

Diabetes Cure Talk: Research Updates from ADA 2016

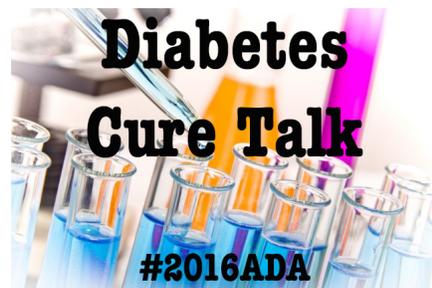
Written by Mike Hoskins | Published on June 27, 2016

We're still catching our breath following the American Diabetes Association's huge 76th Scientific Sessions conference in New Orleans, where diabetes tech and treatments and other science took center stage. So what about cure research, you may ask?

Sorry, no cure yet.

But the topic was certainly touched on with some excitement -- especially in light of recent headlines about steps forward in biological methods to end diabetes once and for all.

We saw a handful of poster presentations at #2016ADA that spoke to this progress, though it's not easy to monitor exactly how much "cure talk" actually took place this year. If you search the list of hundreds of ADA science abstracts for the word "cure," just roughly 18 posters pop up, but to be accurate, you'd need to include specific terms like "islet" or "beta" and then read through them all.



Following ADA, we reached out to some of the more prominent researchers who tend to draw the most attention when ever Cure Talk comes up. Here's what's on our radar, as of this mid-point of June 2016:

Insulin-Free, Thanks to DRI

This year is a big one for the Diabetes Research Institute (DRI) in Miami, as it marks the 10-year anniversary of three PWDs who've been essentially "cured" and remain insulin-free after receiving islet transplants a decade ago.

And with the DRI's BioHub (a bioengineered "mini organ" that mimics the native pancreas) kicking into full force last year, the research group is adding to the number of its "insulin-free" success stories.

Just as the big ADA conference was getting underway, news hit that a 41-year-old Italian man diagnosed with type 1 four decades ago had been essentially cured and was now insulin-free, based on the BioHub protocol spearheaded by scientists from the DRI Foundation. The press release titled "First Type 1 Diabetes Patient in Europe Is Free From Insulin Therapy" is worth a read.

Leading that research are three Italian scientists: Dr. Federico Bertuzzi, who heads up the Islet Transplant Program; Dr. Mario Marazzi of the Tissue Therapy Unit; and Dr. Luciano De Carlis, director of General Surgery and Transplantation.

Dr. Camillo Ricordi, director of the DRI and Professor of Biomedical Engineering at the University of Miami, says the institute is very excited about the "promising step forward" in Europe, as it confirms the results they achieved with their first patient, Wendy Peacock, treated in the U.S. with the same protocol last August.



After Wendy's successful BioHub transplant, the DRI shared the protocol with international researchers. The newer research validates the initial findings and confirms this DRI process works.

These two PWDs join with the three other D-peeps who've essentially been cured through the DRI's work, having undergone islet transplants 10 years ago.

Of course, access remains a big issue and too few islet transplantations are happening, according to Dr. Ricordi, who talked about this in a presentation at ADA.

Among the factors limiting access: overall cost of the procedure and treatments, requirement for systemic chronic immunosuppression, too little global collaboration, lack of insurance reimbursement and the blocking of patents' access to drugs.

What's next? Dr. Ricordi says a new clinical trial is in the final planning stages, called the Diabetes Islet Preservation Immune Treatment (DIPIT). It aims to halt the autoimmune attack and preserve islet function. This trial will be conducted at multiple centers in order to accelerate the timeline, speed collection data and monitor progress.

The DRI has also been focused on developing a reliable and plentiful supply of insulin-producing cells, or regenerating the body's existing cells. Drs. Juan Dominguez-Bendala and Ricardo Pastori and their team published critical data this past year on results using a single, FDA-approved agent, BMP-7, to convert non-endocrine tissue of the pancreas into insulin-producing cells. Their work represents the first time this has been accomplished without the use of any genetic manipulation.

We hear that DRI is planning to host a session at the CWD Friends For Life Conference on July 6, discussing its clinical trials and work. Insulin-free Wendy Peacock will be there, along with one of the islet transplant patients from more than a decade ago, Chris Schuh. Dr. Juan Dominguez-Bendala will also be presenting the results achieved this past year with BMP-7, as well as other islet-focused research.

