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Accuracy of First Recorded "Last Known Normal" Times of Stroke Code Patients

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Abstract

Introduction—Given the time-sensitivity of thrombolytic therapy, the accurate documentation of last known normal (LKN) time is crucial to ensure optimal management of stroke patients. This study investigates whether a difference exists between preliminary LKN times (first responders and ED practitioners) and revised LKN times (neurology/stroke practitioners), and what potential impact on emergent management of acute stroke this discrepancy may pose.

Methods—All stroke code patients from UCSD hospitals from 10/2008 to 7/2013 with treatment time data were included and grouped based on the disparity between preliminary LKN time and revised LKN time: preliminary earlier than revised, two times equal, and preliminary later than revised. We compared baseline characteristics, stroke code intervals, rates of rt-PA administration, 90 day mRS score, discharge disposition, and symptomatic intracranial hemorrhage.

Results—73.6% of 261 patients had disparity between preliminary and revised times. 57.5% had later preliminary LKN than revised; 16.1% had earlier preliminary LKN than revised. Baseline characteristics, stroke code speed, 90 day mRS score, rates of rt-PA administration, discharge disposition, or rates of sICH were not significantly different between the groups. Among rt-PA treated stroke patients whose preliminary time was earlier than the revised time, had the preliminary LKN been used, 29.4% would have had rt-PA withheld inappropriately. In those stroke patients excluded from rt-PA treatment for being outside the treatment window, whose preliminary time was later than the revised time, had the preliminary time been used, 69.7% would have been inappropriately treated outside the relevant rt-PA window.

Conclusions—Most patients had disparity between preliminary and revised LKN times. Had the preliminary LKN time been used for acute stroke decision making, 58% of patients would have potentially been treated outside the approved thrombolytic time window, with higher risk of adverse events and 16% may have been inappropriately excluded from thrombolysis. This study

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highlights the need for training in the determination and refinement of the actual time of stroke onset, especially at hospitals without stroke expertise.

Introduction

Stroke is a leading cause of mortality, and standard of care is treatment with intravenous recombinant tissue plaminogen activator (rt-PA) within a set interval from symptom onset.[1] As time from onset increases, the diminishing benefits are outweighed by the risk of intracerebral hemorrhage.[2, 3] For this reason, the FDA has approved IV rt-PA to be given only within 3 hours of stroke symptom onset. Some studies have since shown that treatment within 4.5 hours may be safe and effective for a select population.[2, 4] Given the time-sensitive nature of stroke treatment, the accurate documentation of true time of onset is crucial to optimize safe and effective management of stroke code patients. When patients have significant deficit, the time of onset is often reported to pre-hospital care practitioners by a witness (often a family member). The pre-hospital emergency providers then relay the information to the ED practitioner, who in turn reports this time to the treating neurologist or stroke specialist. In this relaying of information, there is potential for propagating incorrect information, without reassessment or detailed probing of the patient, witness, or family. This time, if not critically assessed, may be incorrect. There is also potential for confusing the LKN time with the time of symptom recognition. If a patient wakes up with stroke symptoms, the LKN time may reflect the time of awakening instead of the true LKN time (often the prior night). A recent study[5] with 251 patients showed that in patients with wake-up stroke symptoms, EMS underestimated LKN times with an average difference in LKN times of over 3 hours. The LKN time can also, unfortunately, be reported as ‘about an hour ago’ or similar phrase. This statement, propagated to numerous providers over many minutes or hours, without an actual time stamp, is meaningless to help determine true eligibility for rt-PA. In a retrospective study from the United Kingdom which studied stroke patients admitted by emergency ambulance, standard practice did not consistently result in pre-hospital documentation of relevant and accurate information that could aid in treatment decisions.[6] If initial LKN determinations are not ‘accurate’, and revisions are not made, there may be under or overtreatment of stroke code patients resulting in adverse outcomes. In addition, the number of patients enrolled in clinical trials may be adversely impacted by using an incorrect LKN time.[7] Our analysis investigated whether a difference exists between documented preliminary and revised LKN times, and the potential impact of this difference on the emergent management of acute stroke.

