scientifically unusable. Any medical information which is to be the basis of scientific analysis must therefore be checked—and improved—by reproducibility studies on a representative group of patients *before* starting the main study.⁵ The standard of clinical data collection must be improved if it is to match increasingly sophisticated radiological and laboratory investigations and if clinical history and examination are to remain the foundation of medical practice.

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The final version of the history questionnaire may be obtained from Mr Gordon Waddell.

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Hypertension: comparison of drug and non-drug treatments

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Abstract

Thirty-seven reports of the treatment of hypertension by non-pharmacological means were compared with the results of treatment by standard drug regimens. Treatment by drugs produced the greatest lowering of blood pressure. Treatment by weight reduction, yoga, and muscle relaxation each produced smaller, but appreciable, changes in blood pressure. The effects of meditation, exercise training, blood pressure biofeedback, and salt restriction were inferior to those of the other regimens and were not significantly different to the effects of placebo treatment.

Large comparative trials of pharmacological and non-pharmacological treatments are needed before definite conclusions can be made.

Introduction

Recent trials have shown that using drugs to lower blood pressure in mild hypertension reduces the death rate.^{1,2} While this is heartening, the prospect of asking some 17% of the adult population to take antihypertensive drugs for years is somewhat daunting, particularly with regard to possible unforeseen side effects and the considerable personal and public cost of such treatment. More attention needs to be focused on non-pharmacological interventions^{3,4} but it is not clear from the published

reports just which approach the doctor should take in treating the patient with mild hypertension. A randomised, controlled trial of non-drug and drug regimens would help to clarify this issue, on which only slight evidence exists,⁵ though doctors are already advising patients to use non-drug treatments.⁶

Rational decisions need to be made on the basis of existing reports but it is difficult to review the results of a collection of studies in which research design, subject characteristics, treatment modality, and measures of outcome all differ. Glass⁷ introduced an approach called meta-analysis in which the properties of several studies could be recorded in quantitative terms and descriptive statistics applied to derive an overall conclusion. Thus, reviewing the published works ceases to require the judgment of Solomon and becomes a quasiempirical procedure. We used the meta-analytic technique to review non-pharmacological treatments for hypertension. Three questions were explored: (a) how effective are non-drug treatments compared with standard drug regimens? (b) which of the non-pharmacological treatments produce the greatest reductions in blood pressure? and (c) are the reductions in blood pressure maintained?

Method

We studied the published reports on outcome of non-drug treatment of mild hypertension—that is, diastolic blood pressure >90 mm Hg, systolic blood pressure >140 mm Hg. Studies of drugs and placebos were included for comparison. Treatment studies from which means and standard deviations could not be calculated were excluded. In the meta-analytic technique the effects of treatment are expressed as an effect size⁸ calculated from the difference between mean blood pressures (mm Hg) in treated and control groups, standardised by the variability of blood pressures in the control group. The effect size, a measure of the extent of improvement in standard deviation units, is treated as the dependent variable, the other features of the studies being coded numerically and considered as independent variables likely to contribute to the effect size.

By assuming that the frequency distribution of the measures of outcome—usually blood pressure levels—were normally distributed,

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then an effect size of 1 indicates that after treatment the distribution of blood pressures for the treated group will be reduced by one standard deviation; the average treated patient would then be better off than 84% of untreated patients. The effect size statistic allows different treatments to be compared and different measures of outcome (diastolic, systolic, and mean blood pressure) to be related.

Some studies gave data on more than one group of subjects; these were kept distinct if the characteristics of patient or treatment differed. In most cases a study yielded several effect sizes since improvement was often measured at more than one point in time or on more than one measure of outcome—for example, systolic and diastolic blood pressure. There were 37 studies reporting data on 51 patient groups. Each group was coded as to the presence or absence of the following features.

TABLE I—Studies coded: listed by group for each major type of treatment in order of year of publication

