

# Endovascular Aortic Repair: First Twenty Years

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## SUMMARY

Endovascular aortic/aneurysm repair (EVAR) was introduced into clinical practice at the beginning of the nineties. Its fast development had a great influence on clinicians, vascular surgeons and interventional radiologists, educational curriculums, patients, industry and medical insurance. The aim of this paper is to present the contribution of clinicians and industry to the development and advancement of endovascular aortic repair over the last 20 years. This review article presents the development of EVAR by focusing on the contribution of physicians, surgeons and interventional radiologists in the creation of the new field of vascular surgery termed hybrid vascular surgery, and also the contribution of technological advancement by a significant help of industrial representatives – engineers and their counselors. This article also analyzes studies conducted in order to compare the successfulness of EVAR with up-to-now applied open surgical repair of aortic aneurysms, and some treatment techniques of other aortic diseases. During the first two decades of its development the EVAR method was rapidly progressing and was adopted concurrently with the expansion of technology. Owing to large randomized studies, early and long-term results indicate specific complications of this method, thus influencing further technological improvement and defining risk patients groups in whom the use of the technique should be avoided. Good results are insured only in centers, specialized in vascular surgery, which have on their disposal adequate conditions for solving all complications associated with this method.

**Keywords:** aortic aneurysm; endovascular treatment; hybrid procedures; development process

## INTRODUCTION

Aortic aneurysms with increasing diameter are at risk of rupture. Since 1950 rupture prevention has been achieved by synthetic graft replacement of the patient's aortic segment. Since 1991 minimal invasive (endovascular) treatment has brought revolution in the treatment of aortic aneurysmal disease. Introduction of this method into everyday practice was supported by good early results, and tempted with the fact that by using this technique thoracotomy and laparotomy can be avoided. Evidence-based results were continuously preventing overuse of this method while waiting for long term outcome. Fast technical development and permanent improvement of this method, on the other side, made trial results interpretation more complicated, sometimes providing excuses for bad results and at the same time explanations for good ones. Recently, after reported results of these trials, the European Society for Vascular Surgery has published guidelines for the treatment of abdominal aortic aneurysm [1].

## PROCEDURE

Abdominal aortic aneurysm exclusion with the implantation of the stent graft under fluoroscopy has been performed for the first time in 1991 by Juan Parodi, Argentinean vascular surgeon [2]. A few years before Nikolai Volodos had per-

formed the first implantation of the stent graft in the thoracic aorta [3]. Endovascular treatment of different aortic pathology has been used in routine practice in Serbia since 2007. Since then more than 200 procedures were performed in the main Serbian clinics dedicated to the treatment of different aortic disorders. Some of experiences in this field have been already published by authors of this manuscript [4-10]. The stent graft is a synthetic blood vessel made of stainless steel or nitinol (metal alloy of nickel and titanium) for the internal armature, while synthetic material made of Dacron or PTFE is used for coverage of this armature. With this construction, when implanted inside the aneurysm, the stent graft provides its isolation from the systemic blood pressure as well as rupture prevention. The procedure can be performed under general, regional or local anesthesia, and demands placement of the sheaths into the femoral artery (common femoral artery is opened by groin cut down or through percutaneous puncture), followed by the introduction of the wires that serve as a carrier of the stent graft delivery system. When the delivery system is positioned in the area of the aneurysm neck, angiography is performed to mark and deploy precisely the upper limit of the stent graft and the position of the most distal vital aortic branch (renal arteries in case of abdominal aortic aneurysm or left subclavian artery in case of thoracic aortic aneurysm). The stent graft is then released from the delivery system and placed across the aortic

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aneurysm, always fixed on the healthy aortic wall proximally and distally from the aneurysm.

## INDICATIONS

This method has already been accepted worldwide and the quantity of its usage mostly depends on the randomized trial results, economical situation of the country and educational level of the practitioners. Nevertheless, while longer and longer term results are to be defined, the endovascular repair is mostly reserved for the patients that are at high risk in open surgical treatment, having anatomical features suitable for this procedure. While the given necessary anatomical conditions are changing with improvement of technology, the high risk criteria in open surgical treatment are estimated by different scales and according to different risk factors. In general, there are two groups of factors which increase the risk of open repair, requiring alternative method of treatment – promoting endovascular repair as the method of choice.

