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The State of Complex Endovascular Abdominal Aortic Aneurysm Repairs in the Vascular Quality Initiative

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Abstract

Background: Endovascular repair of complex abdominal aortic aneurysms (cAAA) has become increasingly common, but reports have been mostly limited to single centers and single devices.

Methods: We studied all endovascular repairs of cAAA (zone 6 or caudal) from 2014-2018 in the Vascular Quality Initiative (VQI). This included all commercially available fenestrated (FEVAR), chimney/snorkel repairs, and physician-modified devices (PMEG), exclusive of Investigational Device Exemptions (IDEs) and clinical trial devices. We used inverse probability weighted, multilevel logistic regression to compare rates of perioperative outcomes including death, acute kidney injury (AKI), major adverse cardiac events (MACE-the composite of death/stroke/myocardial infarction), and Cox regression for long-term mortality.

Results: During the study period, surgeons performed 1396 endovascular cAAA repairs; 1308 (94%) elective, 63 (4.5%) for symptomatic aneurysms, and 25 (1.8%) for rupture. The number of centers performing endovascular cAAA repairs expanded steadily from 39 in 2014 to 81 in 2017. There were 880 FEVAR (63%), 256 PMEG (18%), and 260 chimney/snorkel repairs (19%). In elective cases, 3214 visceral vessels were incorporated and revascularized: 120 repairs (9%) involved one vessel, 481 (38%) repairs involved two vessels, 560 (44%) involved three vessels, and 113 (9%) involved four vessels. The mean number of arteries incorporated was 2.5±0.8, with

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PMEGs involving the most arteries (3.3 ± 0.8 for PMEG vs. 2.5 ± 0.6 for FEVAR and 1.9 ± 0.9 for chimney/snorkel, P < 0.001). PMEGs were used to treat more extensive aneurysms, and more incorporated the celiac and superior mesenteric arteries. There was no change in aneurysm extent, but the length of proximal seal extended over time. Chimney/snorkel cases employed more arm or neck access, had longer procedure times, and used more contrast. Rates of perioperative death (FEVAR: 3.4% vs PMEG: 2.7% vs Chimney/Snorkel: 6.1%, P = .13), and AKI (17% vs 18% vs 19%, P = .42) were similar, but chimney/snorkel was associated with higher rates of stroke (0.8% vs 0.9% vs 3.3%, P = .03), and MACE (6.1% vs 5.4% vs 11.7%, P = .02). After adjustment, rates of perioperative death, AKI, and overall complications remained similar, but chimney/snorkel was associated with significantly higher odds of stroke (OR 7.3 [1.5 – 36.4], P = .015), MI (OR 18.7 [2.6 – 136.8], P = .004), and MACE (OR 11.1 [2.1 – 58.9], P = .005). Overall survival following elective repair was 91% at one year and 88% at three years, with no difference between repair types in crude or adjusted analysis.

Conclusion: The VQI provides a unique opportunity to study the real-world application and outcomes of complex endovascular aneurysm repair. Perioperative morbidity appears to be higher following chimney/snorkel repair, but further study is needed to confirm these findings and establish the durability of these novel technologies.

Here is the edited TOC summary:

This VQI study of 1396 complex abdominal aortic aneurysm (cAAA) repairs found that chimney/snorkel procedures were associated with higher rates of perioperative major adverse cardiac events and stroke than commercially available fenestrated repair or physician modified endografts despite treating less extensive aneurysms.

Keywords

Endovascular Repair; Juxtarenal; Abdominal Aortic Aneurysm; EVAR; FEVAR; PMEG; Chimney; Snorkel; VQI; Vascular Quality Initiative; Complex Abdominal Aortic Aneurysm; Pararenal

Introduction:

Since the introduction of endovascular aneurysm repair (EVAR) in 1991, its usage and indications have expanded dramatically.[1–3] In the United States, the overwhelming majority of abdominal aortic aneurysms (AAA) are treated with EVAR, and recent data show that even ruptured AAA increasingly undergo EVAR.[4,5] The renal-visceral segment of the abdominal aorta remains one of the final frontiers for endovascular repair, but surgeons developed a broad array of techniques to repair juxtarenal, pararenal, and thoracoabdominal aortic aneurysms. Strategies for managing renal and visceral arteries include fenestrated or branched endografts and chimney/snorkel/periscope techniques, known collectively as complex endovascular aneurysm repair. Although trials of off-the-shelf grafts are ongoing in the U.S., most devices are custom-manufactured endografts or physician-modified endografts (PMEG), designed for a patient’s specific anatomy.

After the first fenestrated endograft, the Zenith Fenestrated AAA Endovascular Graft (Cook Medical, Bloomington, IN) was approved by the FDA in 2012, complex endovascular repair has become increasingly common.[6,7] In Medicare alone, the number of branched-fenestrated repairs increased from 335 in 2011 to 2,143 in 2013, an increase of over 600%.[8] However, this figure likely underrepresents the true number of complex repairs, as it only captures patients enrolled in Medicare, the code for branched-fenestrated repair only recently became available, and many repairs, especially PMEG, are performed as part of clinical trials or physician-sponsored Investigational Device Exemptions (IDE), which would not be captured using Medicare billing data. Most reports of outcomes following complex endovascular repair are limited to clinical trials of devices, and single-center reports from high-volume surgeons.[9–14] Consequently, it is difficult to understand how these complex repairs are implemented in real-world practice.

In 2010, the Society for Vascular Surgery formed the Vascular Quality Initiative (VQI), based on the Vascular Study Group of New England's successful registry.[15] The VQI captures data from 412 centers in 46 states as well as Canada. As of 2012, the VQI captured 15% of total AAA repairs in the United States, a number that has risen dramatically in the intervening years.[16] Of note, the VQI does not report data on procedures performed under IDEs. This registry has been validated for accuracy and procedure capture, and is even considered a valid method of data reporting for eligibility for the Centers for Medicare and Medicaid Merit-Based Incentive Payments System.[17] Hospitals undergo routine audits for data accuracy. Although other long-term outcomes such as re-intervention rates are not always well documented in the VQI, mortality is well captured and validated due to the linkage with the SSDI and Medicare. Consequently, we chose to study the usage patterns of complex endovascular repairs in this real-world registry.

