

HAPPY – Humanity Assurance Protocol in interventional radiotherapy (brachytherapy) – an AIRO Interventional Radiotherapy Study Group project

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Abstract

Purpose: Interventional procedures may produce emotional distress, particularly in interventional radiotherapy (IRT, brachytherapy – BT). This work would like to propose a series of recommendations/interventions to guarantee a human approach in order to favor the psychological well-being of the patient during interventional radiotherapy.

Material and methods: Thirty patients affected by gynecological cancer and treated with endovaginal high-dose-rate IRT (HDR-IRT) were selected from January to March 2019. A specific Multiprofessional Task Group (MTG) was defined in order to analyze the needs of patients. Each component of the task group spoke with the patients to examine their needs and to investigate their fears and perception. The results of the MTG were subjected to evaluation by an Expert Team (ET) of 4 physicians from 4 different institutions for a final evaluation. Both teams discussed the patient's needs to generate a list of necessary interventions to fulfill every single need in order to obtain their inner well-being. Another team (Master Team – MT) performed an independent check.

Results: All patients suggest that the main issue is the "lack of information and fear of the unknown". The fear of feeling pain was a significant source of concern, sadness, and vulnerability for the majority of the patients (76.6%). All patients do not appreciate the use of the word "bunker" to describe the treatment place. In 33.3% of patients the word "brachytherapy" (often unknown) determines insecurity while the term "interventional radiotherapy" reassures. Ninety percent of patients preferred to perform the external genital depilation at home and 80% of them would like the bladder catheter to be placed immediately before the procedure. MTG and ET defined nine "HAPPY recommendations". The MT approved the protocol without changes.

Conclusions: The aim of the present paper was to produce a protocol consisting in intervention that could improve the internal serendipity and emotional state of patients who underwent HDR-IRT.

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Key words: emotional distress, human approach, endovaginal high-dose-rate IRT, patient perspective.

Purpose

Interventional procedures may produce emotional distress (e.g. anxiety and depression) particularly in

interventional radiotherapy (IRT, brachytherapy – BT) because patients are not always asleep and sedated and therefore live the entire procedure with stress. The anxiety and depression may reduce compliance with treat-

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ment, could prolong hospitalization and compound the physical consequences of the disease. The patient's psychological status during the procedures can influence the clinical outcome [1,2,3].

Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) are currently extremely relevant in cancer management and therapeutic choice. In the scenario of personalized medicine [4,5,6,7,8], a multidisciplinary approach is necessary to ensure that patients will be fully informed about treatment but also to obtain their inner serendipity. Instead of that, several studies have been focused on informational needs, time spent to do that, and treatment options [9,10,11,12,13] but there is just sparse research on patients' expectations on treatment, quality of life during and after procedures, reported outcomes and experiences [14].

Thus, it is fundamental to explore the patients' values and perspectives, as these are associated with treatment satisfaction, improved disease perception, anxiety, depression, improved quality and quantity of life [15,16,17,18]. Moreover, a link has been observed between patient satisfaction with the quality of service provided and at the same time survival outcomes related to several oncological settings [19,20,21,22].

Women affected by cancer fear a recurrence, feel sexual dysfunction, identity disturbance and high psychological distress [23]. There are several sources of evidence about how gynecological cancer patients experience physical and psychological symptoms, such as uncertainty, anxiety and depression [24].

Recently, the literature has focused on gynecologic cancer survivors and the information needs of this population [25,26,27]. Stewart *et al.* showed that psychological variables and disease severity are related to an increased desire of information and shared decision-making, and a component of decision-making was patient treatment preference [27]. Many patients seem to have difficulties in formulating their questions and being crucially involved in the treatment decision-making process [28,29]. If patients do not feel adequately involved, lower satisfaction, increased decisional regret and anxiety can be the consequences [30]. Despite the high need for research in the field of doctor-patient communication, there are only a few studies addressing these aspects in gynecological cancer patients [31].

The aim of our study was to examine the needs of patients and their values, expectations and preferences among patients affected by gynecological cancer, focused especially on physician-patient communication and treatment approach, as well as on the need for information concerning therapy effectiveness, side effects, toxicities, by the analysis of collected data as means of generating working hypotheses. This paper would like to propose a series of interventions/recommendations (HAPPY - Humanity Assurance Protocol in interventional radiotherapy) to guarantee a sensitive approach in order to favor the psychological well-being of the patient during interventional radiotherapy. The project was conceived and implemented within the framework of the study group of BT, interventional radiotherapy and intraoperative radiotherapy (IORT), of the Associazione Italia-

na di Radioterapia ed Oncologia Clinica (AIRO - Italian Association of Radiotherapy and Clinical Oncology).

Material and methods

A specific Multiprofessional Task Group (MTG) was defined in order to analyze the needs of the patients. The MTG is composed of 1 interventional radiation oncologist (VL), 1 geriatric oncologist (GFC), 1 nurse (SS), 1 psychologist (AT), 1 resident in radiation oncology (GP) and 1 RT technician (PC). The multiprofessional structure was chosen to assess the needs of different perspectives (multi-dimensional approach). Indeed in our institution, the patient meets during the treatment, routinely, these professionals.

A total of 30 patients affected by gynecological cancer (25 endometrial and 5 cervix) and treated with endovaginal high-dose-rate IRT (HDR-IRT) at Interventional Oncology Center (IOC) of Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy were selected from January 2019 to March 2019.

All patients were treated following the institutional internal protocol that provides, before the implant, external genital depilation, perineum sterilization and bladder catheter positioning in order to have a similar bladder filling during the sessions following the first and for better contouring of the bladder. Based on the gynecological examination, the size of the vaginal applicator is chosen (median diameter 3 cm; range 2.5-3.5) and then it is fixed with a specific vaginal block. Usually we use local transmucosal anesthesia for reducing the applicator pain. Then a rectal probe is inserted, and 3D-CT is performed for treatment planning. After the procedure the bladder catheter is removed. The institutional interventional radiotherapy protocol in adjuvant settings is different from the exclusive IRT as well as from the boost after external beam radiotherapy (EBRT) protocol. The boost after 45 Gy EBRT is delivered with 5 Gy in 2 fractions prescribed to 0.5 cm from the surface of the applicator, while the exclusive IRT is delivered in 6 Gy \times 4 fractions prescribed to 0.5 cm from the surface of the applicator.

Each member of the MTG spoke with the patients to examine their needs and to investigate their fears and perceptions. We performed several independent multi-dimensional conversations with the patients. Every conversation started with a simple question: "What makes this therapy uncomfortable for you?". This process was repeated with each member of the multi-professional team and for each patient. Every patient has had 6 different conversations, which results in a total of 180 conversations. In this way, we applied a multi-dimensional approach to interpret the real needs of patients. After this step, the MTG planned two meetings: the first one to collect, after a long discussion, all the needs coming from patients and to identify common general needs (clusters); the second one, after 15 days, to finalize the classification selecting the needs more represented as result of the 180 multi-dimensional talks (definitive clusters).

The results of the task group were subjected to evaluation by an Expert Team (ET) of 4 physicians from 4 dif-

ferent institutions for a final evaluation (VDS – Rome, VF – Rionero in Vulture, FB – Brescia, CV – Trieste) for a final evaluation. Both teams discussed the patients' needs to generate a list of necessary interventions/recommendation to fill every single need in order to obtain their inner well-being (Table 1).

The interventions list has been defined HAPPY (Humanity Assurance Protocol in interventional radiotherapy). It consists of a protocol that could be adopted by the centers to guarantee humanity and better-quality care and compliance with therapeutic proposals.

Finally, a Master Team (MT) composed by the Chair of Brachytherapy, Interventional Radiotherapy and IORT study groups (LT), a member of AIRO Committee

(MAG), the Chair of the Scientific Commission of AIRO (RC) and the AIRO president (SMM) performed an independent check of the project and endorsed it. The project phases are described in Table 2.

Results

Thirty patients affected by endometrial cancer (83.3%) and cervix cancer (16.7%) were interviewed. The median age was 62.5 years (range 39-83 years). All patients had upfront surgery followed by adjuvant external beam radiotherapy plus HDR-IRT (66.6%) or HDR-IRT (33.4%) alone as exclusive treatment after surgery. Each member of the MTG has collected on average 3 needs/issues (range 2-8). The MTG defined 8 general clusters.

