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CONTROL OF HYPERTENSION IN POPULATIONS

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BLOOD PRESSURE IN POPULATIONS

Arterial blood pressure is a well regulated haemodynamic variable. A considerable number of factors are known to contribute to its regulation, some of them are still incompletely understood and there might be some more unknown factors.

Blood pressure is ceaselessly changing like many other dynamical variables of the living organism, and its assessment would be difficult, were we not to use certain simplifications. These are based on the century-old principle of compressing externally the brachial artery, though a new non-invasive technical approach is very much wanted. "Casual" blood pressure, in terms of systolic and diastolic values, measured with the classical sphygmomanometer, is the main simplification allowing us to classify individuals according to their arterial pressure. The

perennial debate, whether there is a "true" dividing line between "normotension" and "hypertension" depends, of course, on the meaning we convey to these very terms and on the use they are meant for. There is no doubt that these terms, too, are simplifications - but, it should be admitted, very useful, almost indispensable ones.

If blood pressure is being measured in populations at large, adults are usually found having (casual) values of 110-140 mm/Hg systolic and 60-80 mm/hg diastolic pressure. As well known in many populations the values increase with age, in some they do not. However, in most populations a considerable number of individuals is to be found with blood pressure values being, at repeated measurements, definitely higher than the above mentioned range of "usual" pressures. Roughly, ten percent of all the adults, both males and females, may have blood pressure values at or above, say, 60 and/or 95 mm/Hg*in technically developed as well as developing countries.

HYPERTENSION IN POPULATIONS

Although, usually, high blood pressure is a sign without symptoms, it is far from being an irrelevant sign. Even values slightly higher than the usual ones are, statistically, associated with higher than usual

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*There is no sharp line of demarcation between normotensive and hypertensive levels - i.e., it is not possible in the individual to give an absolute figure for the upper limit of normal blood pressure - for screening purposes in population groups certain values may be accepted, using "casual" blood pressure recording: (1) below 140/90 mm/Hg - normal range; (2) 160/95 and above - hypertensive range.

Report of an Expert Committee (1962) Arterial hypertension and ischaemic heart disease, preventive aspect, Wld Hlth Orgn. techn. Rep. Ser., 231

mortality rates. The positive correlation between blood pressure and general mortality is a continuous one, starting already at the lower end. Blood pressure is a graded characteristic and the risk depends on the level of pressure.

At the upper end, naturally, the hazards of high blood pressure become even clinically obvious in the form of its direct complications: hypertensive heart disease, hypertensive renal disease, retinal haemorrhage, and cerebral aemorrhage. However, even less marked elevations do contribute to the development of atherosclerosis, and to its main complications, ischaemic heart disease and ischaemic brain disease. Populations based anatomical studies have shown impressive correlations between both degree and extent of coronary atherosclerosis and blood pressure previously observed. Several prospective epidemiological studies have demonstrated the importance of blood pressure as a risk factor of coronary heart disease, even if only moderately above the usual values in a population. In a WHO epidemiological study, carried out on 7700 persons in seven cities (Hirayama, Malmö, Moscow, Prague, Riga, Ryazan and Saku), those in the upper third of the frequency distribution of blood pressure had a 25 % higher prevalence of coronary heart disease than those in the middle or lower third.

Higher blood pressure thus definitely seems to be incompatible with "complete physical well-being", an essential component of health like the top of an iceberg, only its direct complications are immediately clinically visible. The epidemiological method, however, discloses its bulk, unveils its real impact on the health of populations. If both the frequency

and the relevance of high blood pressure are taken into account, hypertension should be regarded as a large-scale, widely spread epidemic.

ADVANCES IN THE TREATMENT OF HYPERTENSION

The cause of hypertension is usually not known, and therefore cannot be prevented. Even if known, only exceptionally can hypertension be cured by treating the cause. Thus, treatment of hypertension means preventing its complications, and the most plausible way to do so is lowering the blood pressure itself. In the past, hypertension treatment was virtually rarely more than placebo-therapy. During the past two decades, however, several families of potent and relatively harmless hypotensive drugs have been developed. Long-term, efficacious, systematical treatment of hypertension has thus become possible, the more necessary in order to prevent the complications. Between 1961 and 1970 a number of studies has demonstrated the favourable long-term effects of hypotensive treatment in patients with more or less severely elevated blood pressure, the incidence rate of complications and death being smaller in the treated than in the control groups.

The most significant investigation in this field is the well-known Veterans Administration Co-operative Study on Antihypertensive Agents, published in 1967 and 1970. More than 500 male hypertensive patients (diastolic blood pressures ranging from 90 to 129 mm/Hg) were randomized into a placebo and an active therapy group. Treatment was conducted as a double blind trial. Already after 20 months of observation there was a significant difference in the incidence of complications between the two groups in the upper part of the diastolic pressure range (115-129 mm/Hg).

After three more years of observation, it became evident that the prognosis of patients with initial values of diastolic pressure from 105 to 114 also considerably improves with treatment; the benefit in patients having initial values of 90-104 mm/Hg was less clear cut.

THE SITUATION IN COMMUNITIES AND THE NEED FOR ACTION

In view of the high prevalence of hypertension, numerous members in many populations should be eligible for treatment. On the other hand, some observations show that if a community is surveyed as a whole only a fraction of those who need treatment, according to widely accepted standards, are indeed being treated; a still smaller part receives systematical and efficacious treatment.

Community based data from Baldwin County, Georgia by J.A. Wilber and Wilber & Barrow showed that, in a random sample, 42 % of hypertensives were unaware of their condition. Only 30 % of the known hypertensives were under treatment and only 17 % of the known hypertensives were under what was called "good control". Doctors lost track of 56 % of hypertensives within three months. Caldwell et al[4] studied the drop-out problem in anti-hypertensive treatment, in a pilot study of social and emotional factors influencing the patients' ability to follow treatment. Only 11 % of patients first seen and treated for hypertension in 1961 were found to be on treatment after five years. By studying in patients hospitalized for emergency complications of hypertension the causes leading to drop-out, it became evident that in one-third of these patients low income and high cost of treatment was a realistic reason, but that 24 % of "drop-outs" abandoned treatment on advice of their physician, thus clearly demonstrating

the importance of an information programme for physicians. The most important factor was, however, absence of motivation due to lack of health education in the patients and their families.

In a community of a different socio-cultural setting, Tibblin also found a high prevalence of hypertension. The ratio of treated to untreated patients was rather poor in men; approximately two-and-one-half times more hypertensive men were without than with treatment. Half of those being treated had unsatisfactory blood pressure levels, in spite of drug therapy. However, the pattern was considerably more favourable in women.

These and other similar observations indicate that appropriate action is needed for the control of hypertension in populations.

CONTROL PROGRAMMES

The term (disease) "control" may give rise to some misunderatandings and needs, therefore, some comments. It is applied, in this context, in its widest sense, meaning comprehensive struggle against disease. It refers to all aspects of health protection: prevention of a disease or of its complications, early diagnosis, appropriate treatment, rehabilitation, health education, and includes also endeavours to obtain better knowledge of a condition i.a. of its natural history and epidemiology, The French counterpart for "control of hypertension" is "lutte contre l'hypertension" and the Russian term "barba prati hipertonicestoi boljezni".

"Programme" means a designed, organized action and a "community programme" aims at health protection and promotion of a large number of subjects in a community, covering all of its members in the ideal case.

Generally speaking, the ultimate goal of any control programme is, by definition, the conquest of disease. However, this ideal goal is at the end of a very long road passing through several stages. First of all, before establishing a programme reliable information is needed on the state of the particular disease in the particular population or community, its rates of occurrence, natural history, practice of health care and other features. Such information is necessary both in order to be able to build up the plan of a community control programme, and in order to have a baseline to which, later, changes possibly induced by the control programme could be matched. It is understood that data on the structure of the population itself are needed and also on other diseases prevailing in the area.

Second, experience dictates - and common sense as well - that any control programme undergo a test, on a limited scale and within a reasonably limited time, before being extended to a population at large. Such pilot programmes may be analyzed on four levels. First of all, they are expected to show whether a particular control programme is feasible at all, and if so, under what conditions and which adjustments to real-life situations. On the second level, the following question is to be answered: has the programme, if shown to be feasible, any demonstrable health protective effect? Therefore, the changes attributed to the programme should be compared to changes occurring in a similar community where no control programme was operating.

