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Endovascular treatment outcomes using the Stroke Triage Education, Procedure Standardization, and Technology (STEPS-T) program

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Abstract

Background: ‘‘Door to treatment’’ time affects outcomes of acute ischemic stroke (AIS) patients undergoing endovascular treatment (EVT). However, the correlation between staff education and accessible technology with stroke outcomes has not been demonstrated.

Objective: The objective of this paper is to demonstrate the five-year impact of the Stroke Triage Education, Procedure Standardization, and Technology (STEPS-T) program on time-to-treat and clinical outcomes.

Methods: The study analyzed a prospectively maintained database of AIS patients who benefited from EVT through implementation of STEPS-T. Demographics, clinical characteristics, and modified Rankin Score at three months were analyzed. Thrombolysis in Cerebral Infarction (TICI) scale was used to grade pre- and post-procedure angiographic recanalization. Using electronic hemodynamic recording, stepwise workflow times were collected for door time (T_D), entering angiography suite (T_A), groin puncture (T_G), first DSA (T_{DSA}), microcatheter placement (T_M), and final recanalization (T_R). Median intervention time (T_A to T_R) and recanalization time (T_G to T_R) were compared through Year 1 to Year 5.

Results: A total of 230 individuals (age 74 ± 12, between 30 to 95) were enrolled. Median intervention and recanalization times were significantly reduced, from 121 minutes to 52 minutes and from 83 minutes to 36 minutes respectively from Year 1 to Year 5, ($p < 0.001$). Across the study period, annual recruitment went up from 12 to 66 patients, and modified Rankin Score between 0 and 2 increased from 36% to 59% ($p = 0.024$).

Conclusions: STEPS-T improved time-to-treat in patients undergoing mechanical thrombectomy for AIS. During the observation period, clinical outcomes significantly improved.

Keywords

Stroke, quality improvement, angiography, mechanical thrombectomy

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Introduction

Acute ischemic stroke (AIS) is a leading cause of death and disability, with a stroke occurring every 40 seconds and a stroke-related death occurring every 4 minutes in the United States.[1] Studies have shown that clinical outcomes are dependent on reperfusion times.[2,3] Thus, achieving rapid recanalization and reducing time from onset to mechanical thrombectomy (MT) has been a critical goal in case management.[4,5] Despite the proliferation of technology to help manage workflow, there remains a gap in consensus on best practices for driving improvement of effective and efficient case management.

Numerous studies have shown that improvements are possible at every step of the care pathway.[4,6–14] For instance, much attention has been paid to reducing transport times.[15,16] Operational changes, such as prioritization of hospital resources, better training of staff, or use of evidence-based stroke protocols, can influence the quality of care.[17,18] The sum of these findings

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supports the need for improved efficiencies at isolated steps within the care pathway, which requires a systematically integrated refinement of the entire care pathway.

The Stroke Triage Education, Procedure Standardization, and Technology (STEPS-T) program is an integrated approach developed to decrease the total treatment time for stroke patients while maintaining quality of care and improving clinical outcomes. STEPS-T was developed and implemented in a comprehensive stroke center with the specific objective of reducing the time from stroke patient arrival at the hospital (or "door time") to recanalization. The specific goal of this study was to determine the five-year impact of STEPS-T on time-to-treat and outcomes in AIS cases.

Methods

Patient data collection and imaging procedures

Institutional review board approval was obtained for a prospective registry of patients treated with MT for AIS from August 2012 to December 2016 at a comprehensive, high-volume stroke treatment center in the United States. The population included patients who presented with intracranial large-vessel occlusion (LVO) or distal occlusion and were eligible for MT after undergoing a standard computed tomography (CT) protocol (Alberta Stroke Program Early CT Score (ASPECTS) $\geq$6), confirmation of LVO on CT angiography, and absence of intracranial hemorrhage (ICH). Individuals received intravenous (IV) tissue plasminogen activator (tPA) after CT scan, when indicated. Patients with posterior circulation or carotid occlusion were excluded from this study.

Two Accreditation Council for Graduate Medical Education (ACGME) fellowship-trained operators performed all procedures independently of the admission protocol. The following data were collected for each patient: demographic information, clinical characteristics, National Institutes of Health Stroke Scale (NIHSS) score at admission and discharge, modified Rankin Scale (mRS) at 90 days, and Thrombolysis in Cerebral Infarction (TICI) scores.

