Identifying Missed Eligible AIS Patients

Indication

Activase® (alteplase) is indicated for the treatment of acute ischemic stroke (AIS). Exclude intracranial hemorrhage as the primary cause of stroke signs and symptoms prior to initiation of treatment. Initiate treatment as soon as possible but within 3 hours after symptom onset.

Important Safety Information

Contraindications

Do not administer Activase to treat acute ischemic stroke in the following situations in which the risk of bleeding is greater than the potential benefit: current intracranial hemorrhage (ICH); subarachnoid hemorrhage; active internal bleeding; recent (within 3 months) intracranial or intraspinal surgery or serious head trauma; presence of intracranial conditions that may increase the risk of bleeding; bleeding diathesis; and current severe uncontrolled hypertension.

Please see Important Safety Information throughout and full Prescribing Information.

ASSESS OPPORTUNITIES TO IDENTIFY MISSED ELIGIBLE PATIENTS

KEY QUESTIONS TO CONSIDER

What are the top reasons for non-treatment?

Are patients excluded for clinically appropriate reasons (ie, contraindications, other)?

Are reasons for non-treatment consistent with hospital protocols?

Have hospital protocols been reviewed in light of the current Activase® (alteplase) PI?

What are the trends in reasons for non-treatment?

Are eligible patients being missed?

What is your plan to address these gaps?

Which stroke team members would benefit from this analysis?

Important Safety Information

Warnings and Precautions

Bleeding

Activase can cause significant, sometimes fatal, internal or external bleeding, especially at arterial and venous puncture sites. Avoid intramuscular injections and trauma to the patient. Fatal cases of hemorrhage associated with traumatic intubation in patients administered Activase have been reported. The concomitant administration of heparin and aspirin with and following infusions of Activase for the treatment of AIS during the first 24 hours after symptom onset has not been investigated. Because heparin, aspirin, or Activase may cause bleeding complications, carefully monitor for bleeding, especially at arterial puncture sites. Hemorrhage can occur 1 or more days after administration of Activase, while patients are still receiving anticoagulant therapy. If serious bleeding occurs, terminate the Activase infusion.

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TRENDS IN NON-TREATMENT OF PATIENTS WITH ACUTE ISCHEMIC STROKE (AIS)

Trends in Non-treatment of Patients With Acute Ischemic Stroke (AIS) is a suggested format to collect data in order to extract the most relevant information that would help identify reasons for non-treatment and potentially missed eligible patients.

The table on this page is filled in as a hypothetical example. It is not based on actual patient data. The next page provides you with an editable document you can use to help you identify trends for non-treatment in patients with AIS at your institution. Once the form is filled in, it can be printed and posted or incorporated into presentations. Share this report with your teams during a time period of your choosing: monthly, biannually, yearly, etc. to understand areas of improvement, such as individual provider education or review of current protocol with the emergency department team.

For additional information, please visit www.activase.com.

Patient	Physician	Neurologist	Reason for non-treatment[1,2]	Initial NIHSS score	Discharge mRS	Discharge location
Patient F	Adams	N/A	Stroke severity deemed too mild Patient/family refusal	2	2	Rehab
Patient G	Adams	N/A	Patient/family refusal	6	2	Rehab
Patient H	Adams	Bradley	Patient/family refusal Rapid improvement	8	3	Skilled nursing
Patient I	Adams	Bradley	PI warning–hypertension	3	1	Rehab
Patient J	Adams	Bradley	PI warning–recent history of ICH	16	4	Skilled nursing
Patient K	Adams	Goodman	PI warning–pregnancy	1	1	Home
Patient L	Adams	Goodman	PI contraindication–active internal bleeding	6	4	Skilled nursing

Important Safety Information

Warnings and Precautions

Bleeding (cont'd)

In the following conditions, the risks of bleeding with Activase are increased and should be weighed against the anticipated benefits: recent major surgery or procedure; cerebrovascular disease; recent intracranial hemorrhage; recent gastrointestinal or genitourinary bleeding; recent trauma; hypertension; high likelihood of left heart thrombus; acute pericarditis; subacute bacterial endocarditis; hemostatic defects including those secondary to severe hepatic or renal disease; significant hepatic dysfunction; pregnancy; diabetic hemorrhagic retinopathy or other hemorrhagic ophthalmic conditions; septic thrombophlebitis or occluded AV cannula at seriously infected site; advanced age; and patients currently receiving oral anticoagulants, or any other condition in which bleeding constitutes a significant hazard or would be particularly difficult to manage because of its location.

Please see Important Safety Information throughout and full Prescribing Information.

TRENDS IN NON-TREATMENT OF PATIENTS WITH ACUTE ISCHEMIC STROKE (AIS)

Reporting period: _____

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Orolingual Angioedema

Orolingual angioedema has been observed during and up to 2 hours after infusion in patients treated for AIS. In many cases, patients received concomitant angiotensin-converting enzyme inhibitors. Monitor patients treated with Activase during and for several hours after Activase infusion for orolingual angioedema. If angioedema develops, discontinue the Activase infusion and promptly institute appropriate therapy.

Cholesterol Embolization

Cholesterol embolism, sometimes fatal, has been reported rarely in patients treated with thrombolytic agents; the true incidence is unknown. It is associated with invasive vascular procedures and/or anticoagulant therapy.

Coagulation Tests May be Unreliable during Activase Therapy

Coagulation tests and/or measures of fibrinolytic activity may be unreliable during Activase therapy unless specific precautions are taken to prevent in vitro artifacts.

Adverse Reactions

The most frequent adverse reaction associated with Activase AIS therapy is bleeding.

Although exploratory analyses of the AIS clinical studies suggest that severe neurological deficit (National Institutes of Health Stroke Scale [NIHSS > 22]) at presentation was associated with an increased risk of intracranial hemorrhage, efficacy results suggest a reduced but still favorable clinical outcome for these patients.

Allergic-type reactions, e.g., anaphylactoid reaction, laryngeal edema, orolingual angioedema, rash, and urticaria have been reported.

Please see full Prescribing Information for additional Important Safety Information.

References: 1. Activase [prescribing information]. South San Francisco, CA: Genentech, Inc; 2017. 2. Modified Rankin Scale. Internet Stroke Center website. http://www.strokecenter.org/wp-content/uploads/2011/08/modified_rankin.pdf. Accessed April 14, 2016.

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