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Structural validity and distress screening potential of the Hospital Anxiety and Depression Scale in cancer

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ABSTRACT. The Hospital Anxiety and Depression Scale (HADS) is one of the most widely instruments used to assess psychological distress in cancer patients. The main objectives of the study were i) to analyze, using Confirmatory Factor Analysis (CFA), the structure of the scale testing two models: the original bifactorial model and a hierarchical model -two scales and its combination- and ii) to determine, using Receiver Operating Characteristic (ROC) curve analyses, the optimal cutoff score on the HADS to identify clinically significant distress. A heterogeneous sample of 892 cancer patients completed the HADS and the 18 items version of the Brief Symptom Inventory (BSI-18). The CFA supported the use of the total HADS score (HADS-T) as a measure of general distress in cancer setting. The ROC curve analyses suggested the HADS-T as an effective tool to discriminate between oncology patients both with and without clinical distress (AUC=.95 [95% CI: .94-.97]). The cutoff scores on HADS-T between 13 and 16 -both include- had an adequate combination of sensitivity and specificity. Additional analysis indicated that HADS-T ≥16 was the optimal cutoff score.

KEYWORDS. Distress. Hospital Anxiety and Depression Scale. Screening. Cancer. Instrumental study.

RESUMEN. La Escala Hospitalaria de Ansiedad y Depresión (HADS) es uno de los instrumentos más utilizados para evaluar malestar psicológico (distrés) en pacientes con cáncer. Los objetivos principales de este estudio fueron: a) analizar, utilizando Análisis

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Factorial Confirmatorio (AFC), la estructura de la escala poniendo a prueba dos modelos: el modelo bifactorial original y un modelo jerárquico –dos escalas y su combinación–; y b) determinar, mediante curvas ROC (*Receiver Operating Characteristic*), el punto de corte óptimo del HADS para la identificación de distrés clínicamente significativo. Una muestra heterogénea de 892 pacientes oncológicos completó el HADS y la versión de 18 ítems del Inventario Breve de Síntomas (BSI-18). El AFC apoyó el uso de la puntuación total del HADS (HADS-T) como medida de la respuesta de distrés general en el contexto oncológico. El análisis de curvas ROC señaló al HADS-T como un instrumento eficaz para discriminar entre pacientes oncológicos con y sin presencia de distrés clínico (AUC = 0,95 [IC 95%: 0,94-0,97]). Puntos de corte en HADS-T entre 13 y 16 (ambos inclusive) presentaron una combinación adecuada de sensibilidad y especificidad. Un análisis adicional sugirió como punto de corte óptimo HADS-T $\geq$ 16.

PALABRAS CLAVE. Malestar emocional. Escala Hospitalaria de Ansiedad y Depresión. Cribado. Cáncer. Estudio instrumental.

Psychological distress in cancer is conceived as «a multi-determined unpleasant emotional experience of a psychological (cognitive, behavioural, emotional), social and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms and its treatment. This emotional response extends along a continuum, ranging from common normal feelings of vulnerability, sadness and fear to problems that become disabling, such as depression, anxiety, panic, social isolation, and spiritual crisis» (National Comprehensive Cancer Network [NCCN], 2012). Numerous studies have documented from 20 to 40% of oncology patients shown a significant level of distress across the trajectory of the illness –from the time of diagnosis to treatment, end of treatment, survivorship, or recurrence and palliation- (*e.g.*, Andreu *et al.,* 2012; Bardwell and Fiorentino, 2012; Carlson *et al.,* 2004; Zabora, Brintzenhofeszoc, Curbow, Hooker, and Plantadosi, 2001). In this sense, a recent meta-analysis indicates prevalence of any mood disorder in an average 38% (28%-49%) (Mitchell *et al.*, 2011). However, significant discrepancies between the needs for psychological assistance and the use of psychosocial resources are evident -less than 10% of patients are actually identified and referred for psychosocial help (Holland *et al.*, 2010).

