Looking for a Learning Curve in EVAR Based on the Zenith Stent Graft

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Abstract

Keywords

- ▶ abdominal aortic aneurysm
- ▶ endovascular repair
- ▶ endovascular procedure
- ▶ EVAR
- ▶ learning curve
- ▶ Zenith stent graft
- ▶ early results

The purpose of this study was to report the learning curve of endovascular aneurysm repair (EVAR) based on the Zenith stent graft (Cook Medical Inc., Bloomington, IN). In the last 9 years, 101 patients were treated with a Zenith stent graft. To display the learning curve, a cumulative sum (CUSUM) failure analysis curve of the 30-day technical success rate was calculated. For detailed analysis, our EVAR patient cohort was chronologically divided into three groups. Technical and clinical results, basic patient parameters, and procedural data were compared. The CUSUM graph indicated an initial sharp rise within the first 35 cases and a plateau thereafter. The 30-day technical success rate significantly increased from the first to the second group (83 vs. 100%; $p = 0.019$), as did the primary technical success rate (66 vs. 97%; $p = 0.001$). EVAR based on the Zenith stent graft required ~35 cases to reach a stably high rate of short-term technical success.

Endovascular aneurysm repair (EVAR) was introduced in the 1990s as a less invasive treatment option for high-risk abdominal aortic aneurysm (AAA) patients. Since stent grafts have become commercially available, EVAR has been widely adopted because of its minimally invasive character and low operative risk. However, EVAR is a rather sophisticated procedure, and in addition to the risk of major complications, various problems can cause technical or clinical failure in the short or long term.

Since the year 2001, the Zenith stent graft (Cook Medical Inc., Bloomington, IN) was the device of choice for EVAR at our institution. The Zenith graft was used in 101 of 106 procedures performed in the last 9 years. We now analyzed the results of all patients treated with a Zenith stent graft to look for the presence of a learning curve. We also examined the incidence of aneurysms, demographic/anatomic characteristics of the patients, and changes in indication for EVAR.

The purpose of the present study was to report the learning curve of Zenith stent graft–based EVAR procedures and to analyze recent trends in the management of AAA patients in a nonacademic vascular center.

Methods, Materials, and Patients

This study was approved by the local ethics committee. It was performed in strict accordance with the definitions and recommendations given by the reporting standards for AAA repair.¹

EVAR was introduced in our community-based vascular center in 1997. However, until 2000, this treatment was used rather infrequently and only for very high-risk patients. The Talent stent graft (Medtronic Inc., Santa Rosa, CA) was used for these early procedures. There were two cases of lethal complications and several cases of early graft failure due to distal migration within this cohort.

After a personnel change in the department of interventional radiology in January 2001, a team of two experienced interventional radiologists performed the EVAR procedures with increasing frequency, using the Zenith stent graft almost exclusively. ▶ **Fig. 1** gives detailed information about the numbers of AAAs treated electively at our institution within the past 15 years.

After exclusion of five patients treated with an Excluder stent graft (L.W. Gore Inc., Flagstaff, AZ), the results of the 101

Fig. 1 The number of electively treated AAAs in our institution within the past 15 years. The quadrates represent the number of open repairs, which declined since the introduction of endovascular repair (triangles). In the last 3 years, this trend has reversed. The clear increase in the overall numbers (diamonds) is predominantly a result of the increasing number of endovascular procedures.

patients treated with the Zenith stent graft between January 2001 and January 2010 were retrospectively analyzed to look for the presence and configuration of a learning curve.

The 30-day technical success rate, which was exactly identical to the 30-day clinical success rate in our cohort, was analyzed as the primary endpoint. To display the learning curve of this parameter, the cumulative sum (CUSUM) method was used. This method was developed as a mathematical tool for quality control. It has been used in the analysis of learning curves of medical procedures by other authors^{2,3} and is well suited to analyze a learning curve of vascular and endovascular procedures.^{4,5}

To retrospectively analyze the learning curve, we applied a describing CUSUM graph.⁶ This curve may be easily interpreted visually because it rises with every failure. Successes are represented by flat sections of the line. For comparison, a straight line representing a constant failure distribution was drawn. Both lines end at 6.9%, which was the actual final failure rate in our study. Hence, a rise of the CUSUM curve over the straight reference line indicates an increased failure rate in the corresponding time. A CUSUM test including alert and alarm boundaries was not applied because, in our opinion, the arbitrary constitution of boundaries is not appropriate in the retrospective setting.

