

Effect of Implementing Domestic Truth-telling Protocol on Stress, Anxiety, and Depression in Cancer Patients

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Abstract

Background: The present study was conducted to investigate the effect of implementing domestic truth-telling protocol on stress, anxiety, and depression in cancer patients.

Method: In this study, a semi-experimental design was used to examine the effect of truth-telling protocol implementation on psychological factors (i.e., stress, anxiety, and depression) in cancer patients. A total of 60 cancer patients participated in this study, 30 of them in the intervention group (who informed their disease with truth-telling protocol) and 30 others in the control group (who informed their disease with usual way and without protocol). Patients' psychological factors were compared in intervention and control groups, three and eight weeks after the cancer disclosure by depression, anxiety, and stress scale-21.

Results: In this study, except higher stress level of patients in intervention compared to the control group, no statistically significant difference was seen in other variables three weeks after cancer disclosure ($P=0.046$, $Z=-1.99$). Eight weeks after the intervention, all variables were significantly lower in the intervention group ($P=0.000$, $Z=-5.864$; $P=0.000$, $Z=-0.651$; $P=0.000$, $Z=-5.351$).

Conclusion: Exercising truth-telling practice through implementing a localized culture-based protocol, especially after passing the initial acute phase of hearing the bad news, can lead to improved psychological factors in cancer patients.

Keywords: Truth-telling, Domestic protocol, Cancer, Breaking bad news

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Introduction

One of the most challenging communication scenarios faced by physicians is the need to deliver bad news to patients.¹ According to the statistics, each oncologist announces an average of 35 bad news per month, which is over 20,000 in all his years of practice.² In a medical context, bad news is “any news that drastically and negatively changes the patient’s view of his or her future”.³ The more severe and threatening illness is, the more important is the communicative interaction in breaking the bad news to affected individuals.⁴ Cancer as a life-threatening disease, despite significant advances in its treatment or at least its control, is still considered in many cultures equal to death and its diagnosis is associated with significant fear, uncertainty, and a laborious treatment.⁵ Therefore, if bad news disclosure is not properly performed, it can influence patients’ recovery, quality of life, and relationships with health care professionals.^{6,7} On the contrary, effective bad news disclosure will result in easier acceptance of treatment, more satisfaction, and even less anxiety and emotional distress in cancer patients.^{8,9}

Developing a culture-based protocol or guideline for more effective implementation of bad news disclosure process is one of the solutions used by many Western and European countries such as the United States,^{3,10} Australia,¹¹ Canada,¹² and England.¹³ In these societies, health care professionals are trained about the fundamentals of those guidelines and protocols. Several sources, while emphasizing on the importance of teaching communication skills to health care professionals, consider that such skills can be an effective factor in reducing the anxiety of health care team members when breaking bad news and reducing stress and distress in the patients.¹⁴⁻¹⁶ One point that does not seem to be of less importance than communication skills training is the fact that the influence of this training should be assessed on the patient’s outcomes rather than improving the learning indicators and promoting learners’ skills. Stovall¹⁷ emphasizes that communication skills training models should be evaluated through their

impact on patients’ outcomes such as quality of life and their compliance with treatment instructions. However, despite the importance of this issue, few studies have surveyed it. In this regard, Paul et al.¹⁸ reviewed studies on bad news disclosure in cancer patients done between 1995 and 2009. According to this study, of 245 published articles in these years, only 41 articles (16.7%) were interventional studies. Also, of 41 articles published in this 19-year period, only 4 articles have evaluated the impact of information provided during the disclosure of bad news on the improvement of patients’ psychological conditions such as distress and anxiety, as well as increased satisfaction and quality of life.¹⁸ It should be noted that in conducted researches in Iran, no research was found to examine the impact of bad news disclosure on the psychological factors of cancer patients.

Due to the lack of localized protocols for breaking the bad news to cancer patients in Iran, the researchers of this study initially developed a protocol based on a modified Delphi study as the first phase of a mixed-method study. This protocol was performed through a qualitative study, review of the literature and gathering expert opinions. Then, as the second phase of the study, to investigate the effect of training and implementation of the developed protocol on breaking the bad news to cancer patients, the researchers measured the effects of such intervention on the psychological factors of patients (stress, anxiety, and depression). The findings of the second phase of this study are presented in this paper.

