JAFIB
Featured Review
Journal of Atrial Fibrillation
www. jafib.com

EHRA(European Heart Rhythm Association) EP-Wires Surveys: What Is Common Practice In Device Management?

Carina Blomström-Lundqvist[1], Maria G Bongiorni[2]

[1]Department of Cardiology, Institution of Medical Science, Uppsala University, Uppsala, Sweden. [2]Second Cardiology Department, University Hospital of Pisa, Pisa, Italy.

Abstract

Guidelines and recommendations within the field of electrophysiological (EP) practice are usually drawn from the results of multicentre trials, often conducted in selected centers and under special circumstances. In contrast, daily practice is generally influenced by many factors, which may be different from those that are considered in strictly controlled scientific conditions. Even though patient registries may mirror daily practice, the enrollment of consecutive patients for longer periods of time for such purpose within the health care community is costly and time consuming. A short form of survey directed to physicians, could within a reasonable time frame highlight areas where the evidence base for clinical practice and implementation of guidelines needs to be augmented. Such short form of surveys, called EP Wires, are on-line surveys carefully constructed to give a picture of daily cardiac EP practice in Europe without burdening the responders with extensive data collection. The network of centers formed, are contacted on a regular basis every month. It is the purpose of this summary to present the result of four such EP wires, all of which concern devices, with special emphasis on centre differences and adherence to guidelines.

Introduction

Guidelines and recommendations are usually drawn from the results of multicentre trials, which however, are often conducted in selected centers and under special circumstances. In contrast, daily practice is generally influenced by many factors, which may be different from those that are considered in strictly controlled scientific conditions. Although patient registries would be able mirror daily practice, the enrollment of consecutive patients for longer periods of time within the health care community, is costly and time consuming. Another approach that may be helpful to the community of cardiac rhythm management specialists for generating debates and identifying challenges in clinical practice is a short form of survey directed to physicians. Within a reasonable time frame it would be possible to highlight areas where the evidence base for clinical practice and implementation of guidelines needs to be augmented. Such short form of surveys, called EP Wires, are on-line surveys carefully constructed so as not to burden the responders with requirements for extensive data collection, but still able to give a picture of daily cardiac EP practice in Europe. The network of centers formed, are contacted on a regular basis every month, and in each centre there is one physician replying anonymously to the survey. Basic questions included in each EP wire relates to the number and type of device implants and number of ablations performed on an annual basis in each center.

It is the purpose of this summary to present the result of four EP wires, which all concern devices, with special emphasis on centre differences and adherence to guidelines. The surveys included are "Practices of cardiac implantable electronic device follow-up"; "How European centers diagnose, treat, and prevent cardiac implantable electronic devices (CIED) infections", "Approach to cardiac resyncronization therapy", and "Periprocedural anticoagulation therapy for devices and atrial fibrillation ablation".[1-4] The response rate varied from 30 to 50 % of centres belonging to the EP Network.

EP Wires Analyzed

The EP wire on "Practices of cardiac implantable electronic device follow-up"[1] analyzed current practices of follow-up of patients with CIEDs. A total of 40 centers from the EHRA research network participated. Most of the responding centers reported large numbers of primary pacemaker implants (>200/year), while a majority had a modest rate of CRT-P implantations (less than 50 per year) generating more than 2000 pacemaker follow-ups in 40% of centers and up to 500 CRT follow-ups in half of centers. Routines used for device follow-ups are shown in figure 1. Programming CIED parameters was thus seldom performed by nurses and if so it was for pacemaker devices only, and rarely for ICD (one center only), and reportedly never for CRT devices. Formal accreditation or certification of allied professionals to perform follow-ups was not required in the majority of centers (72.5%). The interval between scheduled follow-up visits is shown in Figure 2. Remote device monitoring is used routinely for

Disclosures:
None.

Corresponding Author:
Carina Blomström-Lundqvist
Department of Cardiology,
Institution of Medical Science
Uppsala University
S-751 85 Uppsala
Sweden.

Table 1: Actions depending on type of suspected infection

Actions if suspected pocket infection (pain, swelling and erythema at site of device pocket)	
Hospitalization; lab tests, echocardiography, adequate treatment	68,2%
Start empiric antibiotic therapy	28,8%
"Wait and see"	14,9%
Pocket needle aspiration for bacterial culture.	2,1%
Actions if suspected systemic infection	
CBCC	100,0%
CRP	97,8%
Blood culture x 2	92,9%
Blood culture x 1	72,0%
ESR	88,9%
Procalcitonin	32,3%
TTE	97,5%
TTE	89,9%
Scintleuk	23,1%
ICE	4,2%
Scintpulm	4,0%

Abbreviations: CBCC = Complete blood cell count, CRP =C-Reactive Protein, SR = Erythrocytes Sedimentation Rate, TTE=Trans-Thoracic Echocardiography, TEE=Trans-Esophageal Echocardiography, Scintleuk=Scintigraphy using labelled leukocytes, ICE = Intracardiac and intravascular echocardiography, ScintPulm = Pulmonary scintigraphy.

ICD and CRT-D in 50% of centers, but only by 17.5 % of centers for pacemaker and CRT-P devices.

In the EP wire on "How European centers diagnose, treat, and prevent CIED infections",[2] 48 Network Centers replied, of which 67 % were university hospitals. The annual implantation rate was > 200 pacemakers (including CRT-P) in 62.5% of centers. The prevalence of CIEDs infections during 2010 and 2011 is shown in Figure 3. Only one center reported a higher infection rate than 5%. The procedure with the highest incidence of infection was cardioverter-defibrillator implantation according to 55.3% of centers and the intervention with the highest incidence of infection was replacement of devices according to 48 % of centers. The tests chosen to evaluate suspected pocket infection or suspected systemic infection are shown in Table 1. Most centers (61.2%) usually consult an infectious disease specialist to diagnose and treat CIEDs infections.

The majority of centers defined the following as absolute indications for complete hardware removal; valvular or lead endocarditis, sepsis, pocket abscess, device erosion, chronic draining sinus, or valvular endocarditis without definite lead(s). The presence of occult gram-positive bacteraemia (not contaminant) was considered a Class II indication for lead extraction in the majority (67%) of the centres while only 21 % defined it as Class I indication. In case of local infection, 45,7% of centers had a conservative strategy only when lead extraction was considered at high risk, but 43.5% avoided a conservative approach. The following were regarded as risk factors for CIEDs infections by the majority of centers (82.5 % - 97.6%); replacement and upgrading of devices, diabetes mellitus, procedure duration, fever within 24 h before procedure, chronic renal failure, and CRT recipients. The extraction procedures are performed in a catheterization laboratory in 51.1% of centers, in an operating theatre with ventilation in 35.6% and in a hybrid room in 13.3% of centers.

The EP wire on "Approach to cardiac resyncronization therapy"[3] included 41 centers, of which 29 were university hospitals (71%) and high volume centers with >200 pacemaker implants in the last year. Indications used for CRT implant is shown in Table 2. The CRT implant strategy is to implant three leads (right atrium, right ventricle, left ventricle) for patients with permanent atrial fibrillation (AF) (59%) but only 63% attempt restoration of sinus rhythm, while others are satisfied with rate control, either by using drugs or by AV node ablation. Biventricular pacing without atrial lead is preferred in 37% of the centres and an overwhelming majority (71%) prefers the initial use of drugs for heart rate control, while only 29% resort to AV node ablation as a first line approach. The preference for CRT-P or CRT-D is shown in Table 3.

Criteria used for optimal positioning of the left ventricular (LV) lead are limited to a good pacing threshold in 11%. Other preferred criteria is the radiological position with maximum mechanical delay on echocardiography in 24 centres, and the maximal delay of LV lead electrogram compared to the QRS/RV lead electrogram in another 13 centres. Six centres always use a multipolar (i.e. more than 2 poles) LV lead. If there are no feasible lateral veins for LV lead implantation via coronary sinus, the first preferred alternative is an epicardial LV lead via thoracotomy (54%) or to place the LV lead in the anterior vein (29%). A endocardial transseptal approach is used as first alternative in five centres and dual-site RV stimulation (high septal and apical) in one centre. Methods used for optimisation of time intervals are shown in Table 4. The most important clinical criterion in assessing the CRT response is NYHA class improvement (37% of centres), LVEF improvement (34%) and LV volume change (15 %). Less frequently used criteria are walking test (8%) and quality of life (6%).

