ASSESSMENT OF HYPERTENSIVE HEART BY 2-DIMENSIONAL ECHOCARDIOGRAPHY IN MASS SCREENING

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Two-dimensional echocardiography (2DE) was used in the mass screening of 3,017 participants (1,195 males, 1,822 females, mean age 59) living in 13 areas in Japan. The 2DE findings of left ventricular hypertrophy (LVH) and LV function were compared with the presence and severity of hypertension (Ht). Out of 1,100 patients who had an evident history of Ht above 160/95 mmHg (Ht group), 298 patients (27.4%) were complicated by LVH. In contrast, LVH was also recognized in 60 (11.2%) of 535 borderline Ht cases and in 87 (6.3%) of 1,382 normotension cases. LVH cases in the Ht group were divided into 3 groups: mild (220; 73.8%), moderate (63; 21.2) and severe (15; 5.0). Asymmetric septal hypertrophy (ASH) was recognized in 111 patients (37.2%) of the 298 LVH cases. The prevalence of ASH in these LVH patients was higher according to the severity of the LVH: mild LVH=31%, moderate LVH=51% and severe LVH=67%. The prevalence of LVH was higher in males than in females. This was especially apparent in the moderate to severe LVH groups and also noted to be higher according to the increase of mean blood pressure. The prevalence of mild to moderate LVH was significantly higher in the poorly-controlled group than in the well-controlled group. In contrast, no significant difference in prevalence of severe LVH was noted between the well-controlled and poorly-controlled groups. The prevalence of LV dysfunction was significantly greater in moderate or severe LVH groups than in non or mild LVH groups. It tended to be higher in the poorly-controlled group compared with the well-controlled group. The regression of LVH was frequently detected in the well-controlled group by the follow up study. We conclude that 2DE observation of LV performance in mass screening will be extremely valuable in the long term follow-up of Ht patients.

ALTHOUGH the elevation of left ventricular (LV) systolic pressure due to hypertension (Ht) is well known to increase the tension of the LV wall leading to hypertrophic changes!-4 the prevalence of LV hypertrophy (LVH) in association with Ht differs between investigators. Devereux et al examined fixed Ht patients and found LVH in 26-48% of them; not more than half of the Ht patients had LVH? However, there have been only a few reports on the relation between Ht and the prevalence of LVH in Japan? None of these reports were based on surveys of such a large number of cases as detailed in our present study.

Key words:
Hypertensive heart
Left ventricular hypertrophy
Left ventricular function
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Mass screening

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TABLE I LOCATIONS EXAMINED BY 2-DIMENSIONAL ECHOCARDIOGRAPHY IN MASS SCREENING, AND NUMBER OF PARTICIPANTS

<table>
<thead>
<tr>
<th>Locations examined</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karasuyama-Machi (Tochigi)</td>
<td>101</td>
<td>141</td>
<td>242</td>
</tr>
<tr>
<td>Sakuma-Machi (Shizuoka)</td>
<td>109</td>
<td>193</td>
<td>302</td>
</tr>
<tr>
<td>Koya-Machi (Wakayama)</td>
<td>36</td>
<td>76</td>
<td>112</td>
</tr>
<tr>
<td>Nanakai-Mura (Ibaraki)</td>
<td>88</td>
<td>112</td>
<td>200</td>
</tr>
<tr>
<td>Takane-Mura (Gifu)</td>
<td>153</td>
<td>211</td>
<td>364</td>
</tr>
<tr>
<td>Tenkawa-Mura (Nara)</td>
<td>85</td>
<td>153</td>
<td>238</td>
</tr>
<tr>
<td>Miyakejima (Tokyo)</td>
<td>33</td>
<td>53</td>
<td>86</td>
</tr>
<tr>
<td>Moka-City (Tochigi)</td>
<td>70</td>
<td>208</td>
<td>278</td>
</tr>
<tr>
<td>Oohira-Machi (Tochigi)</td>
<td>13</td>
<td>54</td>
<td>67</td>
</tr>
<tr>
<td>Tsukudzu-Mura (Aichi)</td>
<td>294</td>
<td>303</td>
<td>597</td>
</tr>
<tr>
<td>Miwa-Mura (Ibaraki)</td>
<td>65</td>
<td>117</td>
<td>182</td>
</tr>
<tr>
<td>Tateiwa-Mura (Fukushima)</td>
<td>129</td>
<td>193</td>
<td>322</td>
</tr>
<tr>
<td>Ina-Mura (Fukushima)</td>
<td>46</td>
<td>49</td>
<td>95</td>
</tr>
</tbody>
</table>

