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Abstract

Objectives: The stentgrafts used for endovascular abdominal aortic repair (EVAR) profited from many technological changes since their appearance. The objective of this study was to compare the medium-term results of the 2^{nd} and 3^{rd} generation stentgrafts.

Material and methods: Three hundred thirty-four patients treated by EVAR between 2005 and 2013 were included in this retrospective study. Demographic, anatomical, perioperative and follow-up data were collected in a prospective way in an electronic database and compared between two groups. The preoperative angio-CTs were all analyzed in depth on a suitable 3D work station. Group 1 (n=219) represented the patients treated by 2^{nd} generation stentgrafts (Medtronic Talent®, Cook Medical Zenith Flex®, Vascutek-Terumo Anaconda®, Gore Excluder low-porosity®) and group 2 (n=115) represented the patients treated with 3^{rd} generation stentgrafts (Medtronic Enduring I and II®, Cook Medical Zenith LP®, Gore Excluder C3®).

Results: The mean follow-up was 42.4 ± 26.8 months with a longer duration in group 1 (52.4 ± 27.2 months vs 23.2 ± 10.9 months, p<.0001). The patients of group 2 had significantly more risk factors and cardiovascular comorbidities (coronary disease, tobacco addiction, dyslipidemia, peripheral arterial disease, chronic renal insufficiency). Anatomical characteristics were similar in the two groups, in particular regarding the iliac arteries which were significantly more calcified and had a smaller diameter in group 2. The rate of peroperative complications was similar in the two groups, in particular for complications related to the iliac axes (3.7% vs 2.6%, p=.96). During the follow-up there was no significant difference between the two groups in the rates of survival, reinterventions, or endoleaks and the progression of the aneurysmal sac.

Conclusion: This study shows that 3^{rd} generation stentgrafts allow results comparable with those of the 2nd generation stentgrafts in spite of more complex iliac anatomies. These results

make it possible to expand the indications of EVAR to patients presenting more cardiovascular comorbidities without increasing the risk of complications in the short and medium term.

INTRODUCTION

Current stentgrafts benefited from technological changes compared to those implanted in the first randomized trials. Each industrial company developed a stentgraft whose evolutions with each generation were focused on the delivery system, the design of the graft, or the system of anchoring. For most of the companies, 3rd generation stentgrafts are now implanted. Some of these evolutions can be easily apprehended at the time of the procedure, such as the simplification of the delivery system, but the impact or other changes on the long term results of EVAR may be more difficult to measure. Notwithstanding, these changes coincide with an improvement of the results of the EVAR in comparison with the first randomized trials(1) and with a reduction in the rate of explantation over the time(2). These improvements are probably multifactorial (learning curve, better selection of the patients) but it is interesting to assess how the new devices contribute to these results and if the technological changes are really correlated with an improvement of the results of EVAR.

Several studies showed that 2nd generation stentgrafts made it possible to obtain better long-term results than 1st generation devices (3-5). Although several non-comparative studies on 3rd generation aortic stentgrafts showed good performances(6-13) only one very recent study compared this latest generation of grafts with the preceding one (14). This study compared a new stentgraft manufactured by a single company with results which did not allow concluding to major differences between the two generations of devices. It was thus necessary to evaluate other stentgrafts to confirm or not these results in order and determine the actual benefits obtained with this new generation of stentgrafts. The objective of this study was to compare the mid-term results of 2nd and 3rd generation stentgraft in the treatment of infrarenal abdominal aortic aneurysms (AAA).

MATERIAL AND METHODS

Starting from a prospective institutional register beginning in January 2000, all the patients operated on for infrarenal AAA by EVAR with a 2nd or 3rd generation stentgraft were included retrospectively in this study. The patients treated with first generation or fenestrated or branched stentgrafts were excluded, as well as the patients operated on for fissured or ruptured AAA. In order to compare preoperative vascular anatomies, only the patients having a preoperative angio-CT analyzable on a work station were included. The patients included in this study were operated between January 2005 and December 2013.

Implanted stentgrafts and design of the study groups. The stentgrafts implanted over the period of the study were Talent®, Enduring® I and II (Word medical-Medtronic, Sunrise, FL, USA), Zenith Flex® and Zenith LP® (William Cook Europe, Biaeverskow, Denmark), Excluder® (Low Permeability 2nd generation and 3rd generation with C3 delivery system) (WL Gore, Flagstaff, AZ, USA), and Anaconda® (Sulzer-Vascutek, Inchinnan, Renfrewshire, Scotland). Two groups were designed considering the specific technological changes of each company. Group 1 represented the 2nd generation stentgrafts, including Talent® (Medtronic), Zenith Flex® (Cook), Excluder low-permeability® (Gore), and Anaconda® (Vascutek). Group 2 represented the 3rd generation stentgrafts, including Endurant® I and II (Medtronic), LP Zenith® (Cook) and Excluder® C3 (Gore).

Preoperative clinical and anatomical data. For each patient, the cardiovascular risk factors and the comorbidities were collected (Table I). All the patients were explored by an abdominopelvic preoperative angio-CT with injection of contrast and millimetric cuts. The preoperative anatomical morphological criteria were analyzed with the EndoSize software [15] (Therenva, Rennes, France). Besides the diameters and working lengths for the choice of the stentgraft, measurements "for research" were collected because their influence on the onset of a complication during follow up could be addressed [16]. The usual quantitative parameters measured for the choice of the stentgraft are summarized in table II and the qualitative parameters "for research" are listed in table III. All the anatomical parameters were described with continuous measurements apart from measurements of calcifications and thrombi which were categorized according to a grade of severity [16] ranging from 0 to 3. Grade 0 corresponded to calcifications or of thrombi between 0 and < 25% of the arterial circumference, grade 1 between 25 and < 50%, grade 2 between 50 and < 75% and grade 3 ≥ 75%. Aortic neck was regarded as conical if the diameter 15 mm below the lowest renal artery increased by more than 10% compared to the proximal diameter [17].

