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### **TCT-175 Safety and Complications Associated With the Use of Protamine in Percutaneous Coronary Intervention**

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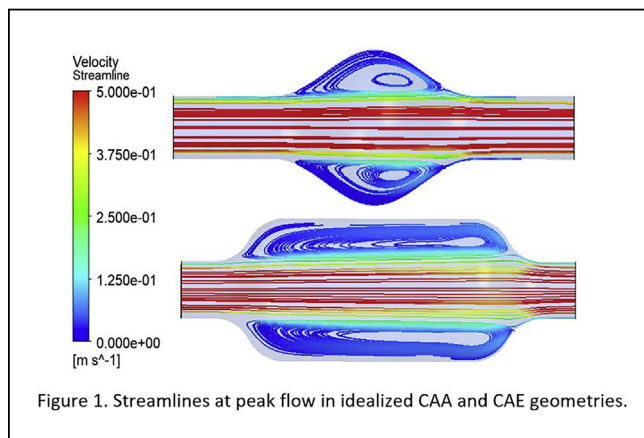


Figure 1. Streamlines at peak flow in idealized CAA and CAE geometries.

**CONCLUSIONS** Our results demonstrate that although having the same diameters and z-scores, CAE can induce higher risk for thrombus formation.

**CATEGORIES CORONARY:** Acute Coronary Syndromes

#### TCT-175

##### Safety and Complications Associated With the Use of Protamine in Percutaneous Coronary Intervention

Hussayn Alrayes,<sup>1</sup> Ayman Alsaadi,<sup>2</sup> Ahmad Alkhatib,<sup>2</sup> Dhruvil Patel,<sup>3</sup> Mohammad Alqarqaz,<sup>4</sup> Tiberio Frisoli,<sup>1</sup> Brittany Fuller,<sup>2</sup> Akshay Khandelwal,<sup>5</sup> Gerald Koenig,<sup>1</sup> Brian O'Neill,<sup>1</sup> Pedro Villablanca,<sup>1</sup> Mohammad Zaidan,<sup>6</sup> William O'Neill,<sup>1</sup> Khaldoon Alaswad,<sup>1</sup> Mir Basir<sup>1</sup> Henry Ford Hospital, Detroit, Michigan, USA; <sup>2</sup>Henry Ford Health, Detroit, Michigan, USA; <sup>3</sup>Wayne State University School of Medicine, Detroit, Michigan, USA; <sup>4</sup>Henry Ford Hospital, West Bloomfield, Michigan, USA; <sup>5</sup>Henry Ford Hospital, Northville, Michigan, USA; <sup>6</sup>Henry Ford Hospital, Beverly Hills, Michigan, USA

**BACKGROUND** There is a paucity of data on the use of protamine after percutaneous coronary intervention (PCI).

**METHODS** We conducted a retrospective analysis of 168 patients who underwent PCI from 2015 to 2021. All patients received protamine intra- or immediately after index PCI. We evaluated baseline characteristics, intraprocedural characteristics including heparin dosing and protamine dosing, and complications such as acute stent thrombosis (ST), dissection, perforation, and access-site bleeding. The primary outcome was the incidence of acute ST, subacute ST, and other thrombotic complications. Secondary outcomes included mortality within 24 hours and within 28 days of the index procedure.

**RESULTS** One hundred sixty-eight patients were included. The mean age of patients was  $72 \pm 12.1$  years, and 36% were women. The majority of patients received antiplatelet therapy prior to the index procedure (90%), and the average ejection fraction (EF) was  $50\% \pm 14.3\%$ . Of the 33 insulin-dependent patients (20%), only 1 (0.5%) used neutral protamine Hagedorn insulin. One hundred fifteen of the procedures (68%) were elective, and the average procedure time was 3 hours 21 minutes (SD 1 hour 43 minutes). Fifty-nine patients underwent rotational, orbital, or laser atherectomy (27, 23, and 9 patients, respectively). An average of  $2.59 \pm 1.38$  stents were deployed, and intravascular ultrasound was used in 96 patients (57%). An average protamine dose of 32 mg was administered. Seventy-three patients (43%) had coronary perforations, and 19 (11%) had pericardial effusions requiring pericardiocentesis. Twenty-one patients (13%) had coronary dissections following PCI, and 6 (4%) had access-site bleeding requiring transfusion. Three patients (2%) underwent urgent cardiac surgery. Eight (5%) died within 24 hours of PCI, and 6 (3.5%) died within 28 days of PCI. Four patients (2%) had acute ST, no patients experienced subacute ST, and 1 patient (0.5%) developed arterial thrombosis (common femoral artery).

**CONCLUSIONS** Use of protamine in PCI typically occurred because of intraprocedural complications. In our series, protamine was tolerated well in the majority of patients, but 3% of patients experienced coronary or arterial thrombosis, warranting caution when using protamine in these challenging scenarios.

**CATEGORIES CORONARY:** Stents; Drug-Eluting

## REVASCULARIZATION IN CALCIFIED LESIONS I

Abstract nos: 176-180

#### TCT-176

##### Randomized Comparison of Intracoronary Lithotripsy and Rotational Atherectomy for the Treatment of Severely Calcified Vessels—ROTA.shock Trial

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**BACKGROUND** Severely calcified coronary lesions provide a particular challenge for percutaneous coronary intervention. Intracoronary lithotripsy (IVL) has been recently introduced for plaque modulation of these lesions. Rotational atherectomy (RA) is the current gold-standard treatment for severely calcified lesions, but it is usually associated with higher procedural risks. The aim of this ongoing study is to show the noninferiority of IVL compared with RA in the treatment of severely calcified coronary lesions regarding minimal stent area.

**METHODS** IVL or RA was performed randomly in 61 patients with severe lesion calcification. Optical coherence tomography was performed preprocedurally as well as immediately postprocedurally. The primary efficacy endpoint was post-percutaneous coronary intervention minimal stent area, measured on optical coherence tomography at an independent core laboratory at completion of enrollment, in all randomly allocated participants who had primary outcome data. The primary safety endpoint was procedural MACE.

**RESULTS** The mean patient age was  $73 \pm 7$  years. All patients were symptomatic with stable angina. There was a trend toward shorter procedure time when comparing IVL with RA ( $66 \pm 19$  min vs  $80 \pm 35$  min;  $P = 0.25$ ). Minimal stent areas were similar after RA ( $6.73 \pm 2.58$  mm<sup>2</sup> vs  $5.97 \pm 2.1$  mm<sup>2</sup> [ $P = 0.62$ ] and  $6.82 \pm 2.44$  mm<sup>2</sup>). There were also no differences in stent symmetry (eccentricity index after lithoplasty  $0.64 \pm 0.09$  vs rotablation  $0.67 \pm 0.07$ ;  $P = 0.61$ ) or strut malapposition (mean malapposition area  $0.70 \pm 0.41$  mm<sup>2</sup> vs  $0.61 \pm 0.41$  mm<sup>2</sup>;  $P = 0.32$ ) between IVL and RA. Troponin I trended toward lower levels after IVL ( $0.38 \pm 0.43$  ng/mL vs  $0.88 \pm 0.90$  ng/mL;  $P = 0.11$ ). There were no periprocedural adverse events.

**CONCLUSIONS** IVL is a promising treatment option for severely calcified coronary lesions and is not inferior to RA in terms of minimal stent area. Most notably, in RA procedure time, contrast volume and radiation dose tend to be higher compared with IVL. These data warrant a large-scale clinical trial to prove clinical outcomes after IVL in comparison with RA.

**CATEGORIES CORONARY:** Coronary Atherectomy, Plaque Modification, Lithotripsy, and Thrombectomy

#### TCT-177

##### Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Lesions: Final 2-Year Results From the Disrupt CAD III Study

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