Simulation of monitoring strategies for atrial arrhythmia detection

Federica Censi[a], Giovanni Calcagnini[a], Eugenio Mattei[a], Alessio Gargaro[b], Gianluca Biancalana[b] and Alessandro Capucci[c]

[a] *Dipartimento di Tecnologie e Salute, Istituto Superiore di Sanità, Rome, Italy*
[b] *Biotronik Italia SpA, Vimodrone, Milan, Italy*
[c] *Clinica di Cardiologia, Università Politecnica delle Marche, Ancona, Italy*

Abstract
Introduction. The current external monitoring strategies used to detect atrial fibrillation (AF) and atrial tachycardia (AT) episodes are based either on transient periods of short-term ECG recordings or on infrequent period of long-term continuous monitoring. The aim of this study was to investigate the ability of short-term daily ECG monitoring strategies for the detection of AF events.
Methods and materials. The investigation was based on simulations performed on data extracted from Burden II study (patients implanted with pacemaker for brady-tachy syndrome), reporting date, time and duration of each episodes.
Results and conclusions. We found that a short-term daily temporally-optimized ECG monitoring allows to detect a higher percentage of episodes than 1-day Holter monitoring and to be at least as effective as a 7-days monitoring.

INTRODUCTION

Atrial fibrillation (AF) and atrial tachycardia (AT) are the most commonly arrhythmias encountered in clinical practice. Although not lethal, they are responsible for considerable morbidity and mortality, given the related risk of stroke [1]. Accurate detection of asymptomatic AT/AF is of extreme importance for patient management and is crucial for guiding anticoagulation therapy.

The intermittent and often asymptomatic nature of AF and AT makes their diagnosis and investigation very difficult. Indeed, given the intermittent nature of both arrhythmic events and current monitoring methods, the ability of monitoring strategy to diagnose AF/AT is highly dependent on whether or not the moment selected for monitoring coincides with the occurrence of AF/AT episodes.

Sporadic ambulatory ECG control, transtelephonic monitoring, event monitor, sporadic 24h Holter, 7-days Holter are the monitoring strategies usually adopted for a paroxymal AF (PAF) patient. These external monitoring strategies are intermittent and based either on transient period of short-term ECG recordings or on infrequent period of long-term continuous monitoring.

Although the current consensus on AF/AT monitoring recommends at least two 24h Holter monitor examinations annually for the detection of recurrence after ablation procedures [2], it has also been shown that this monitoring strategy underdetects AF/AT recurrence, thus overestimating procedural success [3, 4].

Implantable, leadless rhythm recorders, allow continuous monitoring and provides a sensitivity of 100%. However, the implantation of such devices in all patients may seem unrealistic [5].

This led to the belief that intensifying noninvasive ECG monitoring may lead to better and more reliable detection of AF recurrence [3, 6, 7]. Thus a number of papers in the last two years has been published on the effect of increasing the frequency and/or the duration of Holter ECG continuous monitoring [8-11].

Several authors have instead suggested that a daily ECG monitoring at home would represent an efficient monitoring of AT/AF [4, 12-14]. A daily short-term recording seems to be an acceptable solution, more comfortable than long term ECG monitoring. Indeed, event monitor and Holter devices can cause skin irritation, are bulky and often interfere with other daily activities [4].