Peroperative data. During the procedure, the following data were collected: mark and model of stentgraft, the type of femoral access (open or percutaneous), the total duration of the intervention, the parameters of irradiation and the volume of product of contrast used. Peroperative complications were classified as complications related to the accesses, complications related to the iliac axes (dissection or wound), and complications related to the stentgraft.

Early postoperative data (<30 days). The complications were classified as complications of vital functions (cardiac, renal, neurological…) and complications related to the stentgraft (endoleaks, thrombosis…). The complications were also grouped into two categories: major and minor complications. Complications requiring reoperation or with a short term life-threatening forecast were also considered as major, as those with irreversible sequelae. Primary technical success and secondary technical success were defined according to the international standards [18].

Follow up data. The usual follow-up of the patients was angio-CT one, six, 12 and 24 months after the intervention. Beyond two years, the methods and the rhythm of monitoring were adapted to the evolutionary process of the aneurysmal sac, the presence or not of an endoleak and the patient's overall condition [19]. Endoleaks were classified according to the international standards [18].

Statistical analysis. Quantitative data are presented as mean ± standard deviation (SD) and qualitative data as counts and percentages. Quantitative variables were compared by the Student *t* test and qualitative variables by the chi-square test. Follow-up data were analyzed with actuarial curves according to the Kaplan-Meier method and were compared using a Log-rank test. XLStats® software (ADDINSOFT, Paris, France) was used for the realization of the statistical analysis. The significance threshold was set at 0.05.

RESULTS

Three hundred thirty-four patients (668 iliac) were included in this study. Two hundred and nineteen patients (65.6%) (438 iliac) were assigned to group 1 and 115 (230 iliac) to group 2. The distribution of the different types of stentgrafts in each group is presented on Figs. 1 and 2.

Preoperative clinical data (Table I). The mean age of the patients was 74.7 ± 8.2 years in group 1 and 74.7 ± 8.8 years in group 2 (p= 0.98). In univariate analysis, among all the studied characteristics, five were significantly different. There were more patients with a history of smoking in group 2 than in group 1 (91.3% vs 76.7%, p=0.002). There were more patients with a history of dyslipidemia in group 2 than in group 1 (83.5% vs 72.1%, p=0.03). There were more patients with coronary disease in group 2 than in group 1 (75.7% vs 50.2%, p<0.0001). There were more patients with chronic renal insufficiency in group 2 than in group 1 (36.5% vs 6.8%, p<0.0001). Lastly, there were more patients with peripheral occlusive arterial disease in group 2 than in group 1 (17.4% vs 5.9%, p=0.002).

Anatomical data (Tables II and III). Three quantitative characteristics presented a significant difference between the two groups. The diameter of the end of the common iliac arteries was significantly smaller in group 2 than in group 1 (13.9 ± 3.7 mm vs 15.3 ± 3.9 mm, $p<0.0001$). The smallest diameter of the external iliac arteries was smaller in group 2 (7.4 ± 1.6 mm vs 8.3 ± 1.9 mm, $p<0.0001$). The diameter of the celiac aorta was smaller in group 2 (26.9 ± 3.4 mm vs 27.7 ± 2.8 mm, p=0.04). The maximum diameter of the aneurysm tended to be larger in group 2 (58.6 ± 11.9 mm vs 56.14 ± 10.2 mm, p=0.051). Among the qualitative characteristics of the sizing three of them differed between the 2 groups. Iliac calcifications were more important in group 2 than in group 1 (11.7% grade 3 in group 2 vs 2.5% grade 3 in group 1, $p<0.0001$). There were more conical aortic necks in group 2 (24.8% vs 13.3%, p=0.04). Lastly, there were more internal iliac thromboses in group 2 (6.6% vs 2.3%, p=0.01).

Preoperative data. The duration of operation was significantly longer and the volume of injected contrast product was significantly higher in group 1 than in 2. The proportion of percutaneous accesses was significantly greater in group 2 (Table IV). There was no significant difference between the two groups with regard to the complications related to the accesses (n=7, 3.2% in group 1 vs n=2, 1.7% in group 2, p=0.43), those related to the iliac axes (n=8, 3.7% in group 1 vs n=3, 2.6% in group 2, p=0.61) and those related to the stentgrafts (n=30, 13.7% in group 1 vs n=16, 13.9% in group 2, p=0.96). Overall there were three (1.4%) failures of introduction of the stentgraft (one introduction from the side opposite to the operative plan) in group 1 and none in group 2 (p=0.21), without any failure on both sides in the two groups. There was one conversion into open surgery in each group (0.5% in group 1 and 0.9% in group 2, p=0.64). In group 1 the cause of conversion was a failure of deployment and in group 2 it was due to an attempt to correct a proximal endoleak with an aortic extension which was deployed in the meshes of the supra-renal stent. In each group there was one (0.5% in group 1 vs 0.9% in group 2) unplanned coverage of an internal iliac artery (p=0.64). During the procedures, there were four (1.8%) complications at the time of the deployment of the stentgraft in group 1 and five (4.3%) in group 2 (p=0.18), and two stenoses or plications of prosthetic limbs in each group (0.9% in group 1 and 1.7% in group, p=0.51). The four stenoses or plications were treated by angioplasty with stenting.

Immediate postoperative data (<30 days). The mean duration of hospitalization was 8.3 ± 9 days in group 1 and 7.9 ± 2.3 days in group 2 (p=0.68). Mortality rates at 30 days was similar in the two groups (n=4, 1.8% in group 1 vs n=2, 1.7% in group 2, p=0.95). No significant difference was found in the rate of major complication postoperative (n=17, 7.8% in group 1 vs n=12, 10.4% in group 2, p=0.41). The primary and secondary technical success rates were 89.5% and 96.8% in group 1 and 87.8% and 97,4% in group 2 (p= 0.64 and 0.76, respectively).

