The Neurohospitalist
1-4

DOI: 10.1177/1941874416672783
nhos.sagepub.com
SAGE

How a CT-Direct Protocol at an American Comprehensive Stroke Center Led to Door-to-Needle Times Less Than 30 Minutes

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Abstract

Background and Purpose: The safety and efficacy of intravenous tissue plasminogen activator (IV tPA) following acute ischemic stroke (AIS) is dependent on its timely administration. In 2014, our Comprehensive Stroke Center designed and implemented a computed tomography-Direct protocol to streamline the evaluation process of suspected patients with AIS, with the aim of reducing door-to-needle (DTN) times. The objectives of our study were to describe the protocol development and implementation process, and to compare DTN times and symptomatic intracranial hemorrhage (sICH) rates before and after protocol implementation. **Methods:** Data were prospectively collected for patients with AIS receiving IV tPA between January 1, 2010, and May 31, 2015. The DTN times, examined as median times and time treatment windows, and sICH rates were compared pre- and postimplementation. **Results:** Two hundred ninety-five patients were included in the study. After protocol implementation, median DTN times were significantly reduced (38 vs 28 minutes; $P < .001$). The distribution of patients treated in the three time treatment windows described below changed significantly, with an increase in patients with DTN times of 30 minutes or less, and a decrease in patients with DTN times 31 to 60 minutes and over 60 minutes ($P < .001$). There were two cases of sICH prior to implementation and one sICH case postimplementation. **Conclusions:** The implementation of a protocol that streamlined the processing of suspected patients with AIS significantly reduced DTN time without negatively impacting patient safety.

Keywords

tissue-type plasminogen activator, acute stroke, ischemic stroke, evidence-based medicine, door-to-needle time

Introduction

An untreated acute ischemic stroke (AIS) may result in the loss of 1.9 million neurons per minute.[1] Intravenous tissue plasminogen activator (IV tPA) is an effective treatment to dissolve clots and restore blood flow in patients with AIS, but its effectiveness is dependent on timely administration.[2] A well-coordinated evaluation involving multiple departments is required from the time of patient arrival through IV tPA administration. This evaluation must include confirmation of last known normal medical history and examination, National Institutes of Health Stroke Scale (NIHSS) determination, a head computed tomography (CT) scan, and an IV tPA preparation. The American Heart Association and American Stroke Association recommend the time between emergency department (ED) arrival and administration of IV tPA, known as door-to-needle (DTN) time, to be less than 60 minutes to optimize the benefits of the drug.[3] However, less than one-third of patients with AIS in the United States were treated within this time window between 2003 and 2009.[4] In 2014, our Comprehensive Stroke Center implemented a protocol to increase the efficiency of the initial evaluation process for patients with AIS, with an aim to reduce DTN times. This report describes our protocol development and implementation process and compares DTN times and symptomatic intracranial hemorrhage (sICH) rates pre and post protocol implementation.

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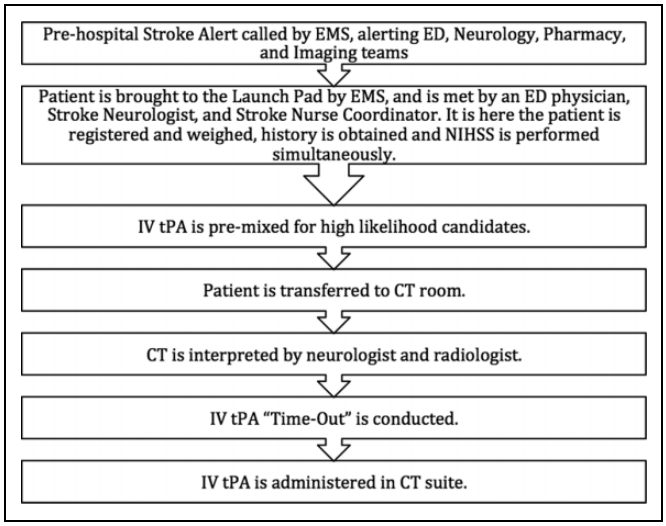

Figure 1. CT-Direct protocol.

