant renal toxicity.

Peptide Receptor Radionuclide Therapy

How is it performed?

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- Choice of radionuclide (Lu-177, Y-90)
- Kidney protection (lysine, arginine, Rotterdam protocol)
- Tumor and organ dosimetry (posttreatment scan)
- Monitoring of toxicity (follow-up)
Results of Individual Patient Dosimetry in Peptide Receptor Radionuclide Therapy with $^{177}$Lu DOTA-TATE and $^{177}$Lu DOTA-NOC

Christiane Wehrmann, Stefan Senftleben, Carolin Zachert, Dirk Müller, and Richard P. Baum
Department of Nuclear Medicine/Center for P.E.T., Zentralklinik Bad Berka, Bad Berka, Germany
Peptide Receptor Radionuclide Therapy

How is it performed?

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• Choice of radionuclide (Lu-177, Y-90)
• Kidney protection (lysine, arginine, Rotterdam protocol)
• Tumor and organ dosimetry (posttreatment scan)
• Monitoring of toxicity (follow-up)

Monitoring for Toxicity
(Re-staging)

- Laboratory tests
  Hematology, liver enzymes, renal parameters (creatinine, BUN).
  The lab tests were repeated at monthly intervals between the therapy cycles
  by the caring physicians and sent to our institution.
- Kidney function (GFR + TER MAG3 always before next PRRT)
RESTAGING OF PATIENTS

Restaging was always performed before the next therapy cycle by:

- Ga-68 DOTA-NOC PET/CT (with oral & i.v. contrast)
- Renal scintigraphy (Tc-99m MAG 3) with TER measurements
- GFR measurements (Tc-99m DTPA)
- Laboratory tests (hematology, liver enzymes, renal parameters)
- Tumor markers (chromogranin, serotonin, glucagon, gastrin etc.)
- MRI of the abdomen / spine (in selected cases)
- FDG-PET/CT (in selected cases)
- F-18-Fluoride-PET/CT (in selected cases)

The lab tests were also performed at monthly intervals between therapy cycles by the caring physicians and sent to our institution. All data are entered into a database containing 270 single items.

Results

- statistical analysis
- clinical results
In total, 475 patients were treated with Y-90 / Lu-177 DOTA-TATE (overall 1,400 treatment courses as of January 31, 2008)

Mean age: 58.1 years (4 - 81 years), 258 male, 217 female

All patients were selected based on high SST-R expression as proven by Ga-68 DOTA-NOC receptor PET/CT

Only progressive GEP NET patients treated with at least 3 cycles of PRRT were included in this analysis

Assessment of therapy response was done after 3 cycles

Three different groups were analyzed: PRRT using Y-90 (n=80), Lu-177 (n=19) and combined use of Y-90 & Lu-177 labeled DOTA-TATE (n=43)

The average cumulative radioactivity administered was 10 GBq Y-90, 16 GBq Lu-177, and 12 GBq Lu-177 / Y-90 DOTA-TATE, respectively
DIFFERENT NET SUBTYPES TREATED WITH PRRT

SITES OF METASTASES

Percentage of patients

Liver: 88%
Bone: 23%
Lymph Node: 36.5%
Others: 3.5%
Combination of Liver/Bone/LN: 46%
Only liver: 47%
Only skeletal: 1.5%
Only Lymph nodes: 5.2%
RESULTS – OVERALL RESPONSE

Progressive GEP NET (n=134)

Response to PRRT after 3 cycles

<table>
<thead>
<tr>
<th>CR/PR/MR</th>
<th>SD</th>
<th>PD</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>42.5</td>
<td>7.5</td>
</tr>
</tbody>
</table>

PRRT – THE BAD BERKA CONCEPT

- **Selection of patients** based on clinical aspects (progressive tumours or uncontrolled symptoms despite maximum conventional therapy) and SMS-receptor expression (determined by PET/CT)

- **Frequent (4-6, up to 8) cycles** of low (2 GBq) or intermediate high (3-4 GBq) therapies: long term low dose, not short term, high dose

- **Combined use** of Y-90 and Lu-177 (in sequence)

