

follow-up may lead to measurable improvements in understanding and compliance which would be reflected in the slope of the incidence curve for undertreatment in fig 1, but the current evidence about the value of this kind of approach is incomplete or conflicting and requires further evaluation. Finally, the evidence from this study suggests that thyroxine medication, its prescribing and control, would be simpler and safer with a single tablet strength of 50 µg.

The methods used in the follow-up system for detecting undertreatment now require modification, including the use of serum thyrotrophin estimations to improve both sensitivity and specificity of the follow-up screening tests. The follow-up system offers opportunities for more detailed studies of those at particular risk of undertreatment or overtreatment.

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Relevance of colour vision and diabetic retinopathy to self-monitoring of blood glucose

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Summary and conclusions

A study was performed to determine the effect of colour vision defects and diabetic retinopathy on diabetic patients' ability to use a visual method of measuring their own blood glucose concentrations. Forty-eight diabetics whose colour vision and retinal status was assessed by an ophthalmologist carried out 311 blood glucose estimations using oxidase-peroxidase test strips which were then compared with laboratory values. There was a trend towards poor performance with advancing age but neither colour vision nor diabetic retinopathy had a significant effect on patients' ability to use this visual method of estimating blood glucose concentrations.

The vast majority of diabetics who will benefit from being able to monitor their own blood glucose control should have no difficulty in using a visual method of testing, even if they do have defects of colour vision.

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Introduction

A major aim in treating diabetics is preventing the serious long-term complications. Watkins¹ has reviewed the recent experimental and clinical evidence which increasingly implicates poor metabolic control as a major factor contributing to diabetic small blood vessel disease. The widely used estimation of urinary glucose excretion is always unreliable when the renal threshold is abnormal, may correlate poorly with blood glucose concentrations even when the renal threshold is apparently normal,²⁻³ and fails to detect hypoglycaemia. Measurement of glycosylated haemoglobin reflects blood glucose control in the previous few weeks but is of little use for the day-to-day adjustment of insulin therapy.⁴ Self-monitoring of blood glucose concentrations by diabetics using reflectance meters has been shown to be practical,⁵⁻⁶ but the accuracy of the instruments has been questioned⁷ and their use does mean a capital outlay.

Experienced observers can now measure blood glucose accurately without a meter using BM Test Glycaemie 20-800 strips.⁸ These glucose oxidase-peroxidase strips simultaneously develop two colours which are matched by eye on a colour comparison scale ranging from 1.1-44.4 mmol/l (19.8-799 mg/100 ml). Colour vision defects of all types are more common in diabetics, however, and patients with retinopathy are particularly liable to defects in blue-yellow discrimination.⁹⁻¹¹ We therefore evaluated the colour vision of 48 diabetics before assessing their ability to use these test strips for blood glucose self-monitoring.

Patients and methods

Forty-eight diabetics without previous experience of blood glucose estimation were selected to represent a wide spectrum of ages. Twenty-nine men and 19 women whose ages ranged from 16 to 71 years (mean 46) were tested in nine groups and the following procedures were used for each group.

Colour vision was assessed using the Farnsworth-Munsell 100 Hue Test¹² under standard conditions. In this test the patient arranges a series of coloured discs in order, according to shade; each disc is numbered on the reverse side to indicate the correct order. Thus a numerical index of any error can be derived and a graph drawn showing the affected part of the visual spectrum. The results were recorded both graphically, to show particular colour vision defects, and as a total error score for each patient. On the basis of the total error score, the patients were classified into three groups. The first, with normal colour vision, had a Farnsworth-Munsell (F-M) score of 100 or less; the second, with moderate colour vision defect, an F-M score of 101-249; and the third with severe colour vision defect, an F-M score of 250 or more.

