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ABSTRACT

Objectives: This study was intended: 1) to evaluate the results of the conventional and endovascular surgical treatment of symptomatic abdominal aortic aneurysms at three institutions, with equal diagnostic and therapeutic algorithm and the same surgical school, over the last 8 years; and 2) to communicate case studies which represent our daily practice and justify the need for a campaign for the early detection of this disease.

Materials and Methods: This is a retrospective study of the conventional and endovascular surgical treatment of symptomatic abdominal aortic aneurysms (SAAA) at three institutions, with demographic and risk factor data, within an 8-year period.

Results: Out of a total of 474 patients operated on between 2008 and 2015 due to abdominal aortic aneurysm (AAA), 71 patients were symptomatic. Mortality with endovascular treatment was 34.2% and with open surgery 80.0%. More than 70% of patients arrived in shock and the time of symptom onset was on average more than 8 hours. Hemodynamic instability (p = 0.013) and long-term assisted mechanical ventilation (p = 0.0001) were predictors of mortality.

Conclusión: The endovascular resolution of SAAA is the best therapeutic option because of low morbidity and mortality, with high short- and long-term efficiency. To achieve good results, we must have appropriate technology and materials and continuing medical and paramedical training. The prevention and early treatment of AAAs through massive detection campaigns is our ideal, ultimate objective.

INTRODUCTIÓN

In 1997, abdominal aortic aneurysms caused around 13,000 deaths in the United States. (1)

However, the aneurysmal disease was diagnosed two thousand years before Christ, and its treatment evolved from ligature through thrombosis, cellophane wrapping, etc. - all with very poor results. It was only in 1951 that Charles Dubost proposed as a surgical technique the replacement of the abdominal aortic aneurysm using a cadaver graft. At that time, this technique revolutionized the entire therapeutic proposal for such pathology.¹

The concept did not undergo any substantial changes until the advent of the endovascular therapeutics. This conceptual change modified the treatment of aneurysms in such a way that today more than 95% of the infrarenal arterial dilatations are performed with this technique.

It is from the 60s and 70s, when the first endoluminal tools (catheters, introducers, wire guides, angioplasty balloons, stents, etc.) were created, that this therapeutic revolution began. In 1990, the concept of "endovascular treatment" materialized combining the existing materials with a bold and innovative idea.²

Since then, new techniques and tools have made it possible to treat this pathology in more challenging anatomies, inexorably displacing the "conventional management". Today, discussion does not center on the benefits of this new current but on its technical aspects.

Vascular surgeons drove this change by getting trained, devising new proposals and establishing hybrid operating rooms as a new workplace.

This study was intended: 1) to evaluate the results of the conventional and endovascular surgical treatment of symptomatic abdominal aortic aneurysms at three institutions, with equal diagnostic and therapeutic algorithm and the same surgical school, over the last 8 years; and 2) to communicate case studies which represent our daily practice and justify the need for a national campaign for the early detection of this life-threatening disease.

MATERIALS AND METHODS

Out of the 474 patients with an infrarenal abdominal aortic aneurysm (AAA) who underwent endovascular or conventional surgery at the three centers mentioned above over the last 8 years, a selection was made of those symptomatic patients (SAAA) that presented the pathology at the time of the doctor's appointment. All patients or their representatives signed a consent form.

If the hemodynamic state allowed so, the necessary materials and devices were available and the anatomy was appropriate, endovascular treatment (EVSAR) was attempted first. In those patients who did not meet the above conditions, the conventional open management of symptomatic abdominal aortic aneurysms (COMSAAA) was performed.

Upon a suspected SAAA, hemodynamically stable patients (conscious, with systolic pressure > 80 mmHg) were transferred to the tomography room for a computed angiotomography (CAT), whereas hemodynamically unstable patients were taken immediately to the operating room. All of them were managed with a resuscitation protocol called "hemostatic resuscitation or permissive hypotension", which is based on the restriction of resuscitation with fluids in an aggressive way, as long as the patient remains conscious and systolic blood pressure is above 80 mmHg.