Follow up. The mean duration of clinical follow-up was 42.4 ± 26.8 months (52.4 ± 27.2 months in group 1 and 23.2 ± 10.9 months in group 2 (p<0.0001)).

Survival. Survival rates at 1, 2 and 3 years were 94.5 ± 1,6%, 87.4 ± 2.3% and 82.0 ± 2.7% in group 1 and 89.5 ± 2.9%, 80.6 ± 4.2% and 75.0 ± 5.0% in group 2, respectively (p=0.07) (Fig. 3). The aneurysm-related death rate at 3 years was 3.3 ± 1.2% (n=7) in group 1 and 4.9 ± 2.2% (n=5) in group 2 (p =0.44). The rate of aneurysmal rupture at 3 years was 0.52% (n=1) in group 1 and 1.28% (n=1) in group 2 (p=0.33). All the patients presenting a rupture died.

Evolution of the aneurysmal sac. At 3 years, the rate of regression of the aneurysmal sac was 48.9 ± 3.6% in group 1 and 52.6 ± 5.6% in group 2 (p=0.09). Conversely, the growth rate of the aneurysmal sac at 3 years was 18.7 ± 2.8% in group 1 and of 13.1 ± 6.9% in group 2 (p=0.13).

Endoleaks. Table V summarizes the endoleaks at three years. Whatever type of endoleak, there was no difference between the groups.

Reinterventions. Including all reinterventions, there was no difference at three years between the groups (fig. 4). The rates of survival without reintervention for endoleak were 85.6 ± 2.5% in group 1 and of 94.0 ± 2.7% in group 2 at 3 years, respectively (p=0.11). The rates of prosthetic limb thrombosis at three years were 5.8 ± 1.6% in group 1 and 8.1 ± 2.9% in group 2, respectively (p=0.43) with the need for a crossover femoro-femoral bypass in all the patients except one who was treated medically. One patient of group 1 (0.5%) and two (1.8%) of group 2 required further surgery for intestinal ischemia without significant difference at three years (p=0.24). The rates of reintervention for limb stenosis and/or plication were not statistically different between the 2 groups, reaching 3.1 ± 2.2% in group 1 and 1.4 ± 0.8% in group 2 at three years (p=0.65). At three years, five patients of group 1 (2.3%) were reoperated on for explantation of the stentgraft whereas no patient of group 2 had to be explanted (p=0.43). The causes of conversion into open surgery were one type IA endoleak at 35 months without possibility of endovascular treatment with a proximal or fenestrated extension, three type II endoleaks with a diameter increase of more than 10 mm (all at 36 months) and one infection at 24 months.

Analyzes by stentgraft. The comparison between the Medtronic devices (largest group of patients in this study) showed a lower rate of survival at three years for the last generation devices (80 ± 3.7% in group 1.70 ± 6.4% in group 2, respectively, p = 0.02). There was no difference concerning the rates of rupture, aneurysm-related death, prosthetic limb thrombosis, survival without reintervention, conversion into open surgery, and reintervention whatever the cause. Contrary to type IA and IB endoleaks, there was a difference in the rate of type II endoleaks in favor of the new generation devices (28.3 ± 4.5% in group 1 vs 10.9 ± 3.7% in group 2), leading to a tendency a reduced number of patients without reintervention for endoleak in group 1 (82.7 ± 3,7% in group 1 vs 95.1 ± 2.8% in group 2, respectively, p= 0.06). Growth rate was 27 ± 4.4% in group 1 and 16.2 ± 11.4% in group 2 (p=0.01). The rate of regression was 39 ± 4.9% in group 1, and 50.6 ± 6.8% in group 2 (p=0.005). In this subgroup, the risk factors were also more severe in the group receiving a new generation stentgraft with higher rates of smoking addiction (88.8% vs 70.8%, p=0.005), PAOD (20% vs

3.2%, p=0.0005), severe chronic renal insufficiency (28.8% vs 4%, p<0.0001) and coronary disease (73.7% vs 47%, p=0.0002).

DISCUSSION

The analysis of the preoperative demographic data of our study explains at least in part the difference observed in the preoperative anatomical data. In group 2, the patients had more cardiovascular comorbidities and risk factors, which can explain the higher proportion of peripheral vascular disease in group 2. Therefore it looks logical that the anatomy of iliac arteries is more complex in terms of calcifications and stenoses in this group. Obviously, this is a selection bias since the patients of this group received stentgrafts of the last generation.

The analysis of the peroperative data showed a significant reduction in the total duration of the procedure (p=0.04) without any reduction in the duration of fluoroscopy or of the amount of irradiation. The more frequent use of a closure system in group 2 can explain this result in part because at least one study showed a reduction in the duration of procedures with the use of a closure system [20]. The volume of product of contrast was also significantly reduced. The learning curve of the operators and the planning of the incidences of angiography thanks to sizing software after 2010 probably made it possible to reduce the number of injections. The higher proportion of patients with chronic renal insufficiency also obliged us to take better precautions regarding the volume of product of contrast injected. Lastly, the performance of some procedures in a hybrid room with image fusion since 2012 could also contribute to this reduction.

In our study, there were not more iliac complications in group 2 in spite of more iliac complex anatomies, which was expected due to the reduction in the profiles of the stentgrafts. Therefore, low profile stentgrafts of 3rd generation seem to be reliable, making it possible to treat more complex anatomies without increasing the perioperative morbi-mortality.

The results of our study regarding follow-up data did not show a significant difference between the two groups with regard to survival, reinterventions, endoleaks and the evolution of the aneurysmal sac. Growth rates of the aneurysmal sac observed in our study can appear high (18.7% in group 1 and 13.1% in group 2), but they are in fact comparable with the data of the literature reporting growth rates between 17% at three years and 41% at five years in the meta-analysis of Schanzer et al.(17). In the study of Mertens et al.(21) the growth rate at five years was 17.5% and in the study of Walker et al.(22), it was 21.4% at three years.

