Utility of a chemotherapy toxicity prediction tool for older patients in a community setting

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ABSTRACT

Background Expert groups have recommended incorporation of a geriatric assessment into clinical practice for older patients starting oncologic therapy. However, that practice is not standard primarily because of resource limitations. In the present study, we evaluated the effect on treatment decisions by oncologists in the community oncology setting of a brief geriatric assessment tool that estimates risk of toxicity.

Methods This prospective longitudinal study in 5 community oncology practices in British Columbia involved patients 70 years of age and older starting a new cytotoxic chemotherapy regimen. Clinical personnel completed a brief validated geriatric assessment tool—the Cancer and Aging Research Group chemotherapy toxicity tool (CARG-TT)—that estimates the risk of grade 3 or greater toxicity in older patients. Physicians were asked if the CARG-TT changed their treatment plan or prompted extra supports. Patients were followed to assess the incidence of toxicity during treatment.

Results The study enrolled 199 patients between July 2016 and February 2018. Mean age was 77 years. Treatment was palliative in 61.4% of the group. Compared with physician judgment, the CARG-TT predicted higher rates of toxicity. In 5 patients, treatment was changed based on the CARG-TT. In 38.5% of the patients, data from the tool prompted extra supports. Within the first 3 cycles of treatment, 21.3% of patients had experienced grade 3 or greater toxicity.

Conclusions This study demonstrates that use of a brief geriatric assessment tool is possible in a broad community oncology practice. The tool modified the oncologist’s supportive care plan for a significant number of older patients undertaking cytotoxic chemotherapy.

Key Words Geriatric oncology, geriatric assessment, chemotherapy, toxicity, elderly patients

INTRODUCTION

Cancer is the 2nd leading cause of death in North America. Currently, about 50% of cancer diagnoses are made in people more than 65 years of age, but that number is expected to increase to 70% by 2030. The occurrence rate is driven in part by shifting demographics, increasing life expectancy, and less mortality from cardiovascular disease. Cancer treatments, particularly cytotoxic chemotherapy, are associated with significant risk of adverse events. Oncology practitioners and older patients themselves frequently have concerns about toxicity. The degree to which side effects affect older patients is unfortunately poorly documented, because older patients are often excluded from participation in clinical trials, and they are greatly underrepresented in trials of cytotoxic therapy.

Chronicologic age alone has been shown to be a poor predictor of frailty or of benefit from, or tolerance of, chemotherapy. The routine oncologic assessment does not include a comprehensive assessment of functional status. The Comprehensive Geriatric Assessment (CGA) for older oncology patients, performed by geriatricians or specialized clinics, has been shown to improve tolerance to chemotherapy and also to influence treatment decisions. A CGA typically includes assessment of various domains tied to interventions. Such assessments might be performed through referral to a geriatrics clinic, but wait lists for those services can be lengthy. Neither brief geriatric...
assessments nor the CGA has been incorporated into routine practice in North America despite recommendations from multiple groups.20–23

In a pivotal study, the Cancer and Aging Research Group (carg) examined a cancer-specific geriatric assessment tool to determine which elements predicted severe toxicity in patients 65 and older undergoing cytotoxic chemotherapy (based on the U.S. National Cancer Institute’s standard Common Terminology Criteria for Adverse Events grades 3–5).14 They found that 11 items from the assessment predicted risk of severe toxicity (area under the curve statistic, receiver operating characteristic curve 0.72):

- Age 72 years or greater (compared with 65–71 years)
- Cancer type being gastrointestinal or genitourinary
- Standard-dose chemotherapy
- Polychemotherapy
- Poor hearing
- Limits in walking 1 block or more
- History of falls
- Anemia
- Poor renal function
- Needing assistance with medications
- Decreased social activity because of health

Their model was more predictive than age or oncologist-rated Karnofsky performance status.25,26

Another model is the Chemotherapy Risk Assessment Scale for High-Age Patients, whose score was shown to separately predict both hematologic and nonhematologic toxicity in older patients with cancer.27 The factors that influenced risk of toxicity in this model included laboratory parameters, type of chemotherapy, performance status, status from the Mini-Mental State Examination, and nutrition status.

