NEW YORK STATE OF OPPORTUNITY. Department of Health

Informed Consent for tPA: Investigating Clinical Outcomes

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Faculty Disclosure Information

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Presentation: Informed Consent for tPA: Investigating Clinical Outcomes

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Background

- In New York State (NYS), patients have the right to receive information about their treatment and to refuse treatment (New York State Public Health Law (NYS PHL) §2803)
- However, no consent is required for emergency treatment (NYS PHL §2805)
- Intravenous tissue-type plasminogen activator (IV t-PA) is an emergency treatment for patients who experience an ischemic stroke. The benefits of the treatment are time-dependent (Kate, Parthasarathy, and Shuaib, 2016)
- A survey administered to NYS Designated Stroke Centers in 2014 showed that a majority required either written or verbal consent to administer IV t-PA to patients arriving within three hours of last known well (Weintraub, Colello, et al, 2016)
- **The goal of this study is to investigate whether there is a difference in crude time to intervention and clinical outcomes for those patients diagnosed with an ischemic stroke who arrive within three hours of last known well when informed consent (written or verbal) is required versus when no informed consent is required.**

Overview of Study

Data Sources

- Stroke Center Annual Review Tool (N=119)
  - Aggregate data for calendar year 2016 (Stroke centers submit num. & denom.)
- Get With The Guidelines (GWTG) (N=63)
  - NYSDOH has data use agreements in place with Coverdell-participating stroke centers to use GWTG discharge-level data

Methodology

- Collect informed consent data for 2016
- Chi-square tests; ANOVA and non-parametric tests*; Paired Analyses; Regression
- Predictor Variable: Informed Consent Status [Verbal, Written, No Informed Consent]

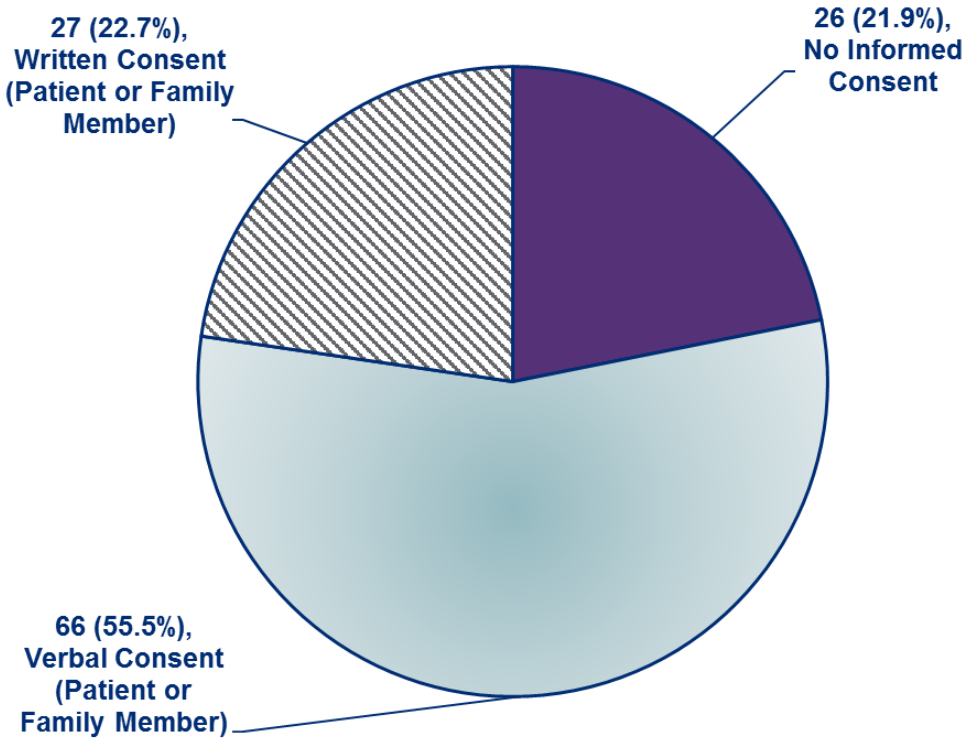
Outcome Variables of Interest

- (1) NYS Performance Measure: Arrive by 2, Treat by 3 - Percentage of patients who arrive within two hours of last known well and receive IV t-PA by three hours
- (2) NYS Time Target (TT): Percentage of patients who meet the NYS TT for IV t-PA administration (TT: Door-to-Needle ≤ 60 min)
- (3) Median time to IV t-PA administration
- (4) Mean Length of Stay
- (5) Mean modified Rankin scale (mRS) at discharge

*Note: This work is being turned into a manuscript. To avoid problems with publication, only the ANOVA and non-parametric test results are shared today.

