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Cancer Treatment Adherence among Low-Income Women with Breast or Gynecologic Cancer: A Randomized Controlled Trial of Patient Navigation

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Abstract

Background—We implemented a controlled randomized trial that compared two interventions - provision of written resource navigation information (enhanced usual care (EUC)) versus written information plus patient navigation (TPN) aimed at improving adjuvant treatment adherence and follow-up among 487 low-income, predominantly Latinas with breast or gynecologic cancer.

Methods—Women are randomized to either TPN or EUC. We assess chemotherapy, radiation and hormone therapy and follow-up over 12 months. Breast and gynecologic patients are analyzed separately.

Results—Overall adherence rates were (87-94%) and there were no significant differences between TPN and EUC groups. Among women with breast cancer, 90% of EUC and 88% of TPN patients completed chemotherapy (14% EUC-26% TPN had delayed completion), 2% EUC-4% TPN failed to complete, and 8% EUC-7% TPN refused, chemotherapy. Radiation treatment adherence was similar between groups -90% completed (40% EUC-42% TPN delayed completion); in both groups, 2% failed completion and 8% refused radiation. Among gynecologic patients, 87% EUC-94% TPN completed chemotherapy (41% EUC-31% TPN with delays), 7% EUC-6% TPN failed completion and 6% EUC refused chemotherapy; 87% EUC-84% TPN completed radiation (51% EUC-42% TPN with delays), 5% EUC-8% TPN failed completion and 8% EUC-5% TPN refused radiation.

Conclusions—Treatment adherence across randomized groups was notably higher than reported in previous studies, suggesting that active telephone patient navigation or written resource informational materials may facilitate adherence among low-income, predominantly Hispanic women. Adherence may have also been facilitated by federal-state Breast and Cervical Cancer treatment funding.

Keywords

Adjuvant Cancer Treatment Adherence; Patient Navigation; Low-Income Hispanics

Despite declines in overall cancer-related mortality,¹ disparity in cancer survival among racial/ethnic minorities remains significant.²⁻⁶ It is, in part, attributable to structural

constraints and contextual factors that restrict access to health care.^{2,7} Low-income and minority women are less likely to receive adjuvant treatment for breast and gynecologic cancer,⁸⁻¹⁴ and more likely to terminate their treatment prematurely and to have higher mortality rates.¹⁵⁻¹⁸ However, in contrast to research on interventions to improve screening and abnormal follow-up,¹⁹⁻²⁴ few studies have tested interventions to improve adjuvant treatment adherence among lower socio-economic populations.²⁵⁻²⁹

Previous studies have found low-income minorities experienced poorer radiation treatment adherence for cervical cancer when compared with national rates (16% vs. 63%), a high rate of treatment interruptions (64%) and discontinuation of treatment for non-medical reasons (20%);³⁰ noncompliance with hematologic oral self-administered medication more than 70% of the time (measured by drug serum levels); and missed appointments more than 30% of the time.^{31,32} An intervention trial on low-income patients with hematologic malignancies found that control patients were noncompliant 73.1% and fully compliant 21% of the time. After controlling for all other variables, disease severity, compliance with allopurinol, and an educational intervention were associated with significantly better adherence and survival rates.³³ Predominantly indigent, minority patients with early breast cancer were less compliant with a standard breast-conservation and radiation therapy program than that reported in clinical trials.³⁴ Suggesting a positive effect on adherence from access to treatment insurance, a SEER-Medicare database of 24,510 patients documented high rates of completion (87%) of 25 or more radiation therapy sessions (although with greater non-completion rates among Black women with mastectomy),³⁵ while analysis of 3,193 Medicare patients with colon cancer found that 78.2% completed the prescribed course of chemotherapy.³⁶

Our controlled randomized trial compared patient adherence to adjuvant cancer treatment and post-treatment follow-up among 487 low-income predominantly Latino women with breast or gynecologic cancer, randomized to a structured patient navigation (TPN) or to modestly enhanced usual care (EUC). To better understand the hypothesized role of socio-economic and culturally mediated attitudes and socio-emotional support in adherence, we conducted semi-structured qualitative interviews with 29 women from both study groups.

