Proportion of Patients with Implanted Permanent Pacemakers with Atrial Fibrillation Receiving Appropriate Medical Prophylaxis in North Wales

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Background: Atrial fibrillation (AF) is associated with an increased long-term risk of stroke, heart failure, and mortality. Previous studies have demonstrated the suboptimal use of anticoagulation therapy in patients with AF.

Methods: A retrospective survey of patients (N = 1,113) fitted with dual-chamber pacemakers found 71 patients (age 69 ± 35, mean ± standard deviation) with atrial tachycardia and AF (defined as >5 minutes per day). Their medical records and anticoagulation status were investigated and used to stratify each patient for stroke risk with the Birmingham 2009 schema (CHA2DS2-VASc) and assessed to determine the rate of appropriate thromboembolism (TE) prophylaxis prescription.

Results: The most common overall concomitant risk factor for stroke was hypertension (54%), followed by age ≥75 (51%), being female and previous stroke/transient ischemic attack/TE (39%). The average CHA2DS2-VASc score was 3.7 ± 1.6. Fifty-six percent of the patients were not receiving appropriate anticoagulation therapy.

Conclusion: This study demonstrates an underutilization of the oral anticoagulant warfarin in patients with known AF and that the clinicians may not be regarding current stroke risk factors when adopting a thromboprophylaxis strategy. (PACE 2012;00:1–8)

atrial fibrillation, stroke, pacemakers, guidelines, treatment

Introduction

The prevention, treatment, and prophylaxis of associated side effects of atrial fibrillation (AF) remain an elusive goal and AF is the most common cardiac arrhythmia, occurring in 1–2% of the general population.1 AF is associated with an increased long-term risk of stroke, heart failure (HF), and mortality, especially in women.2 The mortality rate of patients with AF is about double that of patients in normal sinus rhythm and it is also linked to the severity of underlying heart disease.3,4

The evidence shows that approximately 20% of all ischemic strokes are AF-related and it has been shown that the risk of AF-related stroke can be lowered with adequate antithrombotic therapy.5,6 Stroke prevention with aspirin in AF patients with a low thromboembolism (TE) risk is thought to be satisfactory and wholly justified whereas the stroke prevention treatment for patients with AF who are considered high-risk is the vitamin K antagonists (e.g. Warfarin), referred to as oral anticoagulants (OACs).7

Thromboprophylaxis with OAC has been shown to substantially reduce the incidence of stroke and mortality compared to aspirin, aspirin and clopidogrel, and placebo.6,8 Hart et al.6 showed that warfarin, when used for stroke prevention, reduces the relative risk of ischemic stroke by 67% and death by approximately 25%, whereas antiplatelet therapy was shown to reduce stroke risk by 22%. Similarly, Lip and Lim9 demonstrated that OACs reduce the risk of stroke by two-thirds and that antiplatelet therapy decreased stroke risk only by 22%, but it has also been shown that antiplatelet therapy is associated with higher bleeding rates.10

Long-term OAC therefore seems appropriate for most patients with AF who have risk factors for TE, regardless of treatment strategy and whether AF is documented at any given time,9 but despite this overwhelming evidence, warfarin still remains underutilized.5,11

Ambulatory electrocardiograph recordings and device-based monitoring have revealed that an individual may experience periods of both symptomatic and asymptomatic AF.12 The earlier detection of AF and atrial tachycardias (ATs) may allow for the timely introduction of therapies to protect the patient, not only from the consequences of the arrhythmia, but also from progression of AF from an easily treated condition.

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It has been shown that the likelihood of finding AT/AF increased with longer durations of monitoring, and the daily amount of AT/AF has been related to the risk of TE in patients receiving cardiac rhythm devices.

The aim of the study was to evaluate the proportion of appropriate TE prophylaxis prescription in pacemaker patients with significant AF diagnosed by pacemaker electrogram (EGM).

**Methods**

**Patients**

All pacemaker patients (n = 1,784) who were under routine follow-up care in the Anglesey and Gwynedd region, North Wales, from 2010 to 2011 were retrospectively surveyed. The study protocol was approved by the Audit Central Office, Ysbyty Gwynedd Audit Offices, Bangor. Patients not implanted with dual-chamber pacemakers were excluded (Fig. 1). The medical records of the remaining patients (n = 1,113) were examined.