Methods

All consecutive stroke code patients who were evaluated at UC San Diego hospitals between Oct 2008 and July 2013 with treatment time data available were included in this analysis. Electronic chart review was performed to obtain the first recorded ‘preliminary’ LKN time. These preliminary LKN times were obtained preferentially from EMS runsheets when available, or from ED nursing documentation. ED physician documentation was used when no other preliminary time was found. ‘Revised’ LKN times were obtained from the stroke code documentation, which was included in the prospective stroke code database. These were the final recorded times by the neurologist or stroke specialist (resident, stroke fellow,

or attending) who evaluated the patient. The difference between the preliminary LKN and the revised LKN time was calculated for each patient. Patients were split into three groups based on pattern (Table 1). Group A (preliminary LKN earlier in time than revised): using revised time would result in shortened ‘onset to arrival’ interval, Group B (the two times are equal), and Group C (preliminary LKN later in time than revised): using revised time would result in lengthened ‘onset to arrival’ interval. Baseline characteristics, stroke code speed, rates of rt-PA administration, 90 day mRS score, discharge disposition, and symptomatic intracerebral hemorrhage were compared among groups.

Results

Of 261 patients, 69 (26.4%) had accurate preliminary LKN times that were unchanged with revised LKN documentation (Group B). The other 192/261 (73.6%) had a disparity between preliminary LKN time and revised LKN time; 42/261 (16.1%) of the total were in Group A (preliminary LKN earlier in time than revised), and 150/261 (57.5%) were in Group C (preliminary LKN later in time than revised) (Table 1). The median discrepancy between the times was 30 minutes for Group A and 48 minutes for Group C. Baseline characteristics (age, baseline NIHSS, baseline glucose, gender, race, ethnicity, hypertension, diabetes, atrial fibrillation, cerebrovascular disease) were not significantly different between the groups. Smoking was the only baseline characteristic which showed a difference among groups (C>B>A, p=0.04) in the overall cohort (Table 2).

Stroke/TIA Patients

In the subset of patients with actual stroke or TIA, amounting to 182/261 (69.7%) of the total cohort, baseline characteristics were not different among groups (p=0.113) (Table 3). Of these 182 patients, 49 (26.9%) had accurate preliminary LKN times that were unchanged with revised LKN documentation (Group B). The other 133 (73.1%) had a disparity between preliminary LKN time and revised LKN time; 29/182 (15.9%) of the total in Group A (preliminary LKN earlier in time than revised), and 104/182 (57.1%) in Group C (preliminary LKN later in time than revised) (Table 1). For this subset, using the revised LKN, the ‘onset to stroke code activation’ time interval was significantly different between the groups: Group A median ‘revised LKN to stroke code activation’ interval was 50 min, Group B and Group C medians were 78 min and 86 min, respectively (p=0.01). Similarly, ‘revised LKN to treatment decision’ interval was significantly different among the groups: Group A median interval was 105 min, Group B 135 min and Group C 150 min (p=0.02). However, ‘stroke code activation to treatment decision’ interval was not significantly different among the groups: Group A median interval was 44 min, Group B was 44 min and Group C was 43 min (p=0.28) (Table 4).

In the stroke/ TIA subgroup, IV rt-PA rates approached statistical significance, with a higher rt-PA rate in the Group A where using the revised LKN resulted in shortened ‘onset to arrival’ interval (Group A: 17/29 (58.6%), Group B: 19/49 (38.8%), Group C: 36/104 (34.6%), p=0.069) (Table 4).

Of the 29 patients in Group A stroke/TIA subset (preliminary LKN earlier in time than revised), 17/29 (58.6%) were treated with rt-PA. Of these, 5/17 (29.4%) would have been

excluded due to being outside the appropriate time interval (had the preliminary LKN been used.) In these 5/182 (2.7%) of stroke/TIA patients, without the neurology revised time, rt-PA would have been withheld inappropriately.

