Original research article

Is there a bad time for intravenous thrombolysis? The experience of Polish stroke centers

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ABSTRACT

Background and purpose: The outcome in acute stroke strongly depends on patient-related issues, as well as on the availability of human and diagnostic resources. Our aim was to evaluate safety and effectiveness of intravenous alteplase for stroke according to the time of admission to the hospital.

Materials and methods: We analyzed the data of all acute stroke patients treated with alteplase between October 2003 and December 2010, contributed to the Safe Implementation of Thrombolysis for Stroke registry from 27 Polish stroke centers. According to the time of admission we distinguished between: (1) non-working days (Friday 14:30–Monday 08:00 plus national holidays); (2) out-of-office hours (non-working days plus 14:30–08:00 during working days); and (3) night hours (time from 23:00 to 06:00). Patients admitted during regular working hours (Monday 08:00–Friday 14:30, excluding national holidays) were used as the reference.

Results: Of 1330 patients, 448 (32.5%) were admitted on non-working days, 868 (65.3%) at out-of-office hours, and 105 (7.9%) during night hours. In multivariate logistic regression, none of the evaluated periods showed association with symptomatic intracranial hemorrhage, 7-day mortality, and neurological improvement ≥4 points in the National Institutes of Health Stroke Scale score at day 7. Patients admitted during night hours had lower odds (OR 0.53, 95% CI: 0.29–0.95, p = 0.032) for achieving favorable outcome (modified Rankin Scale score 0–2).

Conclusions: There is no bad time for thrombolysis. Stroke centers should feel confident about the treatment outside regular working hours, irrespective of equipment and staff availability. However, it may be reasonable to pay additional attention during nighttime.

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1. Introduction

Treatment with recombinant tissue plasminogen activator (rtPA, alteplase) within the first 4.5 h from the onset of symptoms is currently the gold standard of stroke care in developed countries [1–3]. Its effectiveness and safety depend not only on patient-related issues, but also on human and diagnostic resources. As the availability of those resources is not equal 24 h a day and 7 days a week (24/7), the time of admission may affect both the quality of care and the final outcome [4,5].

Several studies have described the so-called ‘weekend phenomenon’ [5–12]. Some authors also suggest that patients admitted during out-of-office hours [13,14] or night hours [7,15,16] may achieve less favorable outcome. However, the amount of evidence is still not sufficient, especially regarding treatment with rtPA. In Poland, the weekend phenomenon has been previously addressed only in one study that included unselected ischemic stroke patients, and did not account for thrombolysis [12].

The aim of our study was to evaluate safety and effectiveness of intravenous rtPA for ischemic stroke depending on the time of admission to the hospital, including out-of-office hours, non-working days and night hours. Additional emphasis was put on the treatment logistics.

2. Materials and methods

We analyzed the data of all acute stroke patients treated with intravenous rtPA between October 2003 and December 2010 contributed to the Safe Implementation of Treatments in Stroke – Eastern Europe (SITS-EAST) registry by 27 Polish stroke centers.

SITS-EAST is an international study of implementation of evidence-based stroke therapy supported by the SITS International Registry of Thrombolysis in Stroke (SITS-ISTR). The details of the SITS methodology, rationale for SITS-EAST and Polish participation in the registry have been described in detail elsewhere [17–19]. Briefly, SITS was originally a European Union-based, multinational, academic-driven, monitoring study designed to confirm the safety and effectiveness of thrombolysis in clinical practice [20]. Despite achieving its original aim in 2006, the registry as a platform has been constantly expanding. Currently, it is the largest source of data about licensed thrombolysis for stroke.

The registry in Poland has been approved by the local Ethics Committee. Data for the present analysis were acquired in August 2011 with the approval of the National Coordinator (Prof. Anna Czlonkowska). To ensure completeness of the 3-month follow-up, we decided not to include patients treated in the year 2011.

According to the time of admission, we distinguished between: (1) non-working days – defined as Friday 14:30–Monday 08:00 plus national holidays; (2) out-of-office hours – defined as non-working days plus hours 14:30–08:00 during the working days; and (3) night hours – defined as the time from 23:00 to 06:00.

Our major endpoints were the following: (1) symptomatic intracranial hemorrhage (sICH) according to the ECASS II definition (i.e. any intracranial hemorrhage combined with National Institutes of Health Stroke Scale [NIHSS] score worsening of ≥4 points or leading to death within 7 days); (2) 7-day mortality; (3) significant neurological improvement (i.e. improvement of ≥4 points on the NIHSS or achieving the NIHSS score of 0); (4) favorable outcome at 3-month follow-up (i.e. modified Rankin Scale [mRS] score of 0–2 points, meaning alive and independent) [21]. The ECASS II definition of sICH was chosen because it allows to effectively predict the worst outcome after thrombolysis [22]. As the measures of treatment logistics, we used onset-to-treatment time (OTT), and door-to-needle time (DNT) with special emphasis on DNT ≤60 min.

2.1. Statistical analysis

Categorical variables are presented as a number of valid observations with ratio. Proportions were calculated with exclusion of unknown values from the denominator. Due to non-normal distribution, continuous variables are presented as a median with interquartile range (IQR, representing 50% of average observations surrounding the median).

All analyses were made using regular working hours (Monday 08:00–Friday 14:30, excluding national holidays) as a reference. For basic comparisons, we used χ² test (with Yates correction if the expected value in at least one cell of a 2 × 2 contingency table was <5) or Mann–Whitney U-test. To calculate odds ratios (OR) with 95% confidence interval (95% CI) for each primary endpoint, we used multivariable logistic regression. All regression models were arbitrarily adjusted for age, lack of prestroke disability (mRS score ≤1), baseline NIHSS score, and OTT ≤90 min.

Calculations were carried out in STATISTICA 10.0 (Stat Soft Inc., Tulsa, USA, 2011). We considered a p-value <0.05 statistically significant. In tables, p-values >0.100 are presented as non-significant (NS).

3. Results

In the study period, 1330 cases of intravenous thrombolysis were reported to the registry, including 868 (65.3%) patients admitted at out-of-office hours, 448 (32.5%) admitted on non-working days, and 105 (7.9%) admitted during night hours. The reference group consisted of 462 patients admitted during regular working hours (Fig. 1).

3.1. Out-of-office hours

Patients admitted at out-of-office hours did not differ from the patients admitted during working hours in terms of distribution of vascular risk factors, but more frequently presented with no preexisting disability (92.9% vs. 88.2%, p = 0.004). They had a significantly lower proportion of mild strokes (NIHSS score ≤7) and more frequently showed hyperdense artery sign on the pretreatment brain computed tomography (CT) (Table 1). We found no differences in the median OTT and DNT, but patients admitted at out-of-office hours less frequently received thrombolysis within the first 90 min from the onset of symptoms (7.3% vs. 12.1%, p = 0.003) (Table 1). The occurrence of sICH, neurological worsening and the
distribution of the 3-month mRS scores were similar between the groups (Table 2; Fig. 2). In a multivariate analysis (adjusted for age, lack of pre-stroke disability, baseline NIHSS score and OTT \( \leq 90 \text{ min} \)), the admission out-of-office hours showed no association with major endpoints (Table 3).

3.2. Non-working days

Patients admitted on non-working days had a similar distribution of vascular risk factors compared to patients admitted during regular hours. They more frequently

![Fig. 1 – Groups of patients according to the time of admission. rtPA – recombinant tissue plasminogen activator.](image)

| Table 1 – Baseline characteristics using regular hours admissions as a reference. |
|---------------------------------------------|------------------|------------------|------------------|------------------|------------------|
| Age (years)                                | N    | Value | N    | Value | N    | Value | N    | Value | p     |
| Male gender                                | 462  | 69    | 60  | 76   | 868  | 68    | 59  | 76   | NS    |
| Hypertension                               | 456  | 331   | 72  | 6%   | 855  | 623   | 72  | 9%   | NS    |
| Diabetes                                   | 459  | 80    | 17  | 4%   | 857  | 149   | 17  | 4%   | NS    |
| Hyperlipidaemia                            | 412  | 152   | 36  | 9%   | 797  | 257   | 32  | 3%   | NS    |
| Atrial fibrillation                        | 457  | 145   | 31  | 7%   | 853  | 264   | 31  | 0%   | NS    |
| Congestive heart failure                   | 454  | 83    | 18  | 3%   | 851  | 156   | 18  | 6%   | NS    |
| Prior stroke                               | 460  | 62    | 13  | 5%   | 864  | 106   | 12  | 3%   | NS    |
| No pre-stroke disability                   | 448  | 385   | 88  | 2%   | 835  | 776   | 92  | 9%   | 0.004 |
| Systolic blood pressure (mm Hg)            | 459  | 150   | 138-165 | 863 | 150 | 140-165 | NS  | 447 | 150 | 137-166 | NS |
| Diastolic blood pressure (mm Hg)           | 459  | 85    | 80-90 | 863 | 85  | 80-93   | NS  | 447 | 85  | 80-90   | NS |
| Intravenous antihypertensives              | 445  | 33    | 7.4% | 836 | 59  | 7.1%   | NS  | 430 | 33  | 7.7%   | NS |
| Blood glucose (mg/dl)                      | 443  | 120   | 103-149 | 843 | 121 | 107-142 | NS  | 431 | 122 | 108-145 | NS |

Data are presented as number of observations (ratio) or median (interquartile range).

mRS – modified Rankin Scale, NIHSS – National Institutes of Health Stroke Scale, CT – computed tomography.
Table 2 – Treatment logistics and outcome using regular hours admissions as a reference.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Regular hours</th>
<th>Out-of-office hours</th>
<th>Non-working days</th>
<th>Night hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluated on-time to-treatment</td>
<td>N Value</td>
<td>N Value p</td>
<td>N Value p</td>
<td>N Value p</td>
</tr>
<tr>
<td>time (min)</td>
<td>462 (120-170)</td>
<td>867</td>
<td>NS</td>
<td>448</td>
</tr>
<tr>
<td>- 90 min or less</td>
<td>867</td>
<td>150 (120-170)</td>
<td>NS</td>
<td>148 (120-165)</td>
</tr>
<tr>
<td>Door-to-needle time (min)</td>
<td>462 (54-103)</td>
<td>867</td>
<td>63 (7.3%)</td>
<td>0.003</td>
</tr>
<tr>
<td>- 60 min or less</td>
<td>462 (160-34.6%)</td>
<td>867</td>
<td>72 (55-97)</td>
<td>NS</td>
</tr>
<tr>
<td>siICH according to ECASS II def.</td>
<td>445</td>
<td>24 (5.3%)</td>
<td>847</td>
<td>NS</td>
</tr>
<tr>
<td>Outcome at day 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Improvement ≥4 on NIHSS</td>
<td>445</td>
<td>279 (62.7%)</td>
<td>837</td>
<td>481 (57.5%)</td>
</tr>
<tr>
<td>- Worsening ≥4 on NIHSS</td>
<td>445</td>
<td>53 (11.9%)</td>
<td>837</td>
<td>104 (12.4%)</td>
</tr>
<tr>
<td>- Death</td>
<td>458</td>
<td>34 (7.4%)</td>
<td>837</td>
<td>66 (7.7%)</td>
</tr>
<tr>
<td>Outcome after 3 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Excellent (mRS 0–1)</td>
<td>353 (124)</td>
<td>124 (35.1%)</td>
<td>683</td>
<td>244 (37.5%)</td>
</tr>
<tr>
<td>- Favorable (mRS 2–0)</td>
<td>353 (188)</td>
<td>188 (53.3%)</td>
<td>683</td>
<td>357 (52.3%)</td>
</tr>
<tr>
<td>- Death</td>
<td>355 (63)</td>
<td>63 (17.8%)</td>
<td>685</td>
<td>132 (19.3%)</td>
</tr>
</tbody>
</table>

Data are presented as number of observations (ratio) or median (interquartile range), siICH – symptomatic intracranial hemorrhage, mRS – modified Rankin Scale, ECASS II – the European Cooperative Acute Stroke Study II, NIHSS – National Institutes of Health Stroke Scale.

Fig. 2 – The distribution of modified Rankin Scale (mRS) scores at the 3-month follow-up according to the time of admission.

Table 3 – Odds ratios (OR) for the primary endpoints calculated using multivariate logistic regression.

<table>
<thead>
<tr>
<th>siICH according to ECASS</th>
<th>Death at 7 days</th>
<th>Significant improvement</th>
<th>Favorable outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR (95% CI) p</td>
<td>OR (95% CI) p</td>
<td>OR (95% CI) p</td>
<td>OR (95% CI) p</td>
</tr>
<tr>
<td>Evaluated variables*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Out-of-hours</td>
<td>0.86 (0.50–1.49)</td>
<td>NS</td>
<td>1.08 (0.68–1.71)</td>
</tr>
<tr>
<td>- Non-working days</td>
<td>1.15 (0.64–2.07)</td>
<td>NS</td>
<td>1.30 (0.77–2.17)</td>
</tr>
<tr>
<td>- Night hours</td>
<td>0.71 (0.21–2.48)</td>
<td>NS</td>
<td>1.02 (0.41–2.52)</td>
</tr>
<tr>
<td>Covariables</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No prestroke disability (mRS &lt;1)</td>
<td>0.46 (0.23–0.93)</td>
<td>0.030</td>
<td>1.08 (0.53–2.20)</td>
</tr>
<tr>
<td>- Age (for each 5 years)</td>
<td>1.11 (0.91–1.26)</td>
<td>NS</td>
<td>1.07 (0.96–1.19)</td>
</tr>
<tr>
<td>- Baseline NIHSS (for each 4 points)</td>
<td>1.29 (1.07–1.55)</td>
<td>0.007</td>
<td>1.75 (1.48–2.06)</td>
</tr>
<tr>
<td>- Time to treatment &lt;90 min</td>
<td>0.81 (0.31–2.10)</td>
<td>NS</td>
<td>1.19 (0.59–2.43)</td>
</tr>
</tbody>
</table>

* Each multivariate model included one of the evaluated variables and was adjusted for all four covariables.

presented with no preexisting disability (92.3% vs. 88.2%, \( p = 0.042 \)) and tended to have a lower proportion of mild strokes (Table 1). Despite similar median OTT, they were less frequently treated within the first 90 min from the onset of symptoms (6.7% vs. 12.1%, \( p = 0.003 \)). There were no differences in the occurrence of sICH, neurological worsening and the distribution of the 3-month mRS scores (Table 2; Fig. 2). Patients admitted on non-working days less frequently achieved neurological improvement (55.9% vs. 62.7%, \( p = 0.039 \)), but this association was not confirmed after adjustment for age, lack of prestroke disability, baseline NIHSS score and OTT \( \leq 90 \) min (Table 3).

### 3.3. Night hours

In comparison to the group admitted during regular working hours, patients admitted during nighttime were younger (median 64 vs. 69 years, \( p < 0.001 \)) and less frequently had a history of hypertension (61.5% vs. 72.6%, \( p = 0.026 \)). Despite similar median stroke severity, they had a lower proportion of mild strokes (Table 1). There were no differences in OTT, DNT, the rate of sICH, neurological improvement and mortality (Table 2). However, the proportion of patients with no residual deficit (mRS 0) after 3 months was lower in patients admitted during night hours (6.6% vs. 15.3%, \( p = 0.045 \)) (Fig. 2). The tendency for lower rate of favorable outcome became significant after adjustment for age, lack of prestroke disability, baseline NIHSS score, and OTT \( \leq 90 \) min (OR 0.53, 95% CI: 0.29–0.95) (Tables 2 and 3).

### 4. Discussion

In Poland, intravenous thrombolysis started in October 2003. Since then, many Polish stroke centers have voluntarily joined the SITS registry. Participation in stroke registries is also recommended by the national guidelines [1]. Thrombolysis was initially funded by The National Program for Prevention and Treatment of Cardiovascular Diseases – POLKARD [23]. In 2009, alteplase became reimbursed for stroke by the National Health Fund and the original 3-hour time window was extended to 4.5 h in autumn 2010 [24]. Although the organization of Polish stroke care has been constantly improving [25], the relatively high 3-month mortality rate after thrombolysis [26] reminds that there is still much to be done.

To our knowledge, this is the first nationwide study that uses multivariate methodology and a common reference (i.e. admissions during regular working hours) to simultaneously evaluate the safety, effectiveness and logistics of intravenous thrombolysis for stroke in patients admitted during out-of-office hours, non-working days, and night hours.

Weekend hospital admissions increase the risk of death in both emergency and elective patients [27], including those in intensive care units (ICU) [28]. However, the ICU mortality of nighttime admissions does not seem to exceed the mortality of daytime admissions [28]. In stroke, the time of onset of symptoms shows a circadian pattern with the highest occurrence in the morning, which may partially explain the low proportion of nighttime admissions [29]. A post hoc analysis of the National Institute of Neurological Disorders and Stroke (NINDS) trial showed that the benefit from intravenous thrombolysis did not depend on the time of stroke onset. However, the rate of sICH was the highest in patients who had stroke between 00.00 and 04.00 h [15]. According to our findings, patients admitted at out-of-office hours and on non-working days appear to be very similar to patients admitted during regular working hours, both in terms of baseline characteristic and outcome. The tendency for a lower proportion of mild strokes may correspond with the higher proportion of the hyperdense artery sign, but it does not seem to modify the effect of thrombolysis.

According to a large multicenter study conducted in the USA between 2003 and 2007, stroke patients admitted at out-of-office hours had higher in-hospital mortality, despite only minor differences in the quality of care [13]. Studies comparing thrombolysis administered out-of-office hours and during regular hours agree on the similar baseline characteristics of patients, but provide conflicting results on mortality [14,30].

Stroke patients admitted at weekends are also less likely to receive care in line with the current guidelines [5]. Compared to weekday admissions, their thrombolysis rate tends to be lower [6–8,31,32] and the outcome is either similar [6,7,31,32] or worse [8–11]. In Poland, the weekend phenomenon has been addressed in a large analysis of 19 667 unselected ischemic stroke patients admitted between June 2004 and June 2005 to 78 centers participating in the POLKARD Hospital Stroke Registry [12]. In comparison to weekday admissions, patients admitted at the weekends had increased early mortality and a higher rate of combined early mortality and dependency. Thrombolysis was not addressed in this study, because at that time it was rarely used (<1% of ischemic stroke patients nationwide). However, studies concentrating on patients treated with rTPA show no deleterious effect of the weekend admission on outcome, which is also confirmed by our analysis [7,31].

Strokes occurring during sleep are usually more severe and have worse outcome than other strokes [33,34]. In our material, patients admitted at nighttime were younger, more frequently without preexisting disability, and without hypertension. However, they were less likely to achieve favorable 3-month outcome. Previous studies agree on the younger age [7,16]. It has been also suggested that stroke patients treated with rTPA during night hours have a higher rate of sICH [16] despite fewer vascular risk factors or they are less frequently discharged in a good clinical state [7]. On the whole, it may be advisable to pay more attention to patients admitted at nighttime, but there is no reason to refrain from thrombolysis in eligible cases.

In comparison to patients admitted during regular hours, the proportions of those treated within 90 min from the stroke onset were lower in all evaluated groups. Considering the similar rate of DNT \( \leq 60 \) min, it may be assumed that increased delays were most likely due to prolonged prehospital phase. It concurs with a post hoc analysis of the NINDS trial, showing that patients with the onset of symptoms between 00.00 and 06.00 h are less likely to be treated within 90 min [15]. However, an analysis of the circadian variation of thrombolysis in the SITS-EAST population by Korv et al. [16] demonstrated that both mean OTT and mean DNT were about 10 minutes longer in the nighttime strokes.
4.1. Study limitations

The study is based on data from a voluntary registry of stroke patients treated with rtPA. Therefore, it was not possible to determine the reasons for missing data, to establish the rate of thrombolysis in particular time periods or to identify factors deterring the physician on duty from administering rtPA. We may also not exclude a selection bias. However, the rate of patients admitted between 23.00 and 06.00 h is similar to the rate observed in the NINDS trial [15] and a German stroke registry [7]. To minimize the influence of confounders, we used multivariate logistic regression adjusted for age, lack of prestroke disability, baseline NIHSS score, and OTT <90 min. On the contrary, the registry reflects real life clinical practice of Polish stroke centers.

5. Conclusions

1. There is no such thing as a bad time for intravenous thrombolysis.
2. The safety and effectiveness of thrombolysis seem not to depend on the time of admission and associated disparities in the availability of additional diagnostic equipment and experienced staff. All stroke units in Poland should feel confident about applying the treatment nonstop 24/7.
3. It may be reasonable to pay more attention to patients admitted at nightime.
4. It is necessary to increase the thrombolytic awareness in patients and ambulance staff to shorten the prehospital delays during the non-regular working hours.

Conflict of interest

None declared.

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Ethics

The work described in this article has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans; Uniform Requirements for manuscripts submitted to Biomedical journals.

Appendix

The following centers from the SITS Poland Collaborative Group contributed to this study (name of the hospital and the local coordinator with the number of included patients):

II Klinika Neurologiczna IPiN, Warsaw (A. Kobayashi – 301), SP ZZOOZ in Sandomierz (P. Sobolewski – 162); Szpital Uniwersytecki nr 2, Bydgoszcz (P. Lisewski – 142); Wojewódzki Zespół Neuropsychiatryczny, Opole (S. Romanowicz – 123); Pomorskie Centrum Traumatologii, Gdańsk (W. Fryze – 108); Uniwersyteckie Centrum Kliniczne, Gdańsk (W. Nyka – 69); Szpital Wojewódzki nr 2, Rzeszów (M. Zięba – 63); CSK MSWiA, Warszawa (M. Dorobek – 55); Szpital Wolski, Warszawa (A. Kuczyńska-Zardzewiały – 45); Szpital Specjalistyczny, Końskie (M. Fudała – 43); SP CSK SUM, Katowice (G. Opala – 42); Szpital Specjalistyczny, Pila (M. Wiszniewska – 36); Szpital Powiatowy, Skarżysko-Kamienna (J. Stoński – 35); Wojewódzki Szpital Podkarpacki, Krosno (R. Jucha – 20); Szpital Specjalistyczny, Siedlce (P. Kwiatkowski – 20); Wojewódzki Szpital Zespolony, Konin (H. Krupczyńska – 20); Szpital Kolejowy, Pruszków (J. Pniewski – 15); I Klinika Neurologiczna IPiN, Warszawa (P. Richter – 12); Szpital Wojewódzki, Poznań (J. Michalska – 11); Szpital Specjalistyczny, Kościerzyna (A. Walczak – 9); Uniwersytecki Szpital Kliniczny, Białystok (W. Drozdowski – 9); Szpital Powiatowy, Ostrowiec Świętokrzyski (A. Wesek – 8); SP CSK WUM, Warszawa (ż. Kwiecińska – 7); WIM, Warszawa (J. Stępień – 1); Dolnośląski Szpital Specjalistyczny, Wrocław (K. Gurański – 4); Wojewódzki Specjalistyczny Zespół Opieki Zdrowotnej, Kielce (H. Prędota-Paneczka – 3), Wojewódzki Szpital Specjalistyczny, Olsztyn (A. Tutaj – 1).

References


