Predictors of bleeding or anemia requiring transfusion in complex endovascular aortic repair and its impact on outcomes in health insurance claims

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ABSTRACT

Objective: This study aimed to determine predictors and outcomes associated with bleeding or anemia requiring transfusion (BAT) after fenestrated or branched endovascular aneurysm repair (FB-EVAR).

Methods: Health insurance claims data of Germany's third largest insurance provider, DAK-Gesundheit, were used to investigate BAT in elective FB-EVAR performed between 2008 and 2017. *International Classification of Diseases* and German *Operations and Procedure Key* codes were used.

Results: A total of 959 patients (24.8% with BAT) matching the inclusion criteria were identified during the study period. Compared with patients without BAT, patients with BAT were older (74.4 vs 73.0 years; $P = .015$) and suffered more frequently from congestive heart failure (18.5% vs 9.4%), cardiac arrhythmias (26.9% vs 14.7%), and hereditary or acquired coagulopathy (31.9% vs 6.2%; all $P < .001$). Coagulopathy (odds ratio [OR], 3.65; 95% confidence interval [CI], 2.29-5.84), female sex (OR, 2.67; 95% CI, 1.78-4.00), and multiple comorbidities (OR, 1.10; 95% CI, 1.07-1.14) were independent predictors of BAT (all $P < .001$). BAT was associated with higher in-hospital (11.3% vs 2.6%), 30-day (12.2% vs 3.1%), and 90-day (18.5% vs 4.4%) mortality (all $P < .001$). Furthermore, myocardial infarction (23.9% vs 2.8%) and paraplegia (9.7% vs 0.7%) were more frequent in the BAT group (all $P < .001$). In multivariable analyses, BAT was associated with worse short-term (OR, 3.19; 95% CI, 1.63-6.33; $P = .001$) and long-term survival (hazard ratio, 1.62; 95% CI, 1.24-2.11; $P < .001$).

Conclusions: Patients with hereditary or acquired coagulopathy, patients with multiple comorbidities, and women are at higher risk for development of BAT after FB-EVAR. The occurrence of this event was strongly associated with higher major complication rates and worse short-term and long-term survival. This emphasizes a need to further illuminate the value of patient blood management in FB-EVAR. (J Vasc Surg 2020;71:382-9.)

Keywords: Aortic repair; Patient blood management; Health services research; Health insurance claims data; Outcomes research

During the last decade, endovascular aneurysm repair (EVAR) became the standard of care for abdominal aortic aneurysms (AAAs),[1] thoracic aortic aneurysms, and thoracoabdominal aortic aneurysms (TAAAs) and dissections.[2] Complex aortic repair with fenestrated or branched stent grafts has particular challenges and requirements and is therefore performed in comparatively few experienced vascular centers. Besides major health events such as mortality and myocardial infarction after fenestrated or branched EVAR (FB-EVAR), more outcomes, such as major bleeding and transfusions with a possible impact on survival, deserve further reflection.

Patient blood management (PBM) aims to identify risk factors for and prevention strategies to avoid perioperative anemia and blood transfusions to reduce costs[3] and to improve outcomes in elective surgery.[4] Whereas PBM has gained significant scientific interest in other surgical specialties,[5,6] publications in vascular surgery and aortic interventions are scarce and limited to standard EVAR.[7] Furthermore, the heterogeneity of definitions for bleeding complications in available single-center studies on FB-EVAR limits comparability and emphasizes the need to use standardized bleeding definitions in clinical trials.[8] Hence, there is a wide sex-related variation of bleeding complications between 0% and 42%.[9-11] Rieß et al[12] recently reported remarkably high transfusion rates of 22% in men and nearly 39% in women during FB-EVAR using multicenter health insurance claims data from Germany. The aim of this study was

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This work was supported by the German Stifterverband and the CORONA foundation (S199/10061/2015).

Author conflict of interest: T.K. received travel and research grants, speaking fees, intellectual property, royalties, and proctoring from Cook Medical. He is a consultant with Philips and a shareholder of Mokita Medical GmbH.

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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.2019.02.059

to develop a reliable model for predicting bleeding or anemia requiring transfusion (BAT) in patients undergoing FB-EVAR. A secondary aim was to illuminate the association of BAT with short-term and long-term outcomes after FB-EVAR. We used large-scale health insurance claims data of Germany's third largest insurance provider, DAK-Gesundheit, for this study.

