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A Psychometric Validation of the Decisional Conflict Scale in Italian Cancer Patients Scheduled for Insertion of Central Venous Access Devices

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Abstract. *Background/Aim: In oncological settings, high-quality decision-making takes place when an adaptive pattern of cognitive and behavioural processes occurs, potentially limiting post-decisional regret and leading to an increment of adherence to the final decision. An example of a choice that requires a patient's involvement in the decision-making during cancer treatment occurs when the insertion of Central Vascular Access Device (CVAD) is proposed for chemotherapy administration. The aim of the current study was to develop and evaluate the psychometric properties of an Italian version of the Decisional Conflict Scale (DCS), including its factorial structure and its accuracy in discriminating the level of uncertainty in a sample of cancer patients during their decision-making process for the insertion of a CVAD for intravenous (IV) chemotherapy administration. Materials and Methods: The study included 264 cancer patients with different diagnoses. To test the structural and psychometric properties of the Italian version of the DCS (DCS-ITA), exploratory factorial analysis was conducted followed by traditional classical test theory assessments of internal reliability and criterion validity. Results: The Italian version of the DCS (DCS-ITA) demonstrated good internal consistency, acceptable construct validity, which was tested with exploratory factorial analysis, and good criterion validity, demonstrated by the ability of the scale to differentiate between patients who declared themselves certain about their choice and patients expressing uncertainty about the choice to make. Conclusion: Overall, the results of the study showed that the DCS-ITA is a psychometrically sound instrument that easily discriminates between patients who are experiencing a decisional conflict and those who are not. The DCS-ITA can be used as a valid and easy-to-use tool for the screening of the decisional conflict in oncological settings.*

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Cancer is the most frequent cause of death in Italy, after cardiovascular diseases (1). Along the trajectory of cancer care, there are numerous circumstances in which patients have to make decisions. Moreover, the process of decision making is currently in a transition from a paternalistic model of decision making managed by the doctors (2) to a shared decision-making model with information and decision-making shared by the patient and healthcare providers (3, 4). The decision-making process, however, is a stressful process (5-8), that needs support and understanding between the physician and the patient. Decision making is defined as the choice between different available options. Therefore, high-quality decision-making occurs when the patient is capable of enacting an adaptive cognitive and behavioural pattern (9), potentially limiting post-decisional regret and complying with the decision made (10).

In cancer treatment, an example of a choice that requires a patient's involvement in the decision-making is when the insertion of a central vascular access device (CVAD) is proposed to a patient for chemotherapy administration. In fact,

even if antineoplastic medication should be preferably administrated through a CVAD from a medical standpoint, the choice of catheterization needs to be discussed and shared with the patient (11) based on its therapeutic efficacy, but more importantly based on the need for patient's care and maintenance of the port (12). The CVAD requires the patient to learn specific regimes in the home-based management of the device. Therefore, the implementation of a CVAD requires clear written and spoken information regarding among other things the risks, benefits, and need for patient care of the catheter; thus, this decision needs the active involvement of the patient in the decision-making process (13, 14). A delay in the insertion of a CVAD could expose patients to the risk of extravasations, infiltration and depletion of the venous assets, phlebitis, tissue damage and progressive loss of availability to access the peripheral veins, especially when irritant or cauterising chemotherapeutics are being administrated (12, 15-18). However, professionals often are not inclined to involve patients in the decision-making process and do not consider their choices when selecting the type of CVADs (19).

The complexity of choices especially where the risk is high, in addition to an overload of information, can overwhelm patients who are facing difficult decisions (3, 20). The patients need to balance risks and benefits, advantages, and disadvantages of the choice to be made, sometimes influenced by a high level of uncertainty (21-23). Some initial studies have shown that a number of cancer patients are uncertain about the choice, thus faltering in the selection of treatment options on their own (23-29). In this respect, O'Connor defines decisional conflict as "a state of uncertainty about the course of action to be taken" (21, 22, 30). There are several factors that contribute to patients' decision-making conflict, such as the lack of support, poor knowledge, unrealistic expectations, lack of clarity regarding values and preferences, perceived barriers, the lack of personal resources to make decisions and carry them out to completion and the reduced perception of self-efficacy (31-33).

