REVIEW

Organizing the electrophysiology laboratory and training requirements

Stefan Ailoaei[1,2], Daniel Gafitescu[1,2], Elisabeta Hurjui[1], Elena Parvu[3], Sorin Balasa[4], Robert Alexandru[5], Liviu Stoica[2], Gabriela Creanga[2], Mihaela Grecu[1,2]

Abstract: Electrophysiology is a rapidly evolving field of cardiology dedicated to the diagnosis and treatment of cardiac arrhythmias, with a wide range of procedures being performed in a complex environment. An interventional electrophysiology laboratory involves the acquisition of modern technological systems, and the presence of specialized and well trained medical personnel, consisting of at least one electrophysiologist, one technician and two nurses. To be in line with the current European standards, the laboratory must support the whole spectrum of interventions for heart rhythm disorders. In this regard, a powerful fluoroscopy system, programmable electrical stimulators and advanced ablation and 3D mapping systems are required. In recent years, the attention has focused on both the radiation dose minimization and protective radiological measures in the interventional cardiology laboratories, and thus the medical staff requires a specific set of qualifications. Continuous medical education is of paramount importance in an innovative field with such a steep technological rise as the field of electrophysiology. We considered it to be an opportune time to write this paper, as in February 2018 an official document attesting the training in electrophysiology and cardiac stimulation was officially launched by ministerial order in Romania.
Keywords: electrophysiology, training, education, laboratory, equipment

Rezumat: Electrofiziologia reprezintă unul dintre cele mai rapid evolutive domenii ale cardiologiei, dedicată diagnosticului și tratamentului aritmiilor cardiace și care cuprinde o gamă largă de proceduri efectuate într-un mediu complex. Un laborator de electrofiziologie intervențională implică achiziția unor sisteme tehnologice moderne și prezența unui personal medical specializat, alcătuit din cel puțin un electrofiziolog, un tehnician și doi asistenți medicali. Laboratorul trebuie să fie capabil să susțină tot spectrumul intervențiilor necesare diagnosticului și tratamentului aritmiilor. În acest sens, un sistem performant de fluoroscopie, stimulatoare electrice programabile, precum și sisteme avansate de ablație și de mapping 3D sunt necesare pentru efectuarea ablațiilor simple, dar și a celor complexe. Personalul medical trebuie să aibă competența necesară în domeniul radiațiilor, întrucât atenția s-a concentrat în ultimii ani asupra minimizării dozei de radiații și asupra măsurilor de protecție radiologică. Educația medicală continuă reprezintă piatra de temelie într-un domeniu inovativ cu o ascensiune tehnologică atât de abruptă cum este domeniul electrofiziologiei. Considerăm că este un moment oportun pentru publicarea unui astfel de document, întrucât în februarie 2018 s-a lansat oficial, prin ordin ministerial, atestatul de formare în electrofiziologie și stimulare cardiacă în România, deschizând perspectiva acreditării naționale a tinerilor cardiologi care doresc să se dedice acestui domeniu.
Cuvinte cheie: electrofiziologie, instruire, educație, laborator, echipament

1. INTRODUCTION

Electrophysiology is a rapidly evolving field of cardiology dedicated to the diagnosis and treatment of cardiac arrhythmias, with a wide range of procedures being performed in a complex environment. The growing understanding of the mechanisms involved in the heart rhythm disorders and the continuous development of new modern technologies have granted electrophysiology studies the opportunity to be chosen as first line diagnostic and treatment options.

[1] Department of Cardiology, Institute of Cardiovascular Diseases „Prof. Dr. George I. M. Georgescu", Iasi, Romania
[2] Department of Electrophysiology, Institute of Cardiovascular Diseases „Prof. Dr. George I. M. Georgescu", EHRA Recognized Training Center, Iasi, Romania
[3] Hellimed SRL
[4] Johnson&Johnson Company
[5] Medtronic Company

Contact address:
Mihaela Grecu, „Prof. Dr. George I. M. Georgescu" Institute of Cardiovascular Diseases, Iasi, Romania.
E-mail: mihaelagrecu@yahoo.com

The electrophysiology laboratory

The electrophysiology laboratory is a special designed place to safely perform invasive procedures and must meet predefined standards in terms of space requirements and functionality in order to improve work conditions. The space allocated to the electrophysiology laboratory must be dynamic in order to facilitate the free movement of the staff in this environment, but at the same time to be able to accommodate all the equipment. The dimensions of the electrophysiology laboratory should be a minimum area of 33 m^2, ideally 47 m^2. Also, there should be a clear space of at least 2.43 m between the walls and the edges of the table where the patient lays. The height of the room depends on the size of the fluoroscopic equipment which can be mounted both in the floor or attached to the ceiling, the latter option allowing a more efficient cleaning of the floor[2]. There are special requirements regarding the facilities and equipment necessary for an electrophysiology laboratory, as well as the need for a well-trained staff. Among these facilities we mention the spaces for inpatient and outpatient care. The environment in the electrophysiology laboratory should be sterile and should be provided with good air circulation, optimal brightness, ventilation and adequate heating /cooling[3].

