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ORIGINAL ARTICLE

Development and prospective evaluation of CAPLET, a cancer ambulatory patient physical function longitudinal evaluation tool for routine clinical practice

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Abstract

Purpose A patient's physical function is a critical outcome variable for measuring and improving chronic care management. However, patient-reported outcome measures of physical function are not routinely assessed in cancer outpatients, in part due to limitations of tools available. This study presents the development and evaluation of the Cancer Ambulatory Patient Physical Function Longitudinal Evaluation Tool (CAPLET) as an adaptive response tool for routinely screening for physical dysfunction in oncology clinical practice.

Methods In phase 1, 407 adult outpatients at Princess Margaret Cancer Centre completed the World Health Organization Disability Assessment Schedule (WHODAS) 2.0, Health Assessment Questionnaire Disability Index (HAQ-DI), EuroQuol-5D-3L (EQ-5D-3L), and patient-reported outcome (PRO)-Eastern Cooperative Oncology Group (ECOG). CAPLET was developed based on a branching logic algorithm navigating patients to appropriate domains of HAQ-DI/WHOAS using their responses to the PRO-ECOG/EQ-5D-3L as screeners. Sensitivity/specificity of CAPLET screeners for HAQ-DI/WHODAS items were reported. In phase 2, CAPLET vs the WHODAS/HAQ-DI were alternatively administrated to 318 adult outpatients in a two-arm trial comparing time to completion and acceptability between the tools.

Results Using a patient's ECOG status and the sum of the mobility, self-care, and usual activity dimensions of the EQ-5D-3L to dichotomize patients as with or without difficulty, CAPLET achieved a sensitivity > 90% against recommended WHODAS and HAQ-DI cutoffs for significant dysfunction. Sensitivity of screeners for capturing dysfunction in individual WHODAS/HAQ-DI items ranged from 85 to 100%. Compared to the HAQ-DI/WHODAS, CAPLET was associated with a 50% reduction in administration times and improved patient acceptability, while reducing question burden by 84% for half the sample population.

Geoffrey Liu and Doris Howell are co-senior authors and co-corresponding authors.

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Conclusions CAPLET improves the feasibility of capturing detailed assessments of patient-reported physical function in cancer outpatients.

Keywords Physical function · Patient reported outcome · Cancer · Computer logic · Sensitivity · Specificity

Introduction

Patient-reported outcome measures (PROMs) collect primary source clinical care outcomes by asking patients to report directly on their own health, functional status, or quality of life [1]. Since 2006, Ontario has deployed PROMs routinely to cancer outpatients with the Edmonton Symptom Assessment System (ESAS). Although ESAS is widely successful [2], as a generic symptom measure it overlooks two key aspects of patient-reported health: symptomatic adverse events and physical function [3–5]. While expert committees such as those developed for the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) have focused on validating PROMs that assess symptomatic adverse events [6], validated PROMs suitable for assessing physical function in the cancer setting are lacking. Available tools either assess global physical function without addressing specific dysfunctions [7] or are so detailed that they are difficult to administer outside of clinical trials [8, 9]. Efforts to utilize assessments of disease-related symptoms as surrogate measures for physical function have largely been unsuccessful [10].

Measures of physical function exist in the most commonly used PROMs in cancer care (e.g., SF-36). However, these assessments are limited in that patients respond to all questions of the tool regardless of their health status [4, 11, 12]. Such scales offer only a broad approximation of general functional concerns and ignore difficulties more specific to certain cancer population subgroups. With the advent of computer adaptive testing (CAT), there is an opportunity to develop PROMs that draw on detailed item banks to provide surrogate assessments of physical function from existing validated tools, while at the same time allowing patients to answer only questions most relevant to their current health status [13, 14]. To date, CAT versions of PROMs such as the Quality of Life Questionairre-Cancer (QLQ-C30) have been developed to assess general health outcomes [15]. However, no such PROM exists that is specific for routine screening of physical function in the cancer outpatient setting.

Physical function, a person's perception of what he or she can actually perform [16], is a key outcome measure for both clinical trials and routine care [16–19]. Poor physical function is associated with patient prognosis [20, 21], mental health [22], and institutionalization [17]. Screening for physical dysfunction can identify cohorts appropriate for rehabilitation services, psychosocial care, mental health counseling, and home care [17, 23]. Longitudinal evaluations may even help elucidate the biological origin of functional limitations, as for example, the degree to which physical impairments arise because of cancer, cancer-related treatments, aging, or other pre-existing conditions [18]. Assessments can also inform public policy when used in comparative effectiveness research [24]. By capturing difficulties in areas from mobility to self-care, measures of physical function provide data beyond the metrics of a patient's chart for a holistic and detailed understanding of his or her needs.

Thus, our research goals were threefold: to develop an electronic-based, adaptive response tool for screening for physical dysfunction with a minimum question burden to patients, to compare its sensitivity against gold standard tools in capturing physical dysfunction across an array of functional categories, and to investigate the effect of utilizing this PROM on the feasibility of routinely assessing physical function in the outpatient setting.

Methods

This study had two phases. In phase I, the Cancer Ambulatory Patient Physical Function Longitudinal Evaluation Tool (CAPLET) was developed, and its sensitivity was evaluated against two gold-standard research tools for assessing physical function (the World Health Organization Disability Assessment Schedule [WHODAS] and Health Assessment Questionnaire Disability Index [HAQ-DI]). The sensitivity and specificity of CAPLET's branching logic algorithm in screening for global and specific physical dysfunction was determined by comparing its screening algorithm to having patients complete the entire item bank of the combined WHODAS and HAQ-DI (WHODAS/HAQ-DI). In phase 2, a prospective two-armed trial was used to assess the feasibility and acceptability of implementing WHODAS/HAQ-DI vs CAPLET as a tool for measuring physical function in clinic.

Selection of gold standard, physical function instruments

The patient-reported outcome (PRO)-Eastern Cooperative Oncology Group (ECOG) performance scale—the only cancer specific PROM for capturing physical function—often underestimates functional limitations, particularly in the elderly [18]. Thus, we included the (PRO)-ECOG as only a cursory screening tool for assessing a patient's health status and looked to supplement CAPLET with PROMs from other chronic illness settings. Two psychometrically validated tools were selected as gold standards for assessing physical function because of their

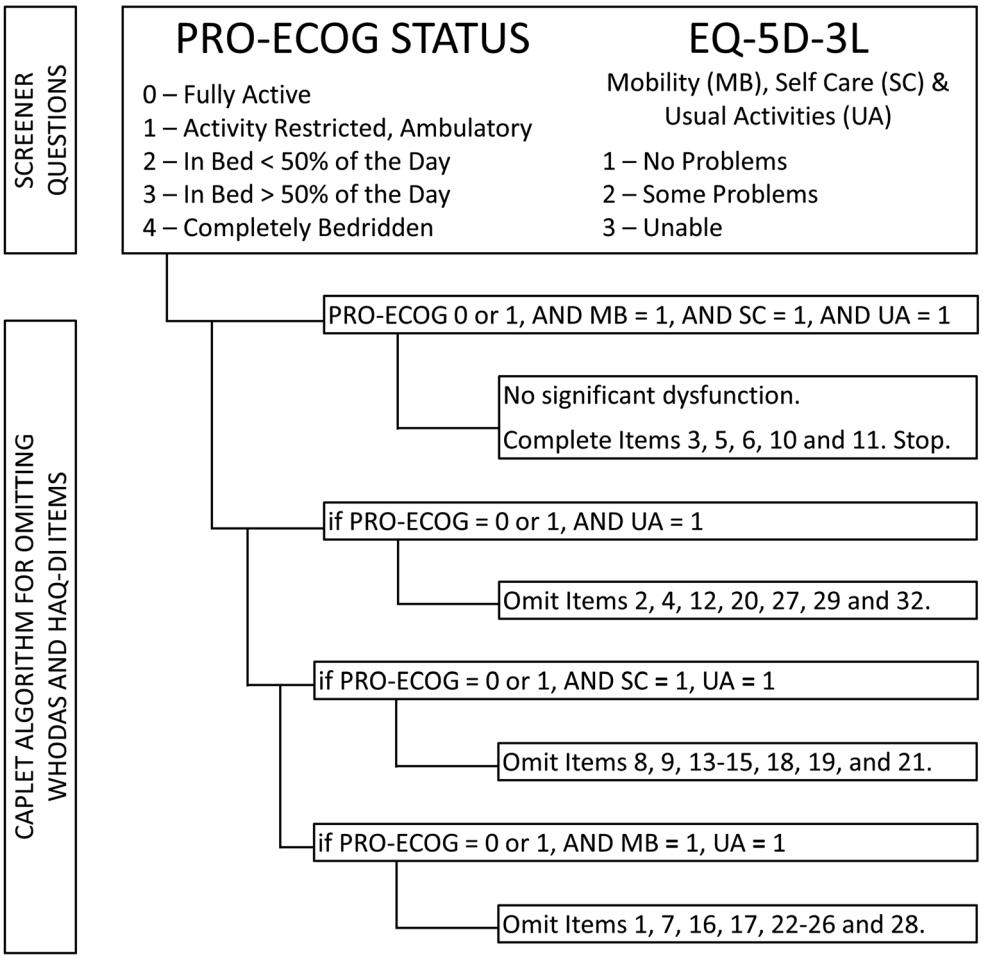

Fig. 1 Outline of CAPLET Screeners and Branching Logic Algorithm. CAPLET screens patients based on their response to the (PRO)-ECOG and mobility, self-care, and usual activity components of the EQ-5D-3L. WHODAS/HAQ-DI items are only presented to patients if they screen positive to the (PRO)-ECOG and physical function components of the EQ-5D-3L; otherwise, items are omitted. In the extreme case where the screener elicits the lowest possible score, all subsequent items are omitted except 3, 5, 6, 10, and 11. These items were always retained because they assess health domains not related to any of CAPLET's screener questions

sensitivity: the Health Assessment Questionnaire Disability Index (HAQ-DI) and World Health Organization's Disability Assessment Schedule (WHODAS 2.0) [8, 9, 22, 25]. After eliminating overlapping content, the WHODAS/HAQ-DI totaled 32 items. Along with the WHODAS/HAQ-DI, both the (PRO)-ECOG and the EQ-5D-3L were assessed at the beginning of the survey. The EQ-5D-3L was chosen in addition to the (PRO)-ECOG, because of its high utility and widespread use in the cancer setting [19]. As a quick five-item tool, the EQ-5D-3L is often used to demarcate patients based on their health status and has been extensively validated in its 20-year history [26].

Phase 1 procedures

A cross-sectional study assessing the WHODAS/HAQ-DI was performed in outpatients across all clinical sites at the Princess Margaret Cancer Centre. This sample of responders who completed the full WHODAS/HAQ-DI was collected for use as the gold standard comparison with which to evaluate CAPLET's sensitivity and specificity as a screening tool. Eligibility criteria were (1) aged 18 years or over at the time of survey, (2) histologically confirmed cancer, (3) cognitively well enough to complete surveys and consent for the study, and (4) fluent enough in English to complete surveys. Patients were approached in outpatient clinic waiting areas. Informed consent was obtained from all individual participants included in the study. After consenting, patients completed the PRO-ECOG, EQ-5D-3L, WHODAS/HAQ-DI, and socio-demographics. All questions were administered in one comprehensive survey entitled the WHODAS/HAQ-DI through FluidSurveys™. The survey was administered using tablet-technology with a research coordinator on hand for the duration of the study. Cancer clinical data were abstracted from electronic medical charts.

Developing CAPLET

The basis of CAPLET is an algorithm that navigates patients to items in domains of WHODAS/HAQ-DI based on their health status, an approach modeled on Elliott [3]. We utilized PRO-ECOG and the three physical function questions of EQ-5D-3L as screening questions for establishing a patient's health status and tested these screeners against global cutoffs for physical dysfunction for HAQ-DI and WHODAS: a WHODAS 12.0 item simple score above 10, and HAQ-DI

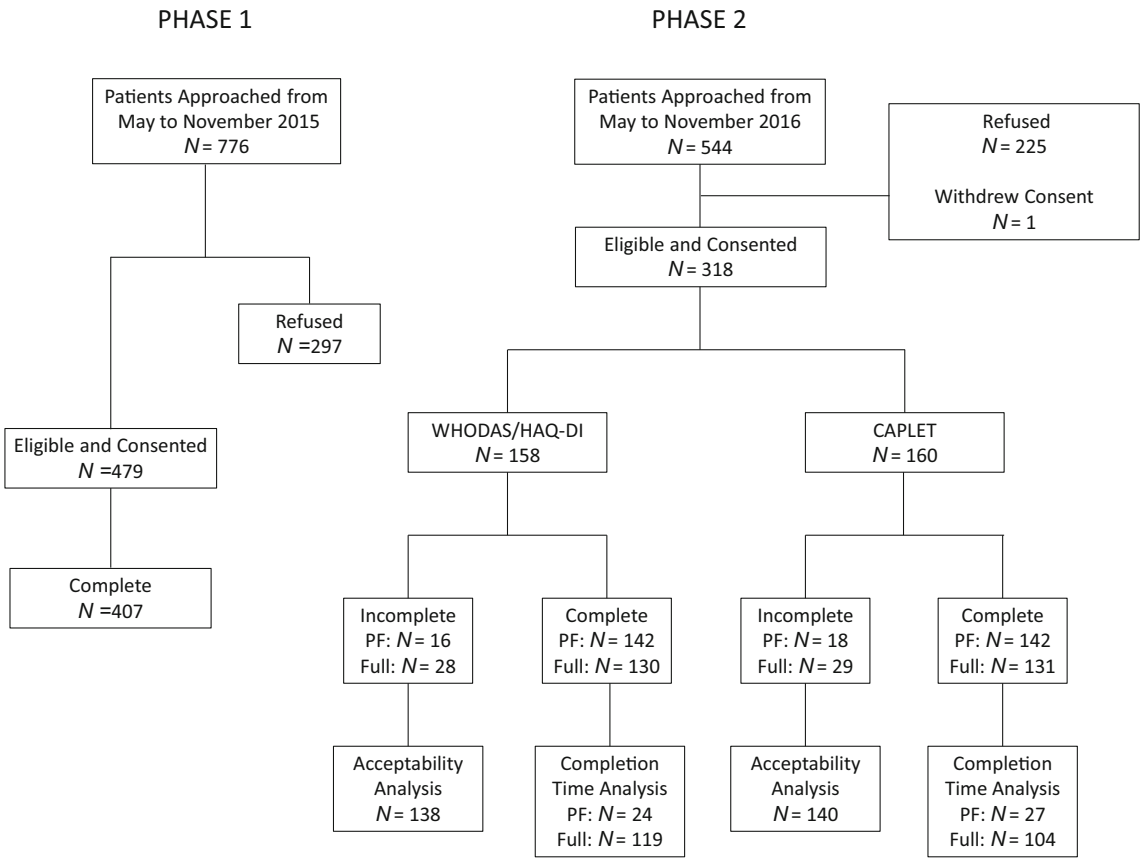

Fig. 2 Summary of Study Sample and Recruitment. For the phase 1 population, assessments were classified as complete if they had responded to the CAPLET screening questions and at least one corresponding item in WHODAS/HAQ-DI. For the phase 2 population, PF denotes the physical function portion of the full questionnaire (PRO-ECOG, EQ-5D-3L, WHODAS, and HAQ-DI). FULL refers to all questionnaires that were administered: either CAPLET or WHODAS/HAQ-DI, acceptability survey, and questions on patient demographics. Assessments were designated as complete if there were no missing values for any of the questions in the PF component of the questionnaire

above 0.5 was taken as significant physical dysfunction [21, 22]. Once (PRO)-ECOG and EQ-5D-3L were confirmed as robust measures for capturing global dysfunction, an initial screener was developed whereby if patients had a (PRO)-ECOG status of 0 or 1 and a score of 1 to the mobility, self-care, and usual activities components of the EQ-5D-3L, CAPLET would terminate and the patient would be screened negative for having any global or specific functional limitations. Next, each of the 32 combined WHODAS/HAQ-DI items was mapped to the mobility, self-care, and usual activities components of the EQ-5D-3L in a simple branching logic design (Fig. 1). CAPLET's branching logic algorithm operates on the scheme that items in the WHODAS/HAQ-DI are only presented to patients if the items they mapped to in the EQ-5D-3L screen positive. Multiple iterations of this algorithm were tested to determine to which item of the EQ-5D-3L the items in WHODAS/HAQ-DI mapped best. Ultimately, each item in the WHODAS/HAQ-D was mapped to the item in the EQ-5D-3L that had the highest sensitivity as a screener for that functional limitation, as long as there was also a clinical basis for such mapping (e.g., it was logical to map the specific questions in this manner).

Phase 2 procedures

Patients were approached as in phase I. A prospective two-arm trial alternately assigned consecutive, consented patients to receive either CAPLET or WHODAS/HAQ-DI. Time to completion of tool, proportion completing tool, and willingness to complete tool regularly were compared across the two arms. Completion times for each tool were measured electronically using FluidSurveys™.

All study protocols were approved by the research ethics board of the University Health Network in Toronto, Ontario, Canada.

Statistical analysis

Descriptive statistics were generated separately for phases I and 2. Sensitivities and specificities of CAPLET were calculated, along with 95% confidence intervals for each of the 32 items of the combined WHODAS/HAQ-DI. For cutoffs, a response of "none" or "mild" to a WHODAS item and "without any difficulty" to a HAQ-DI item was classified as no difficulty (Supplementary Table 3).

Table 1 Patient demographics and clinicopathological variables

Covariate	Phase 1	Phase 2			
		Combined arms	WHODAS/ HAQ-DI	CAPLET	*p* value
Total patients	*N* = 407	*N* = 318	*N* = 158	*N* = 160	
Median age in years (range)	61 (19–93)	61 (18–97)	61 (18–90)	61 (20–97)	0.87
Male (%)	49	40	40	40	1
Primary language English (%)	82	82	81	83	0.75
Currently employed (%)	44	36	36	38	0.99
Caucasian (%)	73	73	74	72	0.34
Married/living with partner (%)	71	63	66	59	0.31
Any post-secondary education (%)	72	70	72	70	0.61
Household income > $80, 000 (%)	55	56	56	55	0.9
Primary cancer site (%)					1
Breast	14	19	19	19	
Gastrointestinal	11	20	19	21	
Genitourinary	11	13	13	12	
Gynecologic	15	14	14	14	
Head/neck	18	11	10	12	
Thoracic	10	14	15	13	
Other	21	9	9	9	
Early stage disease (%)	45	41	40	41	0.78
Treatment for cure (%)	55	58	56	61	0.4
ECOG performance status (%)					0.55
0	44	46	44	49	
1	40	38	38	38	
2 or greater	16	16	18	13	
Median EQ-5D-3L utility scores	0.8 (0.3–1.0)	0.8 (0.3–1.0)	0.8 (0.3–1.0)	0.8 (0.3–1.0)	0.65

p values compare the distribution of clinicodemographic covariates between CAPLET and WHODAS/HAQ-DI arms in phase 2

Acceptability and time-to-completion analyses utilized chi-squared and non-parametric Kruskal-Wallis tests, respectively. Median completion times for both the entire questionnaire and the physical function component (PRO-ECOG, EQ-5D-3L, WHODAS, and HAQ-DI) were compared for CAPLET and WHODAS/HAQ-DI. To determine whether completion times of the physical function component and patient acceptability were correlated, Spearman's rank correlation coefficients were calculated. All analyses utilized SAS 9.4 (SAS institute, Cary, NC, USA).

Results

Recruitment statistics are outlined in Fig. 2. Table 1 summarizes descriptive statistics for both phase 1 and phase 2 study populations.

Phase 1

Besides the 407 phase 1 patients, 141 phase 2 patients also completed WHODAS/HAQ-DI (total *N* = 548). Analyses on all 548 patients are presented.

Among patients who completed the WHODAS/HAQ-DI, 151 (28%) met WHODAS 12-item cutoffs, and 143 (26%) met HAQ-DI cutoffs for being classified as having significant dysfunction By ranking patients with a PRO-ECOG status of 0–1, and a response of "no problems" to the self care, mobility, and usual activities items of the EQ-5D-3L as having no dysfunction, CAPLET achieved a sensitivity of 90% for HAQ-DI and 94% for WHODAS 2.0 in screening positive for patients with global dysfunction (Fig. 3). Likewise, sensitivities of using CAPLET for each of the 32 items of the combined HAQ-DI and WHODAS were upwards of 85% (Fig. 4). Five WHODAS items (3, 9, 6, 10, and 11; see Fig. 4 axis) most related to a patient's mental health and cognition

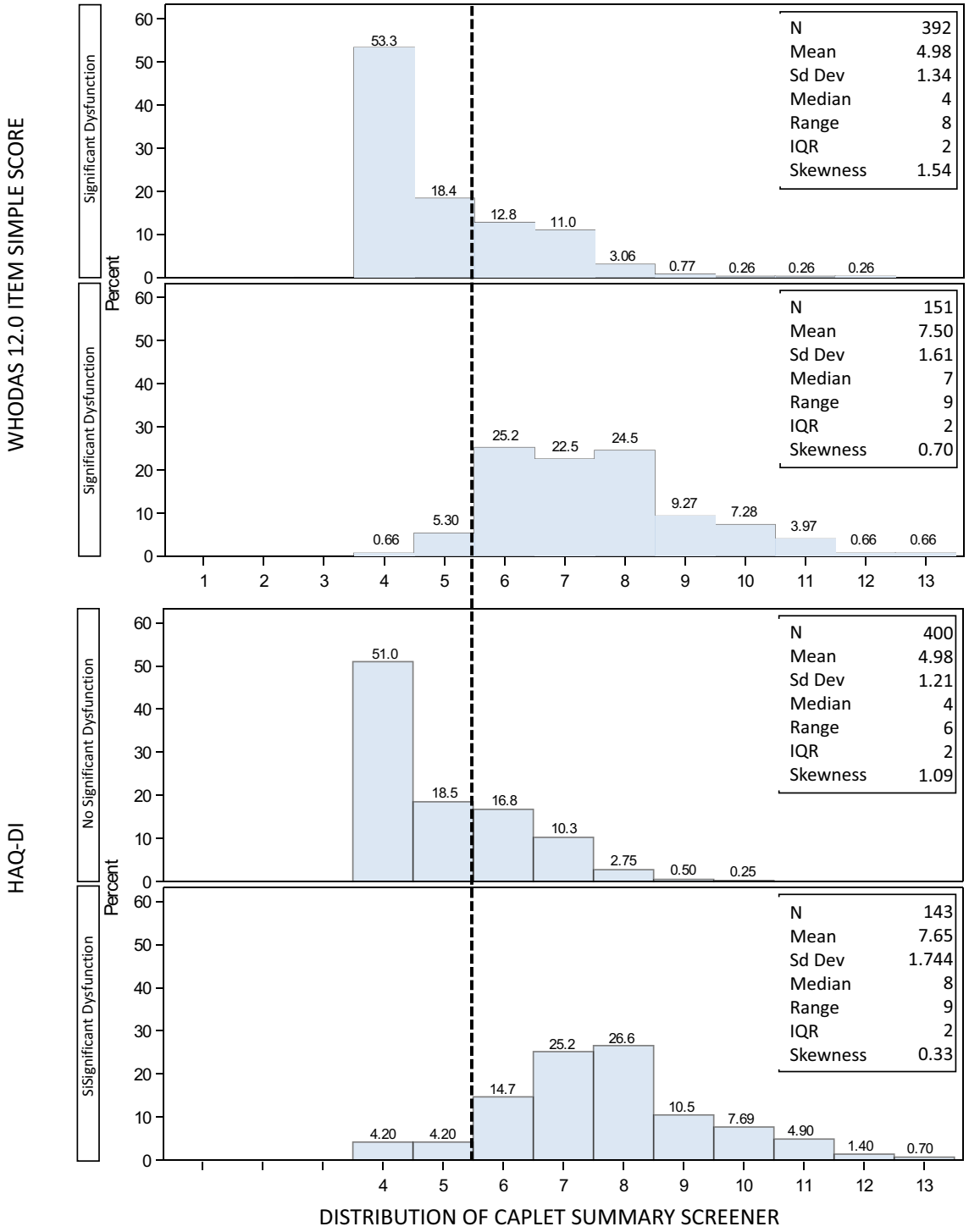

Fig. 3 Comparison of CAPLET Summary Screener cutoff vs recommended WHODAS 2.0 and HAQ-DI cutoffs for Significant Physical Dysfunction. Dotted line represents CAPLET's baseline summary cutoff, which is a PRO-ECOG status of 0 or 1, and no problems to the usual activities, mobility and self-care components of the EQ-5D-3L. Bellow this cutoff, patients are assumed to have no difficulties in physical function. Significant Dysfunction according to the gold-standard tests of WHODAS and HAQ-DI was assessed as a 12-item WHODAS simple score greater than 10, and a HAQ score greater than 0.5 respectively

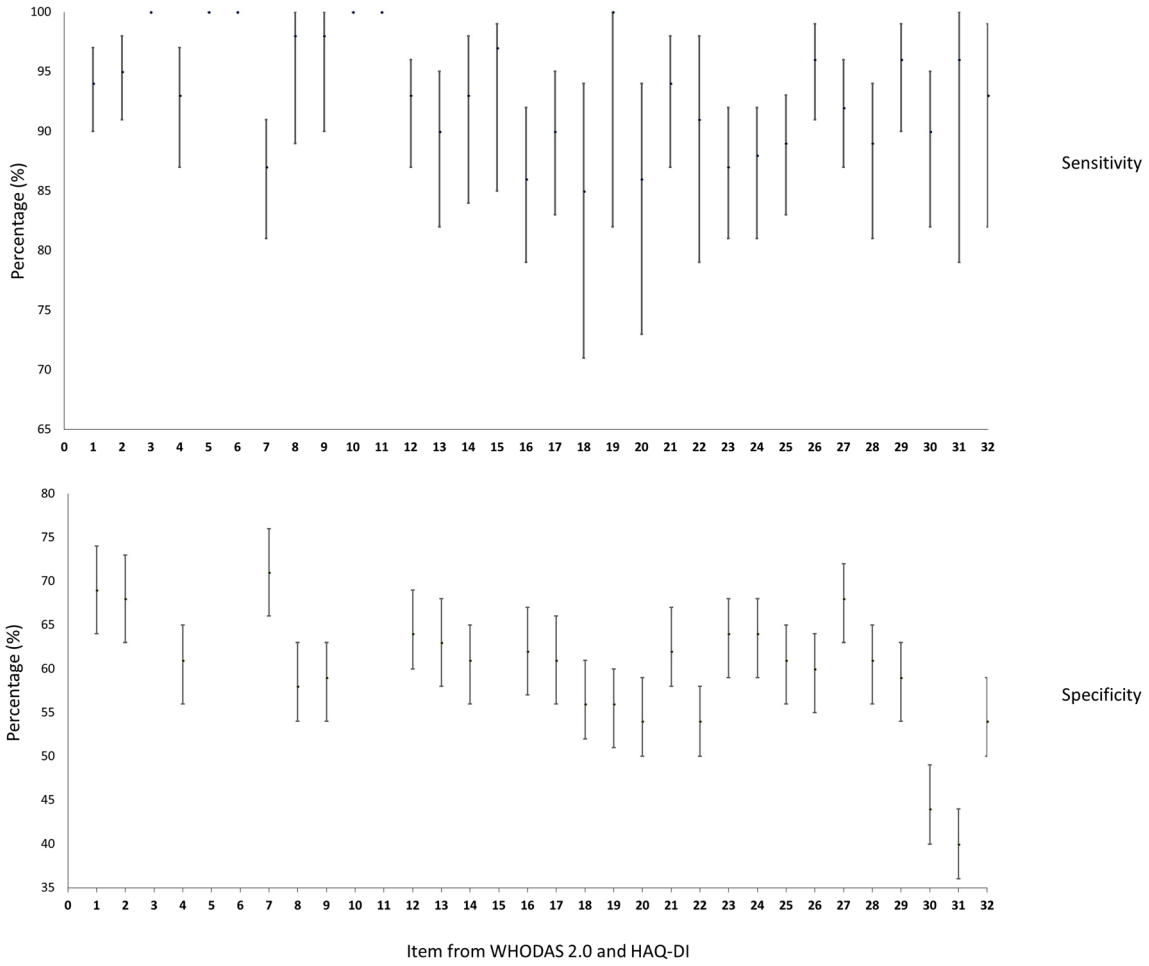

Fig. 4 Sensitivity, specificity, and 95% confidence intervals when using CAPLET, as compared to the gold standard of each individual WHODAS 2.0 and HAQ-DI Item. Sensitivities and specificities compare ability of CAPLET screeners to test for physical dysfunction in items of the WHODAS and HAQ-DI. CAPLET will screen negative (question omitted) or positive (question presented to patient) for items of WHODAS and HAQ-DI based on its branching logic algorithm (see Fig. 1). Above, the success of this screening test in accurately predicting whether patients will report no difficulty in WHODAS and HAQ-DI items is evaluated against the gold standard of what patients actually reported when completing the tool in absence of any branching logic (WHODAS/HAQ-DI). WHODAS and HAQ-DI response levels were dichotomized into either positive for physical dysfunction or negative for no physical dysfunction based on the following definition for no dysfunction: a response of "none" or "mild" to WHODAS and a response of without any difficulty to HAQ-DI. (See Supplementary Table 3)

(MHC) maintain 100% sensitivity; these items were always presented to patients, because they targeted functional domains that did not correspond with screeners. Using CAPLET's algorithm, 275 (50%) subjects could have skipped all but MHC questions.

