Effect of Telephone Follow-up on the Physical Well-Being Dimension of Quality of Life in Patients with Cancer

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Objective. To evaluate the effect of telephone follow-up on the physical well-being dimension of health-related quality of life in patients with cancer.

Design. Randomized, controlled trial.

Setting. Public teaching hospital.

Patients. One hundred fifty patients with cancer who were discharged to home from the hospital.

Intervention. Patients received a telephone follow-up call 48–72 hours after discharge. Information was solicited regarding drug-related (and other) problems. Problems were addressed, and advice and support were given.

Measurements and Main Results. Analysis of variance revealed no differences in the physical well-being dimension of health-related quality of life between patients who received telephone follow-up and a control group who did not. Sixty-eight percent of the follow-up group and 40% of the control group (p=0.007) reported having had at least one contact with a health professional.

Conclusion. One possible explanation for the lack of effect of the intervention is that high-risk patients in the control group received a similar intervention from other health care professionals. We suggest that telephone follow-up be coordinated among health professionals.

(Pharmacotherapy 2002;22(10):1301–1311)

Continuity of care is a concept that has received much attention in recent years. It is particularly important for patients with complex disease states that involve both an acute and a chronic component. Cancer is one such disease.[1]

The coordinated process of discharge from a hospital is an important element of the continuity-of-care model. However, studies have demonstrated that clinicians overestimate patients' understanding of the treatment and follow-up plan after discharge.[2–4] One study demonstrated that patients' perception of the importance of discharge information was higher after discharge, suggesting that patients are more inclined to learn after they have returned home.[5] These investigators suggested telephone follow-up as a method of providing education at a more appropriate time.

Addition of telephone follow-up to the discharge process has demonstrated mixed results. Some studies indicate that telephone

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Presented at the European Society of Clinical Pharmacy's 29th European Symposium on Clinical Pharmacy, Basel, Switzerland, October 11–14, 2000.

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follow-up decreases anxiety and visits to an emergency facility,[6] increases compliance with discharge instructions,[7] and enhances knowledge.[8] However, other studies have not shown significant benefit.[9–11] In those studies, follow-up was provided by physicians or nurses, and outcome measures focused primarily on the use of health care resources rather than quality of life.

The value of the clinical pharmacist on the health care team has been clearly established.[12–14] Clinical pharmacists at the medical center at the University of California San Francisco (UCSF) perform numerous patient-oriented activities, such as prescribing under protocol, managing drug therapy in complex settings, and providing hospital discharge planning and counseling. In 1997, UCSF clinical pharmacists on the inpatient oncology service initiated the call-back program: a telephone follow-up 48–72 hours after patients were discharged to home from the hospital.

The oncology service was chosen for this program because of the potential effect on patients' quality of life; efforts to manage and mitigate side effects are an important part of patient care. Complex regimens after discharge often are required of these patients. In addition, due to cost pressures on the health care system, chemotherapy is administered over increasingly shorter infusion times, often in the outpatient setting, rendering follow-up difficult. Thus, the benefit of call back in enhancing quality of life in this patient population seems likely but has never been measured.

We thought the call-back process could improve patients' symptoms and/or side effects, such as delayed nausea and vomiting, as well as detect and correct new symptoms that develop after discharge. We tested the hypothesis that call back improves symptoms and the physical well-being dimension of quality of life in patients with cancer.

Methods

Sample Selection

We conducted a randomized controlled trial on patients with cancer who have hematologic or solid tumor malignancies and were receiving chemotherapy. These patients received treatment on the inpatient general medicine, oncology, or adult leukemia and bone marrow transplantation services, or in an outpatient cancer infusion center at the medical center at UCSF. Patients were enrolled from January 1999–February 2000. The UCSF institutional review board approved the study, and all patients gave informed consent before enrollment.

