

diaTribe®

research and product news for people with diabetes

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So Jim Hirsch and I were talking. You know Jim. A former reporter for The New York Times and The Wall Street Journal, he has written five books, most recently the best-selling *Willie Mays: The Life, the Legend*. He also wrote the remarkable *Cheating Destiny*, the chronicle of his life with type 1 diabetes and that of his son Garrett. He's also written over 20 Logbook columns for diaTribe since 2006, including this issue's riveting tale about a young platoon sergeant in Vietnam whose survival story rivals any in the history of diabetes (diaTribe managing editor Ben Kozak, diaTribe columnist Kerri Sparling, and I all heard Urban Miyares speak at TCOYD in Providence earlier this fall). Other favorite Logbooks are "How a New York Peep Show Saved a Young Writer," "The Scorekeeper's Daughter," and "The Midnight Hour." Jim has been our senior editor for as long as I can remember. I am truly lucky to know him.

So we were talking. I was asking him if he had any overriding feeling about World Diabetes Day, which of course happens this Sunday.

What he said to me really resonated. He said that his feelings center on how much diabetes has changed as a topic of open conversation, even celebration. For much of the history of the disease, he said, the subject was hidden. Patients and their families would go to extraordinary lengths to ensure that no one knew they had diabetes. Living behind a curtain of shame, many people with diabetes wouldn't tell their friends, co-workers, or teachers. Some diabetic adults wouldn't even tell their children. Lee Iacocca, whose wife died from this disease, once told Jim that back in the 1950s and '60s, diabetic autoworkers were considered "lepers."

In other words, the most important part of World Diabetes Day is that there even is one. It stands as a glorious repudiation of this ailment's sordid history and a sure sign of progress. However else you are feeling about diabetes today, that progress should be remembered and revered. Now and forever, the curtain has been lifted.

Happy World Diabetes Day indeed.

Best,

Kelly L. Close

To get your free subscription to diaTribe, visit www.diaTribe.us.

P.S. Be sure to check out this month's updated Test Drive on my use of Victoza - including the official response letter from Novo Nordisk!

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quotable quotes

On Diabetes Management

“It’s not a sprint, it’s a marathon. You can’t correct everything overnight.”

- *Founder and Director of Taking Control of Your Own Diabetes (TCOYD) Steve Edelman, MD (University of California at San Diego, La Jolla, CA) at the TCOYD meeting in San Diego in October.*

On Longevity

“Well-controlled diabetes is the leading cause of...nothing, except a long and healthy life.”

- *William Polonsky, MD (University of California at San Diego, La Jolla, CA) at the TCOYD meeting in San Diego in October.*

On Policy

“It’s not enough to advocate for policies, we also need to take advantage of them.”

- *Ann Albright, PhD (Centers for Disease Control and Translation, Atlanta, GA) at the TCOYD meeting in San Diego in October.*

Editor’s note: please ask your friends if they have taken the Diabetes Screening Test, paid for by Medicare.

fingersticks

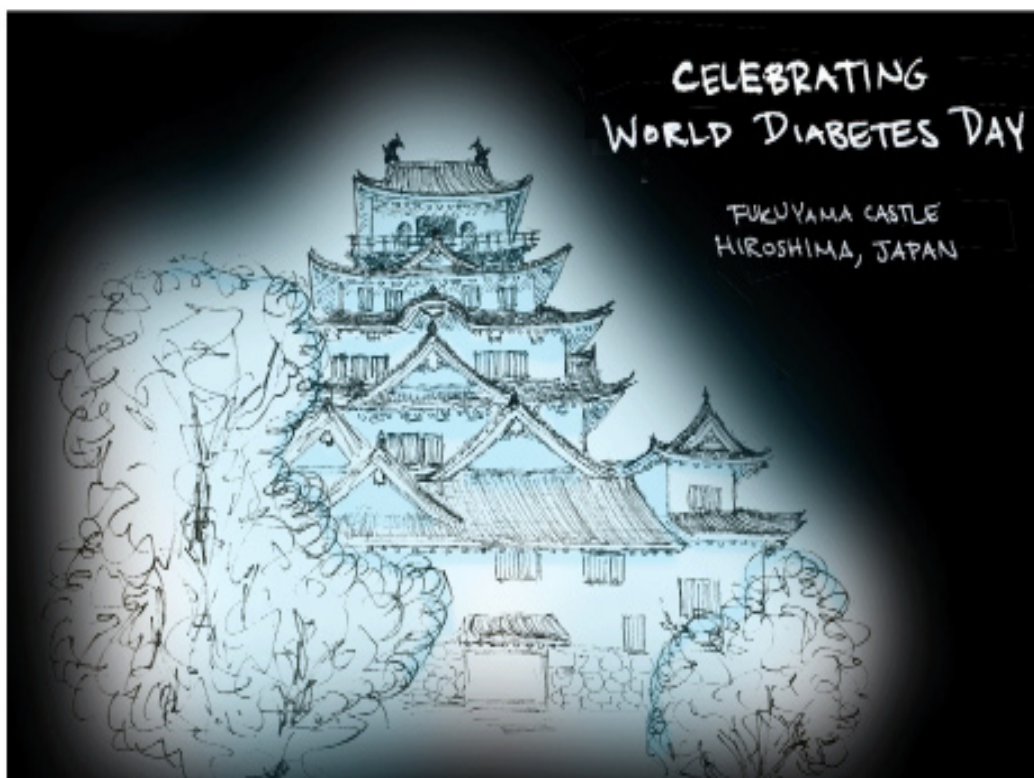


ILLUSTRATION: DANIEL BELKIN

test drive



The adjustable Victoza pen doses all three 0.6, 1.2, and 1.8 mg doses, to aid in finding the right dose.

I promptly called my doctor and said that even though I knew that Victoza was not approved for type 1 patients, I wanted to try it. This would be “off-label use,” as the jargon goes.

T1 An Open Letter to Novo Nordisk

by Kelly L. Close

Editors note: We received great reception to our test drive column in last month's issue, so we've decided to print an updated version this month, including a response letter from Novo Nordisk.

