Reliability of an external loop recorder for automatic recognition and transtelephonic ECG transmission of atrial fibrillation

Axel Müller*, Wilfried Scharner†, Tilo Borchardt†, Wolfgang Och* and Harald Korb‡

*Department of Internal Medicine I, Chemnitz Clinic gGmbH, Chemnitz; †Vitasystems GmbH, Chemnitz; ‡Vitaphone GmbH, Mannheim, Germany

Summary
In order to test a newly developed algorithm for detecting atrial fibrillation in clinical practice, we carried out parallel recordings using a conventional 24-h electrocardiogram (ECG) monitor and telemonitoring with an external loop recorder. Recordings were made in 24 patients with persistent atrial fibrillation and in another 24 patients with sinus rhythm. Atrial fibrillation was detected immediately in 23 of 24 patients with persistent atrial fibrillation and 20 min after fitting the single-channel loop recorder in the 24th patient (sensitivity 100%). On average, 3.1 false positives (i.e. detection of an episode, including the end or beginning of atrial fibrillation) were transmitted per patient. The sensitivity of the algorithms for automatically detecting bradycardiac and tachycardiac atrial fibrillation was also high. In 12 of 24 patients with sinus rhythm, false-positive tele-ECGs were transmitted. These were caused by supraventricular or ventricular extrasystoles and by sinus arrhythmias or sinoatrial (SA) blocks. The external loop recorder was very effective at detecting paroxysmal atrial fibrillation. Possible indications for the clinical use of this recorder include, in addition to diagnosis, monitoring patients for atrial fibrillation recurrence after cardioversion or catheter ablation.

Introduction
Atrial fibrillation is the most frequent type of cardiac arrhythmia, affecting over two million adults in the USA. The most important risk factors are arterial hypertension, chronic cardiac insufficiency, diabetes mellitus and a previous myocardial infarction.1–3 Patients with atrial fibrillation have a significantly higher risk of stroke. Persistent and paroxysmal atrial fibrillation are both associated with a high risk of stroke occurrence.4 The crucial factor found to affect a patient’s outcome was sufficient prophylactic anticoagulant therapy using warfarin to protect against thromboembolic events, in particular, strokes.2 In order to treat atrial fibrillation and provide prophylactic therapy to avoid thromboembolic complications, especially strokes, it is important to be able to detect it reliably. With the aid of 7-day electrocardiogram (ECG) monitoring, Jabaudon and colleagues successfully demonstrated atrial fibrillation to be additionally present in 6% of patients with acute stroke or transient ischaemic attack and with normal standard ECG and Holter monitoring. Using the standard ECG, atrial fibrillation could be detected in 3% of the patients and using Holter monitoring in 5% of them.5 This emphasises the value of prolonged ECG monitoring in this group of patients.

Another problem is the lack of specificity in clinical symptoms when atrial fibrillation occurs. For instance, in the Suppression of Paroxysmal Atrial Tachyarrhythmias (SOPAT) study, only 46% of the patients with paroxysmal atrial fibrillation demonstrated symptoms such as palpitations, tachycardia, dyspnoea, chest pain, dizziness, outbreaks of sweating or polyuria during episodes of atrial fibrillation.6 It therefore appears necessary to use procedures which automatically detect episodes of atrial fibrillation in order to be able to initiate appropriate therapeutic measures, such as oral anticoagulation.

The objective of the present study was thus to examine the reliability of a newly developed external loop recorder for the automatic recognition and automatic transtelephonic transmission of ECG data for atrial fibrillation in clinical practice.

Methods
The loop recorder was a single-channel device (3100 BT, Vitaphone, Mannheim, Germany) which weighed 85 g and was 80 × 100 × 14 mm in size (Figure 1). It recorded event
ECGs either manually, when triggered by the patient, or automatically when there was atrial fibrillation, bradycardia, tachycardia or pauses. The automatic detection of fibrillation was based on recognition of arrhythmia in the QRS complex, as the fibrillation waves are not a safe criterion for automatic recognition due to their low amplitude. False-positive findings were primarily possible due to supraventricular extrasystoles, sinus arrhythmia and sinoatrial (SA) blocks.

To prevent continuous recording and transmission of ECGs during longer periods of atrial fibrillation, only the beginning and end of a fibrillation episode were recorded. Figures 2 and 3 show a single-channel tele-ECG using the automatic detection of atrial fibrillation and the end of an episode with paroxysmal fibrillation. For the device, bradycardia was defined as a heart rate of less than 40/min and tachycardia as a heart rate of more than 140/min.

