

FAST-MAG Times

Volume 1, No 2

November/December 2004

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The FAST-MAG Pilot Trial *Laying the Groundwork*



The FAST-MAG phase 3 clinical trial is the product of seven years of planning, research, and testing. Before launching a large-scale research trial such as FAST-MAG, vital preliminary work must be done to show that study procedures are feasible and safe.

A key piece of preliminary work for the FAST-MAG phase 3 trial was the FAST-MAG pilot trial, conducted from 2000 to 2002. In the pilot trial, three Los Angeles City Fire Department

ambulances (RAs 19, 37, and 71) participated in enrollment and transport of study patients to

UCLA Medical Center, Westwood. The purpose of the pilot trial was to show that prehospital administration of magnesium sulfate in stroke patients was practical and could be performed safely; researchers needed to show justification for taking the study countywide, and asking all paramedics to participate.

Patients in the pilot trial were identified using the Los Angeles Prehospital Stroke Screen (LAPSS), and all were treated with IV magnesium sulfate if their symptoms had begun within 12 hours of paramedic arrival. Twenty patients were enrolled and treated, all of whom were later confirmed to have suffered a stroke. There were no serious adverse events related to field initiation of drug reported in the pilot trial.

Six of the patients showed dramatic early recoveries, including 5 of the 12 who were treated within two hours of symptom onset. Eileen McInerney, RA 37 lead paramedic, participated in the pilot trial. "We were really excited about the study," she says. "We saw a couple of patients who showed great improvement." McInerney particularly remembers one man in his 60's with sudden right-sided paralysis, whom she saw fully recover after receiving magnesium. "To see a man that vibrant stay that vibrant was a great pleasure to everyone - very satisfying" she recalls.

"Stroke is so devastating...It's nice to know there might be some hope out there."

James Schilling, RA 19 lead paramedic, echoes McInerney's sentiments.

"Overall, it was a great experience", he says. "In the beginning I was worried about getting in contact with the doctors, but it worked out well. Once we had the routine down, we got used to it and worked out the kinks."

The success of the FAST-MAG pilot trial led to the current countywide phase 3 clinical trial, funded by a 4-year, \$16 million grant from the National Institutes of Health. Paramedics who participated in the pilot trial are excited about the rollout of the phase 3 study. "We have a chance to really help people with this," says Schilling. "Stroke is so devastating, so life changing for patients," says McInerney. "It's nice to know there might be some hope out there."



Fire Department Profiles

Compton Fire Department

Paramedics at Compton Fire Department, among the earliest to be certified in FAST-MAG procedures, are part of a department serving a population of 100,000 people in the Compton area.

Founded in 1976, the paramedic program at Compton Fire now has 15 assigned paramedics, with another 10 who have moved on to other responsibilities within the department. Rounding out the EMS service for

that city are 54 EMTs, who join with paramedics to respond to 10,000 calls per year. Approximately 85% of those 10,000 are EMS calls.

Compton paramedics serve their population from four stations, utilizing two ALS units which transport primarily to St. Francis Medical Center, Martin Luther King/Drew Medical Center, Memorial Hospital of Gardena, and Suburban Medical Center.

Paramedic activities at Compton Fire Department are coordinated by Deputy Chief Jon Thompson, who reports that the most common question about FAST-MAG is "When are we going to start?"

The FAST-MAG liaison to Compton Fire Department is Jennifer Cavanaugh, RN.

Did you know? High blood pressure is the single most important risk factor for stroke.

Meet Your Nurse Coordinator

Jenny Cavanaugh, RN

Jennifer Cavanaugh, RN, clinical research nurse with FAST-MAG, joined the team in October, 2003, looking for a new challenge and a chance to broaden her professional experience. Jenny brings with her numerous years of experience in busy Southern California emergency departments. A California native who earned her BSN at Loma Linda University, Jenny says she thinks her involvement with FAST-



MAG is "a lifetime chance to be part of something pioneering the future of stroke therapy."

Jenny is liaison to **Compton Fire Department, and LA City Battalions 5 and 18**, and is looking forward to once again working with paramedics. "Because of my ER experience and paramedic ride-alongs, I have the greatest admiration and respect for the paramedics, who

are the heart of this study. I'm so excited to be working with them to make this trial possible."

Jenny's site coordinator responsibilities include **Sherman Oaks Hospital and Health Center, Valley Presbyterian Hospital, and Kaiser Foundation Hospitals, Sunset and Woodland Hills.**



FAST-MAG at the 2004 NAEMSE Symposium

The FAST-MAG team was excited to be a part of the National Association of EMS Educators (NAEMSE) 9th Annual Educational Symposium and Trade Show. This event, held at the Hollywood Renaissance Hotel in September 2004, attracted EMS educators, paramedics, doctors, and nurses from across the country.

FAST-MAG nurse coordinators staffed the trade show booth and



were happy to report a large turnout of symposium participants eager to hear about the study. "It was exciting to dialogue with professionals from across the country about stroke care in the prehospital setting" says FAST-MAG nurse coordinator Theresa Haley, RN, MSN.

