DEVELOPMENT OF A NEW ACTIVITY-INPUT-TYPE AMBULATORY ELECTROCARDIOGRAM AND ITS CLINICAL USEFULNESS

KYOICHI ISHIZAKA, M.D., AKIRA KOBAYASHI, M.D.
AND NOBORU YAMAZAKI, M.D.

There are some problems with interpretation of the results of ambulatory electrocardiographic monitoring of patients with angina pectoris. To eliminate some of these difficulties, we developed a new activity-input-type ambulatory electrocardiogram which could simultaneously record the electrocardiogram and the patient's activities. Daily activities were classified into 8 levels from lying down to running or climbing a slope, in order to record them as analyzable square waves. Accuracy of the activity input to this equipment in 10 patients with effort angina was good, with 86.7% accuracy for eating and 91.7% for defecation. A comparison was made between the first and second recordings of daily activity changes in each exertional level. The numbers, mean duration and maximum duration of actions in each level were not always equal, and often changed between the two recordings. Maximum ST depression in each exertional level showed a favorable correlation of r=0.931 (by 1.76±0.59 vs 1.77±0.66) between the first and the second recordings. The descriptions of activities recorded in patients diaries are unreliable indicators of time, because subjects check the time sometimes during, and sometimes after, the actions concerned. This equipment can easily make real-time recordings of such information, and thus provide advantages in research.

When observing the pathologic condition of patients with angina pectoris and evaluating anti-anginal drug efficacy, information on the activity of each patient is important. This equipment therefore contributes to improving problems of ambulatory electrocardiographic monitoring for the patients with angina pectoris.

AMBULATORY electrocardiographic monitoring is a safe method of observation of electrocardiograms influenced by physical and mental stresses in daily activity. It has been widely used for observation of arrhythmias and myocardial ischemia and for evaluation of the efficacy of drugs. Recently, it has been reported to be useful for observation of asymptomatic ST change in everyday life. However, there are some problems in the evaluation of anti-anginal drug efficacy using ambulatory electrocardiographic monitoring, such as the effects on the electrocardiogram of changing posture during activity and variations in the levels of daily activity of individual patients.

In evaluation of drug efficacy for patients with angina pectoris, it is very important to study accurately the relationships between activity, angina attack, and ST change. Daily activities are, however, variable and use equal. Winsor et al. and Rod et al. have given attention to these problems and have

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Third Department of Internal Medicine, Hamamatsu University School of Medicine, Hamamatsu, Japan
Mailing address: Noboru Yamazaki, M.D., Professor, Third Department of Internal Medicine, Hamamatsu University School of Medicine, 3600 Handa-cho, Hamamatsu 431-31, Japan

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attempted to classify daily activities into constant exertional levels. They divided the ambulatory electrocardiograms into 7 subsets according to activities assessed using patients' diaries.

We developed a new activity-input-type ambulatory electrocardiogram which can record simultaneously information relating to levels of exertion, and electrocardiograms. This enables us to evaluate trends in exertional levels, heart rate and ST changes at a time. This study was designed for the purpose of finding an effective way of analyzing data from ambulatory electrocardiographic monitoring. The study was conducted using this equipment as follows: (1) Changes of activities between the first and the second recordings were observed in patients with effort angina; (2) in order to study the reproducibility of ST change, maximum ST depressions in the first and second recordings were compared at each exertional level.

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Activity-input-type Ambulatory Electrocardiogram

Structure and Function of the Activity-Input-Type Ambulatory Electrocardiogram

Figure 1 shows new activity-input-type ambulatory electrocardiographic recorder.

This equipment contains circuits for input of 8 exertional levels, and an electronic metronome for pacing exercise walking. The circuits can produce 8 kinds of square waves. Activity is classified into 8 exertional levels as follows: level 1, lying down; level 2, reading and watching TV in sitting position; level 3, light work in standing position; level 4, eating meals; level 5, defecation; level 6, slow walking; level 7, exercise walking (5.6 km/h corresponding to 4.0–5.0 Mets); level 8, running or climbing a slope.

