## EXPERIMENTAL RESEARCH

# Simple Measurement of Aneurysm Residual after Treatment: the SMART scale for evaluation of intracranial aneurysms treated with flow diverters

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### Abstract

*Background* Primary endovascular reconstruction with flow diversion represents a fundamental paradigm shift in the technique of endovascular aneurysm treatment. Unlike coil embolization, often there remains residual post-procedural filling within the aneurysm with flow diverters, the curative reconstruction presumably occurring over a period of weeks. Thus, conventional grading scales for post-procedural aneurysm occlusion and recanalization are inadequate. The aim of this paper is to propose a new angiographic grading scale that addresses this fundamentally new treatment option.

*Method* A five-point grading scale describes the location of residual flow within the aneurysm in the venous phase [grade 1: patent aneurysm with diffuse inflow; grade 2: residual filling of the aneurysm dome (saccular) or wall (fusiform);

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A. L. Kühn · M. J. Gounis New England Center for Stroke Research, Department of Radiology, University of Massachusetts Medical School, Worcester, MA, USA grade 3: only residual neck (saccular) or only intraaneurysmal filling with former boundaries covered (fusiform); grade 4: complete occlusion].

*Findings* Grade 0 represents any aneurysm, regardless of occlusion rate with early phase, coherent inflow jet. Intraaneurysmal flow stagnation is categorized into: (a) none, (b) capillary phase, and (c) venous phase. Prevailing parent vessel hemodynamics with in-stent stenosis (ISS) are divided into none (ISS0), mild (ISS1), moderate (ISS2), severe (ISS3), and total (ISS4) occlusion. The proposed grading scales allow assessment of the hemodynamic consequences of stent placement on endosaccular in-flow, stasis, and location of stasis as well as parent vessel hemodynamics.

*Conclusions* Further studies need to show the applicability and possible predictive value of this new grading scale on the

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D. Watson Consultant Biomedical Engineer, San José, CA, USA efficacy of the stent in promoting intra-aneurysmal flow stagnation, thus creating the potential to harmonize the results of future papers. This may help to optimize treatment and future device design.

Keywords Grading scale  $\cdot$  Flow diverter  $\cdot$  Aneurysm  $\cdot$  Endovascular  $\cdot$  Stent

# Introduction

Endovascular treatment of intracranial aneurysms has evolved substantially over the last few years but some important limitations remain. Wide-necked, large and giant, or fusiform aneurysms can frequently be difficult to reconstruct with coils, even when they are used with balloon remodeling or coil supportive intracranial stents, which may lead to recanalization and possible rupture [23].

To further the role of the stent in treatment of intracranial aneurysms, stand-alone devices (flow diverters) for the endovascular reconstruction of a segmentally diseased parent vessel have been developed. Several papers have already been published on the use of flow diverters for aneurysms, and it is likely that many more will follow [1, 3, 5, 6, 18, 21]. As was made possible with the use of the Raymond scale for coil embolizations, a common language is needed for comparison of results with flow-diverter technology [16].

Over the last 2 years this hemodynamic modification of intracranial aneurysms following introduction of flow diverters is increasingly being used. The concept of flow diverters differs fundamentally from predicate endovascular techniques [22].

During conventional aneurysm coiling, the aim is to achieve as dense a filling of the aneurysm as possible in order to reach complete aneurysm occlusion at the time of the initial procedure [2, 14, 22].

Using the concept of flow diversion, the aim is to achieve blood stasis after deployment, which then leads to thrombus formation, resulting in ablation of the residual aneurysmal lumen. Although some aneurysms can improve angiographically (e.g., progressive thrombosis) after coil embolization, a significant proportion recur [7]. One factor in recanalization is compaction of the coil mass within the aneurysm. This compaction is thought to result from pulsatile arterial blood flow exerting pressure on the coil mass.

Typically the immediate post-embolization result will be taken as the angiographic baseline that will either remain stable or progressively deteriorate with time using the Raymond Roy grading scale [15].

In contrast to this, the curative reconstruction that is induced by the flow diverter typically occurs over a period of weeks to months. With flow diverters, commonly and especially after treatment of large and giant aneurysms, residual filling will be noted within the aneurysm after deployment [12].

However, the transit of contrast material into and out of the aneurysm will be variably reduced, often progressing to complete occlusion. Thus angiographic findings are different from those for traditional endosaccular aneurysm occlusion techniques and have to be categorized accordingly, making a new grading scale of aneurysm occlusion necessary [19].

We propose this new angiographic grading scale on the basis of our preliminary experience that takes into consideration the hemodynamic consequences of stent placement on endosaccular flow. In particular, we are looking at inflow characteristics, stasis, and location of stasis within the aneurysm. A second aspect to be considered is the amount of thrombus formation or intimal hyperplasia within the stent.

## Methods and materials

The SMART-scale is simple and consists of a five-point grading scale that can be adapted to both side-wall and fusiform aneurysms. After placement of a flow diverter, residual filling of the aneurysm lumen is typical. However, the pattern of inflow is usually dramatically changed. In particular, the transit of contrast material into the aneurysm is usually transformed. Thus, grade 0 shall be modified with an additional grade-modifier factor (grades a–c) that provides for consideration of the duration of stasis.

Contrary to all previous aneurysm grading scales, this grading scale for assessment of occlusion will be conducted in the venous phase (Fig. 1). In addition, the presence of an inflow jet during the early phase is evaluated.

Five-point grading scheme for assessment of occlusion:

Grade 0: Any aneurysm with an early phase, coherent inflow jet

Grade 1: Completely patent aneurysm with diffuse inflow

Grade 2: Reduced but residual filling which reaches the aneurysm dome, e.g., eclipse sign

Grade 3: Saccular: residual neck filling

- Fusiform: former aneurysm boundaries are covered
- Grade 4: Complete occlusion of the aneurysm

In grade 0, the aneurysm has a, coherent inflow jet in the early phase, which is presumed to be a main risk factor for delayed bleeding. Thus, a partially occluded aneurysm that shows an inflow jet will still be graded as 0. In these aneurysms, stasis might predict likelihood of thrombus formation or early rupture. Thus, the following grade 0 modifiers take this important aspect into consideration.



Fig. 1 Saccular and fusiform aneurysm. Grade 0: early phase, coherent inflow jet. Grade 1: the saccular or fusiform aneurysm is still completely patent but there is only diffuse inflow jet. Grade 2: in saccular aneurysms there is an "eclipse" sign or the dome has a residual component. In fusiform aneurysms there is residual flow that

reaches the aneurysm walls. Grade 3: in saccular aneurysms the dome is occluded but there is residual filling of the neck. In fusiform aneurysms, the formerly contrasted aneurysm walls are occluded; there is, however, residual filling. Grade 4: complete occlusion of the aneurysm

Assessment of flow dynamics:

Grade 0a: No relevant stasisGrade 0b: Stasis remains into the capillary phaseGrade 0c: Stasis remains into the venous phase

In all other grades, the assessment of stasis is not required since the grading of the aneurysm is conducted in the venous phase.

In grade 1, there will only be a diffuse inflow, inferring decreased flow, but the whole aneurysm is still patent.

In grade 2, the dome (saccular aneurysm) is not secured despite reduction of flow (eclipse sign). In fusiform aneurysms, the outer wall of the aneurysm is still unsecured.

Grade 3 identifies residual filling but occlusion of the dome. In fusiform aneurysms, the outer parts of the angiographically seen aneurysm are not patent.

Grade 4 represents complete occlusion.

Yet another aspect of flow-diverter technology is the possibility of partial or even complete occlusion of the parent artery as a result of the stents. A common finding is that of in-stent stenosis (ISS), which may be caused by thrombosis or intimahyperplasia. Again, a five-point scale can assess the severity of the stenosis.

Assessment of stenosis:

ISS Grade 0 No ISS

ISS grade 1 Mild, not hemodynamically significant

ISS grade 2 Moderate, 50-70%

ISS grade 3 Severe but not completely occluded, hemodynamically significant >70% ISS grade 4 Occlusion

Discussion

Exclusion of the aneurismal sac from cerebral circulation is the goal of endovascular embolization. Insufficient reduction of pulsatile blood flow within the aneurysm prevents a proper thrombus organization and endothelial cell proliferation and can lead to aneurysmal recanalization and re-growth [7, 19].