Oncology, non–chemotherapy-naïve adult (≥ 18 yrs old) patients were eligible for the study when they were discharged to home after completing a chemotherapy cycle. Patients were enrolled only once and were excluded if they did not speak English, had impaired hearing or speech, had mental or cognitive disorders, were living outside the United States, or did not have a telephone. For logistical reasons, patients receiving weekly chemotherapy were not enrolled. Because of an established protocol on the adult leukemia and bone marrow transplantation inpatient service that required telephone follow-up for all patients receiving an allogeneic bone marrow transplant and high-dose methotrexate, these patients also were excluded.

Assignment

The clinical pharmacist obtained written informed consent during the patient's hospital stay or visit to the infusion center. After the patient was discharged, the clinical pharmacist obtained a subject number and study assignment from the investigational drug pharmacist. Patients were randomized using a spreadsheet with a block size of four. This approach guaranteed that patient allocation would not influence the discharge process.

Primary and Secondary Outcome Measures

The primary outcome was the physical well-being dimension of health-related quality of life as measured by the physical well-being subscale of the Functional Assessment of Cancer Therapy Scale–General (FACT-G), version 4. Given the complexity of developing and validating a new instrument, we chose from among existing published and validated instruments. After identifying 34 relevant instruments,[15, 16] we selected those that had been developed specifically for patients with cancer, were self-administered, and could be completed within 20 minutes. Previously demonstrated validity and reliability were also important.

Questionnaires designed for specific cancers or involving a possibly misleading visual analog scale were excluded. Two instruments fulfilled our criteria: the European Organization for Research and Treatment of Cancer Quality of Life questionnaire[17] and the FACT-G scale.[18] We used the latter because it proposed aggregated scores. The physical well-being dimension incorporates

items potentially influenced by the call back, such as pain, nausea, fatigue, and adverse effects of treatment. The dimension contains seven items, 0–4 points each; the possible score ranges from 0–28 (worst–best), calculated by adding the scores of all the items.

Since our hypothesis was that the physical well-being dimension would improve with better symptom management, we evaluated symptoms as an intermediate secondary outcome. In addition, we used an instrument designed specifically to assess symptoms of patients with cancer: the Memorial Symptom Assessment Scale (MSAS).[19] The MSAS was selected because it fulfilled the same criteria as the FACT-G. The MSAS measures the frequency and severity of 32 symptoms using three subscale scores: psychological, physical, and global distress. The total MSAS score is the average of all 32 symptoms. Each of the three MSAS subscale scores, as well as the overall score, are averaged, with a resulting range of 0–4 (no symptoms–worst symptoms).

Additional secondary outcomes were measured using the other dimensions of the FACT-G: the social-family well-being subscale (seven items), the emotional well-being subscale (six items), and the functional well-being (distress caused by illness) subscale (seven items). The last secondary outcome evaluated was overall quality of life measured by the FACT-G global score. This score ranges from 0–108 (worst–best quality of life).

Sample Calculation

The sample was calculated based on the primary outcome: changes in the physical well-being dimension of health-related quality of life as measured by the FACT-G. Since the possible score of the FACT-G physical well-being subscale is 0–28 (worse–best, seven items with 0–4 points each), we chose three as the effect size. The study was designed to have at least 80% power to detect a change of three or more points in the FACT-G physical well-being subscale, with a two-sided significance level ($p \leq 0.05$). We considered three points a conservative estimate of clinical significance because one study reports a two-point difference in the total FACT-G score as borderline clinically significant.[20] Each group had 52 patients. Based on the assumption of a 35% nonresponse rate, the total number of patients was 150.[21]

Intervention (Call Back)

A comprehensive and detailed operations manual reinforcing standardized study methodology, procedures, and data collection forms was created and distributed to each clinical pharmacist. The first set of questionnaires (FACT-G and MSAS) was administered shortly after consent was obtained. At least three attempts were made by the clinical pharmacist to reach each patient in the call-back group. The first attempt was made 48–72 hours after hospital discharge. During the call, patients were asked if they had experienced any problems since discharge. Information was solicited on both drug-related and non–drug-related problems. Drug-related questions addressed concerns about access to drugs and adverse drug events. Adequate understanding about and adherence to drug regimens were assessed. When appropriate, patients were given advice, support, and reinforcement of education provided at the time of discharge. Non–drug-related problems were triaged, and appropriate follow-up recommended. Patients in the control group did not receive telephone follow-up.

Both sets of questionnaires solicited information about symptoms and quality of life during the previous 7 days. Mailing the second set was timed so that patients could evaluate the effect of the call back on their quality of life during the previous 7 days. Questions were asked about contact provided by any health care professional since discharge.

If the set of questionnaires was not returned within 2 weeks after the mailing, nonresponders received a telephone reminder. To eliminate bias, an administrative assistant conducted the telephone reminders using a prepared script. If necessary, patients were offered another set of questionnaires. After two telephone reminders a week apart, and without return of the second set of questionnaires, the patient was considered lost to follow-up.

To assess the successful administration of the call back, we collected data on the number of attempts made, the level of training of the pharmacy professional providing the call back (Pharm.D., resident, student), the person reached, the problem(s) identified and action(s) taken, whether the patient's physician was notified of any problem(s), and the time spent to complete the call back (including problem resolution).

Other Data Collected

To assess the comparability of included versus excluded patients and the comparability between groups, we collected the following information about every screened patient: sex, age, ethnicity, type of insurance coverage, inpatient versus outpatient, type of cancer, chemotherapy regimen, and emetogenicity level. We used a specifically designed five-item scale (Hesketh scale) to quantify emetogenicity level.[22] Because the literature is inconsistent regarding measurement of emetogenicity levels,[23] we conducted our statistical analysis on these data in two ways: using the Hesketh five-item scale, and then collapsing this same scale into a three-item (low, medium, high) scale. Karnofsky performance status was also evaluated for each enrolled patient.[24] This score is a standard tool for measuring the ability of patients with cancer to perform ordinary tasks. Scores range from 0–100; higher scores indicate better ability to perform daily activities.

Data about the discharge process consisted of whether planning and counseling were conducted, date of discharge, and the role of the health professional conducting the discharge process (pharmacist, pharmacy resident, pharmacy student, or nurse). Although discharge planning and counseling are routine at UCSF, drugs are obtained by patients from an outside pharmacy of their choice. Therefore, the type of dispensing pharmacy (independent, chain store, mail order) was collected because our hypothesis was that counseling at the point of dispensing could differ by pharmacy type.

Data Management and Quality Control

After discharge for the control group and call back for the intervention group, the FACT-G, the MSAS, and all forms were sent to a study coordinator who entered all data into a database and conducted a quality-control check. Scores of the FACT-G[25] and MSAS[19] questionnaires were calculated directly by the database.

Statistical Analysis

Continuous variables (e.g., age, FACT-G and MSAS scores) were compared using the Student *t* test, ordinal variables (e.g., emetogenicity level and Karnofsky performance status) using the Wilcoxon test, and categorical variables (e.g., ethnicity and type of insurance coverage) with the χ^2 or Fisher exact test. Further analysis of variance was adjusted for baseline differences.

We compared age, sex, ethnicity, type of insurance coverage, number of chemotherapy cycles, and emetogenicity level between included and excluded patients. In addition, all included patients were compared by Karnofsky performance status and by FACT-G and MSAS scores according to their randomization, that is, intent to treat. We also conducted the analysis excluding the four patients in the call-back group who did not receive the telephone follow-up.

Changes in the FACT-G and MSAS score within each group were analyzed with the paired Student *t* test.

