

ETHICAL CONSIDERATIONS ON THE USE OR THE ABUSE OF CT-SCAN INVESTIGATIONS

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REZUMAT. Considerații etice cu privire la uzul sau abuzul investigațiilor de tip CT. Investigațiile imagistice de tipul radiologiei clasice, examinările de tip *Computer Tomograf (CT)*, *rezonanță magnetică nucleară (RMN)* sunt investigații esențiale pentru realizarea unui diagnostic de acuratețe, fiind indispensabile practicării unui act medical de calitate. Investigarea de tip CT reprezintă, în urmă cu numai un deceniu, o practică a medicinei de vârf, devenind în prezent una dintre tehnicile de investigație uzuale, fiind adesea preferată în locul radiologiei clasice. Avantajele pe care le prezintă acest tip de investigație sunt însă costisitoare și totodată expun pacientul la un grad ridicat de iradiere. Nefiind o investigație de rutină, nu este justificată în toate situațiile. Urmările negative ale realizării unor investigații inutile se reflectă pe de o parte asupra sistemului sanitar, prin costurile suplimentare antrenate, și pe de altă parte asupra pacientului, care este iradiat, fără a exista un beneficiu real pentru sănătatea sa. În acest articol, autorii încearcă: 1) să evalueze dimensiunea problematicii excesului de investigație CT, plecând de la analiza unui caz, 2) să identifice principalele cauze care duc la acest exces, 3) indicând totodată și posibilele consecințe negative ale uzului exagerat al acestor practici.

Cuvinte-cheie: *CT- scan, abuz de investigații, iradiere medicala, consimțământ informat, educația pacienților.*

ABSTRACT. The imagistic investigations such as classical radiology, *Computed Tomography (CT)* examinations, *nuclear magnetic resonance (NMR)* are essential investigations for carrying out a diagnosis of accuracy, being indispensable to the practice of a medical act of quality. The CT type of investigation represented, one decade ago, a practice of the high medicine, becoming in present one of the usual techniques of investigation being often preferred instead of classical radiology. The advantages of this type of investigation are however expensive and also expose the patient to a high degree of irradiation. As it is not a routine investigation, it is not justified in all situations. The negative consequences of carrying out unnecessary investigations are reflected on the one hand on the sanitary system

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by the additional costs involved, and on the other hand on the patient, who is irradiated, with no existence of a real benefit for his health. In this article, the authors attempt: 1) to evaluate the dimension of the problematic excess of CT investigations on the basis of the analysis of a case, 2) to identify the main causes which lead to this excess, 3) pointing also possible negative consequences of the exaggerated use of these practices.

Keywords: *CT- scan, Abuse Investigations, Medical Irradiation, Informed Consent, Patients Education.*

CASE REPORT

At the consulting cabinet in the Medical Forensic Department a young patient, age 32 years, went and claimed that she was aggressed in a pub. At the objective medico-legal examination she presented a purplish bruise on the back side of her left hand. The doctor asked her if she had another investigation and she gave him a CT examination paper attesting a specialized investigation with spiral acquisition of the entire body. This type of investigation implied a 10 mSv irradiation. At the doctor's question if she has any medical problems, she mentions that she is 5 weeks pregnant. The legist doctor asks her if the CT investigation was carried out at the request of the clinician doctor in the Emergency Room, but she claims that she took the investigation at her own initiative. The doctor wanted to know if she was informed that this kind of investigation is not recommended for pregnant women, as it affects the embryo or the fetus, but she claimed that she didn't know about that and that she wasn't asked by the previous doctor if she is pregnant or not. When the doctor asked her if she wants to keep the baby, she confirmed, being a wish. The legist doctor recommended the patient to talk with her obstetrician doctor for counseling. The patient decided to interrupt the pregnancy as a result of the counseling with the obstetrician and of the analysis of risks.

THE CASE ANALYSIS

To analyze this case and to set out the eventual committed errors and also the ethical and legal aspects that should be taken into consideration in these situations, we should punctually answer to the following sets of questions:

1. What does it mean the CT investigation?
2. Who does and were these investigations are done?
3. Is there any real abuse of indication of the CT investigations? What may be the causes?

4. What are the negative consequences associated to the abuse of the CT-scan?
5. Who should recommend these investigations and why?
6. Has the patient the right to be informed regarding the specific of the CT investigation?
7. Who has to inform the patient on the risks and benefits of such examination?
8. What should be done if a patient comes to a medical investigation center asking for such examinations at his own initiative?

DISCUSSIONS

1. What does it mean the CT investigation?

Since the first radiographic image realized by Wilhelm Rontgen (1845-1923), the one of his wife's hand, in 1895, 121 years of evolution of the medical imaging have passed. Nowadays all the County Emergency Hospitals have or have access to a computed-tomography. This investigation became a usual one, being recommended even in situations in which the classical radiology, such as radiography and radioscopy, could solve them, considered by the specialists as easy to practice, reproducible and least invasive[1]. On the other hand, this investigation is considered by the patients as a kind of "uncrowned queen" of the medical examinations, the doctors being frequently asked by the patients or by the dependants for a referral ticket to a computed-tomography. There are also situations in which the supplier of medical services is a private company and the patients may directly require and for charge, at own initiative, the carrying out of such investigations with no previous medical prescription.

The radiation dose the human body absorbs has cumulative effects during the life and is measured in mSv (milisiverti). The average dose an American citizen absorbs in the course of a year is of 6.2 mSv and most part of the radiation comes from the atmospheric gases (37%), on the second place being the computed tomography medical investigation (24%), followed by the nuclear medicine (12%), by interventional fluoroscopy (7%) and by conventional radiography and fluoroscopy (5%) [2]. Not the entire population is exposed to a medical irradiation. It is found that the radio imagistic and radio therapeutic medical activities occupy together 48%, practically doubling the average dose of the radioactivity the general population is exposed. It is observed also the big difference between the contribution to the irradiation of the population through CT and through classical radiology.

In Romania, an ordinary individual who is exposed to some additional sources, natural or artificial, of ionizing radiations receives annually a dose of

natural radiation of 2-3 mSv, according to the results of a study published by the National Agency for the Protection of the Environment [6].

The administered ionizing radiations, be they from the classical radiologic investigations, whether from CT-scan techniques are added to those 2-3 mSv from the natural radiation.

With regard to the differences from the view point of the dose of administered ionizing radiations, they are:

Skull radiography: 0.01-0.03 mSv.	Cranial CT: 2 mSv
Thoracic radiography: 0.02-0.06 mSv.	Thoracic CT: 8 mSv
Pelvis radiography: 0.7 mSv	Pelvis CT: 10 mSv. [3].

It is easily noticeable that a CT-scan investigation of the pelvis exposes the individual to a dose equivalent to the natural irradiation corresponding to 3 to 5 years!

The French Code of the Public Health specifies that, with regard to the exposure to ionizing radiations for medical and medico-legal purposes should be applied principles of justifying the investigations by establishing the benefit of such examinations in relation with the risks which it incurs and by optimizing them to obtain information useful to the diagnostic using the smallest possible dose [4].

In Romania, the radiologic norms of security in the practices of radiology, diagnostic and interventional radiology [5] states in art. 60 align. (1) that: "The requirements for radioprotection regarding the justification of practice, the limitation of the doses and protection's optimization and constraints of the dose, drawn in mind. IV from NFSR is applied in radiology taking into account the details specified as follows.

(2) Justification – All the practices that imply the medical exposure to X-ray radiations must be justified weighing the diagnostic benefits these practices can bring with the detrimental the X-ray radiations could cause, being taken into consideration the benefits and risks of the available alternative techniques, but which do not imply the exposure to X-ray radiations. [...].

(4) Optimization of the radioprotection

a) For the medical exposures in the purpose of diagnostic, the optimization of the protection is realized by maintaining patient's exposure to a minimum necessary to realize the objective of the requested diagnostic."

Similar formulations and principles are found in the French and Romanian norm.

The consequences of the exposure to ionizing radiations appear on long-term and short-term. In case of high exposure to radiations it may appear sterility and the so-called disease of irradiation, which can evolve to death, situation not carried on in cases of exposure to medical irradiation. For example,

at 6000 mSv were exposed the workers from the nuclear central from Chernobyl, who have died within a month.

In case of exposure to smaller and repeated doses, such as the irradiation from the imaging medical procedures, the effects are on long-term and consist in the appearance of an oncologic pathology or of some genetic defects, the probability of their occurrence increasing once with the dose [7]. In case of pregnant women, the most exposed is the fetus whose maximum sensitivity to radioactivity as teratogenic factor (mutagen) is between 2 and 15 weeks of pregnancy [8]. In this period of pregnancy by the exposure to small or medium ionizing radiations it is the risk of the appearance of some malformations of the future new-born. On the doses of radiation the mother was exposed and the period of pregnancy the obstetrician could recommend preventive interruption of pregnancy.

2. Who does and were these investigations are done?

The CT exam is realized with a *device* that uses photoreceptors to detect the attenuation of roentgen rays emitted by an X-ray tube which is rotating around the body over multiple diametric pathways in the axial plane. The information acquired is processed by a computer and the result is a series of images with slices aspect of the examined body [10].

