Economic value of covered expanded polytetrafluoroethylene (ePTFE) stent grafts compared to percutaneous balloon angioplasty for treating thrombosed and dysfunctional arteriovenous grafts in haemodialysis patients in Germany

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BACKGROUND

Patients on haemodialysis (HD) require long-term vascular access for successful dialysis sessions. The vascular access circuit can be created using a native fistula or a prosthetic arteriovenous graft (AVG). HD patients can experience dysfunctional graft stenosis or thrombotic occlusion, which require additional intervention procedures to maintain and re-instate flow. Intervention options include percutaneous transluminal angioplasty (PTA) with a balloon and implanting stents or stent-grafts. If the AVG experiences further stenosis or occlusions, then re-interventional procedures are required.

The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface§ (GORE® VIABAHN® Device) is a flexible, self-expanding endoluminal stent-graft for treatment of stenosis or occlusion in an AVG. The stent-graft is an additional investment to PTA alone.
It is crucial for healthcare decision makers to evaluate and understand the potential long-term payoff from these investment decisions, especially in the current climate of financial pressure on healthcare budgets.

OBJECTIVES

This analysis aims to establish the economic value of revising a dysfunctional or occluded AVG with the GORE® VIABAHN® Device compared to PTA using clinical and resource-use data from the Gore REVISE Clinical Study[1] along with cost data specific to German treatment setting.

METHODS

The Gore REVISE Clinical Study[1] (NCT00737672) was a prospective, multicenter, randomized controlled trial (RCT) in the U.S. comparing the GORE® VIABAHN® Device (n = 131) to PTA (n = 138) for treatment of dysfunctional stenosed or thrombosed prosthetic AVGs and followed patients for two years.

The clinical study showed that the GORE® VIABAHN® Device demonstrated statistical superiority over PTA in target lesion and access circuit primary patency.[1]

The trial collected resource utilization data used in this economic analysis, including the number of devices used and types of repeat interventions. Procedure costs are from the 2021 German Diagnosis Related Group (G-DRG) rates.[2] The 2022 list prices are used for the GORE® VIABAHN® Device.

Table 1: Unit costs of procedures (G-DRG)[2]

Procedure	Procedure cost (stent device cost removed)
PTA	€2,676
Implantation of stent-graft	€4,389
Thrombolysis	€6,019
Thrombectomy	€3,474
Surgical revision of AVG	€3,474

The average total treatment costs (ATC) and re-intervention costs (ARIC), over the two year follow-up, were calculated for each patient.

- ATC was comprised of the cost of the initial study procedures and all re-interventions required to maintain the vascular access circuit until the access circuit was abandoned.
- ARIC excluded the cost of the initial study procedure and was comprised of the cost of all the re-interventions performed to maintain vascular access until the access circuit was abandoned.

RESULTS

- Patients in the GORE® VIABAHN® Device arm incurred ATCs per patient of €18,927 at two years compared to €20,112 in the PTA arm, showing savings of €1,185 *(Figure 1)*.
- ATCs include initial study procedure costs, where the GORE® VIABAHN® Device arm had higher procedure and device costs than the PTA arm by €3,114, but average repeat intervention costs (ARICs) over 24 months were lower than the PTA arm by €4,299, making up for the initial study procedure cost difference.

Figure 1: ATCs per patient at 24 months

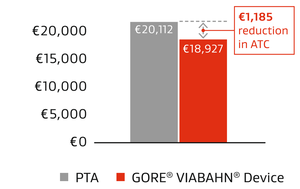


Figure 2: Number of re-interventions over 24 months on access circuit

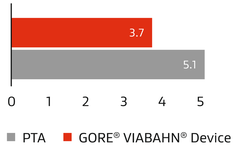
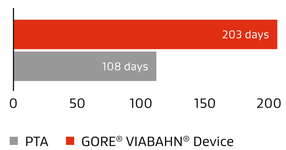


Figure 3: Median time (days) to re-intervention on target lesion



The clinical study showed a reduction in the number of re-intervention procedures at 24 months[1] *(Figure 2)* and an increased time to first re-intervention[3] *(Figure 3)*.

CONCLUSIONS

- Treating dysfunctional and thrombosed AVGs with a GORE® VIABAHN® Device can be a cost saving treatment option for the German healthcare system compared to repeat PTA, that may deliver cost savings to the payer of €1,185 per patient over two years.
- The clinical study demonstrates statistical superiority of the GORE® VIABAHN® Device over PTA in both target lesion and access circuit primary patency and has shown to reduce the number of re-interventions and increases the time between re-interventions to maintain access patency versus PTA.
- Reducing individual patient re-interventions offers a respite for quality of life for patients, reducing hospital re-admissions, freeing up resources for providers and reducing costs for payers.
- Treating dysfunctional and thrombosed AVGs with the GORE® VIABAHN® Device has shown an economic benefit for the German healthcare system compared to PTA in addition to clinical benefit as demonstrated in the REVISE Study.[1]

REFERENCES

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§ As used by Gore, PROPATEN Bioactive Surface refers to Gore's proprietary CBAS® Heparin Surface.

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