Resurrection Isn't Everything

Marvin L. Birnbaum, MD, PhD

We are well into the *decade of accountability.* Like all other disciplines in Medicine, we are being called upon to define what we do and the differences we make. We are being asked, "Is it worth it?"

How will we add up? How will we judge and be judged? Up to now, the efficacy and effectiveness of what we do has been judged by the number of clinically dead persons we successfully have resurrected. And, we do it at all costs regardless of underlying problems or likelihood of a functional recovery. Survival is easy to measure and reports of enhanced survival following clinical death in the prehospital setting got prehospital emergency care started. But, we are not even sure at what point in the chain of disease care that survival should be measured. Unfortunately, we have chosen as our end point, discharge of the previously clinically dead patients from the hospital—following a hospital course with a myriad of factors over which we have little or no control or input. Other than for a few studies, we have not looked at the functional state at discharge; and the few studies that do exist do not bear well for most "successfully" resuscitated from clinical death. Once the dying process has been initiated, we remain paralyzed at reversing the relentless progression toward dysfunction associated with the development of the post-resuscitation syndromes. We really don't know much about reanimatology.

Where then do we make our greatest contributions? Daily, we impact profoundly on the continued functionality of persons who perceive they are experiencing an "emergency"; thus, the label "emergency medical services." "An emergency occurs when the victim perceives that his/her life is *out of control.*"[1] By definition, we respond to the person's *perceived* emergency—and it is *not our emergency!* Our mission, then, is to help persons return control to their life and to prevent further loss of control.

This may seem somewhat soft, especially if we must measure what we do. Measures to demonstrate our effectiveness in helping someone to cope with his/her emergency are more difficult than are measures of survival. And currently, other than survival, we have little upon which to base the efficacy of what we do. Efficacy means that what we do is of benefit to the patient and the society in which we practice. The effectiveness of an intervention is judged on whether, when the intervention is applied, the desired efficacy is attained. It is important in our practices to separate these definitions and use them when evaluating what we do and how we do it.

Where does this take us? How do we judge and how will we be judged? The well-worn answer is, "We prevent death and minimize morbidity." Morbidity must be defined. Perhaps, it has been summed-up best by Daniels: we help people return to normal species functioning and optimize their opportunity range. But this sounds high-falutin' and seems impossible to assess. How can we state that we minimized morbidity—when, if we are effective, it doesn't happen?

The efficacy of prehospital EMS and medicine rests in this elusive arena. We know we prevent cardiac arrest in patients with substernal chest pain and PVCs, but how do we know this patient was one of the 60% who would have died within the first hour of the onset of symptoms. We know we make a difference for the patient who has sustained a cervical fracture and, because of our interventions, does not transect her spinal cord. We know we make a difference in the patient who is hypoglycemic. We

