Frequency and type of interval adverse events during the waiting period to complex aortic endovascular repair

Mario D'Oria, MD, Anders Wanhainen, MD, PhD, Kevin Mani, MD, PhD, *and* David Lindström, MD, PhD,
Uppsala, Sweden

ABSTRACT

Objective: The aim of the present study was to evaluate the frequency and type of adverse events that can occur during the waiting period to complex aortic endovascular repair.

Methods: We performed a retrospective study of all elective patients with complex aortic aneurysms (including pararenal, suprarenal, thoracoabdominal, and aortic arch aneurysms) that had required a custom-made device (CMD) from Cook Medical (Bloomington, Ind) at a tertiary referral vascular center (November 2010 to May 2020). The waiting period was defined as the interval between the date of the stent graft order and the date of the procedure or cancellation. Interval adverse events were defined as any event that had occurred during the waiting period and led to either mortality, aneurysm rupture, or cancellation of the planned procedure.

Results: A total of 235 patients (mean age, 72 years; 25% female) had had a CMD graft ordered (201 planned as a single-stage procedure). The median waiting time until surgery was 106 days (interquartile range [IQR], 77-146 days) in the whole cohort and 101 days (IQR, 77-140 days) for the single-stage cohort. The planned procedure was performed electively in 219 patients (93%), with an overall 30-day elective mortality of 2% (n = 5). A total of 16 interval adverse events occurred during the waiting period. Of these 16 events, 10 were aneurysm ruptures and 6 were cancellations of the procedure owing to non–aneurysm-related deaths (3% of the entire cohort). A total of 10 interval deaths were registered (4.2%), 4 of which were aneurysm related. The risk of rupture during the waiting period (Kaplan-Meier) was 6.1% ± 2.3% at 180 days. The median interval from the stent graft order to aneurysm rupture was 101 days (IQR, 54-200 days). Of the 10 aneurysm ruptures that had occurred, 6 had undergone emergent repair, with 0% mortality at 30 days (one open repair, one t-Branch, one physician-modified endograft, two cases for which the CMD was already available, one case for which a different CMD was available).

Conclusions: The median waiting time from the stent graft order to implantation was ~15 weeks. During this waiting period, a substantial proportion of patients could experience adverse events, either related to aneurysm rupture or underlying comorbidities. The risk of rupture during the waiting period exceeded the risk of perioperative mortality. Thus, efforts to decrease this risk could significantly improve the outcomes. A combination of different techniques might play a vital role in reducing the mortality after cases of interval rupture. (J Vasc Surg 2022;75:1821-8.)

Keywords: Complex aortic aneurysm; Custom-made stent graft; Fenestrated-branched endovascular aortic repair; Outcomes

Fenestrated-branched endovascular aortic repair (F-BEVAR) is a safe and effective therapeutic option in the treatment of complex aortic aneurysms that involve vital side branches of the aorta,[1,2] with benefits to patients compared with standard open repair in terms of perioperative morbidity, especially for high-risk surgical candidates.[3] F-BEVAR has shown satisfactory early- and mid-term results and has been endorsed by current clinical practice guidelines.[4] The stent grafts will usually be customized to meet patient-specific anatomic requirements. Also, patients treated with F-BEVAR technology will usually be deemed morphologically unfit for standard endovascular techniques but also at physiologically high risk for conventional open surgery.

However, manufacturing a patient-specific endograft has been a time-consuming process that includes planning, manufacturing, delivering, and implantation. This process can require 2 to 4 months, thereby limiting this technology to the subset of patients who are

From the Section of Vascular Surgery, Department of Surgical Sciences, Uppsala University.

Author conflict of interest: none.

Additional material for this article may be found online at www.jvascsurg.org.

Correspondence: Mario D'Oria, MD, Section of Vascular Surgery, Department of Surgical Sciences, Uppsala University, Uppsala SE-75185, Sweden (e-mail: mario.doria88@outlook.com).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

https://doi.org/10.1016/j.jvs.2021.11.041

asymptomatic and whose aneurysms are deemed to be a low risk of rupture during the waiting time.

Despite the number of prior studies that analyzed the technical outcomes of F-BEVAR,[5] little is known about the significance of the waiting time on the outcomes of F-BEVAR.[6,7] The aim of our study was to evaluate the frequency and type of serious interval adverse events that can occur during the waiting period between the stent graft order and complex aortic endovascular repair.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective cohort study
- **Key Findings:** Median waiting time from stent graft order for 235 patients with complex aortic aneurysm was 106 days. Ten aneurysms ruptured during the waiting time; four of these patients died and six underwent successful repair. Elective mortality in 219 patients was 2% and risk of rupture during waiting time was 6.1%.
- **Take Home Message:** Efforts to shorten waiting time for stent grafts would likely improve outcome of patients with complex aortic aneurysms.

METHODS

Data collection. We performed a retrospective study of all elective patients with complex aortic aneurysms, including pararenal, suprarenal, thoracoabdominal, and aortic arch aneurysms that had required planning of a custom-made (CMD) stent graft at a single institution from November 2011 through April 2020. Patients treated with off-the-shelf multibranched endografts (n = 35) or physician-modified endografts (n = 7) because of symptomatic or ruptured aneurysms and who had never been assessed for CMD stent graft implantation were excluded from the present study.

The waiting time was estimated by calculating the interval between the date of the stent graft order and the date of procedure (whether elective or urgent owing to aneurysm rupture during the waiting period) or cancellation date. The waiting time was calculated for all CMD orders and again separately for the single-stage procedures.

Patients for whom the procedure was cancelled during the waiting period or not performed were identified and analyzed further to investigate the reason for the cancellation. An interval adverse event was defined as any event that had occurred during waiting time and had led to either mortality (aneurysm related or not), aneurysm rupture, or cancellation of the planned surgical procedure from any cause. The cause of death for the patients who had died before the procedure was obtained either from the hospital admission records (for the patients who had died in-hospital after treatment of their disease) or by querying a nationwide healthcare database (for the patients who had died out of hospital).

The 30-day mortality after elective repairs (ie, any death occurring within the initial 30 days after the index intervention) was assessed by a review of the inpatient and outpatient hospital records. All death dates were updated by cross-matching the patients in the cohort using their unique personal identification number with the Swedish Death Registry, which has 100% accuracy.

Stent graft planning and order process. All the patients had undergone thin-slice computed tomography angiography (CTA) from the neck to the groin within 6 months before the first visit. The type of procedure was decided during the routine weekly meetings of the aortic team, which is composed of three to eight vascular surgeons with additional participation by dedicated cardiovascular anesthesiologists, if necessary, once the cardiopulmonary workup had been completed. The patients' written informed consent for the suggested procedure was then confirmed. Postprocessing centerline lumen reconstruction was then elaborated using dedicated software for advanced vessel analysis (3mensio; Vascular Imaging, Bilthoven, The Netherlands).

The CMD stent graft was planned by the same experienced surgical team who performed the procedure. Using the specifications provided, the planning center (Cook Medical Inc, Bloomington, Ind) generates a CMD technical drawing within 24 to 48 hours, which is then reviewed, modified if necessary, and eventually signed off by the surgeon who had developed the plan. Next, the stent graft is ordered. For most patients, the planning and ordering of a fenestrated graft will be accomplished within 1 to 2 weeks (Supplementary Fig, online only).

Statistical analysis. The continuous variables were tested for normality with histograms and are reported as the mean ± standard deviation or median and interquartile range (IQR). The categorical variables are reported as absolute counts and proportions. A univariate comparison of baseline characteristics was performed between the patients who had experienced rupture during the waiting period and those who had not. Statistical significance was set at the alpha level (P value) $< .05$. The risk of rupture during the waiting time was visualized in a time-to-event analysis using the Kaplan-Meier method. The patients were censored at repair, death, or cancellation of the procedure (whichever occurred first). The graphs were truncated at 180 days when 20 patients remained available for analysis. Statistical analysis was performed using SPSS statistical software, version 22.0 (IBM Corp, Armonk, NY).

RESULTS

Study cohort. During the study period, 235 patients (mean age, 72 years; 25% female) had had a CMD stent graft ordered (Table I). Of the 235 procedures, 201 were

Table I. Baseline patient characteristics (n = 235)

Variable	No. (%), mean ± SD
Female gender	58 (25)
Age, years	72 ± 9
Octogenarians	44 (19)
Ischemic heart disease	73 (31)
Congestive heart failure	32 (14)
Smoking	166 (71)
Diabetes	27 (11.5)
Chronic obstructive pulmonary disease	68 (29)
Chronic kidney disease	52 (22)
Aneurysm extent	
Arch or descending thoracic	20 (9)
Thoracoabdominal	62 (26)
Pararenal or suprarenal	153 (65)
Aneurysm diameter, mm	63 ± 9
Large aneurysm (diameter ≥70 mm)	42 (18)
Postdissection aneurysm	29 (12)

SD, Standard deviation.

planned as single-stage procedures. A steady increase had occurred in the number of CMD stent grafts ordered per year. The mean number of grafts ordered annually had increased from 14 ± 5 in 2011 to 2015 to 40 ± 27 in 2016 to 2019. From 2015 onward, complex stent grafts for treatment of pathology involving the aortic arch had been introduced into clinical practice, with a concomitant steady increase in the number of CMD stent grafts with a three- to four-vessel design (Fig 1).

