
May 22, 2009

First Case of Diabetes Reported Since 2006

A case of diabetes mellitus was reported last month. It is the first case reported in the United States since 2006, the first since the discovery of the INGAP treatment and several years after the conclusion of two comprehensive nationwide diabetes campaigns. One campaign involved using INGAP for Type 1 diabetics and the other for Type 2 diabetics who require insulin shots. The recent case is remarkable because it is so unusual. The outstanding success of the campaigns is a result of the steadfast efforts of the scientific community and private public diabetes funding.

At the 2002 ADA Scientific Sessions in San Francisco we had the opportunity to meet with some of the researchers who reported on their research projects. One of the projects that caught our attention was a little known study from Eastern Virginia Medical School. This study focused on the use of a peptide, which upon injection, caused precursor cells to develop into islet cells and produce insulin in diabetic animals, in which diabetes was completely reversed.

We were granted an interview with one of the chief scientists on the project, Dr. Aaron Vinik. We met with Dr. Vinik for over 3 hours and walked away believing that this was too good to be true! We continued our research into the project by contacting Dr. Vinik's associate, Dr. Lawrence Rosenberg from McGill University in Montreal, GMP, the research company in charge of the research, and Procter and Gamble who is helping to finance the research. The more information we had the more excited we became.

Over the next few issues of Diabetes in Control.com we will present to you information that we have accumulated from interviews with the lead researchers, the GMP companies (research company) and also with P&G Pharmaceuticals, who is a primary investor in the project.

We hope you will find it to be as informative and exciting as we did. We know it is in the early stages, but from the current information, this could be -----

Part 1

THE CURE FOR DIABETES? Or Too Good to be True!

How did it start?

We met with [Dr Lawrence Rosenberg](#) of McGill University while at a conference in Atlanta and he explained.

"It really started back in 1922 when a technique using cellophane that comes from the wrapping of cigarettes packages was used to wrap a liver in the performance of a 2-stage hepatectomy (liver removal) in a dog."

Then in the early 1980's, Dr. Rosenberg a surgical resident was working on developing an animal model for studying the development of a condition called chronic pancreatitis, as part of his PhD thesis. It was known from the previous research, that partial obstruction of the pancreas could cause this condition in the dog, so he modified the procedure by dissecting out the pancreatic duct and directly tying a piece of cellophane tape around it. This is the same tape that is used around gum wrappers or cigarette boxes. In fact the cellophane tape came as a reel from Imperial Tobacco!

Because of the physical properties of the cellophane, a slow progressive obstruction ensued (versus simply tying of the duct which would have caused an acute inflammatory reaction with tissue destruction).

His primary interest at the time was pancreatic cancer and not diabetes. He hypothesized that duct cell proliferation in the pancreas was a precursor to pancreatic cancer, and from the previous dog studies, it was known that the cellophane technique induced cell proliferation in the pancreas.

The animal of choice for the study of pancreatic cancer was (and still is) the hamster. It was impossible to perform the same surgery on the hamster pancreas as was performed on the dog because of the small size. So really out of desperation more than anything else, Dr. Rosenberg wrapped the cellophane tape (cut to a 1 mm wide thickness) completely around the non-dissected head of the pancreas. Luckily, it resulted in the same partial obstruction as was created in the dog.

Serendipitously- they discovered that the cell proliferation, which did ensue, was actually followed by islet cell neogenesis and new islet formation.

Hence was born the cellophane wrap technique coined "**Sarandipity**", for the induction of islet cell neogenesis- the first step on the twenty year road to INGAP (***Islet Neogenesis Associated Protein***).

Using this animal model, he demonstrated that drug-induced diabetes could be reversed in hamsters.

In 1985, Dr. Rosenberg went to the University of Michigan to complete a transplant surgery fellowship and the following year met **Dr. Aaron Vinik**, currently Research Director of the Strelitz Diabetes Institutes (SDI) at EVMS (Eastern Virginia Medical School). Dr. Rosenberg presented the model and data at one of his research conferences and Dr. Vinik, who was present, was intrigued enough to want to strike up a collaboration. Together they would try to sort out how the surgical procedure induced new islet formation. While in Michigan, they prepared a crude pancreatic extract, called Ilotropin, that exhibited the ability to stimulate new islet formation when injected into normal hamsters.

In 1987 Dr. Rosenberg returned to Montreal and in 1990 Arthur Vinik moved to Norfolk. Nonetheless, they continued their collaboration.

Dr. Rosenberg continued to work on the physiology of ilotropin and on the cell biology of islet cell neogenesis, while Arthur and a newly assembled team began to try to isolate from ilotropin (a soup of proteins), the active component. In the interim, they completed a study to demonstrate that ilotropin could reverse diabetes in hamsters, much as the cellophane wrap procedure did.

Finally in 1997, through concerted collaborative effort, they were able to identify the INGAP gene, as had been expressed in a novel fashion in the cellophane-wrapped pancreas, Ultimately the INGAP protein was identified as the responsible agent for islet neogenesis.

Next week we will bring you details that answer the question:

Part 2: **Why this might be a cure?**

In Part 2, we will also provide you with the number to call to get more information on how patients might qualify to participate for the upcoming trials.

