Update On The Sentry Bioconvertible Non-Retrievable IVC Filter. Early Clinical Results And Why It Is A New Horizon

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Background:
Retrievable inferior vena cava filters (IVCF) are intended for use in the growing subset of patients who require transient protection against pulmonary embolism (PE). Low IVCF retrieval rates, retrieval risks, and long term complications when filters are not retrieved have raised serious safety concerns. The Sentry IVC Filter (Novate Medical Ltd., Galway) was designed to provide transient protection against PE, avoid the need for a second invasive retrieval procedure and the complications associated with filter retrieval, while minimizing structural IVC filter complications. The Sentry Filter’s novel features include a “bioconvertible” filter cone and a cylindrical support frame which distributes radial force evenly along the length of the frame. A biodegradable filament secures the 6 metallic arms which form the filter cone during the patient’s high-risk period for PE. When the bio-absorbable filament degrades, the filter cone separates and the filter arms retract into the IVC wall resulting in a patent, unobstructed lumen. Ovine studies have documented the presence of the filter cone at 60 days, subsequent filter arm retraction at 120 days, and tissue incorporation of the metal arms leading to a widely patent IVC lumen at 180 days without retrieval. This unique design is intended for temporary IVC filtration (≤ 60 days) while avoiding a second invasive procedure to remove the filter. The NOVEL trial, a human feasibility study with X-Ray follow-up demonstrated that the Sentry filter was maintained in the filtering configuration during the 60 day protection period without PE. X-Ray and CT venography showed that filter cone separation occurred leading to IVC lumen patency. The cylindrical frame remained structurally intact, as analyzed by 270 day CT reconstruction, without migration, perforation or fracture.

Methods:
NOVEL II is a human feasibility study evaluating the Sentry filter with modified filter arm geometry. Eleven (11) patients have been enrolled and follow-up is ongoing. Study design mandates 45 day CT venography to evaluate the filter for any captured thrombo-embolic material which may require treatment prior to filter conversion. X-ray imaging at 60 days will also assess the filter structural status.

Results:
At the time of presentation, procedural outcomes, 45 day and 60 day imaging will be available.

Conclusion:
NOVEL II will provide expanded insight on early imaging and outcomes of a bioconvertible IVC filter with a stabilizing cylindrical frame as an alternative to retrievable IVCFs for patients at transient risk for PE.