Of the 104 patients with stroke/TIA in Group C (preliminary LKN later in time than revised), 38/104 (36.5%) were treated with rt-PA and 66/104 (63.5%) were not treated. Of those excluded from treatment, 33/66 (50%) were excluded due to being outside the relevant time window (3 hours or 4.5 hours, depending on patient age, DM and prior stroke). Of those outside the relevant treatment window, 23/33 (69.7%) had an 'onset to treatment decision' based on preliminary LKN time that would have actually put them in the window. This accounts for 23/182 (12.6%) of the stroke/TIA subset. In these cases, without the neurology revised time, patients would have been inappropriately treated outside the relevant rt-PA window.

Regarding functional outcomes (mRS 0-1 or return to baseline at 90 days), there was no significant difference between groups (Group A: 10/17 (58.8%), Group B: 11/20 (55%), Group C: 13/33 (39.4%); p=0.375). Discharge disposition home did not differ between the groups (p=0.905). There was no difference in rate of symptomatic intracranial hemorrhages (Group A: 0/18 (0%), Group B: 1/21 (4.8%), Group C: 3/38 (7.9%); p=0.804) (Table 4).

Conclusions

This analysis showed that approximately three quarters (74%) of all stroke code cases evaluated noted a difference between preliminary and revised LKN times; only 26% of patients had accurate preliminary LKN times (Group B). A recent study[5] with 251 patients showed overall consistency between EMS LKN time and revised time, with the difference in LKN being under 15 minutes in 91% of the cohort and under 15 minutes in 80% of stroke patients. In that study, among patients who received IV rt-PA, none would have been incorrectly excluded from IV rt-PA if the EMS LKN time had been used. Conversely, of patients who did not receive IV rt-PA, 6% would have been incorrectly included for IV rt-PA consideration had the EMS time been used. Our analyses highlight multi-faceted concerns regarding the accuracy of preliminary LKN times. In the majority of cases showing a difference between the preliminary and revised LKN times (58% in Group C), the preliminary LKN time was later in the day than the actual revised time (resulting in an initially reported shorter 'onset to arrival' time interval). If this preliminary time were used for thrombolytic treatment decision-making, a shorter, but often incorrect time interval would be calculated, resulting in an excess of patients who would potentially be treated outside the approved thrombolytic time window, increasing their risk of adverse events. This means that 70% of those in Group C who were excluded from rt-PA for being outside the relevant treatment window had an initial 'onset to treatment decision' interval which would have incorrectly put them within the rt-PA treatment window, putting them at risk for adverse events such as ICH. This has implications for hospitals without proper expertise in the investigation and refinement of the actual LKN time in stroke code patients. It further emphasizes the need for enhanced training of all providers from pre-hospital personnel to ED providers and stroke/ neurology teams.

Equally worrisome is the alternate scenario; our analyses showed a high percentage of patients (16% in Group A), where the preliminary LKN time was earlier in the day than the revised time (resulting in an initially reported longer 'onset to arrival' time interval). In these cases, patients who were actually within the rt-PA window would not have received thrombolytic therapy if the preliminary LKN time was used to make the treatment decision. This similarly points to the need for enhanced education to help refine the true LKN time, and enable more patients to be treated.

The discrepancy between the preliminary LKN time and the revised LKN time can in part be attributed to the common practice of providers asking when the patient 'first noticed' their symptoms, instead of ascertaining the actual LKN time. Perhaps enhanced training of EMS providers should teach providers to obtain the LKN, rather than the time of 'onset of symptoms' or 'recognition of symptoms,' and highlight the difference between the three.

Similarly, training ED providers on the importance of reporting an exact LKN time is critical. It is too frequent that the answer obtained in the Emergency Department from EMS in response to 'when were they last known to be normal?' is a relative response, i.e. 'about an hour ago.' This approximation, often based on the EMS report, then perpetuated despite the addition of transport time, evaluation time, and report time, is often incorrect and may lead to improper patient triage.

While EMS education on this issue is crucial, we cannot rely entirely on EMS for the determination of the preliminary LKN time. A study of EMS pre-hospital identification of stroke demonstrated a sensitivity of only 0.41.[8] Another study noted sensitivities ranging from 0.44 to 0.83, depending on the stroke scale used.[9] There will therefore be many stroke patients who present without a LKN, as the EMS have not identified them as a stroke and have not pursued this line of questioning. Education of Emergency Department nurses as well as physicians will undoubtedly be needed to address this issue.

In an analysis of pre-hospital stroke care, the only factor which has impacted time to treatment has been pre-notification of the receiving hospital by EMS.[10] Interventions such as pre-hospital telestroke, in which stroke-trained physicians are able to remotely interact with patients and/or family to obtain true LKN may be beneficial to optimize the appropriate identification and triage of stroke patients.

Of the 261 patients in this analysis, only 26% of patients had accurate preliminary LKN times (Group B). One speculative reason for this may be that these patients had milder deficits, or deficits not affecting language or inattention and were thus able to accurately report their own time of onset correctly. This hypothesis is being further assessed. Also, if family is relied upon for LKN time, their recollection of the events may change as they review the story again and again. Family members also may not have been available or pursued for questioning of LKN time by first responders. Inaccuracy in LKN times may also arise if symptoms are difficult to characterize as signs of stroke (i.e. mild confusion or headache), such that the exact symptom onset time may even be difficult for the patient to determine.

In this analysis, it was reassuring that there was no difference in stroke code run times between the groups. This indicates that the stroke code process did not slow for patients initially thought to be out of the therapeutic rt-PA window based on the preliminary LKN time. The discrepancy in rt-PA treatment rates among groups is interesting and cannot be accounted for by a difference in stroke code run times. No differences were found among groups in total number of rt-PA contraindications, but the analysis was limited by small patient numbers. It was hypothesized that if patients have no contraindications aside from time of onset, the revised time will be pursued more aggressively to establish an exact minute for LKN and treat if the time is revised to be inside the therapeutic window, whereas if the patient has many other rt-PA contraindications, the questioning may not be as thorough. This brings up another limitation - the use of the neurologist's assessment as the “gold standard” for LKN time. While this is an imperfect measure, there is currently no universally accepted surrogate marker of LKN time, so we rely on diligent history taking by a trained specialist.

Limitations of this study include its retrospective design, and the limited numbers of EMS runsheets available (13%) in the Electronic Medical Record (EMR). These runsheets are usually paper records which may be misplaced and are at times not scanned into the EMR. The authors note this only as a possible limitation since the ED nurses and physicians often record the LKN time in the hospital record based on a verbal report from EMS and do not strictly rely on the actual EMS runsheets. Thus, the numbers seen in this analysis are dependent on the first responder's report (not just the runsheets) and are still applicable to actual clinical practice.

Another limitation may be patients (that might otherwise have been in Group A) that are not in the data set at all because a stroke code was never called. There could be patients whose LKN times were initially estimated to be so far out of the window that a stroke code was never called. These patients would not be captured in our analysis. Future studies, already in process at our institution, could review all patients with a final diagnosis of stroke who were seen in the ED setting, to determine if preliminary overestimations of LKN result in a significant number of patients being excluded from the stroke code process altogether. Study of a larger population would also be helpful to determine if the accuracy of one group of first recorders is particularly different than others, and focus education strategies for this group.

Overall, our analysis shows a concerning discrepancy between preliminary and revised LKN times. This has implications for hospitals without stroke expertise, highlighting a need for training in the proper investigation and refinement of the actual time of symptom onset in stroke code patients. Increased education of EMS and ED personnel is required to improve the accuracy of determination of LKN times, to ensure safe and comprehensive care of stroke patients.

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Table 1

Patient Groups

	Group A	Group B	Group C
Preliminary LKN vs Revised LKN	Preliminary LKN earlier than Revised LKN	Preliminary LKN equal to Revised LKN	Preliminary LKN later than Revised LKN
Difference (minutes) between Preliminary and Revised LKN [median (IQR)]	30 (15-182.75)	0 (0-0)	47.5 (19-252.5)
Potential Treatment Error if Using Preliminary Recorded LKN	undertreat	n/a	overtreat
Number of Overall Patients (%)	42/261 (16.1%)	69/261 (26.4%)	150/261 (57.5%)
Number of Stroke/TIA Patients (%)	29/182 (15.9%)	49/182 (26.9%)	104/182 (57.1%)

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Table 2

Baseline Characteristics - Overall Cohort

Baseline Characteristic	Group A (%)	Group B (%)	Group C (%)	Total (%)	p value
Gender					
Female	20 (47.62%)	31 (44.93%)	63 (42%)	114 (43.68%)	0.7775
Male	22 (52.38%)	38 (55.07%)	87 (58%)	147 (56.32%)	
Total	42 (100%)	69 (100%)	150 (100%)	261 (100%)	
Race					
White	33 (78.57%)	58 (84.06%)	132 (88%)	223 (85.44%)	0.6014
Asian	3 (7.14%)	3 (4.35%)	4 (2.67%)	10 (3.83%)	
Pacific Islander	1 (2.38%)	2 (2.9%)	2 (1.33%)	5 (1.92%)	
Black	5 (11.9%)	6 (8.7%)	12 (8%)	23 (8.81%)	
Native American	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Total	42 (100%)	69 (100%)	150 (100%)	261 (100%)	
Ethnicity					
Not Hispanic	37 (88.1%)	57 (82.61%)	122 (81.33%)	216 (82.76%)	0.6331
Hispanic	5 (11.9%)	12 (17.39%)	28 (18.67%)	45 (17.24%)	
Total	42 (100%)	69 (100%)	150 (100%)	261 (100%)	
Hx of Hypertension					
No/Unknown	14 (33.33%)	20 (28.99%)	48 (32%)	82 (31.42%)	0.8511
Yes	28 (66.67%)	49 (71.01%)	102 (68%)	179 (68.58%)	
Total	42 (100%)	69 (100%)	150 (100%)	261 (100%)	
Hx of Diabetes					
No/Unknown	33 (78.57%)	54 (78.26%)	116 (77.33%)	203 (77.78%)	>0.9999
Yes	9 (21.43%)	15 (21.74%)	34 (22.67%)	58 (22.22%)	
Total	42 (100%)	69 (100%)	150 (100%)	261 (100%)	
Hx of Afibrillation					
No/Unknown	32 (76.19%)	52 (75.36%)	125 (83.33%)	209 (80.08%)	0.2834
Yes	10 (23.81%)	17 (24.64%)	25 (16.67%)	52 (19.92%)	

Baseline Characteristic	Group A (%)	Group B (%)	Group C (%)	Total (%)	p value
Total	42 (100%)	69 (100%)	150 (100%)	261 (100%)	
Prior cerebrovascular disease					
No/Unknown	32 (76.19%)	49 (72.06%)	99 (66%)	180 (69.23%)	0.3931
Yes	10 (23.81%)	19 (27.94%)	51 (34%)	80 (30.77%)	
Total	42 (100%)	68 (100%)	150 (100%)	260 (100%)	
Smoking					
No	35 (83.33%)	49 (71.01%)	95 (63.33%)	179 (68.58%)	0.0387
Previous/Passive/Present	7 (16.67%)	20 (28.99%)	55 (36.67%)	82 (31.42%)	
Total	42 (100%)	69 (100%)	150 (100%)	261 (100%)	
Age [mean(SD)]	62.57 (16.96)	62.41 (14.44)	65.51 (16.51)	64.22 (16.07)	0.3189
Baseline NIHSS [mean(SD)]	6.12 (7.76)	5.57 (6.89)	6.33 (7.77)	6.10 (7.53)	0.7829
Baseline Glucose [mean(SD)]	135.04 (58.05)	135.51 (59.87)	139.10 (83.06)	137.49 (73.62)	0.92

Table 3

Baseline Characteristics - Stroke/TIA patients

Baseline Characteristic	Group A (%)	Group B (%)	Group C (%)	Total (%)	p value
Gender					
Female	13 (44.83%)	21 (42.86%)	42 (40.38%)	76 (41.76%)	0.9139
Male	16 (55.17%)	28 (57.14%)	62 (59.62%)	106 (58.24%)	
Total	29 (100%)	49 (100%)	104 (100%)	182 (100%)	
Race					
White	24 (82.76%)	41 (83.67%)	93 (89.42%)	158 (86.81%)	0.686
Asian	2 (6.9%)	2 (4.08%)	4 (3.85%)	8 (4.4%)	
Pacific Islander	1 (3.45%)	2 (4.08%)	1 (0.96%)	4 (2.2%)	
Black	2 (6.9%)	4 (8.16%)	6 (5.77%)	12 (6.59%)	
Native American	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Total	29 (100%)	49 (100%)	104 (100%)	182 (100%)	
Ethnicity					
Not Hispanic	24 (82.76%)	45 (91.84%)	88 (84.62%)	157 (86.26%)	0.3763
Hispanic	5 (17.24%)	4 (8.16%)	16 (15.38%)	25 (13.74%)	
Total	29 (100%)	49 (100%)	104 (100%)	182 (100%)	
Hx of Hypertension					
No/Unknown	8 (27.59%)	11 (22.45%)	31 (29.81%)	50 (27.47%)	0.6812
Yes	21 (72.41%)	38 (77.55%)	73 (70.19%)	132 (72.53%)	
Total	29 (100%)	49 (100%)	104 (100%)	182 (100%)	
Hx of Diabetes					
No/Unknown	21 (72.41%)	39 (79.59%)	80 (76.92%)	140 (76.92%)	0.7817
Yes	8 (27.59%)	10 (20.41%)	24 (23.08%)	42 (23.08%)	
Total	29 (100%)	49 (100%)	104 (100%)	182 (100%)	
Hx of Afibrillation					
No/Unknown	21 (72.41%)	33 (67.35%)	85 (81.73%)	139 (76.37%)	0.1223
Yes	8 (27.59%)	16 (32.65%)	19 (18.27%)	43 (23.63%)	

Baseline Characteristic	Group A (%)	Group B (%)	Group C (%)	Total (%)	p value
Total	29 (100%)	49 (100%)	104 (100%)	182 (100%)	
Prior cerebrovascular disease					
No/Unknown	21 (72.41%)	33 (68.75%)	67 (64.42%)	121 (66.85%)	0.7047
Yes	8 (27.59%)	15 (31.25%)	37 (35.58%)	60 (33.15%)	
Total	29 (100%)	48 (100%)	104 (100%)	181 (100%)	
Smoking					
No	24 (82.76%)	36 (73.47%)	66 (63.46%)	126 (69.23%)	0.1133
Previous/Passive/Present	5 (17.24%)	13 (26.53%)	38 (36.54%)	56 (30.77%)	
Total	29 (100%)	49 (100%)	104 (100%)	182 (100%)	
Age [mean(SD)]	63.24 (16.29)	66.41 (13.13)	68.64 (15.78)	67.17 (15.24)	0.223
Baseline NIHSS [mean(SD)]	8.10 (8.56)	6.78 (7.61)	7.15 (8.35)	7.20 (8.16)	0.784
Baseline Glucose [mean(SD)]	140.88 (61.58)	134.51 (64.89)	143.66 (90.75)	140.74 (79.97)	0.806

Table 4

Results for Stroke/TIA Patients

	Group A	Group B	Group C	p value
Onset to Stroke Code Activation using revised LKN (Median, minutes)	50	78	86	0.011
Onset to Decision using revised LKN (Median, minutes)	105	135	150	0.016
Stroke Code Activation to Decision (Median, minutes)	44	44	43	0.276
Rate of IV rt-PA administration (%)	17/29 (58.6%)	19/49 (38.8%)	36/104 (34.6%)	0.069
Good functional outcome (%)	10/17 (58.8%)	11/20 (55.0%)	13/33 (39.4%)	0.375
Symptomatic ICH (%)	0/18 (0%)	1/21 (4.8%)	3/38 (7.9%)	0.804