

The Safety and Benefits of Direct Intravenous Ozone Therapy (DIV)

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Abstract: Direct Intravenous Ozone Therapy (DIV) has been a method of treating diseases and conditions for many years. Internationally this method has been discouraged due to supposed risks and lack of benefits. Contrary to this opinion held by many, there is no scientific support of these allegations as there is no apparent record of injuries caused by this method or proven lack of benefits, just supposition, rumors and "medical urban myths". In fact, over the last 18 years DIV has been performed over 160,000 times at the clinic with virtually no adverse reactions of any consequence. The supposed criticisms are either academic belief that are contrary to clinical experience, or at best, based on improper method of administration elsewhere. This paper will discuss the supposed risks and show through clinical experience the fallacies and misunderstandings that exist along with the benefits of the Robins Method Protocol for DIV compared to Major Autohemotherapy (MAH).

Purpose: The purpose of this paper is to refute the many misconceptions and misunderstandings on the safety that have been asserted since the 1980's and point out the benefits concerning the use of DIV. In addition, it is the authors' intention to offer a method and protocol that has been proven both safe and effective. It is asserted that the 'Robins Method and Protocol' for DIV is possibly the only safe and effective way to perform the therapy. These protocols have been perfected over the last 17 years with adjustments being made related to reactions and results.

Extensive clinical experience should always outweigh academic opinion in the absence of published scientific evidence. I am certain that misinterpretation of reactions and or improper administration have led to DIV being poorly thought of and have led to the negative opinion about it.

Our volume of experience proves this to be the case. Clinicians working in our clinic, performed over 160,000 DIV's. Traditional MAH was offered for the first five years in our ozone clinic, giving over 45,000 therapies. Perhaps we have a unique clinical experience having practiced both methods of ozone administration in such large numbers. This allowed me to learn the benefits, risks and limitations of each. I also feel that this number of treatments is significant enough to rule out "luck" in avoiding negative reactions.

To facilitate this paper I have chosen to use just 2000 patients over the last 10 years with an average of 70 therapies each totaling 140,000 treatments.

History: While apparently DIV has been used for over 50 years, this method of ozone administration has not been attributed to any one person or clinic for it's first use or development, at least as far as it can be researched here in the USA. Unfortunately most literature on medical ozone therapy is written and published in European medical journals, which cannot easily be accessed here in the United States. So who was the first to develop this method of administration and the details of how it was first performed is

unknown to this author. Perhaps lack of history was valuable, as it did not negatively influence us when beginning to use this method or how to do it properly and safely.

While I do not know how the German (European) method of DIV was performed, it is hypothesized that the incorrect concentration of ozone gas; the incorrect position of the patient; the wrong speed of delivery; the incorrect gauge of needle; the incorrect frequency of treatments, "air" being left in the delivery system or any combination of these possibly led to the negative results and thus the banning of the use of DIV in Germany and in other countries.

Materials and Robins Method and Protocol of DIV:

A Tomco Ozone Generator (USA made) is used at a 55mcg/cc setting for all the patients in the study. A Terumo 27gauge winged infusion set (scalp vein set) and a Terumo 60cc syringe are used for administration.

The largest superficial veins in the forearm or hand are used, along with PICC (peripherally inserted central catheter) lines at times. PICC lines require pushing some sterile saline or water through first before the gas.

After pushing 5cc of oxygen/ozone gas through the infusion set to sterilize and prevent any air that might be in the tubing from entering the body, the needle is inserted into a vein.

The intravenous push is performed at a flow rate from 1cc per 5 to 15 seconds depending on the size and resistance of the vein. Most treatments last from 1 to 8 minutes depending upon the volume of gas delivered to a maximum of 12 minutes for 180 to 240cc treatments. Smaller veins require a slower push than larger veins.

All adult patients are given 20cc at the first treatment increasing 10cc's per treatment until 55cc are achieved. This volume is held until at least 10 to 12 treatments are completed. Additional volumes are given then in 10cc increments until an additional 60cc's are achieved. In some cases a total of 180-240cc are given each treatment. The amount given depends on vein tolerance, patient reaction to "kill-off", and the presenting medical problem(s) being treated.

Infusion frequency is at a minimum of three treatments per week to a maximum of 12 (the Robins Fast-Trac method or RFT). RFT can be performed at a maximum of 2 treatments per day, with a minimum three-hour window between treatments, for no more than 6 days in a row, or in any combination of consecutive or non-consecutive days. One day a week with no therapy is necessary for the body to have an opportunity to clean out the waste created by the kill off from the treatments more completely.

Volume, concentration and frequency is dependent upon: body size, with smaller people being fully perfused with less gas than larger people; medical problem, with more serious problems requiring more gas; ability of the individual to tolerate the waste created and not develop Herkheimer/Jarrisch reactions following treatment; lung reactions, including bronchospasm or a feeling of tightness developing in the upper chest (what this effect is will be discussed later).

Volume, concentration, frequency and rate of administration are adjusted to each patient's individual needs and reactions as necessary at each treatment.

Over the years we have learned how to push the limits of concentration, volume, frequency and rate without causing undo vein damage or other adverse reactions. Not a

single patient has ever been harmed in anyway. *Every patient inducted into this protocol was fully informed of the risks and benefits, and all consented to become part of our ongoing research studies.*

Benefits of DIV and clinical experience vs. criticisms:

Criticism: *“Precise dosing is impossible, because the induction effects of ozone vary according to the volume amount of blood being treated. Since it is impossible to know with any precision what volume of blood is being treated in a direct IV application, it is impossible to maximize the treatment effect.”*

Science and clinical experience:

In fact, a precise dosage is given *each and every treatment* as the concentration and volume of gas is completely controlled by the clinician. The exact volume of blood is simply unimportant as we are treating the body not an amount of blood as in MAH. Maximization of each treatment can be either a predetermined limited amount/concentration given or until the body reacts as “fully perfused”(clinical signs discussed later).

Criticism: *“Signs of cerebral ischemia (paresis of the members) may occur.”*

Science and clinical experience: A feeling like paresis has been very rarely experienced. One or two patients may have this occur in one thousand. It may happen on any visit though virtually never on the first.

It will occur within the first 30 minutes following a treatment. It has never occurred during a treatment. It will last from 2 minutes to 30 minutes with one case lasting approximately one hour.

Muscle strength testing in the office during the reaction shows absolutely no loss of muscle strength, though the patients feel as if they have apparently “no power or total weakness in the limb or limbs”.

It only seems to affect one side, though it may alternate sides. It rarely occurs several times during the course of treatment though for the few that have it happen, usually only once.

Absolutely no residual effects are ever seen. The feeling goes away with immediate and complete return to normal feeling of strength and function.

It is the authors’ clinical opinion that the cause is due to a chelation of toxic metal off cerebral nerve tissue. This causes a temporary inflammation in the brain resulting in the feeling of paresis of a limb or limbs. As the inflammation quickly subsides the feeling disappears. As there are never any lasting effects of any kind, it is a small momentary, though disconcerting, price to pay to get well.

Criticism: *“Autopsy studies of dogs treated with the direct IV method have consistently demonstrated that the technique causes pulmonary embolisms. These embolisms are caused by the oxygen in the gas mixture and not the ozone.”*

“Prof. Bocci has cited a number of fatalities in Italy resulting from subcutaneous (under the skin) ozone injections to treat lipodystrophy, commonly known as cellulite. Three deaths, from March 1998 to December 2002, caused the Italian Ministry of

Health to not only prohibit the use of ozone therapy in all cosmetic and beauty centers, but in public hospitals as well.”

Dr. Bocci says: "I am always very emphatic in proscribing Direct IV injection of the gas [oxygen-ozone] mixture: Unfortunately charlatans and technicians without medical qualification do this because they either are stupid or because they cannot do major AHT. It has been well defined that a gas injection with a volume above 20ml can produce a deadly embolism. Thus why risk harming the patient? Moreover, it does not matter that it is not ozone, but actually oxygen kills the patients. Indeed the minute volume of ozone is immediately dissolved and disappears because of extreme reactive capacity."

