

CORREÇÃO ENDOVASCULAR DE ANEURISMAS DA AORTA ABDOMINAL ROTOS E ELETIVOS: DEVEMOS ESPERAR MAIS COMPLICAÇÕES APÓS R-EVAR?

ENDOASCULAR ANEURYSM REPAIR FOR INTACT AND RUPTURED ABDOMINAL AORTIC ANEURYSMS: SHOULD WE EXPECT MORE COMPLICATIONS AFTER R-EVAR?

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Recebido a 09 de junho de 2017

Aceite a 12 de abril de 2018

RESUMO

Introdução: O tratamento Endovascular do Aneurisma da Aorta Abdominal em rotura (r-EVAR) tem sido progressivamente adotado devido aos benefícios no curto prazo. A sobrevida após alta hospitalar parece semelhante entre r-EVAR e doentes operados eletivamente (el-EVAR). Ainda assim, devido à maior complexidade anatómica é expectável um maior risco de complicações relacionadas com o aneurisma após r-EVAR.

Métodos: Bases de dados MEDLINE foram pesquisadas no sentido de identificar publicações reportando *outcomes* após r-EVAR e el-EVAR. Ensaios clínicos randomizados foram usados para comparação.

Resultado: Após a alta *outcomes* (except mortalidade), foram reportados em 5 estudos incluindo 509 pacientes r-EVAR. Comparação direta entre r-EVAR e el-EVAR foi encontrada em dois estudos incluindo 2895 doentes (256 r-EVAR and 2653 el-EVAR). Taxas de *endoleak* tipo I variaram entre 5.4-21% para o grupo r-EVAR e entre 4.4-10% no grupo el-EVAR. Taxas de reintervenções no grupo r-EVAR variaram entre 16.7-76% e entre 11-27.7% no grupo el-EVAR. Taxa de complicações aos 5 anos após r-EVAR dentro das instructions for use (IFU) foi de 8.8% e reintervenções de 16.7%.

Conclusão: Pacientes r-EVAR apresentam taxas mais altas de *endoleaks* tipo I e intervenções secundárias. Contudo, quando dentro das IFU, as taxas de complicações relacionadas com o aneurisma são sobreponíveis ao el-EVAR. Estratégias de *follow-up* devem ser ajustadas de acordo com a anatomia basal e complicações precoces e não de acordo com *timing* de reparação.

Palavras-chave

Aneurisma roto da Aorta Abdominal; Correção Endovascular de Aneurisma; Resultados.

ABSTRACT

Introduction: Endovascular Aneurysm repair (EVAR) for ruptured abdominal aortic aneurysm (r-AAA) has been increasingly advocated due to short term benefits. Survival after discharge seems to be similar between EVAR for r-AAA (r-EVAR) and for elective patients (el-EVAR). Still, due to higher anatomical complexity more graft-related complications may arise in r-EVAR patients.

Methods: MEDLINE databases were searched to identify publications reporting on outcomes after r-EVAR and el-EVAR. Landmark EVAR randomized controlled trial results were used as comparison.

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Results: After-discharge outcomes (other than mortality), were reported in 5 studies including 509 r-EVAR patients. A direct comparison between r-EVAR and el-EVAR patients was found in 2 studies, including 2895 patients (256 r-EVAR and 2653 el-EVAR). Type I endoleak rates ranged from 5.4-21% in r-EVAR and from 4.4-10% el-EVAR. Rates of secondary intervention in r-EVAR ranged between 16.7-76% and in el-EVAR from 11-27.7%. Five year rate of complications after r-EVAR inside instructions for use were 8.8% and reinterventions were 16.7%.

Conclusions: r-EVAR patients present higher rates of type I endoleaks and secondary interventions. However, when complying with IFU, aneurysm-related complications overlap to the el-EVAR patients. Surveillance strategies should be tailored according to the baseline anatomical complexity and early complications and not to the timing of repair.

Keywords

Ruptured Abdominal Aortic Aneurysms; Endovascular Aneurysm Repair. Outcomes.

