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Functional Status In Older Women Following Gynecological Cancer Surgery: Can Choice of Measure Influence Evidence for Clinical Practice?

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Abstract

Although functional status serves as a major predictor of morbidity, researchers and clinicians use different terms and measures, limiting comparisons across studies. To demonstrate how differing measures may generate varied findings, we compared and contrasted data from the SF-12 Health Survey Physical Component Summary Scale (SF-12 PCS) and the Enforced Social Dependency Scale (ESDS). The sample consisted of 49 women ages 65 and over recovering from gynecological cancer surgery with data collection at baseline (postoperative period) then 3 and 6 months. Analysis of the relationship between SF-12 PCS and ESDS over time using Generalized Estimating Equations (GEE) demonstrated the relationship was less than 1.0, signaling less than perfect agreement between measures (Beta=0.16, p=0.002). These findings suggest that the two measures are not interchangeable and may produce conflicting evidence. This highlights the importance of researchers' and clinicians' careful conceptualization and operationalization of functional status prior to measure selection.

Over 60% of cancer diagnoses and 80% of cancer deaths occur in adults ages 65 and over.¹ As the number of older adults increase over the next two decades, the population with cancer will also increase in number.² Gynecological cancers are typical of the malignancies prevalent among older adults; the primary treatment for these cancers consists of surgery, and may be followed by chemotherapy or radiation therapy depending on the stage of the cancer at the time of diagnosis.³ A patient's functional status, defined as a multi-dimensional

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concept reflecting an individual's performance of activities associated with current life roles, is a major indicator of morbidity and quality of life.^{4,5} Hence, awareness of older women's functional status after surgery associated with gynecological cancer may help clinicians identify patients at risk for adverse events and intervene early to help them maintain or regain pre-illness function.⁶

Clinicians and researchers often conceptualize functional status differently by considering activities of daily living, functional performance (e.g, gait speed), physical health, and overall health status. This may occur both across and within studies, ultimately limiting our understanding or interpretation of findings about functional status.⁵ Comparing and contrasting the data generated by measures representing differing conceptualizations of functional status could help inform researchers and clinicians to understand prior findings and in planning future research design and methods.

Thus we conducted a secondary data analysis of older women undergoing gynecological cancer surgery to examine whether two measures incorporating function, yet derived from differing conceptual frameworks, generate homogeneous patterns of functional status. This information has the potential to underscore the importance of the conceptualization process in research design, the influence of this process on the choice of functional status measures, and the impact on evidence for clinical practice of older women with gynecological cancers. The data for our analysis was obtained from study participants enrolled in a quality of life clinical trial using two measures, the SF-12 Physical Component Summary Scale (SF-12 PCS)⁷ and the Enforced Social Dependency Scale (ESDS).⁸ The SF-12 PCS, a shorter version of the SF-36 Health Survey Physical Component Summary Scale (SF-36 PCS)⁹ measures the physical component of health. It reflects what people are able to do (functioning), how they feel subjectively and evaluate it cognitively. It is useful in discriminating the presence and severity of physical conditions.^{7,10} In contrast, the ESDS, a ten item measurement, was created to assess a person's requirement for help or assistance from others in performing activities or roles that under ordinary circumstances adults can perform by themselves¹¹ (See Table 1).

The purpose of this study was to examine the relationship between the two measures over time to analyze whether the choice of functional status measure may impact evidence for clinical practice of older women with gynecological cancers. We also compared and contrasted the data at individual collection times to investigate whether the two measures generate heterogeneous or homogenous patterns of functional status over time.

Methods

We conducted a secondary analysis to examine data generated by two measures incorporating function among women ages 65 and over undergoing gynecological cancer surgery. Yale School of Nursing Human Subjects Institutional Review Board granted approval for the study. Informed consent was previously obtained from all patients.

Data Source

The data for our current study were collected during a randomized clinical trial targeting women who had undergone abdominal surgery for suspected gynecological cancer (herein termed 'parent study'). The parent study was conducted at a northeastern academic cancer center to test the effects of an Advanced Practice Nurse directed psychosocial intervention (herein termed APN intervention) on quality of life outcomes in women undergoing abdominal surgery for suspected gynecological cancers. Details of the parent study have been described elsewhere.^{8,12}

Briefly, the parent study occurred between December 2003 and June 2006. During that period, study recruiters identified 281 women during the post-operative period for abdominal surgery for suspected gynecological cancer who potentially met study inclusion criteria. The inclusion criteria consisted of women residing in the state of Connecticut with survival prognosis greater than 6 months, and discharged from the hospital with a plan to initiate chemotherapy. Patients were recruited for the parent trial during the post-operative period. Complete description of the parent study recruitment and attrition are described elsewhere, including the demographic and clinical data of the total study population.^{8,12} After further screening, 62 were excluded for either not meeting all inclusion criteria or receiving treatment at another cancer center. Of the remaining 219 women, the recruiters enrolled 145 women and completed baseline data assessments. Among these, 34% (n=49) were ages 65 and over, completed two outcome measures at 6 months, and thus were included in the current analysis reported in this paper. Demographic data and comorbidities were assessed by patient self-report and recorded at baseline. Cancer site, stage, and treatment were collected from treatment records and medical record audits. Functional status, symptoms, and mental health data were reported by patients and collected by research assistants at baseline, and 3 and 6 months.

Intervention—All patients in the parent study received the Symptom Management Toolkit (SMT)¹³, a manual written at the 6th grade level with information on 16 common symptoms experienced post-surgically or with chemotherapy. Each section describes causes of symptoms, strategies for managing them, and when to call the provider.

Upon enrollment in the study, patients were randomized to either the nurse-directed psychosocial intervention or attention control group. Patients in the nursing intervention group received 6 months of tailored specialized care by an oncology APN, including 18 patient contacts during the first 6 months after hospital discharge. The patients who did not receive the intervention were assigned to a consistent research assistant trained in the use of the SMT.

In addition, women were screened at baseline for emotional distress using the Distress Thermometer (DT), a rapid method to evaluate patients' distress. In addition to the distress thermometer, patients completed a 38 item problem list that helped to identify the source of the patient's distress.^{14,15} Women who scored four or greater on the DT, indicating significant distress, and randomized to the intervention received an evaluation by the psychiatric consultation-liaison nurse (PCLN).

Measures

We compared two measures – the SF-12 PCS^{7,16} and the ESDS.¹¹ The SF-12 PCS measures the physical component of health and is used to discriminate the presence and severity of physical conditions. It consists of a subset of 12 items from the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36).^{9,16} The 12 items were selected to represent the Physical Component Summary Scale (PCS) and Mental Component Summary scales (MCS) among the United States population. As with the MOS-SF-36, higher scores represent better physical health. The SF-12 has demonstrated reliability and validity. An assessment of test-retest reliability demonstrated a score of 0.89. The SF-12 PCS also generated multiple R squares of 0.911 in prediction of the SF-36 PCS.^{7,16}

The ESDS consists of two components: personal and social competence. Personal competence includes six activities of eating/feeding, dressing, walking, traveling, bathing, and toileting. Dependency in each activity is reported by the patient and rated by the interviewer on a 6-point scale. Scores for personal competence were summed and ranged from 6 to 36. Social competence consists of home, work, and recreational activities, which

were rated on 4-point scales, and the category communication, rated on a 3-point scale. Scores for social competence are summed and ranged from 4 to 15. Scores for personal and social competence are summed to generate a total dependency score ranging from 10 to 51, with higher scores reflecting greater dependency. The ESDS has demonstrated reliability (Cronbach's alpha = .72 to .96) and validity.^{5,11,17}

Covariates

Age—Age was abstracted from the patient history forms and recorded on a standardized form. All subjects ages 65 and over during the 6 months of the study were included, and ages at 6 months were used for the analysis as a continuous variable.

Symptoms—Number of symptoms was measured by the Symptom Distress Scale (SDS)¹⁸ to quantify the effect of each additional symptom on function. The SDS consists of 13 common symptoms of cancer patients: frequency of nausea, severity of nausea, appetite, insomnia, frequency of pain, severity of pain, fatigue, bowel pattern, concentration, appearance, breathing, outlook, and cough. Subjects rated their distress on a scale from 1 (low distress) to 5 (high distress). Absence of a symptom was defined as values 1 and 2, and presence of a symptom was equal to values 3, 4, and 5. This categorization is consistent with previous studies using these same values to distinguish between low and high symptom distress.¹⁹ Number of symptoms, therefore, represented the sum of present symptoms with highest score equal to 13 and lowest score equal to 0. The SDS has demonstrated content, construct, and criterion validity. The SDS has also demonstrated reliability with reported Cronbach alphas ranging from 0.70 to 0.89.^{18,20,21}

Comorbidities—Comorbidity was defined as other preexisting health condition or disease outside the index cancer. Following procedures from the five original studies, all preexisting health conditions or diseases reported by the study participants were classified by system: Cardiovascular, respiratory, endocrine, eye/ear/nose/throat, mental, neurologic, genitourinary, gastrointestinal, skin, cancer, injuries, infectious, and other. The empirical indicator was sum of comorbidities. Evidence from research studies support concurrent and predictive validity for count of disease as a measure of comorbidity.²²

Data Preparation—The preparation of the data for analysis has been described elsewhere.²³ Briefly, we reversed the ESDS scores to attain consistent direction with the SF-12. Both SF-12 PCS and ESDS data were converted to standardized norm-based scores (mean=50, standard deviation=10) using 0-100 metric and z scores. The SF-12 PCS was calculated based on methods described in the manual “How to Score Version 2 of the SF-12 Health Survey”.¹⁶

Statistical Analysis: Means, standard deviations, and frequencies were used to obtain descriptive statistics of the patient population. We compared the standardized measures by fitting multiple linear regression models using generalized estimating equations (GEE) of the standardized outcomes. We included time of data collection at 3 and 6 months as dummy variables in the model. We assessed the relationship between the standardized ESDS and SF-12 PCS over time among the study population by fitting multiple linear regression models using GEE. Based on partial correlation analysis and evidence within the literature,²⁴ we included age, number of symptoms, and number of comorbidities as covariates to crudely adjust for confounding by these variables. We next assessed the relationship between the standardized measures at each time of data collection again by fitting multiple linear regression models.

Results

Patient Characteristics

The total study population consisted of 49 women ages 65 and over who were recovering from gynecological cancer surgery (See Table 2). The mean age was 72.5 (SD=6.5, range 65 to 87). Nearly half of the study population ranged in ages from 65 to 69 (46.9%). A majority of patients were white (93.9%), unmarried (i.e. single, divorced, or widowed) (55.1%), and lived with another person (59.2%). Most patients had received some college education (61.2%), yet most were not working (71.4%). Over one-third of the population reported an income of \$40,000 or greater (40.8%). The majority of patients were diagnosed with advanced cancer disease (49%) and suffered from three or more comorbidities (71.4%). They were primarily treated with surgery and chemotherapy (63.3%) over the six month period. In addition, over 50% of patients had been randomized to the APN intervention in the parent study.

Comparison of SF-12 PCS and Standardized ESDS Over Time

We compared scores generated by SF-12 PCS and standardized ESDS scores while controlling for the covariates Time of Data Collection, Age, Number of Symptoms, and Comorbidities as covariates (See Table 3). The standardized ESDS scores were significantly improved at both 3 and 6 months (3 months: Beta=9.53, 95% CI 7.0 to 12.07, $p<0.001$; 6 months: Beta=11.40, 95% CI 8.71 to 14.09, $p<0.001$) compared with baseline scores. As seen with the standardized ESDS, the SF-12 PCS also showed that patients reported improvement over time. This relationship, though, did not reach statistical significance at either 3 or 6 months compared with baseline scores.

Analysis of Relationship Between SF-12 PCS and Standardized ESDS

We next explored the relationship between the SF-12 PCS and standardized ESDS while controlling for the covariates Time of Data Collection, Age, Number of Symptoms, and Comorbidities (See Table 4). Although the analysis demonstrated that the standardized ESDS was significantly and positively associated with SF-12 PCS, the relationship was less than 1.0, signaling that there was less than perfect agreement (Beta=0.16, 95% CI: 0.06 to 0.26, $p=0.002$). Figure 1 also demonstrates that there was less than perfect agreement between the two standardized measures.

Analysis of SF-12 PCS and Standardized ESDS at Time of Data Collection

As the previous results suggested that the two measures generated differing scores over time, we further explored the relationship of the standardized measures at each time of data collection. We conducted multiple linear regression analysis using the standardized ESDS as the outcome measure and the SF-12 as the covariate (See Table 5). The findings from the analysis showed no significant relationship between the SF-12 and standardized ESDS at baseline (Baseline: Beta=-0.09, 95% CI -0.33 to 0.14, $p=0.429$) (See figure 2). In contrast, there was a positive, significant relationship at both 3 and 6 months (3 Months: 0.28, 95% CI 0.14 to 0.41, $p<0.001$; 6 Months: 0.48, 95% CI 0.29 to 0.66, $p<0.001$). Although statistically significant, the Beta coefficients were less than one, representing lack of complete agreement between the two standardized measures.

Discussion

We conducted a study to compare and contrast data from two measures that incorporate function yet are derived from different conceptual frameworks. The SF-12 PCS assesses the physical component of health,⁷ whereas the ESDS measures self-care and social and mobility problems reported by patients with cancer.¹¹ Our findings showed less than a

perfect relationship between the SF-12 PCS and ESDS over time, suggesting that the two measures are not interchangeable. The negative relationship between the two measures at baseline demonstrated the potential for conflicting evidence. Hence, the choice of functional status measure may influence clinical evidence for the care of older women undergoing surgery for gynecological cancers.

Another study has also demonstrated that measures derived from differing conceptual frameworks may influence research findings.²⁵ The researchers reported data generated by performance measures and self-report scales, including Activities of Daily Living (ADLs) and the SF-36 PCS, over a 6 month period of time by a convenience sample of older adults undergoing abdominal surgery. The analysis showed that the ADLs and SF-36 PCS measures produced varied findings. The ADL scores returned to baseline between 6 weeks and 3 months, whereas the SF-36 PCS scores returned to pre-operative levels at 3 months.²⁵

Although the varied findings between the two measures included in our study may stem from differing conceptual perspectives of function, other processes may have influenced our findings. Some evidence suggest that the SF-36, the parent measure of the SF-12, has decreased sensitivity among lower scores representing worse function.²⁶ Our analysis of data at each time of data collection showed that the SF-12 PCS and the ESDS measures varied most at baseline (immediate post-operative period) and aligned most at the 6 month period when patients scores were highest. Our findings may also reflect that the SF-12 also possesses decreased sensitivity at lower scores.

Another reason for differing findings from the two measures may stem from the age of the study participants for this study. The SF-12 was developed for the general population without regard to age.²⁷ Findings from previous studies have demonstrated that older adults may be more forthcoming about lack of energy and feelings of depression than the general population, lessening the reliability and validity of the SF-12.²⁸ The ESDS has demonstrated reliability in studies of older adults, however some researchers maintain that the underlying construct of the measure represents functional dependence.^{11,26} This may be the reason why the ESDS was significantly associated with age but the SF-12 PCS lacked significance. Performance-based measures have been incorporated into the assessment of older adults to counter the bias from self-report measures. However, these measures provide limited information by focusing on functional performance and may have low inter-rater reliability.²⁶ This suggests that researchers who are planning to conduct studies of older adults should consider using multiple measures in order to obtain a comprehensive view of patients' function.

Study Strengths

The primary strength of our study consists of the unique opportunity to compare findings generated by the SF-12 PCS and the ESDS from the same study population. By doing so, we were able to demonstrate the differing scores generated by the two measures. Another strength of our study stems from our study population of older women undergoing suspected gynecological cancers, an important and understudied population. Our study findings suggest that this population experiences improved function over time after cancer surgery.

Limitations

Our study has several limitations. The analysis consisted of existing data, thus the variables for the current study were limited to those originally collected in the parent study. In addition, we had a small sample size of 49 women, heightening the chance of measurement error. Although the focus on older women undergoing surgery for suspected gynecological cancer helps inform the literature, this also limits the generalizability of our study results.

Another study limitation concerns potential bias from the APN intervention in the parent study. Although the parent study results suggest that the APN intervention did not significantly affect functional status, we examined whether the inclusion of the APN as a covariate would influence the current study findings. As in the analysis without the APN, the SF-12 PCS demonstrated non-significant improvement over time and the standardized ESDS showed significant improvement of functional status over time. We did not detect any bias in our findings.

Conclusion

Functional status constitutes a major indicator of morbidity and mortality for older women undergoing abdominal surgery for gynecological cancer. Hence, information regarding older women's function after gynecological cancer surgery may help clinicians identify patients at risk for adverse events. Our findings highlight the importance of the choice of the functional status measure, showing that measures incorporating function yet representing differing conceptual frameworks may produce varying evidence after surgery for presumed gynecological cancer. This highlights the importance of researchers' careful conceptualization and operationalization of functional status in studies generating evidence to guide clinical practice of older women with gynecological cancers.

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Figure 1. Relationship Between SF-12 PCS and Standardized ESDS Measures Over 6 Months

Figure 2. Comparison of SF-12 PCS and Standardized ESDS Measures at Baseline, 3 and 6 Months

Table 1
Comparison of SF-12 PCS and ESDS

SF-12 PCS	Enforced Social Dependence Scale
<ul style="list-style-type: none"> • General Health • Limited in moderate activities • Limited in climbing stairs • Accomplished less due to physical role • Limited in kind of activities • Pain interferes with normal work • Have a lot of energy • Physical health or emotional problems interfered with social activities • Accomplished less due emotional role • Did work less carefully than usual • Felt calm or peaceful • Felt downhearted and depressed 	<ul style="list-style-type: none"> • Eating/Feeding • Dressing • Walking • Travel • Bathing • Toileting • Activities in Home • Activities at Work • Recreational and Social Activities • Communication

Table 2
Patient Characteristics (n=49)

Mean Age 72.5 (SD=6.5) range 65.2 86.9		
Type of cancer		
Gynecologic	43	
Other	6	1 uncertain 3 peritoneal 2 appendiceal
Age group		
65 – 69	23	46.9
70 to 74	13	26.5
75 and over	13	26.5
Female	49	100.0
Race		
White	46	93.9
Non-White	3	6.1
Marital Status		
Not married	27	55.1
Married	22	44.9
Living Status		
Lives with someone	29	59.2
Alone	20	40.8
Working		
Not working/retired/unemployed	35	71.4
Working	14	28.6
Education		
12 th grade or less	19	38.7
Greater than 12 th grade	30	61.2
Income		
\$0 to \$19,999	12	24.5
\$20,000 to 39,999	11	22.5
\$40,000+	20	40.8
Unknown	6	12.2
Stage		
Early	13	26.5
Late	24	49.0
Unknown	12	24.5
Comorbidities		
None	3	6.1
1	6	12.2
2	5	10.2

Mean Age 72.5 (SD=6.5) range 65.2 86.9		
3 or more	35	71.4
Recurrent vs new diagnosis		
New diagnosis	29	59.2
Recurrent disease	20	40.8
Treatment		
Surgery alone	4	8.2
Surgery radiation	4	8.2
Surgery chemotherapy	31	63.3
Surgery, chemotherapy, and radiation therapy	10	20.4
APN		
APN	22	44.9
No APN	27	55.1

Table 3
Comparison of SF-12 PCS and Standardized ESDS Measures Over Time (N=49)

	Standardized ESDS	Standardized SF-12 PCS Coefficients
Time of Data Collection		
Baseline	Reference	Reference
3 Months	9.53(1.30) ***	1.41(2.16)
6 Months	11.40(1.37) ***	3.88(2.28)
Age	-0.40(0.12) **	0.10(0.17)
Number of Symptoms	-1.32(0.28) ***	-1.94(0.44) ***
Comorbidities	-0.28(0.35)	-0.04(0.51)
Const	75.81(8.51) ***	31.40(12.38) *

*
p<0.05

**
P<0.01

p<0.001

Table 4
Analysis of Relationship Between SF-12 PCS and Standardized ESDS Measures (N=49)

Variable	Coefficient(SE)	95% CI	Significance
SF-12	0.16 (.05)	0.06 0.26	0.002
Baseline	Reference		
3 Months	9.24 (1.2)	6.78 11.71	<0.001
6 Months	10.75 (1.3)	8.11 13.39	<0.001
Age	-.42 (0.12)	-0.64 -0.19	<0.001
Number of Symptoms	-1.03 (0.28)	-1.59 -0.48	<0.001
Comorbidities	-0.27 (0.34)	-0.93 0.39	0.422
Const	71.0 (8.34)	54.65 87.35	<0.001

Table 5
Comparison of SF-12 PCS and Standardized ESDS Measures at Baseline, 3 and 6 Months
(N=49)

Regressing Standardized ESDS on SF-12 by wave			
	Baseline	3 Months	6 Months
Constant	43.57 (3.85) ***	42.82(2.69) ***	36.15(3.70) ***
Beta Coefficient (sd)	-0.09(0.12)	0.28(0.07) ***	0.48(0.09) ***

**
p<0.01

p<0.001