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Daily ECG transmission versus serial 6-day Holter ECG for the assessment of efficacy of ablation for atrial fibrillation — the AGNES-ECG study

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Abstract

Purpose To compare daily ECG transmissions using trans-telephonic monitoring (TTM) with repeated 6-day Holter ECG in detecting atrial fibrillation (AF) episodes following ablation.

Methods Each patient underwent two types of recordings: daily ECG TTM lasting 30 s and standard 6-day ambulatory ECG monitoring performed 3, 6, and 12 months after ablation. Number of patients with detected AF recurrences, time to first detected recurrence of AF, and AF burden were assessed.

Results Fifty patients (9 females, mean age 57 ± 11 years) were included. The mean duration of the follow-up was 382 ± 38 days. A total of 17,573 (mean 351 ± 111 per patient) TTM recordings were performed and 99.95% of recordings were of quality sufficient to assess cardiac rhythm. Altogether, 14 (28%) patients had AF recurrence. Holter ECG detected AF recurrence in 7 (14%) patients whereas TTM — in 12 (24%) patients, $p = 0.0416$ (TTM only — 7 (14%), Holter ECG only — 2 (4%), and both methods — 5 (10%)). Time to the first AF recurrence tended to be shorter using TTM than Holter ECG (156 ± 91 vs 204 ± 121 days, $p = 0.0819$). There was no significant difference in AF burden assessed by TTM versus Holter ECG recordings 3.1 ± 0.14% vs 4.8 ± 0.2%, $p = 0.21$.

Conclusions Compared with Holter ECG, daily 30-s ECG recordings detected more patients with AF recurrences. Time to first detected AF episode tended to be shorter using TTM. Daily ECG recordings transmitted using smartphone may replace standard Holter ECG in detecting AF after ablation.

Trial registration Clinical Trials Identifier: NCT03877913

Keywords Atrial fibrillation · Ablation · Mobile ECG · Holter ECG

1 Background

The optimal method for the assessment of efficacy of ablation for atrial fibrillation (AF) has not yet been established. The symptom-based evaluation is not accurate because many AF episodes are asymptomatic. It has been well documented that the more frequent and/or longer ECG recording the more the AF recurrences are detected [1]. However, such devices as implantable loop recorders are expensive whereas external ECG monitoring is not well tolerated over a period longer than 1 month [1]. The most frequently used approach, recommended by the 2017 AF ablation guidelines, is periodic 1–7-day Holter ECG monitoring, usually performed 3, 6, and 12 months after the procedure and additional standard ECG recordings when symptoms occur [1]. However, asymptomatic AF episodes occurring between Holter ECG recordings are missed using this method.

Recently, several types of external ECG recorders have been introduced, enabling good quality frequent ECG recordings and transmission via mobile phones [2]. Several studies documented the usefulness of this method in detecting silent AF in a high-risk population [3]; however, the value of short but frequent ECG recordings after AF ablation has not yet been established. Only a few reports dealt with this problem and showed superiority of short but

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frequent ECG transmissions over longer but less frequent ECG monitoring for detecting post-ablation AF recurrences [4–8]. The most recent 2020 AF ESC guidelines recommend post-ablation ECG monitoring using intermittent ECG, Holter ECG, patch recordings, external or implanted loop recorder, or smartphone monitor, however, do not specify which type of recording is preferred [9]. The aim of our study was to compare daily short ECG transmissions using trans-telephonic monitoring (TTM) with repeated 6-day Holter ECG in detecting AF episodes following AF ablation. We hypothesized that daily short TTM ECG recordings have significantly higher yield in AF detection than repeated 6-day Holter ECG.

2 Methods

The Agnes-ECG study was a prospective, investigator-driven study comparing daily 30-s TTM ECG recordings versus 6-day Holter ECG in patients after AF ablation (Clinical Trials Identifier: NCT03877913).

2.1 Patients

We planned to include 50 consecutive patients undergoing AF ablation in our hospital. The follow-up was designed to last 12 months. The AF detection was performed using two recording methods in each patient. The number of 50 patients has been chosen based on the assumption that Holter ECG will detect AF recurrence in 15% of patients and daily transmission will detect AF recurrence in 38% of patients (alfa error = 0.05 and beta error = 0.2).

Inclusion criteria were (1) ablation for AF performed 1–2 days before inclusion in the study, (2) access to smartphone, and (3) ability to maintain TTM and to transmit ECG demonstrated by a patient during training session performed in hospital at the time of inclusion in the study.

