

FAST-MAG Times

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LA County Paramedics Set Records

The Most Patients Ever in a Prehospital Stroke Study

In record numbers, paramedics throughout Los Angeles County are screening and/or enrolling patients in the FAST-MAG trial and single-handedly advancing stroke research in unprecedented ways. By the end of July 2005, 26 patients had been enrolled, the largest number of patients ever enrolled in a prehospital treatment stroke study.

While the number of stroke patients enrolled in the FAST-MAG study to date is record-breaking, the most astounding statistic is the drug delivery time achieved by the paramedics in Los Angeles County. The median time from symptom onset to drug delivery is 51 minutes, with more than two-thirds of enrolled patients receiving study drug

within one hour of symptom onset. "The first 1-2 hours after stroke onset are the "golden window" in which large volumes of threatened brain are still salvageable," says Jeffrey Saver, MD, neurology director of the UCLA Stroke Center and principal investigator for the FAST-MAG study. "The first 26 patients enrolled in FAST-MAG received study drug in this hyperacute time window, which has never before been explored in acute neuroprotective stroke trials."

The FAST-MAG trial is setting a new

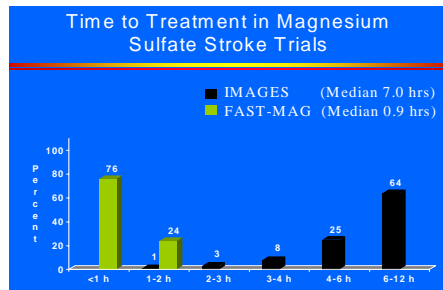
paradigm in acute stroke research. Compared with the benchmark large neuroprotective IMAGES trial published last year, FAST-MAG patients are receiving study drug much more quickly, when more brain tissue is still salvageable. In IMAGES the average time from onset to treatment was 7 hours; in FAST-MAG it is under 1 hour. In IMAGES, only 1% of patients received drug within the 1-2 hour window, and 0% under one hour. In FAST-MAG, all patients are being treated within 2 hours of onset. Paramedics in Los Angeles County are truly making history.

Also of note in the initial FAST-MAG data is that the time interval from paramedic arrival on scene to ED arrival has averaged 34 minutes, well within the typical range of on scene to door times in stroke patients nationally

and in Los Angeles County prior to the start of FAST-MAG. As hoped, FAST-MAG study procedures are not substantially delaying patient ED arrival.

Paramedics may also be interested to know the diagnosis breakdown of these first patients. Among the cerebrovascular disease patients, 59% had a cerebral infarct, 23% had intracerebral hemorrhage, and 17% had a TIA. The average age of patients was 69.7 years.

Once again, we thank the paramedics of Los Angeles County for their continued commitment to the future of stroke care!



Early Data: FAST-MAG Time to Treatment

Fire Department Profiles

La Verne Fire Department

Founded in 1887, the City of La Verne encompasses 9 square miles and serves a population of 34,000. The La Verne Fire Department paramedic program began in 1984 with 6 paramedics and one paramedic ambulance. In 2002, the department expanded to include three full-time paramedic coordinators, and 22 paramedics who staff two rescue ambulances and two assessment engines. The Fire Department fields about 2,500 calls annually, 85% of which involve emergency medical service (EMS).

La Verne Fire Department EMS calls are transported primarily to Pomona Valley Hospital Medical Center, San Dimas Community Hospital, and Foothill Presbyterian Hospital in Glendora.



La Verne FD Station 2

According to Paramedic Coordinator Dave Garcia, La Verne Fire Department paramedics are enthusiastic about participating in the FAST-MAG study, and happy to have an opportunity to expand their skill set. “The La Verne Fire Department paramedics are always interested in broadening their knowledge base, whether it be studies or new scope of practice. We want to stay on the cutting edge,” he says.

FAST-MAG liaison to La Verne Fire is Anna Yanes, RN.

Meet Your Nurse Coordinator

Anna Yanes, RN

Anna Yanes, RN, Nurse Research Coordinator, was motivated to enter nursing, a second healthcare career, to expand her professional skills and broaden her experience base. Her early nursing years were spent in the Emergency Department, meeting and exceeding her desire for new challenges.

Anna joined the FAST-MAG team in September 2003, happy to find a niche where she could combine her prior research, teaching, and patient

care experience. “FAST-MAG has been an incredible learning experience, and an opportunity to work with many different people in the health care community,” she says.

