

Training in Radiological Protection for Interventional Cardiology

To the Editor:

Interventional cardiology in Spain has gained great prestige and the country is a reference for many Latin American and European colleagues. Nevertheless, the development of the clinical and technological aspects of the discipline does not seem to have been accompanied by a similar development in radiological safety measures for professionals and patients.

In 1994, the Food and Drug Administration of the United States issued a warning about possible cutaneous radiation injuries to patients.¹ Later, several documents issued by international organizations²⁻⁴ have tried to guide professionals in complementing the quality of interventional cardiology with high safety standards.

European Directive 97/43/EURATOM on medical exposure, article 9,⁵ addresses interventional techniques exclusively, as an example of a procedure that can involve high doses of radiation to patients, and establishes certain requirements for its practice. The European Commission has published a guide on training in radiological safety for medical exposure⁶ that contains recommendations on training programs and accreditation of interventional practices. In 1988 the American College of Cardiology (ACC) published a consensus document titled Radiation Safety in the Practice of Cardiology,⁷ in which information on the radiological risks of interventional cardiology was updated and specific recommendations were made for performing the procedures with a suitable level of safety. The document, approved by the ACC in October 1997, was endorsed by the North American Society of Pacing and Electrophysiology, the Society for Cardiac Angiography and Interventions, and the American Society of Nuclear Cardiology in June 1998.

In 2001, an editorial in the journal *Heart* on radiological risks to patients deriving from cardiology procedures⁸ sought to bring to cardiology the traditionally high radiological safety standards prevalent in the United Kingdom, with special attention to patients.

What is the current situation in Spain? Spain has scrupulously adapted its national legislation to the European directive on medical exposure.⁵ In 1999, a Royal Decree was published on criteria for quality in radiodiagnosis,⁹ which regulates interventional practices guided by fluoroscopy. This regulation complements another regulation governing the installation and use of X-ray equipment for medical uses, published in 1992.¹⁰ The practice of interventional cardiology in Spain currently requires:

a) The use of equipment specifically designed for this purpose and installed in suitable rooms. Compliance with this measure is reasonably good.

b) Measurement and recording of the doses delivered to patients. Compliance with this measure is probably still irregular.

c) Accreditation of the professionals who perform these procedures in radiological safety (referred to as «second level» accreditation in Royal Decree 1976/1999). This part of Spanish law is not being met by interventional cardiology.

Royal Decree 1976/1999 states textually in article 6.2 that «the specialists who perform interventional procedures are required to have a second level of training in radiological safety oriented, specifically, to interventional practice.» This «second level» is understood to be in addition to the previous training in radiological safety required by Royal Decree 1891/1991, for the installation and use of X-ray apparatuses for medical diagnostic purposes,¹⁰ which states in article 14: «titleholders who direct the operation of X-ray facilities for the purpose of medical diagnosis and operators of the equipment who act under their supervision must accredit before the Council of Nuclear Safety their knowledge, training, and experience in matters of radiological safety.»

Without disregarding the stipulations in the regulations, it seems clear that interventional cardiology in the 21st century should be a high quality technique with an elevated level of safety for professionals and patients. Recently, the Sociedad Española de Radiología Vascular e Intervencionista (SERVEI, Spanish Society of Vascular and Interventional Radiology) organized the first pilot training course in radiological safety for its members (level two, as indicated by Royal Decree 1976/1999), which has been accredited by health authorities.¹¹ The Sociedad Española de Cardiología (Spanish Society of Cardiology) or the corresponding sections should promote similar efforts.

Eliseo Vañó,^a and Francisco Vargas^b

^aServicio de Física Médica.

Hospital Clínico San Carlos. Madrid.

^bSubdirección General de Sanidad Ambiental y Salud

Laboral. Dirección General de Salud Pública.

Ministerio de Sanidad y Consumo. Madrid. España.

REFERENCES

1. U.S. Food & Drug Administration (FDA). Avoidance of serious x-ray induced skin injuries to patients during fluoroscopically guided procedures. *Med Bull* 1994;24:7-17.
2. Efficacy and Radiation Safety in Interventional Radiology. Geneva: WHO, 2000.
3. ICRP Publication 85. Avoidance of radiation injuries from medical interventional procedures. Oxford: Pergamon. Elsevier Science Ltd. *Ann ICRP* 2000;30.
4. Medical electrical equipment. Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures. IEC 60601-2-43. First edition 2000-06. Geneva: International Electrotechnical Commission.
5. Council Directive 97/43 Euratom, on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466 Euratom. *Official Journal of the European Communities* No L 180, 9th July 1997, 22-27.

6. Guidelines on education and training in radiation protection for medical exposures. Radiation Protection 116, European Commission. Directorate General Environment, Nuclear Safety and Civil Protection. Luxembourg, 2000. Disponible en: <http://www.europa.eu.int/comm/environment/radprot>
7. Limacher MC, Douglas PS, Germano G, Laskey WK, Lindsay BD, McKetty MH, et al. ACC Expert Consensus Document. Radiation Safety in the Practice of Cardiology. American College of Cardiology. J Am Coll Cardiol 1998;31:892-913.
8. Wilde P, Pitcher EM, Slack K. Radiation hazards for the patient in cardiological procedures [editorial]. Heart 2001;85:127-30.
9. Real Decreto 1976/1999, por el que se establecen los criterios de calidad en radiodiagnóstico. Boletín Oficial del Estado de 29 enero de 1999;45891-900.
10. Real Decreto 1891/1991, sobre instalación y utilización de aparatos de rayos X con fines de diagnóstico médico. Boletín Oficial del Estado de 3 de enero de 1992;138-48.
11. Vañó E, González L, Canis M, Hernández Lezana A. Curso Piloto de Protección Radiológica (segundo nivel) de la Sociedad Española de Radiología Vascular e Intervencionista (SERVEI). Disponible en: <http://www.sepr.es/notic.htm>