2. THE MEDICAL PERSONNEL

The unit dedicated to cardiac arrhythmia treatment involves not only state-of-the-art equipment and technology but also well-trained personnel that must include minimum an electrophysiologist, two nurses and a technician. Thus, it is easy to infer that the staff working in the electrophysiology laboratory plays a central role in its proper functioning.

In most European countries, electrophysiology is not included among the compulsory modules of the residency program. Young fellows must train themselves in accredited European centers which perform a wide and complete range of ablation and cardiac stimulation procedures in order to gain the necessary knowledge and competence[1]. Likewise, nurses working in the electrophysiology laboratory need additional knowledge regarding the diagnosis and treatment of cardiac arrhythmias. It is crucial to recognize the symptoms and clinical signs of arrhythmias and the various complications that may occur intra- or post-procedurally. Quick and efficient management of these complications represents the key for both the patient safety and the better functioning of the electrophysiology laboratory. Furthermore, there is a special cardiovascular electrophysiology curriculum for nurses and there are accredited modules which provide comprehensive electrophysiology courses for those working in this field.

Electrophysiology training

The *European Heart Rhythm Association* (EHRA) promotes and seeks to ensure a homogeneous education and qualification among European heart rhythm specialists, so it has organized a basic curriculum for arrhythmology specialists including the following: the Syllabus, the development of minimum standards and objectives for the electrophysiology training program (Curriculum), the creation of a model to certify specialists in this field and the training institutions (Accreditation) and the development of a registry for European electrophysiology specialists, their related institutions and their activity (Registries)[4]. Given the complexity of the mechanisms of different arrhythmias and their subsequent understanding, the duration of training in electrophysiology lasts for at least two years after finishing the residency in general cardiology. During these two years, the electrophysiology fellow must participate in the arrhythmology training program for at least 80% of the working hours (10% outpatient care, 10% device tracking, 10% device implantation, 40% invasive electrophysiology)[5].

The Syllabus for the heart rhythm specialist is divided into two components. The first component consists in a general program that includes knowledge about anatomy, physiology, epidemiology, genetics and pathophysiology of rhythm disorders, arrhythmic diseases and syndromes (e.g. ischemic and non-ischemic cardiomyopathy, channelopathies, hereditary syndromes) and techniques for the diagnosis and treatment of cardiac arrhythmias. The second component of the curriculum includes specific knowledge about invasive cardiac electrophysiology and implantable cardiac devices (equipment, principles, implantation / extraction and ablation techniques, complications). Therefore, the purpose of the basic curriculum is to determine the knowledge necessary for the trainee at the end of his/her training[4,5]. Moreover, the electrophysiology fellow must meet a minimal number of invasive and non-invasive procedures conducted as the first operator. It is important to note that a European accredited training center must perform annually at least 250 invasive diagnostic procedures, 200 catheter ablation, 200 pacemaker implants/replacements, 50 ICD implants/replacements, and 20 CRT implants/replace-

ments[4]. To date, in Romania there are only a few centers that are able to meet this number of procedures, since the number of electrophysiologists in a given center is very small.

Obtaining European certification in electrophysiology

In order to obtain European certification in electrophysiology issued by the *European Heart Rhythm Association,* the fellow physician must undergo a proficiency examination that takes place once a year during the EHRA congress. The examination consists of a theoretical part and in submitting a logbook within two years of the written exam which must contain at least 100 electrophysiological (self-standing or pre-ablation) electrophysiological studies and 100 catheter ablations as the first operator. The cases should be collected for two consecutive years[4,6].

To date, there are 8 European accredited electrophysiologists in Romania, out of a total of 594 across Europe.

Obtaining national certification in electrophysiology

In February 2018, an official document attesting the training in electrophysiology and cardiac stimulation was officially launched in Romania by ministerial order, opening the perspective of national accreditation for young cardiologists who want to dedicate themselves to the field of electrophysiology. The Electrophysiology and Cardiac Pacing training programs for the young cardiology specialists will be launched in the centers provided in the curriculum approved by the ministry, starting with the academic year 2018-2019.

