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Authors

Chase, Dana M
Kauderer, James
Wenzel, Lari
et al.

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Factors Associated With Grade 3-4 Treatment-Related Toxicity In Women With Advanced Or Recurrent Cervical Cancer: An Exploratory Analysis Of NRG Oncology/Gynecologic Oncology Group Trials (GOG) 179 And 204

Dana M. Chase, MD[1], **James Kauderer, MA**[2], **Lari Wenzel, PhD**[3], **Lois Ramondetta, MD**[4], **David Cella, PhD**[5], **Harry J. Long III, MD**[6,*], and **Bradley J. Monk, MD**[7]

[1]Creighton University School of Medicine at the University of Arizona Cancer Center at St. Joseph's Hospital and Medical Center, Phoenix, AZ

[2]NRG Oncology/Gynecologic Oncology Group Statistics & Data Management Center; Roswell Park Cancer Institute, Buffalo, NY

[3]University of California at Irvine - Irvine, CA

[4]MD Anderson Cancer Center; Houston, TX

[5]Northwestern University/Prentice Women's Hospital, Chicago, IL

[6]Mayo Clinic, Rochester, MN

[7]Creighton University School of Medicine at the University of Arizona Cancer Center at St. Joseph's Hospital and Medical Center, Phoenix, AZ

Abstract

Objective—To describe pretreatment patient characteristics and baseline quality of life (QoL) scores as they relate to the development of grade 3-4 toxicity in patients receiving chemotherapy for advanced/recurrent cervical cancer.

Methods—The study sample was drawn from Gynecologic Oncology Group (GOG) protocols 179 and 204. Grade 3 or 4 toxicities were considered in four specified categories: peripheral neuropathy, fatigue, hematologic and gastrointestinal. The data variables explored included age, stage, pretreatment radiation, performance status (PS) at treatment initiation and baseline FACT-Cx (Functional Assessment of Cancer Therapy-Cervix) score. A logistic regression model was developed with various adverse events as binary [0/1] outcomes.

Results—Six-hundred-seventy-three patient-reported questionnaires were used in the analyses. At baseline, pain was the most severe patient-reported symptom. Baseline line-item patient

Corresponding Author: Dana M. Chase, MD, Assistant Professor, Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, University of Arizona Cancer Center, Creighton University School of Medicine at, St. Joseph's Hospital and Medical Center, a Dignity Health Member, 500 W. Thomas Road, Suite 600, Phoenix, AZ 85013, Phone: 602-406-7730, Fax: 602-798-0807, Dana.chase@chw.edu.

*Dr. Long passed away in January 2013

Harry J. Long III (deceased)

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concerns did demonstrate specific correlations with the development of individual toxicities. In 401 patients were enrolled on GOG 204 (fatigue not measured on 179), a worse PS predicted the development of grade 3-4 fatigue (OR 2.78 95% CI 1.66-4.68). Exposure to prior radiation, treatment regimen and a worse FACT-Cx score were associated with the reporting of both grade 3-4 leukopenia (P<0.05) and anemia (p<.0005). PS and treatment regimen (p<0.05) were associated with the development of grade 3-4 thrombocytopenia. Age and treatment regimen (p<0.05) were associated with the development of grade 3-4 neutropenia. The FACT-Cx score (p=0.0016) predicted grade 3-4 GI toxicity.

Conclusions—The development of fatigue, hematologic and GI toxicity might be predictable based on factors other than treatment assignment such as age, PS and patient-reported QoL measurement.

Keywords

Quality of life; Gynecologic Oncology Group; cervical cancer; grade 3; grade 4; toxicity

Introduction

Severe sequelae can be associated with cytotoxic therapy. In several Gynecologic Oncology Group (GOG) phase III trials, the prevalence of these toxicities is well-documented with hematologic, fatigue, gastrointestinal (GI), and peripheral neuropathy being the most noteworthy [1-8]. These treatment-related toxicities canbe be persistent and chronic for the patient [1,9]. When giving treatment designed to prolong life, avoidance of toxicity and maintenance of or improved quality of life (QoL) should be integral in planning and continuing cytotoxic treatment. Unfortunately, these toxicities are prevalent and often difficult to predict.

