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Decisional conflict in patients scheduled for insertion of a Central Venous Catheter to receive chemotherapy: protocol for a cross-sectional study

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Introduction

Advances in health care have increased the therapeutic choices and the number of professionals involved in the treatment and decision making process.[1-3] Therefore, patients are increasingly often in uncertain situations when it comes to making decisions.[4-5] Decision-making has been described as a dynamic process. It involves a choice between two or more available options, including action or inaction, and is designed to make a precise decision. High quality decision-making takes place when an adaptive pattern of cognitive and behavioral processes occurs that limits post decisional regret and increases adherence to the final choice. The decision making, however, is a stressful process, influenced by the risk, ambiguity, and conflict present within the choice situation.[6] The difficult decision causes a perception of uncertainty that is related to decisional conflict (DC).[7] The construct of decisional conflict, originally defined by Janis and Mann (1977), refers to the uncertainty a person faces when a choice needs to be made, and when such condition leads to balance the positive and negative aspects of the decision itself.[8]

The patients' perception of self-efficacy in the informed choice, i.e. the patients' belief in their own ability of decision-making, plays a central role in the decision-making process.[9] Enhancing the patients' self-efficacy in the decision-making allows them to take control over treatment choices and to achieve a patient-clinician partnership able to facilitate shared decision-making.[10]

Even though uncertainty is an intrinsic characteristic of the choice among different possible options, some factors such as lack of knowledge, unrealistic expectations, unclear values, pressures from others, social contest and lack of support[11] in the decisional choice can intensify it.[12]

Some studies report the central role of knowledge as a predictor of lower decisional conflict by allowing patients to feel more informed about benefits and risks of the choice.[13] However, results from other studies suggest that this relationship is more complex and that preparation acts as a mediator between knowledge, self-efficacy and decisional conflict. Therefore, the impact of self-efficacy in decision support is essentially mediated by preparation rather than knowledge.[9]

The unsolved conflict can lead patients to a delay in decision, after thought, regret or more likelihood to change their mind, dissatisfaction with the decision taken, nervousness, and a higher intention to sue physicians in cases of harms from treatment.[14] Adverse effects have also been described in patients – such as physical tension-expressed by increased heart rate, muscle tension, and restlessness, and emotional distress.[15] In some patients, an unsolved conflict may translate into clinically significant decisional conflict (CSDC),[16] even after the treatment decision has been made.[17,18]

Identifying patients who experience decisional conflict is the first step to help them solve the uncertainty in the decision. The Ottawa Decision Support Framework (ODSF) has been used to assess patients' decisional needs and perceived self-efficacy, to design intervention, to measure changes in patient outcomes, and to train healthcare professionals to support patients with decisional conflict.[19-21]

The Decisional Conflict Scale (DSC) was developed based on the construct of decisional conflict in accordance with the ODSF.[13] The DCS is a self-administered 16-item questionnaire that assesses patient's uncertainty regarding the healthcare decision-making process. It can be used to diagnose the decisional conflict of patients, to identify their decision support needs (knowledge, values clarification, support), to assess the quality of the decision process and to evaluate the impact of decision support interventions.[21] The DCS includes 5 subscales: information, clarity of values, uncertainty, support and valid decision, which represent the modifiable factors contributing to the decisional conflict.[22] The instrument has been utilized in several studies.[10,23,24]

In particular, the DSC has been widely used among individuals facing hormone replacement therapy, mammography screening, end-of life, BRCA genetic testing, palliative chemotherapy,[25] radiation or chemotherapy,[2,3] prostate cancer[23] and breast cancer.[24,26,27]

The DCS has been translated and psychometrically tested in several countries[28-33] but to our knowledge, not in Italy.

The ODSF provides also the Decision Self-Efficacy Scale[34] which evaluates patient's perceived self-efficacy in decision-mak-

ing. Using this scale along with the DSC it is possible to identify whether there is an association between decisional conflict and self-efficacy in patient decision-making.

Several studies found that a number of patients with cancer are hesitant to choose treatments on their own, because of uncertainty about the correct choice.[10,35] In the context of the treatment for cancer, an example of choice that requires patient's involvement in the decision-making is the proposed insertion of a Central Venous Catheter (CVC) to receive intravenous chemotherapy.

