Why Patients Undergoing Radiotheranostic Treatments Need Individualized Dosimetry

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Introduction

- Image and diagnose disease:
  - Imageable photon, e.g. Ga-68, In-111
- Treat disease
  - Beta or alpha emitter
  - Auger, conversion electrons
  - Short range particles for smaller tumors, long range for larger tumors, or a mixture, ‘cocktail’.

Radionuclide Therapy Strategies

- The effectiveness of a theranostic agent will depend on two key quantities,
  - The range of the principal emission(s) and
  - The physical half-life of the radionuclide.

Nuclide	Half-life	Emissions	Range
^{125}I	60.0 d	Auger, gamma	10 nm
^{211}At	7.2 h	Alpha	65 µm
^{212}Bi	1.0 h	Alpha, gamma	70 µm
^{169}Er	9.5 d	Beta	1.0 mm
^{177}Lu	6.7 d	Beta, gamma	1.5 mm
^{131}I	8.04 d	Beta, gamma	2.0 mm
^{153}Sm	1.95 d	Beta, gamma	3.0 mm
^{186}Re	3.77 d	Beta, gamma	5.0 mm
^{89}Sr	50.5 d	Beta	8.0 mm
^{32}P	14.3 d	Beta	8.7 mm
^{188}Re	16.95 h	Beta, gamma	11.0 mm
^{90}Y	2.67 d	Beta	12.0 mm

TABLE 1
Physical Characteristics of Therapeutic Radionuclides for Bone Pain Palliation

Radionuclide	Half-life	Maximum energy (MeV)	Mean energy (MeV)	Maximum range	γ-Emission (keV)
^{32}P	14.3 d	1.7 (β)	0.695 (β)	8.5 mm	None
^{89}Sr	50.5 d	1.4 (β)	0.583 (β)	7 mm	None
^{186}Re	3.7 d	1.07 (β)	0.362 (β)	5 mm	137
^{188}Re	16.9 h	2.1 (β)	0.764 (β)	10 mm	155
^{153}Sm	1.9 d	0.81 (β)	0.229 (β)	4 mm	103
^{117m}Sn	13.6 d	0.13 and 0.16 conversion electrons		<1 μm	159
^{223}Ra	11.4 d	5.78 (α) (average)		<10 μm	154

Lewington et al. J Nucl Med January 1, 2005 vol. 46 no. 1 suppl 38S-47S.

Introduction

- The highest rates of success are with traditional I-131 NaI therapy against hyperthroidism and thyroid cancer.
- Small amount for diagnosis ($^{99m}TcO_4^-$ a possible substitute, but not the same uptake pathway).
- Fetal thyroid dose – very important for any radioiodine.
- Pregnancy tests mandatory for any therapy administration. Questionable, but perhaps a good idea even for diagnostic ^{131}I scans.

Dose to the fetal thyroid, mGy/MBq administered to the mother

Gestational Age (mo)	I-123	I-124	I-125	I-131
3	2.7	24	290	230
4	2.6	27	240	260
5	6.4	76	280	580
6	6.4	100	210	550
7	4.1	96	160	390
8	4.0	110	150	350
9	2.9	99	120	270

http://www.doseinfo-radar.com/RADAR-INT-NM.html

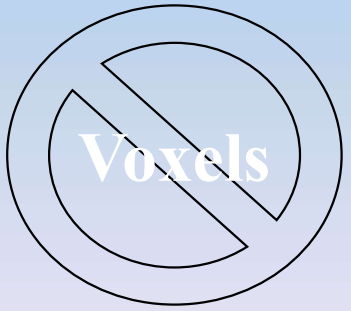
Radioiodine Therapy

- In hyperthyroidism, dosimetry can significantly improve medical practices.
- In thyroid cancer, the thyroid is usually almost completely removed surgically, then treatment of the remnants and mets is not dependent on dosimetry.

Radioiodine Therapy

- Very good dosimetry is possible with a modest investment of effort
  - 4 activity estimates in 48 hr, direct integration or 2-exponential fit
  - Estimate of mass (changing mass*)
  - Uniform, average dose to tissue

$$m(t) = \left[2\left(\frac{kA_m}{c} \exp(-c(t-T)) - \frac{kA_m}{c} + \frac{1}{2} m_T^2 \right) \right]^{1/2}$$



* Traino and DiMartino, various publications

Radiodine Therapy

- Traino et al.: not performing a patient-specific evaluation of thyroid uptake and the change in mass over time resulted in a 9-30% difference in the estimate of thyroid dose in hyperthyroid treatment with ^{131}I-NaI.
- Peters et al.: clear correlation of the success of hyperthyroid therapy with the calculated radiation dose, and they “strongly recommend individual calculation of the iodine activity to be administered for treatment of Graves' hyperthyroidism.”

Radioiodine Therapy

- Kobe et al. (2007), Graves disease:
  - 571 subjects, target dose 250 Gy.
  - Relief from hyper-thyroidism was achieved in 96% of patients who received more than 200 Gy, even for those with thyroid volumes > 40 mL.

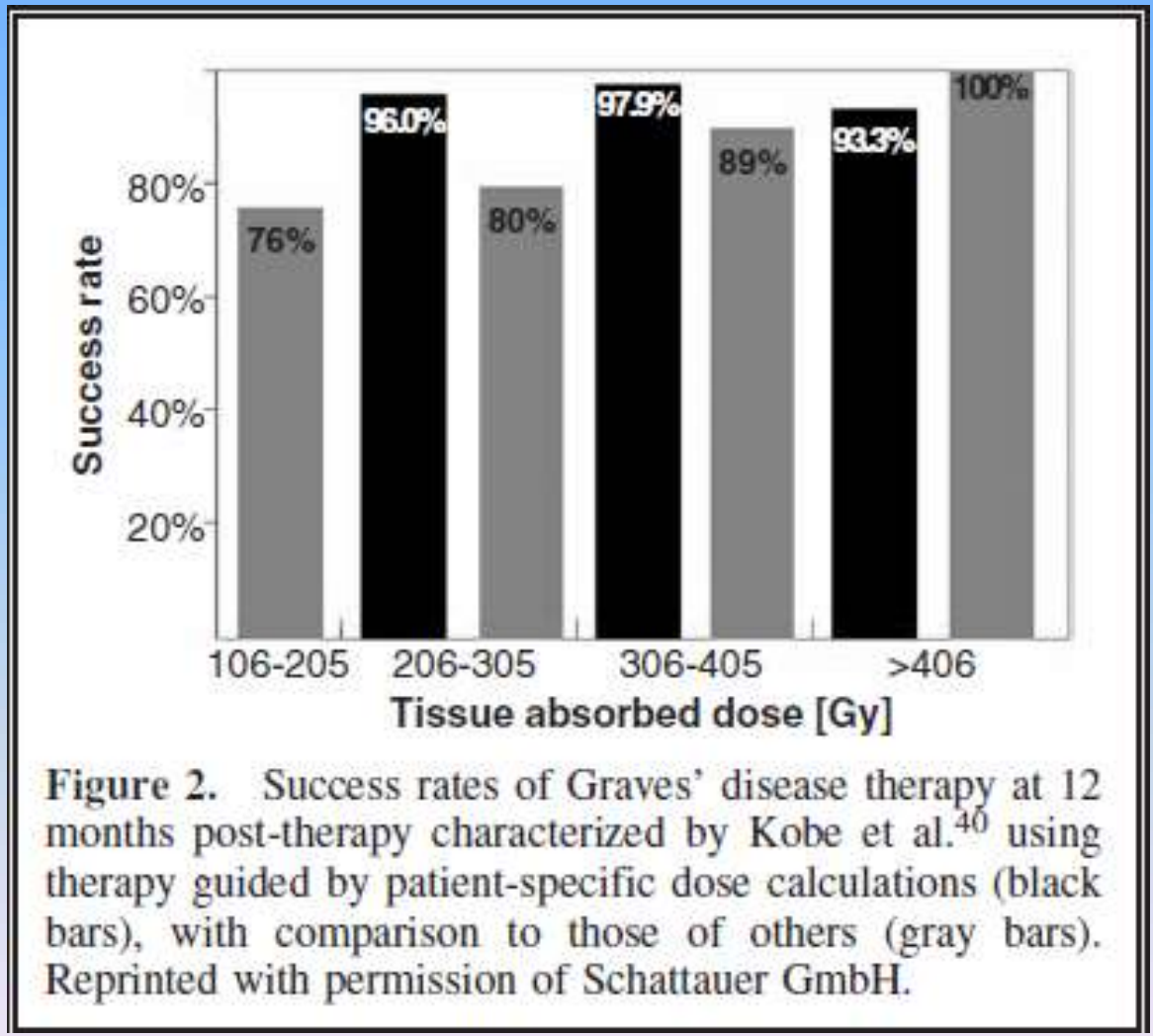
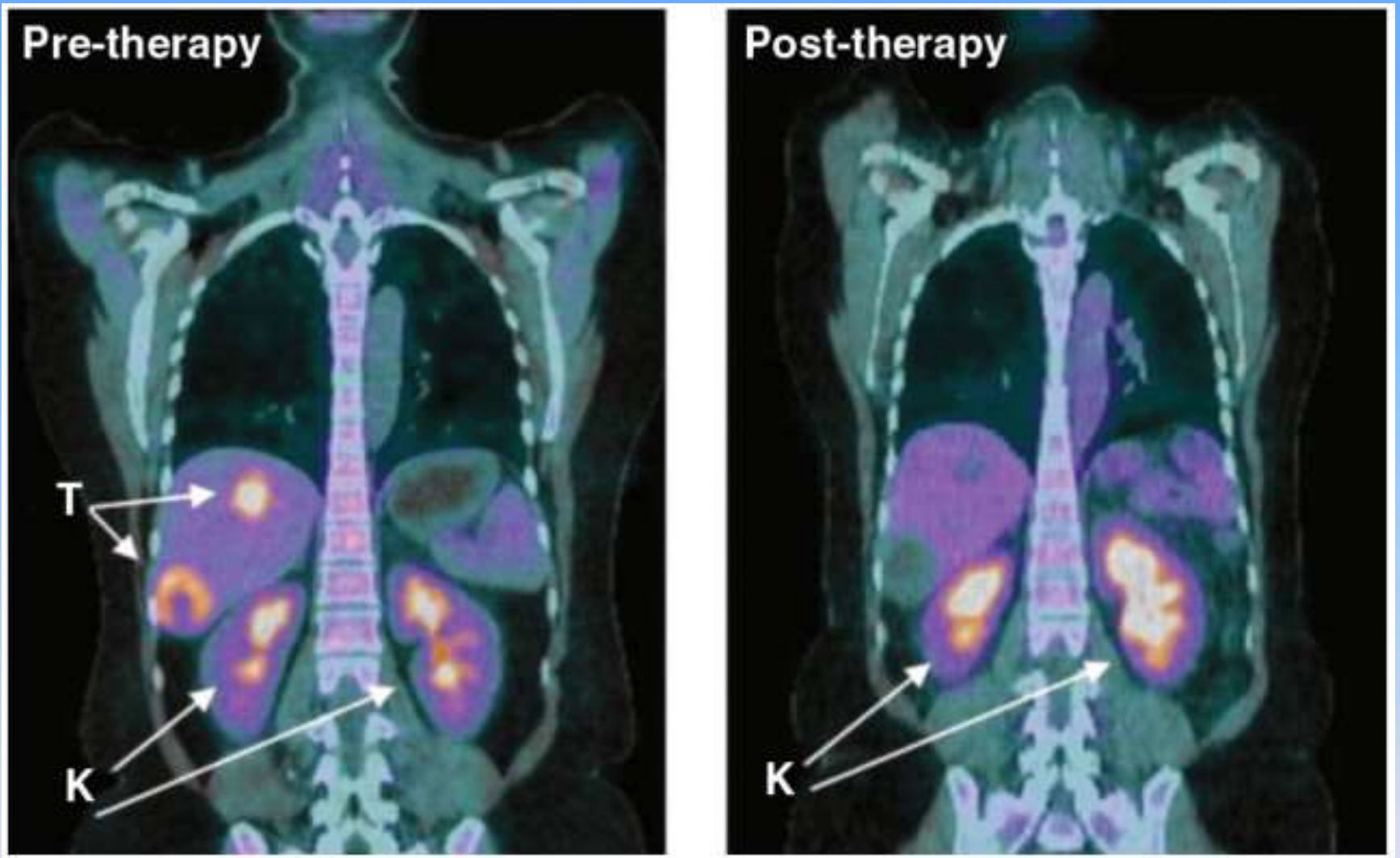