The ability to predict grade 3-4 toxicity with baseline information could lead to improvements in the prevention and management of adverse treatment effects. This is relevant because chemotherapy treatment for metastatic recurrent cervical cancer is life prolonging, but not curative, and toxicities from treatment may be severe and persist long after treatment. Prediction of toxicity prior to its occurrence may enable more effective counseling and prophylaxis. Specifically, predictors which identify patients at the highest risk for developing severe toxicities may help guide decision-making regarding dose calculations and/or treatment intervals [10]. Some associations exist between pre-treatment clinical factors including age or drug type and may predict the development of peripheral neuropathy, however, risk factors are not well-described [11-12].

A dichotomy exists between patient-reported outcomes, those symptoms recorded by the patients, versus those outcomes recorded by health care providers, such as with toxicity scales. Because of this, such organizations as the GOG have incorporated the measurement of patient-reported outcomes (PROs) in multiple prospective phase III randomized trials. While the GOG has described associations between quality of life (QoL) and progression or survival, it has yet to be documented is the association of QoL measurement at baseline (FACT-Cx) with the development of treatment-related toxicities.

If risk factors could be clarified, patient-reported data could be used to predict toxicities related to treatment and possibly assist in treatment planning. The primary objective of this study was to report the association of various pre-treatment characteristics in women with advanced and recurrent cervical cancer in relationship to four common toxicities: peripheral neuropathy, fatigue, hematologic and GI adverse events (AEs). As to limit heterogeneity amongst trials, this study focused on two advanced/recurrent cervical cancer trials [1,13]. The secondary objective of the study was to explore any association of quality of life (QoL) measurements at baseline with the development of grade 3-4 toxicity.

Methods

The study sample was drawn from two randomized controlled prospective GOG studies, GOG-179 and GOG-204 [1, 13]. The data variables explored included age, stage, pretreatment with radiation, performance status and the baseline FACT-Cx (Functional Assessment of Cancer Therapy-Cervix) QoL score. One of the arms of GOG-179, comprised of methotrexate, vinblastine, doxorubicin and cisplatin, was terminated early. Due to the lack of follow-up, these cases were excluded from the current analysis. GOG-204 originally opened with two treatment arms and was later amended, adding two additional arms. Patients that were enrolled before this amendment date were also excluded from the current analysis as the 41 patients enrolled before the amendment date were excluded from the primary analysis of the study.

Moderate to severe toxicities were defined as grades 3 or 4 (defined by Common Terminology Criteria version 2.0). A logistic regression model was developed with the various AEs as the binary outcomes. The outcome variables were grade 3 or 4 peripheral neuropathy, fatigue, hematologic and GI. The patient variables explored included age, stage, pretreatment with radiation, performance status (PS) and the baseline FACT-CxQoL score. Each endpoint (variables above) was considered one at a time, and all the factors were used in each model

Results

The characteristics of the patients on these trials have been previously described but are briefly summarized in Table 1 [14]. A total of 43 patients either did not complete baseline QoL forms or lacked toxicity, leaving 673 eligible and evaluable patients for the following analyses. Out of 673 patients under consideration, patients on these three protocols reported, at baseline, a heightened amount of self-reported pain (item line score 2.12±1.40) in comparison to other line-items (Table 2). At baseline, individual line-items from the FACT-Cx, such as lack of energy and fear of sex, also demonstrated relatively higher scores in comparison to other line-item measurements. Other self-reported symptoms, such as nausea, lack of appetite, vaginal discharge or bleeding, did not appear as heightened as those discussed above. The development of peripheral neuropathy, GI toxicity, and hematologic toxicities were then considered as related to pre-treatment patient characteristics and baseline patient-reported QoL including line-items (See Section I below).

I. Patient characteristics associated with grade 3-4 toxicity (Summarized in Table 5)

a) Peripheral neuropathy—Out of 673 patients under consideration, 13 (2%) reported grade 3 or 4 peripheral neuropathy. This was too small a number to warrant further investigation for this study. Of note, grade 0, 1, and 2 neuropathy were reported in 558 (83%), 86 (13%), and 16 (2%) patients respectively.

b) Fatigue—Fatigue was not specifically collected as a part of GOG-179. Therefore, the following results were derived only from the 401 patients that were enrolled on GOG-204. Of the patient variables of interest, only baseline performance status was significantly associated (p=0.0001) with those patients reporting moderate to severe fatigue at baseline. Those with a performance status of 1 versus 0 were twice as likely to report moderate to severe fatigue (N=53 versus N=26). Age, stage, pretreatment with radiation and FACT-Cx were not related.

c) Leukopenia—Exposure to prior radiation (p=0.0007), treatment regimen (p<.0001) and poorer baseline total FACT-Cx scores (p=0.0104) were significantly associated with reporting of grade 3 or 4 leukopenia during treatment. The treatment type most associated with grade 3 to 4 leukopenia was cisplatin and topotecan (89%) followed by cisplatin/vinorelbine (87%) and cisplatin/paclitaxel (83%). However, in Figure 1, we found that treatment type was predominantly responsible for toxicity and patient FACT-Cx scores whereas prior RT therapy, age, stage, and PS were less important.

d) Anemia—Exposure to prior radiation (p=0.0007), treatment regimen (p=0.0008) and the FACT-Cx (p<0.0001) were related to the reporting of grade 3 or 4 anemia. There were substantial differences in the reporting of grade 3 or 4 anemia across the treatment regimens. Those exposed to prior radiation report more grade 3 or 4 anemia. Although counterintuitive and maybe due to underreporting, those with a higher baseline FACT-Cx (worse QoL) score experienced grade 3 or 4 anemia less frequently than those with a lower FACT-Cx. (p<.0001). Age, Stage, PS were not related to the development of anemia during therapy.

e) Thrombocytopenia—Performance status (p<.0001) and treatment regimen (p=0.0275) were significantly associated with the reporting of grade 3 or 4 thrombocytopenia. Treatment with cisplatin/topotecan had the highest incidence of this toxicity. Age, stage, and prior radiation therapy were not related to the development of thrombocytopenia during therapy.

f) Neutropenia—Age (p=0.0172) and treatment regimen (p<.0001) were significantly associated with the reporting of grade 3 or 4 neutropenia. Age, prior radiation therapy, and PS were not related to the development of neutropenia during therapy. Although older age trended toward significance, treatment arm again is most associated.

g) Gastrointestinal toxicity—The FACT-Cx score (p=0.0016) was significantly associated with the reporting of grade 3 or 4 GI toxicity. Age, prior radiation therapy, treatment type, PS and stage were not associated to the development of GI toxicity during therapy.

II. Relationship of baseline QoL and the development of toxicity

Individual line-items from the FACT-Cx were examined in relationship to the outcome variables (grade 3 or 4 peripheral neuropathy, fatigue, hematologic and GI toxicity). Overall, there were several baseline line-item questions that were more commonly associated with the development of the above discussed toxicities. These included: patient-reported nausea, trouble meeting the needs of family, spending time in bed, vaginal odor, disappointment with the appearance of one's body, constipation, poor appetite and trouble controlling urine.

Patients with baseline nausea and trouble meeting the needs of their family as well as disappointment in the appearance of their bodies were more likely to develop rade 3-4 fatigue over the course of the study ($P<0.05$). Patients with baseline symptoms of vaginal odor and constipation were more likely to develop grade 3-4 leukopenia ($P<0.005$). Although anemia did not correlate well with overall FACT-Cx score (worse QOL at baseline), many of the individual FACT-Cx line-items did correlate with the development of of grade 3-4 anemia (Table 3). Those with the development of grade 3 and 4 anemia were significantly more likely to report at baseline spending more time in bed and having a poor appetite ($P<0.0001$). Baseline nausea, trouble meeting the needs of family and decreased appetite were significantly associated with the development of GI toxicity ($P<0.01$). (Table 4) The FACT-Cxline-item regarding “being bothered by side effects” was associated with both the development of GI toxicity and anemia during therapy.

Discussion

In other cancer types, QoL has been associated with the development of toxicities. For example, Lee et al described how baseline QoL, specifically physical well-being, predicted higher non-hematologic AEs (OR=3.26, 95% CI 1.49-7.15) and greater weight loss (OR 2.37, 95% CI 1.12-5.01) even after controlling for baseline biomedical factors [10]. The documentation of toxicities (AEs), for example fatigue, neuropathic pain and nausea as measured by the CTCAE (Common Toxicity Criteria for Adverse Events), could be a biased measurement as it is completed by the physician or research nurse/assistant. On the contrary, patient-reported outcomes such as that measured by the FACT-Cx can document the patient's perspective of the symptoms associated with her disease, as well as side effects of therapeutic interventions such as chemotherapy and/or radiation.

In the analysis of prior advanced stage cervix or persistent/recurrent disease, balancing toxicities with at least stable QoL during treatment is critical. Prior studies have demonstrated the prognostic significance of patient-reported QoL in these patients [15]. With poor baseline QoL, it can now be recognized that patient treatment outcomes may be compromised. The current analysis examined more closely the specific association of baseline QoL to the development of toxicities. For example worse QoL at baseline (lower FACT-Cx) scores were associated with the development of GI toxicities. Such findings as this could serve to guide counseling patients towards or perhaps away from certain therapies. Furthermore, predicting such symptoms as severe fatigue or GI toxicity could trigger therapeutic symptom-driven interventions which may ultimately improve QoL and positively impact outcomes.

In this patient population this study demonstrated the significance of pretreatment performance status and baseline FACT-Cx in the development of leukopenia, anemia, and GI toxicity (Table 5). Although patient-reported pain (as measured by the FACT-Cx at baseline) was the most elevated line-item in this patient population, this patient-reported symptom did not appear to be associated with the development of the various toxicities discussed in this study. Nevertheless, attention to pain at initial diagnosis should be better examined prospectively. In addition, nausea and poor appetite could be better assessed and addressed prospectively as these symptoms could alter toxicities (as they are associated with the development fatigue, GI toxicity and anemia). The limitations of this study do include its retrospective nature and the exploratory analysis of line-item questions within the FACT-Cx. The findings are therefore hypothesis-generating and should be validated in prospective studies. Future trials may consider addressing baseline QoL concerns prospectively while patients undergo therapy as to both lessen toxicity and improve outcomes. Efforts aimed at either identifying biomarkers for the development of toxicity or means to control symptoms in randomized trials prospectively should be encouraged [16,17].

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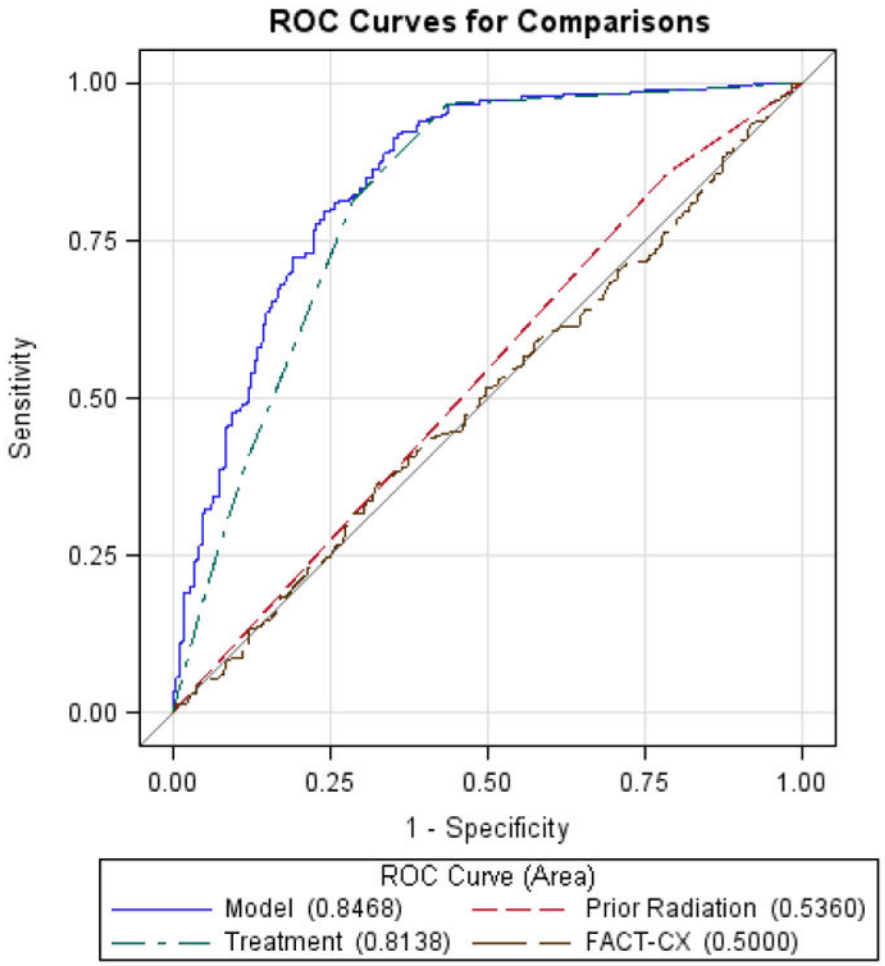

