inefficiency), whereas only 65% of patients with an indication for a device by MTWA are event free. The therapeutic risk of each of these indicators (untreated patients who experience an event) increases only from 0% to 1.5%.

Finally, the predictive values of these tests appear to depend on timing. The EP study was not predictive until nine months or more and remained predictive for two years, whereas the MTWA test was predictive as early as 6 months, but lost its predictive value after 12 months. These findings suggest that periodic screening, combined with more than one risk test may be appropriate.

Myoblast Autologous Grafting in Ischemic Cardiomyopathy (MAGIC) Trial

The Myoblast Autologous Grafting in Ischemic Cardiomyopathy (MAGIC) Trial examined the safety and efficacy of autologous skeletal myoblast cell therapy for improving local or global cardiac contractility in patients with ischemic heart failure. This is the first multi-center, randomized, double blind and placebo controlled trial of skeletal myoblast implantation and one that is designed with the power sufficient to determine whether autologous grafting is a viable solution for ischemic cardiomyopathy.

Patients were randomized to three parallel groups: 33 patients received a low dose of smooth muscle cells (SMC; 400 ± 100 x 10^6 cells), 33 patients received a high dose of SMC (800 ± 100 x 10^6 cells), and 34 patients received placebo consisting of suspension medium alone. All but eight patients had concomitant coronary artery bypass grafting (CABG) in non-cell transplanted segments. According to lead investigator Philippe Menasché, MD, Hôpital Bichat, Paris, it is important to note that "in almost all cases, cells were placed where the heart muscle was not previously revascularized."

The study failed to reach its primary endpoint of improving the contractility of the heart (left ventricle ejection fraction, or LVEF, as measured by echocardiography). The pre-specified secondary endpoint of decreasing left ventricular dilation, however, reached statistical significance at six months. In the placebo or low dose group there was no change, but there was a major decrease in dilation in the high dose group (p=0.006). In half of the patients, LVEF was measured by radionuclide angiography, and in this cohort of patients the increase in ejection fraction was statistically significant (3%) in the high dose group (p=0.04).

Due to concerns that skeletal myoblasts may be proarrythmogenic, as they fail to integrate electro-mechanically to the surrounding myocardium, defibrillators were implanted in all patients prior to hospital discharge. These devices were used to determine time to first ventricular arrhythmia, which was deemed not significantly different between the three groups at 6 months.

"I can tell you that now half of the patients have completed one year of the study and there is still no difference in ventricular arrhythmias between the groups," commented Dr. Menasché, when emphasizing the safety of the procedure.

"While there was absence of significant improvement of regional and or global contractility measured by echocardiography, there is possible evidence for reversal of adverse remodeling," concluded Dr. Menasché. He also emphasized that long-term follow up results are often more important than interim results and the discovery of long-term benefit may lie ahead.