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The fitness to work certificate in a worker exposed to ionizing radiation with an oncological disease: criteria and assessment process

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Abstract – To assess the fitness to work certificate in employees both affected by neoplasia and exposed to ionizing radiation always represents a clinical and professional issue, as well as human and social. The aim of our study is to analyze the case of a 40-year-old clinician (woman, endoscopist, gastroenterologist) who underwent left mastectomy and breast reconstruction with a tissue expander, professionally exposed to ionizing radiation. Due to the presence of the BRCA1 gene mutation and the presence of breast and ovarian cancer familiarity, the patient also underwent a prophylactic right mastectomy and bilateral oophorectomy. According to Italian legislation and international guidelines, several elements and criteria have been taken into account to release the fitness to work certificate in this peculiar case of a female worker exposed to ionizing radiation, resulting in a final positive indication.

Keywords: fitness to work / occupational exposure / cancer / radiation protection

1 Introduction

The ageing of working populations has many epidemiological consequences, including an increased incidence of neoplastic diseases among several categories of workers. Thus, it is more frequent than in the past that the Approved Physician (*i.e.* the clinician licensed to carry out the health surveillance of workers exposed to ionizing radiation, “Autorizzato” according to Italian legislation definition) has to judge working fitness in employees suffering from cancer and at the same time are exposed to ionizing sources. These lasts have been observed to increase the risk of secondary cancer in different clinical situations, such as for instance in patients treated for hepatocellular carcinoma (Kim *et al.*, 2014), and thus the use of ionizing radiation has to be justified, optimized, and limited (Giraud *et al.*, 2009).

The assessment of the fitness to work certificate in employees both affected by neoplasia and exposed to ionizing radiation always represents a clinical issue, as well as human and social. For the occupational physician this process could be a challenging and delicate professional task (Taino *et al.*, 2014; Malesani and Guglielmi, 2017). Our aim is to describe the process and conclusions of an exemplary case of a female worker who underwent left mastectomy, a prophylactic right

mastectomy and bilateral oophorectomy, who successively wanted to return to work in a task professionally exposed to ionizing radiation.

2 Materials and methods

According both to AIRM (Italian Society of Medical Radioprotection) guidelines (AIRM, 2013) and to results of previous studies (Taino *et al.*, 2014; Malesani and Guglielmi, 2017), several elements have to be considered to carefully analyze a specific case in order to evaluate the assessment of fitness in workers affected by neoplastic disease whose job task induces an exposure to ionizing radiation. Four different areas have been taken into considerations (Taino *et al.*, 2014), and their features are presented in the following.

2.1 Characteristics of the neoplastic disease

- Time since the neoplasia has elapsed from clinical onset (< 5 years or ≥ 5 years);
- neoplasia target organ;
- histological type, degree of differentiation and TNM staging of the neoplasm;
- oncological prognostic judgment (probability of recovery or recurrence at 5 years) after the ascertained clinical and instrumental remission of the disease;

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- rank of the neoplasm within the radioinducibility scale;
- evaluation of the causal probability by using the “Probability of Causation” (PC) method.

This first partial judgment can be either favorable or not favorable.

2.2 Health condition of the worker

- Presence of any coexisting diseases not directly related to cancer that can affect the overall health of the worker and/or influence the outcome or the ongoing recovery of treated neoplastic disease;
- evidence of any previous chemo or radiation treatment that can make non-significant (or, conversely, counter indicate) an occupational exposure to ionizing radiation;
- worker psychological condition, important for identifying an alternative work placement without risk from ionizing radiation, also suitable for the employee qualification;
- evaluation of worker qualification, his contract position and career, and also the worker’s will regarding his occupational future.

This second partial judgment can be either favorable or not favorable.