Exclusion criteria were (1) pacemaker implanted, (2) known presence of other than AF cardiac arrhythmias requiring frequent ECG monitoring (ventricular arrhythmia, second or third-degree atrioventricular block), and (3) lack of smartphone or inability to manage TTM.

2.2 TTM recordings

Daily ECG TTM recordings and transmissions were performed using the HR-2000 recorder (Istel, Poland). Figure 1 shows the recorder and an example of original recording with AF. This device enables recording of 30 s of 6-channel ECG (I, II, III, aVR, aVL, aVF) from 4 metal electrodes built in the recorder. In order to record ECG, the device is activated by a patient and attached to the thorax, at the area of sternum. After recording, ECG was transmitted using Bluetooth to patient's smartphone and then transmitted to the central station where data were stored and analyzed. Analysis was performed on a daily basis by an experienced ECG technician, not directly involved in patient's recruitment and treatment. The results of all recordings were available for the study team 3, 6, and 12 months after ablation, at the time when concurrent Holter ECG recordings were analyzed. Only in case of serious, life-threatening arrhythmias (non-sustained or sustained ventricular tachycardia, pauses > 6 s), the study team was informed immediately by a technician about the results of 30-s ECG recording in order to undertake proper action. Specifically, asymptomatic episodes of AF were not unblinded to the study team in order not to interfere with medication and to allow continuing follow-up till next ambulatory ECG monitoring.

2.3 Ambulatory ECG monitoring

The second method of ECG recording was a standard 6-day ambulatory ECG monitoring (DMS 300-4A recorders, Oxford Instruments, UK) performed 3, 6, and 12 months after ablation.

2.4 Additional recordings

The patients were allowed to record additional ECG when symptoms suggesting AF occur. This could be performed by TTM or standard 12-lead ECG if available.

2.5 Follow-up

Follow-up was planned for 12 months. Patients were seen in outpatient clinic 3, 6, and 12 months after inclusion in the study. During these visits, ambulatory ECG recorders were fitted. Also at each time-point (3, 6, and 12 months), the study team analyzed all recorded ECGs and 6-day Holter ECG and made appropriate therapeutic decisions.

Primary endpoint was defined as AF recurrence in any type of monitoring after the blanking period. Secondary endpoints included (1) time to detection of first AF episode after blanking period, (2) total AF burden, and (3) AF episodes in blanking period.

2.6 Definitions

The AF episode was defined as episode lasting ≥ 30 s (in any ECG monitoring). The blanking period was defined as first 3 months after the ablation (AF episodes during this period were not defined as AF recurrence). The AF burden was expressed as percent of time with AF in all performed TTM or Holter ECG recordings.

Fig. 1 The TTM recorder and the example of original recording with AF

2.7 Statistical analysis

All continuous variables were tested for normality with the Shapiro-Wilk test. Variables with normal distribution are expressed as mean ± standard deviation (SD). Non-parametric variables are expressed as median and interquartile range (IQR) and categorical variables as counts (n) with percentages (%). Categorical variables were compared using the chi square test and continuous variables — using Student t-test. Atrial fibrillation-free survival data, using Holter recording or TTM recordings, were analyzed by Kaplan-Meier analysis, and the difference in survival between groups was examined with by the log-rank test. A p-value > 0.05 was regarded as significant.

3 Results

Between August 2018 and April 2020, 210 patients underwent AF ablation in our institution. Of them, 159 were not included in the study due to lack of agreement to participate in the study ($n = 34$), not meeting inclusion criteria ($n = 19$), lack of smartphone and/or anticipated problems with performing recordings and transmissions ($n = 83$), or temporal lack of access to ECG recorders by investigators ($n = 23$). Finally, 51 patients gave written informed consent and were included in the study. Of those, 1 patient withdrew consent which left 50 patients available for analysis. Patient flow is presented in Fig. 2 and patient demographic and clinical characteristics are shown in Table 1.

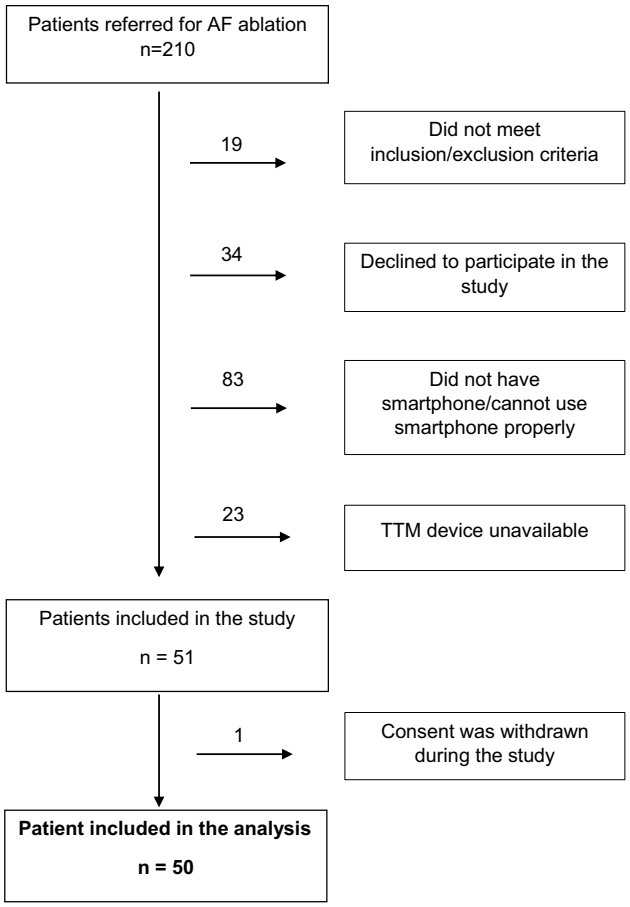

Fig. 2 Patient flowchart

Table 1 Demographics of patients

Age (years, mean ± SD)	57 ± 11
Female	9 (18%)
BMI (median, IQR)	28 (IQR: 27–32)
PAF/perAF	37/13 (44% 46%)
first AF ablation/redo procedure	45/5 (90%/10%)
CHA_2DS_2VASc (median, IQR)	1 (IQR: 0–2)
RF/CB	21/29 (42%/48%)
Concomitant diseases	
Hypertension	33 (66%)
Heart failure	0
Coronary artery disease	4 (8%)
Diabetes	4 (85%)
Stroke/TIA	6 (12%)

Abbreviations: *PAF*, paroxysmal atrial fibrillation; *perAF*, persistent AF; *RF*, radiofrequency ablation; *CB,* cryoballoon ablation; *TIA*, transient ischemic attack

3.1 TTM recordings

In total, 17,573 ECG recordings were performed. The number of recordings ranged from 145 to 738 (mean 351 ± 111 per patient). Of total 17,573 recordings, almost all (17,564) were of quality sufficient to define cardiac rhythm, whereas 9 (0.05%) were technically poor or completely unreadable. The total duration of TTM recordings in the whole study group was 146.4 h (6.1 days). The adherence to TTM recordings (days with of TTM monitoring/days of follow up × 100%) reached 88.3% ± 24.7%.

3.2 Holter ECG recordings

Out of 150 planned Holter ECG recordings (each patient was scheduled to have 3 Holter recordings: 3, 6, and 12 months after ablation), 148 ECG recordings were performed. The duration of Holter monitoring varied from 3 days to 6 days (mean 5.8 ± 0.6 days). Two recordings (both — 6 months after the ablation) were not performed because COVID-19 epidemy precluded visit in the clinic. All Holter ECG recordings were of quality enabling identification of cardiac rhythm. The total duration of Holter ECG recordings in the whole study group was 843 days.

3.3 Follow-up data

The mean duration of follow-up was 382 ± 38 days (range: 357–539 days) and exceeded the planned 1-year follow-up because 7 patients had final ("12-month") Holter ECG performed later than scheduled due to COVID-19 epidemy. In these patients, the usage of TTM was also extended up to the final Holter ECG recording.

During the study, 3 patients had redo procedure which was successful in 2 patients (without AF recurrence during the follow-up) and unsuccessful in 1 patient (early recurrence of persistent AF).

3.4 AF recurrences

In total, 14 (28%) patients had AF recurrence (after the first 3 months of follow-up: "blanking period"), including 8 (23%) AF recurrences in the PAF group ($n = 35$) and 6 (40%) AF recurrences in patients with perAF ($n = 15$). Holter ECG detected AF recurrence in 7 (14%) patients, whereas TTM detected AF recurrence in 12 (24%) patients ($p = 0.0416$, Fig. 3). The AF recurrences were detected only by TTM in 7 (14%) patients, only by Holter ECG — in 2 (4%) patients, and by both methods — in 5 (10%) patients (Fig. 4).