Several international organizations (*e.g.*, International Psycho-Oncology Society [IPOS], 2009; NCCN, 2012; National Institute for Clinical Excellence [NICE], 2004) recommend the implementation of the routine screening programs for detecting and managing psychological distress in cancer population. The effectiveness of screening distress programs begins by the selection of an adequate screening tool in terms of brevity, easily scored and interpreted, and psychometric properties. In this sense, the validation of screening instruments which allow identify with accuracy those patients experiencing clinically significant levels becomes a primary aim in Psycho-Oncology research. In fact, in recent times, efforts to provide tools not only with good psychometric properties, but also brief and easily administered covering range from areas such as quality of life (Van Esch, Den Oudsten, and De Vries, 2011) to more specific topics as the problem of fatigue in cancer patients (De Vries, Van der Steeg, and Roukema, 2010).

The Hospital Anxiety and Depression Scale –HADS- (Zigmond and Snaith, 1983) is a 14-items questionnaire that detects anxiety and depression symptoms in medical setting. The scale is one of the most widely used instruments for screening psychological distress in cancer patients. Indeed, review studies about screening tools for psychological distress in this population found a large number of validation studies in which HADS had been used across disease types and stages of cancer as well as across languages and cultures (Mitchell, Meader, and Symonds, 2010; Vodermaier, Linden, and Siu, 2009). This extensive use is basically justified by two characteristics of HADS: On the one hand, its validation against structured or semi-structured clinical interviews for mental disorders –the «gold standard»-. In fact, the scale has been used even as benchmark measure to validate other screening tools. On the other, the characteristics of the HADS, that is, its briefness, its ease and speed to administer, score and interpret, the patient acceptability, and the lack of items related to somatic symptoms that could be considered as confounded physical symptoms in the context of cancer. Nevertheless, despite its widespread use in the oncology setting as a screening and research tool, two psychometric concerns remain controversial to date, namely, the factor structure of the scale and the cutoff score that would indicate serious or clinically significant levels of distress.

Regarding the dimensional structure of the HADS in oncology population, and leaving aside recently discussed factorial models derived from the tripartite theory of anxiety and depression of Clark and Watson (*e.g.,* Smith *et al.*, 2002), several factor solutions have been found and proposed from an empirical approach: the original bifactorial structure (Zigmond and Snaith, 1983), a single factor model (*e.g.,* Razavi, Delvaux, Farvacques, and Robaye, 1990), even, three and four factor models (*e.g.*, Brandberg, Bolund, Sigurdardottir, Sjoeden, and Sullivan, 1992; Lloyd-Williams, Friedman, and Rudd, 2001). The proposed two-factor model, corresponding to anxiety (HADS-A) and depression (HADS-D) scales, has been the most confirmed structure on research (for an overview see: Bjelland, Dahl, Haug, and Neckelman, 2002; Vodermaier *et al.*, 2009). However, several psychometric aspects such as the statistically significant correlation between two factors or indicators related to the factor analysis support the possibility of the use of HADS as a unitary measure. In this case, researches suggest the use of the total score of HADS -reproached in the HADS administration manual by original authors-, regardless of the use or not of the subscales, to assess general psychological distress (*e.g.*, Ibbotson, Maguire, Selby, Priestman, and Wallace, 1994; Singer *et al.*, 2008). In conclusion, the validity of the HADS in terms of factor structure -two scales, combined scales or both- is still inconclusive and requires further research.

Moreover, the second controversial issue around the HADS –the cutoff to detect serious or clinically significant levels of distress- is closely related to the assumed factorial structure. The original authors of the instrument proposed scores between 8 and 10 for «possible» cases, and scores of 11 or more for «probable» cases in both anxiety and depression scales. Subsequently, numerous studies have attempted to establish the threshold associated with the greatest sensitivity and specificity for detecting clinical cases of anxiety or depression symptoms (subscales scores), or general emotional distress (total score) (for an overview see Mitchell *et al.*, 2010). The results published to date differ widely, perhaps due to methodological differences

related to the design of the study (*e.g.*, sample characteristics, the statistical analyses used), or the researcher's subjective criteria to prioritize the sensitivity to the specificity. Several reviews and meta-analyses about the use of the HADS in cancer patients (Carey, Noble, Sanson-Fisher, and MacKenzie, 2012; Mitchell *et al*, 2010; Vodermaier and Millman, 2011) reflect this controversial topic. Accordingly, further solid evidence to help in the determination of the optimal thresholds for defining caseness using the HADS is needed.

In summary, the Hospital Anxiety and Depression scale is one of the most widely used screening instrument in cancer setting, while it has unresolved issues regarding the psychometric properties that might influence the effectiveness to detect psychological distress. The aims of the present instrumental study (Carretero-Dios and Pérez, 2007; Montero and León, 2007) were: a) determine whether the total score of Hospital Anxiety and Depression Scale can be used as a reliable measure of global psychological distress in a large heterogeneous sample of oncology patients; b) compare –using confirmatory factor analysis- two factorial structure of HADS, that is, the original bifactorial model and a hierarchical model (two scales and its combination); c) determine -using ROC curve analyses- the sensitivity and specificity of various HADS cut-off scores to detect clinical cases of global psychological distress; d) recommend an optimal HADS-T cut-off score for using in oncology population.

Method

Procedure and sample

Consecutive patients who visited the *Fundación Instituto Valenciano de Oncología* (FIVO) –Spanish Institute of Oncology– for any reason (diagnosis, treatment, follow-up), were approached between October 2010 and April 2012. Those that met eligible criteria: a) to be $\geq$18 years; b) to have a cancer diagnosis; and c) to be able to provide informed consent, were selected. After they received information of the study and provided informed consent, participants completed a questionnaire packet that included a demographic data form, HADS (Zigmond and Snaith, 1983), and the 18 items version of the Brief Symptom Inventory [BSI-18] (Derogatis, 2000). Of the 945 approached patients, 53 (approx. 6%) declined to participate in the study. The reasons for this include: not interested (45.3%), too tired (28.3%), too rushed (9.4%), and other (17.0%). Thus, final sample consisted of 892 oncology patients. Gender representation in the sample was 70% for women. Ages ranged from 24 and 93, with an average of 57 years (*SD*=13.3). The majority of the sample was married or living with a steady partner (72%), and had, at least, completed primary studies (85%). As for work status, 32% of the participants were retired, 30% were unemployed or on sick leave, 19% were housewives, and 17% worked outside of the home. Medicals characteristics of the sample are detailed in Table 1.

TABLE 1. Statistical descriptive of the medical variables (*N* = 892).

	N	%
Cancer type:		
Breast	380	42.60
Gynecological	151	16.90
Prostate	105	11.80
Melanoma	59	6.60
Gastro-intestinal	44	4.90
Respiratory	43	4.80
Urinary	41	4.60
Head and neck	29	3.30
Other	40	4.40
Stage of disease (*N*=842):		
0	20	2.20
I	202	22.60
II	257	28.80
III	177	19.80
IV	186	20.90
Phase of the illness process (*N*=880):		
Diagnosis	41	4.70
Treatment*	545	61.90
Follow-up	265	30.10
Survivor (>5 years)	29	3.30
Medical treatment*:		
Surgery	101	18.50
Chemotherapy (CT)	262	48.10
Radiotherapy (RT)	149	27.30
CT + RT	18	3.30
Other	15	2.80

Measures

Sociodemographic data (age, marital status, education level, employment status) were obtained through use of a general information form developed for the study. Medical and treatment data, such as cancer type, stage of disease, phase over the illness process and medical treatment at the moment of the study were obtained from the patient's medical history.

– Hospital Anxiety and Depression Scale (HADS). The HADS (Zigmond and Snaith, 1983) is a self-report scale specifically designed for assessing emotional distress in physically illness. It includes 14 items, half of which measure anxiety and the other half depression. Responses are made on a 4-point Likert scale. The HADS has been widely used in cancer population. For this study, the Spanish translation published by Caro and Ibáñez (1992) was used. This version has shown adequate indices of reliability and validity in different populations –normal, psychiatric and medical– (Caro and Ibáñez, 1992).

