use of eye services and the factors that encouraged people with diabetes to attend eye services. For people who self-reported that they had not had a previous dilated-fundus eye examination, questions on the reasons why they had not visited an eye service were asked. The questionnaire, with a reply-paid envelope, was sent to 1,176 participants who participated in the Program for the Early Detection of Diabetic Retinopathy in two areas of rural Victoria, the LaTrobe and Goulburn Valleys. This program was designed to augment current eye services (3).

A total of 869 (74%) questionnaires were returned. We received notification that 27 people were either deceased (1%) or had a change of address (2%). Information from 842 completed questionnaires was analyzed. Of those who self-reported a previous dilated-fundus examination to detect diabetic retinopathy (631), 61% of respondents indicated that their general practitioner was the main prompt that encouraged them to have their eyes examined; a further 29% nominated their diabetes educators or diabetes clinics. Of those who indicated that they had not had a previous dilated-fundus examination (211), 79% of people indicated that they were not aware of diabetic retinopathy or did not appreciate that they were at risk for diabetic retinopathy. A total of 523 (62%) people indicated that their general practitioner was the best source for keeping them up-to-date regarding diabetes complications.

The study highlighted that general practitioners are the most important conveyors of information to their patients with diabetes regarding diabetic retinopathy and that they provide the main prompt for people to use eye services. However, the results also highlighted that one in five people with diabetes surveyed in this study were not aware of or did not appreciate the significance of diabetic retinopathy. We have a public health obligation to inform all people with diabetes about diabetic retinopathy and the need for regular eye examinations. The message is simple—people with diabetes need an eye examination every 2 years for the early detection of diabetic retinopathy.

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References

1. Livingston PM: Visual impairment in Melbourne: prevalence and socio-economic risk factors. PhD Thesis. Melbourne, Victoria, Australia, University of Melbourne, 1997
2. McCarty CA, Lloyd-Smith CW, Lee SE, Stanislavsky YL, Livingston PM, Taylor HR: Use of eye care services by people with diabetes: the Melbourne Visual Impairment Project. *Br J Ophthalmol*. In press
3. Livingston PM, McCarty CA, Wood CA, Keeffe JE, Taylor HR: Use of focus groups to identify effective promotional strategies for the early detection of diabetic retinopathy. *Aust N Z J Public Health*. In press

Local Adverse Events Associated With Long-Term Treatment by Implantable Insulin Pumps

The French EVADIAC Study Group experience

Insulin therapy with implantable pumps has proven to be effective and feasible for long-term treatment of patients with type 1 diabetes (1–4). Moreover, a decreased risk of severe hypoglycemia was reported with this mode of treatment compared with intensive subcutaneous insulin therapy (5,6). The insulin pump is implanted in the subcutaneous tissue of the abdomen, so local complications at the implantation site can occur, as with any totally implanted device. The clinical consequences of such incidents are variable. They sometimes constitute severe adverse events and can lead to explantation of the pump. These local complications have been the subject of recent reports (7,8), but frequency varies in the studies. The EVADIAC (Evaluation dans le Diabète du Traitement par Implants Actifs) Study Group decided to examine local adverse events in 352 patients with type 1 diabetes treated with a programmable implantable pump for intraperitoneal insulin delivery. All EVADIAC centers registered implantation procedure, characteristics, usual activity, and previous allergy in implanted patients. Throughout the patients' follow-up, local incidents were reported in a medical file during quarterly visits and more often when adverse events occurred in the interval. These results were obtained using a retrospective questionnaire that each center answered.

A total of 548 insulin pumps were implanted in these patients. Cumulative follow-up was 1,180 patient-years. Three pump models were used: the Minimed MIP 2001 pump (Minimed Technologies, Sylmar, CA) (n = 466), the Infusaid M1000 pump (Shiley Infusaid, Norwood, MA) (n = 52), and the Promedos ID3 pump (Siemens Elema, Micro Infusion Systems, Solna, Sweden) (n = 30). The pump was implanted in either the right or the left side of the abdominal wall in a subcutaneous pocket made by the surgeon under local or general anesthesia. The catheter was surgically introduced into the peritoneal cavity. Pumps were filled with U100 or U400 surfactant-stabilized hemisynthetic insulin (HOE 21 PH, Hoechst, Frankfurt, Germany) through a transcutaneous puncture every 1 or 3 months, according to the device.

Among the 352 implanted patients, a total of 84 patients were affected by at least one pump-pocket complication, which represented a mean rate of 7.1% patient-years for first events and 8.6% patient-years with recurrences. This rate was variable among centers from 0 to 28% patient-years. Mean frequency of affected patients was 24% but varied among centers from 0 to 60%. Differences seemed to exist according to the size of the centers but were not significant: in large centers with >24 implanted patients, the mean rate was 6.9% patient-years versus 13.9% patient-years in small centers with <24 treated patients. The incidence of these local complications increased according to the year of implantation: 0% in 1989, 1.2% in 1990, 0.6% in 1991, 5.1% in 1992, 5.9% in 1993, 8.3% in 1994, and 8% in 1995.

