

TASERS

Interpreting the literature

Keith Chambers BSc MHSc MD



Background

- Conflict of interest / Here at the request of the Braidwood Commission for independent view
- My Approach: Similar to that of the Drug Assessment Working Group at UBC (provincial), review editor Cochrane Collaboration Hypertensive Group (global), Ass. Director of the Evaluation Unit (C2E2) at Vancouver Coastal Health Research Unit (VGH), courses taught in Health Care and Epidemiology UBC.
- Apply accepted principles from clinical epidemiology in reviewing the scientific material presented. Scope limited to assessing the available scientific material.


Background

- Its my assumption for the purposes of this presentation that Taser is similiar, in many ways, to medical interventions such as new drug therapies (anti-psychotics and antidepressants control behavior but have potentially harmful side effects) and new medical devices (stents).
- On review of the internet, databases and the company website, it appears that there has been good coverage by the presenters.
- A great deal of scientific material has been presented, by a number of presenters. In addition, a good deal of anecdotal material has also been presented.
- Conflicting interpretations have been made.
- There is a real problem of one of perspective, to find a framework for valid interpretation.

Some Basics

1. Anecdotal experiences. (Should they raise concern? Yes! But often wrong and misleading and can't be used to measure harm or benefit). Subject to bias and lack a valid comparison.
2. What's missing can be as important as what's presented.
3. Beware of statistics. Especially descriptive ones.
4. Beware of extrapolations to the real world.

Some Terms

1. Effectiveness vs. Efficacy/ Generalizability
 2. Comparison groups
 3. Bias potential
 4. Quality (hierarchy) of study design (meta-analysis, systematic review, controlled trial, analytic study vs. animal studies, bench research, volunteer studies, case reports, population data)
 5. Power
 6. Relative risk vs. Absolute risk
 7. Causation
- 

Question 1. What is a meta-analysis and why so important?

1. Combines data from like studies (usually clinical trials) in a statistical way (bigger numbers). Allows a better look at real world populations and differences (heterogeneity and effectiveness).
2. Increases the ability or power to see potential harms and benefits. Eg. In the 1990's, until a meta-analysis on treating heart attacks was published, "Ineffective treatments were being recommended, and highly effective treatments were not"₁
3. It may not be practical or feasible but if missing, " it is a great criticism₁" (of our profession).

Question 1a. What's a systematic review?

- Eg. A review on the treatment of hypertension showed that the risk of death was not reduced in newer drugs as thought_{5,6}
- Systematic reviews summarize similar studies and assess quality without statistically combining the data.
- Taser: No meta-analyses or systematic reviews could be identified₂₋₄.

Question 2. Has a controlled trial been undertaken?

1. Comparison group to measure relative effect size.
 2. Randomized to limit known and unknown bias
 3. Effectiveness vs. Efficacy
 4. Generalizability
- No study was identified (ABA, geog.)
 - Expensive, Feasible?...

Question 3. Are there any human analytic studies (case/control, cohort)?

1. Problems with bias. Recall bias, matching bias, underreporting
 2. Can estimate relative risk
- One case control study was found by Ordog₇. It showed that 50% vs. 1.4% died comparing “.38 special” to a Taser. Problems are small N (N=22), so most injuries (TBI?) not seen. Indicates a relatively high mortality rate for Taser (>1/100). Old study and use has changed?

Question 4. Are there any other human studies, looking at safety?

(Hypothesis generating level? Ideas not answers?)

1. Ho et al, (2006)₉. resting, healthy, single 5 sec shot, attached to back. ECG not during shot. Small N=66.
2. Vilke et al (2008)₁₁. Small N=32, Healthy, single shot 5 sec., attached to back?, ECG changes noted.
3. Levine et al,(2007)₈. small N=105, healthy, single 5 sec. shot, back, increased HR and ECG changes.
4. Cao et al,2007₉, Myocardial capture at >240 BPM by pacemaker after taser.
5. Ho et al, (2007)₁₀ ,Lactate goes up 15.8 to 24.7.

Human Studies: Appraisal

Outcomes:

Cardiac capture? ECG changes? Potential for metabolic changes. Was it shown to be safe as there was no VF or cardiac capture in volunteer studies?

Design of studies:

Small sample sizes as low as 15. N= 66 is very small. Almost no power to detect adverse events, unless very high frequency. Why such small sample sizes?

Design of holding up subjects or having them lie on a mat for protection indicates an area of risk and is not real world.

Most experiments are a limited number of shots (mostly single shot) and to the back which is not the real world.

Health and weight of volunteers likely doesn't match the real world.

Bottom line is these studies not designed for the real world and lack size. In my opinion, one can't extrapolate this data to real world risks.

Question 5. What can we learn from case reports?

1. Ventricular fibrillation_{21,22}
 2. Miscarriage in a pregnant woman.₁₂
 3. Ocular injury in a male₁₈
 4. Intracranial penetration in a teenager₁₉.
 5. Acute spinal injury (compression fracture) while standing₂₀.
 6. Falls/injuries/brain injury rates?
 7. Elderly/osteoporosis?
 8. bone fracture in muscular builds?
 9. Small frames/thin chest wall?
 10. Children/teenagers
 11. Many in real world situations have health issues (heart, drugs, frailty)₂₅
 12. Many receive multiple shocks which may increase risk
- Raises questions of what is a safe population? A safe frequency?
Other injury rates? No denominators, so hard to interpret.

Question 6. What do the animal (swine) studies indicate?

1. Taser shocks can “capture” the heart_{13,14,17}
2. Location of the shock over the heart was a strong predictor of myocardial capture _{13,14}
3. Simulated excited state with adrenalin increased the capture rate. Lethal arrhythmias demonstrated₁₃
4. Fatal episodes of VF could be induced_{14,15.}

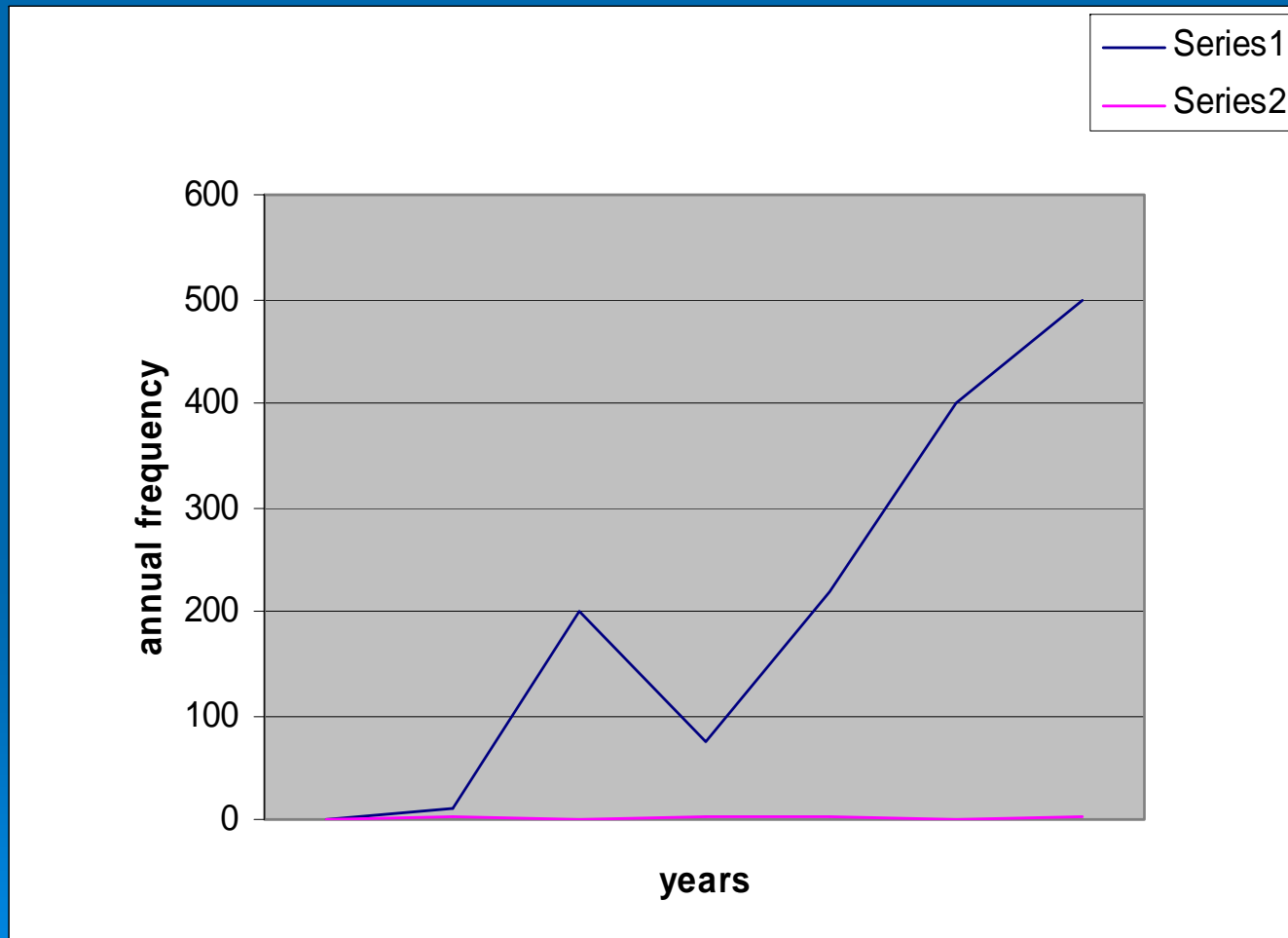
Swine Studies

5. The “X26 Taser current will directly trigger VF in Pigs”, when the stimulation dart is close enough to the heart. The distances that caused VF varied but using one standard deviation as a range implied that distances over 23mm (17+6.48) could trigger VF₁₄.
6. Echocardiography of erect humans shows skin to heart distances of 10 to 57mm₁₄.
7. Prolonged shocks (2x40sec.) caused “severe metabolic and respiratory acidosis”₁₅. The X-26 potential, we are told is 200x5secx19 pulses?
8. No VF in pigs at 19 pulses over 5 sec. similar to X-26_{16,17}.

Possible causative relationship and swine studies

1. A quadruped has more fat and muscle across the chest (poor model?)₁₄.
2. Anesthetized, so not real world. If add epinephrine to try to simulate real world, the rate of capture rises_{14,13}.
3. VF can be induced in pigs. It is biologically plausible.
4. Myocardial capture recorded with intracardiac measurement during shocks₁₃.
5. Dose response type studies.
6. Small sample size is a big problem. Catch it on the t wave. It's clearly hard to do.
7. These studies don't represent the real world.

Question 7. Is the population data compelling?



What is the chance a significant risk is being missed?

1. The problem is the event rate is low. This is an issue for population data as well as a problem for swine and volunteer studies.
2. For example, and only theoretically, lets say we wanted to be sure that a device like the Taser couldn't be responsible (for 1 out of 2 "in custody deaths") or doubling of the risk of mortality. Further, if we know that the risk of death is relatively uncommon for "in custody" situations before the introduction of Taser or when it wasn't used; then I calculated you would need just under 50,000 (23,547 per group) incidents to have 80% statistical power of detecting this increase in relative risk. A 40% increase in risk would require bigger numbers and even a 3 fold increase in risk would require comparing nearly 6000 Taser incidents to 6000 non Taser in custody deaths. This need for large numbers to measure risk is robust.
3. Therefore, There appears to be a serious chance of missing a very significant relative risk due to the use of Tasers given the existing data.

What is the chance of a significant injury being missed?

- Unpublished data from Alberta was presented which showed that approximately 231/271 or 85% of those Tasered had no/mild injury. CL of 80.4 and 89.2 were given, indicating almost certainly that no more than 20% or so would have anything worse than a mild or no injury.
- These CL are based on assumptions including a constant probability of being injured and on each event being independent. If some officers used the Taser more than others and the persons receiving the shocks were diverse in terms of risk of injury then there would be “overdispersion” (a larger variance) and a much wider CL. Simply put, the risk of injury could be higher than indicated by this data.

So where have we been?

1. A number of deaths have been associated with Taser use. This temporality does point to a possible causative relationship, especially if there are other supportive factors.
2. Animal models point to possible biological mechanisms that include myocardial capture as well as a dose response relationship. Biological plausibility and a dose response relationship also favor a causative relationship if supported by other factors such as a temporal relationship²³.
3. Animal studies and volunteer studies don't represent the real world and don't measure the magnitude of the harms or benefits.
4. The relatively small sample sizes of the studies identified, lack the power to identify low event rates.
5. There are no valid meta-analyses, systematic reviews or controlled trials on a population for which Taser use has been designed, to help determine the harms or benefits of this device in the real world.
6. Anecdotal reports and some police data have pointed to benefits^{26,27}. However, no standardized database or validated and published studies that accurately measure benefits were identified based on current use. Case reports have pointed to a number of other injuries and risks for the device.

Where are we now?