METHODS

The health insurance claims data of Germany's third largest insurance provider, DAK-Gesundheit, include the outpatient and in-hospital medical care provided to approximately 6.5 million German citizens (8% of German inhabitants). In Germany (data for 2017), approximately 72 million inhabitants are insured by statutory health insurance; another 10.5 million inhabitants are insured by other types of insurance (eg, private health insurance). DAK-Gesundheit data have been widely used for health services research studies.[12,13] The advantages and disadvantages of this data source and its generalizability to the German population have been explained in another publication.[14] In addition, the health insurance funds in Germany charge the Medical Service of the Health Funds to perform a random and risk-based validation of data.

Inclusion criteria. All statutory health-insured patients with at least one hospital stay between January 2008 and December 2017 for nonruptured thoracic aortic aneurysm, TAAA, AAA, or aortic dissection by *International Classification of Diseases, Tenth Revision* (ICD-10) codes (I71.2, I71.4, I71.6, and I71.9 for aneurysm and I71.00, I71.01, I71.02, I71.03 for dissection) and *Operations and Procedure Key* (OPS) codes for FB-EVAR of the thoracoabdominal or abdominal aorta (5-38a*, 8-842*) were investigated (Fig 1).

Exclusion criteria. Ruptured aneurysms or dissections have been excluded from this study. The German OPS code is adapted to the *International Classification of Procedures in Medicine*. For the identified cases that matched the basic search criteria, we collected data on demographics, primary and secondary procedures done in the hospital (OPS codes), coded comorbidities (ICD-10 codes), and discharge destination. For the long-term survival analyses, we censored patients whose insurance contract expired within the follow-up period. The data set for this study was stratified into relevant subgroups (whether BAT was coded or not). The first repair procedure was included as the primary case (no reintervention cases during the study period were included).

Health insurance claims data consist of standardized information used for reimbursement or administration of medical care performed by health care providers using the ICD-9 or ICD-10 codes for comorbidities. In 1998, Elixhauser et al[15,16] introduced a systematic classification to identify relevant comorbidities among primary or secondary diagnoses at the time of discharge. Major comorbidities, such as congestive heart failure, cardiac arrhythmias, chronic pulmonary disease, diabetes, and chronic renal failure, were categorized in 30 commonly accepted groups. van Walraven et al[17] used the Elixhauser classification and developed a linear sum score ranging from −7 points (for drug abuse) to +12 points (for metastatic cancer) to adjust multivariable models that estimate odds for in-hospital survival using a single metric covariate.

Coagulopathy (also commonly known as bleeding disorder) was stated if any hereditary (eg, von Willebrand disease) or acquired (eg, vitamin K deficiency or intake of anticoagulants) condition is affecting the blood's ability to coagulate.

BAT was stated if any bleeding complication or bleeding anemia (ICD-10 codes D62, T79.2, R57.1, and R58) was coded together with a blood transfusion (OPS 8-800*).

Statistical analysis. Statistical analyses and data reporting are in accordance with the statistical and data reporting guidelines of the *European Journal of Cardiothoracic Surgery* and *Interactive Cardiovascular and Thoracic Surgery*.[18] Tests of normality were conducted using the Kolmogorov-Smirnov test. The tests for categorical variables were χ^2 test and two-way *t*-test for continuous variables. For non-normally distributed data, a Kruskal-Wallis test was performed. Relative risks including 95% confidence intervals (CIs) were additionally calculated for categorical outcomes. Bivariate analyses were conducted to investigate the association of BAT with in-hospital and long-time survival. A predictive model was developed for the entire cohort including covariates from bivariate differences (Table I). Multivariable regression models were used to determine the independent association of BAT with in-hospital and

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter retrospective nonrandomized cohort study
- **Key Findings:** Among 959 patients with complex endovascular aortic repair, 25% exhibited bleeding or anemia requiring transfusion (BAT). Female sex, multiple comorbidities, and any hereditary or acquired coagulopathy are independent predictors of BAT. BAT was associated with significantly higher morbidity and mortality.
- **Take Home Message:** The results of our study emphasize the importance of a feasible and suitable patient blood management for patients being treated with complex endovascular aortic repair.

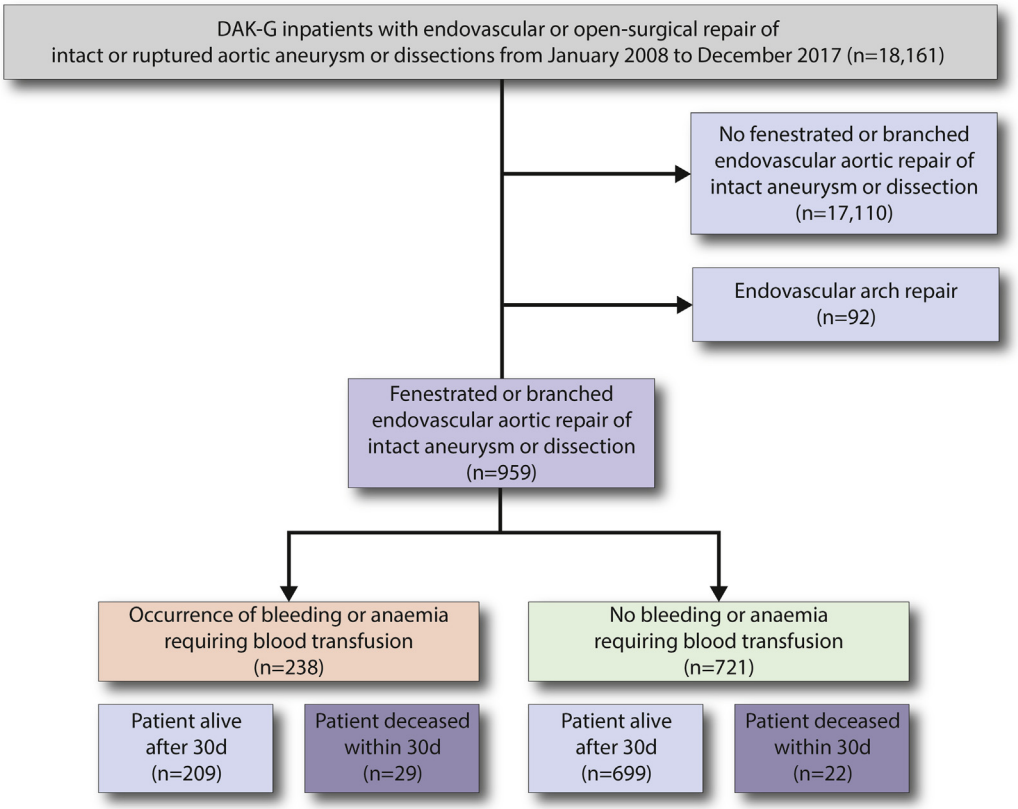

Fig 1. Flow chart: 959 patients with fenestrated or branched endovascular aneurysm repair (FB-EVAR) were identified during the study period (2008-2017).

long-term survival using a logistic and Cox regression approach. The models included older age, female sex, and higher van Walraven comorbidity score. Kaplan-Meier survival curves were used to determine long-term survival and a log-rank test was used. Patients with unknown mortality were censored. Sensitivity analyses using the landmark approach were used to calculate survival, conditional on surviving the procedure (30 days). Statistical significance was defined as P value <.05. No adjustment for multiple testing was performed. All statistical analyses were performed with software R version 3.3.2 (The R Foundation for Statistical Computing, Vienna, Austria).

Ethical considerations. This study complies with the Declaration of Helsinki. For a retrospective analysis of anonymized health insurance claims data, no local ethic committee approval was required, and no patient informed consent was obtained for the study.

RESULTS

A total of 959 patients (796 [83%] male and 163 [17%] female) underwent FB-EVAR between January 2008 and December 2017 (Fig 1). Preoperative anemia was documented in six (0.6%) of the patients. BAT occurred in 238 (24.8%) patients. All BAT occurred during the operation (100%) and during the following hospital stay (90.3%). Of those 238 patients, 63 (26.5%) were female and 175 (73.5%) were male. Baseline characteristics and coexisting conditions are shown in Table I. Patients' mean age (74.4 vs 73.0 years; $P < .001$) and mean van Walraven comorbidity score (11.3 vs 5.3; $P < .001$) were significantly higher in the BAT group. Among patients in the BAT group, a higher proportion of congestive heart failure, cardiac arrhythmia, coagulopathy, and renal and liver diseases was present compared with patients without BAT (Table I).

Perioperative outcomes of the study patients are shown in Table II. A total of 51 (5.3%) deaths occurred after 30 days, 76 (7.9%) deaths occurred after 90 days, and a total of 267 (27.8%) deaths occurred among the entire cohort during the study period (result not shown in table). Higher in-hospital mortality (11.3% vs 2.6%; $P < .001$), 30-day mortality (12.2% vs 3.1%; $P < .001$), and 90-day mortality (18.5% vs 4.4%; $P < .001$) were shown in the BAT group compared with patients without BAT. Furthermore, the rate of major perioperative morbidity, such as acute respiratory and renal failure, acute myocardial infarction, stroke or transient ischemic attack, and colonic and peripheral ischemia, was significantly higher in the BAT group compared with the non-BAT group. A higher rate of paraplegia was found in the BAT group

Table I. Baseline characteristics and Elixhauser coding groups of the study patients

	FB-EVAR		
	BAT: Yes	BAT: No	*P* value
No. of patients	238	721	
Age, years, mean (SD)	74.44 (7.49)	73.00 (7.94)	**.015**
Female sex	63 (26.5)	100 (13.9)	**<.001**
van Walraven comorbidity score, mean (SD)	11.34 (7.49)	5.29 (6.00)	**<.001**
Congestive heart failure	44 (18.5)	68 (9.4)	**<.001**
Cardiac arrhythmias	64 (26.9)	106 (14.7)	**<.001**
Valvular disease	19 (8.0)	42 (5.8)	.303
Pulmonary circulation disorders	5 (2.1)	4 (0.6)	.079
Peripheral vascular disorders	229 (96.2)	533 (73.9)	**<.001**
Hypertension	170 (71.4)	423 (58.7)	**.001**
Chronic pulmonary disease	43 (18.1)	89 (12.3)	**.035**
Diabetes, uncomplicated	31 (13.0)	70 (9.7)	.186
Diabetes, complicated	11 (4.6)	24 (3.3)	.470
Renal failure (all stages)	96 (40.3)	161 (22.3)	**<.001**
Liver disease	10 (4.2)	4 (0.6)	**<.001**
Peptic ulcer disease excluding bleeding	1 (0.4)	0 (0.0)	.560
Lymphoma	3 (1.3)	3 (0.4)	.338
Metastatic cancer	0 (0.0)	2 (0.3)	1.000
Solid tumor without metastasis	6 (2.5)	19 (2.6)	1.000
Rheumatoid arthritis or collagen vascular disease	2 (0.8)	7 (1.0)	1.000
Coagulopathy	76 (31.9)	45 (6.2)	**<.001**
Obesity	24 (10.1)	71 (9.8)	1.000
Weight loss	7 (2.9)	2 (0.3)	**.001**
Fluid and electrolyte disorders	98 (41.2)	109 (15.1)	**<.001**
Blood loss anemia	1 (0.4)	1 (0.1)	.995
Deficiency anemia	1 (0.4)	3 (0.4)	1.000
Alcohol abuse	1 (0.4)	1 (0.1)	.995
Drug abuse	8 (3.4)	5 (0.7)	**.006**

BAT, Bleeding and anemia requiring transfusion; *FB-EVAR,* fenestrated or branched endovascular aneurysm repair; *SD,* standard deviation.
Values are reported in total numbers (%) unless otherwise indicated. Significant *P* values are marked in bold.

(9.7% vs 0.7%; $P < .001$). Regarding the discharge of patients, a longer hospital stay and higher rates of transfer to other hospitals or nursing homes were found in the BAT group. In long-term follow-up, BAT patients required significantly more aneurysm-related reoperations compared with their non-BAT counterparts (90.8% vs 69.9%; $P < .001$; Table II).

Predictors of the occurrence of BAT. Independent predictors of BAT after FB-EVAR in the entire cohort are listed in Table III. In adjusted analysis, female sex (odds ratio [OR], 2.672; 95% CI, 1.780-3.999; $P < .001$), higher van Walraven comorbidity score (OR, 1.104; 95% CI, 1.071-1.139; $P < .001$), and hereditary or acquired coagulopathy (OR, 3.647; 95% CI, 2.288-5.844; $P < .001$) were associated with higher odds of BAT. Older age (increase by 1 year) of the patients and renal failure did not add significantly to the model.

Association of BAT with in-hospital mortality (regression models for entire cohort). Results of the multivariable logistic regression for in-hospital mortality are shown in Table IV. Older age (increase by 1 year) of the patients (OR, 1.056; 95% CI, 1.012-1.104; $P = .015$), female sex (OR, 2.613; 95% CI, 1.335-4.976; $P = .004$), and BAT (OR, 3.194; 95% CI, 1.633-6.325; $P = .001$) were associated with higher odds of in-hospital mortality. No significant impact was found for a higher van Walraven comorbidity score.

Association of BAT with long-term survival (regression models for entire cohort). Ten patients were censored because of the expiration of their health insurance contract, and the mean follow-up duration was 2.6 years. Kaplan-Meier survival curves are shown in Fig 2 (entire cohort). Results of adjusted analysis using the Cox proportional hazards model for the entire cohort are shown

Table II. Perioperative outcomes after fenestrated or branched endovascular aneurysm repair (FB-EVAR)

	BAT: Yes	BAT: No	*P* value	Relative risk (95% CI)
No. of patients	238	721		
In-hospital mortality	27 (11.3)	19 (2.6)	**<.001**	4.30 (2.44-7.60)
30-Day mortality	29 (12.2)	22 (3.1)	**<.001**	3.99 (2.34-6.81)
90-Day mortality	44 (18.5)	32 (4.4)	**<.001**	4.17 (2.71-6.41)
Acute respiratory insufficiency	66 (27.7)	30 (4.2)	**<.001**	6.66 (4.44-10.00)
Acute renal failure	57 (23.9)	20 (2.8)	**<.001**	8.63 (5.30-14.06)
Acute myocardial infarction	16 (6.7)	7 (1.0)	**<.001**	6.92 (2.88-16.63)
Stroke or TIA	7 (2.9)	4 (0.6)	**.008**	5.30 (1.57-17.95)
Paraplegia	23 (9.7)	5 (0.7)	**<.001**	13.94 (5.36-36.25)
Pneumonia	26 (10.9)	10 (1.4)	**<.001**	7.88 (3.86-16.09)
Colonic ischemia	13 (5.5)	3 (0.4)	**<.001**	13.33 (3.77-45.67)
Acute limb ischemia	23 (9.7)	15 (2.1)	**<.001**	4.65 (2.46-8.75)
Lower extremity amputation	3 (1.3)	0 (0.0)	**.019**	–
Sepsis or SIRS	16 (6.7)	1 (0.1)	**<.001**	48.47 (6.46-363.55)
Gastric ulcer	6 (2.5)	5 (0.7)	.052	3.64 (1.12-11.80)
Transfer to another hospital	26 (10.9)	9 (1.2)	**<.001**	8.75 (4.16-18.41)
Discharged to rehabilitation or nursing facility	23 (9.7)	7 (1.0)	**<.001**	9.95 (4.33-22.90)
Length of total hospital stay, days, median (IQR)	16.00 (10.00-27.00)	9.00 (7.00, 14.00)	**<.001**	–
Postoperative hospital stay, days, median (IQR)	13.00 (7.00-22.00)	7.00 (5.00, 10.00)	**<.001**	–
Aneurysm-related hospital readmissions	238 (100.0)	721 (100.0)	1.000	–
Aneurysm-related reoperations	216 (90.8)	504 (69.9)	**<.001**	1.30 (1.22-1.38)

BAT, Bleeding and anemia requiring transfusion; *CI,* confidence interval; *IQR,* interquartile range; *SIRS,* systemic inflammatory response syndrome; *TIA,* transient ischemic attack.
Values are reported in total numbers (%) unless otherwise indicated. Significant *P* values are marked in bold.

Table III. Independent predictors for the occurrence of bleeding or anemia requiring transfusion (BAT)

	FB-EVAR		
	OR	95% CI	*P* value
Older age of the patient (increase by 1 year)	1.008	0.987-1.030	.460
Female sex (vs male)	2.672	1.780-3.999	**<.001**
van Walraven comorbidity score (increase by 1 point)	1.104	1.071-1.139	**<.001**
Coagulopathy	3.647	2.288-5.844	**<.001**
Renal failure	1.129	0.741-1.712	.570

CI, Confidence interval; *FB-EVAR,* fenestrated or branched endovascular aneurysm repair; *OR,* odds ratio.
Significant *P* values are marked in bold.

in Table V. Older age (increase by 1 year) of the patients (hazard ratio [HR], 1.045; 95% CI, 1.028-1.062; $P < .001$), higher van Walraven comorbidity score (HR, 1.039; 95% CI, 1.022-1.056; $P < .001$), and BAT (HR, 1.615; 95% CI, 1.240-2.104; $P < .001$) were associated with shorter long-term survival. No significant impact of female sex was found.

Additional analyses of survival conditional on surviving the procedure. Sensitivity analyses estimated the association of BAT with survival beyond discharge (patients who survived at least the first 30 days after the procedure; Fig 3). Older age of the patients (HR, 1.048; 95% CI, 1.029-1.067; $P < .001$), higher van Walraven comorbidity score (HR, 1.036; 95% CI, 1.017-1.055; $P < .001$), and BAT (HR, 1.403; 95% CI, 1.037-1.898; $P = .028$) added significantly to the model, whereas female sex showed no significant impact on long-term survival (HR, 1.237; 95% CI, 0.874-1.750; $P = .231$; results not shown in the table).

DISCUSSION

BAT during complex aortic repair is a frequent complication in 25% of patients. Female sex, higher van Walraven comorbidity score, and any hereditary or acquired coagulopathy are independent predictors of this complication. BAT was associated with significantly higher morbidity and mortality, emphasizing the importance of a valid PBM in complex endovascular aortic repair.

Few studies on elective major vascular surgery report similarly high postoperative transfusion rates.[8,19] Evidence is strong that bleeding or transfusion is associated with worse outcomes after percutaneous coronary intervention,[20] cardiac surgery,[21,22] and major vascular surgery.[8,19]

In a large multicenter quality improvement registry covering some 3000 patients from 22 hospitals in the United States, Obi et al[7] revealed an increased 30-day morbidity and mortality in patients with transfusions after open peripheral artery disease procedures or any

Table IV. Logistic regression results for in-hospital mortality for fenestrated or branched endovascular aneurysm repair (*FB-EVAR*) by different risk factors

	FB-EVAR		
	OR	95% CI	*P* value
Older age of the patient (increase by 1 year)	1.056	1.012-1.104	**.015**
Female sex (vs male)	2.613	1.335-4.976	**.004**
van Walraven comorbidity score (increase by 1 point)	1.034	0.992-1.077	.105
Occurrence of BAT	3.194	1.633-6.325	**.001**

BAT, Bleeding or anemia requiring transfusion; *CI,* confidence interval; *OR,* odds ratio.
Significant *P* values are marked in bold.

Table V. Cox regression (entire cohort) results for long-term mortality for fenestrated or branched endovascular aneurysm repair (*FB-EVAR*) by different risk factors

	FB-EVAR		
	HR	95% CI	*P* value
Older age of the patient (increase by 1 year)	1.05	1.03-1.06	**<.001**
Female sex (vs male)	1.37	1.01-1.84	.041
van Walraven comorbidity score (increase by 1 point)	1.04	1.02-1.06	**<.001**
Occurrence of BAT	1.62	1.24-2.11	**<.001**

BAT, Bleeding or anemia requiring transfusion; *CI,* confidence interval; *HR,* hazard ratio.
Significant *P* values are marked in bold.

