GUIDELINES

Guidelines issued by the French Society of Cardiology concerning the competence, performance and environment required in the practice of diagnostic and interventional cardiac electrophysiology

Recommandations de la Société française de cardiologie concernant les conditions de compétence, d’activité et d’environnement requises pour la pratique de l’électrophysiologie diagnostique et interventionnelle

Olivier Piot a,∗, Frédéric Anselme b, Serge Bovéda c, Michel Chauvin d, Jean-Claude Daubert e, Pascal Defaye f, Jean-Claude Deharo g, Daniel Gras h, Jean-Sylvain Hermida i, Salem Kacet j, Didier Klug j, Antoine Leenhardt k, Jean-Yves le Heuzey l, Philippe Mabo e, André Pisapia m, Nicolas Sadoul n, Michèle Salvador-Mazenq o, Serge Cazeau p, on behalf of the Cardiac Rhythm and Pacing Group

a Centre cardiologique du Nord, 32—36, rue des Moulins-Gémeaux, 93207 St. Denis, France
b University Hospital, 76031 Rouen, France
c Clinique Pasteur, 31076 Toulouse, France
d Hôpital de Hautepierre, 67000 Strasbourg, France
e University Hospital, 35033 Rennes, France
f University Hospital, 38043 Grenoble, France
ghi La Timone University Hospital, 13385 Marseille, France
gh Nouvelles cliniques nantaises, 44277 Nantes, France
i University Hospital, 80054 Amiens, France
j University Hospital, 59037 Lille, France
k Lariboisière University Hospital, 75010 Paris, France

Abbreviations: AF, atrial fibrillation; AV, atrioventricular; EP, electrophysiology.
∗ Corresponding author. Fax: +33 1 49 33 41 43.
E-mail address: o.piot@ccncardio.com (O. Piot).

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In view of the considerable progress made in recent years in the interpretation, diagnosis and treatment of cardiac arrhythmias, promoting endocardial ablation to the rank of first or second treatment choice for all types of tachyarrhythmias, whether atrial, junctional, or ventricular, it seemed necessary to revisit the 1994 [1] and 1999 [2] guidelines issued by the French Society of Cardiology regarding interventional cardiac EP.

By enabling the recording of endocardial electrograms, the measurement of myocardial refractoriness and the analysis of responses to electrical stimulation, intracardiac EP studies represent the primary means of accurately diagnosing rhythm disturbances, unravelling their mechanism(s) and judiciously identifying the treatment of choice — catheter ablation in particular. Interventional EP includes techniques that consist of detecting then eliminating arrhythogenic sites, accessory pathways or abnormal conductive tissue, with a view to permanently eradicating a tachyarrhythmia or increasing the tolerability of recurrent or incessant tachyarrhythmias. The average procedural complexity varies with the type of targeted arrhythmia. It may be high in some cases due to a structural abnormality or to a complex anatomical location associated with higher risks or requiring the use of special diagnostic or therapeutic techniques. All of these underline the necessity of adequate competence of the responsible operators and a dedicated environment.

The aims of our guidelines are: to define the criteria that guarantee the quality of physician training and patient care, in terms of volume of procedures, institutional environment, medical and paramedical staff, technical equipment and instrumentation, and training centre characteristics; and to describe the conditions required to correctly apply these methods and attain their objectives while preserving patient safety. These recommendations are good practice advice and are not intended to be binding.

Diagnostic electrophysiology

Diagnostic EP includes all intracavitary recordings of cardiac electrical activity under baseline conditions and during electrical, pharmacological or other forms of stimulation; it is performed for diagnostic purposes, as a prognostic tool or in preparation for treatment [3–5].

Physicians’ training in cardiac electrophysiology

EP studies must be performed by board-certified cardiologists or trainees in cardiology. Besides the technical skills, a thorough knowledge of cardiology is needed to determine the procedural indications, mitigate the risk of complications and accurately interpret the data [6–8]. Physicians who completed their training before 2005 should have studied diagnostic EP for 2 years in a teaching centre. Those who completed their training after 2004 or who are currently training must have passed the theoretical and practical examinations in cardiac arrhythmias and pacing set by the Inter-University Board of Cardiac Electrophysiology and Pacing (diplôme inter-universitaire de rythmologie et de stimulation cardiaque) [9]. They must also have participated in ≥ 100 EP studies and acted as principal operator in ≥ 50 EP studies.

Features of a diagnostic cardiac electrophysiology centre

Medical and paramedical staff competency

The centre must be headed by a fully accredited cardiologist and the EP studies must be performed under the responsibility of a cardiologist who has completed the appropriate training, and with at least one registered nurse in attendance throughout the procedure. The staff must have been trained for ≥ 1 month in a centre specifically dedicated to the teaching of diagnostic EP.

Laboratory and technical instrumentation

The EP laboratory must fulfil the prevailing standards applicable to preserve the safety of patients and medical and paramedical staff, particularly with respect to radiological equipment and the observation of sterile techniques. The laboratory must also be designed to contain: an image intensifier, 18–23 cm in diameter image intensifier, with a movable C-arm and mobile table top; a computer-based recorder with at least six channels, three of which are dedicated to the recording of the surface electrocardiogram,
while the others are used to record high- and low-pass filtered unipolar or bipolar intracardiac electrograms, interfaced with a multichannel oscilloscope, a printer and a data storage system; a stimulator capable of delivering pulses of programmable amplitude and duration in trains of fixed cycle lengths between 100 and 2000 ms, adjustable in 1 ms steps, extra stimuli (1 to 3 at least) delivered after a programmable number of spontaneous or paced cycles at coupling intervals programmable in 1 ms steps or bursts of stimuli delivered at > 300 ppm; disposable bi- and multipo
deral electrodes in supplies sufficient to complete a complex procedure; and reanimation equipment for the management of all potential procedural complications, including a properly functioning transthoracic defibrillator tested before each procedure, an external pulse generator and an anaesthesia crash cart stocked with intravenous fluids, oxygen mask, tracheal aspiration cannula and intubation-ventilation equipment.

Hospital facilities
The EP laboratory must be housed in a medical centre that includes a cardiology ward with intensive care or, at a minimum, a continuous cardiac monitoring unit and 24-hour access to coverage by anaesthesiologists/intensivists.

Activities of the diagnostic electrophysiology laboratory
Because the quality and safety of EP studies hinge on the training of the operator and team, the overall number of studies performed must be ≥ 100/year in a laboratory in operation for > 2 years.

Interventional electrophysiology
Interventional EP consists of detecting by endocavitary mapping, based on the results of a prior diagnostic EP, and ablating (term widely used for ‘eliminating’) an arrhythmogenic myocardial area, accessory pathway or conduction tissue, with the goal to curing an arrhythmia or optimizing the tolerability of a recurrent or incessant tachyarrhythmia. Ablation is performed by delivering energy to the arrhythmogenic substrate via a catheter [10–21]. The diagnostic and therapeutic procedures are generally performed at the same time. While the procedural complexity usually depends on the targeted arrhythmia, complicated cases may be encountered due of a particular anatomical structure or localization, associated with specific risks or requiring special techniques.

Physicians’ training in interventional electrophysiology
Candidates for interventional EP accreditation must be board-certified in cardiology, have completed training in diagnostic EP, as defined earlier, and undergo ≥ 1 year of specific, full-time, practical training in interventional EP in a teaching centre, as part of or separately from the Inter-University Board of Cardiac Electrophysiology and Pacing. Physicians who trained before 2005 are recommended the equivalent of 2 years of full-time training in diagnostic and interventional EP in a teaching centre. Physicians who trained after 2004 or who are currently training must have passed the theoretical and practical examinations set by the Inter-University Board of Cardiac Electrophysiology and Pacing and completed 1 year of full-time training in interventional EP in a teaching centre. As required by the Inter-University Board, the candidates must have performed ≥ 50 ablation procedures as the primary operator and under the supervision of a certified trainer, including the slow AV pathway, the accessory AV pathway, atrial flutter and other atrial and ventricular arrhythmias, although not including ablation of the AV junction.

Physicians who perform ablation procedures must be able to manoeuvre the catheters to the cardiac arrhythmogenic zones, which implies a thorough knowledge of cardiac anatomy [22] and the completion of a learning curve [23–25]. Furthermore, the ablation of arrhythmogenic substrates located in the left cardiac chambers requires specific training in transseptal and retrograde transaortic catheterization procedures. Ablation of AF is associated with a higher risk of complications than other ablation procedures, with a clear correlation between complication rates and experience of the operator and medical centre [26–28]. Special technical training is, therefore, recommended, as well as a particular awareness of the specific complications associated with the procedure and their management in an emergency. Besides the number of ablation procedures recommended earlier, physicians in training must have performed ≥ 50 supervised AF procedures in a teaching centre.

The widespread application of endocardial ablation and its indications for increasingly complex substrates have stimulated major developments in new technology. In order to apply these state-of-the-art and developing technologies with maximum safety for the patient, operators must gather sufficient experience regarding the procedural indications, contraindications and particular risks associated with its implementation, acquired by training in expert centres and by attending and participating in dedicated continuing education sessions held during scientific meetings. Despite the anticipated simplification of procedures by recently achieved or upcoming technical advances, operators must acquire and maintain a broad knowledge of EP, which remains mandatory to the performance of all ablations, independent of technological refinements, and perform personally ≥ 30 ablation procedures/year as well as regularly participate in the continuing medical education offered at professional meetings dedicated to interventional EP.

Features of an interventional cardiac electrophysiology centre
Activities of a cardiac electrophysiology centre
The correlation between the number of ablation procedures performed in a medical centre and the complication rate has been confirmed by several studies [29,30]. Intracardiac ablation is a highly technical and mostly elective procedure that requires dedicated, hospital-based facilities. The delivery of care must be adapted to the need of the population and guarantee a high level of technical skill, reflected in high rates of procedural success and efficiency, and low rates of complications. The centres for interventional EP must
maintain a minimum level of activity in order to deliver the appropriate quality of care. At least 50 intracardiac ablation procedures per year, other than ablation of the AV junction, are recommended to maintain this activity level. Centres performing 50 to 100 ablation procedures per year (level 1) are authorized to treat right atrial flutter and ablate the AV junction — indications associated with a low risk of major complications. Centres performing >100 procedures (level 2) may be authorized to ablate slow AV nodal and accessory AV pathways, and atrial and ventricular arrhythmias, which are associated with a higher risk of major complications. Ablation of AF requires the performance of >50 procedures/year over a two-year period in a level 2 centre. The level of a given centre is likely to change as a function of its activities during the preceding years.

Medical staff
The EP laboratory must be under the direction of a cardiologist trained in interventional EP as defined earlier. The procedures must be performed by a cardiac electrophysiologist, preferably with the participation of a second operator ready to assist in the management of possible complications, in the case of complex procedures. A single, properly trained cardiologist may perform the procedures in level 1 centres, while at least two cardiologists trained in interventional EP must staff the laboratories of level 2 centres. A trainee may be the second operator in procedures staffed by two cardiologists.

Paramedical staff
The requirements regarding the attendance and training of nursing staff are those applicable to diagnostic EP. Decree no. 2009-410, published on 14 April 2009 in the Official Journal of the French Republic, defining the operating technical conditions applicable to imaging-assisted, intracardiac, interventional procedures [31], specifies the presence during all procedures of at least two trained paramedical assistants, including at least one nurse (Article D. 6124-181 du Code de la santé publique).

Facilities and technical equipment
The safety features and radiological equipment are the same as those described for diagnostic EP, except that the EP recorder must offer at least 12 channels, including at least three endocardial channels and one arterial pressure recording channel. The system must enable the rapid switch from intracardiac recordings to the 12 surface electrocardiographic leads during pace-mapping and include special filters to preserve a stable electrocardiogram recording during the delivery of radiofrequency energy. Currently available recorders digitize and store the signals. In addition, the ablation energy delivery systems must be officially approved for commercial use and operated according to the manufacturers’ instructions. Radiofrequency energy delivery systems must continuously monitor impedance, delivered energy, and temperature. Finally, dedicated disposable catheters must be available in sufficient numbers to complete the procedure.

The specifications of the programmable stimulator and reanimation equipment are the same as those recommended for diagnostic EP procedures. A readily accessible log of all ablation procedures must be kept regularly.

Supplemental hospital-based resources

Anaesthesia
General anaesthesia might have to be induced during an ongoing interventional EP procedure because of pain, discomfor or prolonged duration. An anaesthesiologist must hence be immediately available.

Surgical coverage
Because major complications of cardiac ablation might require urgent cardiothoracic or vascular surgery, surgical coverage must be planned and detailed in a protocol jointly written by the EP interventional team and a qualified surgical team. The specific risk of tamponade implies the possibility to proceed with pericardial drainage at any time during the procedure, by a physician familiar with the technique or by a surgeon on stand-by in the medical centre. During AF ablation, surgical coverage must be available immediately to handle with life-threatening complications.

Intensive care
A cardiac intensive care unit located near the interventional EP laboratory is indispensable for monitoring patients after complex or complicated procedures.

Features of an interventional cardiac electrophysiology training centre
Besides the features of a level 2 centre described earlier, interventional EP training centres must perform ≥150 ablation procedures yearly, implant pacemakers, cardioverter defibrillators and cardiac resynchronization therapy devices, and conduct regular reviews of cases and internal didactic meetings.

Disclosure of interest
The authors declare that they have no conflicts of interest concerning this article.

References


