THERAPEUTICAL INNOVATIONS AND MEDICAL RESPONSIBILITY: WHAT'S NEW IN OTOLARYNGOLOGY

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ABSTRACT

On one hand the incessant and constant technological and instrumental progress in the medical fieldhas allowed to increase knowledge and to reach new objectives. On the other hand, however, it has also raised the risk linked to professional responsibility, regarding informed consent and law 24/2017 of the Italian Republic, better known as Gelli Bianco. In this work an analysis of relevant literature will be presented, followed by a study on the role of new devices on responsibility profiles in otolaryngology. According to the analysis of the Italian law and considering the weaknesses ofthe above mentioned guidelines, pending legal administrative clarifications, we believe an operational protocol can be proposed in case of application of therapeutical innovations, especially about experimental introductions. Consequently, in our opinion, the risk of incrimination persists in case of use of innovative procedures in the absence of a formal shared opinion expressed in guidelines or in good practices, which still need a satisfactory definition.

Keywords*: law Gelli Bianco, legally valid consent, therapeutical innovation, molecular biology; new technologies, professional responsibility.*

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Introduction

In the last two centuries the relationship between knowledge and applications or, in other words, between science and technology, has undergone a dramatic transformation to the point that the dominant value of science has increasingly reduced as against technology: between the half of the eighteenth and twentieth century, indeed, science used to pave the way for inventions but later technology has been developing at such a fast pace not to allow the relevant scientific explanations, in many cases.

Due to this change, today science doesn't need technologic innovation but vice versa: the available application can influence the scientific method, with adominance of technology on knowledge.

Not only does pharmaceutical research suggest the use of therapeutical targets to treat different otolaryngology diseases, but also surgery technique studies and proposes innovations aiming at decreasing invasiveness and reaching better functional outcomes and a higher quality of life for the patients themselves[1-4]. The present study aims at analysing from a legal and medical point of view the critical points of new technologyin otolaryngology, evaluating - basing on literature - the profile of responsibility of a surgeon and the risk of incrimination due to professional mistake, basing on the suitability of the informed content.

Discussion

Research and innovation need time and experience to validate the prerequisites followed through new technology. If the innovation to be used is introduced for the very first times, a medical-legal issue can arise in case of lack of experience consolidated in literature and in otolaryngology or in case of absence of unanimous scientific consensus expressed through recommendations or specific guidelines for the use of the equipment[5].

Otolaryngology, especially for the different anatomic and functional features in its fields of interest, is one of the most affected disciplines when it comes to innovations proposed for several medical and surgery fields. Examples of modification of the surgical approach are the introduction of endoscopic techniques or reconstructive and/or rehabilitative surgery[6-9], the development of new devices for haemostasis and cauterization like the radiofrequency scalpel[10], coblation[11] or ultrasound technology[12] and several kinds of laser[13]. These new devices consequently changed trans oral surgical techniques and later allowed efficiency and the development of robotic surgery techniques[14].

Other examples of medical-therapeutical progress in otolaryngology are hyperbaric oxygen therapy[15] or, more recently, the encouraging possible applications of molecular biology[16,44].

Even though less than 50 years ago Mosher[17] stated that intranasal ethmoidectomy was "the easiest way to kill a patient", today, after the introduction of the optical fibre devices, the shaver and the neuronavigation systems[18], on one hand we are perfecting the innovations in use[19], on the other we are assessing the possible application of new surgical-therapeutical approaches[20].

If the scenary is culturally exciting thanks to the unrest which influences the field right now, it is al-so true that applying innovative therapeutical instrumental, pharmacological and surgical processes also increases medical-legal risk. The use of any innovative device requires careful evaluation both concerning the information provided to the patient and for the necessary caution in the use of the device itself that, being new, lacks not only of prior experience but also of literature figures. In theabsence of these elements behaviours can be interpreted asnot codified and consequently inappropriate under the legal aspect.

According to a careful analysis of literature, the essential point in any health treatment is informed consent, which can be explained as the patient's acceptance of the treatment or, more precisely, as sharing and informing the patient about the possible choices linked the treatment which is more suitable for the interest of the patient. Giving consent means exercising the right of freedom and giving manifestation of the will of a subject concerning their health[21-22]. The right to be informed is based on art. 13 and 32, c. 2 of the Constitution of the Italian Republic[23]. From the combination of the two constitutional laws derives the freedom of therapeutical self-determination as an implicit constitutional value, which was then completely confirmed and im-plemented both in the European Convention of Human Rights, known as Oviedo Convention[24], and in the European Constitution[25]. Consequently, a person must have the freedom to giveor refuse their consent for every treatment suggested for their disease.

Also, the Code of Medical Ethics envisages at art. 31 comma 4[26] the patient's right to refuse a treatment, ending the paternalistic relationship through which the doctor used to feel authorized to ignore the patient's choices in the name of his power and in the belief to treat the patient in his own interest[27-28].

The judgement of the Court of Cassation n.364 of 15th January 1997[29] has in a way set the main features concerning the duty to inform, asserting that "the duty refers to predictable and unpredict-able risks, and also to abnormal outcomes, even on the borderline with fortuitous events, which don't become relevant according to the id quod plerumque, always considering that a healthcare professional mustalways bear in mind the need to inform, even for a simple surgery. Increasing importance is given to the importance of interests and goods at stake but always without running the risk - for simple statistical calculations - that the patient is not informed on the risks, even the smallest ones, which can influence his physical condition or also of the specific risks as against alternative possible choices. This way the patient, helped by the professional, can move towards one or the other possible choice, through a conscious evaluation of risks and advantages".

