What could be the reasons for giving up the implanted pump treatment?

P Schaepelynck-Bélicar, L Dufaitre-Patouraux, V Lassmann-Vague

SUMMARY
The development of implanted insulin pump treatment has been particularly intense in France and French implanting centers joined to form an association called EVADIAC. The data collected by EVADIAC have clearly documented benefits as well possible problems with this treatment mode. In comparison with SC administration, intraperitoneal (IP) insulin infusion via an implanted pump achieves good metabolic control, improves long-term stability of diabetes and significantly reduces the risk of severe hypoglycemia. Problems can involve pump slowdown, catheter obstruction or local complication at the implantation site. With respect to the benefits, the rate of complications is highly acceptable. However, amongst the implanted diabetic patients, some elect to give up such a treatment mode. In a retrospective study we intended to examine their reasons for giving up this treatment. In our center, the patients who elected by themselves to give up the implanted pump account for 16% of all treated patients. This group of patients did not have, as compared to other implanted patients, less benefits nor more restrictions or incidents that could have impaired their well being. The reasons for giving up the implanted pump seem more often to be related to the refusal of a strict and institutional management linked to this treatment.

Key-words: Insulin · Insulin pumps · Implanted devices · Intraperitoneal infusion · Abandon of treatment.

RÉSUMÉ
Le traitement par pompe à insuline implantée a été développé plus particulièrement en France et les centres implantateurs français se sont réunis pour former un groupe appelé EVADIAC permettant un partage d’expérience. Les résultats de cette expérience ont clairement montré les bénéfices de ce mode de traitement mais aussi les problèmes potentiels. Par rapport à la voie sous-cutanée, la perfusion intrapéritonéale d’insuline par pompe implantée permet un bon équilibre métabolique, améliore à long terme la stabilité du diabète et diminue significativement le risque d’hypoglycémie sévère. Les problèmes peuvent être liés à un ralentissement du débit de la pompe, une obstruction du cathéter ou un incident local au niveau du site d’implantation. Compte tenu des bénéfices apportés, le taux des incidents apparaît très acceptable. Cependant, parmi les patients diabétiques implantés, certains choisissent d’abandonner ce mode de traitement. Nous avons voulu comprendre les raisons de ce choix au moyen d’une étude rétrospective. Dans notre centre, les patients qui, d’eux-mêmes, ont souhaité arrêter la pompe implantée représentent 16% de l’ensemble des patients. Ce groupe de patients, par comparaison aux autres patients implantés, n’a pas retiré moins de bénéfices ou eu davantage de contraintes ou de complications avec la pompe qui auraient pu altérer leur qualité de vie. Les raisons pour abandonner la pompe implantée semblent plus souvent être le refus d’une prise en charge lourde et institutionnelle liée à ce mode de traitement.

Mots-clés: Insuline · Pompes à insuline · Systèmes implantés · Perfusion intrapéritonéale · Abandon de traitement.
The implanted pumps represent another technique for continuous insulin infusion. They provide their efficiency in obtaining both a good metabolic control, an improvement of the diabetes stability and a decrease of the frequency of hypoglycemias. Today, over the world, 406 diabetic patients (amongst them, two-thirds in France) are being treated via an implanted insulin pump. The French experiment is therefore the first in the world due to its importance. Such an experiment is the result of the collaboration of all the French implanting centers, gathered in the EVADIAC group. It makes it possible to analyze, from a centralized and computerized register, the benefits as well as the disadvantages of this treatment mode.

In terms of efficiency, three elements are worth mentioning:

1) The mean glycemic control, during the implanted insulin pump treatment, is improved. HbA1c is significantly reduced after the implantation (from 7.4 to 6.8% on average) and the improvement goes on during the whole follow-up period [1], even in patients who were already subjected to a subcutaneous intensified treatment before the implantation.

2) The diabetes stability, as evaluated by the standard deviation of the capillary glycemias, measured four times a day, is better than with the subcutaneous insulin treatment [1].

