



On the Topic of IVIG to “Treat” PPS

Dr. Richard L. Bruno, HD, PhD
Director, International Centre for Polio Education

Question: What do we know about IVIG (intravenous immunoglobulin) treatment for post-polio syndrome? My friend has been referred to a neurologist who recommends that she join a trial. She wants to know more before she says yes or no.

Dr. Bruno’s Response: There have been several studies of IVIG in polio survivors and not one of them has shown any benefit. The company that did the studies sent out press releases instead of publishing the data in a journal. The press releases made all kinds of fantastic claims about the benefits of the drug. Then they sold the drug to a Japanese pharmaceutical company and there were no more press releases in the West. Here’s a summary of IVIG and PPS “treatment.”

YOU HAVE TO BE CAREFUL ABOUT MEDIA-REPORTED RESEARCH BECAUSE MUCH OF IT CAN BE FALSE...

There is a significant problem with the new world of 24-hour TV news. Drug companies, universities, hospitals and national medical associations distribute press releases about unpublished research to reporters instead of publishing research findings in peer-reviewed medical journals.

One example is a Swedish drug, Xepol, touted as the first medical PPS treatment, which we discussed in February 2008. Xepol actually first surfaced in 2004. A Karolinska Institute press release, headlined “Promising anti-inflammatory treatment for post-polio syndrome,” reported on 16 polio survivors with progressive symptoms of muscle weakness treated with intravenous immunoglobulin (IVIG), a standard treatment for inflammatory diseases: “Most patients...reported improvements in their physical status. However, the value of this is unclear, since this first study did not include a placebo group.

“Most patients” improving doesn’t tell us how many improved or by how much. A Xepol study was finally published in a 2006 medical journal. IVIG was given to 73 polio survivors and placebo to 69, and then given again in three months. Of 10 measures -- including muscle strength, questions about physical symptoms and activity, the distance subjects could walk in six minutes and time it took to stand up -- not one was statistically different between Xepol and placebo.

What’s more there was no before-drug comparison of the Xepol and placebo subjects. Subjects in the placebo group were worse than the drug group to begin with, having 17% percent more pain and walking 17% more slowly, making it harder for them to get any benefit from the drug. The authors concluded that “further studies on responding subgroups, long-term effects, and dosing schedules are needed.”

Then it’s 2008 we get, not a published journal article but another drug company press release:

"PHARMALINK REPORTS POSITIVE RESULTS FOR XEPOL"

Xepol was “effective and well tolerated” in the same subjects reported in the 2006 journal article, but now they were one year post IVIG treatment. Pain, walking ability and self-report of health “all showed significant and clinically meaningful results,” the release reported. Said Pharmedlink’s managing director, “We are very excited about this data as patients in the treated group have experienced a reduction in disease symptoms after just 12 months.”

Whoa! First, the published six-month study showed no “significant” benefits of Xepol.

Second, the new 12-month data hadn’t been published in a peer-reviewed journal, so how can we really know if any of the new results are significant or clinically meaningful in reducing “disease symptoms”?

Third, even without Xepol, the placebo group reported a decrease in pain and increase in walking speed after 12 months. However, their greater pain and walking limitation at the beginning of the study made it unlikely that they could catch up to the drug group.

I've been in this PPS business long enough to remember that one boat sailed long ago: that inflammation causes PPS. A 1995 study found that high doses of prednisone, the king of anti-inflammatory drugs, didn't decrease PPS symptoms but did cause subjects to have horrible side effects. Even a 2007 study from Norway, in which polio survivors also were given IVIG, found no change in "fatigue and muscle strength three months after treatment."

I don't know why Scandinavian researchers are hot on the trail of a treatment for PPS that's gone cold. But, regardless, you have to be careful about media-reported research because much of it turns out to be crap. Medical "facts" presented by the media change from week to week. Chocolate causes obesity, then fights cancer; a daily glass of red wine is a symptom of alcoholism, then it prevents heart disease. In this age of voracious 24-hour cable news, it's vital that we are extremely cautious when medical research is "published" via press release. Be it PPS or any medical condition, we need to read the actual published research studies, not just listen to stories on TV, to understand what's happening to our bodies and really know how to take care of ourselves.

...AND THEN THIS HAPPENED...

Thursday, May 20, 2010 - Grifols SA announced that it has reached an agreement with the Swedish company Pharmalink AB to acquire various forms of intellectual property (IP) associated with the treatment of post-polio syndrome (PPS). The acquisition is expected to be finalized in the next few weeks and will include documentation, know-how, and Swedish regulatory approvals under the trade name Xepol. Furthermore, Grifols also acquires U.S., European and Japanese patents for a specific PPS treatment method utilizing human immunoglobulin and unrestricted use of existing Pharmalink clinical trial data supporting the treatment method.

Acquisition of the PPS drug development project creates new clinical research and therapeutic treatment areas for Grifols. "Exploring the treatment of PPS consistent with our mission of developing therapies for chronically ill and underserved patient populations," said Ramon Riera, Director of Global Sales and Marketing for Grifols. Currently there are no therapies approved for the treatment of PPS.

PPS is widely recognized as a rare disease and the U.S. FDA has granted orphan drug designation for the use of human immunoglobulin in the treatment of PPS. "The promise of research on potential treatments for post-polio syndrome is welcomed by the thousands who experience its debilitating symptoms, and we hope that it is fulfilled," said Joan L. Headley, Executive Director of St. Louis, Missouri based Post-Polio Health International (PHI), the leading organization working to enhance the lives and independence of polio survivors. "It has been challenging to find treatments for this condition. We are pleased that Grifols is investing in the PPS community," Headley added.

It doesn't appear to me that Grifols "is investing in the PPS community". Xepol hasn't been heard from since.

Talk to your physician.

The Encyclopedia of Polio and Post-Polio Sequelae

contains all of [Dr. Richard Bruno's](#) articles, monographs, commentaries and "Bruno Bytes"
<https://www.papolionetwork.org/encyclopedia.html>