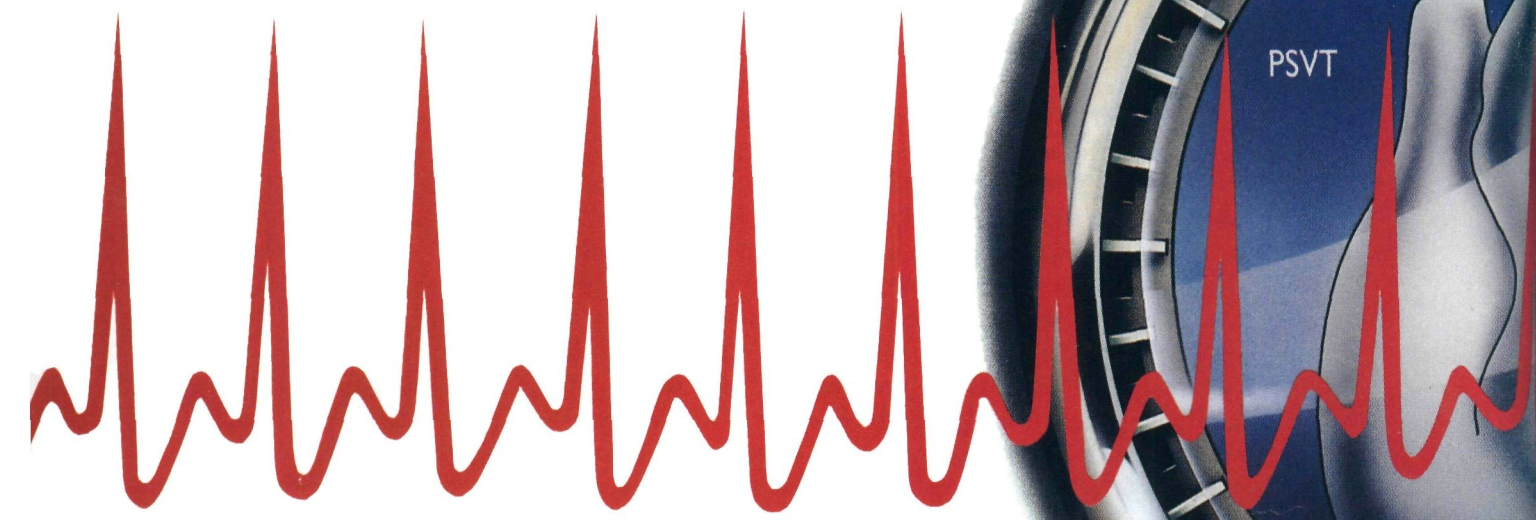
Now initial therapy for PSVT

CARDIOVERSION IN SECONDS...

PSVT.* All current antiarrhythmics act in minutes. Except one. New ADENOCARD.

In double-blind, multicenter studies,[1,2] ADENOCARD converted PSVT to NSR* in seconds. ADENOCARD demonstrated efficacy up to 92% after a 6 mg bolus dose, followed by a 12 mg bolus dose administered when necessary.

*PSVT = Paroxysmal Supraventricular Tachycardia; NSR = Normal Sinus Rhythm



BRIEF SUMMARY ADENOCARD® IV (adenosine) For Rapid Bolus Intravenous Use

DESCRIPTION:
Adenosine is an endogenous nucleoside occurring in all cells of the body. It is chemically 6-amino-9-ß-D-ribofuranosyl-9-*H*-purine.
Adenosine is a white crystalline powder. It is soluble in water and practically insoluble in alcohol. Solubility increases by warming and lowering the pH. Adenosine is not chemically related to other antiarrhythmic drugs.
Adenocard® (adenosine) is a sterile solution for rapid bolus intravenous injection and is available in 6 mg/2 mL vials. Each mL contains 3 mg adenosine and 9 mg sodium chloride in Water for Injection. The pH of the solution is between 5.5 and 7.5.

INDICATIONS AND USAGE:
Intravenous Adenocard (adenosine) is indicated for the following:
Conversion to sinus rhythm of paroxysmal supraventricular tachycardia (PSVT), including that associated with accessory bypass tracts (Wolff-Parkinson-White Syndrome). When clinically advisable, appropriate vagal maneuvers (e.g., Valsalva maneuver), should be attempted prior to Adenocard administration.
It is important to be sure the Adenocard solution actually reaches the systemic circulation (see **Dosage and Administration**).
Adenocard does not convert atrial flutter, atrial fibrillation or ventricular tachycardia to normal sinus rhythm. In the presence of atrial flutter or atrial fibrillation a transient modest slowing of ventricular response may occur immediately following Adenocard administration.

CONTRAINDICATIONS:
Intravenous Adenocard (adenosine) is contraindicated in:
1. Second- or third-degree A-V block (except in patients with a functioning artificial pacemaker).
2. Sick sinus syndrome (except in patients with a functioning artificial pacemaker).
3. Known hypersensitivity to adenosine.

WARNINGS:
Heart Block
Adenocard (adenosine) exerts its effect by decreasing conduction through the A-V node and may produce a short lasting first-, second- or third-degree heart block. In extreme cases, transient asystole may result (one case has been reported in a patient with atrial flutter who was receiving carbamazepine). Appropriate therapy should be instituted as needed. Patients who develop high-level block on one dose of Adenocard should not be given additional doses. Because of the very short half-life of adenosine, these effects are generally self-limiting.
Arrhythmias at Time of Conversion
At the time of conversion to normal sinus rhythm, a variety of new rhythms may appear on the electrocardiogram. They generally last only a few seconds without intervention, and may take the form of premature ventricular contractions, atrial premature contractions, sinus bradycardia, sinus tachycardia, skipped beats, and varying degrees of A-V nodal block. Such findings were seen in 55% of patients.

PRECAUTIONS:
Drug Interactions
Intravenous Adenocard (adenosine) has been effectively administered in the presence of other cardioactive drugs, such as digitalis, quinidine, beta-adrenergic blocking agents, calcium channel blocking agents and angiotensin converting enzyme inhibitors, without any change in the adverse reaction profile.
The effects of adenosine are antagonized by methylxanthines such as caffeine and theophylline. In the presence of methylxanthines, larger doses of adenosine may be required or adenosine may not be effective.
Adenosine effects are potentiated by dipyridamole. Thus, smaller doses of adenosine may be effective in the presence of dipyridamole. Carbamazepine has been reported to increase the degree of heart block produced by other agents. As the primary effect of adenosine is to decrease conduction through the A-V node, higher degrees of heart block may be produced in the presence of carbamazepine.
Asthma
A limited number of patients with asthma have received intravenous Adenocard (adenosine) and have not experienced exacerbation of their asthma. However, inhaled adenosine has been reported to induce bronchoconstriction in asthmatic patients but not in normal individuals. One should be alert to the possibility that adenosine could produce bronchoconstriction in patients with asthma.
Carcinogenesis, Mutagenesis
Studies in animals have not been performed to evaluate the carcinogenic potential of Adenocard (adeno-

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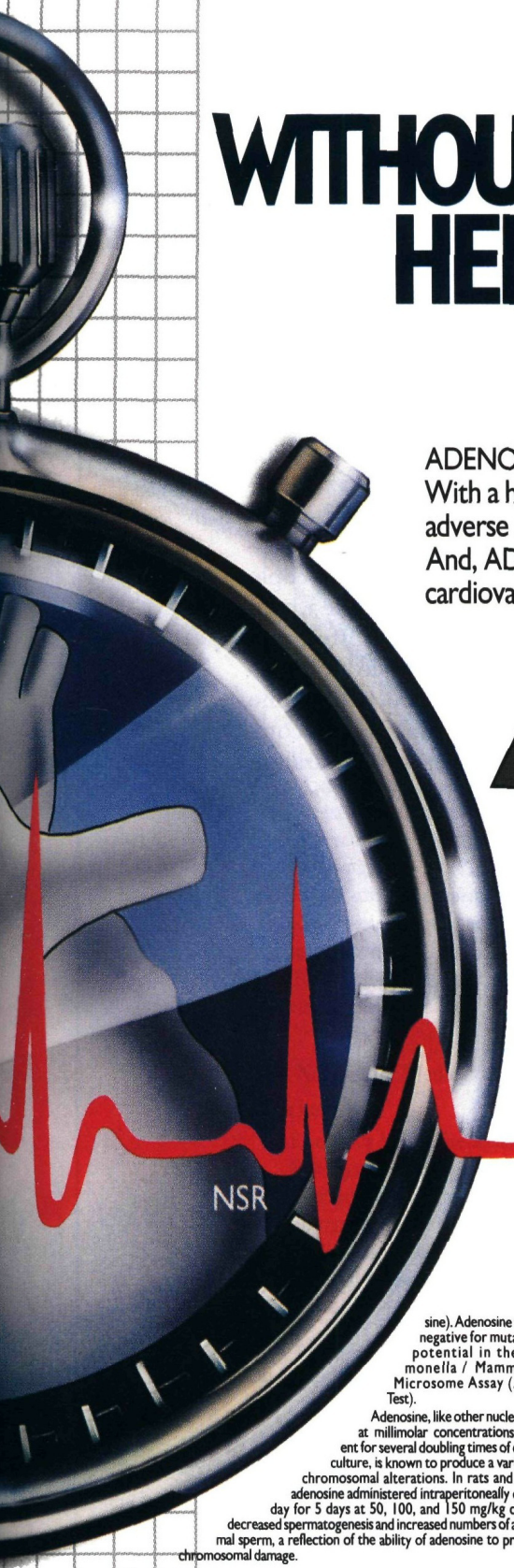
WITHOUT RESIDUAL HEMODYNAMIC REACTION



ADENOCARD has an unsurpassed safety profile.[1,2] With a half-life estimated to be less than 10 seconds, adverse reactions are minimal and of brief duration. And, ADENOCARD has no effect on subsequent cardiovascular therapies.

Adenocard® IV (adenosine)

BECAUSE IN PSVT EVERY SECOND COUNTS

sine). Adenosine tested negative for mutagenic potential in the Salmonella / Mammalian Microsome Assay (Ames Test).

Adenosine, like other nucleosides at millimolar concentrations present for several doubling times of cells in culture, is known to produce a variety of chromosomal alterations. In rats and mice, adenosine administered intraperitoneally once a day for 5 days at 50, 100, and 150 mg/kg caused decreased spermatogenesis and increased numbers of abnormal sperm, a reflection of the ability of adenosine to produce chromosomal damage.

Pregnancy

Category C. Animal reproduction studies have not been conducted with adenosine; nor have studies been performed in pregnant women. As adenosine is a naturally occurring material, widely dispersed throughout the body, no fetal effects would be anticipated. However, since it is not known whether Adenocard can cause fetal harm when administered to pregnant women, Adenocard should be used during pregnancy only if clearly needed.

Pediatrics

No controlled studies have been conducted in pediatric patients.

ADVERSE REACTIONS:

The following reactions were reported with intravenous Adenocard (adenosine) used in controlled U.S. clinical trials. (The placebo group had a less than 1% rate of all of these reactions.):

Cardiovascular:	facial flushing (18%), headache (2%), sweating, palpitations, chest pain, hypotension (less than 1%).
Respiratory:	shortness of breath/dyspnea (12%), chest pressure (7%), hyperventilation, head pressure (less than 1%).
Central Nervous System:	lightheadedness (2%), dizziness, tingling in arms, numbness (1%), apprehension, blurred vision, burning sensation, heaviness in arms, neck and back pain (less than 1%).
Gastrointestinal:	nausea (3%), metallic taste, tightness in throat, pressure in groin (less than 1%).

OVERDOSAGE:

The half-life of Adenocard (adenosine) is less than 10 seconds. Thus, adverse effects are generally rapidly self-limiting. Treatment of any prolonged adverse effects should be individualized and be directed toward the specific effect. Methylxanthines, such as caffeine and theophylline, are competitive antagonists of adenosine.

DOSAGE AND ADMINISTRATION:

For rapid bolus intravenous use only.

Adenocard (adenosine) Injection should be given as a rapid bolus intravenous injection. To be certain the solution reaches the systemic circulation, it should be administered either directly into a vein or, if given into an IV line, it should be given as proximal as possible and followed by a rapid saline flush.

The recommended intravenous doses for adults are as follows:

Initial dose: 6 mg given as a rapid intravenous bolus (administered over a 1-2 second period).

Repeat administration: If the first dose does not result in elimination of the supraventricular tachycardia within 1-2 minutes, 12 mg should be given as a rapid intravenous bolus. This 12 mg dose may be repeated a second time if required.

Doses greater than 12 mg are not recommended.

CAUTION: Federal (USA) law prohibits dispensing without prescription.

