

# Perioperative Complications After Aorto-iliac Stenting: Associated Factors and Impact on Follow-up Cardiovascular Prognosis

O. Iida <sup>a,\*</sup>, Y. Soga <sup>b</sup>, M. Takahara <sup>c</sup>, D. Kawasaki <sup>d</sup>, Y. Yamauchi <sup>e</sup>, K. Suzuki <sup>f</sup>, K. Hirano <sup>g</sup>, R. Koshida <sup>h</sup>, D. Kamoi <sup>i</sup>, J. Tazaki <sup>j</sup>, M. Higashitani <sup>k</sup>, Y. Shintani <sup>l</sup>, T. Yamaoka <sup>m</sup>, S. Okazaki <sup>n</sup>, N. Suematsu <sup>o</sup>, T. Tsuchiya <sup>p</sup>, Y. Miyashita <sup>q</sup>, N. Shinozaki <sup>r</sup>, H. Takahashi <sup>s</sup>, M. Uematsu <sup>a</sup>

<sup>a</sup> Cardiovascular Center, Kansai Rosai Hospital, Amagasaki, Japan

<sup>b</sup> Department of Cardiology, Kokura Memorial Hospital, Kitakyushu, Japan

<sup>c</sup> Department of Metabolic Medicine, Osaka University Graduate School of Medicine, Osaka, Japan

<sup>d</sup> Cardiovascular Division, Department of Internal Medicine, Hyogo College of Medicine, Nishinomiya, Japan

<sup>e</sup> Department of Cardiology, Kikuna Memorial Hospital, Yokohama, Japan

<sup>f</sup> Department of Cardiology, Sendai Kosei Hospital, Sendai, Japan

<sup>g</sup> Department of Cardiology, Saiseikai Yokohama-city Eastern Hospital, Yokohama, Japan

<sup>h</sup> Department of Cardiology, Tokeidai Memorial Hospital, Sapporo, Japan

<sup>i</sup> Department of Cardiology, Nagoya Kyoritsu Hospital, Nagoya, Japan

<sup>j</sup> Department of Cardiovascular Medicine, Graduate School of Medicine, Kyoto University, Kyoto, Japan

<sup>k</sup> Department of Cardiology, Tokyo Women's Medical University, Tokyo, Japan

<sup>l</sup> Department of Cardiology, Shin-Koga Hospital, Kurume, Japan

<sup>m</sup> Department of Vascular 1 Surgeon, Matsuyama Red Cross Hospital, Matsuyama, Japan

<sup>n</sup> Department of Cardiology, Juntendo University Nerima Hospital, Tokyo, Japan

<sup>o</sup> Department of Cardiology, Fukuoka Red Cross Hospital, Fukuoka, Japan

<sup>p</sup> Division of Cardiovascular Trans-catheter Therapeutics, Kanazawa Medical University Hospital, Kanazawa, Japan

<sup>q</sup> Department of Advanced PAD Therapeutics, Shinshu University, Matsumoto, Japan

<sup>r</sup> Department of Cardiology, Tokai University Hospital, Isehara, Japan

<sup>s</sup> Department of Cardiology, Pulmonology and Nephrology, Yamagata University School of Medicine, Yamagata, Japan

## WHAT THIS PAPER ADDS

Because of acceptable durability, low operative mortality, device improvement, and increased operator experience, stent-supported endovascular therapy is widely used and considered first-line therapy for patients with aorto-iliac occlusive disease in clinical practice. In light of the association between perioperative complications (POC) occurrence and clinical outcomes documented in this study, stratification based on number of risk factors for POC occurrence plays an important role in decision making in this therapeutic modality.

**Objectives:** To investigate factors associated with 30-day perioperative complications (POC) after aorto-iliac (AI) stenting, and to compare follow-up cardiovascular prognosis between patients with and without POC.

**Materials and methods:** This was a retrospective multicenter study. We used a multicenter database of 2012 consecutive patients who successfully underwent AI stenting for peripheral arterial disease in 18 centers in Japan from January 2005 to December 2009 to analyze independent predictors of POC and impact of POC on prognosis by logistic regression and a Cox proportional hazard regression model, respectively.

**Results:** Mean age was  $71 \pm 9$  years (median: 72 years; range: 37–98 years), and 1,636 patients (81%) were men. POC occurred in 126 patients (6.3%). In multivariate logistic regression analysis, old age ( $\geq 80$  years), critical limb ischemia (CLI), and Trans Atlantic Inter-Societal Consensus (TASC) II class C/D were independently associated with POC with adjusted odds ratios and 95% confidence intervals (CI) of 1.9 (1.3–2.9), 2.3 (1.5–3.4), and 2.4 (1.6–3.4), respectively. Out of 2012 patients, 1995 were followed up for more than 30 days (mean:  $2.6 \pm 1.5$  years; range: 2–2,393 days). In a Cox hazard regression model adjusted for baseline clinical characteristics, POC was positively and independently associated with follow-up major adverse cardiac events (adjusted hazard ratio [HR]: 1.9; 95% CI: 1.3–2.8;  $p = .002$ ), but not with major adverse limb events and target lesion revascularization (adjusted HR: 1.4; 95% CI: 0.7–2.7;  $p = .25$ ; and adjusted HR: 1.2; 95% CI 0.6–2.6;  $p = .568$ ), respectively.

\* Corresponding author. O. Iida, Kansai Rosai Hospital Cardiovascular Center, 3-1-69 Inabaso, Amagasaki, Hyogo 660-8511, Japan.

E-mail address: [iida.osa@gmail.com](mailto:iida.osa@gmail.com) (O. Iida).