Despite the strenuous, long way to reach the earliest stages of the career as an electrophysiologist, even after obtaining a Free Practice Certificate, continuous medical education remains the cornerstone of this profession and regular educational programs are imperative for maintaining a high level of competence in line with the international standards[1].

Maintaining competence in electrophysiology

Continuous Medical Education (EMC) in all subspecialties of cardiology is essential, since the knowledge and skills needed in these areas are in permanent development. Standards are maintained through continuous learning and practice, as major changes can occur at any time in this field. Thus, it is necessary to participate annually in at least two international seminars and international conferences. Continuous medical practice requires at least 16 work hours per week in the field of electrophysiology, while continuous medical education is defined by the accumulation of 200 EMC credits over a five-year period. The Accreditation as an electrophysiologist is valid for 10 years, after which a new process of reaccreditation and recertification is necessary[4].

3. EQUIPMENT

The standard requirements of an electrophysiology laboratory include a state-of-the-art fluoroscopy system, programmable electrical stimulators, integrated data display systems, 3D mapping systems that are used for the ablation of complex arrhythmias such as atrial fibrillation or ventricular tachycardia, as well as catheter ablation systems designed to fit the anatomy of each patient (Figure 1). There are several systems for recording the surface electrocardiogram and the intracardiac electrograms, depending on the purchase price, the quality of the signals provided and the maintenance costs. The minimum requirements for a monitoring system should include a 12-lead surface electrocardiogram and a 24-channel intracardiac electrogram. For the more advanced laboratories such as those able to perform complex ablations, there are systems with up to 64-128 intracardiac channels. The electrophysiologist represents the decisive factor in choosing a work system, as he has to be familiar with it and with the installation of the latest software[1,7].

Electroanatomic 3D mapping systems used for real-time reconstruction of each patient's heart anatomy are especially required for complex ablations, such as pulmonary vein isolation or ablation of ventricular tachycardia. There are three mapping systems available on the market: CARTO 3D from Biosense Webster Inc. and Ensite NavX at St. Jude Medical Inc and Rhythmia HDxTM from Boston Scientific Corporation. The CARTO 3D system is based on obtaining the catheter's virtual position using a static magnetic field, while the Ensite NavX system depends on the constant measurement of impedance. Robotic navigation systems such as Stereotaxis™ and Electromechanics (Sensei™; Hansen Medical) facilitate mapping and ablation of complex arrhythmias, both offering the advantage of being able to manipulate the catheters inside a control room, thus substantially reducing the exposure of the staff to radiation[8,9].

Many laboratories that perform complex ablation procedures have digital fluoroscopic systems with advanced imaging capabilities such as rotational angiography, rotational CT imaging and offer modalities to

