Predicting Outcomes for Cerebral Aneurysms Treated with Flow Diversion: A Comparison Between 4 Grading Scales

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■ OBJECTIVE: **Despite the development of 4 grading scales of angiographic outcome after flow diversion for cerebral aneurysms, none have been widely adopted in the neurosurgical literature, nor have any been validated in an independent dataset. We evaluated the reported grading scales for their ability to predict aneurysm occlusion at follow-up.**

■ METHODS: **Four reported grading scales were applied in a retrospective analysis of our prospectively maintained institutional database of patients with intracranial aneurysms treated with flow-diverting stents. Analysis of patient factors, aneurysm factors, and outcomes was made to compare the grading scales' ability to predict aneurysm occlusion.**

■ RESULTS: **Ninety-nine aneurysms in 90 patients treated at our institution between 2011 and 2018 were included in the analysis. Lower Flow-Diverting Stent Score (FDSS) scores were associated with higher rates of aneurysm occlusion at final follow-up ($P = 0.004$). The OKM, Kamran-Byrne, and SMART scales scores were not associated with aneurysm occlusion at final follow-up even after adjustments for baseline differences. Area under the receiver operating characteristic curve for the FDSS was 0.675 (0.534–0.816).**

■ CONCLUSIONS: **Although the FDSS was the only reported grading scale that was significantly associated with occlusion at follow-up, its ability to predict occlusion fell below the typical level for widespread clinical utility. The high rate of eventual occlusion of most aneurysms after flow diversion likely limits the clinical utility of a grading score for this application.**

INTRODUCTION

Flow diversion has become increasingly used in the treatment of intracranial aneurysms.[1-3] In an attempt to standardize the evaluation of aneurysm treatment with flow diversion, several grading scales were proposed shortly after their introduction into clinical practice. These 3 scales—the O'Kelly Marotta (OKM),[4] Kamran-Byrne,[5] and Simple Measurement of Aneurysm Residual after Treatment (SMART)[6] scales—were descriptive in nature and were based on factors presumed to be important in the treatment of aneurysms by flow-diverting stents. Interrater reliability of these scales was variable,[7] and they have not been widely used in the literature. These scales were developed based on factors assessed before or immediately after treatment. Conversely, the Flow-Diverting Stent Score (FDSS) was developed based on multivariate analysis of factors predictive of occlusion after flow diversion.[8]

For any clinical relevancy, grading scales must be reliable, be applicable to everyday clinical practice, and have predictive value for treatment-related risk or angiographic and clinical outcome. To assess the predictive value of these 4 existing grading scales in the evaluation of intracranial aneurysms after treatment with flow diversion, we performed an independent objective validation study by applying the scales to our prospective institutional database of patients treated with flow-diverting stents for cerebral aneurysms.

Key words
- Aneurysm
- Endovascular
- Flow diversion
- Outcomes

Abbreviations and Acronyms
AUC: Area under the curve
CI: Confidence interval
FDSS: Flow-Diverting Stent Score
ICA: Internal carotid artery
OKM: O'Kelly Marotta
OR: Odds ratio
ROC: Receiver operating characteristic
SMART: Simple Measurement of Aneurysm Residual after Treatment

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Table 1. Published Grading Scores for Aneurysms Treated with Flow Diversion

Grading Score	Components and Determination	Score
FDSS Scale: Park MS, et al.[8]	Initial Raymond score after treatment	
	Raymond score 1	1
	Raymond score 2	2
	Raymond score 3	3
	Aneurysm size	
	<15 mm	0
	>15 mm	1
	Presence of side branches	
	No	0
	Yes	1
	Patient age, years	
	<60	0
	>60	1
OKM Scale: O'Kelly CJ, et al.[4]	Initial degree of filling	
	Total filling	A
	Subtotal filling	B
	Entry remnant	C
	No filling	D
	Degree of stasis	
	Arterial	1
	Capillary	2
	Venous	3
Kamran-Byrne Scale: Kamran M, et al.[5]	Axis I: Degree of aneurysm occlusion*	
	No change in flow	0
	Residual >50%	1
	Residual <50%	2
	Neck remnant	3
	No filling	4
	Axis II: Patency status of parent artery	
	No change	A
	Narrowing	B
	Occlusion	C
SMART Scale: Grunwald IQ, et al.[6]	Arterial phase	
	Early coherent jet	0
	Venous phase	
	Patent	1
	Unsecured wall/dome	2
	Secured wall	3
	Occluded	4
	In-stent stenosis (ISS)	
	No ISS	0
	Mild, not significant	1
	Moderate, 50—70	2
	Severe >70%	3
	Occlusion	4

FDSS, Flow-Diverting Stent Score; OKM, O'Kelly Marotta; SMART, Simple Measurement of Aneurysm Residual after Treatment.
*Grade outlined for saccular aneurysms; a slightly different classification is outlined for fusiform aneurysms.