Figure 2. Success rates of Graves' disease therapy at 12 months post-therapy characterized by Kobe et al.[40] using therapy guided by patient-specific dose calculations (black bars), with comparison to those of others (gray bars). Reprinted with permission of Schattauer GmbH.

Radioiodine Therapy

- Jonsson and Mattsson (Rad Prot Dos 2004):
  - Comparison of results from dosimetry-based protocol to protocols based on:
    - Fixed activity
    - Fixed activity, volume ranges
    - Activity/g (24 h uptake)
    - Uptake and volume measurements
  - I-131 generally overprescribed without individualized dosimetry.

^{18}FDG – Cancer Diagnosis



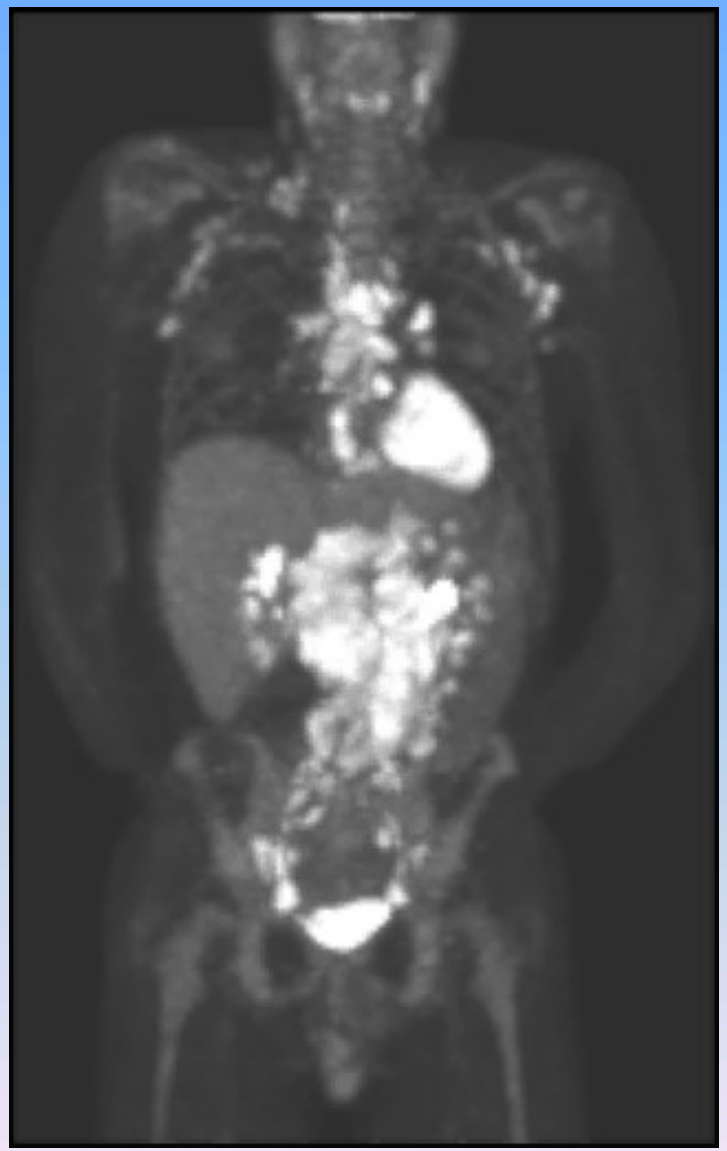
T – tumor in liver (pre- and post-therapy)
K – kidney (does not contain tumor but concentrates FDG)

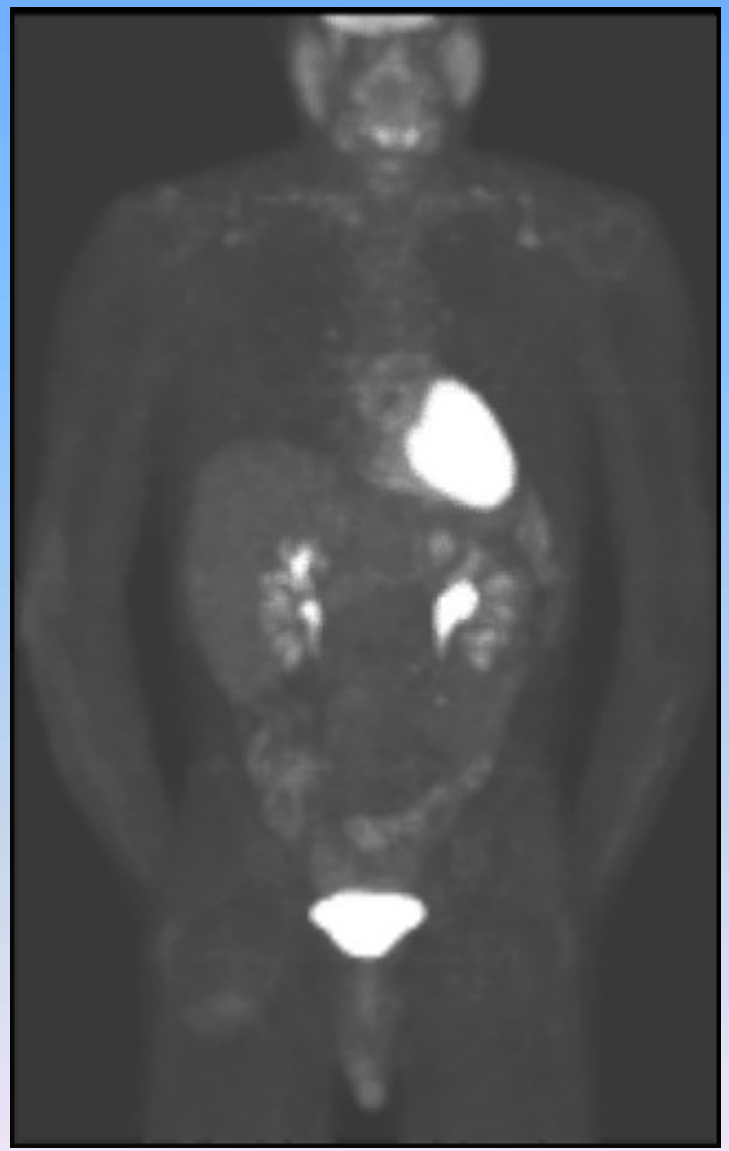
Source: *Science* 324, 1029 (2009).

