Fondazione del Piemonte per l'Oncologia

Le recidive dopo radioterapia: i dati della rete ed una proposta di trattamento

Dipartimento "Rete Oncologica del Piemonte e della Valle d'Aosta"

Pietro Gabriele, Elisabetta Garibaldi
Dipartimento Alte Tecnologie,
DO Radioterapia, IRCC Candiolo (Torino)

"Neoplasie Urologiche"
Carcinoma della Prostata

Torino, 10 novembre 2011

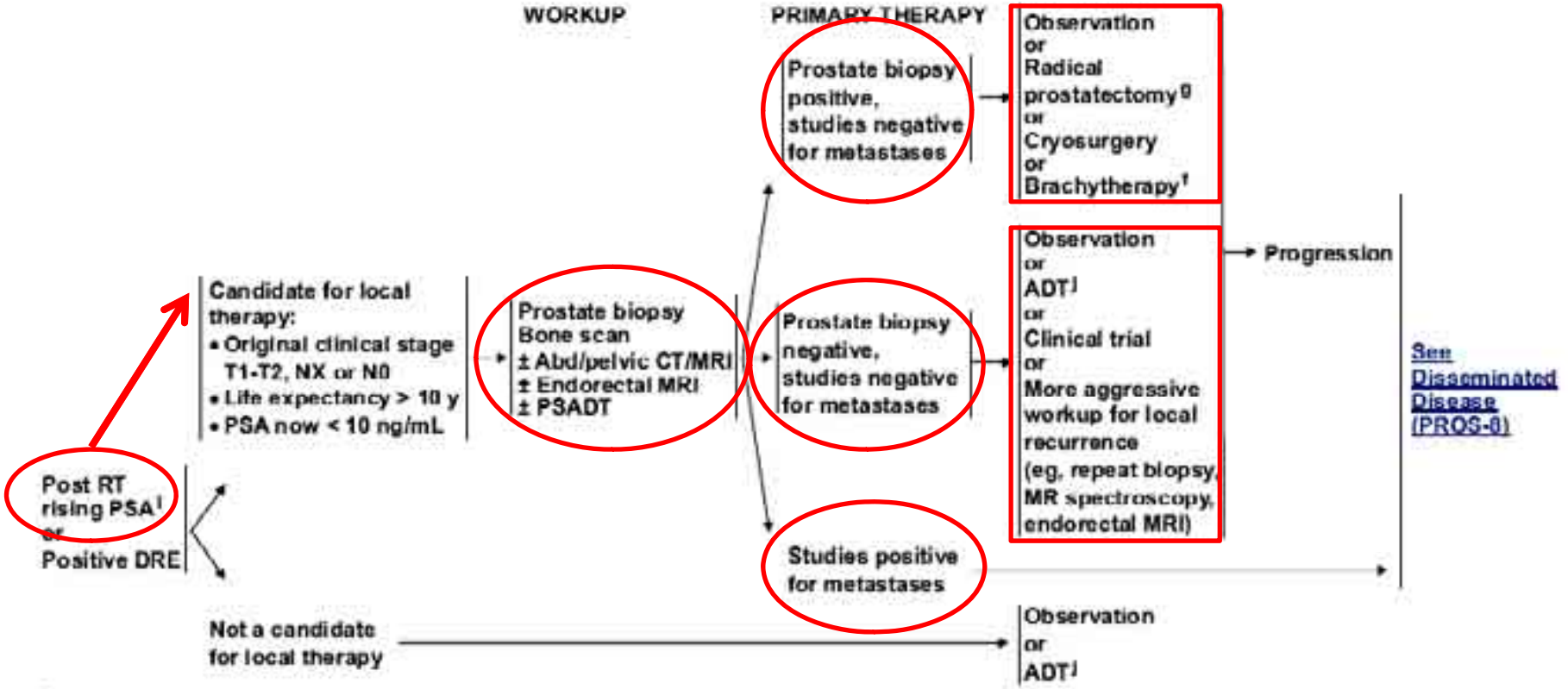
Definizione di recidiva

- Recidiva biochimica dopo RT radicale: un aumento di 2 ng/ml o più sopra il livello del nadir del PSA (RTOG-ASTRO Phoenix Consensus Conference)

- Recidiva locale e/o loco-regionale: recidiva

  (micro o macroscopica) a livello della prostata o delle VS o di linfonodi regionali (sino al livello lomboaortico), confermata da esami strumentali

POST-RADIATION THERAPY RECURRENCE



[f] See Principles of Radiation Therapy (PROS-C).
[g] See Principles of Surgery (PROS-D).
[j] See Principles of Androgen Deprivation Therapy (ADT) (PROS-E).
[m] RTOG-ASTRO (Radiation Therapy Oncology Group - American Society for Therapeutic Radiology and Oncology) Phoenix Consensus - (1) PSA rise by 2 ng/ml or more above the nadir PSA is the standard definition for biochemical failure after EBRT with or without HT; (2) the date of failure is determined "at call" (not backdated). They recommended that investigators be allowed to use the ASTRO Consensus Definition after EBRT alone (with no hormonal therapy) with strict adherence to guidelines as to "adequate follow-up" to avoid the artifacts resulting from short follow-up. For example, if the median follow-up is 5 years, control rates at 3 years should be cited. Retaining a strict version of the ASTRO definition allows comparison with a large existing body of literature.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

Entità del problema: i dati della letteratura

Local tumor control (LTC) → completa e permanente eradicazione del tumore primitivo (misura diretta dell'efficacia della EBRT)

- Non definito in maniera consistente in letteratura;
- E' un dato elusivo;
- La maggior parte degli studi definisce il **LTC** come l'assenza di un progressivo abnorme ingrandimento della prostata o di segni/sintomi suggestivi di una recidiva locale (es ematuria, ostruzione urinaria);
- Tuttavia esiste una considerevole differenza tra la valutazione clinica e i risultati delle biopsie prostatiche post-RT e pochi studi sono stati condotti per valutare questo problema.

Entità del problema: i dati della letteratura

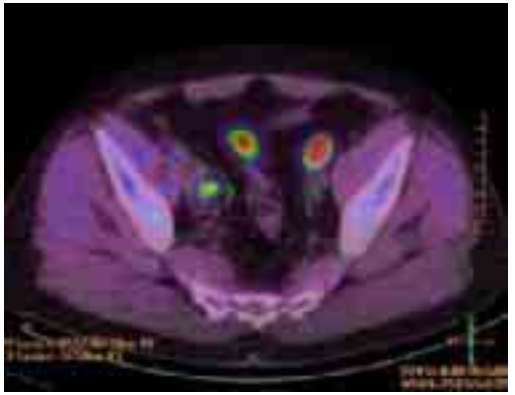
- **LTC** è inversamente correlato allo stadio del tumore (i T1 hanno dal 10-15% in più di probabilità di LC); esiste un trend di maggior rischio di recidiva locale per i tumori scarsamente differenziati.
- Tale rischio esiste per almeno 15 anni dopo la EBRT (attenzione ad interpretare i report con follow-up brevi!)

Clinically Determined Local Tumor Control after Conventional EBRT for Organ-Confined Disease

Study	Stage	N° pts	5Y(%)	10Y(%)	15Y(%)
Bagshaw et al (1993)	T0	96	~ 95	~ 90	~ 85
	T1	335	~ 87	~ 78	~ 67
	T2	242	~ 82	~ 61	~ 48
Hanks et al (1991)	T1-2	104	93	87	--
Hanks et al (1994)	T1	60	96	96	83
	T2	312	83	71	65
Hanks et al (1994)	T1	116	92	85	--
	T2	415	80	71	--
Kuban et al (1995)	T1	101	~ 96	~ 92	~ 62
	T2	281	~ 87	~66-75	~ 50
Zagars et al (1993)	T1	104	99	79	--
	T2	168	89	68	68

Entità del problema: i dati della letteratura

- Pochissimi studi hanno valutato le recidive regionali linfonodali;
- I dati di letteratura riportano < del 3% dei pazienti con recidiva in tali sedi.
- Questo dato è certamente sottostimato, poiché nel follow-up di questi pazienti non viene impiegato routinariamente alcun esame strumentale
- Anche la mortalità correlata alla recidiva linfonodale è un dato non definito

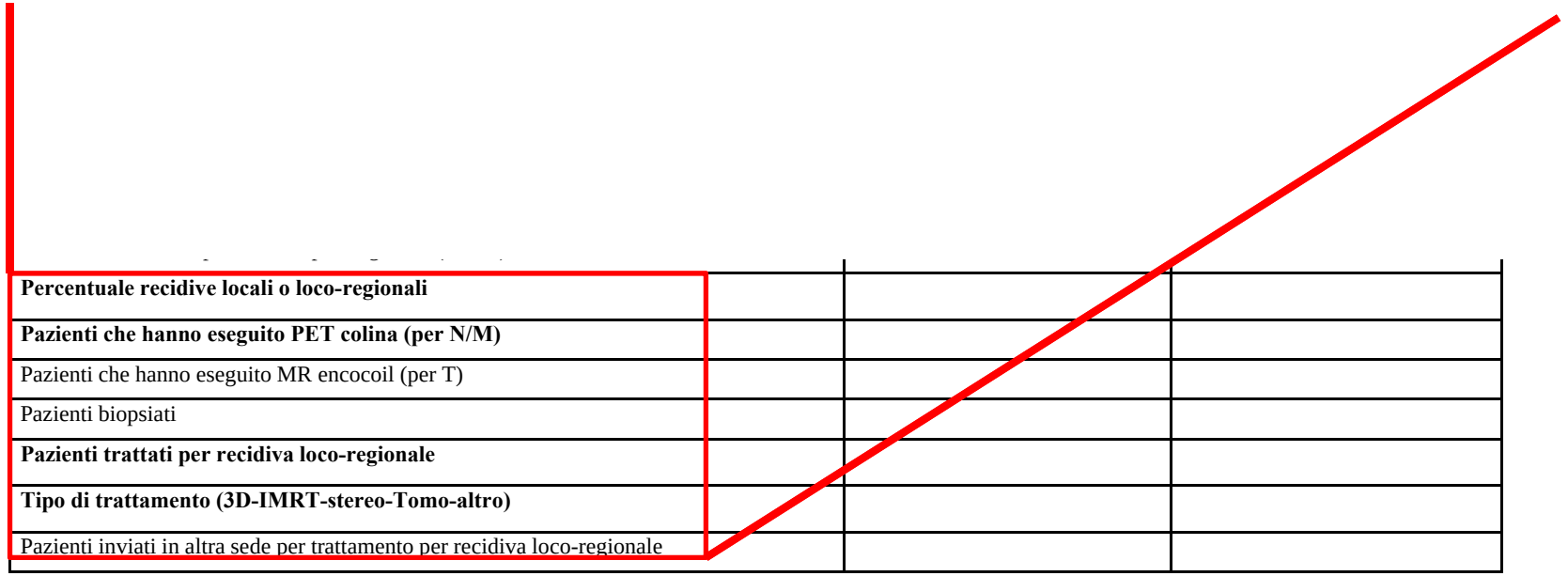


Entità del problema nella nostra Regione: i dati della rete

Valutazione mediante questionario inviato a tutti i centri di Radioterapia della Regione

(14 Centri)

Percentuale recidive locali o loco-regionali		
Pazienti che hanno eseguito PET colina (per N/M)		
Pazienti che hanno eseguito MR encocoil (per T)		
Pazienti biopsiati		
Pazienti trattati per recidiva loco-regionale		
Tipo di trattamento (3D-IMRT-stereo-Tomo-altro)		
Pazienti inviati in altra sede per trattamento per recidiva loco-regionale		



Percentuale recidive locali o loco-regionali			
Pazienti che hanno eseguito PET colina (per N/M)			
Pazienti che hanno eseguito MR encocoil (per T)			
Pazienti biopsiati			
Pazienti trattati per recidiva loco-regionale			
Tipo di trattamento (3D-IMRT-stereo-Tomo-altro)			
Pazienti inviati in altra sede per trattamento per recidiva loco-regionale			

Entità del problema nella nostra Regione: i dati della rete

Quanti Centri hanno risposto?

ASTI
BIELLA
IVREA
NOVARA
ALESSANDRIA
SGAS (TORINO)
MOLINETTE (TORINO)
CANDIOLO (TORINO)

Entità del problema: i dati della rete

Percentuale recidive locali o loco-regionali

Percentuale recidive locali o loco-regionali	2004-2005	2009-2010
ASTI	25%	4,9%
BIELLA	Non disponibile	Non disponibile
IVREA	8%	3%
NOVARA	0	0
ALESSANDRIA	--	0
SGAS (TORINO)	Dato non disponibile (spesso impostata terapia ormonale senza esecuzione della PET)	Dato non disponibile (spesso impostata terapia ormonale senza esecuzione della PET)
MOLINETTE (TORINO)	5.7%	2%
CANDIOLO (TORINO)	18%	15%

Pazienti che hanno eseguito PET colina (per diagnosi N/M)

Pazienti che hanno eseguito PET colina (per N/M)	2004-2005	2009-2010
ASTI	5%	5,8%
BIELLA	Non disponibile	Non disponibile
IVREA	0	12
NOVARA	0	0
ALESSANDRIA	--	0
SGAS (TORINO)	6	10
MOLINETTE (TORINO)	20	45
CANDIOLO (TORINO)	23	37
TOT	49	104

Pazienti che hanno eseguito MR encocoil (per T)

Pazienti che hanno eseguito MR encocoil (per T)	2004-2005	2009-2010
ASTI	--	--
BIELLA	--	--
IVREA	0	0
NOVARA	0	10
ALESSANDRIA	--	0
SGAS (TORINO)	0	6
MOLINETTE (TORINO)	15	30
CANDIOLO (TORINO)	16	19
TOT	31	65

Pazienti biopsiati

Pazienti biopsiati	2004-2005	2009-2010
ASTI	--	--
BIELLA	--	--
IVREA	0	0
NOVARA	0	0
ALESSANDRIA	--	0
SGAS (TORINO)	0	0
MOLINETTE (TORINO)	--	--
CANDIOLO (TORINO)	6	2
TOT	6	2

Pazienti trattati per recidiva loco-regionale

Pazienti trattati per recidiva regionale	2004-2005	2009-2010
ASTI	0	0
BIELLA	0	0
IVREA	0	0
NOVARA	0	0
ALESSANDRIA	--	0
SGAS (TORINO)	1	0
MOLINETTE (TORINO)	0	1
CANDIOLO (TORINO)	9	21
TOT	10	22

Tipo di trattamento (3D-IMRT-stereo-Tomo-altro)

Tipo di trattamento	2004-2005	2009-2010
ASTI	--	--
BIELLA	--	--
IVREA	--	--
NOVARA	0	0
ALESSANDRIA	--	0
SGAS (TORINO)	Brachiterapia	--
MOLINETTE (TORINO)	--	--
CANDIOLO (TORINO)	3DCRT (7)- IMRT (2)	3DCRT (3)-IMRT (4)-TOMO (14)
TOT	9 7 3DCRT – 2 IMRT	21 3 3DCRT, 4 IMRT, 14 TOMO

Pazienti inviati in altra sede per trattamento per recidiva loco-regionale

Percentuale recidive locali o loco-regionali	2004-2005	2009-2010
ASTI	0	0
BIELLA	--	--
IVREA	0	3 (Cyberknife)
NOVARA	0	0
ALESSANDRIA	--	0
SGAS (TORINO)	0	0
MOLINETTE (TORINO)	0	0
CANDIOLO (TORINO)	2	2 (CDI Milano)
TOT	2	5

CONSIDERAZIONI

- **La scarsità dei dati relativi a questo argomento, che costituisce una buona quota della patologia prostatica trattata dai nostri oncologi e per la quale le armi terapeutiche a disposizione sono fondamentalmente scarse, deve farci riflettere**

- **In particolare deve farci riflettere il fatto che le più aggiornate linee guida internazionali a tutt'oggi distinguano, nel tumore della prostata radiotrattato, due possibili scenari:**
  - Da una parte la recidiva locale in assenza di mts a distanza (passibili di un trattamento locale) o addirittura la sola recidiva biochimica (senza segni apparenti di malattia visibile)
  - E dall'altra la malattia metastatica (M0 o M1)

Problema: recidive linfonodali singole o oligometastatiche (M0)

In questi casi il trattamento standard è l' OT sino alla progressione

Ma dopo?

Poche chances terapeutiche

OT di seconda linea

Chemioterapia

Terapie locali (termoablazione con RF, crioablazione, chirurgia, RADIOTERAPIA)

Terapie locali per recidiva

195. Shekarriz B, Upadhyay J, Pontes JE. Salvage radical prostatectomy. Urol Clin North Am 2001;28:545-553. Available at: http://www.ncbi.nlm.nih.gov/pubmed/11590813.

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Terapie locali per recidiva

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- Shariat S et al. Pilot study of radiofrequency interstitial tumor ablation (RITA) for the treatment of radio-recurrent prostate cancer. Prostate 2005, 65(3):260-7.
- Gelet A, et al. **Local recurrence of prostate cancer after external beam radiotherapy: early experience of salvage therapy using high-intensity focused ultrasonography**, Urology 2004, 63(4):625-29.
- Hou AM et al. **Targeted focal therapy for prostate cancer: a review.** Curr Opin Urol. 2009, 19: 283-89.
- Touma NJ et al**: Current status of local salvage therapies following radiation failure for prostate cancer**, J Urol. 2005;173(2):373-9.

Problema: recidive linfonodali singole o oligometastatiche (M0)

Terapie locali impiegate allo scopo di posticipare il più possibile l'inizio della OT

VOLUME 25 · NUMBER 8 · MARCH 10 2007

JOURNAL OF CLINICAL ONCOLOGY

REVIEW ARTICLE

Stereotactic Body Radiation Therapy in Multiple Organ Sites

Robert D. Timmerman, Brian D. Kavanagh, L. Chinsoo Cho, Lech Papiez, and Lei Xing

Radiotherapy and Oncology 93 (2009) 14–17

Contents lists available at ScienceDirect

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journal homepage: www.thegreenjournal.com

Robotic stereotactic radiotherapy

Linac-based or robotic image-guided stereotactic radiotherapy for isolated lymph node recurrent prostate cancer

Barbara A. Jereczek-Fossa[a,&,•], Laura Fariselli[e,f], Giancarlo Beltramo[e], Gianpiero Catalano[a], Flavia Serafini[a], Cristina Garibaldi[b], Raffaella Cambria[b], Lorenzo Brait[c], Marco Possanzini[c], Livia C. Bianchi[c], Andrea Vavassori[a], Dario Zerini[a], Franco Orsi[d], Ottavio de Cobelli[c,g], Roberto Orecchia[a,g]

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0360-3016/$ - see front matter

ELSEVIER

doi:10.1016/j.ijrobp.2010.11.031

CLINICAL INVESTIGATION

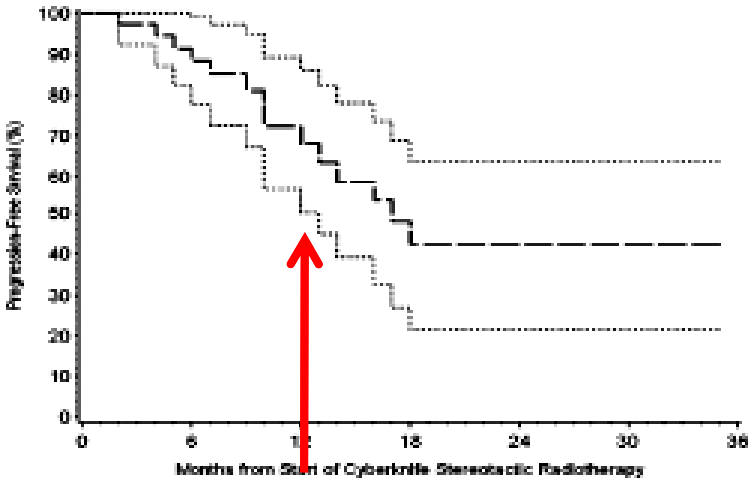
ROBOTIC IMAGE-GUIDED STEREOTACTIC RADIOTHERAPY, FOR ISOLATED RECURRENT PRIMARY, LYMPH NODE OR METASTATIC PROSTATE CANCER

Barbara Alicia Jereczek-Fossa, M.D., Ph.D.,*† Giancarlo Beltramo, M.D.,‡ Laura Fariselli, M.D.,§ Cristiana Fodor, M.Sc.,* Luigi Santoro, M.Sc.,‖ Andrea Vavassori, M.D.,* Dario Zerini, M.D.,* Federica Gherardi, M.D.,*† Carmen Ascione, M.D.,*¶ Isa Bossi-Zanetti, M.D.,*† Roberta Mauro, M.D.,*† Achille Bregantin, M.Sc.,‡ Livia Corinna Bianchi, M.D.,‡ Ottavio De Cobelli, M.D.,* and Roberto Orecchia, M.D.*†

Departments of *Radiotherapy, ‡Urology, and §Epidemiology and Statistics, European Institute of Oncology, Milan, Italy; †University of Milan, Milan, Italy; ‖CyberKnife Center CDI, Milan, Italy; ¶Radiotherapy Unit, Carlo Besta Neurological Institute Foundation, Milan, Italy; and ¶Seconda Università degli Studi di Napoli, Naples, Italy

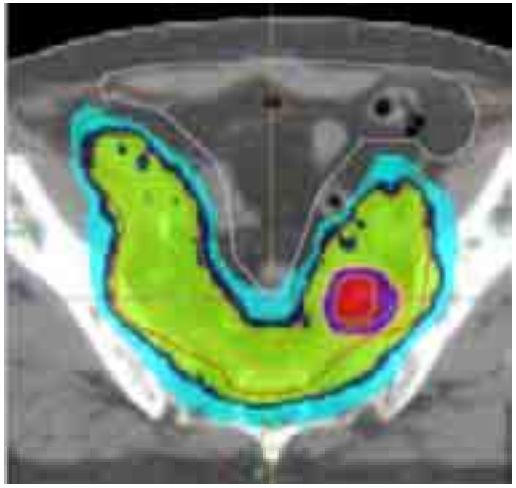
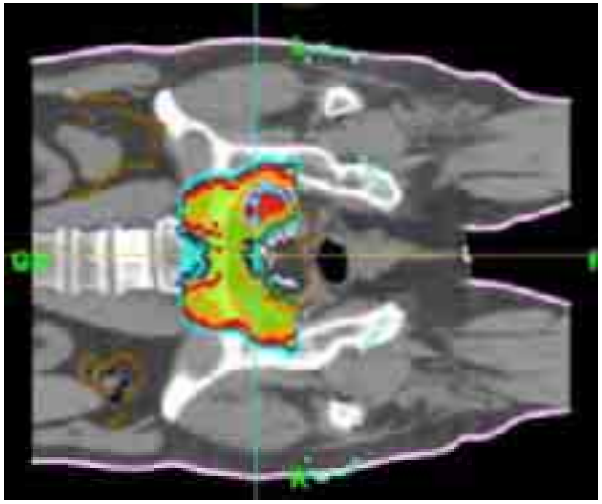
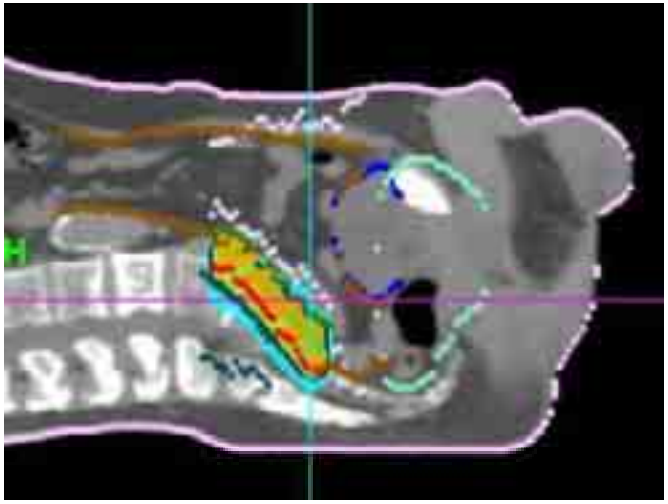
Table 1. Patient characteristics (n = 34 patients)

