

Attitudes and Practices on the Consent Process and Decision-making for Intravenous Stroke Thrombolysis: Physicians' Perspective

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Abstract

Introduction: Earlier treatment with intravenous stroke thrombolysis improves outcomes and lowers risk of bleeding complications. The decision-making and consent process is one of the rate-limiting steps in the duration between hospital arrival and treatment initiation. We aim to describe the attitudes and practices of neurologists in Singapore on the consent and decision-making processes for stroke thrombolysis. **Materials and Methods:** A survey of neurologists and neurologists-in-training in 2 large tertiary public hospitals in Singapore was conducted. **Results:** Among 46 respondents, 94% of them considered stroke thrombolysis an emergency treatment and 67% of them indicated there is a need for written informed consent. The majority (87%) knew that from a legal perspective, the doctor should be the decision-maker in an emergency treatment for a mentally incapacitated patient. However, 63% of respondents reported that it is the next-of-kin who usually makes the decision in actual practice. If confronted with a mentally incapacitated stroke patient, 57% of them were willing to be the proxy decision-maker and 13% of them were not. In 3 commonly encountered vignettes when a mentally incapacitated patient was being considered for stroke thrombolysis, there was no clear consensus on the respondents' practices. **Conclusion:** The next-of-kin is usually the decision-maker for stroke thrombolysis in practice for a mentally incapacitated patient despite most doctors considering thrombolysis an emergency treatment. This, together with the lack of consensus and variance in decision-making and consent practice amongst neurologists for stroke thrombolysis, demonstrates the need to develop best practice guidelines to standardise healthcare practices for greater consistency in health service delivery.

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Introduction

Stroke has serious consequences, and is the leading cause of adult disability worldwide¹ and the fourth most common cause of mortality in Singapore.² Intravenous (IV) stroke thrombolysis with recombinant tissue plasminogen activator (rt-PA) is the only approved acute drug treatment for ischemic stroke.³ When given within 4.5 hours of stroke onset, IV thrombolysis is proven to improve functional outcome and reduce the likelihood of dependency⁴⁻⁷ but it is also associated with an increased risk of bleeding complications including the devastating symptomatic intracerebral hemorrhage (sICH).^{7,8} The earlier stroke thrombolysis is initiated, the greater the likelihood of benefit and the lower the sICH risk. Thus the door-to-needle time, from hospital presentation to initiating thrombolytic treatment, should be minimised. The current guidelines

from the American Stroke Association recommend this to be 60 minutes or less.³

Rate-limiting steps of the door-to-needle time include the decision-making and consent processes.^{9,10} There are unique considerations with stroke thrombolysis. The consequences of stroke may impair a patient's consciousness, cognition and language. The urgency to initiate stroke thrombolysis adds a time pressure to the decision-making and consent process. The decision is made more difficult by the seriousness of potential complications such as sICH that may cause mortality or significant morbidity. In many centres in the United States, Europe and Australia, written consent is not mandated nor a routine part of practice.³ In Singapore, there are currently no guidelines on the consent process for stroke thrombolysis and written consent is usually obtained from

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the patient or their next-of-kin.

We aimed to study the opinions of neurologists and neurologists-in-training in Singapore on the consent process and decision-making for IV stroke thrombolysis, their willingness to be the decision-maker for stroke thrombolysis in cases of mentally incapacitated patients, as well as to determine their attitude and practices in commonly encountered clinical scenarios.

Materials and Methods

We conducted a survey of neurology consultants and registrars at 2 large tertiary public hospitals in Singapore, which manage more than half of all stroke patients in Singapore. All potential participants are involved in IV stroke thrombolysis treatment. Participation was voluntary. We sent an email, containing a soft copy of the survey (Appendix 1), to all potential participants informing them of the survey and inviting them to participate. The survey was self-administered. The survey contained a total of 5 case vignettes where physicians are confronted with an ischaemic stroke patient who fulfilled the eligibility criteria for IV stroke thrombolysis. The last 3 case vignettes replicated scenarios commonly faced by practising neurologists wherein the patient lacks the mental capacity to consent to thrombolysis. These 3 scenarios were designed with just 2 possible answers for the respondents to choose from. The physicians had to choose between prescribing thrombolysis in the patient's best interest, or obtaining consent from the patient's next-of kin. Additionally, we collected basic demographic information such as gender and number of years in neurology practice at registrar level and above. To maintain anonymity of respondents, no identifiers were included on distributed surveys. Participants submitted their completed survey form via email or by hand through a dropbox. The Institutional Review Board for both hospitals advised that ethics approval was not required for this survey. We used descriptive statistics to summarise the findings of the survey and the chi-squared statistical test for comparison between dichotomised categorical variables, using SPSS version 17.0 software.

Results

Of 49 physicians who were contacted to participate in the survey, 46 responded (94% of responder rate). The composition of participants was 59% neurology consultants and 41% neurologist registrars. The median duration of practice in neurology from registrar level and above among the respondents was 7 years (IQR, 2 to 13). The respondents represented 69% of the 67 registered neurologists in Singapore.¹¹

When asked the question whether stroke thrombolysis

was an emergency treatment, an overwhelming majority of 94% of respondents said that it was. A smaller majority of 67% of respondents indicated that written consent for stroke thrombolysis should be obtained from competent patients. To ascertain the stroke patients' mental capacity to consent to thrombolysis, 78% of respondents use the neurological examination only and another 11% of them a combination of methods including neurological examination, minimal state examination (MMSE) and patient's ability to comprehend.

Respondents were then asked whom they thought the decision-maker, under the law, was for a patient who lacks mental capacity (Table 1). In the context of emergency treatment, 48% of respondents selected the option of the doctor and another independent consultant doctor, and 39% of them, the doctor alone. For non-emergency treatment, 54% of them selected the option of doctor and another independent consultant, and 20% of them for the doctor alone. However, when asked who is most often the decision-maker for stroke thrombolysis for a patient who is mentally incapacitated based on their on the ground experiences, 63% of them identified the patient's next-of-kin. When the patient is mentally incapacitated, 57% of respondents expressed a willingness to act as the proxy decision maker (11% "very willing", 46% "willing") for stroke thrombolysis, 28% were ambivalent, 11% of them were unwilling, and 2% of them were very unwilling. This level of willingness did not differ between consultants and registrars ($P = 0.258$).

Respondents were asked what the practice should be in 3 hypothetical scenarios. These are situations commonly encountered by neurologists in which a mentally incapacitated patient is being considered for stroke thrombolysis. In the first scenario where the next-of-kin is not around and may arrive in the next 15 minutes, 57% of them responded that the doctor should make the decision in the patient's best interest and 41% of them would wait

Table 1. Responses on Who Should be the Decision-maker for Stroke Thrombolysis for Mentally-incapacitated Patients from a Legal Standpoint

	Emergency treatment, n (%)	Non-emergency treatment, n (%)	Actual clinical experience, n (%)
Doctor and another concurring independent consultant	22 (48%)	25 (54%)	6 (13%)
Doctor alone	18 (39%)	9 (20%)	8 (17%)
Next of kin	2 (4%)	7 (15%)	29 (63%)
Others (e.g. legal guardian)	4 (9%)	5 (11%)	3 (7%)

for the next-of-kin to arrive to get their consent. In the second scenario where the next-of-kin is present, 67% of them responded that the doctor should make the decision after consulting with the next-of-kin but not asking for their consent, and 33% of them would get written consent from the next-of-kin and withhold thrombolysis treatment if the next-of-kin declines to give consent. In the third scenario where the next-of-kin is present but is unwilling to accept responsibility for consenting to thrombolytic treatment due to its associated risks, 70% of respondents selected that the doctor should make the decision in the patient's best interest and 28% of them chose to accept the next-of-kin's decision and withhold thrombolysis.

Discussion

Our findings show that an overwhelming majority of neurologists perceive IV stroke thrombolysis as an emergency treatment. This demonstrates the neurologists' understanding of the urgency to deliver stroke thrombolysis within the 4.5 hour window period. Two thirds of respondents indicated written consent from mentally competent patients should be obtained for stroke thrombolysis, and this is consistent with what is commonly practised locally. The American Stroke Association Guidelines state that when considering IV rt-PA for stroke, "although a written consent is not necessary, patients and their families should be informed about the potential risks and benefits".³ It is important for doctors to understand that written consent does not offer protection against a medical negligence claim regarding the appropriateness of treatment. The patient's signature on a form consenting to treatment is merely evidence of consent¹² and it does not mean that the doctor has discharged the standard of care simply because the patient signed the consent form.

The majority response was that under the law, doctors should be the decision-maker for emergency treatment for a mentally incapacitated patient. However, 48% of respondents were of the opinion that legally, 2 doctors had to be in agreement with proposed treatment decision making. Although this is a common practice among neurologists in Singapore, it is not a requirement within the legal framework. Under the Singapore Mental Capacity Act, the doctor must ascertain the patient's mental capacity to make the treatment decision at the time it needs to be made.^{13,14} However, if the patient lacks capacity to make decisions relating to life-sustaining treatment or treatment to prevent a serious deterioration, the doctor is the final decision-maker.^{13,14} To determine the patient's best interests, the decision-maker must consider the clinical factors, weighing up the benefits and burdens of treatment; and the holistic factors, which include the patient's past and present wishes, their culture and religious beliefs, and the views of relatives and carers.^{13,14}

Many respondents expressed the opinion that the next-of-kin is usually the decision-maker for mentally incapacitated patients regarding stroke thrombolysis treatment, a practice that is inconsistent with the Mental Capacity Act.^{13,14} The basis for the next-of-kin taking on the role of the decision-maker is likely related to the culture of strong family influences in Singapore. The contradiction posed by the fact that 67% of respondents are of the opinion that doctors should make the decision after consulting with the next-of-kin but not asking for their consent is a conundrum that should be addressed by medical and legal groups. Whilst it is good clinical practice to involve the next-of-kin and inform them of the proposed treatment plan when the patient lacks capacity to make treatment decisions, the next-of-kin has no authority to give consent or decline treatment on behalf of the patient.¹⁵ A probable misconception is that securing the next-of-kin's consent may offer doctors some medico-legal protection. However, doctors should not be deterred from administering potentially beneficial therapy which in their opinion is in the patient's best interests, in accordance with the Mental Capacity Act.^{13,14} The law normally requires the physician to obtain consent from a patient before commencing care or treatment. If consent is not obtained, the patient may sue the physician for battery. The Mental Capacity Act protects physicians from such an action where they care or treat for patients who lack capacity to make those care or treatment decisions.^{13,14} To qualify for such protection, the physician must take reasonable steps to determine whether the patient lacks capacity on the specific matter in question, before carrying out the care or treatment, and reasonably believe the patient lacks capacity in relation to the matter, and that it is in the patient's best interests to carry out that care or treatment. The Mental Capacity Act does not explicitly confer medico-legal protection to physicians making emergency treatment decisions on behalf of the mentally incapacitated patient, and no Singapore case has yet ruled out this particular matter. Doctors should be cognisant that carrying out the next-of-kin's wishes may not always be in the patient's best interests. It is notable that the majority of medicolegal malpractice lawsuits relating to IV stroke thrombolysis are for the failure to treat.^{16,17} Of note, there have been no lawsuits in relation to IV stroke thrombolysis in Singapore.

There was a relatively high prevalence (57%) of willingness to be a proxy decision-maker for a mentally incapacitated patient with only 13% of respondents being unwilling to do so. This result, together with the majority's perception of IV stroke thrombolysis as an emergency treatment, reflects a positive attitude towards utilisation of IV thrombolysis. This is important as a negative attitude has been shown to undermine the use of IV thrombolysis treatment where it is appropriate or indicated.¹⁰ There is a

paucity of data on clinicians' opinions and attitudes on stroke thrombolysis decision-making. We found that seniority did not influence willingness to be a proxy decision-maker for thrombolysis. In the only published paper on the influence of prior experience on utilisation of stroke thrombolysis, albeit among emergency medicine physicians rather than neurologists as is our survey, those who had less experience with IV stroke thrombolysis were less willing to initiate it.¹⁸ The possible reasons for our findings are that our junior physicians have considerable experience with thrombolysis due to the high patient volume, and that thrombolysis decision-making by registrars is usually in concurrence with a consultant.

The responses to the hypothetical clinical scenarios concerning a stroke patient who is mentally incapacitated were varied and demonstrated a lack of consensus amongst practicing Singapore neurologists. In the scenario of the next-of-kin arriving in 15 minutes, 41% of them responded that the practice should be to delay initiating thrombolytic treatment although this would potentially reduce the likelihood of benefit and increase the risk of complications.^{7,8} Furthermore, waiting for the next-of-kin's arrival may result in the patient being out of the time window for thrombolysis. However, if the waiting is only for a very short period, that may be the appropriate approach because the physician may be able to better glean the patient's best interest, thus making a holistic decision. Nonetheless, this must be weighed against the necessity of acting quickly to increase the chances of successful thrombolysis treatment. In the other 2 scenarios, 33% of them stated the practice should be to withhold thrombolysis if the next-of-kin declines treatment and 28% of them would withhold treatment if the next-of-kin was not willing to accept responsibility. Neither of these practices are supported under Singapore law. These results highlight a dissonance between the doctor's knowledge and attitude about stroke thrombolysis and their practice. The practice of the next-of-kin giving consent for mentally incapacitated patients may be culturally expected and acceptable in Asian societies such as Singapore. However, doctors should adhere to local ethical and legal standards¹⁹ on autonomy, best interest and surrogate decision-making as codified in the Singapore Mental Capacity Act.^{13,14} In addition, they should also bear in mind that the choice of the patient may be discordant with the choice of the next-of-kin, which has been reported in previous consent studies.²⁰

The findings of this survey demonstrate a lack of consensus and variance in actual practice amongst practicing Singapore neurologists on the decision-making and consent processes for stroke thrombolysis treatment. It would therefore be helpful to develop a consensus statement and best practice guidelines to standardise acute stroke thrombolysis clinical decision-making and reduce door-to-needle time. These

guidelines should be consistent with the Mental Capacity Act, thus informing patients, their next-of-kin and doctors of their rights and obligations under the law. The opinions of neurologists as determined in this survey, and the perspectives of stroke patients and their next-of-kin, which is being studied in an ongoing research project, should be reviewed when developing these guidelines.

The strengths of the study are the very high response rate among those approached (94%) and the respondents representing the majority (69%) of registered neurologists in Singapore. However our survey was limited to neurologists at 2 public hospitals and did not include those in other public hospitals or private practice. In view of the specific context with regards to the legal framework, local clinical practice and cultural attitudes, the findings of this study pertain to Singapore and its generalisability is limited. Other limitations include the paucity of contextual detail in the survey including no specific definition of next-of-kin and the use of provided options for responses.

This is the first survey on the consent and decision-making processes regarding stroke treatment in Singapore. There are likely cultural and country biases on consent and decision-making for medical treatments and thus our findings are relevant and specific for Singapore.

Conclusion

Neurologists in Singapore consider IV stroke thrombolysis an emergency treatment. The view of the majority of neurologists surveyed that they should be the decision-makers for a mentally incapacitated patient is supported by the law. Most are also willing to act as proxy decision-makers. These views are consistent with the law but at odds with the practice on the ground of the next-of-kin often being the substituted decision-maker. There is a lack of consensus on the appropriate practice in commonly encountered situations regarding IV stroke thrombolysis for mentally incapacitated patients. These findings suggest the need to develop protocols and guidelines that are aligned with the law and the perspectives of doctors, patients and their families, in order to better standardise acute stroke care.

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Appendix 1. Physician Survey form

☐
SC

This is a survey questionnaire examining the attitudes and perceptions on the informed consent process and decision-making on intravenous stroke thrombolysis (IV TPA). Please put a check (☑) in the box that best represents your answer. This project has been approved by the Singhealth IRB. All of your answers will be kept confidential.

Gender: ☐ 1) Male ☐ 2) Female

☐
Sex

What is your position? ☐ 1) Registrar ☐ 2) Associate Consultant
 ☐ 3) Consultant ☐ 4) Senior Consultant

☐
Pos

How many years have you practiced neurology (at registrar level or above)? _____

☐
Yrs

Would you consider IV stroke thrombolysis (TPA) an emergency treatment?

☐ 1) Yes ☐ 2) No

☐ 3) It depends: _____

☐
TPA

Based on your knowledge, from the legal standpoint, who should be the decision-maker regarding *emergency* treatment when a patient is mentally incapacitated?

☐ 1) Next of kin ☐ 2) Doctor and another concurring independent consultant
☐ 3) Doctor ☐ 4) Others: _____

☐
Leg1

Based on your knowledge, from the legal standpoint, who should be the decision-maker regarding *non-emergency* treatment when a patient is mentally incapacitated?

☐ 1) Next of kin ☐ 2) Doctor and another concurring independent consultant
☐ 3) Doctor ☐ 4) Others: _____

☐
Leg2

Based on your experience on the ground, who is most often the decision-maker regarding stroke thrombolysis when a patient is mentally incapacitated?

☐ 1) Next of kin ☐ 2) Doctor and another concurring independent consultant
☐ 3) Doctor ☐ 4) Others: _____

☐
Leg3

Please read the vignettes then answer the following questions.

You are managing an ischemic stroke patient who fulfills the eligibility criteria for IV TPA as per your hospital protocol.

Scenario 1: The patient is mentally competent. You have explained the risks and benefits of IV TPA and have let the patient read through the Patient Information Sheet. The patient is competent and agrees to receive the treatment.

☐
S1

Do you think written informed consent should be practiced for IV stroke thrombolysis?

- ☐ 1) Yes ☐ 2) No

Reasons: _____

Scenario 2: The patient is mentally incompetent due to the neurological deficits of stroke. The next of kin is not around.

For stroke patients with borderline capacity being considered for thrombolysis, how do you usually ascertain and decide on capacity to give consent?

☐

S2a

- ☐ 1) Neurological examination ☐ 2) Mini-mental state examination (MMSE)
☐ 3) Psychiatrist opinion ☐ 4) Others: _____

How willing are you to act as proxy decision-maker?

- ☐ 1) Very willing ☐ 2) Willing ☐ 3) Neither willing nor unwilling
☐ 4) Unwilling ☐ 5) Very unwilling

☐

S2b

Reasons: _____

Scenario 3: The patient is mentally incompetent due to the neurological deficits of stroke. Everything is ready for the drug to be administered. The next of kin is not around but you are told they may arrive in the next 15 minutes. What would you do?
☐

S3

- ☐ 1) Make the decision and administer the drug in the best interests of the patient (getting 2 consultants to sign if this is hospital protocol)
☐ 2) Wait for the next of kin to arrive and get their consent

Scenario 4: The patient is mentally incompetent due to the neurological deficits of stroke. The next of kin is present. What do you think should be the practice?
☐

S4

- ☐ 1) Doctor makes the decision in the best interest of the patient (getting 2 consultants to sign if this is hospital protocol). Next of kin is consulted but is not asked for their consent.
☐ 2) Next of kin signs the informed consent form and treatment is given. If the next of kin does not give consent, you withhold treatment.

Scenario 5: The next of kin is unwilling to accept the responsibility of consenting for the treatment due to the associated risks. There are no contraindications for IV thrombolysis. There is no indication that the patient would not want this treatment. What do you think should be the practice?
☐

S5

- ☐ 1) Doctor decides in the best interests of the patient to provide treatment
☐ 2) Accept the next of kin's decision and withhold treatment

Thank you for participating in this survey. If you have any comments you wish to add about any of the questions or vignettes, please share them with us:
