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FILTER-SCAD Study Results Demonstrate Need for Point of Care Rule-Out Options for Coronary Artery Disease in Low-Risk Patients

Malmö, Sweden — Acarix, a leader in advanced acoustic-based cardiac diagnostics, announced that the results of the FILTER-SCAD trial released today demonstrated that a deferred testing strategy is plausible and safe in low-risk patients with new-onset stable symptoms of coronary artery disease (CAD). The results of the investigator-initiated study were presented today at the European Society of Cardiology and published in the European Heart Journal.

FILTER-SCAD is a randomized multicenter investigator-initiated implementation trial that examined the safety of adding the Acarix CADScor System as a rule-out test in patients referred with symptoms suggestive of stable CAD. The study, conducted at one site in Sweden and five sites in Denmark, looked at the cumulative number of diagnostic tests and occurrence of major adverse cardiac events (MACE) at one year after randomization. The results showed a deferred testing strategy is safe with low-risk patients, despite implementation challenges seen during the study.

“This study reinforces the critical need for a rapid point of care rule-out option, like the CADScor System, for coronary artery disease,” said Aamir Mahmood, president and CEO of Acarix. “We are pleased that CAD-scores were measured in 95% of patients and that 40% of those patients were deemed low risk, which highlights the huge potential to safely reduce unnecessary testing in this population. Going forward, we remain committed to ensuring that the CADScor System is implemented successfully and consistently in order to safely reduce overtesting in low-risk populations.”

While results showed a numerical reduction in the cumulative number of diagnostic tests in the CAD-score group, the result was not statistically significant for the superiority endpoint. However, other significant outcomes were observed. Lower risk patients had a 23% absolute reduction in cumulative number of diagnostic tests. Additionally, the CADScor strategy indicated that patients who received a CAD-score trusted the results of the test and did not pursue additional testing from their physician. Patient preference was cited as the cause for additional testing in 23% of the control group but only 2% of the CAD-score group. These findings suggest a potential reassuring effect of the CAD-score strategy.

With a sensitivity of 88.7% and a negative predictive value of 97.2%, a CAD-score ≤20 indicates a low likelihood of obstructive CAD. The study shows that the performance and ease of use make the CADScor System a suitable first-line rule-out tool in populations with suspected CAD and a low prevalence of disease.

“Disruptive technologies must be safe and effective,” said Dr. George Chrysant, Chief Medical Officer for INTEGRIS Heart Hospital/INTEGRIS Cardiovascular Physicians in Oklahoma City, OK. “The high negative predictive value demonstrated in FILTER-SCAD is extremely important to clinicians who do not want to miss potential events in low-risk patients. This trial will be an anchor for future trials and could also represent significant cost savings to payors managing large populations of patients. The future appears to be promising."

While the CADScor System was shown to be safe and effective, protocol adherence was a significant issue during the study. Adherence to the rule-out strategy was strongly encouraged, but ultimately left at the discretion of the treating physician. The five clinical sites in Denmark were composed of many physician sub-investigators. In contrast, the sixth site in Sweden was nurse-driven and had a limited number of physicians involved. This notable difference in implementation between the sites is reflected in the results of the study, with the Swedish site demonstrating an absolute reduction (32%) in the cumulative number of diagnostic tests.

Finally, the CAD-score group was non-inferior to the control for MACE. Patient safety was favorable with 2.4% of the population experiencing a MACE over the one year follow-up, supporting prior findings that these patients with stable symptoms have an overall favorable prognosis.

“It’s important to separate the performance of the CADScor System from the implementation approach utilized in this study,” said Dr. Tony Das, a nationally-recognized board-certified interventional cardiology specialist at Baylor Heart Hospital in Dallas, TX and a member of the Acarix Board of Directors. “Over testing, even in the setting of a randomized clinical trial, is a stubborn and persistent issue. Behavior change in healthcare is difficult and requires physician support and education for the whole healthcare team.”

This is the first paper presented out of the FILTER-SCAD study and the first in a series of results that will be subsequently released.

“We look forward to further analysis and studies to be presented from FILTER-SCAD, further confirming the clinical value of the CADScor System when used correctly in conjunction with improved implementation,” said Mahmood.

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About Acarix

Acarix is a Swedish medical device company that innovates solutions for rapid rule out of coronary artery disease (CAD) at point of care. The CE-approved and FDA DeNovo-cleared Acarix CADScor System is intended for patients experiencing chest pain with suspected CAD and designed to help reduce millions of unnecessary, invasive, and costly diagnostic procedures. The CADScor System has been used on more than 29,000 patients. Acarix recommends CADScor System as a first-line diagnostic aid that uses highly sensitive acoustics and advanced computational processing to analyze coronary blood flow to rule out significant coronary artery disease (CAD), with at least 96% certainty at point of care. Acarix is listed on the Nasdaq First North Premier Growth Market in Stockholm (ticker: ACARIX) and cross-traded on the OTCQB market in the US (ticker: ACIXF). Carnegie Investment Bank is the Certified Advisor of Acarix. For more information, please visit **www.acarix.com**

Attachments

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