However, the ability of a daily short-term monitoring to identify arrhythmic episodes is related to the correct timing of such monitoring: the short-term monitoring should be active during the day moments when the probability to experience the arrhythmia is the highest. This information can be obtained by analyzing the daily temporal distribution of AT/AF episodes. Patients with cardiac implantable devices represent a good experimental model to perform the analysis of the temporal distribution of AT/AF episodes, given the ability of such devices to store information about AF
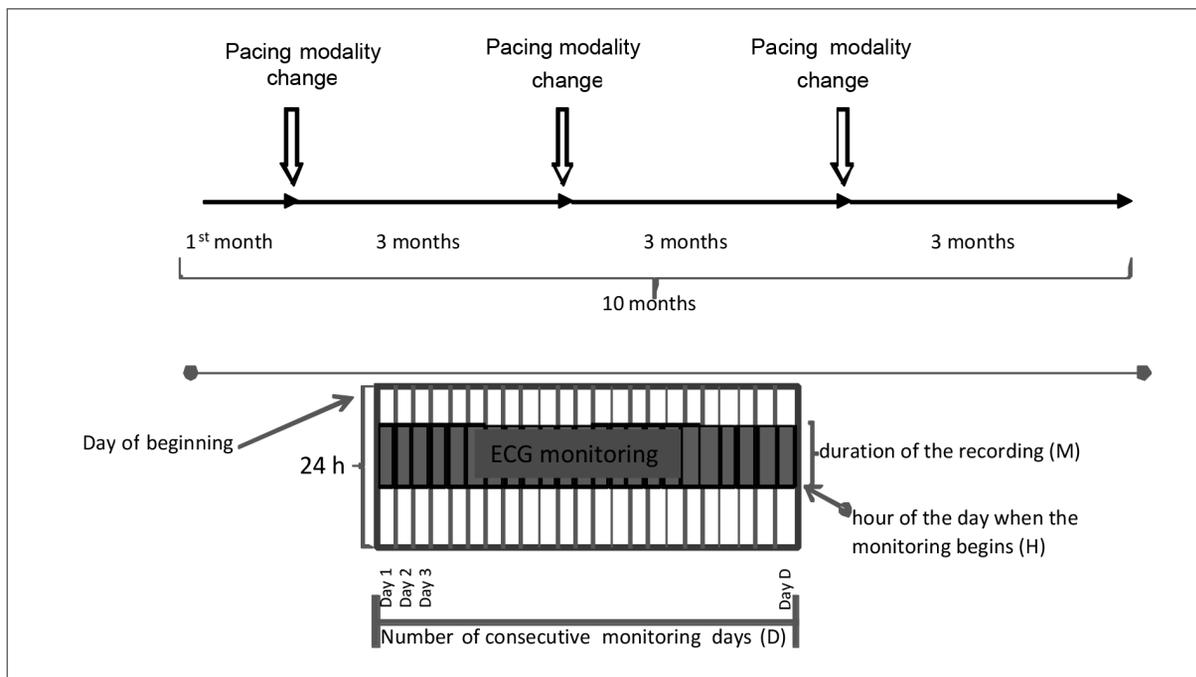
Address for correspondence: Federica Censi, Dipartimento di Tecnologie e Salute, Istituto Superiore di Sanità, Viale Regina Elena 299, 00161 Rome, Italy. E-mail: federica.censi@iss.it.

Figure 1
Schematic representation of simulated monitoring strategies

and AT episode, such as date and duration [15-18].

The aim of this study was to investigate the ability of short-term daily ECG monitoring strategies for the detection of AF events. The investigation was based on simulations performed on data extracted from Burden II study (patients implanted with pacemaker for brady-tachy syndrome), reporting date, time and duration of each mode switch episodes.

METHODS AND MATERIALS
Study population
We analyzed data from 250 patients enrolled in Burden II investigation [19]. Burden II study involved patients with brady-tachy syndrome, symptomatic sinus bradycardia, and at least one documented AT or AF episode within 3 months prior to pacemaker implant. Exclusion criteria include: chronic heart failure, angina pectoris, dilated left atrium (> 50 mm), prior or intended atriumventricular (AV) node ablation, indication for dialysis/ hemofiltration.

According to the protocol, scheduled follow-ups occurred 1 month postimplant and afterwards every 3 months, up to the tenth month. Antiarrhythmic therapy was unchanged throughout the study follow-up.

Patients were included in the analysis if they had less than 30% of episode misclassification for each follow-up (as documented by the stored electrograms), if they had at least 10 documented episodes of atrial arrhythmias during the observational period, and if they concluded the protocol (all 4 follow-ups).

