COMMENT

Evolution - research - training from practice to law and ethics

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Introduction

During the last century, radiology became an established discipline defined on the basis of examinations performed for diagnostic purposes initially using mainly x-rays. Little by little, and especially over the past decades, interventional radiology was "invented" and interventional neuroradiologic procedures developed dramatically, leading to a completely new "hyperspecialisation".

Near half a century of patience and tenacity was necessary to forge neuroradiology as we know it today. But has this neuroradiology reached adulthood, that is to say maturity?

An analysis of the situation today leads us rather to think that our current neuroradiology is still particularly fragile: it will be able to continue to develop, or even just to survive, only at the price of a significant effort of thinking to determine the future strategies that it is advisable to adopt. That is what I am going to try to demonstrate.

To succeed in the future, interventional neuroradiology has to take up many challenges:

The challenges of the future can be schematically divided into two main categories: conceptual and organisational problems. The ethical problems, which are of considerable importance, cannot be dissociated from all the questions raised, so they will be discussed step by step:

- On the conceptual level, it is necessary to define what interventional neuroradiologists must be -- their training, their competence, their proper role in daily practice but also their research activity without which no speciality can develop or even survive.
- On the organisational level, it is advisable to determine how interventional neuroradiology must be integrated and work within the framework of the neurosciences, which obliges us to specify how neuroradiology is related to all the various specialities which deal with the nervous system (neurology, neurosurgery, cognitive neurosciences, neuroanatomy, neurobiology...).

Historical background

A short recapitulation of the history of neuroradiology will enable us to better understand the stakes with which we are confronted, taking into account the extraordinary rapidity of the technological progression in this field which tends to assume more importance than theoretical thinking.

- During the era of pioneers (1960 - 1975), practically "anything was allowed" since the indications of interventional neuroradiology were those of "the last chance", because there was no real competitive surgical treatment to oppose the new indications which were outlined. Interventional neuroradiology attacked diseases impossible to treat by surgery or diseases whose therapeutic risks exceeded the limits of what was reasonable.
- The period of development (1975-1990) which followed was characterised by basic technical evolutions and the foundation of new teams, new working groups and new scientific societies. Simultaneously, all this progress allowed a better selection of patients, taking into account the progression of our theoretical knowledge and, particularly, the progressive establishment of new classifications that were better adapted to the selection of indications for interventional radiology. During this period, the indications of interventional neuroradiology began to compete with neurosurgery: the best example is given by the progressive increase in the rate of intracranial aneurysms treated by the endovascular approach.
- The period of maturation (1990-2000) was certainly very interesting but also difficult, mainly because of the absence of an official training programme and also because, with the support of commercial companies, many doctors began to perform interventional neuroradiology procedures after a very short period of training, only centered on technical problems. The multiplication of so-called "how-to-do-it sessions" explains this tendency very well.

What are the main difficulties?

Some simple examples, drawn from daily practice, help us to understand the acuteness of the problems currently encountered. This will then enable us to try to outline some steps to solve the main problems.

Within the framework of the development of techniques of intracranial aneurysm endovascular occlusions, the leading industrial companies regularly propose that the various teams of interventional neuroradiology try out new microcoils. These new coils differ from the previous devices in shape, size, flexibility, detachment method, coating and capacity to increase their volume spontaneously ... A priori, all these new products could constitute a factor of permanent progress only on the condition that the experiments, carried out with strict respect for elementary ethical rules, are continued on sufficiently large

cohorts of patients and for a sufficient number of years to make a real long-term follow-up possible.

However we all know that the reality is different. The experiments are generally carried out with the aim of encouraging operators to use the new product in preference to the others available on the market. The situation is worsened by the increasingly shorter lifespan of all the new techniques used so that for the large majority of new products, nobody will never know the real long-term follow-up. This is all the more problematic as more and more indications concern the fortuitous discovery of aneurysms, and only a precise comparison between the natural history in the long run and the real long-term follow-up would enable us to progress.

