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Ozone therapy as a treatment for low back pain secondary to herniated disc: a systematic review and meta-analysis of randomized controlled trials

FN Magalhaes, L Dotta, A Sasse, MJ Teixeira, and ET Fonoff.

Review published: 2012.

CRD summary

This review concluded that percutaneous ozone therapy for treatment of chronic low back pain appeared to yield positive results and low morbidity rates. These conclusions accurately reflect the findings of the included evidence but the evidence consisted of a small number of studies with several methodological limitations.

Authors' objectives

To evaluate percutaneous injection of ozone for low back pain secondary to disc herniation.

Searching

PubMed, EMBASE, The Cochrane Library, DARE and HTA databases were searched from inception to September 2011 without language restrictions. Search terms were reported.

Study selection

Randomised controlled trials (RCTs), observational studies and reports of complications were eligible for inclusion if they evaluated injections of an oxygen-ozone mixture in adults (aged ≥ 18 years) with low back pain due to lumbar disc herniation or degenerative disc disease. Studies had to follow-up participants for at least six months and report pain relief as the primary outcome measure.

Three reviewers independently assessed study eligibility. Disagreements were resolved by discussion or arbitration by a fourth reviewer.

Assessment of study quality

Three reviewers independently assessed the methodological quality of RCTs using a 92-point scale adapted from a previous review of steroid injections for low back pain. Disagreements were resolved by discussion or arbitration by a fourth reviewer. This scale addressed issues of study design, reporting and participant selection, allocation, blinding and follow-up.

The methodological quality of observational studies was assessed using a 100-point scale developed by US Agency for Healthcare Research and Quality.

Data extraction

Dichotomous outcome data from RCTs were extracted to enable calculation of odds ratios and related 95% confidence intervals.

Three reviewers independently extracted data. Disagreements were resolved by discussion or arbitration by a fourth reviewer.

Methods of synthesis

For RCTs, pooled odds ratios and 95% confidence intervals were calculated using a random-effects model. Observational studies and reports of complications were combined in a narrative synthesis.

Results of the review

Four randomised trials (861 patients) were included in the meta-analysis. Trials scored between 56 and 84 points on the methodological assessment scale. Most common limitations were inadequate randomisation, more than 20% loss to follow-up, lack of placebo control and absence of an intention-to-treat analysis. Comparators were steroids with/without local anaesthetic or sham injection. Pain/disability was measured using a variety of different scales.

Ozone treatment was associated with greater relief from pain at six months (OR 2.66, 95% CI 1.94 to 3.63; four RCTs; $I^2=0\%$)

Eight observational studies were included in the review. Studies scored between 50 and 72 points on the 100-point methodological scale. None had a comparison group. Studies varied in terms of patient groups, follow-up periods and outcome measurement; these generally reported reductions in pain at follow-up and were described individually in the review.

Authors' conclusions

Percutaneous ozone therapy for treatment of chronic low back pain appeared to yield positive results and low morbidity rates.

CRD commentary

The review question was supported by suitable inclusion criteria. Despite the authors' described attempts to minimise errors and bias in study selection, several studies were excluded for unspecified methodological reasons. It was not possible to determine how appropriate these exclusions were. The authors attempted to identify all the relevant published literature but the possibility of publication bias favouring the inclusion of positive studies cannot be excluded.

The authors' conclusions accurately represent the findings of the included evidence but readers should be aware that this was based on only a small number of studies with several methodological limitations.

Implications of the review for practice and research

Practice: The authors stated that ozone therapy may be an alternative to surgery for lumbar disc herniation-related low back pain that failed to respond to conservative treatment.

Research: The authors stated that further studies were needed to demonstrate whether ozone therapy effects persist over time.

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Record Status

This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.

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CRD has determined that this article meets the DARE scientific quality criteria for a systematic review.

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