

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Pilot study for the Registry of Complications in Rheumatic-Diseases from the German Society of Surgery (DGORh) – Evaluation of methods and data from the first 1000 patients
AUTHORS	Kostuj, Tanja; Rehart, Stefan; Matta-Hurtado, Ronald; Biehl, Christoph; Willburger, Roland; Schmidt, Klaus

VERSION 1 - REVIEW

REVIEWER	Bella Mehta Hospital for Special Surgery, New York, United States of America
REVIEW RETURNED	23-Jan-2017

GENERAL COMMENTS	<p>The authors present an interesting and a relevant project. It is important to know the determinants to know poor prognostic indicators in surgical outcomes. I have the following comments:-</p> <ul style="list-style-type: none">- The authors mention “During the pilot study the risk-factors were considered only in patients where complications occur in order to obtain a quicker overview”. Thus there is a potentially huge bias when concluding the study.- The authors have not clearly defined what they mean from the terms they repeatedly use in the text – What do infections mean? Serious infections where IV antibiotics were used or patients who were hospitalized?- Also the authors need to define what their definition of “complication” is.- The inclusion and exclusion criteria for the study need to be clearly defined. Also how many patients refused to participate once approached can be put into a chart or a table for clarification purposes. Especially when the authors comment “Patient IDs were lost in the system”- I would recommend certain terminology to be more standard – For eg - Bechterew’s disease to be written as ankylosing spondylosis or Morbus stills to be written as Still’s disease. Etc.- Terms like collagenosis are also too vague and need more clarification.- It would be important to know if all the data collected was patient reported or physician reported. And what were the measures taken to ensure validity.- It would be interesting to have data on pathology from
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	<p>synovectomies, or joint replacements etc in the larger studies.</p> <p>Overall it is understandable that it is difficult to measure so many different variables in a registry but clear definitions and protocols would help.</p>
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REVIEWER	<p>Lauren Barnett Arthritis Research UK Primary Care Centre Research Institute for Primary Care & Health Sciences Keele University United Kingdom</p>
REVIEW RETURNED	22-Feb-2017

GENERAL COMMENTS	<ol style="list-style-type: none"> 1. This may need to be proof read again. <ol style="list-style-type: none"> a. In the abstract section design and participants “consent form all patients undergoing surgical treatments” should be “consent from all patients...” b. In strengths and limitations “extended statistical analyzes cannot be done” should be “analyses cannot be done”. c. In the introduction: “these procedures as well and the number of surgical treatments” should be “these procedures as well as the number...” d. Under the results heading “Over all more than half” should be “Overall more than half...” e. In the discussion “as data collection moved forward” should be “as data collection moves forward” 2. The extensive use of quotation marks (in the introduction) is unnecessary, and is slightly off-putting during reading. I think it would be better to paraphrase and then reference. 3. I’d express the main aims of the paper in a separate paragraph at the end of the introduction rather than bullet points. 4. The only way you can adjust for confounders is by doing statistical analyses, which you stated you didn’t do in the abstract. I don’t see the point in including confounders in this pilot study since you didn’t actually use them in your descriptive analyses. 5. The number of cases (given as 26) is very small, even for a pilot study. I do understand that the researchers can’t help this, but given that this is out of 1000 patients, the incidence is very small. Even if you were to increase overall sample size, it appears as though the number of cases may still be too small to give you much statistical power. 6. Figure 2 is too small. 7. I may have become confused. From what I understand from the paper you have information on 1000 patients. However in the strengths and limitations section you have stated “1000 datasets from twelve centres”. I understand datasets to be sets of data rather than individual patients. It may help understanding if you were to rephrase this sentence, i.e. “information on 1000 patients from twelve centres”. 8. As a statistician I am curious as to how you intend to incorporate the different type of surgical procedures done on patients, and the varying pharmacotherapy. It would also be nice to perhaps include a brief description of the statistical analyses you intend to do on the overall data. Form what I understand about pilot studies it’s simply to show that you can conduct your study accurately on a small sample, as proof it will work on the larger one. You also haven’t included how many patients you think you will gave in your final sample, which links to point 5 above in regards to the low incidence of cases.
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	9. I think table 4 could be condensed into a more descriptive format rather than listing information about individual patients.
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VERSION 1 – AUTHOR RESPONSE

This is the revised article. Three of the reviewer's comments could not be taken into account in the revised document:

1. reviewer 1: - It would be interesting to have data on pathology from synovectomies, or joint replacements etc in the larger studies.

reviewer 1: Data on pathology are partially available in the centres, they could be asked from the centres in a context of a study later on. We are afraid, that including them in the register directly will lead to a lower acceptance of the forms. After establishing the forms for the real-time register, we got already the feedback, that it will be hard to answer the longer forms.

2. reviewer 1: -Terms like collagenosis are also too vague and need more clarification.

reviewer 1: No further classification were given by the surgeons. – We will take this into account in the real time register!

3. reviewer 2: - As a statistician I am curious as to how you intend to incorporate the different type of surgical procedures done on patients, and the varying pharmacotherapy. It would also be nice to perhaps include a brief description of the statistical analyses you intend to do on the overall data. Form what I understand about pilot studies it's simply to show that you can conduct your study accurately on a small sample, as proof it will work on the larger one. You also haven't included how many patients you think you will gave in your final sample, which links to point 5 above in regards to the low incidence of cases.

reviewer 2: Regression analyses or propensity score can be suited to do so, final decisions will be made in close cooperation to our statisticians at the university of Berne / Switzerland where the real-register is hosted.

VERSION 2 – REVIEW

REVIEWER	Lauren Barnett Research Institute for Primary Care and Health Sciences, Keele University
REVIEW RETURNED	24-Apr-2017

GENERAL COMMENTS	<p>1. This needs to be proof read again, there are still language errors. e.g. "confounders must to be reported in the basic form" should be "confounders must be reported..."</p> <p>2. You can't conclude that "immune-modulating medications appears to impact wound complications" because you've done no formal statistical analysis, and the significance test you did (Fisher's) came up with a non-significant result.</p>
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VERSION 2 – AUTHOR RESPONSE

Dear Mr. Barnett.

Thank you for your comments.

The manuscript has been proof readed by the nativespeaker once again and by another nativ spaker. Both were born and grown up in the USA.

The sample of 26 patients with wound complications is too small, that we can expect a statistical significance: If the medication / interruption of medication should lead to an increase of wound complications of an amount of e.g. 15 or 20 %, this will bne clinically relevant. We focussed on the clinically relevance and conclude, that the medication may affect wound healing and that this should be re-evaluated in the future, based on the ragister's data.