

# Every Patient with Symptomatic Abdominal Aortic Aneurysm Should Undergo Endovascular Treatment

## Agonist

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### BACKGROUND

The prevalence of abdominal aortic aneurysm (AAA) in men above 60 years old is 5%. The expansion of the aneurysmal sac occurs at random, and no symptoms develop in the great majority of cases, until spontaneous rupture happens unexpectedly. Current recommendations for elective rupture of AAA include:

- Aortic diameter = 5.5 cm (in women this limit is lower); the risk of rupture above this number exceeds the operative risk.
- Rapid increase in aneurysmal diameter > 1 cm/year.
- Presence of symptoms (abdominal or low back pain). (1)

Two randomized trials demonstrated that surgical repair of AAAs = 5,5 cm does not increase long-term survival of patients. (2, 3) Each of these studies assessed more than 1000 patients with AAA with a diameter between 4.0 cm and 5.4 cm, assigned to elective surgery or to periodical control with computed tomography or ultrasound scan every 6 months; mean follow-up was greater than 4 years. More than 60% of patients in the control group of both studies underwent surgery during follow-up as a consequence of aneurysmal sac expansion. This reflects both the need of a permanent follow-up of patients with AAA and also the progressive nature of the disease.

The estimated annual risk of rupture of AAA with a diameter of 5.0 to 5.9 cm is 3-15%, and increases to 10-20% when the diameter is > 6.0 cm (4)

When an AAA ruptures, 80% of patients die instantly, or in the postoperative period, in cases when they have undergone surgery. (5) Operative mortality is still as high as it was 20 years ago (about 50%) and no significant improvements have been observed. (6)

AAA symptoms are pain and/or rupture. Low back pain is generally caused by aneurysm rupture with blood leakage into the retroperitoneal space producing distension of the cavity. Pain may also appear when large aneurysms compress lumbar and aortic nervous structures. Aneurysmal sac rupture may be contained or massive. Patients with contained rupture present pain with signs of physiologically compensated hemodynamic involvement, characterized by hypotension (systolic blood pressure > 50 mm Hg), moderate

arrhythmias and decrease in the hematocrit. In cases of massive rupture, patients present severe hemodynamic instability (systolic blood pressure < 50 mm Hg), resulting in shock and even death. Hemorrhagic shock and reperfusion lesion trigger several inflammatory pathways producing an inflammatory syndrome with activation of immune cells and inflammatory mediators that damage vital organs (heart, lungs, liver, kidneys, etc.).

### ENDOVASCULAR TREATMENT

During the last two decades minimally invasive endovascular techniques for the treatment of AAAs have significantly reduced the morbidity and mortality of these procedures compared to standard open surgical repair. (7, 8) These procedures are less aggressive and may be performed with local and regional anesthesia, thus they are considered an alternative option to conventional treatment in selected patients with symptomatic or ruptured abdominal aortic aneurysms.

The first studies performed have suggested that endovascular treatment of ruptured AAAs is feasible, with morbidity and mortality rates similar to surgical repair performed at referral centers. (9, 10)

Symptomatic AAAs' with a suitable anatomy for endovascular repair with self-expanding endoprostheses present lower rates of morbidity and reinterventions, and lower costs than those with an unsuitable anatomy. (11) At present, the anatomical criteria for endovascular repair of ruptured AAAs are less strict, as this minimal invasive technique is indicated to patients with high risk at surgery. (12) Table 1 summarizes the different anatomical criteria for endovascular repair of ruptured AAAs and symptomatic AAAs. (13)

In patients with ruptured AAAs and hemodynamic instability, the immediate control of the aortic bleeding is of vital importance. Endoprosthesis implant or placement of an elastomeric balloon device proximal to the aortic rupture is effective to control bleeding. Bifurcated or aortomoniliac devices may be used. Implant of aortomoniliac stent-grafts is fast as they have only one branch but they require a femoro-femoral bypass grafting to irrigate the contralat-

**Table 1.** Anatomical criteria of suitability for endovascular repair of ruptured AAAs.

Criterion	eAAA	rAAA
Max nex Ø	28 mm	32 mm
Neck length	15 mm	8 mm
Neck angulation	60°	90°
Neck conicity	4 mm	8 mm
Max common iliac Ø	16 mm	22 mm
Iliac tortuosity	Moderate	Severe

eAAA: Elective abdominal aortic aneurysms. rAAA: ruptured abdominal aortic aneurysms

eral limb. Bifurcated devices are anatomically ideal; however, the need of catheterizing the contralateral branch makes the procedure last longer.