Waiting period. The distribution of lead days from the stent graft order to elective implantation was analyzed (Fig 2). The median waiting time was 106 days (IQR, 77-146 days) for the whole cohort and 101 days (IQR, 77-140 days) for the subgroup of single-stage procedures (Table II). Stratification by aneurysm diameter (<70 mm vs ≥70 mm) showed no differences in the median waiting time (107 vs 104 days). The total waiting period was significantly different when stratified by the type of CMD that was planned and ordered ($P = .039$ for a head-to-head comparison):

1. Arch branch/fenestrated thoracic endovascular aortic repair: median, 136 days; IQR, 97 to 164 days
2. F-BEVAR with three-vessel or more design: median, 107 days; IQR, 83 to 145 days
3. Zenith fenestrated with less than three-vessel design: median, 86 days; IQR, 66-132 days

For 10 of the 62 patients whose waiting time was >120 days, a specific reason for delaying the procedure could be found. The reasons for postponement of graft implantation were as follows: four cases of unavailability of intensive care resources, one case of acute cholecystectomy, three cases of infection, and two cardiovascular events (one acute myocardial infarction, one decompensated congestive heart failure). For all 10 patients, the CMD stent graft was eventually implanted electively.

Interval adverse events. The planned procedure was performed electively for 219 patients (93%), with an overall 30-day elective mortality of 2% (n = 5).

A total of 16 interval adverse events had occurred during the waiting period (Table III). Of the 16 events, 10 were aneurysm ruptures (4% of the entire cohort) and 6 were cancellations of the planned procedure because of non–aneurysm-related death (3% of the entire cohort). The risk of rupture during the waiting period using a Kaplan-Meier analysis (Fig 3) was estimated to be 6.1% ± 2.3% at 180 days of waiting time. The median waiting period from the stent graft order to aneurysm rupture was 101 days (IQR, 54-200 days).

A total of 10 interval deaths were registered, 4 of which be classified as aneurysm related. Of the 10 cases of aneurysm rupture that had occurred, 6 had undergone emergent repair, with 0% mortality at 30 days (one open surgical repair, one off-the-shelf t-Branch stent graft, one physician-modified endograft, two cases in which the CMD had already been shipped to the hospital and was available for implantation, and one case in which the CMD of a different patient was suitable for urgent implantation in the index case). No significant differences were noted in the mean diameter of the aneurysms that had ruptured during the waiting period vs those that had been repaired electively (66 ± 9 mm vs 62 ± 5 mm; $P = .31$). A comparison of the baseline characteristics between the patients who had experienced aneurysm rupture during the waiting period and those who had undergone scheduled elective repair are summarized in the Supplementary Table (online only).

DISCUSSION

The present study, encompassing the experience at a single, high-volume academic institution, analyzed the waiting period for an F-BEVAR procedure and identified the major adverse events that had occurred during the delay in implantation of a customized endovascular graft for patients with complex aortic pathologies. The median waiting time in our series of 235 consecutive patients was ~15 weeks and did not change significantly during the study period. The results of our Kaplan-Meier analysis showed that the waiting time adds a substantial risk of rupture, with an estimated rupture rate of 6% at 180 days. No ruptures had occurred during the first 30 days after the stent graft order. All patients with aneurysm rupture who had undergone emergent repair (either open or endovascularly) had survived at 30 days, thereby showing the usefulness of endovascular and open skills to treat acute symptomatic complex aortic

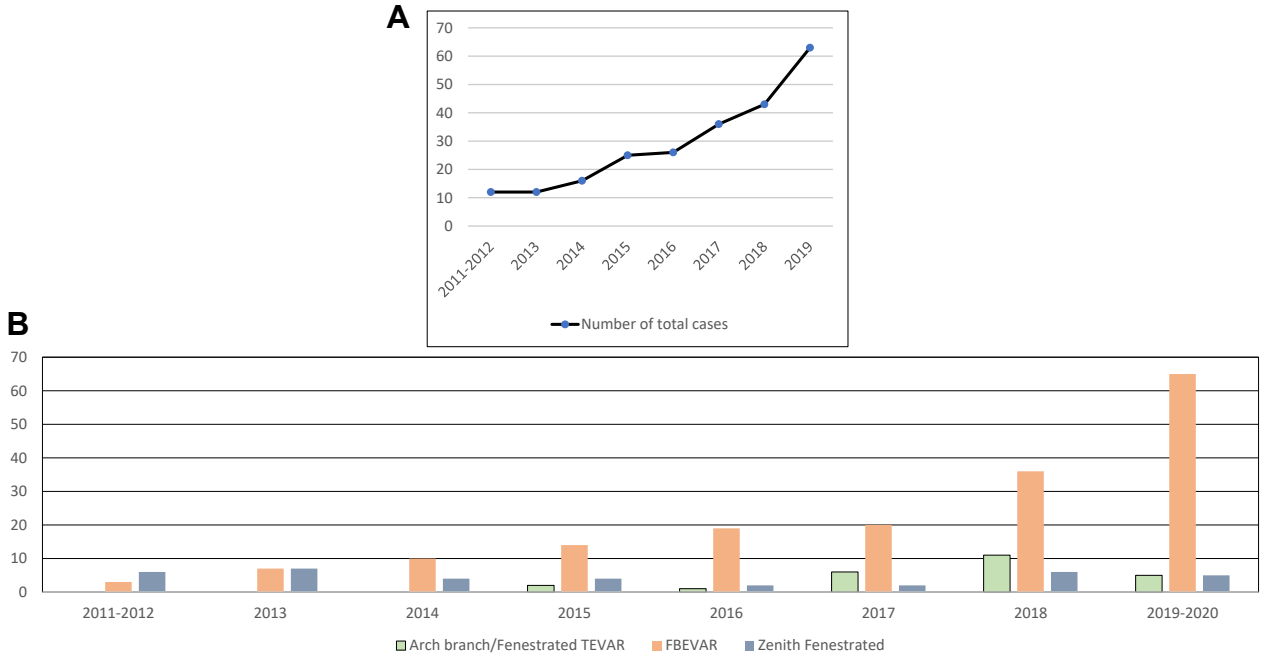


Fig 1. A, Total number of custom-made device (CMD) stent grafts ordered each year. **B,** The CMDs were divided into three categories: arch devices (fenestrated/branched endografts for aortic arch aneurysms); fenestrated-branched endovascular aortic repair (F-BEVAR) devices (fenestrated/branched endografts with three or more target vessels for pararenal, suprarenal, or thoracoabdominal aortic aneurysms); Zenith (Cook Medical) fenestrated grafts (fenestrated endografts with two or less target vessels). Annual numbers only reported for full calendar years from 2011 and 2012 to 2019, excluding 2010 and 2020.

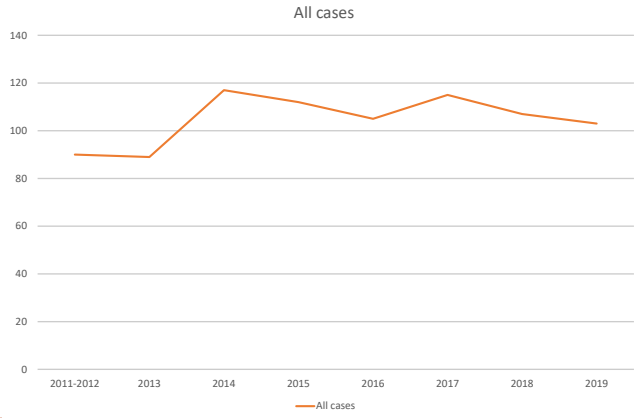


Fig 2. Total median waiting time in days from stent graft order to stent graft implantation per year. Annual numbers only reported for full calendar years from 2011 and 2012 to 2019, excluding 2010 and 2020.

aneurysms.[8] For those patients with a very long waiting time (>120 days), we could only find specific reasons for 16%. These reasons were linked to underlying medical comorbidities, thereby potentially indicating room for improvement in the overall management algorithm.

