

Ozone therapy - a miraculous treatment or a toxic substance?

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Is ozone therapy safe?

At a glance:

- There are two different sides of ozone therapy and its safety. One side says that ozone can only be toxic. The other side says ozone therapy yields beneficial results. What does each side say?
- Claims on the dangers: the FDA, Journal of Oncology, American Cancer Society, and Journal of Cardiology claim ozone therapy is dangerous. There is a lot of information about the dangers of *breathing* ozone but not about the dangers of *ozone therapy*.
- Claims on the safety: It is the job of ozone therapy advocates to prove ozone therapy is safe, not the job of skeptics to prove its dangers. Ozone is approved in many countries, growing in scientific resource, increasing in amount of scientific organizations, and has a large social backing.
- While the FDA maintains that ozone is a toxic gas, they approved Vasogen through phase III FDA trials which means they considered ozone therapy safe and effective in that instance.
- Dr. Re asks, "Is it possible that ozone therapy is the medicine of the future?" An upward trend in the popularity and scientific resource of ozone therapy continues to grow with no sign of slowing down.

It seems to be an extremely easy question.

Some say “ozone can only be toxic.” [\(1\)](#) Others say “ozone therapy is a miracle cure.” [\(2\)](#)

Two drastically different opinions on the subject, how could this be?

The alleged reports of death and large institutions attempt to discredit ozone therapy but ozone therapy advocates provide substantial scientific resources accompanied with anecdotal reports, claiming ozone therapy is safe. The burden of proof remains on the shoulders of ozone therapy advocates. What does each side argue?

Before we get into claims about ozone therapy safety, note a few things:

- Ozone therapy is a huge category. It’s administered in dozens of different ways. For the sake of simplicity, I condensed ozone therapy and do not differentiate between the protocols. Perhaps at a later time we can take a deeper look into each individual modality.
- I am not giving my opinion on the matter. I am not a medical professional and cannot give any medical advice. None of this should be considered medical advice. I am collaborating information that has been published by other parties.

- We are looking at the claims about the safety about ozone therapy and not the effectiveness. Safety precedes effectiveness on the scale of importance.

The dangers of ozone and its role as a pollutant is overwhelmingly acknowledged. This information is readily available and easy to find. (3, 4) Ozone is extremely caustic to the lungs. However, nobody argues this point. Everybody agrees. Ozone therapy antagonists and protagonists both say, “ozone is harmful to the lungs.” Ozone is an extremely strong oxidant and will quickly break down vulnerable materials or tissues. (5)

Which begs the question, *does ozone cause different effects based on the tissue it’s exposed to?*

We will circle back around to this question. In a nutshell, ozone therapy advocates claim that ozone yields a different response based on the tissue that it’s exposed to. It is clear that ozone is toxic to the lungs. Environmental ozone is created when pollutants and toxins are pumped into the sky, creating smog. They argue that while it is harmful to the lungs, a judicious dose of pure, medical-grade ozone can stimulate a beneficial response in the blood. (6)

Claims of ozone therapy dangers

The Food and Drug Administration (FDA) is a weighty organization. They hold the power to decide what can be considered medicine in the United States.

They take a very strong stance on ozone when they say, “Ozone is a toxic gas with no known useful medical application.” (7)

To me, it makes complete sense the FDA makes this statement about ozone. Why would they give any other opinion?

Ozone therapy has very little chance of FDA approval. FDA approval is an incredibly expensive process and requires millions and millions of dollars. (8) Ozone therapy cannot generate much revenue because it runs on oxygen, which only cost a few cents.

The other issue is that ozone therapy is not patentable.

Pretend that a company spent millions of dollars to get FDA approval for ozone therapy. Let’s call this company ACME. Usually, ACME would acquire a patent to protect their product and avoid competition from other companies. Afterall, they just spent millions to get a new treatment approved so they can sell a product. However, with ozone therapy, it’s not possible to get a patent. So ACME would risk millions of dollars just to compete with all the other companies in the industry.

Nobody is going to spend money on FDA approval if they cannot patent a product, like ozone. Large companies do not take risks like this, it might even be considered imprudent.

It wouldn't make sense for the FDA to make any consideration for ozone therapy. *Why would they endorse something that has little to no chance of their approval?* If they made any other statement, they would give ground to ozone therapy advocates and thereby have to put more effort into regulating it.

Why would an already busy organization want to manage such a small therapy? They are busy and could use that time to manage therapies that have a broader reach.

At the end of the day, the FDA has a sensible stance because there is an overwhelming amount of data showing the negative effects on the lungs.

However, the FDA also approved a company (Vasogen) to phase III FDA trials with ozone therapy. ([9](#), [10](#), [11](#), [12](#)) According to FDA standards, Vasogen had to prove to the FDA that ozone therapy was safe before they could move to phase II. ([13](#)) In phase II they have to prove efficacy and side effects. Again, the FDA pushed ozone therapy to stage III, meaning they were approved in phases I and II.

Albeit, these FDA trials were for a specific form of ozone therapy called minor autohemotherapy where they mixed the blood with ozone and injected it back into the patient. So this was not a blanket trial for ozone therapy but focused on one particular modality.

Nonetheless, the FDA retains that ozone is a toxic gas. They allegedly confirmed the safety and efficacy of Vasogen's ozone therapy.

The Journal of Oncology and the American Cancer Society claim ozone therapy is dangerous when they say, "The American Cancer Society strongly urges cancer patients not to seek oxygen treatments." ([14](#))

They go on to list some of the side effects of ozone therapy: local pain, burning, erythema, edema, and hematoma. I was disappointed with their cited source. The journal only listed one study and none of the adverse effects had to do with ozone. The study they cited reported positive results with the ozone therapy. The local pain, burning, erythema, edema, and hematoma were all due to the use of needles, not ozone therapy. ([14](#), [15](#))

The Journal of Oncology stated that ozone therapy was dangerous but substantiated themselves with a study that indicates the exact opposite of what they tried to say.

Interestingly, the International Scientific Committee of Ozone Therapy (ISCO3) is another organization claiming dangers about ozone therapy. Yes, even in the world of ozone there is controversy.

They claim that a certain application, direct intravenous ozone, is dangerous. Direct intravenous ozone (DIV) is strongly discouraged due to the risk of air embolism. ISCO3 takes a strong stance in a document called the Madrid Declaration. This document is a living document with the hope of setting forth a worldwide standard for ozone therapy. The Madrid Declaration reads,

"Its application is strongly discouraged due to the risk of air embolism which can occur even in the case of using an slow infusion pump and volumes of 20 ml. The complications of stroke range from a simple axillary bubbling sensation, then cough, a feeling of retrosternal

weight, dizziness, to changes in vision, hypotensive crisis, with signs of cerebral ischemia, and death.” (16)

In this particular paper, ISCO3 failed to cite any sources for the claims they made about DIV.

Two popular doctors in the United States, Dr. Robbins and Dr. Rowen, claim to have administered hundreds of thousands of DIV treatments with minimal adverse events. They claim that the few adverse events were not substantial and certainly not stroke or death. (17, 18) However, they fail to put forth chronicled data to display their claims.

Ozone therapy advocates claim, among many things including water, caffeine, or ozone, the poison is in the dose. They say, ozone must be used judiciously because too much will stimulate a toxic effect. (19) Most ozone therapy practitioners have accepted a standard of dosing regulations set forward by the scientific community, namely Dr. Velio Bocci. (20, 21, 22, 23, 24, 25)

Dr. Bocci remarks on the potential toxicity of ozone when he wrote,

“The success of ozonotherapy depends in using small and safe ozone doses, just above the threshold level, able to stimulate a number of biochemical pathways, finally responsible for the activation of the natural healing capacity. This concept echoes an old intuition by Paracelsus (1493–1541), who wrote that: ‘the body possesses the high art of wrecking but also restoring health ... Poison is in everything, and no thing is without poison. The dosage makes it either a poison or a remedy.’”

Reports of adverse events with ozone therapy

Adverse reports of ozone therapy are few and far between but include everything from discomfort to death. I was quite surprised at the lack of adverse events listed with ozone therapy. Hundreds of thousands of ozone therapy treatments are administered around the world on a weekly basis. For a therapy of this volume I would expect to find more adverse events listed. Perhaps not everyone is going to report an adverse event.

It’s impossible to miss the reported deaths when researching ozone therapy.

Many antagonists make their stance based on a website reporting five deaths due to ozone therapy. There are a few reports of death not listed on this website but are published elsewhere. (28) To better understand the context of these reported deaths, I chose to comment on the three that have information readily available. Most of the reported deaths do not have any resources or information published online, including my research into local obituaries, newspapers, and funeral homes, so I will not be commenting on these because there is no evidence of their existence.

The most common report of death is two men who tricked a woman. (26) They posed as doctors but were not medical professionals. They invited this poor woman to their apartment where they administered gas with a non-medical grade machine called the “octozone.” The gas they administered caused an embolism which resulted in the death of this woman.

We are not exactly sure what they were doing, how they administered the treatment, the precautions they took, or any other details for that matter. We know these two hoodlums injected some sort of gas directly into this woman’s vein and claimed it was “ozone therapy”.

Another death reported is of a woman treated in Thailand under a Dr. Satori. (27) Again, this was an under the radar type of doctor. It was stated that he administered a liquid into her veins. It doesn't make sense because ozone is a gas, not a liquid. So we are not exactly sure what Dr. Satori was administering to this woman. Nonetheless, this woman died a few months after the treatment and it was attributed to the ozone therapy.

There is one case of death published in the Journal of Forensic Medicine and Pathology and is attributed to the controversial method of direct intravenous ozone. This is the very method that the International Scientific Committee of Ozone Therapy warned medical practitioners about. In a very brief abstract, the case study writes, (29, 30)

“An unexpected death is described that was caused by gas embolism that occurred during oxygen-ozone (O₂/O₃) therapy administered by autohemotransfusion for psoriasis. This unusual complication suggests the necessity of investigating benefits and adverse effects of medical ozone application.”

At the time of this writing, information surrounding death due to ozone therapy is ambivalent *except in one case*. They may be true but the conflicting information and lack of details makes it difficult to know.

The next serious adverse event was a heart attack, listed by the Journal of Cardiology. (31) In this scenario, the man had an ozone therapy in the morning. Later in the afternoon he went into the hospital due to a heart attack. In the journal, they didn't seem sure of the cause but speculated it may have been ozone therapy.

In another instance, a man was reported to have temporary blindness after a back injection with ozone. (32) He recovered his sight after a short amount of time. The doctors did due diligence to identify the cause but were unable to definitively nail it down.

Beyond the cases listed above, most of the adverse reactions were minor and consisted of rashes, discomfort, cramping, and other similar issues.

The scientific and medical boards supporting ozone therapy claim these adverse reactions are typically due to malpractice and not ozone therapy itself. They claim that ozone therapy is safe when applied judiciously and correctly. Perhaps the lack of adverse events is also supportive of their claim. (6)

Considering the millions of treatments, ozone therapy seems to have a pretty low count of published adverse events.

Claims of ozone therapy safety

Organizations and government agencies

The most substantial claim on the safety of ozone therapy involves the CE medical federation. The CE medical federation is the European equivalent of the FDA. Their authority extends all across Europe into Asia and is the medical standard in dozens of countries. They have approved ozone generators as medical ozone devices, which means the safety of the generator and therapy has been demonstrated and approved.

As of 2017, ozone therapy is approved in twelve countries, a drastic increase from four back in 2012. (33) The primary countries consisting of Spain, Russia, Greece, China, Dubai, Brazil, and Italy, have been pushing the forefront of ozone therapy.

Although Europe accepts the medical practice of ozone therapy, it is not approved by the FDA in the United States and has been met with a lot of skepticism. (1) Many doctors and practitioners continue to use ozone therapy despite the statements made by the FDA. A number of organizations have emerged to represent these doctors, the primary organization being the American Academy of Ozone Therapy (AAOT) with Dr. Frank Shallenberger as the president. (34) Their motive is to educate practitioners about ozone therapy and enhance its scientific credibility. AAOT has been conducting an institutional review board (IRB), a constituted group which has license to research ozone therapy on humans. (35) AAOT claims that doctors would be protected from regulatory agencies if they listed themselves under the IRB. Although I was unable to find resources, there has been conjecture that the IRB by AAOT is no longer in place.

The largest scientific organization for ozone therapy, ISCO3, made a very bold claim when they said,

“In German-speaking territories 2,819 surveys were distributed to all the ozone therapists, of which 644 responses were received ... Considering all the cases of complications, they were produced in 6 out of every 100,000 sessions, which meant one complication for each 16,667 cases of ozone application. The cases were analyzed to determine in which the cause of the complication had been the ozone itself;... In the remaining 84% of the cases, the complications were not related to the actions of the ozone, but rather they were the result of incorrect anticoagulant treatments; or of other types of improper treatment, such as the use of medication, wrong techniques of administering the ozone and non-sterile handling.” (20)

This is a very drastic claim, only **6 out of 100,000 ozone therapy sessions**. Which makes it all the more disappointing they did not publish a full report. There is no paper trail. I believe that ISCO3 should release a full report to the public if they want this claim to be taken more seriously.

If their claim holds true, ozone therapy would have an extremely low rate of complications.

Scientists

Dr. Velio Bocci published many papers and books on ozone and was one of the first to bring a scientific foundation to ozone therapy. He observes that environmental ozone and breathing ozone is different from ozone therapy,

“In conclusion, although [environmental] ozone is not the only culprit for adverse health effects, it significantly contributes to exacerbate respiratory illnesses and enhances mortality in about 40% of the total US population.”

Dr. Bocci is clearly aware of the significant health issues posed by breathing ozone. But that does not deter him from making a more interesting observation,

“A mild acute oxidative stress induced by ozone in blood ... often leading to both a repair and an increased defense capacity... This new achievement, added to an increasing wide consensus in carefully using gases as NO, CO, H₂S, N₂O and H₂ as real medical drugs, suggests that also ozone may be soon included into this category.” (36)

Essentially, Dr. Bocci believes ozone therapy will yield beneficial results when used judiciously. Prior to viewing the effectiveness of ozone therapy, he evaluated the safety of ozone. His comments on the safety of ozone mark some safe and some dangerous applications,

“There have been several arguments for prohibiting the use of ozone in medicine: the first is that ozone is a strong oxidant and a toxic gas that should never be breathed. The second is due to the fact that several diseases are perpetuated by a chronic oxidative stress, and therefore a gas generating free radicals should be proscribed. The third has been the fault of unscrupulous quacks who, without any medical qualification, have injected the gas mixture (O₂-O₃), intravenously causing lung embolism. Thus, it has been easy to label ozonotherapy as a dangerous quackery, but the previous sections should have clarified why tropospheric ozone is toxic and why a single pulse of a precisely measured ozone dose in blood is not. The success of ozonotherapy depends in using small and safe ozone doses, just above the threshold level, able to stimulate a number of biochemical pathways, finally responsible for the activation of the natural healing capacity.” (6)

Many other scientists have made contributions to ozone therapy but Dr. Bocci is the one who stands above the rest at this time. His research has largely contributed to the acceptance of ozone therapy in Europe and other countries around the world. Dr. Bocci's work carries weight to the scientific community.

Anecdotes

For whatever it's worth, there are thousands of reports claiming the safety of ozone. (37, 38) Many are anecdotal but provide a reasonable amount of social backing to ozone therapy and continue to build its credibility in non-scientific standards.

We cannot be convinced by anecdotes alone. Just because the masses say something is true, doesn't mean it is. (39) From a purely observational standpoint, I find the thousands of positive reports interesting, since the large institutions claim ozone is significantly dangerous and always toxic.

FDA Trials

The cherry on top of ozone therapy safety is the FDA.

The FDA approved Vasogen through phase III FDA trials which means they considered ozone therapy safe and effective. In phase I Vasogen reported to the FDA that ozone therapy was safe. The FDA approved their claim. Vasogen made it to phase II where they reported the efficacy of ozone therapy. Again, the FDA approved their claim. Albeit, this was for a specific form of ozone where they drew the blood out and reinjected it back into the patient. It did not cover every single protocol for ozone therapy. (9, 10, 11, 12)

So on one side, the FDA states, ozone is a toxic gas with no known medical application. On the other side, they approved Vasogen through phase II FDA trials which allegedly demonstrated the

safety of ozone therapy. Their comments about the toxicity of ozone therapy takes precedence because it is their official statement.

Conclusion

So... is ozone therapy safe?

I was disappointed in the research done by those who claimed ozone therapy is dangerous. The Journal of Oncology and the American Cancer Society did not cite sources well enough to make the statements that they did. The Journal of Cardiology made conjecture but no definitive progress. There is a lot of information about the dangers of breathing ozone but not about the dangers of ozone therapy.

As you put everything together, there is little information claiming ozone therapy is dangerous but large institutions maintain ozone is only toxic.

It appears there was more information affirming that ozone therapy is safe. This does not make ozone therapy safe, only adds information to claims about its safety.

All things considered, an increasing amount of approval for ozone therapy has begun to snowball but the burden of proof still lies on the shoulders of ozone therapy advocates. It is their job to prove that ozone therapy is safe, not the job of skeptics to prove its dangers.

Is it possible that ozone therapy is the medicine of the future? An upward trend in the popularity and scientific resource of ozone therapy continues to grow with no sign of slowing down.

<https://www.linkedin.com/pulse/ozone-therapy-miraculous-treatment-toxic-substance-micah-low/>

To view citations please go to full article on link above.

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