

## Letters to the Editor

## **e** A Systematic Review of RCTs with Nucleoplasty – An Update

### **To THE EDITOR:**

In 2010 Gerges et al (1) published a meta-analysis on the topic of nucleoplasty. This investigation showed that nucleoplasty constitutes an effective, minimally invasive treatment option for patients with symptomatic contained disc herniations. In their conclusion statement, the authors called for more randomised and controlled trials (RCTs) in order to make an evidence-based assessment of the efficacy and safety of nucleoplasty. Our study aimed to present the current data available from RCTs on the application of nucleoplasty.

We conducted a systematic review of the literature using the search terms nucleoplasty and plasma disc decompression in the MEDLINE database up to the end of December 2012. Five clinical RCTs (2-6) and one experimental RCT (7) were identified. Based on the extracted data, pooled analyses – where possible – were performed using Cochrane Review Manager 5.1 statistics software. The efficacy and safety of nucleoplasty were thereby examined with respect to the parameters pain reduction (Visual Analog Scale [VAS] or Numeric Pain Scale [NPS]), functional capacity (Oswestry Disability Index [ODI]), and complication rate. Furthermore, the experimental RCT presented values for nucleoplasty volumetry of the nucleus pulposus (7).

No RCTs comparing nucleoplasty with open surgi-

cal procedures or other interventional techniques were identified. This fact is most likely due the difference in indication for the procedures, thus making randomization difficult or impossible.

### **Results**

The data sets by Gerszten et al (6) and Cesaroni and Nardi (4) were taken into consideration for the parameter pain reduction collected via VAS or NPS. Fig. 1 compares the 12-month scale course for nucleoplasty with that for the averaged control groups conservative therapy and epidural steroid injection.

The studies by Reverberi et al (5), Nardi et al (3), and Birnbaum (2) could not be considered in our analysis due to missing statistical parameters. However, all publications describe improvement in pain values for nucleoplasty compared to the control groups epidural steroid injection or conservative therapy. In the trial by Reverberi et al (5), this improvement was significant compared to epidural steroid injection.

Functional capacity, measured via ODI, was only investigated by Gerszten et al (6). They concluded that the 6-month application of nucleoplasty was superior to steroid injections for treating symptomatic contained lumbar disc herniation. Consequently, the pa-

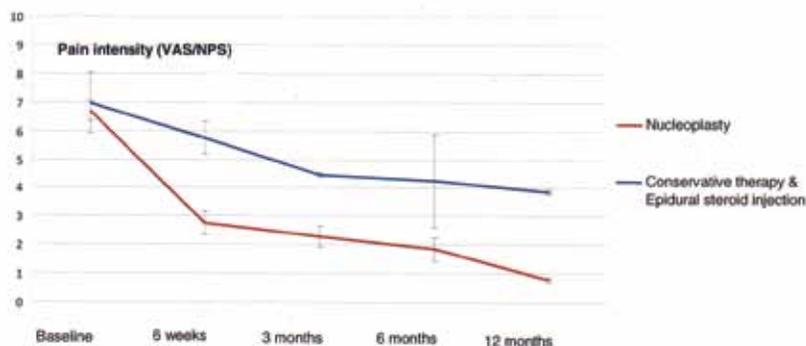


Fig. 1. Reduction of pain intensity

tients' functional capacity improved significantly (nucleoplasty [46 patients] vs. epidural steroid injection [44 patients]:  $42 \pm 14$  vs.  $43 \pm 17$  as baseline values,  $27 \pm 22$  vs.  $49 \pm 15$  after 6-month treatment).

Four prospective RCTs were used to calculate the complication rate. The trials by Birnbaum (2), Nardi et al (3), and Cesaroni and Nardi (4) chose conservative treatment for their control groups. No complications were ascertained for nucleoplasty treatment or for the control group. Gerszten et al (6) reported a complication rate of 11% for nucleoplasty and 18% for the control group receiving epidural steroid injections. Nucleoplasty therefore had an almost 40% lower probability of complications.

The experimental study by Kasch et al (7) on volume calculation of the thoracic and thoracolumbar nucleus pulposus in porcine discs showed significant superiority for nucleoplasty (26 discs) compared to the placebo group (26 discs) treated using an identical procedure not involving Coblation®. Magnetic resonance imaging evaluators were blinded to the kind of procedure performed.

### Conclusion

Nucleoplasty significantly reduces pain in patients with symptomatic contained disc herniation and also increases their functional capacity. According to currently available data from RCTs, it can be confirmed that nucleoplasty is an effective, safe, and minimally invasive treatment option in cervical, thoracic, and lumbar contained disc herniations.

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