The length of the ECG recording could be set from 25 s to 300 s before the event and from 15 s to 120 s after it. Overall, the loop recorder could record events for up to 40 min. For the present study, the times selected were 30 s before the event and 60 s after it. This meant that the ECG recorded was from 30 s before detection of the event to 60 s after it. Codes designating the type of event (manual triggering, beginning of atrial fibrillation, end of atrial fibrillation, bradycardia, tachycardia and pauses) were always transmitted. This made it possible to classify the event detected by the loop recorder. After the recording, the ECG was automatically transmitted to a mobile phone via a Bluetooth connection. As the telephone number of the central office was stored in the recorder, the ECG transmitted to the phone via Bluetooth after the recording was sent automatically, without the patient having to take any action whatsoever.

At the central office, the ECG and the other transmission data were processed so that they could be sent to the physician via email or fax straightaway. Personal privacy was guaranteed because only the device number was transmitted, not patient details. The ECG data were also encoded for security. The ECG was evaluated either on a printout or by using the ECG viewer software.

The reference method for the external loop recorder was 24-h ECG recording. A three-channel recorder was employed (CardioMem CM 3000, Getemed, Teltow, Germany), using adhesive electrodes (Blue Sensor, Ambu, Denmark). The electrodes of the 24-h ECG and the external

![Figure 1](image1.png)  
**Figure 1** Single-channel loop recorder (Vitaphone 3100 BT) for automatic recognition of atrial fibrillation and transtelephonic ECG transmission

![Figure 2](image2.png)  
**Figure 2** A single-channel tele-ECG with automatic detection of fibrillation using the newly developed algorithm
loop recorder were linked to the patient via a T electrode connector (Figure 4). This guaranteed that the ECG was recorded from the same points.

After approval by the appropriate ethics committee, 48 consecutive patients were enrolled at the Department of Internal Medicine I at the Chemnitz Clinic. The inclusion criterion was the presence of an indication for a 24-h ECG. Patients with antibradycardiac pacemakers and implantable cardioverters and defibrillators (ICDs) were excluded.

Results

There were 24 patients with persistent atrial fibrillation and 24 patients with a sinus rhythm (see Table 1).

Patients with persistent atrial fibrillation

Fibrillation was detected in 23 of the 24 patients with persistent atrial fibrillation immediately after the loop recorder was fitted. In the 24th patient, fibrillation was not detected, and the tele-ECG was not transmitted until 20 min after the loop recorder was put on. The loop recorder thus achieved a sensitivity of 100% for detecting atrial fibrillation.

During the 24-h observation period, further tele-ECGs were transmitted for 16 of the 24 patients (67%). In these cases, the loop recorder incorrectly detected episodes (end or beginning of atrial fibrillation phases), i.e. these were false-negative results. In other words, the device incorrectly detected the end of an episode of atrial fibrillation. Thus in these 16 patients, 75 additional tele-ECGs were transmitted. For each of the 24 patients with atrial fibrillation, an average of 3.1 false positives (detecting an episode with the end or beginning of atrial fibrillation) were transmitted per patient.

The loop recorder automatically detected episodes of bradyarrhythmic and tachyarrhythmia during atrial fibrillation. For four of the 24 patients, a total of 180 episodes (3–88 episodes) of bradyarrhythmic fibrillation were detected and corresponding tele-ECGs were transmitted.

Table 1 Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Patients with atrial fibrillation</th>
<th>Patients with sinus rhythm</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>No. of males</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>Mean age, years</td>
<td>65 (39–83)</td>
<td>57 (17–76)</td>
</tr>
</tbody>
</table>

Figure 3 A single-channel tele-ECG showing the automatically triggered recording of the end of an episode of paroxysmal fibrillation

Figure 4 Test arrangement for the simultaneous recording of an ECG with a 24-h ECG (CardioMem CM 3000, Getemed) and with the loop recorder using a T-electrode connector
bradyarrhythmia was incorrectly detected in two patients during atrial fibrillation. In this connection, 25 tele-ECGs (5 in one patient, 20 in the other) were transmitted. There were no false-negative results for any patient during atrial fibrillation (Table 2). A total of 427 episodes of unlimited tachyarrhythmia with atrial fibrillation (heart rate >140/min) were correctly detected in 14 of the 24 patients, while 13 false-positive episodes with tachyarrhythmic atrial fibrillation were detected in three patients. Only one episode of tachyarrhythmic atrial fibrillation was incorrectly detected in one patient (Table 2). Overall, there were 38 episodes of false-positive brady- or tachyarrhythmic atrial fibrillation. This corresponds to an average of 1.6 episodes for each of the 24 patients.

All the episodes of unlimited bradyarrhythmia were detected. Only one of the 428 episodes of tachyarrhythmic atrial fibrillation was not detected, based on a comparison with the 24-h ECG.

Patients with sinus rhythm

In 12 of the 24 patients with a sinus rhythm, 124 tele-ECGs were recorded and transmitted during the 24-h recording as a result of a false detection of atrial fibrillation. This corresponds to a rate of 5.2 false-positive tele-ECGs per patient. These false-positive results were caused by supraventricular or ventricular extra systoles (46 tele-ECGs for ten patients) and sinus arrhythmia or blockage (78 tele-ECGs for three patients). The results of the automatic detection of atrial fibrillation with regard to sensitivity and specificity are shown in Table 3. The algorithm used for automatic detection of atrial fibrillation thus demonstrated a sensitivity of 100% and a specificity of 50%.

Discussion

External loop recorders have been employed to detect arrhythmias since the end of the 1980s. Precise ECG documentation of the arrhythmias is a precondition for effective therapy. In patients with symptoms (palpitation alone, presyncope, syncope with or without palpitation), it was possible to use a 320-g loop recorder to make 80-s recordings (70-s pre-event and 10-s post-event) that were triggered by the patient. The ECGs thus recorded were printed out a week later using an ECG device. With this system, we succeeded in proving the presence of paroxysmal atrial fibrillation in 10 of 100 consecutive patients.

The advantage of the external loop recorder is in detecting the initial sequence of the arrhythmias and recording short phases of arrhythmias. Transtelephonic ECG monitoring permits rare or sporadic episodes of such symptoms to be documented (e.g. palpitations, dizziness) if the 24-h Holter ECG is inconspicuous.

Despite their promise, these systems have not been able to fully establish themselves in clinical practice. In addition to the substantial weight of a loop recorder, it was not possible for the recorder to automatically detect atrial fibrillation or to transmit the ECG via telephone within a short period of time. Limitations on transtelephonic ECG monitoring also resulted in some cases because the clinical symptoms lasted only a short period of time and because patients found it difficult to use the systems.

The low sensitivity and specificity for the clinical symptoms was particularly problematic for detecting paroxysmal atrial fibrillation. In the Prevention of Atrial Fibrillation After Cardioversion (PAFAC) study, 848 patients with atrial fibrillation were randomized into three groups (therapy using placebo, sotalol and quinidine/verapamil) following successful cardioversion in the sinus rhythm. The follow-up observation utilized ECG monitoring cards. Once a day, the patients recorded a single-channel ECG for a period of 1 min. The ECG was transmitted via telephone to a centre for evaluation. Only 181 of the 605 patients (30%) with renewed occurrence of atrial fibrillation after cardioversion had the corresponding symptoms.

The traditional diagnostic methods (12-channel ECG, 24-h ECG) exhibit a low sensitivity for detecting asymptomatic atrial fibrillation. In the BEATS (Balanced Evaluation of Atrial Tachyarrhythmias in Stimulated Patients) study, for example, a 12-channel ECG, a 24-h ECG, and an intracardiac two-channel ECG (EGM) were compared with regard to detecting paroxysmal atrial tachyarrhythmias in 254 patients with a dual-chamber pacemaker. Using the 12-channel ECG and the 24-h ECG,

### Table 2 Automatic detection of bradyarrhythmic (heart rate <40/min) or tachyarrhythmic (heart rate >40/min) atrial fibrillation

<table>
<thead>
<tr>
<th></th>
<th>Number of patients</th>
<th>Number of transmitted tele-ECGs</th>
<th>Mean number of tele-ECGs per patient/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bradyarrhythmia in atrial fibrillation correctly detected</td>
<td>4</td>
<td>180 (3–88)</td>
<td>45</td>
</tr>
<tr>
<td>Bradyarrhythmia false positive</td>
<td>2</td>
<td>25 (5–20)</td>
<td>12.5</td>
</tr>
<tr>
<td>Bradyarrhythmia false negative</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Tachyarrhythmia in atrial fibrillation correctly detected</td>
<td>14</td>
<td>427 (2–76)</td>
<td>30.5</td>
</tr>
<tr>
<td>Tachyarrhythmia false positive</td>
<td>3</td>
<td>13 (1–10)</td>
<td>4.3</td>
</tr>
<tr>
<td>Tachyarrhythmia false negative</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