Results

Patient Characteristics

Of 261 patients who were screened, 100 either refused to participate or met at least one exclusion criterion (Figure 1). Some differences were noted between included and excluded patients: enrolled patients were younger (53 ± 14 vs 58 ± 16 yrs, p=0.008), more likely to be Caucasian than other ethnicity (78% vs 65%,

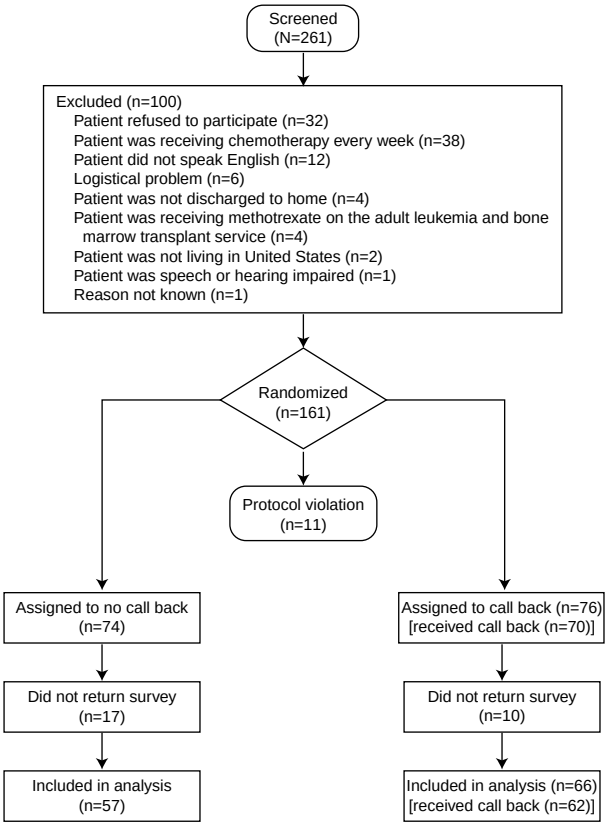

Figure 1. Patient flow schematic.

Table 1. Baseline Characteristics of Respondents

	Control Group	Call-Back Group	p Value
No. of patients	57	66	—
Age, mean ± SD (yrs)	53 ± 12	53 ± 14	0.787
Age > 65 yrs (no. of pts)	9	18	0.134
M/F	25/32	27/39	0.855
Ethnicity (no. of pts)			
Asian or Pacific Islander	6	6	—
African-American	4	2	—
Caucasian	44	53	—
Hispanic	3	5	—
Other	0	0	—
Caucasian/all others	44/13	53/13	0.825
Type of coverage (no. of pts)			
Private	47	79	—
Medicaid	2	3	—
Medicare	8	13	—
Self-pay	0	1	—
Private/all others	47/10	49/19	0.383
Inpatient/outpatient (no.)	28/39	30/36	0.728
Chemotherapy cycles, mean ± SD (no.)	2.6 ± 1.4	2.5 ± 1.9	0.180
Emetogenicity level,[a] mean ± SD	3.8 ± 1.5	4.3 ± 1	0.079
Karnofsky performance status,[b] mean ± SD	82 ± 14	84 ± 12	0.583
Discharge counseling provided: yes/no	54/3	65/1	0.336
Person providing discharge counseling (no.)			
Pharmacist	46	51	—
Resident	1	3	—
Student	6	11	—
Nonpharmacist	1	0	—
Pharmacist/all others	46/8	51/14	0.478
Type of dispensing pharmacy (no.)			
Independent	5	6	—
Chain store	49	55	—
Mail order or unknown	3	5	—
Chain store/all others	49/8	55/11	0804

[a]Hesketh's five-item scale: 1 = nonemetogenic with less than 10% of patients vomiting, 5 = extremely emetogenic with more than 90% of patients expected to vomit without antiemetic prophylaxis.
[b]Measure of the ability of patients with cancer to perform ordinary tasks. Score ranges from 0–100; higher scores indicate better ability to perform daily activities.

p=0.024), had private insurance coverage (77% vs 60%, p=0.007), and had received chemotherapy with a higher emetogenicity level on the Hesketh scale (4.0 ± 1.3 vs 3.4 ± 1.5, p=0.002).

A total of 161 patients were randomized; of these, 11 were excluded after randomization because of protocol violations. Of the remaining 150 patients, 76 were assigned to the call-back group and 74 to the control group, who received no telephone follow-up. In the control group, 17 patients did not return the survey; therefore, 57 control patients were included in the analyses. Of the 76 patients assigned to call back, three could not be reached after three attempts, two were not called because of logistical problems, and one refused further discussion. We used an intent-to-treat approach and therefore included patients assigned to the call-back group who did not actually receive telephone follow-up. Of the 76 patients in the call-back group, 10 did not return the survey; therefore, 66 call-back patients were included in the analyses.

The call back was provided by a pharmacist for 80% of the patients, a resident for 13%, and a student for the remaining 7%. The mean time between discharge and call back was 3.2 days. The mean duration of call back and problem resolution was 7.4 ± 6 minutes (range 0–30 min).

Of the 150 patients enrolled, 52% returned the second set of questionnaires immediately; 137 telephone reminders were conducted, and 13 sets of questionnaires were resent. Twenty-one percent of patients returned the questionnaires after the first call; 9% returned them after the second call. The global response rate was 82%. Patients who did not receive telephone follow-up

Table 2. Primary and Secondary Outcomes: Comparison of Scores at Baseline and After Intervention Between Patient Groups

Assessment Tool	Control Group (n=57)	Within-Group p Value[a]	Call-Back Group (n=66)	Within-Group p Value[a]	Between-Group p Value
FACT-G					
Physical					
Baseline	19.7 ± 5.8		19.6 ± 5.1		0.321
After intervention	18.2 ± 6.2		18.1 ± 5.9		0.745
Difference[b]	-1.44 ± 5.02	0.034	-1.52 ± 5.37	0.025	0.604
Social					
Baseline	23.6 ± 4.9		23.7 ± 4.8		0.878
After intervention	22.8 ± 5.0		22.8 ± 5.8		0.292
Difference[b]	-0.74 ± 2.81	0.053	-0.96 ± 3.84	0.047	0.019
Emotional					
Baseline	19.0 ± 4.3		18.4 ± 3.4		0.088
After intervention	18.9 ± 4.1		18.2 ± 3.9		0.657
Difference[b]	-0.15 ± 2.36	0.639	-0.21 ± 3.40	0.619	0.006
Functional					
Baseline	18.6 ± 5.6		18.9 ± 5.3		0.665
After intervention	16.6 ± 6.4		16.2 ± 5.9		0.493
Difference[b]	-2.02 ± 4.73	0.002	-2.69 ± 4.88	<0.001	0.811
Total score					
Baseline	80.7 ± 15.2		80.6 ± 14.0		0.492
After intervention	76.4 ± 17.2		75.3 ± 15.9		0.531
Difference[b]	-4.37 ± 10.70	0.003	-5.37 ± 11.80	<0.001	0.454
MSAS					
Psychological					
Baseline	0.9 ± 0.6		1.1 ± 0.7		0.362
After intervention	1.0 ± 0.7		1.1 ± 0.8		0.128
Difference[b]	-0.01 ± 0.59	0.387	-0.01 ± 0.70	0.421	0.203
Physical					
Baseline	0.8 ± 0.6		0.9 ± 0.6		0.614
After intervention	0.9 ± 0.5		1.0 ± 0.6		0.557
Difference[b]	-0.18 ± 0.50	0.009	-0.15 ± 0.56	0.029	0.370
Global distress					
Baseline	0.9 ± 0.5		1.0 ± 0.6		0.421
After intervention	1.0 ± 0.6		1.1 ± 0.7		0.125
Difference[b]	-0.16 ± 0.47	0.011	- 0.15 ± 0.62	0.056	0.042
Total score					
Baseline	0.7 ± 0.4		0.8 ± 0.4		0.665
After intervention	0.8 ± 0.4		0.9 ± 0.5		0.193
Difference[b]	-0.11 ± 0.34	0.018	-0.14 ± 0.41	0.008	0.149

FACT-G = Functional Assessment of Cancer Therapy Scale–General; MSAS = Memorial Symptom Assessment Scale.
[a]Paired Student *t* test.
[b]A negative difference means worsening of quality of life or symptoms.

were at greater risk of not returning the second set of questionnaires (relative risk 2.08, 95% confidence interval 0.97–4.45). Mean time between completion of the two measures was 20 ± 12 days in the call-back group and 17 ± 11 days in the control group (p=0.16).

