



The Effectiveness of Psychological Therapy in Patients with Gynecological Cancer

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Abstract

Objective: The psycho-emotional burden begins when the cancer diagnosis arrives and it accompanies the women throughout the diagnostic and therapeutic path. It continues over time because the patients have to learn to accept the physical changes, the worsening of quality of life and different needs. In these cases, in fact, a supporting clinical psychological intervention is necessary to drive women through the process of adaptation of treatments, which are not always linear, but it is specific to the type of neoplasia of each patient. This study aims to evaluate the effectiveness of psychological support in patients with gynecological cancer also according to the site of the tumor, in terms of reducing levels of distress, anxiety, and depression.

Methods: Two hundred six women with gynecological cancer who were admitted to the Female Tumors Day Hospital or oncological gynecology ward of Policlinico Universitario Agostino Gemelli Foundation IRCCS were recruited. All patients completed questionnaires to assess distress, anxiety and depression at T0 and T1 times. Some of these patients had psychological support sessions between T0 and T1.

Results: A significant decrease in distress ($p=0.000$), anxiety ($p=0.000$) and depression ($p=0.000$) was observed in the psycho-oncological intervention group, instead, in the control group, no statistically significant differences were found in any of the three scales.

Conclusion: Our findings show a significant decrease in distress, anxiety and depression for the intervention groups. In line with other study, these results indicate that psycho-oncological interventions might reduce psychological distress during an inpatient stay.

Keywords: Anxiety; Depression; Distress; Efficacy; Psychological interventions; Gynecological cancer

Introduction

Whatever the diagnosis, the prognosis and the response to treatment are, there are no minor cancers. In fact, cancer always represents, for the patient and his family - but also for the therapists - a shocking existential proof. This proof concerns all aspects of life: the relationship with one's own body, the meaning given to suffering, illness, death, as well as family, social and professional relationships. All individuals suffering from neoplastic pathology experience, or can experience, a wide range of physical and psychological disorders in relation to the different moments of the path of illness and the adverse effects of the specific treatment.

Emotional difficulties such as depression, anxiety and a fear of dying have been found to be especially prevalent around the diagnosis phase and the treatment phase [1]. Cancer requires a constant and repeated effort on adaptation for the patient, more than any other disease. Cancer psychology aims to promote individual resources, coping strategies, and psychological adaptation. Psychological adaptation, in particular, aims to promote and ensure the mental and physical integrity of the patient, address modifiable disorders and integrate irreversible ones; it consists of a series of cognitive, emotional and behavioral responses. In each phase of the illness, in fact, a person's psychological reactions are the result of a complex integration between the memory of

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experiences, the perception of the future threat and the available resources. Cancer has a devastating impact not only on the patient, but also on the entire family unit, on the couple's relationship and on the children. Psychological treatment allows the patient and his family to acquire the necessary tools to manage in the best possible way the discomfort induced by the disease and any behaviors of denial and avoidance related to the course of treatment, in particular, allows you to learn techniques to recognize and manage negative emotions, dysfunctional thoughts, maladaptive behaviors and internalize effective methods of problem-solving.

Cancers affecting the female genital tract account for 10 to 15 percent of the total cancers affecting women. Regarding cervical cancer, about 3,500 new cases are diagnosed each year; cancer of the uterus corresponds to about 6,200 new diagnoses per year; ovarian cancer, meanwhile, is diagnosed in about 4,600 women per year [2].

Treatment of gynecological cancers (e.g. hysterectomy, radiotherapy of the pelvis, bilateral oophorectomy) may also induce other psychological effects, including depression.

To improve cancer care, the management of patients with gynecologic cancers is increasingly important. Indeed, evidence suggests that once women are in the health care system, more energy must be expended to help them cope with the great impact of the diagnosis and the treatments they must undergo [3]. It is known, for example, that women undergoing cancer treatment may not only experience psycho-physical symptoms for up to a year after diagnosis, but also often report lack of access to adequate support [4,5].

