Araştırma Sunumu / Research Article

Siena and St. George Vascular Institute Risk Scoring Systems in Predicting the Complications and Cost of Evar / *Evar'ın Komplikasyonlarını ve Maliyetini Öngörmede Siena ve St. George Damar Enstitüsü Risk Skorlama Sistemleri*

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Gönderim Tarihi | Received: 30.09.2019, Kabul Tarihi | Accepted: 3.03.2020, Yayım Tarihi | Date of Issue: 30.12.2020, DOİ: 10.25279/sak.626809

Atıf | Reference: "ARIKAN, A.A; YAVUZ, Ş; BERKİ, K.T. (2020). Siena and St. George Vascular Institute Risk Scoring Systems in Predicting the Complications and Cost of Evar. Sağlık Akademisi Kastamonu (SAK), 5 (3), s.209-218."

Abstract

Introduction: Endovascular aneurysm repair is a widely used modality in the treatment of abdominal aortic aneurysms. Siena Endovascular Aneurysm Repair Score and St. George Vascular Institute scores are risk scores to predict possible endovascular aneurysm repair related reinterventions. This study was aimed to compare the predictivity of the scoring systems for hospital costs in our population. Materials and Methods: 39 patients with infrarenal abdominal aortic aneurysms that had a follow-up period from at least 6 months are included in our study. Siena Endovascular Aneurysm Repair and Saint George Vascular Institute scores are calculated. The relation of the complications (adjuncts at the index operation, reinterventions during follow up), costs (index procedure and overall), aneurysm related mortality are compared among the risk groups. Results: In our study, Saint George Vascular Institute score had a predictivity among high and low-risk groups involving reinterventions during follow up, cost on index operation and mortality ($p<0.05$). Siena Endovascular Aneurysm Repair Score had no significant predictivity ($p>0.05$). Conclusion and suggestions: The health care providers and assurance system can count on a higher cost on index operation, a higher risk of reintervention and mortality during long term follow up on patients scheduled for endovascular aneurysm repair with a high-risk value in Saint George Vascular Institute score. Saint George Vascular Institute score is an effective way to predict the cost of endovascular aneurysm repair.

Keywords: Abdominal Aortic Aneurysm, Endovascular Procedures, Risk Assessment, Health Care Costs, Reoperation.

Öz

Giriş: Endovasküler anevrizma onarımı, abdominal aort anevrizmalarının tedavisinde yaygın olarak kullanılan bir yöntemdir. Siena Endovasküler Anevrizma Onarımı Skoru ve St. George Vasküler Enstitüsü Skoru, endovasküler anevrizma onarımı ile ilgili olası müdahaleleri öngörmek için kullanılmaktadır. Bu çalışmada, risk skorlama sistemlerinin popülasyonumuzun hastane maliyeti açısından öngörücülüğünün karşılaştırılması amaçlandı. Gereç ve Yöntem: Çalışmamıza en az 6 ay takip süresine sahip infrarenal abdominal aort anevrizmalı 39 hasta

dahil edildi. Siena Endovasküler Anevrizma Onarımı Skoru ve St. George Vasküler Enstitüsü Skoru hesaplandı. Risk grupları arasında komplikasyonların (ilk operasyonundaki ek işlemler, takip sırasında girişim ihtiyacı), maliyet (ilk işlem ve genel), anevrizmaya bağlı mortalite arasındaki ilişki karşılaştırıldı. Bulgular: Çalışmamızda St. George Vasküler Enstitüsü skorunun, yüksek riskli ve düşük riskli grupları arasında, takip sırasında girişim ihtiyacı, ilk işlem maliyeti ve mortalite açısından anlamlı fark bulundu ($p<0.05$). Siena Vasküler Enstitüsü Skorunun anlamlı bir öngörücülüğü yoktu ($p>0.05$). Tartışma Endovasküler anevrizma onarımı yapılacak olan hastalarda St. George Vasküler Enstitüsü skorundaki yüksek risk, sağlık hizmeti sağlayıcıları ve sosyal güvence sistemini, ilk işleminlerde daha yüksek bir maliyet ve uzun süreli takip sırasında daha yüksek oranda yeniden girişim ihtiyacı ve ölüm riski açısından uyarmaktadır. Sonuç ve öneriler: St. George Vasküler Enstitüsü skoru, endovasküler anevrizma onarımının maaliyetini öngörmede etkin bir yöntemdir.

