

## Statement from the Regional HTA Centre of the Western Region in Sweden

### FENESTRATED AORTIC REPAIR OF AORTIC ANEURYSM

The Regional Health Technology Assessment Centre (HTA-centrum) of the Western Region in Sweden (Region Västra Götaland, VGR) has the task to make statements on HTA reports carried out in VGR. The statement should summarise the question at issue, level of evidence, efficacy, risks, and economical and ethical aspects of the particular health technology that has been assessed in the report.

Urban Wingren, Head of the Section of Vascular Surgery, Sahlgrenska University Hospital, Göteborg, Sweden, requested the present HTA.

A working group under the chairmanship of Håkan Roos, MD, the Section of Vascular Surgery, Sahlgrenska University Hospital, Göteborg, Sweden produced the HTA report. The other members of the working group were Mårten Falkenberg, MD, PhD, the Section of Interventional Radiology, Karin Zachrisson, MD, the Section of Interventional Radiology, and Urban Wingren, MD, PhD, the Section of Vascular Surgery. All at the Sahlgrenska University Hospital, Göteborg, Sweden.

The participants from the HTA centre were Ola Samuelsson, MD, PhD, Lennart Jivegård, MD, PhD, Therese Svanberg, librarian, and Eva Alopæus, chief librarian.

Christian Rylander, PhD, Department of Anesthesiology, Sahlgrenska University Hospital, Göteborg, Sweden, has critically appraised the report.

The project lasted during the time period 2009-08-26 – 2010-06-02.  
The literature search covered the time up to August 2009.

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**Question at issue:**

Is the survival better and/or the rate of complications lower in patients with juxtarenal, suprarenal and thoracoabdominal aortic aneurysm when they are treated with “fenestrated” or “branched” endovascular aortic repair (FEVAR) in comparison to open surgical intervention?

**PICO**

P 1 = Adult patients (> 18 years old) with a juxtarenal or suprarenal aortic aneurysm (AAA)

P 2 = Adult patients (> 18 years old) with a thoracoabdominal aortic aneurysm (TAAA)

I = Fenestrated or branched endovascular repair (FEVAR)

C = No intervention or open surgical intervention or any other type of intervention

O = 1) 30 day survival, in-hospital death, and overall survival 2) permanent spinal cord injury  
3) permanent need of dialysis 4) days in hospital (in ICU and total) 5) reintervention  
6) numbers of revascularised arteries 7) other complications

**Summary of the health technology assessment:**

**Method and patient category:**

An aortic aneurysm is a dilation of the aorta, usually representing an underlying weakness in the aortic wall due to a degenerative process at that location. An aneurysm usually develops late in life, and it is five times more common in men than in women. While the stretched vessel may cause some minor discomfort the great concern is the risk of rupture, which without prompt treatment results in a quick death. The current treatment for an AAA distal to the renal arteries is either surgical repair of the aorta or endoluminal treatment by a minimally invasive insertion of an endovascular stent into the diseased portion of the aorta (i.e. endovascular aortic repair, EVAR). Patients with AAA very close to or including the renal arteries (juxtarenal, suprarenal or thoracoabdominal aneurysm) have a much higher peri- and postoperative morbidity and mortality than patients with aneurysm located distal to the renal arteries. It is now possible also to treat these categories of patients with non-invasive endovascular procedures. An endovascular graft with fenestrations (i.e. holes) for the renal arteries and/or the other arteries proximal to the renal arteries, so called FEVAR, is then percutaneously implanted in the aneurysmatic portion of the aorta.

**Level of evidence:**

The systematic literature search identified one non-randomised, controlled study and 16 case series. No randomised, controlled trial was found in which FEVAR has been compared with any other type of intervention. The controlled study was a follow-up study of patients with either juxta- or suprarenal AAA treated with FEVAR, EVAR or open surgery. The study was of low scientific quality due to uncertain external and internal validity, and with a low statistical power. No differences between the study groups were observed in 30-day mortality or long-term survival. The level of evidence with regard to survival according to the GRADE system is very low (⊕)

**Risks**

In the case series which have reported the number of patients in need of re-interventions or with a permanent need of dialysis or a permanent spinal cord injury the rates of these complications varied between 0 – 24 %.

Ethical aspects:

The main ethical question is whether a new specialised treatment should be introduced in routine clinical care of high-risk patients when the level of evidence of the method is very low, the risk of complications is substantial and the cost-effectiveness is not clarified.

Economical aspects

The total cost during the hospital stay for patients with juxtarenal AAA who electively have been treated with open surgery during 2009 at the Sahlgrenska University hospital was on the average 160 000 Swedish crowns (about 15 900 Euro). The corresponding cost for patients with surgery of thoracoabdominal aneurysm was 750 000 Swedish crowns (about 74 000 Euro)

The cost of a fenestrated or branched endovascular stent graft is 250 000 – 350 000 Swedish crowns (about 24 900 – 34 900 Euro). The averaged total hospital cost for the implantation of a fenestrated stengraft in patients with juxta- or suprarenal AAA has been 435 000 SEK Swedish crowns (about 43 300 Euro) since the start of the use of this procedure at Sahlgrenska University hospital in 2005.

Concluding remarks

The scientific documentation of the eventual beneficial effect on survival and on the rate of complications following treatment of complicated aortic aneurysms with fenestrated endovascular aortic repair (FEVAR) in comparison to other interventions is very low (Grade ⊕).

On behalf of HTA-centrum Göteborg, Sweden, 2010-06-02

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