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Michael Forsting
Chairman of the Institute of Radiology and Neuroradiology at the University Clinics Essen, Germany

Introduction

Michael Forsting, Editor

Dear colleagues,

Welcome to the latest issue of the Neurointerventional Newsletter, I am sure that you will like it.

One part of the newsletter deals with endovascular treatment of acute stroke and the recent literature is really promising! The MR CLEAN study is a milestone and a breakthrough – it means many sites around the world will now accept endovascular thrombectomy as a first line treatment of acute intracranial vessel occlusion.

On the other hand, endovascular treatment of intracranial aneurysms has been first line treatment almost everywhere for more than a decade and we are now in the process of continuous improvement of endovascular methods. We are not talking (and writing) about 'simple' aneurysm anymore, but increasingly thinking about more complex aneurysms and how to decrease the risks of treatment and increase the success rate. And we are now looking at our long-term results – and again the results are promising.

I am very happy that we had these interesting papers and I thank all the reviewers for their work and their honesty in their comments.

Warm regards

Michael Forsting

Contributions to this issue: Tommy Andersson, Anil Arat, Lucio Castellan, Michael Forsting, Alejandro Gonzalez, Marius Hartmann, Sarah Power & Timo Krings, Juan Macho, Jorge Olier, Marc Ribo, Rodrigo Rivera & Rodrigo Riveros

Critical Review of Literature Acute Ischemic Stroke

A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke

Berkhemer OA et al.; MR CLEAN Investigators
N Engl J Med. 2015 Jan;372(1):11-20. Epub 2014 Dec 17

These are the results of the Dutch MR CLEAN Study* looking at the outcomes in acute stroke patients treated with endovascular thrombectomy.

In total 500 patients were enrolled, 233 of whom were assigned to endovascular thrombectomy and 267 to usual care. The vast majority – 89% – were treated with intravenous alteplase before randomization. Eligible patients had a proximal arterial occlusion in the anterior cerebral circulation that was confirmed on vessel imaging and that could be treated intraarterially within six hours after symptom onset. In 190 of the 233 patients (81.5%) assigned to intraarterial treatment retrievable stents were used for recanalization. There was an absolute difference of 13.5 percentage points in the rate of functional independence (modified Rankin Score, 0-2) in favor of the intervention (32.6% versus 19.1%). There were no significant differences in mortality or in the occurrence of symptomatic intracerebral bleeding. The conclusion of the authors is that Intraarterial treatment administered within six hours after stroke is effective and safe in acute stroke patients.

Personal comment

This paper is accompanied by an editorial, written by Werner Hacke from Heidelberg. The title of the editorial is: Interventional thrombectomy for major stroke – a step in the right direction.

And Werner Hacke picked up the right points: We needed a study on intraarterial treatment enrolling patients with severe strokes, having proof of proximal vessel occlusion, initiating treatment as early as possible, and using modern thrombectomy devices. And now we have this study and it was successful. In parallel, there were similar studies looking at the effect of intraarterial thrombectomy, all of which are now on hold, and we are look forward to seeing the interim results of these studies. There are rumors that they will support the results of MR CLEAN. So far, this is a very promising result for our patients.

Continued on next page

However looking further ahead, this study confirmed that recanalization is the most important predictor for a good outcome (75.4% versus 32.9%). It does not necessarily mean that recanalization has to be achieved by mechanical thrombectomy. If there were an intravenous drug with an improved recanalization rate the effect would be the same. And regardless of how fast the number of interventionalists grow and enable thrombectomy all over the country, an intravenous therapeutic approach,,with a recanalization rate above 70%, would be easier to go. For the moment the endovascular approach is the best way to go and we all should work on having this method available all over the place.

At the end: congratulation to our Dutch colleagues. This is an outstanding study.

Michael Forsting, Essen, Germany

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Society of Vascular Interventional Neurology 2014 Meeting

Hollywod, Nov 7-9, 2014

The last meeting of the Society of Vascular Interventional Neurology was dominated by the recently presented positive results of MR CLEAN (Multicenter Randomized Clinical trial of Endovascular treatment for Acute ischemic stroke in the Netherlands) and the announcement that the ESCAPE trial (Endovascular treatment for Small Core and Anterior circulation Proximal occlusion with Emphasis on minimizing CT to recanalization times) was prematurely stopped after an interim analysis of the first 243 randomized patients showed overwhelming achievement of the pre-specified efficacy endpoints.

Both trials basically showed the superiority of endovascular treatment of acute stroke with stent retrievers as compared to best medical treatment in selected patients.

The general consensus was to be cautious with immediate further decisions, such as prematurely stopping other ongoing trials.

However, if after final publication of the studies the results are confirmed and replicated by several other similar ongoing trials (SWIFT PRIME, REVASCAT…) they will most certainly produce major changes in clinical guidelines, regulatory requirements and reimbursement conditions, leading ultimately to an exponential spread of this beneficial treatment around the world.

Most comments and interventions during the SVIN meeting were aimed at emphasising the importance of these results and presuming that we are probably facing the most exciting days in acute stroke treatment in the last 15 years.

All other presentations at the meeting, although scientifically interesting, seemed somehow shaded by these exciting news.

Marc Ribó, Barcelona, Spain

Recanalization and Clinical Outcome of Occlusion Sites at Baseline CT Angiography in the Interventional Management of Stroke III Trial

Demchuk AM, Goyal M, Yeatts SD, Carrozzella J, Foster LD, Qazi E, Hill MD, Jovin TG, Ribo M, Yan B, Zaidat OO, Frei D, von Kummer R, Cockroft KM, Khatri P, Liebeskind DS, Tomsick TA, Palesch YY, Broderick JP; IMS III Investigators

Radiology. 2014 Oct;273(1):202-10. Epub 2014 Jun 5

This subgroup analysis of IMS III subjects for whom baseline CT angiography was performed, provides valuable insight into which subgroups of patients with moderate or severe acute ischemic stroke may benefit from endovascular therapy versus IV tPA alone. Recanalization at 24 hours was significantly more frequent in the endovascular arm.

