



RTOG 0129

Report Based on Data Through: 02/28/2019

A Phase III Trial of Concurrent Radiation and Chemotherapy (Followed by Surgery for Residual Primary/N2-3 Nodal Disease) for Advanced Head and Neck Carcinoma

S	<u>Tumor Site</u>	R	<u>Arm 1:</u>	6-8 weeks post-RT/chemo	<u>Selected Patients:</u>
T	1. Larynx	A	Standard Fractionation (SFX): 70 Gy / 35 fx for 7weeks		Surgery
R	2. Non-larynx	N	plus cisplatin: 100 mg/m ² on days 1, 22, and 43	<u>All Patients:</u>	Residual primary: Surgical removal
A	<u>Nodal Stage</u>	D		CT Scan: To reassess primary and nodal disease	N1/Residual Disease: Neck dissection
T	1. N0	O	<u>Arm 2:</u>		
I	2. N1or N2a-b	M	Accelerated Fractionation by Concomitant Boost (AFX-C): 72 Gy/42 fx for 6 weeks	If suspicion of relapse: Directed biopsy	N2-N3 Disease: Mandatory neck dissection
F	<u>Zubrod Performance Status</u>	E	plus cisplatin: 100 mg/m ² on days 1 and 22		
Y	1. 0				
	2. 1				

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Activated: 07/30/2002

Closed: 06/23/2005

Status: Follow-up, primary endpoint published

- **Study Description**

RTOG 0129 is a phase III trial comparing standard fractionation radiation therapy with cisplatin to accelerated fractionation radiation therapy with cisplatin for patients with locally advanced squamous cell carcinoma of the head and neck. The primary endpoint is overall survival.

- **Patient Accrual**

RTOG 0129 opened to patient accrual on July 30, 2002 and closed on June 23, 2005, after accruing a total of 743 patients (Table 1). The average monthly accrual in the last 6 months when the trial was open was 26.3 compared to a projected rate of 13.3. Median follow-up time for vital status is 6.1 years.

- **Adverse Events**

Chemotherapy and acute radiation (≤ 90 days) toxicities were graded using CTC version 2.0. Late radiation toxicities were graded using the RTOG/EORTC Late Radiation Morbidity Scoring Scheme. As of February 28, 2019, grade 4-5 chemotherapy and acute radiation toxicities were experienced by 73 (20.2%) and 55 (15.4%) patients on the SFX+cisplatin and AFX-C+cisplatin arms, respectively (Table 2). There were no new grade 5 chemotherapy or acute radiation events since the last report. Grade 4 late radiation toxicities were experienced by 21 (6.0%) and 34 (9.9%) patients on the SFX+cisplatin and AFX-C+cisplatin arms, respectively (Table 3). There were more grade 4 acute blood/bone marrow toxicities on the SFX+cisplatin arm [26 (7.2%)] than on the AFX-C+cisplatin arm [19 (5.3%)] (Table 4). Also, there were more grade 4 acute gastrointestinal toxicities on the SFX+cisplatin arm [25 (6.9%)] than on the AFX-C+cisplatin arm [15 (4.2%)]. Conversely, on the AFX-C+cisplatin arm, 13 patients (3.8%) had grade 4 late bone toxicities compared to 7 (2.0%) on the SFX+cisplatin arm (Table 5). In addition, on the AFX-C+cisplatin arm, 11 (3.2%) patients had grade 4 late mucous membrane toxicities compared to 4 (1.1%) on the SFX+cisplatin arm. No grade 5 late toxicities have been reported up to the report date.

Table 1
Case Status

	SFX+cisplatin	AFX-C+cisplatin	Total
Total patients entered	372	371	743
Ineligible	9	8	17
Withdrew consent	2	2	4
Eligible/pending	361	361	722
With on-study information	361	361	722
With toxicity information	361	357	718
No protocol treatment	0	4	4

4 patients received no study treatment and are not included in adverse event tables.

