

# The psychometric evaluation of the Italian version of the Surgical Fear Questionnaire in adult patients waiting for major cardiac surgery

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**Keyword:** *Surgical Fear questionnaire; reliability; validity; cardiac surgery; surgical fear; preoperative*

**Parole chiave:** *Questionario sulla paura chirurgica; affidabilità; validità; cardiocirurgica; paura chirurgica; preoperatorio*

## Abstract

**Background and aim.** Preoperative surgical fear is an emotional reaction that can be observed in many patients who are waiting to undergo a surgical procedure. The Surgical Fear Questionnaire was originally developed to determine the level of fear in patients who are expected to undergo elective surgery. This study aims to test the validity and reliability of this Italian version in a population of patients waiting for major cardiac surgery.

**Study design.** Methodological research model.

**Methods.** The population of this methodological study included the patients who presented to Lecco Hospital in Italy between January 2022 and October 2023 and were scheduled to undergo valve surgery, aortic surgery or coronary surgery; the sample involved 416 patients who met the inclusion criteria.

**Results.** Results of the analyses showed that the Surgical Fear Questionnaire can be used with two subscales; the "Surgical Fear Questionnaire-S", which shows the fear of the short-term consequences of cardiac-surgery, and the "Surgical Fear Questionnaire-L", which shows the fear of the long-term consequences of cardiac-surgery. The mean score of the patients was  $26.32 \pm 9.23$  on the former,  $27.62 \pm 11.89$  on the latter, and  $53.94 \pm 19.16$  for the entire questionnaire. The Cronbach's  $\alpha$  coefficient was 0.952 for the "Surgical Fear Questionnaire-S", 0.920 for the "Surgical Fear Questionnaire-L", and 0.914 for the entire questionnaire.

**Conclusion.** Based on the validity and reliability tests, we consider the questionnaire adaptable to the Italian reality, specifically to the population waiting for major cardiac surgery.

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## Introduction

Surgical or preoperative fear is a well recognizable emotional state for many patients waiting for surgery and is a risk factor for socio-economic burden and major personal problems (1-2). Various studies have found that surgical fear is associated with impaired psychosocial and physical recovery, such as increased levels of acute and chronic postoperative pain, anxiety and depression (1-3). Therefore, preoperative assessment of surgical fear could provide essential information for improving perioperative care and could be a first step towards targeted intervention bringing the patient to the center of the care plan.

Objects of surgical fear can be heterogeneous. Different studies have listed more than twenty objects of fear, arising from fear of the surgical procedure itself to fear of the anaesthesia, having to undergo blood transfusions, being stung with needles, losing dignity or even dying (4-5).

During surgical operations, patients experience disparate emotions, such as the fear related to the lack of control over their own bodies and lives or to the loss of an organ or tissue, as well as the hope and expectation of recovering from their condition (6).

If fear is present among patients evaluated before elective surgery, it is hypothesized that the fear itself may be even worse and more evident among patients undergoing major surgery.

Currently, post-operative mortality after cardiac surgery has decreased significantly (7-8) which highlights the progress in the care of these patients, however the incidence of postoperative morbidity still remains significant (8). Approximately 10% of cardiac surgery patients require prolonged postoperative care (9) with longer intensive care unit (ICU) stays and worse long-term outcomes (10-12). Cardiac surgery performed to correct functional mitral insufficiency, cardiogenic shock or aortic stenosis are still a significant cause of morbidity and mortality today (13). Functional mitral valve regurgitation is frequently observed in patients with ischemic and non-ischemic cardiomyopathy and is associated with poor clinical outcomes in patients with heart failure with reduced ejection fraction due to dilated remodeling of the left ventricle (14). Many patients with cardiogenic shock are referred for coronary artery bypass grafting (CABG) due to coronary anatomy unsuitable for percutaneous coronary intervention (PCI) and/or due to mechanical complications such as rupture of the ventricular septum or muscle papillary (14). Existing

evidence highlights the importance of patients' clinical condition and frailty before cardiac surgery as predisposing factors for poor post-transcatheter aortic valve replacement (TAVR) outcomes (13). However, to date, patients undergoing TAVR typically have an advanced age and multiple comorbidities and the prevalence of frailty can reach 50-63% of observed cases (13).

Most patients when exposed to stressors, such as chronic diseases and surgeries, are prone to adverse events, procedural complications, prolonged recovery, physical and psychological functional decline, and mortality (15).