Endovascular therapy is most likely to be of benefit in patients with occlusions of the terminal ICA, with or without MCA occlusions. Although there was only a borderline significant benefit in favor of endovascular therapy, this data indicates that CTA or other intracranial vascular imaging will be important in assessing the best use of endovascular therapy in clinical practice and clinical trials.

Decreasing time to reperfusion is probably of the utmost importance, but patient selection by clinical and radiographic criteria is also critical.

Furthermore, this study showed that the safety endpoints were not significantly different in both treatment groups.

Unfortunately, the trial was stopped prematurely before stent retriever technology could be used except for a handful of patients.

Anyhow, this subgroup analysis from IMS III could show, as recently published data from MR CLEAN confirms, that for patients with acute ischemic stroke caused by a proximal intracranial arterial occlusion, confirmed by a baseline CT angiography, intraarterial treatment with new generation devices is a highly effective emergency revascularization.

Marius Hartmann, Berlin, Germany

Vessel Wall Magnetic Resonance Imaging in Acute Ischemic Stroke: Effects of Embolism and Mechanical Thrombectomy on the Arterial Wall

Power S, Matouk C, Casaubon LK, Silver FL, Krings T, Mikulis DJ, Mandell DM
Stroke. 2014 Aug;45(8):2330-4. Epub 2014 Jun 24

In this article the authors apply the technique of high-resolution, contrast-enhanced, vessel wall magnetic resonance imaging (VW-MRI) on acute ischemic stroke patients to investigate whether mechanical thrombectomy, as well as the embolus itself, has any visible effects on the vessel wall appearance. They further discuss and compare their findings with those from known, but less common, intracranial causes of stroke such as atherosclerosis, vasculitis and reversible cerebral vasoconstriction syndrome (RCVS).

The VW-MRI was performed after the stroke as part of a secondary prevention protocol and included time-of-flight and T1-weighted so-called 'black blood vessel wall sequences', with and without intravenous contrast administration. The images were evaluated looking for grade of recanalization and intramural blood products, as well as thickening and enhancement of the arterial wall.

The findings were then related to the cause of stroke, as found in a detailed chart review, and the treatment modality, i.e. intravenous thrombolysis (10 patients) and/or mechanical thrombectomy (six patients).

The imaging revealed that two patients had residual arterial stenosis, one due to a remaining thrombus and the other because of a probable atherosclerotic plaque. Patients treated with mechanical thrombectomy all had definite or possible arterial wall thickening and enhancement on VW-MRI.

This was in contrast to patients treated with medical therapy alone, for which VW-MRI revealed definite or possible thickening or enhancement of the vessel wall in 50% and 40%, respectively. These differences between the patients treated medically or with endovascular techniques were significant.

The authors conclude that concentric arterial wall thickening and enhancement is more common among patients treated with mechanical thrombectomy and that the pattern resembles that seen on VW-MRI imaging in various neurovascular inflammatory conditions.

Endothelial denudation may explain the arterial wall enhancement and a vessel wall oedema may be reflected in the increased thickness, even though no signs of intramural blood products were detected in this study. In addition, VW-MRI at this early time point after onset was not able to differentiate between the various causes of the stroke, except when there was a local intracranial etiology, i.e. a focal atherosclerotic plaque.

The authors conclude that if VW-MRI is utilized in ischemic stroke patients, it´s important to recognize the post-thrombectomy appearance, not to wrongly interpret arterial thickening and enhancement as an underlying arteritis and, conversely, consider the possibility of arteriopathy if the same imaging pattern exists in stroke patients treated with medical therapy alone.

Personal comment

The technique of VW-MRI is certainly very interesting and promising. To be able to better diagnose inflammatory disease is a great achievement. If, in the future, it also becomes possible with this technique to identify, for instance, which intracranial aneurysms are prone to rupture, it would be even more valuable.

It seems to me that the use for the majority of acute stroke patients may still be of less value, at least when the investigation is done, as in this article, close to the onset and treatment as part of a secondary prevention protocol.

That mechanical thrombectomy may cause acute arterial enhancement and thickening is hardly a surprise, nor is the finding that this is observed less with medical treatment alone, even though the thrombus itself scarcely may be the source for such abnormalities. It´s important to remember that mechanical thrombectomy, if performed without procedure related complications, seems by itself very unlikely to cause at least clinically significant vessel wall damage.

Acute re-stenosis is hardly ever seen after thrombectomy of a thromboembolus and long-term clinically significant alterations are at least probably very uncommon. It would be of interest though, like the authors write, to study potential long-term effects from mechanical thrombectomy on the arterial wall and to see if potentially found alterations are clinically significant.

To me, this would be a more interesting and valuable use of this fascinating technique as compared to finding the very few 'ordinary' acute stroke patients who also suffer from an underlying arterial arteritis. The overwhelming majority of stroke patients have their stroke from a thromboemboli, cardiac or carotid, whereas a minority have an intracranial focal problem, almost exclusively caused by atherosclerosis.

Primary intracranial arteriopathy, such as vasculitis or RCVS, as stroke etiology, or even as a co-existent condition, is in this particular population, for the 'every-day' stroke patient, still very uncommon.

However, in selected patients, for example children and young adults, VW-MRI may prove to be very valuable in the diagnostic work-up as this subgroup has a different etiological panorama for ischemic stroke in which inflammatory conditions play a much greater role.

In conclusion, the authors have beautifully shown the possibilities of this technique but to me, the true potential regarding stroke patients lies in the long-term follow up and especially in the work-up for children and young adults with a different etiological spectrum.

Tommy Andersson, Kortrijk, Belgium

Mechanical Thrombectomy for Ischemic Stroke: The First UK Case Series

Nasar Ahmad, Sanjeev Nayak, Changez Jadun, Indira Natarajan, Palbha Jain, Christine Roffe

PLOS ONE. 2013 Dec 26;8(12):e82218

The authors have carried out a prospective assessment of their first 106 endovascular procedures, treating occlusions of large encephalic arteries in patients recruited between 2010 and 2012.

The Introduction explains that treatments of this type are regarded as experimental in the UK and that there is scant regulation of these procedures at most centers in the country.

The authors have also addressed the issue of whether mechanical thrombectomy is clinically more efficacious than intravenous thrombolysis alone, the fundamental uncertainty currently hanging over endovascular rescue for stroke.