| Cases                   | 1,222 | 1,863 | 3,085 |

Many investigators have stated that echocardiography can provide more reliable information needed for the detection of cardiac hypertrophy than do chest X-ray studies or electrocardiography. With this in mind, we have employed 2-dimensional echocardiography (2DE) for cardiovascular mass screening in order to improve diagnostic accuracy. In the present study, we evaluated morphological and functional changes associated with Ht in the heart using a large number of cases from various points of view. We especially focused on the relation of the prevalence of LVH with sex, age, the presence or absence of treatment, and the state of blood pressure (BP) control. The most significant findings are described.

SUBJECTS

Thirteen regions in Japan, including some places served by doctors who graduated from Jichi Medical School, were selected as subject regions. Residents (most aged 40 years or older) who volunteered to undergo mass screening for this study after being randomly selected and recommended by the public office, were used as subjects regardless of the current absence or presence of symptoms or past medical history. This study was conducted along with the regular cardiovascular mass screening performed in the subject regions. Mass screening included an interview, physical examination, urinalysis, ECG, chest X-P and blood sample.

The subject regions and the numbers of participants by sex are illustrated in Table I. Adequate echocardiograms were taken in 3,017 cases (1,195 men and 1,822 women -97.8%) out of a total of 3,085. They ranged from 23 to 95 years of age (mean age, 59 years). Sixty-eight patients were excluded due to technically inadequate studies. Out of the study cases that were used, 232 underwent a second echocardiographic examination in the 2-year follow-up. Thus, a total of 3,249 echocardiographic examinations were performed.

The numbers of examinees stratified according to sex and age are illustrated in Fig. 1. Although male and female cases showed similar age distribution patterns, about 1.5 times more females were examined than men; the majority of both were in the 50's and 60's age groups.

METHODS

Thickness of ventricular septum (VST), thickness of LV posterior wall (LVPWT), LV end-diastolic dimension (LVDD) and LV end-systolic dimension (LVDS) were measured using parasternal long-axis echocardiograms. Wall and cavity measurements were made by leading edge methodology. These were obtained by the 2DE method in combination with the M-mode method using a Toshiba SSH-60A ultrasound imaging system. LV end-systolic volume (LVESV) and LV end-diastolic volume (LVEDV) were derived from LV volume (V) calculated by the method of Teichholz et al as V = 7D(3/2)(4+D), where D indicates the short axis. Ejection fraction (EF) was then calculated as EF = (LVEDV-LVESV)/LVEDV. All measurements were conducted at the Department of Cardiology, Jichi Medical School by the authors who have at least 3 years of experience in echocardiography.

LVH was defined as VST and/or LVPWT of 12 mm or more. LVH was graded as one of 3 stages: namely, mild, moderate or severe when the thickness was 12–14 mm, 15–17 mm and 18 mm or more, respective-

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Fig. 1. Age distribution of 3,017 cases studied.

Fig. 2. Prevalence of hypertension group and non-hypertension group. In the hypertension groups, 784 cases were treated with 316 cases untreated. Abbreviation: Ht = hypertension.

ly. We also analyzed LVH for the presence or absence of asymmetric septal hypertrophy (ASH: VST/LVPWT ≥ 1.3). LV dysfunction was defined as 54% or less EF.

The evaluation of Ht was performed by reference to the WHO criteria13 and the criteria established by U.S.A. Joint National Committee in 1988.14 BP was classified as Ht when systolic BP (SBP) ≥ 160 mmHg and/or diastolic BP (DBP) ≥ 95 mmHg, or diastolic BP (DBP) ≥ 95 mmHg, borderline Ht when 140 mmHg ≤ SBP < 160 mmHg and/or 90 mmHg ≤ DBP < 95 mmHg, and normal BP when SBP < 140 mmHg and DBP < 90 mmHg. Ht was further classified as systolic Ht (syst. Ht) when SBP ≥ 160 mmHg and DBP < 95 mmHg, diastolic Ht (diast. Ht) when SBP < 160 mmHg and DBP ≥ 95 mmHg, and as systolic and diastolic Ht (syst. & diast. Ht) when SBP ≥ 160 mmHg and DBP ≥ 95 mmHg. Mean BP was also calculated as DBP + 1/3 pulse pressure.

All of the examinees were divided into Ht and non-Ht groups for comparison. The Ht group was further subgrouped into a treatment group of examinees who had an apparent history of Ht and were receiving oral medication, and a non-treatment group of examinees who were receiving no medication in spite of the presence of Ht at the time of examination, regardless of the presence or absence of a history of Ht. The cases in the treatment group were further divided into a "well-controlled group" when their SBP and DBP levels at the time of examination were maintained at 159 mmHg or lower and at 94 mmHg or lower, respectively. The remaining Ht cases in the treatment group and the Ht cases in the non-treatment group were included in a "poorly-controlled group". We also carried out a comparative study between the well-controlled and poorly-controlled groups.

A 2-year follow-up study was done in regions A and B. Adequate echocardiograms were obtained in 232 cases. In the initial study, 100 cases were identified as being in the Ht group. We assessed the relationship between the progression/regression of LVH and BP control during the interim period between the initial study and the 2-year follow-up.
<table>
<thead>
<tr>
<th>Sex</th>
<th>40's</th>
<th>50's</th>
<th>60's</th>
<th>70's</th>
<th>80's</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>17.9%</td>
<td>29.1%</td>
<td>44.1%</td>
<td>55.4%</td>
<td>70.8%</td>
<td>39.8% (436/1095)</td>
</tr>
<tr>
<td>Female</td>
<td>15.4%</td>
<td>28.2%</td>
<td>45.8%</td>
<td>57.8%</td>
<td>66.7%</td>
<td>37.8% (651/1720)</td>
</tr>
</tbody>
</table>

**Table II: Prevalence of Hypertension Cases by Age and Sex**

**Table III: Causes or Complications of Left Ventricular Hypertrophy in 480 Cases**

<table>
<thead>
<tr>
<th>Causes</th>
<th>Cases</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>298</td>
<td>(62.1)</td>
</tr>
<tr>
<td>Borderline hypertension</td>
<td>60</td>
<td>(12.5)</td>
</tr>
<tr>
<td>Aortic stenosis</td>
<td>26</td>
<td>(5.4)</td>
</tr>
<tr>
<td>HCM</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>HOCM</td>
<td></td>
<td>(1.9)</td>
</tr>
<tr>
<td>Apical hypertrophy</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>OMI</td>
<td>3</td>
<td>(0.6)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>2</td>
<td>(0.4)</td>
</tr>
<tr>
<td>WPW syndrome</td>
<td>1</td>
<td>(0.2)</td>
</tr>
<tr>
<td>Mitral valve prolapse</td>
<td>1</td>
<td>(0.2)</td>
</tr>
<tr>
<td>Unknown (normotensive)</td>
<td>80</td>
<td>(16.7)</td>
</tr>
<tr>
<td>Total</td>
<td>480</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** HOCM = hypertrophic (obstructive) cardiomyopathy, OMI = old myocardial infarction, WPW = Wolff-Parkinson-White.

The measurement of BP was performed by a doctor or nurse using the auscultatory method. Measurements were given in the sitting position on the upper arm at least twice at intervals of 5 minutes. Stable values among the values we obtained were averaged and used for analysis.

Statistical analysis was performed with the $\chi^2$-test; $p<0.05$ was regarded as indicating significant difference.

**RESULTS**

Out of all the 3,017 examinees, 1,100 (36.5%) were classified as the Ht group, of which 784 and 316 were further divided into the treatment and non-treatment groups, respectively (Fig. 2). BP was well controlled in 526 (designated as the well-controlled group) of the 784 cases in the treatment group, while 574, which included the remaining 258 of the treatment group who had Ht at the time of examination and the 316 cases in the non-treatment group, fell in the poorly-controlled group. Among all of the examinees, 555 (17.7%) and 1,382 (45.8%) showed borderline Ht (non-treated) and normal BP, respectively.