Blood glucose concentrations were estimated by the patients on fresh venous blood using the BM Test-Glycaemie 20-800 glucose oxidase-peroxidase test strip according to the manufacturer's instructions, which divide the values into seven ranges (see table I). Each patient estimated blood glucose values for all members in the group. Simultaneously fluoride samples of the same venous blood were analysed on a Beckmann analyser to obtain the true plasma glucose concentration, which was later corrected by a factor of 10% to derive a blood glucose value comparable with the patients' results. Each patient's glucose estimation was compared with the corrected laboratory result and was recorded as unsatisfactory if it disagreed with the laboratory value by more than the equivalent of one gradation on the BM Test colour scale. By expressing the number of satisfactory results as a percentage of the total number of estimations, a blood glucose performance rating was derived for each patient.

Ocular complications of diabetes in each patient were assessed by a consultant ophthalmologist and graded: 0, no retinopathy; 1, simple background retinopathy; 2, advanced retinopathy (including exudative, proliferative, and/or photocoagulated retinopathy).

Results

Our 48 subjects recorded 311 blood glucose estimations encompassing a laboratory range from 1.4 to 24.7 mmol/l (25.2-444 mg/100 ml) (table I). The patient's estimation was in the correct range band—that is, in agreement with the laboratory—on 128 occasions; 149 estimations were in an adjacent range band to the laboratory result and 34 were in another range band (table I). The mean performance rating was 84%, without difference between the sexes, but there were great individual variations: three patients made only half their estimations accurately, while 18 patients were 100% accurate.

Fourteen patients had normal vision, 24 had a mild to moderate defect, and 10 had severely defective colour vision. Except for five men with a mild red-green colour defect, the distribution of colour vision defects was similar in both sexes. The relationship between the patients' colour vision status and performance rating is shown in

table II. Those with severe colour vision defects were less adept at accurately estimating blood glucose concentrations (their mean performance rating was 79% compared with 88% and 89% in those with moderate and no defects respectively), but the difference was not statistically significant.

Thirty-one of the 48 patients did not have retinopathy, nine had background retinopathy, and the remaining eight had advanced retinopathy. Retinopathy was found in 43% of patients over 50 years of age and in 24% of those under 50 years. Colour vision deteriorated in the presence of retinopathy. The mean F-M score of those without retinopathy was 137, of those with background retinopathy 232, and of those with advanced retinopathy 291. Only one patient with retinopathy had normal colour vision. Retinopathy had little effect on performance ratings: patients with advanced retinopathy had a mean rating of 89% while the other two groups both had mean ratings of 83%.

There was a clear relation between increasing age and deteriorating colour vision. Those with normal colour vision had a mean age of 33 years, while those with moderate and severe defects had mean ages of 43 and 56 years respectively. The mean F-M score of those patients under 50 years of age was 127, whereas it was 239 in those aged over 50 years. This effect of age was independent of retinopathy (table II).

Older patients performed the blood estimations less accurately than the younger patients, although this trend did not reach statistical significance. The mean performance rating of those under 50 years was 87%, while those over 50 years had a mean performance rating of 80%. That older patients were less accurate was true for all grades of retinopathy and colour vision (table II).

Discussion

By using a visual colour comparison technique BM Test Glycaemie 20-800 glucose oxidase test strips allow blood glucose concentrations to be measured without a reflectance meter and at much less expense. Our results show that most diabetics can estimate blood glucose concentrations accurately using this method in nine out of ten tests. A few patients, most of whom were elderly, were much less accurate. Although the results appear to suggest a correlation between deteriorating colour vision and poor performance of blood glucose estimation, this finding can be explained on the basis of age. Of the 10 patients with severely abnormal colour vision only two were under 50 years of age and they measured blood glucose as well as those with normal colour vision. In addition, further analysis showed no correlation between poor performance and any particular type of colour vision defect. The association between increasing age and poorer performance was independent of both retinopathy and abnormalities of colour vision but was not statistically significant (using such non-parametric statistical methods as the Kolmogorov-Smirnov test), perhaps because of the small number of patients.

Despite the theoretical grounds for believing that the diabetic's tendency to develop colour vision defects and retino-

TABLE I—Blood glucose results in the seven ranges of the BM test (1.1-44.4 mmol/l) in relation to laboratory estimation

Range (mmol/l):	1.1-2.2	2.2-4.4	4.4-6.7	6.7-10	10-13.3	13.3-22.2	22.2-44.4	Total estimations
Agree with laboratory	0	10	20	12	39	44	3	128
In next range band	1	25	20	23	30	47	3	149
In another range band	0	1	12	2	2	13	4	34
Total	1	36	52	37	71	104	10	311

Conversion: SI to traditional units—Glucose: 1 mmol/l \approx 18 mg/100 ml.

TABLE II—Colour vision (F-M score) and blood glucose estimation (mean performance rating) in relation to age and retinopathy

Age	Mean F-M score		Mean performance ratings (%)		Mean performance ratings (%)		
	No retinopathy	Retinopathy	No retinopathy	Retinopathy	Normal colour vision	Moderate colour vision deficit	Severe colour vision deficit
<50 years	108	177	86	91	89	86	90
≥50 years	178	318	77	82	79	82	77

pathy would impair their ability to use the BM Test colour comparison scale, this has not proved to be the case in practice. Although the value of home monitoring of glucose concentrations has been questioned,¹³ the vast majority of those likely to benefit from the technique, especially the adolescent, pregnant women, and diabetics who cannot rely on urine tests, are unlikely to have any difficulty due to defective colour vision. All patients introduced to the technique should be assessed carefully before relying on their observations, particularly if they are elderly, but routine testing of colour vision seems unnecessary.

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Effect of treatment of hyperlipidaemia on haemostatic variables

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Summary and conclusions

The haemostatic function of 11 men with hyperlipidaemia was measured before and after they were treated with a carbohydrate-reduced, fat-modified diet. After treatment, which significantly reduced serum triglyceride and cholesterol concentrations, they showed a significant fall in mean levels of clotting factors VII, VIII, and X and a rise in fibrinolytic activity.

These findings suggest that haemostatic function may be important in the pathogenesis of ischaemic heart disease.

Introduction

The Northwick Park Heart Study has produced evidence of an association between high concentrations of factor VII, factor VIII, and fibrinogen and an increased risk of later cardiovascular death.¹ We describe here the changes in these and other haemostatic variables in men who were treated for hyperlipidaemia.

Patients and methods

Eleven men were studied. Nine were participants in the Northwick Part Heart Study referred for further investigation of hyperlipidaemia found at entry to the study; three of these men were also found to have chemical diabetes on oral glucose tolerance tests. Two known maturity-onset diabetics were also studied. The mean age of the 11 men was 50 years (range 31-65), and their mean body weight before treatment was 76.3 kg.

All the men were treated with a carbohydrate-reduced, fat-modified diet.² The diets contained 120-150 g carbohydrate and 5.0-6.3 MJ (1200-1500 kcal) a day, depending partly on previous intake. The daily cholesterol intake was about 300 mg. The ratio of polyunsaturated to saturated fats was 1.4:1. Two men also received clofibrate 1 g twice daily. There was no evidence of excess alcohol consumption in any of the men, and they did not change their smoking habits during the study.

Biochemical and haemostatic tests were performed before and after treatment, which lasted a mean of three months (range 1-5). Venous blood was taken through an indwelling cannula between 9 and 10 am after an overnight fast. Serum triglyceride, cholesterol, and blood glucose concentrations were measured by standard enzymatic techniques; data on individual lipoprotein fractions in eight of the men have already been published.³ Fibrinogen and clotting or biological antithrombin activity levels of factors II, V, VII, VIII (denoted VIII_c), and X; III; factor VIII-related antigen (denoted VIII_a); and fibrinolytic activity were measured by methods described elsewhere.^{4,5} Clotting-factor assays were all carried out against the same standard and values were expressed as percentages of this standard. Fibrinolytic activity was expressed as 100/lysis time in hours.

Results before and after treatment were compared using Student's paired *t* test (two-tailed).

Results

The findings are shown in the table. There was a sharp reduction in the mean concentration of fasting serum triglycerides and there were also significant reductions in total serum cholesterol and fasting

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