Considering all these factors, therefore, the anxiety and fear should be clearly asked when evaluating patients before surgery, and the causes related to the fear and anxiety should be analyzed. It is clear that such interventions can instill fear and apprehension in patients awaiting surgery.

Although there are studies in the Italian literature regarding the general anxiety, depression or post-traumatic stress disorders of patients, according to tools that have been tested for validity

and reliability, there are no tools that have been tested for validity and reliability of preoperative fear.

Therefore, this study aims to test the validity and reliability of the Surgical Fear Questionnaire (SFQ) translated to Italian in a population of patients waiting for major cardiac surgery.

## Methods

### *Study design*

Before starting with the study, a quick bibliographic review was conducted by the first three authors to evaluate whether the SFQ (16) had already been validated in Italian. The bibliographic review was conducted on Pubmed, Cinhal, Ilisi and on Google Scholar.

After bibliographic review and before starting with the validation study of the SFQ, authorization was requested via-email contact from the author of the questionnaire (Professor Maurice Theunissen) (16). During contact with Professor Theunissen, we learned that an Italian language translation study was already underway. However, in agreement with the author and creator of the FSQ, we decided to test the questionnaire anyway, continuing with the study on cardiac surgery patients because its reliability and validity had never been tested on this specific

population or in adult patients waiting for major surgery. However, in agreement with Professor Theunissen and Dr. Eva Koetsier of the Cantonal Hospital of Italian Switzerland, who was following the linguistic translation study, a comparison of our and their translation before administration to patients was deemed appropriate.

The methodological research model was used in this validation study, which was conducted between January 2022 and October 2023 with patients who were scheduled to undergo major cardiac surgery admitted to Lecco Hospital in Italy.

### *Sample and setting*

The population of this study consisted of the all patients who presented to cardiology, rehabilitation cardiology or preoperative cardiac surgery department at the Lecco hospital in Italy between January 2022 and October 2023 and were scheduled to undergo valve surgery, aortic surgery, coronary surgery.

For inclusion in this study, patients had to be older than 18 years, in a conscious state, voluntarily consent to cooperate and communicate, not previously diagnosed with any mental disorders, be scheduled to have major cardiac surgery procedure under general anaesthesia and be included in either Class 1 (Patient in good health conditions, without systemic, organic or psychiatric diseases) or Class 2 (Patient with modest, mild systemic disease, without functional limitations (e.g. diabetes or hypertension), according to the categorization of the American Society of Anesthesiologists (ASA) Physical Status Classification (ASA I; ASA II).

The study sample involved 416 patients from within this population who met the inclusion criteria.

### *Data collection*

The data were collected through face-to-face interviews conducted after the patients were informed

about the study and their oral consents were obtained. The data collection tools were administered to the patients the day before the surgery.

It took approximately 10 to 20 minutes to complete the personal information form and the scales,

which included the SFQ (16) and the Hospital Anxiety and Depression Scale (HADS) (17). The parallel form reliability method (18) was used during data collection to determine the reliability of the SFQ, and HADS was used as the second scale to assess the fear and anxiety or depression level of the patients.

### *Questionnaires*

The questionnaires used for the study and administered to the patients consisted of three sections.

*The first section* concerned the collection of the demographic data (eg. age, gender, marital status, type of cardiac surgery, family type, occupation and ASA Physical Status Classification).

*The second section* concerned the collection of the Surgical Fear Questionnaire (SFQ) (16). This questionnaire was developed by Theunissen and colleagues in 2014 to determine the level of fear that patients expecting to undergo elective surgery felt regarding the short-term and long-term results of the surgical procedure (16). Arranged as an 11-point Likert type scale, the questionnaire includes eight items, which are scored between 0 and 10, with a score of 0 indicating not fear at all and a score of 10 indicating a profound fear. The questionnaire has two subscales, each of which feature four items on the cause of fear. Items 1 to 4 assess the fear caused by the short-term results of the surgery, whereas items 5 to 8 assess the fear caused by the long-term results of the surgery. The sum of the scores of the four items on each of the subscales yields the subscale scores, and the sum of both subscale scores yields the total score of the entire questionnaire. The minimum and maximum subscale scores are 0 and 40, respectively, whereas the minimum and maximum total score of the questionnaire are 0 and 80, respectively. A high score indicates a high level of surgical fear. No cut-off was well identified among the fear scores. However, the expressed score can be used as a percentage of the level of fear expressed (0% or 100%).