Anna is FAST-MAG liaison to the **La Verne Fire Department**, and **Los Angeles City Fire Department Battalions 4, 6, and 9**. “When I worked in the ED, I felt like I was on the “front lines.” Having spent time in the



field with the paramedics, I now know that they are the true “front liners. I have a great respect for the work they do, and am privileged to work with them to try to help stroke patients,” Anna says.

Anna’s site coordinator responsibilities include **Saint John’s Health Center in Santa Monica, Harbor-UCLA Medical Center, and Pomona Valley Hospital Medical Center.**

FAST-MAG Enrollment by Provider Agency

Los Angeles City Fire Department	13
Los Angeles County Fire Department	9
Santa Monica Fire Department	2
La Verne Fire Department	1
Burbank Fire Department	1



FAST-MAG Factoids

- At all ages, 40,000 more women than men have a stroke.
- 28% of people who have a stroke each year are under age 65.
- 7.6% of ischemic strokes and 37.5% of hemorrhagic strokes result in death within 30 days.
- 14% of people who have a stroke or TIA will have another within a year.
- About 4.7 million stroke survivors (2.3 million men, 2.4 million women) are alive today.

FAST-MAG Feedback Forum

Congratulations to the many Los Angeles County paramedics who participated in the first 26 FAST-MAG enrollments! You have kept your promise to provide feedback to us, and, in an effort to hold up our end of the bargain, we have instituted the “Feedback Forum,” a regular feature for the foreseeable future. You can contact us through your FAST-MAG nurse liaison, the FAST-MAG hotline (310-825-FAST), or website (www.fastmag.info). We welcome all questions to the Forum and thank you again for your pivotal role in this study.

1. What is the first thing to do after determining that the patient is mLAPSS positive?

The very first thing to do is determine your destination hospital. If the destination hospital is an active FAST-MAG site, call the enrolling physician number. If the destination hospital is not yet active, the patient is not eligible for FAST-MAG. Bypass of the usual destination hospital in order to enroll patients in FAST-MAG is not permitted by EMS Agency guidelines. We are working hard to have all hospitals participating in FAST-MAG sites so that this will not be an issue in the future. For now, however, **you should proceed to your usual destination hospital.**

2. My patient met all mLAPSS criteria. Why weren't they enrolled in the study?

The mLAPSS assessment is only the first step in determining eligibility for the study. **Only about two-thirds of patients who meet mLAPSS criteria will be enrolled in the study.** The following are common reasons that patients are not enrolled:

a. The patient is unaware he/she is having a stroke. “Denial of illness” is a common symptom of large right brain strokes. Patients who are unaware they are having a stroke must be considered not competent to consent. If there is no on scene family member to provide informed consent, such patients cannot be enrolled in FAST-MAG.

b. The patient cannot speak clearly. A patient may be able to understand they are having a stroke, but have serious difficulty speaking. When this happens, the patient is competent, so only the patient (and not a family member) can provide consent. If the enrolling physician cannot understand the patient's responses, they are not permitted to enroll the patient. Research ethics and regulations require that the consenting doctor be able to directly communicate with and clearly understand the patient.

c. Symptoms were first noted within 2 hours, but last known well time was more than 2 hours ago. If a patient wakes up with new right-sided weakness, it is not known if the stroke began just after he/she went to sleep or just before he/she woke up. Patients may initially report the stroke just started, but on further questioning it may become clear that, although symptoms were only just noted, the last time the patient was definitely known well is more than 2 hours ago.

d. The story changes. As frequently happens in the field and in the hospital, what the patient says to the physician may be different from what the patient says to you. Again, the FAST-MAG physician is obligated to go by only what the patient says directly to him/her. This is no reflection on the physician's trust in the history provided by the paramedics; it is simply a research requirement.

FAST-MAG is collecting data on all patients screened for the study, not just those who receive study drug. Your calls to the enrolling physician regarding patients who are not enrolled in the study are just as important to the success of the study as in those who are enrolled. Slowly, but surely, we'll get to the 1298 “perfect candidate” FAST-MAG patients that will determine magnesium's effectiveness in acute stroke patients.

(over)

3. Why have there been problems reaching the FAST-MAG enrolling physician?

As most of you know, the FAST-MAG study is the first of its kind in many ways. One of the most significant “firsts” is the field consenting of patients by the research physicians. To avoid asking the paramedics to page the physician and wait for a return call, we have opted to receive calls directly via cell phone.

In about 90% of the calls we’ve received thus far, this has worked as planned. Some of you, however, have experienced the acute frustration of not being heard by the physician, of having your call picked up by “voice mail,” or simply not getting an answer. Please know that we fully understand the high level of frustration created when you have found a potential FAST-MAG candidate, introduced the study, and been unable to go forward.

