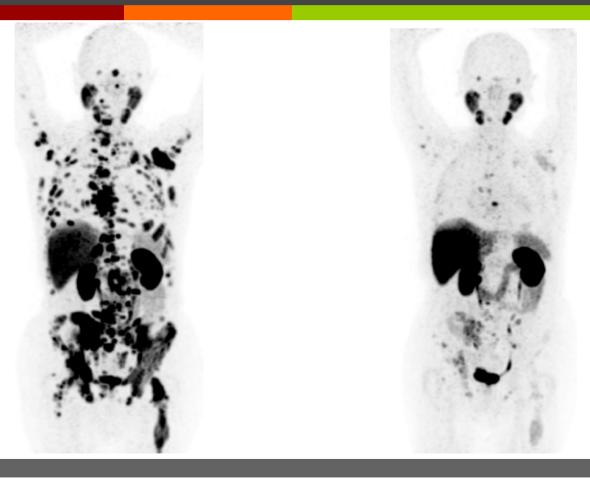
Lu-177-PSMA Real World Clinical Study: Out-patient or Inpatient Treatment

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Pret-herapy

Post-therapy

Cerrahpaşa Medical Faculty experience

June 2013

Peptide availability July 2013

 Ethical committee clearance and finding fund August 2013

 Receiving peptide and first synthesis September 2013

First human study

December 2014

• First Lu-177-PSMA patient

June 2014, decision of full coverage by social security system, all diagnostic and therapeutic applications and getting institutional permission from ministry of health

Goal of radiation therapy



- To deliver effective radiation dose to cancer cells while protecting critical organs from excessive radiation absorbed dose.
 - **7** Bone marrow
 - Kidneys
 - Salivary and lacrimal glands
- In the meantime unnecessary radiation exposure to family members, caregivers and general public should be avoided.
- Nuclear medicine team, physicians, physicists, radiopharmacists, nurses and technologists should be protected as well.

To deliver effective radiation dose:

Radiation dose is important

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Critical organ dosimetry

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	Parotid gland	Kidneys	Bone marrow
Delker et al.	1.4	0.6	0.04
Yaday et al.	1.2	0.1	0.05
Fendler et al	1.0	0.6	0.002

Maximum Safe Doses of Lu-177-PSMA-617

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In-Patient therapy: A costly procedure

- Recommendations to limit the radiation exposure
 - **7** ICRP
 - **7** EURATOM
 - **7** IAEA
 - National authorities (Turkish Atomic Energy Authority; TAEK)
- TAEK requires Isolation in a room
 - Lead shielded rooms (1.6 cm lead thickness)
 - → Specially designed sanitary tank
- Dose rate measurement before release from the therapy room
 - **3**0 μ Sv h⁻¹ from 1 m

Isolation in a room

- Patient should bear extra cost and expenses if they stay a long period of time at the hospital
- Isolation may cause potential emotional disturbances
- It was estimated that hospital acquired infection risk increases by 1.37% when hospital stay prolonged (Hassan et al. 2010)
- This causes additional inconvenience for a large group of patients who can not afford medical insurance covering hospital admission for a long time.
- So an outpatient protocol application might be more plausible

Radionuclide therapy in outpatient basis



Palliation of pain associated with metastatic bone cancer using samarium-153 lexidronam: a double-blind placebo-controlled clinical trial.

JOURNAL OF CLINICAL ONCOLOGY

...... Official Journal of the American Society of Clinical Oncolony

Randomized Controlled Trial of Yttrium-90–Labeled Ibritumomab Tiuxetan Radioimmunotherapy Versus Rituximab Immunotherapy for Patients With Relapsed or Refractory Low-Grade, Follicular, or Transformed B-Cell Non-Hodgkin's Lymphoma

Out-patient therapy

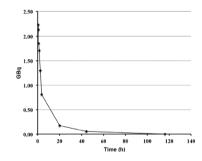
- It is much more convenient to the patient and caregivers
- It is less costly so it is much more convenient for the financing institutions.
- The number of patients you can treat is not limited to the number of beds you have
- It is much more easy to organize post-therapy scan acquisition schedule for the patient.
- It is cheaper if you buy higher amounts of Lu-177

To develop an out-patient protocol

- Bio-distribution characteristics
 - Blood clearance
 - Excretion rates
- Radiation absorbed doses
 - **7** To the caregivers
 - Medical team
 - Nurses
 - Physicians
 - Radiopharmacists
 - Physicists
 - Technologists

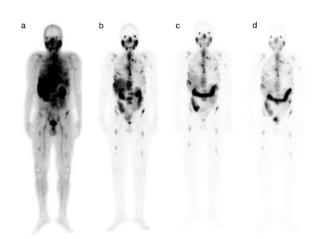
Biodistribution of Lu-177-PSMA-617

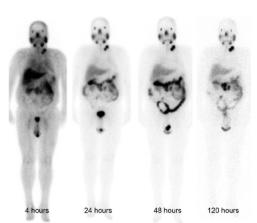
Levent Kabasakal¹, Türkay Toklu², Nami Yeyin¹, Emre Demirci³, Mohammad Abuqbeitah¹, Meltem Ocak⁴, Aslan Aygün¹, Emre Karayel¹, Hüseyin Pehlivanoğlu¹, Nalan Alan Selçuk²



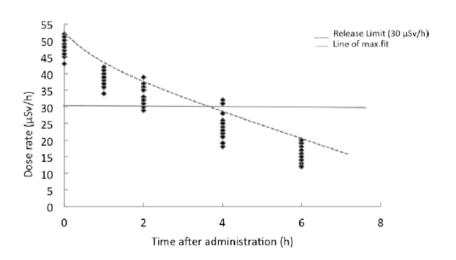
24 h excretion rate: 57% (42%-65%)

Elimination half-life: 10.8h

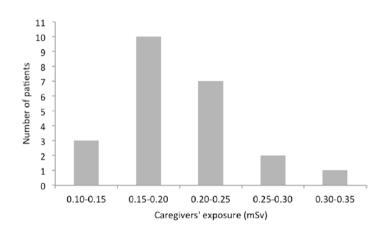




Radiation exposure after Lu-177-PSMA-617 therapy



Radiation exposure to medical staff and caregivers



PSMA vs Dota-Tate

Mohammad Abuqbeitah, et al.

Conclusion

- Lu-177-PSMA-617 therapy is a well tolerated safe treatment for prostate cancer patients
- A large amount of radiopharmaceutical is excreted within 6 h
- **3** 5 h after injection, dose rates decreases below 30 μSv and 6 h after decreases below 20 μSv
- Radiation exposure to caregivers below the standard limit of 5 mSv.
- ► Lu-177-PSMA-617 therapy may be adopted to an outpatient therapy protocol according to our national regulations