Improving Compliance with Therapeutic Regimens in Hypertensive Patients in a Community Health Center

JORMA TAKALA, M.D., NILO NIEMELÄ, M.D., JUHANI ROSTI, M.D., AND KAI SIEVERS, M.D.

SUMMARY  A 1-year, randomized study was conducted to test the possibility of improving compliance with therapeutic regimens in hypertensives by means of certain simple arrangements. Patients were given written treatment instructions concerning hypertension, a personal blood-pressure follow-up card, and, for those who failed to attend their blood-pressure check-up, an invitation for a new check-up. Using matched pairs, 202 Finnish hypertensives were randomly allocated either to an ordinary or a reorganized treatment group. By means of the latter system, patient compliance could be significantly (p < 0.01) improved: Only 4% of the patients in this group dropped out of treatment, compared with 19% in the ordinary treatment group. By the end of the year, blood pressure had been lowered by at least 10% in 95% of the patients in the reorganized group and in 78% of those in the ordinary group (p < 0.01). This was achieved in approximately 60% of cases using chlorthalidone alone.

HYPERTENSION IS A MAJOR ISSUE in public health because of its high prevalence and serious complications. Although the treatment of hypertension is clearly useful, at least with selected middle-aged men, only part of the hypertension population is under adequate treatment, or indeed any treatment at all, because hypertensive patients frequently drop out of treatment.

At the community level, low compliance has been a central problem in the treatment of hypertension. Our study examines whether simple rearrangements of health education and organization can improve compliance with the therapeutic regimen. These rearrangements included providing written and verbal information, noting the time of the next visit on each patient's blood pressure (BP) follow-up card, and inviting the patient to come for a new check-up if he or she failed to keep an appointment.

Patients and Methods

A hypertension screening survey, the results of which have been published elsewhere, was carried out in Säkylä, a municipality in southwestern Finland, in 1973–1974. This survey covered the middle-aged population (40–64 years), and was attended by a total of 1245 persons, 94% of those who were invited to participate. Those subjects whose BP as determined in the screening met the criteria for high BP (specified below) were invited to come for a second measurement after 6 months. Those subjects whose BP readings at both measurements met the criteria for high BP, and who were not under treatment at the time of the investigation, were randomly divided into two groups using matched pairs. Patients in one group were treated according to the ordinary treatment system and patients in the other according to the improved system. Medical care for all patients was provided by the same physicians in a community health center. In matching, the factors likely to influence compliance with antihypertensive therapy were taken into account, including age, sex, severity of the disease, and prior treatment of high BP or awareness of its presence. The criteria for high BP were as follows: BP ≥ 160 mm Hg systolic or ≥ 95 diastolic in patients age 40–49, BP ≥ 170 mm Hg systolic or ≥ 105 diastolic in patients age 50–64 years. After the groups were established, all patients were notified that their BPs were repeatedly above the normal range and therefore required medical examination. At the same time an appointment was set up for them with a physician in the health center.

Drug therapy was begun in all patients whose BP, when examined by a physician, again met the above criteria. On the first visit the same verbal information on hypertension and the importance of treating it was given by the physician to patients in both groups.

Under the improved treatment system, the patients were given treatment instructions in writing in addition to the oral information. Each patient also received a follow-up card on which BP readings measured during visits to the health center, medication prescribed, and the exact time of the next visit were recorded. The second appointment with the physician occurred after 1 month, the third after 2 months, the fourth, fifth and sixth appointments after 3 months from the previous visit. The failure of patients to attend BP check-ups was discovered by reviewing weekly the BP records of patients being treated under the improved system. An invitation for a new check-up was sent to those who failed to keep their appointments.

Under the ordinary system, the patients received neither the written treatment instructions nor the follow-up card, and were requested to make an appointment well in advance for the next check-up in the community health center after either 1, 2, or 3 months depending on the number of follow-up visits already paid. In this group, those who withdrew from treatment did not receive an invitation to come for a new BP check-up.

