Impact of atrial prevention pacing on atrial fibrillation burden: Primary results of the Study of Atrial Fibrillation Reduction (SAFARI) trial

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BACKGROUND The role of atrial-based pacing algorithms in preventing atrial fibrillation (AF) remains controversial. The inconsistent results noted in previous trials may be due in part to differences in endpoints, pacing algorithms, and study design. SAFARI, a worldwide, prospective, randomized clinical trial, was designed to address these issues and to evaluate the safety and efficacy of a suite of prevention pacing therapies (PPTs) among patients with paroxysmal AF.

METHODS AND RESULTS Patients who met standard pacemaker indications and documented symptomatic AF were implanted with a pacemaker (Vitatron Selection 9000). At 4 months, only patients with documented AF despite dual-chamber pacing were randomized to PPTs ON or PPTs OFF and followed for 6 months. Incidence of permanent AF and change in AF burden were compared between the two groups. Among the 555 patients enrolled, 240 had AF burden at 4 months and were randomized. The risk of developing permanent AF was similar in both groups (0 in the PPTs ON group vs. 3 in the OFF group). However, there was a significant reduction in AF burden between baseline and 10-month follow-up in the ON group compared with the OFF group (median decrease of 0.08 hours/day vs no change, P = .03).

CONCLUSION: Among patients with paroxysmal AF and standard bradycardia indications, PPTs are safe and associated with less AF burden compared with conventional pacing.

KEYWORDS: Arrhythmia; Pacing; Prevention; Atrial fibrillation

Atrial-based pacing, in either single- or dual-chamber mode, reduced the incidence of atrial fibrillation (AF) in several prospective multicenter studies.1–6 More recently, a variety of preventive atrial pacing strategies, including continuous overdrive pacing, pacing in response to atrial premature beats, postmode switch and postexercise pacing therapies, were developed to reduce the burden of AF among patients with known atrial tachyarrhythmias.7–12 However, the magnitude of AF prevention due to dedicated preventive pacing algorithms and the identification of responder candidates remains unclear.13–15

The Study of Atrial Fibrillation Reduction (SAFARI) was designed to determine the impact of preventive pacing algorithms on AF among patients with paroxysmal AF. In the largest preventive pacing trial to date, a unique combination of six triggered and continuous overdrive prevention pacing therapies (PPTs) was applied to target multiple triggers of AF. The primary study objectives was to determine whether PPTs were safe and effective in reducing AF burden, without increasing the incidence of permanent AF.
Methods
SAFARI was an international, multicenter, prospective, randomized controlled parallel-group clinical trial. Patients were enrolled at 74 medical centers in North America (n = 40) and Europe (n = 34). The study protocol was reviewed and approved by the local human subjects committee of each participating center, and all patients provided written informed consent.

Study population and data collection
The design of this study was reported previously. Patients with class I or II bradycardia indications for pacing and documented symptomatic paroxysmal AF, with at least two symptomatic AF episodes within 3 months and one episode documented by rhythm strip within 12 months prior to enrollment, were included in the study. Patients with persistent or permanent AF or patients who were cardioverted within 6 months prior to enrollment were excluded. Further details of the study design have been described previously.

The general and cardiovascular health history, cardiovascular medication use, and quality-of-life information were gathered at baseline for each patient. At implantation, protocol required programming was DDD mode with a lower rate of 60 bpm, PPTs off, and arrhythmia recording turned on. Patients were followed for a 4-month period to allow for lead maturation and optimization of AF detection. At 4 months, patients who (1) had AF burden greater than 0%, (2) showed no evidence of oversensing issues, such as far-field R waves or undersensing issues (e.g., 2:1 blanking), (3) had not developed permanent AF, and (4) had no atrial flutter/atrial tachycardia ablation procedure after enrollment were randomized to PPTs ON or PPTs OFF and followed for an additional 6 months. Patients with far-field R waves or 2:1 blanking were excluded because far-field R waves artificially increases AF burden whereas 2:1 undersensing artificially decreases burden. AF burden was calculated based on device-stored data over two time periods: from 1 to 4 months postimplant (baseline, i.e., prerandomization phase) and from 4 to 10 months postimplant (randomization phase).

