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Comparison of Pressure-Controlled Provocation Discography Using Automated Versus Manual Syringe Pump Manometry in Patients with Chronic Low Back Pain

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Abstract

Purpose. The study compares the rate of positive discograms using an automated versus a manual pressure-controlled injection devise and compares the pressure and volume values at various pressures and initial evoked pain and 6/10 or greater evoked pain.

Study Design. A retrospective study prospectively collected patient study data used in a prior prospective study and with prospectively collected data which is routinely collected per our institutional standardized audit protocol. Two custom-built disc manometers (automated injection speed control; manual injection speed control) were sequentially employed during provocation discography in 510 discs of 151 consecutive patients. Two hundred thirty-seven discs of 67 patients with chronic low back pain were evaluated using the automated manometer (automated group) and 273 discs of 84 patients were evaluated with a manual manometer (manual group).

Result. No significant differences in positive discogram rates were found between the automated and manual groups (32.1% vs 32.6% per disc, respectively, $P > 0.05$). No significant differences in low-pressure positive discogram rates were found (16.0% vs 15.0% per disc, automated group versus manual group, respectively, $P > 0.05$). However, there were significantly increased volumes and lower pressures at initial and "bad" pain provocation.

Conclusion. The study results found equivalent positive discogram rates following a series of pressure-controlled discography using either an automated or manual pressure devise. There were, however significant increases in volume at both initial onset of evoked pain and at 6/10 pain when using the automated injection devise that may have caused the observed lower opening pressure and lower pressure values at initial evoked pain. Assuming increased volumes are innocuous, automated injection is inherently more controlled and may better reduce unintended and often unrecorded spurious high dynamic pressure peaks thereby reducing conscious and unconscious operator bias.

Key Words. Back Pain; Discogram; Diskogram; Block; Pressure Manometry; Provocative Discography; Pressure Controlled Provocative Discography

Introduction

Although the intervertebral disc is a common source of chronic axial pain [1–6], there is ongoing controversy over the criterion standard used to diagnose discogenic pain. Since the 1950s, lumbar discography has been widely used for evaluating chronic low back pain despite the

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controversy over its diagnostic validity [6–12]. Theoretically, provocation discography (PD) identifies discogenic pain by stimulating nocioceptors in the outer third of the annulus, within neo-innervated annular tears extending into the nucleus, or stimulation of nociocepters within the endplate [3,13–15]. However, the specificity of disc pressurization is challenged by a few research groups based on reported high false positive rates in patients with confounding factors using uncontrolled manual injections and using only statically recorded pressures by a suboptimal pressure control devise [16,17].

Provocation of patient pain during PD pressurizes the disc annulus and adjacent endplates by the intranuclear injection of contrast media. Current standards used to determine a positive pain response [17–19] include pressure limits which are highly dependent on the speed of injection. To lower the incidence of false positive responses due to excessive pressure stimulation, Derby in 1993 [20,21], Bogduk et al. in 1995 [22], and subsequently others [23] proposed that pressures should be used as a primary criteria to determine whether a discogram was positive or negative. Derby et al. standards included a 50 psi above opening [24,25] limit as a maximal cutoff stimulus applied to a disc.

Manual injection of 0.5 mL is typically accomplished in less than 2 seconds and thus the rapid increase in dynamic pressures may overstretch innervated structures including asymptomatic annular tears or the normally innervated outer annulus. Recording only the lower static pressures may increase false positive rates in patients and in clinical trials of asymptomatic volunteers [17,26–28]. Current PD techniques, however, typically measure only static pressures and are not therefore an accurate reflections of true intradiscal pressure [24,25].

Manometric dynamic peak pressure is influenced by resistance of the needle, rate of injection, and the resistance of intradiscal tissue. By using a slow injection speed, the difference between dynamic and static pressures is lessened [27,28]. Derby et al. were the first to use carefully controlled injection speeds using a twist manometer at a rate of 0.05 mL/s measuring both dynamic and static pressures in asymptomatic volunteers and patients. However, consistent injection speed using a manual twist devise required training by each interventionalist to achieve a consistent injection rate [28].

A sensor placed directly inside the disc is the most accurate method to measure intradiscal pressure; however, the excessive invasiveness precludes its use in all but animal and a few human research studies [7,10,27–33]. In clinical practice, intradiscal pressure is digitally measured using a manometer that is attached to the injection syringe [27,29–35].