Patients were eligible for further inclusion if the patient had a dual-chamber pacemaker implanted with atrial diagnostic capabilities and if the atrial high-rate episodes (AHREs) diagnostic feature was turned on and was capable of continuously monitoring AF burden for 12 months, or at least for the duration between follow-up visits. Patients were not required to have a history of AF, and were not required to have symptoms commonly associated with AF and paroxysmal AF.

Patients were excluded if they had a single-chamber pacemaker, biventricular pacemaker, implantable cardioverter defibrillator, or had a dual-chamber pacemaker with limited atrial diagnostic features or that the stored intracardiac EGMs were not available for each episode because of device memory limitations. If intracardiac EGMs were not available for the episodes or for at least 1 day because of technology or device memory constraints, the patient was excluded from the study. Patients were also excluded if they documented long-standing persistent AF, and had their pacemaker function changed to a single-chamber function (i.e. VVI mode).

Patients with AF > 5 minutes/24 hours on any day (n = 71) were further studied at 1-, 3-, 6-, or 12-month intervals. AF burden was defined as the total cumulative duration of AF detected by the device in a given day. The atrial arrhythmia detection rate was 174 ± 15 beats/min, in accordance with current usage. AF burden may consist of multiple episodes on a single day or a portion of a single episode that spans consecutive days. The presence of at least 5 minutes of AF burden occurring on 1 day of the year was deemed significant. Additionally, only AHREs lasting at least 5 minutes were analyzed, based on previously published data that the 5-minute cutoff excludes most episodes of oversensing.

Patients who had received a dual-chamber cardiac pacemaker because of bradycardia indications according to the above guidelines and who had >5 minutes AF burden on 1 day throughout a 12-month follow-up were included.

The medical notes were examined for age and gender, to assess TE risk using the CHA2DS2-VASc scoring system along with current medication.

**Pacemaker Devices**

The patients included in the study had dual-chamber pacemakers (DDD) implanted with advanced algorithms designed for rhythm discrimination. The manufacturer of the pacemaker was not considered to be a determinant of inclusion or exclusion. The pacemaker devices that were included consisted of primarily Medtronic (Minneapolis, MN, USA), St. Jude Medical (St. Paul, MN, USA), and Guidant (Sylmar, CA, USA). The pacing modes that were utilized at the discretion of the physician or cardiac physiologist were DDDR, DDD, DDIR, and DDI.

**Current Recommendations for Antithrombotic Therapy**

The current European Society of Cardiology (ESC) guidelines state that the use of antithrombotic therapy should be based on the presence (or absence) of risk factors for stroke and TE, rather than the previous division into high-, moderate-, or low-risk categories. The CHA2DS2-VASc stroke risk stratification scheme was used to assess stroke risk.

**Statistical Analysis**

Statistical analysis was performed with SPSS statistical software (release 12.01, SPSS Inc., Chicago, IL, USA). For categorical variables,
comparisons were performed by means of \( \chi^2 \) or Fisher exact test, as appropriate; \( \chi^2 \) statistics were used to compare the groups gender, and to assess differences in medications. For continuous variables, a two-imailed (assuming unequal variances) Student’s \( t \)-test was performed. A probability (P) value < 0.05 was considered significant. All P-values reported are two-tailed. Continuous variables are reported as mean and standard deviation (SD).

**Results**

In all, 1,784 patients were included in the study and retrospectively checked; 671 patients (37.6%) were excluded because they had no dual-chamber pacemaker, leaving 1,113 patients for analysis (62.3%) (Fig. 1). Of these, 167 (15%) were excluded because they had an unsuitable pacemaker (126, 11.3%) or programming was insufficient for AF detection (41, 3.7%). From the remaining 946 patients, 71 patients (7.5%) had documented AF episodes with a burden of at least 1 day with AF burden for > 5 minutes during 24 hours. The remaining 875 patients (92.5%) had no AF or an AF burden of < 5 minutes during 24 hours. The age of the patients was 69 ± 35 years (mean ± SD, range 44–93) with 33 female patients. No statistical difference was found between the mean age of the patients with a CHA\(_2\)DS\(_2\)-VASc score ≥ 2 that were receiving warfarin or not (P = 0.665).