MATERIALS AND METHODS

Data Collection and Patient Population

A prospective database of all patients treated for cerebral aneurysms was queried for all aneurysms treated with flow diversion between July 2011 and January 2018. Demographics (age, sex, comorbidities, smoking status), aneurysm characteristics (size, aneurysm type, location, ruptured status, relationship to branch vessels), and treatment characteristics (previous treatment, treatment strategy, inclusion of coil embolization, Raymond score, clinical and angiographic follow-up) were collected. Additionally, procedural and follow-up angiographic images were assessed in a retrospective fashion according to the requirements of the 4 disparate grading scales (the Raymond score filling of the aneurysm dome, contrast stasis within the aneurysm, and the presence and extent of in-stent stenosis). Assessment of outcome was performed by the primary author (D.R.) and was corroborated by review of imaging reports by the proceduralist who performed follow-up angiography. The reviewer was not blinded to final occlusion but assessed the imaging follow-up chronologically. Patients without angiographic follow-up were excluded from the analysis, and a minimum of 3 months' follow-up was required for inclusion in the analysis.

Antiplatelet therapy consisted of a standardized protocol. For unruptured cases, patients were given dual antiplatelet therapy (aspirin 325 mg and clopidogrel 75 mg daily) 5 to 10 days before the planned procedure. Platelet function assays (Accumatrix VerifyNow) were performed before the procedure, and nonresponders were treated with alternative antiplatelet agents, selection of which was at the discretion of the treating physician. For ruptured cases, dual antiplatelet therapy was commenced upon stent placement, and the efficacy of platelet inhibition confirmed by similar assays. Dual antiplatelet therapy was continued for 6 months, followed by lifelong aspirin therapy.

Classification/Grading Scores and Outcomes

The aneurysms included in this cohort were classified according to 4 different published grading scores, which are described in detail in the referenced publications (Table 1).[4-6,8] Inasmuch as these grading scales were intended to be used for all intracranial aneurysms treated by flow diversion, no subgroup analyses based on aneurysm location or other factors were performed. Follow-up was assessed based on the time point of latest angiogram.

Statistical Analysis

All statistical analyses were performed using with Stata (version 14.2; StataCorp; College Station, Texas, USA). All analyses were performed on a per aneurysm basis, and aneurysms were dichotomized based on occlusion at final follow-up (occlusion and no-occlusion groups). Patients with aneurysms that did not occlude but were subsequently treated with subsequent flow diverter placement were censured at the time of second treatment, were considered in the no-occlusion group, and were not recounted even if their aneurysms went on to eventually occlude. Baseline characteristics were compared between occlusion and no-occlusion groups. Continuous and categoric variables were compared with the Student t test or the Mann-Whitney U test and the Pearson χ^2 or the Fisher exact tests, respectively, where appropriate. Univariable binary logistic regression was performed on the groups to assess the relationship between aneurysm occlusion and prediction scores. The findings from the logistic regression analysis were adjusted for covariates of the groups with $P < 0.10$.

To assess the performance of the scoring systems in predicting aneurysm occlusion, parametric receiver operating characteristics (ROC) curves were generated, and the areas under the ROC curves (AUC) were calculated using trapezoidal approximation, and ties were corrected using linear interpolation. Confidence interval estimates were obtained using 1000 bootstrap replications. Subsequently, the ROC curves and corresponding AUC curves were adjusted for covariates of the groups with $P < 0.10$ using linear regression models. An AUC curve of 0.5 indicates no discrimination, and an AUC curve of 1.0 indicates perfect discrimination. The AUC curves were compared. Statistical significance was defined as $P < 0.05$, and all tests were 2-tailed. Missing data were not imputed.

RESULTS

Demographics

The study cohort comprised 103 patients with 125 aneurysms treated by flow diversion between July 2011 and January 2018. Thirteen patients and 26 aneurysms were excluded from the final analysis for the following reasons: extracranial aneurysm location in 5 patients, no available imaging or clinical follow-up after stent placement in 8 patients, and aneurysm rupture immediately after pipeline embolization device (PED) placement with subsequent death in 1 patient. Six patients who were included in the analysis had multiple aneurysms not covered by the flow diverter device, and these 10 additional aneurysms were not included in the analysis. The remaining 99 aneurysms in 90 patients were included in the final analysis. Table 2 outlines baseline patient and aneurysm characteristics in our cohort. Prior treatment had been performed at an earlier hospitalization in 17 patients and consisted of simple coiling in 13 cases, stent-assisted coiling in 2 cases, and clipping in 2 cases. The locations of aneurysms treated with flow diversion in our series were as follows: cavernous internal carotid artery (ICA) 20%; paraophthalmic 11%; paraclinoid ICA 41%; posterior communicating artery 6%; anterior choroidal 5%; ICA terminus 8%; middle cerebral artery 1%; posterior cerebral artery 3%; and superior cerebellar artery 5%. In this series, 92.2% of patients had unruptured aneurysms that were treated with flow diversion. In our cohort, 93% of patients received maintenance with dual antiplatelet therapy for 6 months after treatment, with aspirin and clopidogrel. Other antiplatelet regimens used in a minority of patients included clopidogrel only in cases of aspirin allergy, and aspirin with prasugrel or ticlopidine in cases of clopidogrel nonresponse.

Table 2. Comparison of Baseline Characteristics in Patients Treated with Flow Diversion for Intracranial Aneurysms

Characteristic	Total (N = 90)
Patient characteristic	
Age, mean, years (SD)	55 (12.8)
Male, number (%)	15 (16.7)
Smoking, number (%)	59 (65.6)
Hypertension, number (%)	39 (43.3)
Presentation with SAH (%)	7 (7.8)
Aneurysm characteristics	
Total aneurysms, number	99
Prior treatment, number (%)	17 (17.2)
Maximum aneurysm diameter, mean, mm (SD)	10.0 (6.9)
Aneurysm neck diameter, mean, mm (SD)	6.7 (5.9)
Fusiform aneurysm, number (%)	26 (26.3)
Coils used, number (%)	2 (2.0)
Number of PED used, median (IQR)	1 (1—1)
Follow-up, mean, months (SD)	28.4 (22.3)
Aneurysms occluded at last follow-up, number (%)	65 (65.7)

SD, standard deviation; SAH, subarachnoid hemorrhage; PED, pipeline embolization device; IQR, interquartile range.

There were no significant differences in baseline patient or aneurysm characteristics between those who achieved complete occlusion and those who did not, with the exception that follow-up for aneurysms that achieved occlusion were longer compared than were those for aneurysms that did not achieve occlusion (mean 31.6 vs. 20.9 months, $P = 0.014$). Other baseline characteristics including age, sex, history of smoking, history of hypertension, prior aneurysm treatment, aneurysm rupture status, aneurysm morphology and dimensions, use of coils, and number of PED used were comparable between the 2 groups.

Grading Scale Performance in Predicting Complete Occlusion

Table 3 demonstrates the relationships between aneurysm grading scales/scores for PED placement and aneurysm occlusion at final follow-up.

Table 3. Relationship Between Prediction Scores and Aneurysm Occlusion

Prediction Score	OR (95% CI)	*P* Value	Adjusted OR (95% CI)*	Adjusted *P* Value*
FDSS	0.436 (0.248—0.767)	0.004	0.343 (0.181—0.652)	0.001
OKM Scale (method 1)†	0.856 (0.680—1.077)	0.185	0.836 (0.655—1.067)	0.149
OKM Scale (method 2)‡	0.888 (0.746—1.057)	0.181	0.889 (0.743—1.065)	0.203
Kamran-Byrne Scale	0.775 (0.479—1.253)	0.298	0.728 (0.442—1.198)	0.212
SMART Scale	0.720 (0.357—1.450)	0.357	0.623 (0.299—1.299)	0.207

OR, odds ratio; CI, confidence interval, FDSS, Flow-Diverting Stent Score; OKM, O'Kelly Marotta; SMART, Simple Measurement of Aneurysm Residual after Treatment.
*Adjusted for covariates of fusiform aneurysm and follow-up.
†The score was analyzed as ascending scale of A1, A2, A3, B1, B2, B3, C1, C2, C3.
‡The score was analyzed as ascending scale of A1, B1, C1, A2, B2, C2, A3, B3, C3.

Lower FDSSs were associated with higher rates of aneurysm occlusion at final follow-up (odds ratio = 0.436 [0.248—0.767], P = 0.004). This association remained significant after adjustments for baseline differences in fusiform aneurysm morphology and follow-up period (odds ratio = 0.343 [0.181—0.652], P = 0.001). Other grading scales/scores, including the OKM, Kamran-Byrne, and SMART scales, were not associated with aneurysm occlusion at final follow-up, even after adjustments for baseline differences. Aneurysm occlusion rates at final follow-up for the FDSS were 82.8%, 78.7%, 62.5%, and 16.7% for scores of 3, 4, 5, and 6, respectively (Figure 1A). Aneurysm occlusion rates for the OKM grading scale, when analyzed in ascending order of initial degree of aneurysm filling after PED placement, were 87.5%, 66.7%, 70.7%, 0%, 50%, 72.2%, and 50% for grades of A1, A2, A3, B1, B2, B3, and C3, respectively (OKM method 1, Figure 1B). When the same grading scale was analyzed in ascending order of degree of stasis after PED placement, aneurysm occlusion rates were 87.5%, 0%, 66.7%,

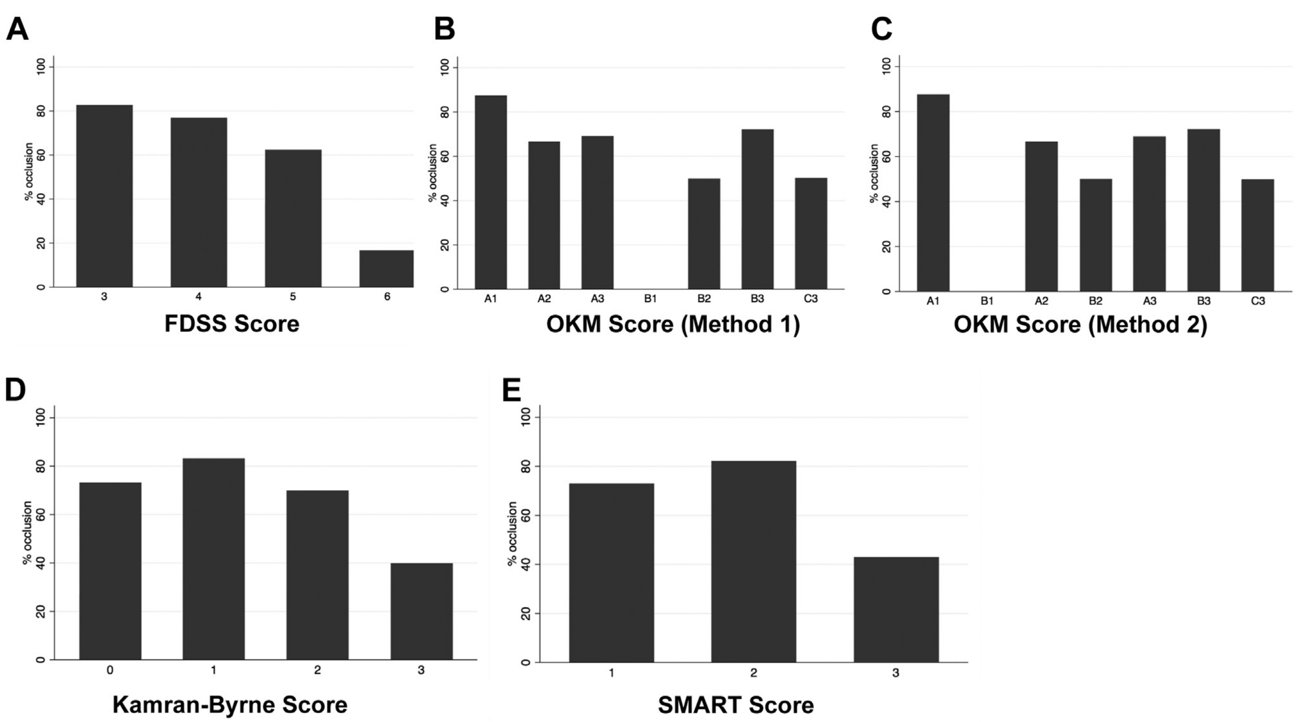

Figure 1. Complete occlusion after flow diversion for intracranial aneurysms, analyzed by initial score on the FDSS, OKM, SMART, and Kamran-Byrne grading scales. The OKM score (method 1) was analyzed as ascending scale of A1, A2, A3, B1, B2, B3, C1, C2, C3. The OKM score (method 2) was analyzed as ascending scale of A1, B1, C1, A2, B2, C2, A3, B3, C3. FDSS, Flow-Diverting Stent Score; OKM, O'Kelly Marotta; SMART, Simple Measurement of Aneurysm Residual after Treatment.

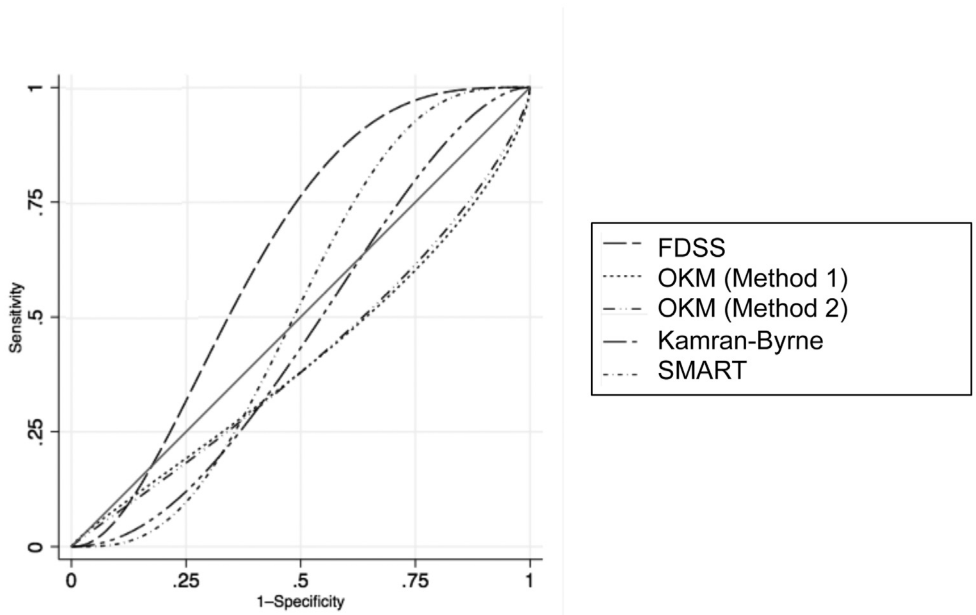

Figure 2. Performance of grading scales in predicting aneurysm occlusion. Area under receiver operating characteristics curves for the FDSS, OKM (analyzed in ascending order of initial degree of aneurysm filling), OKM (analyzed in ascending order of degree of stasis), Kamran-Byrne, and SMART scales were 0.638 (0.510—0.767), 0.407 (0.293—0.522), 0.409 (0.293—0.525), 0.463 (0.347—0.578), and 0.513 (0.403—0.624), respectively. FDSS, Flow-Diverting Stent Score; OKM, O'Kelly Marotta; SMART, Simple Measurement of Aneurysm Residual after Treatment.

50%, 70.7%, 72.2%, and 50% for grades of A1, B1, A2, B2, A3, B3, and C3, respectively (OKM method 2, Figure 1C). Aneurysm occlusion rates at final follow-up for the Kamran-Byrne score were 74.3%, 83.3%, 70%, and 40% for scores of 0, 1, 2, and 3, respectively (Figure 1D). Aneurysm occlusion rates at final follow-up for the SMART scale were 74%, 82.4%, and 42.9% for scores of 1, 2, and 3, respectively (Figure 1E).

