poisoning[14] and have shown a decreasing need for intensive care since 1978.[15]

Because of the change in types of drugs commonly taken in overdose over the past 15 years it may no longer be possible to detect an association between alcohol intake and severity of poisoning. Benzodiazepines, barbiturates, and dextropropoxyphene, all of which interact adversely with alcohol,[5-7] now account for a smaller proportion of overdoses than before. Furthermore, it has become increasingly recognised that alcohol has pharmacological actions which may moderate the effects of certain types of drug overdose. In the acute phase alcohol may decrease the severity of self poisoning by decreasing the intestinal absorption of the drug taken in overdose.[16] In more chronic usage alcohol may cause tolerance to the depressive effects of an overdose on the central nervous system and by inducing hepatic enzyme activity enhance the rate of drug metabolism.

Thus, though there appears to have been no increase in the severity of overdoses associated with increasing alcohol use, there has been a rise in total admission rates. Overdoses associated with alcohol tend to occur at night and therefore impose a considerable workload on casualty departments and acute admitting units.

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Vegetarian diet in mild hypertension: a randomised controlled trial

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Abstract

In a randomised crossover trial 58 subjects aged 30-64 with mild untreated hypertension were allocated either to a control group eating a typical omnivorous diet or to one of two groups eating an ovolactovegetarian diet for one of two six week periods.

A fall in systolic blood pressure of the order of 5 mm Hg occurred during the vegetarian diet periods, with a corresponding rise on resuming a meat diet. The main nutrient changes with the vegetarian diet included an increase in the ratio of poly-unsaturated to saturated fats and intake of fibre, calcium, and magnesium and a decrease in the intake of protein and vitamin B_{12}. There were no consistent changes in urinary sodium or potassium excretion or body weight.

In untreated subjects with mild hypertension, changing to a vegetarian diet may bring about a worthwhile fall in systolic blood pressure.

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Introduction

A blood pressure lowering effect of an ovolactovegetarian diet has been suggested by studies reporting a smaller rise in blood pressure with age in Seventh Day Adventist vegetarians[1] and macrobiotic vegetarians[2] than in the general population. This effect appears to be independent of differences in body weight and other differences in lifestyle, as Seventh Day Adventist vegetarians also have lower blood pressures than Mormon omnivores, who in common with Seventh Day Adventists also avoid alcohol, tobacco, and caffeine.[3] More direct evidence comes from a controlled trial of a vegetarian diet in healthy normotensive meat eaters, which found a diet related reduction in systolic blood pressure of 5-6 mm Hg independent of changes in body weight.[4]

We have examined the effect of a vegetarian diet in subjects with mild hypertension.

Subjects and methods

Between June and November 1983 the National Heart Foundation of Australia conducted a risk factor prevalence survey in which 1788 residents of Perth, Western Australia, aged 25 to 64 were selected at random for measurement of coronary risk factors. Blood pressures were measured in duplicate on the right arm after five minutes' sitting by a trained nurse using a standard mercury sphygmomanometer. All subjects whose blood pressures were between 150 and 200 mm Hg systolic or between 90 and 115 mm Hg diastolic and who were not currently being treated for hypertension (inclusion criteria) were asked to return a week later for a second blood pressure measurement with a view to possible participation in the dietary trial.

At the second and all subsequent visits blood pressures were measured in duplicate on the right arm after five minutes' sitting using an automatic oscillometric device (Dinamap recorder). If the blood pressure readings still met the inclusion criteria at this and a subsequent visit a week later subjects

attended after a further week for full clinical evaluation in a hypertension clinic. Evaluation was conducted by specialist physicians and included history, physical examination, analysis of blood and urine, chest radiography, and electrocardiography. Subjects were then excluded from consideration for the trial if they showed evidence of heart failure, angina, or claudication; if there was any renal impairment; if they were taking psychotropic or anti-inflammatory agents or oral contraceptives; of if they were being treated for diabetes. In the absence of these findings they attended a week later for a final pretrial blood pressure measurement. If all blood pressure readings had met the inclusion criteria and no two consecutive readings exceeded 180 mm Hg systolic or 110 mm Hg diastolic patients were then asked to enter the trial. Appropriate further surveillance or management was arranged for patients who were excluded on any grounds or who refused to participate.