In my 24 years with type 1 diabetes, things have gotten better each year. There were great years – when rapid-acting insulin analogs were invented; when lancets changed from 25 gauge to 27 (and then 31!); when I finally realized how great wearing a pump would be; when next-gen CGM emerged – and other years when the improvements were quite small. But the trend line has always been for the better.

So I'm not really sure why this year the whole diabetic enterprise has been harder than usual. My frustration is growing. I'm more tired. I'm trying to fix things more. My blood sugar is too high, then too low, then too high.

One of my worst moments occurred when my five-year-old, Coco, was telling her friend a secret. They were in the back of the car, and Coco leaned over and whispered, “Don't worry if my mom gets frustrated. It is her diabetes and she's trying hard.” She peeked up, not realizing that I heard, and said, “Mommy! Please drive! Don't worry about us.”

Yes... There's just not very much I can say about that one.

But just when you think things can only get worse, something quite unexpected pulls you out. In my case, it was Victoza.

In January, the FDA approved Victoza, a once-daily injection, for use in people with type 2 diabetes. The product is part of a class of drugs known as “GLP-1 receptor agonists” that are best known for their ability to help the pancreas produce more insulin after eating, but have been implicated in a wide variety of other important bodily functions not necessarily related to blood glucose control. Another drug in this class is Byetta.

We have written about Victoza for diaTribe a number of times (see NewNowNext in diaTribe issue #20), as well as in other newsletters that Close Concerns publishes. I received an email after one of these pieces.

“Kelly, got your story about Victoza results. I have a couple of friends who have type 1 who are using Victoza with astonishing success. Their sensor data shows essentially normal blood sugars for days on end. Have you heard of this?”

I promptly called my doctor and said that even though I knew that Victoza was not approved for type 1 patients, I wanted to try it. This would be “off-label use,” as the jargon goes.

When I looked at the pen the next day, I noticed I could take 0.6 mg again or that I could take a tiny bit more – there were five clicks to the pen between 0.6 mg and 1.2 mg. Presumably, the first click was 0.7 mg, the following 0.8 mg, etc.



Kelly proudly displays her CGM readings - there are still highs and lows, but far more “time in zone” – her readings over 180 mg/dl are down over 70% since starting on Victoza a little over six weeks ago.

I want to stress that if you ever consider taking anything not approved for a specific use, you have to talk to your doctor. Your doctor can approve it, but only with careful thought and with a full discussion about the possible benefits and risks.

I was fortunate. My doctor knew the safety background of Victoza very well, and she knew that I had had a hard year with my diabetes. I was thrilled that she approved my use of this new drug.

Thrilled, but also cautious, I delayed starting Victoza for some time because I had heard that this type of medicine causes nausea. I also had major work commitments, and then we were going on vacation.

When I finally started in August, I was a little nervous.

There are three approved doses with Victoza: 0.6, 1.2, and 1.8 milligrams (mg). I was motivated to lower my A1c, to reduce the variability in my blood glucose, to feel better, and to lose weight. But I never dreamt that all those things would actually happen – and in my case, so fast.

At any rate, I took my first Victoza dose of 0.6 mg. I felt nothing. No change in my blood glucose.

Though the instructions said to take 0.6 mg for one week, I ignored that and the next day I took 1.2 mg. What can I say? I’m an impatient patient. Well, I threw up the entire night!

I guess I’m stubborn as well, because when I looked at the pen the next day, I noticed I could take 0.6 mg again or that I could take a tiny bit more – there were five clicks to the pen between 0.6 mg and 1.2 mg. Presumably, the first click was 0.7 mg, the following 0.8 mg, etc. My doctor had told me to take 0.6 mg for a week, so I did that for several days and then feeling no nausea, I took 0.7 mg – although this contradicted the “official” titration schedule (titration means how you move up from a low dose to a higher dose), I couldn’t help but notice on the pen that it was possible to make smaller “increases” than officially recommended. And, I assumed (correctly) that moving up more slowly prompted less nausea. I felt a little bit of nausea that first week but nothing that was a big deal.

By the time I got to a 0.9 mg dose, my glucose numbers were evening out. I was actually waking up with hypoglycemia and kept reducing my basal rate. By the second week, Gary Scheiner, my across-the-country Skype educator, asked me if I was taking less insulin. I said I didn’t know, and he said, “Um, one way to find out. Check your total daily dose on your pump.”

I did and I gasped! Before starting Victoza, I had been routinely taking about 40 units a day, and sometimes as much as 45 units a day. But the pump told me that for the previous two weeks, I had taken between 25 and 30 units! Now, after a couple of months, my insulin intake is typically between 20 and 25 units, only higher if I have a really big, high-carb dinner.

Someone asked me how I use Symlin in my new diabetes regimen that includes a daily shot of Victoza. While initially I stopped using Symlin for a little while, I’m now using it again, with insulin and Victoza – not before every meal, but definitely before all my high-carb meals. My sense is that as a patient with diabetes, I am probably missing multiple important hormones. Symlin works very well for me in lowering my post-meal blood

I hope Novo Nordisk sees that Victoza is being used by a small number of type 1 patients, that that number could increase dramatically if Victoza were approved for those patients, and that next time, starting testing in type 1s earlier might make sense.

glucose levels and when I'm eating pizza or a sandwich or fettucini, I still take Symlin to reduce these numbers – and it does. I am eager to eventually try a insulin/Symlin combo, since I have heard from so many people that Symlin works best in a pump – here's hoping that will be developed soon. (I tried Symlin in an extra pump myself and loved it and only quit because my insurance didn't reimburse the extra pods – I'd rather wear one pump and have the combined insulin/Symlin to take, if this could be created in a formulation that worked for many people.)

I am worried about waking up “high” – and of late that hasn't been a problem. My numbers in the morning are often low (my CGM wakes me), or they are around 70-80 mg/dl – this is amazing.

My CGM tracings have also improved markedly. They are not perfectly flat, but they are much flatter than they were and now they zig-zag more within the zone, not outside it! If I eat Chinese food or pizza, my blood sugar numbers will still go sky high (we haven't cured diabetes, after all), but it's far more likely I pick up my CGM these days and see 80, 90, 119 mg/dl. What is amazing is how many fewer highs I have – and this has made me realize how many highs I was overtreating and then going far too low, overtreating, etc. The numbers look good – the time spent high (over 180) has gone down 70%, and my time in zone has increased 20 percentage points to over 70% (on my CGM, my time in zone is between 80 and 180 mg/dl). And, I've lost nearly ten pounds! I did get my A1c checked when I began Victoza, and it was 7.1% – not as low as I'd like, but I really feel Victoza has had an effect and I feel certain (and will update this column!) the next score will be lower. I'll have my A1c checked again at the three-month mark, but I can already tell from my CGM that because I'm “in zone” so much more that I'm doing much better. Another piece of good news is that my hypoglycemia in the day has been reduced (since I'm not chasing so many highs down); I also think the average hypoglycemia rates will drop in the early morning hours once we refine the best basal rates (we're still dropping them!).

The biggest bonus may be something that no one can quantify: I feel better and am somehow less tired. My wonderful husband said to me a couple of weeks after going on this GLP-1, “You're so much nicer on Victoza!” Wow. What more could anyone want.

Oh. One other very important thing. Victoza is expensive, so I'm lucky that my insurance did actually approve it. (I got my first two pens as samples from my doctor.) My co-pay isn't insignificant at \$50, but this would be over \$300/month without insurance, so I'm very happy about the cost, whether or not it is a mistake... (Victoza isn't approved for type 1 so I'm surprised that my insurance did approve it, since insurance typically does not cover therapies for unapproved uses - I'm hoping this lasts but not necessarily expecting it to.)

I'm not suggesting that Victoza is a miracle drug or a diabetic elixir. It's not, but it is working for me in new ways and complementing the insulin. Clearly, my pancreas doesn't make insulin any more, so the drug is not working in exactly the same way it does for people with type 2 diabetes. But GLP-1s also affect appetite (you don't get so hungry) and satiety (you don't eat such large portions) and they also reduce the amount of sugar that the liver releases into the blood. My guess is that the combination of these things leads to weight loss and better control after meals. We don't really know for sure because there is relatively little work has been done on GLP-1 and type 1 diabetes.

I realize, in my case with Victoza, that I am a sample of only one, but in that one, Victoza not only improved my glucose control but also bolstered by faith in the continued progress of diabetic therapies. All type 1 patients should have that opportunity. I urge Novo Nordisk to make the commitment, make the investment, and make it happen.

The main point – and a big reason I’m writing this column – is that I’m disappointed that I have to take Victoza “off label,” which connotes something improper. I understand that many type 1 patients won’t try Victoza for just that reason. And I wouldn’t ever encourage anyone to take a drug off label! But, the only way to remove that barrier is for Novo Nordisk to begin meaningful trials with type 1 patients – and I wish this had been done long ago. Large-scale trials aren’t cheap, but they’re necessary to gain the approval of products that can achieve real breakthroughs. Insulin likely isn’t the only thing type 1 patients are missing - here’s to a study that can find out more about gut hormones in type 1 diabetes.

I realize, in my case with Victoza, that I am a sample of only one, but in that one, Victoza not only improved my glucose control but also bolstered my faith in the continued progress of diabetic therapies. All type 1 patients should have that opportunity. I urge Novo Nordisk to make the commitment, make the investment, and make it happen.

And, thank you to the researchers and scientists who developed this new class. You’ve made me feel so much better, all of you. Thank you, thank you.

* * *

Here is Novo Nordisk’s response to this column, which was originally published in diaTribe #26. We thank them and very much hope to see Victoza studied in individuals with type 1 diabetes soon, either through company-sponsored or investigator-initiated trials. For now, I feel very lucky to be able to take Victoza and am happy to personally take on the additional risk. This column should not be perceived as any recommendation for any individuals with type 1 diabetes to take Victoza as an adjunct to insulin, but we do hope any companies studying GLP-1 will examine its use in this patient population soon.



7 November 2010

Kelly Close
Close Concerns

Dear Kelly

We read the diaTribe article describing your recent experience using Victoza® as an adjunct to insulin to treat your type 1 diabetes. We are happy to hear that Victoza® has lowered your mean glucose levels and also has resulted in a decrease in the frequency of both high and low glucose levels.

Our development program established a strong foundation for the use of Victoza® as monotherapy or in combination with one or two oral agents in type 2 diabetes. As you pointed out, Victoza has not yet been studied in or approved for the treatment of type 1 diabetes, and it is not a substitute for insulin. However, your personal experience provides one of many reasons why Novo Nordisk is currently considering exploring the use of Victoza for type 1 diabetes in well-designed, controlled, randomized clinical trials. While we can not guarantee the time course or the outcome, we are carefully evaluating the possibilities for launching such a program.

Thank you for making us aware of your experience and for sharing so many insights about living with diabetes.

Best regards

Alan C. Moses, MD, FACP
Global Chief Medical Officer
Novo Nordisk A/S

Mads Krosgaard Thomsen
Executive Vice President & Chief Science Officer
Novo Nordisk A/S

NewNowNext



Editor-in-Chief Kelly Close (center) with friends celebrating World Diabetes Day 2008 in front of San Francisco City Hall aglow in diabetes blue.



Celebrating World Diabetes Day in 2009 at San Francisco's Ferry Building.



The Metreon, the site of this year's World Diabetes Day festivities in San Francisco.

Join Us In Celebrating World Diabetes Day 2010

T1/2 Every year on November 14, we pay homage to everyone living with or caring for someone with diabetes on World Diabetes Day. First celebrated in 2007 following a UN Resolution championed by then-college-student Clare Rosenfeld, the date marks the birthday of Frederick Banting, who was instrumental in the discovery of insulin in 1922. World Diabetes Day engages millions of individuals worldwide in diabetes awareness, education, and advocacy with activities such as walks, sporting events, free screenings for diabetes and its complications, and radio and television programs. Our favorite of all is the World Diabetes Day Monument Challenge – when landmarks around the globe are illuminated in blue, the color of the International Diabetes Federation's (IDF) diabetes symbol, a circle that signifies life, health, and unity. Last year alone, over 1,000 monuments were lit up worldwide, from village hospitals in India to city halls in the United States. As diabetes prevalence also rises worldwide, the World Diabetes Day campaign hopes to slow the trend with a five-year (2009-2014) emphasis on Diabetes Education and Prevention.

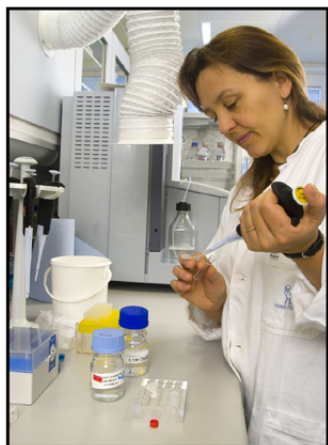
Here in San Francisco, the diaTribe team is sponsoring World Diabetes Day for the fourth straight November 14. We look forward to this event every year – gathering with family, friends, and colleagues to support diabetes awareness, we are reminded of how strong the diabetes community can really be. This year we'll be lighting up the Metreon shopping center to cap off a daylong celebration in the heart of downtown San Francisco. The day's activities (the schedule of which can be found at www.diaTribe.us/wdd.php or on the very last page of this issue) include live, interactive discussions with members of the Juvenile Diabetes Research Foundation and the American Diabetes Association on managing and living with type 1 and type 2 diabetes, free bowling at Yerba Buena Gardens, a performance by the local band "Solar Prominence," and the official kick-off party for CDE Theresa Garner's fabulous organization Dance Out Diabetes, an exciting new organization whose mission is to "prevent and manage diabetes through dance and education" in a fun setting for people with or at risk of getting diabetes, their family, and their friends to dance. At the kick-off party and the subsequent monthly sessions around San Francisco (soon to be expanded nationwide), individuals will be able to enjoy both dance instruction and free-form dancing to a wide variety of music genres. Also at the Dance Out Diabetes party, members of the diaTribe staff will be helping rally everyone to take the Big Blue Test – test, exercise for 14 minutes, test again! – to raise awareness of the good that exercise can do us (see below). Finally, following this sure-to-be fun and entertaining dance party, we will catch our breath, stand together, and watch the lighting of the Metreon.

We invite everyone in the Bay Area to swing by downtown San Francisco and join us in celebrating World Diabetes Day on Sunday, November 14. We thank sponsors Abbott Diabetes Care and J&J LifeScan, maker of OneTouch blood glucose monitoring systems, as well as co-organizers TuDiabetes and DiabetesMine for helping make this spectacular event happen. And for those of you who can't make it to the San Francisco Bay Area, we encourage you to take part in activities closer to your own hometown (visit www.worlddiabetesday.org/en/get-involved for an updated list of events worldwide). For more up-to-date information on our and others' plans for World Diabetes Day, follow us on twitter at @diaTribeNews as well as @bigbluetest and @wdd and @sixuntil me. -- ST/BK/JS

Diabetes Hands Foundation's BiG Blue Test

T1/2 This year for World Diabetes Day, the Diabetes Hands Foundation (DHF), is holding a wonderful event called the BiG Blue Test. On Sunday, November 14th, at 2:00 pm (local time), every individual with diabetes around the world is asked to test

their blood sugar, do fourteen minutes of exercise, test again, and then post their results on www.bigbluetest.org. Why you may ask? Well, Manny Hernandez, DHF co-founder, wants to really highlight the importance of regular blood glucose testing and exercise for proper diabetes self-management. We encourage everyone to participate, and for more information, please see the amazing BiG Blue Test video on the website above--as an added bonus, every time this video is watched, a child in need of insulin is provided a week's supply for free by Eli Lilly, Novo Nordisk, and Roche. Every view counts so please, check it out!--BK



T1/2

Biodel's Ultra-Rapid-Acting Insulin Linjeta Faces Significant Set Backs in its Path to Regulatory Approval in the United States

In unfortunate news, Biodel's ultra-rapid-acting insulin Linjeta (formerly known as VIAJect; see Learning Curve in diaTribe #9 and Conference Pearls in diaTribe #26) recently failed to receive FDA approval. The FDA has requested for Biodel to conduct two additional phase 3 studies for Linjeta to better characterize its efficacy, tolerability, and stability. Biodel is now weighing its options, deciding whether to conduct the studies or to start again with one of its newer formulations of Linjeta, which should have better tolerability, comparable drug properties (e.g. rate of absorption, duration of effect), and comparable effects of the drug on the body. (The newer formulations use the same ingredients as Linjeta, just in different amounts.) What this means is that it will most likely take until at least 2012 for Linjeta or another one of Biodel's ultra-rapid-acting insulin candidates to get approved and come to market, assuming a favorable review. Since the need for faster-acting insulins is urgent, we are saddened by these developments. Looking ahead, the FDA will give its decision on Afrezza (see NewNowNext in diaTribe #20), MannKind's ultra-rapid-acting inhalable insulin, on December 29. Further down the road, we hope to see progress with Halozyme Therapeutics' PH2O, a therapy currently in phase 2 studies that aims to bring about faster insulin absorption and higher insulin concentrations upon co-administration. There is tremendous interest in faster-acting insulin by patients, doctors, educators, and families and we hope the FDA can work with the companies to help them bring innovation to patients and to make insulin both faster-acting and ultimately even easier to use. -- VW



T1/2

Stanford University's Better Choices, Better Health Program Offers Free Online Diabetes Workshops in Seven Pilot States

Often, a lack of knowledge or an absence of support makes it hard to become healthier and improve our diabetes management. But a new online program from Stanford University called Better Choices, Better Health is trying to dramatically improve the self-care practiced by those with conditions like diabetes, asthma, arthritis, high blood pressure, heart disease, stroke, and osteoporosis. The program will be offered free to patients with chronic conditions in seven states (California, New Jersey, Massachusetts, Oregon, Iowa, Maine, and Hawaii). Those who sign up can join up to 25 others in an interactive workshop and participate in easy-to-follow online sessions, which are posted each week for six weeks. Users simply log on at their convenience two or three times per week for a total of two hours per week. Better Choices, Better Health is unique in that sessions are highly participative: users set their own personal health goals and offer mutual support through internal messaging and online discussion boards. Users can choose to remain anonymous, and the program does not require proof of anything. Some of the topics that will be covered include exercise, healthy eating, use of medications, and disease-related problem solving. We hope to see the program expand soon to include additional states. For more information or to sign up, please visit www.selfmanage.org.

logbook

T1/2

Saving Sergeant Miyares: How A Man Had To Die In Order To Live



by James S. Hirsch

Rays of light pour through the windows of a large gymnasium, and soldiers in blue honor guard uniforms and white gloves solemnly march across the wooden floor. All is quiet save their drum-like steps. They walk slowly, because the floor is covered with body bags carrying the dead. But when the soldiers pass a bag, it violently kicks. Then they pass another bag, and it too kicks... then another... and another...

But the soldiers never notice. The dead are alive but trapped, desperate, forgotten... And then it's over. Sweating and shaking, Urban Miyares wakes up from his dream, without knowing who in the body bags is rescued, and who is left to die. The dream would be a cruel nightmare, except to Urban Miyares, it's all too real.

The history of diabetes is rich with miracle stories, survivor tales in which improbable heroes overcome every possible odd to cheat certain death. But for drama, inspiration, and courage – amid a backdrop of a bloody war and then a haunting mystery – few stories can compare to that of Urban Miyares.

He grew up in Manhattan, a good athlete with a love of sailing but little interest in college. In 1967, he was drafted by the Army and one year later was sent to South Vietnam as a 20-year-old Army platoon sergeant, a strapping 5'10", 182 pounder with a wedding band on his finger. He had married his childhood sweetheart, JoAnn, during basic training.

Miyares was in Vietnam only a few weeks before he began to feel ill. Losing weight and feeling sluggish, he went to the sick hall and was tested for malaria. The results were negative, and he was diagnosed with battle fatigue. He would return to the sick hall several times. Once he was diagnosed with peptic ulcers and given Maalox, which fit nicely in his ammunition bag. But his health continued to deteriorate. On combat missions, his backpack alone weighed 50 to 60 pounds, and the jungle heat wore everyone down. When Miyares complained of fatigue, his commanding officer suspected he was angling to go home and threatened to drop him in rank.

Finally, on August 12, 1968, another blistering hot day, Miyares's platoon was ferried by helicopter to a village in the Mekong Delta that had come under attack, but he never made it. While walking through a field, he began to vomit, his vision was blurred, and he thought he heard mortar bombs. He recalls some yelling and screaming and falling over and hitting water covered with rice paddies. Then all went black.

* * *

Brian Leet was raised in a small town in North Dakota. His father was a combat medic in World War II, serving in New Guinea and the Philippines, and Brian thought he would make a good medic as well. He joined the Army at age 18, excelled in his training, and was sent to Vietnam in 1967. He was stationed in Lai Khe (pronounced lie kae), about 60 miles northwest of Saigon. It was a small Vietnamese village that was also a French rubber plantation and an American military base. It was known as "Rocket City" from the Viet Cong's 122mm rockets. Leet worked at a primitive aid station and performed a kind of triage for the casualties – military and civilian, American and Vietnamese, men, women, and children – who were flown in by helicopter. Sometimes doctors were on the



Miyares, back in his army days during the Vietnam War

base, sometimes not, so at times Leet's supervisors asked him to do things for which he was little qualified. He once amputated a leg, another time an arm. He delivered a shot of epinephrine into a 17-year-old's heart. He squeezed so much fluid – blood and saline – into so many bodies, his hand developed a spasm. He once delivered a baby. When rockets shook debris from the ceiling, he tried to protect the injured by his placing his body over the patients'. He slept with his rifle.

But on one hot day when he was making his checks, he unzipped a body bag, felt the neck for a pulse...and found one. This body was alive.

After a one horrific day, he went into a separate room and broke down crying. He thought he wasn't going to make it. But he regained his composure, told himself he'd be no good if he behaved like this, and returned to his duties.

One of Leet's jobs was to check the soldiers who had arrived in Killed In Action bags. They were placed in a separate room, and Leet was to unzip each body bag, confirm the body was dead by checking for a pulse on the neck, and then put a body tag on a big toe. In August of 1968, Leet had been in Lai Khe for 11 months, and he had never found a pulse on any body that had arrived in a KIA bag. But on one hot day when he was making his checks, he unzipped a body bag, felt the neck for a pulse . . . and found one. This body was alive.

"I was terribly excited but also scared," he later said. "It's like working at a morgue, and someone sits up."

Leet made no effort to identify the person. He just picked up the body and carried it to a medical treatment room. A helicopter then airlifted the body out. Leet wrote about the incident in a letter to his fiancée, but he was never told what became of "the man with the heart beat." Leet returned to the United States one month later. In one year in Vietnam, he had unzipped between 350 and 450 KIA bags. Each body was dead, except one.

* * *

They thought you were dead...they threw you in a body bag.

The picture became a bit clearer when the nurse told him about his medical problem: he had diabetes and had fallen into a diabetic coma...

Urban Miyares woke up and saw a blond nurse, and he thought he was in heaven. But he soon realized he was in a military hospital in Saigon two days after he had collapsed in the rice paddies. He had no idea what happened or how he got there, but a clerk from his infantry unit told him that he was "one lucky son of a bitch."

"They thought you were dead," the clerk said. "They threw you in a body bag." The picture became a bit clearer when the nurse told him about his medical problem: he had diabetes and had fallen into a diabetic coma from high blood sugar when he collapsed. Miyares had never heard the word "diabetes" and wondered if he had caught it from a mosquito or perhaps from something he had eaten. As he later said, "I thought they would patch me up and send me back into the field."

Instead, he was sent to a hospital in Japan to try to get his blood sugars under control. He had lost 63 pounds and now weighed 119, but his doctors initially allowed him to eat only 700 calories a day. That didn't last, and Miyares gradually regained his strength and his weight. He was discharged from the army and sent back home. He was never told who discovered him in the body bag.

* * *

Life went on for Urban Miyares, but not easily. He battled depression, had various phobias (at movie theaters, he'd break out in a sweat), and was misdiagnosed with bi-polar disease. He suffered bias on two fronts: having diabetes and being a Vietnam vet, when sentiment against those who served ran high. Miyares says a Wall Street firm fired him when it discovered his military record. With diabetic complications emerging quickly, his health created even greater obstacles. Within months of returning to the US, he began to lose feeling in his legs from diabetic neuropathy. He tried working as a roofer but fell off

a house because of problems with his legs. He experienced blurred vision from diabetic retinopathy. He was told he had 20 years to live.

He did the best he could. He used a cane to help with his walking, but there was no remedy for his vision. In 1981, he began taking laser treatments for his eyes, but the therapy was crude, and by 1984 he was legally blind and dependent on a seeing eye dog. In 1982 he was also diagnosed with end-stage kidney disease. It was life-threatening, but his kidney continued to function until he received a transplant in 2004.

It would have been easy for Miyares to use his health or his employment struggles as an excuse to give up, but he didn't. He and JoAnn had a son, and Miyares wanted to be a role model and was not going to allow any disability to interfere.

In his experiences, rehab counselors had always told him what he couldn't do in the workforce, so in 1985 he founded the Disabled Businesspersons Association, a non-profit organization that helps disabled individuals either start a business or expand their existing one. Services include everything from market evaluations for new products to equipment research for special needs of disabled employees. "The business world is an able-bodied world," Miyares likes to say, so the disabled need an extra boost.

"The business world is an able-bodies world," Miyares likes to say, so the disabled need an extra boost.

Miyares also wanted to demonstrate that his impaired vision, mobility, and kidney need not deter his athletic aspirations. In 1987, he took up Alpine skiing – yes, Alpine skiing – and, with leg braces and Canadian crutches as poles, was soon zipping around corners at more than 60 m.p.h. How does a blind man ski? By wearing an electronic earpiece, with a companion skier telling Miyares when to turn or stop. By 1990, he was the U.S. National Disabled Alpine Ski Champion (in the total blind division) and ranked as the fastest total blind Alpine skier in the world.

Going hell-bent down a mountain was relatively easy compared to sailing across the ocean. Miyares, who had settled down in San Diego, co-founded Challenged America, a therapeutic and rehabilitation sailing program. In 2003, he joined with five other sailors – all but one disabled – and completed the Transpacific Yacht Race, a 2,225-mile run from Los Angeles to Honolulu. They were the only disabled crew to ever compete in the prestigious biennial race, and they did it again in 2005.

Clearly, Miyares has not allowed his diabetes to interfere with his ambitions. He tests his blood sugar eight to ten times a day and has used a "talking glucometer" since 1989 and an insulin pump since the 1990s. He now uses an Animas pump and can accurately bolus by listening to the beeps – a half a unit of insulin is one beep. He says that counting carbs is difficult, because he can't see what he's eating, so he relies on trial and error: one slice of pizza, for example, requires four units of insulin. His A1c's are in the low sixes.

Miyares' achievements have been widely recognized, including at the White House, where in 1992 President Bush awarded him one of his "Points of Lights" winners for his volunteer service. Miyares sat next to Michael Jackson.

He's also become a popular lecturer, using humor as his ally. He explains, for example, why the blind are better off than those with sight. ("When my wife is driving and someone cuts her off, it ruins her whole day. But it doesn't bother me one bit. I often wonder how you sighted people make it through the day. It's a rough world you live in.")

The anger that he once felt is gone, he says, as evidenced by the title of one of his speeches: "Diabetes Saved My Life." He explains that of the eight or nine members from his

platoon, he was the only one to return from Vietnam. He had to nearly die in order to live. But not everything was settled. He couldn't escape those dreams with the white-gloved soldiers and the kicking body bags. At times he was scared to go to sleep and would stay up for a day or two at a time, then start taking naps during the day, and then after five or six days, he'd finally crash. A deep slumber kept the nightmares at bay.

Then in 2006, he wrote a story for the Disabled American Veterans newsletter, describing his experiences in Vietnam and the remarkable sequence of events that placed him in a body bag, only to be rescued by someone unknown. He wrote that he really wanted to thank that person.

* * *



Miyares, out on the water.

Brian Leet had his own health issues when he returned from Vietnam, as he suffered from post-traumatic stress disorder. He later ruptured a disc in his back and became 50 percent disabled, which explains why he was reading the newsletter for disabled vets, when he came across Urban Miyares's story.

"I thought this can't be real," said Leet, who lives in Minnesota outside of Minneapolis. "I got chills up and down my spine."

He wasn't sure what to do. The body bag incident occurred 38 years ago, and Leet had tried to put the entire Vietnam experience to rest. He had struggled with his own emotional state when he returned, so what emotions might this unleash? And how could he even be sure he was the one who rescued Urban Miyares? But his wife vividly recalled the letter he had written describing that event, and the basic facts – the location, the date, the circumstances – all seemed to match up.

Some time passed, but Leet finally sent an email to Miyares, who promptly responded. Phone calls followed, and the two men retraced the steps that brought their lives together in the Mekong Delta. They had other things in common as well: Like Miyares, Leet had devoted his career to helping Vietnam vets as a vocational rehabilitation counselor.

In 2008, Miyares received a phone call from Leet. "What are you doing for lunch today?" he asked. "I'm in town, and I think it's time we met."

They and their wives got together, and as Miyares says, "It was the longest lunch I've ever had."

For Leet, the meeting brought back a flood of memories, some searing. "It stirred things up pretty good," he said, "but I won't say in a bad way."

Indeed, the friendship blossomed, with the two men talking regularly on the telephone and now seeing each other at veterans' events. Leet said the whole thing "is still hard to fathom" but suggests a personal void in his life has been filled. "Very few people ever thanked me for the things I did in Vietnam," he said, "but Urban was one of them. Obviously, that makes me feel good."

For Miyares, who sees his life as string of improbable blessings, he is grateful not only that he could thank the man who saved him but for discovering such a special man in-

Our greatest heroes are those who sacrifice their own lives to help others.
- Urban Miyares

deed. “He’s so humble, he doesn’t want anything,” Miyares said. “Our greatest heroes are those who sacrifice their own lives to help others.”

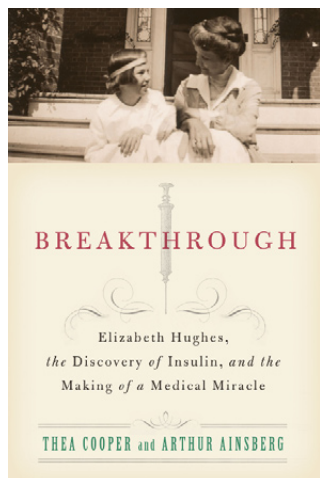
Miyares has another reason to be grateful. At last, all his dreams are pleasant.

what we’re reading

T1/2

Breakthrough: Elizabeth Hughes, the Discovery of Insulin, and the Making of a Medical Miracle

by Joseph Shivers and Kelly L. Close



It’s been said that there’s never been an easier time than now to have diabetes, and that’s rarely been clearer to us than when we read *Breakthrough*, Thea Cooper and Arthur Ainsberg’s new book about the discovery of insulin. (James Hirsch also wrote a Logbook about *Breakthrough* in *diaTribe* issue #23.) Cooper and Ainsberg explain that in the 1920’s, diagnosis with type 1 diabetes meant one of two things. Without treatment, it meant death could be expected within a year. Individuals with type 1 diabetes who sought treatment could extend their life expectancy to eighteen months, with one caveat: the most successful therapy prior to 1922 was a starvation diet of as little as 400 calories a day. (This translates roughly to a single bagel every 24 hours, except that one of the diet’s central provisions was “no desserts or bread, ever.”) Every morsel of food (mostly “eggs, cream, bran rusks, all in extremely limited quantities”) had to be weighed and recorded, with daily intake precisely maintained to avoid hyperglycemic coma on the one hand and death from malnutrition on the other.

Individuals with type 1 diabetes who sought treatment could extend their lives by eighteen months - with one caveat: the most successful therapy prior to 1922 was a starvation diet of as little as 400 calories per day.

Breakthrough’s central character, Elizabeth Hughes, is 12 years old when she receives her diagnosis of diabetes in the spring of 1919. The lively, likable daughter of former Supreme Court Justice and presidential candidate Charles Evans Hughes, Elizabeth has access to the best diabetologist in the state of New York. Frederick “Dr. Diabetes” Allen is the brilliant but insensitive man credited for realizing that proteins and fats, as well as carbohydrates, are problematic for people with diabetes – hence the all-around starvation diet. Despite his lack of people skills, Dr. Allen convinces Elizabeth’s parents to commit her to his intensive therapy, and he even gets Mr. Hughes to back the establishment of new inpatient facilities for Elizabeth and other children with diabetes. It is a tribute to Cooper and Ainsberg’s storytelling that they make their narrative consistently engaging, even though they give away the ending in the first chapter: Elizabeth survives to adulthood, thanks to the miraculous discovery of a substance called “insulin.”

The authors describe the story of insulin’s development the same way they narrate Elizabeth’s life: with urgent dialogue and frequent cliffhangers. If some of the scenes appear to be too dramatic, it may be because they didn’t happen. The authors acknowledge that “in some cases,” dialogue and incidents have been “invented or augmented for narrative purposes” – a concession that, in our view, diminishes an otherwise noble story. Readers often don’t know what the authors believe to be true and what was simply invented. Nonetheless, it is known that researchers around the world had been painfully close to purifying insulin for well over a decade when Frederick Banting, the Ontario-born orthopedic surgeon who led the efforts to isolate and purify the substance, and his assistant Charles Best started experimenting with dogs in 1921. “[Banting] would later say that if he had been more familiar with the literature on the subject and had known about the previous attempts, he would not have pursued his idea at all,” writes Cooper and Ainsberg. “Fortunately for Elizabeth Hughes and millions of other children, he knew next to nothing.”

And we are grateful of that, thanks to a 90-year-old medical breakthrough, millions of people with diabetes can now think about how - not just how long - they will live their lives.

The insulin discovery research story is remarkable all the way from its humble beginnings (Banting and Best, sweaty and surrounded by dog feces, struggling to isolate insulin from canine pancreases in a dingy laboratory) to its controversial conclusions. As the researchers enjoy more and more success, Banting becomes increasingly unstable, paranoid that his colleagues will steal credit for his and Best's early work. He clashes constantly with Macleod, the seasoned scientist who oversees the experiments and attaches his name to the insulin research papers so they will be more likely to publish. Ultimately, however, Banting and his colleagues maintain just enough harmony to earn worldwide fame for the discovery of insulin and even to win a Nobel Prize (Canada's first, awarded jointly to Macleod and Banting in 1923). With sudden demand for insulin and no consistent means of producing the miracle drug, the researchers also reluctantly patent insulin and its purification so that they can partner with Eli Lilly. In an age when many physicians considered patents a violation of the Hippocratic oath and drug companies lacked internal research and development divisions, insulin's path to the marketplace changed the course of the pharmaceutical industry. Most dramatically, from the moment that Eli Lilly began selling insulin in October 1923, the drug has saved millions of lives.

For some patients, the benefits came even sooner than that. By the summer of 1922, Elizabeth Hughes has outlasted Dr. Allen's most optimistic estimates, but she is nearing death. Her desperate mother pleads with Banting to treat her daughter, but his insulin supply is still sorely limited and he refuses to extend it beyond his few current patients. But then in August he changes his mind: Elizabeth goes to Canada and begins taking insulin, undergoing an immediate and dramatic improvement. She goes on to live a long, successful life in which she successfully hides her diabetes from more or less everyone, doing (as far as anyone knows) little to support diabetes-related causes. So is her story then one of persistence or privilege? Cooper and Ainsberg take a fairly sympathetic view, and from our perspective, it's difficult to condemn the Hughes family's conduct during a time when diabetes was much deadlier and more greatly stigmatized. And we are grateful of that, thanks to a 90-year-old medical breakthrough, millions of people with diabetes can now think about how – not just how long – they will live their lives.

Editors note: Arthur Ainsburg will be speaking at Kelly and John Close's home in San Francisco on January 15th. If you would like to be invited please visit cpslectures.com and sign up to be on the mailing list for their salon.

trial watch

T2

Evaluation of Exenatide in Patients with Diabetic Neuropathy

ClinicalTrials.gov Identifier: NCT00855439

<http://clinicaltrials.gov/ct2/show/NCT00855439>

Peripheral neuropathy is a complication of diabetes that results in loss of sensation, numbness, and tingling, particularly in the hands and feet. Because controlling blood glucose is thought to heal or slow down the nerve damage that causes neuropathy, the ability of Byetta (Amylin/Eli Lilly's GLP-1 agonist) to control blood glucose may improve neuropathy. A study to investigate Byetta and neuropathy will enroll 60 patients ages 18 to 70 in the University of Michigan Health System. Participants will be randomized to either taking Byetta twice-daily or an injection of the basal insulin Lantus (sanofi-aventis's insulin glargine) once-daily for 18 months; nerve function in hands and feet will be assessed at the end of the study. Inclusion criteria include having type 2 diabetes, being on

one or more oral anti-diabetes medications, and having diabetic peripheral neuropathy (described above), but not having any risk factors or conditions other than diabetes that would cause neuropathy. Some criteria for exclusion include nursing or being pregnant, having neuropathy not related to diabetes, or having an A1c above 10%. Those interested in the study may contact Dr. Rodica Pop-Busui at 734-936-5504 or at rpbusui@umich.edu. --LR

T1

The Effectiveness of Continuous Glucose Monitoring in Diabetes Treatment for Infants and Young Children

ClinicalTrials.gov Identifier: NCT00875290

<http://clinicaltrials.gov/ct2/show/NCT00875290>

This trial will look at whether the use of a CGM improves glucose control in children younger than four years of age when they are started on an insulin pump.

Constant glucose control and the initiation of insulin pump therapy can be challenging, particularly for children with type 1 diabetes. This phase 3 trial will look at whether use of a continuous glucose monitor (CGM) improves glucose control in children younger than four years old when they are started on insulin pump therapy. Conducted at Seattle Children's Hospital, this trial will enroll 40 children ages zero to three. Participants will be randomized to either a control group, which will receive no CGM intervention, or an experimental group, which will use real-time sensors that continuously monitor blood glucose levels (Medtronic's Minimed Paradigm Real-Time Sensor). Both groups will be using insulin pumps (receiving a continuous infusion of insulin under the skin). After one year, glycemic variability and the number of adverse events experienced will be compared between the two groups. To be eligible, children must have had diabetes for at least three months. Children older than four or those who have diabetes caused by a single gene (a very rare condition called monogenic diabetes) will be excluded. For more information, please contact Dr. Patricia Fechner at 206-987-5037 or patricia.fechner@seattlechildrens.org. --LR

T2

TODAY Genetics Study

ClinicalTrials.gov Identifier: NCT00722397

<http://clinicaltrials.gov/ct2/show/NCT00722397>

It is hoped that information gained from this study can be used to develop new diagnostic tests, new treatments, and new preventative measures for type 2 diabetes.

It is still unclear what genetic factors cause individuals under the age of 18 to be at risk for type 2 diabetes. To better understand the relationship between genes and type 2 diabetes, the TODAY Genetics Study will collect blood samples from 2,500 individuals with type 2 diabetes. The blood will be analyzed for the expression of certain genes as well as for glucose levels and indicators of beta cell function. Inclusion criteria include a diagnosis of type 2 diabetes, a body mass index (BMI) greater than the 85th percentile, and an age younger than 18. Exclusion criteria include having a genetic disorder that would affect glucose tolerance or being on a medication that could affect glucose tolerance or insulin sensitivity within 60 days of diagnosis. It is hoped that the information gained from this study can be used to develop new diagnostic tests, new treatments, and new preventive measures for type 2 diabetes. The study is being conducted at sites in California, Colorado, Connecticut, Massachusetts, Missouri, New York, Ohio, Oklahoma, Pennsylvania, and Texas. For more information, please contact Dr. Kathryn Hirst at 301-881-9260 ext 8025 or khirst@bsc.gwu.edu. Click [here](#) for a full list of trial locations. --LR



FOUR EVENTS ONE CAUSE

Sunday, November 14 • San Francisco
Help us bring diabetes awareness
to our community.

11:30 AM to 1:00 PM

Type 1 Talk

InterContinental Hotel (888 Howard St.)

Get together with others from your community and log on to a special live streaming presentation from JDRF staff and volunteers. We'll be addressing topics and answering questions submitted by those affected by type 1 diabetes all over the United States.

Cost: Free

RSVP: Pam Sagan at
pksagan@gmail.com



11:30 AM to 1:00 PM

Type 2 Talk

InterContinental Hotel (888 Howard St.)

Join the ADA for a FREE discussion about Type 2 diabetes. Learn about management techniques, healthy living tips and risk factors for family members. We will have recipes and health professionals available to answer questions, so please join us for an informative and fun Type 2 Talk!

Cost: Free

RSVP: Lindsay Rango at lrango@diabetes.org

1:00 PM to 4:00 PM

Dance Out Diabetes Kick-off Party

Metreon City Views, 4th Floor (101 4th St.)

Dance Out Diabetes is a new organization that provides an innovative, diabetes-friendly place to dance that includes all ages, types of diabetes, family and friends, along with all kinds of music, light dance instruction and free dance opportunities. Dance Out Diabetes is for:

- People ages 5 and up, all levels of fitness and dance ability
- People with type 1 and type 2 diabetes, pre-diabetes, gestational diabetes, and their friends and family

Cost: \$10 per adult; \$5 for ages 8-17, above 60, or those with an EBT card, Medicare or Medi-Cal Card (with photo ID); free for kids 7 and under



More Info: staff@danceoutdiabetes.org

5:00 PM to 8:00 PM

Strike Out Diabetes & Awareness Party

The Rooftop at Yerba Buena Gardens & Bowling Center (750 Folsom St.)

Brought to you by JDRF, ADA and diaTribe - An event in honor of diabetes awareness, appropriate for all ages and all types of diabetes! Enjoy views of the Metreon next door lit up in brilliant blue while celebrating with bowling, live music by local band "Solar Prominence", games, snacks and inspirational presentations. Remember to wear royal blue for diabetes and dress in layers as there are both indoor and outdoor activities..

Cost: Free bowling for the first 100 people to RSVP
RSVP: Carolyn Eisen at ceisen@jdrf.org

Blue Lighting sponsored by



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