Simulation of monitoring strategies
We simulated several daily monitoring strategies by varying the following key parameters: the hour of the day when the monitoring begins (hour, H), the duration

of the monitoring (in minutes, M), and the number of consecutive days the monitoring lasts (days, D). The day when the monitoring starts (day of beginning, DB) was randomly chosen over the 10-months follow-up period *(Figure 1)*. Particularly, 10 simulations with different days of monitoring beginning were performed for any combinations of the key parameters. Key parameters were varied as follows: H: from 0 am to 23 pm, 1 hour step; M: 30, 60 and 120 minutes; D: 30 and 60 days.

Furthermore, a combination of two H parameters will be simulated (H_1 and H_2), in order to simulate two monitoring per day, at different day moments. In these simulations, the patients detected at H_1 will be combined with those detected at H_2.

To perform a comparison with the standard 24h Holter monitoring strategies, we also simulated the classical 1-day ECG monitoring and the more recent 7-days and 30-days ECG monitoring. Even in this case, the beginning of the monitoring was randomly chosen over the 10-months follow-up period, performing 10 simulations.

Results are presented as the percentage number of AF-detected patients, computed as the ratio between the number of patients experiencing AF during the monitoring period, and thus virtually detected, and the total number of analyzed patients. Percentage number of AF-detected patients were expressed as mean ± standard deviation of the results obtained by groups of simulations.

RESULTS
Analysis was performed on 119 patients fulfilling the inclusion criteria, for a total number of more than 12000 AT/AF episodes. *Figures 2 and 3* show the results obtained for any combination of the key parameters
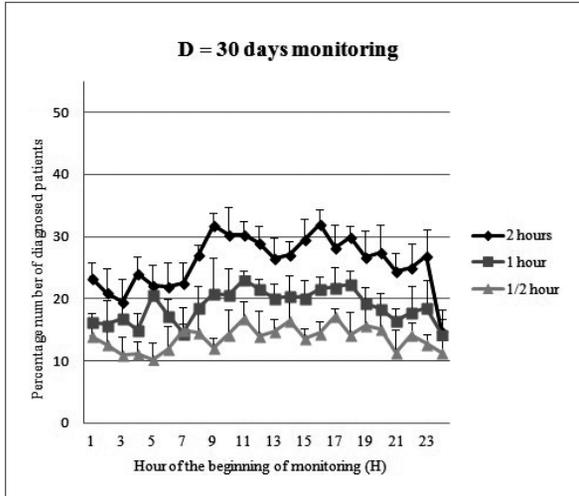
Figure 2
Percentage number of detected patients as a function of H (hour of the day the monitoring starts), for different durations of recording in terms minutes/day (M) and for 30 days of consecutive monitoring
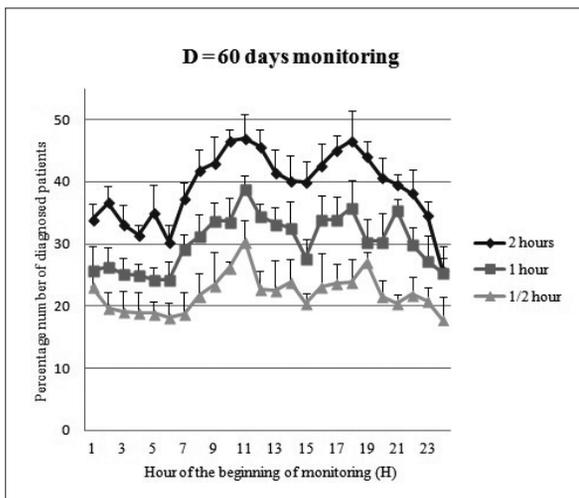

Figure 4
Percentage of virtually diagnosed patients for standard 24h Holter monitoring (lasting 30 days, 7 days and 1 day), and for the temporally optimized one, plotted form the less efficacious monitoring method to the most efficacious one

Figure 3
Percentage number of detected patients as a function of H (hour of the day the monitoring starts), for different durations of recording in terms minutes/day (M) and for 60 days of consecutive monitoring

H, M and D. Particularly, the percentage number of detected patients is reported as a function of H (hour of the day the monitoring starts), for different durations of recording in terms of both number of minutes/day (M) and of number of consecutive monitoring days (D = 30 days in *Figure* 2; D = 60 days in *Figure 3*).