Patients with gynecological cancer experience a range of psychological difficulties, related not only to the lowering of mood, the sense of overall psychophysical loss, the patient's characteristic passive attitude, etc., but also and above all to the sense of loss of female identity, early menopause, infertility, altered couple life and social isolation [6].

The psycho-emotional burden begins when the diagnosis arrives and accompanies the woman during the entire diagnostic and therapeutic pathway; afterwards, this psychological discomfort continues over time because patients must learn to accept physical changes, quality of life, balances and different needs. Often in these cases, in fact, a supportive clinical psychological intervention is necessary to guide the woman in the process of adaptation to a treatment that is not always linear, but is specific for each patient and type of neoplasm.

The psycho-oncological intervention guarantees to cancer's patients and their families, a better quality of life, solid support during the illness, a better management of emotions and a total psychosomatic assistance. It also has been shown a significant decrease in anxiety and depression even with only one psycho-oncological therapy intervention, confirming that psycho-oncology interventions can reduce the wide range of psychological and psychosomatic distress during the hospital stay, thus contributing to a more functional care pathway [7,8].

By the way, research on effectiveness in institutional contexts presents different kind of problems concerning the scientific need to standardize some situations, such as: heterogeneity of cared out patients, different kind of proposed treatments (that may have variable duration), comorbidity with other clinical situations, double diagnoses, different clinicians and their intervention techniques. Any

kind of planning of psycho-oncological interventions has to balance the needs of less intrusiveness of research in clinical work with the need to use measures quantitative and repeated over time.

In our gynecologic oncology department, a psychologist with proven experience with cancer patients is available for all patients. Psychological support aims to reduce the emotional impact of gynecologic cancer on patients. The aim is to help patients cope with the disease and improve their QoL. This is a service assessment project in which we routinely assess patients psychologically and hypothesize that patients will benefit psychological support during their pathway of care.

The main objective of this study was to assess patients' distress, anxiety, and depression at admission to the ward or Day Hospital and reassess them at discharge to investigate whether psychological support interventions had achieved the goal of reducing these levels of psychological distress. In the current study, then, our first hypothesis was that distress, anxiety and depression can be reduced more efficiently by a psycho-oncological therapy session.

Methods

Participants

Two hundred and six women with gynecological cancer were considered in this observational study. All patients were afferent to the Female Tumors Day Hospital or oncological gynecology ward of Policlinico Universitario A. Gemelli Foundation.

As per standard daily clinical activity, all patients were given questionnaires to assess levels of distress, anxiety and depression, upon their admission to the ward or day hospital (T0) and subsequently after 28 days (T1). Interested patients provided informed consent approved by Institutional Ethical Committee of Fondazione Policlinico Gemelli.

Of these patients, 103 conducted at least 4 psychological support interviews between T0 and T1. These patients received psychological support either because it was expressly requested by them, or because it was necessary on the basis of the scores obtained in the T0 questionnaires or even because it was requested by the ward doctors. The control group did not carry out the psychological support interviews because, even if their scoring was over the cut-off, the patients themselves refused psychological support, this is the reason why randomization process was not used for the group allocation: We simply observed a natural distribution of patients in two different groups, those who decided to have psychological support, and those who did not. And then we compared the scoring between the groups.

Participants were recruited according to the following inclusion criteria: 1) age \geq 18 years; 2) diagnosis of ovarian, endometrial or cervical cancer; 4) active oncological treatment. Exclusion criteria for were the following: 1) previous or current psychiatric diseases; 2) age $>$ 75 years.

The characteristics of the sample were reported on Table 1. The two populations were homogeneous in age and diagnosis (Table 1), as well as the scores obtained for the T0 tests (Table 2).

All procedures were approved by Institutional Ethical Committee of Fondazione Policlinico Gemelli (Prot. ID 3273, N. 0030653/20).

Measures

All patients were assessed with two questionnaires, the aim of

measures were distress, anxiety and depression state.