– Brief Symptom Inventory -18 (BSI-18). The BSI-18 (Derogatis, 2000) is a self-report measure of emotional distress. The 18-items are rated on a 5-point Likert scale. The instrument enables to obtain a total score which consists of the sum of the 18 items, and a score for each subscale of 6 items (*Anxiety, Depression*, and *Somatization*). For this study, the Spanish translation published by Derogatis (2000) was used. This version has shown adequate construct validity and reliability in previous studies with oncology population (Galdón *et al.*, 2008; Martínez, Andreu, Galdón, and Durá, in press). In the present study we only used the total score on BSI-18 as a measure of psychosocial distress which showed a satisfactory internal consistency (Cronbach's α = .91). In addition to continuous scoring, cutoff scores are recommended by the author of the instrument for "caseness" of distress. BSI-18 has been normed for use with cancer patients. Note that, based on the BSI-18 manual (Derogatis, 2000), subjects with a T-score of 63 or higher in general distress (PT) or at least in two of the BSI-18 dimensions are considered caseness.

Statistical analysis

Firstly, confirmatory factor analysis (CFA) was carried out using the EQS program. Two models derived from the empirical research were tested: (i) original model with two latent factors of the first-order level (anxiety and depression) defined according to the original established items of the instrument (Zigmond and Snaith, 1983), and (ii) a hierarchical three-factor model consisting of two original latent factors of the first-order level –the previous model- and an additional factor of the second-order level representing a combination of all items –global psychological distress (HADS-T). Maximum likelihood was employed to estimate the model since it has been reported (Hair, Anderson, Tatham, and Black, 1999) to perform reasonably well. The goodness of fit of the models to the data was evaluated using a number of robust statistics (acceptable criteria level in parenthesis): Root Mean Square Error of Approximation (RMSEA) [< .08; 90% confidence interval (CI)], Non-Normed Fit Index (NNFI) (> .90), Robust Comparative Fit Index (RCFI) (> .90), and Incremental Fit Index (IFI) (> .90). The criterion values used were in line with those proposed by Hu and Bentler (1999). Additionally, the Satorra–Bentler chi-square (S-Bχ^2) was considered; *P* values over .5 indicate a good fit between the observed and estimated matrix by the proposed model. This index divided by df (S-Bχ^2/df) –to correct the influence of the number of subjects- were also considered. S-Bχ^2/df <2 indicates a good fit (Hair *et al.*, 1999). Finally, the Akaike Information Criterion (AIC) was employed; this index adjusts χ^2 for the number of estimated parameters and can be used to compare competing models that do not need to be nested (Hu and Bentler, 1999). The higher is the value, the worse is the model fit. In the event of an unsatisfactory fit with the confirmed models, the significance of the different saturations, the existence of covariances between errors, and unexpected saturations according to the models submitted to a confirmatory analysis (crossloadings) are examined. In addition, reliability (internal consistency) of the HADS was calculated by Cronbach's α coefficient using SPSS (version 19.0).

Secondly, receiver operating characteristics (ROC) analyses were used with SPSS program (version 19.0) to explore an optimal cutoff score on the HADS as a measure

of emotional distress (HADS-T). The analysis generates a ROC curve, a graphic representation of the trade-off between the sensitivity (true positive rate) and specificity (true negative rate) for every possible cutoff score on the HADS-T. Area under the curve (AUC) is a statistic that provides an estimate of the overall discriminative accuracy of the HADS-T relative to the established BSI-18 cutoff score for identifying clinically significant distress (criterion). AUC values vary from 0 to 1, with values > .75 reflecting good discrimination, and values > .90 reflecting excellent discrimination (Franco and Vivo, 2007). Furthermore, ROC analysis provides a broad range of possible cutoff associated with specificity and sensitivity values. There is no standard way to determine the optimal cutoff point. However, two criteria were considered for the selection of one of them. Firstly, values close to or greater than .80 in sensitivity and specificity were considered (Domenech, 2004). Secondly, a criterion that took into account the prevalence of distress, that is, the accuracy index -a combination of sensitivity and specificity weighted prevalence and its complement, respectively- (Franco and Vivo, 2007).

