Enhancing Patient-Provider Communication With the Electronic Self-Report Assessment for Cancer: A Randomized Trial

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ABSTRACT

Purpose

Although patient-reported cancer symptoms and quality-of-life issues (SQLIs) have been promoted as essential to a comprehensive assessment, efficient and efficacious methods have not been widely tested in clinical settings. The purpose of this trial was to determine the effect of the Electronic Self-Report Assessment–Cancer (ESRA-C) on the likelihood of SQLIs discussed between clinicians and patients with cancer in ambulatory clinic visits. Secondary objectives included comparison of visit duration between groups and usefulness of the ESRA-C as reported by clinicians.

Patients and Methods

This randomized controlled trial was conducted in 660 patients with various cancer diagnoses and stages at two institutions of a comprehensive cancer center. Patient-reported SQLIs were automatically displayed on a graphical summary and provided to the clinical team before an on-treatment visit ($n = 327$); in the control group, no summary was provided ($n = 333$). SQLIs were scored for level of severity or distress. One on-treatment clinic visit was audio recorded for each participant and then scored for discussion of each SQLI. We hypothesized that problematic SQLIs would be discussed more often when the intervention was delivered to the clinicians.

Results

The likelihood of SQLIs being discussed differed by randomized group and depended on whether an SQLI was first reported as problematic ($P = .032$). Clinic visits were similar with regard to duration between groups, and clinicians reported the summary as useful.

Conclusion

The ESRA-C is the first electronic self-report application to increase discussion of SQLIs in a US randomized clinical trial.

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INTRODUCTION

Patients with cancer arrive in the therapeutic setting with varying levels of symptomatology during the diagnostic period. Once treatment begins, another profile of symptoms commences as toxicities and treatment-related complications develop. Communication between patients and clinicians is essential to management of troublesome symptoms and adverse effects. Reporting of symptoms and quality-of-life issues (SQLIs) has shifted recently from a traditional clinician synthesis report to the patients' self-report. Inclusion of patient-reported outcomes in oncology settings and care has been promoted by federal agencies,¹ clinicians,²⁻⁵ and investigators.^{2,3,6}

To date, most clinical settings have not established efficient methods to collect patient-reported SQLIs.⁴ Technologies do exist to provide opportunities for electronic self-report, but these have been tested most often outside the United States.^{5,7-10} Our research team has developed a feasible, usable, and acceptable system, the Electronic Self-Report Assessment–Cancer (ESRA-C).¹¹⁻¹⁴ We now report results of a randomized trial testing the impact of ESRA-C on patient-clinician SQLI communication in two ambulatory sites of a comprehensive cancer center (CCC). The purpose of this trial was to determine the effect of ESRA-C on the likelihood of SQLIs being discussed between clinicians and patients with cancer in ambulatory clinic visits.

Secondary objectives included comparison of visit duration between groups and usefulness of ESRA-C as reported by clinicians.

PATIENTS AND METHODS

Study Design and Patients

The ESRA-C study was a prospective, randomized clinical trial designed to compare the likelihood of discussion of SQLIs in an intervention group, where the ESRA-C summary report was available to the clinical team, and a control group, where the ESRA-C report was not available. The study was conducted between April 2005 and June 2007 in a CCC, with approval by the Institutional Review Board of the Fred Hutchinson Cancer Research Center/University of Washington Cancer Consortium.

Adult ambulatory patients (≥ 18 years old) with any cancer diagnosis, starting a new medical or radiation treatment regimen at the Seattle Cancer Care Alliance or the University of Washington Medical Center, were invited to participate. Clinicians who potentially would assess patients during on-treatment clinical visits were also invited to participate. Written informed consent was obtained for all patients and clinicians.

Symptom and Quality-of-Life Measures

Development of the software has been reported previously,¹⁵ and adequate patient acceptability and feasibility of the ESRA-C assessment application used in this trial are reported elsewhere.^{12,13} Patients completed validated questionnaires (Data Supplement) comprising the ESRA-C on touch-screen, notebook computers in clinic waiting rooms at two visits; the time 1 study point occurred before starting treatment, and time 2 (T2) was 4 to 6 weeks later when treatment-related SQLIs were expected. After the T2 assessment, patients were randomly assigned automatically by the ESRA-C application to study groups (1:1); block random assignment ensured that clinicians did not see more than two patients in the same study group in succession. In addition, only two patients per principal clinician (typically the attending) per month were enrolled to prevent a training effect for clinicians viewing the intervention. T2 clinic

visits were audio recorded to measure impact of the intervention on clinician-patient communication about SQLIs.

Intervention and Control Conditions

The intervention in this trial consisted of providing a two-page, color graphical summary, automatically generated by ESRA-C, of the participants' self-reported SQLIs. Each SQLI reported at or above a predetermined threshold (RTh) was flagged by color and height of a bar graph (Data Supplement). The summary report was printed and handed to the clinician or attached to the patient's chart immediately before the targeted T2 clinic visit. No recommendations were offered to address any reported SQLI; usual best practices were applied by the clinicians in each service. Although control group participants completed the ESRA-C questionnaires, no summary was printed for the clinician. During the time of the trial, clinics at the study sites had no systematic method for collecting patient-reported SQLIs other than clinician verbal interview during the face-to-face visit.

Outcome Measures

To obtain our primary outcome measure, discussion of SQLIs by clinicians and patients, we audio recorded all communication between clinicians, patients, and accompanying friends or family members at each T2 visit (Data Supplement). Secondary outcomes included clinic visit duration and clinician evaluation of the intervention, measured by an investigator-developed post-study questionnaire asking about receipt of the summaries and their usefulness in identifying appropriate SQLIs, guiding clinical interviews, and promoting communication with patients. Patients self-reported demographics on the time 1 ESRA-C assessment; additional clinical variables were coded from the medical record (eg, diagnosis).

Statistical Analyses

The trial sample size was computed using $\alpha = .05$ and $\beta = .1$ as 315 patients per arm (630 patients total) based on the effect size of a composite communication score reported by Detmar et al.³ The accrual goal was increased to 702 patients to allow for attrition. Before analysis, the primary end point was changed to the binary SQLI discussed (or not), and the primary

Fig 1. Number of patients enrolled onto the study, randomly assigned to a control or intervention group, and included in the analysis. T1, time 1; T2, time 2.

analysis was modified to model the likelihood of being discussed with adjustment for whether the SQLI was RTh, a modeling strategy that overcomes the limitations of simply counting items discussed.

Each patient received a score of whether each self-reported SQLI in ESRA-C was discussed (yes or no). The multiple assessments were correlated. The measure of group effect on whether an SQLI was discussed was the ratio of the odds of being discussed in the intervention group divided by the odds of being discussed in the control group. An odds ratio is unity when there is no between-group effect, less than unity when the odds of an SQLI being discussed is higher in the control group, and greater than unity otherwise. The odds ratio is the natural effect measure for the subsequently described statistical modeling.

We used generalized estimating equations (GEEs)¹⁶ to assess for group global effect. GEE modeling takes into account the correlations of the multiple scores. The primary GEE model included the following terms: a main effect for group, main effects for the SQLI, main effects for whether each SQLI was RTh on the ESRA-C (yes or no), the interaction between group and RTh terms, and the interaction between SQLI and the corresponding RTh. SQLI by RTh interaction terms allowed the odd ratios of SQLI being discussed to differ across the combinations of SQLI and RTh. The model was specifically structured to assess whether RTh was a modifier of group effect (interaction) and was tested at the $P = .05$ level. This test for interaction was not directional. If the RTh by group interaction had not been significant, then the GEE model would have been re-estimated without the RTh by group interaction term and the group main effect tested at $P = .05$. Addition of terms for clinical site and/or type of clinical site led to the global models with too many parameters (convergence failure). Future analyses of this data set will focus on assessing the role of clinical site attributes on individual SQLIs.

Logistic regression modeling was used to assess each SQLI separately to descriptively assess directionality. These SQLI-specific logistic regression

models include RTh and group main effects and their interaction. Contribution of the interaction term in these exploratory models was assessed at a significance level of $P = .1$, and the estimated odds ratios and their CIs are displayed as forest graphs. Given evidence of interaction, the separate odds ratios were estimated for each level of RTh.

RESULTS

Sample

Of 1,104 patients assessed for eligibility, 31 patients did not meet eligibility requirements; 308 patients declined participation, most stating they were too busy, sick, or not interested, whereas eight patients declined to be audio recorded and five patients did not want to use computers. Of 765 enrollees, 660 (86%) completed the T2 assessment and were randomly allocated to control or intervention group (Fig 1). Of 295 clinicians who possibly would interact with future patient participants, 262 (89%) agreed to participate.

Table 1 lists the demographics and clinical characteristics of the 660 randomly assigned patients. There were no significant differences between groups for any demographic measure. Table 2 lists the demographics of the clinician participants. A total of 590 discussions were analyzed. During the recorded clinic visits, a total of 76 principal clinicians and various other consented clinicians were present. Because we maintained anonymity of the consented clinicians in the audio data, we only documented the sex and type of each clinician present at each visit; thus, each clinician may have

Table 1. Demographics and Clinical Characteristics of Randomly Assigned Patients

Demographic or Clinical Characteristic	Control (n = 333)		Intervention (n = 327)		P
	No. of Patients	%	No. of Patients	%	
Sex, male	177	53.2	179	54.7	.68
Age, years					.55
Mean	54		54		
Range	18-86		18-89		
Ethnicity, Hispanic/Latino	5	1.6	7	2.2	.56
Race, minority or multiple	29	8.7	34	10.4	.46
Married/partnered	228	69.3	232	71.2	.60
Low income ($\leq$ \$35,000/HH annual)	86	28.1	70	23.3	.19
Some college or college graduate	240	72.3	233	71.9	.92
Frequent computer use	259	79.9	264	81.5	.62
Service line					.83
Medical	158	47.4	150	45.9	
Radiation	74	22.2	49	24.2	
Stem-cell transplantation	101	30.3	98	30.0	
Cancer diagnosis					.88
Breast	22	6.6	21	6.4	
GI	40	12.0	40	12.2	
Genitourinary	41	12.3	38	11.6	
Gynecologic	29	8.7	31	9.4	
Head and neck	24	7.2	30	9.2	
Leukemia	57	17.1	45	3.8	
Lung	23	6.9	18	5.5	
Lymphoma	47	14.1	53	16.2	
Myeloma	26	7.8	26	7.8	
Other	24	7.2	30	9.0	
Recurrent disease	53	16.6	55	17.4	.80

Abbreviation: HH, household.

Table 2. Demographics of Clinician Participants

Demographic	No. of Clinicians (n = 202*)	%
Sex, male	88	43.6
Missing	5	2.5
Age, ≥ 50 years	66	32.6
Missing	3	1.5
Hispanic/Latino	2	1.0
Missing	5	2.5
Minority or multiple race	40	19.9
Missing	7	3.5
Position		
Attending physician	69	34.2
Resident/fellow	29	14.4
Nurse or nurse practitioner	69	34.2
Physician assistant	8	4.0
Other (eg, social worker)	16	7.9
Missing	11	5.5
Specialty		
Medical oncology	71	35.1
Radiation oncology	30	14.9
Hematology/oncology	75	37.1
Other (eg, urology)	19	9.4
Missing	7	3.5

*Two hundred two of 262 enrolled clinicians returned a demographic form.

been present in one or more recorded visit. There was no identifying link between the list of enrolled clinicians and those present for recordings.

Primary Outcome

Numbers and types of SQLIs reported (RTh) and discussed in all recorded visits are listed in Table 3. For the discussed outcome GEE model, the RTh by group interaction term in the GEE model had $P = .032$, meeting the criterion for evidence of an ESRA-C intervention group effect. Because the group effect was manifest in an interaction term, the ESRA-C effect depends on whether the SQLI was reported by the patient at a level indicating a problem (RTh). The odds ratio effect estimate for RTh = no was 1.007 (95% CI, 0.885 to 1.131), thereby failing to provide evidence that the odds of an SQLI being discussed was group dependent when the SQLI has RTh = no. When the SQLI was RTh = yes, the odds ratio estimate was 1.287 (95% CI, 1.047 to 1.583). Thus, when the SQLI had been reported at threshold, there was evidence that the ESRA-C resulted in a nearly 29% increase in the odds of the SQLI being discussed compared with the control condition.

