Richard A Schatz, J Clin Exp Cardiolog 2017, 8:11 (Suppl)
DOI: 10.4172/2155-9880-C1-082

Richard A Schatz

Scripps Clinic, USA

Cardiac applications of gene and stem cell therapy, update: 25 years and counting

Despite over 25 years of intense research and development at great expense there has yet to be an approved gene or stem cell for cardiac applications. The earliest work began with using VEGF injected as a plasmid DNA directly into the myocardium by thoracotomy, then intra myocardially using a trans-aortic delivery mapping catheter for refractory angina. Others used VEGF/FGF genes or proteins injected intra coronary or intravenously. Despite encouraging phase I and II results, phase III trials were either abandoned or negative. This approach was soon replaced with using stem cells, first autologous then allogenic, for not only refractory angina but for refractory CHF and post MI remodeling. Again, despite encouraging phase I and II results no phase III trial has yet proven positive. This talk will discuss in detail these trials and why there has yet to be a positive trial. There is still controversy regarding the type of cells to use, the method of delivery, the dose and the proper patient subset to treat. Study design is important in order to standardize trials to make it easier to recruit and to win regulatory approval. Endpoints must be carefully chosen to assure a realistic outcome not just for FDA approval but for acceptance by the cardiology community. One of the more interesting lessons learned from these trials is the profound placebo effect that appears in all trial designs and outcomes. Trial design must account for this and power the studies appropriately. Currently there is only one FDA approved trial underway in the USA for refractory CHF and the results are pending. Stem cell therapy for refractory CHF, refractory angina and post MI remodeling represents a great opportunity yet has been unfulfilled thus far. Hopefully with lessons learned from past experience, improved products, delivery and study designs we will see a clinically useful indication for this difficult subset of patients without other options.

Biography

Richard A Schatz is best known for his role in developing the Palmaz-Schatz stent, the first balloon expandable stent used worldwide. His work started a revolution in interventional cardiology that continues today. Since 1998 he has participated in many gene and stem cell trials as a Principal Investigator. He continues to practice at Scripps Clinic in La Jolla, CA and lecture worldwide.

schatz.richard@scrippshealth.org

Notes: