CCTG SC.24/TROG 17.06: A Randomized Phase II/III Study Comparing 24gy in 2 Stereotactic Body Radiotherapy (SBRT) Fractions Versus 20gy In 5 Conventional Palliative Radiotherapy (CRT) Fractions for Patients with Painful Spinal Metastases

Arjun Sahgal, MD

Sunnybrook Odette Cancer Centre, University of Toronto

ASTRO ANNUAL MEETING 2020

Disclosures

- Employer: University of Toronto
- Research grants: Elekta, BrainLAB, Varian
- Consulting services: Elekta, Merck, Abbvie, Roche
- Honoraria and Travel Support: Elekta, Medtronic, BrainLAB, Varian, Accuray
- Advisory Board: Varian, VieCURE, ISRS, AOSPINE Tumour Knowledge forum co-chair

- **Full author list**: Arjun Sahgal (PI), Sten Myrehaug, Shankar Siva, Giuseppina L. Masucci, Mathew Foote, Michael Brundage, Jim Butler, Edward Chow, Michael G. Fehlings, Zsolt Gabos, Jeffrey Greenspoon, Marc Kerba, Young Lee, Mitchell Liu, Pejman J. Maralani, Isabelle Thibault, Rebecca K. Wong, Maaike Hum, Keyue Ding, Wendy R. Parulekar

Sunnybrook
ODETTE CANCER CENTRE
A Cancer Care Ontario Partner

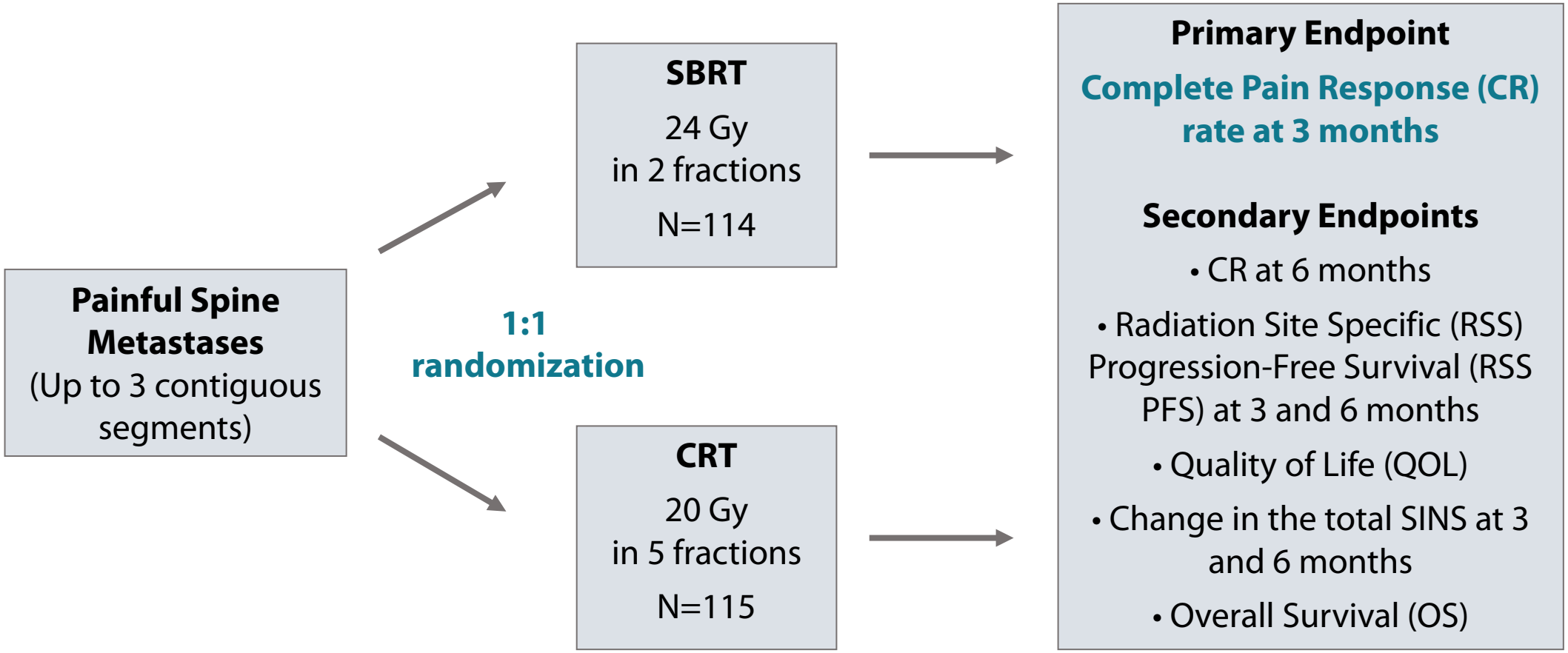
Radiation Oncology
UNIVERSITY OF TORONTO