Characteristics	All patients (n = 34)
Age at CBK-SRT	
n	34
Mean ± SD (y)	68.8 ± 6.2
Median (range) (y)	68.3 (57–82)
KPS at CBK-SRT	
90	4 (12%)
100	30 (88%)
Initial PSA*	
n	31
Median (range) (ng/mL)	9.8 (1.5–410)
Initial Gleason score†	
n	30
Median (range)	7 (4–9)
Initial disease category (NCCN 2008) (1)	
Low	4 (12%)
Intermediate	9 (26%)
High	14 (41%)
Very high	4 (12%)
Unknown	3 (9%)
Initial treatment	
RT ± ADT	20 (59%)
RRP ± LND ± ADT ± RT	14 (41%)
Interval between diagnosis of prostate cancer and CBK-SRT [mean (range)] (mo)	66 (24–180)
Former radiotherapy	
Yes	31 (91%)
EBRT	30 (88%)
BRT	1 (3%)
No	3 (9%)
Status at last observation (May 2010)	
No evidence of disease	19 (56%)
Alive with disease	15 (44%)



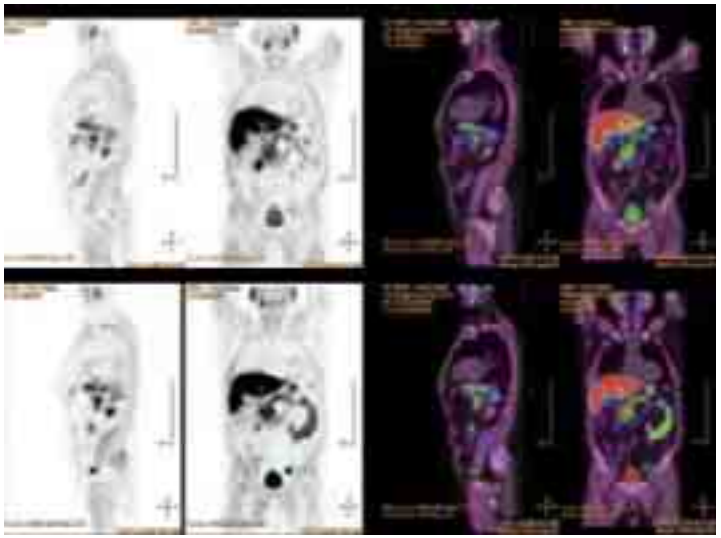
Problema: recidive linfonodali singole o oligometastatiche (M0)

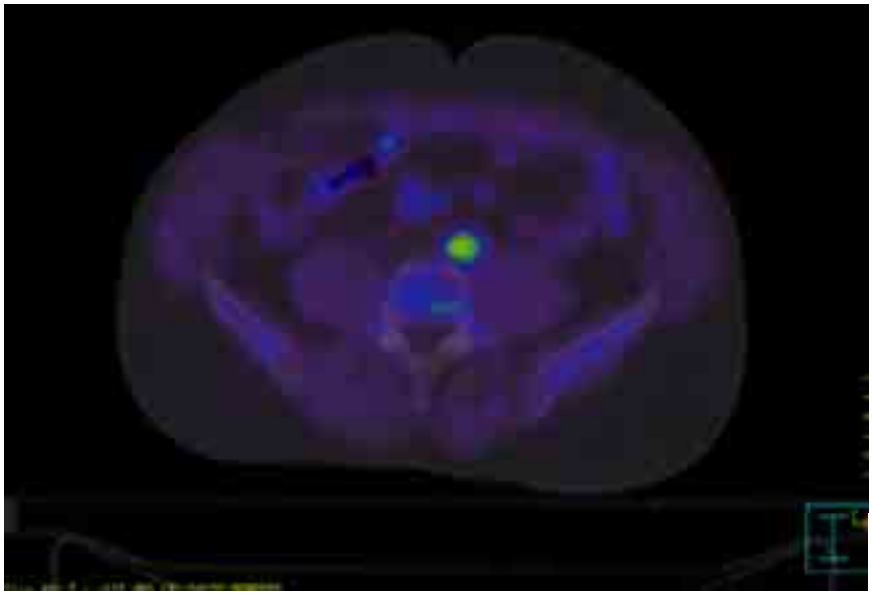
- Dove sono le sedi di recidiva? Frequentemente in altri linfonodi
- Ipotesi: probabilmente questi pazienti necessitano di essere irradiati non solo sui linfonodi macroscopicamente coinvolti ma anche, profilatticamente, a livello dei linfonodi regionali di drenaggio

Background

Widespread use of choline-PET
(available in our Region since 2005,
and now in our Institution since 2010)





ECCO 13 - the European Cancer Conference
PARIS, FRANCE, 30 OCTOBER - 3 NOVEMBER 2005

"Clinical application of ^{11}C-Choline PET in patients with biochemical relapse of prostate cancer"

G. MALINVERNI et al.
IRCC - CANDIOLO - TURIN - ITALY

ESTRO EUROPEAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY

Tomotherapy activities in Candiolo

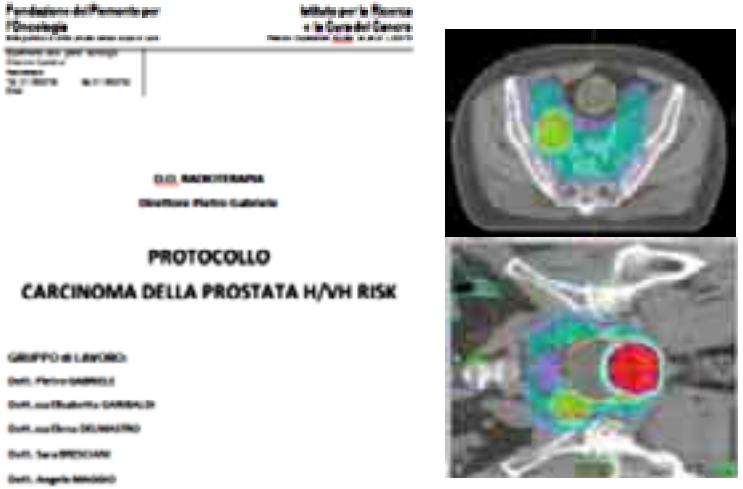
CANDIOLO Fondazione del Piemonte per l'Oncologia

- Tomotherapy delivery: September 2010
- User courses: October 4-22th 2010
- **First patient: October 19th 2010**

Writing protocols

We identified 2 group of patients, with PCa, in which Tomotherapy can be advantagious:

PROTOCOL 1



PROTOCOLLO

CARCINOMA DELLA PROSTATA H/VH RISK

PROTOCOL 2

Protocollo di trattamento delle recidive da adenocarcinoma della prostata mediante Tomoterapia elicoidale

- Patients affected by HR/VHR PCa (needing irradiation on extensive volumes with high doses) → **protocol 1**
- **Patients affected by nodal recurrences of PCa, with/without local relapse, after radical treatment (needing irradiation on extensive volumes and/or re-irradiation) → protocol 2**

Helical tomotherapy in high/very high risk and in nodal recurrences of prostate cancers: preliminary results

Elisabetta Garibaldi, Sara Bresciani, Elena Delmastro, Angelo Maggio, Rocco Panaia, Michele Stasi and Pietro Gabriele

High Technology Department,

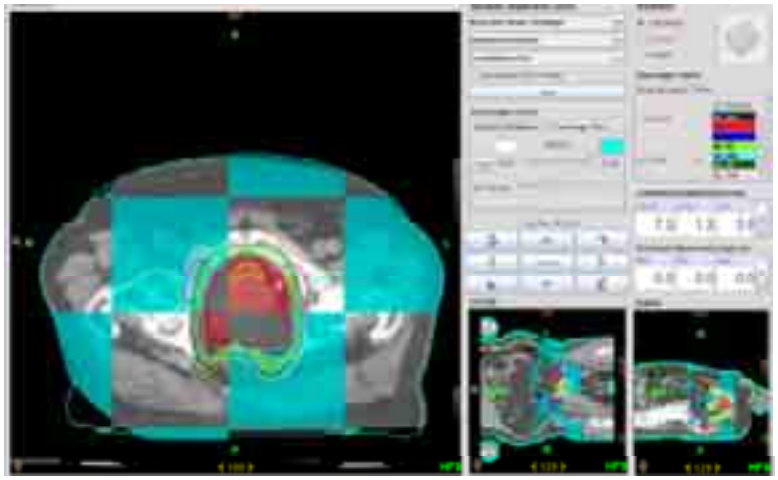
Radiotherapy and Medical Physics

IRCC Candiolo (Turin - Italy)

Fondazione del Piemonte per l'Oncologia

Aim of our study

To assess feasibility of IGRT by HT



In terms of patient compliance
and acute/subacute toxicity
Secondary end point: outcome (PSA control and imaging).

Our experience: material & methods

October 2010 – August 2011:

37 patients:

- **24** pts with HR-PCa/ VHR-PCa (**N+** at diagnosis): **protocol 1**
- **13** pts with **N+ recurrence** after radical treatment: **protocol 2**

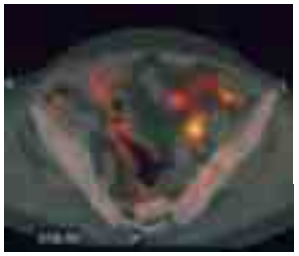
N+ in pelvic and/or lumbar-aortic chains

Patient caractheristics	Protocol 1 H/VH-R PCa	Protocol 2 N+ recurrences
N° pts	24	**13**
Mean age	70 (range 59-82)	**64,9 (range 50-75)**
Comorbidity n° pts (%)	CVD: 10 (42%) AI: 10 (42%) Diabetes: 3 (12,5%) lowerGID: 4 (16,7%) upperGID: 1 (4,2%)	**CVD: 2 (15%)** **AI: 5 (38,5%)** **Diabetes: 0** **lowerGID: 1 (7,7%)** **upperGID: 0**
Urinary Sinptoms preRT: n° pts (%)	5 (20,8%)	**3 (23%)**
Previous RT: P&SV bed	--	**9 (69%)**
Previous RT: pelvis+P&SVbed	--	**2 (15,4%)**
Previous abdominal surgery	9 (37,5%)	**5 (38,5%)**
Previous other local therapies	1 (4,2%)	**--**
Ormonal therapy	22 (91,7%)	**13 (100%)**

Updated September 2011

Our experience: diagnostic workup

Protocol 1 H/VH-R PCa	**Protocol 2** **N+ recurrences**
Endocoil-MRI Bone scan Choline-PET	**Bone scan** **Choline-PET**



Eur Radiol (2009) 19: 761–769
DOI 10.1007/s00330-008-1174-8

UROGENITAL

Stefano Cirillo
Massimo Petracchini
Lorenza Scotti
Teresa Gallo
Annalisa Macera
Maria Cristina Bona

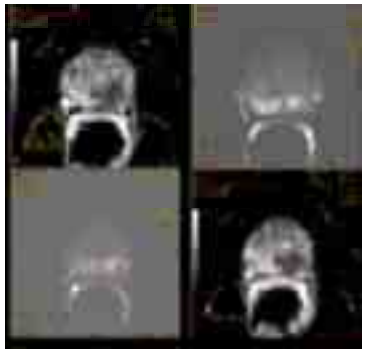
Endorectal magnetic resonance imaging at 1.5 Tesla to assess local recurrence following radical prostatectomy using T2-weighted and contrast-enhanced imaging

Tumori, 94: 65-69, 2008

Comparison of endorectal magnetic resonance imaging, clinical prognostic factors and nomograms in the local staging of prostate cancer patients treated with radiotherapy

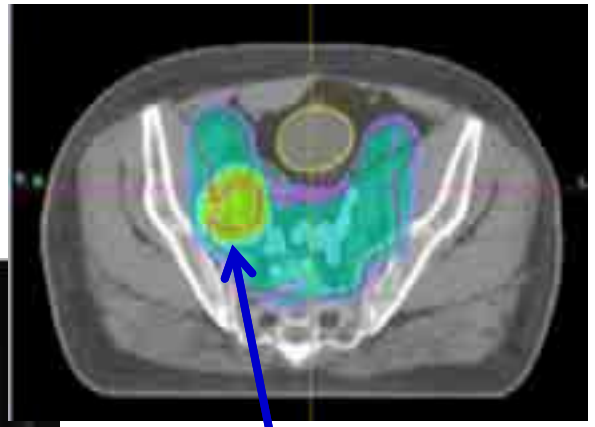
Stefano Cirillo[1], Massimo Petracchini[1], Cristina Maria Bona[2], Sabina Durando[3], Cinzia Ortega[3], Roberto Vormola[3], Michele Stasi[4], Giuseppe Malinverni[2], Massimo Aglietta[3], Daniele Regge[1], and Pietro Gabriele[2]

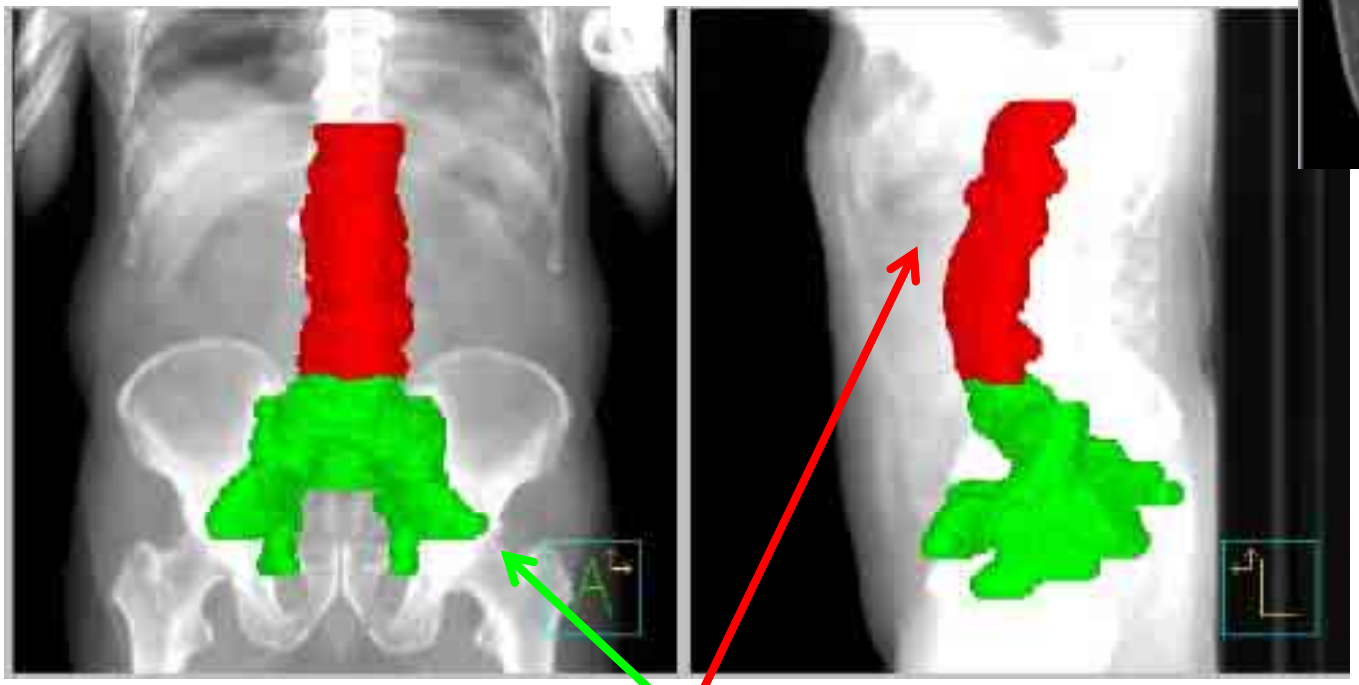
[1]Unit of Radiology; [2]Radiation Therapy; [3]Medical Oncology; and [4]Medical Physics, Institute for Cancer Research and Treatment IRCC, Candiolo, Turin, Italy



Volumes & dose prescriptions. Protocol 2: N+ recurrences

Volumes	Doses (Gy)
PTV 1 N+	60-66 Gy
PTV 2 N-	51-54 Gy
Fraction number	30
Doses per fraction	1.7-1.8-2-2.2