The type of anesthesia should also be taken into account. Local anesthesia is mostly proposed before the opening of both femoral arteries in order to avoid hypotension induced by general anesthesia and thus prevent greater hemodynamic instability. (14)

In patients with ruptured AAAs treated with endovascular repair, risk-benefit ratio analysis differs from asymptomatic AAAs, as mortality rates associated with conventional surgery are still high, from 35% to 70%. Endovascular repair of ruptured AAAs is less invasive, reduces surgical stress, and induces less hemodynamic instability as it avoids arterial clamping and may be performed with local anesthesia or local and regional anesthesia. The only prospective and controlled trial included 32 patients with ruptured AAAs randomized to conventional surgery or endovascular repair. Mortality rate in both groups was 53%, but the sample was too small to make statistically significant conclusions. (15)

In non randomized trials, the mortality rate reported with endovascular repair was low (mean mortality 17%, range 0-45) compared to operative mortality in control groups or current studies (mean mortality 34%, range 0-70), and it was directly associated with less bleeding, need of blood transfusion and hospital stay at the coronary care unit. (15, 16)

A retrospective analysis by Ockert et al compared the outcomes at short-term and mid-term between endovascular repair and surgery in 58 patients with ruptured AAAs. An endoprosthesis device was implanted in 29 patients and 29 patients underwent conventional surgery; hemodynamic instability was present in 48% in each group. Perioperative mortality was 31% in both groups; during follow-up, mortality in the endovascular repair group was 17% and 10% in the surgery group. (17)

A recent meta-analysis pooled 18 observational studies, representing a total of 436 patients with ruptured AAAs; global mortality was 12% in the endovascular repair group in a selected population.

The study concluded that further research should determine if this difference in mortality may be attributed to patients' selection or to advantages of the method per se. (18)

## ENDOVASCULAR REPAIR IMPLICATIONS

Endovascular repair shows advantages compared to conventional surgery in terms of perioperative mortality in patients with symptomatic or ruptured AAAs; nevertheless, some considerations should be made:

- The results of several published studies clearly show that the learning curve is different, even in those center with great experience in asymptomatic patients. The different outcomes might be related to the need of an endoprosthesis bank with diverse sizes and configurations and of a trained multidisciplinary medical team available 24 hours/day.
- Definitions of ruptured AAA and hemodynamic instability are not uniform. Precise criteria should be established to determine these definitions, as comparisons between stable and unstable ruptured aneurysms is impossible; endovascular repair is feasible in the former scenario but the advantages of this treatment are not so evident in the latter.
- Another controversial issue is the need of performing a multislice computed tomography in all patients with ruptured AAAs prior to a minimal invasive treatment. Multislice computed tomography is very important to define not only the anatomical characteristics of the aorta and the aneurysm but it is also a diagnostic tool to rule out the condition. Nevertheless, in cases of hemodynamic instability, patients should be transferred to the endovascular "operating room" as soon as possible; an angiography should be performed to characterize the anatomical suitability for endovascular repair.
- In such emergency situations, anatomical selection criteria are broader in order to reduce the mortality in these patients, and endoprosthesis are implanted in short, angular and conic necks. Aorto-moniliac endoprosthesis are the devices of choice as they are implanted faster and bleeding is effectively controlled.

## CONCLUSION

Endovascular repair of symptomatic or ruptured AAAs is feasible with lower perioperative mortality than conventional surgery.

The procedure requires the presence of a trained multidisciplinary team available 24 hours/day, an endoprosthesis bank with different sizes and a tertiary cardiovascular center; nevertheless we may affirm that all patients with ruptured AAAs might benefit from endovascular repair.

If these requirements are not available, conventional surgery will remain as the only feasible treatment.

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## Antagonist

MIGUEL RUBIO

The *Revista Argentina de Cardiología* published in 2002 a similar debate to discuss the treatment of the uncomplicated aneurysm. That article ruled out any attempt of controversy from the point of view of the conventional surgical approach, as it concluded that the election of the procedure depended on the criterion of the attending physician. (19) It is obvious that medical decisions need the implementation of scientific method. In this sense, randomized and prospective studies may generate evidence to guide medical behaviors. I discard that no evidence is also useful evidence for the seasoned reader.