### Table 3 Sensitivity and specificity of the initial automatic recognition of atrial fibrillation with the loop recorder for 48 patients with sinus rhythmic or permanent fibrillation

<table>
<thead>
<tr>
<th></th>
<th>Patients with permanent atrial fibrillation (n = 24)</th>
<th>Patients with sinus rhythm (n = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinus rhythm or atrial fibrillation correctly detected</td>
<td>24</td>
<td>12</td>
</tr>
<tr>
<td>Sinus rhythm or atrial fibrillation incorrectly detected</td>
<td>0</td>
<td>12</td>
</tr>
</tbody>
</table>
it was possible to detect atrial tachyarrhythmias in 37 patients (15%), in contrast to 137 patients (54%) using EGM. At the time of arrhythmia, 108 of the 137 patients (79%) with documented atrial tachyarrhythmias were asymptomatic. On the other hand, 70 of the 117 patients without atrial tachyarrhythmias reported corresponding symptoms (palpitations, rapid heart rate, dyspnea or dizziness). The reported symptoms thus showed a sensitivity of 21% and a specificity of 40% for the manifestation of atrial tachyarrhythmias.\textsuperscript{12}

Senatore and colleagues used daily transtelephonic ECG monitoring (30-s ECG recording) and found that there was a recurrence of atrial fibrillation in 20 of 72 patients (28%) during a 90-day follow-up period after successful radiofrequency ablation. The recurrence was only detected in 14% of the patients ($P < 0.001$) using a 12-channel ECG and a 24-h ECG. Ten of the 20 patients with a recurrence had at least one asymptomatic episode of atrial fibrillation, and eight were completely asymptomatic.\textsuperscript{12} The authors concluded that the rate of recurrence following catheter ablation or drug therapy was underestimated by evaluations of clinical symptoms and the use of a 12-channel ECG and a 24-h ECG. This has far-reaching consequences on the indication for therapy with oral anticoagulants.\textsuperscript{12}

Event recording with the external loop recorder is an effective clinical and economic supplement to the well-known diagnostic instruments (12-channel ECG, 24-h ECG). In contrast to an implantable loop recorder, the external devices are noninvasive and are more economical.\textsuperscript{13}

In the present study, the sensitivity for automatic detection of atrial fibrillation was 100%. Atrial fibrillation and other forms of arrhythmia are recognized by the loop recorder on the irregularity of the R wave. This inevitably leads to false-positive recordings, particularly with sinus arrhythmias, SA blocks and supraventricular extrasystoles. The quality of R-wave recording is thus crucial for the automatic detection of atrial fibrillation as well as for recognition of bradyarrhythmias or tachyarrhythmias. Modifications to the newly developed algorithm that is integrated into the loop recorder for automatically detecting atrial fibrillation would be at the cost of sensitivity. Another aspect is the possibility of automatically transmitting the ECG transtelephonically within a short period of time. A transtelephonic medical service centre could inform the patient by telephone at any time of the detected arrhythmia and initiate the appropriate measures. Another aspect is the use of coumarins to manage oral anticoagulation. The goal of using vitamin K antagonists is to prevent thromboembolism (stroke, peripheral embolism).\textsuperscript{15} Mistakes in oral anticoagulation can lead to thromboembolic complications and to other bleeding. One form of telemedical anticoagulation management was tested in one of the first pilot studies with the TOPCARE telemedicine system (Telematic Homecare Platform in Cooperative Health Care Provider Networks).\textsuperscript{16} The patients determined their international normalized ratio (INR) value at home using a monitor (CoaguChek, Roche Diagnostik, Mannheim). The INR data were then transmitted via telephone to the hospital. The patient was informed by telephone about the changes in warfarin therapy. Despite some technical problems, the system appeared to both patients and medical staff to be suitable for anticoagulation management.\textsuperscript{16}

The combination of telemedical management of rhythm and anticoagulation makes it possible to extend the therapeutic measures and increase patient safety. Close coordination between the general practitioner, cardiologist and neurologist appears to be necessary in order to tackle the growing challenges regarding the optimum steps for stroke prevention and managing the rhythm of patients with atrial fibrillation.\textsuperscript{3}

In the present study, a newly developed external loop recorder for the automatic detection and transtelephonic ECG transmission of atrial fibrillation was tested in clinical practice. Patients felt only minor discomfort from the device and judged it to be simple to operate. The new device offers a diagnostic aid for automatic recognition of atrial fibrillation and automatic transtelephonic transmission of ECG data.
A Müller et al. Reliability of a tele-ECG recorder

References