The most common overall concomitant risk factor for stroke was hypertension (54%), followed by age ≥75 (51%), female gender (46%), and previous stroke/transient ischemic attack (TIA)/TE (39%) (Tables I and II). The incidence of major risk factors in the study population, for congestive HF, hypertension, age (≥75), diabetes mellitus (DM), TIA/stroke, vascular disease, age (65–74 years), and gender were 8%, 54%, 51%, 7%, 39%, 34%, 37%, and 46%, respectively.

**Comparisons to ESC 2010 Guidelines**

Patients (n = 71) with AF were identified and, excluding patients (n = 3) with contraindications to antithrombotic therapy, 73% were receiving warfarin, aspirin, or clopidogrel. The mean CHA\(_2\)DS\(_2\)-VASc score was 3.7 ± 1.6 (Fig. 2).

In the patients with CHA\(_2\)DS\(_2\)-VASc score 0–1, 50% received aspirin antithrombotic therapy, all patients with a CHA\(_2\)DS\(_2\)-VASc score of 0, and 1 with a CHA\(_2\)DS\(_2\)-VASc score of 1 (Fig. 2). A total of 58 (82%) of the 71 patients had two or more risk factors for stroke (CHA\(_2\)DS\(_2\)-VASc score ≥ 2). Of the total patients with a CHA\(_2\)DS\(_2\)-VASc score ≥2, 15% were prescribed warfarin (Fig. 3). The remaining 85% (83% excluding contraindications to warfarin) of these patients were taking aspirin (67%), clopidogrel (2%), aspirin and clopidogrel (2%), or had no prescribed anticoagulation (29%). These data show that five-sixths (5/6 or 83%) of the total 71 patients were not receiving appropriate anticoagulation, according to the ESC guidelines.\(^{11}\) In the patient group with a CHA\(_2\)DS\(_2\)-VASc score ≥2, there was a statistical difference between those taking warfarin and those that were not (P = 0.011).

Warfarin was prescribed in 10 of 56 patients (18%) with a CHA\(_2\)DS\(_2\)-VASc ≥3. Among the
high-risk patients, the proportion who received warfarin varied with the CHA$_2$DS$_2$-VASc score, 5/16 (31%) in those with a score of 4, 3/10 patients (30%) with a score of 5, and 2/8 (25%) with a score of 6. No patients received warfarin with a CHA$_2$DS$_2$-VASc score of 3 or 7.

In total, 25 patients (35%) with a CHA$_2$DS$_2$-VASc score $\geq$2 had a documented history of AF prior to the study and seven (11%) patients were taking warfarin (Fig. 3). Of the remaining patients with CHA$_2$DS$_2$-VASc score $\geq$2 and documented evidence of AF, 14 were taking aspirin, clopidogrel, or both as an alternative, and one was receiving no anticoagulation medication (Fig. 3). Thus, 56% of the patients with documented evidence of AF were not receiving an anticoagulation therapy according to the ESC 2010 guidelines.$^{11}$ (Fig. 3).

Univariate analysis showed that vascular disease (21% vs 8%, $P < 0.05$) is an independent predictor of warfarin use (Table III). The other CHA$_2$DS$_2$-VASc risk factors did not predict warfarin use, although there was a trend toward use of warfarin in patients with a CHA$_2$DS$_2$-VASc score of $\geq$3 who had risk factors, including previous stroke (18% vs 13%, $P > 0.05$) or hypertension (18% vs 15%, $P > 0.05$), left ventricle (LV) dysfunction/HF (8% vs 5%, $P > 0.05$), and were more likely to be on warfarin than patients with age $>75$, or diabetes or age 65–74 years. Advancing age appears to be an independent predictor of warfarin underutilization; the rates of oral anticoagulation prescription dropped off substantially in the elderly (22% vs 10%, $P = 0.0166$). Warfarin therapy did not alter the mean overall CHA$_2$DS$_2$-VASc score, which was 4.7 $\pm$ 0.82 on warfarin and 3.9 $\pm$ 1.5 ($P = 0.383$) not on warfarin (Table II).