Robust data suggest that incorporation of a geriatric assessment into oncologic care has an effect on the physician’s treatment plan11,16,18,28; however, it is not clear whether use of a shorter toxicity assessment tool, such as the cARG’s chemotherapy toxicity tool (cARG-TT) would have any effect. Furthermore, the utility of the cARG-TT has not been evaluated outside the academic setting, where most older cancer patients receive care. Our study aimed to address those gaps.

The primary objective of the study was to determine whether the use of the cARG-TT in the community oncology setting would affect treatment decisions in older patients undergoing chemotherapy. Specifically, would the tool prompt a change in type, dose, or intent of cytotoxic chemotherapy? With respect to secondary outcomes, we assessed whether the tool prompted use of extra supports for patients, and we recorded the incidence of serious toxicity in this patient group.

**METHODS**

The study was approved by all local research ethics boards. All patients signed informed consent forms.

**Study Design**

This prospective longitudinal study enrolled patients attending 1 of 5 community oncology sites that are a part of the British Columbia Community Oncology Clinical Trialists in British Columbia. This established network of physicians provides about half the medical oncology services in the lower mainland region of British Columbia (population: 2.5 million). Clinic personnel completed all study assessments and follow-up.

**Patient Selection**

With the exception of an age cut-off and inclusion of patients with myeloma, patient selection mirrored that of the original cARG trial. Patients had to be 70 years of age or older with a primary diagnosis of a solid tumour, lymphoma, or myeloma within the preceding 12 months. They had to be planned for the start of a new outpatient cytotoxic chemotherapy regimen of at least 2 cycles within either the adjuvant or neoadjuvant setting (curative-intent therapy) or the metastatic setting (palliative-intent therapy). The age of 70 years was chosen to define the older patient population because 70 is the most commonly used cut-off in modern geriatric oncology studies. Patients were excluded if they were undergoing concurrent chemoradiation therapy, were hospitalized at the time of therapy initiation, or were unable to complete the informed consent.

**Measures and Data Collection**

Figure 1 summarizes the study schema. The clinical study processes were performed using existing centre staff and resources. Per those standard processes, patients were initially assessed by physicians and were then booked for chemotherapy teaching sessions with allied health staff (nurse or pharmacist). Patients were screened either at the time of the initial physician visit or during the teaching session. Once a patient consented, their physician completed the baseline questionnaires, which included their estimate (based on clinical judgment) of the patient’s risk for grade 3 or greater toxicity during the planned treatment regimen. That risk estimate was to use the same scale as the cARG-TT: low, medium, or high.

Clinic staff (nurse or clinical pharmacist, depending on the centre) then completed the CARG-TT assessment.

![Study procedure schema. BCCOT = British Columbia Community Oncology Clinical Trialists; CARG = Cancer and Aging Research Group.](image-url)
Per the original CARG publication, patients were assigned a score of 2 for meeting any of these criteria: age 72 years or older, gastrointestinal or genitourinary cancer type, standard-dose chemotherapy, polychemotherapy, hearing fair or worse, limits in walking 1 block or more. They were assigned a score of 3 points for a history of falls in the preceding 6 months, for anemia, and for a creatinine clearance less than 34 mL/mL. They were assigned 1 point for trouble with medication use and decreased social activity because of health. Total scores of 0–5 denoted low risk for toxicity; 6–9, medium risk; and 10–19, high risk. Figure 2 shows the scoring tool as used in this study.

Clinic staff gave physicians each patient’s CARG-TT result (low, medium, or high risk), together with the risk of toxicity associated with that result in the original CARG publication (30% for low-risk patients, 52% for medium-risk patients, and 83% for high-risk patients). The primary outcome was assessed by asking the physicians to complete a questionnaire about whether the results of the CARG-TT changed their treatment decision (change in dose, regimen, or intent of therapy) or prompted extra patient supports. Both questions were posed as yes-or-no choices, with an option for the physician to elaborate on the choices. If no change in the current treatment plan was made, the physician was asked for additional information about the reasons for maintaining the plan.

At each follow-up visit, physicians were asked to complete a follow-up questionnaire. That questionnaire asked if the patient had experienced grade 3 or greater toxicity, the type of toxicity, and whether any changes had been made to the treatment (dose reduction, dose delay, or change in therapeutic agents). The questionnaires were completed for up to 6 months, or until completion or discontinuation of a patient’s therapy.

Statistical Analyses
The IBM SPSS Statistics software application (version 21: IBM, Armonk, NY, U.S.A.) was used for all analyses. Descriptive, clinical, and outcome variables are summarized using descriptive statistics (continuous variables) or frequencies and proportions (categorical variables). Correlation between the physician-assessed toxicity risk and the CARG-TT result was assessed using the kappa test for agreement.

RESULTS

Patient Demographics
Between July 2016 and February 2018, the study enrolled 199 patients. Baseline data were complete for 192 of those patients (96.5%), who were therefore included in the analysis. Table 1 summarizes their demographic characteristics. Mean age in the group was 77 years (range: 70–96 years), and 104 of the patients (54.2%) were men. The most common tumour types were colorectal cancer (n = 48, 25.0%), lymphoma (n = 36, 18.7%), lung cancer (n = 22, 11.5%), breast cancer (n = 17, 8.9%), and pancreatic cancer (n = 14, 7.3%). Treatment was given for curative intent in 71 patients (37.0%) and for palliative intent in 118 patients (61.5%). Multi-agent chemotherapy was given to 146 patients (76.0%).

Physician Judgment Compared with Objective Toxicity Measurement
Based on clinical judgment alone, physicians estimated low risk of toxicity for 78 patients (43.3%), medium risk for 76 patients (42.2%), and high risk for 26 patients (14.4%). The physician score for 12 patients was missing. The risk calculated by the CARG-TT was low in 29 patients (15.1%), medium in 121 patients (63.0%), and high in 42 patients (21.9%). For patients having both physician and CARG-TT scores available, we analyzed the concordance in the risk scores (Table II). Concordance between the risk estimates was observed in 82 patients (45.6%), including 19 patients in the low-risk group, 50 patients in the medium-risk group, and 13 patients in the high-risk group. Using the kappa test for agreement, the correlation was 0.142 (95% confidence interval: 0.037 to 0.248), corresponding to poor correlation.

Treatment Changes Based on CARG-TT Score
Based on the CARG-TT, oncologists modified treatment in 5 patients (2.6%). All modifications were dose reductions. Of those 5 patients, 4 were judged to be at high risk by the CARG-TT. In the remaining patients whose treatments were not changed, physicians reported that the CARG-TT score did not add additional information (n = 59, 30.7%), that the treatment was already felt to be the least toxic option (n = 39, 20.3%), that the score made the physician more comfortable with the current choice of treatment (n = 33, 17.2%), and that the treatment was felt to represent the only option (n = 23, 12.0%).

Based on the CARG-TT, physicians were prompted to provide extra supports for 74 patients (38.5%). Those supports included extra vigilance in monitoring 66 patients (more frequent follow-up visits or testing of laboratory parameters), instituting additional external supports for 11 patients, initiating end-of-life discussions or referral to palliative care for 6 patients, using growth factor support in 3 patients, discussing family supports with 4 patients, and social work referral in 2 patients.
Follow-up toxicity data were available for 173 patients (90%). Within the first 3 cycles of treatment, 37 patients (21.3%) had experienced grade 3 or greater toxicity. Among the 46 toxicity events reported in the first 3 cycles, 12 were hematologic (26.1%). Of the patients who completed 6 cycles of treatment, 46 experienced grade 3 or greater toxicities (26.6%). A change in therapy (dose reduction, dose delay, or change in regimen) was necessary in 50 patients (28.9%) by cycle 3 and in 65 patients (37.6%) by cycle 6.

In an exploratory analysis, we used logistic regression to assess for predictors of toxicity with the available data. In univariate analyses, we did not find a statistically significant correlation between either physician-rated toxicity or CARG-TT-rated toxicity. Age alone also did not correlate with toxicity. In multivariate analysis, increased supports provided by physicians were not associated with a lower risk of toxicity.

**DISCUSSION AND CONCLUSIONS**

In this multicentre community oncology study, we found that incorporation of a brief geriatric assessment tool was possible within existing clinical processes. Furthermore, we found that incorporation of the tool was able to modify physician behaviour with respect to a broad population of older cancer patients. To our knowledge, this study is the first performed in a non-academic setting to assess the routine incorporation of a chemotherapy toxicity tool in older patients.

Although use of the CARG-TT did not change the treatment plan for a significant number of patients, it did prompt extra support for 38% of the patients in the study. In previous studies using the cga before chemotherapy, the cga resulted in a change in treatment in about 30% of patients. The discrepancy between those results and the findings in our study are likely multifactorial. First, a cga has consistently been shown to detect unknown problems (including cognitive impairment, depression, falls, nutritional deficiencies, and so on), resulting in decisions to de-intensify treatment. Those problems and potential interventions were not identified when only a brief toxicity tool was used. Furthermore, the timing of the CARG-TT could have played a role. In our study, patients would typically have 2–3 weeks between the initial physician visit and the start of chemotherapy. That window might not have allowed physicians to reassess a patient before making a change in dose or intensity. Finally, given that, since the

| Characteristic        | Value          |
|-----------------------|----------------|
| Patients (n)          | 192            |
| Age (years)           |                |
| Mean                  | 77             |
| Range                 | 70–96          |
| Age group [n (%)]     |                |
| 70–74 Years           | 84 (43.8)      |
| 75–79 Years           | 55 (28.6)      |
| 80 Years              | 53 (27.6)      |
| Sex [n (%)]           |                |
| Men                   | 104 (54.2)     |
| Women                 | 88 (45.8)      |
| Karnofsky PS [n (%)]  |                |
| 50                    | 5 (2.6)        |
| 60                    | 16 (8.3)       |
| 70                    | 38 (19.8)      |
| 80                    | 61 (31.8)      |
| 90                    | 45 (23.4)      |
| 100                   | 26 (13.5)      |
| Unknown               | 1              |
| Treatment intent [n (%)] |            |
| Curative              | 71 (37.0)      |
| Palliative            | 118 (61.4)     |
| Unknown               | 3 (1.6)        |
| Tumour type [n (%)]   |                |
| Colorectal            | 48 (25.0)      |
| Lymphoma              | 36 (18.8)      |
| Lung                  | 22 (11.4)      |
| Breast                | 17 (8.8)       |
| Pancreatic            | 14 (7.3)       |
| Gastroesophageal      | 11 (5.7)       |
| Bladder               | 11 (5.7)       |
| Myeloma               | 7 (3.6)        |
| Prostate              | 7 (3.6)        |
| Ovarian               | 6 (3.1)        |
| Other                 | 13 (6.8)       |

**TABLE I** Demographics of the study patients

| Characteristic        | Value          |
|-----------------------|----------------|
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| Prostate              | 7 (3.6)        |
| Ovarian               | 6 (3.1)        |
| Other                 | 13 (6.8)       |

**TABLE II** Estimated risk of toxicity by physician and by CARG-TT

CARG-TT = Cancer and Aging Research Group Chemotherapy Toxicity Tool.
publication of some of the pivotal geriatric oncology studies, geriatric oncology principles are increasingly taught and discussed, the physicians in our study might already have been inherently comfortable incorporating some of that knowledge within their practice and would already have modified treatment plans accordingly. The CARG-TT tool incorporates polychemotherapy (compared with a single-agent approach) as a risk factor for toxicity, and many physicians might have already adjusted doses based on their own assessment. Although we were not able to reliably capture all dose adjustments, we did observe, for example, that 18 of 48 patients with colon cancer in the study (37.5%) were offered single-agent therapy where doublet therapy would be the standard in young, fit patients.

Nevertheless, we feel that our findings that the CARG-TT results prompted extra supports for patients is clinically significant. The CARG-TT is not intended to be a dose calculator, and so the extra supports instituted might have been a more appropriate intervention than de-intensifying therapy. Increased vigilance and using additional allied health supports could have helped to limit toxicity in vulnerable older adults.

Compared with the population in the original CARG trial, our study population showed some important differences. First, we selected only patients 70 years of age and older; in the original study, 35% of the patients were less than 70 years of age. Patients in our study also had a lower median Karnofsky performance status (80% vs. 90%), likely reflecting the fact that, in the original CARG trial, patients were treated at an academic centre and had to consent to more involved study procedures. Our study had a similar number of palliative-intent patients. Common tumour types (breast, colorectal, gastrointestinal, genitourinary) were well represented in both studies; however, our study included a greater number of patients with lymphoma and a lower number of patients with gynecologic cancer. We also allowed patients with myeloma receiving cytotoxic therapy to enrol, which was a departure from the original trial.

The overall rates of toxicity reported in our study are lower than those in the CARG study. However the rates for treatment changes (dose delays, dose reductions) are similar23, which might be a more practical assessment of toxicity in a non-academic setting. Because our study depended on physician reporting of toxicity rather than on objective measures, reported toxicity rates were likely underestimated. Other studies that have examined the use of the CARG-TT in specific tumour sites also reported rates of toxicity that were lower than those in the original study30,31.

Our study was not designed to assess feasibility; however, we were able to recruit our target sample size in less than 24 months. One weakness of the study is that we were not able to capture patients who were screened, but who declined to participate. However, using data from the clinical pharmacy about the number of chemotherapy starts in patients more than 70 years of age during the time period of the study, we calculated that approximately 50% participated in the trial. That observation adds confidence that our sample was representative of the community oncology population and that incorporation of the brief geriatric assessment tool was possible in a busy clinical practice.

The number of studies of geriatric assessment conducted in the community oncology setting is limited. Existing data suggest that incorporation of such assessment tools is feasible32,33. Further data concerning the modification of physician behaviour or patient outcomes are still awaited. Molhile et al.34 recently reported data obtained using a Web-based geriatric assessment in community oncology practices, prompting increased discussion about age-related concerns in that population. Our study is distinct from those studies in that it was conducted without support and resources from an adjacent academic centre.

Our study supports the most current guideline from the American Society of Clinical Oncology, published in 2018, which specifically recommends, at a minimum, the use of a validated tool such as the CARG-TT in older cancer patients23. We found that incorporating the CARG-TT into community practice was possible and that the assessment provided value to clinicians. However, our study underlines the need to select patients who could benefit from a full cga, which could help to better tailor their overall treatment plan. A number of brief geriatric assessments are available, and one approach is to use “cut-points” to select patients for a cga35–37. However, that approach still relies on the universal application of the brief tool. Oncology clinicians outside academic centres might be more willing or able to refer patients based on selected clinical factors. Furthermore, data about the effect of cga on oncologic and long-term functional outcomes are still lacking. Two centres that participated in our study are currently participating in a randomized clinical trial of cga in the older population, and we expect that it—and other ongoing trials—will provide further evidence to guide clinical practice.

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CONFLICT OF INTEREST DISCLOSURES
We have read and understood Current Oncology’s policy on disclosing conflicts of interest, and we declare that we have none.

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