Table 2
Summary of Worst Toxicity per Patient
Chemotherapy and Acute Radiotherapy Toxicity

Toxicity	Grade	SFX+cisplatin (n=361)	AFX-C+cisplatin (n=357)
Worst non-hematologic	1	4 (1.1%)	6 (1.7%)
	2	79 (21.9%)	70 (19.6%)
	3	222 (61.5%)	231 (64.7%)
	4	51 (14.1%)	40 (11.2%)
	5	2 (0.6%)	5 (1.4%)
Worst overall	1	0 (0.0%)	5 (1.4%)
	2	56 (15.5%)	58 (16.2%)
	3	230 (63.7%)	236 (66.1%)
	4	71 (19.7%)	50 (14.0%)
	5	2 (0.6%)	5 (1.4%)

Table 3
Summary of Worst Toxicity per Patient
Late Radiotherapy Toxicity

Grade	SFX+cisplatin (n=350)	AFX-C+cisplatin (n=342)
1	48 (13.7%)	39 (11.4%)
2	166 (47.4%)	160 (46.8%)
3	64 (18.3%)	70 (20.5%)
4	21 (6.0%)	34 (9.9%)
5	0 (0.0%)	0 (0.0%)

Table 4
Number of Patients with a Toxicity by Category, Term, and Grade
Chemotherapy and Acute Radiotherapy Toxicity

Category Term	SFX+cisplatin (n=361) Grade					AFX-C+cisplatin (n=357) Grade				
	1	2	3	4	5	1	2	3	4	5
ALLERGY/IMMUNOLOGY	2	0	0	0	0	0	0	0	0	0
Rhinitis allergic NOS	2	0	0	0	0	0	0	0	0	0
AUDITORY/HEARING	17	76	9	1	0	23	48	7	0	0
Hearing impaired	4	52	8	1	0	7	24	5	0	0
Hearing-Other	18	32	3	0	0	23	29	2	0	0
Otitis externa (exc boil of meatus) NOS	3	3	0	0	0	2	1	0	0	0
Otitis media serous NOS	1	5	0	0	0	1	2	2	0	0
BLOOD/BONE MARROW	63	124	132	26	0	89	120	103	19	0
Bone marrow depression NOS	1	1	0	0	0	0	0	0	0	0
CD4 lymphocytes decreased	0	0	0	0	0	0	1	0	0	0
Hematologic-Other	13	2	0	0	0	8	4	0	0	0
Hemoglobin decreased	162	132	29	4	0	186	95	21	3	0
Hemoglobin for leukemia	0	0	0	0	0	1	0	0	0	0
Leukocytes for BMT	1	0	0	0	0	1	0	0	0	0
Leukopenia NOS	66	131	94	14	0	67	111	65	13	0
Lymphopenia	5	16	27	0	0	6	15	21	1	0
Neutropenia	55	82	79	17	0	54	54	60	14	0
Neutrophils/granulocytes for BMT	1	0	0	0	0	0	1	0	0	0
Packed red blood cell transfusion	0	0	7	0	0	0	0	7	0	0
Platelet count decreased	77	12	13	1	0	64	14	9	0	0
Platelet transfusion	0	0	0	0	0	0	1	0	0	0
CARDIOVASCULAR (ARRHYTHMIA)	2	4	2	1	0	3	2	1	0	0
Arrhythmia NOS	1	0	0	0	0	1	0	0	0	0
Atrioventricular block NOS	0	0	0	0	0	0	1	0	0	0
Palpitations	1	3	1	0	0	1	1	0	0	0
Sinus tachycardia	0	0	0	0	0	1	0	0	0	0
Supraventricular arrhythmia NOS	0	1	0	1	0	0	0	0	0	0
Vasovagal attack	0	0	1	0	0	0	0	1	0	0
CARDIOVASCULAR (GENERAL)	15	13	11	3	0	17	16	10	3	0
Cardiac troponin T increased	0	0	0	1	0	0	0	0	0	0
Circulatory or cardiac-Other	0	1	3	0	0	1	2	0	1	0
Edema NOS	9	4	1	0	0	14	5	0	0	0
Hypertension NOS	2	0	1	0	0	2	4	0	0	0
Hypotension NOS	7	8	7	0	0	3	7	7	1	0

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Chemotherapy and Acute Radiotherapy Toxicity