Prevalence of Ht by sex is stratified according to age in Table II. Out of 2,815 examinees aged 40 years or older, 1,087 (38.6%) were diagnosed as Ht; 39.8% of men and 37.8% of women were found to have Ht, showing a higher prevalence in males but without significant difference. Although the prevalence increased with aging, there were no significant differences between males and females.

LVH was detected in 480 (15.9%) of all the examinees. These 480 cases with LVH were analyzed in detail with respect to their causative diseases and/or complications (Table III). The majority of them were included in the Ht group. The next highest number of cases was found in the borderline Ht group, while 26 (5.4%) cases were complicated with aortic stenosis. Hypertrophic (obstructive) cardiomyopathy and apical hypertrophy figured in 9 (1.9%) of the cases. However, causative diseases could not be defined in 80 (16.7%) normotensive cases; these cases tended to be more common in the older population than the younger population.

Prevalence of LVH in the Ht, borderline Ht and normotensive groups is illustrated in Fig. 3: 298 of the 1,100 cases in the Ht group, 60 of the 535 cases in the borderline Ht group, 87 (including 3 old myocardial infarctions, 2 atrial fibrillations, 1 WPW syndrome and 1 mitral valve prolapse) of the 1,382 cases in the normotensive group were diagnosed as LVH, showing significant intergroup differences among the 3 groups.

As shown in Fig. 4, LVH was evaluated mild, moderate and severe in the 298 cases from the Ht group, while ASH was seen in 111 cases. Next, we analyzed the prevalence...
of ASH among cases with LVH in the Ht group according to the severity of the LVH (Fig. 5). It indicated that the more severe the LVH, the higher the prevalence of ASH.

When the severity of LVH was compared between males and females in the Ht group (Fig. 6), it was found that mild LVH appeared in 23.8% of males (105/441) and 17.5% of females (115/659). Moderate and severe LVH was seen in 8.4% (37/441) of males and 3.9% (26/659) of females and in 2.7% (12/441) of males and 0.5% (3/659) of females, respectively. In comparison with female Ht cases, male Ht cases were more likely to develop mild to severe LVH; significant differences were especially remarkable in moderate to severe LVH.

Prevalence of complication with LVH by sex in the Ht group is stratified according to age in Fig. 7. LVH was detected in 25.0% of males and 10.5% of females in the 40’s age group, in 34.1% and 19.1% of the 50’s age group, in 38.0% and 22.5% of the 60’s age group, in 36.6% and 25.7% of the 70’s age group, and in 35.3% and 27.1% of the 80’s or older age group. Although the prevalence...
Fig. 5. Prevalence of asymmetric septal hypertrophy in 3 degrees of left ventricular hypertrophy. Abbreviations: NS = not significant, see Fig. 4 for other abbreviation.

Fig. 6. Difference of prevalence and severity of left ventricular hypertrophy by sex. See Fig. 4 for abbreviation.

Fig. 7. Prevalence of left ventricular hypertrophy by age and sex.

of LVH increased with aging, LVH was seen at almost the same degree among all patients aged 70 years or older. Male Ht cases were more frequently complicated with LVH than female Ht cases in all age groups; these differences were the most significant in the 40’s to 60’s age groups.

When the prevalence of complication with LVH in the Ht group was compared between the treatment and non-treatment groups, no significant differences were found even though the prevalence was lower in the treatment group (26.1%; 205/784) than in the non-treatment group (29.4%; 93/316), as shown in Fig. 8. Next, the prevalence of complication with LVH was compared between the well-controlled and poorly-controlled groups. It was found to be significantly lower in the former group (22.1%; 116/526) than in the latter group (31.7%; 10

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Fig. 8. Prevalence of left ventricular hypertrophy in groups identified by treatment and blood pressure control conditions. See Fig. 5 for abbreviation.

Fig. 9. Difference of prevalence and severity of left ventricular hypertrophy by well-controlled or poorly-controlled groups. See Fig. 4 and 5 for abbreviations.

182/527) (p<0.001). As Fig. 9 illustrates, when the prevalence of LVH according to its severity was further compared between the well-controlled and poorly-controlled groups, significant differences were seen in mild to moderate LVH, but not in severe LVH.

