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Editorial

Endovascular Therapy of Iliac Artery Disease: Stent Matters

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Korean patients with peripheral arterial disease (PAD) have a poorer quality of life than those with renal failure or arthritis.[1] Instead of surgical bypass in patients with PAD, endovascular therapy (EVT) has been widely used and is less invasive with less perioperative morbidity, so it plays an important role in treating PAD.[2][3] Even in patients with iliac artery disease, EVT is more commonly applied than surgical bypass, and it has become the standard treatment for vascular revascularization.[2] Recent recommendations describe EVT as a primary treatment for aorto-iliac artery disease, not only for TASC II A and B but also for complex lesions, such as TASC II C and D.[3]

Revascularization with self-expandable (SE) stents, balloon-expandable (BE) stents, and covered stents may be used for EVT of iliac artery disease, but the question regarding what type of stent should be used is ongoing.

First, physicians must compare the results from SE and BE stents in the iliac artery. One multicenter retrospective study of 2,147 patients showed no difference; one-third used a BE stent, two-thirds used a SE stent, and the primary patency rate at 5 years was 79% in the BE stent group and 75% in the SE stent group.[4] The study had some limitations. The SMART™ stent, which was previously used mainly because the EPIC™ stent was not available, was used in 73.7% and 38.7% of patients who had combined infrainguinal arterial lesions.

Two important studies showed different results. The randomized multicenter Iliac Artery Stents for Common or External Iliac Artery Occlusive Disease (ICE) trial of 660 patients compared BE and SE stents. Included patients had the following lesions: 58.9% with common iliac artery lesions, 16.5% with complete obstructive lesions, and 25.6% with severe calcified lesions. One-year duplex ultrasound revealed that the rate of binary restenosis was better in the SE stent than the BE stent (6.1% vs. 14.9%, respectively; p=0.006). The Kaplan-Meier analysis also showed better results in the SE stent in freedom from target lesion revascularization (TLR) (97.2% vs. 93.6%, p=0.042).[5] Secondly, the prospective, nonrandomized, multicenter Efficacy Study of Iliac Stents to Treat Trans-Atlantic Inter-Society Consensus (TASC) A-B-C-D Iliac Artery Lesions (BRAVISSIMO) study showed 2-year primary patency rates of 92.1% for the SE stent and 85.2% for the BE stent. These resuls are impressive even though the SE stent was used more frequently in more severe TASC II C and D lesions.[6]

The BE stent may create artificial vessel straightening due to enhanced sheer force, perhaps promoting more neointimal hyperplasia. On the other hand, it is thought that the SE stent had

slightly better results because it is a little more flexible, fits more easily to the vessel wall, has better healing and less neointimal hyperplasia.[5)7)] These studies provided sufficient evidence to establish the use of the SE stent in iliac artery interventions. The BE stent, however, is still necessary. For example, the BE stent provides high radial outward force and the ability for precise stent placement, and it is used more often in ostial common iliac lesions.

Second, several types of SE stents, with different structures and characteristics, can be used for iliac artery revascularization. The EPIC™ stent used in the K-EPIC registry was launched in South Korea in 2013, and it is a SE stent that is commonly used in the iliac artery.[8)] The structure of the EPIC™ stent is a hybrid stent architecture. End rows of the stent are closed cell geometry that are intended to aid in the uniform deliverability of the stent. The mid-section of the stent is open cell geometry, which is intended to enhance its flexibility. The EPIC™ stent has consistently shown good results in studies on primary patency and efficacy. In the EPIC Nitinol Stent System in the Treatment of Atherosclerotic Lesions in Iliac Arteries (ORION) study, a single-arm, prospective, multicenter trial in 125 patients, the 1-year primary patency rate and freedom from TLR were 94.4% and 95.4%, respectively, and these results were similar to those of the K-EPIC registry: 94.5% and 97.2%, respectively.[9)] It is noteworthy that compared to the ORION study, the K-EPIC registry showed similar results, even though the lesion length was longer and more patients had diabetes and total occlusions. In a retrospective multicenter trial from Japan, the EPIC™ stent was used in 217 patients with the following results: the primary patency rate at 1 year was 92.2% and freedom from TLR was 96%.[10)] The results, which were worse than those of the K-EPIC registry, were thought to be due to differences in the subjects. In terms of patient characteristics, the subjects of the K-EPIC registry were younger and more likely to be taking a statin, and the numbers of patients with chronic kidney disease and coronary artery disease were small. In terms of lesion characteristics, the rate of TASC II C/D lesions was small, more cases had solitary common iliac artery lesion, fewer cases had common to external iliac artery lesion, and the mean lesion length and stent length were shorter. In the K-EPIC registry, there was no difference in primary patency rate according to TASC II classification, which showed similar results to the ORION study and Japanese multicenter trial. Therefore, the EPIC™ stent is a valuable stent in iliac artery disease.

Female gender, diabetes, renal dysfunction, not taking aspirin, small vessel diameter and the presence of stenosis in the outflow were reported as predictors of restenosis after EVT in iliac artery lesions.[4)] The predictors of revascularization after SE stent were analyzed in several studies, and the kissing stent technique and obesity were related to revascularization in the BRAVISSIMO study,[6)] whereas diabetes was related to revascularization in the Japanese EPIC study.[10)] In the K-EPIC registry, there was no association with diabetes, but mean stent diameter and mean stent length were related, and coronary artery disease was especially related to freedom of TLR. As mentioned in the K-EPIC registry, it is not clear how coronary artery disease increased the frequency of TLR, but atherosclerotic arterial disease may occur simultaneously in multiple vascular beds.

The K-EPIC registry showed that the SE stent had an excellent 1-year primary patency rate and freedom from TLR, and it demonstrated that the SE stent can be a recommended treatment method for most iliac artery lesions. In particular, it is considered as an encouraging technique and as such, much research is being conducted in several centers in South Korea that will hopefully show good results. Afterwards, I look forward to the emergence of studies that demonstrate the effectiveness of specific stents according to patient subsets as well as a head-to-head comparison of SE stents.

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Finally, EVT with a stent is an important method for the treatment of iliac artery lesions, and the SE stents showed better clinical results than the BE stents. The EPIC™ stent is a valuable stent in iliac artery lesions, regardless of lesion characteristics.

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