Randomized Prospective Trial Exploring the Impact of Structured Journaling in Patients With Sarcoma on the Management of Treatment-Related Adverse Events

N.J. Speece, BBA, MS1; Menglin Xu, PhD2; Gabriel Tinoco, MD2; David A. Liebner, MD2,3; and James L. Chen, MD2,3

QUESTION ASKED: Does the low-tech intervention, symptom journaling, in treatment-naive patients with sarcoma undergoing systemic anticancer therapy improve communication and the management of treatment-related adverse events contributing to an enhanced quality of life (QOL)?

SUMMARY ANSWER: More than half of the participants who performed symptom journaling noted better management of treatment-related adverse events and improved communication with their medical team, ultimately increasing their QOL.

WHAT WE DID: We conducted a prospective randomized two-arm crossover design pilot study evaluating the utility of treatment-related symptom journaling by treatment-naive sarcoma patients undergoing systemic anticancer therapy. Patients with sarcoma were randomly assigned to receive either a symptom journal that was reviewed at every visit after the start of anticancer therapy or after two therapy cycles.

WHAT WE FOUND: Participants who received the journal early were less likely to report a decrease in QOL during anticancer therapy as compared with the late symptom journal arm. In addition, 55% of participants reported the symptom journal to be at least moderately useful. These participants were more likely to report improved communication scores, symptom management, and QOL. Approximately 94% of participants reported either moderately or greatly improved communication with their oncologist and nursing team when using a symptom journal. Those participants noting the usefulness of symptom journaling also reported greater symptom management and QOL.

BIAS, CONFOUNDING FACTOR(S): This study was conducted in patients with sarcoma where there are a multitude of systemic therapies used as first-line therapy. Our results therefore may not necessarily be shared by other tumors or modalities of treatment.

REAL-LIFE IMPLICATIONS: Resources that promote communication and mitigate treatment-related adverse events are key. Although technological solutions are important to explore, simpler and cost-effective resources should not be overlooked. Our data demonstrate that simple, low-tech, symptom-focused journaling improves communication and QOL in patients undergoing systemic anticancer therapy and could be considered for all patients with sarcoma initiating systemic therapy.

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abstract

PURPOSE Treatment-related adverse events associated with systemic anticancer therapy (SACT) can deter patients with sarcoma from completing treatment. With self-monitoring, patients may be better empowered to self-advocate for improved symptom management. We hypothesized that by incorporating journaling, a structured form of self-monitoring, care team communication, and symptom management would improve. We thus designed a prospective randomized trial exploring journaling as a therapeutic adjuvant for symptom management (NCT03258892).

METHODS Participants with sarcoma initiating SACT were randomly assigned to receive either a symptom management journal at the start of SACT or after completing two cycles of SACT. Symptom journals were designed jointly by a cancer patient focus group and by education experts. Journals were reviewed with clinical staff at each visit. Participant responses were obtained through questionnaires. Patient call volume was obtained through the electronic health record.

RESULTS Of 64 participants consented for the trial, 53 were evaluable for analysis. Fifty-five percent of participants reported that the journal was at least moderately useful. These participants were more likely to report improved communication scores ($P = .027$), symptom management ($P = .011$), and quality of life (QOL) ($P = .019$). Participants who received the journal early were less likely to report a decrease in QOL as compared with the late journal group ($P = .757 \vee P = .035$).

CONCLUSION To our knowledge, this is the first prospective randomized trial evaluating the use of structured journaling as a low-cost means to improve treatment-related adverse event management and QOL in patients with sarcoma undergoing SACT. These promising results will need to be confirmed by additional studies.

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In recent times, patient-reported outcome (PRO) tools have garnered much attention in oncology with their association with survival outcomes. Other studies conducted on patients during the palliative phase of their cancer diagnosis concluded that by using a symptom-monitoring instrument, patients felt more in control of the prevalence and severity of physical symptoms.