For More Information:

Cloning and Sequencing of the Pancreatic Islet Neogenesis Associated Protein (INGAP) Gene and Its Expression in Islet Neogenesis in Hamsters. Please visit <http://www.jci.org/cgi/content/full/99/9/2100> to read the entire research article

To review the Abstract please visit http://www.evms.edu/diabetes/ingap_abstract.html

To review other collaborations between Dr. Vinik and Dr. Rosenberg please visit <http://www.evms.edu/diabetes/research-pubs-abstracts2.html> and

<http://www.evms.edu/diabetes/research-pubs-abstracts1.html>

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About the Scientists



Aaron (Arthur) I. Vinik, MD, PhD, FCP, FACP Director, Diabetes Research Institute Scientific Director, Department of Medicine, Professor of Medicine, Eastern Virginia Medical School

One of the leading diabetes researchers in the world, Dr. Vinik is key in the Strelitz Diabetes Institutes' quest to cure diabetes. His focus of attention is 1) the prevention and reversal of diabetic neuropathy and 2) the development of islet cell regeneration research as a cure for diabetes. Dr. Vinik spearheaded the discovery of "ilotropin," a chemical substance that can reawaken a cell's potential to produce insulin and the gene, INGAP, the protein responsible for this reawakening.

Dr. Vinik came to the Strelitz Diabetes Institutes from the University of Michigan at Ann Arbor where he was professor in Internal Medicine and Surgery. At the University of Michigan he established an international reputation for his research in the areas of hormone secreting tumors and the complications of diabetes, particularly diabetic neuropathy.

Dr. Vinik has been invited to present his work all over the world. Recognized as a pioneer and scholar, Dr. Vinik has authored five books, 75 book chapters, and has published more than 300 papers in peer-reviewed, highly reputable journals. He has also published more than 260 abstracts, and he and the fellows he has trained have presented scientific papers and innumerable national and international meetings.

Dr. Vinik is a member of a number of professional societies including the American Endocrine, Diabetes, Gastroenterology, and the European and International Diabetes associations. Dr. Vinik was a member of the National Institute of Health General Clinical Research Center Study Section and the NIH Data Management Committee. He was also Chairman of the American Diabetes Association task force on Nutrition, which established the previous 1985 guidelines for nutritional management of diabetes, and Chairman of the

subcommittee for development of guidelines for neuropathy testing; in addition, he was also a member of the committee to develop guidelines for managing lipid disorders in diabetes.

Dr. Vinik has received research funding for his studies from the National Institutes of Health, the National Cancer Institute, the Kroc Foundation, the American Diabetes Association, and pharmaceutical industries.



Lawrence Rosenberg, M.D., Ph.D. received his M.D. from McGill University in 1979 and completed surgical training in General Surgery at the Montreal General Hospital. During his residency, Dr. Rosenberg completed a Ph.D. in Experimental Surgery at McGill University. He completed post-doctoral studies, including a transplant surgery fellowship at the University of Michigan, and in 1987 he was appointed Assistant Professor of Surgery and Medicine at McGill University. He is currently Professor of Surgery and Medicine and Director of the Division of Surgical Research at McGill University, and the A.G. Thompson Chair of Surgical Research at the McGill University Health Center.

Dr. Rosenberg's current studies address islet cell neogenesis, pancreatic stem cells, and islet cell death and survival. He is the co-discover of INGAP, a novel pancreatic differentiation factor, presently in clinical trial as a novel therapy by the in-vivo induction of islet cell neogenesis.

Dr. Rosenberg has served on grant review panels of the Juvenile Diabetes Research Foundation (JDRF) and the Canadian Diabetes Association (CDA), and reviews on an ad hoc basis for NIH study sections. He is a member of the Investigator Awards Committee of the Canadian Institutes for Health Research (CIHR) and the College of Electors for Canada Chairs, and was a founding member of the Stem Cell Network of Canada. He has consulted for several well known pharmaceutical and biotechnology companies in the areas of pancreatitis, pancreatic cancer, and cell therapy of diabetes and has developed expertise in issues related to technology transfer. Dr. Rosenberg is on the editorial boards of *Graft* and *Pancreatology* and is a reviewer for many prestigious journals. He is an author on more than 250 peer-reviewed publications, book chapters and abstracts. He has been continuously funded by the Canadian Institutes for Health Research for almost 15 years. He is currently the PI on several research grants, including a JDRF Center grant for Beta-Cell Replacement, for which he is the Director. He is a frequent guest lecturer on issues related to the cellular therapy of diabetes, including islet cell neogenesis and stem cells, and pancreatic cell plasticity.

The contributions of Dr. Rosenberg have been acknowledged by many national and international agencies including the Juvenile Diabetes Research Foundation (JDRF), the Canadian Institute of Health Research (CIHR), and the Stem Cell Network of Canada. In addition, Dr. Rosenberg has received many career awards and fellowships, including: a Medical Research Council of Canada Fellowship, McLaughlin Foundation Fellowship, Medical Research Council of Canada Scholarship, a Senior Clinician-Scientist Award and National Scientist Award both from the government of Quebec. He is the only Canadian to have been a recipient of the prestigious American Surgical Association Foundation Fellowship.