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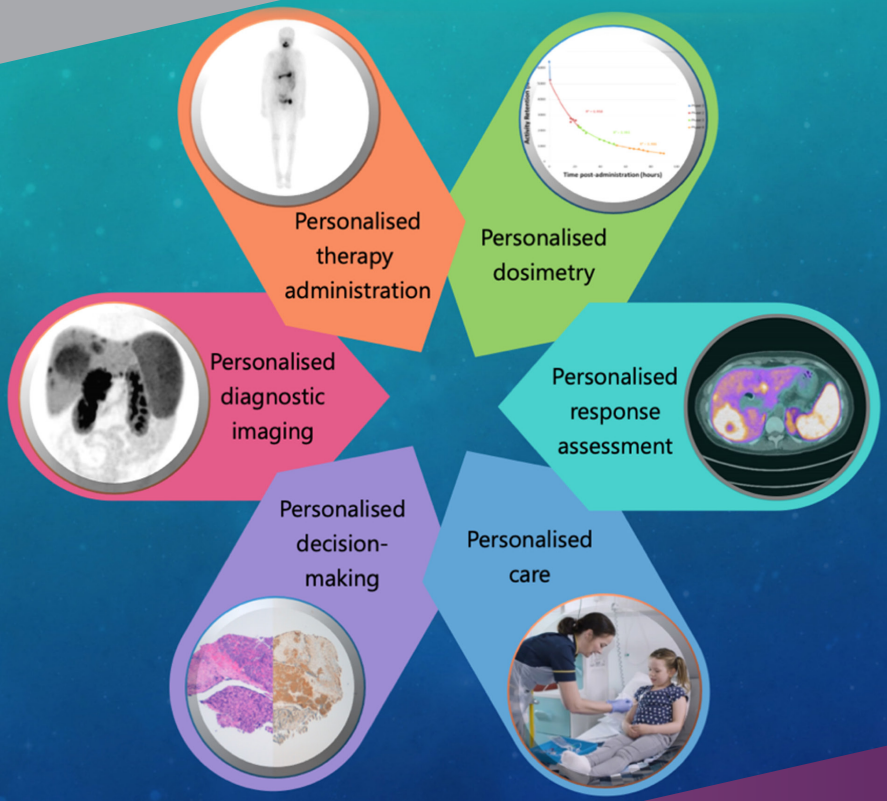
Nuclear Medicine Theragnostics



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Nuclear Medicine Theragnostics

The standard of care approaches for cancer treatment is evolving towards highly targeted treatments utilizing precise image guidance and predictive therapy biomarkers of response and toxicity.

Theragnostics medicine is a diagnostic molecular biomarker, specific for a tumor marker expressed on malignant cells that is utilized for the treatment. In the field of nuclear oncology, application of the theragnostics is attracting increasing attention as a targeted, safe, and efficient therapeutic strategy in the era of precise personalized medicine. Actually, nuclear medicine theragnostics offers the unique facility to detect and quantify the expression of a specific tumor biomarker with a certain isotope-labeled molecules, emitting radiation suitable for imaging. Then, the same radiopharmaceutical labeled with a radionuclide that emits α or β particles to obtain antitumor effect also allows for the acquisition of images that confirm the uptake of the radiopharmaceutical as well as lesions and their changes over time.

Nuclear medicine theragnostics, also known as radionuclide therapy (RNT), is not a new class of therapy but one of the first targeted therapies in modern oncology.

In era of precision medicine in oncology, theragnosics is the ultimate example of targeted, personalized diagnostic and treatment **as we treat what we see.**

In the near future, molecular targeted radioligand therapy will become a major part of daily clinical nuclear medicine.

The **KHATAM PET/CT center** offers several theragnosics for various cancers, including somatostatin receptor PET/CT ([^{68}Ga]Ga-DOTA-TATE or [^{68}Ga]Ga-DOTA-TOC) with [^{177}Lu]Lu-DOTA-TATE for neuroendocrine tumors, [^{68}Ga]Ga-PSMA PET/CT and [^{177}Lu]Lu-PSMA for prostate cancer.

Also, several other theragnosics agents such as chemokine receptor 4 (CXCR4), fibroblast-activation-protein inhibitors (FAPI) and … are under investigation for research purposes in diagnosis and treatment of various cancers.

Peptide Receptor Radionuclide Therapy with [^{177}Lu]Lu-DOTA-TATE for Neuroendocrine tumors

Neuroendocrine tumors (NETs) could involve multiple organ systems, with the most common NETs originating from gastroenteropancreatic region or lung. The incidence of NETs has increased over the recent decades.

