Applicability of ASA classification system in elective endovascular aneurysm repair

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ABSTRACT

Objectives: This study aims to examine the American Society of Anesthesiologists (ASA) classification of Physical Status as a preoperative risk prediction method for early mortality and morbidity in patients undergoing elective endovascular aneurysm repair (EVAR) of an infrarenal abdominal aortic aneurysm (AAA).

Patients and methods: A total of 134 consecutive patients (124 males, 10 females; mean age 69.6±6.9 years; range, 52 to 85 years) with an infrarenal AAA who underwent EVAR between January 2012 and January 2018 were retrospectively analyzed. The patients were divided into two groups as Group 1 (low risk; ASA I-II; n=63) and Group 2 (high risk; ASA III-IV; n=71). Early and postoperative one-year mortality and morbidity were evaluated.

Results: The overall early mortality rate was 1.4%. None of the patients were converted to open surgery and overall technical success was 100%. Unibody grafts were performed in 33% patients in Group 1 and 59.2% patients in Group 2 (p=0.003). The length of intensive care unit and hospital stay was longer in Group 2, although it did not reach statistical significance. A total of 64% of local/locoregional anesthesia was performed in Group 2 high-risk patients.

Conclusion: Regardless of the ASA risk group, EVAR can be performed successfully. The ASA classification may be useful for decision of treatment modality. Patients unfit for open surgery can be managed safely by EVAR.

Keywords: American Society of Anesthesiologists classification, endovascular, infrarenal abdominal aortic aneurysm.

Endovascular aneurysm repair (EVAR) has become a powerful alternative to conventional surgical methods with its non-invasive nature and excellent results in the treatment of abdominal aortic aneurysms (AAAs). Endovascular aneurysm repair has been reported to have superior results in the early period, compared to open surgery, in high-quality randomized-controlled trials and has become the first choice in the current guidelines for all anatomically suitable cases.[1-3]

Patient selection is the most important factor for successful EVAR. Anatomic compliance, functional status, and comorbidity of the patient should be evaluated in detail in the preoperative period for patient selection. Long-term survival is largely dependent on the patient comorbidity. Several grading methods are used to objectify patient comorbidity. The American Society of Anesthesiologists (ASA) classification of physical status is one of these methods which is widely used for categorizing the preoperative status of patients. Many physicians use it as a means of preoperative risk assessment and some have described them as a sign of postoperative morbidity and mortality.[4,5]

Several objective risk assessment scoring systems including Glasgow Aneurysm Score (GAS), Customized Probability Index (CPI), and ASA have been developed for accurate prediction of outcome after open surgery; however, their performance in patients undergoing EVAR has not fully evaluated, yet. In the present study, we aimed to evaluate the ASA classification for accuracy of prediction of

early mortality and morbidity in patients undergoing elective EVAR for an infrarenal AAA.

PATIENTS AND METHODS

This single-center, retrospective study included a total of 134 consecutive patients (124 males, 10 females; mean age 69.6±6.9 years; range, 52 to 85 years) with an infrarenal AAA who underwent EVAR between January 2012 and January 2018. Urgent cases, patients with concomitant cardiac operations, coronary interventions or hybrid operations were excluded from the study. An aneurysm diameter of >55 mm, saccular aneurysms, and symptomatic aneurysms were planned for repair. All patients were evaluated with contrast computed tomography (CT) for anatomic compliance and surgery indication was decided by the Medical Council consisting of cardiovascular surgeons. In the preoperative period, routine blood tests, cardiac function tests including electrocardiogram (ECG) and transthoracic echocardiography, or coronary angiography in symptomatic patients, and pulmonary function tests, radiography, comorbidities of the patients were evaluated. The patients with risk factors were consulted to the relevant departments preoperatively for comorbidities. If any treatment was considered necessary, it was applied. Patients demographics and risk factors for two groups are listed in Table 1. The patients were classified into two groups: Group 1 (low risk; ASA I-II; n=63) and Group 2 (high risk; ASA III-IV; n=71). All patients were assigned to a class by the attending anesthesiologist. The ASA classification was based on guidelines set by the American Society of Anesthesiologists. Criteria used to define each class are as follows: Class I-healthy status, Class II-mild systemic disease, Class III-severe systemic disease, and Class IV-life-threatening severe systemic disease.[4,5] Anesthesia type was chosen based on the patients' status, as local, locoregional, or general anesthesia by anesthesiologists and cardiovascular surgeons General anesthesia was performed, if there was possibility for conversion to open repair due to challenging anatomy or if there would be intense femoral dissection for exposure or technically difficult cases with a possibility to last long or not suitable for regional anesthesia due to coagulopathy or if the patient was unable to tolerate local anesthesia well. Local anesthesia was forced in every patient; however, if the patient's mental or psychological status was not eligible for local anesthesia, general anesthesia was used. In the operation theatre, a radial arterial line, a peripheral venous catheter (14 or 16 gauge), a central venous catheter, and a urinary Foley catheter (Ribbel International Ltd., Haryana, India) were placed routinely. During the operation, the patients were monitored with continuous ECG, invasive arterial blood pressure, and transcutaneous oxygen saturation. Two different endovascular prosthetic graft systems

