EHRA Position Documents on new technology or standards of care

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Disclosures

Laurent Fauchier:

- *Lecture fees:* Bayer, BMS Pfizer, Daiichi Sankyo, Boehringer Ingelheim, Medtronic
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EHRA scientific documents

- EHRA has published a number of scientific documents over the past years. Some of these have been produced in collaboration with main players in the field of Arrhythmias and systematically published in EP Europace Journal. Today EHRA continues to cover new areas of interest in the field and produce scientific statements, recommendations and position papers.
- Since 2008, EHRA has also produced Scientific Documents in collaboration with different organisations (HRS, ACC, AHA, ESC, APHRS, SOLAECE...), and is continuously launching new Task Forces that tackle new and challenging scientific topics.

EHRA scientific documents

- The goal of the committee work is to provide sound advice, based on scientific data and generated by experts in the field, in emerging areas relevant to the management of arrhythmias in Europe.

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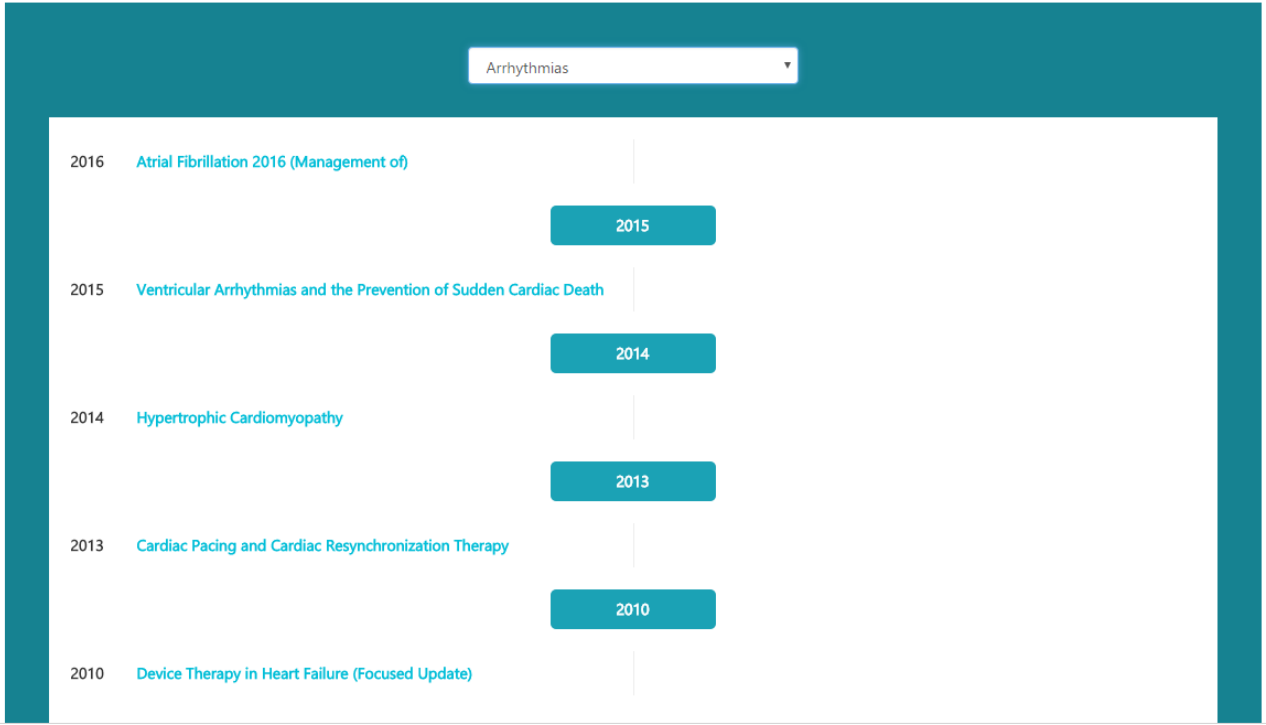