Science and clinical experience: The ISCO3 paper on “Ozone Therapy and Its Scientific Foundations” contradicts Dr. Bocci’s opinion as it states:

“It is important to clarify that ozone as well as oxygen do not cause embolism, due to the fact that the blood is thirsty for them and dissolves them very quickly. The few cases of embolism and death during the practice of ozone therapy have been due to various factors. The direct inoculation of the gas in the blood stream by a physical effect; the coagulation mechanisms are activated by introducing a great volume of gas. In other cases, embolism has been produced when equipment is used that generates medical ozone from the atmospheric air or when the ozone was injected in cavities or within the bone marrow. In all cases, the accidents were produced by iatrogenesis, that is, caused by the irresponsibility of the healthcare personnel that used inappropriate methods or low-quality ozone for the therapy.”

The ozone machines used in our clinics employ only medical grade oxygen with glass tubing. Great care is taken to avoid allowing any “air” to enter or be introduced into the system or syringe and infusion set. Techniques have been developed by us to prevent this from happening, even when disconnecting and exchanging syringes during treatment. We only treat people, not animals, and do not know what methods and protocols were used on any animals mentioned in the research above. Also, please remember that we have experience in both methods, originally performing over 45,000 MAH treatments and through comparison and contrast have chosen to only do DIV.

Though it has often been written and said that “DIV has resulted in death”, we have been unable to substantiate this through Internet research nor has anyone we have consulted been able to offer written evidence/proof of this occurrence. Perhaps it is just a “medical urban myth”. All ozone physicians I have approached have told me they had never seen written reports of these “deaths” but had read “somewhere” or been told so by another colleague.

Internet searching for “deaths from intravenous ozone” lead only to websites discussing hydrogen peroxide therapy (saying it had similar effects as ozone on the body) used on cancer patients who died, not DIV or MAH. Also, there is never any discussion to say how the H₂O₂ contributed to the death.

Deaths occurring in Italy happened when woman were being treated in beauty salons to destroy cellulite with injections directly into the fat. Untrained, non-medical and unlicensed salon workers likely performed these treatments though who performed the treatments is not mentioned. However, after all, what physician works in a beauty salon? It seems most likely the people suffered fat embolism. Clearly, however, the report never mentioned DIV. The overreaction by the Italian government clearly demonstrates why

only licensed, trained medical professionals should ever be permitted to perform this or any other medical therapy.

We have used as much as 240cc's of oxygen/ozone gas on a therapy without causing any "coagulation mechanism" activation. Perhaps a larger amount might cause this problem but we have never offered more to any patient and rarely use this amount. Most get between 20cc and 115cc. Please keep in mind that embolism would lead to stroke or heart attack and possibly death which would have terminated any further treatments by our government. While pharmaceutical medicine is permitted when appropriately prescribed which may result in death of any number of patients, not one death, stroke or heart attack is permitted with what is considered here to be "alternative medicine", ie. DIV or MAH.

Criticism: Perhaps the most common and greatest criticism is: *"The embolisms associated with direct IV injection will induce bronchospasm, which in the case of patients with a history of either asthma or chronic lung disease may result in fatal acute respiratory failure."*

Science and clinical experience:

We agree that the ISCO3 is correct that oxygen does not cause embolisms. We also agree with Dr. Bocci that ozone does not cause the "supposed lung embolisms". However we disagree that the ozone completely dissolves in the blood as it does in MAH, but that some may actually attach to empty Fe molecules on the red blood cells that are partially devoid of oxygen. As there is minimal blood available in the vein at the moment of infusion during DIV, so some ozone at least reaches the heart and we believe the lungs and cells around the body.

Bronchospasm occurs in many patients, though some patients never experience it at all.

It is very important to note that this occurs most commonly on the first treatment and diminishes on subsequent treatments, even though **increasing amounts of oxygen/ozone are administrated.** In fact, clinical experience has shown that by the 8th through the 12th treatment in virtually all patients, each receiving approximately 55cc at 55mcg(gamma)/cc have it diminishes to the point that a second syringe may be given (in 10cc increments) with no increased lung irritation.

The discomfort is rarely so severe that it may discourage patients from continuing treatment. When it occurs it lasts from a few seconds up to 20 minutes, rarely exceeding that time. However, on occasion, even in patients who have been receiving treatment regularly, if the discomfort becomes too uncomfortable (usually caused by administrating the gas too fast for that patient) oxygen given by nasal cannula at a rate flow of 3liters/minute will eliminate it within 5 to 20 minutes. **There are no residual negative or harmful after effects.** This now very rarely occurs as careful administration is our standard.

So what is actually happening? What causes this reaction? Why does it diminish and/or stop?

It has been suggested that the lungs "adapt". This might be true but it does not explain why most patients do not re-experience this when several weeks or months go by after stopping treatments followed by resumption of therapy.

Contrary, I believe that the ozone and its analogs are reacting with harmful free radical gases such as carbon monoxide (as much as 3% or more of the gases found in blood), creating larger than normal amounts of carbon dioxide and other gases that can be eliminated from the blood through respiration. The buildup of these gases around the lung tissue causes the feeling of pressure, tightness or discomfort in the upper chest. This also causes the lungs to try and expel these gases through coughing. I am a clinical doctor and so I do not have the equipment nor have I had the inclination to test the patients and prove my hypothesis. I will leave it up to the academics to discover the truth behind my clinical findings.

Also, we have found that coughing spasms and lung discomfort may be completely avoided by shallow/gentle, breathing. This alone or in combination with sipping purified cold water or hot decaffeinated organic green tea, will relieve and diminish the uncomfortable feeling until it dissipates. We have treated thousands of patients, over 150,000 treatments, and virtually no one has stopped therapy due to this temporary, uncomfortable reaction.

It is important to note that we have treated patients with asthma, COPD, tobacco and marijuana smokers, as well as pulmonary fibrosis without “fatal acute respiratory failure”. Quite the contrary, we have had nothing but great success and no harmful results.

Criticism:

“The treatment of many clinical conditions requires fairly large doses of ozone. While these doses are readily achieved using MAH [Major Autohemotherapy], they are extremely time-consuming using the direct IV method.”

Science and clinical experience:

We have used as much as 240cc's of oxygen/ozone gas on a therapy without causing any negative reaction. Most patients receive between 20cc and 115cc; while some receive as much as 180cc. Little to no ozone enters the body with MAH.

DIV using the Robins Method takes between 1 and 12 minutes depending on the size of the vein and the volume of gas that is being given. MAH normally is a one to one and a half hour procedure.

Criticism:

“Phlebitis at the injection site is a common side effect of this modality.”

Science and clinical experience:

Veins want to be “left alone” to fulfill their purpose of transporting blood back to the heart.

Any and all intravenous therapies may cause phlebitis. However our extensive clinical experience with DIV shows that it happens less than 1% of the time. This is no more common than any other IV therapy.

When phlebitis does occur, using warm wet compresses applied repeatedly every 10 to 12 minutes over the effected area has safely and quickly eliminated it. After no more than three or four applications, if the inflammation persists, 800mg. of ibuprofen has been used to end the phlebitis. It is extremely rare to have to resort to using this medicine.

Criticism: *“Dr. Bocci has also spoken out strongly against direct IV injection. In a 1995 speech on the future of ozone therapy presented at the Twelfth World Congress of the International Ozone Association in Lille, France, he cautioned: “[The] use of the intravenous administration route is extremely dangerous because even if the gaseous mixture of oxygen-ozone is administered very slowly with a pump, it frequently procures lung embolization and serious side effects, particularly when daily dosing is up to 120 ml.” “He also points out that in the oft-cited 1983 German survey on the safety of ozone applications, the only adverse side effects were attributed to direct IV injection.”*

Science and clinical experience:

In my opinion, DIV should never be performed by pump, only by syringe in the hand of the therapist. I have previously dismissed his opinions concerning “lung embolisms and serious side effects”, even using doses exceeding 120cc.

We have used as much as 240cc’s of oxygen/ozone gas, per therapy, without causing any adverse reaction of consequence. Perhaps a larger amount might cause a problem but we have never offered more to any patient and rarely use this amount. Most get between 20cc and 115cc.

I am of the opinion that the method of DIV used in Germany prior to its being banned was dangerous. The Robins Method of DIV has been proven safe as well as amazingly effective in completely eradicating most diseases and conditions.