- **Intra-arterial PRRT** for inoperable primary tumors

- **Standardized evaluation** before therapy and systematic restaging

- All clinical data are entered into a systematic prospective database

- The management of the patient during PRRT is controlled by the nuclear medicine physician in cooperation with other specialists
SUMMARY AND CONCLUSIONS

- PRRT is an effective therapy – even for very advanced cases – and leads to a significant improvement of clinical symptoms
- Cure is rarely possible - but good palliation can be achieved
- In patients with progressive NET, combined sequential Y-90 / Lu-177 PRRT is most effective (highest percentage of PR and SD)
- Significant kidney damage can be reduced (avoided) by extending the treatment intervals and by using lower therapy activities more frequently as up to 8 courses given over several years were tolerated very well by most patients (no end stage renal insufficiency).
- PRRT should only be performed at specialized centres as NET patients are frequently very ill patients (multimorbidity) and need interdisciplinary treatment and long term care

Future Perspectives

Pre-therapeutic organ and tumor dosimetry using receptor PET/CT and longer lived positron emitters, e.g. Sc-44, Y-86 Cu-64 or Cu-61 and comparison with Ga-68 results.

Selection of the optimal peptide and radionuclide for individual therapy of each patient (“personalized medicine“) by pretherapeutic measurement of organ and tumor doses.
Molecular imaging of bombesin receptors in various tumors by Ga-68 AMBA PET/CT: First results

R. P. Baum¹, V. Prasad¹, N. Mutloka¹, M. Frischknecht², H. R. Maecke², J. C. Reubi³

¹Dept. of Nuclear Medicine / Center for PET–CT
Zentralklinik Bad Berka, Germany,
Radiochemical Research Laboratory, Kantonsspital, Basel Switzerland²
Institute of Pathology, University of Berne, Switzerland³

A novel molecular imaging agent for diagnosis of recurrent HER2 positive breast cancer.
First time in human study using an In-111 or Gallium-68 labeled Affibody molecule

R. P. Baum, A. Orlova*, V. Tolmachev*, J. Feldwisch*
Dept. of Nuclear Medicine / PET Center, Zentralklinik Bad Berka, Germany
*Affibody AB, Bromma, Sweden
Coworkers:

MDs: A. Niesen, C. Zachert, V. Prasad, M. Kupfer, J. Breitling
Radiochemistry: R. Wortmann, I. Klette, S. Müller
Technicians: P. Katzemann and coworkers
Nurses: M. Wieditz, B. Schneiting and coworkers
Med. Physics / Dosimetry: S. Senftleben, C. Wehrmann
Secretary / Logistics: A. Cihar

Collaboration: Helmut Mäcke, Basel; Jean Claude Reubi, Bern; Frank Rösch, Mainz; Jeong JM, Seoul
….and thanks to many colleagues for excellent cooperation

Thank you!

National Flower of Singapore
Vanda Miss Joaquim

Botanic Garden, March 3rd, 2008
First Announcement
www.event-pet-zentralklinik-badberka.de

10 Years Anniversary PET and Nuclear Medicine Bad Berka
(1998-2008)

International Symposium
Molecular Diagnostics and Therapy of Cancer in Nuclear Medicine
The future is now!

May 2-3, 2008
Symposium Venue
Zentralklinik Bad Berka GmbH
Zentralklinik Bad Berka
99437 Bad Berka
Germany

Preliminary Program/Topics

- PET/CT and PET/MR - the next decade
- New radiotracers for diagnostics and therapy produced by powerful cyclotrons and new generation gamma camera systems
- Novel clinical applications for PET/CT
- Molecular and genetic therapies of tumor - novel concepts
- Radiopharmaceutical therapy - proven and new indications
- Peptide receptor radionuclide therapy - from a niche indication (NET) to broader application?
- Intracranial radiosurgery of primary and secondary brain tumors
- Radiosurgical therapy of brain tumors
- Molecular radiation therapy planning (MRTP)
- Nuclear medicine in developing countries - a quantum leap in one decade

We are happy to invite you to take part in the 10 Years Anniversary PET and Nuclear Medicine Bad Berka meeting at the Zentralklinik Bad Berka – near Weimar, the most beautiful and charming cultural capital city of Europe in 1906.

For further information please contact
www.event-pet-zentralklinik-badberka.de

Or e-mail to:
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