STUDY DESIGN

After agreeing to the trial subjects were observed for two weeks (period 1), during which they were asked to maintain their usual diet and lifestyle and to record on alternate days everything they ate and drank. They were then allocated at random to one of three treatment groups for two consecutive six week dietary periods (periods 2 and 3). Subjects in group 1 were told to maintain their usual dietary practices throughout both periods 2 and 3. Subjects in group 2 were asked to follow an ovolactovegetarian diet during period 2 and to return to their usual diet during period 3. Subjects in group 3 were asked to maintain their usual diet during period 2 and to follow an ovolactovegetarian diet during period 3. All subjects were told not to alter their current smoking habit, alcohol consumption, physical activity, and use of salt for the duration of the study. In addition, each subject was asked to take one vitamin C tablet daily. Subjects were told that the study would assess whether a small dose (50 mg) of vitamin C with or without a vegetarian diet could reduce blood pressure. Vitamin C was introduced in the hope of generating a uniform placebo response that would minimise any placebo response to the vegetarian diet.

When taking the vegetarian diet subjects were told to avoid eating meat, fish, and poultry and to eat only wholegrain cereals, use only wholemeal bread, double their fruit intake, increase vegetable intake, and use polyunsaturated vegetable margarines and oils as spreads and in cooking instead of animal and other more saturated fats. The aim of the dietary intervention was to reproduce as nearly as possible the diet of long term vegetarians.[3] Subjects were advised to eat their usual amount of food so as to avoid weight loss. Canned meat substitutes (Sanitarium Health Food Co) were made available free of charge and booklets of easy to prepare vegetarian recipes given to each subject.

DATA COLLECTED

Blood pressure—Subjects returned every two weeks throughout the study and had their blood pressure measured in duplicate by Dinamap[5] after five minutes' sitting. All blood pressures were measured on the right arm.

Weight and height—Height was measured once with a Stadiometer. Weight was measured with a calibrated beam scale each time blood pressure was measured.

Dietary records—In addition to the dietary records kept during period 1, subjects were asked to keep seven 24 hour estimated dietary records in each of periods 2 and 3 such that by the end of each period each day of the week had been surveyed. All subjects were given detailed instructions on how to keep dietary records using household measures. Completed records were checked every two weeks by an experienced nutritionist, who used household measures and food models when necessary to estimate sizes of portions. Dietary records were subsequently coded and then analysed using McCance and Widdowson's food tables as modified for use in Australia.[6]

Urine—A 24 hour urine sample was collected into 10 ml 50% acetic acid on the last Sunday of each of the three study periods. Subjects were given written instructions on when and how to collect the sample. Aliquots were drawn for estimation of sodium, potassium, creatinine, and urea concentrations (sequential multiple analysis by autoanalyser) and 3-methylhistidine excretion.[7] Samples were checked for protein (all were negative) and centrifuged for three minutes in a 1/1 solution of 0·05M phosphate buffer. Amino acids were separated by gradient elution using various buffers and analysed by a Waters amino acids analysis system; peak areas were measured by integration. The within batch coefficient of variation was 4·1% and the between batch coefficient 4·6%. The concentration of 3-methylhistidine in urine has been directly correlated with recent meat intake[8,9] and was used as a check on compliance with the vegetarian diet.

Questionnaires—A general health and lifestyle questionnaire was completed by all subjects at their first visit. At their last visit the subjects were asked to complete a detailed questionnaire covering change in various lifestyle factors during the study, compliance with the dietary recommendations, effect of the dietary change on bowel function, and frequency of intake of foods expected to change during the period of the vegetarian diet.

Results

The 1788 subjects who participated in the National Heart Foundation survey represented 85% of those who were invited and could have attended. About 10% of the participants were identified as having mild untreated hypertension and invited to reattend. Sixteen per cent of these subjects refused to reattend and half of those whose blood pressures were remeasured were excluded, mainly because their blood pressures fell below the value for inclusion. Seventy six subjects were asked to participate in the trial, of whom 60 entered the trial and 58 (76%) completed it.

