High frequency of brachiocephalic trunk stent fractures does not impair clinical outcome

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Objective: **Stenting is the preferred, minimally invasive treatment for innominate artery (IA) stenosis or occlusion. Stent fractures in the IA have not been assessed in larger cohorts. In this retrospective study, we examined the frequency and risk factors of IA stent fractures.**

Methods: **The final analysis included 32 patients (15 women; mean age, 59.4 ± 12.0 years) with 32 balloon-expandable stents (2000 to 2009). In 2010, the patients were asked to come back for a fluoroscopic examination of the implanted stents. Stent fractures and their relationship to atherosclerotic risk factors, lesion characteristics, postprocedural symptoms, and in-stent restenosis were analyzed. Fisher exact test and univariate Cox regression analysis were used in the statistical evaluation.**

Results: **Lesions were >20 mm in 14 patients (44%) or heavily calcified in 13 (41%). The mean follow-up time was 33.4 ± 21.0 months. Postprocedural symptoms were noted in nine patients (28%). Significant restenosis was detected in 22% of the implanted stents, and 11 stent fractures (34%) were found. The prevalence of heavily calcified lesions, postprocedural symptoms, and in-stent restenosis did not differ significantly between groups with and without fracture. Long lesions were associated with an increased incidence of stent fracture (hazard ratio, 5.09; 95% confidence interval, 1.33-19.48; $P = .017$). No correlation was observed between stent fractures and old age (≥70 years), female gender, smoking, hypertension, hyperlipidemia, or diabetes mellitus.**

Conclusions: **IA stent fractures are common but seem to have no effect on symptoms and in-stent restenosis rates. (J Vasc Surg 2014;59:781-5.)**

Innominate artery (IA) stenosis or occlusion can be asymptomatic or symptomatic. The cerebrovascular symptoms include signs of posterior circulation ischemia due to flow reversal in the right vertebral artery (subclavian steal syndrome) and, less commonly, transient ischemic attack (TIA) or stroke as a result of distal embolization. The right upper extremity symptoms are related to hypoperfusion or distal embolization.

Endovascular or surgical recanalization procedures are required in symptomatic patients.[1] Percutaneous transluminal angioplasty (PTA) combined with stenting was first reported in the 1980s, and since then, has become the primary treatment of IA stenosis. The efficacy of IA stenting has been validated in follow-up studies, which showed low complication and high primary patency rates.[2-5] Surgical reconstruction is preserved for patients with a high amount of calcium deposition or difficult anatomy.

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Recent studies have extensively investigated stent fractures in the lower limb, coronary, carotid, and vertebral arteries.[6-9] However, with the exception of individual case reports[10,11] and a small survey of nine patients,[12] no comprehensive data have been published on stent fracture prevalence in the IA. We hypothesized that IA stent fractures are common due to the proximity of the beating heart and movements of the shoulder girdles and the arms. The purpose of this retrospective study was to determine the frequency and risk factors of IA stent fractures. We also aimed to examine the effect of stent fractures on postprocedural symptoms and in-stent restenosis rates.

METHODS

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Semmelweis University Ethics Committee. All participants provided written informed consent. No compensation was provided for participation in the study; only travel expenses were covered.

Patient selection and lesion characteristics. All patients who underwent IA stenting between January 1, 2000, and December 31, 2009, were included: 49 IA lesions were treated with stent implantation in 49 patients. Six of the 49 patients did not have a follow-up examination because of death caused by stroke in 1 patient, at 3 months, acute myocardial infarction in 2 patients, at 5 and 11 months, and cancer in 3 patients. The study excluded three patients who received self-expandable stents, and eight patients did not return for fluoroscopic examination.

The final analysis therefore included 32 patients with 32 balloon-expandable stents. The procedures were performed in the Heart and Vascular Center of Semmelweis University (Budapest, Hungary).

Lesions were considered long if their length was ≥20 mm. Lesions were defined as heavily calcified if calcification was present along the entire length of the IA by fluoroscopy.

Innominate artery stenting protocol. The preprocedural work-up included clinical data collection (symptoms, risk factors, which were described in detail previously,[13] and medical history), radial pulse palpation and blood pressure measurement in both arms, neurologic evaluation, and duplex scan of the neck arteries. In recent years, computed tomography (CT) or magnetic resonance angiography have become part of the preprocedural imaging protocol in patients with multivessel supra-aortic disease to evaluate which lesion should be treated first.

Acetylsalicylic acid (100 mg) was given orally for at least 3 days before the procedure and was continued permanently. Heparin (5000 IU) was administered intra-arterially at the beginning of the procedure. Blood pressure and electrocardiogram waves were monitored continuously. The procedures were carried out through femoral artery access. In patients with IA occlusion, the right brachial artery was also punctured.