A long time has gone by since Dubost performed the first surgery of an aortic abdominal aneurysm in 1952 (2), to the endovascular approach introduced by Parodi (3) in 1990. The development of new proce-

dures seems to minimize the great advances achieved by conventional surgery. The lack of current methods for primary prevention and the ignorance of the genetic basis of the disease have magnified the creativity to solve established problems. Nevertheless, practices based on sophisticated technological requirements generate situations within the health care system that are not easy to solve.

The heading of the controversy modifies the position of the argument line. At present, published papers make evident a clear interest to exhibit new technologies that seem to overshadow what has already been done using conventional methods. (4) Undoubtedly they tend to displace the mid-point towards areas more favorable to endovascular repair. Innovations are always interesting, although their advantages still need to be confirmed.

“Imagination is more important than knowledge”

ALBERT EINSTEIN

Firstly, let us see the possibilities of an aortic abdominal aneurysm to develop symptoms:

1. Fissure.
2. Wall inflammation.
3. Large diameter with an increase in wall tension.
4. Medical error.

Secondly, which is the clinical presentation?

1. Without hemodynamic involvement
2. With hemodynamic involvement:
  - A Mild hypotension without signs of shock.
  - B Severe hypotension with or without clinical evidence of shock (this is the most compromised population with poor probabilities of survival).

Patients with no evidence of rupture, without a hematoma demonstrated by CT scan or during surgery, cannot be considered for this analysis and, unfortunately, they are frequently included in populations of patients for emergency endovascular repair (symptomatic patients with unconfirmed rupture). (5)

During the last years, the recommendations for the use of endoprosthesis tried to emphasize the incidence of adverse events related to conventional approach in terms of morbidity and mortality. Nowadays, mortality is almost zero in series reported by surgical teams well-trained in this elective surgery. Mortality rates about 10% are currently unacceptable, and if they happened, they might not be attributed to the technique itself but to the lack of quality control of the acting institution.

It is not necessary to mention that patients submitted to conventional treatment do not need surgeries or additional procedures during the perioperative period; in contrast, these procedures are required with endovascular repair. (6) The scar becomes the strongest argument and ejaculation disorders do not seem to be an important issue in a population with an average age older than 70 years, no longer at the life stage of procreating.

Inflammatory aneurysm (characterized by local fibrosis and systemic response associated with the presence of biomarkers) is a distinct entity with better outcomes when treated with an endovascular approach. Retroperitoneal thickness and the periaortic fibrotic tissue adherent to the duodenum may complicate surgical repair. (7)

We shall now analyze the emergent situation of a patient arriving at the emergency room with severe hemodynamic involvement. Operative mortality in patients with hemodynamic impairment and signs of shock is greater than 50%, and time elapsed to consultation is one of its determining factors. Since the late seventies, the established medical behavior states that the patient should be referred from the emergency room to the operating room in order to undergo immediate surgery. Even the presence of the aneurysm and of free fluid within the retroperitoneal cav-

ity at the ultrasound scan is enough for the diagnosis of ruptured AAA.

In 1994, Hopkinson performed the first endovascular repair of a complicated aortic aneurysm in Nottingham, England. (8) The patient needs to be referred to a room with a high-quality radiology service to accurately assess the anatomical details of the aneurysmal neck, the entire aneurysm, the characteristics of the iliac arteries, and the presence of anatomical vascular variations. Malina and Veith have described that the insertion of an occlusive aortic balloon is an essential requisite to perform an adequate endovascular approach. (9) Obviously, the completion of the procedure demands the best radiology team and environment to perform a successful conversion to open surgery in situ. Current communications have not informed the feasibility to perform an endovascular approach without a previous CT scan. A recent report by Mehta (10) performed on 40 patients at a center with trained staff available in situ, showed a mean time of 20 minutes since the arrival at hospital to the beginning of the endovascular procedure. These results confirm a high technical performance as the procedure lasted 80 minutes in average and mortality was 18%. However, 75% of the population study had no hemodynamic compromise; in consequence these outcomes are disfigured. In addition, almost 10% of patients required a second strategy within the first year as a consequence of endoleaks. Morbidity was significant, with intestinal ischemia, acute renal failure and abdominal compartment syndrome.

