Evolution of practices in Treatment of abdominal aortic aneurysm in France between 2006 and 2015

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This study was unfunded.

The authors have no conflict of Interest and no financial disclosure.

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36 Aortic Aneurysm

37 Abdominal

38 Aortic Rupture

39 Endovascular Procedures

40 Word count: 3522

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42 Abstract

43 Introduction

44 The main objective of this study was to identify the changes that have occurred in the
45 treatment of abdominal aortic aneurysms (AAA) in France over a period of 10 years.

46 Materials and methods

47 Comprehensive data for AAA surgical activity from all French health establishments between
48 2006 and 2015 was collected from the records of the “Agence Technique de l'Information sur
49 l'Hospitalisation”. Based on the common classification of medical procedures, our research
50 was conducted on surgical procedures involving open and endovascular surgical treatment of
51 AAA. A year-by-year descriptive analysis was completed for the number of procedures, the
52 change in the type of surgery performed in each type of institution, and the mean duration of
53 hospital stays.

54 Results

55 During the study period, the number of AAA treated increased overall by 28.2% (from 6412
56 procedures in 2006 to 8221 in 2015). The proportion of endovascular procedures increased in
57 this period (from 27.0% in 2006 to 68.5% in 2015) like their number from 1735 to 5632. The
58 number of fenestrated endovascular aneurysm repair (listed since 2013) increased from 251 to
59 373 in three years. Open repair decreased from 4677 interventions in 2006 to 2589 in 2015
60 with higher proportion of supra-renal clamping in open surgery (from 23% in 2006 to 40% in
61 2015). The number of ruptured AAA treated in open surgery remained stable over this period
62 (473 in 2006 and 462 in 2015).

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65 Conclusion

66 In France, the number of AAA operated between 2006 and 2015 increased by 28.2%. There
67 was a significant increase in endovascular techniques, which became largely predominant in
68 2015. In open repair, the proportion of complex procedures increased in this period. However,
69 this transformation, which is in line with current recommendations and major publications,
70 needs to be reassessed in the long term.

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Introduction

The treatment of abdominal aortic aneurysms (AAA) has changed significantly in recent years, with an increase in endovascular management in all countries¹. In France, the group of experts convened by the “Agence française de sécurité sanitaire des produits de santé” (Afssaps) in 2001 recommended restricting endovascular treatment of AAA to patients at high surgical risk only². But the randomized studies^{3,4} comparing 30-day outcomes between open surgery and endovascular aneurysm repair (EVAR) published in 2005 were favorable to short-term endovascular treatment; the 5-year results then described equivalent survival curves in the 2 groups, at the cost of a higher rate of secondary interventions after endovascular treatment⁵⁻⁷. This reassessment of the risk-benefit ratio has modified the recommendations, and, since 2009, endovascular treatment has been authorized in France for patients at normal surgical risk if anatomical criteria are favorable, after the patient has been informed of the benefits and risks of both methods⁸. Furthermore, previous work has identified significant disparities in indications and techniques between countries⁹. For example, the operative indication for asymptomatic AAA is most often based on the transverse maximum diameter alone, with a threshold of 5.5 cm in most countries and 5 cm in France^{10,11}. To date, there is little existing epidemiological data for France¹².

The main objective of this study was to determine the number of AAA operated in France and how they have been treated over the last 10 years.

Methods

We conducted a descriptive study on AAA surgery practices in France over a 10-year period from first of January 2006 to 31st of December 2015.

Using the records of the “Agence Technique de l'Information sur l'Hospitalisation” (ATIH), we collected all aortic surgery data for AAA in French health care institutions between 2006 and 2015. Research was conducted on procedures from the “Common Classification of Medical Procedures” (CCAM) for abdominal aortic aneurysm surgery; 13 codes were retrieved (Table I). A search was conducted for each CCAM code for each year and each establishment.

The available data were the number and type of procedures per year and per establishment, the type of establishment in which the procedure was performed (public or private), and the average length of stay. The description of the procedures, for open surgery, made it possible to differentiate the type of clamping (infra or supra-renal), the type of prosthesis used (straight or bifurcated) and the symptomatology (ruptured or intact AAA). For EVAR, types of stent (aorto-bi-iliac, aorto-uni-iliac, straight and branched or fenestrated) could be describe. However, it was not possible to differentiate between ruptured and intact AAA for endovascular procedures.

A descriptive analysis of the data was done on a year by year basis. We analyzed the number of procedures, the variations in the type of surgery and equipment used for each type of institution, and the average length of patient stays. We analyzed the proportion of EVAR during the period and its 95% confident interval.

