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The PERSONS score: A new tool for cancer patients' symptom assessment in simultaneous care and home care settings

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Abstract

Background. Scientific societies recommend early interaction between oncologic and supportive care, but there is still a lack of systematic evaluations regarding symptoms from the perspective of oncologists.

Patients and methods. The aim of this prospective study was to evaluate the PERSONS score, in both “simultaneous care” and “supportive care” settings using the Edmonton Symptom Assessment Scale (ESAS) as a comparator.

Results. From November 2017 to April 2018, 67 and 110 consecutive patients were enrolled in outpatient and home care cohorts, respectively. The final study population comprised 163 patients. There were no significant changes over time in the total PERSONS scores and total ESAS scale. The intra-interviewer reliability (ICC_{2,1}) and inter-interviewer reliability (ICC_{2,k}) showed good reproducibility (test-retest) in each group of patients: 0.60 (0.49–0.70) and 0.82 (0.75–0.87), respectively, for the home care patients and 0.73 (0.62–0.81) and 0.89 (0.83–0.93), respectively, for the outpatient cohort. There were high correlations between PERSONS and ESAS, both at the baseline and final assessments. The mean PERSONS and ESAS scores between the home care patients and outpatients were not different at the baseline and final assessments. Receiver operating characteristics (ROC) curve for the PERSONS total score revealed good diagnostic ability. Area under the curve (AUC) was 0.825 and 0.805 for improvement and deterioration, respectively.

Conclusions. The PERSONS score is an easy to apply tool for symptom assessment. Importantly, the PERSONS score showed high concordance with the established ESAS scale and, therefore, provides an alternative for everyday use in supportive care assessment.

Introduction

International scientific societies recommend early interaction between oncologic and palliative care as one of the most important tasks of modern oncology practice (Zagonel *et al.*, 2017; Ferrel *et al.*, 2017; Davis *et al.*, 2015). Some recent clinical trials and literature reviews showed that early integration of palliative care could improve the quality of life of patients with cancer and symptom management, but the impact on survival still remains a matter of debate (Davis *et al.*, 2015; Bakitas *et al.*, 2015; Temel *et al.*, 2010; Haun *et al.*, 2017). A prompt symptom evaluation is the first step of that process and should be an integral part of the “basic basket of services” that must be guaranteed for every patient. A recent study further validated the importance of early symptom assessment, reporting that it could improve survival by up to 5 months (Basch *et al.*, 2017). Indeed, Basch and colleagues conducted a clinical trial involving patients with advanced cancer undergoing chemotherapy, who were randomly assigned to either usual care or the use of “electronic patient-reported outcomes” (PRO). When the PRO group participants reported a severe/worsening symptom, an automatic alert was emailed to the clinicians. Intriguingly, PRO group patients had a significantly longer overall survival, as compared with the usual care patients (Basch *et al.*, 2017).

Nevertheless, assessment is challenging in everyday practice, because of restricted time resources; a survey conducted by the Italian Association of Medical Oncology reported that only 20% of oncologists regularly use validated tools to evaluate symptoms (Zagonel *et al.*,

2016). Moreover, although early palliative care is increasing, only a few oncologists provided a systemic evaluation of symptoms (Giusti et al., 2017; Porzio et al., 2005). The lack of systematic evaluation probably stems from many different causes; the workload of outpatient cancer care centers leads clinicians to underestimate symptom burden, and oncologists might be focused on disease-oriented therapies as they consider these therapies of primary importance (Grávalos et al., 2012; Greer et al., 2013). Several questionnaires and scoring tools have been investigated for symptom assessment; among them, the Edmonton Symptom Assessment Scale (ESAS) is the best known and most often used (Bruera et al., 1991; Chang et al., 2000). Recently, a new questionnaire, called “PERS²ON score,” has been designed. It assesses 7 items: pain, eating (loss of appetite/weight loss), rehabilitation (physical impairment), social situation (possibility for home care), suffering (anxiety/burden of disease/depression), O₂ (dyspnea), and nausea/emesis, on a scale ranging from 0 (absence) to 10 (worst imaginable), resulting in a score ranging from 0 to 70. In the first study, the “PERS²ON score” was shown to be feasible for symptom assessment in an advanced palliative care setting (Masel et al., 2016). Our study group recently investigated the feasibility of a modified version, called the “PERSONS score,” in a simultaneous care context in patients on active treatment, changing just 1 item and replacing “social situation” with “sleep.” We reported that the PERSONS score is a feasible tool for screening and monitoring symptoms because it was “user friendly” (Cortellini et al., 2018).

We designed a prospective study to evaluate the PERSONS score in both home care and outpatient care settings, to test its interrater reliability, validity, and ability to detect symptom changes (responsiveness).

Materials and Methods

The PERSONS score and study design

The PERSONS score includes the following items: pain, eating (loss of appetite), rehabilitation (asthenia), sleep (sleep disorders), O₂ (dyspnea, cough), nausea/emesis, and suffering (anxiety/depression). Each item is rated on a numeric scale between 0 (no burden) and 10 (worst imaginable burden). All 7 points are summed, resulting in an overall score between 0 and 70 (Supplementary file 1)

The aim of this prospective multicenter study was to investigate the PERSONS score, both in a “simultaneous care” and a “supportive care” setting using the ESAS scale as a comparator. Patients were enrolled from both outpatient and home care settings; they were either recruited at Medical Oncology of St. Salvatore University Hospital, in L’Aquila, Italy, or by the home care service of the Tuscany Tumors Association, in Florence, Italy. PERSONS and ESAS questionnaires were administered during “pre-chemotherapy administration” visits and during routine home visits, at baseline, after 1 month, and after 2 months. The questionnaires were administered independently by clinicians in each center. Continuous data were tested initially for equality of variances using the Levene test. The Shapiro normality test was subsequently used for normality. Based on these findings, statistical comparisons were performed using parametric tests. To analyze whether the Eastern Cooperative Oncology Group Performance Status (ECOG-PS) could affect baseline PERSONS scores, linear regression and correlation analyses were performed, considering the following 4 ECOG-PS categories:

Table 1. Patients’ features

	Home care patients		Outpatients	
	<i>n</i>	%	<i>n</i>	%
Total	96	100	67	100
Gender				
Male	39	41	20	30
Female	57	59	47	70
Age, mean, (ds)	72 (14)		62 (12)	
Treatment				
Yes	50	48	67	100
No	46	52	0	0
Primary tumor				
Breast	5	5	21	31
Lung	28	29	2	3
Gastrointestinal	23	24	28	42
Gynecological	13	14	8	12
Prostate	4	4	–	–
Melanoma	2	2	–	–
Central nervous system	1	1	–	–
Genitourinary	6	6	5	7.5
Hematological	12	13	–	–
Sarcoma	1	1	–	–
Head and neck	1	1	1	1.5
Unknown primary cancer	–	–	1	1.5
Mesothelioma	–	–	1	1.5
ECOG-PS				
0	25	26	45	67
1	21	22	18	27
2	30	31	4	6
3	18	19	–	–
4	2	2	–	–

0, 1, 2, and 3–4. Reliability indicates both the “internal consistency” of a scale and the “reproducibility” of scores for the different ways of estimating it. Internal consistency reliability, usually measured by Cronbach alpha, was not investigated as it was inappropriate for a symptom scale (Moro et al., 2006). We estimated the interrater reliability with intraclass correlation coefficients (ICCs). ICCs and their 95% confidence intervals (CI) were based on a mean rating ($k=3$), consistency agreement, and 2-way random-effects model to assess inter-interviewer (ICC_{2,1}) and intra-interviewer (test-retest) (ICC_{2,k}) reproducibility, respectively (Shrout & Fleiss, 1979; Koo & Li, 2016). Estimated ICCs were interpreted as follows: ≤ 0.25 , poor agreement; 0.26–0.49, fair agreement; 0.50–0.69; moderate agreement; 0.70–0.89, high agreement; and 0.90–1, very high agreement (Portney & Watkins, 2009). To evaluate the validity of the PERSONS score,

Table 2. PERSONS scores at baseline and the final assessment by group. Values are expressed as mean and standard deviation

PERSONS symptoms	Home care patients				Outpatients			
	Assessment		t*	p value	Assessment		t*	p value
Baseline	Final	Baseline			Final			
P: Pain	2.2 ± 2.2	1.6 ± 1.7	2.9	0.0046	2.4 ± 2.4	2.3 ± 2.4	0.10	0.9172
E: Eating	3.4 ± 2.5	3.2 ± 2.8	0.7	0.4877	2.5 ± 2.2	2.8 ± 2.6	-1.1	0.2686
R: Rehabilitation	3.9 ± 2.9	2.8 ± 2.5	3.4	0.0010	4.4 ± 2.7	3.9 ± 2.8	1.6	0.1156
S: Sleeping disorder	2.4 ± 2.4	2.6 ± 2.6	-0.5	0.5936	2.9 ± 2.8	3.0 ± 2.8	-0.2	0.8558
O: O₂ Dyspnea	1.3 ± 2.0	1.9 ± 2.4	-1.9	0.0647	1.8 ± 2.7	2.0 ± 2.6	-0.7	0.4825
N: Nausea/emesis	1.3 ± 2.0	1.9 ± 2.3	-2.4	0.0142	2.6 ± 2.8	2.2 ± 2.4	1.1	0.2512
S: Suffering	2.0 ± 2.2	1.9 ± 1.9	0.2	0.8352	2.6 ± 2.9	2.5 ± 2.6	0.2	0.8190
Total score	16.92 ± 8.5	16.0 ± 9.8	1.02	0.3079	19.1 ± 10.9	18.6 ± 13.0	0.38	0.7016

*Paired t test. Bold values stand for $p < 0.05$.

the ESAS scale was chosen as a comparator. The relationship between the total PERSONS score and total ESAS score at baseline and the final assessment was investigated using Pearson correlation coefficient (r) with 95% CIs. The Pearson correlation coefficients (r) were interpreted as follows: ≤ 0.19 , very weak correlation; 0.20–0.39, weak correlation; 0.40–0.69, moderate correlation; 0.70–0.89, strong correlation; and 0.90–1.00, very strong correlation (Evans, 1996). To assess responsiveness, we considered the PERSONS scale as a “diagnostic test” for discriminating between improved and unimproved patients; with this hypothesis, we used the receiver operating characteristics (ROC) curve to describe the PERSONS’ ability to detect improvement or deterioration. The ROC curve was calculated, assessing the minimal clinically important difference (MCID) for improvement and deterioration of the total PERSONS score. The ROC curve was constructed with the sensitivity–specificity approach on the y-axis and x-axis, for differences in the score values. In plotting the ROC curve, ESAS cutoffs estimated by Hui et al. were used: $\geq +3$ points for improvement, and ≤ -4 for deterioration (Hui et al., 2015). Then, the AUC related to PERSONS was calculated, and the optimal cutoff was determined for improvement and deterioration using Youden’s J statistic. The analyses were performed separately for outpatients and home care patients using STATA statistical software version 14.2 (Stata Statistical Software College Station, TX: StataCorp LP). MedCalc Statistical Software version 16.4.3 (MedCalc Software bvba, Ostend, Belgium; <http://www.medcalc.org>; 2016) was used for the ROC analysis. The level of statistical significance was set at a p of ≤ 0.05 .

Patient eligibility

This study enrolled consecutive patients with cancer who had a histologically proven cancer diagnosis. In the outpatient group, all patients underwent a concomitant disease-oriented antineoplastic treatment (intravenous and/or oral), and, in the home care group, patients who were “out of treatment” were also enrolled.

Results

From November 2017 to April 2018, 67 and 110 consecutive patients were enrolled in the outpatient and home care cohort,

respectively. Among the home care cohort, 14 patients (13%) were excluded, because they were lost to follow-up and because of a lack of data availability. The final study population consisted of 163 patients. Baseline demographic and clinical characteristics of the patients are reported in Table 1. Notably, 50 patients (52%) from the home care cohort underwent disease-oriented treatments, and 46 patients (48%) were out of treatment. No significant relationship between baseline PERSONS scores and ECOG-PS levels were observed in the entire cohort ($r = 0.1506$; $p > 0.05$, $\beta = 1.36$, $p = 0.055$, respectively). There were no significant changes over time in total PERSONS scores. Significant changes were reported only for pain, rehabilitation, and nausea/emesis items in the home care patient group as shown in Table 2. Similarly, there were no significant changes over time in total ESAS scale scores. Significant changes were reported only for tiredness, depression, anxiety, and appetite in the home care patient group as shown in Table 3. Table 4 reports the ICC_{2,1} and ICC_{2,k} showing high inter-interviewer reproducibility (test-retest) in each group of patients. The coefficients (r) between total PERSONS score and total ESAS score showed high correlations. As for the home care patients, they were 0.778 (95% CI 0.684–0.846 [CIs for Pearson’s product-moment correlation was based on Fisher’s transformation], $p < 0.05$) at baseline and 0.789 (95% CI 0.698–0.854 [CI for Pearson’s product-moment correlation was based on Fisher’s transformation], $p < 0.05$) at the final assessment. Similarly, for outpatients, the coefficients of correlation were 0.904 (95% CI 0.847–0.940 [CI for Pearson’s product-moment correlation was based on Fisher’s transformation], $p < 0.05$) at baseline and 0.942 (95% CI 0.907–0.964 [CI for Pearson’s product-moment correlation was based on Fisher’s transformation], $p < 0.05$) at the final assessment. The mean PERSONS and ESAS scores between home care patients and outpatients were not different, at neither baseline nor the final assessments (Table 5). ROC for the total PERSONS score revealed that the AUC was 0.825 and 0.805 for improvement and deterioration, respectively, indicating good responsiveness. The minimal clinically important difference (MCID) for improvement was >3 scale points, and for deterioration, it was ≤ -6 (Figure 1). The MCID calculated by groups for improvement was >3 (sensitivity = 66.7; specificity = 92.3) for home care patients and >7 (sensitivity = 64.7; specificity = 100.0) for outpatients. The MCID calculated by groups for deterioration

Table 3. Edmonton Symptom Assessment Scale (ESAS) scale scores at baseline and the final assessment by group. The values are expressed as mean and standard deviation

ESAS items	Home care patients				Outpatients			
	Assessment		t*	p value	Assessment		t*	p value
	Baseline	Final			Baseline	Final		
Pain	2.3 ± 2.1	2.1 ± 1.7	0.8	0.4242	2.4 ± 2.3	2.3 ± 2.3	0.3	0.7596
Tiredness	4.2 ± 2.3	3.2 ± 2.8	3.6	0.0005	4.1 ± 2.7	3.8 ± 2.7	-1.1	0.2513
Nausea	1.2 ± 2.1	1.2 ± 1.6	0.4	0.6297	2.6 ± 2.7	2.4 ± 2.5	0.6	0.5887
Depression	1.9 ± 2.2	2.6 ± 2.6	-2.8	0.0070	2.2 ± 2.8	2.3 ± 2.5	-0.2	0.8357
Anxiety	1.8 ± 2.3	3.1 ± 2.9	-4.1	0.0001	2.5 ± 2.8	2.4 ± 2.5	0.2	0.8070
Drowsiness	2.7 ± 3.1	2.5 ± 2.3	0.4	0.6593	3.1 ± 2.9	2.8 ± 2.4	0.8	0.4128
Appetite	2.3 ± 2.4	1.6 ± 1.9	2.8	0.0060	2.3 ± 2.3	2.7 ± 2.5	-1.4	0.1661
Best well-being	3.4 ± 2.0	2.9 ± 2.4	1.7	0.0892	2.4 ± 2.7	2.8 ± 2.7	-1.6	0.1063
Shortness of breath	2.2 ± 2.1	2.3 ± 2.3	-0.4	0.7187	1.2 ± 2.3	1.5 ± 2.2	-1.1	0.2908
Other	NR	NR	-	-	NR	NR	-	-
Total score	22.1 ± 10.7	21.8 ± 12.2	0.3	0.7557	23.1 ± 14.1	23.1 ± 15.7	-0.1	0.9582

*Paired t test. Bold values stand for $p < 0.05$.

was ≤ -6 (sensitivity = 71.4; specificity = 82.4) for home care patients and ≤ -5 (sensitivity = 77.3; specificity = 81.2) for outpatients.

Discussion

To reach the coveted early integration of supportive care into oncological practice, we have to define the goals clearly and how to reach them with available time and tools (Verna *et al.*, 2016). Guidelines, scientific society, and position papers recommend a prompt symptom evaluation as the first step of this process. In today's clinical practice, there are several tools for symptom evaluation that "fit" both in terms of acceptability by patients and in terms of efficiency. Among them, the ESAS scale is the best validated and universally recognized one. To be clear, we used the ESAS scale to validate the PERSONS score right because it is the most widely used. Our aim was not to establish superiority nor inferiority of one over the other. Therefore, any comparative evaluation, in terms of performance, would be inappropriate. Our speculations will, therefore, focus on what

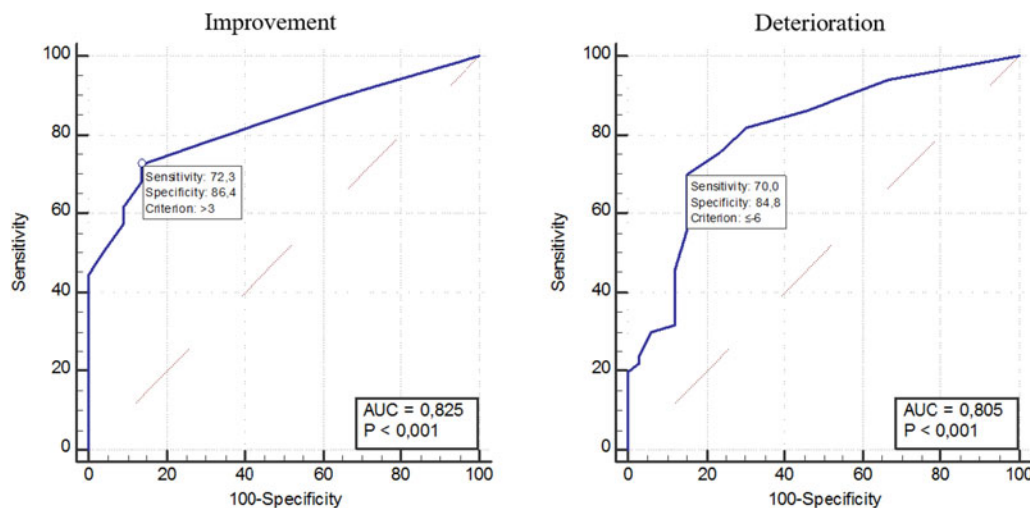
we think are still gray areas on the topic, despite all efforts. In our opinion, the question is: do these tools also "fit" for clinicians? Probably not. In addition to the abovementioned data regarding the poor attitude of oncologists in regularly using validated tools to evaluate symptoms (Zagonel *et al.*, 2016), a recent study showed that there are several barriers to using the ESAS scale in daily practice among cancer care professionals (Pereira *et al.*, 2016). Providing an explanation for these findings is not simple; does the increasing interest in disease-oriented treatments divert attention from supportive care? Could it be explained by the lack of time and workload in outpatient care centers? Surely, oncological practice is becoming more complex; we are going towards "precision oncology" that requires time and resources. In such a complex scenario, being realistic, we need to carve out a space for symptom assessment, and we must do it using simple tools that do not add "complexity to complexity." Moreover, we must not forget that the majority of patients are followed in peripheral cancer centers, without availability of a palliative care consultant, so a simple tool could be of service, particularly in centers with limited resources. Aware of these

Table 4. Inter-interviewer reproducibility $ICC_{(2,1)}$; intra-interviewer reproducibility $ICC_{(2,k)}$ by group (ICCs).

PERSONS symptoms	Home-care patients		Outpatients	
	$ICC_{(2,1)}$ (95% CI)	$ICC_{(2,k)}$ (95% CI)	$ICC_{(2,1)}$ (95% CI)	$ICC_{(2,k)}$ (95% CI)
P: Pain	0.49 (0.37–0.61)	0.74 (0.64–0.82)	0.61 (0.48–0.72)	0.82 (0.74–0.89)
E: Eating	0.57 (0.46–0.67)	0.80 (0.72–0.86)	0.55 (0.42–0.68)	0.79 (0.68–0.86)
R: Rehabilitation	0.56 (0.44–0.66)	0.79 (0.70–0.85)	0.65 (0.42–0.68)	0.85 (0.77–0.90)
S: Sleeping disorder	0.62 (0.52–0.72)	0.82 (0.77–0.88)	0.62 (0.49–0.73)	0.83 (0.74–0.89)
O: O₂ -Dyspnea	0.45 (0.33–0.57)	0.71 (0.59–0.80)	0.64 (0.52–0.75)	0.84 (0.76–0.90)
N: Nausea/emesis	0.50 (0.38–0.61)	0.75 (0.65–0.83)	0.56 (0.42–0.68)	0.79 (0.69–0.87)
S: Suffering	0.45 (0.32–0.57)	0.71 (0.59–0.80)	0.64 (0.51–0.74)	0.84 (0.76–0.90)
Total score (overall distress)	0.60 (0.49–0.70)	0.82 (0.75–0.87)	0.73 (0.62–0.81)	0.89 (0.83–0.93)

Table 5. Differences in PERSONS and ESAS scale between home care patients and outpatients. *unpaired *t* test.

	Assessment	Home care patients	Outpatients	mean difference (95% CI)	<i>p</i> value*
		Mean ± SD	Mean ± SD		
PERSONS	Baseline	16.9 ± 8.5	19.1 ± 10.9	2.14 (−0.87 to 5.15)	0.162
	Final	16.0 ± 9.8	18.6 ± 13.0	2.67 (−0.85 to 6.2)	0.136
ESAS	Baseline	22.1 ± 10.8	23.1 ± 14.1	0.94 (−2.9 to 4.8)	0.629
	Final	21.8 ± 12.2	23.2 ± 15.7	1.4 (−2.9 to 5.7)	0.522

**Fig. 1.** Receiver-operating characteristic curves (ROC) in improvement and deterioration for the PERSONS total scores.

gaps, we moved toward searching alternative easy to apply tools that could be better transposed into everyday clinical practice. While considering the results of the pilot studies in both advanced palliative care and simultaneous care settings (Masel et al., 2016; Cortellini et al., 2018), PERSONS has proven to be the “user friendly tool” that we seek.

The study population was from a dual setting: the outpatients represented the typical sample of patients to whom “ideal simultaneous care” is devoted, in whom symptoms have to be assessed independently from the disease stage and the cause that triggered them (disease and/or treatments). Indeed, 20 out of 67 enrolled patients (30%) were on adjuvant chemotherapy. The home care patients represented the advanced population to whom “palliative care” has been historically provided. Despite that, 50 out of 90 enrolled patients (48%) were on active disease-oriented treatment. In this study, the PERSONS score showed high reliability in each group of patients, with high correlations between PERSONS and ESAS, both at baseline and the final assessment. ROC curves revealed AUC of 0.825 and 0.805 for improvement and deterioration, respectively, and, thus, confirmed good diagnostic ability. Although it was not an objective of the current study, it is correct to note that there were no significant changes over time in total PERSONS scores contrary to what we observed before (Masel et al., 2016; Cortellini et al., 2018). However, there were also no significant changes in total ESAS scale scores, so the differences in the populations enrolled might have played a role. Moreover, in the palliative care setting, symptoms might not improve on a numeric level because of declining clinical conditions.

Conclusion

With this study, we can confirm that the PERSONS score is a good diagnostic tool for symptom assessment/monitoring. Our intention was to try to provide simple answers to complex questions; in our opinion, the PERSONS score could be that tool that not only “fits” for the patients, but also “fits” for the clinicians. We hope that other researchers want to test the PERSONS score in other settings, to improve the early integration of supportive care in oncological clinical practice.

Ethical statement

All patients provided informed consent to participate to this observational non-interventional study. The procedures followed were in accordance with the precepts of Good Clinical Practice and the Declaration of Helsinki. The study was conducted following the rules of the local bioethical committee competent on human experimentation (Comitato etico per le province di L’Aquila e Teramo). All authors declare no competing interests on the topic of the study. This was a spontaneous study, without sponsors nor a funding source.

Availability of data and materials

The datasets used during the present study are available from the corresponding author upon reasonable request.

Supplementary material. To view supplementary materials for this article, please visit <https://doi.org/10.1017/S1478951519000543>

Conflict of interest. The authors declare no competing interest.

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