Except for the improvement of the profile of the delivery system making it possible to navigate in complex iliac anatomies, the technological changes between 2nd and 3rd generation do not constitute a major change in the concept and the architecture of stentgrafts (improvement of the fineness of the fabric, modification of the material or of the structure of the stents), and it is difficult to determine in what these evolutions could have improved to a significant degree mid-term results in particular regarding the rates of endoleaks.

For this study we chose to distribute the different types of stentgrafts in two groups. Four types of stentgrafts were proposed by Medtronic: Aneurx®, Talent® (2005), Enduring® I (2011) and II (2012). The first generation stentgraft (Aneurx®) was excluded from this study. Talent® was thus classified in group 1 (2^{nd} generation). The main developments between Talent® and Enduring® were the addition of hooks positioned at the level of the supra-renal stent, the removal of the lateral reinforcement bar, and the reduction in the profile of the delivery system. We chose to gather up Enduring® I and II in group 2 (3^{rd} generation) because the structural differences were much less prominent than between Talent® and Enduring® I. The addition of radioopaque markers and the reduction in the diameter of the delivery system for some diameters of main bodies constitute the principal differences between the two models of Enduring®. It is important to note that the sub-group analysis for this company found different results in the follow-up data which were not found in the initial tracking cohort. These results relate to the total survival at three years which was lower in group 2 and a better rate of type II endoleaks in the same group. These results are explained in part because of the preoperative demographic factors. Indeed the patients had a stronger history a tobacco addiction. Patients were thus more exposed to complications related to this risk factor of cardiovascular morbi-mortality but also to the risk of cancer, which may have contributed to the lower survival. As to the lower rate of type II endoleaks, it was reported in several publications [(23-25)] that tobacco had paradoxically a protective effect on the occurrence of type II endoleaks, probably through the prothrombogenic effect of tobacco. While this was not always found in the other studies, the higher frequency of type II endoleaks can explain the higher rates of reintervention for endoleak and aneurysmal growth in group 1, and on the opposite a higher rate of aneurysmal sac shrinkage in group 2. The presence of an important difference in the population in this subgroup makes it difficult to conclude that the new generation stentgrafts are better. However, these results at least consolidate the data of equivalence between the two generations of stentgrafts with broader anatomical eligibility criteria. In order to neutralize these demographic differences the application of a propensity score would be interesting, but it requires a thorough statistical analysis which could be the subject of additional studies.

As regards the Cook stentgrafts, the distribution of Zenith Flex® in group 1 and Zenith LP® in group 2 was already used in the study of Sobocinski et al. [(14)]. The main changes between these two models were a longer proximal non covered stent and a finer polyester fabric in Zenith LP®. The material of the stents also changed from stainless steel to nitinol with a lower profile of the delivery system of the bifurcated modules. Concerning Gore stentgrafts, the first generation of Excluder® was made available in 1997, the Low Permeability appeared in 2004, and the 3rd generation with the C3 Delivery System appeared in 2010. As for Aneurx®, the first generation Excluder® was excluded from the study, and none of this type of stentgraft was implanted out in our institution. Gore Excluder Low Permeability® was thus classified in group 1 and Gore Excluder C3 Delivery System® in group 2. The principal differences between these two models were initially the introduction of the repositioning system and also the reduction in the profile of the delivery system of the main body and the extensions. Lastly, for the Vascutek-Terumo stentgrafts, three models were marketed. BluGlide™ and ONE-LOK™ are the two last generations and we only used the first one, which was classified in group 1.

Studies had already shown the superiority of the 2nd generation stentgrafts. The study of Verzini et al.[5] showed significantly better long-term results in terms of explantations, reinterventions, and growth of the aneurysmal sac at seven years. This monocentric study concerned 1412 patients and reported longer-term results (five and seven years) that our study. However, the composition of the groups was different, with the grouping of AneurX® and Talent® in the older generation group and the grouping of the Zenith® and Endurant® in the newer generation group. This composition of the groups is open to discussion since 1st and 2nd generation stentgrafts of the same company were included in the same group. Other studies already showed better results for Talent® when compared to Aneurx® [26, 27]. Consequently the comparison with Zenith® and Endurant® is biased and makes the results of this study more difficult to interpret. In our study we compared stentgrafts of similar generation with comparable results between the different stentgrafts of each group [28]. Ouriel et al.[26] reported a series of 703 patients comparing five different first generation (Ancure®, original Excluder® and AneurX®) and second generation (Talent® and Zenith Flex®) stentgrafts. The principal results of this study were the absence of difference in the rates of reinterventions at one year, and significantly lower rates of endoleaks at one year for the second generation stentgrafts as well a higher rate of aneurysmal sac shrinkage for 2nd generation stentgrafts. This study thus concluded on the superiority of second generation stentgrafts compared to first generation devices. Another study of Wales et al.[28] compared the results of 2nd generation stentgrafts in 286 patients receiving Zenith and Talent grafts and did not show a significant difference concerning type 1 or 3 endoleaks, survival without reintervention, and survival all causes of death confused at three years. In the Zenith group there were significantly higher proportions of short necks and neck angulation > 60°. The analysis of the preoperative anatomy did not report qualitative and quantitative measurements of iliac accesses. The study of Mensel et al.[29] compared Endurant® and Talent®. This study on 71 patients had results only over the first 30 days. The clinical success rate was significantly better in the Endurant® group (97.2% vs 80.0%, p=0.028).

