

Periprocedural anticoagulation therapy for devices and atrial fibrillation ablation

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This EP Wire surveyed clinical practice with regard to the use of antithrombotic therapy in relation to device implantation (pacemakers, ICT, resynchronization therapy) and atrial fibrillation ablation in 71 centres—members of the European Heart Rhythm Association research network. The results of this survey show variation in clinical practice, but reassuringly some consistency with guidelines and consensus recommendations on the management of periprocedure (devices, ablation) antithrombotic therapy.

Keywords Ablation • Anticoagulation • Atrial fibrillation • Devices • Pacemakers

Introduction

Periprocedural use of antithrombotic therapy during electrophysiological procedures was addressed in a position document from the European Heart Rhythm Association in 2006,¹ which addressed practice recommendations for peridevice management [e.g. during pacemaker (PPM) implantation] and ablation procedure. Since then, additional developments have included the increasing use of implantable cardioverter-defibrillator (ICD)/cardiac resynchronization therapy (CRT) devices and the requirement for many such patients to have anticoagulation, for example, due to paroxysmal atrial fibrillation. The 2010 European Society of Cardiology guidelines² also introduced new risk stratification schemes, such as the CHA₂DS₂-VASC³ and HAS-BLED⁴ scores, for stroke and bleeding risk assessment, respectively.

The purpose of this EP Wire is to survey clinical practice with regard to the use of antithrombotic therapy in relation to device implantation (PPM, ICT, CRT) and atrial fibrillation ablation.

Results

Seventy-one multinational centres, the members of the EHRA research network, responded to this survey published on the EHRA website in spring 2012.

Devices

The median number of devices implanted in 2011 at the centres surveyed was 445 (range 50–1500), with pacemakers, ICD, and CRT being 263 (42–1000), 100 (0–600), and 70 (0–300), respectively. Of the overall number, a median of 25% (0–70) were on a vitamin K antagonist (VKA), with only a minority (mean 1.6%) on a new oral anticoagulant (OAC) in 2011. A median of 42% (8–90) were on antiplatelet therapy, whereas 30% (2–80) were on no antithrombotic drugs.

In managing a patient on OAC (mostly VKA), common practice was to stop and bridge with heparin in ~40–45% of patients with ICD/PPM/CRT but 59% of those with prosthetic valves. Oral anticoagulant was stopped for a median of 3 days (range 2–7) and OAC usually restarted on the following day after the procedure of patients with ICD/PPM (60%) or CRT (50%) but 49% of those with prosthetic valves would have their OAC started the same day. If VKA is used, most centres surveyed would use a loading dose, and protamine was not used in any centre surveyed to reverse heparin.

Many centres would perform the procedure while the patient is still on OAC, PPM/ICD (60%), CRT (50%), or prosthetic valves (57%). If on VKA, the median INR accepted would be 2.5 (range 1.4–4.0) for PPM/ICD, 2.2 (1.4–4.0) for CRT, and 2.5 (1.4–5.0) for prosthetic valves. If the patient had coronary artery disease and a stent (<12 months), most (86–89%) centres would not stop their antiplatelet drug.

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Table 1 How long do you continue OAC post-ablation after an apparently successful procedure?

	Total responses to question	<3 months	3–6 months	6–12 months	Longer than 12 months
CHA ₂ DS ₂ -VASc score					
0–1	51	34 (67%)	11 (22%)	3 (6%)	3 (6%)
≥2	68	0	4 (6%)	7 (10%)	57 (84%)
CHADS ₂ score					
0	49	38 (78%)	10 (20%)	1	
1	50	26 (52%)	8 (16%)	6 (12%)	10 (20%)
≥2	52	0	4 (8%)	3 (6%)	45 (9%)

Figures denote numbers (%). Percentages are rounded to nearest whole figure.
OAC, oral anticoagulation therapy

If the patient was on antiplatelet therapy, 78.1% of centres (57 of 73) 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.

In patients with AF, 95.8% (70/73) would routinely estimate stroke risk (eg. CHADS₂, CHA₂DS₂-VASc) but the score would influence their antithrombotic regime in 93.1% (68 of 73). In contrast, only 60.3% (44 of 73) would routinely estimate bleeding risk (eg. HAS-BLED score) and this would influence the antithrombotic regime in 54.8% (40 of 73).

For pacemakers, direct cephalic cannulation would be performed in 67.1% (49 of 73) while 32.9% would perform subclavian puncture. The median rate of haematoma was 5% (range 0–20) for patients on OAC, and 5% (0–15) on antiplatelet therapy. In patients on OAC, 10.7% (5 of 56) would routinely use wound drainage but only 3.6% (2 of 56) routinely used wound drainage in patients not on OAC. The centres reported a median of 0 (range 0–10) coronary sinus perforations in the last year following a CRT procedure.

Ablation: general considerations

Of the centres surveyed, a median of 330 (0–2000) ablations were performed, and of the overall population, 40% were on OAC, 20% on antiplatelet drug, and 40% were on no antithrombotic therapy. Current practice surveyed would be to stop and bridge with heparin in 56.7% (34 of 60) of those non-valve patients, and 57.6% (34 of 59) of prosthetic valve patients. In those patients where heparin is used for bridging, this would be stopped at a median of 12 h (2–48). If OAC was used, practice would be to stop OAC the same day in 42.1% (16 of 38) of non-valve patients and on next day in 57.9% (22 of 38). Corresponding figures for prosthetic valve patients was 65.0% (26 of 40) and 35.0%, respectively. If VKA was used, a loading dose was not used in 65.8% of respondents (27 of 41) in non-valve patients and 56.4% (22 of 39) in prosthetic valve patients. If heparin bridging was used, most (>90%) would not use protamine to reverse the heparin bridge. The centres surveyed would perform the procedure while still on OAC in 53.6% (30 of 56) non-valve patients, and 57.6% of prosthetic valve patients (34 of 59). 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% (60 of 63) would not stop.

In approaching an AF patient for ablation, 96.8% (61 of 63) would estimate stroke risk using a risk score (eg CHADS₂, CHA₂-DS₂-VASc), which would influence their decision on antithrombotic drug regime in 95.1% (58 of 61). Bleeding risk assessment was routinely done in 57.1% (36 of 63) of centres and this would influence the antithrombotic drug regime in 54.1% (33 of 61) of centres.

Following an ablation procedure, the centres reported that an approximate rate of haematoma overall in patients on OAC was a median of 3% (0–40), and was 2% (0–20) in patients on antiplatelet therapy.

Ablation of atrial fibrillation

During ablation of atrial fibrillation, the median ACT used by centres was 350 (range 150–420). Transoesophageal echocardiography (TEE) was performed routinely in 82.5% (47 of 57) of centres, and this was mostly done the day before (63.2%; 36 of 57) or on the same day (35.1%; 20 of 57). Following the AF ablation, OAC was restarted the same day in 65.6% (40 of 61) or the day after in 34.4% (21 of 61). As seen in *Table 1*, the duration of continuation of OAC post-ablation did vary by stroke risk, whether by CHA₂DS₂-VASc or CHADS₂ score, although some centres did discontinue OAC even in patients at high risk.

Only 31.1% of centres would do an ablation while the patient happened to be taking one of the new OACs (eg. Dabigatran); however, as mentioned earlier, current uptake was low given the relatively recent approval of dabigatran and rivaroxaban in late 2011. The approximate rate of clinical stroke/thromboembolism reported by centres surveyed was a median of 1% (range 0–5).

Discussion

In this EP Wire survey, we have shown wide variation in clinical practice in relation to management of antithrombotic therapy in patients undergoing device implantation and ablation of AF.