*The third section* concerned the collection of the Hospital Anxiety and Depression Scale (HADS) (17). This scale was developed by Zigmond et al in 1983 to determine the risk of anxiety and/or depression and to assess the change in their severity (17). The HADS scale is a 4-point Likert-type scale, which includes 14 questions: seven on the symptoms of depression (HAD-D) and seven on the symptoms of anxiety (HAD-A). The odd-numbered questions assess anxiety, whereas the even numbered questions assess depression. For each scale, the scores collected indicate: no problem score 0-7; mild problems score 8-10; moderate problems score 11-14; severe problems score 15-21. The scale aim to determine the risk group by conducting a quick scan of the anxiety and depression levels of those with physical diseases rather than to make a diagnosis. The scale is also used to analyze the changes in the emotional status of the

patient and therefore does not include any physical symptom.

### Statistical Analysis

The study size was based on the total number of patients meeting inclusion criteria and admitted to the Lecco Hospital from January 2022 and October 2023 waiting for major cardiac surgery. A descriptive analysis was used to study the frequency distribution of all variables of interest. For normally distributed data, mean and standard deviation (SD) were applied, while median and interquartile range were used for data that did not exhibit normal distribution.

Data were analyzed using SPSS 22.0 software package (IBM, Armonk, NY). The demographic data derived from the personal information form were analyzed using numbers and percentage.

As part of the reliability analysis, the Cronbach's coefficient, and Pearson's product-moment correlation coefficient were used to determine internal consistency and homogeneity.

The validity of the questionnaire was determined through the i) opinions of specialists, ii) the Barlett test, iii) the Kaiser-Meyer-Olkin (KMO) Index, iv) the exploratory factor analysis, v) the confirmatory factor analysis, vi) the principal component analysis, and vii) the varimax rotation test.

No missing data and no sensitivity analyses were addressed.

### Ethical considerations

Before starting with the study, authorization was requested from the local Ethics Committee (No. 6642/2022), the Institutional Review Board of Lecco Hospital and the Director of the Departments involved. All participants provided their informed written consent to participate at the time of interview. Consent was obtained by the nursing staff 24-36 hours before surgery.

The dataset was pseudonymized before data analysis. The study protocol was in line with the Oviedo Convention for the protection of human rights and dignity of the human being with regard to the application to biology and medicine (1996) and with the Helsinki Declaration, as revised in 2013.

## Results

### Sample

A total of 416 patients were included in the study; 328 of them (78.8%) were males and 88 (21.2%)

Table 1 - Characteristics of patients.

Characteristics (n= 416)	
Gender	
Male n; %	328; 78.8
Female n; %	88; 21.2
Age (year) mean; sd	68.1; 9.2
Weight (kg) mean; sd	79; 12.9
Body Max Index mean; sd	25.26; 8.9
Type of Cardiac-surgery	
Valve surgery n; %	142; 34.1
Aortic surgery n, %	136; 32.7
Coronary surgery n, %	108; 26
Mixed surgery n, %	30; 7.2
Presence of at least one comorbidity before surgery n; %	411; 98.8
Comorbidities	
Hypertension n; %	312; 75
NYHA class II-III n; %	298; 71.6
Arrhythmia n; %	69; 16.6
History of myocardial infarction n; %	52; 12.5
Type I diabetes without insulin therapy n; %	40; 9.6
Chronic obstructive pulmonary disease n; %	28; 6.7
Type I diabetes on insulin therapy n; %	15; 3.6
Osteoarthritis and musculoskeletal disorders n; %	4; 0.9
Marital Status	
Single n %	143; 34.4
Married n %	273; 65.6
The ASA score	
Group 1 n %	361; 86.8
Group 2 n %	55; 13.2

ASA, American Society of Anesthesiologists; SD, standard deviation

females. The mean age was  $68.1 \pm 9.2$  years. The patients mainly underwent valve surgery (34.1%), aortic surgery (32.7%) and coronary surgery (26%) (Table 1). The 98.8% of patients had at least one comorbidity before surgery, and hypertension was present in the medical history of 75% of patients (main comorbidity). The 86.8% were included in Group 1 of the ASA Physical Status Classification (Table 1).

### Linguistic validity and adaptation

Although we were aware that an Italian translation study was in progress, we still had to carry out a language translation ourselves, in order to be able to test the questionnaire on cardiac surgery patients.



To test the validity of the SFQ in its adaptation to Italian culture and in its adaptation to major surgery context, the following process was performed. The SFQ was first translated into Italian by VD and GD and then by one academic member. After conducting a review of the translated forms, a single version of the questionnaire was developed and adapted to the cardiac surgery context. The translated forms were then back-translated into English by a linguist fluent (master's degree in languages, with 5 years' experience in translations) in both languages and closely familiar with both cultures (author: LF). The original questionnaire and its Italian translation were compared, and it was determined that the meaning of the items did not change. The translations made in both of the forms that had been determined to best reflect each of the items were selected and then submitted to ten specialists for their opinions. The ten specialists who contributed to the evaluation of the linguistic translation were: 3 cardiac-surgeons, 2 anesthesiologists and 5 critical care nurses.

Finally, our translation of the questionnaire was compared with the translation carried out by Dr. Koetsier. No substantial differences were found between the translated versions. The versions were considered compatible and usable in the Italian cardiac surgery context.

#### Content validity

The content validity index was used to confirm the language and culture equivalence of the items, as well as their content validity with numerical values, and to properly evaluate the specialists' opinions. The specialists were asked to assess each item with a minimum and maximum score between 1 and 4, where 4 indicates completely appropriate, 3 very appropriate,

Table 2 - Results of Surgical Fear Questionnaire

Subscale	Minimum and Maximum scores	Mean scores of the questionnaire mean, sd
SFQ-S	0-40	26.32±9.23
SFQ-L	0-40	27.62±11.89
Total score	0-80	53.94±19.16

Sd, standard deviation; SFQ-S, Surgical Fear Questionnaire-Short; SFQ-L, Surgical Fear Questionnaire-Long

2 appropriate but small changes needed, and 1 not appropriate. The result of the content validity criterion/content validity index was 1.00. At the end of the assessment, as the content validity of the questionnaire was found to be statistically significant, none of the items were excluded from the questionnaire.

Finally, it was decided not to make additions or modifications to the questionnaire in relation to the specific population under study.

#### Results of SFQ

The results of the SFQ are summarized in Table 2.

The mean score of the cardiac surgery patients is shown to be 26.32±9.23 on the SFQ-S subscale (short-term consequences of cardiac surgery), 27.62±11.89 on the SFQ-L subscale (long-term consequences of cardiac surgery), and 53.94 ±19.16 on the entire questionnaire.

#### Reliability and Factor analysis of the SFQ

The total score correlation of all items was between 0.80 and 0.90, and the Cronbach's  $\alpha$  coefficient was 0.914 for the entire questionnaire, 0.952 for the SFQ-S subscale, and 0.920 for the SFQ-L subscale (Table 3).

Table 3 - Cronbach's  $\alpha$  Coefficients of the Questionnaire and total Item Correlations

SFQ	n	Mean	SD	Total Item Correlation	Cronbach's $\alpha$ value when the item is deleted
Item 1: Operation	416	4.91	3.18	0.721	0.928
Item 2: Anesthesia	416	4.52	3.21	0.719	0.928
Item 3: Pain	416	4.11	3.20	0.709	0.930
Item 4: Side effects	416	4.46	3.19	0.768	0.927
Item 5: Health deterioration	416	4.73	3.19	0.800	0.923
Item 6: Failed operation	416	5.10	3.17	0.821	0.922
Item 7 Incomplete recovery	416	4.97	3.15	0.819	0.923
Item 8: Long rehabilitation	416	4.81	3.05	0.812	0.921

Cronbach's  $\alpha$  of the SFQ-S Subscale: 0.952; Cronbach's  $\alpha$  of the SFQ-L Subscale: 0.920; Cronbach's  $\alpha$  of the entire SFQ: 0.914; SD, standard deviation; SFQ, Surgical Fear Questionnaire; SFQ-S, Surgical Fear Questionnaire-Short; SFQ-L, Surgical Fear Questionnaire-Long

The KMO index was used to determine whether the sample size was adequate for factor analysis, and the Bartlett's test of sphericity was used to evaluate the appropriateness for factor analysis and to determine whether the variables were in correlation with each other before assessing the factor structure of the SFQ. The KMO index was 0.89, Bartlett's test was  $\chi^2(416) = 2992.089$ , and  $P < .001$ . The significance of this test shows that the sample size was adequate for factor analysis and that the correlation matrix was appropriate.