Category	SFX+cisplatin (n=361) Grade					AFX-C+cisplatin (n=357) Grade				
Term	1	2	3	4	5	1	2	3	4	5
Myocardial ischaemia	1	1	0	1	0	0	1	1	1	0
Thrombosis NOS	0	0	2	2	0	0	0	1	0	0
Visceral arterial ischaemia	0	0	0	0	0	0	0	1	0	0
COAGULATION	3	1	0	0	0	3	1	0	0	0
Activated partial thromboplastin time prolonged	1	0	0	0	0	0	0	0	0	0
Coagulation disorder NOS	0	1	0	0	0	1	0	0	0	0
Prothrombin time prolonged	2	0	0	0	0	1	0	0	0	0
Thrombotic microangiopathy NOS	0	0	0	0	0	1	0	0	0	0
Thrombotic microangiopathy for BMT	0	0	0	0	0	0	1	0	0	0
CONSTITUTIONAL SYMPTOMS	63	139	52	1	0	75	138	29	4	0
Constitutional symptoms-Other	0	2	1	0	0	4	1	1	0	0
Fatigue	76	104	31	1	0	82	103	12	4	0
Pyrexia	23	6	2	0	0	24	6	3	0	0
Rigors	10	1	0	0	0	9	1	0	0	0
Sweating increased	4	2	0	0	0	3	2	0	0	0
Weight decreased	62	92	19	0	0	59	79	16	0	0
Weight increased	4	0	0	0	0	1	1	0	0	0
DERMATOLOGY/SKIN	84	164	31	0	0	80	149	33	2	0
Alopecia	20	4	1	0	0	13	2	0	0	0
Culture wound negative	1	0	0	0	0	0	0	0	0	0
Culture wound positive	0	2	0	0	0	1	2	2	0	0
Dermatitis exfoliative NOS	12	6	2	0	0	9	9	3	0	0
Dermatitis radiation NOS	71	144	29	0	0	66	131	29	2	0
Dry skin	7	0	0	0	0	4	2	0	0	0
Erythema multiforme	4	3	0	0	0	3	8	0	0	0
Injection site reaction NOS	0	1	0	0	0	3	0	0	0	0
Localized exfoliation	1	0	0	0	0	1	0	0	0	0
Nail abnormality NOS	1	0	0	0	0	0	0	0	0	0
Photosensitivity reaction NOS	0	0	0	0	0	1	0	0	0	0
Pruritus NOS	1	0	0	0	0	4	0	0	0	0
Rash/desquamation for BMT	0	1	0	0	0	1	1	0	0	0
Skin discoloration	12	1	0	0	0	14	0	0	0	0
Skin-Other	16	11	1	0	0	10	3	0	0	0
Toxicoderma	7	2	0	0	0	1	1	0	0	0
Urticaria NOS	0	0	0	0	0	1	0	0	0	0

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Category	SFX+cisplatin (n=361) Grade					AFX-C+cisplatin (n=357) Grade				
Term	1	2	3	4	5	1	2	3	4	5
ENDOCRINE	2	8	1	0	0	2	4	0	0	0
Endocrine-Other	2	3	1	0	0	0	2	0	0	0
Hypothyroidism	0	3	0	0	0	1	2	0	0	0
Menopausal symptoms	0	2	0	0	0	1	0	0	0	0
GASTROINTESTINAL	11	115	202	25	0	18	103	212	15	0
Anorexia	33	46	14	13	0	34	29	14	8	0
Constipation	28	36	9	0	0	27	21	6	0	0
Dehydration	22	105	76	0	0	12	82	67	0	0
Diarrhea (with colostomy)	0	1	0	0	0	0	0	0	0	0
Diarrhea NOS	28	6	7	0	0	17	10	2	0	0
Diarrhea for BMT	0	1	0	0	0	0	0	0	0	0
Dry mouth	65	119	1	0	0	63	90	3	0	0
Dyspepsia	10	7	1	0	0	7	3	0	0	0
Dysphagia	12	54	79	3	0	14	46	75	1	0
Esophageal spasm	12	32	37	0	0	14	32	29	2	0
Esophagitis NOS	23	80	28	2	0	24	55	48	0	0
Fistula-pharyngeal	0	0	0	0	0	0	0	1	0	0
Flatulence	0	0	0	0	0	1	0	0	0	0
GI-other	7	10	3	0	0	8	7	2	0	0
Gastritis NOS	0	1	0	0	0	0	0	0	0	0
Ileus	0	0	1	0	0	0	0	0	0	0
Nausea	77	89	72	0	0	79	92	52	0	0
Pancreatitis NOS	0	0	1	0	0	0	0	1	0	0
Parosmia	0	2	0	0	0	0	1	0	0	0
Radiation mucositis	47	124	133	8	0	58	129	112	5	0
Salivary gland disorder NOS	36	84	1	0	0	46	70	0	0	0
Stomatitis	7	20	6	1	0	7	13	2	0	0
Stomatitis/pharyngitis for BMT	1	0	1	0	0	1	0	0	0	0
Taste disturbance	45	67	2	0	0	50	66	1	0	0
Tracheo-oesophageal fistula NOS	0	0	1	0	0	0	0	0	0	0
Vomiting NOS	44	61	66	0	0	52	65	42	0	0
HEMORRHAGE	11	1	0	0	1	8	2	2	1	2
Epistaxis	0	0	0	0	0	2	0	0	0	0
Hematemesis	2	0	0	0	0	0	0	1	1	0
Hematuria present	0	0	0	0	0	2	0	0	0	0
Hemoptysis	7	0	0	0	0	3	1	0	0	0
Hemorrhage-Other	1	0	0	0	1	1	0	0	1	1