The recent availability of automated injection devise (CDS System, Smith & Nephew, Andover, MA, USA; APCD system, Cybermedic Corp, Iksan, Korea) allow for the continuous monitoring of slow controlled injection speeds. We compared pressure, volume, and pain responses from data collected during pressure-controlled discography using a manual injection devise compared with an automated device. Using two cohorts of patients in one private practice, our goal was to determine whether automated versus manual injection results in a statistical difference in the number of positive discographies using the same pressure, volume, structure, and pain provocation criteria.

Materials and Methods

Subject Recruitment

We retrospectively designed and gathered data utilizing prospectively collected data from two groups of patients. The first was a series of patients undergoing pressure-controlled discography using a manual twist system [28] from a research study approved by the Institutional Review Board of Quorum Review, Inc. After the availability of an automated system, we switched to the automated devise because we felt automated controlled injection speeds would provide more consistent diagnostic information. As per our usual practice parameters, we prospectively collected data that we routinely collect for documentation, reporting and ongoing practice audits. The second group of patient data included this routinely collected data from a consecutive series of patients undergoing pressure-controlled diagnostic provocative lumbar discography. The first series of patients were informed of the nature of study and the risks of discography before consenting to the procedure. None of the first-group participants received any remuneration for partaking in the study, and the second group underwent routine discography.

The exclusion criteria were as follows: allergy to contrast media, iodine, inability to undergo magnetic resonance imaging (MRI) scanning because of ferromagnetic implants or severe claustrophobia, and inability to tolerate positioning for MRI or discography.

Patients were instructed in the use of the 0-point to 10-point pain numerical rating scored (NRS) for pain intensity responses. Those completing the pain NRS were instructed that 0 indicated no pain, 6 indicated bad pain, and 10 indicated the worse pain imaginable. All patients were required to obtain or to provide an MRI scan of the lumbar spine that had been taken within the previous 6 months.

Pressure-Controlled Provocative Discography

PD was performed in a surgical suite, under aseptic conditions, by the first author who had over 25 years of experience using PD and over 15 years of using pressure-controlled discography. Intravenous antibiotics (2 g of cephalosphorin) were administered 20 minutes prior to the procedure. Subjects were premedicated with 0.025 mg/kg midazolam prior to the procedure. A few participants were given a minimal dosage (10–20 mg) of propofol during needle insertion. Throughout the procedure, subjects were

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monitored with pulse oximetry and a blood pressure cuff. Supplemental oxygen was administered by nasal cannula.

Prior to injection, fluoroscopic examination of the spine was performed to confirm the segmentation and to identify the segments to be tested. Using a standard posterolateral approach, a 20-gauge, 3.5-inch introducer needle was advanced over the superior articular process. Through the introducer needle, a 25-gauge, 6-in. needle was passed into the center of the disc nucleus, and its position confirmed with anterior posterior (AP) and lateral fluoroscopic imaging. Nonionic contrast medium mixed with 6 mg/mL cephalosporin was injected into each disc at 0.04 cc/s with automatic pump (automated group) or at ~0.05 mL/s with manual twist syringe.

At the time of disc injection, each subject was awake, alert, and able to respond to instructions or questions. They were asked to report the nature and location of any pain evoked during the procedure, and to rate its intensity on a 0–10 numerical pain rating scale by the discographer and recorded by one to three independent observers.

The opening pressure was recorded when contrast medium was first seen to enter the disc. As each subsequent 0.5 mL of contrast medium was injected, both static and dynamic pressures, the location of contrast medium, and any pain response were recorded. Intradiscal pressure was defined as the dynamic pressure minus opening pressure (psi a.o.; pounds per square inch above opening pressure). Injection was continued until one of the following endpoints was reached: the subject experienced pain that they rated as having a severity of at least 6; or intradiscal pressure reached 80–100 psi a.o in discs without radial annular tears or 50 psi a.o. in discs with grade 3 or greater annuar tear(s). When each injection was terminated, AP and lateral spot films were obtained to record the distribution of contrast medium. Post-discogram computed tomography (CT) was performed at all levels evaluated.