2.3 Work activities and tasks carried out by the worker

- Analysis of the work tasks performed within the specific task, analysis of the prevention and protection measures in place, risk extent in standard working conditions and in potential exposure situations following an accidental event;
- radiation protection classification performed by the qualified expert (not exposed, B category, A category);
- type of potential exposure: partial external irradiation, global external irradiation, possible internal contamination (specific organs or apparatuses affected by possible internal contamination);
- use of individual protection devices to avoid the exposure of the area of the previous neoplasm (for example the possibility of using a suitable “collar” for thyroid protection).

This third partial judgment can be either favorable or not favorable.

2.4 Legislation and indications from the guidelines

Ministerial decree 2001 No.488 lists a series of physiopathological conditions that although they do not exclude the fitness to work, they represent a case that must be assessed with particular attention by the physician during the health surveillance ([Italian Ministry of Health, 2011](#)). ICRP 103: the International Commission on Radiological Protection approved in 2007 new recommendations which replace the previous ones (1991). In particular, the present recommendations update the radiation and tissue weighting factors in the

quantities equivalent and effective dose and update the radiation detriment ([ICRP, 2007](#)). International Atomic Energy Agency ([IAEA, 2004](#)) provide three guidelines: one contains recommendations on professional radiation exposure conditions for which monitoring is required, both for the risk of introduction of radionuclides and for the risk of external irradiation. Particularly, with reference to the subject of our discussion, the document states that: “there is no reason why employees who have undergone radiotherapy have to be excluded from work. Each worker must be evaluated individually, considering the type of treatment, the prognosis and other considerations related to health, will of the worker and type of work” ([IAEA, 2004](#)).

The explained elements of judgment ([AIRM, 2013](#); [Taino *et al.*, 2014](#)), if analyzed and applied to the individual case, could represent a useful help for the elaboration of a suitability judgment.

3 Case description

We analyzed the case of a 40-year-old doctor, endoscopist gastroenterologist, professionally exposed (category A) to ionizing radiation, subjected to left mastectomy for an invasive ductal carcinoma [G3 pT1c (1.4 cm), N0M0] and breast reconstruction with a tissue expander. Due to the presence of the BRCA1 gene mutation and the presence of breast and ovarian cancer familiarity, the patient was subjected to a prophylactic right mastectomy and bilateral oophorectomy ([Finch *et al.*, 2006](#); [Rebbeck *et al.*, 2009](#)). In this clinical case, the criteria and the groups of elements of judgment proposed in the scientific literature were considered ([Tubiana, 2005](#); [AIRM, 2013](#); [Taino *et al.*, 2014](#)): characteristics of neoplasia; general condition of the worker; characteristics of the work at risk; law references and guidelines on this subject.

The evaluation of the Probability of Causation (PC) was not considered, due to the low values of cumulative dose for the total life-exposure of the worker.

At the end of the evaluation pathway ([Appendix A](#)) based on the instructions found in the literature and explained also in the Personal Health Record (PHR), the employee was judged suitable for the work of endoscopist gastroenterologist, activity to which she dedicated (and wished to dedicate) her entire working life.

4 Discussion

Judging the fitness to work of an employee affected by cancer to perform work tasks at risk from ionizing radiation is very complex and is always discussed between two extreme opinions, which are still acceptable today. One position is supported by many authors and by the [ICRP \(2007\)](#): the potential occupational exposure to levels below the threshold limit for the workers exposed to ionizing radiation is considered as such, even in those with previous oncological disease, not to be able to introduce a significant additional risk factor of cancer, also considering the “bottom” of the so-called “spontaneous” or “natural” tumors. The other position (also supported by many authors ([NCRP, 2001](#)) and “prudentially” acceptable for the purposes of radioprotection), starting from the hypothesis of non-existence of a threshold dose for the

induction of the phenomenon of carcinogenesis, supports that is not possible guaranteeing a minimum level of acceptable risk in people with negative-influencing pathologies in their evolution from exposure to ionizing radiations.