Treatment modalities for NETs include surgical resection when applicable as well as somatostatin analogues (eg, octreotide), various targeted agents (eg, everolimus and sunitinib), chemotherapy and liver-directed therapies.

A new effective promising treatment option is [^{177}Lu]Lu-DOTA-TATE peptide receptor radionuclide therapy (PRRT) that approved by FDA (January 26, 2018) for patients with advanced gastroenteropancreatic neuroendocrine tumors.

NETs express somatostatin receptors (SSTRs), predominantly SSTR2. To produce [^{177}Lu]Lu-DOTA-TATE, somatostatin analog (tyrosine3-octreotate) is radiolabeled with ^{177}Lu by a linker molecule (DOTA). The Octreotate component binds to the SSTR and then the entire complex, including the ^{177}Lu, is taken into the NET cells, causing tumor selective ionizing radiation damage.

Patients should be evaluated in a multidisciplinary team, including an oncologist as well as a nuclear medicine specialist to decide on the appropriateness and timing of PRRT. Potential candidates should undergo an SSTR PET/CT scan (eg, [^{68}Ga]Ga-DOTA-TATE PET/CT) or SSTR scintigraphy (eg, [^{99m}Tc]Tc-Octreotide scan) to evaluate SSTR expression status.

PRRT is indicated for treatment of patients with metastatic or inoperable NETs that have positive expression of SSTR2. Candidate patients for radionuclide therapy with [^{177}Lu]Lu-DOTA-TATE are mainly those with SSTR2-expressing NET of the gastroenteropancreatic and bronchial tracts, but may also include patients with phaeochromocytoma, paraganglioma, neuroblastoma, medullary thyroid carcinoma and any malignancy with high SSTR2 expression (eg. Merkel cell carcinoma, Meningioma).

[^{177}Lu]Lu-DOTA-TATE is usually administered intravenously with an activity of 7.4 GBq (200 mCi) every 8 week for 4 cycles. To reduce the high kidney retention of radiopeptides, positively charged amino acids, such as L-lysine and L-arginine (usually diluted in 2 L normal saline) are coinfused to inhibit the reabsorption of the radiopeptide. The coadministration of these amino acids leads to a significant reduction in the renal absorbed dose. Intravenous initiation of amino acid solution is 30 minutes before administering and continued up to at least 4 hours after [^{177}Lu] Lu-DOTA-TATE injection.

Nausea and vomiting may occur during the administration of amino acid solutions. Therefore, it is recommended to use an intravenous premedication regime consisting of a 5-HT3 antagonist (e.g. ondansetron). Steroids such as dexamethasone can also be administered after infusion of [^{177}Lu]Lu-DOTA-TATE for control of nausea/vomiting.

Dose modification of [^{177}Lu]Lu-DOTA-TATE or number of treatment cycles may be considered by multidisciplinary team, according to patient's condition.

It is recommended that PRRT treatment be scheduled at least 4 week after the last long-acting somatostatin analogue therapy (eg. Sandostatin LAR) to prevent interference with SSTR binding. For symptomatic patients, short-acting somatostatin analogues being used as a bridge that should be stopped at least 24 hour before treatment. Subsequent somatostatin analogue doses can be administered as soon as several hours after the completion of the radiopharmaceutical therapy.

Contraindications of [^{177}Lu]Lu-DOTA-TATE include pregnancy, severe acute concomitant illness and unmanageable psychiatric disorder. Breast feeding should be stopped before treatment. Contraception should be used for 6 months after completion of the final treatment. Severely compromised renal or hepatic function as well as severely suppressed bone marrow are considered as treatment contraindications. Laboratory values should be checked shortly before the treatment is ordered (typically 1-2 week before each cycle). These should include blood urea nitrogen, creatinine, albumin, alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase, total bilirubin, white blood cell with differential, hemoglobin and platelet counts. Recommended laboratory thresholds for PRRT treatment are; hemoglobin > 8 g/dL, white blood cell count (WBC) ≥ 3000 /mm3, platelet count > 70000 / mm3, creatinine level < 1.7 mg/dL, estimated glomerular filtration rate (eGFR) > 50 mL/min, total bilirubin < 3 times the upper limit of normal and serum albumin > 3.0 g/dL. Also, renal outflow obstruction should always be ruled out (by ultrasound and diuretic renal scan as needed) or otherwise corrected before PRRT.

The therapy could be perform in inpatient or outpatient setting, depending the patient's condition and local regulations. In our center, PRRT performs as an outpatient therapy. A post-therapy whole body [^{177}Lu]Lu-DOTA-TATE scan during 48-72 hours after each cycle will be done to document radiopeptide distribution in metastatic lesions and an estimation to predict therapeutic response.