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Scientific Documents

2015-2017

Title	Publication Details
Management of supraventricular arrhythmias: A consensus document by the EHRA endorsed by the HRS, APHRS, and SOLAECE	Europace doi:10.1093/europace/euw301
Pre-participation cardiovascular evaluation for athletic participants to prevent sudden death: A position paper by from the EHRA and the EACPR, branches of the ESC. Endorsed by APHRS, HRS and Sociedad Latinoamericana de Estimulacion Cardiacay Electrofisiologia (SOLAECE)	Europace doi:10.1093/europace/euw243
How to Prevent Atrial Fibrillation: A position paper by the European Heart Rhythm Association(EHRA) and European Association of Cardiovascular Prevention and Rehabilitation (EACPR) endorsed by the Heart Rhythm Society (HRS) and Asia Pacific Heart Rhythm Society (APHRS)	Europace doi:10.1093/europace/euw242
Left univentricular pacing for cardiac resynchronization therapy. Thanks to an unrestricted grant from Medtronic The scientific content has not been influenced in any way by its sponsor.	Europace - doi/10.1093/europace/euw179
The wearable cardioverter-defibrillator: current technology and evolving indications. Thanks to an unrestricted grant from Zoll The scientific content has not been influenced in any way by its sponsor.	Europace - doi/10.1093/europace/euw180
EHRA/HRS/APHRS/SOLAECE expert consensus on Atrial cardiomyopathies: definition, characterization, and clinical implication	Europace - doi:10.1093/europace/euw161
EACVI/EHRA Expert Consensus on the role of Multi-Modality Imaging for the evaluation of patients with Atrial Fibrillation	European Heart Journal – Cardiovascular Imaging (2016) 17, 355–383, doi:10.1093/ehjci/jev354

2013-2015

Title	Publication Details
Updated European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist anticoagulants in patients with non-valvular atrial fibrillation	Europace (2015- doi:10.1093/europace/euv309
2015 HRS/EHRA/APHRS/SOLAECE Expert Consensus Statement on Optimal Implantable Cardioverter-Defibrillator (ICD) Programming and Testing	Europace (2015)
European Heart Rhythm Association/Heart Failure Association joint consensus document on arrhythmias in heart failure, endorsed by the Heart Rhythm Society and the Asia Pacific Heart Rhythm Society	Europace (2015) 10.1093/europace/euv191
A roadmap to improve the quality of atrial fibrillation management: proceedings from the fifth Atrial Fibrillation Network/European Heart Rhythm Association consensus conference	Europace (2015) 10.1093/europace/euv304
AFNET/EHRA Press Release	19 October 2015
Antithrombotic management in patients undergoing electrophysiological procedures: a European Heart Rhythm Association (EHRA) position document endorsed by the ESC Working Group Thrombosis, Heart Rhythm Society (HRS), and Asia Pacific Heart Rhythm Society (APHRS)	Europace (2015) 10.1093/europace/euv190
Chronic kidney disease in patients with cardiac rhythm disturbances or implantable electrical devices: clinical significance and implications for decision making a position paper of the European Heart Rhythm Association endorsed by the Heart Rhythm Society and the Asia Pacific Heart Rhythm Society	Europace (2015) 10.1093/europace/euv202
Syncope Unit: rationale and requirement – the European Heart Rhythm Association position statement endorsed by the Heart Rhythm Society	Europace (2015) 10.1093/europace/euv115
Cardiac tachyarrhythmias and patient values and preferences for their management: the European Heart Rhythm Association (EHRA) consensus document endorsed by the heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), and Sociedad Latinoamericana de Estimulacion Cardiaca y Electrofisiologia (SOLEACE)	Europace (2015) 10.1093/europace/euv233
EHRA Review article on state of the art of leadless pacing. Thanks to an unrestricted grant from St Jude Medical The scientific content has not been influenced in any way by its sponsor.	Europace (2015) 10.1093/europace/euv096

Scientific rationale of recommendations

Definitions where related to a treatment or procedure	Consensus statement instruction	Symbol
Scientific evidence that a treatment or procedure is beneficial and effective. Requires at least one randomized trial, or is supported by strong observational evidence and authors' consensus (as indicated by an asterisk).	'Should do this'	
General agreement and/or scientific evidence favour the usefulness / efficacy of a treatment or procedure. May be supported by randomized trials based on small number of patients or not widely applicable.	'May do this'	
Scientific evidence or general agreement not to use or recommend a treatment or procedure.	'Do not do this'	