Results

From 2006 to 2015, 80048 AAA were treated in France, i.e. an average of 8005 per year [6885-8683-]. During this period, the annual number treated AAA increased by 26.1% from 6885 procedures in 2006 to 8683 procedures in 2015 (Table II, Figure 1). The number of AAA treated increased in public (3594 treated in 2006 vs 4606 in 2015) as in private institutions (2818 in 2006 vs 3615 in 2015). Over the entire period, 54.0% CI [53.6%;54.4%] of patients were treated with EVAR, rising from 27.0% CI [25.9% ;28.1%] in 2006 to 68.5% CI [67.5%;68.5%] in 2015. The proportion of care in private institutions was stable at 45.5% CI [45.1%;45.9%] during the period. The transition from open surgery to endovascular surgery was comparable in the two types of establishments: the proportion of EVAR implanted in public and private establishments was 30.7% CI [29.2% ; 32.2%] and 22.4% CI [20.9%;23.9%], respectively, in 2006, and 65.4% CI [64.0%;66.8%] and 72.4% CI [70.9%;73.9%] in 2015.

The number of intact AAA treated by open surgery decreased from 2006 (4677 AAA treated) to 2015 (2589 AAA treated). The evolution was the same in public or private establishment since the procedures went from 2491 to 1591 in the public and from 2196 to 998 in the private from 2006 to 2015. The CCAM data also allowed us to study the type of suprarenal or infrarenal clamping and the graft used in open surgery (straight or bifurcated tube). The absolute number of suprarenal clamps remained relatively stable over time (Figure 2), but increased proportionally from 23.2% (n=1086) in 2006 to 40.0% (n=1035) in 2015. The evolution of suprarenal clamps was different in public or private institution; in 2006 the number of suprarenal clamps was almost equivalent (581 vs 505), while in 2015 the number was higher in public institution (664 vs 371). The proportion evolved in the same way in both institutions. The types of prosthesis varied little over time, with a stable proportion of straight

tubes (aorto-aortic bypass) of 35.1% CI [33.7%; 36.5%] in 2006 and 34.4% CI [32.6%;36.2%] in 2015 (Figure 3).

The number of endovascular procedures increased throughout the study period, indeed before 2010 the number of EVAR (excluding fenestrated or branched stents) per year was 2580 (± 755) and since 2010 there was 4878 (± 356). In public institutions, the number of EVAR per year was 1458 (± 314) before 2010 and 2519 (± 167) after; in private establishments the number of procedures per year has doubled from 1123 (± 441) to 2359 (± 193) before and after 2010. There were significant changes in the types of endovascular procedures performed over the course of the study period (Figure 4). Excluding fenestrated or branched stents, the proportion of aorto-bi-iliac stents increased from 64.7% CI [62.5%;66.9%] to 84.9% CI [83.9%;85.9%] between 2006 and 2015, while aorto-uni-iliac stents decreased in ratio from 27.7% CI [25.6%; 29.8%] to 8.3% CI [7.6%;9.0%]. The proportion of straight tubes remained marginal (7.6% CI [6.4%;8.8%] in 2006, 6.8% CI [6.1%;7.5%] in 2015). A specific classification was added in 2013 for more complex fenestrated or multi-branch stent grafts (CCAM code: DGLF012), which made it possible to identify these procedures and to record an increase over the period. There were 251 procedures in 2013 and 373 in 2015, 84.3% CI [82.0%;86.6%] of which were carried out in public structures. The number of ruptured AAA treated by open surgery has remained stable over time (Figure 5), with an average of 498 (± 27) patients per year [455-530]. Ruptured AAA (treated by open surgery) was increasingly treated in public facilities (68.7% CI [64.5%;72.9%] in 2006 versus 82.9% CI [79.5% ;86.3%] in 2015).

The average length of stay (LOS) was calculated for open surgery for public facilities and was 15.6 days (± 0.5) in 2006 and 14.6 days (± 0.4) in 2015 while in private establishment the average LOS was 12.8 days (± 0.5) in 2006 and 11.9 days (± 0.3) in 2015. The average LOS

164 for endovascular repair decreased for both public and private facilities in the period with,
165 respectively, 11.7 days (± 0.5) in 2006 versus 7.5 days (± 0.2) in 2015 and 9.4 days (± 0.6) in
166 2006 versus 6.3 days (± 0.2) in 2015.

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Discussion

This 10-year descriptive analysis revealed an overall increase in the number of AAA treated per year, and a radical change in the management of the disease. Indeed, the total number of surgeries for AAA increased by 28.2%, and treatment shifted towards endovascular procedures which rose from 27.0% of cases in 2006 to 68.5% of cases in 2015.