Harkin et al (11) have recently performed one of the most interesting reviews on endovascular repair of ruptured AAAs on 34 studies (only one randomized trial with a majority of retrospective studies); they concluded that in *selected cases*, short-term outcomes are comparable (but **not superior**) to conventional surgery.

At the University of Columbia, New York, Greco et al (12) analyzed a population from four states which included almost one third of the country population; they reported mortality rates of 39.3% and 47.7% for ruptured aneurysms treated with endovascular repair versus surgery, respectively. These figures are not consistent with what would be expected from a supposedly less aggressive approach. When hospitals with a great volume of open surgeries are discriminated, these authors have found a mortality of 44.3%. Endovascular repair outcomes differed only when the procedure was performed by highly trained teams. The lack of prospective studies prevents to determine if the improvements of the research were related to endovascular technique or only to population selection.

In Italy, Coppi et al (13) included patients who were considered according to an intention-to-treat model with endovascular repair in 124 cases of ruptured AAAs, from 1999 to 2006. Patients with symptomatic or acute (but not ruptured) AAAs were not included in this study. The outcomes were as follows:

eligibility rate for endovascular repair 52%, effective treatment rate 27%, mortality rate for endovascular repair 30%.

In 2007, Visser et al (14) analyzed 478 procedures which included 330 open surgeries in 10 studies; when the results were adjusted according to the hemodynamic status, no significant differences were observed.

In our country Cerezo (15) reported the result of 30 cases with mortality around 20% and a high incidence of percutaneous aortic occlusion during the procedure.

The analysis of this data enables us to make several conclusions:

At present, open surgery remains as the initial treatment of choice in symptomatic aortic abdominal aneurysm. The procedure may be performed at any center of cardiovascular surgery; the cost of the endoprosthesis is low and is easily available. In addition, although endovascular approach is feasible in ruptured AAA, not all patients are eligible for this procedure; mortality rates associated with such a "minimal invasive" technique are disappointing and they evidence the presence of other factors still not exactly defined which might play an important role in the final outcomes. The need of expensive technical and human resources which are difficult to apply even in developed countries turns the attempt to indicate endovascular repair as a treatment of first choice in an illusion in our country. Only one or two cardiovascular centers located at the capital city of our country might be capable of applying immediately a protocol with free availability of several models of endoprosthesis and of the necessary instruments for navigation through the arteries. An aortic endovascular balloon occlusion device may be the first attempt before continuing with conventional open surgery. It should be taken into account that high occlusion of the aorta with renal ischemic impairment is a frequent situation; nevertheless, a direct approach may produce an occlusion distal to the origin of the renal artery. Patients with severe and irreversible respiratory insufficiency may constitute the only cases intractable by surgery as extraperitoneal access is not the access of choice for ruptured aneurysms.

In our country, a significant number of experienced cardiovascular surgeons are capable of clamping the aorta, and this procedure solves the condition with low costs; nevertheless, if multiorganic failure occurs and the patient requires prolonged mechanical ventilation, subsequent infections might compromise patients' life in the short-term.

A final and sensible consideration demonstrates the failure in public health policies in our country as well as in developed countries, as there is no rational explanation to justify the absence of an early diagnosis of this disease. In patients older than 50 years of age, a single ultrasound performed every year, which is an inexpensive procedure with no complications, might lead to the disappearance of this clinical entity,

and, subsequently, our controversies would only be based on the elective treatment of aortic abdominal aneurysm.

Making an analogy with medical behavior regarding coronary artery disease, it seems difficult to believe that coronary stabilizing drugs, discovered more than 20 years after the development of coronary revascularization, are based on the most basic and rustic mechanical technology that medicine may use to solve a problem of such a magnitude. Why hasn't endovascular repair been implemented in patients in hemodynamic shock since its beginning? It was ethically necessary to test these techniques due to the high probability of fatal outcomes.

Innovative technologies should focus on achieving versatile prosthesis easily adaptable to the different diameters and arterial volumes, and to simplify their implant. Maybe in a near future we might conclude that we have taken the worst and most complex way when the solution is simpler than we have initially thought.

State of the art does not authorize endovascular repair to become the treatment of choice of symptomatic aneurysm. The procedure should only be indicated according to the anatomical characteristics of the aneurysm, to the clinical presentation and to the center where it will be performed. A conventional cardiovascular surgeon is a still fully valid operator to treat this complex and severe condition.

As this issue is by no means a closed chapter, I dare pose a controversial situation:

Should we treat octogenarian patients with ruptured aortic abdominal aneurysms, clinical shock, previous chronic renal failure, COLD and ischemic or idiopathic myocardial dysfunction?

Neither conventional surgery nor endovascular repair have offered an adequate answer to this clinical situation.

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5. "At present, open surgery remains as the initial treatment of choice in symptomatic aortic abdominal aneurysm." This is true only in absence of a team trained in endovascular therapy, of a bank of endoprostheses and in case of unsuitable anatomy for endoprosthesis implant. If the aforementioned is available, this patient would benefit from a minimal invasive technique.

6. "Mortality rates associated with such a "minimal invasive" technique are disappointing and they evidence the presence of other factors still not exactly defined which might play an important role in the final outcomes." A reduction in mortality of at least a 5% compared to surgery does not seem disappointing, although probably it may not be statistically significant.

7. "The need of expensive technical and human resources which are difficult to apply even in developed countries turns the attempt to indicate endovascular repair as a treatment of first choice in an illusion in our country". Long hospital stays at the coronary care unit, several blood transfusions and infusions of precipitates, etc, treatment of hospital infections with expensive antibiotic agents and the delay in social reinsertion are factors with an undoubtedly greater economic impact.

Dr. Hernán Bertoni

#### A REPLY FROM THE AGONIST

Some considerations related to Dr. Rubio's manuscript:

1. "The development of the new procedures seems to minimize the great advances achieved by conventional surgery" Operative mortality in ruptured AAA treated with conventional surgery remains the same as it was 20 years ago.
2. "Nowadays, mortality is almost zero in series reported by surgical teams well-trained in this elective surgery." In randomized and prospective studies performed on selected patients at tertiary centers in the world, operative mortality is 5-8%.
3. "Ejaculation disorders do not seem to be an important issue in a population with an average age older than 70 years" Several septuagenarian patients emphasize their concern on their sexual performance after surgery during the medical consultation. Keep in mind that ejaculation is important not only for procreating...
4. "The lack of prospective studies prevents to determine if the improvements of the research were related to endovascular technique or only to population selection" I agree with this comment.

#### A REPLY FROM THE ANTAGONIST

The agonist of this controversy does not succeed in tilting the needle of the scale towards his side. He concludes that endovascular repair is a feasible procedure, though not the treatment of choice in a ruptured and symptomatic aortic abdominal aneurysm.

Environment conditions are fundamental to try to perform the procedure. They include high-cost facilities with a high-tech computed tomography scanner, a multidisciplinary and complex human team and a fixed cost in endoprosthesis and catheters of about 50,000 American dollars.

In symptomatic patients, randomized trails did not show superiority with endovascular repair. The results of the meta-analysis induce to believe that there has been a selection of patients to apply this technique and that the differences reported arise from this reason.

Dr. Bertoni states that 5% of the population older than 50 years has this condition. Considering that this number may be possible for people older than 65 years, we are facing a serious public health problem. According to the INDEC (National Institute for Statistics and Census) this population consists on 3,500,000

of persons in Argentina (5% = 175,000). Sixty percent will receive treatment (105,000).

Endoprosthesis cost is 1 575,000,000 American dollars, while conventional surgery costs 52,500,000 American dollars. The difference is obvious in an elective disease. Symptomatic aneurysm may represent 20% of the entire condition; this means 315,000,000 American dollars for emergency treatment with endovascular repair, and 10,500,000 American dollars for conventional surgery.

This elementary cost analysis considers the following issues:

15% to 20% of patients will need a new endovascular procedure – an additional cost for a new prosthesis or

extension, other patients will be operated on if the expansion has not been repaired and all of them will need control with expensive image methods.

Costs related to hospital stays have not been included; however, we are conscious that these costs are lower in our country compared to those in developed countries. Major complications that require prolonged stays at the ICU also occur in patients treated with an endovascular approach. The need of rehabilitation after conventional surgery is a possibility, although the economic impact is lower due to the low rate of labor activity in this aged population.

**Dr. Miguel Rubio**