Disc Manometer and Speed-Controlled Injection

The collected data was used to compare the automated versus the manual pressure manometers. The standard disc manometer uses a manual syringe crank injection pump and delivers 0.5 mL per 360 degree rotation (Intellisystem, Merit Medical Systems, South Jordan, UT, USA). To achieve a relatively consistent injection speed using the manual syringe devise, the first author rotated the syringe one full revolution in ~10–12 seconds to achieve an injection rate of ~0.05 mL/s to 0.04 mL/s as each 180 degrees twist delivered 0.5 ml of contrast. To approximate the dynamic and static pressure [27], we used an injection speed of 0.04 mL/s when using the automated disc manometer devise (CDS System, Smith & Nephew).

Evaluation of Pain

Primary outcomes included pain intensity and concordance at 0.5 mL incremental volumes in relation to recorded dynamic and static pressures. Subjects reported pain on a 0–10 point pain NRS. Fleeting responses, such as short burst of pain, lasting only one or less than a few seconds, were discounted unless confirmed on subsequent pressurization. Such responses could occur when fissures suddenly open, or when a thin outer membrane covering a grade 3 annular tear is torn. For a disc to be considered painful, the response to disc stimulation had to be sustained, the evoked pain had to persist for a period of at least 30 seconds and the static pressure had to be sustained at a measurable magnitude. The pain had to also be reproducible on a subsequent injection. As per our usual protocol, we recorded pressures and injected volumes at which pain was first evoked and at 6/10 pain NRS and at 15, 30, and 50 psi above the opening pressure if those pressures were reached prior to obtaining a positive response.

Image Analysis

Annular disruption was graded using the modified grading system described by Derby, Kim et al. [19] This grading system classifies annular disruption grade via a Dallas Discogram Scale [7] in which the scale is extended to include instances where contrast medium spread circumferentially through the annulus fibrosis as described by Aprill and Bodguk [36]. This added grade is defined as grade 4 disruption and is distinguished from grade 3 by the spread of contrast medium circumferentially within the substance of the annulus fibrosis, subtending a greater than 30° arc at the disk center. The Derby [19] grade also includes a grade 5 to describe contrast medium leaking through the outer disc capsule. The MRI of each disc tested was graded for signal intensity using a 1 to 5 scale for disc degeneration. An abnormal MRI was defined as greater than or equal to Grade 3.

Positive Discogram Criteria and Subgroups

The MRIs of each disc tested were graded for their signal intensity using I to V scale for disc degeneration. The CT discogram were graded for the presence and extent of radial fissures as 0, 1, 2, 3, 4, and 5 according to Derby, Kim et al. [19] discogram scale. Five criteria have been previously used to determine the presence of positive disc on discography: 1) an abnormal disc (Dallas scale grade ≥3); 2) a pain NRS pain response of 6 or more out of 10; 3) pressure level 50 psi a.o. or less; 4) pain described by patient as familiar (concordant); and 5) a negative control disc [37]. In contrast with the criteria of Walsh et al., we did not require two or more pain behaviors documented by videotape to establish a positive level. Subjects were divided into discogram positive versus discogram negative subgroups according to these five criteria. A low-pressure positive discogram was defined as having a dynamic pressure of less than 15 psi a.o. at pain provocation ≥6/10 [17,18]. Low pressure positive rates were compared for each CT discogram grade and MRI grade of degeneration. Mean opening pressure, mean pressure at initial evoked pain, mean injected contrast media volume at initial evoked pain, and mean injected contrast media

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volume at 6/10 pain NRS evoked pain were calculated from positive discogram subgroup of each group. Also, mean pain NRS and pain NRS variation from 15 psi a.o. to 50 psi a.o. was calculated from the positive and negative discogram subgroups of each group.

Data Analysis

All statistical analyses were performed with the Statistical Package for the Social Sciences/PC+ software (SPSS Inc., Chicago, IL). When comparing positive rates between the two devices, the chi-square test was used. The independent *t*-test was used to determine whether there was a difference between groups with 1) mean opening pressure; 2) mean pressure at initial evoked pain; 3) mean injected contrast volume at initial evoked pain; 4) mean injected contrast media volume at 6/10 pain NRS evoked pain; and 5) pain NRS variation from 15 psi a.o. to 50 psi a.o. Statistical significance was set at $P < 0.05$.

Results

Demographic Characteristics

PD was performed on a total of 510 discs in 151 patients. Discography using the automatic system was performed on 237 discs in 67 patients (automated group). Discography using a manual twist devise was performed on 273 discs in 84 patients (manual group). The demographic data of the subjects is presented in Table 1. There was no statistical significance in the gender distribution between groups, automated group (M : F = 42:25) versus manual group (M : F = 57:27). The age of the automated group (47.9 ± 11.82) was statistically significantly older than that of the manual group (42.7 ± 11.94, $P < 0.05$), with an age difference of 5.2 years. However, no correlation was found between the mean pain NRS pain scores (at 15, 30, and 50 psi a.o.) and mean age.

No statistically significant differences between two groups were present with height, weight, or duration of low back pain. The automated and manual groups were examined in terms of number of discs per a given grade of annular disruption. There was no statistically significant difference between the automated and manual groups in annular disruption when the degree of annular disruption was grouped by clinical significance (grade 0–2: 47 vs 70 discs; grade 3–4: 133 vs 121 discs; grade 5: 57 vs 79 discs).

Comparison of Automated Versus Manual Manometers

The positive rate of discograms calculated per disc was 32.4% (165/510 discs) for the entire study population. The positive rate of discograms per disc for the automated group and manual group were 32.1% (70/237 discs) and 32.6% (89/273 discs), respectively, with no significant difference between groups ($P > 0.05$) (Figure 1). The rate of low-pressure positive discograms (per disc) of the total study population was 15.5% (79/510 discs). The low-pressure positive rates of discogram (per disc) for the

Table 1 Demographic characteristics of automated group and manual group subjects

	Age*	Sex (M : F)	DRAM (N : R : DD : DS%)	Height	Weight	Duration CLBP	Annular Disruption (%)		
							0–2	3–4	5
Automated	47.9 ± 11.82	42:25	14:17:4:5 (35:42:10:13)	67.8 ± 5.08	176.8 ± 47.1	64.7 ± 54.7	47 (19.8)	133 (56.1)	57 (24.1)
Manual	42.7 ± 11.94	57:27	15:42:22:5 (18:50:26:6)	68.1 ± 3.94	186.0 ± 53.0	51.9 ± 64.0	70 (25.9)	121 (44.8)	79 (29.3)

* Statistically significant difference ($P < 0.05$).
Automated = automatic manometer; Manual = manual manometer; DRAM = Distress and Risk Assessment Method; N = normal; R = at risk; DD = distressed depressive; DS = distressed somatic; CLBP = chronic low back pain.

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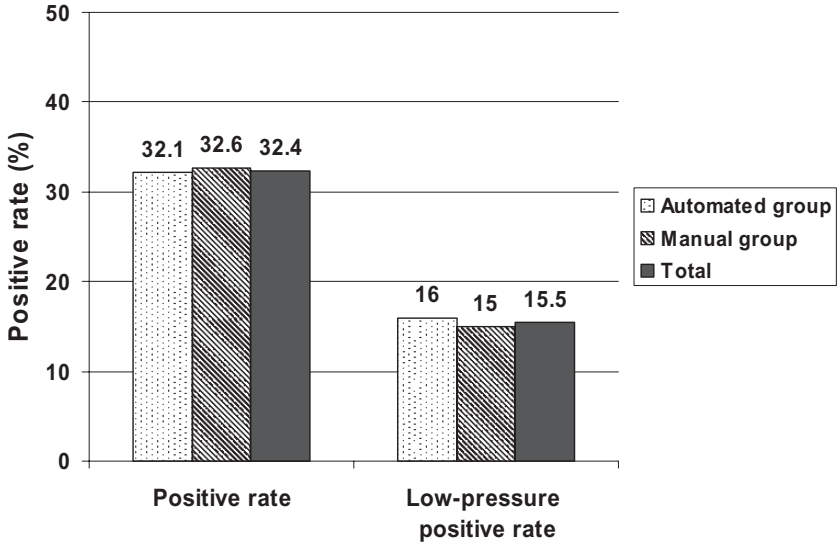

Figure 1 Rate of positive discograms in automated and manual group. Automated = automated manometer; Manual = manual manometer; Low pressure positive rate = meets International Spine Intervention Society/ International Association for the Study of Pain criteria with a dynamic pressure of less than 15 psi a.o. at pain provocation.

automated group and manual group were 16.0% (38/237 discs) and 15.0% (41/273 discs), respectively, with no significant differences between groups ($P > 0.05$) (Figure 1). Low-pressure positive discogram rates per disc for the automated and manual group in grades 3, 4, and 5 were 21.8% (29/133 discs) versus 14.1% (17/121 discs), 15.8% (9/57 discs) versus 16.5% (13/79 discs), respectively. There was no significant difference in grades 3, 4, and grade 5 (Figure 2).

Significant differences were found in 1) mean opening pressure (8.05 ± 7.74 psi versus 13.99 ± 11.22 psi, automated group versus manual group, respectively, $P < 0.01$) (Figure 3); 2) mean pressure at initial evoked pain (11.91 ± 10.06 psi a.o. vs 20.10 ± 12.55 psi a.o., automated versus manual group, respectively ($P < 0.01$) (Figure 3); 3) mean injected contrast volume at initial evoked pain (1.67 ± 0.93 mL vs 0.84 ± 0.60 mL automated versus manual group, respectively ($P < 0.01$) (Figure 4); and, 4) mean injected contrast media volume at 6/10 pain NRS evoked pain (1.96 ± 1.01 mL vs 0.83 ± 0.52 mL, automated group versus manual group, respectively, $P < 0.01$) (Figure 4).

The mean pain NRS pain scores were reported at 15, 30, and 50 psi a.o. in both the automated and manual groups for both positive and negative discograms (Figure 5). No significant difference was found in mean pain NRS pain scores during pressurization between the automated or manual negative discogram groups (0.85 ± 1.76, and 0.40 ± 0.90, respectively) or positive discogram groups (automated = 6.61 ± 2.36 versus manual group 6.82 ± 2.38).

The difference in pain NRS pain score at 15 psi a.o. versus 50 psi a.o. was 2.19 ± 3.75 in the discogram positive

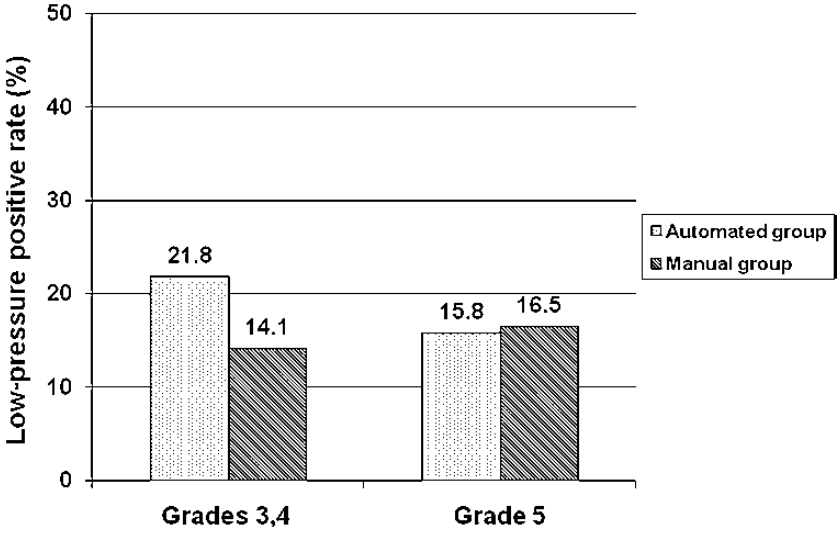

Figure 2 The low-pressure positive rates at each grade of automated and manual group. Automated = automated group using automated syringe pump with manometer; Manual = manual group using manual syringe pump with manometer.

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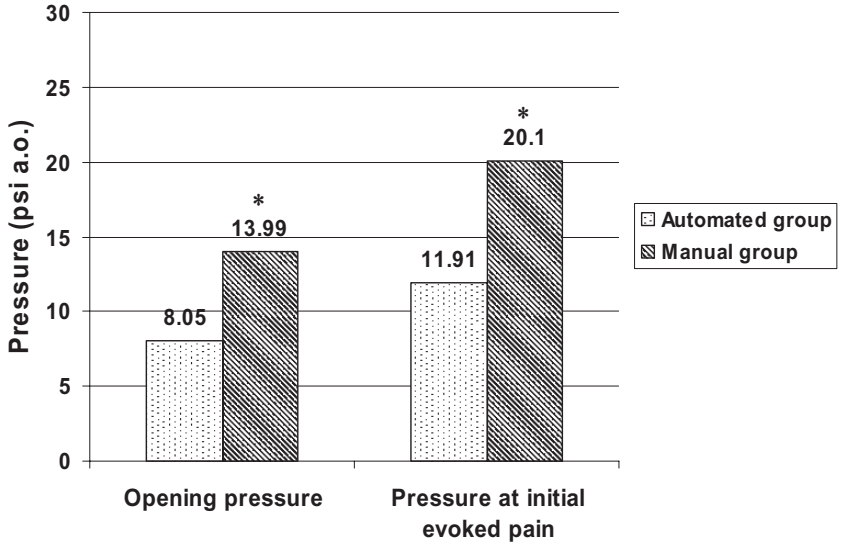

