What factors counteract the mid-term survival following endovascular repair of abdominal aortic aneurysms?

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Abstract

Background.Endovascular aortic aneurysm repair (EVAR) for abdominal aortic aneurysm (AAA) is increasingly used and become the standard treatment option for AAA. The aim of the current study was to evaluate the outcomes and predictors of survival of endovascular treatment of AAA at the short and medium-term. Methods.A total of 222 patients having endovascular AAA repair between January 2013 and December 2019 by the same surgical team were included in the study. Patient demographics, perioperative and follow-up data including mortality,complications and need for secondary intervention were collected.Primary endpoint was all-cause mortality.Kaplan-Meier analysis was conducted for survival and Cox regression models were assessed for predictors of survival. Results. Median age was 70 years with male predominance(202 patients,91%). Thirty-day mortality was 1.8%. Median follow-up to the primary endpoint was 20 months(range,1 to 80 months). Survival rates at one, three and five years were 93.5%,81.4% and 62.2% respectively. Freedom from secondary intervention rates were 95.5% at one year,88.7% at three years and 82.1% at five years. Cox proportional hazard models showed that preoperative creatinine levels [?]1.8 mg/dl(hazard ratio (HR) 2.68, 95%CI1.21-6.42, p=0.027), hemoglobin levels <10 gr/dl (HR 3.38 95%CI 1.16-9.90,p=0.026), ejection fraction < 30% (HR 5.67,95%CI1.29-24.86,p=0.021)and AAA diamete[?]6.0 cm(HR 2.20,95%CI1.01-4.81,p=0.049)were independently associated with mid-term survival. Conclusion.EVAR is a safe procedure with low postoperative morbidity and mortality. This study confirms that the mid-term survival and results are favorable.However, the analyzed factors in this study that predict reduced survival(high preoperative creatinine,ow hemoglobin,low ejection fraction and larger aneurysms) should be judged when planning EVAR.

Introduction

Endovascular aneurysm repair (EVAR) has become the preferred treatment modality for abdominal aortic aneurysm (AAA).[1,2] It is recognized that early and late outcome after endovascular procedures is comparable to and even better than open surgery to some extent.[3,4] There are some controversial arguments for the late survival benefit following the long-term results of randomized trials.[3-5] The definitely known early benefit of EVAR seems to be lost after several years.[5] However, OVER trial demonstrated non-consistent findings with the other two randomized trials.[4] Survival rates and identifying the predictors of late mortality after EVAR is an important key factor to be assessed to ensure the real benefit of EVAR. Moreover, real world data along with randomized trials should be taken into consideration to make interpretations about outcomes and survival.

The aim of this paper is to emphasize the survival rates and predictors of reduced survival after EVAR procedure that has performed by a single team of endovascular surgery.

Methods

Patients

All patients underwent endovascular AAA repair between January 2013 and December 2019 were identified retrospectively from the database of hospital records. Patient demographics, perioperative variables and early and midterm outcomes were achieved from hospital database and death certificates. All of the methods within this study were in compliance with the declaration of Helsinki (7^{th}revision, 2013) and were approved by the Institutional Review Board. The requirement for the informed consent was waived due to the retrospective nature of the study.

Indications for EVAR included (1) AAA $>$ 5.5 cm in maximum diameter, (2) saccular type of aneurysms and (3) symptomatic aneurysms. Patients with hostile neck (which is defined as neck length [?] 10 mm and/or reverse conical shaped necks) were all included in the study.

EVAR procedure

All EVAR procedures were performed in a hybrid operating room by a specific team of cardiovascular surgery. The unibody endografts have been mainly used in the early period of the study. Afterwards, modular endografts have taken place for our practice in recent years. The devices used in this study were Ankura AAA (Lifetech) in 89 patients (40.1%), AFX® (Endologix) in 68 patients (30.6%), EndurantII (Medtronic) in 58 patients (26.1%), Gore$^{(r)}$Excluder$^{(r)}$ (Gore) in five patients (2.3%) and E-vita Abdominal XT (Jotec) in two patients (0.9%).

