

In vitro measurement of pressure differences using manometry at various injection speeds during discography

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Abstract

BACKGROUND CONTEXT: Lumbar discography has been widely used to evaluate discogenic low back pain. Anecdotal evidence suggests that pain reproduction during discography is more closely correlated with peak dynamic pressure than with static postinjection pressure. Although there can be a significant difference between dynamic and static pressures, to date most discographic evaluations use static pressure recorded postinjection (which is stable and easily measured). The use of readings taken after injection, rather than readings of maximum dynamic peak pressure recorded during injection, appear to increase false positives in lumbar discography. High-speed intradiscal injections also appear to have potentially confounding effects that may increase the rate of false-positive responses during lumbar discography. To date there has been no study for the evaluation of peak dynamic intradiscal pressures or for differentiating dynamic from static pressures in the nucleus pulposus (NP) in response to various speeds of intradiscal injection.

PURPOSE: The goal of this study was to obtain additional data on potential confounding factors that could affect discographic results by assessment of pressures within the NP during discography at various injection speeds. The purpose of data collection was to more precisely evaluate pressure differences between dynamic and static pressure within the NP, evident during discography.

STUDY DESIGN: In vitro laboratory study.

SAMPLES: A total of 82 trials were performed on intervening discs of 82 porcine cadaver lumbar spines.

METHODS: Dynamic and static intradiscal pressures were measured with manometry, using two pressure sensors simultaneously during intradiscal injection of contrast media at various speeds. The tip of a 25-gauge needle was placed in the center of the NP and connected with a pressure manometer, which recorded the pressure and therefore the speed of injection. A second pressure reading was obtained using a sensor tip connected to a transducer; the sensor tip was located separately in the same NP tissue. The needle and transducer locations were confirmed by fluoroscopy.

OUTCOME MEASURES: At low controlled injection speeds (below 0.08 mL/s), the mean peak pressure difference in the NP was 4.06 (± 1.52) psi. With high-speed injections of 0.08 mL/s or greater, the mean increased abruptly up to 14.52 (± 4.11) psi ($p < .05$). The data indicate that injections applied slowly resulted in smaller differences in pressure within the NP, registered by both manometry and the needle sensor tip. Additional samples were taken using both devices to confirm this threshold level.

RESULTS: With low injection speeds, especially those below 0.08 mL/s, differences between dynamic and static pressures on both pressure sensors were minor. These differences increased as injection speed became faster. However, at fast injection speeds of 0.08 mL/s and above, those differences were significantly higher.

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CONCLUSION: Dynamic and static intradiscal pressures are of similar value when measured by manometer and by needle sensor at slow injection speeds during discography. However, the pressure differences appeared to rapidly increase in response to incremental increases in injection speed. The data from these 82 samples suggest that uncontrolled high speeds of intradiscal injections are a potential confounding factor, which may increase false-positive responses during lumbar discography. © 2007 Elsevier Inc. All rights reserved.

Keywords: Discography; Intradiscal pressure; Low back pain

Introduction

Discography is a potential solution to the diagnostic dilemma concerning which patients to treat surgically and at what segmental level. In 1995, the North American Spine Society stated that discography, particularly when followed by computed tomography scanning, may be the only study capable of providing a diagnosis or permitting precise description of the internal anatomy of a disc and the integrity of disc substructures [1]. Although new diagnostic imaging tools have been developed and are widely used, discography is still practiced for diagnosing lumbar discogenic pain even though there have been debates about the efficacy and interpretation of the discography [2–8]. Discography remains particularly useful in problematic cases not definitively diagnosed by magnetic resonance imaging or myelography and in patients for whom surgery is contemplated [9].

Discography is a provocation test that reproduces the patient's pain by stressing the disc and increasing pressure within the disc through the injection of a contrast medium. A precision injection of contrast dye into the disc nucleus stimulates nerve endings and reproduces concordant pain in torn pathologic discs. Therefore, intradiscal pressure may reflect the intensity of the stimulus; consequently it is crucial to measure the exact intradiscal pressure during discography. Because it is a provocation test, discography is characterized by the liability inherent in all provocation tests: the response may be dependent on the intensity of the provocation stimulus.

There have been several studies in which pain response and the intensity of the stimulus were measured and calibrated [10–12]. O'Neill and Kurgansky [10] sought to measure the pain threshold using an analytical model and concluded that discography should be performed with controlled pressure. To assess the accuracy of discography, Carragee et al. also evaluated pain intensity and pain-related behavior in cohorts of subjects without low back pain [5,6,13,14].

