IS THE SIZE CRITERION FOR SURGERY DECISION OF ASCENDING AORTIC ANEURYSM CHANGED? LEFT SHIFT OF THE AORTIC DIAMETER

To the Editor:

We read with great interest and pleasure the article by Saeyeldin and colleagues¹ on decision making for surgery in patients with ascending aortic aneurysm. Their group is the most reliable one able to develop an algorithm for aortic disease because of their large database patients with good follow-up; however, we have comments to be able to clarify some points.

Indications for surgery are based on aortic diameter and derived from findings on natural history regarding the risk of complications weighed against the risk of elective surgery. Regardless of etiology, surgery should be performed in patients who have a maximal aortic diameter of at least 55 mm in the current guidelines.^{2,3} Surgery is indicated, however, in patients with aortic diameters 50 mm or smaller who have connective tissue disease and bicuspid aortic valve or in patients with additional risk factors, including family history of dissection, size increase 3 mm/y, severe aortic regurgitation, or desire for pregnancy.^{2,4} Saeyeldin and colleagues¹ have made a new decision-making algorithm that supports lower aortic diameter against the guideline's recommendations for surgery indication. It is notable, however, that in this study, the compared groups did not include the same patient's characteristics. The "medical group" was formed from the symptomatic-free patients with ascending aortic diameter 4.0 to 4.9 cm. The other group, the "surgery noncompliant and overwhelming comorbidities group," was formed from the patients triaged to surgery who did not undergo surgery because of patient refusal, insurance issues, or severe comorbidities. That surgery noncompliant group included patients with ascending aortic diameter greater than 5 cm and symptom-free patients with ascending aortic diameter 4.0 to 4.9 cm. If the study population had been designed with same aortic diameters between 5.0 to 5.5 cm classified one for the medical group and the other for surgery group, the conclusion for new decision-making algorithm would have been more definitive, and it could have been changed the guidelines for protective surgery. In addition,

the logistic regression of the triaging algorithm is unclear as to whether all patients with surgery recommended or only study population have been included.

The main aim of medical therapy for aortic aneurysm is to reduce shear stress on the aortic wall by reducing blood pressure and cardiac contractility. A large number of patients with aortic diseases have comorbidities, such as coronary artery disease, chronic kidney disease, diabetes mellitus, dyslipidemia, and hypertension. It is because of this that treatment strategies must be similar to those indicated for the comorbidities.^{2,3} There is no information, however, about the medical strategy and medication protocols of the groups. In addition, hypertension, chronic kidney disease, and coronary artery disease have been found statistically significantly different between the groups. The significant discrepancy of medication between the groups thus may affect the outcomes.

We would like to congratulate Saeyeldin and colleagues¹ for their algorithm including outcomes with rich literature content. After all, recent analyses have revealed that a left shift of the aortic diameter for early prophylactic surgery may be necessary. Large-scale prospective clinical studies with these recommendations are therefore now needed.

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REPLY: RANDOMIZED CONTROLLED TRIALS IN AORTIC SURGERY: A CALL TO ACTION

Reply to the Editor:

The article by Saeyeldin and colleagues¹ on decision making for patients presenting with ascending aortic aneurysm has stirred a lot of interest in the surgical community. Although the letter to the Editor by Bugan and colleagues² is primarily directed toward the original article, we have been asked by the Editors of the *Journal* to comment on the letter in question.

In their letter to the Editor, Bugan and colleagues² point out significant differences in the baseline characteristics of those patients who underwent a watchful waiting strategy relative to those who were recommended to undergo surgery but did not for a variety of reasons. The study by Saeyeldin and colleagues¹ is not a randomized controlled trial; it is a retrospective, observational study. Although the concerns raised by Bugan and colleagues² are important, they can only be addressed by a prospective, randomized trial. We think that instead of further discussing the current article published by the Yale group, we should direct our efforts toward defining the framework requirements for a randomized trial in the treatment of ascending aortic aneurysm.

Elefteriades and Farkas³ have shown that 9 of 10 patients with thoracic aortic aneurysms are symptom free until the first event. We therefore already know that even a randomized trial will represent only a minority of patients with thoracic aortic disease. Furthermore, we know that by including the patient in a structured follow-up program, we alter the natural history of the disease even if the patient does not undergo surgery.⁴ When following the discussions at meetings, it becomes apparent that indications for surgery vary widely among centers. The current guidelines^{5,6} do not take into account basic but important factors such as age and the general condition of the patient, factors that certainly affect decision making for the individual patient. Furthermore, it will be difficult to design a trial that randomizes patients into a

watchful waiting strategy if they already have an indication for surgery according to the current guidelines.

Some obstacles seem almost insurmountable; for example, strictly speaking, every patient would have to undergo genetic testing to make sure that he or she is not harboring a mutation that increases the risk for dissection at smaller diameters. Furthermore, there is a large group of patients with mutations associated with thoracic aortic disease, but we do not know whether they have an increased risk for aortic dissection (or surgery, by the way). And then there is probably an even larger group of patients for whom we do not know yet whether the genetic variant they harbor is indeed associated with thoracic aortic disease.

In our mind, an ideal population to include in a randomized trial comparing best medical treatment and watchful-waiting with best medical treatment and surgery would be symptom-free, young, active patients with a low surgical risk who present with ascending aortic diameters between 4.5 and 4.9 cm. If they do not have Loeys-Dietz syndrome or Marfan syndrome with additional risk factors, these patients do not qualify for elective surgery according to the current guidelines. Nevertheless, the aorta is certainly too large, and it can be expected that they will fulfill the criteria for elective surgery in the future. Furthermore, most of these patients have very active professional and private lives, and the effect of an active lifestyle on the risk of aortic events at this diameter is unclear. This is the patient population for whom a randomized trial could affect the way we treat these patients.

It is unlikely that one center alone would have sufficient numbers to make these efforts worthwhile. But if everybody who has read the article by Saeyeldin and colleagues¹ would invest a little bit of time and energy toward setting up a randomized trial, we could actually move a step forward in the treatment of patients with thoracic aortic disease. Furthermore, only a randomized trial will eliminate the problem that Sundt⁷ highlighted in his recent letter to the Editor regarding the article in question, that just because we can perform an operation safely does not mean that every patient will benefit from it.

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