Currently, only one study [14] compared 2nd and 3rd generation with mid-term results. This study concerned 208 patients receiving stentgrafts of the same company (Cook Zenith Flex® vs Zenith LP®) which was methodologically more valid, but it excluded inter alia all the stentgrafts marketed by other companies which reduced the scope of the conclusions on the results of 3rd generation stentgrafts. Besides the characteristics of the aortic neck, the analyzed anatomical characteristics in this study were primarily the tortuosity and the minimal diameter of the iliac arteries. The results of this study were in agreement with ours since it did not show significant differences at one and two years concerning the rates of survival without reinterventions and the rates of survival all causes of death confused. The iliac anatomies were also more complex in the Zenith LP® group with a higher proportion of external iliac arteries with a diameter < 7 mm.

In addition to its retrospective character and the absence of randomization, a limit of this study was the significant difference in the duration of follow-up of the patients between the groups which prevents from any conclusion on the long-term results. Since last generation stentgrafts are implanted since less than five years, it is still too early to obtain long-term data beyond five years. The advantage of including several stentgrafts is to get wider conclusions on the benefit brought by the new generation of stentgrafts even if the majority of the stentgrafts used were marketed by two firms (Cook and Medtronic), which reflects the current market. The other bias of this study was a rather long period of inclusion which was necessary to include a sufficient number of patients in each group and to allow statistically valid comparisons. The advantage was to have a long follow-up for many patients, but that could integrate more heterogeneous practices regarding the preoperative sizing or the procedure than in a study with a shorter inclusion period and a single operator, as reported by Sobocinski et al. [14]. Lastly, among the many data collected in this study, we did not report the rates of stentgraft migration. However migration is a late event in the follow-up of stentgrafts which is diagnosed on regular CT-scans. In our institution and in accordance with the recommendations, long-term duplex ultrasound is the key examination in the absence of complication detected at the time of the follow-up, and, in the recent studies, migrations became rare [9, 30].

CONCLUSION

Third generation stentgrafts made it possible to increase the number of eligible patients for EVAR with the improvement of the profiles of the stentgrafts, they but did not show their superiority to 2nd generation stentgrafts in terms of postoperative clinical results and of mid-term specific complications. The reduction in the profiles of the stentgrafts required technological changes which require a longer follow-up to determine if the results found in this study are maintained or not.

Conflict of interest

None

Legend of figures

Fig. 1. Group 1, 2nd generation stentgrafts.

Fig. 2. Group 2, 3rd generation stentgrafts.

Fig. 3. Kaplan-Meier estimates for total survival at 3 years.

Fig. 4. Kaplan-Meier estimates for freedom from reintervention at 3 years.

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Table I. Demographic and clinical data

	Total population (n=334)	Group 1 (n=219)	Group 2 (n=115)	P
Age (years, mean ± SD)	74.7 ± 8.4	74.7 ± 8.2	74.7 ± 8.8	0.98
Gender (men)	309 (92.5%)	200 (91.3%)	109 (94.8%)	0.25
Hypertension	258 (77.2%)	166 (75.8%)	92 (80.0%)	0.37
Dyslipidemia	257 (76.9%)	158 (72.1%)	96 (83.5%)	0.03
Diabetes	41 (12.3%)	24 (11.0%)	16 (13.9%)	0.47
Tobacco	273 (81.7%)	168 (76.7%)	105 (91.3%)	0.002
Coronary disease	197 (59.0%)	110 (50.2%)	87 (75.7%)	<0.0001
Aorto-coronary bypass	36 (10.8%)	26 (11.9%)	10 (8.7%)	0.37
Aortic valvular replacement	18 (5.4%)	12 (5.5%)	6 (5.2%)	0.92
Coronary angioplasty	48 (14.4%)	28 (12.8%)	20 (17.4%)	0.25
Chronic renal insufficiency (GFR<60)*	57 (17.1%)	15 (6.8%)	42 (36.5%)	0.0001
Chronic respiratory insufficiency	21 (6.3%)	15 (6.8%)	6 (5.2%)	0.53
Dialysis	4 (1.2%)	2 (0.9%)	2 (1.7%)	0.58
Peripheral vascular disease	33 (9.9%)	13 (5.9%)	20 (17.4%)	0.002
Carotid atheroma	25 (7.5%)	15 (6.8%)	10 (8.7%)	0.56
Hemoglobin (g/dL ; mean ±SD)	14.1 ± 1.7	14.1 ± 1.7	14.1 ± 1.7	1
Creatinine rate (µmol/l ; mean ± SD)	97.6 ± 54.0	95.6 ± 33.4	98.8 ± 63.9	0.72
FEVG* (% ; moyenne ±DS)	55.0 ± 11.8	56.0 ± 11.4	51.1 ± 13.0	0.06

* Ventricular ejection fraction

* Glomerular filtration rate expressed as mL/min/1.73m² according MDRD

Table II. Quantitative anatomical data

	Total population (n=334)	Group 1 (n=219)	Group 2 (n=115)	P
Proximal neck diameter (mm)*	23.5 ± 3.3	23.7 ± 3.2	23.1 ± 3.4	0.13
Mid neck diameter (mm)*	24.0 ± 3.6	24.1 ± 3.5	23.9 ± 3.7	0.66
Distal neck diameter (mm)*	24.8 ± 4.0	25.0 ± 4.0	24.5 ± 4.0	0.31
Neck length (mm)*	27.7 ± 12.7	28.0 ± 12.7	27.0 ± 12.6	0.48
Common iliac diameter (mm)*	14.8 ± 3.9	15.3 ± 3.9	13.9 ± 3.7	<0.0001
Aneurysm length (mm)*	110.3 ± 16.7	109.4 ± 16.6	111.8 ± 17.0	0.23
Common iliac length (mm)*	64.1 ± 17.4	64.1 ± 15.9	64.0 ± 20.1	0.93
Aortic bifurcation diameter (mm)*	27.2 ± 7.7	26.6 ± 7.5	28.2 ± 7.9	0.07
Aneurysm maximum diameter (mm)*	57.0 ± 10.9	56.1 ± 10.2	58.6 ± 11.9	0.051
Celiac trunk diameter (mm)*	27.4 ± 3.0	27.7 ± 2.8	26.9 ± 3.4	0.04
Aortic neck angulation (°)*	32.0 ± 15.3	31.8 ± 15.5	32.5 ± 15.1	0.68
Iliac minimum diameter (mm)*	8.0 ± 1.9	8.3 ± 1.9	7.4 ± 1.6	<0.0001