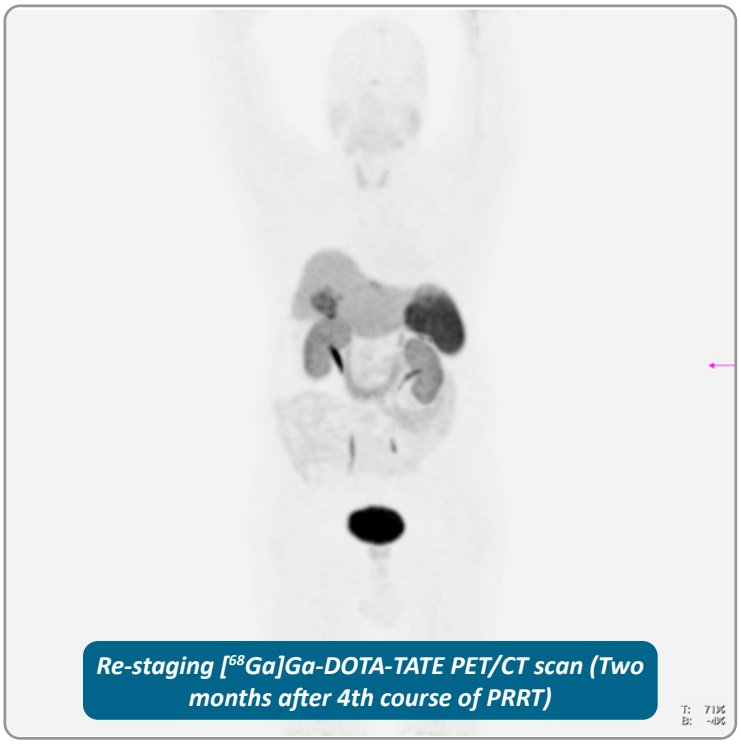
Monitoring of patients after PRRT treatment is an essential part of the treatment plan. Laboratory tests and diagnostic imaging studies will be requested regularly and monitored by multidisciplinary team.

[^{177}Lu]Lu-DOTA-TATE has been considered to be a treatment option that is highly effective in controlling advanced, metastatic or inoperable progressive neuroendocrine tumor disease. Although [^{177}Lu]Lu-DOTA-TATE is rarely curative but has been shown to help relieve symptoms, improves patient's quality of life, shrink tumoral lesions and slow the progression of the disease.

Case: A 64 year old man with progressive metastatic pancreatic neuroendocrine tumor, referred for radionuclide therapy with [^{177}Lu]Lu-DOTA-TATE.

Baseline [^{68}Ga]Ga-DOTA-TATE PET/CT scan

(Figure 1) *revealed intensely DOTA-positive pancreatic tail mass (primary malignancy) along with DOTA-positive metastases in multiple liver lesions in bilateral liver lobes, a splenic lesion and several retroperitoneal lymph nodes.*
The patient received four doses (200 mCi per cycle) of [^{177}Lu]Lu-DOTA-TATE every eight weeks.



Re-staging [^{68}Ga]Ga-DOTA-TATE PET/CT scan (Two months after 4th course of PRRT)

(Figure 2) *revealed interval resolution or significant decrease in DOTA-TATE uptake of the previously seen liver metastatic lesions and resolution of prior splenic lesion as well as near complete resolution of previously seen several retroperitoneal lymph nodes. Also, the primary tumor in the pancreatic tail showed reduction in size and DOTA-TATE uptake.*
When compared with baseline Ga-DOTATATE PET/CT scan the re-stating PET/CT scan interpreted as partial response to therapy.

Radionuclide therapy with [^{177}Lu]Lu-PSMA for prostate cancer

Prostate cancer is the most common cancer and second most frequent cause of cancer related death among men. The five years survival rate of locally prostate cancer is nearly 100%; while, this rate significantly reduced in the case of metastatic disease (31%).

Whilst most men present with localized cancer, some men who present with or progress to metastatic prostate cancer that after initial treatment with androgen deprivation therapy (ADT) eventually progress to a castration-resistant state.

Thus, developing new strategies for diagnosis, imaging and treatment of metastatic prostate cancer is of major importance.

There are limited therapeutic options for patients with metastatic castration-resistant prostate cancer (mCRPC). More recently, prostate-specific membrane antigen (PSMA) based radioligand therapy has been used.

Treatment of mCRPC patients with [^{177}Lu]Lu-PSMA achieves biochemical response (> 50% decline of PSA) in about 50-60% of patients. Prostate-specific membrane antigen (PSMA), also known as glutamate carboxypeptidase II is attached to the cell membrane of prostate epithelial cells.

The PSMA is highly expressed on prostate epithelial cells and strongly up-regulated in prostate cancer. The PSMA expression is correlated to androgen independence, the presence of metastases and prostate cancer progression.

Patients should be evaluated by a multidisciplinary uro-oncology team, including a medical oncologist, radiation oncologist, and urology surgeon as well as a nuclear medicine specialist to decide on the appropriateness of PSMA radionuclide therapy.

Currently, the main clinical indication of [^{177}Lu]Lu-PSMA is patients with metastatic, castration-resistant prostate cancers (mCRPC) who have exhausted or are ineligible for approved alternative options with adequate uptake of PSMA ligands on the basis of a pre-therapy imaging studies ([^{68}Ga]Ga-PSMA PET/CT or [^{99m}Tc]Tc-PSMA SPECT/CT).

Contraindications:

- Life expectancy is less than 6 months (ECOG performance status > 2); unless the main objective is alleviating suffering from disease-related symptoms.
- Unmanageable urinary tract obstruction or hydronephrosis in patients with diagnosed or who are at high risk of urinary retention. Therefore, [^{99m}Tc]Tc-EC or [^{99m}Tc]Tc -DTPA renal scintigraphy should be considered as a baseline exam.
- Progressive deterioration of organ function (GFR < 30 mL/min or creatinine > 2 mg/dL; liver enzymes > 5-fold ULN).
- Myelosuppression:

a. *Total white cell count less than 2.5 × 10^9/L*

b. *Hb ≤ 8 g/dL*

c. *Platelet count less than 75 × 10^9/L*

- Previous chemotherapy or bone-targeted radionuclide therapy and extended external beam irradiation fields to the bone marrow (pelvis, spine), if performed during 6 weeks preceding the radionuclide therapy.
- Conditions which require timely interventions (radiation therapy, surgery), e.g. spinal cord compression and unstable fractures, PSMA radionuclide therapy might be performed afterwards upon patient's condition. Borderline cases should be evaluated within the multidisciplinary tumor board for the individual benefit-to-risk ratio.

Corticosteroids before and up to several days after radionuclide therapy are mandatory in case of cerebral, spinal or other metastases with risk of painful or obstructive swelling; otherwise, they are optional and case dependent. Prophylactic antiemetic therapy, e.g. ondansetron could be administered as needed.

Intravenous or oral hydration as per individual cardiovascular and voiding conditions should be initiated before start of therapy. In patients with low cardiovascular risk, 1 L normal saline may be given I.V at 20 cc/min flow rate.

[^{177}Lu]Lu-PSMA is administered by slow intravenous injection over few minutes.

Administered activity per treatment has a range from 3.7–9.3 GBq (100–250 mCi).

Time interval between cycles is usually 6–8 weeks and number of cycles is two to six (depending on response, prognosis and renal risk factors).

Radionuclide therapy performs as an outpatient process in our center.

A post-therapy whole body [^{177}Lu]Lu-PSMA scan during 48-72 hours after each cycle will be done to monitor adequacy and presence of targetable PSMA-expressing disease and provide dosimetry estimates of absorbed radiation to normal and tumoral tissue.

Monitoring of patients after PRRT treatment is an essential part of the treatment plan. Laboratory tests and diagnostic imaging studies will be requested regularly and monitored by multidisciplinary team.

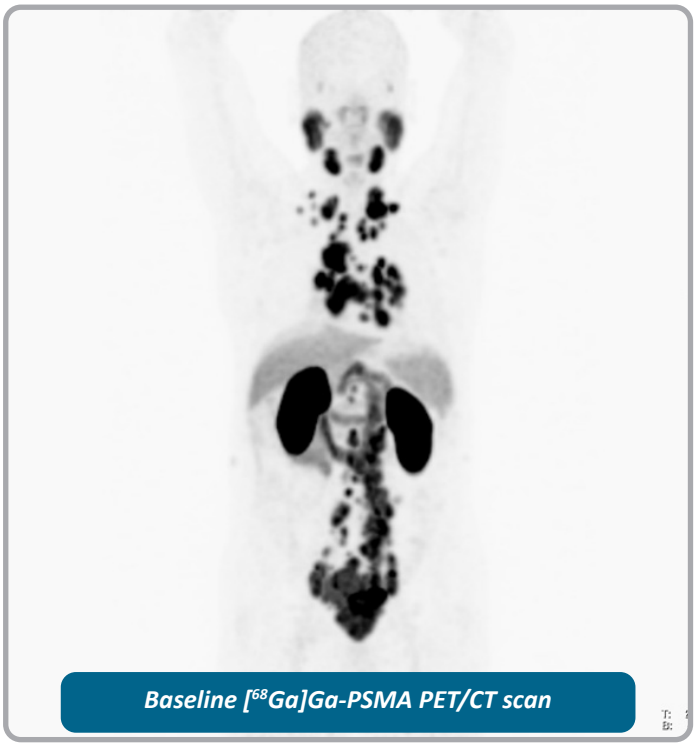
Assessing treatment efficacy in mCRPC involves a combination of biochemical (PSA), radiographic and clinical endpoints.

