Glycosuria Tests Performed by Diabetics at Home

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THE LITERATURE and instructional materials given to patients with newly diagnosed diabetes stress the importance of urine testing (*1*, *2*). After initial instruction, many of these patients test their urine daily in the home. The glycosuria test they are taught to use, however, is often based upon subjective judgment of physicians and nurses who may instruct diabetic patients to use a glycosuria test which may not be the most accurate. One professional nurse working in a metabolic clinic stated, "If the patient is young and able to understand easily, I give him the Clinitest; if he is old and has trouble understanding, I give him Tes-tape."

Many authorities agree that good diabetic control tends to eliminate or decrease the occurrence of numerous long term complications frequently associated with the disease (*3*). However, the only recent study reported in the literature of the ability of the diabetic to manage his disease at home was that by Watkins and co-workers in 1967 (*4*). They found that 45 percent of 60 patients visited at home who tested their own urine used the results in a way which was likely to be detrimental to diabetic control of the disease. The authors did not specifically state how the glycosuria testing was detrimental, but this observation pointed up the need to study further the urine tests used by diabetics at home and the interpretation of the results.

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Objective and Method

This study was made to determine which of two frequently used glycosuria tests, Tes-tape or Clinitest, could be read more accurately by diabetics in the home. The 42 diabetics studied comprised the entire caseload from a university metabolic clinic over a 3-month period. Excluded were those patients known to have vision problems and those who did not test their urine with Tes-tape or Clinitest. Thirty-one women and 11 men, ranging from 42 to 79 years of age with a median age of 62, participated. Their educational background ranged from 0 to 14 years of schooling with a median of 8 years.

The plan for the study required two visits to the home of each diabetic. On the first visit information was obtained on storage and age of the testing material, length of time since the patient's diabetes had been diagnosed, method of testing taught, importance and frequency of testing, which urination was tested, reasons for not testing, charting of results, and reporting of results to the physician.

A urine specimen was then obtained sufficient to make four tests—one by the investigator and one by the diabetic in the home and two tests in the laboratory. While the investigator watched, the diabetic tested his urine for glu-

cose employing the method and materials he had been using. The investigator noted errors in procedure as well as the quality of the testing material used. The investigator then tested the diabetic's urine using testing materials of recent date to validate the diabetic's test results. Some time was spent in transporting the urine samples from the diabetic's home to the laboratory. However, samples were kept cool in sterile containers, and all specimens were tested within an hour from the time they had been collected.

In the more controlled laboratory setting, urine was tested by the investigator and independently by another person versed in the two glycosuria test techniques. In an attempt to rule out the human factor in matching the colors of the glycosuria tests with the standards supplied by the manufacturer, we originally planned to use a spectrophotometer. Because this procedure proved unsuccessful, we checked reliability by having the independent observer test the samples in the laboratory with the same material the diabetic and the investigator had used. This change of procedure resulted in the loss of six urine samples.

A return appointment was made for the diabetic for the following week. The patient and the investigator made the same tests on this second visit. Following completion of the urine tests in the home, a vision screening test for daltonism was given by the investigator to check the patient's color vision. Urine samples from the second visit were again checked in the laboratory by the investigator and the independent observer.

Results

The glycosuria test results were compared to the standard laboratory-controlled color charts recommended for use in detecting elevated glucose levels in the urine. Tes-tape has a five-color chart ranging from a clear yellow to a dark green, each shade indicative of the percentage of glucose in the urine and recorded as 0, 1+, 2+, 3+, and 4+ (*A*). These numerals represent the following percentages: 0=0 percent, 1+=0.1 percent, 2+=0.25 percent, 3+=0.5 percent, and 4+=2 percent or more (*A*). Clinitest has six colors used for comparison—blue (negative)=0 percent, dark green (trace)=0.25 percent, green (1+)=0.5 percent, olive green (2+)=0.75 percent, orange red (3+)=1 percent, and orange (4+)=2 percent (*B*).

Table 1 shows the percentage agreement of

Table 1. Percent agreement of readings between diabetic, investigator, and observer on Tes-tape and Clinitest results

Place of testing and agreement between—	Visit	Tes-tape		Clinitest	
		Number of tests	Percent agreement	Number of tests	Percent agreement
		Negative readings			
Home, diabetic-investigator	1	21	86	8	88
	2	18	100	8	100
Home, diabetic-laboratory, investigator	1	21	86	8	75
	2	18	100	8	88
Home, diabetic-laboratory, observer	1	18	89	7	71
	2	18	100	8	88
Laboratory, investigator-observer	1	16	100	5	100
	2	18	100	7	100
		Positive readings			
Home, diabetic-investigator	1	6	33	7	86
	2	9	56	7	71
Home, diabetic-laboratory, investigator	1	6	33	7	100
	2	9	22	7	86
Home, diabetic-laboratory, observer	1	5	80	6	83
	2	9	11	7	71
Laboratory, investigator-observer	1	7	57	8	88
	2	9	78	8	88

the test results between the diabetic in the home and the investigator in the home, the diabetic in the home and the investigator in the laboratory, the diabetic in the home and the independent observer in the laboratory, and the investigator in the laboratory and the observer in the laboratory.

Tes-tape. On the first visit when readings were negative, the variation in agreement ranged from 86 to 89 percent between the diabetic, the investigator at home and in the laboratory, and the independent observer. When the readings were positive, however, the percentage of agreement dropped to a range of 33 to 80 percent.

There was 100 percent agreement on all negative readings on the second visit. However, when readings were positive on the second visit, they ranged from 11 to 56 percent agreement. Percentage agreement between the investigator and the independent observer was 100 percent for all negative tests from both visits. Agreement between the investigator and the independent observer for positive tests after the first visit was 57 percent, and after the second, 78 percent.

Clinitest. Table 1 also shows the percent agreement between the diabetic, the investigator, and the independent observer when Clinitest was employed to detect glycosuria. In the first readings when the results were negative, agreement ranged from 71 to 88 percent; when the readings were positive, agreement ranged from 83 to 100 percent. On the second visit when negative readings were obtained, agreement ranged from 88 to 100 percent; and when positive readings resulted, the agreements ranged from 71 to 86 percent. There was 100 percent agreement between the investigator's Clinitest readings and those of the independent observer for the negative urine samples collected during both visits, and there was 88 percent agreement for the positive urine samples collected during the two visits.

Tes-tape versus Clinitest. A primary objective of this study was to assess which glycosuria test was more reliable when used by diabetics at home. Therefore, two chi-square tests of significance with Yates' correction were done on data appearing in table 1. Data entered in the tables, which can be seen in table 2, were number of agreements and disagreements between diabetics' readings at home and investigator at home and in the laboratory and observer in the the laboratory on Tes-tape and Clinitest results. The chi-square obtained ($\chi^2=1.78$, $P>0.05$) suggested a lack of differential reliability between tests when negative readings were obtained by the diabetic at home. However, a significant chi-square ($\chi^2=15.33$, $P<0.001$) on positive readings indicates that Clinitest is more reliable than Tes-tape when positive readings are reported by the diabetic at home. That is, when testing at home, the diabetic is less likely to report a false positive reading if Clinitest is used.

Steps of disagreement. In addition to tabulating the percentage agreement of the readings, the degree of differences in the readings was established by determining steps of disagreement. An example of one-step disagreement for Tes-tape would be a reading of 0.1 percent by the diabetic and a reading of negative or 0.25 percent by the investigator. A two-step disagreement would be 0.5 percent reading for the same test; a three-step would be a reading of 0.1 percent by the diabetic and a 2 percent reading by the investigator. The total number of tests performed and the number of disagreements by steps for each group is presented in table 3.

Table 3 shows that in the 312 Tes-tape readings, 51 tests or 16 percent had steps of disagreement. Seven of these had three steps of disagreement. Of the 174 Clinitest readings, 26 tests or 15 percent showed steps of disagreement. The

Table 2. Chi-square tests of the number of agreements and disagreements between diabetic at home and investigator at home and in the laboratory and observer in the laboratory on Tes-tape and Clinitest results

Test	Positive readings [1]		Negative readings [2]	
	Agree	Disagree	Agree	Disagree
Tes-tape	16	28	106	8
Clinitest	34	7	40	7
Total	50	35	146	15

[1] $X^2=15.33$ $P<0.001$. [2] $X^2=P>0.05$

Table 3. Disagreement by steps of readings of Tes-tape and Clinitest results by diabetics at home, the investigator at home and in the laboratory, and the observer

Testing reading	Visit	Total tests	Number of disagreements by steps		
			1 step	2 step	3 step
Tes-tape negative	1	110	5	0	3
	2	108	0	0	0
Tes-tape positive	1	40	10	1	4
	2	54	23	5	0
Clinitest negative	1	41	7	0	0
	2	47	4	0	0
Clinitest positive	1	43	3	3	0
	2	43	5	4	0

widest disagreement for Clinitest readings was two steps.

Errors made. Not only were there differences made in reading test results, but numerous errors were made by the diabetic in the manner of testing. Errors were failure to use the color chart, improper timing, use of material beyond the marked date of expiration, improper storage of testing material, and incorrect measurement of solution. The combined results of those using Clinitest and Tes-tape indicated that 26 percent of the diabetics failed to use the chart to check the color readings. Eighty-six percent timed the test improperly. For example, one diabetic stated that you leave the Tes-tape in the urine for 3 minutes; however, she left it in the urine for only 1 minute then immediately read the results. Nineteen percent used material beyond the marked date of expiration. Sixty-seven percent stored their testing material improperly—Clinitest on a sunny window sill and unprotected Tes-tape on an open shelf above the hot water tap. One diabetic used the Clinitest material with the Benedict's procedure.

In an effort to determine the effect these errors had on the accuracy of the readings, the percentage of agreement between the readings by the diabetic in the home and the readings by the investigator in the laboratory was tabulated, by combining the Tes-tape and Clinitest samples (table 4). Also shown in table 4 are percentage agreements for the following variables: length of time the person had diabetes, educational level, age level, the sample of urine that was tested, method of testing that the patient was taught and used, how frequently the diabetic tested his urine, and vision errors found with the daltonism test.

Chi-square tests of significance with Yates' correction, comparing the diabetics who agreed with the investigator in the laboratory with those who did not, were computed for the variables shown in table 4. None of the chi-square values reached significance at the 0.05 level.

Information obtained from the 42 diabetics indicated that 40 percent regularly charted the results of their tests, and 38 percent of the group showed them to their physicians. Fifty-two percent tested their urine daily. Twenty-one percent stated they had never been taught the importance of testing their urine, and 31 percent admitted they did not test their urine as often as they should because they could not afford to buy the test materials.

Discussion

The glycosuria test diabetics perform is one of the most frequently performed clinical chemical tests. These tests are simple and not diffi-

Table 4, Relation of certain variables to percent agreement between readings of first-visit tests by diabetics at home and investigator in the laboratory

Variable	Number	Percent agreement
Errors:		
Less than 4	17	80
4 or more	25	76
Period since diagnosis of diabetes:		
2 years or less	13	92
3 years or more	29	72
Education:		
8 years of school or less	24	79
9 years or more	18	78
Age:		
64 years or less	23	78
65 years or more	19	79
Urination sample:		
Second of morning	8	100
First of morning	34	74
Method used:		
Original one taught	24	83
Method other than first one taught	18	72
Frequency of testing:		
Once a day or more	22	91
Occasionally	20	65
Daltonism test:		
Less than 12 errors	23	83
12 or more errors	19	74

cult to teach, and the procedure is easily learned by the diabetic. Therefore, there is a tendency to assume that they are accurately performed and provide accurate information. The findings of this study clearly indicate how wrong these assumptions are.

This study was designed to answer the question: Which of two glycosuria tests was read more reliably by a sample of diabetics at home? The question was not resolved as neither glycosuria test was read with consistent agreement by the diabetic, the investigator, or the independent observer. It was surprising to find that the investigator and the independent observer, even under standard conditions and with experience and training in careful observation, disagreed in their reading of the test results. Testape and Clinitest have been used for a number of years to test urine for glucose, and physicians have used the readings in the medical management of the individual diabetic. However, the findings of this study point out the urgent need to develop a glycosuria test in which the human error in reading the test is markedly reduced.

An unexpected finding of this investigation was the diabetics' lack of understanding of their disease. The following comments illustrate this point. Two diabetics stated that they had "caught diabetes from being in the hospital." A patient who was visited a month after Christmas stated, "Oh, I ate some chocolates on Christmas Day, and that is why my urine shows positive." Another said, "I got diabetes by eating red beets."

Needed are a valid glycosuria test which can be read more accurately and a plan of teaching the diabetic so that he will have a better understanding of his disease.

Summary

Glycosuria testing was performed in the home by 42 diabetics; 27 used Tes-tape and 15 used Clinitest. Portions of the same urine sample tested by the patient were checked by (*a*) the investigator in the home, (*b*) the investigator in laboratory, and (*c*) the independent observer in the laboratory. Percentage agreements between the diabetic's test results and the investigator's and observer's test results were tabulated. When the patient's tests were negative using Tes-tape, agreement ranged from 86 to 100 percent; when the patient's tests were positive, agreement ranged from 11 to 80 percent. Clinitest agreements for both the postive and negative tests ranged from 71 to 100 percent. Therefore, when the tests results were negative, Tes-tape was read with the greater percent agreement. When the test results were positive, Clinitest readings had the greater percent agreement.

In addition to errors in reading test results, the diabetics made numerous errors in carrying out the tests; for example, 86 percent timed them improperly, 19 percent used test material beyond the marked expiration date, and 67 percent stored the material improperly.

The findings of this study pointed out how important it is to study critically and objectively at periodic intervals methods and tests accepted as sound and reliable. Physicians, nurses, and health service personnel must reevaluate the testing methods used by the diabetic in his home. Is daily urine testing important if it is read inaccurately and is unreliable? Can the results be detrimental to the diabetic in the management of his disease? Ignoring the problem of glycosuria testing is not the answer.

REFERENCES

(*1*) Guidebook for the diabetic. Ames Company, Elkhart, Ind., undated, pp. 6–10.

(*2*) A guide for the diabetic. Eli Lilly and Company, Indianapolis, Ind., December 1965, pp. 47–50.

(*3*) Etzwiler, D. D.: Who's teaching the diabetic? Diabetes 16: 111–117, February 1967.

(*4*) Watkins, J. S., et al.: A study of diabetic patients at home. Amer J Public Health 57: 452–459, March 1967.

SUPPLY REFERENCES

(*A*) Dispenser package of Tes-tape. Tes-tape dispenser with urine sugar analysis paper and color comparison chart with directions. Eli Lilly and Company, Indianapolis, Ind., $1.50 per dispenser.

(*B*) Clinitest urine-sugar analysis set. Clinitest reagent tablets (bottle of 36), special test tube, unbreakable dropper, and color chart with instruction and analysis record. Ames Company, Division Miles Laboratories, Inc., Elkhart, Ind., $0.59 per 36.