Indications for inclusion in the study were patient age of less than 80 years, good quality of life before the stroke, onset less than 4.5 hours earlier for strokes in the anterior circulation, and less than 10.5 hours earlier for strokes in the posterior circulation, contraindication preventing or non-response to intravenous thrombolytic therapy, and performance of a plain CT scan and CT angiography.

Most procedures were carried out under general anaesthesia (87%), with mechanical thrombectomy by means of various devices (83%), aspiration (14%) or thrombolysis (13%). Treatment was angiographically efficacious in 84% of cases (TICI ≥ 2b).

At three months 48% of treated patients were functionally independent (mRS score ≤ 2). Total mortality was 15% 90 days after treatment.

The most frequent complications were distal embolism (8%), subarachnoid hemorrhage (5%), and stent dislodgement (three cases using the Solitaire FR device). CT demonstrated cerebral hemorrhage after rescue in 36% of cases, though 74% of these were asymptomatic.

In their discussion the authors point to flaws in the results of the IMS III, MR RESCUE, and SYNTHESIS trials which failed to find any benefit from endovascular rescue for stroke compared with intravenous thrombolysis alone. The reasons they give are that those studies used outmoded thrombectomy devices and overly long time windows for endovascular rescue (eight hours in the MR RESCUE trial), resulting in low repatency rates and high futile recanalization rates.

Homogeneous comparison of the results for their series with the results of the SITS registry showed that mechanical thrombectomy following intravenous thrombolysis statistically bettered the results of intravenous thrombolysis therapy alone by a factor of 1.4 without increasing the overall risk of mortality or symptomatic hemorrhage.

Personal comment

Mechanical thrombectomy for stroke is a relatively recent technique. The operator learning curve, the development of new thrombectomy and arterial recanalization devices and methods, and the treatment indications and protocols all play an essential role in determining clinical patient outcomes.

According to the authors, the published results of recent randomized trials cannot be extrapolated to the current situation because patients were enrolled during the early stages of development of the technique and the devices used are now obsolete.

Furthermore, the patient inclusion protocols were overly lax. Development of new methodologies commonly gives rise to initial enthusiasm conducive to an optimistic slant on trials. Assessment of the results offsets that bias and puts methods in their proper place.

As discussed by Ahmad et al., time to rescue is a fundamental factor, but it is not the only one. The extent of collateral blood flow in the occluded vascular territory, the initial NIHSS score, and age are also extremely important prognostic factors.

At the present time most series dealing with endovascular rescue for stroke achieve recanalization rates greater than 90%, far higher than the percentage of patients able to lead an independent life over the medium term. Time from onset, poor collateral blood flow, and advanced age are the main factors contributing to futile recanalization and concomitant poor procedure outcomes.

Time from onset is probably the most important factor. It is appropriate to set a time limit for thrombectomy, which most authors place at fewer than six hours from stroke onset. Still, it is important to keep in mind that the impact of time as a factor follows a geometric progression and that outcomes are appreciably better the sooner procedures are performed after stroke onset. The extent of collateral blood flow is another key factor that may act to lengthen or shorten the time window to rescue.

Unfortunately, this information requires a CT angiography, which takes time. Lastly, age is another factor that needs to be taken into account, especially when the initial neurological deficit is high. An elderly person with a high NIHSS score is unlikely to achieve a decent quality of life even after morphologically efficacious vascular recanalization.

Soon to be published randomized trials like MR CLEAN, ESCAPE, and EXTEND IA will doubtless bear out the conclusions reached by Ahmad et al. in their article.

As things stand at present, it can be affirmed that endovascular thrombectomy is a helpful procedure in stroke patients who do not respond to, or who are not candidates for, intravenous thrombolytic therapy, provided that the protocol for selecting patients who will benefit from mechanical thrombectomy is strictly applied.

Jorge Olier, Pamplona, Spain

Endovascular Treatment of Internal Carotid Artery Bifurcation Aneurysms: A Single Center Experience and Systematic Review and Meta-Analysis

Morales-Valero SF, Brinjikji W, Murad MH, Wald JT, Lanzino G

AJNR Am J Neuroradiol. 2014 Oct;35(10):1948-53. Epub 2014 Jun 5

The authors report a comprehensive literature review on the endovascular treatment of internal carotid artery bifurcation aneurysms, including their own experience from the Mayo Clinic (Rochester, MN).

The data from six clinical studies were considered, with an overall number of 158 patients and 163 aneurysms. The reported rate of complete or near-complete occlusion after the endovascular treatment was 88% and 82% at the long-term follow-up.

Details of the endovascular techniques for the 37 aneurysms treated at the Mayo Clinic were provided – coiling in 35 cases, balloon-assisted coiling in sic cases, flow diversion in two cases.

The overall procedure-related morbidity was 4.0% and the procedure-related mortality was 3.0% (in ruptured aneurysms 9.0% and 6.0% respectively). Good neurologic outcome was achieved in 93.0% of patients.

However the study shows a high recanalization rate at the follow up (34% in the Mayo Clinic series) while a significant rate of retreatments (14.0% of all the cases) is pointed out from the comprehensive review of the literature.

Personal comment

Firstly I think we have to appreciate the effort of the authors to analyze the results of endovascular treatment of internal carotid bifurcation aneurysms, highlighting the features related to the particular location as well as the other aneurysmal characteristics more frequently considered in the literature (size, neck, etc).

The present study points out at least three important features about the endovascular treatment of the carotid bifurcation aneurysms:

- *there is a confirmation of the feasibility, safety and immediate efficacy of the endovascular approach that guarantees results comparable in terms of outcomes and complication rates to those obtained in other intracranial vascular districts*
- *because the results of endovascular treatment compare favorably with those after surgical treatment, it is correct to consider the endovascular treatment as the first option in the management of the ICA bifurcation aneurysm*
- *despite the good immediate angiographic results and the good clinical outcomes, there is evidence of high probability of recanalization after coiling requiring a new embolization in the 14% of cases*

On this last point, the authors explain this high recanalization rate after endovascular treatment with the peculiar hemodynamic characteristics of the ICA bifurcation (similarly to other arterial bifurcation as basilar tip or MCA bifurcation) that increase the probability of compaction of the coils cast and aneurysmal recurrence, quite independently to the aneurysm size.

Actually, in addition to the hemodynamic factors, I think it is important to keep in mind the used endovascular techniques and their long-term results.

In particular, in recent years, several studies demonstrated that stent-assisted coiling is associated with higher stability than simple coiling, also reducing the number of retreatments sometimes associated with a higher risk of intraprocedural complications[1-3]. More recently, some papers describe the potential role of flow diverters and intrasaccular devices in the treatment of bifurcation aneurysms if these new therapies have not yet been shown to be superior to more traditional techniques[4].

However, because in the Mayo Clinic series (where the technique details are available) only six patients (17%) had balloon-assisted coiling, none had stent-assisted coiling and only two patients (5%) were treated in a staged fashion with a flow diverter, we can assume that in the future the recanalization rate could be reduced with a more extensive use of stenting or flow diverter devices, as primary approach or in a staged fashion.

Lucio Castellan, Genova, Italy

1. *Piotin M, Blanc R, Spelle L, Mounayer C, Piantino R, Schmidt PJ, Moret J. Stent-assisted coiling of intracranial aneurysms: clinical and angiographic results in 216 consecutive aneurysms. Stroke. 2010;41(1):110-5.*
2. *Consoli A, Vignoli C, Renieri L, Rosi A, Chiarotti I, Nappini S, Limbucci N, Mangiafico S. Assisted coiling of saccular wide-necked unruptured intracranial aneurysms: stent versus balloon. J Neurointerv Surg. 2014. (Epub ahead of print).*
3. *Jeong W, Han MH, Rhee K. The hemodynamic alterations induced by the vascular angular deformation in stent-assisted coiling of bifurcation aneurysms. Comput Biol Med. 2014; 53:1-8.*
4. *Yavuz K, Geyik S, Saatci I, Cekirge HS. Endovascular treatment of middle cerebral artery aneurysms with flow modification with the use of the pipeline embolization device. AJNR Am J Neuroradiol. 2014;35(3):529-35.*

Effect of Structural Remodeling (Retraction and Recoil) of the Pipeline Embolization Device on Aneurysm Occlusion Rate

Jou LD, Mitchell BD, Shaltoni HM, Mawad ME

AJNR Am J Neuroradiol. 2014 Sep;35(9):1772-8. Epub 2014 Apr 10

In the September 2014 issue of AJNR, in an article entitled 'Effect of structural remodeling (retraction and recoil) of the pipeline embolization device on aneurysm occlusion rate', Jou et al published their findings regarding the structural changes occurring in Pipeline devices (Covidien) on follow-up. They describe 14 consecutive carotid circulation aneurysms exclusively treated by placement of a single Pipeline device. It is to be noted that the authors have treated more than 100 aneurysms with Pipeline and the subset in the article is a small portion of their experience.

The patients had a flat panel CT (DynaCT) examination during the endovascular procedure, as well as during follow-up at about six months. From DynaCT data set, the Pipeline devices were extracted from the surrounding tissues. Although the authors do not mention how this was accomplished, it is possible that they utilized a special software known to be available to their group[1]. Once the devices were segmented out, the authors used an automated thresholding and co-registration utility on the workstation. This allowed them to superimpose the images of the same Pipeline device obtained at two different time points, that is to say endovascular treatment and six months follow-up, so that they can determine the changes in the structure of the device with time. Additionally they obtained measurements of predetermined points along the axis of the devices as well as circumference measurements on proximal and distal segments of each device. Using these measurements, and the nominal diameter and length (size of each device as printed on its package) of the devices, the authors compared seven out of 14 aneurysms which were angiographically occluded on six month follow-up (group 1) with the remaining seven, which were not occluded totally (group 2).

In both groups, there was an overall increase in diameter (mean 0.23 mm) and a decrease in length (mean 2.88 mm) of the Pipeline device. The shortening was around 10% (8.4 for group 1 and 11.6 for group 2). There was evidence that the curve of the devices underwent a change and that some devices tended to shorten from mainly the proximal end, without any consequences. There was a significant 'elongation' (difference between the lengths of the deployed stents versus the nominal lengths) when the two groups were compared, with the elongation more prominent in group 2. On the contrary there was no difference between the groups in terms of the device measurements as compared with nominal diameters of the stents. The authors referred to the latter comparison as 'oversizing'. The authors concluded that during follow-up, Pipeline devices demonstrate gradual remodelling/shortening and they attributed this phenomenon to suboptimal apposition of the devices to the vessel wall. They also added that elongation of the device results in a lower occlusion rate.

Personal comment

Although the conclusion of the study is likely to be valid and accepted in general, it appears that the findings can only partially support the conclusion in this article. On the other hand the observations made by the authors are critically important and surprisingly un(der)reported by others. Occlusion of aneurysms after flow diverter placement is the result of a constellation of factors including, but not limited to, the target artery (eg. shape, degree of taper, presence of stenosis, tortuosity), the device (choice of both the diameter and the length, precision of deployment including absence of hour-glass formation, fish-mouthing), the aneurysm (dissecting versus saccular, presence of side branches and their size, neck size) and the patient (response to antiplatelet medication, response to stent – degree of neointimal hyperplasia, diabetes, smoking, etc).

The study population is very limited in this regard to draw firm conclusions on elongation of the device as a definite cause of residual aneurysms. Although both patient groups appear to be statistically equivalent on the low number of cases included, there is a 'statistically insignificant' difference of mean size, 6 mm vs 9 mm, between the two groups. Group 2 aneurysms has a mean size 50 % larger than group 1 and this may be one of the reasons for a higher rate of residual aneurysms in this group. Besides, the shortening and further expansion of the devices may merely be the result of enlargement of the stented segment of the artery similar to that seen in carotid stenting[2]. Yet, in our opinion, the finding that FD may remodel with time, by itself, is a novel and important finding. This suggests that angiographic follow-up after flow diverter placement is essential and, if possible, follow-up angiograms are to be scrutinized as thoroughly as possible, in a manner similar done by the authors, to determine any change in the structure of the flow diverter. It also suggests that sufficiently long distal and proximal landing zones are needed to avoid unpleasant surprises on follow-up.

Another interesting finding is the 50% rate of residual aneurysms after placement of a single Pipeline device, despite the observation of stagnation within the aneurysms immediately after the endovascular treatment. This contrasts with the high rate of obliteration in some previous reports regarding early follow-up results after use of a single Pipeline device. Just as the authors demonstrated their ability and expertise in detecting relatively subtle configurational changes in the Pipeline device, their detailed and objective search for any residual filling may have disclosed aneurysmal opacification that would have been overlooked by many others. This may have contributed to the lower rate of complete obliteration noted in this series.

For sure, having read the authors' work, most of us will obtain and scrutinize follow-up angiograms for flow diverters in more detail. It remains to be shown whether the phenomenon described by the authors also holds for other flow diverters and whether any consequences will arise secondary to this phenomenon during angiographic and clinical follow-up.

Anil Arat, Ankara, Turkey

1) *Jagani M, Chinnadurai P, Chintalapani G, Shaltoni H, Morsi H, Mawad M. P-005 Evaluation of an Automatic Detection and Segmentation Tool for Flow Diverters (Pipeline™ Embolization Device) from C-arm CT Images. J Neurointerv Surg. 2014 Jul;6 Suppl 1:A23*

2) *Men S, Lownie SP, Pelz DM. Carotid stenting without angioplasty. Can J Neurol Sci. 2002 May;29(2):175-9.*

3) *Chalouhi N, Tjoumakaris S, Phillips JL, Starke RM, Hasan D, Wu C, Zanaty M, Kung D, Gonzalez LF, Rosenwasser R, Jabbour P. A single pipeline embolization device is .sufficient for treatment of intracranial aneurysms. AJNR Am J Neuroradiol. 2014 Aug;35(8):1562*

Surpass Flow Diverter in the Treatment of Intracranial Aneurysms: A Prospective Multicenter Study

Wakhloo AK, Lylyk P, de Vries J, Taschner C, Lundquist J, Biondi A, Hartmann M, Szikora I, Pierot L, Sakai N, Imamura H, Sourour N, Rennie I, Skalej M, Beuing O, Bonafé A, Mery F, Turjman F, Brouwer P, Boccardi E, Valvassori L, Derakhshani S, Litzenberg MW, Gounis MJ; for the Surpass Study Group.

AJNR Am J Neuroradiol. 2015 Jan;36(1):98-107. Epub 2014 Aug 14

Materials and methods: At 24 centers, 165 patients with 190 intracranial aneurysms of the anterior and posterior circulations were enrolled. The primary efficacy end point was the percentage of intracranial aneurysms with 100% occlusion on six-month DSA. The primary safety end point was neurologic death and any stroke through a minimum follow-up of six months.

Results: Successful flow-diverter delivery was achieved in 161 patients with 186 aneurysms (98%), the mean number of devices used per aneurysm was 1.05. Clinical follow-up (median, six months) of 150 patients (93.2%), showed that the primary safety end point occurred in 18 subjects. Permanent neurologic morbidity and mortality were 6% and 2.7%, respectively. Morbidity occurred in 4% and 7.4% of patients treated for aneurysms of the anterior and posterior circulation, respectively.

Neurologic death during follow-up was observed in 1.6% and 7.4% of patients with treated intracranial aneurysms of the anterior and posterior circulation, respectively. Ischemic stroke at ≤30 days, SAH at ≤7 days, and intraparenchymal hemorrhage at ≤7 days were encountered in 3.7%, 2.5%, and 2.5% of subjects, respectively. No disabling ischemic strokes at >30 days or SAH at >7 days occurred. New or worsening cranial nerve deficit was observed in 2.7%. Follow-up angiography available in 158 (86.8%) intracranial aneurysms showed 100% occlusion in 75%.

Conclusions: Clinical outcomes of the Surpass flow diverter in the treatment of intracranial aneurysms show a safety profile that is comparable with that of stent-assisted coil embolization. Angiographic results showed a high rate of intracranial aneurysm occlusion.

Personal comment

The issue of how best to treat wide-necked, giant intracranial aneurysms is still unresolved. No method currently in use furnishes definite, safe, and effective long-term outcomes.

The arrival of flow diverters on the scene as a therapeutic option for this type of aneurysm in the past five years has raised high expectations.

Initial angiographic and clinical results have been mixed, which may be attributable to overuse. These devices do not yield a definite outcome in all cases, can be subject to certain safety problems such as delayed bleeding, and are technically challenging and overly dependent on operator expertise.

Devices incorporating new technical innovations that can replace or add to the currently available therapeutic arsenal are therefore welcome.

This article reports on a series with results that seem to confirm that the Surpass™ Flow Diverter (Stryker Neurovascular) is at least the equal of other flow diverters currently in terms of safety and efficacy. It has two distinct conceptual differences with respect to other devices:

1. *Different numbers of strands for different parent vessel lumen sizes, that is, the device design incorporates the concept of tailored density with a considerable increase in mesh density.*
2. *An Over The Wire (OTW) system which, though it has its pros and cons, does offer enhanced stability and precision in cases in which repositioning and/or telescoping within complex anatomies is called for, thanks to distal positioning of an independent 0.014 inch guidewire in all cases.*

In particular, two aspects stand out concerning the series reported as compared to previous series in which other devices were used:

1. *The number of devices that had to be employed per patient per aneurysm to achieve comparable results. The findings point to use of a single device as opposed to an average of three PEDs (Covidien) in the PUFS series, with comparable outcomes.*
2. *The absence of delayed bleeding of the repaired aneurysms in the study. All the episodes of bleeding described in the series occurred in the first seven days, and practically all involved cases in which the technique was employed during the acute stage.*

Past experience shows that indiscriminate use of innovative devices of this kind often leads to surprises when not backed by preliminary studies at selected centers. The finding of 5% of severe secondary stenosis (>50 %), though asymptomatic, seems relevant. The response of the artery wall to higher mesh density and greater rigidity of the device, combined with the well-established fact that braided stents are less able to adapt to complex anatomies, means that special attention needs to be given to the landing zone for these devices.

Welcome, Surpass. This option merits consideration where distal support or higher stability is needed.

Juan Macho, Barcelona, Spain

The Durability of Endovascular Coiling Versus Neurosurgical Clipping of Ruptured Cerebral Aneurysms: 18 Year Follow-Up of the UK Cohort of the International Subarachnoid Aneurysm Trial (ISAT)

Molyneux AJ, Birks J, Clarke A, Sneade M, Kerr RS

Lancet. 2014 Oct 28. Epub ahead of print

The International Subarachnoid Aneurysm Trial (ISAT)* was a multicenter randomized controlled trial that aimed to assess the relative safety and efficacy of endovascular coiling versus neurosurgical clipping of intracranial ruptured aneurysms in patients who were suitable for either treatment, enrolling 2143 subjects in 43 centers between 1993 and 2002.

Clinical outcomes at one year, medium term results determining differences between the two treatments in the prevention of target aneurysm rebleeding, and long term results with mean follow-up of nine years (range 6-14 years) have been reported previously[1-4].

The ISAT investigators have now published the long-term death and clinical outcomes data for the UK patient cohort, reporting 10-18.5 years of follow up on 1644 patients enrolled in 22 participating UK centers.

Patient follow-up was in the form of an annual questionnaire using the self-reported modified Rankin Scale (mRS) to determine dependency.

UK patients registered in the ISAT study were flagged with the Office of National Statistics and investigators received automatic notification of any deaths. Data for recurrent aneurysms and rebleeding events were collected from questionnaires and from hospital and general practitioner records. Data was analyzed by intention to treat.

In the UK, 1331 (80%) of the 1644 patients had survived 10 years after their original subarachnoid hemorrhage (SAH). At 10 years, 1003 (75%) of patients returned a questionnaire.

The proportion of patients with mRS score of 0-2 did not significantly differ between the two groups (OR 1.25, 95% CI 0.92-1.71), however the probability of independent survival at 10 years was significantly better for the group allocated to coiling rather than clipping (OR 1.34, 95% CI 1.07-1.67).

Sensitivity analyses for the probability of independent survival calculated by replacing missing 10 year mRS scores with available 11 year, 9 year, 8 year or latest available mRS scores also yielded similar results favoring the endovascular group and indicating that the 10-year mRS analysis was not biased by missing values.

As data for recurrent SAH occurring before one year of follow up was published previously, the current publication reports only data for patients with recurrent SAH occurring greater than one year following their initial hemorrhage.

Recurrent SAH occurred in 33 patients; in 17 cases bleeding was from the initially treated aneurysm, while in 16 cases bleeding was from another source. At the end of follow-up the cumulative risk of a rebleed from the target aneurysm was 0.0216 (95%CI 0.0121-0.0383) for patients in the endovascular group, compared with 0.0064 (95%CI 0.0024-0.0173) for the neurosurgical group (log-rank p=0.02).

There were 13 patients in the endovascular group who rebled from the initially treated aneurysm between 1.9 and 13.2 years after the procedure. In the neurosurgical group rebleeding from the initially treated aneurysm occurred in four patients between 6.1 and 11.4 years post procedure.

During the 18.5 year follow-up period 338 (24%) patients died. Of the six deaths that occurred due to recurrent SAH from the target aneurysm after one year, four were in the coiling group, and two in the neurosurgical group, while over the same time period nine deaths occurred due to rupture of another known, unknown, or de-novo aneurysm.

The majority of deaths however were not related to cerebral aneurysms or the previous SAH.

Most deaths were due to cancer and cardiovascular disease, with significantly more deaths in the survivors in both groups than in the general age-matched population.

Personal comment

ISAT was a landmark trial which changed worldwide practice and established coiling as a viable option for treatment of ruptured aneurysms, providing class 1 level A evidence that coiling compared with clipping improves short-term and medium-term clinical outcomes for selected patients[1,2,4]. The current publication now provides long-term follow-up data for ISAT patients, thereby addressing previously raised issues within the neurovascular community regarding long-term efficacy of coiling and whether improved clinical outcomes of coiling persist in the long term.

The published long-term follow up data is however only for the UK patient cohort, and does not include all patients initially enrolled in the study.

The major concern raised for coiling has always been uncertainty regarding long-term durability of aneurysm occlusion and whether coiled aneurysms are protected from future rupture. ISAT is the only prospective longitudinal multicenter randomized controlled trial comparing clipping and coiling after SAH that has addressed such long-term follow up and now gives the most reliable data to answer this question.

The long-term follow-up data does show a small, but statistically significant, excess risk of recurrent SAH from the treated aneurysm in the coiling group compared with the surgical group.

However, this did not translate into a significantly worse clinical outcome in the coiling group, and the overall risk of death or dependency from rebleeding did not differ between the groups.

Overall the number of rebleeding events from the treated aneurysm occurring after the initial one year of follow up is low for both groups, and similar to risk of bleeding from another source.

Regarding clinical outcomes, previously published one year outcome data showed 23.5% of the endovascular group were dead or dependent at one year compared to 30.9% of neurosurgical patients, with an absolute risk reduction for death or dependency of 7.4% for the endovascular group[2].

Medium term follow up showed that risk of death at five years was significantly lower in the endovascular group than the clipping group (relative risk 0.77, 95% CI 0.61-0.98, p=0.03).

However, the proportion of survivors who were independent did not significantly

differ between the two groups (83% for endovascular group versus 82% for neurosurgical group)[4].

The long-term follow-up data from the UK cohort published here shows similar findings to the mid-term analysis.

The proportion of patients independent at 10 years was not significantly different between the groups (endovascular 82% vs neurosurgical 78%, OR 1.25, 95% CI 0.92-1.71).

However, the probability of being alive and independent was significantly higher for the endovascular compared to neurosurgical group (OR 1.34, 95%CI 1.07-1.67). This suggests that the clinical benefit of coiling remains significant in the long-term, and can be taken as reassurance that the slightly higher rebleeding rate in the coiling group does not cancel out the initial effectiveness.

There are, however, some caveats regarding this data and its interpretations. Data analysis in ISAT was based on intention to treat, cross over was allowed and occurred between groups. Nevertheless, patients were analyzed with their originally allocated groups rather than the treatment type ultimately received.

