Brief Methodological Report

Validity and Reliability of the Decision Regret Scale in Cancer Patients Receiving Adjuvant Chemotherapy

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Abstract

Objectives. Decisional regret is an indicator of satisfaction with the treatment decision and can help to identify those patients who need more support and evaluate the efficacy of decision support interventions. The objectives of this study are, 1) to evaluate the psychometric properties of the Decision Regret Scale and 2) to analyze the moderating effect of psychological distress on functional status and regret in patients with cancer following adjuvancy.

Methods. A prospective, multicenter cohort of 403 patients who completed the Decision Regret Scale (DRS), Health-Related Quality of Life (EORTC QLQ-C30), and Brief Symptom Inventory (BSI). The evaluation was conducted six months after receiving adjuvant treatment in patients with resected cancer.

Results. After treatment, most participants (51.9%) experienced no decision regret; 33.7% felt mild regret, and 14.4% exhibited high levels of regret. The Spanish version of the DRS demonstrated satisfactory properties: it had a strong, clear unidimensional factorial structure with substantial loadings. Decisional regret was related with lower scores on functional, symptom, and quality of life scales, and higher levels of psychological distress (all $P = 0.001$). Psychological distress was found to have a moderating effect on the relationship between functional state and decision regret.

Conclusions. The Spanish version of the DRS is a reliable, valid tool to evaluate regret and post-decisional quality in clinical practice and further highlights the potential clinical implications of psychological distress for the relation between physical status and regret.   J Pain Symptom Manage 2019;57:828−834. © 2018 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.

Introduction

Decision-making as to the advisability of receiving or rejecting adjuvant chemotherapy that seeks to lessen the risk of recurrence after tumor resection is complex for patients with cancer.[1] Medical oncologists provide their patients with information about the risks and benefits of chemotherapy to facilitate an informed decision.[2]

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Accepted for publication: November 18, 2018.

Regret is a negative emotional reaction resulting from the untoward effects of a given choice. Evaluating regret in medical decision-making is uncommon, given the lack of reliable, valid measures. Although a systematic review of regret measures yielded 10 instruments,[3] only three were applicable to decision-making in the context of medical care: *Regret Scale*[4] that appraises regret in men with prostate cancer; *Anticipatory Regret Questionnaire*[5] that captures a sense of regret in the future about donating blood, and *Decision Regret Scale (DRS)*[6] that gauges regret in patients who have already made a medical decision.[6]

Regret has been correlated with low degrees of satisfaction with preoperative information, depression, anxiety, and stress[7]; with negative body image and psychological distress[8] in patients with breast cancer; and with impaired quality of life (QoL) in patients with prostate cancer.[9] The psychological factors involved in regret include perception of health and psychological distress, both of which are common in individuals with cancer beginning adjuvant treatment.[10] With this background, this study seeks to analyze the psychometric properties of DRS in patients with resected cancer treated with adjuvant chemotherapy and to examine the moderating effect of psychological distress between functional status and regret.

Methods

Research Design and Study Population

A multi-institutional, prospective, observational research design was used to examine the incidence of decision regret with respect to adjuvant therapy and evaluate the psychometrics of DRS. Within this design, DRS data were collected at a single time point (see below); consequently, all analyses performed in this study are cross-sectional. The study pooled consecutive patients recruited at 14 teaching hospitals in Spain from June 2015 to December 2017 and was approved by the Ethics Review Board at each institution and by the Spanish Agency of Medicines and Medical Devices (AEMPS). STROBE guidelines were used to ensure the reporting of this study (Additional file 1).[11] Inclusion criteria were as follows: aged >18 years; have a histologically confirmed, nonadvanced, resected solid tumor; and be eligible for adjuvant treatment.

Sample Characteristics

A total of 403 patients with cancer (55.3% women and 44.7% men) completed the assessment 6 months after receiving adjuvant chemotherapy. Mean age was 58.4 years (range 25−84); most were married or partnered (79.4%), unemployed (58.8%), and had attained a primary level of education (61%). The most common tumor sites were colon (43.9%) and breast (31%), stages I-II (53.6%). All received chemotherapy, and 30.8% received associated radiotherapy.

DRS Adaptation. The DRS was first developed in English.[6] It was adapted to Spanish by forward-backward translation[12] of the English version by two independent bilingual translators; both of whom are native Spanish speakers and fluent in English. The two Spanish versions were translated back into English by a professional translator with experience in medical translation and by two medical doctors who had not been involved in the forward translation. Another two bilingual translators blind to the original English version back-translated the revised Spanish version; finally, the study directors compared and synthesized the back-translation with the original questionnaire, culminating in a final Spanish version of the DRS.

Data Collection

Data collection was similar for all hospitals. Following a full explanation of study objectives and procedures, candidates were invited to participate and complete the questionnaire at home. Study participation was voluntary and anonymous. Participants completed the questionnaires individually, with no time limit. This visit was structured according to standard practice at each center, although it was agreed that as a minimum, risk of relapse, options for adjuvant treatment, risk of adverse effects, and possible treatment efficacy should be discussed with the patients. Flow chart comprising inclusion and exclusion criteria of participants is given in Figure 1.

Decision Regret Scale. The DRS is a five-item, self-report scale to evaluate decisional regret. Items are scored on five-point Likert scales, ranging from 1 to 5. Scores were reversed for items 2 and 4; mean scores were obtained and then converted by subtracting 1 and multiplying by 25. Scores range from 0 to 100, with higher scores indicating greater regret. Internal consistency reliability estimates (α) range from 0.81 to 0.92 for oncology patients.[6]

Health-Related Quality of Life. The EORTC QLQ-C30 (V.3.0) is a cancer-specific measure of health-related QoL.[13] It consists of 30 items that assess QoL with respect to functional scales and a global QoL scale.[14] All scale scores are linearly transformed to a 0−100 scale. Higher scores represent a higher level of functioning or QoL and more symptom burden. Cronbach's alpha estimates range from 0.74 to 0.88.[13]

Brief Symptom Inventory-18. The BSI-18[15] is a self-report inventory designed to evaluate psychological distress, using a five-point scale from 0 to 4. Raw scores
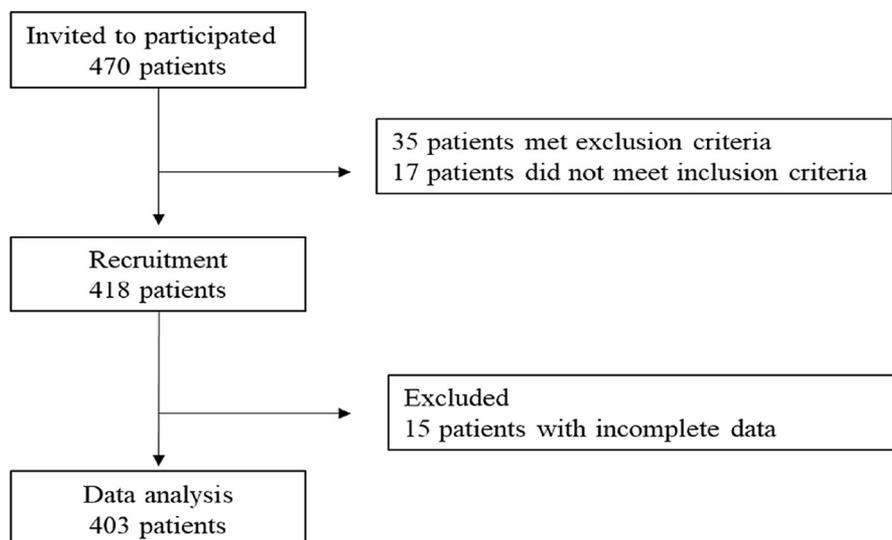
Fig. 1. Participant's flow chart.

are converted to T-scores based on gender-specific normative data. Higher scores indicate greater psychological distress.[15] Cronbach's alpha estimates range from 0.72 to 0.84.[16]

