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STROKE: THE URGENCY OF EARLY DIAGNOSTICS



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Stroke remains the leading cause of disability and one of the leading causes of death in the United States. Each year, more than 700,000 people suffer a stroke.

There are more than three million people living with permanent physical and mental impairments caused by stroke. Fortunately, new treatments are starting to change the outcome of this disease; however, it is clear that these therapies will add a new level of urgency to the acute management of stroke patients. Unfortunately, as stroke care evolves from the hyper-acute setting, we can expect to see an increased element of liability as well.

In the clinical arena, stroke preparedness will require a well-planned, multistep algorithm. The first element hinges on patient recognition of the problem. Due primarily to the lack of recognition of stroke warning signs, the majority of patients will not present to a healthcare provider in time to initiate hyper-acute therapy such as t-PA. The first step in stroke treatment will need to include broad public education on the basic symptoms of stroke disease. In a sense, this means that stroke treatment starts long before the patient experiences their first stroke symptom.

Once a patient presents to the physician, the time of onset of stroke symptoms should be rapidly ascertained. If the patient cannot provide these details, or no witnesses are present, it should be assumed that stroke symptoms began when the patient was last observed to be asymptomatic. After an appropriate evaluation/examination has been performed, a STAT head CT should be obtained to differentiate between

“The costs associated with strokes have been estimated to exceed \$40 billion each year. In 1999-2000, the average payment for stroke-related claims was \$493,220. The financial and emotional implications for the patient and the family are significant.”

hemorrhagic and ischemic causes of stroke. Hemorrhagic stroke patients are referred for appropriate neurological and/or surgical interventions; whereas, ischemic stroke patients must be

rapidly assessed for exclusion or inclusion into a thrombolytic protocol.

Although the results of thrombolytic therapy for stroke have been controversial in the past, the most convincing data now come from the 1995 National Institute of Neurological Disorders and Stroke (NINDS) trial of t-PA in acute ischemic stroke. Patients who satisfy the inclusion criteria in that study clearly showed a significant advantage in both overall survival and survival without disability when compared to placebo-treated patients. This advantage was conferred across all stroke types and in all age groups.

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Inclusion criteria required that the patient receive t-PA infusion within three hours of the onset of their first ischemic symptoms. **This remains the guideline for clinical use.**

Patients who were treated in the first hour fared substantially better than patients treated in the third hour, emphasizing the need for timely intervention. Once a patient is judged to be a candidate for thrombolysis, appropriate informed consent must be obtained.

Once acute treatment has been initiated, it is necessary to diagnose the etiology of the patient's cerebrovascular event. Where no etiology is self-evident, a thorough work-up is indicated. This would include a carotid duplex ultrasound to rule out a surgically amenable carotid stenosis. Echocardiogram should be performed to exclude an obvious cardio-embolic source. In a younger patient, transesophageal echocardiography is preferred because of its superior ability to diagnose intra-atrial clot and aortic atheromatous debris. A Holter monitor is occasionally indicated to rule out paroxysmal atrial fibrillation. Fasting lipid profile, RPR, sedimentation rate, CBC, PT and PTT should be included in any stroke work-up. In a younger stroke victim, drug screen and studies for hyper-coagulability should be considered. A sickle cell screen should be performed in any African-American stroke victim who presents at an unusually young age.

Finally, intermittent disorders that mimic stroke should be excluded. These include multiple sclerosis, migraine and hypoglycemia.

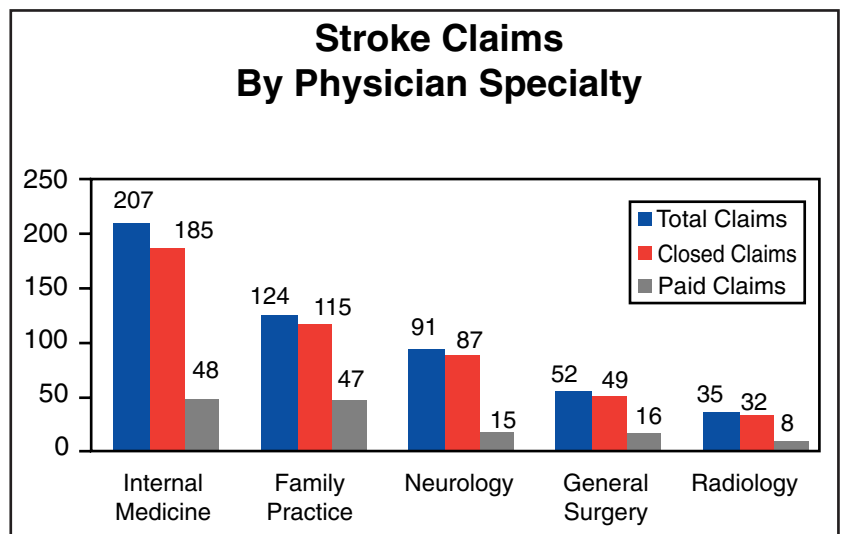
The issue of when to use Heparin is a difficult one and remains a topic on which experts continue to disagree. In general, Heparin is used in clearly cardioembolic cases of stroke or in cases that suggest unstable ischemia or a stroke-in-evolution. For a completed stroke, Heparin still

may be warranted if a cardioembolic source cannot be ruled out. Strokes that are clearly completed and are small vessel in nature, such as lacunar infarcts, benefit little from Heparin anti-coagulation.

Long-term stroke prophylaxis would typically include Coumadin for all cardioembolic strokes and atrial fibrillation patients. Clinical judgment should be used in patients who are at high risk for non-compliance or falling. Warfarin is com-

monly used in high grade verte-brobasilar stenoses as well, although the evidence supporting this approach is less convincing. Virtually all other intracranial stenoses are treated with anti-platelet therapy first including aspirin, Plavix, Ticlid or Aggrenox.

To summarize, we can no longer think of stroke as an untreatable disease. Effective treatments are evolving rapidly but will require a well-orchestrated, interdisciplinary approach. The "stroke team" needs to rely upon cooperation between the Emergency Department, primary care physician, neurologist and radiologist. Putting all the pieces into place is no simple task, but, in the end, will be extremely rewarding to both patients and physicians. As public awareness of these new treatments expands, patients will certainly be expecting access to these very exciting developments, and we owe it to them to ensure that we are prepared. ●



Physicians Insurers Association of America (PIAA)
Stroke Claims by Physician Specialty (1998)

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Table 6. Differential Diagnosis of Stroke

- Hemorrhagic stroke
- Ischemic stroke
- Craniocerebral/cervical trauma
- Meningitis/encephalitis
- Hypertensive encephalopathy
- Intracranial mass
 - Tumor
 - Subdural/epidural hematoma
- Seizure with persistent neurological signs (Todd's paralysis)
- Migraine with persistent neurological signs
- Metabolic disturbances
 - Hyperglycemia (nonketotic hyperosmolar coma)
 - Hypoglycemia
 - Postcardiac arrest ischemia
 - Toxicological cause
 - Endocrine disorder (myxodoma)
 - Uremia
- Psychiatric syndromes
- Shock and CNS hypoperfusion

Transient Ischemic Attack (TIA)

A TIA is a neurologic deficit that resolves within 24 hours (although more than 80% resolve within 30 minutes) and is most commonly associated with thrombotic strokes. The incidence of prior TIAs is 50%-75% in patients with subsequent thrombotic, extracranial carotid artery strokes, but only 10% in all other stroke types. TIAs have been thought to cause reversible brain injury; however, recent studies indicate that over 60% may be associated with computed tomography (CT) findings of infarction. The true significance of TIAs is their associated 5%-6% risk of stroke per year.

Thrombolytic Agents

The results of the National Institute of Neurological Disorders and Stroke (NINDS) study demonstrate that intravenous administration of t-PA is recommended for carefully selected patients with acute ischemic stroke if they have no contraindications to fibrinolytic therapy and if the drug can be administered within 3 hours of the onset of stroke symptoms. Thrombolytic therapy is not recommended unless the diagnosis of acute ischemic stroke is established by a physician experienced in diagnosing stroke and unless the CT scan of the brain is assessed by physicians capable of evaluating such images.

Recommendations for management of acute ischemic stroke are:

- Give t-PA intravenously (0.9 mg/kg, maximum 90 mg), with 10% of the dose given as a bolus followed by an infusion lasting 60 minutes.

- Treatment must be initiated within 3 hours of the onset of ischemic symptoms. t-PA *cannot* be recommended for a person who has had a stroke more than 3 hours earlier, except in an investigational setting.
- Intravenous t-PA is not recommended when the time of stroke onset cannot be ascertained reliably, including strokes recognized on awakening.
- Strict inclusion and exclusion criteria are listed below.

The use of thrombolytic agents carries the real risk of major bleeding. Whenever possible, the risks and potential benefits of t-PA should be discussed with the patient and the patient's family before treatment is initiated.

Careful patient selection and strict adherence to the treatment protocol are essential.

t-PA Criteria

Inclusion Criteria

1. Age 18 years or older
2. Clinical diagnosis of ischemic stroke causing a measurable neurological deficit
3. Time of symptom onset well established to be less than 180 minutes before treatment would begin

Exclusion Criteria

1. Evidence of intracranial hemorrhage on noncontrast head CT
2. Only minor or rapidly improving stroke symptoms
3. High clinical suspicion of subarachnoid hemorrhage even with normal CT
4. Active internal bleeding (eg, gastrointestinal bleeding or urinary bleeding within last 21 days)
5. Known bleeding diathesis, including but not limited to
 - Platelet count <100,000/mm
 - Patient has received heparin within 48 hours and had an elevated activated partial thromboplastin time (greater than upper limit of normal for laboratory)
 - Recent use of anticoagulant (eg, warfarin sodium) and elevated prothrombin time > 15 seconds
6. Within 3 months of intracranial surgery, serious head trauma or previous stroke
7. Within 14 days of major surgery or serious trauma
8. Recent arterial puncture at noncompressible site
9. Lumbar puncture within 7 days
10. History of intracranial hemorrhage, arteriovenous malformation or aneurysm
11. Witnessed seizure at stroke onset
12. Recent acute myocardial infarction
13. On repeated measurements, systolic pressure >185 mm Hg or diastolic pressure >110 mm Hg at time of treatment, requiring aggressive treatment to reduce blood pressure to within these limits

Suspected Stroke

EMS Assessments and Actions

- Immediate assessments performed by EMS system personnel, include
- Cincinnati Prehospital Stroke Scale (includes difficulty speaking, arm weakness, facial droop)
 - Los Angeles Prehospital Stroke Screen
 - Alert hospital to possible stroke patient
 - Rapid transport to hospital

- ✓ Detection
- ✓ Dispatch
- ✓ Delivery

- ✓ Door

Immediate general assessment: <10 min from arrival

- Assess ABCs, vital signs
- Provide oxygen by nasal cannula
- Obtain IV access; obtain blood samples (CBC, electrolytes, coagulation studies)
- Check blood sugar; treat if indicated
- Obtain 12-lead ECG: check for arrhythmias
- Perform general neurological screening assessment
- Alert Stroke Team: neurologist, radiologist, CT technician

Immediate neurological assessment: <25 min from arrival

- Review patient history
- Establish onset (<3 hours required for fibrinolytics)
- Perform physical examination
- Perform neurological examination:
 - ✓ Determine level of consciousness (*Glasgow Coma Scale*)
 - ✓ Determine level of stroke severity (*NIH Stroke Scale* or *Hunt and Hess Scale*)
- Order urgent noncontrast CT scan (door-to-CT scan performed: goal <25 min from arrival)
- Read CT scan (door-to-CT read: goal <45 min from arrival)
- Perform lateral cervical spine x-ray (if patient comatose/history of trauma)

Does CT scan show intracerebral or subarachnoid hemorrhage?

No

Yes

- ✓ Data

Probable acute ischemic stroke

- ✓ Review CT exclusions: are any observed?
- ✓ Repeat neurological exam: are deficits variable or rapidly improving?
- ✓ Review fibrinolytic exclusions: are any observed?
- ✓ Review patient data: is symptom onset now >3 hours?

Consult neurosurgery

Blood on LP

Initiate actions for acute hemorrhage

- Reverse any anticoagulants
- Reverse any bleeding disorder
- Monitor neurological condition
- Treat hypertension in awake patients

- Initiate supportive therapy as indicated
- Consider admission
- Consider anticoagulation
- Consider additional conditions needing treatment
- Consider alternative diagnoses

No to All of Above

If high suspicion of subarachnoid hemorrhage remains despite negative findings on CT scan, perform lumbar puncture. Fibrinolytic therapy is contraindicated following a lumbar puncture.

No Blood on LP

- ✓ Decision

Patient remains candidate for fibrinolytic therapy?

No

Yes

- ✓ Drug

- Review risks/benefits with patient and family: If acceptable —
- Begin fibrinolytic treatment** (door-to-treatment goal <60 min):
- Monitor neurological status: emergent CT if deterioration
- Monitor BP; treat as indicated
- Admit to Critical Care Unit
- No anticoagulants or antiplatelet treatment x 24 hours

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CLOSED CLAIM ABSTRACT

by Karol DeVito, R.N., Risk Management Consultant

CASE #1

The following case is taken from the Winter 2001 edition of PIAA *Research Notes*.

Over the course of several years, a male patient was diagnosed with hypertension, memory loss, short-term change in vision and short-term numbness/weakness on one side of his body. The patient was seen by an internist and several neurologists during this time, but was not treated for these symptoms. At the age of 49, the patient suffered a massive stroke. After the stroke, he was unable to work and unable to care for himself independently. He was placed on Coumadin and had no further strokes.

Suit was brought against the internist and the neurologist because of a failure to diagnose and to properly respond to an at-risk patient. The plaintiff's attorney claimed that had the patient been properly diagnosed and started on anticoagulant therapy, the stroke would have been avoided. An economist testified at the trial that the estimated cost of lifetime care and lost income was valued at \$1.5 million. The jury agreed and awarded the plaintiff \$2.5 million, \$1.5 million for lost earning potential and \$1 million for pain and suffering. The amount of the award in this case reflected not only the severity and nature of the patient's injury but also the

relatively young age of the patient.

The issue in this case is the physician's failure to address the patient's risk factors. This failure is highlighted by the Agency for Healthcare Research and Quality (AHRQ) consumer information pamphlet on strokes. This publication makes the following statement about strokes: "Warning signs include sudden unexplained numbness or tingling (especially on one side), slurred speech, blurred vision, stumbling or clumsiness." These were all symptoms that the patient in the case example exhibited.

CASE #2

A 31-year-old male presented to the ER complaining of being awakened from sleep by "the worst headache of my life." Associated symptoms included nausea, vomiting and dizziness. A CT scan of the head without contrast was normal. Lumbar puncture was performed with "normal" results, with the exception of 122 RBC's in tube #4 and an opening pressure of 25. Nine hours later, the patient returned to the same ER with a complaint of nausea, vomiting and dizziness. There was a new finding of "positive nystagmus in all ranges of extraocular movements." An ENT specialist was consulted. The ENT physician admitted the patient overnight to the 23-hour

observation unit with a diagnosis of viral labyrinthitis. Two days later, the patient presented to the ER at another facility complaining of headache, nausea, emesis and dizziness. Within two hours of presentation, the patient became unresponsive and required intubation. Ultimately, he was diagnosed with a left cerebellar infarction with tonsillar herniation secondary to vertebral basilar artery aneurysm dissection. This claim was settled prior to trial.

While this case involves an atypical presentation, not all presentations are textbook. Physicians must be aware of and respond to these atypical scenarios and clinically rule out a stroke. The main allegations in this case were the physician's failure to recognize CNS symptoms, failure to obtain a neurology consult and failure to order further testing such as a repeat CT scan. Stroke is a clinical diagnosis. It may take from 12-24 hours for signs of an acute stroke to show up on a CT. Therefore, even if the first CT is "normal," a repeat CT at 24 hours may be warranted.

From a risk management perspective, hyper-acute stroke management should include obtaining a head CT prior to therapy. Additionally, physicians should consider and offer, if appropriate, thrombolytic therapy in a timely manner, noting published exclusion criteria for thrombolysis.

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RISK MANAGEMENT GUIDELINES

- Certain treatment choices become unavailable if there is a prolonged delay between the onset of symptoms and the initial treatment time
- Educate the public as to the warning signs, risks, available treatment options, and realistic expectations of treatment.

Warning signs include:

- Sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- Sudden confusion, trouble speaking or understanding
- Sudden trouble seeing in one or both eyes
- Sudden trouble walking, dizziness, loss of balance or coordination
- Sudden, severe headache with no known cause
- Use available resources such as the American Stroke Association (888-4stroke or www.strokeassociation.org) to provide information and brochures to patients
- Educate physicians so they can identify patients at risk for stroke. Patient profiles to recognize as at-risk are:

Increasing age
Prior stroke
Cigarette smoking
Carotid artery disease
Drug abuse
High RBC count
Hypercholesterolemia
Physical inactivity
Family history
Hypertension
Diabetes mellitus
Peripheral artery disease
Transient ischemic attacks
Sickle cell anemia
Hyperlipidemia
Obesity

- Document why a patient at risk for stroke was or was not placed on anticoagulation therapy
- After a clinical diagnosis of stroke:
 - Take immediate action
 - Document your conversations and actions
 - Obtain informed consent after educating the patient concerning the risks, benefits and alternatives to anticoagulation therapy
- Follow established policies or protocols

- If protocols are not followed, be sure to document your reasons for the deviation
- Establish written procedures for monitoring patients on long-term anticoagulation therapy and perform follow-up to ensure therapeutic levels
- Remember, the diagnosis and treatment of cerebrovascular disease changes so fast, it is important to keep abreast of available treatments

For more information on stroke prevention and treatment:

www.chc.gov/nchs,
www.ahrq.gov,
www.ninds.nih.gov,
www.stroke.org,
www.unmassmed.edu/strokestop
and www.americanheart.org.

The PIAA has recently published a study on Atrial Fibrillation and Stroke Prevention. It is available on their Web site, www.thepiaa.org.

NOTE: The March 24, 1999 JAMA contains the National Stroke Association Stroke Prevention Guidelines.

MAG Mutual does not presume to establish any standard of care or establish rules for the practice of medicine. The particular patient-care strategies or range of patient-care strategies mentioned in this newsletter should be tempered by the physician's judgment.

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