

Home AEDs Did Not Reduce Post-MI Mortality

BY PATRICE WENDLING
Chicago Bureau

CHICAGO — Placing an automated external defibrillator in the homes of patients with a previous anterior wall MI did not reduce mortality in a large randomized, multicenter trial.

The primary end point of death from any cause was not significantly different between patients who were randomized to the control response of calling emergency medical services and performing CPR, and patients who were randomized to use of an automated external defibrillator (AED), followed by calling emergency services and performing CPR.

With a median follow-up of 37 months, 228 of the 3,506 (6.5%) patients in the control group died, compared with 222 of the 3,495 (6.4%) patients in the AED group (hazard ratio 0.97), principal investigator Dr. Gust H. Bardy and his associates reported at the annual meeting of the American College of Cardiology.

Of the 450 deaths in the Home Automated External Defibrillator Trial (HAT), cardiac death occurred in 129 patients in the control arm and in 138 patients in the AED group; noncardiac death occurred in 89 control patients and 81 AED patients; and tachyarrhythmia occurred in 84 control patients and 85 AED patients. Thirteen deaths could not be classified.

Patients enrolled in HAT were not candidates for implantation of a cardioverter-defibrillator. In addition, unlike standard care, they were advised about the risk of sudden cardiac arrest, said Dr. Bardy of the Seattle Institute for Cardiac Research. The patients' median age was 62 years, and their median left ventricular ejection fraction was 45%.

AEDs were used in 32 patients, of which 14 received an appropriate shock. Of those 14 patients, 9 died within 48 hours, 1 died 48 hours after shock was delivered, and only 4 (28.6%) survived to the study's end. There were no inappropriate shocks in the study, which was sponsored by the National Heart, Lung, and Blood Institute and performed at 178 clinical sites in seven countries. Of note, AEDs were used by neighbors or visitors in seven patients in cardiac arrest, and two of those patients survived long term, he said.

With the exception of diabetes, there was no significant interaction between AED use and any outcome with regard to age (65 years or older vs. younger than 65 years), gender, Q-wave versus non-Q-wave MI status, heart failure class, revascularization, or nationality (United States vs. all other countries).

The lack of benefit observed with home AED therapy in HAT is likely attributable to the lower than expected rate of overall mortality and sudden cardiac arrest, Dr. Bardy explained. This probably reflects the participants' excellent adherence to pharmacologic therapies, such as β -blockers, ACE inhibitors, and statins; their high rate of previous revascularization (72%); and their increased awareness of the risk of sudden cardiac death.

In addition, the study was based on the assumption that patients would be at home

and in the presence of their spouses or partners more than 50% of the time. In reality, only 117 events occurred at home, and only 58 of those were witnessed. About one-third of deaths started at night, and many of the daytime patients were in asystole, said Dr. Bardy, who disclosed relationships with Cameron Health Inc.

Dr. Bruce D. Lindsay, a discussant and director of cardiac electrophysiology at Washington University, St. Louis, asked Dr. Bardy to speculate on whether there

would be a benefit in recommending home AEDs for higher-risk MI patients during the 3-month period recommended in the guidelines before primary prevention therapy can begin. Dr. Bardy responded that there is no downside to the device and that all MI patients should be made aware of the risk of sudden cardiac arrest and CPR techniques.

"They need to know that this is only one small part of their overall care post MI," he said. Based on the data, however, he

said he couldn't vigorously recommend that high-risk patients buy a home AED. "But I wouldn't argue against it, if someone wanted to do it."

Anecdotally, families were happy to have a home AED, he said, even if the patient ultimately died. Survivors were "ebullient" that it was available.

In two cases, the device advised the spouse or partner not to shock, and the patient died. In one case, the patient inadvertently turned off the device. ■

Relax, we've got
painful muscle spasm
under control.

amrix[®]
Cyclobenzaprine HCl
Extended-Release Capsules



Once-daily **AMRIX**...the proven efficacy of
cyclobenzaprine with low rates of somnolence.¹

AMRIX (Cyclobenzaprine Hydrochloride Extended-Release Capsules) is indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Improvement is manifested by relief of muscle spasm and its associated signs and symptoms, namely, pain, tenderness, and limitation of motion. *AMRIX* should be used only for short periods (up to 2 or 3 weeks) because adequate evidence of effectiveness for more prolonged use is not available and because muscle spasm associated with acute, painful musculoskeletal conditions is generally of short duration and specific therapy for longer periods is seldom warranted. *AMRIX* has not been found effective in the treatment of spasticity associated with cerebral or spinal cord disease or in children with cerebral palsy.

AMRIX is contraindicated in patients who are hypersensitive to any of its components. *AMRIX* is contraindicated with concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after their discontinuation. *AMRIX* may have life-threatening interactions with MAO inhibitors. *AMRIX* is contraindicated during the acute recovery phase of myocardial infarction; in patients with arrhythmias, heart block conduction disturbances, or congestive heart failure; or in patients with hyperthyroidism. *AMRIX* may enhance the effects of alcohol, barbiturates, and other CNS depressants. *AMRIX* should not be used in elderly patients or in patients with impaired hepatic function.

In clinical trials, the most commonly reported adverse reactions ($\geq 3\%$) with *AMRIX* were dry mouth, dizziness, fatigue, nausea, dyspepsia, and constipation.

Please see brief summary of full prescribing information on the following page.

Reference: 1. Data on file. Studies 1105 and 1106. Cephalon, Inc.; 2004.



©2008 Cephalon, Inc. All rights reserved. AMR139 May 2008 Printed in USA.
AMRIX is produced with Eurand Diffucaps[®] technology.

For more information about *AMRIX*, call Cephalon Medical Services at

1-800-896-5855 or visit www.AMRIX.com