Completion of PROs electronically (ePROs) has been a focus of several recent studies, given the ease of dissemination and potential to integrate survey results with the electronic health record. However, these ePROs require technical and domain-specific knowledge to implement and complete; furthermore, automated dissemination of these ePROs can place patients at risk for survey fatigue from too many questions. Indeed, for patients who are not tech savvy or who may not have readily available access to the internet or handheld smart device, navigating an ePRO may not be a viable option. More accessible PRO options, such as keeping a symptom journal as explored in this study, may provide a low-cost, easier to implement, and personal alternative. In a recent retrospective study, the majority of participants indicated that the use of a symptom diary prevented them from forgetting or minimizing symptoms, thus improving symptom control and communication with their healthcare provider. Another smaller retrospective study demonstrated that self-monitored nausea and vomiting TRAEs in patient diaries allowed providers to better manage TRAEs in subsequent cycles, reducing symptoms by 13%.

Given these promising data, to our knowledge, we performed the first prospective randomized, single-institution study examining the utility of journaling as a method of improving the management of TRAEs in patients with sarcoma. The purpose of this pilot study was to determine the impact of incorporating structured journaling among systemic anticancer therapy (SACT)-naive patients as standard of care.

METHODS

Participants and Inclusion Criteria

Eligible participants were derived from the Sarcoma clinic at The James Cancer Hospital and Solove Research Institute between August 23, 2017, and May 19, 2019. Participants had to be English-speaking, literate adults age 18 years and older. Participants had to be SACT-naive.

Intervention

Trial participants were provided a Sarcoma Treatment Guide (STG). The STG is a small pocket-sized journal for participants to document information relevant to their treatment, such as symptom severity and frequency, medication needs, questions for the medical team, and personal journaling. Sample pages are provided in the Data Supplement (online only). The research team designed the STG in collaboration with a professional graphic designer, which was approved by The Ohio State Patient Education Department. The approval process included a patient focus group that provided feedback regarding format, wording, and content. Education on common TRAEs and symptom management is included in the STG.

Patient Surveys

Two on-treatment patient surveys were administered: one after two cycles of SACT and the other after two additional therapy cycles (Data Supplement). Patient on-treatment surveys focused on the patient’s perception of their communication with their providers, symptom management, and QOL. There was an additional end-of-treatment survey that, in particular, addressed whether the STG provided value for the patient in regard to their treatment (Data Supplement).

Outcomes Evaluated

The primary end point of the trial was to evaluate whether symptom management and communication were improved in SACT-naive patients who received an STG as compared with those who did not, as measured by a participant survey, and whether tracking telephone calls related to TRAEs were reduced. The secondary end point was to explore whether patients who have previously undergone SACT (arm B participants) benefited from an STG in regard to symptom management and had improved communication with providers as measured by an administered survey, along with tracking telephone calls related to TRAEs. Finally, we also assessed patient satisfaction with using the STG at the end of the trial. Composite variables were created to represent the constructs of symptom management, communication, QOL, and end of study or patient satisfaction by averaging across the corresponding survey items. Also, the number of patient telephone calls was summed to represent the total calls. Except for the end of study survey, all of the variables were assessed at both time 1 (end of the first two cycles of systemic therapy) and time 2 (end of the study, two cycles apart from time 1).

Institutional Review Board Approval

This study was approved by The Ohio State Institutional Review Board (2017C0052) and listed on ClinicalTrials.gov (NCT03258892).

Trial Design

The trial was a prospective randomized two-arm crossover design. Figure 1A illustrates the trial schema. Arm A group participants (early intervention) were issued an STG pre-treatment, whereas arm B group participants (late intervention) received the STG after two cycles of treatment, using the STG for cycles 3 and 4.

Participant Evaluation

Participants were instructed to indicate symptoms and rate their severity using the 10-point Likert scale provided in the STG. Participants reviewed the STG entries with nursing
A

STG provided

Arm A

Treatment cycles 1 and 2

Survey 1

Treatment cycles 3 and 4

Survey 2

End of study survey

Arm B

Treatment cycles 1 and 2

Survey 1

Treatment cycles 3 and 4

Survey 2

End of study survey

STG provided

B

Assessed for eligibility
(N = 70)

Excluded
(n = 6)

Enrolled
(n = 64)

Randomly assigned to arm A group
(n = 33)

Randomly assigned to arm B group
(n = 31)