In the same intracranial aneurysm field, some authors have recently shown that the wall of a giant intracranial aneurysm was responsible for the development of these aneurysms, independently of the flow. Consequently, many repeated attempts to treat these giant aneurysms with intrasaccular coiling failed and the failures were sometimes responsible for major complications. It is very important to create a scientific working group which is able to try to understand the mechanisms of growth in order to find the best and most efficient solutions to treat these giant aneurysms.

The use of alcohol in endovascular interventional neuroradiology is another interesting example. Alcohol is certainly a very efficient agent for endovascular sclerosis; it can also be very dangerous. The risks are increased because alcohol is not spontaneously radio opaque and also extremely fluid. This product has been used by many teams in multiple, highly varying, indications during the last decades. Some very interesting results have been presented and some have been published but unfortunately, most of the complications have not been published or really honestly analysed. For many years, all interventional neuroradiologists have known that many very serious complications have been observed in the treatment of not only in diseases of the central nervous system (like brain Arteriovenous malformations) but also in other benign diseases (such as venous malformations of the limbs, digestive or kidney diseases). These complications can be local but also general and responsible for the death of patients. Obviously some deaths are ethically absolutely unacceptable, mainly when the disease to be treated is a really very benign condition. There are multiple similar examples, but these suffice to justify a common thinking about a better organisation of our speciality.

How can we better organise interventional neuroradiology at the beginning of the 21st century? It is essential to set up a structured organisation to make it possible to solve the main problems currently encountered. Consequently, we have to standardise the conditions and the quality of the training of future interventional neuroradiologists, and devise an organisation of the scientific structures, academic or otherwise, which are able to define the main ways of research, control the results and daily practice.

Training interventional neuroradiologists

It is important to recall that the neuroradiologist must be a clinician completely responsible for his/her own activity. According to the dictionary, a clinician is a practitioner of clinical medicine, which involves multiple tasks. So what exactly does the word "clinician" mean? Examining the patient? Questioning and listening to the patient? Mastering symptomatology and pathology? Taking the clinician's place? Keeping up to date with new diagnostic and therapeutic procedures? Absolutely not! Being a clinician involves being recognised as a legitimate partner with a valuable opinion on patient management, not as a mere service provider. In a growing number of countries, the technical part of the radiologist's work is now performed by radiographers. This reinforces the idea that radiologists should act as practitioners, that is to say, as a human being who can use his scientific knowledge and the technical means he has access to, for preventive and curative purposes or to relieve patients' pain.

If we want to make headway, we need to ponder the current conditions of radiology practice. Invasive explorations for diagnostic purposes have largely receded.

This tendency is particularly evident in neuroradiology: encephalographies and myelographies disappeared many years ago. Today, most diagnostic angiographies have been replaced by CT scan and MR investigations, during which the only "aggression" is a usually insignificant intravenous injection. Meanwhile, although invasive diagnostic investigations have practically disappeared, the invasiveness of therapeutic procedures has considerably increased, unquestionably implying greater risk for the patient. What makes risk all the more difficult to accept is that many procedures are undertaken for preventive purposes on diseases that were discovered incidentally.

In any case, whether it be for diagnostic purposes or in the course of an interventional procedure, this is where the radiologist's responsibility begins. In many countries, and particularly so in France, the law is perfectly clear: the person who performs the procedure is responsible for the indication of the procedure. A clinician may suggest an indication for a given patient but in the end, the decision to perform the suggested investigation is the radiologist's. Radiologists are often unaware that they are held liable for the indication, especially if they consider themselves service providers. Liability involves choosing the procedure with the lowest risk, an often difficult decision that may prove impossible to make if technical support is lacking, as is the case for MRI in "developing countries". Once the indication problem has been solved, radiologists are naturally held liable for the actual procedure.

In interventional neuroradiology, just as in surgery, the problem of the person operating arises at this point, although on a different scale in state-owned and private practices. The postoperative follow-up of the patient is of course also placed under the responsibility of interventional neuroradiologists. The point is not to take the clinician's or the anesthesiologist's place, but after an interventional procedure, interventional

neuroradiologists must follow up their patients, even if they are hospitalised in the intensive care unit. They must be involved in the decision-making process with the rest of the team in case of complications and must, of course, follow up their patients over the course of time. At every step of the process, the same problem seems to arise: taking the place of the clinicians. But how can interventional neuroradiologists assess the results of their therapeutic procedures if they do not follow up their patients themselves several months or years later? How can they find out whether the treatment was fully effective?

