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EHRA CONSENSUS STATEMENT

The use of imaging for electrophysiological and devices procedures: a report from the first European Heart Rhythm Association Policy Conference, jointly organized with the European Association of Cardiovascular Imaging (EACVI), the Council of Cardiovascular Imaging and the European Society of Cardiac Radiology

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Implantations of cardiac devices therapies and ablation procedures frequently depend on accurate and reliable imaging modalities for pre-procedural assessments, intra-procedural guidance, detection of complications, and the follow-up of patients. An understanding of echocardiography, cardiovascular magnetic resonance imaging, nuclear cardiology, X-ray computed tomography, positron emission tomography, and vascular ultrasound is indispensable for cardiologists, electrophysiologists as well as radiologists, and it is currently recommended that physicians should be trained in several imaging modalities. There are, however, no current guidelines or recommendations by electrophysiologists, cardiac imaging specialists, and radiologists, on the appropriate use of cardiovascular imaging for selected patient indications, which needs to be addressed. A Policy Conference on the use of imaging in electrophysiology and device management, with representatives from different expert areas of radiology and electrophysiology and commercial developers of imaging and device technologies, was therefore jointly organized by European Heart Rhythm Association (EHRA), the Council of Cardiovascular Imaging and the European Society of Cardiac Radiology (ESCR). The objectives were to assess the state of the level of evidence and a first step towards a consensus document for currently employed imaging techniques to guide future clinical use, to elucidate the issue of reimbursement structures and health economy, and finally to define the need for appropriate educational programmes to ensure clinical competence for electrophysiologists, imaging specialists, and radiologists.

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Imaging technologies in electrophysiology: the problem

Electrophysiology is the most rapidly growing area of cardiology. Currently >50 000 catheter ablations are performed in Europe every year and >200 000 patients receive a device for arrhythmia treatment, sudden death prevention, or cardiac resynchronization.[1] The advantages and limitations of fluoroscopy are well known. The rapid development of implantable cardiac devices therapies and ablation procedures all depend on accurate and reliable imaging modalities for pre-procedural assessments, intraprocedural guidance, detection of complications, and the longitudinal follow-up of patients. This fundamental role of imaging is reflected in the 2.5 billion cardiovascular imaging tests performed worldwide.[2,3]

A number of different imaging technologies with overlapping capabilities are available. The rapid development of cardiovascular imaging and clinical research, and the increasing clinical use of cardiac imaging constantly expand the range of available tests and their diagnostic and predictive value. An understanding of echocardiography, cardiovascular magnetic resonance imaging (MRI), nuclear cardiology, and X-ray computed tomography (CT), as well as positron emission tomography (PET) or vascular ultrasound is indispensable for electrophysiologists as well as radiologists, and it is currently recommended that physicians should be trained in several imaging modalities.[4] However, there are no current guidelines or recommendations that have been jointly produced by electrophysiologists, cardiac imaging specialists, and radiologists, on the appropriate use of cardiovascular imaging for selected patient indications.

A Policy Conference on the use of imaging in electrophysiology and device implantation and management in 2011 was a first step towards a collaboration between experts from different areas of radiology and electrophysiology. Organized jointly by European Heart Rhythm Association (EHRA), the European Association of Cardiovascular Imaging (EACVI), the Council of Cardiovascular Imaging, and the European Society of Cardiac Radiology (ESCR), the objective was to assess the state of the evidence and the possibility for formal recommendations on the development and use of new imaging tools within the fields of electrophysiology and device implantation. In recognition of the necessary interaction between clinical research and commercial developers of imaging technologies and device therapies, the conference included representatives from device and imaging industries. The objective was to assess the level of evidence for currently employed imaging techniques and to develop a consensus document to guide future clinical use.

Core areas of consideration include indications, techniques, and personnel, which all need to be addressed for implantation of pacemakers, implantable cardioverter-defibrillators (ICDs), and cardiac resynchronization therapies (CRTs) as well as for catheter ablation procedures, respectively. Secondly, as imaging technologies consume a substantial part of health-care budgets, the issue of reimbursement structures and best use of financial resources needs to be addressed to ensure that imaging is used where it adds value. Thirdly, the need for appropriate training programmes to ensure acquisition and maintenance of clinical competence for electrophysiologists, imaging specialists, and radiologists as well as for allied professionals was addressed.

