# Critical Review Form
## Therapy

An Emergency Department Diagnostic Protocol for Patients with Transient Ischemic Attack: A Randomized Controlled Trial, *Annals of EM* 2007; 50:109-119

**Objectives:** **"To determine whether treatment of transient ischemic attack patients using an accelerated diagnostic protocol in the ED is associated with a decrease in the index visit length of stay and cost and with comparable diagnostic and 90-day clinical outcomes relative to traditional inpatient care." (p 110)**

**Methods:**

**Single center prospective randomized trial with patients screened for enrollment 24/7. Exclusion criteria included cerebral hemorrhage or mass, known embolic source or carotid stenosis, persistent acute neurological deficit, non-focal neurological symptoms, severe headache or fever, medical conditions necessitating admission, severe dementia or nursing home patient, previous large stroke, history of IVDA, or social issues limiting follow-up likelihood (Fig 1, p.111). After the decision to admit the patient was made by the treating clinician, subjects were consented and randomized with allocation concealed by "sealed envelopes with randomization assignments enclosed on a 1:1 ratio", although "envelopes were assigned computer-generated random study numbers".**

**The study arm patients were admitted to an accelerated diagnostic protocol room in ED observation, while the control patients were admitted to the hospital ward (usually IM). Both groups had the same 4 diagnostic tests ordered per protocol: carotid imaging, echocardiography, cardiac x 12 hours monitoring, and serial neurological exams. Without deterioration or abnormal diagnostic testing, subjects in the accelerated arm were discharged when the 4 tests were completed.**

**The primary outcome was the index visit length of stay; while secondary outcomes included 90-day total cost and stroke rates or medical recidivism 90-day follow-up occurred through medical record review at 2 area hospitals and structured telephone follow-up, the study had 80% power to detect an absolute reduction in LOS of 1-day.**

| Guide | | Comments |
|---|---|---|
| **I.** | **Are the results valid?** | |
| **A.** | **Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?** | |
| 1. | Were patients randomized? | Yes, "after consent randomization occurred by the attending physician's opening the sealed envelope containing randomization assignment and admission order forms" (p 110) |
| 2. | Was randomization concealed (blinded)? | "Physicians, patients, investigators, and all providers were blinded to randomization assignment before the envelope was opened" (p 110) |
| 3. | Were patients analyzed in the groups to which they were randomized? | "Including data for the 2 excluded patients on an intention-to-treat basis provided the same lengths of stay for both study groups" (p 113) |
| 4. | Were patients in the treatment and control groups similar with respect to known prognostic factors? | "Study patients were similar between groups in terms of age, sex, stroke risk factors, and presenting symptoms" (p 112) However, review of Table 1 (p 113) suggests that the inpatient cohort may have started at higher baseline risk since a greater proportion had TIA lasting > 10 minutes, diabetes and subsequent stroke. |
| **B.** | **Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?** | |
| 1. | Were patients aware of group allocation? | No – see above. |
| 2. | Were clinicians aware of group allocation? | No – see above. |
| 3. | Were outcome assessors aware of group allocation? | No – see above. |
| 4. | Was follow-up complete? | Yes. Telephone follow-up and hospital record review were completed on all study subjects. (p 116) |

| II. | What are the results (answer the questions posed below)? | |
|---|---|---|
| 1. | How large was the treatment effect? | • 151 patients were enrolled from Aug 2003 – June 2005, although 2 were excluded by eligibility criteria.<br>• Accelerated protocol patients had significantly shorter median LOS than inpatients (25.6 vs. 61.2 hours, p<0.001). Most of these cost differences were attributed to room/board, non-imaging diagnostics, and pharmacy expenses.<br>• Median index visit direct cost was cheaper in the accelerated protocol group ($864 vs. $1528, p<0.001).<br>• Median cost savings were maintained at 90-days.<br>• Accelerated protocol patients were more likely to obtain all ordered diagnostic testing including carotid imaging (97% vs. 91%) and echo (97% vs. 73%).<br>• All admissions of accelerated protocol patients (15%) were because of clinical events detected on serial exam, not because of diagnostic test results.<br>• All strokes were small or ineligible for thrombolytic therapy.<br>• Combined, both groups had a 3.3% 90-day stroke rate and both groups also had 12% related ED recidivism rates. |
| 2. | How precise was the estimate of the treatment effect? | Wide inter-quartile ranges are reported reflecting the relatively small sample size and limited number of events. |

| III. | **How can I apply the results to patient care (answer the questions posed below)?** | |
|---|---|---|

| | | |
|---|---|---|
| 1. | Were the study patients similar to my patient? | Yes. Detroit (suburban) ED patients at Royal Oak hospital. |
| 2. | Were all clinically important outcomes considered? | No, patients' satisfaction, admission rates, hospital bed flow and diagnostic occurring were not assessed. |
| 3. | Are the likely treatment benefits worth the potential harm and costs? | Yes, "if 18% of the 300,000 annual transient ischemic attack patients presented to US hospitals that offered an accelerated diagnostic protocol instead of admission, then the annual cost savings would be $29.1 million dollars" (p 117) |

Limitations:

1. Single center study with inter-departmental cohesion and well-established rapid testing protocol and infrastructure with hospital support might not be replicated in other settings. Furthermore, ED personnel motivated to demonstrate a benefit to their streamlined TIA pathway might have pushed harder to complete ordered studies and disposition patients than their floor colleagues.
2. Professional costs were not considered. Doing so would have widened the cost difference between the groups and even more impressively favored the ED-based accelerated diagnostic model.
3. Hospital chart review might have missed unreported evaluations at other hospitals.
4. The investigators applied their rapid diagnostic testing to all TIA patients. Using the $ABCD^2$ rule, a portion of these patients might require no immediate testing which would enhance the feasibility of the protocol for other hospital systems.

Bottom Line:

A single center ED-observation based model offers an encouraging method to optimize TIA evaluation with best-evidence diagnostic testing at substantially reduced expense and length-of-stay. Future research should expand outcomes to include interventional post-TIA stroke reduction and application of the rapid protocol to high-risk patients using the $ABCD^2$ prognostic tool. Implementing an ED-based rapid testing protocol likely requires interdepartmental collaboration and strong institutional support so external validity may be limited.