Trash Talk!
5 Papers to STOP Recycling

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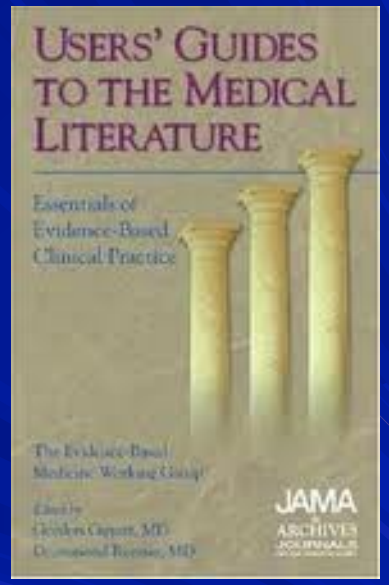
EMS & the Medical Literature

- Goal: Evidence based EMS
- Critical appraisal required:
  - No shortcuts
  - Need to do our homework before accepting & applying conclusions
  - Read the article itself, not the hype!
  - Just because it's published doesn't make it true—or applicable to what we do

Pitfalls in the source

- VALIDITY & BIAS
  - Desire to report favorable results
  - Design & methods
    - Randomized dbl blind controlled?
    - Peer-reviewed?
  - Sampling, selection, measurement bias
    - Confounders
  - Statistical analyses
  - Limitations
- APPLICABILITY TO MY EMS SETTING



Pitfalls for the Reader

- Reading just the Title &/or Abstract
  - or skipping to discussion/conclusion
  - or reading just the media report !
- Discomfort with questioning what's published
- Assuming data, stats, conclusions are correct
- Not weighting the level of evidence AND APPLICABILITY TO OUR EMS SYSTEMS
- OUR TIME CONSTRAINTS

Trash Talk #1

Prehospital Intubations and Mortality: A Level 1 Trauma Center Perspective

Cobas, Miguel A. MD*; De la Peña, Maria Alejandra MD*; Manning, Ronald RN, MSPH†; Candiotti, Keith MD*; Varon, Albert J. MD*

Incidence of "failed prehospital intubations" (PHI) in pts brought to Level 1 Trauma Center over a ~ 3 yr period:

- 31% failed PHI (63/203, incl 34 SGAs, 4 cric, 25 missed esophageal ETTs)
- Air Rescue better than ground EMS crews
- 'No difference in mortality between patients who were properly intubated and those who were not, supporting the use of BVM as an adequate method of airway mgmt'

Anesth Analg 2009:109:489-93

But:

1. Ridiculous definition of "Failed PHI":
   - all SGAs = FAILED PHI, whether or not any ETT attempt made
   - Mistakenly thought EMS protocols mandated ETT attempt first, but choice is up to OIC
   - Good ETTs = "success" regardless of # attempts
   - Didn't include arrivals with BVM vent after failed tube attempt

Partial list of flaws

2. “25 unrecognized esophageal ETTs”
   - rarely confirmed, MD just pulled out
   - In those 3 yrs, they only told us about one !!
3. Missed a LOT of cases
   - Data collected by paper questionaires done by anesthesiologist on duty
   - EMS guestimate 1/day brought in tubed
4. Mixed up who transported vs. who tubed
5. Never read final run reports or ETCO2

Additional Notes

- Authors were told of main flaws twice prior to submission
- Journal declined to print Letter to Editor without changing our critique
- Yes, there are serious airway concerns to deal with in EMS, but TRASH this article

#2: Read carefully!

Atropine Sulfate for Patients With Out-of-Hospital Cardiac Arrest due to Asystole and Pulseless Electrical Activity

The Survey of Survivors After Out-of-hospital Cardiac Arrest in KANTO Area, Japan (SOS-KANTO) Study Group

- 7448 pts with OHCA
- Epi + atropine (1712 pts) vs epi alone (5736 pts)
- Atr in asystole:↑ ROSC (32.5 v 19%) but = outcome
- Atr in PEA: ↑ ROSC but ↓ 30-day outcome (p=0.01)

Circ Japan 2011;75:580-588

But 5 problems

1. Observational design, not randomized
2. Time to first atropine dose was 30 min after EMS contact because it was only given after ED arrival + 1 epi
3. No standardization of ED Rx (58 EDs)
4. Guidelines 2000 so how good were compressions? Vent rate?
5. Post ROSC care not standardized, plus:
   - Hypothermia used in <<1% of ROSC
   - 2/3 caused by ACS but <<1% reperfused

+ 5 more

1. ~10% of the included cases had VF/VT as initial rhythm, and 18% were defib'ed
2. PEA: Were they even bradycardic?
3. Which group included the agonal rhythms? ("PEA" included wide complex slow rhythms)
4. Total dose of atropine unknown
5. EMS system used semi-AEDs, so long pauses to analyze rhythm

#3 Prehospital epinephrine use and survival among patients with OHCA

Hagihara et al, JAMA 2012;307(11):1161-8

- 417,000 arrests: 15K got epi, 402K did not
- Prehospital epi ↑ ROSC but ↓ survival and good functional outcome at 1 month

Comments:

Not debating epi, just whether this study is useful

Observational study, not randomized or controlled

Timing and total dosage NOT STATED

EMS system in Japan different from US

Cardiac Arrests in Japan

- All-Japan Utstein Registry of OHCA
- EMS Crew of 3 usually includes at least 1 emergency life-saving technician (ELST) who can place IV
- Some ELSTs certified to place ETT & give epi under on-line physician instruction; no other ACLS drugs
- Semi-AEDs, so pauses in compressions
- From epi study by Nakahara et al (Acad EM 2012):
  - only 3% got epi in <10 min from EMS start of CPR
  - this "early epi" ↑ good neuro outcome

For good review of epi see Callaway, Curr Opin Cardiol 2013

#4 Hypothermia post ROSC: ICE, The Italian Job

- Higher mortality if cooling began < 2 hrs p ROSC vs later, but confounders

Resuscitation. 2012 Jul;83(7):823-8. doi: 10.1016/j.resuscitation.2011.12.002. Epub 2011 Dec 8.