Performance of these grading scales/scores in predicting aneurysm occlusion is illustrated by the ROC curves in Figure 2. AUC curves for the grading scales/scores of FDSS, OKM method 1, OKM method 2, Kamran-Byrne, and SMART scales were 0.638 (0.510—0.767), 0.407 (0.293—0.522), 0.409 (0.293—0.525), 0.463 (0.347—0.578), and 0.513 (0.403—0.624), respectively. AUC curves were comparable among these grading scales/scores ($P = 0.066$). Performance of these grading scales/scores in predicting aneurysm occlusion, after adjustments for baseline differences in fusiform aneurysm morphology and follow-up period, is illustrated by the ROC curves in Figure 3. Covariate-adjusted AUC curves for the FDSS, OKM method 1, OKM method 2, Kamran-Byrne, and SMART scales, respectively, were 0.675 (0.534—0.816), 0.337 (0.204—0.470), 0.390 (0.244—0.536), 0.348 (0.173—0.523), and 0.371 (0.197—0.544). Covariate-adjusted AUC curves were not statistically significant among these grading scales/scores ($P = 0.070$).

DISCUSSION

Simple grading scales allow standardization in the assessment of any treatment modality, giving clinicians a common language with which to discuss its application, results, and complications. Perhaps more importantly, grading scales should provide some predictive power to help guide management decisions. The only grading scale for flow diversion that was based on a multivariate analysis of outcomes is the FDSS,[8] which has not been validated objectively in an independent patient cohort. To validate this grading scale, we applied it in a retrospective manner to our prospectively maintained database of patients treated with flow-diverting stents. In addition, we compared the FDSS, SMART, OKM, and Kamran-Byrne scales to determine which grading scale has the best predictive power for eventual aneurysm occlusion.

Our validation cohort demonstrated that lower FDSS scores were significantly associated with higher rates of occlusion at follow-up, which remained significant after adjustments for baseline differences in fusiform aneurysm morphology and follow-up period. In comparison, the OKM, Kamran-Byrne, and SMART grading scales were not associated with predictable changes in occlusion at follow-up. Indeed, in our multivariate analysis, apart from the FDSS, all other scales were not predictive of occlusion. Statistical methods were not used in the development of any scale apart from the FDSS, so it is not unreasonable to find that these

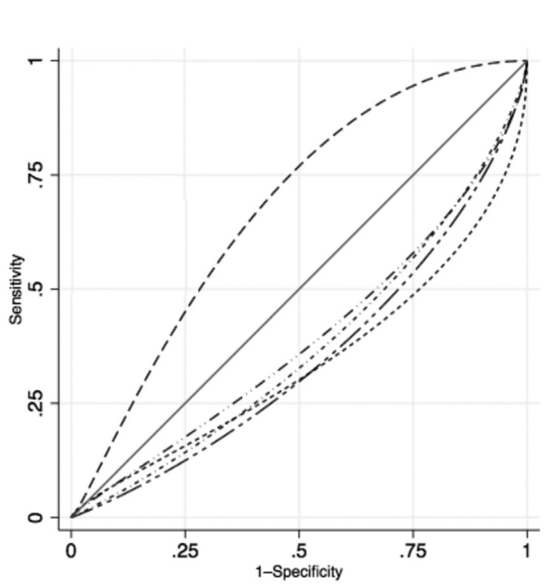

Figure 3. Performance of grading scales in predicting aneurysm occlusion, after adjustments for baseline differences in fusiform aneurysm morphology and follow-up period. Covariate-adjusted area under receiver operating characteristics curves for the FDSS, OKM (Method 1), OKM (Method 2), Kamran-Byrne, and SMART scales were 0.675 (0.534—0.816), 0.337 (0.204—0.470), 0.390 (0.244—0.536), 0.348 (0.173—0.523), and 0.371 (0.197—0.544), respectively. FDSS, Flow-Diverting Stent Score; OKM, O'Kelly Marotta; SMART, Simple Measurement of Aneurysm Residual after Treatment.

scores are in fact not predictive and, after covariate adjustments, possibly even worse than guessing. The 95% confidence interval of the OKM, Kamran-Byrne. and SMART scores crosses 0.5 and thus approximates random chance. Although these scales were developed using components initially thought to be important in the assessment of efficacy of flow diversion, it is likely that other factors in the multivariate analysis combined to more accurately predict occlusion. However, it remains a possibility that patient factors in our cohort influenced the validation of the grading scales in this study.