Based on the analysis and study of the 4 groups of elements of judgment proposed, it was possible to express, at the end of the evaluation and decision-making process, a favorable final judgment regarding the fitness to work at risk of ionizing radiation, subject to a series of assessment conditions and prescriptions that the current knowledge of medical physics and the latest technical acquisitions allow to implement through a proactive and multidisciplinary collaboration among the figures involved in prevention in the workplace: occupational physician, “qualified expert” (medical physicist) and employer. The expression of an overall favorable final judgment requires the positive outcome in the evaluation process of at least two of the first three groups of elements of judgment (concerning the neoplastic disease, the worker’s psycho-physical conditions and the characteristics of the work at risk). The final judgment, after completing the purely medical and technical analysis, is then evaluated with respect to the normative provisions and scientific indications.

Regarding the factors related to the neoplasia, it should be noted that, if the Probability of Causation calculation (PC), based on the cumulated dose by total exposure, induces the hypothesis that the neoplasia is radio-induced, the physician should consider the possibility of further worker’s exposure to ionizing radiation, because, having already received a significant dose, the observed neoplasia could be the first but not the only one (AIRM, 2013). In the case of a positive calculation of the probability of causation (PC), it will also be desirable to proceed according to the law (Italian Law, 2005; Taino *et al.*, 2017), the AIRM guidelines (AIRM, 2013) and the criteria also present in the literature (Taino *et al.*, 2013) to the reporting of suspected professional origin. In the evaluation process, we considered the primary role that should be attributed to the psychological conditions of the worker (IAEA, 2004; Taino *et al.*, 2014) compared to the continuation of a work activity with potential radiological risk, as well as professional interest and career opportunities placed by the worker in the work at risk. Today, more and more frequently, there is the problem of the possibility and plausibility of ethics and legislation (not yet foreseen), in selected cases and in which the final overall opinion is favorable, to propose an explicit consent signed by the worker to carry out work at risk. In relation to the psychological condition of the worker, we always consider equally the fact that the work activity, beyond the economic and professional aspects, represents in many cases for the worker a real possibility of return to the “normal” life previously carried out and a real form of “escape” from the concerns and the therapeutic and follow-up constraints that the neoplastic disease has involved or still requires. Let us not forget, in fact, that for the WHO the state of health of a person is not only the absence of illness, but also a state of complete physical, psychological and social well-being.

5 Conclusion

According to Italian legislation and international guidelines, several elements and criteria have been taken into account to release the fitness to work certificate in this peculiar case of female worker exposed to ionizing radiation, resulting in a final positive indication.

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Appendix A Evaluation form and criteria used for the formulation of the fitness judgment.

Clinical case

Female, gastroenterologist (endoscopist), 40-year-old. In anamnesis, left mastectomy for an invasive ductal carcinoma [G3 pT1c (1.4 cm), N0 M0], prophylactic right mastectomy and breast reconstruction with a tissue expander, RE%0, PG%0, Mib%80, Her score 1+, fish not amplified. Grade III. BRCA1 mutated gene, breast and ovarian cancer familiarity; prophylactic oophorectomy.

Neoplastic disease characteristics	Positive Judgment	Negative Judgment
Age of onset of neoplasia	> 5 years	≤ 5 years (1 year)
Histological type		invasive ductal carcinoma
TNM staging or other	G3/Stage pT1c N0 M0	
Oncological prognosis	Positive because the worker was subjected to bilateral mastectomy and bilateral prophylactic oophorectomy	
Neoplastic position radioinducibility scale		high