Thus it is unclear whether the 13 patients randomized to the endovascular group who had recurrent SAH from the target aneurysm were actually treated with coiling, while the same holds true for the four patients with recurrent SAH allocated to the surgical group. Since outcome results are described in this manuscript only for the UK patient cohort, direct comparison of clinical outcomes, number of rebleeding events and aneurysm retreatments between the current manuscript and previously published follow up data is difficult.

Previously published data from the ISAT cohort showed that late aneurysm retreatments were performed approximately seven times more frequently among patients treated with coiling than clipping, however analysis at that time showed no significant difference in rebleeding rates between the two groups, and retreatment did not cause significant additional morbidity[3].

What's missing in the current publication is the angiographic data, a significant limitation, as also mentioned by the authors. Without imaging it is impossible to correlate degree of aneurysm occlusion from original procedure, aneurysm recanalization, or change in size or configuration of an aneurysm remnant with the published long-term rebleeding risk. Criticism has previously been directed at ISAT[5] regarding inclusion of rebleeding events that occurred prior to aneurysm treatment, as the surgical allocated group had a higher rate of rebleeding and death prior to treatment.

It is also worth mentioning, that the results of ISAT continue to apply to those patients who were eligible for the study, i.e. those patients in whom clinical equipoise existed regarding clipping or coiling at the time. The majority of aneurysms (95%) were anterior circulation and less than 10mm (90%).

As with earlier publications from the ISAT investigators, the long-term results published here cannot be extrapolated to all aneurysms and cannot be translated into believing that coiling is safer for all aneurysms.

In applying the long-term follow up results of ISAT to any individual patient it is important to consider different additional factors, including anatomy and location of aneurysm, age and clinical state of the patient as well as resources and skill set available in a given neurovascular center. It is also worth mentioning that treatment modalities and techniques, especially from an endovascular point of view, have evolved over time, thus rendering application of the ISAT trial to current practice not necessarily accurate.

In summary, the long-term follow-up of the ISAT data shows slightly increased risk of rebleeding from target aneurysm in the coiling group, although this does not translate to increased morbidity or mortality, and the benefit of endovascular coiling in terms of probability of independent survival remains significant in the long term.

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Lifelong Rupture Risk of Intracranial Aneurysms Depends on Risk Factors: A Prospective Finnish Cohort Study

Korja M, Lehto H, Juvela S

Stroke. 2014 Jul;45(7):1958-63. Epub 2014 May 22

Background and Purpose: Our aim was to define for the first time the lifelong natural course of unruptured intracranial aneurysms (UIAs) and identify high-risk and low-risk patients for the rupture.

Methods: 118 patients (61 women) with UIAs were diagnosed between 1956 and 1978 and followed up until death or subarachnoid hemorrhage (SAH). The median age at the diagnosis was 43.5 years (range, 22.6–60.7 years). The median size of the UIA at the diagnosis was 4mm (range, 2–25mm). Analyzed risk factors for a rupture included sex, age, cigarette smoking, systolic blood pressure values, diagnosed hypertension, UIA size, and number of UIAs.

Results: 34 (29%) out of 118 people had SAH during the lifelong follow-up. The median age at SAH was 51.3 years (range, 30.1–71.8 years). The annual rupture rate per patient was 1.6%. Female sex, current smoking, and aneurysm size of ≥7 mm in diameter were risk factors for a lifetime SAH. Depending on the risk factor burden, the lifetime risk of an aneurysmal SAH varied from 0% to 100%, and the annual rupture rate from 0% to 6.5%. Of the 96 patients with small (<7 mm) UIAs, 24 (25%) had an aneurysmal SAH during the follow-up.

Conclusions: Almost 30% of all UIAs in people of working age ruptured during a lifelong follow-up. The risk varied substantially on the basis of risk factor burden. Because even small UIAs ruptured, decisions about treatment should perhaps be based on the risk factor status.

Personal comment

This is an interesting Finish study which, as authors say, might never be repeated because nowadays it would be really hard to leave a group of diagnosed aneurysms under observation without any treatment until they die or bleed.

It is a cohort study of people diagnosed with an aneurysm between 1956 and 1978. The endpoint was death from any cause or SAH.

A total of 118 patients entered this cohort. Several variables were analyzed as age, sex, smoking habit, blood pressure, aneurysm number and its size (less than 7mm or >= 7mm).

In our opinion the first bias of this work is that in 93% of patients (110/118) their UIA was diagnosed after a SAH from another aneurysm, a well-known subgroup with high risk for rupture. Thus, in this cohort, we are not dealing with 'true' UIA, and nowadays there is not too much doubt about treating an unruptured aneurysm when there is a previous SAH from another aneurysm.

Another concern is the retrospective nature of data collection, especially when we are dealing with epidemiological records and this could be a major bias.

Nevertheless, because of the nature of this lifelong study, some interesting data could be pulled out.

From diagnosis, the mean time to rupture was 12 years. Thirty-eight patients bled, with a 1.2% annual risk of aneurysm rupture. The authors did not separate the aneurysm by their location, nor were they differentiated in anterior or posterior circulation,a well-known risk for rupture.

Data showed that you are more prone to have a SAH if you are diagnosed under the age of 40. With a mean rupture age close to 50 years, could this mean that aneurysms get more stable in older ages? We don't know when the aneurysm was formed. Is this difference only due to other causes of death before aneurysm rupture in the older group?

Lifetime risk for rupture was greater for women, as was smoking as largely described in literature. On the other side, hypertension did not have an association with rupture.

A usual concern in this disease is aneurysm growth. Half of UIA had a control angiography during lifetime or measurement at autopsy, with a surprising half of them that grew more than 2mm during a certain period. Unfortunately it does not seem possible to calculate a growth rate. Thus, in 22 ruptured aneurysms below 7mm at baseline, 17/22 grew over 7mm size when controlled at rupture. Using this data, maybe it is not sufficient to clear out risk based on a baseline measurement.

So clearly we should follow up UIA under 7mm when decided not to treat.(does this make sense?) But, how often? Up to when? Using which diagnostic imaging? One out of four UIA that ruptured was diagnosed with less than 7mm. But then only one in five was below this size at the SAH episode.