Understanding of decision-making conflict has been framed within a broader paradigm: the Ottawa Decision Support Framework (ODSF). The ODSF is based on the health belief model (HBM) (34), the theory of planned behavior (35), socio-cognitive theory (SCT) (36), and decisional conflict model (21). The ODSF takes into account the association between needs of the person involved in a decision-making process, the quality of the choice and the support received. For example, in the ODSF model as it relates to health and illness, the needs of the person may reflect uncertainty about treatment choices that the person confronts in the context of an illness like cancer. In order to evaluate the decisional conflict in the context of the ODSF, several instruments have been proposed and tested. In particular, among the instruments that are consistent with the OSDF model, the decision conflict scale (DCS) has demonstrated reliability and validity in different settings and cultures (22, 30). The DCS is a tool that evaluates the degree of decisional conflict experienced by patients who are making decisions, especially in healthcare contexts (22). DCS is composed of 16 items with a five-point Likert scale (0 "strongly agree" to 4 "strongly disagree"); the total score ranges from 0 to 100 (where 0 corresponds to extremely high decisional conflict).

The items, in the original version represent three factors: the first, labelled as "Uncertainty" is composed of three items that evaluate the level of uncertainty a patient perceives related to a specific healthcare decision (*e.g.*, "This decision is hard for me to make"). The second factor, labelled as "Factors Contributing to Uncertainty," contains nine items (*e.g.*, "I need more advice and information about the choices") that refer to how much particular variables (informative, values, and emotional distress) contribute to uncertainty. The last factor, "Perceived Efficacy Decision Making," is composed of three items that measure the patient's perception about the decision in terms of its effectiveness and whether it is information-based, and consistent with personal values.

The internal consistency coefficients of the three factors, in their original validation, ranged from 0.78 to 0.89 and test-retest reliability indices were higher than 0.80 on every factor. In a later version of the DCS, the subscale "Factors Contributing to Uncertainty" was split into three subscales, composed of three items each and labelled, "Informed", "Values Clarity", and "Support" (30). In its first validation study of the newer version, the authors reported a test-retest coefficient of 0.81 and internal reliability coefficients of 0.58 to 0.92 (22).

A recent review of the literature (37) identified 375 unique studies that used DCS for research or clinical purposes over the initial 20 years from the creation of the scale (1995-2015). Some of those studies included translation and psychometric evaluation of the DCS in several countries (38-43) that showed good internal consistency, but posed issues in terms of construct validity. For example, a psychometric testing of the DCS scale has been conducted in Dutch on cancer patients by Koedoot and colleagues in 2001 (38). In this validation study, the authors found a four-factor model, which is different from the original scale. Specifically, they initially used a confirmative factorial analysis (CFA) to test the original three-factors structure, which demonstrated a poor fit of the data. Subsequently, they computed an exploratory factorial analysis (EFA) with a principal component analysis method to further investigate the structure of the DCS. When comparing the Dutch model in relation to the revised five-factor model (30), their optimal solution did not differentiate between the subscales of "Factors Contributing to Uncertainty" and "Support", while, at the same time, the factor "Perceived Effective Decision

Making" was confirmed as in the original scale with the exception that one item did not reach a factor loading of 0.30 in any of the four identified factors. Along those lines, in 2006 Mancini and colleagues (39) published a psychometric assessment of the DCS based on a French sample of 644 cancer patients. Results of the EFA showed a four-factor model in which "Informed" and "Support" subscales combined into a single factor as well as some items loading on different factors with respect to the original model.

In another test of the DCS, Urrutia and colleagues in 2008 (40) used in the original version on a Spanish sample of college students. Their validation study confirmed the original factor structure of the scale. However, Katapodi and colleagues in 2011 (44) tested the factorial structure of the original scale on a sample of 342 women in the US who were deciding about the genetic testing for breast cancer risk. The authors reported a three-factor model (Lack of Knowledge about the Decision; Lack of Autonomy in Decision Making; Lack of Confidence in Decision Making), which were different factors than those found in the original three-factor model of the scale described by O'Connor in 1995 (22). Similarly, Lam and colleagues in 2012 (42) evaluated the construct validity of the DCS in a sample of 421 breast cancer patients. EFA identified a three-factor model: Informed and Values Clarity", "Uncertainty and Effective Decision Making", and "Support. However, results failed to differentiate the different subscales with some items loading on more than one factor.

In a slightly different approach, Kawaguchi and colleagues in 2013 (41) validated the DCS in a study involving 94 Japanese cancer patients, using cluster analysis. As with other studies their results yielded a five factors model with a different set of factors than the original scale, even with some similarities. Finally, Kim *et al*., (46) 2017, evaluated the psychometric properties of the DCS in a Korean sample of 273 elderly persons. An EFA yielded a two-factor model, which they labelled "Informed/Values Clarity Subscales" (Factor 1) and the rest of the items loading on the "Uncertainty" subscale (Factor 2).

In summary, there appears to be variation in the factor structure across a number of studies, which may be a function of different cultures, different medical diagnoses, different demographics or the combination of these variables. Whereas the utility of the DCS is exemplified by its use for choices of treatment, for example regarding hormone replacement therapy (47), end of life palliative care (43), genetic testing for breast cancer (48), cancer treatments (23, 49, 50), prostate cancer (28), and breast cancer treatments or prevention (26, 45, 51), there are many factors that impinge upon decision making, especially culture and the prevailing models of medical practice. Therefore, there is a need to establish the structure and validity of the DCS in each cultural setting, which is the focus of the current study.

Although the DCS has been translated and also used in Italy (52), there is a lack of critical research on an Italian cultural and psychometric validation of the scale. Furthermore, the DCS has never been used with cancer patients who are making decisions regarding the use of a CVAD. The aim of the current study was to evaluate the psychometric properties of an Italian version of the DCS, evaluating its factorial structure and its accuracy in discriminating the level of uncertainty in a sample of cancer patients during their decision-making process for the insertion of a CVAD for intravenous (IV) chemotherapy administration.

Materials and Methods

Samples and settings. The study was conducted between May 2016 and September 2017, at the National Cancer Institute IRCCS 'Fondazione G. Pascale', Naples, Italy. Patients were selected to include a demographically and clinically heterogeneous sample using a consecutive sample strategy and according to the following criteria of inclusion: age ≥18 years old; indications from the oncologist that the insertion of the CVAD for the chemotherapy administration was an option; fluency in Italian. Patients who already started the IV chemotherapy and were waiting for the insertion of the CVAD either in the hospital or in a surgery context were included. Patients excluded were those who needed CVAD insertion for complimentary or nutritional therapies and those with a prognosis of ≤6 months.

Development of the Italian version of DCS. The DCS was translated in Italian starting from the original English version using the forward and backward translation method. For the current study the scale was adapted to the patient's decision relating to the options of the insertion of various types of CVADs (non-tunneled or tunneled (t-CVC), totally implanted (PORT) or peripherally inserted, also known as PICC).

The process of translation and cultural adaptation followed the recommendation of Sousa and Rojjanasrirat (53) for the cross-cultural adaptation and the validation of questionnaires (Figure 1). Two different translators independently translated the scales from the English to the Italian (step 1). The first was a professional translator, expert in cultural knowledge and linguistic, and the other is a researcher in nursery. A third expert, who was bilingual, produced a common version (step 2). The Italian translation was then back-translated by an expert English (first-language) translator, who had no knowledge of the original tool (step 3). The English version was evaluated by the first English translator, a researcher and member of the nursing team (step 4), in order to verify the semantic and conceptual equivalence of the content of the scale. Conceptual equivalence refers to concepts that can be found both in the culture of origin and culture to which is directed. The level of agreement between translators on each evaluated item varied between 0.90 and 0.99 then, the scale was considered correct.

The back-translation that was critically analysed was then sent to the author of the original scale who evaluated the correspondence of the semantic and conceptual similarity between the Italian version of DCS and the original scale. The final Italian version of the DCS (DCS-ITA) was then adapted to the decision-making

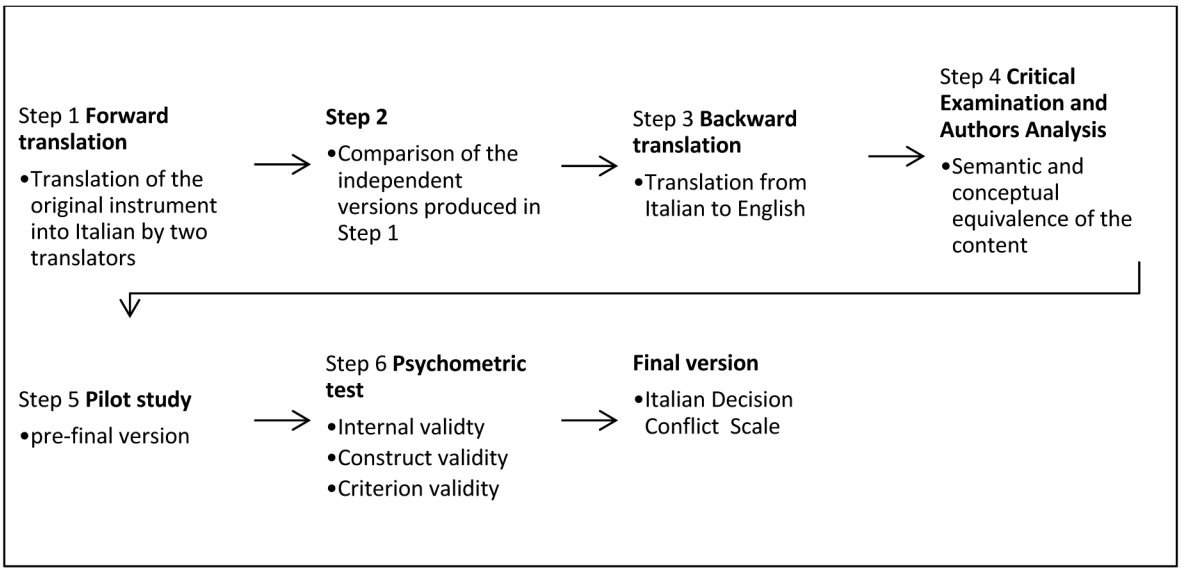

Figure 1. *Steps in the translation and cultural adaptation of a measurement instrument based on Sousa and Rojjanasrirat (53).*

process of the patients who were candidates for the insertion of a CVAD for the infusion of the chemotherapy.

Ethics statement. The study was approved by the Ethic Committee of the National Cancer Institute, Fondazione "G.Pascale" in Italy (nr: 10/16).

Pilot study. As first step the clarity of the scale and its face validity were evaluated through a think-aloud procedure in a cross-sectional sample of 15 patients (54). The results confirmed thorough coverage of the intended theoretical construct (step 5). The sample was selected between those on the waiting list for the insertion of a central device, after an oncologic evaluation at the National Cancer Institute.

Study procedure. During their appointment for chemotherapy infusion, patients were seen by an oncologist, who introduced the possible implementation of the CVAD for the patient. At that point the patient's name and contact information was inserted into a hospital waiting list for that procedure. A trained research assistant recruited the patients for participating in the study by contacting them directly from the waiting list and inviting them to a short meeting to explain the aim of study and collect written informed consent. If the patients consented to participate, a case report form (CRF) was used in order to insert the patients' demographic data (age, gender, education, cancer diagnosis) and the patients' DCS questionnaire responses into the database for the study.

The data collected were entered into an Excel spreadsheet and every patient was given a unique code to preserve confidentiality. The quality of the collected data was affirmed by random planned checks that aimed to analyse the congruency between the data in the system and the questionnaire responses collected.

Statistical analysis. Statistical analyses were performed using the R language v.3.6.3 (55) and the RStudio environment v.1.2.5033 (56), employing a statistical significance at α=0.05. The libraries used in the current study were 'psych' (57) and 'GPArotation'(58). Descriptive statistics were computed to present sample characteristics. Item distribution was evaluated in order to verify a normal multi-distribution of the DCS scale, using the 'MVN' library (59).

Internal consistency. The reliability of the scale and subscales was evaluated. For reliability estimation, the internal consistency approach (Cronbach alpha) has been used. According to scientific literature, value over 0.70 can be considered satisfactory (60).