All procedures were performed using biplane angiographic systems (Innova IGS 630, GE Healthcare, Chicago, IL) equipped with 30 cm $\times$ 30 cm flat panel detectors and advanced imaging capabilities such as Cone Beam CT. This equipment afforded both ergonomic and workflow efficiencies, such as:

- A centralized joystick, which provided the operator optimal control at the table side, of the table, frontal plane, and lateral plane using one hand.
- Automatic exposure control, which used a dedicated algorithm to automatically estimate effective patient thickness, thus delivering excellent image quality at minimal radiation doses.

STEPS-T

STEPS-T is an integrated program for reducing door-to-recanalization time. The program is based on the principle that three domains are interrelated inputs that affect the speed and quality of care: (1) procedure workflow, (2) technologies, and (3) education. Further, STEPS-T integrates "digital objects," or macro-enabled systems, which record each workflow step and connect staff in the care pathway, as called for by the American Heart Association Data Summit on the importance of integrating digital objects in modern stroke care.[19] Prior evidence indicates the importance of these three interrelated domains.[15,16,18] To reduce treatment time, workflow in the biplane suite was divided into steps, and actions and actors of the intervention, i.e. nurses, technologists, and physicians, operated in a parallel and standardized manner, Figure 1.

STEPS-T was implemented at the stroke center in three phases. Integrated daily training and customization were conducted for the first 30 days, then advanced training was performed monthly, and finally, process optimization was iteratively complete over a six-month period. Thereafter, processes were monitored and refined on a rolling basis, as deemed clinically necessary by the technology provider, neurointerventionalist, administration, and nursing staff. Staff participation in training was mandatory, and new staff were required to undergo peer-to-peer training for about three to six months, during which they would shadow on-call procedures.

Workflow data

Workflow data were collected in a stepwise manner using digital objects (macros) assigned to each step in the care pathway. Times for each step were recorded as digital objects using the Mac-Lab Hemodynamic Recording System (GE Healthcare, Chicago, IL), which enables use of customized step-by-step macro elements for collection of time stamps, device(s) information, and medication administration(s). Overall times for each segment of the care pathway were obtained, including patient arrival at the center (door time, T_D), arrival time at the angiography suite (T_A), time of groin puncture (T_G), acquisition of first digital subtraction angiography (DSA) (T_{DSA}), placement of microcatheter (T_M), and time of recanalization (T_R).

Statistical analysis

Descriptive summaries were prepared for clinical workflow intervals, including setup time (T_A to T_G), catheterization time (T_G until completion of T_{DSA} and T_M), and clot retrieval time. The primary measures of total intervention (from T_A to T_R) and recanalization time (from T_G to T_R) were analyzed using a Wilcoxon rank-sum test. Workflow times and admission NIHSS scores

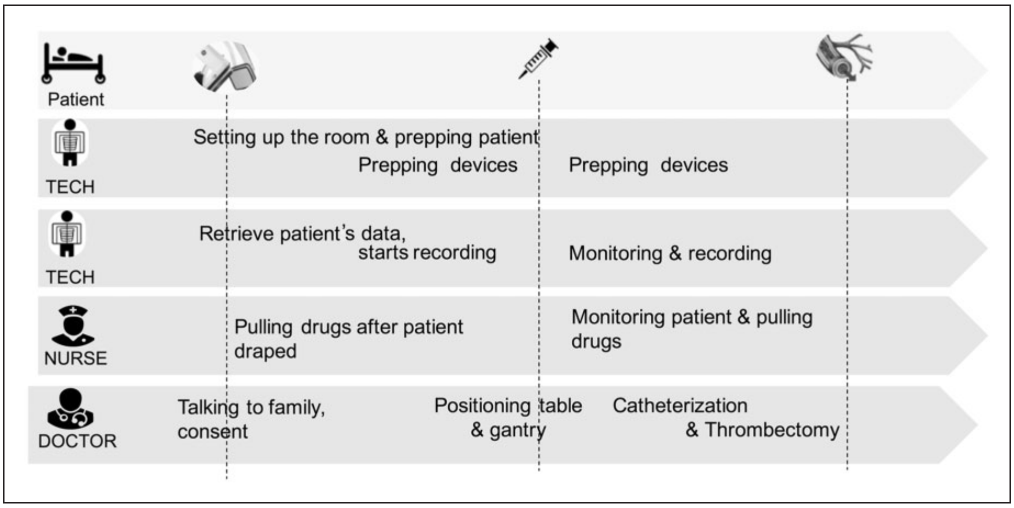

Figure 1. Workflow in the biplane suite illustrating the parallel nature of tasks by the different actors in the room. The ''interventional time'' starts when the patient arrives in the biplane suite.
Tech: technician.