Methods

Study design

A semi-experimental design was used to examine the effect of truth-telling protocol implementation on psychological factors including stress, anxiety, and depression in cancer patients.

Patients

A total of 60 cancer patients participated in this study; 30 of them in the intervention group and 30

Table 1. Steps of the implemented protocol for the intervention group (continued)

Steps	Explanation
Assessment	The patient and their closest family member are assessed by the nurse and their initial information and pathological outcomes are recorded in special forms. The most important point that a nurse considers at this step is the patients' willingness to be informed about their disease as well as the desire of the patient's family member about informing the patient of their disease.
Planning	Based on the information obtained at the previous step (assessment), one of the three following situations was expected to occur and in each of these situations the nurse has to act as determined in the protocol: Situation A) Both the patient and his family member want to know about his/her diagnosis and agrees to diagnosis disclosure to the patient himself. Situation B) The patient wants to know about his/her diagnosis but his family member is reluctant to hear the truth. Situation C) The patient is reluctant to know his/her diagnosis and preferred to provide this information to his/her family member.
Preparation	The preparation step consists of three sub-steps: family preparation, environmental preparation, and patient preparation. Family preparation is done in "situation B. In this situation, considering the fact that the close family member of a patient is reluctant to truth-telling, a private conversation with the presence of team nurse and patient's family member is carried out in the room dedicated to the truth-telling team. The purpose of this meeting is to justify the family of the need to inform the patients of their disease. Team members try to convince patient's family member that since the patient had already remarked their tendency to be informed of his/her disease information during the assessment step, team members are bound to provide this information in the correct manner. The family member's preparation session is very vital and team members have to use their best endeavors to assure the patient's family that the information about the disease would be disclosed to the patient in a simple, step-by-step, unhurried, hopeful way, as requested by the patient and not more than their inclination. After this session and in the case of family consent, necessary measures were taken for news disclosure by the physician. It should be noted that during the family preparation session with the nurse, psychologist tries to communicate with the patient and fill the gap due to the absence of a close family member. Environmental preparation should be implemented in all three situations (A, B, and C) before any interview with the patient or the family. In this sub-step, a private, comfortable, clean room with enough chairs, tissue papers, bottles of water, glasses and without any disturbing factors is prepared for the purpose of disclosing the cancer diagnosis to the patient. Patient preparation is done when cancer disclosure session begins. The physician should ask relevant questions in order to collect a clear view of the patient's understanding of his/her medical condition.
News disclosure	The truth-telling session is held with the presence of the physician, nurse, patient, and the patient's family member. <ul style="list-style-type: none"> - Simple, clear, and non-medical language should be used, to tell the truth to the patients. - Relevant information must be disclosed step by step and in small chunks. The physician must make sure that the patient has clearly understood the information by asking questions such as "You see what I mean?" - It may help to use eye contact with patients and their family members, sit close to patients and use touch techniques such as putting your hands on their shoulder or holding their hands (if the patient and the physician are of the same sex and there are no cultural barriers). - The physician should replace the word "cancer" with words such as "malignant mass" or "malignant tumor" when disclosing the cancer diagnosis. - Although disclosure of the news should be straight and clear, it is advisable to use an expression of compassion, empathy, and respect when breaking the news. - Information about the prognosis can only be given when directly requested by the patient and his/her family, and upon establishing that the patient is ready and has the right understanding to receive it. - The physician must avoid talking about death. If the patient or the family members need to know about the estimated time of death in order to make some important decisions, rather than giving them a definite time, for example saying, "You would survive for 6 months", the physician can give them a time range that is the average of the patients' life expectancy, such as "from some days to several weeks" or "from some months to several years."