RESEARCH ASPECTS

A pilot control programme may well show to be feasible and also efficacious, and yet a large scale extension may not be justified, if its output does not outweight the input, at a third-level analysis. The input includes not only the financial and material cost of a programme, but also energy and time invested and, above all, the hazards of the programme such as unwanted effects of medication and possible psychological harm caused to apparently well-off individuals. The output englobes all beneficial effects of the programme, e.g. prophylaxis of complications, prolongation of fruitful life, prevention of human suffering. Some of these items can be readily quantified (e.g. direct financial cost). Others are difficult to assess or are even imponderable (e.g. psychological harm, prevention of suffering). Clearly, a comprehensive assessment of the true gain of a programme is extremely difficult and can be done to-day only by rough approximation, probably in qualitative rather than in quantitative terms, but there should be no reason to refrain from such an essay.

Estimation of benefit versus "costs" is not a specific feature of hypertension or any other control programme. It is a general principle in any human decision taking underlying to constraints and therefore underlying to the principle of trade-off. Even in the far less complicated situation of deciding whether hypertensive treatment should be started in an individual patient, the physician is weighing the pros and cons in the particular case taking into consideration the inconveniences and possible hazards of therapy - there is no harmless medication - and the expected benefits to the patient. This analysis of a given situation

cannot be replaced by any overall rule: the reason why, in the WHO study to be discussed later, only therapeutic guidelines, but no definite instructions are given concerning drug treatment in hypertensive subjects.

There is also a fourth level of analysis: assessment of efficiency. Two drugs, or two programmes, may require a similar input (cost, hazards) but yield different benefits. The one giving better results is the more efficient one. Obviously, efficiency of community control programme can be evaluated only if two different, yet comparable programmes are operating side by side, a condition which will hardly be encountered at the time being.

Pilot programmes thus have several important objectives, situated at various levels, and realization of a higher-level objective cannot be evaluated unless the objective of the preceding level has been attained. A pilot hypertension control programme is thus more than a mere attempt to start hypertension control on a limited scale; it is a complex study which, ideally, should be evaluated on a series of consecutive levels. Nevertheless, the basic goal of a pilot programme for the control of hypertension is, naturally, to demonstrate how hypertension could be controlled in populations at large. A pilot programme is both an operating model and a major research undertaking.

THE NEED FOR INTERNATIONAL CO-OPERATION

Accordingly, the control of hypertension in populations should be preceded by pilot programmes. WHO is striving to initiate a series of such pilot programmes within the frame of an internationally co-operative project.

There are several reasons in favour of international co-operation in this field.

Hypertension is a world-wide problem, prominently important in many countries, regardless of the level of technical development attained.

The pilot programmes are also complex research projects, and methodological assistance may facilitate their tasks. By proposing a common methodology, results from various centres might be comparable.

On the other hand, there are considerable differences between the various socio-cultural settings in which hypertension control programmes are to be established. International co-operation may give rise to an exchange of experience from these various settings.

Hypertension is a chronic, usually slowly progressing, condition. In order to arrive at an evaluation of the incidence of hypertensive complications, a long observation period would be needed. However, by increasing the number of observed subjects, the observation time could be held within practical, acceptable limits. Big numbers of observations can hardly be carried out by any one centre, while in a co-operative project, hopefully, many observations can be pooled within the time limits of a pilot programme.

WHO ACTIVITIES

Definitions and epidemiological aspects of hypertension were outlined in previous publications of WHO, in 1959, 1962 and 1963.

The need for programmed large-scale control of hypertension was first formulated by WHO at a meeting on the Prevention, Treatment and Rehabilitation of Cerebrovascular Diseases. Guidelines for such programmes were outlined at a meeting on the control of stroke and hypertension in 1971. At present, WHO is promoting an international co-operative project for the establishment of a network of pilot hypertension control programmes in a number of communities. The basis of the project was established at a WHO meeting on the community control of stroke and hypertension, held in Göteborg in late 1971.