In the EP wire on "Periprocedural anticoagulation therapy for devices and atrial fibrillation ablation"[4] 71 centers from the research network responded. The median number of devices implanted at the

Table 2: Indications used for cardiac Resynchronization therapy (CRT)

	CRT indications used	% Centres
Always CRT if:	NYHA fc II, LBBB, QRS duration >120 ms, LVEF <35%, on optimal medical Rx	32,0%
	Additionalcriteriarequired	55,0%
	Additional QRS duration >150 ms	49,0%
	Additional echocardiographic criteria of asynchrony	34,0%
	Never this approach	13,0%
Always CRT if	NYHA fc III–IV, LBBB, QRS duration >120 ms, LVEF <35%, on optimal medical therapy	68,0%
	Additional criteria needed; QRS duration >150 ms, echocardiographic criteria of asynchrony, no significant scars on echo/MRI.	32,0%
Always CRT if	RBBB, NYHA fc III–IV, QRS duration >120 ms, LVEF <35%, on optimal medical Rx	10,0%
	Additionalcriteria	51,0%
	addEchocardiographicasynchrony parameters	41,0%
	add QRS duration >150 ms	22,0%
	Bothcriteriarequired	50,0%
	Meaning of presence of non-ischemic dilated cardiomyopathy	7%
	Never this approach	39,0%
	Permanent AF, QRS duration >130 ms, LVEF<35%, NYHA fc III or IV.	54%
	Never this approach	2%
	Additional criteria required; QRS duration >150 ms, echocardiographic criteria of asynchrony, or both simultaneously.	44%

Abbreviations: LBBB= left bundle branch block, RBBB = right bundle branch block, LVEF = left ventricular ejection fraction, Rx = therapy, fc = functional class, AF = atrial fibrillation

Table 3: Indications for type of device - CRT-P or CRT-D

Always CRT-P, unless indication for secondary prevention of SCD	24%
Always CRT-D	10%
CRT-P only if severe co-morbidities, non-ischemic dilated cardiomyopathy or ambulatory NYHA fc IV.	66%

Abbreviations: SCD = sudden cardiac death, as in table 2.

centers was 445 (range 50-1500) and a median of 25% (0-70) were on warfarin, while only a minority (mean 1.6%) were on a new oral anticoagulant. The median numbers of AF ablations performed were 330 (range 0-2000) and 40% were on warfarin, 20% on antiplatelet drug and 40% were on no anti-thrombotic therapy.

The common routine was to stop warfarin for a median of 3 days (range 2-7) and bridge with heparin in 40-45% of patients with devices. Oral anticoagulation (OAC) most commonly restarted after the procedure on the following day but in case of prosthetic valves 49% would start warfarin the same day. Many centers would perform procedures with patients still on OAC; 60% for pacemakers and ICD patients and 50% for CRT. The median INR accepted would be 2.2 - 2.5 (range 1.4-4.0) for devices. In case of coronary artery disease and a stent {<12 months), most (86-89%) centers would not stop their antiplatelet drug. If the patient was on antiplatelet therapy, 78.1% of centers would not stop their drug, and if they did stop, this would be at a median of 5 days (range 1-7) prior to the procedure. The median rate of haematoma was 5% for both patients on OAC and on antiplatelet therapy. The centers reported a median of 0 (range 0-10) coronary sinus perforations in the last year following a CRT procedure.

For AF ablation patients, the current practice would be to stop warfarin and bridge with heparin in 56.7% of non-valve patients, and 57.6% of prosthetic valve patients. If heparin was used for bridging, it would be stopped at a median of 12 hours (2-48). The centers would perform the procedure while still on OAC in 53.6% non-valve patients. If on VKA, a median INR of 2.5 (1.4-3.5) was generally acceptable. If the patient was on antiplatelet therapy, 95.2% would not stop. After the AF ablation, OAC was restarted the same day in 65.6% or the day after in 34.4%. Following an ablation procedure, the approximate median rate of haematoma overall was 3% in patients on OAC, compared to 2% in patients on antiplatelet therapy. During ablation of atrial fibrillation, the median ACT used by centers was 350 (range 150-420). Only 31.1% of centers would do an ablation whilst the patient is taking one of the new OACs.

Discussion

Remote device monitoring is helpful in decreasing hospital workload and improving the standards of care.[5, 6] According to the results of this survey, remote monitoring of CIED is used to different extent in various European centers, mostly for complex devices like ICD and CRT-D, and surprisingly to a smaller extent for pacemaker patient groups. It also shows that routines for CIED follow-ups are not homogeneous between the respondent EHRA Research network centers. During CIED follow-up procedures not only physicians, but also nurses and technicians were often involved, despite the fact that 72.5% of responders stated that formal accreditation/certification was considered not necessary for allied professionals who participated in CIED follow-up. Thus, official recommendations and standardized routines regarding standards of clinical care for device follow ups are warranted in order to help us to improve standards of care.

