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Publication Date

2023-08-01

DOI

10.1016/j.avsg.2023.02.020

Peer reviewed

Novel Risk Score Calculator for Perioperative Mortality after EVAR with Incorporation of Anatomical Factors

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Background: Hostile proximal aortic neck anatomy has been associated with an increased risk of perioperative mortality after endovascular aneurysm repair (EVAR). However, all available mortality risk prediction models after EVAR lack neck anatomic associations. The aim of this study is to develop a preoperative prediction model for perioperative mortality after EVAR incorporating important anatomic factors.

Methods: Data were obtained from the Vascular Quality Initiative database on all patients who underwent elective EVAR between January 2015 and December 2018. A stepwise multivariable logistic regression analysis was implemented to identify independent predictors and develop a risk calculator for perioperative mortality after EVAR. Internal validation was done using bootstrap of 1,000 reps.

Results: A total of 25,133 patients were included, of whom 1.1% ($N = 271$) died within 30 days or before discharge. Significant preoperative predictors of perioperative mortality were age (odds ratio [OR], 1.053; 95% confidence interval [CI], 1.050–1.056; $P < 0.001$), female sex (OR, 1.46; 95% CI, 1.38–1.54; $P < 0.001$), chronic kidney disease (OR, 1.65; 95% CI, 1.57–1.73; $P < 0.001$), chronic obstructive pulmonary disease (OR, 1.86; 95% CI, 1.77–1.94; $P < 0.001$), congestive heart failure (OR, 2.02; 95% CI, 1.91–2.13, $P < 0.001$), aneurysm diameter $\geq$ 6.5 cm (OR, 2.35; 95% CI, 2.24–2.47, $P < 0.001$), proximal neck length < 10 mm (OR, 1.96; 95% CI, 1.81–2.12; $P < 0.001$), proximal neck diameter $\geq$ 30 mm (OR, 1.41; 95% CI, 1.32–1.5; $P < 0.001$), infrarenal neck angulation $\geq 60^\circ$ (OR, 1.27; 95% CI, 1.18–1.26; $P < 0.001$), and suprarenal neck angulation $\geq 60^\circ$ (OR, 1.26; 95% CI, 1.16–1.37; $P < 0.001$). Significant protective factors included aspirin use (OR, 0.89; 95% CI, 0.85–0.93; $P < 0.001$) and statin intake (OR, 0.77; 95% CI, 0.73–0.81; $P < 0.001$). These predictors were incorporated to build an interactive risk calculator of perioperative mortality after EVAR (C-statistic = 0.749).

Conclusions: This study provides a prediction model for mortality following EVAR that incorporates aortic neck features. The risk calculator can be used to weigh risk/benefit ratio when counseling patients preoperatively. Prospective use of this risk calculator may show its benefit in long-term prediction of adverse outcomes.

Conflicts of interest: The authors declare that they have no conflicts of interest relevant to the content of this manuscript.

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. Poster presentation at the 2020 Society for Clinical Vascular Surgery Annual Meeting (canceled).

Author contributions: A.M., A.A., N.E., G.R., I.N., and M.B.M. contributed to the conceptual framework, methodology, design of the study, interpretation of results, and critical revision. A.M. and I.N. performed the analysis. A.M., A.A., G.R., and N.E. wrote the manuscript.

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Ann Vasc Surg 2023; 94: 289–295
https://doi.org/10.1016/j.avsg.2023.02.020

Manuscript received: July 26, 2022; manuscript accepted: February 22, 2023; published online: 1 March 2023

INTRODUCTION

Early detection and management of intact abdominal aortic aneurysm (iAAA) aims to prevent rupture-related mortality.[1] Over the last decades the prevalence of intact AAA repair has substantially increased.[2,3] This is due to the implementation of national AAA screening programs in many countries.[4,5] Operative management of AAA has significantly changed since the introduction of endovascular abdominal aortic repair (EVAR). The minimally invasive nature of EVAR and its low mortality rates have led to its utilization as the primary mode of operative management and have expanded the scope of AAA patients who can be treated safely with this modality but not with open repair.[6–8]

Several studies including randomized trials have shown lower mortality and morbidity rates with EVAR when compared to open repair.[9–14] Perioperative mortality following EVAR ranges from 1% to 2.5%.[9,15–17] The significant early mortality benefit and the minimally invasive nature of EVAR has led to its widespread to reach 80% of all AAA repairs in the United States.[7,18]

However, up to 43% of patients undergoing repair for intact AAA in the United States have not reached the diameter threshold established by international guidelines.[19] The impact of this practice on aneurysm-related mortality is debated.[20,21] Decision-making regarding the treatment of AAA must consider the ratio between rupture and postoperative mortality risks.[7] For that purpose, multiple mortality risk prediction models have been established, either for patients undergoing EVAR or open AAA repair, yet they all lack proximal neck–specific anatomic factors.[22–26] A suitable proximal neck anatomy is the most critical requirement for a successful EVAR and several reports have identified anatomic factors as independent predictors of perioperative mortality following this minimally invasive procedure.[27–29]

Thus, the aim of this study is to develop a preoperative prediction model and risk calculator for perioperative mortality after EVAR incorporating both patients' demographic and comorbidities and important aneurysm-specific anatomic factors.

METHODS

Study Population and Primary Outcome

We performed a retrospective analysis of all patients in the Vascular Quality Initiative (VQI) database who underwent elective EVAR for intact infrarenal AAA between January 2015 and December 2018. These dates were selected because anatomic factors were incorporated in the VQI database in 2014. Patients with ruptured AAA and those with suprarenal, juxtarenal, or pararenal aneurysms were excluded from the study, whereas patients with symptomatic intact AAA were included. This decision was supported by several reports showing no difference in operative mortality between symptomatic and asymptomatic intact AAA.[30,31] VQI database detail is extensively available and can be accessed at www.vqi.org. This project is covered under an approved VQI Research Advisory Committee proposal. Variables available in the VQI database include demographics, medical comorbidities, and medication use in addition to intraoperative details and postoperative outcomes. As of 2014, data collected also include proximal aortic neck features such as neck length, neck diameter, infrarenal, and suprarenal angulation. Chronic kidney disease was defined as estimated glomerular filtration rate of < 60 mL/min.

The primary outcome was perioperative mortality defined as death occurring within 30 days after surgery or before discharge.

This study was approved by the VQI Research Advisory Committee protocol (ID: 4,927), which provided a deidentified database for the analysis; therefore, the need for institutional review board and informed consent was waived for this study.

Creation of Prediction Model and Internal Validation

Descriptive analysis was performed comparing patients with perioperative death (POD) versus those who survived. These analyses included both demographics and neck anatomical variables. Univariable methods such as X^2 test, Student's *t*-test, or Wilcoxon rank sum test were used as appropriate. Continuous variables were grouped into categories on the basis of their distribution. Variables that were significantly different on univariable analysis and clinically relevant variables were added to a logistic regression model. Stepwise logistic models with backward elimination based on the Akaike information criterion statistic were used to identify the independent predictors of perioperative mortality following EVAR for AAA. Bootstrap of 1,000 repetitions was done to validate the model. The estimated coefficients of the predictive factors obtained from the stepwise logistic regression analysis were used to calculate the risk score using the following equation:

(logit $[\widehat{L}]$) of a patient: $\widehat{L}$ = intercept + ($ß_1$*risk factor 1) + ($ß_2$*risk factor 2) … + ($ß_x$*risk factor x);

Table I. Association between preoperative characteristics and perioperative mortality after EVAR: univariable analysis

Variables	No perioperative death (*N* = 24,862, 98.9%)	Perioperative death (*N* = 271, 1.1%)	*P* value
Age, mean ± SD	73.2 ± 9	77.6 ± 10	<0.001
Female, *N* (%)	4,660 (18.7)	86 (31.7)	<0.001
Black, *N* (%)	1,379 (5.6)	17 (6.3)	0.53
Comorbidities			
CAD, *N* (%)	7,337 (29.6)	116 (43.3)	<0.001
Smoking, *N* (%)	21,580 (86.9)	215 (79.9)	0.001
COPD, *N* (%)	8,451 (34.1)	127 (47.21)	<0.001
HTN, *N* (%)	20,595 (83)	244 (90.7)	<0.001
Diabetes, *N* (%)	5,076 (20.5)	59 (21.9)	0.55
CKD, *N* (%)	8,158 (33.4)	135 (52.9)	<0.001
CHF, *N* (%)	3,164 (12.8)	68 (25.4)	<0.001
Medications			
Aspirin, *N* (%)	16,133 (65)	161 (59.9)	0.07
Beta-Blockers, *N* (%)	13,041 (52.6)	165 (61.3)	0.004
Statin, *N* (%)	17,507 (70.6)	183 (68.3)	0.4
Anatomic Factors			
AAA Ø (mm), mean ± SD	55.9 ± 13.7	61.6 ± 15.8	<0.001
Neck Length (mm), mean ± SD	26.2 ± 13	23.8 ± 12	0.02
Neck Diameter (mm), mean ± SD	23.8 ± 5.1	24.9 ± 5.6	0.77
Infrarenal angle ≥60, *N* (%)	887 (6.4)	18 (12.8)	0.002
Suprarenal angle ≥60 *N* (%)	543 (3.8)	11 (7.8)	0.016

CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; HTN, hypertension; DM, diabetes mellitus; CKD, chronic kidney disease; CHF, congestive heart failure; AAA, aortic abdominal aneurysm; Ø, diameter.

where $_{ßx}$ represents the regression coefficients of the respective risk factor obtained from the multivariable model.

The estimated probability percentage of perioperative mortality of a patient was then computed as follows:

Estimated probability of perioperative mortality(%) $= \frac{100*e\hat{L}}{1+e\hat{L}}$

The model was evaluated for predictive ability using the area under the receiver operating characteristic curve. Analysis was carried out using the STATA software version 16.1 (StataCorp, College Station, Texas). The significance level was set at $P < 0.05$.

RESULTS

A total of 25,133 patients underwent EVAR for infrarenal intact AAA between January 2015 and December 2018. Perioperative mortality rate in this group was 1.1% which occurred in 271 of the cohort. Perioperative mortality was more prevalent among older (mean age: 78 ± 10 vs. 73 ± 9, $P <$ 0.001) and female (31.7% vs. 18.7%, $P < 0.001$) patients. Postoperative mortality was also more common among patients with certain comorbidities such as hypertension (90.7% vs. 83%, $P < 0.001$), coronary artery disease (43.3% vs. 29.6%, $P <$ 0.001), chronic obstructive pulmonary disease (COPD) (47.2% vs. 34.1%, $P < 0.001$), and chronic kidney disease (CKD) (52.9% vs. 33.4%, $P < 0.001$) (Table I).

Anatomic features studied were more commonly observed among patients who suffered from POD and are summarized in Table I. These anatomical features included larger aneurysm diameter (6.2 ± 1.6 cm vs. 5.6 ± 1.4 cm, $P < 0.001$), significantly shorter proximal aortic neck (23.8 ± 12 vs. 26.2 ± 13, $P = 0.02$), severe (≥ 60°) infrarenal neck angulation (12.8% vs. 6.4%, $P = 0.002$), and a severe suprarenal neck angulation (7.8% vs. 3.8%, $P = 0.016$). A complete comparison of baseline characteristics between the 2 groups is outlined in Table I.

Risk Model

All statistically significant variables on the univariable analysis were included in the initial logistic regression model. Using methodology outlined previously, the variables retained in the final risk predictive model of POD included age (odds ratio [OR], 1.053; 95% confidence interval [CI],

Table II. Risk factors of perioperative mortality in patients undergoing EVAR using stepwise logistic models with backward elimination method

Variable	Beta coefficient[a]	OR	95% CI	*P* value
Age	0.052	1.053	1.050−1.056	<0.001
Female sex	0.38	1.46	1.38−1.54	<0.001
COPD	0.62	1.86	1.77−1.94	<0.001
CHF	0.7	2.02	1.91−2.13	<0.001
CKD	0.5	1.65	1.57−1.73	<0.001
Aspirin	−0.11	0.89	0.85−0.93	<0.001
Statin	−0.25	0.77	0.73−0.81	<0.001
AAA Ø ≥ 65 mm	0.85	2.35	2.24−2.47	<0.001
Neck length < 10 mm	0.67	1.96	1.81−2.12	<0.001
Neck Ø ≥ 30 mm	0.34	1.41	1.32−1.5	<0.001
β angle ≥ 60	0.24	1.27	1.18−1.26	<0.001
α angle ≥ 60	0.23	1.26	1.16−1.37	<0.001
Constant	−9.68			

CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; AAA, aortic abdominal aneurysm; Ø, diameter; β angle, infrarenal angulation; α angle, suprarenal angulation.

