TITLE: Intervertebral Disc Biacuplasty for Back Pain: Clinical and Cost-Effectiveness

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RESEARCH QUESTION:

1. What is the clinical effectiveness of performing intervertebral disc biacuplasty for the treatment of back pain?

2. What is the cost-effectiveness of performing intervertebral disc biacuplasty for the treatment of back pain?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, The Cochrane Library (Issue 4, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. Results include articles published between 2003 and October 2008, and are limited to English publications only. No filters were applied to limit the retrieval by study type. Internet links are provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS:

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by economic evaluations, randomized controlled trials (RCTs), controlled clinical trials, and observational studies.
Two systematic reviews, one RCT, and one observational study were identified pertaining to the clinical effectiveness of performing intervertebral disc biacuplasty (IDB) for the treatment of back pain. No relevant health technology assessments, economic information, or controlled clinical trials were identified. Additional information that may be of interest had been included in the appendix.

OVERALL SUMMARY OF FINDINGS:

Systematic reviews:
One systematic review that pertains directly to intradiscal therapy for low back pain, and one pertaining to radiofrequency denervation for both neck and back pain were identified.

Urrutia et al. systematically reviewed the evidence pertaining to the efficacy, effectiveness, and safety of percutaneous thermocoagulation intradiscal techniques for discogenic low back pain. Two percutaneous thermocoagulation intradiscal techniques were considered: percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) and intradiscal electrothermal therapy (IDET). Randomized and non-randomized trials were searched and a qualitative synthesis of the results of the six included studies (a total of 283 patients) was performed. Two non-randomized trials showed IDET to be superior to PIRFT and two RCTs showed no difference between PIRFT and placebo or between different PIRFT techniques. Two additional RCTs compared IDET with placebo. One showed differences in pain and disability where as the other (considered the highest quality RCT included in the analysis) showed no differences between IDET and placebo. The authors concluded that the available evidence does not support the efficacy or the effectiveness of PIRFT.

To assess the effectiveness of radiofrequency denervation for the treatment of neck and back pain, Niemisto et al. conducted a systematic review of RCTs. Nine articles reporting on seven RCTs were identified, only one of which pertained to discogenic low-back pain. The single relevant study suggested that intradiscal radiofrequency thermocoagulation was not effective for treating discogenic low-back pain. Authors concluded a need for further high-quality RCTs with larger patient samples and long-term follow up.

RCTs
The only RCT identified evaluated the efficacy of percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), by modifying the duration of heating, for relieving pain and improving functional disability. A total of 60 patients with chronic low back pain were screened, 39 of which were eligible for the study. The 39 selected patients were randomized to receive either 120 seconds or 360 seconds of PIRFT at 80°C. Patients were assessed for pain relief and functional improvement before treatment, immediately after treatment, at 1 week, 2 weeks, 1 month, 3 months, and at 6 months after treatment. There were no statistical differences in pain relief and functional improvement between the two groups (P>0.05). Compared to pre-treatment scores, the immediate, 1 week, 2 week, and 1 month scores decreased significantly (P<0.05), but this decrease was no longer present at the 6 month follow-up (P>0.05). Authors concluded that there is no significant difference between PIRFT given for the two durations tested.

Observational studies:
Two observational studies, one specifically pertaining to intervertebral disc biacuplasty, were identified.
Chao et al. used percutaneous pulsed radiofrequency to treat cervical and lumbar radicular pain.\textsuperscript{4} One hundred and fifty four patients with lumbar or cervical pain due to a herniated intervertebral disc or previously failed surgery underwent pulsed radiofrequency therapy in two to four spinal levels. Forty-nine patients were treated for cervical pain and 116 for lumbar pain. Follow-up duration ranged from one week to one year after the procedure. Fifty-three percent (n=26) of cervical and 51% (n=59) of lumbar patients had initial improvement of 50% or more after the 1 week follow-up assessment. At the 3 month follow-up, 55% of cervical and 45% of lumbar patients had pain relief of 50% or more. For patients that had pain relief of 50% or more lasting at least one month, the most effective period was found to be one month post-operation. No complications were reported. The authors concluded that the application of pulsed radiofrequency is safe and useful for cervical and lumbar radicular pain but that long-term follow-up studies are needed.

Kapural et al. evaluated intradiscal biacuplasty (IDB) in 15 patients with chronic low back pain.\textsuperscript{5} Patients underwent one or two level IDB treatment of their lumbar discs. IDB was performed using two radiofrequency probes positioned bilaterally in the intervertebral disc. Follow-up questionnaires, including the Oswestry and Short Form (SF)-36 questionnaires for pain disability, were administered at one, three, and six months. Thirteen patients completed follow-up. Median visual analog scale pain scores and Oswestry scores improved from the initial assessment to one month follow-up, and both remained consistent at six month follow-up. SF-36 Physical Functioning scores improved from 51 to 70 points after six months and SF-36 Bodily pain scores improved by a similar magnitude. Opioid use did not change significantly from baseline and no procedure-related complications were detected. Overall, patients reported improvement in several pain related scales following IDB for discogenic pain. Authors felt a randomized controlled study was needed to assess the efficacy of IDB.

Overall, there is little high-quality evidence showing the clinical effectiveness and no evidence pertaining to the cost-effectiveness of intervertebral disc biacuplasty for back pain. IDB is safe and has been shown to have some effectiveness in relieving pain in the short term.\textsuperscript{4,5} More RCTs and studies with extended follow-up times are needed to make definitive conclusions regarding the clinical effectiveness of IDB. Economic evaluations are required to assess cost-effectiveness of IDB.
REFERENCES SUMMARIZED:

Health technology assessments
No literature identified

Systematic reviews and meta-analyses


Economic analyses and cost information
No literature identified

Randomized controlled trials


Controlled clinical trials
No literature identified

Observational studies


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APPENDIX – FURTHER INFORMATION:

Case studies and series


Review articles


Additional references