PTV 1 (positive nodes: N+) 60-66 Gy

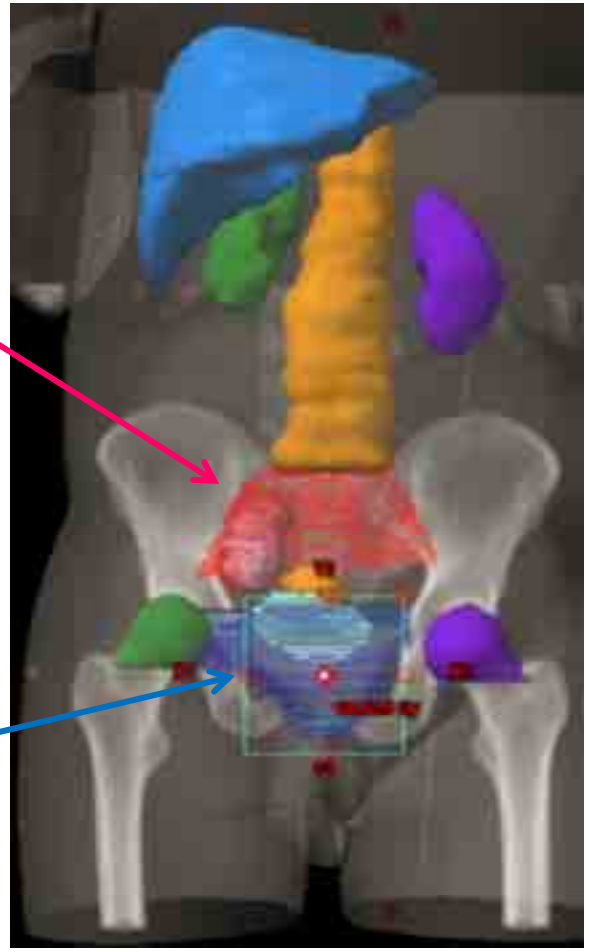
PTV 2 (negative nodes: N-) 51-54 Gy

Updated September 2011

In patients previously irradiated, the prior RT planning was reviewed in order to evaluate the overlapping of the irradiated volumes.

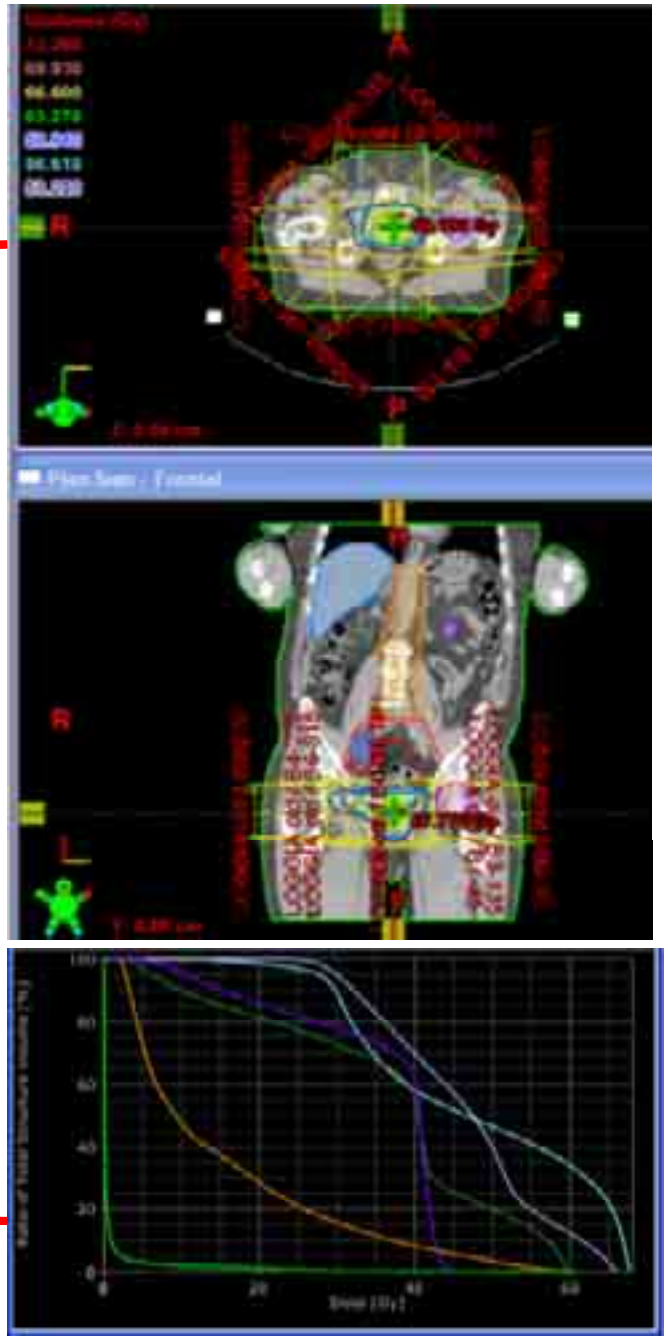
New volumes

Old volumes



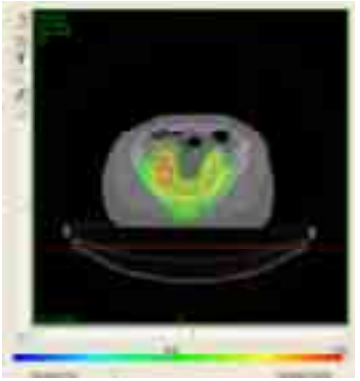
Old RT

3DCRT (72 Gy/40 fr on prostate bed & M1)



Re-irradiation by Tomotherapy

ARTIVIEW- AQUILAB



- *Import DICOM RT Doses from all TPS (Tomotherapy, Pinnacle, Eclipse, CyberKnife,…..)*
- *Dose Visualization in all plan and modalities*
- *DVH Calculation*
- ***Dose summation and subtraction***
- *Export of volume information , DVHs and indices computed in Excel format.*

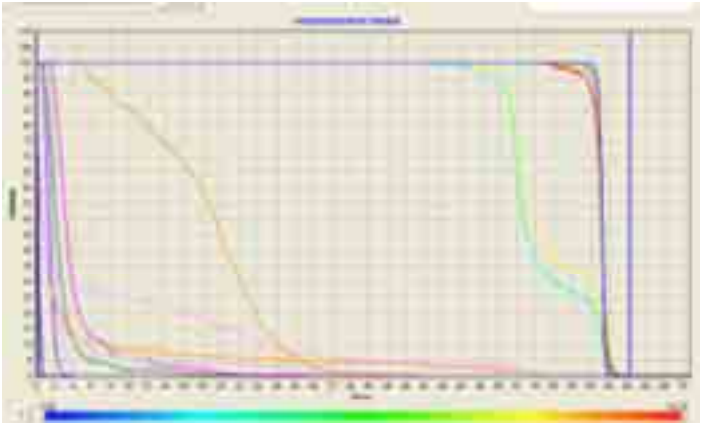
Pz: 64 years old

May 2003: Prostate + seminal vesicles treatment.

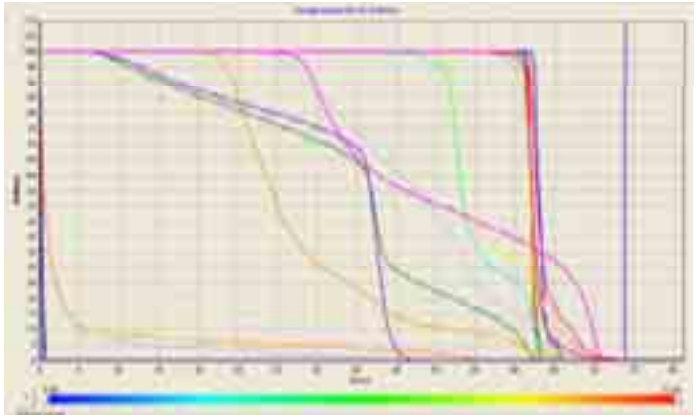
7/10/2010: Prostate Ca recurrence.