INITIAL CHARACTERISTICS

There were no substantial differences in initial characteristics among the three study groups (table I). More people, however, added salt at the table in group 1 than in the two other groups ($\chi^2_1 = 5{\cdot}2$; $p < 0{\cdot}05$). Initial blood pressures recorded in the National Heart Foundation survey did not differ significantly among the groups, though group mean systolic and diastolic pressures were highest in group 3. By comparison with all participants in the National Heart Foundation survey, those who completed the trial were more likely to drink alcohol, be slightly overweight, and be male.[10]

TABLE I—*Demographic and lifestyle characteristics of subjects in the three study groups*

	Group		
	1 (n=19)	2 (n=19)	3 (n=20)
M:F ratio	14:5	13:6	15:5
Mean age (years) (SD)	50·7 (10·8)	50·5 (7·7)	49·4 (10·1)
No (%) always adding salt at table	11 (58)	7 (37)	4 (20)
No (%) ever told they had high blood pressure	6 (32)	7 (37)	10 (50)
Initial values recorded in National Heart Foundation survey:			
Mean systolic blood pressure (mm Hg) (SD)	154·4 (15·2)	150·4 (9·9)	160·1 (15·3)
Mean diastolic blood pressure (mm Hg) (SD)	98·5 (9·7)	97·3 (5·2)	102·3 (9·0)
Mean body mass index (kg/m^2) (SD)	26·7 (3·0)	26·9 (3·5)	28·3 (6·2)

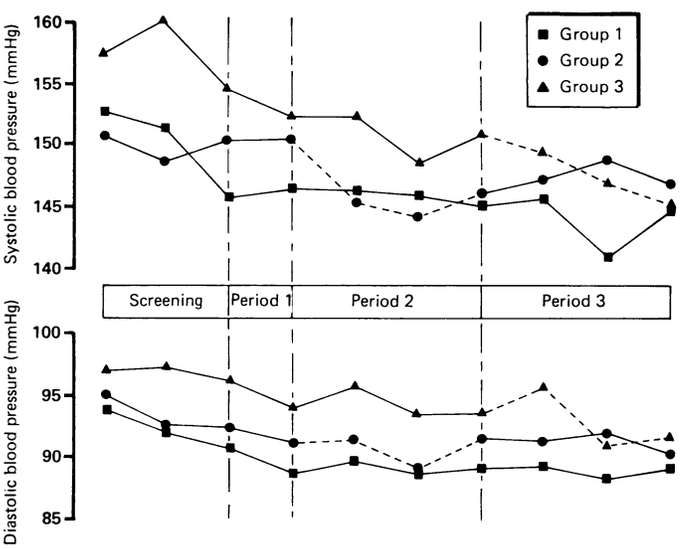

FIG 1—Mean blood pressures in the three groups during trial. Broken lines represent period of ovolactovegetarian diet.

BLOOD PRESSURE

Figure 1 shows the blood pressures measured at the initial survey visit (standard mercury sphygmomanometer) and at all subsequent visits (Dinamap). Pressures fell 4-5 mm Hg during period 1 before the introduction of any planned dietary change: this fall probably represented effects of both familiarisation and regression to the mean.

Figure 2 shows the changes in blood pressure from the beginning of period 2. There were further significant falls in systolic ($p<0·05$; paired t tests) but not diastolic blood pressures during periods 2 and 3 in subjects following a vegetarian diet. The diet related fall in each group was of the order of 5 mm Hg. Groups not taking the vegetarian diet during either of these two periods showed a change in systolic blood pressure of only about 1-2 mm Hg.