Response assessment: PSA and post-therapeutic emission scans should be evaluated at every cycle.

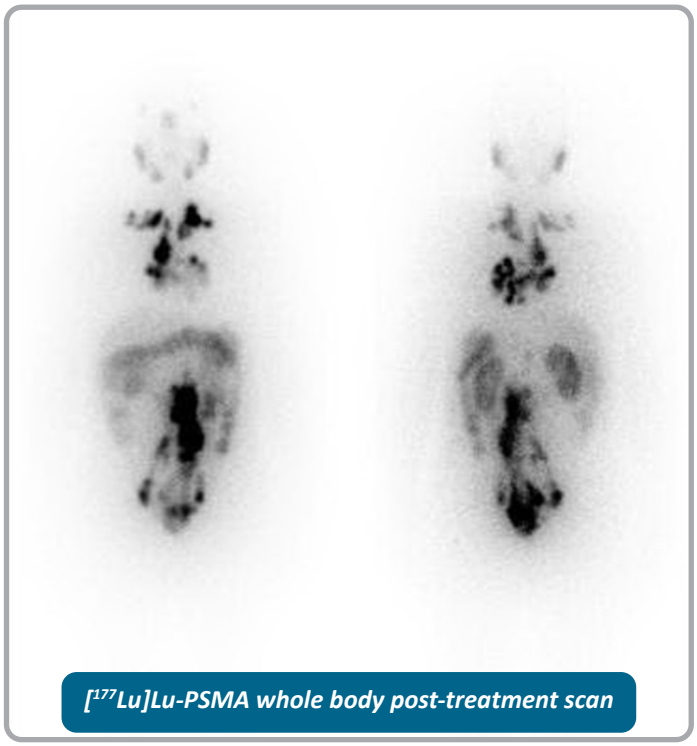
The PSMA-based imaging and radionuclide therapy is a theragnostic approach, which is currently applied in metastatic castration–resistant prostate cancer. Radionuclide therapy with [^{177}Lu]Lu-PSMA is a promising treatment for metastatic patients with prostate cancer. Recently, results of phase III study (VISION trial) of [^{177}Lu]Lu-PSMA in patients with metastatic castration-resistant prostate cancer published which announced [^{177}Lu]Lu-PSMA treatment is a well-tolerated regimen that improves radiological progression free survival and prolongs overall survival compared with standard of care alone in men with advanced-stage PSMA-positive metastatic castration–resistant prostate cancer.

[^{177}Lu]Lu-PSMA has been extensively studied in mCRPC patients and has shown favorable outcomes in multiple prospective and retrospective studies. The recently concluded phase 2 TheraP trial also reported superior efficacy and safety profiles with [^{177}Lu]Lu-PSMA compared to Cabazitaxel in patients with mCRPC.

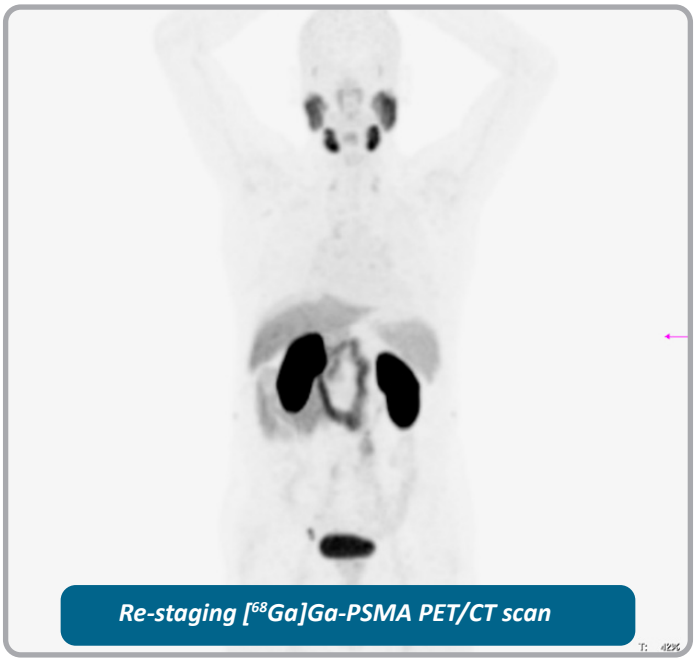
Case: A 72 year old man with chemo-naive metastatic castration-resistant prostate cancer, referred for radionuclide therapy with [^{177}Lu]Lu-PSMA. The PSA level was 97 ng/mL.