The time to the first AF recurrence tended to be shorter using TTM rather than Holter ECG (156 ± 91 versus 204

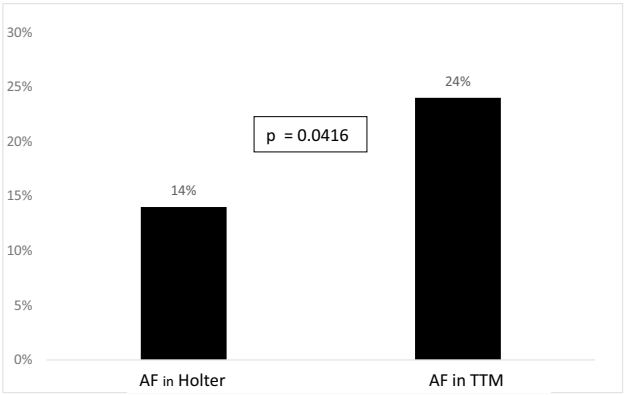

Fig. 3 Proportion of patients diagnosed with AF recurrences by TTM vs Holter monitoring

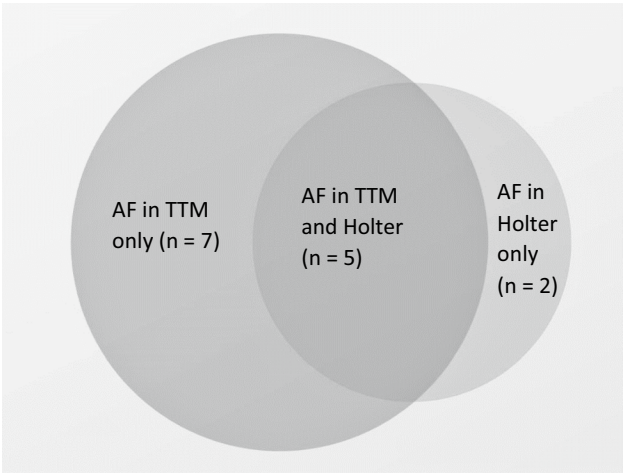

Fig. 4 Number of patients with AF recurrences detected only by TTM monitoring, only by Holter ECG, or by both methods

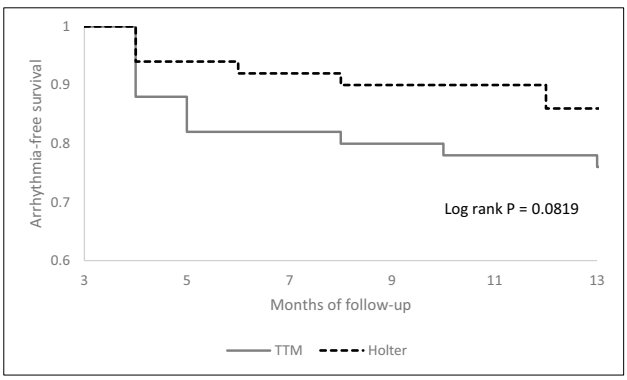

Fig. 5 The Kaplan-Meier curves showing time to first AF recurrence detected by TTM recorder and Holter

± 121 days, $p = 0.0819$). The Kaplan-Meier curves showing time to first AF recurrence detected by TTM and Holter ECG are presented in Fig. 5.

3.5 AF episodes during blanking period (TTM recordings)

In 19 (38%) patients, AF episodes were detected during the first 3 months of follow-up. Among these patients, 10 had AF recurrences during later follow-up (5 recorded in TTM and Holter monitoring, 2 only in Holter and 3 only in TTM). Only 4 patients with AF recurrence during follow-up did not have AF episodes in the blanking period.

3.6 AF burden

In 12 patients with AF recurrences, 300 TTM recordings with AF episodes were collected. The number of AF recordings in a patient with AF recurrence varied from 1 to 133 and AF burden defined as percent of recordings with AF (after the 3-month blanking period) ranged from 0.36 to 95.68%. In 7 patients with AF recurrence in Holter monitoring, AF burden varied from 0.0068% (35 s of arrhythmia) to 100% (persistent AF). There was no significant difference in AF burden assessed by TTM versus Holter ECG recordings 3.1 ± 0.14 % vs 4.8 ± 0.2 % ($p = 0.21$).

Detailed data on the exact number and timing of each AF episode in individual patients with AF recurrences are presented in Fig. 6.

4 Conclusions

The present study showed that daily 30-s ECG recordings were superior to 6-day Holter ECG performed 3, 6, and 12 months after ablation in detecting AF recurrences.