As you might imagine, and likely know from your own cell service, finding a system that works without a glitch from Antelope Valley to Long Beach is challenging. Based on feedback from the paramedics, we have made several changes and will continue to explore new options and technologies, including different cell carriers and voice over internet telephony. We will keep you apprised of all developments. We are also conducting daily tests of the enrolling numbers, and recruiting additional physicians for the Spanish line.

While it is unlikely that any system will ever be 100%, we are hopeful that recent improvements will help minimize these problems. We solicit your continued feedback as together we pioneer prehospital research.

As always, we remind you that it is not our desire to create inordinate field delays. If you are unable to contact the enrolling physician in a timely manner, you should proceed with your usual care of the patient.

FAST-MAG Paramedic Hall of Fame

Congratulations to the following first time enrolling paramedics! Space permitting, we will continue to list new enrolling paramedics in future newsletters.



Date(s)	Paramedic	Agency/Unit
5/10/05	Micheal Botenhagen Pat Kelly	LA County RS 61
5/29/05	John Smolin Dave Silva	LA County RS 164
6/1/05	Jose L. Perez Tom DeSteuben	LA City RA 102
6/4/05	Danny Montoya Jason Lee	La Verne RS 61
6/9/05	Eric Suarez Chris Siok	LA County RS 54
6/11/05	Michael Hiestand Brian Hinsley	LA County RS 107
6/13/05	Ramon Haro James Hynes Gary Stameison James Just	LA City Eng 23 LA City RA 69
6/15/05	Steven Marquez Randy Dyer	LA City RA 98
6/15/05 and 6/30/05	Mark Bridges Tom Corbridge	Santa Monica Eng 4
6/19/05	Bryan Nassour Anthony Cecola	LA City RA 89
6/22/05	Anthony Woods Ruben Munoz	LA County RS 11
7/7/05	Armando Carranza Lionel Johnson	LA City RA 105
7/8/05	Phil Rivera Jayed Swenseid	LA County RS 68
7/9/05	Bruce Alpern Steve Betteridge	LA County RS 111
7/12/05	Barry Steigelman Bob Bribiesca	LA City RA 101
7/12/05	John Baker Chris Allender	LA County RS 149
7/16/05	Mike McKean Bart Erich Javier Marquez	Santa Monica Eng 4
7/18/05	Kristina Kepner C. Cook	LA City RA 87



Thanks to you all, and to those who enrolled previously! If you participated in an enrollment between these dates and don't see your name here, please let us know and we will include you in the next newsletter!

**On behalf of the entire FAST-MAG team
THANK YOU !!!**

UPDATES

Enrollments

26 !

FAST-MAG patients enrolled as of August 16, 2005

FAST-MAG Hospitals

We now have 21 Los Angeles County hospitals open for enrollment of FAST-MAG patients. Next to each hospital name is the number of patients enrolled to date:

- California Hospital
- Glendale Adventist
- Good Samaritan Hospital
- Henry Mayo Newhall (3)
- Kaiser- Woodland Hills
- LAC- Harbor-UCLA
- LAC- Olive View (3)
- LAC- USC Medical Ctr
- Little Co. of Mary-San Pedro (1)
- Methodist Hospital of So. Cal. (1)
- Northridge Hospital (1)
- Pomona Valley Hospital
- Presbyterian Intercommunity
- Providence St. Joseph (3)
- Saint John's Health Ctr (2)
- Saint Francis Medical Ctr (2)
- San Dimas Community (2)
- Santa Monica-UCLA (2)
- Sherman Oaks Hospital
- UCLA Medical Ctr (4)
- West Hills Hospital (2)

Look for more hospitals to join the list very soon!

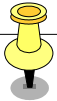
FAST-MAG CLINICAL TRIAL COORDINATING CENTER

1072 Gayley Avenue
Los Angeles, CA 90024
310-794-6160

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

FAST-MAG

“Because Time is Brain”



FAST-MAG FAQs

Q: What is the half-life of magnesium sulfate?

A: About 5 hours

Q: Does a patient have to be positive on all three motor tests to be mLAPSS positive?

A: No, a positive result on any one motor test is sufficient to answer “yes” to question 8 on the mLAPSS form. Also, remember that any findings must be unilateral and reproducible to make them eligible to go further with the study.

Q: Once paramedics are on scene, how long is it taking patients to get the study drug?

A: The on-scene to drug delivery time has averaged just under 26 minutes. Considering that this includes patient assessment, study introduction, the informed consent process, and starting the study drug, this is a remarkable achievement!

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.