Table III. Independent Predictors of Warfarin Use in All Patients

<table>
<thead>
<tr>
<th>CHA$_2$DS$_2$-VASC Category</th>
<th>Not Appropriate N = 39</th>
<th>Appropriate N = 163</th>
<th>P-Value</th>
</tr>
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<tbody>
<tr>
<td>HF/LV Dys</td>
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<td>8</td>
<td>0.0667</td>
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<tr>
<td>Hypertension</td>
<td>18</td>
<td>18</td>
<td>0.0010</td>
</tr>
<tr>
<td>Age $&gt;75$ years</td>
<td>22</td>
<td>10</td>
<td>0.0166</td>
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<tr>
<td>DM</td>
<td>2</td>
<td>3</td>
<td>0.1780</td>
</tr>
<tr>
<td>TIA/Stroke</td>
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<td>18</td>
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<tr>
<td>VASC</td>
<td>10</td>
<td>21</td>
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<tr>
<td>Age 65–74 years</td>
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<tr>
<td>Sex</td>
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<td>10</td>
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</table>

Bold numbers are values that represent a statistical significance ($P < 0.05$).
Discussion

This study confirms that AF was detected in 6% (with 4% previously undiagnosed AF) patients with implanted dual-chamber pacemakers capable of recording atrial diagnostics. This number is substantially lower than that of other studies with similar detection and monitoring periods. This study is one of few to link CHADS$_2$-VASc score with the AF presence/duration, providing more accurate risk stratification.\(^{20}\)

The CHA$_2$DS$_2$-VASc score was $3.7 \pm 1.6$, with six patients (8.5%) having a CHA$_2$DS$_2$-VASc score less than 2. The inclusion criteria for this study did not necessitate that risk factors for stroke had to be present for eligibility. Nonetheless, the majority of patients (82%) enrolled in this study had a CHA$_2$DS$_2$-VASc score $\geq 2$, which is consistent with the ASSERT study.\(^{21}\) Patients in this study thus have a heightened risk for developing AF and subsequent increased risk of stroke. The present stroke prevention guidelines stress that the detection of AF in patients at high risk for stroke will strongly influence anticoagulation decisions.\(^{11}\)

It has been well established that the risk factors associated with stroke also predispose the patient to an increased risk of developing AF. It has been shown that the absence of predisposing cardiac diseases is only seen in a small percentage of patients with AF (12.4% of all patients,\(^{22}\) and 10.2%\(^{5}\)). The present data show that the most common concomitant medical condition was hypertension, followed by age $\geq 75$, being female, and previous stroke/TIA/TE. Numerous previous studies have demonstrated the relationship between concomitant medical conditions that are associated with increased stroke risk and the potential additive effect they can have on the perpetuation of AF.\(^{5,22–24}\)

There is an expanse of research when considering stroke prophylaxis in a patient diagnosed with AF from a surface electrocardiogram (ECG). There is, however, uncertainty concerning the definition of an appropriate duration of device-detected AF that constitutes a risk of stroke comparable to AF identified by surface ECGs in clinical practice. In order to summarize research findings and facilitate their translation into daily practice, the guidelines for stroke prevention in patients with AF diagnosed by surface ECG have been used in this study. The present study data show that there were 25 patients with a documented history of AF, with seven patients (28%) receiving anticoagulation ($P = 0.025$). This percentage is comparable with results from other studies.\(^{25,26}\) Capucci et al.\(^{27}\) carried out a multicenter study on a large cohort of patients with implanted pacemakers capable of atrial diagnostics, paced for bradycardia, suffering from AF. Their results showed that only about 36% of the patients were anticoagulated with OACs (warfarin and acenocumarol) in line with recommended clinical practice guidelines. Additionally, patients with documented AF in the MOST study\(^{18}\) and in the CTOPP study\(^{28}\) who were prescribed anticoagulant therapy were 24% and 34%, respectively. More recently, Lim and Lip\(^{29}\) demonstrated that of a total of 39,541 identified patients with AF, 70.3% were at high risk for TE events and 18.3% were at highest risk; however, their results showed that only 24.7% of the overall population cohort received appropriate antithrombotic therapy.

