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Aortic Neck IFU Violations During EVAR for Ruptured Infrarenal Aortic Aneurysms are Associated with Increased In-Hospital Mortality

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Abstract

Objective: Vascular surgeons treating patients with ruptured abdominal aortic aneurysm must make rapid treatment decisions and sometimes lack immediate access to endovascular devices meeting the anatomic specifications of the patient at hand. We hypothesized that endovascular treatment of ruptured abdominal aortic aneurysm (rEVAR) outside manufacturer instructions-for-use (IFU) guidelines would have similar in-hospital mortality compared to patients treated on-IFU or with an infrarenal clamp during open repair (ruptured open aortic aneurysm repair [rOAR]).

Methods: Vascular Quality Initiative datasets for endovascular and open aortic repair were queried for patients presenting with ruptured infrarenal AAA between 2013–2018. Graft-specific IFU criteria were correlated with case-specific proximal neck dimension data to classify rEVAR cases as on- or off-IFU. Univariate comparisons between the on- and off-IFU groups were performed for demographic, operative and in-hospital outcome variables. To investigate mortality differences between rEVAR and rOAR approaches, coarsened exact matching was used to match patients receiving off-IFU rEVAR with those receiving complex rEVAR (requiring at least one visceral stent or scallop) or rOAR with infrarenal, suprarenal or supraceliac clamps. A multivariable logistic regression was used to identify factors independently associated with in-hospital mortality.

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Author Contributions: DZ and CH conceived and designed the study. Statistical analysis was carried out by DZ, and the results analyzed and interpreted by RS, JR, PG, JI and MW. The article was written by RS and all authors approved the final manuscript. Overall responsibility for this work is assumed by CH as senior author.

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SUPPLEMENTARY MATERIALS

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Results: 621 patients were treated with rEVAR, with 65% classified as on-IFU and 35% off-IFU. The off-IFU group was more frequently female (25% vs. 18%, $P = 0.05$) and had larger aneurysms (76 vs. 72 mm, $P = 0.01$) but otherwise was not statistically different from the on-IFU cohort. In-hospital mortality was significantly higher in patients treated off-IFU vs. on-IFU (22% vs. 14%, $P = 0.02$). Off-IFU rEVAR was associated with longer operative times (135 min vs. 120 min, $P = 0.004$) and increased intraoperative blood product utilization (2 units vs. 1 unit, $P = 0.002$). When off-IFU patients were matched to complex rEVAR and rOAR patients, no baseline differences were found between the groups. Overall in-hospital complications associated with off-IFU were reduced compared to more complex strategies (43% vs. 60–81%, $P < 0.001$) and in-hospital mortality was significantly lower for off-IFU rEVAR patients compared to the supraceliac clamp group (18% vs. 38%, $P = 0.006$). However, there was no significantly increased mortality associated with complex rEVAR, infrarenal rOAR or suprarenal rOAR compared to off-IFU rEVAR (all $P > 0.05$). This finding persisted in a multivariate logistic regression.

Conclusions: Off-IFU rEVAR yields inferior in-hospital survival compared to on-IFU rEVAR but remains associated with reduced in-hospital complications when compared with more complex repair strategies. When compared with matched patients undergoing rOAR with an infrarenal or suprarenal clamp, survival was no different from off-IFU rEVAR. Taken together with the growing available evidence suggesting reduced long-term durability of off-IFU EVAR, these data suggest that a patient's comorbidity burden should be key in making the decision to pursue off-IFU rEVAR over a more complex repair when proximal neck violations are anticipated preoperatively.

INTRODUCTION

Endovascular aortic repair (EVAR) has quickly become the standard of care for abdominal aortic aneurysm (AAA) due to early reports of its morbidity benefits over open repair.[1, 2] It is well known that the initial advantages of EVAR dissipate when long-term outcomes are examined because of the increased proportion of later reinterventions associated with endoleak and device failure.[3–5] Use of EVAR devices are governed by strict indications for use (IFU) criteria that are unique to each device and defined by proximal neck length, aneurysm neck angulation, and aortoiliac diameters. Stent grafts that are implanted off-IFU are associated with a higher rate of reinterventions[6–7] due to inadequate landing zones or angulation, which impairs apposition of the modular components of the graft and leads to increased Type I and III endoleaks.[7–10]

Despite being associated with worse outcomes, the off-IFU application of endografts is common in both emergent and elective surgery. Previous studies report that between 31–69% of patients undergoing EVAR have at least one IFU violation on retrospective review,[6–8, 10–11] and roughly half of patients have an IFU violation related to the length or angulation of the aortic neck.[6, 12] While minimal information is available to determine the rate of device-specific IFU adherence in the randomized controlled trials of EVAR for ruptured abdominal aortic aneurysm (rAAA),[13–15] aortoiliac morphology has been tied to inferior late outcomes in these trial cohorts.

Data from the elective setting suggest that off-IFU EVAR is associated with lower overall survival compared with on-IFU repair in both the short- and long-term setting,[7, 12] but the majority of literature examining IFU criteria-based outcomes exclude rAAA. There is some evidence that long-term mortality is worse for off-IFU rEVAR compared with on-IFU rEVAR,[6] however, there is very little available information regarding in-hospital outcomes. As such, there is minimal information available to guide clinicians in weighing the repair options for rAAA patients with aortic anatomy that deviates from IFU criteria. The aim of this study was to investigate the association of off-IFU endovascular ruptured infrarenal AAA (rEVAR) repair with in-hospital mortality, and to compare outcomes for patients treated with off-IFU rEVAR to those receiving on-IFU rEVAR or ruptured open aortic aneurysm repair (rOAR).

METHODS

Study Design

This is a retrospective cohort study using data from the Society for Vascular Surgery Vascular Quality Initiative (VQI) database.[16] The VQI is a database that collects preoperative risk factors, intraprocedural variables and postoperative outcomes for several distinct vascular procedures, including EVAR and OAR. The VQI accrues data from >500 participating centers encompassing both the community and academic spheres. Because the datasets within VQI are procedure-specific, there is a high level of granularity with regards to patient aortic anatomy, aortic neck length and angulation, as well as device manufacturer. This allows a thorough interrogation of whether or not a particular endograft was applied for on- or off-IFU indications based on the patient's specific reported aortic anatomy.

The primary study cohort was defined by interrogating the endovascular AAA repair procedure database from 2013 to 2018 to identify all patients who underwent repair of rAAA. Only patients with angiographic, computed tomography angiography or operative confirmation of rupture are designated as "ruptured" in the VQI; patients whose level of urgency was designated as "symptomatic" or "elective" were excluded from this cohort. Proximal neck anatomy including diameter, length, and angulation were compared with the IFU dimensions specific to the devices used in each case; a case was designated off-IFU if any of the aneurysm neck dimensions exceeded those of the IFU-prescribed neck dimensions (Supplementary Table 1). Iliac anatomy was underreported in the database and was not included as part of the IFU determination.

A secondary study cohort was created for a matched multivariable analysis, and included patients undergoing repair of rAAA via either an rEVAR, complex rEVAR, or rOAR approach. The complex rEVAR and rOAR patients were identified from the complex endovascular aortic repair and open AAA procedure VQI databases during the same 2013–2018 period and defined with the same criteria used in the primary analysis. Within the VQI, complex EVAR is defined as endovascular repair of an aneurysm with its 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.[16] The Institutional Review Board at the University of California San Francisco approved this study and waived informed consent requirements given that this was a retrospective analysis of a de-identified data source.

Study Outcomes

The primary outcome of this study was in-hospital mortality. Secondary outcomes included intraoperative outcomes including Type I and III endoleaks identified on completion angiography, conversion to open repair (for rEVAR patients), reoperation, post-operative transfusion volume, hospital length of stay, ICU length of stay, and postoperative complications including stroke, myocardial infarction, new dysrhythmia, heart failure, pneumonia, reintubation, bowel ischemia, acute kidney injury based on the RIFLE criteria,[17] new hemodialysis, lower extremity ischemia, and surgical site infection. Due to a high rate of missing data with respect to long term outcomes in the VQI database, we elected to examine only in-hospital outcomes for this analysis.

Statistical Analysis

We described the study cohort, anatomic characteristics and postoperative outcomes using descriptive statistics. For the primary analysis, we compared outcomes for the on-IFU versus off-IFU groups using univariate analysis including χ^2, Student's t, and Mann-Whitney testing for categorical and continuous variables. Multivariable logistic regression was then performed to assess the association of off-IFU status with in-hospital mortality. All variables in Table I, as well clustering by physician, were included in the initial model. Backwards stepwise elimination then removed variables from the model with $P > 0.1$. Variables that changed the Harrel's c-statistic more than 0.1 on removal were returned to the model.

For the secondary analysis, the off-IFU rEVAR patients identified in the primary analysis were matched with similar complex rEVAR and rOAR patients using coarsened exact matching (CEM) with full blocking on the strata of variables. First, we compared off-IFU rEVAR versus complex rEVAR versus rOAR with infrarenal, suprarenal, and supraceliac clamps using univariate analysis including χ^2, ANOVA, and Kruskall-Wallis testing for categorical and continuous variables (Supplementary Table 2). Next, CEM was performed including all variables that were statistically different on univariate analysis (age, BMI, tobacco abuse, diabetes, lowest systolic blood pressure, maximum AAA diameter, mental status, and previous infrarenal AAA repair). The L1 statistic generated before and after matching reflected the change in bias associated with CEM; the L1 value declined from 0.99–0.94, indicating a reduction in cohort bias. Postoperative outcomes from the primary analysis were then compared with univariate analysis between the matched groups. Multivariable logistic regression was subsequently performed to examine factors associated with in-hospital mortality. Similar to our primary analysis, all variables from Supplementary Table 2 were included in the initial multivariable model. Backwards stepwise elimination then removed variables from the model based on a $P > 0.1$.

All statistical analyses were performed using Stata Version 15.1 (StataCorp LP, College Station TX). Values were reported as statistically significant at a level of $\alpha \leq 0.05$.

RESULTS

Study Cohort

Overall, 621 patients underwent rEVAR during the study period. Of these, 217 (35%) received stent grafts applied off-IFU based on aortic neck anatomy. Overall mean age was 73 years (95% CI 72–75), 20.5% of patients were women, and 86.6% were white. The majority of patients had hypertension (74.9%) and current or prior smoking (74.6%), and the mean BMI was 28 kg/m^2 (95% CI 28–29 kg/m^2). Other common major comorbidities included coronary artery disease (24.5%), COPD (26.7%) and diabetes (15.9%). A higher proportion of off-IFU versus on-IFU patients were women (24.9% vs. 18.1%, $P < 0.05$). There were no other significant differences between the on and off-IFU groups with respect to demographics, comorbidities, preoperative domicile, or previous vascular interventions (all, $P > 0.05$; Table I).

Patients receiving off-IFU rEVAR had a larger mean aneurysm diameter compared to patients receiving an on-IFU rEVAR (76 mm vs. 72 mm; $P = 0.01$). Preoperative characteristics were otherwise largely similar for the off-IFU vs. on-IFU rEVAR groups. A similar proportion of patients were deemed unfit for open repair (29.0% vs. 23.5%; $P = 0.27$), and lowest pre-intubation blood pressure, pre-operative hemoglobin, mental status, and prevalence of cardiac arrest were similar between groups (all $P > 0.05$; Table I).

Aortic Anatomy and Intraoperative Details

Patients receiving off-IFU rEVAR had aortic necks that were significantly shorter (15 mm vs. 24 mm; $P < 0.001$) and more angulated (45% vs. 20% with >45%; $P < 0.001$) compared to patients receiving on-IFU rEVAR, but there was no significant difference in mean neck diameter (24 mm vs. 24 mm; $P = 0.51$). There were no significant differences between off-IFU versus on-IFU rEVAR symptom-to-stent or admission-to-stent time (both, $P > 0.05$; Table II). The off-IFU rEVAR group had a significantly longer median operative time (135 min. vs. 120 min; $P = 0.004$) and mean fluoroscopy time (31 min vs. 25 min; $P < 0.001$) when compared with the on-IFU group. Off-IFU rEVAR was also associated with a higher mean contrast volume (126mL vs. 104mL), higher median blood loss (728mL vs. 472mL), and more units of packed red blood cells administered intraoperatively (median 2 units vs. 1 unit) (all, $P < 0.05$).

There were no significant differences in graft configuration or device manufacturer between the two groups (both, $P > 0.05$; Table II). The off-IFU group had significantly more oversizing (mean 30% vs. 19%; P < 0.001) and required significantly more proximal aortic extensions (20% vs. 18%, $P = 0.04$) than the on-IFU group. Off-IFU rEVAR was associated with a higher rate of completion Type 1a endoleak (6% vs. 2%, $P = 0.049$) and a higher frequency of intraoperative conversion to open repair (4% vs. 2%, $P = 0.04$) compared to on-IFU rEVAR.

In-Hospital Outcomes

In-hospital mortality was significantly higher for the off-IFU compared to the on-IFU rEVAR group (22% vs. 14%; $P = 0.02$). Off-IFU rEVAR was also associated with increased postoperative blood transfusion requirements ($P = 0.001$; Table III). There were no significant differences in length of hospital or ICU stay, reoperation, or any of the organ-specific complication endpoints recorded in the VQI database for off-IFU versus on-IFU rEVAR (all, $P > 0.05$; Table III).

After adjusting for baseline differences between groups, the odds ratio for in-hospital mortality was significantly higher for off-IFU versus on-IFU rEVAR (OR 1.83, 95% CI 1.06–3.15; Table IV).

Predictors of In-Hospital Mortality

Based on the demographic, comorbidity and technical variables described in Table I, off-IFU rEVAR patients were then matched with similar patients undergoing complex rEVAR and OAR for ruptured AAA (Supplementary Table 2). After matching, 104 patients underwent off-IFU rEVAR, 235 patients underwent rOAR (122 with an infrarenal clamp, 71 with a suprarenal clamp, and 52 with a supraceliac clamp), and 50 patients underwent complex rEVAR. Crude in-hospital outcomes between the groups after CEM are listed in Supplementary Table 3. In-hospital mortality was similar for off-IFU rEVAR (18%) compared to complex rEVAR (18%), OAR with an infrarenal clamp (22%), and OAR with a suprarenal clamp (20%), but significantly higher for OAR with a supraceliac clamp (38%, $P = 0.006$ versus off-IFU rEVAR). A multivariable logistic regression performed on these matched patients demonstrated significantly increased in-hospital mortality associated with rOAR requiring a supraceliac clamp compared to off-IFU rEVAR (OR 4.81, 95% CI 1.96–11.82). There was no significantly increased mortality associated with complex rEVAR, infrarenal rOAR or suprarenal rOAR compared to off-IFU rEVAR (all $P > 0.05$; Table V).

DISCUSSION

A large number of endovascular repairs for rAAA are performed outside of the strict IFU-recommendations established by the device manufacturers.[6, 18] Our study confirmed this result, demonstrating that more than 1/3 of patients with ruptured AAA receive EVAR off-IFU. There is a growing body of evidence to suggest that elective EVAR performed off-IFU has worse outcomes and increased secondary interventions compared to EVAR performed on-IFU, but little is known about the in-hospital outcomes of off-IFU stent grafts placed in the emergent setting. In the present analysis, we sought to compare in-hospital outcomes for rEVAR performed on-versus off-IFU. We found a statistically higher frequency of in-hospital mortality for patients undergoing off-IFU rEVAR, as well as significantly increased operative time, fluoroscopy time, and blood product utilization associated compared to on-IFU. A multivariable analysis with matched rOAR patients demonstrated no mortality benefit of rEVAR over either complex rEVAR or rOAR requiring either an infrarenal or a suprarenal clamp. Overall, these data suggest that off-IFU rEVAR results in inferior short-term outcomes compared with on-IFU rEVAR, and that either complex rEVAR or open aortic repair should be considered in appropriately selected patients if a hostile aortic neck (neck diameter >32 mm or >45° angulation) is identified preoperatively.