The stability of endovascularly treated aneurysms is probably related to a combination of factors, including local hemodynamics, vessel geometry, and the presence of intraluminal thrombus. To avoid the limitations of coil embolization in fusiform and extremely wide-necked intracranial aneurysms, modern devices (flow diverter, covered stents) try to approach the elimination of an aneurysm by excluding it from the circulation and remodel the blood flow characteristics to reduce the possibility of re-growth [8].

They direct the blood towards the distal part of the parent vessel, which reduces/eliminates the inflow into the aneurysm. Blood stasis then leads to thrombus formation, fibrotic growth, and eventually, thrombus organization, resulting in ablation of the residual aneurysmal lumen.

The relative stiffness and limited flexibility of covered stents has so far prevented them from routine use in intracranial aneurysm therapy [9].

To avoid these issues, the pipeline embolization device (PED, Covidien), for example, uses closely braided metal strands that cover the neck of the aneurysm to about 30–35%. Although this amount of metal coverage has been shown to achieve thrombus formation within the aneurysm, often

placement of a flow diverter will affect the intra-aneurysmal flow but may not be sufficient for aneurysm occlusion initially [4]. Also, sac recanalization of some aneurysms has been seen even after exact stent placement [12].

Conventionally, for the treatment of endosaccular aneurysms with coils post-procedural results are graded using the Raymond Roy classification scheme [15]. However, the technique of flow-diverter reconstruction differs fundamentally from that of conventional coil embolization and the Raymond Roy scale does not take into consideration the flow dynamics inside the aneurysm, where conventionally complete angiographic occlusion of the aneurysm would be aimed for.

With flow diversion, residual filling after stent placement is the rule, but the pattern of inflow is usually dramatically different. In particular, the transit of contrast material into the aneurysm is usually transformed [10, 11].

The aim is to reduce the inflow jet to a "wash in" of contrast media during the arterial and early capillary phase of angiography. Thus, the immediate post-embolization result that with traditional coil embolization is taken as the angiographic baseline to later assess stability or recanalization of the aneurysm, does not apply when aneurysms are treated with flow diverters. Angiographic quantification of contrast medium washout, calculating temporal variation in average gray-scale intensity within a region of interest has previously been assessed in an in vitro experiment [17] in order to quantitatively depict alterations in aneurysmal blood flow. Here, for best results of the mathematical model, the maximum frame rate that can be used over the period of contrast agent washout should be used [17].

A recent paper proposed grading of aneurysms treated with flow diverters as complete only when 95% occlusion or greater is achieved [13]. Incomplete was defined as a 5– 95% occlusion. This will seemingly classify most aneurysms as grade B (5–95%), because incomplete occlusion or a neck remnant is almost always evident in aneurysms treated with flow diverters. Also, this scale does not take into account the failure to eliminate the inflow jet currently presumed to be a major risk factor for late re-bleeding.

In addition, the dome of an aneurysm, which, with conventional coiling is generally more protected than the neck, is thought to be the most vulnerable area for rupture. The converse is true for flow-diverter-treated aneurysms. A new grading scale should take this into consideration, especially as an often encountered clearing phenomenon in aneurysms treated with flow diverters is that of the "eclipse sign", which is also not considered in the recently published scale. Here the length of stasis will then be a predictor on whether subsequent thrombus formation occurs. This is addressed in our scale, as it includes the flow dynamics within the aneurysm, assessing location and prolonged stasis of residual contrast filling in the venous phase. Two major complications that have been encountered with the use of flow diverters are in-stent thrombosis and early post-procedural rupture, presumed to be caused by a persistent inflow jet with subsequent remodeling of the thrombus [20].

These issues need to be taken into consideration when classifying the results of endovascular treatment.

Regarding in-stent stenosis that can be caused by either thrombus or intimahypoplasia, we propose conventional grading according to the severity and its hemodynamic effect. A mild (ISS grade 1) and moderate (ISS grade 2) stenosis (50–70%) would traditionally not be considered hemodynamically significant, whereas an ISS grade 3 ( $\geq$ 70%) stenosis or occlusion (ISS grade 4) would be hemodynamically significant.

Regarding aneurysm occlusion, the two-part aneurysm grading scale we describe allows categorization of cases where definitive aneurysm occlusion is accomplished in one step with the deployment of a flow diverter across the aneurysmal segment (grade 4) as well as cases where apposition of the flow diverter is inadequate, setting up the potential for "endoleaks" or jet inflow which can maintain patency of the aneurysm sac and disrupt the overgrowth of a homogeneous, contiguous layer of neointima and neo-endothelium over the surface of the stent (grade 0-3).

The major aim is the reduction and disruption of the initial early phase, coherent inflow jet. If this is not achieved, we propose classification of the aneurysm as a grade 0 occlusion. In cases of residual patency of the aneurysm but with disruption of the initial inflow jet, grade 1 would be applied. When contrast material can be seen layering within different dependant portions that involve the dome, often forming an eclipse sign on subtracted images, these would then be categorized as grade 2. In grade 3 saccular aneurysms, the dome is not patent but there is residual filling of the neck. In fusiform aneurysms, the initial boundarys of the aneurysm are not patent but there remains residual filling within the aneurysm.

Generally, the transit of contrast material into and out of the aneurysm will be variably reduced, often progressing to complete occlusion. The contrast material in the aneurysm becomes static and typically persists, depending on the amount of washout, into varying phases of the angiography. This retained contrast material within the aneurysm often surrounds the reconstructed parent artery, which demonstrates normal arterial phase washout of contrast material.

In an attempt to take these hemodynamics within the aneurysm into account, we propose evaluation in the venous phase and a differentiation of aneurysms that show inflow jet into no significant stasis (a), stasis in the parenchymal (b), or venous (c) phase of angiography.

Intra-aneurysmal stasis during the late venous phase (c) that is demonstrated by a persistent dependant layering of contrast material within the aneurysm sac indicates a

marked disruption of aneurysm inflow and predicts the progression of these lesions to angiographic occlusion.

Whilst the interventionalist should expect residual postprocedural filling, it is important for the operator to angiographically recognize inadequate reduction and disruption of the initial inflow jet and persistent patency into follow-up that might make placement of additional telescoping devices as part of a staged treatment necessary. This can later be supplemented by additional crosssectional imaging to assess shrinkage or further growth of the aneurysm.

## Conclusion

Primary endovascular reconstruction with flow diversion represents a fundamental paradigm shift in the technique of endovascular aneurysm treatment. Contrary to coil embolization, with flow diverters, commonly residual postprocedural filling will be noted within the aneurysm, the curative reconstruction typically occurring over a period of weeks to months. The grading scale proposed on our preliminary experience takes into consideration the hemodynamic consequences of stent placement on endosaccular flow and provides for a common language that can be employed to standardize future studies. Further studies will need to show its applicability and possible predictive value in the treatment of a segmentally diseased parent vessel with flow diverters.

Conflicts of interest None.

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## Comment

Grunwald et al. propose a new scale for the evaluation of aneurysm residual after flow-diversion stenting. They suggest a five-point scale that represents five radiologic phenomena within the aneurysm sac that are seen after flow-diversion stenting throughout the arterial, capillary, and venous phases. Grade 0 (a–c) represents any flow seen within the aneurysm in the early arterial phase. The rest of the scale describes the flow in the aneurysm seen during the venous phase: grade 1—diffuse flow with a patent aneurysm, grade 2—reduction of flow with filling of the dome/outer wall of the aneurysm, grade 3—residual neck filling with occlusion of the dome/outer wall, and grade 4—complete occlusion. Another proposal is a scale for the effect of this technology on the parent artery, i.e., in-stent stenosis (grade 0—no stenosis and grade 4—occlusion of the stent).

The authors have incorporated the radiologic phenomena seen after flow diversion into a scale that may help us to understand this evolving technology and to better understand these changes and, thus, to reduce the risk of post-stenting rupture. The authors' novel radiologic scale for the assessment of the flow in aneurysms after flow-diversion stenting is an easy scale to use, without the need for further technology. The scale takes into account the principles of flow-diversion technology and the radiologic presentation of the flow changes in the aneurysm, with extrapolation of these phenomena on the risk for rupture. Further studies with more cases will be needed to show the predictive value of this scale.

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