Table 4: Methods used for optimisation of time interval

Initial:	
AV interval first, standard (fixed VV) or optimised VV interval (ECG)	51%
None	24%
Manufacturers algorithms	12%
VV intervalfirst	10%
After implantation:	
M-Mode/Doppler echocardiography	66%
QRS morphology/duration	54%
Tissue Doppler Imaging	37%
Speckle-trackingechocardiography	20%
3D echocardiography	10%
Invasive dp/dt max, noninvasive cardiac index by impedance	0%

The reported incidence of CIED infections is substantially under 1% in the majority of centers which is quite low, compared to the recently reported rates of complications in the Danish pacemaker registry ranging from 0,8 to 1,9 % [7] and data from other published literature, 2,4 %.[8] One cannot exclude, however, that this EP wire voluntary surveys may be associated with under reporting of complications even though the surveys are anonymous. A limitation was also the low number of small volume centers which may have reported higher rates of infections. There were differences in case of managing local infections, whereas in case of systemic infection or evidence of lead or valvular endocarditis, 95% of centers employed lead extraction, which indicates a good adherence to guidelines. The survey shows that Cardioverter-defibrillator implantation is associated with the highest incidence of infection (55.3% of centers), followed by pacemakers (27.7%) and then both CRT-P and ICD (23.4%), which is in agreement with previous studies. The observation that replacement of devices, followed by revision and upgrading of CIEDs, were the procedures with highest incidence of infections, is also consistent with current reports. When centers were asked to report the class of indication for complete hardware removal, not all centers had a complete adherence to the guidelines despite their expected high experience. Valvular endocarditis without definite lead(s) involvement was correctly considered as a Class I indication

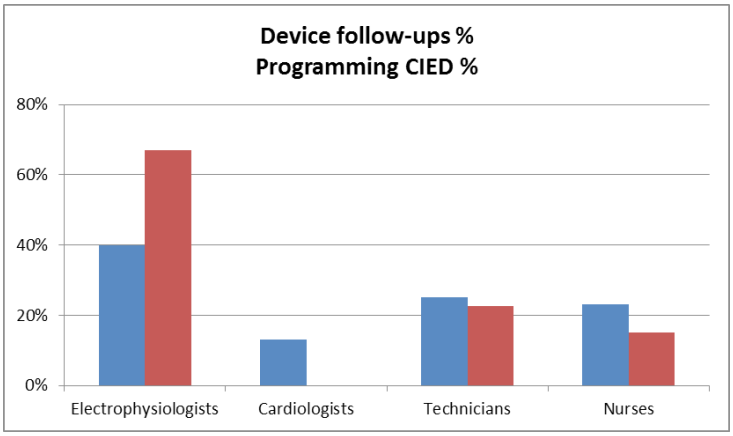

Figure 1: Personal resources used for device follow-ups and for programming devices.

The figures on y axis indicate % of centers

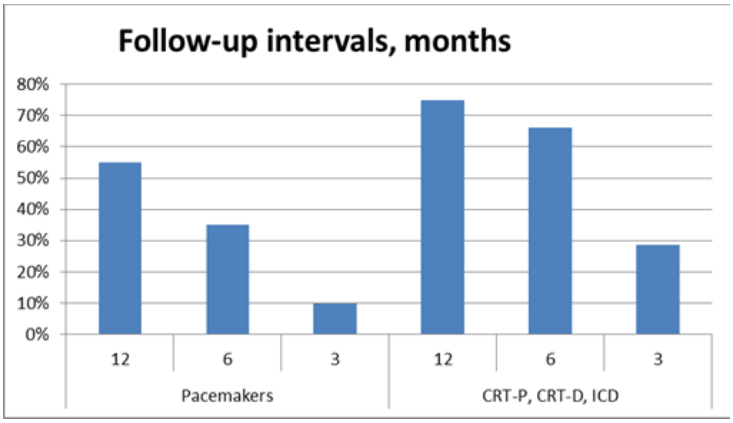

Figure 2: The different follow-up intervals used among the centers depending on the type of device.

The figures on y axis indicate % of centers.