The first group involves conditions precluding safe aortic cross clamping or surgery in general anesthesia with significant blood loss. Those factors are met in patients with severe cardio-respiratory co-morbid conditions, which, before endovascular era, would have been rejected from open surgery and left to the natural history of the disease – final rupture. Renal failure significantly increases the risk of open surgical repair, however nephrotoxic contrast usage has to be minimized during endovascular treatment and thus make treatment risks acceptable. Much less frequently seen are factors such as hemorrhagic diathesis that makes performance of surgery more difficult, or neurological disorders that impede recovery. Patients older than 75 years are always at higher risk of open surgery regardless of co-morbid conditions.

The second group involves risk factors that hinder approach to the aneurysm (previous procedure in abdominal cavity, retroperitoneum or thorax). The level of limitations for open surgery in these cases also depends of the operators experience, however if there is an additional concomitant risk factor from the first group, endovascular treatment is a preferable treatment option. In the Western countries and North America patients preference or insurance company „advice“ play a significant role in the process of choosing treatment option.

## LIMITS

The process of safe implantation and fixation of the stent graft requires that some conditions are satisfied. Those conditions are related to the proximal and distal landing zone in terms of diameter, length and angulations. The aortic segment where the stent graft is fixed serves to secure fixation of the stent graft at the desired location. This segment is located proximally and distally from the aneurysm and is called the “landing zone” (LZ). On the other side, the quality of the iliac and femoral arteries as an access vessels need to be assessed concerning tortuos-

ity, calcification and diameter in order to allow passage of the sheath and delivery system. In reality, it means that the endovascular procedure is not possible if the proximal and distal LZ are short, angulated or both, and if iliac and femoral arteries are too tortuous, calcified or of the lower diameter than the outer diameter of the delivery system.

Although this method has brought new revolution to the treatment of aneurysms, since the beginning it faced these limits and deficiencies that are continually being overcome by clinicians on one side and engineers on the other. For the last twenty years three generations of the stent grafts conquered multiple shortcomings of this method, while at the same time vascular surgeons created a new hybrid - vascular surgery in order to increase the number of treatable patients.

## CONTRIBUTION OF CLINICIANS

Fixation of the stent graft is provided by radial force of the stent that is oversized to the diameter of the aorta for 10-20%, and by the length of the LZ that should be 15 mm for the abdominal and 20 mm for the thoracic aorta. Angulations of LZ of 75% and more could preclude fixation as well. Hybrid procedures have been developed in order to overcome these limitations and increase the number of treatable patients.

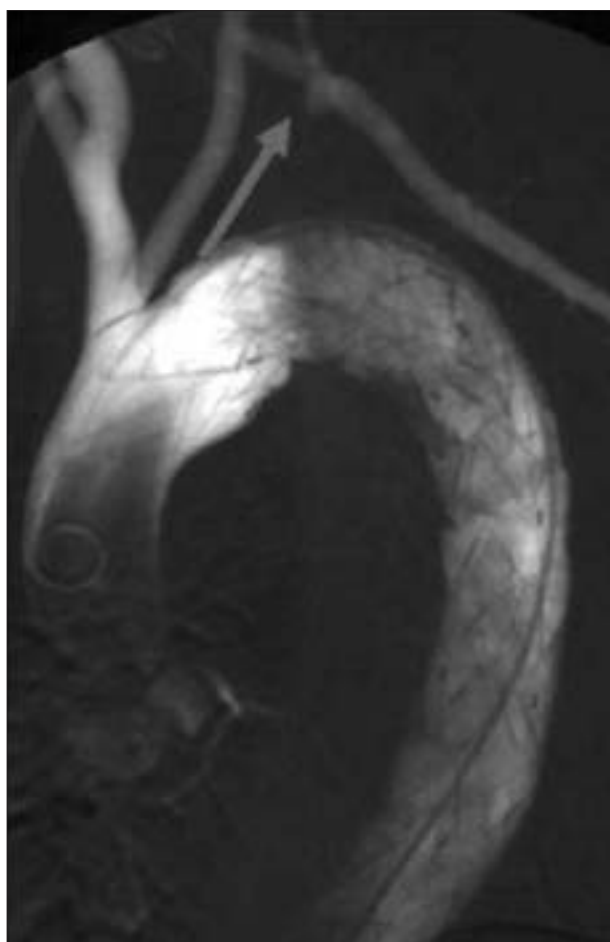
A common border of the proximal LZ is usually at the level of the origin of the left subclavian artery (LSA) for the thoracic aorta, and at the level of the origin of most distal renal artery (DRA) in case of abdominal aortic aneurysm. A significant number of aneurysms start at the level or even more proximally from the origin of the LSA and DRA. A short LZ in the area of the origin of LSA could be overcome by simple covering of the origin of this artery. This maneuver could be complicated, not only by upper limb ischemia, but also with stroke and spinal ischemia [11, 12]. Predictors of stroke after covering the LSA are occlusive disease of the carotid or right vertebral artery, dominant left vertebral artery or existence of its origin directly from the aortic arch. Patients are more susceptible to the development of spinal core ischemia when covering more than 250 mm of the length of the thoracic aorta, in case of previous reconstruction of the abdominal aorta or in case of occlusion of lumbal and hypogastric arteries. All these complications can be prevented by revascularization of the LSA with its transposition into the left carotid or by a carotido-subclavian bypass (Figure 1). A recent meta-analysis has shown that these procedures do not prevent stroke; the incidence of spinal cord ischemia could be reduced by revascularization of the left subclavian artery [13]. Regardless of these facts, the decision to perform revascularization of the LSA is left to the preference of the surgeon.

The problem is weightier when aneurysm is located more proximally close to the origin of the left common carotid artery. Implantation of the stent graft is possible only with previous extraanatomic reconstruction (carotido-carotid and carotid-LSA bypass), or even if the aneurysm is proximal; anatomical reconstruction of supraaortic branches is necessary in order to exclude this aneurysm with the stent graft (Figure 2). These procedures

called “debranching” make possible the treatment of the aneurysm of the aortic arch in patients at risk for open treatment. However, these procedures are followed by a significant number of fatal or non-fatal complications [14].

When the aortic (thoracic or abdominal) aneurysm is close to the origin of visceral branches, implantation of the endovascular stent graft could compromise flow in this vascular bed. In order to provide visceral perfusion, besides exclusion of the aneurysm, previous visceral debranching procedure is performed; hepato-renal, spleno-renal, iliaco-hepato, spleno-renal bypass, or any other kind of visceral revascularization with inflow from the healthy aorta or iliac arteries (Figure 3) [15]. This type of procedures are reserved for patients that are at high risk for open repair, or in symptomatic patients when waiting for the custom made graft is impossible, so the indications for these complicated and cumbersome procedures demanding suture of fifteen different anastomoses are narrow [16]. If the celiac trunk is the only branch involving the aortic aneurysm or the LZ, some authors suggest its covering, but it is advisable to perform angiography probe before [17].

Finally, hypogastric arteries are not so frequently remote from the aortoiliac aneurysms, and in order to perform a safe graft fixation they had to be covered. While some authors advocate that this is a safe maneuver even when bilateral, others would rather try to provide vascularization in order to prevent colon ischemia, gluteal skin necrosis



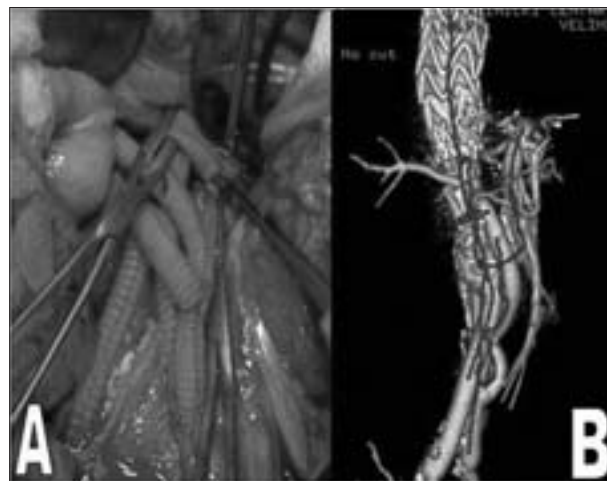
**Figure 1.** Control angiography after thoracic stent graft implantation and carotid-subclavian bypass (arrow)

or buttock claudication. Bypass or transposition of the hypogastric artery can be performed at least unilaterally to provide a minimum pelvic and buttock blood supply after extensive aneurysm exclusion with the stent graft [18].

The delivery system is to be placed through the femoral and iliac vessels that could be stenotic, occluded or hypoplastic, particularly in young adults and women. When luminal diameter of the femoral or iliac vessels is smaller



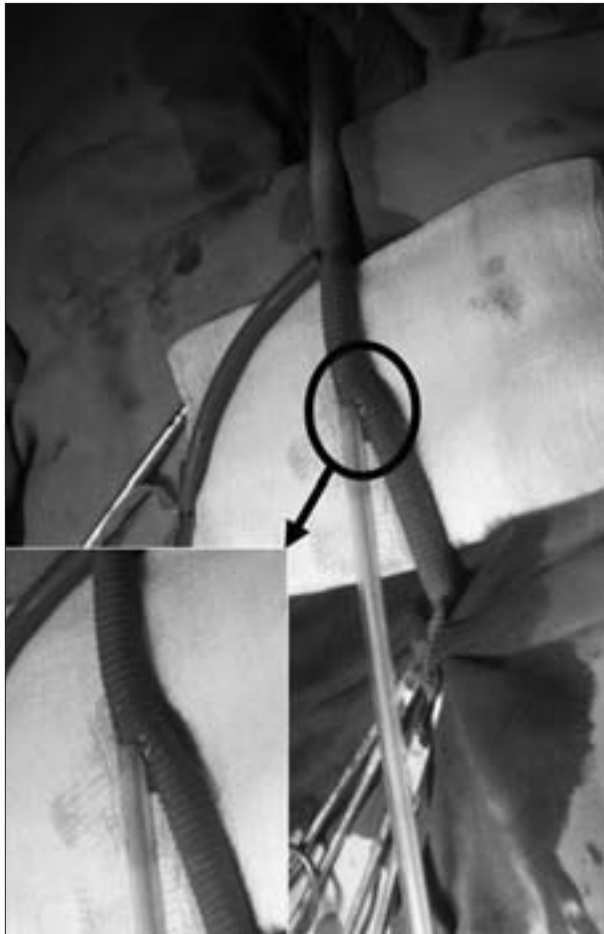
**Figure 2.** Four-arm Dacron graft sutured proximally for ascending aorta and distally in all supraaortic branches



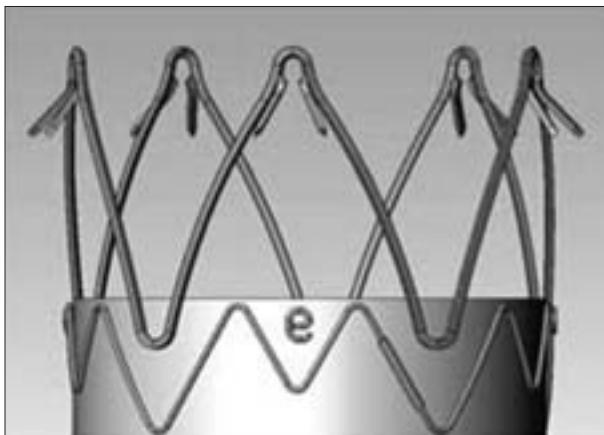
**Figure 3.** A. Reconstruction of aortoiliac segment and revascularization of all visceral branches as preparation for stent graft implantation covering the visceral segment of the abdominal aorta. B. Control MSCT after stent graft implantation

than outer diameter of the delivery system, implantation of the stent graft is possible with additional construction of iliac conduit made of the 10 mm synthetic graft sutured to the healthy iliac vessel or distal aorta. After delivering the stent graft this conduit can be oversewn at its origin, or anastomosed with the ipsilateral femoral artery (Figure 4).

If some of the branches are to be covered accidentally, one of the resolutions for this potentially severe complication is implantation of the stent (bare or covered) in this branch next to the stent graft. Positive results after treatment of this



**Figure 4.** A 10 mm Dacron graft sutured to common iliac artery, placed under inguinal ligament into the groin to provide passage of the delivery system through stenotic iliac segment.



**Figure 5.** Proximal segment of abdominal stent graft with bare stent and anchoring barbs improving proximal fixation

complication have enforced clinicians to perform this procedure in elective manner. It was performed for the first time in a case of AAA in 2003, and in a case of THAA in 2005, while in 2008 M. Malina named it the “Chimney” technique [18, 19, 20]. Since then this method has been accepted more widely gaining its supporters and opponents [21].

## CONTRIBUTION OF THE INDUSTRY

While vascular surgeons and interventionalists were fighting with the limits of the endovascular aneurysm therapy, representatives of the industry were developing newer generations of stent graft devices requiring fewer limitations and conditions, increasing the number of treatable patients. We are describing some of the improvements.

Proximal fixation has been improved by constructing a most proximal bare stent that can be placed over renal arteries, the so-called suprarenal fixation, what was later applied in thoracic stent grafts as well [22]. Additional hooks or anchoring barbs in the proximal end of the stent graft allowed treatment of patients with shorter and angulated necks (Figure 5). Other company provided stent graft with anchoring barbs and conical shaped proximal ring adapting its concavity to the origin of the renal arteries (Figure 6). Improvement of proximal fixation allocated treatment of complicated cases, and dividing the stents provided better adaptation on these curvatures, especially at the level of iliac arteries, decreasing limb thrombosis rate (Figure 7).



