First UAE Pilot Study on the Therapeutic Potential of Oxygen-Ozone Mixtures

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SUMMARY - For many years ozone therapy has represented a challenge in the treatment of several pathologies of apparent different aetiology.

The first uses mainly addressed aesthetic problems and only minimum efforts were made to improve the scientific interpretation of ozone's therapeutic potential. In recent years, many reports have revealed the ability of ozone to reduce pain in several osteoarticular diseases and in lumbar disk herniation. In addition, the blood ozonation technique has been proved to improve the antioxidative potential of the organism inducing an unusual sense of well-being.

The lack of randomised clinical trials still induce scepticism even tough direct clinical evidence has reinforced the hypothesis that oxygen-ozone mixtures could be useful in different illnesses and in reducing the intake of the most widely used drugs such as cortisones and anti-inflammatory agents.

This work is the first large pilot study aimed at a clinical characterization of the efficacy of low ozone concentrations.

Introduction

The natural gas ozone has been widely used in recent decades to treat several pathologies in conjunction with oxygen (O_2-O_3). Even if its use increased dramatically in the last few years, much criticism has focused on the lack of randomised clinical studies. Nevertheless, efforts have been made [1] to fill this gap by collecting a large number of direct clinical observations with more accurate epidemiological studies.

We believe that the major difficulties of many pioneers in this new field are mainly due to a preventive closure to this new approach for the simple reason that many physicians are still anchored to the pharmacological concept of dose-effect drug action. Our experience, based on some basic results [2-3], is consistent with different molecular mechanisms, perhaps at the biochemical level, with the induction of pathways that could be activated by various mediators such as nitric oxide (NO) or enzyme induction processes.

Indeed, many recent basic data reveal its efficacy also in contrast to the overproduction of free radicals by means of a facilitatory effect on the most important enzymes responsible for scavenger activity within the cells [4].

Despitethe existing difficulties in determining some clinical parameters such as the distribution, half life and bio-disposability of ozone due to its rapid kinetics the systematic refusal of this therapy avoiding any efforts to validate it scientifically is surprising.

The main criticism is claimed to be a placebo effect induced by O_2

O_3. To our knowledge, it is very difficult to explain a placebo effect lasting one or more years. In addition, looking at the failure of many recent drugs which [*after initial government approval fol-*

lowing the more ethical and complete studies of toxicology, pharmacokinetics and pre-clinical trials as stated by the current law] have been withdrawn from the market (see Lipobay), the complete neglect of the safety and usefulness of O_2-O_3 treatment is even more surprising.

In our opinion, looking at the wide epidemiology (more than four million people all over the world) and the virtual absence of side effects (less than 0,001%, mainly iatrogenic), more attention must be focused on O_2-O_3 therapy. We suggest that new protocols of validation be devised taking into account the chemistry of ozone and its biological action following alternative schemes, not exclusively bound to the mass-action theory.

Following the recent literature, the administration of low concentrations of O_2-O_3 mixture has been proved to improve patient status in some immune and inflammatory syndromes [5].

As proposed at the last IOA congress in London, one of the most important effects of O_2-O_3 could be its indirect antioxidant action with a potential antiageing effect [2]. Indeed, *ozone* is known to be a potent oxidant and, when used at low concentrations, could induce a positive preconditioning, making the cell less vulnerable to the constant oxidizing stress. This is one of the most attractive interpretations concerning *ozone* action and currently represents a major scientific challenge [3-4]. The hypothesis has been accepted and scientifically tested in the case of the ischaemic preconditioning.

Practical experience all over the world shows how health departments are trying to develop new technologies capable of solving scientific, logistic and financial problems to reduce healthcare costs. Important reports and information on the use of ozone from Germany, the United States, Austria, Italy, Cuba, Russia and France suggested its use both in hospitals and in local healthcare facilities with great advantages for the public health service. Looking at the various medical treatments proposed we understand how *ozone* application could represent an important complement to the multiple drug treatments officially proposed for the same pathologies. Among these we cite the reports on hypertension [6], central nervous system lesions [7], diarrhoea due to Giardia Lamblia [8], which, as reported from WHO, infests 2% of Europeans, hepatitis [9], HIV [10], peripheral ischemia [11-12] and rheumatoid arthritis [13]. The development of research constantly gives us more important basic knowledge [14, 15], which is leading to more specific and safe uses.

Without considering specialist pathologies, for which O_2-O_3 and ozone derivatives provides excellent results while having no side effects (arthrosis pain, mycotic superinfections, leg tiredness, acne, etc.), O_2-O_3 could represent a key agent for healthy living and an antiageing factor.

Following the above considerations, and under the approval of the local authorities, we started a clinical approach in a major healthcare facility in the United Arabian Emirates.

Clinical Protocols

The pilot study was designed for the treatment of various common pathologies using ozone-oxygen (O_2-O_3) therapy [16] and was devised to evaluate the most important clinical signs in a population of 276 subjects. Due to some recent data dealing on pancreatic damage protection [17] and the high incidence of diabetes in this country, particular attention was paid to these patients by means of a controlled protocol of rectal insufflations (60-100 ml mixture 30-50 μg/ml ozone/oxygen) joined with the minor autohaemo (see below).

The local intradermic (200 ml mixture 5-12 μg/ ml ozone/oxygen) and systemic minor autohemo (10 ml mixture 30-60 μg/ml ozone/oxygen in 10 ml blood) in conjunction with the major autohemo (120 ml mixture 30-60 μg/ml ozone/oxygen in 120 ml blood) were assessed as protocols for O_2-O_3 therapy.

Admission statements, all admitted after clinical and diagnostic evaluation of the pathological status.

Exclusion statements, clinical evidence of hyperthyroidism and pregnancy.

Results

276 patients were scheduled for the O_2-O_3 protocol. Among these, 12 (4.3%) were excluded prior to the study due to the exclusion statements. During the first two months 1040 treatments were performed. 65 patients completed the treatment (23.5%) while 154 (55.8%) reached the middle phase of the programmed sessions. The remaining 45 patients (16.3%) are still in progress with the indicated treatment.

The figure shows the distribution between sexes with a medium age of 47 years both for females and males.

The patients were classified for a main clinical sign or diagnosis followed by three minor or collateral symptoms. The following figure shows the distribution of the patients according with the reported clinical statement.

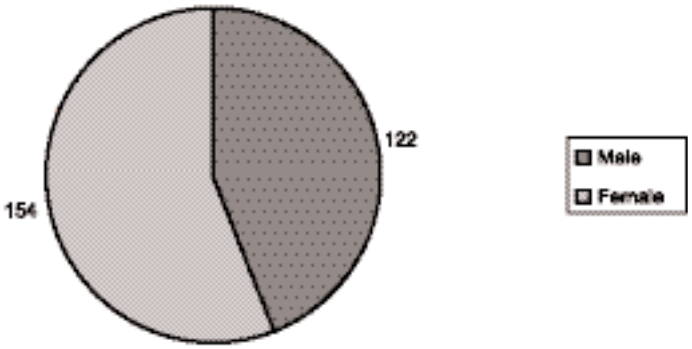
Low back and knee pain represented the main clinical signs for both sexes with a mean percentage of 29.7% and 27.9% respectively.

For the patients who reached the end of treat-

ment (8-12 sessions), the reduction of the symptoms during treatment (mid) and at the end of the therapy (end) was evaluated according to the VAS scale by assuming the start value of 100%.

The next figure shows the distribution of the 65 patients and the relative distribution between the male and female subjects. The best result was obtained in males who achieved a 71% reduction of clinical signs compared to the 64% reduction in females at the end of the treatment. The average reduction of pain for both sexes was 40% in the mid and 67% in the end phase of the treatment, respectively.

Similar results were obtained for the sessions still in progress (154 patients) with significant reductions of the reported symptoms as shown in the next figure. The mean symptoms reduction in the mid phase was 38% with respect to the control value. The data obtained are the same when compared to the same result obtained in the closed sessions (40%).