INTRODUCTION

Abdominal Aortic Aneurysm (AAA) is a common disease affecting approximately 7-9% of the population over age of 65 years with higher prevalence in smokers.⁽¹⁾ In case of rupture lethality reaches up to 80%.⁽²⁾

Endovascular aneurysm repair (EVAR) is now increasingly used in the management of AAA as a less invasive alternative to open surgical repair.⁽³⁾⁽⁵⁾ The increasing experience with EVAR and a new generation of devices have allowed its applicability in emergency situations as well. EVAR for ruptured AAA (rEVAR) is often preferred due to the minimally invasive nature and potential short-term benefits in survival.⁽⁶⁾⁽⁷⁾ Additionally, in patients surviving in-hospital stay long-term mortality seems to be similar between r-EVAR and elective EVAR (el-EVAR).⁽⁸⁾⁽⁹⁾ Nevertheless, rAAA presents with a more hostile anatomy and, consequently, more aneurysm-related complications may arise.⁽¹⁰⁾⁽¹¹⁾ However, mid and long term results of r-EVAR and how they compare to el-EVAR are scarcely described.

The aim of the present study is to compare mid-term survival and aneurysm related complications between r-EVAR and el-EVAR.

METHODS

A literature search was performed to identify studies investigating mid to long-term results after standard r-EVAR as well as studies comparing outcomes between el-EVAR and r-EVAR patients. MEDLINE databases were searched between January 2000 and May 2016. Only standard EVAR with bifurcated or aorto uni-iliac stent grafts were considered. Studies including fenestrated grafts, chimney-EVAR or other off the shelf procedures were not included. Observational studies with less than 50 r-EVAR were not included. Landmark EVAR randomized controlled trials were also used as comparison.

DEFINITIONS

Aneurysm-related complications were defined as a composite of the following: direct (type 1 or 3) endoleak, aneurysm sac growth, migration, device integrity failure, AAA related death, late post-implant rupture or any AAA-related secondary intervention.

ENDPOINTS

The primary study endpoint was freedom from aneurysm related complications. Secondary endpoints were thirty-day mortality and individual components primary composite endpoint (aneurysm rupture, type 1A, type 1B and type 3 endoleaks, secondary interventions, graft or limb thrombosis, graft infection, conversion to open repair or death as a result of aneurysm-rupture or aneurysm-related treatment) as well as overall-survival during follow-up.

RESULTS

Six studies were included reporting r-EVAR outcomes after discharge (other than mortality), describing more than 3200 patients (561 r-EVAR and 2653 el-EVAR). Two of them represent direct comparison between mid to long term outcomes between r-EVAR and el-EVAR (256 r-EVAR and 2653 el-EVAR).

Randomized Controlled Trials (RCT) in rAAA

Three main RCTs comparing outcomes between open repair (OR) vs endovascular repair for rAAA are published: AJAX trial,⁽¹²⁾ ECAR trial⁽¹³⁾ and IMPROVE trial.⁽¹⁴⁾ In the first two trials patients were anatomically selected while the third represents a pragmatic clinical practice, as patients were randomized before performing pre-operative CT scan.

In the AJAX trial patients were recruited between April 2004 and February 2011 in three centers in Amsterdam.



A total of 520 patients with clinical suspicion of rAAA were identified. CT scan confirmed rAAA in 365 patients and, after exclusion due to anatomy or other factors, 116 patients were included (57-r-EVAR and 59 - OR).

Similar 30-day (EVAR 21% vs OR - 25%, $P=0.66$) and 6-month mortality (EVAR 28% vs OR 31%, $P=0.84$) were the main findings. No difference in severe complications (cardiac, bowel ischemia, reinterventions, stroke, amputation and spinal cord ischemia) were reported between groups. Two major limitations can be associated to this trial: only aorto-uni-iliac endoprosthesis were used and then it is not representative of current practice. Secondly, only 22% of patients with rAAA were included, most being excluded due to unsuitable anatomy, and then overall mortality may be underestimated as more complex cases were excluded.⁽¹²⁾

In the ECAR trial, 107 patients (56-r-EVAR and 51- OR) were recruited between January 2008 and January 2013. Thirty-day (18% EVAR and 24% OR) and 1-year mortality (30% r-EVAR and 35% - OR) was not statistically different between groups.⁽¹³⁾

The third and the largest trial was the IMPROVE. Contrarily to the two previous trials, patients were randomized at the time of diagnosis, often before CTA to ascertain suitability for endovascular repair. Due to differences in study design, IMPROVE was better able to assess the efficacy of an endovascular first strategy and was more generalizable to the entire ruptured aneurysm patient population.

Thirty-day (35% EVAR and 37% OR, $P=0.62$) and 1-year mortality (41% EVAR and 45% OR; $P=0.325$) were also not different between groups. Still, EVAR showed a trend toward better outcome in the elderly (OR: 0.86 IC 95% 0.54-1.35 in patients > 77 years old) and seriously ill patients (OR: 0.42 IC 95% 0.21-0.85 if $\text{Hardman} \geq 2$). Subgroup analysis showed that endovascular strategy was more effective in women than in men (OR: 0.43 95% IC 0.21-0.89).⁽¹⁴⁾⁽¹⁵⁾

Three year results of IMPROVE trial presented at SVS Annual Meeting, 2017, demonstrated a trend toward a lower 3-year mortality in r-EVAR (48.2% vs 55.9; $P=0.058$).⁽¹⁶⁾

Survival after discharge

Several risk factors are known to predict rupture: smoking, arterial hypertension, female gender and aneurysm diameter.⁽¹⁷⁻²⁰⁾ So, it is expected that rAAA patients present with a higher burden of comorbidities conditioning their long term survival. Bastos-Gonçalves et al also found similar 5-year mortality between r-AAA patients (60% were r-EVAR) surviving first 30 days and i-AAA (approximately 42 % r-AAA and 40% i-AAA, $P=0.482$).⁹ Baderkhan and coworkers described a 34.4% after-30 day mortality in r-EVAR over a median follow-up period of 2.5 years.⁽²¹⁾

Noorani et al, reported a 73% survival rate at 2 years for r-EVAR (52% for OR)⁽²²⁾ and Saqib et al published a 42% survival rate at 3-years survival for r-EVAR patients.

Aneurysm-related Complications

Few studies have focused on aneurysm-related complications after r-EVAR. Bastos-Gonçalves et al in a multicentric observational study found that r-EVAR (vs el-EVAR) does not represent a significant risk factor for late complications (HR: 0.87 CI 95% 0.43-1.79, $P= 0.712$). In more recent study, a 5-year rate of graft-related complications of 8.8% in r-EVAR performed inside IFU (vs 76.5% in r-EVAR outside IFU, $P<0.001$) was encountered.⁽²¹⁾ Over a median follow-up period of 31 months 35% of any complications were described for r-EVAR, not only aneurysm related.⁽²²⁾

Type I and III endoleaks

Regarding type I endoleaks Quinn et al (N=2032; 166-rEVAR and 1880 el-EVAR) described, over a mean follow-up of 30 months, a 5.4% rate of type I endoleaks in r-EVAR vs 4.4% in el-EVAR, $P=0.68$.⁽²³⁾ Broos et al, in a single center study (N=863, 90 r-EVAR and 773 el-EVAR), described a 21% rate of type I/III endoleaks in r-EVAR and 10% in el-EVAR ($P=0.003$) at 5 years.⁽²⁴⁾

Type II endoleaks

Regarding type II endoleaks Quinn et al reported a 9.04% incidence of type II endoleak in r-EVAR patients and 20% in el-EVAR group ($P<0.001$).⁽²³⁾

Limb thrombosis/Endograft Obstruction

Broos et al described a 13% incidence of endograft obstruction in r-EVAR group and 8.1% in the el-EVAR group ($P=0.073$). Rate of reintervention for graft obstructions were significantly higher for r-EVAR group ($P=0.034$).⁽²⁴⁾

Secondary Interventions

A 5-year rate of secondary interventions of 22.2% in r-EVAR and 15.8% in el-EVAR ($P=0.064$) was recently reported.⁽²⁴⁾ Baderkhan (N = 112) and colleagues described a 5-year rate of secondary interventions of 16.7% in r-EVAR performed inside IFU (vs 76% performed outside IFU). Quinn et al found an incidence of reinterventions of 19.9% in the r-EVAR and 23.3% in el-EVAR group ($P= 0.37$). Additionally, Roos et al in a study reporting reinterventions after EVAR (N= 405, 68 r-EVAR and 337 el-EVAR) described a 20% rate of secondary interventions at two years for r-EVAR and 11% for el-EVAR ($P= 0.002$).⁽²⁵⁾ Noorani et al described a 9.6% rate of reintervention after r-EVAR over 31 months of follow-up.⁽²²⁾

Data on follow-up of patients from the AJAX trial were published in 2015 reporting a re-intervention rate of 48% at 5 years.⁽²⁶⁾ Data from the IMPROVE showed a 26% reintervention rate at 3 years.⁽¹⁶⁾

Results of Landmark EVAR randomized Controlled Trials

The landmark RCT's (EVAR-1, DREAM, OVER and ACE trials) have presented long term results which offer reliable data for comparison as only electively treated patients could be included in these trials. EVAR-1 trial 10-year results show estimated overall-mortality of 46%. Rate of secondary interventions was 23.3%.⁽²⁷⁾ In the DREAM trial, the authors stated a 6-year estimated overall mortality of 31.1%, 6.9% of type I endoleak (12/173 patients) and a rate of 27.7% of reinterventions.⁽²⁸⁾ More recently, the OVER trial also presented long term outcomes. In this study, 22.1% of secondary reinterventions were described.⁽²⁹⁾ Finally the ACE trial showed a 3-year estimated mortality of 13.7%, 6.6% of type I endoleak (10/150 patients) and 16% of secondary interventions.⁽³⁰⁾

DISCUSSION

The use of EVAR in the treatment of ruptured AAA has increased rapidly over the past years.⁽³¹⁾⁽³²⁾ Endovascular repair for rAAA demonstrated superior short-term survival when compared to open repair in most multicenter and single-center studies⁽³³⁻³⁵⁾ although no early survival benefit was found in randomized controlled trials.⁽¹²⁾⁽¹⁴⁾

Comparison of long-term mortality rates between RCT for ruptured and intact aneurysms, adjusted for in-hospital casualties, may give a glimpse on the influence of emergent vs elective treatment on long-term survival. A 48.2% 3-year mortality was presented for r-EVAR patients of the IMPROVE trial significantly higher than the 29% observed in the EVAR-1 trial at 4 years 36, 31% in the DREAM trial at 6 years and 32% in the OVER at a mean follow-up of 5.2 years.⁽²⁸⁾⁽²⁹⁾ Important to note that in the IMPROVE trial 30-day mortality was 35% while in the EVAR trial was only 1.7%, 1,2% in the DREAM trial and 0,5% in the OVER trial.⁽³⁾⁽¹⁴⁾⁽³⁷⁾⁽³⁸⁾ Then, considering only patients who survive in-hospital stay, one may conclude that mid to long term survival seems to be similar between r-EVAR and el-EVAR patients. Confirming these findings, two observational studies described similar long term survival between r-AAA patients who survive 30 days and 90 days, respectively, and el-EVAR patients.⁽⁸⁾⁽⁹⁾ Mani et al reported on the trends after rAAA correction in 12848 patients (8663 i-AAA and 4171 r-AAA) from the SwedVasc Registry. Among 90-day survivors, the authors described a 2.3% difference in overall mortality between rAAA and i-AAA patients (CI95% 0.4-6.8).⁽⁶⁾ In this study most of rAAA patients were treated with OR, giving the idea that regardless of the method of treatment no differences on long term survival remains after hospitalization days. Although seems counterintuitive,

given several cardiovascular risk factors associated to aneurysm rupture, this suggests that an increment in peri-operative survival is the most influential factor for improving vital prognosis of rAAA patients. This means that the hemodynamic impact of shock occurring with rupture is decisive for in-hospital mortality but do not seem to condition long term survival among patients who survive this period.

