

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Lumbar spine surgery across 15-years: trends, complications and reoperations in a longitudinal observational study from Norway
AUTHORS	Grotle, Margreth; Småstuen, Milada; Fjeld, Olaf; Grøvle, Lars; Helgeland, Jon; Storheim, Kjersti; Solberg, Tore; Zwart, John-Anker

VERSION 1 – REVIEW

REVIEWER	Sumihisa Orita Chiba University, Japan
REVIEW RETURNED	05-Feb-2019

GENERAL COMMENTS	<p>The authors investigated the trend of lumbar spine surgery in the last 15 years based on the national database to report the substantial increase in the operative cases in accordance with the ageing society.</p> <p>The study period, 1999-2013, includes drastic changes in spine surgery.</p> <p>I would like to know the rates and changes in the approaches, i.e. anterior surgery or posterior surgery, if possible. If impossible, they better include discussions regarding that point.</p>
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REVIEWER	Brook I. Martin, PhD University of Utah, Salt Lake City, Utah, USA Reviewer receives partial salary support for Federal Research Grants in Orthopaedics. The reviewer also serves as a deputy editor for The Spine Journal.
REVIEW RETURNED	19-Apr-2019

GENERAL COMMENTS	<p>Very nice epidemiological paper describing trends in lumbar spine surgery in Norway from 1999-2013. The authors used national hospital data to describe spine surgery admissions, separately grouped by sex, age, and "simple" (eg. decompression) vs. "complex" (eg. fusion), excluding cases for non-lumbar indications, cancer, trauma, infection, pregnancy and inflammation. They found that rates of lumbar spine surgery in Norway increased substantially since 1999, particularly for older age groups and for complex spine procedures. Increasingly, complex spine surgery accounts for an increasing share of all spine operations, and substantially increased the risk of 30 day complication. The authors acknowledge that a private ambulatory spine surgery is not accounted for in their analysis, likely leading to a 7% underestimation. Minor concerns should be easy to address in the manuscript:</p>
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	<p>1) The authors use procedure codes unique to Norway. Please provide any information about the validity of this algorithm for classifying spine procedures.</p> <p>2) The authors cite a slightly outdated study to report U.S. Trends. For fusion surgery, a more recent update of U.S. trends is available: Martin BI, Mirza SK, Spina N, Spiker WR, Lawrence B, Brodke DS. Trends in Lumbar Fusion Procedure Rates and Associated Hospital Costs for Degenerative Spinal Diseases in the United States, 2004 to 2015. <i>Spine (Phila Pa 1976)</i>. 2019 Mar 1;44(5):369-376. However, the article does not include rates for non-fusion operations and/or ambulatory spine procedures.</p> <p>3) The results section described trends in reoperations as having declined from 1999 to 2013. However, some additional methods are required to describe this analysis. In particular, please confirm that each index case had the same amount of surveillance (ie. an initial case in December of 2013 may not have a full 30 days of follow-up).</p> <p>4) I am confused by the seemingly inconsistent findings between the final paragraph in the results reporting "There was a large decrease in the proportion of patients who received a reoperation...." and the sentence in the conclusion "Mean complication rate during the study period was low, but it increased to 2.4%... This increase may be explained by the increase in reoperations ...". Please clarify this apparent discrepancy.</p> <p>5) The authors are encourage to expand the discussion of policy effects and implications. They specifically state that increased rates may be explained by MRI, lack of clinical consensus, and financial incentives" Please elaborate on these themes to bolster a policy perspective.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comment	Our response to Reviewer 1
<p>The authors investigated the trend of lumbar spine surgery in the last 15 years based on the national database to report the substantial increase in the operative cases in accordance with the ageing society.</p> <p>The study period, 1999-2013, includes drastic changes in spine surgery. I would like to know the rates and changes in the approaches, i.e. anterior surgery or posterior surgery, if possible. If impossible, they better</p>	<p>Unfortunately, we do not have access to these details. However, it is likely that there are very few cases with anterior surgery, e.g. those with a prosthetic replacement (n=140) and some of those with fusion surgery (n=10.420). According to our paper on spinal stenosis surgery based on this material (ref 22 in the manuscript, Lars Grøvle et al), the numbers of fusions decreased by almost 50% in the period from 1999 to 2013. Moreover, the fusion rates due to spinal stenosis in Norway were substantially lower than those reported in the USA and South Korea during the 2000s (see discussion in the paper of Grøvle et al.)</p> <p>Therefore, it is reasonable to believe that anterior surgery was performed in only a minor proportion of those with complex surgery in the current material. Since we have not provided any results regarding anterior and posterior surgery in the current paper, we do not find it natural to discuss this issue here. We hope that the Reviewer 1 will understand and accept our decision.</p>

include discussions regarding that point.	
Reviewer 2 comments	Our response to Reviewer 2
Very nice epidemiological paper describing trends in lumbar spine surgery in Norway from 1999-2013. The authors used national hospital data to described spine surgery admissions, separately grouped by sex, age, and "simple" (eg. decompression) vs. "complex" (eg. fusion), excluding cases for non-lumbar indications, cancer, trauma, infection, pregnancy and inflammation. They found that rates of lumbar spine surgery in Norway increased substantially since 1999, particularly for older age groups and for complex spine procedures. Increasingly, complex spine surgery accounts for an increasing share of all spine operations, and substantially increased the risk of 30 day complication. The authors acknowledge that an private ambulatory spine surgery is not accounted for in their analysis, likely leading to a 7% underestimation. Minor concerns should be easy to address in the manuscript:	Thank you for this positive assessment of our paper.
1) The authors use procedure codes unique to Norway. Please provide any information about the validity of this algorithm for classifying spine procedures.	The NOMESCO Classification of Surgical Procedures (NCSP) has since 1999 been used in all the Nordic countries, including Sweden, Denmark, Finland, Iceland and Estonia in addition to Norway. The NSCP algorithm used in this study has been validated by the Norwegian registry for spine surgery (NORspine) and the Norwegian patient registry under the Norwegian Directorate of Health. More information about this can be found at the website;

	<p>https://www.kvalitetsregistre.no/sites/default/files/datakvalitet-arsrapport_2014.pdf</p> <p>At the following website under the Norwegian Directorate of Health more information regarding the algorithm can be found: https://www.helsedirektoratet.no/tema/statistikk-registre-og-rapporter/helsedata-og-helseregistre/norsk-pasientregister-npr/innhold-og-kvalitet-i-npr/_/attachment/download/e2e96893-e676-4a56-be07-7a37589c4e83:d4503aa7adeb89ec661a9a44ee12b44cb9167add/17-9624-2%20Dekningsgrad_rapport_NKR_2015-16.pdf Please, note that we have added this information and references in the method section.</p>
<p>2) The authors cite a slightly outdated study to report U.S. Trends. For fusion surgery, a more recent update of U.S. trends is available: Martin BI, Mirza SK, Spina N, Spiker WR, Lawrence B, Brodke DS. Trends in Lumbar Fusion Procedure Rates and Associated Hospital Costs for Degenerative Spinal Diseases in the United States, 2004 to 2015. Spine (Phila Pa 1976). 2019 Mar 1;44(5):369-376. However, the article does not include rates for non-fusion operations and/or ambulatory spine procedures.</p>	<p>RESPONSE: Thanks again, the more updated reference is now included.</p>
<p>3) The results section described trends in reoperations as having declined from 1999 to 2013. However, some additional methods are required to describe this analysis. In particular, please confirm that each index case had the same amount of surveillance (ie. an initial case in December of 2013 may not have a full 30 days of follow-up).</p>	<p>RESPONSE: Thanks again. You are right; more information on this should have been added. We have added the following: “To make sure that all surgeries could be followed for potential complications (within 30 days) and reoperations (after 30 days for at least 90 days), initial surgeries performed in the time period between September 1, 2013 and December 31, 2013 were omitted from the analysis; the same applied to surgeries performed in the first 90 days of the study period.</p>

<p>4) I am confused by the seemingly inconsistent findings between the final paragraph in the results reporting "There was a large decrease in the proportion of patients who received a reoperation...." and the sentence in the conclusion "Mean complication rate during the study period was low, but it increased to 2.4%... This increase may be explained by the increase in reoperations ...". Please clarify this apparent discrepancy.</p>	<p>We agree that this seems inconsistent, but it can be explained by the definition of some of the complications; if a repeat surgery occurred within the first month it was classified as a complication, and not repeated surgery. During the study period there was an increase in repeat surgery within 1 month, and a decrease in repeat surgery after 1 month, please see table 2.</p> <p>In order to clarify this, we have amended the sentence you refer to as follows; "During the 15-year period, there was an increase in reoperations within 30 days, leading to a large increase in the complication rate , from 0.7% in 1999 to 2.4% in 2013"</p>
<p>5) The authors are encourage to expand the discussion of policy effects and implications. They specifically state that increased rates may be explained by MRI, lack of clinical consensus, and financial incentives" Please elaborate on these themes to bolster a policy perspective.</p>	<p>As requested by the reviewer, we have now elaborated a bit more on a policy perspective, and added the following to the discussion section: "There is a need for high-quality scientific evidence as well as clinical consensus regarding an optimal use of resource-demanding investigations and treatments connected to spinal disorders. Many of the new technologies and more complex procedures have questionable clinical or cost-benefit efficacy. For example, recent UK and USA clinical guidelines recommend that patients should not be offered disc replacement or spinal fusion surgery for low back pain, and recommend fusion surgery only as part of a randomised trial (29). Furthermore, we need stronger scientific evidence with respect to the selection of patients to surgical treatment. Both in a clinical and societal perspective, non-surgical management might be an appropriate option for patients who wish to defer or avoid surgery. "</p>

VERSION 2 – REVIEW

REVIEWER	Sumihisa Orita Chiba University, Japan
REVIEW RETURNED	14-Jun-2019
GENERAL COMMENTS	The authors responded the comments of the reviewers.
REVIEWER	Brook Martin University of Utah United States of America
REVIEW RETURNED	12-Jun-2019
GENERAL COMMENTS	Dear Editor, Thank you for inviting me to review this manuscript. The authors have sufficiently addressed my previous concerns. Although claims-based analysis of national databases are frequently limited in the ability to provide detailed clinical information, they are an

	<p>excellent source for describing general epidemiological trends. The authors have nicely presented a study of trends for spine surgery in Norway. They have clarified the confusion I raised from the previous review and have expanded the discussion of study implications. The paper will be of interest to readers of BMJ Open and to those interested in back pain / spine surgery research.</p>
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