5/11/2010: 51 Gy/30 fr ->pelvic lymph nodes + 60 Gy/30 fr -> positive PET Lymph nodes

Tomotherapy treatment Plan

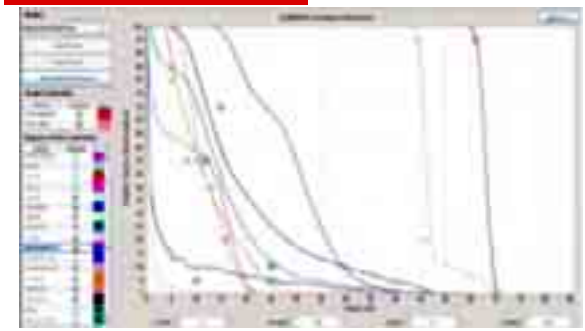


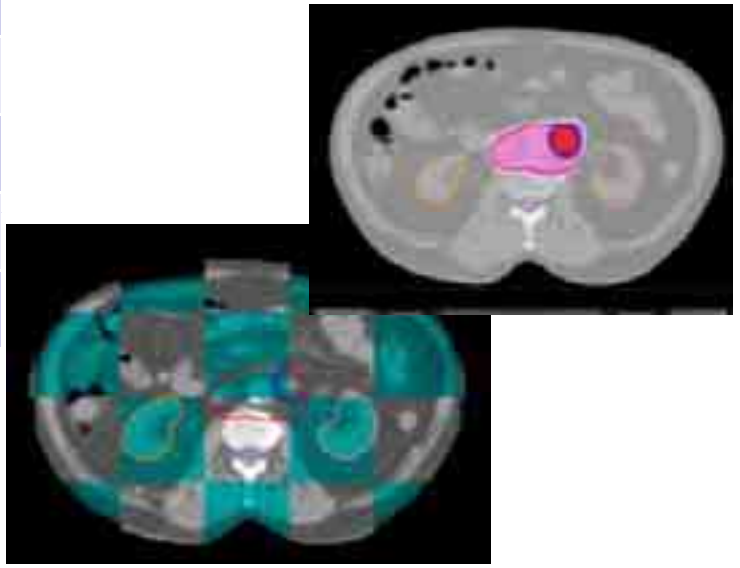
Tomotherapy Plan + OLD plan



Dosimetric characteristics	Protocol 2 N+ recurrences
OAR	**Average doses**
Pancreas	26.8± 7.8 Gy
Spleen	10.8 ± 3.6 Gy
Small bowel	17.7 ± 4.8 Gy
Liver	11.7 ± 4.3 Gy
R-Kidney	11.7 ± 1.5 Gy
L-Kidney	12.4 ± 1.8 Gy
Spinal cord (Dmax)	26.8 ± 3.4 Gy
Target Volumes	**D95%**
N+	64.2 ± 3.1 Gy
N-	53.3 ± 1.5 Gy

QUANTEC



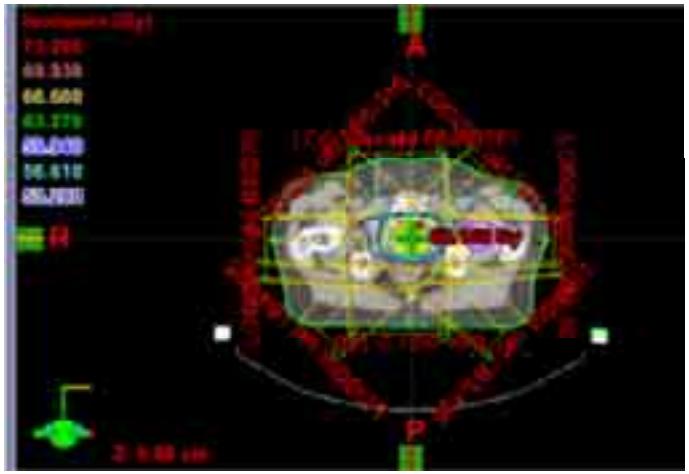


Updated September 2011

Clinical case (protocol 2) (PG)

- (PG) Patient 64 years old, PS ECOG 0
- **08/2003:** PCa, **cT3N0M1** (bone scan &MRI: ischio-pubic M1), GS 9 (4+5), iPSA > 17 ng/ml

- BAT + RT: **3DCRT box technique on prostatic bed + M1 → 41.4 Gy/23 fr + boost (six fields) on prostate bed 25.2 Gy/14 fract + boost (six fields) 5.4 Gy on prostate gland (TD 72 Gy)**



- FU negative until August 2010 → rising PSA (2.8 ng/ml)
- **Choline CT-PET (09/2010): positive in righ lobe of prostate gland and in 2 lymph nodes (right internal iliac)**

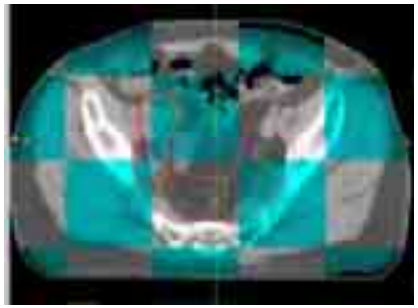
Clinical case (protocol 2) (PG)

TREATMENT STRATEGY

HIFU on prostate gland

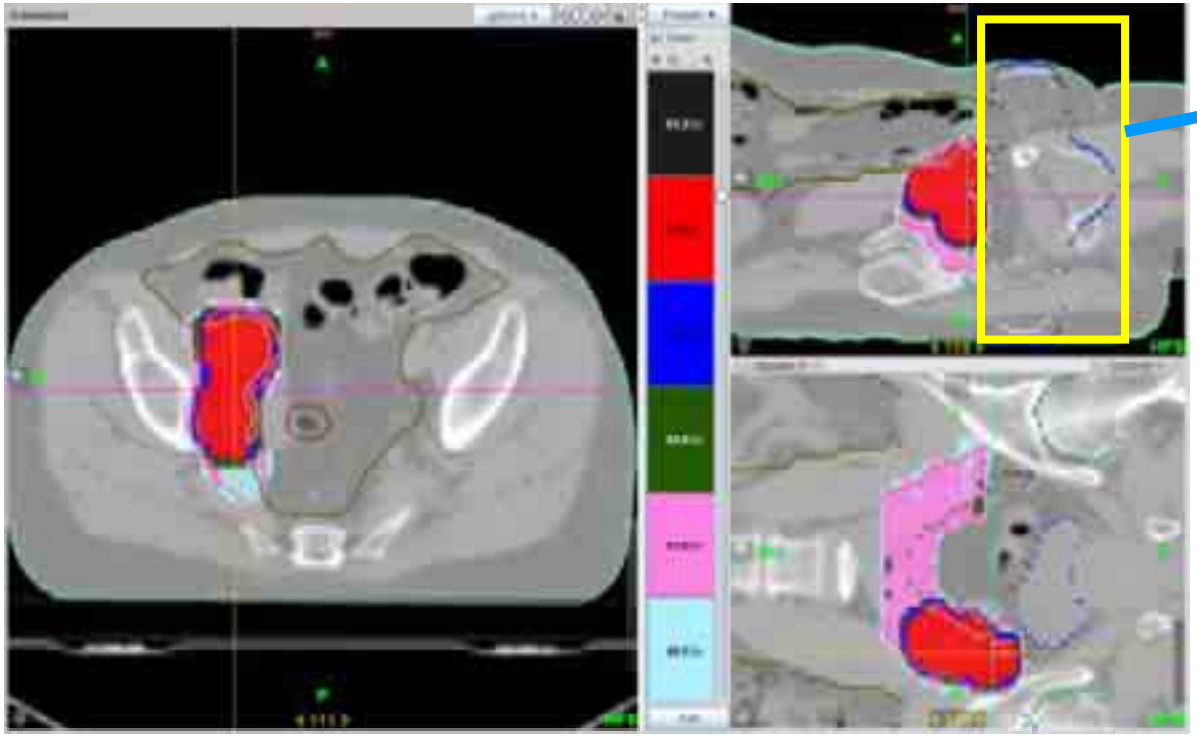
+

TOMOTHERAPY on lymph nodes



+OT

Clinical case (protocol 2) (PG)



Isodoses of previous treatment

TOMOTHERAPY
IMRT-SIB-IGRT

PTV pelvis = 51 Gy (1.7 Gy/die)

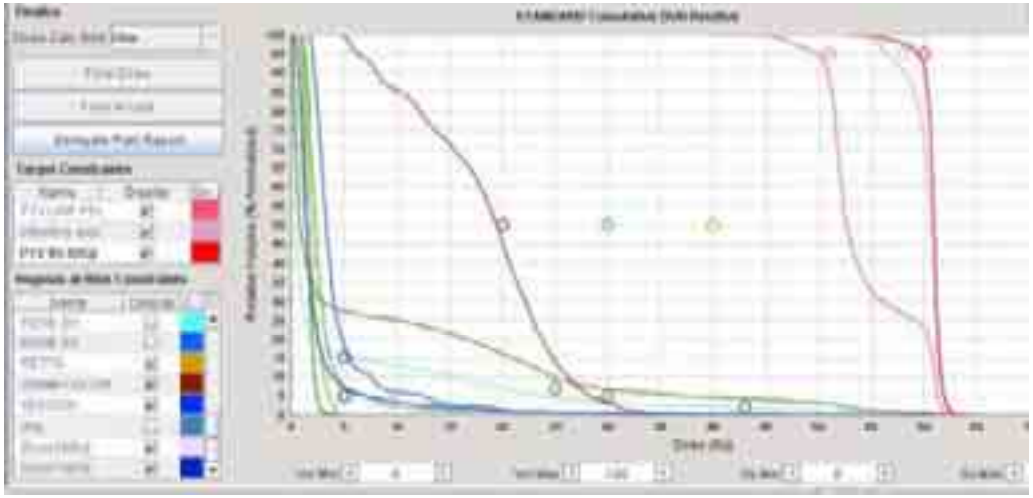
PTV N+ = 60 Gy (2 Gy/die)

Bowel: V45Gy = 180 cc

D-femour, L-femour: D_{max}= 4Gy

Rectum: D_{mean}= 2 Gy

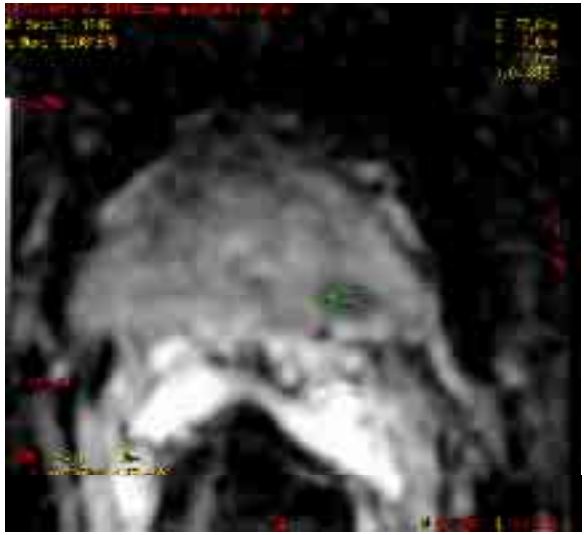
OFF RT 12/2010



Clinical case (protocol 2) (PG)

P.G. FOLLOW-UP: OFF RT 12/2010

- **MRI (01/2011):** in left lobe area of probable neoplastic nature (diameter 10 mm). N-.
- **PSA (02/2011): 0.08 ng/ml**
- **Prostatic biopsy** (02/2011): micro-focus of adenoca with alteration compatible with radiation treatment in 2/28 samples



HIFU ON PROSTATE GLAND

- **STOP OT 02/2011**

PSA (09/2011): < 0.03 ng/ml

Our experience. Results: toxicity

All patients completed treatment

Acute upper GI	Protocol 2 N+ recurrences (13 pts)
G0	10 (76.9%)
G1	3 (23%)
G2	0
G3	0
G4	0

Acute lower GI	Protocol 2 N+ recurrences (13 pts)
G0	9 (69.2%)
G1	4 (30.8%)
G2	0
G3	0
G4	0

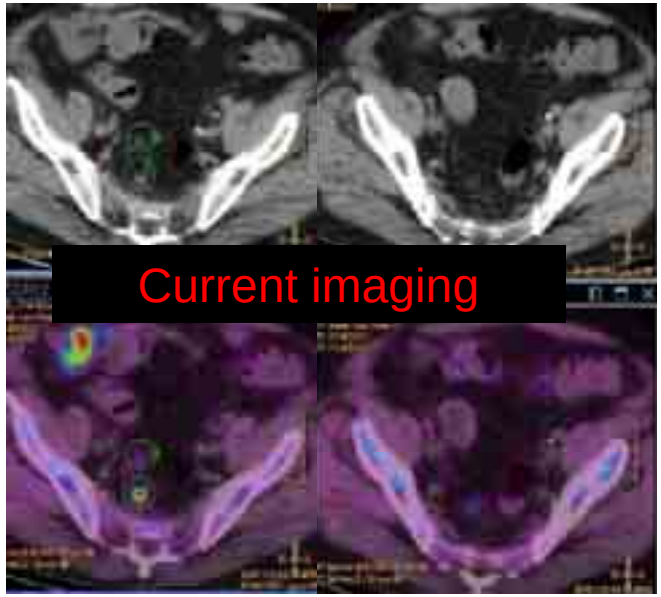
Acute GU	Protocol 2 N+ recurrences (13 pts)
G0	12 (92.3%)
G1	1 (7.7%)
G2	0
G3	0
G4	0

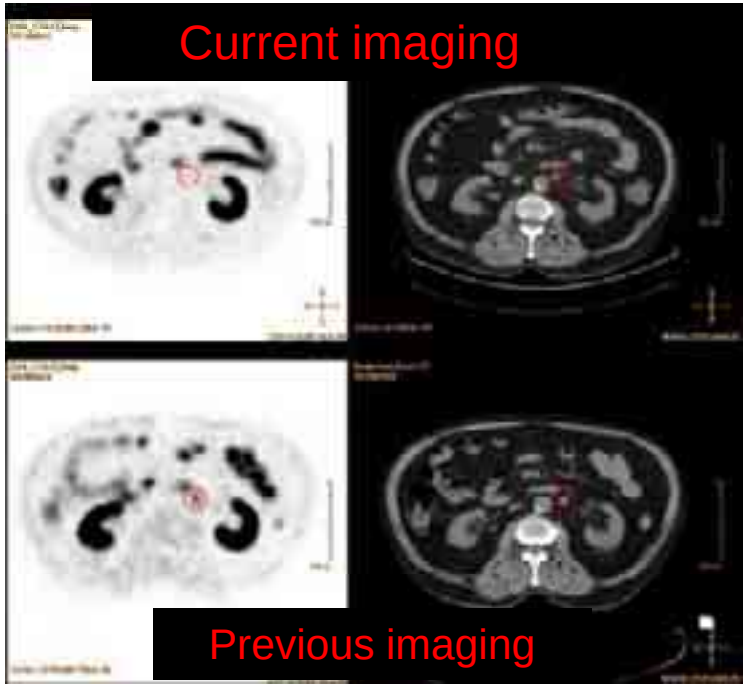
Haematological	Protocol 2 N+ recurrences (13 pts)
G0	9 (69.2%)
G1	4 (30.8%)
G2	0
G3	0
G4	0

Updated Sept 2011

Our experience. Results: outcome

Outcome	
PSA control	13 (100%)
Imaging (PET positive)	1 (7.7%)





Updated September 2011

Conclusioni

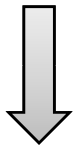
- **Difficoltà a valutare il reale numero e la sede delle recidive loco-regionali**

- **Pochi pazienti sono avviati ad approfondimento diagnostico**
  - Età del paz? (breve aspettativa di vita che induce il medico a sottoporre a OT il paz?)
  - Mancata disponibilità di esami strumentali (RM endocoil, PETcolina)?
  - Scarsa tendenza a ri-biopsiare?
  - Avvio rapido della OT che non consente ulteriori accertamenti?

Conclusioni

- **Sarebbe utile conoscere il reale numero e la sede delle recidive loco-regionali?**

- In pazienti selezionati trattamenti locali potrebbero portare a procrastinare l'inizio della OT ed impattare sulla QoL? considerando che, soprattutto in pazienti giovani, l'idea di non avere altre armi terapeutiche costituisce uno stress psicologico notevole e che l'OT non è scevra di effetti collaterali?



Definire/individuare i pazienti che potrebbero beneficiare di un trattamento locale, può essere utile?

Grazie per l’attenzione

CANDIOLO Fondazione del Piemonte per l’Oncologia