Imaging tests should be evaluated according to their accuracy, sensitivity, specificity, and positive and negative predictive values; however, utility, reproducibility, feasibility in routine clinical practice, safety and convenience to patients, impact on clinical outcomes, and cost-effectiveness should be assessed as well.[4] For many imaging modalities, these requirements and criteria may not be possible to address at the present state of knowledge. Importantly, it is recognized that there is a major lack of prospective, randomized, double-blinded trials on the benefits of different imaging modalities and their predictive value guiding patient selection and procedures. The generation of solid evidence remains a major future task.

Pacemaker, implantable cardioverter-defibrillator, and cardiac resynchronization therapy: indications, technique, and personnel

Guidelines for cardiac device therapies require in many circumstances pre-operative assessment of left ventricular ejection fraction (LVEF) by any cardiac imaging technique of LVEF.[5,6] Guidelines however do not specify a preferred method for LVEF measurement; and as a result, in clinical practice, several echocardiographic modalities, cardiac MRI, contrast ventriculography, or radionuclide angiography are employed. In clinical practice, all these cardiac imaging techniques are used in complimentary manner for assessment of LVEF in candidates for ICD implantation. Normal range of LVEF parameters, reproducibility, and influence of regional dys- or hypokinesia as well as substantial inter-observer variability, render the readout of the different methods highly variable. With the lack of data from randomized clinical trials, personal preferences and experiences as well as local availability, influence the choice of method, which may have a profound impact on cost-effectiveness of the use of ICD.

Although the importance of systolic dysfunction as a risk factor for arrhythmias and sudden cardiac death and as indication for ICD is well established, there remains uncertainty about the role of cardiac imaging techniques in the evaluation of heart failure patients as indication for CRT. More recently, there is also a great deal of interest on (i) how to predict response to CRT and, (ii) how to enhance response to CRT. Several uncontrolled studies have been performed evaluating the potential value of different cardiac imaging techniques in each of these two areas. The results, however, have been frequently conflicting or inconclusive.[7,8] The PROSPECT trial[9] provided an indication of the difficulties in respect of evaluation of mechanical dyssynchrony in CRT patients. PROSPECT was one of the few large-scale, prospective, multicentre studies evaluating prediction of response to CRT, in 498 patients at 53 centres internationally and three core laboratories. Twelve echocardiographic parameters of mechanical dyssynchrony, based on both conventional and tissue Doppler-based methods were evaluated. However, large intra-observer and inter-observer variations were documented. The modest sensitivity and specificity despite training and central analysis led the investigators

to conclude that no single echocardiographic measure of mechanical dyssynchrony may be recommended to improve patient selection for CRT beyond standard electrocardiogram (ECG) analysis. In the MADIT-CRT trial the superiority of CRT was driven by a 41% reduction in the risk of heart-failure events, a finding that was primarily evident in a pre-specified subgroup of patients with a QRS duration of 150 ms or more.[10] Current ESC guidelines for CRT do not comment on the role of specific parameters of mechanical dyssynchrony[6] and other guidelines recommend against withholding CRT from patients on the basis of an echocardiography study.[11] On the other hand, there is the clinical unmet need to identify heart failure patients with normal QRS duration, or those patients with QRS duration between 120 and 150 ms who may benefit from CRT. Since the modern goals of CRT nowadays include response improvement to CRT and further response enhancement in those patients who favourably respond to CRT, more global evaluation of myocardial function including delineation of myocardial scar (transmurality, location, and extension) and myocardial viability as well as precise assessment of coronary vein anatomy and electrical activation mapping has been performed[12] The well-known large variation in measured ejection fraction depending on the technique used is still a problem though.

CRT is the therapy that raises most questions around the role of different imaging modalities, both to improve response rates and to optimize the delivery of the therapy. Intuitively, not only morphological data are needed but also functional data. The lack of standardized methods for imaging modalities means that without concerted efforts, resources may be wasted on more inconclusive trials like PROSPECT. Comparative effectiveness studies are needed for imaging modalities. Such endeavours call for the establishment of consortia of industry and professional societies to design trials looking at modalities and the clinical value to patients. Manufacturers of imaging modalities have not traditionally relied on randomized clinical trials to prove the value of their products and closer interaction between disciplines would help in designing trials with increased chance of useful outcomes. However, it is recognized that cardiology have represented only a small fraction of the market for many imaging modalities, which so far have limited the commercial incentives to invest in developments specifically for cardiology. With the increasing needs for effective CRT in heart failure patients, a closer interaction between disciplines and an establishment of consortia of industry and professional societies would help in designing randomized clinical trials with increased chance to prove the useful value of various imaging modalities.

Ablation: indications, technique, and personnel

Cardiac imaging is a prerequisite before, during and after ablation procedures. A shift towards greater use of imaging to provide pre-interventional information has the potential to reduce fluoroscopy time during procedures and to increase safety.

Echocardiography provides useful information on anatomy, LV function, and possible presence of underlying diseases or abnormalities such as hypertrophic cardiomyopathy. It is often performed in the routine workup of patients, preceding the ablation procedure. Echocardiography has the advantages of no emission of radiation, low cost, ready availability, and rapidity. In cases where there is no reasonable suspicion of abnormalities, an echocardiogram may not be necessary.

Many centres routinely employ transoesophageal echocardiography (TEE) prior to left atrial ablation. Transoesophageal echocardiography can reveal the presence of thrombus and dense spontaneous echo contrast and minor interatrial septum abnormalities. The risk of thromboembolic events at the time of the procedure remains one of the most serious complications of catheter ablation in patients with atrial fibrillation (AF); reported incidence rates of symptomatic events are $<7\%$ but true rates may be higher.[13–17] However, the contribution of the underlying heart disease and therapeutic anticoagulation before the ablation procedure is not well understood. While some observational studies of moderate size (>100 patients) have come to the conclusion that prior TEE would be necessary for the patients with planned catheter ablation for AF,[18,19] other studies of similar size do not support its use prior to circumferential pulmonary vein (PV) ablation in patients with paroxysmal AF and no left atrium (LA) dilation or structural cardiopathy.[20] Transoesophageal echocardiography carries costs as well as a not negligible risk,[21] and its value remains to be proven in randomized trials. Transoesophageal echocardiography is currently awarded a level C recommendation.

Magnetic resonance imaging has a role in the planning of an intervention, in identifying potential complications from the procedure (infarct and PV stenosis) and to predict outcomes of the ablation procedure. Magnetic resonance can be an alternative to echocardiography in cases of low echogenicity to define anatomy and underlying disease and also monitor for complications in such circumstances. Images are produced in three dimension (3D) with acceptable spatial resolution and excellent reproducibility. Drawbacks are mainly the relatively high costs of acquisition and personnel with the procedure. The value of MRI to determine the positions of PVs is well established, but the usefulness and reliability of different modalities in the mapping of other parts of the atria are less solidly evidenced. The main difficulty is inadequate motion correction. The use of MRI in patients with implantable devices is becoming less of a problem with increasing number of MRI-compatible pacemakers,[22] but ICDs and CRT devices may pose problems.[23,24] It has been estimated that around half of pacemaker and ICD patients will require an MR scan during the lifetime of their device, mainly for non-cardiac reasons.[25]

Atrial fibrillation and ventricular tachycardia (VT) ablations are the only two arrhythmias where procedural success rates are relatively low and reliable predictors of response and procedural success are needed. By visualizing the behaviour of LA tissue following ablation,[26,27] MRI has been mooted as a tool to evaluate the procedural anatomical effects during follow-up after the procedure, although this use currently remains experimental. A further potential use for MRI is in risk stratification before the ablation procedure, based on the location and extent of atrial fibrosis. Atrial fibrillation is associated with extracellular matrix remodelling involving atrial fibrosis,[28] and heterogeneous spatial distribution of fibrosis governs AF dynamics and fractionation during AF in failing hearts.[29] Mapping the extent of structural remodelling and fibrosis, which are considered to be linked to clinical

outcomes, may aid in stratifying patients according to risk and in guiding procedures, follow-up, and interventions. However, atrial mapping of fibrosis by MRI remains an investigational technique at present. No validated and independently reproducible stratification algorithm methods are available at present.

Like MR, CT has a use as alternative to echocardiography to establish anatomy and underlying disease and to identify complications in cases with low echogenicity. Computed tomography is useful to map anatomy for procedure planning, identifying possible complications such as infarction, variation of PVs, or congenital heart disease. Computed tomography is also valuable to assess complications such as perforation and PV stenosis. Images have high spatial resolution and visualize extracardiac structures in 3D with excellent reproducibility. Limits to the modality are mainly the low functional information and the lack of temporal resolution. As MRI, it needs dedicated hardware, software, and personnel.

Radiation is an issue with CT. Recent innovations to the technique, however, have substantially reduced exposure to radiation. Various vendours have implemented an array of technical solutions for dose reduction such as ultra-high-pitch, very large detectors, advanced reconstruction algorithms, and the step-and-shoot mode.[30] The 'step-and-shoot' image-acquisition protocol, in which the X-ray tube rotates around the stationary patient approach and the table is advanced to a new location for each subsequent scan, appears to reduce the radiation dose substantially.[31]

Ablation is a procedure that exposes patients and potentially physicians to high levels of radiation for extended times. A radiofrequency (RF) ablation procedure produces 350–2000 times the radiation of a chest X-ray.[32] It is imperative to reduce the need for fluoroscopy as much as possible and the use of non-fluoroscopic navigational mapping systems to guide the ablation procedure are strongly recommended. Electroanatomical mapping (EAM)[33] or non-contact mapping[34] has the potential to reduce fluoroscopy and procedure times. Intracardiac echocardiography (ICE) can be incorporated into EAM,[35] facilitating the reconstruction of a 3D shell of the chambers of interest before mapping, and may visualize cardiac and extra-cardiac structures that need to be protected during the ablation procedure. Other non-fluoroscopic navigation systems that determine electrode position from impedance changes in a high-frequency current emitted by three pairs of orthogonally placed patches,[36] may also reduce fluoroscopy times during ablations.[37,38]

Recommendations for the use of imaging in ablation differ between normal hearts and different complex ablation procedures. Normal ablations are all procedures except for ablation of AF, atrial flutter, VT, incessant tachycardia, and GUCH (grown ups with congenital heart defects). Ablation procedures in children should be considered separately.

For normal hearts, if ECG readings and physical examination show no abnormalities and the patient has no history of cardiac disease, no imaging would be required immediately prior to procedure. If there is suspicion of cardiac abnormalities, echocardiography should be conducted but its use is not mandatory in routine cases. Age should not be a decisive factor when considering on whether to conduct an echocardiographic study. Three-dimensional (3D) echocardiography may be used, but this is not necessary when performing a balloon ablation. There are no recommendations at present to conduct an MRI for the purpose of risk stratification.

Fluoroscopy is necessary during the ablation procedure, but radiation time and dose should be minimized as far as possible. Echocardiography is recommended to monitor for complications and tamponade and should likewise be employed after the procedure to monitor for complications. If echocardiography is not applicable, MRI (preferable to minimize radiation exposure) or CT should be considered as alternatives.

In complex ablations of AF or atrial flutter, 2D (3D-) echocardiography should be performed to chart the anatomy and to assess LV function and the presence of underlying disease. When echocardiography is not suitable, MRI (preferably) or CT should be employed to chart the anatomy. The use of coronary angiograms or vascular ultrasound is recommended when there is a suspicion of disease. Transoesophageal echocardiography is recommended for thrombus identification.

The minimum imaging requirements during the procedure are echocardiography to monitor for complications and tamponade and fluoroscopy. Radiation doses should be minimized and exposure time and dose monitored closely. In standard RF-based procedures, non-fluoroscopic navigation systems including ICE are strongly recommended. The use of rotational angiography, MRI, CT, or 3D echocardiography for image integration is optional. The recommendations post-procedure are the same for ablation of normal hearts: echocardiography or, if not applicable, MRI or CT to monitor for complications.

Pre-procedure imaging requirements in ablation of VT and underlying heart disease are similar to those for AF: use of echocardiography to assess anatomy, LV function, and underlying disease. As many of these patients may have an implanted defibrillator, MRI may not be applicable. The use of MRI of CT for risk stratification is investigational and not ready for general use at the present time. When disease/ischaemia is suspected, coronary angiography should be employed and vascular ultrasound is recommended when there is suspicion of peripheral artery disease. Echocardiography and fluoroscopy are recommended during the procedure. As with AF ablation, radiation doses should be minimized and exposure time and dose monitored closely. Non-fluoroscopic navigation systems including ICE are strongly recommended. The use of rotational angiography, MRI, CT, or 3D echocardiography for image integration is optional. Echocardiography or, if not applicable, MRI or CT is recommended post-procedure to monitor for complications and to assess the effect of the ablation procedure on cardiac function.

Ablation of GUCH requires the use of echocardiography pre-procedure to assess anatomy, LV function, and underlying disease. Transoesophageal echocardiography is recommended for thrombus identification. In patients with complex anatomy, MRI may be considered. Depending on the complexity of the disease, CT may be considered but the first option should be MRI. Dose-saving protocols should be employed whenever possible. The use of MRI and CT will depend on the complexity of the disease. Fluoroscopy is necessary during the procedure, with efforts to minimize radiation doses and exposure time monitored closely. Non-fluoroscopic navigation systems including ICE are strongly recommended. Rotational angiography, MRI, CT, or 3D echocardiography

for image integration is optional. Echocardiography or, if not applicable, MRI or CT is recommended post-procedure to monitor for complications and to assess the effect of the ablation procedure on cardiac function.