Despite no differences in mortality, more aneurysm related complications may be expected in r-EVAR due to significantly more hostile anatomies. Still, Bastos-Gonçalves et al did not find r-EVAR as an independent risk factors for late complications when compared to el-EVAR (HR: 0.87 CI 95% 0.43-1.79, P= 0.712).⁽³⁹⁾ Regarding individual components of the latter outcome, Quinn et al described a 5,4% rate of type I endoleak, similar to observed in el-EVAR group meeting those described in DREAM or ACE trial.⁽²³⁾⁽²⁸⁾⁽³⁰⁾

On the other hand, Broos et al reported 21.8% rate of type I/III endoleak at 5 years, significantly higher than the 10% encountered in the el.-EVAR group and also than the 6.9% observed in the DREAM and 6.6 in the ACE trial.⁽²⁴⁾⁽²⁸⁾⁽³⁰⁾

Possible explanations for these differences may relate to the longer follow-up period in Broos' study and to the implanted endografts. While in Quinn's publication the most common stent-graft in the r-EVAR group was Excluder (W. L. Gore & Associates, Inc., USA) (63%), in the latter study Talent (Medtronic Vascular, Inc., USA) represented the most used graft (63.3%).⁽²³⁾⁽²⁴⁾ More neck-related events are found with Talent stent-graft, when compared new generation grafts, namely, the Endurant (Medtronic Vascular, Inc., USA), its successor.⁽⁴⁰⁾ As new generation grafts were mostly used in Quinn's study, probably it may justify better outcomes.

Incidence of limb thrombosis after r-EVAR is also scarcely described in the literature, although being one common cause of reintervention, its troubleshooting usually does not lead to increased mortality or morbidity.⁽²⁴⁾

Higher incidence of secondary interventions may also be expected after r-EVAR. Broos found higher, yet, non-significant rate of reinterventions in r-EVAR group (22.2% vs 15.8%; P= 0.064).⁽²⁴⁾ Additionally, reinterventions rates reported by Broos et al are also overlapping those observed in DREAM or OVER trials.⁽²⁸⁾⁽²⁹⁾ Baderkhan et al reported a 16.7% rate of secondary interventions after r-EVAR within IFU (vs 76% for outside IFU r-EVAR).⁽²¹⁾ Then, the likelihood of secondary interventions seems to relate to the anatomical complexity of the AAA and not to the timing of correction itself. On the other hand, patients from the AJAX trial present with a 48% rate of secondary interventions, significantly higher than obtained for patients treated in the elective setting.⁽²⁶⁾ However, analyzing all the patients



in the Amsterdam Ambulance region and not only patients randomized to the AJAX trial, 30-day survivors present a 34% rate of secondary interventions at 5 years not significantly different from the 28% found in the DREAM trial.⁽²⁶⁾⁽²⁸⁾

Although the RCTs that we used for comparison only included elective patients and therefore offer reliable data for comparison, most of them used older generation stent grafts and endovascular expertise at the time of RCT was limited. This may result in higher rates of complications when compared to current practice. This is found in contemporary EVAR registries: 5-year results of the Endurant IDE trial (150 patients included, all electively treated) showed 0.6% of aneurysm-related mortality (ARM), 1.3% of type I endoleaks and 11% of reinterventions.⁽⁴¹⁾ Also in a report from Greenberg et al. including only Zenith stent grafts (n=158), 5-year overall mortality was 17%, ARM 2%, late endoleaks occurred in 12-15 % and there were no post-implant ruptures.⁽⁴²⁾ Both these studies show a significantly lower incidence of complications compared to landmark RCTs and also r-EVAR studies. When compared to inside IFU r-EVAR patients (9.8% endoleaks requiring intervention and 16.7% of reintervention at 5-years) differences are no longer very prominent. Then, anatomical complexity and compliance to IFU rather than timing of repair may be important predictors of post-discharge complications. This review has limitations that warrant consideration. All the reviewed r-EVAR vs el-EVAR studies are limited by their retrospective design. Additionally, most are single-center reports with limited populations, making them susceptible of a publication bias. Additionally, most of these centers gained experience in EVAR over the last years and the logistics for EVAR in emergent setting have also been improving recently. As such, better results are expected nowadays than they were in the past. Finally, many studies only has mid-term follow-up, with older generation grafts not permitting long-term conclusions with contemporary methods.

CONCLUSION

Due to higher complex anatomy, r-EVAR patients seems to have higher rates of type I endoleaks and secondary interventions. However, when treated with modern stent-grafts complying with IFU, aneurysm-related complications seems to be similar to the el-EVAR patients. Surveillance strategies should be tailored according to the aneurysm anatomical complexity and not to the timing of repair.

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