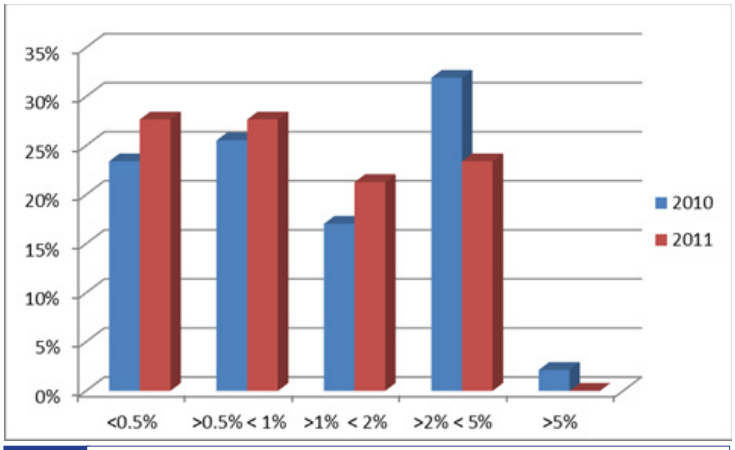

Figure 3: Prevalence of device infections during 2012 and 2011.

The figures on y axis indicate % of centers.

in 50% of the centers while the presence of occult gram-positive bacteremia (not contaminant), which is a Class I indication in the guidelines, was considered a Class II indication for lead extraction in the majority of the centers and a Class I indication in only a minority of centers. Even though the majority of centers seem to have a good knowledge of the main risk factors related to CIED infections, a more widespread knowledge of how to manage CIED infections would most likely improve the effectiveness of this treatment.

Recent guidelines state that CRT is indicated in patients with NYHA functional class III or IV heart failure, who are in sinus rhythm, with left bundle branch block (LBBB) and a QRS duration of ≥120 ms, and a left ventricular ejection fraction (LVEF) ≤ 35%.[9,10] In the CRT EP wire survey, this CRT indication is adopted by 68% of the responding centres, while the others require further criteria, mainly related to QRS complex duration or echocardiographic parameters of asynchrony. The observation that more than half of the centres required additional criteria for CRT in patients with right bundle branch block (RBBB), and that 29% of the centres never use CRT in these patients, is assuring since CRT use in patients with RBBB morphology is still controversial.

Only one third of responding centres use CRT in patients with functional class NYHA II and more than half of these request additional criteria, most often related to QRS duration, despite the fact that recent trials show beneficial effects of CRT in patients with mild HF. Moreover, most of the responding centres would use CRT in patients with AF even though these patients have not been adequately studied in large trials. In the EP wire survey, only a minority, 10%, of the centres implant CRT-D devices on a regular basis whenever CRT is recommended, while a quarter of the centres only use CRT-D for secondary prevention of SCD. The choice of CRT-D over CRT-P is supported by one large meta-analysis,[11] while the superiority of one CRT strategy over the other could not be demonstrated in the Companion trial, as the comparison between CRT-D and CRT-P was not pre-specified.

The chosen strategies concerning the implant and management after CRT implantation vary widely from one centre to another. There are, however, no clear recommendations concerning the implant strategy and management after CRT implantation. Radiological positioning of the left ventricular lead consistent with a zone of maximal mechanic delay on echocardiography is associated with a better prognosis.[12] Moreover, numerous methods for CRT optimization have been suggested but without clear recommendations. Further randomised trials with long-term clinical endpoints comparing methods are needed.

The EP wire survey showed an increasing trend towards using continuous warfarin while performing AF ablation procedures. The 2012 HRS/EHRA/ECAS Expert Consensus Statement reported high incidence of bleeding complications when bridging was used, especially at the site of vascular access.[13] The observed variable duration of continued OAC post-ablation is of concern, as is the fact that some centers even discontinue OAC in patients at high risk, despite the 2010 ESC guidelines[14] recommending long term anticoagulation in patients with a CHA_2DS_2-VASc score of ≥2. Similarly, the 2012 joint HRS/EHRA/ECAS Expert Consensus Statement advised that 'discontinuation of warfarin or equivalent therapies post-ablation is not recommended in patients who have a high stroke risk according to $CHADS_2$ or CHA_2DS_2-VASc score'. The approximate rate of clinical stroke/thromboembolism reported by centers surveyed was low, at a median of 1% (range 0-5). Under reporting of complications cannot be excluded eventhough the EP wires were anonymous. The availability of the new OACs (eg. dabigatran, rivaroxaban, apixaban) offers new challenges for devices and ablation. Only 31.1% of the centers surveyed would continue with a new OACs whilst performing an AF ablation.

These EP wire surveys shows variation in clinical practice, but reassuringly some consistency with guidelines and consensus recommendations.

Conclusion:

These EP wire surveys shows variation in clinical practice, but reassuringly some consistency with guidelines and consensus recommendations.