Criterion validity. In order to determine the ability of DCS to discriminate between patients who were certain of their decision and who are not, criterion validity of the scale was investigated by analysing patients' answer to a specific item of the questionnaire created by the authors, which assessed the extent of their conviction to implement the CVAD: "Are you sure you want to implement the CVAD ?" Answers for this question were restricted to "yes, I am sure about this decision" and "no, I am not sure about this decision". Independent t-tests differences both in total score and in subscales scores were tested between those who chose "yes" and "no". According to the DCS manual, the total score is calculated by summing all 16 items, dividing by 16 and multiply by 25; thus, total score ranges from 0 (no decisional conflict) to 100 (high decisional conflict).

Construct validity. An EFA was conducted with oblique rotation (oblimin). Because Kaiser criterion has been criticized and considered problematic (61-64), Horn's Parallel Analysis (65) was performed in order to determine the number of the factors to be retained. Horn's Parallel Analysis (65) compares the observed eigenvalues extracted from the correlation matrix to be analysed with those obtained from uncorrelated normal variables. The method uses the Monte Carlo simulation process, since 'expected' eigenvalues are obtained by simulating normal random samples that

Table I. *Demographic and medical information of participants*.

	n	%
Gender		
Males	103	39.0
Females	161	61.0
Age	58.13±13.3 (19-83)*	
Education level		
Elementary school	46	17.4
Middle school	86	32.6
High school	81	30.7
Bachelors/Master's degree	43	16.3
None	3	1.1
Missing	5	1.9
Cancer diagnoses		
Breast	57	21.6
Colo-rectal	48	18.2
Stomach	38	14.4
Lymphoma	38	14.4
Ovarian/uterus	28	10.6
Testicular	10	3.8
Lung	9	3.4
Sarcoma	9	3.4
Pancreas	7	2.7
Kidney	6	2.3
Prostate	4	1.5
Hepatic	4	1.5
Missing	4	1.6

*Mean±Standard deviation (range).

parallel the observed data in terms of sample size and the number of variables (66). A factor-loading coefficient of 0.30 or higher was chosen (67). The fit indices results were evaluated following the conventional criteria (68): RMSEA value below 0.06, and SRMR value below 0.08. The sample size estimation for factorial analysis was set at a minimum of 160 patients, based on the number of items composing the scale (69).

Results

Samples. From May 2016 to February 2018, 264 patients were enrolled, 61% of which were female, with a mean age of 58.13 years (standard deviation=±13.3; range=19-83). About two-thirds of samples (63.3%) had completed middle or secondary school. Types of cancer diagnosis varied and included breast, colorectal, stomach, lymphoma, ovarian-uterus, lung, and others.

The demographic and medical characteristics of the samples are described in Table I.

Internal reliability. The reliability of the DCS-ITA was evaluated using Cronbach's alpha coefficient for the total score was 0.96, which is excellent. Cronbach's alpha coefficient was also calculated for all the subscales and all the values were greater than 0.90.

Construct validity. To investigate the psychometric validity of the scale we conducted an EFA with a principal axis factoring method (PAF) and "oblimin" rotation on the 16 items. Prior to conducting an EFA with PAF, Bartlett's test of sphericity and the Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) were evaluated. The correlation matrix showed that most of the items had a correlation greater than 0.35. Bartlett's test of sphericity was significant ($p<0.001$), and the KMO value was >0.6 (KMO=0.913) indicating that factor analysis was appropriate for the data (70).

Parallel analysis was undertaken using the Horn's procedure. Using 5,000 parallel datasets, $\alpha=0.01$, parallel analysis indicated a three-factor solution. Subsequently, principal axis factoring resulted in three-factors accounting for 63.0% of total variance. One item (number 16) cross-loaded >0.32 on two factors, but it was retained (61). Fit indices for the EFA were considered acceptable (RMSEA: 0.08, TLI: 0.92, SRMR: 0.03), which indicated a consistent factor structure (see Table II for factor loadings). The items that clustered on the same factors suggest that factor 1 represented "Informed and Values Clarity", factor 2 "Uncertainty and Support", and factor 3 "Effective Decision Making". Considering the original structure of the scale, the current analysis had only three items (items 8, 10 and 11) that loaded on different factors than the original measure. Only one item (item 16) cross-loaded on two factors (Table II).