#### *Correlation Between the SFQ and the HADS*

Because people's moods change from time to time, the parallel form reliability method was used to determine the reliability of the SFQ. The HADS, which assesses the depression and anxiety level of the patients, was used as the second scale. A positive significant relationship was found between the mean scores of all subscales of the HADS and the mean scores of all subscales and total score of the SFQ.

Parallel forms equivalence results are summarized in Table 4.

Table 4 - Parallel Forms Equivalence Results

Subscales-SFQ		HADS-A	HADS-D
SFQ-S	<i>r</i>	0.802	0.754
	<i>P</i>	.000	.000
SFQ-L	<i>r</i>	0.804	0.746
	<i>P</i>	.000	.000
Total SFQ	<i>r</i>	0.888	0.832
	<i>P</i>	.000	.000

HADS-A, Hospital Anxiety and Depression Scale-Anxiety; HADS-D, Hospital Anxiety and Depression Scale-Depression; SFQ, Surgical Fear Questionnaire; SFQ-S, Surgical Fear Questionnaire-Short; SFQ-L, Surgical Fear Questionnaire-Long. Bold text denotes statistical significance.

#### *Results of exploratory factor analysis*

The explained variance was 82.742 for the total SFQ score, whereas the factor load of all items of the SFQ was greater than 0.40 (Table 5). These results show that the SFQ consisted of two subscales and that its factor structure was adequate.

#### *Results of confirmatory factor analysis (CFA)*

The index values were found to be  $\chi^2/\text{standard deviation} = 3.51$ , goodness of fit index = 1.00, adjusted goodness of fit index = 1.00, comparative fit index = 1.00, root mean square error of Approximation =

Table 5 - Results of Factor Analysis

SFQ's Items	SFQ-S	SFQ-L
Item 1: Operation	0.247	<b>0.907</b>
Item 2: Anesthesia	0.324	<b>0.891</b>
Item 3: Pain	0.298	<b>0.823</b>
Item 4: Side effects	0.361	<b>0.833</b>
Item 5: Health deterioration	<b>0.866</b>	0.296
Item 6: Failed operation	<b>0.800</b>	0.344
Item 7 Incomplete recovery	<b>0.887</b>	0.319
Item 8: Long rehabilitation	<b>0.871</b>	0.346
Explained variance (%)	<b>43.573</b>	40.132

Total explained variance (%) = 82.742

SFQ, Surgical Fear Questionnaire; SFQ-S, Surgical Fear Questionnaire-Short; SFQ-L, Surgical Fear Questionnaire Long. Factor loadings .07 are in bold.

0.076, and standardized root mean square residual = 0.030. These index values indicate that the SFQ was at an acceptable level and consisted of two subscales (Table 6).

As seen in the path diagram, the original structure of the SFQ was accepted without any modification. The factor loads of the SFQ ranged between 0.81 and 0.92, and the *t* value was greater than 1.96 for all items (Figure 1).

Table 6 - Fit Index Values for the SFQ

Index	Acceptable Value	Normal Value	Values Found
$\chi^2/SD$	< 5	< 2	3.51
GFI	> 0.90	> 0.95	1.00
AGFI	> 0.90	> 0.95	1.00
CFI	> 0.90	> 0.95	1.00
RMSEA	< 0.08	< 0.05	0.076
SRMR	< 0.08	< 0.05	0.030

AGFI, adjusted goodness of fit index; CFI, comparative fit index; GFI, goodness of fit index; RMSEA, root mean square error of approximation; SD, standard deviation; SFQ, Surgical Fear Questionnaire; SRMR, standardized root mean square residual.