Our results are in line with a few previous reports which compared periodic long-term ECG monitoring with frequent but short ECG transmissions. Kimura et al. [4] tested three methods (repeated 10-s standard ECG recordings, 24-h Holter ECG performed every month, and short 30-s ECG recordings performed twice daily) in 30 patients during 6-month follow-up and showed that the latter method was the most efficient in detecting AF recurrences. Similar study was conducted by Senatore et al. [5] who compared diagnostic yield of twice daily ECG transtelephonic transmission versus repeated 24-h ECG recordings in 72 patients after AF ablation. Using daily ECG transmissions, significantly, more patients had AF episodes detected (27.8% vs 13.9%, $p = 0.001$). In another study [6], twice daily ECG transmissions using smartphone and AliveCor system were compared with standard medical care in patients with a history of AF undergoing ablation or cardioversion. Also in this study, frequent

Pt#	Type of recording	Month of follow-up												
		Blanking period												
		1	2	3	4	5	6	7	8	9	10	11	12	(13)
2	TTM					17%							8%	
	HOLTER													
6	TTM				3%									
	HOLTER													
8 *	TTM	96%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
	HOLTER				100%			100%					100%	
15*	TTM	58%	100%	100%	100%	13%*								
	HOLTER				100%									
19	TTM			39%	9%			9%		12%				
	HOLTER													
25	TTM	3%											4%	
	HOLTER												13%	
29	TTM	5 %			2%			2%						
	HOLTER													
36	TTM	7%												
	HOLTER								5%					
38	TTM	17%	3%											
	HOLTER													0.03%
39	TTM							6%						
	HOLTER													
42	TTM		4%									13%		
	HOLTER						0.017%							
43 *	TTM	7%	17%	100%	100%	100%	100%	100%	30%*		5%			
	HOLTER				100%									
46	TTM					4%								
	HOLTER													
47	TTM	4%				3%	4%			8%				
	HOLTER													

Fig. 6 Details on timing and AF burden in 14 patients with AF recurrences. AF burden in TTM recordings represented as percent of recordings with AF per month and AF burden in Holter ECG recordings represented as percent in AF out of 6-day Holter ECG. Recurrences recorded by TTM enshadowed in light grey color and recorded by Holter ECG, in black. *Patients with redo procedure during follow-up

ECG transmissions using smartphone occurred more effective in detecting AF recurrences than standard care (61% vs 30%; $p = 0.04$). Also Chovancik et al. [8] showed that daily ECG monitoring with episodic card recorder detected more AF recurrences after ablation than periodic 1 week monitoring with episodic loop recorder. In addition, it has been demonstrated in the STAR AF II substudy that weekly transtelephonic ECG monitoring had additive value in detecting AF episodes to standard 24-h ECG monitoring performed every 3 months after ablation [10]. Finally, Hermans et al. [7] in 126 post-ablation patients demonstrated superiority of ECG monitoring performed using smartphone with AliveCor application (4 weeks, 3 times daily, 30 s) over standard 24-h Holter ECG performed 3, 6, and 12 months after AF ablation.

Our study differed from the abovementioned reports in some methodological aspects. Firstly, we used 6-day ambulatory ECG monitoring performed 3, 6, and 12 months after ablation whereas other studies used only 24-h ambulatory ECG recordings. It has been shown that extending Holter ECG recordings from 1to 4–7 days significantly increases the detection rate of AF [11]. Thus, in our study, the control Holter ECG arm was designed according to the current guidelines [1, 9]. In addition, some other investigators [7] used frequent ECG recordings for much shorter period of time (4 weeks) which might have decreased the diagnostic yield of daily ECG recordings because AF recurrences may occur over wider range of follow-up.

Although the total duration of TTM recordings was much shorter than that of Holter ECG monitoring in our study, diagnostic yield was higher. Similar findings have been reported by others [8]. It may be explained by the fact that some proportion of TTM recording was triggered by symptoms due to AF whereas ambulatory ECG recordings were scheduled for predefined periods. If during such a period patient had no AF, no arrhythmia was detected using Holter ECG. In addition, it may be speculated that even only once-a-day short ECG recording but performed over the whole follow-up duration has higher diagnostic yield in detecting AF than periodic 6-day Holter ECG due to well-known fact that AF may recur in clusters during which ambulatory ECG monitoring was not scheduled.