Results

Structural validity

A CFA of the structure was performed, testing two models: the Zigmond and Snaith's original two-factor model and the hierarchical three-factor model -anxiety and depression subscales and the total scale. Two factor models tested and accompanying fit indices are shown in Table 2. An examination of fit indices for each model revealed that both models indicate appropriate and similar values in RCFI, NNFI, IFI (higher than .90 in all cases) and RMSEA (lower than .08); S-Bχ^2/df was 2.36 in the three-factor model compared with 3.07 in two-factor model. The indexes of the first model were slightly better. At last, the AIC model comparison showed that the three-factor model could be considered the best fitting model (AIC_{3D} = 27.23 vs. AIC_{2D} = 85.10). Hence, taking into account all fit indices, it is possible to conclude that the hierarchical three-factor model performs better than the two-factor model. The hierarchical three-factor model is presented in Figure 1, where the items factor loadings at the first-order factor, as well as the second-order factor, and error variances are shown.

TABLE 2. Indexes yielded by confirmatory factor analysis of each model (N = 892).

Model	*RMSEA (90% CI)*	*RCFI*	*IFI*	*Robust NNFI*	*S-Bχ^2*	*Df*	*S-Bχ^2/df*	*AIC*
Null	-	-	-	-	3054.23	91	-	-
Original 2D	.05(.04-.06)	.96	.95	.94	243.10**	79	3.07	85.10
Hierarchical 3D	.04 (.03-.05)	.97	.97	.96	177.23*	75	2.36	27.23

Note. RMSEA = Robust Root mean-square error of approximation; RCFI = Robust comparative fit index; IFI = Incremental Fit Index; NNFI = Bentler-Bonett non-normed fit index; S-Bχ^2 = Satorra-Bentler chi-square; Df = degree of freedom; AIC = Akaike Information Criterion.
*$p \leq .05$. ** $p \leq .01$.

FIGURE 1. Structural model of the HADS.

Reliability

Cronbach's alpha of the HADS subscales (anxiety and depression) was .83 in both cases, and somewhat higher (α = .89) in the total scale (psychological distress).

Identification of the HADS-T cutoff score

In the ROC analysis (Figure 2), AUC was .95 (95% CI: .94-.97) indicating that the total HADS score had an excellent diagnostic utility relative to the BSI-18. An interval of cutoff scores -between 13 to 16- highlighted about the rest, due to optimal levels ($\geq$ .80) in sensitivity and specificity at the same time. Table 3 presents indices of sensitivity, specificity, accuracy index and prevalence of a selected range of cutoff scores of HADS-T.

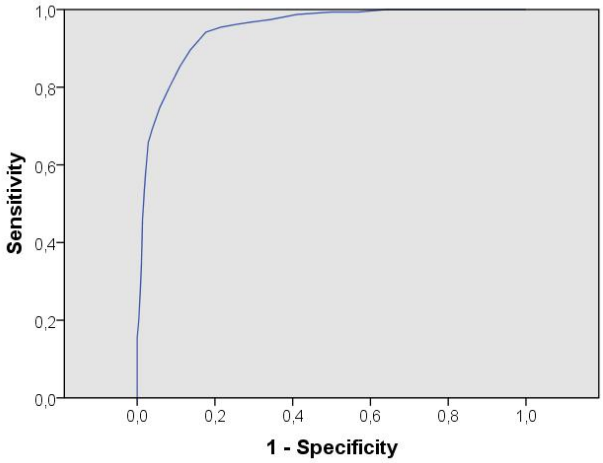

FIGURE 2. ROC curve analysis comparing HADS-T scores to established BSI-18 cutoff score.

TABLE 3. Sensitivity, specificity, accuracy index (AC), and prevalence of HADS-T as a screening tool of distress.

cutoff HADS-T scores	*sensitivity*	*specificity*	*AC*	*Prevalence (%)*
≥ 10	.97	.71	.76	41.30
≥ 11	.96	.75	.79	37.70
≥ 12	.96	.79	.82	34.60
≥ 13	.94	.83	.85	31.20
≥ 14	.90	.87	.87	27.10
≥ 15	.85	.90	.89	24.00
≥ 16	.80	.92	.90	21.00
≥ 17	.75	.95	.91	18.00

Discussion

Currently, the importance of screening for psychological distress –the 6th vital sign- is a major issue for Psycho-oncology (Bultz and Johansen, 2011). In fact, its incorporation as a standard in the guidelines for the psychosocial care in oncology is increasingly common (*e.g.*, IPOS, 2009). Related to this, the selection of an adequate tool to assess the psychological distress in terms of brevity, ease to administer, score and interpret, and certainly, suitability of the psychometric characteristics is key because the effectiveness of the screening programs could be compromise. One of the most frequently used instrument as measure of psychological distress in oncology setting is the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983). However, to date two important questions related to the validity of the scale remain still unresolved, that is, the factorial structure and the optimal cutoff score to detect caseness. Present study is a contribution to these relevant issues.

Using a large sample, we studied the structural component of the HADS testing two models: a) the original structure proposed by Zigmond and Snaith (1983) in which anxiety and depression are two independent dimensions and b) a hierarchical three-factor structure in which two previous factors can be grouped into a superior dimension understood as psychological distress. The confirmatory factor analysis (CFA) revealed that both models fitted well to the data. However, the considered fit indices -slightly higher in the hierarchical model-, and especially, the AIC -better again in this model-, underlined the hierarchical three-factor solution as the most appropriate structure to use in oncology population. Therefore, the results of CFA underline specifically the obtainment of an overall score as a dimension of psychological distress and allow, at the same time, the distinction between symptoms of anxiety and depression –defended by the original authors of the instrument-. In addition CFA, and in line with other studies (Bjelland *et al.*, 2002), the high correlation between HADS subscales (r = .77; p = .000), and the satisfactory levels of internal consistency of the total scale (α = .89) also favored the use of the second order dimension of HADS.

In the other hand and regarding to the accuracy of HADS as a screening tool for distress, the results of the present study indicated that the total score of HADS presented an adequate diagnostic utility. In fact, the area under the ROC curve was close to 1.00, indicating good overall performance relative to the BSI-18. Regarding to the sensitivity - the proportion of correctly identified casesness- and the specificity - the proportion of correctly identified non-casesness-, a range of cutoff scores (between 13 and 16 both included) underlined over the rest due to satisfactory levels ($\geq$ .80) obtained in both indicators. The AC index was the second criterion that guided the decision making to select the optimal cutoff point. The AC which combines sensitivity and specificity and also considers the prevalence, showed that a HADS total score $\geq$ 16 offers the highest accuracy to detect significant levels of distress. Concretely, the likelihood -using the cutoff point $\geq$ 16- that the HADS will correctly identify patients with clinical distress and patients with non clinical distress according to the BSI-18 was a 90%. Thus, HADS-T score $\geq$ 16 was the optimal combination of sensitivity (80%) and specificity (92%), offering the fewest number of the false-positive cases (6.5%) and indicating a prevalence of distress close to 18% obtained with the criterion (BSI-18).

In conclusion, findings obtained in the present study provide evidence for the use of the total score of HADS to detect psychological distress in oncology population. The hierarchical model of the HADS has obtained a rigorous methodological support and may be more usefully than the original bifactorial model in screening programs of psychological distress, since it allows a total score. According to our results, we recommend the HADS-T score $\geq$ 16 as the optimal cutoff point for distress caseness due its good demonstrated accuracy. However, other proposed cutoff points ranging between 13 and 16 could also be used due to the adequate levels of sensitivity and specificity associated. In fact, the choice of a particular cutoff point depends on the user's requirements for sensitivity and specificity. Note that decreasing the cut-off to improve sensitivity will reduce the specificity, so there will be more false positives.

Finally, there are several limitations that should be noted. First, there was limited diversity to the studied sample with regard to the specific types of cancer that would

affect the generalizability of findings. Second, the use of a self-report scale (BSI-18) as criterion. A preferable design would have included a semi-structured or structured diagnostic interview against which to validate the HADS. However, although interview methods are the gold standard, a recent meta-analysis (Mitchell *et al.*, 2011) found that the prevalence of any mood complication measured by interview was close to that measured by self-report. Future research should explore the psychometric properties of HADS taking into account previous aspects. On the other hand, the main strengths of the present study, comparing to the prior researches, were the large sample data -892 oncology patients- and the methodological approach used -CFA and ROC curve analyses-.

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