The CVCs have become the lifeline for cancer patients and have reduced the incidence of extravasation injury.[36] Of the more than 13 million patients living with invasive cancer in the United States, at least 4 million have a long-term CVC,[37] although it is difficult to estimate the number of CVCs that are actually being used for oncology patients.

Various types of long-term CVC are used: non-tunneled or tunneled (t-CVC), totally implanted (PORT) or peripherally inserted (PICC). The choice of the type of catheter should not be influenced only by the chemotherapy regimens and their expected duration, but also by the patient's ability to perform self-care. Therefore, these matters should be discussed[38] in collaborative processes among patients and health professionals.[39,40] Nevertheless, clinicians sometimes do not involve patients in decision-making and do not consider their values and preferences when selecting a vascular access device.[41] Moreover, when giving information to patients, they mainly focus on technical aspects and medical procedures.[42] The delayed decision for a CVC placement could cause venous depletion by exposing to risks, such as extravasation infiltration,[43] phlebitis, local tissue damage, and progressive loss of available peripheral veins,[39,44] especially in case of intravenous chemotherapy with highly irritating and sclerosing drugs.[45,46] Thus, in the patient diagnosed with cancer undergoing chemotherapy, the ideal venous access is central rather than peripheral since many antineoplastic drugs are notoriously vesicant.[36]

CVCs and in particular totally implanted ports, provide greater freedom of movement and are safer than peripheral venous catheters for the administration of chemotherapy. Patients with totally implanted ports are less restricted when undertaking dressing and personal hygiene than those with not implanted CVCs.

However, patients sometimes report negative perceptions of the port,[47,48] worries[49] lack of satisfaction with the esthetic result of the implantation[50] and inadequate knowledge,[51,52] particularly in absence of written information.[53] A qualitative study [54] revealed that the choice of positioning the CVC was mandatory because of venous depletion and impossibility to proceed with the administration of peripheral chemotherapy. Patients perceived this decision as associated with an unfavorable course of the disease and expressed regret for not having had the chance to make a choice.

It seems not unlikely that patients with cancer to whom a CVC placement is proposed experience decisional conflict. However, this phenomenon has never been studied.

Study Aims

The main objectives of this study are:

1. To translate the DCS in the Italian language and test its psychometric properties;
2. To psychometrically test the Decision Self-Efficacy Scale, based on the ODSF;
3. To psychometrically test the Knowledge Test, based on the ODSF;
4. The secondary objectives are:
5. To investigate whether cancer patients to whom the placement of a CVC for the administration of intravenous (IV) chemotherapy has been proposed experience decisional conflict;
6. To describe the factors that can have an impact on the onset of the decisional conflict.
7. To assess the patient' perception of self-efficacy in the decision-making;
8. To assess the patient' knowledge about CVC.

Materials and Methods

A cross-sectional survey will be conducted using three self-administered questionnaires to assess the decisional conflict, self-efficacy and knowledge of patients to whom a CVC placement has been proposed. The questionnaires are based on the ODSF and comprise 16, 11 and 16 items respectively.

Setting and Sample

The study will be conducted at the wards and outpatient clinics of the National Cancer Institute Pascale Foundation of Naples, which is the largest "Clinical Care and Research Cancer Center" in Southern Italy.

The patient participants will be selected based on heterogeneous demographic and clinical characteristics using a consecutive sampling strategy.

The tools will be psychometrically tested on a sample of 160 patients. This sample size was decided based on the rule of having at least 10 respondents for every item of the scale.[55] To investigate the differences in function of different patients' characteristics and considering that the DCS provides an effect size of 0:30 or 0:40, a sampling of 160 patients allows 80% power at a significance level of 5% of identifying an effect size amounting to 0.45.[22]

Inclusion Criteria

- Indication and proposal of CVC placement for the administration of intravenous chemotherapy;
- Inclusion in the surgery list for a CVC placement;
- Age ≥ 18 years;
- Signed informed consent;
- Adequate knowledge of the Italian language (as assessed by the researcher).