Table 1 Demographic data and comorbidities

Variable	Group 1	Group 2	Group 3	p value ^a
Age, y, median (range)	72 (51–83)	69 (36–81)	72 (57–87)	ns
Patients over 75 y (%)	29	20	39	ns
ASA class 1 or 2 patients (%)	23	31	19	ns
Preoperative creatinine, mg/dL (median)	1.3	1.2	1.1	ns
Aneurysm diameter, mm (median)	57	57	59.5	ns
Aneurysm length, mm (median)	80	82	82	ns
Adverse neck anatomy (%) ^b	33	31	36	ns
Iliac artery aneurysm (%)	34	31	42	ns

Abbreviations: ASA, American Society of Anesthesiologists; ns, nonsignificant; y, years.

^aEach group was tested against each other.

^bDeemed positive when one of the following parameters was fulfilled: neck length < 15 mm; neck diameter > 27 mm; neck angle > 60°; severe circumferential calcification; and inverse funnel-shaped neck.

Fig. 2 The gray line represents the actual CUSUM curve of our patient cohort. The black reference line indicates a hypothetical constantly distributed failure rate. EVAR procedures are plotted in chronological order on the x-axis, and the failure rate in percent is plotted on the y-axis. Each failure causes a rise in the curve, whereas successful procedures are represented by a flat line. CUSUM, cumulative sum.

Subsequently, the whole cohort was divided into three groups of equal size based on treatment date. Group 1 included 34 patients treated between January 2001 and August 2004; group 2 included 34 patients treated between September 2004 and March 2007; and group 3 included 33 patients treated between April 2007 and January 2010.

The results of the first group were compared with the later groups under the assumption that a learning curve would be reflected in significantly inferior results among patients in the first group. In addition, baseline demographic and clinical parameters were compared with investigate trends in patient selection for EVAR versus open repair. Finally, procedural details were also analyzed for differences among groups.

Statistics

For statistical analyses, all available data were used. Missing values were not replaced.

Comparisons of Three Subgroups

For metric variables and variables measured on ordinal scales, a nonparametric analysis of variance (Kruskal–Wallis test, $\alpha = 5\%$) was used, including post hoc tests by Nemenyi multiple comparisons. Data from categorical variables were compared by the exact chi-square test ($\alpha = 5\%$).

Comparisons of Two Subgroups

For dichotomous variables, Fisher exact test was used. For metric variables, the *t* test for independent samples (test for normality: Kolmogorov–Smirnov with Lilliefors significance correction, $\alpha = 5\%$) was used.

No adjustment for the type I error was made; therefore, the relevant *p* values are only descriptive.

Unless otherwise mentioned, descriptive data in the text reflect medians and quartiles (in brackets).

For all calculations except the CUSUM curve, PASW Statistics 18 (SPSS Inc., IBM Company Headquarters, Chicago, IL) was used. The CUSUM curve was calculated with CARDIAC Software (s2 Engineering, Steyr-Gleink, Austria).

Results

Among the three groups, there were no significant differences in baseline clinical characteristics, including demographic data and comorbid conditions. Details of baseline patient characteristics are shown in ►Table 1. However, upon closer examination of the data, changes in the pattern of use of EVAR became evident. Initially, EVAR was used only for very high-risk patients. With time, patient selection for EVAR has become increasingly liberal. Consequently, median age of the EVAR patients decreased, and the proportion of EVAR patients without severe comorbidities increased from group 1 to group 2. During this time, the number of open aneurysm repairs performed at our institution also declined. Only within the last few years has this trend begun to reverse.

