

PEDAGOGICAL TOOLS AND METHODS

The outcome wheel: a potential tool for shared decision-making in ischemic stroke thrombolysis

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ABSTRACT

A stroke can be a catastrophic experience. Patients are confronted with alarming symptoms and then a devastating diagnosis, after which they are expected to make an “informed decision” regarding intervention. Informed decision-making is a term that, unlike informed consent, implies that the decision is made by the physician, the patient and the family based on available evidence and information. The 3-hour treatment window for thrombolysis in ischemic stroke imparts very little time for a clinician to sit down with a patient and present information in an unbiased, useful manner. The purpose of this paper is to offer a tool that may assist the physician, the patient and the family in making an informed decision in a time-sensitive manner for thrombolytic intervention in stroke. This tool visually displays outcomes and the role of chance in an intuitive “spin the wheel” type fashion. Until at least May 2011, an interactive version of this clinical tool kit will be available for download at www.sem-bc.com/cvatoolkit.

Keywords: stroke thrombolysis, informed decision, shared decision-making, risk/benefit, decision tool

RÉSUMÉ

Un accident vasculaire cérébral (AVC) peut être une expérience catastrophique. Les patients éprouvent des symptômes alarmants, puis reçoivent un diagnostic dévastateur. On s’attend ensuite à ce qu’ils prennent une « décision éclairée » concernant l’intervention. La décision éclairée est un terme qui, contrairement au « consentement éclairé », suppose que la décision a été prise à la fois par le médecin, le patient et sa famille d’après les preuves et l’information disponibles. La fenêtre de trois heures avant la thrombolyse en cas d’accident ischémique cérébral offre très peu de temps au clinicien pour s’asseoir avec un patient et lui présenter l’information de façon impartiale et utile. Cet article vise à offrir un outil qui pourrait aider le médecin, le patient et la famille à prendre une décision éclairée dans un court délai concernant un traitement thrombolytique en cas d’AVC. Cet outil affiche les résultats et les probabilités, de manière intuitive, comme un jeu de roulette. Au moins jusqu’en mai 2011, on peut télécharger une version interactive de cet outil clinique à partir du site www.sem-bc.com/cvatoolkit.

Introduction

Patients having a stroke are confronted with alarming symptoms and then a devastating diagnosis, after which they are expected to make an “informed decision” regard-

ing intervention. Patients and their families are often verbally presented with an array of numbers and expressions such as “risks,” “benefits,” “adverse outcome,” “odds ratio” and other such terms, which are typically not well understood by the general population.

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Unlike thrombolysis for acute ST-segment elevation myocardial infarction, the benefit of thrombolytic therapy in stroke remains controversial.¹⁻⁴ Presentation of risk and benefit to a patient may be coloured according to the presenting clinician's bias.^{5,6} The resulting perception of the treatment by a patient is influenced by how the information is presented.⁷

In addition to reports in the scientific literature, the public news media has reported extensively on thrombolysis for stroke. Patients may have heard or read about dramatic and miraculous cures of severe stroke presentations in the media. Such reports can impact a patient's expectations regarding thrombolysis despite what the actual evidence demonstrates.

Informed decision-making is a term that, unlike informed consent, implies that a decision has been made by the physician, the patient and the family based on available evidence and information. The 3-hour treatment window for thrombolysis in ischemic stroke imparts very little time for a clinician to sit down with a patient and present information in an unbiased, useful manner. The purpose of this paper is to offer a tool that may assist the physician, the patient and the family in making an informed decision in a time-sensitive manner for thrombolytic intervention in stroke.

Thrombolysis for ischemic stroke

In 1995, the National Institute of Neurological Disorders and Stroke (NINDS) Stroke Study Group performed a randomized, double-blind, placebo-controlled trial on the administration of recombinant tissue plasminogen activator (rt-PA) in acute ischemic stroke within 3 hours of symptom onset.⁸ There were very rigorous inclusion and exclusion criteria. Patients who were treated with (tissue plasminogen activator) t-PA were at least 30% more likely to have minimal or no disability at 3 months when compared with the placebo group.

A subsequent reanalysis of data from the original NINDS study suggested that the benefits of thrombolysis varied depending on the initial clinical presentation.⁹ Patients who had mild strokes were more likely to be harmed by thrombolysis and those with somewhat more severe symptoms showed the greatest benefit. Patients with severe strokes had some benefit, but did poorly overall. In both the original NINDS study and the reanalysis, patients who died or had more than minimal disability were grouped together.

Intracranial hemorrhage is the most serious complication of thrombolysis, and because of the potential harm to the patient, many physicians are hesitant to offer this treatment.¹⁰

In the NINDS study, when strict inclusion and exclusion criteria were used, the rate of intracranial hemorrhage was 6%. A Cleveland-area study of stroke patients who were managed outside the setting of a rigorous study demonstrated a rate of protocol violation of 50% and a symptomatic intracranial hemorrhage rate of 16%.¹¹

Studies have identified the following risk factors for intracranial hemorrhage: baseline National Institutes of Health Stroke Scale (NIHSS) score greater than 20, serum glucose greater than 16.7 mmol/L, blood pressure greater than 185/110 mm Hg, and edema or mass effect on the initial computed tomography (CT) scan.^{8,9,12,13} Unfortunately, no study has stratified the risk of intracranial hemorrhage by initial clinical presentation, although some have demonstrated an increased rate of intracranial hemorrhage with the most severe strokes. As a result, it is difficult to accurately predict the risk of intracranial hemorrhage for a given patient.

Clinical tool kit

Canadian stroke guidelines have been established that take into account those patients who are most likely to benefit, or most likely to be harmed, by thrombolysis.¹⁴ Protocols have strict exclusion criteria based on existing studies. Patients are ineligible for thrombolysis if they

- present with high blood pressure;
- present with an NIHSS score of less than 5 or greater than 20;
- present with CT mass effect;
- present with hyperglycemia;
- are on anticoagulants;
- have a history of recent stroke;
- have had symptoms for longer than 3 hours; or
- have risk of internal hemorrhage (e.g., recent gastrointestinal bleed, recent surgery, aneurism).

As teleradiology becomes widespread, CT scan interpretation and off-site neurologist consultation are becoming increasingly available in community hospitals. In smaller communities with CT imaging, it is often possible for patients to present to the hospital within minutes of their stroke symptoms and for CT and clinical assessment to be performed in a very timely manner. There is tremendous public pressure for every patient presenting early with a stroke to be considered for thrombolysis. It is imperative, therefore, that systems be in place for the appropriate clinical assessment and the presentation of treatment options to patients who present within the 3-hour window.

This proposed tool kit for stroke assessment and management includes an easily followed NIHSS assessment and the ability to document the clinical exam, exclusion and inclusion criteria. The tool kit then generates a visual pre-

sentation of the risks and benefits of thrombolysis that is easily interpreted by both patients and clinicians to allow for rapid, informed decision-making.

Figure 1 illustrates the computer-based clinical assessment form, which automatically calculates the NIHSS score and determines patient eligibility based on exclusion and inclu-

Visual Aid for Informed Consent: Thrombolysis in Acute Ischaemic Stroke

Note: This toolkit is based on 1998 Canadian Stroke Consortium Consensus Statement and data from the NINDS trials. It does not include information from subsequent studies. This toolkit has not been validated and is not intended to replace clinical judgement.

NIHSS Score:

<p>Level of Consciousness: <input type="text" value="0 Alert"/></p> <p>Response to questions: <input type="text" value="0 Answers both correctly"/></p> <p>Response to commands: <input type="text" value="0 Performs both tasks correctly"/></p> <p>Best gaze: <input type="text" value="0 Normal"/></p> <p>Visual: <input type="text" value="0 No visual loss"/></p> <p>Best Language: <input type="text" value="0 Normal"/></p> <p>Dysarthria: <input type="text" value="0 Normal"/></p> <p>Sensory: <input type="text" value="0 Normal"/></p> <p>Extinction and Inattention: <input type="text" value="0 No abnormality"/></p> <p>Inclusion Criteria</p> <p>Exact time of Sx onset: <input type="text" value="known"/></p> <p>Time from Sx < 180 min: <input type="text" value="yes"/></p> <p>CT negative for bleed/mass: <input type="text" value="yes"/></p>	<p>Facial Palsy: <input type="text" value="0 Normal symmetrical movement"/></p> <p>Motor arm: right: <input type="text" value="0 No drift"/></p> <p>Motor arm: left: <input type="text" value="0 No drift"/></p> <p>Motor leg: right: <input type="text" value="0 No drift"/></p> <p>Motor leg: left: <input type="text" value="2 Some effort against gravity"/></p> <p>Limb Ataxia: <input type="text" value="0 Absent"/></p> <p>TOTAL NIHSS SCORE (National Institute of Health Stroke Score) 9</p> <p>Must be >5 and <20 to meet criteria to proceed</p> <p>Exclusion Criteria</p> <p>Major surgery <1 month: <input type="text" value="no"/></p> <p>Symptoms rapidly resolving: <input type="text" value="no"/></p> <p>Stroke, head injury <3 months: <input type="text" value="no"/></p> <p>Thrombolysis: <input type="text" value="no"/></p> <p>Anticoagulated/thrombocytopenia: <input type="text" value="no"/></p> <p>BP>185/110: <input type="text" value="no"/></p> <p>Blood glucose <2.7 or >22 mmol/L: <input type="text" value="no"/></p> <p>AMI within 3 weeks: <input type="text" value="no"/></p> <p>Aortic dissection or pericarditis: <input type="text" value="no"/></p> <p>Post-ictal state: <input type="text" value="no"/></p>
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Meets criteria to proceed? NO To Outcome Wheels

Fig. 1. Computer-based form for determining eligibility for thrombolysis. National Institutes of Health Stroke Scale (NIHSS) scores and patient eligibility are automatically calculated according to NIHSS score, and inclusion and exclusion criteria are based on recommendations by the 1998 Canadian Stroke Consortium.¹⁴ AMI = acute myocardial infarction, BP = blood pressure, CT = computed tomography, NINDS = National Institute of Neurological Disorders and Stroke.

sion criteria. Criteria are based on the Canadian Guidelines for Intravenous Thrombolytic Treatment in Acute Stroke.¹⁴ Completed forms may be subsequently audited to assess the numbers of patients presenting with stroke, proportion eligible for thrombolysis and proportion of protocol violations. This form may be adapted for paper-based use.

Patient–clinician shared decision-making

Once a patient is deemed to be a potential candidate for thrombolysis, the next step is to present the risks and benefits of thrombolysis to the patient and family for an informed decision. This must be done expeditiously. Although computer-based calculators exist that calculate the risk and benefit of thrombolysis,¹⁵ the manner in which such information is presented is not always easily understood by patients. Members of the general public are unlikely to easily understand terms such as “number needed to harm or treat,” “probability,” or “odds ratio.” A layperson may have difficulty understanding concepts such as a “30% risk reduction” or what a “25% risk of disability” means in terms of his or her real functional ability. Moreover, clinicians have been found to be reluctant to offer thrombolytics, even when patients qualify for treatment.¹⁰

Studies have demonstrated that patients can better understand information that is visually presented.^{16,17} Hoffman and colleagues,¹⁸ in an article entitled “The roulette wheel: an aid to informed decision making,” created a useful visual tool that would allow the patient to conceptualize the risks and benefits of a given intervention. They used a dartboard or roulette wheel with different patient outcomes covering different percentages of the board or wheel. The authors felt that conventional pie charts or graphs for 2 distinct treatment strategies presented side by side did not allow patients to understand the random nature of their individual outcomes. On a pie chart with an 80% good outcome, for example, the patient may expect that he or she falls into that 80% rather than the 20% with a bad outcome (or vice versa).

The aforementioned pie charts, however, can also be presented as “wheels of fortune,” with which the patient may choose the preferred “outcome wheel” that the clinician will give a “good, strong spin.” In this manner, the concept of chance is kept in the discussion, potentially leading to more informed decision-making.

When presented with information in this visual manner, and with the clinician aiding in the understanding of the information, patients see that there is a difference in the treatment and nontreatment arms, and that the treatment only increases the chance of a better outcome but does not guarantee it.

It is important to note on the graph that the “death or dis-

ability” outcome represents a gradient of disability and dependency from moderate to severe, dependent on the patient’s initial clinical presentation. Unfortunately, the NINDS study grouped death and any disability that was classified more than “minimal” (Barthel Index < 90) into 1 group. Because of this, it is impossible to predict where a patient may lie within this range. Death is represented in black, and varying degrees of disability are represented by varying shades of grey. The NINDS study did not distinguish between symptomatic and asymptomatic intracranial hemorrhage. In the intracranial hemorrhage partition, there is also a gradient representing death and disability. The probability of death in patients with symptomatic intracranial hemorrhage may be as high as 75%.¹²

Variations in the probability of disability and death can have differing impacts on a patient’s decision-making depending on the individual’s experience, personal viewpoints and clinical presentation. If the patient believes that the risk of immediate death is of greater importance than reducing the chance of long-term disability, then that patient’s choice may be different from that of a patient who places utmost importance on decreasing their risk of dependency. It is important to emphasize that “no thrombolysis” does not mean “no treatment” and that referral to an appropriate stroke or rehabilitation unit will occur regardless of whether the patient receives thrombolysis.

Examples of outcome wheels for stroke and thrombolysis

Example 1: A previously healthy 68-year-old man arrives within 45 minutes of stroke onset. He has dysphasia and dysarthria, is anxious and perseverating, and has no motor or sensory findings. His NIHSS score is calculated to be 5. His wife arrives with the patient and is aware that “clot busters” exist to reverse early strokes. The patient and his wife are presented with the outcome wheels shown in Figure 2. The clinician explains to them that the outcome wheels represent the chances of a given outcome. They can clearly see that the patient would not benefit from thrombolysis and has a very good chance of full recovery without this therapy.

Example 2: A 70-year-old woman is brought by her daughter directly to the emergency department 20 minutes after symptom onset. The patient has dysphasia, mild dysarthria, comprehension problems and right-sided motor and sensory findings. Her NIHSS score is 10. She has no exclusion criteria and meets all inclusion criteria for thrombolysis. The patient and her daughter are presented with the outcome wheels shown in Figure 3.

These outcome wheels allow the clinician, patient and

family to appreciate that the overall chance of a good outcome is better with thrombolysis, although the treatment does carry significant risk. Even if the patient and family expect a good outcome from the thrombolytic therapy, it is important for the clinician to emphasize that the ultimate outcome is subject to chance.

What if we hypothetically change the scenario to a 43-year-old single parent of 3 children aged 3–12 years, who presents with stroke symptoms on her nondominant side and an NIHSS score of 6. Would she accept the possible 4%–6% risk of leaving her children orphans? We do not know, but with the outcome wheel, perhaps the patient will

feel more comfortable with the appropriateness of her decision, regardless of the clinician’s beliefs.

As stroke severity scores increase, it is apparent that the outcome differences between thrombolytic therapy and conventional therapy become smaller and the chance of a good recovery drops. A patient’s decision could be affected by his or her beliefs regarding death and dying, infirmity and dependence. The outcome wheels may assist in bringing a patient’s expectations of thrombolysis into a more realistic light.

Example 3: A 65-year-old man is brought to hospital by ambulance 70 minutes after the sudden onset of a left-

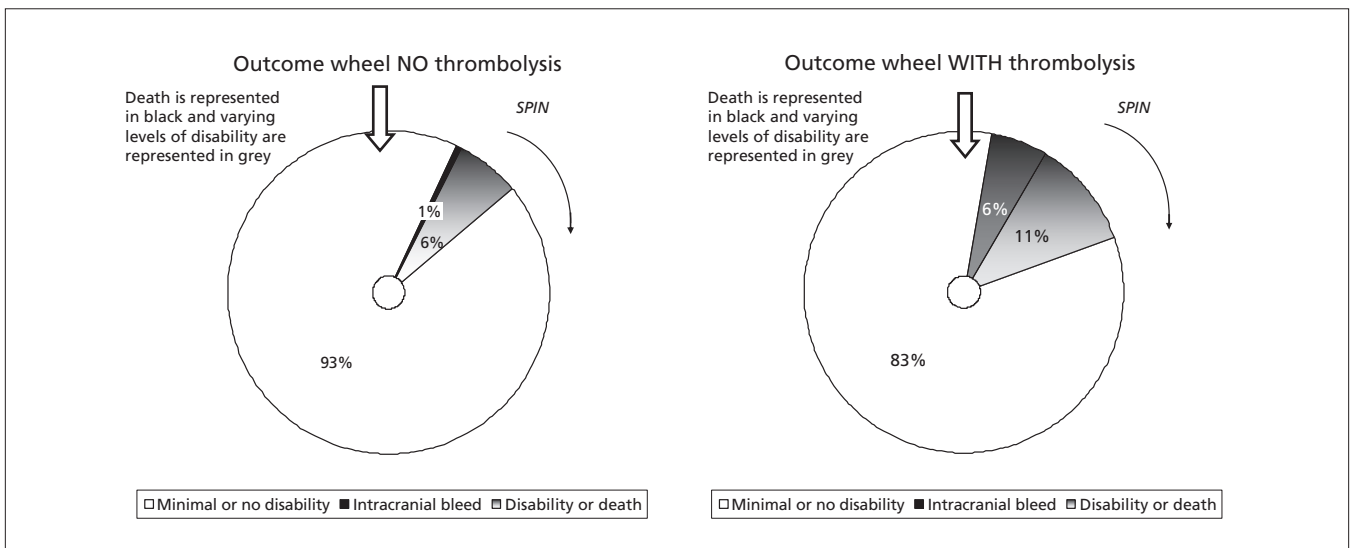


Fig. 2. Outcome wheels for National Institutes of Health Stroke Scale score of 1–5. Minimal or no disability is defined as a Barthel Index of greater than 90. Results are based on findings from the reanalysis of the National Institute of Neurological Disorders and Stroke tissue plasminogen activator for acute ischemic stroke treatment trial.⁹

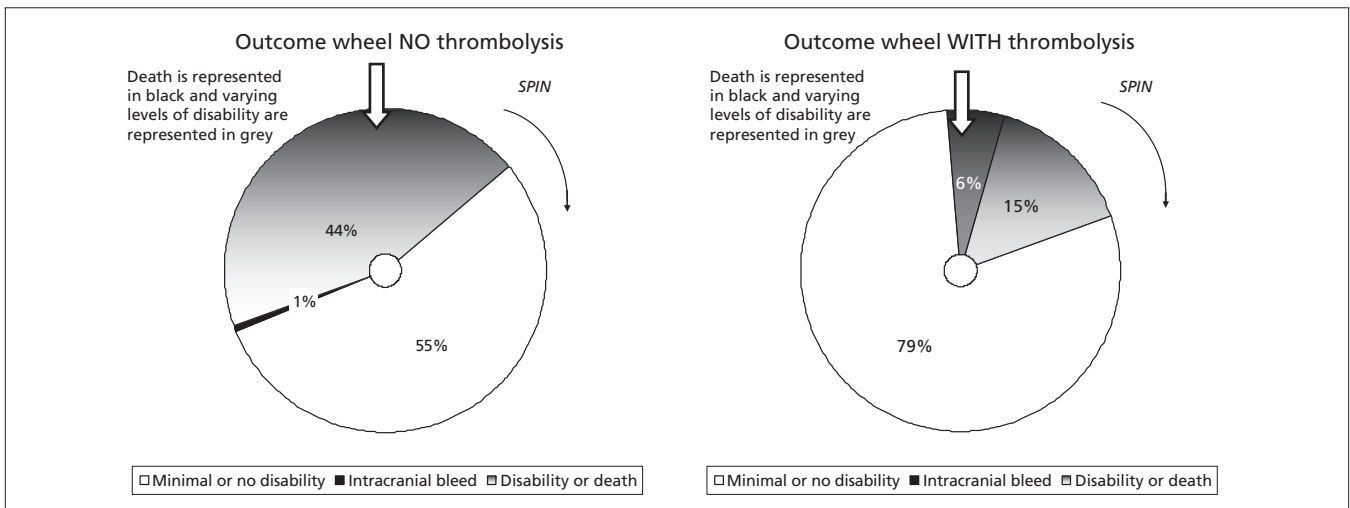


Fig. 3. Outcome wheels for National Institutes of Health Stroke Scale score 6–10. Minimal or no disability is defined as a Barthel Index of greater than 90. Results are based on findings from the reanalysis of the National Institute of Neurological Disorders and Stroke tissue plasminogen activator for acute ischemic stroke treatment trial.⁹

sided hemiparesis involving his face, and upper and lower extremities. His NIHSS score is 11. He has no history, laboratory or clinical findings that would exclude him from thrombolysis and he meets all inclusion criteria. He is terrified that he is going to die; he has not written his will and his “affairs are a mess.” He is presented with the outcome wheels shown in Figure 4.

Looking at the outcome wheels, the patient perceives that the chance of recovery is *somewhat* better with thrombolysis.

Example 4: You are at a family reunion. Your parent suddenly collapses and has a decreased level of consciousness, severe hemiparesis, dysarthria, dysphasia and gaze palsy. The NIHSS score is 18. What would you recom-

mend to your other parent and your siblings? The outcome wheels for this scenario are shown in Figure 5.

An online version of this tool kit for use by clinicians

Until at least May 2011, an interactive version of this clinical tool kit will be available for download at www.sem-bc.com/cvatookit. Using this, a patient’s NIHSS score can be rapidly calculated by way of drop-down menus. Inclusion and exclusion criteria are obtained in a similar manner and the program automatically calculates whether or not the patient is a candidate for thrombolysis according to current Canadian guidelines.¹⁴ There is a hyperlink in the program to the appropriate outcome wheel depending on the patient’s clinical presentation. The tool kit takes 2–3 minutes to use