Table 1. Baseline demographic and clinical characteristics of patients							
	Group 1 (n=63)			Group 2 (n=71)			
Variables	n	%	Mean±SD	n	%	Mean±SD	p
Age (year)			69.4±7.1			69.7±7.1	0.130
Gender							
Male	57	90.5		67	94.4		0.515
Hypertension	30	47.6		47	66.2		0.030
Coronary artery disease	15	23.8		55	77.5		<0.001
Chronic obstructive pulmonary disease	13	20.6		27	38.0		0.028
Coronary artery bypass grafting	4	6.3		32	45.1		<0.001
Hyperlipidemia	15	23.8		25	35.2		0.150
Diabetes mellitus	7	11.1		20	28.2		0.014
Chronic renal failure	0	0		14	19.7		<0.001
Peripheral artery disease	2	3.2		11	15.5		0.016
Congestive heart failure	0	0		7	9.9		0.014
Smoker	25	39.7		26	36.6		0.716
Malignancy	3	4.8		9	12.7		0.109
Symptomatic	9	14.3		26	36.6		0.003
Previous operation	10	15.9		7	9.9		0.296
Aneurysm diameter (cm)			62.4±13.0			62.1±12.1	0.750
Ejection fraction (%)			55.2±4.4			47.5±10.8	<0.001

SD: Standard deviation.

were used: unibody and modular endografts. Unibody endograft consists of a main bifurcated unibody and a proximal aortic extension. The graft has a 17-French (Fr) introducer system for the ipsilateral side and 9-Fr sheath for contralateral side. One side femoral artery exploration is enough for unibody endografting. The fixation of the unibody graft is at the native aortic bifurcation. The contralateral side can be performed percutaneously. Modular endograft consists of a main module with suprarenal fixation and ipsilateral leg and contralateral leg graft module. Two-side femoral artery exploration is needed, while performing modular endografts. Technical success was defined as the deployment of the endovascular graft in the absence of endoleak and other endovascular complications as twist, kink, or obstruction. The duration of the intervention and fluoroscopy time and the amount of contrast material were compiled. In the postoperative period, renal, cardiopulmonary complications, length of intensive care unit (ICU), length of hospital stay, and routine blood tests were evaluated. In the follow-up period, all patients underwent abdominal aortic color Doppler ultrasonography and, based on the procedural features, contrast-enhanced CT at one and three months and, thereafter, at six and 12 months in the outpatient setting. Early postoperative mortality and morbidity rates at one year were evaluated. A written informed consent was obtained from each patient. The study protocol was approved by the Türkiye Yüksek İhtisas Training and Research Hospital, Ethics Committee, (Date: 15.11.2018, No. 29620911-929). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Statistical analysis

Statistical analysis was performed using the SPSS version 15.0 software (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed in mean ± standard deviation (SD), while categorical variables were expressed in number and percentage. The variables were investigated using visual (histograms, probability plots) and analytical methods (Kolmogorov-Simonov/Shapiro-Wilk test) to examine whether they were normally distributed. Demographic characteristics and perioperative variables were compared using the Mann-Whitney U test for continuous variables and the chi-square test or Fisher's exact test for categorical variables. A p value of <0.05 was considered statistically significant.

RESULTS

In Group 1, there were 63 patients (47.01%) with a mean age of 69.4±7.1 years, while there were 71 patients (52.98%) with a mean age of 69.7±7.1 in Group 2. Hypertension, coronary artery disease, chronic obstructive pulmonary disease (COPD), coronary artery bypass grafting, diabetes mellitus, chronic renal failure, peripheral artery disease (PAD), and congestive heart failure (CHF) were the risk factors of the patients which were statistically significantly higher in Group 2. Also, ejection fraction values of the patients in Group 2 were statistically significantly lower in Group 2 than Group 1 (p<0.001).

The overall early mortality rate was 1.4% (n=1 in Group 2). None of the patients were converted to open surgery and overall technical success was 100%. In addition, EVAR was performed under general anesthesia in 92 patients (68%) and under local/locoregional anesthesia in 64% of high-risk patients. Unibody grafts were performed in 33.0% patients in Group 1 and 59.2% patients in Group 2 (p=0.003). We used 28 iliac extensions for patients: 12 (19.0%) in Group 1 and 16 (22.5%) in Group 2 (p=0.620). Perioperative morbidities were not statistically significantly different between the groups

Table 2. Perioperative data

Variables	Group 1 (n=63)			Group 2 (n=71)			p
	n	%	Mean±SD	n	%	Mean±SD	
Modular graft	42	66.7		29	40.8		0.003
Unibody graft	21	33.3		42	59.2		
General anesthesia	48	76.2		44	62.0		0.077
Local/locoregional anesthesia	15	23.8		27	38.0		
Procedure time (min)			157.2±55.7			141.4±38.7	0.124
Scopy time (min)			20.3±13.2			17.3±5.4	0.767
Opaque (mL)			71.4±22.0			69.9±21.2	0.811
Iliac extension	12	19.0		16	22.5		0.620

SD: Standard deviation.

Table 3. Postoperative data

Variables	Group 1 (n=63)			Group 2 (n=71)			p
	n	%	Mean±SD	n	%	Mean±SD	
Early mortality	0	0		1	1.14		1.000
Renal morbidity	3	4.8		2	2.8		0.666
Migration	0	0		0	0		-
Graft interposition	3	4.8		3	4.2		0.653
Intensive care unit period (hours)			6.4±5.0			11.9±29.1	0.120
Length of hospital stay (days)			2.6±1.9			3.5±3.1	0.053

SD: Standard deviation.

and were often associated with the femoral access site. Due to the femoral artery injury, graft interposition was performed in three patients (4.8%) in Group 1 and three patients (4.2%) in Group 2. There was no statistically significant difference between the groups in terms of additional procedure rates, procedural time, fluoroscopy time, and contrast material volume. Length of ICU and length of hospital stay were longer in Group 2; however, it did not reach statistical significance. Perioperative data are summarized in Table 2.

Furthermore, one-year mortality was higher in high-risk group, although not statistically significant (p=0.06) (Table 3). Postoperative major morbidities were similar between the two groups (Table 4).

DISCUSSION

Owing to less tissue trauma, reduced stress response, avoidance of aortic cross-clamp, and its non-invasive nature, successful results, and early patient turnover, EVAR has gained wide acceptance as the predominant treatment for the AAAs in anatomically suitable patients in recent years. Although the risk/benefit analysis were conducted to determine the appropriate treatment for patients in many studies, defining high risk is still controversial in the endovascular era.

Table 4. Postoperative one-year data

Variables	Group 1 (n=63)		Group 2 (n=71)		p
	n	%	n	%	
One-year mortality	0	0	5	7.0	0.060
Migration	0	0	0	0	-
Iliac occlusion	0	0	3	4.2	0.247
Endoleak	5	7.9	7	9.9	0.697
Type 1a	0	0	1	1.4	
Type 1b	1	1.6	1	1.4	
Type 2	2	3.2	4	5.6	
Type 3	2	3.2	1	1.4	

Grading systems are used to classify patients as low-risk or high-risk for predicting patient outcomes after surgical procedures. These systems yield different success rates and they are attempted to be adopted for EVAR. The GAS, Vascular Physiology and Operative Severity Score for the Enumeration of Mortality and Morbidity (V-POSSUM), CPI, and modified CPI (m-CPI) are some of these systems. Bohm et al.[6] reported that GAS, V-POSSUM, CPI, and m-CPI were poor predictors of early mortality and morbidity following EVAR. Similar findings were reported by Patterson et al.[7,8] Still, there is no excellent grading system and methods of predicting patient outcomes preoperatively is a major concern for surgeons. Researches are still in progress to identify the most suitable scoring system to predict patient outcomes for EVAR. A reliable and accurate scoring system is essential for clinical decision making and treatment choice.

The ASA classification system is one of these methods. It is the most preferred system due to ease of use and wide applicability. It was prepared for comparing patient data related to anesthesia.[9] But many physicians used this classification to determine the patients at high risk for surgical operations and reported the ASA is functional in predicting patient outcomes.[4] In a prospective study of 6,301 surgical patients in a university hospital, Wolters et al.[4] reported significantly higher hospital mortality as the ASAc grade advanced from I to IV.[4] As the same, Prause et al.[10] reported that ASAc could be a predictor of perioperative mortality for the elective surgical procedures.[10] American Society of Anesthesiologists classification system appear to be suitable to predict the patient outcomes undergoing open surgery. However, its qualification for EVAR is ambiguous. In our study, EVAR procedures could be successfully performed, regardless of the risk profile of the patient.

Boult et al.[11] examined the data of 961 patients who underwent EVAR between 1999 and 2001 prospectively and found the five-year survival rate of ASA II, ASA III, and ASA IV patients to be 81%, 63%, and 40%, respectively. The authors concluded that the strongest single predictor of survival was the ASA status. In another study, the aneurysm diameter was an independent predictor of perioperative mortality and this along with age, chronic renal insufficiency, and ASA score were the predictors of three- and five-year mortality after EVAR.[12] In addition, age, aneurysm size, CHF, COPD, PAD, use of aspirin, and ASA status were identified statistically significant as independent predictors of mortality in the study of Mastracci et al.[13] In our AFX® study, EVAR yielded successful outcomes in the early and postoperative first year, irrespective of the age of the patients.[14]

On the contrary, there are some authors who report that the ASA classification is insufficient to predict postoperative morbidity and mortality. Technical and clinical success rates, postoperative complications, and survival were not related to the ASA class in the Conners' report.[15] In a prospective study of Dijkstra et al.,[16] 1,263 patients who were treated with Endurant™ stent graft was enrolled. The patients were categorized using both ASA and Society for Vascular Surgery/American Association for Vascular Surgery (SVS/AAVS). Finally, they reported that the ASA score was not useful in predicting 30-day and one-year outcomes. In this study, general anesthesia was used in a higher frequency for ASA IV patients (78.9%), compared to ASA I patients (59.7%). In total, 13.2% of the patients received local anesthesia. In our series, we performed local/locoregional anesthesia, if possible, for high-risk patients (38%). Avoidance of the endotracheal intubation is one of the main advantages of local anesthesia which may prevent pulmonary complications. Also, it provides shorter ICU stay and length of hospital stay. Patient movements caused by anxiety, discomfort, and persistent coughing may have an impact on imaging quality in local anesthesia and, therefore, problems may occur during endograft placement. Sedation with local anesthesia may overcome these problems. In our study, we observed none of these problems. Supporting our ideas, Akay et al.[17] also used sedation and local anesthesia could be the first choice for patients undergoing EVAR. We believe that more liberal use of local anesthesia may further emphasize the non-invasive nature of the procedure.

The EVAR-2 trial examined the safety and efficacy of EVAR in patients who would be considered high-risk or ineligible for open AAA repair.[18] The study showed that EVAR did not increase overall life expectancy in patients who were ineligible for open repair, although it could reduce aneurysm-related mortality. The 30-day mortality for EVAR in the EVAR-2 trial was 9% and AAA-related mortality at four years was 14% for EVAR and 19% for no-intervention group. However, mortality results of EVAR-2 creates doubts about the superiority of EVAR over the natural history of untreated AAA in high-risk patients. High risk patients with a short life expectancy from non-aneurysmal diseases may be appropriate for watchful waiting and EVAR may be the most optimal treatment for the rest. In our study, even high-risk patients had successful early and postoperative one-year results. Consistent with our findings, the United State Investigational Device Exemption (US IDE) trial reported superior results to EVAR-2 trial.[19] The 30-day mortality for the US IDE trial was lower than the EVAR-2 (2.7% vs. 9%) and four-year AAA-related mortality rate was significantly lower (4% vs. 14%). The survival rate in the aforementioned study was also statistically significantly longer, compared to the EVAR-2 (56% vs. 34%). This study indicates that EVAR provides excellent protection against AAA-related mortality without any significant difference compared to open surgery controls.[19]

Adverse anatomic factors which affect technical success also increase the risks of persistent or recurrent endoleak and secondary intervention and are known to have a significant impact on the outcome of EVAR. Caution should be, therefore, applied to the use of these scoring systems for risk stratification and patient and treatment selection. Unfit patients for open surgery should be evaluated anatomically for risk/benefit of EVAR procedure not to perform any intervention and leave the patient to the natural course of aneurysm or not. In our study, one-year mortality was higher in high-risk group, although it did not reach statistical significance (p=0.06). Technical and clinical success rely on anatomic suitability of the patient according to the endovascular guidelines. Minimally invasive nature provides the feasibility of high-risk patients for endovascular procedures. That is the reason why ASA status of the patient is not associated with technical success or mortality.

Nonetheless, there are some limitations to this study. The retrospective design and non-randomized nature of the study are the main limitations. In addition, the classification of the groups as high-risk

and low-risk was supported with objective variables to a certain degree. Post-hoc power analysis for this population was estimated as 88% (with α=0.05) when the effect size was 0.3 (ω=0.3).

In conclusion, early and postoperative one-year mortality and morbidity rates did not significantly differ among the risk groups stratified according to the ASA classification. Non-invasive nature of EVAR facilitates satisfactory results for all risk groups. Medical conditions do not interfere with technical success of EVAR procedure. High-risk patients should be endovascularly treated to prevent aneurysm-related mortality. Anatomic suitability is the mainstay of early and midterm technical success and to prevent possible endovascular complications. However, a novel scoring system including anatomic features is needed to successfully predict the events following EVAR.

Declaration of conflicting interests

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