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The Spine Journal 15 (2015) 857–865

THE SPINE JOURNAL

Clinical Study

Percutaneous laser disc decompression versus conventional microdiscectomy in sciatica: a randomized controlled trial

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Received 14 July 2014; revised 8 December 2014; accepted 10 January 2015

Abstract

BACKGROUND CONTEXT: Percutaneous laser disc decompression (PLDD) is a minimally invasive treatment for lumbar disc herniation, with Food and Drug Administration approval since 1991. However, no randomized trial comparing PLDD to conventional treatment has been performed.

PURPOSE: In this trial, we assessed the effectiveness of a strategy of PLDD as compared with conventional surgery.

STUDY DESIGN/SETTING: This randomized prospective trial with a noninferiority design was carried out in two academic and six teaching hospitals in the Netherlands according to an intent-to-treat protocol with full institutional review board approval.

PATIENT SAMPLE: One hundred fifteen eligible surgical candidates, with sciatica from a disc herniation smaller than one-third of the spinal canal, were included.

OUTCOME MEASURES: The main outcome measures for this trial were the Roland-Morris Disability Questionnaire for sciatica, visual analog scores for back and leg pain, and the patient's report of perceived recovery.

METHODS: Patients were randomly allocated to PLDD (n=57) or conventional surgery (n=58). Blinding was impossible because of the nature of the interventions. This study was funded by the Healthcare Insurance Board of the Netherlands.

FDA device/drug status: Approved for this indication (percutaneous laser disc decompression).

Author disclosures: ***PAB:*** Nothing to disclose. ***RB:*** Nothing to disclose. ***MEvdA-vM:*** Nothing to disclose. ***WCHJ:*** Grants: Eurospine—odontoid fractures surgery versus conservative observational study (D, Paid directly to institution), ZonMw (Dutch government) trial—minimal invasive fusion for spondylolisthesis with cofinancing of Medtronic, Inc. (20%) (G, Paid directly to institution, Grant no. 837002405), ZonMw (Dutch government) trial—conservative versus surgery for cervical disc herniation (F, Paid directly to institution, Grant no. 171202016). ***BS:*** Nothing to disclose. ***AAvdB-H:*** Nothing to disclose. ***BWK:*** Nothing to disclose. ***MAvB:*** Nothing to disclose. ***MPA:*** Royalties: Silony (1 percent of Total amount of implants); Scientific Advisory Board/Other Office: Biomet, In-Spine, Silony (B per day, Paid directly to institution); Research Support (Investigator Salary, Staff/Materials): Amedica CASCADE trial (F), Barricaid trial (E), MISOS trial (G, Paid directly to institution). ***WCP:*** Grant: This trial was funded by the Healthcare Insurance Board of the Netherlands (G, Paid directly to institution, Grant no. 28019289); Speaking and/or Teaching Arrangements: BBraun Aesculap (B, Paid directly to institution); Grants: ZonMw (Dutch government) trial—minimal invasive fusion for spondylolisthesis with cofinancing of Medtronic, Inc. (20%) (G, Paid directly to institution, Grant no. 837002405), Eurospine—odontoid fractures surgery versus conservative observational study (D, Paid directly to institution), ZonMw (Dutch government) trial—conservative versus surgery for cervical disc herniation (F, Paid directly to institution, Grant no. 171202016), Braun Aesculap—trial for surgical interventions (fusion, disc replacement, and discectomy) (A, Paid directly to institution), Paradigm Spine—trial coflex versus decompression (A, Paid directly to institution).

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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http://dx.doi.org/10.1016/j.spinee.2015.01.020

RESULTS: The primary outcome, Roland-Morris Disability Questionnaire, showed noninferiority of PLDD at 8 (−0.1; [95% confidence interval (CI), −2.3 to 2.1]) and 52 weeks (−1.1; 95% CI, −3.4 to 1.1) compared with conventional surgery. There was, however, a higher speed of recovery in favor of conventional surgery (hazard ratio, 0.64 [95% CI, 0.42–0.97]). The number of reoperations was significantly less in the conventional surgery group (38% vs. 16%). Overall, a strategy of PLDD, with delayed surgery if needed, resulted in noninferior outcomes at 1 year.
CONCLUSIONS: At 1 year, a strategy of PLDD, followed by surgery if needed, resulted in noninferior outcomes compared with surgery.