Manufactured for Fujisawa Pharmaceutical Company
by Lyphomed, Division of Fujisawa USA, Inc.,
Deerfield, IL 60015 45514A Revised: April 1990

References: 1. A double-blind, multicenter comparison of intravenous adenosine (ADENOCARD®) to intravenous placebo in the termination of spontaneous or induced paroxysmal supraventricular tachycardia, data on file, Fujisawa Pharmaceutical Company, *1989*. **2.** A double-blind, placebo controlled parallel group multicenter comparison of intravenous adenosine (ADENOCARD®) to intravenous verapamil and placebo in the termination of spontaneous or induced paroxysmal supraventricular tachycardia, data on file, Fujisawa Pharmaceutical Company, 1988.

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know we make a difference for the person suffering hypovolemic shock. But these ministrations really are preventative, and how do we know he/she would have crashed if we hadn't been there?

We need to devise some ways to demonstrate our impact on these patients. Unfortunately, controlled experiments in these areas are not possible. But, there are ways to measure the impact of our interventions and achievement of beneficial outcomes. First, we must identify areas in which we believe we make a difference (produce benefits). Second, we must develop tools that are sufficiently sensitive to show changes in patient conditions during the short time we spend with them; we could demonstrate changes in severity for specific conditions. For example, we could evaluate changes in the Glascow Coma Score during our contact with a patient with an altered conscious state. We could demonstrate changes in the severity of a shock state using the American College of Surgeons' classification of severity of shock. These are severity scoring systems, and we must focus on their use. Third, we must define standards of practice in these specific arenas. Thus, we could judge and be judged according to established standards. Once standards of practice for little bits and pieces of what we do are established, criteria by which to judge our effectiveness in achieving these standards can be developed. If we are to become a well-defined part of medicine, we must define our standards. Each organization sponsoring this Journal has a major role in developing minimum standards and the criteria by which to judge our achievement of these standards. Minimum Standards must be stated for specific areas of practice. We must concentrate on well-defined bits of our practice.

We *must* come away from concentrating on how many clinically dead people we resurrect and begin to define where and how we really make a difference. The establishment of standards of practice and of criteria by which to define our ability to attain them really comprise the mission of each organization for this decade of accountability.

Reference:

1. Personal communication with Barb Bina, 1979.

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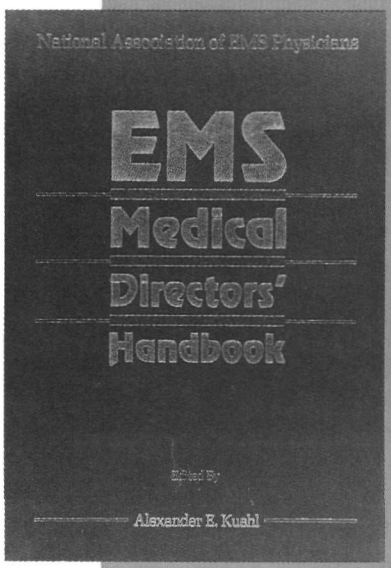

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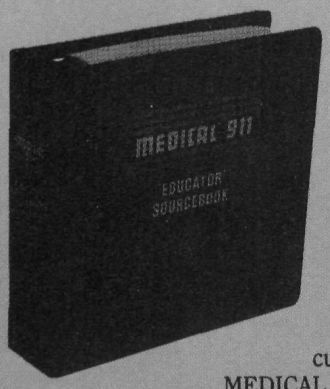

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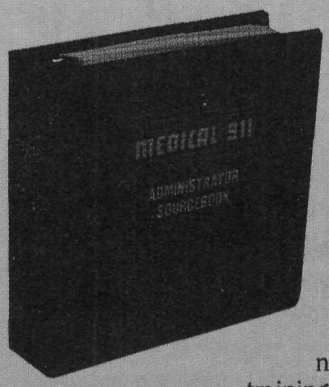

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