Additional considerations:

The only real adverse reactions that have occurred from DIV, occurred in three patients.

After 30-60 treatments, each patient had a temporary rash occur within thirty minutes of the treatment, two treatments in a row. While it is possible that they were just “purging” toxins, it is entirely possible they had become “sensitive or allergic” to ozone. Treatment was discontinued to prevent a possible anaphylactic reaction.

The problems we faced with MAH included the need for very large blood needles necessitating the need for large veins, which would preclude many patients from receiving therapy as many patients have very small superficial veins and are near “impossible sticks”. The Robins Method uses 27gauge needles, which makes it possible to treat almost any patient easily including children.

The use of this gauge needle also puts a stream of extremely small gas bubbles into the vein facilitating the safe dissolving of the gas in the blood and its attachment onto the red blood cells.

MAH requires the use of Heparin to prevent clotting. DIV avoids this and any possible reactions and problems from using this drug.

The collapsing of a vein may stop the transfusion of blood back into the body. This is completely avoided by DIV. Also, if a vein collapses during a DIV treatment it takes only a minute to access another vein and finish the therapy.

The possibility of accidental “blowing off” of the infusion apparatus due to the pressure of the gas in the blood container and failure of the tape holding it to said container, with the loss of blood and the cleanup problems of blood spill, are eliminated with DIV.

The resulting large amount of medical waste and the high cost of disposing of it from MAH are eliminated with DIV.

MAH permits a fewer number of treatments able to be performed each hour by a single therapist raising the cost of care compared to DIV (up to 7-8 patients per hour) and a fewer number of treatments per week.

As it is extremely less costly overall to perform DIV over MAH, it becomes more affordable to patients and insurance companies, reducing the financial stress on the individual and the health care system and allowing more patients to afford it, many without medical insurance coverage.

When Dr. Bocci appeared on a national radio show several years ago here in the USA, he stated, to paraphrase, “MAH helps improve most medical diseases and conditions, but rarely cures them”.

Our experience with 45,000+ MAH treatments over five years between 1990 and 1995 concurs with his opinion. ”. Everyone who does MAH knows this to be true.

Therefore, the most compelling reason for using the Robins Method and Protocol of DIV (over MAH) is the overwhelming benefits and results in reversing or completely eliminating disease and illness.

Some of the diseases and conditions that we have seen the Robins Method and Protocol for DIV consistently, tremendously improve and most often often completely eliminate are:

Herpes I, II, VI; Herpes zoster (Shingles) including post-herpetic nerve pain; Epstein-Barr Virus; Cytomegalovirus; Adenovirus; Coxsackie virus; Lyme Disease (all stages); AIDS; HIV; Multiple Sclerosis; Pulmonary Fibrosis; all viral, fungal and bacterial lung infections; all causes of sinusitis; Viral meningitis; Measles; perforated ear drum; Rheumatoid Arthritis; Lupus; Scleroderma; Candidiasis; E. coli; H. pylori; Crohn’s disease; ALS; RSD/CRPS (first in the world); Chronic fatigue Syndrome; Diabetic gangrenous ulcers; Diabetic peripheral neuropathy; Fungus infections of all types in skin and nails; Hepatitis B, C; dry eye; temporary blindness caused by embolism from “mini-stroke”; glaucoma; HPV; upper respiratory tract infections (common cold); all forms of Influenza; Thrush; sleeping disorders; depression and anxiety (when due to medical problems; Bells Palsy; Fibromyalgia; Fibroids on uterus and thyroid gland; decubitus ulcers; infected wounds and ulcers.

Conclusion and summary:

DIV ozone has been used for many years in the “modern medical ozone era” (following WWII). Whatever the true reasons for it being banned in Europe we have shown by sheer numbers of patients and treatments performed over the last 18 years, that the Robins Method for DIV, using the Robins Protocol for DIV is both extremely safe and, most importantly, has a more beneficial overall result than MAH. It can be performed faster, more frequently, less costly, easier, and safer and has the ability to completely eliminate all diseases and conditions medical ozone is used to treat. It is the authors’ opinion that this method should be given new consideration and eventually adopted as the primary method of choice for intravenous ozone therapy based on safety and results.

References:

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