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Letter to the Editor

Ozone therapy seems to be safe, but is it really clinically effective?

L. TYLICKI, B. RUTKOWSKI

Department of Nephrology, Transplantology and Internal Medicine, Medical University of Gdansk, Gdansk - Poland

Dear Editor,

In the March issue of the International Journal of Artificial Organs a comprehensive editorial concerning ozone therapy was published (1). Given that the English-language medical literature on this subject is very limited, the idea of the Editors to review the main aspects associated with ozonated autohemotherapy (O_3-AHT), the generally used route of ozone implementation should be particularly appreciated. The main concern related to the therapeutic implementation of ozone in medicine is the lack of controlled clinical studies evaluating the safety as well as the clinical effectiveness of this still controversial approach. In this regard, we would like to present some of the results of recent studies performed in our center.

The main criticism related to ozone therapy concerns the oxidative properties of ozone and its potentially harmful influence on cells and biological processes. Since medical ozone is commonly administered as a major O_3-AHT during which gas interacts with blood, the possible detrimental effects may involve blood cellular elements and plasma components. To shed more light on this aspect, we performed a series of controlled studies to check the safety of O_3-AHT using the therapeutic dose of ozone - 50 µg/mL oxygen-ozone mixture in the patients with peripheral arterial disease chronically treated with dialysis. Although a significant decrease in the glutathione level in erythrocytes was seen, most probably associated with its increased consumption under oxidative conditions, the antioxidant defence system was able to protect the cells against oxidative damaging processes. The plasma concentration of the final products of protein and lipid peroxidation, as well as hemolysis extent, did not change after O_3-AHT, when compared to autohemotherapy without ozone exposure, which served as a control (2). Given the possible role of reactive oxygen species and oxidative stress in the development of arteriosclerosis, the influence of O_3-AHT on some processes related to this common pathology were evaluated as well. No changes in the plasma activity of von Willebrand factor, commonly treated as an index of endothelial cell injury, were observed (3). In addition, the degree of spontaneous and agonist-induced platelet aggregation did not differ from that seen after control authohemotherapy (4). Finally, very recent studies (not yet published) revealed that O_3-AHT did not induce the inflammation process assessed by C-reactive protein and interleukin-6 plasma level or influence deleteriously the cytotoxic activity of natural killer cells, which represent the first line of cellular innate immunological response.

Although O_3-AHT has been used for almost three decades, therapeutical effectiveness is still unproven. The evidence-based medicine approach requires well-designed controlled studies for this purpose. Given some previous encouraging observations (5, 6), we performed a cross-over controlled study to evaluate the influence of O_3-AHT on walking ability in patients with intermittent claudication. The significant prolongation of maximal walking distance by 22.7% and pain-free walking distance by 62.8%, assessed in a standardized march test on a treadmill, was seen (7). Given some design limitations and the fact that the main outcome was determined in treadmill tests which are based on subjective information given by the patients, the possibility cannot be excluded that a placebo effect, at least in part, plays a role in these favorable effects. Therefore, we consider that the widespread use of O_3-AHT in clinical practice should be preceded by further clinical trials involving more objective scientific methods to assess treatment effects.

Address for correspondence:
L. Tylicki, MD
Department of Nephrology,
Transplantology and Internal Medicine
Medical University of Gdansk
Gdansk 80-236
ul. Debinki 7, Poland
e-mail: leszek.tylicki@wp.pl

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