

1237

Lau T¹, Weinstein M¹, Wakamatsu M¹, Macklin E¹, Pulliam S¹

1. Massachusetts General Hospital

IS LOWER BACK PAIN CORRELATED WITH PELVIC ORGAN PROLAPSE?

Hypothesis / aims of study

Pelvic organ prolapse (POP) is a common problem and is associated with a variety of symptoms. Traditionally, low back pain (LBP) has been described as a symptom of POP. The prevalence of LBP in a population with POP is unknown. Despite the frequent association of LBP and POP in gynecology textbooks, there has only been one study evaluating this association. Heit et al [1] reported no such association in a case-control study, controlling for age and prior prolapse surgery. The aim of this study is to determine if there is a correlation between low back pain (LBP) and pelvic organ prolapse (POP) by assessing for any change in LBP after surgical correction of POP. We hypothesized that surgical correction of POP would lead to improvement in LBP.

Study design, materials and methods

Patients undergoing surgical repair of POP were recruited from the practices of three fellowship-trained urogynecologists to participate in this prospective observational study. Patients received assessment of their prolapse and counselling regarding the surgical method and route of repair per standard of care. Patients with prolapse in any compartment who planned to undergo surgical correction were eligible to participate. Patients with a history of chronic opiate abuse or history of lower back (lumbar or sacral) surgery, trauma, fracture, or spinal disease were not eligible to participate in this study.

Study participants completed the Oswestry Disability Index (ODI) at their pre-operative visit and post-operatively at 1, 3, 6, and 12 months. The Oswestry Disability Index (ODI), a validated back pain questionnaire, is a gold standard in LBP assessment. It is composed of 10 subscales evaluating such activities as walking, sitting, travelling, and social life. A higher ODI score represents more severe disability, on a scale of 0-100. A 9 point change in the scale has been found to represent a minimal clinically important difference [2, 3].

The primary outcome was the change in ODI scores from pre-op to 3 months post-op. ODI scores at 3 and 6 months post-op were used to confirm the presence of any observed change in LBP. Serial ODI scores were analyzed in repeated-measures ANOVA. Power analysis showed that a sample size of 50 participants will have 88% power to resolve a true improvement of 9 points on the ODI using a two-tailed test with alpha = 0.05.

Results

Between October 2008 and January 2010, fifty-one patients were recruited to participate in this study and met inclusion criteria. Of the 51 participants, 43 completed one month and 32 completed three month follow up surveys.

The mean ODI scores at the pre-op visit and the 1, 3, 6, and 12 months post-op visits were 15, 19, 9, 11, and 8. The mean change in ODI score between pre-op to 1 month post-op worsened by 4 points (4, CI 0.3 to 7.8, p = 0.07). Our primary outcome, the mean change in ODI score from pre-op to 3 months post-op, improved by 6 points (-6, CI -10.2 to -1.2, p = 0.014). The mean change in ODI score from 3 to 6 months post-op slightly worsened by 2 points (2, 95% CI -3.4 to 7.1, p = 0.49).

Only 7 participants (22%, CI 12-36%) demonstrated a minimal clinically important improvement, while 22 participants (69%, CI 53-81%) demonstrated no substantial change. Three participants (9%, CI 4-21%) experienced a minimal clinically important worsening between the preoperative and 3-month postoperative visits.

Interpretation of results

We demonstrated a statistically significant change in ODI score by a decrease (improvement) of 6 points between preop and 3 months post-op. However, a minimal clinically important change (a change of 9 or more points in the ODI score) was not identified. As such, our study did not find a clinically significant improvement of LBP after surgical repair of POP. This suggests that back pain is not a symptom of pelvic organ prolapse. Confirmation of these findings will be based on later analysis of 6- and 12-month follow-up surveys.

Concluding message

Surgical repair of pelvic organ prolapse does not clinically improve symptoms of low back pain.

References

1. Heit M, Culligan P, Rosenquist C, Shott S. Is pelvic organ prolapsed a cause of pelvic or low back pain? *Obstet Gynecol.* 2002;99(1): 23-8.
2. Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine* 2000;25(22):2940-52.

3. Davidson M, Keating JL. A comparison of five low back disability questionnaires: reliability and responsiveness. Phys Ther. 2002;82(1):8-24.

<i>Specify source of funding or grant</i>	Internal funding from obstetrics & gynecology department
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Partners Human Research Committee
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes