

Delay In Consent Is A Common Reason For Delay In tPA Administration

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Background

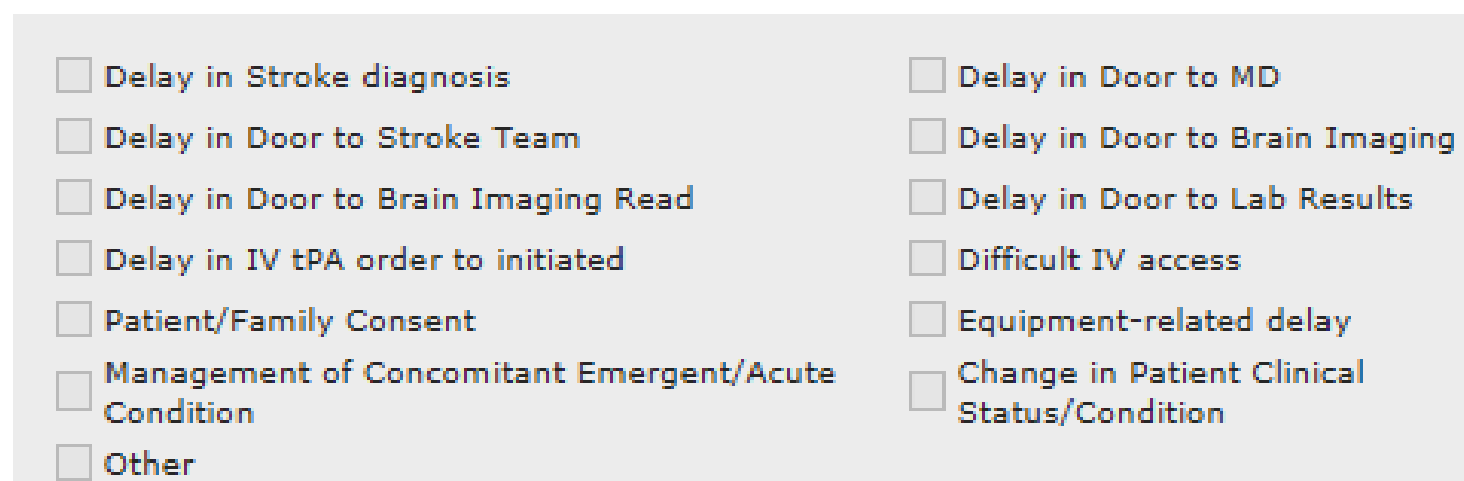
- Benefit of IV tPA time dependent
- Treatment should be initiated ASAP with a guideline recommended door-to-needle < 60 minutes¹
- This target is missed in >50% of cases, reported as high as 70%²
- Hospital delays in evaluation, diagnostic tests & delay from order to IV tPA initiation are most often targeted with improvement strategies
- 2013 ASA guidelines for early management of ischemic stroke state informed patient consent for IV tPA is indicated¹
- Regulatory precedents in the U.S. & internationally support the use of IV tPA in patients lacking capacity if alternative form of consent can't be obtained within the treatment window¹
- Difference of opinion & practice regarding signed, written informed consent & implied consent for IV tPA
- Previous studies have addressed adequacy or quality of consent & capacity of acute stroke patients to give consent^{3, 4}

Objective

- Determine the frequency of the reasons for delay in IV tPA treatment within New York State (NYS)
- Identify factors specifically associated with delay in patient/family consent

Methods

- Reasons for delay in IV tPA beyond 60 minutes of hospital arrival were collected in the Get With The Guidelines®-Stroke (GWTG-S) Patient Management Tool



- Data were collected by NYS Department of Health hospitals participating in the NYS DOH Stroke Center Designation program
- Data were a reporting requirement for all 2012 patient discharges
- Abstractors selected all reasons either explicitly documented or clearly apparent
- Aggregate data for all NYS hospitals were obtained
- Chi squared was used to test differences (2-tailed)

References

1. Jauch, EC et al. *Stroke*. 2013;44:870–947
2. Fonarow, GC et al. *Circulation*. 2011;123:750-758
3. White-Bateman, SR et al. *Arch Neurol*. 2007 Jun;64(6):785-92
4. Thomas, L et al. *Front.Neur*.2012 Aug;3:128



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Results

- 23,850 ischemic strokes enrolled in GWTG-Stroke in 2012 from 120 hospitals in NYS
- Inpatient stroke cases were excluded (1,230) leaving 22,620 ischemic strokes
- IV tPA was given to 1,991 (8.8%)
- Delay in tPA occurred in 1,145 (58%) with reason for delay in 1,116 (97%)

Total	1,116	
	N	%
Delay in Stroke diagnosis	52	4.7
Delay in Door to MD	23	2.1
Delay in Door to Stroke Team	19	1.7
Delay in Door to Brain Imaging	32	2.9
Delay in Door to Brain Imaging Read	44	3.9
Delay in Door to Lab Results	74	6.6
Delay in IV tPA order to initiated	114	10.2
Difficult IV access	19	1.7
Patient/Family Consent	239	21.4
Equipment-related delay	18	1.6
Management of Concomitant Emergent/Acute Condition	233	20.9
Change in Patient Clinical Status/Condition	124	11.1
Other	369	33.1

- Females were more likely to experience delay due to patient/family consent compared with males (62% vs. 38%, p = 0.005)

	Ischemic Stroke	IV tPA at This Hospital	Reason for Delay in IV tPA	Patient/Family Consent	P Value
Total	22,620	1,991	1,116	239	
Female	11,763 (52.0)	1,045 (52.5)	588 (52.7)	147 (61.5)	0.005
Male	10,846 (48.0)	944 (47.4)	526 (47.2)	91 (38.1)	

- Over representation of consent related delays on weekends

	Ischemic Stroke	IV tPA at This Hospital	Reason for Delay in IV tPA	Patient/Family Consent	P Value
Total	22,620	1,991	1,116	239	
Weekend	5,801 (25.6)	542 (27.2)	318 (28.5)	87 (36.4)	0.007
Weekday	1,6815 (74.4)	1,449 (72.8)	798 (71.5)	152 (63.6)	

Limitations

- Only aggregate level data available
- Only select patient characteristics could be analyzed
- Could have underestimated consent related delays
- Only 1 year of data
- NYS data only. May not be generalizable
- "Other" reasons not individually analyzed
- Data collection was designed for quality improvement & not for a research study

Conclusions

- Our state-level data suggest that issues with consent are one of the most common reasons for delay in IV tPA
- Previous studies have shown that delay in IV tPA occurs more frequently on off-hours & female gender
- A potential gender issue is raised requiring further study
- Delay on weekend vs. weekday suggests Stroke Centers review variations in stroke center processes that may be present on weekends
- Training & tools to improve & shorten the consent process may reduce delays
- Further study is needed to assess other patient and hospital characteristics that may be associated with delay in patient/family consent & determine if any of the variables are independent predictors

Contact Information