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EDITORIAL COMMENT

# The Lariat Device

## R.I.P. or Buried Alive*

William W. O'Neill, MD

In this issue of the *Journal*, Turagam et al. (1) provide evidence for a potential new advantage of epicardial left atrial appendage (LAA) closure, employing the Lariat device (SentreHEART, Redwood California). This device has had a rather circuitous route to clinical usage for LAA closure. SentreHEART first received 510k U.S. Food and Drug Administration (FDA) approval of this device for suture-based soft tissue approximation in June 2006. The device uses an ingenious combination of an endocardial magnet-tipped wire that is advanced through trans-septal access and a second magnet-tipped wire that is placed in the epicardial space through pericardial access. This combination creates a rail to allow a suture and cinch device to be delivered through the pericardial space and around the appendage to the base of the appendage. At this point, the suture is mechanically cinched, the appendage is closed, and the cinch device is removed. Typically, a pericardial drain is left in place for 1 to 2 days. Patients are admitted to an intensive care unit for observation and until the pericardial drain can be removed.

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Lee et al. (2) first reported the feasibility of this approach in a canine model. Bartus et al. (3) first reported clinical use in 13 patients undergoing mitral valve surgery or atrial fibrillation ablation. Despite lack of specific FDA approval for this indication, many centers, including our own, began using this device for LAA occlusion. Lakkireddy et al. (4) have reported the largest compilation of clinical outcomes in 712 patients treated in 18 U.S. hospitals. Although the device was successfully deployed in 95% of cases, 24 patients had cardiac perforation during pericardial access, and 34 patients had pericarditis following implantation. These types of extremely serious complications and others such as complete LAA detachment from the heart led the FDA to issue a safety alert in July 2015. This warning plus the lack of reimbursement coverage from the Centers for Medicare & Medicaid Services in the first national coverage determination led most centers in the United States to abandon the use of Lariat for routine LAA occlusion. Safety concerns and lack of a clear reimbursement both seemed to portend the death of this device for LAA occlusion.

Ironically, although SentreHEART and implanting cardiologists were heavily criticized for using this device for a non-FDA-approved indication, it is likely that this decision saved the device from a premature death. Had a medically controlled, randomized trial been performed with the initial device and initial pericardial access technique, the trial would have failed on safety concerns. The original technique for "dry" pericardial access with a large-bore pericardiocentesis needle was fraught with risk of epicardial laceration, myocardial perforation, and cardiac tamponade. In addition, the first-generation device was limited in LAA diameter that could be enclosed, and the cinch device was occasionally difficult to remove.

The procedure has been made safer by routine use of a micropuncture needle (5). In addition, Greenbaum et al. (6) have developed a novel method of insufflating the pericardial space with carbon dioxide. This allows percutaneous access of the pericardial space much more reliably. Finally, the new Lariat XT

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From the Center for Structural Heart Disease, Henry Ford Hospital, Detroit, Michigan. Dr. O'Neill has been a paid consultant for Boston Scientific, which manufactures the Watchman Device, Medtronic, and Abiomed.

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suture delivery device allows easier cinch removal. Thus, in experienced centers, the LAA occlusion with the device may rival safety and efficacy of endocardial occlusion with the Watchman device (Boston Scientific, Marlborough, Massachusetts).

The Lariat procedure is more technically challenging than the Watchman implantation. It requires post-procedure intensive care unit monitoring. The need for a pericardial drain can be uncomfortable for the patient, especially if post-procedure pericarditis occurs. For these reasons, even if reimbursement was readily available, it is unlikely that Lariat LAA ligation would capture market share compared with endocardial occlusion with Watchman or Amulet (Abbott, Abbott Park, Illinois) devices.

In this context, the work of Turagam et al. (1) provides a strong rationale to reconsider the death of Lariat. The Kansas City group deserves great credit for perseverance, not only in refining the technique, but also for providing insight into other benefits of epicardial LAA ligation. They have demonstrated that the mechanical function of the left atrium is improved and reverse LA remodeling occurs with ligation (7). This group also performed a small pilot study of LAA ligation before pulmonary vein isolation in patients with chronic, refractory atrial fibrillation (8). The theory was that ligation would isolate triggers existing in the LAA that were the substrate for pulmonary vein isolation (PVI) failure. On the basis of encouraging pilot results, a large, multicenter prospective randomized trial (LAA Ligation Adjunctive to PVI for Persistent or Longstanding Persistent Atrial Fibrillation [aMAZE]; NCT02513797) of PVI alone versus PVI with LAA ligation is being conducted.

In addition to enhanced efficacy of atrial fibrillation ablation, the Kansas City group has studied the interaction between the LAA and the renin-angiotensin-aldosterone system. They carefully followed 39 patients treated with Watchman devices and compared them with 38 patients treated with the Lariat LAA exclusion (9). Neurohumoral profiles were assessed in 24 h and 3 months. They found that blood norepinephrine, epinephrine, and aldosterone levels were lowered in the Lariat group at 24 h and 3 months but remained unchanged in the Watchman group. As a result, blood pressure was lowered in the Lariat group but unchanged in the Watchman group (10). These blood pressure findings were corroborated in a larger 76-patient report (10).

In the current report, Turagram et al. (1) expand these observations with a large, multicenter, observational nonrandomized registry. Before consideration of the findings, some deficiencies must be pointed out. No discussion of informed consent is provided. No start or end date of the trial is provided. It is unclear whether this report incorporates patients from the 2 previous reports. It is unclear whether all hypertensive atrial fibrillation patients treated with devices in each center were included. Obviously, it is not possible to blind the patients to implant type. These caveats must be kept in mind because they plagued the development of renal artery denervation for therapy of systemic hypertension (10).

Nevertheless, the results of this large, multicenter, well conducted registry are fascinating. Patients treated with epicardial exclusion (largely the Lariat device) had significantly lower systolic blood pressure at 3 months and 1 year. No change occurred in the group treated with the endocardial occlusion (Watchman). The 10-point drop in systolic blood pressure, accompanied with a decrease in number of antihypertensive medications required, is truly clinically meaningful.

These persistent investigators must be congratulated for finding a potentially revolutionary observation regarding LAA occlusion. The results must be corroborated by a true prospective, patient-blinded randomized trial. The field of device-induced blood pressure control is hampered by investigator and even patient bias. Patient compliance with antihypertensive therapy is difficult to control in an unblinded trial. If the results of this registry are confirmed, a new direction for both atrial fibrillation ablation and antihypertensive control may be launched. Nowhere would this be more logical than during routine open heart surgery. LAA exclusion can be done directly with minimal increase in bypass time and little increased risk. It is possible that all patients with underlying atrial fibrillation or systemic hypertension could benefit from LAA exclusion at the time of surgery. Perhaps the Lariat device was buried alive. It will be fascinating to see this field develop. The Kansas City investigators must be commended for their persistence in studying and demonstrating clinical benefit from LAA occlusion with the Lariat device.

**ADDRESS FOR CORRESPONDENCE:** Dr. William W. O'Neill, Henry Ford Hospital, 2799 West Grand Boulevard, CFP 435, Detroit, Michigan 48202. E-mail: Woneill1@hfhs.org. Twitter: @BillONeillMD, @HenryFordNews.

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**KEY WORDS** left atrial appendage, occlusion