(Figure 3) *revealed PSMA-avid soft tissue lesion within prostate gland along with numerous PSMA-positive cervical, thoracic and abdominopelvic lymphadenopathies.*



(Figure 4) *acquired 48 hours after administration of 170 mci [^{177}Lu]Lu-PSMA, which revealed intense PSMA uptake in primary and metastatic lesions similar to the PET/CT scan findings. The patient also continued Triptorelin Acetate injection every three months.*



(Figure 5) *During follow-up and before the 3rd course of treatment the PSA levels dropped to less than 0.1 ng/mL. Therefore re-staging [^{68}Ga]Ga-PSMA PET/CT scan was requested. When compared with pre-treatment PSMA PET/CT scan, the re-staging PSMA PET/CT scan is compatible with complete molecular response to therapy due to interval resolution of PSMA activity of the previously seen prostate soft tissue lesion as well as near complete resolution of the previously seen cervical, thoracic and abdominopelvic lymphadenopathies, with only faintly PSMA positive residual lesions.*

Radionuclide therapy of painful bone metastases

Metastatic bone disease is a common and severe complication of several types of advanced cancers. Breast, prostate and lung cancers are collectively responsible for about 80% of secondary metastatic bone disease. Pain is a major healthcare problem in patients with bone metastases. It has been reported that up to 90% of patients with metastatic or advanced cancer will experience significant cancer-related pain and the majority of them will experience bone pain. The spine, pelvis and ribs are often the earliest site of metastases, but most bone metastases are found in the axial skeleton.

Treatment of cancer-induced bone pain usually progresses through the sequence: non-steroidal analgesics to opioids often combined with radiotherapy, surgery, chemotherapy, hormone treatment, bisphosphonates and radionuclide therapy. Substantial advantages of bone radionuclide therapy include its ability to simultaneously treat multiple sites of disease, ease of administration, repeatability and potential integration with the other treatments.

Bone radionuclide therapy should be used within a multidisciplinary approach to choose the best option for each patient in a correct sequence.

Common indication for radionuclide bone therapy with beta-emitting radionuclides is painful metastatic bone lesions with osteoblastic activity, as confirmed by areas of intense uptake on bone scintigraphy (No longer than 4–8 weeks prior to therapy).

Pregnancy and breastfeeding are absolute contraindications of radionuclide bone therapy. A low blood cell count is a relative contraindication to radionuclide bone treatment because of possible myelotoxicity. The following values can be considered; Haemoglobin > 90 g/L, Total white blood cell count > 3.5×10^9/L, Platelet count > 100×10^9/L.

Poor renal function reduces the plasma clearance of bone-seeking radiopharmaceuticals, resulting in a higher whole-body dose and greater risk of myelotoxicity. Therefore, patients with severely reduced renal function, i.e. creatinine > 2 mg/dL and/or glomerular filtration rate <30 mL/ min, should be excluded from radionuclide bone treatment.

Treatment can be safely performed after local field external beam radiotherapy. The use of wide field (hemi-body) radiotherapy within 3 months of radionuclide therapy of bone metastases is likely to result in increased myelosuppression and is relatively contraindicated. Also, long-acting myelosuppressive chemotherapy should be discontinued at least 4 weeks before bone radionuclide therapy and withheld for 12 weeks post-therapy to avoid concomitant myelosuppression.

There are no contraindications for concomitant or sequential use of radionuclide therapy and bisphosphonates for the treatment of patients with painful bone metastases.

A full haematological and biochemical profile should be obtained within 7 days of proposed treatment. A pregnancy test should perform on the day of treatment for women of childbearing age unless there is a clear history of prior tubal ligation or hysterectomy precluding pregnancy.

Radionuclide therapy of bone metastases have no place in the management of acute spinal cord compression or in treating pathological fractures. Metastases at risk of such complications should be appropriately evaluated on the basis of clinical and neurological symptoms and examination. The presence of cervicodorsal spinal metastases may be associated with increased risk of spinal cord compression. Radiological imaging with MRI should consider to exclude severe lytic lesions with risk of pathological bone fracture or cord compression.

