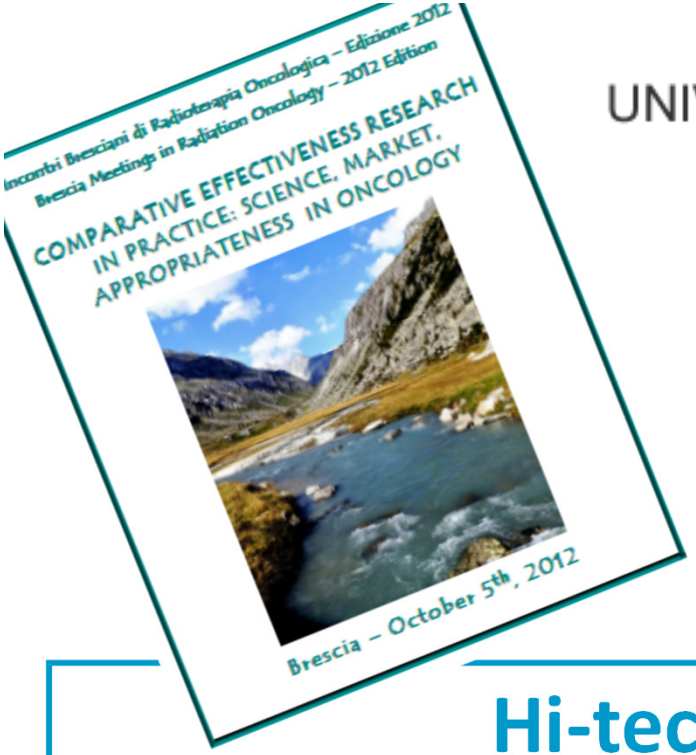
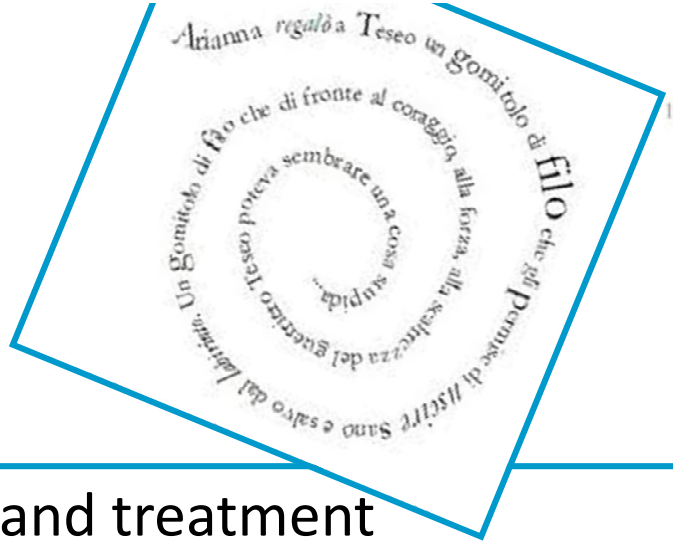


UNIVERSITA' DEGLI STUDI DI BRESCIA

Hi-tech treatments: results, perspectives, suggestions for future comparative effectiveness studies Brain metastases

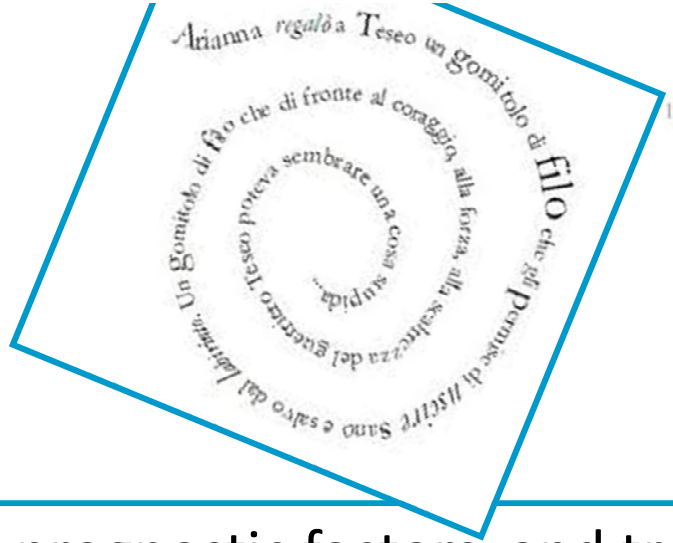
Michela Buglione
Cattedra di Radioterapia – Università di Brescia

The trail……



- ✓ Brain metastases: background and treatment
- ✓ The basis of hypo-fractionation in brain metastases
- ✓ Modality of hypo-fractionation : stereotactic RT alone;
  WB + stereotactic boost;
  surgery + stereotactic boost;
  concomitant boost.
- ✓ Different techniques means different results, toxicities, costs?
- ✓ Future……..

The trail……



✓ Brain metastases: background, prognostic factors and treatment

Brain metastases - background

✓20% to 40% of cancer patients

✓98,000 to 170,000 new cases are diagnosed in the United States each year

✓ the patients require/expect treatment

Mehta M et al Neoplasms of the central nervous system. In: DeVita VT Jr et al: Cancer: Principles and Practice of Oncology. 9th ed. 2011

Brain metastases - prognostic factors

✓Prognostic indices : RPA

RPA	Karnofsky Performance Status	Median OS (mo)
I	KPS ≥ 70; age < 65; Controlled primary disease, no extracranial metastases	7.1; 13.5 for single met, 6.0 multiple mets
II	KPS >=70, age>65, progressive primary tumour, other mts	4.2 8.1 for single met 4.1 multiple mets
III	RPA 2 and KPS >70	2.3

Gaspar L et al IJROBP 1997 37(4):745-51

Brain metastases - prognostic factors

✓Prognostic indices : GPA

	0 points	0.5 points	1 point
Age	>60	50-59	<50
KPS	<70	70-80	90-100
N° mets	>3	2-3	1
Extracranial mets	Present		absent

GPA score	Median OS (mo)
0-1	2.6
1.5-2.5	3.8
3,0	6.9
3.5-4	11

✓ Possible role of primary site of disease

Sperduto PW, et al IJROBP 2010 77(3):655-61

Brain metastases - prognostic factors

✓Prognostic ir

Tab 4. Univariate ar
RPA class

N° p	
Age	
NPS-MI	
KP	
Histol	
Other	
N° brain	
Thera	
RT D	

KPS = Karnofsky
Research Council; R

Tab 5. Multivariate analysis of overall survival: statistical significance of the different variables in each RPA class

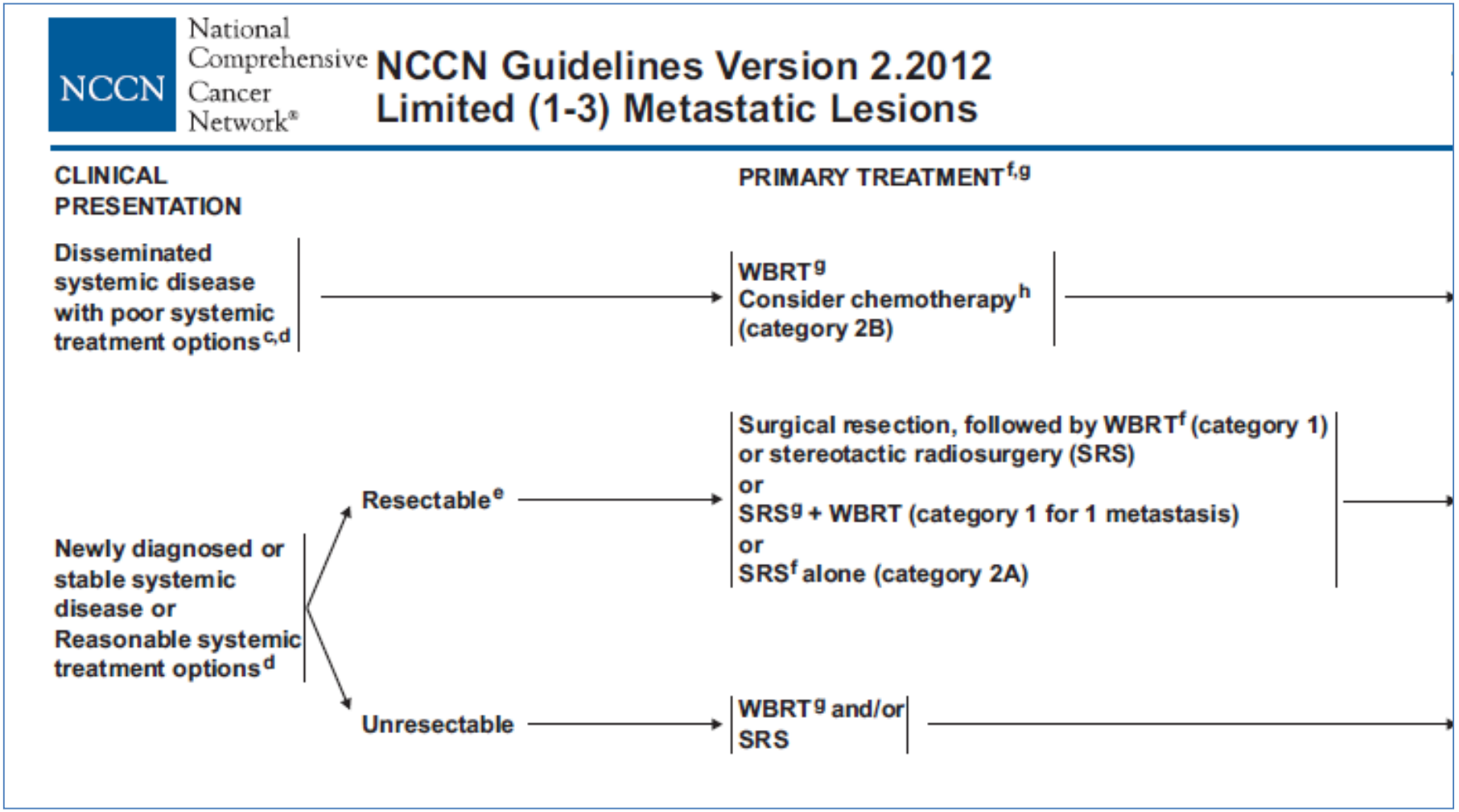
All cases			RPA class 1			RPA class 2		
Variable	p	RR	Variable	p	RR	variable	p	RR
Age	**0.031**		**Other mets**	**ns**		**Dose**	**0.000**	
< 65		1	Yes		1	30 Gy		1
>65		1.325	no		0.568	20 Gy		2.088
KPS	**0.004**		**KPS**	**0.000**		**Histology**	**0.002**	
> = 90		1	> = 90		1	Breast		1
< 90 >/= 70		1.824	< 90 >/= 70		3.032	Lung (adenoca)		0.798
<70		1.466	<70	nopts		Lung (SCLC)		0.817
RPA class	**0.019**		**N° brain mets**	**0.001**		Lung (squamo)		2.136
1		1	>=1 <=3		1	Renal		0.248
2		1.236	>3		1.534	Melanoma		1.609
3		2.502	**Therapy**	**ns**		Other		1.256
N° brain mets	**0.001**		Surgery + RT					
>=1 <=3		1	RT					
>3		1.266	**Dose**	**0.003**				
Therapy	**0.021**		30 Gy		1			
Surgery + RT		1	20 Gy		2.385			
RT		1.640	**Histology**	**0.030**				
Dose	**0.001**		Breast		1			
30 Gy		1	Lung (adenoca)		1.11			
20 Gy		1.589	Lung (SCLC)		1.976			
Histology	**0.004**		Lung (squamo)		1.073			
Breast		1	Renal		0.557			
Lung (adenoca)		1.043	Melanoma		5.643			
Lung (SCLC)		1.064	Other		1.19			
Lung (squamo)		1.423						
Renal		0.574						
Melanoma		2.419						
Other		1.454						