BCG Vaccine Research by Dr. Denise Faustman

A year ago, we reported that Dr. Denise Faustman in Massachusetts was finally ready to start the second phase of her clinical research on a possible vaccine to cure diabetes.

For those not familiar with Dr. Faustman's work, she has long been studying something called BCG (Bacillus Calmette Guerin), a generic vaccine that's been around for almost a century and was originally designed to combat tuberculosis (TB). The idea: boosting BCG could stop the pancreas from killing off beta cells, allowing those affected by diabetes to regenerate these insulin-making cells. She made a groundbreaking discovery in mice in 2001, but wasn't initially able to replicate that, and her research has kicked off a firestorm of controversy among the medical community and research orgs who doubted her approach.

She finished the Phase I of her research in 2010, and last year she was ready to move on to Phase II.

At the most recent ADA, Dr. Faustman had two scientific posters (1072-P and 1290-P) on display showing updates on her work. We connected with her following the NOLA event, and she told us her work continues moving forward successfully.



The big update: 120 of the total 150 patients from the first trial are enrolled in this Phase II trial, and 75 of those PWDs have been given at least one dose of BCG.

In this trial, they're multi-dosing BCG or a placebo in longstanding type 1s who've been living with this condition for 15-20 years. Participants will receive either 6 vaccination or placebo doses over the course of this five-year, FDA approved trial.

Dr. Faustman is looking at A1C as the primary endpoint, measuring the trial's success based on the amount that A1C drops.

We know there's a big push to look beyond A1C in clinical trials and regulatory processes. When we asked Dr. Faustman about this point related to her research, she noted that her team is measuring more than seven biomarkers that include C-Peptide and Tregs (T-regulatory cells), but the most important biomarker for drug approval remains the A1C.

"A lot of people are looking beyond A1C because a generation of type 1 trials (and billions of dollars) failed to meet A1C endpoint and they think it's not possible. It's sort of moving the goal posts. We are essentially kicking the goal posts where they are now, and based on long term follow up in BCG trials around the globe, we remain hopeful," she says.

Faustman also points out that several other BCG trials are going on globally, ranging from evaluating prevention in newborns to drug trials with MS patients happening in Italy. That's all important related work, and the researchers are in touch and sharing their findings to better determine how the BCG is working.

Of course, it will be some time before we hear any results from her five-year trial. But next year, Faustman says her team will present data from the long-term Phase 1 trial follow-up, which will have been completed for seven years by then and show years of important follow-up data. Her research remains in fundraising mode, and she's raised \$20M to date. Faustman says her team is also looking for more study volunteers who can connect with them through the website FaustmanLab.org.

ADA's Pathway to Stop Diabetes

One session at ADA featured a handful of researchers working as part of the ongoing grant-funded, prestigious Pathway to Stop Diabetes program. Among them was Dr. Thomas DeLong, a researcher in Colorado who also lives with T1D and whom we interviewed about his work earlier this year. Thomas is studying the body's immune system attacks and how beta cells are destroyed, in hopes of understanding why that happens and what can be done to prevent it.

Other Cure-Related Research

As noted, there were a handful of other posters at ADA that directly addressed cure research. D-blogging peep Joshua Levy shared some perspectives on what he saw and heard, and his post is worth checking out.

Still, all this cure talk often gets misrepresented and over-hyped, i.e. media headlines the likes of these:

"Diabetic Stem Cells Were Just Transformed Into Insulin-Producing Cells" (story here)

"Scientists find cure for type 2 diabetes in rodents, don't know how it works" (story here)

"Probiotics a Diabetes Cure? Amazing Research You Should See" (story here)

Nevertheless, we remain cautiously optimistic thanks to the advances mentioned above and other serious work toward a cure, including:

JDRF and ViaCyte: Earlier this month, the JDRF released a video featuring the org's Chief Mission Officer Aaron Kowalski, who's a fellow type 1 himself, offering updates on cure-related research. This includes the ViaCyte device that's showing preliminary promise of turning precursor pancreas cells into insulin-producing ones that can withstand the immune system attack that leads to type 1.



D-Research Connection: You can learn about a number of other smaller, lesser-known cure research projects via the Diabetes Research Connection and its online hub of crowdfunding for cure research -- which is just a snippet of all the efforts going on around the world.

No matter what comes next, we have to extend a huge THANK YOU to the scientists doing this research, who've invested themselves in making a difference for PWDs everywhere.

Disclaimer: Content created by the Diabetes Mine team. For more details click here.