GUIDELINES

Position paper concerning the competence, performance and environment required in the practice of complex ablation procedures

Position du groupe de rythmologie et de stimulation cardiaque de la SFC concernant les conditions requises pour les ablations complexes

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Abbreviations: 3D: three-dimensional; AF: atrial fibrillation; GUCH: grown-up congenital heart; ICD: implantable cardioverter defibrillator; MRI: magnetic resonance imaging.

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Summary  The introduction of catheter ablation techniques has vastly improved the treatment of cardiac arrhythmias. However, as complex ablations are technically demanding and can cause various complications, they require a high level of expertise to maximize success rates and minimize complication rates. As French recommendations regarding the required technical competence and equipment are not yet available, this position paper has been compiled by the Working Group of Pacing and Electrophysiology of the French Society of Cardiology, detailing the required features of an interventional cardiac electrophysiological centre for complex ablation procedures: (1) sufficient institutional volume; (2) physician training, qualifications and experience; (3) paramedical staff training and attendance; and (4) institutional facilities and technical equipment. The importance of being able to diagnose, monitor and manage complications associated with complex ablations is highlighted. Supplemental hospital-based resources are also discussed, such as anaesthesia, surgical back-up, intensive care, haemodynamic assistance and imaging. Further, the ideal features of an interventional cardiac electrophysiology training centre are considered. Lastly, the need for quality evaluations and national registries for complex ablations is discussed.
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Background
The management of cardiac arrhythmias has improved dramatically since the advent of catheter ablation techniques. Radiofrequency and cryoablation—which are currently used to treat common atrial flutter, ativoventricular node reentrant tachycardia and accessory pathways—have very high long-term success rates and low complication rates when conducted by experienced teams. Initially, only a few physicians were involved in this area of interventional cardiology. However, techniques and indications have evolved, and considerable progress has been made recently in the percutaneous treatment of more complex cardiac arrhythmias such as atrial fibrillation (AF), right and left atrial tachycardia (apart from cavotricuspid isthmus-related atrial flutter) and ventricular arrhythmias. Catheter ablation for AF is
becoming a class I or IIa indication in many clinical situations [1]; this is also the case for non-cavotricuspid isthmus-dependent atrial flutter [2], whereas there are increasing indications for ventricular arrhythmia ablation [3,4].

Complex ablations are currently performed in many centres in France. Although recommendations regarding the required technical competence and skills of physicians and the necessary technical equipment have been proposed in some European countries [5], such documentation is not currently available for France. The purpose of this article is to give the position of the Working Group of Pacing and Electrophysiology of the French Society of Cardiology on these matters, and to serve as a reference for statutory considerations in the future.

Complex ablations are very technically demanding procedures, where expertise, skill and mastery are essential to achieve high success rates and minimize complication rates. Adequate operator competence is required, along with a dedicated environment, staff and hospital-based facilities. Furthermore, delivery of care must be adapted to the needs of the local population, while guaranteeing a high level of technical skill, reflected in high rates of procedural and long-term success, together with the lowest possible rates of complications. Finally, such arrhythmias are very common, and the number of patients requiring treatment is increasing [6,7]. Therefore, optimal indications for ablation and the cost-effectiveness of these procedures may have major effects on public health and economic resources [6]. Consequently, redefinition of the required conditions and training for physicians performing such complex procedures are becoming mandatory. The accreditation of every centre that performs the simpler ablation procedures is probably neither reasonable nor advisable. Thus, the French Working Group of Pacing and Electrophysiology feel that it is now necessary to redefine the 1994 [8], 1999 [9] and 2011 [10] guidelines issued by the French Society of Cardiology regarding interventional cardiac electrophysiological procedures, focusing on those dedicated to complex ablations.

The aims of this position paper are, therefore, to define the criteria that guarantee the quality of physician training and experience and patient care in complex ablation procedures, in terms of volume, institutional environment, medical and paramedical staff, technical equipment and instrumentation and training centre characteristics. Also, to describe the conditions required to apply these methods correctly and reach their objectives, while ensuring patient safety.

**Definition of complex ablation procedures**

Complex ablation procedures may be defined as ablations requiring high technical expertise, carrying a significant risk of severe (potentially deadly) complications and requiring adequate specialized competence of operators, environment and staff. Although some well-known issues may be encountered, ablation of common atrial flutter, accessory pathways, atrioventricular node reentrant tachycardia or the atrioventricular node does not seem to carry comparable complexity and hazard. Ablation of non-cavotricuspid isthmus-dependent right atrial tachycardia, any atrial arrhythmia for which the target is located in the left atrium (AF or left atrial tachycardia) and any arrhythmia whose substrate is located in either the left or right ventricle (either ventricular tachycardia or premature ventricular contractions) will be considered as complex procedures, as well as any procedure requiring epicardial access.

