

doses of antihistamine required to suppress these reactions are frequently associated with sedation.<sup>7</sup> We and others<sup>8</sup> have suggested simultaneous injection of small amounts of corticosteroids with insulin in patients experiencing these reactions, and recent reports have found this useful in treating reactions to the human insulins administered by intermittent injection.<sup>8</sup>

The mechanism by which corticosteroid therapy blocked the local reactions in our patient is unclear. It is impossible to rule out the possibility that immunologic insulin "desensitization" occurred, but it is improbable that it would have occurred simultaneously with the administration of corticosteroid. In this regard, previous reports (summarized in ref. 9) have demonstrated that late-phase reactions may be blocked by corticosteroid treatment. Use of corticosteroids in small doses mixed with insulin appears to facilitate insulin therapy in patients with local hypersensitivity to human insulin.

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## A Precision Index for Evaluation of Techniques for Self-Monitoring of Blood Glucose

Diabetic patients must maintain a delicate equilibrium between diet, exercise, and hypoglycemic medication to control blood glucose homeostasis. Until a practical glucose sensor is developed, self-monitoring of blood glucose (SMBG) provides the essential feedback for day-to-day therapeutic adjustments.<sup>1-5</sup> Most of the SMBG methods are relatively accurate provided the technique is carefully respected.<sup>6-8</sup> The patients use these self-generated data to make critical decisions such as insulin dose adjustments. Therefore, it is important to perform a quality control of the individual patient's technique. For that purpose, blood should be sampled for laboratory analysis at the time the patient performs his SMBG technique and this should be repeated many times. Most of these patients are outpatients, and therefore it is difficult to obtain more than 5-12 corresponding values for an individual patient. The coefficient of correlation, currently used in the evaluation of SMBG methods, may be an inadequate tool to assess individual patient reliability.

Recently, we made a quality control assessment of the SMBG techniques of 18 randomly selected type I or type II diabetic patients. These patients measured capillary blood glucose with visual reading strips for periods varying from 2 wk to a few months. We made no attempt to improve their technique. Their SMBG results were compared with laboratory glucose (G) measurements made on filter paper blood spot<sup>9,10</sup> sampled at home at the corresponding time (Table 1).

A case-by-case analysis indicated that neither the coefficient of correlation nor the mean of the differences were good indexes to achieve our goal. Indeed, a good correlation depends partially on a good dispersion of the values from the low range to the high range. In individual case studies, the 5-12 corresponding values available were not always dispersed, particularly in well-controlled patients whose values ranged from 70 to 120 mg/dl. Some well-controlled patients had very small (G - SMBG) differences but a poor correlation due to lack of dispersion (patient 8:  $r = .451$ , difference = -22.3 mg/dl; patient 11:  $r = .104$ , difference = 9.2 mg/dl). Inversely, some patients with good correlations ( $r > .80$ ) owing to a good dispersion had significant (G - SMBG) differences (for example, patient 4:  $r = .912$ , difference = -63.9 mg/dl; patient 6:  $r = .823$ , difference = -62.3 mg/dl). Moreover, a difference of 30 mg/dl does not have the same significance at 100 mg/dl and at 300 mg/dl levels.

Thus, to evaluate the quality of the SMBG technique with respect to G, we derived the following precision index,  $PI = 1 - [\Sigma(|G - SMBG|/G)]/N$ , which represents the extent to which the SMBG technique deviates (in absolute values) from the linear regression  $G = SMBG$  going through

TABLE 1  
Individual results for each of the 18 patients participating in the study

Patient no.	Mean difference* (G - SMBG) (mg/dl)	r†	PI‡
1	4.1	.861	.837
2	18.5	.823	.830
3	-63.9	.912	.575
4	-36.9	.507	.665
5	12.2	.962	.871
6	-62.3	.823	.514
7	-33.4	.873	.626
8	-22.3	.451	.784
9	62.8	.357	.744
10	-15.3	.944	.785
11	9.2	.104	.886
12	-16.6	.911	.728
13	94.4	.014	.619
14	-19.9	.605	.699
15	33.6	-.794	.810
16	-46.2	.826	.568
17	-18.8	.942	.796
18	47.2	.798	.686
X ± S.D.	-2.0 ± 41.7	0.620 ± 0.446	0.733 ± 0.115

\*Mean of differences.

†Coefficient of correlation.

‡Precision index.

the origin, relative to the reference technique ( $N$  = number of observations by patient). The advantage of this index over the correlation coefficient is that it assumes as a perfect relationship between the G and SMBG techniques a linear regression through the origin with a slope = 1, while the correlation coefficient assumes the general linear regression  $G = a + b$  (SMBG): an undesired regression if  $a \neq 0$  and  $b \neq 1$ .

The advantage of the index over the usual mean of differences is that it is not meaningfully decreased by a sum of positive and negative values, which occurs when the observed data cross the linear regression  $G = \text{SMBG}$ . Moreover, the index gives relative importance to the observed differences.

Thus, we believe that our precision index can be a practical tool for the evaluation of the SMBG techniques. Although the present data illustrate the use of the method, they are not sufficient for its validation. We arbitrarily defined the results as good ( $PI > .80$ ), fair ( $PI = .70$  to  $.80$ ), and bad ( $PI < .70$ ). These values indicate relative errors of  $<20$ ,  $20-30$ , and  $>30\%$ , respectively. They seemed reasonable for visual reading strips with differences of  $40-60$  mg/dl between reference levels in the range of  $40-240$  mg/dl and the possibility for the patient to extrapolate between these reference levels. However, further studies on larger groups of patients are necessary to better define these criteria, to validate the reliability of the PI, and to establish the number of samples needed for a reliable assessment of a single patient.

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## Potential Danger of Extending SMBG Techniques to Hospital Wards

Self-monitoring of blood glucose (SMBG) is a widely accepted technique and is a very helpful adjunct in the outpatient management of diabetes mellitus.<sup>1,2</sup> The fact that