We found that 35% of patients undergoing EVAR for ruptured infrarenal AAA received a stent graft that was off-IFU based on aortic neck dimensions in the VQI database. This is similar to the 38% rate off-IFU rEVAR published previously[6] and on the low end of the ranges of off-IFU application cited in elective EVAR cases.[7, 8, 10, 11] However, it should be noted that our cohort is restricted to aortic neck IFU violations only. Prior investigations into the effect of aortoiliac anatomy on off-IFU outcomes in elective EVAR suggest that iliac diameter and the associated distal IFU violations may have the greatest effect on EVAR outcomes.[19] Aortoiliac anatomy was underreported in VQI, and therefore not included in our analyses. However, data from the elective setting suggests that some of the more granular adverse outcomes, such as endoleak and organ-specific complications, may be underreported in our analysis since we were only able to define off-IFU rEVAR based on adverse aortic neck anatomy.

While the perioperative mortality benefits of EVAR the elective setting have established with Level 1 evidence to be around 4% compared to open surgery,[20] recent meta-analyses have suggested that the perioperative mortality of rEVAR may be up to half that compared to patients undergoing open repair for rAAA[21] and that both short- and long-term mortality following rEVAR is improving with time.[21, 22] In our study, we found an 8% crude increase in in-hospital mortality associated with off-IFU compared to on-IFU rEVAR, a result with limited comparable data in the literature. The IMPROVE,[13] AJAX[15] and ECAR[14] trials examining EVAR outcomes in the setting of rAAA excluded patients not meeting IFU criteria. A small multicenter study in Europe specifically examining off-IFU EVAR outcomes for rAAA in 112 patients reported a 15% increase in 30-day mortality for off-IFU versus on-IFU EVAR,[6] although this did not reach statistical significance likely due to lack of power. Of note, while it has been implicated in decreased long term survival and increased late interventions, IFU status has not been demonstrated to have an impact on short-term mortality in the elective EVAR setting.[11, 12, 23]

Overall, the short-term outcomes of patients undergoing rEVAR have been shown to be equivalent to those undergoing rOAR despite a significantly higher burden of unoptimized comorbidities in rEVAR patients.[24, 25] As a result, we expected that mortality benefits of rEVAR over rOAR would persist even if rEVAR had to be applied off-IFU. Prior research evaluating the outcomes of off-IFU rEVAR had not demonstrated differences in short-term mortality; however, that study was limited by small numbers.[6] To address the question in larger and more specific subgroups, we matched rAAA patients receiving off-IFU rEVAR repair with similar patients undergoing complex rEVAR and rOAR. There were no significant differences in the odds of in-hospital mortality for off-IFU rEVAR, complex EVAR, or OAR with an infrarenal or suprarenal clamp. The only significant difference in the odds of in-hospital mortality was for off-IFU rEVAR compared with rOAR with a supraceliac clamp. Our results also demonstrated significantly increased resource utilization associated with off-IFU rEVAR, including intraoperative and postoperative blood transfusion, operative time, fluoroscopy time, and intraoperative conversion to open surgery. These findings suggest that the benefits of EVAR are marginal in the rAAA population, and that off-IFU application of rEVAR is not effective in realizing the benefits of the minimally invasive endovascular approach, even after comorbidities are taken into account.

Off-IFU rEVAR has been shown to correlate with a significantly higher rate of long-term graft related complications and increased 5-year mortality when compared with on-IFU rEVAR based on a small (N = 112) retrospective study from Europe.[6] Likewise, aortic neck IFU violations in rEVAR have been linked with a higher rate of adverse neck-related events than similar IFU violations in elective EVAR,[18] suggesting that this population is uniquely vulnerable to durability concerns related to off-IFU stent-graft placement as there is a tear in the aorta that may or may not persist after repair. Our study adds to the existing knowledge on this topic by demonstrating a significantly higher rate of in-hospital mortality for off-IFU compared to on-IFU rEVAR in a national U.S. cohort. While the present analysis is not optimized to examine outcomes beyond the initial hospital stay, the longer-term data from the literature are useful for contextualizing the present results. Together the data highlight the lack of both short-term and long-term benefit of off-IFU EVAR placement for ruptured AAA. Previous authors have used the high rate of long-term reintervention as evidence that off-IFU rEVAR may be effective for emergent exclusion with a future conversion in mind.[18] However, the present data call this strategy into question. The mortality detriment associated with off-IFU rEVAR in our results, along with equivalent short-term survival in matched complex rEVAR and rOAR patients, suggest that off-IFU rEVAR should not knowingly be used as a bridging maneuver in ruptured infrarenal or juxtarenal AAA if upfront rEVAR or rOAR is feasible.