Buglione M et al La Radiologia Medica 2011; 117 (1):133- 147

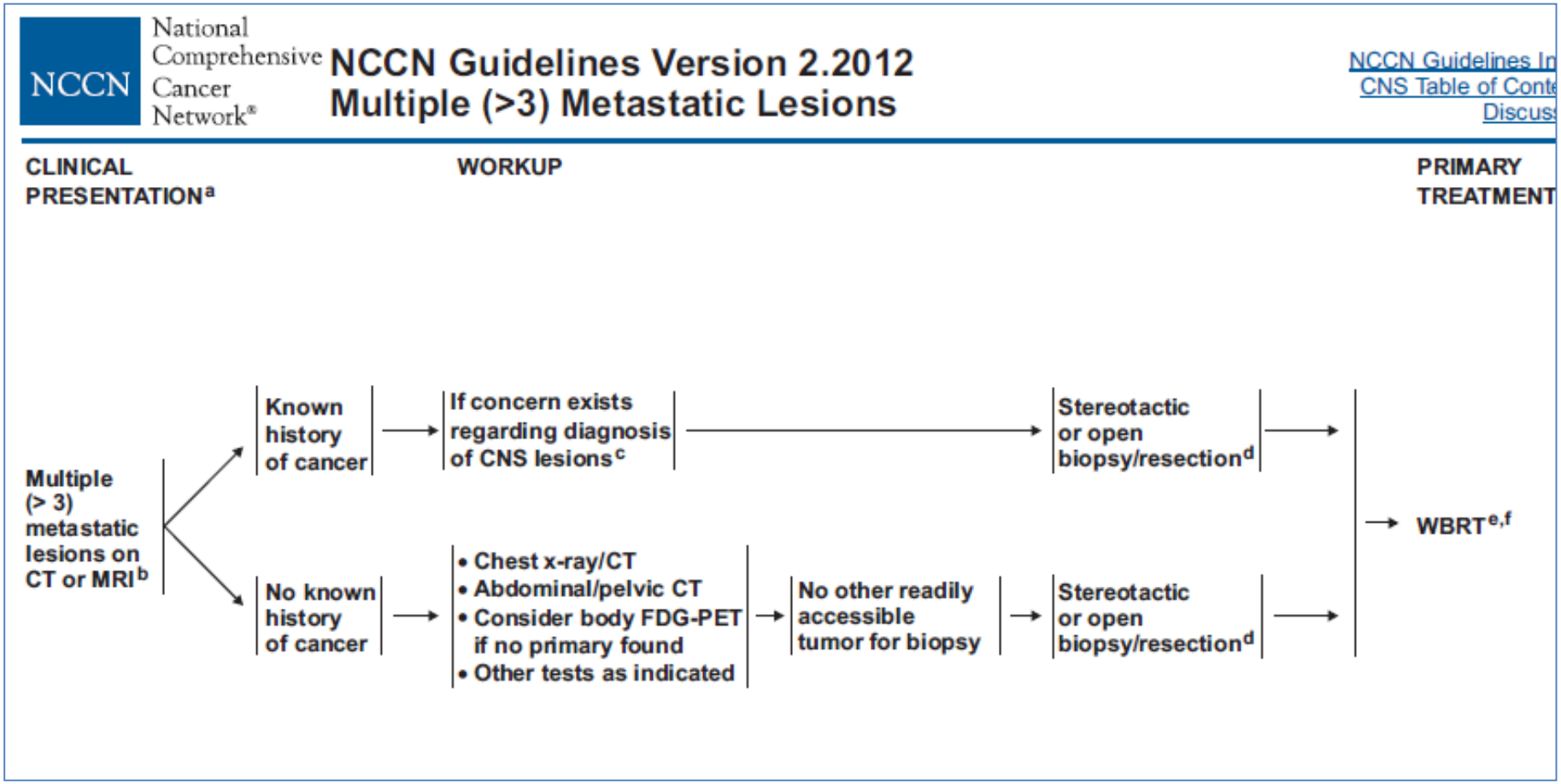
Brain metastases - treatment

- ✓ surgery
- ✓ whole brain radiotherapy
- ✓ stereotactic radiotherapy /radiosurgery

Brain metastases - treatment



Brain metastases - treatment



The trail……

- ✓ Brain metastases: background prognostic factors and treatment
- ✓ The basis of hypo-fractionation in brain metastases

The basis of hypo-fractionation

- ✓ Hypo-fractionated/single fraction RT has a growing role in the treatment of single/<3 brain metastases

Systematic review

Dose–effect relation in stereotactic radiotherapy for brain metastases.
A systematic review

Ruud Wiggenraad [a,*], Antoinette Verbeek-de Kanter [a], Henk B. Kal [b], Martin Taphoorn [c,e], Thomas Vissers [d], Henk Struikmans [a]

[a] Radiotherapy Centre West, The Hague, The Netherlands; [b] Maassluis; [c] Department of Neurology; [d] Medical Library, Medical Center Haaglanden, The Hague, The Netherlands; [e] Department of Neurology, VU Medical Center, Amsterdam, The Netherlands

- ✓ 6 mo local control rate is higher than 80% in hypo-frationated and single fraction
- ✓ 12 mo LCR >80% with a single dose >20 Gy
  >70% with FSRT
  >60% SRT >18Gy
  <50% SRT 15 Gy

- ✓ BED_{12} of at least 40 Gy is necessary → LCR 12mo of >70%

Wiggenraad R et al Radioth &Oncol 2011

The basis of hypo-fractionation

- ✓ Different methods of dose prescription and isodose specification not related to tumor volume but to estimated late radiation toxicity rate

