Comparison Between Intra Articular Ozone and Placebo in the Treatment of Knee Osteoarthritis: A Multicentric, Comparative, Randomized and Double-Blinded Clinical Trial

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Background/Purpose: Osteoarthritis (OA) is a common, progressive condition, which is associated with severe pain, functional disability and impairment of health related quality of life, causing a significant social and economic burden. There are no currently approved OA treatments capable of slowing OA-related structural progression or delaying the need for total knee replacement. Ozone (O3) is a triatomic variety of oxygen, applied to the human organism with therapeutic aims, mainly in chronic diseases that have little benefit with allopathic medicine, like the rheumatic disease osteoarthritis. However, there are only a few articles about the use of intra articular ozone in the treatment of knee osteoarthritis and they are just case reports. Objective: To determine if knee osteoarthritis treatment with intra articular ozone is more effective than knee osteoarthritis treatment with intra articular placebo in relation to pain reduction, joint functional improvement and quality of life. Methods: Randomized, double-blinded, placebo controlled clinical trial. Ozone was generated by using an Ozone & Life O&L 3.0RM generator. Patients from treatment group received an injection of ozone 20µg/ml 10ml. Patients from placebo group received an injection of air 10 ml. Both groups were treated once a week during 8 consecutive weeks. We evaluated Visual Analogic Scale (VAS), Lequesne’s Index, Timed Up and Go Test (TUG Test), SF-36 questionnaire, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Geriatric Pain Measure (GPM) after allocation, after 4th and 8th injections and 8 weeks after the last injection. Normally distributed variables were analyzed using parametric methods and those with asymmetric distribution with nonparametric statics. It was performed an intention-to-treat analysis.

Results: 98 subjects, 63 from ozone group and 35 from placebo group completed the study. Groups were similar in relation to sociodemographic data. TUG presented no significant
difference between the groups. In relation to Lequesne’s Index, there was a significantly statistical difference from 4th week on (p<0.001) and that was maintained until 16th week (p<0.001), favorable to ozone group. Similar results were observed in relation to VAS (p<0.000) and to GPM (p<0.001), showing a pain reduction and improvement in daily activities in ozone group soon after the beginning of the intervention and during the treatment. From the second evaluation on, according to SF36, there was sensible improvement in all levels of quality of life, showing that ozone had a remarkable effect on the treatment group patients’ lives. **Conclusion:** Our study showed the efficacy of intra articular treatment of knee osteoarthritis with ozone in relation to pain reduction and improvement of joint function and life quality.

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