The nature of these adverse events consisted of the following: local inflammatory reaction in 34.5%; atrophy of the subcutaneous tissue and skin erosion in 44%, with exteriorization of the pump in 16%

of these patients; chronic seromas of the pump-pocket in 16%; and local infection in 9.5% of the patients. The mean delay between pump implantation and outcome of complication was 11.3 months (range: 1–28 months). These events were severe but never fatal, and 64.3% of the patients required pump explantation.

The potential predisposing factors (sex ratio, age, BMI, duration of diabetes, physical activity, and previous allergy) were not different in patients who presented one or more incident compared with patients who did not experience any complication. Physical activity and previous allergy, however, were only assessed in 241 and 199 patients, respectively.

We examined the possible risk factors associated with the implantation procedure. Again, no significant difference was observed between affected and nonaffected patients for abdominal side (left or right) of the pump-pocket, presence of a side port, number of surgical procedures, duration of abdominal contention after pump implantation, or delay between surgery and return to previous level of physical activity.

Throughout these 1,180 patient-years, the mean rate of first local adverse events was 7.1% patient-years (8.6% patient-years including recurrences) and ~25% of implanted patients were affected. Differences were observed among centers, probably because of increased experience and a better-trained medical and surgical staff in large centers as opposed to small new centers. But some other factors (related to the implantation procedure) could be involved, since even among large centers frequency varied from 10.8 to 28.7%.

The rate of local complications reported in pilot trials (1,2) was variable. This rate was 1 and 44% patient-years in the Pims and Point studies, respectively. But these pilot studies were performed in a small number of patients over a short period. Furthermore, a square pump was used in the Point trial, and the high rate of local problems led, in part, to the discontinued use of this pump model. In more recent studies (7,8), variable rates were also observed. Scavini et al. (8) reported a rate of 5.3% patient-years during the Infusaid trial, and mean frequency was 13.8% of affected patients. In one EVADIAC center, Renard et al. (7) reported a rate of 24% patient-years for pump-pocket complications, including first events and recurrences and a frequency of 17.5% of affected patients. However, Renard's trial concerned a restricted number of patients with frequent recurrences, and cumulative follow-up was 58.5 patient-years. This study emphasizes the difficulty in precisely recording the recurrences or the continuation of a same incident and confirms the differences among centers.

In this study, local complications associated with long-term treatment by implantable insulin pump are significant events, since ~25% of implanted patients were affected. The evolution of such incidents can be severe, if not fatal. These complications can become chronic and depressing and often require surgical removal of the pump to achieve a cure. In addition to morbidity, these events account for discomfort with prolonged hospitalizations or frequent medical visits. Despite large differences among centers, no evident risk factor was recognized. So to reduce the incidence of local events, EVADIAC hopes to get smaller pumps implanted by well-trained surgical and medical staffs.

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References

1. Point Study Group: One-year trial of a remote-controlled implantable infusion system in type I diabetic patients. *Lancet* ii:866–869, 1988
2. Saudek CD, Selam JL, Pitt AH, Waxman K, Fisher RE, Charles MA: A preliminary trial of the programmable implantable medication system for insulin delivery. *N Engl J Med* 321:574–579, 1989
3. Selam J-L, Micossi P, Dunn FL, Nathan DM, Implantable Insulin Pump Trial Study Group: Clinical trial of programmable implantable insulin pump for type I diabetes. *Diabetes Care* 15:877–885, 1992
4. Hanaire-Broutin H, Broussolle C, Jeandidier N, Renard E, Guerci B, Haardt M-J, Lassmann-Vague V, the EVADIAC Study Group: Feasibility of intraperitoneal insulin therapy with programmable implantable pumps in IDDM: a multicenter study. *Diabetes Care* 18:388–392, 1995
5. Broussole C, Jeandidier N, Hanaire-Broutin H, the EVADIAC Study Group: French: French multicenter experience of implantable insulin pumps. *Lancet* 343:514–515, 1994
6. Jeandidier N, Selam J-L, Renard E, Guerci B, Lassman-Vague V, Rocher L, Hanaire-Broutin H, the EVADIAC Study Group: Decreased severe hypoglycemia frequency during intraperitoneal insulin infusion using programmable implantable pumps (Letter). *Diabetes Care* 19:780, 1996
7. Renard E, Bringer J, Jacques-Apostol D, Lauton D, Mestre C, Costalat G, Jaffiol G: Complications of the pump pocket may represent a significant cause of incidents with implantable systems for intraperitoneal insulin delivery. *Diabetes Care* 17:1064–1066, 1994
8. Scavini M, Cristallo M, Sarmiento M, Dunn FL, the Infusaid Multicenter Implantable Insulin Pump Study Group: Pump-pocket complications during long-term insulin delivery using an implanted programmable pump (Letter). *Diabetes Care* 19:384–385, 1996

Increased Hydrogen Peroxide Formation in Polymorphonuclear Leukocytes of IDDM Patients

The review entitled "Oxidative Stress and Diabetic Vascular Complications" (1) presents an accumulation of evidence indicating that oxidative stress may be involved in the initiation and development of vascular complications in diabetic patients. Diabetes represents a state of increased oxidative stress, based on evi-