The most effective method of measuring intradiscal pressure is to place a sensor inside the disc directly. However, the relatively large size of the pressure sensor tip may be harmful to the disc. Further, the two needles required in this procedure, placed inside the disc, could cause additional damage. In clinical practice, during the injection of contrast media, the only means currently available for

measuring pressure inside the disc involves the use of a manometric syringe. Therefore, intradiscal pressure is estimated indirectly through manometric pressure.

Given the indirect nature of manometry, the current study focused on data produced with this methodology. The majority of previous studies have been based on readings of plateau static pressure, recorded postinjection [15,16]. Researchers also anecdotally reported two pressures—dynamic and static—but dynamic pressures have not typically been utilized in clinical situations [17,18]. Investigative and clinical studies have reported only static pressure. Although some physicians have used dynamic pressure, to date the parameters have not been well defined [3,5,6,13,14,19–21].

Injection speed could be a potential confounding factor. Although static pressure has been the focus of research and clinical procedures, preliminary observations suggest that in discography and in daily living, the real pressure of evoked pain reflects dynamic peak pressure within the disc [21]. Clinically, increased dynamic pressure is frequently observed to reproduce familiar pain, which appears to correlate with patients' symptoms.

Using manometric dynamic pressure, Derby et al. sought to measure the pain response and the intensity of the stimulus in asymptomatic subjects [21,22]. These results indicate that pain intensity in the disc most accurately corresponds with manometric peak dynamic pressure, rather than static pressure. However, manometric peak pressure may be influenced by technical aspects of the procedure, such as the resistance of the needle, injection volume, or injection speed. To date, there has been no study of pressure differences between the dynamic and static pressures in the nucleus pulposus in response to injections at various speeds and evaluation of the exact level of pressure within the disc.

Methods and study design

A total of 82 trials were performed on intervening discs of fresh porcine lumbar vertebrae. Each specimen was frozen at -20°C in double plastic bags, and to avoid drying, they were kept moist during storage. Each specimen was thawed to room temperature in double plastic bags for 4–6 hours [22].

For the measurement of intradiscal pressure, two pressure sensors were used for each disc. One sensor was

connected to a pressure manometer, a device for recording pressure within a syringe (Merit System; Merit Medical Systems Inc., South Jordan, Utah). The other sensor was attached a device for measuring pressure directly through the needle tip (OrthoAR; Medical Measurements, Hackensack, NJ). Before the study, readings from the needle sensor were calibrated with the manometer and their validity was confirmed. No differences were found between the initial readings of the two devices.

In each trial, a 25-gauge needle attached to the pressure manometer was introduced into the center of the nucleus pulposus of each disc from the anterior lateral approach. The needle sensor connected to the transducer was also introduced into the central portion of the nucleus with the guidance of fluoroscopy, and its precise central positioning was confirmed. A water-soluble contrast agent, Omnipaque (GE Healthcare, Princeton, NJ), was used in all injections. Pressures registered on the transducer and those on the manometer were monitored and recorded simultaneously during the 0.125-mL contrast injection.

Baseline pressures recorded using the manometer and needle sensor were observed and noted by video analysis. The starting and ending time of the injections were evaluated by reviewing digital video film sequences created at 30 sections per second. With this information, the injection speed was then calculated using the following equation:

Comparative injection speed = volume of injection / duration of injection (ending time of injection – starting time of injection); for example, comparative injection speed = 0.125 mL / x sec. During and after each injection, the pressures recorded on both devices were evaluated for each film sequence.

When dye was injected, pressure within the nucleus pulposus and that registered on the manometer were found to increase to a certain point and then decrease to an end point after the contrast injection. The highest pressure measured is described as peak dynamic pressure and the final pressure as postinjection static pressure. Differences between dynamic and static pressures were calculated for both devices in each of the 82 trials.

After analyzing the pressure distribution of responses to injection speed, our analysis focused on the point at which the difference between mean dynamic and static pressures abruptly changed. The injection rate of 0.08 mL/s was determined to be the threshold speed. Injections administered more rapidly than 0.08 mL/s showed a greater difference between dynamic and static pressures. Consequently, we divided the samples into two groups, defined as slow (<0.08 mL/s) and fast (\geq 0.08 mL/s) injection speeds. The mean differences between peak dynamic and postinjection static pressure were compared, and the correlation coefficient was analyzed. Using regression analysis, the estimated differences between these two levels of pressure were calculated.

All statistical analyses were executed with SPSS/PC+ software (SPSS, Inc., Chicago, IL) using the standard *t* test, Pearson's correlation, and linear regression analysis.