- **This categorisation for a consensus document should not be considered as being directly similar to that used for official society guideline recommendations which apply a classification (I-III) and level of evidence (A, B and C) to recommendations.**

New devices in heart failure: an EHRA report

Review of new devices for the treatment of HF patients introduced in clinical practice or under clinical evaluation :

- cardiac contractility modulation
- spinal cord stimulation
- carotid sinus nerve stimulation,
- cervical vagal stimulation,
- intracardiac atrioventricular nodal vagal stimulation
- implantable haemodynamic monitoring devices.

Kuck KH et al. *Europace 2014*

EHRA/EAPCI expert consensus statement on catheter-based LAA occlusion

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- *« The main indication for LAA occlusion today is a relative or absolute contraindication to (N)OACs in patients with AF and a CHA2-DS2-VASc score ≥2.*
- *This recommendation is based on observational studies and registries only.*
- *To be a candidate for LAA occlusion, patients should be able to receive at least several weeks of dual AT followed in most cases by lifelong single antiplatelet drug therapy.*
- *If antiplatelet therapy is not an option, percutaneous endocardial/epicardial or minimally invasive surgical epicardial LAA occlusion may be alternatives. »*

Meier B et al. *Europace 2014*

Tips and tricks for LAA device implantation

(1) Using a PFO for transseptal access may lead to suboptimal delivery sheath alignment with the LAA. Sometimes this problem can be solved by custom shaping the sheath with or without hot air gun
(2) Minimize device sheath time in the LA especially in large LA with LAA sludge and/or pronounced smoke (longer indwelling gear time increases device-associated thrombus risk)
(3) Minimize the risk of air embolism
  (a) Generously backbleed the transseptal and access/delivery sheath allowing air to exit the sheath prior to inserting any equipment or devices (keep the haemostatic valve and device arm below the midline of the chest). Keeping the haemostatic valve, proximal sheath end, and side arm under water may prevent air entering the system during backbleeding
  (b) Remove dilators, catheters, and transseptal puncture needles slowly
  (c) Flush the device and delivery catheter generously prior to insertion
(4) Choosing a device
  (a) Avoid implanting a Watchman device if the LAA length is less than the device diameter
  (b) Avoid implanting a Watchman device if the LAA diameter is <17 or >30 mm
  (c) Avoid implanting an ACP if the landing zone diameter is >29 mm (31 for Amulet)
  (d) Avoid implanting an ACP if the LAA length is <10 mm (7.5 for Amulet)
  (e) If the LAA is too large for either the Watchman or ACP (but the maximal diameter <40 mm), suture occlusion with the Lariat technique could be considered
  (f) Avoid Lariat suture ligation in patients with a superiorly oriented LAA or in LAAs that course behind the pulmonary artery (removal of the Lariat loop may be challenging or impossible). Use of the Lariat is contraindicated in patients with prior heart surgery (due to pericardial adhesions) and may be exceedingly difficult or impossible in patients with pectus excavatum
(5) Confirm adequate position

  Watchman
  (a) The shoulder should not protrude beyond the LAA ostium by >20% of its diameter (<4.2 mm for a 21 mm device, <4.8 mm for a 24 mm device, <5.4 mm for a 27 mm device, <6 mm for a 30 mm device, and <6.6 mm for a 33 mm device)
  (b) Assure optimal compression (10–20%) by both TOE and fluoroscopy
  (c) Do not accept residual leaks of >3 mm
  (d) Look in all standard TOE views (see above)

  ACP
  (a) Assure slightly concave disc shape
  (b) Optimally, the lobe should be slightly compressed (tyre-shaped), no compression or deformity suggests a too small size or too proximal position, whereas too much compression with significant alteration of the shape suggests too large size or too distal positioning
  (c) The lobe should not protrude more than one-third beyond the left circumflex coronary artery
  (d) Optimally, the disc and lobe should be separated slightly
  (e) Look in all standard TOE views (0°, 30°, 45°, 90°, and 135° for adequate seal and coverage of all lobes)

ACP, Amplatzer Cardiac Plug; LA, left atrium; LAA, left atrial appendage; TOE, transoesophageal echocardiography.

