EECP® Newsletter
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Enhanced External Counterpulsation Therapy (EECP®) And Diabetes

EECP® Therapy demonstrated effective in the management of glycemic control

By John CK Hui, Ph. D.

Diabetes mellitus is a metabolic disease which results from having too much glucose (sugar) in the blood because the pancreas has failed to secrete an adequate amount of insulin (insulin deficiency, or type 1), the insulin is ineffective in transporting sugar to target tissues such as fat and muscle, or these cells do not recognize the presence of insulin (insulin resistance, or type 2). In pre-diabetes and type 2 diabetes mellitus (T2DM), cells become resistant to the action of insulin, and the pancreas is unable to make enough insulin to overcome this resistance. This lack of glycemic control is the principal complication leading to the development of cardiovascular disease, kidney and peripheral artery disease.

EECP® Therapy has been demonstrated to be effective in the treatment of cardiovascular disease. It relieves symptoms, increases exercise tolerance and improves quality of life by recruiting new blood vessels, suppressing endothelial dysfunction and reducing inflammation pathogenic responses. Subsequently, it was believed that these mechanisms of EECP® might also help to manage glycemic control in patients with T2DM by reducing the inflammatory damage and increasing blood supply to tissue to promote glucose absorption. Indeed, we have often heard about isolated cases reported by EECP® providers observing the improvement of glycemic control in their diabetes patients.

Finally, we have confirmatory data supporting this hypothesis. In March 2012, Dr. Martin and colleagues at the University of Florida in Gainesville published a paper in the Journal of Applied Physiology[1] on a randomized controlled study of 18 subjects with abnormal glucose tolerance (AGT). AGT was defined to have a plasma glucose concentration of >140 mg/dl 2 hours after an oral glucose tolerance test (OGTT) with 75 g of glucose. Subjects were assigned randomly in a 2:1 ratio to receive either 7 weeks (35 1-h sessions) of EECP® (n=12) or 7 weeks of standard care (control; n=6). The objective was to evaluate the effects of EECP® on outcomes of arterial function, glucose tolerance, and skeletal muscle morphology in subjects with AGT. Fasting plasma glucose (FPG) was reduced significantly from 143.9 ± 8.5 to 127 ± 6.6 mg/dl ($p<0.05$) (see figure 1), and OGTT at 120 minutes reduced from 224.4 ± 24.6 to 196.1 ± 24.7 mg/dl ($p<0.05$) in the EECP® group (see figure 2), while there were no changes in the Control group.

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HIGHLIGHTS

Current Issue

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Enhanced External Counterpulsation Therapy (EECP®) And Diabetes

continued

Fasting Plasma Glucose
(mg/dL)

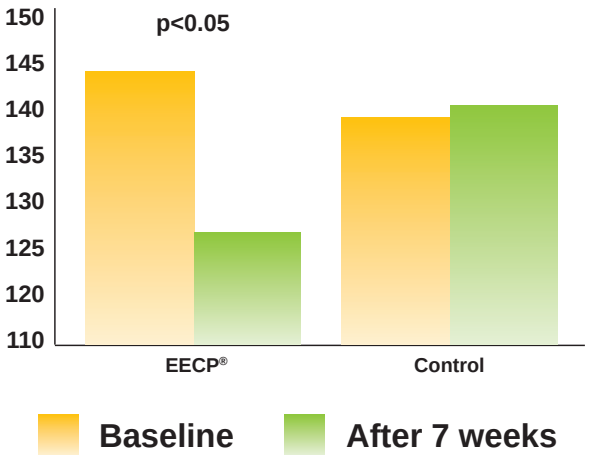

Figure 1

Plasma Glucose 120 minutes after OGTT
(mg/dL)

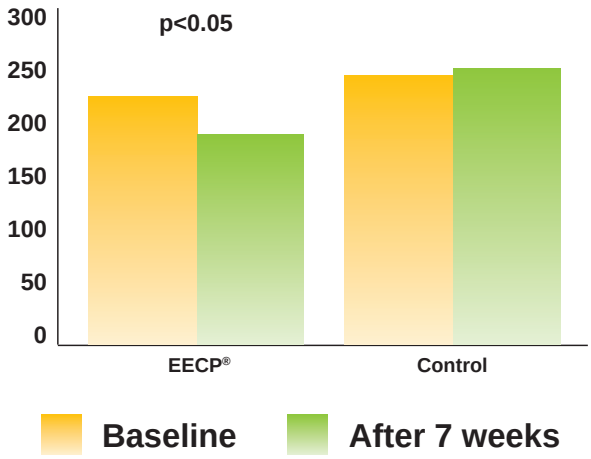

Figure 2

In addition, the homeostasis model assessment of insulin resistance (HOMA-IR), a measure of insulin resistance, decreased by 31%, while the whole body composite insulin sensitivity index (CISI) increased by 21% in the EECP® treated group ($p<0.05$), and no changes in the Control group.

In order to understand the mechanisms involved during EECP® treatment that would help to manage glycemic control in T2DM, peripheral vascular function, biochemical assays, and skeletal muscle morphology were evaluated before and after EECP® or Control. EECP® increased flow-mediated dilation in the brachial artery, a measure of endothelial function, by 27%, plasma nitrite/nitrate (NOx) increased by 30%, and 8-isoprostane-PGF-F2$_\alpha$, a marker of lipid peroxidation that promotes free radicals, decreased by 23%. In addition, capillary density in the vastus lateralis skeletal muscle following EECP® increased from 454 ± 21 to 497 ± 19 /mm^2 ($p=0.018$), with no significant changes observed in the Control group. There was also a significant increase by 47% following EECP® in the glucose transporter 4 (GLUT-4) protein expression, a glucose intake and metabolic signaling protein, while no changes in the Control group. These findings provide novel evidence that EECP® has a beneficial effect on peripheral arterial function, increases blood supply and sensitizes transport of insulin into skeletal muscle which accounts for 65-90% of glucose metabolism, thereby providing help to manage glycemic control in subjects with T2DM.

Data from the 2011 National Diabetes Fact Sheet (released Jan. 26, 2011) reported 25.8 million diabetics in the United States, or 8.3% of the population. There were 1.9 million new cases diagnosed in people aged 20 years and older in 2010. The total cost of diagnosed diabetes in the United States in 2007 was $174 billion ($116 billion for direct medical costs, $58 billion for indirect costs that include disability, work loss and premature mortality). T2DM accounts for 90-95% of all diabetes cases. The specific etiologies are not known, but reduced relative insulin production, impaired delivery systems due to limited blood flow, endothelial dysfunction and an ineffective tissue signaling system due to inflammatory damage may be the cause. EECP® treatment has been demonstrated to produce an effective remedy to these deficiencies. Given the enormous benefits of having a noninvasive therapy to manage glycemic control, attention to the development of EECP® Therapy in this field should be given top priority.

References:

[1] Martin, *et. al,* Enhanced External Counterpulsation improves peripheral artery function and glucose tolerance in subjects with abnormal glucose tolerance. *J of Applied Physiology 112:868-876, 2012.*

NOTE: Diabetes is not an FDA cleared indication for EECP® Therapy.

EECP® Therapy Patient Story

EECP® And My Quality Of Life: A First-Hand Account From An EECP® Therapy Patient

As a patient with advanced heart disease, the overwhelming fatigue and discomfort associated with my condition eroded my independence and narrowed the walls of my world, gradually at first and then more rapidly. The tasks of daily living, which I had once performed routinely and without conscious effort became mountains I lacked the strength to climb. A simple trip to the supermarket meant that the next day would be spent in bed. Having experienced a heart attack in 2007 followed by CABG X4 with subsequent heart attack and coronary stenting, there were recurrent symptoms of shortness of breath and fatigue. At CADV's Washington Township office, Dr. Fertels explained the EECP® Therapy to me and expressed his confidence that I was an excellent candidate for the treatment.

At the time of this writing, I have completed 23 of the 35 one-hour sessions needed for the therapy. The treatment is non-invasive, completely painless and at times I actually fall asleep while visualizing the collaterals forming to increase blood flow and oxygenation to my heart and brain. The benefits that have accrued thus far are my legs are no longer purple; I sleep soundly through the night with one pillow instead of three; movies and malls are back in my routine and I have been able to travel more than 300 miles to attend my 50th class reunion. Naps during the day are once again a pleasant indulgence rather than a command by my body to lie down before I fall down. The dramatic improvements in my energy level, the lessening fatigue and the decrease in episodes of shortness of breath are milestones I can track daily. I look forward to more changes as the treatments draw to a close – to a quality of life I once feared was lost to me.

- Name withheld for privacy
68 year old female patient of Cardiovascular Associates of the Delaware Valley, PA

EECP® Therapy Center Spotlight

The Ohio Heart And Vascular Center Has Treated Well Over 1,000 Patients With EECP® Therapy

Use of the non-invasive, FDA cleared Enhanced External Counterpulsation (EECP®) Therapy system at the Ohio Heart and Vascular Center in Cincinnati, Ohio has become a "standard of care" in treating patients with angina and congestive heart failure. With well over 1,000 patients treated for the relief of chest pain, fatigue, shortness of breath and other conditions associated with restricted coronary blood flow, Ohio Heart and Vascular Center continues to promote EECP® Therapy to their patients because of the positive results achieved in using EECP® Therapy for 14 years.

Dr. Charles W. Abbottsmith is one of the founding members of The Ohio Heart and Vascular Center. His vision and nearly 40 years experience in cardiovascular health has helped many patients relieve their symptoms and change their life through EECP® Therapy. "We've found that EECP® Therapy is effective in reducing or eliminating angina pain and significantly increasing stamina, exercise tolerance and quality of life for about 75 to 80% of the patients receiving it, and these benefits can last as long as three to five years" says Dr. Abbottsmith.

Working with Dr. Abbottsmith is Doris Osborne, the EECP® Coordinator who is instrumental in the success of the EECP® program at Ohio Heart and Vascular Center. Ms. Osborne's belief in EECP® Therapy is apparent in her many years of administering this specialized therapy to patients. "On every one of my emails, I let everyone know two very important facts about EECP® Therapy - Every cardiologist has an EECP® patient and EECP® relieves refractory angina by helping to develop collateral circulation & improving endothelial function". Ms. Osborne further states "If I hadn't experienced the results of EECP® Therapy first hand, I wouldn't communicate these statements to the world".

The Ohio Heart and Vascular Center is an affiliate of The Christ Hospital in Cincinnati, Ohio. The practice includes 40 physicians sub-specialized in coronary intervention, advanced heart failure, electrophysiology, cardiac surgery, advanced imaging, peripheral vascular disease, clinical cardiology and pulmonary hypertension. Ohio Heart and Vascular works closely with the Carl & Edyth Lindner Center for Research and Education at The Christ Hospital to offer patients the latest treatments and techniques available through clinical research. This includes over 1,200 clinical trials and many "first" procedures done in both the U.S. and worldwide.

EECP® Therapy Reimbursement Update

Reviewing the CMS Coverage Guidelines

The current CMS Guidelines for EECP® Therapy state:

"CMS (Centers for Medicare and Medicaid Services) reimbursement coverage is provided for the use of ECP for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass because:

1. Their condition is inoperable, or at high risk of operative complications or post-operative failure;
2. Their coronary anatomy is not readily amenable to such procedures; or
3. They have co-morbid states which create excessive risk."

Despite over 190 published articles including many peer reviewed scientific studies, these guidelines have not changed since originally approved in 1999. While some view them to be limited or restricted, many providers have used the guidelines successfully to demonstrate the medical necessity for providing the therapy to their patients. They have identified those Class III or Class IV patients who are still experiencing angina or angina equivalent symptoms, despite maximal medical therapy who are "NOT READILY AMENABLE" (Note: Coverage language uses "not readily amenable", not "refractory") to palliative invasive procedures (PCI & CABG) because their current medical history puts them at a higher risk of operative complications, incomplete revascularization, or post-operative failure. In the cardiologist's or cardiothoracic surgeon's opinion, the patient may be a qualified candidate for coverage because their current coronary anatomy is not amenable to such procedures. Additionally, patients who may also have co-morbid states such as ischemic heart failure, diabetes, peripheral vascular disease, renal disease, cerebrovascular disease and other diseases of the cardiovascular system are also identified as high risk and eligible to meet the CMS coverage policy. Vasomedical continues to work towards more liberal CMS coverage language and greater acceptance and use by physicians.

Upcoming ACC/AHA Angina Guidelines Update

We have also been in communication with the ACC/AHA Policy and Guidelines Committee. Despite the positive clinical evidence in support of EECP® Therapy, the ACC/AHA Angina Guidelines have not updated their recommendation level for EECP® Therapy from a IIb to a IIa rating since first published over 10 years ago in 2002. Vasomedical, with support from many EECP® Therapy providers around the country have written to the Guidelines Committee of the ACC/AHA asking for their support of the higher rating in the new guidelines. In our last communication with the ACC/AHA Director of Clinical Policy, we were notified that new guidelines are expected to be released early this summer. We trust that based upon the clinical evidence presented, they will raise the guideline recommendation; however, your continued support is necessary. Please communicate your support for raising the Guideline recommendation level to IIa by directing letters and emails to:

Ms. Lisa Bradfield, CAE, ACCF/AHA Director, Clinical Policy and Guidelines, American College of Cardiology, 2400 N Street, NW, 732, Washington, DC 20037 (Email: Lbradfie@acc.org).

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