

III Sessione: Terapie palliative o adiuvanti

***Nuovi approcci di radioterapia per le
metastasi ossee***

Vittorio Donato

Gruppo INI

VII Congresso Nazionale ISO Roma 20-21 ottobre 2022

Finalità della radioterapia in medicina palliativa

Intervento terapeutico destinato a :

- alleviare i sintomi della malattia
- migliorare la qualità della vita.
- >>prevenire peggioramento della qualità di vita

Fondamentale è il controllo della sofferenza globale
(*effetto antalgico sul dolore: fisico*, psicologico, sociale, esistenziale)

Razionale radiobiologico della radioterapia nel trattamento delle metastasi ossee osteolitiche

effetto antalgico:

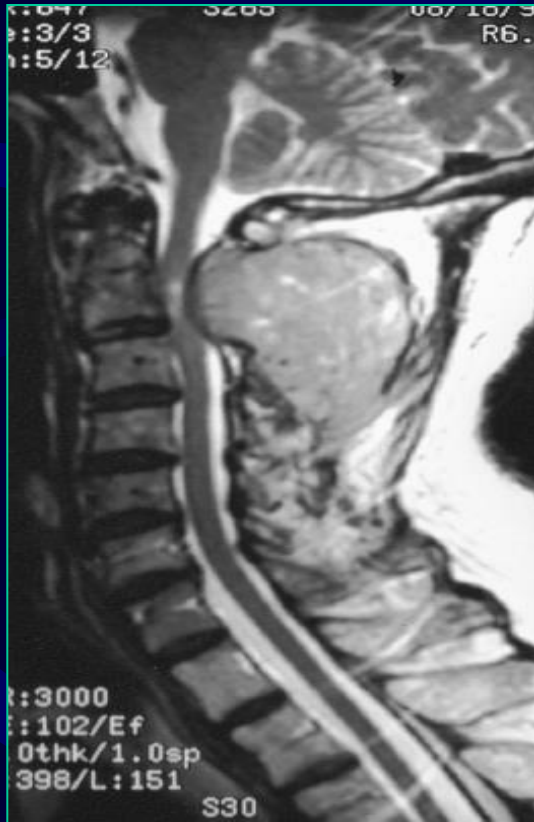
- a) da inibizione della secrezione locale di mediatori chimici algogeni (Garrett IR. Semin Oncol 20:4-9,1993)
- b) aumento della risposta intracellulare mediata da enzimi lisosomiali ad azione antiedemigena > *miglioramento della cenestesi*

effetto riparativo:

- a) dovuto alla degenerazione e successiva necrosi delle cellule neoplastiche>
- b) proliferazione collagene e formazione stroma fino alla calcificazione per attivazione osteoblastica > *riparazione ossea*

Indicazione principale della radioterapia in medicina palliativa: dolore osseo

Dolore e compressione midollare



Caratteristiche della radioterapia in medicina palliativa

- Il risultato atteso deve essere superiore al costo biologico del trattamento (minimi effetti collaterali)
- La durata del trattamento deve comportare la minore interferenza sulla possibile autonomia e vita di relazione del paziente
- Indicati tre tipi di frazionamento “short course” 8Gy x 1fr, 4Gy x 5 fr, 3Gy x 10 fr o *altro*>> *In presenza di malattia controllata e paziente in “buone” condizioni*

V. Donato: radioterapia sintomatica

- Radiotherapy in the symptomatic treatment of the oncological patients. Anticancer Research 19: 3375-3382 (1999)**
- Radiation therapy for oncological emergencies. Anticancer Research 21: 2219-2224 (2001)**
- Short course radiation therapy for elderly cancer patients. Critical Reviews in Oncology/Hematology 45: 305-311 (2003)**
- Hypofractionated radiotherapy. Cancer Futures vol:2 202-206 (2003)**

“The proposal of treating patients with a single 8 Gy fraction radiotherapy, performing all the procedures in same day, is giving very good results in terms of pain relief, quality of life improvement and patient clinical management”

Rapid Palliative Radiotherapy Unit: multidisciplinary management of bone metastases

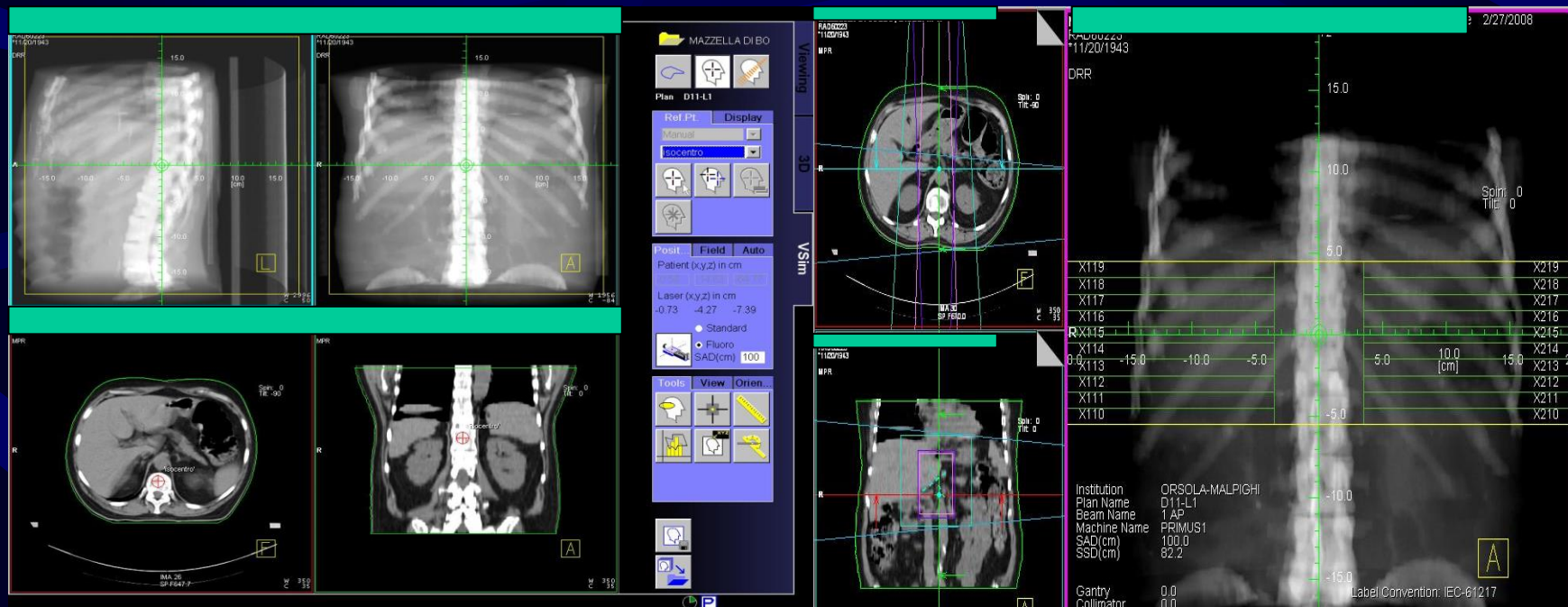
**V. Donato, M. Cianiulli, M. Crescenzi, A. Monaco, C. Caruso,
A.Morrone**

La Radiologia Medica 2012 Vol 117, N.6, pp.1071-1079

Tecnica radioterapica in medicina palliativa

Campi diretti e obliqui con simulazione virtuale esecutiva.

Preferire il trattamento piu' semplice e di minor durata



Come si inserisce la MODERNA RADIOTERAPIA nel trattamento delle metastasi ossee

- Il concetto di **oligometastasi** e della possibile miglior prognosi ad esse associate
- La nozione che la “**palliazione**” oltre al controllo dei sintomi può aumentare la sopravvivenza del malato senza effetti collaterali di rilievo nei pazienti con malattia «cronicizzata»
- A) L'utilizzo sempre più diffuso di **tecniche ad alta conformazione del fascio** (soprattutto la **RT stereotassica**) anche nel paziente metastatico
- B) La maggiore diffusione nella pratica clinica della **re-irradiazione** delle metastasi

CLINICAL TRIAL

Oligometastatic breast cancer treated with curative-intent stereotactic body radiation therapy

Michael T. Milano · Hong Zhang · Su K. Metcalfe ·
Ann G. Muhs · Paul Okunieff

Abstract *Purpose* Prospective pilot study to assess patient outcome after stereotactic body radiation therapy (SBRT) for limited metastases from breast cancer. *Methods* Forty patients with ≤ 5 metastatic lesions received curative-intent SBRT, while 11 patients with >5 lesions, undergoing SBRT to ≤ 5 metastatic lesions, were treated with palliative-intent. *Results* Among those treated with curative-intent, 4-year actuarial outcomes were: overall survival of 59%, progression-free survival of 38% and lesion local control of 89%. On univariate analyses, 1 metastatic lesion (versus 2–5), smaller tumor volume, bone-only disease, and stable or regressing lesions prior to SBRT were associated with more favorable outcome. Patients treated with palliative-intent SBRT were spared morbidity and mortality from progression of treated lesions, though all developed further metastatic progression shortly (median 4 months) after enrollment. *Conclusions* SBRT may yield prolonged survival and perhaps cure in select patients with limited metastases. Palliative-intent SBRT may be warranted for symptomatic or potentially symptomatic metastases.

Table 4 Characteristics of lesions treated with curative-intent stereotactic body radiation therapy

	Number (%)
Number of lesions	85
<i>Sites involved with oligometastatic disease</i>	
Liver	33 (39)
Lung	19 (22)
Bone	17 (20)
Thoracic lymph nodes	14 (16)
Pelvic or abdominal lymph nodes	2 (2)
GTV	Range 0.1–400 ml, mean 23 ml, median 7 ml, SD = 49 ml

GTV = gross tumor volume; SD = standard deviation



doi:10.1016/j.ijrobp.2010.11.026

ASTRO GUIDELINE

PALLIATIVE RADIOTHERAPY FOR BONE METASTASES: AN ASTRO EVIDENCE-BASED GUIDELINE

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3D-CRT

SBRT

Table 2 - ASTRO task force questions and guideline statements regarding palliative radiation therapy for bone metastasis

Questions	Guideline statements
1. Which fractionation schemes have been shown to be effective for the treatment of painful and/or prevention of morbidity from peripheral bone metastases?	Although various fractionation schemes can provide good rates of palliation, numerous prospective randomized trials have shown that 30 Gy in 10 fractions, 24 Gy in 6 fractions, 20 Gy in 5 fractions, or 8 Gy in a single fraction can provide excellent pain control and minimal side effects.
2. When is single fraction RT appropriate for the treatment of painful and/or prevention of morbidity from uncomplicated bone metastasis involving the spine or other critical structures?	No evidence from reviewing the data to suggest that a single 8-Gy fraction provided inferior pain relief compared with a more prolonged RT course in painful spinal sites.
3. Are there long-term side effect risks that should limit the use of single fraction therapy?	Numerous prospective, randomized trials have failed to show any significant difference in long-term toxicity between a single 8-Gy fraction and more prolonged RT courses for uncomplicated, painful bone metastases. No additional studies are suggested to confirm this recommendation at this time.
4. When should patients receive repeat treatment with RT for peripheral bone metastases?	The rates of repeat treatment have been 20% with single-fraction palliative RT schedules compared with 8% with lengthier RT courses. The Task Force recommends that, whenever possible, patients should be included in prospective randomized trials.
5. When should patients receive repeat treatment with RT to spinal lesions causing recurrent pain?	Sites of recurrent pain in spinal bones can be successfully palliated with EBRT repeat treatment. Care must be taken when the re-irradiated volume contains the spinal cord, and it might be appropriate to sum the biologically effective doses from the initial and repeat treatment regimens to estimate the risk of radiation myelopathy.
6. What promise does highly conformal RT hold for the primary treatment of painful bone metastasis?	Stereotactic body RT is a technology that delivers high doses to metastatic spinal disease with a steep dose gradient that might allow superior sparing of the adjacent neural structures, including the spinal cord and cauda equina. SBRT should not be the primary treatment of vertebral bone lesions causing spinal cord compression.
7. When should highly conformal RT be considered for repeat treatment of spinal lesions causing recurrent pain?	Some early data have suggested that repeat treatment to spinal lesions with SBRT might be feasible, effective, and safe, although the Task Force believes that the use of this approach should be limited to the setting of clinical trial participation.
8. Does the use of surgery, radionuclides, bisphosphonates, or kyphoplasty/vertebroplasty obviate the need for palliative RT for painful bone metastasis?	The available data have suggested that surgery, systemic radiopharmaceuticals, bisphosphonates, or kyphoplasty/vertebroplasty does not obviate the need for EBRT for patients with bone metastases.

CRITICAL REVIEW

STEREOTACTIC BODY RADIOSURGERY FOR SPINAL METASTASES: A CRITICAL REVIEW

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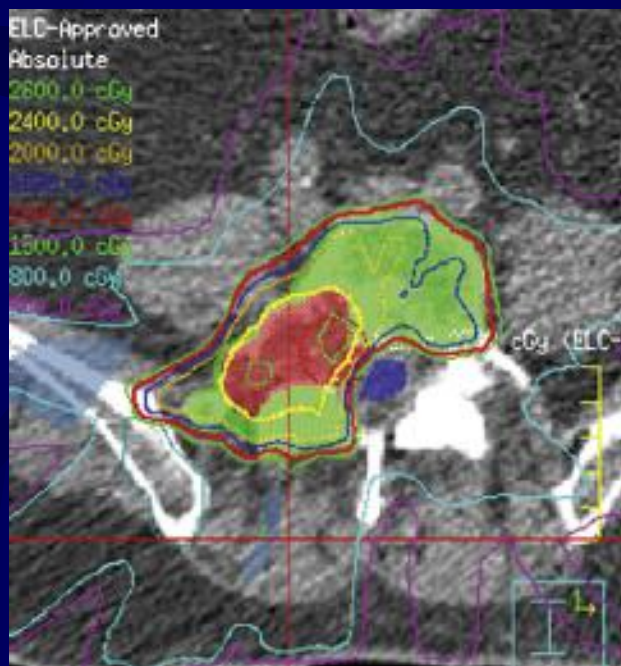


Table 2. A summary of specified relative inclusion and exclusion criteria for spine SBRS

Inclusion

- Solitary or oligometastatic disease or bone only disease in otherwise high-performance status patients*
- Maximum of two consecutive (28) or noncontiguous (8, 17) spinal segments involved by tumor
- Failure of prior XRT (up to one course and 45 Gy maximum) or surgery (8, 17)
- Nonmyeloma tumor type (8, 17)
- Gross residual disease or deemed high risk for recurrence postsurgery (17)
- Patient refusal or medical comorbidities precluding surgery (17)
- Gross tumor optimally more than 5 mm from the spinal cord (17)[†]
- Karnofsky performance status >40–50 (17, 50, 51)
- MRI- or CT-documented spinal tumor (17, 20)
- Histologic confirmation of neoplastic disease (17, 20)
- Age >18 (50)

Exclusion

- Pacemaker such that MRI cannot be performed or the treatment cannot be delivered safely (17)
- Scleroderma or connective tissue disease as a contraindication to radiotherapy*
- Unable to lie flat (*i.e.*, tolerate treatment)*
- Treated with ⁸⁹Sr or systemic chemotherapy within 30 days before SBRT (8, 17)
- External beam radiotherapy to the same area within 3 months before SBRT (8, 17, 28)
- Significant or progressive neurologic deficit (8, 17, 23)
- >25% spinal canal compromise (23)
- Malignant epidural spinal cord compression (8, 19) or cauda equina syndrome (19)[‡]
- Spine instability (8, 17, 19) or neurologic deficit resulting from bony compression of neural structures (50)

Abbreviations: SBRS = stereotactic body radiosurgery; XRT = X-ray therapy; MRI = magnetic resonance imaging; CT = computed tomography; SBRT = stereotactic body radiotherapy; MDACC = M.D. Anderson Cancer Center.

* These represent unpublished specific criteria and included per the authors' recommendation as general criteria to be considered.

[†] This criteria, according to the MDACC, is relaxed should the multidisciplinary team judge the case still suitable for spine SBRS.

[‡] Malignant epidural spinal cord compression has been allowed by some investigators and treated with radiosurgery alone (11).



Contents lists available at ScienceDirect

Journal of Clinical Neuroscience

journal homepage: www.elsevier.com/locate/jocn



Technical Note

Technique for stereotactic body radiotherapy for spinal metastases

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A B S T R A C T

Stereotactic body radiotherapy (SBRT) is an emerging technique for spinal tumours that is a natural succession to brain radiosurgery. The spine is an ideal site for SBRT due to its relative immobility and the potential clinical benefits of high dose delivery, particularly to optimise local control and avoid disease progression that can result in spinal cord compression. However, the proximity of the tumour to the spinal cord, with the potential for radiation myelopathy if the dose is delivered inaccurately or if the spinal cord dose limit is set too high, demands technical accuracy with radiation myelopathy a feared complication. Spine SBRT has been delivered with either a robotic-based linac system such as the Cyberknife, or with linac-based systems equipped with a multileaf collimator and image guidance system. Regardless of the technology, spine SBRT demands sophisticated treatment planning and delivery. This case-based technical review outlines the SBRT apparatus, planning and treatment delivery in use at the University of Toronto, Toronto, Canada.

CYBERKNIFE FRAMELESS STEREOTACTIC RADIOSURGERY FOR SPINAL LESIONS: CLINICAL EXPERIENCE IN 125 CASES

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Received, May 19, 2003.

Accepted, March 1, 2004.

OBJECTIVE: The role of stereotactic radiosurgery for the treatment of intracranial lesions is well established. Its use for the treatment of spinal lesions has been limited by the availability of effective target-immobilizing devices. Conventional external beam radiotherapy lacks the precision to allow delivery of large doses of radiation near radiosensitive structures such as the spinal cord. The CyberKnife (Accuray, Inc., Sunnyvale, CA) is an image-guided frameless stereotactic radiosurgery system that allows for the radiosurgical treatment of spinal lesions. This study evaluated the feasibility and effectiveness of the treatment of spinal lesions with a single-fraction radiosurgical technique using the CyberKnife.

METHODS: The CyberKnife system uses the coupling of an orthogonal pair of x-ray cameras to a dynamically manipulated robot-mounted linear accelerator with six degrees of freedom that guides the therapy beam to the intended target without the use of frame-based fixation. Real-time imaging allows the tracking of patient movement. Cervical spine lesions were located and tracked relative to cranial bony landmarks; lower spinal lesions were tracked relative to fiducial bone markers. In this prospective cohort evaluation of a spine radiosurgery technique, 125 spinal lesions in 115 consecutive patients were treated with a single-fraction radiosurgery technique (45 cervical, 30 thoracic, 36 lumbar, and 14 sacral). There were 17 benign tumors and 108 metastatic lesions. All dose plans were calculated on the basis of computed tomographic images acquired from 1.25-mm slices with an inverse treatment planning technique. Radiosurgical circular cones ranging in diameter from 5 to 40 mm were used.

RESULTS: Tumor volume ranged from 0.3 to 232 cm³ (mean, 27.8 cm³). Seventy-eight lesions had received external beam irradiation previously. Tumor dose was maintained at 12 to 20 Gy to the 80% isodose line (mean, 14 Gy); canal volume receiving more than 8 Gy ranged from 0.0 to 1.7 cm³ (mean, 0.2 cm³). No acute radiation toxicity or new neurological deficits occurred during the follow-up period (range, 9–30 mo; median, 18 mo). Axial and radicular pain improved in 74 of 79 patients who were symptomatic before treatment.

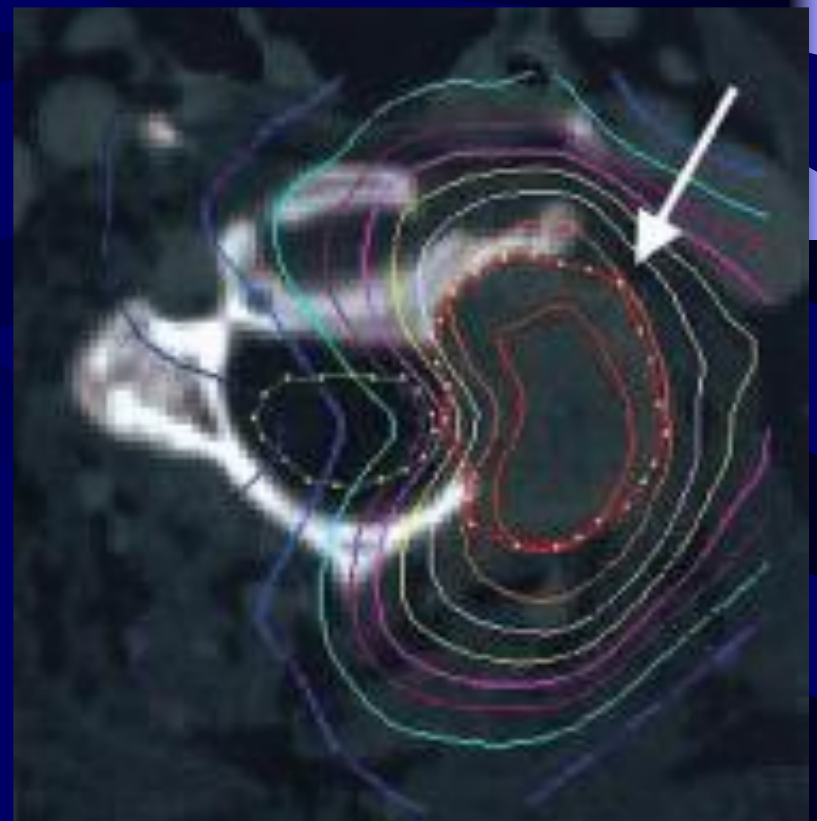
CONCLUSION: This is the first large prospective evaluation of this frameless image-guided spinal radiosurgery system. The CyberKnife system was found to be feasible, safe, and effective. The major potential benefits of radiosurgical ablation of spinal lesions are short treatment time in an outpatient setting with rapid recovery and symptomatic response. This technique offers a successful therapeutic modality for the treatment of a variety of spinal lesions as a primary treatment or for lesions not amenable to open surgical techniques, in medically inoperable patients, in lesions located in previously irradiated sites, or as an adjunct to surgery.

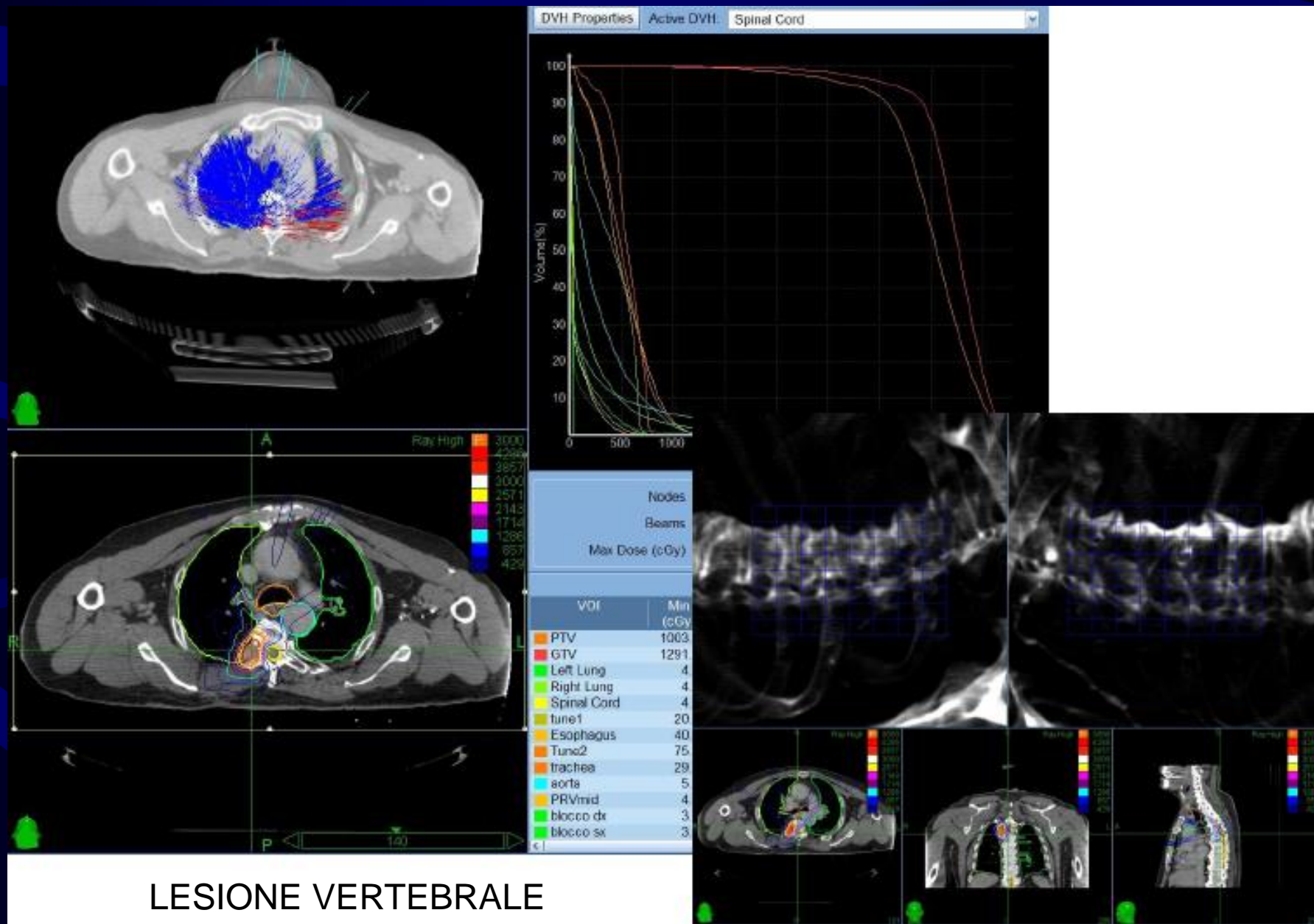
KEY WORDS: CyberKnife, Image-guided surgery, Robotic surgery, Spine tumors, Stereotactic radiosurgery

Neurosurgery 55:89–99, 2004

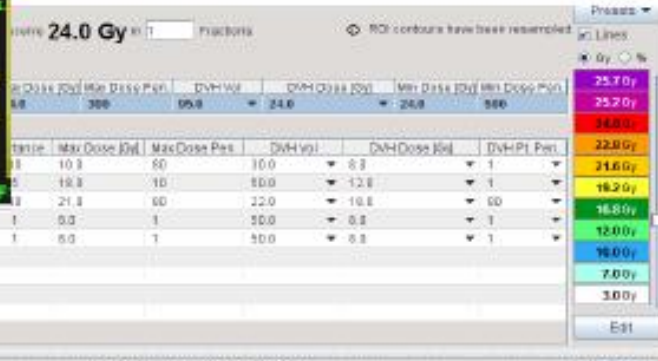
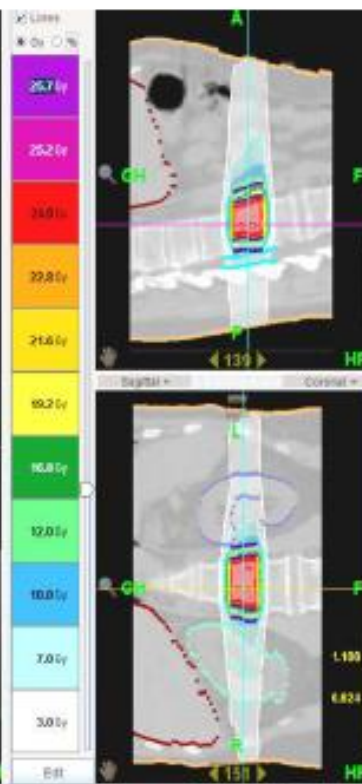
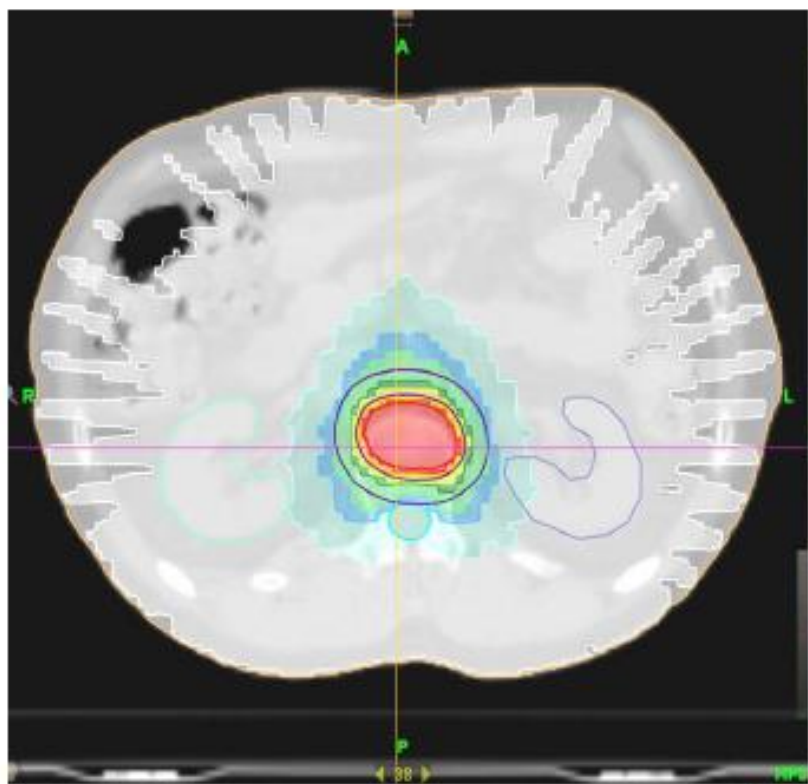
DOI: 10.1227/01.NEU.0000124673.03045.47

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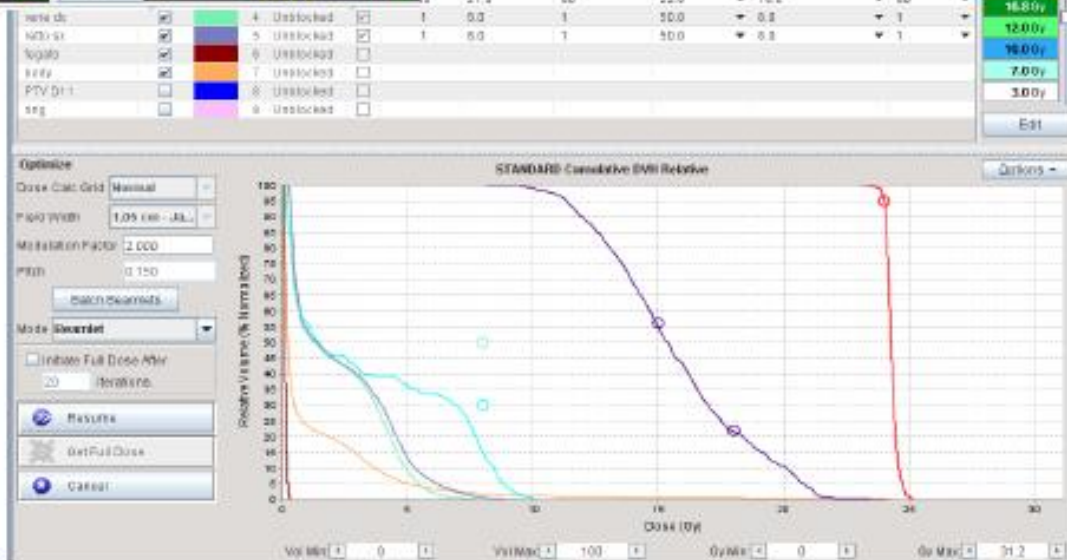


24Gy Single fraction



- Modulation factor $\uparrow\uparrow$
- Field width 1 cm
- Pitch $\downarrow\downarrow$

Highly conformed dose distribution even for:
Small target
Extremely irregular shape



Paziente di 75 anni affetto da neoplasia prostatica Stadio IV

Comorbidità: Ipertensione, Diabete Mellito



Anamnesi Patologica Prossima:

RM prostata con e senza mdc (14/07/2021): Lesione prostatica in regione medio-basale sinistra eteroformativa, Sospetta lesione secondaria a livello del collo femorale di destra (16mm).

PSA (09/2021): 8.33 ng/dl

Biopsia Prostatica (10/09/2021): Adenocarcinoma del tipo acinare, Gleason 7 (4+3). Non invasione perineurale, angiolinfatica o estracapsulare. Stadio T1c sec. AJCC/UICC 2017

PET/TC (20/10/2021): **Accumulo del radiofarmaco nella ghiandola prostatica (SUV 9.1)**

Patologica fissazione in corrispondenza del collo femorale di destra (SUV 19.8).

Scintigrafia (15/11/2022): Iperfissazione del tracciante nella regione del collo femorale destro

RM femore dx (14/11/2022): A livello del collo femorale dx lesione secondaria (Dmax 18mm)

File Options Utilities View



Isodose Lines

Isodose lines are Max dose cGy

Add Line(s)...

All Lines On

Remove Line...

All Lines Off

Line Details...



Value	Color	2D Display	3D Display
6300	red	Off	Off
6000	green	Off	Off
5700	blue	Off	Off
5400	yellow	Off	Off
3550	red	On	Off
3000	forest	On	Off
2850	lavender	Off	Off
2700	orange	Off	Off
1500	blue	Off	Off

Dose Display & Analysis

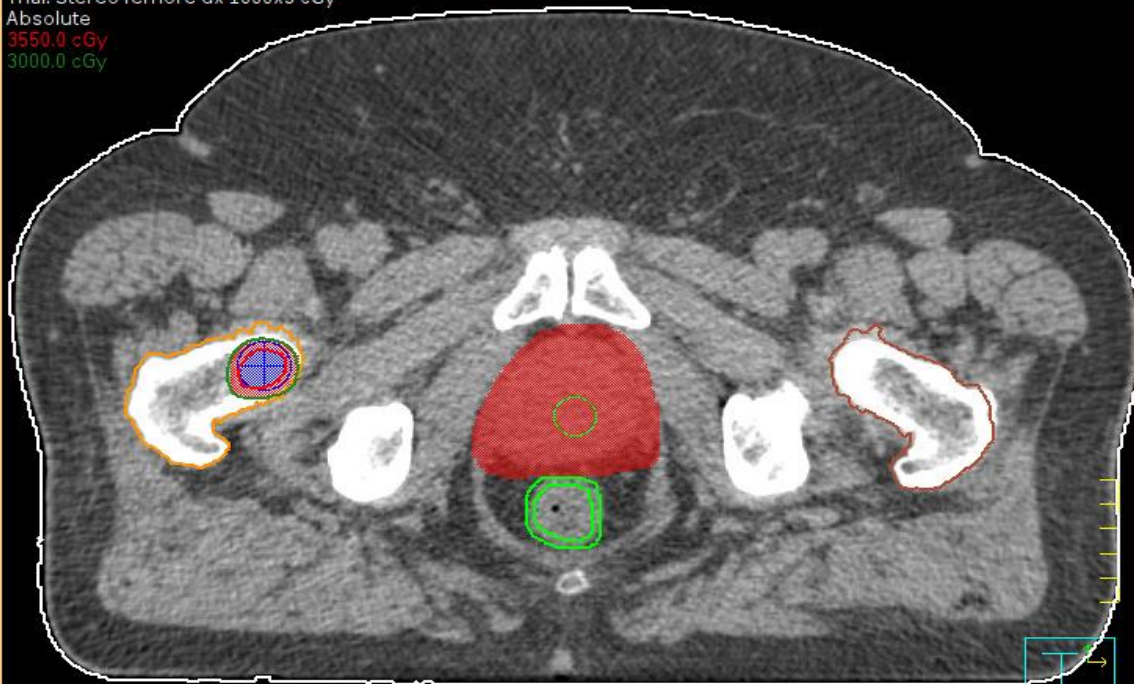
2D Colorwash Display ☐ On ☒ Off3D Colorwash Display ☐ On ☒ OffMax dose point display... ☐ On ☒ Off

Point of Interest Dose Table...

Dose Volume Histogram...

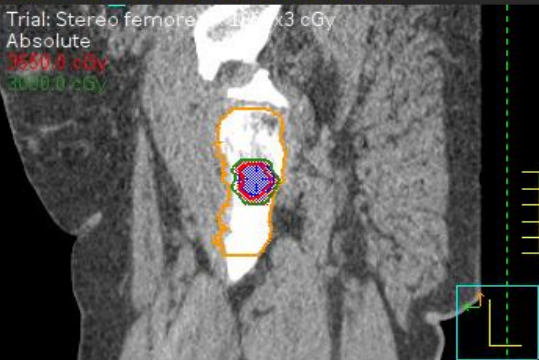
Beam Weighting...

Trial: Stereofemore dx 1000x3 cGy

Absolute
3550.0 cGy
3000.0 cGy

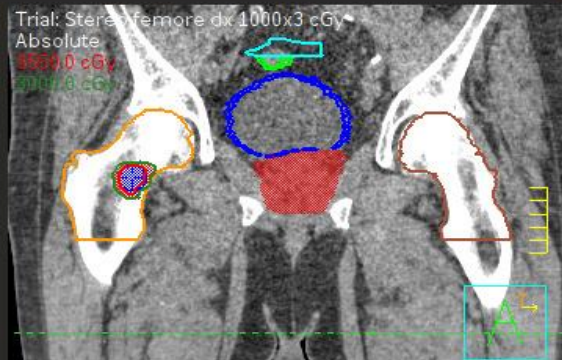
Slice 225: Z = -5.60 cm DILAURO*PRIMIO

Trial: Stereofemore dx 1000x3 cGy

Absolute
3550.0 cGy
3000.0 cGy

Slice 137: X = -11.72 cm DI LAURO*PRIMIO

Trial: Stereofemore dx 1000x3 cGy

Absolute
3550.0 cGy
3000.0 cGy

Slice 268: Y = -7.33 cm DI LAURO*PRIMIO

☒ Primary ☐ Secondary ☐ Fusion

Reset to T/S/C

Secondary

File Options Utilities Display



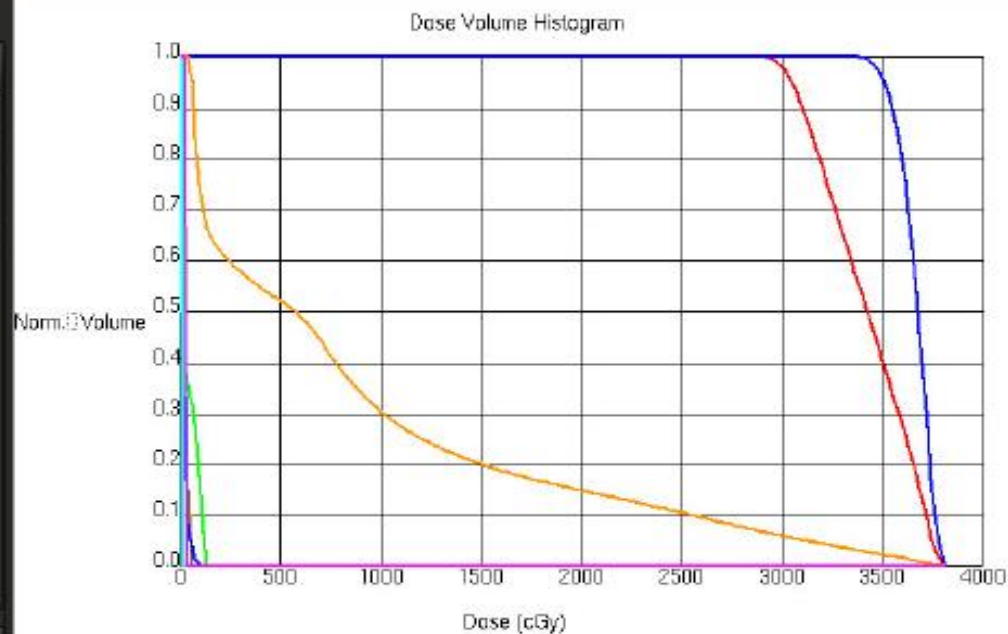
ROI ROI Group

Trials

Display	Name	Line Type
<input type="checkbox"/>	prostata 300x20	Medium S...
<input type="checkbox"/>	Trial_1	Medium...
<input checked="" type="checkbox"/>	Stereo femore	Medium S...

ROIs

Display	Name	a
<input checked="" type="checkbox"/>	PTV femore 1000 cG	1
<input type="checkbox"/>	PTV prostata 300 cG	1
<input checked="" type="checkbox"/>	CTV	1
<input checked="" type="checkbox"/>	testa femorale dx	1
<input checked="" type="checkbox"/>	testa femorale sin	1
<input checked="" type="checkbox"/>	vescica	1
<input checked="" type="checkbox"/>	retto	1
<input checked="" type="checkbox"/>	intestino	1
<input type="checkbox"/>	CTV prostata	1
<input checked="" type="checkbox"/>	bulbo penieno	1
<input type="checkbox"/>	PTV-CTV fem	1



DVH Calculation

☒ Cumulative ☐ Differential

Dose Axis Display

☐ Normalized Dose☒ Absolute Dose☒ Auto-Compute Max☐ Specify Max Dose

Volume Axis Display

☒ Normalized Volume☐ Absolute Volume

Tabular DVH...









DVH Tools



Reset

ROI Statistics

Compute

	Line Type	ROI	Trial or Record	Min.	Max.	Mean	Std. Dev.	% Outside Grid	% > Max	Generalized EUD
<input type="radio"/>		PTV femore	Stereo f12773.1	3811.0	3415.5	227.7	0.00 %	0.00 %	0	
<input type="radio"/>		CTV	Stereo f13252.4	3811.0	3664.6	83.3	0.00 %	0.00 %	0	
<input type="radio"/>		testa femora	Stereo f140.7	3811.0	866.8	968.7	0.00 %	0.00 %	0	
<input type="radio"/>		testa femora	Stereo f14.2	55.2	23.2	13.2	0.00 %	0.00 %	0	
<input type="radio"/>		vescica	Stereo f16.4	108.7	19.0	15.2	0.00 %	0.00 %	0	
<input type="radio"/>		retto	Stereo f16.4	132.8	41.4	40.7	0.00 %	0.00 %	0	
<input type="radio"/>		intestino	Stereo f11.7	11.8	4.8	1.6	0.00 %	0.00 %	0	
<input checked="" type="radio"/>		bulbo penile	Stereo f121.9	34.3	28.1	3.4	0.00 %	0.00 %	0	

Trattamento



Paziente asintomatico

Ormonoterapia: BAT con Firmagon + Bicalutamide 50mg

PSA pre-RT: 8.33 ng/ml

Radioterapia:

Prostata + VS (Dose totale 6.000 cGy; Dose per frazione: 300cGy/20fr)

Lesione collo femorale destra (Dose totale 3.000 cGy; Dose per frazione: 1.000cGy/3fr)

Follow-up

6/9/2022 PSA: 0,02 ng/ml Testosterone: 0.5 ng/ml

Prosegue con TO

doi:10.1016/j.ijrobp.2010.08.012

CLINICAL INVESTIGATION

Spine

STEREOTACTIC BODY RADIOTHERAPY REIRRADIATION FOR RECURRENT EPIDURAL SPINAL METASTASES

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Purpose: When patients show progression after conventional fractionated radiation for spine metastasis, further radiation and surgery may not be options. Stereotactic body radiotherapy (SBRT) has been successfully used in treatment of the spine and may be applicable in these cases. We report the use of SBRT for 60 consecutive patients (81 lesions) who had radiological progressive spine metastasis with epidural involvement after previous radiation for spine metastasis.

Methods and Materials: SBRT was used with fiducial and vertebral anatomy-based targeting. The radiation dose was prescribed based on the extent of spinal canal involvement; the dose was $8 \text{ Gy} \times 3 = 24 \text{ Gy}$ when the tumor did not touch the spinal cord and $5 \text{ to } 6 \text{ Gy} \times 5 = 25 \text{ to } 30 \text{ Gy}$ when the tumor abutted the cord. The cord surface received up to the prescription dose with no hot spots in the cord.

Results: The median overall survival was 11 months, and the median progression-free survival was 9 months. Overall, 93% of patients had stable or improved disease while 7% of patients showed disease progression; 65% of patients had pain relief. There was no significant toxicity other than fatigue.

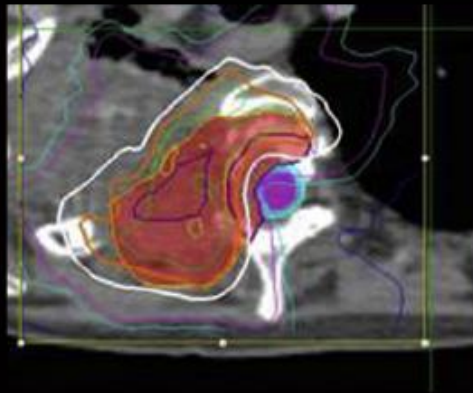
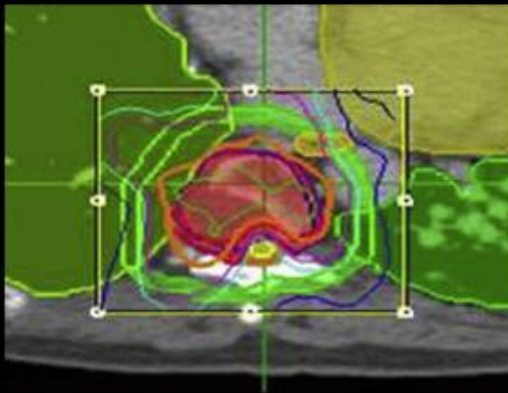
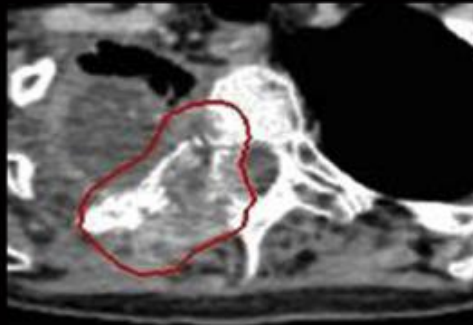
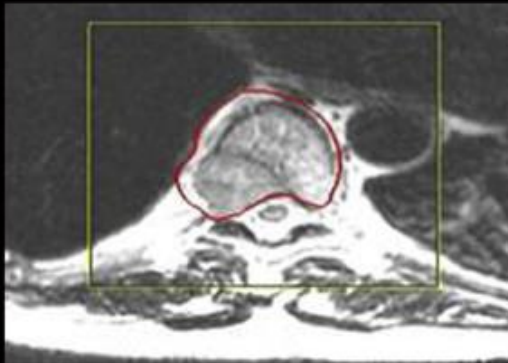
Conclusions: SBRT is feasible and appears to be an effective treatment modality for reirradiation after conventional palliative radiation fails for spine metastasis patients. © 2011 Elsevier Inc.