Meier B et al.
Europace 2014

Parameters for registries of LAA occluders

- **14 sections with 1 to 13 items**

(1) Demographic data
- Name or registry code
- Gender
- Age

(2) Type of device implanted
- Watchman
- ACP
- Other
- Previous failure of LAA occlusion device (type, date, reason)

(3) Type of atrial fibrillation
- Paroxysmal
- Persistent
- Long-standing persistent (permanent)

(4) Cardiovascular history
- Ischaemic heart disease
- Congestive heart failure
- Valvular heart disease
- Cardiomyopathy
- Arrhythmic history other than AF

(5) $CHADS_2$ score

(6) CHA_2DS_2-VASc score

(7) HAS-BLED score

(8) Antithrombotic therapy given prior to the implant
- ASA
- Clopidogrel
- Warfarin
- Apixaban
- Dabigatran
- Rivaroxaban
- Prasugrel
- Ticagrelor
- Low-molecular-weight heparin
- Fondaparinux
- Other
- None

(9) Indication for implant
- Low compliance
- History of intracranial bleeding (intracerebral and subdural)
- History of urinary tract bleeding
- History of spontaneous bleeding other than intracranial or urinary tract bleeding (i.e. retroperitoneal haematoma)
- Recurrent falls
- Cognitive impairment
- Use of non-steroidal anti-inflammatory drugs, steroids
- Personal preference

(10) Technical data of implant
- Success/failure
- Size of the device implanted
- Measure LAA opening, landing zone, and depth

LAA morphology (unilobar, multilobar, 'cauliflower type', chicken wing, wind sock, etc.)

Need for device replacement during the procedure (type and size)

(11) Periprocedural complications
- Death
- Ischaemic stroke
- Transient ischaemic attack
- Haemorrhagic stroke
- Pericardial effusion with tamponade
- Valvular complication (i.e. mitral valve damage)
- Device embolization
- Bleeding
  - Major
  - Minor
- Peripheral vascular complication
- Pulmonary oedema
- Myocardial infarction
- Arrhythmia (type)
- Pulmonary embolism

(12) Antithrombotic therapy at discharge and length of therapy
- ASA
- Clopidogrel
- Warfarin
- Apixaban
- Dabigatran
- Edoxaban
- Rivaroxaban
- Prasugrel
- Ticagrelor
- Low-molecular-weight heparin
- Fondaparinux
- Other
- None

(13) TOE follow-up at 6 weeks, 6 months, and 1 year
- Device position (as at implant)
- Device-related thrombi
- Para-device leak (size)
- Device embolization

(14) Clinical follow-up at 6 weeks, 12 months, and yearly thereafter
- Death
- Ischaemic stroke
- Transient ischaemic attack
- Haemorrhagic stroke
- Device embolization
- Major bleed
- Minor bleed
- Peripheral vascular complication
- Pulmonary oedema
- Myocardial infarction
- Arrhythmia (type)
- Pulmonary embolism
- Type of antithrombotic therapy

Meier B et al.
Europace 2014

How to establish a syncope unit: rationale and requirement

- This position paper offers a pragmatic approach to the rationale and requirement for a syncope unit, based on specialist consensus, existing practice, and scientific evidence.
- This document is addressed to physicians and others in administration, who are interested in establishing a syncope unit in their hospital, so that they can meet the standards proposed by ESC-EHRA-HRS.

