

Gender difference in pain and patient reported outcomes: a secondary analysis of the NCIC CTG SC.20 randomized trial

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Objective

- Assess whether there exists a difference in pain between men and women with advanced cancer

Methods

- Secondary analysis of the NCIC Clinical Trials Group Symptom Control Trial SC.20 (NCIC CTG SC.20), which was a non-blinded, randomized, controlled trial that investigated the efficacy and safety of single versus multiple fraction e-irradiation
- Patients were accrued between January 2004 and May 2012 from nine countries
- Adults diagnosed with cancer reporting pain corresponding to sites of previously irradiated, radiologically confirmed bone metastases were eligible
- Scores from the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire Core 30 (QLQ-C30) and Brief Pain Inventory (BPI) at baseline and 2 months post-radiotherapy were analysed
- Subgroup analyses were carried out amongst responders and non-responders
- Due to multiple comparisons, p-values less than 0.01 were considered statistically significant

Conclusions

- In cancer patients with bone metastases undergoing re-irradiation, there may be a gender difference in pain severity
- There was no significant difference in response to radiation
- Despite equivalent pain responses, women were more likely to report improved QOL after treatment

Results

- There were 847 evaluable patients - 499 were men and 358 were women
- Males were more likely to experience mild pain at baseline
- There was no difference in response to radiotherapy at 2 months post-treatment
- Female responders reported better improvement in general activity, mood, walking ability, normal work and relation with other people as opposed to female non-responders
- Male responders noted better improvement in all BPI items
- Female responders recorded better improvement in physical/role/emotional functioning, pain and global quality of life
- Male responders noted similar improvements as female responders

Patient demographics and baseline characteristics

Primary Cancer Site	Males	Females
Breast	3(0.6)	220(63.4)
Lung	121(24.2)	69(19.9)
Prostate	229(45.8)	0(0.0)
Others	147(29.4)	58(16.7)

Karnofsky performance status (KPS)

Score	Males	Females
50-60	106 (21.2)	75 (21.6)
70-80	279 (55.8)	187 (53.9)
90-100	107 (21.4)	82 (23.6)
Unknown	8 (1.6)	3 (0.9)

Worst pain score at baseline

Score	Males	Females
1 to 4	79 (15.8)	23 (6.6)
5 to 8	310 (62.0)	239 (68.9)
9 to 10	96 (19.2)	74 (21.3)
Unknown	15 (3.0)	11 (3.2)

Site of painful bone metastases

Site	Males	Females
Spine or Head and Neck	183 (36.6)	124 (35.7)
Pelvis/Hips	172 (34.5)	135 (38.9)
Upper or lower limbs	69 (13.8)	60 (17.3)
Superficial bones	75 (15.0)	28 (8.1)
Unknown	1 (0.2)	0 (0.0)

Baseline total daily oral morphine equivalent (OME) (mg)

Statistic	Males	Females
N	479	337
Mean (SD)	131.6(324.9)	139(291)
Range	0-4130	0-3120

Changes in BPI scores for responders and non-responders

Domain	Responders			Non-responders			P value
	N	Mean	SD	N	Mean	SD	
General activity	123	-2.9	3.4	101	-2.6	3.4	0.53
Mood	123	-2.3	3.1	101	-2.4	3.1	0.75
Walking ability	122	-2.1	3.4	100	-2.2	3.4	0.88
Normal work	122	-2.2	3.5	102	-2.5	3.5	0.43
Relationships with others	123	-1.8	3.0	101	-1.3	3.0	0.18
Sleeping	123	-2.1	2.9	102	-2.1	2.9	0.95
Enjoyment of life	120	-2.2	3.0	102	-1.9	3.0	0.42

