

## SIR: Ozone Shots As Effective As Surgery for Back Pain

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SAN DIEGO, March 11 -- Ozone gas injected into herniated disks may relieve back-related pain and disability without the risks of surgery, researchers said.

The improvements were well above clinical significance thresholds and comparable to surgical discectomy, Kieran J. Murphy, M.D., of the University of Toronto, and colleagues reported to the Society of Interventional Radiology here.

In the meta-analysis, 79.7% of ozone injection patients improved at least one category on the modified McNab composite pain and functional scale.

The investigational treatment, appears to be a gentler way to take pressure off nerves pinched by the bulging disk, Dr. Murphy said.

Action Points

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- Explain to interested patients that ozone injections are not FDA approved for treatment of back pain and that further study is needed to confirm efficacy.
  - Note that these studies were published as abstracts and presented orally at a conference. These data and conclusions should be considered to be preliminary until published in a peer-reviewed journal.

In the group's experimental and animal studies, also reported here, a tiny drop in disk volume (0.3 cc), which occurred when ozone broke protein down into water and carbon dioxide, eliminated one-third of pressure on the disk (10 psi).

"If open surgery is one option and doing nothing is another option, this fits in the gap between," Dr. Murphy said.

Although Dr. Murphy recently invented a device to deliver a consistent dose (2% ozone-to-oxygen) to the spine with a 22-gauge needle, Italian researchers had pioneered the technique.

Finding the European results difficult to believe, Dr. Murphy said he started to investigate for himself.

In pigs, his group's experiments showed that muscle was unaffected by any level of ozone, whereas a 2% ozone-in-oxygen injection appeared to be optimal both for cytokine levels and effect on disk volume.

Chinese hamster ovary cell lines confirmed that ozone, not oxygen, broke down proteins found in the nucleus pulposus of the disk.

To determine ozone's effect on human spines, the group reviewed the literature and pooled data from 12 studies with a total of more than 8,000 patients who had been treated with ozone for back pain at multiple European centers.

The average improvement -- with study results weighted by study quality -- was 3.9 on the 10-cm Visual Analog Scale for pain (95% CI 3.2 to 4.5) and 25.7 on the 50-point Oswestry Disability Index (95% CI 18.8 to 32.6).

The procedure was "extremely safe," added Dr. Murphy. The complication risk with ozone injection was 0.003% (95% confidence interval 0.000% to 0.024%), much lower than surgical discectomy, he said. No serious complications were reported.

"In addition, the recovery time is significantly shorter for the oxygen/ozone injection than for the discectomy," Dr. Murphy added.

The meta-analysis did reveal significant bias on the order of less than 10% in the pain and disability findings, but the smaller studies also appeared to underestimate the treatment effect.

"The estimated improvement in pain and function is impressive in light of the broad patient inclusion criteria that included patients ranging in age from 13 to 94 with all types of disk herniations," he said.

These promising findings need confirmation in U.S. as well, commented SIR president Brian Stainken, M.D., of Roger Williams Hospital in Providence, R.I.

"The solutions we have out there for this aren't very good," he said at the press conference he moderated. "We need

minimally invasive targeted therapies."

Dr. Murphy said his group is negotiating with the FDA over the design of the first such North American human trial, which he expects to begin in the next six months.

Dr. Murphy reported being inventor of an ozone spinal delivery device. Dr. Stainken reported no conflicts of interest.

**Primary source:** Society of Interventional Radiology

Source reference:

Steppan J, et al "A meta-analysis of the effectiveness and safety of ozone treatments for herniated lumbar discs" *SIR* 2009; Abstract 37.

**Additional source:** Society of Interventional Radiology

Source reference:

Steppan J, et al "Ozone's mechanisms of action for relieving pain associated with herniated intervertebral discs" *SIR* 2009; Abstract 38.

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