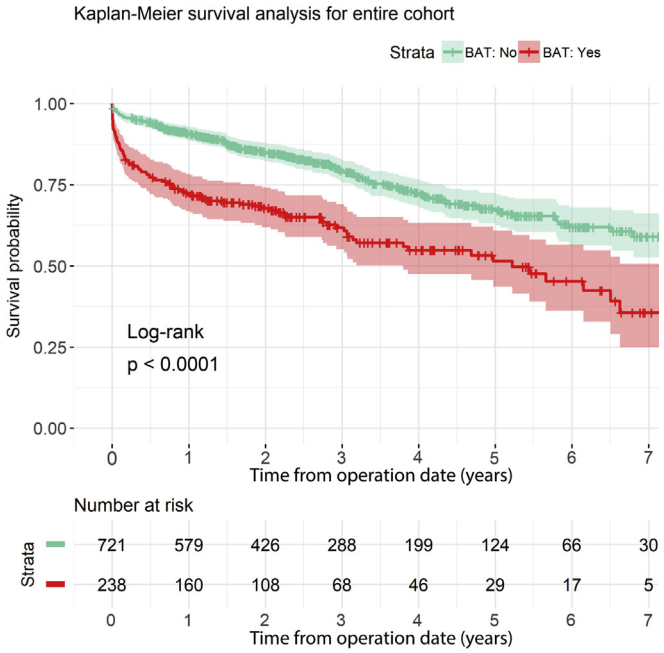

Fig 2. Kaplan-Meier survival analysis for the entire cohort. The *light green* and *light red* areas mark the standard deviation. *P* value was calculated using the log-rank test. *BAT,* Bleeding or anemia requiring transfusion.

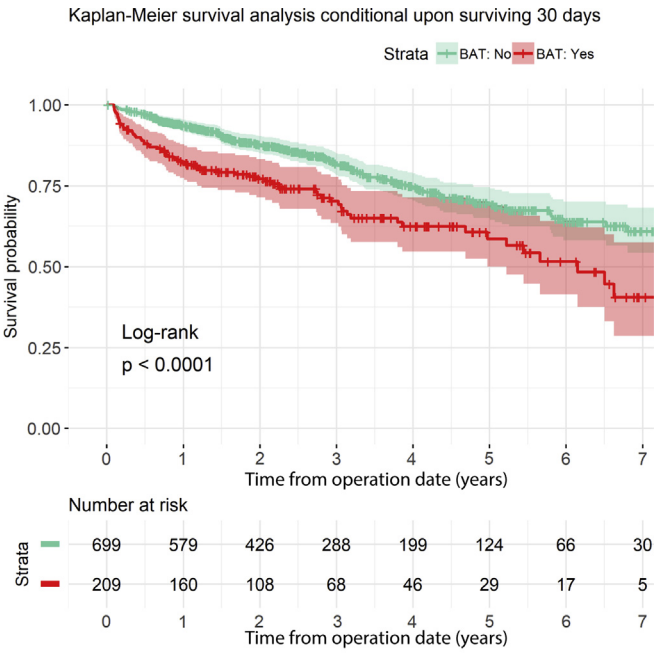

Fig 3. Kaplan-Meier survival analysis conditional on surviving the first 30 days (landmark analysis). The *light green* and *light red* areas mark the standard deviation. *P* value was calculated using the log-rank test. *BAT,* Bleeding or anemia requiring transfusion.

open or endovascular AAA repair. Furthermore, the authors found female sex to be independently associated with the occurrence of transfusions and underlined the need for prospective transfusion threshold studies in vascular surgery patients. In accordance with the findings by Rieß et al,[12] this study could confirm a strong independent predictive value of female sex on the likelihood that BAT will occur. This sex difference is not completely new. In a large multicenter study enrolling 6530 patients with elective cardiac surgery, hip replacement surgery, and knee replacement surgery, Gombotz et al[23] found higher transfusion rates and volume in women compared with men. The authors concluded that clinicians tend to apply the same absolute transfusion thresholds for both sexes, leading to overtransfusion in female patients. Our data including FB-EVAR add to the knowledge base and confirm the association between transfusion rates and worse outcomes.

