We read with interest the recent paper by Sedaghat et al. (1) in which they report a high incidence of thrombus between the left upper pulmonary vein and the Amulet device (St. Jude Medical, St. Paul, Minnesota) on transesophageal echocardiogram performed 11.0 ± 8.2 weeks following left atrial appendage (LAA) occlusion. These thrombi were observed in 4 of 24 cases (16.7%) in spite of a strategy of dual antiplatelet therapy and no thrombus was visualized in any of 32 patients on follow-up transesophageal echocardiogram. Our patients received 6 weeks of double antiplatelet therapy and no thrombus was visualized in any of 32 patients on follow-up transesophageal echocardiogram at 6 to 8 weeks post-implantation. Our results are in line with the other published series of Amulet device implants, in which the prevalence of thrombi on follow-up imaging ranged from 0% to 4% (3).

This discrepancy between the findings of Sedaghat et al. (1) and other published series could simply be explained by statistical fluctuation, given the low number of patients. However, a genuine reason for the higher prevalence of thrombus in their patients might be found in their observation that thrombus was associated with incomplete coverage of the ridge between the LAA and the left upper pulmonary vein. In our experience (2), and that of others (3), intra-procedural echocardiography (either transesophageal or intracardiac) is invaluable in helping achieve complete LAA occlusion. The mere use of fluoroscopy, even in a biplane lab, cannot provide the level of detail of LAA anatomy contributed by echocardiography (4,5). It is notable that Sedaghat et al. (1) do not mention the use of echocardiography to guide device implantation in their methods. However, given that their procedures were all performed under conscious sedation and with an average procedure duration of <40 min, it is highly unlikely that transesophageal echocardiogram was used.

Furthermore, Sedaghat et al. (1) recognized the small size of their study population, but they did attempt to compare features of the 4 patients with thrombi with the 20 patients without, concluding that “our analysis indicates a multifactorial cause of device-related thrombus with the Amulet occluder device.” We would tend to agree with their initial observation and point out the inherent limitations of engaging in subgroup comparisons with such small numbers.

We thank Sedaghat et al. (1) for sharing their experience, which strongly highlights the critical importance of ensuring complete coverage of the LAA at implantation and the challenge of getting this right without echocardiographic guidance.

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Please note: Dr. Gupta is on the proctors’ panel for St. Jude Medical Ltd. for implantation of Amulet devices. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

REFERENCES
We read with interest the letter by Dr. Bartoletti and colleagues referring to our paper, which has been recently published in JACC: Clinical Electrophysiology (1). The authors report their own experiences with the Amplatzer Amulet device (St. Jude Medical, St. Paul, Minnesota) in a small patient cohort (2) and they found a relevantly lower number of device-related thrombi (DRT). In their letter Bartoletti and colleagues question the reliability of our findings and raise some concerns, to which we are happy to respond.

First, all the left atrial appendage (LAA) occluder in our series was implanted with echocardiographic guidance by use of 3-dimensional transesophageal echocardiography (TEE). The relatively short implantation time of 40 min is not relevantly different to other experienced centers and does not imply the lack of TEE use. In all our cases we aimed for complete coverage of the LAA, which was not possible in a subset of patients with difficult LAA anatomy or prominent left upper pulmonary vein ridge. Therefore, in our opinion, it is inappropriate to interpret that inadequate peri-procedural imaging was the predominant factor causing the reported high DRT rate.

Second, we agree with the authors that in general the published rates of DRT with the Amulet devices are lower than in our study and we discussed possible reasons for this obvious discrepancy intensively in our paper. In brief, most reported findings are based on transthoracic echocardiography performed in small patient cohorts and transthoracic echocardiography is not the gold standard for thrombus detection in the left atrium. Additionally, most data on the Amulet device have been collected from retrospective registries implying a relevant selection bias, and prospective studies with this system are scarce.

Although we acknowledge that statistical fluctuation may have played a role in the relatively high incidence, our results from this prospective study with systematic TEE examinations are in concordance with an earlier study published by Plicht et al. (3).

Third, even if Dr. Bartoletti and colleagues had a similar clinical risk profile (CHADS2-VASc [Congestive heart failure, Hypertension, Age ≥75 years, Diabetes mellitus, Prior stroke or transient ischemic attack or thromboembolism, Vascular disease, Age 65 to 74 years, Sex]), altered LA hemodynamics seem of equipotent importance in this setting. This issue was reflected by the high incidence of previous LAA thrombi in the subcohort of patients with DRT. Therefore, we would like to encourage Bartoletti and colleagues to quantify the severity of spontaneous LA echo contrast, LAA peak emptying velocities, and left ventricular ejection fraction in this context. These are established risk factors for the development of LA thrombi and according to our reported experience and patients with impaired LA hemodynamics may therefore be prone to thrombus formation with the insertion of extraneous materials such as an occluder device.

Finally, we felt the necessity to report our results—despite from a small patient cohort—because we found a surprising high incidence of DRT even with the recommended dual antiplatelet therapy. This finding is of relevant importance for daily clinical practice because the optimal anticoagulant or anti-platelet regimen after LAA closure in general, but especially with the Amulet device, remains to be defined and evidence from prospective studies is lacking. As a note of caution, we would like to emphasize that vitamin K antagonist treatment is mandatory after insertion of the Watchman device (Boston Scientific, Marlborough, Massachusetts), which up to now remains the only system that has been tested in a prospective randomized study (4). Furthermore, available evidence has shown impressively that antiplatelet therapy ineffectively protects from cardioembolic stroke in atrial fibrillation patients (5). Therefore, our results underline the unmet need for a prospective study evaluating the optimal anticoagulant regimen after LAA occlusion with different devices. As a consequence of our findings, we encourage all colleagues to perform close TEE follow-up in patients at high thromboembolic risk undergoing LAA occlusion with the Amulet device followed by antiplatelet therapy, especially when optimal occlusion of the LAA at the level of the ostium could not be achieved.

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With the Amulet Device
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