Table 1. Population characteristics.

Data	Value
N	230
Age in years, mean (minimum–maximum)	74 (30–95)
Ethnicity	
Hispanic	166 (72.2%)
Caucasian	63 (27.4%)
African American	1 (0.4%)
Weight (kg), mean (minimum–maximum)	81 (41.7–169.6)
Female, *n* (%)	118 (51.3%)
Hypertension, *n* (%)	211 (92%)
Atrial fibrillation, *n* (%)	89 (39%)
Diabetes mellitus, *n* (%)	104 (45%)
Smoker, *n* (%)	18 (8%)
Coronary artery disease, *n* (%)	73 (32%)
Chronic heart failure, *n* (%)	29 (13%)
Admission NIHSS, median (minimum–maximum)	17 (0–34)
Treated with IV-tPA, *n* (%)	92 (40%)

NIHSS: National Institutes of Health Stroke Scale; IV: intravenous; tPA: tissue plasminogen activator.

were compared year to year from baseline (Year 1) through the five-year period (Years 2–5) using a Kruskal–Wallis test. Results were classified as significant when p values were less than 0.05.

Results

A total of 230 patients (51.3% female) were enrolled in this study, representing clinical characteristics typical of an AIS population (see Table 1). Procedural workflow characteristics and clinical follow-up are reported in Table 2 and Figure 2.

Over the five-year study period, median door-to-biplane-suite time was 66 minutes (confidence interval (CI): 26 minutes to 113.5 minutes) and did not significantly change. In the same time, median total intervention time, i.e. from arrival in the biplane suite to recanalization, was significantly reduced from 121 to 52 minutes ($p < 0.001$), as all steps of the procedure were shortened significantly, including setup (–39%), groin to first DSA (–37%), first DSA to microcatheter (–68%) and finally clot retrieval time (–64%). In the same period, annual recruitment increased from 12 (Year 1) to 66 patients (Years 4 and 5). Median admission NIHSS remained stable (18, 18, 17, 16 and 17) along the successive years.

Clinical outcomes, as measured by 90-day mRS of 0 to 2, evolved from 36% during Year 1, to 52%, 76%, 71% and 59% the following years. There was a significant improvement between Year 1 and Year 5 ($p < 0.05$). Looking at the last three years together, 90-day mRS of 0 to 2 was equal to 68%.

There was no significant difference in recanalization rates (TICI 2b–3) during the five years, although an increase happened between Year 1 and Year 2 (75% to 91%, NS). Overall, 88% of patients had a successful recanalization during the study period. Symptomatic ICH rate was 8.7% (20 patients).

Discussion

Time-to-treatment is an important metric to assess quality improvements to workflow and has proven to directly affect stroke outcomes.[12] The current study demonstrated that, over a five-year period, the STEPS-T program significantly reduced total intervention and recanalization times by a median of 57% ($p < 0.001$) and helped improve mRS from 36% to 59% ($p < 0.05$). Furthermore, STEPS-T sustainably

Table 2. Procedural workflow characteristics and clinical outcomes.

