Endovascular surgery for abdominal aortic aneurysm

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Abdominal aortic aneurysm can be treated using a vascular prosthesis which is placed in the aorta via another vessel (endovascular procedure). The procedure is considered to be a milder intervention for patients compared to conventional open surgery. There is moderate* scientific knowledge concerning several of the methods used in this treatment approach. Knowledge about the benefits and risks to patients is limited to open studies and short follow-up times. There is poor* scientific knowledge about the long-term effects and the cost-effectiveness of the method. Endovascular surgery should be used only in controlled studies and should be compared with the conventional method to assure the highest level of safety and acquire relevant scientific knowledge. Future studies should also include costs and the quality of life in patients. Data should also be registered in the European Quality Registry (Eurostar).

*This assessment by SBU Alert uses a 4-point scale to grade the quality and evidence of the scientific documentation. The grades indicate: (1) good, (2) moderate, (3) poor, or (4) no scientific evidence on the subject. For further information please see “Grading of evidence”.

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Technology

Abdominal aortic aneurysm is caused by degeneration of the elastic components of the vascular wall, resulting in a weakening of the blood vessel and subsequent dilatation. The occurrence of abdominal aortic aneurysm is associated with arteriosclerosis. Aneurysms are usually located below the renal arteries and, may be located also in the pelvic arteries. The natural course of an abdominal aortic aneurysm involves a successive increase in the diameter of the vessel, which may ultimately lead to rupture. Rupture without treatment leads to death. If patients are quickly transported to a hospital, a ruptured aneurysm can be operated. Mortality in patients who arrive at a hospital and receive surgery is approximately 40 percent (Swedish Vascular Registry, Annual Report, 1997).

The number of endovascular operations for abdominal aortic aneurysms has increased in recent years. The objective of such an operation is to exclude the aneurysm from the circulation and thereby prevent it from rupturing. In 1991, Parodi et al reported the first results following endovascular surgery for abdominal aortic aneurysm. Treatment involved deployment of a vascular prosthesis in the aorta using instruments inserted via one femoral artery [1]. This method has been further developed and now takes several forms. Nearly a dozen different systems are available on the market [2]. A common feature of the different types of procedures is that fluoroscopy is used when implanting the vascular prostheses used to replace the diseased section of aorta. The vascular prosthesis consists of synthetic material, the most common material being polyester. Furthermore, it is common for the vascular prosthesis to be supported by metal mesh. A metal stent is used to attach the ends of the vascular prostheses. The upper end is positioned just below the renal arteries and the lower ends usually in the iliac arteries. The blood which circulated through the abdominal aortic aneurysm prior to the operation will be diverted through the vascular prostheses if surgery is successful and will eliminate the stress on the dilated aortic wall. Since the vascular prosthesis should be fastened to the existing vascular wall above and below the aneurysm, the diameter measurements of the vessels at these sites must be exact soo that the correct size of implant can be selected.

The endovascular procedure does not need to be performed under general anesthesia and usually requires a shorter hospital stay than conventional surgery.

Target group

Abdominal aortic aneurysm is a common disorder, occurring mainly in men above 60 years of age where 5 to 10 percent are estimated to have the disease [3,4]. In Sweden, 1212 individuals died 1996 with aortic aneurysm as the underlying cause of death, whereof 826 were men, corresponding to 1.8 percent of all male deaths. Since the disease is usually asymptomatic prior to rupture of the aneurysm, the prevalence of aneurysm in the population is difficult to determine. The risk for rupture depends on the aneurysm diameter. In Sweden, it is considered that a diameter exceeding 5 cm presents a high risk for patients, and surgery is recommended. Aneurysms with a diameter exceeding 5 cm occur in 0.5 percent to 1 percent of males above the age of 60 years. With aneurysms having a diameter of 4 cm to 5.5 cm, the mortality rate is the same for patients receiving immediate surgery as for those who are regularly checked by ultrasound and only operated if the aneurysm expands above 5.5 cm, or grows rapidly, or becomes symptomatic [5]. All patients with aneurysms requiring treatment are not necessarily candidates for endovascular intervention. There is uncertainty concerning the percentage of patients who, from a strictly technical standpoint, can be treated using the new method. Depending on the system used, estimates vary from 10 percent to 55 percent [6].