Anahtar Kelimeler: Abdominal Aort Anevrizması, Endovasküler İşlemler; Risk Değerlendirmesi, Sağlık Masrafları, Reoperasyon.

1. Introduction

Since its first introduction, Endovascular aneurysm repair (EVAR) has gained popularity and higher rates of abdominal aortic aneurysms are repaired via endovascular techniques than open surgery(C. Setacci ve diğerleri, 2017). Regular follow up is needed after the procedure, for screening EVAR specific complications. Endoleak, graft migration, kinking, limb occlusion can occur and lead to failure of the procedure. In 1 to 37% of cases treated with EVAR a reintervention has been reported (A Karthikesalingam et al., 2010). Due to these complications, EVAR loses its advantage of survival, quality of life, and cost-effectiveness over surgery (Lübke & Brunkwall, 2014; members ve diğerleri, 2014; Powell ve diğerleri, 2017; Rutherford, 2006). Siena EVAR and St.George Vascular Institute Scores (SGVI) are scoring systems for predicting EVAR related aortic reinterventions (Alan Karthikesalingam et al., 2013; F. Setacci ve diğerleri, 2012). EVAR poses an economic burden to the health care provider and assurance system as a result of the need for regular follow up, with no long-term survival benefit (Prinssen, Wixon, Buskens, & Blankensteijn, 2004). The aim of this study was to analyze whether Siena EVAR or SGVI scores could directly predict the cost of the index procedure, overall costs, reinterventions and mortality of EVAR.

2. Materials and Method

2.1. Type of Research

This research is a retrospective study.

2.2. Research Universe and Sample

The place and time of the research: Records of patients treated with EVAR between September 2009 and August 2015 at our institution are evaluated. Between 2009 and 2015, EVAR was performed in 88 patients in our center. 39 patients treated with EVAR for a non-ruptured infrarenal AAA, and with a follow-up period for at least 6 months are included in the study. 27 patients with ruptured AAA, 9 patients who did not completed the 6-month follow-up period, and 13 patients who had missing data are excluded from the study.

2.3. Data Collection

Morphologic parameters prior to EVAR are measured from computed tomography records with the PACS (Sectra Workstation IDS7, Linköping, Sweden) system. Creatinine clearance is calculated with the Cockcroft-Gault formula. The outpatient admissions, findings on imaging studies, adjunct interventions during index operation, reinterventions during follow-up, complications are investigated from hospital records. Hospitalization costs are detected as Turkish Lira (TL).

The Siena EVAR score is calculated as described by Setacci ve diğerleri (F. Setacci et al., 2012) SGVI score is calculated as described by Karthikesalingam ve diğerleri (Alan Karthikesalingam et al., 2013) According to the Siena system; renal status of the patient, the anatomic features of the proximal neck of the aneurysm, and the experience of the operator all contribute to the score calculation. Scores are divided into three risk groups (low, medium, high). The SGVI score is calculated according to the maximum sac and maximum common iliac artery diameters with two risk groups (low, high).

EVAR was performed when the infrarenal AAA diameter exceeded 55mm. In all of the patients, the endovascular procedure was performed under general anesthesia via the femoral arteries. Talent® (Medtronic Vascular, Santa Rosa, California, USA) or Endurant (Medtronic Vascular, Santa Rosa, California, USA) aorta-to-biiliac grafts were used. After discharging the patient, regular follow-up was performed at 1, 6 and 12th months followed by annual imaging. Reinterventions were performed for complications (type I, type III, and type II endoleak with sac expansion greater than 5 mm, and endograft migration exceeding 5 mm) and rupture.

The relation of the complications (adjunct procedures at the index operation, reinterventions during follow up), costs (index procedure and overall), aneurysm related mortality are compared among the risk subgroups.

2.4. Data Analysis

Statistical analysis is made with an IBM SPSS 20.0 (SPSS Inc., Chicago, IL, USA) program. The normality of the distribution is assessed with a Kolmogorov-Smirnov Test. Numerical variable with normal distribution are given as means ± standard deviations, numerical variables not showing normal distribution are given as medians and 25-75 percentiles (IQR), and categorical variables as frequency (percentage). The difference between the groups is determined by the Student t-test for the numerical variables with normal distribution, and by the Mann Whitney U test for not-normally distributed variables. The relationships between categorical variables are evaluated by Chi-square analysis. A non-parametric Spearman's correlation test is applied to examine the correlations between variables of the risk scores and total cost. A $p<0.05$ is considered to be sufficient for statistical significance.

2.5. Ethical Aspects of the Research

Kocaeli University Clinical Research Ethics Committee approval was obtained for the study protocol. (01/09/2015 Project nr: KOÜ KAEK 2015/278; 10.11.2019). During the research, the authors acted in accordance with the Helsinki declaration.

3.Results

39 patients (37 males, 2 females), with a mean age of 68 years (range:62-79 years) are included in the study. The mean follow-up time was 41.8 ±23.0 (range:6-84) months. The main demographic characteristics are shown in Table 1.

Quantitative aortic aneurysm, iliac artery and mean neck measurements are shown in Table 2. The mean creatinine clearance in patients who did not require dialysis was 64±24 mL/min/m^2.

In eleven cases adjunct procedures were needed on index operation including proximal or distal endovascular graft extension for a leak, iliac stent implantation for stenosis or dissection, and femoro-femoral bypass procedures. No endoleak persisted at the end of the index operations. Seven patients were hospitalized for reintervention during follow-up due to endoleaks (3 type IA, 2 type IB, 2 type II). Four of these patients were presented with a rupture.

The distribution of cases according to their risk groups among Siena EVAR Score and SGVI Score groups and the presence or absence of a complication at any time are shown in Table 3. Siena EVAR Score had no significant predictivity for complications ($p > 0.05$). A significant relation between SGVI Score risk groups and the outcomes was present ($p < 0.05$).

The patients in the calculated risk scores are compared with reinterventions on the follow-up period (Table 4). The relation between reinterventions on follow-up and distribution on risk groups was statistically insignificant for Siena EVAR score (Chi-squared Continuity Correction; $p>0.05$), but it was significant for SGVI (Chi-squared Continuity Correction; $p=0.0025$).

Aneurysm related mortality occurred in 4 patients during intensive care unit stay, following reintervention due to rupture. 6 patients died from non-aneurysm related causes (4 malignancy, 1 pneumonia, 1 stroke). There was no significant relation between aneurysm related mortality and Siena EVAR score risk groups (Fisher's Exact Test, $p>0.05$), but a significant relation was present for the risk groups of the SGVI score (Chi-squared Fisher's Exact Test $p=0.009$) (Table 5).

The median hospital costs were 27159 TL (IQR: 24861-32213 TL) for initial EVAR operation for all cases. The median hospital costs were 28797 TL (IQR: 24861-40628 TL) for all patients including follow up reinterventions. Median costs for cases with adjuncts on index operation was 30874 TL (IQR:26005-40628 TL; n=14), the median cost was 26354.5TL (IQR:24294-29912 TL; n=25) for cases without adjuncts; the difference was statistically significant ($p=0.032$; Mann-Whitney U Test). Median costs for all complicated cases were 40628 TL (IQR:27159-60808 TL; n=15). The median cost was 25338TL (IQR:23663-30285 TL; n=24) for uncomplicated cases; the difference was statistically significant (p:0.002; Mann-Whitney U Test).