METHODS

The IMPAACT (Improving Patient Access and Adherence to Cancer Treatment) trial and the qualitative study were approved by USC Health Sciences IRB. We recruited women with breast or gynecologic cancer to test a culturally tailored patient navigation model that was previously found to be effective in improving abnormal screen follow-up.²⁴ The TPN model combined interactive health education (decisional support), counseling (emotional support), written care site and community service navigation information, and navigator active assistance to facilitate access and adherence to adjuvant treatment. Patients age ≥ 18 were recruited in oncology clinics at an urban public safety net medical center if they had a primary diagnosis of breast (Stage 0-III) or gynecologic FIGO 0-4B cancer. We excluded palliative care patients.

Study Participants

Of 596 eligible patients, we enrolled 487 (82%) from June 2002 to July 2004 with no statistically significant differences between enrolled and non-enrolled by age, ethnicity, or cancer stage. We randomly assigned patients to IMPAACT TPN intervention (n=248) or to EUC (n=239).

Study Design

IMPAACT is integrated with oncology care provided under “real world” service delivery conditions and is designed to enhance standard care through quality improvement enhancements provided by a bilingual, bicultural Patient Navigator (PN) and MSW team or distribution of written materials. There was no “only usual care” group based on previous trials of showing patient navigation to improve screening and abnormal screen adherence. 19-24

EUC patients received site standard oncology care, financial department facilitation of receipt of Medi-Cal Treatment Funding and supportive services available to all cancer patients *plus* an English or Spanish listing of community resources (e.g., mental health services, cancer support groups), and medical center social work, financial, and transportation and childcare resources services and a patient and family member educational pamphlet on depression and cancer at baseline. These written materials were not routinely provided as part of usual care in this public sector safety net care system.

TPN is tailored to improve treatment and follow-up access and adherence by influencing predisposing (knowledge/attitudes), reinforcing (social support/cues to action), and enabling (barrier reduction skill) consistent with the Health Belief Model³⁷ and Socio-cultural Explanatory Theory.³⁸⁻³⁹ TPN provides: an initial structured telephone interview assessing adherence barriers; health education, problem-solving, and self-management support; and applies a structured adherence risk algorithm to assign service intensity: Level 1 service (6 and 12 month follow-up call); Level 2 (telephone or in-person navigation services); Level 3 (MSW brief depression or anxiety counseling and/or referral).

Measures

Demographic and Clinical Characteristics—Patient demographics, cancer site, stage, and treatment phase at study enrollment came from medical records or baseline interviews. Among women reporting pain, further assessment was made using the Brief Pain Inventory (BPI).⁴⁰⁻⁴¹ Patients self-reported **functional status** using the Karnofsky Performance Status Scale (KPSS), an 11-point rating scale which ranges from normal functioning (10) to death (0).⁴² The Functional Assessment of Cancer Therapy Scale – General (FACT-G),⁴³⁻⁴⁴ a valid and reliable 27-item Health Related Quality of Life (HRQL) assessed physical, functional, social/family, and emotional well-being. Co-morbid health conditions came from patient self-report. PHQ-9 assessed major depressive disorder and⁴⁵⁻⁴⁶ the Brief Symptom Inventory to assess anxiety.⁴⁷ Experienced abstractors collected **adherence data** from all available charts (n=444, 91.2% of study enrollees). Adherence to external beam radiation or IV-chemotherapy is defined as completed as scheduled (CAsScheduled), completed but delayed (C-Delay) due to missed treatment appointments, did not complete (DNComplete) or declined; unless the interruption was physician prescribed or resulted from machine breakdown. Receipt of hormone and anti-depressant medication was obtained from site pharmacy records. We randomly recruited **qualitative study** patients from 164 women following completion of the 6-month interview; 29 provided written consent (15 TPN and 14 EUC, 24 Hispanic). We tape-recorded individual in-person or telephone guided interviews (11 in English, 18 in Spanish).

Statistical Analysis

Mean, standard error and percentage were used to describe the general characteristics and distributions of predicting and outcome variables. Logistic Regression and Polytomous Logistic Regression models test intervention effects on treatment adherence. We assess breast and gynecologic patients separately using SAS, version 9.1 (SAS Institute, Cary,

North Carolina). **Qualitative Transcript Data** were coded and analyzed using standard methodology of “Coding Consensus, Co-occurrence, and Comparison”⁴⁸⁻⁵¹

RESULTS

Study Enrollment and Attrition

Consort Figure 1 details enrollment and attrition over 12 months. Attrition rates do not vary significantly between groups and reasons for attrition are similar between groups. Baseline characteristics were compared between patients who had completed outcome measures at two follow-up waves (61%) and non-completers at any follow-up wave (39%). Patients lost to follow-up are more likely to be 8.9% US born vs 63% foreign born, $p=0.019$), less than 10 years in US (68.7% vs. 80.6%, $p=0.003$), and to have gynecologic cancer (65.6% vs 42%, $p<0.001$).

Sample Characteristics

Patients are predominantly Latina, Spanish-speaking, foreign born, unemployed and with Medi-Cal Cancer Treatment Funding or local government medical insurance at enrollment (Table 1). There were no significant differences between study groups at baseline on key characteristics including cancer treatment phase (prior to treatment, active cancer treatment, or follow-up care), age, ethnicity, cancer stage, self-reported KPSS, major depression, or severe pain between study groups.

Survival and Quality-of-Life Outcomes

Logistic regression models with control of baseline scores and cancer stage find no significant effect on survival or quality-of-life improvement except for a significant improvement in emotional well-being in gynecologic EUC patients at the end of 12 months (OR=2.72, 95% CI: 1.25-5.9, $p=0.01$).

Treatment Adherence

Treatment profiles did not vary significantly between TPN and EUC (Table 2). The majority of patients received chemotherapy. Breast cancer patients received hormone therapy after acute treatment. Overall adjuvant treatment adherence rates were notably high and there were no significant differences between study groups (Table 3).

Among women with breast cancer, 76% EUC-62% TPN completed chemotherapy as scheduled (CAsSched), while an additional 15% EUC-26% TPN completed with delays (C-Delay) (10% EUC-22% TPN attributable to toxicity or other medical reasons (ToxDelay), 5% EUC-4% TPN to non-medical reasons (OthDelay)). Only 1 EUC and 3 TPN patients did not complete (DNComplete) and 5 patients in each study group declined chemo treatment. Adherence to radiation treatment was similar between breast cancer EUC and TPN groups (50% CAsSched, 40% C-Delay, 2% DNComplete and 8% declined).

Among gynecologic patients, 46% CAsSched, 28% ToxDelay, 13% OthDelay, 7% DNComplete, 6% declined in EUC and 63% CAsSched, 21% ToxDelay, 10% OthDelay, 6% DNComplete in TPN. About 87% gynecologic patients in each study group completed radiation treatment, including C-Delay 51% EUC-42% TPN. Only 2 EUC and 3 TPN patients failed to complete, and 3 EUC and 2 TPN refused, radiation treatment.

Controlling for study group using Polytomous logistic regression models, gynecologic patients with advanced cancer (stage 3, 4 or recurrent) had significantly higher odds of being non-adherent to chemotherapy ($p<0.01$). Cancer stage was not associated with radiation adherence for gynecologic patients, or either treatment adherence for breast patients. In

addition, there were no significant differences in adherence rates when comparing patients' baseline status (i.e., prior-to-initiating treatment versus during or post acute treatment) between study groups.

Nearly 1/3 of breast and more than 1/3 of gynecologic patients in each study group were not fully adherent to follow-up appointments, having missed at least one scheduled follow-up appointment or failing to return to clinic. Site pharmacy records indicated that 44 patients obtained tamoxifen or arimidex, with overall 59% adherence and no significant difference in rates between study groups. Of 27 patients receiving antidepressants, adherence rates, defined as obtaining the prescribed number of refills, were significantly better among TPN patients - 67% (10 out of 15) versus 25% among EUC patients (3 out of 12), $p=0.03$.