Figure 3 Opening pressure and pressure at initial evoked pain in each positive discogram subgroup of automated and manual group ($P < 0.01$). Automated = automated manometer; Manual = manual manometer. Pressure at initial evoked pain = psi a.o.; pounds per square inch above opening pressure. * statistically significant difference.

automated subgroup and 3.76 ± 3.05 in the discogram positive manual subgroup ($P = 0.03$). A statistically significant difference was noted between discogram positive subgroups of using the automated versus manual manometer (Figure 5). Among negative discograms, there was no significant difference in pain NRS pain score from from 15 psi a.o. to 50 psi a.o. between the automated and manual groups (0.46 ± 1.48 vs 0.74 ± 1.66, respectively, $P > 0.05$).

Discussion

The validity and utility of discography as the criterion standard for diagnosing discogenic pain engenders strong diverging opinions. Some authors report an unacceptably high false-positive rate in asymptomatic subjects; whereas, a recent systematic review with a meta-analyses of false-positive rates found that false-positive rates can be kept below 10% if operator adhere to strict criteria.

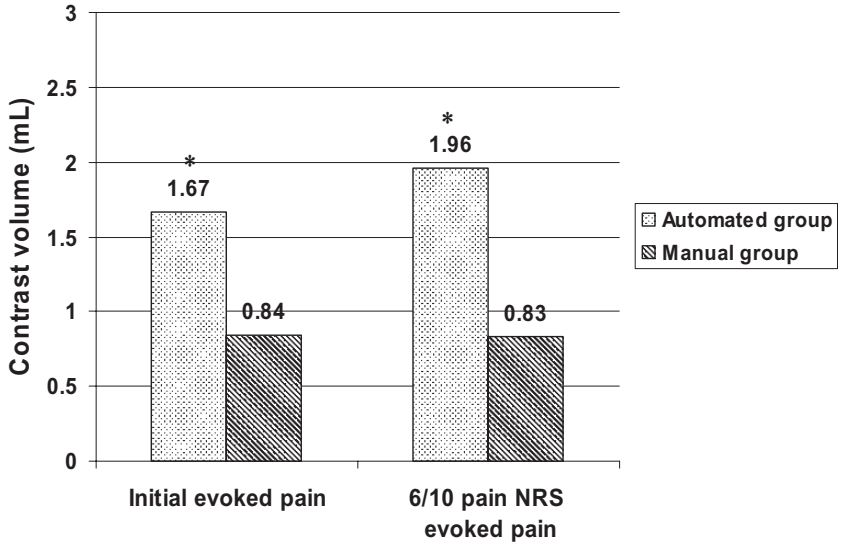

Figure 4 Mean injected contrast volume at initial evoked pain and at 6/10 pain NRS evoked pain in each positive discogram subgroup of automated and manual group ($P < 0.01$). Automated = automated group using automated syringe pump with manometer; Manual = manual group using manual syringe pump with manometer. Pain NRS = numeric rating scores of pain, pain was rated via a 0–10 numerical rating scale, * = showing statistically significant difference.