Procedures performed in the hybrid room under general (169 patients, 76.1%) or loco-regional anesthesia (53 patients, 23.9%), based upon surgical team, anesthesiologist and patient preference. Modular endografts were deployed with standard fashions and the technique for unibody endograft deployment has been previously described.[6] The Endologix AFX$^{(r)}$device (unibody) consists of a main bifurcated unibody and a proximal aortic extension. This endograft is the only graft with anatomical fixation at the aortic bifurcation. The aortic extension is placed at the infrarenal position. Completion angiography was performed after the procedure. Type 1 endoleaks were treated by balloon angioplasty and placement of extension cuff if needed. Type 2 endoleaks were followed.

Postoperative surveillance

Postoperative evaluation consisted of clinical and radiological assessment at discharge, 1 month, 6 months, 12 months and annually thereafter. Both computed tomographic examination and Doppler ultrasonography were performed at 1 month. If there were no type 1 or 3 endoleaks at first evaluation, subsequent assessments of endoleak and sac diameters were performed only by Doppler ultrasonography. Type 2 endoleaks were also assessed only by Doppler ultrasonography as they are accepted as benign endoleaks in the absence of sac enlargement. If there was suspicion of sac enlargement at ultrasonographic examination, this finding was checked by tomography. Sac enlargement was defined as minimum of 5 mm enlargement compared to the preoperative diameter. Contrast angiography was performed at the hybrid room only when a secondary intervention was needed.

Estimating the possible predictors for survival

Possible predictors were assessed by two mainly used risk models for vascular surgery; Vascular Quality Initiative and Vascular Study Group of New England risk prediction models.[7,8,9] . The combined possible predictors of these two risk models were analyzed in the current study as follows. The predefined patient demographics (age as a continuous variable, gender and comorbid factors such as diabetes, chronic obstructive pulmonary disease, concomitant cardiac disease) were identified. Urgent repair was defined as symptomatic aneurysm treated within 24-48 hours of admission. Preoperative renal insufficiency was defined as creatinine level [?] 1.8 mg/dl and preoperative anemia was defined as hematocrit values below 30%. Furthermore, aneurysm diameter was categorized as $<$ 6.0 cm or [?] 6.0 cm.[10]

Statistical analysis

The variables were investigated using visual (histograms, probability plots) and analytical methods (Kolmogorov–Smirnov/Shapiro–Wilk test) to determine the normality of their distribution. Normally distributed continuous variables were expresses as mean +- standard deviation (SD) or median values with range if not normally distributed. Categorical variables were expressed as number and percentages. Demographic parameters, operating variables and follow-up data were compared using the Mann-Whitney U test and chi-square test. Wilcoxon test was conducted to analyze pre-operative and follow-up diameter of aneurysm sac. Kaplan-Meier analysis was conducted to demonstrate freedom from all-cause mortality and freedom from secondary interventions. The hazard ratio (HR) and 95% confidence intervals (CI) were estimated with different Cox proportional hazard models to estimate the independent predictors of survival with adjustment of the predefined possible rick factors. A p value of < 0.05 was considered to be statistically significant, and all statistical analyses were performed using the SPSS for Windows version 15.0 statistical software program (SPSS Inc., Chicago, IL, USA).

Results

A total of 222 patients underwent EVAR procedure at 7 years period and the procedures were carried out by the same team of cardiovascular surgeons. Baseline characteristics of the patients are summarized in Table 1. The median age of the patients was 70 years (range, 46 to 92 years) and study population was predominantly male (202 patients, 91%).

The median stay in the intensive care unit and in the hospital were 4 hours (range, 2 to 240 hours) and 2 days (range, 1 to 20 days) respectively. Perioperative features are reviewed at Table 2.

In hospital mortality was 1.8% (four patients of 222). Follow-up was available in all 218 survivors. Excluding four in-hospital mortalities, routine follow-up of remainders was included in the outcome assessment. The median follow-up period was 20 months (range, 1 to 80 months). The follow-up data are shown in Table 3.

Five-year freedom from any endoleak was 65% with a 95% confidence interval (CI) of 54.3-74.9%. On the other hand, freedom from type 1a endoleaks, type 1b endoleaks, type 2 endoleaks and type 3 endoleaks was 97.5% (95% CI: 95.1-99.9%), 92.5% (95% CI: 85.2-99.8%), 83.9% (95% CI: 74.1-93.7%) and 86.5% (95% CI: 75.5-97.5%), respectively.

There were 36 late deaths (16.5%). Kaplan-Meier survival analysis revealed that overall survival at one, three and five-years were 93%, 81% and 62% respectively (Figure 1). Freedom from secondary intervention were 96%, 89% and 82% respectively for one, three and five years (Figure 2). Indications for secondary intervention (endovascular or open) were type III endoleak (6 patients), stent-graft limb thrombosis (4 patients), type Ib endoleak (4 patients), type Ia endoleak (3 patients), vascular access problems (2 patients) (Table 3)

Aneurysm sac diameter tend to be decreased after the procedure regarding to the preoperative measurements (from median 60 mm to 58 mm, p=0.047). At the follow-up period, 86% aneurysms were detected to be decreased in size or remained stable, when considering that an increase 5 mm of diameter as an enlargement.

Predictors of survival

Multivariate Cox regression models revealed that the independent predictors for late mortality were the creatinine [?] 1.8 mg/dl (adjusted HR 2.68; 95% CI 1.21-6.42; p=0.027), hemoglobin $<$ 10 g/dl (adjusted HR 3.38; 95% CI 1.16-9.90; p=0.026), ejection fraction $<$ 30% (adjusted HR 5.67; 95% CI 1.29-24.86) and AAA diameter [?] 6.0 cm (adjusted HR 2.20; 95% CI 1.01-4.81; p=0.049) (Table 4). Age, gender and symptomatic status of the patient did not interfere the late survival of the patients. For further analysis, follow-up variables such as endoleak presence, endoleak type, reintervention and sac enlargement ($>$ 5 mm) were also assessed by hazard models. Among these covariates, sac enlargement was found to be related with survival only at univariate analysis (HR 3.78, 95% CI 1.15-12.45; p=0.029).

Discussion

This report presents the mid-term outcome (median follow-up of 20 months) and predictors of survival after endovascular procedures with the use of all type of available endografts for the treatment of AAA by our

single endovascular team. Freedom from all-cause mortality was 93% at 1 year, 81% at 3 years and 62% at 5 years. Main predictors of lower survival rates after EVAR were poor ventricular function, aneurysms above 6 cm and various comorbidities that are decreased renal function and anemia.

In recent two decades, EVAR is increasingly becoming the standard treatment modality for un-complex infrarenal AAA.[2]EVAR has numerous advantages especially early survival benefit compared to open surgery, including the fact that the procedure has a minimally invasive nature and has a shorter recovery period.

During a median follow-up of 20 months 36 deaths (16.5%) had occurred in our study population. 5-year overall mortality was documented as 73.6% at meta-analysis of four randomized trials [3]. The main controversy of this reported value is the selection criteria of the patients in the randomized trials and all the patients in the trial were within limits of IFU. The numbers at the real world are slightly different from the randomized trials. ENGAGE registry which documented the outcomes of a single endograft (Medtronic Endurant) reported that 17.8% of 1263 patients were out of IFU limits and above 10% with hostile necks. The 5-year overall survival rate was reported as 67% at ENGAGE registry [11]. Other earlier real-world reports have reported similar survival rates between 63% and 72% as well.[10,12] The survival rates of the current study occurred as 93% at one-year, 81% at 3-years and 62% at 5-years which is very comparable with the real-world data. On the other hand, Jeon-Slaughter et al demonstrated that inferior mid-term survival after EVAR is independently associated with larger AAA diameters, especially above 6.0 cm. [10]. Five-year survival rates of $<$ 6.0 cm and [?] 6.1 cm were 73% and 52% respectively in the current study which is comparable with the above-mentioned report.

Anatomical factors predicting survival after EVAR stay as the main topic of several studies in the literature.[7,8,10,13,14]Aneurysm diameter, the anatomical properties of aneurysm and neck angle was determined to be associated with midterm survival.[15] The initial aneurysm diameter independently predicted mortality at long-term. There was an almost three-fold increase of mortality risk at patients with initial aneurysm diameter [?] 6.0 cm in this study. Similarly, a recent study investigating the database of Vascular Quality Initiative has demonstrated a one and a half fold increase of 5-year mortality at patients with large aneurysms ([?] 6.5 cm). [16] Jeon-Slaughter et al have reported increased mid-term mortality risk with aneurysm above 6.0 cm.[10] Furthermore, shorter life expectancy and higher rupture risk at endovascularly treated large aneurysms were documented by Zarins et al. [17] Median diameter of AAA in our series was 60 mm with 58% of which was equal or above to 60 mm. Majority of reports and registries assessing predictors for mortality have mean diameter of aneurysms between 5.5 and 6.0 cm.[7,8,14,17] Registry of Vascular Quality Initiative which composed of over 18000 EVAR patients have reported to have aneurysms above 6.0 cm at only 24% of the registry.[7]Moreover, the mean diameter of aneurysm has been reported as 58 mm at Vascular Study Group of New England risk prediction model.[8] Three-fold increase of mortality risk in our series which is more than other series may be clarified with the relative increased diameter of our patient population.

In addition to aneurysm diameter, some demographic features and comorbidities have been found to decrease survival for EVAR patients.[7,9,14] Simplified risk score model that has been mentioned at the report of Neal et al, recognized that low ejection fraction has a very high score (+5 score) for risk prediction.[9] Similarly, preoperative ejection fraction below 30 was predictive of mortality with five-fold increase at risk in our study. Piffaretti et al, reported an almost similar predictive value of heart failure on late all-cause mortality.[18] In addition, several other studies also have documented heart failure as a risk factor for long-term mortality.[19,20]

On the other hand, age, gender and some comorbidities such as diabetes and chronic obstructive pulmonary disease were not associated with survival. The association between survival and age along with gender has been previously reported by numerous studies.[7,8,14]Majority of the studies reporting predictors of survival has a mean age of over 70's.[13,18,20] Limited number of studies could not associate age with survival.[21] The relatively younger population and small number of the study may be the reason for no relationship of age and survival.

Gender is generally reported as a covariate for survival[20,22-24], although there are some controversies about its predictive value at other studies.[12,20,25-27]Women who undergo endovascular repair tend to be older than men

in most of the studies and the older age may contribute to its predictive effect. However, the median age of women in our study was not significantly different from men's age. The results of our study are nevertheless reliable in high-volume reports.[12,20,25-27] The other confounding issue was the male predominance of our study (91%) which may impede the clarification of results regarding gender.

Alternatively, overall all-cause mortality at midterm was significantly three times lower for the patients without renal disease or anemia. Saratzis et al concluded that impaired renal function was independently associated with an increase mortality following EVAR.[21] Similarly, Khashram et al identified baseline renal impairment (creatinine $>$ 1.7 mg/dl) as an important predictor of survival.[20] Additionally, there are several other studies reporting hazard ratios between 1.6 and 2.1 and confirming the results of our study.[24,28] On the other hand, concerning anemia, a few single center observational studies have reported an association with reduced mid- and long-term survival.[28] Another observational study regarding severe anemia ($<$ 10 gr/dl) which is similar to our definition, reported 2.6 fold increased risk of in-hospital mortality after EVAR.[29] Furthermore, our study is unique given that poor mid-term survival is associated preoperative severe anemia (HR 3.4). This relationship is very reasonable that anemia may present itself with a diminished cardiac reserve and associated comorbid conditions. The underlying condition may be addressed to overcome this condition.

Limitations

This study includes some notable limitations. Firstly, these results were analyzed retrospectively and evaluated from a single endovascular team which may have established a selection bias. Overall number of the study population was relatively low. Secondly, unfortunately, the cause of late deaths could not be identified for some patients. Therefore, analysis for aneurysm-related death and non-aneurysm-related death could not be constructed for this study. Lastly, considerably short follow-up time may be a limitation to assess the predictors of survival accurately. On the other hand, projection of 5-year survival which is comparable to the literature, satisfactorily assessed by the analyses in this study.

Conclusion

The outcomes of EVAR patient in the current study demonstrates safety and acceptable durability of the endografts at AAA patients at five years with survival rate over 60% and freedom from secondary intervention exceeding 80%. Large aneurysms, low ejection fraction, poor renal function and anemia are independent predictors of reduced survival after endovascular repair of aneurysm. Longer-term follow-up is expected to be reported through 10-years.

Declaration of Conflicting Interests

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Tables

Table 1. Baseline characteristics of the patients

Table 2. Perioperative features

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Table 4. Predictors of survival (unadjusted and adjusted hazard ratios analyzed by Cox regression analysis)

Figure legends

Figure 1. Kaplan-Meier estimate of cumulative survival

Figure 2. Kaplan-Meier estimate of freedom from secondary intervention

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