The distribution of cases according to their risk groups among Siena EVAR Score and SGVI Score with the index cost (cost of the index procedure) and total cost (index procedure and reinterventions during follow up) are shown in Table 6. A significant relation between SGVI Score risk groups and index cost ($p <0.05$) and total cost ($p <0.01$) was present. Siena EVAR score did not predict index or total costs ($p>0.05$).

The effect of operator experience on complications (need for adjunct intervention at index operation and, reinterventions on followup) was investigated. From 13 cases with a low operator experience (<50 cases) 6 had complications, from 26 cases with adequate operator experience (>50 cases) 9 had complications. The difference among groups was not significant (Chi-squared Continuity Correction; p=0.7).

Correlations between the costs for all complications, maximum aneurysm diameter of the iliac artery diameter, creatinine clearance, neck length, neck diameter, neck angle was investigated. There was only a significant correlation between iliac aneurysm diameter and total procedure cost (Spearman's rho = 0.42, p = 008).

4. Discussion

Evolution of EVAR has allowed more AAAs to be treated (Hinchliffe, Braithwaite, & Hopkinson, 2003). Early and midterm results of EVAR are found superior to open repair. Lesser utilization of blood products, shorter ICU and hospitalization periods, a better quality of life, a lower rate of complications and a lower cost in hospitalization despite using a more expensive graft are the main reasons for choosing EVAR (Bulut & Demirağ, 2013; Prinssen et al., 2004). Large trials favouring EVAR included patients in whom the specific anatomic requirements defined in the device instructions for use were met, but it has also been reported that 31-58% of EVAR devices are used outside their instructions of use in practice (Schanzer & Messina, 2012). Studies reveal that the benefit on mortality, cost-effectiveness and quality of life over open surgical repair disappears in three years, and to avoid secondary complications, indefinite period follow-up is needed (Members et al., 2014; Prinssen ve diğerleri, 2004; Rutherford, 2006; C. Setacci ve diğerleri, 2017). Endoleak and rupture incidence following EVAR are reported to be 14.7-27.8% and 1-20 % respectively(Skervin, Lim, & Sritharan, 2017; Yazman et al., 2016).

It has been stated that in high-risk patients, EVAR is not a binding option in the treatment of AAA (Hastaoğlu, Toköz, Bilginer, & Bilgen, 2014). There has not been a decrease in EVAR associated device costs within the past years, despite its widespread use (Chaikof et al., 2018). The late outcomes make EVAR a matter of question, for its effects on national health economies, and utilization on resources (Chaikof et al., 2018; Paraskevas, Bessias, Giannoukas, & Mikhailidis, 2010).

In index procedures endoleaks are seen up to 52% and, in most cases, re-ballooning is sufficient to cease the leakage (Sampaio et al., 2009). But for persistent endoleaks adjunct procedures are necessary. A relation between adjunct procedures during the index intervention and recurrent endoleaks on follow up has also been demonstrated (A Karthikesalingam et al., 2010; Sampaio et al., 2009). As the adjunct procedures augment the costs of the index EVAR procedure its prediction as a high-risk operation can be helpful to categorize its economic burden. A risk score can be used to predict the cost of EVAR such as EuroSCORE for open-hearth surgery(Nilsson, Algotsson, Hoglund, Luhrs, & Brandt, 2004). In our EVAR population, associated costs for cases with adjunct interventions on index operations and the associated costs for all complicated cases were significantly higher than uncomplicated procedures. In our population, the SGVI score successfully predicted the costs of the procedure. A high-risk estimation can be either used to plan hospital payments with the assurance system in EVAR, or whether it is feasible to perform an open repair. Especially in our national assurance system where payments to a hospital are made based

on an "operation packed" without regarding its content, a grading of payment for EVAR according to the risk of the procedure could be helpful.