* : all the measurements are presented as mean ± SD

Tableau 1. Table III. Qualitative anatomical data (for research) of the sizing

		Total population (n=334)	Group 1 (n=219)	Group 2 (n= 115)	P
Iliac calcifications	Grade 0	189 (28.3%)	141 (32.2%)	48 (20.9%)	0.0006
	Grade 1	306 (45.8%)	191 (43.6%)	115 (50.0%)	
	Grade 2	135 (20.2%)	95 (21.7%)	40 (17.4%)	
	Grade 3	38 (5.7%)	11 (2.5%)	27 (11.7%)	
Aortic neck calcifications	Grade 0	191 (57.2%)	128 (58.4%)	63 (54.8%)	0.44
	Grade 1	96 (28.7%)	57 (26%)	39 (33.9%)	
	Grade 2	41 (12.3%)	30 (13.7%)	11 (9.6%)	
	Grade 3	6 (1.8%)	4 (1.8%)	2 (1.7%)	
Neck thrombus	Grade 0	179 (53.6%)	115 (52.5%)	64 (55.7%)	0.08
	Grade 1	87 (26%)	51 (23.3%)	36 (31.3%)	
	Grade 2	51 (15.3%)	39 (17.8%)	12 (10.4%)	
	Grade 3	17 (5.1%)	14 (6.4%)	3 (2.6%)	
Shape of the neck	Conical	65 (19.5%)	29 (13.2%)	29 (25.2%)	0.04
Aneurysm shape	Sacciform	33 (9.9%)	17 (7.8%)	16 (13.9%)	0.07
PAOD	Thrombosed	102 (30.5%)	60 (27.4%)	42 (36.5%)	0.08
Internal iliac artery	Thrombosed	25 (3.7%)	10 (2.3%)	15 (6.5%)	0.01
Associated internal iliac aneurysm	Yes	12 (1.8%)	6 (1.4%)	6 (2.6%)	0.30
Polar artery	Yes	69 (20.7%)	44 (20.1%)	24 (20.9%)	0.83

PAOD: peripheral occlusive arterial disease.

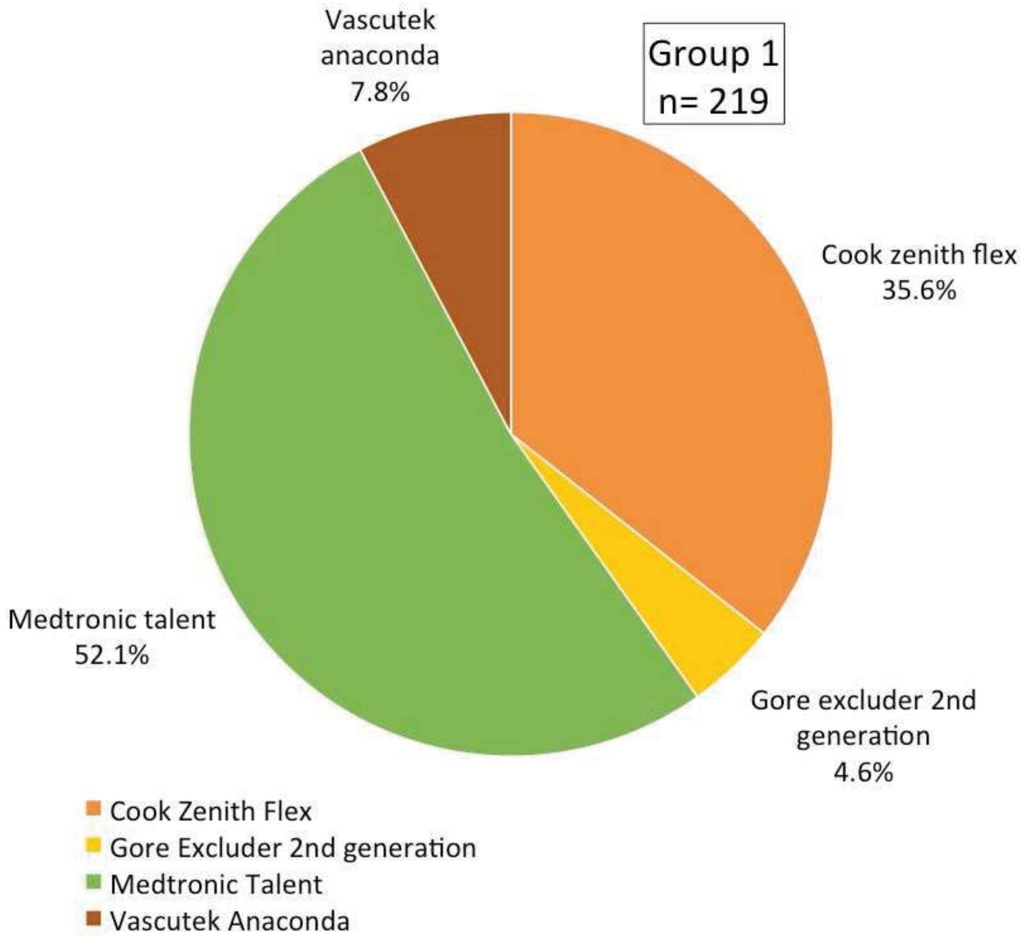
Table IV. Peroperative data

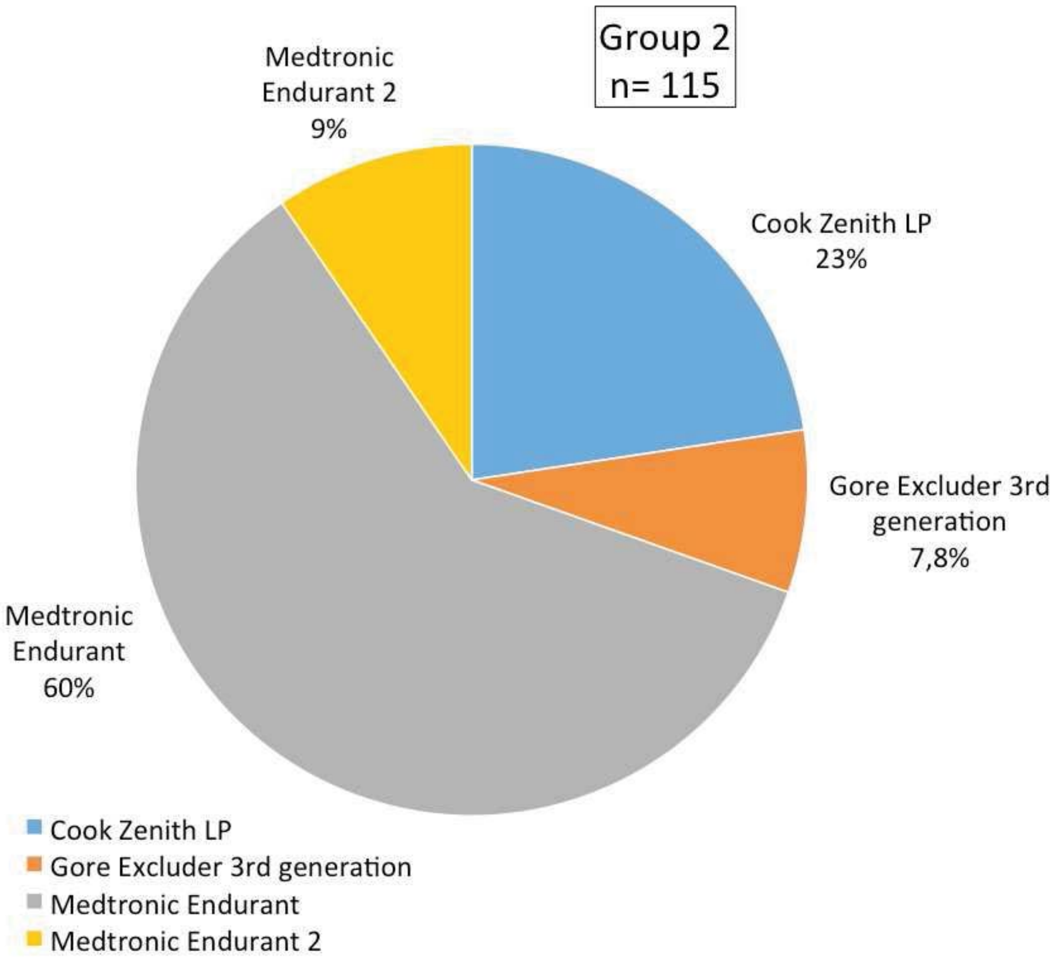
	Total population (n=334)	Group 1 (n=219)	Groupe 2 (n=115)	P
Duration of procedure (min. mean ± SD)	181.3 ± 114.6	193.2 ± 70.2	162.9 ± 159.6	0.04
Contrast product (mL. mean ± SD)	137.1 ± 89.4	181.9 ± 105.4	105.8 ± 59.1	<0.0001
Duration of fluoroscopy (min. mean ± SD)	20.5 ± 15	19.6 ± 12	21.1 ± 17	0.54
DAP* (mGy.m^2. mean ± SD)	6.6 ± 6.9	6.2 ± 5.7	7.0 ± 7.7	0.51
Percutaneous access (n. (%))	80 (24%)	30 (13.7%)	50 (43.5%)	<0.0001