Materials and Methods

Process Development

This study was conducted at a high-volume, urban Comprehensive Stroke Center. A DTN Task Force, comprising leadership from the ED, neurology, pharmacy, and radiology departments, was assembled in late 2013 to reduce DTN times for patients with AIS. Influenced by a widely cited Finnish protocol that demonstrated the efficacy of a lean evaluation process,[5] our task force implemented the CT-Direct protocol in early 2014, presenting a simplified algorithm for suspected patients with AIS, achieved by eliminating wasteful procedures. Demonstrated in Figure 1, the protocol instructs that the patient be taken directly to a "launchpad," eliminating the often time-consuming task of moving the patient into and out of an ED room. The launchpad is a designated area located between the emergency medical services entrance and CT suite, equipped with a weigh bed and a dedicated IV pump for tPA administration. The protocol encourages mixing IV tPA prior to CT imaging for patients with AIS presenting within the tPA treatment window deemed as high likelihood candidates for the drug. Patients taking anticoagulants or presenting with a decreased level of consciousness, elevated blood pressure, headache, nausea, vomiting, or advanced stage cancer are not eligible for premixing IV tPA. Once imaging is completed and the patient is deemed eligible, an IV tPA time-out is held and the elements listed in Table 1 are reviewed and confirmed prior to administering IV tPA. The drug is administered in the CT suite, again eliminating the task of transferring the patient to the ED.

Data Collection and Analysis

Data were prospectively collected for adult patients with AIS consecutively admitted to our Comprehensive Stroke Center and treated with IV tPA. This research was conducted in accordance with the Declaration of Helsinki and was approved by the HealthOne institutional review board; a waiver of informed consent was granted. We compared outcomes pre- (January 1, 2010 to March 31, 2014) and post-implementation (April 1, 2014, to May 31, 2015) of the CT-Direct protocol. Patients who received IV tPA prior to hospital admission were excluded.

Table 1. Intravenous tPA Time-Out.

- Has the time of last known normal been confirmed?
- Is the patient still within the IV tPA time window?
- Has the patient's use of anticoagulants been reviewed?
- Have pertinent lab values been reviewed?
- Has the calculated dosage been double-checked by 2 nurses or physicians?
- Is blood pressure still within parameters?
- Does the patient still meet inclusion criterion?
- Have all relative and absolute exclusion criteria been considered?

If all answers are yes, proceed with IV tPA administration.

Abbreviation: IV tPA, intravenous tissue plasminogen activator.

Our primary outcome was DTN time, examined as both median DTN time and time treatment windows—defined as the proportion of patients treated with IV tPA within 30 minutes or less, between 31 and 60 minutes, and greater than 60 minutes. We also compared sICH rates before and after protocol implementation. Demographic (age, race, and gender) and clinical characteristics (NIHSS and intra-arterial [IA] intervention rates) were additionally compared between populations.

Median DTN times were compared using the Mann-Whitney U test. Time treatment windows and demographic and clinical characteristics were compared using Fisher's exact χ^2 analysis. Statistical analyses were performed using SPSS software (version 23; Chicago, Illinois).

Results

Protocol Implementation

The DTN task force implemented the CT-Direct protocol through formal, didactic training and digital source materials. Physicians and nurses from the ED, CT, neurology, and pharmacy departments were approached to obtain input and buy in. Initial concerns regarding the change in departmental work flow led to educational sessions on the safety profile of IV tPA, guided walks to highlight the fastest routes between pharmacy and CT suite, reviews of equipment in the CT suite for ED physicians and nurses, and mock cases involving all departments.

Outcome Evaluation

Two hundred ninety-five patients with AIS were treated with IV tPA during our study period: 211 patients were treated before and 84 patients were treated after protocol implementation. Demographic and clinical characteristics of gender, race, initial NIHSS values, and receipt of IA intervention were