Stereotactic body radiotherapy, Stereotactic radiosurgery, Spinal metastases, Reirradiation.

800 cGy x 3
(total dose
2400 Gy)



500-600 cGy x 5
(total dose
2500 - 3000 cGy)



Conclusioni: EBG ASTRO

Kyphoplasty and vertebroplasty have theoretically shown the most promise in patients with metastatic spinal disease causing instability of the vertebral body, although the lack of completed prospective studies should limit their standard use (Table 10). Small series of patients have been treated with kyphoplasty or vertebroplasty plus EBRT, stereotactic radiosurgery, or interstitial samarium-153. However, the results do not allow for definitive statements regarding the use of these combined regimens. Future prospective trials of vertebroplasty and kyphoplasty should address questions such as proper patient selection, efficacy, toxicity, and timing in relation to radiotherapeutic interventions.

CONCLUSIONS

External beam radiotherapy has been, and continues to be, the mainstay for the treatment of painful, uncomplicated bone metastases. Although various fractionation schemes can provide good rates of palliation, numerous prospective randomized trials have shown that 30 Gy in 10 fractions, 24 Gy in 6 fractions, 20 Gy in 5 fractions, or 8 Gy in a single fraction can provide excellent pain control and minimal side effects. The longer course has the advantage of a lower inci-

dence of repeat treatment to the same site, and the single fraction has proved more convenient for patients and caregivers. Repeat irradiation with EBRT might be safe, effective, and less commonly necessary in patients with a short life expectancy. Bisphosphonates do not obviate the need for EBRT for painful sites of metastases and might, indeed, act effectively when combined with EBRT. SBRT might be useful for patients with newly discovered or recurrent tumor in the spinal column or paraspinal areas; however, the Task Force suggests that SBRT be reserved for patients who fit specific inclusion and exclusion criteria, who undergo treatment at centers with sufficient training and experience, and should preferably be treated within the confines of a therapeutic trial.

The use of radionuclides seems most appropriate in circumstances in which patients have several sites of painful osteoblastic metastases in an anatomic distribution greater than that which could conveniently or safely be treated with EBRT. Hemibody RT is an option for these patients who reside in geographic areas where radionuclides are not readily available or when they are medically contraindicated.

Riferimenti per impostare un corretto trattamento radioterapico

Caratteristiche del malato

- Performance status
- Età
- Comorbidità

Caratteristiche della malattia

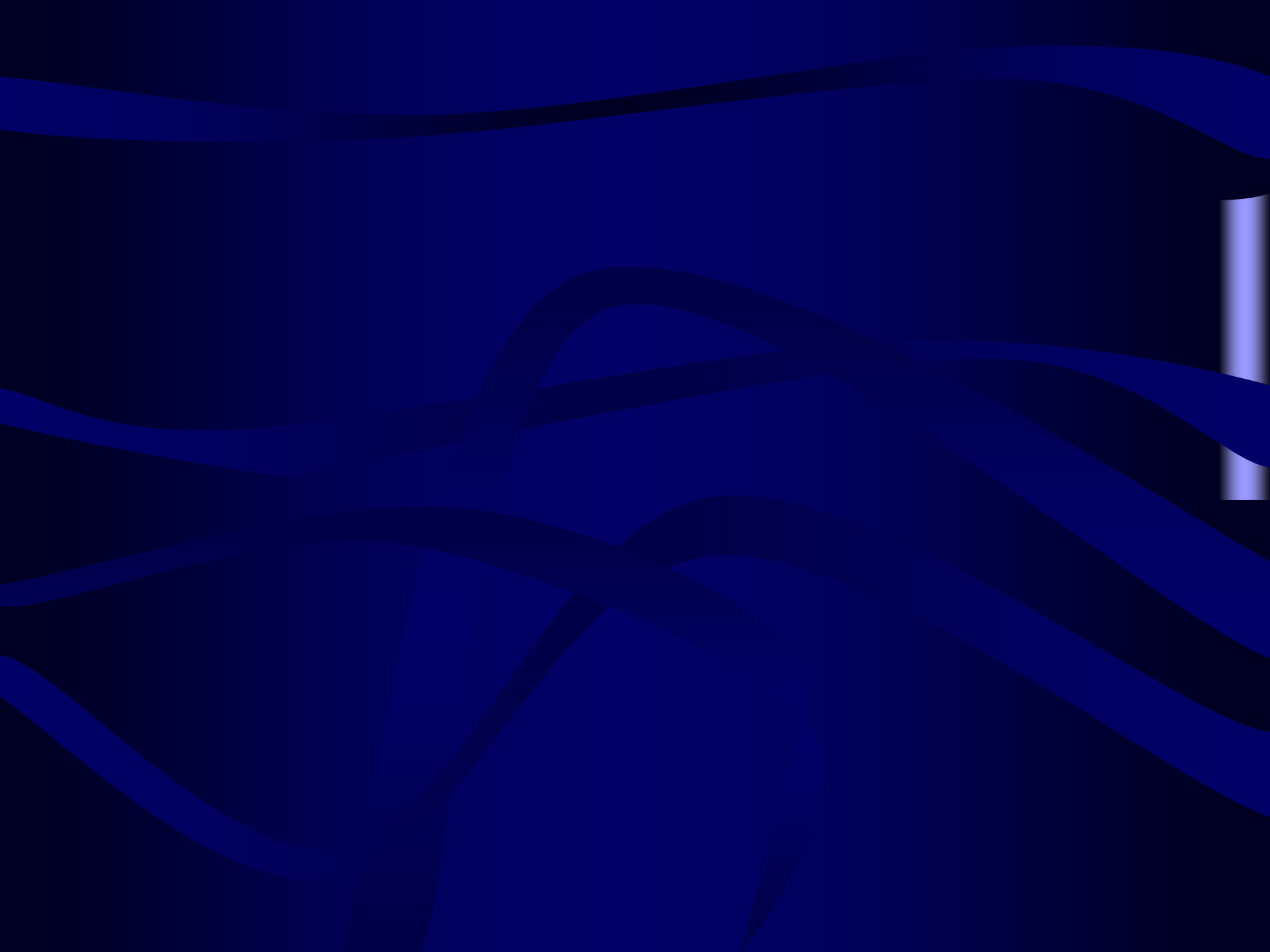
- intervallo libero di malattia,
- stabilità della malattia residua,
- reale estensione delle metastasi,
- aspettativa di vita,
- rischio/beneficio

Condivisione della scelta

Consenso informato del pz.
Approccio multidisciplinare

**PIU' DELLA TECNICA E'
IMPORTANTE LA CLINICA**





Dal curare al prendersi cura
il **Dolore Totale**
oncologico



AZIENDA OSPEDALIERA SAN CAMILLO-FORLANINI
SOCIETÀ ITALIANA CURE PALLIATIVE, REGIONE LAZIO

Venerdì **23** Febbraio 2007

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Venerdì **22** Febbraio 2008

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