

Morphological and functional modifications of the aneurysm-endograft complex following endoluminal exclusion in 30 consecutive cases

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Abstract. Data from 30 consecutive excluded abdominal aortic aneurysms (AAA) have been analysed, to verify whether important morphological changes take place after exclusion, and whether these can be considered as risk factors for functional (leaks, flow alterations) and clinical complications (rupture, obstruction). All AAAs have been initially successfully excluded and patients have been followed up by clinical examinations and ct scan controls post-operatively, at the third and sixth month, then yearly. At a mean follow-up of 17 months, dimension of the proximal neck increased significantly (>2 mm in diameter) in five pts and graft was distally dislodged in two. Maximum aneurysm diameter reduced significantly (at least 10% than originally) in half of the cases and more than 25% in 10% of cases. Four AAAs presented an initial increase, that reduced only in two. Calculation of length of the AAA was unreliable due to tortuosity. Two secondary type II leaks and one secondary type III leak were observed associated to stable or slightly increased AAA diameter (the latter patient suddenly died probably for myocardial infarction, but a rupture could not be formally excluded). Marked tortuosity of the graft was seen in five patients, all associated with frank shrinkage of the aneurysmal sac. Parietal thrombosis without explanation was observed in five, and in one progressed to obstruction of an iliac branch. Two pts needed anticoagulation. These data indicate that endoluminal aneurysm exclusion can not be considered as a definitive solution, for long-term outcome is unforeseeable in a number of patients.

Key words: Abdominal aortic aneurysm, endoluminal exclusion, stent graft

In the last few years, endoluminal exclusion of aneurysms of the abdominal aorta (AAA) has been widely accepted due to the lesser surgical trauma, though some doubts still exist on the long term outcome. In the EUROSTAR study carried out in 2002 (1), out of 4.291 patients treated mainly with first and second generation endoprothesis in 113 centers from March 1996 to March 2002, the peri-operative mortality was 2.4%, with an early conversion rate of 1.3%: At an average follow-up period of 12 months, 35 aneurysms ruptured and late conversion rate was 2%,

with a cumulative risk of failure of 3% per annum. In another recent study (2), out of 703 patients treated in the same period in a single center, the peri-operative mortality was 1.7%. Twelve deaths were aneurysm related at one year, with a cumulative risk of 1.7%. Subsequently, 3 late aneurysmal ruptures, 19 occlusions of aortic branches, 25 displacements of the endoprothesis, 104 surgical or endovascular reinterventions with 8 deaths were reported, thus reaching a death rate related to aneurysm of about 3% without any significant difference between the six different types of prosthesis

used. Another recent study of 1193 patients treated with a single type of prosthesis (3) in 19 different centers from 1996 to 1999 had similar results: 1.8% of deaths related to aneurysm with an further 1.8% risk of death at one year. The risk of rupture of the aneurysm after 4 years was estimated at 1.6%. Thus, the exclusion of the aneurysm does not prove to be a definitive solution in a significant number patients.

Material and methods

Thirty AAAs were excluded successfully by use of endoluminal prosthesis (14 Talent, 9 Excluder, 4 Vanguard, 3 AneuRx). All patients were put on antiplatelets therapy with either full dose ticlopidin or aspirin. After an initial CAT scan carried out before discharge the patients or within one month from the procedure, the patients underwent clinical and radiological controls at 3 and 6 months and subsequently on a yearly basis. The data obtained were inserted in a prospective data base. The primary end-point was any cause of aneurysm-related and secondary end-points were aneurysmal rupture and need for further endoluminal or surgical correction.

For the present study, all radiological images were re-analyzed by both a radiologist and a surgeon, who measured the major dimensions (maximum diameter and length) of the neck and the aneurysm sac. Leaks, thrombosis and variations of the morphology of the endoprosthesis were detected. An increase of more than 2 mm of the proximal neck was considered significant, because superior to the oversize of the stent and out of any possible error during measurement. The real length of the new neck is considered the distance between the distal renal artery and the proximal extremity of the stent. Applying the same considerations, a 10% variation in the diameter of the aneurysm sac with respect to the initial diameter was considered significant.

Results

At an average follow-up period of 17 months, two patients were dead; one due to a tumor the other to a sudden death 10 later probably months due to a

myocardial infarction although a rupture could not be fully excluded (a type III secondary leak without shrinkage, discovered a month before, and epigastric pain the day before death). There was an asymptomatic occlusion of an iliac branch. A narrowed site of insertion of another iliac branch was only partially dilated with a balloon. Two patients had to be anticoagulated because of progressive parietal thrombosis of the stent-graft.