Radionuclide therapy of bone metastases is inappropriate in patients with a life expectancy of less than 4 weeks. Life expectancy should preferably be greater than 3 months.

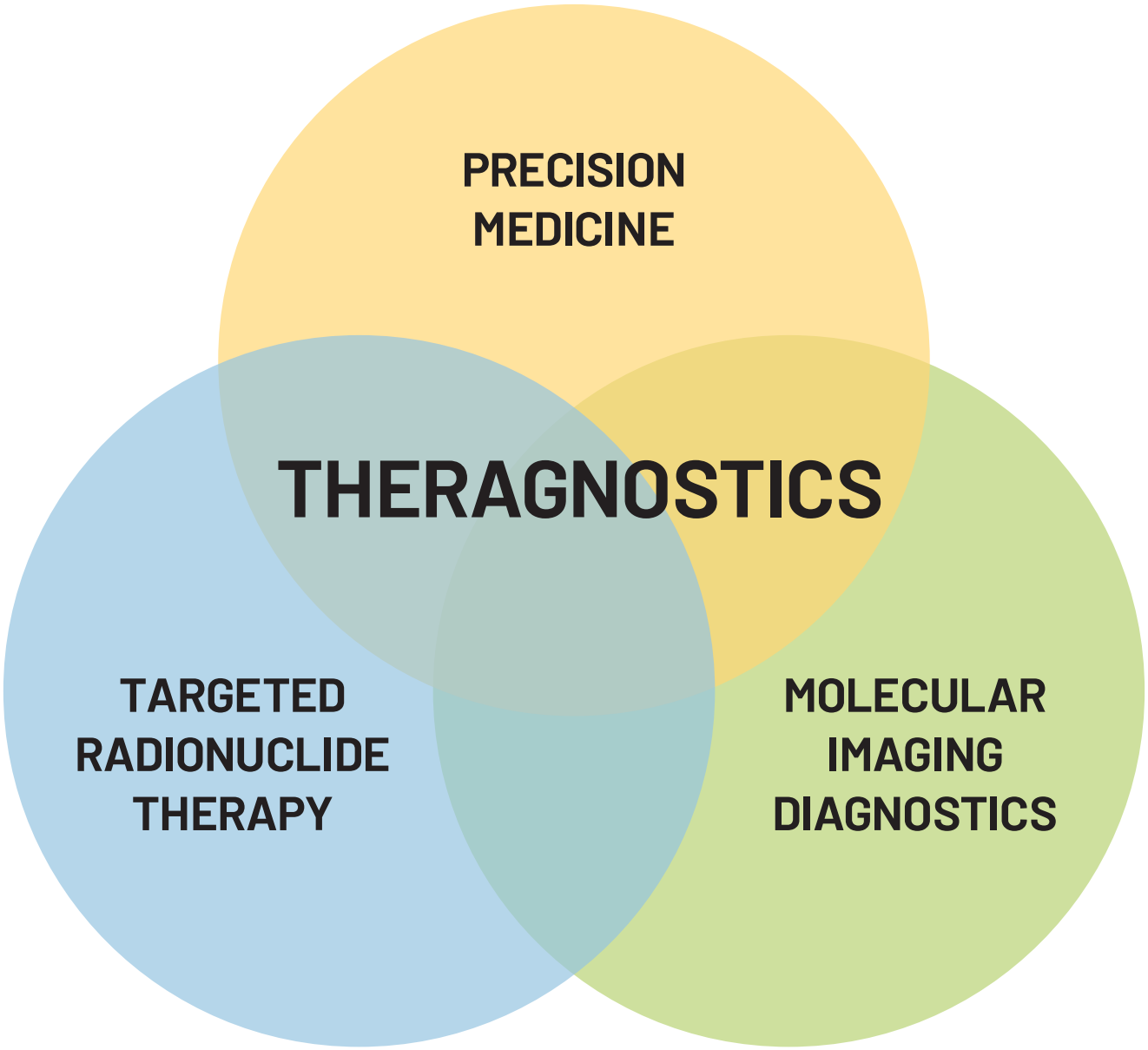
Available radiopharmaceuticals for radionuclide therapy of bone metastases in our center are [^{153}Sm]Sm–EDTMP, [^{188}Re]Re–HEDP and [^{177}Lu]Lutetium-EDTMP.

In our center, radionuclide therapy of bone metastases performs as an outpatient therapy. Patients should be appropriately hydrated before and after treatment. Radiopharmaceuticals administered by slow infusion via an indwelling intravenous catheter followed by a 0.9% saline flush. The patients will remain in the treatment center for 4–6 h after administration to assess any possible early side effects, then discharged.