Received STG
(n = 33)

Did not receive STG before T2
(n = 7)

Discontinued STG
(n = 2)

Discontinued STG after T2
(n = 0)

Survey 1
Symptom
(n = 24)

Communication
(n = 24)

QOL
(n = 23)

Survey 2
Symptom
(n = 23)

Communication
(n = 23)

QOL
(n = 23)

End of study survey
(n = 19)

Survey 1
Symptom
(n = 21)

Communication
(n = 21)

QOL
(n = 21)

Survey 2
Symptom
(n = 22)

Communication
(n = 22)

QOL
(n = 23)

End of study survey
(n = 22)
During follow-up clinic visits. Specifically, participant feedback was captured at the following: (1) during the study at two specified timepoints to evaluate communication, symptom management, and QOL as shown in Figure 1A; (2) at the end of study survey; and (3) call volumes extracted at the end of the study. Surveys included ratings pertaining to symptom management, communication, and QOL using a 10-point Likert scale. The participant end of study survey evaluated the usefulness and effectiveness of the STG using a 4-point Likert scale and one open-ended question focusing on format, usefulness, and usability.

**Statistical Plan**

Target accrual was 50 participants. The sample size was calculated on the basis of a two-sample t-test. Setting $\alpha$ to .05, power at 0.80, and effect size (Cohen’s $d$) at 0.8, we needed at least 50 patients in total, 25 in each arm. Sample characteristics were summarized by descriptive statistics for the whole sample and by treatment arm. Frequencies and percentages were used for categorical variables, whereas means and standard deviations were used for continuous variables. Group differences between arms A and B were tested for each variable. We used an intention-to-treat analysis. Chi-square tests were used for categorical variables, whereas t-tests were used for continuous variables. For arms A and B, Wilcoxon’s signed rank test was adopted to assess the change from time 1 (end of two cycles) to time 2 (end of study) for the number of patient calls, the subdimensions of symptom management, communication, QOL, and utility of the STG, respectively. Additionally, group differences in the number of patient calls and the subdimensions were assessed by Wilcoxon’s rank-sum test. The effect size was calculated on the basis of Rosenthal’s $d$ (1994) method.

**RESULTS**

**Patient Accrual and Disposition**

Of 70 candidates with sarcoma who were SACT-naive from The Ohio State University Medical Oncology Sarcoma clinic, 64 were consented for the study. These participants were randomly assigned to either arm A—early intervention ($n = 33$)—or arm B—late intervention ($n = 31$). In arm B, only 24 were evaluable, as seven of the participants did not continue with SACT and thus never would have received an STG. Reasons for discontinuation included the following: change to surveillance therapy ($n = 1$), change to surgery ($n = 2$), moved away ($n = 2$), and patient preference ($n = 2$). As a result, 53 participants were evaluable for the trial. All evaluable participants completed at least some of the STG. During the course of treatment, seven patients from arm A discontinued the trial because of treatment discontinuation ($n = 3$), patient preference ($n = 2$), change in therapy ($n = 1$), transferred care ($n = 1$) and one transitioned to surveillance. The disposition of these participants is illustrated in Figure 1B.

**Demographics**

Participant demographics are listed in Table 1. Patients with sarcoma were treated with various agents, some of which were delivered in the inpatient or the outpatient setting. The types of medications also varied. The random assignment was well-balanced with regard to age, medication route (intravenous or oral), and delivery setting (inpatient or outpatient). Age ranged from 20 to 90 years with means of 60.3 years in arm A and 60.19 in arm B. Arm B was noted to contain an excess of females ($n = 15$) than in arm A ($n = 8$). When we break out the treatments administered, there were no relevant differences among therapeutic agents’ choices (Appendix Table A1, online only).