Our findings seem largely concordant with those described recently by other groups. In the review of a single-center experience with 906 patients scheduled for F-BEVAR from 2010 to 2018, Katsargyris et al[6] found that 95.3% of their patients (n = 862) had eventually undergone the procedure as planned, with a median waiting time from the date of graft order to the date of graft implantation of 12 weeks. However, 37 patients (4.1%) had died before the procedure, with aneurysm rupture the cause of death for 15 patients (1.7%). Similarly, Gallitto et al[7] reported on 144 patients scheduled for F-BEVAR from 2008 to 2017 at their institution. They reported a mean lead period of 90 days, with five aneurysm ruptures (3.8%) occurring during the waiting time.[7] Our reported waiting time was slightly longer than in these previous studies. We found no clear indication of the reason from our data; however, at our center, most complex cases are referred from other centers in Sweden or abroad, which could have contributed to the overall delay. During the waiting period, an inherent risk exists of both aneurysm rupture and that the patients will deteriorate from other medical conditions, which could eventually lead to cancellation of the previously planned procedure.

According to the general consensus, the manufacturing process will usually require 6 to 12 weeks and has been reported as one of the major limitations of the F-BEVAR technique. In our experience, the total waiting time for most cases was 8 to 16 weeks, and our waiting period has slowly increased over time. Although strong

Table II. Summary of events during study period (n = 235)

Variable	Mean ± SD, No. (%), Median (IQR)
Total cases/year, No.	35 ± 9
Staged repairs	34 (14)
Waiting time	
Total cases	106 (77-146)
Single-stage group (n = 201)	101 (77-140)
Elective procedure	219 (93)
30-Day mortality after elective repair	5 (2)
Cancellation or rupture during lead time	16 (7)
Aneurysm rupture	10 (4)
Procedure cancelled	6 (3)
Death during lead time	10 (4)
Aneurysm-related	4 (2)
Non–aneurysm-related	6 (3)

IQR, Interquartile range; *SD*, standard deviation.

inferences regarding the reasons beyond such changes could not be determined, some reasonable explanations could still be sought. First and foremost, even at dedicated aortic centers, logistic issues should be expected and anticipated. These are likely to increase as the volume and complexity of F-BEVAR procedures increase. In our experience, the number of CMD stent grafts that were planned and ordered increased over time. This process was accompanied by a shift toward more complex stent graft designs, which would entail the need for more in-hospital resources to accomplish safe and effective operations. As expected, we found a statistically significant difference in the median waiting time according to the type of CMD stent grafts that had been ordered. This finding could be reasonably explained by the concomitant presence of several mechanisms. These mechanisms include the need to accommodate an increasing volume of complex aortic operations within the surgical schedule, the performance of more extensive repairs (which were prevalent in later years) that would usually require more extensive infrastructural resources, and the longer pathway required to obtain devices intended for treatment of aortic arch disease because those were not directly planned at our institution but at the manufacturer's planning center. Thus, it is crucial that centers performing F-BEVAR have dedicated logistic protocols in place and undertake regular reviews of their results to identify potential pitfalls in their internal pathways of care.

All CMD stent grafts in the present series were from a single manufacturer (Cook Medical Inc), making any cross-comparisons with the waiting time for other medical devices suppliers unfeasible. At present, other manufacturers have claimed that they can provide CMDs with shorter waiting times. Nevertheless, Cook Medical has a dedicated pathway in place for an expedited ordering and shipping process that can be requested on a case-by-case basis by treating physicians based on their assessment of the rupture risk. In our practice, we have, during the latest years, been using this for patients deemed to have a higher risk of rupture or large aneurysms (usually those >75 mm in maximal diameter at diagnosis). However, broader participation of industry stakeholders could represent a potential step forward to further improving the overall process of patients who are candidates for complex aortic endovascular grafting.

The waiting time after the treatment decision can be differentiated into two distinct phases: the time required for the endograft to be manufactured and shipped and the time required for the operation to be scheduled once the endograft is available at the treating facility. Therefore, we could potentially reduce the overall waiting time by scheduling the procedure closer to the delivery date, with the aim of shortening the delay from delivery to implantation to not more than 2 weeks. We have also performed the vast majority of stent graft planning ourselves at the same time the patient was evaluated for physical fitness (a process that, in itself, is highly variable) to minimize the waiting time to the greatest extent possible. However, physicians do not have any direct control over the former, and in-house protocols should aim to minimize the latter to the greatest extent possible (notwithstanding that competing adverse events [eg, deterioration of patient status] could also occur, which could affect the waiting time). In addition, our series has also shown that having the endograft already available could represent a lifesaving option for patients should the aneurysm rupture during the last phase of waiting. In our study, the aneurysm had ruptured in two patients when the CMD was already available at the hospital, and emergent repair could be accomplished without 30-day mortality.