References:

1. Marinskis G, van Erven L, Bongiorni MG, Lip GY, Pison L, Blomström-Lundqvist C; Scientific Initiative Committee, European Heart Rhythm Association. Practices of cardiacimplantableelectronicdevice follow-up: results of the European Heart Rhythm Association survey. Europace. 2012 Mar;14(3):423-5.
2. Bongiorni MG, Marinskis G, Lip GY, Svendsen JH, Dobreanu D, Blomström-Lundqvist C; Scientific Initiative Committee, European Heart Rhythm Association.

How Europeancentres diagnose, treat, and prevent CIED infections: results of anEuropeanHeartRhythmAssociationsurvey. Europace. 2012 Nov;14(11):

3. Dobreanu D, Dagres N, Svendsen JH, Marinskis G, Bongiorni MG, Blomström-Lundqvist C. Approach to cardiacresyncronizationtherapy.Europace. 2012 Sep;14(9):
4. Lip GY, Proclemer A, Dagres N, Bongiorni MG, Lewalter T, Blomström-Lundqvist C; Scientific Initiative Committee, EuropeanHeartRhythmAssociation. Periprocedural anticoagulation therapy for devices and atrial fibrillation ablation. Europace. 2012 May;14(5):741-4.
5. Burri H, Heidbuchel H, Jung W, Brugada P. Remotemonitoring: a cost or an investment? Europace 2011;13:ii44–ii48.
6. Ricci RP, Calcagnini G, Castro A, Giada F, Igidbashan D, Landolina M, et al. [Consensusdocumentonremotemonitoringofcardiacimplantableelectronicdevices: technology, indications, organizationalmodels, acceptability, responsibility, and economicissues]. G ItalCardiol 2011;12:450–67.
7. Kirkfeldt RE, Johansen JB, Nohr EA, Jørgensen OD, Nielsen JC.Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. EurHeart J. 2014 May;35(18):1186-94
8. Greenspon AJ, Patel JD, Lau E, et al. 16-year trends in the infection burden for pacemakers and implantable cardioverter-defibrillators in the United States: 1993–2008. J Am CollCardiol 2011;58:1001– 6.
9. Dickstein K, Vardas PE, Auricchio A, Daubert JC, Linde C, McMurray J, Ponikowski P, Priori SG, Sutton R, van Veldhuisen DJ. 2010 focused update of ESC Guidelines on device therapy in heart failure. European Heart Journal 2010; 31:2677–2687
10. McMurray JJ, Adamopoulos S, Anker SD, Auricchio A, B?hm M, Dickstein K, Falk V, Filippatos G, Fonseca C, Sanchez MA, Jaarsma T, Kober L, Lip GY, Maggioni AP, Parkhomenko A, Pieske BM, Popescu BA, Ronnevik PK, Rutten FH, Schwitter J, Seferovic P, Stepinska J, Trindade PT, Voors AA, Zannad F, Zeiher A. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. European Heart Journal 2012; 33:1787–1847.
11. LamSK, Owen A. Combined resynchronisation and implantable defibrillator therapy in left ventricular dysfunction: Bayesian network meta-analysis of randomised controlled trials. Br Med J 2007;335:925-35
12. Ypenburg C., van Bommel R.J, Delgado V; Mollema SA, Bleeker GB, Boersma E, Schalij MJ, Bax JJ. Optimal left ventricular lead position predicts reverse remodeling and survival after cardiac resynchronization therapy, J Am CollCardiol 52 2008 1402-1409.
13. Calkins H, Brugada J, Packer DL, Cappato R, Chen SA, Crijns HJ et al. HRS/EHRA/ECAS Expert Consensus Statement on catheter and surgical ablation of atrial fibrillation:recommendations for personnel, policy, procedures and follow-up: areport of the Heart Rhythm Society (HRS) Task Force on Catheter and SurgicalAblation of Atrial Fibrillation Developed in partnership with the European HeartRhythm Association (EHRA) and the European Cardiac Arrhythmia Society(ECAS); in collaboration with the American College of Cardiology (ACC), AmericanHeart Association (AHA), and the Society of Thoracic Surgeons (STS).Europace 2007;9:335–7
14. Camm AJ, Kirchhof P, Lip GY, Schotten U, Savelieva I, Ernst S et al. Guidelines forthe management of atrial fibrillation: the task force for the management of atrialfibrillation of the European Society of Cardiology (ESC). Europace 2010;12: 1360–420.