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REPLY: Differences in Experience With a New Delivery Device for LAA Ligation Among Various U.S. Centers

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We thank Dr. Rasekh and colleagues for their interest in our multicenter study of transcatheter left atrial appendage (LAA) closure with the Lariat suture delivery device (SentreHeart, Redwood City, California) (1). They cite concerns about the participating centers, operator training, and inclusion criteria, and claim that our study "shows how a procedure can have suboptimal outcomes if not executed properly." However, this assertion is without merit.

At time of the conception of the registry, all U.S. sites that were performing the Lariat procedure were identified with the assistance of the manufacturer and invited to participate. Centers that collaborated in data sharing and provided complete data sets were included. We find it intriguing that the authors are critical of our site selection, yet were invited to participate and declined (A.R., S.K., A.M., and D.L.), with the exception of the University of California-San Francisco (N.B.), which was not included because of perceived conflicts of interest.

All procedures followed the manufacturer's protocols. The manufacturer reviewed all cardiac computed tomograms before the procedure to confirm anatomic eligibility according to their pre-defined specifications. A clinical specialist or other representative employed by the manufacturer was present during all procedures. Reflecting their technical skill set, several of the operators involved in the study served as proctors for the procedure at the request of the manufacturer.

Our registry included, by design, early procedural experience; proficiency may improve with ongoing collective experience. There was no significant relationship between site volume and procedural success, and the inclusion of low volume sites cannot fully explain our findings.

Dr. Rasekh and colleagues further assert that our findings are inconsistent with the clinical experience of other operators. Since our publication, another multicenter study has reported safety and efficacy event rates similar to that of our study, thereby supporting our overall conclusions (2). Dr. Rasekh and colleagues cite their own "quick survey" that they claim shows a substantially better safety profile with the Lariat. The methodological soundness of an informal survey is unclear, and their findings must be subject to peer review before they can be considered valid. We commend the authors for their attempt to systematically collect data and look forward to the publication of their findings.

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Although we observed very high rates of technical success, our study raises questions about the safety and the efficacy of the procedure. The authors argue that safety can largely be addressed with the use of a micropuncture needle for pericardial access. However, this would only affect the risk of right ventricular (RV) perforation. Just one-quarter of the pericardial effusions that occurred in our report were felt to be secondary to pericardial sheath placement. Of the 34 adverse events (including several deaths) associated with the Lariat that were reported in the Food and Drug Administration MAUDE (Manufacturer and User Facility Device Experience) database between January 2012 and April 2014, only 2 were attributed to RV perforation; the remainder were LAA perforations, lacerations, or avulsions (3). Improving pericardial access would not influence the incidence of important post-procedural adverse events, such as stump thrombus, pleural effusion, and stroke.

The authors correctly state that our study encompasses only a fraction of the >2,000 patients who have been treated with the Lariat. Regrettably, our small study of 154 patients represents approximately one-half of the entire peer-reviewed data set for a device that is being used in the absence of any clinical trial or a Food and Drug Administrationapproved indication for stroke prevention; however, it may be associated with substantial morbidity. A multicenter, randomized trial with independent oversight is urgently needed to robustly define the safety and long-term efficacy of transcatheter LAA ligation.

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