Adherence, Mortality and Quality-of-Life Outcomes

There are no significant interactions between study group and adherence (CAsSched or Not CAsSched) for either mortality or quality of life outcomes. Therefore, combined data from TPN and EUC is used to evaluate the associations between timely adherence and death rate and quality of life FACT-G subscales (Table 4). Gynecologic patients who failed to complete the prescribed chemotherapy regimen as scheduled had a higher death rate at 12 months (29.17% vs 10.34%, $p=0.01$). FACT-G subscale means do not vary between timely and not timely adherence groups in regression models controlled by baseline scores and cancer stage. Patient costs of care worries are similar between TPN and EUC groups. Polytomous logistic regression models compare odds of adherence to treatment between patients with or without reported cost concerns at either 6 or 12 months. Adherence is not significantly associated with cost concerns in either breast or gynecologic patients.

Qualitative Study Results

Information collected from the semi-structured interviews provided additional insight on economic, cultural and systems barriers to adherence. Although all women in this study were receiving care in a public safety net system, lack of insurance to pay for treatment and related out-of-pocket costs were cited as barriers to care by 21% of women interviewed. In contrast, women also cited strong efforts on their part to be adherent to prescribed treatment and follow-up appointments; and attributed their desire to adhere to treatment to several factors, including respect for the advice of caring physicians and family members and a strong desire to survive.

DISCUSSION

The high rate of adjuvant treatment adherence by women in both TPN and EUC groups is striking, and is in contrast to previous adherence intervention trials among low-income minority women described above.³⁰⁻³³ Thus, this study raises key questions about what degree of patient navigation assistance is needed to improve cancer treatment adherence in safety net care systems. In this study, informational material on community resources and depression and cancer, and patient navigation to facilitate receipt of financial and supportive services may have facilitated treatment adherence.

Social structural factors (e.g. lack of health insurance, out-of-pocket treatment, lost wages and transportation costs) may also affect treatment adherence.⁵² Thus, relatively high adherence rates across study groups might be partly attributable to the study site routine referral to the California Cancer Treatment Fund (under the federal-state Breast and Cervical Cancer Prevention and Treatment Act's funding of poor women) implemented within Medi-Cal in January, 2002 (prior to the initiation of study recruitment). The similarity of

adherence rates in our trial with studies of Medicare insured patients³⁵⁻³⁶ suggests that available treatment funding for this population is likely to facilitate treatment participation.

Study limitations include patient attrition, demographic and cancer site differences between adherent and non-adherent, lack of medical charts for all patients, relatively small numbers in subgroup analyses raise questions about treatment adherence among patients lost to follow-up. Moreover, in a previous longitudinal analysis of this study trial population, socio-economic stress was significantly associated with depression and poorer quality-of-life over time.⁵³ However, brief intervention for patients meeting criteria for major clinical depression (referral for brief counseling followed by referral to a mental health provider) did not result in significant differences in receipt of antidepressants for patients who reported major depressive symptoms. In contrast, two randomized controlled trial of intensive collaborative care management that included antidepressant medication and/or psychotherapy plus relapse prevention and maintenance care significantly improved major depression over 12 months in a similar low-income minority population⁵⁴⁻⁵⁵ and in a population in Scotland.⁵⁶

Conclusion

This study's high adjuvant treatment adherence results raise the probability that a treatment funding program and routine efforts to ensure that eligible patients receive the funding plus either telephone delivered navigational information and reminders or written informational materials (in this case in Spanish when preferred) may facilitate cancer treatment adherence among underserved low-income Hispanic women in safety net programs. Further research, ⁵⁷ including an ongoing multi-site study⁵⁸ on patient navigation community practice models, may provide additional answers to questions of efficacy for specific populations as well as comparative cost data and degree of effectiveness of diverse navigational programs. Evaluation of national and state data on the effects of publicly financed treatment funding will also add to our understanding.