In the case of stable patients, if the CAT confirmed that the anatomical characteristics of the aneurysm were appropriate for endovascular treatment, the patient was considered eligible for this procedure (EVSAR). If patients were unstable, without previous CAT, at the operating room they underwent an intraoperative angiography, which served to determine the adequate anatomical characteristics for EVSAR. In some other cases, due to the extreme instability of the patient or to the lack of appropriate resources or means, it was decided to perform CMSAAA.

The morphological characteristics considered appropriate in patients with SAAAs were modified in relation to the "instructions for use" of the different available endoprostheses. Local anesthesia was the first option for those patients.

The hemodynamic variables were recorded upon admission, establishing the severity of the clinical picture and other hospital parameters. Other outcomes included 30-day mortality and postoperative complications.

STATISTICAL ANALYSIS

Data were entered in a database (Microsoft Excel 97) and then analyzed using the statistical package (SPSS 19 and Medcalc 16.4). For all variables, their distribution of frequencies and/or percentages was established in relation to the total number of cases. For ordinal or higher-scale measurements, the following statistics were computed: number of cases, minimum value found, maximum value found, median, mean, standard deviation.

For the group-by-group analysis and the estimation of survival time (100-event probability), the Kaplan-Meier survival analysis technique was used, whereas the Log-Rank test was used as the significance test, considering an alpha value below 0.05 as the significance level.

For the multivariate analysis, the Cox regression technique was used considering alpha = 0.05 as the input alpha level for independent variables and alpha = 0.10 as the output level. For the final model, the collinearity and goodness-of-fit assumptions of the model were compared.

For the determination of the cut-off point in variables measured on a proportional scale (quantitative) that are associated with the event, the logistic regression technique and the analysis of predicted probability values (Study 3) were used. Then, the curve that allows to determine the value of the inflection point of the plotted curve (cutoff point) was plotted.

RESULTS

Between May 2008 and December 2015, 71 patients with symptomatic abdominal aortic aneurysm (SAAA) underwent surgery. Average age: 72.3 years, male/female ratio: 7:1. In all cases, the diagnosis was confirmed by ultrasound or tomography; 45 patients had more than 6 hours of symptom onset, and 57 were conscious at the time of admission.

24% had a history of AMI, 29.5% of COPD, 9.8% of chronic renal failure. 91% had a history of smoking and 87.3% of arterial hypertension.

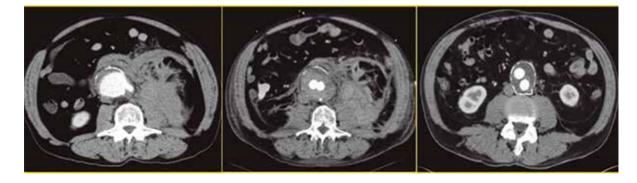
30-day global mortality was 34.2% in the group of endovascular treatment (EVSAR) and 80% in the group of conventional management (CMSAAA) (OR 7.7, 95% confidence interval 2.55 to 23.24, p = 0.000). If the various populations are analyzed separately, it is observed that there were situations which could be called "ideal": patients with less than 6 hours of rupture, hemodynamically stable upon admission and who received endovascular treatment. This subgroup had no 30-day mortality. Instead, those hemodynamically unstable patients that, given the urgency, received general anesthesia and underwent CMSAAA had a mortality rate of more than 80%.

In the EVSAR group, death occurred within the first 30 days. Two patients died within 72 hours because of severe hypovolemic shock, one died due to the compartment syndrome, and one as a result of a type I endoleak not treated due to the high risk of the patient.

On the contrary, in the CMSAAA group, 10 patients were admitted hemodynamically stable but their mortality also was 80% (Figure 1). AMI, renal failure, ischemic colitis and the compartment syndrome were the causes of mortality. The 3-year cumulative survival rate was 44%.

A univariate analysis explored the mortality-related risk factors in patients with symptomatic aortic aneurysm. For this purpose, it established correlations with age, sex, hemodynamic stability, rupture time above 6 hours, need for preoperative intubation, prior coronary angioplasty or myocardial revascularization surgery, prior AMI, cerebrovascular disease, peripheral vascular disease, heart failure, COPD, renal failure, obesity, type of anesthesia, need for aortic occlusion balloon, possibility

Figure 1. Tomography prior to surgery, during the immediate postoperative period and on the follow-up of a patient with ruptured aortic aneurysm treated endovascularly. Sack decrease and hematoma resorption are observed.



of endovascular treatment, need for hypogastric artery embolization, deliberate hypogastric artery occlusion, additional proximal cuff, need to perform the chimney technique, presence of a major complication, conversion to open surgery, and postoperative complications such as AMI, ARF with hemodialysis, long-term assisted mechanical ventilation (AMV), ischemic colitis, compartment syndrome, multi-organ failure, paraplegia and stroke.

The analysis suggested mortality risk factors such as hemodynamic instability, consciousness upon admission, previous endotracheal intubation, obesity, the use of general anesthesia, the use of aortic occlusion balloon, open surgery, the type of endoprosthesis used, the presence of major postoperative complications such as long-term AMV, compartment syndrome and multi-organ failure (Table 1). However, when these factors are grouped by collinearity, one realizes that instability hemodynamics, the state of consciousness upon admission, preoperative endotracheal intubation, general anesthesia and the use of occlusion balloon are variables directly related to the preoperative hemodynamic state. Major complications such as long-term AMV, compartment syndrome and multi-organ failure relate to a postoperative period with a high mortality rate. For this reason, a multivariate analysis with a collinearity test was conducted then.

Collinearity was found between independent variables (linear correlation coefficient $r \ge 0.6$ significant). Therefore, only the variables between which there was no collinearity and which were most statistically and clinically relevant for the prediction of the event were included in the initial model. The multivariate analysis in Table 2 describes the initial model.

Table 1. Multivariate analysis before collinearity tests.

RISK FACTORS	В	SE	Sig.	OR	95% CI for OR	
					Lower	Upper
Hemodynamic stability	-2.155	0.549	.000			
Conscious upon admission	-1.968	0.809	0.015			
Preop intubation	2.313	0.802	0.004	10.109	2.101	48.633
Obesity	-1.109	0.517	0.32	3.032	1.101	8.348
Local anesthesia	-3.321	0.809	0.000			
Aortic balloon	2.015	0.888	0.025	7.500	1.290	43.608
No EVSAR	-2.043	0.563	0.000	7.7142	2.559	23.2484
No Zenith endoprosthesis	-1.123	0.552	0.043	3.072	1.0358	9.0909
No Endurant endoprosthesis	-2.364	0.861	0.006	10.6363	1.9693	57.446
Major complication	2.482	0.572	0.000	11.968	3.903	36.704
Long-term AMV	3.397	0,659	0,000	29,867	8.216	108.570
Compartment syndrome	1.419	0.831	0.088	4.133	0.811	21.070
Multi-organ failure	1.405	0.703	0.046	4.074	1.027	16.168

RISK FACTORS	В	SE	Sig.	OR	95% CI for OR	
					Lower	Upper
Instability	-1.8777	0.916	0.40	6.55	1.086	39.302
Obesity	-0.244	0.829	0.768	0.783	0.154	3.975
Surgery with local anesthesia	-1.757	1.347	0.192	0.173	0.12	2.421
No Zenith endoprosthesis	-0.495	1.164	0.671			
No Endurant endoprosthesis	1.880	1.970	0.340	6.553	0.138	311.368
AMV	3.120	1.001	0.002	22.648	3.181	161.231
Multi-organ failure	0.140	1.352	0.918	1.150	0.081	16.288

According to these results, in the presence of the other variables, the risk factors of obesity, anesthesia, type of endoprosthesis and multi-organ failure lose statistical significance in relation to the event. Table 3 describes the final model.

Table 2. Initial model for the multivariate analysis.

RISK FACTORS	В	SE	Sig.	OR	95% CI for OR	
					Lower	Upper
Hemodynamic instability	-1.735	0.702	0.013	5.667	1.431	22.4368
Long-term AMV	3.139	0.698	0.000	23.077	5.875	90.644

In conclusion, the perioperative mortality of patients with symptomatic aortic aneurysm is directly influenced by their hemodynamic state upon admission to the institution. Undoubtedly, in the case of a patient in shock that undergoes aneurysm repair surgery, any major complication parameter in the postoperative period will mark a torpid evolution that in most cases ends with the death of the patient.

DISCUSSION

Despite great advances in the knowledge of pre, intra and postoperative management and new anesthetic techniques, the conventional open management of symptomatic abdominal aortic aneurysms (CMSAAA) has maintained a mortality rate of more than 40%. These figures could not be modified in the last 20 years.⁴ On the contrary, various series have shown results of mortality associated with the endovascular treatment of symptomatic aneurysms (EVSAR) with values lower than 25%.⁵⁻⁶ It is already known that the endovascular management of this mortal pathology involves lower morbidity, lower hemodynamic compromise as long-term aortic clamping (essential in high-risk patients) is avoided, lower anesthesiology impact, and more rapid recovery – all resulting in lower mortality.

Our figures coincide with a meta-analysis recently published with US Medicare data, on a population treated for symptomatic abdominal aortic aneurysms (SAAAs) in the 2001-2009 period, in which 30-day mortality of the EVSAR group was 33.8% as compared to 47.7% of the CMSAAA group.⁸

More recently, three studies comparing EVSAR and COAAAR have been published. The first one to be published was the Dutch study

Table 3. Results of the final multivariate model.

Amsterdam Acute Aneurysm Trial (AJAX),⁵ followed by the presentation of the French study ECAR⁶ and the English study Immediate Management of the Patient with Rupture: Open versus Endovascular Repair (IMPROVE).⁷

In the AJAX study, in-hospital mortality was 21% for patients in the endovascular group and 25% for those treated with open surgery, showing no significant difference. The results were better than expected due to an improvement in patient logistics, the use of tomography imaging and, above all, the centralization of patients in only 3 institutions of high academic level.

In the IMPROVE study recently presented, 54% were treated endovascularly with an associated mortality rate of 25%. However, when both groups were compared, no significant difference could be established. Preoperative blood pressure under 70 mmHg (hemodynamically unstable) and the type of anesthesia used were predictors of mortality.

In our study, as regards mortality, hemodynamic instability was associated to an HR of 5 and assisted mechanical ventilation to an HR of 23.

The abdominal compartment syndrome is a known complication of endovascular treatment. It normally occurs in hemodynamically unstable patients with a large retroperitoneal hematoma. The result is intra-abdominal hypertension and multiple organ system dysfunction. In and II Early recognition, or even suspicion, through the measurement of bladder pressure and surgical decompression are needed to improve survival. The use of an aortic occlusion balloon, coagulopathy, massive transfusion and conversion to an aorto-uni-iliac device are predictors of the syndrome. In our experience, it was a cause of mortality and was present in 3 of our 71 patients.

CONCLUSION

In our country, anatomical constraints and, especially, logistics (banks of endoprostheses) make the endovascular technique difficult to apply for the treatment of patients with symptomatic aneurysms. However, our approach is to attempt endovascular treatment as the "first treatment option" for patients with symptomatic aneurysms.

The authors of this paper are involved in this approach since its inception, totally convinced that it is the best therapeutic option for patients suffering from this disease.

The vast difference between the two approaches – EVSAR and CMSAAA –, shown in this humble communication and supported by international literature, dispels any doubts as to which the best therapeutic option is.(9) In this presentation, we have documented the early technical success and good long- and short-term results obtained with the endovascular treatment of SAAAs.

After the period of endovascular training at the same surgical school, our job was to attempt to create and coordinate "aorta treatment centers" that include a multidisciplinary group of specialists (cardiology, cardiac surgery, vascular medicine, vascular surgery, cardiovascular anesthesia, imaging, nurses and technicians) expert in the diagnosis and treatment of the aneurysmal disease.

The creation of these centers, with the appropriate provision of

materials and infrastructure, would help to provide EVSAR to most patients with SAAA.

However, we know that finding the most intelligent solution to this problem, beyond the technique to be used in emergency cases, does not imply high costs, sacrifices or unattainable procedures but just the determined and tenacious search for such pathology. This could be achieved through national massive detection campaigns.

With this paper, our ultimate objective is to contribute to their implementation. Detecting an abdominal aortic aneurysm early only requires an abdominal ultrasound scan.

