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CLINICAL INVESTIGATION

# Safety and Feasibility of Transradial Access for Visceral Interventions in Patients with Thrombocytopenia

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**Abstract**
*Purpose* Transradial access (TRA) has shown lower morbidity and decreased bleeding complications compared to transfemoral access. This study evaluates the safety and feasibility of TRA in thrombocytopenic patients undergoing visceral interventions.
*Methods and Materials* Patients who underwent visceral interventions via the radial artery with platelet count less than or equal to 50,000/μL were included in the study. Outcome variables included technical success, access site, bleeding, transfusion, and neurological complications.
*Results* From July 1, 2012, to May 31, 2015, a total of 1353 peripheral interventions via TRA were performed, of which 85 procedures were performed in 64 patients (mean age 62.2 years) with a platelet count <50,000/μL (median 39,000/μL). Interventions included chemoembolization ($n = 46$), selective internal radiation therapy ($n = 30$), and visceral embolization ($n = 9$). Technical success was 97.6 % with two cases of severe vessel spasm requiring ipsilateral femoral crossover. There was no major access site, bleeding, or neurological adverse events at 30 days. Minor access site hematomas occurred in five cases (5.9 %) and were treated conservatively in all cases. Preprocedural platelet transfusions were administered in 23 (27.1 %) cases. There was no statistically significant difference in access site or bleeding complications between the transfused and nontransfused groups.
*Conclusions* Transradial visceral interventions in patients with thrombocytopenia are both feasible and safe, possibly without the need for platelet transfusions.

**Keywords** Clinical practice · Specialty, Arterial intervention · Specialty, Artery · Organ, Intra-arterial · Subspecialty/technique

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## Introduction

Thrombocytopenia is defined as a platelet count below 150,000/μL [1]. A platelet count below this threshold has been shown to cause bleeding complications following endovascular interventions (EVI) and to be associated with increased blood product transfusion [2]. Grade 3 thrombocytopenia, which begins at less than 50,000 platelets/μL [3], is often cited as a threshold for transfusing platelets in advance of endovascular and open surgical procedures [4,

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5]. Thrombocytopenia therefore increases peri-procedural risk by increasing the potential for bleeding complications and by potentially exposing patients to the risks associated with blood product transfusion.

Arterial access for EVI is principally achieved through transfemoral access (TFA). Studies comparing TFA and TRA in percutaneous coronary interventions (PCI) have demonstrated that TRA is associated with fewer access site and bleeding complications [6–9]. These benefits of TRA over TFA have not been demonstrated as robustly for peripheral, noncoronary interventions.

The Society of Interventional Radiology Standards of Practice currently recommend platelet transfusion for platelet counts under 50,000/μL in procedures considered low, moderate, and significant risks of bleeding [5]. Platelet transfusion has been associated with complications including febrile reaction, allergic reaction, bacterial sepsis, and rarely other blood-borne infections [4]. Multiple studies comparing TRA and TFA in PCI cases have demonstrated that patients undergoing TRA-PCI have significantly fewer bleeding and access site complications [10, 11] and receive fewer post-procedural blood product transfusions [12]. We report the first study of peripheral vascular interventions using TRA in thrombocytopenic patients with platelet counts below the transfusion threshold recommended by the SIR Standards of Practice.

## Materials and Methods

### Study Design

This single center study was Health Insurance Portability and Accountability Act compliant and approved by the local institutional review board. We collected data prospectively on 1353 consecutive procedures in 856 patients who underwent peripheral vascular interventions via the radial artery from January 1, 2012, to May 31, 2015. Pre-procedural laboratory values were obtained retrospectively by searching the electronic medical record system (EPIC Inc, Verona, WI).

Patients included in the study had a platelet count of less than 50,000 platelets/μL. The most recent pre-procedural set of laboratory values was used in all cases; the platelet counts provided were obtained pre-transfusion and pre-procedure. Platelet transfusions in a 14-day window (pre-7-day and post-7-day) were recorded. Peri-procedural laboratory values including creatinine, INR, aPTT, and platelet count were obtained. Peri-procedure anticoagulant medications were managed in accordance with the Society of Interventional Radiology consensus guidelines [5].