The metabolic cost in each representative exertional level was estimated to be from 1.0 to 8.0 Mets\(^{23}\) (Table I) However, we can change the exertional levels which will be input in the equipment, according to the triggers and the severity of ischemia of the patients.

When a patient selects a key corresponding to the level of an activity about to be performed, a square wave of 40 ms width is instantly recorded on a tape at intervals of 2.40, 1.20, 0.80, 0.60, 0.48, 0.40, 0.34 and 0.30 seconds (Fig. 2). Each exertional level is expressed as an histogram on a trend sheet, as shown in Fig. 3 and Fig. 4. Our advanced model inputs data in a digital form.

In order to give a constant exercise load during ambulatory electrocardiographic monitoring, the equipment has an electronic metronome for pacing. When the patient selects the key for exercise walking, the prescribed speed of 5.6 km/h (level 7) is signalled by a metronome tone frequency based on

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Fig. 3. This case is a 46 year-old male with effort angina pectoris. He put on an activity-input-type ambulatory electrocardiogram at 10:40 and started jogging (level 8) at 11:00. The heart rate increased from 75 to 150/min, whereas ST was depressed by 3.2 mm. After several periods of slow walking (level 6), the heart rate increased from 80 to 100/min, whereas ST depression was less than 1.0 mm. In actions of level 8 and 6, reproducible ST change was recognized.

Fig. 4. This case is a 55 year-old male with variant angina pectoris. He put on an activity-input-type ambulatory electrocardiographic recorder at 11:30. He performed frequent slow walking (level 6) in the morning and afternoon. The heart rate increased from 50 to 75/min, whereas ST depression of more than 1.0 mm was not recognized. However, at 3:10 while sleeping, ST depression for 2 min and subsequent ST elevation were recognized. The heart rate increased from 55 to 105/min according to ST elevation.
TABLE II SUBJECTS

<table>
<thead>
<tr>
<th>No.</th>
<th>Age</th>
<th>Sex</th>
<th>Coronary angiographic findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>62</td>
<td>M</td>
<td>LAD 75%, LCX 90%, RCA 95%</td>
</tr>
<tr>
<td>2</td>
<td>67</td>
<td>F</td>
<td>LMT 50%, LAD 100*, LCX 75%, RCA 99%</td>
</tr>
<tr>
<td>3</td>
<td>40</td>
<td>F</td>
<td>LMT 50%, LAD 50%, LCX 50%</td>
</tr>
<tr>
<td>4</td>
<td>65</td>
<td>M</td>
<td>LAD 100*, LCX 75%, RCA 100*</td>
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<tr>
<td>6</td>
<td>53</td>
<td>M</td>
<td>LAD 90%, LCX 90%, RCA 99%</td>
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<td>7</td>
<td>77</td>
<td>M</td>
<td>LAD 100*, LCX 75%, RCA 75%</td>
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<td>69</td>
<td>M</td>
<td></td>
</tr>
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<td>9</td>
<td>70</td>
<td>M</td>
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</tr>
<tr>
<td>10</td>
<td>72</td>
<td>M</td>
<td>LAD 90%, LCX 90%, RCA 90%</td>
</tr>
</tbody>
</table>

62.9±11.0 years old

LAD: Left anterior descending artery, LCX: Left circumflex artery, LMT: Left main trunk, RCA: Right coronary artery. *: Collateral flow (+)

the patient's stride length.

To reduce error, the selected key lights up. Also, to reduce input chattering by the patient, each key is recessed 2 mm and has to be pushed for 1 second to function.

Figure 3 and 4 show analyses of ambulatory electrocardiographic monitoring using this equipment in patients with effort and rest angina. The trend-gram enables us to find easily any correlations between changes in exertional level, heart rate, and ST segment characteristics.