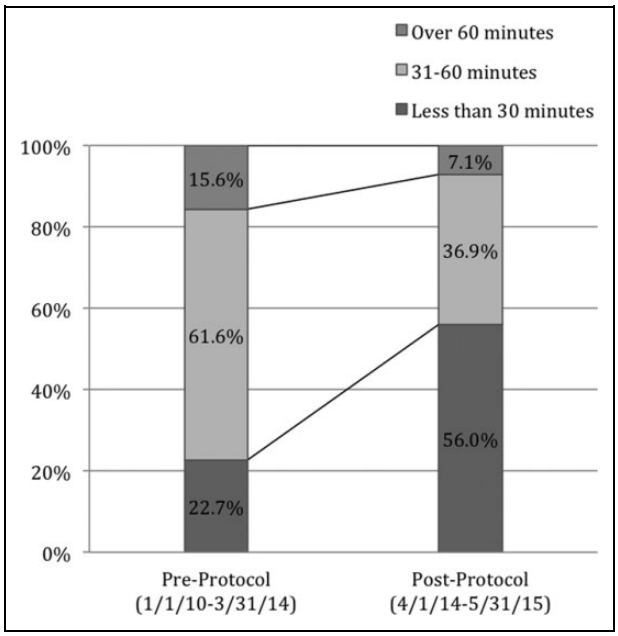

Figure 2. Treatment time windows, pre and post protocol implementation.

similar between the two populations ($P > .05$ for all). Mean (standard deviation [SD]) age was significantly higher after protocol implementation (72.1 [18.0] vs 76.5 [13.8]; $P < .05$).

Median DTN times were significantly reduced by 10 minutes after protocol implementation, from 38 to 28 minutes ($P < .001$). The distribution of patients treated in the three designated time treatment windows also changed significantly, with a considerable increase in the proportion of patients with DTN times in 30 minutes or less and subsequent decrease in the proportion of patients with DTN times 31 to 60 minutes and over 60 minutes ($P < .001$; Figure 2). There were two sICH cases prior to protocol implementation (0.9%), and one case after implementation (1.2%).

Discussion

Implementation of a protocol that emphasized a streamlined, uninterrupted flow of patient care and the elimination of unnecessary steps led to reduced DTN times at our urban, high-volume Comprehensive Stroke Center without compromising patient safety. Specifically, implementation of the CT-Direct protocol led to a 10-minute decrease in median DTN times, an increase in the proportion of patients treated within 30 minutes, and a reduction in the proportion of patients with a DTN of 31 to 60 and greater than 60 minutes. Our overall sICH rate (1.0%) remained lower than the national average rates throughout the study period.[6]

Since 2010, Target: Stroke has focused on promoting strategies to reduce DTN times for participating stroke centers, resulting in improvements in DTN times.[6] The second Target: Stroke initiative, rolled out in January 2015, aims to increase the proportion of patients treated with IV tPA in less than 60 minutes to 75% of patients.[7] We believe eliminating processes no longer needed in today's stroke care environment, such as transferring a patient to an ED room before and after imaging, implemented through educational approaches emphasizing gathering feedback and continual education, can help American stroke centers reach DTN times of under 60 minutes and possibly under 30 minutes. To continue to improve our DTN times, the DTN task force has recently instituted a policy to store IV tPA in the ED, rather than in the pharmacy; thus, a pharmacist reports to the CT suite to mix the drug, saving additional time.

Our study was able to significantly decrease DTN times by tailoring our protocol to our institution, and other studies have also achieved decreased DTN via process improvements. A recent study showed the addition of an acute care nurse practitioner as a 24/7 first responder to stroke alerts significantly reduced the median DTN to 45 minutes in patients with an ischemic stroke.[8] Meanwhile, a second study saw significantly decreased median DTN times to 47 minutes, after the treatment process was enhanced by borrowing relevant principles from the automotive industry.[9] Although the achieved median DTN times in these studies were nearly 20 minutes longer than what was observed in the current study, they are a testament to the ability of process improvements to significantly decrease treatment times in acute stroke care.

It is possible that decreasing DTN times are accompanied by small increases in stroke mimic treatment rates.[10] However, because we know that early treatment of AIS is beneficial, and that the treatment of stroke mimics with IV tPA is not deleterious,[11,12] we feel this protocol is more beneficial than harmful. Further research is needed to examine the effects of the CT-Direct policy on functional patient outcomes. As our study was set at a single institution, our ability to generalize our results and recommendations to stroke centers of different environments is limited.

Summary

Implementing a protocol to streamline the initial evaluation process for patients with AIS can result in reduced DTN times without increasing sICH rates. We attribute the success of the protocol to a dedicated team that thoroughly examined the evaluation process, removed steps that did not add value, and remained responsive. We hope this report provides a road map for similar comprehensive stroke centers to rework the initial evaluation process for suspected patients with AIS, which may reduce DTN times.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Swedish Medical Center (Englewood, CO).

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