Trattamento non chirurgico delle oligometastasi

Radioterapia stereotassica

-Colonna vertebrale-

Stefania Manfrida

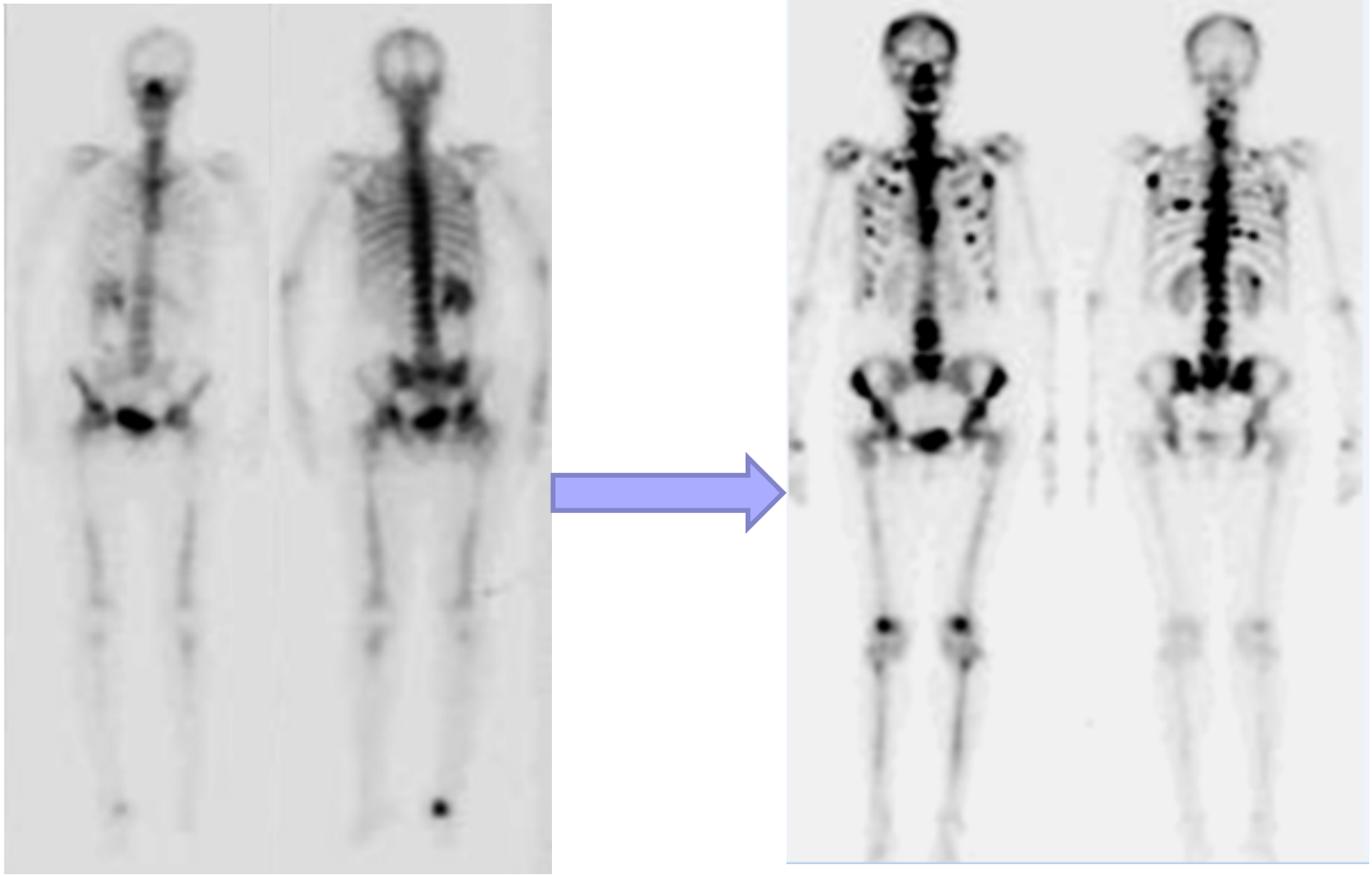
Radioterapia – UCSC- Roma

Metastasi ossee

- 40-70% dei pazienti oncologici
- Impatto sulla QoL
  - dolore, instabilità strutturale,
  - compromissione neurologica
  - 20% compressione midollare

- **25% -50%dei trattamenti RT**

Stevens, Aus Radiol 1995 - Changs 2007- L A.I.R.O.2007



Bone only Oligometastasis

Palliation

Prognosi

Survival from Time of Initial Distant Recurrence Relative to Site of the Recurrence

Site of initial recurrence	No. of patients	Median survival (mos)
Bone (all)	116	35
Bone: 1 site	47	53
Bone: 2 sites	22	38
Bone: ≥ 3 sites	44	22
Bone: unspecified[a]	3	—
Lung	43	19
Pleura	16	19
Liver	12	11
Brain	10	12
Distant lymph nodes	10	26
Others	17	12
Multiple with bone	42	10
Multiple without bone	29	13
Total	295	

Jacobson AF et al. Cancer 2001

Prognosi
RPA (recursive partitioning analysis) index

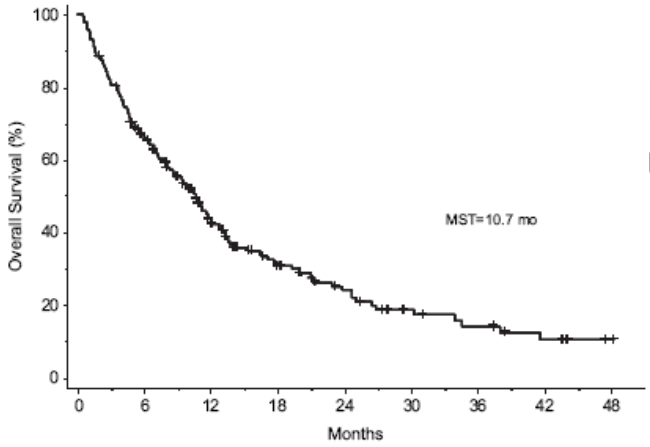


Fig. 1. Overall survival for patients treated with SBRT to the spine (n = 174).

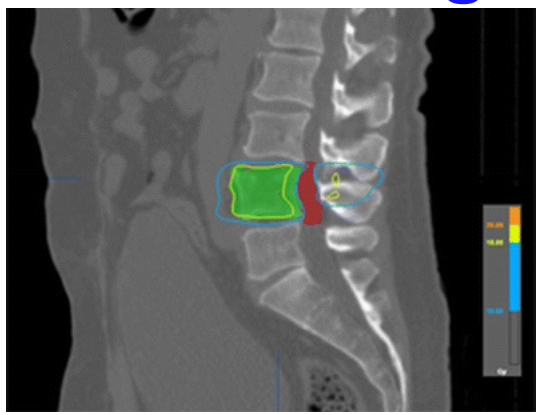
Istotipo, genere,KPS, età, TPD (tempo dalla dg del primitivo), Estensione malattia vertebrale, Malattia extraossea, upfront/salvage therapy, precedente CH, dose SBRT

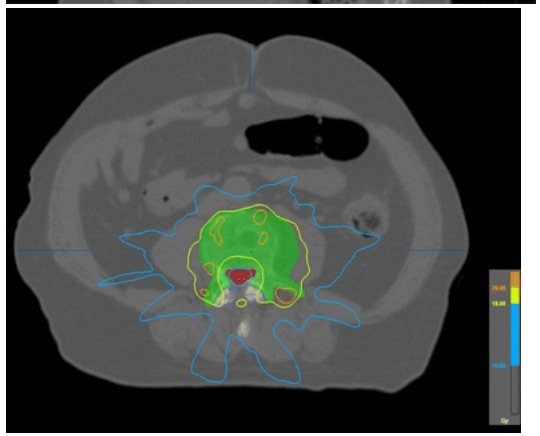
RPA class	Criteria	Overall survival
I	TPD >30 months and KPS >70	**21 months**
II	TPD >30 months and KPS ≤70	**8.7 months**
	TPD ≤30 months and age <70 y	
III	TPD ≤30 months and age ≥70 y	**2.4 months**

Chao S IJROBP 2012

Radioterapia stereotassica

Somministrazione di *dose elevata focalizzata, conformata, biologicamente attiva ed ablativa*





Regimi ipofrazionati (1-5 frazioni)

BED 43 -82 Gy_{10}

Elevata dose al target

rapida caduta della dose nei **tessuti sani circostanti,** strutture nervose **(midollo spinale, cauda equina)**

Ritrattamento

Timmerman R., 2005

SBRT:indicazioni

Patiente

IINCLUSIONE ≥18 y ; KPS ≥40–50
Inoperabile-rifiuto pz

ESCLUSIONE
Mallattia connettivale attiva
peggioramento o progressione del deficit neurologico
incapacità a mantenere la posizione sul lettino per SBRT
Aspettativa di vita < 3 mesi o paziente in hospice

Tumore

INCLUSIONE istologia di neoplasia
(renale,polmonare,melanoma, mammella,prostata)
Biopsia della lesione metastatica (se è la prima presentazione metastatica)
paziente oligometastatico o sola malattia ossea

ESCLUSIONE Istologia radiosensibile come il MM
malattia extraspinale non eleggibile per altri trattamenti

Lutz S. Astro EB-Guidelines IJROBP 2011

SBRT: indicazioni

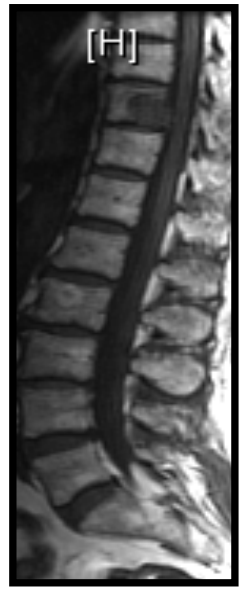
Precedente trattamento

Uno dei seguenti:

Precedente EBRT <45-Gy dose totale

Fallimento di precedente chirurgia a livello vertebrale

Presenza di residuo di malattia post-chirurgia



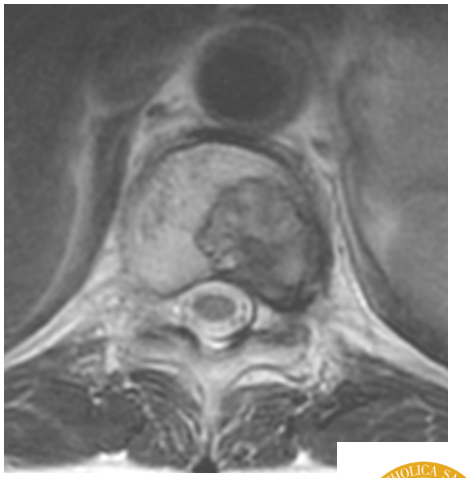
Quadro radiologico

INCLUSIONE Metastasi vertebrali o paravertebrali visibili alla MRI; coinvolgimento di non oltre 2 segmenti consecutivi o 3 non contigui coinvolti

ESCLUSIONE RM non eseguibile; compressione epidurale; interessamento del canale midollare >25%

Instabilità che richiede stabilizzazione chirurgica

localizzazione tumorale entro 5 mm dal midollo o cauda equina



Lutz S. Astro EB Guidelines IJROBP 2011

Prescrizione della dose

IPOFRAZIONAMENTO

20 Gy/5frx;

30 Gy/5frx;

24 Gy/3frx

27 Gy/3frx;

DOSE SINGOLA **10- 24 Gy**

Scenario Clinico

- **Re - irradiazione**
- **Istotipo tumorale** *Radioresistente vs Radiosensibile*
- **Volume**
- **Organi a rischio circostanti**

Definizione delle procedure chirurgiche oncologiche

Intralesionale

Rimozione a pezzi o escissione in blocco con margine di taglio dentro il tumore

Marginale

Escissione in blocco lungo la pseudocapsula

Ampio

Escissione in blocco fuori la pseudocapsula

Radicale

Escissione in blocco dell'intero compartimento

Palliativo

Qualsiasi procedura con scopo solo funzionale

Definizione target

Table 1 Differences between centers and the definition used by the Radiation Therapy Oncology Group (RTOG) phase II/III sSBRT trial (RTOG 0631)

Institution	Imaging modality	Treatment unit	Planning target volume definition
Henry Ford Hospital [16]	CT/MRI fusion	Novalis (BrainLab)	Entire involved spinal segment+gross epidural/paraspinal disease
University of Heidelberg, Germany [38]	CT/MRI fusion	6/15-MV linear accelerator (Siemens)	GTV+entire vertebral body
University of Florida [21]	CT/MRI	Synergy-S (Elekta)	GTV+10-mm bone margin±2-mm extension beyond if GTV is close to the bone surface.
RTOG 0631 [39]			ed to epidural disease GTV ody±right and left pedicles (depending on GTV location)
Cleveland Clinic [23]	CT/MRI	Novalis (BrainLab)	GTV±vertebral body±right and left pedicles
MDACC [17]			ial areas
MSKCC [40]			he cord
UPMC [14]	CT	CyberKnife	GTV
Stanford [15]	CT	CyberKnife	Target lesion+2-mm margin
UCSF [13]	CT	CyberKnife	GTV

GTV = CTV PTV= GTV+ 0-2 mm

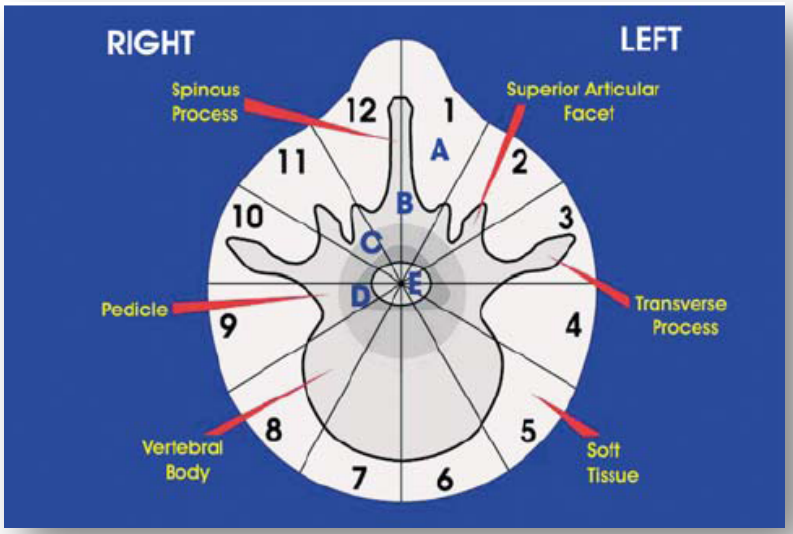
GTV + CTV margin based on the anatomic routes of spread within the spinal segment

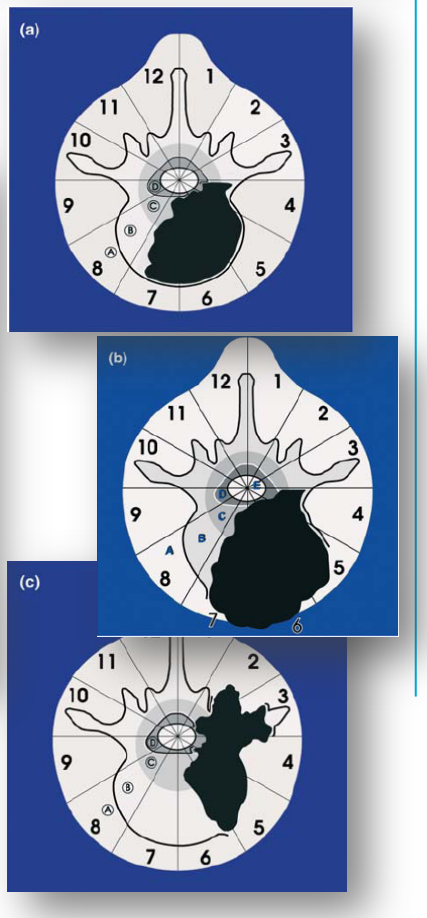
Balagamwala J Radiat Oncol 2012

Journal of Neuro-Oncology **69:** 273–290, 2004.

Tumors of the osseous spine

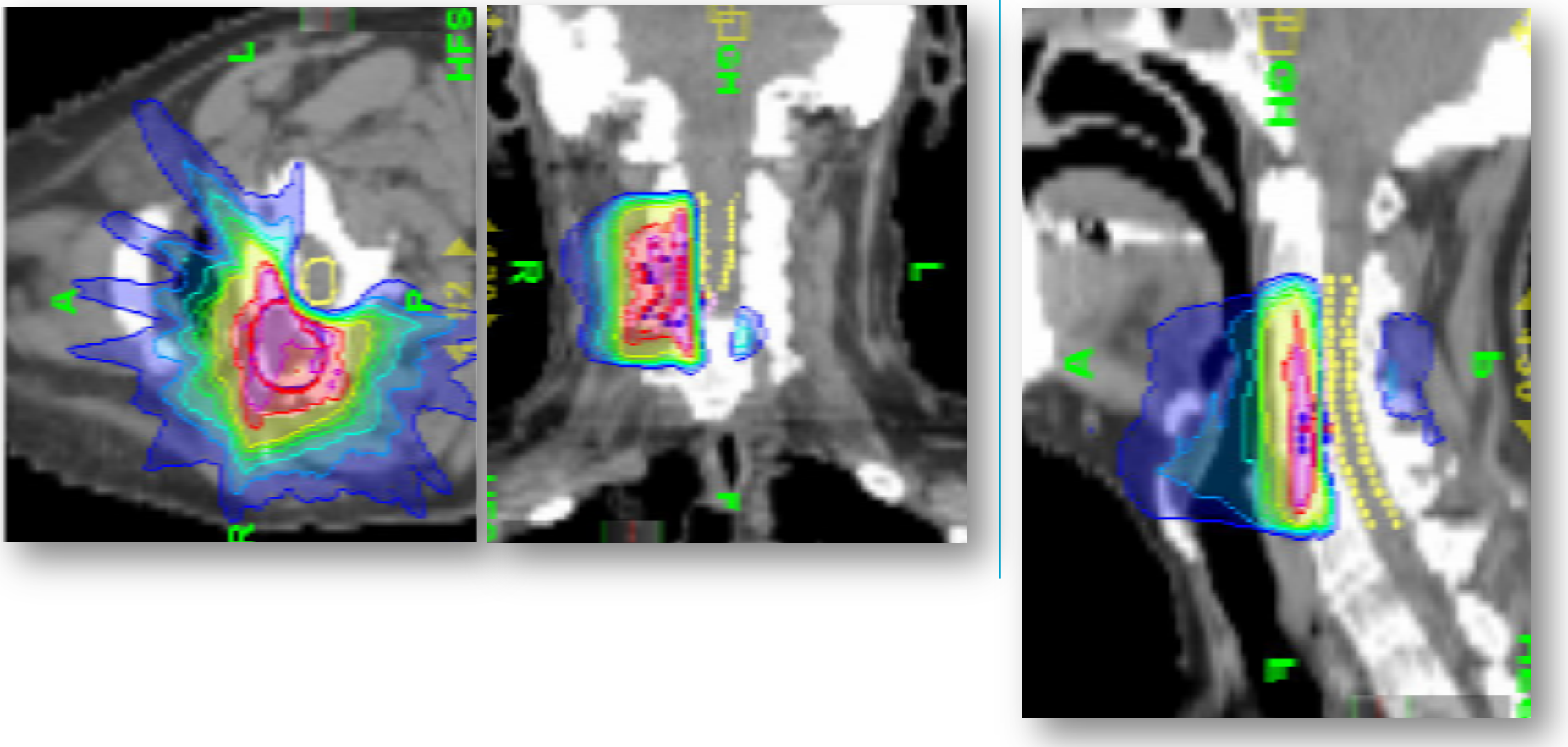
Narayan Sundaresan[1,2], Stephano Boriani[3], Allen Rothman[1] and Robert Holtzman[4]
[1]*Department of Neurosurgery, Mount Sinai Medical Center, New York, NY;* [2]*Medtronic Sofamor Danek, Memphis, TN, USA;* [3]*Ospedale Maggiore, Insitute Rizzoli, Bologna, Italy;* [4]*Department of Neurosurgery, Lenox Hill Hospital, New York, NY, USA*



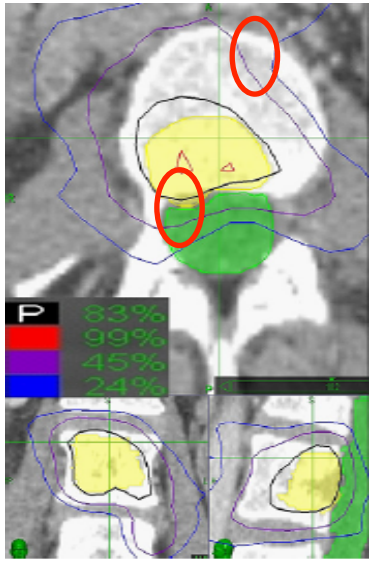


In the transverse plane, the vertebra is divided into 12 radiating zones (numbered 1–12 in a clockwise order) and into five layers (A to E, from the paravertebral extraosseous region to the dural involvement). The longitudinal extent of the tumor is deduced by recording the spine segment(s) involved

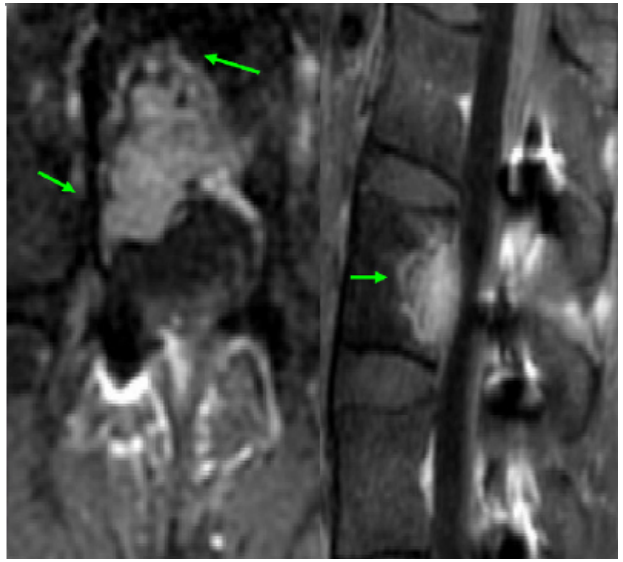
Tecnica radioterapica



Definizione target



Under-dosed sub-volume

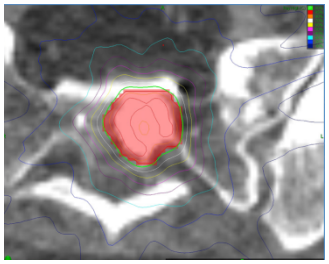


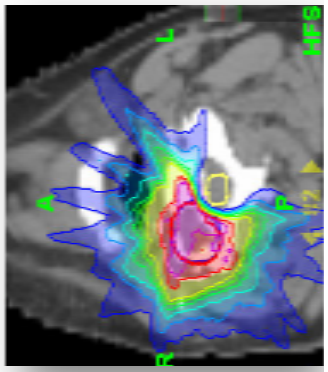
RM- progressione post SBRT

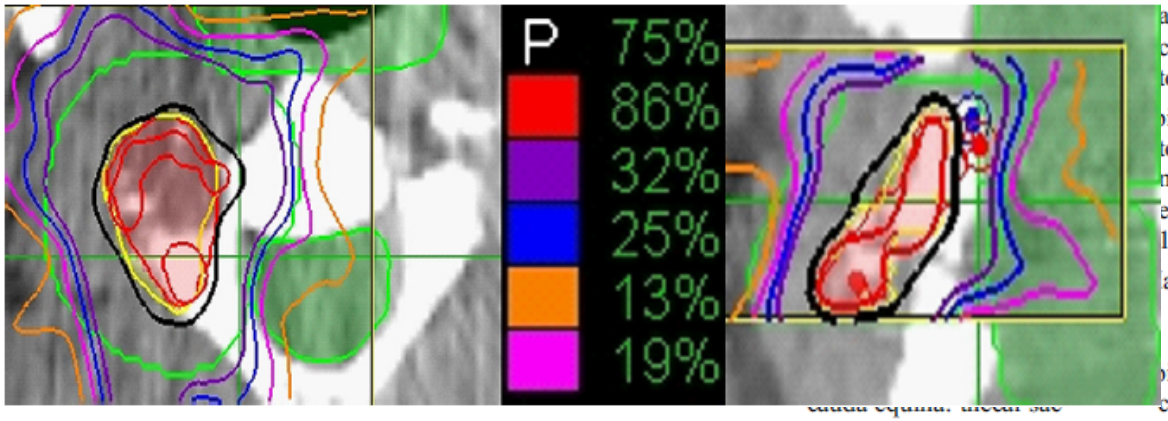
Ryu S- Cancer, 2010

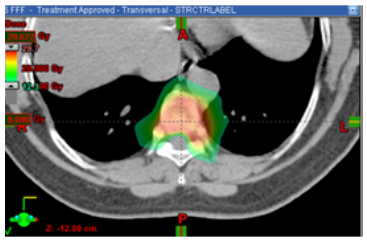
OAR-dose constraint

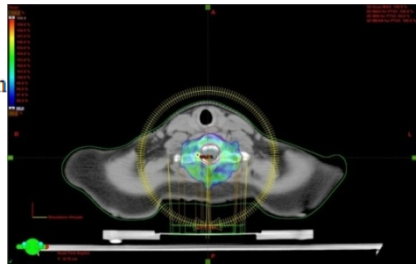
Institution	Imaging modality	NCS contour definition	Threshold criteria for NCS
Henry Ford Hospital [16]	CT/MRI fusion	Spinal cord: spinal cord+6-mm cranial and caudal extensions	Spinal cord: 10 Gy or more to 10 % or less of PTV; cauda equina: 12 Gy or more to 10 % or less of PTV
University of Heidelberg, Germany [38]	CT/MRI fusion	Spinal cord: spinal cord+2–3 safety margin	Reirradiation: <20 Gy/10 fx/median % of cord >30 % prescribed dose: 23–40.5 %
University of Florida [21]	CT/MRI fusion	Spinal cord or cauda equina with margin of 1 spinal level above and below	No history of RT: 12 Gy to 1 cc; history of prior RT: 5 Gy to 5 cc
RTOG [39]	CT/MRI fusion	Spinal cord: spinal cord+6-mm cranial and caudal extensions	Spinal cord: <10 Gy to 10 % PTV and limit 0.35 cc to <10 Gy and limit 0.03 cc to <14 Gy; cauda equina: limit <0.03 cc to 16 Gy and limit <5 cc to 14 Gy
			inal cord: 10 Gy or more to 10 % or less of PTV and max dose <14 Gy; cauda equina: 12 Gy or more to 10 % or less and max dose <16 Gy
			ax dose=10 Gy
			inal cord max dose=14 Gy; cauda equina max dose=16 Gy
UPMC [9]	MRI	Spinal cord: spinal cord; cauda equina: thecal sac; margin of 1 spinal level above and below	Spinal cord: max dose=11 Gy (1 fx) or 18 Gy (3 fx); cauda equina: 12 Gy (1 fx) or 18 Gy (3 fx)
Stanford [15]	CT	Spinal cord: spinal cord	Max dose=10 Gy in single fraction
UCSF [13]	CT	Spinal cord: thecal sac; cauda equina: thecal sac; 20-mm margins	Not published











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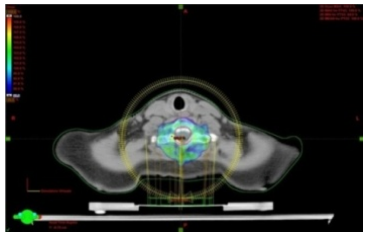
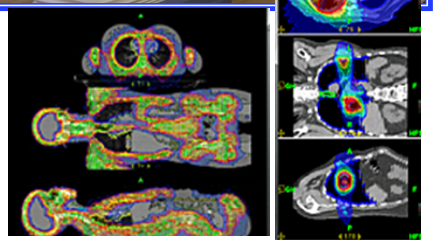
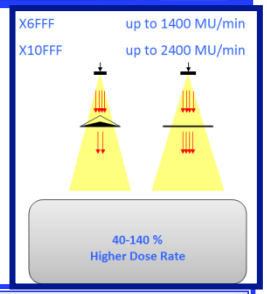
Apparecchiature

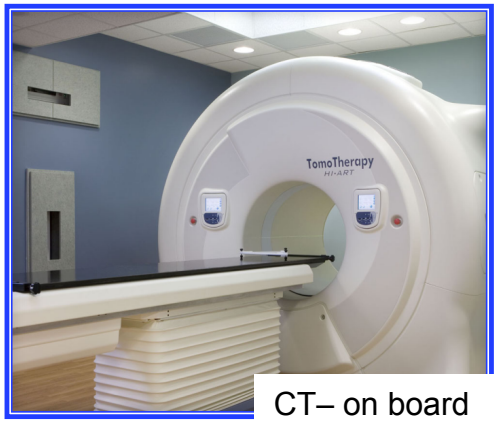




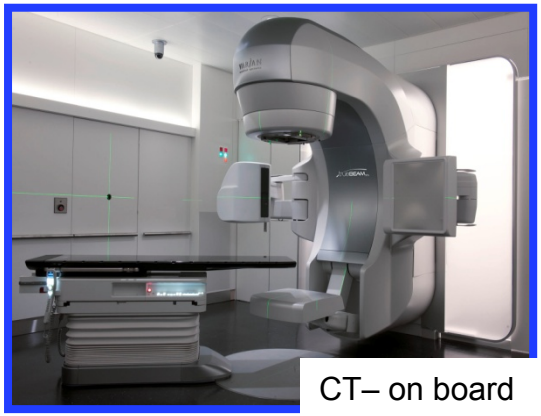


Apparecchiature

CT– on board



CT– on board



CT– on board

IGRT

Optical traking

Automatic LINAC adjustament

Optical traking

Real time tumor tracking and motion managment

SBRT clinical outcomes: Ritrattamento

Table 1. Summary of reported outcomes in selected reirradiation series.

Study (year)	Tumors treated/ patients treated	Tumors treated/ patients previously treated with RT (median prior total dose)	Follow-up, months (range)	Local control	Number of local failures post-SBRT	Overall survival	Tumor dose/number of fractions	Pain response (%)	Ref.
Choi *et al.* (2010)	51/42	51/42 (40 Gy)	Median: 7 (2–47)	87% (6 months) 73% (12 months)	25% (13 out of 51 tumors)	68% (12 months)	Median 20 Gy/2 fx (range: 10–30 Gy/ 1–5 fx)	65	[18]
Maha-devan *et al.* (2010)	81/60	81/60 (30 Gy)	Median: 12 (3–39)	93%	7% (4 out of 60 tumors)	Median overall survival: 11 months	25–30 Gy/5 fx (35 tumors)/ 24 Gy/3 fx (46 tumors)	65	[21]
Garg *et al.* (2011)	63/59	63/59 (30 Gy)	Mean: 17.6 (0.9–67.5)	76% (12 months)	25% (16 out of 63 tumors)	76% at 1 year	27 Gy/3 fx (50/59)/ 30 Gy/5 fx (8/59)/ 20 Gy/5 fx (1/59)		[17]
Damast *et al.* (2011)	97/94	97/94 (30 Gy)	Median: 12.1 (0.2–63.6)	66% (12 months)	45% in those treated with 20 Gy/5 fx (19 out of 42 tumors) 26% in those treated with 30 Gy/5 fx (14 out of 55 tumors)	52% at 1 year in patients treated with 20 Gy/5 fx 59% at 1 year in patients treated with 30 Gy/5 fx	20 Gy/5 fx (42 tumors) 30 Gy/5 fx (55 tumors)	85 had some pain relief (35/41 patients)	[16]
Sahgal *et al.* (2009)	60/39	37/25 (36 Gy)	Median: 7 (1–48)	92% (12 months)	8% (3 out of 37 tumors)	45% (24 months)	Median: 24 Gy/3 fx (range: 8–30 Gy/1–5 fx		[14]
Total	352/294	329/280	Median: 11.14 (0.2–67.5)	260 of 329 tumors treated (79%)	69 of 329 tumors treated (21%)				

fx: Fractions; RT: Radiotherapy; SBRT: Stereotactic body radiotherapy.

Masucci ,Yu, Expert Review 2011

SBRT clinical outcomes

Table 4. Summary of current data for spinal SBRT for spinal metastases

Study	Patients (*n*), tumors (*n*), histologic type	Fractionation	Repeat RT	Pain relief	Complete response	Local control/ definition	Investigator	Year
Cohort study	69, 127, various histologic types	Mean: 15.5 Gy/2 Fx	15 patients	61/69	NR	96.8% FFP at 10 mo; 123/127 (97%)/ imaging	Tsai	2009
Cohort study	38, 60, various histologic types	Median: 24 Gy/3 Fx	37 tumors	31/46	NR	Repeat RT: 34/37 (92%); no previous treatment: 18/23 (78%); entire cohort: 85%, 1-y FFP*/ imaging and pain	Sahgal	2009
Cohort study	93, 103, various histologic types	Median: 24 Gy/ 1 Fx	0	NR	NR	90% FFP at 15 mo	Yamada	
Cohort study	32, 33, various histologic types	Median 18 Gy/3 Fx	22 patients	30/32	13/32 at 1 mo	28/32/imaging and/or pain	Nelson	2008
Phase I-II study with defined stopping rules	63, 74, various histologic types	30 Gy/5 Fx (32/ 63) or 27 Gy/ 3 Fx (31/63)	35 patients	Narcotic use declined from 60% to 36% at 6 mo	NR	57/74; 1-y FFP: 84%/imaging	Chang	
Cohort study	393, 500, various histologic types	Mean 20 Gy/1 Fx	344 tumors	290/336 improvement	NR	440/500/ imaging	Gerszten	2007
Cohort study	49, 61, various histologic types	10–16 Gy/1 Fx	0	52/61	NR	57/61/imaging and pain	Ryu	2005
Cohort study	21, 21	Median 20 Gy/5 Fx	20 patients	NR	NR	19/21/imaging	Yamada	2005
Cohort study	5, 5	10 Gy/1 Fx	5 patients	NR	NR	5/5/imaging and/or pain	Hamilton	1995

Studi retrospettivi
! Misura end-point

in-field control rate was 84–100%

Pain relief 85%

Lutz. S; ASTRO. EB GuidelinesIJROBP 2011

SBRT clinical outcomes

Table 3 Selected fractionation schemes reported in the literature and their reported outcomes

Study	Type of study	No. of pts/no. of tumors	Indication	Prescription dose	Media follow-up	Outcomes
Chang et al. [17]			Mixed	30 Gy/5 fx or 27 Gy/3 fx	21.3 months	1 year PFS, 84 %
Amdur et al. [21]			Mixed	24 Gy/3fx or 25–30 Gy/5 fx (if PTV touched cord)	8 months	LC=95 %, pain relief=43 %
Gerszten et al. [14]	Retrospective	393/500	Mixed	20 Gy/1 fx (range, 12.5–25 Gy)	21 months	LC=88 %; pain relief=86 %; neurological improvement=85 %
Gibbs et al. [15]			Mixed	14–25 Gy/1–5 fx	9 months	Pain relief=84 %
Yamada et al. [24]	Retrospective	93/103	Mixed	24 Gy/1 fx (range, 18–24)	15.7 months	Actuarial LC=90 %;
Mahadevan et al. [42]	Retrospective	60/81	Reirradiated	24 Gy/3fx or 25–30 Gy/5 fx (if PTV touched cord)	12 months	R-LC 93 %, 65 % pain control
Damast et al. [27]	Retrospective	97/97	Reirradiated	20 or 30 Gy/5 fx	12.1 months	LC, 20 Gy=55 %; 30 Gy=74 %
Ryu et al. [43]	Retrospective	62/85	Spinal cord compression	24 Gy/1 fx (range, 12–20)	10.3 months	Tumor response rate=80 %; 65 % reduction in tumor volume at 2 months; 63 % of those with neurologic deficits showed improvement

Studi retrospettivi
! Misura end-point

in-field control rate was 84–100%

Pain relief 85%

Balagamwala J Radiat Oncol 2012

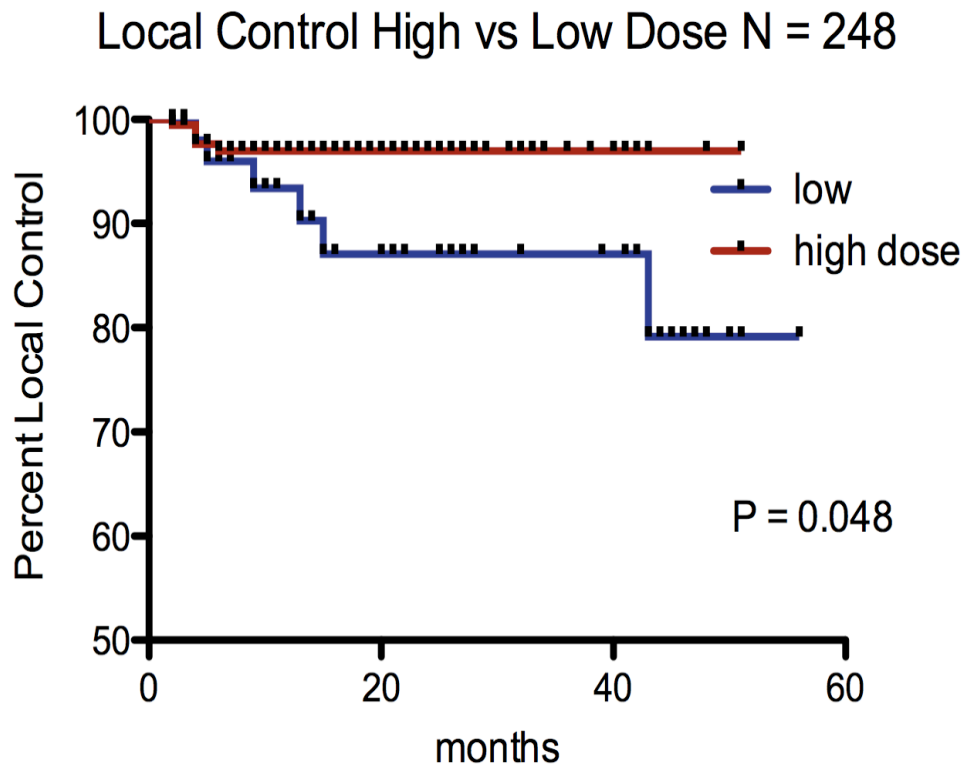
SBRT clinical outcomes

Table 5. Summary of current data for spinal SBRT for spinal metastases reporting on specific histologic types

Study	Patients (*n*), tumors (*n*), histologic type	Fractionation	Repeat treatment	Pain relief	CR	Local control/ definition	Investigator	Year
Cohort study	48, 55, renal cell	30 Gy/5 Fx; 24 Gy/3 Fx; 24 Gy/1 Fx	22 patients	52% of patients had durable response and were pain free at 12 mo	52% of patients had durable response and were pain free at 12 mo	43/55, 1-y FFP 82%/imaging	Nguyen	2009
Cohort study	NR, 93, renal cell	Mean maximum intratumor dose 20 Gy/1 Fx*	NR	94%	NR	87%/imaging	Gerszten	2007
Cohort study	NR, 83, breast	Mean maximum intratumor dose 20 Gy/1 Fx*	NR	96%	NR	100%/imaging	Gerszten	2007
Cohort study	NR, 80, lung	Mean maximum intratumor dose 20 Gy/1 Fx*	NR	93%	NR	100%/imaging	Gerszten	2007
Cohort study	NR, 38, melanoma	Mean maximum intratumor dose 20 Gy/1 Fx*	NR	96%	NR	75%/imaging	Gerszten	2007

Lutz. S; ASTRO GuidelinesIJROBP 2011

SBRT clinical outcomes:Singola frazione

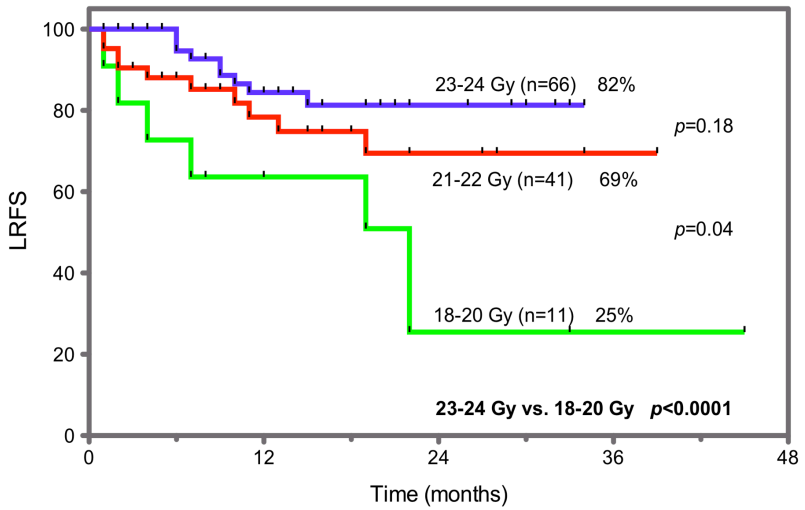


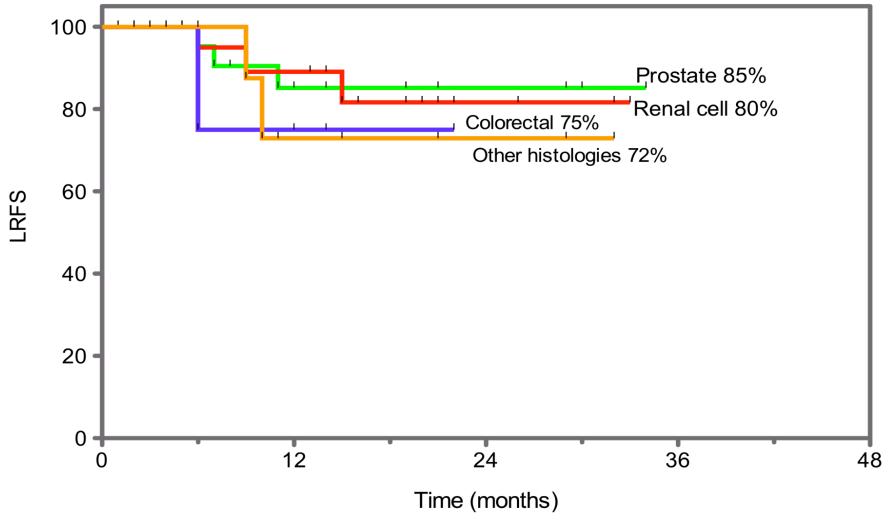
SF IGRT 18-24 Gy

Overall local control rate:
90% at a median follow-up of 15 months

Yamada IJROBP 2008

SBRT clinical outcomes:Singola frazione





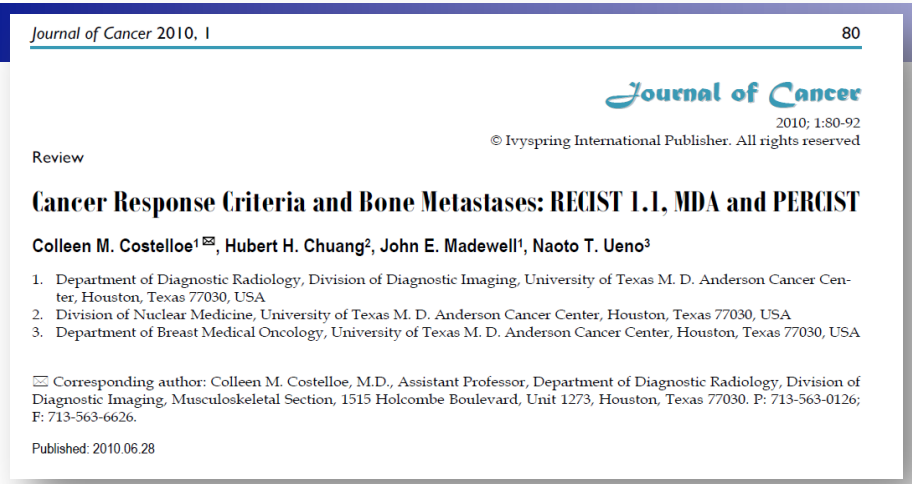
high dose vs. low dose (82% vs. 25%) was highly significant (p < 0.0001)

- 94 bone lesions → SD-IGRT to 18-24 Gy
- Overall 2-year actuarial LC rate 64%
- The median time to local failure 9.6 months

Greco C, et al. IJROBP 2010

Clinical outcome reporting

- **Risposta clinica:** criteri di risposta antalgica e sintomi neurologici
- **Controllo locale**: criteri radiografici
- **Tossicità acuta e tardiva:** mielopatie, fratture vertebrali



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2010; 1:80-92

Review

Cancer Response Criteria and Bone Metastases: RECIST 1.1, MDA and PERCIST

Colleen M. Costelloe[1] ✉, Hubert H. Chuang[2], John E. Madewell[1], Naoto T. Ueno[3]

1. Department of Diagnostic Radiology, Division of Diagnostic Imaging, University of Texas M. D. Anderson Cancer Center, Houston, Texas 77030, USA
2. Division of Nuclear Medicine, University of Texas M. D. Anderson Cancer Center, Houston, Texas 77030, USA
3. Department of Breast Medical Oncology, University of Texas M. D. Anderson Cancer Center, Houston, Texas 77030, USA

✉ Corresponding author: Colleen M. Costelloe, M.D., Assistant Professor, Department of Diagnostic Radiology, Division of Diagnostic Imaging, Musculoskeletal Section, 1515 Holcombe Boulevard, Unit 1273, Houston, Texas 77030. P: 713-563-0126; F: 713-563-6626.

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RECIST

Response Evaluation Criteria in Solid Tumors

….. updated to **RECIST 1.1** (in 2009)

One of the differences between RECIST and RECIST 1.1 is that **bone metastases with soft tissue masses measuring ≥ 10 mm are now accepted as target lesions**.
The soft tissue component is to be measured in an identical manner to that used for other target lesions

RECIST 1.1 specifies contrast administration for both MRI and CT scans.

RECIST 1.1

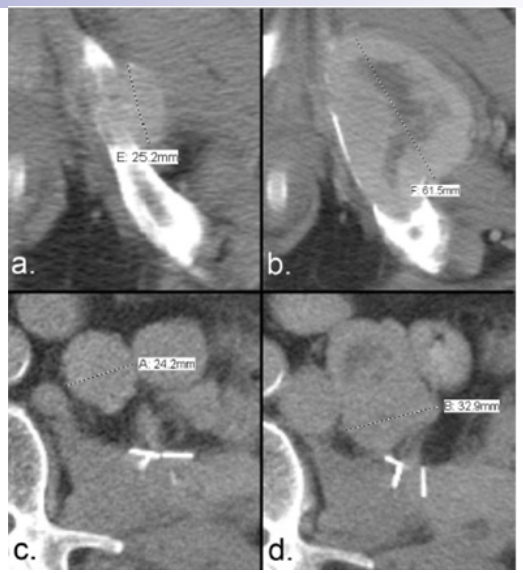

Table 1 Response Evaluation Criteria in Solid Tumors (RECIST 1.1)*

Response category	Criteria
Complete response	Disappearance of all target lesions
	Reduction in short axis of target lymph nodes to < 10 mm
Partial response	Decrease in target lesion diameter sum ≥ 30%†
Progressive disease	Increase in target lesion diameter sum ≥ 20%‡
	≥ 5 mm increase in target lesion diameter sum
	New, malignant FDG uptake in the absence of other indications of progressive disease or an anatomically stable lesion, and confirmed on contemporaneous or follow-up CT
	Unequivocal progression of nontarget lesions
Stable disease	Does not meet other criteria‡

*Measurements are based on the sum of the unidimensional measurement of the greatest diameter of a maximum 5 lesions.

†Reference standard: baseline sum.

‡Reference standard: smallest recorded sum.

Table modified from Eisenhauer et al. (11).

Review

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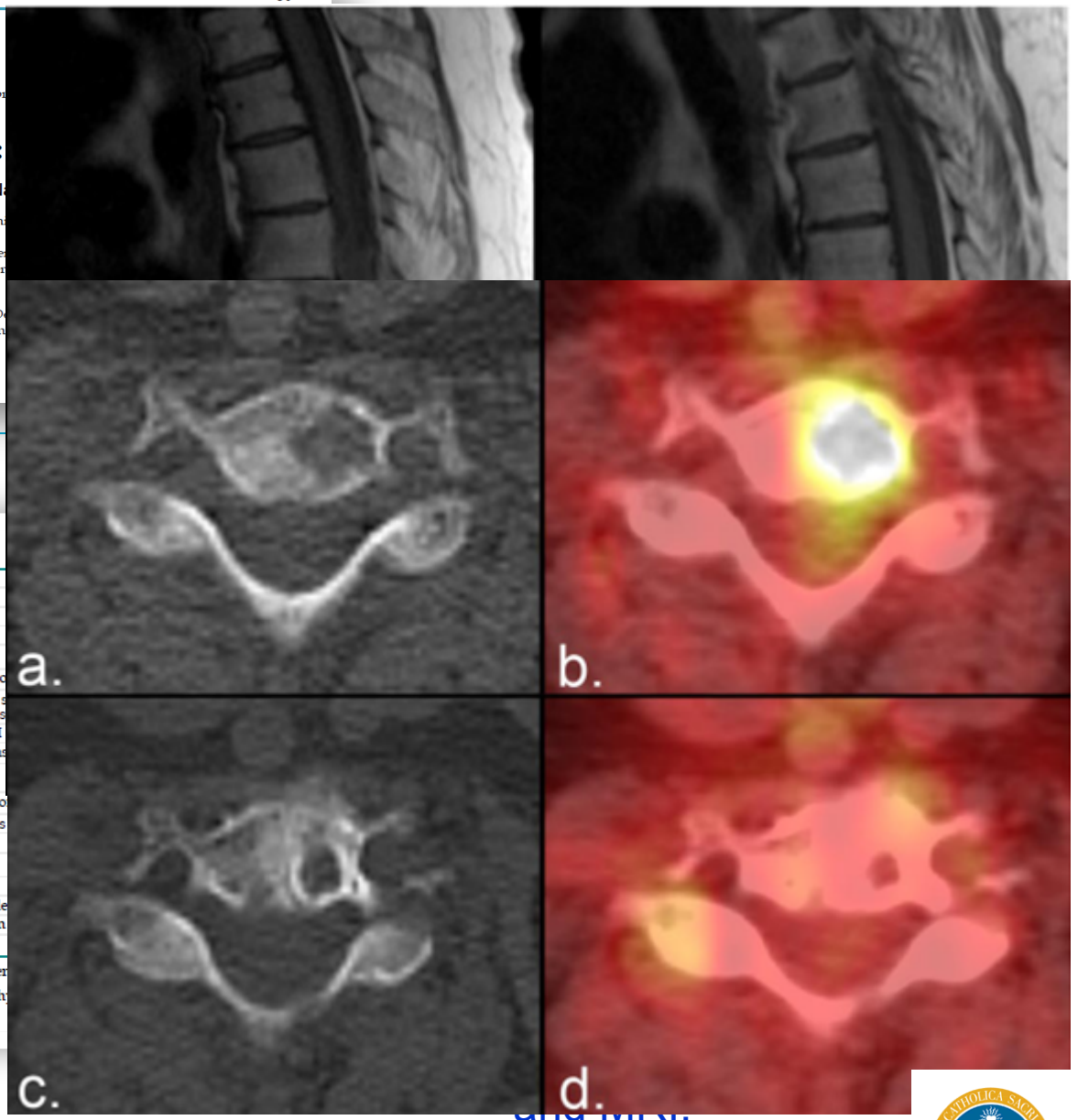
able 2 MD Anderson (MDA) criteria*

Response category	Criteria
Complete response	Complete sclerotic fill-in of lytic lesions on XR or CT
	Normalization of bone density on XR or CT
	Normalization of signal intensity on MRI
	Normalization of tracer uptake on SS
Partial response	Development of a sclerotic rim or partial sclerotic fill-in c
	Osteoblastic flare - Interval visualization of lesions with s other signs of PR and absence of progressive bony diseas
	≥ 50% decrease in measurable lesions on XR, CT, or MRI
	≥ 50% subjective decrease in the size of ill-defined lesions
	≥ 50% subjective decrease in tracer uptake on SS
Progressive disease	≥ 25% increase in size of measurable lesions on XR, CT, o
	≥ 25% subjective increase in the size of ill-defined lesions
	≥ 25% subjective increase in tracer uptake on SS
	New bone metastases
Stable disease	No change
	< 25% increase or < 50% decrease in size of measurable le
	< 25% subjective increase or < 50% subjective decrease in
	No new bone metastases

*Measurements are based on the sum of a perpendicular, bidimensional measuremer

Abbreviations: XR, radiography; CT, computed tomography; SS, skeletal scintigraph

Table modified from Hamaoka et al. (18).



and MRI.

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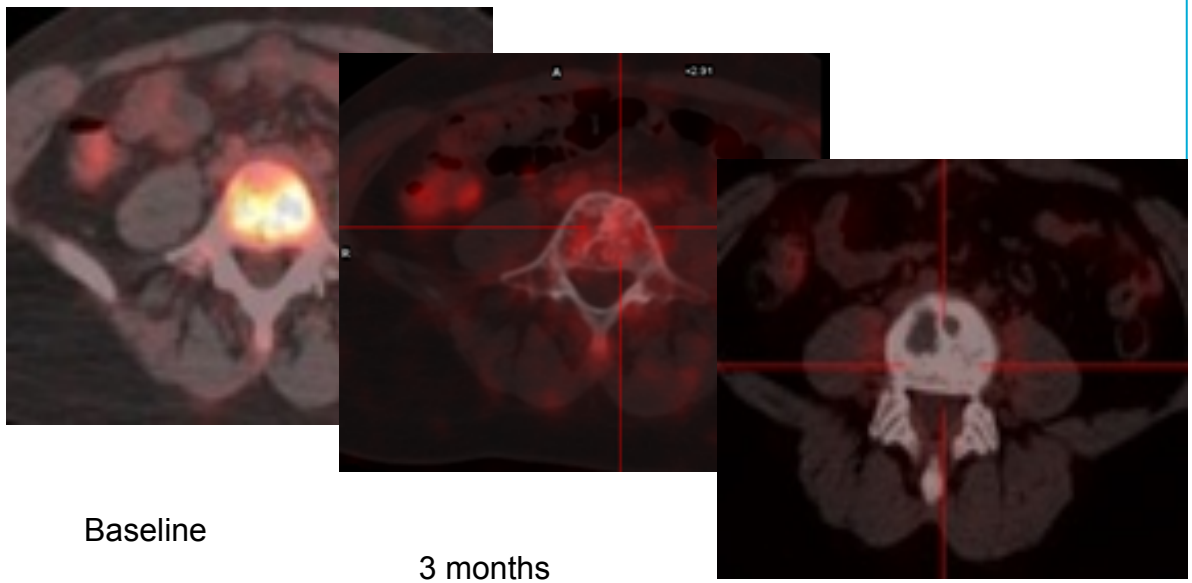
PERCIST
Pet Emission Tomography Response Criteria In Solid Tumors



Baseline

3 months

18 months

PET has the potential to revolutionize the definition of measurable tumors because it introduces **imaging criteria based on function**. The regular, well-defined tumor margins that are necessary for reproducible anatomic measurements are of lesser importance in functional imaging.

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3. Department of Breast Medical Oncology, University of Texas M. D. Anders

Table 3 Positron Emission Tomography Respor

Response category	Criteri
Complete metabolic response	Norma equal t
	Verifica sion
Partial metabolic response	> 30%
	Verifica
Progressive metabolic disease	> 30% i
	> 75% i
	Visible
	New le
	Verifica
Stable metabolic disease	Does n

*Primary outcome determination is measured on the sir
outcome determination is the summed activity of up to

Abbreviations: SUL, standardized uptake value using l

able modified from Wahl et al. (27).

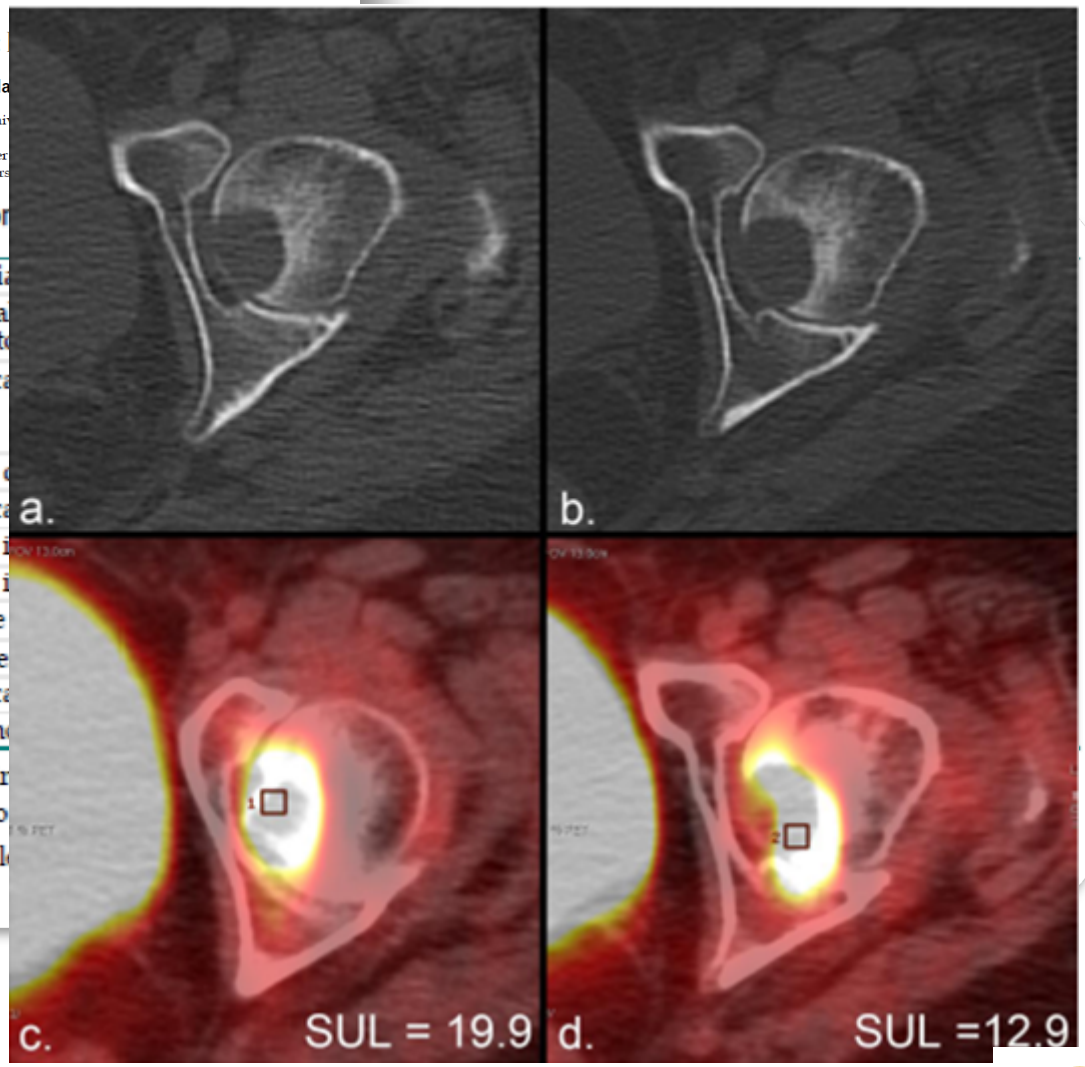

Table 4. Comparison of RECIST, MDA and PERCIST

	RECIST	MDA criteria	PERCIST
Characteristics	Anatomic response criteria for soft tissue metastases	Anatomic response criteria for bone metastases	Functional response criteria reflecting tumor metabolism
Advantages	Common use allows direct comparison of the results of different studies	- Allows the response of the majority of bone metastases to be factored into therapeutic response	Allows response determination regardless of the location of the metastasis
		- Provides response criteria for patients with bone-only disease	
Disadvantages	- Limited to "measurable" soft tissue metastases or unequivocal progression of unmeasurable disease	Limited to bone metastases	Limited to FDG avid metastases

All criteria are subject to minimum lesion size limitations and PERCIST is also subject to minimum FDG uptake limitations.

Radioterapia stereotassica vertebrale

Tecnica ad alto impiego risorse

Definizione del target /OAR

Delivery complessa

IGRT

Selezione dei pazienti

Criteri di indicazione e prognostici

Verifica dei risultati

Controllo sintomi (dolore, compromissione neurologica)

Criteri di risposta radiologica e definizione di controllo locale

Monitoraggio tossicità acute e tardive **(mielopatia, frattura vertebrale)**

Valutazione della qualità di vita