The number of detected patients varies depending on the hour of the day when the monitoring starts (H), with peaks in the morning (9-10 am). The lowest number of detected patients is obtained at late evening (10-11 pm). A 2-hour ECG daily monitoring temporally optimized to be active between 9-10 am for 60 consecutive days can detect about 50% of patients experiencing PAF episodes in the observational period; when performed on 30 consecutive days the percentage
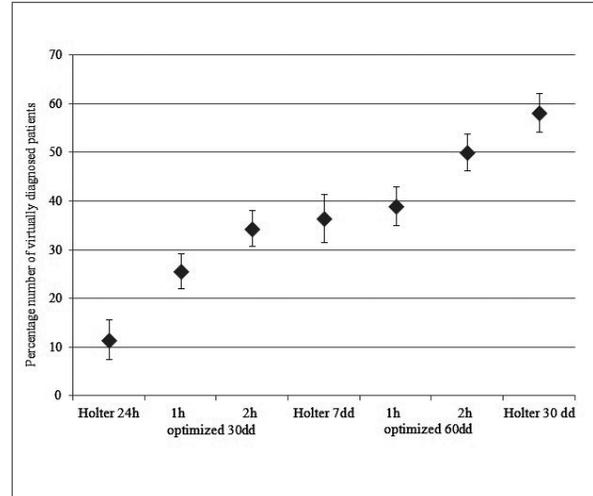
of detected patients is about 35%. A shorter monitoring (half-an-hour) allows to detect up to 25% (for 60 consecutive days).

These results indicate that a temporally-optimized monitoring should begin in the morning, starting at about 9-10 am.

Figure 4 shows the results obtained from the comparison with the standard Holter ECG monitoring, performed randomly over the observational period. In this figure, the temporally-optimized monitoring is set to begin at 10 am. Similar results have been obtained when the beginning of recording is set to 8 am and 10 am. For the double monitoring strategies, performing 2 ECG measures/day, day hours were set to 10 am and 5 pm. Best performing strategy resulted to be the one based on 2 ECG monitoring per day, lasting 2 hours each, one in the morning at 10 am and one in the afternoon at 5 pm.

One-day and 7-days Holter monitoring turned out to detect about 10% and 35% of patients with AF episodes, respectively. Temporally-optimized monitoring allows to detect a higher percentage of patients than 1-day Holter monitoring. In addition, a 2h/day ECG temporally optimized monitoring turns out to be at least (with D = 30) as effective as a 7-days 24h monitoring.

DISCUSSION

Reliable and accurate detection of AF recurrence is thus of special importance for the evaluation of pharmacological or ablation therapies as well as when decisions on changes in anticoagulation or antiarrhythmic therapy are to be made.

