

THE CORE

SVIN Newsletter • Volume 1, Number 1 • August 2012

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Society News

- 1. The 5th SVIN Annual meeting for 2012 is tentatively planned for October 27-28, in Miami, at the Fontainebleu and will be led by Dr. Italo Linfante. For any recommendations on suggested content or how to improve this meeting, please email: director@svin.org.
- 2. We are pleased to announce the launch of a new journal, The Stroke Interventionalist, the first peer-reviewed publication dedicated to the science, practice and art of acute treatment of stroke. The journal editors-in-chief are Drs. Jeff Saver and Dr. Osama Zaidat. More details in this edition of The Core.
- 3. The SVIN and American Association of Neurological Surgeons (AANS), Cerebrovascular Section will have a liaison whose role will be to promote both society interests with each other. Dr. Osama Zaidat has been voted to be the liaison for this position.
- 4. The AANS and SVIN will be holding a fellows course in Memphis, Tennessee on October 20-21.
- 5. The second SVIN practicum and interactive laboratory is planned tentatively for Winter 2013.

PRESIDENT'S MESSAGE

Dear SVIN Members,

My decision to become an Interventional Neurologist (IN), similar to the decision made by most of you, was based on a belief in the tremendous potential of endovascular therapy for the patient with a major acute ischemic stroke (AIS). The anecdotal AIS patient who has an immediate dramatic improvement in her severe neurological deficit within minutes of recanalization with endovascular therapy, on the angiography table - the Lazarus effect makes it hard not to believe that endovascular therapy works! The temporal proximity of the intervention to the clinical improvement, the strong scientific rationale - restoration of blood flow to ischemic brain- and the similarity to the mechanism of action (recanalization) to the established standard of care - IV tPA, support this strong belief in Intra-Arterial Cerebral Thrombolysis (IACT) for AIS. Since the PRO-ACT trials showed the benefit for IACT using pro-urokinase, the field has been galvanized to reconfirm the efficacy of IACT using the available endovascular recanalization therapies and also to show superior benefit as compared to IV tPA. In the last few months, two key events have occurred in the unfolding story of IACT that will define our field moving forward: the exciting positive results of the SWIFT trial which fueled unbridled optimism, and the finding of futility in IMS III by the Data Safety Monitoring Board (DSMB), which quickly sobered up the former outburst of exuberance.

The results of SWIFT were presented by SVIN Board member Dr. Jeff Saver at the late-breaking session of ISC 2012 on February 2, 2012. In this trial comparing the new stent retriever Solitaire to the approved MERCI retriever (55 Merci, 58 Solitaire) in an open-label randomized protocol, the new device performed much better as measured by successful recanalization without SICH (60.7% vs 24.1%, p=0 .0001),



good neurologic outcome at 90 days (58.2% vs 33.3%, p=0.017) and mortality at 90 days (17.2% vs 38.2%, p=0.020). Not only were these results the first ever to compare a new device to a previously approved one for IACT, the performance of the new device exceeded most expectations! While the study was small in size, powered for the primary endpoints of recanalization and non-inferiority to the previous device, and did not have a medical arm, the concordance of better recanalization leading to better clinical outcomes further strengthened one's belief in IACT.

However, just when celebrations of the results of the SWIFT trial were beginning, the DSMB for IMS III - the first phase III trial of IACT combined with IV tPA versus IV tPA alone put the trial on hold for futility, although no significant safety concerns were found. The trial, which was begun in 2006, had enrolled 656/900 when it was put on hold on April 19, 2012. The study data remains blinded to the investigators at this point. After analyzing data from 587 enrolled patients, the DSMB found that there was a very low likelihood of finding superiority (>/= 10% favorable clinical outcome of mRS 0-2 at 3 months) in the interventional arm if the trial went to complete enrollment. The likelihood was lower than the prespecified rule of <20% for stopping (personal communication, Dr. Pooja Khatri). Given that we do not have any further results from IMS-3 at this time, one can only speculate about the reasons for its futility. It will likely be true that the heterogeneity of the IACT strategies (IA tPA, IA tPA with EKOS ultrasound catheter, Merci retriever, Penumbra,

PRESIDENT'S MESSAGE (continued)

plus the less than 1% treated with Solitaire device), while designed to mimic clinical practice of the times, is inconsistent with the currently practiced IACT strategies to achieve the best outcomes in interventional arm. The different IACT strategies in the IMS-3 trial were never proven to be equal, they were just assumed to be so. Especially after the SWIFT results, we know that they are not so. It is also likely that selection of patients with a non-contrast head CT and a high NIHSS score are insufficient to achieve benefit from IACT. Since the IMS III trial was designed, most centers have evolved to use advanced imaging to select their patients based on emerging data and experience. It will be crucial to know if the small subset of patients in IMS III that did advanced imaging and showed salvageable brain tissue show a positive signal of efficacy. In the IMS-3 study "intention to treat" results will include all patients regardless of visualization of large artery occlusion, and patients with recanalized arteries prior to intervention will dilute the efficacy of IACT in the trial. If the result is positive in the subset of patients who had an angiographically proven large artery occlusion, it will consolidate the evidence from multiple Phase II studies showing that recanalization of an occluded artery with IACT is associated with improved outcomes.