The current study population’s incidence of major risk factors, including hypertension, vascular disease congestive HF, and diabetes mellitus, was 54%, 34%, 8%, and 7%, respectively, compared with Albers et al. with 55%, 30%, 39%, and 22%, respectively; Go et al. with 51%, 29%, 31%, and 17%; and Waldo et al. with 67%, 42%, 34%, and 22%. This comparison demonstrates that the proportional incidence of congestive heart failure and DM within this study cohort is significantly less than that of previous studies. Interestingly, the incidence of hypertension ranged from 32% to 58% in the ASSERT Trial,\(^{31}\) the Boston-area anticoagulation trial for AF,\(^{8}\) the CAFA study,\(^{32}\) the stroke prevention in nonrheumatic AF study,\(^{33}\) and the stroke prevention in AF III trials,\(^{34}\) which is consistent with this study, with 54% incidence.

The dissemination of the data from this study shows that of all well-known stroke risk factors, vascular disease was most strongly associated with OAC prescription (Table I). The impact of vascular disease, particularly myocardial infarction, on increasing TE risk in AF has been systematically reviewed.\(^{9}\) These data may reflect an adoption of parts of the CHA$_2$DS$_2$-VASc scoring system because vascular disease, along with gender, age 65–74, and hypertension were more recently incorporated into the decision to prescribe warfarin in patients with AF.\(^{11}\)

The underutilization of effective TE prophylaxis was most apparent in the most elderly population; advancing age was shown to be a potential barrier to appropriate anticoagulation therapy. Age $\geq 75$ years is widely considered a high-risk factor for stroke in AF patients. Singer et al.\(^{35}\) showed using the ATRIA cohort that the benefit of a reduction in absolute stroke risk with warfarin was greater in very elderly patients (age $\geq 85$ years). More recently, this trend has been confirmed by an updated meta-analysis of 11 randomized controlled trials, including
BAFTA, which also demonstrated that OAC significantly reduced the risk of ischemic stroke in the elderly compared with aspirin and placebo (OAC-adjusted hazard ratio per decade increase: 0.36; 95% confidence interval [CI]: 0.29–0.45; antiplatelets: 0.81; 95% CI: 0.72–0.90). Pugh and Mead found that physicians were reluctant to anticoagulate elderly patients, especially those over 80 years old, even if otherwise healthy and without contraindications to warfarin.

It is important to remember that ischemic strokes that can be prevented by anticoagulant therapy outnumber intracerebral hemorrhages in most AF patients. The results of the RE-LY study demonstrate that the hemorrhage risk for patients ≥75 years old is 0.47% per year. Additionally, Mant et al. demonstrated that the yearly risk of extracranial hemorrhage was 1.4% (warfarin) versus 1.6% (aspirin) (relative risk 0.87, 0.43–1.73; absolute risk reduction 0.2%, −0.7 to 1.2).

This study suggests that the clinicians may not be regarding current risk factors for stroke when deciding upon a thromboprophylaxis strategy, with the study showing that of a total of 71 patients, three patients (4%) had documented evidence of a contraindication to warfarin. The contraindications were listed as “reduced cardiovascular risk for stroke,” “patient refusal,” and “stopped due to possible hemorrhage.” The results showed that aspirin was used as an alternative in two of the three cases, although it is not recommended in the ESC guidelines. Additionally, it was shown that the patient with a possible prior major bleed was not receiving an antiplatelet drug alternative.

On the basis of the stroke risk factors, the ESC guidelines provide recommendations for antithrombotic treatment, and state that AF subtype should not influence the management decision; the anticoagulation decision should be based specifically on the presence or absence of these stroke risk factors. However, evidence on paroxysmal AF being a stroke risk factor when compared with chronic AF is not consistent. The threshold burden of paroxysmal atrial fibrillation or pacemaker-detected AHRE required to justify chronic anticoagulation therapy has not been clearly defined but clinical practice guidelines currently recommend prophylactic therapy based on the understanding that PAF and persistent AF carry similar risks of TE.

Study Limitations

This retrospective survey of 1,113 patients was confined to one district general hospital which did not allow the control for any bias or discrepancies in patient treatment. A refined approach would require a much larger sample size and a longer observational period.

Data were combined from several sources such as medical records, pacemaker notes, and from correspondence with the individual patients’ general practitioner. These data were sometimes incomplete, illegible, or contradictory. Some patients included in our analysis may have had AF that was known but not documented prior to study enrollment.

