Decision-making support using a standardized script and visual decision aid to reduce door-to-needle time in stroke

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The Master's Thesis submitted to the Department of Medicine, the Graduate School of Yonsei University in partial fulfillment of the requirements for the degree of Master of Medical Science

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December 2016

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December 2016

ACKNOWLEDGEMENTS

I would like to express my deep appreciation to my director, Professor Ji Hoe Heo, for his supervision and encouraging suggestions throughout my academic life. Without his advices, this dissertation would not have been possible. I sincerely thank to co-author Professor Hye Yeon Choi for her contribution in this research. I am grateful to Professor Hyo Suk Nam and Professor Young Dae Kim for their precious and constructive advices. I also appreciate professor In Cheol Park for his concerns in this research.

Mostly, I would like to thank my loving family who has been with me and always given me lots of support and love.

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ABSTRACT

Decision-making support using a standardized script and visual decision aid to reduce door-to-needle time in stroke

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Background and Purpose: Rapid administration of intravenous recombinant tissue plasminogen activator (IV tPA) is an effective way to enhance thrombolytic efficacy in stroke patients. The process of decision-making by patients or their families may cause a delay in treatment. We investigated how a protocol using decision-making support (DMS) for patients and their families could reduce door-to-needle time in acute stroke.

Methods: We implemented a DMS protocol using a standardized script and visual decision aid for explanations to patients and their families. Reasons for delay were identified in cases with door-to-needle time >40 min. We compared door-to-needle time and reasons for treatment delay before (January 2007 to December 2009) and after (January 2010 to December 2012) implementation of the DMS protocol.

Results: After the implementation of DMS protocol, median door-to-needle time was reduced from 46 min to 40 min (p=0.001). The proportion of patients with door-to-needle time ≤ 40 min was greater after the implementation (64/118 [54.2%] vs. 40/111 [36.0%], p=0.006). The proportion of cases with delay due to waiting for informed consent was significantly reduced from 32.4 % to 14.8% (p=0.024). Multivariable logistic regression analysis showed that the implementation of the DMS protocol was independently associated with door-to-needle time ≤40 min (adjusted odds ratio 2.13, 95% confidence interval 1.23-3.67).

Conclusion: Decision making support for the patient or family's decision using standardized scripts and visual aids was helpful in reducing door-to-needle time. More widespread implementation of this approach is warranted because it is simple and can be easily implemented.

Key words : stroke, thrombolysis, clinical decision support, time-to-treatment, quality improvement

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I. INTRODUCTION

Shortening the interval between hospital arrival and thrombolytic treatment is critical to improve the efficacy of the treatment because of its time-sensitive effect.[1] Reducing the time from hospital arrival to thrombolytic treatment (door-to-needle time) is the main goal of quality improvement (QI) initiatives for patients with acute stroke. Door-to-needle time is often delayed by many factors because there are several steps from the patient's arrival at the emergency department (ED) to medical evaluation and treatment. Thus, QI initiatives for reducing door-to-needle time have targeted various processes.[2-7]

Decision-making by patients or their families is an essential step during the process of thrombolytic treatment. However, this process may cause delay to treatment.[6, 8] Obtaining informed consent is often necessary and even

obligatory in some countries. In an emergency situation, decision-making by patients or their families relies mostly on the physician's explanation concerning the benefits and risks of thrombolytic treatment. However, the explanations may vary according to the physician, and the explanations of the benefits and harms of the treatment can often be biased by the physician. In this regard, a physician's concise, standardized, and easily understandable explanation of the thrombolytic treatment is important for the process of decision-making and for obtaining informed consent from patients or their family.

Various interventions and QI initiatives for reducing treatment delay have been reported.[4, 5, 7] However, those targeting the decision-making process of patients and their families have not been well-described. Previously, we have shown that a code stroke program using computerized physician order entry and continuous QI (CQI) could successfully reduce door-to-needle time.[2, 3, 6] A visual decision aid that depicts the benefits and risks of thrombolytic treatment has been developed by the University of California Los Angeles stroke center. This may aid patients or their families in making a decision regarding the thrombolytic treatment. This study investigated whether the implementation of a protocol using a standardized script and visual decision aid in addition to an on-going CQI initiative is helpful for the patient's and family's decision-making, thus, further reducing door-to-needle time.

II. MATERIALS AND METHODS

1. Study population

The study was based at a 2000-bed university hospital located in Seoul, Korea. All patients who visited the emergency department (ED) and were treated with IV tissue plasminogen activator (tPA) within the 3-h time window were included in this study. We excluded patients who were transferred from other hospitals along with their imaging scans.

2. Decision-making support using a standardized script and visual decision aid

We have previously shown that a QI initiative using computerized physician order entry could reduce time from ED arrival to evaluation and IV tPA by facilitating rapid and accurate communication between team members.[2, 3] Thereafter, to further improve the existing process, we set two objectives: 1) target door-to-needle time of ≤ 40 min, 2) regular monitoring of the performance with review of reasons for treatment delay in cases with door-to-needle time longer than 40 min.[6] We found that the most common reason for delay in treatment was waiting for informed consent. Therefore, we developed a decision-making support (DMS) protocol using a standardized script and visual decision aid. The standardized script was developed for physicians who are responsible for providing explanations regarding thrombolysis treatment and then obtaining informed consent from patients or their families. The visual decision aid (http://stroke.ucla.edu/workfiles/VDA-for-TPA.pdf) was used by physicians to help explain the benefits and risks of IV tPA treatment to candidates for this treatment. The script and visual decision aid were included in the resident's pocket manual for stroke care so that they were easily available. This protocol was implemented from January 2010.

3. Data collection

The target time from ED arrival to IV tPA was set at ≤ 40 min. The performance of the stroke team was monitored regularly at a weekly stroke conference by reviewing the interval between ED arrival and notification to a neurologist, CT scanning, receipt of complete blood count (CBC) results, and administration of IV tPA. The possible reasons for delay were identified at the weekly stroke team meeting if the door-to-needle time was longer than 40 min. If there were several reasons for delay, the most important cause was selected by consensus.

4. Statistical analysis

The effect of DMS was investigated by comparing the door-to-needle time before (the pre-DMS group, January 2007–December 2009) and after (post-DMS group, January 2010–December 2012) the implementation of the DMS protocol. Data were expressed as a number (%) or median (interquartile range [IQR]). To compare demographic factors and time intervals, the Mann–Whitney U test was used for continuous variables and the chi-square test was used for categorical variables. Linear regression was used to evaluate if there was any trend for door-to-needle time during each period. To determine factors associated with a door-to-needle time >40 min, multivariable logistic regression analysis was performed. Age, sex, and variables with $p<0.1$ in the univariable analyses were entered for multivariable analysis. Statistical significance was set at $p<0.05$. SPSS for Windows (version 17.0, SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

III. Results

1. Baseline characteristics

A total of 2172 and 2078 patients with cerebral infarction were admitted to the neurology department during the 3-year pre-DMS and 3-year post-DMS periods, respectively. Of them, 232 patients were treated with IV tPA. After excluding three patients who were transferred from other hospitals with the results of imaging studies, 229 patients (the pre-DMS group 111 [5.1%], the post-DMS group 118 [5.7%], $p=0.412$) were included in this study. Compared with the pre-DMS group, the prevalence of diabetes mellitus was higher and that of a history of previous cerebral infarction was lower in the post-DMS group. Baseline National Institute of Health Stroke Scale (NIHSS) score was lower in the post-DMS group. Other demographic characteristics were not significantly different between the groups (Table 1).

Table 1. Characteristics of patients treated with intravenous tissue plasminogen activator before and after the implementation of the decision-making support (DMS) protocol

	Pre-DMS group (n=111)	Post-DMS group (n=118)	*P*-value
Age, year	69 [58-77]	69 [62-74]	0.498
Sex, men	67 (60.4)	68 (57.6)	0.674
Hypertension	80 (72.1)	86 (72.9)	0.891
Diabetes mellitus	24 (21.6)	43 (36.4)	0.014
Atrial fibrillation	38 (34.2)	36 (30.5)	0.547
Smoking	24 (21.6)	24 (20.3)	0.812
Dyslipidemia	11 (9.9)	14 (11.9)	0.636
Previous infarction	21 (18.9)	11 (9.3)	0.036
Previous hemorrhage	3 (2.7)	1 (0.8)	0.284
Baseline NIHSS	15 [9-20]	13 [8-17]	0.013

Values are number (%) or median [interquartile range]

NIHSS indicates National Institute of Health stroke scale.

2. Comparison of time intervals between the groups

The median door-to-needle time was significantly reduced after the implementation of the DMS protocol (from 46 min [IQR 38–58] to 40 min [IQR 34–47], p=0.001). The proportion of patients who received IV tPA treatment within 40 min was greater in the post-DMS group (64 /118 [54.2%]) than in the pre-DMS group (40/111 [36.0%], p=0.006). The reduction of door-to-needle time was observed soon after the implementation of the DMS protocol and was sustained for the 3-year follow-up period (R^2=0.003, p=0.549) (Fig. 1.).

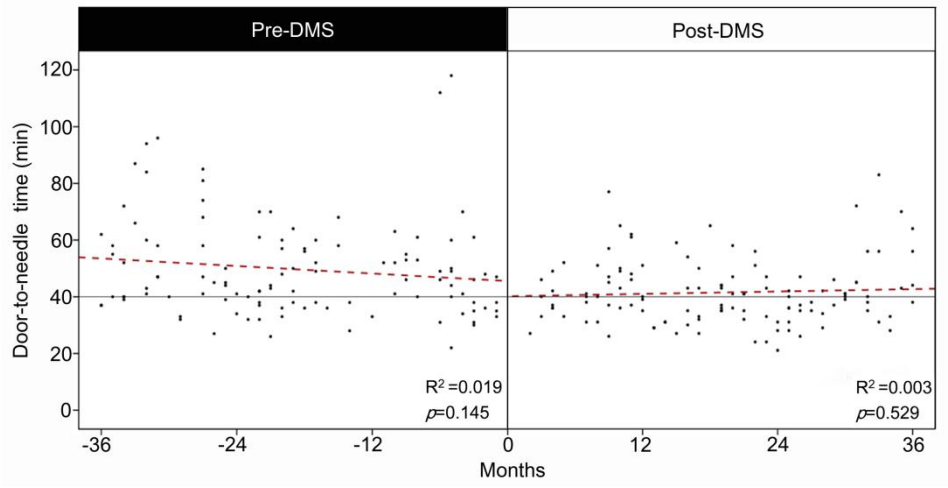

Figure 1. Door-to-needle time for intravenous tissue-type plasminogen activator before and after implementation of decision making support protocol. Door-to-needle time was reduced soon after the implementation of the DMS protocol and maintained for the 3-year follow-up period.

The median time from symptom onset to tPA was also significantly reduced in the post-DMS group (from 103 min [IQR 82-140] to 95 min [IQR 73–124], p=0.04). The door-to-CBC time was shorter in the post-DMS group than in the pre-DMS group (24 min [IQR, 19.75–37] vs. 27 min [IQR, 21–36], p=0.041). Other time intervals were not different between the groups (Table 2).

Table 2. Comparison of the time interval from arrival to various evaluation steps and thrombolytic treatment

Time interval	Pre-DMS group (n=111)	Post-DMS group (n=118)	*P*-value
Door to notification to a neurologist	7 (4-11)	7 (5-10)	0.875
Door to CT	15 (9-20)	15 (9-19)	0.935
Door to CBC	27 (21-36)	24 (20-30)	0.041
Door to needle	46 (38-58)	40 (34-47)	0.001

Data are median (interquartile range) minutes

DMS indicates decision-making support, CT; computed tomography, CBC; complete blood counts

Multivariate analysis showed that the implementation of the DMS protocol was independently associated with a door-to-needle time ≤40 min (adjusted odds ratio 2.13, 95% confidence interval 1.23-3.67), as was dyslipidemia (Table 3).

Table 3. Factors associated with door-to-needle time ≤40 min

	Univariable analysis		Multivariable analysis	
	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Age	0.10 (0.98-1.02)	0.906	1.01 (0.98-1.03)	0.525
Sex	1.22 (0.72-2.07)	0.468	1.31 (0.73-2.34)	0.365
Hypertension	1.51 (0.84-2.73)	0.172		
Diabetes mellitus	1.14 (0.65-2.02)	0.647		
Atrial fibrillation	0.58 (0.33-1.03)	0.062	0.63 (0.35-1.15)	0.134
Dyslipidemia	3.53 (1.41-8.82)	0.007	3.60 (1.39-9.36)	0.009
Smoking	0.92 (0.48-1.74)	0.794		
Previous infarction	0.80 (0.37-1.70)	0.558		
Previous hemorrhage	3.68 (0.38-35.95)	0.262		
Baseline NIHSS	0.99 (0.94-1.03)	0.529		
Group				
Pre-DMS	1		1	
Post-DMS	2.10 (1.24-3.58)	0.006	2.13 (1.23-3.67)	0.007

OR indicates odd ratio, CI; confidence interval, CBC; complete blood counts, NIHSS; National Institute of Health stroke scale, DMS; decision-making support.

3. Reasons for treatment delay

Reasons for treatment delay were identified in patients whose door-to-needle time was >40 min (Table 4). In the pre-DMS group, waiting for informed consent due to the indecision of family members was the most common reason for delay (23/71, 32.4%), followed by various patient-related factors. After the implementation of DMS protocol, the delay due to waiting for informed consent was substantially reduced (8/54, 14.8 %) (p=0.024). No specific reasons were identifiable in 10 patients of the pre-DMS group and 10 patients of the post-DMS group. These patients without identifiable reasons had shorter door-to-needle time than the patients with identifiable reasons (43 min [IQR, 41-47] vs. 53 min [IQR, 46-62], p=0.001).

Table 4. Reasons for door-to-needle time > 40 min

	Pre-DMS group (N=71)	Post-DMS group (N=54)	*P*-value
Waiting for informed consent	23 (32.4)	8 (14.8)	0.024
Incorrect triage	9 (12.7)	5 (9.3)	0.548
CT-related factors	5 (7.0)	2 (3.7)	0.421
CT room occupied by another patient	4 (5.6)	2 (3.7)	0.617
Technical problems	1 (1.4)	0 (0)	0.381
Laboratory-related factors	4 (5.6)	8 (14.8)	0.084
Delayed blood sampling	1 (1.4)	1 (1.9)	0.845
Delayed laboratory results	3 (4.2)	7 (13.0)	0.074
Patient-related factors	18 (25.4)	21 (38.9)	0.106
Need to control high blood pressures	3 (4.2)	5 (9.3)	0.255
Necessity to confirm PT results due to prior warfarin use	7 (9.9)	4 (7.4)	0.632
Initially incorrect witnessing of symptom onset	1 (1.4)	4 (7.4)	0.09
Difficult decision making due to comorbidity	1 (1.4)	1 (1.9)	0.845

Fluctuating neurological deficits	0 (0)	4 (7.4)	0.02
Poor cooperation of patient †	3 (4.2)	1 (1.9)	0.455
Intubation procedure	1 (1.4)	2 (3.7)	0.406
Others	2 (2.8)	0 (0)	0.214
Insufficient knowledge of a new technician on code stroke program	2 (2.8)	0 (0)	0.214
No specific reasons	10 (14.1)	10 (18.5)	0.503

Data are number (%).

DMS indicates decision-making support, CT; computed tomography, ED; emergency department.

† Vomiting during CT scanning or assessment

IV. Discussion

This study demonstrates that door-to-needle time was significantly reduced in the post-DMS group that used a standardized script and visual decision aid for tPA treatment. The proportion of patients who were treated later than the target time (a door-to-needle time of 40 min) was also substantially reduced.

Although many QI initiatives and programs have been implemented to reduce any delay in reperfusion therapy in stroke,[2-6, 9-11] there has been little concern regarding the decision-making process of patients or their family, including obtaining informed consent. We aimed at improving this process because we found that waiting for informed consent due to the indecision of patients or their families could be an important cause of delay in thrombolytic treatment.[6] We interviewed neurology residents who were primarily responsible for obtaining informed consent. We recognized that the script and length of explanations on the benefits and risks of IV tPA differed among residents, and might also be biased. Therefore, we provided standardized scripts for residents containing key messages to explain. This script was helpful for standardizing the explanations, preventing potential bias, and shortening the time taken for providing the explanation and obtaining informed consent.

We also used a visual decision aid that shows how many patients benefitted or experienced adverse consequences when they are treated with IV t-PA within 3 h after symptom onset. Patients and their family often have difficulties in understanding medical terms. Furthermore, they may have difficulty in understanding the benefits and risks of reperfusion treatment despite the physician's explanations. These factors can prevent timely decision-making and obtaining informed consent, which results in treatment delay. The visual decision aid showing the benefits and risks of tPA treatment as a simple cartoon was helpful for our study population, allowing them to better understand the benefits/risks of the treatment and to make an informed decision. Recent pooled analysis revealed that decision aids significantly improved people's knowledge regarding options, and reduced their decisional conflict,[12] which supports our findings.

To reduce delay in thrombolysis treatment, it is necessary to improve many steps including triage, physical and neurologic assessment, brain imaging, laboratory studies, decision of thrombolysis eligibility, and administration of tPA.[4, 9, 13-15] Efficient communication/notification and coordination of a multidisciplinary team are also important.[9, 10] Thus, efforts to improve the process should be multi-directional. While the priority of the process to be improved may be different among hospitals, we have focused on the process of obtaining informed consent, an issue identified during an ongoing CQI initiative. Although the 6-min reduction of door-to-needle time, by improving the patient's or family's decision-making, may not seem very significant, it was achieved by using a simple protocol that could be easily implemented in any hospital setting. In addition, the effect of the standardized script and visual decision aid seems to be immediate and sustainable. In this study, the reduction of door-to-needle time was observed soon after the protocol implementation and was maintained throughout the 3-year follow-up period.

In this study, door-to-needle time was reduced to 40 min after the

implementation of DMS, which is faster than the 60 min specified in the guidelines.[16] Specific reasons were unidentifiable in some patients who were treated rapidly (median 43 min) in the present study. This suggests that slight delay in reaching the target of door-to-needle time of 40 min may occur without a specific fault or reason. However, further reduction of door-to-needle time is necessary and achievable. Patients are currently being treated within 30 min after hospital arrival in some stroke centers.[17-19]

This study has some limitations. Although waiting for informed consent was the most common cause of treatment delay in the pre-DMS group of this study, the reason for treatment delay may vary among different hospitals because their care systems and cultures differ from one another.[8] Therefore, the effects of DMS may be different between hospitals. The visual decision aid that was used in this study was developed for depicting the benefits and risks of IV tPA within 3 h of symptom onset. However, tPA treatment is now approved for use within 4.5 h of symptom onset.[20] In addition, the visual decision aid does not reflect the benefits and risks of endovascular treatment, which is currently recommended in the guidelines following success in recent major trials in acute stroke.[21-25] Therefore, a revised or new version of the visual decision aid should be used in the future.

V. CONCLUSION

Decision making support for the patient or family's decision using a standardized script and visual decision aid was helpful in reducing door-to-needle time. More widespread implementation of this approach is warranted because it is simple and can be easily implemented. In addition, continuous monitoring of performance and efforts to identify reasons in treatment delay are necessary to improve the process for thrombolytic treatment.

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ABSTRACT (IN KOREAN)

급성뇌졸중 혈전용해치료의 병원 내 시간지연을 줄이기 위한 표준 설명문 및 그림 도표의 사용

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김 은 혜

배경: 뇌졸중에서 정맥 내 조직플라스미노겐활성인자의 빠른 투여는 혈전용해 효과를 강화시키는 효과적인 방법이다. 환자와 보호자가 치료에 대한 의사 결정을 내리는 과정이 치료가 지연되는 원인이 될 수 있다. 본 연구는 급성기 뇌졸중 환자에서 환자와 보호자에게 의사결정 지원 프로토콜이 병원 도착부터 혈전용해제 투여까지의 시간을 얼마나 줄일 수 있는지 고찰해 보고자 한다.

방법: 환자와 보호자에게 동의서 취득 시, 표준 설명문과 시각적인 그림 도표를 이용하여 그들이 의사 결정을 내리는 데에 도움을 줄 수 있는 프로토콜을 적용하였다. 병원도착부터 약물 투여까지의 시간이 40분이 초과된 경우에 그 지연 이유를 확인하였다. 프로토콜이 적용되기 전 (2007년 1월부터 2009년 12월까지) 과 후 (2010년 1월부터 2012년 12월까지)의 병원도착부터 약물 투여까지의 시간과 치료 지연 이유를 비교하였다.

결과: 프로토콜 적용 후 병원도착부터 약물 투여까지 평균 시간이

46분에서 40분으로 감소하였다 (p=0.0001). 정맥 내 혈전용해제 투여를 받은 환자 중에 병원도착부터 약물 투여까지의 시간이 40분 이하인 환자의 비율은 적용 후에 크게 증가하였다 (64/118 [54.2%] vs. 40/111 [36.0%], p=0.006). 치료가 지연된 환자 중 환자와 보호자의 늦은 결정으로 인한 경우가 32.4%에서 14.8%로 유의하게 감소하였다(p=0.024). 다변량 로지스틱 회귀분석에서 의사결정 지원 프로토콜이 40분 이하의 병원도착부터 약물 투여까지 시간에 독립적으로 연관되어 있음을 보여 주었다 (adjusted odds ratio 2.13, 95% confidence interval 1.23-3.67).

결론: 환자와 보호자의 결정을 돕기 위해 동의서 취득 시 설명에 사용된 프로토콜은 병원도착부터 약물투여까지의 시간을 줄이는데 도움이 되었다. 이 프로토콜은 단순하고 도입이 쉽기 때문에 좀더 광범위하게 적용할 수 있을 것으로 보인다.

핵심되는 말 : 뇌졸중; 혈전용해; 임상적 결정 도움; 치료까지의 시간; 질향상