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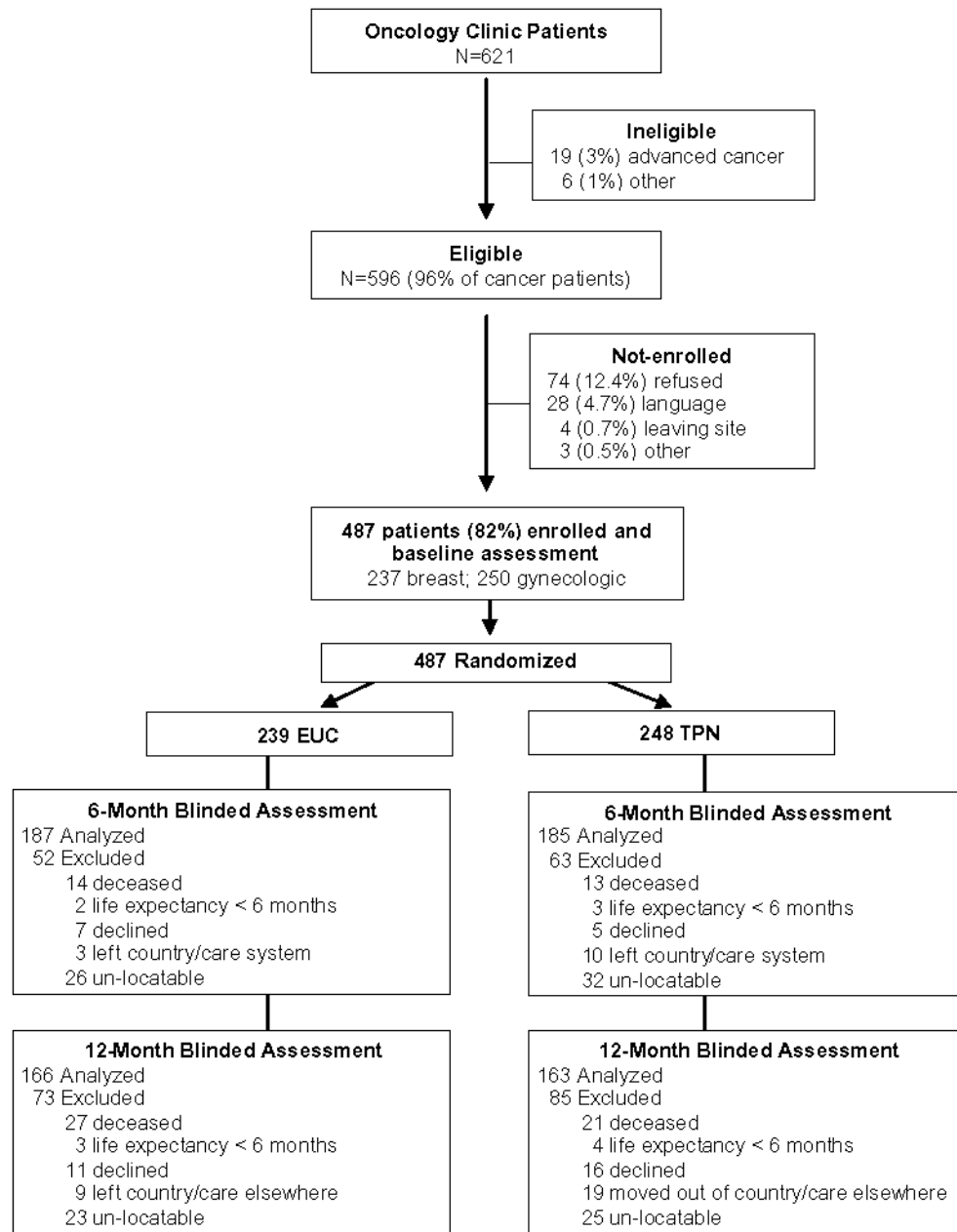