An initial investigation by Nieuwlaat et al. indicated that 45% of patients in their AF cohort were not prescribed warfarin, but after a more detailed review of medical records for reasons why warfarin was not used found that the underutilization rate fell to only 7%. This study shows overestimation of warfarin underutilization when using administrative databases. Although administrative databases were not used to collect data the possibility exists that there may be more patients than reported who have contraindications to warfarin.

A careful and reliable assessment of AF burden and episode duration would considerably benefit any stroke prevention strategy, provided that risk stratification and verification of the arrhythmia can be validated. A potential limitation of this study would be the subjective interpretation of the pacemaker arrhythmia log and the unchallenged personal decision of the attending cardiac physiologist for arrhythmia classification. This limitation was anticipated and was addressed by implementing an alternate analysis using another cardiac physiologist’s judgment. In the event that the two classifications were opposed, for this study, the event in question would have been discounted, which could potentially result in an exclusion from the study. The situation in question did not arise for this study, but the method could potentially lead to an underestimation of the distribution of AF in the population.

Another limitation is that the absence of EGMs for all episodes precluded the precise diagnosis of the atrial arrhythmias in all enrolled subjects, which may also underestimate the incidence of AF in the study population.

Antithrombotic therapy was decided by the physicians on a patient-by-patient basis without a predefined strategy; this may have affected the event rate. Additionally, the patients’ physician was not asked what the exact reason was for not prescribing antithrombotic treatment, but we report associations of characteristics with this prescription.

However, about half of the patients received antithrombotic therapy (warfarin, aspirin, or both), which reflects standard clinical practice.
Many large-scale and long-term surveys have shown a similar picture in the general AF population. Specifically, it has been reported that underprescription of warfarin is especially linked to intermittent AF. A further limitation may be the duration of the AF events that were considered significant, which for this study was >5 minutes in a single episode. This criterion was utilized due to the findings and recommendations by previous studies. By defining AF as a minimum of 5 minutes of device-detected AT/AF in an episode, it is possible that the true incidence of AF may have been underreported. Implantable devices typically require atrial arrhythmias to persist for >30 seconds for detection to occur. However, such short durations of AT/AF are more likely to include false-positive detections.

Botto et al. suggest that if the proportion of time is less than 5 minutes per day it probably does not matter if the CHA₂DS₂-VASc score is between 0 and 2, whereas when the CHA₂DS₂-VASc score is ≥3 the patients have sufficient risk even with little or no AF to justify anticoagulation. Only a large multicenter study will have sufficient power to address a dose response/threshold relation between PAF and stroke.

**Future Perspectives**

Upcoming trials such as ASSERT will provide further insight into the direct relation of AF duration and systemic embolisms in a large group of patients with an implantable device. If these studies confirm the findings of Glotzer et al. and that an AF duration of greater than 5 minutes increases risk for systemic embolism, the wider challenge would be to measure AF duration in a noninvasive manner and to confirm this relation in a wider spectrum of AF patients. The challenge in pacemaker patients, a subgroup that has continuous ECG monitoring, is to recognize the threshold for AF and to ensure that proactive interventions are implemented in order to increase appropriate OAC use.

It is important that the medical profession play a significant role in critically evaluating the use of diagnostic procedures and therapies as they are introduced and tested in the detection, management, or prevention of disease states.

**Conclusion**

This analysis was aimed at providing inputs for clinical decisions on antithrombotic therapy. This study demonstrates that the present stroke prevention guidelines, in terms of thromboprophylaxis, are generally not being adhered to at the local district general hospital.

In a cohort of pacemaker patients, 6% (4% previously undiagnosed) of patients were identified as having significant AF via a device with continuous monitoring capabilities. The proposed TE risk was relatively high in this group of pacemaker patients with a high mean CHA₂DS₂-VASc score of 3.7 ± 1.6. Additionally, the quantitative AT/AF burden detected by implanted devices may be a TE risk factor that is independent of standard clinical stroke risk factors.

Pacemakers provide important information on cardiac rhythm and represent a useful means of detecting subclinical AF. Identification of asymptomatic PAF/AHRE in older patients with associated cardiovascular risk factors may identify individuals with heightened risk of stroke, with corresponding implications for antithrombotic therapy. The rate of appropriate anticoagulation prescription may be improved through specific treatment recommendations to treating physicians in accordance with established guidelines.

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