Figure 1.
The influence of treatment assignment versus prior radiation and FACT-Cx on leukopenia.

Table 1

Patient characteristics (mean and percentage across all arms of trial)

	GOG179	GOG204
Age (mean)	47	48
PS (%)		
0	47	57
1	45	52
2	8	--
Stage (%)		
IVB	12	19
Persistent	10	13
Recurrent	79	77
Prior cis (%)	57	76

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Table 2

Baseline Line-Item FACT-Cx scores (each score on a scale of 0-4)

		Protocol 204 alone		Protocol 179 and 204	
	Question	**mean**	**stddev**	**mean**	**stddev**
PWB	LACK OF ENERGY	1.89775561	1.1945794	1.85438336	1.16606887
	NAUSEA	0.7575	1.0939312	0.76716418	1.06841991
	TROUBLE MEETING NEEDS OF FAMILY	1.4085213	1.36577976	1.44245142	1.34978063
	PAIN	2.11278195	1.41592239	2.12686567	1.4058475
	BOTHERED BY SIDE EFFECTS	0.91364903	1.19860617	0.9339934	1.20423477
	FEEL ILL	1.13810742	1.25936716	1.19178082	1.24684701
	SPEND TIME IN BED	1.27777778	1.33449317	1.32330827	1.33392297
Cx	DISCHARGE OR BLEEDING	0.82871537	1.27559913	0.83058471	1.2757004
	VAGINAL ODOR	0.7275	1.23979291	0.75707899	1.25508154
	AFRAID TO HAVE SEX	1.62234043	1.69734879	1.60952381	1.67082078
	FEEL SEXUALLY ATTACTIVE	1.29765013	1.34793607	1.29102167	1.35445743
	VAGINA SHORT OR NARROW	0.99191375	1.33657058	1.01112878	1.34550567
	FERTILITY CONCERNS	0.18518519	0.73386632	0.170347	0.68104849
	FEAR THAT TREATMENT HARMING BODY	1.37659033	1.26799761	1.38636364	1.28282531
	INTEREST IN SEX	1.20984456	1.42154351	1.24191063	1.41694988
	LIKE THE APPEARANCE OF BODY	1.72634271	1.29071504	1.78603945	1.29344358
	CONSTIPATION	1.2893401	1.39702995	1.37160121	1.42518205
	GOOD APPETITE*	2.1209068	1.36162825	2.11261261	1.36142012
	TROUBLE CONTROLLING URINE	0.94949495	1.34351692	0.92192192	1.32865466
	BURN WITH URINE	0.38227848	0.90300675	0.37556561	0.89094485
	DISCOMFORT WITH URINE	0.63888889	1.11985658	0.62349398	1.10249511
	ABLE TO EAT FOODS THAT I LIKE*	2.56962025	1.43455846	2.56193353	1.39642981

PWB= physical well-being subscale; Cx= cervical cancer subscale

*For these two items a higher score reflects the fact that the patient agree with the statement that she has “good appetite” or is “able to eat foods that I like”

