Cost-consequence analysis of ePTFE vascular grafts with heparin end point covalent bond compared to standard ePTFE vascular grafts in below-knee surgical bypass for critical limb ischemia PAD patients in Germany

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BACKGROUND

Peripheral arterial disease (PAD) is mainly caused by atherosclerosis that reduces blood flow to the limbs. Critical limb ischemia (CLI) is an advanced stage of PAD, presenting as a severe blockage in the arteries of the lower limbs. Treatment options include a lower limb surgical bypass to treat stenosed or occluded arteries. Prosthetic vascular grafts are frequently used as a conduit in lower limb bypass procedures. In Germany, annual PAD in-hospital treatment costs have been rising to over €2.56 billion with over 18,000 major amputations[1] performed annually, posing a significant financial burden to healthcare payers.

OBJECTIVES

This study assesses the economic value to payers in Germany over three years, of adopting the GORE® PROPATEN® Vascular Graft with Heparin end-point covalent bond (G-PVG) compared to standard ePTFE grafts (S-VG) in patients with CLI.

METHODS

A Markov model was developed to measure costs and clinical consequences over three years of treating patients with G-PVG compared to S-VG (*Figure 1*). After the initial bypass procedure patients start in the primary patency health state and move to other health states depending on how the initial bypass is performing.

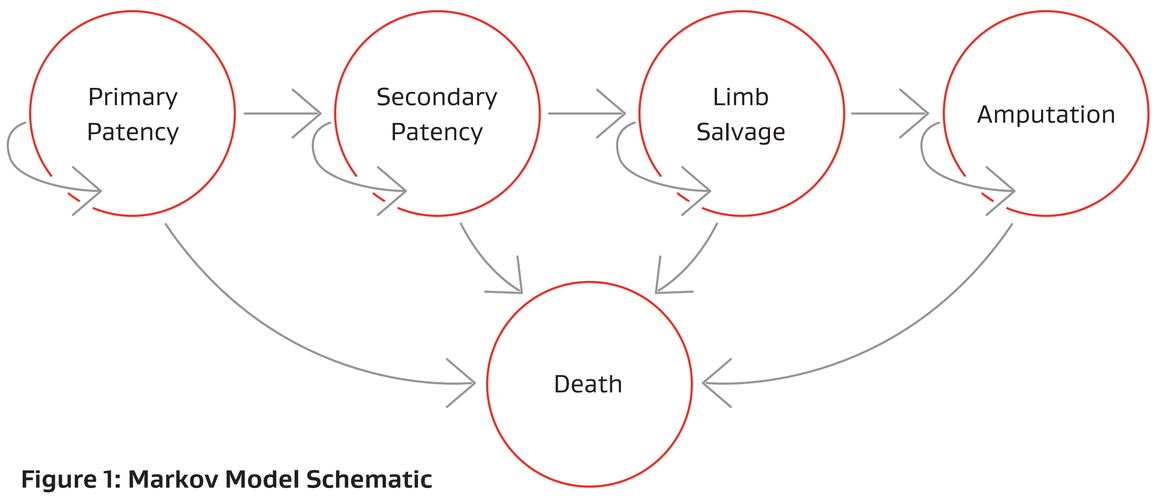


Figure 1: Markov Model Schematic

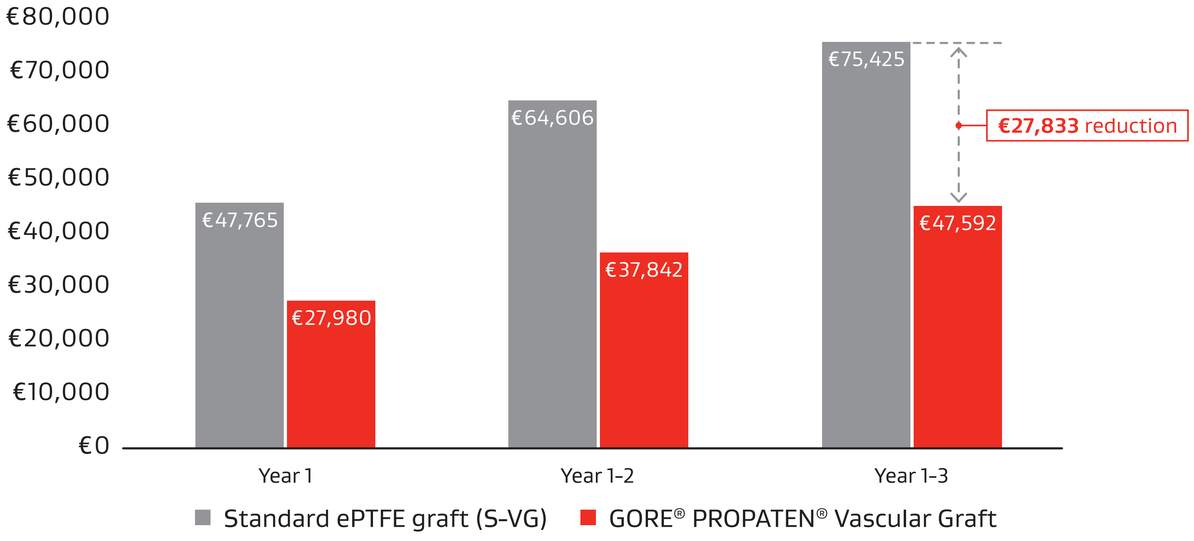
Primary patency — The graft is functioning and no reintervention has been required.
Secondary patency — The graft is functioning but has required at least one reintervention.
Limb salvage — A revision or replacement bypass has been performed.
Amputation — A major (above the ankle) amputation has been performed.
Death — Patient has died.