It is a matter of raising awareness, informing the community and getting the attention of the health authorities.

The treatment of a patient with symptomatic abdominal aorta aneurysm is a frustrating, challenging emergency situation which stretches the surgical team to the limit. The difference between the endovascular and conventional approaches is significant, but even more significant is the difference between treating symptomatic and asymptomatic aneurysms.

For this reason, today our daily actions are focused on the prevention and early detection of aneurysms and on the search for excellence in the endoluminal technique.

REFERENCES

- 1- Fairman R, Wang G. Abdominal Aortic Aneurysms. Endovascular Treatment. Rutherford's Vascular Surgery 8 th edition vol 2, chapter 132, 2014: 2046-61
- 2- Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:491-9.
- 3- Consenso para el tratamiento endovascular del aneurisma de aorta abdominal- 2009. Actualización 2015. Sociedad CELA. Técnicas Endovasculares 2014;17:12-26
- 4- Elliot L. Chaikof, David C. Brewster, Ronald L. Dalman, Michel S. Makaroun, Karl A. Illig, Gregorio A. Sicard, Carlos H. Timaran, Gilbert R. Upchurch Jr, and others.SVS practice guidelines for the care of patients with an abdominal aortic aneurysm: Executive summary. Journal of Vascular Surgery, 2009 Oct; Vol. 50, Issue 4, p880–96
- 5- Kapma MR, Dijksman LM, Reimerink JJ, de Groof AJ, Zeebregts CJ, Wisselink W, Balm R, Dijkgraaf MG, Vahl AC.Cost-effectiveness and cost-utility of endovascular versus open repair of ruptured abdominal aortic aneurysm in the Amsterdam Acute Aneurysm Trial. Br J Surg 2014;101:208-15.
- 6- Desgranges P, Kobeiter H, Katsahian S, Bouffi M, Gouny P, Favre JP, Alsac JM, Sobocinski J, and others. ECAR (Endovasculaire ou Chirurgie dans les Anévrysmes aorto-iliaques Rompus): A French Randomized Controlled Trial of Endovascular Versus Open Surgical Repair of Ruptured Aorto-iliac Aneurysms. Eur J Vasc Endovasc Surg. 2015 Sep; 50(3): 303-310. doi: 10.1016/j.evjs.2015.03.028
- 7- IMPROVE Trial Investigators. Endovascular strategy or open repair for ruptured abdominal aortic aneurysm: one-year outcomes from the IMPROVE randomized trial. Eur Heart J 2015;36:2061-9.
- 8- American College of Cardiology Foundation; American Heart Association Task Force; Society for Cardiovascular Angiography and Interventions; Society of Interventional Radiology; Society for Vascular Medicine; Society for Vascular Surgery, Rooke TW, Hirsch AT, Misra S, Sidawy AN, Beckman JA, Findeiss LK, Golzarian J, Gornik HL, Halperin JL, Jaff MR, Moneta GL, Olin JW, Stanley JC, White CJ, White JV, Zierler RE.2011 ACCF/AHA focused update of the guideline for the management of patients with peripheral artery disease (updating the 2005 guideline). Vasc Med 2011;16:452-76.
- 9- Moll FL, J.T. Powell, G. Fraedrich, F. Verzini, S. Haulon, M. Waltham, J.A. van Herwaarden, P.J.E. Holt, and others.Management of Abdominal Aortic Aneurysms Clinical Practice Guidelines of the European Society for Vascular Surgery. European Journal of Vascular and Endovascular Surgery. 2011 Jan; Vol. 41, S1–S58

- 10- Ruppert V, Leurs LJ, Rieger J, Steckmeier B, Buth J, Umscheid T; EUROSTAR Collaborators.Risk-adapted outcome after endovascular aortic aneurysm repair: analysis of anesthesia types based on EUROSTAR data..J Endovasc Ther 2007;14:12-22.
- 11- Broos PP, Stokmans RA, Cuypers PW, van Sambeek MR, Teijink JA; ENGAGE Investigators. Effects of Anesthesia Type on Perioperative Outcome After Endovascular Aneurysm Repair. J Endovasc Ther 2015;22:770-7.