$\widehat{L}$ =− 9.68 + 0.052 × Age +0.38 × female +0.62 × COPD +0.7 × CHF +0.5 × CKD − 0.11 × Aspirin − 0.25 × Statin +0.85*(AAAØ ≥ 6.5 cm) + 0.67*(Neck length < 10 mm) + 0.34*(Neck Ø ≥ 30 mm) + 0.24*(β angle ≥ 60) + 0.23*(α angle ≥ 60).

[a]Based on the model, a preoperative risk score ($\widehat{L}$) is calculated using the formula.

1.050−1.056; $P < 0.001$), female sex (OR, 1.46; 95% CI, 1.38−1.54; $P < 0.001$), CKD (OR, 1.65; 95% CI, 1.57−1.73; $P < 0.001$), COPD (OR, 1.86; 95% CI, 1.77−1.94; $P < 0.001$), CHF (OR, 2.02; 95% CI, 1.91−2.13, $P < 0.001$), aspirin use (OR, 0.89; 95% CI, 0.85−0.93; $P < 0.001$), statin intake (OR, 0.77; 95% CI, 0.73−0.81; $P < 0.001$), aneurysm diameter ≥ 6.5 cm (OR, 2.35; 95% CI, 2.24−2.47, $P < 0.001$), proximal neck length < 10 mm (OR, 1.96; 95% CI, 1.81−2.12; $P < 0.001$), proximal neck diameter ≥ 30 mm (OR, 1.41; 95% CI, 1.32−1.5; $P < 0.001$), infrarenal neck angulation ≥ 60° (OR, 1.27; 95% CI, 1.18−1.26; $P < 0.001$), and suprarenal neck angulation ≥ 60° (OR, 1.26; 95% CI, 1.16−1.37; $P < 0.001$) (Table II).

These variables were used to calculate the risk score ($\widehat{L}$) as per the following equation:

$\widehat{L}$ =−9.68 + 0.052 × Age + 0.38 × female + 0.62 × COPD + 0.7 × CHF + 0.5 × CKD − 0.11 × Aspirin − 0.25 × Statin +0.85*(AAAØ ≥6.5 cm) + 0.67*(Neck length < 10 mm) + 0.34*(Neck Ø ≥ 30 mm) + 0.24*(β angle ≥ 60) + 0.23*(α angle ≥ 60).

The interactive risk calculator takes in values of 0 or 1 for absence or presence for categorical predictors and values for continuous variables. Once all required input is entered, the risk calculator returns a percentage estimate of perioperative mortality in patients undergoing EVAR for iAAA. Table III demonstrates the risk calculations for two-sample EVAR candidates.

The C-statistic for the predictive probabilities was 0.749 within the derivation cohort (Fig. 1).

DISCUSSION

In this study, we analyzed a comprehensive VQI dataset with patients who underwent EVAR for intact AAA to develop a preoperative risk prediction model for perioperative mortality that includes anatomic factors.

In the past few decades, multiple investigators have tried to set prediction models for patients undergoing either open or endovascular repair of AAA, yet they all had some limitations. The Vascular-Physiological and Operative Severity Score for Enumeration of Mortality and morbidity was built up on patients undergoing different arterial interventions.[32] Its main limitation was that it included both elective and emergency AAA repairs. The very different mortality rates between elective and emergency repair would dominate any such model. The Glasgow aneurysm score was legitimized for open aneurysm repair but not for EVAR.[33,34] Most contemporary models include both open and endovascular repair.[22,25,35,36] However, the adoption of EVAR as the first approach for treating iAAA has significantly increased in the past decade[19] highlighting the need for a model that specifically predicts adverse outcomes among patients undergoing EVAR.

In our model, aneurysm diameter ≥ 6.5 cm was associated with a 2.4-fold increase in perioperative mortality. In their Investigational Device Exemption trial, Zarins et al. found that patients with larger aneurysms have shorter life expectancy and a higher risk of post EVAR rupture and aneurysm-

Table III. Risk estimates of perioperative mortality in two-sample octogenarian patients using the risk calculator

Variables	Patient A[a]	Patient B[b]
Age	70	75
Female sex	0	1
COPD	0	1
CHF	0	1
CKD	1	0
Aspirin	1	1
Statin	1	0
AAA Ø ≥ 65 mm	0	0
Neck length < 10 mm	0	1
Neck Ø ≥ 30 mm	0	1
β angle ≥ 60	0	1
α angle ≥ 60	0	0
Risk score	−5.9	−2.94
Predicted risk, %	0.3%	5%

Based on the predictive model, the authors suggest performing EVAR on the first patient and managing the second patient conservatively.