This study analyzed several ECG daily monitoring strategies for AF episode detection. The currently adopted methodologies to monitor the recurrence or the first occurrence of AF are based on the use of one single ECG monitoring performed few minutes in an ambulatory or 24h by an Holter recording system. The
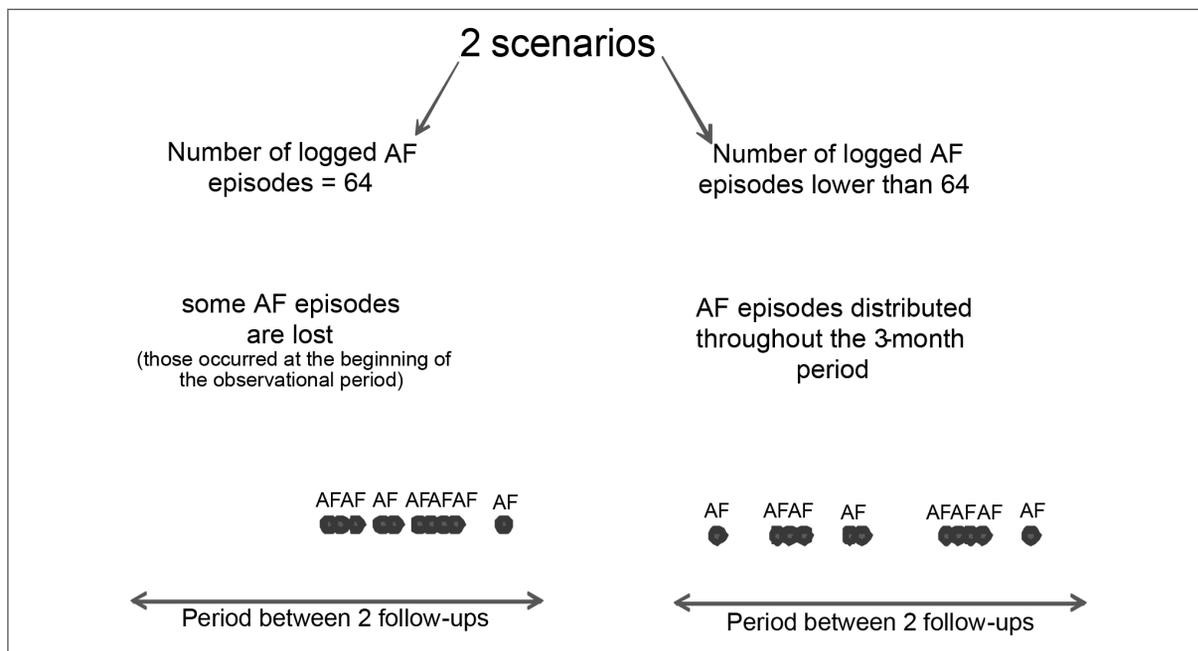
Figure 5
The two possible scenarios given the finite number of storable AF episodes on pacemaker memory

day and the moment of the day when this single ECG monitoring is performed is chosen by chance. Given the intermittent nature of the arrhythmia, the current strategies revealed to be less sensitive and specific.

The knowledge of the daily temporal distribution of AF episodes, would be very helpful to detect the presence of specific moments when AF episode are more likely to occur. This information could in turn be used to optimize the ECG monitoring in PAF patients, currently undergone to sporadic ambulatory or 24h Holter ECG recording, with scarce results in terms of AF episodes detection. Recently Arya et al. [14] analysed the accuracy of several follow-up strategies after AF ablation, indicating that the method with a degree of accuracy closer to the theoretic gold standard – or to the implantable device – is the daily ECG. Following this indication, it could be of extreme importance to understand if AF episode occur randomly throughout the day or if there are some moments when the AF is more prone to appear.

Previous attempts to investigate the temporal distribution of AF episodes were based on the retrospective analysis of 24h Holter ECG monitoring or of symptomatic AF episodes [20-27].

The experimental model we used allows us to analyzed AF episodes distribution over a 10-months period, regardless symptoms, overcoming many limitations of the two previously described approaches. After the construction of the database, obtained from implantable devices log files, we could perform an objective analysis of the temporal distribution of AT/AF episodes, in terms of their onset and maintenance.

The results recently published on this database [28] show that the number of virtually detected patients is highest when the ECG monitoring is performed in the morning starting from 8 am. Thus it appears

that the monitoring of PAF patients would be optimized if it were done soon after the waking up, in agreement with the results of simulations showed in Figures 2 and 3. In ref. [28] the daily probability of AT/AF onset and occurrence were higher during daytime hours (about two-fold, between 8.00 am and 8.00 pm) than during night time, resulting in a circadian pattern with a with clustering of events in the morning and (to a lesser degree) in the afternoon. These results are in agreement with the finding that when compared with standard, and less comfortable, 24h Holter approach, a temporally-optimized ECG monitoring strategies turned out to outperform. Particularly, 1-day Holter monitoring resulted to be a weak strategy to detect patients with PAF, since it can detect only 10% of patients. The 30-days long Holter recording resulted rather suitable to monitor PAF patients. The new simulated strategies based on a temporally-optimized daily ECG monitoring for a short period (1 or 2 hours) turned out to perform better than 7-days Holter technique, being undoubtedly more comfortable.