3) The severe hypoglycemia frequency is considerably decreased using the implanted pump [2, 3]. These are often the price of the insulin treatment when intensified by means of multiple subcutaneous injections [4]. Thus, in a study comparing two groups of diabetic patients [3], severe hypoglycemia frequency was 0.69 per patient and per year with the multiple injection or external pump treatment and 0.11 per patient and per year with the implanted pump.

Another benefit is related to the quality of life which is completely transformed, according to the patients.

Considering these results, the disadvantages linked to the pump and the catheter are highly acceptable and require expiating in only 2.7 cases out of 100 patients or using surgery in only 3.7 cases out of 100 patients per year. Such disadvantages are:

1) A pump flow rate being slowed down because of insulin deposits on the pumping mechanism which may iteratively occur. Such a slow down is reversible after a pump rinsing procedure using an alkaline solution, carried out as outpatient care,

2) A catheter obstruction, resulting in a fast metabolic disorder. Obstruction is removed in most cases via transcutaneous "flush" of the catheter. When the flush fails, a laparoscopy is performed in order to clear the catheter,

3) A local infection or a skin ulceration has been reported with a frequency of 8 cases out of 100 patients per year [5]. This type of incident most often requires the pump to be explanted.

Finally, the patients’ follow-up is necessarily performed in the hospital environment to refill the pump every two months.

Because of the cost of the implanted pump treatment, the latter has not been suggested in the first place to all the insulin treated patients. Then it is required to select the patients that make the best profit of it. The current indications [6] mainly lie on the users’ experience and on the observed metabolic effects. The implanted pump is indicated to a patient suffering from an unstable type 1 diabetes and/or complicated with severe hypoglycemias or moderate but recurrent hypoglycemias, incapacitating in every day life despite a subcutaneously intensified insulin treatment (multi-injections or external pump). The second main indication is represented by a subcutaneous resistance to insulin which remains an infrequent phenomenon.

However, amongst the implanted diabetic patients, some elect to give up such a treatment mode. We intended to examine the reasons for giving up in order to better understand the candidates for the implanted pump but also bearing in mind the best cost-efficiency ratio. Indeed, a recent technical improvement in the pump relates to the extension of the working period which went from 3 to 10 years. Since January 1990, forty-nine type 1 diabetic patients have been implanted in our centre. At the implantation time, those patients had been diabetic for 18 years and were 37 years old on average. The implantation duration was from 2 to 10 years depending on the patients (through the successive implantation of several pumps) and the results of the study are expressed compared to the cumulated follow-up which is 274.4 patients x year. The patients could be classified into three groups: a group I of 25 active patients (51% of the patients) continuing the treatment, a group II of 16 explanted patients for medical reason (32.7%) because of a local subcutaneous problem (n = 11), recurring obstructions of the catheter (n = 1) or a lack of compliance (n = 4) and a group III of 8 patients (16.3%) who gave up the treatment by themselves. All three groups do not differ in age, diabetes duration or moderated hypoglycemia frequency before implantation. On the contrary, even if the difference is not significant, the pre-implantation frequency of severe hypoglycemias tends to be less in group III. HbA1c at the end of the period being studied is comparable for all three groups: 7.4% for group I, 7.6% and 7.4% for groups II and III. The frequency of outpatient technique interventions for flushing the catheter or for rinsing the pump is identical in the three groups. The frequency of the complete obstructions of the catheter requiring surgery is respectively for groups I, II and III: 3.2, 4 and 1.8 per 100 patients per year for conventional surgery, 2.2, 0.3 and 0 per 100 patients per year for laparoscopy. The pre-implantation follow-up duration is significantly shorter in group III patients. After giving up the treatment, 4 patients out of 8 were lost for follow-up, 4 patients out 8 continued less frequent visits in the diabetes unit.
In conclusion, the patients who elected by themselves to give up the implanted pump account for 16% of all the patients who had been indicated for this treatment for thirteen years in our center. We did not succeed in individualizing any common criterion in this group of persons who did not have, as compared to other patients, less benefits nor more restrictions or incident of medical nature that could have impaired their well being or their satisfaction regarding the treatment. The reason for giving up the implanted pump seems more often to be related to the refusal of a strict and institutional management linked to this treatment than to objective medical reasons.

References