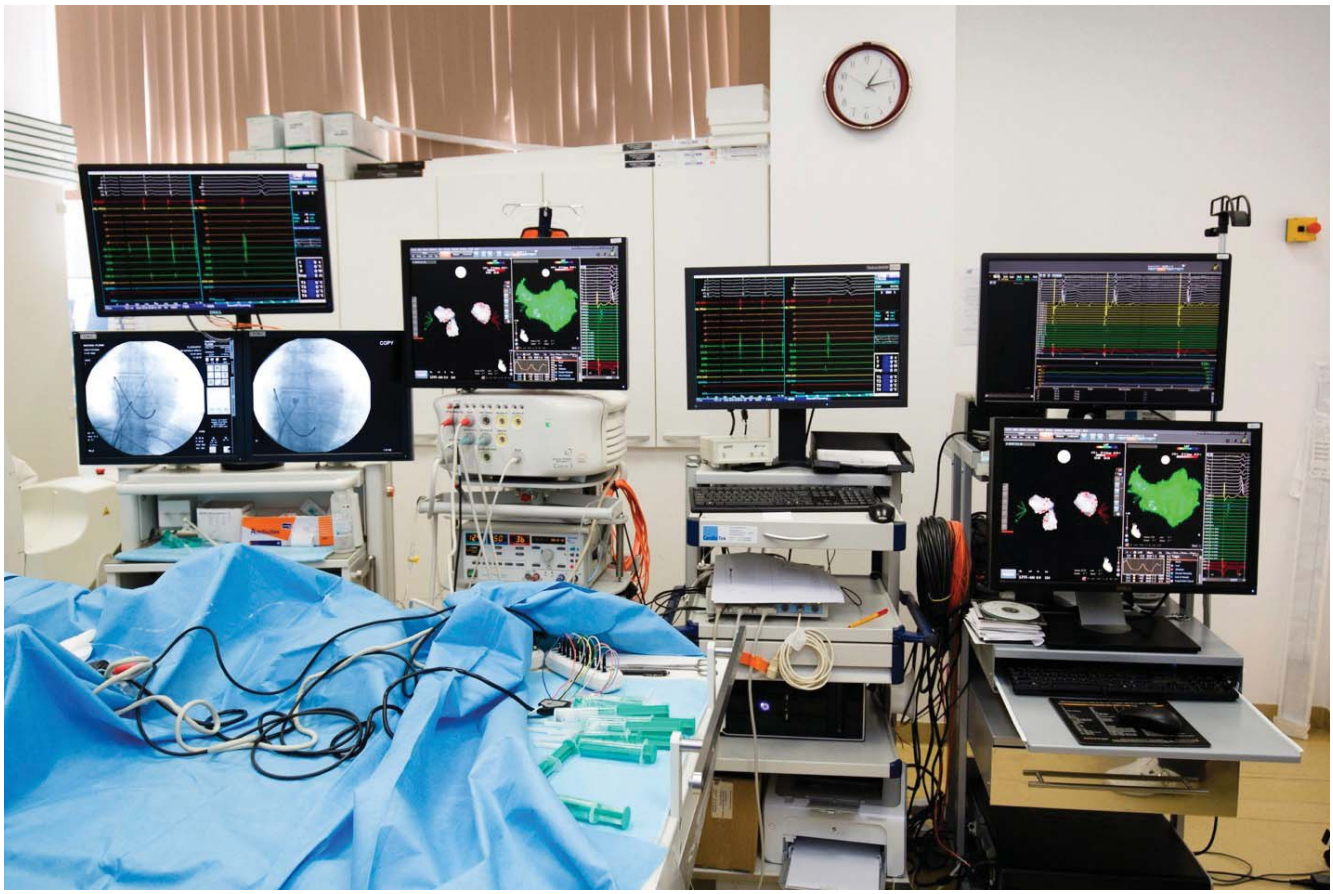

Figure 1. The EP laboratory equipment, including integrated data display systems and CARTO 3D system.

integrate 3D CT and MRI imaging. Reconstructed 3D imaging based on CT or cardiac MRI helps the electrophysiologist to guide the catheter and choose an ablation technique. A common case is represented by the atrial fibrillation ablation procedure when a preprocedural 3D image may prove to be extremely useful if the patient presents particularities in the anatomy of the left atrium and / or the pulmonary veins[10,11].

The programmable electrical stimulators are the cornerstone in conducting an electrophysiological study and have between two to four programmable output channels in order to adjust the amplitude and the duration of the stimulus. Burst pacing and extrastimuli testing coupled at different cycle lengths are standard in the electrophysiology laboratory, being able to reveal the mechanism of an arrhythmia and to differentiate between intracardiac potentials, or to simply measure the refractory period of the tested structures[7].

In order to perform a safe catheter ablation procedure, an electrophysiology laboratory requires a modern ablation system which includes generators, cables and catheters connected to an energy source in the form of radiofrequency, cryo, ultrasound, or laser ablation. The most widely used sources are radiofrequency and cryo ablation. Over the years, radiofrequency ablation has been proven to be the most effective and safe therapeutic method for the treatment of a wide range of cardiac arrhythmias. However, the selection of a particular ablation technique depends on the operator's preference, the anatomical particularities of the patient and, last but not least, the ablation target[12,13].

Radiation

The field of interventional cardiac electrophysiology is dependent on images obtained by the fluoroscopy system in order to position catheters/electrodes correctly within the heart. Thus, the exposure of the medical staff and of the patient to radiation is inevitable. Radiation protection and minimization to the exposure have become priorities in interventional cardiology laboratories, therefore the medical staff must be well-trained in the field of radiation safety[7].

The most important parameters recorded by the fluoroscopic equipment are the fluoroscopic time,

the radiation dose (expressed in Gy) which measures the deterministic effects of the potential injury, and the dose-area product (cGy·cm^2) which measures the stochastic effects of the potential injury. Deterministic effects refer to harmful tissue reactions caused by a threshold dose of absorbed radiation (e.g. skin burn), whereas stochastic effects include malignant proliferation due to DNA damage. The latter are not directly determined by the radiation dose, but higher doses increase the likelihood of adverse effects. It is important to note that the stochastic effects of repeated exposure to radiation are cumulative, and the physician who exposes the patient to fluoroscopy should primarily consider the irradiating history of the patient[14-16].

