NYU Hospitals Center
Department of Nursing
Neuroscience Departmental Process Standard

PROTOCOL **Management of the Patient Receiving Intravenous Thrombolytic Therapy (rt-PA -tissue plasminogen activator)**

PURPOSE:

1. To provide the registered nurse with guidance in assessing and providing care to adult acute ischemic stroke patients receiving intravenous (IV) rt-PA.
2. To emphasize expedient, accurate assessment and interventions based on the National Institute for Neurological Disease and Stroke (NINDS) evidence for time from initial evaluation to initiation of treatment into NYUHC practice.

LEVEL: Interdependent

SUPPORTIVE DATA:

1. The NINDS randomized, double-blind trial of IV recombinant tissue plasminogen activator (rt-PA) for ischemic stroke published in 1995 demonstrated that those patients treated with rt-PA were at least 30 % more likely to have minimal or no disability at three months as compared to patients given a placebo.
2. There is an approximately 6.4% risk of intracranial hemorrhage in patients that receive IV rt-PA within 3 hours and 7.9% for those who receive IV rt-PA within 4.5 hours, however the improvement in functional outcome greatly outweighs the risk of bleeding.
3. IV rt-PA (0.9 mg/kg; maximum of 90 mg), with 10% of the dose given as a bolus over one minute, followed by an infusion lasting 60 minutes, is the recommended treatment up to 4.5 hours of onset of ischemic stroke.
4. Thrombolytic therapy is not recommended unless:
   a. The diagnosis is established by an Attending Physician with expertise in the diagnosis of stroke; **and**
   b. A non-contrast head CT scan is assessed by a Physician with expertise in reading this imaging study; **and**
   c. Inclusion criteria are present and exclusion criteria are absent.
5. Knowing the accurate time of onset is critical. If the event is unwitnessed, the time of onset is defined as the time the patient was "last seen well".
6. The time from evaluation to treatment targets (established by NINDS) are as follows:

Door to Attending Physician evaluation	$\leq$10 Minutes
Door to Stroke Team Contact	$\leq$15 Minutes

Door to CT	≤25 Minutes
Door to CT Interpretation	≤45 Minutes
Door to needle/drug therapy	≤60 Minutes

7. **Inclusion Criteria:**
   a. Age ≥ 18 years or older
   b. Diagnosis of ischemic stroke causing measurable neurological deficit
   c. Less than 4.5 hours from symptom onset or last known to be at baseline
8. **Exclusion Criteria:**
   a. History of previous intracranial hemorrhage
   b. Symptoms suggest subarachnoid hemorrhage
   c. Uncontrolled hypertension with persistent SBP > 185 mmHg or DBP > 110 mmHg despite aggressive treatment to lower the blood pressure
   d. Active internal bleeding
   e. Acute bleeding diathesis, including but not limited to :
      i. Platelet count < 100,000/mm3
      ii. Heparin received within 48 hours, resulting in abnormally elevated aPTT greater than the upper limit of normal or an anti-XA level≥ 0.3 units/ml
      iii. Current use of anticoagulant with INR > 1.7 or PT > 15 seconds
      iv. Current therapy with an oral factor Xa inhibitor or direct thrombin inhibitor in the presence of elevated sensitive laboratory tests(such as aPTT, INR, platelet count, and ECT; TT; or appropriate factor XA activity assays) or last dose < 48 hours (assuming normal renal function)
   f. Significant head trauma or prior stroke in previous 3 months
   g. Recent intracranial or intraspinal surgery
   h. Arterial puncture at non-compressible site in previous 7 days
   i. CT demonstrates multilobar infarction (hypodensity > 1/3 cerebral hemisphere
   j. Blood Glucose concentrate < 50 mg/dL (2.7mmol/L)
   k. Known of suspected infective endocarditis
   l. Intracranial neoplasm, arteriovenous malformation, or aneurysm

9. **Relative contraindication/precautions IV rt-PA** (consider risk to benefit ratio on a per patient basis)
   a. Pregnancy or early postpartum period (<14 days from delivery)
   b. Seizure at onset with postictal residual neurological impairments
   c. Only minor or rapidly resolving stroke symptoms (clearing spontaneously)
   d. Recent acute myocardial infarction (within previous 3 months)

e. Acute pericarditis

f. Major surgery or serious trauma within previous 14 days

g. Recent gastrointestinal or urinary tract hemorrhage (within previous 21 days)

h. **Relative contraindication/precautions IV rt-PA** (consider risk to benefit ratio on a per patient basis)If symptom onset is between 3 and 4.5 hours

i. Older than 80 years of age

ii. Taking an anticoagulants regardless of INR

iii. Severe stroke (NIHSS > 25)

iv. History of both diabetes mellitus and previous stroke

*Neuro-intervention should be considered for all patients with evidence of a large vessel occlusion and/or at the at the Stroke Service Attending Physician's discretion per the NYUHC *Guidelines for Neuro-Interventional Treatment of Ischemic Stroke.*

CONTENT:

I. PATIENT ASSESSMENT/INTERVENTION:

The professional registered nursing staff may encounter the patient with signs and symptoms of acute stroke in any setting, inpatient or outpatient. The time to evaluation to treatment targets (see Supportive Data #6) compels urgent action.

A. Phase I: Pre-Thrombolytic Therapy

Professional nursing staff in the Emergency Department (ED) or any other setting is responsible for:

1. Evaluating the patient for sudden onset neurological symptoms, determine time of symptom onset and activate the Stroke Team.
2. Notify Primary Team that the Stroke Team was activated;
3. Obtaining complete set of vital signs (HR, BP, RR, Temp, O2 sat) at time of initial evaluation or admission;
4. Placing patient on continuous cardiopulmonary and pulse oximetry monitoring;
5. Obtaining blood glucose;
6. Inserting 2 large bore IVs and administering IV fluids as ordered;
7. Obtaining stat labs as ordered (to be resulted within 45 minutes from arrival if ordered);
8. Obtaining stat EKG and CXR to be completed within 45 minutes from order), if ordered;
9. Obtain vital signs and neuro/stroke assessment per ESI level and report any changes to Primary Team and Stroke Team;

10. Maintaining patient NPO until dysphagia screen is completed;
11. Preparing patient for transport to radiology for non-contrast head CT scan/CTA;
12. Documenting vital signs and neuro/stroke assessment in the Electronic Medical Record (EMR).

B. SAFETY/CORRECTIVE ACTION;

1. **IF** any of the following occur, **THEN NOTIFY** Primary Team and Stroke Team promptly:
   a. Systolic BP≥185 and /or Diastolic BP≥110
   b. Heart rate >100 or <50
   c. Temp >100.4F or <96.8F
   d. Resp/min>20 or <10
   e. O2 Sat (%) < 90
   f. Blood glucose < 50 or >400 mg/dl

C. Phase II: Administration of Thrombolytic Therapy

Professional registered nursing staff in the ED, Radiology, or other setting where IV rt-PA is to be administered is responsible for (IVrt-PA may be mixed by a clinical pharmacist at the bedside, Stroke Team, ED RN or Alert Team RN):

1. Collaborating with Stroke Team following non-contrast head CT scan for appropriateness of thrombolytic therapy per inclusion/exclusion criteria.
2. Corroborating with LIP to ensure verbal consent, education of patient/family regarding the procedure, explaining the risks to the patient, and intent of treatment.
3. Obtaining patient weight in kilograms – actual/stated if clinical condition permits, otherwise document estimated weight).
   a. If estimated weight is used, the expected margin is to be within 10% of actual weight
4. Collaborate with ordering LIP for determining weight based dose for IV rt-PA (0.9 mg/kg; maximum of 90 mg).
5. Reconstituting rt-PA per manufacturer's guidelines in a 1:1 concentration in diluent provided (sterile water). Note that rt-PA is supplied as Activase (alteplase) and must be reconstituted at time of administration.
6. Reviewing dose with ordering LIP: (0.9 mg/kg; maximum of 90 mg) to identify appropriate weight based total dose.
7. Following manufacturer instructions for Alteplase reconstitution:
   a. Using the transfer device provided, add the contents of the accompanying 100 ml vial of sterile water to the contents of the 100 mg vial of Alteplase powder as follows:

b. Remove protective flip caps from one vial of Alteplase and one vial of sterile water for injection.

c. Remove the protective cap from one end of the transfer device and keep the vial of sterile water upright, insert the piercing pin vertically into the center of the stopper of the sterile water vial. Do not invert the vial of sterile water.

d. Remove the protective cap from the other end of the transfer device and place the vial of Alteplase upside down over the piercing pin.

e. Push the vial of Alteplase down so the piercing pin is inserted through the center of the vial stopper.

f. Invert the two vials so the vial of Alteplase is on the bottom (upright) and the vial of sterile water is upside down, allowing the water to completely flow down through the transfer device, taking approximately two minutes.

g. Swirl the Alteplase vial gently to dissolve the powder. Do not shake.

h. Remove transfer device and empty sterile water vial and discard.

i. Remove discard dose of Alteplase from vial to leave dosage ordered per LIP.

j. Draw up 10% of total dose per LIP order to be administered as a bolus by the LIP; being careful not to prime syringe with air, and insert syringe away from the puncture made by the transfer device.

8. Providing the bolus dose to the Stroke Team to administer over 1 minute.
9. Administering remainder of total dose (90%) immediately unless clinically contraindicated as a continuous infusion over 1-hour through an infusion pump (set volume limit to 26 ml less than volume to be infused to allow warning to hang NS and prevent air from getting into the IV tubing).
10. Hang 50 cc NS at completion of continuous infusion at the previous infusion rate to ensure full delivery of any remaining rt-PA in the tubing.
11. Vital signs and neuro/stroke assessment documentation is initiated 15 minutes after the IV rt-PA bolus administration. Refer to *Process for Vital Signs and Neurological/Stroke Assessment Leeway*
12. Monitoring vital signs (HR, BP, RR and O2 sat) and neuro/stroke assessments every 15 minutes during the rt-PA infusion and for the first hour following the completion of the infusion (a total of 2 hours).

D. SAFETY/CORRECTIVE ACTIONS:

1. Add no other medications to infusion solutions containing Alteplase.
2. IV rt-PA total dose should **never exceed 90 mg**.
3. **IF** any of the following occur, **THEN NOTIFY** Primary Team and Stroke Team promptly:
   a. Systolic BP>180 and /or Diastolic, BP>105;
   b. Heart rate >100 or < 50;

c. Temp > 100.4F or <96.8 F;

d. Resp/min > 20; or < 10

e. O2 Sat (%) < 90.

f. Blood glucose < 50 or > 400 mg/dl

4. BP Management (prior, during or after IV rt-PA)
   a. **IMPLEMENT** blood pressure management per LIP order.
      i. Examples of medication used are: Nicardipine, Labetalol
5. Maintain bleeding precautions and assess for signs of hemorrhage during infusion:
   a. Avoid insertion of a Foley catheter
   b. Avoid arterial and non-compressible venous punctures, unless absolutely indicated.
   c. Avoid nasal gastric tube insertion unless absolutely indicated.
   d. Avoid intramuscular injections unless absolutely indicated.
   e. Apply compression dressing to any IV sites where lines are removed.
   f. Monitor urine and stool for blood.
   g. Monitor patient for gingival, gastrointestinal (GI), genitourinary (GU) or subcutaneous bleeding.
6. Monitor patient for signs of allergic reaction, including angioedema
7. **ASSESS** for signs and symptoms of intracranial hemorrhage and/or increased intracranial pressure, and **NOTIFY** Primary Team and Stroke Team immediately for any decline in neuro status, such as:
   a. Change in LOC
   b. Nausea and vomiting
   c. Decreased motor exam
   d. Restlessness/agitation
   e. Headache
   f. Seizures
   g. Increased BP and HR, or abnormal respirations.
8. **IF** any change in the following:
   a. Neuro status and/or headache
   b. Nausea or vomiting
   c. Signs of allergic reaction, including angioedema
   d. Significant GI/GU bleeding or bleeding from a non-compressible arterial site

   THEN
   e. **NOTIFY** Primary Team and Stroke Team immediately, and
   f. **DISCONTINUE** the IV rt-PA if still infusing, and

g. **PREPARE** for emergency non-contrast head CT; if hemorrhage **THEN**

h. Follow Stroke TPA Reversal orders.