Theresa Haley staffs the FAST-MAG booth at the NAEMSE symposium.

FAST FACTOID

According to the American Stroke Association, aspirin is the single most important therapeutic agent for stroke prevention. It can save your life if you have heart problems, or have had a stroke or TIA.

Good to know!

Introduction to Stroke*

Stroke is a clinical syndrome characterized by a sudden onset of neurological symptoms due to blockage or rupture of a blood vessel in the brain. Stroke types include ischemic stroke, an interruption in blood supply to the brain, and hemorrhagic stroke, a bleeding into the brain. Ischemic strokes account for 85% of all strokes, and hemorrhagic strokes, 15%.

There are a wide variety of stroke signs and symptoms, ranging from mild weakness to unilateral paralysis, to loss of speech or vision. The ultimate severity and permanence of symptoms are factors that differentiate the so-called "minor stroke" from a major stroke.

A transient ischemic attack (TIA)



is a temporary neurological deficit that resolves completely within 24 hours. The majority of TIAs, however, are of a short duration, usually resolving within one hour. Even though symptoms are short-lived, patients who have had a TIA are at greater risk of a subsequent stroke. About 5% of patients have a stroke within 2 days following a TIA, and about 10% within 90 days.

The penumbra is the zone of "stunned but salvageable" brain tissue surrounding the area of lethally injured cells. FAST-MAG is targeting this penumbral area, with the goal of minimizing permanent brain injury from stroke.

* "Introduction to Stroke" is the first in a series of articles on a variety of

The Road to Enrollment

For the past year, with the able assistance of a cadre of Los Angeles County physicians, nurses, paramedics, pharmacists, educators, and hospital administrators, FAST-MAG has been working its way toward the first enrollment of a FAST-MAG patient.

In one short year, 36 hospital research boards have approved the FAST-MAG study, paramedics in 25 EMS provider agencies have been certified in FAST-MAG procedures, more than 250 physicians have signed on as study investigators, and nearly 500 nurses have completed FAST-MAG training. IV tubing has been tested, drug kits created, case report forms developed, the FAST-MAG website built, and a how-to manual for every phase of study operations

have been written.

In addition, FAST-MAG personnel have procured study approval from the Los Angeles County and California State EMS authorities and worked with federal agencies on regulatory compliance issues.

For those who were among the first physicians to be contacted or the first paramedics to be trained, it may seem a long time since you first encountered FAST-MAG. The FAST-MAG team thanks you for your patience and continued support and wants to assure all that very shortly you will spot your nurse coordinator armed with drugs kits, quick guides and "Everything-You-Need-to-Know-About-FAST-MAG" manuals.

UPDATES

Enrollments

Watch this space for Enrollment Updates!

New FAST-MAG Hospitals

This space will tell you which hospitals are "ready to roll!"

For a complete list of participating hospitals, go to our website at www.fastmag.info

Be the first to enroll!

This space will list all enrolling stations since the last newsletter!

As of press time, paramedic training is complete for the following Fire Departments:

Alhambra
Arcadia
Beverly Hills
Burbank
Culver City
Compton
Downey
El Segundo
Hermosa Beach
La Verne
Long Beach
Los Angeles City
Los Angeles County, BN 14
Manhattan Beach
Monrovia
Montebello
Monterey Park
Pasadena
Redondo Beach
San Gabriel
San Marino
Santa Fe Springs
Santa Monica
South Pasadena
Torrance
West Covina

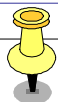
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Visit FAST-MAG on the web!
www.fastmag.info



“Because Time is Brain”



FAST-MAG FAQs

Q: Can a patient sign a consent form with an “X?”

A. No. If the patient is illiterate, they cannot read the consent form, and cannot be enrolled in the study.

Q. What if a stroke affects the writing hand?

A. If the patient is unable to use their dominant hand, they may sign using their non-dominant hand.

Q. When can someone other than the patient sign for the patient?

A. A legally authorized representative (usually a close family member) may sign for a patient **only** when the patient is not cognitively competent to sign for him or herself.

Q. What if the patient is cognitively competent, but speaks only a language other than English or Spanish?

A. If the patient is cognitively competent, but does not speak English or Spanish and cannot personally read the consent form or speak with an enrolling physician, the patient may not be enrolled. A family member may never sign for a cognitively competent patient.

What is FAST-MAG?

FAST-MAG (Field Administration of Stroke Therapy - Magnesium) is a clinical research study designed to test whether field administration of IV magnesium sulfate by paramedics improves the outcome of stroke patients when given within two hours of stroke symptom onset.

Patients who meet study criteria and in whom informed consent to participate is obtained will receive a bolus of FAST-MAG study drug (magnesium or placebo) in the field, followed by a 24-hour infusion of study drug in the hospital. Patients will be assessed by FAST-MAG key personnel at designated points over the three months following their stroke.

The study will enroll 1298 patients, involve up to 70 Los Angeles County hospitals, and more than 3,000 paramedics in 27 provider agencies. The study is funded by the National Institutes of Health, and approved by the California Statewide EMS Authority and the Los Angeles County EMS Agency.