The diagnosis and the surgery were carried out one year earlier, so the patient cannot be considered “disease-free”. The mutation of the BRCA1 gene turns out to be a negative prognostic factor. However, as shown by a meta-analysis of 10 studies conducted in mutated BRCA patients (5), there is a reduction in the risk of ovarian cancer of about 80% after bilateral adnexectomy. Similarly, in a large prospective study conducted on 1079 BRCA mutated women (6), bilateral adnexectomy leads to a reduction in risk of gynecological tumors (ovarian, fallopian tube, peritoneal carcinomas) of 85% compared to the control group a median follow-up of three years. The contralateral prophylactic mastectomy represents, in this case, an additional effective option to reduce the risk of the onset of a second neoplasia. An increased risk of developing colon cancer was reported in women aged < 50 years with BRCA1 mutated: SIR 4.8 (95% CI 2.2-9). For this reason and adhering solely to the genetic pattern of the worker and the increased likelihood of developing colon neoplasia (residual susceptible organ), even with some reservations, the assessment for this valuation item is overall “not favorable” to the potential occupational exposure risk.

Conditions of the worker	Positive Judgment	Negative Judgment
Presence of other significant diseases	X	
Radio-chemotherapy treatment		X
Psychological conditions conducive to the resumption of work at risk	X	
Personal interest and professional conditions favorable to the return to work	X	

The worker has undergone chemotherapy (40 FEC 90 and 12 taxol), but she has always strongly expressed with determination the will to resume her work as an endoscopist gastroenterologist In consideration of the importance of the assessment of psychological conditions, an advice has been requested from the psychologist who has followed her since the beginning of the oncological health problems: from the interview emerged the positive impact that the profession has on the worker's mental health and on the sense of personal realization.

Considering the importance of the emotional sphere as a possible determining factor, also prognostic of the disease, the overall judgment concerning the “Conditions of the worker“ is “favorable” to the professional activity of gastroenterologist endoscopist with risk from exposure to ionizing radiation.

Appendix A (Continued)

Working activity characteristics	Positive Judgment	Negative Judgment
Type of exposure irradiation		global and partial external
Type of radiation or radionuclids		X-Rays
Use of PPE	available and used	

Thanks to the use of personal PPE (lead apron with 0.5 mm Equivalent Lead thickness capable of protecting the remaining susceptible tissues, residual ovarian tissue and colon) and of the DPC (strips to be placed on the bed to be protected from diffuse radiation of the patient), as regards the study of the characteristics of the work activity, the overall judgment was “favorable”.

Elements of judgment related to applicable/doubtful Legislation or guidelines	Positive Judgment	Negative Judgment	Not
Ministerial order 2001 No. 488		X	
IAEA (2004)	X		

According to the Ministerial Order 2001 No. 488 is not recommended to keep exposed to ionizing radiation radiosensitive tissues which are more vulnerable to develop neoplasia due to genetic predisposition. For the IAEA (2004) the judgment is favorable, as to the current state of knowledge does not result that exposure to ionizing radiation, within the limits of the doses required by law, involves – in workers with previous neoplasias treated – a significant increase, compared to healthy workers, the risk of radio-induced tumors. The overall judgment for this item turns out to be “doubtful”.

Case summary**Overall judgment: positive**

Considered aspects judgment	Positive judgment	Negative
Neoplastic disease characteristics		X
Conditions of the worker	X	
Working activity characteristics	X	

On the basis of the 3 main groups of elements examined, the overall judgment is positive for carrying out work at risk. In particular, this judgment has been expressed considering that: prophylactic surgery has been performed to avoid the development of new neoplasia (the main target organs have been removed); it is possible to perform colonoscopy and assay of CA 125 as an annual screening exam; there was also a strong motivation for the resumption of work and the desire to preserve the professional role achieved; PPE and DPC are available to protect susceptible tissues residues (lead aprons, protective shields). A dosimeter was also included under the lead apron to promptly document the absence of exposure below the PPE used to protect the residual critical organ (colon). The assessment of the whole body dosimetric calculation by the Qualified Expert in radiation safety every 2 months was also prescribed in order to limit the number of procedures with exposure to RI (it should be noted that the analysis of the individual Exposure Register for the period 2007–2016, the total annual global body exposures have always been between 0.5 and 2 mSv).

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