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Planning for Nationwide Endovascular Acute Ischemic Stroke Care in the United States: Report of the Interventional Stroke Workforce Study Group

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Abstract

Background: In the United States, regional systems of care for acute ischemic stroke are poised to undergo a major transformation in structure and function, with the imminent launch of Joint Commission certification of Comprehensive Stroke Centers and continued accumulation of evidence supporting the use of endovascular recanalization therapy for select patients. Planning

Methods: A Study Group was convened of leading endovascular neurointerventionalists and stroke neurologists. The group reviewed available data and multispecialty perspectives to develop projections and recommendations for workforce, infrastructure, and policy modifications to insure acute ischemic stroke patients have access to endovascular recanalization therapy and the appropriate levels of care.

Results: The frequency of performance of acute endovascular recanalization therapy (ERT) interventions is projected to at least quadruple, from 14,000 in 2008 to more than

60,000 annually in coming years. To deliver ERT, 200-300 Comprehensive Stroke Centers with neurointerventional capability are desirable in the United States. Professional workforce needs are projected at 600-900 practicing neurointerventionalists, with an average case volume of 70-100 cases per year. Recommendations are provided for EMS and hospital interactions within regional systems of care, state and county analyses of neurointerventional center needs, professional society consideration of potential modest training program expansion, public education, completion of randomized clinical trials and econometric analyses, development of CPT codes for neurothrombectomy, refinement of patient selection by clinical features and penumbral imaging, neurointerventionalist relationship-building with Emergency Department staff, and sharing of best practice models.

Introduction

In June 2011, a Study Group was convened of leading endovascular neurointerventionalists and stroke neurologists to assess the implications of a potentially imminent, substantial increase in acute ischemic stroke patients with indications for endovascular recanalization intervention: whether the current workforce of neurointerventionalists and infrastructure of stroke centers is sufficient to address the demand, and, if not, recommend pathways forward to better serve patients suffering from acute ischemic stroke (AIS).

Rationale

The rationale for assessing workforce and infrastructure needs at this time is that care for acute ischemic stroke is on the threshold of a new era. The epoch from 1950 to 1995 was the age of development and dissemination of supportive care for acute ischemic stroke, including treatments to minimize medical complications (deep venous thrombosis prophylaxis, early mobilization, dysphagia screening), support collaterals and physiologic parameters (maintain euvolemia, oxygenation, normothermia, and normoglycemia), and deter early recurrent infarction (early aspirin).[1]

Beginning around 1990, the first era of reperfusion therapy for acute ischemic stroke began. Reperfusion therapies for acute arterial occlusions in different organ beds naturally evolve in two successive eras. In the first, intravenous thrombolysis (IVT) launches the reperfusion age, as the first useful, widely disseminated therapy, but its

success is constrained by only modest recanalization rates. Then, in the second, endovascular recanalization techniques (ERT) are developed that are far more effective at achieving reperfusion and supersede IVT alone to become the definitive, ongoing standard of care. This two stage pattern characterized the evolution of reperfusion therapy for acute myocardial ischemia. Reflecting the greater complexity and fragility of the brain and its vasculature, the evolution of acute ischemic stroke care was slower, but also traversed this same historical path. The period from 1990 to 2010 was the era of intravenous thrombolysis for acute ischemic stroke, as IVT evolved from untested therapy through clinical trial validated intervention to standard therapy embedded in nationwide hospital systems of care at certified Primary Stroke Centers (PSCs).[2-4]

During the latter part of the IVT era, the seeds were sown for a successor era of endovascular recanalization therapy. In drug and device development and early clinical trial, rapid, iterative technologic advance has occurred. Over the past decade, the endovascular armantarium has expanded from intra-arterial fibrinolysis alone to corkscrew retrievers, suction thrombectomy, primary stenting, and stent retrievers. Randomized clinical trials of ERT are advancing, fitfully, but inexorably, from PROACT 2 and MELT,[5, 6] through the ongoing MR RESCUE, IMS 3, SYNTHESIS EXP, MR CLEAN and other studies. Should these trials continue to show positive results, an evidential threshold will be passed, and endovascular recanalization will be an accepted element of evidence-based acute stroke care. The tipping point for declaring ERT fully evidence-based and worthy of the highest grade endorsement in national treatment guidelines is close enough that now is an appropriate time to begin preparing for the next step in the ERT era: planning and then implementing changes in the organization of care to provide patients with wide access to proven ERT interventions in routine practice. The products of this Study Group may assist to establish the metrics, rationale and agenda for academicians, professional organizations, industry and government to address important aspects of this issue to help

Methods

Study Group representatives were selected to ensure representation of key specialties involved in acute neuroendovascular care, including interventional neuroradiology, interventional neurology, endovascular neurosurgery, and noninterventional vascular neurology. To accelerate decision-making without

bureaucratic delays, the task force did not request official appointments from leading specialty societies, though members were familiar with positions of the Society of Neurointerventional Surgery, Society of Vascular and Interventional Neurology, the American Academy of Neurology, and the American Stroke Association. At an in person meeting in Chicago in June 2011 and through email exchanges afterwards, members identified salient literature through comprehensive Medline review and knowledge of manuscripts in process, and collectively reviewed the epidemiology of acute ischemic stroke, the size of the current and projected neurointerventional workforce, the distribution of certified stroke centers, and the barriers and opportunities for building out a sufficient national infrastructure of ERT care.

Eligible Patients - Data and Projections

The number of patients treated with endovascular recanalization in the United States has been steadily increasing. Estimates from both the Nationwide Inpatient Sample (NIS) and Coverdell Stroke Registry suggest that from 1999-2001, an era when ERT consisted primarily of intra-fibrinolysis without mechanical techniques, the number of patients treated annually in the US with intra-arterial fibrinolysis was about 5,500.[7, 8] When mechanical embolectomy additionally became available as an intervention, its use rapidly grew to exceed that of intra-arterial fibrinolysis. Estimates from the only manufacturer marketing an approved device at the time were that 1400 cases were treated in 2005 and 2300 in 2006.[8] NIS data indicate the number of patients treated with endovascular clot retrieval in the US were at least 1,330 in 2006, 4000 in 2007, and 13,990 in 2008.[9]

Projecting the future volume of endovascular recanalization cases requires multiple assumptions. Values must be estimated for the proportion of acute ischemic strokes that 1) are due to large artery occlusions located in accessible vessels, 2) present within a time frame when tissue is still salvageable and treatment may confer benefit. A diverse array of epidemiologic, registry, and clinical trial datasets are available that provide relevant but imperfect estimates of these parameters. The upper limit on the pool of potential endovascular cases can be estimated with simple assumptions. Of the 795,000 acute strokes each in the US, 87% are ischemic,[10], 20-37% of these have an NIH Stroke Scale score of 8-10 or higher, suggesting high likelihood of proximal large artery occlusions,[11, 12], and 85% of these have onset while

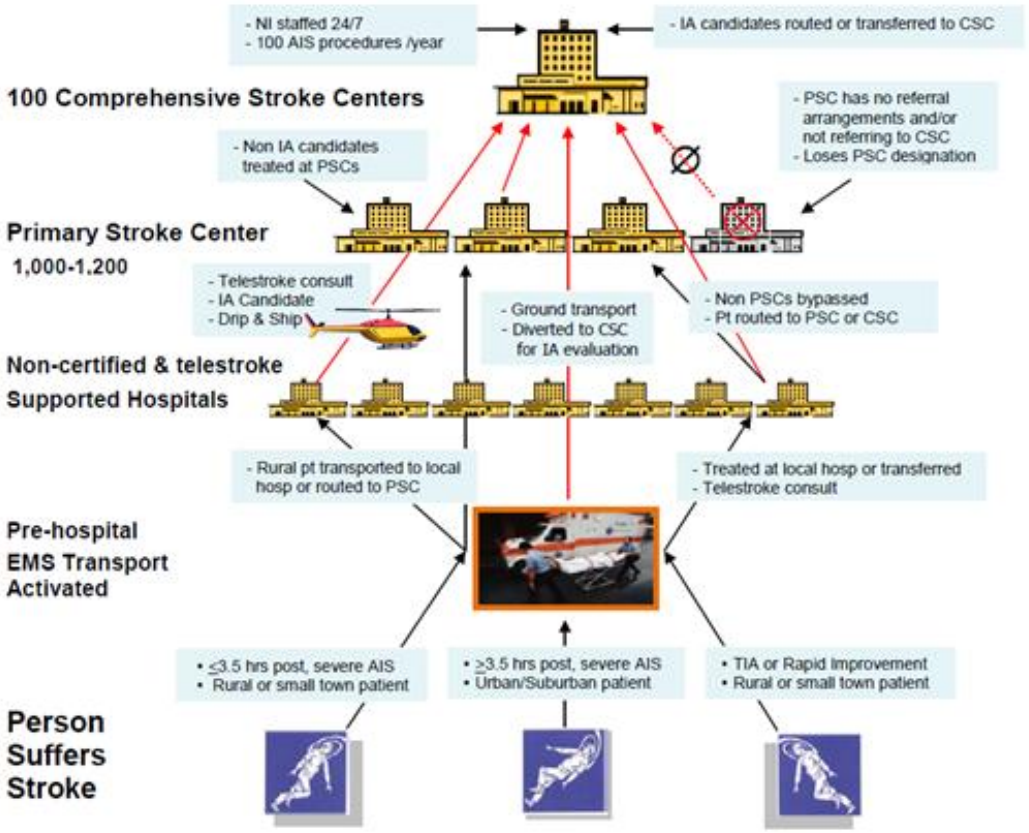
awake and so able to present in a treatable time period,[13] yielding a pool of 117,000-218,000 patients a year. Estimating the volume of likely treatable cases requires more a more complex set of analyses. Zaidat and colleagues reported the results of 6 such projects, including 2 from prior studies by Cloft and colleagues and Hirsch and colleagues and 4 new methods.[8, 11, 12] The case volume point estimates ranges from 26,000 – 122,000, with a mean of 62,000. This mean estimate would represent 9% of all ischemic strokes each year in the US. This number may increase in coming decades as the volume of stroke cases increases with the aging of the US population.[14]

A conservative consensus estimate, then, is that the case volume of endovascular recanalization for AIS will quadruple from the 14,000 actual cases performed in 2008 to over 60,000 cases annually in coming years.

Neurointerventional Centers – Data and Projections

A nationwide template for regional organization of acute stroke systems of care in the United States has been established in a series of publications from the Brain Attack Coalition and the American Heart Association/American Stroke Association.[15-19] The planned system includes three tiers of facilities: 1) Acute Stroke Ready Hospitals that are able to perform initial stabilization, imaging, and intravenous fibrinolysis, often with telemedicine support, 2) Primary Stroke Centers (PSCs) that can not only provide initial intravenous fibrinolysis but also a complete package of supportive inpatient, and 3) Comprehensive Stroke Centers (CSCs) that provide neuroendovascular, neurosurgical, and neurocritical care interventions. It is anticipated that endovascular recanalization therapies will generally be deployed at Comprehensive Stroke Centers and that each CSC will act as a hub support a network of spoke PSC and acute stroke ready hospitals.

Figure: Patient flow within regional acute stroke systems of care. Patients appropriate for endovascular recanalization intervention are preferentially routed to Comprehensive Stroke Centers via a variety of potential pathways.



From 2000-2010, the greatest attention was focused upon building out the infrastructure of Primary Stroke Centers in the United States. By the end of the decade, more than 1000 acute care hospitals were certified as stroke centers, either by national accreditation bodies like the Joint Commission or by state Department of Public Health and Emergency Medical Services agencies.[19] At the end of 2010, legislation or regulations requiring preferential transport by EMS of acute stroke patients directly to certified stroke centers had been enacted in 18 states and several additional large counties, encompassing 53% of the US population.[20]

In contrast, the development of formal recommendations and certification of Comprehensive Stroke Centers proceeded at a slower pace, constrained by lesser supporting data and by the need to have a well-developed first tier of PSCs in place before a second tier of CSCs could be added. However, the development of CSCs is now accelerating. Recommendations for the constituents of a CSC were promulgated in 2005[16] and metrics to assess CSC performance published in 2011.[21] From 2008-2011, individual states (e.g. Texas) and counties (e.g. Santa Clara, California) implemented CSC recognition and EMS routing policies. In 2011, the Joint Commission convened a

technical advisory panel to assist in the development of a formal certification for nationwide certification of CSCs, anticipated to be piloted and launched in 2012.

Comparatively little study has been performed of the number of Neurointerventional Centers that will be needed to provide optimal access to neurointerventional care. In 2008 in the US, there were 1779 Emergency Departments in highly populated urban regions and 2834 in rural regions.[22] ERT requires a complex neuroangiographic capital equipment, expert neurointerentionalist physicians, and highly trained cath lab nurses, technologists, and anesthetists. Accordingly, ERT is not a treatment that will be available at every hospital in the country, but instead at select secondary and tertiary hospitals. At the time of publication of the 2005 CSC Recommendations paper, it was estimated that there were only 20-30 hospitals in the country meeting all criteria to quality as CSCs, but another 100-200 were seen as meeting many criteria and capable of becoming fully qualified with minimal additional investment and organizational effort. (Alberts M, 2006, pers communication) A geographical information systems (GIS) analysis in 2003 found that 82% of the US population resided within 3 hours transport time of a facility with at least one neurointerventionalist on staff.[23] However, no estimate was provided regarding optimal access for acute ischemic stroke, which might require patients reside within 30 minutes transport time of a facility with at least 3 neurointerventionalists on staff, thereby capable of providing ERT on a 365/24/7 basis.

Detailed, region-specific, GIS analyses are required to identify the optimal number and distribution of PSCs and CSCs in each US County. Typically, the desirable ratio of PSCs to CSCs might range from 3 to 1 to 10 to 1. Mapping should take into account the distribution of the population weighted by stroke proclivity and travel times by ground and air ambulance given local landscape and traffic conditions. Until such analyses are undertaken, only extremely broad estimates may be generate of the number of CSCs required in the US to optimize ERT access. A rule of thumb that on average a CSC may be needed for every 5 PSCs would suggest that 200-300 Neurointerventional Centers are desirable in the US.

Neurointerventionalists – Data and Projections

The current number of neurointerventionalists in practice in the United States is not available from a single source. However, Zaidat and colleagues recently compiled

an estimate by consulting the membership rolls of the Society of Neurointerventional Surgery (SNIS) and Society of Vascular and Interventional Neurology and the contact lists of companies marketing thrombectomy devices.[12] They estimated that there are currently approximately 800 trained neurointerventionalists, a figure that has more than doubled since 2002. The neurointerventionalists include approximately 600 interventional neuroradiologists, 100 endovascular neurosurgeons, and 100 interventional neurologists. Assessing training programs, they estimate that approximately 40 new neurointerventionalists graduate annually and enter practice. The number leaving practice for retirement or other reasons is not currently well-estimated, but is likely to be only relatively small given the relative young age of the discipline.

If at least 3 neurointerventionalists are needed to provide round the clock coverage at each of 200-300 neurointerventional centers, a minimum of 600-900 practicing neurointerventionalists are needed nationally. Delivering 62,000 ERT treatments annually, these 600-900 neurointerventionalists would have an annual average case volume of 70 – 100 cases per year, more than ample for maintaining experience.

Recommendations

Available data suggest that existing infrastructure and workforce is not fully capable of meeting the likely imminent demand of endovascular recanalization therapies, but with modest additional investment, manpower, and organization can be brought to the desirable capacity. In the course of reviewing current readiness, the Study Group identified several areas of potential action that would oster preparations for the coming era of AIS endovascular care. The Study Group recommends:

<u>1. National Recommendations for Interactions with Regional Systems of Care:</u>

The Study Group strongly endorsed the AHA/ASA effort underway to develop these recommendations addressing the best ways for EMS, acute stroke ready hospitals, PSCs, and CSCs to interact in a unified regional system of care needs to be clarified by national recommendations. These policy statements would provide guidance on when patients should bypass acute stroke ready hospitals and PSCs to deliver select patients directly to CSCs, which patients should undergo interfacility transfers from lower to higher levels of stroke care, and allocation of DRG payments across the participating facilities in a single episode of care.