The Hospital Anxiety and Depression Scale (HADS) [9] is a self-report questionnaire investigated Anxiety (HADS-A) and Depression (HADS-D), and consists of 14 items, 7 for assess anxiety and 7 for assess depression and has proven validity and reliability [10]. Both HADS subscales consist of 7 item answered on a 4-point likert scale (from 0= lack of symptom to 3= maximum severity, resulting in scores from 0 to 21. A score of 0 to 7 is considered normal anxiety or depression, score of 8 to 10 is considered borderline abnormal and 11 to 21 abnormal.

The Distress Thermometer [11,12] is a questionnaire for the evaluation of psychosocial distress in cancer patients. Is a single anchor item, which evaluates the emotional distress perceived by the patient, through an analogue-visual scale (thermometer with score 0 to 10) plus a list of problems listed in five areas (practical, family, emotional, spiritual-religious and physical problems).

Psychological intervention

Concerning the psycho oncological sessions that some patients have carried out, as described above, these are aimed to guarantee an emotional hold back "space" and promoting psychological adaptation. Psychological adaptation consists of a series of cognitive, emotional and behavioral reactions and it aims to ensure patient's psychic and physical integrity, deal with modifiable disorders and integrate irreversible ones. In each phase of the illness, in fact, a person's psychological reaction is the result of a complex integration between the memory of past experiences, the perception of the future threat and the available resources.

Through psychological intervention we try to reduce anxiety, to clarify perceptions and misinformation that can sometimes be dangerous; we help people to feel less inept and challenged, encouraging them to become more responsible and responsive to medical treatment. In particular, in this study we proposed almost four psychological interventions, structured in a ward/dh setting with one interview per week.

The psycho-oncological approach was based on psychodynamic principles: (a) accounting for the person's internal developmental process, (b) accounting for adaptive mechanisms, (c) accounting for the foundations (including unconscious) on which attitudes and behaviors are based and develop, (d) allowing the person to become aware of internal dynamics. The objective of this approach is to help patients to "restructure" themselves, to become more aware of their experiences, helping them to process the diagnosis and related emotions that risk interfering with the path of treatment.

During these interventions, patients are encouraged to identify the emotions they are feeling and to recognize and process thoughts and behaviors functional and dysfunctional to the cancer care pathway.

Statistical methods

The scoring of the questionnaires was performed according to the test manuals. To compare the groups and check their homogeneity considering age the T-test for non-parametric sample was applied, considering diagnosis and levels of distress, anxiety and depression at baseline was used the χ^2 -test for nominal variables, as appropriate.

Results were expressed as *p* value, arithmetic means with Standard Deviations (SD) or frequencies with percentages. Changes over time in each group were ascertained by non-parametric McNemar test for

nominal variables.

The statistical analysis was conducted to verify whether there were statistically significant differences between scores obtained at T0 and those obtained at T1, both for the group that carried out the psychological support and for the control group. The same analysis was performed within both groups in order to take into account the diagnosis.

The sample size was calculated in order to compare the results obtained at the 2 times by the patients divided into two groups. Whereas, $\alpha = 0.05$, power = 80%, 2 groups, 2 measurements, a sample size of $N=180$ (90 per group) is sufficient to intercept an effect size of 0.15.

Probability (*p*) values were considered statistically significant for a <0.05 value. IBM SPSS Statistics, version 25 was used for all the analysis.

Results

We analyzed the treatment effect on distress, anxiety and depression (T1 vs. T0) separately for each group, each made up of 103 patients. The means and SD, as well as the probability (*p*) values for statistical difference, for distress, anxiety and depression at the beginning and at the end of the hospital stay are shown in Table 2. As shown in Table 2, the two groups were statistically homogeneous in terms of scores obtained at distress ($p=0.161$), anxiety ($p=0.366$) and depression ($p=0.374$) levels at time T0.

A significant decrease in distress ($p=0.000$), anxiety ($p=0.000$) and depression ($p=0.000$) was found in the group that carried out the psychological support interviews. On the other hand, in the control group no statistically significant differences were found in any of the three scales (DT: $p=0.161$; HADS A: $p=0.366$; HADS D: $p=0.374$).

The control group and the group that carried out the psychological support interviews were compared on the basis of the scores obtained in the DT test to assess distress and the HADS test to assess anxiety and depression.

The McNemar test, on the other hand, highlighted the differences in test results at T0 and T1 times in both populations.

Discussion

This study aims to investigate the effectiveness of psychological therapies intervention in gynecological cancer patients as a routine

Table 1: Characteristics of the sample.

	Experimental Group (n=103)	Control Group (n=103)	P value
Age M (SD)	53.6 (12.6)	49.7 (12.8)	0.274
DT M (SD)	7.7 (1.6)	6.6 (2.1)	0.161
HADS A M (SD)	12.7(3.9)	9.0 (3.8)	0.366
HADS D M (SD)	11.7 (4.0)	8.1 (3.0)	0.374
Diagnosis N(%)			0.429
Ovary	70 (68)	58 (56.3)	-
Cervix	14 (13.6)	18 (17.5)	-
Endometrium	8 (7.8)	15 (14.6)	-
Vulva	6 (5.8)	7 (6.8)	-
Uterus	5 (4.9)	5 (4.9)	-

Table 2: Distress, anxiety and depression scores in Study and Control group.

	M (SD)						P value		
	DT T0	DT T1	HADS A T0	HADS D T0	HADS A T1	HADS D T1	DT	HADS A	HADS D
Study group									
Entire group	7.7 (1.6)	5.3 (1.6)	12.7 (3.9)	11.7 (4.0)	8.4 (3.0)	7.9 (3.4)	0.000	0.000	0.000
Ovary	7.8 (1.6)	5.3 (1.6)	12.5 (3.8)	11.7 (4.1)	8.5 (3.0)	7.8 (3.0)	0.000	0.000	0.000
Cervix	8.0 (1.8)	5.6 (1.4)	13.7 (4.7)	11.9 (4.4)	8.5 (3.8)	8.9 (5.3)	0.031	0.031	0.002
Endometrium	7.0 (1.5)	5.0 (1.3)	12.4 (4.2)	11.8 (3.7)	7.4 (2.5)	7.3 (3.3)	0.500	0.031	0.125
Vulva	9.0 (0.0)	4.3 (0.6)	13.0 (2.6)	10.3 (3.1)	8.7 (2.1)	8.7 (1.5)	0.250	0.500	0.250
Uterus	7.3 (1.5)	5.3 (0.6)	13.3 (6.1)	13.0 (3.6)	7.7 (2.1)	5.3 (2.5)	0.250	0.250	0.250
Control group									
Entire group	6.4 (2.3)	5.8 (2.0)	8.6 (4.2)	6.9 (4.1)	6.5 (3.6)	6.1 (3.1)	0.161	0.366	0.374
Ovary	6.1 (2.4)	5.4 (1.7)	8.3 (4.0)	6.8 (4.0)	6.4 (3.6)	5.9 (3.1)	0.180	0.289	0.013
Cervix	6.9 (1.1)	7.1 (1.7)	9.4 (3.9)	7.2 (3.9)	6.8 (3.0)	6.6 (3.0)	0.016	0.508	1.000
Endometrium	6.4 (3.0)	5.4 (2.2)	8.2 (5.1)	6.3 (4.5)	6.2 (4.2)	6.1 (3.3)	0.625	1.000	0.250
Vulva	8.3 (1.1)	7.4 (1.8)	10.7 (3.6)	8.9 (4.1)	7.9 (4.0)	7.0 (2.9)	1.000	0.625	1.000
Uterus	2.4 (3.7)	1.8 (2.9)	2.8 (5.7)	2.6 (4.7)	2.2 (4.4)	2 (4.5)	1.000	1.000	1.000

service. We used a psychodiagnostic evaluation consisting of the distress thermometer to assess distress levels and the HADS test to assess anxiety and depression levels.

