

MALPRACTICE IMPLICATIONS CONCERNING THE USE OF NEW PHARMACOLOGICAL AGENTS AND SURGICAL TECHNOLOGIES IN OTORHINOLARYNGOLOGY

V. Zainea^{1,2}, S. Pițuru¹, Andreea Marinescu¹, Andreea Rusescu^{1,2}, Cătălina Pietroșanu¹, Irina Ioniță¹, M. Daoud¹, R. Hainăroșie^{1,2}

¹The “Carol Davila” University of Medicine and Pharmacy, Bucharest, Romania

²“Professor Doctor D. Hociota” Institute of Phonoaudiology and Functional ENT Surgery, Bucharest, Romania

Corresponding author: Răzvan Hainăroșie

Phone no: +40727224447

E-mail: razvan@riaclinic.com

Abstract

The aim of this article is to relate some ethical aspects concerning the use of new pharmacological agents and modern technologies in the field of otorhinolaryngology and their implications in malpractice. The objective is to point out some aspects identified in clinical practice which need particular attention, concerning the approach of the doctor-patient relation. As a method we chose to analyze clinical cases and their history with emphasis on the “route” the patient followed up to the moment of admission to the hospital. These data will be associated with lecturing relevant literature concerning bioethical issues. The results concern practical aspects which aim to prevent a non-ethical behavior of the surgeon, especially related to the applications of new pharmacological agents and modern technologies in surgical practice that can lead to malpractice.

Keywords: *ethical aspects, pharmacological agents, new surgical technologies*

Introduction

The bioethical principles applied to the pharmacological and medical practice are:

1.the principle of the patient’s autonomy concerning his option to accept the medical or surgical treatment suggested by the doctor is frequently expressed in the clinical practices by signing the informed consent, after understanding all the data included.

2.the “primum non nocere” principle is translated by the surgeon’s capacity to choose the correct technologies that do not cause secondary lesions. It requires a preliminary evaluation, taking into account that the primary purpose of the intervention might be the complete removal of a lesion. The use of certain

new pharmacological agents or modern surgical technologies in the course of an intervention must be mentioned in the plan of the intervention.

3.the principle of therapeutic benefit refers to the relation between the disease and the state of health of the patient. These will be evaluated both subjectively (question forms) and objectively (biologically, radiological, endoscopic, biopsy, secretions, complementary tests).

The principle is expressed in the surgical practice first of all by a positive outcome of a surgical intervention (removal of the lesion) in radical surgery, the benefit of palliative surgery, the treatment of affected anatomical structures (maxillary fracture after craniofacial trauma).

These principles are expressed in the current surgical practice by choosing and implementing surgical technologies that allow minimally invasive procedures and preserve healthy tissue. The problem has multiple aspects that must be looked upon from different angles, which are a clear indication, the intervention allows the management of the lesion, the surgeon has the necessary equipment and qualification, the patient present no contraindications. We must mention the analysis of the patient's opinion that may be influenced by data obtained via internet, with no information obtained from qualified personnel, that does not apply for the case in question. The doctor also has the obligation to conduct a thorough research on the problem and redirect the patient towards another specialist whenever the situation imposes it.

In other words, it is the ethical obligation of a specialist to at least formulate the clear indication of a surgical intervention, justified by the disease or the lesion, and maybe to express a justified opinion concerning the type of technology that may be used.

It is obvious that the final decision concerning the use of certain pharmacological agents and/or modern surgical technologies (laser, radiofrequency, coblation, classic surgery, endoscopic surgery, robotic surgery) is made by the same doctor that will perform the intervention.

4.the principle behind nondiscrimination and an ethical approach of every clinical case refers to the indiscriminate access at using modern technologies in the best interest of the patient. The access to modern technological resources and to specialized centers are ethical problems with which the health systems and public health policies are confronted everyday [1-4].

Materials and method

Descriptive and observation method were applied in order to achieve the goal of our research. We took into account a 5-year retrospective study regarding malpractice accusations concerning the use of new pharmacological agents and modern technologies. This study took place between

2011-2016 in „Prof. Dr. D. Hociota” Institute of Phonoaudiology and Functional ENT Surgery in Bucharest, which is a tertiary center with approximately 10.000 patients every year. After selecting cases that were relevant for our premise, we analyzed the ethical implications regarding the use of new medication and technologies. We performed a comparative study of various cases and we identified the elements that lead to professional liability in malpractice cases.

