FERNE/EMF Grant Award

# An Emergency Department Diagnostic Protocol For Patients With Transient Ischemic Attack: A Randomized Controlled Trial

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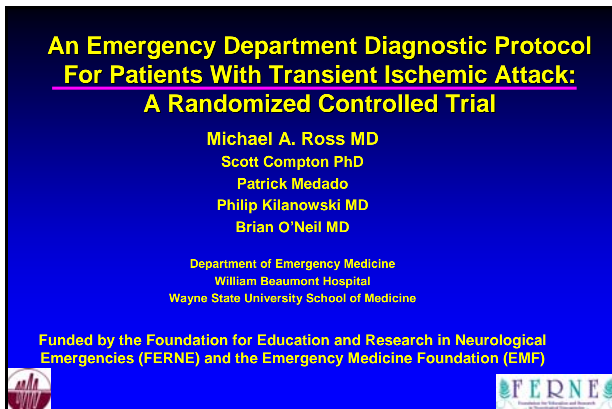
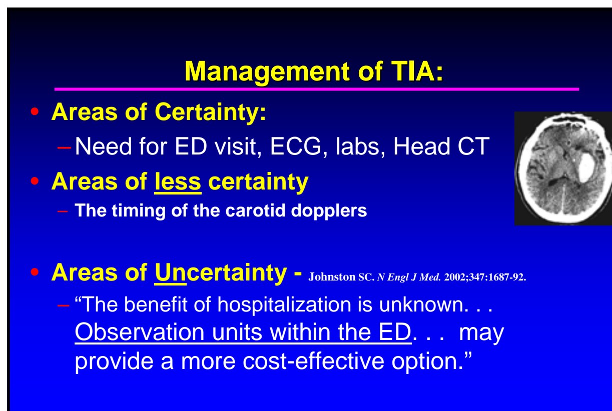



## Background

- 300,000 TIAs occur annually
  - 10.5% suffer a stroke within 90 days of an ED visit
- Stroke is preceded by TIA in 15% of pts
- Stroke is the THIRD leading cause of death
  - National cost of stroke = $51 billion annually!




## Study Objective:

To determine if emergency department TIA patients managed using an accelerated diagnostic protocol (ADP) in an observation unit (EDOU) will experience:

- shorter length of stays
- lower costs
- comparable clinical outcomes

. . . relative to traditional inpatient admission.

## Methods

An IRB approved prospective randomized study

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## Setting:

- William Beaumont Hospital: A high-volume university-affiliated suburban teaching hospital
  - Emergency department
    - 2005 ED census = 115,894
  - ED observation unit = 21 beds
    - Emergency physician - "admitting" physician for all patients

## Patient population:

- Presented to the ED with symptoms of TIA
- ED evaluation:
  - History and physical
  - ECG, monitor, HCT
  - Appropriate labs
  - Diagnosis of TIA established
    - Decision to admit or observe
    - SCREENING FOR STUDY

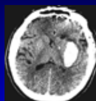
## Methods: Randomization

- Patients were consented, then:
- Sealed envelope opened -
  - Randomized to:
    - EDOU (ADP orders)
    - Inpatient bed (inpatient orders)
  - Data collection forms
- Once randomized - primary care physician notified

## Methods: TIA ADP Protocol

- Developed by multidisciplinary group
  - Used for ~1 year prior to study
- Target pathology being sought:
  - Crescendo TIAs or occult stroke
  - Paroxysmal atrial fibrillation, major arrhythmias
  - Carotid stenosis >50%
  - Intra-cardiac source of clot - (PFO, valves, etc.)

## Methods: ADP Exclusion criteria



- Persistent acute neurological deficits
- Crescendo TIAs
- Positive HCT
- Known embolic source (including a. fib)
- Known carotid stenosis (>50%)
- Non-focal symptoms
- Hypertensive encephalopathy / emergency
- Prior stroke with large remaining deficit
- Severe dementia or nursing home patient
- Unlikely to survive beyond study follow up period
- Social issues making ED discharge / follow up unlikely
- History of IV drug use

## Methods: ADP Interventions

- Four components:
  - Serial neuro exams
    - Unit staff, physician, and a neurology consult
  - Cardiac monitoring
  - Carotid dopplers
  - 2-D echo
- BOTH study groups had orders for the same four components

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## Methods: ADP Disposition criteria

- <u>Home</u>
  - No recurrent deficits, negative workup
  - Appropriate antiplatelet therapy and follow-up
- <u>Inpatient admission from EDOU</u>
  - Recurrent symptoms or neuro deficit
  - Surgical carotid stenosis (ie >50%)
  - Embolic source requiring treatment
  - Unable to safely discharge patient

## Methods: 90-day Study Follow Up

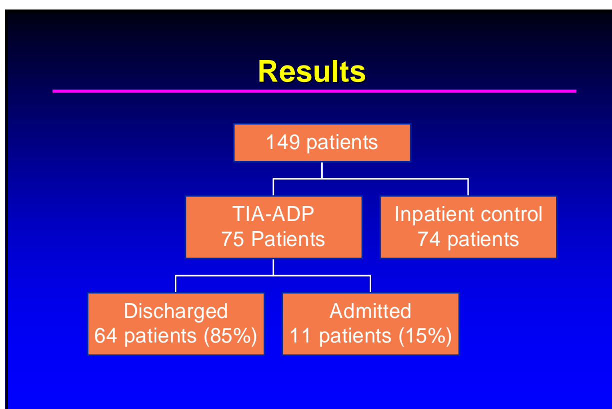
- **Methods:**
  - **Structured telephone interview**
  - **Electronic records review**
  - **Paper chart review**
- **Recidivism:**
  - **Related return visit to ED or hospitalization**
    - **Scheduled or unscheduled**
    - **Not routine office or clinic visits**