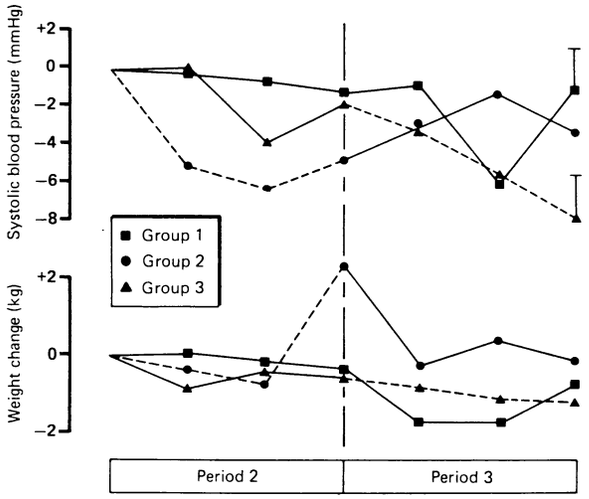

FIG 2—Changes in systolic blood pressure and weight in the three groups during trial. Broken lines represent period of ovolactovegetarian diet.

Repeated measures analysis of variance showed that during the vegetarian diet the fall in systolic but not diastolic blood pressure was significantly different from background variation (F ratio 3·4; df=6, 315; p=0·005).

The change in blood pressures during the third period in groups 2 and 3 was also analysed by the method of Hills and Armitage for a two period crossover design.[11] For systolic blood pressure there was a significant treatment effect (mean change due to vegetarian diet −3·5 mm Hg, 95% confidence interval (CI) −7·0 to −0·1 mm Hg). The period effect for systolic blood pressure was not significant (mean change from period 2 to period 3 −2·2 mm Hg, 95% CI −5·7 to +1·3 mm Hg). For diastolic blood pressure there were no substantial treatment or period effects (mean change with treatment −1·2 mm Hg, 95% CI −3·1 to +0·8 mm Hg; mean change with period +0·8 mm Hg, 95% CI −1·2 to +2·7 mm Hg).

DIETARY CHANGE

Table II shows the nutrient intakes measured during the trial. Usual intakes of nutrients before the dietary periods were similar in all groups. When subjects were taking the vegetarian diet there were substantial and significant increases in the ratio of polyunsaturated to saturated fats (80%) and in intakes of dietary fibre (35%), vitamin C (56%), vitamin E (32%), calcium (19%), and magnesium (17%). Intakes of vitamin B_{12} (62%) and protein (21%) decreased, and potassium and energy intakes did not change. The only variation in body weight was during the last two weeks of the second period in group 2 (eating a vegetarian diet), when the average weight for that group rose about 2 kg (fig 2).

URINE

The data for urinary constituents were not normally distributed (Kolmogorov-Smirnov goodness of fit tests) and results were therefore expressed as geometric means (table III). 3-Methylhistidine excretion fell when subjects ate a vegetarian diet and rose again in group 2 on return to an omnivorous diet. Similarly, urinary urea was lower after subjects had been taking the vegetarian diet for six weeks. There were no consistent dietary effects on urinary sodium, potassium, or creatinine excretion.

OTHER LIFESTYLE CHANGES

At the last visit subjects were asked whether they had changed their level of physical activity, alcohol and tobacco consumption, use of tea and coffee, or use of salt at the table. No subjects reported change in use of tea and coffee. About a quarter of all subjects reported some reduction in use of salt.

TABLE II—*Estimated daily intakes of principal nutrients by group and period. Values are means (SD in parentheses). Values in italics represent results during period of ovolactovegetarian diet*

	Group		
	1	2	3
Energy (kJ):			
Usual diet	8861 (2526)	10065 (3280)	9573 (2217)
Period 2	8406 (3011)	*9753 (3455)*	9375 (2752)
Period 3	8154 (2916)	10133 (3277)	*8985 (2593)*
Total carbohydrate (g):			
Usual diet	204·7 (63·4)	242·4 (79·7)	394·3 (149·3)
Period 2	191·2 (55·9)**	*257·3 (82·3)*	404·9 (135·1)
Period 3	196·5 (66·2)**	255·9 (83·7)	350·5 (147·8)
Total fat (g):			
Usual diet	88·9 (34·8)	108·4 (48·2)	95·7 (24·9)
Period 2	84·7 (46·2)	*99·9 (48·2)*	94·4 (37·3)
Period 3	79·2 (38·1)	103·9 (44·6)	88·4 (34·5)
Dietary fibre (g):			
Usual diet	16·0 (5·9)***	29·0 (12·2)	20·9 (9·4)
Period 2	16·7 (7·8)***	*35·8 (11·7)*††	21·1 (11·7)
Period 3	16·2 (5·1)***	27·7 (10·4)†††	*30·9 (11·5)*†††
Polyunsaturated to saturated fat ratio:			
Usual diet	0·48 (0·30)	0·53 (0·30)	0·42 (0·19)
Period 2	0·55 (0·28)	*0·77 (0·27)*†††	0·44 (0·19)
Period 3	0·53 (0·39)	0·62 (0·28)††	*0·78 (0·38)*†††
Protein (g):			
Usual diet	90·4 (35·0)	90·0 (21·8)	95·8 (24·5)
Period 2	88·8 (27·6)*	*76·4 (23·5)*†††	92·1 (23·8)
Period 3	86·2 (33·1)**	91·5 (27·1)	*68·2 (20·0)*†††
Calcium (mg):			
Usual diet	753 (339)	923 (4274)	866 (293)
Period 2	717 (259)***	*1072 (364)*††	887 (359)
Period 3	700 (300)***	932 (294)†	*1079 (380)*††
Magnesium (mg):			
Usual diet	280·4 (85·7)***	405·0 (155·3)	330·1 (107·0)
Period 2	287·4 (95·7)***	*458·7 (158·5)*††	336·5 (105·4)
Period 3	316·4 (111·9)*	415·5 (132·9)†	*403·6 (147·3)*††
Potassium (mg):			
Usual diet	2921 (900)*	3591 (917)	3433 (779)
Period 2	2988 (916)*	*3626 (983)*	3381 (795)
Period 3	3336 (1133)	3948 (1074)†	*3528 (1140)*††
Sodium (mg):			
Usual diet	2551 (967)	3124 (1138)	2916 (1038)
Period 2	2401 (985)	*3038 (1262)*	2875 (1027)
Period 3	2430 (1173)	2725 (1077)	*2772 (999)*

Significance of between group differences (ANOVA F ratio): *p<0·1; **p<0·05; ***p<0·01.
Significance of difference from value in previous period (two tailed paired t test): †p<0·1; ††p<0·05; †††p<0·01.
Conversion: SI to traditional units—Energy: 1 kJ≈0·24 kcal.

A few subjects in each group reported increased physical activity and reduced alcohol consumption since the beginning of the study. Roughly a third to half of the subjects had made some change in their lifestyle other than in diet during the study. Overall the controls (group 1) appeared to have made more health related changes than subjects in groups 2 and 3.

MULTIPLE REGRESSION ANALYSIS

Backward stepwise multiple regression analysis was carried out including change in body weight, smoking, alcohol consumption, exercise, baseline blood pressure, and a dietary "factor" derived from a principal components analysis describing the main nutrient changes relating to blood pressure. Only baseline blood pressures (T=2·83; p=0·009) and the dietary factor (T=2·16; p=0·04) accounted for significant variation (r^2=0·36) in systolic blood pressure (F=7·33; p=0·003). No variables accounted for any significant amount of the small variation in diastolic blood pressure.

TABLE III—*Geometric mean 24 hour urinary excretion of electrolytes and 3-methylhistidine in the three study groups. Values in italics represent results at end of ovolactovegetarian period*

	Group		
	1	2	3
3-Methylhistidine (μmol/24 h):			
End period 1	365·8	343·4	320·9
End period 2	348·3	*212·1***	345·7
End period 3	339·2	304·4**	*264·0**
Sodium (mmol/24 h):			
End period 1	152·3	161·6	129·6
End period 2	162·5	*132·0**	148·7
End period 3	155·6	132·7	*148·6*
Potassium (mmol/24 h):			
End period 1	66·3	63·0	56·7
End period 2	64·9	*57·9*	58·7
End period 3	65·4	52·6	*61·4*
Creatinine (mmol/24 h):			
End period 1	15·2	14·1	13·3
End period 2	14·5	*12·3*	14·7
End period 3	14·2	13·0	*13·6*
Urea (mmol/24 h):			
End period 1	384·4	371·9	340·8
End period 2	339·2	*292·9**	358·1
End period 3	363·8	341·7	*318·3*

Significance of difference from value at end of previous period (two tailed paired *t* test): *p<0·05; **p<0·01.