Data Analysis

The internal psychometric properties of the DRS were examined using a three-stage series of analyses. First, basic item descriptive statistics were explored. Second, a confirmatory factor analysis (CFA) was performed to study the scale's expected unidimensionality, as well as the pattern of item-trait relations. Third, provided that the DRS behaved as essentially unidimensional, the reliability of its scores was scrutinized. The unidimensional CFA solution in step 2 above was fitted using robust weighted least squares estimation with mean and variance corrected fit statistics as implemented in the Mplus program.[17] Model fit and appropriateness were assessed with three groups of measures. First, model residuals and relative fit were evaluated with standardized root mean square residual (SRMSR) and root mean squared error of approximation (RMSEA) statistics. Second, relative comparative fit was examined with the comparative fit index (CFI) (as a relative measure of fit with respect to the null independence model). Finally, additional indices of appropriateness were also obtained to verify the strength and replicability of the solution (h-index), as well as closeness to unidimensionality (explained common variance index)[18] with the FACTOR software program.[19] As for reference values, CFI values $\geq$ 0.95 are indicative of good model fit,[20] whereas SRMSR values $\leq$ 0.08 and RMSEA values $\leq$ 0.06 are considered satisfactory fitting models.[21,22] Finally, once the proposed structure had been fitted and found suitable, DRS score reliability

was assessed using the omega coefficient.[23] Validity analysis involved two stages. First, the product-moment correlations between DRS scores and EORTC scores, BSI scores, and toxicity degree were obtained. Second, multiple linear regression was used to examine the potential moderating effects between QoL and psychological distress on decision regret. Validity analyses were conducted using IBM-SPSS 23.0 statistical software package (SPSS, INC., Chicago, III) for Windows.

Results

Descriptive Analyses

The mean DRS score was 10.6 (SD = 15.4). Most participants (51.9%, n = 209) experienced no decision regret. Degrees of decisional regret were not significantly influenced by gender [$F_{(1,401)}$ = 0.503, P = 0.478], age [$\leq$60 years vs >60 years; $F_{(1,401)}$ = 1.310, P = 0.253], or education [primary level vs $\geq$high school; $F_{(1,401)}$ = 0.133, P = 0.716]. Likewise, decisional regret was not significantly affected by treatment [chemotherapy vs chemotherapy and radiotherapy; $F_{(1,401)}$ = 1.203, P = 0.273].

DRS item score distributions were unimodal and asymmetrical (positively skewed). Item-total correlations were all >0.40. Provided that the scale behaves unidimensionally, this result indicates that the items have adequate discriminating power and are strongly related to the construct they measure (Table 1).

Confirmatory Factor Analysis

Given 1) the ordered-categorical nature of the response variables, 2) the skewed item distributions, and 3) the relatively high item discriminating power, we opted to use the underlying-variables approach

Item Descriptive Statistics of the Spanish DRS (*n* = 403)

Questions	Mean (SD)	Skews	R$_{\text{item-total}}$
It was the right decision	1.22 (0.57)	2.7 (.1)	0.62
I regret the choice	1.65 (1.33)	1.8 (.1)	0.59
I would make the same choice if I had to do it over again	1.28 (0.76)	3.4 (.1)	0.61
The choice did me a lot of harm	1.73 (1.23)	1.6 (.1)	0.60
The decision was a wise one	1.26 (0.55)	2.8 (.1)	0.62

DRS = Decision Regret Scale; SD = standard deviation.
Score ranges from 1 (*strongly agree*) to 5 (*strongly disagree*). In brackets, the standard error for the skew statistics. R $_{\text{item-total}}$ = item-total corrected correlation.

and fit the factor analysis model to the inter-item polychoric correlation matrix.[24] The initial fit of the unidimensional model was unacceptable by all standards. Inspection of the results, however, clearly revealed that the sole source of misfit was the correlated residual between items 2 and 4. This result, confirmed by cross-validation, is to be expected because 1) these are the two reverse-keyed items (i.e., a method effect) and 2) they share specific content. After freeing the residual covariance, an almost perfect fit was obtained: SRMSR = 0.01; RMSEA = 0.0; and CFI = 1. The remaining indices of appropriateness were also relatively acceptable. The explained common variance value was 0.81, indicating that the solution could indeed be considered essentially unidimensional, whereas the h-index was 0.91, suggesting that the solution was both robust and replicable.[25] Note that all loadings are well above their corresponding standard error, and those of items 1, 3, and 5 are particularly high. This result is consistent with the substantial item-total correlations found previously and suggests that the DRS items are strongly related to the construct they measure. The omega reliability estimate for the raw scores was 0.87, which is remarkably high, given the limited number of items.

