Intradiscal Ozone for the Treatment of Sensitized Vertebral Discs

Dr. John C. Hughes, D.O.

AAOM 29th Annual Conference
April 18-21, 2012
Creative people have an “openness to new experience that permits them to observe things that others cannot…[this] openness is accompanied by a tolerance for ambiguity. Creative people do not crave the absolutism of a black and white world; they are quite comfortable with shades of gray. In fact, they enjoy living in a world that is filled with unanswered questions and blurry boundaries.”

Credits To Creative People

- Kent Pomeroy, MD
- Frank Shallenberger, MD
- Melvin Judkins, MD
- William Sutherland, DO
- Chris Davenport

http://www.youtube.com/watch?v=Xz31vd8ahkE
Ultrasound Guided Disc Injections

- Introduction: Why Inject?
- O3
  - Properties
  - Physiological Effect
  - Studies using Intradiscal Ozone
- Neuromuscular Ultrasound-Benefits, Disclaimers, Visualization of Orthopaedic Lesions
- Case Studies-US guided disc injections
- Final Words about US Imaging and Guided Injection of Vertebral Discs
Introduction - Why Inject?

- Antiinflammatory (Steroid, Traumeel Injections)
- Pain and Anesthesia (Epidural, Spinal)
- Cushioning (Orthovisc, Synvisc)
- Healing (Ozone, Dextrose, Nutrients)
- Nutrient or Drug Delivery (Insulin, Heparin, etc.)
- Cosmetic (Botox, etc)
- Infectious Disease (Vaccination or Active Infection)
Introduction - Why Inject?
Ozone (O3)--Properties

- A highly reactive oxygen species
- Known in upper stratosphere to protect against UV light
- Unstable allotropic form of oxygen with the symbol O3
- Molecular weight of 48 kDa
Ozone (O3), or trioxygen, is a triatomic molecule.
Ozone (O3) -- Physiologically

- Stimulates cartilage regrowth
- Stimulates the production of white blood cells
- Kills most bacteria at low concentrations
- Is effective against all types of fungi
- Inactivates viruses
- Increases the flexibility and elasticity of red blood cells
- Accelerates Glycolysis
- Has analgesic and antiinflammatory effects
- Degrades petrochemicals
Ozone (O3)-Italian Study

- http://www.ajnr.org/cgi/content/full/24/5/996/F2
- (American Journal of Neuroradiology)
- From 1999 to 2001, 600 patients aged 20–80 years treated with a single dose of oxygen-ozone therapy. (All done in Italian hospitals).

- Three hundred patients (group A, received an intradiscal (4 mL) and periganglionic (8 mL) injection of an oxygen-ozone mixture with an ozone concentration of 27 µg/mL
Ozone (O3)-Italian Study

- The other 300 patients (group B,) received identical oxygen-ozone injections, followed by a periganglionic injection of corticosteroid (1 mL of Depo-Medrone 40 mg and anesthetic (2 mL of Marcain 0.5%

- The L4–5 level was the most frequently treated (61.8%); L1–2, 0.7%; L2–3, 1.2%; L3–4, 8.7%; L5-S1, 27.6%.
Puncture at L4-L5 performed under CT guidance.
Ozone-Italian Study

- Selection criteria: Low back pain resistant to conservative management (drugs, physiotherapy, and others), lasting at least 3 months.

- Exclusion criteria for oxygen-ozone therapy were neuroradiologic evidence of disk prolapse or free fragments of herniated disk, and major neurologic deficit correlated to disk disease.

