

# Letter to the Editor

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## **All Treatments in Tinnitus Are Experimental, Controversial, and Futuristic: A Comment on “Experimental, Controversial, and Futuristic Treatments for Chronic Tinnitus” by Folmer et al (2014)**

With interest we read the paper entitled “Experimental, Controversial, and Futuristic Treatments for Chronic Tinnitus” (Folmer et al, 2014). The authors state that the article is not meant to be an exhaustive review but that “the article reflects the authors’ professional biases and prerogatives.” This is a very correct and realistic approach because today there are no available treatments for tinnitus that are not experimental, controversial, and futuristic, if evidence-based medicine is considered as the golden standard for making the distinction between established, noncontroversial, generally accepted treatments and “experimental, controversial, and futuristic approaches.” However, in their article the authors do distinguish tinnitus treatment options between what they consider as established and evidence-based on one side and experimental, controversial (nonevidence based) and futuristic, on the other. Subsequently, the authors suggest that most patients can be treated with the established treatments in a satisfactory way. From an evidence-based point of view, neither the distinction between these two forms of treatments (established versus controversial/experimental), nor the statement that the established treatments are satisfactory are correct. We want to stress the point that the same criteria should be used to judge the scientific evidence behind the effectiveness of different treatments. When doing that, it turns out that the evidence for some treatments considered as established by Folmer et al (e.g., hearing aids) is relatively low (Hoare et al, 2014), whereas the evidence for treatments they consider as controversial/experimental is not that low (Khedr et al, 2008; Khedr et al, 2009; Anders et al, 2010; Marcondes et al, 2010; Tass et al, 2012). The fact that throughout history (all the way to nowadays), these experimental, controversial, and futuristic tinnitus treatments have been developed, likely signifies that there must be a need for them. The need clearly stems from the fact that a proportion of patients still remain untreated, suffering from their tinnitus and associated disorders.

Historically, before the advent of science, any medical treatment was experimental. Medicine developed from witchcraft and sorcery, with the insight that disease is a natural phenomenon that could be cured by natural means, without invoking supernatural powers (Smith,

1997). Founded on the work of Bacon, Newton, and the philosophical back up of Locke, the eighteenth century enlightenment brought empiricism and reductionism to science (De Ridder, 2013), although initially medicine was more art than science, scientific methods began to be applied to medicine as well. Myths that explained the world followed the same historical pathway and are still held for the same reasons that now lead to scientific knowledge (Kuhn, 1962), permitting a fluent transition from sorcery to science.

The question has been asked what drives progress in science, ideas or tools (Dyson, 2012). The Kuhnian concept proposes that science evolves through the development of new ideas, whereas the Galisonian concept proposes that new tools drive innovation in science. Kuhn, a physicist-turned philosopher, suggested that new paradigms arise when older explanations cannot explain all experimental findings anymore, and a new revolutionary explanation is forwarded. Initially it is accepted by few other scientists because of the beauty of the new idea and not so much on its evidence. Gradually, more evidence is accumulated by what Kuhn calls “normal scientists,” converting the new explanation to become the new generally accepted paradigm. Subsequently, this generally accepted idea will also be replaced by an even more fitting explanation. This is, therefore, a kind of evolutionary approach to science, in a saltatory way, like Steven Jay Gould’s punctuated equilibrium in biologic evolution, and the fittest idea will survive. The people that come up with these revolutionary new ideas, according to Kuhn are not the established scientists, but young people, new to the field and unbiased by too much prior knowledge. In Maslow’s words, “As Kuhn has shown, ‘normal science’ has been established, not by the great eagles of science—the paradigm-makers, the discoverers, the revolutionizers, but on the contrary by the majority of ‘normal scientists’, who are rather like those tiny marine animals who are building up a common coral reef. And so it is that science has come to mean primarily patience, caution, care, slowness, the art of not making mistakes, rather than courage, daring, taking big chances, gambling everything on a single throw, and ‘going for broke’” (Maslow, 2002).