	Overall (Years 1–5)	Year 1	Year 2	Year 3	Year 4	Year 5	% Change	*p* value
N	230	12	32	54	66	66		
Door to angiography suite (T_D to T_A)	66 (26, 114)	71 (57, 99)	89 (54, 115)	81 (61, 136)	99 (56, 149)	71 (51, 140)		*NS*
Setup (T_A to T_G)	17 (11, 22)	26 (20, 32)	16 (12, 25)	17 (12, 21)	16 (10, 23)	16 (11, 20)	−39%	<0.001
Groin to first DSA (T_G to T_{DSA})	4 (3, 6)	6 (4, 14)	4 (3, 6)	4 (3, 8)	4 (3, 6)	4 (3, 6)	−37%	<0.001
DSA to microcatheter (T_{DSA} to T_M)	6 (3, 14)	16 (6, 23)	13 (9, 19)	8 (3, 15)	3.5 (2, 8)	5 (3, 12)	−68%	<0.001
Clot retrieval (T_M to T_R)	21 (12, 37)	58 (15, 104)	37 (24, 44)	16 (11, 29)	16 (9, 29)	21 (12, 36)	−64%	<0.001
Total recanalization (T_G to T_R)	37 (23, 56)	83 (42, 116)	56 (43, 71)	32 (22, 53)	27 (20, 45)	36 (22, 55)	−57%	<0.001
Procedure (T_A to T_R)	54 (41, 75)	121 (67, 142)	71 (61, 92)	47 (39, 72)	48 (36, 63)	52 (40, 73)	−57%	<0.001
TICI 2b–3 Post *n* (%)	202 (88%)	9 (75%)	29 (91%)	48 (89%)	58 (88%)	58 (88%)		
mRS 0–2 *n* (%)		4 (36%)	16 (52%)	41 (76%)	47 (71%)	39 (59%)		0.024
sICH *n* (%)	20 (8.7%)							
In-hospital mortality *n* (%)	39 (17%)							

Data are presented as medians (Q1, Q3) in minutes, rather than means to account for outliers. Percentage change (% change) was calculated as median values for (Year 1–Year 5)/Year 1.
Time of: arrival at the angiography suite (T_A), groin puncture (T_G), acquisition of first DSA (T_{DSA}), microcatheter placement (T_M), and recanalization (T_R).
DSA: digital subtraction angiography; mRS: modified Rankin Scale; TICI: Thrombolysis in Cerebral Ischemia; sICH: symptomatic intracranial hemorrhage.