Clinical Application

Method

Subjects: The subjects were 10 patients (8 males and 2 females, 62.9±11.0 years old) with severe effort angina pectoris who experienced chest pain in daily activities and showed significant ischemic change on their electrocardiograms on angina attack or exercise loading. Patients with bundle branch block or taking cardiac glycosides were not included, because these conditions were considered to interfere with analysis of ST segment changes. (Table II).

Ambulatory Electrocardiographic Monitoring: Tracker I was used, which is a direct recording ("AM") system. An electrocardiogram with a bipolar lead formed the input. We chose CM5, because this lead was the nearest precordial lead of maximum ST segment depression in the previous exercise loading. As mentioned previously, information on the exertional level of daily activity was inputted from the keyboard through a pulse generator as square waves simultaneously with the input from the electrocardiogram.

Ten patients with severe effort angina pectoris were recorded 2 times in one week using this equipment. Changes in activity between the first and second recordings were observed, and changes in the number, mean duration, and maximum duration of actions in each exertional level were compared. The accuracy of key input was checked through questioning of the patient. Maximum ST depressions at each exertional level in the two recordings were also compared, in order to check the reproducibility of the data and permit reliable evaluation of the efficacy of anti-anginal drugs.

For analysis of the electrocardiogram, a Pathfinder II was used. Exertional level was conventionally assessed through heart rate analysis, and ST segment was measured 40 ms after the J point. Data for ST depression were collected at each exertional level, and the data for each exertional level were determined as the maximum level of ischemic ST depression during 24 h. For example, Fig. 5 shows trend sheets of case 6 in the first and the second recording. In the first recording period, the activity-input-type ambulatory
electrocardiographic recorder was activated at 14:45. The patient performed light work in a standing position (level 3) seven times, slow walking (level 6) ten times, exercise walking (level 7) once, and climbing a slope (level 8) 3 times. Maximum ST depressions in level 3 (11:40), level 6 (13:40), level 7 (15:30) and level 8 (16:50) were 1.4 mm, 2.9 mm, 2.0 mm, and 1.6 mm, respectively. In the second recording, the recording was begun at 13:40. The patient performed at level 3, 4 times, level 6, 11 times, and level 8 once, but did not perform at level 7 during this period. Maximum ST depressions in level 3 (10:50), level 6 (16:20), and level 8 (16:50) were 1.3 mm, 2.7 mm, and 2.6 mm.
respectively.

Statistics: The data obtained from the study are expressed as mean±SD. Mean values for measurements in the first and the second recording were compared. Reproducibility of maximum ST segment changes between the first and the second recording was measured using the correlation coefficient.

RESULTS

Changes in Number of Actions in Each Exertional Level between the First and the Second Recordings

Figure 6 shows a scatter plot for each exertional level.

(1) In lying down (level 1), 7 out of 10 cases corresponded both time. The frequency in 1 case was greater and that in 2 cases was less in the second recording than that in the first (r=0.301).

(2) In reading or watching TV in a sitting position (level 2), 2 out of 10 cases corresponded. Two cases increased, and 6 decreased in the frequency of this action (r=0.664, y=0.54x + 3.45).

(3) In light work in the standing position (level 3), 1 case corresponded. An increase occurred in 2 cases, and a decrease in 7 (r=0.823, y=0.55x + 0.49).

(4) In taking a meal (level 4), correspondence was found in 8 cases, increase in one, and decrease in one. Upon inquiry, all patients said that they ate meals 3 times daily (total 60 times). On the activity trendgram, the frequency was 52 times (86.7%), so that 8 inputs were missed (r=0.583, y=0.58x + 1.08).

(5) In defecation (level 5), there was correspondence in 4 cases, increase in 3, and decrease in 3. The number upon inquiry was 24, while 22 were recorded in the activity trend (91.7%) (r=−0.309).

(6) In slow walking (level 6), correspondence was found in 3 cases, increase in one, and decrease in 6 (r=0.575, y=0.44x + 2.04).

(7) In exercise walking (level 7), correspondence was found in 3 cases, increase in 2,
and decrease in 5 ($r=0.008$).