### Patient Demographics

Sixty-four patients met the inclusion criteria of the study. Patient demographics, medical comorbidities, past medical history, peri-procedural platelet transfusions, and pre-procedure laboratory values were obtained using electronic medical records. A summary of patient baseline characteristics is provided in Table 1.

### Transradial Technique

The standardized technique for peripheral vascular interventions described by Fischman et al. [13] was utilized to gain radial access. With the patient in a supine position, the radial pulse in the left wrist was palpated immediately proximal to the radial styloid process. A Barbeau test was performed in all cases using pulse oximetry to quantify perfusion [14]. Patients were graded according to Barbeau classification [14], and all patients were confirmed as having type A, B, or C waveforms prior to obtaining vascular access. Pre-procedure quantification of the left radial artery diameter was performed using ultrasound; all patients were demonstrated to have a radial artery diameter greater than 2 mm prior to intervention.

The left arm was taped to an arm board, and the left wrist was supinated. A standardized surgical sterilization technique utilizing femoral access drapes was performed. Ultrasound-guided puncture of the radial artery was then performed using a single-wall technique with a 21-gauge, 1.5″ (38 mm) echogenic-tip needle (Terumo, Somerset, NJ). After visualization of arterial blood, a 0.021 nitinol guide wire (Terumo, Somerset, NJ) was placed within the radial artery lumen. If no resistance was encountered, the needle was exchanged for a 5- or 6-French hydrophilic-

**Table 1** Baseline patient demographics ($n = 64$)

| Characteristics | Value |
|---|---|
| Age (years) | 62.2 ± 10.1 |
| Sex | |
| Male | 44 (68.8) |
| Female | 20 (31.3) |
| BMI (kg/m$^2$) | 25.4 ± 6.3 |
| HCC | 56 (87.5) |
| Hypertension | 25 (39.1) |
| Diabetes | 19 (29.7) |
| ESRD | 2 (3.1) |

Values represented as number (percentage), mean ± SD, and median (interquartile range) as appropriate. *BMI* body mass index, *HCC* hepatocellular carcinoma, *ESRD* end-stage renal disease

coated Glidesheath (Terumo, Somerset, NJ), which was cautiously advanced into the artery. A solution of 3000 units of heparin, 200 mg of nitroglycerin, and 2.5 mg of verapamil was administered intra-arterially through the access sheath to diminish the risk of vasospasm [15].

Procedures were then performed using 4, 5, or 6 French catheters ranging from 80 to 125 cm. After procedure completion, all wires and catheters were removed and a TR band (Teurmo, Somerset, NJ) was placed over the arteriotomy site. Patent hemostasis was obtained by inflating the TR band cuff to the point of applying external compression without sufficient pressure to occlude the radial artery [16]. After the documentation of a distal radial pulse and the absence of any access site bleeding, the cuff was left in place for 90 min. The cuff was then incrementally deflated and removed. Upon cuff removal, the radial artery and access site were reexamined, and sterile dressings were applied.

### Technical Success and Complications

Procedures completed as intended without the use of a secondary access site or open surgical intervention were considered technically successful. For transarterial locoregional therapies and peripheral embolizations, this was defined by the delivery of chemoembolic, radiation, or organ-embolic therapy to the pre-procedurally designated target sites. The inability to cannulate any vessel previously designated as a primary target for therapeutic intervention was deemed a technical failure. Nontarget areas of embolization or stent deployment were also considered technical failures. Major and minor adverse access site complications and bleeding within 30 days of the procedure were recorded. Major complications included limb ischemia, pseudo-aneurysm, any access site complication requiring open surgical intervention, and death. Minor complications included the loss of radial pulse without evidence of distal ischemia, development of hematoma, and blood loss not requiring transfusion or open surgical repair. Transfusion reactions included development of fever, urticaria, or anaphylaxis attributed to blood product administration. Evaluation of the access site was performed pre-procedurally, immediately post-procedurally, and at 30-day post-procedural time intervals. All access and bleeding complications were graded according to Society of Interventional Radiology guidelines [17]. Neurological complications were documented according to the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 [3]. All patients received a pre-procedural, immediate, and 30-day post-procedural clinical neurological examination. Any detectable change during this time was considered a major complication.

