Supplement to

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Endovascular TODAY

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Current Concepts in Comprehensive Stroke Care

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Stroke is the number one cause of disability and the third leading cause of death in the US, yet it remains an undertreated disease in our healthcare environment despite its high incidence rate. Due to its acute nature and physical repercussions, even the accepted "gold standard" therapies must be administered quickly after the onset of symptoms.

In addition to the increasingly accepted standard therapy of intravenous injection of tissue plasminogen activator (tPA), endovascular options including mechanical embolectomy are now available. Mechanical embolectomy expands the time window for acute stroke intervention and has been studied for up to 8 hours after the onset of symptoms, enabling interventionists trained in this technique to offer additional options to their stroke patients.

Recognizing the need for additional options and the desire to ensure quality stroke treatment in this challenging population, many hospitals and independent centers have launched comprehensive stroke care programs with dedicated teams of interventional physicians and support staff. Medicare reimbursement makes treating stroke via IV tPA or mechanical embolectomy feasible, and some regions have established telestroke care networks as a means to provide organized and optimal care even in remote areas.

This supplement to *Endovascular Today* highlights these and other current trends in the evolving field of stroke therapy.

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Acute Stroke Intervention

A review of clinical data for available treatment options.

BY GRETCHEN BENKO MRUK, MS, MBA

Annually in the US, more than 780,000 individuals of varying ages suffer a stroke, 500,000 of which are first attacks.[1] The overwhelming majority (87%) are ischemic. As the number one cause of disability in the US and the third leading cause of death, stroke is a healthcare priority for our society. Indeed, for 2008, the estimated cost of stroke in the US is $65.5 billion.[1]

This article focuses solely on ischemic stroke and the currently available treatment options, namely thrombolysis and mechanical intervention. For this discussion, it is important to draw awareness to large-vessel strokes as a subset of acute ischemic stroke (AIS). Large-vessel strokes are reported to comprise 30% to 50% of AIS and are known to have an especially poor prognosis and high mortality rates (Table 1).[2,3]

IV TPA AS THE STANDARD OF CARE

Intravenous tissue plasminogen activator (IV tPA) is considered a gold standard for AIS treatment, yet less than 8% of stroke patients are eligible to receive IV tPA primarily due to the limited 3-hour window for treatment.[7] The current estimated utilization rate in the US is at 5% or less.[7,8] This means that only a fraction of AIS patients are eligible to receive the standard treatment, and even fewer actually receive it. Additionally, studies have shown that IV tPA commonly fails to open large-vessel strokes due to the significant clot burden in these vessels.[9] Figure 1 illustrates the frequency with which IV tPA opens large-vessel occlusions.

It has been reported that when IV tPA successfully recanalizes a large vessel, it occurs most frequently in the first 60 minutes (Figure 2).[10] After 1 hour, it becomes increasingly less likely that IV tPA will successfully recanalize the vessel. Interventional stroke centers often indicate in their protocols that patients receiving IV tPA are reassessed at 1 hour to determine the effectiveness of the therapy and to consider additional interventional options.

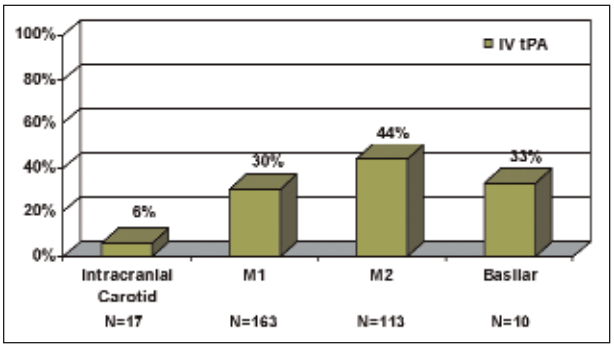

Figure 1. Revascularization rates using IV tPA in selected vessels.[9]

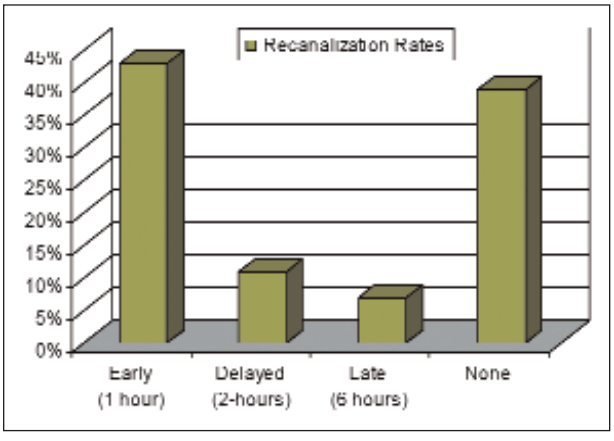

Figure 2. Time to revascularization using IV tPA.

TABLE 1. PUBLISHED MORTALITY RATES FOR UNTREATED OR UNDERTREATED LARGE-VESSEL STROKES

Vessel	Mortality Rate	Reference
Carotid T lesions	53% at 24 days	Jansen et al[4]
Middle cerebral artery	27% at 90 days	Furlan et al[5]
Basilar artery	83%	Brückmann et al[6]

ENDOVASCULAR INTERVENTION IN AIS: MECHANICAL EMBOLECTOMY

As noted previously, the primary reason cited for the lack of IV tPA utilization is the limited 3-hour window for treatment. Mechanical embolectomy is performed to remove a clot from the cerebral vasculature and restore blood flow to the affected brain region and has been studied in patients up to 8 hours after onset of symptoms, thereby expanding the treatment window. For patients who are ineligible for IV tPA for other reasons such as pharmacologic contraindications, mechanical embolectomy offers an alternative.

The MERCI and Multi MERCI trials demonstrated that the Merci Retriever® achieves revascularization of large vessels in AIS patients.[11-13] The MERCI trial reported a postprocedure revascularization rate of 60%. The Multi MERCI trial reported a postprocedure revascularization rate of 68% with a 9.8% symptomatic hemorrhage rate (2.4% symptomatic PH-2) and a 5.5% rate of clinically significant procedural adverse events (most of which overlapped, so that the rate of either a symptomatic hemorrhage or a clinically significant procedural adverse event was 10.4%).

Figure 3 compares the revascularization rates for large-vessel strokes undergoing different interventions: IV tPA or mechanical embolectomy (all devices in Multi MERCI). Figure 3 also depicts the retrieval rates for the L5 subset as described in Multi MERCI.

The Merci Retriever (Concentric Medical, Inc., Mountain View, CA) received FDA clearance in August 2004 and, today, over 9,000 patients have been successfully treated with mechanical embolectomy. The procedure allows physicians to expand the treatment time window and to offer an option for those who either fail IV tPA or are ineligible for IV tPA due to a myriad of other exclusion criteria including patients with unknown symptom onset time.

Todo et al report that strokes with unknown time of onset, or "wake-up strokes," comprise approximately 25% of all ischemic strokes and "are usually excluded from acute stroke treatments, such as thrombolysis with [IV tPA] since the time of stroke onset cannot be definitely identified."[14]

Todo et al found that many of these stroke patients demonstrate patterns on imaging that suggest they may benefit from recanalization. However, the restrictive criteria for IV tPA make them ineligible for this option. Mechanical embolectomy may play a significant role in this patient population.

Layton et al summarize the potential of mechanical embolectomy stating that, "Thrombolytic therapy is generally given intravenously in the first 3 hours and up to 6 hours via the intra-arterial route for pharmacological clot disruption. The maximum time frame for mechanical thrombectomy devices has yet to be determined."[3]

Single-center publications by Kim and Devlin et al show that recanalization rates and safety measures reported in the MERCI and Multi MERCI trials could be independently replicated in a broader cohort of patients treated in academic and community hospitals.[15,16] These publications indicate that mechanical embolectomy can be successfully applied with comparable results beyond the investigational setting to a broader population. Furthermore, these single-center studies demonstrated drastically improved health outcomes correlating with recanalization.

REVASCULARIZATION CORRELATES WITH IMPROVED OUTCOMES

In the MERCI trial, investigators looked for predictors of good outcome (defined as functional independence at 90 days). Over 30 variables were included in the model. The only variables significantly predicting outcome were age, baseline National Institutes of Health Stroke Scale

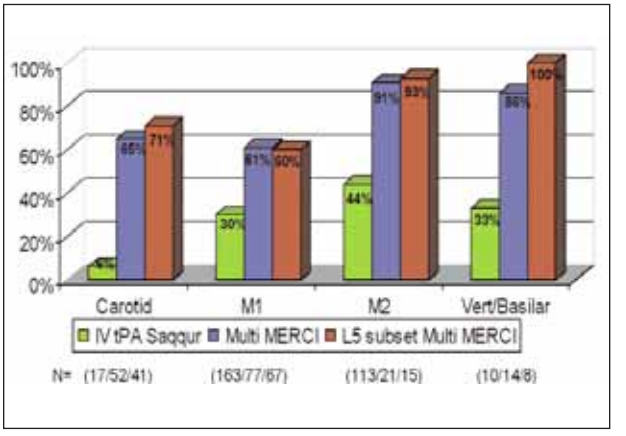

Figure 3. Revascularization rates for IV tPA versus mechanical embolectomy.

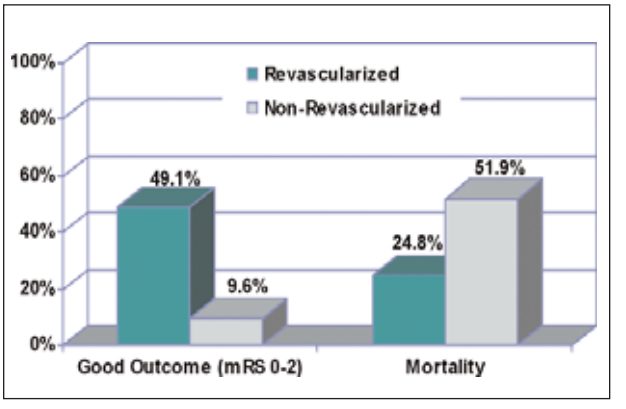

Figure 4. Outcomes compared in revascularized and non-revascularized patients.

TABLE 2. DIFFERENCES IN INCLUSION CRITERIA AND VESSELS TREATED IN EACH STUDY

Trial Differences	PROACT II (N=121)	Multi MERCI (N=98)
Vessels treated	MCA only	Carotid, MCA, and Vertebrobasilar
Age	18 to 85	≥18 (no upper limit)
NIHSS	4 to 30	≥8 (no upper limit)
Time window for treatment	3 to 6 hours	Up to 8 hours

MCA, middle cerebral artery.

score procedure time, revascularization, and right brain infarct. By far, the strongest predictor of good outcome was revascularization (odds ratio = 12.8; *P*<.0001) (Figure 4).

The final Multi MERCI trial publication reported a postprocedure revascularization rate of 68% with 90-day good outcomes in 36% of patients. Revascularization has been shown to improve patient outcomes, and those patients in the Multi MERCI trial who achieved revascularization, 49% achieved good outcome at 90 days (functional independence); this compared to less than 10% of nonrevascularized patients who achieved a good clinical outcome at 90 days (Figure 5). Additionally, the mortality rate for patients who were recanalized was significantly lower than for those who were not.[12]

In the Multi MERCI article, Smith reports[12] that, "Nearly half of recanalized patients had a good neurological outcome, and there were fewer disabled survivors among those with recanalization; therefore, patients did not appear to be saved only to live disabled."[12]

Further evidence of this positive correlation comes from the results of pooled data from MERCI and Multi MERCI Part 1 published by Duckwiler et al.[17] This peer-reviewed abstract was published in *Stroke* in February 2007 and shows a significant difference in good outcome and mortality based on recanalization status in the 0- to 3-hour and 3- to 6-hour time windows.[17] A trend toward improved outcome and lower mortality rate based on recanalization status was also seen in the 6-plus hour time window.

The Rha and Saver analysis reviewed 53 published articles (1985–2002) with data regarding vessel recanalization and functional outcome. Of 2,066 cases reviewed, data were available on clinical outcome and revascularization status for 998 patients in 33 articles. This meta-analysis reported a good outcome rate of 58% when vessels were recanalized compared to a good outcome rate of just 25% of those that were not recanalized (Figure 6).

Recanalization has been shown not only to correlate with improved functional outcomes but also decreased mortality rates and no significant difference in symptomatic intracranial hemorrhage rate (13.7% and 12.5%). The reported mortality rate was 14% for those recanalized, and the nonrecanalized mortality rate was 42%. The authors

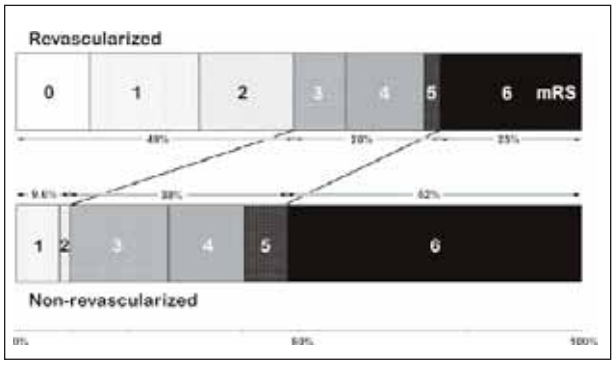

Figure 5. Clinical outcomes at 90 days by modified Rankin score.

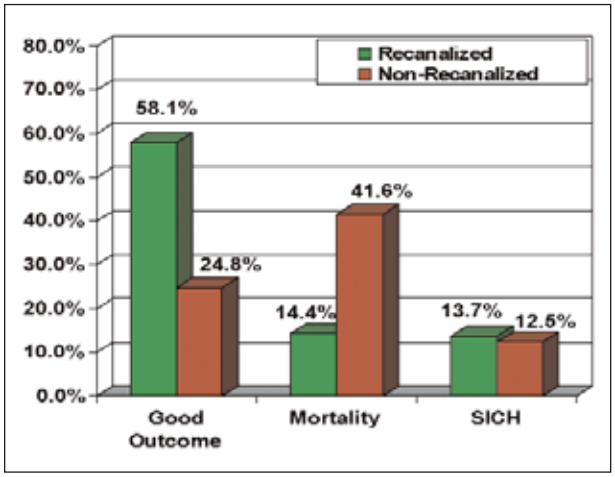

Figure 6. Meta-analysis of outcomes in recanalized versus nonrecanalized patients.[18]

TABLE 3. OUTCOMES IN THE TREATMENT ARM OF PROACT II AND THE MULTI MERCI MCA SUBSET

MCA Vessels	PROACT II Treatment Arm	Multi MERCI
Percentage of patients with MCA occlusion	100%	60%
Percentage of MCA occlusions		
M1	62%	79%
M2	38%	21%
Revascularization rate for MCA	**66%**	**67%**
Revascularization rate for		
M1	Not reported	61%
M2	Not reported	91%
Functionally independent (mRS ≤ 2)	**M1/M2: 40%**	**M1 36%** **M2 50%**
SICH rate	10.2%	M1 10% M2 6.7%

MCA, middle cerebral artery; SICH, symptomatic intracranial hemorrhage.

state, "Formal meta-analysis confirms a strong correlation between recanalization and outcome in acute ischemic stroke. Recanalization is strongly associated with improved functional outcomes and reduced mortality. . ."[18]

ASSESSING THE VALUE OF NEW TECHNOLOGY

The patient population for whom endovascular intervention is generally considered is a population with limited or no options in acute stroke intervention (those who do not respond to or are not eligible for IV tPA).

Generally, when discussing the attributes of a newer therapy such as mechanical embolectomy, the technology is compared to an existing treatment; however, there is no other approved, existing therapy that serves this specific patient population, those with large-vessel stroke that fail to respond to IV tPA or are ineligible for IV tPA. The alternative for this group of patients is basically a "wait-and-see" approach to care. Some physicians have suggested comparing mechanical embolectomy and outcomes to the PROACT II data.

MULTI MERCI DATA VERSUS PROACT II

When considering data from Multi MERCI and PROACT II,[12,16] one must first consider that the studies were quite different in design, in terms of both vessels treated and the inclusion criteria (Table 2). PROACT II studied intra-arterial infusion of prourokinase in occluded middle cerebral artery (MCA) (M1/M2) vessels only. These vessels are a subset of vessels treated in the Multi MERCI study. Multi MERCI also included carotid and vertebrobasilar strokes, comprising 32% and 8% of the vessels studied, respectively. One can allow for a more accurate comparison of recanalization and outcomes for these two studies by limiting the Multi MERCI data to MCA vessels only. Table 3 depicts the data for PROACT II and the MCA subset of Multi MERCI data and suggests that the results with mechanical embolectomy (studied up to 8 hours) are comparable to intra-arterial lytic in the 3- to 6-hour time frame.

Understanding that the Multi MERCI established especially conservative outcome measures when reporting on revascularization lends important perspective to the data. In the Multi MERCI, each vessel (carotid, M1, M2, and vertebrobasilar arteries) and its distal, treatable branches were analyzed, and the vessel with the poorest TIMI flow was used as the reported overall TIMI score.

SUMMARY AND ADDITIONAL COMMENTS

Stroke places a large burden on the healthcare system due to the number of patients affected and the resultant direct and indirect cost to society from care and lost pro-

ductivity. Advancing stroke care in a safe and effective manner should be a priority for all healthcare providers and payers.

Mechanical embolectomy has been shown in multiple studies to recanalize cerebral vessels, and recanalization has been repeatedly shown to positively correlate to improved health outcomes. When considering treatment options for AIS, such as mechanical embolectomy, it is important to understand who is considered a candidate for this procedure: those who present with a large-vessel stroke and who are ineligible for or fail IV tPA. These patients have limited options for acute intervention. Supporting mechanical embolectomy as part of an endovascular stroke program can provide patients with an important option in acute stroke care. ■

Gretchen Benko Mruk, MS, MBA, is Senior Program Manager, Concentric Medical, Mountain View, California. She has disclosed that she is salaried by Concentric Medical, Inc. Mrs. Benko Mruk may be reached at (650) 938-2100; gbenko@concentric-medical.com.

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Robotic Telestroke Program: Transforming Stroke Care

From the Proceedings of the Third Annual Remote Presence Clinical Innovations Forum, July 17–19, 2008.

BY FUJI LAI, MS

Stroke is the second cause of death worldwide and the third leading cause of death in the US. Recent development of new interventions including thrombolytic therapy and neuroendovascular procedures offers real hope to change the once bleak prognosis for acute stroke victims. However, these new therapies are not widely available. Most community hospitals do not have the basic patient-assessment capability in place on a 24/7 basis, nor have they established the appropriate emergency department (ED) treatment protocols. Furthermore, very few hospitals have the specialists on staff required for neuroendovascular procedures. Therefore, stroke patients are either immediately transferred without proper evaluation or go untreated. This scenario is no different and is especially true in the farther reaches of the state of Michigan. The Michigan Stroke Network (MSN) was launched in response to this need.

METHOD

The MSN is a collaborative network of hospitals working together to deliver the most comprehensive stroke care in Michigan. The goal of the MSN is to ensure that hospitals across Michigan, regardless of size or resources, can offer patients advanced stroke care. This would be done by addressing issues associated with delayed stroke care including time to hospital, time to diagnosis, finite window for intervention, lack of on-site expertise, and lack of infrastructure and resources (eg, tissue plasminogen activator [tPA], personnel, critical care, and transfer protocols). The idea was to bring expertise to the access point with 24/7 availability of stroke experts, encourage local expertise, make available algorithms for care, and assist in evaluation and triage of potential stroke victims. This would be accomplished by providing 24/7 access to stroke experts via a toll-free number, consults via telemedicine, and rapid transfer of patients as necessary via med flight.

The MSN uses a "hub-and-spoke" network model whereby the hub stroke center of excellence provides expertise to 31 (at last count) spoke community and rural hospitals via telemedicine so that stroke patients across the state can now receive around-the-clock access to stroke expertise. The hub, which has comprehensive stroke center capabilities, offers tertiary care by providing 24/7 access to stroke expertise, 24/7 access to neuroendovascular specialists, access to study protocols to increase the potential treatment window, and access to technology to increase treatment window.

The development of the hub-spoke network showcased the collaborative nature of this endeavor. The implementation of the MSN brought together multiple stakeholders to collaborate on processes, which included recruiting and establishing relationships, training and in-servicing for readiness, robot installation and orientation, and the development of guidelines, to assist member hospitals to initiate acute interventions. The member hospitals ranged across the spectrum from critical access hospitals to larger community hospitals. The vision they shared was to enable stroke patients across the state to have access to stroke expertise and the right level of care.

The stroke expertise was delivered using the Remote Presence (RP) robotic technology (InTouch Health, Santa Barbara, CA). When a stroke patient presents at a spoke hospital ED, the ED staff call a toll-free number to activate the network and page the on-call hub stroke expert. The stroke expert uses a mobile laptop and wireless Internet to connect to the RP robot and be virtually at the patient's bedside within minutes. The RP system is unique compared to traditional telemedicine systems in that the RP solution affords the physician complete autonomy and reliability to be able to initiate a connection without the need for support from either ED nursing or technical information technology staff. The significance of this is that the physician is able to

conduct an acute stroke consult on demand, immediately, from anywhere, at any time. Furthermore, once the connection is made, the physician is able to drive and maneuver the robot around the ED, essentially giving the physician complete mobility at the remote site, as if he/she were physically there. The stroke expert is able to use the two-way audio and video capability to conduct a neurological assessment with the patient, to read data visually off monitors and devices in the room by zooming in, and to interact with the family and ED staff (Figure 1). The entire process enables the stroke expert to have the information needed to make the most informed decision for management of the patient.

Courtesy of the Michigan Stroke Network.

Figure 1. An MSN stroke expert beams in to robot at spoke hospital ED to conduct acute stroke consult.

RESULTS

The MSN has successfully met its mission and objectives to enable stroke patients throughout the state of Michigan to receive around-the-clock access to stroke expertise. The established network included 31 member hospitals, which served as access points to tertiary care. These member hospitals had very diverse characteristics ranging in size and availability of resources (Figure 2).

Results thus far have exceeded expectation and initial projections. The overall effect of the stroke network on the community and hospitals involved includes:

- On-demand access to stroke expertise any time.
- 24/7 access to tertiary care and neuroendovascular specialists.
- Triage of complex cases to stroke centers of excellence.
- Timely delivery of appropriate care.
- Elimination of inappropriate patient transfers.
- Network-wide stroke awareness and education program.
- Positioning of hub hospital as neuroscience center of excellence.

18-Month Clinical Results

- More than 300 calls initiating stroke consultations

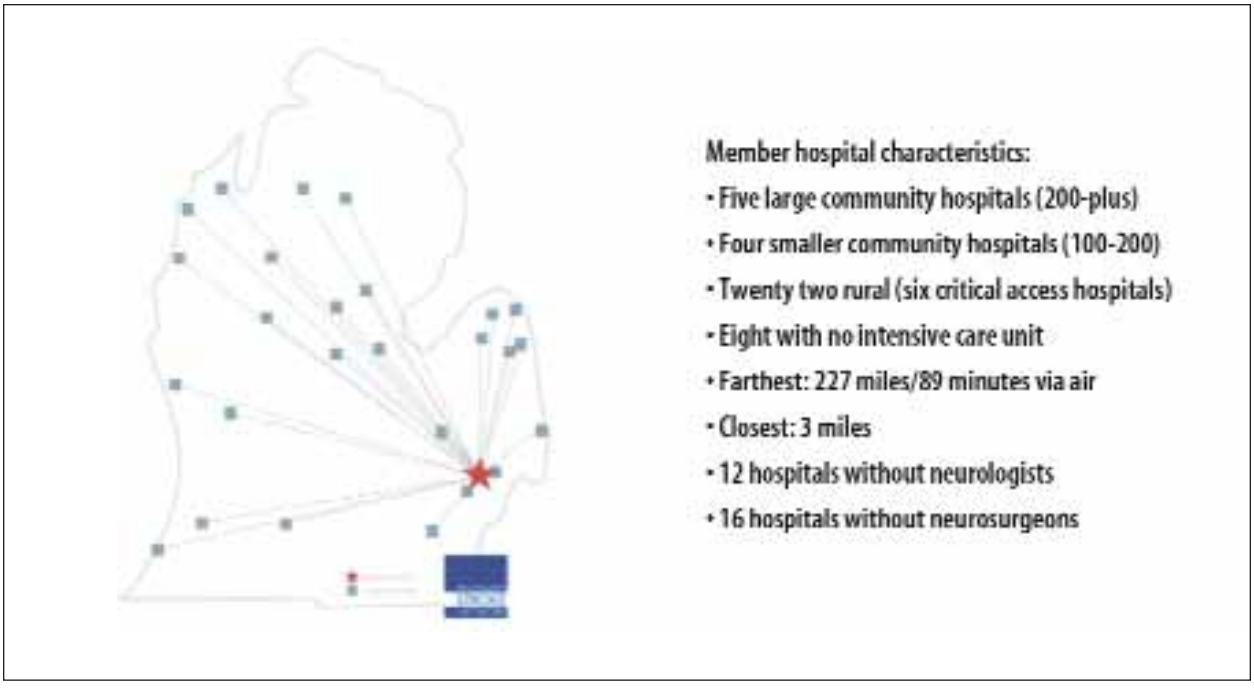

Figure 2. The geographical reach of MSN and access point characteristics.

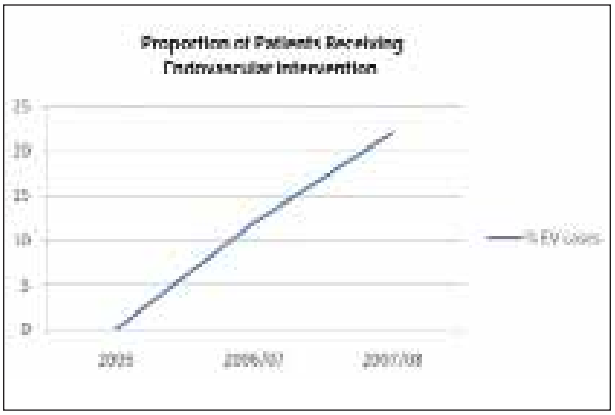

Figure 3. MSN resulted in an increased proportion of patients receiving an endovascular intervention.

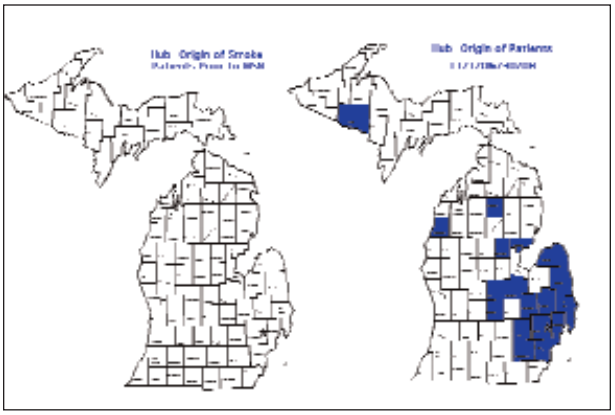

Figure 4. Extending the reach of stroke expertise to patients throughout the state of Michigan.

have occurred thus far during the life of the program.

- 83% of eligible patients received intravenous tPA.
- MSN enabled stroke patients at spoke hospitals to have faster access to stroke expertise:
  - Time interval from time patient last seen normal to patient arrival at spoke ED=67 minutes;
  - Time interval from patient arrival at spoke ED to MSN callback=8.5 minutes;
  - Time interval from MSN callback to tPA administration (at remote site)=33 minutes;
  - Door-to-needle time=8.5+33=41.5 minutes.
- 18 hospitals administered tPA for the first time.
- 30% of patients were transferred to hub for advanced care.
  - 25% of patients transferred went to catheterization lab.
  - Of those transferred to catheterization lab, about 50% received an intervention.
- 22% of patients received interventional procedures: emergent and elective endovascular cases have grown progressively to comprise a larger proportion of cases (0% in 2005; 12% in 2006/2007; and 22% in 2007/2008) (Figure 3).
- Average National Institutes of Health Stroke Scale scores: admission=10; discharge=3.

Other Results

Additional results from the program include an increased number of stroke patients presenting at the network from locations throughout the state of Michigan (Figure 4). The hub hospital also realized a doubling of stroke patient volume over the prior year. The use of a robot for telestroke has captured the imagination of the community and generated significant attention, resulting in over 100 television and public relations events. The work of the MSN has also been recognized at the state level—the MSN received the 2007 Detroit "Health Heroes" award. Furthermore, the success of the network for delivering stroke care throughout the state has prompted initiatives to expand on the network by layering other specialty services, such as cardiology, to be delivered through the network as well.

DISCUSSION

From the endovascular specialist perspective, although intravenous tPA remained stable, the number of interventional stroke cases as well as the number of elective endovascular cases have grown and have become an even larger segment of the practice. The philosophy was to encourage local expertise at each of these spoke hospitals. Education and assistance were provided to each of the sites so that they could become better stroke facilities. Training and education of spoke hospital ED staff in assessment of stroke resulted in the spoke hospital staff now being more comfortable administering tPA and handling certain kinds of patients. The more stroke patients the spoke hospitals saw, the more tertiary-level stroke patients the hub saw. The goal was for the stroke expert to help the spoke hospitals rapidly triage their patients. Today's emergency rooms (ERs) are often overwhelmed with patient flow, and the average ER physician is in the triage business. ER physicians excel at acute stabilization and management of patients but do not have the time to sit down and take a detailed history, which is what is needed for the proper management of a stroke patient. Ninety percent of stroke patients can be taken care of emergently and acutely by ER physicians; however, in the middle of the night in a small rural hospital, sometimes a second opinion from a stroke expert can prove invaluable. Services delivered through the RP robot added an element of safety to help the ED determine the best course of action for the patient.

The MSN has effectively delivered expert care to an underserved population in Michigan. The enabling technology that has defined this program is Remote Presence robotics, which has allowed the MSN to leverage expertise across huge geographic regions within the state. In particular, with this technology the standard of care being delivered has been demonstrated to be at 40 to 60 times the national average. The result is enhanced patient safety, patient satisfaction, efficiency, and physician satisfaction.

CONCLUSION

The MSN experience has demonstrated how a Remote Presence telestroke network has enhanced stroke care in Michigan. Similar models could be used around the country to give stroke patients everywhere a better chance of survival by delivering faster and more efficient access to state-of-the-art stroke expertise and care. ■

Fuji Lai, MS, is with InTouch Health, in Santa Barbara, California.

ABOUT REMOTE PRESENCE

Remote Presence is a next-generation telemedicine technology platform that combines the power of robotics, wireless, and the Internet to enable hospitals and physicians to bring the right care to a patient at the right time. Capabilities include two-way audio/visual communication, mobility at both ends, and a software architecture that ensures reliable and robust connections from anywhere with Internet access. This enables a physician to "beam in" immediately to the patient's side to render care. Remote Presence systems have already been deployed in more than 100 stroke network hospitals around the country, with results including improved geographical reach of stroke specialists and more timely delivery of appropriate stroke care.

These networks have also resulted in enhanced stroke education and awareness throughout the community, further improving stroke care and patient outcomes.

ABOUT INTOUCH HEALTH

InTouch Technologies, Inc. (d.b.a. InTouch Health) is a privately held company based in Santa Barbara, California. The company has pioneered Remote Presence technology for healthcare providers. Through its Remote Presence Robotic System, a proprietary mobile robotic and communications platform, doctors are able to consult with hospital-based patients and staff more easily and frequently.

The InTouch Health solution leverages the time and expertise of healthcare professionals across multiple care facilities, improving the efficiency and effectiveness of care delivery. The company now has more than 200 RP systems deployed in acute care settings, which are utilized for a range of clinical applications, including stroke and multidisciplinary outreach, remote critical care coverage, on-call services, and rounding.

For more information about InTouch Health, please visit www.intouchhealth.com.

Investing in an Endovascular Stroke Program

Recognizing the potential benefits and requirements of comprehensive stroke care.

BY GRETCHEN BENKO MRUK, MS, MBA

Each year in the US, more than 780,000 patients suffer a stroke; 87% of those are ischemic.[1] Stroke is the third leading cause of death and the number one cause of severe disability. The diagnosis-related group (DRG) for medical management of a stroke patient has been commonly reported as among the top 20 Medicare DRG payments to hospitals,[2] and the estimated cost of stroke in 2008 is expected to be $65.5 billion.[1]

CURRENT TREATMENT FOR ACUTE ISCHEMIC STROKE PATIENTS

Intravenous tissue plasminogen activator (IV tPA) is becoming accepted as standard of care in the US for patients who reach the hospital within 3 hours of symptom onset. The Joint Commission on the Accreditation of Healthcare Organizations' 2008 harmonized measures for primary stroke center certification will more closely evaluate the utilization rate for IV tPA. IV tPA received a unique DRG with improved payment rates effective October 2005. Even under these circumstances, the utilization of IV tPA remains at 2% to 5%, primarily due to the limited time window and contraindications for certain patients.

MECHANICAL THROMBECTOMY/ EMBOLECTOMY

The need for additional options for patients led to the development of mechanical embolectomy as an intervention for acute ischemic stroke. Mechanical embolectomy offers acute stroke patients a significantly expanded time window for intervention and a chance for restored blood flow with published positive outcomes.[3] Medicare has set a reimbursement rate that makes the adoption of this technology feasible for most hospitals.

Merci Retrieval System™ Summary

In August 2004, Concentric Medical, Inc. (Mountain View, CA) received FDA clearance for the Merci Retriever® for patients who are ineligible for IV tPA or fail to respond to IV tPA. This device offered physicians and patients options for stroke intervention and created a departure from the historically limited methods of caring for acute ischemic stroke patients.

TABLE 1. ESTIMATED 2009 NATIONAL AVERAGE MEDICARE PAYMENT RATES

2009 MS-DRG	2007 DRG	Description	2009 National Average Hospital Payment	Average Length of Stay (d)
Principal Procedure: Mechanical Embolectomy/Thrombectomy				
23	543	Craniotomy with major device implant or acute complex CNS PDX with MCC	$28,087	12.7
24		Craniotomy with major device implant or acute complex CNS PDX without MCC	$19,210	9

The estimated 2009 national average Medicare payment rates for various surgical Medicare severity diagnosis related groups (MS-DRGs) for hospitals with a wage index greater than one (ie, urban or suburban hospitals). With stroke as a principal diagnosis, these MS-DRGs may be applicable. Depending on other procedure codes or other diagnosis codes that may be present, other MS-DRGs may be applicable. MCC, major complication or comorbidity; CNS PDX, central nervous system principal diagnosis. From 2007 MedPAR data, mechanical embolectomy had an average length of stay of 9 days.

TABLE 2. MEDICAL MS-DRGs AND ESTIMATED FISCAL YEAR 2009 NATIONAL AVERAGE MEDICARE PAYMENT RATES

2009 MS-DRG	2007 DRG	Description	2009 National Average Hospital Payment	Average Length of Stay (d)
Principal Procedure: Thrombolytic Therapy				
61	559	AIS with use of thrombolytic agent with MCC	$15,945	6.8
62		AIS with use of thrombolytic agent with CC	$10,848	5.3
63		AIS with use of thrombolytic agent without CC/MCC	$8,408	3.9
Medical Management				
64	014, 015	Intracranial hemorrhage or cerebral infarct with MCC	$10,245	5.5
65		Intracranial hemorrhage or cerebral infarct with CC	$6,530	4.3
66		Intracranial hemorrhage or cerebral infarct without CC/MCC	$4,686	3.1

Medical Medicare severity diagnosis related groups (MS-DRGs) and estimated fiscal year 2009 national average Medicare payment rates for hospitals with a wage index greater than one (ie, urban or suburban hospitals). With stroke as a principal diagnosis, these MS-DRGs may be applicable, depending on other procedure codes or other diagnosis codes that may be present. MCC, major complication or comorbidity; CC, complication or comorbidity not considered to be major; AIS, acute ischemic stroke.

TABLE 3. ANALOGIES BETWEEN PROGRAM GUIDELINES

ST-Elevation Myocardial Infarction[4]	**Acute Ischemic Stroke[5]**
• 10 minutes for ED evaluation • 30 minutes door-to-needle/fibrinolytic therapy • 90 minutes door-to-balloon/endovascular intervention • 3 hours (from symptom onset) fibrinolytic therapy or percutaneous coronary intervention • Total ischemic time: 120 min • Golden hour: first 60 min All patients undergo rapid evaluation for reperfusion therapy and have a reperfusion strategy implemented.	• 10 minutes for ED evaluation • 25 minutes door to CT scan • 45 minutes door to CT interpretation • 60 minutes for initiation of treatment • 3 hours (from symptom onset) fibrinolytic therapy
Procedure Specifics Facilities report a setup time of approximately 5 minutes and a procedure time of 1 to 2 hours.	

TABLE 4. ECONOMIC EFFECT OF STROKE INTERVENTION	
Intervention With the Merci Retrieval System	No Intervention
48-year-old patient Basilar occlusion Acute length of stay=5 d Discharged to home to return to work Cost to private payer for acute hospital stay=$51,312	50-year-old patient Basilar occlusion Acute length of stay=33 d Discharged to skilled nursing facility permanent resident Cost to private payer for acute hospital stay=$95,939

The Merci Retriever has repeatedly been shown to restore blood flow in the vessels of the brain through the removal of blood clots. More than 9,000 patients worldwide have undergone this procedure, and it has been performed at more than 500 US hospitals.

The Merci Retriever is a tiny, corkscrew-shaped nitinol wire that is inserted into the femoral artery and navigated to the intracranial vessels in a similar fashion to other neuroendovascular devices. The device works by wrapping around the clot and trapping it. A balloon guide catheter temporarily occludes blood flow as the physician aspirates the clot through the catheter. The clot is retrieved and removed from the body.

The system is FDA cleared for use in patients who are beyond the 3-hour time window for IV tPA, who are contraindicated for IV tPA, or who fail to respond to IV tPA.

Clinical Effectiveness

The results of the final Multi MERCI trial reported that the Merci Retriever restored blood flow to the brain 68% of the time when used with adjunctive therapy such as intra-arterial lytic. Of the patients who had blood flow restored, 49% were functionally independent at 90-day follow-up.[3]

Staffing and Operational Requirements

Physician(s) credentialed to perform neurointerventional procedures will be required. A neurologist or neurology group committed to advancing stroke care may also be required. Some successful centers directly employ a stroke neurologist or hospitalist. Remote presence technology or telemedicine may also allow access to stroke neurologists. In some centers, a direct referral model (emergency department [ED] to interventionist) is an option, although it requires a close working relationship between the ED and interventionist.

A stroke "champion" committed to advancing the program through outreach and education across functions is important for long-term success.

Well-developed and implemented protocols for moving a patient quickly from the ED to the angiography lab are also critical for success. Established transfer agreements with area hospitals, including education on appropriate clinical profile for transfer, are the foundation for growth of the program.

Investment Requirements

Most facilities with a neurointerventional program, such as aneurysm coiling and precerebral stenting, have the capabilities and capital equipment to build an endovascular stroke program. Biplane angiography is becoming the technology of choice for interventional stroke care. Compared to single-plane C-arm, biplane offers better vessel visibility as well as the potential for decreased contrast and radiation. For initial evaluation and diagnostic workup, hospitals may begin with standard CT imaging and move to CT angiography or CT perfusion as the program develops. Other centers utilize MRI diffusion/perfusion-weighted imaging. Advanced imaging may be beneficial when symptom onset is unknown.

There is no new capital investment required for the Merci Retrieval System. Investment in the disposable device system is similar to other endovascular interventions, such as stents.

Reimbursement

Medicare coverage is determined on a local basis at the carrier level, and payment is through the Medicare severity diagnosis related groups system. Reimbursement tables for acute stroke care are included in this article (Tables 1 and 2).

Commercial insurers have varying coverage policies. Some consider mechanical embolectomy to be investigational and have noncoverage policies. Others may cover the procedure for a specific patient population.

Service Line Impact

One facility reported an increase in the number of neurologic interventional procedures after investing in an interventional stroke program. The number of stroke cases presenting to the hospital grew at a significant rate over several years: 10% in the first year and 65% over 6 years. It also created a halo effect for other neurologic interventions such as aneurysm repair and intracranial and subarachnoid hemorrhage procedures. Patients began seeking neuro treatment from the local center of

excellence as defined by their ability to treat acute stroke.

Because ischemic/embolic strokes have frequently been found to have a cardiac-related cause,[6] physicians have determined that additional follow-up of patients may be required to determine the underlying cause of clot. Examples of cardiac disease related to clot formation include structural heart defect (such as patent foramen ovale), cardiac atherosclerotic disease, and/or heart rhythm abnormalities.

Additional Considerations

Challenges to an interventional program include a lack of awareness of stroke signs and symptoms and inconsistent referral patterns from the ED to the angiography suite; both delay the time to patient treatment.

Some hospitals report that when implementing an interventional stroke program, they modeled their program after the pathway for acute cardiac care, drawing on the lessons learned from implementing protocols to move patients quickly from door to intervention. Analogies between the program guidelines are listed in Table 3.

Economic Information

In a formal cost-utility analysis conducted at the University of California, San Francisco, by Johnston and Nguyen-Huynh and presented at the 2008 Internation Stroke Conference (publication in preparation, 2008), large-vessel strokes treated with the Merci Retriever at greater than 3 hours not only reduced cost but led to increased quality-adjusted life years. Table 4 is a case example from a leading US stroke center on the economic effect of acute stroke intervention. ■

Gretchen Benko Mruk, MS, MBA, is Senior Program Manager, Concentric Medical, Mountain View, California. She has disclosed that she is salaried by Concentric Medical, Inc. Mrs. Benko Mruk may be reached at (650) 938-2100; gbenko@concentric-medical.com.

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