Keywords: Sciatica; Disc herniation; Discectomy; Minimal invasive techniques; Randomized clinical trial; Percutaneous disc decompression

Introduction

Lumbar disc herniation is the most common cause of the lumbosacral radicular syndrome, also known as sciatica. Most patients recover from their sciatica with conservative treatment within a period of 6 weeks [1]. An additional number of patients may recover during the next 6 months, but their sciatica can be severe and debilitating. In these cases, it is difficult to decide on surgical intervention and the timing thereof [2]. In general, this intervention consists of a microdiscectomy, in which the herniated disc fragment is removed. A drawback of surgery, however, is potential damage to posterior elements and muscles, possibly resulting in back pain that is frequently unresponsive to the back pain in the current treatments.

Theoretically, minimally invasive (percutaneous) procedures are of shorter duration, safer, require less hospital time, enable faster recovery, and cause less scarring. However, if these benefits are reached at the cost of a lower efficacy is not clear. One of these minimally invasive techniques is percutaneous laser disc decompression (PLDD), which is based on the principle of decreasing the intradiscal pressure by applying laser-induced heat to the nucleus pulposus [3]. Although the US Food and Drug Administration approved this treatment in 1991, no randomized controlled trials were performed to date, and its effectiveness has not been evaluated systematically [4].

In this article, we present the results of the first randomized controlled trial comparing the effectiveness of a strategy of PLDD with the strategy of conventional surgery in patients with sciatica refractory to conservative treatment.

Materials and methods

We performed a multicenter randomized prospective open trial aimed at showing noninferiority of the treatment effect of a PLDD strategy to the strategy of conventional surgery. Both treatments were compared in a parallel-group design with the Roland-Morris Disability Questionnaire (RDQ) for sciatica (the primary measure on which the study was powered), visual analog scale (VAS) for back and leg pain, and 7-point Likert scale of perceived recovery as other primary outcome measures. The trial was registered in Current Controlled Trials ISRCTN25884790. Details of the design of this study have been published previously [5]. We received full approval of the institutional review boards of all participating hospitals, and written informed consent was obtained from all patients.

Patients and randomization

All patients between 18 and 70 years with sciatica that was refractory to conservative management for more than 6 to 8 weeks and who were candidates for surgery were considered eligible for inclusion in the trial if a disc herniation at the corresponding level was shown by magnetic resonance imaging and if the herniated fragment was smaller than one-third of the spinal canal (Fig. 1). This subgroup of herniations was considered suitable for this kind of treatment based on early PLDD publications [6,7]. Herniated discs without magnetic resonance imaging–confirmed nerve root compression were excluded from the study as were patients with cauda equina syndrome, previous spinal surgery at the same disc level, lytic or degenerative spondylolisthesis, sequestered disc herniation, disc height less than 7 mm, central canal stenosis, pregnancy, severe somatic or psychiatric diseases, inadequate knowledge of the Dutch language, or emigration planned within 1 year of study inclusion. All eligible patients were examined and questioned by the treating neurosurgeon and a research nurse who recorded the baseline variables, follow-up questionnaires, and outcome measures. Patients were randomly allocated to a strategy of PLDD or conventional surgery on a 1:1 ratio. A computer-generated randomization list was prepared for each research nurse and each of the participating academic hospitals (n=2) and teaching hospitals (n=6). Blocks of random size (varying between two and four) of random numbers were formed to ensure equal distribution of the randomization among hospitals and nurses, the variable block size being used to minimize predictability. The data manager at the Department of Medical Statistics and Bioinformatics, who was not involved in the selection and allocation of patients, prepared coded sealed envelopes containing the treatment allocation. The envelopes were opened in the