

Response to the Letter to the editor concerning "A propensity-matched study of patients with symptomatic lumbar spinal stenosis opting for surgery versus not" by Rikke K. Jensen et al.

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Response to the Letter to the editor concerning "A propensity-matched study of patients with symptomatic lumbar spinal stenosis opting for surgery versus not" by Rikke K. Jensen et al.

Thank you for your thorough and well-considered critique of the study by Friis Pedersen et al. (2024). Your concerns touch on key methodological aspects, but we would like to clarify that, despite some methodological limitations, the study's conclusions remain robust within the context of the study.

It is true that a standardized description of non-surgical care would have been beneficial for making a direct comparison between the groups. However, it is important to note that all patients in Friis Pedersen et al.'s study had undergone the Danish treatment guidelines of at least twelve weeks of non-operative treatments before being referred for surgery. The patients in this study, therefore, represent those who are "non-operative treatment failures" – in other words, those who had not experienced sufficient improvement through non-surgical methods. This makes the argument about the lack of description of the non-surgical arm less relevant since the study specifically focuses on patients for whom non-surgical treatment had proven ineffective. In addition, robust evidence supporting the effectiveness of non-surgical treatment for patients with spinal stenosis is lacking. Thus, it is questionable whether a more detailed description of non-operative treatment would have significantly altered the overall results.

While randomized controlled trials (RCTs) are the gold standard for controlling confounders, well-executed observational studies can still provide valuable insights. The propensity score matching used in this study is a widely recognized tool for reducing bias in observational studies and for approximating the conditions of an RCT when randomization is not feasible (Anglemyer et al., 2014) (Abel and Koch, 1999). The contention that the propensity score model omits several key confounders reflects unfamiliarity with the basic theory of propensity matching. Using multiple factors to create two comparable groups based on known known and known unknown variables, in theory, also matches on unknown unknown variables (McKnight, 2017). The other most widely used method to control for confounders in observational studies, regression analysis, only uses known variables that have been specifically (with or without bias) selected (Morgan and Harding, 2006).

The fact that the study includes data from a continuous cohort of patients with spinal stenosis reflects the clinical reality and strengthens the relevance of the results in real-world practice, where patients in our setting always undergo non-surgical treatment before surgery is considered.

Although it would have been more ideal to use standardized differences or distributions of propensity scores to assess balance, this does not mean that the methods we used are invalid. P-values and mean differences, while not perfect, can still provide valuable information on differences in baseline characteristics and treatment outcomes. This approach reflects the common practice used in many clinical studies and offers a practical understanding, especially for clinicians who may not

specialize in advanced statistical methods.

Indeed, a sensitivity analysis would have strengthened the study's conclusions regarding unmeasured confounders. This is an area where the study could have been stronger. However, the lack of a sensitivity analysis does not entirely undermine the study's value. The observed results are still relevant and shed light on treatment effectiveness differences based on the clinical practice from which the study is derived.

Concerning the E-value there are no threshold values or formal guidelines around appropriate conclusions that can be drawn based on the E-value.

While the study does not delve deeply into the factors that led to the selection of surgical versus non-surgical treatment, it is important to remember that all patients had undergone long-term non-operative treatments before being considered for surgery. This emphasizes that these are patients for whom non-surgical treatment had already been tried without success, and who were then evaluated for surgical intervention. This detail is central to understanding the study, as it primarily highlights the outcomes of surgery in patients who had not responded to non-surgical treatments.

Lastly, it would be unethical to perform and RCT in these patients (Black, 1996). It would be unethical to have patients undergo an additional six to twelve weeks of non-operative care if they have already failed non-operative care. It would also be unethical to have patients undergo surgery when they have not exhausted all non-operative options available.

In summary, our study has some methodological weaknesses, but it reflects the reality for a group of patients where non-surgical treatments have not yielded satisfactory results. This makes the study highly relevant, as it provides important knowledge about the effects of surgical treatment in this specific population. The raised critique points are crucial for improving future studies, but they do not necessarily undermine the overall conclusions of this study.

Declaration of competing interest

The authors declare no competing financial or personal relationship influencing the current manuscript.

References

Abel, U., Koch, A., 1999. The role of randomization in clinical studies: myths and beliefs. J. Clin. Epidemiol. 52 (6), 487–497 [Internet]. [cited 2024 Aug 20]. https://pubmed.ncbi.nlm.nih.gov/10408986/.

Anglemyer, A., Horvath, H.T., Bero, L., 2014. Healthcare outcomes assessed with observational study designs compared with those assessed in randomized trials. Cochrane Database Syst. Rev. 2014 (4), MR000034. https://doi.org/10.1002/ 14651858.MR000034.pub2. Black, N., 1996. Why we need observational studies to evaluate the effectiveness of health care. BMJ Br. Med. J. (Clin. Res. Ed.) 312 (7040), 1215 [Internet]. [cited 2024 Aug 23] Available from:/pmc/articles/PMC2350940/?report=abstract.

McKnight, B., 2017. Chapter: Matched Case-Control Studies p63-76. Handbook of Statistical methods for Case-Control Studies.

Morgan, S.L., Harding, D.J., 2006. Matching estimators of causal effects: prospects and pitfalls in theory and practice. Sociol. Meth. Res. 35 (1), 3–60.

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