Another interesting finding from our experience was that staged FEVAR or BEVAR (usually consisting of thoracic endovascular aortic repair preceding CMD implantation) did not seem to significantly delay the overall time required to complete the procedure (median, <1 week). Staging the repair for thoracoabdominal aortic aneurysms is a well-acknowledged strategy to minimize the incidence of spinal cord ischemia.[9] However, concerns have been raised regarding the inherent risk of aneurysm rupture during the delay required to stage the procedure. We did not observe any aneurysm rupture during the delay for staging, in line with previous reports by other groups.[10]

Independently of the cause of the possible delays during waiting time, it is evident that every effort should be made to expedite the procedure and that all patients

Table III. Details of wait time ruptures and cancellations

Year	Age, years; gender	Aneurysm diameter, mm	Period from stent graft order to interval event, days	Event	Details	Outcome
Aneurysm rupture						
2015	70; Male	65	66	Rupture	Repair with t-Branch	Alive at 30 days
2016	72; Female	67	485	Rupture	Not repaired (patient had refused to travel to hospital for treatment before rupture occurred)	Died
2017	69; Female	72	91	Rupture	Repaired with CMD (stent graft delivered to hospital 1 week before rupture, with elective procedure scheduled for week after)	Alive at 30 days
2017	55; Female	67	77	Rupture	Repaired with physician-modified graft	Alive at 30 days
2017	72; Male	62	48	Rupture	Open surgical repair	Alive at 30 days
2018	85; Male	65	112	Rupture	Repaired with CMD (rupture occurred on same day patient scheduled for elective repair)	Alive at 30 days
2018	68; Male	61	36	Rupture	Repaired with CMD (repair undertaken using device ordered for a different patient whose anatomy matched emergent case)	Alive at 30 days
2018	73; Male	63	127	Rupture	Not repaired (out-of-hospital cardiac arrest; autopsy finding)	Died
2019	76; Male	70	57	Rupture	Not repaired (out-of-hospital cardiac arrest; autopsy finding)	Died
2019	75; Male	72	306	Rupture	Not repaired (heart failure decompensation after first stage and rupture during interval to delayed second stage)	Died
Other deaths						
2014	64, Female	62	37	Cancellation	Cerebral hemorrhage	Died
2015	79, Female	63	408	Cancellation	Sepsis (underwent staged conduit; developed graft infection and deteriorated)	Died
2015	80, Male	60	200	Cancellation	Cancer	Died
2018	59, Male	67	203	Cancellation	Congestive heart failure	Died
2018	67, Male	55	11	Cancellation	Acute pancreatitis	Died
2019	78, Female	62	123	Cancellation	Congestive heart failure	Died

CMD, Custom-made device.

undergoing a customized procedure should have their concomitant underlying medical diseases and comorbidities closely monitored and treated. Almost one half of the overall death events recorded during the waiting time in our experience could be directly attributed to causes other than the aneurysm. A better selection process would be beneficial such that other severe concomitant comorbidities are noted, such that planning can be aborted if futility of care can be reasonably expected (especially considered that many of these patients would otherwise not be considered for open surgical repair).

Recent studies have identified that an aneurysm diameter >70 mm was associated with aneurysm rupture during the waiting period, consistent with previously reported data showing a diameter-related increased risk of natural complications in aortic aneurysms.[7,11]

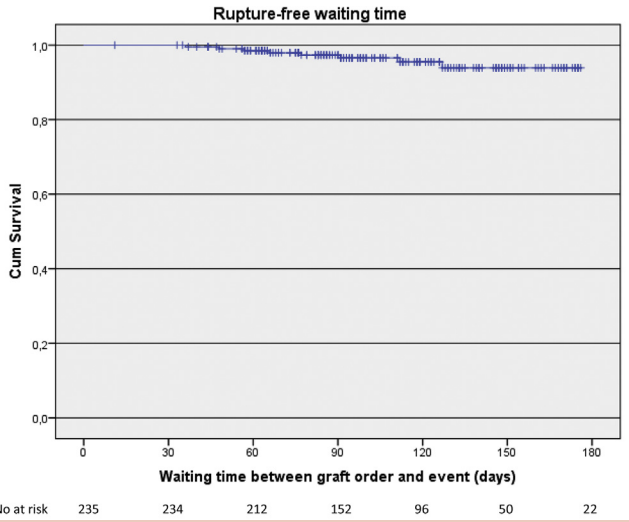


Fig 3. Kaplan-Meier analysis of rupture risk during waiting time (graph truncated at 180 days when 20 patients were left). *Cum,* Cumulative.