It is intuitive to conclude that in order to minimize the patient's exposure to radiation, it is needed to reduce the radiation dose as much as possible. The most effective factors contributing to the reduction of radiation exposure are the minimization of fluoroscopy time and the decrease of the fluoroscopy pulse rate, at the cost of temporal resolution of the image. The main measures required in order to reduce the exposure to radiation of the medical staff are increasing the distance to the source of radiation, minimizing the scattered radiation and limiting the dose used. In this regard, a protective apron, eye protection, thyroid protection and proper table shielding are of paramount importance for greatly reducing the radiation. Moreover, the distance from the radiation source considerably reduces the dose received, as it decreases with the square of the distance from the source[17,18].

Pre-procedural care

The pre-procedural preparation of the patient should be performed by qualified medical personnel, as the correct positioning of all the patches, the correct recording of the surface electrocardiogram, the administration of the necessary medication, the careful monitoring of the vital parameters and the ease in manipulating the systems' hardware and software are necessary skills for the proper functioning of the laboratory[1,7]. Most electrophysiological studies are performed after the discontinuation of the antiarrhythmic drug therapy. The procedures that involve the left chambers of the heart are performed under oral anticoagulation and / or intra-procedural intravenous anticoagulation. To the greatest extent, the procedures are performed under local anesthesia. Sometimes profound anesthesia is required, especially for complex ablations such as atrial fibrillation, ventricular tachycardia or pediatric ablation. Orotracheal intubation is preferred in the case of ventricular tachycardia ablation, particularly in electrical storms, as hemodynamic instability may be high and there is often a need for multiple intra-procedural external electrical shocks.

Post-procedural monitoring

Patients should be carefully monitored electrocardiographically and hemodynamically in a recovery or intensive care unit after complex ablation procedures and implantation of devices. In this regard, external cardiac defibrillators, pacemakers, and transthoracic echocardiography should be available at all times. Immediate echocardiography, as well as a day after the procedure should be performed in all patients in order to exclude the presence of pericardial effusion. Moreover, patients who have benefited from the implantation of a cardiac device should routinely perform a chest X-ray to exclude pneumothorax and to evaluate the position of the electrodes within the heart. In cases where pseudo-aneurysms, arteriovenous fistula, or groin hematoma is suspected at the site of puncture, duplex ultrasonography should be performed. Last but not least, it is important to note that a close collaboration between a large volume electrophysiology center and a cardiac surgery unit represents an essential step that provides backup in case of cardiovascular emergencies[1,7].

The outpatient clinic

The outpatient clinic consists of two components: a unit designed for the treatment of cardiac tachyarrhythmias and another for bradyarrhythmias and implantation of pacemakers. In most cases, patients are directed to the electrophysiology center by other physicians within the territory, but there are cases when they are self-referrals and are evaluated on the basis of the symptoms and on the interpretation of the electrocardiogram that documents the arrhythmia.

The arrhythmological consultation involves explaining treatment options, including interventional treatment when the patient has indication. An integral part of the consultation is represented by the presentation of the hospitalization time, the risks of the procedure and the success rates according to the electrophysiologist's own experience. A 12-lead electrocardiogram, echocardiography, Holter monitoring, and exercise-testing are immediately available to the patient, while computer tomography, coronary angiography and nuclear magnetic resonance imaging may be scheduled if necessary.

All patients that undergo an ablation or implant procedure are consulted in the outpatient clinic at

least one day prior to admission and informed consent is obtained prior to each procedure. Usually, the vast majority of the patients can be discharged one day after the procedure, after receiving a letter that contains the procedure protocol, the physician's recommendations, and a scheduled date for the next consultation.

Another key component of the electrophysiology program is represented by the postprocedural follow-up of all patients in order to assess their current status, to analyze their heart rate and rhythm, to interrogate their cardiac device, or to discuss other treatment options. Hospitals that offer outpatient monitoring have the advantage of being able to track the evolution of the patient in the long term, thus improving the quality of the medical service. New telemonitoring technologies are gaining more and more ground by providing the possibility of immediate transmission of recorded data. Therefore, in the case of an arrhythmically life-threatening event, the on-call physician can manage the situation in a very short time, increasing the patient's chances of survival. Moreover, regular visits to the doctor may also no longer be necessary in patients without arrhythmic events or, on the contrary, they may be promptly arranged in patients with acute arrhythmic symptoms or events[1].

Conflict of interest: none declared.

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