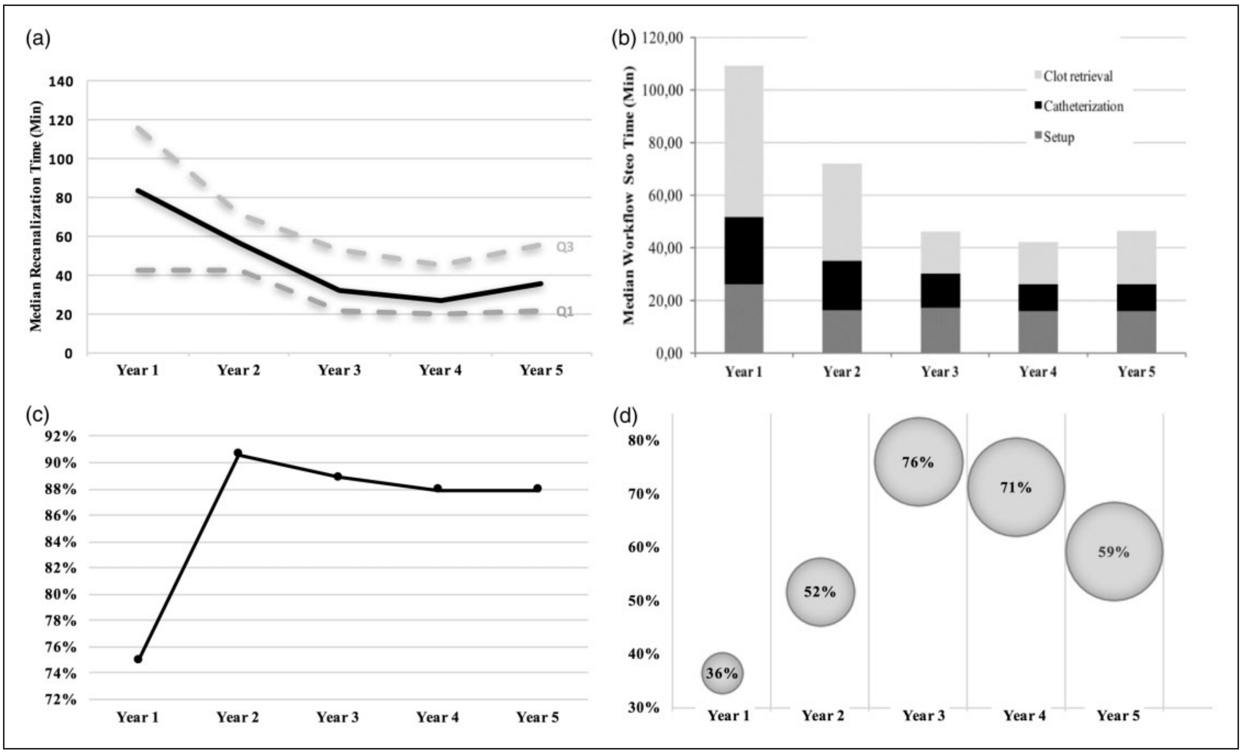

Figure 2. Improvement in median total recanalization time ((a) *top left*) and median component workflow step times (setup, catheterization, and clot retrieval; (c) *top right*) over the five-year period. Notably, setup and catheterization time are significantly reduced year over year. Thrombolysis in Cerebral Infarction (TICI) 2b–3 at the end of the procedure ((b) *bottom left*). Modified Rankin Score (mRS) of 0–2 at 90 days ((d) *bottom right*). The size of the bubble is proportionate to the sample size per year.

reduced the time required across all steps evaluated in the angiography suite.

Although reducing patient transfer can generate time savings, the impact of optimizing treatment duration has also demonstrated value. McTaggart et al. recently reported that a standardized methodology can decrease time from groin puncture to recanalization.[4] After implementation of their methodology, a recanalization time similar to the one observed in the current study was reported. However, the McTaggart et al. study was conducted over a one-year observational period of a smaller cohort ($N = 22$, mean 37 minutes, CI: 32.1 to 42.5), and clinical outcomes at 90 days were not reported.

While other stroke workflow programs have focused solely on staff training, STEPS-T added digital technology to capture evidence in a user-friendly context, thus allowing clinical staff to further engage in workflow efficiencies that improve stroke outcomes.[19–21] Once adopted, STEPS-T can be customized to accommodate nonacute procedures to increase hospital throughputs and improve quality of care.

Empowered care teams perform with rapid, coordinated responses. When neurointerventionalists are tasked with making many decisions and leading a team in a high-pressure environment, the resultant "cognitive load" can delay critical decisions and care.[4] Rehearsal scenarios have been shown to help mitigate this risk but require regular reinforcement,[22] and use of standardized protocols can contribute to fast care delivery.[18] During our STEPS-T implementation, a graded program of monthly training was conducted. Performance variability and questions from clinical staff were reduced, allowing the operator to focus on patient treatment. When implementing new programs, resistance to change can limit effectiveness. During STEPS-T implementation, regular and mandatory training, and support from the information technology department and administration, contributed to the success of the program. STEPS-T was embedded in a wider initiative, starting in the emergency department, with a "stroke champion," i.e. a dedicated to stroke staff member, trained to help speed up triage to CT, administrate thrombolysis, and ensure speedy patient transfer to the angiography suite.[13]

The current study had certain limitations. For instance, the retrospective nature of the data analysis precluded randomization of the approach, and a detailed analysis was not conducted to evaluate how the time from onset to treatment evolved over the five-year study period. Also, the inclusion of more wake-up strokes or patients outside the six-hour time window during the DAWN trial (clinicaltrials.gov number, NCT02142283) slightly affected our last year of data. It should be noted that increased AIS patient recruitment, following publication of trials proving superiority of MT over the previous standard of care,[5,7,23–25] led to a higher than normal staff turnover in Year 5, which affected our rigorous training program. Finally, although there was no evolution of our practice, the steady increase of patients throughout the study likely contributed to improved operator skills and speed when performing MT, independent of STEPS-T implementation. Nevertheless, it is important noting that stent-retriever with aspiration was the therapy used in more than 95% of cases. Regarding limitations of the program itself, implementation of STEPS-T in a lower-volume center may take longer, so multi-institutional data sharing and harmonization is encouraged.[26]

Conclusion

Significant improvements were achieved using the STEPS-T program, which enabled iterative evidence-based process improvements, thereby sustaining significant reductions in intervention and recanalization times, and improving clinical outcomes over a five-year period for patients undergoing mechanical thrombectomy for AIS. Future standardization of digital objects and staff training will be necessary to further improve evidence-based quality programs at all steps of the acute stroke care pathway.

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Declaration of conflicting interests

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