It is known that endoleaks are responsible for the majority of the ruptures. In our study 4 of the 7 reinterventions were admitted with rupture, and all were due to endoleaks. Despite being compliant to regular follow up and having normal imaging results ruptures could not be prevented in these patients. It was previously reported that despite regular follow up, 59–91% of the cases with complications needing reinterventions were admitted due to symptoms rather than being detected in the outpatient clinic (A Karthikesalingam et al., 2010). Therefore, it is essential to individualize the follow-up intervals of a patient. Several studies are made to identify the most suitable scoring system to predict outcomes for EVAR(Aytekin ve diğerleri, 2019; Patel et al., 2017). Siena EVAR score is created by 6 months follow up of 976 patients who underwent EVAR for unruptured and asymptomatic AAA and, used anatomic, clinical and operator based data(F. Setacci et al., 2012). SGVI score is created with follow up data for a median of 36 months of 761 patients with unruptured AAA who underwent EVAR and is based only on anatomic parameters(Alan Karthikesalingam et al., 2013). The goal of the proposed scores was to choose the patients for whom stiffer follow-up periods would be necessary.

In our study, the SGVI score had a predictivity of all complications seeking intervention, reinterventions during follow up, and mortality while the Siena EVAR score had no predictivity (Table 3, 4, 5). The costs of the index operation and, the overall costs (index operation and reinterventions) were also significantly correlated with risk groups of the SGVI score (Table 6). A direct relationship between the studied scores and costs is not shown. Large trials for the validation of SGVI scoring for reinterventions has been reported recently (De Bruin et al., 2016; A Karthikesalingam et al., 2015). Our data correlate with these studies and additionally reveals that the SGVI score can estimate the expenses of a hospital for the initial procedure and overall intervention costs.

Patients with high SVGI scores are advised to have shorter intervals for imaging. But it is not yet known if the risk-stratified follow up with the SGVI score will improve patient outcomes (De Bruin et al., 2016).

SGVI score was also tested in the outcomes of open surgery and was found related to higher complications following open repair but half of them were wound complications which are not comparable with catastrophic long term aortic complications of EVAR (De Bruin et al., 2016). It should be stated that high risk in the SGVI score can warn the surgeon to either reassess open surgery or if it is still necessary the health care providers and assurance system should be aware of higher index operation costs and reinterventions of EVAR. Another important aspect is to have the consent of a patient by sharing the probability of a reintervention and emphasizing the importance of follow up on high-risk EVAR.

Interestingly by comparing the results of an operator experience less or higher than 50 cases, with the need for reintervention, we found no correlation ($p>0.05$). The operator experience had a high weight in the Siena EVAR score and might have affected its predictivity in our study.

A significant correlation between associated costs and iliac artery diameter was found in our results, on the other hand, no correlation with aneurysm diameter, creatinin clearance, neck length, diameter, and angulation was present. SGVI score is based only on aortic and iliac diameter and it is easier to calculate than previously suggested anatomic scores(Best et al.,

2016). These results show that EVAR is a technical issue related to the morphologic parameters of the patient. The extent of aortoiliac aneurysm predicts the outcomes.

5. Conclusion

This retrospective analysis suggests that to assess the feasibility of open repair in suitable patients with high-risk SGVI score can reduce an economic burden, and reduce aneurysm related adverse events. Although the patient population was not large enough to make a definite conclusion for all of the patients undergoing EVAR, still we believe that SGVI scoring is a promising system for predicting cost-effectiveness in EVAR.

