
Design: Prospective matched cohort study

Population/sample size/setting:
- 150 volunteers (112 men, 38 women, mean age 40) without current low back pain (LBP) who participated in a study of the effects of discography on normal discs from L3 to S1
  - 75 of the volunteers received lumbar discography and 75 served as non-injected controls, matched on spinal disc history
    - Each group of 75 had the same composition of subjects: 40 had documented cervical disc disease, 25 had a history of lumbar disc herniation which had completely resolved symptomatically, and 10 had no history of either lumbar or cervical disc disease but had a history of psychological distress consistent with somatoform disorder
  - Groups were also matched on age, sex, psychometric profiles, low back pain questionnaires, x-rays, and MRI scans
    - Psychometric tests included Zung Depression Test, Modified Somatic Pain Questionnaire, and Medication Scales
  - Inclusion required that participants not be receiving or seeking treatment for LBP, not be taking medication for LBP, and have no activity restrictions from LBP

Main outcome measures:
- All participants in the discography group had the same protocol
  - Discographers performed discography on a mix of study participants and active LBP patients who were not part of the study, and were not informed of which patients were study participants
  - Pressure readings were taken after each 0.5 ml injection, with a pressure relief valve set at 100 psi maximum at each level
  - A “low pressure” positive injection was recorded when pain was provoked at less than 22 psi static pressure
  - A “negative” control disc was required to determine a “positive” discogram
- Main outcome was the status of the disc on MRI taken 10 years after the discogram under a protocol of MR sequences for disc degeneration at the lowest 5 disc segments
  - Observers were 2 radiologists and 2 orthopedic spine surgeons; each MRI was evaluated by 2 examiners, and if they disagreed on the image interpretation, the image was evaluated by 2 additional observers, with resolution of disagreement by consensus discussion
  - Disc signal intensity was determined relative to adjacent CSF signal, with change expressed as the percentage of signal change compared to baseline
- Disc degeneration, disc herniation, Modic endplate changes, anular high intensity zones (HIZ), and disc height were graded.

- At baseline, 71 of the 75 discography participants and 73 of the 75 control participants competed the protocol.

- At the 10 year follow-up, 57 of the 71 discography and 54 of the 73 control participants were successfully contacted and interviewed by telephone by a research assistant to determine interval medical history.

  - Several criteria would exclude the participant from a follow-up MRI: new spine fracture/dislocation, any lumbar spine surgery or intradiscal therapy, another lumbar discogram, lumbar infection/tumor, new rheumatic disease diagnosis requiring treatment, or new contraindication to MRI (such as cardiac pacemaker).

  - After these interviews, 5 discography participants were excluded due to new lumbar surgery; 4 controls were excluded.

- 52 discography and 50 control participants were eligible for the 10-year follow-up MRI; many had acceptable interval MRI within the past 3 years and new MRI was not needed; the remaining participants who had not had a recent scan got a new MRI.

  - MRI images at L3/4, L4/5, or L5/S1 were available for 155 previously injected discs in the discography group and for 150 never-injected discs in the control group.

  - MRI images were also obtained at the L1/2 and L2/3 discs, which had not been subjected to discography.

- Principal finding was that participants who had had discography had greater progression of MRI disc degeneration than the control group.

  - New herniation was seen in 55/155 discs in the discography group but only 22/150 in the control group.

  - The discography group had an average of 13.28% disc signal loss, compared to 8.46% disc signal loss in the control group.

- In contrast, the non-injected discs at L1/2 and L2/3 had similar baseline and follow-up MRI findings for both the discography and control groups.

- There were 134 needle injections with a 25 gauge needle and 21 injections with a 22 gauge needle; these numbers were too small to show a difference in needle size on the risk of new disc herniation.

- The side of the discography injection appeared to make a difference: among the new MRI herniations, 34 were ipsilateral to the injected side, 14 contralateral, and there were 4 central herniations; this appeared to be greatest at the foramen and far lateral disc regions, at the expected site of needle entry.

- It did not appear to make a difference whether there had been pain at the injected disc when the discograms were done 10 years previously; there had been 32 painful and 273 negative injections, but the painful discs were not more likely than the non-painful discs to have herniated 10 years later.

Authors’ conclusions:

- Small bore needle puncture from a discogram can increase the frequency of progression of disc degeneration 10 years later.
- This progression does not always occur; among the 91 grade I or grade II discs injected at baseline, 50 remained grade I or II 10 years later.
- The practice of injecting “control discs” with a low probability of being pain generators may make the control discs more vulnerable to later progression of degenerative changes.
- Most of the patients in this study had a greater than average risk of disc degeneration; however, since most patients undergoing discography also have a greater than average risk of disc degeneration, the results can be expected to apply to patients seen in most clinical practice.
- Careful consideration of risk vs. benefit should be done when deciding on discography, since the small bore needle puncture may make the discs more vulnerable to later degenerative changes.

Comments:
- The participants were recruited from three earlier studies of discography, one published in 2002 and two published in 2000.
- It is difficult to discern how the patients were recruited and how the controls were recruited, since the earlier studies did not clearly designate which participants were to be considered controls for a later comparison.
- Some of the numbers quoted in the Methods section do not appear to come from the earlier studies, either for the 75 discography or the 75 control participants.
  - There were 25 discography participants with successful treatment of previous lumbar disc disease, presumably from the 2000 study; however, in that study, there were only 20 participants who had discography.
    - In that same study, it is not clear where the control participants could have come from; only 36 lumbar disease patients agreed to participate, and only 16 could have served as controls for the 20 patients who actually had discography.
- The recruitment of the matched controls is also difficult to discern, and the method of matching is not clearly described.
  - In individual matching, each participant in the discography group would be paired with a single individual with the same age and sex and disc history in the control group; this appears not to have been done.
  - In frequency matching, the overall composition of the control group is similar to the experimental group for the matched variables.
  - Reporting that continuous variables were compared with a “Student t test” does not clarify the kind of matching which was done, since such a test can be either a paired t-test (for individual matching), or an independent samples t-test (for frequency matching).
  - Because there were several variables for which matching was done (age, sex, previous lumbar/cervical disc troubles, psychometric profiles, and LBP questionnaires), a fairly large pool of eligible
controls would be needed for such matching, and the previous reports are far from clear in reporting where the controls came from
- Therefore, it appears that the study may not have made optimal use of the potential advantages of matching
- The fairly large difference in the number of herniated discs (55 versus 22) makes it unlikely that enough bias could have arisen from the selection of controls to compromise the basic conclusion about the later effects of disc puncture from discography
- Several participants were excluded from the 10 year follow-up because of lumbar spine events in the intervening years; if these were reported as the equivalent of “failures” or bad outcomes, the discography group still has a higher rate of later lumbar disc problems than the control group; the group comparison is not biased because of these exclusions

Assessment: Adequate for evidence that discography with a small bore needle increases the risk of later disc herniation at the level of the injected disc, and that this risk should be taken into account when deciding on referral for discography

References:


