

**The Efficacy of Cardiac Shock Wave Therapy in the Treatment of Refractory Angina: A Prospective, Randomized, Double-blind Trial**

*Leibowitz, D<sup>1</sup>; Weiss, A<sup>1</sup>; Rott, D<sup>1</sup>; Ben-Ivgy, F<sup>1</sup>; Dvir, N<sup>2</sup>; Hakim, G<sup>2</sup>; Lotan, C<sup>1</sup>*

*<sup>1</sup>Hadassah-Hebrew University Medical Center, Jerusalem, Israel; <sup>2</sup>Medispec, LTD., Yehud, Israel*

Background: Medical therapy for refractory angina not amenable to revascularization is limited. Animal studies have demonstrated that the use of low-energy extracorporeal shock waves (ESW) can contribute to angiogenesis and potentially improve symptoms of angina. The objective of this prospective study was to evaluate the efficacy of ESW therapy in patients with refractory angina.

Methods: Patients with refractory angina on medical therapy and ischemia on thallium testing with coronary disease not amenable for revascularization were eligible for the study. Patients with acute coronary syndromes, PCI or CABG within three months were excluded. All candidates underwent exercise treadmill testing on a modified Bruce protocol prior to beginning treatment. Patients were randomly assigned in a double-blind manner to active or sham treatment in a 2:1 ratio. ESW treatment directed at the ischemic areas on thallium testing was performed over a two month period in nine sessions with 300-500 low-energy shocks used in each session. Exercise testing was repeated at one and three months after completing the protocol. The primary endpoint of the study was change in exercise time as compared to baseline.

Results: 18 patients have been enrolled in the study (mean age  $66.1 \pm 18$  yrs. ; 17 male) and 15 have completed at least 1 month follow-up exercise testing. The 9 patients receiving active therapy had an average significant improvement in exercise tolerance at one-month follow-up with a mean improvement of  $150.2 \pm 162.7$  seconds, p-value < 0.02. The 6 patients in the placebo group had a non significant change of  $57.8 \pm 161.8$  seconds, p-value < 0.42. There were no side effects or complications noted in any of the subjects.

Conclusion: Non-invasive, extracorporeal shock wave therapy is safe and appears to be efficacious in the treatment of refractory angina. Our initial findings warrant further and larger studies of ESW efficacy in patients with ischemic heart disease.