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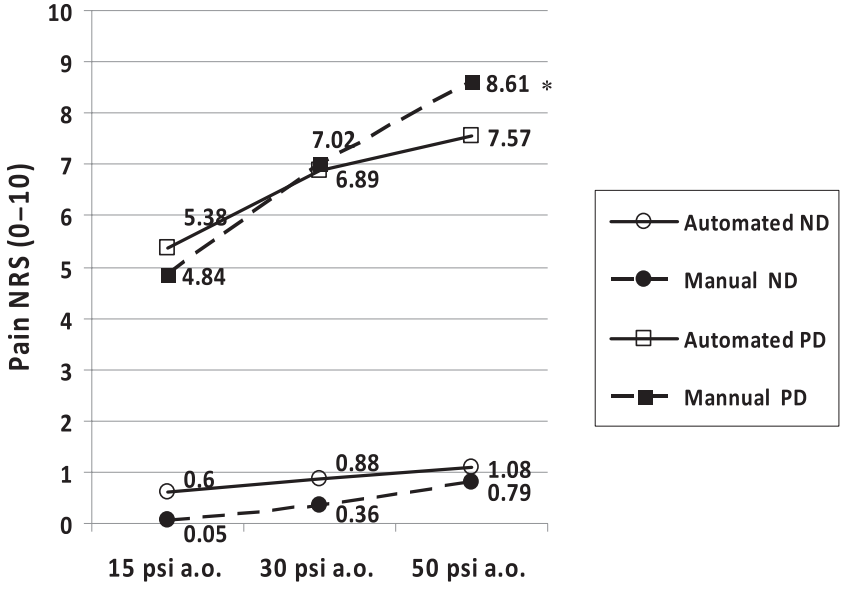

Figure 5 Mean pain NRS in three different injection pressures of each positive and negative discogram subgroup of automated and manual group. Automated PD = discogram positive of automated subgroup; Automated ND = discogram negative automated subgroup; Manual PD = discogram positive manual subgroup; Manual ND = discogram negative manual subgroup, psi a.o. = pounds per square inch above opening pressure. Pain NRS = numeric rating scores of pain, pain was rated via a 0–10 numerical rating scale.* showing statistically significant difference.

One concern regarding the results of PD is variability in intra- and inter-operator stimulus provocation secondary to variable unrecorded degrees of disc stimulation that may artificially increase the false positive rate [17,38]. No prior studies except Derby et al. measured dynamic pressures and most did not measure pressure or measured static pressure alone with a suboptimal system [12,38]. Most currently available pressure-controlled injection devises used for discography have a manual crank system that allow variable speeds of injection. Uncontrolled, high-speed injections will cause high dynamic intradiscal pressures which are significantly different from the static pressures [34]. Moreover, it is the dynamic, as opposed to the static pressure that is correlated with evoked pain response [24,25]. Only within the last several years have automated injection devises been available that facilitate precisely controlled injection speeds that prevent high spurious dynamic pressure peaks.

We compared PD results using automated manometry disc injection in 237 discs of 67 patients with chronic low back pain to PD results using manual manometry in 273 discs of 84 patients. The collected data revealed no significant differences ($P > 0.05$) in the percentage of positive PD results using either automated manometer (32.1%) versus manual manometer (32.6%), and thus, either system should provide similar results.

Although the percentages of positive discograms were statistically equal, there were significant increases in volumes of injected contrast in the automated group compared with the manual injection group. This increased volume may explain the decreased average recorded pressure values for the onset of initial pain and pain equal or greater to various pressure thresholds. Possible causes of increased volume include the slower and steadier injection speeds in the automated injection devise that allowed for more complete filling of annular tears and more complete mixing within the proteogycan content of the nucleus and inner annulus [39]. If volume itself is an independent variable that acts in parallel with pressure to provoke pain, increased volume may explain the increased percentage of low-pressure positive (<15 psi a.o) discograms in the automated group and the lower pressures at initial and bad (≥6/10) pain threshold. Larger volumes could stimulate tissue not reached by lower volumes, and larger volumes would be more likely to more completely fill, stretch, or open annular fissures. While the injection speed was lower in the automated group by 0.01 m/s, in reality, it is difficult to maintain a consistent slow injection speed using a manual twist devise and some of the difference may be explained by unintentional high dynamic pressures produced by erratic manual injection. The more reliable pressure volume stimulus of automated injection may also explain the more consistent pain NRS values, regardless of pressure, in the critical threshold region of NRS 5–7 range.

Although the study's primary purpose was to compare the positive rate of discography using manual versus

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automated injection, the automated data also confirms, or prior data showing that provocative discography in patients with grade 3 or greater annular tears results in only ~1/3 positive rate if performed by an expert using a precise technical protocol and scored using strict standards. In addition, the findings in the automated group confirms our prior study [24] showing a clear difference in positive responses versus negative responses at all recorded pressures in patients with chronic pain. These findings are contrary to the claim that discography results in an unacceptably high rate of positive responses in patients with confounding factors. Ruling out the disc as a source of pain and thus preventing unnecessary interventional or surgical treatment may be the most valuable information gained by the test and using an automated system may facilitate more accurate assessment.

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