Validity Analyses

After treatment, higher levels of decisional regret correlated significantly with lower scores on the functional (*r* = −0.316, *P* = 0.001) and global QoL (*r* = −0.257, *P* = 0.001) subscales. Higher levels of decisional regret, however, correlated significantly with higher symptom (*r* = 0.278, *P* = 0.001) and psychological distress (*r* = 0.297, *P* = 0.001) scores. Of the four interactions tested, one was significant—the moderational effect of psychological distress on the relationship between functional status and regret (*B* = −.015, 95% CI [0.02, 0.05], β = −.96, *t* = 2.87, *P* = 0.004). The analysis indicated that 12.2% of the variation in regret was explained by functional status and the interaction effects between functional status and psychological distress [$F_{(3,397)}$ = 19.51, *P* < 0.001] (see Table 2 and Fig. 2) Thus, when functional status is high, there are minimal differences in regret experienced by both patients suffering from high and those with low levels of psychological distress.

Given the positively skewed distribution (i.e., floor effects) of DRS scores, as well as measurement error in the reported measures, the validity results discussed thus far are likely to be somewhat attenuated. Therefore, these results can be better considered as lower limits, and the latent relations between the constructs of interest (decisional regret, psychological distress …) are likely to be stronger than the product-moment correlations and proportions of shared variance based on what the "proxy" measures suggest.

Discussion

This study presents important findings. First, few patients with cancer (14.4%) regret having undergone adjuvant treatment after surgery for a nonmetastatic tumor despite its side effects. Our results are consistent with previous studies that have evaluated decision regret in oncology patients and suggest that most patients are satisfied with their treatment and present low levels of decisional regret.[8,9,26] Studies using the DRS to assess decision regret found that 19.5% of

Moderational Effects Between QoL Scales and Psychological Distress on Decision Regret: Multiple Linear Regression Analyses Summary

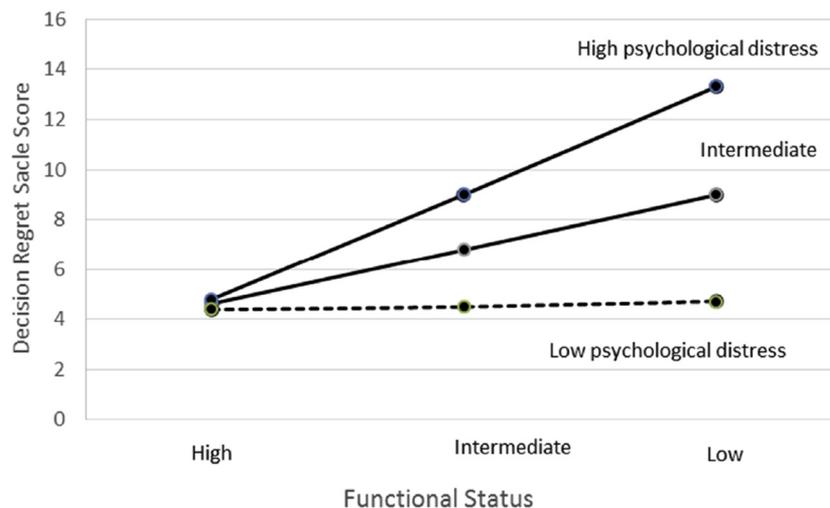| Model	Unstandardized coefficients		Standardized coefficient		
	B	Std. Error	β	*t*	*P*
1					
(Constant)	2.187	12.987		0.168	0.866
Functional status	−0.166	0.055	−0.205	−3.019	0.003
PD	0.332	0.148	0.153	2.243	0.025
2					
(Constant)	−79.959	31.343		−2.551	0.011
Functional status	0.852	0.358	1.056	2.379	0.018
PD	1.485	0.427	0.682	3.477	0.001
Functional*PD	−0.015	0.005	−0.964	−2.874	0.004

PD = psychological distress.