2. State and County Analyses of Neurointerventional Center Needs:

State Departments of Public Health and interested academicians should undertake detailed, region-specific, GIS to identify the optimal number and distribution of neurotinterventional centers in each US County. Mapping should take into account the distribution of the population within the region, weighted by stroke proclivity and travel times by ground and air ambulance given local landscape and traffic conditions. These analyses can build upon studies undertaken of Primary Stroke Center distribution in the US.[24, 25] These analyses are essential to generate improved national estimates of the neurointerventional workforce needs.

3. Professional Society Analysis of Practitioner Number and Potential Modest Training Program Expansion:

Professional societies with an interest in neurointervention should analyze member practice patterns to provide regular (e.g. triennial) estimates of the number of neurointerventionlists in active practice in the US and their geographic distribution. Based on these data and estimates of workforce need, a modest increase in number of training slots may be indicated for the next several years, and could be facilitated by the professional societies.

4. Public Educational Programs on Stroke Symptoms and MT Procedures

The public currently has little knowledge of endovascular recanalization therapy. As positive trials accumulate, there is a tremendous opportunity to leverage the natural lay interest in endovascular devices to promote awareness of stroke warning signs and the need to activate the 911 EMS system immediately after stroke onset. ERT-based public education has the potential to re-energize public stroke messaging programs and increase the proportion of patients who arrive in the first hours after onset.

5. High Grade Evidence for Endovascular Recanalization Therapy

Completion of additional randomized trials that demonstrate unequivocally the efficacy of ERT is essential. Only high grade evidence will be sufficient to drive system change among state EMS agencies, governmental and third-party payors, and hospital associations. In addition, analysis of cost-effectiveness data would be helpful in convincing payors to cover ERT costs.

6. Developing the Financial Case for Hospitals to Establish MT Programs

Developing a sufficient number of certified neurointerventional centers will require administrative and financial commitments from hospital leadership. Hospital executives at facilities that are currently Primary Stroke Centers are often inexperienced in understanding the fiscal advantages and disadvantages of pursuing a neurointerventional program. Models, scenarios, and templates could be helpful in assisting them to understand return on investment opportunities and to recognize when developing an ERT program would be beneficial.

7. Analysis of Penumbral Imaging vs. Time Alone as Determinant of ERT Candidacy

Time alone is likely to be an imperfect guide to selection of candidates for ERT in windows beyond the first 3 hours. Some patients will have already completed their infarct by as early as 6 hours, and achievement of reperfusion would be futile. Others may still harbor substantial salvageable tissue beyond 8 hours after onset, and would benefit from reperfusion even though it occurred chronologically late. As data on studies using tissue clocks rather than time clocks for patient selection accumulates, projection of case volumes should incorporate information from imaging studies in addition to the epidemiology of presentation times.

8. Neurointerventionalist Relationship-Building with Emergency Department Staff

Emergency Department physicians play a vital role in the care of patients undergoing endovascular recanalization therapy, including initial patient identification and stabilization, acceleration of door to imaging and door to cath lab times, and care of medical co-morbidities. Emergency physicians currently often do not have detailed knowledge of the techniques, capabilities, and outcomes of endovascular recanalization therapy. It is vital that the ED staff is knowledgeable about ERT opportunities and collaborate with neurointerventionalist to insure patients are appropriately treated. Regular feedback to ED physicians and support staff on process metrics (e.g. door to on clot time) and outcome metrics is essential to underscore impediments, solutions and further refinements.

9. Sharing Successful System Models

Many successful programs exist that have already confronted and successfully overcome many barriers to establishing and growing ERT programs. These should be chronicled and broadly shared.

10. Develop CPT Codes for Neurothrombectomy Procedures

No meaningful CPT codes currently exist that cover neurothrombectomy procedures for acute ischemic stroke. Developing coding and reimbursement unique to neurothrombectomy devices would be practical and beneficial.

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