Comments and Perspectives

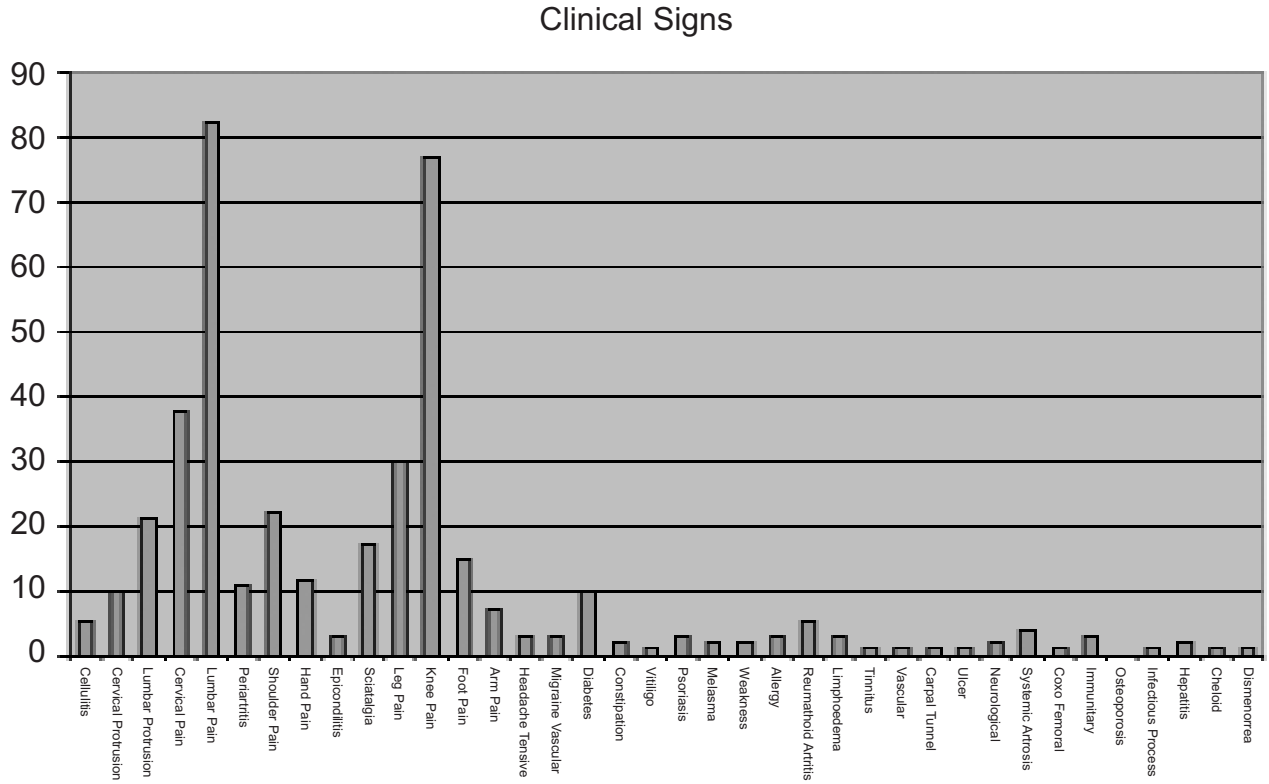
The study is still in progress and a follow-up period of one year has been scheduled to reach final confirmation of the actual data. Particular attention will be focused on a potential combination therapy in conjunction with the bio-resonance technique.