Open questions

As with the use of imaging to predict response to CRT, most information on the value of different modalities used in catheter ablation is derived from single-centre studies and represents local usage and conditions. For most of the modalities, a standardization of methodologies would improve the scope for reproducible imaging and comparisons between investigations. There is no generally agreed best way to determine when there is difficult anatomy.

The value of TEE will need to be clarified by prospective randomized trials. The role of MRI late-enhancement based fibrosis imaging as a predictive tool has not been established conclusively at present and it is unclear whether the technology will fulfil its considerable promise in this area. Magnetic resonance imaging diagnoses increased interstitial space/distribution volume and/or contrast dynamics, which is not necessarily fibrosis. The importance of fibrosis remains unclear; there may be different kinds of fibrosis and not all are relevant to outcomes. Fibrosis needs to be correlated to outcomes in adequately designed clinical studies.

It is very important to reduce radiation exposure. Dose-saving protocols for CT are already available and should be used whenever possible. Further reductions in radiation dose are desirable, as are reductions in fluoroscopy times. Prospective trials would be necessary to provide conclusive evidence of the potential for techniques such as 3D image integration to reduce radiation exposure. At present, data are little better than anecdotal. If properly designed trials show an alternative system to reduce overall radiation, it should probably become mandatory in order to reduce radiation exposure.

Cost-effectiveness and reimbursement

Heart disease is one of the most expensive medical conditions in developed countries[39] and imaging contributes significantly to the costs. In the USA, an estimated $80 billion dollars are spent on imaging tests annually.[40] The number is increasing, driven by the evolution towards minimally invasive interventions, that need pre-, intra- and post-procedural imaging.

In Europe, the European Commission has emphasized the need to ensure that technology and medical devices are properly evaluated and used in the most effective way.[41] However, the role of imaging in improving the cost-effectiveness of interventional cardiology is not well established. As has been noted,[42] there are several additional links in the chain between the interim aim of an imaging test (to make the correct diagnosis or guide a catheter) and the ultimate aim (to improve patient health).

Typically, payers will ask several specific questions of any treatment or diagnostic tool: Is it needed? Does it work in everyday clinical practice (i.e. effectiveness: clinical benefits in every day clinical practice, in contrast to efficacy as reported in controlled clinical trials)? What is the added-value to current standard of care and which are the value drivers? Are the clinical benefits worth the cost? Is it affordable (what are the investments necessary, what savings might be provided elsewhere)? Affordability does not necessarily mean cost-effective and conversely, a technology that brings savings elsewhere may not be affordable. It is justifiable for a health-care system to invest in new technologies for routine practice only when there is clear scientific evidence that the new modality represents a substantial improvement and more cost-effective alternative to prior technologies.[4]

A flow chart for a diagnostic therapy assessment to identify any weak or missing links in the causal chain of benefits from imaging has been suggested by Mackenzie and Dixon.[42,43] The elements are hierarchical and a positive effect at the highest level is required for a positive effect at the following levels. The degree to which benefits at a given level will influence successive levels will vary according to clinical setting. Cost-effectiveness is not primarily addressed in the flow chart, however. The heterogeneity of reimbursement systems across Europe compounds any calculation of supranational cost-effective thresholds. Moreover, the use of thresholds for coverage of a technology is controversial, as it imposes a simple yes/no dualism on a complex issue.

Imaging is not routinely included as a component of the cost of therapies in electrophysiology. For example, echocardiography has a confirmatory role in ICD patients, as reduced LVEF is the main indication of eligibility, but the cost-effectiveness of ICD therapy is usually calculated without taking into account the costs of imaging to define appropriate patients. Similarly, imaging is used to assess indications for CRT and also to identify potential non-responders to therapy, as discussed in an earlier section. Yet neither cost nor potential savings from a reduction in unnecessary device implantations are typically included in calculations. Until the outstanding issues of what determines response to CRT are solved, the choice of appropriate imaging tests (if any) is undecided and the true value of those tests cannot be quantified. The same is true for the use of echocardiography or other imaging modalities to optimise CRT performance. The cost-effectiveness of MRI, CT, PET, and similar modalities of ever-increasing use in cardiology is difficult to assess. It is unclear how cost of purchase should be weighted and how cost of service should be calculated. Moreover, the costs from false positives or false negatives may need to be included in the calculations, compounding the complexity and uncertainty.