Results

In 82 trials, the injections were applied at speeds ranging from 0.02 mL/s to 0.26 mL/s. The peak dynamic pressure ranged from 27 psi (186,158.44656 newton/square meter) to 191 psi (1,316,898.64048 newton/square meter) registered on the Merritt manometer and from 24 psi (165,474.17472 newton/square meter) to 178 psi (1,227,266.79584 newton/square meter) on the OrthoAR needle sensor (1 pound/square inch [absolute] = 6,894.75728 newton/square meter or pascal). The static pressure after the completion of the injection ranged from 26 psi (179,263.68928 newton/square meter) to 163 psi (1,123,845.43664 newton/square meter) on the manometer and from 24 psi (165,474.17472 newton/square meter) to 167 psi (1,151,424.46576 newton/square meter) on the needle sensor.

Real time pressure changes are shown in Figure 1. With slow injections of 0.02 mL/s, intradiscal pressure gradually increased to a peak of 11 psi (79,842.33008 newton/square meter) and decreased to 9 psi (62,052.81552 newton/square meter) after the injection. At fast speeds of 0.26 mL/s, intradiscal pressure abruptly increased as high as 60 psi (413,685.4368 newton/square meter) above baseline and typically decreased to 14 psi (96,526.60192 newton/square meter) after injection. If dye is injected into the intervertebral disc at a faster rate, then it accumulates faster and raises the pressure of the disc more rapidly. The maximum dynamic peak pressure with both slow and fast injections differed significantly (49 psi: 337,843.10672 newton/square meter), whereas little difference was evident between static pressures recorded postinjection (range 5 psi: 34,473.3864 newton/square meter).

Additional samples were taken to further evaluate effects of injection speed. Data were gathered on a series of slow injections applied at speeds of 0.02 mL/s; fast injections were applied at 0.26 mL/s. Pressure at 0.05 mL/s was 4.39 ± 2.57 psi ($30,267.9844592 \pm 17,719.5262096$ newton/square meter) and increased significantly at 0.26 mL/s injection speed 11.56 ± 9.19 psi ($79,703.3941568 \pm 63,362.8194032$ newton/square meter) ($p < .05$). This series provided additional data

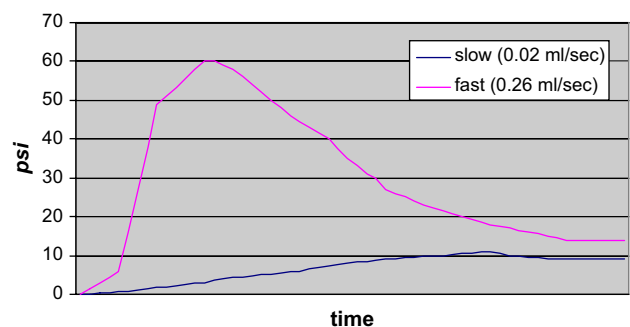


Fig 1. Pressure changes of nucleus pulposus with 0.02 mL/s and 0.26 mL/s injection speeds. At slow injection speeds, the peak pressure was 11 psi (75,842.33008 newton/square meter) above baseline; however, at fast injection speeds, peak pressure was 60 psi (413,685.4368 newton/square meter). Postinjection static pressures at both speeds were similar.

confirming a significant increase in pressure during more rapid injections.

Data analysis

The differences between dynamic and static pressures ranged from 1 psi to 64 psi (6,894.75728 to 441,264.46592 newton/square meter) recorded with the manometer and from 0 psi to 46 psi (0 to 317,158.83488 newton/square meter) on the needle sensor. The distribution of the difference between dynamic and static pressure is shown in Figure 2.

With low injection speeds, especially those below 0.08 mL/s, differences between dynamic and static pressures on both pressure sensors were minor. These differences increased as injection speed became faster. The correlation coefficient of injection speed was 0.901 for pressure differences recorded with the manometer and 0.896 for those registered via needle sensor ($p < .01$).

At slow injection speeds below 0.08 mL/s, the mean difference between dynamic and static pressures was 9.93 ± 3.81 psi (68,464.9397904 \pm 26,269.0252368 newton/square meter) registered on the manometer and 6.22 ± 2.68 psi (42,885.3902816 \pm 18,477.9495104 newton/square meter) registered inside disc with the needle sensor (Fig. 4). However, at fast injection speeds of 0.08 mL/s and above, those differences were significantly higher: 39.90 ± 11.98 psi (275,100.815472 \pm 82,599.1922144 newton/square meter) on the manometer and 27.57 ± 9.19 psi (190,088.4582096 \pm 63,362.8194032 newton/square meter) inside the disc ($p < .001$).