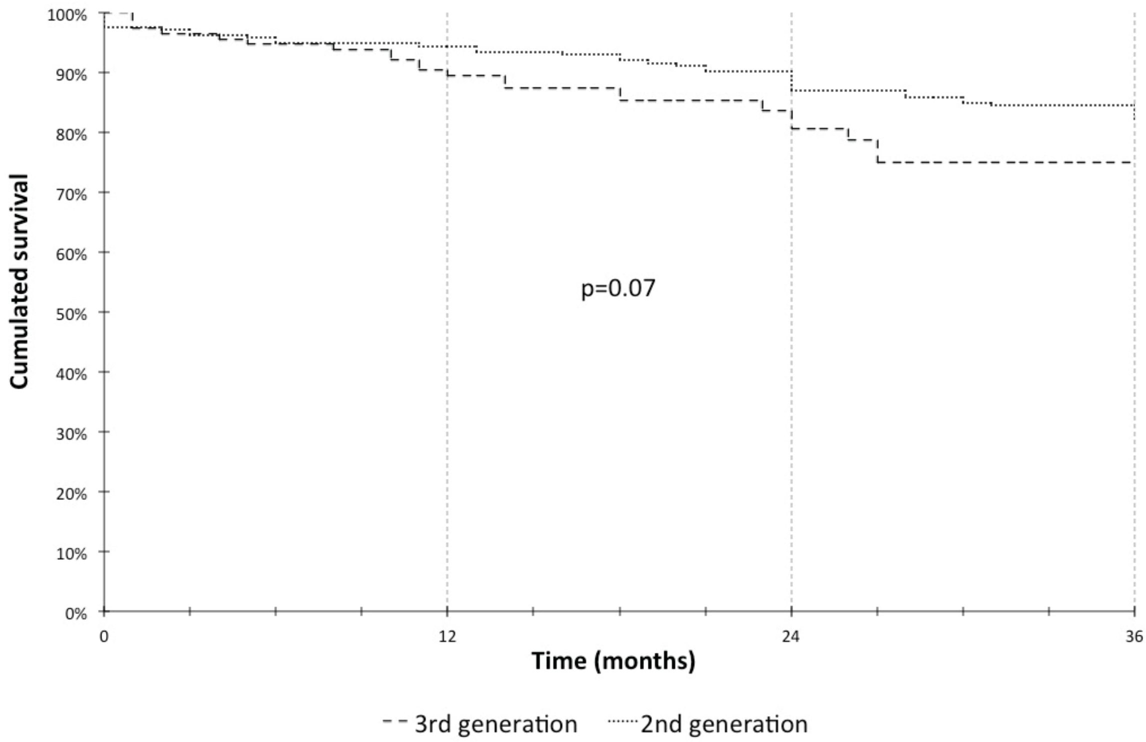
*Dose-area product

Table V. Endoleaks occurred during the follow-up

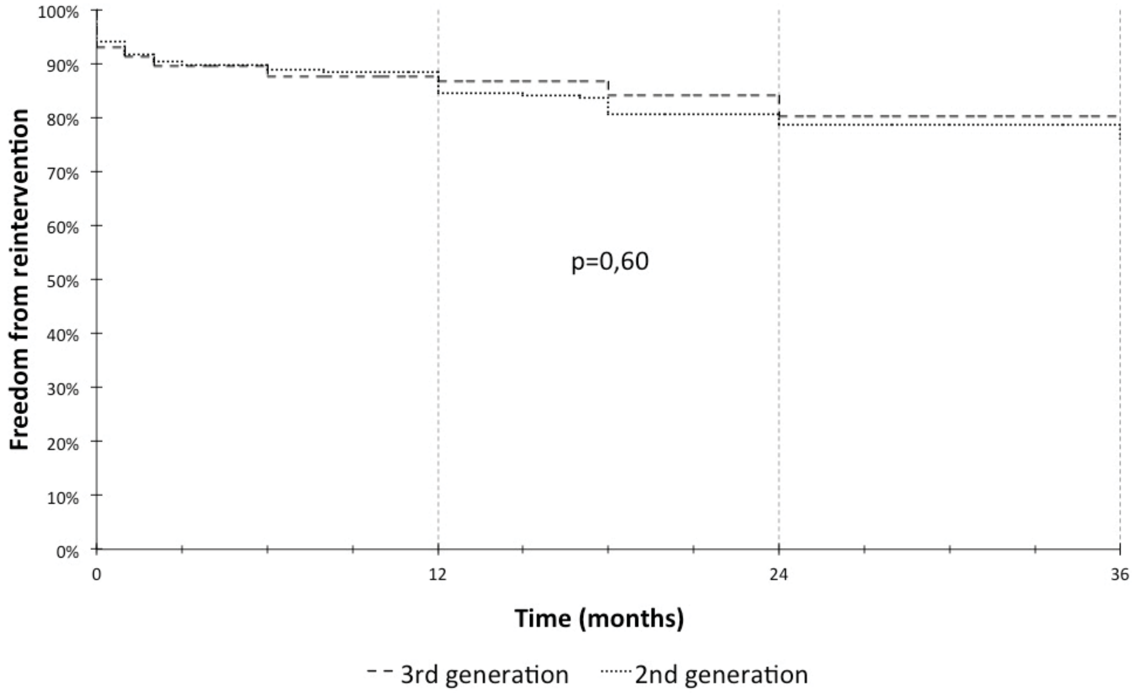
	Total population (n=332)	Group 1 (n=218)	Group 2 (n=114)	P
All types of endoleaks (n. %)	87 (26.2%)	63 (28.9%)	24 (21.1%)	0.37
Type IA endoleaks (n. %)	11 (3.3%)	10 (4.6%)	1 (0.9%)	0.17
Type IB endoleaks (n. %)	16 (4.8%)	12 (5.5%)	4 (3.5%)	0.97
Type II endoleaks (n. %)	64 (19.3%)	46 (21.1%)	18 (15.8%)	0.50
Type III endoleaks (n. %)	5 (1.5%)	4 (1.8%)	1 (0.9%)	0.58


Group 1
n= 219
Vascutek
anaconda
7.8%
Cook zenith flex
35.6%
Medtronic talent
52.1%
Gore excluder 2nd
generation
4.6%
Cook Zenith Flex
Gore Excluder 2nd generation
Medtronic Talent
Vascutek Anaconda


Group 2
n= 115
Medtronic Endurant 2
9%
Cook Zenith LP
23%
Gore Excluder 3rd generation
7,8%
Medtronic Endurant
60%
Cook Zenith LP
Gore Excluder 3rd generation
Medtronic Endurant
Medtronic Endurant 2



	Months	6	12	18	24	30	36
Group 1	N at risk	206	203	199	193	178	170
(2nd generation)	Survival (%)	94.9	94.5	92.1	87.4	85.5	82.0
	Standard error (%)	1.5	1.6	1.8	2.3	2,4	2.7
Group 2	N at risk	109	103	78	54	33	14
(3rd generation)	Survival (%)	94.7	89.5	85.3	80.6	75.3	75.0
	Standard error (%)	2.1	2.9	3.4	4.2	5.0	5.0



	Months	6	12	18	24	30	36
Group 1	N at risk	188	183	170	159	143	135
(2nd generation)	Survival (%)	88.9	84.5	80.1	78.6	78.6	75.1
	Standard error (%)	2.1	2.5	2.7	2.8	2.8	3.1
Group 2	N at risk	98	91	67	43	25	10
(3rd generation)	Survival (%)	87.6	86.7	84.1	80.2	80.2	80.2
	Standard error (%)	3.1	3.2	3.6	4.4	4.4	4.4