# Why EVAR Has Failed in Belgium

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Although endovascular aneurysm repair (EVAR) was introduced 15 years ago and yielded satisfying results for well-defined patient populations, it is still not included in the current Belgian nomenclature. The reason why the Belgian government has not implemented a reimbursement strategy for EVAR in routine health care is based on historical grounds. This article gives an overview of the past events that have led to the current situation in Belgium.

## THE SOLIDARITY FUND

From the introduction of EVAR until the end of the 1990s, EVAR procedures in Belgium with first-generation endoprostheses were performed under proctoring and only in selective cases. However, reimbursement was obtained by using an already existing "Solidarity Fund," which was installed in the lap of the Belgian National Health Service (RIZIV/INAMI). This Solidarity Fund functioned as a safety net for procedures falling outside of the nomenclature or for bailout procedures. In only 2 years, 235 patients were treated with abdominal aortic aneurysm (AAA) endografts, accounting up to €1.85 million. When social security and private insurances were unwilling to continue to refund the costs of the endoprostheses implanted, the news hit the media like a bomb. Several Belgian newspapers reported on the injustice that was done to the patients, who were either obliged to pay for the endoprosthesis out of their own pockets, or had to leave the aneurysm untreated, awaiting certain death when the AAA burst.

This was the spark that incited the Belgian government to urge the RIZIV/INAMI to find an adequate solution. A historical assembly of an *ad hoc* committee, consisting of representatives from the Belgian Society for Vascular Surgery and from the Radiologist Society, together with the Board of Medical Superintendents of the various mutualities, gathered and made a framework agreement.

## EUROSTAR BELGIUM

As of April 2001, EUROSTAR Belgium was initiated. All EVAR patients had to be reported to the RIZIV/INAMI in order to obtain reimbursement for the endoprostheses implanted, using EUROSTAR as a platform. The fact that EUROSTAR Belgium was an obligatory registry had the advantage that all patients were registered and could be closely followed. A maximum of 380 EVAR cases were to be reimbursed annually during the next 5 years, if the center and specialist met certain acknowledgement criteria. First, the hospital was required to have two full-time equivalent specialists with 50% of their activity in vascular treatment. Second, the hospital needed 24-hour access to a medical imaging department and had to be in possession of a C-arm with subtraction and spiral CT. Third, the center needed to have an ICU and a "specialized emergency" section. Fourth, a vascular surgeon needed to be readily available at any time in case of complications during EVAR. Finally, the specialist-implanter was required to have theoretical and practical training, as well as sufficient experience by having implanted a minimum of 20 endografts. In centers where the specialist did not meet the criteria, EVAR procedures could be performed under proctoring, as long as all other center requirements were met. The most important anatomical inclusion criteria were that the AAA diameter had to be 50 mm, or twice the size of the native aorta, or that there was an evidence of growth of a minimum 5 mm over 6 months. Furthermore, the aneurysm itself had to be anatomically suitable for EVAR.

## BELGIAN HEALTH CARE KNOWLEDGE CENTRE ASSESSMENT

In October 2005, the Belgian Health Care Knowledge Centre (KCE), which is an independent advisory board reporting to the Belgian government, published a health and technological assessment report concerning EVAR in Belgium. This was done only a few months before the EUROSTAR Belgium report, meaning that the KCE decided to base its opinion on preliminary results from 1,400 patients instead of the total 2,068 inclusions. In the report, the KCE claimed EVAR was a failed experiment that was

not cost-effective, performed on a research basis, at the patient's expense. The KCE stated EVAR was not worth the investment and advised the Belgian Ministry of Health that EVAR was, consequently, not ready for reimbursement in routine health care. Furthermore, the KCE advised that EVAR should only be performed in high-volume centers, and should only be applied for AAA diameters of 55 mm in male patients and 50 mm in female patients.

## DIFFERING CONCLUSIONS

The conclusions drawn by the KCE report were not the ones that can be found in the final report on EUROSTAR Belgium, which was published in February 2006. This report gives the results on 2,068 inclusions between April 2001 and October 2005 in 75 participating Belgian centers. Mean AAA diameter of the Belgian patient population was found to be 2.5 mm smaller than in the overall EUROSTAR population, which was possibly due to the inclusion of a larger number of iliac aneurysms and more AAAs with a diameter twice the diameter of the native aorta.

After 48 months of follow-up, there were several results found. For all-cause mortality, the RIZIV/INAMI and other EUROSTAR patient groups had similar results of 24.2% and 23.6%, respectively. The aneurysm-related mortality rate was also similar for the Belgian and the other European populations, with 4.3% and 4.6%, respectively. Also, late conversion to surgery was similar in both groups, at 4.3% and 4.2%, respectively. Also, for type I or type III endoleaks, there was no significant difference found between the RIZIV/INAMI and other EUROSTAR population, with rates at 8.7% and 13.4%, respectively.

Concerning patient recruitment, 41 (55%) of the sites performed 20 or fewer EVAR procedures (ie, fewer than five per year). This means that 55% of all patients were treated in low-volume centers. However, no relationship could be found concerning the recruitment volume of the hospital and the AAA diameters included, the amount of procedural complications, or the aneurysm-related mortality rate. The four main conclusions drawn by the EUROSTAR Belgium were: (1) that morbidity and mortality rates are lower than those of open repair; (2) low-volume centers do not have more complications than high-volume centers due to proctoring; (3) morbidity, mortality, failure rates, and procedure time of the EUROSTAR Belgium results are completely in line with the European EUROSTAR data; and (4) the treatment of comorbidities (eg, diabetes, hypertension) is as important as the technique of repair to maintain the EVAR mortality benefit.

The publication of the KCE report incited a worldwide polemic discussion. In their decision-making process, the KCE deemed all FDA trials commercially driven and unreliable. Only prospective, randomized, multicenter trials (level I evidence) were taken into consideration. This means that, according to the investigators, only EVAR 1, EVAR 2, and the DREAM trials are to be taken seriously. The EVAR 1 and DREAM trials reported a 3% mortality benefit for EVAR in favor of open repair for the first 3 years. EVAR 2 concluded that EVAR is not beneficial in high-risk patients. Oddly enough, these conclusions were completely ignored in the KCE report, and only those points that met the investigators' suppositions were selected from these studies. Out of the EVAR study came the reasoning that it is better to wait for the aneurysm to rupture than to implant an endoprosthesis in elderly, ill patients. The claim by the KCE that EVAR is not cost-effective is based exclusively on the findings of the DREAM trial. The KCE investigators have taken a small selection and applied their results to the population as a whole, completely ignoring the fact that the DREAM trial is underpowered to prove such a statement. The investigators' initial standpoint was that EVAR is not cost-effective, and it does not offer any advantages in terms of morbidity and mortality rates. The report is biased by the urge to prove these presumptions.

## A SHAMEFUL CONCLUSION

Should the KCE have waited for the publication of the final EUROSTAR Belgium report, the situation may have been very different concerning EVAR reimbursement policy in Belgium. Yet, based on the negative feedback stated by the KCE report, the Belgian government is reluctant to include EVAR in the nomenclature. Alternatively, there is an extension of the framework, as it was before, until July 30, 2007, because the government is still not convinced of the benefits of EVAR for the patients, remembering the statement of the KCE report that EVAR is a "failed experiment." Unfortunately, there are currently no hopes for any of the latest EVAR developments, such as fenestrated or branched endografts, to be considered for reimbursement or further evaluation.

It is a shame and a scandal that in a European country such as Belgium, with a very high standard of national health care, there is no inclusion in the nomenclature for such a promising technique as EVAR. ■

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