- In the latter cases, the patients underwent surgical treatment.
Ozone-Italian Study

- Treatment was a success in 211 patients (70.3%) in group A and 235 patients (78.3%) in group B.
FIG 3. Therapeutic outcome 6 months after oxygen-ozone therapy. Light gray bars indicate group A (n=300); dark gray bars, group B (n=300). Numbers at top of bars are percentages.
Ozone-Italian Study

- The dose of ozone administered is crucial (33) and must not exceed the capacity of antioxidant enzymes (SOD, glutathione)
Microdiscectomy of O3 treated discs

- Showed dehydration of the fibrillar matrix of the nucleus pulposus, revealing collagen fibers and signs of regression
- And chondrocyte hyperplasia at the lesion margin, proliferating and large, and signs of new blood cell formation

- Disk shrinkage may also help to reduce venous stasis caused by disk compression of vessels, thereby improving local microcirculation and increasing the supply of oxygen
Conclusion: oxygen-ozone therapy is an option to treat lumbar disk herniation that has failed to respond to conservative management, before recourse to surgery or when surgery is not possible.
Ozone Study MetaAnalysis

- March 11, 2009 (San Diego, California) —
- Oxygen/ozone injections into herniated lumbar equal in efficacy to surgical discectomy
- but the complication rate is considerably lower
- and the recovery time is significantly shorter--
- (a new meta-analysis presented here at the Society of Interventional Radiology 34th Annual Scientific Meeting).
Dr. Murphy, program chair at the SIR, said he learned the process in Naples, Italy, working with Mario Muto, MD, and colleagues. He said the oxygen/ozone therapy is de rigueur in Italy. From June 2000 to December 2006, the Muto group performed the oxygen/ozone procedure on 2900 patients with lumbar disc herniation.
According to Murphy,

- Oxygen/ozone mixture injected into the disc works through a redox (or reduction–oxidation) reaction.
- The proteoglycan's core protein in the disc that is broken into smaller portions, shrinking disc volume, which in turn relieves the pain," he said.
Murphy said that, "based on these results, we're working on a clinical-trial design involving 50 patients and should hear from the [US Food and Drug Administration] within the next 18 months to 2 years."

“When you have 79.7% of patients with a herniated disc getting improvement from this procedure, that's pretty cool.”
Ozone Study MetaAnalysis

- Video Link from Medpage Today
- Presentation from Dr. Murphy
  - http://www.medpagetoday.com/MeetingCoverage/SIR/13206
Other Ozone Studies

- http://linkinghub.elsevier.com/retrieve/pii/S018840907002950
- http://www.appliedozone.com/references.html
- http://www.ajnr.org/cgi/content/full/24/5/996
Neuromuscular Ultrasound-Benefits

- Why do I use ultrasound guidance for the majority of injections?
  - Safety
  - Efficacy
  - Accuracy
  - Instant visible results
  - Patient satisfaction and education
  - Financial
  - Easy
Neuromuscular Ultrasound-Benefits

- No harmful radiation involved
- Accurate placement of needle guided injections
- Able to see immediate results
- Patient feel more relaxed as they watch the screen
- Relatively inexpensive
- Easy to store images to compare results
Creating a proper neuromuscular ultrasound image takes years of training.
Visualization and understanding these images also requires extensive work.
Download to a pdf can compromise some image quality.
Injection of a substance such as a liquid or gas into the view significantly.
It is all still better than going at it blindly.
Neuromuscular Ultrasound-Disclaimer

- Note: The ultrasound is an excellent feedback and confirmatory tool.
- However, the images are not fail-safe and it is vital to trust your own palpatory skills and training
- And likewise helpful to have a trained ultrasound tech in order to do any procedure well
Neuromuscular Ultrasound - Anatomy and Injection Solutions

- **Trigger Point:** procaine, magnesium sulfate (less than 0.5 cc), sterile water f/u by O3
- **Osteophyte/Bone spur:** procaine, sterile H2O, magnesium sulfate, HCL, Phosphatidyl Choline f/u by O3
- **Joint (OA):** procaine, dextrose, glucosamine, joint formula, HA, B12, folate, sterile H2O f/u by O3
- **Joint (ACL, PCL, sprain):** procaine, tiny amount of dextrose, sterile water f/u by O3
Neuromuscular Ultrasound - Anatomy and Injectable Solutions

- **Ligaments/Tendons**: procaine, dextrose, sterile H2O (sometimes add ascorbic acid, folate, traumeel, B12) f/u by O3

