marked diagnostic imprecision associated with nonreplicated OGTT determinations (13).

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New Semiquantitative Dipstick Test for Microalbuminuria

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Objective: We compared a new semiquantitative dipstick test for microalbuminuria (Micral-Test) with a quantitative immunoturbidimetric method. Research Design and Methods: This correlation study was performed at a pediatric and medical outpatient clinic at a university hospital. Overnight urine samples containing <200 mg/L albumin from 186 diabetic patients were analyzed. Results: The correlation coefficient between the new semiquantitative method and the immunoturbidimetric reference method was 0.82. Elevated albumin concentration was defined as >20 mg/L albumin in overnight urine, and the prevalence of samples with values above this level was 28%. By this definition, the Micral-Test assay level ≥20 mg/L had a sensitivity of 92.3% and a specificity of 82.1%. Of the diabetic subjects, 84.9% were correctly classified as having elevated urinary albumin concentration or not. Conclusions: The Micral-Test is useful for in-clinic screening for elevated urinary albumin concentration and monitoring the development of urinary albumin excretion in the low microalbuminuric range. ***Diabetes Care*** **14:1094–97, 1991**

Microalbuminuria is a predictor for later clinical diabetic nephropathy in both insulin-dependent diabetes mellitus (IDDM; 1–3) and non-insulin-dependent diabetes mellitus (NIDDM; 4) and for increased cardiovascular mortality (5). Elevated urinary albumin excretion is potentially reversible when near normoglycemia (6,7) or lowering of blood presure (8) is obtained and is therefore an important parameter of clinical care of patients with IDDM or NIDDM. The awareness of the importance of bringing tests closer to patients and the advantage of getting the result before the patient leaves the outpatient clinic have led to the demand for a simple, semiquantitative side-

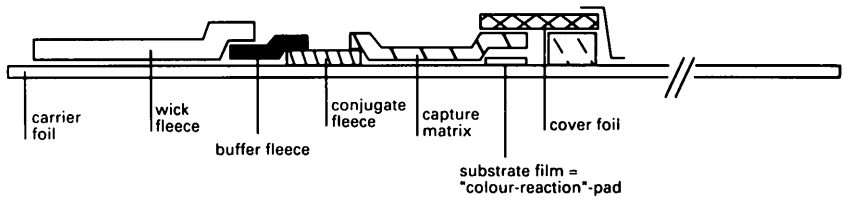

FIG. 1. Test strip structure.

room test for detecting urine albumin in the range of 10–100 mg/L. So far, the available methods are qualitative (9–11). This study compared a new semiquantitative test, the Micral-Test, with a quantitative immunoturbidimetric test.

RESEARCH DESIGN AND METHODS

Micral-Test is an albumin-specific dipstick test based on a combined immunological and chromatographic principle (Fig. 1). The test assay levels are 10, 20, 50, and 100 mg/L albumin. The test strip is dipped into a urine sample at room temperature for 5 s. The stick is placed on a nonabsorbent surface. A color scale is read after 5 min. Results read >6 min after the strip is dipped must be disregarded, because this is not an end-point method.

Results obtained by this semiquantitative method were compared with values obtained by an immunoturbidimetric method (albumin concentration, Orion, cat. no D-148, Espoo, Finland). Calibration was performed with dilutions of Seronorm-Protein (Nycomed, Olso, Norway), and absorbances were read in a Cobas-Bio instrument. The coefficient of variation of the method is 5% in the 20- to 30-mg/L assay level.

The two methods were applied on 203 consecutive overnight urine samples from IDDM and NIDDM patients. The patients were from 9 to 73 yr old (mean 30 yr), and they delivered samples when visiting the outpatient clinic. The samples were stored for 24–48 h at a temperature of 4°C. The Micral-Test was read precisely between 5 and 6 min after the strip was dipped in unprocessed urine in series of 10 samples by one person (K.T.) before the results of the reference method were known. Seventeen of 203 samples contained >200 mg albumin/L and were excluded from subsequent analysis. Values <10 mg/L were set to 5 mg/L. For statistical calculation, linear correlation by the least-squares method was used.