Patients were randomized using center-specific randomization schedules implemented in sequence in individually sealed envelopes. Randomization was stratified into two groups by baseline AF burden: high burden group (≥6% burden from 1–4 months) and low burden group (<6% burden from 1–4 months). Patients were blinded to their randomization assignment until 10-month follow-up. Only randomized patients who had at least 90 consecutive days between 4 and 10 months with validated AF detection were included in the efficacy cohort. AF detection was validated by independent trained reviewers who assessed all pacemaker-recorded AF episodes throughout the study (15,586 detailed onset reports) to identify far-field R waves or 2:1 undersensing. AF burden data occurring during periods identified with sensing issues were eliminated, both for randomization purposes and for endpoint analysis. Patients with inappropriate AF detection were asked to return for pacemaker reprogramming to resolve this problem when possible. Reviewers were blinded to patient randomization status.

Data about pacemaker settings and diagnostics, including AF burden, AF frequency, percent atrial and ventricular pacing, detailed onset reports, and other clinical data, were collected at enrollment/implant, predischarge, and scheduled follow-up visits at 2 weeks, 1 month, 4 months, 7 months, and 10 months postimplant.

Device characteristics, PPTs, and AF detection
The device used for the study, the Selection model 9000 with AF 3.0 software (Vitatron, Arnhem, The Netherlands), is a bipolar, multiprogrammable, dual-chamber, dual-sensor (activity and QT interval), rate responsive pacemaker, with stored detailed onset reports providing information on arrhythmia episodes. The AF 3.0 software features a suite of six AF PPTs classified as continuous overdrive and triggered overdrive pacing therapies. The six PPTs have been described in detail elsewhere. Atrial arrhythmia data were obtained from the pacemaker data logs, which recorded the total time a patient was in AF. The accuracy of this pacemaker for measuring AF burden was validated in a previous trial, which found 100% specificity and sensitivity for AF burden detection and 100% specificity and 90% sensitivity for episode count analysis. Throughout the study, investigators were recommended to optimize AF detection and minimize ventricular pacing.

Endpoints
The primary efficacy endpoint was postrandomization AF burden, defined as the average number of hours per day spent in atrial tachyarrhythmia during the longest period of at least 90 days between the 4-month and 10-month visits during which there was sensing-issue free atrial detection. The primary safety endpoint (assessed by each patient’s physician) was permanent AF, defined as an AF episode that failed to convert spontaneously, for which all efforts at cardioversion failed, and no further plans were made to restore sinus rhythm.

Statistical analysis
Statistical analysis was performed using SAS statistical software (SAS Institute, Cary, NC, USA). Patients were analyzed as randomized. The efficacy sample size was at least 91 patients in each treatment arm with validated AF burden data at 10 months to detect a difference in AF burden of 25% between the ON (average of 3.0 hours/day) and OFF arms (4.0 hours/day in the OFF arm), with known group standard deviation of 2.5 hours/day, at a significance level (alpha) of 0.05 and at least 80% power. To meet sample size requirements for both the primary safety and efficacy endpoints, a minimum of 540 patients needed to be enrolled. Baseline characteristics, including age, gender, New York Heart Association class, health status, medication use, and baseline AF burden defined as cumulative device measured burden from the 1-month visit to the 4...
month-visit, are reported as mean ± SD for continuous variables and as frequency distribution or percentages for discrete variables. The Farrington-Manning noninferiority test was used to compare the incidence of permanent AF between the two groups. Because AF burden was not expected to follow a normal distribution, the Wilcoxon-Mann-Whitney nonparametric test was used to compare AF burden and change in burden between groups with a superiority design. Analysis of covariance using rank transformation was used to investigate further the effect of PPTs, and logistic regression was used to model the probability of improvement/nonworsening of AF burden. P-values for the non-inferiority tests are one-sided; for statistical modeling they are 2-sided.