Recommendations for ablation procedures in children are not included here; particular knowledge of congenital heart diseases and collaboration with cardiopanicians are mandatory for carrying out ablation procedures in children, which is outside the scope of this paper. However, pending dedicated recommendations, ablation of supraventricular or ventricular tachycardia in patients with grown-up congenital heart (GUCH) may follow the same recommendations, with the assistance of congenital disease experts and imaging, provided that surgical/intensive care departments have experience in the management of patients with GUCH. Special considerations when carrying out ablation procedures in GUCH and children will be the subject of a separate position paper.

**Required features of an interventional cardiac electrophysiological centre for complex ablation procedures**

**Level of activity of the cardiac electrophysiological centre**

An inverse correlation between the number of complex ablation procedures performed at an electrophysiological centre and the complication rate has been confirmed by many studies [11–14]. Centres performing interventional electrophysiological procedures, including complex ablations, must maintain a minimum permanent level of activity to ensure appropriate quality of care. 

Alongside standard “non-complex” ablations (common atrial flutter or reciprocating supraventricular tachycardia) at a sufficient annual rate (e.g. ≥ 50), ≥ 100 catheter ablation procedures for AF or left atrial tachycardia [5] and ≥ 30 for ventricular arrhythmia per year per centre seems a reasonable requirement to maintain expertise. Centres that are only willing to perform AF or left atrial tachycardia procedures should not also have to perform ventricular ablations. Procedures for ventricular arrhythmia should be carried out mainly in patients with structural heart diseases—with a limited number of healthy heart ventricular arrhythmias—especially if the centre is expecting to manage such patients. Centres that do not achieve and maintain these patient numbers should be questioned about their ability and legitimacy to carry on performing such activities if a sufficient increase is not expected soon.

Each centre should accommodate a sufficiently large local population to reach these thresholds, and having several centres with inadequate referral in the same geographic area is to be avoided. In a situation where several centres in the same geographic area do not each have a sufficient number of patients, gathering of the activities at one site is strongly encouraged.

As interventional electrophysiological therapy includes ablation procedures, pacemaker implantation, resynchronization therapy and implantable cardioverter defibrillator
(ICD) implantation, centres performing complex ablations should also be experienced in all of these other techniques. It therefore seems reasonable to state that centres performing complex ablations should also implant a sufficient number of such devices (≥ 300 devices per year).

Medical staff

Electrophysiological laboratories are operated under the direction of one or more senior electrophysiological physicians trained in complex ablation procedures. To perform complex ablation procedures, electrophysiological physicians should have completed specialist cardiology training (cardiovascular Diplôme d’Études Spécialisées) or an equivalent foreign accepted certification. Ideally, they should also 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 stimulation cardiaque) [15] or have an equivalent certification (for instance, European Heart Rhythm Association certification) [16]. To perform such complex ablations as a principal operator, the French Working Group of Pacing and Electrophysiology feel that it is further recommended to: (1) have gone through an international or national fellowship (e.g. the European Heart Rhythm Association fellowship), e.g. have ≥ 1 year of specific full-time practical training in interventional electrophysiology in a teaching centre; and/or (2) have acted as a principal operator in ≥ 300 complex ablation procedures in recent years. Adequate experience in pacemaker or ICD implantation and programming is also mandatory.

Complex procedures must be performed by a senior cardiac electrophysiological physician, preferably with the participation of a second operator (who may be a trainee) who is ready to assist in the management of possible complications. For complex ablation procedures, we recommend that at least two trained operators are present locally, although not necessarily in the electrophysiological laboratory.

For ablation of arrhythmogenic substrates located in the left cardiac chambers, which account for most complex procedures, physicians should be specifically trained in transseptal and retrograde transaortic access. As percutaneous epicardial access is sometimes needed for ventricular tachycardia ablation and for performing percutaneous epicardial ablation, physicians should already be trained in this technique and have undertaken a minimum of 30–50 ablations of ventricular arrhythmias in structural heart disease. Otherwise, they should rather refer such patients to neighbouring centres with the ability to perform such procedures. Finally, experience in surgical or hybrid ablation with a dedicated surgical staff is encouraged.

Paramedical staff

The requirements regarding the attendance and training of nursing staff for complex ablation procedures are the same as those applicable to diagnostic electrophysiological procedures [17], together with special experience for complication management. Nurses involved in complex ablation procedures are encouraged to register with the Inter-University Board of Cardiac Electrophysiology and Pacing for allied professionals (Diplôme Universitaire de rythmologie interventionnelle pour le personnel paramédical [17]) or have an equivalent foreign certification.