Monoclonal Antibodies against Non Hodgkin's Lymphoma

- Individual B and T cells of the immune system express a broad variety of surface antigens, which are cell surface markers.
- As with other cell types in the body, B cells and T cells may become malignant and develop into immune system tumors, such as B-cell NHLs.
- B-cell NHLs are cancers of the immune system which currently afflict approximately 300,000 patients in the United States.
- Treatment alternatives for B-cell NHL patients include chemotherapy, radiation therapy and Rituxan.

Tumor Response with Zevalin



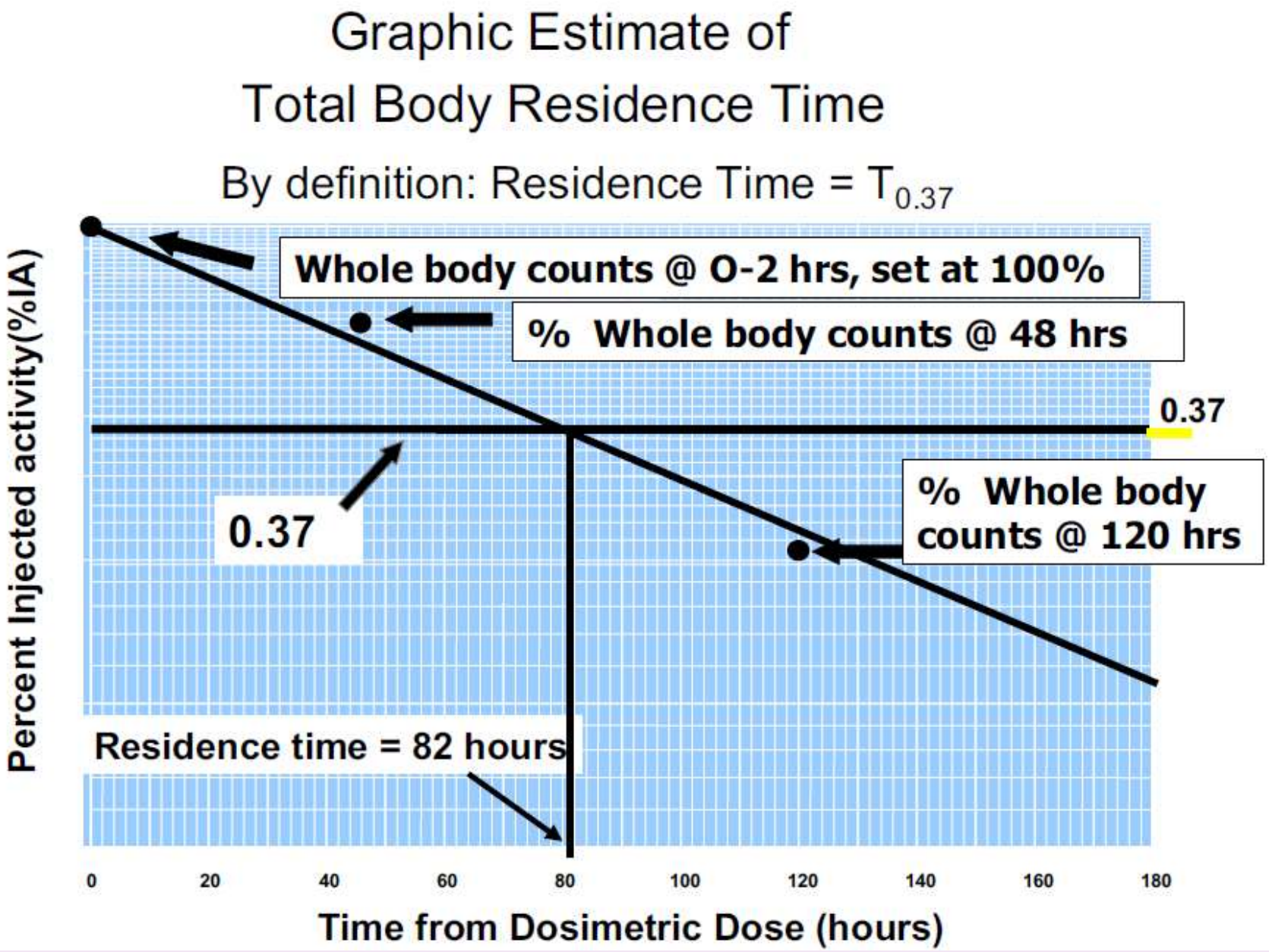


Slide courtesy of Dr. Greg Wiseman, Mayo Clinic, Rochester, MN

Monoclonal Antibodies against Non Hodgkin's Lymphoma

- I-131 tositumomab (Bexxar)
- Y-90 ibritumomab tiuxetan (Zevalin)
- Treatment with either agent appears well tolerated.
- Reversible hematologic toxicity is dose-limiting.
- Approach to radiation dosimetry differs:
  - I-131 is directly imaged. Dose to "total body" in patient-specific ellipsoid correlated with marrow toxicity, used to guide administration.
  - In-111 labeled Zevalin used to infer distribution and dosimetry of Y-90 Zevalin, using MIRDOSE/OLINDA dose calculations and some patient-specific modifications.

Bexxar



Goldsmith, Seminars in Nuclear Medicine, 40:122-135, 2010

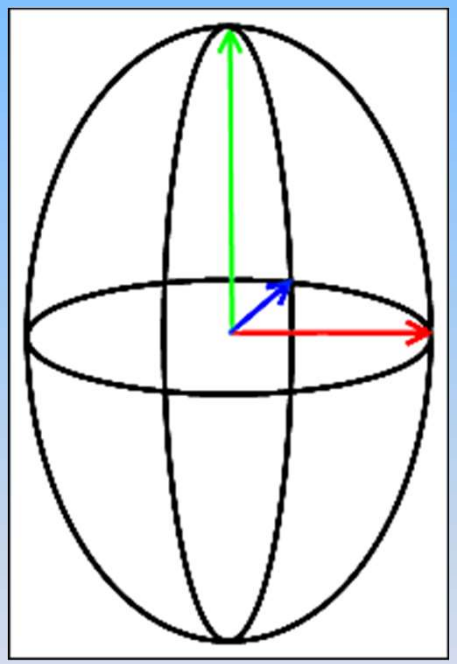
Bexxar

Table 2 Activity Hours to Deliver 75 cGy TBD with ^{131}I for a given Body Mass

Body Mass (Kg)	Activity Hrs	Body Mass (Kg)	Activity Hrs	Body Mass (Kg)	Activity Hrs
90	9633	94.5	10068	99	10500
90.5	9682	95	10117	99.5	10548
91	9730	95.5	10165	100	10595
91.5	9779	96	10213	100.5	10643
92	9827	96.5	10261	101	10690
92.5	9875	97	10309	101.5	10738
93	9924	97.5	10357	102	10785
93.5	9972	98	10404	102.5	10833
94	10020	98.5	10452	103	10880

"Activity Hours" is the product of the activity to be administered and the residence time that would result in 75 cGy whole body radiation absorbed dose. The patient specific residence time is divided into this product (activity hrs) to determine the amount of activity to be administered (in mCi). If it is desirable to administer only 65 cGy (platelets <150,000 but >100,000), 0.87 of the activity is used (65/75 or 0.87).

Dosimetric Model:



Monoclonal Antibodies – I-131 Bexxar

- June 30, 2003: approved for use in patients with non-Hodgkins lymphoma.
- In September, the drug also was approved for Medicare reimbursement.
- Zevalin was approved for reimbursement in October 2002.
- Sadly, because of lack of use, Bexxar is off the market, and Zevalin is close to the same fate.

Radionuclide Therapy Strategies: Radiolabeled Peptides

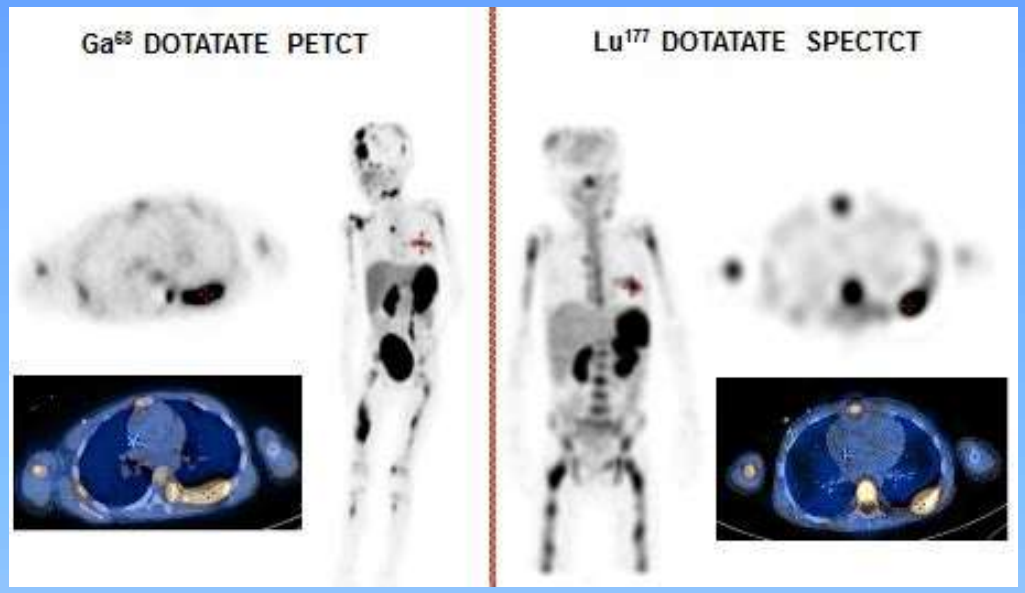
- Radiolabeled peptides (amino acid sequences, often small pieces of antibodies that have receptor binding properties) have several advantages over antibodies mainly related to immunogenicity and size.
- Tumor localization and total body clearance of peptides are more rapid compared to antibodies.

Radionuclide Therapy Strategies: Radiolabeled Peptides

- An example is octreotide, which is a piece of the hormone somatostatin. Octreotide can be labeled directly with ^{99m}Tc or to ^{111}In by the linker DTPA or to ^{90}Y by the linker DOTA.
- ^{90}Y-DOTATOC (yttrium-90 DOTA-D-Phe1-Tyr3-octreotide) is used for treatment of patients with neuroendocrine tumours, gliomas, and even thyroid carcinomas that express somatostatin receptors.

Radionuclide Therapy Strategies: Radiolabeled Peptides

- ^{68}Ga DOTATATE may be used to obtain diagnostic information for application of ^{177}Lu DOTATATE.
- However the short half-life limits its predictive value for dosimetry.
- Fortunately, ^{177}Lu has a rather low abundance photon (208 keV at 11%), so one can obtain images during the first treatment cycle to develop dosimetry for subsequent cycles.


Ga68 DOTATATE PETCT
Lu177 DOTATATE SPECTCT

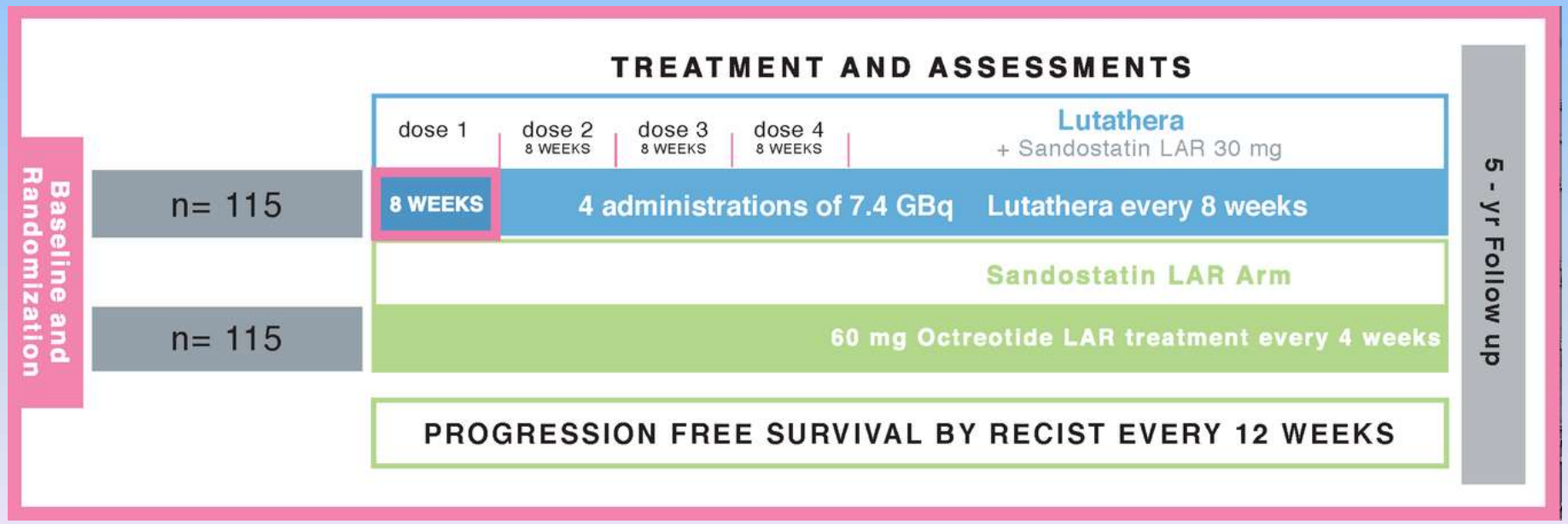

TREATMENT AND ASSESSMENTS
Baseline and Randomization
n= 115
n= 115
dose 1
dose 2
8 WEEKS
dose 3
8 WEEKS
dose 4
8 WEEKS
Lutathera
+ Sandostatin LAR 30 mg
8 WEEKS
4 administrations of 7.4 GBq Lutathera every 8 weeks
Sandostatin LAR Arm
60 mg Octreotide LAR treatment every 4 weeks
PROGRESSION FREE SURVIVAL BY RECIST EVERY 12 WEEKS
5 - yr Follow up

TABLE II.—*Data collection and processing.*

	Data collection	
Pharmacokinetics		
Blood	blood sample (*e.g.*, 1 mL) collection with time schedule for fast clearance (*e.g.*: at 5, 10, 20, 30 min, and 1, 4, 6, 16, 20, 28, 44, 52 h p.i.)	Activity concentration in blood to derive the curve of the clearance from the blood
Urine	Complete urine collection up to 48-64 h p.i. at established time-intervals (*e.g.*: 0-1; 1-3; 3-6; 6-16; 16-24; 24-40; 40-48; 48-64 h p.i.).	Activity concentration in urine (considering the urine volume collected at each time-interval) to derive the activity cumulatively eliminated in the urine *vs.* time
Anatomical data		
CT scan	Close to the date of therapy	Actual organ mass evaluation
Imaging		
WB transmission	Before administration	Using a flood source or a scout from CT
Whole body	At least 4-5 acquisitions (*e.g.*, at 1; 3-4; 16-24; 40-48; 64-80 h p.i.)	Ant and post windows set for the energy peaks of ^{111}In or ^{177}Lu (±15-20%)
Scintigraphy SPECT (SPECT-CT)	If possible, at least one acquisition at 16-24 h (especially at the level of the kidneys)	If possible, scatter energy windows should be added (especially for ^{111}In) Attenuation correction to be included

Radionuclide Therapy Strategies: Radiolabeled Peptides

- Bodei et al. – Peptide receptor radionuclide therapy with ^{177}Lu-DOTATATE
- 51 patients, multiple cycles.
- 3.7–5.18 GBq/cycle, group 1; 5.18–7.4 GBq/cycle, group 2)
- Cumulative activities ranged from 3.7 to 29.2 GBq.

Radionuclide Therapy Strategies: Radiolabeled Peptides

- No major acute or delayed renal or haematological toxicity occurred (one grade 3 leukopenia and thrombocytopenia).
- Cumulative renal absorbed doses were 8–37 Gy (9–41 Gy bioeffective doses).
- Median decrease of creatinine clearance of 21.7% 6 months after PRRT, 23.9% after 1 year and 27.6% after 2 years was observed.

