

EDITORIAL

When a dream comes through. . .

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Abstract

This is a follow-up of a paper “My dream” published in *Climacteric* (2004;7:322–3) in which it was imagined that the WHI investigators would one day apologize to the women of the world for the unjustified damage they has caused with the misinterpretation of the WHI results. Time has shown that this is about to happen as the recent reanalysis of the study show that, contrary to what they had written, HRT does protect from cardiovascular diseases when started in the early postmenopause. Furthermore comments are made about the political background of the reported results as a disservice to the medical community and to the women, themselves.

I at once felt that there was something wrong about the noise that had been generated by the release of the results of the Women’s Health Initiative (WHI) study.

I read it again and again and, much to my astonishment, my interpretation of the announced results did not match with what had been divulgated. Therefore I decided to publish my own conclusions [1] which clearly indicated that women under 60 years of age, with vasomotor symptoms, were not at risk of cardiovascular diseases (CVD) while being treated with estrogens plus progestins. The National Institutes of Health (NIH)/WHI investigators had concluded otherwise, saying that ‘the findings applied to all women, regardless of age or health status’ [2].

Furthermore, although I did understand that the design of such a clinical trial required that all women had to take the same dose of the tested medication, as a clinician I could not accept that older women were medicated with doses much higher than what their age required. Obviously this resulted in a large number of dropouts due to side-effects (uterine bleeding, etc.).

Consequently the WHI results could not be extrapolated into good clinical practice as pretended by the WHI investigators.

There was something wrong. Among those who participated in the WHI there were, no doubt, many good clinicians who could not apply those data in their daily practice as menopause caregivers!

It was then that one night I had a ‘dream’ which I shared with the readers of *Climacteric* [3]. I imagined that the day would come when the WHI investigators would apologize to women, all over the world, for the damage they had caused with their wrong advice. I imagined that a message was being sent, through the news agencies, by many physicians to women all over the world: ‘We, the physicians who participated in a widely publicized study, known as the Women’s Health Initiative (WHI), deeply regret that our results were so severely misinterpreted by the media and also by a large segment of the medical profession. . . As investigators of that study we did our best to accurately report the findings. However, as physicians, we feel a collective responsibility to explain to all women and doctors what these results meant in order to avoid the ongoing misinterpretations. . . As physicians we feel an ethical and social responsibility to tell the people, beyond our frontiers, wherever those results have reached, that women should not be unduly alarmed. Signed by the physicians who participated in the WHI.’ This was my dream.

It is now my great pleasure to see that it seems that my dream is coming true. It took 4 years since my own interpretation of the WHI [1] until the WHI was submitted to several re-analyses [4] that confirmed what I had already concluded: women in the early menopause being treated for the relief of their vasomotor symptoms were protected from CVD [5].

During the WHI press conference in 2002 one investigator said the following: 'The Nurses' Study and one like it could be right and the Women's Health Initiative could be wrong, or vice versa... If each is right may be because the women in the two types of studies are different in a way that researchers have not yet figured out' [6].

This was probably his wise premonition of what the WHI was and what the WHI was not. How right he was and how much he has certainly suffered over the years...

The truth of the matter always comes to the surface as the years go by. In a recent article [3] of *The Wall Street Journal* that above-mentioned investigator, Jacques Rossouw, was quoted as having said: 'some investigators were upset that they weren't included in writing the first report. That was an NIH decision supported by the WHI executive committee' and adding that 'study officials wanted to make a dramatic statement'.

As put succinctly by other commentators: 'To publish data that may or may not be entirely true, or certainly premature, is a disservice to the medical profession and, most important, to our patients' [7].

It is unbelievable that such an important and authoritative department of the US Government as the NIH may have antidemocratically shut the mouth of the scientists who did the study and lied to the women and physicians of the world – that their political concerns were far more important than the American tax-payers, who ought to be reassured that their money had been well spent.

Unbelievable, but unfortunately very true!

Many remaining mysteries will certainly be unveiled in the near future, like why was the estrogen-only arm of the WHI suspended? Certainly not because of the risk of stroke. It seems that if one extra case of breast cancer had been detected in the control group, the conclusion would have been statistically very significant in that estrogens alone do protect from breast cancer! Who benefited from that? Not the women, for sure. An immediate consequence was an early suspension of the Wisdom Study [8]. The follow up of the women that had meanwhile been recruited was recently published [9], confirming that hormonal treatments soon after the menopause protect from cardiovascular diseases.

I want to take this opportunity, as I am awaking from my dream, to pay tribute to those who had, long before, foreseen the truth. Like Tom Clarkson with his experiments in monkeys [10]: time of initiation of the hormonal treatment is of capital importance as confirmed recently [11].

I presume that there are still many who remember a meeting of the North American Menopause Society during which Clarkson presented again his outstanding conclusions. It was a session not to be

forgotten, when many pseudo-scientists attacked him almost to the point of being offensive.

Nietzsche once said that 'convictions are more enemies of the truth than lies' and somebody else also said that 'the mind is like a parachute: they both work better when they open'.

In a recent lecture Leon Speroff said that 'the future of hormone therapy requires prepared minds. Let us not suffer from an insufficient number of prepared minds.'

Let us hope that American tax-payers will now force the WHI to tell the truth, the whole truth and nothing but the truth, so help them God!

We tried, two years ago, to confront American WHI investigators with some European leaders of opinion in a symposium published in *Maturitas* [11]. Unfortunately, much to everybody's surprise, only one WHI investigator refused to send his text for publication although it is available on a DVD recorded during the sessions. Why? Who knows?

The time has come to move forwards [13–15] as stipulated by many authoritative scientific associations such as the International Menopause Society [16–19], the European Menopause and Andropause Society [20] and the North American Menopause Society [21], there should not be a limit for a well-medicated hormone treatment if there are no upcoming contraindications and if its objectives are fulfilled.

It takes but a few wrong statements to cause a tsunami of panic. It takes years to correct the disaster and give back good quality of life to the women of the world.

Preventing a woman from the benefits of sound postmenopausal hormone therapy because of the fear of rare side-effects does not seem to be satisfactory medicine [1].

When World War II ended, what Sir Winston Churchill said in the House of Commons is also applicable to the ongoing discussions about hormonal treatments for the menopause: 'This is not the end, nor even the beginning of the end. It is, perhaps, the end of the beginning.'

It seems that my 'dream' was nothing but a premonition.

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