Table 1. Steps of the implemented protocol for the intervention group (continued)

Steps	Explanation
Support	<p>- Information on the prognosis must be provided with an emphasis on the positive aspects rather than negative ones. In other words, the physician should highlight what can be done rather than the things that cannot be controlled by the healthcare team members.</p> <p>- It is important to talk to the patient and his/her family about the uncertainty of the prognosis. For example, the physician can say, "I can just tell you things that usually happen to patients who suffer from a disease like yours, but I cannot predict what will happen to you with certainty".</p> <p>After disclosing the cancer diagnosis, the physician should try to provide sufficient emotional support to the patient and his/her family members. In some cases, after disclosing the news and answering the patient's questions, the physician assigns the session to the nurse and the psychologist. They will, in turn, prepare the patient and his/her family members to properly express their emotions by providing further explanation, resolving the misconceptions, finding the source of anxiety, and helping them to express their feelings more and more.</p> <p>After the truth-telling session, based on the need of the patient and their family members some sessions are held. In these sessions, the patient and his/her family members are provided with the necessary information in a simple language on the diseases, its treatment, complications, post-surgical and chemotherapy cares. In addition, important points are also provided in writing in the form of a training booklet. Furthermore, according to their needs, necessary information is provided on useful educational websites, health and counseling centers for cancer patients with their contact details. The team psychologist attends all training sessions with the patient and their family members and provides them with the necessary psychological counseling. In cases of psychological disorders, the psychologist refers the patient to the psychiatrist. All training and counseling sessions with the patient, their family members or both are face-to-face and fully tailored to their needs. The appropriate time for holding each session and their duration are adjusted according to the patient's desires.</p>
Conclusion	<p>Conclusion phase is performed by each member of the team individually; that is, the physician at the end of the truth-telling session and the nurse and psychologist at the end of each support and training sessions concluded the session with a summary of important points and answered the patient's and their family members' questions.</p>

others in the control group. The inclusion criteria for patients in this study were: confirmed diagnosis of a cancer type based on pathologic results, lack of patients' awareness of their cancer diagnosis, willingness to participate in the study, and absence of psychological disorders history. In order to take the patients' informed consent, they were told that they were receiving some information about their disease and then its subsequent effects on some psychological variables are measured. Patients who were reluctant to collaborate at each step of the study, did not want to receive any information about their disease, preferred to provide this information to their family members (C situation in the protocol) were excluded.

Compliance with ethical standards

This study was approved by the Ethics Committee of Isfahan University of Medical Sciences. We obtained verbal and written consent

from participants. All necessary measures were taken to maintain participant anonymity. We provided the participants with key information about the study purpose and emphasized that they could withdraw from the study anytime.

Physicians

Two physicians (an oncologist and a surgeon) attended in the study. Physicians were randomly selected from the list of physicians at Isfahan University of Medical Sciences. Firstly, the patients in the control group were selected for each physician. Then, the physician was asked to disclose the bad news of cancer diagnosis to them in their usual way. Next, both physicians underwent a single-session training on how to implement the truth-telling protocol. After the training session, the physicians carried out the disclosure of cancer diagnosis to the patients in the intervention group using the protocol principles

Table 2. Frequency distribution of demographic variables in intervention and control groups

		Intervention group N=30		Control Group N=30		Test
		Number	Percentage	Number	Percentage	
Sex	Female	26	86.7	25	83.3	$P=0.523$ Fisher test
	Male	4	13.3	5	16.7	
Education	Illiterate	1	3.3	3	10	$P=0.699$ $X^2=1.43$ df=3
	Less than a high-school diploma	8	26.7	8	26.7	
	high-school diploma	14	46.7	11	36.7	
	Academic	7	23.3	8	26.7	
Job	Housewife	19	63.3	19	63.3	$P=0.879$ $X^2 = 0.259$ df = 2
	Employee	8	26.7	9	30	
	Freelancer	3	10	2	6.7	
Cancer type	Gastrointestinal	5	16.7	5	16.7	$P=0.994$ $X^2=0.227$ df=4
	Breast	18	60	19	63.3	
	Ovarian	3	10	3	10	
	Hodgkin	3	10	2	6.7	
	Testis	1	3/3	1	3.3	
Age	<20	0	0	0	0	$P=0.451$ t=-0.758 df=58
	20-29	3	10	2	6.7	
	30-39	8	26.7	4	13.3	
	40-49	6	20	9	30	
	50-59	7	23.3	9	30	
	60-69	6	20	5	16.7	
	70-79	0	0	1	3.3	
Mean		46.3		48.6		
Standard Deviation		11.6		12.2		

and in collaboration with the truth-telling team. With the explanation provided by 30 patients in the intervention group, each of the physicians disclosed the cancer diagnosis to 15 patients. Therefore, of 30 patients in each intervention and control group, 15 patients were informed of their diagnosis by physician 1 and the rest by physicians 2. The samples in this research were collected through the convenience method.