In 2008, the Scientific Initiatives Committee of EHRA published a consensus document on antithrombotic therapy in the setting of electrophysiological procedures.¹ In this document, the consensus recommendations for catheter ablation of AF advised warfarin for at least 4 weeks prior to the ablation procedure, then to stop warfarin 4–5 days before the ablation procedure. Bridging therapy

with heparin (either low-molecular-weight heparin or unfractionated heparin) was until the day before the ablation procedure. This document did not cover periprocedural management of devices. More contemporary management was reflected in the recent 2012 joint HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation.⁵

We found that common practice when approaching an anticoagulated patient was to stop OAC and bridge with heparin. Nevertheless, many centres would perform the procedure while the patient is still on OAC. The 2012 HRS/EHRA/ECAS Expert Consensus Statement⁵ recognized that bridging resulted in a high incidence of bleeding complications, especially at the site of vascular access.^{6–8} Thus, our EP Wire survey highlights the increasing trend towards performing AF ablation procedures in patients who are continuously therapeutically anticoagulated with warfarin.^{9–11} Interestingly, protamine was infrequently used to reverse heparin in our survey, but clearly can be considered in cases of persistent periprocedural bleeding or cardiac tamponade.

If the patient had coronary artery disease and a stent (<12 months), most centres would not stop their antiplatelet drug. The management of such anticoagulated patients remains complex, and with concomitant AF, there is a need to balance the prevention of thromboembolism against the reduction of recurrent cardiac ischaemia and/or stent thrombosis, and the risk of serious bleeding.^{12–14}

In patients with AF, most respondents would routinely estimate stroke risk and the score would influence their antithrombotic regime in 93.1% (68 of 73). A smaller proportion (~60%) would routinely estimate bleeding risk (e.g. HAS-BLED score) and this would influence the antithrombotic regime in only 55%. Indeed, a high HAS-BLED score is not a means to stop OAC *per se*, but to advise caution and/or regular review and to use the opportunity to correct reversible risk factors for bleeding where possible.¹⁵

During ablation of atrial fibrillation, TEE was performed routinely by most centres. One interesting practice observation from this survey is the variable the duration of continuation of OAC post-ablation, which did vary by stroke risk, whether by CHA₂DS₂-VASc or CHADS₂ score. Surprisingly, some centres did discontinue OAC even in patients at high risk. The 2010 ESC guidelines³ did recommend long-term anticoagulation in patients with a CHA₂-DS₂-VASc score of ≥ 2 . Similarly, the 2012 joint HRS/EHRA/ECAS Expert Consensus Statement⁵ advised that 'discontinuation of warfarin or equivalent therapies post-ablation is not recommended in patients who have a high stroke risk as determined by the CHADS₂ or CHA₂DS₂-VASc score'.

A recent analysis by Chao *et al.*¹⁶ found that the CHA₂DS₂-VASc score could be used to further stratify the patients with CHADS₂ scores of 0–1 into two groups with different event rates (7.1 vs. 1.1%, $P = 0.003$) at a cutoff value of 2, thus allowing the identification of a patient category who were 'truly low risk' post-ablation where OAC can be safely stopped. The approximate rate of clinical stroke/thromboembolism reported by centres surveyed was low, at a median of 1% (range 0–5). This is consistent with a recent large nationwide cohort study showing that patients with a CHADS₂ score of 0 were not all 'low risk', with 1 year stroke/thromboembolism event rates ranging from 0.84 (CHA₂-DS₂-VASc score = 0) rising to 1.75 (CHA₂DS₂-VASc score = 1),

2.69 (CHA₂DS₂-VASc score = 2), and 3.2 (CHA₂DS₂-VASc score = 3).¹⁷ Thus, anticoagulation decisions simply based on a CHADS₂ score of 0 may be insufficient to avoid stroke/thromboembolism in patients with AF.

The availability of the new OACs (e.g. dabigatran, rivaroxaban) offers new challenges for devices and ablation.¹⁸ Two papers have addressed the subject of ablation while managed with dabigatran. The small series by Winkle *et al.*¹⁹ suggested that a protocol-based management with dabigatran led to safety and efficacy in relation to preventing thromboembolism and a low risk of bleeding. However, another multicentre series reported an increased risk of thromboembolism and bleeding with dabigatran use.²⁰ Only 31.1% of the centres surveyed would do an ablation while the patient happened to be taking one of the new OACs (e.g. dabigatran) pending more experience with these drugs following their recent availability in Europe.

Conclusions

This EP wire survey shows variation in clinical practice, but reassuringly some consistency with guidelines and consensus recommendations on the management of periprocedure (devices, ablation) antithrombotic therapy.

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