1078-5884/\$ — see front matter © 2013 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved

<http://dx.doi.org/10.1016/j.jvs.2013.09.024>

**Conclusions:** Age >80 years, CLI, and TASC C/D lesion were positively associated with POC after AI stenting. Occurrence of POC appears to adversely affect follow-up cardiovascular, but not limb and vessel prognosis.

© 2013 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved

Article history: Received 4 July 2013, Accepted 24 September 2013, Available online 2 October 2013

**Keywords:** Aorto-iliac occlusive disease, Endovascular therapy, Perioperative complications, Stent

## INTRODUCTION

For localized (Trans Atlantic Inter-Societal Consensus [TASC] A/B) aorto-iliac occlusive disease (AIOD), stenting is considered the treatment of choice with high technical success rate<sup>1</sup> and acceptable durability thanks to recent device improvements and increased operator experience.<sup>2,3</sup> Extensive (TASC C/D) AIOD also is treated with stent-supported endovascular therapy (EVT) depending on site and operator experience, and studies have documented encouraging durability and low procedural mortality rates.<sup>4</sup> Although in the latter setting the long-term primary patency rate cannot yet compete with that reported for open reconstruction surgery, primary patency loss is predominantly treated by repeat EVT achieving secondary patency rates of 80–90%, which appear comparable to those of surgical bypass therapy.<sup>5,6</sup> Moreover, from the recent covered versus balloon expandable stent trial (COBEST) trial, covered stents perform better for TASC C and D lesions than bare stents in terms of longer-term patency and clinical outcome.<sup>7</sup> Because a wide range has been reported for rates of perioperative complications (POC) after stent-based AIOD treatment likely secondary to heterogeneity in techniques, devices, study populations, and comorbidities, we investigated clinical factors associated with 30-day POC after aorto-iliac (AI) stenting and assessed impact of POC on mid-term cardiovascular outcomes.

## METHODS

### Study population

This study enrolled consecutive patients who underwent stent placement for de novo atherosclerotic AI lesions in 18 centers in Japan from January 2005 to December 2009. In all participating centers in this study, AI disease was defined as arterial lesions spanning from the juxtarenal aorta to the external iliac artery (Fig. 1). Exclusion criteria have been reported previously<sup>7</sup> as (1) asymptomatic or with unknown symptoms before procedure ( $n = 53$ ); (2) treatment with angioplasty alone ( $n = 161$ ); (3) restenotic lesions ( $n = 125$ ); (4) lesions secondary to radiation or dissection ( $n = 0$ ); (5) history of lower extremity bypass surgery or EVT ( $n = 169$ ); (6) acute onset limb ischemia ( $n = 0$ ); (7) failed endovascular revascularization ( $n = 51$ ); or (8) inadequate data ( $n = 84$ ). Clinical factors associated with 30-day POC after AI stenting and impact of POC on follow-up prognosis were assessed in an overall population of 2012 consecutive patients who successfully underwent AI stenting and completed 30-day POC assessment. The study protocol was designed in accordance with the Declaration of Helsinki, approved by the ethics committee of each participating hospital, and registered with the University Hospital

Medical Information Network-Clinical Trial Registry (UMIN000006032). All patients provided written informed consent.

### Interventional procedure

Indication and strategy for endovascular procedure were decided by consensus among consulting vascular specialists, including vascular surgeons and interventional radiologists, based on findings in computed tomography or duplex ultrasound prior to diagnostic angiography of the lower limb. EVT was performed by an interventional radiologist at all centers but one, which reflects the fact that the vast majority of cardiac and peripheral vascular procedures in Japan are done by interventional cardiologists and radiologists. Indication of revascularization for AIOD included lesions with >50% diameter stenosis assessed by angiography and mean pressure gradient >10 mmHg evaluated by a 4-Fr diagnostic catheter. The EVT approach and stent selection were decided by the operators based on anatomical features. In general, for AIOD stenotic lesions, a 6-F sheath was inserted retrogradely through a femoral access, and 5,000 units of unfractionated heparin were injected intra-arterially. A 0.035- or 0.014-inch wire was advanced into the lesion, and the stent was directly deployed followed by dilation of an optimally sized balloon for 60 seconds. For totally occlusive lesions, a bi-directional approach, namely antegradely from brachial artery and retrogradely from ipsilateral femoral artery, was regularly used for recanalization and the intraluminal approach was generally used, with the subintimal approach with the wire loop technique being reserved for cases of failed wire-crossing. Re-entry devices were not approved for use in Japan at the time of the study. After successful wire-crossing of chronic total occlusion (CTO) lesions, direct stenting with encouraging angioplasty was done for prevention of distal embolization and vessel perforation based on each individual site's interventional experience. Post-procedure, the Angioseal STS PLUS (St. Jude Medical, St Paul, MN, USA) closure device was employed whenever possible. Iso-osmolar contrast medium was used during procedures with inconsistent use among centers of low osmolarity contrast medium. Dual antiplatelet therapy (aspirin 100 mg/d and cilostazol 200 mg/d, or ticlopidine 200 mg/d) was started at least 1 week prior to EVT and continued until follow up completion; clopidogrel was not approved for use in Japan at the time of study onset. All patients were followed up at 1 and 4 weeks, and every 3 months thereafter. Duplex ultrasound and ankle-brachial index (ABI) assessment for restenosis were routinely conducted at follow-up. The decision for target lesion revascularization (TLR) was clinically driven by recurrent symptoms and by angiographic assessment.

Download English Version:

<https://daneshyari.com/en/article/5958507>

Download Persian Version:

<https://daneshyari.com/article/5958507>

[Daneshyari.com](https://daneshyari.com)