Original Article

Patient-Centered Decision Support in Acute Ischemic Stroke: Qualitative Study of Patients’ and Providers’ Perspectives

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Background—National guidelines endorse recombinant tissue-type plasminogen activator (r-tPA) in eligible patients with acute ischemic stroke to improve patients’ functional recovery. However, 23% to 40% of ideal candidates with acute ischemic stroke for reperfusion are not treated, perhaps because of the difficulty in explaining the benefits and risks of r-tPA within the frenetic pace of emergency department care. To support better knowledge transfer and creation of a shared decision-making tool, we conducted qualitative interviews to define the information needs and preferred presentation format for stroke survivors, caregivers, and clinicians considering r-tPA treatment.

Methods and Results—A multidisciplinary team used qualitative research methods to identify informational needs and strategies for describing the benefits and risks of r-tPA in a clinical setting. Through focus groups (n=10) of stroke survivors (n=39) and caregivers (n=24) and individual interviews with emergency physicians (n=23) and advanced practice nurses (n=20), several themes emerged. Survivors and caregivers preferred a broader definition of a good outcome (independence, rather than no significant disability), simpler graphs as compared with detailed pictographs, and presentation of both population and individualized benefits (framed positively) and risk of receiving r-tPA. Some physicians expressed skepticism with the data and the ability to present risk/benefit information emergently, whereas other physicians and most advanced practice nurses thought such information would improve care. Physicians stressed the importance of presenting the risk of thrombolytic-related intracranial hemorrhage.

Conclusions—This study suggests that a positively framed risk–benefit tool with graphical presentations of general and patient-specific risk estimates could support patients and providers in considering r-tPA for acute ischemic stroke.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01864928.

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Key Words: caregivers ■ intracranial hemorrhage ■ stroke ■ survivors ■ treatment outcome

Stroke is the most common cause of serious disability and the fifth leading cause of death in the United States.1 Treatment with thrombolytic therapy for acute ischemic stroke (AIS) can reverse ischemia-related stroke symptoms and improve outcomes, particularly 90-day neurological functioning as measured by the modified Rankin Scale (mRS; Table 1).2-7 Recombinant tissue-type plasminogen activator (r-tPA) is a guideline-endorsed standard of acute stroke care within 3 hours of symptom onset for eligible patients (Food and Drug Administration approved), and ≤4.5 hours in selected patients.8 However, the American College of Emergency Physicians recently rescinded their recommendation to provide more qualified support r-tPA.9 In their revised statement, American College of Emergency Physicians emphasized the importance of engaging patients and their caregivers in shared medical decision making to include a discussion of the risks and benefits of treatment.10 Communicating the risks and benefits needs to happen quickly, however, faster treatment with thrombolytic therapy is associated with greater treatment benefit, reduced symptomatic intracranial hemorrhage (ICH), increased independent ambulation, and increased discharge to home.11-13

Although treatment rates in the United States have improved, only 7% of patients with AIS are treated with thrombolytics.14 Even among ideal patients presenting within 2 hours of symptom onset, 23% to 40% of patients are not treated.14,15 National initiatives to improve acute stroke care...
WHAT IS KNOWN

• National guidelines endorse thrombolytic therapy for acute ischemic stroke, but 23% to 40% of ideal candidates are not treated.
• It is a complex conversation in a hurried emergency setting and is not tailored to the individual patient’s benefits and risks of receiving a thrombolytic.

WHAT THE STUDY ADDS

• This study gathers multiple perspectives to define good and bad outcomes, refines the Thrombolytic Predictive Instrument predictive risk model, and then combines it with patient data to create the individualized Rapid Evaluation for Stroke Outcomes using Lytics in a Vascular Event risk–benefit tool.
• Shared decision making can occur in the emergency setting of an acute ischemic stroke.

have emerged since the approval of r-tPA for stroke in 1996, including Get With the Guidelines-Stroke, resulting in modest improvements in the timely treatment of patients with AIS eligible for thrombolytic therapy. Yet substantial undertreatment and delayed treatment persist. A potential explanation for undertreatment is therapeutic uncertainty related to the marked heterogeneity of treatment benefit and risks as a function of patient characteristics, which can make it difficult to appreciate the treatment benefits for an individual patient. To address this challenge, multiple risk models have been proposed to better identify patients who will benefit from r-tPA. Despite their potential to tailor treatment to those who benefit most, these models have not been routinely used to support treatment, partly because of their complexity. To address this challenge, our team created a Web-based tool, ePRISM (Personalized Risk Information Services Manager), to generate personalized documents that are embedded with patient-specific outcomes projections from well-validated risk models and has been programmed with a modified version of the Stroke-Thrombolytic Predictive Instrument model. Before implementing tools to support precision medicine in routine clinical care, it is important to define how best to present the results to patients and providers. Tailoring information to patients’ needs is strongly aligned with the Institute of Medicine’s goals for evidence-based care that respects patients’ individual preferences. Moreover, previous efforts to create decision support tools for AIS have been found wanting by Gadchia et al in a recent review. Similarly, a meta-analysis by Flynn et al found that many decision aids used for AIS are suboptimally developed, observing that advice of key stakeholders was not routinely used. Regardless of the patient’s cognition during their presentation with AIS symptoms, or the stressful situation of family members, it is important to include them in discussions and decisions to the best of their ability.

To create a decision support tool with a balanced presentation of benefit and risk, we sought to (1) define patients’ preferences for what constitutes a good and bad outcome after AIS to inform refinement of a prediction model and (2) define a readily interpretable format to present this information in the setting of AIS. These goals are intricately linked, as the output of the model(s) needs to project meaningful and important outcomes to patients and providers in a format readily understood and actionable by both. This article describes the process and results of our efforts to illuminate a good or bad outcome after AIS, and how these data can best be presented to patients, caregivers, and providers to develop a precision medicine-based decision support tool, Rapid Evaluation for Stroke Outcomes using Lytics in a Vascular Event (RESOLVE) tool for AIS.

Existing AIS and r-tPA Materials

Before meeting with stakeholders, the team gathered examples of existing AIS and thrombolytic therapy patient education materials. The search focused on materials for a lay audience and graphic representations of outcomes after treatment with thrombolytic for AIS. Patient preference for description of stroke outcomes in terms of functional states (free of severe language, motor or cognitive deficits; mRS) has been identified from earlier work by Solomon et al. Materials found in the public domain were (1) a pictograph representing National Institute of Neurological Disorders (NINDS) data from UCLA Stroke Center; (2) an Alteplase Leaflet from The Leeds Teaching Hospital; (3) a color-coded graph depicting r-tPA outcomes from a 2010 pooled analysis of r-tPA trials from Duke Stroke Center; (4) an industry-developed patient discussion guide with pictograph; and (5) an r-tPA patient discussion guide with color-coded chart from the American Academy of Emergency Medicine. These materials were explored by Gadchia et al in a recent review and proved less than satisfactory. Accordingly, the research team and medical illustrator developed multiple ways of presenting results from a pooled analysis of the 2 NINDS trials, the European Cooperative Acute Stroke Study (ECASS) 2, and the Echoplanar Imaging Thrombolytic Evaluation Trial. These materials (Appendix I in the Data Supplement) were offered at each focus group with the goal of presenting the predictive
Stroke Survivor and Stroke Survivor Family or Caregiver Perspectives

Qualitative methods were used during focus groups with a 2-point agenda: defining a good and bad outcome after AIS and refining the output of a patient decision tool for thrombolytic therapy in AIS. Focus group members were recruited from 2 large healthcare systems (UCLA and Saint Luke’s Hospital of Kansas City) by posting fliers in public areas near stroke clinics and public meeting rooms (to reach support group members) at each hospital. Additional subjects were recruited by fliers from the American Stroke Foundation in Kansas City and through collaboration with New Bethel Church of Kansas City, a predominantly black church, to assure patient diversity. Interested subjects contacted the research staff for screening and those meeting criteria (stroke survivor [preferably ischemic stroke] or family/caregiver of survivor during the acute event) were subsequently invited to attend one of the upcoming focus groups. To define which disability transition was favored by patients as the best definition for a dichotomized favorable outcome, focus groups elicited survivors’ subjective interpretations of what levels of functioning after a stroke would be considered a good outcome. Functional outcomes of AIS recovery were described according to the preferred definition would then be used as the outcome for the predictive model. All focus groups followed a structured interview guide that explored patients’ stroke experience, decision-making preferences, level of functional outcome tolerance, and feedback about decision aids for AIS treatment.

Graphical Output Materials

To refine the graphic output of the predictive model, focus group participants were given a 2-part decision tool. The first part explained the qualitative data were evaluated across transcripts. In addition, the feedback from a panel of expert clinicians (emergency medicine physicians, neurologists, and advanced practice nurses [APNs]) was used to assure accuracy and ease of interpretation of the patient and clinician materials.

Clinicians: Emergency Medicine Physicians’ and Neurology and Emergency Department–Based APNs’ Perspectives

After the stroke survivor and family caregiver interviews, the research team conducted in-depth telephone interviews with US stroke care providers. An interview guide elicited their experience using r-tPA to elicit their approach to discussing or consenting to r-tPA therapy with patients and families, and cultural attitudes within their institutions.

Methodological Rigor

Study soundness for qualitative analysis was established several ways. Stroke survivors and family caregiver transcripts were coded separately from the physician and APN transcripts for identification of themes specific to each cohort. Content was reviewed and coded within a single focus group or interview and conclusions drawn from the qualitative data were evaluated across transcripts. In addition, the use of 4 coders with different backgrounds (2 nurses, an anthropologist, and a dietitian health researcher) was important in establishing the credibility of the coding scheme. The researchers thoroughly discussed similarities and differences within an individual transcript and then, across the cohort, to reach consensus. Trustworthiness of the assessments was established through discussions with other team members, including neurologists at UCLA and Saint Luke’s Hospital of Kansas City.

Results

Stroke Survivors and Family or Caregiver Perspectives

Ten patient and caregiver focus groups were conducted at 2 US sites, involving 63 subjects, of whom 39 were stroke survivors. The mean age of participants was 58.9 years; 43% were male and 46% were black. Quotes reflective of the theme...
are presented and unique identifiers were assigned to each participant: P (patient) or C (caregiver), M (male) or F (female), the number assigned to that individual, and KC (Kansas City) or UCLA.

Survivors typically did not recall being educated about acute stroke or its treatment during their hospitalizations, although families provided vivid, emotional recollections of the event. There was unanimous agreement among all participants that a decision tool for thrombolytic therapy in AIS would have been helpful and was needed for future stroke patients. Participants also expressed feelings of information overload and stress-induced confusion during the decision-making process. One family member said: “I didn’t know if he was understanding anything that was being said to him or what was going on because he couldn’t talk at that time” (CM17KC). Stroke survivors who did recall discussions or education had unclear memories of the event: “I was conscious the whole time…it was kind of blurry, though, once I got in the emergency room” (PF18KC). One female family member in a KC focus group said “Because, when you’re in a crisis situation like we were in, you’re not thinking real clearly” (CF51KC).

Four themes emerged as participants expressed a need for more information: (1) for definition of good outcome, participants preferred a more inclusive definition including mRS level 0, 1, and 2 over a more restrictive definition including only mRS level 0 and 1, (2) to provide both population level and personalized risks and benefits, (3) frame risk positively, and (4) present both risk and benefit data. Table 2 displays the themes and representative quotes from patients and families or caregivers.

Although the majority of participants thought that achieving an mRS score of 0 to 2 was a satisfactory threshold for good outcome, there was some divergence of opinion: some stroke survivors felt that an mRS score of 0 or 1 would be considered a good outcome and 1 patient felt that only an mRS score of 0 was a good outcome. There was consensus among all participants that a bad outcome was severe disability or death (mRS score of 5–6). The most commonly reported theme was participants felt that both risks and benefits should be presented. They felt that a balanced presentation of risk/benefit could help them make a more informed decision.

Participants’ opinions sometimes differed from the researchers’, such as the choice of shading to depict good outcome or death. For example, when disability and death were lighter, 1 participant said: “…it’s kind of like life stages. You know, you’re vibrant here and then in this thing you’re not going to be so vibrant, and then less vibrant, and boom, you’re dead” (CF09KC). Darker colors were preferred because they emphasized or highlighted information, drawing the eye and conveying a positive message.

Development of the Patient With Stroke, Family, or Caregiver RESOLVE Decision Aid
On the basis of feedback from multiple groups, we created a final draft of the RESOLVE shared decision-making tool for patients. Contrary to some existing stroke decision tools and clinical trial primary end point definitions, most participants preferred broadening the definition of a good outcome to independence in activities of daily living (ie, mRS score of 0–2) over narrower ones of being nondisabled (mRS score of 0–1) or symptom-free (mRS score of 0). Participants preferred viewing outcomes statistics in a positive frame, that is, chance of a good outcome, rather than the decreased chance of a bad outcome, such as death. Thus, materials were formulated to address these prominent themes.

The majority of current decision tools use a pictographic format, thus several different versions of a pictograph were developed and presented. Despite these efforts, when shown all 3 formats, participants indicated the pictograph to be confusing and the stacked bar to be most informative, which was easiest to understand when printed in full color, rather than black and white and were thus modeled after the Leeds Teaching Hospital leaflet.33

Clinician Perspectives
Forty-three provider interviews were conducted from 18 different sites across the United States. EMPs (n=23; male=74%; average years of experience=12) and APNs (n=20; male=5%; average years of experience=9.4). They described 2 themes in common that supported treatment: (1) timely presentation of the patient to the ED and (2) the presence or availability of neurology support. However, EMPs and APNs shared differing perspectives that emerged in 4 themes: (1) knowledge of long-term outcomes, (2) impression of data, (3) communication of risk and benefit, and (4) the use of written/educational material. Table 3 displays representative quotes about each of the themes presented by subject number and years in practice. For example, 1 EMP stated “That [knowing long-term outcomes beyond the ED discharge] would be another good thing, if there were some details of what happens afterwards” (No. 05, 2.5 years), whereas an APN described her awareness of the long-term outcomes: “Yes, I conduct a post-stroke clinic… It’s [for] anybody who has had an ischemic stroke” (No. 33, 12 years). Another example of the different perspectives among EMPs and APNs is in communication and emphasis on risk or benefit. One EMP stated “…I usually spend a fair amount of time going into the negatives about it. Then I go over the percentages of [the] likelihood of getting better” (No. 03, 3.5 years), whereas an APN described “There is a risk. However, we feel that the benefits outweigh the risk with r-tPA” (No. 27, 9.5 years).

Development of the RESOLVE Clinician Decision Aid
A draft clinician tool was compiled by the research team following half of the interviews and was shown to the final third of clinicians. The team concurred with the clinician findings that the risk of ICH as a result of r-tPA therapy must be included on the clinician tool. In addition, Web-based follow-up surveys were completed by 7 physicians. In this small sample, 86% of subjects felt the tool would be helpful in decision making about r-tPA, and 67% stated the tool would be most useful as part of a clinical order set.

Complete and Final RESOLVE Tool
The RESOLVE tool for patients is designed to have 3 pages: 1 page visually presenting and describing an ischemic stroke,
These models require only 6 data elements to execute and finally validated the new models on the ECASS 3 trial data. Thrombolytic Predictive Instrument model and then exter-

Use of written materials We’re very familiar with what’s out there and I’ve looked at

Knowledge of long-term outcomes That [knowing long-term outcomes] would be another good thing, if there were some details of what happens afterwards too. No. 05, 2.5 y

Impression of data … in some studies it has been shown that [rt-PA] has been beneficial to a small degree. In other studies it wasn’t shown to be beneficial. And in fact some it showed harm. No. 12, 15 y

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Table 3. Clinician Perspectives: Four Themes and Representative Quotes

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<td>Use of written materials</td>
<td>We’re very familiar with what’s out there and I’ve looked at everything and have found that for our patient population, providing this information has not added any value or benefit in the decision process. No. 09, 18 y</td>
<td>We have the one page, very simple information piece that talks about what rt-PA is. No. 40, 4 y</td>
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mRS indicates modified Rankin Scale.

and 2 pages for risk–benefit presentations, one at the population level and the other based on patients’ individual estimated benefits and risks (Appendix II in the Data Supplement). In contrast, the optimal clinician tool was determined to be a single page that graphically presents the unique benefit of r-tPA (Appendix III in the Data Supplement), as a function of time, for an individual patient in whom the clinician is considering thrombolytic therapy, as well as the risks of a bad outcome, which also includes the risks of an ICH resulting in a severe disability or death.21,42 The multivariable model was updated to predict mRS score of 0 to 2 as the good outcome and mRS score of 5 to 6 as the bad outcome by Kent et al,28 who report using the combined original data sets from NINDS 1 and 2, ATLANTIS A and B, and ECASS 2, to simplify the Stoke-Thrombolytic Predictive Instrument model and then externally validated the new models on the ECASS 3 trial data. These models require only 6 data elements to execute and develop evidence-based, personalized estimates of outcome: age, systolic blood pressure, diabetes mellitus, a 3-item stroke severity scale,43 and time from symptom onset and glucose.28

The final tool was evaluated by the research team using the content and development sections of the International Patient Decision Aids Standards instrument Criteria Checklist,40 to help developers verify that the tool meets current standards of content, development, and effectiveness. The tool scored high (score 37; maximum score, 48) in all relevant aspects of the content and development domains.

Discussion

Explaining the benefits and risks of r-tPA is typically done with hurried verbal explanations in the ED, and may not be understood by patients and caregivers. Decision making about r-tPA can thus be difficult for patients and families, compounded by the need to balance risk/benefit ratios with therapy in a highly

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<th>Caregiver (Family/Friend)</th>
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<td>Good outcome=0–2 mRS</td>
<td>I think that 0–2 is really a good outcome as [I’ve] seen severely disabled patients throughout recovery (PM07KC)</td>
<td>[At a 2] you would want to be able to look after affairs without assistance or be able to carry out all previous activities (CF34KC)</td>
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<td>Provide population level and personalized risks and benefits</td>
<td>[The individual risk]…that’s ours, that’s what we want to worry about. Don’t care about the rest of it. [The population data] Later… down the road (PF33KC)</td>
<td>Tell me my individual risk, and then show me how that compares to the general population. As far as the general population, maybe your risk is higher than others (CF10KC)…I would do both [population and personalized]. I’d say this is the general population, but we put your information in and maybe yours is going to be something else—and you can see both of those. To me, that makes sense (CF19KC)</td>
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<td>Risks framed positively</td>
<td>I would sure rather see improvement… You don’t want to see any doom and gloom (PM31KC)</td>
<td>Bad Outcome'; I don’t like those words. You’re talking about somebody I love, you know (CF10KC)</td>
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<td>Present both risks and benefits</td>
<td>I would be open to take a risk if I thought there would be a good chance of a major improvement (PM08KC)</td>
<td>I think the individual [risk] is [important] but I’d still like to know good and bad… I think you need an overall, a whole picture (CM50KC)</td>
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EMP indicates emergency medicine physician; and r-tPA, recombinant tissue-type plasminogen activator.
time-pressured situation. Patients and families depend greatly on information provided during the acute treatment phase, and such information must be readily understood. Decision support tools that succinctly present the medical condition and the effect of treatment on good and bad outcomes in a format that patients and caregivers can readily understand is an important goal and can support shared medical decision making, as lengthy discussions have potentially deleterious consequences because of rapid loss of brain cells and decreased efficacy of thrombolytic therapy over time. In this qualitative research study, we learned from multiple stakeholders how best to construct such a tool to support the consideration of acute AIS treatment with r-tPA.

The clinician interviews demonstrated a difference between EMPs and APNs, although both groups felt that an increased likelihood of receiving r-tPA was associated with the patient’s timely presentation to the ED and having access to or the presence of a neurology consult. Our findings of the complexity of presenting risk estimates was substantiated by a recent report from the United Kingdom about the challenges of effective risk communication in a hyper-acute setting of stroke thrombolysis. In addition, it was important to provide equal space for presenting evidence for good as well as bad outcomes.

Underuse of r-tPA may be traced to a fundamental lack of a systems-based approach to acute stroke care. Barriers within individual hospitals and within EDs have been identified previously, including communication between the emergency and radiology teams, poor availability of neurologists, delay in patient presentation, and lack of motivation and familiarity with treatment guidelines by ED physicians. All these barriers, however, ignore the challenge of communicating information to patients or their families in an effort to gauge their preferences before treatment, a step emphasized by recent American College of Emergency Physicians guidelines as being critically important. Moreover, the complexity and rapidity of care will require careful integration of data collection into clinical workflow so that a tool can be generated and shared with patients and providers rapidly and without delaying door-to-needle time. This work thus represents one of the first steps in a longer process of clinical implementation and use, as a tool that is readily understood by patients and providers must be created first. Now that the RESOLVE tool has been designed, we are embarking on a pilot project to define the best strategies for implementation, without delaying treatment times, in 3 Midwest EDs.

This qualitative work should be interpreted in light of the following potential limitations. Qualitative research is exploratory and not intended for generalization; therefore, a limitation of this study may be lack of representativeness in the sample and generalizability to a broader population. Although saturation was obtained from a diverse group of patients and caregivers, they were drawn from 2 large metropolitan areas (Kansas City and Los Angeles), and participants from other locations may have additional insights not captured by this study. In addition, studying patients and caregivers drawn from other groups with varying race, ethnicity, education levels, and socioeconomic status may elicit different information or they may express preference for differing tool formats that could be more effective for specific subgroups. Physicians and APNs were interviewed through snowball sampling that may have perpetuated a similar philosophy among the respondents, although steps were explicitly taken to interview clinicians with opposing views. We did not sample neurologists, so the input of physicians with the most expertise in the disease state was not captured in thematic analysis. Other clinicians who work with patients with AIS may report different strategies for determining optimal treatment and may report different experiences.

Finally, end user preferences may reflect cognitive biases and be suboptimal from other perspectives. For example, although ED clinicians had a clear preference for a tool that separately reports the risk of symptomatic ICHs, this information is already incorporated in predictions of functional outcomes, and presenting a separate prediction may lead to an asymmetrical double counting of the risks of therapy but not the benefits. Similarly, stroke survivor preference for simple graphical formats led to development of a visual decision aide showing only dichotomized outcomes, whereas treatment benefits are actually conferred over the entire range of the disability spectrum. As a result, the personalized benefit-risk aide displays only a portion, approximately one third, of the actual amount of benefit accrued from thrombolytic therapy. Furthermore, because risk distributions especially for low incident events tend to be skewed, individualizing risk is likely to show that risks of a bad event is lower than average for most patients (although it may be much higher than average in a few)—and thus individualizing risk should show appropriately lower risks for most patients.

**Conclusions**

Currently, the risk of ICH is predominantly communicated to patients with AIS considering r-tPA in generic and variable ways with an emphasis on risks, as it is difficult to present the individualized benefit of treatment with the current tools. This may negatively bias the conversation and lead to lower treatment rates. The RESOLVE tool is responsive to patients’ requests for information by generating the estimate of a patient’s likelihood of benefit, with the hope of improving patient/caregiver understanding, improving evidence-based decision making, and supporting treatment rates and time to treatment. The RESOLVE decision aid incorporated feedback from multiple perspectives and resulted in a 3-page patient tool and a single sheet for clinicians that include individualized risk prediction models. Ultimately, examining whether the RESOLVE tool improves patient’s understanding of risk and benefits of thrombolytic therapy and confidence and comfort with decision making would need to be tested in actual clinical practice.

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**Disclosures**

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of California. The University of California, Regents receive funding for Dr Saver’s services as a scientific consultant regarding trial design and conduct to Coviden, CoAxia, Stryker, BrainsGate, and St. Jude Medical. Dr Saver has served as an unpaid site investigator in multicenter trials run by Lundbeck for which the UC Regents received payments on the basis of clinical trial contracts for the number of subjects enrolled. Dr Saver has declined all honoraria from Genentech since 2002. Dr Saver serves as an unpaid consultant to Genentech advising on the design and conduct of the PRISMS trial; neither the University of California nor Dr Saver received any payments for this voluntary service. The University of California has patent rights in retrieval devices for stroke. E. Chen is an employee of Genentech (significant). Dr Kent has received research grant from Genentech (significant). Dr Speratus is a member of advisory board for United Healthcare (Modest); consultant to Genentech advising on the design and conduct of the ALATIS Trials Investigators; ECASS Trials Investigators; NINDS rt-PA Study Group Investigators. Association of outcome with early stroke treatment; pooled analysis of ALTATIS, ECASS, and NINDS rt-PA stroke trials. *Lancet*. 2004;363:768–774. doi: 10.1016/S0140-6736(04)15692-4.


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What is a stroke?

Arteries bring blood to the brain. An ischemic stroke occurs when an artery to the brain is blocked. When that happens, a part of the brain does not get the blood it needs, so it starts to die.

The first picture shows a stroke from a blocked artery, like the one you are experiencing right now.

Please choose between Figure 1 & Figure 2 shown below:
Figure 3 and Figure 4 are currently available for use by physicians and patients.

Figure 3

TPA for Cerebral Ischemia within 3 Hours of Onset-Changes in Outcome Due to Treatment

Changes in final outcome as a result of treatment:
- Normal or nearly normal
- Better
- No major change
- Worse
- Severely disabled or dead

Early course:
- No early worsening with brain bleeding
- Early worsening with brain bleeding

Figure 4

Fig 2: Example of a Pictograph for Patients/Families
Figure 5

<table>
<thead>
<tr>
<th>Condition</th>
<th>TPA</th>
<th>No TPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal/Near Normal</td>
<td>42%</td>
<td>26%</td>
</tr>
<tr>
<td>Moderately Disabled</td>
<td>20%</td>
<td>26%</td>
</tr>
<tr>
<td>Severely Disabled</td>
<td>19%</td>
<td>26%</td>
</tr>
<tr>
<td>Deceased</td>
<td>17%</td>
<td>20%</td>
</tr>
</tbody>
</table>
**Figure 6**

<table>
<thead>
<tr>
<th>Condition</th>
<th>tPA</th>
<th>No tPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal / Near Normal</td>
<td>42%</td>
<td>26%</td>
</tr>
<tr>
<td>Moderately Disabled</td>
<td>20%</td>
<td>26%</td>
</tr>
<tr>
<td>Severely Disabled</td>
<td>19%</td>
<td>26%</td>
</tr>
<tr>
<td>Deceased</td>
<td>17%</td>
<td>20%</td>
</tr>
</tbody>
</table>

- Hemorrhage
### Figure 7

<table>
<thead>
<tr>
<th></th>
<th>Normal/Near Normal</th>
<th>Moderately Disabled</th>
<th>Severely Disabled</th>
<th>Deceased</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TPA</strong></td>
<td><img src="image" alt="TPA Normal/Near Normal" /> 42%</td>
<td><img src="image" alt="TPA Moderately Disabled" /> 20%</td>
<td><img src="image" alt="TPA Severely Disabled" /> 19%</td>
<td><img src="image" alt="TPA Deceased" /> 17%</td>
</tr>
<tr>
<td><strong>No TPA</strong></td>
<td><img src="image" alt="No TPA Normal/Near Normal" /> 26%</td>
<td><img src="image" alt="No TPA Moderately Disabled" /> 26%</td>
<td><img src="image" alt="No TPA Severely Disabled" /> 26%</td>
<td><img src="image" alt="No TPA Deceased" /> 20%</td>
</tr>
</tbody>
</table>

*Hemorrhage*
Figure 8

If 100 stroke patients were given TPA less than 3 hours after onset...

<table>
<thead>
<tr>
<th>Condition</th>
<th>TPA</th>
<th>No TPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal/Near Normal</td>
<td>42%</td>
<td>26%</td>
</tr>
<tr>
<td>Moderately Disabled</td>
<td>20%</td>
<td>26%</td>
</tr>
<tr>
<td>Severely Disabled</td>
<td>19%</td>
<td>26%</td>
</tr>
<tr>
<td>Deceased</td>
<td>17%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Hemorrhage
Figure 9

If 100 stroke patients were given TPA less than 3 hours after onset...

<table>
<thead>
<tr>
<th>Normal/Near Normal</th>
<th>Moderately Disabled</th>
<th>Severely Disabled</th>
<th>Deceased</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPA</td>
<td>42%</td>
<td>20%</td>
<td>19%</td>
</tr>
<tr>
<td>No TPA</td>
<td>26%</td>
<td>26%</td>
<td>26%</td>
</tr>
</tbody>
</table>

Hemorrhage
What are MY OWN chances of having a good outcome?

Note that the figure below uses data from previously treated patients. Your results may differ from these prior patients. Based on patients like you (from Kent 2006 criteria) the best science predicts that you will achieve the following outcomes without and with tPA.

Please choose between Figure 10 and Figure 11:

Figure 10

Chance of a Good Outcome at 90 Days

![Graph showing chance of a good outcome at 90 days without and with tPA.]

Figure 11

Chance of a Good Outcome at 90 Days

![Bar chart showing chance of a good outcome at 90 days without and with tPA.]
Please choose between Figure 12 and Figure 13:

**Figure 12**

### Chance of a Bad Outcome at 90 Days

```
<table>
<thead>
<tr>
<th></th>
<th>No tPA</th>
<th>tPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>10%</td>
<td>5%</td>
</tr>
</tbody>
</table>
```

**Figure 13**

### Chance of a Bad Outcome at 90 Days

```
<table>
<thead>
<tr>
<th></th>
<th>0%</th>
<th>10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>tPA</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>No tPA</td>
<td>10%</td>
<td></td>
</tr>
</tbody>
</table>
```
**APPENDIX B: RESOLVE Decision Aid – Patient**

**Page 1**

**Ischemic Stroke**

**What is a stroke?**

An artery carries blood to the brain. An ischemic stroke occurs when an artery in the brain is blocked by a blood clot. When an artery in the brain is blocked, the brain does not get the blood it needs, so it starts to die.

**How is a stroke treated?**

rt-PA (also called tPA, alteplase, or Actemra®) is an IV medication that can treat ischemic stroke. rt-PA can dissolve a blood clot.

The picture below shows an artery in the brain before and after treatment with rt-PA.

![Diagram showing blocked and unblocked arteries before and after rt-PA treatment](image)

**Page 2**

**Ischemic Stroke**

Your stroke is caused by a blood clot in your brain. rt-PA, also called alteplase or Actemra®, is an IV medication that can dissolve a blood clot. It can take up to 90 days to see full results from treatment with rt-PA.

The chart below shows results 90 days after treatment with and without rt-PA for the typical person with a stroke.

<table>
<thead>
<tr>
<th>rt-PA</th>
<th>No rt-PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 people had no symptoms or major disability</td>
<td>20 people had no symptoms or major disability</td>
</tr>
<tr>
<td>10 people had moderate disability</td>
<td>30 people had moderate disability</td>
</tr>
<tr>
<td>20 people had severe disability</td>
<td>20 people had severe disability</td>
</tr>
<tr>
<td>17 people died</td>
<td>17 people died</td>
</tr>
</tbody>
</table>

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APPENDIX C: RESOLVE Decision Aid – Clinician

Ischemic Stroke - Physician

Name: Doe, John  Age: 60  Date: 8/13/2015 1559

Last Known Well Time: 08/13/15 1430  Arrival Time: 08/13/15 1517

Chance of Good Outcome
(No Symptoms or Slight Disability - mRS 0-2) at 90 Days\(^a\)

Door to Needle Goal ≤ 60 min

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>rt-PA(^*)</th>
<th>No rt-PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>80%</td>
<td>70%</td>
</tr>
<tr>
<td>30</td>
<td>75%</td>
<td>65%</td>
</tr>
<tr>
<td>45</td>
<td>70%</td>
<td>60%</td>
</tr>
<tr>
<td>60</td>
<td>65%</td>
<td>55%</td>
</tr>
<tr>
<td>75</td>
<td>60%</td>
<td>50%</td>
</tr>
<tr>
<td>90</td>
<td>55%</td>
<td>45%</td>
</tr>
<tr>
<td>105</td>
<td>50%</td>
<td>40%</td>
</tr>
</tbody>
</table>

\(^a\)Benefit is likely 3 times greater than shown considering improvement across all functional levels.

Risk of Severe Disability or Death (mRS 5-6) from Stroke or Bleeding at 90 days\(^ab\)

<table>
<thead>
<tr>
<th>% Risk</th>
<th>rt-PA(^*)</th>
<th>No rt-PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^ab\)The rt-PA bar above incorporates symptomatic ICH risk of 6%.

RN initials __________ RN signature ____________________________

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