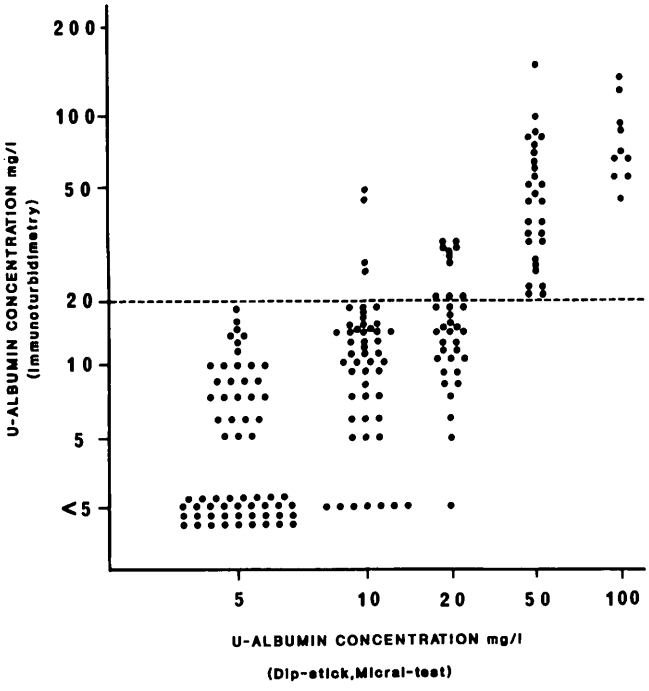

FIG. 2. Urinary albumin concentration measured by immunoturbidimetry and by dipstick method (Micral-Test) in 186 patients.

RESULTS

The results of the comparison between the dipstick test and the quantitative immunoturbidimetric method are given in Fig. 2. The correlation coefficient was 0.82 but was reduced to 0.78 if values <10 mg/L by the reference method were disregarded.

An albumin concentration 20 mg/L corresponds to 30 mg/24 h urine (provided normal urine flow of 1 ml/min) and an albumin excretion rate of 15 μg/min in timed overnight urine, which has been accepted as an upper normal level (12). With the albumin concentration of 20 mg/L as a discriminate level, 52 (28%) of the samples were above this level and 134 (72%) below. Micral-Test assay levels ≥20 mg/L had a sensitivity of 92.3% [48/(48 + 4)] (Table 1), a specificity of 82.1% [110/(110 + 24)], a negative predictive value of 96.5%

TABLE 1
Number of patients distributed according to results obtained by semiquantitative (Micral-Test) and quantitative reference (albumin concentration) methods

	Albumin concentration	
	≥20 mg/L	<20 mg/L
Micral-Test		
≥20 mg/L	48	24
<20 mg/L	4	110

Albumin concentration was determined by immunoturbidimetry.

[110/(110 + 4)], and a positive predictive value of 66.7% [48/(48 + 24)]. Of the diabetic subjects, 84.9% [(110 + 48)/186] were correctly classified as having elevated urinary albumin concentration or not.

CONCLUSIONS

We demonstrated a good correlation between the semiquantitative Micral-Test and a quantitative immunoturbidimetric method. This makes the Micral-Test useful at the different levels of elevated albumin excretion rate that have been linked to the later development of diabetic nephropathy, i.e., Viberti et al. (1) used 30 μg/min, Mogensen (3) and Mogensen and Christensen (4) used 15 μg/min (comparable to 20 mg/L) in timed overnight urine samples, whereas Parving et al. (2) used 40 mg/24 h urine.

If elevated urinary albumin concentration is defined as >20 mg/L in overnight urine, the Micral-Test assay levels ≥20 mg/L correctly identified 84.9% of the patients as having or not having elevated urinary albumin excretion. With a sensitivity of 92.3% and a negative prediction value of 96.5%, very few patients with elevated urinary albumin concentration are missed. The positive predictive value of the Micral-Test assay level (≥20 mg/L) is 66.7% and implies many false-positive results. However, this is not uncommon in tests used mainly for screening purposes. In the screening setting, high sensitivity and high negative predictive value are the most important parameters. However, the low positive predictive value means that many of the patients have to deliver additional urine samples. This is not a problem because the definition of incipient nephropathy is based on repeated measurements. We propose that two Micral-Tests of ≥20 mg/L within 6 mo should lead to a timed quantitative albumin excretion analysis.

The limitation of all the methods that measure urine albumin concentration is the influence of the diuresis. This and the wide day-to-day variation of urinary albumin excretion in the same patient (12,13) should always be taken into consideration regardless of which definition or method is used.

The previously available screening tests for microalbuminuria have been qualitative (9–11) and unsuitable for following patients in the important 15–100 mg/L range. There is increasing evidence for the possibility of arresting or even reducing the expected increment in albumin excretion in IDDM patients with elevated urinary albumin excretion by near normoglycemia (6,7) or lowering blood pressure (8). The semiquantitative Micral-Test might therefore be valuable not only for screening but also for monitoring when a quantitative method is not convenient. The advantage of having the actual urinary albumin concentration when talking to the patient makes the test useful in a clinical setting. The test is easy to perform and requires little technical skill; the concordance between readers was found to be 88.3% in one study and 91% in another when two lots of test strips were read by five individuals (P. Muller, Boehringer Mannheim Gmbtt Mannheim, Germany unpublished observations). The only disadvantage is that the test has to be timed correctly and read between 5 and 6 min after the strip is dipped.

We conclude that this dipstick test is a good tool for screening elevated urinary albumin concentrations and monitoring the development of urinary albumin excretion in the lower microalbuminuric range in both NIDDM and IDDM patients.

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Factors Determining Recall of Examination Results in Diabetic Population

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Objective: To determine factors influencing recall of examination results after 4 yr. Research Design and Methods: At two examinations that were 4 yr apart, a diabetic population was asked, "Have you been told that your diabetes has affected the back of your eyes, that is the retina?" Participants were informed by letter whether they had retinopathy. Subjects in this study included younger-onset (*n* = 311) and older-onset (*n* = 279) diabetic subjects who had retinopathy at baseline and did not know it. Results: Forty-two percent of younger-onset and 29% of older-onset subjects recalled at follow-up that they had been told their diabetes had affected their eyes. People in both groups were more likely to recall they had retinopathy if they had more severe retinopathy, had more symptoms of neuropathy and peripheral vascular disease, had seen an opthalmologist within 2 yr, or monitored their blood glucose more often. In addition, younger-onset diabetic subjects with poorer visual acuity or who were on a combination insulin regimen and older-onset people taking insulin, having more education, or who were younger were more likely to recall they had retinopathy. Factors not associated with recall in either group included sex, duration of diabetes, proteinuria, glycosylated hemoglobin, and family income. Conclusions: These results underscore the need to develop better methods to deliver health-care information to people who have diabetes. *Diabetes Care* 14:1097–100, 1991

It has been shown that timely photocoagulation treatment of diabetic retinopathy can prevent much of the vision loss associated with this condition (1). However, the maximum benefit of retinal photocoagulation can only be achieved through the active involvement of primary-care physicians, eye-care providers, and the patients themselves. In particular, these individuals must be knowledgeable about the patients' condition so that treatment may be applied when indicated.

In this investigation, we report on how well diabetic subjects recalled the results of a screening for retinopathy when reexamined 4 yr later, the purpose being to determine the efficiency of the screening for informing diabetic subjects of their condition. In addition, we examined factors such as education and frequency of visits to an eye-care provider, which may influence a subject's knowledge of his/her condition to determine whether any subgroups were less likely to be knowledgeable.

RESEARCH DESIGN AND METHODS

Case identification methods and descriptions of the population appear in previous reports of the Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR; 2–5). Briefly, the study area was comprised of 11 counties in southern Wisconsin. During 1 July 1979 to 30 June 1980, lists of diabetic patients were kept by 452 of 457 primary-care physicians in the area, and 10,135 diabetic subjects were identified. A two-part sample of 2990 of the diabetic subjects was invited to participate in the baseline examination in 1980–1982. The first part consisted of the entire population of insulin-taking subjects diagnosed before 30 yr of age (*n* = 1210) and is referred to as the younger-onset group. The second part consisted of a probability sample, stratified by duration of diabetes, of subjects diagnosed at ≥30 yr of age, regardless of insulin-taking status, but meeting other eligibility criteria (*n* = 1780) and is referred to as the older-onset group. The population was predominantly white; <2% were nonwhite. Surviving members of the sample were invited to participate in a 4-yr follow-up examination in 1984–1986.

Both the baseline and follow-up examinations followed a similar protocol. Pertinent procedures included obtaining informed consent, verifying the participant's address, determining best-corrected visual acuity for distance, dilating the pupils, administering a medical history questionnaire, taking stereoscopic color fundus photographs of seven standard fields, and determining urine protein and glycosylated hemoglobin levels.

To determine severity of retinopathy, all fundus photographs were graded with a modification of the Airlie