The examinations are carried out in the areas of imaging-radiology of state sanitary unities – emergency county hospitals or the municipal hospitals or in specialized clinics with private capital. According to the emergency degree and to available funds, these examinations are paid either by the Health Insurance House or by the patients in question. In many situations, especially, in clinics with private capital, there is no radiologist with CT competence to interpret the results, sending them to a specialist in a different locality who will interpret it without direct relation with the patient. For example, the private centers providing such services from Bistrița cooperate with specialists from Târgu-Mureș or from Cluj, because in Bistrița-Năsăud there were no radiologists with CT competence. The patients do not get in touch with the doctor, the ones who carry out the positioning of the patient and the handlings of the device were the nurses or the technicians. They insure also the communication with the patient, the anamnesis and the training, patient's informing on the type of the investigation and in what it consists. Also they give the results after the specialist interpreted the images. This practice is contrary to the Ethical Code of the Radiology and Medical Imaging Society from Romania, which states that: "Radiologists must set such a relationship with their patients that allow them to interpret the images and to decide on the interventions in the context of the general medical situation of the patient. They must ensure that all the relevant information regarding the medical history of the patient and the previous results reached them optimally." [11].

The medical deontology code of the Romanian doctors adopted in 2012, art.24 emphasizes on: "The unmediated character of the relation doctor-patient: except of some exceptionally objective situations and impossible to remove, any medical decision will be based firstly on personal and unmediated examination of the patient by the doctor concerned." And in art.31 is referred to "the medical act from distance", thus: "The investigation or the medical intervention from distance, in any existent forms and modalities, is allowed only in when the patient is directly assisted by his doctor and the purpose of the investigation and procedures the patient is supposed to is to help the doctor to set the diagnostic, to establish the treatment or to use another medical procedure to finish the medical act or medical intervention in case of surgery. The emergency situations are the exception." [5].

In the interpretation of these stipulations will result that the practice referred to above is not in accordance with the deontological norms from Romania.

3. Is there any real abuse of indication of the CT investigations? What may be the causes?

The possible causes of the excess of computed-tomography investigations were identified as patients urgings, professional uncertainty (doctor's hope that the CT could highlight something else), the material co-interest carried out by the contracts in cooperation signed by the providing companies of such services with the doctors, the desire to document to a maximum the case in the condition of the defensive medicine practice.

One raised problem is the one of the ethics of a payment carried out by the doctor on behalf of a recommendation to an investigation involving risks for the patient, even when not potentially lethal or immediately pathogen. There is also the possible idea of the existence of the risk a doctor may be tempted to recommend this type of investigation in spite of other investigations more harmless, which in some cases (obviously, not in all) it would lend as well as outlining the diagnostic.

Beyond the letter of the radiology security norms in the radiologic diagnostic practices and interventional radiology which foresee that always should be recommended the investigation with the smaller dose of irradiation, appears also the analogy with the letter a) from art.383 of the Law no. 95/2006, "the pursuit of the profession of doctor is incompatible with: a) the quality of an employee or a collaborator of the unities of production or of distribution of pharmaceutical products or sanitary materials;" and with art.23 from the Medical deontology code. Therefore, "it represents a serious touch brought to the independent character of the medical profession the following acts:

a) Except the situations provided by the law and the previous announcement of the profession's organs, association or collaboration, under any form and modality, direct or indirect, between the doctor and a person which produces or distributes medicines; [...]

c) The involvement, directly or indirectly, in the distribution of medicines, medical devices, medical or of other products for medical use;"

The reasons for which the legislator provides this incompatibility are that a doctor, employee or collaborator of a unity of distribution or production of the pharmaceutical products may be tempted to prescribe preferentially the products of the company which materially co-interests him. Consequently, neither the co-interest of the doctor to recommend certain investigations seems recommendable. We find ourselves in each of these two situations, both the one of the doctor-pharmacist and the one of the doctor prescribing investigations by which he receives the share in a superposable situation over one of the definitions of the conflict of interests, namely the case in which the personal interest comes into conflict with the professional obligation to support the interest of another part, compromising the expectations relating to a reasonable objectivity and impartiality with respect to the other side[9].

Another problem is related to the allocation of resources. The CT-scan investigation is one of high accuracy, but much more expensive than the classical radiological investigation, in so as far as in the case of carrying it out in the private health system where is directly paid by the patient or it is settled on by the Health Insurance House. Supposing that the only problem is the recommendation of a CT when it is sufficient a radiography or a fluoroscopy, the system's resources were already abused, by recommending an expensive investigation instead of a cheaper one which gives the same diagnostic. The abuse of such resources takes a new dimension when we are speaking about the situations in which occurs the lack of justification of any type of imaging investigation.

Generally, it can be noticed an affinity of the general population to the computed-tomography investigation, which they require both when they were patients and for their relatives, when they were dependants, the perception on this investigation being high idealized. A negative phenomenon is that some patients, especially those traumatized, when the emergency specialist, neurologist, neurosurgeon or surgeon does not consider necessary the CT investigation, chose to go by their own to the unities carrying out such medical services, paying them from own funds.

4. What are the negative consequences associated to the abuse of the CT- scan?

The abuse of CT investigation may have negative consequences on the patients, on the personnel working in such unities and on the health system.

The effects on the patients consist firstly in their exposure to doses of ionizing radiations with no benefit to the real diagnostic. As mentioned, the ionizing radiations have cumulative effect, their effects occurring depending on the total dose an individual was exposed to during his life and the CT investigation involves exposure to a high dose of radiations with possible mutagen effects (the occurrence of malformations at descendants) or with the increase of the risk of the occurrence of oncologic pathology. In the situation in which the patients are those at the initiative of which is carried out the investigation, the negative effect is also the pecuniary one, the costs being paid by them. Another problem is the one relating to the excessive confidence of the patients in this investigation, which may cause a feeling of false safety: the patient to whom this investigation has not revealed any kind of pathology is willing to give up to other investigations, being convinced by the infallibility of this method. There are also situations in which the examination does not reveal any pathologic, which does not mean that there is no pathology: the brain contusion, for example, becomes visible for the CT only after an evolution of 4-48 hours.

The effects on the personnel can be negative by the exposure to ionizing radiations. The personnel of these services wear a check box for the monitoring of the radioactivity they were exposed and the modern equipment has a good radioprotection, but the risks are not totally removed.

The negative effects on the health system can have the abuse of indication by the specialists of this type of investigation, taking into account the expensive costs and the limited financial resources.

5. Who should recommend these investigations and why?

The carrying out of the CT investigations is performed theoretically by the specialist in order to elucidate the diagnostic. There are many ways to carry out this type of investigation – CT with spiral acquisition, CT with contrast substance etc., and on the type of investigation can only decide usually the treating doctor or, preferably, the treating doctor after consulting with the radiologist with CT competence. Therefore, in the conditions of suspecting the existence of formations with subcentimetric dimensions – of the type of cerebral hemorrhage or of tumor type – it will be agreed on a certain set of images of slices type more frequent or for spiral acquisition with small step (which involves a high dose of irradiation, but does not allow the formation to get between sections and should not be visible). Under the existence of a known formation of larger size whose evolution is monitored, the images can be done in “slices” thicker, the irradiation being much more reduced. The investigation carried out at the patient’s request is one at least unprofessional.

6. Has the patient the right to be informed regarding the specific of the CT investigation?

Taking into consideration that this investigation is presenting risks and possible negative consequences for the patient, the patient has the right and the doctor has the obligation to inform him and to obtain the informed consent to carry out the CT type exam.

As idea of principle, any treatment or examination which presents risks for the patient and for his life involves patient's consent for the medical act. *The informed consent* is the decision taken by a **competent** individual by whom he agrees to partake of a research or to take a treatment his doctor proposed. This implies that the individual **has received the necessary information**, that he **understood it** and that he **took the decision without being the subject of some coercion, induced influences, incites or intimidations** [12].

Patient's consent is the connection between the obligation of the doctor to treat and the personal right of the patient to manage his own health and life.

According to art.6 of *The universal declaration of bioethics and human rights* released by The United Nations Educational, Scientific and Cultural Organization (UNESCO), in 2005, "*any medical intervention which has a preventive character, diagnostic or therapeutic must not be initiated only with the previous consent, free and expressed of the person in question, based on sufficient information*"[13].

The doctor should inform his patient taking into consideration patient's level of understanding and of the condition in which he is at that moment. Therefore, according to the *Law no.95/ 2006 on the reform in the health system*, art.649 (3), the patient will be informed about: the diagnostic, the nature and purpose of the treatment, the risks and their consequences, the prognostic of the disease without applying the treatment.

The consent does not extend on other interventions than the ones the patient was informed about and gave his consent.

The doctor has the professional obligation to respect the stages of the procedure of obtaining the informed consent, taking into consideration the characteristics of the patient's condition, as well as the condition of anxiety, the features of his personality, giving him the necessary explanations. One of the difficulties the doctor encounters frequently is the one of giving pertinent information to his patient and adequate to his level of understanding.