## **Discussion**

Although there are many scales used in Italy to assess the anxiety of patients, no specific tools were found to assess the fear that patients experience waiting for cardiac surgery. Therefore, this study was conducted to analyze the validity and reliability of the SFQ in Italy, in a specific patient population

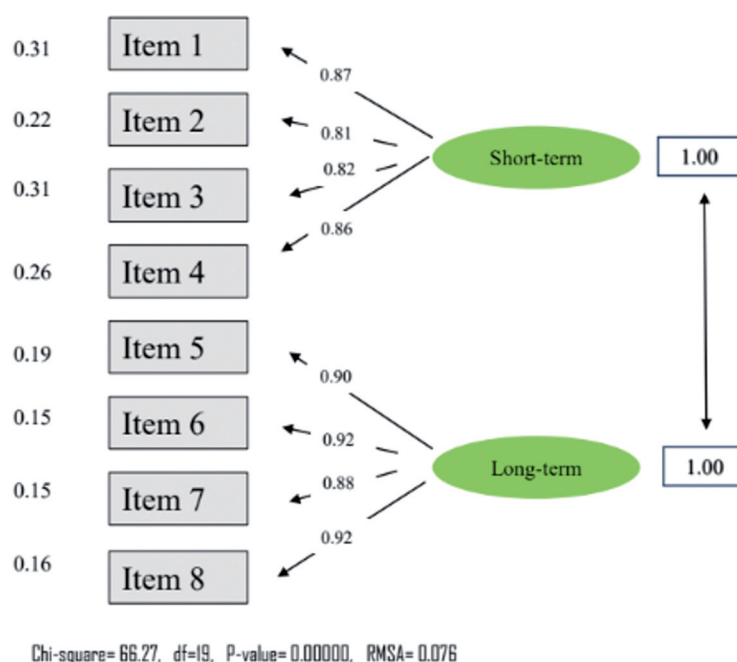


Figure 1 - The path diagram for the Surgical Fear Questionnaire Italian version. RMSEA, root mean square error of approximation.

for major cardiac surgery. The results regarding the SFQ, which consists of eight items and two factors, look promising.

Cronbach's  $\alpha$  coefficient is frequently used in the scale development and adaptation studies to determine the reliability of internal consistency. Its aim is to reveal the consistency level of the items in the scale with each other (18). In the present study, the Cronbach's  $\alpha$  coefficient was 0.914 for the entire questionnaire, 0.952 for the SFQ-S subscale, and 0.920 for the SFQ-L subscale. Theunissen et al found the Cronbach's  $\alpha$  coefficient to be 0.89 for the entire SFQ, 0.86 for the SFQ-S subscale, and 0.87 for the SFQ-L subscale in their three studies (16). These findings show that the SFQ has high reliability in assessing the fear patients experience waiting for surgery.

The parallel form reliability method was used to determine the stability of the SFQ and the HADS Scale, which assesses the depression and anxiety level of the patients, was used as the second scale. A positive significant relationship was found between the two scales. However, we would have liked to compare the stability of the SFQ even better with another scale that evaluates surgical fear but, unfortunately, we did not find any in the literature (tools validated in Italian).

Theunissen et al (6) and Ba digen et al (16) in their validation studies also used the parallel form reliability

method and found a significant relationship. These results indicate that the SFQ has high reliability.

In the present study, the factor load of all items was found to range between 0.80 and 0.90, whereas that of Theunissen et al was shown to be in the range between 0.65 and 0.93 (16). These findings indicate that the items of the SFQ have high factor loads. When interpreting, by one rule of thumb in confirmatory factor analysis, factor loadings should be 0.70 or higher to confirm that independent variables identified *a priori* are represented by a particular factor, on the rationale that the 0.70 level corresponds to about half of the variance in the indicator being explained by the factor.

The explained variance rate was 82.7% in this study on the adaptation of the SFQ to Italian cardiac surgery patients. Theunissen et al on the other hand, found the explained variance rate to be 60.2% for the original form of the SFQ (16). Nonetheless, the findings of the explained variance rate reveal that the SFQ consists of two subscales (SFQ-S and SFQ-L) and that its factor structure is adequate, just as in the original questionnaire.

The index values were found to be = 3.51, goodness of fit index = 1.00, adjusted goodness of fit index = 1.00, comparative fit index = 1.00, root mean square error of approximation = 0.076, and standardized root mean square residual = 0.030. The relevant fit index

values observed in our study validation, indicate the form to be at an acceptable level as it is.

Compared to the initial validation studies by Theunissen et al (16) or the Turkish validation by Ba digen (6), we observed much higher scores regarding the perception of pre-operative fear, with a total mean of the scale of approximately 58.4. In the Turkish validation study it was 37.5 (6). However, this is normal data for us, considering that we administered the questionnaire to patients waiting for major cardiac surgery which can increase fear and tension compared to a different elective surgery.

Finally, the confirmatory factor analysis, performed to confirm the exploratory factor analysis for the original questionnaire, also shows that the SFQ had two subscales. From a methodological point of view, there are a lack of a confirmatory analysis including the Tucker-Lewis Index (TLI), that is used to evaluate the goodness of adaptation of the data to the proposed model. However, previous studies have adopted different strategies to achieve acceptable fit indices (19, 20). Some have modified the basic model, whereas others have used different estimation methods. Several different estimation procedures are available for CFA and there are statistical arguments in favor of the alternative approaches. The widely used maximum likelihood and generalized least squares methods assume of multinormal distributions (19, 20). Using CFA, it is possible to estimate the correlation between the hypothesized latent factors; thus the effect of random measurement error can be partialled out. The effect of one form of systematic measurement error, acquiescence, be addressed using an independent measure of that response style (20). Because there is no conclusive evidence for the superiority of any single approach and because several have previously been used in SFQ analyses, we tested the models using these estimation methods (19).

This study demonstrated that the SFQ is a concise and generic instrument for the assessment of surgical fear, suitable for major adult surgery. For further research we suggest additional testing of the convergent validation using biomarkers such as preoperative stress hormone levels. Also the effect of linguistic and cultural influences on the SFQ needs further study. Finally, for diagnostic use, optimal cut-of points of the SFQ need to be established. The results of which are expected to contribute to nursing or healthcare interventions made to eliminate the fear patients may experience while waiting for surgery.

Fear of death, fear of unknown origin, and fear of postoperative complications can be significant

predictors of preoperative anxiety (21). The preoperative nursing care focused on appropriate fear-reducing methods such as preoperative education, family-centered preparation for surgery, providing psychological care and medication can be required for surgery patients who develop high levels of preoperative fear.

Strong fear of surgery is very common and sometimes leads the patient to postpone the scheduled operation. The fear in question, in fact, can become marked and persistent, reaching the characteristics of a specific phobia (22). The patient generally reports being afraid of dying during surgery or having adverse reactions to local or general anesthesia and difficulty remembering what he should eat the night before an operation. Fear before surgery, therefore, represents an important problem for patients, because it can cause emotional fluctuations, mental and physical disorders. It is therefore essential to detect the patient's fear to best assist him (22).

Fear generates anxiety. Patients who have fear of death have statistically significantly higher anxiety scores than the patients who do not have this fear (22). Patients who have fear of waking up during surgery have statistically significantly higher anxiety scores than those who do not have this fear (22).

The use of the SFQ is useful in increasing shared decision making with the patients or the quality/quantity of information to be provided before surgery.

Before carrying out surgery it is possible to contact a specialist and undertake specific pharmacological therapy and/or a psychotherapy program working on the management of emotions that lead to the avoidance of operations.

We think that being aware of patients' fears and finding appropriate approaches to their fears can be valuable. The SFQ is an effective method for measuring patients' fear and may be useful to use during preoperative visits. In this way, patient satisfaction and superior results can be achieved.

### *Limitations*

Our validation study has the following severe limitations.

The most important limitation we report is that although the questionnaire assesses fear before surgery, we have tested the validity of the questionnaire only on cardiac surgery patients even if they were still undergoing elective surgery. This may have exposed our findings to a selection bias.

We did not define a sample size before the study.



However the significance of KMO index test shows that the sample size was adequate for factor analysis and that the correlation matrix was appropriate.

We report the lack of test-retest reliability, a statistical measure commonly used to assess the consistency and reproducibility of results obtained. Once a test-retest reliability coefficient has been found, the scores can be used to officially determine the stability and consistency of an assessment.

Nonetheless, the reproducibility over time, otherwise known as test-retest reliability, is just one of various methods to evaluate and measure reliability, which also includes internal consistency, inter-rater reliability and convergent validity compared to the gold-standard tool. In addition, as already reported in the discussion, there are the lack of a confirmatory analysis including the Tucker-Lewis Index (TLI).

This is a single-center validation study so we do not guarantee that fear before surgery will emerge with the same perceptions in other hospitals or settings.

Finally, we performed a parallel form reliability method between SFQ and HADS. Methodologically it was more correct to perform this test by comparing the SFQ with another scale that evaluates fear and anxiety, and not depression and anxiety. The choice of the HADS as the gold-standard comparison scale and the lack of use of The Amsterdam Preoperative Anxiety and Information Scale (APAIS) (23) in the comparative evaluation, were done because the HADS scale had been in use for some time in our hospital setting (24, 25). So even if it is not methodologically correct, we are confident that this approach makes our results very close to clinical reality and is not only suitable for the purpose of pure research.