Results

A total of 555 patients (259 men and 286 women, mean age 73.5 ± 9.1 years) were enrolled in the study and 545 were implanted. Of these, 240 were randomized to ON (n = 118) and OFF (n = 122) groups and composed the safety endpoint cohort; 284 patients were excluded because of 0% AF burden (209 patients), presence of AF detection issues (55 patients), and other reasons (20 patients). Figure 1 shows a flow chart of enrolled patients and attrition. Patients in the safety cohort had a mean follow-up time of 5.4 ± 1.3 months between the 4-month and 10-month visits. There were no apparent differences in key demographic and health characteristics of patients in the safety cohort ON and OFF groups at baseline (Table 1). Medication use at baseline, 4-month follow-up, and 10 month follow-up is summarized in Table 2. Overall, rates of use were similar in both groups for all medication classes at the time points measured.

Development of permanent AF

No (0%) patients in the ON group developed permanent AF compared with 3 (2.5%) patients in the OFF group. The observed difference was −2.5% (P < .001 for equivalence
within 10%), demonstrating that the risk of permanent AF in the ON group was no greater than that in the OFF group.

**Prevention of AF**

Of the 240 randomized patients, 193 patients were included in the efficacy cohort, 93 in the ON group and 100 in the OFF group. Forty-two patients were excluded because of missing data. There were no significant differences between the groups for the characteristics listed.

## Table 3

<table>
<thead>
<tr>
<th>Stratum Randomization</th>
<th>No. of patients</th>
<th>Mean change hours/day</th>
<th>25th percentile hours/day of AF</th>
<th>Median hours/day of AF</th>
<th>75th percentile hours/day of AF</th>
<th>P value (analysis of variance)</th>
<th>P value (Wilcoxon)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td><strong>ON</strong></td>
<td>51</td>
<td><strong>−2.09 ±4.90</strong></td>
<td><strong>−3.12</strong></td>
<td><strong>−1.38</strong></td>
<td>0.07</td>
<td>.0005</td>
</tr>
<tr>
<td></td>
<td><strong>OFF</strong></td>
<td>50</td>
<td><strong>1.78 ± 5.90</strong></td>
<td><strong>−0.78</strong></td>
<td><strong>0.31</strong></td>
<td>3.21</td>
<td>.1245</td>
</tr>
<tr>
<td>Low</td>
<td><strong>ON</strong></td>
<td>42</td>
<td><strong>0.92 ± 3.23</strong></td>
<td><strong>−0.11</strong></td>
<td><strong>0.04</strong></td>
<td>0.67</td>
<td>.032</td>
</tr>
<tr>
<td></td>
<td><strong>OFF</strong></td>
<td>50</td>
<td><strong>0.18 ± 0.93</strong></td>
<td><strong>−0.28</strong></td>
<td><strong>−0.04</strong></td>
<td>0.19</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td><strong>ON</strong></td>
<td>93</td>
<td><strong>−0.73 ± 4.50</strong></td>
<td><strong>−1.49</strong></td>
<td><strong>−0.08</strong></td>
<td>0.41</td>
<td>.0074</td>
</tr>
<tr>
<td></td>
<td><strong>OFF</strong></td>
<td>100</td>
<td><strong>0.98 ± 4.26</strong></td>
<td><strong>−0.39</strong></td>
<td><strong>−0.00</strong></td>
<td>0.84</td>
<td></td>
</tr>
</tbody>
</table>

**AF** = atrial fibrillation.

To investigate the impact of this imbalance, analysis of covariance using rank transformation was used to determine whether the effect of PPTs varied by the two baseline AF burden strata: high (≥6% burden) and low (<6% burden). The model included treatment group (ON, OFF) and randomization stratum (high, low) as the explanatory variables and postrandomization AF burden rank as the response variable. Although the effect of PPTs was not significant overall, both randomization stratum ($P < .0001$) and the interaction between PPTs and randomization stratum ($P < .029$) were significant, indicating that the effect of PPTs varied by baseline AF burden level. Thus, efficacy analysis was performed by comparing the change in AF burden between baseline and randomization periods in the ON and OFF groups.