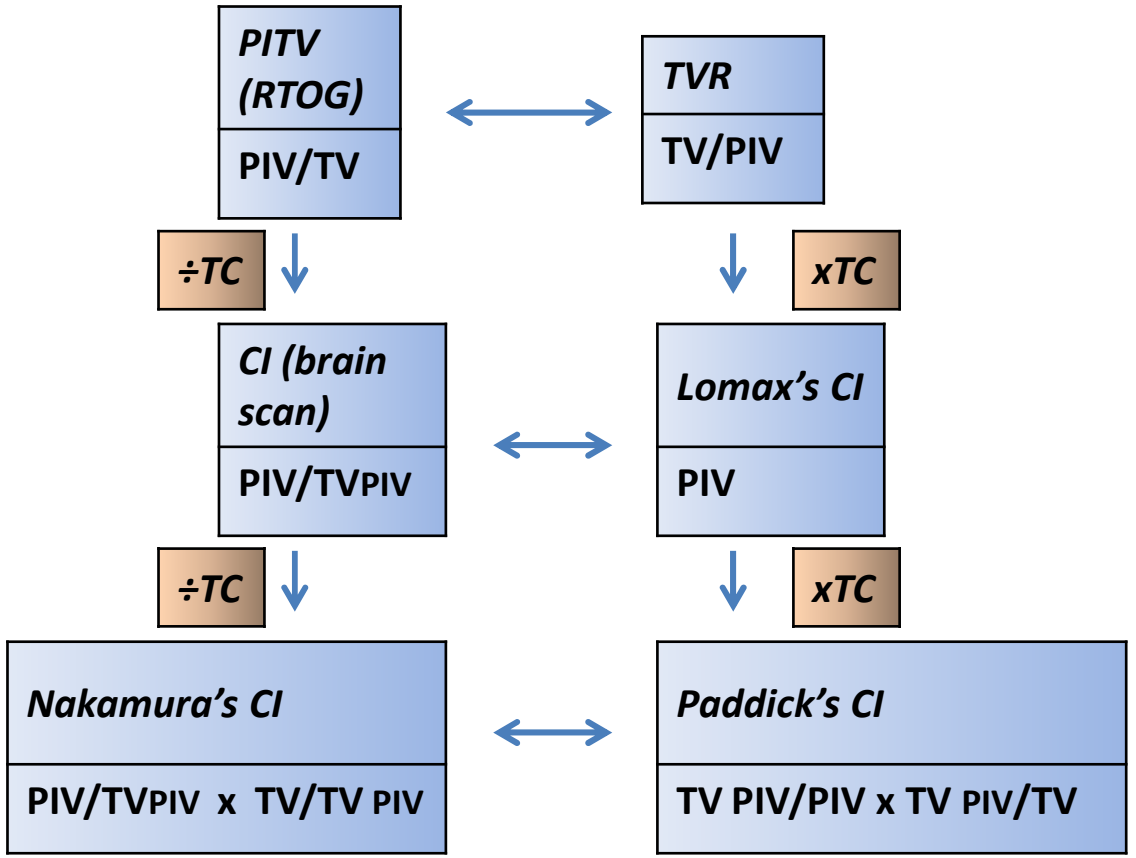
- ✓ Wide range of dose levels
  → different algorithms to compare different prescription methods;
  → RTOG 90-05 : disease without margin
  50-90% isodose line (encompassing the lesion)
  24 Gy → >/=20mm
  18 Gy → 21-31 mm
  15 Gy → 31-40 mm

Flickinger JC et al IJROBP 1990, 19(1):143
Shaw E et al IJROBP 2000, 47(2): 291

The basis of hypo-fractionation

- ✓ Conformity index →quantitatively evaluate the dose conformity
- ✓ The choices of CI and reference isodose are left to the planners
- ✓ Differences in methods to evaluate the target coverage using different conformity indices

CI: conformity index
PIV: prescription isodose volume
PITV: ratio of prescription isodose volume/target volume
TV_{PIV}: the volume of the target receiving the prescription dose;
TVR: treatment volume ratio;
TC: target coverage
TV: target volume



Ohtakara k et al Br J of Radiol 2012, (85): e223

The trail……

- ✓ Brain metastases: background prognostic factors and treatment
- ✓ The basis of hypo-fractionation in brain metastases
- ✓ Hypo-fractionation modality : stereotactic RT alone;
  WB + stereotactic boost;
  surgery + stereotactic boost;
  concomitant boost.

Hypo-fractionation modality

✓Stereotactic RT alone vs WB + stereotactic boost

Ok, but…

Author	Treatment	Dose	LC/OS
Aoyama JAMA 2006	RS RS+WB	22-25Gy/18-20Gy Dose <30% + 30Gy in 10-12 #	72.5%/ns **88.7**%/ns
Chang Lancet oncol 2009	RS RS+WB	18-12 Gy 18-12 Gy + 30 Gy in 12 #	67.7%/15.2mo **100**%/5.7 mo
Mueller and Kocher JCO 2009 and 2011	RS o S RS o S + WB	20 Gy 20 Gy + 30 Gy in 10 #	67.6%/ns **82.4**%/ns
Muacevic J Neurooncol 2008	RS RS+WB	17-27 Gy 14-27 Gy + 40 Gy in 20 #	74.2%/ns **97**%/ns

Scoccianti S. and Ricardi U. Radioth & Oncol 2012, (102): 168

Hypo-fractionation modality

✓WB + stereotactic boost vs WB alone

- multiple metastases (>4) → no better survival

- in patients with 1-4 metastases → no better survival but better local control, better functional outcome and decreased steroid requirement

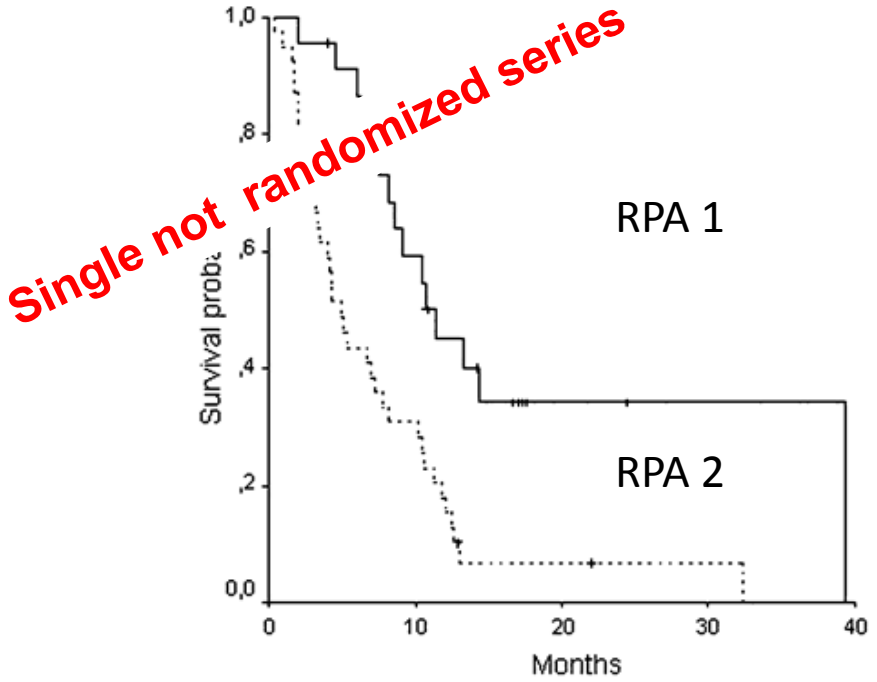
- in patients with **RPA 1**; 1 metastasis → better local control and better survival

Patil CG et al The Cochrane Collaboration 2012

Hypo-fractionation modality

✓Hypofractionated/SRS RT alone

- 24 Gy in 3 #
- LC → 75% at 9 mo and 45% at 24 mo



Marchetti et al Neurol Sci 2011, 32 (3): 393

Hypo-fractionation modality

✓Surgery + stereotactic boost

Hartford AC et al IJROBP in press 2012

- LC → 1y 85.5%; 2 y 66.9%;
-OS →1y 52.5%; 2y 31.7% ; 15.3Gy (range 10.75-23.5Gy);
- size <2 cm → better LC;
lower brain recurrence;
lower intracranial recurrence;
> time to WB

Robbins JR et al Neurosurgery in press 2012

-LC → 1y 81.4%; 2 y 75.7%; median OS 12.1 mo;
median marginal dose 16 Gy

Critical Review

Radiosurgery to the Postoperative Surgical Cavity: Who Needs Evidence?

David Roberge, M.D.,*,† Ian Parney, M.D., Ph.D.,‡ and Paul D. Brown, M.D.§

*Division of Radiation Oncology, Department of Oncology, McGill University, Montreal, QC, Canada; †Department of Radiation Oncology, Centre Hospitalier de l'Université de Montréal, Montreal, QC, Canada; ‡Department of Neurologic Surgery, Mayo Clinic College of Medicine, Rochester, MN; and §Department of Radiation Oncology, University of Texas M. D. Anderson Cancer Center, Houston, TX

Prospective trials needed!!

Hypo-fractionation modality

✓ Concomitant WB + boost

Lagerwaard et al IJROBP 2009

- 1° experience in 2009
- 20 Gy/5# and 40 Gy in 5# → higher conformity index than WB>SRS

Rodrigues et al Radiother&Oncol 2011

-20 Gy/5 and 40Gy/5 #
- 30 Gy/10 and 36-50 Gy/10 #
- multivariate → primary lung, systemic mets, low WHO PS, predictive of shorter **OS**;
- cumulative brain mets volume → **LC**

Hypo-fractionation modality

Original Article

al Practi
al Conse
astases: Third
and Symptom

Profession (n = 445)	
Radiation oncologist	412 (92.6%)
Neurologist	1 (0.2%)
Other	32 (7.2%)

Multidisciplinary meetings in the institution of practice for patients with brain metastases (n = 438)	
No	128 (29.2%)
Yes	310 (70.8%)

	30 Gy in 10 daily fractions	20 Gy in 5 daily fractions
Alone	41%	40%
With surgery	55%	19%
With radiosurgery	48%	14%

Radiosurgery dose prescription (survey questions 6–8)

Target size (cm)	15 Gy	18 Gy	20 Gy	22 Gy	24 Gy	Other	Total number of responses
<2 cm	8%	21%	28%	9%	13%	21%	321
2–3 cm	13%	44%	15%	5%	3%	20%	319
3–4 cm	47%	16%	7%	2%	4%	24%	310

Treatment options for single brain metastasis (survey questions 14–17)

Survey question number (n)	Surgery alone	Radiosurgery alone	Surgery and WBRT	Radiosurgery and WBRT	WBRT	Surgery and radiation boost	Surgery, radiation boost, WBRT	Comfort measures only
14 (661)	7%	14%	40%	17%	5%	9%	8%	0%
15 (661)	12%	15%	37%	14%	6%	8%	8%	0%
16 (488)	1%	32%	1%	42%	23%	1%	0%	0%
17 (512)	8%	1%	56%	5%	11%	10%	9%	0%

Treatment options for initial management of multiple brain metastases (survey questions 20–22)

Survey question number (n)	Radiosurgery alone	Radiosurgery and whole brain radiotherapy	Whole brain radiotherapy	Comfort measures only
20 (453)	14%	42%	44%	0%
21 (449)	5%	7%	78%	10%
22 (456)	1%	1%	40%	58%

Tsao MN et al Clinical Oncol 2012, 24: e81-92

Hypo-fractionation modality

Original Article

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	30 Gy in 10 daily fractions	20 Gy in 5 daily fractions
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With radiosurgery	48%	14%

A survey of practice among more than 400 radiation oncologists confirms some practice patterns:

1. **No selective high dose treatments for prognostic worse pts;**
2. **Larger use of SRS/FSRT in selected RPA 1, < 4 mets pts;**
3. **Addition of WB to SRS is favoured;**
4. **Mainly WB in pts with > 4 mets.**

Treatment options for initial management of multiple brain metastases (survey questions 20–22)

Survey question number (n)	Radiosurgery alone	Radiosurgery and whole brain radiotherapy	Whole brain radiotherapy	Comfort measures only
20 (453)	14%	42%	44%	0%
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22 (456)	1%	1%	40%	58%

Tsao MN et al Clinical Oncol 2012, 24: e81-92

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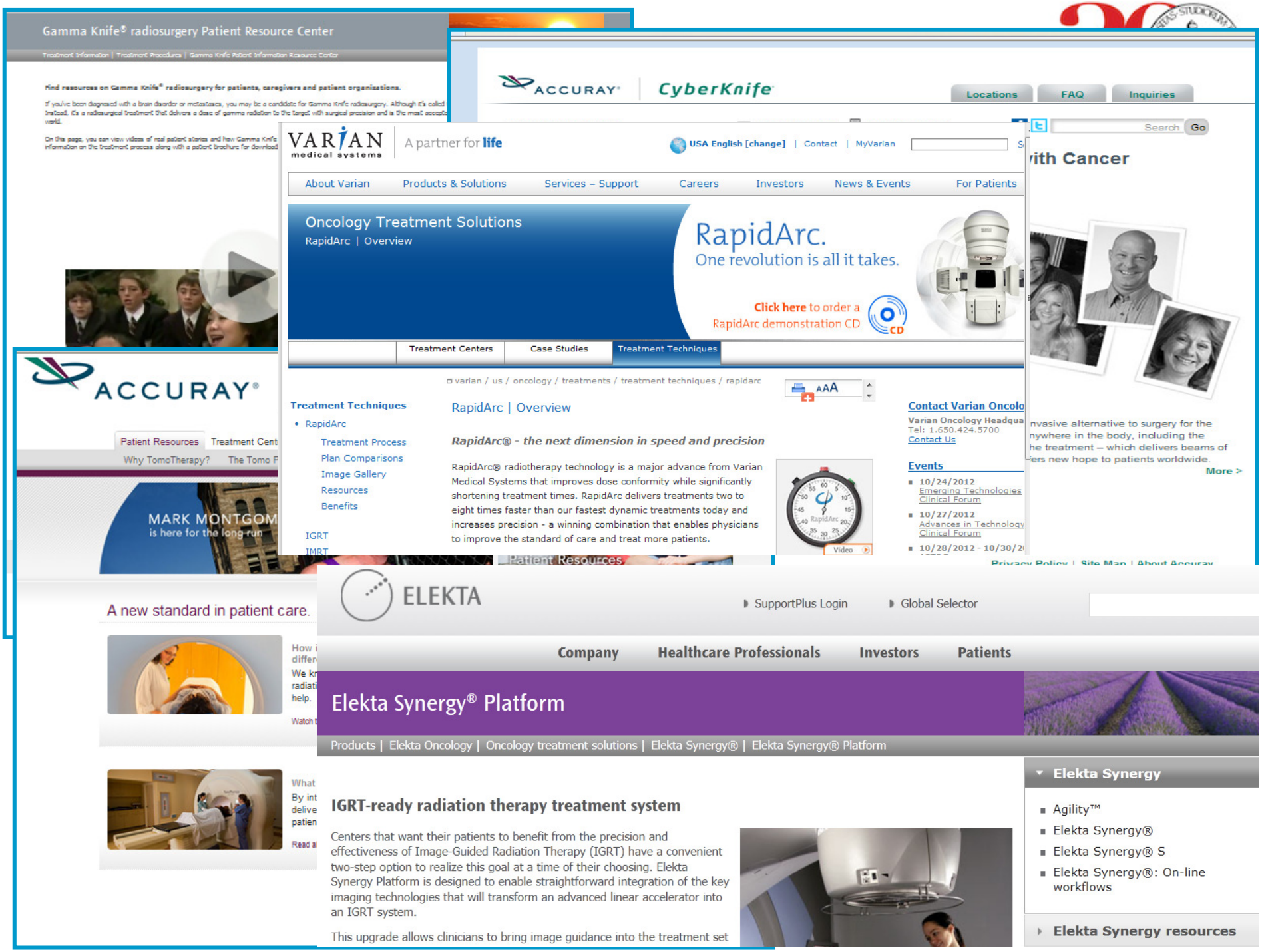
  surgery + stereotactic boost;
  concomitant boost.
- ✓ Different techniques means different results, toxicities, costs?

Different techniques.....

- ✓ Fixed-gantry angle IMRT – 3D
- ✓Dynamic conformal arc therapy (DCA)→multiple non-coplanar arcs
- ✓Arc based IMRT
- ✓Serial→ HELICAL THOMOTHERAPY
- ✓Intensity Modulated Arc Therapy → VMAT/Rapid Arc

Jin IY The cancer Journal 2011, 17(3): 166-176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Elekta Synergy®: On-line workflows
Elekta Synergy resources

Different results?.....dosimetric/clinical evaluation

Author	Treatment	techniques	Observations	LC
Hazard LJ et al (rew) IJROBP 2009	SRS	**DCA** **3D** **GK** **CyberK** **Proton**	- CI: if reported ….comparable → ? -3D: more dose homogeneity in TV - **necessary a standardized method to choose prescription isodose**	NR
Penagaricano JA Radiation Oncol 2006	SRS	**HT** **GK**	-CI, TV coverage are comparable - min dose to PTV higher with GK - low-dose spillage volume is higher in **HT**	NR

✓ **concomitant WB+boost**

- feasible only with HT or VMAT/Rapid Arc
- → no results in terms of local control between different techniques

(Rodrigues G R&O 2011)

Different toxicity?.....

Author	Treatment	Techniques	Observations	Necrosis/nerologic
Hazard LJ et al (rew) IJROBP 2009	SRS	**DCA** **3D** **GammaKnife** **CyberK** **Proton**	GK dose inhomogeneity in TV	Increased risk of complications (?)
Penagaricano JA Radiation Oncol 2006	SRS	**HT** **GK**	- Low doses in HT - Non-homogeneity dose in TV	Problems related to low-doses in HT?; Increased risk of complications (?)

✓ **concomitant WB+boost**

- feasible only with HT or VMAT/Rapid Arc
- no published data

Different costs?.....