Table 1. General cluster and HAPPY interventions/recommendations

	Patient's needs/issues general clusters	HAPPY interventions/recommendations
1	Lack of information and the fear of "unknown"	Procedure information booklet, possibly with FAQs, and sharing patient story, to be delivered many days before the therapy Improving the patient's participation in therapeutic choices also using decision support tools and discussing predictive models
2	Comfortable and relaxing environment	Possibility of hearing music chosen by the patient and/or watching relaxing videos
3	Ability to reduce anxiety	Psychological support in the interventional room and/or prescription of anxiolytics if necessary
4	Fear of the word "Bunker"	Use alternative words like "Interventional Room" or "Treatment Room"
5	Use of the word "Brachytherapy" often not known and heard for the first time by the patient	Use a more conventional term such as "interventional radiotherapy"
6	Embarrassment over external genital depilation (if necessary) in the interventional room	Suggestion to perform external genital depilation at home
7	Discomfort due to the long maintenance of the bladder catheter	The bladder catheter will be placed in the interventional room just before the procedure
8	Sense of loneliness in the room	If possible, an operator holds the patient's hand during the applicator positioning and plans optimization making human proximity perceived

FAQ – frequently asked questions

Table 2. Project workflow

Phase	Team's name	Team members	Task
1	Multiprofessional Task Group	1 interventional radiation oncologist 1 geriatric oncologist 1 nurse 1 psychologist 1 resident in radiation oncology 1 RT technician	Patient interview Clusters needs definition
2	Expert Team	4 physicians from 4 different institutions	Multiprofessional Task Group results evaluation
3	Multiprofessional Task Group + Expert Team	Multiprofessional Task Group members Expert Team members	Discussion on the patient's needs Generation of a list of necessary interventions (HAPPY)
4	Master Team	Brachytherapy, Interventional Radiotherapy and IORT Study Group Chair AIRO Committee Member Chief of AIRO Scientific Commission AIRO President	Project independent check Endorsement

IORT–intra-operative radiotherapy, HAPPY – Humanity Assurance Protocol in interventional radiotherapy, AIRO – Italian Association of Radiotherapy and Clinical Oncology

Based on the internal procedure the patient received 2 conversations regarding the procedure and for signing the informed consent: one during the first patient evaluation and another on the day before the procedure. Although 70% of the patients reported that they had received very good information about the procedure before the treatment (first moment) and all patients reported that the information had been completed in the second discussion (the day before the procedure) with the physicians, 100% of the patients suggested that having a small book of explanations can decrease the possible "lack of information and fear of the unknown" because not all the information can be understood the first time, so they can read it calmly at home".

This issue could be managed using a procedure information booklet, possibly with FAQs (frequently asked questions), to be delivered before the therapy. Not knowing what to expect and the fear of feeling pain were a significant source of concern, sadness, and vulnerability for most of the patients (76.6%). They felt that sharing stories with other patients, at the same time, helped to provide reassurance as well as a sense of community or family. All patients did not appreciate the use of the word "bunker" used to describe the treatment place. In 33.3% of patients the word "brachytherapy" determined insecurity because it was often the first time they heard this term, while the term "interventional radiotherapy" reassured because it was more familiar and meant a minimally invasive procedure. Ninety percent of patients preferred to perform the external genital depilation at home and 80% of them would like the bladder catheter to be placed immediately before the procedure, avoiding a long stay with the catheter in place.

The anxiety, fear, worry, and vulnerability could be decreased through psychological support and creating a comfortable environment, and setting up a monitor in the room with which the patient could listen to music or watch videos.

The expert group accepts the classification without changes. MTG and ET defined nine HAPPY interventions/recommendations as reported in Table 1. The Master Team approved the protocol without changes.

