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The Tactile Circumferential Discriminator: an Instrument for Detecting Patients at Risk of Foot Ulceration

In a paper recently published in *Diabetes Care*, L. Vileikyte et al. (1) show that the tactile circumferential discriminator (TCD) is a simple screening device to identify diabetic patients at risk of foot ulceration.

With a similar design, we have published in a recent issue of *Revista de la Asociación Latinoamericana de Diabetes* (2) our experience with the TCD. We studied 57 NIDDM patients (19 women, 38 men). The mean age was 60.02 years and median duration of diabetes was 11.38 years. Vibration perception thresholds (VPTs) were measured with a biothesiometer at the great toe, with the probe balanced vertically on the pulp of the toe. We used a cutoff point of 25 V as a criterion for ulcer risk as Young et al. (3) defined in their prospective study. Tests with the TCD were done using a similar protocol, but were performed over the first phalanx, not on the plantar aspect. We also compared quantitative sensory testing with the 5.07 monofilament.

Although we used different areas of perception, our results were similar. A TCD >6 had a sensitivity and specificity of 81 and 86%, respectively, to find the patients with VPT >25 V. The inability to perceive the 5.07 monofilament had a sensitivity and specificity of 86 and 87%, respectively.

However, to determine the strength of any diagnostic test, it is more important to define the negative predictive values (NPVs) and the positive predictive values (PPVs). In our 57 patients, the PPVs to have VPT >25 V were relatively low (0.54 for TCD >6 and 0.63 for the inability to perceive the 5.07 monofilament). The NPVs, for both, were 0.96. If a patient has a TCD <6 or if the ability to perceive the filament is normal, the chance of having a VPT <25 is 96%.

We believe that these tests have good NPVs and are useful to exclude a level of neuropathy associated with an increased risk for foot ulceration.

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Incidence of Type 1 Diabetes in Germany Is Not Higher Than Predicted

Neu et al. (5) published the incidence of type 1 diabetes in former West Germany. They calculated the incidence in 0- to 14-year-old individuals to be between 10.6 and 11.6 cases per 100,000. The authors repeatedly say that this is much higher than assumed. However, the authors fail to consider the effect of bacille Calmette-Guérin (BCG) vaccination, which can explain the higher rate.

Our studies (1-3) have compared the incidence of type 1 diabetes in 0- to 14-year-olds living in western European countries not administering BCG to the incidence in countries administering BCG starting at birth and school age. The incidence of type 1 diabetes in countries not immunizing with BCG (Iceland, Netherlands, Spain, Belgium, and Luxembourg) was 10.92 cases per 100,000 (range, 9.8-12.4), compared with 7.4 cases per 100,000 (range, 6.8-7.8) in countries immunizing at birth (Republic of Ireland, France, Austria, Switzerland, and Portugal) and 19.02 (range, 16.4-20.8) in countries immunizing at school age (Northern Ireland, England, Scotland, Denmark, and Norway). Our ecological data is supported by analysis of Swedish birth cohorts (1) and by our analysis (unpublished observations) of data from Montreal (4).

BCG was infrequently given in the former West Germany after the early 1980s (World Health Organization data) and the incidence of type 1 diabetes is very similar to that of other countries listed above not giving BCG. The authors made their prediction based on data from the old East Germany, which was 7.4 cases per 100,000.

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BCG vaccine was routinely given at birth in East Germany (6), and the incidence of type 1 diabetes resembled that of countries listed above that give BCG at birth. We believe the findings of Neu et al. can be explained by BCG immunization status and believe this factor should be considered in any study on the incidence of type 1 diabetes.

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Response to Classen and Classen

Incidence of IDDM in Germany higher than expected

As a result of an epidemiological study, incidence rates of childhood diabetes in Germany according to internationally accepted standards were presented for the first time (1).

Previously reported incidence estimations referred to a registry kept in the for-

mer German Democratic Republic (2). Although these incidence rates were not validated by a secondary data source, the data were commonly quoted assuming the incidence to be 7.5 per 100,000 for Germany as a whole. With 10.6 and 11.6 per 100,000, the Baden-Wuerttemberg incidence rates were markedly higher than those reported from former East Germany.

The hypothesis of Classen and Classen according to which bacille Calmette-Guérin (BCG) immunization status could explain these differences is interesting, although other studies could not confirm this observation and reported incidence rates unaffected by BCG vaccination (3).

In fact, BCG immunization was done more frequently in East Germany than in West Germany. However, there are considerable differences between various regions. In Baden-Wuerttemberg, the federal state in which our incidence study was done, 60.7% of all children are vaccinated with BCG (4). Therefore, it is definitely not correct to put Baden-Wuerttemberg in a line with countries not using BCG.

Many environmental factors such as coffee intake (5) and rainfall (6) as well as immunization status (7) have been associated with the occurrence of type 1 diabetes. Yet the complex pathogenesis of the disease seems to be ignored by Classen and Classen, reducing this process to one single cause. As a matter of fact, between federal states in East and West Germany, many environmental conditions are obviously different and could be correlated with the incidence of diabetes. Whether there is a causal relationship is, however, questionable.

The first objective of an epidemiological study is the collection of data on the frequency of a disease. A further step is to consider underlying causes for the data found. At present, we are concentrating our work on the documentation of incidence rates and not the analysis of the cause of the disease. The preliminary results of our ongoing study indicate a rising incidence in Baden-Wuerttemberg in the last decade without any change in BCG immunization activity in this area.

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Mitochondrial DNA 3243 Mutation Is Infrequent in Japanese Diabetic Patients With Auditory Disturbance

In a recent article, Di Leo et al. (1) concluded that cochlear dysfunction is common in type 1 diabetes. Sensorineural auditory disturbance has been indicated to be associated with diabetes with mitochondrial mutation at an A-to-G transition at position 3243 of tRNA^{Leu}(UUR) (2-4). The frequency of the diabetic patients with this mutation has been reported to be ~0.9-2.0% in Japanese patients with type 2 diabetes (5,6). A previous report (6) has shown that as many as 3 out of 5 (60%) diabetic patients with auditory disturbance