Even if a consensus could be found on how to calculate the costs of tests in principle, reliable evidence is needed for the capacity of imaging to improve outcomes and reduce complications, and for the reductions in radiation that can potentially be achieved with 3D imaging and other alternatives to fluoroscopy. Without this knowledge, the benefits cannot be qualified appropriately.

There is an ongoing debate on the appropriate place of cost-utility analysis in the provision of healthcare.[44] The focus on quality-adjusted life-years saved that dominated cost-utility analyses in the last decade may have softened somewhat with plans in the UK to introduce a new value-based system of pricing therapies, mandated to take into account several aspects of value: the wider societal benefit, burden of illness and the level of unmet need, and therapeutic innovation and improvement. This reflects

a shift towards a value-based pricing (establishing a 'fair price' worth paying) and budget-impact analysis, away from the standard cost-utility analyses that have historically reigned supreme.[45] Whether other European countries will follow this shift remains to be seen.

Innovative approaches to reimbursement may also be needed in the future as more data become available. Reimbursement systems are traditionally heavily based on assessments of proven therapies and methods. The role of risk-sharing approaches between providers and payers would seem a promising topic to explore further, but this has been neglected hitherto. In particular, innovative reimbursement schemes, such as coverage with evidence development, should be considered for imaging in electrophysiology and device implantation and management, as an enabler of market access.[46,47] Locally, there may be scope for a flexible approach within a disease-related group (DRG) system where the exact allocation of costs within a DRG can be decided at the discretion of the provider not the payer. This may not be possible in all environments; many hospital-funding systems are not evidence-driven to any significant degree and generalizations are difficult.[48]

The challenge of providing health economics and outcomes research will increasingly need to be taken up by professional societies that have traditionally stayed clear of health-utility analyses, disciplines that do not belong to the cultural background of physicians.[49,50] Without data from large-scale trials in clinical settings, new imaging modalities may not be reimbursed and will not be acquired by hospitals. This is a strong argument for commercial manufacturers of imaging modalities to become more involved in outcomes research. European Heart Rhythm Association has recently established a Committee on Health Economics and Clinical Outcomes research,[49] with the aim of bringing together the many different stakeholders in the complex processes of funding, organizing, and delivering healthcare.

Imaging growth has yet to be correlated with prevention or postponement of major adverse CV events.[51] It is hoped that by facilitating communications across disciplines that historically have remained separate, the Committee will support a systematic approach to the evaluation and assessment of imaging modalities similar to those of other tools and interventions.

Patients' access and future developments to various imaging investigations

Imaging equipment tends to be large, immovable, and expensive, and requires specific expertise, all of which may reduce the options to provide patients access to appropriate diagnostic modalities. Telemedicine and remote imaging have the potential to provide specialized health-care consultation to patients in remote locations without physical referral. For aged and terminally ill patients, a reduction in the number of necessary visits to specialty hospitals for long term follow-up care is an additional benefit, which may also save clinical and financial resources by reducing the need for physical infrastructure in hospitals in remote locations.

The digital nature of cardiac imaging data enables remote transfer and storage, giving physicians access to computerized, comprehensive data on patients offline as well as in real time. The analysis can be conducted at a geographic distance from the imaging equipment and expert advice can be sought rapidly, for improved diagnosis and better treatment management. For hospitals, there is scope for earlier discharge of patients and reductions in unnecessary visits and hospitalizations for specialized care at tertiary hospitals.

However, telemedicine and remote imaging has three core issues that have to be safeguarded. First and foremost is that of patient privacy. The use of secure servers and access restricted to health-care providers with a professional relationship to the patient is mandatory. Commercial manufacturers of device therapies have been working together with physicians on such systems for remote device follow-up and automated event alerts for the last decade and similar partnerships would be necessary for imaging systems. Further, the use of patient data in clinical research should be allowed only after written confirmation by the patient.

A second point is data safety and storage. Data need to be stored safely, but rapidly available and easily exchanged. The latter two needs call for a significant degree of redundancy in storage, with a number of backup locations. However, the existence of multiple copies increases the risk of unauthorized dissemination of confidential data and it is crucial that appropriate safety systems are in place for restricted and tracked access.

Thirdly it needs to be ensured that electronically stored image information is of sufficient quality for clinical use. User interfaces need to be sufficiently simple and software compatible across multiple user platforms, to ensure that different potential users evaluate identical data.

Image processing and the combination of information from complementary imaging modalities carries a great promise to provide a comprehensive understanding of an individual patient's cardiac anatomy and arrhythmia substrates. Image-information fusion techniques can be used to establish anatomical correspondences and to generate image-based computational physiology models. Computational physiology, personalized through multimodal imaging, may enhance the predictive capacity and enable testing of various treatment scenarios. To realize these prospects, a necessary tool would be to integrate imaging maps for several different modalities to provide a statistical atlas covering many different anatomies.[52,53] With an atlas that represents motion in a standard spatio-temporal coordinate system, characteristics of patients can be compared using quantitative indexes of abnormality. More effective modified indices for patient selection would help, developed based on the variety of imaging modalities and automated through advanced image analysis. Such projects reinforce the need for multidisciplinary collaboration.

Intra-observer variability is a major barrier to evaluating imaging parameters for their diagnostic and predictive values. Reliable integrated models and automated analysis procedures may be a way forward. If sufficiently sophisticated, automated algorithms have the potential to increase the reproducibility and reliability of diagnoses and would make it worthwhile to conduct randomized multicentre clinical trials on imaging modalities. Such automation work is on-going, e.g. on the process of scar identification with late

gadolinium enhancement MRI, combining both intensity and spatial information.[54] Yet, although industry is making significant efforts to design automated algorithms, vendors will not be able to develop clinically relevant tools for automatic evaluations of imaging modalities if there is no expert consensus on specific needs.

Emerging technologies for image integration may become valuable tools to guide pre-procedure decisions in AF and VT ablation. Moreover, intra-procedure guidance may become available based on available technology that integrates fibre optics into catheters, thereby enabling both intervention guidance and the assessment of lesion formation in real time. While possibly useful in the study of lesion formation, the correlation between reconduction rates and lesion formation needs to be demonstrated for the technique to be accepted.

Increased use of sophisticated remote control technologies might offer a way to reduce exposure to radiation. The need to diminish the risk to physicians from X-ray radiation should be a goal in itself and a key objective for the future. It remains unclear whether the increased physical distance between patient and physician with remote procedures would be acceptable to either or both groups, but this aspect may become less of an issue with greater familiarity with remote procedures. Magnetic resonance has the potential to combine radiation-free imaging with real-time guidance of therapy and monitoring of lesion formation with high-contrast resolution. Safety issues remain to be solved, however, as strong magnetic and RF fields may induce heat and electric currents in wires, catheters and ablation devices.

Educational and training activities

Mastery of the complexity of disease presentations and the necessary evaluations and treatments in electrophysiology requires an intimidating combination of comprehensive knowledge of cardiac disorders, sharp analytical faculties and practical skills in cardiovascular catheter manipulation and device implantation.[55,56] Given the central role of imaging modalities at each step of patient management, it is imperative to support solid training and qualification in the use of cardiac imaging among professionals in Europe.

There is no lack of guidelines and recommendations that stress the need for appropriate training in imaging techniques of physicians across a wide range of cardiology specialties.[4,55,57] Current core curricula for the heart-rhythm specialist include general knowledge in imaging techniques (fluoroscopy, echocardiography, MRI, CT, nuclear imaging, angiograms, and others).[55] However, this is probably too vague to serve as a guide to courses and accreditations. Conversely, imaging curricula and accreditations do not mention electrophysiology except tangentially[57] and it would be desirable if there were greater overlap between educational activities of the different specialist associations within the European Society of Cardiology.

The EHRA Education Committee is committed to offer continuous medical education to cardiologists specialized in pacing and arrhythmias. Teaching is mainly targeted on electrophysiology fellows in training, but other audiences include established cardiologists and electrophysiologists. There is also increased activity in the field of training employed professionals, with a specific accreditation for both Industry Employed and clinical Allied Professionals. The EHRA education for fellows currently follows two main tracks, a device track and an interventional electrophysiology track. Apart from teaching knowledge and skills, educational activities also include specific lectures on the use of imaging. It is EHRA's goal to expand that portfolio with imaging-oriented e-learning, like case-based approach on the upcoming ESCeL platform and Webinars. The content of the educational activities is based both on the ESC curriculum and on the topics addressed in accreditation exams.

