

# Discrepancy in patient-rated and oncologist-rated performance status on depression and anxiety in cancer: a prospective study protocol

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## ABSTRACT

**Objective:** Psychological distress is common in patients with cancer. We need a rapid means of screening for and identifying depression and anxiety in patients with cancer. The present study evaluates the potential of the Eastern Cooperative Oncology Group (ECOG) performance status (PS) scoring as a brief screening tool to assess psychological distress in routine cancer care. The ECOG PS is widely used by oncologists and the WHO, as a standardised measure to assess general well-being in patients with cancer and quality of life in cancer trials. We examine the discrepancy between patient-rated and oncologist-rated PS scores on the ECOG in a comparative assessment against the Hospital Anxiety and Depression Scale (HADS).

**Methods and design:** This is a prospective evaluation of approximately 500 ambulatory adult cancer patients from a large academic medical centre. Participants will be asked to assess their own ECOG PS on a scale of 0–4, which will be compared to ECOG PS as rated by their oncologists. Higher ECOG PS scores indicate poorer daily functioning. Both patient-rated and oncologist-rated ECOG PS and their absolute differences will be tested for predictive and concurrent validity against the HADS. A HADS cut-off  $\geq 15$  will be used. Ethics approval for this study has been secured from the institutional ethics board. Outcomes are re-evaluated at 4-week to 6-week and 1-year follow-up.

**Conclusion:** This study holds practical significance for rapid screening of psychological distress in the cancer clinic with the use of the ECOG PS scoring. Given the high prevalence of anxiety and depression in patients with cancer, screening is important to increase its recognition, which will, in turn, help to direct referrals and deliver appropriate intervention. This study also generates greater insight into the association between psychosomatic complaints and psychological distress.

**Trial registration number:** MEC 896.52.

## INTRODUCTION

We need a rapid means of screening for and identifying depression and anxiety in patients with cancer. While having patients

## ARTICLE SUMMARY

### Article focus

- We need a rapid means of screening for and identifying depression and anxiety in patients with cancer given its high prevalence and association with poorer long-term outcomes.
- We propose the use of the Eastern Cooperative Oncology Group (ECOG) Performance status (PS) scoring as a brief screening instrument for psychological distress in patients with cancer. It is hypothesised that discrepancy between patient-rated and oncologist-rated performance status scores at baseline and follow-up are associated with higher levels of psychological distress and poorer clinical outcomes in patients with cancer.

### Key messages

- This study holds practical significance for rapid screening of psychological distress in the cancer clinic with the use of the ECOG performance status scoring.
- Although the ECOG was not developed specifically to detect depression or anxiety, it has good potential to assist in the recognition of distress.
- Implementation of the ECOG as part of routine systematic screening for psychological distress appears feasible because of its distinct advantage of fundamental use in PS scoring in oncology.

### Strengths and limitations of this study

- This is the first study to examine discrepancy in ECOG PS as a predictor of anxiety and depression in cancer patients using a prospective design.
- Further study is needed to determine if the relationship between PS and anxiety and depression is predictive, prognostic, causal or merely associative.
- Further validation using criterion-standard structured clinical interviews is still required.

undergoing psychological assessment interviews or complete standardised anxiety and depression questionnaires is ideal, cancer

clinics are busy places where oncologists and staff nurses are often overworked.<sup>1</sup> Oncologists are often not sufficiently trained in psychological assessment or testing, nor do they have the time to do so.<sup>2</sup> Several studies have shown that oncologists are not especially skilled in either discussing psychological problems in general,<sup>3</sup> or at recognising anxiety and depression.<sup>2 4</sup> Published data suggest that the ability of doctors to accurately detect psychiatric morbidity in patients is often little better than that of chance.<sup>2</sup>

As a result psychological distress may go undetected and when recognised, it is more likely to run a more severe and unremitting course, and in some cases to be clearly impacting patients' lives and even cancer treatment in some way. Although tremendous attention has been given to the early detection and treatment of cancer, the issue of psychological distress has lagged behind. There is little consensus with regard to even the criterion and management of anxiety and depression associated with cancer. Early detection is as crucial in the matter of treatment and prognosis in cancer as in anxiety and depression, with greater psychological distress linked to poorer health outcomes.<sup>5</sup>

We lack adequate screening instruments measuring psychological distress in oncology settings.<sup>6</sup> For a screening or monitoring tool to be accepted in routine practice, it needs to be brief, relevant in its utility and simple enough to interpret while retaining the necessary specificity and sensitivity.<sup>5</sup> What we need is to capitalise on an existing tool as a brief form of assessment that can function as a surrogate tool for screening depression and anxiety.<sup>7</sup> The Eastern Cooperative Oncology Group (ECOG) performance status (PS) is one such measure. As a standardised measure of PS in routine oncology practice, the ECOG bears the potential for widespread usage to screen for psychological distress in this setting due to its high acceptability and ease of use.

PS is one of the most widely accepted patient evaluations used in clinical practice and oncology trials. It is typically assessed for all types of cancer due to its demonstrated efficacy in the measurement of treatment responses, survival length, prognostic value as well as a criterion for suitability for chemotherapy and clinical trials.<sup>8</sup> Yet rarely, if ever, are PS scores compared across different cancer types. Most commonly reported as part of a randomised clinical trial, the majority of cancer studies or trials where PS also measured present data where sample sizes are generally inadequate or moderate at the best.<sup>9</sup> The average cancer trial size wherein PS is most frequently measured is 200, or an average of 175 for randomised clinical trials.<sup>10</sup>

Oncologists have generally found the ECOG easy to use in daily clinic practice.<sup>7 8 11</sup> Although traditionally scored by the oncologist, several studies have arrived at rather interesting results when comparing PS scores as rated by the patients to those rated by their oncologists.<sup>7</sup> Prior studies in this area already show that there is a significant difference between patient-rated and

oncologist-rated PS,<sup>12</sup> with depression being a confounder where it comes to functional status.<sup>3</sup> These previous studies examining discrepancy between patient-rated and oncologist-rated ECOG, however, are also restricted to patients with cancer in a single site, with most of such studies focusing primarily on non-small cell lung cancer.<sup>7 11-13</sup> Findings from these studies may not be representative of psychological distress in patients with other types of cancer. It would therefore be interesting to extend this study to include patients with other cancer types.<sup>11</sup>

The main goal of this proposed study is to examine the feasibility of the ECOG PS as a psychological distress screening instrument. We intent to test the predictive and concurrent validity of the ECOG PS against the Hospital Anxiety and Depression Scale (HADS). The present study is the first to prospectively investigate the use of discrepancy between patient-rated and oncologist-rated ECOG PS to gauge psychological distress in patients with cancer.

## RESEARCH QUESTIONS

1. To what extent do patient-rated versus oncologist-rated ECOG PS agree? If discrepant, what is their underlying cause?
2. To what degree does the ECOG assess psychological distress? Does discrepancy in PS predict psychological distress at baseline and subsequent 4-week to 6-week and 1-year follow-up?

## HYPOTHESIS

It is hypothesised that poorer or discrepant PS scores are associated with higher levels of psychological distress, rather than the level of activity. It is also posited that discrepancy between patient-rated ECOG at baseline and follow-up is also associated with an increased likelihood of comorbid anxiety or depression in patients with cancer.

## METHODS/DESIGN

This is a prospective single-centre study, in the context of patients about to see their oncologist for a consultation in an academic medical centre. Patients will be asked to assess their own ECOG PS score on a scale between 0 and 4. We then compare these to ECOG scores rated by their oncologists (extracted from their medical records). The absolute discrepancy in scores will then subsequently be analysed against patient HADS scores.

We will attempt to enrol approximately 500 consecutive patients who have been referred to the adult clinical oncology unit with a diagnosis of cancer from November 2011 to August 2012. Patients should be receiving or plan to receive at least one form of treatment (i.e, chemotherapy or radiotherapy) at any point in their disease trajectory. Patients aged less than 18 years are excluded, as are

those with an incomplete diagnosis and language issues, specifically the inability to understand the instrument language in English or comprehend interviews conducted in all major spoken languages: English, Chinese or the Malay language. We chose not to apply additional exclusion criteria that would limit the applicability of findings to the general patient with cancer population unnecessarily.

### Study variables

A data extraction form that has been specifically developed will be used to obtain relevant demographic and clinical data from patient records. The specific variables and selected outcome variables of interest include age, sex, race, marital status, education and employment status. Relevant clinical information examined includes the primary cancer site and tumour stage. Other variables that will be looked at include treatment planned or received such as surgery, chemotherapy and/or radiotherapy.

### Research tools

The questionnaires used in this study include the ECOG PS as rated by patients themselves and by their oncologists, as well as the HADS scale. All questionnaires used have obtained permission for use from the respective authors and will be cited.

The ECOG PS is highly valid and is one of the most widely used instruments in clinical cancer practice and research.<sup>7 8 11</sup> In this study, the single-item score will be rated by both patients and their oncologists on a scale of 0–4 (worse scores denoting poorer PS and higher levels of psychological distress). The ECOG PS score of 5 (indicating death) will not be used in the patient version of the scale. Refer to appendix 1 for a copy of the ECOG.

The HADS, a 14-item instrument has also been well-validated and will be employed for use in the detection of anxiety and depression among cancer patients. Overall scores range from 0 to 42, with higher scores indicating greater distress. A cut-off point of greater than or equal to 15 will be used. Preliminary testing with 18 patients (male-to-female ratio=1:1) conducted in October 2011 for the HADS yielded an  $\alpha$  of 0.91.

### Sample size estimation

Using an online sample size calculator (Raosoft),<sup>14</sup> we adopted a 0.05% margin of error which required a total of 306 participants to accurately (95% CI) represent a variable with 50% response distribution in a population of approximately 1500 patients with cancer seen annually. Although an estimated figure of 306 patients would be sufficient to test our hypothesis in a cross-sectional design, a final sample size of 500 was chosen to balance attrition at various follow-up points (estimated at 20–40%) and to facilitate regression analyses. Pilot testing computed an  $r=0.75$ , which, following Cohen's conventions, can be interpreted as a large effect size. A priori power calculation using an observed effect size of 0.75 with the conventional

probability level of 0.05 in a sample size of 306 would result in an observed power of 0.99 (two-tailed).

### Procedure

Patients will be directly approached in the waiting room of the adult oncology unit while waiting to see their oncologist. Participants will first be given verbal information on the goal of the study and screened to check whether they meet all inclusion and exclusion criteria. Upon assent to participate, informed consent will be obtained and an additional information leaflet be given. Participants will be asked to circle the number that best describes the overall distress that they experienced over the previous week for both the ECOG and HADS. Face-to-face interviews will be conducted in all major languages (English, Bahasa Malaysia and Chinese). The follow-up time ranges from 4 to 6 weeks and 1 year, at which the assessments will be repeated via face-to-face interview, or via telephone interview if necessary.

### Questionnaire administration

The use of a questionnaire design makes this study cost-efficient and allows for rapid yet effective screening of psychological distress in our population. Oncologist-assessed ECOG PS scores will be extracted from patient oncology records.

### ANALYSIS OF DATA

The mean and SDs for anxiety and depression for each cancer type will be determined. All data will be coded based on the instructional guidelines as contained in the questionnaire scoring manuals. Responses to the HADS will be analysed according to published recommendations.<sup>15</sup> Two-sided tests will be used, while  $p$  values of  $\leq 0.05$  will be regarded as statistically significant. For all analyses, a two-sided  $p$  value  $\leq 0.05$  will be applied. All analyses will be performed using the Statistical Package for Social Sciences (SPSS) V.20.

### Comparison of mean scores

Comparison of baseline scores, change in scores between and within groups, as well as identification of subjects with improved, stable and worsened scores over time will be performed using a  $t$  test, Mann-Whitney test, analysis of variance (ANOVA) or, alternately, a non-parametric approach such as Kruskal-Wallis as deemed appropriate. Proportions will be compared using  $\chi^2$  test or Fisher's exact test.

### Comparison between ECOG and HADS scores

Comparison between the good (0–1), intermediate (2) and poor (3–4) PS patient groups will be made using one-way ANOVA. Pearson correlation coefficient ( $r$ ) will be used to express the relationship between the psychological distress as measured using the HADS and PS using the ECOG. Differences in the two subscales of the HADS as well as mean ECOG scores will also be

reported. Correlations in each patient group among overall levels of psychological distress and PS will be measured using Spearman's correlation coefficient.

Kendall's tau ( $\tau$ ) coefficient will be used to measure the portion of ranks that match between patient-rated and oncologist-rated PS. Additionally, a paired t test, or the non-parametric Kolmogorov-Smirnov test (KS-test) may be used to determine whether there is a significant difference between the patient-rated versus oncologist-rated dataset.

### Descriptive statistics

Descriptive statistical analysis will be performed for all variables. Continuous variables will be reported using means and SDs or median and IQR. For dichotomous variables, absolute numbers and percentages will be presented. Differences between concordant and discrepant PS groups in demographic characteristics, clinical variables, anxiety, depression and PS will be assessed using t test or Mann-Whitney tests for continuous variables, and the  $\chi^2$  statistic or Fisher's exact test for categorical variables. Linear regression, logistic regression or the Wilcoxon-Mann-Whitney rank sum test will be used as appropriate to assess the impact of demographic and clinical variables on group differences in depression, anxiety and PS. Variables included in subsequent analyses include those that demonstrate statistically significant differences between the study groups in univariate analyses.

### Imputation of missing values

All responses with more than 5% missing values will first be removed from the data set. For the remaining items, missing values will be replaced by an imputation process based on an expectation-maximisation algorithm using NORM software. This imputation ensures that should subsequent exploratory factor analysis be done, which processes a large number of items, the data set is not reduced too greatly. In order to assess the influence of imputation on the psychometric results, all analyses will additionally be carried out with non-imputed values after the factor analysis. Should differences arise, findings from both imputed and non-imputed data will be presented to allow for comparison. Careful note will be made for all missing data on individual items. Missing data, however, remains a serious issue for quality of life studies.<sup>15 16</sup>

## DISCUSSION

This is the first study to longitudinally examine the use of discrepancy in ECOG as a predictor of anxiety and depression in cancer patients in a comparative assessment over time. We propose the use of the ECOG as a brief screening instrument for depression and anxiety in cancer patients and hypothesise that poorer or more discrepant patient-rated ECOG scores may be an indicator of greater psychological distress. Given the high prevalence of anxiety and depression in cancer, screening is

critical in increasing case recognition to deliver appropriate interventions and prioritise referrals.

While the ECOG was originally developed as a measure of PS, its brevity and simplicity makes it feasible for widespread adoption as a surrogate tool to detect anxiety and depression. Most oncologists lack familiarity with psychiatric nosology.<sup>1</sup> Screening for anxiety and depression using the ECOG PS scale does not require special training because PS is routinely assessed by oncologists across all cancer types.

There is an emerging trend towards simplifying the assessment of depression and anxiety in outpatient cancer settings,<sup>17</sup> particularly as treatment and care has shifted to ambulatory settings. Shorter than any other standard assessment such as the HADS and Beck Depression Inventory, the ECOG functions much like the single-item Distress Thermometer. We predict that the acceptability of the ECOG as a measure would likely be higher and less likely to burden the clinic in terms of time and cost compared to any other form of assessment.

Patients have been shown able to accurately assess their own PS.<sup>13</sup> The single-item ECOG PS is also easy for patients to rate, especially with the emergence of different versions of the PS scale in visual analogue format<sup>13</sup> suitable for paediatric or illiterate cancer populations, or simply where communication issues might arise from a language barrier.

While data which come directly from those experiencing the cancer afford an insightful perspective, there is greater practical value in using the ECOG to comparatively measure discrepancy in PS scores, rather than solely relying on either patient-rated or oncologist-rated scores. Discrepancy on the ECOG is also easy to eyeball, while scores can be quickly compare over time when reviewed at each visit.

This study carries several important implications for oncology clinic practice, in that discrepancy in ECOG scores, or patient-rated ECOG can be used as a patient-reported outcome measure to raise, discuss as well as routinely monitor psychological concerns.<sup>11</sup> Asking patients to score their own ECOG opens up avenues for discussion of psychological concerns and reduces the likelihood of measurement, cultural and educational bias.

Special attention should be given to cancer patients who demonstrate poorer self-rated PS. As suggested by Ando,<sup>12</sup> patients who rate themselves significantly higher on ECOG scores compared with assessment by their oncologist may actually be presenting a subconscious bid for care and reassurance towards their oncologists. This is consistent with the local cultural influence which is not dissimilar to those of other Asian cultures where emotions are suppressed.<sup>18</sup>

Owing to indefinite symptomatology such as fatigue, lack of appetite and weight loss,<sup>19</sup> differentiating symptoms caused by cancer and its treatment from standard criteria-based syndromes of major depression and clinical grade anxiety is not easy.<sup>20</sup> The use of the ECOG

can indicate the presence of psychological distress that does not exclude psychosomatic distress. Multiple socio-cultural barriers are inherent in seeking medical and psychosocial information, treatment and care.<sup>18</sup>

Regardless of physical disease,<sup>17</sup> it is not uncommon for mood disorders to be expressed as somatic rather than psychological symptoms across a number of cultures, partly to avoid the perceived stigma of a psychiatric disorder.<sup>1</sup> Patients from Asian cultures tend to focus on somatising and physiologic symptomatology rather than mental symptoms<sup>18–21</sup> and to be culturally constrained where it comes to reporting emotional states such as depression.<sup>21</sup>

Physicians too are often reluctant to probe into psychological concerns.<sup>2</sup> This may be, in part, due to the biomedical training and orientation of oncologists, who may prove wary of forming attachment to patients, which is also a barrier to supportive care. A rigid biomedical agenda also means oncologists are more comfortable treating somatic symptoms such as pain, nausea and dyspnoea. It is likely that physicians who are trained locally would be even less comfortable addressing distress due to cultural constraints. This gives rise to the question of how likely oncologists are to refer patients for further psychological or psychiatric assessment. Previous studies report the consultation rate from oncologists to consultation-liaison psychiatrists to be only 4–10% among cancer patients.<sup>5, 22</sup>

The majority of cancer patients with (clinically significant) anxiety and depression do not see mental health professionals but do see their oncologists. However, relatively few oncologists have sufficient knowledge and expertise to assess and treat psychological distress.<sup>3</sup> Prior research in this context shows that oncologists are often unable to detect depression and anxiety, often stemming from a lack confidence in assessing distress and using psychometric instruments.<sup>23</sup>

By no means, however, should assessment of psychological distress using the ECOG replace comprehensive psychiatric evaluation.<sup>5</sup> Systematic screening using the ECOG can nonetheless increase case recognition and allow for referral of distressed patients for consultation-liaison or ideally psycho-oncology services.<sup>2, 5, 19</sup> Further study is needed to determine whether the relationship between PS and anxiety and depression is predictive, prognostic, causal or merely associative.

## IMPLICATIONS

Although the ECOG was not developed specifically to detect depression or anxiety, it has good potential to assist in the recognition of distress. Findings from this study would help to validate the surrogate function of an existing clinic tool. Implementation of the ECOG as part of routine systematic screening for psychological distress appears feasible because of its distinct advantage of fundamental use in PS scoring in oncology, although further validation using criterion-standard structured clinical interviews is still required.

## ETHICS

This study is part of a project approved by the ethics committee of the UMMC (MEC Ref. No: 842.2). Individual written informed consent will be obtained following every recommendation in accordance with the ethics of medical research.

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## APPENDIX 1

**Table A1** ECOG performance status score

ECOG	Score
Fully active, able to carry on all predisease performance without restriction	0
Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, eg, light house work and office work	1
Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours	2
Capable of only limited self-care, confined to bed or chair more than 50% of waking hours	3
Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair	4

Source: Oken *et al*<sup>8</sup>.

ECOG, Eastern Cooperative Oncology Group