Figure 1.
IMPAACT Consort Flowchart

Table 1

Patient Demographic and Clinical Characteristics at Baseline

	Breast Cancer			Gynecologic Cancer		
	EUC N=114	TPN N=123	p	EUC N=125	TPN N=125	p
Age ≥ 50 y	n(%)	n(%)	0.90	n(%)	n(%)	0.80
	63(55%)	69(56%)		65(52%)	63(50%)	
Hispanic	80(70%)	89(72%)	0.71	98(78%)	103(82%)	0.43
English speaking	30(28%)	32(28%)	0.94	34(28%)	28(23%)	0.40
Foreign Born	96(84%)	109(89%)	0.32	108(86%)	109(87%)	0.85
In US ≥ 10 y	67(72%)	84(82%)	0.09	73(69%)	70(65%)	0.59
Less than high school education	58(51%)	64(53%)	0.71	78(63%)	66(53%)	0.11
Unemployed	95(83%)	89(72%)	0.04	101(81%)	111(89%)	0.08
Unmarried	60(53%)	68(55%)	0.68	78(62%)	83(66%)	0.51
Health Insurance/Benefits						
Medi-Cal/Medicare	39(34%)	40(33%)	0.95	57(46%)	58(46%)	0.89
Local government	41(36%)	47(38%)		35(28%)	32(26%)	
Other	7(6%)	9(7%)		2(2%)	1(1%)	
None	27(24%)	27(22%)		31(25%)	34(27%)	
Cancer Stage						
Stage 0, 1, 2, unstaged	93(82%)	103(84%)	0.66	73(58%)	74(59%)	0.90
Stage 3, 4, recurrent	21(18%)	20(16%)		52(42%)	51(41%)	
Cancer Treatment Phase						
Prior to treatment	50(44%)	68(55%)	0.19	27(22%)	23(18%)	0.80
Active treatment	59(52%)	52(42%)		72(58%)	74(59%)	
Follow-up	5(4%)	3(2%)		26(21%)	28(22%)	
Comorbid medical condition	65(57%)	66(54%)	0.60	69(55%)	76(61%)	0.37
Depression						
Major Depression (PHQ-9 ≥10) + Dysthymia	21 (18%)	21 (17%)	0.99	8 (6%)	8 (6%)	0.92
Major Depression	15 (13%)	15 (12%)		14 (11%)	11 (9%)	
Dysthymia	18 (16%)	20 (16%)		15 (12%)	17 (14%)	
Anxiety (BSI score ≥14)	7(20%)	2(6%)	0.08	7(11%)	9(14%)	0.59
Reporting Pain	48(42%)	47(39%)	0.58	69(55%)	69(55%)	1.00

	Breast Cancer			Gynecologic Cancer		
	EUC N=114	TPN N=123	0.08	EUC N=125	TPN N=125	0.59
(BPI score ≥ 7)	7(20%)	2(6%)	0.08	7(11%)	9(14%)	0.59
	Mean(SE)	Mean(SE)		Mean(SE)	Mean(SE)	
KPSS	6.8(0.2)	7.1(0.2)	0.27	6.3(0.2)	6.7(0.2)	0.09
Functional Well-Being	14.1(0.5)	14.3(0.5)	0.87	14.5(0.5)	14.8(0.5)	0.70
Emotional Well-Being	15.4(0.5)	14.8(0.5)	0.44	16.5(0.4)	16.7(0.4)	0.81
Physical Well-Being	21.2(0.6)	22.7(0.5)	0.04	19.5(0.5)	19.0(0.6)	0.49
Social-Family Well-Being	17.0(0.5)	16.9(0.5)	0.87	19.3(0.6)	19.0(0.6)	0.72

Table 2

Adjuvant Treatment over 12 months

	Breast Cancer		Gynecologic Cancer	
	EUC	TPN	EUC	TPN
<u>Chemotherapy and Radiation</u> *				
• Received chemotherapy + RT	33 (32%)	30 (27%)	25 (22%)	26 (22%)
• Only chemotherapy	25 (24%)	33 (30%)	24 (21%)	25 (22%)
• Only RT	13 (13%)	17 (15%)	9 (8%)	8 (7%)
<u>Hormone Therapy</u> **	71 (62%)	82 (67%)	n/a	n/a
<u>Pain Medication</u>	89 (78%)	84 (68%)	103 (82%)	108 (86%)
<u>Antidepressants</u>	25 (22%)	28 (23%)	15 (12%)	11 (9%)
<u>End of trial</u>				
• Follow-up	58 (56%)	61 (55%)	55 (48%)	58 (50%)
• Continuing chemotherapy/RT	8 (8%)	9 (8%)	4 (3%)	9 (8%)
• hospice care			1 (1%)	1 (1%)
• Deceased	5 (5%)	6 (5%)	20 (17%)	14 (12%)
• Receiving care elsewhere	4 (4%)	3 (3%)	2 (2%)	4 (3%)
• Lost follow-up	28 (27%)	31 (28%)	33 (29%)	30 (26%)