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The method used in taking BPs both in the screening and the treatment phase was a single BP measurement by a mercury manometer with the patient in the sitting position after a 3-5-minute rest. The readings were accurate to 2 mm Hg and the fifth-phase level was recorded as the diastolic BP.\textsuperscript{10} The drug treatment of all patients was begun with chlorthalidone. If this drug failed to lower the BP to the desired level (under 50 years: BP < 160 mm Hg systolic and < 95 mm Hg diastolic; over 50 years: BP < 170 mm Hg systolic and < 105 mm Hg diastolic), methyldopa was added to the treatment. In patients in whom serious side effects were caused by methyldopa, this drug was replaced by alprenolol. The results presented below are based on observations made during the years 1974 and 1975.

In the statistical processing of the data, the $t$ test was used to test the significance of the mean values obtained for the systolic and diastolic pressures; elsewhere, comparisons between two frequencies were used.

Results

Twenty-four of 572 men (4%) and 55 of 673 women (8%) who participated in the hypertension screening survey were under treatment for hypertension at the time of the investigation. Applying the above-mentioned criteria for high BP, 223 men (39%) and 252 women (37%) had untreated high BP. Of these subjects, 200 men (90%) and 226 women (90%) participated in the second BP measurement and 115 women (51%) and 87 men (44%) still had high BP and were randomly assigned to treatment groups. After the division into the two treatment groups, the appointment with the physician was kept by 93 of 100 subjects treated under the improved system. Of those who failed to come, two had sought treatment from a private practitioner, one was dead, and four had moved away from the locality. Of the 102 subjects treated under the ordinary system, 100 subjects accepted the invitation while the other two refused to keep the appointment. (After randomization, we noted that a husband and wife had been put in different groups. Due to the nature of the study we felt it necessary to place married couples in the same group. The two of them were then placed (by lot) in the group treated under the ordinary system, causing a difference in the sizes of the two groups).

Drug therapy was begun for 78 patients (84%) under the improved system and for 86 (86%) of those under the ordinary system. Drug treatment was not considered necessary for the other patients, because, upon reexamination, their BP readings no longer met the criteria for high BP. This may be ascribed either to a regression to the mean or to adaptation to the measurement situation.

The factors likely to influence compliance with therapeutic regimens were evenly distributed among patients in the two groups on drug therapy and fell into a pattern similar to that of the original randomized groups (table 1). None of the differences between the groups on drug therapy were statistically significant. The mean age of those receiving drugs was 51.7 years for the improved treatment group and 51.4 years for the ordinary group. In the former group the mean for systolic pressure was 179.5 mm Hg and for diastolic pressure was 101.4 mm Hg. In the latter group the corresponding figures were 178.3 and 100.9 mm Hg (these mean values were obtained on the basis of each subject's mean, calculated from two separate screening-phase readings). Neither the mean ages nor the mean pressures differed significantly.

During the year, three persons out of 78 (4%) dropped out of treatment under the improved system while under the ordinary system 16 of 86 (19%) dropped out. The difference was statistically significant ($p < 0.01$). By the end of the year the desired BP level had been attained by 63 (81%) of the patients under the improved system and 55 (64%) of those under the ordinary system ($p < 0.05$). A pressure reduction of at least 10%\textsuperscript{11} had taken place in a total of 73 (94%) of the former and 67 (78%) of the latter group ($p < 0.01$). The degree of reduction was satisfactory both in patients under 50 years of age and those over this age, and was of the same order of magnitude under both the treatment systems (table 2). Of those patients under the reorganized system who had reached the desired BP level, chlorthalidone (25-50

<table>
<thead>
<tr>
<th>Factors influencing compliance</th>
<th>Improved system</th>
<th>Ordinary system</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Subjects randomly divided</td>
<td>Subjects on drug therapy</td>
</tr>
<tr>
<td>Women</td>
<td>(n = 100)</td>
<td>(n = 78)</td>
</tr>
<tr>
<td>Under 50 years of age</td>
<td>57 (57%)</td>
<td>47 (60%)</td>
</tr>
<tr>
<td>Knowledge of elevated blood</td>
<td>54 (54%)</td>
<td>41 (53%)</td>
</tr>
<tr>
<td>pressure before screening</td>
<td>26 (26%)</td>
<td>21 (27%)</td>
</tr>
<tr>
<td>Under treatment at sometime</td>
<td>10 (10%)</td>
<td>7 (9%)</td>
</tr>
<tr>
<td>previously</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Systolic pressure elevated</td>
<td>35 (35%)</td>
<td>27 (35%)</td>
</tr>
<tr>
<td>*Diastolic pressure elevated</td>
<td>19 (19%)</td>
<td>14 (18%)</td>
</tr>
<tr>
<td>*Both systolic and diastolic</td>
<td>46 (46%)</td>
<td>37 (47%)</td>
</tr>
</tbody>
</table>

*Based on the mean of readings taken at two separate screening measurements.
mg) was the only antihypertensive drug administered to 44 patients (70%) at the end of the year; in 15 patients (24%) it was used in combination with methyldopa (chlorthalidone 25 mg and methyldopa 250–750 mg). For those whose pressure reduction had been at least 10%, the figures were 45 (62%) and 23 (32%), respectively. Of those patients under the ordinary system who had reached the target level, the antihypertensive medication consisted of chlorthalidone in 37 cases (67%) and chlorthalidone and methyldopa in 14 cases (25%). The figures for those with a pressure reduction of at least 10% were 39 (58%) and 21 (31%), respectively. In six patients of the 144 (4%) who remained in the treatment program and whose treatment was started with chlorthalidone (in one patient with liver disease, treatment was initiated with alprenolol) the drug had to be discontinued because of headache (two patients) or hypokalemia (four patients). Their treatment was continued with Moduretic or methyldopa or both. Among the patients who received chlorthalidone there was, in addition to the cases mentioned, one patient with hypokalemia whose antihypertensive medication was modified by adding triamterene to the chlorthalidone treatment. Of the 56 subjects who were treated with chlorthalidone in combination with methyldopa and who were followed for 1 year, four patients (7%) had spells of fever likely to have been caused by methyldopa, so this drug had to be discontinued. In three cases it was replaced by alprenolol, and in one case chlorthalidone alone was adequate therapy. In two patients, drug therapy (chlorthalidone only) could be terminated altogether, since their BPs returned to normal, apparently due to regression to the mean or to adaptation to the measurement situation.

Discussion

Finnerty and co-workers4 were the first to demonstrate that compliance with therapeutic regimens by hypertensive patients can be improved considerably by organizational and administrative rearrangements. Working at the polyclinic of their training hospital in Washington, D.C., they were able to reduce the proportion of dropouts among hypertensive patients from 42% to 8% by providing more personalized medical care, by providing 24-hour medical services for the patients, and by making medical care more convenient for the patients. Good results have also been obtained in New York in a hypertension polyclinic provided by an occupational health care system for department store employees,11 in Gothenburg, Sweden in medical consultations provided for hypertensives,12 in a training hospital participating in a primary preventive study,13 and in Finland in the community health centers in which the antihypertensive treatment program of the North Karelia project is run.14 None of these were randomized studies. Sackett et al.,15 in a controlled study of the factors pertinent to compliance, did not indicate any favorable effect of health education or convenience of care on patient compliance in general.

In the present randomized study, the compliance of hypertensive patients could be improved considerably by a few rearrangements in organization, health education and convenience of care. After 1 year 96% of the patients under the improved system were still participating in the treatment program.

In the United States, those who drop out of treatment for hypertension are in general younger, more likely to be black, have less education, are blue collar workers and have lower incomes than those who stay in treatment.4 The good results in this investigation were not due to selection bias in favor of patients with better education and higher income. Only four (5%) of the 78 persons in treatment under the improved system had 12 years or more of education, 74 (95%) less than 12 years, and 65 (83%) less than 9 years. For the ordinary treatment system the figures were 2 (2%), 84 (98%) and 76 (88%), respectively. For 69% of the subjects under the improved system and 67% of those under the ordinary system the income was 20 000 Fmk (5,618 U.S. dollars) or less.

No selection took place, even in the beginning of the investigation, because 94% of those who were invited

<table>
<thead>
<tr>
<th>Treatment system and age group</th>
<th>Number of patients</th>
<th>Mean systolic and diastolic pressure before drug therapy* (mm Hg)</th>
<th>Mean reduction in blood pressure (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved under 50 yrs</td>
<td>39</td>
<td>175/107</td>
<td>26/12</td>
</tr>
<tr>
<td>over 50 yrs</td>
<td>36</td>
<td>192/106</td>
<td>35/11</td>
</tr>
<tr>
<td>Ordinary under 50 yrs</td>
<td>36</td>
<td>175/109</td>
<td>29/15</td>
</tr>
<tr>
<td>over 50 yrs</td>
<td>34</td>
<td>196/108</td>
<td>38/16</td>
</tr>
</tbody>
</table>

*These mean values for blood pressures did not differ in the same age groups of the different treatment systems at a statistically significant level.
†These mean values differed at a statistically significant level (p < 0.001) from the corresponding mean values obtained before drug therapy.
did participate in the hypertensive screening survey, and 90% of those with untreated high BP took part in the second measurement.

In Finland, most hypertensives are treated in community health centers, which are responsible for health education, screening for diseases, and treating the inhabitants of their districts, according to the Public Health Act (1972). Therefore we felt that a community health center would be the most adequate milieu for our research into ways of enhancing compliance with therapeutic regimens in hypertensives.

The physicians' fees and the payments for laboratory and radiological services are very low in these centers, and antihypertensive medication is available to persons with high BP at no cost to the patient, as provided by the Sickness Insurance Act; thus, financial factors could not have influenced the compliance with antihypertensive treatment in the present study. One-fifth of those who were placed under the ordinary system dropped out of treatment within 1 year. The number of dropouts in the present study, which dealt with a Finnish rural population, was not nearly as high as that obtained in some studies carried out on populations from metropolitan areas in the United States. Our findings, nevertheless, clearly show that the passive approach to antihypertensive therapy prevalent in Finland and, we believe, in most other countries, is insufficient, and that even modest effort can greatly reduce the number of drop-outs.

The initial BP target-level was not achieved in all cases, even under the improved system. However, a consideration more important than the efficacy of treatment is that as many hypertensives as possible remain under medical care, for studies indicate that in the case of both severe and mild hypertension, maximally efficacious medication is not needed to reduce complications of hypertension, compared with the absence of medication altogether.

BP could be returned to normal using chlorthalidone alone in 59% of the patients who remained in the program under the improved system, and in 53% of patients under the ordinary system. In other studies as well, the administration of only one drug has been found to be adequate in the treatment of hypertension in most cases. If most hypertensives can be treated by very simple medication the possibility of keeping patients under continuous, in most cases lifelong medical care is significantly improved. The simpler the medication, the better the compliance with treatment, and simpler medication enables paramedical personnel to take charge of the treatment of most hypertensive patients.

The simple, compliance-enhancing, organizational rearrangements put on trial in the present study are included among the recommendations of the Committee for Hypertension, appointed by the Finnish Ministry of Health and Social Affairs, in its recently published report. On a large scale these measures may prove to be of great significance for public health, particularly in a country like Finland, where the prevalence of cardiovascular diseases and their attendant mortality is among the highest in the world in women and is the highest in men.

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