Study No	Authors	Year	No of subjects	Principal treatment	No of effect sizes calculated
1	Freis <i>et al</i> ⁹	1967	32	Drugs	2
2	Datey <i>et al</i> ¹⁰	1969	22	Drugs	1
3	Smith ¹¹	1977	175	Drugs	2
4	HDFP ²	1979	4267	Drugs	4
5	HDFP ²	1979	3180	Drugs	4
6	Reader <i>et al</i> ¹	1980	1721	Drugs	1
7	Taylor <i>et al</i> ¹²	1977	10	Muscle relaxation	2
8	Bali ¹³	1979	9	Muscle relaxation	2
9	Bali ¹³	1979	8	Muscle relaxation	2
10	Brady ¹⁴	1979	4	Muscle relaxation	1
11	Nath and Rinehart ¹⁵	1979	6	Muscle relaxation	2
12	Datey <i>et al</i> ¹⁰	1969	10	Yoga	2
13	Patel ¹⁶	1973	20	Yoga	2
14	Patel ¹⁷	1975	20	Yoga	5
15	Patel ¹⁸	1975	16	Yoga	2
16	Patel ¹⁸	1975	16	Yoga	4
17	Patel and North ¹⁹	1975	17	Yoga	4
18	Patel and North ¹⁹	1975	16	Yoga	2
19	Patel ²⁰	1976	14	Yoga	2
20	Johnson and Grover ²¹	1967	4	Exercise	1
21	Boyer and Kasch ²²	1970	23	Exercise	2
22	Choquette <i>et al</i> ²³	1973	37	Exercise	3
23	Parijs <i>et al</i> ²⁴	1973	15	Salt restriction	2
24	Morgan <i>et al</i> ²⁵	1978	28	Salt restriction	4
25	Morgan and Myers ²⁶	1981	12	Salt restriction	1
26	Morgan and Myers ²⁶	1981	12	Salt restriction	1
27	Morgan and Myers ²⁶	1981	12	Salt restriction	1
28	Morgan and Myers ²⁶	1981	12	Salt restriction	1
29	Lindner and Blackburn ²⁷	1976	18	Weight loss	2
30	Reisen <i>et al</i> ²⁸	1978	24	Weight loss	2
31	Reisen <i>et al</i> ²⁸	1978	57	Weight loss	2
32	Tuck <i>et al</i> ²⁹	1981	15	Weight loss	1
33	Tuck <i>et al</i> ²⁹	1981	10	Weight loss	1
34	Goldring <i>et al</i> ³⁰	1956	31	Placebo	2
35	Frankel <i>et al</i> ³¹	1978	7	Placebo	2
36	Reader <i>et al</i> ¹	1980	1617	Placebo	1
37	Benson <i>et al</i> ³²	1971	7	Biofeedback	1
38	Elder <i>et al</i> ³³	1973	4	Biofeedback	1
39	Elder <i>et al</i> ³³	1973	5	Biofeedback	2
40	Elder and Eustis ³⁴	1975	22	Biofeedback	2
41	Goldman <i>et al</i> ³⁵	1975	7	Biofeedback	2
42	Krist and Engel ³⁶	1975	4	Biofeedback	1
43	Kleinman <i>et al</i> ³⁷	1977	8	Biofeedback	2
44	Frankel <i>et al</i> ³¹	1978	7	Biofeedback	2
45	Benson <i>et al</i> ³²	1974	22	Meditation	4
46	Benson <i>et al</i> ³⁹	1974	14	Meditation	2
47	Blackwell <i>et al</i> ¹⁰	1976	6	Meditation	2
48	Stone and De Leo ¹¹	1976	14	Meditation	2
49	Pollak <i>et al</i> ¹²	1977	20	Meditation	5
50	Seer and Raeburn ¹³	1980	14	Meditation	3
51	Seer and Raeburn ¹³	1980	14	Meditation	3

Characteristics of patient group—Mean age; mean severity diastolic blood pressure; mean severity systolic blood pressure; percentage men; source of patients.

Treatments—Biofeedback; muscle relaxation; yoga; meditation; salt restriction; exercise; weight loss; drug treatment; placebo treatment.

Methodology—Type of measure of outcome; reliability of measure of outcome; mode of allocation to groups; type of control group; percentage patients lost to assessment; interval from treatment to assessment.

In addition, the validity of research design was estimated from the presence or absence of random allocation of patients, measurement with random zero sphygmomanometer or other reliable device, interval of at least three months from treatment to assessment, and attrition of less than 5% of patients at final assessment.

Table I lists the references to each group analysed, the principal treatment used, and the number of effect sizes generated from that group.

Results and comment

CHARACTERISTICS OF STUDIES

Two-thirds of the subjects were men, their median age was 46, and the median blood pressure of the groups before treatment was 152/98 mm Hg. In three-quarters of the studies the patients came from clinics and in one-quarter from population screening or in response to advertisements. The phase 3 drug studies tended to be of large groups, but the phase 1 and phase 2 non-drug studies had a median of 15 patients per group. Sixty-five per cent used baseline pre-post designs and 34% used test control designs with matched or randomised control groups.