Declerations:

The authors declare no conflict of interest. The authors declared that this study has received no financial support. Kocaeli University Clinical Research Ethics Committee approval was obtained for the study protocol. (01/09/2015 Project nr: KOÜ KAEK 2015/278; 10.11.2019). During the research, the authors acted in accordance with the Helsinki declaration. Authorship contribution: Ideas: AAA, ŞY, KTB; Design: AAA, ŞY, KTB; Inspection: AAA, ŞY, KTB; Resources: AAA, ŞY, KTB; Materials: AAA, ŞY, KTB; Data collection and/or processing: AAA, ŞY, KTB; Analysis and/or interpretation: AAA, ŞY, KTB; Literature research: AAA, ŞY, KTB; Writing: AAA, ŞY, KTB; Critical review: AAA, ŞY, KTB.

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Table 1. Demographic characteristics

Arterial hypertension	24 (61,5%)
Diabetes mellitus (type II)	10 (25,6%)
Active smokers	14 (35,8%)
Coronary artery disease	17(43,5%)
Chronic renal failure	6 (15,3%)
Chronic obstructive pulmonary disease	13(33,3%)

Numbers of patients and percentages among the study population are given.

Table 2. Morphologic measurements

Mean aneurysm diameter	68,7 ±13,7 mm
Mean aortic neck length	25±13 mm
Median iliac artery diameter	15 mm (IQR: 12-19mm),
Mean neck diameter	25,7±4,4mm
Mean neck angulation	25,7±4,4mm

Expressed as ± standard deviation or IQR (interquartile range).

Table 3. Validation for Complications

	Siena EVAR Score			St George Vascular Institute Score		
	Low risk	Moderate risk	P-value	Low risk	High risk	P-value
Complication (+)	4	11	0,5439	5	10	0,0005*
Complication (-)	10	12		22	2	

*Two-tailed Chi-squared Continuity Correction is used. *: A significant relation between SGVI Score risk groups and the complications was present. Complication: complications needing treatment with adjunct procedures on index operation and/or reintervention during follow up. Complication (+): the presence of any complications. Complication (-): the absence of a complication. SGVI: St. George Vascular Institute.*

Table 4. Validation for Reinterventions

Follow up	Siena EVAR Score			St,George Vascular Institute Score		
	Low risk	Moderate risk	P-value	Low risk	High risk	P-value
Reintervention (+)	2	5	0,9911	1	6	0,0025*
Reintervention (-)	12	20		26	6	

*Two-tailed Chi-squared Continuity Correction is used. *: A significant relation between SGVI Score risk groups and reintervention was present. Reintervention (+): intervention on follow up due to an EVAR related complication, limited to follow up period. Reintervention (-): No intervention on follow up was needed. SGVI: St. George Vascular Institute.*

Table 5. Validation for Mortality

	Siena EVAR Score			St,George Vascular Institute Score		
	Low risk	Moderate risk	P-value	Low risk	High risk	P-value
Mortality (+)	1	3	0,6315	0	4	0,0095*
Mortality (-)	13	22		27	8	

**Chi-Square Tests Fisher's Exact Test is used. A significant relation between SGVI Score risk groups and mortality was present. Mortality (+): Presence of aneurysm related mortality. Mortality (-): Absence of aneurysm related mortality. SGVI: St. George Vascular Institute.*

Table 6. Validation for Cost

	Siena EVAR Score			St,George Vascular Institute Score		
	Low risk	Moderate risk	P value	Low risk	High risk	P value*
Index Cost	26106 (24113-29828)	29232 (25156- 32265)	0,298	25452 (23462- 30337)	29733 (27090- 39069)	0,0101
Total cost	26970 (24113-41282)	30130 (25196- 40697)	0,592	25665 (23432 -30471)	48607 (28511- 61499)	<0,001

*Mann Whitney U test is used. Values are expressed as s median values and 25-75 percentiles as Turkish Lira. * A significant relation between SGVI Score risk groups and index cost and/or total cost was present. Index cost: cost of the index procedure. Total cost: Index procedure and reinterventions during follow-up. SGVI: St. George Vascular Institute.*