Smaller iliac access vessels in female patients may account for a higher frequency of substantial blood loss during FB-EVAR. Bilateral large-bore access is required for the fenestrated main bodies and for a contralateral 20F to 24F large sheath to carry the sheaths for the target vessels. Another limitation of FB-EVAR in female patients due to smaller access vessels appears to be rotational control.[24]

Besides remarkably higher rates of respiratory, renal, and cardiac events in the BAT group, the difference of

paraplegia rates by the occurrence of BAT attracts special attention. Blood transfusion requirement is a known risk factor for spinal cord ischemia (SCI) in open repair of TAAA.[25] Available studies on SCI after endovascular repair for TAAA rarely report blood loss and transfusion.[26] Although intraoperative blood loss with a transfusion requirement appears to be an important factor for major adverse outcomes like SCI, no recommendations on transfusion threshold and PBM can be found in current guidelines for TAAA repair.[27] However, for elective surgery with high risk of subsequent transfusions, a blood hemoglobin threshold of 11 g/dL in men and 10 g/dL in women is commonly accepted in Germany to initiate further differential diagnostics before the procedure.[28] One of the limitations to reporting of blood loss in endovascular procedures is the difficulty in estimating blood loss from endovascular sheaths into the patient's draping. In this study, the occurrence of bleeding or blood transfusion was strongly associated with higher rates of paraplegia, confirming prior results.

Colonic ischemia, another devastating complication, was also associated with the occurrence of BAT after FB-EVAR in our study. After elective endovascular AAA repair, the incidence of colonic ischemia was reported to be approximately 0.5% to 1.0%, with increased odds of morbidity and mortality.[29-31] Interestingly, to the best of our knowledge, no valid association between bleeding, transfusion, and colonic ischemia after complex aortic repair was reported before this study.

The results of our study emphasize the importance of PBM for patients being treated with FB-EVAR. High-volume centers worldwide already use cell savers to minimize intraoperative blood loss, but to the best of our knowledge, there is no broad awareness and no evidence-based approach to implement a sex-related PBM in complex endovascular aortic repair. We suggest using a commonly consented reporting standard for bleeding and transfusion as stated by the Bleeding Academic Research Consortium.[8] According to Clevenger et al,[4] PBM in elective FB-EVAR should focus on three pillars of care: the detection and treatment of preoperative anemia, reduction of perioperative blood loss, and harnessing and optimizing the patient-specific physiologic reserve of anemia.[32] Existing thresholds vary significantly throughout the world. To evaluate the benefit and potential harms of PBM and sex-related thresholds in elective complex aortic repair, a prospective randomized and controlled trial should be conducted.

This study has limitations. First, no anatomic, device-specific, or laboratory information, such as access or iliac vessel diameter or preoperative hemoglobin level, was available to adjust for these possible confounders. The complexity and duration of the procedure probably have an impact on outcomes. Hence, the question arises as to whether women are more frequently anemic at presentation and are therefore predisposed to more transfusions. It also remains uncertain how an inhomogeneous transfusion threshold in real-world practice might confound treatment practice. However, the results of this study are interesting and hypothesis generating. Future prospective studies are needed to examine possible confounders. Second, it has to be highlighted that nonrandomized retrospective studies are limited to associations. It is for the vascular community to ponder statistical significance vs clinical relevance. Third and last, the primary purpose of the data collection should be taken into account in using it for secondary purposes. All data used for research purposes should undergo validation. Against that backdrop, health insurance funds perform random cross-checks with patient files on a regular basis.[33,34] Certainly, coding errors are possible, but they would affect both study groups equally.[35]

CONCLUSIONS

Patients with coagulopathy, patients with multiple comorbidities, and women are at higher risk for development of BAT after FB-EVAR. The occurrence of this event was strongly associated with higher major complication rates and worse short-term and long-term survival. This emphasizes a need to further illuminate the value of PBM in FB-EVAR.

The authors thank the DAK-Gesundheit for supporting this quality improvement and research project. The authors would like to thank Adam Beck (Birmingham, Alabama), Kevin Mani (Uppsala, Sweden), Nikolaj Eldrup (Aarhus, Denmark), and the Anaemia and Transfusion in Complex Aortic Repair (ATICAR) study group for their critical revisions of the manuscript.

AUTHOR CONTRIBUTIONS

Conception and design: CB, TS, HR, AS, TK
Analysis and interpretation: CB, TS, HR, AS, TK
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Critical revision of the article: CB, ED, TS, MD, VM, AS, TK
Final approval of the article: CB, ED, TS, HR, MD, VM, AS, TK
Statistical analysis: CB, TS, AS, TK
Obtained funding: CB, ED
Overall responsibility: CB

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Submitted Sep 26, 2018; accepted Feb 24, 2019.