



# Thrombus aspiration in patients with large anterior myocardial infarction: A Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia trial substudy

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**Background** The TASTE trial did not demonstrate clinical benefit of thrombus aspiration (TA). High-risk patients might benefit from TA.

**Methods** The TASTE trial was a multicenter, randomized, controlled, open-label trial obtaining end points from national registries. Patients (n = 7,244) with ST-segment elevation myocardial infarction (STEMI) undergoing percutaneous coronary intervention (PCI) were randomly assigned 1:1 to TA and PCI or to PCI alone. We assessed the 1-year clinical effect of TA in a subgroup with potentially large anterior STEMI: mid or proximal left anterior descending coronary artery infarct lesion, thrombolysis in myocardial infarction 0 to 2 flow, and symptom onset to PCI time  $\leq 5$  hours. In this substudy, patient eligibility criteria corresponded to that of the INFUSE-AMI study.

**Results** In total, 1,826 patients fulfilled inclusion criteria. All-cause mortality at 1 year of patients randomized to TA did not differ from those randomized to PCI only (hazard ratio [HR] 1.05, 95% CI 0.74-1.49,  $P = .77$ ). Rates of rehospitalization for myocardial infarction, heart failure, and stent thrombosis did not differ between groups (HR 0.87, 95% CI 0.51-1.46,  $P = .59$ ; HR 1.10 95% CI 0.77-1.58,  $P = .58$ ; and HR 0.75, 95% CI 0.30-1.86,  $P = .53$ , respectively). This was also the case for the combined end point of all-cause mortality and rehospitalization for myocardial infarction, heart failure, or stent thrombosis (HR 1.00, 95% CI 0.79-1.26,  $P = .99$ ).

**Conclusion** In patients with STEMI and large area of myocardium at risk, TA did not affect outcome within 1 year. (Am Heart J 2016;172:129-34.)

Thrombus aspiration (TA) is a well-established technique for removal of thrombus and restoration of blood flow in the setting of ST-elevation myocardial infarction (STEMI).<sup>1</sup> The findings of the TASTE trial were neutral regarding clinical benefit at 30 days and at 1 year.<sup>2,3</sup> Hypothetically, TA should be more effective in high-risk patients with a large area of myocardium at risk, but the number of low-risk patients enrolled in TASTE

(mortality rate 2.9% at 30 days and 5.5% at 1 year) may have obscured a significant effect of TA in this important subgroup.

Proximal coronary lesions especially in infarct-related arteries supporting the anterior wall are associated with a poor prognosis.<sup>4,5</sup> The combination of high potential risk and relative ease of treatment access could imply that interventions are more effective in proximal than in distal lesions, especially in the left anterior descending coronary artery (LAD).<sup>6</sup>

In the INFUSE-AMI study, 452 patients with an extensive area of myocardium at risk and receiving bivalirudin treatment were randomized in a  $2 \times 2$  factorial design to manual TA versus no aspiration and to intralesion abciximab versus no abciximab.<sup>7</sup> Patients showed proximal or mid-LAD culprit lesions with thrombolysis in myocardial infarction (TIMI) flow of 0 to 2, and anticipated symptom onset to device time  $\leq 5$  hours. The 30-day primary end point of infarct size as assessed by cardiac magnetic resonance imaging was not

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reduced by TA, and TA did not significantly improve any clinical end points at 30 days.<sup>7</sup> However, significantly fewer patients were rehospitalized for heart failure (HF) in the TA group compared to the percutaneous coronary intervention (PCI)-only group after 1 year,<sup>8</sup> but the trial was not powered for clinical end points.

The aim of this substudy of the TASTE trial was to evaluate the clinical effect of TA in a population with a large area of myocardium at risk, corresponding to the criteria for patients included in INFUSE-AMI. Our hypothesis was that any clinical treatment effect of TA would be most pronounced in these patients.

## Methods

The trial design of the TASTE study has been previously described in detail.<sup>2,9</sup> In brief, the TASTE study was a multicenter, prospective, registry-based, randomized, controlled, clinical, open-label trial designed to determine the efficacy and safety of routine use of manual TA in STEMI. Patients  $\geq 18$  years old were considered for inclusion if diagnosed with STEMI within 24 hours of onset of symptoms and recommended for PCI after coronary angiography. The subjects were randomized 1:1 to PCI + TA or conventional PCI. In total, 7,244 patients underwent randomization, with an additional 4,697 patients screened but not enrolled mainly due to exclusion criteria. The Internet-based comprehensive Swedish Coronary Angiography and Angioplasty Registry (SCAAR), which is a component of the Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies (SWEDEHEART) registry, was used for randomization and for online recording of clinical and procedural data. The SCAAR registry holds data on all patients from the 29 centers performing coronary angiography and PCI in Sweden and from 1 coronary center in Iceland. For the TASTE study, an additional center in Denmark contributed by entering all relevant data. The SCAAR registry is sponsored by the Swedish public health authority and is independent of commercial funding. Monitoring and verification of registry data have been performed in all hospitals since 2001 by comparing 50 variables in 20 randomly selected interventions per hospital with patient records per year. The overall correspondence of data is 95.2%.<sup>10</sup> Long-term follow-up of vital status and date of death were obtained from the national population registry. Data of other secondary end points were obtained from the SWEDEHEART registry and the national discharge registry. The regional ethical review board of Uppsala, Sweden, approved the study (Dnr 2010/111).

Patients included in TASTE with symptom onset to device time of  $\leq 5$  hours, an infarct lesion located in the proximal or mid-LAD, and a TIMI flow score  $< 3$  were eligible for the substudy. One-year secondary end points from the TASTE

trial were included in the analysis: all-cause mortality, time to rehospitalization with myocardial infarction (MI), time to rehospitalization with HF, and time to stent thrombosis (ST). For patients enrolled in 2013 ( $n = 150$  in the substudy),  $< 12$  months, but at least 9 months, of data on time to rehospitalization with HF were complete since patients were censored from the analysis (December 31, 2014). For patients included in Iceland ( $n = 33$  in the substudy), no data on rehospitalization for HF were available and were treated as missing data in the analysis. Data on stroke were not available for Denmark ( $n = 52$  in the substudy). The definition of MI was International Classification of Diseases (ICD) codes I21 and I22, the definition of HF was ICD code I50, and the definition of stroke was ICD code I60-I64. The study was funded by the Swedish Association of Local Authorities and Regions, the Swedish Heart-Lung Foundation, The Swedish Research Council, Svenska Hjärtförbundet, and unrestricted grants from Terumo Medical Corporation, Medtronic, and Vascular Solutions. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the manuscript, and its final contents.

## Statistical analysis

Baseline characteristics were expressed as mean and SD or median and interquartile range for continuous variables and percentages for discrete variables. The Kaplan-Meier method was used for presentation of cumulative event rates within 1 year. Hazard ratios (HRs) for end points at 1 year were calculated using the Cox proportional hazard method with randomized treatment group as the only factor. The results were analyzed according to the intention-to-treat principle. The end points at 1 year were all-cause mortality; rehospitalization for recurrent MI or HF; ST; and the composite of all-cause mortality, MI, HF, or ST. All reported *P* values are 2 sided.  $P < .05$  was considered significant. Analyses were performed with the use of SPSS statistical software version 20.0 (Chicago, IL).

## Results

During the study period, 7,244 patients underwent randomization in the TASTE study. No patients were lost to follow-up, but 6 patients withdrew consent and were included in the analyses only until the date of withdrawal. In total, 70.1% ( $n = 5,080$ ) were treated within 5 hours of symptom onset, 39.6% ( $n = 2,867$ ) were treated for a lesion in the proximal or mid-LAD, and 89.7% ( $n = 6,500$ ) exhibited a TIMI flow from 0 to 2 before PCI. Overall, 1,826 patients (25.2%), 897 randomized to TA and 929 randomized to PCI only, fulfilled the INFUSE-AMI-based criteria. Baseline clinical characteristics according to treatment group for the present substudy and for patients included in the INFUSE-AMI study are listed in the [Table](#).

**Table.** Baseline characteristics of INFUSE-AMI-like patients from the TASTE study and for patients included in the INFUSE-AMI study according to treatment group

Characteristics	INFUSE-AMI-like patients from TASTE, n = 1826		INFUSE-AMI patients, n = 452*	
	TA, n = 897	PCI only, n = 929	TA, n = 229	PCI only, n = 223
Age (y), median (Q1-Q3)	67.0 (59.0-76.0)	65.0 (57.0-74.0)	60.0 (52.0-66.0) to 62 (53.0-73.0)	56 (49.0-68.0) to 62.5 (52.5-71.0)
Male sex, n (%)	696 (77.6)	738 (79.4)	169 (73.8)	165 (74.0)
Hypertension, n (%)	358 (39.9)	362 (39.0)	76 (33.2)	66 (29.6)
Hyperlipidemia, n (%)	148 (16.5)	174 (18.7)	38 (16.6)	33 (14.8)
Diabetes mellitus, n (%)	102 (11.7)	123 (13.7)	34 (14.8)	17 (7.6)
Previous MI, n (%)	84 (9.4)	112 (12.1)	1 (0.4)	3 (1.3)
Previous PCI, n (%)	73 (8.1)	100 (10.8)	5 (2.2)	5 (2.2)
Current smoker, n (%)	238 (26.5)	258 (27.8)	98 (42.8)	108 (48.4)
Heparin before PCI, n (%)	362 (40.4)	380 (40.9)	145 (63.3)	142 (63.7)
Bivalirudin therapy during PCI, n (%)	708 (78.9)	722 (77.7)	228 (96.6)	223 (100.0)
Glycoprotein IIb/IIIa therapy during PCI, n (%)	159 (17.7)	187 (20.1)	116 (50.7)	112 (50.2)
Killip class I, n (%)	819 (91.3)	850 (91.5)	181 (79.0)	186 (83.4)
Time from symptom onset to PCI (min), median (Q1-Q3)	145 (108-200)	140 (105-195)	141 (120-201) to 151 (117-205)	166 (126-233) to 160 (126-217)
Infarct artery lesion location, n (%)†				
Proximal left anterior descending	537 (59.9)	546 (58.8)	142 (62.0)	150 (67.3)
Mid left anterior descending	360 (40.1)	383 (41.2)	96 (41.9)	92 (41.3)
TIMI flow before PCI, n (%)				
0-1	770 (85.8)	788 (84.8)	168 (73.4)	156 (70.0)
2	127 (14.2)	141 (15.2)	61 (26.6)	67 (30.0)

Q1-Q3 denotes interquartile range. There were no significant differences between the TA group and the PCI-only group in the INFUSE-AMI-like cohort from the TASTE study.

\* Adopted from Stone et al.<sup>7</sup>

† Some patients had both proximal and mid left anterior descending stenoses.

## Procedures

In this substudy, 95.7% (n = 858/897) of the patients randomized to TA underwent TA, whereas 96.9% (n = 900/929) of patients in the PCI-only group had PCI only. All patients were treated according to international guidelines, with a high proportion receiving preprocedural platelet inhibition and a high proportion of radial access and use of drug-eluting stents<sup>2</sup>; 78.3% (n = 1,430) were treated with bivalirudin, and 18.9% (n = 346) received Gp2b3a blockers during the procedure.

## Substudy patients compared to nonsubstudy patients

The mean age for patients included in the substudy was similar to that of patients from TASTE but not included in the substudy (66.3 years vs 66.1 years, *P* = .66). Female gender was less frequent in the substudy group compared to the group not included in the substudy (n = 392 [21.5%] vs n = 1428 [26.4%], *P* < .001). The substudy patients were less often treated for hypertension and hyperlipidemia compared to nonsubstudy patients (n = 720 [39.4%] vs n = 2352 [43.4%], *P* = .003, and n = 322 [17.6%] vs n = 1194 [22.0%], *P* < .001, respectively). Previous MI and previous coronary artery bypass graft surgery was also less frequent in patients included in the substudy compared to nonsubstudy patients (n = 202 [11.4%] vs n = 716 [13.8%], *P* = .04, and n = 7 [0.4%] vs n = 136 [2.9%], *P* < .001, respectively) as was active smoking (n = 479 [27.1%] vs n = 1,720 [33.0%], *P* < .001).

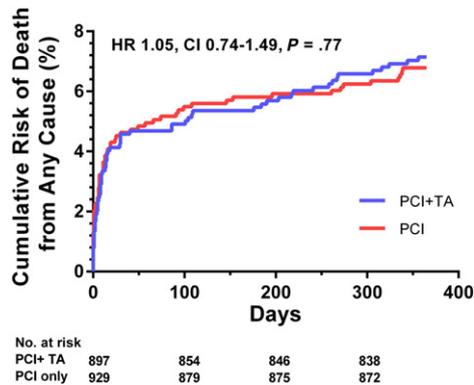
## Clinical outcome in substudy patients compared to nonsubstudy patients

At 1 year, 127 (7.0%) of the patients included in the substudy had died, compared with 266 (4.9%) (*P* = .001) of the patients randomized in TASTE not fulfilling inclusion criteria for this substudy. The risk of rehospitalization for HF at 1 year was higher among TASTE subjects included in this substudy compared to those who were not included (n = 119 [6.6%] vs n = 205 [3.9%], *P* < .001), whereas there was no significant difference in the risk of rehospitalization for MI (n = 57 [2.5%] vs n = 138 [3.1%], *P* = .19) or ST (n = 19 [0.7%] vs n = 40 [1.0%], *P* = .21) at 1 year.

## Clinical outcome in substudy patients according to treatment group

In the substudy cohort, 64 patients (7.1%) randomly assigned to TA died within 1 year, compared to 63 (6.8%) of patients randomized to PCI only (Figure 1) (HR 1.05, CI 0.74-1.49, *P* = .77). Of patients randomized to TA, 26 (2.9%) were hospitalized for MI within the following year compared to 31 (3.3%) in the PCI-only group (Figure 2) (HR 0.87, CI 0.51-1.46, *P* = .59). Sixty-one patients (7.0%) randomized to TA were hospitalized for HF during the first year compared to 58 patients (6.3%) in the PCI only group (Figure 3) (HR 1.10 CI 0.77-1.58, *P* = .58). Stent thrombosis did not differ significantly at 1 year and was reported in 8 patients (0.9%) in the TA group and 11

Figure 1



Estimated cumulative probability of death from any cause within 1 year of PCI only (PCI) or PCI with thrombus aspiration (PCI + TA).

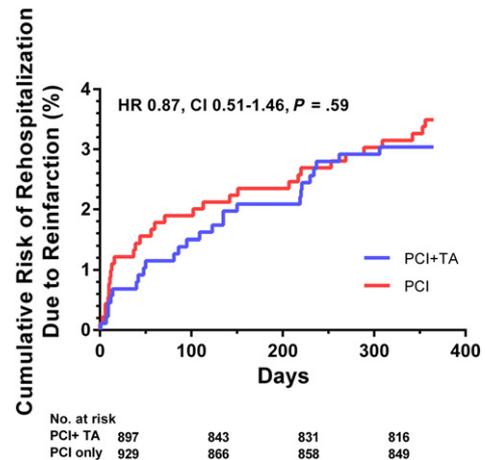
patients (1.2%) in the PCI-only group (Figure 4) (HR 0.75, CI 0.30-1.86,  $P = .53$ ). The 1-year combined end point of all-cause mortality and rehospitalization for MI, HF, or ST occurred in 137 patients (15.3%) in the TA group and in 141 patients (15.2%) in the PCI-only group (Figure 5) (HR 1.00, CI 0.79-1.26,  $P = .99$ ). There was no significant difference in the reported frequency of in-hospital neurologic complications or rehospitalization for stroke at 1 year between the 2 treatment groups (14 patients [1.6%] in the TA group and 12 patients [1.3%] in the PCI only group,  $P = .69$ ). The results of the present substudy cohort were consistent with those of the entire study population with no statistically significant interactions between outcomes of randomized group and inclusion in the substudy ( $P$  value for interaction ranging from .23 to .61).

## Discussion

The chief finding in this substudy of the TASTE trial is that of no significant clinical effect of TA within 1 year, even when focusing only on large anterior MIs with early intervention.

Hypothetically, for any revascularization procedure to improve clinical outcome, it must reduce infarct size because the extent of myocardial necrosis is strongly related to mortality and morbidity.<sup>8,11</sup> For TA, it is also plausible that intervention, by removing a portion of the thrombus, increases the probability of correct stent placement and apposition,<sup>12</sup> which, in the long term, could lead to fewer STs and reinfarctions. In either case, the effect of TA on clinical end points should hypothetically be amplified in a high-risk/high-gain setting with a large area of myocardium at risk. The present substudy from the TASTE material was designed to maximize sensitivity to the likelihood that any such effect of TA would be transferred to clinical outcome. The selected

Figure 2

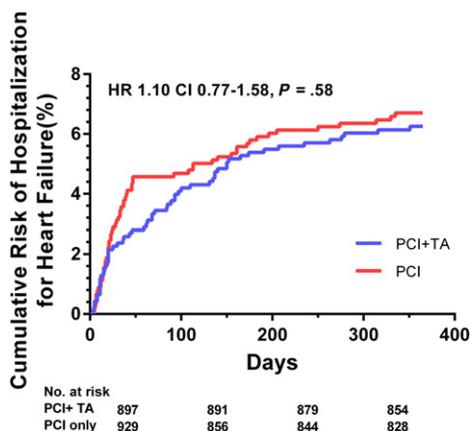


Estimated cumulative probability of hospitalization for reinfarction within 1 year of PCI only (PCI) or PCI with thrombus aspiration (PCI + TA).

subgroup had a higher risk of death or rehospitalization for HF at 1 year compared to the patients randomized in TASTE who did not fulfill inclusion criteria for this subgroup. However, patients with STEMI admitted to the participating hospitals but not randomized in the TASTE trial had an even higher risk of death and adverse cardiovascular outcomes. The primary reason for not being included in TASTE was inability to provide informed consent.<sup>2</sup>

In the INFUSE-AMI trial, the total 1-year all-cause mortality rate was 5.7%, the reinfarction rate was 0.9%, and the rate of rehospitalization for HF was 2.9%. Thus the 1-year risk of death, MI, or HF was higher in a cohort with similar inclusion criteria in our study (7.0%, 3.1%, and 6.6%, respectively), whereas the risk of ST was numerically marginally lower in our study (1.5% vs 1.0%). These findings probably primarily reflect differences in baseline risk profiles of the different study cohorts, especially concerning age. In INFUSE-AMI, the median age ranged from 56 to 62 years in the 4 randomized groups, whereas in this substudy, the median age was 66 years (Table). Impact of differences in treatment protocols cannot be excluded, the most important being that, in the INFUSE-AMI study, 100% of patients were treated with bivalirudin, compared to 78% in our study, and 50% were treated with Gp2b3a blockers (intracoronary) in INFUSE-AMI compared to 19% (intravenously) in our study. In the INFUSE-AMI trial, there was no significant difference in mortality at 1 year between the TA and PCI-only groups, but TA was associated with a significantly lower 1-year risk of rehospitalization for heart failure. However, the INFUSE-AMI study was not powered for clinical events, and the observed reduction was based on 13 events, making the results susceptible to

**Figure 3**



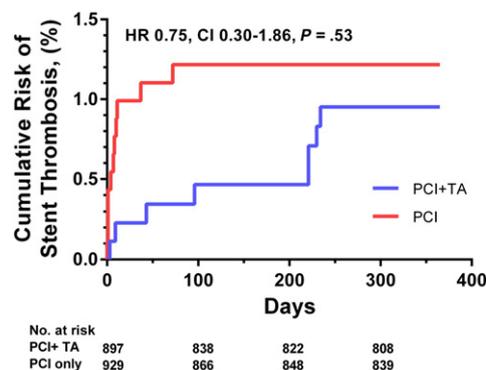
Estimated cumulative probability of hospitalization for heart failure within 1 year of PCI only (PCI) or PCI with thrombus aspiration (PCI + TA).

fortuitous findings. The negative findings in our study are based on 119 events. The INFUSE-AMI study findings do not suggest a pathophysiological explanation for the lower risk of HF because there was no difference in infarct size between the TA and the PCI-only groups at 30 days as estimated by cardiac magnetic resonance imaging. Our substudy revealed no significant benefit of TA with respect to the 1-year risk of readmission for HF. This finding corresponds with the demonstrated lack of effect of TA on left ventricular function as estimated during the index hospital stay.<sup>13</sup>

In this substudy, we selected only patients with a potentially extensive area of myocardium at risk. The studied subgroup of 1,826 patients is more than 4 times the population studied in the INFUSE-AMI trial<sup>7</sup> and substantially larger than the single-center TAPAS-trial (1,071 patients)<sup>14</sup> and most other published randomized trials in the field<sup>15</sup> apart from the recently published TOTAL trial (10,063 patients)<sup>16</sup> The TOTAL study was negative concerning the primary end point (a composite of cardiovascular death, recurrent MI, cardiogenic shock, or HF within 180 days) but suggested an increased stroke risk associated with TA. In our study, there was no sign of an increased risk of stroke associated with TA. In TOTAL, for the prespecified subgroups of TIMI flow 0 to 1, short (<6 hours) symptom duration, and anterior wall infarction, there was no statistically significant interaction suggesting a beneficial effect of TA.

Based on these findings, we suggest that manual TA as an adjunct to PCI in STEMI patients with large anterior MI is ineffective in optimizing perfusion and limiting myocardial damage and adverse clinical outcome. Other measures need to be explored. In the INFUSE-AMI study, all patients were treated with bivalirudin, and the combination of intralesion abciximab and TA

**Figure 4**

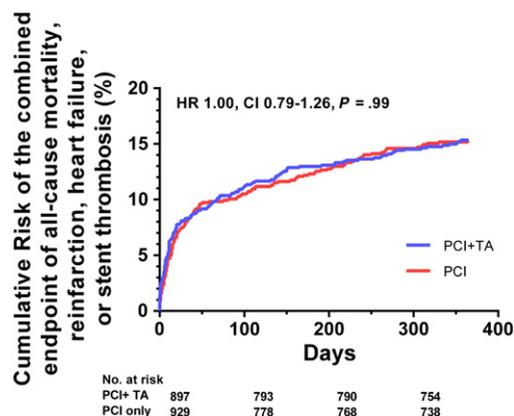


Estimated cumulative probability of stent thrombosis within 1 year of PCI only (PCI) or PCI with thrombus aspiration (PCI + TA).

was associated with a lower rate of death, heart failure, and ST at 1 year compared to no active treatment, although there was no significant evidence of an additive effect. In the TASTE study, there was no indication of a more pronounced clinical effect of TA in patients treated with intravenous bivalirudin or Gp2b3a blockers.<sup>2,3</sup> Nevertheless, the path forward might be to focus investigation on treatment combinations, as opposed to mechanical or pharmacological treatments per se and a number of pharmacological agents have been investigated for intracoronary use in the setting of acute revascularization, not only for reduction of thrombus burden, such as abciximab, but also for reduction of reperfusion injury, such as cyclosporine<sup>17</sup> and exenatide.<sup>18</sup>

This study has several limitations. The study was open label, and clinical end points were not adjudicated. However, the national registries that we used for collection of clinical events are comprehensive and reliable,<sup>19-22</sup> and there is no reason to assume systematic reporting bias with respect to treatment group. Second, although we aimed to include high-risk patients, the patient group with the highest risk was those who did not undergo randomization, mostly due to inability to provide consent.<sup>2</sup> Third, 1-year data on rehospitalization for HF and stroke was not complete for all patients, and these end points are therefore probably, to a minor extent, underreported in this study. Fourth, this is a non-prespecified post hoc analysis of the TASTE material, and the TASTE study was not powered to demonstrate clinical differences in the studied subgroup. Nevertheless, this study is by far the largest study in the field focusing on patients with extensive myocardium at risk, and we found no trend toward a more pronounced effect of TA in this subgroup compared to the findings in the main TASTE trial. We believe that the size of this substudy gives weight to our findings.

Figure 5



Estimated cumulative probability of the combined end point of all-cause mortality, hospitalization due to reinfarction, heart failure, or stent thrombosis within 1 year of PCI only (PCI) or PCI with thrombus aspiration (PCI + TA).

## Conclusion

In the TASTE trial, in STEMI patients with a large area of myocardium at risk and the highest potential clinical effect, TA did not reduce all-cause mortality or other clinical end points at 1 year.

## Disclosures

S.K.J. reports receiving institutional grants for the TASTE trial from Medtronic, Vascular solutions, and Terumo. O.F. reports receiving consultant fees from Biosensors and Biotronik. The other authors do not report any potential conflicts of interests.

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