8) In running or climbing a slope (level 8), correspondence was seen in 5 cases, increase in one, and decrease in 4 ($r=0.608$, $y=0.53x+0.16$).

Thus, in the comparative study of changes in the number of actions in each exertional level between the first and the second recordings, a correspondence of more than 70% was recognized in lying down (level 1) and eating (level 4). However, the correspondences in other exertional levels were lower by 10 to 50%.

Changes in The Mean Duration of Actions in Each Exertional Level between the First and Second Recordings

Figure 7 shows a scatter plot for each exertional level.

1) In lying down (level 1), the mean duration was from 74 to 580 min (mean±SD: 400.7±196.2 min) in the first recording period, and from 68 to 675 min (440.9±198.1 min) in the second recording period. The mean duration was increased in 6 cases ($r=0.784$, $y=0.79x+124.0$).

2) In reading or watching TV in a sitting position (level 2), the mean duration was from 17 to 80 min (50.3±21.9 min) in the first recording period, and from 30 to 158 min (61.8±38.5 min) in the second. Six cases showed an increase in mean duration between the 2 recordings. ($r=0.616$, $y=1.08x+7.4$)

3) In light work in a standing position (level 3), the mean duration was from 0 to 71 min (32.8±24.2 min) in the first recording period, and from 0 to 63 min (21.3±21.1 min) in the second. Two cases showed an increased duration in the second recording. ($r=0.371$)

4) In taking a meal (level 4), the mean duration was from 12 to 32 min (21.0±6.9 min) in the first recording period, and from
10 to 30 min (19.4 ± 6.3 min) in the second. Five cases showed an increased duration in the second recording. (r=0.384)

(5) In defecation (level 5), the mean duration was from 0 to 40 min (11.7 ± 11.3 min) in the first recording period, and from 0 to 15 min (6.5 ± 4.1 min) in the second. One case demonstrated an increase between the two recordings. (r= -0.200).

(6) In slow walking (level 6), the mean duration was from 5 to 31 min (16.7 ± 9.6 min) in the first recording period, and from 6 to 43 min (19.5 ± 11.7 min) in the second. Seven cases were found to have an increased duration in the second recording. (r=0.642, y=0.78x + 6.5)

(7) In exercise walking (level 7), the mean duration was from 0 to 21 min (7.7 ± 5.9) in the first recording period, and from 0 to 28 min (9.4 ± 9.3 min) in the second. The mean duration in the second recording was longer in few cases. (r=0.586, y=0.93X + 2.2)

(8) In running or climbing a slope (level 8), the mean duration was from 0 to 10 min (4.3 ± 4.2 min) in the first recording period, and from 0 to 20 min (4.3 ± 6.7 min) in the second. Two cases showed an increased duration in the second recording. (r=0.631, y=1.11x + 5.3)

In the comparative study of changes in the mean duration in each exertional level, level 1, level 2, level 6 and level 8 showed a moderate correlation between the first and second recordings, but reproducibility of the data was not so high in level 1, level 2 and level 6.

Changes in The Maximum Duration of Actions in Each Exertional Level between the First and Second Recordings

Figure 8 shows a scatter plot for each exertional level.

(1) In lying down (level 1), the maximum duration of activity in each exertional level
was from 390 to 580 min (mean±SD: 500.2±66.0 min) in the first recording period, and from 370 to 675 min (538.4±84.6 min) in the second. Five cases increased in the maximum duration of this action between the two recordings. \((r=0.112)\)

(2) In reading or watching TV in a sitting position (level 2), the maximum duration was from 42 to 234 min (144.6±69.1 min) in the first recording period, and from 72 to 222 min (139.2±52.5 min) in the second. Six cases increased in maximum duration in the second recording. \((r=0.267)\)

(3) In light work in a standing position (level 3), the maximum duration was from 0 to 180 min (64.0±63.7 min) in the first recording period, and from 0 to 210 min (56.2±66.9 min) in the second. Four cases exhibited a longer duration in the second recording. \((r=0.647, y=0.68x+12.2)\)

(4) In taking a meal (level 4), the maximum duration was from 12 to 45 min (28.2±11.5 min) in the first recording period, and from 5 to 40 min (23.1±11.2 min) in the second. Two cases showed an increased duration in the second recording. \((r=0.332)\)

(5) In defecation (level 5), the maximum duration was from 0 to 40 min (12.3±11.6 min) in the first recording period, and from 0 to 20 min (8.0±5.9 min) in the second. One case showed an increase in duration in the second recording. \((r=−0.434)\)

(6) In slow walking (level 6), the maximum duration was from 6 to 78 min (36.1±21.7 min) in the first recording period, and from 6 to 100 min (37.1±27.0 min) in the second. Three cases showed an increased duration in the second recording. \((r=0.354)\)

(7) In exercise walking (level 7), the maximum duration was from 0 to 24 min (9.7±7.1 min) in the first recording period, and from 0 to 36 min (15.1±12.9 min) in the second. Four cases increased in maximum duration in the second recording. \((r=0.402)\)

(8) In running or climbing a slope (level 8), the maximum duration was from 0 to 15 min (5.4±5.6) in the first recording period, and from 0 to 35 min (6.5±12.5) in the second. Two cases showed an increased

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**Fig. 9. Reproducibility of maximum ST depression. The horizontal axis shows maximum ST depression in the first recording, whereas the vertical axis shows maximum ST depression in the second recording.**
duration in the second recording. \( r = 0.435 \)

In the comparative study of changes in the maximum duration in each exertional level in the first and second recordings, level 3 showed moderate correlation, though the reproducibility of the data was not high.

**Reproducibility of maximum ST Depression between the First and the Second Recordings**

Corresponding ST depression was recognized in 26 exertional levels, and this reproducibility of maximum ST depression was studied (Fig. 9). The regression line was 
\[ y = 1.04x - 0.07 \ (1.76 \pm 0.59 \ vs \ 1.77 \pm 0.66), \]

hence there was good correlation between the first and the second recordings \( r = 0.931 \); so highly reproducible ST sampling could be done.

**DISCUSSION**

In the evaluation of anti-anginal drug efficacy for patients with angina pectoris, wide use has been made of electrocardiograms with graded exercise loading as an objective examination method. Ambulatory electrocardiographic monitoring, which has a high safety profile and allows recording in everyday life, has been used for patients with effort angina\(^5\)–\(^10\), rest angina\(^24\) or unstable angina\(^25\). However, there are some problems with interpretation of the information obtained by ambulatory electrocardiographic monitoring.

A consistent routine does not exist for daily activities, and equivalent activities are not performed each day. Winsor et al\(^{21}\) attempted to sort daily activities into constant exertional levels in 2 recording periods. They classified daily activities into 7 exertional levels and divided the recorded electrocardiograms into 7 subsets for those exertional levels. Complicated data from ambulatory electrocardiographic monitoring were analyzed for each exertional level, and 7 data subsets per day were considered. They analyzed heart rate and ST changes, in order to evaluate them, in each exertional level according to diaries kept by patients.

To simplify this method, we developed an activity-input-type ambulatory electrocardiogram which allowed us to simultaneously input exertional levels and electrocardiograms, and to express them as a trend-gram. Then, we studied the clinical usefulness of this equipment.

In order to check the accuracy of input by patients during the recording, the number of instances of eating and defecation obtained from inquiry and trend-gram were compared. The number of meals eaten according to inquiry was 60 in total, whereas the number in the activity trend-gram was 52 in total (86.7%). The number of defecations according to the inquiry was 24, whereas the number in the trend-gram was 22 (91.7%). Thus, it was considered that satisfactory accuracy was obtainable.

In this study, patients were instructed that similar activities should be performed during each recording. However, correspondence rates of more than 70% were recognized for the activities of lying down and eating meals. The rates in the other activities ranged from 10 to 50%. We also studied the changes in the mean duration and maximum duration of individual cases in each exertional level between two recordings.

In mean duration, level 1, level 2, level 6 and level 8 moderate correlation was shown. But reproducibility of those data was not high in level 1, level 2 and level 6. In maximum duration, level 3 shows moderate correlation, but again the reproducibility of those data was low. Thus, daily activities in both periods are changeable. Therefore, this activity-input-type ambulatory electrocardiogram is useful for checking the correlations between the changes in activity, heart rate and ST segment.

Winsor et al\(^{21}\) and Rod et al\(^{22}\) reported that patients’ daily activities were not equal and then classified activities into seven exertional levels, from lying down to heavy work. In corresponding activities during observation and treatment periods, ST segments were compared to evaluate the efficacy of drugs, according to diaries kept by patients.

However, the analysis referring to diaries was sometimes troublesome either because the times entered by some patients in their diaries were wrong or because broad descriptions were used. There were two difficulties in the patients’ diaries. First, patients must write the time and activities on the diaries when they perform activities. It is very complex work for patients to check the time and

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write it on the diaries. But this equipment is very convenient for patients because they can record the time and activities at the touch of the key pad. Second, interpreters must analyze whole electrocardiograms and make retrograde searches for changes in the electrocardiograms according to the diaries, which is not real-time analysis. But this new equipment can make real-time recording of information on activities.

We also obtained high reproducibility of maximum ST depression in each exertional level using the activity-input-type ambulatory electrocardiogram. It was considered to be useful for the evaluation of anti-anginal drug efficacy. In our study, subjects were patients with severe effort angina pectoris, so the exertional levels in our classification and equipment were lighter efforts than those by Winsor et al.21 and Rod et al.22 We can, however, change the grade of the exertional levels inputted to this equipment, according to the triggers and the severity of ischemia of patients. If we use it for patients with rest angina, we can change the items of activities into smoking, hyperventilation, mental stresses and so on. We can also change the speed of the electronic metronome in level 7 (exercise walking) according to the patients’ characteristics.

For the aged and patients with severe effort angina pectoris who can not perform treadmill exercise, this equipment is considered to be useful.

As recommended by American Heart Association,23 Krasnow24 reported that ST changes on ambulatory electrocardiographic monitoring were affected by body position, which would disturb diagnosis of ST changes. Tanabe et al.26 developed a positional sensor and then made simultaneous recordings of body position and electrocardiograms. They reported that simultaneous recording of information on body position and electrocardiograms was useful in the evaluation of ischemic ST change.27 They also reported that the ST segment was influenced by anteflexional left torsional lateral decubitus position when lying down. In Fig. 5, there are ST depressions at 0 and 6 o'clock while sleeping, but these are false ST depressions caused by body position.

Although it is difficult to infer the detailed body position in lying down without positional sensors, information on the body position, except when lying down, is almost implied if the activities are known. Continuous recording of information on activities is thus also useful for evaluation of changes of electrocardiogram according to body position changes. Shang and Pepine5 studied the relationships between daily activities, ST depression and chest pain in twenty cases of effort angina. Seventy-five percent of cases with ST depression had no chest pain, and ST depression was seen at rest or while slow walking in 72% of those cases.

Under usual analysis of ambulatory electrocardiograms, interpreter goes largely by heart rate to determine whether the patient is probably at rest, engaging in mild or strenuous exercise, up and about, asleep in bed. If our equipment is used, relationships between asymptomatic ST depression and exertional level can be easily and accurately analyzed.

Ischemia frequently induces important rhythm disturbances. Two electrocardiogram leads for improved accuracy of arrhythmia interpretation are needed, and this feature is included in our advanced model.

This activity-input type ambulatory electrocardiogram will contribute to improvement of problems such as inequality of activities, changes of body position and asymptomatic ST depression, in patients with angina pectoris. Particularly, this is useful for the aged and those with severe angina pectoris.

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