### Statistics

Categorical data are reported as number (percentage), and continuous data are reported as either mean (SD) or median (interquartile range) as appropriate. Independent samples *t* test was used to determine differences in baseline laboratory values between the transfused and nontransfused groups. A Chi-square test was used to test for differences in complications between transfused and nontransfused groups. All statistical analysis was performed using IBM SPSS Statistics software for Windows, version 20.0.0 (IBM Corporation, Armonk, New York).

## Results

Eighty-five peripheral vascular interventions were performed and are summarized in Table 2. The pre-procedure laboratory values are similarly summarized in Table 3. The technical success rate was 97.6 %. Liver-directed therapies including chemoembolization and selective internal radiation therapy (mapping and delivery of radiation) comprised the majority of procedures. In addition, embolization procedures were performed in the splenic, gastroduodenal, left circumflex humeral, left prostate, and left renal arteries. There were two cases of severe vessel spasm necessitating ipsilateral femoral artery access in order to complete the procedures as planned. Two mortalities occurred within 30 days of a procedure. The first occurred in a patient with a gastroduodenal artery hemorrhage in the immediate postoperative period following a Whipple pancreaticoduodenectomy; the patient was undergoing a planned embolization and developed abdominal compartment syndrome necessitating emergent surgical intervention and later expired. The second mortality occurred in a patient with prostate hemorrhage in the setting of prostate cancer; the patient underwent a failed cystoscopy and fulguration, underwent successful left prostate artery embolization, but expired 7 days post-procedure while transitioning to hospice care. There were no other major adverse events at 30 days. There were no neurological complications within 30 days.

Pre-procedure platelet transfusions were administered in 23 (27.1 %) of the 85 cases. There was a statistically significant difference in the pre-procedure mean platelet count ($p = 0.005$) between the transfused group (33.8/nL; 95 % CI 30.1–37.5/nL) and the nontransfused group (40.2/nL; 95 % CI 38.6–41.8/nL). There was no statistically significant difference between the pre-procedure creatinine ($p = 0.136$), pre-procedure INR ($p = 0.695$), and the pre-procedure PTT values ($p = 0.111$). A median of 2 units of platelets (range 1–4 units) were transfused pre-procedure.

**Table 2** Procedure characteristics ($n = 85$)

| Characteristic | Value |
|---|---|
| Intervention | |
| Chemoembolization | 46 (54.1) |
| SIRT mapping | 24 (28.2) |
| SIRT | 6 (7.1) |
| Embolization—Splenic | 5 (5.9) |
| Embolization—Other[a] | 4 (4.7) |
| Barbeau test | |
| A | 15 (17.6) |
| B | 68 (80.0) |
| C | 1 (1.2) |
| Sheath size | |
| 5-Fr | 81 (95.3) |
| 6-Fr | 4 (4.7) |
| Catheter | |
| 5-Fr Sarah | 69 (81.2) |
| 5-Fr Launcher | 3 (3.5) |
| 5-Fr Sos 1 | 2 (2.4) |
| 5-Fr Cobra | 2 (2.4) |
| 6-Fr Judkins Right | 2 (2.4) |
| Other[b] | 7 (8.2) |

Values represented as number (percentage), mean ± SD, and median (interquartile range) as appropriate. *SIRT* selective internal radiation therapy, *Fr* French, *INR* international normalized ratio, *aPTT* activated partial thromboplastin time; 5-Fr Sarah Radial (Terumo, Somerset, NJ), 5-Fr Sos Omni 1 (Angiodynamics, Latham, NY), 5-Fr Launcher (Medtronic, Minneapolis, MN), 5-Fr Cobra (Terumo, Somerset, NJ), 6-Fr Judkins Right 110 cm (Oscor Inc, Palm Harbor, FL)

[a] Gastroduodenal artery, left renal artery, left prostate artery, and left circumflex humeral artery

[b] 5-Fr Jacky Radial (Terumo, Somerset, NJ), 5-Fr Ultimate 3 (Merit Medical, South Jordan, UT), 5-Fr Glidecath (Terumo, Somerset, NJ), 5-Fr Sherpa IMA (Medtronic, Minneapolis, MN), 5-Fr Sherpa AL1 (Medtronic, Minneapolis, MN), 6-Fr Runway MP2 (Boston Scientific, Marlborough, MA), 4-Fr Tempo Aqua (Cordis, Fremont, CA)