In light of the considerable significance of the above events to SVIN and its members, the leadership of SVIN has initiated the following actions in response: 1. The SVIN Research Consortium (SVINRC) is drafting a plan to form a clinical trials network that can consolidate the strength of the active members of SVIN for upcoming IACT trials. 2. An electronic survey of opinions on next steps will be sent to all Active SVIN members to determine strategies that have the most support amongst practicing INs. 3. A SVIN position statement based on available evidence on peri-operative management of patients undergoing IACT is being commissioned to standardize periprocedural protocols in future trials. 4. A SVIN Eforum for members to post their opinions on IACT trials and practice will be available soon.

In the next few months, with the un-blinding of IMS III data and presentation of MR RES-CUE results, we will know much more about how we need to move forward with IACT. Regardless of the findings, one can be confidant that we practice our craft in an extremely dynamic field and in very exciting times!

Dileep Yavagal, MD SVIN President

EDITOR'S CORNER Newsletter Staff

Yousef Hannawi, MD Syed Hussain, MD Sophia Janjua, MD Amit Kansara, MD Thanh Nguyen, MD Mohammed Teleb, MD Annette Schott Viktor Szeder, MD Ramy El Khoury, MD Dileep Yavagal, MD Osama Zaidat, MD

The Core

In this edition of the SVIN Newsletter, The Core, we present a special tribute and memoriam to Dr. C. Miller Fisher (1913-2012) who passed away this past April. Dr. Fisher was a pioneering stroke neurologist, for whom we are in deep gratitude to his descriptions of stroke syndromes, stroke pathophysiology, and treatments. His work was transforming to our field.

There are several trial, journal, and study updates in The Core. In the SVIN President's message, Dr. Dileep Yavagal discusses the recent results of the SWIFT trial leading to the FDA approval of the Solitaire device. Dr. Yavagal also provides an update on the IMS III trial and its impact on our practice.

We also have special guests, Drs. Jeff Saver and Osama Zaidat who introduce "The Stroke Interventionalist", a new journal dedicated to the treatment of acute stroke.

Dr. Amit Kansara and Dr. Alireza Noorian provide us important updates from the International Stroke Conference and American Academy of Neurology Conferences from 2012.

We are also very grateful to have an invited guest to The Core, Mr. Andrew Fisher, who describes his experience as an interventional stroke patient under the care of Dr. Abou Chebl. We encourage you to read this unique patient perspective.

We thank our newsletter staff for their contributions in this edition of The Core. We hope





to continue to recruit other SVIN members or interested readers at large to maintain an informative newsletter. This will require a coordinated team effort and we are looking forward to working with all of you. If you have any ideas or interest in writing articles, editorials, or commentary for future SVIN newsletter editions, this would be most welcome.

Sincerely, Thanh Nguyen SVIN Newsletter Editor

Syed Hussain SVIN Newsletter Associate Editor

THE STROKE INTERVENTIONALIST: THE CLINICAL JOURNAL OF ACUTE STROKE TREATMENT

Endorsed by The Society of Vascular and Interventional Neurology

CO-EDITORS-IN-CHIEF: JEFFREY L. SAVER, MD AND OSAMA ZAIDAT, MD

PUBLISHER: THE STROKE GROUP, INC.

CORRESPONDENCE TO PUBLISHER: TSGHOUSER@AOL.COM

As co-editors, we are pleased to announce the launch of The Stroke Interventionalist (TSI), a new open access journal dedicated exclusively to acute stroke treatment, emphasizing neurointerventional approaches. TSI is the result of a collaboration between The Society of Vascular and Interventional Neurology (SVIN) and the journal's publisher, The Stroke Group. The Stroke Interventionalist is the first peer-reviewed publication devoted solely to the science, practice and medical art surrounding the acute treatment of stroke. The website is tsijournal.com.

TSI is very timely, as we witness the practice of stroke treatment integration and intervention rapidly evolving, albeit with accompanying controversies and challenges. It is our intent, via TSI, to help advance, chronicle and expand our interdisciplinary approaches by providing a forum for exchanging and communicating original articles, clinically-related research, reviews, clinician perspectives and commentary.

TSI offers the members of SVIN the immediate opportunity to submit and have your manuscripts rapidly published online and in print at no cost. We have designed the author submission process to be convenient, the peerreview process to be efficient and the publication of your content to be rapid. TSI represents a unique platform to address issues and aspects of interventional stroke therapy important to you and to the field. TSI online will include discussion of the topics contained in the journal along with a good deal of commentary we invite you to contribute.

As a clinically-focused journal, the content is intended to be informative, pragmatic and applicable; stimulating, benchmarking and expanding the ethos and mechanics of stroke treatment paradigms. We invite authors to offer insights into treatment modalities, present innovative care-delivery models, take on controversies and illuminate overarching issues which may affect the practices, policies and resources significant to our disciplines and to our field.

Publication categories include the following:

- Original Articles
- Innovations in Clinical Practice, Therapeutic Approaches and System Organization
- Healthcare Policy Considerations
- Reviews
- Case Reports
- Perspectives on Acute Stroke Treatment
- Editorials
- Letters to the Editor

We have assembled an extraordinary editorial board, drawn from SVIN board members as well as other respected stroke treatment clinicians who have agreed to collaborate with us on this new publication.