Aortic aneurysms that extend into the renovisceral segment are known to have particularly high mortality in the setting of rupture.[26] This is consistent with our results, which demonstrate increasing short-term mortality benefits among patients receiving off-IFU rEVAR or complex EVAR when compared with matched patients requiring a more proximal (supraceliac) open aortic cross clamp. Recent investigations into the short-term mortality of patients undergoing complex EVAR in the setting of rupture demonstrated a significant survival benefit over open repair.[26] However, this strategy has unique challenges and may require multiple adjunctive procedures to achieve an adequate repair.[27] Further research is needed to explore the advantages of maintaining an endovascular strategy in the face of a ruptured AAA with significant renovisceral involvement, even if it requires violating IFU standards.

Limitations of this study include the retrospective nature of the analysis as well as the self-reported nature of the database, which may lead to selection bias in reported cases. There is also relative underreporting of some variables within the VQI, resulting in missing data for some of the cases and limiting the power of some of our secondary analyses. In particular, there was relative underreporting of iliac anatomy data that limited our ability to compare on and off-IFU rEVAR applications with respect to distal dimensions; this introduces the possibility that some of the on-IFU group may have been misclassified. Finally, substantial missing follow-up in the VQI aortic databases limits our ability to assess late reinterventions and mortality in the off-IFU rEVAR group that may contribute to additional, unforeseen morbidity associated with this approach. Due to the nature of CEM, fitness for open repair by definition unfortunately cannot be factored into the multivariable model; however, it should be noted that the fitness for open repair was not significantly different between the two IFU-status groups at baseline.

CONCLUSIONS

Off-IFU application of EVAR for ruptured abdominal aortic aneurysm is associated with significantly increased in-hospital mortality when compared with on-IFU applications. Based on multivariable logistic regression using matched complex EVAR and open repair ruptured aneurysm patients, despite reducing in-hospital complications off-IFU rEVAR did not offer a significant up-front mortality benefit over either complex rEVAR or open repair if an infrarenal or suprarenal clamp could be placed. These findings suggest that many patients with hostile aortic necks receiving off-IFU EVAR devices are not realizing the potential benefits of endovascular repair for ruptured aneurysm, and the application of EVAR in violation of proximal IFU should not be used as a bridging maneuver for rAAA in fit patients. Alternative options for repair with better short -and long-term outcomes should be considered when possible in order to give patients a definitive repair upfront.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table I.

Demographics, comorbidities, and presenting characteristics for patients presenting with ruptured AAA treated with on-IFU versus off-IFU EVAR

	Off IFU	On IFU	*P* value
n, (%)	217 (35)	404 (65)	
Center volume, median (25–75%), patients/year	3 (2–4)	3 (2–5)	0.96
Demographics and Comorbidities			
Age, mean (95% CI), y	73 (72–75)	73 (72–74)	0.27
Women, %	54 (25)	73 (18)	0.05
White race, %	187 (86)	351 (87)	0.90
Hispanic, %	12 (6)	12 (3)	0.12
Hypertension, %	167 (77)	298 (74)	0.33
Diabetes, %	41 (19)	58 (14)	0.13
Tobacco abuse, %	160 (74)	303 (75)	0.65
CAD, %	60 (28)	92 (23)	0.17
CHF, %	28 (13)	56 (14)	0.75
COPD, %	61 (28)	105 (26)	0.54
Pre-op Statin, %	91 (42)	155 (38)	0.51
eGFR, mean (95% CI), mL/min/1.73 m^2	56 (53–59)	58 (55–60)	0.51
BMI, mean (95% CI), kg/m^2	29 (28–30)	28 (28–29)	0.45
Pre-operative domicile			0.73
Home	212 (98)	392 (97)	
Nursing home	5 (2)	11 (3)	
Homeless	0	1 (0)	
Previous vascular treatment			
Carotid, %	3 (1)	7 (2)	0.74
Lower extremity, %	12 (6)	15 (4)	0.29
Major amputation, %	2 (1)	1 (0)	0.25
Preoperative characteristics			
Unfit for open repair, %	63 (29)	95 (24)	0.27
Lowest pre-intubation sys BP, mean (95% CI), mm Hg	95 (91–99)	95 (92–98)	0.97
Pre-op hemoglobin, mean (95% CI), g/dL	11.6 (11.3–11.9)	11.5 (11.3–11.7)	0.68