7. Who has to inform the patient on the risks and benefits of such examination?

As a basic rule, the patient should be always informed by his treating doctor. It is one of the essential rights of the patient, right found in all international and intern legal regulations relative to the patient's rights. To be

informed to this right allows the construction of a relationship of quality with the treating doctor and the other professionals involved in the medical act.

The patients are more informed and more interested to actively partake of the medical act which reflects on health, on projects of life and quality of their life. In quality of citizens, holders of rights we benefit of this right, but not sufficient informed to take decision in full knowledge of facts? The answer is affirmative, when the medical information is given by the treating doctor or by the specialist and when he fulfills his obligation to inform the patients on: the diagnostic, nature and the purpose of the treatment, the risks and the consequences of the proposed treatment, viable alternatives of treatment, the risks and their consequences, the prognostic of the disease without applying the treatment, according to *Law no.95/ 2006 on the reform in the health system* states in art.649 (3). In our case the information could not come from a treating doctor or specialist, as there were no doctors in such private unities. Therefore, the question is to what extent the medical personnel which receives the patients is sufficient trained to compensate the absence of the doctor and of the pertinent information coming from someone who knows the risks and which are the alternatives. From what can be seen in our case, it seems that the medical personnel from the private unity where the woman has done this investigation did not fulfilled this exigency, thing that led to the serious consequence produced (interruption of pregnancy).

8. What should be done if a patient comes to a medical investigation center asking for such examinations at his own initiative?

Patient's confidence in the CT examination has positive valences, rarely encountered the situation in which those concerned have the feeling that they've been carried out an useless investigation, even the case in which because of lack of funds from the public health system they paid their own money. There are also situations in which the patient comes to the private imagistic clinic and requires a CT examination without having the recommendation of a specialist. Some of the private providers of such medical services have a firm policy in not accepting to carry out investigations in the absence of a referral ticket. In practice are encountered, frequently, patients coming to the medico-legal examination with an analysis report containing the interpretation of a CT examination which does not reveal any kind of internal injuries and which was carried out at the patient's request, in private centers. Usually, these practices of the private clinics should be discouraged, eventually by including in the legislative norms of interdiction of carrying out investigations which involve the use of ionizing radiations, inclusively in private regime, when there is no recommendation of a doctor with the right of free practice.

CONCLUSIONS

The computed-tomography investigation offers a large quantity of information of outstanding accuracy in the conditions in which is adequately used, having as disadvantages high costs and high dose of irradiation of the patient. It can be noticed the tendency of the general population to ask as last diagnostic argument the CT-scan investigation. When the case allows similar diagnostic results the use either of the classical radiology, or of the computed-tomography examination, it is recommended the radiography as the dose of irradiation on the patient is up to hundreds smaller than the dose given by CT-scan. The price of the computed-tomography is generally much higher than the one of the radiologic investigations. In the conditions in which approximately half of computed-tomography investigations analyzed in the medico-legal documents taken in the evaluation have no justification by the symptomatology prism, of the objective examination, of the anamneses or other clinical data, we could appreciate that there is a certain degree of abuse of compute-tomography investigation in the health system from Romania. The possible causes of excess recommendations of carrying out the computed-tomography examination may be patient's pressures, doctor's professional insecurity, practice of medicine defensive and last but not least the material co-interest of the doctors in recommending that investigation. The consequences of computed-tomography examination in excess are of two types. Some of the possible consequences on long term on patients' health, irradiation of an individual during his life being cumulative and the probability that these develop an oncologic pathology being proportional to the sum of all doses of radiations to which he was exposed and other are immediate on the health insurance system, which is exposed to some expensive and useless costs.

The practice of the imaging clinics deprived of accepting to carry out such investigations with ionizing ray at the simple request of the patients, without asking a referral ticket from a specialist, is engraved by risks especially for the patients who can be irradiated useless. It is imposed a regulation to bring these companies closer the health services area and more far from the market one.

The ethical problems raised by the analysis of our case are related to some clear regulations regarding the carrying out such investigation in the private regime and by the lack of patient's informing on the risks these examinations suppose. At the same time patients should be informed on the existent alternatives in such cases and, firstly, the patients should be advised to consult a doctor to recommend them the necessary, not to address by their own to such unities/centers. The steps a patient has to follow when facing some problems, such as those presented in our case, should be established by certain

guidelines which should be applied both in the public medical unities/centers and in the private ones and the patients should not be encouraged or shall not be recommended shortcuts or alternatives by those who are not their doctors and assume some negative consequences such as those presented in our case.

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