Author	Treatment	Techniques	Delivery time/immobilization	Costs
Hazard LJ et al (rew) IJROBP 2009	SRS	**DCA** **3D** **GammaKnife** **CyberK** **Proton**	3D less time /NR	NR
Penagaricano JA Radiation Oncol 2006	SRS	**HT** **GK**	30-49 minutes 14-36 minutes / Non invasive (HT)	NR

✓ **concomitant WB+boost**

- feasible only with HT or VMAT/Rapid Arc
- the problem of HT is the delivery time

Different costs?.....

OPEN ACCESS HTA-Kurzfassung

Medizinische und gesundheitsökonomische Bewertung der Radiochirurgie zur Behandlung von Hirnmetastasen

Medical and health economic assessment of radiosurgery for the treatment of brain metastasis

- ✓ 1495 medical paper
- ✓ 15 meet inclusion criteria
- ✓ limited study quality
- 320 economic paper
- 5 eligible

The efficiency of the different equipments depends to a great extent on the number and the indications of the patients treated. If dedicated systems are used to their full capacity, there is some evidence for superior cost-effectiveness. If more treatment flexibility is required, adapted systems seem to be advantageous. However, equal treatment effectiveness is a necessary assumption for these conclusions.

Studies focusing on the comparative effectiveness and cost-effectiveness of different treatment options and their combinations, especially for the German setting, are warranted.

Muller-Riemenschneider F et al GMS Health Tech Assessment 2009 Vol 5

Different results, toxicity, costs ?.....

✓ WB+boost → SIB or sequential; VMAT/Rapid Arc vs HT

Objective:

✓Dosimetric comparision
✓ OAR
✓ delivery time

Borghetti P, Buglione M, Avitabile R, Spiazzi L, Elengikal S. ..... SM Magrini unpublished

Different results, toxicity, costs ?.....

In general :

✓ PTV coverage of metastases is better with sequential boost (the planning is concentrated on the lesion)

✓ no great differences between VMAT and tomotherapy;

✓ Organ at risk respect is better and simpler with the concomitant boost rather with sequential

Borghetti P, Buglione M, Avitabile R, Spiazzi L, Elengikal S. ..... SM Magrini unpublished

Different results, toxicity, costs ?.....

	A VMAT-SIB			B VMAT-SRS			C TOMO-SIB			D TOMO-SRS		
	HI											
1	0,07											
2	0,09											
3	0,16											
4	0,13											
4	0,12	1,71	0,69	0,04	0,69	NA	0,06	1,62	0,37	0,06	1,12	0,50
5	0,06	3,84	0,22	0,02	4,83	0,51	0,02	1,83	0,46	0,04	1,48	0,46
6	0,05	2,08	0,73	0,06	6,67	0,36	0,04	1,69	0,41	0,04	1,56	0,47
media	**0,10**	**2,99**	**0,60**	**0,04**	**3,64**	**0,35**	**0,04**	**2,14**	**0,36**	**0,08**	**2,05**	**0,61**

- **HI are more or less the same**
- **CI → better results with HT-SRS**
  worse results with VMAT-SRS

Borghetti P, Buglione M, Avitabile R, Spiazzi L, Elengikal S. ..... SM Magrini unpublished

	brain- PTV *boost*				chiasma	brainstem	camera ant dx	camera ant sx	n.ott. dx	n.ott. sx
	V35 (%)	V40 (%)	V45 (%)	V12 (cc)	Dmax	Dmax	Dmax	Dmax	D10	D10
	1 BG									
A VMAT-SIB	2,95	1,03	0,04		34,04	34,67	4,77	4,53	27,28	5,56
B VMAT-SRS				0,00	30,15	30,43	2,45	2,66	30,02	29,84
C TOMO-SIB	2,35	0,85	0,00		30,51	31,41	6,55	6,76	29,54	29,83
D TOMO-SRS				9,01	30,20	30,47	2,49	2,70	30,07	29,89
	2 MS									
A VMAT-SIB	3,56	1,14	0,10		34,16	31,36	4,81	5,31	28,01	25,14
B VMAT-SRS				36,25	30,54	30,84	3,22	4,37	30,71	30,69
C TOMO-SIB	12,63	5,85	0,13		30,37	31,91	3,66	3,89	29,35	29,39
D TOMO-SRS										
A VMAT-SIB	3,43	0								
B VMAT-SRS										
C TOMO-SIB	14,39	5								
D TOMO-SRS				10,65	30,42	30,91	2,61	2,68	29,55	30,21
	4 DG									
A VMAT-SIB	16,88	5,64	0,79		34,76	38,58	2,74	3,03	22,01	23,19
B VMAT-SRS				26,41	38,89	42,87	6,31	3,75	36,29	33,33
C TOMO-SIB	10,68	3,36	0,00		30,50	31,53	3,19	3,04	30,27	30,19
D TOMO-SRS				36,20	32,42	35,25	2,84	2,41	32,05	31,26
	5 DV									
A VMAT-SIB	3,58	1,34	0,07		32,53	33,93	4,13	4,4	28,41	28,39
B VMAT-SRS				87,82	38,45	41,78	7,84	3,60	37,37	30,87
C TOMO-SIB	4,32	1,55	0,00		30,14	30,26	3,98	3,71	29,06	28,26
D TOMO-SRS				16,35	32,57	35,68	3,98	3,86	31,62	31,38
	6 ZL									
A VMAT-SIB	2,58	1,06	0,06		31,81	33,00	3,14		29,22	
B VMAT-SRS				59,56	30,43	30,61	2,44		30,85	
C TOMO-SIB	3,96	0,93	0,00		29,58	30,31	3,01		29,24	
D TOMO-SRS				10,45	30,32	30,50	2,37		30,54	

OAR

- All constrains are respected
- Better “brain” avoidance with SIB

Different results, toxicity, costs ?.....

	Delivery time (seconds)						
	1	2	3	4	5	6	media
A VMAT-SIB	277	193	168	195	237	235	218
B VMAT-SRS	386	419	375	543	578	549	475
C TOMO-SIB	980	247	409	480	485	401	500
D TOMO-SRS	1150	1266	1188	2712	1222	1051	1432

Borghetti P, Buglione M, Avitabile R, Spiazzi L, Elengikal S. ..... SM Magrini unpublished

Different results, toxicity, costs ?.....

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-Not yet clinical results

Next step→ clinical analysis on higher number of patients

Borghetti P, Buglione M, Avitabile R, Spiazzi L, Elengikal S. ..... SM Magrini unpublished

The trail……

- ✓ Brain metastases: background and treatment
- ✓ The basis of hypo-fractionation in brain metastases
- ✓ Modality of hypo-fractionation : stereotactic RT alone;
  WB + stereotactic boost;
  surgery + stereotactic boost;
  concomitant boost.
- ✓ Different techniques means different results, toxicities, costs?

To know the patient
To choose the right treatment

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SRS and SFRT enhance local control; problem: results comparision

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SRS and SFRT enhance local control; problem: results comparision

It doesn't seem

Probably yes...?

- Chose the right treatment for the right patient

We are not so sure…..!

We need much experience

To know the patient
To choose the right treatment

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  tic boost;
  concomitant boost.
- ✓ Different techniques
- ✓ Different technique
- ✓ **Future……..**

SRS and SFRT enhance local control; problem: results comparision

It doesn't seem

Probably yes

Solve clinical problem
→ prospective trials are needed to evaluate -
toxicity/neurotoxicity @ DVH
- clinical advantage

- Chose the right treatment for the right patient

Neurocognitive toxicity

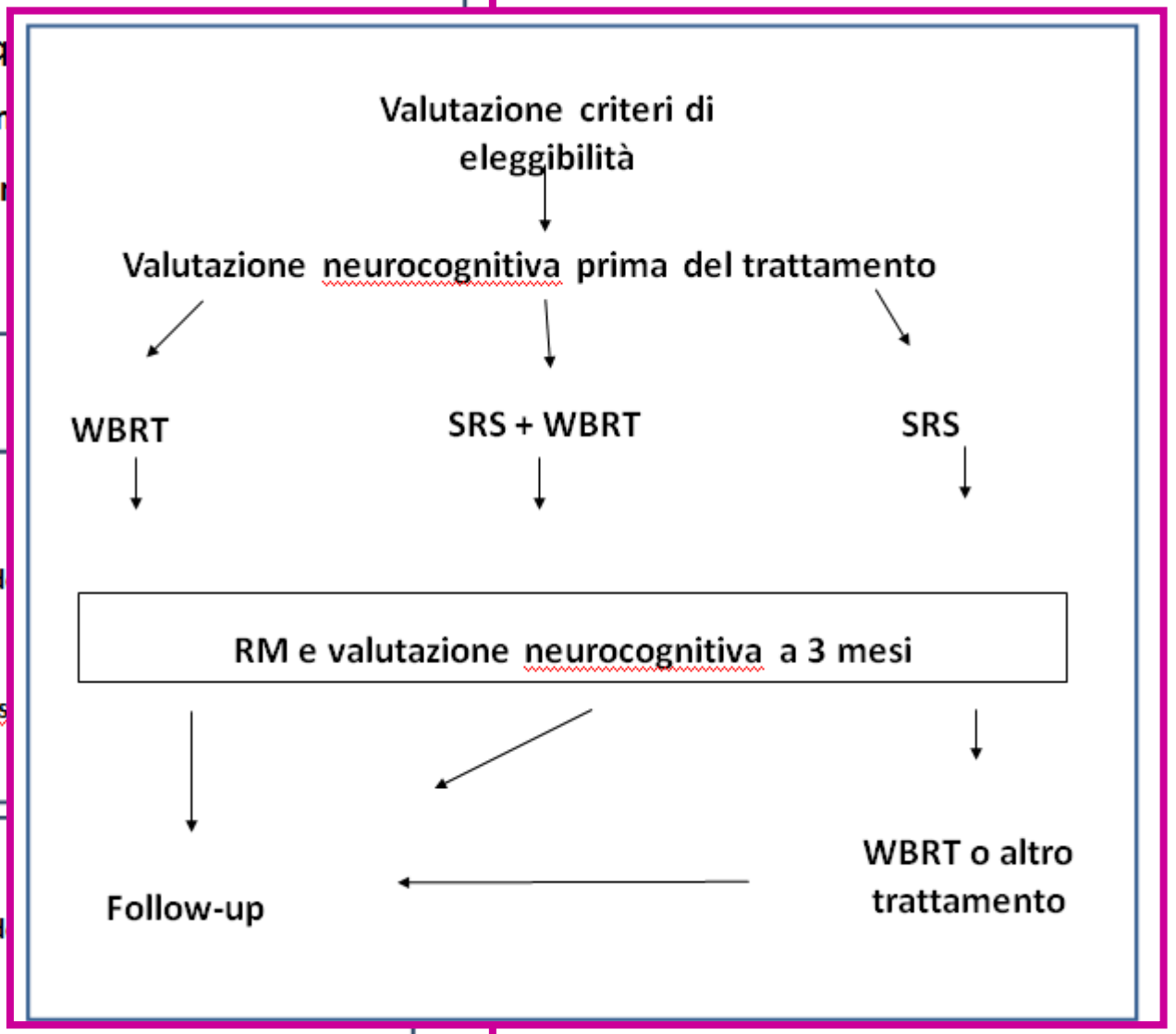
Associazione Italiana Radioterapia Oncologica
Gruppo di Lavoro Neoplasie Cerebrali

Valutazioni neuro-cognitive e q

trattati con radioterapia per r

clinico osservazionale multicer

Studio osservazionale – prospettico



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Dott.ssa Ida Milanesi

Data center:

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Dott.ssa Michela Buglione
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Clinical advantages

- ✓ trials needed to verify clinical advantages
- ✓ not considering/considering differences in techniques to verify better/worse results

Thanks for your attention !!!