Baseline scores from BPI and C30

BPI Domain	Males			Females			P value
	N	Mean	SD	N	Mean	SD	
General activity	460	5.8	2.9	320	6.1	2.9	0.21
Mood	459	4.3	2.9	322	4.8	2.9	0.02
Walking ability	457	5.5	3.2	321	5.7	3.2	0.36
Normal work	453	6.1	3.1	322	6.7	3.1	0.01
Relationships with others	460	3.3	2.9	322	3.3	2.9	0.88
Sleeping	460	4.2	3.1	323	4.5	3.1	0.32
Enjoyment of life	460	5.3	3.3	321	5.5	3.3	0.32

Changes in BPI and EORTC QLQ-C30 scores at month 2 from baseline

BPI Changes Domain	Males			Females			P value
	N	Mean	SD	N	Mean	SD	
General activity	296	-1.4	3.6	219	-1.6	3.6	0.35
Mood	293	-1.0	3.5	220	-1.6	3.5	0.05
Walking ability	294	-0.8	3.5	219	-1.5	3.5	0.02
Normal work	288	-0.9	3.7	221	-1.7	3.7	0.02
Relationships with others	296	-0.7	3.4	219	-0.6	3.4	0.70
Sleeping	297	-1.2	3.3	221	-1.6	3.3	0.18
Enjoyment of life	291	-0.8	3.7	218	-1.5	3.7	0.03

Changes in EORTC QLQ-C30 scores for responders and non-responders

Domain	Responders			Non-responders			P value
	N	Mean	SD	N	Mean	SD	
Physical functioning	82	5.6	18.3	87	-2.0	18.3	0.01
Role functioning	82	12.0	28.2	87	0.2	28.2	0.01
Emotional functioning	78	8.9	21.1	87	0.1	21.1	0.01
Cognitive functioning	81	2.5	19.7	87	1.0	19.7	0.66
Social functioning	81	8.0	26.0	86	2.5	26.0	0.19
Fatigue	78	-7.5	26.7	87	-0.5	26.7	0.07
Nausea and vomiting	78	-3.4	21.7	86	-1.2	21.7	0.57
Pain	75	-28.9	27.2	84	-7.3	27.2	<0.01
Dyspnea	81	2.9	33.0	87	2.3	33.0	0.91
Sleep	78	-16.2	33.4	87	-7.7	33.4	0.1
Appetite	78	-9.8	27.5	87	1.9	27.5	0.03
Constipation	77	-8.7	32.2	87	-3.1	32.2	0.32
Diarrhea	77	7.4	25.1	86	-0.4	25.1	0.06
Financial	81	-1.2	25.5	87	-2.3	25.5	0.78
Global QOL	79	8.2	24.3	85	-1.5	24.3	0.01

Changes in EORTC QLQ-C30 scores for responders and non-responders (Males)

Domain	Responders			Non-responders			P value
	N	Mean	SD	N	Mean	SD	
Physical functioning	90	7.9	18.8	115	-6.4	18.8	<0.01
Role functioning	90	8.3	32.2	115	-8.8	32.2	<0.01
Emotional functioning	88	9.4	21.2	112	-0.6	21.2	<0.01
Cognitive functioning	89	7.7	18.1	115	-2.0	18.1	<0.01
Social functioning	88	6.3	29.7	112	-6.8	29.7	<0.01
Fatigue	90	-6.7	24.1	114	6.7	24.1	<0.01
Nausea and vomiting	90	-1.7	24.0	114	3.7	24.0	0.13
Pain	90	-27.4	26.7	112	-6.3	26.7	<0.01
Dyspnea	90	1.1	26.2	113	1.8	26.2	0.86
Sleep	89	-15.0	32.6	114	-6.7	32.6	0.09
Appetite	90	-2.2	36.0	114	6.1	36.0	0.11
Constipation	89	-9.0	29.2	112	-1.5	29.2	0.11
Diarrhea	90	5.6	21.9	115	5.8	21.9	0.95
Financial	88	0.8	19.6	112	4.2	19.6	0.28
Global QOL	88	8.0	23.0	108	-4.9	23.0	<0.01

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