The initial diagnosis was confirmed by thoracic aortography before the stent placement in all patients. A 4F pigtail catheter (Cordis Corp, Johnson & Johnson Co, Miami, Fla) was inserted into the aortic arch over a standard polytetrafluoroethylene-coated 0.035-inch wire (J-curved on one end, straight on the other end). Selective catheterization (H1, JB2, or SIM2; Cordis Corp) of the IA was performed in all patients, except those with IA occlusion.

A hydrophilic (standard or stiff) angled-tip 0.035-inch Terumo guidewire (Terumo Medical Corp, Tokyo, Japan) was advanced into the IA to pass through the stenosis or occlusion under fluoroscopic control. Thereafter, the 4F introducer sheath (Terumo Medical Corp) was exchanged for a long 7F sheath (Cordis Corp) over a standard or a hydrophilic stiff (Terumo) or a super-stiff 0.035-inch Amplatz wire (Boston Scientific Corp, Natick, Mass). We did not use embolic protection devices for the intervention.

The diameter of the patent segment and length of the lesion were measured on selective angiograms for accurate sizing of the stent. The indication for stent placement was a suboptimal PTA due to unfavorable lesion morphology (eg, heavily calcified lesions, occlusions) or a failed angioplasty. Different balloon and stent types were used, depending on the availability of devices and personal preference of the interventional radiologist. The angioplasty balloons were Wanda (size, 7-10 mm × 40 mm; Boston Scientific Corp) in eight patients and Pheron (size, 7-8 mm × 40 mm; Biotronik AG, Bülach, Switzerland) in seven. Direct stent implantation was performed without predilatation in 17 of the 32 patients. One Bard (3%) stent (size, 12 mm × 20 mm; C.R. Bard Inc, Murray Hill, NJ) and 31 Palmaz Genesis (97%) stents (size, 8-10 mm × 19-29 mm; Cordis Corp) were deployed. When it was necessary because of difficult access due to angulation at the origin of the IA or high-grade stenosis or occlusion, a long Mach 1 guiding catheter (Boston Scientific Corp) was used, and the stenosis was dilated first with a 3- to 4-mm coronary balloon over a 0.014-inch wire then with a 5- to 6-mm peripheral balloon, after which the stent was easily pushed through the lesion.

On completion angiography, the IA was imaged in a 30° to 45° right anterior oblique plane, the ipsilateral cerebral arteries in a posteroanterior 30° to 45° (right and left) anterior oblique and lateral planes, and the ipsilateral upper extremity arteries in a posteroanterior plane. Finally, the sheath(s) were removed and the punctured artery(ies) were compressed manually, followed by pressure bandage(s) overnight or, in more recent cases, the femoral artery was closed by an Angio-Seal percutaneous closure device (St. Jude Medical Inc, Little Canada, Minn). Patients were discharged 1 or 2 days after the procedure.

Technical success was defined as <30% residual stenosis without dissection or extravasation, whereas clinical success meant resolution of the symptoms.

Follow-up. Follow-up visits were scheduled at 4 weeks and at 6 and 12 months after the stenting, and annually thereafter. The postprocedural examinations included clinical data collection, radial pulse palpation, blood pressure measurement in both arms, and a duplex scan. On the basis of these evaluations, patients in whom significant IA in-stent restenosis or reocclusion was suspected had no palpable right radial pulse, had a blood pressure difference (≥30 mm Hg) between arms, or right subclavian steal syndrome. The suspected IA in-stent restenoses or reocclusions were verified with CT angiography in symptomatic patients.

In 2010, the patients were asked to come back for an additional follow-up visit, when a fluoroscopic evaluation was also performed in addition to the above-mentioned examinations. The patients were told that X-rays usually have no side effects in the typical diagnostic range for this examination. The high-magnification fluoroscopic examinations were done in the angiography suite (AXIOM Artis FA; Siemens Medical Solutions AG Company, Erlangen, Germany) with the following parameters: 7.5 fps, 100 to 125 kV, and 550 to 800 mA.

To visualize the implanted stents, three cine loops with a length of three cardiac cycles were recorded in posteroanterior, right, and left anterior oblique 30° to 45° projections. The postprocessing was performed on a Leonardo Workstation (Syngo 2003; Siemens Medical Solutions). The fluoroscopic images were analyzed by two experienced interventional radiologists (K.H., B.N.) in consensus.

Stent fractures were defined according to a nitinol stent fracture classification that has been proposed by the Cardiovascular Institute of the South (Houma, La).[14] Type I is a single-strut fracture, type II fractures represent multiple stent fractures that can occur at different sites, type III is a complete transverse fracture without stent