**Differences in Participants With and Without the Sarcoma Treatment Guide**

Arm A participants during the first two cycles of SACT tended to have a higher call volume mean of 1.32 ($\pm$1.29) as compared with 0.8 ($\pm$1.21) for arm B. The difference between groups trended toward significance at $P = .20$. Interestingly, when we look at time 2, after introducing the STG to the arm B participants, the arm A median was 0.55 ($\pm$0.74) and the arm B median was 0.38 ($\pm$0.59), which

**TABLE 1. Participant Characteristics**

| Variable          | Total (n = 53) | Arm A (n = 28) | Arm B (n = 25) | P   |
|-------------------|---------------|----------------|----------------|-----|
| Sex               |               |                |                |     |
| Male              | 25            | 16             | 9              | .043|
| Female            | 23            | 8              | 15             |     |
| Age (M, SD), years| 60.2 ± 17.5   | 60.3 ± 19.1    | 60.1 ± 16.2    | .961|
| IP                | 12            | 6              | 6              | .731|
| OP                | 36            | 18             | 18             |     |
| Medication route  |               |                |                |     |
| IV                | 37            | 18             | 19             | 79.2|
| Oral              | 11            | 6              | 5              | 20.8|

**NOTE.** $P$ value is based on the group difference (arm A v arm B) test results for each variable. Abbreviations: IP, intraperitoneal; IV, intravenous M, mean; OP, outpatient; SD, standard deviation.
The Majority of Participants Found Structured Journaling Beneficial in Symptom Control

We next turned our attention to the end-of-treatment survey to get a better sense of the participants’ perception of the STG. When we evaluated the end of study survey and asked “How useful was the STG when tracking symptoms associated with your chemotherapy treatments?”, 92% of evaluable participants (n = 40) stated that the STG was at least moderately useful, with 42% reporting that they found the journal very useful. Similarly, more than half of the respondents (57.9%) felt that their symptoms were better managed once they started tracking them using the STG and reviewing them with their care team. Importantly, call volume in neither arm was significantly correlated with participant perception of the STG.

Structured Journaling Improved Communication Between the Participants and Care Team

At the end of the study questionnaire, participants were asked whether the use of the STG aided them in their communication with both the physician and the nursing staff. Participants felt that their communication was at least moderately improved with the physician (64%) and nursing staff (61%). Noteworthily, 28% and 30.8% felt that communication was greatly improved with their physician and nursing staff, respectively. Interestingly, a minority of participants wrote free text to varying degrees providing additional details in the STG along with additional details of their symptoms. These free-text responses were generally items that were not as well covered by the STG in its current format—in particular, psychosocial concerns such as depression and anxiety. These free-text items were used to provide education and also engage social work or psychology to help with the participants’ overall treatment plan.

Participants Who Felt That the Journaling Was Useful Were Also More Likely to Perceive Better Symptom Management, Communication, and QOL

When analyzing participants’ perception of journaling and their perception of symptom management, we noticed a significant correlation. Table 2 shows that participants who perceived the journaling to be useful were more likely to report higher symptom management (Spearman’s \( r = 0.398, P = .011 \)). Similarly, journaling and communication (Spearman’s \( r = 0.35, P = .027 \)) and QOL (\( r = 0.375, P = .019 \)) were also associated. Perhaps unsurprisingly, better communication was significantly related to improved symptom management (Spearman’s \( r = 0.45, P = .002 \)).

DISCUSSION

Health-related QOL (HRQOL) includes how disease and treatments affect everyday function and disability, both physically and mentally. Improving communication among people undergoing cancer treatment and their providers is key to improving symptom management and may improve HRQOL and patient satisfaction during treatment. This therapeutic patient-caregiver relationship has positive effects on patients’ health outcomes for not only cancer but also chronic illnesses such as the HIV; indeed, standards for relationship building have been developed on the basis of patient values. With an ever-growing list of cancer patient surveys in this age of digital health, survey fatigue is a real risk for patients. This is unfortunate, as understanding TRAEs associated with cancer therapy is critical in helping patients complete their treatment. The impact of TRAEs on physical health, QOL, and emotional well-being makes prompt recognition and management critical.

With this modern context in mind, we evaluated this low-tech patient empowerment tool to help report TRAEs. We learned through this experience that patients want to know that they are being heard. Most computer-generated surveys provide generic data—they allow the patient to capture details through checking a box with little or no room to provide a narrative or personal context. Providing cancer patients with a low-tech monitoring tool in the form of a traditional journal allows them to record and share their stories in a meaningful way, not only for themselves but also for their medical team. The STG encouraged self-reporting in the form of journaling, which provided, at times, valuable narrative data. Narrative data revealed through journaling includes subjective data reflecting the patient’s story, insight, mental state, and body awareness. Participants reported that the STG allowed them to recall information, helped [them] describe better, helps remind [them], and write freely what is happening like a journal or diary would. Several studies confirm the positive effects of journaling: patients with cancer who express thoughts and feelings are more likely to report fewer negative physical symptoms, have fewer medical appointments related to cancer-related morbidities, and experience a reduction in emotional distress.

Here, we note a trend toward significance. Trial participants who were using the STG were more likely to reach out to their provider to discuss treatment toxicities compared with those participants who were not using the STG. Clinic nurses provided participants with education on using the STG, which included specific symptoms to note, a corresponding rating scale, for the symptoms, and when to contact the office. Moreover, all sarcoma clinic patients received instruction on the importance of contacting the treatment team regarding changes in their health during the
course of their cancer care. It is possible that simply providing more face time during the additional STG education provided more time for nursing to emphasize the importance of notifying the provider of their symptoms. Earlier symptom intervention may decrease emergency room visits for symptoms that escalated, which could have been managed through telephone nurse triage. Providing a voice to passive participants with the STG might possibly have led to more open and effective communication for those individuals. For some patients, the psychologic effects (sadness, fear, and anxiety) of cancer and its treatments can be overwhelming, clouding their ability to recognize their symptomology and the need to reach out for help. The STG might have served as a tool for the patient to better organize thoughts and symptoms, empowering them to be proactive.

Additionally, arm A participants might have been triggered to contact the office between clinic visits when tracking their symptoms in the STG, recalling portions of nursing-provided education of when to report severity or frequency of symptoms. During clinic visits, nursing staff reviewed the STG entries with the participants and followed up on symptoms reported between clinic visits, verifying resolution or need for additional intervention. It is possible that the additional time and attention from the nursing team led to establishing the therapeutic nurse-patient relationship sooner, allowing patients to feel more confident or comfortable in reporting, knowing that previous concerns had been heard. Research has shown that patients later recall about half the information received during a medical appointment.28-30 Therefore, the opportunities that the STG provided arm A participants might have encouraged them to reach out to their providers more frequently for better management of side effects, leading to improved HRQOL and overall patient satisfaction.

Alternatively, arm B participants might have delayed sharing TRAEs until their appointment out of concern that it may appear that they were no longer tolerating treatment if they contacted the provider more so than with previous treatment cycles. There might have been a fear that they would be perceived not to be a good patient.

Anecdotally, in this study, we noted participants who were very attached to their STG and journaled regularly to the point that extra STGs were provided to them. Participants, in the form of free text, noted mental health concerns in addition to details of symptom management, action taken, and those interventions that worked well. On the flipside, there were participants who did not use the journal fully. In particular, one participant used the STG once and then told us that he had no symptoms and thus did not need the STG. This heterogeneity might have also led to decreased power to detect clear differences between intervention groups and in some survey questions. We might also have been underpowered to detect a difference between TRAE between groups, given the heterogeneity among the participants and their relationship to journaling. Another possibility is that when completing the first survey after two cycles of treatment, knowledge and experience were limited, so the patients believed that their experiences were positive and complete. As time passed, with more exposure to their medical team, established rapport, and better self-management, participants were not able to note the improvement compared with previously high-rated survey responses during time point 1.

Nevertheless, we remain heartened by the fact that nearly all participants (> 92%) felt that the STG was useful in some capacity. The STG impact might not be dramatically obvious, but those who found the journaling useful also experienced higher rates of satisfaction with provider communication and symptom management. Despite an increase in telephone call volume among arm A participants, the clinic nursing staff did not experience an overwhelming increase in workload. In fact, the additional information obtained during telephone triage created follow-up opportunities during future clinic appointments enhancing the toxicity assessment. Undoubtedly, there were a number of patients with sarcoma for whom journaling provided excellent management for TRAE prevention. Additional studies and analyses will need to be performed to identify patients for whom structured journaling is the most effective. Given the extremely low cost of this intervention and the high potential for benefit, we recommend tools similar to the STG be offered to patients with cancer undergoing therapy.

In conclusion, structured journaling through the use of the STG was perceived to improve communication and symptom management in patients with sarcoma initiating systemic therapies. The use of structured journaling also appeared to modestly increase the number of communication episodes with the care team. More extensive studies will need to be conducted to validate these findings and identify which patients would benefit most from this low-tech intervention.
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AUTHORS’ DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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### APPENDIX

#### TABLE A1. Treatment Characteristics

| Treatment Type                              | No. | Arm A | Arm B |
|---------------------------------------------|-----|-------|-------|
| Oral                                        | 11  | 3     | 8     |
| Imatinib                                    | 4   | 1     | 3     |
| Palbociclib                                  | 2   |       | 2     |
| Pazopanib                                   | 4   | 1     | 3     |
| Trametinib                                  | 1   | 1     |       |
| Intravenous chemotherapy                    | 36  | 19    | 17    |
| Gemcitabine                                 | 1   | 1     |       |
| Gemcitabine/docetaxel                       | 3   | 2     | 1     |
| Carboplatin/docetaxel/pembrolizumab         | 1   |       | 1     |
| Paclitaxel                                  | 2   | 1     | 1     |
| Doxorubicin                                 | 1   |       | 1     |
| Doxorubicin/dacarbazine                     | 2   | 1     |       |
| Olaratumab/doxorubicin                      | 9   | 4     | 5     |
| Trabectedin                                 | 2   |       | 2     |
| AIM                                         | 10  | 5     | 5     |
| VAC                                         | 1   | 1     |       |
| HD ifosamide                                | 1   | 1     |       |
| MAP                                         | 2   |       | 2     |
| VDC/IE                                      | 1   |       | 1     |
| Immunotherapy                               | 4   | 2     | 2     |
| Nivolumab                                   | 1   | 1     |       |
| Pembrolizumab                               | 3   | 1     | 2     |
| Trial medications                           | 3   | 1     | 2     |
| Trial drug 15300                            | 1   | 1     |       |
| Trial drug 17131                            | 1   |       | 1     |
| ARST-A                                      | 1   | 1     |       |

Abbreviations: AIM, adriamycin, ifosfamide and mesna; ARST-A, Children’s Oncology Group and NRG Oncology ARST1321 Trial ARM A; HD, high-dose; MAP, methotrexate, doxorubicin, cisplatin; VAC, vincristine, adriamycin, cyclophosphamide; VDC/IE, vincristine, doxorubicin, cyclophosphamide / ifosfamide, etoposide.
|                | Sympt Mgmt Time 1 | Sympt Mgmt Time 2 | Comm Time 1 | Comm Time 2 | QOL Time 1 | QOL Time 2 | Call Volume Time 1 | Call Volume Time 2 |
|----------------|-------------------|-------------------|-------------|-------------|-----------|-----------|-------------------|-------------------|
| **Arm A**      |                   |                   |             |             |           |           |                   |                   |
| Mean           | 8.86              | 8.42              | 9.25        | 8.67        | 8.30      | 8.59      | 1.32              | 0.55              |
| Median         | 9.00              | 9.00              | 9.75        | 9.50        | 9.00      | 9.50      | 1.00              | 0.00              |
| SD             | 1.28              | 1.76              | 1.04        | 1.66        | 2.32      | 1.74      | 1.29              | 0.74              |
| **Arm B**      |                   |                   |             |             |           |           |                   |                   |
| Mean           | 9.08              | 8.97              | 9.33        | 9.36        | 8.62      | 7.83      | 0.81              | 0.38              |
| Median         | 10.00             | 9.50              | 9.50        | 9.50        | 9.00      | 8.00      | 0.00              | 0.00              |
| SD             | 1.51              | 1.39              | 1.15        | 0.64        | 1.50      | 2.41      | 1.12              | 0.59              |

NOTE. Wilcoxon's rank-sum tests showed nonsignificant group differences for all of the variables listed in the table.
Abbreviations: comm, communication; QOL, quality of life; SD, standard deviation; sympt mgmt, symptom management.