

Ilia Volkov, "Modern Clinical Research: Guidelines for the Practicing Clinician or Source of Confusion?" *The Journal of Clinical Ethics* 24, no. 4 (Winter 2013): 395-6.

## *Personal Perspective*

# Modern Clinical Research: Guidelines for the Practicing Clinician or Source of Confusion?

*Ilia Volkov*

### ABSTRACT

There is a dilemma in modern medicine, and, as a general family practitioner, this dilemma has great impact on me as a professional with a responsibility to my patients, and on the treatments I prescribe. Every day we receive a lot of updated information about relevant issues in treatment of various conditions we encounter in our daily practice. There is a great deal of interesting, serious research; however, frequently results and conclusions are very different and at times, contradictory. It is extremely difficult to evaluate updated research information, and to understand trends in current medicine. Our responsibility to our patients is to find a solution for this problem.

There comes a time in our lives that we feel the need to take account. There is a dilemma in modern medicine, and, as a general family practitioner, this dilemma has great impact on me as a professional with responsibility to my patients, and on the treatments I prescribe. I wish to share this dilemma with you.

Leonardo da Vinci is reported to have said, "Simplicity is the ultimate sophistication." In this article I will not propose multifaceted sophisticated

thoughts, but rather I would like to initiate a simple discussion of some problems we encounter in our daily activities as physicians, for which the solutions may need to be sophisticated and complex. Some of my thoughts will be of interest and useful for those of my colleagues who, after accumulating extensive experience can identify with my dilemma, as well as for doctors who are just beginning their professional careers.

I have been a physician for 25 years, a family physician, and, as we all do, I update my formal education with the current status of and advancements made in research, and I have become aware of a problem concerning basic treatment for my patients.

Modern medicine is very dynamic. Every day we receive updated information about relevant issues in treatment of various conditions that we encounter in our daily practice. There is a great deal of interesting, serious research; however, frequently results and conclusions are very different and, at times, contradictory. It may seem peculiar, but sometimes I feel a sense of nostalgia for the good old days, when we practiced medicine based on research that might have been inconclusive, and/or at best speculative. As a rule only a few of the results were significant, even though the design and logic were impressive: a random sample, researched and reported by a serious team of scientists and physicians, from reputable clinics. The conclusion of the research

included determined guidelines for a long-term treatment strategy, and the principles were clear to clinicians.

What about today? In the morning I read the results of a new, highly reputable study, with recommendations to change a treatment strategy for a particular ailment, and in the evening or the next day I read a different conclusion of other experimentation regarding the same ailment. How does this affect me and my patients? Both studies are written by reputable research teams. Usually they are double-blinded, placebo-controlled studies that are conducted in large clinical centers, and their results published in good professional journals. The problem is to choose the right treatment for the patient and avoid complications and contradictions.

Here is an example of an analysis of recommendations/guidelines for using aspirin as a preventative measure in cardiovascular events. This is a chronological account of research conclusions and recommendations from respected medical journals.

- 2004: "Despite daily aspirin treatment, many patients break through aspirin treatment and experience cardiovascular events."<sup>1</sup>
- 2005: "In this large, primary-prevention trial among women, aspirin lowered the risk of stroke without affecting the risk of myocardial infarction or death from cardiovascular causes."<sup>2</sup>
- 2006: "For women and men, aspirin therapy reduced the risk of a composite of cardiovascular events due to its effect on reducing the risk of ischemic stroke in women and MI [myocardial infarction] in men."<sup>3</sup>
- 2007: "Aspirin resistance, defined by an aggregation-based rapid platelet function assay, is associated with an increased risk of adverse clinical outcomes in stable patients with CAD [coronary artery disease]."<sup>4</sup>
- 2008: "In this study of patients with type 2 diabetes, low-dose aspirin as primary prevention did not reduce the risk of cardiovascular events."<sup>5</sup>
- 2009: "Aspirin reduces the risk for myocardial infarction in men and strokes in women."<sup>6</sup>
- 2010: "The administration of aspirin compared with placebo did not result in a significant reduction in vascular events."<sup>7</sup>
- 2011: "Aspirin was ineffective or even harmful in the majority of patients."<sup>8</sup>
- 2012: "Our study shows that among diabetic patients without previous vascular events, statins but not aspirin reduce thrombotic risk."<sup>9</sup>

What can we conclude? Aspirin—yes or no? Other examples could be found concerning control of diabetes mellitus, the use of B-blockers, psychiatric medications, different vitamins, et cetera.

No doubt the achievements in modern medicine depend on medical research, and clinical guidelines base their recommendations from evidence based upon this research, but today, for practitioners, it is extremely difficult to evaluate updated research information, and to understand trends in current medicine. Our responsibility to our patients is to find a solution for this problem.

#### NOTES

1. H. Arjomand, M. Cohen, and M.D. Ezekowitz, "Combination antithrombotic therapy with antiplatelet agents and anticoagulants for patients with atherosclerotic heart disease," *Journal of Invasive Cardiology* 16, no. 6 (May 2004): 271-8.

2. P.M. Ridker et al., "A randomized trial of low-dose aspirin in the primary prevention of cardiovascular disease in women," *New England Journal of Medicine* 352, no. 13 (31 March 2005): 1293-304, epub 7 March 2005.

3. J.S. Berger et al., "Aspirin for the primary prevention of cardiovascular events in women and men: a sex-specific meta-analysis of randomized controlled trials," *Journal of the American Medical Association* 295, no. 3 (18 January 2006): 306-13.

4. W.H. Chen et al., "Aspirin resistance and adverse clinical events in patients with coronary artery disease," *American Journal of Medicine* 120, no. 7 (July 2007): 631-5.

5. H. Ogawa et al., "Japanese Primary Prevention of Atherosclerosis With Aspirin for Diabetes (JPAD) Trial Investigators. Low-dose aspirin for primary prevention of atherosclerotic events in patients with type 2 diabetes: a randomized controlled trial," *Journal of the American Medical Association* 300, no. 18 (12 November 2008): 2134-41, epub 9 November 2008.

6. T. Wolff, T. Miller, and S. Ko, "Aspirin for the primary prevention of cardiovascular events: an update of the evidence for the U.S. Preventive Services Task Force," *Annals of Internal Medicine* 150, no. 6 (17 March 2009): 405-10.

7. F.G. Fowkes et al., "Aspirin for Asymptomatic Atherosclerosis Trialists. Aspirin for prevention of cardiovascular events in a general population screened for a low ankle brachial index: a randomized controlled trial," *Journal of the American Medical Association* 303, no. 9 (3 March 2010): 841-8.

8. J.A. Dorresteijn et al., "Aspirin for primary prevention of vascular events in women: individualized prediction of treatment effects," *European Heart Journal* 32, no. 23 (December 2011): 2962-9.

9. A. Macchia et al., "Statins but Not Aspirin Reduce Thrombotic Risk Assessed by Thrombin Generation in Diabetic Patients without Cardiovascular Events: The RATIONAL Trial," *PLoS ONE* 7, no. 3 (March 2012).