It's clear that law aims at overcoming asymmetries which make the figure of the doctor inevitably preeminent on the patient. For the consent to be represented by the will of the subject and to be considered legally valid, it has to respect the

1	It has to be informed
2	Free and revocable and linked to available good
3	The subject has to be legally and practically capable
4	It must be a manifestation of genuine and aware will

Table 1: Legally valid consent.

following prerequisites, summarized in table n. 1.

Starting from the first point of the chart: to be considered informed, consent must necessarily concern pre and post-op phases, the different executive methods, the objective and technical risks relat-ed to the subjective situation, the state of art, the used or alternative instruments and, in conclusion, the hospital situation and relevant devices and equipment and their regular functioning[30], with consequent duty to address the patient to structures which are more suitable from a technological point of view.

The aim of such a complex informed consent is to give the patient the opportunity to decide, in full awareness of their clinical situation, if undergoing the proposed operation or the medical treatment and to evaluate and accept risks and advantages included in every therapeutical hypothesis, especially in the presence of possible alternative choices for the treatment of the same disease, since an adequate and preventive information is an indispensable condition for the validity of the consent, which needs to be informed, to a surgical or therapeutical treatment[31].

It's therefore clear that every innovation, both concerning technical surgery[32] or research application[33], must consider to inform the patient about the reasons and the suggested therapeutical choic-es, the differences in the relationships between risk and advantages and technology and research application and other more traditional solutions and, consequently, the doctor will have to adapt therapeutical procedures according to the informed decision of the patient. Otherwise, in case of lack of consent, a possible result could be to proceed with an arbitrary treatment, with inevitable consequences not only from a civil and/or penal point of view, but also on an insurance basis.

Another issue which needs to be addressed when talking of using innovationsregards the existenceof specific guidelines and related legal aspects.

Article 5 of law Gelli Bianco[1], indeed, states that healthcare professionals have to conform "except for specific concrete situations, to the recommendations suggested from the guidelines published and elaborated from public and private organizations and institutions and from scientific societies and techno-scientific associations of healthcare professions, or in the absence of the abovementioned recommendations, to the good practices in the health care sector. The binding nature is so strong that in the following article 6 of the same law punish ability of healthcare staff in case of malpractice is excluded "as long as the recommendations of the guidelines are followed or, in absence thereof, that good practices in the health care sector look adequate to the specificity of the concrete case"[1].

It is necessary to define the concept of guidelines: according to the definition of the National Academy of Medicine of the USA released in 2011[34], these are papers containing recommendations aiming at optimising the assistance to the patient, based on a systematic revision of efficiency tests and on an assessment of benefit and losses of alternative health-care options.

The points on which guidelines are based are summarized in table 2[34]. The concept of the good practices in the health care sector is more complex and, waiting for the interpretation of the law 24/2017[1], it seems to overcome the 11 ministerial recommendations stated in 2005 to "reduce risks and promote taking on responsibility by the professionals to encourage a change in the system", including all the therapeutical practices which, even though still lacking of the dignity required to be called guidelines, follow, for instance, at least the research criteria and scientific demonstration of efficiency.

1	Must be elaborated from a multidiscipline group of experts and representatives from the different involved groups
2	Must take into consideration significant subgroups of patients
3	Must be based on an explicit and transparent process, reducing distortions, bias and conflicts of interest
4	Must provide a precise illustration of the logical relationships between alternative healthcare options and consequences on health
5	Must be reconsidered and kept up-to-date

Table 2: Development points of a guideline.

An example of application in the otolaryngol-

ogy sector is the evaluation of the different options deriving from the use of phonatory prosthesis in a patient subjected to laryngectomy[35] or the domestic wrist cardiovascular monitoring in pediatric OSAS[9,36-38].

What is supported from literature and validated by observational multicentre studies can be applied on a daily basis, even if not mentioned in the guidelines because still discussed in the scientific community[16,39-40].

The use of an instrumental or therapeutical innovation can't be legally implemented if there is no shared consent on its applicability and valid scientific research. Apart from the ethical aspects, indeed, it needs to be clarified whether it is indictable or not to carry out neck dissections when the choice is not universally shared[41] or if preferring innovative choices[42] can be considered a good alternative as against consolidated ones, without being perfectly sure that results would be more fa-vourable: the risk would be incrimination in case of adverse event for loss of chance.

Results

According to the analysis of the Italian law and considering the weaknesses ofthe above mentioned guidelines, pending legal administrative clarifications, we believe an operational protocol can be proposed as shown in table 3, in case of application of therapeutical innovations, especially about experimental introductions.

1	Preventive authorisation from the Company/Institute for the use of the technologic innovation
2	Acquisition of the opinion of the Ethical Committee
3	Precise ad hoc consent of the technology if it is both new and innovative
4	Making clear in the insurance policy for professional indemnity insurance that coverage for the hypothesis of damage to the State and other public agency or institution is included

Table 3: Proposal for a protocol for the use of therapeutical innovation.

Conclusion

The introduction of the new article 590-sexies in the Penal Code, disciplining the responsibility for death or personal injuries in healthcare referred to in law Gelli Bianco[1], in a way allows the specificity and peculiarity of medical act in Italy, but still looks "unprecise" in its implementation and does not take into consideration the fast pace of research in the healthcare sector and the relevant consequences in its application[43].

Consequently, in our opinion, the risk of incrimination persists in case of use of innovative proce-dures in the absence of a formal shared opinion expressed in guidelines or in good practices, which still need a satisfactory definition.

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