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Throwback device moving back to the forefront

Trina Health, Animo's 'pump' shown to be effective at mimicking pancreatic function

By Omar Ford, Staff Writer

A device developed more than two decades ago could finally be used as an effective treatment in diabetes. Trina Health Midwest LLC's Bionica Microdose pump was demonstrated to "closely replicate" normal pancreatic function, results from a study published in the July edition of *The Journal of Diabetes, Metabolic Disorders & Control* show.

The study, titled "Microburst insulin infusion: results of observational studies – carbohydrate metabolism, painful diabetic neuropathy, and hospital/emergency department utilization," looked at more than 2,000 patients.

The Bionica Microdose pump uses IV infusion to mimic the insulin pulses of a healthy pancreas in what the company calls the Artificial Pancreas Treatment (APT). This in turn stimulates the liver to produce the enzymes necessary for carbohydrate metabolism, which lowers lipid metabolism, resulting in more cellular energy in body tissues.

The process is monitored by frequent glucose levels and metabolic measurements. APT is done over one-hour periods with a rest period between each session for three courses each day of treatment. Typically, APT is performed on a weekly or bi-weekly basis following the first week of two back-to-back daily sessions.

To commercialize the device, which is a little larger than a smartphone, Sacramento-based Trina Health began a partnership with San Clemente, Calif.-based Animo Health Inc., late last year.

"The FDA-approved device was still in use, it just wasn't commercialized enough to the point where it would start helping people en masse," Mark Pound, president and CEO of Animo Health, told *BioWorld MedTech*.

He stressed the device is not a cure for diabetes.

Study results

The study published in *The Journal of Diabetes, Metabolic Disorders & Control* is based on data from three observational retrospective studies that underscore the effectiveness of microburst insulin infusion.

The carbohydrate metabolism portion of the study suggests APT has a dramatic effect on carbohydrate metabolism; this is of particular importance as the inability to properly metabolize carbohydrates represents a core dysfunction in diabetes.

In the painful diabetic neuropathy portion of the study, among the 412 patients studied over a three month period, APT completely eliminated or significantly reduced pain in 93 percent of the patients.

Finally, in the two-year retrospective hospital and emergency room validation portion of the study, which evaluated 1,524 patients, it was shown that APT significantly reduced the number of hospital and emergency

visits. According to Matched National Hospital Discharge Survey and U.S. Agency for Healthcare Statistics, expected hospitalization rate is 94 per 1,000 patients over a two-year period and the study showed the APT rate was five. Expected emergency room visits are 116 per 1,000 patients over two years and the APT rate was seven.

"I think the study points out what we've known for a while and we put this together to prove it," Pound said.

Stepping out of the shadows to take on the competition

Trina Health was formed by Ford Gilbert after it was discovered his daughter suffered from type 1 diabetes in the early 1980s. Gilbert, who was once an attorney, enrolled in medical school, started a nonprofit research institute and eventually created the Bionica Microdose pump. Gilbert's daughter received the first treatment from the device when she was 5-years-old. Now she is 34-years-old, and has given birth to five children.

"He gave up his legal career and immersed himself in the medical world, specifically in the world of diabetes," Pound said. "It's really an amazing story."

Other products on the market

Other companies such as Dublin-based Medtronic plc and Germantown, Md.-based Senseonics Inc. have made waves with artificial pancreas applications.

Medtronic received FDA approval for its Minimed 670G hybrid closed loop system in September 2016, and launched the device in June. (See *BioWorld MedTech*, Sept. 30, 2016.)

"It's not apples to apples," Pound said when comparing Medtronic's device and the APT therapy. "There is a difference. What Medtronic calls an artificial pancreas is really a closed-loop glucose monitoring system that is developed subcutaneously. Whereas we're actually an artificial pancreas treatment."

There could be tremendous opportunities for companies to compete with Medtronic's artificial pancreas, said Sean Lavin an analyst with BTIG.

"Of note, from the 700-patient training phase [of Minimed 670G], Medtronic disclosed 83 percent satisfaction with the device and 96 percent satisfaction with the training," Lavin said. "The device satisfaction is strong, but at 83 percent in a hand-picked group of patients indicates to us that the 670G will not be for everybody."

Senseonics could see an approval by the beginning of next year.

"We assume a panel and approval near year end, but it could come sooner if the FDA decides not to have a panel," Lavin said.

Pound said while the competition is much bigger and not much is known about Trina Health, the publication of the data could help bring awareness to the Bionica Microdose pump.

"We've already started to see [an increased] interest in the technology," Pound said.

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