Similar to a number of other countries, the number of AAA treated in France increased during the study period. Several factors may explain this increase: the introduction of an AAA screening campaign¹³, the ageing of the population¹⁴, a high prevalence of AAA in the European population¹⁵ and an increase in treatment indications in the most fragile patients with the development of endovascular techniques. The proportion of patients treated for elective AAA in France is surprisingly similar to that of the United States during the same period (estimated at 11.7 per 100,000 inhabitants in France and 10.2 in the United States)^{16,17} despite a higher threshold diameter. It is lower in the United Kingdom (estimated at 5.4 per 100,000 inhabitants)¹⁷, which could be due to differing recommendations for intervention¹¹, notably a higher threshold for diameter, and to a different level of health and welfare protection¹⁸.

These changing practices should lead us to examine the management of increasingly fragile patients through technically advanced procedures which present their own set of complications. The leading randomized study on the subject does not favor endovascular procedures over therapeutic abstention¹⁹. Though, in the long term, endovascular procedures in patients not eligible for open surgery reduce the risk of aneurysm-related mortality, they do not reduce overall mortality²⁰.

The trend toward endovascular techniques will certainly stabilize because of the intrinsic

limitations of these procedures. Compliance with anatomical implant conditions limits their feasibility: certain studies indicate that 20 to 40% of patients do not meet anatomical requirements^{21,22}. It would seem that we are at the height of their development, knowing that failure to adhere to the guidelines for stent use is commonly at the root of endovascular treatment failure, resulting in an increase in aneurysm diameter²³. Moreover, there is still concern regarding the durability of stents, along with more mixed long-term results, less long-term survival, a poorer quality of life and more fragile health compared to open surgery²⁴⁻²⁶.

There is a great disparity in treatment methods from one country to another. In Germany, the proportion of endovascular AAA treatment between 2005 and 2013 was 53.9%²⁷. From 2005 to 2010, 37% of patients in the United Kingdom received endovascular treatment compared with more than 64% in the United States ($p<0.01$), with a similar increase in both countries¹⁷.

This work also clearly shows an advance in the skills and expertise of French health care centers in the field of endovascular treatment for simple or complex AAA. We have observed a marked development of the most complex techniques (aorto-bi-iliac stents replacing aorto-uni-iliac systems, or development of branched and fenestrated stents) (Figure 4)^{28,29}.

However, expertise in open surgery does not appear to be decreasing given that, despite the sharp overall decline in open surgery, complex cases with supra-renal clamping have remained stable. The current trend is to offer endovascular treatment in simple cases and open surgery for the most complex cases. These complex cases seemed to be mainly treated in public centers, but we didn't know the volume activity of this center. This raises the legitimate question of whether younger doctors should be trained to perform open surgery, for which a significant number of simple dedicated cases needs to be seen initially in order to then undertake more complex cases. Moreover, if hospitals intend to remain at the same level

of quality currently achieved in open surgery in terms of morbidity and mortality, they must maintain a sufficient number of procedures. In aortic surgery, as in other types of surgery, it has been proven that the quality of care is directly linked to the volume of activity^{30,31}. *Budtz-Lilly et al.* used international cohorts to demonstrate that intraoperative mortality in open surgery had increased significantly from 3.9% in 2005-2009 to 4.4% in 2010-2013¹.

NICE Guideline³² updated in May 2018 advised “to not offer EVAR to people with an unruptured infrarenal AAA if open surgical repair is suitable” and “to not offer EVAR to people with an unruptured infrarenal AAA if open surgical repair is unsuitable because of their anaesthetic and medical condition”. This new guidelines didn’t represent current practices in 2015; maybe in few years the number of AAA treated will be stabilized with a lower proportion of EVAR.

The LOS observed seemed lengthy, regardless of the type of surgery and institution. For open repair, LOS remained the same in the period despite the increase in complex surgeries. In England and in the United States, the median LOS was respectively shorter (10 and 6 days)¹⁷. Despite the shortening of LOS in EVAR during the period in France, it remained higher than in England and the United States (respectively 5 and 1 days)¹⁷. This could be explained by the French health system that allows patients to stay in hospital longer.

The annual number of ruptured AAA repairs remained stable in France throughout the study period (498 per year, on average over the 10 years) (Figure 5); however, the data only take into account ruptured AAA which is operated in open surgery since there is no specific CCAM code for ruptured AAA which is treated with stent grafting. The overall increase in endovascular techniques suggests that there is likely an increase in the overall number of ruptured AAA being managed. Contrary to Norway, where *Reite et al.* reported a stable trend in the incidence of ruptured AAA repair between 2000 and 2012³³, the screening campaigns

conducted in France since 2012 ¹³ have not yet led to a stabilization in the incidence of ruptured AAA.