Training of team members for implementation of the protocol

In addition to two physicians, a psychologist and a nurse participated in the training session for disclosure of bad news to patients in the intervention group based on the truth-telling protocol. Before running the training session, the full text of the protocol was made available to all members and they were allowed to study it

carefully for a week. The training session lasted roughly 90 minutes; with 45 minutes in the form of lecture and question and answer and the remaining 45 minutes for role-playing.

Implementation of the protocol in the intervention group

The protocol used to break the news of cancer diagnosis to patients in this study consists of six steps: patient and family assessment, planning, preparation, news disclosure, support, and conclusion. These steps are described in table 1.

Measurement of psychological factors

In this study, patients' psychological factors including stress, anxiety, and depression were compared in intervention and control groups 3 and 8 weeks after the cancer disclosure by DASS-21.¹⁹ The Depression, Anxiety, and Stress Scale-21

Table 3. Frequency distribution and comparison of depression, anxiety, and stress level among patients 3 weeks after the truth-telling in the intervention and control groups

		Intervention group N=30		Control group N=30		Z	P
		Number	Percentage	Number	Percentage		
Depression	Normal	14	46.7	18	60	Z=-0.951	0.342
	Mild	2	6.7	4	13.3		
	Moderate	7	23.3	1	3.3		
	Severe	4	13.3	4	13.3		
	Extremely severe	3	10	3	10		
	Mean Rank	32.47		28.53			
Anxiety	Normal	12	40	16	53.3	Z=-1.56	0.115
	Mild	2	6.7	4	13.3		
	Moderate	3	10	4	13.3		
	Severe	6	20	3	10		
	Extremely severe	7	23.3	3	10		
	Mean Rank	33.85		27.15			
Stress	Normal	11	36.7	21	70	Z=-1.99	0.046
	Mild	2	6.7	0	0		
	Moderate	8	26.7	2	6.7		
	Severe	6	20	5	16.7		
	Extremely severe	3	10	2	6.7		
	Mean Rank	34.62		26.38			

(DASS-21) is a set of three self-report scales designed to measure the emotional states of depression, anxiety, and stress. Each of the three DASS-21 scales contains 7 items, divided into subscales with similar content. The depression scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/involvement, anhedonia, and inertia. The anxiety scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. The stress scale is sensitive to levels of chronic nonspecific arousal. It assesses difficulty relaxing, nervous arousal, and being easily upset/agitated, irritated/ over-reactive and impatient. Scores for depression, anxiety, and stress are calculated by summing the score for the relevant items. Scores on the DASS-21 will need to be multiplied by 2 to calculate the final score.

Statistical analysis of data

In order to analyze the obtained data, SPSS software version 16 was used. Independent T-test, Fisher, and chi-square were used to compare gender, age, occupation, type of cancer, and education level. The Mann-Whitney test was

applied to compare the stress, anxiety, and depression variables in the patients 3 and 8 weeks after the truth-telling in intervention and control groups.

Results

In this study, data collection lasted for 6 months (from January to July 2016), during which the researchers attended each of physician's office three days a week. The frequency distribution of demographic variables showed that the majority of patients in both intervention and control groups were female (86.7% and 83.3%) and housewife (63.3%) with high school education (46.7% and 36.7%) and breast cancer (60% and 63.3%). In addition, the mean and standard deviation of patients' age in the intervention and control groups were 46.3 ± 11.66 and 48.6 ± 12.2 years, respectively. None of the above variables was statistically significant in both intervention and control groups (Table 2).

The findings of the study showed that among the patients in the intervention group who received their cancer diagnosis through the truth-telling team and with developed protocol, 12 patients (40%) were in situation A of the protocol and 16

Table 4. Frequency distribution and comparison of depression, anxiety, and stress level among patients 8 weeks after truth-telling in intervention and control groups