Therefore, patients with an aneurysm diameter >70 to 75 mm should be properly informed about the risk of rupture during the waiting time for F-BEVAR. However, we did not find a statistically significant difference in the maximal diameter of ruptured vs nonruptured aneurysms in our series, which could have reflected a type 2 error owing to the small sample size. Nevertheless, if the decision is to treat the patient, we believe the patient should be informed of the risk of rupture during the waiting time and that therapeutic alternatives and their relative risks should be explored and discussed. Other alternative solutions to CMD stent grafts exist, including off-the-shelf multibranched stent grafts, physician-modified endografts, parallel-graft techniques, and open surgery. These remain suitable in emergencies, as shown by our results. Because the observed delay with CMD aortic technology was associated with a non-negligible rupture risk, it might be reasonable to consider alternative treatment strategies for very large aneurysms that have been deemed at high risk of rupture, such as physician-modified stent grafts or in situ laser fenestrations, which nevertheless have their own intrinsic shortcomings. However, it was not possible from our results to determine a specific size threshold for when the use of patient-specific devices should not be considered. This should be decided individually with consideration of other patient factors and any planned procedure should be performed as soon as achievable once the CMD has been delivered to the hospital.

Finally, financial issues related to procedure cancellation when a CMD has been already ordered deserve further discussion. Although each hospital must adopt those practices that best suit their local and national regulations, the issues of cost should be considered when planning an F-BEVAR procedure. The direct costs related to stent grafts remain the most important determinant of in-hospital expenditures and should be considered in the overall decision-making process.[12] In our practice, payment of CMD stent grafts occurs after their shipment to the treating institution, and no insurance policy was stipulated with the manufacturer for the return of grafts not used.

Study limitations. The results from the present study must be interpreted within the context of its inherent limitations. It was a retrospective, single-center experience with a relatively small patient cohort. However, the sample size was similar to that of two other comparable reported studies, and the baseline and outcomes data were retrieved for 100% of the study population. Another critical issue was the definition and evaluation of the waiting time, which we considered as the interval between the endograft order to the manufacturer and implantation. Accordingly, we did not consider the period between the CTA examinations, multidisciplinary discussions regarding the suitable type of procedure, endograft planning, and the eventual order. Also, we were unable to extract the exact date of endograft delivery to the hospital for most patients. Thus, we were unable to analyze what portion of the waiting time could be attributed to the scheduling of the surgical procedure. However, given the stability of the center's policy during the study period, which is to schedule the procedure for the first available time after graft delivery, we believe it is unlikely that this bias could have affected the study findings. Finally, the waiting times observed in the present series might not be generalizable to lower volume centers or nations with different health care settings and regulations.

CONCLUSIONS

The median waiting time from stent graft order to implantation was ~15 weeks in our single-center experience. Approximately 7% of patients had experienced an adverse event during the waiting time, either related to aneurysm rupture or an underlying comorbidity. Improvements in patient selection and decreases in the waiting time are important tasks for the future. For ruptured aneurysms, the combination of different techniques, including off-the-shelf multibranched endografts and open surgical repair, and the availability of the CMD stent graft could play a vital role in reducing the associated mortality rate.

AUTHOR CONTRIBUTIONS

Conception and design: MD, DL
Analysis and interpretation: MD, AW, KM, DL
Data collection: MD
Writing the article: MD
Critical revision of the article: MD, AW, KM, DL

Final approval of the article: MD, AW, KM, DL
Statistical analysis: MD, DL
Obtained funding: Not applicable
Overall responsibility: DL

REFERENCES

1. Oderich GS, Ribeiro M, Hofer J, Wigham J, Cha S, Chini J, et al. Prospective, nonrandomized study to evaluate endovascular repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on supraceliac sealing zones. J Vasc Surg 2017;65:1249-59.
2. Verhoeven EL, Katsargyris A, Bekkema F, Oikonomou K, Zeebregts CJ, Ritter W, et al. Ten-year experience with endovascular repair of thoracoabdominal aortic aneurysms. Eur J Vasc Endovasc Surg 2015;49:524-31.
3. Swerdlow NJ, Wu WW, Schermerhorn ML. Open and endovascular management of aortic aneurysms. Circ Res 2019;124:647-61.
4. Wanhainen A, Verzini F, Van Herzeele I, Allaire E, Bown M, Cohnert T, et al. Editor's choice — European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. Eur J Vasc Endovasc Surg 2019;57:8-93.
5. Mastracci TM, Eagleton MJ, Kuramochi Y, Bathurst S, Wolski K. Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms. J Vasc Surg 2015;61:355-64.
6. Katsargyris A, Uthayakumar V, de Marino PM, Botos B, Verhoeven EL. Aneurysm rupture and mortality during the waiting time for a customized fenestrated/branched stent graft in complex endovascular aortic repair. Eur J Vasc Endovasc Surg 2020;60:44-8.
7. Gallitto E, Faggioli G, Spath P, Pini R, Mascoli C, Ancetti S, et al. The risk of aneurysm rupture and target visceral vessel occlusion during the lead period of custom-made fenestrated/branched endograft. J Vasc Surg 2020;72:16-24.
8. Katsargyris A, de Marino PM, Botos B, Nagel S, Ibraheem A, Verhoeven ELG. Single center experience with endovascular repair of acute thoracoabdominal aortic aneurysms. Cardiovasc Intervent Radiol 2021;44:885-91.
9. Etz CD, Zoli S, Mueller CS, Bodian CA, Di Luozzo G, Lazala R, et al. Staged repair significantly reduces paraplegia rate after extensive thoracoabdominal aortic aneurysm repair. J Thorac Cardiovasc Surg 2010;139:1464-72.
10. Bertoglio L, Katsarou M, Loschi D, Rinaldi E, Mascia D, Kahlberg A, et al. Elective multistaged endovascular repair of thoracoabdominal aneurysms with fenestrated and branched endografts to mitigate spinal cord ischaemia. Eur J Vasc Endovasc Surg 2020;59:565-76.
11. Kuzmik G, Sang A, Elefteriades J. Natural history of thoracic aortic aneurysms. J Vasc Surg 2021;56:565-71.
12. D'Oria M, Wanhainen A, DeMartino RR, Oderich GS, Lepidi S, Mani K. A scoping review of the rationale and evidence for cost-effectiveness analysis of fenestrated-branched endovascular repair for intact complex aortic aneurysms. J Vasc Surg 2020;72:1772-82.

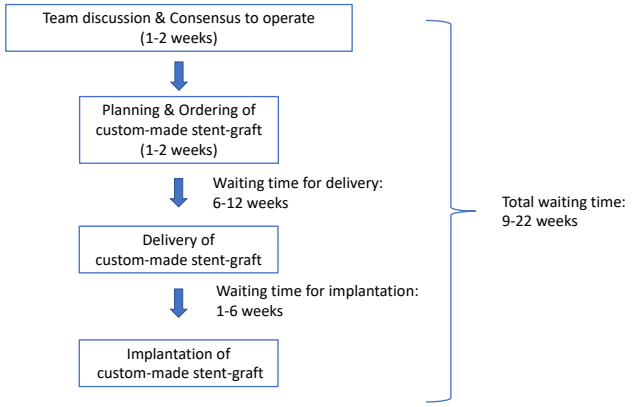
Submitted Jun 29, 2021; accepted Nov 6, 2021.

Additional material for this article may be found online at www.jvascsurg.org.

Supplementary Table (online only). Baseline patient characteristics stratified by aneurysm rupture status

Variable	Aneurysm rupture		*P* value
	Yes (n = 10)	No (n = 225)	
Female gender	3 (30)	55 (24)	.69
Age, years	72 ± 4	72 ± 8	.92
Octogenarians	1 (10)	43 (19)	.47
Ischemic heart disease	4 (40)	69 (95)	.46
Congestive heart failure	2 (20)	30 (13)	
Smoking	7 (70)	159 (70)	.48
Diabetes	1 (10)	26 (11)	1.00
Chronic obstructive pulmonary disease	3 (30)	65 (29)	.23
Chronic kidney disease	4 (40)	48 (21)	.11
Aneurysm extent			.82
Arch or descending thoracic	1 (10)	19 (8)	
Thoracoabdominal	3 (30)	59 (33)	
Pararenal or suprarenal	6 (60)	147 (66)	
Aneurysm diameter, mm	66 ± 9	62 ± 5	.31
Large aneurysm (diameter ≥70 mm)	3 (30)	40 (18)	.18
Postdissection aneurysm	1 (10)	28 (12)	.83

Data presented as number (%) or mean ± standard deviation.



Supplementary Fig (online only). Clinical pathway from initial patient encounter to custom-made (CMD) stent graft implantation.