

Insights and Clinical Implications from the pELVIS Registry for the Treatment of Aneurysms Involving the Iliac Bifurcation

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Abstract

The pErfomance of iLiac branch deVices for aneurysmS (pELVIS) Registry is the largest retrospective analysis of prospectively collected data on the use of iliac branch devices (IBD) for the treatment of iliac and aortoiliac aneurysms. It shows the feasibility of the technique with good short- and mid-term results. The most common anatomical challenge for IBD use is the presence of aneurysmal deterioration of the internal iliac arteries (IIA). Experience acquired in the registry treating concomitant aneurysmal lesions of the IIA provides significant information on the performance of IBDs for this specific clinical presentation. Treatment of isolated aneurysms in the common iliac artery without extension to the infrarenal aorta showed favourable results with lower costs, and lower use of irradiation and contrast media. Overall, the relatively low procedure-related complications and repeat interventions show broad applicability of the technique. Further analysis is required to evaluate the longstanding performance of IBD.

Keywords

pELVIS Registry, iliac branch, iliac aneurysm, aortoiliac aneurysm, isolated iliac aneurysm, hypogastric aneurysm

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Preservation of internal iliac artery (IIA) flow has been previously evaluated in the literature.¹ In that sense, placement of iliac branch devices (IBDs) represents one of the most popular endovascular options when anatomically feasible.^{2,3} The first paper reporting the results of The pErfomance of iLiac branch deVices for aneurysmS involving the iliac bifurcation (pELVIS) Registry included 575 patients undergoing 650 IBD implantations with ZBIS (Cook Medical) or Gore (WL Gore & Associates) IBDs. This retrospective analysis of prospectively collected data by prearranged protocols of the first six European vascular centres (Münster, Florence, Rome, Thessaloniki and Perugia) was published in 2017 and it showed good mid-term patency (at 32.6±9.9 months clinical follow-up) with a low reintervention rate (7.3%).⁴ In this same year, universities in Lille, Hamburg and Leipzig joined the registry. The aim of this report is to provide the latest long-term evidence and to evaluate the performance of IBDs in challenging conditions outside their normal usage.

Instructions for Use for Iliac Branch Device

The recommendations for IBDs refer to the length and diameter of the external iliac artery (EIA), the IIA and the common iliac artery (CIA). Generally, uniform artery length of the EIA, IIA and CIA should be more than 20 mm, 10 mm and 50 mm, respectively, while the IIA diameter should not exceed 11 mm to be acceptable for proper sealing (4–11 mm for ZBIS IBDs from Cook Medical; 6.5–13.5 mm for Gore IBD).

In 2010, Karthikesalingam et al. published an overview of the morphological suitability of patients with aortoiliac aneurysms for the

use of commercially available IBDs.⁵ The majority of the people in this patient group were not fully compliant with selection criteria for IBD deployment according to the published guidelines by expert vascular surgeons nor the device manufacturer noting that the most common single anatomical challenge for IBD use was an aneurysmal IIA (AIIA). Other common limitations for IBD use are the presence of short (<50 mm) or narrow CIA, or the presence of ostial IIA disease.

Co-existing Internal Iliac Artery Aneurysm

There are several difficulties to ensuring an adequate sealing zone when there is a co-existing AIIA. If the IBD branch diameter is 8 mm, an 8-mm balloon-expandable covered stent which varies in length between 22–59 mm needs to be employed. Consequently, an IIA diameter of more than 12 mm would be associated with an inadequate distal seal. Therefore, in case of a co-existing AIIA, sealing into the posterior trunk or one of the main IIA branches is needed to guarantee adequate sealing. However, this would create a diameter discrepancy between the IBD branch (posterior trunk) and the IIA branch used for distal landing. Hence, more than one bridging device should be used to seal the device and achieve better docking.

The presence of AIIA can be associated with a higher incidence of type I endoleak, stenosis or thrombosis of the branch. In addition, the available stent grafts have different features and performance, especially in angulated IIAs. To our knowledge, there are only two published series with fewer than 20 patients each that describe the use of IBD in co-existing AIIAs. The Münster group described a

technique for a sufficient peripheral sealing zone in concomitant AIIAs.⁶ The use of a proximal balloon-expandable covered stent was preferred to stabilise the bridging device in the internal branch of the IBD. Additionally, a self-expandable covered stent was deployed distally in the posterior trunk of the IIA to improve the transition in mainly kinked IIA arteries, creating a landing zone of at least 2 cm in a healthy segment. Finally, a bare metal self-expanding stent was used to reline the transition between the bridging devices. This technique seemed to be successful for this small sample size providing good mid-term patency.