Canadian Cancer Trials Group
Groupe canadien des essais sur le cancer

Overview

- **Purpose**: For patients with painful spinal metastases, determine if complete pain response rate can be improved with spine SBRT vs. CRT
- SBRT fractionation scheme of 24 Gy in 2 fractions* compared with standard of care CRT regimen of 20 Gy in 5 fractions
- Phase 2/3 randomized controlled trial

Trial Design



Trial Participants

- Initial Phase 2 RCT converted to a Phase 3 RCT without interruption of accrual
- Accrual period: January 2016 – September 2019

	SBRT	CRT	Total
Total patients randomized	114	115	229
Did not receive study treatment	4	10	4
Not evaluable at 3 months	16	22	38
Intent to treat (ITT) analyses	114	115	229
Safety/QA Analyses (as-treated)	110	115	225

Results: Pain Response Rates

	3 Month Assessment		6 Month Assessment	
	SBRT (N=114)	**CRT** (N=115)	**SBRT** (N=114)	**CRT** (N=115)
Complete response	**35%**	**14%**	**32%**	**16%**
Partial response	18%	25%	9%	16%
Stable disease	24%	30%	23%	27%
Progressive disease	6%	12%	4%	7%
Indeterminant	18%	19%	32%	34%
Mean change in total SINS (SD)	**-0.94 (1.69)**	**-0.49 (1.61)**	**-0.73 (1.86)**	**-0.74 (1.99)**

Multivariable Analyses for CR at 3 and 6 months

	3 Month Assessment			6 Month Assessment		
Variable	**Odds Ratio**	**95%CI**	**P Value**	**Odds Ratio**	**95%CI**	**P Value**
SBRT	**3.47**	**1.77-6.80**	**0.0003**	**2.45**	**1.28-4.71**	**0.007**
CRT	**1**			**1**		
Age ≥ 65	1.58	0.82-3.06	0.17	0.65	0.34-1.25	0.20
Age < 65	1			1		
Male	1.33	0.54-3.26	0.54	1.39	0.56-3.45	0.48
Female	1			1		
ECOG 2	0.74	0.19-2.89	0.67	0.39	0.08-1.86	0.24
ECOG 0 or 1	1			1		
Pain Score at Baseline						
8 to 10	0.92	0.39-2.20	0.85	1.39	0.60-3.21	0.44
5 to 7	0.74	0.36-1.54	0.43	0.94	1.45-1.96	0.86
2 to 4	1			1		
Primary Cancer:						
GU (excluding RCC)	1.22	0.32-4.65	0.77	0.99	0.26-3.79	0.99
Lung	1.49	0.54-4.08	0.44	0.96	0.36-2.63	0.95
Other	0.58	0.09-3.77	0.57	0.74	0.14-3.86	0.72
Breast	1			1		
Total baseline SINS						
7 to 12	1.12	0.58-2.15	0.57	0.91	0.48-1.71	0.78
≤ 6	1			1		

Conclusions

- This is the first Phase 3 randomized trial to show that dose escalation with modern radiation therapy techniques improves pain outcomes for patients with spinal bone metastases
- Spine SBRT is superior to CRT and achieved a 21% absolute increase in the CR to pain at 3 months, which was durable at 6 months and statistically significant
- A regimen of 24 Gy in 2 SBRT fractions was safe, non-destabilizing and associated with better patient financial perception