Phase 2

Of 318 phase 2 subjects, 158 received WHODAS/HAQ-DI and 160 CAPLET. There were no significant differences in any demographic or clinicopathological variables between the two

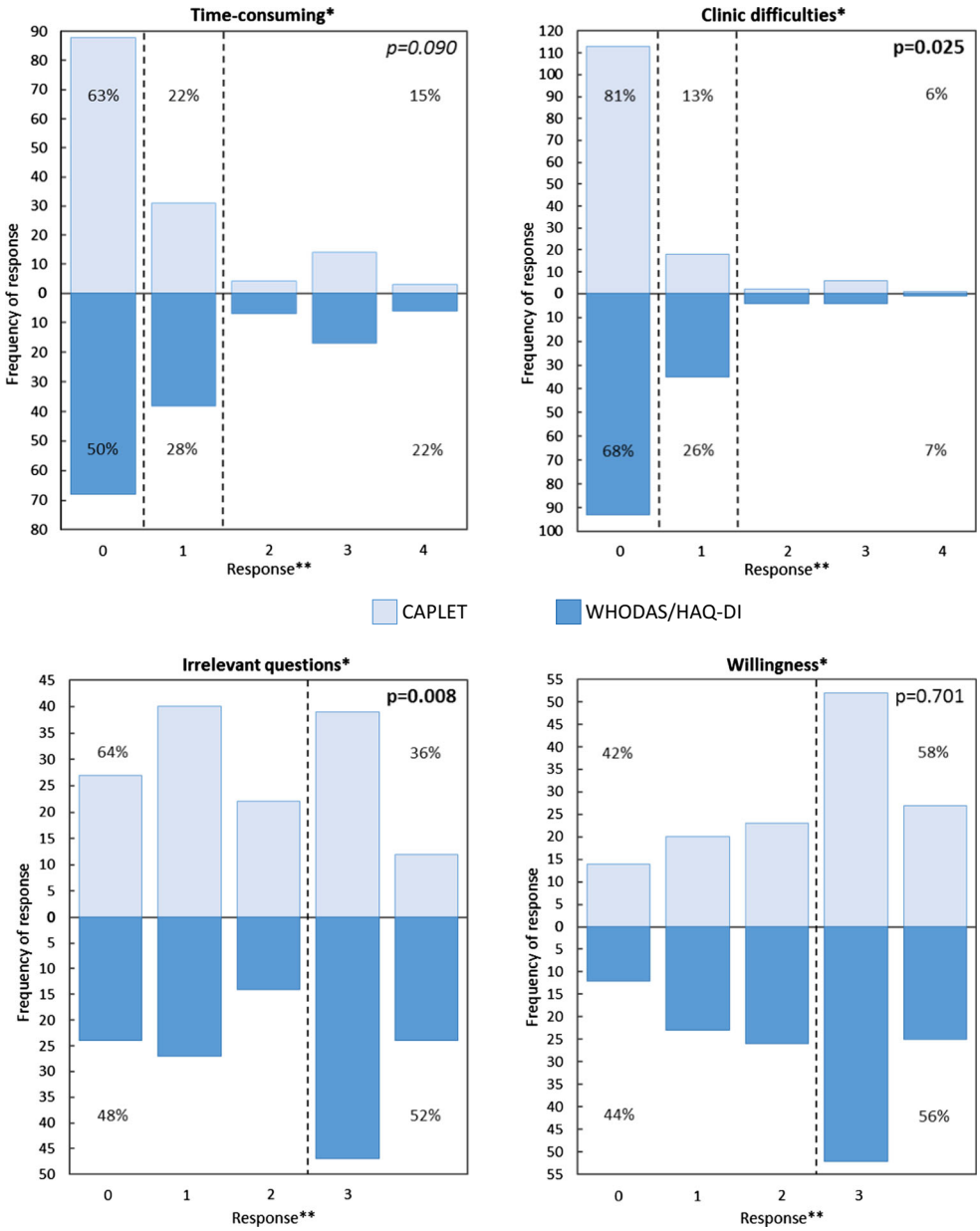

Fig. 5 Patient-reported acceptability of WHODAS/HAQ-DI vs CAPLET. Vertical dotted line(s) in each graph indicate categories which have been combined for analysis. Significance was assessed using chi-square tests. Significant *p* values are bolded; *p* values trending towards significance are italicized. Time-consuming ➔ Was the completion of the survey time-consuming? Clinic difficulties ➔ Did the completion of the survey make your clinic visit more difficult? Irrelevant questions ➔ Were any of the questions irrelevant to you? Willingness ➔ Would you be willing to complete similar surveys at every clinic visit? Response Levels. 0 = Definitely not; 1 = Probably not; 2 = Not sure; 3 = Probably yes; 4 = Definitely yes

arms. Participant responses to key acceptability statements about WHODAS/HAQ-DI vs CAPLET are represented graphically in Fig. 5 and outlined fully in Supplementary Table 1.

Compared to WHODAS/HAQ-DI, CAPLET resulted in a median completion time reduction of 3.8 min [median and range of 8.5 (3.8–20.1) vs 12.3 (4.1–28) min; $p < 0.001$] and a 50% decrease for the physical function section, [4.0 (1.2–20.1) vs 8.2 (4.4–29) min; $p < 0.001$] (Supplementary Fig. 1). Although CAPLET-derived WHODAS 12-item simple scores and HAQ-DI scores did vary compared to WHODAS/HAQ-DI derived scores, these differences were not clinically meaningful [27, 28]. Median number of questions asked of CAPLET responders was 5. While most patients across both arms did not report that the survey was time consuming nor made their clinic visit more difficult, a greater proportion of CAPLET responders held a stronger conviction in their answers ($p < 0.09$ and $p < 0.025$ respectively). Fewer CAPLET responders than WHODAS/HAQ-DI responders reported that the questionnaire contained irrelevant questions ($p < 0.008$). A combined 88% of WHODAS/HAQ-DI and CAPLET responders reported "probably yes" or "definitely yes" to being willing to complete similar surveys at every clinic visits.

Discussion

Functional limitations are pervasive in cancer outpatients. Finding efficient methods of screening for such difficulties is

important for improving clinical management [1, 17, 19, 29]. Historically, highly sensitive measures of physical function are not collected in this population, because they have been too lengthy or too static to be administered to such a heterogeneous, ambulatory patient sample. Our cross-sectional study presents the development and critical evaluation of CAPLET as a tool for fulfilling this need in outpatient clinics.

While our study is not the first to examine PROMs for physical function [30], it is novel in presenting a cancer-specific tool that summarizes the WHODAS and HAQ-DI. Several excellent reviews have been published in the last decade outlining the benefits of integrating knowledge from geriatrics and cancer to produce PROMs that are highly sensitive in screening for functional difficulties and ideal for use in chronic care [16, 18, 19]. Our sample of 548 WHODAS and HAQ-DI responders is the first source of normative data for WHODAS and HAQ-DI in a cancer population, and may be useful to epidemiological research, or to future healthcare providers looking to administer these tools to patients. Our finding that 62% of participants reported at least one difficulty to WHODAS/HAQ-DI is consistent with previous literature on the prevalence of functional limitations in cancer patients as reported by Brown [20].

Our report is only the second to explore whether Ontario cancer patients would be willingly to complete PROMs routinely during clinic appointments. Overall, acceptability of tools in both arms was high, which supports previous findings by Naik [31]. Most striking was that 91% of responders across both arms agreed "the information collected should be kept in their personal notes." Thus, patients felt that their physical function reports were valuable for reference and management by their healthcare team. The greatest limitation of our study is that our population was a convenience sample. This bias may explain why we found few differences in acceptability between the two arms, especially for willingness to complete a similar survey at every clinic visit. Although it was not possible to collect comprehensive data on non-responders, our sample was distributed across different disease stages, sites, and treatment types. Moreover, it is likely that CAPLET would perform equally well across diverse populations, as HAQ-DI and WHODAS are validated for use across varying socio-ethnic groups; one limitation of CAPLET is that it was not evaluated for construct validity; however, psychometric validation of individual HAQ-DI and WHODAS items is well established in previous literature [8, 9, 25].

Further prospective analysis of CAPLET is needed to better evaluate CAPLET's utility in producing surrogate functional scores comparable to those generated with the WHODAS/HAQ-DI. Additional follow-up is also needed to evaluate to what extent CAPLET has value in screening for at risk patients by comparing CAPLET scores to a practitioner's assessment of disability. In the future, CAPLET could be adapted to be administered on any laptop or desktop with Internet access, in clinic or even remotely from a home setting. CAPLET is not specific to any bespoken software; thus, it may easily be programmed for use on any number of survey software platforms that allow branching logic. Recently, EQ-5D-5L has been developed and will likely supplant EQ-5D-3L in the future [32]; evaluating CAPLET using the five-level EQ-5D version rather than the three-level version currently used in its screening process would be another goal for this tool that could further increase its specificity. Objective measures of physical function, such as wearable trackers, may be trialed as potential next steps to follow-up on patients who self-report having significant functional disability [33]. Finally, long-term follow-up is needed to evaluate to what extent CAPLET may have predictive value in identifying patients with long-term care needs [34].

In conclusion, our data suggests that CAPLET improves the feasibility of routinely assessing physical functioning in the cancer clinic. CAPLET's high sensitivity and detailed item bank make it a tool suitable for administration in a heterogeneous population. Whether measuring physical function to inform comparative effectiveness research predicts future health outcomes, or provides targeted preventative care, CAPLET offers a critical opportunity for increasing patient centeredness in oncology clinical practice.

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Compliance with ethical standards

All study protocols were approved by the research ethics board of the University Health Network in Toronto, Ontario, Canada.

Disclosures A portion of the data included in this manuscript has been presented (1) at the American Society of Clinical Oncology Survivorship Symposium, January 29, 2017 and (2) at the American Society of Clinical Oncology Quality Care Symposium.

Conflict of interest The authors declare that they have no conflict of interest.

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