Table 3
Grade 3-4 anemia and Baseline line-item FACT-Cx scores

PWB QUESTION	OR	C.I.		P-value
LACK OF ENERGY	1.254	1.0087	1.447	0.0019
NAUSEA	1.317	1.134	1.529	0.0003
TROUBLE MEETING NEEDS OF FAMILY	1.239	1.097	1.4	0.0006
PAIN	1.156	1.026	1.303	0.0176
BOTHERED BY SIDE EFFECTS	1.308	1.138	1.504	0.0002
FEEL ILL	1.055	0.868	1.283	0.5877
SPEND TIME IN BED	1.355	1.196	1.534	<0.0001
Cx SUBSCALE				
DISCHARGE OR BLEEDING	1.125	0.992	1.276	0.0667
VAGINAL ODOR	1.201	1.059	1.362	0.0043
AFRAID TO HAVE SEX	1.102	0.996	1.22	0.0604
FEEL SEXUALLY ATTACTIVE	0.871	0.766	0.991	0.0358
VAGINA SHORT OR NARROW	1.239	1.096	1.402	0.0006
FERTILITY CONCERNS	1.312	1.041	1.655	0.0217
FEAR THAT TREATMENT HARMING BODY	1.006	0.883	1.145	0.9325
INTEREST IN SEX	0.882	0.779	0.998	0.466
LIKE THE APPEARANCE OF BODY	0.911	0.8	1.038	0.1605
CONSTIPATION	1.128	1.005	1.266	0.0416
GOOD APPETITE	0.78	0.689	0.883	<0.0001
TROUBLE CONTROLLING URINE	1.076	0.952	1.217	0.2391
BURN WITH URINE	1.249	1.048	1.489	0.0131
DISCOMFORT WITH URINE	1.298	1.125	1.497	0.0004
ABLE TO EAT FOODS THAT I LIKE	0.809	0.719	0.911	0.0004

PWB = physical well-being subscale; OR = odds ratio; C.I – Confidence Interval

Table 4
GI toxicity and baseline line-item FACT-Cx scores

FACT-PWB QUESTIONS		OR	C.I.	P-value
LACK OF ENERGY	1.207	1.03	1.414	0.0199
NAUSEA	1.433	1.222	1.68	<0.0001
TROUBLE MEETING NEEDS OF FAMILY	1.194	1.044	1.365	0.0097
PAIN	1.142	0.999	1.306	0.0518
BOTHERED BY SIDE EFFECTS	1.209	1.037	1.41	0.0155
FEEL ILL	1.055	0.868	1.283	0.5877
SPEND TIME IN BED	1.173	1.025	1.343	0.0209
FACT-Cx SUBSCALE				
DISCHARGE OR BLEEDING	0.962	0.829	1.116	0.6066
VAGINAL ODOR	0.947	0.814	1.103	0.4867
AFRAID TO HAVE SEX	1.107	0.988	1.241	0.08
FEEL SEXUALLY ATTACTIVE	0.879	0.759	1.017	0.0835
VAGINA SHORT OR NARROW	1.167	1.018	1.337	0.0265
FERTILITY CONCERNS	1.179	0.919	1.512	0.1951
FEAR THAT TREATMENT HARMING BODY	1.012	0.876	1.169	0.8743
INTEREST IN SEX	0.979	0.857	1.119	0.7546
LIKE THE APPEARANCE OF BODY	0.841	0.727	0.974	0.021
CONSTIPATION	1.176	1.035	1.336	0.0126
GOOD APPETITE	0.824	0.719	0.945	0.0057
TROUBLE CONTROLLING URINE	1.165	1.021	1.329	0.023
BURN WITH URINE	1.207	1	1.457	0.0497
DISCOMFORT WITH URINE	1.102	0.938	1.294	0.2375
ABLE TO EAT FOODS THAT I LIKE	0.903	0.793	1.028	0.1225

PWB = physical well-being subscale; GI = gastrointestinal; OR = odds ratio; C.I – Confidence Interval

Table 5
Summary of Toxicities and Associated Factors

TOXICITY	PREDICTIVE FACTOR	P-value
Fatigue	Performance Status	P<0.005
Leukopenia	Prior radiation	P<0.005
	Treatment regimen	P<0.005
	Poor baseline QOL	P<0.05
Anemia	Prior radiation	P<0.005
	Treatment regimen	P<0.005
	Poor baseline QOL	P<0.0005
Thrombocytopenia	Performance status	P<0.0005
	Treatment regimen	P<0.05
Neutropenia	Age	P<0.05
	Treatment regimen	P<0.0005
GI Toxicity	Poor baseline QOL	P<0.005

QOL = quality of life; GI = gastrointestinal