Criterion validity. As expected, the total scores of DCS were significantly higher in the group that described themselves as uncertain about the choice. In addition, the differences between the certain and uncertain groups was significant for all the three subscales (Table III).

Discussion

The present study evaluated the validity and reliability of the Italian version of the DCS in Italian patients with cancer diagnosis making decisions for CVAD insertion. Exploratory factor analysis was performed to identify the underlying dimension of the DCS and revealed that a three-factor solution: (i) "Informed and Values Clarity", (ii) "Uncertainty and Support" (iii) "Effective decision making" was optimal. The original DCS was presented as a three-factor measure (22) and a few years later, as a five-factor measure (30). The original factorial solution of the scale was composed of three subscales with the first factor labelled "Uncertainty," which referred to the level of uncertainty a patient perceives concerning a certain healthcare decision. The second subscale, "Factors Contributing to Uncertainty," measured the extent to which certain factors (informative, values and emotional distress) contributed to uncertainty. Finally, the last subscale "Perceived Efficacy Decision Making" measured the patients' perception about the efficacy of their decision. In the five-factors model the subscale

Table II. *Exploratory factorial analysis of Italian decisional conflict scale (DCS-ITA, principal component analysis, oblimin rotation).*

	Item #	F1	F2	F3	Communality
I am clear about how important the risks and the side effects are to me (V)	5	0.96			0.81
I know the benefits of each option (I)	2	0.86			0.84
I know the risks and the side effects of option/choice (I)	3	0.85			0.68
I am clear about how important the benefits are to me (V)	4	0.82			0.72
I know which options are available (I)	1	0.65			0.65
I am clear about which is most important to me (V)	6	0.54			0.61
I feel sure about what to do in this decision (U)	11	0.41			0.61
The decision is easy for me to make (U)	12		0.73		0.41
I have enough advice to make a choice (S)	9		0.73		0.67
It is clear what choice is best for me (U)	10		0.66		0.59
I feel I have made an informed choice (E)	13		0.59		0.68
I had the right amount of support from others in making this choice (S)	7		0.57		0.40
I'm satisfied with my decision (E)	16		0.53	0.41	0.59
I expect to stick with my decision (E)	15			0.89	0.78
My decision shows what is most important for me (E)	14			0.80	0.66
I'm choosing without pressure from others (S)	8			0.52	0.34

I, Informed subscale. V, Values clarity subscale. S, Support subscale. U, Uncertainty subscale. E, Effective Decision Making subscale (according to the original five-factor scale).

"Factors Contributing to the Uncertainty" was split into three subscales (*i.e.* Informed, Values Clarity and Support subscales).

Our results showed a slightly different structure from the original subscales with all the items of the "Informed" and "Values clarity" subscales loading in one single factor. Furthermore, another item related to the perception of "Uncertainty" (*i.e.* "I'm sure what to do in this decision"), loaded on the same factor, however it had the lowest loading (item loading=0.40; see Table II). Our results failed to differentiate these two subscales ("Informed" and "Values clarity") and this same result was found in other validation studies (42, 46). We consider this result culturally coherent for our sample because both the aspects of dealing with "information" and the "values clarity", helped the patients to understand the available choices, comprising related risks and benefits of CVAD.

At the same time, results showed that the "Support" subscale was not loading on the same factor of the "Informed and Values Clarity" subscale as expected, since in the three factors model these subscales were all loading on one single factor. Conversely the items related to the "Support" loaded on a factor comprised of the items related to the "Uncertainty About the Choice".

However, one of the three items related to the perceived support 'Are you choosing without pressure from others?' from the "Support" subscale did not load on the expected factor but fit on the "Effective Decision Making" factor. Inspection of the items of the "Support" subscale indicates that the other two items overall assessed the perception of support from others about the decision to be made, whereas 'I'm choosing without pressure from others' item is related to the interference that others can interject into the decision-making process. Thus, this difference in terms of the perception of support could also account for the different loading from a psychometric point of view. The same results have been reached by Koedoot and colleagues (38) who evaluated the Dutch version of the DCS on cancer patients choosing breast cancer surgery or palliative chemotherapy; they found that this item loaded onto the "Uncertainty" subscale. Also Lam *et al.* in 2012 (45) found the same item loading onto a factor they labelled "Uncertainty and Perceptions of Effective Decision Making".