Fig. 2. Moderational effect of psychological distress between perception of functional status and experiencing regret.

women with breast cancer regretted reconstruction after mastectomy[8] and only 4% of men with prostate cancer regretted their decision one year after surgery.

As for internal psychometrics, the Spanish version of the DRS displayed good properties. It had a clear, strong unidimensional factorial structure with substantial loadings and the scores derived from it demonstrated acceptable reliability even for individual assessment. These results are remarkable, taking into account that they were obtained with only five items. Despite these good properties, however, there is still room for further improvement. The two negatively keyed items had weaker discriminating power than the remaining ones and shared residual variance that had to be accounted for in the model to achieve an acceptable level of fit. One hypothesis is that participants (Spanish patients) confuse the wording of these items and follow the pattern of response for positively worded statements.[25] Other researchers have suggested that the inclusion of the reverse-worded items increases the risk of inattention and confusion.[27,28] Replacing negatively worded items with alternative items to measure decision regret would help eliminate error and improve the scale's variance.

As regards external validity, convergent validity was acceptable and a pattern of significant correlations with health outcomes was observed in the expected direction. This is particularly relevant because adjuvant chemotherapy is the treatment of choice after surgery for certain locally advanced cancers, such as breast and colon cancer, and treatment tends to have immediate, negative repercussions for patients' physical status, symptomatology, and global QoL,[29] although their adverse effects are usually temporary.[29] Our results indicate that the patients most likely to regret treatment are those with worse QoL, including physical status, presence of symptoms, and greater psychological distress. Other authors found that regret was

greater in patients with heart disease with worse perceived physical health,[30] and regret was associated with depression, anxiety, and stress in women with breast cancer.[31] We did not find differences in regret by gender, age, educational level, or type of treatment. It must be remembered that in medical contexts, patients tend to provide socially acceptable responses on questionnaires that rate their attitude toward the quality of care and treatment received.[7] We have attempted to avoid this problem by guaranteeing participants' anonymity.

The moderating role of psychological distress provides a more complete view of the relation between physical status and regret. Thus, when physical status is adequate, no significant differences are seen among patients with cancer with respect to regret, whatever their level of psychological distress. In contrast, when health is perceived as poor, those patients with high levels of psychological distress report significantly higher degrees of decisional regret. These findings correlate in part with the monitoring process model,[32] according to which a person's perception of their own health impacts how they confront and respond to it. To the best of our knowledge, there are no other studies that analyze the moderating role of psychological distress between physical status and decision regret in oncology patients. In future studies, it would be interesting to ascertain if this regret is reversible; that is, whether decision regret decreases if/when patients' physical and/or psychological status improves.

This study has a series of **limitations**. First, the sample is heterogenous, to enable subgroup analyses to be performed based on tumor site. Second, because the study was designed to include a single evaluation of regret, information about causality cannot be examined, nor can we offer a possible explanation as to how regret evolves over time. Third, it may be that the results of our study cannot be extrapolated to

patients with advanced tumors, whose clinical situation and prognosis differ markedly. Finally, we must be cautious when interpreting these results, bearing in mind that all the patients eligible to participate did so voluntarily, which may have introduced a self-selection bias. Likewise, a limitation of clinical significance is the absence of appropriately matched comparison samples of patients to assess regret regarding their decision not to proceed with chemotherapy. Future research is required to explore the contribution of other psychological factors that may influence decision regret, for example, outcome expectations and fear of recurrence.

Conclusions

The results of this study indicate that the Spanish version of the DRS exhibits satisfactory psychometric properties, with a clear and strong unidimensional factorial structure and acceptable reliability and validity. The moderating effect of psychological distress in the relation between physical status and regret tells us that the effect of physical status on regret is more accentuated if patients display greater psychological distress. This result points to the need to perform individualized interventions that promote improvement of physical status following chemotherapy. In general, after completing adjuvant treatment, there are fewer visits to the oncologist. However, some individuals, due to their deteriorated physical and psychological condition as a result of residual toxicity of chemotherapy, will require more frequent visits to help them improve their status, boost recovery, and lessen the likelihood of postchemotherapy rejection. Maintaining a certain level of psychological well-being will likely benefit patients in their recovery.

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