PPTs led to a median reduction of 0.08 hours/day of AF burden in the PPTs ON group compared with no change in the OFF group ($P = .03$, Table 4). Patients in the high burden ON group had a median reduction of 1.38 hours/day of AF burden compared with an increase of 0.31 hours/day in the high burden OFF group ($P = .0007$). Patients in the low burden ON group had a median increase of 0.04 hours/day compared with a median decrease of 0.04 hours/day in the low burden OFF group ($P = .11$). Results from the analysis of covariance confirmed that the effect of PPTs was significant in the high burden group ($P = .038$) but not in the low burden group ($P = .31$). Baseline characteristics such as gender, geography, New York Heart Association class, and cardiovascular medication use had no significant impact on the outcome.

Logistic regression was carried out to model the probability of improvement/nonworsening of AF burden in the
high and low groups. In the high group, the odds ratio of improved/nonworsening of AF between PPTs ON and OFF was 3.10 (95% confidence interval [CI], 1.35, 7.11), that is, a 3.1-fold higher odds of having improved/nonworsening of AF in the ON group versus the OFF group. There was no difference observed in the low burden group (P = .42). As shown in Table 5, 72% of patients in the high ON group improved or sustained their condition, compared with only 46% in the high OFF group. However, the percentage of patients that improved in the low burden groups was similar in the ON and OFF arms, with 48% and 55% showing an improvement or sustaining their condition, respectively.

Changes in AF burden in the low burden group appeared more random and were evenly distributed. Figure 2 shows the distribution of change in hours/day of AF burden for all 193 patients. At every percentile level, the ON group experienced greater improvement in AF burden than the OFF group during the postrandomization phase.

### Atrial and ventricular pacing

The proportions of atrial and ventricular pacing were compared between the ON and OFF groups at baseline and at 10-month follow-up. The percent atrial pacing was similar during baseline (59% and 57%, respectively, P = .90). As expected given the activation of an overdrive algorithm, during the randomization period patients in the ON group had a significantly higher mean percent atrial pacing than patients in the OFF group (96% vs 58%, respectively, P < .0001; Table 6). The percent ventricular pacing did not differ significantly at baseline (46% in the ON group vs 55% in the OFF group, P = .09) and was similar during the randomization period (54% vs 55%, P = .87 by the Wilcoxon test). However, the change between baseline and randomization was significantly different (mean increase of 11.6% in the ON group vs 1.9% in the OFF group, P = .0003) and likely reflected more ventricular pacing due to increased atrial pacing.

### Adverse events

Kaplan-Meier estimates of adverse event rates revealed that there were no differences in the rates of adverse events and deaths between the ON and OFF groups. There was no difference in the cumulative patient survival probability at 6 months postrandomization in the two groups (97.3% in the ON group and 97.5% in the OFF group, P = .42).

### Discussion

The main observation of the present study was demonstration of the safety and efficacy of the suite of PPTs for prevention of AF among patients with bradycardia and paroxysmal AF. Although the effect was small overall, the benefit was greater among patients with a high baseline AF burden. The safety of these pacing therapies was demonstrated by the absence of any increase in adverse events or permanent AF. Complications from implantation or therapy were similar to those in other large multicenter studies.

The goal of SAFARI was to evaluate the effect of prevention pacing algorithms using a study design that addressed some of the limitations of earlier studies. This study was the first to evaluate PPTs in a rigorously selected AF patient population with an extended run-in period to stabilize lead function, minimize sensing problems, and exclude patients who improved with dual-chamber pacing alone. No large-scale study previously showed a significant benefit of prevention algorithms with total AF burden as an endpoint. Device-measured AF burden was selected as the efficacy endpoint because it is an objective, clinically relevant measure of disease burden and is not subject to potential investigator bias or that from patient self-reporting of symptomatic events. Of note, asymptomatic events are more frequent; therefore, continuous monitoring is a more accurate measure of AF burden. Furthermore, evidence from a study based on data from the Atrial Therapy Efficacy and Safety Trial (ATTEST) and the Atrial Septal Pacing Efficacy Clinical Trial (ASPECT) suggests a significant, but weak, positive correlation between changes in AT burden or frequency and changes in rates of cardiac hospitalization, in a cohort very similar to that in the present study.

Differences were observed with regard to the percent of ventricular pacing in the ON patients compared with OFF patients. At the end of the 10-month randomization period, the ON group had a more significant decrease in AF burden; however, this was accompanied by a significant increase in ventricular pacing relative to baseline. This likely reflects the increase in percent atrial pacing and heart rate, with

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**Table 5** Number and percentage of patients who showed improvement/nonworsening or worsening in AF burden at 10 months in high and low burden groups

<table>
<thead>
<tr>
<th>Condition</th>
<th>PPTs ON</th>
<th>PPTs OFF</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High burden group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improved/sustained</td>
<td>37 (72.54%)</td>
<td>23 (46.0%)</td>
<td>60</td>
</tr>
<tr>
<td>Worsened</td>
<td>14 (27.45%)</td>
<td>27 (54.0%)</td>
<td>41</td>
</tr>
<tr>
<td>Total</td>
<td>51 (100%)</td>
<td>50 (100%)</td>
<td>101</td>
</tr>
<tr>
<td><strong>Low burden group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improved/sustained</td>
<td>20 (47.61%)</td>
<td>28 (55.10%)</td>
<td>48</td>
</tr>
<tr>
<td>Worsened</td>
<td>22 (52.38%)</td>
<td>22 (44.89%)</td>
<td>44</td>
</tr>
<tr>
<td>Total</td>
<td>42 (100%)</td>
<td>49 (100%)</td>
<td>92</td>
</tr>
</tbody>
</table>

AF = atrial fibrillation; PPTs = prevention pacing therapies.
resultant prolongation of atrial and AV nodal conduction, thus resulting in more ventricular pacing due to the maximal programmable AV delay of 300 ms with this device. It is interesting to speculate whether an even greater benefit of PPTs would have been observed if ventricular pacing was minimized with newer algorithms.\textsuperscript{23}

AF is a complex disease, and multiple factors may be responsible for arrhythmia onset.\textsuperscript{24,25} A recent study that analyzed AF onset scenarios in paced patients found that 72% of AF episodes investigated had rhythm or rate changes before onset of AF. The onset trigger was paroxysmal atrial beats in 48% of onsets, bradycardia in 33%, and seemingly unrelated atrial beats in 17%.\textsuperscript{24} These data suggest that a treatment approach targeting multiple triggers of AF will be more effective for reducing AF. The PPTs were designed specifically to target these diverse triggers of AF and can handle multiple triggers in the same patient.

An interesting observation of the SAFARI results was confirmation of the benefit of dual-chamber pacing alone on AF, with approximately 40% of study patients showing no AF at the end of the 4-month run-in period. This is larger than the reduction of AF noted with multicenter studies comparing atrial-based pacing with ventricular pacing, although those studies had much longer follow-up.\textsuperscript{26} Further analysis of the nonrandomized patients in the present study will provide data on whether AF is prevented more chronically in this cohort or whether recurrence is simply delayed. Nevertheless, a further reduction of AF burden was achieved with PPTs, indicating that dedicated pacing algorithms that target multiple triggers of AF may benefit this population.