Furthermore, unexpectedly, the factor that we labelled "Uncertainty and Support" included one item ("I feel I have made an informed choice; Table II) related to the "Efficacy of Decision Making" subscale. Other scholars found a

Table III. *Comparison on the DCS-ITA between "Certain" and "Uncertain" patients.*

	Group	N	Mean	Sig.
DCS – ITA Total score	Certain	178	41.75 (16)	<0.000
	Uncertain	85	58 (12.75)	
DCS – ITA Factor 1	Certain	178	1.93 (0.80)	<0.000
	Uncertain	85	2.50 (0.67)	
DCS – ITA Factor 2	Certain	178	1.06 (0.70)	<0.000
	Uncertain	85	1.76 (0.63)	
DCS – ITA Factor 3	Certain	178	1.85 (0.80)	<0.000
	Uncertain	85	2.55 (0.59)	

Factor scores were calculated as mean of the item loadings of the items for that factor in the EFA.

similar issue with the same item of the DCS, for example Lam and colleagues (45) in their validation study found the same item cross loading on two factors, one of which was substantially composed of the "Support" items. Mancini *et al*., in 2006 (39) in a French validation study, also found the item "I feel I have made an informed choice" loaded on a factor, labeled "Uninformed Unsupported Choice", that comprised "Support" related items. Lastly, our results showed the other three items related to "Efficacy of the Decision Making", loaded together on one factor, however there was one item cross loading both on the second and the third factors.

It is important to note that different scholars found various alternative factorial structures of the DCS. These different results found by other scholars suggest that the original factor structure of the DCS should be validated and adapted within a cultural setting because of the cultural differences between populations in terms of health care decisions. Furthermore, the heterogeneity of the models found by the different studies may reflect some specificity of the samples in terms of the type of medical decision being studied. For example, O'Connor in 2010 (30) validated the scale on a sample of healthy adults who were going to decide about influenza immunization, whereas the French and the Dutch validation studies were based on a sample of cancer patients deciding between treatments (38, 39). Finally, a three-factor structure was identified based on a sample of American women deciding about genetic testing for hereditary breast and ovarian cancer (44).

The Italian version of the DCS (DCS-ITA) showed optimal internal consistency for the total scale, as well as for the factors identified. The DCS-ITA also showed good criterion validity revealed by the ability of the scale to differentiate between patients who declared themselves certain about their choice and patients expressing uncertainty about the choice to make.

In conclusion, this study represents the first Italian validation of the DCS. Overall, the results of the study showed that the DCS-ITA is a psychometrically sound instrument able to easily discriminate between patients that are experiencing a decisional conflict. So far, there was the absence of any valid tool able to evaluate the conflict of an oncological patient involved in his health care decisions. The DCS-ITA use would be powerfully efficacious in the oncological context to assess one's personal conflict when there is a need to make decisions related to the health care process. The strength of the tool is not only to evaluate personal decisional conflict, but in identifying the factors that intervene in exacerbating the decisional conflict for the implementation of tailored interventions in order to improve the satisfaction of the medical care, the perception of the efficacy of their choice, thus reducing the impact of the distress of the patients on their quality of life (71).

Following the recommendation made by the recent review of Garverlink and colleagues (37), it is important to underline that the scale was not modified in terms of rewording the items and its structure was not very different from what was found in other similar studies dealing with cancer-related decisions. Another strength of the study is the timing of the data collection, made at the moment of the proposed (baseline) insertion of the device. This timing is strongly suggested by the author of the scale as it reflected the dynamics of the decision-making process at the time that the actual decision is made. Data collection conducted after the decision, in fact, would engage retrospective reflection that might have been based on their experiences with the device. This study has certain limitations. A convenient, consecutive and single-center approach was used, which could be subject to a selection bias. Furthermore, because this was a cross-sectional study, future studies should include a longitudinal approach in order to test the stability of the scale over time.

Conflicts of Interest

The Authors declare no potential conflicts of interest.

Authors' Contributions

MRE ideated the study; AC and MRE wrote the manuscript and revised accordingly; AC and FG performed data analysis; MRE, AG, TR, MP, and MGDM collected the data and revised the final version of the manuscript.

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