Table 3 Dosimetry data in 12 patients

Patient #	Injected activity (IA, GBq)	Kidney dose/IA (Gy/GBq)	Cumulative kidney dose (Gy)	Cumulative kidney BED (Gy)	Bone marrow dose/IA (Gy/GBq)	Cumulative bone marrow dose (Gy)	Liver dose/IA (Gy/GBq)	Cumulative liver dose (Gy)	Spleen dose/IA (Gy/GBq)	Cumulative spleen dose (Gy)
5	22.2	1.65	37	41	0.06	1.3	0.20	4.4	1.95	43
10	22.1	0.87	19	21	0.05	1.1	0.26	5.7	2.91	64
13	26.6	0.62	17	17	0.04	1.1	0.08	2.1	0.64	17
14	29.2	0.52	15	16	0.03	0.9	0.89	25.9	0.42	12
18	26.5	0.74	20	21	0.03	0.8	0.45	11.8	0.65	17
20	25.9	0.92	24	26	0.05	1.3	0.15	3.9	1.96	51
24	25.2	0.61	15	17	0.02	0.5	0.41	10.3	0.59	15
26	25.2	1.05	26	31	0.03	0.8	n.a.	n.a.	n.a.	n.a.
28	25.2	0.54	18	15	0.02	0.5	0.23	5.7	1.57	40
29	25.2	0.59	15	16	0.02	0.5	n.a.	n.a.	n.a.	n.a.
30	25.2	0.33	8	9	0.02	0.5	0.16	4.0	0.47	12
33	28.9	1.10	32	38	0.03	0.9	1.01	29.2	0.42	12

Patients #5, 10, 13, 14, 18 and 20 from group 1; #24, 26, 28, 29, 30 and 33 from group 2

n.a. not assessed

Biologically Effective Dose (BED)

Protracted irradiation at a decaying dose rate

$$ln(SF) = -\alpha D - \frac{\lambda}{\lambda + \mu}\beta D^2$$

$$BED_{TRT} = D\left(1 + \frac{D\lambda}{(\mu + \lambda)(\alpha / \beta)}\right)$$

BED for a fractionated high dose rate treatment

$$BED_{XTB} = D\left(1 + \frac{D / n}{\alpha / \beta}\right)$$

α,β are radiosensitivity parameters
λ is the effective dose-rate decay constant
μ is the repair constant

Dose rates and renal toxicity

TABLE 2

Comparisons of Absorbed Doses and Dose Rates to Kidneys with Radionuclide Therapies

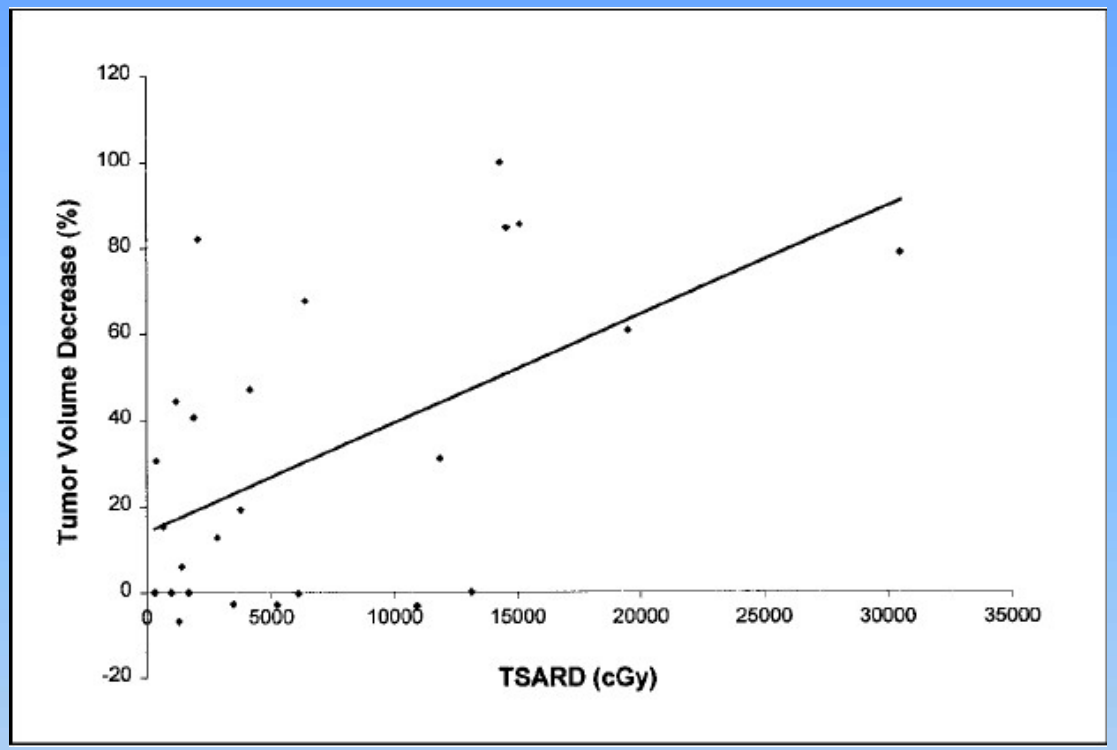
Therapy	N_{frac}	A (GBq)	D (Gy)	R_0 (Gy/h)	RE	BED (Gy)
^{90}Y-DOTA-octreotide	3	13.3	27	0.15	1.2	32
^{111}In-DTPA-octreotide	8	83	34	0.07	1.1	37
^{177}Lu-DOTA-octreotate	4	29.6	26	0.04	1.1	29
^{166}Ho-DOTMP	1	167	7.5–15	4.2–8.4	2.4–3.7	18.0–55.5
External-beam irradiation	16	NA	23	NA	1.6	37
Total-body irradiation	6	NA	12	NA	1.8	22

I-131-mIBG therapy for neuroblastoma and phaeochromocytoma

- Fixed activity fractions (e.g. McCluskey 2005)
  - Simple and easy to implement quickly.
  - No understanding or correlations of dose/effect possible.
- Activity/kg body weight approach (e.g. Sisson et al. 1994)
  - Correlations of marrow toxicity with activity/kg of body weight.
  - Again, no dose/effect correlations possible.

I-131-mIBG therapy for neuroblastoma and phaeochromocytoma

- Dose-based approaches (e.g. Matthay et al. 2001)
  - Total body, marrow, and tumor doses.
  - Hematologic toxicity was correlated with activity/kg, marrow dose, total body dose.
  - Calculated tumor dose predicted response.



Correlation of TSARD with subsequent tumor volume decrease. Decrease in tumor volume is shown as positive percentage. Spearman rank correlation, $P = 0.02$.

Spearman Rank Correlations Among ^{131}I-MIBG Activity, TSARD, Target Lesion Volume Response, Whole-Body Irradiation Dose, Red Marrow Radiation Dose, and Hematologic Toxicity

Variable (X)	Variable (Y)	r_s	P
Red marrow irradiation	Blood irradiation	0.43	0.04
	Neutrophil nadir	−0.47	<0.01
	Platelet nadir	−0.35	0.02
	Volume decrease (%)	0.48	<0.01

TABLE I.—*Range of absorbed doses delivered to whole-body and tumour for I-131 mIBG treatment of neuroblastoma.*

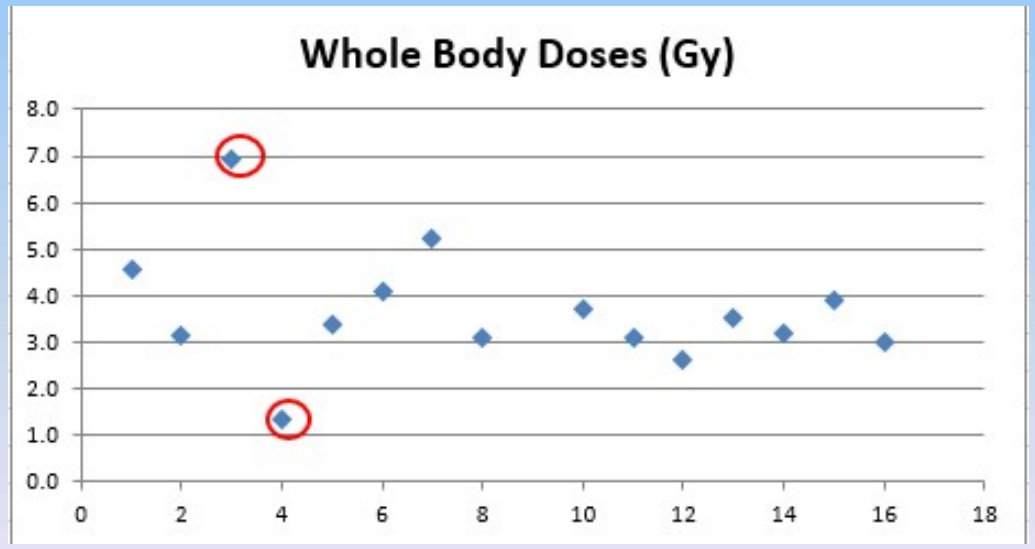
Number of patients (number of intervals)	Administered activities (MBq)	Absorbed WB dose (mGy/MBq)	Total absorbed WB dose (Gy)	Absorbed tumour dose (mGy/MBq)	Total absorbed tumour dose (Gy)	Comments
6 (1-5)	1536-5550	0.30-0.35	0.56-2.57	N/A	N/A	Absorbed doses derived from combination of pretherapy & post-therapy data [25]
6 (1-3)	4884-8410	0.13-0.45	0.13-0.23	N/A	N/A	External probe measurements [16]
16 (1)	5726-8383	0.15-0.39	1.56-2.87	1.41-5.06	15-56	Treatments based on 444 MBq/kg [18]
26 (1-5)	1759-32871	0.04-0.42	0.46-3.51	N/A	N/A	Treatments based on 444 MBq/kg. External counts. Correlation between WBD and neutrophilia [28]
8 (2)	3590-13300	0.18-0.43	0.93-2.90	N/A	N/A	Initial treatment based on 444 MBq/kg. Second treatment to total 4 Gy cumulative WBD [32]
42 (1)	3330-30969		0.057-0.65		0.31-300	Treatments based on 555 MBq/kg [17]
4 (1)	7400	0.16	N/A	N/A	N/A	Treatments based on 7400 MBq [23]
25 (1)	2400-12100	0.14-0.63	0.7-2.6	N/A	N/A	Absorbed dose escalation study [22]