Given the evidence for group effect for the entire set of SQLIs, each SQLI was then descriptively assessed using a logistic regression model for the discussed outcome. Evidence of effect modification was found for the following SQLIs: concentration, cognitive function, impact on sexual activities and interest, and social function. The forest graph in Figure 2 shows the model odds ratio estimates and 90% CIs for each of these SQLIs by whether they were reported at threshold (RTh = no or yes). These odds ratio estimates are from the SQLI-specific logistic regression model with the interaction term included. Observed frequencies associated with odds ratio estimates are shown in Figure 2. There is evidence of qualitative interaction for the SQLIs of concentration and cognitive function. When patients reported these

SQLIs at threshold in the ESRA-C group, the odds of being discussed were lower than when patients in the control group reported similar levels; whereas patients in the ESRA-C group who reported minimal or no problems with these SQLIs had higher odds of SQLIs being discussed than similar patients in the control group. Two other SQLIs with effect modification, social function and impact on sexual activities and interest, were found to have quantitative interactions; odds of these SQLIs being discussed in the patients with RTh = yes in the intervention group was greater than for patients with RTh = yes in the control group, as was the case for patients with no or minimal problems (RTh = no) with these SQLIs. There was no evidence of RTh effect modification for the remaining 18 SQLIs. Figure 3 displays group odds ratio estimates and 90% CIs for these remaining SQLIs with the same kinds of frequencies shown in Figure 2. Although none were significant as main effects, 12 of the 18 SQLIs had odds ratios greater than unity, suggesting a higher likelihood of being discussed in the intervention group.

Secondary Outcomes

In 75 (25.4%) of the 295 recordings in the intervention arm, clinicians made direct verbal references to the ESRA-C summary report. There was no significant difference ($P = .352$) between groups for the average length of clinic visits; the mean length in the control group was 31.7 minutes (standard deviation, 18.8 minutes), whereas the mean length in the intervention group was 30.3 minutes (standard deviation, 17.9 minutes). Visits ranged from 2 to 121 minutes.

Of 262 enrolled clinicians, 113 (43.1%) responded to a questionnaire regarding usability of the ESRA-C summary report. Of those, 57 (50.4%) reported receiving at least one report. On a scale of 1 to 5 (higher score = most usable), scores of 4 or 5 were reported by 38 (67.8%) of 55 clinicians for identifying appropriate areas of SQLI; by 36 (64.3%) of 56 clinicians for guiding the interview; by 28 (50.0%) of 56 clinicians for promoting communication; and by 30 (53.6%) of 56 clinicians for identifying appropriate areas for referral. Nurses were more likely than other clinicians to report that the ESRA-C summary was highly useful in identifying appropriate areas of SQLI ($P = .004$) and identifying appropriate areas for referral ($P = .015$).

DISCUSSION

Although previous clinical trials in oncology conducted in Europe^{7,8} showed that electronic measurement of patients' symptoms had positive impact on patient-clinician communication, to our knowledge, the ESRA-C system is the first self-report application with a direct measure of communication to be evaluated within a randomized clinical trial in all ambulatory services of a CCC in the United States. The intervention was effective in prompting discussion of troublesome SQLIs and was able to focus the clinic visit conversation on issues relevant to the patient's experience without extending the visit.

The ESRA-C trial was able to build on prior research but differed with regard to study design, sample, setting, and method of outcome measure. Basch et al¹⁷ compared clinician- and patient-scored adverse symptom events in a sample of 163 patients with lung cancer and reported that electronic patient reports were of higher concordance

Table 3. SQLIs Reported at Threshold and Discussed (n = 590)

SQLI	Control Group						Intervention Group					
	Discussed						Discussed					
	Reported		Initiated by Clinician		Initiated by Patient or Family		Reported		Initiated by Clinician		Initiated by Patient or Family	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SDS (plus two items)												
Nausea frequency	28	9.5	118	40.0	73	24.7	21	7.1	132	44.7	64	21.7
Nausea intensity	6	2.0	18	6.1	55	18.6	8	2.7	23	7.8	56	19.0
Appetite	47	15.9	116	39.3	70	23.7	46	15.6	126	42.7	67	22.7
Insomnia	63	21.4	49	16.6	73	24.7	57	19.3	55	18.6	73	24.7
Pain frequency	71	24.1	152	51.5	111	37.6	64	21.7	155	52.5	107	36.3
Pain intensity	49	16.6	43	14.6	114	38.6	44	14.9	46	15.6	109	36.9
Fatigue	61	20.7	93	31.5	112	38.0	51	17.3	100	33.9	105	35.6
Bowel pattern	23	7.8	139	47.1	62	21.0	16	5.4	131	44.4	53	18.0
Concentration	19	6.4	2	0.7	14	4.7	16	5.4	13	4.4	13	4.4
Appearance	9	3.1	11	3.7	36	12.2	8	2.7	10	3.4	25	8.5
Impact on sex	120	40.7	7	2.4	3	1.0	122	41.4	20	6.8	7	2.4
Breathing	5	1.7	88	29.8	23	7.8	4	1.4	89	30.2	21	7.1
Outlook	32	10.8	22	7.5	58	19.7	33	11.2	27	9.2	58	19.7
Cough	7	2.4	63	21.4	28	9.5	10	3.4	68	23.1	29	9.8
Fever/chills	3	1.0	104	35.3	17	5.8	5	1.7	100	33.9	25	8.5
PHQ-9												
Depression	63	21.4	27	9.2	14	4.7	54	18.3	34	11.5	15	5.1
Suicidal ideation	2	0.7	3	1.0	2	0.7	1	0.3	7	2.4	1	0.3
EORTC QLQ-C30												
Physical function	46	15.6	78	26.4	96	32.5	35	11.9	68	23.1	102	34.6
Emotional function	25	8.5	53	18.0	74	25.1	12	4.1	70	23.7	71	24.1
Social function	80	27.1	15	5.1	37	12.5	82	27.8	24	8.1	40	13.6
Cognitive function	16	5.4	10	3.4	26	8.8	23	7.8	21	7.1	20	6.8
Role function	93	31.5	34	11.5	68	23.1	86	29.2	31	10.5	70	23.7
Global QOL	90	30.5	28	9.5	28	9.5	74	25.1	27	9.2	30	10.2

Abbreviations: SQLI, symptom and quality-of-life issue; SDS, Symptom Distress Scale; PHQ-9, Patient Health Questionnaire 9; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; QOL, quality of life.

with self-reported quality of life and that only clinician reports were significantly associated with death and emergency room visits. Velikova et al⁷ conducted a study at a cancer center site in England with a patient sample (N = 296) consisting mainly of women with metastatic breast cancer and gynecologic cancers, plus 28 clinic oncologists. The team used a prospective design randomly assigning patients to use a self-report assessment or not. A graphed summary of quality-of-life scores (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30 [QLQ-C30] subscales) was provided to the clinicians for each intervention group patient. Although a recording was made of an on-treatment visit, the scoring may not have been blinded, and the authors reported some evidence of practice effect among clinicians. The intervention group was coded as having discussed significantly more SQLIs. However, because the control group did not answer the QLQ-C30, the analysis could not be focused on whether those discussions were about troublesome issues, and the interaction between whether it was a problem and being discussed could not be determined.

In a more recent Dutch study, Hilarius et al⁸ used a nonrandomized, sequential cohort design to test touch-screen QLQ-C30 assessments in 219 patients and a graphical summary given to 10 oncology clinic nurses. The authors reported that the patients in the postinter-

vention cohort discussed significantly more symptoms with their nurses. Smaller studies^{9,10} of electronic, self-report cancer symptom assessments have resulted in positive results, but the lack of a randomized design and indirect measures of outcomes preclude direct comparison to our current results. In these studies, simple comparisons of frequency were made for the SQLIs addressed with no accounting for the possibility that such issues are differentially discussed depending on the nature and level of the problem.

Exploration of whether ESRA-C could influence verbal discussions of individual SQLIs revealed mixed results. Common SQLIs and those regulated by accrediting commissions were discussed often, whether or not the SQLI was a problem. The intervention resulted in greater likelihood of discussing the impact of cancer and/or treatment on sexual activities and interest and issues relevant to social functioning (family life and social activities). These SQLIs were more often problematic yet discussed much less often than common, regulated SQLIs in either group. ESRA-C may have acted as an icebreaker to open a conversation about sexuality, typically a sensitive topic for many cancer clinicians. Although our study was not powered to test differences for individual SQLIs, the logistic regression findings suggest that certain problematic symptoms highlighted on the ESRA-C summary report, notably those

Fig 2. Odds ratio estimates and 90% CIs for symptoms and quality-of-life issues (SQLIs) that had significant effect modification. Note: For each SQLI, separate odds ratio estimates are shown for whether the SQLI was reported at threshold (RTh; no [N] or yes [Y]) and are from the SQLI-specific logistic regression model with the interaction term included. The observed frequencies associated with each odds ratio estimate are also shown. The numerator is the observed odds of being discussed in the intervention group, and the denominator is the observed odds of being discussed in the control group. Odds ratios computed from observed frequencies will not necessarily be the same as the odds ratio estimates from models. ESRA-C, Electronic Self-Report Assessment–Cancer.

related to cognitive functioning, may have been avoided by clinicians. There is little evidence for how to avoid or treat cognitive dysfunction without diminishing dose during cancer therapy, and clinicians may choose to focus on SQLIs for which they can make a difference.

Hesitancy on the part of patients with cancer to bring up unsolicited SQLIs and clinicians' verbal avoidance of patient-reported concerns have been reported in other research^{18,19} and are topics for further study in the ambulatory cancer care setting. Whether a resource or a knowledge issue, lack of attention to treatment adverse effects can be dangerous; therapeutic protocols often involve dose-limiting toxicities, many of which are subjective in nature and must be assessed reliably and systematically. ESRA-C creates an opportunity to take the first step. Using ESRA-C, patients' needs can be identified with a method that requires little staff effort and creates a database from which symptom and quality-of-life data can be quickly retrieved, processed, and used clinically.

Although this study was conducted in large ambulatory cancer care settings with all major cancer diagnoses represented, the sample did not include patients receiving surgery alone. The patient sample was predominately white and educated with computer experience, limiting generalization to other races and, for example, to those with less than high school educations. Once the ESRA-C intervention summary was delivered to the clinicians, the audio recording provided little information about whether or not the clinician used the summary, although the efficacy of the intervention was observed despite this lack of intervention dose information. Presence of an audio recorder in the clinic room may have influenced verbal behaviors of all participants. Because only one audio recording was made during the study for each participant, these data are only a snapshot of patient-

Fig 3. Odds ratio estimates and 90% CIs for symptoms and quality-of-life issues (SQLIs) for which there is no evidence of effect modification. Note: The odds ratio estimates are for the group main effect in the SQLI-specific logistic regression main-effect model. For each SQLI odds ratio, estimates are shown for the group main effect in the SQLI-specific logistic regression main-effect model. The observed frequencies associated with each odds ratio estimate are also shown. The numerator is the observed odds of being discussed in the intervention group, and the denominator is the observed odds of being discussed in the control group. Odds ratios computed from observed frequencies will not necessarily be the same as the odds ratio estimates from models. ESRA-C, Electronic Self-Report Assessment–Cancer; QOL, quality of life.

clinician communications, and relevant SQLI discussions may have occurred at other times.

The ESRA-C is an innovative method for electronic self-report of cancer symptoms and quality-of-life issues combined with a summary report for providers. Use of ESRA-C in ambulatory oncology care can result in greater focus on issues that are most relevant to the patient's experience of cancer treatment. Discussion of such issues is the first step to a comprehensive plan of care, including patients' priority concerns, treating troublesome symptoms, and addressing diminished quality of life.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

AUTHOR CONTRIBUTIONS

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