Relation to other technology

Conventional treatment for abdominal aortic aneurysm consists of open surgery where the diseased aorta is replaced by a synthetic vascular graft. An open procedure usually involves at least one day in the intensive care unit, and mortality is approximately 4 percent (Swedish Vascular Registry, Annual Report 1997). A surgical method which is less traumatic for the patient is therefore desirable.

Patient benefits

Outcome measures used to assess endovascular procedures include the number of successful implants, the prevalence of leakage, the percentage of cases converted to open surgery, and surgical mortality. The results of endovascular surgery vary depending on patient selection, but generally the primary outcomes are considered promising.

A review of 13 published, open studies from 1995 through 1997 included 767 patients, whereof 84 percent reported successful implantations [7]. Successful implantation is defined as implantation of a vascular prosthesis where open surgery is not needed. The same review showed that 8 percent of the patients needed open surgery in conjunction with an attempted endovascular procedure. Surgical mortality was 4 percent. Leakage was identified in 14 percent of the patients, of which one third healed spontaneously. No randomized controlled studies have compared the endovascular method with open surgery.

Currently, it is difficult to conduct randomized studies since the various types of vascular prostheses are in the product development phase, and long-term results are lacking.

Complications and side effects

Four main types of complications may accompany endovascular surgery: leakage, dislocation of the vascular prostheses, mechanical failure of the prostheses or its components, and reduced flow through the prostheses caused by kinking.

Leakage may occur along the side of the vascular prostheses either at the upper or lower fixation sites. Blood flow in the previous aneurysm sac, ie, outside the vascular prosthesis, can also occur via other arteries originating from the aneurysm. In successful treatment, ie, where no perigraft flow occurs, the aneurysm shrinks, but when perigraft flow occurs it does not. Furthermore, several cases have been reported where rupture has occurred in patients with leakage. Leakage requires either a repeat endovascular procedure or open surgery.

In systems using a metal support of the prostheses, the connection between the metal and the prostheses has been shown to break. Dislocation of the graft has been demonstrated, which is sometimes associated with a kink in the graft, a condition which can lead to obstruction of blood flow. Risks and side effects have been reported in several studies, but reliable data concerning the frequency of these events are not yet available.

Costs and cost-effectiveness

A study of 44 patients compared the costs of endovascular procedures and open surgery [8]. The costs for the procedure itself were higher for the endovascular method (10 699 ECU versus 4 032 ECU) while inpatient days were substantially lower (5.6 days versus 13.3 days). Although the devices for endovascular surgery are considerably more expensive than the vascular prostheses used in conventional surgery, the total costs for surgery and hospital stay were 14 percent lower with the new method. None of the patients in this study were converted to open surgery. These results however, can be overturned in larger studies if it is shown that patients who are treated by endovascular methods require surgery after a certain period due to the complications mentioned above. Furthermore, the costs that are incurred from closely monitoring patients, which is necessary for an extended period after endovascular intervention, should be included in future studies.

Structure and organization of health services

To enable assessment, the method should be used only in controlled studies at a limited number of centers until further notice. This method requires specialized expertise and close collaboration between radiology specialists and surgeons. If, in the future, the method proves to be superior to conventional methods for most patients, the number of operations based on conventional methods will probably decline. It is possible that the total number of operations will increase during the transition to a method

having lower risks and lower costs. Before this occurs, the benefits of broadening indications should be demonstrated.

Ethical aspects

Patients who are candidates for endovascular surgery should be informed that the new method has not been fully assessed, and they will require close monitoring for an extended period via repeated computed tomograph scans or other radiological examinations.

A special ethical dilemma concerns patients who are considered to be too ill to undergo conventional surgery. The question is whether or not it is acceptable to use the new method in these patients before the complete facts are available about its safety and benefit.

Diffusion in Sweden

In Sweden, the greatest experience with this method is found at the MAS University Hospital in Malmö. Other centers having relatively comprehensive experience are Lund, Karolinska Hospital in Stockholm, and Örebro, while other university and regional hospitals have performed only few procedures.

Current evaluation research

Research and development of the technology for treating aortic aneurysm via endovascular methods is under way in Sweden and internationally. One of the questions being asked concerns the best way to attach the graft.

A collaborative European project (Eurostar) is following patients who have undergone this type of procedure. Departments in Sweden where endovascular surgery is offered are recommended to report their data to this registry and as well in the Swedish Vascular Registry.

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