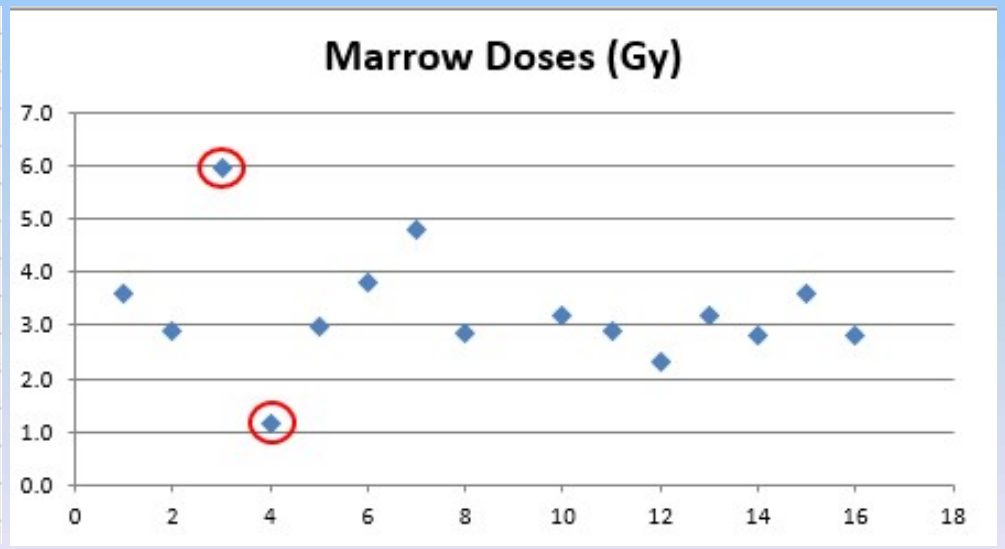
TABLE II.—*Range of absorbed doses delivered to whole-body and tumour for I-131 mIBG treatment of adult neuroendocrine tumours.*

Indication (number of intervals	Administered activities (MBq)	Mean absorbed WB dose (mGy/MBq)	Total absorbed WB dose (Gy)	Absorbed tumour dose (mGy/MBq)	Total absorbed tumour dose (Gy)	Comments
5 CA (1-3) 3 PC (1-6) 1 MTC (1)	5550-11110	0.07-0.09	0.52 ± 0.13 0.56 ± 0.19 0.64	N/A	N/A	Doses based on combination of pretherapy & post-therapy data [25]
5 PC (1-3)	7357-1096	0.12-0.13	0.98-1.44	1.09-5.77	10-60	Treatments based on 444 MBq/kg [18]
1 PG (1)	10716	0.13	1.40	4.29	46	Treatments based on 444 MBq/kg [18]
9 PC	7400	0.07-0.16	N/A	0.4-16.9	N/A	Treatments based on 7400 MBq [23]
6 PC (1-3)	8600-13400	0.05-0.20	0.60-2.0	N/A	N/A	Improved response over administered activity of 5550 MBq [53]

CA: carcinoid; PC: phaeochromocytoma; MTC: medullary thyroid cancer; PG: paraganglioma.


Half-Lives (hr)
90
80
70
60
50
40
30
20
10
0
0
5
10
15
20


Whole Body Doses (Gy)
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0
2
4
6
8
10
12
14
16
18


Marrow Doses (Gy)
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0
2
4
6
8
10
12
14
16
18

Lu-177 PSMA

- Metastatic castration-resistant prostate cancer (mCRPC) has a poor prognosis with estimated 27,540 prostate cancer deaths in the US in 2015 (1).
- Prostate specific membrane antigen (PSMA) is a glutamate carboxypeptidase II (GCPII), over-expressed in prostate cancer.
- Baum et al. analyzed the safety and efficacy of ^{177}Lu-labeled DOTAGA-based PSMA ligand ^{177}Lu-DOTAGA-(I-y)fk(Sub-KuE) (^{177}Lu-PSMA) in a cohort of patients with mCRPC. The end points of their analysis, which was performed in correlation with kinetics and dosimetry, were safety, objective response, progression-free survival and overall survival.

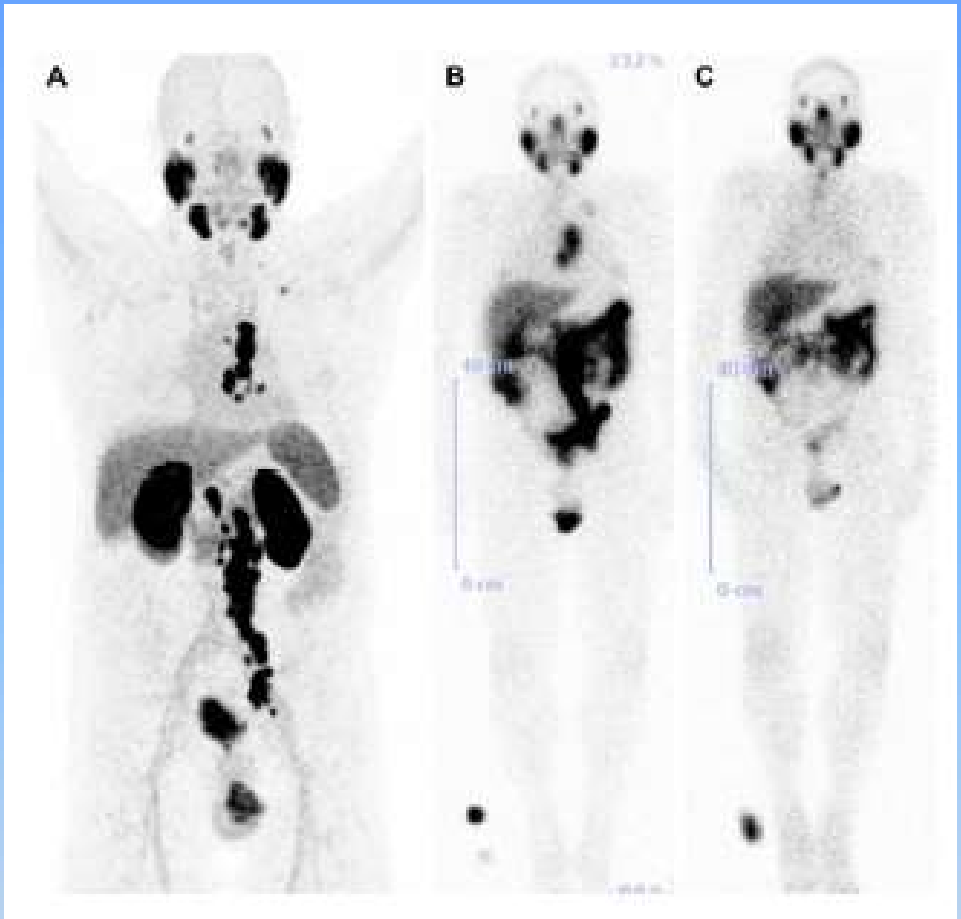


FIGURE 2: 70-year-old patient with PSMA-avid lymph-node metastases on pre-therapy ^{68}Ga-PSMA PET/CT *(A)*, and on ^{177}Lu-PSMA scintigraphy after 1st PSMA-RLT *(B)*; with remarkable reduction of uptake after 2nd PSMA-RLT *(C)*, consistent with excellent therapy response.