Methods:

Patients:

We identified all patients undergoing endovascular repair of complex aneurysms in the VQI between 2014 and 2018. We defined a complex aneurysm as a proximal extent between the top of the celiac artery and the lowest renal artery, or an aneurysm with a proximal extent below the renal arteries that was repaired with at least one scallop, fenestration, branch, or chimney/snorkel into a renal or visceral artery. The VQI does not release data for patients enrolled in IDE studies or pivotal trials. Only commercially available FEVAR devices are included, unless a device was modified by the physician at the time of implant (PMEG) or chimneys/snorkels placed. The VQI records the number of endograft pieces, the renal and visceral arteries intervened upon, and the type of devices implanted (e.g. bare-metal stent, covered stent, etc., up to two devices per branch). The surgeon documents these variables after each case and enters whether each artery was fenestrated, scalloped, chimney/snorkeled, and whether or not a stent was placed. A PMEG was any repair in which at least one endograft was modified by the surgeon. For the cases in which there was a chimney placed alongside a commercially available FEVAR (n=25) or physician-modified endograft (n=10), we included them as chimneys for the purposes of baseline characteristics but excluded them from the analyses.We excluded hybrid procedures (n=16), complex repairs for indications other than aneurysm such as dissection, penetrating aortic ulcer, or thrombus (n=474), and patients with missing data on incorporation of renal/visceral arteries (n=575).

This left us with a final sample of 1396 patients. The VQI records patient demographics, comorbid conditions, perioperative complications, one-year follow-up, and long-term mortality through linkage to the Social Security Death Index through March 7, 2018. The Beth Israel Deaconess Medical Center Institutional Review Board approved this study and waived the need for patient consent due to the nature of the design and minimal risk to human subjects.

Definitions and Variables:

We calculated the estimated glomerular filtration rate (GFR) by the CKD-EPI formula. This allowed us to stratify chronic kidney disease by the National Kidney Foundation Guidelines into eGFR >60 mL/min/1.73m^2, 45 – 60 mL/min/1.73m^2, 30 – 44 mL/min/1.73m^2, and < 30 mL/min/1.73m^2. We classified smoking status as never, former, or current (i.e. within 30 days of the procedure), and stratified chronic obstructive pulmonary disease into none, mild-moderate, and requiring home oxygen. Congestive heart failure (CHF) we categorized as none, mild (NYHA Class I or II), or moderate to severe (NYHA Class III or IV). Age and maximum aortic diameter were divided into quintiles. Based on previous work, we considered preoperative anemia as a hemoglobin < 10 mg/dL.[18] We classified postoperative renal dysfunction, or acute kidney injury (AKI), by the RIFLE criteria based on the peak postoperative creatinine value.[19] The VQI defines stroke as any new motor or sensory loss, speech abnormality, or documentation of any other neurological symptoms related to the right or left hemisphere, lasting >24 hours. We defined perioperative death as occurring within 30 days or discharge dead from index hospitalization. Myocardial infarction (MI) includes elevated troponins or electrocardiographic changes with symptoms. Re-interventions and conversion to open refers to those performed during the index hospitalization. Access site complications included thrombosis, embolus, hematoma, and infection. The VQI records access site complications as a binary variable, without specifying which site the complication occurred in (arm, neck, groin, etc). We defined any complication as death, re-intervention, AKI, stroke, transient ischemic attack (TIA), access site complication, MI, new arrhythmia, new onset CHF, pneumonia, re-intubation, or mesenteric ischemia. A major adverse coronary event (MACE) was perioperative death, stroke, or MI. Hospital volume was classified into quintiles based on the average annual volume over the study period.

Statistical Analysis:

We compared categorical and continuous variables using chi-squared and ANOVA tests respectively. Case details, complications and survival were compared only for elective cases. To adjust for non-random assignment to each treatment, we calculated propensity scores using multinomial logistic regression models in which the three treatments were the outcome. These propensity scores were used to create inverse probability weights (the inverse of the probability of undergoing the treatment the subject received). We used propensity scores rather than standard multivariable regression as the relatively low absolute rates of the outcomes precluded robust adjustment. Because the number of events dictate the number of covariates allowed in a standard multivariable analysis (usually no less than 10 to 15 events per variable), this can often limit the robustness of multivariable analyses. In contrast, to construct propensity scores, *every patient experiences the outcome of interest* (in this case the repair type). This allows us to adjust for more covariates without the risk of overfitting. Propensity weighting offers an advantage over propensity matching in that it retains the entire sample size, and therefore may reduce the effect of unmeasured confounding. Covariates included in the propensity score models included age, sex, race, aortic diameter, prior aortic surgery, chronic kidney disease, diabetes, hypertension, COPD, coronary artery disease, prior myocardial infarction, congestive heart failure, smoking, body mass index, anemia, Medicaid/self-pay, aspirin, statin, beta-blocker, ACE or ARB inhibitor use, aneurysm extent, proximal extent of the repair, number of vessels incorporated, and quintiles of hospital volume. For perioperative outcomes, we used propensity-weighted multilevel logistic regression, clustering at the center level, and for long-term outcomes we constructed propensity-weighted Kaplan-Meier curves and used Cox regression. Our primary analysis controlled for the number of vessels incorporated, but as a separate sensitivity analysis we also looked at outcomes stratified by the number of vessels incorporated (excluding four-vessel cases since no commercially available fenestrated cases incorporated four vessels).

Results:

Patients:

During the study period, surgeons performed 1396 endovascular cAAA repairs. Of these, 1308 (94%) were performed in the elective setting, 63 (4.5%) were for symptomatic aneurysms, and 25 (1.8%) for rupture. There were 880 FEVAR (63%), 256 PMEG (18%), and 260 chimney/snorkel repairs (19%). Characteristics of the patient population, both overall and by repair type, are presented in Table IA, and the subset of elective cases is shown in Table IB. The majority of the patients were white males not on Medicaid or self-pay, although females comprised a significantly larger proportion (22%) of the study population than most reports of infrarenal EVAR.[2,20–22] Ten percent of the patients had prior aortic surgery, most frequently those undergoing PMEG (25% vs. 6% for FEVAR/BEVAR and 12% for chimney/snorkel, $P < .001$). Cases involving symptomatic aneurysms more often involved PMEG (12%) or chimney/snorkel (11%), compared to 0.5% for FEVAR ($P < .001$). Ruptured aneurysms were more often repaired using chimney/snorkel (7%), compared to only 2% for PMEG and 0.3% for FEVAR ($P < .001$). Patients undergoing chimney/snorkel were more often female, anemic, and had CKD and hypertension, while PMEG patients had larger aneurysms, higher rates of COPD, and more often had prior aortic surgery. Comorbidities were distributed similarly in the elective cases.

Centers:

The number of centers performing endovascular cAAA repairs expanded steadily from 39 in 2014 to 81 in 2017 (Figure 1). Including 2018 (a partial year), there were a total of 98 centers where are least one repair occurred during the study period. All three repair types increased in number from 2014 to 2016, but the number of PMEGs leveled off by 2017 whereas the number of FEVAR and chimney/snorkels continued to rise steadily (Figure 2). It is worth noting that PMEGs performed under IDEs are not reported by the VQI, and so this may undercapture PMEGs as several centers obtained IDEs during the study period (e.g a center may report their PMEGs from 2014-2016, but then after obtaining an IDE in 2016, subsequent PMEGs would not be reported). The mean number of repairs performed annually per center was 13 ± 11, with a median of 10 (interquartile range 5 – 19), and a range of 1 to 44. Centers annually performed a median of 6 [2 – 11] FEVAR repairs, 0 [0 – 3] PMEG, and 0 [0 – 3] chimney/snorkels. All but 3 centers performed FEVAR, but only 31 (32%) performed at least one PMEG, and only 45 (46%) at least one chimney. Only 18 centers (18%) performed all three repair types.

Case Details, Elective Cases:

3214 renal/visceral vessels were incorporated and revascularized: 120 repairs (9%) involved one vessel, 481 (38%) repairs involved two vessels, 560 (44%) involved three vessels, and 113 (9%) involved four vessels. Case details for elective cases are presented in Table II. The mean number of arteries incorporated was 2.5 ± 0.8, with PMEGs involving the most arteries (3.3 ± 0.8 for PMEG vs. 2.5 ± 0.6 for FEVAR and 1.9 ± 0.9 for chimney/snorkel, P < .001).

Chimney/snorkel cases employed more arm or neck access, had longer procedure times, and used more contrast. PMEG were more often performed through bilateral percutaneous access. Aneurysms treated with PMEG extended more proximally, and landing zones were more proximal as well (Figure 3). FEVAR was used to treat less proximal aneurysms (unsurprising given that the only commercially available fenestrated device is somewhat limited in the proximal extent of disease that fits within IFU). Correspondingly, cases employing PMEGs more often involved revascularization of the celiac and superior mesenteric arteries (Table II). There was no change in aneurysm extent over the course of the study period (p = .48), but landing zones moved more proximally (Figure 4). The mean number of arteries revascularized per case did not change over time. Surgeons landed 9% of their grafts in zone 5 in 2014 compared to 13% in 2017, and the amount of proximal seal increased from half a zone in 2014 to 1.5 zones in 2018 (P < .001). For reference, an aneurysm with a proximal extent in zone 9 (infrarenal) with a proximal landing zone in zone 8 (between the highest and lowest renal arteries) would represent a difference of 1.

Perioperative Complications, Elective Cases

Perioperative complications (i.e. in-hospital complications) of elective cases are presented in Table III. In unadjusted analyses, perioperative mortality was similar between repair types (FEVAR 3.4% vs. PMEG: 2.7% vs. Chimney/Snorkel: 6.1%, P = .13), as were rates of AKI (17% vs 18% vs 19%, P = .42) and overall complication rates (27% vs 29% vs 34%, P = .16). However, chimney/snorkel was associated with higher rates of stroke (0.8% vs 0.9% vs 3.3%, P = .027), the composite of stroke/death (4.0% vs 3.6% vs 8.3%, P = .031), and MACE (6.1% vs 5.4% vs 11.7%, P = .017). Cases involving either arm or neck access were associated with higher rates of access site issues (10.2% vs 5.6%, P = .003), as well as higher stroke rates (3.2% vs 0.5%, P < .001). This was true even if the adjunctive access site was only used for a brachial-femoral wire (aka “body-floss”) alone (5.1%).

Adjusted odds ratios are presented in Table IV. In adjusted analysis, rates of perioperative death, AKI, and overall complications remained similar, but chimney/snorkel was associated with significantly higher odds of stroke (OR 7.3 [1.5 – 36.4], P = .015), MI (OR 18.7 [2.6 –

136.8], P = .004), and MACE (OR 11.1 [2.1 – 58.9], P = .005). Results were consistent when stratified by the number of arteries incorporated in the repair.

Complications Based on Arteries Incorporated, Elective Cases

There were 1144 repairs in which both renal arteries were revascularized (83%), and 990 cases involving at least one mesenteric vessel (63%). Excluding dialysis patients, the rate of AKI varied inversely with the number of renal arteries incorporated (no renals: 60%, one renal: 26%, both renals: 16%, P < .001). There were 849 repairs in which are least one mesenteric vessel was incorporated (61%), but rates of postoperative bowel ischemia were similar regardless of visceral vessel incorporation (P = .25).

Medium-Term Survival, Elective Cases

Overall survival following elective repair was 91% at one year and 88% at three years. There was no difference between procedure types (3-year survival: 90% FEVAR vs. 87% PMEG vs. 85% chimney/snorkel, P = .19 (Figure 5). After adjustment, there was no association between procedure type and mortality (P = .40).

Discussion:

This study demonstrates the unique potential of the VQI to study the contemporary application of endovascular therapies for complex aortic pathology. With over 2,000 repairs, this represents the largest registry of complex cases to date. Early results from these complex cases demonstrate acceptable perioperative morbidity and mortality as well as medium-term survival, although chimney/snorkel cases were associated with higher rates of perioperative morbidity.

Endovascular repairs of complex AAAs utilize a relatively new technology, with the first fenestrated endograft approved by the FDA in 2012. Despite this, fenestrated repairs rapidly proliferated, with the number of repairs increasing more than 6-fold between 2011 and 2013.[8] As with any novel technology, it is important to rigorously evaluate its outcomes. To date, however, reports have been limited to pivotal trials and single-center reports.[7,14,23,24] Although these reports are important, these results do not always translate into real-world practice. Clinical trials enroll carefully selected patients and rigorously adhere to the manufacturer's instructions for use (IFU). In addition, they are performed by experienced, high-volume surgeons. In contrast, a recent analysis of the only FDA-approved fenestrated device (Cook Zenith Fenestrated-ZFEN, Cook Medical, Bloomington, IN) showed that between 2012 and 2015, 77% of the physicians who attended training sessions ordered less than 6 devices, with the average physician ordering only three devices per year.[25] Complex endovascular repairs are more likely to mirror the volume-outcome relationships seen in the more challenging cases such as open surgery rather than more straightforward infrarenal EVAR, so the results from high-volume centers are unlikely to generalize to the population at large.[26,27]

This study demonstrates the unique potential of the VQI to reveal how trial results translate to the real world. Administrative data sets such as Medicare lack clinical granularity on details such as aneurysm size and extent, as well as important operative details such as the number of vessels incorporated and by what manner (scallop, fenestration, etc). Other registries such as NSQIP have smaller sample sizes and are limited to 30-day outcomes. The VQI provides both the necessary granular detail, and longer-term outcomes which allow for a detailed analysis. Increasingly, the FDA turns to these registries for further evidence of device safety. For example, the FDA recently approved a new indication for transcatheter aortic valve replacement (TAVR) based on data from the Society of Thoracic Surgery/ American College of Cardiology's Transcatheter Valve Therapy (TVT) registry.[28–30] Also, the FDA, physicians and industry sponsors initiated a collaboration utilizing the VQI for post-market surveillance of outcomes of thoracic endovascular aneurysm repair (TEVAR) for the treatment of acute and chronic type B aortic dissection.[31] Our study reveals the potential for the VQI to provide similar data for other novel technologies such as PMEG and custom-manufactured grafts.