**Figure 6.** Stent graft with proximal conical ring providing suprarenal fixation in 2/3 of circumference



**Figure 7.** Stent graft with segment iliac limbs improving adaptation in elongated iliac arteries



Increased flexibility of the delivery system contributed to the treatment of patients with a tortuous, stenotic or hypoplastic ilio-femoral segment. A new deployment system with a top cap and constraining strings allows segmental deployment with repositioning of the stent graft when needed, which is important in angulated and short abdominal aortic necks, as well as in the great diameter aorta.

Some diseases of the thoracic aorta (penetrating aortic ulcer, aortic dissection and traumatic lesions) and some anatomical features of the aortic arch and descending aorta demand some corrections and pathology specific improvements of the thoracic stent grafts. Absence of the proximal bare stent decreases injury of the fragile dissected aorta, increases flexibility and conformability of the stent graft in the aortic arch, while longitudinal bars provide better columnar strength in this position. Short stent grafts and small diameter stent grafts have been constructed for traumatic aortic injuries, while stent graft with distal bare stent construction keep the true lumen patent when acute aortic dissection is treated. All of these corrections and innovations have significantly improved results in the treatment of acute and chronic specific thoracic aortic pathology [23].

One step beyond has been made with construction of the fenestrated stent grafts. Scallops and fenestras are constructed to keep visceral branches patent for the abdominal aneurysms with short proximal and thoracic aortic pathology and a short distal LZ. For visceral branches originating from the aneurysm sac a stent graft with branches have been constructed [24]. By using fenestrated or branched stent grafts the necessity for complicated reconstruction of the visceral arteries could be avoided. However the usage of these stent grafts is also precluded in some cases depending on the position and diameter of the visceral branches and the distance between each other, aortic and lumen diameter. The same technology of the branched stent graft has been used to prevent exclusion of the hypogastric arteries [25]. All this represents a great contribution of the industry to increase the number of treatable patients, and in the treatment of increasingly complicated abdominal and thoracoabdominal aneurysms, but there are still some progressions to come. The process of implantation is cumbersome even to the most skilled surgeons. The process of production is complex and time consuming (4-6 weeks) preventing treatment of urgent and emergent cases, while price is higher comparing to the regular stent grafts. This technology is not as convenient for aortic arch aneurysms as it is for thoracoabdominal, because of the unique characteristics of the brain vascularization, however there is a progress in the creation of solution for this complex problem as well [26, 27, 28].

If one of the iliaco femoral sides is unapproachable or unusable due to occlusion or severe stenosis, it is possible to implant the aorto-uni graft that covers aorta from renal to other healthy and patent iliac artery, while blood supply for the other limb is provided by a femoro-femoral "cross over" bypass (Figure 8).

Another issue is accurate measurement and planning of endovascular procedure. Tortuosities that are physi-



**Figure 8.** Control MSCT after aorto-uniiliac stent graft implantation and femoro-femoral cross over bypass

ological in the segment of the aortic arch and iliac arteries can be encountered in some other areas as well. Axial cross sections on the MSCT in these segments are unable to provide accurate diameter and length of this sector. For these purposes dedicated software has been created. Its purpose is to allow the clinician to create his own central aortic line and to stretch the aorta through this line providing an orthogonal section related to this line and not to the bogy surface area. With this technique, showed in Figure 9, diameter and length measurements are more accurate especially in elongated segments. Neck length estimation and procedure planning are most valuable.



**Figure 9.** A. Stretched thoracoabdominal aneurysm with central line analysed with working station "Trimensio". B. Measuring the distance between different aortic segments.

## RESULTS FROM TRIALS

In order to compare endovascular repair of AAA three randomized control trials were organized in Europe, Great Britain and United States, while some data "from the field" could be taken from registers like EUROSTAR in Europe and MEDICARE in the United States. Among randomized trials are EVAR 1 and 2 (Endovascular Aneurysm Repair Trial 1 and 2), DREAM (Dutch Randomized Endovascular Aneurysm Repair) and OVER study (Open Versus Endovascular Aneurysm Repair) [29-34]. Results of these studies are correlating with early results being in favor of endovascular repair in terms of mortality, morbidity, length of hospitalization and rate of intra-operative blood loss. However, during follow-up, this advantage of endovascular repair is diminishing after second to fourth year in all three studies. In the EVAR 1 study this difference was compensated due to the late death related to the implanted stent graft, while in other studies there is no difference in the cause of mortality. Late reintervention rate was higher after endovascular procedure in all three studies. Data from the Medicare database showed no difference in terms of reintervention rate comparing the two procedures. Study following the cause of death after aortic repair showed no difference between open and endo-repair in 13,971 patients with frequency of 0.3% aneurysm related deaths in both groups [35]. High rate of reinterventions could be related to the first undeveloped generation of stent grafts, measurement (in) accuracy and implantation related experience and the learning curve.