Later, Noel-Lamy et al. reported outcomes in 15 patients with AIIAs treated with IBDs.⁷ The Canadian group used self-expandable covered stents as bridging device and extended into the superior gluteal artery without relining the stents. The preliminary results were encouraging. However, due to the limited number of inpatients (n=15; n=16), no robust conclusions can be drawn from these series.

The pELVIS Registry covers 12 years of experience of IBDs in nine European vascular centres. The recently published findings from treating 264 patients with coexisting IIA aneurysms provides significant information about the performance of IBDs for this specific clinical presentation.⁸

Isolated Common Iliac Aneurysm

Recommendations from manufacturers state that a proximal aortic endograft placement in the infrarenal aorta is mandatory to guarantee proper proximal sealing of IBDs. However, when an adequate neck that is at least 10 mm is present in the CIA, implantation of isolated IBD can be effective and will reduce costs and avoid covering the healthy aorta. Up to now, only single-centre experiences with a small number of isolated IBD implants have been reported.⁹ The next topic for evaluation by the pELVIS Registry is the safety and evaluation of freedom of reinterventions in case of isolated placement of an IBD for common iliac aneurysms with a proximal seal of more than 10 mm compared with the manufacturer's recommendations to extend the seal in the infrarenal aorta.

Subgroup analysis from the pELVIS Registry has shown that an adjunctive procedure with complementary devices in the proximal CIA was necessary in more than 60% of the cases.¹⁰ The goal of these procedures was to achieve complete coverage of the CIA extending the sealing zone for at least 10 mm.¹⁰ There were no statistically significant differences when comparing extension to the infrarenal aorta and non-extension in terms of early or long-term type IA endoleaks. Occlusion and high-grade stenosis were the cause for one-third of the reinterventions of the branched device (n=13/40; 32.5%), which increases concerns about the adaptability of the Z-stents on elongated iliac arteries and tight aortic or iliac bifurcations. The number of devices per implant was lower in the group without extension to the infrarenal aorta suggesting that a certain degree of cost savings would exist when compared with more extensive procedures. In fact, the duration of the procedures, the fluoroscopy time and the amount of iodine contrast medium were significantly reduced in patients undergoing isolated IBD. Even if a cost analysis was not possible due

to different regulatory laws and device costs, the isolated use of IBD showed several economic advantages with an equivalent efficacy and should be considered in selected cases.

Secondary Procedures

An overview of the secondary procedures in the pELVIS Registry was published in 2017 by our group.⁴ The low 30-day mortality and high technical success confirmed the safety and feasibility of IBDs. The mean clinical and radiological follow-up were 32.6 ± 9.9 months and 29.8 ± 21.1 months, respectively. Out of 650 successfully deployed ZBIS and Gore IBDs, nine (1.6%) reinterventions for occlusion or endoleak were performed within the first 30 days. The overall postoperative reintervention rate was 8.9%. Procedure-related secondary procedures were mainly performed in case of occlusion of the EIA/CIA segment of the IBD and type I/III endoleak. It seemed that the relatively rigid limb of the ZBIS device implies its poor conformability in elongated EIA. Therefore, the use of flexible nitinol stents was suggested to improve the transition in kinked EIAs.

The fact that most of the type I endoleaks and occlusions appeared during the follow-up period highlighted the importance of radiological surveillance with annual CT angiographies and restricting the use of duplex scanning, especially in obese patients.¹¹ Within the pELVIS Registry, all cases with occluded IIA (11/650 IBDs [1.6%]) were asymptomatic with patent contralateral IIA. Therefore, no reinterventions were required to recanalise the occluded IIA. A meta-analysis comparing IBD with coiling or plugging the IIA and extension to the EIA showed higher risk for gluteal claudication for the patients who had coiling and plugging.¹² This stresses that IBD had better results, especially in young patients.

Conclusion

The pELVIS Registry is the largest multicentre, retrospective analysis of the use of IBD to treat iliac and aortoiliac aneurysms. The results are promising with good outcomes in terms of safety, feasibility and mid-term patency. The most common single anatomical challenge for IBD use is the presence of aneurysmal IIA. The registry's findings about the treatment of concomitant aneurysmal lesion of the IIA artery will provide significant information about the performance of IBDs for this specific clinical presentation. The treatment of isolated CIA aneurysms without extension to the infrarenal aorta when feasible has shown similar results with lower costs, lower use of irradiation and contrast medium. Overall, the relatively low procedure-related complications and reinterventions show the broad applicability of this technique. However, further analysis of the long-term results is required to further evaluate the longstanding performance of this technique. ■

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