Mortality rates in this study are similar to those from previous reports, with elective mortality of 3-7% depending on repair type.[7,10,32–36] Of note, the 2.7% perioperative mortality following PMEG is similar to the initial series reported by Starnes et al. (3.8% and 5.1% mortality in the two series), Scali et al. (6.3%), and the systematic review by Georgiadis et al. (3.2%).[11,12,37,38] However, it is worth noting the wide range of aortic pathologies treated in this series, ranging from four-vessel PMEGs to single vessel fenestrations. It is therefore difficult to directly compare the whole of this report to previous case series. Consequently, the primary purpose of this study is not to compare the results in the VQI to previous literature, but rather to demonstrate the potential to use the VQI to perform these comparisons in the future.

Although this report is mostly exploratory and descriptive in nature, the higher morbidity and trend towards higher mortality following chimney/snorkel repairs is worthy of further study. Even after adjustment, chimney/snorkel was associated with eleven-fold the odds of MACE as FEVAR or PMEG cases, and significantly higher odds of stroke and MI. Previous publications on chimney/snorkel repairs have demonstrated mixed results, with 30-day mortality ranging from 0. 4% to the 6.6% in this current study.[32,39–44] In the largest systematic review of 28 studies including 1748 patients undergoing FEVAR and 757 undergoing chimney/snorkel, chimney/snorkel procedures were associated with twice the 30-day mortality rate of FEVAR (4% vs 2%).[41] However, two earlier systematic reviews as well as a single-center comparison found no significant differences in perioperative mortality.[40,43,44] Chimney/snorkel repairs in our report also involved significantly more arm/ neck access, with 90% of repairs involving at least one adjunctive access site. Consequently, it is not surprising that these patients suffered higher rates of stroke/TIA, likely due to more wire and catheter manipulation in the aortic arch. Although there was no statistically significant difference, there was a trend towards higher rates of perioperative death following chimney/snorkel repairs that merits further study.

A note of caution is warranted when interpreting the results of this study. These three techniques are not necessarily applicable to every patient, and are not available at every center. For example, commercially available FEVAR devices can only incorporate three vessels, and takes weeks for a graft to be made and delivered. Some centers prohibit the use of PMEG, as it is not an FDA-approved technique. In addition, our sample size and event rates limit our power to detect a difference so further study is needed before any definitive conclusions can be made. Chimney/snorkel repairs remain important options for complex repairs in symptomatic or ruptured patients where custom-made endografts may not be available given time constraints. The aneurysm sizes and extents treated by the three device types in this study are significantly different, and individual centers may vary in their experience and comfort with each repair type. As such, these results should be considered exploratory in nature; even with robust multivariable analyses, we cannot account for all of the important clinical factors that weigh into the choice of repair modality.

This study must be interpreted in the context of its design. As the VQI relies on surgeon reporting of procedural characteristics, as well as the specific intervention, coding errors are always possible. The VQI also does not capture cases performed under IDEs, so we lack data from certain high-volume surgeons and centers. As the VQI is a voluntary quality initiative, we do not know how the results of surgeons who opted to join the VQI generalize to the wider population. It is also worthy of note that once a surgeon's IDE is approved, their results are no longer released to investigators using the VQI. As a result, the results from experienced, high-volume surgeons that currently have IDEs may be limited to the early part of the learning curve. This is especially true for novel techniques such as PMEG. We also do not know if chimney or snorkel grafts were used as a rescue, and not as a planned parallel graft, which could bias towards inferior outcomes with chimney/snorkel. Additionally, the VQI blinds the specific endograft used, so we cannot make comparisons between different graft types. Although mortality is well captured through the linkage to the Social Security Death Index, data on reinterventions are lacking due to low follow-up rates. Fortunately, the recent linkage to Medicare will improve the capture of these data going forward.

Conclusion:

The VQI provides a unique opportunity to study the real-world application and outcomes of complex endovascular aneurysm repair. Perioperative morbidity and mortality appear to be higher following chimney/snorkel repair, but further study is needed to confirm these findings and establish the durability of these novel technologies.

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Key Findings:

This study of 1396 complex abdominal aortic aneurysm (cAAA) repairs found that chimney/snorkel procedures were associated with higher rates of perioperative major adverse cardiac events and stroke than commercially available fenestrated repair or physician modified endografts despite treating less extensive aneurysms.

Take Home Message:

Results of endovascular repair of cAAAs are promising, but longer-term VQI data are needed, especially on chimney/snorkel.

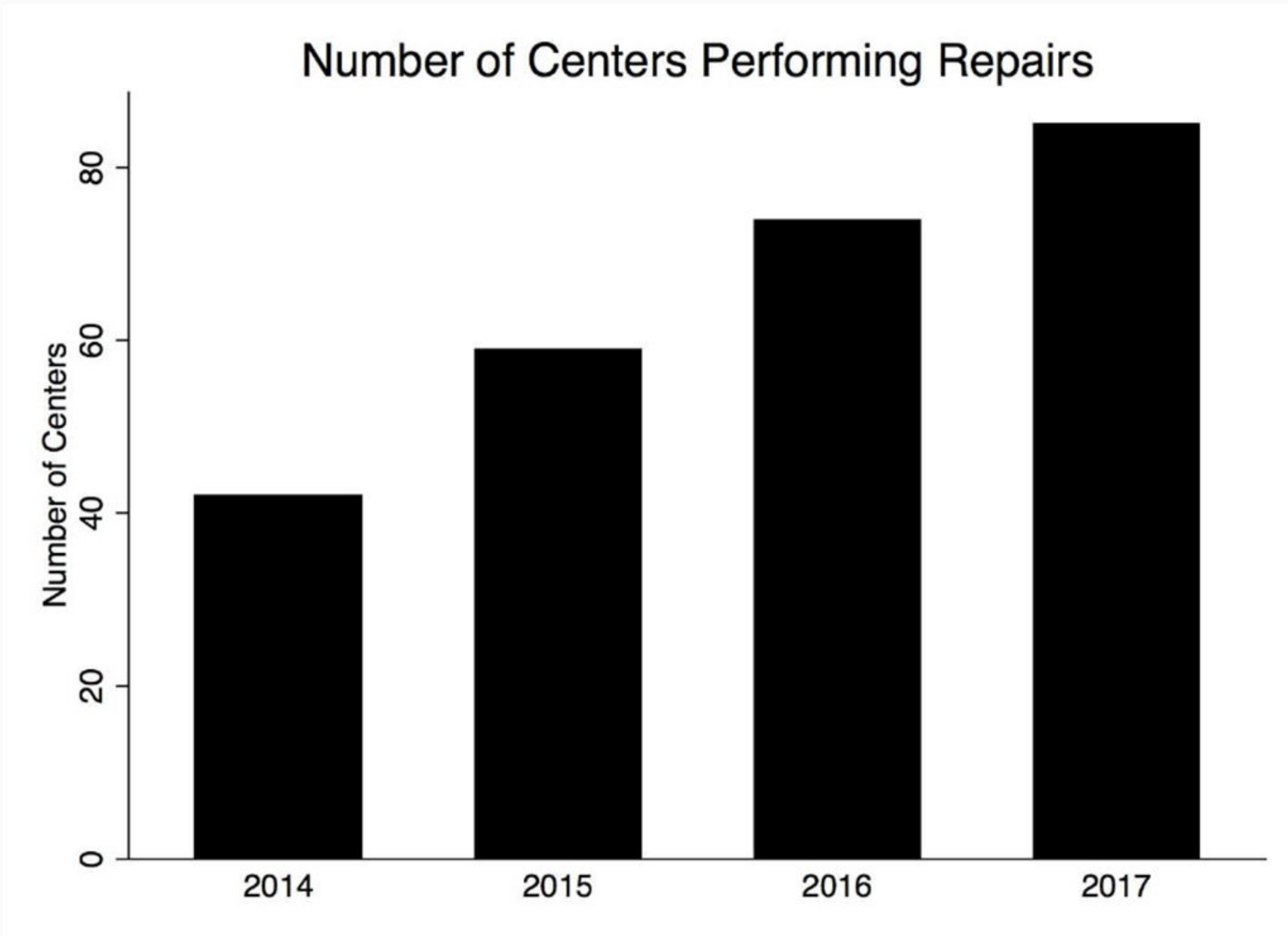

Figure 1.
The number of centers recording endovascular complex abdominal aortic aneurysm repairs in the VQI each year.

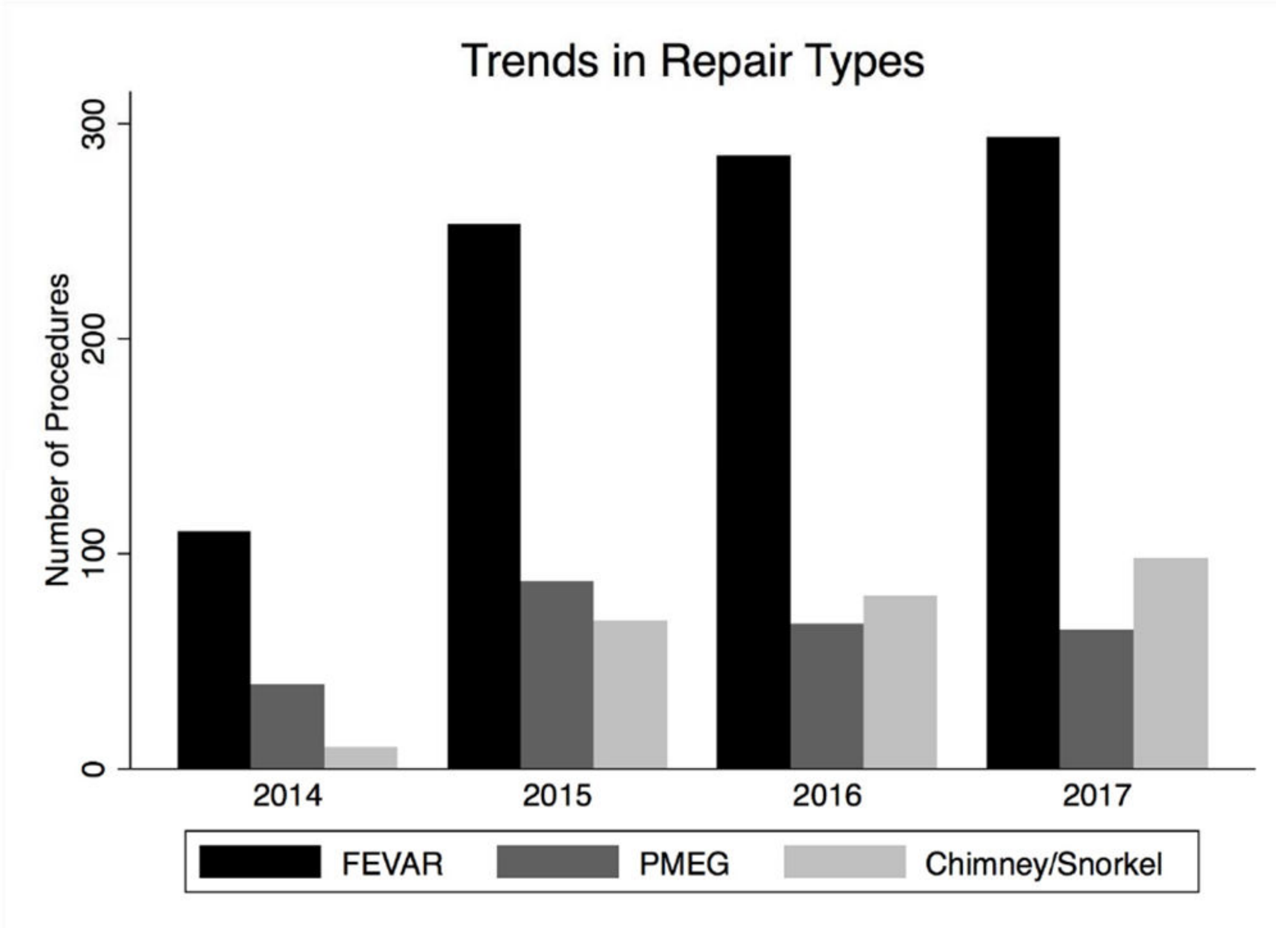

Figure 2.
The annual number of repairs by each repair type. *FEVAR: fenestrated, PMEG: physician-modified endograft.*

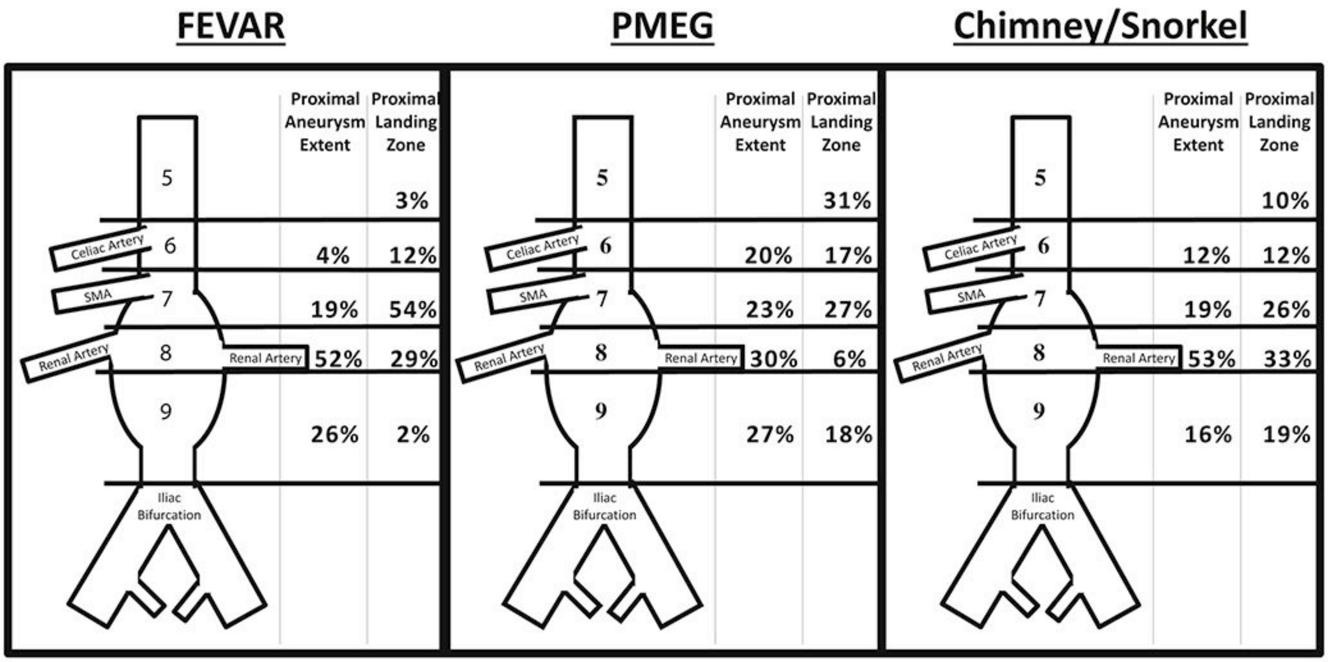

Figure 3.

Distribution of Aneurysm Extents and Landing Zones between the Repair Types. *FEVAR: fenestrated,. PMEG: physician modified endograft. SMA: superior mesenteric artery.*

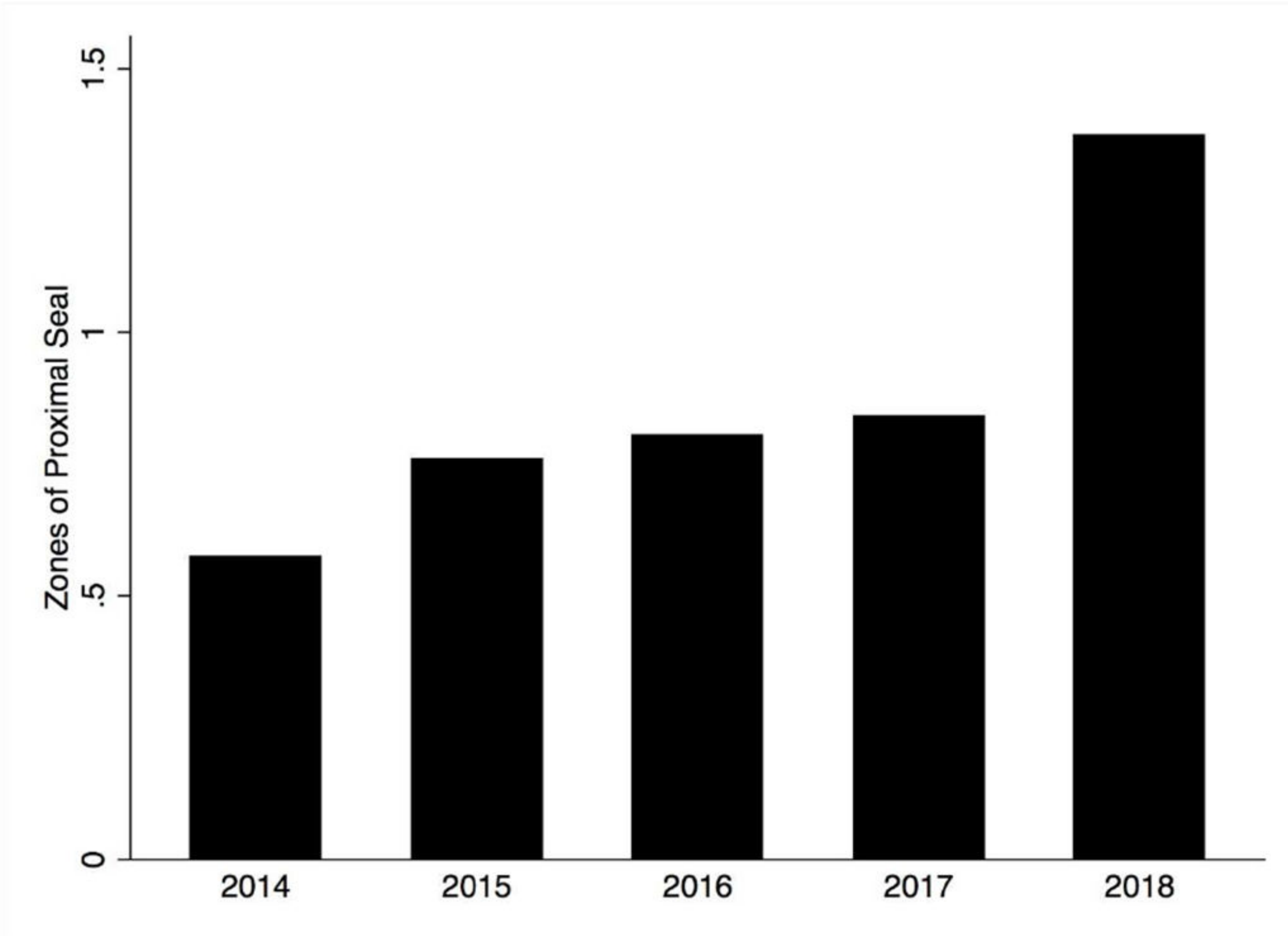

Figure 4.

Differences between Proximal Aneurysm Extent and Proximal Landing Zone. For reference, an aneurysm with a proximal extent in zone 9 (infrarenal) with a proximal landing zone in zone 8 (between the highest and lowest renal arteries) would represent a difference of 1. P < .001 for differences over the years.