Apart from the number of patients with AF recurrence and time to first AF recurrence, the AF burden is another clinically important parameter. In our study, there was no significant difference between AF burden assessed by TTM versus Holter ECG recordings; however, such a comparison is of limited value because the total duration

of Holter ECG monitoring in the whole study group was markedly longer than that of TTM (843 versus 6 days), enabling more accurate assessment of AF burden. Perhaps, short-lasting ECG recordings such as those performed using TTM are not suitable for AF burden assessment and new wearable devices capable of nearly continuous rhythm monitoring, notification of irregular rhythm, ECG confirmation, and AF burden assessment will be preferred.

In our study, we used patient-initiated hand-held 6-lead monitor which records 30-s ECG from a patient chest. The device was well tolerated and, in general, there were no problems with recordings and transmissions. All patients were capable of transmitting ECG with smartphone for a 1-year period; however, the number of recordings varied from 145 to 738 due to various reasons such as stopping the recording due to confirmed recurrence of persistent AF, non-compliance to daily transmissions, or symptoms triggering additional recordings. The overall adherence was acceptable, reaching 90%. The quality of TTM recordings was very good (> 99% could be evaluated) and it seems that such a type of recorder is user-friendly and may be used in everyday practice. Perhaps 6-lead system may offer more accurate P wave assessment and better distinction between true AF and atrial ectopy or artifacts than a single ECG lead devices.

An important practical issue is what proportion of patients undergoing AF ablation is capable of using such a recorder. In our study, out of 210 consecutive patients undergoing AF ablation between August 2018 and April 2020, only 50 (23.8%) were included in the study. The main reasons for not including in the study were patient-related: lack of smartphone/being unable to properly use smartphone, not willing to enter the study (mainly because of the need to show up for fitting Holter ECG monitors), or logistic problems (temporary lack of available recorders in our hospital). This may very between countries and regions; however, it shows that not all patients may be monitored after AF ablation using smartphone-based recorders. It may also be speculated that with the wider and wider use of smartphones and new wearables such as smartwatches or activity trackers (capable of recording single lead ECG), the proportion of patients willing to use these devices for ECG transmissions will increase.

Another issue is whether capturing short AF episodes in asymptomatic patients, missed by usual care, adds any important clinical information. In our study, AF was defined as episodes lasting > 30 s; however, all captured episodes were in fact probably longer because they lasted from the very beginning to the very end of a 30-s recording. Also, documenting even short AF episodes may help in decision-making as far as chronic anticoagulation is concerned in patients with borderline indications such as CHA_2DS_2VASc 1 or 2.

The obvious problem with frequent remote heart rhythm monitoring using various recorders is the enormous volume of data to be analyzed. It has been well documented that one cannot rely fully on automatic diagnosis of AF made by ECG recorder (for example, implantable loop recorder or AliveCor) and manual assessment is required [7, 12]. However, it may be speculated that evaluation of ECG recordings obtained using such recorders as TTM can be performed by primary care physicians and not necessarily by cardiologists. ECG strips are usually of very good quality and identification of P wave as well as diagnosing AF is easy in almost all recordings.

Our study confirmed previously published data that early AF recurrences (during so-called blanking period) may have prognostic significance and these patients have more AF recurrences during long-term follow-up [13]. This shows that it is probably wise to monitor patients after AF ablation also during blanking period and perhaps modify therapeutic decisions based on these results.

Finally, the role of remote ECG monitoring in the modern era of smartphones, internet, and wireless devices is rapidly growing and will certainly diminish the use of standard Holter ECG in AF detection after ablation. In addition, COVID-19 epidemic drastically showed that all monitoring techniques requiring patient personal presence in hospital or clinic for fitting equipment and giving it back may not be accepted by some patients. In addition, restrictions in patient transportation and locomotion make the usage of traditional ambulatory ECG monitoring even more difficult.

5 Limitations

The study group was relatively small, however, enough to demonstrate the superiority of daily 30-s ECG recordings over standard Holter ECG in detecting AF recurrences. The TTM recordings were performed once-a-day and more frequent recordings (3–4 times-a-day) might have had higher diagnostic yield. The follow-up duration was 1 year and usually more AF recurrences occur during longer follow-up which might have influenced the results. Finally, we had no full knowledge which TTM recordings were elective and which were triggered by symptoms which might have favored TTM over Holter ECG in detecting AF recurrences.

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Declarations

Ethics approval The study was approved by the Bioethics Committee of the Centre of Postgraduate Medical Education (No. 86/PB/2018).

Consent to participate Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare no competing interests.

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