This study has several limitations, including inaccuracy in the analysis of the populations studied (no access to demographic data, patient characteristics and co-morbidities), and the intra-hospital mortality, the inability to fully enumerate the population of ruptured AAA due to the absence of a specific rating code for endovascular treatment of ruptured AAA. The type of EVAR (fixation, company) and the description of the AAA (proximal neck angulation, length of the neck, tortuosity, presence of thrombus in the neck) and the instructions for use missed to discuss the proportion of EVAR in the treatment of AAA. Complex fenestrated or multi-branch stent grafts could be treatment for thoraco-abdominal and abdominal aortic aneurysm and we had no information of the type of aneurysm. The major limitation was that we had no possibility to be sure that the right code has been declared and used but statement is made on the good faith of the surgeons.

Conclusion

This observational study showed an overall increase of 28.2% in the number of AAA treated in France between 2006 and 2015, and an increasing preference for endovascular techniques which grew from 27% to 68.5% of all procedures, in accordance with current recommendations. However, these findings raise questions concerning the real benefit of the indications given to the most fragile patients, the long-term future of those who undergo endovascular surgery, and the need to maintain high-quality open surgery.

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Figure 1: Change in the number of total procedures (green curve), endovascular procedures (violet curve) and surgical procedures (plum curve) performed each year for the treatment of intact abdominal aortic aneurysms.

Figure 2: Number of infrarenal clamps (light blue curve) and suprarenal clamps (violet curve) in open surgery for the treatment of abdominal aortic aneurysms.

Figure 3: Proportion of straight aorto-aortic prothesis (green), bifurcated aorto-bi-iliac bypasses (red) and aorto-bi-femoral bypasses (blue) performed annually in open abdominal aortic aneurysm surgery.

Figure 4: Number of endovascular surgical procedures performed per year and by type of procedure: aorto-bi-iliac stents (blue), aorto-uni-iliac stents (red) and straight stent (green).

Figure 5: Total number of ruptured abdominal aortic aneurysms treated annually in open surgery (green), public health facilities (blue) and private health facilities (red).

Figure 1

Figure 2

Figure 3

Figure 5

Figure 4

Table I: acts of the common classification of medical acts (classification commune des actes médicaux (CCAM)) collected for analysis

Procedure code	Description
DGPA001	Open repair of aorto-ilio-femoral aneurysm with aorto-ilio-femoral bifurcated prosthetic replacement, by laparotomy with suprarenal clamping
DGPA005	Open repair of unruptured infra-renal aortic aneurysm with infra-renal aorto-aortic prosthetic replacement, by laparotomy with infra-renal clamping
DGPA008	Open repair of unruptured infra-renal or aorto-bi-iliac aortic aneurysm with aorto-bi-iliac prosthetic replacement, by laparotomy with supra-renal clamping
DGPA010	Open repair of unruptured infra-renal or aorto-bi-iliac aortic aneurysm with aorto-bi-femoral prosthetic replacement, by laparotomy with infra-renal clamping
DGPA012	Open repair of unruptured infra-renal or aorto-bi-iliac aortic aneurysm with aorto-bi-iliac prosthetic replacement, by laparotomy with infra-renal clamping
DGPA013	Open repair of unruptured infra-renal or aorto-bi-iliac aortic aneurysm with aorto-bi-femoral prosthetic replacement, by laparotomy with supra-renal clamping
DGPA016	Open repair of aorto-ilio-femoral aortic aneurysm with aorto-ilio-femoral bifurcated prosthetic replacement, by laparotomy with infra-renal clamping
DGPA017	Open repair of unruptured infra-renal aortic aneurysm with infra-renal aorto-aortic prosthetic replacement, by laparotomy with supra-renal clamping
DGPA018	Open repair of ruptured infra-renal or aorto-bi-iliac aortic aneurysm with prosthetic replacement, by laparotomy
DGLF001	Endovascular repair with aorto-bi-iliac bifurcated stent graft, by arterial percutaneous procedures
DGLF002	Endovascular repair with aorto-uni-iliac stent graft , by arterial percutaneous procedures
DGLF005	Endovascular repair by infra-renal aortic aneurysm straight stent graft, by arterial percutaneous procedures
DGLF012	Multi-branched stent or fenestrated endovascular aneurysm repair in the abdominal aorta for complex aneurysm, by arterial percutaneous procedures

Table II: Total number of elective endovascular and surgical abdominal aortic aneurysm surgeries performed per year

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Number of endovascular surgeries	1735	2239	2879	3470	4266	4689	4904	5297	5423	5632
Number of open surgeries	4677	4434	4214	3893	3399	3139	2713	2846	2631	2589
Total number of elective AAA surgeries	6412	6673	7093	7363	7665	7828	7617	8143	8054	8221