MEDICAL ERROR – GENERAL TERM AND ITS OVERVIEW IN RADIOLOGY

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ЛЕКАРСКА ГРЕШКА - ОСНОВНИ ПОЈАМ И ЊЕН ПРИКАЗ У РАДИОЛОГИЈИ

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САЖЕТАК

Грешке у лечењу оболелих део су свакодневног живота. Познавање закона и националних препорука може да помогне доктору да спречи компликације у лечењу пацијената и тиме и сва правна питања. Термин стручне грешке традиционално је повезан с лекарском праксом, а израз "лекарска грешка" се усталио, иако може да се односи на поступке било ког здравственог радника.

Радиологија заузима важно место у свету медицине због свог значаја у областима дијагностике и лечења. Подаци о стручним грешкама у области радиологије претражени су у судској пракси Републике Србије, у којој није пронађена правоснажна пресуда против радиолога. Спроведено је обимно претраживање публикација из области права и медицине, које је показало да у Републици Србији нема објављених радова о овој теми, као ни прегледних радова ни оригиналних студија. Стога је циљ овог рада био да се прегледа страна литература, без обзира на врсту правног система, да би се стекао увид у ову проблематику и припремио простор за истраживања у овој области.

Важно је напоменути да је дошло до значајног повећања броја судских поступака због лекарске грешке у радиологији што може бити спречено едукацијом радиолога, радиолошких техничара и пацијената. Ово је област која ће доживети експанзију у наредним годинама и стога је важно спровести правовремено образовање и спречити грешке које могу да буду фаталне за пацијента.

Кључне речи: стручна грешка, радиологија, медицинско право, правна медицина, преглед

INTRODUCTION

Life and health have been the topic of research since the emergence of mankind. There are numerous definitions of life. According to Stedman, life is "a state of existence characterized by the following functions: metabolism, growth and development, reproduction, adaptation and response to stimuli" (1). Physiology

ABSTRACT

Mistakes in the treatment of the diseased are a part of everyday life. Both the knowledge of state law and appropriateness criteria can help the doctor to prevent complications in treatment and consequently any legal issues with patients. The term professional error is traditionally associated with the physicians' practices, and the term "medical error" has become established, although it can be related to the actions of any healthcare professional.

Radiology occupies an important place in the world of medicine due to its significance in the fields of diagnostics and treatment. Data on professional errors in the field of radiology have been researched in the judicial practice of the Republic of Serbia, which showed no final verdict against radiologists. An extensive research of publications in the field of law and medicine was conducted, which showed that there were no published papers with this topic in the Republic of Serbia, neither as reviews nor as original studies. Therefore, the aim of this paper was to review the foreign literature, regardless of the type of legal system, in order to gain insight into this issue and prepare an area for research in this field.

It is important to note that there has been a significant increase in the number of court proceedings due to medical errors in radiology, which can be decreased by educating radiologists, radiology technicians and patients. This is an area that will experience expansion in the upcoming years and it is therefore important to implement timely education and to prevent mistakes that can be fatal to the patient.

Key words: medical error; radiology; medical law; legal medicine; review

defines life as a form of existence from the moment of conception (2). None of the life definitions imply health as a prerequisite for existence, but rather a condition for which human strives. The World Health Organization defines health as "a state of complete physical, mental and social well-being, and not just the absence of disease and disability" (3). However, human's life and health can be endangered in various ways. The basic goal of medicine is

to protect life and health, to improve the quality of life and extend its duration, all in accordance with modern medical standards (2,3).

In Serbia, the healthcare activity is defined by the Health Care Law of the Republic of Serbia, from 2005 as "the activity that provides health care for citizens, which includes the implementation of measures and activities of health care that are in accordance with the medical doctrine and with the use of health technology, used to preserve and improve health, and performed by the health service. "The healthcare activity is performed by a physician with all other healthcare workers and associates, where all their activities must be based on scientific evidence, i.e. they must be safe and effective and in accordance with the principles of professional ethics (4).

With advances in medicine and modern technologies, palliative measures reduce the incidence of diseases, while diagnostic and therapeutic measures treat newly emerging diseases. Nevertheless, with increase in the number of medical procedures, the risk of treatment also rises (5). This risk is also influenced by medical procedures and therapeutics, but also by professional errors of health workers (4).

THE TERM AND CLASSIFICATION OF MEDICAL ERROR

Mistakes in the treatment of the diseased are a part of everyday life (6). These mistakes leave the consequences not only to the patient and his immediate family, but also to the physician and the whole health system (7). A lot of problems of medical malpractice are generally related to two issues: the physician-patient relationship or improper medical care leading to bodily harm (8). Both the knowledge of state law and appropriateness criteria can help the doctor to prevent complications and consequently any legal issues with patients (9).

The term professional error is traditionally associated with the physicians' practices, and the term "medical error" has become established, although it can be related to the actions of any healthcare professional (10). The reason for this is a public opinion that physician solely has the responsibility for patient's life and health, as well as the fact that the majority of court proceedings are initiated against a doctor (11).

There are different definitions and classifications of a medical error. Virchow defined it as "a violation of the generally accepted rules of patient management due to a lack of proper attention or carefulness." (12). Legal experts present a medical error as a failure of a doctor who, by its act or omission, violates the duty to respect professional medical standards. Medical error implies the contra legem artis behavior (13). The Health Care Law of the Republic of Serbia uses the term "professional error" because it is considered that besides a doctor, other health professionals may also make a mistake. The definition of a medical error is contained in Article 197, paragraph 4, of the Health Care Law. Positive jurisprudence in Serbia defines professional error as "unprincipled treatment, i.e. neglect of professional duties in the provision of health care that is, non-compliance or lack of knowledge of established rules and professional skills, in the provision of health care, leading to deterioration, worsening, injuries, loss or damage to the health or parts of the patient's body" (4). This legal norm constitutes the basis for assessing the possible ethical and also legal liability of a physician, whose negligence violated patient's health or led to his/her death.

In addition to the concept of a medical error, other terms are also used: irregular medical actions, medical errors, medical professional errors, treatment errors, inadvertent or improper medical behavior (13,14). Term medical malpractice is used in English while the corresponding Serbian term is unprincipled treatment.

Other terms, which do not have the same meaning as "medical error", are also used. An example of this is the "unwanted outcome of treatment" (13). This outcome is due to the specific etiopatogenesis of the disease or the late notification of the disease to the expert service by the patient himself.

In practice, medical errors are commonly classified into: 1) errors in medical treatment; 2) errors in patient notification; 3) errors in the management of medical records; 4) errors in the work organization and supervision; 5) errors in the use of medical devices and apparatus (15).

Surgical experts divide medical errors into: diagnostic errors, tactical errors, technical errors, mistakes in the organization, errors in keeping medical records, mistakes in the behavior of medical personnel (13).

There is also the classification of medical errors into those: caused by the action, caused by non-action, caused by taking an unindicated procedure or caused by not doing the indicated procedure (13,15).

MEDICAL MALPRACTICE IN RADIOLOGY

Radiology occupies an important place in the world of medicine. In addition to its essential significance in diagnostics, modern radiology has become an important part of patients' treatment. In legal terms, this results in new tasks and new responsibilities for radiologists.

Data on professional errors in the field of radiology have been researched in the judicial practice of the Republic of Serbia, which showed that no final verdict against radiologists, due to unprincipled treatment of patients, has been issued to date. An extensive research of publications in the fields of law and medicine was conducted, which showed that there were no published papers with this topic in the Republic of Serbia, neither as reviews nor as original studies. Therefore, the aim of this paper is to review the foreign literature, regardless of the type of legal system, in order to gain insight into this issue and prepare an area for research in this field.

It has been reported that errors in radiology are relatively frequent, occurring in 4% of diagnostic examinations, but most of them are of minor importance (16,17). Medical experts in Germany and the USA have dealt with the issue of an expert fault in radiology, in the past. They came to the conclusion that "missing a radiographic diagnosis or complication during interventional procedures are mistakes, and disregard for protocols and rules is malpractice" (18). However, legal experts and patients did not agree with this conclusion (16,17).

The research of malpractice suits in the United States has shown that the most common causes for the initiation of a judicial procedure against radiologists are: errors in diagnosis (14.83 claims per 1000 persons per year); inadequate communication of a radiologist with a patient (0.40 claims per 1000 persons per year) or with referring physician (0.71 claims per 1000 persons per year); and the lack of recommendation for additional imaging (0.41 claims per 1000 persons per year). The most common complications of interventional procedures are vascular (1.31 (95% CI: 1.06, 1.63) claims per 1000 persons per year) (17).

Italian law practice showed an annual incidence of 3.6 to 12.6% suits against radiologists. In 66.7% of cases, the reason was the wrong diagnosis; in 10.3% mistakes in technique and procedure (for example, administration of contrast), half of which is from the field of interventional radiology (risk is 47.3 per 1000 procedures) (19,20). The most common mistakes were made on "the skeletal system (44.5%), breasts (25.8%), chest (11.4%) and abdomen (8.3%)" (19). The main causes for suits in the field of interventional radiology were: vascular complications in 43.9% of subjects, complications after needle biopsy in 14.3%. Postponing or abstaining the interventional procedure as well as failure to obtain informed consent from the patient are also known in European judicial practice (20).