- **Neuroma**: Hypertonic saline (1.0% to 1.5%) (do not use Marine plasma; do not use local)
Neuromuscular Ultrasound - Anatomy and Injectable Solutions

- **Disc (Herniated):** procaine, sterile H20 f/u by O3

- **Disc (Degenerative):** like knee joint with OA with less dextrose: procaine, dextrose, glucosamine, joint formula, HA, sterile H20 f/u by O3
Credits To Creative People-Andy Lewis

http://www.youtube.com/watch?v=diA6sFnPDi8
Case Study-Fred O. (Cervical Disc Bulge)
Case Study-Fred O. (Cervical Disc Bulge)

- 36 year old male with chronic neck pain, 8/10 achy with moments of sharp pain radiating down left arm; with periods of numbness and tingling; reports diving off a boat into a sandbar 3 years ago; went to shaman in South America and numerous chiropractors; has followed up with PCP; takes Percocet and Vicodin daily; drugs make him feel sick; not sleeping well; worsened by activity

- Denies Past Medical/Surgical hx

- Percocet; Vicodin as needed
Case Study-Fred O. (Cervical Disc Bulge)

- NKDA
- Family History: Denies osteoarthritis
- Denies Tobacco, EtOH, DA; uses cannabis to relax neck muscles
- Works as school teacher; lives with wife and newborn baby; eats healthy diet; regular exercise when not in pain
Case Study-Fred O. (Cervical Disc Bulge)

- ROS: Denies current headaches, denies blurry vision, denies ear ringing, denies chest pain, denies dental problems (TMJ); denies abdominal pain; denies bowel or bladder problems; denies muscle weakness, MS-as per hpi; Neuro; as per hpi; tingling and numbness in fingers and forearm Psyche: denies mood changes
Case Study-Fred O. (Cervical Disc Bulge)

- Physical Exam
  - 112/76 78 12 Vitals stable; In no acute distress; NC/AT; EOMI; RRR S1 S2; no murmurs; CTA-B
  - MS: TTP in C3-C7 spinous processes and facets on L side; decreased left side bending and rotation; tight paraspinal muscles, scalenes, SCM bilaterally; more pronounced on the left; 4/5 strength with L forearm flexion; normal tone
  - Neuro: CN II-XII intact; decreased sensation in lateral portion of left forearm; and lateral 2 fingers
Case Study-Fred O. (Cervical Disc Bulge)

- Neuro: (continued); 2/4 reflexes in UE bilaterally
- Psyche: Stable affect
- MRI (C spine): multi-level disc degeneration of C-spine; C5-6, C7-T1 discs abut the cord; foraminal stenosis at C6-C7, C7-T1 on left side
- Assessment:
  - Cervical disc hernation with radiculopathy
  - Chronic pain
  - Chronic muscle spasms-Cervical Area
Dermatomes Upper Extremity
FINAL Diagnostic Imaging Report

Account: [Redacted]
Patient: [Redacted]
Sex: Male
DOB: Feb 17 1974
Age: Age 33

Status: Active
Referring: [Redacted]

MR1 #097717: C-Spine W/O Contrast - Oct 10 2007

Facility: Aspen Valley Hospital Report

MRI OF THE CERVICAL SPINE, 10/10/07, 1415:

COMPARISON: None.

HISTORY: Neck pain.

TECHNIQUE: Multiplanar multisequence MRI of the cervical spine performed.

FINDINGS: Cervical vertebral height and alignment are preserved. Marrow signal intensity is normal. Cervical cord has normal configuration and signal characteristics. The cervicomedullary junction and cerebellar tonsils are normal.

At C2-3, there appears to be developmental fusion of the disc space and facets.

At C3-4, there is right eccentric disc protrusion and osteophyte causing right foraminal stenosis and mild impression on the right side of the thecal sac.

At C4-5, there is broad-based disc and osteophyte with mild impression on the thecal sac.

At C5-6, central disc protrusion and bilateral facet hypertrophy are seen. This abuts the cord. There is no cord deformity or abnormal cord signal.