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Category Term	SFX+cisplatin (n=361) Grade					AFX-C+cisplatin (n=357) Grade				
	1	2	3	4	5	1	2	3	4	5
Hemorrhage-bleeding with grade 3 or 4 thrombocy	0	1	0	0	0	0	0	0	0	0
Hemorrhagic stroke	0	0	0	0	0	0	0	0	0	1
Melaena	1	0	0	0	0	0	0	0	0	0
Petechiae	0	0	0	0	0	0	0	1	0	0
Rectal bleeding	1	0	0	0	0	0	1	0	0	0
HEPATIC	74	40	9	1	0	60	35	4	0	0
Alanine aminotransferase increased	22	7	3	0	0	31	1	2	0	0
Aspartate aminotransferase increased	21	4	2	0	0	25	2	2	0	0
Blood albumin decreased	45	30	4	0	0	29	33	2	0	0
Blood alkaline phosphatase NOS increased	25	2	0	1	0	12	1	0	0	0
Blood bilirubin increased	9	5	1	0	0	13	1	0	0	0
Gamma-glutamyltransferase increased	2	0	0	0	0	1	0	0	0	0
Hepatic failure	1	0	0	0	0	0	0	0	0	0
Hepatic-Other	7	0	0	0	0	3	1	0	0	0
INFECTION FEBRILE NEUTROPENIA	7	31	35	1	0	3	34	37	2	2
Febrile neutropenia	0	0	15	0	0	0	0	18	0	0
Implant infection	0	1	3	0	0	0	0	0	0	0
Infection NOS	1	18	13	0	0	0	27	7	1	0
Infection with grade 3 or 4 neutropenia	0	1	4	1	0	0	0	10	1	2
Infection with unknown ANC	0	1	0	0	0	0	2	2	0	0
Infection, Other	8	12	5	0	0	6	9	2	0	0
LYMPHATICS	1	3	1	0	0	5	1	0	0	0
Lymphangiopathy NOS	1	2	0	0	0	3	0	0	0	0
Lymphatics-Other	0	1	1	0	0	2	1	0	0	0
METABOLIC/LABORATORY	128	39	67	15	1	114	28	49	13	0
Alkalosis NOS	1	0	0	0	0	0	0	0	0	0
Blood amylase increased	1	1	1	0	0	1	0	0	0	0
Blood bicarbonate decreased	3	0	0	0	0	4	0	0	0	0
Blood creatine phosphokinase increased	0	1	0	1	0	1	0	0	0	0
Blood magnesium decreased	74	18	4	0	0	63	8	0	2	0
Hypercalcemia	8	3	3	0	0	8	1	1	0	0
Hypercholesterolemia	1	0	0	0	0	0	0	0	0	0
Hyperglycemia NOS	43	19	11	2	0	38	16	4	0	0
Hyperkalemia	35	8	7	0	0	18	5	4	1	0

Table 4
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Chemotherapy and Acute Radiotherapy Toxicity

Category	SFX+cisplatin (n=361) Grade					AFX-C+cisplatin (n=357) Grade				
Term	1	2	3	4	5	1	2	3	4	5
Hypermagnesemia	6	2	4	0	0	4	0	2	0	0
Hypernatremia	9	1	3	0	0	5	0	1	0	0
Hyperuricemia	11	1	1	2	0	11	1	2	3	0
Hypocalcemia	41	29	3	1	0	31	19	3	0	0
Hypoglycaemia NOS	10	1	0	0	0	4	3	1	0	0
Hypokalemia	70	2	23	5	0	58	3	12	7	0
Hyponatremia	95	4	31	9	1	73	5	30	3	0
Hypophosphatemia	6	2	6	0	0	3	0	4	0	0
Lipase increased	0	0	1	0	0	0	0	0	0	0
Metabolic-Other	22	3	2	0	0	21	9	0	0	0
MUSCULOSKELETAL	18	12	4	1	0	19	13	3	1	0
Arthritis NOS	2	0	0	0	0	1	1	0	0	0
Joint, muscle, or bone-Other	11	10	2	0	0	11	8	1	1	0
Muscle weakness NOS	6	3	2	0	0	7	5	1	0	0
Myositis	0	0	0	0	0	0	1	0	0	0
Osteonecrosis	0	0	0	1	0	1	0	1	0	0
NEUROLOGY	47	40	18	1	0	32	32	12	1	1
Amnesia NEC	0	0	0	0	0	3	1	1	0	0
Anxiety NEC	1	2	1	0	0	5	4	1	0	0
Arachnoiditis	1	0	0	0	0	1	0	0	0	0
Ataxia NEC	0	0	0	0	0	0	1	0	0	0
Cerebral ischaemia	0	0	0	1	0	0	0	0	1	1
Confusion	1	0	0	0	0	1	1	2	0	0
Depressed level of consciousness	0	1	0	0	0	0	0	0	0	0
Depression NEC	5	13	3	0	0	5	13	2	0	0
Dizziness (exc vertigo)	5	4	4	0	0	7	7	1	0	0
Extrapyramidal disorder NEC	0	0	0	0	0	2	0	0	0	0
Insomnia NEC	9	11	1	0	0	7	10	0	0	0
Learning disorder NOS	1	0	0	0	0	1	1	0	0	0
Neurologic-Other	4	1	1	0	0	2	4	1	0	0
Peripheral motor neuropathy	4	7	1	0	0	2	2	1	0	0
Peripheral sensory neuropathy	42	14	2	0	0	21	8	0	0	0
Personality change	0	1	0	0	0	0	0	0	0	0
Speech disorder NEC	0	1	0	0	0	1	1	0	0	0
Syncope	0	0	7	0	0	0	0	5	0	0
Tremor NEC	0	0	0	0	0	0	1	0	0	0
Vertigo NEC	1	0	0	0	0	0	0	0	0	0

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Category Term	SFX+cisplatin (n=361) Grade					AFX-C+cisplatin (n=357) Grade				
	1	2	3	4	5	1	2	3	4	5
OCULAR/VISUAL	2	7	0	0	0	1	3	0	0	0
Conjunctivitis NEC	1	0	0	0	0	0	0	0	0	0
Diplopia	0	2	0	0	0	0	0	0	0	0
Dry eye NEC	1	0	0	0	0	0	0	0	0	0
Lacrimation increased	1	1	0	0	0	1	0	0	0	0
Ocular-Other	1	0	0	0	0	0	1	0	0	0
Vision blurred	2	5	0	0	0	0	2	0	0	0
PAIN	38	115	39	1	0	35	121	41	1	0
Abdominal pain NOS	3	1	0	0	0	0	3	0	0	0
Arthralgia	2	3	0	0	0	1	1	1	0	0
Bone pain	1	1	0	0	0	1	1	0	0	0
Chest pain	0	0	1	0	0	3	1	0	0	0
Dyspareunia NEC	0	0	0	0	0	1	0	0	0	0
Earache	4	1	0	0	0	2	6	0	0	0
Headache NOS	7	5	2	0	0	6	4	3	0	0
Myalgia	2	2	0	0	0	3	5	1	0	0
Neuralgia NOS	0	1	0	0	0	2	0	0	0	0
Pain due to radiation	24	99	29	1	0	22	95	32	0	0
Pain-other	19	26	9	0	0	15	26	7	1	0
Pleuritic pain	0	1	0	0	0	0	1	0	0	0
Proctalgia	0	0	0	0	0	0	0	1	0	0
Tumour pain	1	3	0	0	0	0	2	1	0	0
PULMONARY	59	41	14	5	0	45	39	14	6	0
Adult respiratory distress syndrome	0	0	0	0	0	0	0	0	2	0
Apnoea	0	0	1	0	0	0	0	0	0	0
Cough	23	5	0	0	0	22	10	2	0	0
Dysphonia	47	24	4	3	0	31	19	6	0	0
Dyspnea NOS	2	9	3	1	0	3	8	4	1	0
Hiccups	8	6	0	0	0	7	2	0	0	0
Hypoxia	0	0	0	0	0	0	2	1	1	0
Pleural effusion	0	0	1	0	0	0	0	0	0	0
Pneumonitis NOS	1	0	3	2	0	4	2	3	0	0
Pneumothorax NOS	0	0	0	0	0	0	1	0	0	0
Pulmonary fibrosis	1	0	0	0	0	0	0	0	0	0
Pulmonary-other	1	6	4	0	0	2	1	2	2	0

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Category Term	SFX+cisplatin (n=361) Grade					AFX-C+cisplatin (n=357) Grade				
	1	2	3	4	5	1	2	3	4	5
RENAL/GENITOURINARY	82	55	19	3	0	57	36	13	1	0
Blood creatinine increased	65	47	14	2	0	44	32	9	1	0
Dysuria	2	0	0	0	0	0	0	0	0	0
Proteinuria present	1	0	0	0	0	1	1	0	0	0
Renal failure NOS	0	5	1	1	0	1	4	1	0	0
Renal/GU-Other	24	12	7	0	0	16	7	3	0	0
Urinary frequency	3	0	0	0	0	1	0	0	0	0
Urinary incontinence	1	0	0	0	0	0	0	1	0	0
Urinary retention	0	1	1	0	0	1	2	0	0	0
SECOND MALIGNANCY	0	1	0	0	0	1	0	0	0	0
Secondary malignancy, Other	0	1	0	0	0	1	0	0	0	0
SEXUAL/REPRODUCTIVE FUNCTION	2	2	0	0	0	0	0	0	0	0
Impotence	0	1	0	0	0	0	0	0	0	0
Infertility female	1	0	0	0	0	0	0	0	0	0
Sexual/reproductive function-Other	1	1	0	0	0	0	0	0	0	0
SYNDROMES	0	1	0	0	0	0	0	0	0	0
Syndromes-Other	0	1	0	0	0	0	0	0	0	0
PENDING CLARIFICATION OF TERM	0	0	1	0	0	0	0	0	0	0

Toxicities were graded with CTC version 2.0.

Table 5
Number of Patients with a Toxicity by Type and Grade
Late Radiotherapy Toxicity

Toxicity	SFX+cisplatin (n=350) Grade					AFX-C+cisplatin (n=342) Grade				
	1	2	3	4	5	1	2	3	4	5
Bone (incl. osteonecrosis)	11	7	10	7	0	15	9	7	13	0
Brain	11	2	0	1	0	15	2	1	0	0
Esophagus	76	43	31	2	0	73	60	37	3	0
Joint	37	10	1	0	0	43	13	5	0	0
Larynx	98	54	11	4	0	87	38	13	6	0
Mucous membrane	83	55	1	4	0	87	52	3	11	0
Other	60	85	29	5	0	61	80	31	4	0
Salivary gland (xerostomia, taste impairment)	94	161	15	0	0	75	178	19	0	0
Skin (within RT field)	114	28	7	0	0	112	35	2	0	0
Spinal cord	12	3	0	0	0	18	2	1	0	0
Subcutaneous tissue (within RT field)	83	66	9	2	0	86	78	7	3	0

Toxicities were graded with RTOG/EORTC Late Radiation Morbidity Scoring Schema.