Prevalence of syst. Ht, diast. Ht and syst. & diast. Ht among the 574 cases in the poorly-controlled group are stratified according to age in Fig. 10. Diast. Ht was most frequently found in the 40's age group (about half), while syst. Ht more frequently appeared with aging and was found in as many as 80% of the cases in the 80's or older age group. Syst. & diast. Ht was most frequently found in the 50's age group (about 40%), gradually decreasing with age.

Prevalence of LVH in the above-mentioned 3 Ht groups is illustrated in Fig. 11. A significant difference was found between the diast. Ht and syst. & diast. Ht groups (p<0.05), but not between the syst. Ht and diast. Ht groups. However, it tended to
Fig. 10. Prevalence of 3 different hypertension groups in 574 cases by age. Abbreviations: syst. Ht = systolic hypertension, diast. Ht = diastolic hypertension.

Fig. 11. Prevalence of left ventricular hypertrophy in 3 different hypertension groups. See Fig. 5 and 10 for abbreviations.

Fig. 12. Prevalence of left ventricular hypertrophy by mean blood pressure in 1,100 cases.
be higher in the syst. Ht group than in the diast. Ht group.

As Fig. 12 illustrates, the relation between mean BP and the prevalence of LVH was then determined in a total of 1,100 cases, including 574 in the poorly-controlled group and 526 borderline Ht cases (this number excludes 6 aortic stenosis and 3 hypertrophic cardiomyopathy cases). LVH was found in 0% of cases with 80–89 mmHg mean BP and 12% of cases with 90–99 mmHg mean BP. The prevalence of complication with LVH increased and reached as high as 60% when mean BP exceeded 140 mmHg.

Complications with LV dysfunction in the Ht group were found as shown in Fig. 13, indicating that the prevalence of LV dysfunction significantly increased as LVH became more severe. Furthermore, the percent of cases with poorly-controlled BP among those cases of LV dysfunction tended to rise with an increase in the severity of LVH.

In the initial study, 29 LVH cases were recognized out of the 100 cases in the Ht group. Zero LVH cases were seen among the 132 cases of the non-Ht group. During the 2-year follow-up study, 10 cases of the 100 Ht group cases showed newly developed complications with LVH. The state of LVH was unchanged in 7 cases and was abated or normalized in 22 cases. During the observation period, BP was poorly controlled in 14 (82%) of the 17 cases with either unchanged LVH or newly developed LVH complications. However, BP was sufficiently controlled in 16 (73%) of the 22 cases with improved LVH.

**DISCUSSION**

We have actively employed 2DE for cardiovascular mass screening since 1985 in order to improve the accuracy of diagnosis of cardiovascular diseases, and have published our findings each time. In the present study, since examinees of mass screening were used as subjects, casual BP was used. In epidemiologic surveys such as the Framingham study, it has been confirmed that casual BP values are closely related to life prognosis. it has also been shown that anti-Ht therapy based on casual BP values is definitely effective in improved prognosis of vascular complications such as cerebral hemorrhage.

The prevalence of Ht determined according to sex and age in this study was compared with that obtained from the nationwide basic survey of cardiovascular diseases performed in 1980. Our study found it to be about 8–10% higher in males aged 60 years or older and about 10% higher in females aged 50 years or older. However, similar rates were detected for both below the ages of 60 and 50, respectively. The prevalence of Ht seen in this study was almost
the same as that obtained from the nationwide basic survey performed in 1971. This slightly higher prevalence was thought to be due to the fact that we mainly examined residents in agricultural and mountain villages.

Although the diagnosis of LVH has been conventionally performed through chest X-ray studies and/or ECG, it is sometimes difficult to detect early cardiac hypertrophy without cardiac enlargement using chest X-ray films. We have already reported our findings of the diagnosis of LVH through ECG as a study in this series. Provided that the diagnosis with 2DE is accurate, sensitivity and false positive rates of the diagnosis of LVH by ECG can be calculated to be 43.6\% and 16.0\%, respectively.