The two groups had similar baseline characteristics (Table 1). The discharge counseling process and type of dispensing pharmacy did not differ between groups.

Outcome Measures

No differences were seen in the primary outcome measure (physical well-being subscale) between the two groups (Table 2). These scores decreased between measures obtained before and after intervention, indicating a worsening of quality of life.

Secondary outcomes, such as global quality of life or symptoms, did not differ between the two groups (Table 2). Within-group comparisons revealed a decrease in all quality-of-life dimensions and a worsening of symptoms except in the emotional well-being dimension of the FACT-G and the psychological symptoms dimension of the MSAS.

Table 3. Problems Identified in Call-Back Group

	No. of Patients	Patients Telephoned (%)
Patients called	70	100
Patients with at least one problem identified	46	66
Problems		
Drug pickup or delivery	3	4
Insurance coverage	0	0
Poor understanding of instructions for taking drugs	5	7
Compliance	2	3
Dispensing error	0	0
Adverse effects	35	50
Other	6	9

Since the emetogenicity level was marginally different (p=0.079), this has been considered a potential confounder. Analysis of variance, adjusted for emetogenicity level measured on both the five-item scale and the collapsed three-item scale, did not indicate any differences in primary or secondary outcomes. Results of an analysis excluding the four patients in the call-back group who did not receive telephone follow-up were similar to those of the intent-to-treat analysis.

Assessment of the Call Back

During the call back, the clinical pharmacist identified at least one problem in each of 46 patients; half of these were related to chemotherapy or ancillary therapy (Table 3). Other problems were poor understanding of instructions for taking drugs, pickup or delivery of prescriptions, compliance problems, or disease-related problems. Thirty-eight patients were counseled, one dispensing clarification was made, four new prescriptions were ordered, and six patients were triaged to another health care provider (Table 4).

An example of a serious adverse reaction that was found on call back involved a 72-year-old man with non–small-cell lung cancer who was admitted to the infusion center for his second cycle of chemotherapy with paclitaxel and carboplatin. His bone scan showed widely metastatic bone disease. He also had multiple pulmonary nodules and mediastinal adenopathy, as well as liver metastases versus liver cysts. Due to his lack of response, the patient was to receive only palliative therapy in the future. He had a history of deep venous thrombosis. His drug regimen consisted of warfarin, famotidine, and guaifenesin with dextromethorphan cough syrup. He was placed in the call-back group and was called 2 days after his second chemotherapy cycle. At that time he complained of constant coughing, chest pain, and nosebleeds. His laboratory data on the day of chemotherapy indicated an elevated international normalized ratio and prothrombin time. A recommendation was made that the patient stop taking warfarin and come to the clinic for evaluation. The patient's oncologist was notified, and the patient was seen the following morning in the clinic.

Contact with a Health Professional After Discharge

Forty-five (68%) of 66 patients in the call-back group and 23 (40%) of 57 patients in the control group (p=0.007) reported having had at least one contact after discharge with a health professional who counseled them.

Table 4. Actions Taken in Response to Problems Identified in Call-Back Group

	No. of Patients	Patients Telephoned (%)	Patients with Problems (%)
Patients called	70	100	66
Actions taken			
Patient counseling	38	54	83
Dispensing clarification	1	1	2
New prescription ordered	4	6	9
Drug-related triage	3	4	7
Non–drug-related triage	3	4	7
Physician notified of any problem or question	8	11	17
Other	9	13	20

Table 5. Patients in Control Group Who Had Contact versus Those Who Had No Contact with Health Care Professional at Baseline and After Intervention

	No Contact (n=34)	Had Contact (n=23)	Between-Group p Value
FACT-G			
Physical			
Baseline	19.0 ± 5.9	20.8 ± 5.7	0.258
After intervention	18.5 ± 6.6	18.0 ± 5.7	0.763
Difference[a]	-0.5 ± 4.2	-2.8 ± 5.8	0.090
Social			
Baseline	22.5 ± 5.4	25.2 ± 3.6	0.039
After intervention	22.0 ± 5.8	24.1 ± 3.2	0.128
Difference[a]	-0.5 ± 2.8	-1.1 ± 2.9	0.393
Emotional			
Baseline	18.5 ± 4.9	19.7 ± 3.0	0.322
After intervention	18.6 ± 4.8	19.2 ± 2.9	0.638
Difference[a]	-0.1 ± 2.8	-0.5 ± 1.5	0.329
Functional			
Baseline	17.9 ± 6.1	19.7 ± 4.7	0.238
After intervention	16.7 ± 6.7	16.4 ± 6.2	0.873
Difference[a]	-1.2 ± 4.4	-3.3 ± 5.0	0.104
Total Score			
Baseline	77.9 ± 16.8	85.1 ± 11.5	0.084
After intervention	75.8 ± 19.3	77.2 ± 13.7	0.775
Difference[a]	-2.1 ± 10.3	- 7.9 ± 10.5	0.045
MSAS			
Psychological			
Baseline	0.9 ± 0.7	0.9 ± 0.6	0.759
After intervention	0.8 ± 0.6	1.2 ± 0.6	0.045
Difference[a]	0.1 ± 0.6	-0.3 ± 0.6	0.056
Physical			
Baseline	0.8 ± 0.5	0.7 ± 0.6	0.572
After intervention	0.9 ± 0.6	1.0 ± 0.4	0.229
Difference[a]	-0.1 ± 0.5	-0.3 ± 0.5	0.045
Global Distress			
Baseline	0.9 ± 0.5	0.8 ± 0.5	0.222
After intervention	0.9 ± 0.6	1.2 ± 0.6	0.139
Difference[a]	0.0 ± 0.4	-0.4 ± 0.5	0.001
Total Score			
Baseline	0.7 ± 0.4	0.7 ± 0.5	0.759
After intervention	0.8 ± 0.4	0.9 ± 0.4	0.304
Difference[a]	-0.1 ± 0.3	-0.2 ± 0.3	0.092

FACT-G = Functional Assessment of Cancer Therapy Scale–General; MSAS = Memorial Symptom Assessment Scale.
[a]A negative difference means worsening of quality of life or symptoms.

Subanalyses

In a post hoc subgroup analysis of patients in the control group, we compared those who had had a contact with a health professional with the others (Table 5). Those who had had a contact experienced greater worsening of their symptoms (p=0.001 for global distress index) and quality of life (p=0.045 for total FACT-G).

Discussion

Results of analyses did not show any difference in the physical well-being dimension of quality of life. Improvements in other dimensions of quality of life, overall quality of life, and MSAS scores were not found. Intervention with patients with cancer evaluated in other studies have yielded mixed results when measuring changes in quality of life.[26] We explored possible reasons for finding no differences: duration of study period, types of measures applied, sample, selection bias, heterogeneity in provision of call back, and lack of actual influence of call back.

Mean time between the two measures of

quality of life and symptoms was 20 days in the call-back group and 17 days in the control group (p=0.16). One study showed that the instrument used demonstrated good sensitivity to change over a 2-month period.[18] Within-group comparisons (Table 2) revealed a worsening of the physical well-being dimension of quality of life. This showed the instrument's ability to detect changes in a shorter period.

The two telephone reminders were successful and increased the answer rate to 82%, which was higher than the 65% rate we expected. The standard deviation of the population included in this study was close to the one used for the power calculation. This confirms that the study was adequately powered to detect a change of three or more points in the primary outcome (physical well-being subscale of FACT-G).

Two hundred sixty-one patients were screened; 100 (38%) of these were excluded. The excluded patients were older, tended to have government insurance coverage, and were more likely to be non-Caucasian and to have received chemotherapy with a lower emetogenicity level than the included patients. One can hypothesize that these excluded patients tended to have less contact with the health care system and would have benefited more from a call back.

