

Guest Lecture :

COMMUNITY EXPERIENCE WITH CONTINUOUS SUBCUTANEOUS INSULIN INFUSION

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Studies of small groups of patients utilizing rigid protocols have been published concerning the efficacy of continuous subcutaneous insulin infusion (CSII). The results have demonstrated marked improvement in glycosylated hemoglobin values, blood glucose concentrations, reversibility of vascular permeability of the eye, a decrease in microscopic hematuria and a decrease in hypoglycemic reactions. Because of these encouraging results it becomes incumbent to attempt to offer this form of treatment to a broader segment of the diabetic population in a more traditional practice setting. The results of a large clinical trial have been recently published by physicians practicing in a large urban multi-specialty circumstances. Our experience although less in number spans a longer period of time (36 months) and represents that of a teaching community hospital.

Patients

Covering the period of March 1980 thru March 1983, there were twenty two patients who were treated with the insulin pump. The group was composed of 15 females and seven males. The mean age was 39 years and the average duration of diabetes was 16.7 years prior to the initiation of the insulin pump including one patient who had diabetes only for a year. The mean duration since initiation of the pump is 12 month the longest duration being 36 months. Two patients were felt to have Type II diabetes because of age of onset (40 and 52 years respectively) and lack of ketosis. In the remaining 20 patients the onset was at age 35 years or younger.

Infusion Pumps

The subcutaneous insulin infusion pump utilized was the Autosyringe model AS6C (Autosyringe Co., Hooksett, New Hampshire) in 14 individuals. Two were however initially started on the AS2C. Eight patients used the CPI/Lilly 9120 series (Cardiac Pacemakers Inc. Division of Eli Lilly Co. St. Paul, Minnesota) The pumps were initially set and programmed on a breakdown of insulin requirement as follows: 40% basal and pre-meal boluses 18% at breakfast, 15% lunch, 15 % dinner and 12 % hs snack given 15-30 minutes before each meal. As we gained more experience the pre-meal bolus dose became more flexible based upon home glucose monitoring (HGM) observations. The 24-hour dosage ranged from 30-105 units of beef pork regular or purified pork insulin.

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Methods

The patients were admitted to a 3-bed metabolic unit for a general physical examination and initial laboratory assessment. They were placed on a weight maintenance diet consisting of three meals and hs snack containing 50% carbohydrate, 20% protein and 30% fat. The fiber content was approximately 22 grams. In two patients a hypocaloric diet was prescribed.

During the hospitalization, the patients were carefully instructed about diets, exercise routines, attendance at regular diabetic classes and the principles of the insulin pump. They were also instructed in the use of Chemstrip-bG (Chemstrip-bG, Biodynamics Co., Indianapolis) for which sampling of capillary blood for home glucose monitoring, the results of which were utilized for the adjustment of insulin requirements. The average hospital stay was 4 days.

Subsequent outpatient visits were made approximately every 3 months to evaluate the status of their diabetic control. Chemstrips were used for home glucose monitoring and most patients were required to check their capillary blood glucose four times a day. This has resulted in a further improvement in hemoglobin A₁ values over the past six months from $10\% \pm 2\%$ to $8.8\% \pm 1.3\%$ (See Table 1). Glycosylated hemoglobin A₁ values prior to and after pump placement were compared. The hemoglobiri A₁ was the major yardstick utilized for evaluating glycemic control. Student's test was used to compare the mean SD.

Results

Prior to initiation of the insulin pump, eight patients had undergone laser treatments for diabetic retinopathy. No further deterioration of their visual status after being on the pump for an average of 6 months was observed by their ophthalmologists. However, one patient with severe and difficult to control hypertension eventually developed a vitreous hemorrhage after being on the pump. Presently she is undergoing laser treatment for hemorrhage detected in her left eye and is also being dialyzed for severe renal insufficiency. Seven patients who complained of weakness and numbness of extremities prior to pump placement were noted to be more energetic and claimed the numbness was less after being on the pump. Another patient became pregnant after 16 months of treatment and was delivered by caeserean section uneventfully at the 32nd week. One other patient is presently on her 16th week of pregnancy and good glycemic control. Two male patients who were complaining of erectile impotence improved after being on the pump. Two males and a female patient discontinued the pump within the first several weeks of treatment. The remaining patients are extremely pleased with the results.

Table 1

Comparison of glycosylated hemoglobin-values over a six-month period, mg. %

Patient	September, 1982	March, 198
1	12.7	9.7
2	11.9	11.9
3	8.1	7.6
4	8.1	8.1
5	8.6	7.4
6	8.1	7.7
7	11.2	7.3
8	11.1	9.4
9	7.9	9.4
10	12.1	7.9
11	11.1	11.1
12	10.1	10.1
13	8.8	8.8
14	8.2	8.2
15	8.1	8.1
mean±SD	10.0% ±2.0%	8.8% ± 1.3%

Fifteen patients have been followed 3 months or longer and showed a significant decrease in glycosylated hemoglobin values from 12.0 % ± 3.0 % to 8.8 % ± 1.3 % with $p < 0.025$ (See Table II).

Complications

While on the pump, 3 patients developed a skin abscess at the needle site. This was corrected by advising the patients on a more sterile technique of needle placement, change of needle site every 48 hours and switching to purified pork insulin. In one patient mild ketoacidosis was precipitated by skin infection.

Table 2**Glycosylated hemoglobin values of 15 patients before and after pump placement, mg%**

Patient	Before pump	After pump
1	12.2	9.7
2	13.0	11.9
3	10.6	7.6
4	11.3	8.1
5	14.0	7.4
6	11.6	7.7
7	10.3	7.3
8	9.3	9.4
9	20.3	9.4
10	14.5	12.5
11	12.5	11.1
12	9.9	10.1
13	10.4	8.8
14	10.4	8.2
15	10.2	8.1
mean±SD	12.0%±3.0%	8.8%±1.3%

Five patients had one or two episodes of hypoglycemia which was reversed by oral glucose. One female patient had to increase her insulin requirement by 10% during her menstrual period because of higher blood glucose levels. One patient died from an acute abdominal catastrophe which precipitated profound ketoacidosis. There was no documentation of a malfunctioning insulin pump at the time of her death. Another female patient died of severe infection due to osteomyelitis despite intensive medications.

Discussion :

The goal of achieving improved metabolic control in 15 patients with insulin dependent diabetes was successful with the use of CSII and home glucose monitoring. This was reflected by the marked decrease in the values of hemoglobin A1 and the reversal of clinical symptomatology. The glycosylated hemoglobin measurement proved to be an extremely useful tool for the management of patients with diabetes. Such a parameter is very valuable to the clinician since blood glucose determinations are subject to rather marked fluctuations. It is an index of blood glucose control over an extended period of time, 2-3 months prior to its measurement. Based on its values adjustment in insulin requirement were done accordingly. The determination of hemoglobin A1 is particularly useful in following ambulatory visits even in difficult cases.

Complications of the insulin pump include skin infections at the injection sites. This can be minimized by the use of a more sterile technique, teflon catheter, decrease insulin volume, rotating the needle site every 48 hours or earlier and also by switching to purified pork insulin. Awareness of the development of ketoacidosis in the event of infection should be emphasized so that proper insulin adjustment may be made. Hypoglycemic reactions were reported in five patients which is certainly not unique to insulin pump therapy. However making known to the patients its occurrence and immediate management will prevent further complications. In the cases presented none required hospitalization for hypoglycemic episodes.

It has been reported in some studies of diabetes that 80% of all diabetics have shown electrophysiologic and morphologic abnormalities of peripheral nerves and 10% have symptomatic neuropathy. In our cases numbness of the extremities, blurring of vision and difficulties with penile erection were the main highlights. Reversal of symptoms after pump placement was gratifying.

In conclusion therefore, the use of CSII can be successfully employed in clinical practice to improve diabetic control provided that there is adequate intensive educational support by health professionals and patient motivation and compliance with home glucose monitoring.

Currently, we are utilizing the CPI Betatron utilizing the single basal rate. Hospital stay for pump initiation has now been reduced from 4 days to 48 hours.

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