Additionally, reintervention rate could be the consequence of therapeutic over-activity of the practitioners included in the study since about 30% of reinterventions are due to endoleak type II.

These large studies evaluated cost effectiveness as well. Although endovascular procedures are less cost-effective, these studies are lacking complete costs analysis. Both procedures are bearing long term costs that are difficult to follow, estimate and count, like cardiac and renal insufficiency after open repair or costs of follow-up and reinterventions after endovascular procedure, meaning that new studies are needed to compare these two methods in terms of cost effectiveness on a long term basis. In the meantime clinicians are going to use both methods according to the latest results, their skills and advantages of newer generation of stent grafts that are hopefully going to be cheaper.

The latest publications are showing first long term results of fenestrated and branched stent grafts in the treatment of juxtarenal and thoracoabdominal aortic aneurysms [36]. Although these results are very affirmative, they represent good possibilities of new technology, however these results are owned by few best high volume European centers, and real life results are still about to come [37]. However, a French multicentric study presents mortality of 3% in 16 university centers. The price of the fenestrated and branched stent graft is important fact as well, and delivery time is also of value (4-6 weeks).

In case of thoracic aneurysms, avoiding thoracotomy, aortic cross clamping and extra corporal circulation thus reducing blood loss are obvious advantages that are favoring endovascular versus open repair and reducing paraplegia, mortality and morbidity rate. Hospitalization length and intensive care unit stay are significantly lower, while graft infection rate is still unchanged, 1-3%, with mortality of 50-100% [38-41]. Still, some pathological features of the descendent thoracic aorta and aortic arch are making them prone to different diseases, like dissection, dissected aneurysm, traumatic rupture and penetrated aortic ulcers, while anatomy of the aortic arch is sometimes making serious limits to endovascular repair. New decade of endovascular therapy will bring us resolution for these limitations.

## CONCLUSION

During the first two decades the endovascular procedure has rapidly evolved and technology has been significantly improved, while its results are becoming known, different complications and risk factors are becoming better defined. The evolution of this technique has changed planes of education of young surgeons and its adoption should be modified at the level of initial years of surgeons' education. Good results are about to come only in high volume centers that are capable of resolving all possible complications. Current limits are hopefully going to be overcome by technological development, decreasing complication rate and costs.

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## Првих двадесет година ендоваскуларног третмана обољења аорте

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### КРАТАК САДРЖАЈ

Ендоваскуларно лечење аортних анеуризми (енгл. *endovascular aortic/aneurysm repair – EVAR*) у клиничку праксу је уведено почетком деведесетих година двадесетог века. Брз развој ове методе значајно је утицао на клиничке лекаре, програме едукације, болеснике, индустрију и здравствено осигурање. У раду је приказан допринос клиничких лекара и представника индустрије у развоју и напретку *EVAR* у протеклих двадесет година. Описани су развој ове методе, допринос лекара, хирурга и интервентних радиолога, настајак нове области васкуларне хирургије – хибридне васкуларне хирургије, као и допринос технолошког усавршавања који су значајно потпомогли представници индустрије – инжењери и њихови саветници. У раду се анализирају и

студије које су упоређивале успешност методе *EVAR* са досад примењиваним отвореним хируршким лечењем аортних анеуризми, као и неке технике лечења других обољења аорте. Током прве две деценије развоја ова метода се брзо развијала и усвајала упоредо с развојем технологије. Захваљујући великим рандомизираним студијама, рани и удаљени резултати нам указују на специфичне компликације ове методе, утичући на даље унапређење технологије и дефинисање ризичних група болесника код којих примену ове методе треба избегавати. Добри резултати су извесни само у центрима специјализованим за васкуларну хирургију, где постоје услови за решавање свих компликација ове методе.

**Кључне речи:** анеуризма аорте; ендоваскуларни третман; хибридне процедуре; процес развоја

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