Arctic Front® catheter system approved for atrial fibrillation

Medtronic have announced the US FDA approval of its Arctic Front® Cardiac CryoAblation Catheter System, making it the first and only cryoballon in the USA indicated for the treatment of drug refractory paroxysmal atrial fibrillation. This novel technology uses a balloon-based technology delivered through a catheter with a coolant rather than heat, creating circumferential lesions around the pulmonary vein to block the conduction of arterial fibrillation in cardiac tissues.

This freezing technology also allows for greater catheter stability as the catheter is able to adhere to the tissue during ablation. “This technology represents a significant improvement over currently used focal ablation treatment for atrial fibrillation” enthused Vivek Reddy, Director of Electrophysiology Laboratories at The Mount Sinai Medical Center.

The FDA approval of the Arctic Front system was based on results from the pivotal Sustained Treatment of Paroxysmal Atrial Fibrillation (STOP AF) trial, which were presented at the American College of Cardiology 2010 Scientific Sessions last year. Investigators of the trial enrolled 245 patients with paroxysmal atrial fibrillation at 26 centers with the purpose of comparing the cryoballoon ablation technique with antiarrhythmic drug therapy.

“This unique ablation approach ... [provides] a straightforward and efficient approach to pulmonary vein isolation, while giving patients a new, minimally invasive treatment approach proven to be safe and effective...”

The results demonstrated that 69.9% of patients treated with the Arctic Front system were free from atrial fibrillation at year one, compared to 7.3% of patients treated with drug therapy only.

The device also had a good safety profile with limited procedure-related adverse events (3.1%) and patients enrolled in the study displayed a significant reduction of symptoms, a decrease in the use of drug therapy and substantial improvements in both physical and mental quality-of-life factors.

“This unique ablation approach fills an unmet need in arterial fibrillation ablation by providing a straightforward and efficient approach to pulmonary vein isolation, while giving patients a new, minimally invasive treatment approach proven to be safe and effective” concluded Reddy.


Heart failure risk associated with bevacizumab used in the treatment of breast cancer, study suggests

Bevacizumab, a chemotherapy agent used in the treatment of metastatic cancers, has been implicated in an increased risk of heart failure in those receiving treatment by a new study published in the Journal of Clinical Oncology. The study, led by Toni Choueiri, associated the drug with a five-fold increased risk of congestive heart failure (CHF) in patients receiving treatment for metastatic breast cancer. An editorial by Nitin Verma and Sandra Swain of the Washington Cancer Institute, published alongside the study, advised ‘extreme caution’ in the interpretation of these results. This comes on top of a recent announcement from the FDA that it was seeking to remove market approval of the drug in the treatment of metastatic breast cancer, saying it does not prolong overall survival and comes with severe toxicity risks.

Bevacizumab is a humanized monoclonal antibody, used in the treatment of cancer, it recognizes and blocks VEGF A and is associated with risks of high blood pressure and hemorrhage. The published study by Choueiri involved a meta-analysis of five trials on bevacizumab in the treatment of breast cancer, which were selected from a PubMed search of articles between 1966 to March 2010 and data presented at the American Society of Clinical Oncology and San Antonio Breast Cancer Symposium annual meetings. The analysis aimed to establish if the therapy carried an associated risk of CHF in patients.

The selected trials consisted of 3784 subjects – patients with uncontrolled hypertension, CHF, vascular disease, angina and a recent history myocardial infarction were excluded. However, the trials did include patients previously treated with anthracyclines, known to cause irreversible damage to heart cells.

Results of the analysis showed that, incidence of CHF was significantly higher in the bevacizumab-treated group when compared to the placebo group. In further analyses, no significant differences were observed in CHF risk between patients treated with low versus high doses of bevacizumab or those treated with different bevacizumab regimens. The authors state that “this is the first comprehensive report to show that bevacizumab is associated with an increased risk of significant heart failure in patients with breast cancer.”

However, the accompanying editorial criticized these results, stating a number of limitations – previous anthracycline use among some selected patients being the major one. In the report, anthracycline exposure among patients in the five trials was from 30 to 100%. “Patients with previous anthracyclines already have a damaged heart, so it is possible that the bevacizumab could add to that. Or, it could just be related to the anthracyclines, period, and not at all related to the bevacizumab,” comments Swain. Lack of