A large number of investigators have studied the morphological diagnosis of the heart with echocardiography and confirmed the usefulness of this method. The diagnosis of LVH by this method is proved to be especially reliable via the comparison with autopsy findings in the heart. LV wall thickness represented by VST and LVFWT, and LV weight have been widely utilized for the diagnosis of LVH through echocardiography. In the present study, we evaluated LVH using VST and LVFWT.

Many factors are known to be involved in the occurrence of cardiac hypertrophy; namely, such hemodynamic factors as the increase in wall stress due to pre- or after-load, increased requirement of energy due to exercise and the deficit of ATP due to ischemia, and such humoral factors as catecholamine, thyroid hormone and renin-angiotensin systems. Other than these, heredity, race and age are also included.

In the analysis of 480 LVH cases, about 75\% were found to have HT of borderline HT suggesting the presence of great influence of BP, as we expected. However, about 17\% of them had LVH without HT. Although causes of LVH could not be defined, these LVH cases seemed to appear with greater frequency among the more elderly cases. In the near future, we expect to see an increase of non-rheumatic valvular disease with LVH as the aged population increases in number.

As a result of examination of many HT cases using the 2DE method, we found that about 30\% of them were complicated with LVH. This figure seemed to be very reasonable when compared with the data obtained by Devereux et al. At the same time, it should be noted that about 70\% of the HT cases were not complicated with LVH.

The prevalence of ASH greatly differs in reported results. Some investigators found ASH in almost no patients with cardiac hypertrophy due to HT while others found it at 4-47\%. In the present study, ASH was found in 10.1\% of all the HT cases (111/1100), and in 37.2\% of the LVH cases. Thus, we thought that the incidence of ASH in our study was not particularly high in comparison with those found in some of the other studies. In addition, ASH more frequently appeared as LVH became more severe.

As for the prevalence of LVH by sex, it was found that prevalence of mild to severe LVH was significantly higher in males than in females; moderate to severe LVH was more frequently observed in males. We are very interested in these findings because they may indicate a difference in response to chronic stress between men and women. Furthermore, our comparison performed with sex and age stratification revealed that the prevalence of LVH significantly differed between men and women at their 40's, 50's and 60's while such differences became indistinct by the age of 70 years or older. This study may be the first to point out this pattern of difference between males and females. These findings should be useful in the future in assessing the difference between males and females in terms of cardiovascular morbidity and mortality.

Although there was no significant difference in the prevalence of LVH between the treatment and non-treatment groups, the prevalence was found to differ significantly when these cases were compared after being divided into well-controlled and poorly-controlled groups. This suggests that the level of BP control is more important than the presence or absence of treatment.

The prevalence of mild to moderate LVH significantly differed between the well-controlled and poorly-controlled groups. However, there was no significant difference in the prevalence of severe LVH in those 2 groups. These findings indicate the interesting possibility that sufficient management of BP may fail to be effective if LVH excessive-
ly progresses.

With aging, SBP gradually increases while DBP decreases. We should regard these changes as occurring in association with sclerotic lesions in large arteries, but not occurring due to the dilatation of peripheral resistant vessels. Our findings shown in Fig. 10 well reflect hemodynamic changes with aging; namely, hypertensive cardiac output and stroke patterns expressed by flowmetric waves are constant unless hypertensive heart failure occurs. Under such conditions, mean BP (not SBP) is representative of the state of peripheral resistant vessels, and pulse pressure expresses the characteristics of relatively large arteries and the size of reflex waves. In fact, the increase in mean BP was closely correlated with the prevalence of LVH in the present study.

The fact that LV dysfunction more frequently appeared as LVH progressed in association with Ht seems clearly to reflect the general mechanism of adaptation to Ht in the heart. Since changes in the morphology of the heart and LV function were thought to reflect directly the therapeutic effect, we believe that the follow-up of Ht patients through 2DE greatly contributes not only to the making of therapeutic decision, but to the evaluation of prognosis of the hypertensive heart as well.

As a result of the 2-year follow-up, it was confirmed that LVH freshly occurred or regressed depending upon the state of BP control; therefore, once more we strongly suggest the importance of adequate BP control.

It is generally indicated that patients with LVH are at increased risk of cardiovascular morbidity and mortality. We expect the relation of LVH with prognosis or anti-Ht drugs to be made more clear through periodical long-term follow-ups based on the data obtained from a large number of cases in this study.

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