Discussion

The present paper is focused on the lack of knowledge related to the needs and expectations of patients affected by gynecological cancer, with the aim to hypothesize solutions able to improve the patients' emotional and sensitive status. Positive behavior may improve patient-physician communication and lead to shared clinical decision-making, better quality care and compliance with therapeutic proposals. Each staff member has an important role in the patient's management: the physician and the residents are an essential source of information as well as symptom management; the psychologist provides psychological support; the nurses and medical radiology technicians are fundamental to reassure and accompany patients during treatment. All the staff together helps coping with the disease [32,33,34,35,36,37,38].

Shared decision-making is based on the interaction between physician and patient, while the patient's treat-

ment choices are influenced by different factors such as age, socioeconomic status, educational level, language, country-specific data such as geographic area, urban or rural context, spirituality, gender, sexual orientation, occupation, and disability defined culture [39,40]. Cultural factors shape patients' perceptions of disease and their responses to treatments [41,42]. Several studies have found that the involvement of patients in the decision is a strong indicator of satisfaction, and the decision-making process can be improved if patients are aided in understanding treatment options [30,43].

The choice of the physician to decide which type of information has to be shared with the patients may be influenced by the physician's perception of how the patient has understood information, the relationship with the patient, the physician's perception of the patient's vitality, the patient's information-comprehension and emotional well-being. On the basis of these data the physician can use explanations tailored or framed on the patient's features and ability or understanding or analogies used to clarify the information given. The autonomy of cancer patient is always related to/limited by their social and cultural scenario, beliefs, and social status [30,43].

Physicians, moreover, share the information with the patients also on the basis of the patient's age or socioeconomic status. Step et al. conducted an observational study on 40- to 80-year-old patients with breast cancer. The study results showed that physicians communicated with older patients in a more direct, slower manner than with younger patients, giving to older patients a single treatment recommendation while they gave more treatment options to younger patients [44]. The behavior of patients in the various age groups is also different. Younger patients appear to be more demanding, while older patients required less information [45,46,47,48,49]. Probably, to overcome the problem of "incomplete or not understandable" information, a complete informative booklet or brochure could help [50,51].

Even if today we tend, guaranteeing radiation protection, to perform treatments, based on technology and type, in protected areas with a less claustrophobic impact, another important point is the environment and the atmosphere in which the patients underwent the treatment. Music therapy may aid in anxiety management [52] and may be especially beneficial in cases of high baseline anxiety; it may produce significant anxiety reduction in only 5 minutes [52,53,54]. The preferred music may stimulate the relaxation response through activation of the parasympathetic system, because it delivers what is expected. Familiar melodies may help to relieve the stress, restoring balance to the autonomic nervous system [52,53,54].

Another concern of patients was the fear of feeling pain during the procedure [55,56]. Several studies have demonstrated the clinical potential offered by psychological interventions [57,58,59], especially in the context of pain, documenting a significant association between anxiety/depression scores and pain [60,61,62]. The phenomenon of placebo analgesia is entering routine clinical practice [63] because it was shown that placebo analgesia uses similar neurobiological mechanisms as those of pharmacological analgesic treatment [59,60,61,62]. Interventions that op-

timize treatment expectations and thus engage placebo mechanisms reportedly have a medium to large effect on experimental and acute procedural pain [64]. Furthermore, various aspects of doctor–patient communication, including the number and duration of medical briefings as well as warmth and empathy of communication, demonstrably increase the magnitude of placebo effects [61,65,66]. Another finding supported by the literature which was mentioned by participants during focus groups was the importance of having family or friends present at appointments [67].

The complexity of cancer care potentially enhances some of the inherent tensions in all patient–doctor communication. The use of the same words may produce misunderstanding between doctors and patients but also may create unfounded fears [40]. The patients need to understand not only the meaning of the word but also its potential limitations. The patient and the physician, therefore, must often negotiate between their different views of illness and of health to achieve their common therapeutic aim. Further studies should focus on these aspects using a well-planned structural method to provide evidence for a tailored clinical approach.

Conclusions

The aim of the present paper was to produce a protocol consisting in interventions/recommendations that could improve the internal serendipity and emotional state of patients undergoing HDR-IRT. The staff's role is important not only as a source of information about the disease but also in coping with the disease.

Disclosure

The authors report no conflict of interest.

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