9. Continue IV rt-PA vital signs and neuro/stroke assessment as per order.
10. Completing and documenting dysphagia screening tool prior to any oral intake, if not already completed.

E. Phase III: Post-Thrombolytic Therapy

Professional registered nursing staff in unit where IV rt-PA administered, and/or unit to which the patient is transferred, e.g., ED, ICU or Stroke Unit/Neuroscience Progressive Care Unit, is responsible for:

1. Monitoring vital signs (HR, BP, RR and O2 sat) and neuro/stroke assessments in accordance with the parameters outlined above and document in EPIC:
   a. then q 30 minutes x 6 hours,
   b. then q 1 hour x 16 hours
   c. Anytime that there is assessment of decline in neurological status
   d. Monitor BP every 15 minutes during antihypertensive therapy or per orders
   e. Actively maintain SBP <180 but no less than 140
   f. Actively maintain DBP <105 but no less than 60
   g. Maintain blood glucose > 100 or < 180 mg/dl
2. BP Management
   a. **IF** Systolic BP≥180 and /or Diastolic, BP≥105; **THEN IMPLEMENT** orders for blood pressure management per LIP.
      ii. Examples of medication used are: Nicardipine, Labetalol
3. **IF** the patient develops severe headache, acute hypertension, nausea, or vomiting, or decline in neuro status **THEN**
   a. **NOTIFY** Primary Team and Stroke Team immediately, and
   b. **DISCONTINUE** the IV rt-PA if still infusing, and
   c. **PREPARE** for emergency non-contrast head CT; if hemorrhage **THEN**
   d. Follow Stroke TPA Reversal orders
4. Maintaining bleeding precautions for 24 hours post infusion of IV rt-PA to include:
   a. Avoid insertion of a Foley catheter
   b. Avoid arterial and non-compressible venous punctures, unless absolutely indicated.
   c. Avoid nasal gastric tube insertion unless absolutely indicated.
   d. Avoid intramuscular injections unless absolutely indicated.
   e. Apply compression dressing to any IV sites where lines are removed.

f. Monitor urine and stool for blood.

g. Monitor patient for gingival, gastrointestinal (GI), genitourinary (GU) or subcutaneous bleeding.

5. Maintaining patient NPO per LIP order, and performing dysphagia screen prior to PO intake, if not already completed.
6. Do not administer antiplatelets or anticoagulants for 24 hours post infusion of IV rt-PA.
7. Using intermittent pneumatic compression devices (ICPDs) for VTE prophylaxis for the first 24 hours post infusion.
8. Maintain bedrest for the first 12 hours post infusion of IV rt-PA. Reassess and advance activity orders per patient's clinical status, LIP order and physical therapist evaluation.
9. Limit invasive procedures for 24 hours post IV rt-PA administration.
10. Observe for evidence of allergic reaction, angioedema.
11. Facilitating imaging as per LIP order.

II. PATIENT & FAMILY EDUCATION:

A. Educate the patient and family about:

1. IV rt-PA
2. Need for frequent vital signs, neuro/stroke assessments, and level of care required
3. Risk of and need to monitor for bleeding
4. Dysphagia screening

III. DOCUMENTATION:

A. Document the following in the Electronic Medical Record (EMR):

1. Assessments and reassessments per protocol
2. Time of rt-PA bolus and infusion doses in medication administration record
3. I & O to ensure adequate hydration
4. Results of dysphagia screen utilizing the screening tool
5. Responses to interventions
6. Patient and family education and response
   a. Stroke recognition
   b. Emergency treatment
   c. Risk reduction for secondary prevention

B. Initiate Stroke Management Tool/Flowsheet and place in EMR, as appropriate.

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