		Intervention group N=30		Control group N=30			
		Number	Percentage	Number	Percentage		
Depression	Normal	27	90	6	20	$Z = -5/351$	0/000
	Mild	2	3.3	5	16.7		
	Moderate	1	6.7	10	33.3		
	Severe	0	0	3	10		
	Extremely severe	0	0	6	20		
	Mean Rank	19.55		41.45			
Anxiety	Normal	28	93.3	11	36.7	$Z = -0.651$	0.000
	Mild	1	3.3	2	6.7		
	Moderate	1	3.3	8	26.7		
	Severe	0	0	2	6.7		
	Extremely severe	0	0	7	23.3		
	Mean Rank	21.60		39.40			
Stress	Normal	29	96.7	6	20	$Z = -5.864$	0.000
	Mild	1	3.3	6	20		
	Moderate	0	0	8	26.7		
	Severe	0	0	6	20		
	Extremely severe	0	0	4	13.3		
	Mean Rank	18.70		42.30			

(53%) were initially at situation B. However, those in situation B, after family satisfaction meeting and receiving family consent for truth-telling, moved to situation A. Two patients (7%) were in situation C, which, over time, expressed their willingness and consent to get information about the disease, and were placed in situation A. Only one patient was in situation C, who did not even agree to receive information about his illness over time. According to the mentioned exclusion criteria, this patient was removed from the samples.

Training and support sessions for patients and their family members in the intervention group were determined according to their needs. The majority of patients (40%) were provided with two sessions with the assistance of a nurse and a psychologist to receive related data about cancer, its treatment, and complications or receiving a consultation for psychological support. Nine patients (30%) had three sessions or more. The duration of support session for the majority of patients (67%) was shorter than 30 minutes. Seven patients (23%) had 30-60 minute sessions and 3 of them had sessions longer than 60 minutes (10%).

The findings of the study regarding the comparison of patients' psychological variables three weeks after the truth-telling session showed that the mean rank of stress, anxiety, and depression in the intervention group was 34.62, 33.85, and 32.47; and in the control group as 26.38, 27.15, and 28.53, respectively. Among these three variables, only the stress level of patients in the two groups was statistically significant ($P=0.046$, $Z=-1.99$) (Table 3).

Eight weeks after the truth-telling, the mean levels of stress, anxiety, and depression in the intervention group were 18.70, 21.60, and 19.55 and in the control group was 42.30, 39.40 and 41.45, respectively. All these variables were significantly different in the intervention and control groups ($P=0.000$, $Z=-5.864$; $P=0.000$, $Z=-0.651$; $P=0.000$, $Z=-5.351$). Eight weeks after the truth-telling, more than 90% of patients in the intervention group were at the normal level of stress, anxiety, and depression; while in the control group, 33.3%, 26.7%, and 26.7% of patients had moderate depression, anxiety, and stress, respectively (Table 4).

Discussion

Based on the findings of this study, three weeks after cancer disclosure to patients, the mean rank of stress in the intervention group, which informed this news through truth-telling protocol, was significantly higher than that of the control group. The reason for the higher level of stress in patients in the intervention group might be the more information provided in this group. This information includes the emphasis on the malignancy of the tumor, disease prognosis, and therapeutic methods, especially chemotherapy, and its complications. In cultures like that of Iran, where cancer is still a taboo, it may be possible that more information the patient receives on the disease, no matter how appropriate and effective it is disclosed by members of the healthcare team, the more stress it can cause in the patient, especially in the early days. The study conducted by Valizadeh et al. also confirms that patients who directly receive more information on cancer diagnosis will experience more severe but shorter stress, compared to other patients.²⁰

Three weeks after the truth-telling session, the level of anxiety and depression in the intervention group was more than that in the control group; however, there was no statistically significant difference between two groups in these variables. This finding was similar to the results of many other studies on the effect of communication skills offered to physicians for bad news disclosure on patients' anxiety.²¹⁻²⁴ Vogel et al. also found that depression score in patients with cancer was high one week after the first treatment session, but decreased over time. In fact, the patients' awareness of the disease and their satisfaction with professional communication of physician in the early stages of a cancer diagnosis can lead to less depression in the later stages of the disease.²⁵ According to the researchers, the lack of meaningful difference between anxiety and depression in intervention and control groups can be attributed to different factors. Firstly, the initial phase of questionnaire completion in many patients in intervention and control groups coincided with the onset of treatment (such as

chemotherapy or surgery). In this regard, surgery or chemotherapy is a complex and challenging step for patients, which can be the source of severe anxiety and depression. Secondly, lack of such a difference can be attributed to a high level of anxiety and depression in the intervention group to receive more information on cancer taboo, on one hand, and lack of sufficient healthcare team experience in manipulating breaking bad news protocol for disclosing this taboo, on the other hand.