Qualitatively speaking, the results obtained by this analysis show that strategies based on monitoring for several consecutive days are more efficacious than sporadic monitoring. Indeed random 24-h monitoring turned out to be the less efficacious approach; 7-days Holter (corresponding to 168h monitoring) resulted to be as efficacious as a 30-days short-term monitoring and less effective than a 60-days short-term approach (corresponding to 120h monitoring).

Another important result is that a double monitoring approaches based on two optimized ECG measures per day (at 10 am and 5 pm) is highly effective to detect AF episodes. The results obtained by these simulations show that, when monitored for 60 consecutive days,

more than 60% of patients experience at least one episode of AF in the morning and/or in the afternoon.

Apparently, 2 hours for an ECG monitoring seem to be a long time; however, given the nature of the database, 2 hours are necessary to cover the different schedules used by each patient to perform the morning and/or afternoon activities. If we hypothesized that morning and afternoon are the moments of the day more favourable for AF episodes because of the actions associated to the beginning of a new day (waking up, going out to work etc.) and to the end of the working day, such actions are performed at different times for different patients. Thus, more than the monitoring duration of 2 hours, one of the relevant result of this investigation is that the moment of the day when AF episodes are more likely to occur are morning and afternoon. Thus, probably, even a few-minutes recording for each patient can be adequate if performed during morning and afternoon and if further optimized for that patient.

It is worth noting, however, that the number of detected patients from our database could be an under-estimation of the potential detectable patients from a real population, given the finite number of storable AF episodes on pacemaker memory (64 episodes). So if a patient in the period between 2 follow-ups (3 months) experienced less than 64 episodes, the 3-month period has been correctly monitored by the pacemaker; if the number of AF episodes logged in this 3-month period were 64, it is possible that some occurred episodes are lost, and they cannot be considered for the analysis. *Figure 5* gives a representation of this limitation, explaining the two possible scenarios given the finite number of storable AF episodes on pacemaker memory. On the left, some episodes cannot be included in the database, since more than 64 episodes occurred during the period between 2 follow-ups. On the right, the 3-month period has been correctly monitored by the pacemaker in terms of AF episode occurrences.

However, besides these limitations, the results obtained by this experimental model represent an important indication for the optimization of ECG daily monitoring for PAF or post-ablated patients.

Technological innovation

The 2012 focused update of the ESC Guidelines for the management of atrial fibrillation, do not mention the technology to continuously monitor patients at risk for AF. As far as the AF screening is concerned, the guidelines "recommend that, in patients aged 65 years or over, opportunistic screening for AF by pulse palpation, followed by recording of an ECG to verify diagnosis, should be considered for the early detection of AF" [29].

According to the latest survey of the European Heart Rhythm Association Research Network [30], the current practice of AF detection and monitoring is basically committed to implantable devices, either implanted pacemakers/defibrillators or specially tuned subcutaneous leadless rhythm monitoring devices.

Between these two monitoring strategies, there are a number of solutions which could be more precise and reliable than pulse palpation and less invasive than implantable device, although almost equally accurate.

Portable and self measurement systems for blood pressure are available now for the detection of AF. Portable ECG monitor are present in the market since several years, some performing ECG from the fingers.

Last but not least the web offers apps for smartphones (not yet certified/authorized) by which it is possible to estimate the pulse irregularity by placing the index finger over the camera; the app detects the small changes in skin color and the appearance of underlying blood vessels using the smartphone's camera and light-source.

If an app developed on a smartphone can reliably detect AF, it will be possible in the future to implement similar app on dedicated integrated circuit, which receive signals from proper clinical sensors (such as small dry/textile electrodes placed on the skin) to increase the accuracy of the diagnosis.

CONCLUSION

In conclusion we found that a short-term daily ECG monitoring could be optimized if performed starting from about 8 am (almost 50% of diagnosed patients). Temporally-optimized monitoring allows to detect a higher percentage of patients than 1-day Holter monitoring and to be at least as effective as a 7-days 24h monitoring.

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