According to the legislation defining the technical conditions applicable to interventional cardiac procedures [18], at least two trained paramedical assistants, including at least one nurse, should be present during the procedure. If two nurses are not constantly present, another nurse working in a neighbouring laboratory should be immediately available, if needed. Alternatively, when trained, one of the nurses may replace a specialized technician for manoeuvring the three-dimensional (3D) systems (see below).

Facilities and technical equipment

The electrophysiological equipment requirements are the same as those described for standard catheter ablation, with an electrophysiological recorder system including ≥ 12 surface electrocardiogram leads, a sufficient number of intracardiac channels and invasive pressure-recording channels.

One or more 3D electroanatomical navigation systems should be available in the electrophysiological laboratory. Experience in manoeuvring and using the 3D mapping system is required for electrophysiological physicians, but they can receive help from specialized technicians from the manufacturers and/or from trained paramedical staff. Even in centres that mainly perform cryoablation for AF, experience in radiofrequency ablation and 3D mapping systems is considered mandatory for treating left atrial tachycardia or persistent AF when needed. In addition, the staff must have a thorough knowledge of the ablation energy delivery systems—either radiofrequency or cryoablation—while dedicated catheters must be available in sufficient numbers, type and size to complete any procedure.

Fluoroscopy equipment must offer the possibility of multiple views with sufficient imaging quality and radiation dose reduction, allowing low-dose fluoroscopy, with a fixed arm and mobile table top. Contrast injectors and image and movie storage capacities should be available.

Readily accessible comprehensive logs/files of all ablation procedures must be kept. Continuous evaluation of the results should be part of the learning process in centres performing complex ablations. Ideally, such centres should have academic counterparts and activity.

Complications and their management

AF, left atrial tachycardia and ventricular arrhythmia ablation are associated with a significant risk of acute or late complications, some of which might result in lifelong disability or death [1,13]. Complications that may occur during/after complex ablation procedures include pericardial effusion/tamponade, pericarditis, stroke, transient ischaemic attack, pulmonary vein stenosis, atrial oesophageal fistulae, phrenic nerve palsy, air embolism, valve damage, catheter entrapment, sinus tachycardia, gastric hypomotility, perioesophageal vagal nerve injury, acute coronary artery occlusion/stenosis, stiff left atrial syndrome, cough, radiation exposure hazards and vascular complications [1]. Centres performing such ablations
should be able to diagnose, monitor and manage these complications according to the current guidelines [1], with special attention paid to recognizing evocative symptoms during and after the first weeks following the procedure [1].

Supplemental hospital-based resources

Anaesthesia

Although not required [1], general anaesthesia or deep sedation may be performed during interventional electrophysiological procedures for complex arrhythmias because of pain, stress, haemodynamic impairment, risk of movement (leading to shifts in the 3D maps), discomfort or prolonged duration.

According to recent guidelines, the choice of anaesthesia should be determined by the institutional preference and the patient’s suitability for conscious sedation [1]. In case of a procedure performed under conscious sedation, the presence of an “on demand” anaesthesiologist in the hospital is mandatory; they should be ready to perform deep sedation/anaesthesia in the event of a complication.

Surgical back-up

As major complications during or after cardiac ablation for complex arrhythmias sometimes require urgent cardiothoracic or vascular surgery, such surgical coverage must be immediately available when needed. Ideally, this should be planned and detailed in a protocol written jointly by the electrophysiological interventional team and a qualified surgical team.

The specific risk of tamponade necessitates the ability to proceed with percutaneous pericardial drainage at any time during or after the procedure. The electrophysiological physician should therefore be familiar with this technique. Further, surgical pericardial drainage by a thoracic or cardiac surgeon on standby in the medical centre should be available at any time during and after the procedure. In centres without on-site cardiac surgeons, the presence of a thoracic surgeon is acceptable, if there is some local experience for managing cardiac perforation, at least transiently, pending specialized definitive correction at a neighbouring centre when transportation is judged safe. However, the presence of an on-site cardiac surgeon is mandatory when performing percutaneous epicardial ablation.

Intensive care

A cardiac intensive care/resuscitation unit in the vicinity of the interventional electrophysiological laboratory is essential for monitoring patients after complicated procedures, if required. Conventional resuscitation equipment and physicians should be available at all times. Help from an electrophysiological physician should be also available at any time, when needed.

Haemodynamic assistance

Centres willing to perform scheduled ventricular tachycardia ablations in very sick patients must be familiar with haemodynamic assist device implantation (e.g. extracorporeal membrane oxygenation or Impella” [Abiomed Inc., Danvers, MA, USA]), either as planned haemodynamic support before the ablation [19] or as an emergency salvation procedure because of refractory arrhythmias, cardiogenic shock or electromechanical dissociation related to the procedure. Ideally, such patients should be managed by centres that can provide heart transplantation. These recommendations also apply to urgent non-scheduled salvation procedures for intractable electrical storms, except when referral to other institutions is impossible.

A neurological emergency department (stroke centre) and adequate neurological imaging should be available at any time for the management of a stroke or cerebral haemorrhage occurring during or after the ablation procedure, with the availability of any required therapy (e.g. percutaneous vascular desobstruction). If there is no on-site stroke centre, protocols—planned in collaboration with the stroke centre—should be in place.

Imaging and image integration

Cardiac imaging is becoming mandatory before—but also during and sometimes after—ablation procedures. Increased use of imaging to provide preinterventional information not only potentially reduces fluoroscopy time, but also increases safety and ablation success rates. Fluoroscopy is still necessary during most ablation procedures, but fluoroscopy time and radiation dose should be minimized, while maintaining reliability and navigation safety. Thus, the use of non-fluoroscopic navigational mapping systems to guide the ablation procedure is strongly recommended, and is even mandatory in centres performing complex ablations. On rare occasions, however, electrophysiological physicians should be able to perform most of these complex procedures using only fluoroscopy when required (e.g. pulmonary vein isolation or ventricular arrhythmia ablation).

Transsthoracic echocardiography should always be available to monitor for complications such as tamponade. Transoesophageal echocardiography remains a class IIa indication before most ablations of left atrial arrhythmias, to eliminate the presence of left atrial thrombus [1]. Transoesophageal echocardiography should therefore be available before—or at the beginning of—each procedure in centres that perform such complex ablations.

The use of cardiac computed tomography and magnetic resonance imaging (MRI) for delineating anatomy, scars, fibrosis or complications has increased dramatically in recent years [20]. Most patients referred for ventricular arrhythmia ablation are already implanted with an ICD. The use of MRI in patients with implantable devices is becoming less of a problem with the increasing number of MRI-compatible pacemakers. According to the current consensus statement [21], a computed tomography scan may sometimes replace an MRI in patients with pacemakers that are not MRI compatible [20]. Recent technical innovations have substantially reduced radiation exposure during computed tomography scans [20]. Use of these imaging techniques should therefore be encouraged, and they should be available at any centre dealing with complex ablations. The use of rotational angiography for image integration is optional, but is encouraged when available. Finally,
coronary angiography must be available at any time in the electrophysiological laboratory when there is a suspicion of coronary artery complications, especially for ventricular arrhythmia ablation or in case of epicardial access.

**Ideal features of an interventional cardiac electrophysiology training centre**

Ideally, interventional electrophysiological training centres for complex arrhythmias should perform ≥ 400 ablation procedures (≥ 200 complex) and implant ≥ 400 pacemakers, ICDs or cardiac resynchronization therapy devices each year; they should also conduct regular reviews of cases and have internal didactic meetings. Lower yearly numbers of procedures may be acceptable, especially for institutions devoted to training (e.g. academic centres), provided that the number of physicians undergoing training is compatible with the activity of the centre. Recent guidelines for training require a minimum number of 15 atrial tachycardia, 50 AF and 30 ventricular arrhythmia ablations for each trainee [1,22]. Thus, rather than a fixed number of procedures, each training centre should perform a sufficient number of cases yearly for training each fellow/trainee. In other words, training centres should have the number of trainees that is compatible with the above-mentioned requirements.

**Integrated management of patients with AF or ventricular arrhythmia**

The availability of integrated care for patients with AF or ventricular arrhythmia is highly recommended [6]. Integrated care requires the cooperation of cardiologists, cardiac surgeons, AF/ventricular arrhythmia specialists, dedicated heart failure units, intensive care units, stroke specialists and patients, encompassing a wide range of therapeutic indications, lifestyle interventions, treatment of underlying cardiovascular diseases and AF- or ventricular arrhythmia-specific therapy.

**Quality evaluations and national registries**

Scientific advances and technological improvements in complex electrophysiological interventions come with associated responsibilities to ensure that these costly therapies result in high-quality care and low complication rates. National registries should be developed in the field of complex ablations to allow quality evaluations. Use of electronic medical records and participation in electrophysiological national registries are thus strongly encouraged, and may become mandatory. The development of quality controls in electrophysiology may be done by experts under the academic supervision of the French Working Group of Pacing and Electrophysiology.

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**References**