Interventional neuroradiologists are obviously liable for the quality of the equipment used. Since 1993, French law has declared that specialists do not have the right to use old or out-of-date equipment that puts patients at greater risk than more recent and modern equipment. This is especially applicable to ionizing radiation. This raises the problem of investing and upgrading equipment, which may prove difficult to solve since more often than not the decision is the hospital administrators' more than the medical practitioners'. Interventional neuroradiologists may also be held liable for the operating quality of equipment, which is why they absolutely must be involved in the decisions concerning machine maintenance. This is important since maintenance costs usually skyrocket during nights and holidays. Some of our neuroradiologist colleagues have been charged because a particular piece of equipment was unavailable for an emergency on a Sunday or a holiday.

When neuroradiologists are not involved in important decisions, they absolutely must take preventive measures with the local and regional administrative authorities not to be held liable in case of a problem.

Consequences of these duties on the ethics of training. Obviously, daily practice proves that the current organisation of training is very poor in the majority of the countries. Indeed many complications continue to occur regularly and these complications are directly linked to an ignorance of elementary rules. This insufficiency leads the new actors to rediscover repeatedly that patients depend on the well-known notions of the experienced teams.

In order to practise interventional neuroradiology properly, sound initial training is necessary. Nowadays, finding a good interventional neuroradiology training is difficult because of the lack of official standards and true references in the world. The training that would be first diagnostic followed by training in interventional skills is currently submitted to the aura of such and such a school of thought, or to the influence of a renowned team...and the length of the course is highly variable.

The quality of the ensuing practice, however, depends on the efficiency but mainly on the rigour of this initial training. It is interesting to note that each doctor determines his own training path, really, according to his own consciousness, and that its length may vary from a few days...to several years!

It is the duty of universities, national and international scientific societies and world federations to define training standards that can serve as references to those who wish to undertake such a practice. That is the price to pay if we want to avoid experimentation by "self made men" whose victims are the first patients of the newly self-proclaimed specialist. On the other hand, teams agreeing to train young colleagues should have adequate means to ensure maximum training quality and efficiency. Because of the current situation, the team must also assume responsibility for assessing the training received. This should then be vouched for not only by a training certificate confirmed by a log book, but by a true diploma.

The most elementary ethics impose a total dissociation between training structures and commercial companies. Even though companies have to look after their possible medico-legal responsibility, training cannot and should not focus on equipment or devices. Acquiring a technique can constitute no more than a tool in the course of training. Training must necessarily remain clinical and scientific.

In 1996, the World Federation of Interventional and Therapeutic Neuroradiology (WFITN) published standards of training in interventional neuroradiology. These standards have recently been adapted by the Executive Committee of the European Society of Neuroradiology and will be discussed during the coming months within the World Federation Neuroradiological Societies (WFNRS). The following summarises the most important rules:

- The invasive nature of this specialty requires special training and skills.
- To be familiar with the signs and symptoms of disorders amenable to diagnosis and treatment by neurointerventional techniques;
- To conduct thorough and accurate neurologic examinations to evaluate patients with neurological disorders;
- To understand the pathophysiology and natural history of these disorders;
- To know the indications for and contraindications to neurointerventional procedures; to be skilled in the clinical and technical aspects of their implementation;
- To be familiar with other therapeutic alternatives;
- To have a thorough understanding of the pre and post operative management of patients;
- To have an appropriate understanding of neurointensive care management;
- To understand the fundamentals of radiation physics, radiation biology and radiation protection, and the basic sciences related to technical aspects of neurointerventions.

Until now in most countries, continuing education was entirely left up to the individual doctor. It depended solely upon the "goodwill" of the specialist, upon his/her motivations, and, ultimately, upon his/her conscientiousness. But as we well know, medicine is becoming more and more effective, and consequently more and more iatrogenic: incompetent doctors hold weapons, in their hands or in their brains, which are becoming more and more dangerous. In order to ensure

the quality of medical care, and more particularly, to protect the patient, we will soon find society increasingly imposing continuing education, because the rapidly developing new technologies require it. Maintaining and developing one's knowledge are part of the ethical rules that society must impose, since it does not spontaneously strike all practitioners as "normal and essential". It is already organised in the United States since radiologists are obliged to be recertified every five years.

