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# Clinical Study

# Does provocative discography cause clinically important injury to the lumbar intervertebral disc? A 10-year matched cohort study

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#### Abstract

**BACKGROUND CONTEXT:** Provocative discography, an invasive diagnostic procedure involving disc puncture with pressurization, is a test for presumptive discogenic pain in the lumbar spine. The clinical validity of this test is unproven. Data from multiple animal studies confirm that disc puncture causes early disc degeneration. A recent study identified radiographic disc degeneration on magnetic resonance imaging (MRI) performed 10 years later in human subjects exposed to provocative discography. The clinical effect of this disc degeneration after provocative discography is unknown. **PURPOSE:** The aim of this study was to investigate the clinical effects of lumbar provocative discography on patients subjected to this evaluation method.

STUDY DESIGN/SETTING: A prospective, 10-year matched cohort study.

**PATIENT SAMPLE:** Subjects (n=75) without current low back pain (LBP) problems were recruited to participate in a study of provocative discography at the L3–S1 discs. A closely matched control cohort was simultaneously recruited to undergo a similar evaluation except for discography injections.

**OUTCOME MEASURES:** The primary outcome variables were diagnostic imaging events and lumbar disc surgery events. The secondary outcome variables were serious LBP events, disability events, and medical visits.

**METHODS:** The discography subjects and control subjects were followed by serial protocol evaluations at 1, 2, 5, and 10 years after enrollment. The lumbar disc surgery events and diagnostic imaging (computed tomography (CT) or MRI) events were recorded. In addition, the interval and cumulative lumbar spine events were recorded.

**RESULTS:** Of the 150 subjects enrolled, 71 discography subjects and 72 control subjects completed the baseline evaluation. At 10-year follow-up, 57 discography and 53 control subjects completed all interval surveillance evaluations. There were 16 lumbar surgeries in the discography group, compared with four in the control group. Medical visits, CT/MRI examinations, work loss, and prolonged back pain episodes were all more frequent in the discography group compared with control subjects.

FDA device/drug status: Not applicable.

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

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**CONCLUSION:** The disc puncture and pressurized injection performed during provocative discography can increase the risk of clinical disc problems in exposed patients. © 2016 Elsevier Inc. All rights reserved.

Keywords:

Lumbar discography; Disc degeneration; Lumbar surgery; Degenerative disc disease; Low back pain

## Introduction

Provocative discography involves a pressurized injection of fluid into an intervertebral disc to elicit a patient's typical pain, potentially identifying the disc as the anatomic source of primary back or neck pain. The test is controversial because there is a lack of clear test validity, and multiple studies have demonstrated poor specificity and high patient-specific false positivity [1-3]. Recent guidelines by the American Pain Society recommend against its use in the evaluation of back pain syndromes [4]. Nevertheless, many continue to use provocative discography as a test for discogenic back pain. Proprietary data from a large insurance carrier reveal that there were 0.22 discograms performed per 1,000 members in 2013. With a US population of 316 million people in 2013 (www.census. gov), the estimated number of people exposed to provocative lumbar discography in 2013 was almost 70,000. Given this information, it is clear that practitioners continue to regularly use provocative lumbar discography.

Further complicating the use of provocative discography is the morbidity associated with the needle puncture and pressurized injection. Many report that the risks associated with provocative discography are very low but could include: discitis, neurologic injury, visceral injury, dye reactions, and others [5]. These reported risks do not account for the possibility of accelerated disc degeneration. Animal studies indicate that disc puncture, even with small gauge needles, can lead to immediate and progressive mechanical and biological disruption [6–8]. Indeed, disc puncture is often used as a model to experimentally induce disc degeneration and disruption in animal research [9]. Needle puncture in human cervical discs has also been implicated in accelerated disc degeneration [10].

Recent work by our group has demonstrated that experimental lumbar discography in subjects without serious low back pain (LBP) problems at baseline demonstrated accelerated disc degeneration on qualitative and quantitative magnetic resonance imaging (MRI) compared to matched control subjects [11]. We now report on the comparative incidence of lumbar spine surgery, clinical imaging events, and low back disability events in subjects exposed to discography compared with control subjects over a 10-year follow-up period. Our hypothesis is that there will be no difference in the rate of surgery, imaging, or low back disability adverse events for subjects exposed to discography compared with control subjects.

#### Materials and methods

Study design

A prospective 10-year matched-cohort study was designed to investigate the effect of provocative discography on the subsequent development of adverse events associated with LBP or radiculopathy.

### Subject recruitment

Between 1996 and 1998, 75 subjects were recruited and enrolled in a study of provocative discography (L3-S1) in asymptomatic or minimally symptomatic persons for LBP. Subjects were recruited from one of three patient pools: subjects having documented cervical disc disease (n=45); subjects having previous lumbar disc herniation with complete symptom resolution (n=20); and subjects with no history of cervical or lumbar disc illness but who did have a history of serious psychological distress consistent with a somatization disorder (n=10). From the same three subject pools, 75 matched subjects who would not have discography performed were simultaneously recruited to act as control subjects. These subjects were recruited in the same proportions as discography subjects and were matched to age, gender, previous cervical/lumbar disc procedures, and psychometric profiles. Both groups underwent the same baseline evaluations (LBP questionnaires, psychometric questionnaires, Xrays, and MRI scan) with the sole exception of the provocative discography (L3–S1).

After the baseline evaluations, 75 discography subjects were scheduled to undergo lumbar discography (L3–S1). The results of these studies have been previously reported [1,2,12]. Discography and control subjects were then followed up at intervals for clinical LBP problems. At 1, 2, 5, and 10 years after the start of the study, discography subjects and controls were contacted for follow-up clinical evaluation. Clinical LBP problems up to 5 years after enrollment in these discography and control subjects have previously been reported [13,14].

#### Baseline entry criteria

The detailed entry criteria were previously described [1,2,12]. All subjects were screened for current low back problems using a screening questionnaire and the Oswestry Disability Index. Where subjects were involved as patients or subjects of concurrent studies, the original medical

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