Based on the findings of this study, eight weeks after cancer disclosures, the level of stress, anxiety, and depression in the intervention group who received the news using breaking bad news protocol was significantly lower than the control group. These findings suggest that despite unpleasant nature of cancer disclosure in patients, it is possible to significantly reduce the adverse effects of truth-telling on psychological variables with effective implementation of this task through teamwork with a patient-centered manner tailored to their preferences, comprehensive needs, and cultural beliefs. Many studies also confirm that patients' satisfaction with news disclosure and meeting their informational needs, as well as the proper use of supportive skills such as empathy and ability to discover emotions in patients by skills such as asking exploratory questions by healthcare professionals, are associated with reduced anxiety in patients.^{24, 26-28} In addition, various authors confirm that the psychological stress created in cancer patients is reduced through the implementation of patient-centered supportive and emotional skills by physicians, nurses, and other members of the healthcare team.^{4, 15, 29} In Iran, similar to many Asian and the Middle East countries, the main reasons for not informing cancer patients from their diagnosis are the family's view believing that patient's morale may decline after receiving the news, the fears of healthcare team especially physicians fear of inappropriate reaction of the patients (such as anger and scream) after hearing the news, and fear of the patient's family complaint for this disclosure.³⁰ However, in this study, since the

disclosure of cancer diagnosis was performed using a localized protocol based on the patients' desires and wishes, it did not cause more depression such that even the level of depression in these patients eight weeks after receiving the news was significantly lower than the control group. Among the principles implemented through the protocol in this study, one was non-use of the word "cancer" for disclosing the diagnosis and substituting it with less negative words such as "malignant mass" or "malignant tumor". These terms were used entirely in accordance with the desires of the patients and their family members and established at the stage of drafting the protocol. In addition, avoidance of talking about death, its approximate time, and other information in this regard unless directly asked by the patient, and with emphasis on positive aspects but not with the aim of creating false optimism, was another principle used by team members that were completely based on desires of patients and their family members.³¹ Many of these cultural desires are particular to Asian and Eastern cultures and do not have any implication in Western societies. For example, Scofield et al. showed that behaviors such as the use of the term "cancer", discussion on illness severity, and longevity in a news disclosure session had meaningful relations with declined level of depression in the patients, 4 and 13 months after the beginning of the disease.³² This result is completely contrary to the desires of Iranian society. Such results reveal the need for paying more attention to cultural preferences and developing localized protocols in accordance with the values of each society. Because only with careful attention to this solution about breaking the bad news, you can for sure reduce the unpleasant effects of cancer disclosure to patients and help their easier adaptation with this crisis.

Limitations of the Study

A limitation of this study is the lack of basic information about variables before the disclosure of bad news. In this research, stress, anxiety and depression variables of patients were measured only three and eight weeks after the truth-telling

session. However, to achieve more accurate and reliable results, it could be best to assess these variables before the truth-telling session. The researchers believe that prior to visiting physician, patients had various concerns about their test results; therefore, the request for filling out a questionnaire, not only does not seem ethical but also the obtained data will not be reliable. Another limitation of this study was a short follow-up period after cancer disclosure. In this research, the effect of truth-telling on patient's psychological variables was assessed only up to 8 weeks after the disclosure. Meanwhile, monitoring these variables for longer periods such as 3 to 6 months after cancer disclosure could provide researchers with more accurate and reliable information. Furthermore, the effect of antineoplastic agents on depression and other variables should be considered.

Conclusion

The society fear of creating anxiety, worry, and poor morale in the patient after cancer disclosure is a prevailing belief in many Eastern and Middle East countries that prevents cancer patients from getting informed of their disease. This challenge not only deprives them of their absolute right to get informed from their diagnosis but also causes ambiguity and confusion about their medical condition, which brings them multiple adverse effects. By emphasizing how to break the bad news (rather than hesitating on disclosing the news) and developing protocols based on the culture of each community and training of the healthcare team to effectively implement this procedure, it would be possible to avoid stress, anxiety, and depression in the long run. Moreover, it will also help the patient's better alignment with the news.

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Conflict of Interest

None declared.

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