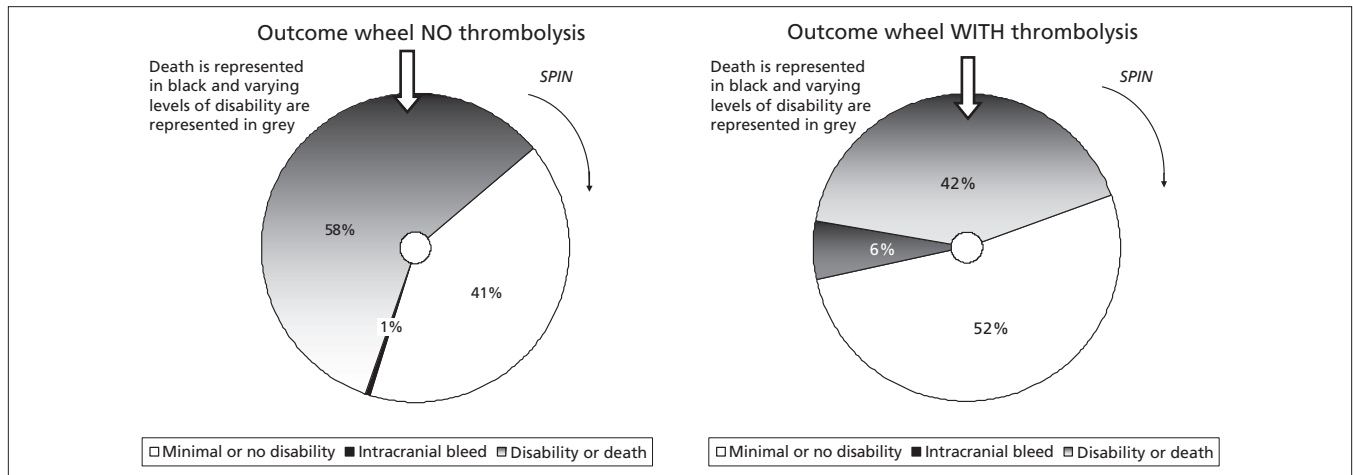


Fig. 4. Outcome wheels for National Institutes of Health Stroke Scale score 11–14. Minimal or no disability is defined as a Barthel Index of greater than 90. Results are based on findings from the reanalysis of the National Institute of Neurological Disorders and Stroke tissue plasminogen activator for acute ischemic stroke treatment trial.⁹

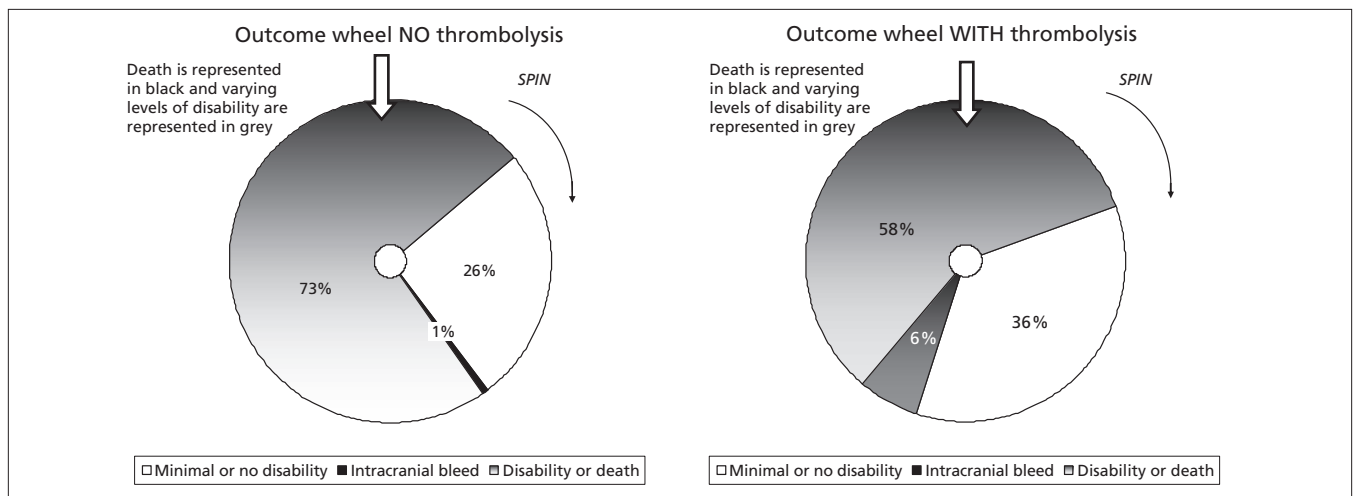


Fig. 5. Outcome wheels for National Institutes of Health Stroke Scale score 15–20. Minimal or no disability is defined as a Barthel Index of greater than 90. Results are based on findings from the reanalysis of the National Institute of Neurological Disorders and Stroke tissue plasminogen activator for acute ischemic stroke treatment trial.⁹

and the outcome wheels can be printed and presented to patients and families to assist them in shared decision-making.

Conclusion

This paper offers a tool that is intended to assist physicians, patients and families in making informed decisions in a time-sensitive manner for thrombolytic intervention in stroke. The usefulness of this tool kit and has not been formally studied, although anecdotal reports on its use have been favourable. Patient perceptions and preferences for presentation of information with outcome wheels or roulette wheels have not been studied and research in this area would be beneficial. Although intuitively the tool kit presented here may reduce protocol violations and assist in shared decision-making, formal studies should be undertaken to validate its effectiveness.

Competing interests: None declared.

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