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Sharapova Case Reveals Deep Crisis Rocking Russian Medicine

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While Maria Sharapova waits for the Women's Tennis Association to decide her fate for having tested positive for meldonium, samples taken from dozens of other Russian athletes have also shown traces of the drug. Ever since Jan. 1, when the World Anti-Doping Agency (WADA) officially included the drug on its list of prohibited substances, many athletes have fallen victim to the ban — but especially in the former Soviet republics where meldonium is most prevalent.

Interestingly, WADA prohibits not only drugs that have been proven to enhance physical performance, but also those that athletes simply believe will give them an edge. In fact, WADA issued a warning last year that it would include meldonium on its list of prohibited drugs in 2016, so Russian athletes who continue to use it have only themselves, their coaches or their doctors to blame for their current troubles. More disturbing is that serious doubts remain as to whether meldonium is even effective as a medicine, much less as a doping agent.

Grindeks, the Latvian company that manufactures meldonium, or Mildronate, as it is known by its trade name, recommends the drug for a very wide range of disorders — everything from stroke and heart attack to overtiredness and withdrawal symptoms. Mildronate is very popular in Russia, where it is advertised in magazines for medical practitioners, the Health Ministry officially considers it a standard treatment and the government has included it on its list of vital drugs.

I decided to see just how convincing the evidence is concerning Mildronate's effectiveness. Because no drug can do everything, I focused on its use as a treatment for exertional angina — a type of chest pain caused by blockage of blood flow through a coronary artery or blood vessel, and brought on by activity or stress. The most thorough research on the effects of Mildronate focused on that particular condition and made use of so-called randomized clinical trials that are the generally accepted standard for proof of efficacy.

Vilnis Dzerve, the lead author of that study, stated in an interview: "We managed to increase load duration by almost one minute! At first glance, one minute does not seem like much. But in reality, that is a very good result: for example, a patient who could climb two flights of stairs without pausing could easily climb three flights after taking Mildronate. That is a big achievement!"

Further insight into that study can be found in an article published in 2010 in Seminars in Cardiovascular Medicine, a journal published by the Latvian Society of Cardiology. However, that journal is not listed on the international Medline database, and I was only able to access the article on the Grindeks website.

The article contains numerous errors. For example, the results summary states that 317 patients participated in the study, while the text of the article says that only 278 completed the trials and the data tables put that figure at 253. It is not unusual for a certain number of patients to drop out of a study, but the fact that this discrepancy is not mentioned in the article raises suspicions that the authors used the differing numbers to exaggerate the effectiveness of the drug.

The article did not state whether, in addition to Mildronate, the patients received any other treatments or surgical procedures such as angioplasty or bypass surgery that could have significantly influenced the results. It also fails to mention whether the Research Protocol was published before the study began, and that is the only guarantee that the rules of the game did not change over the course of the experiment.

The article states that some of the patients experienced chest pain even before they were subjected to physical stress, which indicates that they suffered from ailments other than exertional angina. There were other irregularities as well.

The study actually reported very modest results. Although the subjects' load duration did increase by roughly one minute, it was not the difference of, say, 1 minute versus 2 — a 100 percent increase — as Dzerve's words seem to suggest, but of 8 minutes versus almost 9 minutes after taking the drug — an increase of roughly 12 percent.

Critically-minded physicians doubt the credibility of such publications and reputable medical journals refuse to publish them at all because they cannot pass the peer review process.

Russian physicians are reluctant to adopt Western standards for determining the effectiveness of drugs and treatment methods. They prefer relying on the opinions of famous Russian doctors, official agencies and reports from loyal patients. Any demand for proof is usually perceived as nitpicking — "The drug helps. What else do you need?" — and attempts to apply scientific methods sometimes look less than convincing.

Mildronate inventor Ivars Kalvins claims that his drug has saved thousands of lives, but offers no substantive evidence as proof. Western scientists respond to such assertions with undisguised amazement. A CNN report cited Dr. Steven Nissen, former president of the American College of Cardiology as saying that Kalvins' statements in that interview were "filled with pseudoscience and unsupportable claims. It was almost humorous, it was so over the top."

Unfortunately, the doping scandal reflects not simply a problem in Russian athletics, but a profound intellectual crisis in Russian medicine.

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