[a]Example 1: A 70-year-old male presented with a 5.5 cm AAA. He has CKD and he is taking aspirin and statin. CTA showed an aortic neck length of 18 mm, an aortic neck diameter of 25 mm, an infrarenal angle of 30°, and a suprarenal angle of 20°.

[b]Example 2: A 75-year-old female presented with a 5 cm AAA. She has COPD and CHF. She is taking aspirin but no statin. CTA showed an aortic neck length of 7 mm, an aortic neck diameter of 33 mm, and an infrarenal angle of 75°.

related death following EVAR.[37] Similarly, Peppelenbosch et al. identified aneurysm size as an independent predictor of early mortality following EVAR.[38] The unique feature of this present study is inclusion of many neck anatomical features previously missing. Our model confirmed multiple aortic neck features that were associated with a higher risk of perioperative death including short or large proximal neck and severe suprarenal or infrarenal angulation.

Most manufacturers' instructions for use recommend EVAR in patients with proximal neck length ≥ 10 mm, neck diameter ≤ 32 mm, and a β and an α angle ≤60°. Off-label use of EVAR has been associated with increased aneurysm-related complications.[36] Consistently, a study including 3,500 patients from the EUROSTAR registry showed a 77% increase in 30-day mortality among patients with shorter proximal aortic necks.[39] Interestingly, Ouriel et al.[40] found an inter-relationship between key anatomic factors. For instance, as aneurysm sac length increased, proximal aortic neck length decreased. Furthermore, Aburahma et al.,[41] in a study of 526 patients, showed that short aortic neck increased the risk of death by 3 folds, while severe neck angulation increased it by 6 folds.

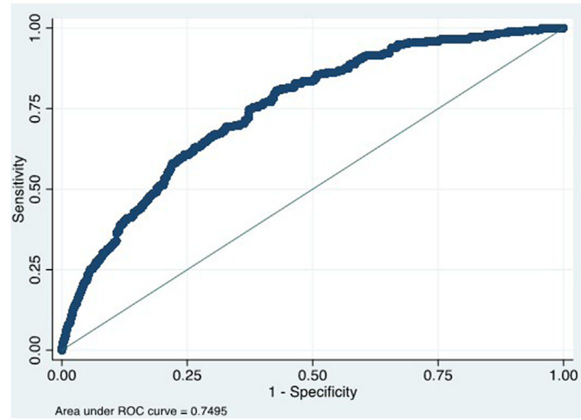

Fig. 1. Receiver operating characteristic curve of the multivariable logistic model used in constructing the risk calculator.

Similarly, our group investigated the impact of suprarenal neck angulation on EVAR outcomes and found significantly higher perioperative mortality among patients with severe α angulation.[29]

Our study has several strengths and shortcomings. First, this is an easy-to-use interactive risk model derived from real-world data, inclusive of most important anatomical factors, and it can serve as a useful tool for risk stratification and patient selection. An easy application can help surgeons make use of this prediction model in the decision-making and opt for a conservative approach if the risk of death overweighs the risk of aneurysm rupture. Furthermore, our model's area under the curve is 0.75, which is above to the recommended C statistic of 0.70 and is thus considered fit for clinical use.[42]

However, our model is limited by the lack of external validation, potential for coding errors, and all of the inherent biases of a retrospective analysis. Another limitation is that it includes only the preoperative variables available in the dataset. There may be other variables that could potentially affect outcomes but which were not collected routinely. Nonetheless, we attach weight to the importance of its clinical implications in view of the paucity of literature on that matter.

CONCLUSION

In this study, we report a perioperative mortality prediction model for elective EVAR that incorporates aortic neck anatomic factors. The risk calculator can be used to weigh risk/benefit ratio when counseling patients preoperatively. Identifying patients with a high risk of perioperative mortality might guide toward either open repair or conservative management and follow-up depending on their risk of rupture and symptomatic status. External validation of this model is a next step to assess its clinical usefulness in other populations of patients.

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