- No idea of the relative risk of death in a large population due to Taser use. A significant risk could be being missed due to a lack of study in the real world.
- No handle on what other injuries associated with Taser use might also be important (standing fractures, falling fractures, spinal cord injury, brain injury) as these are not being routinely followed in a systematic way.
- No standards for when to use the Taser between agencies according to presenters.
- No accountability for changing technology (ie. New generations of devices) and changing uses (usage creep, time to deployment).
- A bottom line is that badly needed large sample size data on which to base policy decisions is missing and is not being systematically collected at present.
- It may be too late to conduct proper controlled trials but not to set up some form of Models System₂₄ to track outcomes.

Where should we be going?

- Guidelines are badly needed. It appears reasonable to make these conservative with some form of use limitation, until appropriate population data comparing harms to benefits is available.
- Guidelines should be standardized (at the least, provincially).
- Condition of use and indications for use, by an agency, should require compliance with a standardized reporting mechanism.
- Reporting should be linked to an outcome database.
- Stakeholders (Taser International, enforcement agencies, government) should be encouraged to get together to find common ground to develop research strategies including the creation of a large, independent multi-centered database (North American wide?) to resolve unanswered questions.

Types of database areas or domains? Has variability been measured?

- Recipient characteristics?
- Recipient outcomes?
- Officer characteristics?
- Officer outcomes?
- Agency characteristics

References

1. Methods for Meta-Analysis in Medical Research. A. Sutton. Text.
2. www.cochrane.org
3. www.campbellcollaboration.org
4. www.tj.ubc.ca/cochrane
5. www.CMAJ.ca
6. J. Wright, C. Lee, K. Chambers. Systematic review of antihypertensive therapies. *CMAJ* 161(1) 1999.
7. G. Ordog, J. Wasserberger, J. Schlater et al. Electric Gun (Taser) Injuries. *Annals of Emerg. Med.* 16(1):73-8,1987.
8. Levine et al. (2007). Cardiac monitoring of human subjects exposed to the Taser. *J. Emerg. Med.* 33(2):112-117.
9. Ho et al. (2006). Cardiovascular and physiological effects of conducted electrical weapon discharge in resting adults. *Acad. Emerg. Med.* 13(60):589-595.
10. Ho et al. (2007). Respiratory effect of prolonged electrical weapon application to human volunteers. *Acad. Emerg. Med.*
11. Vilke et al. (2007). Physiological effects of a conducted electrical weapon on human subjects. *Ann. Emerg. Med.*, 50(5)569-575.
12. Mehl et al. (1992). Electricity injury from taser and miscarriage. *Acta Obstet. Gynecol. Scand.* 71:118-123
13. Nanthakumar et al. (2006). Cardiac electrophysiology consequences Of neuromuscular incapacitation device discharges. *J Amer. Col. Caed.* 48(4): 798-804.

References

14. Wu, Webster et al. (2007). Taser dart-to-heart distance that causes ventricular fibrillation in pigs. *IEEE Transactions on Bio. Med.Eng.* 54(3) 503-8.
15. Dennis et al. (2007). Acute effects of Taser X26 discharges in a swine model. *J Trauma-Injury Infection & Critical care.* 63(3):581-90.
16. Lakkireddy et al. (2006). Effects of Cocaine Intoxication on the Threshold for stun gun induction of Ventricular fibrillation. *JAC Card.* 48(4)805-11.
17. Lakkireddy et al. (2008). *Pacing & Clin. Elect.* 31(40):398-408.
18. Ng. (2005). Taser Penetrating Ocular injury. *Ophthalm.* 139:713-15.
19. Marinaro. (2007). Intracranial Penetration of a Taser dart. *A.J. Emerg. Med.* 25:733.
20. Sloane et al. (2008). Thoracic spine compression fracture after Taser activation. *J. Emerg. Med.* 34(3):283-85
21. Sadhu et al. (2006). Ventricular fibrillation and death after Taser injury. *Heart Rhythm.* 3(5):572.
22. Bergen R. (2007) Doctors question safety of Tasers after deaths. *National review of Medicine.* 4(19). (Franklin et al. (2005) letter to editor. *New England Journal of Medicine*).
23. Sackett et al. (1985). *Clinical Epidemiology A basic Science for clinical medicine.* Little, Brown & Co. C.9.
24. Stover et al. (1995). *Spinal Cord Injury. Clinical Outcomes from the Model Systems.* Aspen Publishers.
25. Antigone Barton. *Drugs Shadow Taser Cases.* (2005). PalmBeachPost.com Aug.14.
26. Jenkinson et al. (2005). The Relative Use of police use-in-force options. *Clin. For. Med.* 13:229-41