Results

In the ENT current practice we can encounter the following situation: a patient with an incorrect, “fantasy” surgical indication, that imposes the use of technologies that are not suitable for that case in particular (the respective lesion), due to the uninformed overuse of certain technologies (for example, a curative LASER intervention for advanced laryngeal cancer). Another situation is the request of the patient to use some pharmacological agents “off topic”, treatment that is not suitable for the respective situation. It is a clear situation where the ethical principles are not respected due to incomplete data concerning the pharmacological agents or technology in question. If the respective medication or technology is recommended by a misinformed doctor, this behavior will lead to a useless complication in the relationship between the patient and the surgeon that will perform the intervention due to the unrealistic expectations of the patient for a “miracle making” medication or technology.

In the oncologic surgery we are faced quite often with such situations, that put us in the position to have to change the patient's conviction and hope related to a certain homeopathic agents or technology that out patients sees as “miracle performing”. Only after that, based on an explained and informed consent, may we act using surgical technologies that are adequate to the case and stage of the disease.

The use of selected surgical technologies implies theoretical and technical training, sufficient data and ethical principles for the

surgeon that performs the intervention. The surgeon must have the capacity to provide solid data that will support his decision (surgical experience concerning the respective pathology, experience in using the surgical technology in question), alternatives technologies for performing the intervention. He must also take into account the anticipated result following surgery, the biological situation of the patient, the risk factors and a personalized therapeutical approach for the case in question.

The doctor-patient relationship also includes ethical aspects by which the doctor can justify the choice of a certain surgical technology in his relation to the patient.

In the current surgical practice we could observe the following situations:

a. expectations that are too high concerning the efficiency of a certain pharmacological agent and/or technology.

b. the enthusiasm that follows the acquisition and use of a new surgical technology (radiofrequency, LASER, coblation) which may associate the lack of a detailed analysis of the literature concerning the use of that technology and practical training.

c. incomplete or not suitable incomplete medical treatment, instruments, due to economic reasons or, more rarely, to lack of knowledge.

d. incidents and accidents that are caused by the improper use of new pharmacological agents and/or surgical technologies (related to the functional parameters).

e. the "illusion" of technologies that are mentioned in the media, without analyzing if that certain technology is suitable for the current case.

f. the fight against incomplete medical training or the misunderstanding of data available on the internet or in the media may lead to tensions in the doctor-patient relationship.

The two parts of the doctor-patient relationship must include the rules of ethics and trust in the informed consent. Without properly informing the patient on all aspects of his case, mutual trust and actions that must lead to

identifying and applying adequate therapeutically solutions for the patient we cannot discuss about a complete and efficient medical management [1,2].

The idea of this discussion is that of the difficulty of the task of identifying complementary medical and ethical solutions in the frame of limited financial resources [4].

The ethical criteria must be discussed for each case in particular and are extremely hard to generalize. Always a parallel must be drawn between similar cases, taking into account the social and familiar resources for rehabilitation. These so-called "objective" criteria may not be sufficient and efficient to allow us to make a choice [3].

Conclusions

We want to underline that our medical and ethical opinion completely excludes all the total "subjective" criteria. We plead for identifying a large area of at least minimal objective criteria of the ethical conditions associated with main and complementary medical criteria in choosing the surgical technologies during the analysis and decision making for each clinical case.

References

- [1] Tung, Th.; Organ C. H. Jr. (2000). Ethics in Surgery- Historical Perspective. Arch Surg. 135(1):10-13;
- [2] Wall, A.; Angelos, P.; Brown, D.; Kodner, I.J.; Keune, J.D. (2013 MAR). Ethics in surgery. Curr Probl Surg. 50(3):99-134;
- [3] Jones, J.W.; McCullough, L.B.; Richman, B.W. (2008). The Ethics of Surgical Practice: Cases, Dilemmas, and Resolutions. Oxford University Press (New York). 340 pp. ISBN: 978-0-19-532108-1 (cloth); 978-0-19-532109-8 (paper);
- [4] Seidman, M.D.; Shapiro, D.P.; Shirwany, N.A. (1999 JUN). Ethical issues for otolaryngology and surgery in the elderly. Ear Nose Throat J. 78(6):422, 424-6, 428.