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Radiation Oncology in Italy: The Past, the Present, the Future

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History and Practice of Radiation Oncology in Italy

Radiation therapy in Italy has a long tradition, with Italians being early adopters of this new technology. In 1901, an Italian publication reported the work of Arnone, who treated a case of leukemic splenomegaly with x-rays (1). In 1904, Nieddu published a review of the technique and dosimetric evaluation of 10 patients treated with x-rays, describing beneficial effects on skin epitheliomas and malignant adenopathies. In 1913, the journal *La Radiologia Medica* was launched, and in the following decades, along with reports of the diagnostic field of radiology, it also published articles on radiation therapy. In those early years and, indeed, right up until the 1980s, the activities of radiation biology and radiation therapy were performed by radiologists who were also practicing diagnostic radiology. This extreme flexibility served as an incentive for creativity but, at the same time, carried the risk of a rather shallow understanding of the unique judgments required in the practice of radiation therapy.

In 1926, the Italian Ultraviolet Association was founded, expressing its scientific activity in their journal *Rivista Italiana di Actinologia*. The purpose of this association was to develop and coordinate studies on ultraviolet radiation and to effectively incorporate international scientific progress in every field of research and application of radiation. At that time, external beam radiation therapy was performed with cathode ray tubes able to produce beam energies of up to 250 kV, which, together with plesiotherapy a form of superficial radiotherapy, remained the most widely used therapy until the advent of tele-cobalt. In this regard, it should be remembered that the first tele-cobalt unit operating in Europe was installed in 1953 in the Hospital San Lorenzo, in Borgo Valsugana, making Italy, at that time, a center of leadership and excellence in cancer care (2). In rapid succession, other Italian institutions formed centers with high-energy units, including the Institute of Radiology of the University of Rome (1959) and later the Institute of Radiology of the University of Modena (1966), the Institute of Radiology of the University and the National Cancer Institute of Milan (1968), and the Institute of Radium O. Alberti in Brescia (1969).

For several years, only radiologists, who were eligible to practice both diagnostic radiology and radiation therapy, could deliver radiation therapy treatments. The postgraduate school in radiology consisted of both radiology and radiation therapy, but by 1980, the need to separate the schools after the common first 2 years of training was recognized. From that time on, training in a formal postgraduate school in radiation therapy was required to perform radiation therapy. Finally, in 1996, the 2 postgraduate schools were separated completely.

For many years, radiation therapy shared a scientific society with radiology and nuclear medicine, and consequently, the Italian Society of Medical Radiology (Società Italiana di Radiologia Medica [SIRM]) was the center for all clinical and research activities that took place in the radiological arena. Within the SIRM, a section for the study

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of radiation therapy had existed for many years, and in 1979, recognizing that this discipline was developing scientific and professional independence, the Autonomous Section of Radiation Oncology (Sezione Autonoma di Radioterapia Oncologica [SARO]) was then founded. Finally, in 1990, SARO was annulled and on September 14, during the annual congress of the European Society for Radiotherapy and Oncology (ESTRO), the Italian Association of Radiation Oncology (Associazione Italiana di Radioterapia Oncologica [AIRO]) was founded, with its specific organization, and completely separated from SIRM.

During the years 1988 to 1989, ESTRO conducted a survey of radiation therapy in Europe, which gathered data from 18 countries. A comparison of the results of that survey with those of a similar survey carried out by SARO in 1974 is of particular interest. In 1974, the existence of 224 radiation therapy services in various Italian hospitals was recorded, whereas in 1988, only 84 centers answered the ESTRO survey. This drastic reduction in a few years of the radiation therapy centers in Italy was the evident consequence of a silent revolution in Italian radiation therapy, similar to changes that occurred in other European countries. First, the departments that managed both the services of radiology and of radiation therapy had disappeared. Second, the upgrading of technological infrastructure necessary to bring Italy into the modern era was, improperly, considered too expensive by local and regional authorities. Indeed, several local administrators slowed down the necessary process of technological upgrading of radiation therapy centers in Italy. It should be pointed out that most of the 224 radiation therapy centers included in the survey performed in 1974 consisted of radiation therapy units equipped with Roentgen therapy alone, which was inadequate at all levels. Consequently, many Italian radiation therapy centers with old facilities and outdated technologies were simply not renovated, and most were closed between 1970 and 1980. Since the 1990s, things have changed, and now in Italy there are 188 radiation therapy centers, but as we shall see later, there is an uneven distribution that penalizes some regions of central and southern Italy. To better understand this phenomenon, it is appropriate to discuss the Italian health system.