Several subgroups with different risks for aneurysm rupture were identified by the authors,. With the lowest risk (0%) in men who never smoked with a small aneurysm, to high risk group in women smokers with big aneurysms (100%).

We have doubts if this data could be extrapolated or used in the usual incidental UIA that we all face in the daily medical practice with no previous SAH. The question to treat or not in this group could not be assessed using the risk table and grouping suggested in this paper.

Thus, it has a value in UIA with previous SAH. As previously stated, in our practice we treat these aneurysms when technically feasible endovascularly or surgically. Nevertheless we could use data expressed in this investigation for counseling or in the decision-making process in some special cases, such as patients not wiling to be treated, medical risk factors, very small aneurysms, etc.

Rodrigo Rivera & Rodrigo Riveros, Santiago, Chile

Optimized Angiographic CT Using Intravenous Contrast Injection: A Noninvasive Imaging Option for the Follow-Up of Coiled Aneurysms?

P. Gölitz, T. Struffert, I. Kaschka, K. Roessler, F. Knossalla and A. Doerfler

AJNR Am J Neuroradiol 2015; 36:98-107

Because recanalization of coiled cerebral aneurysms is reported to occur, follow-up imaging is mandatory, ideally noninvasively.

This study aimed to evaluate the accuracy of an optimized angiographic CT by using intravenous contrast material injection, compared with MR angiography and digital subtraction angiography, in the assessment of coiled cerebral aneurysms.

Sixty nine patients with 76 coiled cerebral aneurysms were included. In each patient, an angiographic CT with intravenous contrast material injection with a dual rotational acquisition, a time-of-flight MR angiography, and a DSA was performed.

The angiographic CT with intravenous contrast material injection data was post-processed by using newly implemented reconstructions modes and a dual-volume technique.

An aneurysm occlusion rate was assessed in angiographic CT with intravenous contrast material injection and MRA. Remnants were measured and correlated with DSA, respectively.

Twenty-eight remnants were revealed by DSA with a mean size of 3.1 × 3.1 mm. Angiographic CT with intravenous contrast material injection demonstrated a sensitivity of 93% and a specificity of 96% in remnant detection. MRA showed almost identical accuracy (sensitivity of 93%, specificity of 100%).

Assessment of remnant size by angiographic CT with intravenous contrast material injection and by MRA revealed a high significant correlation with DSA, respectively ($P < .001$).

Optimized angiographic CT with intravenous contrast material injection and MRA demonstrated accuracy comparable with that of DSA in the follow-up of coiled aneurysms, respectively. The assessment of remnant size showed a high correlation with DSA for both techniques.

Due to the lack of radiation exposure, MRA seems to be the preferred technique.

However, angiographic CT with intravenous contrast material injection can be considered a reliable, noninvasive alternative in patients with MR imaging contraindications, or in cases of compromising artifacts due to metal implants (ie, clips).

Personal Comment:

The authors address a very important topic: Can we do CTA during follow-up of coiled aneurysms? Ideally, follow-up is done by MR.

However, there are patients with contraindications for MR and these were previously thought to need an invasive DSA for follow-up due to the metallic artifacts of the coils on CT.

The group around Arnd Doerfler in Erlangen nicely demonstrated that CTA is an excellent alternative for those patients. The number of patients requiring an invasive angiography during their follow-up period is now approaching zero.

Michael Forsting, Essen

MRA Versus DSA for Follow-Up of Coiled Intracranial Aneurysms: A Meta-Analysis

van Amerongen MJ, Boogaarts HD, de Vries J, Verbeek AL, Meijer FJ, Prokop M, Bartels RH

AJNR Am J Neuroradiol. 2014 Sep;35(9):1655-1661. Epub 2013 Sep 5

Van Amerongen et al. have performed a meta-analysis to assess which of two neuroimaging techniques (TOF-MRA and CE-MRA) is better at detecting the presence of residual flow within aneurysms treated by endovascular packing with coils. Sensitivity (86%) and specificity (84-89%) of the two techniques were quite similar compared to angiography (DSA).

Compared with DSA, detection of residual necks and residual aneurysms by these two imaging methods was lower, CE-MRA being less sensitive than 3D TOF.

The authors conclude that these neuroimaging techniques are both suitable for aneurysm follow-up.

Personal comment

Protocols for, and experience with, follow-up of aneurysms treated using coils at individual centres can be highly variable. Clinical practice guidelines (CPGs) contain no specific recommendations as to duration, neuroimaging modality, or periodicity for follow-up of aneurysms treated by means of coils[1].

There is agreement only on the fact that aneurysms require long-term follow-up. The CPG issued by the American Heart Association in 2012 contained a Class I Level B recommendation for follow-up of aneurysms after endovascular or surgical repaired.

This very general recommendation provides that repaired aneurysms should be followed up using an imaging technique, with follow-up duration and imaging modality being left to be determined in each individual case[2].

While cerebral angiography and 3D modalities are currently regarded as the methods of choice for follow-up of aneurysms treated by means of coils, the methods are invasive, expensive, and not devoid of risk and, as such, are not considered advisable for extended follow-up.

MR angio with 3D TOF sequences and CE MR angio are suitable for follow-up of aneurysms repaired by coil packing, but there is no evidence as to which of these two methods is better, and there are no randomized studies contrasting them with DSA. There is also no scientific evidence demonstrating the superiority of 3T magnets over 1.5T magnets for aneurysm follow-up.

What stands to reason, and what experience tells us, is that scans of aneurysms repaired using coils should be carried out on the same equipment, always using the same sequence, and results should be evaluated by a neuroradiologist.

Each center's own experience and resources are basic to deciding whether repeat DSA is indicated on suspicion of aneurysm growth or changes.

There is also no agreement as to proper aneurysm follow-up duration. Some authors have recommended follow-up for three years[3]. Others have suggested one year if aneurysm occlusion is stable, whereas still other teams have continued follow-up for up to 10 years after repair[4].

Perhaps the scientific community should try to reach a consensus on setting general guidelines for follow-up of aneurysms repaired using coils, specifying radiological findings, the neuroimaging modalities to be employed, and follow-up duration and intervals, with a view to obtaining better clinical results and optimizing the rational use of available resources.

Alejandro González, Sevilla, Spain

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