Early- versus late-initiation of therapeutic hypothermia after cardiac arrest: preliminary observations from the experience of 17 Italian intensive care units.

Italian Cooling Experience (ICE) Study Group.

- Non-randomized, observational study
- Only 122 pts among 17 ICUs, incl 80% OHCA, all rhythms
- Early group dropped to 34°C much faster, sicker to begin with, more were asystole

#5 Good Study – Bad Hype

AMIODARONE FOR RESUSCITATION AFTER OUT-OF-HOSPITAL CARDIAC ARREST DUE TO VENTRICULAR FIBRILLATION

PETER J. KUDENCHUK, M.D., LEONARD A. COBB, M.D., MICHAEL K. COPASS, M.D., RICHARD O. CUMMINS, M.D., ALIDENE M. DOHERTY, B.S.N., C.C.R.N., CAROL E. FAHRENBRUCH, M.S.P.H., ALFRED P. HALLSTROM, PH.D., WILLIAM A. MURRAY, M.D., MICHELE OLSUFKA, B.S.N., AND THOMAS WALSH, M.I.C.P.

Randomized, dbl blind, placebo controlled; good design & applicability

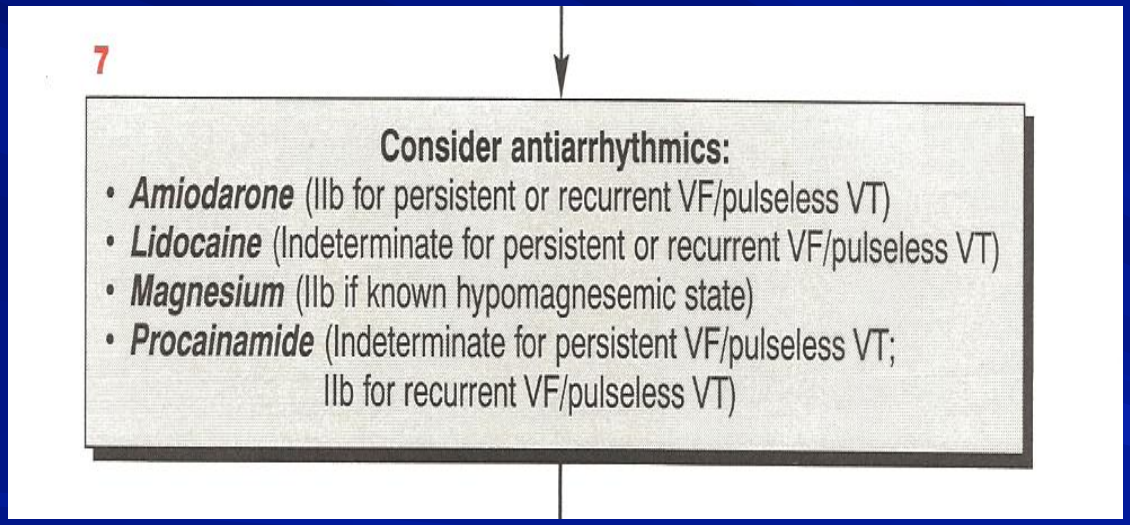
In OHCA w refractory VF/VT, <u>better survival to hospital admission</u> with amio added to ACLS

Time from dispatch to study drug: avg 21 min

Most pts got lidocaine too

NEJM 1999;341:871-8

AHA ECC Guidelines 2000: VF/VT



Drug Company Hype Gone Wild

SO….

- Do your homework
- Dig deeper
- Don’t jump on bandwagons
- As little as 10% of published peer-reviewed articles provide good evidence ready for clinical application
- Consider EMS applicability:
  - Times: dispatch, response, treatment
  - System design
  - Medic level of skill/autonomy
  - ED / Hospital care

For further reading

Evidence-based Medicine: Critical Appraisal of the Literature (Critical Appraisal Tools)

Marc A. Raslich and Gary M. Onady

Pediatr. Rev. 2007;28;132-138

DOI: 10.1542/pir.28-4-132

Users' Guides to the Medical Literature

II. How to Use an Article About Therapy or Prevention

B. What Were the Results and Will They Help Me in Caring for My Patients?

Gordon H. Guyatt, MD, MSc; David L. Sackett, MD, MSc; Deborah J. Cook, MD, MSc; for the Evidence-Based Medicine Working Group

Clinical Trials: Discerning Hype From Substance

Thomas R. Fleming, PhD

The interest in being able to interpret and report results in clinical trials as being favorable is pervasive throughout health care research. This important source of bias needs to be recognized, and approaches need to be implemented to effectively address it. The prespecified primary analyses of the primary and secondary end points of a clinical trial should be clearly specified when disseminating results in press releases and journal publications. There should be a focus on these analyses when interpreting the results. A substantial risk for biased conclusions is produced by conducting exploratory analyses with an intention to establish that the benefit-to-risk profile of the experimental intervention is favorable, rather than to determine whether it is. In exploratory analyses, *P* values will be misleading when the actual sampling context is not presented to allow for proper interpretation, and the effect sizes of outcomes having particularly favorable estimates are probably overestimated because of "random high" bias. Performing exploratory analyses should be viewed as generating hypotheses that usually require reassessment in prospectively conducted confirmatory trials. Awareness of these issues will meaningfully improve our ability to be guided by substance, not hype, in making evidence-based decisions about medical care.

Ann Intern Med. 2010;153:400-406. www.annals.org

For author affiliation, see end of text.