Although the vastness of the field makes it 'impossible to be an expert in imaging'[58] a significant unmet need remains. Ideally, all EHRA courses should provide more time for the teaching of imaging techniques together with cardiological imaging subsocieties and our radiology partners from the ESCR. The aspiration is to equip electrophysiologists with sufficient knowledge of benefits, pitfalls, risks, and accuracy to allow logical choice between alternative imaging modalities and ensure efficient and effective use in clinical practice. This aspiration is stated with the caveat that in order to train properly, there has to be consensus among the cardiology community on which imaging techniques are clinically important and which remain investigational or accessory. Without proper clinical trials, this knowledge remains patchy at present. Beyond the diagnostic and clinical content, radiation protection should be at the core of any curriculum for accreditations in imaging. There is a shift towards more women training in cardiology which may generate greater pressure for more teaching on how to reduce radiation risk.

The formats in which EHRA training is delivered are courses and interactive webinars. Courses and educational content on the EHRA web site include information on fluoroscopic imaging for positioning of leads or catheters, echocardiographic data for heart failure device indication and evaluation, and 3D mapping technology for ablation, but the information is not presented in a predefined structured manner at present. The amount of e-learning is limited and additional experts are necessary to expand the offerings in this field. There is also scope for more continuous educational activities over the year. However, for proper training in imaging techniques, interdisciplinary teaching and additional teaching modes are necessary: hands-on tutorials, cross-modality imaging, or simulator workshops. This expansion of formats calls for facilities that are currently unavailable and will remain so unless a partnership can be established with the industry. Industry sponsorships are fundamental to the financing of medical education as healthcare systems so far do not pay for these activities.

Commercial and academic interests in education share significant common ground: to increase the efficacy of procedures and the safety for patients; to optimize patients' access to therapies and maximize the implementation of guideline recommendations; to facilitate interactions with experts; and to support care in emerging countries. Hence, the goal of the newly established EHRA Educational Framework: to coordinate and integrate the Association's own theoretical courses with industry-based practical teaching sessions. European Heart Rhythm Association currently collaborates closely with device companies and similar interactions with imaging companies could be established to mutual profit. There is a stated interest from these corporate organizations,

but the processes and structures need to be put in place. A greater involvement from the imaging industry would provide the additional benefit of making EHRA courses more attractive to non-electrophysiologists, which would help to develop a common language between electrophysiologists and radiologists.

An internationally renowned interdisciplinary expert faculty is necessary, whose members are present during the full course and take full responsibility for its conduct and content. With more than one company sharing in the same course, bias can be avoided. Moreover, industry-associated parts of courses need to be EBAC accredited and vetted by the Association. Proper Industry-conducted courses would be labelled as 'affiliated to the EHRA Educational Framework'. There should also be a place for e-learning tools in the Educational Framework. A project is on its way to develop interactive cases on the EHRA Web site and references can be made to quality material hosted by others.

The question of accreditation remains unsolved at present. To design appropriate accreditation exams, collaboration with radiologists and experts in cardiac imaging is necessary to ensure questions are appropriate for an electrophysiologist audience. Too many current questions are related to procedures or complications and not enough to patient evaluation prior to procedures or to follow-up of arrhythmic or device patients by cardiac imaging.

As European countries differ in their local conditions and in the range of devices and imaging modalities used in practice, not all information in a curriculum will be applicable to all participants. Local accreditations will remain the cornerstone for the foreseeable future, but supranational societies such as EHRA and ESCR can provide accreditations (e.g. European Diploma on Cardiac Imaging) that set benchmarks, even if they cannot override local conditions. The proper role for European diplomas is to provide an additional quality indicator alongside national diplomas.

Outlook

The survey and discussion of available data and expertise pinpointed a number of open questions that should have the highest priority for researchers, clinicians, professional organizations, and industry representatives in the next few years. The key needs are for proper evidence for the values of different imaging modalities, for appropriate cross-specialty training and education, and for deeper collaboration and the development of a common language between electrophysiologists, radiologists, and their partners in the device and imaging industries. The Policy Conference was a first step towards these goals:

It is important to recognize the limits and the gaps in our evidence. In general, there is a tendency of researchers to rush to get investigational findings into wider clinical use. It has been estimated that >40% of guideline recommendations are based on no evidence.[59] With automated evaluation systems, there is a tendency of users to trust the system blindly and to perform too few visual inspections and reality checks of the outputs. Physicians need to be aware of the limits of their craft. As scientists we have the responsibility not to raise too high expectations, not only among clinicians but also among patients.

To call for more research often resembles a cliché, but for the sake of patients and for the affordability and effectiveness of electrophysiological interventions, it is imperative that we base future use of imaging modalities on reliable, unbiased data.

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