OBSERVATIONS

Implantable Pump Therapy Restores Metabolic Control and Quality of Life in Type 1 Diabetic Patients With Buschke's Nonsystemic Scleroderma

Buschke's nonsystemic scleroderma is an uncommon dermatosis characterized by thickened and indurate skin of unknown origin, mostly affecting upper parts of the body but also the abdominal area. While diabetes is rarely associated, subcutaneous insulin treatment may be hardly feasible and effective because of incomplete absorption of insulin (1).

After approval of our institutional ethical committees, four type 1 diabetic patients (one male and three female subjects) affected by this condition received Medtronic MiniMed implantable pumps (Northridge, CA) for intraperitoneal insulin delivery (2) between 1994 and 2004. The patients, aged 45.2 ± 2.9 years, had a mean duration of diabetes of 33.5 ± 1.3 years, including multiple microvascular complications. Biopsies of the affected skin, performed in three patients, confirmed expanded dermis with enlarged collagen bundles and, in one case, visible mucin. None had evidence of systemic sclerosis by biopsy and other investigations at baseline or during follow-up. Skin status was clinically assessed on a yearly basis, diabetes complications surveyed as required, and HbA_{1c} (A1C) measured using a high-performance liquid chromatography method (normal values <5.6%) on a quarterly basis.

From implantation time, improvement of glucose control was sustained as shown by mean yearly A1C moving from 9.3 ± 0.7% (baseline) to 7.9 ± 1.3% (2005). Microvascular complications remained stable or decreased. All patients experienced a dramatic decrease of skin induration as early as a few months after implantation. We found clinical improvement of the skin aspect in terms of redness, swelling, and induration, even if we did not have tools at our disposal to measure skin elasticity.

Several published case reports describe either poorly effective therapeutic options for Buschke's scleroderma (3,4) or the effective, albeit rather extreme, radiation therapy (5). Poor glycemic control may play a role in worsening of the skin condition, resulting in a vicious cycle of worsening control and worsening disease driven by poor absorption of insulin (6). Although not documented by pathological or biochemical skin analyses, our findings support previous hypotheses that glucose excess causes impairment through increased glycation alterations of tissue collagen, which are involved in Buschke's scleroderma, and that this process can be reversed with improved glucose control. We suggest implantable pump therapy as an option in patients with type 1 diabetes affected by this uncommon skin condition when optimized subcutaneous insulin treatment fails to achieve acceptable blood glucose control.

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Possible Problem With Optipen Pro-1

Should diabetic patients continue to use this product?

Insulin glargine is a modified basal insulin analog that has been recently introduced and is now available worldwide. Insulin glargine is available in 3-ml cartridges that can be used with the OptiPen Pro-1 (Sanofi-Aventis). The Medicines and Healthcare Products Regulatory Agency (MHRA; executive agency of the Department of Health in the U.K., which enhances and safeguards the health of the public by ensuring the effectiveness of medicines and medical devices) has received a significant number of reports concerning difficulties in the operation and use of the OptiPen Pro-1 insulin pen injection system. A fault was found with some batches of the OptiPen Pro-1 system, whereby the dosage button failed to engage at the end of an injection (1).

A total of 32 type 1 diabetic patients (age 17.0 ± 4.4 years [mean ± SD]) on multiple daily injection regimens, who had been treated with insulin for at least for 6 months and were insulin glargine naive, were transferred from NPH insulin to insulin glargine between May 2004 and March 2005. Two patients without any evidence of infection or of skipped insulin doses had ketosis on the 3rd and 4th month of insulin glargine treatment, respectively. When the patients were questioned about the reasons for ketosis, they stated leakage of insulin from the sides of the pen during injection.

An inquiry form regarding OptiPen Pro-1 was given to all subjects on the 6th month of therapy. Leakage from the sides of the pen was noted by 58.8% of subjects, and a problem with the dosage button not locking when it was fully depressed following injection of the desired dose of insulin was reported by 38.2%. The patients were asked to rate