At C6-7, there is left lateral disc and osteophyte leading to left foraminal stenosis. Mild impression on the thecal sac is seen.

At C7-T1, there is left eccentric disc and osteophyte abutting the cord and leading to left foraminal stenosis.

IMPRESSION:

1. Multilevel degenerative changes in the cervical spine. Disc and osteophyte at C5-6 and C7-T1 abut the cord. The left C7-T1 and left C6-7 foramina are stenotic.

2. Developmental C2-3 fusion.
Case Study-Fred O. (Cervical Disc Bulge)

Plan:
1) Physical therapy including traction, exercises
2) Pain management-continue narcotic meds as needed; add Nucynta as needed;
3) If above therapy fails, consider intradisc injection with ozone with proliferative therapy into ligaments and facets
Case Study-Fred O. (Cervical Disc Bulge)

- Outcome: 4 procedures: 2 weeks apart
- Ultrasound guided disc injections with 1% procaine into each herniated (bulge) disc (3cc) followed by O3 at 27-36 ug/cc (10cc) per disc
- Ultrasound guided proliferative injections with 2% procaine mixed equally with 50% dextrose into each interspinous ligament (2cc) followed by O3 at 27-36 ug/cc (3cc) per ligament
- Ultrasound guided proliferative injections into left sided facets (with identical solution as proliferative injections)
Fred O.-Interspinous Ligament
Fred O.-Facet Injections
Case Study-Fred O.

- After 2 months of injectional therapy, patient complains of minor tingling in L pinky finger; and slight tightness in neck muscles after working out.
- Now able to surf and play tennis without complaint.
- Disc height has maintained expansion and herniation has reduced by 80-85% by US.
Case Study-Chris C. (Lumbar Disc Hernation)

- 40 yo male who herniated L4-L5 disc while doing yoga; cannot sit down in office; has limited ability to bend over; pain radiated down L leg; has received little benefit from physical therapy
- Meds: Vicodin as necessary
- Med/Surg Hx: Denies prior
denies tob, etoh, da; lives with wife; works as solar roof installer
US guided injection of an Intervertebral Disc

MRI-L4-5 disc herniation

US L4-5 disc herniation
Case Study-Chris C. (Lumbar Disc Hernation)

- PE: VSS; TTP in L side of L4 transverse process; sidebending to the L in lumbar spine exacerbates condition; tight lumbar paraspinals; laxity at L4-5 interspinous ligament; hypersympathetic state
- MRI confirms L sided disc herniation at L4-5
- Assessment
  - Disc herniation with radiculopathy
  - Sciatic pain
  - Ligamentous Laxity
Case Study-Chris C.
(Lumbar Disc Hernation)

Plan:
- Injectional treatment using O3 into L4-5 disc
- Proliferative injection in L4-5 interspinous ligament
- Physical therapy; traction
Case Study-Chris C. (Lumbar Disc Hernation)

- Procedure: 4 injections 1-2 weeks apart of 1% procaine (2-3cc) followed by 10cc 03 at 28 ug/cc into L4-5 disc
- After 3rd injection, an early osteophyte was noted so magnesium sulfate (1cc) was added to the procaine solution
Case Study-Chris C.

- Results:
  - John, I am feeling great! I have started pilates which has been a good maintenance tool. I am telemark skiing, skate skiing even skinning up Snowmass. I do still feel back pain and occasional sciatic pain but the severity has diminished 90%. It has become just slightly annoying which is much better than intolerable. I have recommended you to a number of people.
The question is no longer, “Can we visualize Intervertebral Disc Herniations using Ultrasound (instead of a CT or MRI image)?”

But, “Does the vertebral disc actually need to be injected?”

And, if so, “Are you able to do it with confidence?”
US Guided Disc Injections-Final Words

Answer Key: Ozone, Horseshoes, and Hand Grenades

Note: This is an introductory lecture. There are serious dangers with injecting close to the cervical and the upper lumbar discs; please do not attempt these types of injections without more extensive training.