Conversion: SI to traditional units—3-Methylhistidine: 1 μmol/24 h≈0·17 mg/24 h. Sodium: 1 mmol/24 h=1 mEq/24 h. Potassium: 1 mmol/24 h=1 mEq/24 h. Creatinine: 1 mmol/24 h≈0·1 g/24 h. Urea: 1 mmol/24 h≈0·06 g/24 h.

Discussion

This study has shown for the first time that a vegetarian diet can lower systolic blood pressure in untreated subjects with mild hypertension. The results are consistent with findings in normotensive subjects and add to evidence from cross sectional population studies suggesting that a vegetarian diet decreases the prevalence of hypertension.[3,4]

Careful attention was paid to excluding other factors which might have influenced blood pressures during the study. Changes in smoking, alcohol consumption, and exercise were minimised and when included in a multiple regression analysis did not influence the dietary effect on systolic blood pressure.

Though we attempted to "blind" subjects to the reason for the dietary intervention, probably this was only partially achieved. There had been some local media attention given to the benefits of a vegetarian diet, and possibly blood pressures fell when subjects were taking the vegetarian diet simply because of their expectations.

The absence of a significant change in diastolic blood pressure may have been due to the limited statistical power of the study. The 95% confidence interval about the estimated mean treatment related change in diastolic blood pressure was −3·1 to +0·8. Results were therefore consistent with as much as a 3 mm Hg lowering in diastolic blood pressure due to the vegetarian diet.

The size of the dietary effect on systolic blood pressure (fall of about 5 mm Hg) was similar to that seen in normotensive subjects taking a vegetarian diet.[4] A larger effect might have been expected in those with increased pressures. Though the two studies were similar in design, however, the normotensive subjects had most of their meals provided, so that their compliance with dietary recommendations was likely to have been greater and more uniform. This is supported by the observation that estimated changes in dietary fibre and ratio of polyunsaturated to saturated fats were substantially greater in the normotensive subjects than in the hypertensive subjects in our study. That a measurable reduction in meat intake was achieved in both studies was shown by the falls in urinary excretion of 3-methylhistidine.

It is not clear which components of the diet were responsible for the changes in blood pressure in our series. The estimated intakes of most nutrients when subjects were taking the vegetarian diet were similar to those of long term Seventh Day Adventist vegetarians in Western Australia[3] and included increases in dietary fibre, polyunsaturated fats, magnesium, calcium, vitamin C, and vitamin E and decreases in saturated fat, cholesterol, total protein, and animal protein. Estimated intakes and excretion of sodium and potassium did not change appreciably during the study and changes in body weight did not explain the results. It appears from previous studies that increasing only the polyunsaturated to saturated fat ratio does not affect blood pressure in normotensive[12] or hypertensive subjects (F M Sacks *et al*, personal communication), and increasing dietary fibre is similarly ineffective.[13] Which, if any, of the remaining changes in dietary components may have been responsible for the changes in blood pressure remains a matter for speculation.

Data from the Pooling Project Research Group suggested that a reduction of 5 mm Hg in systolic blood pressure in 55-59 year old men would result in a 7% reduction in the number of major coronary events.[14] This suggests that significant long term benefit might result from a sustained reduction in blood pressure of the size reported here, even in older men.

It appears from our data and from other epidemiological studies[1-3] that some dietary components that differ between meat and vegetarian diets are at least as important as dietary sodium in determining population blood pressure levels. It will be important to identify the responsible nutrients, as most of our subjects were eager to return to their usual diets at the end of the studies. Thus more acceptable dietary changes are needed if the effect of a vegetarian diet is to be used to make any long term impact on the incidence of hypertension.

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