Practice in interventional neuradiology

Even if we are able to improve training inside the next decade, it is important to think about daily practice. During recent months, important work has been done within the WFITN to establish some general rules for practice in INR. These rules have recently been published in the journal *Interventional Neuroradiology*. In summary, these rules explain what must be the theoretical organisation of INR: "A healthcare institution can be authorized to practice interventional neuroradiology if it provides at the same site the following facilities : In-patient hospital beds (who is doing the service and work--two neuroradiologists are not enough, nurses, physicians etc.....) - interventional angiography and operating suite suitably equipped for these activities - a department of neurosurgery and neurology with vascular expertise - an intensive care unit - a department of neuroradiology. In order to qualify as an interventional neuroradiology approved facility, the institution shall provide the services on a full time basis all year around.

"The 24h service can be provided by agreement with other interventional neuroradiology sites. Patient transfer should be carried out within a time frame compatible with safety imperatives. Authorization to practice interventional neuroradiology can only be granted or renewed if the applying institution provides evidence of annual activity. Projected activity is permitted during the development phase of a service. An agreed level of activity will be defined by the accrediting authority for each applying institution. Acceptable levels of activity will be set, bearing in mind local circumstances, such as the population of the healthcare catchment area, population density and excessive travel time. Each intervention requires the presence of the following experienced individuals: an interventional neuroradiologist - a radiographer (technician/ technologist) and a nurse, a radiographer or an additional interventional neuroradiologist. The practice of interventional neuroradiology requires having access at all times to properly staffed facilities: MRI, CT, doppler imaging tests - intracranial pressure measurement and continuous recording devices - appropriate laboratory testing... intensive care unit with monitoring - MRI minimum 1.5 Tesla with functional imaging (diffusion and perfusion), MRA..."

Obviously all these rules have to be considered recommendations that the different countries can adapt to their own way of life and legislation. But, we can hope that these rules will play an important role in improving the level of interventional neuroradiology practice all over the world.

Research in interventional neuroradiology

If a well adapted training and a good supervision of practice are difficult to organise, research is certainly more difficult to master. It is within the general scope of research that all the experimentations of new tools or "slightly modified tools" are organised. The temptation to accelerate procedures and to reduce experimentation to the shortest time possible is very important for all commercial companies. Outside the general rules which govern research activities in medicine, we must try to organise research in INR under the responsibilities of scientific societies or world federations. But everybody knows that it is very difficult because the people in charge of regulation are also the research workers. It seems necessary and possible to create national and supranational scientific committees in charge of giving an opinion on the usefulness of such or such way of research. This kind of organisation will be increasingly necessary because many new possibilities will appear in the near future with the rapid development of "nanotechnologies".

Any time scientific work is carried out, results must be published, whether it be actual experimentation, clinical studies or other types of work. But in a world of competition, the temptation to cheat is great. Most humans like to show themselves to their advantage and, consequently, to present interesting results, especially so if they are in competition with rival teams. If we overlook the cases of what can be considered mere personality traits, the situation can be much more delicate than it may seem -- in certain countries where scientists do not have the right to make mistakes for fear of losing their position. It is then difficult to resist the temptation to "improve" results. Apart from questioning its honesty, such behaviour has tremendous ethical implications. To withhold or to hide the failures of a technique from publication inevitably leads other teams to attempt the very same technique and to cause a new series of complications for other patients.

Conclusions

Common sense tells us that interventional neuroradiology cannot be reduced to different techniques allowing the brain or spinal vessels to close or to reopen ...INR is obviously a part of the neurosciences and future doctors working in that field have to be true neuroscientists. Consequently, the best solution would be to create an emergency common basic training compulsory for all the future specialists (neuroradiologists, neurologists, neurosurgeons, neurobiologists...) and to organise many bridges between all the classical specialties. In the same way, we must facilitate grouping together all the hyperspecialised departments in a neurosciences institute or organisation which will facilitate the permanent necessary exchange between the different teams.

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