At the Göteborg meeting, investigators from fifteen centres from four continents agreed on a common basic procedure for carrying out pilot community control programmes. Participating investigators envisaged co-operation between programmes in the following places: Barbados; Leuven, (Belgium); North Carelia, Finland, Lyon & Paris, France; Dublin, Ireland; Tel-Aviv, Israel; surroundings of Verona, Italy; Fukuoka, Japan; Ulan Bator, Mongolia; villages near Ibadan, Nigeria; Goteborg, Sweden; a rural area near Ankara, Turkey; Boreham Wood, near London, UK; and the Tushino district of Moscow, USSR. Some of the programmes already started in 1971, e.g. in Goteborg, Fukuoka and Moscow. Others started early in 1972, e.g. in Lyon, Northern Caselia and Ulan Bator; yet others are in preparation.

The population groups involved vary widely. Some of them are occupational groups (e.g. factory workers and employees), others cover a defined general population or one of its strata. Some of them are urban, others are rural population groups in developed or in developing countries.

Approximately 20 000 persons are comprised in occupational groups, while the general populations include 30-100 000 inhabitants of a defined area. On the whole, communities with altogether some 750 000 members will be covered by the pilot programmes.

The first step is a baseline survey. This is to establish the present situation concerning hypertension: its prevalence, the proportion of previously known versus unknown cases, the number of those who had received regular medical care as compared to those who did not have appropriate care, and the reasons for it. In smaller groups (e.g. the occupational groups) all members are being screened; in larger population groups, a representative sample of the community is being screened at the baseline survey, to arrive at a definition of the baseline situation. On the whole, approximately 130 000 persons are envisaged to be screened.

A baseline survey will be carried out also in some reference communities of similar characteristics, without being followed by any particular control programme. Reference communities will be left to cope with hypertension with the usual types of health care. After a period of five years, at the end of the pilot stage, a terminal survey to be carried out in both programme and reference communities should show the differences, if any, according to endpoints as follow:

Morbidity and mortality: Incidence and mortality of complications of hypertension: stroke, hypertensive heart disease with failure, renal failure due to hypertension, incidence and mortality of coronary heart disease; prevalence of known hypertensive subjects with and without left ventricular hypertrophy and organ damage; prevalence of undiagnosed hypertension; total mortality.

Data related to programme operation and health care delivery: estimate of input to health care and its part related to hypertension, including complications, input to the hypertension programme itself.

The sources of morbidity and mortality data will be: regular mortality statistics; hospital statistics; stroke and myocardial infarction registries (if existing), terminal rescreening of another sample of the population.

In view of the heterogeneity of the populations and conditions of work, it may not be possible to obtain a proper follow-up of the reference community in all places. In such instances, the question of feasibility will be answered only, and the question of efficacity will be left open. But hopefully, a number of co-operating centres will be able also to answer the question whether community control programmes, as outlined in this project, are feasible and useful as well.

PRINCIPLES OF THE CONTROL PROGRAMME

Hypertension seems to be so frequent and so important a disorder that the general approach to its control includes, as in any large-scale epidemic, appropriate management of whole communities, in addition to giving adequate medical care to individuals. In order to do this, the "first line of attack" against disease - the general public - and the second line, the general practitioners, should be mobilized, in addition to creating good specialized services. Therefore, emphasis is on the management of whole communities as socio-biological entities, though of course individual patients will be treated adequately, according to up-to-date standards of

medical sciences. Concerted, simultaneous action is thus needed along three lines. general health education, physicians' education and better care for hypertensives, including timely diagnosis and appropriate treatment.

An important feature of the control programme is active follow-up of identified hypertensives. If a hypertensive person does not appear for a periodic ex re-examination, a health visitor will enquire for the reasons of his absence. A more detailed annual re-examination (registered on special forms) will keep the programme centre informed on the course of each hypertensive subject that has been identified in the studied population group.

The control programme is based primarily on available resources. Basically, it is conceived as a movement of intensification and extension of already existing current activities. The general practitioners, either private or employed, should become associated with the programme team, whenever possible. A hypertension clinic, operated by the Programme Centre, is giving advice to the co-operating physicians, i.e. doing special laboratory investigations, if necessary. Data handling and analysis, physicians' information programme and research are some of the other activities of the Programme Centre, co-operating with other centres and WHO (Fig.1).

SOME OPEN QUESTIONS

An important question will find no answer in the present project: it is related to mild or borderline hypertension. Where is the level below which it would be unjustified to leave a person without a hypotensive intervention? Up to now, the only secure guidelines are coming from the

well-known US Veterans' Administration study. The present WHO project is not supposed to give an answer to this question; it will be reviewed in another WHO meeting in 1972. For the time being it is pointed out that the decision, whether and what type of drug treatment should be instituted is the responsibility of the treating physician, who should take into account not only the blood pressure values, but the patient as a whole. However, error is esteemed to be less on the active than on the conservative side, and guidelines for therapy are given to the co-operating physicians.

There are several methodological impediments to the study. For instance, it will be difficult to avoid "contamination" of a reference community by the programme in an adjacent community. Contamination tends to lower the visible effects of a programme, and though its true effects may be satisfactory, the differences to be observed may be less than expected.

The communities to be studied cover a very wide socio-cultural range indeed. In addition to the common basic procedures, accepted at the WHO meeting in Goteborg, each centre is free to adopt approaches best suited to the local conditions.

WHAT THE PROJECT IS EXPECTED TO GIVE

Several points of importance should be made clear by this project. The survey done at the initial stage (baseline survey) should assess the burden of hypertension on various populations, and also the true situation concerning its actual management, including inadequacies and their causes.

The control programmes themselves should lead to experience in operating large-scale projects for the control of a common, and often symptomless condition. They should also show the best ways for operation in various socio-cultural settings. It should become clear, whether therapeutic measures successfully applied to hospitalized patients can equally successfully be applied in the general practice at large. Whether an organized programme has advantages over medical care as administered in the respective areas in the usual way is a basic question to be answered by the project. More insight into the natural history of hypertension should also be gained.

A duration of five years is fereseen for the project. It is understood that if a pilot programme proves to be successful, it should be continued as a model programme in the respective area, and should eventually be expanded to cover even larger population groups. It should also be integrated with other control programmes for cardiovascular diseases in the area, e.g. stroke and myocardial infarction programmes, the eventual objective being a comprehensive programme for the control of cardiovascular diseases, and also other chronic diseases in entire populations.

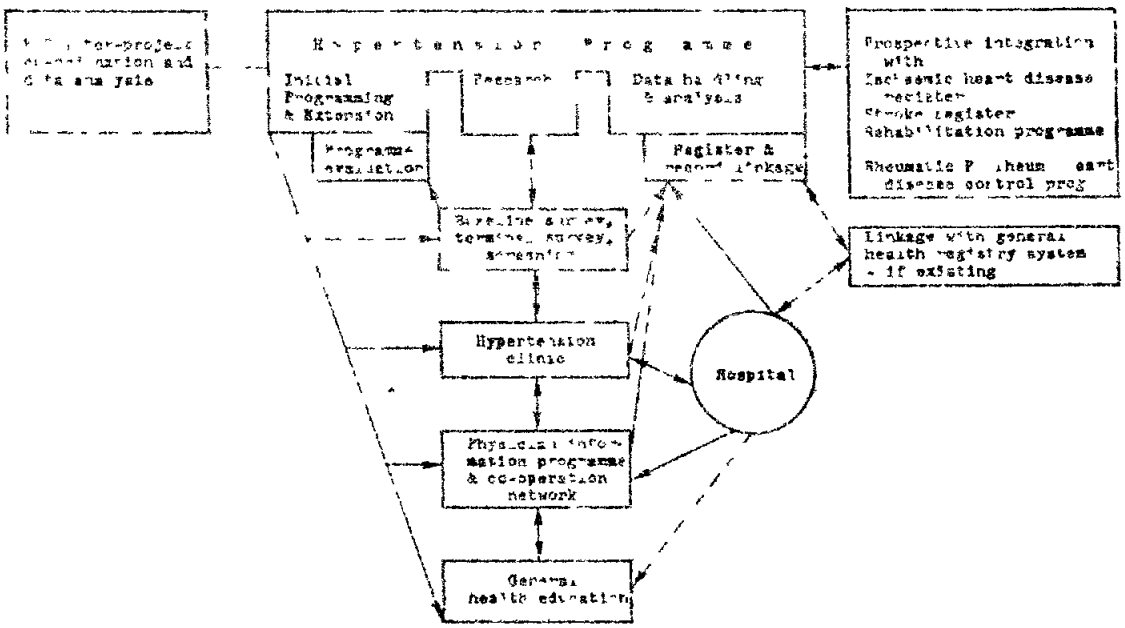

CHART OF FUNCTIONAL RELATIONSHIPS