## Methods: Study Outcome Measures

- **Length of stay**
  - **ED arrival to hospital discharge**
- **90-day Total Direct Cost**
  - **Index visit costs + 90-day related costs**
  - **"EPSi" – hospital cost accounting system**
  - **Professional costs not included**
- **Clinical outcomes - stroke, recidivism**

## Statistical Methods

- **Power analysis:**
  - The study sample size had a "strong" power (.80) to detect a 25% absolute difference in the primary outcome of length of stay.
    - equivalent to 24 hours
- Analysis:
  - Univariate and descriptive statistics used
  - Difference between medians estimated by the Hodges-Lehmann method




## Results: Patient Characteristics

| | Inpatient <u>Total</u> n=74 | TIA-ADP <u>Total</u> n=75 |
|---|---|---|
| Mean Age (sd) | 67.7yr (15.4) | 68.4yr (15.3) |
| Male n (%) | 34 (46%) | 31 (41%) |
| TIA Stroke Risk Factors - mean (sd) * | 2.7 (1.4) | 2.4 (1.1) |
| Median (IQR) Initial ED Length of Stay | 6.2 hrs (5.0-6.2) | 5.7 hrs (4.5-5.5) |

* Johnston - *JAMA*. 2000;284:2901-6.

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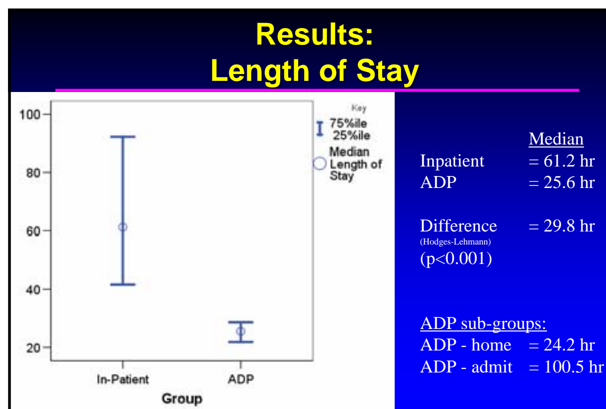
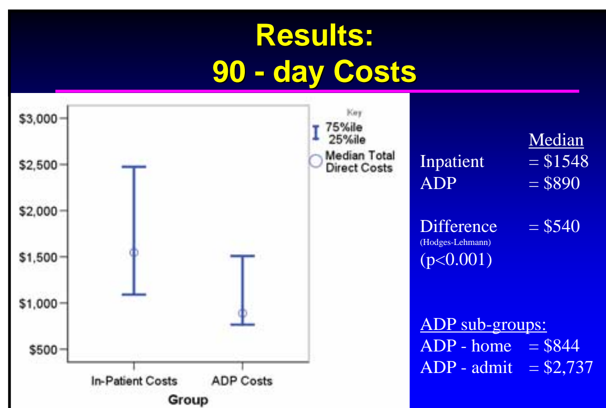
## Results: Performance of clinical testing

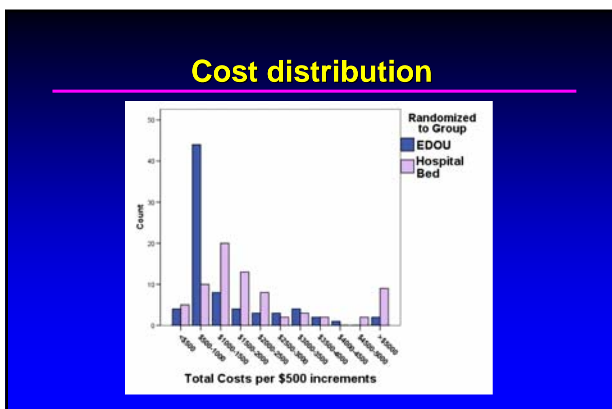
| | Inpatient (n=74) | TIA-ADP (n=75) |
|---|---|---|
| Carotid imaging | | |
| Number completed (n, %) | 67 (90.5%) | 73 (97.3%) |
| Time to completion | 25.2 hr (17.3 – 37.1) | 13.0 hr (8.4 – 18.0) |
| Echocardiography | | |
| Number completed (n, %) | 54 (73%) | 73 (97.3%) |
| Time to completion | 43.0 hr (23.8 – 63.8) | 19.1 hr (16.7 – 22.5) |




## Results: 90-Day Clinical Outcomes

| 90 Day Outcomes | Inpatient Total n=74 | TIA-ADP Total n=75 |
|---|---|---|
| Related return visits | 9 (12%) | 9 (12%) |
| Clinical Outcomes | | |
| Index visit CVA | 5 | 7 |
| Subsequent CVA (90 day) | 2 | 3 |
| Total 90 day CVA | 7 (9%) | 10 (13%) |
| Related Major event or MACE | 4 | 4 |




## Limitations and Issues:

- Limitations:
  - Not powered for individual clinical outcomes
  - Single center, EDOU
    - May not be applicable outside the EDOU
- Future Issues:
  - ADP for small strokes (NIH <3)?

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## Implications

- National feasibility of ADP:
  - 18% of EDs have an EDOU
  - 220 JCAHO stroke centers
- National health care costs
  - Potential savings if 18% used ADP:
    - $29.1 million dollars
  - Medicare observation APC
- Impact of shorter LOS
  - Patients – satisfaction, missed Dx . . .
  - Hospitals – bed availability

## Summary:

A diagnostic protocol for TIA in an EDOU is more efficient, less costly, and demonstrated comparable clinical outcomes to traditional inpatient admission.

## Acknowledgements

- FERNE / EMF
- Beaumont research staff and residency

## Questions?