## Conclusions

On the basis of our findings, which aimed to add the Italian version of the SFQ to the literature for cardiac surgery patients, we concluded that the SFQ can be used in the Italian culture and context, as no differences were found between the opinions of the specialists regarding the items of the SFQ that had been translated into Italian using content validity and inter observer reliability criteria. Each item can be reliably used, as confirmed by the statistically significant relationship found between the items and the questionnaire according to the total item score correlations of the items of the SFQ, which resulted in none of the items being excluded from the questionnaire. The Italian SFQ has a high

internal consistency reliability coefficient for the study sample, which means that each item represents the questionnaire. In addition, we confirm that the Italian SFQ has two subscales, as in the original questionnaire. We conclude, to summarize, that the SFQ is a valid and reliable eight-item index of surgical fear, consisting of two subscales: fear of the short-term consequences of major cardiac surgery and fear of the long-term consequences of major cardiac surgery. The SFQ can be used to determine the level of fear that patients experience waiting for a major cardiac surgery in Italy.

## Authors' contributions

All authors contributed equally to the manuscript and read and approved the final version of the manuscript. In particular, **VD** First author, principal investigator, project manager, translation of the questionnaire into Italian; **LC** and **LM**: Direct participation in the writing and revision of the article; **AD**: Writing study protocol and writing results section and tables, **LF**: Language translation review; **MM**: Final evaluation of the manuscript, bibliographic control and adherence to the journal guidelines, consistency check of responses to reviewers, **GD**: Direct participation in the writing and revision of the article, translation of the questionnaire into Italian.

## Data availability

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

## Conflict of Interest

The Authors declare that they have no conflicts of interest.

## Funding Statement

The Authors report no involvement in the research by any sponsor that could have influenced the outcome of this work.

## Acknowledgments

The Authors would like to extend their gratitude to the nurses, the patients and to the ten specialists who contributed to the evaluation of the linguistic translation, and to the cardiac-surgeons and the anesthesiologists who participated in this study.

## Riassunto

*Valutazione psicometrica della versione italiana del Questionario sulla Paura Chirurgica tra i pazienti adulti in attesa di cardiocirurgia*

**Introduzione e obiettivo.** La paura chirurgica preoperatoria è una reazione emotiva che può essere osservata in molti pazienti in attesa di sottoporsi ad un intervento chirurgico. Il questionario sulla paura chirurgica (SFQ) è stato originariamente sviluppato per determinare il livello di paura nei pazienti che devono sottoporsi a un intervento chirurgico in elezione. Questo studio si propone di testare la validità e l'affidabilità di questa versione italiana in una popolazione di pazienti in attesa di intervento di chirurgia maggiore di cardiocirurgia.

**Disegno dello studio.** Modello di ricerca metodologica.

**Metodi.** La popolazione di questo studio metodologico comprendeva tutti i pazienti che si sono presentati all'Ospedale di Lecco in Italia tra gennaio 2022 e ottobre 2023 e dovevano essere sottoposti

a intervento chirurgico valvolare, chirurgia aortica o chirurgia coronarica. Il campione ha coinvolto 416 pazienti che soddisfacevano i criteri di inclusione.

**Risultati.** I risultati delle analisi hanno mostrato che il questionario sulla paura chirurgica può essere utilizzato con due sottoscale; lo “SFQ-S”, che mostra la paura delle conseguenze della cardiocirurgia a breve termine, e lo “SFQ-L”, che mostra la paura delle conseguenze della cardiocirurgia a lungo termine. La media dei punteggi del questionario era di  $26.32 \pm 9.23$  per la SFQ-S, di  $27.62 \pm 11.89$  per la SFQ-L e di  $53.94 \pm 19.16$  per l'intero questionario. Il coefficiente di Cronbach era di 0.952 per la SFQ-S, 0.920 per la SFQ-L, e di 0.914 per l'intero questionario.

**Conclusioni.** Sulla base dei test di validità e affidabilità, riteniamo il questionario adattabile alla realtà italiana, in particolare alla popolazione in attesa di intervento di cardiocirurgia maggiore.

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