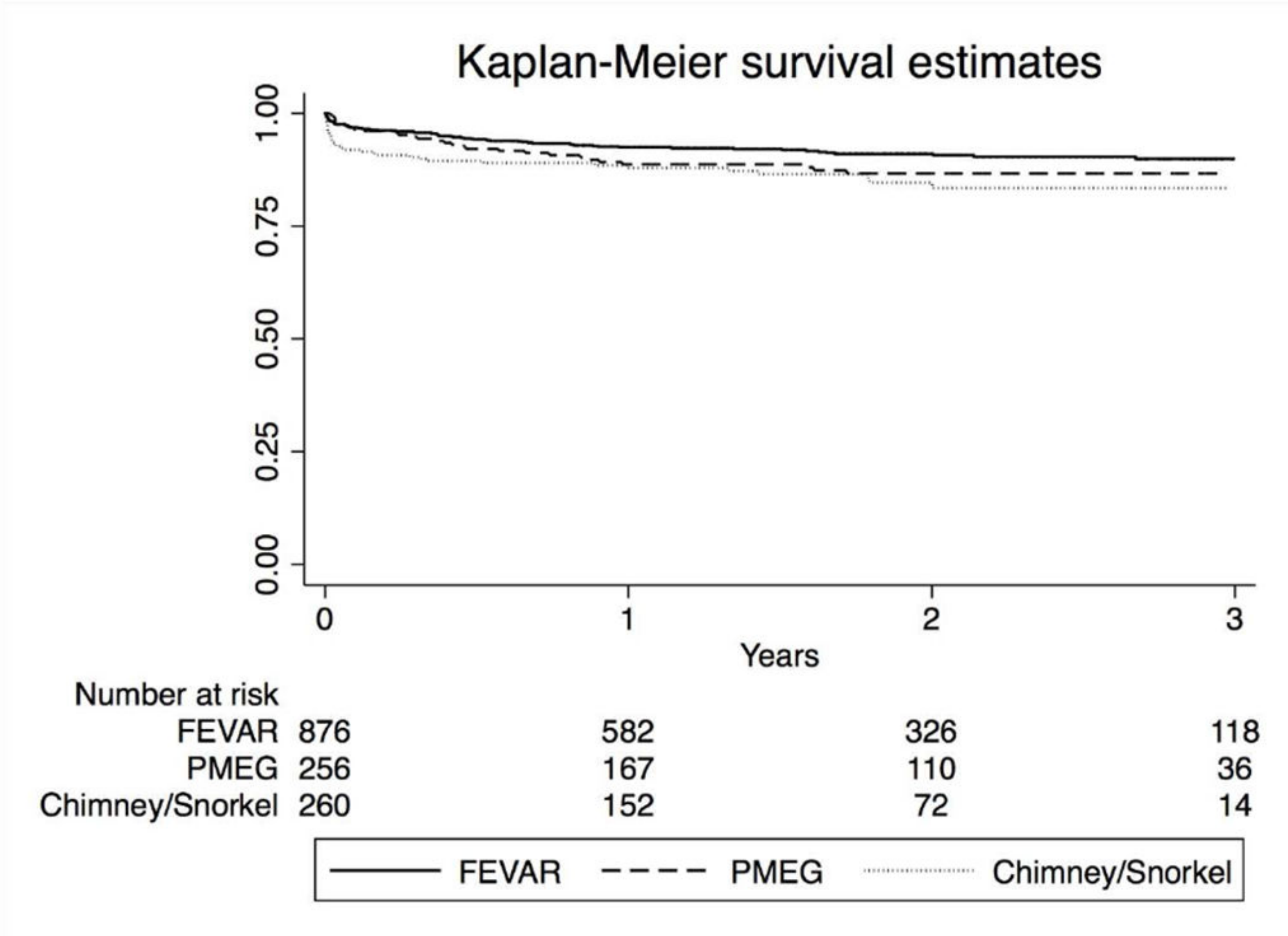

Figure 5.
Medium-term survival by repair type. Standard errors < 0.1. P = .19.

Table IA.

Baseline Characteristics of the study population. *MI: myocardial infarction. COPD: chronic obstructive pulmonary disease. GFR: glomerular filtration rate. Hb: hemoglobin*

Characteristic	Overall (n=1396)	FEVAR (n=880)	PMEG (n=256)	Chimney/Snorkel (n=260)	P
Age	74 ± 8	73 ± 8	74 ± 8	75 ± 8	0.001
Male Sex	78	78	82	72	0.013
White Race	95	96	95	92	0.038
Diameter (cm)	6.1 ± 1.1	5.9 ± 1.0	6.6 ± 1.4	6.4 ± 1.4	< 0.001
<4.5	3	3	2	4	
4.5-5.0	7	7	4	8	
5.0-5.5	24	29	13	20	
5.5-6.0	27	30	24	19	
6.0-6.5	15	14	17	15	
6.5-7.5	14	11	21	15	
7.5+	11	6	19	19	
Urgency					< 0.001
Elective	94	99	86	82	
Symptomatic	5	0.5	12	11	
Ruptured	2	0.3	2	7	
Hypertension	87	85	87	91	0.048
Diabetes	19	20	18	17	0.34
Coronary Artery Disease	47	47	43	49	0.29
Prior MI	25	25	26	24	0.88
Smoking					0.62
Ever	89	90	88	87	
Current	35	36	32	33	
Former	54	53	56	54	
Congestive Heart Failure	15	14	14	17	0.57
mild-mod	12	12	11	15	
severe	2	2	3	1.5	
COPD	36	36	40	35	< 0.001
mild-moderate	30	32	29	27	
on home oxygen	6	4	10	8	
Body Mass Index (BMI)					0.19
Underweight	2	2	2	3	
Normal	30	29	28	34	
Overweight	39	40	37	39	
Obese	26	27	29	22	
Morbidly obese	3	3	4	1	4
Chronic Kidney Disease	43	41	42	51	0.001
GFR 30-60	37	36	34	40	
GFR <30	5	4	5	8	

Characteristic	Overall (n=1396)	FEVAR (n=880)	PMEG (n=256)	Chimney/Snorkel (n=260)	P
Dialysis	1.3	0.5	2.7	2.7	
Anemic (Hb < 10)	6	4	7	12	< 0.001
Medicaid/Self-pay Medications	2	3	3	2	0.61
Aspirin	68	68	71	65	0.36
Statin	77	76	81	74	0.10
Beta Blocker	60	59	57	67	0.043
ACE/ARB	49	50	44	53	0.11
Prior Aortic Surgery	10	6	25	12	< 0.001

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Table IB.