	Off IFU	On IFU	*P* value
Mental status, %			0.79
Normal	161 (75)	308 (77)	
Disoriented	35 (16)	57 (14)	
Unconscious	20 (9)	36 (9)	
Preoperative cardiac arrest, %	21 (10)	26 (7)	0.15
Pre-op anticoagulation, %	21 (10)	60 (15)	0.08
Previous infrarenal aortic surgery, %	9 (4)	23 (6)	0.40
AAA max AP diameter, mean (95% CI), mm	76 (73–79)	72 (70–74)	0.01
Neck length, median (25–75%), mm	15 (10–25)	24 (18–30)	**<0.001**
Neck diameter, mean (95% CI), mm	24 (23–25)	24 (24–25)	0.51
Infrarenal neck angle, degrees			**<0.001**
<45	120 (55)	323 (80)	
45–60	28 (13)	81 (20)	
61–75	46 (21)	0	
76–90	14 (6)	0	
>91	9 (4)	0	

Table II.

Intraoperative details for ruptured AAA patients treated with on-IFU versus off-IFU EVAR

	Off IFU	On IFU	*P* value
Procedure time, median (25–75%), min	135 (97–189)	120 (85–174)	**0.004**
Fluoroscopy time, mean (95% CI), min	31 (27–36)	25 (23–26)	**<0.001**
Symptoms-to-stent time, median (25–75%), h	9 (7–20)	11 (7–27)	0.06
Admission-to-stent time, median (25–75%), h	4 (3–6)	4 (3–6)	0.76
Anesthesia, %			0.26
Local	28 (13)	66 (16)	
Epidural	4 (2)	3 (1)	
GETA	185 (85)	335 (83)	
Contrast, mean (95% CI), mL	126 (117–137)	104 (98–109)	**<0.001**
Crystalloid, mean (95% CI), mL	2,000 (1,200–3,245)	1,800 (1,100–2,600)	**<0.001**
EBL, median (25–75%), mL	728 (485–972)	472 (354–590)	**0.04**
Intra-op pRBC transfused, median (25–75%), units	2 (0–5)	1 (0–4)	**0.002**
Percent oversize, mean (95% CI), %	30 (25–35)	19 (17–21)	**<0.001**
Graft configuration, %			0.69
Bifurcated	199 (92)	362 (90)	
Uni-iliac	15 (7)	34 (8)	
Aorto-aortic	3 (2)	8 (2)	
Company			0.08
1	35 (16)	55 (14)	
2	102 (47)	154 (38)	
3	71 (33)	170 (42)	
4	1 (1)	7 (2)	
5	8 (4)	18 (4)	
Proximal aortic extension			**0.04**
1 cuff	28 (13)	55 (14)	
2 cuffs	9 (4)	11 (3)	
3 cuffs	7 (3)	2 (1)	
Renal artery covered, %	8 (4)	14 (3)	0.88

	Off IFU	On IFU	*P* value
Intra-op conversion to open, %	9 (4)	6 (2)	**0.04**
Endoleak on completion, %			
Any	47 (22)	65 (16)	0.09
Type 1a	12 (6)	10 (2)	**0.05**
Type 1b	5 (2)	4 (1)	0.19
Type 3	2 (1)	0	**0.05**

Table III.

Crude in-hospital postoperative outcomes for patients presenting with ruptured AAA treated with on-IFU versus off-IFU EVAR

Outcome	Off IFU	On IFU	*P* value
Length of stay, median (25–75%), days	5 (2–9)	5 (3–9)	0.30
ICU stay, median (25–75%), days	2 (1–5)	2 (1–4)	0.81
Post-op pRBC, median (25–75%), units	2 (0–7)	2 (0–5)	**0.001**
Failure to rescue, %			
Any complication, %	113 (52)	184 (46)	0.12
Post-op stroke, %	6 (3)	10 (2)	0.82
Post-op MI, %	18 (8)	33 (8)	0.94
New post-op dysrhythmia, %	23 (11)	42 (10)	0.92
New post-op CHF, %	8 (4)	10 (2)	0.39
Post-op pneumonia, %	9 (4)	13 (3)	0.54
Reintubation, %	26 (12)	50 (12)	0.90
Intestinal ischemia, %	10 (5)	13 (3)	0.38
Post-op renal dysfunction			0.46
Acute kidney injury, %	37 (17)	19 (9)	
New dialysis requirement, %	75 (19)	25 (6)	
Leg embolus, %	5 (2)	12 (3)	0.63
Surgical site infection, %	6 (4)	5 (1)	0.19
Reoperation, %	35 (16)	55 (14)	0.40
Discharge Disposition			
Home, %	108 (50)	225 (56)	0.15
Rehab, %	26 (12)	45 (11)	0.76
Nursing Home, %	29 (13)	60 (15)	0.61
Other hospital, %	7 (3)	15 (4)	0.75
In-hospital mortality	47 (22)	58 (14)	**0.02**

Table IV.

Multivariable logistic regression assessing factors associated with in-hospital mortality for ruptured AAA treated with on-IFU versus off-IFU EVAR, including all factors from Table I identified as significant on backwards stepwise elimination

	Odds Ratio	95% CI	P value
rEVAR			
On IFU	1 (ref)	-	-
Off IFU	1.83	1.06–3.15	**0.03**
Preoperative cardiac arrest	27.10	11.52–63.76	**<0.001**
Congestive heart failure	2.15	1.09–4.24	**0.03**
Infrarenal neck angle, degrees			
<45	1 (ref)	-	-
45–60	1.75	0.98–3.13	**0.06**
Neck diameter, mm	1.06	1.02–1.11	**0.002**
Age, per year	1.02	0.99–1.05	0.18
Lowest pre-intubation systolic blood pressure, mm Hg	0.98	0.97–0.99	**0.001**
Pre-operative hemoglobin, per g/dL	0.90	0.81–1.00	**0.05**

rEVAR, ruptured EVAR.

Harrell's c-statistic = 0.82.

Hosmer-Lemeshow Goodness of Fit = 3.11, $P = 0.93$.

Table V.

Multivariable logistic regression assessing factors associated with in-hospital mortality in coarsened exact matched ruptured AAA patients treated with off-IFU EVAR, complex EVAR, or open repair

	Odds ratio	**95% CI**	***P* value**
Repair			
Off IFU rEVAR	1 (Ref)	-	-
Complex rEVAR	1.03	0.38–2.79	0.96
Infrarenal clamp	1.74	0.80–3.79	0.16
Suprarenal clamp	1.58	0.70–3.54	0.27
Supraceliac clamp	4.81	1.96–11.82	**0.001**
Preoperative cardiac arrest	14.94	4.19–53.27	**<0.001**
Unconscious at presentation	7.84	0.66–93.56	0.10
Congestive heart failure	2.39	1.08–5.29	**0.03**
Age, per year	1.04	1.00–1.08	**0.04**
eGFR, per mL/min/1.73 m^2	0.98	0.96–0.99	**0.002**
Coronary artery disease	0.81	0.40–1.67	0.57
Pre-operative anticoagulation	0.30	0.10–0.91	**0.03**
Hispanic ethnicity (versus non-Hispanic)	0.22	0.04–1.27	0.09

rEVAR, ruptured EVAR.

Harrell's c-statistic = 0.80.

Hosmer-Lemeshow Goodness of Fit = 5.40, $P = 0.71$.