SOUTHWESTERN NEWS

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Editor's note: Patients available for interviews.

UT SOUTHWESTERN DIABETES RESEARCHER'S FAITH IN INSULIN PUMP JUSTIFIED AFTER 10-YEARS OF RESEARCH

DALLAS — July 28, 1993 — For years Dr. Philip Raskin was convinced there was a better way to treat diabetes. Now a 10-year national research project has shown that the diabetes researcher's faith in intensive treatment for insulin-dependent diabetes mellitus (IDDM) is justified.

Raskin, a professor of internal medicine at The University of Texas Southwestern Medical Center at Dallas, has been studying the effectiveness of the insulin pump for more than 15 years. He said his experience led him to believe that mimicking the body's normal glucose level is the best way to treat patients with IDDM, also called type I diabetes. And the small, programmable insulin pump, which can be carried easily in a pocket, is designed to do just that. Instead of the sudden injection of insulin delivered by the usual maintenance program, the pump supplies a constant, measured stream of insulin through a tube to a tiny needle inserted under the patient's skin.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD) recently announced the results of a 10-year study it sponsored involving 1,441 patients at 29 medical centers in the United States and Canada to compare standard treatment with intensive treatment. The goal of standard treatment is to stabilize the glucose level. The goal of intensive treatment is to achieve a normal blood-glucose level.

Raskin, who directs the diabetes clinic at Parkland Memorial Hospital, one of UT Southwestern's major teaching hospitals, headed the Texas section of the NIDDKD study. Fourteen of Raskin's 60 research volunteers were in the study the entire 10 years.

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The study found intensive treatment of diabetes to be far superior to standard treatment in heading off major complications of the disease. Intensive treatment also was proven far more effective in slowing the progression of these complications, including blindness, kidney disease and nerve damage, often leading to amputation.

"This study will no doubt influence the way diabetes is treated from now on," predicted Raskin. He said the evidence that serious diabetic complications are related to blood-glucose levels is so convincing that findings may also influence the way all forms of diabetes are treated as well as IDDM.

Intensive therapy was shown to delay the onset of diabetic retinopathy, or diabetic eye disease, by 76 percent as well as slowing its progression by 54 percent in cases where it had already started. Intensive treatment also prevented or delayed the development of diabetic kidney disease, or nephropathy, by 35 to 56 percent. Intensive therapy reduced neuropathy or diabetic nerve damage complications by 60 percent.

"I certainly believe it is fair to extrapolate these results to the treatment of adult-onset (type II or non-insulin dependent) diabetes, especially when the patient is still young," he said.

All but two of Raskin's volunteers who received intensive treatment used the insulin pump. Those two volunteers checked their blood-sugar level six to eight times a day and adjusted their insulin levels accordingly by giving themselves injections, which is an alternate option of intensive treatment.

Volunteers at the 29 centers were divided into two groups, those receiving intensive treatment and those who continued the standard treatment of two shots a day. All, however, included diet therapy and exercise in their treatment program, and these components were considered in calculating the patient's individual insulin doses.

Trial coordinator Suzanne Strowig was available to talk over any problems volunteers were having with their treatment plans. Strowig is a faculty associate in internal medicine and was a first-line contact with patients. Other

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research team members included nutritionist Susan Cerçone, research scientist in internal medicine, who worked with Strowig in designing dietary treatment strategies for each individual's needs, and Dr. Monica Basco, assistant professor of psychiatry, who helped patients with behavioral changes and provided psychological treatment and support.

With study results in, Raskin said he and his team will spend time addressing professional and patient groups on intensive therapy. He also will meet with UT Southwestern study patients to discuss individual results and ask if the patient would like to change treatment. The research team believes many of their standard-treatment patients will switch to the more intensive regimen.

"This is an exceptional group of patients," Strowig said. "Everyone who came into the study had to accept random assignment to the different treatment groups. They had to be prepared to follow an extremely demanding protocol."

Although the study proves the long-term benefits of intensive therapy, Raskin warns that it is not for everyone. Patients with other medical problems, such as heart disease or prior strokes, may not be candidates for the insulin pump or multiple injections. People who drive frequently or operate heavy equipment might not be suitable because of potential fainting spells related to low blood-glucose levels.

Since the goal of intensive therapy is to keep the glucose level normal, there is a much higher chance that a patient may suffer from hypoglycemia, a condition in which the blood sugar drops below normal levels, causing fainting spells or other neurologic symptoms. Patients in the intensive-therapy group had three times as many episodes of hypoglycemia as their counterparts in the standard-therapy group. Raskin said his patients, whether they were on intensive or standard therapy, were counseled never to drive an automobile without first checking their glucose levels.

He also cautioned about the use of intensive therapy with teenagers. "Since teenagers think they're immortal by definition, you really need a mature

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youngster to try the pump," he said. But participating in athletics need not prohibit treatment with the pump. "Patients who play sports have the option of taking their pumps off for practice and games," Raskin said.

Many patients are put off by the idea that the pump, attached to a catheter in the side, is unsightly and cumbersome, Raskin said. "When we started, the pumps were about the size of six-shooters. Now they're about the size of beepers or pagers. Since they're attached near the waist, men often put them in their pockets, and they'll fit under a suit coat or jacket. Some women are able to put them under their blouses and snap them to their bra straps."

Karen Bearden, an intensive-treatment patient who receives her insulin via pump, was a San Antonio resident when she entered the study. When she and her family moved to Wyoming, she asked if she could be treated via telephone.

Bearden didn't want to gamble with her health or the health of her unborn baby. She has spent two of her four pregnancies on the pump.

"The team has been wonderful," she said. "I was scared to death when I moved away, but we kept in touch as often as once a day, and they're always there if I need them."

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