Exclusion Criteria

- Cognitive deficit impairing the autonomous completion of the questionnaires (as assessed by the researcher);
- Rejection or inability to fill in the tests;
- Previous experience of CVC placement;
- Prognosis with life expectancy < 6 months.

Demographic and Clinical Characteristics

The demographic and clinical information of patient participants will include: sex, age, education level, cancer site and type of chemotherapy.

Instruments

The Decisional Conflict Scale (DCS)

The scale includes 16 items rated on a 5-point Likert Scale (from 0 = strongly agree to 4 = strongly disagree), with a total score that ranges from 0 (no decisional conflict) to 100 (extremely high decisional conflict). Scores < 25 are associated with a low level of decisional conflict, while scores > 37.5 are associated with late decision or decision uncertainty.

Psychometric properties of the original DCS have been tested, with satisfactory estimates of internal consistency and stability (test-retest correlations and Cronbach's alpha coefficient both exceeding 0.78).[22] The construct validity was tested and found that DCS correlates to related constructs of knowledge, regret and discontinuance; moreover it discriminates between known groups: those who make and those who delay decisions (effect size ranges 0.4 to 0.8).[22]

The DCS has been translated into Italian for this study through a process of forward and backward translation.[56] The translation from English into Italian has been conducted independently by two translators, one of which was a professional translator; a third translator has produced a common version. The backward translation was performed by an independent translator, a native English speaker, with no knowledge of the original scale. This translation version was returned to the author of the instrument, who evaluated the semantic and conceptual equivalence with the original instrument.

Knowledge Test

To evaluate the patient's knowledge on CVCs a test has been created by a pull of experts (oncology nurses, nursing researchers and experts in questionnaire development), based on the ODSF and on the literature.[57] The test included 16 items covering the most relevant information regarding central venous devices, such as, for instance, indications, types, advantages, disadvantages and risks of CVCs. Each item presents a piece of information that the respondent is required to define by choosing one of the following: true, false, I do not know.

The test is scored with 1 point for each correct answer and 0 point for each incorrect or 'I don't know' answer. The sum of scores of the 16 items represents the total score, which can range from 0 to 16. Higher scores indicate greater knowledge on CVCs.

Decision Self-Efficacy Scale

The Decision Self-Efficacy Scale evaluates the patient's self-efficacy in obtaining data or relevant information in the decisional process.[12] It is based on the ODSF and includes 11 items measured on a 5-point Likert scale (ranging from 0 'not at all confident' to 4 'very confident'). The mean score of the 11 items multiplied by 25 represented the total score of the scale, with a possible range from 0 (not at all confident) to 100 (very confident). This scale demonstrated good psychometric properties (Cronbach's alpha coefficient = 0.92), and was correlated with decisional conflict subscales of feeling informed (r = 0.47), when used with osteoporotic women.[19]

Data Collection and Procedures

Trained research assistants, who are not involved in the choice of CVC placement, will approach potential participants after:

1. The oncologist indicates the insertion of a central device and proposes it to the patient;
2. The patient's consent to the placement of a central device;
3. The request to position a CVC is sent by the oncologist to the "Central Venous Catheter Implants and Management Structure". The head of this Structure communicates to the research assistants the names of the patients who are put on the list for the positioning of the devices.

The research assistants, will approach hospitalized patients in the wards and the outpatients in the clinics after the visit with the oncologist or with other physicians. Eligible patients will be informed about the study aims and procedures. Willing patients will be asked to sign an informed consent to participation in the study and will be administered the DCS, the Decisional Self-Efficacy Scale and the Knowledge test.

Pilot Test

The questionnaires will be administered to a sample of 15 patients, to ensure that the respondents can adequately understand the questions. When needed the questionnaires will be modified to increase clarity before being distributed to the whole sample.

Outcomes

The expected outcomes will include:

- Psychometric properties and dimensions of the DCS;
- Psychometric properties and dimensions of the Decisional Self-efficacy Scale;
- Psychometric properties and dimensions of the Knowledge questionnaire;
- Scores obtained with the DCS;
- Scores obtained with the Decisional Self-efficacy Scale;
- Scores obtained with the Knowledge questionnaire.

Data Analysis

Descriptive statistics of sample socio-demographic variables and of the questionnaires' variables (item and total scores) will be calculated.

Normality of the items of the DCS, the Decision Self-efficacy scale and the Knowledge test will be ascertained considering both skewness and kurtosis indices. The dimensionality of the Italian version of the DCS and Decision Self-efficacy scale will be investigated through confirmatory factor analysis (CFA) and that of the knowledge test through exploratory factor analysis (EFA). Preliminary Kaiser-Meyer-Olkin (KMO) and the Bartlett's test of sphericity will be used to examine the factoriability of the data.

The models will be assessed adopting a multifaceted approach to fit evaluation, using several indices and criteria among the fallowing: Chi-square ($\chi 2$) significance (if chi square is not significant, the model reached a perfect fit with the observed data); Comparative Fit Index[58] and Tucker-Lewis Index (TLI),[59] values ≥.95 indicate a good fit; Root Mean Square Error of Approximation[60] (RMSEA): values ≤.05 or .08 indicate a good fit, as well as the acceptance of the null hypothesis (for $p < .05$) associated to its 90% confidence interval[61] and the Standardized Root Mean Square Residual (SRMR) as suggested by Kline.[62] The quality of the factors will be then analyzed through the factor score determinacy coefficients and the reliability through the Cronbach's Alpha Coefficient.

Correlation between the scores of the Decision Self-efficacy Scale and of the Knowledge test and the DCS will be evaluated by Pearson' correlation coefficient.

To investigate the effect of any variable measured (sample socio-demographic, self-efficacy and knowledge) on decisional conflict, univariate analyses will be performed with the scores obtained with DCS as dependent variables. Multiple linear regression analyses including statistically significant variables from the univariate analysis will be conducted to identify which are independent predictors of decisional conflict.

Significance is set at < 0.05. Statistical analyses will be performed using STATA 10.0 and Mplus 7.1.[63]

Ethical Considerations

Potential participants will be informed orally and in written by nurse research assistants about the study aim and procedures.

They will be informed that they are free to participate and provided with time to reflect on it before being asked to sign an informed consent.

The study was approved by the Ethics Committee of the "Istituto Nazionale Tumori, G. Pascale", Naples, Italy with Protocol number 10/16 OSS registered "Studio DeconCVC-01".

Discussion

To our knowledge, this is the first study that investigates the patient's decision-making process in choosing a placement of a CVC for the administration of chemotherapy. Such choice may be accompanied by the patient's uncertainty during the decision process.

The CVCs have an important role in most intravenous (IV) cancer treatments. Therefore, the reliability of IV chemotherapy and the shared choice of the device that best meets patients' safety combined with their individual needs is gaining increasing importance.

International guidelines[38,39,64] recommend sharing with the patient and caregiver the most appropriate choice of the CVC type to be inserted for the administration of chemotherapy. This is necessary because patients or their caregivers-family members need to acquire the appropriate knowledge and skills for the management of devices through educational intervention, but also because the clarity of the information, and patient's preferences are important factors that affect the decision process.

This study could provide valid and reliable tools able to identify patients with decisional conflict, to assess their perceived self-efficacy and their knowledge on CVC. Regular use of these tools in clinical practice will identify whether there is a decisional conflict, what are the perceived self-efficacy and knowledge of patients. This will enable clinicians to be aware of potential problems and will help their communication with patients on the choice to be made.

The results of this study will also provide evidence about the variables affecting the decisional conflict to inform future interventions able to improve decision-making. Health professionals working in oncology can improve patients' knowledge and perceived self-efficacy, by involving them in decision-making and using education-based empowerment strategies.[57]

Moreover, the study will enable to measure self-efficacy in making a choice in order to identify the patient's need for support in requesting information from health professionals.[9] This will avoid a low perceived self-efficacy that could adversely affect the decision to insert a CVC and, consequently, could increase the decisional conflict.

Another contribution of the study is to understand whether patients need more information about CVCs, such as for instance their benefits and risks, another element that affects the decisional conflict.

Finally, results from this study will help to understand what aspects of the support should be improved and which decision aids should be put in place to reduce the decisional conflict. It can also clarify what skills the health care professionals need to develop, in order to improve shared decision making and patient-centred care.

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