In the original description of the FDSS, a score of 4 or greater was associated with a lower rate of complete occlusion on an assessment of sensitivity and specificity. In an analysis of our independent cohort, patients with a residual had an average FDSS score of 4.4 ± 0.9, whereas those with complete occlusion had an average score of 3.9 ± 0.7 ($P < 0.01$); that is, a cutoff score of 4 does not appear to be useful in this analysis. Of the 32 residual aneurysms, 28 had a score of ≥ 4 (sensitivity 84.4%). A cutoff score of 4 on the FDSS resulted in a specificity of 33.8% and a positive predictive value of 38.6%. This is somewhat lower than the sensitivity of 97.8%, specificity of 50.9%, and positive predictive value of 40.5% stated in the original FDSS report.[8] These differences may partially be due to a higher number of patients with an initial score of 4 who went on to experience complete occlusion; among patients with an initial FDSS of 4, 69% went on to experience complete occlusion and 31% did not. Despite having a significant association with occlusion rates, the FDSS score performed inadequately in an AUC assessment of predictive value (0.638 unadjusted; 0.675 adjusted). The AUC is 0.5 when the predictive value of a diagnostic test is as good as random chance.[9] An AUC of <0.8 is generally not considered an optimal test for clinical use. This relatively poor predictive performance may, in part, be due to other prognostic factors not identified in the initial development of the FDSS. In other large retrospective series of aneurysms treated with flow diversion, predictors of eventual occlusion included previous stent placement[10-12] and adjunctive coil embolization.[13,14] The FDSS did identify the presence of side branches to be a significant factor in predicting final occlusion.[8] However, the size of the covered side branch, particularly in relation to inflow from other vessels in the circle of Willis, may also be important factors in progression to eventual aneurysm occlusion.[15] In addition, occlusion rates for intracranial aneurysms treated with flow diversion are generally high, with large series reporting rates of 85% to 100% for large or giant ICA aneurysms,[16] 65% to 100% for distal anterior circulation aneurysms[3,17-23] and 80% to 100% for posterior circulation aneurysms.[1,24-27] Series with longer follow-up times have demonstrated progressive occlusion over time in most cases.[28,29] With occlusion rates of over 80%, especially for aneurysms with long follow-up times, a predictive test performed at the time of treatment might not be able to identify what may be quite small differences between success and treatment failures.

Another important aspect of the assessment of grading scales is interrater reliability. The interrater reliability was assessed in the initial publications of the FDSS[8] and Kamran-Byrne scales.[5] A separate independent assessment of the interrater reliability of the OKM, SMART, and Kamran-Byrne scales was found to be relatively poor, which was attributed to the complexity of the assessment components.[7] Because of this, assessment of outcome was performed by a single practitioner (D.R.); although this may have introduced observer bias, interrater variability in grading scale assignment was minimized. Together, these factors may help explain why the scales have not been widely accepted in the neurointerventional literature.

Limitations of this study include the relatively small number of patients, which, combined with the large number of variables in the scoring systems, limits the universal application of our findings. Additionally, heterogeneous follow-up was performed, according to individual practitioner discretion. We did not use a time-specific metric to determine aneurysm occlusion, rather determining treatment failure based on ultimate aneurysm occlusion irrespective of time. Although there have been calls for a more standardized imaging follow-up protocol,[28] to date, these calls have been unheeded. We did find that follow-up for aneurysms that achieved occlusion were significantly longer than for those that did not achieve occlusion, which likely reflects a bias favoring occlusion in aneurysms simply followed up for a longer time after intervention. However, mean follow-up times in both groups (20.9 months in the no-occlusion and 30.6 months in the occlusion groups) was comparable with those in other series providing statistical comparisons of outcomes after flow diversion.[10-14] To create an objective statistical comparison between grading scales, several assumptions were required. The OKM scale, in particular, is a grid of possible scores, which do not easily fit into an ascending order. Although we analyzed this scale in the 2 ways that were most clinically relevant, several other possible permutations of the statistical analysis were possible. Finally, we did not assess interrater reliability with this endeavor.

CONCLUSIONS

The FDSS was the only grading system significantly associated with aneurysm occlusion after flow diversion in this independent validation study. Whereas the predictive value of the FDSS was superior to that of the OKM, Kamran-Byrne, and SMART systems, the FDSS still had an inadequate covariate-adjusted AUC curve of 0.675 (0.534—0.816). These results likely limit the clinical utility of any of the currently published grading scales.

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