Baseline Characteristics of Elective Cases. *MI: myocardial infarction. COPD: chronic obstructive pulmonary disease. GFR: glomerular filtration rate. Hb: hemoglobin*

Characteristic	Overall (n=1274)	FEVAR (n=873)	PMEG (n=221)	Chimney/Snorkel (n=180)	P
Age	74 ± 8	73 ± 8	73 ± 8	75 ± 8	0.005
Male Sex	78	78	82	72	0.042
White Race	95	96	96	93	0.16
Diameter (cm)	6.1 ± 1.1	5.9 ± 1.0	6.4 ± 1.2	6.3 ± 1.4	< 0.001
<4.5	3	3	2	3	
4.5-5.0	7	7	4	10	
5.0-5.5	25	29	14	21	
5.5-6.0	28	30	28	18	
6.0-6.5	15	14	18	17	
6.5-7.5	13	11	21	15	
7.5+	9	6	13	16	
Hypertension	87	85	88	93	0.006
Diabetes	19	21	17	17	0.30
Coronary Artery Disease	47	47	43	50	0.33
Prior MI	25	25	25	24	0.97
Smoking					0.47
Ever	90	90	91	91	
Current	35	36	33	32	
Former	55	53	58	59	
Congestive Heart Failure	15	14	14	17	0.68
mild-mod	12	12	11	15	
severe	2	2	3	2	
COPD	36	36	40	35	< 0.001
mild-moderate	31	32	30	28	
on home oxygen	6	4	11	8	
Body Mass Index (BMI)					0.27
Underweight	2	2	1	3	
Normal	30	29	28	33	
Overweight	40	39	38	42	
Obese	22	27	28	22	
Morbidly obese	1	3	5	1	
Chronic Kidney Disease	43	41	44	52	0.001
GFR 30-60	37	37	35	43	
GFR <30	4.7	4	6	7	
Dialysis	1.1	0.5	3.2	1.9	
Anemic (Hb < 10)	5	4	5	9	0.023
Medicaid/Self-pay	2.2	2.4	2.7	1	0.36
Medications					

Characteristic	Overall (n=1274)	FEVAR (n=873)	PMEG (n=221)	Chimney/Snorkel (n=180)	P
Aspirin	69	69	72	70	0.61
Statin	78	76	82	79	0.24
Beta Blocker	60	59	55	68	0.015
ACE/ARB	50	50	46	55	0.16
Prior Aortic Surgery	10	6	23	12	< 0.001

Table II.

Procedural characteristics of the elective cases. Details presented as % or mean ± standard deviation.

Procedural Characteristics	Overall	FEVAR	PMEG	Chimney/Snorkel	P
General Anesthesia	98	98	98	97	0.49
At least one side Perc	65	63	77	61	< 0.001
Bilateral Percutaneous	60	58	73	50	< 0.001
Percutaneous Success	95	94	97	99	0.062
Arm/neck access	25	11	19	91	< 0.001
Procedural Time	242 ±105	238 ±100	239±118	263 ±101	0.005
Diameter (cm)	6.1 ± 1.1	5.9 ± 1.0	6.4 ± 1.2	6.3 ± 1.4	< 0.001
Vessels incorporated	2.5 ± 0.8	2.5 ± 0.6	3.3 ± 0.8	1.9 ± 0.9	< 0.001
Celiac Artery	11.6	1.6	55	7.2	< 0.001
SMA	59	55	90	37	< 0.001
Right Renal Artery	91	95	94	69	< 0.001
Left Renal Artery	91	94	91	76	< 0.001
Blood Loss	411±532	397 ± 488	458±712	416±486	0.31
Contrast Volume	123 ± 73	124 ± 65	101 ± 69	144 ± 95	< 0.001
Fluoro Time	69 ± 36	70 ± 36	65 ± 35	69 ± 36	0.26

Table III.

Perioperative Complications in Elective Cases. With the exception of perioperative death, rates refer to in-hospital events. *Perioperative death is death within 30-days or within the index hospitalization. MACE: major adverse cardiac event: composite of perioperative death, in-hospital stroke and in-hospital myocardial infarction. ESRD: end-stage renal disease. TIA: transient ischemic attack. Risk, Injury, Failure, Loss of Function and ESRD are defined according to the RIFLE criteria.*

Complication	Overall	FEVAR (n=873)	PMEG (n=221)	Chimney/Snorkel (n=180)	P
Perioperative Death	3.8	3.4	2.7	6.1	0.13
Stroke/Death	4.6	4.0	3.6	8.3	0.031
MACE	6.8	6.1	5.4	11.7	0.017
Any Complication	29	27	29	34	0.16
Length of Stay	6.0 ± 25	6.4 ± 29	4.6 ± 6	5.1 ± 5	0.54
Acute Kidney Injury	17	17	18	19	0.42
Risk	7	7	6	4	
Injury	4	4	4	6	
Failure	4	4	6	5	
Loss of Function	1	1	0.5	1.9	
ESRD	1.5	1.3	1.4	2.3	
Reintervention	5	5	2.7	7	0.25
aneurysm-related	4	4	2.7	6	
unrelated	0.9	1	0	1.4	
conversion to open	0.3	0.2	0.5	0.5	0.78
Access Site Issue	6	6	6	10	0.066
Pulmonary	4	3.9	4.1	6.5	0.23
pneumonia	1.5	1.6	1.8	1.4	
reintubation	3	2.5	3.2	5.6	
Mesenteric/Colonic Ischemia	2.5	2.5	2.2	2.3	0.89
medical management	1	1.2	0.9	0.5	
surgical intervention	1.5	1.4	1.4	1.9	
Cerebrovascular	1.2	0.8	0.9	3.3	0.027
TIA	0.4	0.1	0.5	1.4	
Stroke	0.8	0.7	0.5	1.9	
Arrhythmia	6.7	6.9	5.0	7.8	0.49
Myocardial Infarction	3.4	3	2.7	5.6	0.14

Table IV.

Adjusted odds ratios for perioperative outcomes.

Models adjusted for: age, sex, race, aortic diameter, prior aortic surgery, chronic kidney disease, diabetes, hypertension, COPD, coronary artery disease, prior myocardial infarction, congestive heart failure, smoking, body mass index, anemia, Medicaid/self-pay, aspirin, statin, beta-blocker, ACE or ARB inhibitor use, aneurysm extent, proximal extent of the repair, number of vessels incorporated, and quintiles of hospital volume

Outcome	Odds Ratio [95% CI]	P Value
Death	FEVAR is referent value	
PMEG	0.7 [0.3 - 2.0]	0.58
Chimney	1.2 [0.5 - 3.1]	0.68
AKI		
PMEG	1.1 [0.7 - 1.9]	0.62
Chimney	0.7 [0.3 - 1.7]	0.39
Any Complication		
PMEG	1.0 [0.7 - 1.3]	0.78
Chimney	2.8 [0.6 - 11.8]	0.17
Stroke		
PMEG	0.5 [0.1 - 3.0]	0.49
Chimney	7.3 [1.5 - 36.4]	0.015
MI		
PMEG	0.8 [0.3 - 2.5]	0.75
Chimney	18.7 [2.6 - 136.8]	0.004
Stroke/Death		
PMEG	0.8 [0.3 - 1.7]	0.52
Chimney	2.3 [0.7 - 8.0]	0.18
MACE		
PMEG	0.7 [0.3 - 1.6]	0.36
Chimney	11.1 [2.1 - 58.9]	0.005