Kenny RA et al. *Europace 2015*

Syncope unit: Quality indicators

Quality indicator	Process indicator	Desirable outcome target
1. SU		
To reduce the rate of unexplained T-LOC	At least 70% of patients receive a definite diagnosis (according to ESC guidelines definitions)	Absolute rate of unexplained T-LOC ≤20%
To reduce the rate of hospitalization (in patients at intermediate–high risk from ED)	At least 20% of patients with unexplained syncope after initial ED evaluation have fast-track access to SU for early assessment	≤20% of patients with unexplained T-LOC admitted after ED initial evaluation (according to ESC guidelines definition)
To reduce costs per patient	At least 20% reduction in costs relative to usual local practice	
To improve the outcome	Less than 5% re-admissions for syncope recurrence in patients with an established and successfully treated diagnosis (according to ESC guidelines definitions)	Less than 20% of paced patients have recurrence of syncope at 1 year

3. Operations	
Number of patients	At least 100 new cases per year per SU
Tests	>95% of patients have a documented ECG>90% of patients have documented orthostatic tests>90% have carotid sinus massage, tilt table test, external loop recorder and implantable loop recorder performed according to ESC guidelines indications
Waiting list (first visit and follow-up)	70% of low risk patients seen within 3 months90% of intermediate risk patients seen within 2 weeksNo waiting list for high-risk patients

Kenny RA et al. *Europace 2015*

Cardiac tachyarrhythmias and patient values and preferences for their management

Critical elements of patient-healthcare professional discussions regarding OAC

- Explain link between AF and stroke and why OAC is usually recommended lifelong
- Patient's individual risk of stroke by CHA_2DS_2-VASc
- OAC treatment options
- Patient's risk of bleeding on OAC and risk/benefit profile
- Drug-specific education
- Emphasise importance of medication adherence
- Bleeding side effects and how to manage these
- In patients taking VKA, importance of anticoagulation control (TTR≥70%)

OAC, oral anticoagulation; TTR, time in therapeutic range; VKA, vitamin K antagonist

Lane DA et al.
Europace 2015

Cardiac tachyarrhythmias and patient values and preferences for their management

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Key topics for initial discussions with AF patients

- Basic anatomy/physiology of AF
- Explanation of possible symptoms; emphasise that asymptomatic AF is common
- Factors increasing risk of AF development; focus on factors related to patient
- Trajectory of AF – what can the patient expect?
- Discuss consequences of AF
- Discuss treatment options (including OAC)
- Treatment education (pharmacological, non-pharmacological, lifestyle)
- Agree an action plan and follow-up care (who and when)

Lane DA et al.
Europace 2015

New documents in progress 2016/2017 – Publication 2017

NAME	CHAIRS	STATUS / ACTION
EHRA Position Paper on Device Detected Subclinical Atrial Tachyarrhythmias: Definition, Implications and Management	Bulent Gorenek Giovanni Luca Botto	Ongoing – reviewers to be appointed
Screening for Atrial Fibrillation: the European Heart Rhythm Association (EHRA) consensus document endorsed by the Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), and Sociedad Latinoamericana de Estimulation Cardiaca y Electrofisiologia (SOLAECE)	Georges H. Mairesse Guiseppe Boriani	Ongoing – reviewers to be appointed
EHRA/Council on Hypertension joint position document on Arrhythmias in Hypertension, endorsed by HRS, APHRS and SOLEACE	Gregory Lip Antonio Coca	Ongoing – reviewers to be appointed
Consensus document on occupational radiation exposure in the electrophysiology laboratory to personnel with childbearing potential and during pregnancy	Andrea Sarkozy Tom De Potter	Ongoing – reviewers to be appointed
Antithrombotic therapy in valvular AF	Gregory Lip Steen Husted	Ongoing – reviewers to be appointed
Arrhythmias in Grown up Congenital Heart Disease	Juha-Matti Happonen Antonio Hernandez Madrid	Ongoing – reviewers to be appointed

Conclusion

- **The scientific documents committee of EHRA is highly active, promoting new scientific documents as position statements, many of which are in collaboration with other Associations, Working Groups and scientific societies.**

- **A comprehensive coverage of arrhythmias is intended, with the aim to provide 'state of the art' consensus on current topics, controversial areas, and offer management options.**

Best place where to stay when you are not in Palma

Definitions where related to a treatment or procedure	Consensus statement instruction	Symbol
Scientific evidence that a treatment or procedure is beneficial and effective. Requires at least one randomized trial, or is supported by strong observational evidence and authors' consensus (as indicated by an asterisk).	'Should do this'	

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