There was a trend toward performing more complex procedures among the last third of patients, with a particular increase in the number of additional procedures such as hypogastric artery embolization. This was accompanied by a significant increase in intervention and fluoroscopy time in group 3 after the intervention time had decreased with increasing experience from group 1 to group 2. The incidence of complications decreased with increasing experience ($n = 4$ vs. 0 vs. 1) but due to the small absolute numbers, this trend was not statistically significant.

In terms of the primary endpoint, 30-day technical success, the CUSUM graph clearly indicated a learning effect. Technical failures accumulated at the beginning. This was represented by a sharp increase in the CUSUM curve until

Table 2 Procedural data

	Group 1	Group 2	Group 3	Group 1 vs. group 2	Group 1 vs. group 3	Group 2 vs. group 3
Variable						
Operation time, min (median)	117	101	125	$p = 0.04$	ns	$p = 0.001$
Contrast load, mL (median)	150	132	160	ns	ns	ns
Fluoroscopy time, min	16	14	23	ns	$p = 0.02$	$p = < 0.001$
Hypogastric artery embolization (%)	25	11	31	ns	ns	ns
Complication (%)	11	0	3	ns	ns	ns
Postimplantation syndrome ^a	85	82	65	ns	ns	ns
Results						
30-day mortality	0	0	0	ns	ns	ns
30-day technical success (%)	83	100	95	$p = 0.019$	ns	ns
Primary technical success (%)	66	97	86	$p = 0.001$	ns	ns

Abbreviations: min, minutes; ns, nonsignificant.

^aElevated temperature and leukocytosis after implantation.

~35 procedures. After a bend at this point, the curve was rather flat in the latter two-thirds, ending at a cumulative failure rate of 6.9% (►Fig. 2). In statistical testing of the groups against one another, 30-day technical results among patients in group 2 proved to be significantly superior to those of group 1 ($p = 0.019$). However, for group 3 versus group 1, the difference was not statistically significant. Even higher significance was present in the comparison between group 1 and group 2 for the primary technical success rate immediately after stent graft placement ($p = 0.001$). ►Table 2 provides further details.

Discussion

Data from the EUROSTAR registry, which reported on a large cohort of ~2,800 patients, strongly suggest that there is a learning curve in EVAR. Laheij et al reported a correlation between EVAR outcomes and the experience of the interventionalist performing the procedure. Patients treated by the most experienced specialists had a significantly lower mortality ($p = 0.05$) and a 68% lower reintervention rate, compared with patients treated by less experienced teams.⁷

Studies addressing the problem of learning curves in EVAR are scarce in the published literature. However, Forbes et al provided a detailed report on their early EVAR experience; their learning curve showed a turning point at 60 patients.⁸ Later, this group reported that a single surgeon would need ~20 cases to reach optimal results in an experienced environment.⁹ They did not find differences in the learning curve for different devices.

The present study is, to our knowledge, the first to report the specific learning curve for the Zenith stent graft. As expected, the CUSUM analysis clearly indicated a learning effect; in our cohort, results significantly improved after ~35 procedures. Our basic patient and procedural data also indicate that indications for EVAR change with time among AAA patients. When EVAR was first used at our institution, it was

reserved only for high-risk patients. As the operating physicians grew more comfortable with the procedure, it was extended to younger and standard-risk patients. However, with growing insights into the limitations and complications of EVAR, patient selection improved, and the number of EVAR procedures performed declined slightly. This may represent the typical course of implementation for a new minimally invasive procedure.

In summary, the implementation of EVAR has clearly improved treatment options for older and high-risk patients with AAAs. In our institution, the number of patients treated using EVAR doubled within the past 15 years. Within the past 10 years, the majority of AAA patients were treated endovascularly (►Fig. 1). To further improve patient selection and outcomes for EVAR and given new technical possibilities such as branched grafts, randomized controlled trials of new interventional techniques are necessary. The learning curve should be considered in the planning of such trials.

Conclusions

A learning curve was present in EVAR procedures using the Zenith stent graft. The short-term technical success rate significantly increased after ~35 cases and was constant thereafter.

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