**Table 3** Pre-procedure laboratory values

| Laboratory values | Nontransfused | Transfused | *p* value |
|---|---|---|---|
| Creatinine (mg/dL) | 0.96 ± 0.26 | 1.30 ± 1.05 | 0.136 |
| INR | 1.37 ± 0.34 | 1.33 ± 0.24 | 0.695 |
| aPTT (s) | 35.9 ± 4.8 | 38.5 ± 8.3 | 0.111 |
| Platelets ($\times 10^9$/L) | 41.3 ± 6.8 | 33.8 ± 9.2 | *0.005* |

Italic value indicates statistical significance ($p$ value $< 0.05$)

Values represented as mean ± SD

*INR* international normalized ratio, *aPTT* activated partial thromboplastin time

In 16 of the 23 transfused cases, platelets were administered for peri-procedural prophylaxis at the discretion of the operator in conjunction with consulting teams of physicians. The current guideline at this institution is to administer platelet transfusion for a patient with a platelet level <40,000/μL. However, this guideline was not uniformly applied in all cases. Four transfused cases were performed urgently in patients with active hemorrhage. Two of the twenty-three transfused cases were performed on a patient with transfusion-dependent myelofibrosis. One transfused case was performed on a patient with idiopathic thrombocytopenia.

Minor access site hematomas (grade 1 or 2) [18] were observed in 3/62 (4.8 %) of the nontransfused cases and in 2/23 (8.7 %) of the transfused cases with no statistically significant difference between the two groups ($p = 0.502$). One case of grade 1 hematoma occurred in the setting of a radial artery loop, a variant of radial artery anatomy (Fig. 1). Two radial artery occlusions characterized by loss of radial pulse without evidence of distal ischemia were observed. One of the sixty-two (1.6 %) nontransfused cases was complicated by radial artery occlusion compared with 1/23 (4.3 %) of the transfused cases with no statistically significant difference between the two groups ($p = 0.460$). One of the twenty-three transfused patients developed urticaria and shortness that resolved following the administration of steroids, diphenhydramine, and nebulized albuterol.

## Discussion

Peri-procedural bleeding complications have been associated with increased transfusion requirements and increased morbidity and mortality in patients undergoing PCI [12]. Thrombocytopenia, thereby, compounds the risk of performing endovascular procedures, as interventionalists must weigh the risks of transfusion against the risk of bleeding complications.

The vast majority of data comparing TRA and TFA are focused on PCI where the benefits in bleeding complications, access site complications, and mortality have led to significant growth in the utilization of TRA over the preceding two decades [6–9, 12]. While the benefits of radial access have been satisfactorily shown in cardiology literature for cardiac interventions, radial access has been less extensively studied in peripheral interventions. Procedures in these patient populations differ significantly in the technical aspects of each intervention as well as patient demographics. For example, 88.4 % of our cohort is diagnosed with hepatocellular carcinoma with underlying liver disease, which predisposes patients to bleeding complications. However, concerns over the theoretical risk of cerebral microemboli, which are potentially incurred through transradial access but not yet demonstrated to

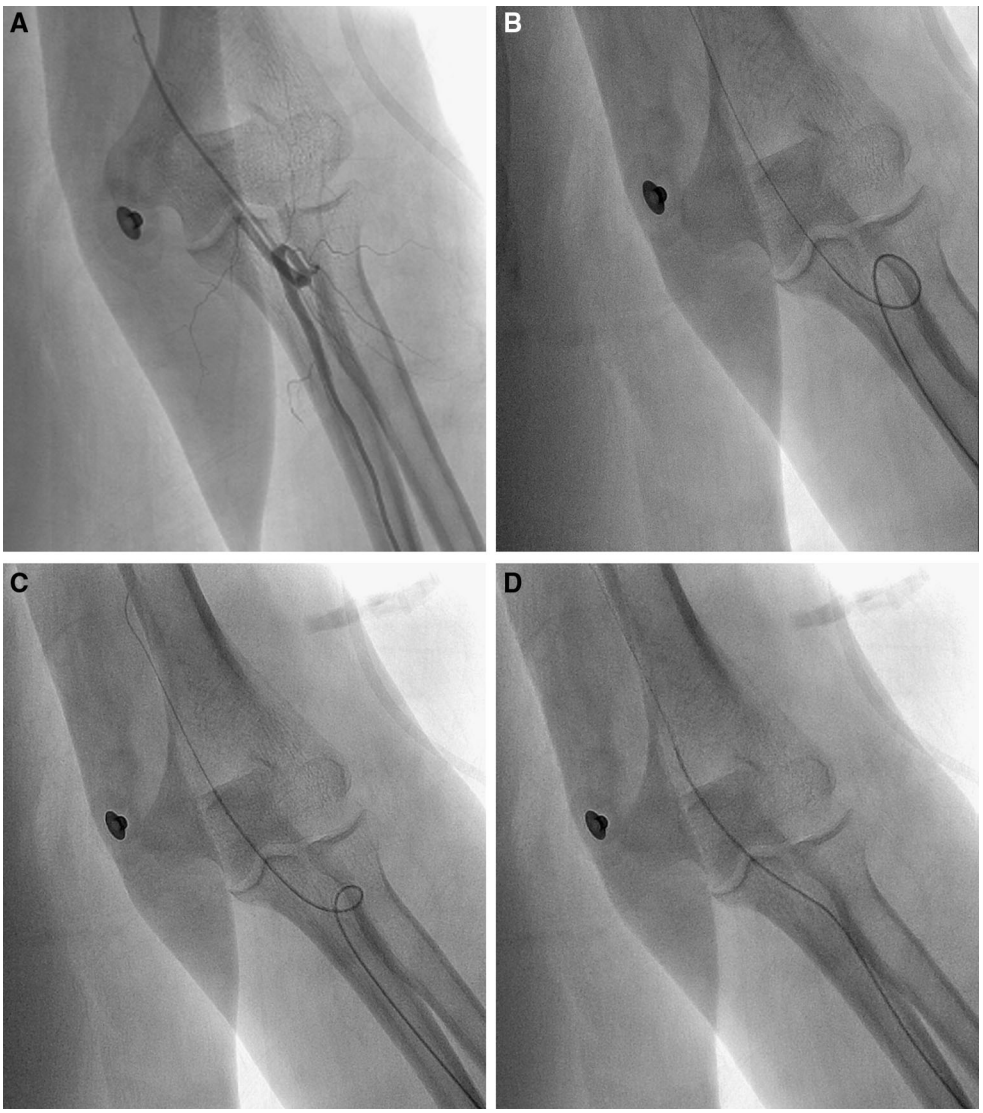


**Fig. 1** A left radial artery loop is identified over the proximal left radius and ulna (**A**). The left radial artery loop is crossed with a Bentson wire (**B**) and subsequently reduced (**C**, **D**). The catheter manipulation at the left radial artery access site required to reduce the left radial artery loop likely contributed to grade 1 hematoma development

occur in peripheral interventions, slowed the uptake of its use in peripheral interventions [19, 20].

We report a number of peripheral EVI performed via the radial artery including transarterial locoregional therapies and peripheral embolizations with a 97.6 % technical success rate. These favorable outcomes occurred while using a broad range of catheter types and anatomic target locations, suggesting minimal technical limitations with sufficient operator experience.

There is established difficulty surrounding the use of manual compression as a vascular closure technique following TFA [21]. Femoral vascular closure devices have documented failure rates and overall complication rates ranging from 3.1 to 11.4 % [22]. This established complication rate combined with the established difficulty of attaining hemostasis in thrombocytopenic patients compounds the risks of access site and bleeding complications for patients undergoing TFA interventions even with appropriate precautionary measures in place.

The reported failure rate of TR band (Terumo, Somerset, NJ) is substantially lower than transfemoral vascular closure devices [23]. In addition, the TR band offers the potential of rapid redeployment should failure occur. Moreover, rare but serious complications of vascular access such as limb threatening ischemia, which can occur post-TFA [24], are exceedingly rare in cases of TRA given the dual blood supply to the hands and the standard pre-procedural assessment of ulnar artery patency in all patients [14].

Interventional radiologists at our institution follow SIR Standards of Practice [17] when determining the

management of thrombocytopenic patients. In the patient population undergoing TRA, however, we believe that the guidelines may be too stringent and may lead to unnecessary blood product administration. Therefore, the decision to administer platelet transfusion is made on a case-by-case basis in coordination with referring physicians. The difference in pre-procedure platelet levels between the transfused and nontransfused groups reflects our practice pattern in that more severe thrombocytopenia cases are more likely to be transfused.

The risks of blood product transfusion in general—and platelet transfusion in particular—are well documented [4]. Indeed, one of the cases included in our study in which peri-procedural prophylaxis with platelet transfusion was undertaken resulted in a reaction characterized by the development of urticaria. Additionally, blood product transfusion has been associated with increased mortality in patients undergoing endovascular coronary and peripheral vascular interventions [12, 25]. It has also been shown that TRA can reduce transfusion rates by as much as half compared with TFA for patients undergoing PCI [12]. It is the authors' hope that this evidence in combination with our promising results will serve as the basis for further studies involving TRA and reductions in peri-procedural transfusions.

More peripheral to the care of an individual patient but relevant to healthcare systems generally is the cost of platelet transfusion. The base cost of a unit of platelets has been cited at approximately $500.00; however, when accounting for the costs of procurement, testing, and storage, the cost is likely above $2000.00 per unit of platelets [26]. While our study did not focus directly on the costs of interventions performed via the radial artery, it appears that fewer units of platelets could be administered to thrombocytopenic patients in these scenarios without increasing bleeding or access site complications and thereby eliminating the costs of prophylactic platelet administration for select patients.

Of the eighty-five interventions included in our study, no neurological complications occurred within 30 days. Previous studies focused on cardiac interventions performed by radial access have demonstrated that TRA increases the risk of cerebral microemboli compared with TFA and that cerebral microemboli are associated with subclinical neurological deficits [19, 27, 28]. Conflicting studies have also emerged; Hamon et al., for example, showed no significant difference in silent cerebral infarcts between TRA and TFA and even hypothesize that the difference in patterns of catheter friction against the aorta between TRA and TFA could render TRA more desirable in reducing cerebral microemoli [20]. Further, the left radial approach has been shown to decrease the risk of cerebral microemboli compared to a right-sided radial artery approach by decreasing catheter exchanges and intravascular mechanical manipulation [29], but the risk is still present. However, successful completion of peripheral interventions does not require catheter manipulation commensurate with that required to cannulate a coronary artery. Ultimately, prospective studies will be required to explicate the relationship between TRA in peripheral interventions and cerebral emboli.

Our results are promising within the limitations of our study design. Our relatively small sample size restricts the certainty of our safety outcomes. The nonuniform application of institutional guidelines for platelet administration at a particular platelet level limits the generalizability of our results. In addition, the generalizability of our results is also limited by the significant TRA experience of our interventional radiologists, who have collectively performed over 1300 TRA procedures. Although none of the procedures included in our study resulted in neurological complications, the relationship between TRA in peripheral interventions and cerebral emboli formation remains unresolved. While TRA-PCI has been shown to have fluoroscopy times equivalent to TFA-PCI [30], our study does not measure procedure and fluoroscopy times compared to TFA interventions required to achieve our 97.6 % rate of technical success. Similarly, the lack of a comparable TFA cohort limits our ability to ascertain relative benefits across access sites.

In conclusion, TRA is a viable alternative to TFA for an array of peripheral vascular interventions in patients with thrombocytopenia. While our sample size imposes certain limitations, the absence of major access site and neurological complications suggests TRA can be performed safely in thrombocytopenic patients.

#### Compliance with Ethical Standards

**Conflict of interest** J J. Titano, D.M. Biederman, B.S. Marinelli, N.E. Tabori, F.S. Nowakowski: Nothing to disclose; R.S. Patel: Consultant: Sirtex Medical Ltd, Reverse Medical Corp; Speaker's Bureau: Penumbra, Inc., St. Jude Medical, Inc., Terumo Interventional Systems; E. Kim: Consultant: Onyx Pharmaceuticals; Advisory Board: Onyx Pharmaceuticals, BTG International Ltd; Speaker's Bureau: BTG International Ltd; R.A. Lookstein: Consultant: Boston Scientific Corporation, Cordis Corp, MEDRAD Interventional/Possis Partnership; Advisory Board: Boston Scientific Corporation; A.M. Fischman: Consultant: Surefire Medical, Terumo Interventional Systems; Advisory Board: Terumo Interventional Systems; Speaker's Bureau: NeuWave Medical, Surefire Medical, Terumo Interventional Systems.

**Ethical standard** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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