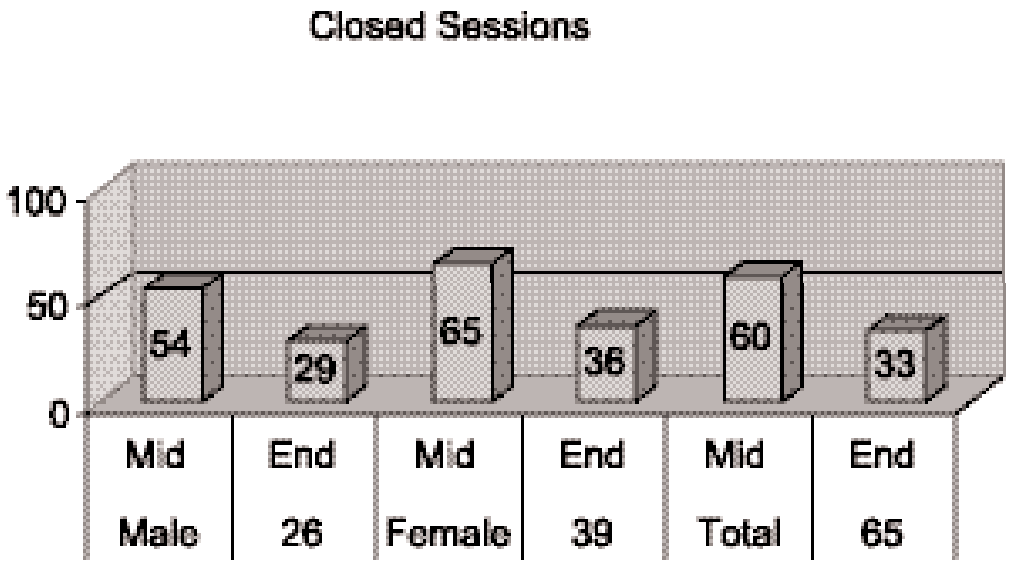
In addition, a parallel study with a patient group treated by parallel orthodox pharmacological treatment will be scheduled and randomised with the present O_2-O_3 epidemiological data.

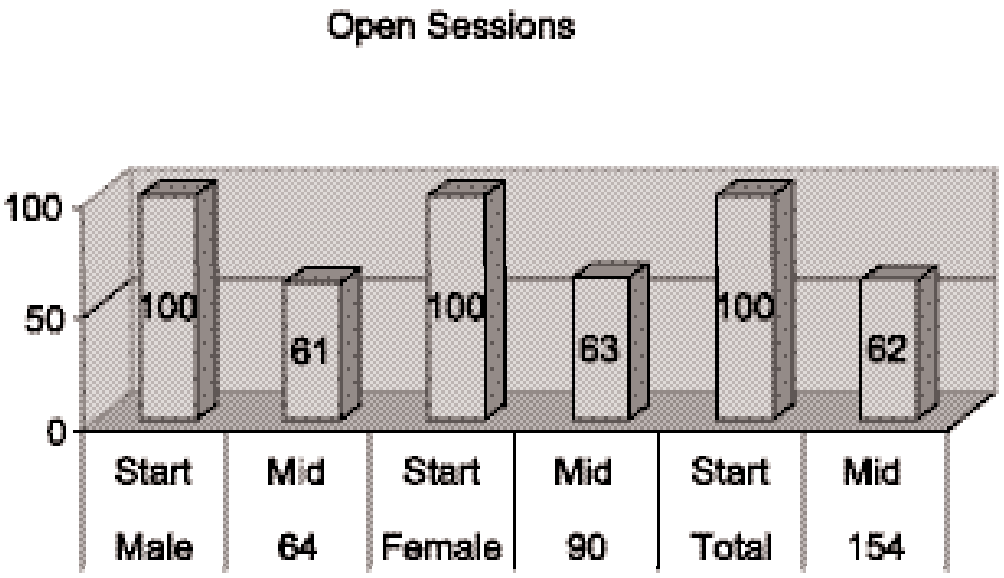
At clinical level:

– All the O_2-O_3 patients showed a more rapid relief of symptoms after taking FANS or other symptomatic drugs when compared to the period preceding the O_2-O_3 treatment;

– The haematological parameters, including ESR, transaminases and hemochromo-cytometric data, resulted in the normal range after the final O_2-O_3 session;







– All the patients submitted to the protocol constantly referred an unusual psychological well-being.

In conclusion, the present results are similar to those of the other studies carried out using O_2-O_3 therapy. We hope that in conjunction with, and not as an alternative to the most common pharmacological therapies for all the pathologies that most frequently affect the human population, O_2-O_3 treatment could represent a valid adjunct as a

more ethical and safe medical treatment.

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