

than the maximum energy, inefficiencies of focusing, and the absorption and dissipation of laser energy by the stratum corneum (13).

In conventional finger-puncture procedures for obtaining capillary blood samples, necrotic tissue may be injected under the surface of the skin, producing residual pain over several days in patients who require frequent sampling. Theoretically, use of the Lasette laser skin perforator may reduce the pain associated with capillary blood sampling by reducing the amount of residual necrotic tissue in the wound. Although there was no reduction in perceived pain associated with the Lasette in these studies, no attempt was made to minimize discomfort by varying the output setting of the device in these protocols. Finally, the reduction in sharp medical waste offered by the laser skin perforator may provide significant advantages to diabetic patients who perform frequent CBG monitoring.

A limitation of these studies is the fact that only patients with diabetes were enrolled. Additionally, some patients experienced difficulty obtaining a sufficient sample with the Lasette compared with standard stainless steel lancets in study 1, but this problem was rectified in study 2 when the desired sampling volume was decreased and the maximal energy setting of the Lasette was increased. In a clinical setting, skin sensitivity to the effects of the laser skin perforator will vary, and subjects will likely need to experiment with the unit to discover the lowest energy setting that works consistently and effectively for them. Despite these limitations, the availability of the laser skin perforator does provide an alternative for capillary blood sampling in patients who are unable to use standard stainless steel lancets. Moreover, the Lasette may be attractive to physicians' clinics and other institutional settings, such as nursing homes, where capillary blood sampling is performed multiple times daily. Use of the device will reduce sharp medical waste and may possibly reduce the risk of exposure to blood-borne infection.

We conclude that the Lasette laser skin perforator, compared with stainless steel lancets, is safe and effective for the attainment of capillary blood samples in patients with diabetes and that these two methodologies for sampling result in equivalent determinations of CBG and hematocrit. The optimal clinical indication

for using the Lasette remains to be determined.

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## Glucose Intolerance in Pregnant Women and Its Effects on Newborn Outcomes

The role of maternal hyperglycemia below the threshold for the diagnosis of gestational diabetes mellitus (GDM) in the etiology of macrosomia (>4,000 g) remains a subject of controversy (1–3). The World Health Organization (WHO) and the National Diabetes Data Group define GDM as any glucose intolerance (GI) that occurs during pregnancy (4,5). We used the one-step WHO test to identify GI (2-h glucose levels from 140 to 199 mg/dl) and GDM (2-h glucose levels >200 mg/dl) in normal Latin Mexican pregnant women ( $n = 667$ ), disclosing 13% with GI and 3% with GDM (6). The prevalences of macrosomia for the women with GI and for those with a normal glucose response were 10.3 and 5.4%, respectively ( $P < 0.05$ ) (6).

We followed another group of 107 pregnant women with GI whose pregnancies had already ended; these patients received routine antenatal care without any special advice on diet. Of these, 12 women (11.21%) had macrosomic newborns, a similar proportion to the previous observation and also a significant difference ( $P < 0.05$ ), compared with pregnant women with a normal glucose response.

The main clinical characteristics of the women who had normal-weight newborns ( $n = 95$ ) and the women who had macrosomic newborns ( $n = 12$ ) were as follows (mean  $\pm$  SD): age 27.63  $\pm$  5.59 years (16–42) vs. 27.30  $\pm$  7.15 years (20–41) (NS); weeks of gestation at the glucose challenge 33.02  $\pm$  5.56 (24–40) vs. 32.46  $\pm$  3.99 (24–39) (NS); maternal weight at the moment of the glucose test 75.47  $\pm$  13.60 kg (51–105) vs. 79.83  $\pm$  10.26 kg (67–102) (NS); and weight of newborns 3.339  $\pm$  0.357 kg (2.475–3.925) vs. 4.254  $\pm$  0.260 kg (4.000–4.780) ( $P < 0.01$ ). The weight of new-

borns was the only significant difference between the groups. The hospital policy for diagnosed macrosomic newborns is elective cesarean section; 11 of these infants were delivered by cesarean section; the other one was not diagnosed and suffered severe asphyxia during labor. There were no episodes of hypoglycemia, polycythemia, or hyperbilirubinemia.

Macrosomia in this group of patients was significantly associated with GI, although other morbid effects usually associated with GDM in the newborns were absent. These results support the idea that Latin Mexican women, despite age or weight, should be systematically screened for GDM. GI seems to be a significant diagnosis affecting the outcome of newborns, and women detected with GI should receive dietary advice and follow-up of their glucose levels.

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**Cannula Occlusion With Use of Insulin Lispro and Insulin Infusion System**

In their July 1997 *Diabetes Care* article, "Stability of Insulin Lispro in Insulin Infusion Systems," Lougheed et al. (1) state that there were no occlusions of the catheters by insulin precipitation and that the latter was not observed in catheters, pump syringes, or collection vials. These in vitro results differ from our in vivo findings. One of us (A.W.D.W.), using lispro (Humalog) in a Mini Med 504S continuous subcutaneous insulin infusion system (Mini Med Technologies, Sylmar, CA) over a 10-month period, personally experienced five occlusions of the cannula sufficient to trigger the obstruction alarm and cause short-term hyperglycemia.

During the previous 8 years, he had used Velosulin HM (Novo Nordisk, Bagsvaerd, Denmark) with the same system and techniques and had experienced no obstructions of the catheter or syringe.

Insulin precipitation in artificial infusion devices has been under investigation for many years (2). One variable is pH of the insulin preparation. Velosulin has a neutral pH. Humalog was stated to have a pH of 7.4 in the article by Lougheed et al. (1), but in a separate article by some of the same members of this group (3), it had a pH of 5.65, which corresponds with the pH given in the product monograph.

From our experience, the greatest advantage to pumping with Humalog is the convenience of injecting boluses immediately before food consumption.

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**Response to Wright and Little**

Drs. Wright and Little point out a discrepancy between the pH values reported by Lougheed et al. (1) and Zinman et al. (2). Insulin lispro (Humalog, insulin lispro injection) is buffered with sodium phosphate and has a pH of 7.4, as reported by Lougheed et al. The article by Zinman contained an erroneous pH value for insulin lispro, for which an erratum has been published (3). Unfortunately, the pH value was also misprinted in the Canadian product monograph. The value 5.65 refers to the isoelectric point (pI) of lispro. Thus, insulin lispro and Velosulin HM (Novo Nordisk, Bagsvaerd, Denmark) are both phosphate-buffered and have similar pH values.

We agree with Drs. Wright and Little that in vivo experiences may differ from in vitro bench testing. In a controlled randomized prospective trial, we were unable to demonstrate any difference in catheter occlusion between Humalog and regular insulin (2). Furthermore, in our own personal experience with at least 20 patients being treated with continuous subcutaneous insulin infusion (CSII) and Humalog, we have seen no obvious increase in catheter obstruction. Clearly, as indicated by Drs. Wright and Little, patients appreciate the advantages of administering meal insulin immediately before eating and of the increased flexibility in adjusting meal boluses for varying nutrient intake. Nevertheless, the safe and effective use of CSII requires appropriate patient education and particular attention given to pump function and catheter maintenance.

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