In the current study, our first hypothesis was that distress, anxiety and depression can be reduced more efficiently by a psycho-oncological therapy session. Patients who carried out at least four psychological support interviews reduced the levels of distress, anxiety and depression in a statistically significant way when compared with a non-intervention group. In general, the study confirmed the effectiveness of the psycho-oncological interviews thus replicating previous results [8].

A similar study by Powell et al. [7] involving women with gynecologic cancer focused on the effect of a 1-h psychosocial intervention on specific psychosocial outcomes including anxiety and depression. The authors reported a decrease in anxiety and depression scores in the intervention group and a decrease in anxiety, but an increase in depression, in the control group without the intervention. All patients were included in this study, regardless of their anxiety and depression scores [8].

Cancer patients face multiple physical, social, psychological, and emotional issues such as anxiety and depression after diagnosis and during treatment. In fact, as Toscano points out [13] the most frequent direct expressions of the oncological patient's crisis seem to be: Denial, as a denial of one's disease and an obstacle to adherence to the treatment pathway; anxiety, as a fear of death, loneliness, loss of physical abilities; depression as resignation, loss of motivation.

Accordingly, the psycho-oncological therapy we perform in our routine work is offered in an attempt to provide cancer patients with aid in alleviating their psychological distress and adjustment. These therapies include counseling and formative role-playing, problem solving and coping strategies, storytelling, and emotion processing.

However, the evidence on their effectiveness appears to be contradictory. In fact, some studies support that psychological treatments can attenuate depressive, anxiety and distress symptoms in cancer patients, while other studies do not support their role [8].

Our findings show a significant decrease in distress, anxiety and depression after the psychological sessions. In line with other study [8], these results indicate that psycho-oncological interventions might reduce psychological distress during an inpatient stay. This is because an "emotional containment space" could help patients to explore their emotions, to recognize and express them. In addition, psychological support is also useful because through an appropriate intervention it is possible to explore and assess the resources and needs of the patient, the socio-environmental context in which he/she is inserted and the expectations with respect to the oncological treatment pathway. In fact, the psychological activity in the hospital context focuses mainly on the management of anxiety-depressive disorders of a reactive nature and not specifically of personality traits.

The patient's well-being can be damaged as much by physical illness, which can penalize functioning in important areas of life (work, daily activities, family relationships), as by psychological discomfort or symptoms. In these cases, therefore, individual psychotherapy can help the patient to learn process and know his condition and to identify ways of thinking and behaving to deal effectively with critical situations.

Study limitations

A limitation of our study is the lack of homogeneity of diagnoses within each sample. In fact, due to the statistically higher number of hospitalizations of patients with ovarian cancer compared to other types of tumors, a number of patients too different for diagnosis were considered in the study, and this did not allow verifying whether the psychological support was more effective in specific pathologies.

Clinical implications

Our study has shown that in the current continuum of gynecological cancer care, in order to achieve an optimal outcome of the patient's treatment path, psychological care must be included.

Our results have in fact highlighted the usefulness of psycho-oncological interviews to reduce the levels of distress, anxiety and depression of patients with gynecological cancer.

The important message of this study is therefore that in order

to ensure an "all-round" treatment of the patient it is necessary to include psychological treatment among all medical care.

Conclusions

This finding suggests that incorporating psychosocial services as an integrated part of the new patient consultation may be very important to address patient's distress. In fact, this study highlights the importance of an attitude of psychological intake of patients with gynecologic cancer during their course of care with the aim of improving the psychological conditions of a complex population with greater physical and psychological vulnerability. Future studies with larger sample sizes may reveal more significant differences.

On the basis of the results we would like to evaluate the impact of psycho-oncological therapy before and after surgery in patients with gynecological cancer, with or without maternity experience.

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