* 444 patient medical charts reviewed (103 breast UC, 110 breast TPN, 115 gynecologic UC and 116 gynecologic TPN)

** Hormone therapy was not mutual exclusive from chemotherapy and/or radiation therapy

Table 3

Treatment Adherence between TPN and EUC Groups

	Breast				Gynecologic					
	n(%)	OR	95% CI	P	n(%)	OR	95% CI	P		
	EUC	TPN			EUC	TPN				
Chemotherapy										
NC/Declined	6 (10%)	8 (12%)	1		7 (13%)	3 (6%)		1		
C-Delay	9 (14%)	18 (26%)	1.50	(0.40 - 5.65)	0.55	22 (41%)	16 (31%)	1.70	(0.38 - 7.59)	0.49
CAsSched	48 (76%)	42 (62%)	0.66	(0.21-2.05)	0.47	25 (46%)	33 (63%)	3.08	(0.72-13.12)	0.13
RT										
NC/Declined	5 (10%)	5 (10%)	1		5 (13%)	5 (13%)		1		
C-Delay	20 (40%)	21 (42%)	1.05	(0.26-4.19)	0.94	20 (51%)	16 (42%)	0.80	(0.2-3.25)	0.76
CAsSched	25 (50%)	24 (48%)	0.96	(0.25-3.74)	0.95	14 (36%)	17 (45%)	1.21	(0.29-5.06)	0.79
Follow-up										
Non-adherent	32 (31%)	36 (33%)	1		44 (38%)	40 (34%)		1		
Adherent	71 (69%)	74 (67%)	0.93	(0.52-1.65)	0.80	71 (62%)	76 (66%)	1.18	(0.69-2.01)	0.55

CAsSched: completed as scheduled; C-Delay: completed but delayed; NC/Declined: not completed or declined.

Table 4

Quality-of-Life and Adherence

	Breast			Gynecologic		
	Not CAsSched	CAsSched	p	Not CAsSched	CAsSched	p
Chemotherapy						
Death (n (%))	4 (9.76%)	4 (4.44%)	0.15	14 (29.17%)	6 (10.34%)	0.01
FACT-G (Mean (SE))						
• Functional	15.56 (1.07)	17.04 (0.64)	0.24	13.91 (1.21)	16.58 (0.96)	0.10
• Emotional	17.85 (0.80)	18.31 (0.49)	0.63	17.78 (1.04)	17.58 (0.82)	0.89
• Physical	21.29 (0.88)	22.56 (0.54)	0.22	19.76 (1.07)	22.06 (0.84)	0.11
• Social-Family	18.96 (0.97)	18.40 (0.59)	0.62	17.65 (1.28)	18.70 (1.01)	0.53
Radiation Therapy						
Death (n (%))	2 (3.92%)	3 (6.12%)	0.31	2 (4.35%)	4 (12.90%)	0.13
FACT-G (Mean (SE))						
• Functional	16.12 (0.88)	17.54 (0.86)	0.26	15.70 (1.06)	16.38 (1.49)	0.71
• Emotional	17.96 (0.63)	18.38 (0.61)	0.64	18.35 (0.87)	17.11 (1.26)	0.43
• Physical	22.07 (0.78)	22.60 (0.76)	0.64	21.08 (0.94)	22.84 (1.32)	0.29
• Social-Family	18.45 (0.84)	18.86 (0.82)	0.73	18.73 (1.05)	15.59 (1.46)	0.09

Abbreviation: CAsSched=completed as scheduled