Each study was characterised by the principal treatment used. Thirteen of the 109 effect sizes were from blood-pressure biofeedback, nine from muscle relaxation, 23 from yoga, 21 from meditation, six from exercise, eight from weight loss, and 10 from salt restriction. Drug treatments scored for comparison contributed 14 of the effect sizes and placebo treatment five. Some studies used one of the other principal treatments as ancillary treatments. When drugs were so used the effect size of the non-drug treatment was calculated by using the drug effect as a baseline. The median duration of treatment was six hours, range two to 50. Sixty per cent of the effect sizes were based on diastolic blood pressure measured in clinics and 32% on systolic pressure measured in clinics. Seventy per cent of the studies used automated recording, random zero sphygmomanometers, or repeated blind clinic measurement. The interval from treatment to assessment was less than one month in 14 of the 51 groups studied, 1-3 months in 14, 3-6 months in 11, and later in 12. Attrition was small, and three-quarters of the authors had been able to follow up at least 85% of their patients. Each study was scored on a scale of experimental validity from 0-4, 0 being poor and 4 good; the mean was 1.6.

EFFECTIVENESS OF NON-DRUG REGIMENS

The mean of the 90 effect sizes associated with non-drug treatments was 1.0. The average reduction in mean blood pressure after treatment was 8.6%. Table II shows the average effect size for each of the six classes of treatment. The benefits of drug treatment averaged 2.88 standard deviations improvement (SEM=0.35), and this is the reference against which the non-drug treatments are compared. The effect sizes for weight reduction (1.62), yoga (1.40), and muscle relaxation (1.32) were less than that for drugs, but considerably more beneficial than meditation (0.71), exercise (0.69), blood-pressure biofeedback (0.66), and salt restriction (0.58), which were not significantly different from the effect sizes obtained by plausible placebo treatments (0.60). Effect sizes for systolic and diastolic blood pressure were not significantly different for any of the non-drug treatments. Table II presents the rated internal validity of the research designs. As there was an association between the validity of the research design and the effect size ($r=0.44$), the good results reported by some treatments could not be explained by poor methodology.

Decisions about the effectiveness of a treatment should not depend solely on the average effect size. The effects of an initially strong treatment may be transient while the effects of an initially less powerful treatment may be better in the long term. Table II shows the effect sizes of the separate treatments at differing intervals from treatment to assessment. It is evident that in the long term drug

TABLE II—Mean effect sizes, effect size by treatment to assessment interval, and validity of research design

	Total no	Mean	Effect size				Validity of research design (0 = poor 4 = good)	
			SEM	By treatment to assessment (weeks)				
				0-4	5-13	14-26		>27
Drugs	14	2.9	0.35	2.9			2.9	1.9
Weight loss	8	1.6	0.16		1.5	1.8		2.2
Yoga	23	1.4	0.12	1.1	1.5	1.5	1.7	1.8
Muscle relaxation	9	1.3	0.29	1.0		0.5	2.0	1.4
Meditation	21	0.7	0.11	0.5	0.5	1.0		2.0
Exercise	6	0.7	0.22		0.0	0.9		1.8
Biofeedback	13	0.7	0.14	0.6	0.7			0.8
Placebo	5	0.6	0.32		0.4		0.7	1.6
Salt restriction	10	0.6	0.11	0.6	0.5	0.9	0.4	1.2
Total	109	1.2	0.20					1.6

treatment is the most effective treatment for mild hypertension. The benefits in weight reduction, yoga, and muscle relaxation also continue over time. Meditation, exercise, biofeedback, and salt restriction do not, even in the long term, offer any specific advantage over an intelligent placebo treatment such as sensible advice about a healthy lifestyle.¹

Discussion

Whether or not non-pharmacological interventions in hypertension produce appreciable reductions in blood pressure is an important question. The 37 studies summarised here represent a sufficiently powerful body of data on which to base some guidelines, but definite conclusions will have to await large comparative trials of non-pharmacological and pharmacological treatments.

The meta-analytic technique is new, and much depends on the probity of calculations of effect size. The mean effect size and the percentage reduction in blood pressure for each treatment were strongly correlated ($r=0.93$), which suggests that the calculated effect size was appropriate. If a clinically important reduction in mean blood pressure is defined as being in excess of 8⁰₀—that is, 10 mm Hg—three months or more after treatment, then weight reduction, yoga, and muscle relaxation are the only effective non-drug interventions. These three interventions produced the largest mean effect sizes of the non-drug treatments but smaller effect sizes than drug treatment. The reduction in blood pressure produced by these three interventions appeared to be relatively stable, being maintained for three to 12 months after treatment. The quality of research in the 13 studies of these treatments was high and it seems highly improbable that the demonstrated benefit could be an artefact of either publication bias or undetected type 1 error.

The effect sizes relating to salt restriction and exercise were small. Overall they have not been shown to be effective treatment strategies, though a recent paper has reported that in 12 patients with moderate hypertension (diastolic blood pressure > 105 mm Hg) the response to salt restriction was comparable with the response to chlorothiazide.²⁶ In the earlier studies of salt restriction, only a slight reduction in sodium intake was achieved: indeed, effective salt restriction is possible only when subjects use salt-free bread and do not dine out. The effect sizes related to blood-pressure biofeedback were similarly disappointing. Despite elaborate and expensive equipment the benefits appeared to be only comparable with the modest reductions in blood pressure that occur from taking your own blood pressure at home over an extended period.¹⁴

Somewhat surprisingly the effect size produced by meditation was considerably less than that produced by the two other relaxation techniques of yoga and progressive muscle relaxation. The reductions in blood pressure produced by these three techniques are usually viewed as acting by the common pathway of reduction in anxiety or arousal. As these techniques have been shown to be equally effective in reducing anxiety¹⁵ our results would suggest that this assumption should be questioned. Sitting quietly and contemplating a repetitive thought or mantra was common to most of the studies but only those entailing active muscular relaxation showed appreciable reductions in blood pressure, reductions which were maintained over 24 hours in which no deliberate relaxation was attempted.¹⁶ A recent study¹³ using both progressive muscle relaxation and mantra repetition showed a pronounced reduction in both blood pressure and anxiety but could show no correlation between the two. It would appear that muscular relaxation exercises have some beneficial properties quite separate from their property of inhibiting anxiety. These properties might be identified through investigation of the haemodynamic or other physiological changes accompanying the reduction in blood pressure.

Weight loss produced significant mean reductions in blood pressure (mean = 15%) and the largest effect size of the non-pharmacological interventions. The study by Reisin and others²⁸

reports such a reduction in association with a mean weight loss of 10 kg without concurrent reduction in salt intake. This relation was true for all degrees of obesity in excess of 110% of recommended body weight. Given the large proportion of persons with essential hypertension who are more than 10% above recommended body weight, this is a very encouraging result. Long-term maintenance of the reduced weight and blood pressure is still to be shown but preliminary results suggest that weight loss required for the treatment of cardiovascular disease is more permanent than weight loss for cosmetic reasons.

The drug studies included for comparative purposes generally used a "stepped care" treatment package rather than a single antihypertensive drug. The value of non-pharmacological treatments might be further shown in a comparative trial with step 1 monotherapy such as a diuretic. The Australian National Blood Pressure Study has reported that only 30% of hypertensive patients in the sample were controlled by chlorothiazide alone.¹⁷ This would suggest that weight loss, progressive muscle relaxation, and yoga could provide competitive alternatives to step 1 drug treatment. Most general practitioners will already be familiar with strategies for weight reduction^{48 49} and progressive muscle relaxation^{50 51}; whether they would choose to familiarise themselves with yoga techniques is not known. Certainly doctors have the potential to carry out effective non-drug treatments for hypertension.

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Evaluation of digitalis in cardiac failure

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Abstract

Ten patients in sinus rhythm with symptomatic cardiac failure participated in a study investigating the value of digitalis at rest and during dynamic exercise. A haemodynamic profile and left ventricular ejection fraction were measured before treatment, after intravenous ouabain, and after six weeks of maintenance treatment with digoxin.

There was no significant change in the haemodynamic profile or in the left ventricular ejection fraction at rest after either glycoside. During exercise there was a

significant reduction in left ventricular filling pressure from 39 ± 3 mm Hg to 34 ± 3 mm Hg ($p < 0.05$) after ouabain and to 33 ± 3 mm Hg ($p < 0.02$) after digoxin. Cardiac index improved from 3.3 ± 0.3 l/min/m² to 4.0 ± 0.4 l/min/m² ($p < 0.01$) after ouabain and to 3.8 ± 0.4 l/min/m² ($p < 0.01$) after digoxin. During exercise stroke volume index and stroke work index also improved significantly with both glycosides. This was accompanied by an increase in left ventricular ejection fraction from $29 \pm 2\%$ to $36 \pm 3\%$ ($p < 0.05$) after ouabain and digoxin.

In this study both intravenous ouabain and maintenance treatment with oral digoxin exerted a modest positive inotropic effect in patients with cardiac failure in sinus rhythm. The haemodynamic benefit, however, was manifest only during exertion.

Introduction

For many years digitalis preparations have been advocated as the principal positive inotropic agents for cardiac failure. Experiments showed a cardiotonic effect, while studies of acute administration confirmed improved myocardial performance.¹⁻⁷ Nevertheless, the translation of these findings into clinical

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