Birth of the Italian National Health System: An Evolving Story

Before the creation of the National Health System and the era in which human rights were respected, many years of innovation, evolution, growth, fall, and rebirth passed. To understand the actual health care organization, we should recount the events that preceded the present system and provide the necessary information to understand the institutional and organizational evolution. There are 2 dates to remember: 1861, the year of the unification of Italy, and 1948, the Proclamation of the Italian Constitution. After 1861, the organization of health care was entrusted to the central government (Ministero degli Interni) at the central level and to prefects and mayors, locally. It was at the aforementioned department where, in 1888, the General Directorate of Health (Direzione Generale della Sanità) was established. This was the first sign of the importance and gravity given to health in the reunified Italy. Special duties and responsibilities were assigned to the General Directorate of Health, which functioned until 1945. The unification of Italy in 1861 led to a desire to standardize health care nationally through legislation. At that time, medical care still retained the characteristics of a charitable activity, most of which was supported financially by donations and charities. In 1890, Crispi's Law (Legge Crispi) proved to be historically significant for the national system of health care. By this measure, hospitals, nursing homes, and charities were transformed from private institutions into Public Institutes of Welfare and Charity (Istituti Pubblici di Assistenza e Beneficenza [IPAB]). During the fascist regime (1922-1943), a pension-insurance system able to ensure health care to workers was implemented. Until 1946, several mutual health funds were established with pension and health care tasks. In July 1945, the High Commissioner for Hygiene and Health was formed (Alto Commissariato per l'Igiene e la Sanità [ACIS]), finally replacing the General Directorate of Health. It was charged with many activities, including "the protection of public health, coordination, and technical supervision on health-care organizations and entities that are designed to prevent and to combat social ills." This was the scenario before the enactment of the Constitution of the Italian Republic in 1945 and the new standards of health contained within it.

The Health System after the Constitution

Changes in the health system were not effective immediately, and it took several years before the organization of the whole sector evolved adequately. While in Britain the government gave organic arrangement to the law and the protection of health by establishing their National Health Service (NHS) in 1949, Italy, by contrast, continued a policy based on a public system of insurance both for social health and occupational accidents. On March 13, 1958, the Ministry of Health (Ministero della Salute) was created to replace the ACIS, with a unique and better articulated vision for public health.

The year 1968 was important for the recognition of human and social rights of Italian citizens. It was the year of the Hospital Reform (Riforma Ospedaliera). Nevertheless it was not until 1978 that a dramatic revolution in public health national service occurred, when the National Health Service (Sistema Sanitario Nazionale [SSN]) was established. This office reformed the entire system of health in Italy through radical reorganization. This system was based upon the principles of unity and universality desired for a national health service in Italy. This law appeared to

allow the previous organization based on a system of insurance to be overcome, and thereafter, it permitted greater coordination between hospitals and territory, as well as the introduction of prevention activities and rehabilitation. From a political point of view, the most significant innovations were considered both the introduction of the principle of equality for all Italian citizens and the decentralization of decision making powers away from the central government to regional and local levels. Local health units (Unità Sanitaria Locale [USL]) were established and entrusted with the management of health.

This first health reform soon collided with the economic and financial Italian system, mainly because of the rising costs related to the economic management of this new organization. The separation of powers between those who were the real source of economic funding (central government) and those who actually spent the economic resources in the regions (local governments) was intrinsically unstable. As a result of this situation, national health care costs soon became uncontrollable. Moreover, in the absence of legislation indicating the minimum levels of assistance, some regions created an unreasonable level of offices and services, further increasing the deficit. Another limitation of this reform came from the growing dissatisfaction of citizens with the quality of health services, which was often poor due to increasing demand and the difficulties the regions had providing appropriate responses to the needs of citizens. These problems led to the end of the national health system launched in 1978 and the need to introduce, once again, radical changes to the organization of public health. In the early 1990s, a second health care reform was initiated, this time changing the legal and administrative structure of the National Health System, with a transfer of a large part of the decision making powers, especially in the management of economic resources, from the central government to the local structures (regions and USLs). This led to a strengthening and increased independence of these local structures especially in terms of economic planning of resource use.

The second health care reform triggered a real process of corporatization, using management models typical of private companies for the insertion of market factors in the supply-and-demand ratio and for the introduction of organizational, administrative, and economic autonomy of the local organizations (USLs).

This innovative path for the whole industry was then completed with the third health care reform of June 19, 1999. This was designed to strengthen local autonomy of the USL, emphasizing its corporate nature; to introduce the concept of corporate autonomy of the local health units and hospitals; and to introduce a system of accountability for results.

In essence, the role of the state, represented by the Ministry of Health, has gradually transformed from a leading position as organizer and manager of services to a guarantor of the execution of the health right (Article 32, Italian Constitution), with the task of determining the basic levels of care assistance. Regions have the task of implementing the public health services and hospital care. In addition, the Ministry of Health performs the legislative and administrative tasks of a planning, organizational, and surveillance nature and finances the USL with an appropriate division of the regional health fund. The inevitable consequence of a health system organized with this decentralized structure was to create substantial differences among the many Italian regions. The regions best administered, of course, would be able to offer the best services to their inhabitants; whereas those in which there was waste and inefficiency would provide services that were inevitably worse. Obviously the organizational and economic situation of radiation oncology in Italy is affected by these differences in the various regional and local administrations.

Radiation Therapy Oncology in Italy: The Present and the Future

Currently, Italy has 186 radiation therapy centers, with a national average of approximately 3 centers per 1 million inhabitants. There is a lower number of centers in the south (2.7 centers per 1 million inhabitants), and the highest numbers of centers are located in central Italy (3.7 centers per 1 million inhabitants). There are now 377 linear accelerators (LINACs) available and 38 radiation therapy units able to perform special techniques, located mostly in the north, including 21 tomotherapy units, 8 Cyberknife units (Accuray), 6 Gamma Knife units (Elekta), and 3 Vero units (BrainLab-Mitsubishi). In addition there is a hadron therapy center already functioning and another about to start activity, both located in the north of Italy (3).

The national average is approximately 6 LINACs per 1 million inhabitants, but the LINACs' territorial distribution varies considerably from region to region.

There are regions such as Lombardia, Lazio, Friuli, and Toscana where the national average of 6 LINACs per 1 million inhabitants is far exceeded (for example, there are 9.73 LINACs in Friuli) and other regions such as Puglia, Basilicata, Sardinia, and Sicily where this value is substantially lower (eg 4.08 in Calabria). Specifically, in the northern regions (such as Valle d'Aosta, Piemonte, Lombardia, Trentino Alto Adige, Friuli, Veneto, Liguria, and Emilia Romagna) there are 184 LINACs, equal to 6.7 LINACs per 1 million inhabitants, in the center (Tuscany, Umbria, Marche, Lazio, Abruzzo, Molise), 99 LINACs equal to 7.4 LINACs per 1 million inhabitants, and in the south and islands (Campania, Puglia, Basilicata, Calabria, Sicilia, and Sardegna), 94 LINACs, equal to 4.9 LINACs per 1 million inhabitants.

Thus there is evident regional inhomogeneity, with some regions operating in accord with European directives and sometimes even surpassing them (directives suggest 7-8 high-energy machines per 1 million inhabitants), but others that are far below. Although it should be noted that this situation is gradually improving, as shown by the current

increase in the number of LINACs (16 new machines) compared to that cited in the latest census performed in 2011. However, only 5 of them were installed in the south. According to the number of patients (450) treated per machine per year, as proposed by the Directory Radiotherapy Centers, and considering the incidence of 366,000 cases of malignancies/year provided by the Cancer in Italy site, of whom 228,000 require radiation treatments, Italy needs 506 radiation therapy units relative to the 415 currently existing; thus, there is a shortfall of 91 machines (4).

It must also be noted that of the 353 of 377 LINACs for which it was possible to find data, 124 were installed more than 10 years ago, and only 100 were installed in the last 5 years. Considering that the average life of a LINAC is approximately 10 years, it is evident that those 124 old machines need to be replaced.

Based on these epidemiological data and the census of the machines, each regional government must be made aware of the technical categorization of the radiation treatment that can be offered locally to cover the needs of their residents. Moreover, the number of centers able to provide treatments with special techniques must be programmed at a national level, taking into account the characteristics of the various centers and patients' ease of access to the center.

Other concerns surround the quality and safety standards that must be met by each radiation therapy center. The report by Istituto Superiore di Sanità (ISS) (5) recommends that, "in accordance with ESTRO guidelines, it is appropriate that each center periodically takes stock of and assesses its levels of staff, expertise, equipment and infrastructure." It is desirable that these goals be classified within a national and regional program to ensure a balanced distribution of resources to all citizens throughout the country in a uniform way. The definition of the targets is considered a dynamic process that can vary in relation to changes in facilities and programs. In defining its functions, each center should at least specify:

- Available resources (staff, equipment, infrastructure);
- Number of treatments delivered (documented on the basis of the activity in the previous year);
- Maximal technical category of the performance that it is able to provide, in relation to the available resources, established according to well-defined criteria;
- Any specific expertise available and ongoing research programs.

Staff requirements in radiation therapy centers are based mainly on recommendations drafted by experts. These recommendations vary widely among European countries and are strongly influenced by the current situation in each country; however, technical equipment and working staff everywhere are below the recommended levels. Discrepancies in recommended levels are particularly critical for medical physicists and medical radiology technicians, whereas they are more defined for the radiation oncologist. A proper and detailed analysis of each of the functions of each of the professional figures involved in radiation therapy procedures may allow a more accurate assessment of the actual needs that, together with epidemiological data, may lead to evidence-based recommendations. Several published models exist that allow assessment of the time required to perform activities related to the use of different procedures. As a first approximation, it can be said that the recommendations of ISTISAN 96/39 and 02/20, which are widely used in our country and have been adapted for the implementation of technology, still allow a good estimate of technological equipment needs and the definition of roles and duties for each professional involved in radiation therapy procedures. Such recommendations provide:

- A radiation oncologist for every 150 to 200 patients treated per year; the lower number is appropriate for centers in which more complex techniques are widely used, whereas the higher number refers to cases in which mainly the simplest treatments are performed. On the basis of these data, the number of radiation oncologists required in Italy may be calculated at approximately 1300. However, this number will rise in the coming years in view of the increase in the incidence of tumors due to an aging population.
- A full-time physicist for every 200 to 300 patients treated per year, with the same considerations made previously for the number of radiation. The number of full-time physicists in radiation therapy may therefore be estimated at approximately 1000, which is also likely to increase over time.
- Two medical radiology technicians for each LINAC who are always present during treatments and additional technical staff for other tasks such as simulation or support for the physicists. The total number cannot be easily calculated as it depends upon the organizational situations and the length of the machine's working day.

Overall it can be said that the numbers of staff dedicated to radiation therapy in Italy do not reach the recommended levels for any of the professionals involved. Therefore, in the medium term an adjustment of these numbers must be planned on the basis of organizational solutions adapted to actual Italian scenarios. Furthermore, it is desirable that the staffing should be planned for at least a 12-hour treatment day in order to maximize the use of costly equipment with relatively rapid obsolescence such as that used in radiation therapy.

The problem of geographical distribution also needs to be addressed in an integrated manner, looking at the entire nation and taking into account different local realities. It may be defined as a choice between 2 different patterns of response by the institutions: strengthening of existing centers or creating new ones. Given that radiation therapy is a highly specialized therapy that requires high technology and interactions with other disciplines at a highly specialized level, its natural place is in highly specialized hospitals. In order to promote patient access to radiation therapy

treatments for residents in areas far from highly specialized hospitals, however, there could be centers able to conduct treatments of lesser complexity within organizational models that also guarantee an operative link with more than 1 specialized center (at least 1 per 1 million inhabitants). Such a model, has already been successfully carried out in northern Europe and North America and has the following objectives:

- Optimization of the investment in resources of high technology, ideally reducing costs and rationalizing the specific characteristics of the equipment (eg use of magnetic resonance imaging [MRI] and positron emission tomography/computed tomography [PET/CT] for treatment planning and specialized techniques such as stereotactic or intraoperative radiation therapy should be provided), as follows;
- Optimization of human resources using a departmental organization, attributed to the establishment of intercompany and transmural departments of radiation therapy that can manage personnel (physicians, physicists, and technicians), thereby reducing the total number of people involved and consequently the operating costs;
- To allow creation and rapid growth of new centers, which, thanks to the close cooperation of the staff of the main centers, may employ expertise immediately and offer a qualified service to the local population; this would minimize the learning curve which exists for centers of high technology and specialization and which, for an autonomous and unchaperoned center, can be very long and shallow.

Such a concept of modular growth would allow the optimization of both technological and staff resources, thus saving money and giving birth to and raising new centers in a more efficient, faster, and safer manner. This model not only will offer the same service to the entire population but should do so more rapidly (with staff already trained and institutionally linked with the main center) and with the possibility of an integrated use of more advanced techniques (MRI, PET/CT, stereotactic radiation therapy, intraoperative radiation therapy, intensity modulated radiation therapy, and others), when necessary. Such reorganization should then allow Italy to achieve the goal of "widespread excellence and a highly specialized network" throughout the nation.

Italian radiation oncologists still frequently admit patients to the hospital and care for them while they are inpatients. This is now driven primarily by the following oncological activities:

- Hospitalization for brachytherapy, metabolic radiation therapy, and radioimmunotherapy in rooms that are adequately protected;
- Combined chemoradiation therapy treatments in which the right timing of drug administration and execution of radiation therapy is crucial; in such cases, patient management by a single medical team is preferred in order to optimally control all aspects of treatment, including treatment of any side effects;
- Supportive medical treatments in relation to the critical conditions of patients who cannot be managed on an outpatient basis (eg brain metastases, bone metastases, and others) and/or who experience critical side effects.

For all these indications, Italian centers should reserve beds for hospitalization that, ideally, would be located in departments of radiation oncology or in oncology departments under the direct responsibility of radiation oncologists. Finally, it must be added that universities need institutional beds for hospitalization, as these are part of the prerequisites required for the postgraduate schools of radiation oncology, and an inpatient service remains an important part of the oncologic training of new radiation oncology specialists.

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