Pressure levels registered during fast injections were threefold higher than those < 0.08 . With regression analysis, the difference between dynamic and static pressures on the manometer was calculated using the following formula: Pressure difference = B (constant coefficient) \times injection speed + constant (Table 1). In the slow-speed injection group the coefficient was 131, a low value. In the fast-speed injection group, the coefficient was as high as 200.

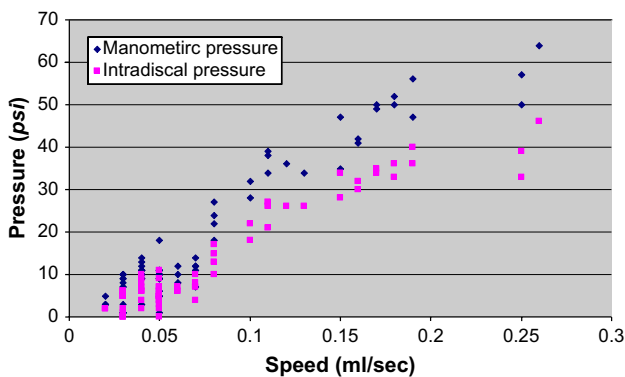


Fig. 2. Differences between dynamic and static pressures registered with the needle sensor in the nucleus pulposus and with the manometer at various injection speeds. With lower injection speeds, the pressure differences were minimal and became greater as injection speed increased.

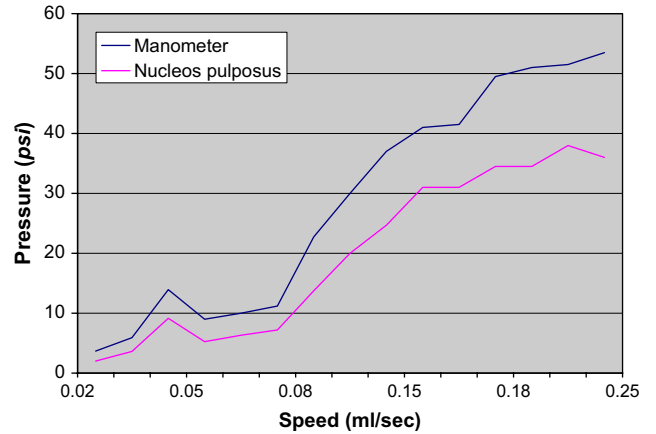


Fig. 3. Mean differences between peak dynamic pressure and postinjection static pressures at various injection speeds. Mean peak pressure differences increased abruptly at speeds ≥ 0.08 mL/s.

Calculated pressure

Currently another method is also used to estimate intradiscal pressure. Clinically or experimentally many discographers measure pressure with a third method, referred to as calculated pressure, using the following formula: static pressure + 1/3 (dynamic – static pressure) [21].

For this study, we compared intradiscal peak pressure by analyzing all three pressure parameters (Fig. 5). Comparing dynamic pressure levels recorded on the manometer, pressure differences showed small ranges, from 0 to 15 psi (0 to 103,421.3592 newton/square meter). However, comparing static pressure readings on the manometer, intradiscal peak dynamic pressures were much higher, ranging from 1 to 49 psi (6,894.75728 to 337,843.10672 newton/square meter). At slow injection speeds, all three parameters showed similar intradiscal peak pressure. As injection speed increased (particularly at speeds ≥ 0.08 mL/s), static and calculated pressure parameters showed clinically significant differences in intradiscal peak pressure [21].

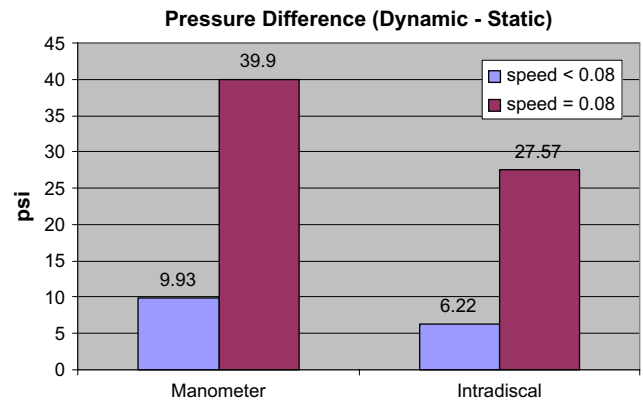


Fig. 4. Differences between dynamic and static pressures in response to slow injections (of < 0.08 mL/s) or fast injections (0.08 mL/s or higher). Samples injected at faster rates showed significantly greater differences between peak dynamic pressure and static postinjection pressure as registered on both the manometer and pressure sensor.