TSI content will be peer-reviewed, indexed and initially published in both print and electronic versions. Ultimately, it will be published exclusively online with features unique to that

THE STROKE INTERVENTIONALIST (continued)

medium. It is important to note that this is an open-access journal, immediately availing it to the broader global stroke treatment community. It is funded through grants and other non-subscription sources. The inaugural year of TSI publication is supported through an unrestricted educational grant from ev3, Covidien.

The print version will be circulated to stroke centers, academic libraries and targeted healthcare professionals. It will be published frequently dependent upon the volume of quality submissions the journal receives. The online unrestricted open access version will be updated as new manuscripts are reviewed and accepted by our editorial board.

Together with the TSI editorial editors and publisher, we are pleased to issue you and your colleagues the invitation to submit manuscripts or perspective articles to the journal. Authors are also invited to include video and full color images supporting their work. Because of underwriting support, there are no author fees associated with manuscript submission. Please contact the publisher, Gary Houser at tsghouser@aol.com for guidance in preparation and submission of manuscripts, articles and letters to the editor. Our hope and intent is that TSI will prove to be a vital new resource supporting our shared ethos of continually improving the clinical knowledge, therapeutic modalities, treatment tools and systems of care we employ to optimize the outcomes of patients with acute stroke.

Website link: http://71.208.236.132/tsijournal.com/

Sincerely,

Jeffrey Saver, MD Sam Zaidat, MD Co-Editors-in-Chief

The International Stroke conference took place this year in New Orleans, Louisiana

INTERNATIONAL STROKE CONFERENCE 2012 NEW ORLEANS, USA

The International Stroke conference took place this year in New Orleans, Louisiana between February 1st and February 3rd 2012. As usual it was a site for bustling discourse, networking and presentation of long anticipated clinical trials. We are including a review of noteworthy abstracts and presentations from the sessions.

ABSTRACT REVIEWS

SOLITAIRE[™] With the Intention for Thrombectomy (SWIFT) Trial



Jeffrey L Saver, Reza Jahan, Elad Levy, Tudor G Jovin, Blaise Baxter, Raul Nogueira, Wayne Clark, Ronald Budzik, Osama O Zaidat for the SWIFT Trialists

The SOLITAIRETM Flow Restoration device (SOLITAIRETM) is a self-expanding stent retriever designed to yield rapid flow restoration in acute cerebral ischemia. The SWIFT trial was a multicenter RCT designed to demonstrate non-inferiority of SOLITAIRETM compared with the MERCI Retrieval System® and safety and efficacy of SOLITAIRETM in subjects requiring mechanical thrombectomy diagnosed with acute ischemic stroke within 8 hours of symptom onset. Key entry criteria



were the following: age 22-85; NIHSS 8-29; ineligible or failed IV TPA; intracranial ICA, M1, M2, BA, or VA occlusion. The study population had 113 randomized patients, 58 SOLITAIRE™, 55 MERCI®. Among the randomized patients, the SOLITAIRE™ and MERCI® treatment arms were comparable in age, pretreatment NIHSS (17.3 vs 17.5), onset to treatment time (294 vs 320 mins, p=0.14) and 13 additional demographic and medical history variables; but differed in history of atrial fibrillation (45% vs 67%, p=0.022). Procedure-related adverse events were similar in the two treatment groups. The primary efficacy outcome, successful recanalization (TIMI 2-3) without SICH, was achieved more often in SOLITAIRE[™] vs MERCI[®] patients, 60.7% vs 24.1%, noninferiority p<0.0001, superiority p=0.0001. Additional efficacy outcomes are shown in the Table. Authors concluded that SOLITAIRE[™] Flow Restoration device is superior to the MERCI® Retriever in achieving successful recanalization free of symptomatic hemorrhagic transformation, reduced mortality and good neurological outcome at 3 months.

exclusively online with features unique to that medium. It is important to note that this is an open-access journal, immediately availing it to the broader global stroke treatment community. It is funded through grants and

> Image from Machi P et al. J NeuroIntervent Surg 2012;4:62-66

Based on the SWIFT trial results, The SOLITAIRETM Flow Restoration device (SOLITAIRETM) got FDA approval in USA in March, 2012 for revascularization in acute ischemic stroke.

Final Results From The Trevo Study (Thrombectomy REvascularization of large Vessel Occlusions in acute ischemic stroke)

Nils Wahlgren, Juan Macho, Monika Killer, David Liebeskind, Olav Jansen

The Trevo® System utilizing StentrieverTM Technology is a novel device for removal of thrombus in patients suffering an acute ischemic stroke. This device has been engineered to maximize thrombus integration to potentially provide an easy and predictable method of mechanical thrombectomy. Seven centers in Europe participated in this multi-center, prospective, single-arm trial evaluating mechanical thrombectomy with the Trevo System. Patients with persistent large vessel occlusion aged 18-85 with an NIHSS of 8-30 and symptom onset within 8 hours were included. The primary endpoint was target vessel revascularization, defined as TICI 2a or better, read by the independent imaging core lab. Secondary endpoints included clinical outcomes at 90 days, defined as modified Rankin Score (mRS) = 0-2. A total of 60 subjects were enrolled. The median age and NIHSS was 65 and 18, respectively. The mean time from symptom onset to arterial puncture was 3.5 hours. IV lytic was given to 60% of the subjects and IA lytic was administered in 10%. Revascularization success was achieved in 89.6% of cases following Trevo use and 91.4% at the end of the procedure. The median 24h and 7d NIHSS was 9 and 4, respectively. By 7 days, 45% had achieved an mRS score of 0-2. The 90d days good outcome rate was 57% and 90 days mortality was 22%. SICH rate was 5 %. Authors concluded that Trevo system showed high rates of revascularization and procedural success.

CT Perfusion Increases Time to Reperfusion and May Not Enhance Patient Selection for Endovascular Reperfusion Therapies in Acute Ischemic Stroke

R. Gupta, D. Wisco, A.H. Tayal, B. Miller, J. Terry, D. Gandhi, T.G. Jovin, M.S. Hussain, T.N. Nguyen, B. Ludwig, C. Cronin, M. Tian, K.N. Sheth, R.G. Nogueira.

In this retrospective study, authors reported patients from seven institutions who utilize endovascular reperfusion therapies for 338 patients with a mean age of 67±14 years and mean NIHSS of 18±5 acute anterior circualtion ischemic stroke within 8 hours. Patients were selected with a non-contrast head CT or CTP based on institutional protocols. Goal was to determine if patients selected with CTP had longer times to treatment or differences in outcomes. There were no differences in baseline demographics including age, site of vascular occlusion, and pre-treatment NIHSS in patients selected with CTP compared to non-contrast. There was no difference in rates of symptomatic hemorrhage in patients imaged with CTP compared to CT (6.8% vs. 6.6%, p<0.82), good outcomes (36.5% vs. 38.9%, p<0.72) and final infarct volume (80±64 cm3 vs. 88±62 cm3, p<0.32). Patients who were selected with CTP were noted to have significantly longer times from CT acquisition to groin puncture times and reperfusion compared to patients with non-contrast CT (132±57 mins. vs. 97±60 mins., p<0.01) and (227±109 mins. vs. 199±91 mins., p<0.001). Authors concluded that acquisition of CTP may lead to delays in initiating endovascular procedures and suggested a future prospective study to determine if non contrast CT is not inferior to CTP in selecting patients for endovascular therapies in acute ischemic

Clinical And Imaging Outcomes For Target Aneurysm Retreatment For Remnant Intracranial Aneursym

Dhruvil J Pandya; Mohammed A Issa; Marc A Lazzaro; Rochelle Sweis; Muhammad Taqi; Michael Abraham; Ayman Gheith; John R Lynch; Osama O Zaidat

In this study, authors reported outcome and complications after target aneurysmal retreatment. There were a total of 155/1169 (13.3%) cases that underwent TAR with mean age of 55. One hundred four (67%), had aneurysm located in the anterior circulation, 4/116 (3%) underwent TAR for recurrent acute SAH, 72/116 (62%) required stent and 10/116 (9%) required balloon assist. There were 5/115 (4%) intraoperative perforations (IOP), and 8/115 (7%) thromboembolic events from which 2/115 (2%), and 1/115 (1%) were symptomatic respectively for a total of 3/115 (2.6%) patients. 117/151 (77%) had complete immediate obliteration of the aneurysm after TAR. Total of 90/155 (58%) patients had average follow up of 14 months with 8/90 (9%) requiring a 2nd TAR and 1/90 (1%) requiring 3rd TAR for recanalization. There was no re-rupture after the 1st TAR for the duration of follow-up period of 14 (in total of 90 patients).

They concluded that TAR after an initial endovascular treatment is safe with an acceptable rate of complications and may be effective, suggested by lower rate of re-rupture.

Results of DEFUSE 2: Clinical Endpoints

M.G. Lansberg, S. Kemp, M. Straka, M. Mlynash, L.R. Wechsler, T.G. Jovin, M.J. Wilder, H.L. Lutsep, T. Czartoski, R.A. Bernstein, C.W.J. Chang, S. Warach, F. Fazekas, D. Thai, M. Inoue, A. Tipirneni, S.A. Hamilton, G. Zaharchuk, M.P. Marks, R. Bammer, G.W. Albers.

In this prospective cohort study, consecutive patients at 9 stroke centers underwent acute endovascular therapy within 12 hours of stroke onset, if they had an NIHSSS>5 and could undergo an MRI with perfusion (PWI) and diffusion-weighted imaging (DWI) immediately before the intervention. Patients were classified as Target Mismatch (TMM) if they had a ratio of PWI(Tmax>6s) over DWI volume >1.8, DWI <70ml, and a PWI(Tmax>10s) volume <100ml. Early reperfusion was defined as a >50% reduction in Tmax>6s volume between baseline and early follow-up. The baseline characteristics of patients with TMM (n=70) were: mean age 67, median NIHSS 15, treated with iv tPA 43%, mean time from symptom onset to endovascular treatment 6.7 hrs, mean DWI volume 18 ml, and Tmax>6s volume 82 ml. Early reperfusion was achieved in 64% of the TMM population and favorable clinical response was more common in TMM patients with early reperfusion than in TMM patients who did not reperfuse (69% vs 24%; p<0.001). The odds ratio for favorable clinical response associated with reperfusion was higher in TMM patients (7.0; 95% CI 2.3-21) than in those without TMM (0.1; 95% CI 0.1-1.6) (p<0.01 for difference between odds ratios). These odds ratios remained similar after adjustment for differences in baseline characteristics (OR 7.8 vs. 0.2; p<0.01 for difference between odds ratios). Authors concluded that early

reperfusion following endovascular therapy is associated with substantial clinical benefits in patients with the Target Mismatch profile with the use of PWI/DWI on baseline MRI.

Treatment of Basilar Artery Occlusion Without Time Constraints: Clinical outcomes, safety and predictors of favorable results

Matthew T Starr; Syed F Zaidi; Mouhammmad A Jumaa; Vivek K Reddy; Maxim D Hammer; Brian T Jankowitz; Michael B Horowitz; Lawrence R Wechsler; Tudor G Jovin

In this retrospective study, authors reported 85 patients (median age 63, median NIHSS 18)) with basilar artery occlusion who underwent endovascular therapy based on their clinical and imaging parameters rather than timing parameters. Median time from last seen well (TLSW) to groin puncture: 774 min (12.9 hrs) (IQR 324min-2262min). Median procedure duration: 105.5 min (IQR 67min-145min). 18% of patients received IV tPA. TIMI 2-3 recanalization occurred in 87% of patients treated. Favorable outcomes were noted in 34% of patients. mRS of 3 was achieved in 9.4%. Mortality was 46%. PH was noted in 8.2% of patients. Treatment modalities included IA lytics (56.4%), MERCI device (39%), Penumbra (6%), Manual Aspiratoin Thrombectomy (27%), Stenting (42%), Angioplasty (46%). In 76.4% of patients the procedure was performed in an intubated state. In multivariate analysis, age, successful recanalization and admission glucose were found to be significantly associated with favorable outcomes. Of note TLSW to treatment initiation was not found in univariate or multivariate analyses to be significantly associated with favorable outcomes. They concluded that endovascular treatment

in selected patients with BAO without time window considerations is associated with similar rates of symptomatic hemorrhage (SICH) and rates of favorable outcomes compared to available literature data where selection is based on strict time windows. The role of time as selection criteria for treatment of BAO should be clarified by future prospective trials.

Clinical Outcomes Following Endovascular Stroke Treatment Facilitated via Telestroke Evaluation

Stacie Demel; Amin Aghaebrahim; Vivek Reddy; Maxim Hammer; Lori Massaro; Mouhammad Jumaa; Tudor Jovin; Lawrence Wechsler; Syed Zaidi

Authors reported clinical outcomes of patients undergoing endovascular stroke treatment triaged either through telestroke or nontelestroke means. Between 3/2007 and 5/2011, thirty four patients underwent endovascular stroke treatment following telestroke evaluation versus 354 patients who were triaged through other means. Baseline characteristics were similar between the groups. Time to endovascular treatment (595 vs. 767 minutes; p = 0.5), pretreatment with systemic tPA (51.6 vs. 56.9%, p=0.6), recanalization (TIMI 2; 91.2% vs. 84.8%; p = 0.31), favorable outcome (modified rankin score 2; 50% vs. 40.4%; p = 0.29) and mortality rates (28.1%) vs. 34.9%, p=0.44) were comparable. Multivariate logistic regression model identified young, successful recanalization and baseline ASPECT score as predictors of favorable outcome. They concluded that telestroke guided endovascular stroke treatment is feasible and the outcomes are similar to those patients who were triaged by traditional means.

Largest United States Pipeline Case Series After PUFS: Feasability, Technique, and Complications

Rohan Chitale; Fernando Gonzalez; Ciro Randazzo; Aaron S Dumont; Stavropoula Tjoumakaris; Robert H Rosenwasser; Hayan Dayoub; Pascal Jabbour

Following the FDA approval of the Pipeline embolization devices (PED), the authors reported case series of 25 patients who have undergone such embolization and examine feasibility, technique, early results, and complications. Twenty-five patients with 31 aneurysms were treated in the series (2 male; 23 female; ages 34-82; mean age 60.9 years). All of the aneurysms were located in segments of the internal carotid artery (1 petrous, 1 lacerum, 13 cavernous, 2 clinoid, 12 ophthalmic, 2 superior hypophyseal). PED placement was successful in all patients. The number of stents used per patient ranged from 1 to 5, with most patients being treated with 1(n=6) or 2(n=13) PEDs. One aneurysm was treated with both PED and coil embolization. Postoperative complications included intracerebral hemorrhage(n=3), dissection(n=1), stroke(n=2), and death(n=1). Authors concluded that treatment of simple or complex intracranial aneurysms with PEDs alone or in conjunction with coil embolization is technically feasible with low chance of intraoperative complication. However, major perioperative adverse events must be studied.

Brain AVM Embolization With Onyx: Clinical And Anatomical Results In A Prospective, Multicenter, European Study (BRAVO)

Laurent Pierot; BRAVO investigators

Onyx has been recently introduced in the armamentarium for AVM embolization. but large, multicenter evaluation is lacking. BRAVO (Brain ArterioVenous malformations embolization with Onyx) was a multicentric, prospective, consecutive study. 117 patients harbouring brain AVMs embolized with Onyx were included. Clinical presentation was mostly hemorrhage (30.8%) and epilepsy (27.4%). AVM size was less than 3cm in 52.1% of cases and more than 3cm in 47.9% of cases. A mean number of 2.05 embolization sessions / patient were performed with injection of a mean of 2.4 ml Onyx / session. Complete occlusion was obtained with Onyx embolization alone in a high percentage of cases (23.5% of all cases and 36.7% of AVM smaller than 3cm). Intra and post-operative bleeding related to the treatment was observed in 9.4% leading to death in 3.4% and neurologic worsening in 1.7%. Nonhemorrhagic permanent deficits were observed in 6.0% of cases. Treatment related morbidity (mRS>2) and mortality were respectively 5.1% and 4.3%. Authors concluded that embolization of brain AVMs with Onyx is associated with a high rate of complete occlusion with acceptable morbidity and mortality. Onyx was suggested as the first line embolization agent for the treatment of brain AVMs.

AMERICAN ACADEMY OF NEUROLOGY AN-NUAL MEETING REVIEW: NEW ORLEANS, USA

ALIREZA NOORIAN, MD

The American Academy of Neurology annual meeting was held in the Ernst N. Morial Convention Center in New Orleans, LA from April 21st to April 28th, 2012, covering a vast array



of neurological condition across all subspecialties. There were thousands of participants from nearly 24,000 members of the academy. Several sessions and courses for non-vascular neurologists were held on management of acute stroke and new developments in the field.

On the first day of the conference, Drs. Azeemuddin Ahmed and Enrique Leira had a session, on "Surviving Stroke Call: A Guide for non-vascular Neurologists", in which they discussed common scenarios and pitfalls in the initial assessment of acute stroke patients and consideration of IV rtPA in the acute setting.

During the second day of the conference, there was a session devoted to developing stroke centers, entitled "What is in a stroke center: members, services, organization and goals.", during which the basics of integrated acute stroke care in primary stroke centers, using telemedicine to expand the reach of coordinated stroke care, and types of stroke centers and systems were discussed by Drs. Nerses Sanossian, Bart Demaerschalk and Pooja Khatri.

Dr. Pooja Khatri discussed the current evidence-based pharmacologic and endovascular treatments in acute ischemic stroke. She also gave an update on the recent Interventional Management of Stroke- III (IMS-III), a phase III, randomized, multi-center, open label, 900 subject clinical trial to compare combined intravenous (IV) and intra-arterial (IA) approach to recanalization is superior to standard IV rt-PA alone initiated within three hours of acute ischemic stroke onset. Patients had NIHSS \geq 10 at the time that IV rt-PA is begun or an NIHSS >7 and <10 with large vessel occlusion. Intra-arterial treatment started at less than five hours and was completed by seven hours, after symptom onset, using either IA- rtPA, EKOS, Merci, Penumbra or Solitaire devices. A preplanned interim analysis was reviewed by the trial's independent Data and Safety Monitoring Board (DSMB) on April 18, 2012. The data showed that the study had a very low likelihood of demonstrating the pre-specified, clinically significant difference in benefit between the treatment arms of the study. The DSMB's decision was based upon the primary outcome in the study, the Modified Rankin Score at 3 months, meeting the threshold for futility. This analysis included data from 587 participants enrolled at over 50 sites world-wide. While enrollment was stopped because of futility, no serious safety concerns were identified.

She also mentioned another ongoing trial, currently enrolling patients, The Randomized, Concurrent Controlled Trial to Assess the Penumbra System's Safety and Effectiveness in the treatment of Acute Stroke (THERAPY) on acute ischemic stroke patients with NIHSS of 8 or greater or aphasia at presentation, eligible for IV- rtPA with large vessel occlusion in the anterior circulation with a clot length of 8mm or longer in non-contrast CT scan, to compare functional outcome at 30 days and complications in IV-rtPA group vs IV rtPA and IA treatment with the Penumbra System.

The results of Solitaire TM FR With the Intention For Thrombectomy (SWIFT) Study were also highlighted in this session. This study compared the new stentriever, Solitaire TM FR

AMERICAN ACADEMY OF NEUROLOGY ANNUAL MEETING REVIEW (continued)

with Merci device in acute stroke patients with large vessel occlusions, NIHSS≥8 and <30 and showed a superiority for Solitaire in recanalization rate (69% vs 30%), mortality rate (17% vs 38%) and good outcome (modified Rankin scale ≤2 or 10 point NIHSS change) at 90 days (58% vs 33%). Based on this evidence, Solitaire received Food and Drug Administration 510K clearance in March 2012.

Dr. Khatri also briefly talked about other recently completed: MR RESCUE (Mechanical Retrieval and Recanalization of Stroke Clots Using Embolectomy), TREVO (Thrombectomy revascularization of large vessel Occlusions in acute ischemic stroke), and ongoing trials 3D (A Randomized, Concurrent Controlled Trial to Assess the Safety and Effectiveness of the Separator 3D as a Component of the Penumbra System in the Revascularization of Large Vessel Occlusion in Acute Ischemic Stroke), EXTEND (Extending the Time for Thrombolysis in Emergency Neurological Deficits and) and CRISP (CT- Perfusion to predict response to recanalization in ischemic stroke project).

On the fifth day of the conference there was a dedicated half day course on the advances of telemedicine systems. It started with an introductory session by by Dr. Bart Demaerschalk on the implementation of tele-neurology obstacles and strategies, followed by a focused presentation by Dr. Lawrence Wechsler on the tele-stroke systems, current models of comprehensive and primary stroke centers in stroke care, development of hub and spoke models and how telemedicine can facilitate and improve efficiency and increase coverage for patients requiring endovascular treatments.

On the sixth day of the meeting, there was a half-day dedicated course entitled, "Update on Endovascular Treatment of Cerebrovascular Disease", with discussions on selection of patients for endovascular acute stroke therapy by Dr. Tudor Jovin, update on endovascular treatment in acute ischemic stroke by Dr. Thanh Nguyen, endovascular management of extracranial and intracranial atherosclerotic disease by Dr. Rishi Gupta and update on endovascular management of intracranial aneurysms, AVMs, and dural AV fistulae by Dr. Raul Nogueira.



5th Annual Meeting



October 27-28, 2012 Fontainebleau Hotel • Miami Beach, Florida For More Information Please Visit www.svin.org

SURVIVING A STROKE: A PATIENT'S STORY

ANDREW FISHER

March 18th, 2009. The only person in my family that had been affected by stroke was my 98 year old grandfather. Most of my family including myself



believed that stroke was a disease that happened when you reached a certain age. In fact, if you had asked me on that day I would have told you with confidence that it was a disease for the aged. Stroke was a part of being old and there was nothing that you could do about it. Fortunately for me there was an ever so small group of Neurologists that knew better.

On March 19th, 2009 I learned the hard way strokes can happen to anyone regardless of their age. I was 35 when I suffered my stroke. I had a brainstem stroke with a basilar artery occlusion. I do not need to explain to the audience of this newsletter the danger of this stroke and the harsh reality of the normal treatment that goes with it.

I was still able to speak when the doctor who diagnosed me sat down and told me my chances of making it and also what my quality of life would most likely be if I was fortunate enough to survive. When he informed me that there was an Interventional Neurologist at the University of Louisville that may be able to help me, I didn't know what to think. All I knew is that I had one of the few Neurologists that believed in a new procedure for stroke victims like me and was willing to look past hospital politics and get me to a place that could possibly help me. The rest was a whirlwind. Within the next few hours I was on a helicopter heading to Dr. Alex Abou-Chebl at the University of Louisville Hospital. I was also dying and dying quickly. I could no longer talk and was slipping into complete paralysis. Not only that but I was having a lot of trouble clearing my throat and

swallowing.

When faced with my own mortality and with the low likelihood of survival I turned down the procedure. I was scared and alone. I desparately wanted to see my twin 18 month old boys one more time. This procedure that I turned down was Angioplasty and stenting in my basilar artery. I didn't know the dangers of waiting; how each minute I waited I was letting my brain die.

Thank God Dr. Abou-Chebl knew these dangers and when my family finally consented, over 36 hours into my stroke, he was willing to help me. He wasn't ready to give up on me. At 4am on Saturday March 21st, 2009 a miraculous procedure was performed at the University of Louisville.

The rest is history and well documented. In fact I had a book published by a traditional publisher in May of 2011, which featured a forward written by the man who saved my life, Dr. Alex Abou-Chebl. He is not only a brilliant Doctor but a great humanitarian. I also call him a friend. We have gone all the way to Washington DC together to gather support for this controversial procedure, at the time. I have been on more than a few TV shows from Davenport, Iowa to Evansville, Indiana, as well as Indianapolis and Louisville. I have become a rather articulate public speaker that has become very adept on this topic.



SURVIVING A STROKE: A PATIENT'S STORY (continued)



In my book I go into great detail of the time when I was slipping into a locked in state and I document my downward spiral along with each and every moment of the procedure I was kept awake for. I have spent much of my spare time helping the American Stroke Association with stroke awareness and have also been commissioned a Kentucky Colonel for the work I do with the University of Louisville. My goal is to help make these procedures as common as angioplasty of the heart.

I have also made it my life goal to help change state legislation to mandate that stroke victims be taken to stroke certified hospitals, and when within reasonable distance, I would like to see them get to regional hospitals such as the University of Louisville. I hope that after reading my story you will be driven to help me help you get Interventional Stroke Treatment into the mainstream media.

Dr. Ramsey, President of the University of Louisville, Dr. Abou-Chebl along with the Stroke center at the University of Louisville are all aware of what a powerful message I have and how many lives it can save. We can also help to educate the general public on Stroke awareness. And when the normal timeframe for traditional treatment has been surpassed, we can also educate medical professionals everywhere the options that may be available. I am healthier now than I ever have been and if not for this procedure I would either be dead or quadriplegic.

My book is called Surviving A Stroke, which can be found on Amazon.com or at my publishers website, ButlerBooks.com.

I would love to travel the world to speak about how this procedure changed my life. Help me lobby congress for legislative changes as to the treatment of stroke patients.