The neck remained intact in about 50% of the patients, increased less than 2 mm in about a third and above this limit in five cases. When an increase was present, it manifested early or within the first month. No increase was seen when the endoprosthesis was inserted above the renal arteries. In two patients, the length of the new neck increased by over half a centimeter with respect to the immediate post-operative control and in both cases the diameter increased above the oversize. We consider these cases as dislocation of the graft without evidence of secondary leaks at the moment.

Almost none of the aneurysm sacs remained unchanged. At least half of them showed an early reduction in the maximum diameter and the others reduced within a year. In about half of the cases the reduction is significant and in 10% is more than one quarter of the initial diameter in. Four patients presented an initial increase in diameter, two of which regressed within a year, while the others didn't reduce or increased in size without any evidence of leak. Measurement of the lengths of the aneurysm sac was not reliable because it required a number of geometric calculations, also considering the tortuous nature of the aorta.

Two type I primary leaks were seen which rapidly disappeared at subsequent controls; the same happened for three type II primary leaks. Only one type II secondary leak was observed and one type III secondary leak, with a stable or slight increase of the aneurysm diameter. The latter was the patient who suddenly died (without autopsy, this leaves some doubt about the possibility of a rupture of the aneurysm).

Besides the two probable displacements, six endoprosthesis presented an uninfluential increase in the tortuousness. All were associated with a significant shrinking of the sac. A probable disassembling of the iliac branch was revealed by a type III secondary leak. Unexpectedly, a parietal thrombus, more than 1 mm

thick was found in five endoprosthesis and is one case it progressed til complete occlusion of an iliac branch (no previous kink or stenosis); in two cases oral anti-coagulation was required.

Discussion

In this limited group of patients, indications for endoluminal exclusion were determined following strictly the generally accepted criteria. However, at a mid-term follow-up period (one and a half years) six out of thirty patients, i.e. one fifth of the cases, had clinical problems related to the procedure. In one patient who had an abrupt death, a rupture of the AAA could not be excluded. All morphologic and functional changes, except the iliac branch thrombosis, were promptly detected by the protocol for clinical and radiological follow-up.

A significant increase in the size of the proximal neck, i.e. superior than oversize, was observed in five patients. In two of these, the length also increased, due to a distal displacement of the prosthesis. An increase in diameter by 1-2 mm is frequently seen in the first 6 months and can be attributed to the radial force exerted by the stent independently of the type used (4, 5). In other studies, an increase in diameter was observed only in some cases and was independent of the previous diameter and the presence of leaks. The insertion of the stent above or at the level of the renal arteries seems to offer some protection to the proximal neck, as dilation occurs less frequently (13.8 vs 21.8%) and later (6). However, an increase in diameter is also observed in about a third of patients after traditional surgery to correct AAA and particularly when the initial diameter is above 28 mm. Probably this is also in relation with progression of the degenerative process (7). After positioning the endoprosthesis, the relationship of the stent and the proximal neck is fundamental for longterm efficiency of the exclusion, because it represents the point of anchorage of the prosthesis. For the prosthesis we used, anchorage capacity is directly proportional to the radial force exerted by the stent and the length of the proximal neck. The progressive dilation of the proximal neck can favor the distal dislocation of the prosthesis and the instauration of a type I secondary leak, causing an increased pres-

sure in the aneurysmatic sac. This has not yet been seen in our patients but it might be a question of time. Actually, the pre-operative anatomy of the neck in terms of its wideness, length, curvature and parietal thrombosis can be the major factor that determines stability or not. An angle $>45^\circ$ can be responsible for failure at a short-term considered as internal leaks, distal dislocation, need to change to open surgery, especially when associated with other unfavorable features like posterior deformity (8). This is the case of a patient (not included in this series), that we had to operate in emergency, with success for rupture of AAA after endoluminal exclusion performed elsewhere: the cause was identified in a sharp curvature of the proximal neck, which already required two subsequent proximal extensions which however did not prevent rupture.

After positioning the endoprosthesis, the aneurysm sac can undergo some remodeling, termed shrinkage, which is characterized by a progressive reduction of the volume both by reduction of its diameter and length. The most significant variations occur in the first year (9), although it continues afterwards as well (10). By means of angioCAT scans a variety of patterns at medium and long-term was observed. In two thirds of cases, there is an early and progressive reduction in volume, which is considered significant when it is at least 10% (11). At times, reduction is preceded by an initial increase in volume, which can be explained by the backflow from the lumbar and inferior mesenteric arteries, or due to pressure exerted by the endograft against the thrombus and the surrounding wall of the aorta (12-14). In 10% of cases no modification of volume is observed. And in a quarter of cases a significant increase is observed from the beginning (16%) or after an initial period of stability (10%) (11). This is a cause of concern because it is frequently associated with type I and III endoleaks and a high risk of rupture (15, 16), thus must be considered as a failure. In our patient who died abruptly, a type III leak with an increase in volume was identified a month before his death. Calcification of the aorta also hind the collapse of the sac, but only when very extensive and occupying at least 75% of the aortic circumference (10).

It has been demonstrated that the complete exclusion of the aneurysm sac determines its depressuri-

zation (17), while the presence of endoleaks is associated with the persistence of high pressure in the aneurysm. Type I primary endoleaks are found at an average rate of 7.5% and the cause has been found in an inadequate proximal anchorage of the graft due to the shortness of the neck (<1.5 cm), sharp curvatures (18, 19). The possibility that endoleaks of this nature can occur lately (secondary) in up to 10% of cases after three years is well recognized and mainly due to a progressive dilation of the proximal neck. Type II endoleaks are initially found in up to 53% of cases and are correlated to a viable inferior mesenteric arteries or many lumbar arteries, especially when they are large (20). These endoleaks usually undergo spontaneous obliteration which is compatible with the stability and shrinkage of the aneurysm, especially if the flow in the branches is transitory. Cases of dilation of the aneurysm without any evidence of leakage have been described in many other experiences. This demonstrates the persistence of high pressures in the aneurysm for unknown reasons: difficulty in identifying leaks with a flow less than 1 ml/min, transmission of mechanical stress through the thrombotic material present at the site of anchorage or occlusion of the leak (after embolization or spontaneous resolution), weakness of the wall due to enzymatic activity (metalloproteinase and collagenase) in the surrounding thrombus, "igroma" like mechanism in the sac. (21-25).

Shrinkage is not necessarily equivalent to success at long-term because paradoxically, it could lead to displacement of the prosthesis, separation of the various components, kinking of one of the iliac branches due to build up of an abnormal mechanical stress which was not present at the moment of insertion (26). Distal dislocation of the graft is variably described in 9%-45% of cases, frequently associated to secondary proximal endoleaks, kinking and thrombosis of the graft and its branches (20) and it is considered at risk of late rupture (4.5%, EUROSTAR experience). The only significant data associated with distal dislocation of the graft seems to be a diameter of the neck above 28 mm, which corresponds to an increase in the forces towards the direction of blood flow (8). In the post-operative period the tendency of displacement seems to be more significant when the diameter of the proximal neck increases more than above a 3 mm, because of a reduction of the contact area between the

aortic wall and the stent. Blood flow can exert tangential forces on the walls of the graft and when they become superior to the radial forces which maintain the graft in place, they become responsible for the distal dislocation of the graft. Dislocation is not invariably related to the characteristics of the proximal neck and importance has been attributed to positioning above the renal arteries (30), smoking and hypertension (which are all known factors for vascular wall degeneration), maximum diameter of the aneurysm and the endoprosthesis (29), symmetry of the bifurcation of the graft.

Excessive shrinkage and dislocation of the graft were both associated with morphological variations of the graft due to the presence of kinkings and torsions. This was more frequent when the grafts were not supported by metallic stents through out their whole length and this led to frequent occlusions of the prosthesis and acute ischemia (31, 32). An excessive metallic support may not adapt well to shrinkage and this favors dislocations. Animal studies have demonstrated that PTFE grafts not completely supported, remain unobstructed for a longer period with respect to those that are fully supported, (33) and this has also been clinically demonstrated (34). Other causes of stenosis of the iliac branches could be excessive tortuosity of the native arteries or preexisting stenotic lesions which responded only temporarily to dilation.

Excessive thrombus formation in the grafts has been reported with respect to traditional prosthesis made with the same material, with the formation of parietal thrombus that can be seen in the sequential CAT scan in about 10% of the cases (35). Outflow obstruction (kinking, torsions or stenosis) has been identified only in a few cases that could explain the thrombotic evolution. We observed five cases in which the thrombus originated at the wall of the graft, it was progressive in three cases and in one case led to the occlusion of one branch, without any plausible cause. In one patient, a late diagnosis of carcinoma of the pancreas was made one year after insertion of the endoprosthesis.

It can be agreed that endoluminal exclusion of abdominal aortic aneurysm is not a definitive cure because it creates a new anatomic and functional complex, made by the interaction between the neck, the aneurysm and the endoprosthesis which does not re-

main stable with time. This requires continuous morphologic controls. Modifications detected radiologically could at least partially prevent evolving complications.

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