Informed Consent Required for tPA Administration?

The pie chart shows the count and percentage (N,%) of those NYS Designated Stroke Centers that fall into each informed consent status category for those patients who arrive within three hours of last known well.



Source: 2017 Annual Review Tool for NYS Designated Stroke Centers (N=119)

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Results (Annual Review Tool Data)

- **Unit of Analysis:** NYS Designated Stroke Center
- **N:** 119 NYS Designated Stroke Centers
- **Outcome 1:** Percentage of patients who arrive within two hours of last known well and receive IV t-PA within the hour (Arrive by 2, Treat by 3)
  - Median (IQR): Written Consent – 100% (9%); Verbal Consent – 97% (10%); No Consent – 93% (12%)
  - Test: Kruskal-Wallis (KW) Non-Parametric Test
    - Why KW? Data is skewed and some informed consent status categories have <30 stroke centers in the category
    - Tests whether three groups (Written, Verbal, and No Consent) have the same distribution
    - **There is no difference in the distributions for the three categories of informed consent status for the percentage of patients who satisfy the Arrive by 2, Treat by 3 measure (p-value = 0.1314)**
- **Outcome 2:** Percentage of patients who meet the NYS time target for IV t-PA administration (Door-to-Needle ≤ 60 minutes)

Not Statistically Significant but May be Practically Significant

  - Median (IQR): Written Consent – **67%** (58%); Verbal Consent – 82% (37%); No Consent – **81%** (28%)
  - Test: Kruskal-Wallis Non-Parametric Test
  - **There is no difference in the distributions for the three categories of informed consent status for the Door-to-Needle time target (p-value = 0.1463)**

Results (GWTG Discharge-Level Data)

- **Unit of Analysis:** NYS Designated Stroke Center (3,796 GWTG records rolled up to hospital level)
- **N:** 63 NYS Designated Stroke Centers Participating in the Paul Coverdell National Acute Stroke Program
- **Outcome 3:** Median time to IV t-PA administration
  - Median (IQR): Written Consent – **63 min** (10 min); Verbal Consent – 58 min (21 min); No Consent – **57 min** (13 min)
  - **There is no difference in the distributions for the three categories of informed consent status for median time to IV t-PA administration (p-value = 0.4434)**

Not Statistically Significant but May be Practically Significant

- **Outcome 4:** Mean Length of Stay
  - Mean (SD): Written Consent – 7.7 (3.9) days; Verbal Consent – 7.4 (2.0) days; No Consent – 7.9 (1.4) days
  - Analysis of Variance (ANOVA) Test
    - Tests for equal means between the three groups (Written, Verbal, and No Informed Consent)
    - **There is no difference in the mean Length of Stay between the three groups (p-value = 0.7468)**
- **Outcome 5:** Mean modified Rankin scale (mRS) at discharge (0 – No Symptoms to 7 – Death)
  - Mean (SD): Written Consent – 2.7 (0.7); Verbal Consent – 2.6 (0.6); No Consent – 2.7 (0.4)
  - **There is no difference in the mean mRS score at discharge between the three groups (p-value = 0.7098)**

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Next Steps

- Finish paired statistical analyses (October 2017)
- Address limitations of analysis:
  - GWTG data - only included discharges if patient arrived within 3 hours of last known well and had t-PA administered.
    - Expand analysis to look at gap between brain image read and tPA for all patients with a final diagnosis of ischemic stroke to make sure there was no delay in tPA administration due to the requirement for informed consent.
    - Analyze individual discharge records to track patients from time arrived until tPA to make sure the informed consent did not delay tPA administration such that patients were pushed outside tPA treatment window.
- Publish results in peer-reviewed journal

For additional information or questions, please contact tara.cope@health.ny.gov

References

- Kate, M., Parthasarathy, R., Shuaib, A. (2016). Intravenous Thrombolysis and Anti-thrombotics. In B. Ovbiagele & T. Turan (Eds.) Ischemic Stroke Therapeutics (13-26). New York, NY: Springer.
- Weintraub, M., Collello, A., Johnson, S., McClellan, F., Cole, S., Benesch, C., Rudolph, S., Levine, S. (2016). Informed Consent for IV tPA in New York State Designated Stroke Centers: A Current Snapshot. Poster presented at the 2016 International Stroke Conference, February 17-19, 2016, Los Angeles, CA.