To reduce heterogeneity between patients, we excluded those who were chemotherapy naïve. Problems identified during call back were largely related to adverse effects. Other problems, such as those related to prescription pickup or delivery, insurance coverage, understanding instructions, or dispensing drugs, were infrequent. Our hypothesis is that chemotherapy-naïve patients may have had more problems. One study found greater patient satisfaction in a call-back group than in a control group.[27] However, the patient population consisted of patients from the general medicine service who were discharged after a single admission. In contrast, the problems identified in patients with cancer who were receiving subsequent chemotherapy cycles are probably fewer than, and different from, those of patients whose conditions were treated on the medicine service. The former are accustomed to the discharge process, and insurance and dispensing problems have been solved previously.

In our study, 95% of the randomized patients received comprehensive discharge counseling from a pharmacist. In addition, nurses integrated patient teaching about adverse effects during outpatient administration of chemotherapy in the infusion center. This demonstrates the high priority placed on continuity of care in the services participating in the study. Discharge counseling and call back are complementary activities. It would have been desirable to evaluate both. Because discharge counseling is considered a standard of care by the Joint Commission on the Accreditation of Healthcare Organizations, its randomization was not feasible. The high quality and rate of discharge counseling could explain the lack of difference between the call-back and control patients. Last, we hypothesized that drug counseling at the point of dispensing could have influenced our results.

A final consideration about selection bias concerns the different emetogenicity levels between the two study groups despite randomization. This baseline difference was addressed in the analysis of variance.

Although heterogeneity in services and in the training of pharmacists could have reduced the efficacy of the call back, we believe this heterogeneity reflects real-world practice and increases the ability of the study to be generalized.

The number of patients reporting that they had had at least one contact with a health practitioner is higher in the call-back group than the control group (68% vs 40%, respectively). Because patients in the control group who had contact with a health professional experienced greater worsening of their global distress index and quality of life, we cannot dismiss the fact that patients in the control group were at high risk and received additional interventions from other health professionals. This too, could explain the lack of difference between the groups.

Problems were identified in 46 of 70 call-back patients, which represents a substantial number. Many side effects, occasionally serious, were identified, and counseling was provided. The importance of this finding cannot be underestimated. However, patient follow-up is unknown and deserves further study. Perhaps selection of a process-oriented outcome or patient-satisfaction measure, as used in one study,[27] would yield a positive result. In fact, we suggest that the higher response rate in the call-back group could serve as a proxy measure for improved patient satisfaction.

Our study has limitations. First, patients included differed from those excluded. This implies that extrapolation to the excluded population is questionable. In general, randomized controlled trials favor internal rather than

external validity. Second, postintervention quality of life and MSAS scores were evaluated only once. A second measure may have been useful, but the cyclic administration of chemotherapy would have confounded this effort. Third, patients may have begun a subsequent chemotherapy cycle before completing the second set of questionnaires. However, since the mean time between completion of the two measures did not differ significantly between groups, we do not think that this could be a confounding factor.

Conclusion

Call back by a pharmacist increased patient contact with a health care professional, resulting in increased problem identification. However, 40% of control group patients had contact with a health care professional, which indicates that call-back intervention should be better integrated among health professionals.

Our study showed no difference in symptoms and quality of life in call-back patients with cancer who were not chemotherapy naïve versus the control group, who did not receive telephone follow-up. The positive effect of the call back on patient satisfaction has been demonstrated.[26] Future studies should focus on a way to better identify and target high-risk patients and should examine other intermediate or process outcomes, as well as final outcomes such as quality of life.

One possible explanation for the lack of effect of the intervention is that high-risk patients in the control group received similar intervention from other health care professionals. We suggest that telephone follow-up be better coordinated among health professionals.

Acknowledgments

We thank Monica Lee, Lucy Maa, Kelly Rabun, Kethen So, Herman Wong, and Courtney Yuen for providing the telephone follow-up and collecting data; Scott Fields for patient randomization; B. Joseph Guglielmo and Michael Winter for their strong support and feedback; and the administrative assistants of the Department of Clinical Pharmacy, University of California San Francisco, for completing telephone reminders.

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