In their article, Folmer et al state that “well-designed, placebo-controlled clinical trials should be conducted and analyzed before claims of efficacy are made” and that “research must demonstrate that a significant change (clinical or statistical) has occurred that can be attributed to the treatment above and beyond a placebo effect.” However, contrary to the claims of the

authors, meta-analytic studies have failed to show any evidence that available treatments have an effect on tinnitus loudness. This is the case for hearing aids (Hoare et al, 2014), sound maskers (Hobson et al, 2012), medication (Hoekstra et al, 2011; Baldo et al, 2012; Hilton et al, 2013), hyperbaric oxygen therapy (Bennett et al, 2007), acupuncture (Park et al, 2000), and neuromodulation (Meng et al, 2011). Meta-analytic evidence has only shown a beneficial effect for cognitive behavioral therapy on quality of life of tinnitus patients, but not on tinnitus loudness (Hesser et al, 2011).

In addition, Folmer et al state that tinnitus is a non-life-threatening symptom. This is the case for the majority of patients. But there is a subset of desperate tinnitus patients with suicidal ideation, who are only kept alive by the hope that better treatments will be available in the near future. Those patients who have not responded to conventional treatments may be attracted by centers that are known to develop what Folmer et al categorize as “experimental, controversial, and futuristic” treatments. These more severely impaired tinnitus patients differ from those that attend the majority of tinnitus clinics. It might become important to ask patients who are highly distressed and not helped by conventional treatments what they think of treatments considered as “experimental, controversial, and futuristic”. Is it ethical to withhold those patients from such a treatment with some chance of success if the patients are willing to undergo it, after detailed information about potential benefits and risks and after approval by an ethical committee? When the more established treatments fail, is it not the duty of the health-care provider to develop alternatives, to offer them clinical trials with appropriate methodology, and to report the results, even if this means the use of experimental, controversial, and futuristic treatments?

One of those highly distressed tinnitus patients has already spoken out loud and founded the Tinnitus Research Initiative ([www.tinnitusresearch.org](http://www.tinnitusresearch.org)). Acknowledging himself that “normal science” (Maslow, 2002) is definitely needed, but that it requires “patience, caution, care, slowness, the art of not making mistakes” (Maslow, 2002) and that it should be combined with risk-taking revolutionary ideas to move forward, he personally made the largest million dollar investment into tinnitus (Cederroth et al, 2013), to support not only science, but the development of experimental futuristic and potential controversial treatments, as well.

In real life, most likely an interaction between the two theoretical developmental concepts of science coexists (Kuhnian: new ideas versus Galisonian: new tools). Tinnitus treatment will only move forward by new insights that will lead to the development of new tools, which in turn will bring further new insights and even-

tually new treatments. Indeed, historically, more often than not, the mechanism of action is only discovered and proved after a treatment has been used. Thus, these experimental, controversial, and futuristic treatments are not only acceptable but essential and highly needed for the scientific development of tinnitus research, which will hopefully one day bring a solution to this enigmatic symptom. Eventually, experimental, controversial, and futuristic treatments might become evidence based and established, with the ongoing efforts to improve patient assessment (Langguth et al, 2007) and clinical trial methodology (Landgrebe et al, 2010; Cima et al, 2012; Landgrebe et al, 2012; Hoare et al, 2013; Pantev et al, 2014).

We agree with Folmer et al that promoting a potential, but unproven, treatment for tinnitus is ethically dubious. But here again, the same rigid scientific approach concerning promotion should be applied to the so-called established treatments. However, we could ask ourselves if excitement concerning new experimental treatments (whether vagal nerve stimulation, coordinated reset stimulation, or whatever other novel treatment) might in fact not turn out to be beneficial toward attracting investors to tinnitus, a research field that is in desperate need of support whether from private individuals, companies, grant bodies, or governments.

In summary, similar to Folmer et al who have expressed their “professional biases and prerogatives” in their article, every clinical approach used today in tinnitus is largely based on the personal philosophy of the clinician. This clearly derives from the fact that the majority of tinnitus treatments are not backed up by scientific evidence and therefore, there is no such thing like a standard of care in treating tinnitus patients. Moreover so, it derives from the availability of treatment tools the clinician/researcher has in hand. In Maslow’s words, “if you only have a hammer, everything looks like a nail” (Maslow, 2002). However, a too dogmatic approach to medicine arrests its further development. From a historical, philosophical, psychological, clinical, scientific, and ethical point of view, it is mandatory that experimental, controversial, and futuristic treatments continue to be developed and scientifically evaluated, to increase the chances for better treatments in the future. That this occurs with a risk-benefit analysis in codecision with the patient and ethical committee approvals is, of course, self-evident. Time will tell which approach or approaches will work for the millions of patients awaiting a solution that will bring relief to their problem.

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