Data from England indicate that breast carcinoma is the most frequent subject of wrong diagnosis (73/199) and then the pathology of skeletal system (21).

Dutch studies have shown the difficulty of diagnosis in screening mammography as well as the high public pressure, which is the reason for frequent suits in this area (22). German court practice has shown that the most frequent motive for suits are the following radiological modalities: x-ray (20.2%), angiography (18.4%) and mammography (16.4%). Of this, 30% were convicted in

civil proceedings, and 5.5% were convicted in criminal proceedings (23).

CONCLUSION

In conclusion, it is important to note that there has been a significant increase in the number of court proceedings due to the medical error in radiology. The United States has the highest data in this area and they indicate that in a five-year level 40% of radiologists have been sued (19,24). It is necessary to pay attention to this area, first of all by educating radiologists and radiology technicians and also the patients. This is an area that will experience expansion in the upcoming years and it is therefore important to implement timely education and to prevent mistakes that can be fatal to the patient.

REFERENCES

- Stedman's medical dictionary. Stedman, Thomas Lathrop, 1853–1938. 27th ed. Philadelphia: Lippincott Williams & Wilkins, c2000.
- AC Guyton & JE Hall. Medical physiology, tenth edition. W.B. Saunder company 2000; Phyladelphia, Pensilvania, USA. Prevod: Savremena administracija 2003; Beograd.
- World Health Organization. WHO definition of Health, Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19–22 June 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. In Grad, Frank P. (2002). "The Preamble of the Constitution of the World Health Organization". Bulletin of the World Health Organization. 80: 982.
- Закон о здравственој заштити, "Службени гласник РС", 107/2005, 72/2009 – др. закон, 88/2010, 99/2010, 57/2011, 119/2012, 45/2013 – др.закон, 93/2014, 96/2015 и 106/2015.
- Bal SB. An Introduction to Medical Malpractice in the United States. Clin Orthop Relat Res 2009; 467: 339–47.
- Youngson GG. Medical error and disclosure a view from the U.K. Surgeon. 2014; 12:68-72.
- 7. White AA, Gallagher TH. Medical error and disclosure. Handb Clin Neurol 2013; 118:107–17.
- Katsi VK, Boudoulas KD, Lytrivi ID et al. Medical error in clinical practice: "errare humanum est". Hellenic J Cardiol 2013; 54:131-5.
- Kalra J, Kalra N, Baniak N. Medical error, disclosure and patient safety: a global view of quality care. Clin Biochem 2013; 46:1161-9.

- Oyebode F. Clinical errors and medical negligence. Med Princ Pract 2013; 22:323-33.
- 11. Guillod O. Medical error disclosure and patient safety: legal aspects. J Public Health Res 2013; 2: e31.
- Virchow R. Gesammelte Abhandlungen aus dem Gebiete der öffentlichen Medizin und der Seuchenlehre. Berlin: Nabu Press; 1879.
- Пирић Ј. Кривично дело несавесног лечења болесника. Зборник бр 1, п:11–109.
- 14. Ћирић Ј. Надрилекарство. Правни Информатор, Септембар 2006, п: 66–71.
- Радишић Ј. Медицинско право. Правни факултетет Универзитета Унион у Београду, Издавачко предузеће "Номос" Београд, Београд, 2008.
- Berlin L. Radiologic errors and malpractice: a blurry distinction. AJR Am J Roentgenol 2007; 189:517-22.
- 17. Whang JS, Baker SR, Patel R, Luk L, Castro A 3rd. The causes of medical malpractice suits against radiologists in the United States. Radiology 2013; 266:548-54.

- Berlin L. Does the "missed" radiographic diagnosis constitute malpractice? Radiology 1977; 123:523-7.
- Fileni A, Magnavita N. A 12-year follow-up study of malpractice claims against radiologists in Italy. Radiol Med 2006; 111:1009-22.
- 20. Magnavita N, Fileni A, Mirk P, Magnavita G, Ricci S, Cotroneo AR. Malpractice claims in interventional radiology: frequency, characteristics and protective measures. Radiol Med 2013; 118:504-17.
- 21. Halpin SF. Medico-legal claims against English radiologists: 1995-2006. Br J Radiol 2009; 82:982-8.
- 22. Van Breest Smallenburg V, Setz-Pels W, Groenewoud JH et al. Malpractice claims following screening mammography in The Netherlands. Int J Cancer 2012; 131:1360-6.
- 23. Tomczak R, Schnabel S, Ulrich P, Brambs HJ, Rilinger N, Nierhoff C. [Frequency and causes of civil and criminal proceedings in radiology. Analysis of a survey]. Radiologe 2006; 46:557-66.
- 24. Traina F. Medical malpractice: the experience in Italy. Clin Orthop Relat Res 2009; 467:434-42.