Thank-you and God bless each of you,

Andrew Fisher drewfish32@yahoo.com 812-449-9332 5843 Lisa Lane Newburgh, IN. 47630

C. MILLER FISHER, IN MEMORIAM 1913-2012

THANH NGUYEN

"Neurology is learned stroke by stroke." -C. Miller Fisher

The neurology community lost one of the greatest stroke neurologists this past spring. Charles Miller Fisher was the pioneering figure of cerebrovascular neurology, defining

the pathophysiology and landmark stroke syndromes including transient ischemic attack, lacunar disease, carotid occlusive disease, and retinal ischemia related to the carotid artery. Born in 1913 in Waterloo, Canada, Dr. Fisher attended medical school at the University of Toronto. He subsequently served as Surgical Lieutenant Commander on the Voltaire British Naval Ship. Dr. Fisher was taken prisoner of war (POW) in a German camp when his ship sunk in 1941 off the coast of Cape Verde, and he was retrieved from

the ocean after staying afloat for 9 hours. He served as POW for 3.5 years, during which time "he read avidly, learned not to complain and just get on with things" (Hachinski). He was dismissed in a prisoner exchange when another colleague volunteered his spot for Dr. Fisher (Caplan).

Dr. Fisher resumed his medical career, as Fellow in Neurology at the Montreal Neurological Institute (1946-1948) where he came in contact with Dr. Wilder Penfield, a pioneer neurosurgeon. Dr. Fisher transitioned as Neuropathologist at the Montreal General Hospital. While studying stroke patients in Montreal (1947), Dr. Fisher suspected that emboli could originate from the carotid artery. He observed patients with blindness in one eye to have ensuing paralysis of the contralateral side. Dr. Fisher confirmed this hypothesis with the study of 1100 autopsies in Montreal, leading to the nascent practice of carotid endarterectomy. "It is even conceivable that some day vascular



surgery will find a way to by-pass the occluded portion of the internal carotid artery during the period of ominous fleeting symptoms." The first carotid stenosis surgery was performed by Raul Carrea in Buenos Aires in 1953, heralding a new era of stroke treatment (Hachinski).

In 1954, Dr. Fisher was recruited by Dr. Raymond D. Adams to the Boston City Hospital and Massachusetts General Hospital, where he continued to advance the field of stroke and general neurology over 50 years. In

Dr. Vladimir Hachinski's obituary on Dr. Fisher, TIAs were explained as fleeting vasospasms and the commonest cause of stroke was thought to be occlusion of the middle cerebral artery, until Dr. Fisher performed detailed clinical and pathological work to prove the role of transient decreases in cerebral blood flow and carotid disease. Dr. Fisher was the first to note the role of atrial fibrillation leading to stroke, and advocated for anticoagulation in this disease.

Dr. Fisher mentored many leaders of the stroke field, including Dr. Louis Caplan, Dr. JP Mohr, Dr. Philip Kistler, Dr. Walter Koroshetz, Dr. Carlos Kase and Dr. Phil Wolf. Dr.

C. MILLER FISHER, IN MEMORIAM (continued)

Fisher worked tirelessly in the care of patients, paying little attention to the pressures of time. He described findings objectively as they were, and kept meticulous notes in carefully classified folders, enabling him to later describe clinical syndromes from his observations. Following his retirement, Dr. Fisher remained active conducting CMF teaching rounds for neurology residents at the MGH; he was often found in libraries writing and conducting research. Among other awards, Dr. Fisher was inducted into the Canadian Medical Hall of Fame in 1998. The MGH stroke service was renamed the CMF service in honour of Dr. Fisher's legacy to the hospital.

Dr. Fisher passed away April 14, 2012 in Albany New York at the age of 98. He is survived by three children Peter, Hugh and Elizabeth, and four grandchildren. We are saddened by the loss of Dr. Fisher, one of the greatest pioneers in stroke. His memory and legacy will live on and continue to influence our daily practice of medicine through his teachings and impact to the stroke field.

REFERENCES

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- 3. Hachinski V. C. Miller Fisher Obituary. World Neurology June 2012.
- 4. Mohr J, Kistler JP, Caplan. C. Miller Fisher: An appreciation. Stroke June 2012.

UPCOMING MEETINGS

2nd International Congress of

Interventional Neurology

September 6th-8th Minneapolis, Minnesota Program Chair: Adnan I. Qureshi MD

10th Annual Neurocritical Care Society Meeting October 4th-7th Denver, Colorado

Joint AANS/SVIN Fellows Course October 20-21st Memphis, Tennessee

SVIN 5th Annual Meeting October 27-28, 2012 Fontainebleu Hotel, Miami, Florida Chair: Italo Linfante

International Stroke Conference 2013

February 6-8, 2013 Hawaii Convention Center 1801 Kalakaua Avenue Honolulu, HI

13th Congress of WFITN November 10-14, 2013 Buenos Aires, Argentina

Dear SVIN Members,

We would like to add a new section in the SVIN Newsletter: SVIN Members in the News. This section will include SVIN members who have been featured in the news, awarded with new research grants or interim publications. We welcome you to contribute to this section to help us highlight your achievements. Please send announcements to info@svin.org.