Table 1

Coefficients and constants: estimation of the differences between peak dynamic pressures and postinjection static pressures

	Injection speed	Coefficients	Constant	R square
Manometer	<0.08 mL/s	131.140*	2.781	0.212
	≥0.08 mL/s	200.485*	10.761*	0.837
Intradiscal Sensor	<0.08 mL/s	83.738*	1.591	0.175
	≥0.08 mL/s	151.14*	5.789*	0.808

Pressure difference = B (constant coefficients) × injection speed + constant.

* p < .01.

Discussion

For some patients, lumbar discography is the primary test found to identify and confirm diagnosis in those who have chronic persistent low back pain with referred buttock and leg pain, a condition historically described as internal disc disruption syndrome [7,21,23–26]. There have been several reports indicating that internal disc pain appears to be a result of disruption of disc architecture, which frequently has vague symptoms and consequently is not easily detected. The contour of the disc remains normal, or essentially so, and consequently, the disc may appear normal on magnetic resonance imaging, a computed tomography scan, or on myelography [27]. Consequently, the accuracy of discographic measurements is important in patient diagnosis.

The response of patients appears to be dependent on the intensity of the provocation stimulus; unless the patient expresses pain, the investigator has no way to determine the status of disc pain. Therefore, it is crucial to measure the exact peak dynamic intradiscal pressure, the pressure level most likely to reproduce the painful response during intradiscal injections.

The goal of this study has been to determine how the intensity of stimulus can be most accurately measured. In investigative studies, if intradiscal dynamic pressure can be measured directly using a needle sensor, the intensity of stimulus can be more closely assessed, potentially improving the accuracy of discogenic research and methodology.

These results showed that when injecting up to 0.08 mL/s, the mean peak pressure differences were minimal, but injecting at 0.08 mL/s or faster resulted in an abrupt increase in mean pressure differences (Figs. 1–5). In general, contrast media should be injected slowly, at a speed of less than 0.08 mL/s, to reduce the possibility of false-positive discographic results.

A shortcoming of the present work is that these were in vitro animal disc experiments. The same experiment using in vivo human discs is rarely feasible owing to safety considerations, because two or more pressure sensors were introduced into the nucleus pulposus to record pressure simultaneously. Additionally, the OrthoAR needle sensor tip, due to its large size, can be potentially damaging to in vivo nucleus pulposus tissue. Although this device is used as a research tool with cadavers and animal models, it is not appropriate for use on live human subjects. Another limitation was the fact that porcine spinal discs are smaller in volume and size than human discs.

However, our study is the first to evaluate the changes between dynamic and static pressure within the nucleus pulposus using investigational discography. The results may provide a possible explanation for the cause of various clinical artifacts noted in outcomes of discography. In future research and clinical procedures, injection protocol could be adjusted to reduce the rate of false positives.

From these results, we can conclude that injection speed is one of the confounding factors in measuring intradiscal pressure. It is more desirable to measure maximum peak dynamic pressure during discography and when injecting dye. If it is not possible to obtain a reading of dynamic pressure, then the injection speed should be decreased (in our study 0.07 mL/s or below, in porcine cadaver). When injection speed is controlled, there is less of a difference between dynamic and static pressure, which will increase the accuracy of discography. Uncontrolled high speeds of intradiscal injection are potential confounding factors, which may increase false-positive responses during lumbar discography.

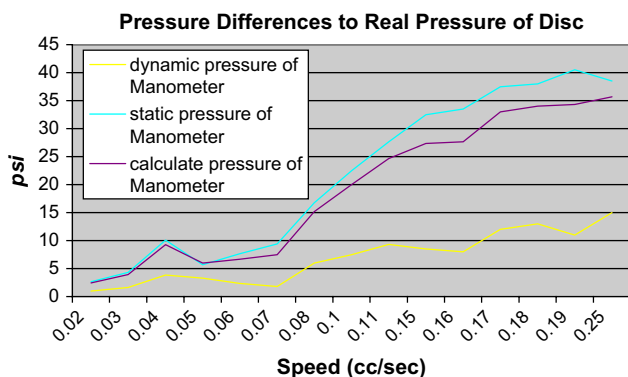


Fig. 5. Pressure differences among dynamic, static, and calculated manometric pressure parameters with intradiscal pressure measured by the OrthoAR needle sensor. With incremental changes in speed, the differences were increased in static and dynamic pressure.

Conclusion

Dynamic and static intradiscal pressures are of similar value when measured by manometer and by needle sensor at slow injection speeds during discography. However, the pressure differences appeared to rapidly increase in response to incremental increases in injection speed. The data from these 82 samples suggest that uncontrolled high speeds of intradiscal injection are a potential confounding factor, which may increase false-positive responses during lumbar discography.

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