**Study limitations**

This study should be interpreted in light of certain methodologic limitations. Although the overall study duration was 10 months, the postrandomization follow-up period was only 6 months. However, this follow-up period is as long as or longer than in previous studies of device-based AF therapies. A number of patients were excluded from analysis because of sensing issues. It is unlikely that this affected the results, as these patients had very similar characteristics as randomized patients included in the efficacy analysis. The percentage of ventricular pacing was higher than desired but still less than that in many other prevention studies.\textsuperscript{11,21} The higher percentage of ventricular pacing in the ON group is unlikely to have been responsible for the reduction in AF burden, given the deleterious effects of ventricular pacing on the frequency of AF.\textsuperscript{21} Rather, it is more likely to have underestimated the benefit of PPTs. Approximately 50% of the patients were taking antiarrhythmic drugs while participating in this trial; therefore, the results should be interpreted as part of a hybrid approach. Finally, the suite of six prevention algorithms were applied in an all-or-none fashion in this study. Therefore, the relative benefit of each algorithm cannot be determined individually.

**Conclusion**

The SAFARI study demonstrates that PPTs are safe and effective among patients with paroxysmal AF and bradycardia. These therapies reduce AF burden beyond that achieved with dual-chamber pacing alone, particularly among subjects with frequent AF (>6% burden). These results suggest that PPTs may be useful adjunctive therapy for AF when atrial-based pacing and antiarrhythmic drug therapy are insufficient to achieve a low burden of arrhythmia. Further study is needed to determine the relative value of the different algorithms and to identify specific patient groups or arrhythmia onset mechanisms that benefit most from atrial pacing therapy.

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**Appendix**

Other investigators who participated in the SAFARI study: Etienne Aliot, C.H.U. de Nancy–Hôpital De Brabois, Vandoeuvre-Les-Nancy, France; Ray Allen, Cardiology Specialists, Memphis, TN; Barry Alpert, The Western Pennsylvania Hospital, Pittsburgh, PA; Felix Ayala-Paredes, Centre Hospitalier Universitaire de Sherbrooke, Sherbrooke, Quebec; Dominique Babuty, C.H.U.–Hôpital Trousseau, Tours, France; Johan Benneki, Martini Ziekenhuis, Groningen, The Netherlands; Malcolm Bersohn, VA Greater LA Healthcare System, Los Angeles, CA; Marc Bloom, Pepin Heart Institute, Tampa, FL; Alessandro Capucci, Ospedale Civile “G. da Saliceto,” Piacenza, Italy; James Cooper, Washington Regional Medical Center, Fayetteville, AZ; George Crossley, Mid-State Cardiology, Nashville, TN; Thomas Deering, Cardiac Disease Specialists, PC, Atlanta, GA; Greg

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**Table 6** Proportion of atrial and ventricular pacing in the ON and OFF groups

<table>
<thead>
<tr>
<th>Phase</th>
<th>Randomization</th>
<th>No. of patients</th>
<th>Mean % pacing</th>
<th>Median % pacing</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial pacing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>ON</td>
<td>93</td>
<td>59% ± 27%</td>
<td>60%</td>
<td>.90</td>
</tr>
<tr>
<td></td>
<td>OFF</td>
<td>100</td>
<td>57% ± 29%</td>
<td>60%</td>
<td></td>
</tr>
<tr>
<td>Postrandomization</td>
<td>ON</td>
<td>93</td>
<td>96% ± 7%</td>
<td>99%</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td></td>
<td>OFF</td>
<td>100</td>
<td>58% ± 30%</td>
<td>58%</td>
<td></td>
</tr>
<tr>
<td>Ventricular pacing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>ON</td>
<td>93</td>
<td>46% ± 33%</td>
<td>44%</td>
<td>.09</td>
</tr>
<tr>
<td></td>
<td>OFF</td>
<td>100</td>
<td>55% ± 34%</td>
<td>57%</td>
<td></td>
</tr>
<tr>
<td>Postrandomization</td>
<td>ON</td>
<td>93</td>
<td>54% ± 36%</td>
<td>66%</td>
<td>.87</td>
</tr>
<tr>
<td></td>
<td>OFF</td>
<td>100</td>
<td>55% ± 36%</td>
<td>58%</td>
<td></td>
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</tbody>
</table>
References