A post-therapy whole body scan during 24-48 hours after therapy will be done to document radiopeptide distribution in metastatic lesions. Hematological toxicity is the main side effect of bone-seeking radiopharmaceuticals. Therefore, periodical hematological monitoring will be useful up to 6 weeks post-therapy to exclude possible myelosuppression. Following treatment, patients must avoid pregnancy for at least 6 months after treatment.

Radionuclide therapy is advised as a palliative treatment which could improve the quality of life in patients suffer painful bone metastases with osteoblastic or mixed pattern (osteoblastic/osteoclastic) features.

Radionuclide treatment for palliation of painful bone metastases is a safe and effective option for patients with multifocal bone metastases.



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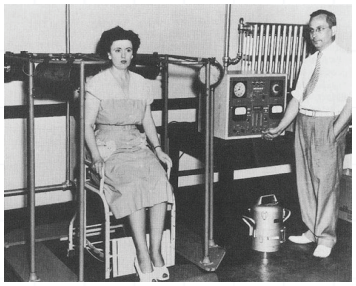
Theragnostics = Diagnostics & Therapy
"we treat what we see"

RAI Therapy

1941

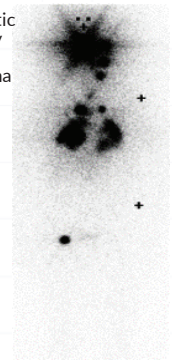
March 31
First patient treated by Dr. Saul Hertz for **Thyroid Cancer**



Dr. Saul Hertz with assistant demonstrating Multi-Scaler image courtesy of the Hertz family

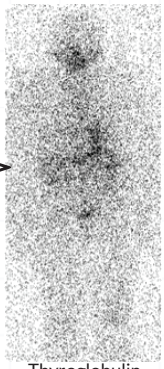
Further Readings:
WARMTH position statement on the initial radioiodine therapy for differentiated thyroid carcinoma pubmed.ncbi.nlm.nih.gov/31040741/

Metastatic Papillary thyroid carcinoma



Thyroglobulin 6540 ng/mL

3 cycles of RAI therapy (150mCi, 150mCi & 100mCi) followed by ongoing remission



Thyroglobulin 0.39 ng/mL

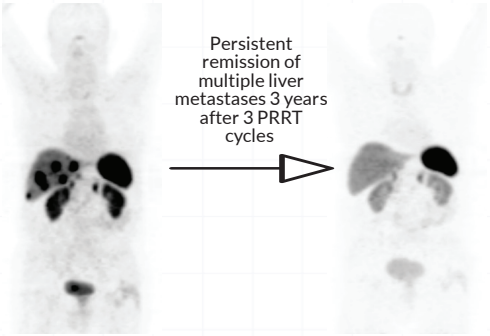
Images courtesy of A. Siswoyo, Universitas Indonesia

PRRT for NETS

1994

First in human use of PRRT to treat Neuroendcrine Tumors

Well-differentiated, non-functioning neuroendocrine neoplasm of the rectum



Persistent remission of multiple liver metastases 3 years after 3 PRRT cycles

Further Readings:
NETTER-1 trial
nejm.org/doi/full/10.1056/NEJMoa1607427

Registration Status:
Approved in US, UK and EU

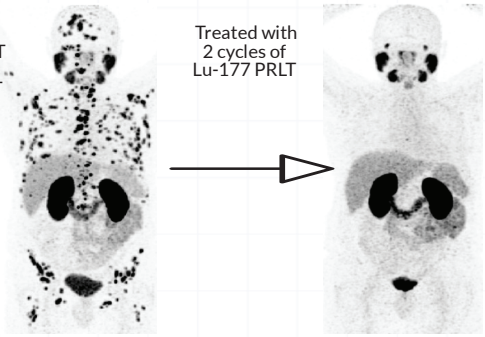
Images courtesy of Zentralklink Bad Berka Germany

PSMA

2021

Reporting of VISION Trial for Lu177 - PSMA617 for Metastatic **Prostate cancer**

Progressive Disease on ADT + Abiraterone and after EBRT



Treated with 2 cycles of Lu-177 PRLT

Further Readings:
VISION - Phase III trial
clinicaltrials.gov/ct2/show/NCT03511664

ThearaP trial
thelancet.com/journals/lancet/article/PIIS0140-6736(21)00237-3/fulltext

Registration Status:
Awaiting approvals

Images courtesy of Zentralklink Bad Berka Germany

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