RADAR Guide: Standard Methods for Calculating Radiation Doses for Radiopharmaceuticals, Part 1—Collection of Data for Radiopharmaceutical Dosimetry

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RADAR Guide: Standard Methods for Calculating Radiation Doses for Radiopharmaceuticals, Part 2—Data Analysis and Dosimetry

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Planar

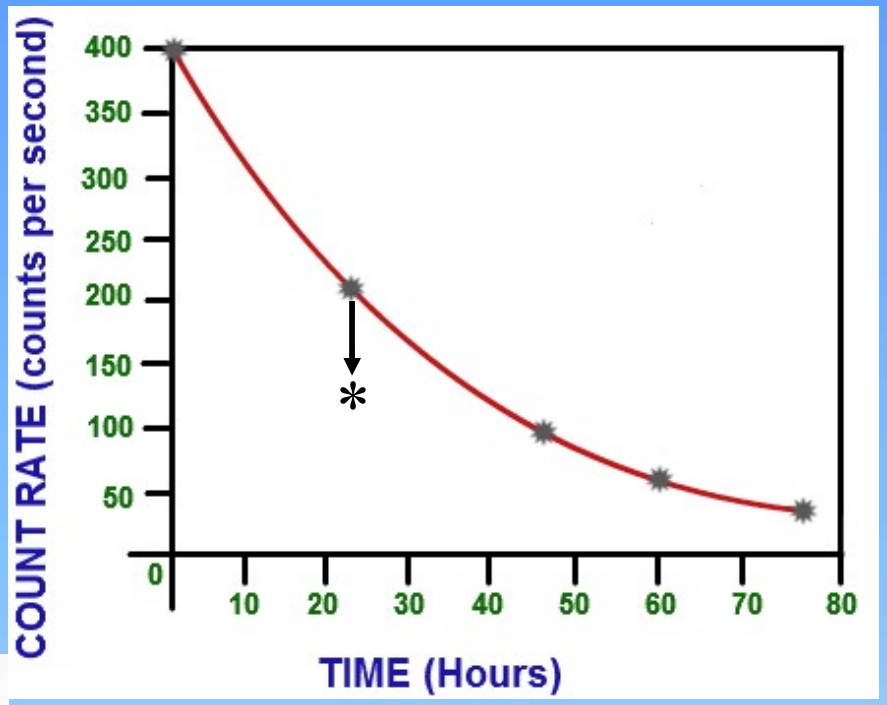

SPECT
Camera Head
Patient x.s.


Planar


Planar


Planar

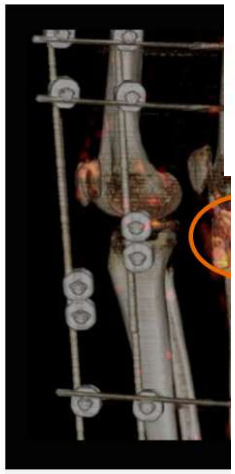

Planar


COUNT RATE (counts per second)
400
350
300
250
200
150
100
50
0
10
20
30
40
50
60
70
80
TIME (Hours)
*

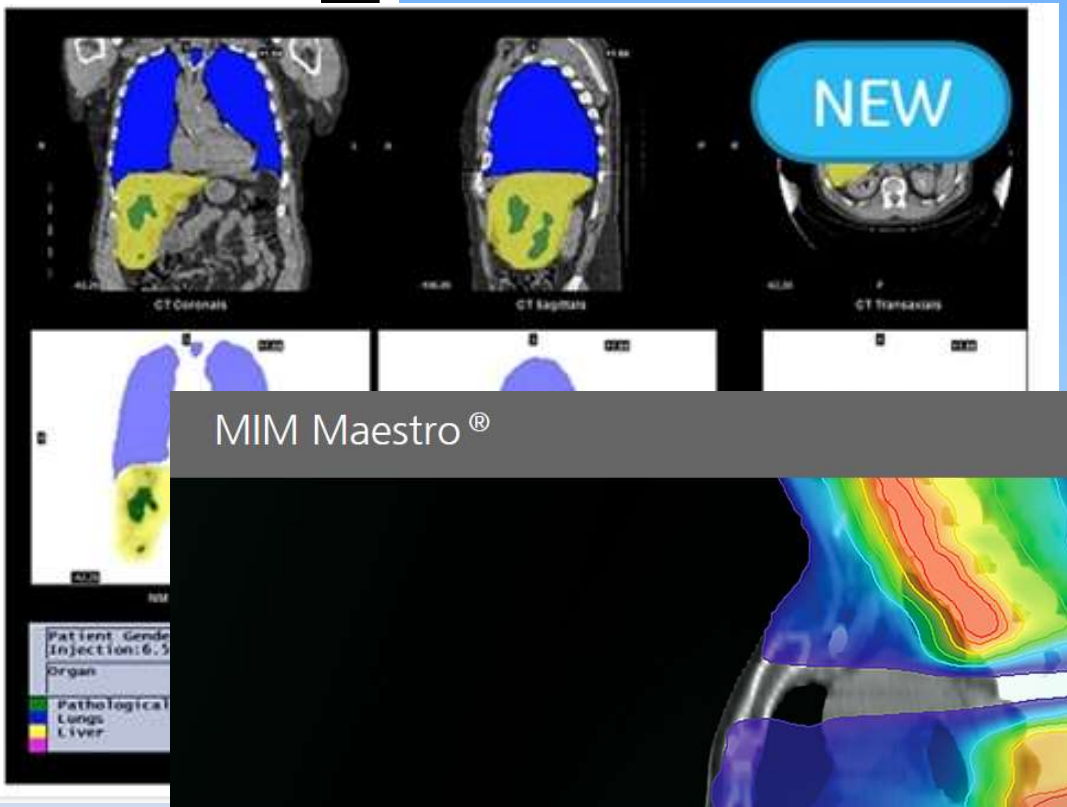
xSPECT Technology

The complete integration of SPECT and CT.

Overview Features & Benefits



Q.Metrix



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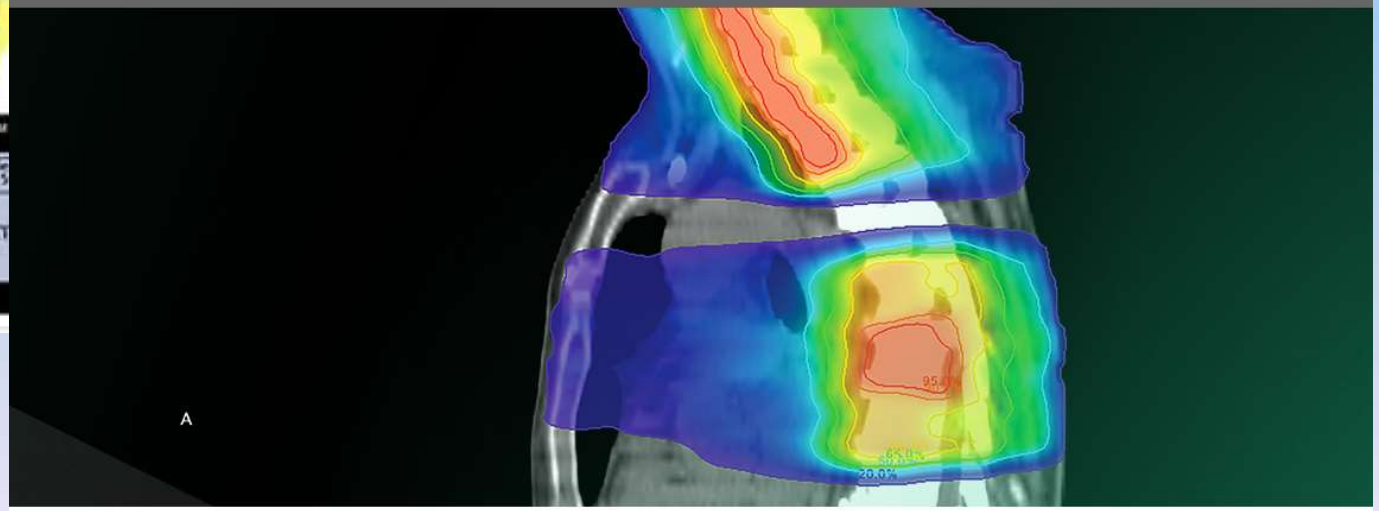

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Radiation oncology is at the heart of today's fight against cancer. It's an everyday process to precisely tailor treatment plans to each patient. You need a smart and efficient system of tools to help you do this.

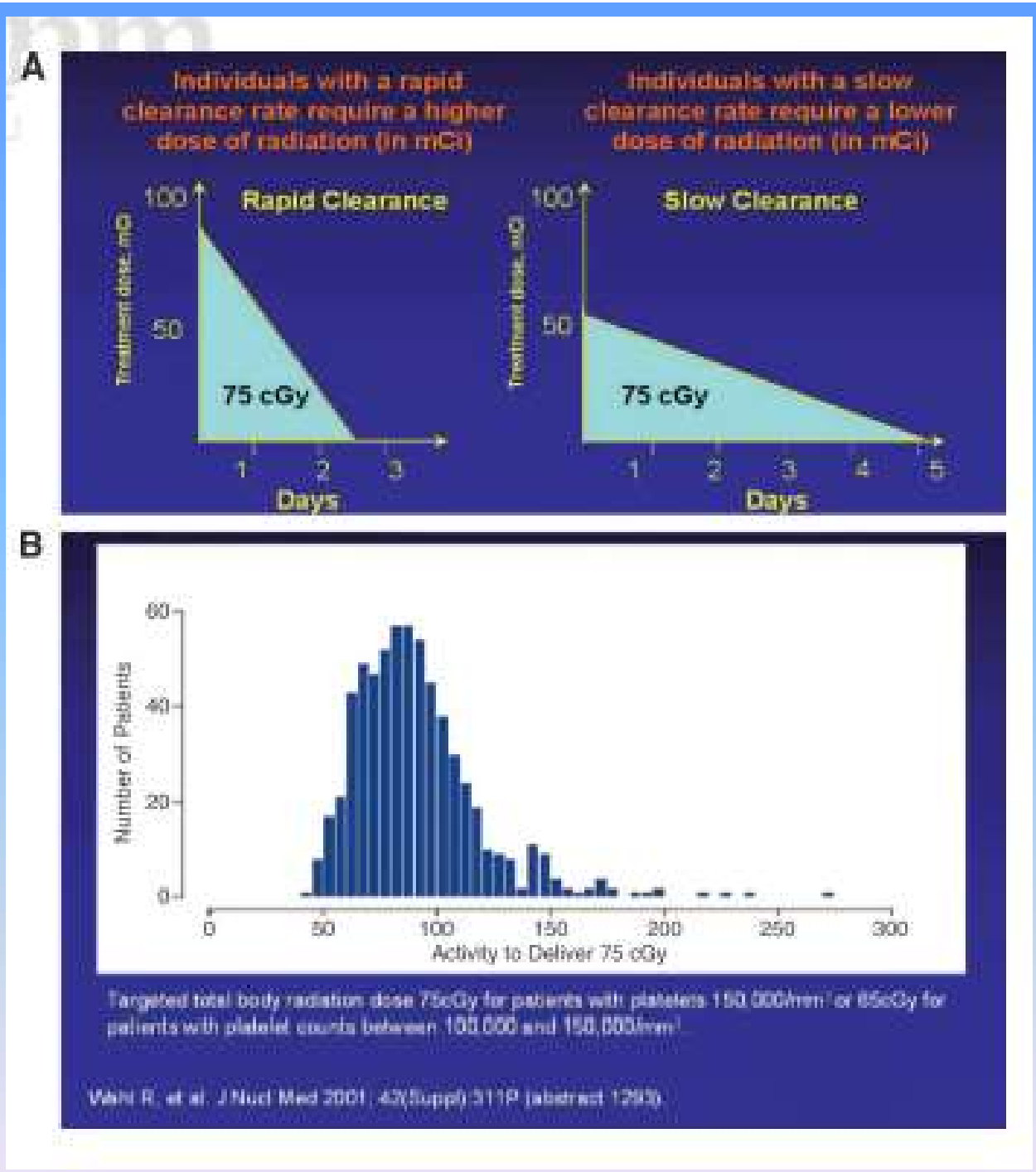
Introduction

- The #1 challenge:
- Getting physicians to actually perform dosimetry for radiopharmaceutical therapy patients!!!!

Uncertainties in Internal Dose Calculations for Radiopharmaceuticals

J Nucl Med 2008; 49:1–8

- ..the combined uncertainties in any given radiopharmaceutical dose estimate are typically, at a minimum, a factor of 2 and may be considerably greater, in general because of normal human variability, and particularly in disease states.
- In therapy applications, if patient-individualized dosimetry is performed, …the total uncertainty in an individual dose estimate can be reduced to a value of perhaps ~10%–20%.



Wahl, J Nucl Med 2005; 46:128S–140S

Patient-Individualized Medicine

The Case for Patient-Specific Dosimetry in Radionuclide Therapy

CANCER BIOTHERAPY & RADIOPHARMACEUTICALS
Volume 23, Number 3, 2008

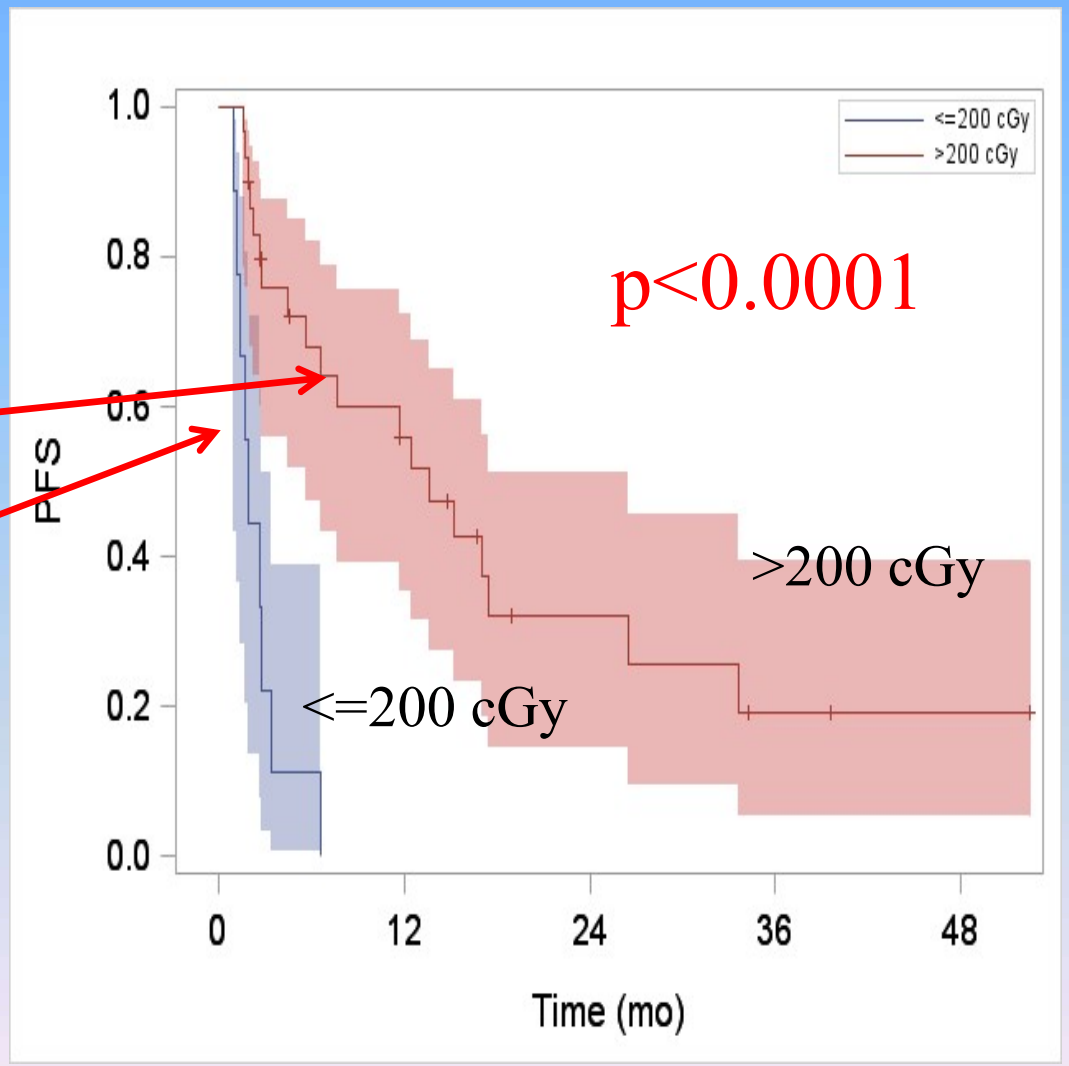
- "Treating all nuclear medicine patients with a single, uniform method of activity administration amounts to consciously choosing that these patients be treated with a lower standard of care than patients who receive radiation externally for cancer treatments."

Patient-Individualized Medicine

- Performing external beam radiotherapy on cancer patients without a dosimetry workup would constitute:

PFS Stratified by Tumor Dose

- Longer PFS for mean tumor absorbed dose >200 cGy
- Median PFS
  - 13.6 mo (>200 cGy)
  - 1.9 mo (<200 cGy)



Lymphoma patients, Y Dewaraja et al, with permission

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Dosimetry-Guided Radiopharmaceutical Therapy

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ARTICLES | VOLUME 6, ISSUE 1, P17-29, JANUARY 01, 2021

Personalised versus standard dosimetry approach of selective internal radiation therapy in patients with locally advanced hepatocellular carcinoma (DOSISPHERE-01): a randomised, multicentre, open-label phase 2 trial

Prof Etienne Garin, MD * • Lambros Tselikas, MD * • Prof Boris Guiu, MD • Julia Chalaye, MD • Julien Edeline, MD • Prof Thierry de Baere, MD • et al. Show all authors • Show footnotes

Published: November 06, 2020 • DOI: https://doi.org/10.1016/S2468-1253(20)30290-9 • Check for updates

DOSISPHERE-01 was a randomised, multicentre, open-label phase 2 trial done at four health-care centres in France. Patients were eligible if they were aged 18 years or older and had unresectable locally advanced hepatocellular carcinoma, at least one measurable lesion 7 cm or more in size,…

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Compared with standard dosimetry, personalised dosimetry significantly improved the objective response rate in patients with locally advanced hepatocellular carcinoma. The results of this study suggest that personalised dosimetry is likely to improve outcomes in clinical practice and should be used in future trials of selective internal radiation therapy.


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