Clinical outcomes, including occlusion, amputation and mortality rates were based on a meta-analysis of clinical publications[2]. Procedures unit costs were sourced from German DRG rates and other public databases[3-7], costs of post-amputation rehabilitation care in Germany were sourced from published literature[8]. Patient treatment pathways in Germany were verified by German KOL survey. The time horizon was three years and the healthcare payer perspective was used.

RESULTS

At the end of three years the average cumulative treatment costs per patient were 37% lower for G-PVG, €47,592, compared to €75,425 for S-VG, delivering savings of €27,833 (*Figure 2*).

Figure 2: Average cumulative treatment cost per patient years 1-3

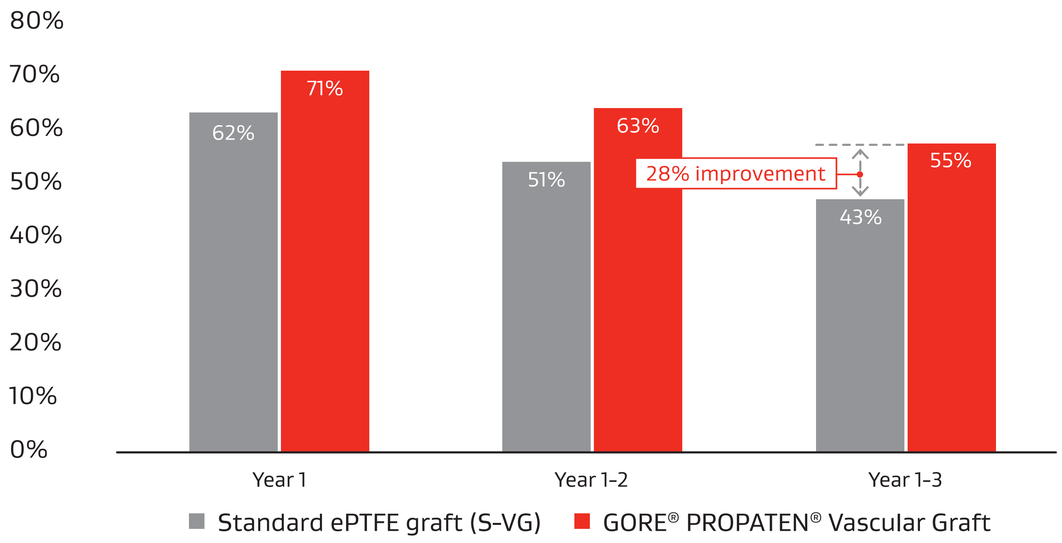


Over 50% of the savings came from preventing amputations and subsequent cost of care and rehabilitation.

Modelling a cohort of 100 patients in each arm, compared to S-VG, the G-PVG arm had

- 36% fewer revision procedures (197 versus 308) and
- 28% more patients had amputation free survival (55 versus 43) (*Figure 3*).

Figure 3: Below-knee cumulative amputation-free survival‡



‡ Amputation-free survival (avoided loss of limb or life) is the average reported mortality rate for standard ePTFE and the average reported amputation rates for standard ePTFE and GORE® PROPATEN® Vascular Graft.

The results were sensitive to clinical performance rates.

CONCLUSIONS

- Adopting G-PVG grafts could save the healthcare payer in Germany €27,833 per patient in treatment costs over three years.
- It can improve patient outcomes by reducing revision procedures and amputations, reducing hospital re-admissions.
- GORE® PROPATEN® Vascular Graft with Heparin end-point covalent bond demonstrates positive clinical outcomes and measurable economic value when compared to standard ePTFE grafts.

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